TRIAL INTERACTIVE

Trial Interactive User Guide v10.2

TRANSPERFECT LIFE SCIENCES

APPROVALS

Product Owner

Name: **JAY SMITH**	Title: Sr. Director, Product
Refer to the approval captured in the "Trial Interactive: v10.1 - User Guide Approval v1" on 25-Sep-2020.	

Quality Assurance

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Refer to the approval captured in the "Trial Interactive: v10.1 - User Guide Approval v1" on 25-Sep-2020.	

VERSION HISTORY

Author	Revision #	Date	Comment
Steve Clark	1.0	25-Sep-2020	Initial document created

Contents

HARDWARE AND SOFTWARE REQUIREMENTS

The following describes the hardware and software requirements to use the Trial Interactive eTMF platform.

System in Scope	
Operating System	• Windows Version 7 or higher • All currently supported Mac OSX releases • iOS and Android for myTI mobile app (see myTI release notes)
Browser	• Microsoft Edge: Version 20 or later • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • Internet Explorer: Version 11 or later NOTE: Microsoft® stopped supporting Internet Explorer™ 8 and Internet Explorer™ 9 in January 2016 and stopped support for Internet Explorer™ 10 in January 2020. We expect slight degraded performance with Internet Explorer™ 11, and no longer support Internet Explorer™ 10. Users accessing Trial Interactive with this and older browsers will see in some cases a degraded experience and may have trouble using certain features.
Client Software	• Optional: Adobe Acrobat®, Acrobat® Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. • Optional: Drag and Drop from Outlook to Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available for support of this feature on Internet Explorer® and Firefox®.
Optional Add-Ons	• Optional: For SAS Datasets, SAS Viewer or compatible software must be installed. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74 • DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) **NOTE**: The Snowbound Viewer is now deprecated in TI 10.2 All features of Snowbound are now available in the TI Viewer.

Chapter 1. Signing into Trial Interactive

Everything starts somewhere and the first step on the road to making use of any portion of Trial Interactive's suite of products is to sign into the system. The steps below may vary somewhat based upon your individual setup. For those who are using a Single Sign On (SSO) setup or who have a dedicated instance of Trial Interactive, your login steps will be dictated largely by your internal IT team.

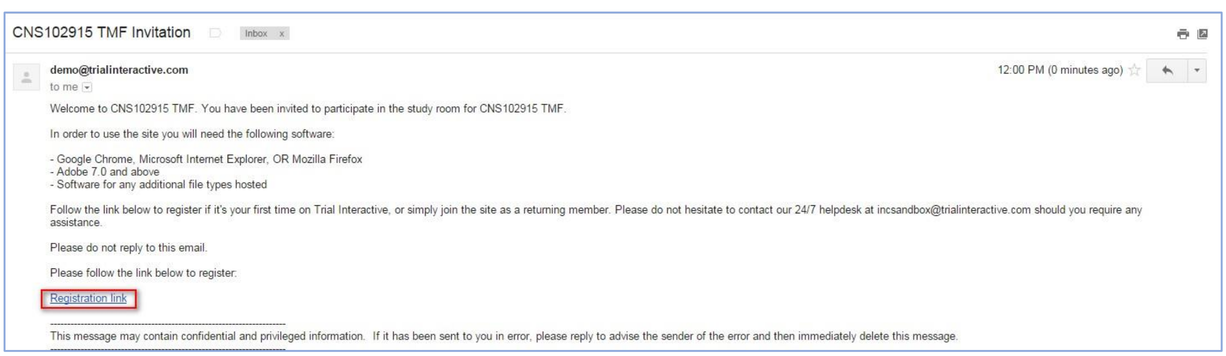
The information below is intended to show the basics for getting logged into the system using our standard login setup with Username and Password as well as some other less-common cases.

This section includes basic information that will help you get started with Trial Interactive 10.1.

- Receiving and responding to a Room Invitation
- User Registration
- Multifactor Authentication
- Logging in on Subsequent Visits
- Requesting a Password Reset from the Login Page
- Logging in without access to rooms

Receiving and Responding to a Room Invitation

Once a Trial Interactive room Administrator has sent you an invitation, you will receive an email message from the room email address with a welcome message and a Registration link. If you have already completed a registration to access a room then you will receive an email letting you know that you have been granted access to another room. This new room will be visible to you on your Home Screen.



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

Follow on to the User Registration page for the complete process.

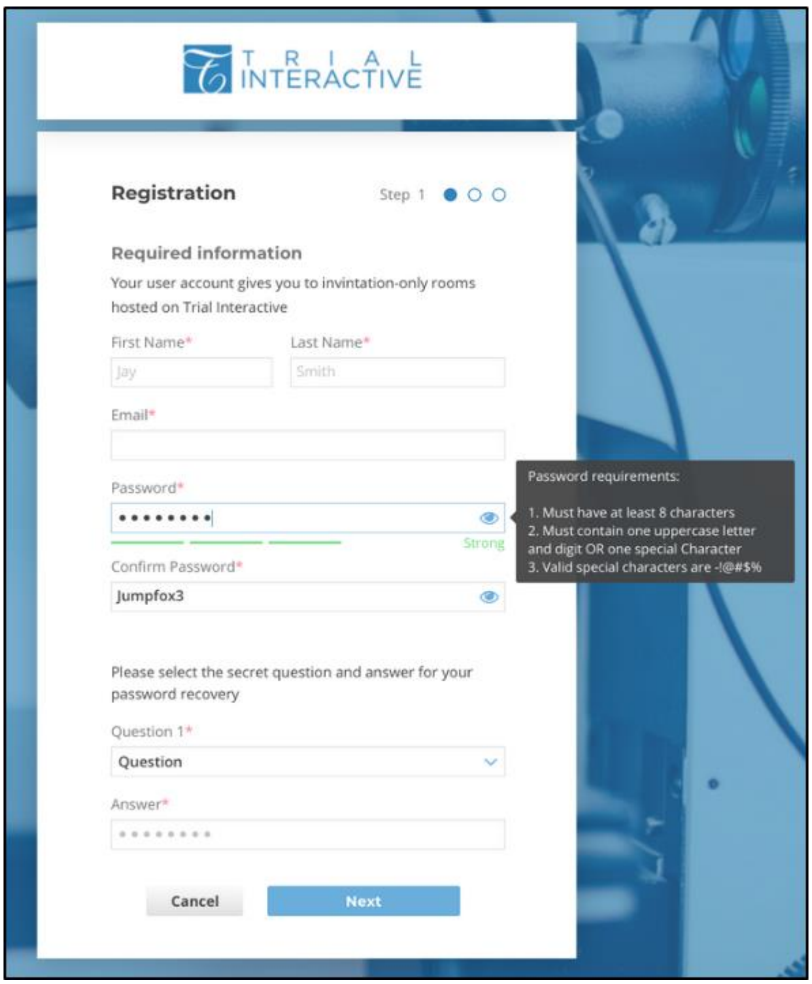
User Registration

Important:

1. *You register to the application only once as a first-time user when you are invited to a room through an email.*
2. *Once you register, you can sign into your room.*
3. *If you are invited to other rooms hereafter, you need not register again but need to sign in to access the rooms.*
4. *For all subsequent invitations to rooms, you are notified by emails.*

After you have received your invitation email with a welcome message and Registration link, you will need to follow the steps as below to register:

Step 1: Registration - Required Information



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

2. Type in your first name, your last name, and your email address as requested on the page in the appropriate fields.
3. Create your secure password, and confirm the password by re-typing it in the **Confirm password** field.

   Note: Hover the mouse over the Password field to see the tool tip on password requirements.

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

Step 2: Registration - Optional Information

On this page enter your contact address, phone number, and other details as required and click **Next** to take you to **Step 3** or **Previous** to take you to **Step 1** if you want to change any information.

Note: You can skip this page and fill it up later from your User Login after you have logged in.

Step 3: Registration - Custom Information

Enter your contact email. You may want to click **Previous** to go back and verify the information entered or click **Register** to be taken to a confirmation page.

Click the link to the secure Trial Interactive website to **login** and begin work.

Signing in on Subsequent Visits

To log in to Trial Interactive:

1. Using your preferred internet browser, navigate to http://www.trialinteractive.com
2. Click the **Client Login** button located at the top-right corner of the page.
3. The Trial Interactive Login page with links to a suite of e-clinical solutions offered by TransPerfect Life Sciences appears. Click the links to delve further into the solutions provided by TransPerfect Life Sciences or log in.
4. Enter the **Username** and **Password**. The **Username** is the full email address that was submitted by the client-appointed Administrator.
5. Click **Login**.

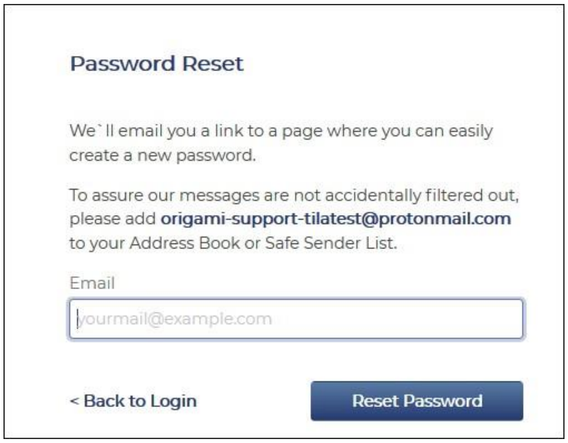
   If you are logging in the first time, the Trial Interactive **Homepage** for the account associated with the login username appears. If you were recently logged in and are logging back in during the same browser session, you will be redirected to your last location within the system.

Note: *You can bookmark **http://www.trialinteractive.com** on your browser for easier access to the Trial Interactive corporate homepage. By accessing Trial Interactive through this site, you will consistently see news and new information about Trial Interactive.*

Requesting a Password Reset from the Login Page

Users do not need to contact the Help Desk. In most cases, the user can perform the Password Reset without any assistance.

If you have forgotten your password, click **Forgot Your Password?** link at the bottom of the login window to initiate an account password reset.

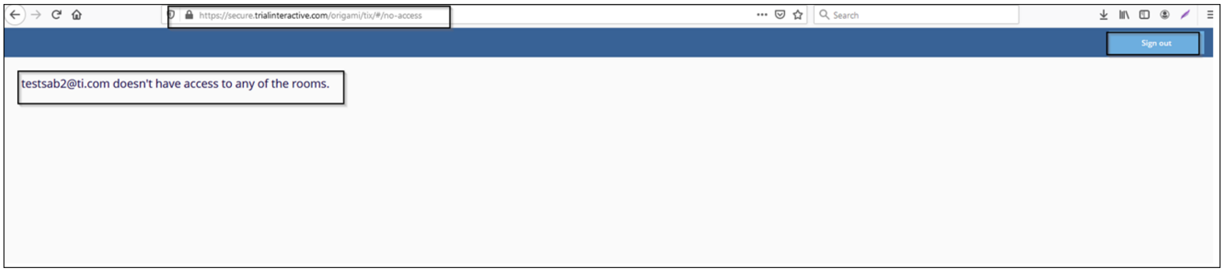


1. **Enter your email** address in the field provided. Click **Reset Password**.
2. You will receive an email with the **Reset Password** link.
3. Click the link to lead you to the **Password Reset** page.
4. Respond to the security questions and click **Next**.
5. You will be taken to the **Change Password** page. Enter a new password and confirm it.
6. Click **Set New Password**.
7. The system will confirm that the password was successfully reset. Click **Back to the login page** to log in with your new password.

Signing in without access to rooms

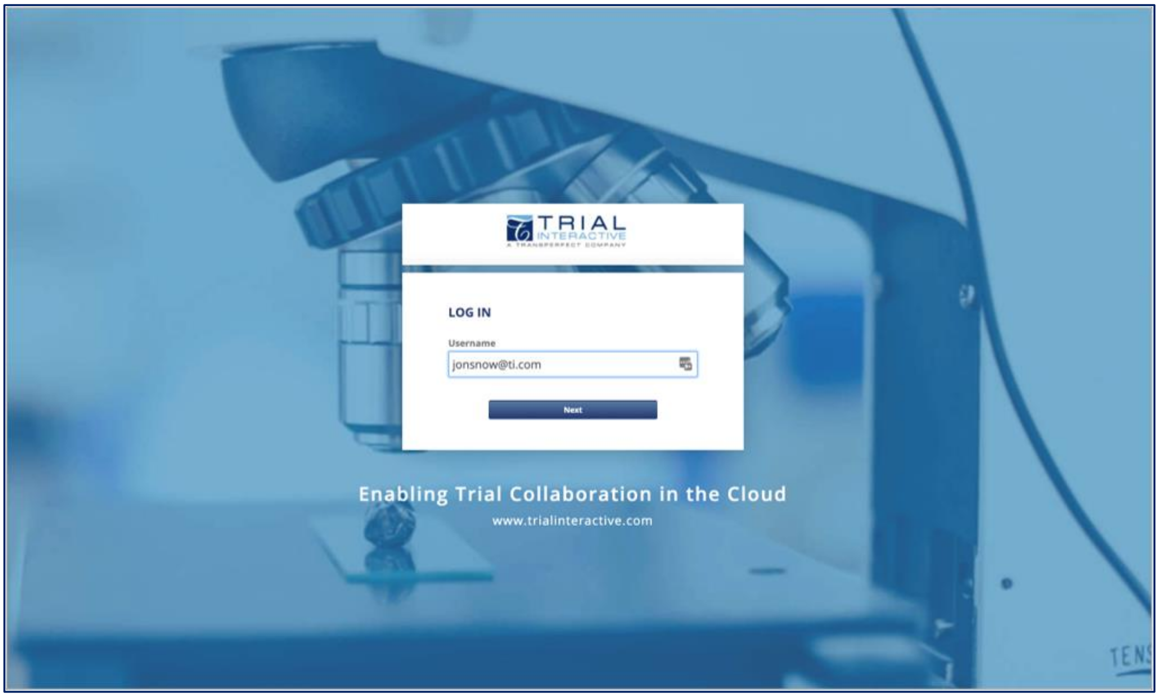
If a user who does not have access to rooms in the system tries to log in, the user is automatically redirected to a separate advisory page. A user might not have access to rooms if the user’s access to the rooms has expired or been revoked.

The screenshot below shows a typical advisory page.



Click the **Sign Out** button to redirect to the standard login page.

Multi-tenant SSO



Trial Interactive includes support for SAML Federated Single Sign-On for the TI multi-tenant platform. Now, all customer domains on multi-tenant can be configured with single sign-on through their own Corporate Directory, as well as third party IAM providers.

A change to the sign in page has been made to reflect the possibility of multiple providers.

The Trial Interactive sign in page will now first prompt the user for their email address, and based on the domain, will either prompt for a password or redirect to the configured Identity Provider. Users who do not have SSO configured will be directed to the normal login page where they will enter their password.

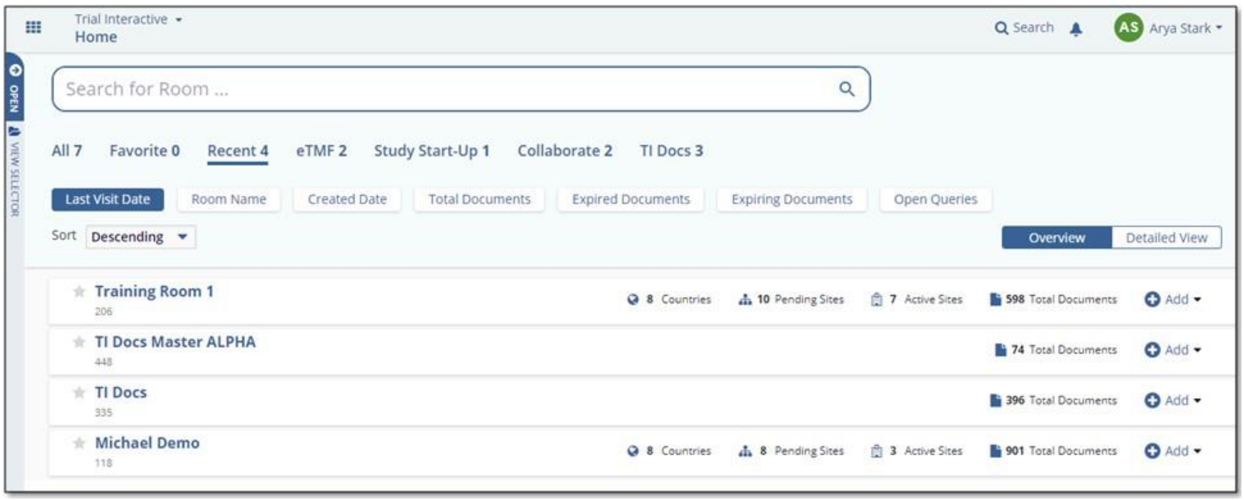
Please reach out to your Trial Interactive representative to discuss setting up SSO for your organization.

Chapter 2. The Trial Interactive Home Page

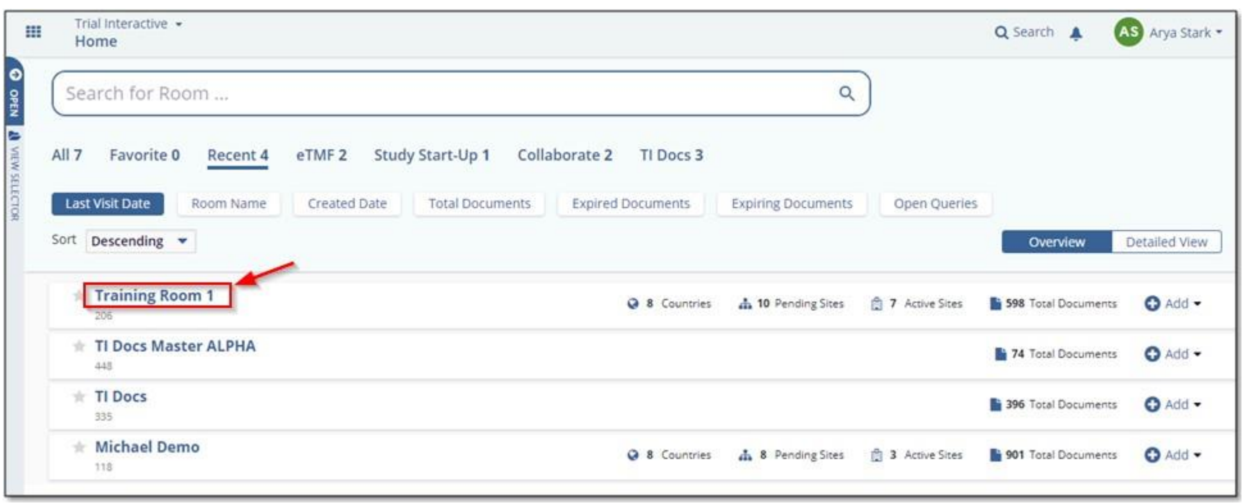
After successfully logging into Trial Interactive, the user is presented with a Home Page. The purpose of this page is to help users locate the room in which they intend to work. Users with five or fewer rooms will see a simplified version of the screens shown below which displays room information for those rooms to which they have been granted access. For users who have more than five rooms, the section below will assist in utilizing the available search tools to locate a specific room.

This section will help you access rooms as well as an Overview or Detailed summary of rooms in case you need to view an overall status of a room without entering it to run a specific report or view a dashlet.

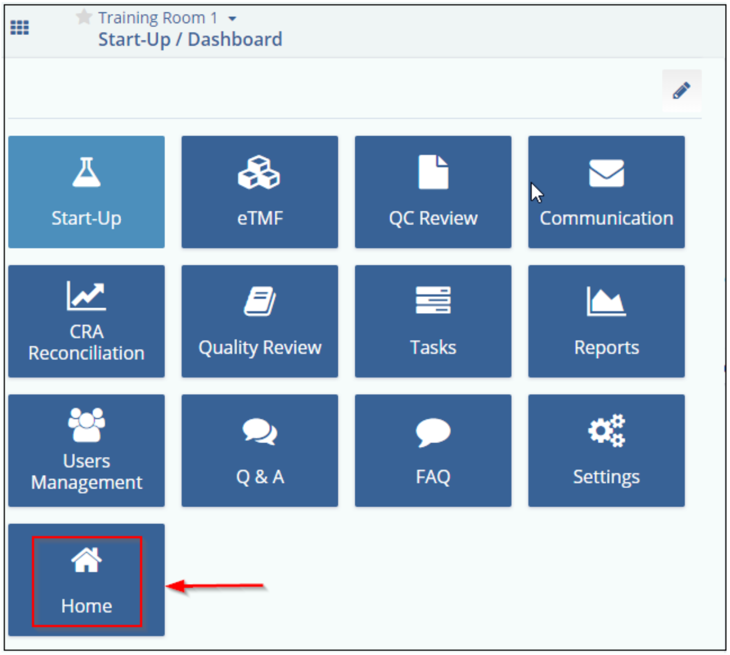
After signing in to Trial Interactive, you are landed on the Trial Interactive Home Page as shown in the screenshot below:



Click the required Room Name to enter a room.



Note: Once inside a room, you can reach this page from the Main Navigation by clicking the **Navigation Grid** icon. Refer to the screenshot below:



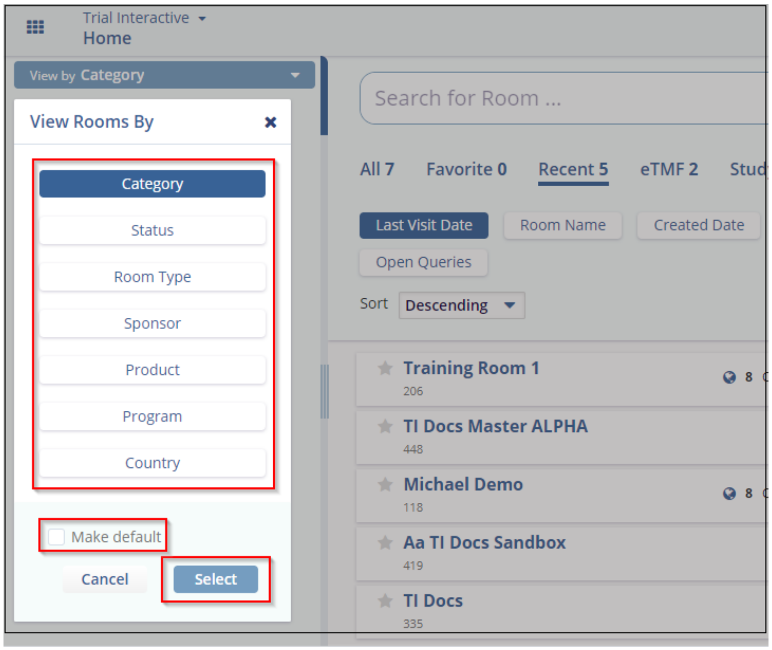
You can do the following from the Trial Interactive 10.1 Home Page:

- Filtering the List of Available Rooms
- Searching for Studies, Sponsors, and Sites across all rooms
- Cross Study Document Search
- Get a Summarized Overview of rooms
- Get a Detailed View of rooms
- Upload Documents to a Room
- Add Users to a Room
- Filter and Sort Rooms
- View and Mark favorite rooms

All the above are accessible from the left panel of this help.

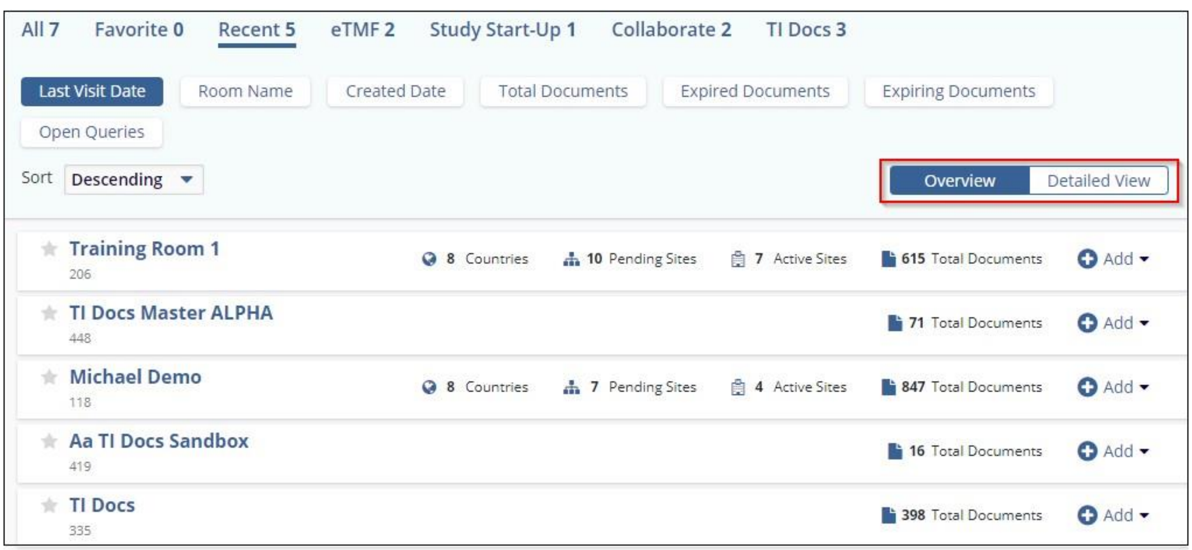
Filtering the List of Available Rooms

The TI Home page provides you with different filters by which you can narrow down the list of rooms that are displayed. Filter categories are in the left panel. If it is closed, expand the panel by clicking **Open** at the left side of the screen to open it.



Viewing Room Details

You can also view details of a room and related information by clicking the '**Overview**' or '**Detailed View**' toggle switch above and to the right of the list of rooms. Refer to the screenshot below:



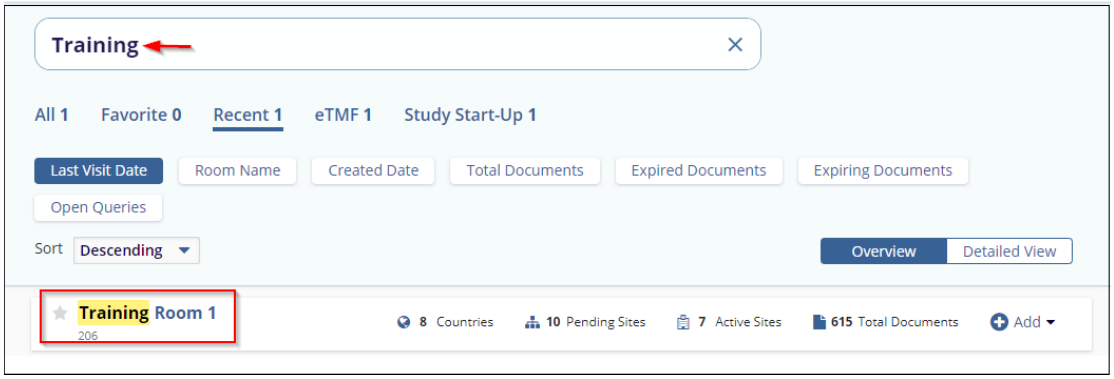
Searching for, and Accessing, a Trial Interactive Room

Room Search (for users with access to more than five rooms)

Trial Interactive allows you to search for rooms easily regardless of how many rooms you have access to.

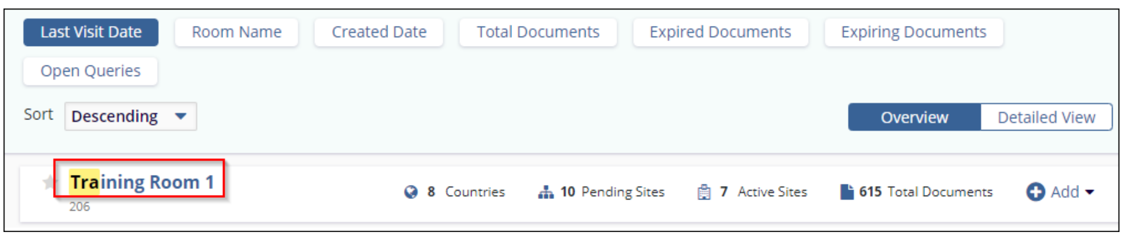
To perform a room search:

1. Enter the room name or keyword in the **Search box** at the top of the page and press **Enter**.
2. Rooms matching the search criteria are displayed in the panel below the filters. If your search returns no results, a "**No Rooms Found"** message is displayed. Refer to the screenshot below:



Accessing a Trial Interactive Room

Click on the name of a room in the list to enter. Refer to the screenshot below:

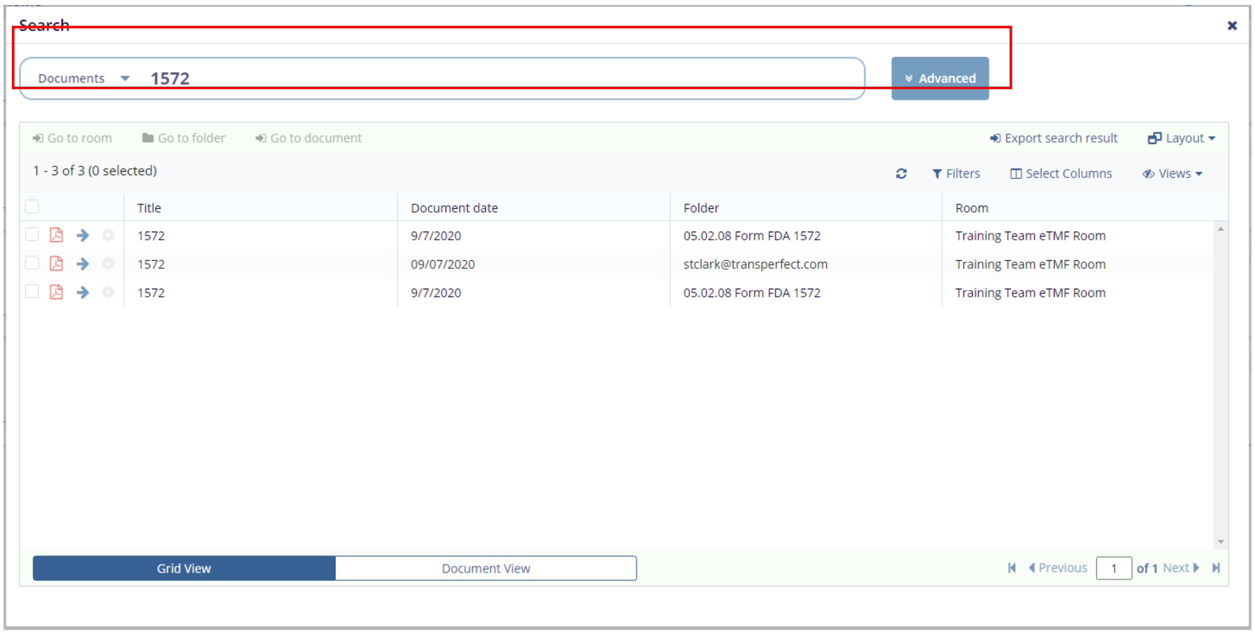


Cross Study Document Search

Documents Search

To perform a cross-study documents search, perform the following steps:

1. From the Home Page, click the **Search** icon located at the top right corner of the screen. Note, this is not the same search as the Room search mentioned earlier.
2. The **Search** window appears, which consists of the following sections:
   a. The **Search** textbox.
   b. The **Advanced** search button
3. Enter the keyword(s) in the text box

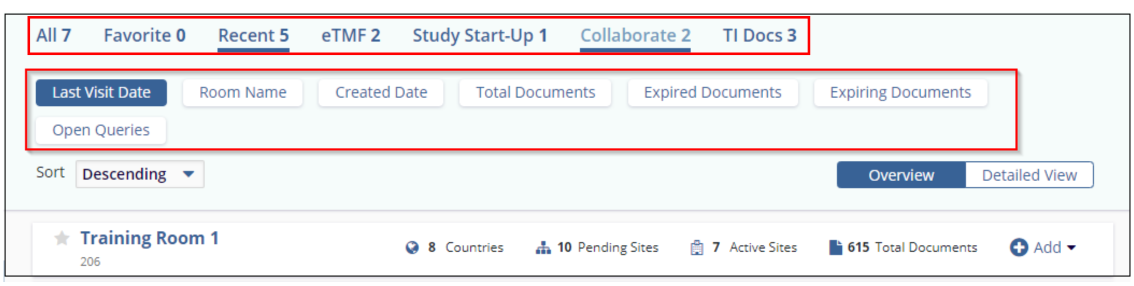


You can perform the following actions from the Search Window:

1. Export the search results
2. Adjust the Grid columns
3. Go directly to the document or to the related Room or Folder in the index
4. View a document

TI Home Page Filters

TI Home Page provides a variety of filters by which you can filter the list of rooms to which you have been granted access. Refer to the screenshot below:



The filters available are:

1. **All:** This displays all rooms that the user has access to.
2. **Favorite:** This displays the list of all rooms that the user has marked as favorites.
3. **Recent**: This displays the list of rooms that the user has visited recently.
4. **eTMF**: This displays all of the user's eTMF rooms.

5. **Study Start-Up**: This displays all of the user's rooms with Study Start-Up enabled.
6. **Collaborate**: This displays the list of all of the user's TI Collaborate rooms.
7. **TI Docs**: This displays the list of all of the user's TI Docs rooms.

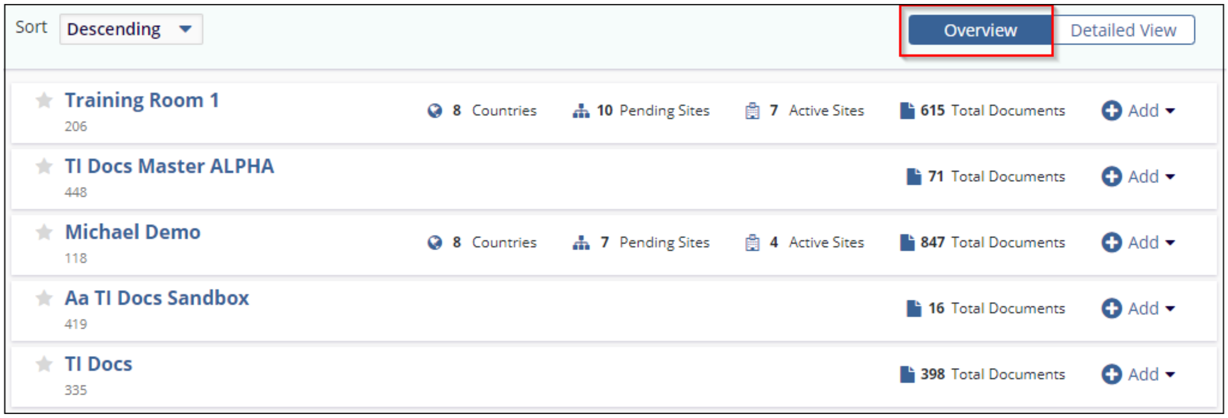
Below these main filters, TI Home Page provides **Additional** buttons which can be used to display specific information about the rooms being shown.

Overview View of Rooms

From the Home Page, click the **Overview** button located at the top right corner of the page to get a listing of the rooms that you have access to with the following metadata:

1. Countries where sites are located
2. Pending Sites
3. Active Sites
4. Total Documents

Refer to the screenshot below:



Countries

The **number** next to **Countries** link shows the **total count** of the countries where clinical trial sites are located.

Active Sites

The **number** next to **Active Sites** link shows the **total count** of sites that are activated.

Pending Sites

The **number** next to **Pending Sites** link shows the **total count** of sites that are pending for activation.

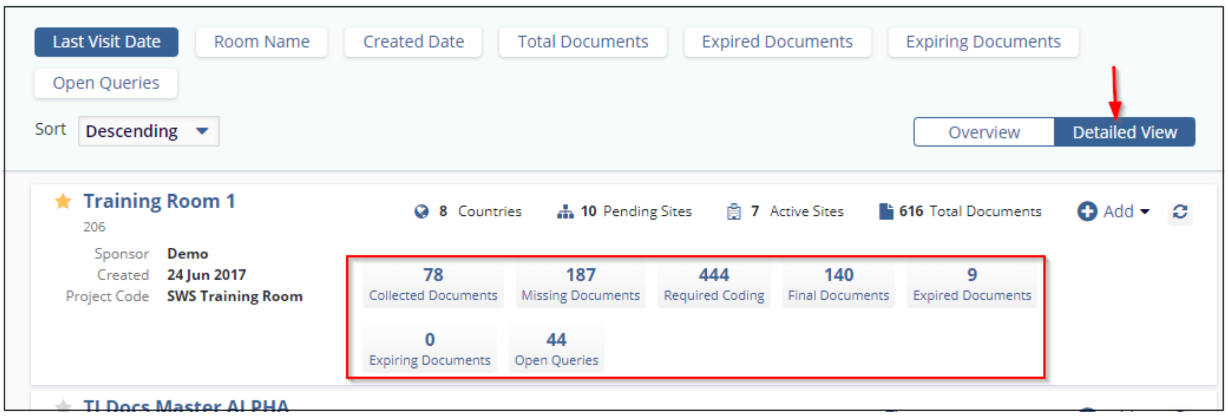
Total Documents

The number next to **Total Documents** link shows the **total count** of documents pertaining to a room.

Detailed View of Rooms

From the Home Page, click the **Detailed** button located at the top right corner of the page to view rooms and studies as large cards with the following information:

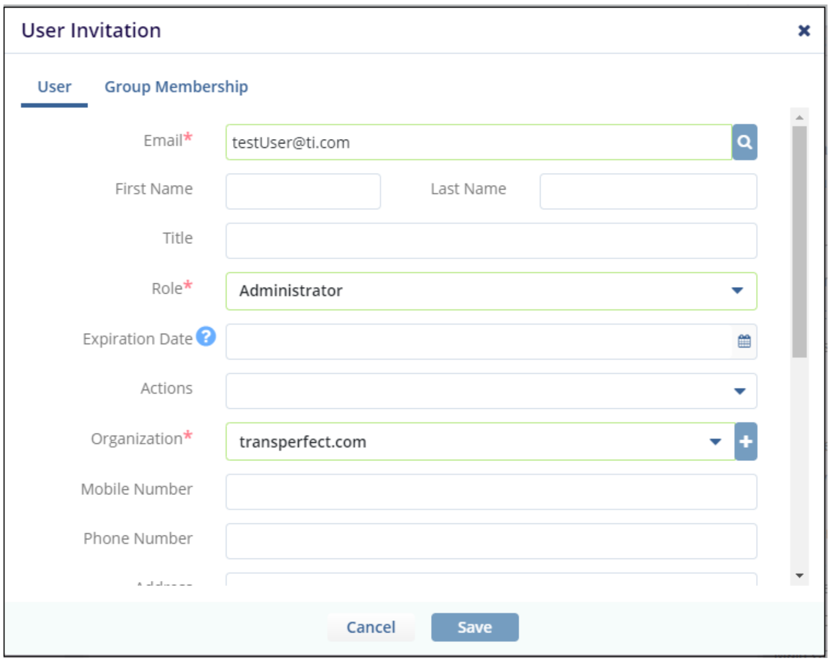
1. Collected Documents
2. Missing Documents
3. Expired or Expiring Documents
4. Require Coding
5. Final Documents
6. Open Queries
7. Rejected Documents Refer to the screenshot below:



Adding a User to a Room from the Home Page (Administrators Only)

Follow the steps below to add users to a room from the Home Page:

1. Click the **Add** dropdown menu at the right side of the Room line on the home page.
2. Click the **Add Users** option from the dropdown list that appears. The **User Invitation** window opens. Refer to the screenshot below:

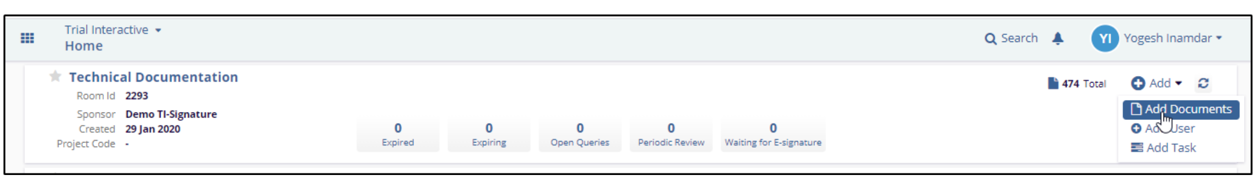


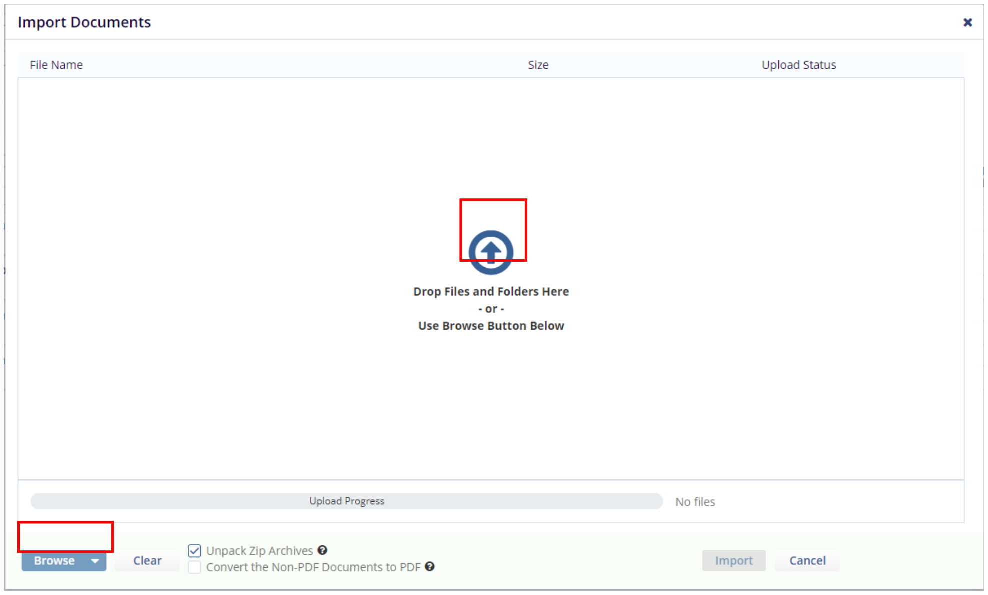
3. Enter the **Email Address** of the user, assign a **Role** to the user, select **Actions** to assign to users.
4. Select the **Groups** to add users to the group if required.
5. Click **Create**.
   *For additional assistance, please see the job aid "How to Invite Room Users"

Upload Documents to a Room from the Home Page

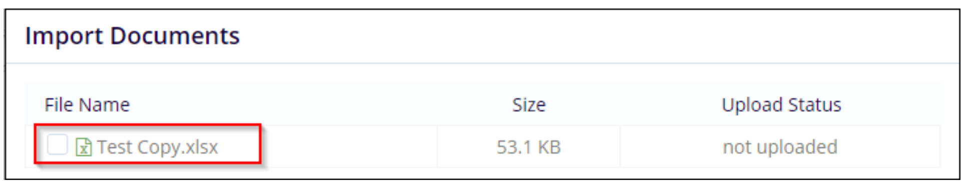
Follow the steps below to upload documents to a room from the Home Page:

1. Click the **Add** dropdown menu at the right side of the Room line on the home page to reveal the options.
2. Select the **Document** option from the dropdown list that appears.
3. Drag and drop the files from your computer, click the arrow in the center of the window, or click Browse at the bottom of the page to navigate to the required document to be uploaded. See below screenshots:





4. Once the document is added, click on the **Import** button to import the document.

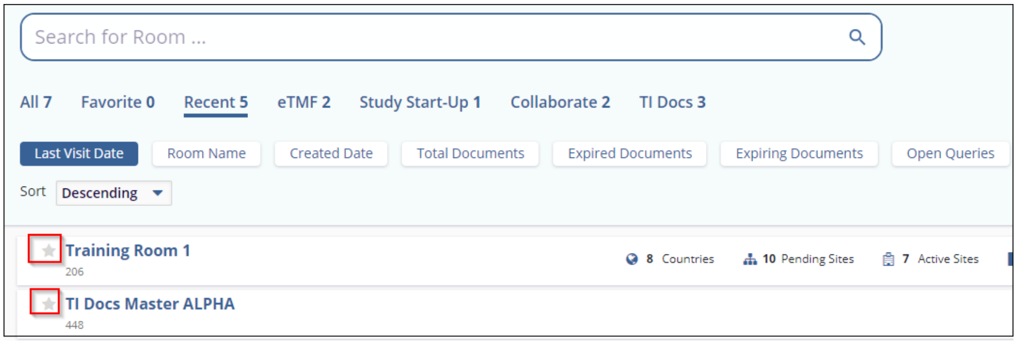


5. Once the document uploading is completed, the system displays a notification to the user regarding the status of the job.

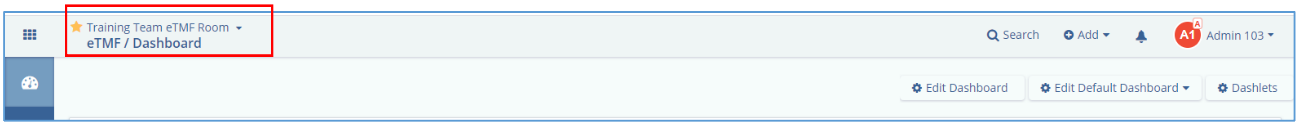
Marking Favorite Rooms

Many users are granted access to more than one Trial Interactive room. Users can make particular rooms easier to locate by marking rooms as Favorites. This can be done in two ways.

1. On the Home Page, click the star. It will change to gold, indicating that the room has been designated as a favorite. Clicking the star again will remove the room from your list of favorites. Refer to the screenshot below:



2. On entering a study room, you can mark it as a Favorite by clicking the star at the top left corner of the page where the room name is displayed. The room can easily be removed from the list by clicking the star again.

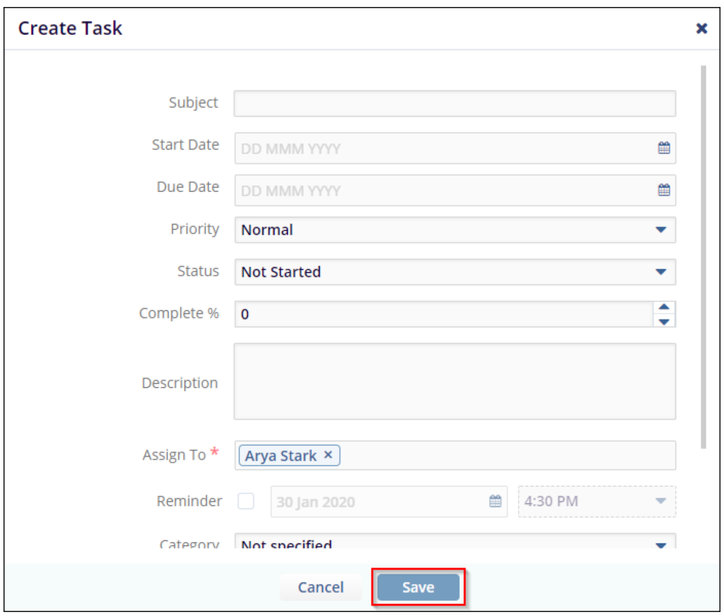


Adding Tasks to a Room

To add documents to a room:

1. Click the **+Add** dropdown to the right of the required room name and select the **Add Task** option. Refer to the screenshot below:

2. The **Create Task** window opens.
3. Fill in the details as instructed on the screen.



4. Click **Save** when all the information is filled.

Chapter 3. Main Navigation and Inter-Room Navigation

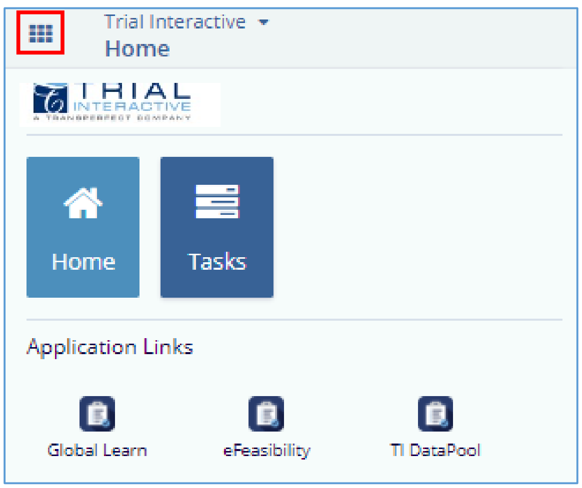
Depending upon system access rights, a user may have access to a large number of rooms and possibly several different products on the TI Platform. The issue then becomes quickly locating and accessing the intended room or other area of the system. Trial Interactive has several tools to assist with easily locating and navigating to the correct room or application as needed both from with a room and from the Home Page.

The following section will discuss the various ways in which a user can navigate between rooms and applications. In particular, we will be covering the following:

1. Using the Navigation Grid from the Home Page
2. Using the Navigation Grid from Within a Room
3. Navigating between Rooms

Using the Navigation Grid from the Home Page

The Navigation Grid can be accessed from the Home Page by clicking the **Navigation Grid icon** located at the top left corner of the page (marked with a red box in the screenshot below).

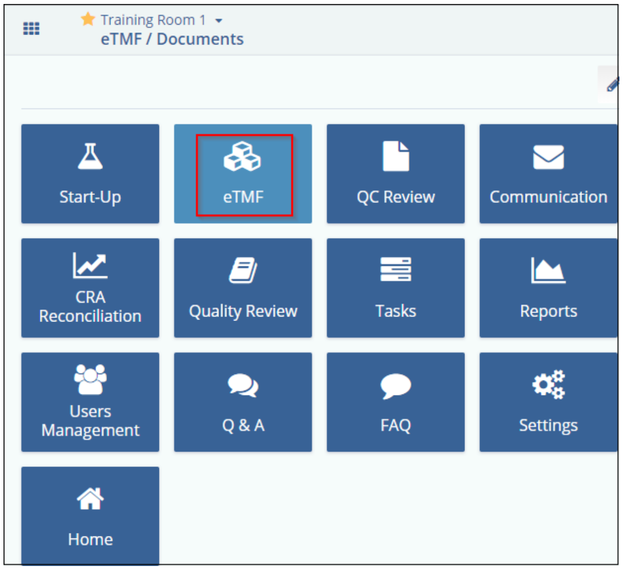


Given that this is the Home Page, your navigation options are limited. You can return to the initial Home screen which you landed on when entering the room or you can access the Tasks Module. If your company or group has access to other Trial Interactive products such as Global Learn, eFeasibility, or DataPool, you can access those from the Home Page as well. These application links take you to the website for the chosen product.

Using the Navigation Grid from within a Room

On entering a room from the Home Page, users who have not set up a default context configuration (a specific part of the system which they will be taken to upon entering a room) a user is typically taken to the dashboard or other default page. The Navigation Grid is located at the upper-left portion of the screen.

From within a room, as a user of Trial Interactive, you can choose which application to access by clicking the **Navigation Grid** located at the top left corner of the page. Refer to the screenshot below:

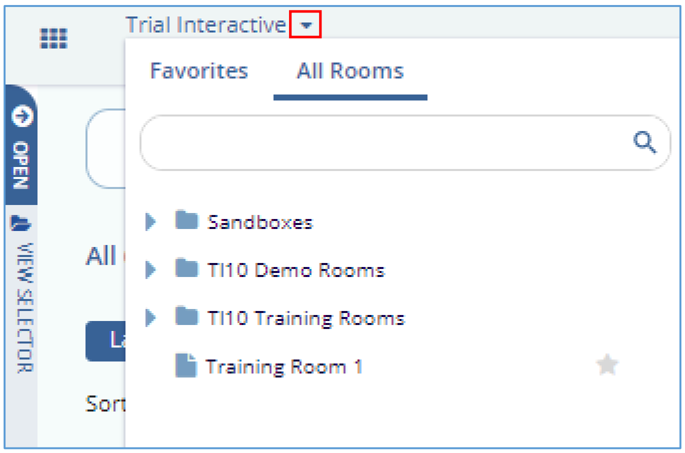


The modules that can be accessed from this menu depend on which elements of the system your group is using and also which of those features you have been granted permission to access by the room administrators. The possibilities include the following modules which can be found in the Navigation Grid:

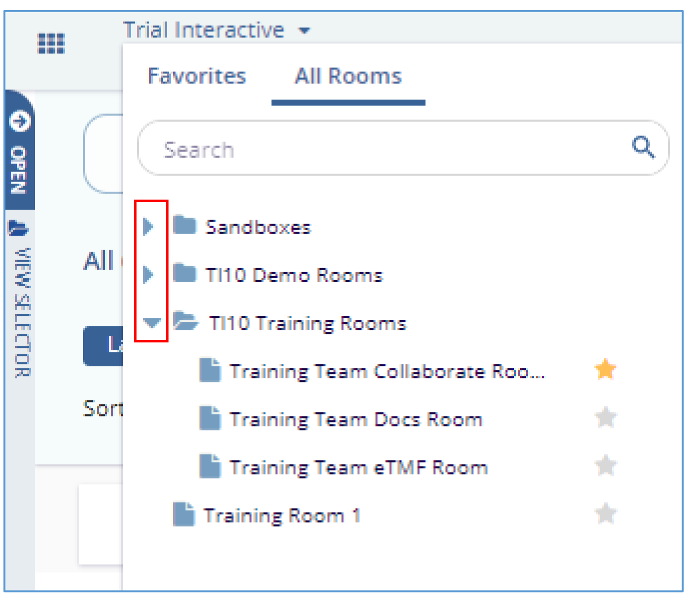
1. Home
2. Tasks
3. eTMF
4. Quality Control (QC Review)
5. Study Start-Up (Start-Up)
6. Quality Review/Audit
7. Communication
8. CRA Reconciliation
9. Q&A
10. FAQ
11. Users Management (Admins Only)
12. Reports
13. Collaborative Workspace
14. Settings (Admins Only)

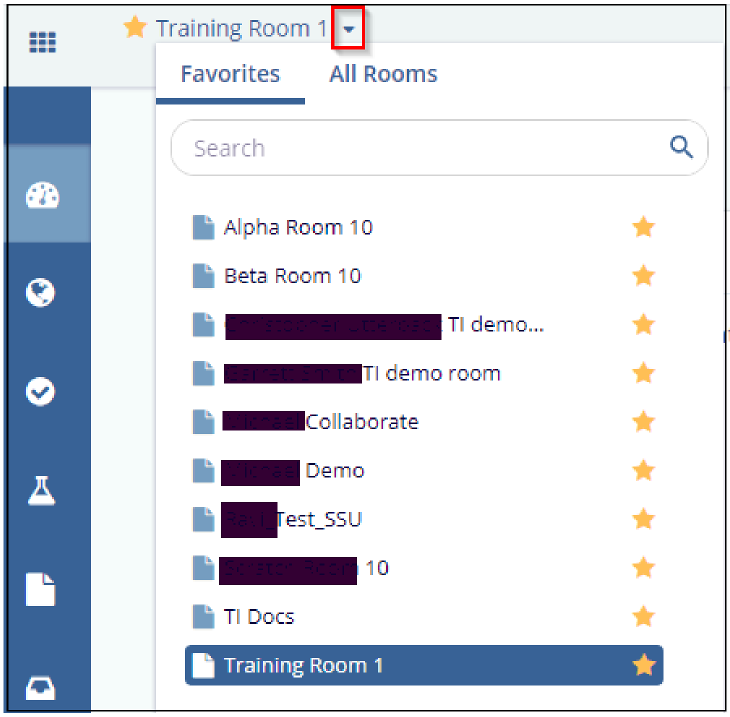
Navigating between Rooms

Within Trial Interactive, you can change rooms from any location within the application without having to navigate back to the home page. Just click the dropdown next to the room name to open a popup window with the list of all the rooms to which you have access. Refer to the screenshot below:



Click the arrow next to the room name. Select a room from the dropdown list that appears. Refer to the screenshot below:




Training Room 1
Favorites
All Rooms
Search
Alpha Room 10
Beta Room 10
[redacted] TI demo...
[redacted] TI demo room
[redacted] Collaborate
[redacted] Demo
[redacted] Test_SSU
[redacted] 10
TI Docs
Training Room 1

Chapter 4. User Name Menu

In the top-right portion of the screen the user can see their "Avatar" which is either a colored dot (the color is determined by the user's access level) with the user's initials or a picture that was chosen by the user Clicking on the user's name or on the user's avatar will open up a menu called the "User Name Menu." This menu has a multiplicity of uses including the following:

1. About This Room – This will display room-specific information.
2. Help (Contact Support) – Create a ticket for our Support Desk quickly and easily.
3. My Profile Settings – Change settings associated with your user account.
4. Language Settings – Users can choose to have the TI user interface translated.
5. Notifications – Subscribe to or unsubscribe from room-generated email notifications.
6. Guide – Access our full Online User Guide, including all job aids and videos.
7. Logout

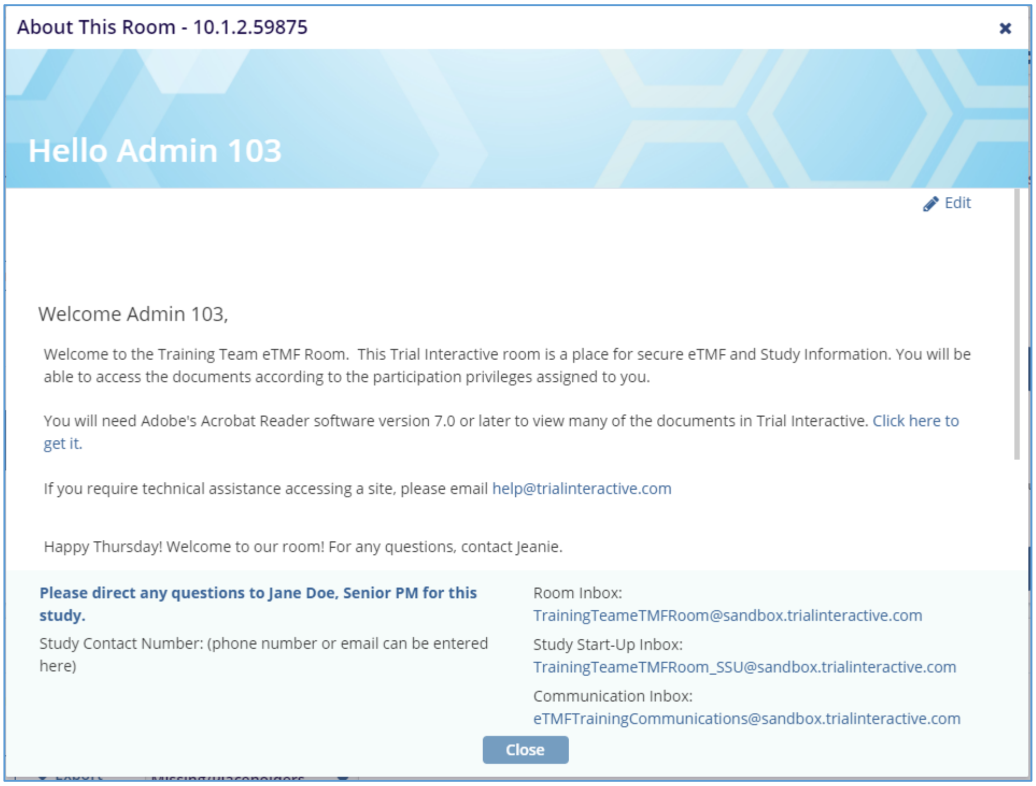
Each of these is discussed below.

About This Room

Click the **Show** button to reveal the **About This Room** window. This is typically configured by room Administrators to welcome new users and provide them with information pertaining to the room contents, focus, study, intent, etc. Administrators can update this information from this window or from the Settings area.

Some suggested uses for the Welcome message are:

- The correct contact for technical assistance with the room.
- Whomever is available to answer internal questions such as study-related questions.
- Links to special browser plug-ins so that you can view encrypted documents as necessary.



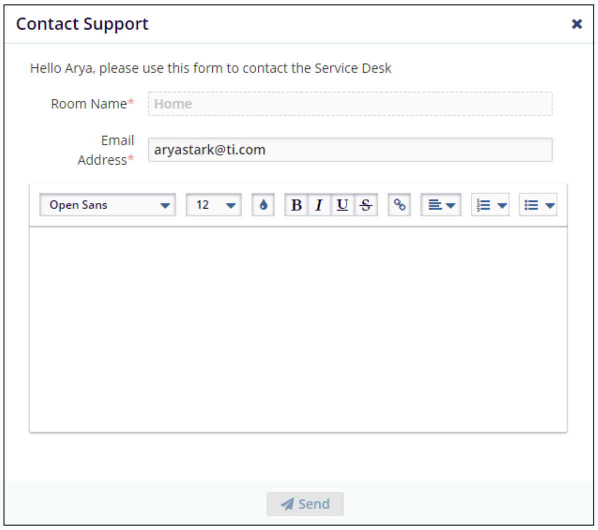
Administrators can click the **Edit** icon at the top right corner of the window to type in new information or to edit existing information. After editing the contents, click **Save** to save the contents and exit, or **Cancel** to exit from the Edit screen. Any changes made will be immediately visible to all room users.

Help

If you encounter any unexpected system behavior or just generally need help related to Trial Interactive, you can contact the Service Desk by clicking Help in the User Name Menu.

Clicking Help opens the Contact Support email window. Enter the details for the request (issue encountered, request for information, etc.) and send it to the Service Desk.

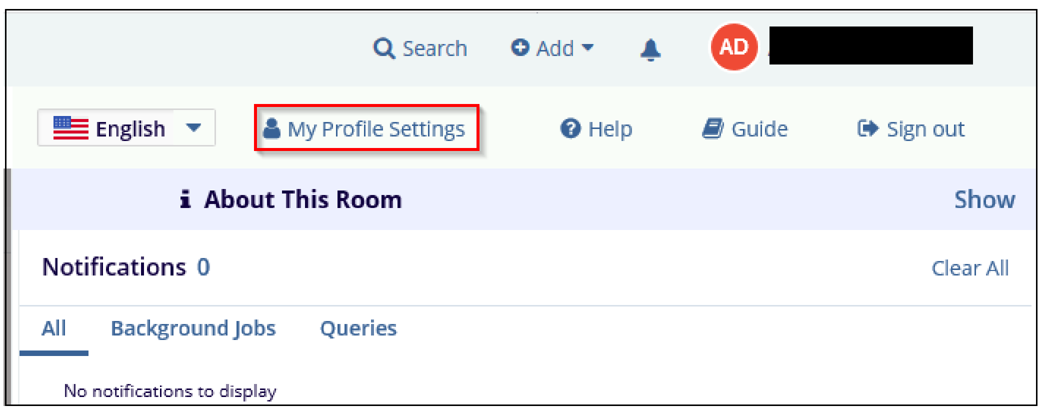
Refer to the screenshot below:



My Profile Settings

From here, you can manage your profile. This includes options such as resetting your password, changing your security questions, adjusting time and date settings, and telling the system where you would like to be taken to when you first log in.

1. Click the **Username Dropdown** located at the top right corner
2. From the popup that appears, click **My Profile Settings**
3. You are taken to your profile settings page. Refer to the screenshot below:



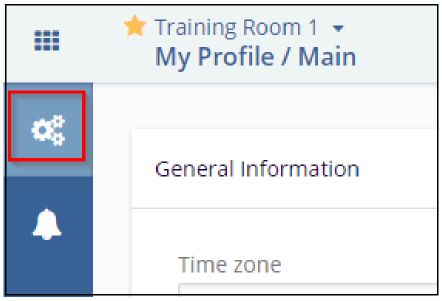
The My Profile Settings is divided into the following two sections:

1. My Profile Main Section
2. My Profile Notifications Section.

Each of these is discussed in detail in separate topics. Navigate to the left pane to access the required topic.

My Profile Main Section

From the My Profile Settings page, click the Main section from the left panel. Refer to the screenshot below:



From here you can access the following:

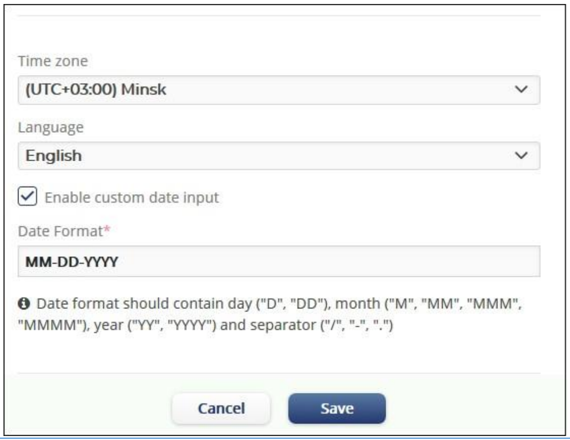
Sub-sections with the My Profile Main Section	Purpose
General Information	From this section, you can set your time zone, language for your user interface, and the date format preferred by you
Change Password	From this section, you can change your existing password to set a new one
Password Recovery - Secret Questions	You are required to set the answers to two secret questions to help recover your password if you happen to forget it
User Avatar	From this section, upload a new avatar image for your user profile
Sites Filtering Options	From this section, you can choose to view only those sites where you are CRA
Change Email Address	From this section, set your contact email address
Default Context Configuration	From this section, you can set the default landing page when you enter a room

Each of these is discussed in detail in the sections below:

General Information - Time Zone

To set the time zone applicable to you:

1. Click the **Time zone dropdown** to reveal the available time zones.
2. Scroll up or down to locate your time zone and click the appropriate time zone to select it.
3. The selected time zone displays in the box.
4. Click **Save**.



General Information - Language

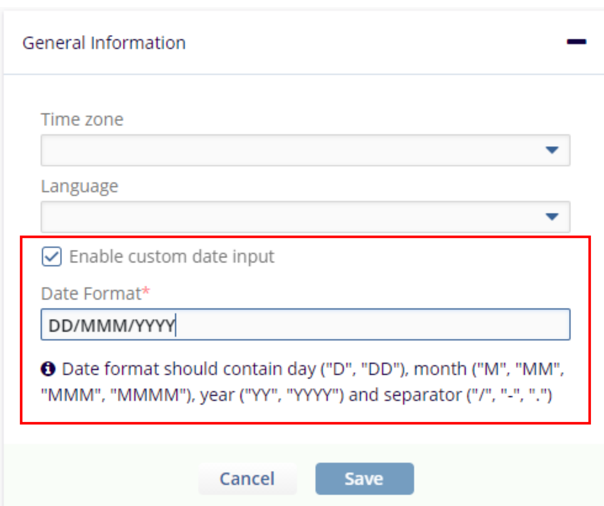
To set your preferred language:

1. Click the Language dropdown.
2. Scroll down to locate your preferred language.
3. Click the language to select it.
4. The selected language displays in the box.
5. Click Save.

General Information - Enable Custom Date Input

With the Trial Interactive 10.1 release, while coding a document, in addition to selecting the date from the Calendar Date tool, you can directly type in dates in whichever format is preferred by you. The system interprets the date entered by you manually and saves it.

To be able to manually type-in dates, check the box to enable the manual entry of custom dates. Refer to the screenshot below:



1. Check the box labeled '**Enable custom date input.'**
2. The Date format textbox is activated. Enter the date format as preferred by you. Some of the most common date formats are **MM/DD/YY**, **DD/MM/YY**, **MM/DD/YYYY**, **DD-MMM-YY**.
   - The informational text below the field can be used to help you enter the date format correctly.
3. Once done, **Save** the changes. You will now be able to enter dates in the new format.

Change Password

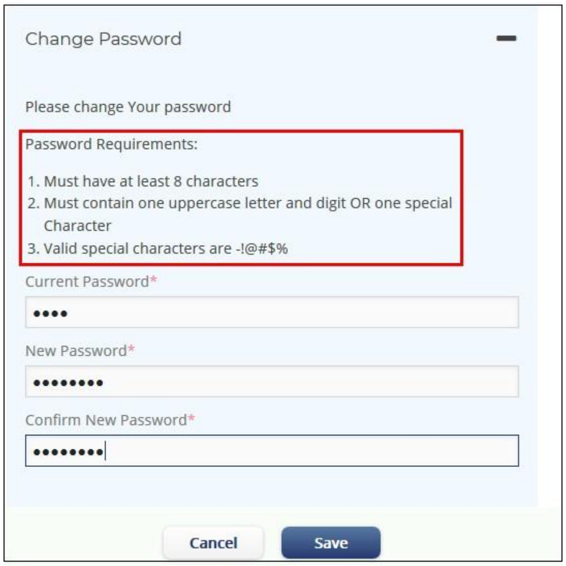
From this section, you can change your existing password to set a new one.

Remember: *Follow the rules displayed under Password Requirements heading while setting the password*.

To set the password:

1. Enter the new password in the **New Password** text field.

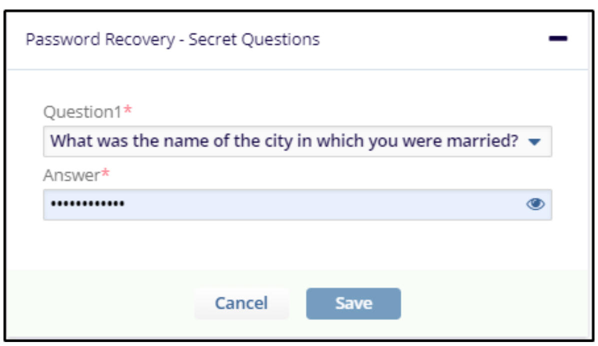
2. Re-enter the password in the **Confirm New Password** field.
3. Click **Save** for the new password to be applicable**.** Refer to the screenshot below:



Password Recovery - Secret Questions

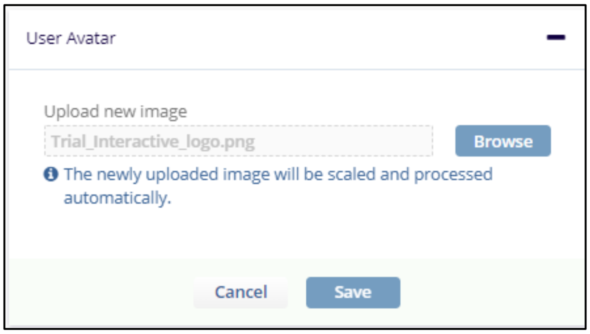
You are required to set the answers to two secret questions to help recover your password if you happen to forget it. To set the secret questions and their answers:

1. Click the down arrow in the **Question 1** field.
2. Scroll the popup through the list of questions and click on a question of your choice to select it.
3. Enter the answer in the **Answer** field.
4. Repeat steps 2 and 3 to set **Question 2** and its answer.
5. Click **Save.**



User Avatar

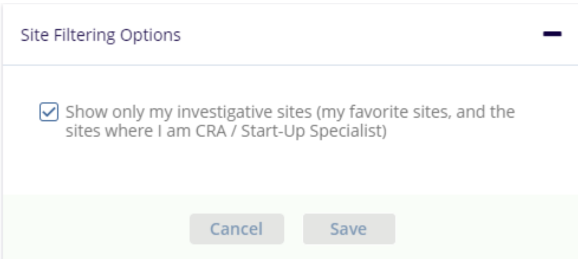
Click Browse in the panel to upload a new picture for your account and click Save.


User Avatar
Upload new image
Trial_Interactive_logo.png
Browse
The newly uploaded image will be scaled and processed automatically.
Cancel
Save

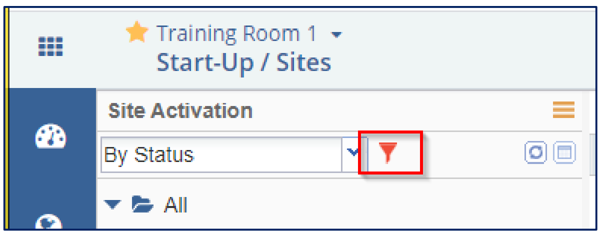
Sites Filtering Options

You can choose to view only those sites where you are specifically assigned either in the Sites module or in SSU by ticking this checkbox and saving the changes. Refer to the screenshot below:

On selecting this option, the toggle in the Sites module of SSU changes color to red. Refer to the screenshot below:

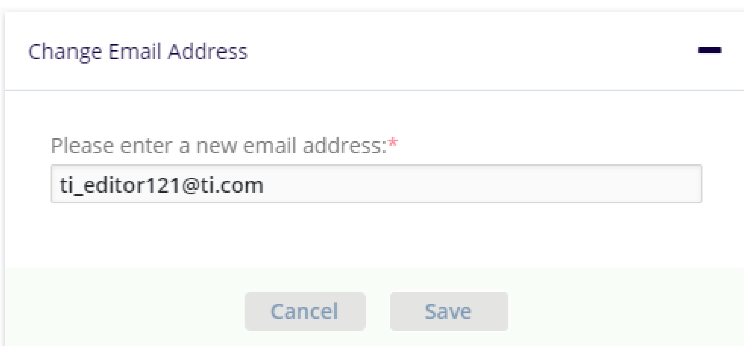


Change Email Address



This will change the email address to which notifications and other communications are sent for the user. Enter your new email address and click Save. You will now be able to receive emails at the new email address. Refer to the screenshot below:

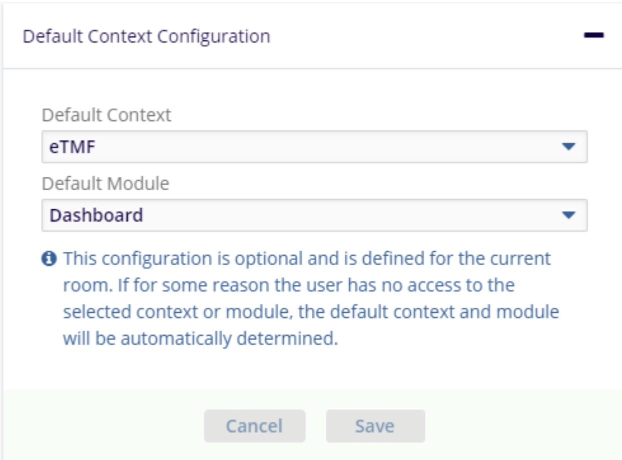
Note: *If the email id entered matches that of another user or login id then an error message will be displayed, and you will not be able to change the email id unless you enter another one that does not match any other user credentials.*



Default Context Configuration

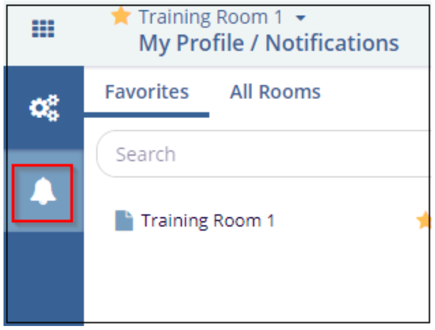
You can choose which part of the system should be your preferred landing page by selecting your Default Context as shown in the screenshot below:

1. Select the **Default Context** from the **Default Context** dropdown.
2. Select the preferred view from the **Default module** dropdown.
3. Click **Save.**



Notifications

The Notifications section allows you to specify which email notifications you would like to enable for your account for each of the Trial Rooms to which you have been granted access. Refer to the screenshot below:



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 to disable some notifications or to make some mandatory as well.

The notification options will vary by user depending upon their access level.

You can elect to receive either a mini summary of notifications or nightly newsletters recapping all of the new events in the past 24 hours for each of the notification categories.

Important:

The availability of the notification option is determined by the client-appointed Administrator in each room. Some notifications may not be enabled and appear greyed out to the user. For example, workflow notifications may not be available to users with Editor access.

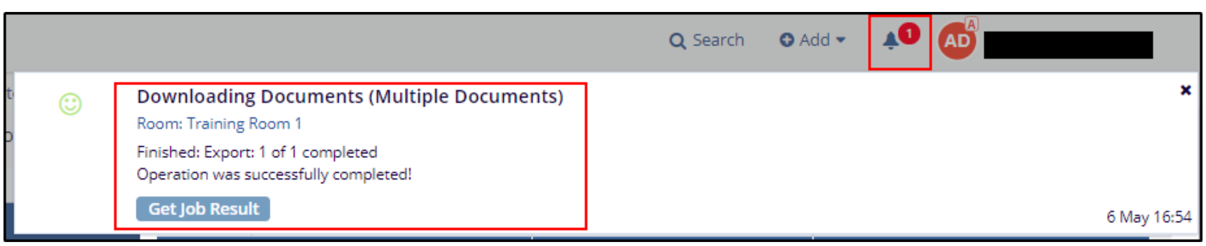
Language Settings

This allows you to set the language of your choice for your login.

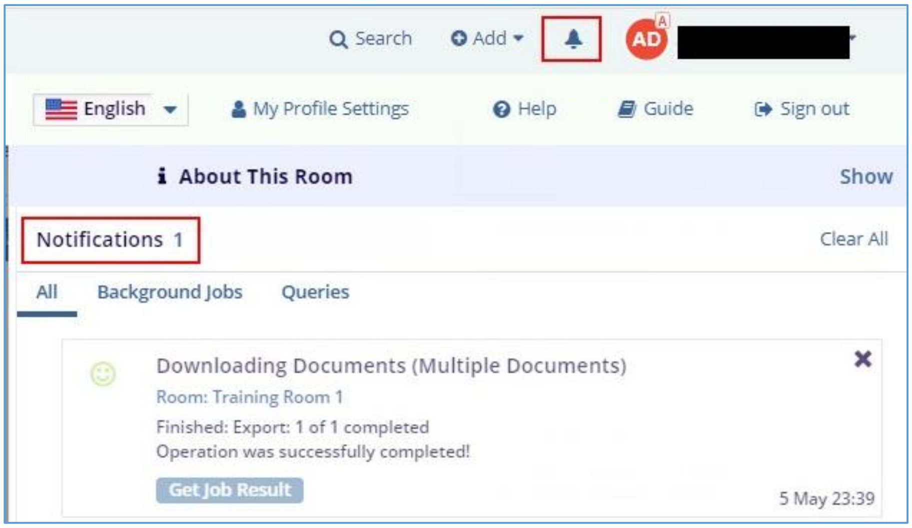
1. Click the **language** dropdown scroll to locate the language of your choice.
2. Click the language to select it to make it the default language for your User Interface. Refer to the screenshot below:

User Requested Job Notifications

Through the notifications panel, located within the User Name Menu, you can view messages and results of various jobs that you perform in Trial Interactive. The bell icon in the screenshot below shows the number of notifications waiting for the user. Refer to the screenshot below:



Clicking on the bell icon will open the User Name Menu and display the user's notifications.

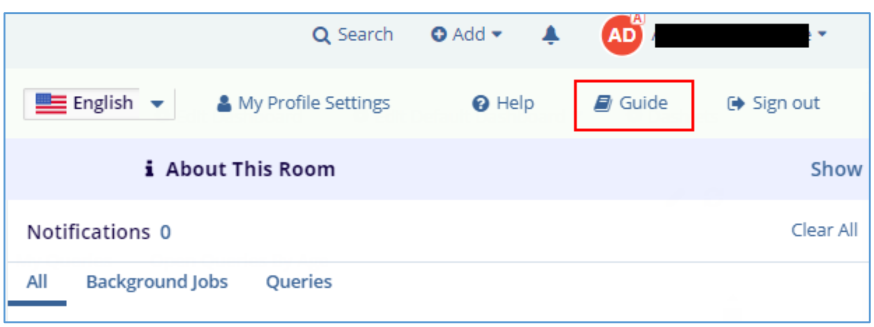


This section has the following tabs:

- **All:** Click this tab to get a list of all the tasks that are ongoing, pending, or are 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 executing or is completed.
- **Queries:** Click this tab to get a list of all the queries pending for action. You can click any individual query link to lead you to the Queries sub-module for you to initiate your actions on it.
- 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 zip.

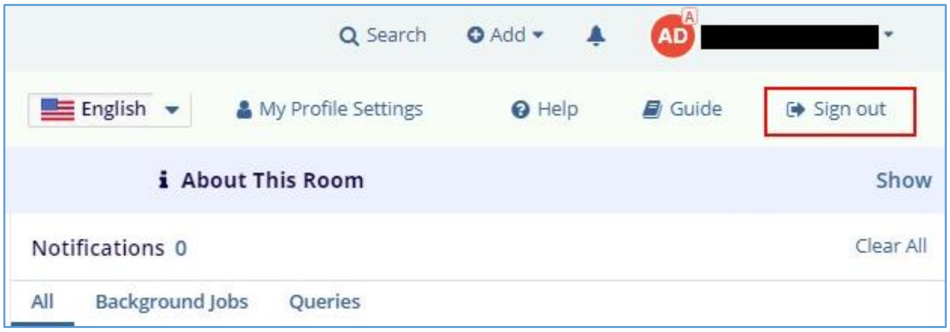
Guide

You can access the online help of the version of the Trail Interactive from here. Clicking Guide opens the help in the browser. Refer to the screenshot below:



Sign Out

Click ‘Sign out’ to end your current session and exit the application. Refer to the screenshot below:

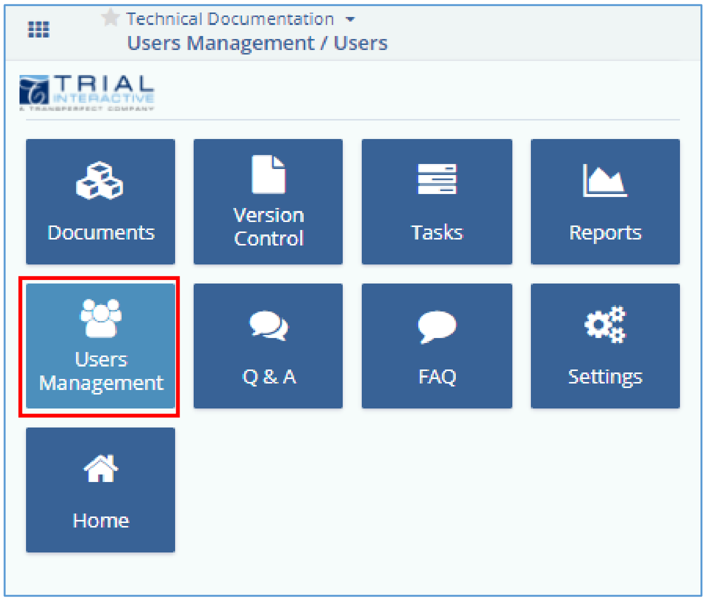


Chapter 5. Users Management

The initial users for a study room will often be invited by Trial Interactive as indicated on the Configuration Manual for the room. However, it is not uncommon for Administrators to find themselves needing to manage Groups, Users, and Contacts over the lifetime of the room. Administrators can add new users, revoke access to users, or simply edit the access for an existing user through the Users Management module of TI. Some examples of what a room administrator can do are listed below:

1. Invite new users to a room/study
2. Create a group of users
3. View lists of room users under different categories
4. Edit user profile
5. Change access level of users in a room and of groups to which they are assigned
6. Resend invitations to room users
7. Filter and Export users
8. Delete users

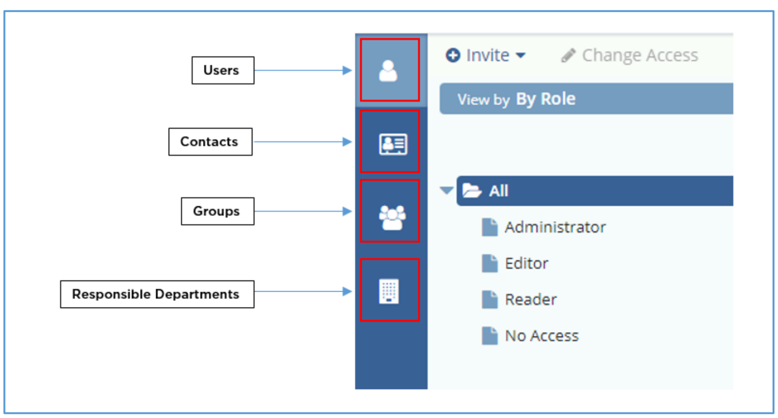
You can reach this page from Main Navigation by clicking the Users Management application. Refer to the screenshot below:



From the User Management page:

a. Click the "**Users**" icon for the **Users** page to create/edit/delete groups in a room. This is also the default page that you land in when you open the *User Management* application.
b. Click the "**Contacts"** icon from the left pane to access site contact such as Principal Investigators, Study Coordinators, etc.
c. Click the "**Groups**" icon from the left pane for the **Groups** page to add/edit/delete users in a room.
d. Click the "**Responsible Departments**" icon for the **Responsible Departments** page to add/edit/delete members and document types to different departments.

Refer to the screenshot below:



Users Management - Users

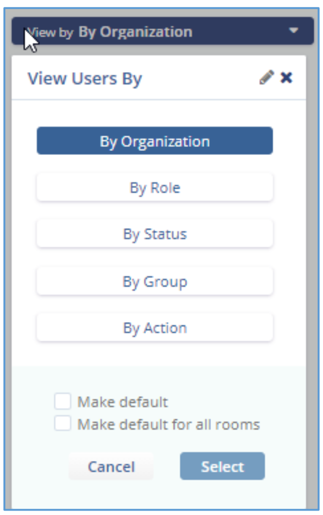
From this page, you can do the following:

1. Invite users through a Regular Invitation or a Quick Invitation
2. View room users sorted by category
3. Edit a user's Role (Reader, Editor, Administrator)
4. Change the user's access rights to the room
5. Resend an invitation to a room user
6. Delete a user access
7. Export User information

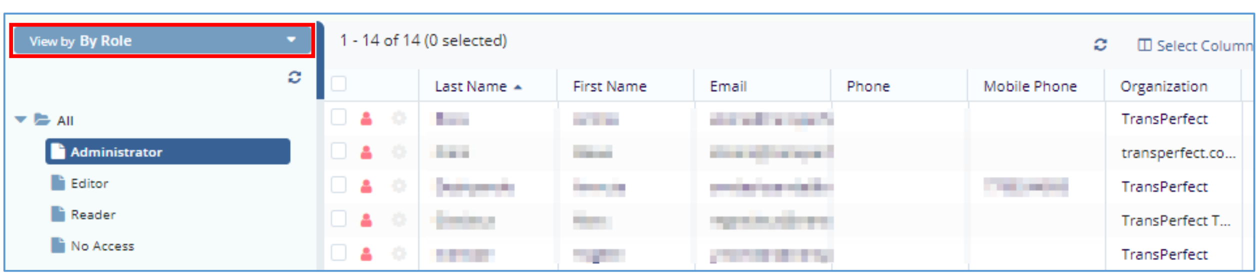
User Viewing Options

Users in Trial Interactive can be grouped under several categories for easy viewing. This is particularly useful when you want to audit the room users to ensure that everybody has the correct level of access or that all of the users associated with a particular partner organization are categorized appropriately. Follow the steps below to view users by one of the available categories:

1. Click the **View by** dropdown menu at the left side of the screen.
2. This opens the **View Users By** popup window with the list of categories for user viewing. Refer to the screenshot below:



1. Select the category by which you want to sort the users.
2. Click **Select**. You can also make this the default view by selecting the **Make Default** checkbox.
3. The screen will refresh to show the users by the category chosen.
4. Choose from any available sub-categories. In the screenshot below, the user has selected to view all users by their **Role** and they have selected to view all **Administrator** level users.



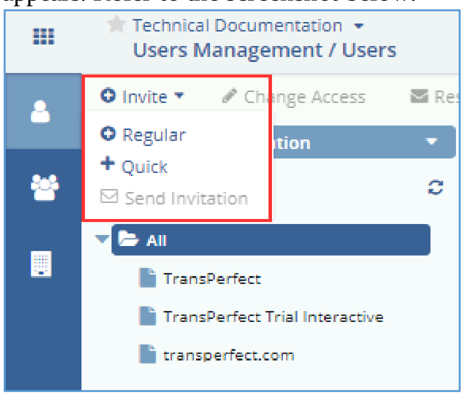
Inviting a user via the 'Regular' invitation

When inviting new users to a room in Trial Interactive, the room administrator can choose from two different types of invitations: Regular or Quick. The Regular method is best used when the administrator wants full control over the information entered and wants to be sure that all of the user's information is complete prior to being sent an invitation. In short, this method is for inviting one user at a time while inputting all of their information.

When inviting large numbers of users, it may be more efficient to use the Quick invitation method (shown later in the chapter). This method differs in that it requires less information to be entered for each user prior to the invitation being sent. Each recipient will then be required to complete a registration process prior to entering the room for the first time. When using this method, it is important that the administrator use the available management tools to ensure that all information was entered completely and correctly during this process.

Follow the steps below to create a new user using the "Regular" invitation method:

1. Navigate to Users Management.
2. Click the **Invite** dropdown menu from the menu bar near the top of the screen and then select '**Regular**' from the list that appears. Refer to the screenshot below:

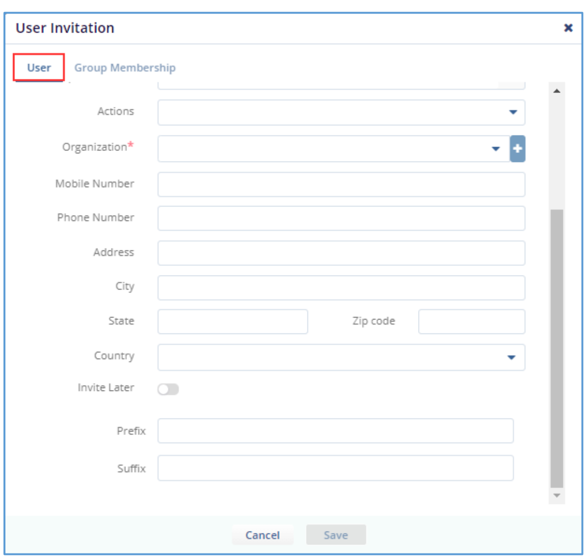


3. The User Invitation pop-up opens.
4. Complete the required fields and fill in any optional information as desired.
5. If you would like to add the user to a group while you are creating their invitation, click on the **Group Membership** tab at the top and select the desired groups.
    a. If you would like to create the user but not send an invitation right away, use the **Invite Later** option. This will create a **Pending** user account.
6. Once you are done, click **Save**.
7. The user will be created and, unless the **Invite Later** option has been selected, the invitation will be sent.

Note: The *Edit User* and *Group Memberships* pages are discussed in separate sections below.

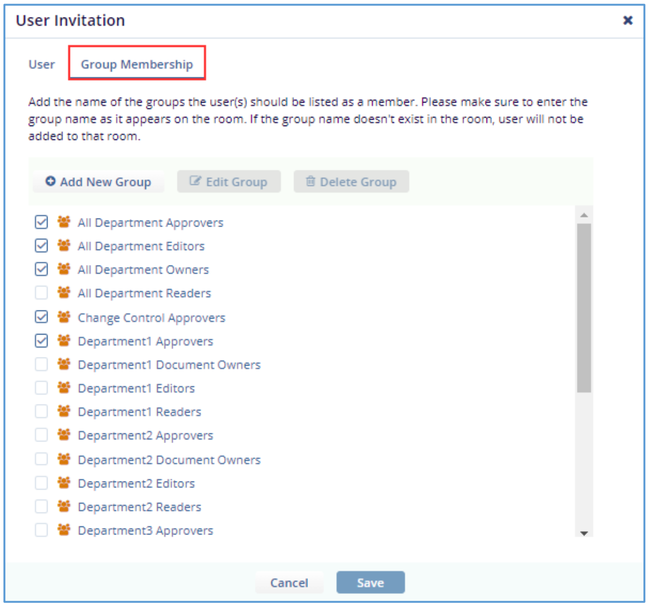
Completing the User Profile

1. In order to complete the User Profile as required during the invitation process, select the Regular invitation as shown below.



2. The fields of importance are discussed below:
   a. **User Email**: This is used by the system as a unique log in for Trial Interactive. This can be typed in manually or, if the user is already present in the system, you can search for it by clicking the magnifying glass icon at the end of the field.
   b. **Role**: Choose the user's access level by selecting their Role from the dropdown menu. The roles can be **Admin**, **Editor,** or **Reader**.
      - User access is awarded on a room-by-room basis and can vary as needed.
   c. **Actions**: These are actions or permissions that can be awarded to a user above and beyond their basic user access role privileges.
   d. **Expiration Date**: Enter this date if you want the user's access to be revoked on a specific day.
      - This is particularly useful for temporary user accounts such as external auditors or short-term contractor access.
   e. **Organization**: Choose the organization to which the user belongs from the dropdown menu if the organization has been previously used in the room. If necessary, the Administrator can also create an organization by clicking the '+' sign at the end of the textbox.
   f. **Invite Later**: Click the toggle switch on if you want to create a user account in the room but not send the invitation yet. The administrator can select the account and send the invitation whenever they are ready using the **Send Invitation** option in the **Invite** dropdown menu at the top of the screen.

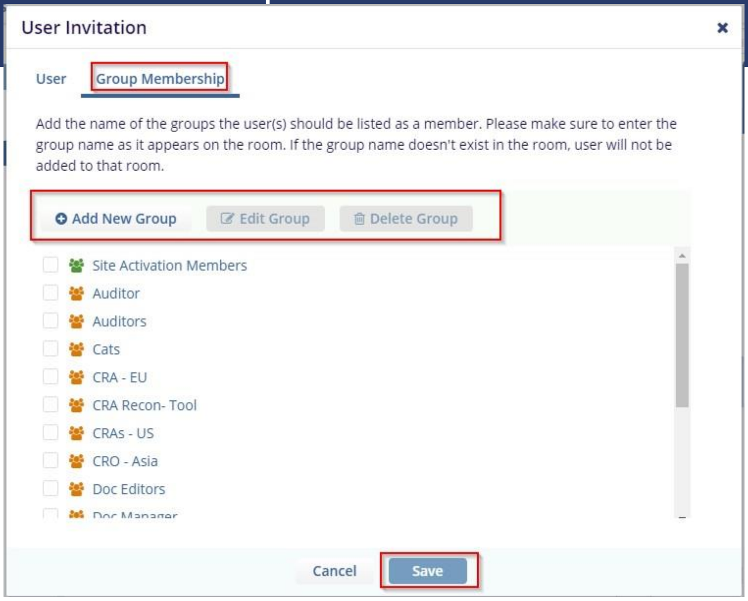
3. When all the required fields are filled, the "**Group Membership"** tab becomes active. Click on the icon to open the "**Group Membership"** page. Refer to the screenshot below:



Groups Memberships

From this page, you can select the required groups from a pre-created list of groups to add the user as a member. If the group does not exist, then you may create the group on the fly through **Add New Group**. Besides, you can also **edit** or **delete** a group.

*Note that the **Edit Group** and the **Delete Group** buttons enable on when you select the group from the list*. Refer to the screenshot below:



The following topics are discussed later in this chapter:

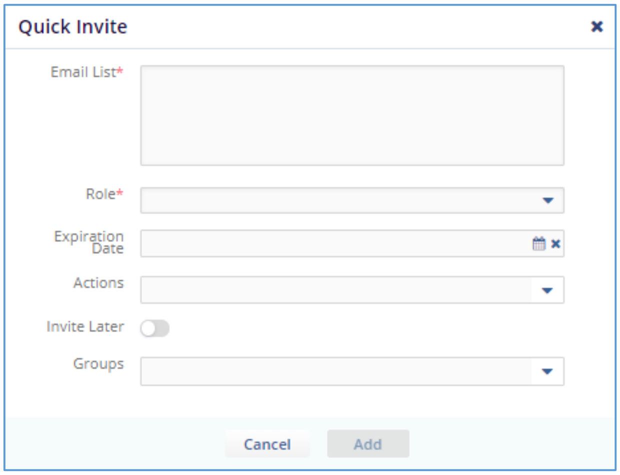
1. Add New Group
2. Edit Group
3. Delete Group

Inviting a user via the 'Quick' Invitation

You can use the **Quick Invite** method when you want to invite a group of users at the same time. These users will all be granted the same role, actions, access period, and group membership. This requires less time on the front end but it does mean that the room administrator will need to follow up to ensure the accuracy and completeness of the information provided by the users during the registration process.

Follow the steps below to use the Quick Invitation to invite users:

1. From the **Users Management** area, click the **Invite** dropdown from the top menu bar and then select **Quick** from the list of options that appear.
2. The **Quick Invite** window will open.
3. Enter the email addresses of all the users to be invited.
4. Complete the remaining required fields as well as any optional fields necessary.
    a. Whatever information is entered will be applied to all users invited.
5. Click the **Groups** dropdown menu to grant these users any group membership required.
6. Click **Add**. Refer to the screenshot below:



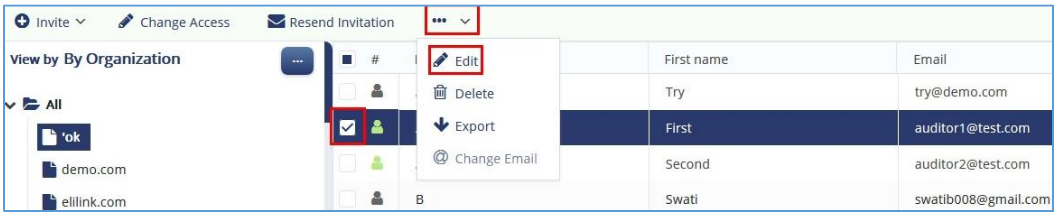
The invited user(s) will receive an email invitation to register in the Trial Interactive room.

Editing and Deleting Existing Users

Editing Users

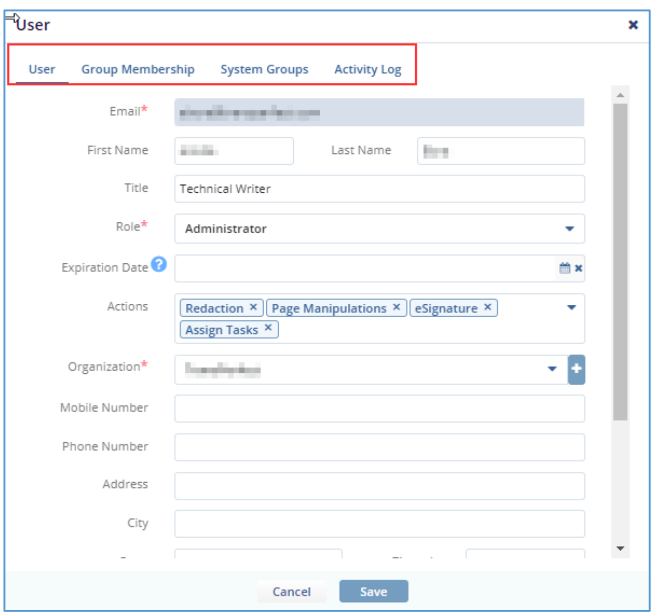
Follow the steps below to edit user access:

1. From the Navigation Grid, select Users Management.
2. Locate the user whose account needs to be edited.
3. Select the user from the list on the grid
4. From the top menu bar, click the three dots and then click Edit from the options that appear. Refer to the screenshot below:
    a. Editing a user account can also be done via the pane at the right side of the screen or by right-clicking on a user in the grid and selecting **Edit.**

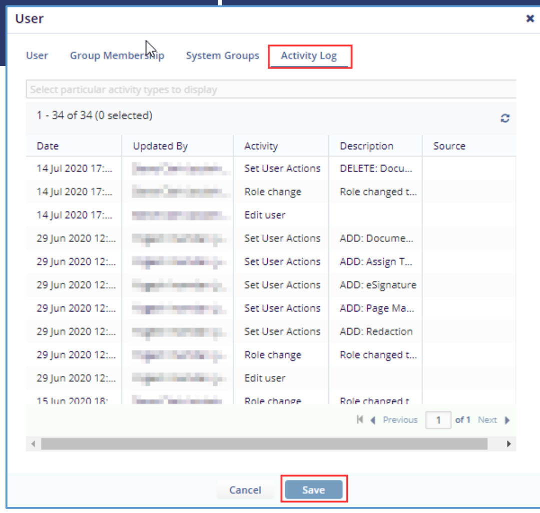


5. The Edit User popup will open. From here, you can select from the following tabs:
    a. User
    b. Group Membership
    c. System Groups
    d. Activity Log

Refer to the screenshot below:



6. Select the **User** section to edit the user details.
7. Select the **Group Membership** to edit the user's group membership.
8. Select the **Systems Group** section to manage the user's assigned security groups.
9. Select the **Activity Log** section to view the timestamp of activities for the user. See the screenshot below:

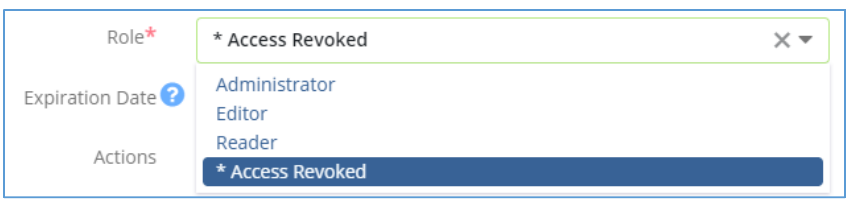


Deleting Users and Revoking User Access

Please note that deleting a room user should not be used unless the invitation was sent in error and the user has never entered the room. It is our best practice recommendation to use the steps below to Revoke User Access instead.

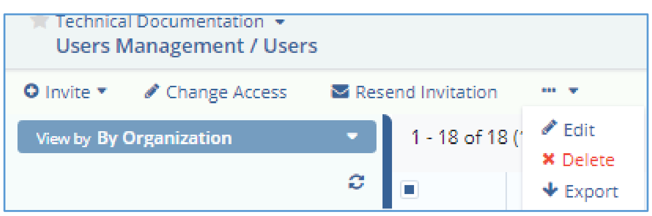
In order to **Revoke access** for a room user, use the steps listed above to Edit an existing user and make the following changes:

1. Expand the Role dropdown menu.
2. Choose Revoke from the list of options as shown in the screenshot below.



When appropriate, follow the steps below to **Delete** users from a room:

1. Locate the user whose access needs to be removed.
2. From the menu at the top, click the **three dots** and then click **Delete** from the options that appear. Refer to the screenshot below:

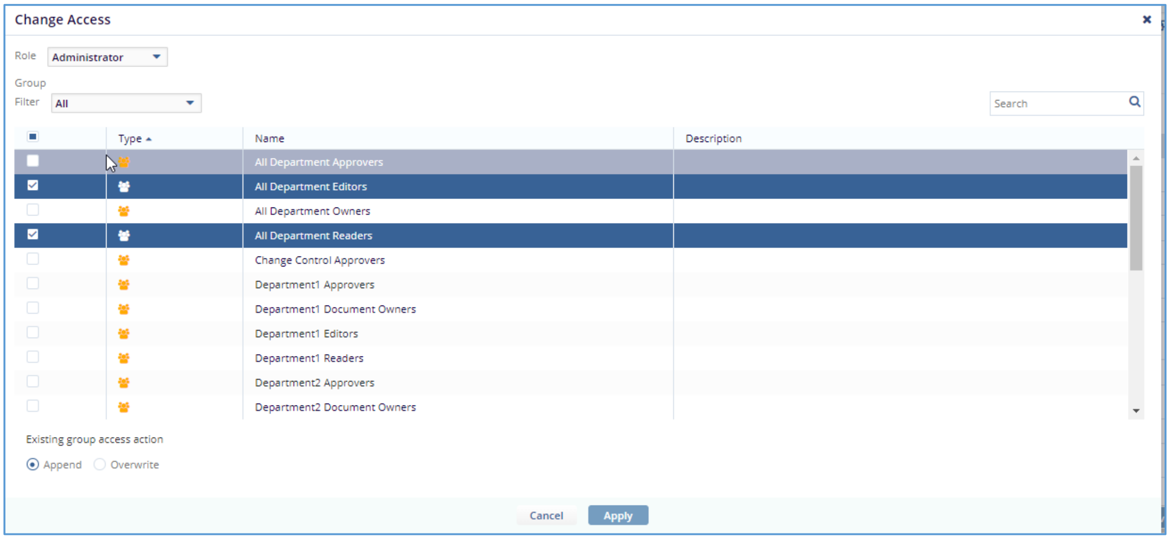


Changing User Access

Follow the steps below to edit user access:

1. Navigate to **Users Management → Users.**
2. From the left pane **Index View**, select the preferred category to view the user.
3. From the list of users displayed in the right pane under the selected category, tick the checkbox of the user whose access you want to change.
4. From the top ribbon bar, click the **Change Access** icon.
5. The **Change Access** popup opens.

6. Complete the details as required.
7. Click **Apply**. Refer to the screenshot below:



The fields of importance are discussed below:

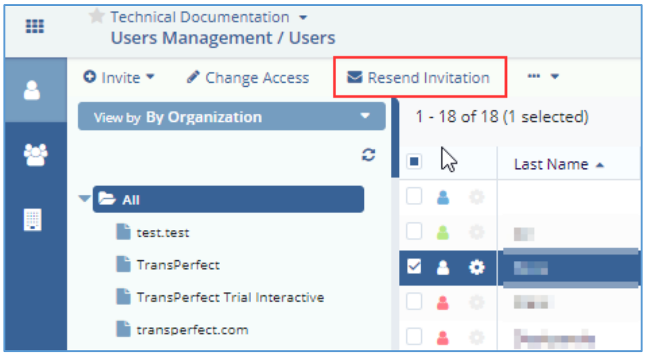
a. **Append** group access will add the user to the new group without removing the user from previous groups.
b. **Overwrite** group access will remove the user from all the previous groups and add the user to the selected group.

Resending Invitation

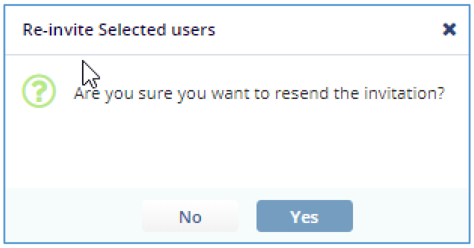
Room Administrators can resend an invitation to a user if the user has been invited but has not visited the room.

To re-invite users:

1. Locate the user or users in the grid and tick the checkbox for users to whom you want to resend the invitations.
2. From the top ribbon bar, click the **Resend Invitation** icon. A popup appears asking you to confirm. Refer to the screenshot below:



3. Click **Yes**.



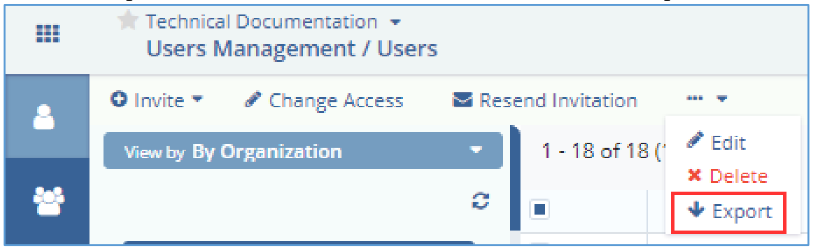
4. Invitations are resent to the selected users, and a confirmation notification appears for the same.

Exporting Users

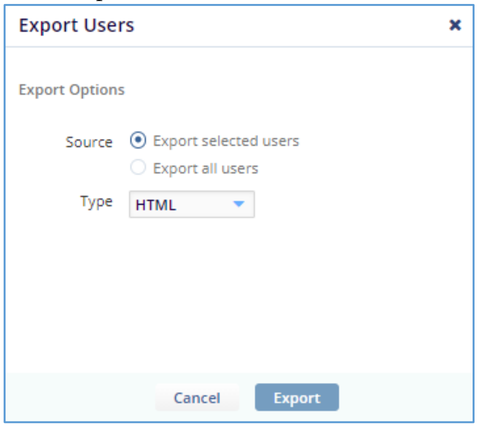
You can either export all the users available in the room, or export only selected users as required. Each of the processes is discussed in separate sections below:

Exporting Selected Users

1. Navigate to Users Management → Users.
2. From the left pane Index View, select the preferred category to view the users.
3. From the list of users displayed in the right pane under the selected category, tick the checkboxes of the users whose information should be exported.
4. From the top ribbon bar, click the three dots and then click Export from the options that appear. Refer to the screenshot below:



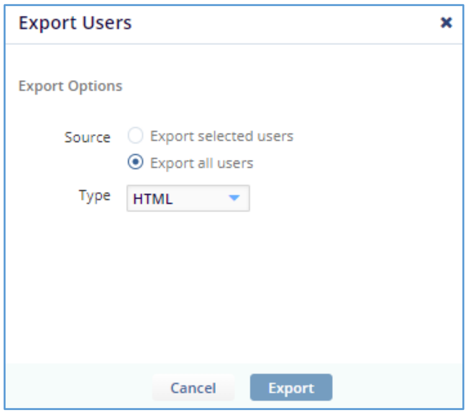
5. The Export Users popup opens with the Export Selected Users radio button highlighted.
6. Select the Type of export file format. You can select either HTML, Microsoft Excel, or Microsoft Word.
7. Click Export. Refer to the screenshot below:



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

Exporting All Users

1. From the top ribbon bar, click the **three dots** and then click **Export** from the options that appear.
2. The **Export Users** popup opens with the **Export all Users** radio button selected.



3. Select the **Type** of export file format. You can select either **HTML**, **Microsoft Excel**, or **Microsoft Word**.
4. Click **Export**.
5. You will receive a notification about the job completion.
6. Click **Get Job Result** to download the document.

User Management - Contacts

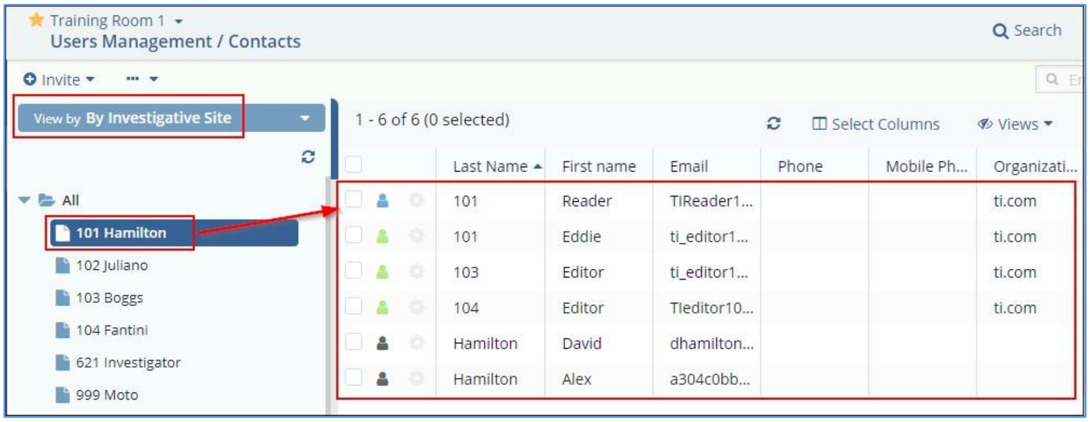
From this page, you can do the following:
1. View contacts by Investigative Sites
2. View Investigative Site Main Contacts Only

Viewing Contacts

This section allows you to view contacts that are available in the Investigative Sites.

Follow the steps as below to view users under various categories available in Trial Interactive:

1. From the **Users Management**, click **Contacts** from the left menu.
2. Select the category under which you want to view the users.
3. Click **Select** located at the bottom of the popup window.
4. The category and the list of users grouped under the categories are displayed in the Index Pane. The screenshot below shows the users added to the **investigative sites** '**Hamilton'**.



User Management - Groups

For those who have a smaller team, managing user actions and security privileges on a user-bu-user basis may be entirely feasible. However, as a team grows, managing user access individually can become difficult and inefficient. To that end, we have created the Groups feature in Trial Interactive.

Groups can be associated with user actions or access rights to certain folders of the index and those system access rights pass on to those users who are added to the group. One example might be adding the CRA Reconciliation action to a team of 50 CRAs and their managers. Doing that one user at a time would be time consuming and inefficient. Instead, creating a group whose members would be granted the CRA Reconciliation action and then adding all of the necessary room users would take only a matter of a few minutes.

Similarly, managing index folder access privileges individually can be very complicated whereas creating a group and assigning security rules to the group greatly reduces the potential confusion when determining who has been granted access to a folder or zone of the index. See the section on Managing Security for more information regarding this function.

Administrators can create, edit, and delete Groups as well as manage their membership by adding and removing users from the group as necessary.

Administrators can perform the following activities from the Group management area:

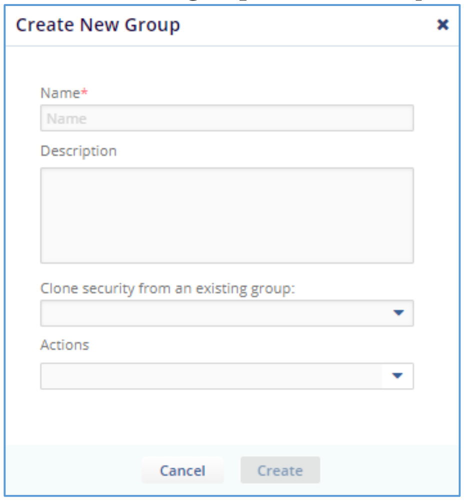
1. Add a New Group
2. Add a Child Group
3. Edit a Group
4. Delete Group

Each of these is discussed in separate topics below. Navigate to the topics from the left menu to access them.

Adding a New Group

New Groups can be added by clicking the Add Group button from the left of the Groups panel.

1. To add a new group, click the **Add Group** button at the top of the left pane.
    a. Please note: If any group has been highlighted in the left pane, the system will assume that the user is attempting to create a sub-group to that group. This is referred to as a "Child Group."
2. The **Create new group** window will open. Refer to the screenshot below:



3. Enter the new group's name.
4. Add the description of the new group.
    a. This step in particular, while not required, is highly recommended so that others immediately know the intended use of the group.

Note: *You have the option here to clone security settings from an existing group. If you know that the settings for this new group are identical to another group already established in the room, select that group from the dropdown menu and continue.*

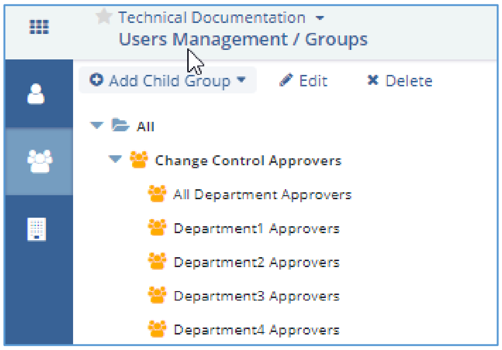
5. ***Optional:*** Using the Actions dropdown menu, select which actions the group's members will have access to.
    a. Note: A user added to a group which grants an action which is beyond their User Access Role will ***not*** be granted access to perform that action in the room. The user can still be added to the group, but the action will not be awarded to that user.
        i. Ex: A reader level user is assigned to a group which grants the Redaction action. Readers cannot perform this task and, therefore, the action will not be awarded to the user.
6. The Administrator can also view the actions available in a room along with their purpose from the **Main Navigation -> Settings -> General -> Actions.** This is discussed in Section **Actions**.

7. Click **Create**. The new security group will appear in the Groups list with no users assigned to it.

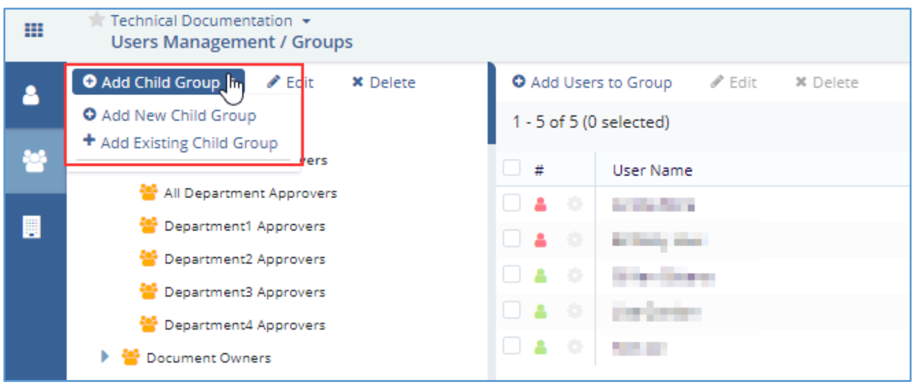
Adding Child Group

Follow the steps below to create child groups:

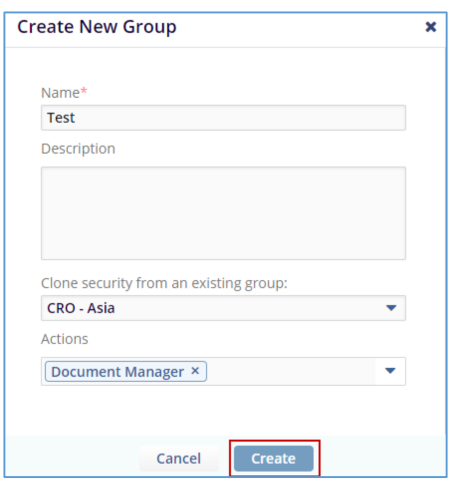
1. Click the arrow to the left of **All** to expand the list of groups and select the parent group from the list. Note that the **Add Group** button at the top left now changes to **Add Child Group** and the buttons Edit and Delete are also enabled. Refer to the screenshot below:



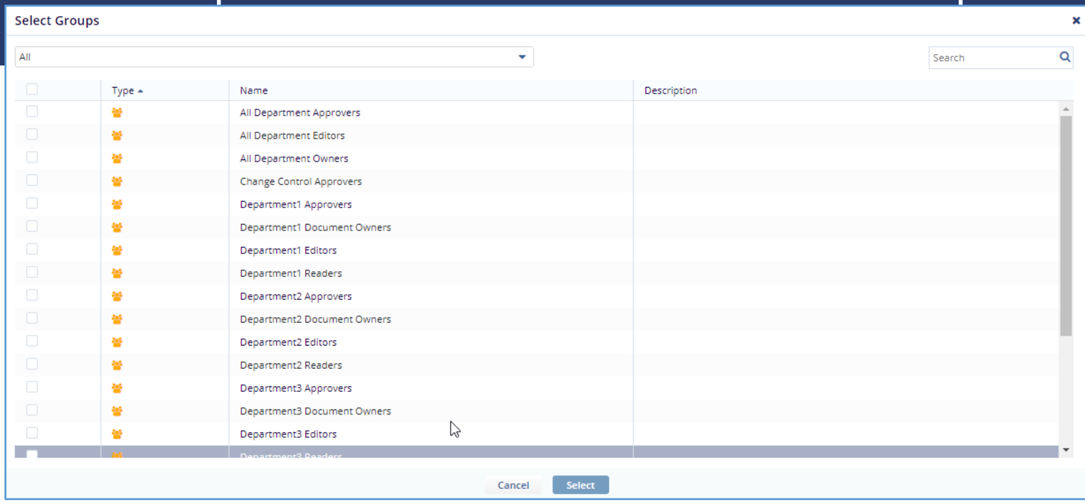
2. Click **Add Child Group** from the menu. There are two options for group addition: a) **Add New Child Group**, b) **Add Existing Child Group**. See the screenshot below:



3. If **Add New Child Group** is selected, then the Create New Group window will appear. Enter the details of the group to be created and click the **Create** button.



4. If the option of **Add Existing Child Group** is selected, then the **Select Groups** window will open.
5. Select the required group from the list for which you want to create a child group.
6. Click **Select**. Refer to the screenshot below:



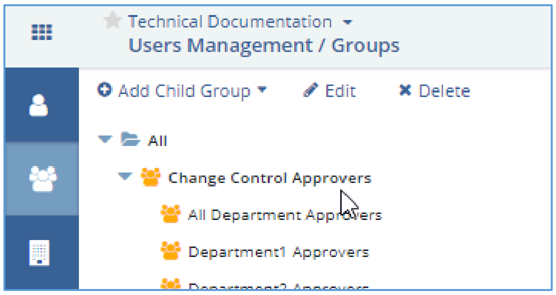
The group will be added to the **Parent Group**.

Editing a Group

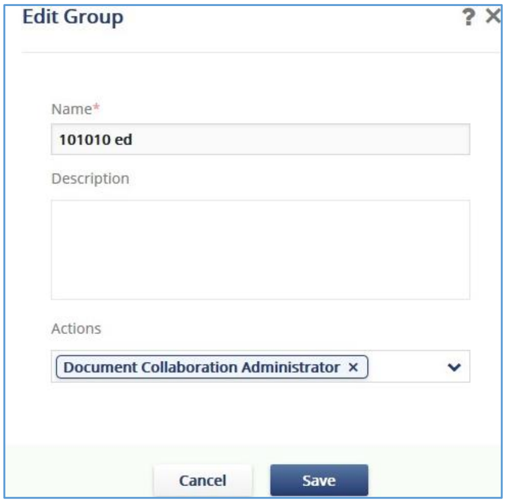
You can reach this page by clicking the Groups icon from menu bar on the left of the Users Management application.

Follow the steps below to edit a new group:

1. Select the group you wish to edit from the list of groups in the left pane.
2. Click the **Edit** button above the list of groups.



3. The **Edit Group** popup window will open.
4. Make any necessary changes.
5. Click **Save**. Refer to the screenshot below:

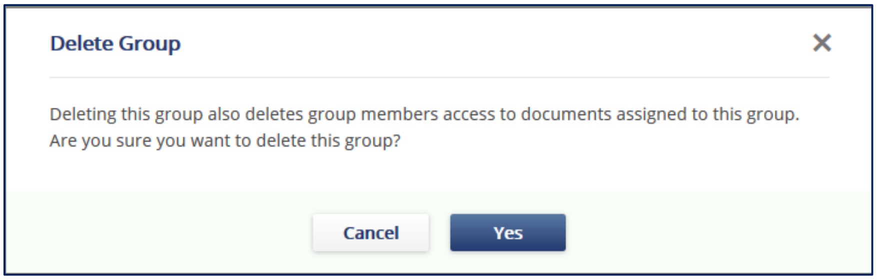


Deleting a Group

Groups can be deleted from the list of groups. Deletion of a group does not delete its users. Instead, any permissions or security rights associated with membership in the group will be removed from the group's former members unless those rights are added individually or via membership in another group. A confirmation window will open to warn you about the potential implications of deleting the group.

Follow the steps below to delete a group:

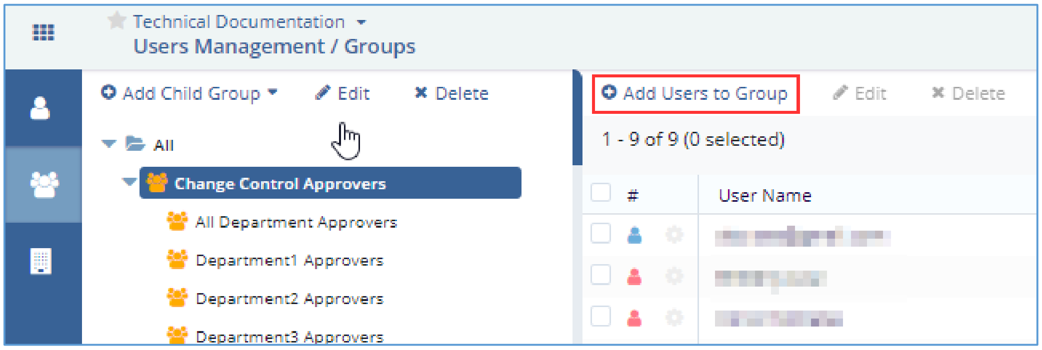
1. Select the group from the list of groups.
2. Click the Delete icon from the menu above the list.
3. A confirmation window will open.
4. Click **Yes**.



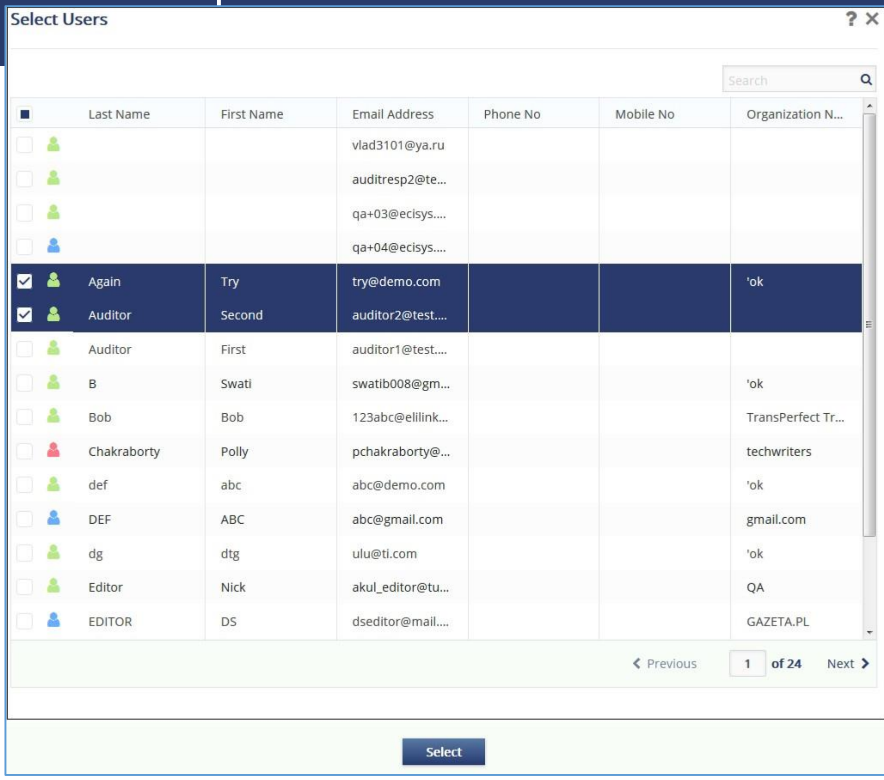
Adding Users to a Group

Follow the steps below to add users to a group:

1. Navigate to Users Management using the Navigation Grid.
2. Select the Groups icon at the left side of the screen.
3. Select the group to be modified. The list of users will appear to the right.
4. Click **Add User to Group** from the top menu in the right pane to add the user to the group.



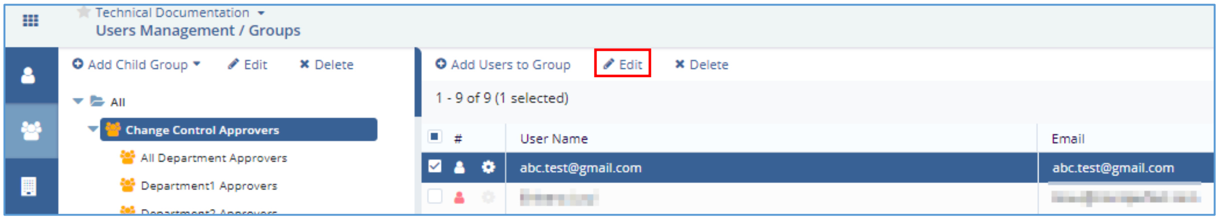
5. The **Select Users** window opens up.
6. Select the users you wish to add to the group and click **Select**. The users will be added to the group. Refer to the screenshot below:


Select Users
Search
Last Name
First Name
Email Address
Phone No
Mobile No
Organization N...
vlad3101@ya.ru
auditresp2@te...
qa+03@ecisys....
qa+04@ecisys....
Again Try try@demo.com 'ok
Auditor Second auditor2@test....
Auditor First auditor1@test....
B Swati swatib008@gm... 'ok
Bob Bob 123abc@elilink... TransPerfect Tr...
Chakraborty Polly pchakraborty@... techwriters
def abc abc@demo.com 'ok
DEF ABC abc@gmail.com gmail.com
dg dtg ulu@ti.com 'ok
Editor Nick akul_editor@tu... QA
EDITOR DS dseditor@mail.... GAZETA.PL
Previous
1
of 24
Next
Select

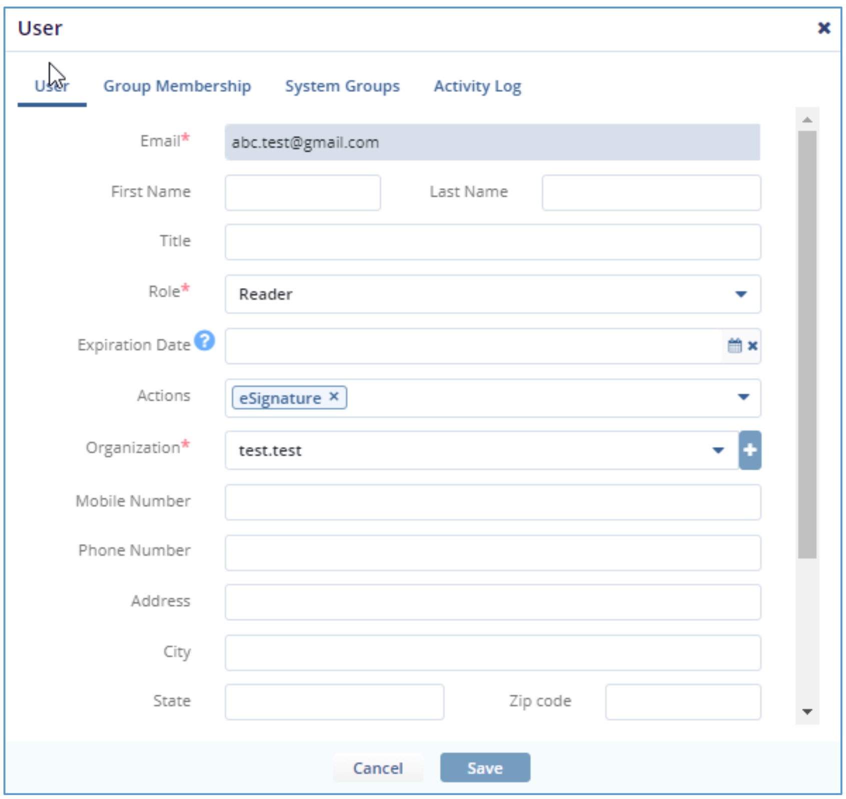
Editing and Deleting Users from a group

Editing a User in a Group

A room Administrator can edit an individual user's profile via the Group list as well as by using the Users area of the User's Management module. Editing an individual user's profile from the User's area is discussed earlier in this chapter. Users in a group can be edited by selecting the user from the list of group members and clicking **Edit** above the list of group members. Follow the on-screen instructions to edit the user details. Refer to the screenshot below:

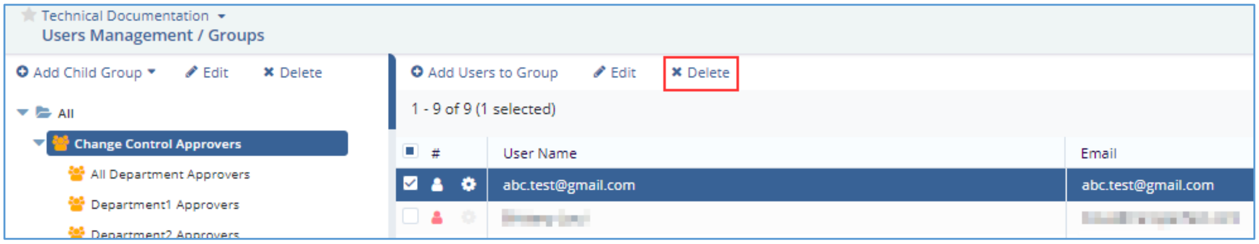


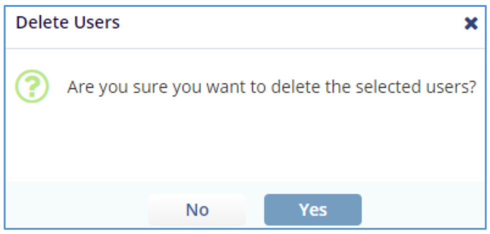
The User window will appear:



Deleting User from a group

Select the user from the list of group members and click **Delete** above the list in order to delete the user from the group. Click **Yes** on the confirmation window that opens if you wish to delete the user. Refer to the below screenshots:





Users Management – Responsible Departments

Room administrators can indicate which internal department is ultimately responsible for the collection of specific document types. This will allow for more detailed reporting of the health of the eTMF and will enable team leaders to readily identify those documents for which they are responsible and which are still missing from the system. The list of Responsible Departments can be managed from the Users Management module.

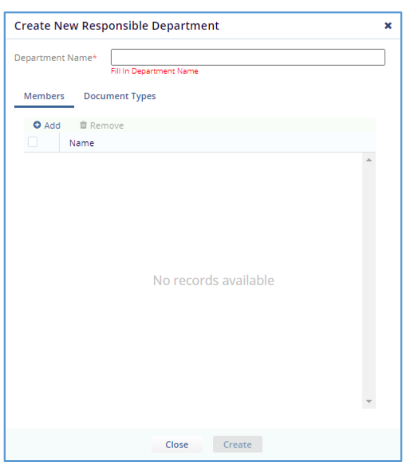
Administrators can choose from the following options with regard to Responsible Departments:

- Create a new department
- Add or remove department members
- Add or remove document types associated with the department
- Delete an existing department

Creating a new Department

To create a new department, follow the below steps:

1. In the Users Management area, Click on the "**Responsible Departments**" icon from the menu at the left side of the screen.
2. Click '**Add**' from the top ribbon bar. The **Create New Responsible Department** window will open.



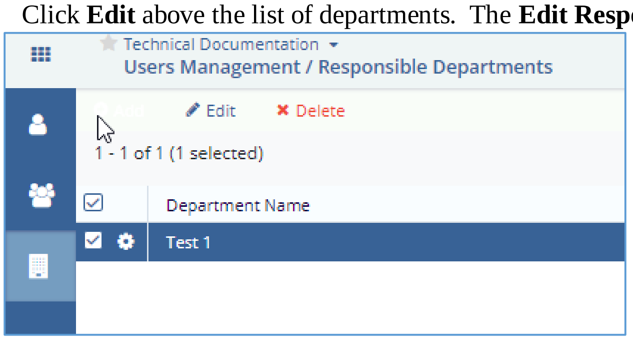
3. Enter a name for the Department in the field at the top of the window.
4. Associate room users with the department by adding them as department members. Add members to the department by clicking on the **Add** button.

5. Choose the users to be added to the department from the **Add Users and Groups** window that opens.
6. Click **Add.**
7. Once users have been added to the department, select the **Document Types** tab and click the **Add** button.
8. The **Select Document Type** window will open. Drill down in the document categories or use the search bar to locate the document types which will be associated with the department.
9. Check the box next to the document type
10. When all required document types have been selected, press **Select.**
11. Press **Create** to finish creating the department.
12. The new Responsible Department will appear in the list of departments.

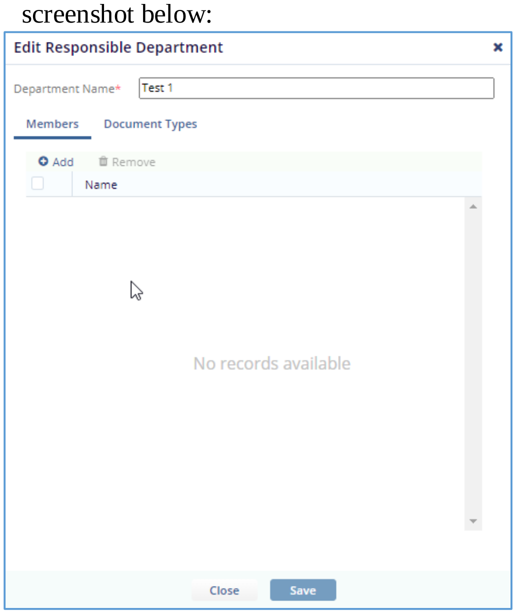
Editing an existing department and its members

To edit an existing department, follow the steps below:

1. Select the Responsible Departments area from the Users Management module.
2. Select the department to be edited from those listed.
3. Click **Edit** above the list of departments. The **Edit Responsible Department** pop up appears.



4. Add or remove any members or document types assigned to the department as needed and click '**Save**'. Refer to the screenshot below:

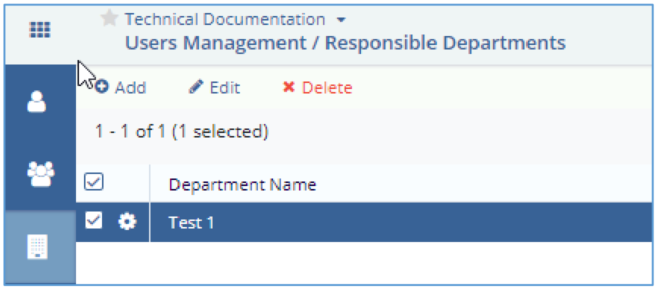


Deleting an existing department

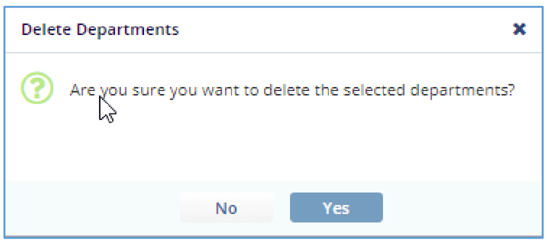
Administrators have access to delete departments when necessary. To do so, follow the steps below:

1. Before a department can be deleted, any associated document types must first be removed using the steps listed above for editing a Responsible Department.

2. Select the department to be deleted from the list of departments.
3. Click ‘Delete’ from the options above the list.

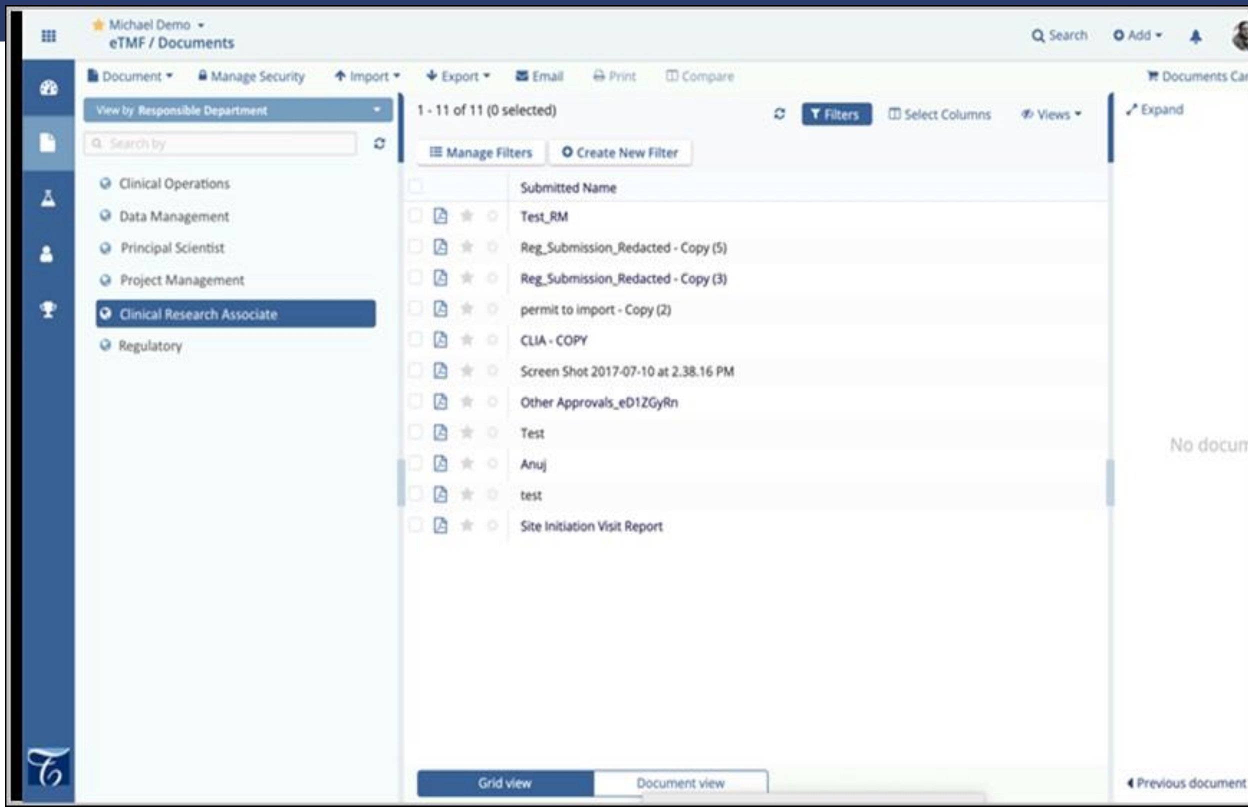


4. A confirmation message will pop up:



5. Click ‘Yes’ to delete the department.

Responsible Department Views



One of the business challenges with eTMF is the ability to ensure that documents are submitted ina timely fashion as the trial progresses. To ensure that this happens, it is important to know whichperson or department is responsible for authoring, collection, and submission of each required document and placeholder.

While CRAs are often responsible for document collection from the sites, many other documentsmust be collected from internal groups, regulatory authorities, IRBs/IECs, and partners.

10.1 introduces the definition of Responsible Parties and Owners to Trial Interactive. For each Document Type, the responsible group or person may be defined. These definitions may be set up using groups within the room for a flexible assignment of ownership. Once configured, an eTMF Completeness View is now available that shows the required documents, placeholders,collected, and final documents for each Responsible Department or Owner.

Setting up Responsible Departments

In order to set Responsible departments, the user should navigate to the Users Management Module. There is a new icon present on the menu at the left side of the screen which represents theResponsible Department management area.

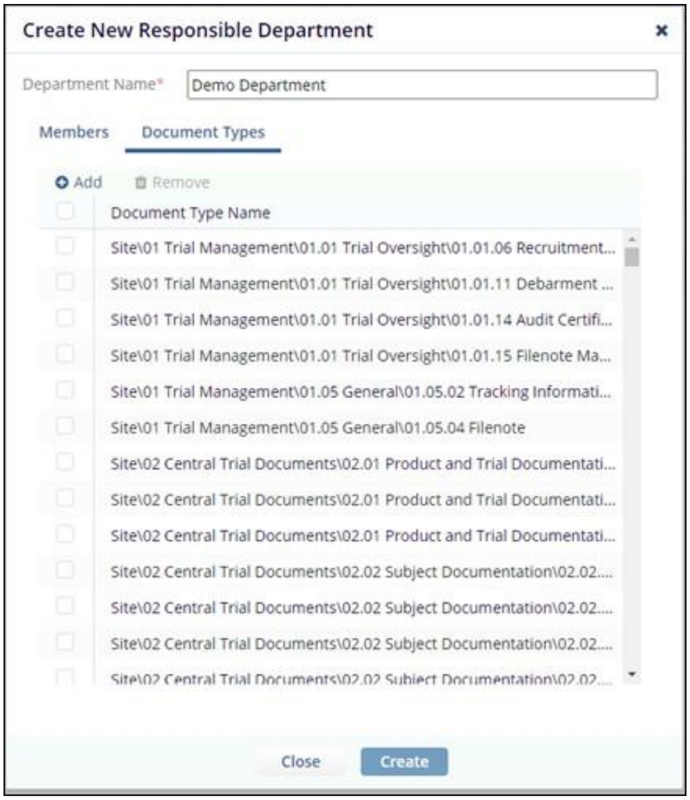
Clicking on this will open the **Responsible Department** management area.

1. Press the Add button in order to create a new department. The user could also press the Edit button in order to make changes to a preexisting department.
2. Enter the Department Name.
3. Select the Members tab to add users to the department.

Once the department members have been selected, change to the Document Types tab. From here,the user can drill down in the folder structure to assign specific document types to this department.Check the box next to the document type and press Add.

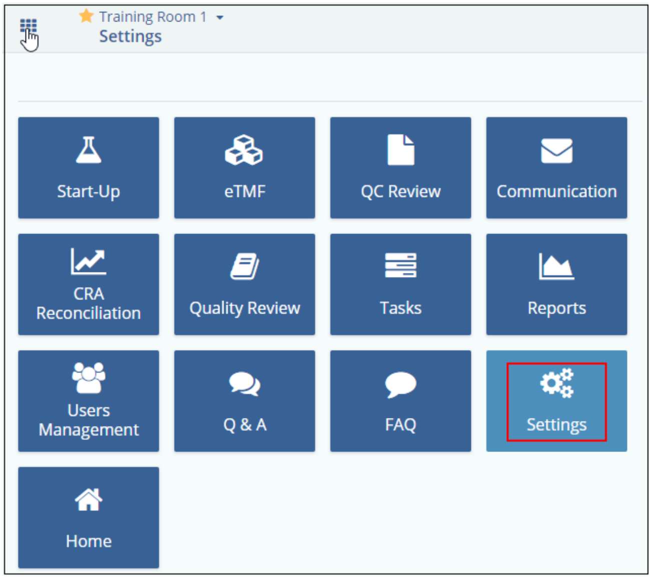
If there is no box next to the desired document type, this indicates that the document type has alreadybeen assigned to another department.

Once all required members and document types have been assigned to the department, press theCreate button in order to create the department.


Create New Responsible Department
Department Name*
Demo Department
Members
Document Types
Add
Remove
Document Type Name
Site\01 Trial Management\01.01 Trial Oversight\01.01.06 Recruitment...
Site\01 Trial Management\01.01 Trial Oversight\01.01.11 Debarment ...
Site\01 Trial Management\01.01 Trial Oversight\01.01.14 Audit Certifi...
Site\01 Trial Management\01.01 Trial Oversight\01.01.15 Filenote Ma...
Site\01 Trial Management\01.05 General\01.05.02 Tracking Informati...
Site\01 Trial Management\01.05 General\01.05.04 Filenote
Site\02 Central Trial Documents\02.01 Product and Trial Documentati...
Site\02 Central Trial Documents\02.01 Product and Trial Documentati...
Site\02 Central Trial Documents\02.01 Product and Trial Documentati...
Site\02 Central Trial Documents\02.02 Subject Documentation\02.02....
Site\02 Central Trial Documents\02.02 Subject Documentation\02.02....
Site\02 Central Trial Documents\02.02 Subject Documentation\02.02....
Close
Create

Chapter 6. Room Settings

Access the **Room Settings** from the **Main Navigation** by clicking the **Settings** application. Refer to the screenshot below:



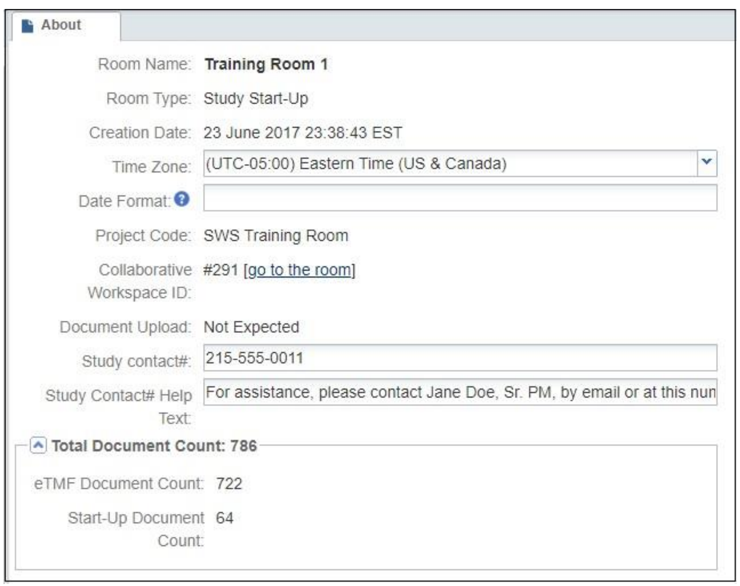
- The Administrator can access the modules from the left pane of the Room Settings page.
- By default, when Administrator users click on Settings, it only displays the first item of the **General Settings**, which is the **About** page of the study room.
- The modules of the Room Settings are displayed in the left pane.
- Every room setting module that displays on the left column is divided into sub-sections, allowing specific modifications for each defined category.
- To view and modify a specific module of the room settings, click the **Expand** button which is located next to each module name. This reveals the sub-sections in the respective module.
- When each sub-section of the room setting tab is clicked, it appears as a separate tab on the right side of the screen. If users click multiple sub-sections, it will not override the previous tab; instead, separate tabs will be created for each item clicked.
- To close the tab, right click on the tab and select **Close Tab**.
- Right-clicking a tab will also provide an option to **Close All Tabs** and **Close Other Tabs**. A **Search** box is also available in the Settings.
- If users wish to search for specific settings, simply type in the word without looking through the entire settings menu. The features mentioned will further be discussed in the following sections.
- Administrator users can view and change most of the room settings in Trial Interactive. The client is given orientation on making the initial settings and on changing the settings in the client walkthrough.
- Typically, the room's settings will be decided upon during the client walkthrough, and the settings will remain unchanged, for the most part, for the duration of the study.

Refer to the screenshot below:

General Settings

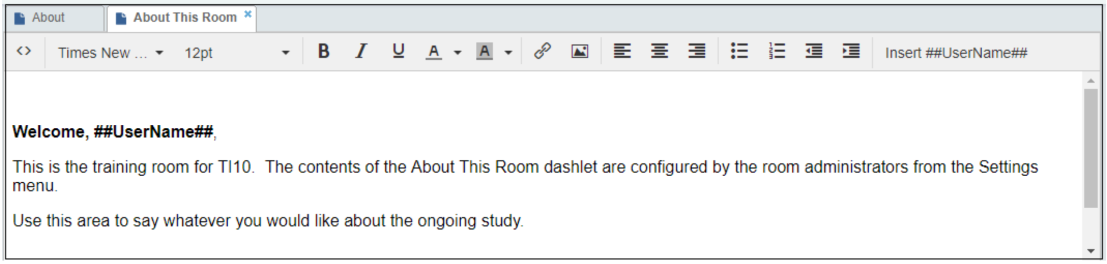
Individual settings windows are typically available to you as an Administrator under the **General Settings** tab.

About



This window displays the room's name, room type, and creation date besides other details. Here you can add a phone number for the Study contact person along with the text of the message that will pop up on the screen when a user exercises this option. The total page count and document count for the room are also available here. You can click on the expand icon to view details. Once desired changes have been made, click **Save** at the bottom of the box.

About This Room



In this window, the user can see and change the information contained in the room's Welcome message, which is the message that all users see when they access the room. This space can be used to share important information about the study once the study is in full swing, and the welcome message is no longer necessary. Once you have made the desired changes, click **Save** in the lower-left corner of the box.

You can view the Change Log History by using the **Change Log** button that is directly available on the bottom right corner of the **About this Room** dashlet.

Instructions

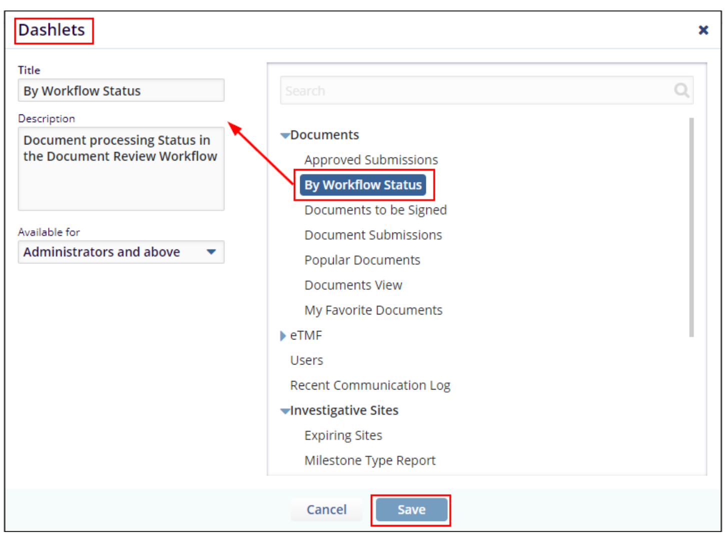
Instructions under general settings will be filled out by Administrator-level users. By doing so, this portlet will give 'instructions' to those users who can perform limited actions on SSU documents (i.e.,they will be given a simplified User Interface). Unless a user is viewing a simplified UI, this instruction portlet will not be visible to general level users.

Dashboard Setup

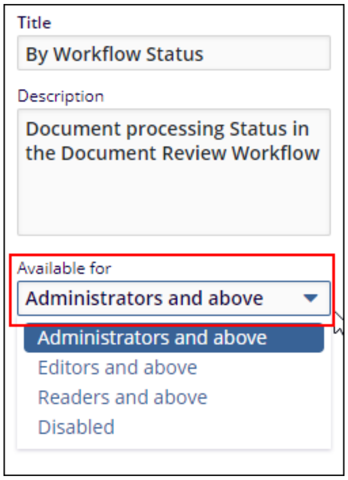
Dashboard setup can be accessed via modules. Select any module through the **Main Navigation**. For example, select **eTMF**. You can see the setup options like this:

To **modify the availability of dashlets** to users, click on **Dashlets** button.

1. This Dashlet setup screen appears:



2. Expand the options by clicking on arrow and select the desired one. Once the option is selected, details such as **Title**, **Description**, and **Available For**, get displayed on the left pane.
3. You can edit the **Title** and keep it as per the choice.
4. In the **Available For** field, you can select the option for whom the dashlet will be set. See below image:



5. Click **Save** upon the changes is made.

From the Dashboard Settings, the following activities are available:

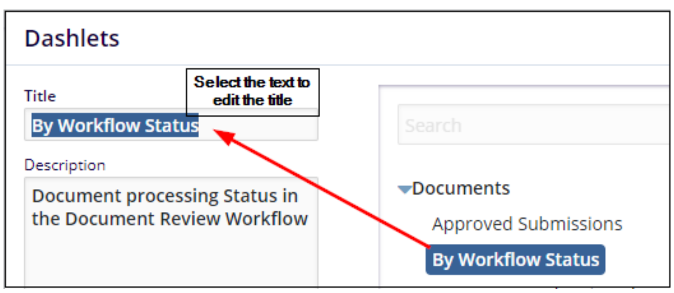
1. Setting and Renaming a Dashlet
2. Default Dashboard Setup

The above activities are discussed in detail in the sections below.

Renaming a dashlet

To **Rename a Dashlet** follow the steps as below:

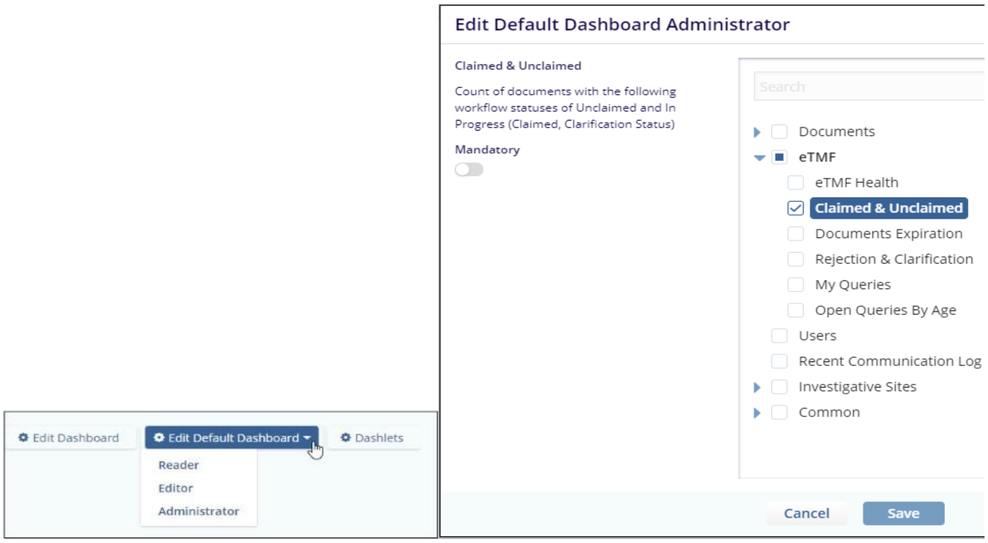
1. Select the dashlet and click in the **Title** field to edit its name.



2. Click **Save**.

Default Dashboard Setup

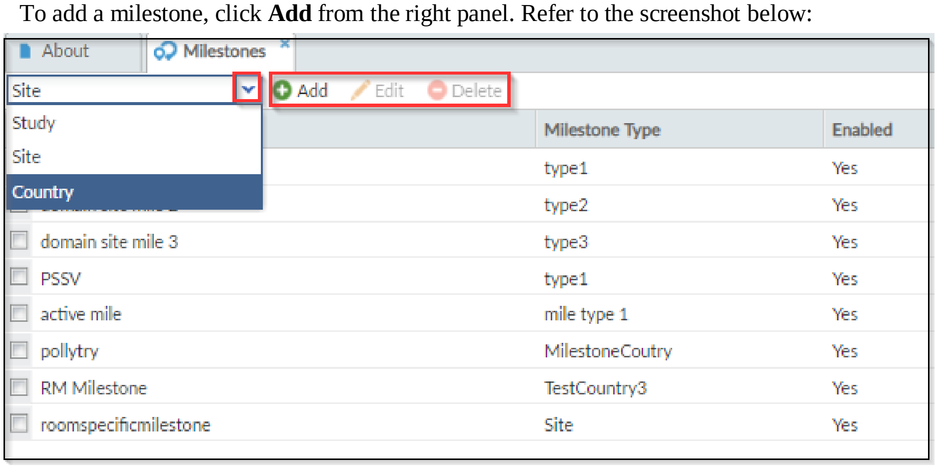
You can set the default dashboard for the minimum level role by clicking the button **Edit Default Dashboard**. The **Default Dashboard Setup** window opens. Make the appropriate choices as required and click **Save**.



Milestones Settings

Follow the steps below to configure milestones:

1. Navigate to **Main Navigation-> Settings->Milestones**.
2. The Milestones window opens with the list of milestones.
3. To add a milestone, click **Add** from the right panel. Refer to the screenshot below:



4. The **Milestones Profile** window opens. Refer to the screenshot below:

5. Choose from the **Existing list** of milestones to enable that milestone for your room **or** enter the milestone name to create a New milestone. Refer to the screenshot above.

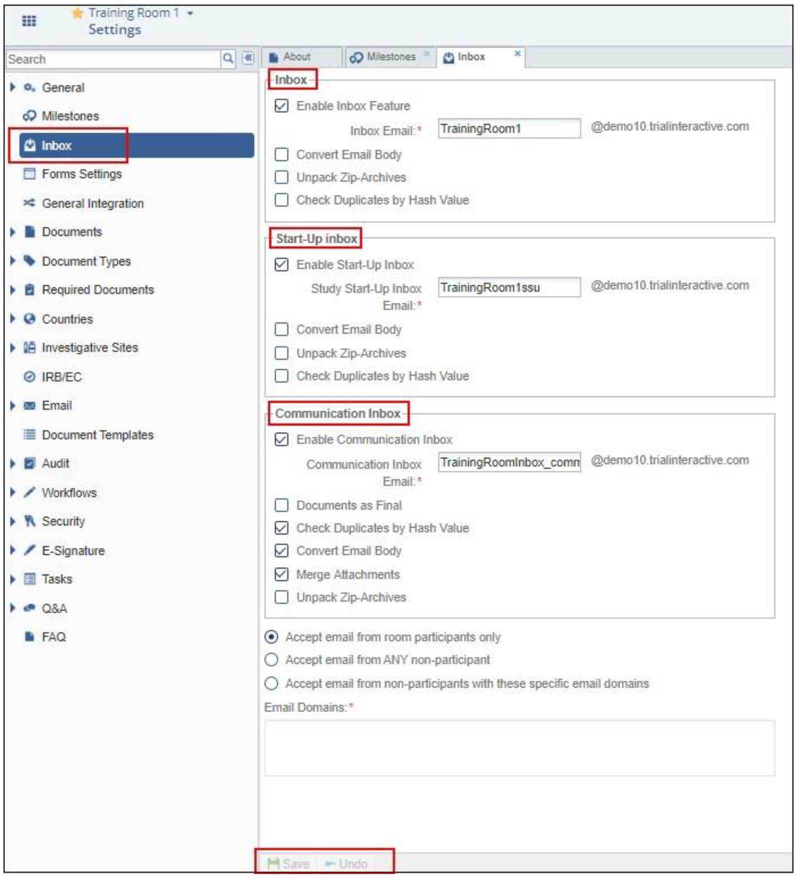
   i. Select the **Milestones Category** as **Study, Site, or Country**.
   ii. Select the **Milestone Type** from the dropdown and click **Ok**.
   iii. To select the **Milestone Type** of your choice, you will need to add milestone types.
      a. You can create **Milestones Type** on the fly by clicking the '**+**' icon in the **Milestone Type** field.
      b. Once a milestone type is created, it will not automatically populate in the textbox. Select the milestone type from the dropdown.

6. The milestone thus created is enabled by default.
7. Double-click a milestone, or select an existing milestone and click **Edit** to edit a milestone.
8. Select a milestone and click **Delete** to delete it.

Inbox Settings

From this page, Admin can enable the Inbox feature.

1. Navigate to **Main Navigation->Settings->Inbox**. Refer to the screenshot below:



Inbox

1. Admin can **Enable Inbox Feature** by ticking the checkbox to make it possible for room participants to send trial documents directly to the room's inbox.

   Note: *The Administrator has the ability to disable the inbox feature or to allow non-participants in the room to send documents to the room's inbox.*

2. Ticking the checkbox of **Convert Email Body** option will automatically convert the emails that enter the Inbox into PDFs.
3. Choose **Unpack Zip-Archives** to extract files from an attached zip folder.
4. To prevent duplicate publishing of email converted documents to the room, activate the **Check duplicates by the hash value**.

Start-Up Inbox

1. Admin can **Enable Start-Up Inbox** by ticking the checkbox, and the user can send the documents to the Start-Up Inbox.

2. Ticking the checkbox of **Convert Email Body** option will automatically convert the emails that enter the Inbox into PDFs.
3. Choose **Unpack Zip-Archives** to extract files from an attached zip folder.
4. To prevent duplicate publishing of email converted documents to the room, activate the **Check duplicates by the hash value**.

Communication Inbox

1. To enable the **Communications Inbox**, tick the checkbox next to it. These emails can be located in the Inbox from the **Communications Module.**
2. If you choose to file email converted documents to the eTMF as Final, tick the checkbox **Documents as Final next to it**.
3. Enable the **Merge Attachment** option to merge attachment into one document. Besides the above options, you can also

enable the following options for the Inbox:

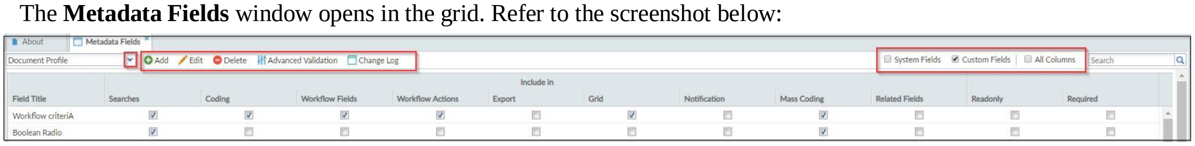
1. **Accept email from room participants only:** This option, when enabled, only the room participant can send the documents.
2. **Accept email from ANY non-participant**: This option, when enabled, allows a user outside the room to send documents via emails.
3. **Accept email from non-participants with these specific email domains**: This option, when enabled, a user can send the documents via emails with the domains defined in the **Email Domains** text box below the options. Refer to the screenshot above.

Forms Settings

Clients sometimes request custom settings to form fields that appear in several forms throughout a TI data room, such as document type metadata fields, question and answer forms, and audit form options.

- Metadata system fields can be switched off and on from this view.
- Changes here will affect the fields that users have the availability to view in document profiles for all different document types in a room.
- Settings here work in conjunction with **Q&A Settings**, with **Document Types** settings, and with **Countries** settings. Custom metadata fields can be created and set up here, too.
- Making changes to these advanced settings should only be done in close consultation with the Project Manager.

1. Navigate to **Settings** module and select **Forms Settings**
2. The **Metadata Fields** window opens in the grid. Refer to the screenshot below:



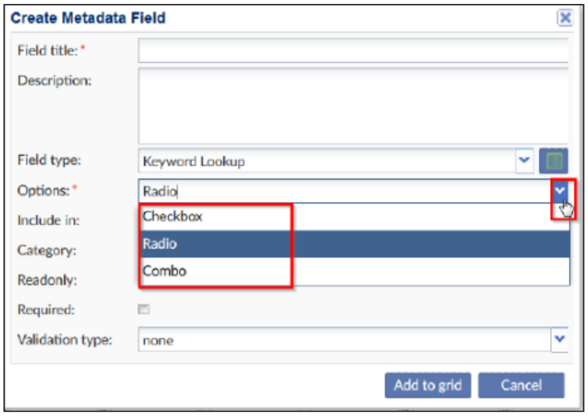
Though the individual fields and field options differ from form to form, the operations to add, to delete, and to edit these settings are consistent across the array of forms. From here you can perform the following settings functions:

Adding a Custom Field Editing a Metadata Field Deleting a Field

Setting Advanced Validation Fields

Adding a Custom Field

1. Click **Add** from the menu bar.
2. The **Create Metadata Field** window opens. Refer to the screenshot below:



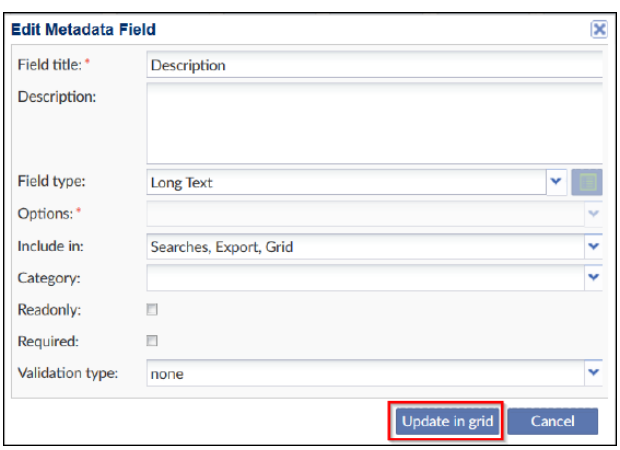
3. Select the appropriate option.
   - **Checkbox** – the values entered display as a list and users can choose one or more
   - **Radio** – user must choose only one value from the list
   - **Combo** – users can choose only one value from a dropdown list
4. Click the **Include in** dropdown arrow and select the appropriate option.
5. Select the Document Type **Category** or categories in which this new custom field will appear.
6. Click the **Read-only** checkbox if the client has requested that option.
7. Click the **Required** checkbox if the client has requested that option.

Note: *If this option is activated, users can't save the form unless this field is filled out when they have made modifications to a document's Document Profile metadata.*

8. The **Validation type** field is dependent on **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**. The view returns to the full **Document Profile Form** display.

Editing a Metadata Field

1. Click **Edit** in the menu ribbon. The **Edit Metadata Field** window opens. Refer to the screenshot below:



2. Make appropriate changes in the available fields.
3. Click **Update in grid** at the bottom of the window.

Deleting a Field

1. Select the field to be deleted. The row highlights in light blue.
2. Click the **Delete** from the menu ribbon.

   Note: *If the field is already in use, you will see a warning message, asking if you really want to delete the field.*

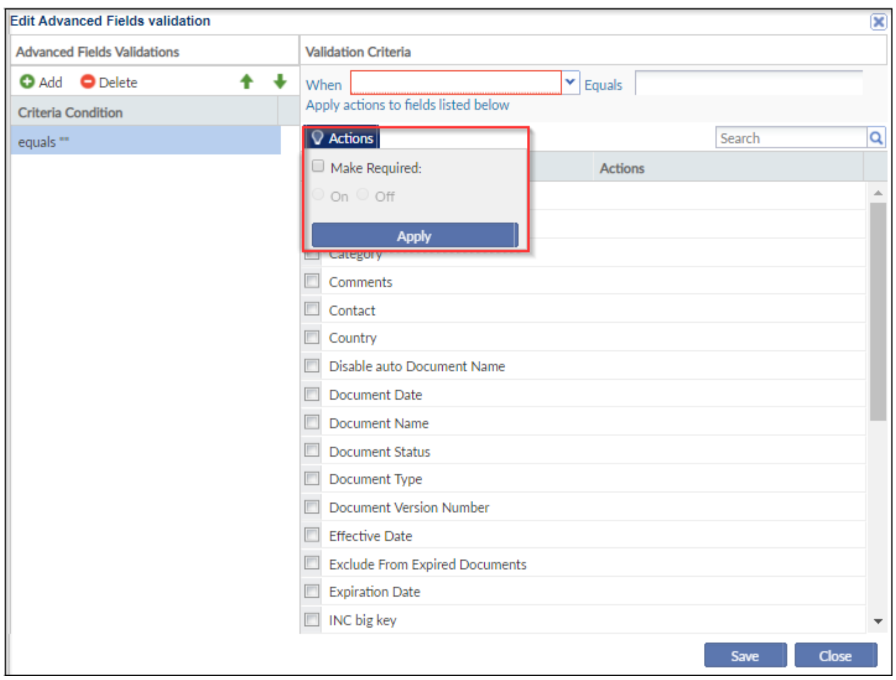
3. If you delete by mistake, you can click the **Undo** button to undo the changes.

Setting Advanced Validation Fields

This advanced function that links two or more metadata fields based on specified validation criteria is not generally used by Administrators.

Note: *Consult closely with the Trial Interactive management team before making any changes here.*

1. Click **Advanced Validation** in the menu ribbon. The **Edit Advanced Fields validation** window opens. Refer to the screenshot below:



2. Click **Add** in the **Advanced Fields Validations** panel on the left. The **Validation Criteria** panel on the right activates.
3. From the **When** field dropdown, select the metadata field that will trigger an action in another metadata field or fields. Those fields are selected in step 7 of this process.
4. Complete the **Equals** field.

   Note: *For fields for which the field data must be selected from a particular set of options, you need to choose from the dropdown menu of selections. For date-related metadata fields, the Equals field converts to acalendar selection. For some metadata fields, the Equals field is a textbox.*

5. 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.
6. Click the checkbox or checkboxes for the field or fields that you want to be affected in this field validation.
7. 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.

General Integration

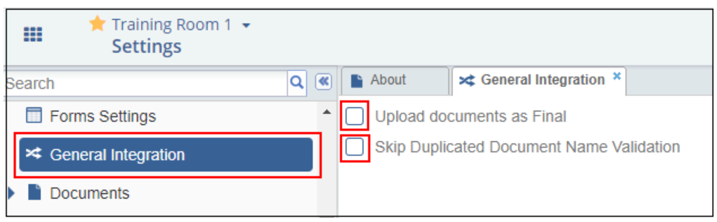
By default, all documents uploaded into the system will take its place in a subfolder by the name of the user uploading the document that is created automatically under the **Upload** folder. Such documents will then go through the normal workflow process.

Through Integrations, the client can opt to skip the workflow process of a document and upload it directly with its status as Final. To allow uploading of documents as final, two criteria must be fulfilled:

1. Assign a related folder for the document types of the documents to be uploaded, and
2. Enable auto-indexing for the documents.

Documents, on uploading, 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 **Main Navigation->Settings--> General Integration**.
2. Tick the checkbox to upload documents as **Final**
3. Tick the checkbox to skip validation of duplicated document name.



Documents

All settings related to documents in a room are made here. You can perform the following document settings from here:

1. Documents Module
2. Document Process Option
3. Document Replacement Reasons
4. eTMF Health
5. Index Outline
6. Non-PDF to PDF Conversion
7. Export Configuration

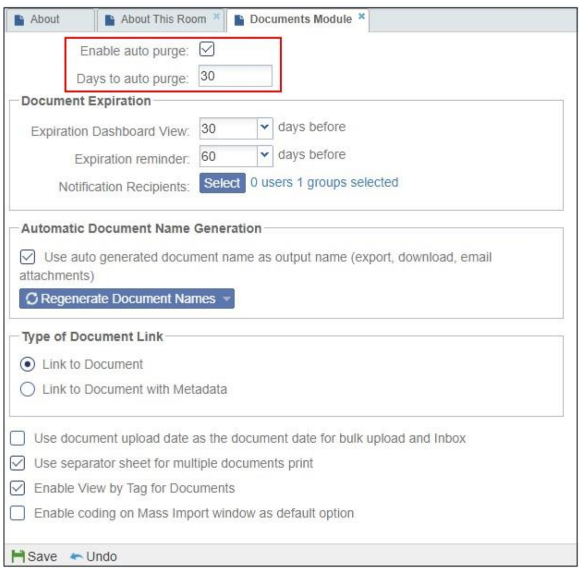
All of the above are discussed in separate topics accessible from the left panel of this help.

Documents Module

Auto Purge Settings

Clients might ask that documents that have, for some reason, been uploaded or sent to the room and then deleted, be purged completely from the room.

1. Navigate to **Main Navigation** -> **Settings** -> **Documents Module** -> **Auto Purge**.
2. Click the checkbox next to **Enable auto purge**. Refer to the screenshot below:

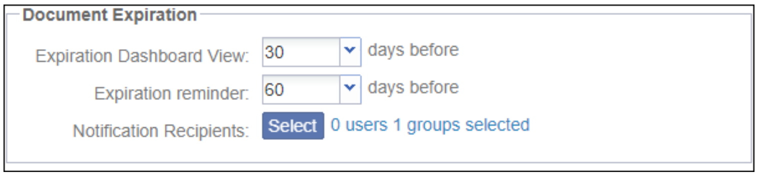


1. Adjust **Days to auto purge** by clicking the box and typing the number requested by the client.
2. If that is the only requested change to the settings in this module, click **Save**.

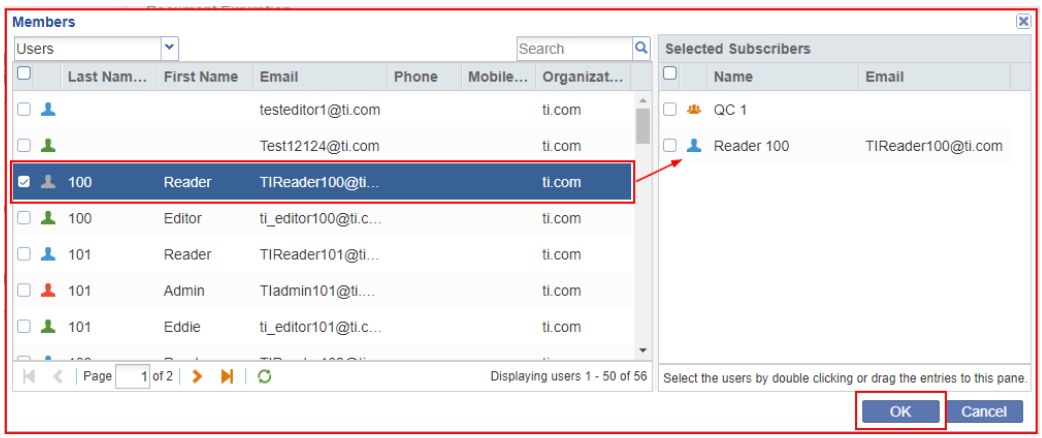
Document Expiration Settings

As an Administrator, you might want to specify the time by which a document will expire and require a new version.

1. Navigate to **Main Navigation -> Settings -> Documents Module -> Document Expiration**. Refer to the screenshot below:



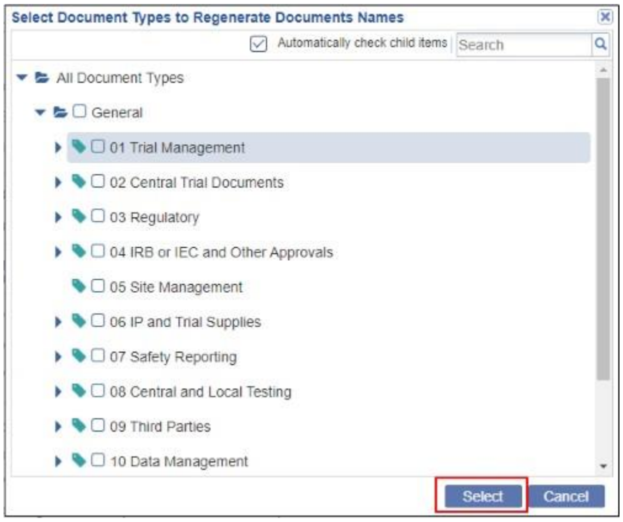
2. The **Expiration dashboard view** field controls how long before a document expires that it will appear in the **Expiring Documents list** in users' Dashboard view.
3. Insert the **number of days** requested by the client.
4. The **Expiration reminder** field controls how many days before expiration, a reminder email will be sent to users and groups selected in the option below to receive this reminder. Insert the number of days requested by the client. By default, the value of both fields is 10 days before.
5. Click **Select** from the **Notification Recipients field** to select users/groups to receive a notification email.



Automatic Document Name Generation

Clients can choose to set the auto naming pattern for a document type and generate the document name automatically as per the pattern.

1. Tick the checkbox to enable **Use auto-generated document name as output name** option.
2. Click **Regenerate Document Names** button to regenerate document names of selected document types.
3. The **Select Document Types to Regenerate Documents Names** window. Select the **document types and their categories for which you want to regenerate document names. Refer to the screenshot below:**



4. You can also choose to Regenerate all the document names in the dataroom by clicking the dropdown option **Regenerate all document names in the dataroom**. Confirm the popup by clicking **Yes** to proceed further.
5. For either of the options mentioned above, a background job starts which then exports the document names in a **.xlsx file**. On receiving a notification about completion of the job, click **Job Result** to retrieve the file.

Document Upload Date as Document Date

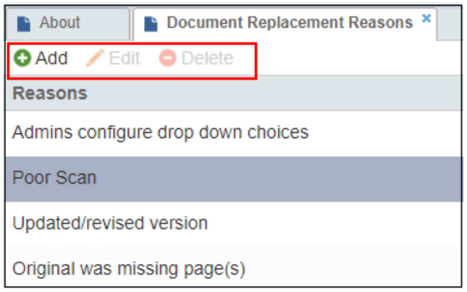
Note: *Even though it is not advised to do so, an Administrator can change the naming and dating conventions used for documents that are bulk uploaded or delivered to the room through the Inbox.*

1. Enable the **Use document upload date as the document date for bulk upload and Inbox** option by ticking the checkbox.
2. Now, the upload date will automatically be assigned as the document date in the document profile. Refer to the screenshot below:

Document Replacement Reasons

From this section, an Administrator can configure the set of reasons that might be applicable to replace an attachment to a document. These reasons, so configured, will appear in the dropdown of Choose replace reason while replacing a document.

1. Navigate to **Main Navigation->Settings -> Document -> Document Replacement Reasons**. Refer to the screenshot below:



2. Click **Add** from the top ribbon bar. **Create new reason** popup opens.
3. Enter the reason and click **Create**.
4. The reason thus created is added to the list of reasons in the panel.
5. You can also choose to **Edit** or **Delete** a selected reason from the top ribbon bar options.

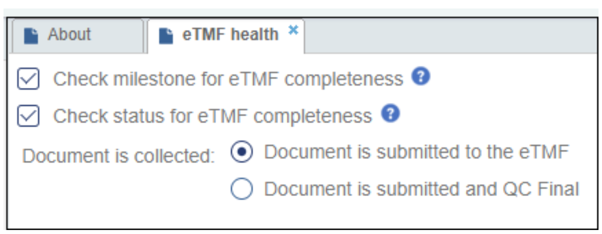
eTMF Health Settings

The eTMF Health dashlet provides information regarding the current health of the eTMF system by indicating what percentage of required eTMF documents are collected/missed so far.

The eTMF Health functionality under Settings -> Documents Module -> eTMF Health, if enabled, checks for:

1. The configurations and current status of milestones
2. The status configurations and current status of a document

   This check helps to leverage the eTMF completeness reports and the eTMF Health dashlet to reflect the correct health of the eTMF system. Refer to the screenshot below:



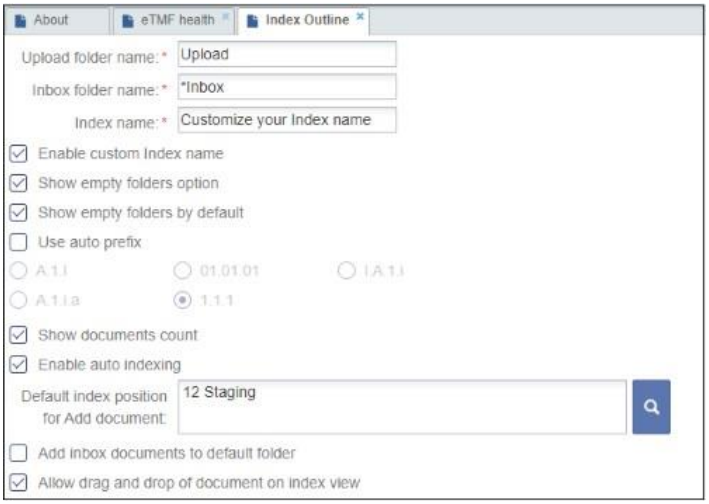
These settings will affect all dashlets and reports related to eTMF Health and completeness. Moreover, clients can also choose to reflect in the reports documents collected and submitted to **eTMF** or **QC Final** by selecting one of the **radio** options as shown above.

Index Outline

The administrator can decide on several functions and appearances related to the Trial Interactive room's index.

1. Navigate to **Main Navigation->Settings->Documents->Index Outline**
2. All documents imported are populated in the **Upload folder**. Refer to the screenshot below:

Note: *A new Index sub-folder inherits the permissions from its parent folder.*



3. If a user emails documents to the room, such documents get stored in the **Inbox folder** of the room.

Note: *Index Outline is a group of settings that Administrators should leave unchanged. The settings here are those chosen by the client during the initial room setup. Before making changes here, consult with the Project Manager and/or the Client Services Team.*

Auto Prefix

The folders in a room index are numbered, and the subfolders follow a standard numbering system.

- These folder numbers are called as Folder Prefixes, whose settings can be decided from the **Auto Prefix** option.
- Activate or inactivate Auto Prefixing of folders in the room's index by ticking the **Use auto prefix** checkbox. Refer to the screenshot above.
- If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index.
- Auto prefixing inserts the client's requested prefix of numbers or letters to identify the levels of the folders in the index.
- Click the radio button for the prefix pattern requested by the client.

Documents Count

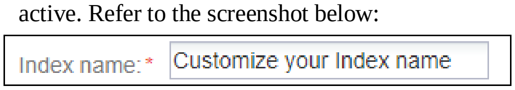
Numbers in parentheses after the folder names indicate how many documents are available to you in each folder.

- Click a folder to open the documents contained in it in the Documents Grid.
- Tick the **Show documents count** checkbox in the settings.
- Users in the room will see a number in brackets that indicate how many documents are in each index folder.

Changing the Index Name

If the client has requested some unique name for the room's index besides the standard 'Index', then you have to first enable the custom index name, and then type the custom name in this field.

1. If the client wants to customize the name of the Index, click the box to activate it. The Index Name field then becomes active. Refer to the screenshot below:



2. Type in the custom name requested by the client.
3. If this is the only change requested for this panel, click **Save** at the bottom of the panel.

Empty Folders Options

In this next section of this panel, you make selections for the client regarding the appearance of Empty Folders.

- You can enable or disable the **Show Empty Folders Option**.
- By showing that option, users in the room will see this checkbox at the bottom of the room's folder index.
- Another option sometimes called for by the client is to show empty folders all the time.
- If that is the case with the room you're configuring, click this box – **Show Empty Folders by default**.
- Then, the room's full index will always show in the documents view, whether the folders are empty or not.

Hide index on add new document

Note: *This setting is used only for non-admin users.*

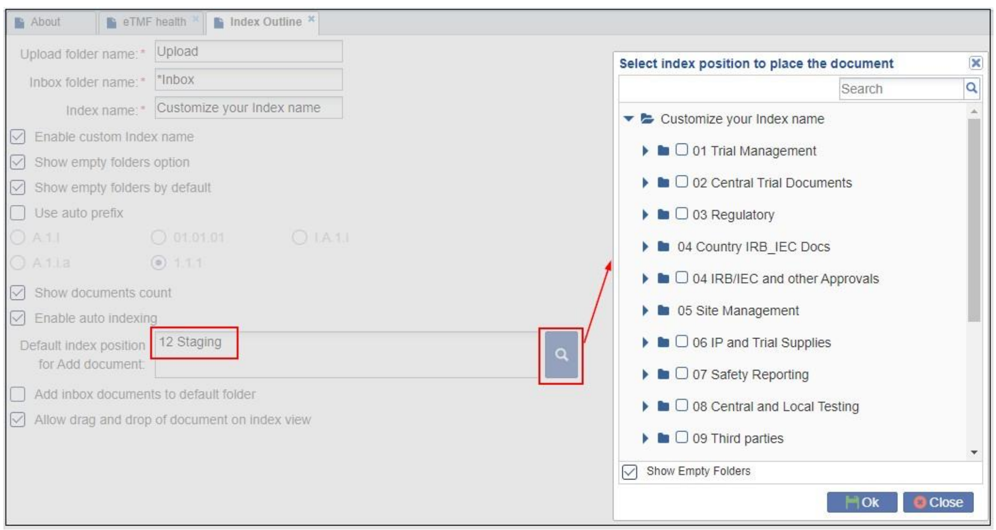
If this option is enabled:

- Index position will be hidden in the new document window.
- But in case if auto-routing logic can't determine index position, this control will be displayed, so the user will be able to specify index position manually.
- A document cannot be copied or dragged to a different location/folder by editors.

Auto Indexing

In order to activate either of these next two options – **Enable Auto Indexing** or **Hide Index on add new document** – this Default Index Position for Add Document field must be completed.

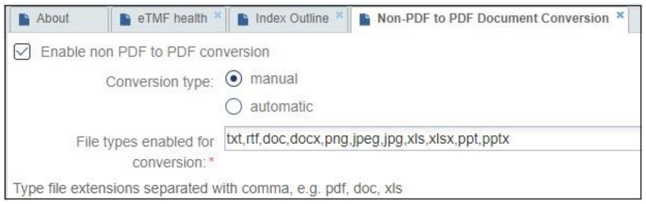
- Click the magnifying glass. The full index



1. list appears.
2. Select the folder indicated by the client.
3. Click **OK**. The window closes.
4. Click **Save** at the bottom of the **Index Outline** panel.

Non-PDF to PDF Document Conversion Settings

1. Navigate to **Main Navigation -> Settings -> Documents->Non PDF to PDF Conversion**.
2. Tick the checkbox to **Enable non PDF to PDF conversion**. Refer to the screenshot below:



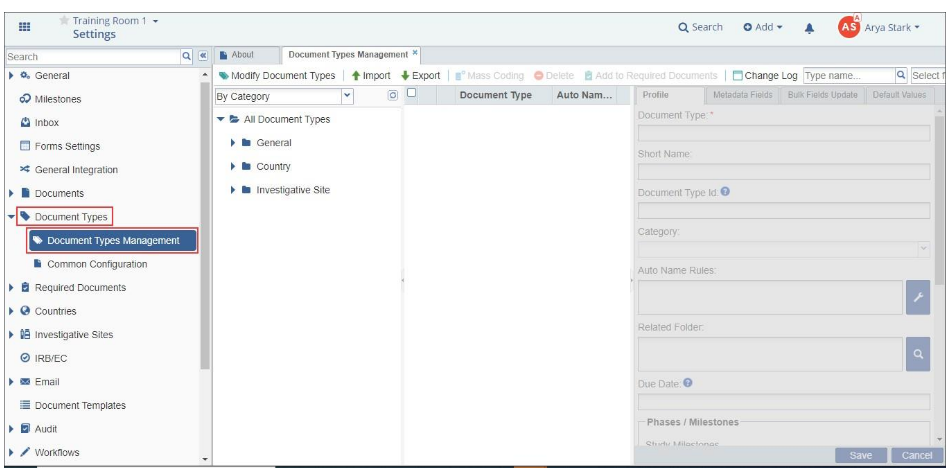
3. Select the appropriate radio button to make the conversion, **Manual or Automatic**.
4. Edit the list of file types that can be converted.

Document Types and Management

In this section, we discuss creating **Document Types** and various functionalities related to it. 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.

All of these document types need to be set up and defined in the Trial Interactive room:

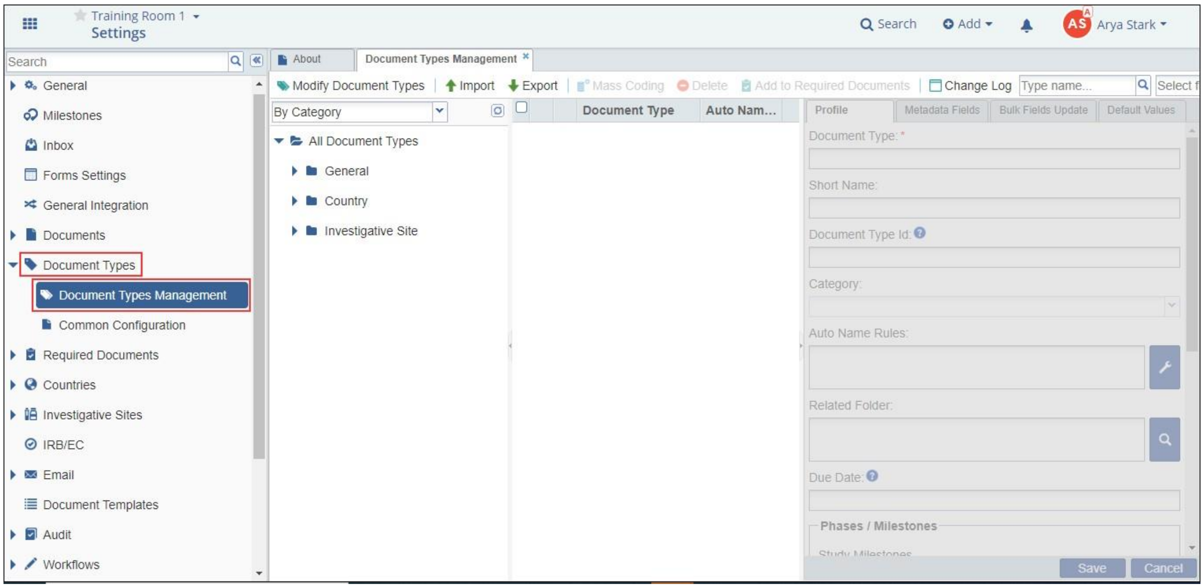
1. Navigate to **Main Navigation -> Settings**. The Room Settings page opens.
2. Select **Document Types** from the menu on the left.
3. The **Document Types** option expands to reveal two sub-options:
   a. The **Document Types Management** and
   b. The **Common Configuration.**
4. Click and view each panel separately. Refer to the screenshot below:



Document Types Management

Note: *Super Administrator users have the ability to turn On and Off Administrator access to Document Types Management Settings.*

Attention: *This tab may not be available in your data room. The Document Types Management tab, if enabled, for Administrator users, allows access to the auto-naming rules and to linking metadata fields to document types, enabling conditional metadata. Auto-naming settings are complex, and it is preferred that Administrators work with the Trial Interactive*



Click the **Document Types Management** tab to open its dashboard on the right.

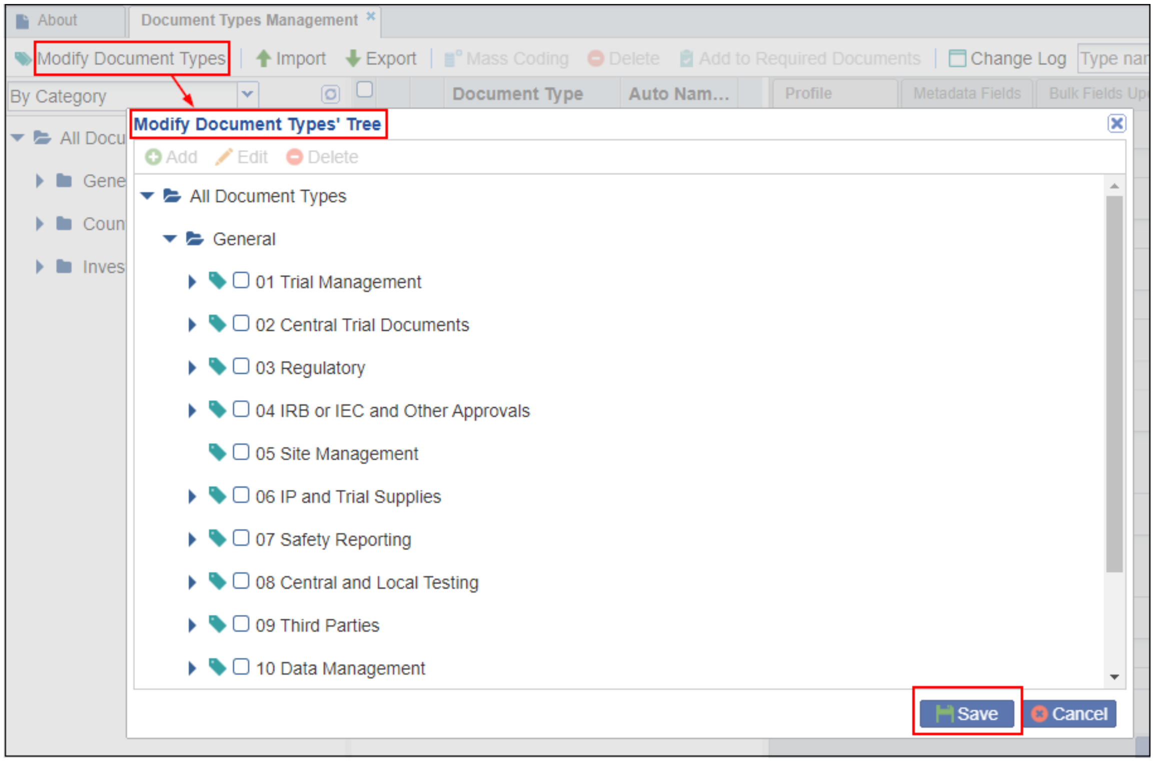
From this page, you can perform various actions as below. All of these are discussed in separate child-topics. Expand this topic from the left pane of this help to reveal the following child-topics:

1. Modify Document Types Tree
2. Building the Document Type Profile
3. Specifying the Related Folder
4. Include Phases/Milestones
5. Adding Document Types to Required Documents
6. Include in Document Tracker Report
7. Auto Document Type Prediction Keyword(s)
8. Modifying Document Types Fields
9. Default Values

Modify Documents Types

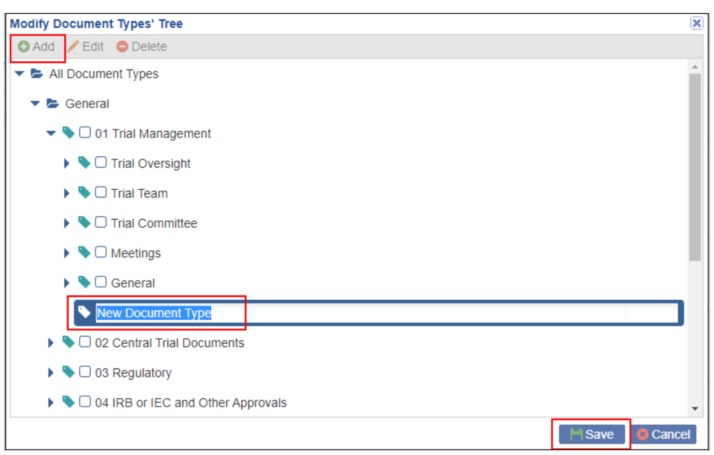
1. Click **Modify Document Types** option from the ribbon above the dashboard.
2. A new **Modify Document Types' Tree** window opens, displaying the folder structure of Document Types in a tree view. Document Types can be added to the category folders, edited in their current positions, and deleted through this view. In the figure below, the **Investigative Site** folder is open, displaying the document types that are added in that category.

Figure 6: Modify Document Types' Tree



a. To add a new document type, click the main category into which the new document type is to be assigned. If the folder already contains document types, click the + sign next to the category's folder icon to see the document types already contained in the category. The categories are marked by the yellow folder icons and the actual document types by the blue document icon.

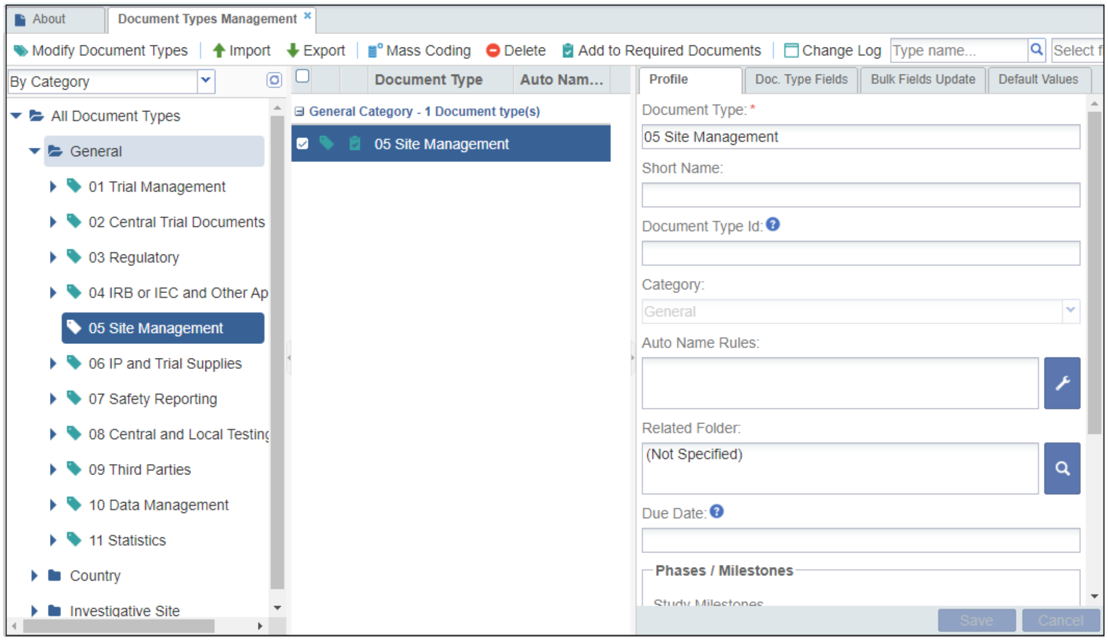
b. Click the **Add** button near the top of the window, or right-click the folder where you want to add the new document type, or right-click the document type under which you want to add a sub-type. A new line appears with an editable field that reads **New Document Type**. Refer to the screenshot below:



c. Type the name of the new document type to be added to the category folder.

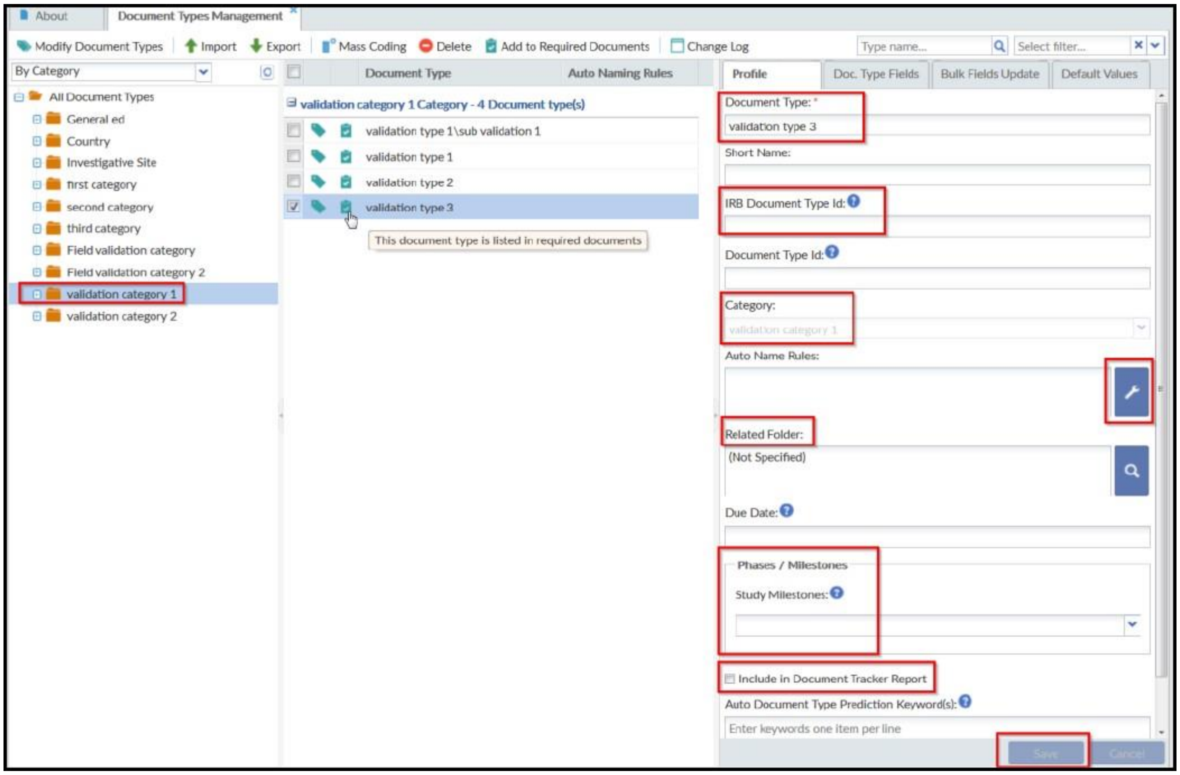
d. Press the **Enter** key. If you have more document types to add to this or other categories, you can repeat this process.

e. When you have added all of the necessary new document types, click **Save** at the bottom of the window. That window closes, and you return to the primary **Document Types** view. The document types that you have just created has not been routed to a proper index position. Refer to the screenshot below:



f. Similarly, you can also edit or delete document types.

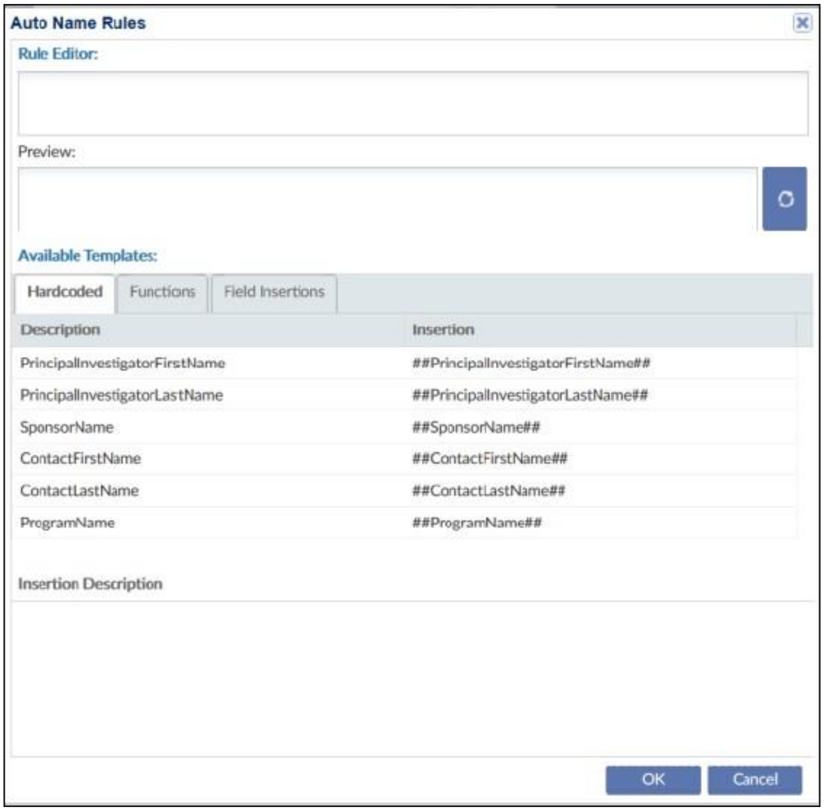
Building the Document Type Profile



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.

1. 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.
2. The **IRB Document Type ID** is one of the fields besides 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.

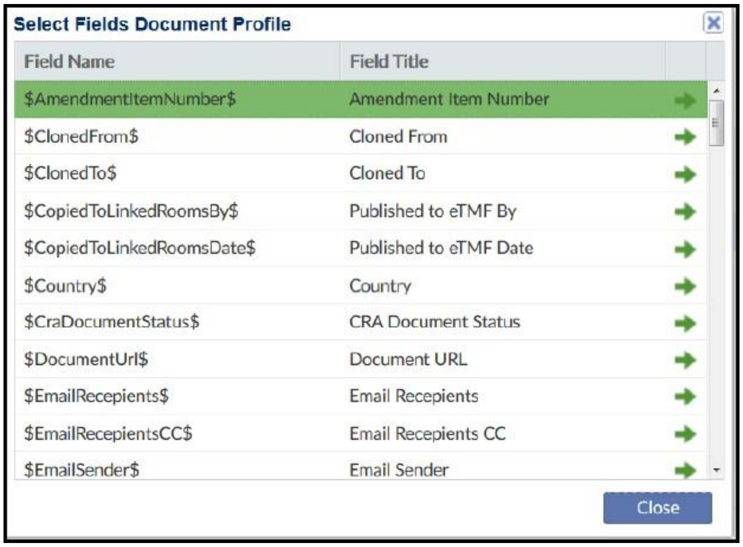
   This field can accept multiple values separated by semi-colon and should be unique within the document type category.
3. The **Category** has already been assigned by your first steps of creating the new document type, so this field is not enabled.
4. Click the wrench icon next to the **Auto Name Rules** 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. The client typically supplies a file with prescribed document types and the auto naming rules that they want to be assigned to the document types. An **Auto Name Rules** window opens. Refer to the screenshot below:



The following set of instructions describes the insertion of a standard set of fields for 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 Sponsor Name.

a. Under the **Hardcoded** tab, double-click a description to be inserted as auto naming rule. The insertion appears in the **Rule Editor**.

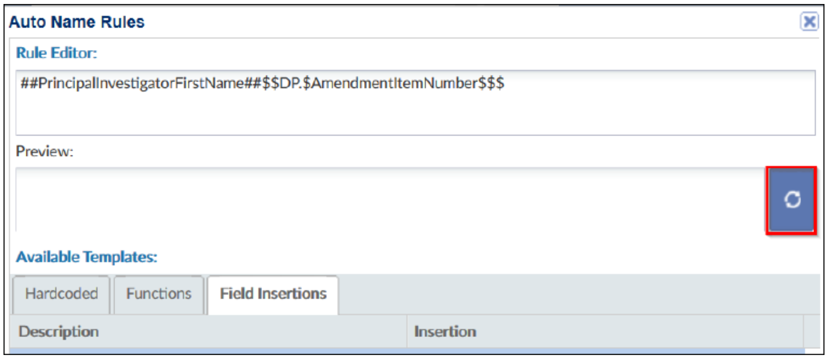
b. If you want to include fields present under the **Field Insertion** tab, double-click the description and further click the green arrow in the **Select Fields Document Profile**. This too gets appended in the **Rule** Editor. The order in which you select these naming elements is the order in which they will display.



c. 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.*

d. 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.



e. Click **OK** at the bottom of the window. You return to the main **Document Types** view.

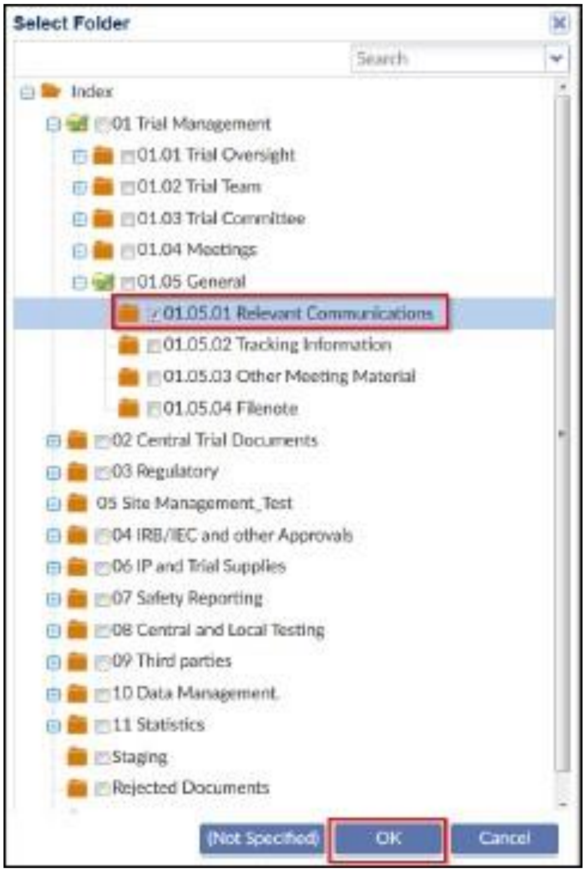
f. Click **Save** at the bottom right of the **Profile** tab window.

Specifying the Related Folder

1. 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.

2. Select the proper folder or subfolder for the document type.

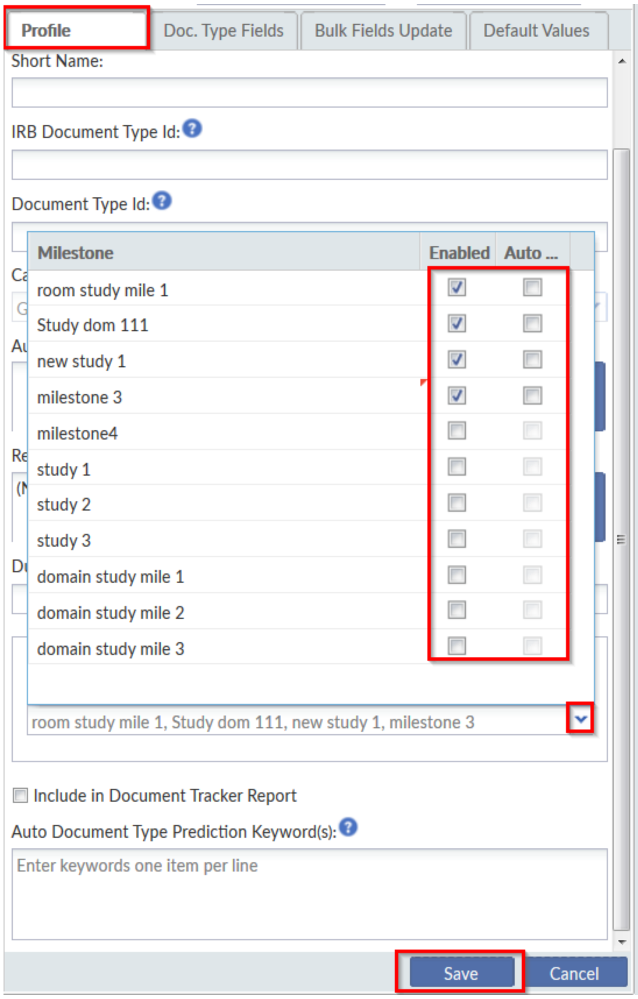


In this example, we have chosen the **Relevant Communications** folder.

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.

Include Phases/Milestones

To add Document Types to Milestones in your room, click the **Study Milestones** dropdown in the **Phases/Milestones section** of the **Document Type Profile window**. Refer to the screenshot below:



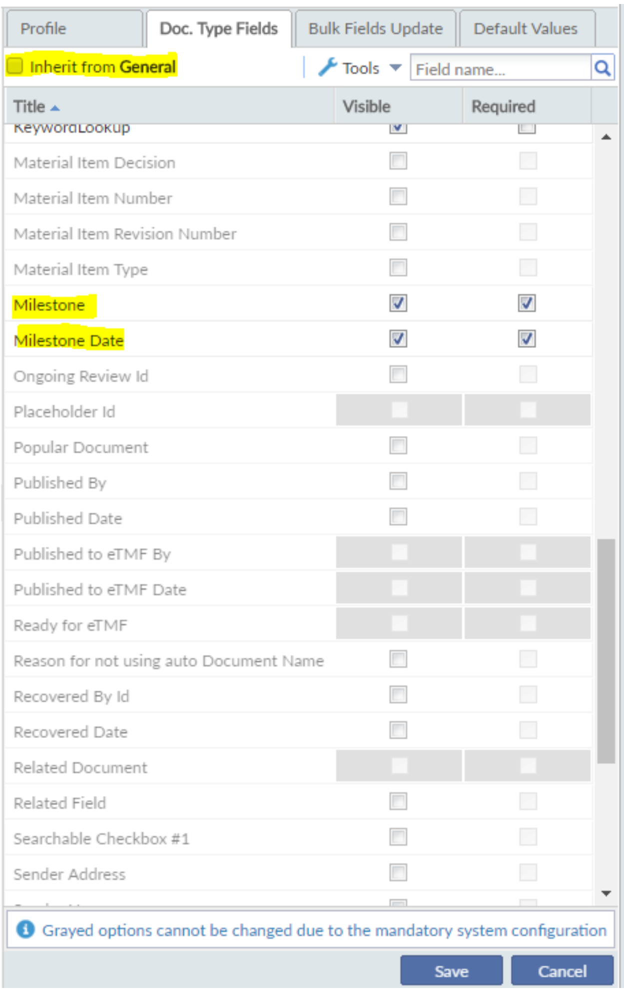
From the list of milestones that appear:

1. Tick the checkboxes to select the milestones that apply to the current document type
2. Click **Save**.

These milestones, when added to the document types, help to track the **eTMF Completeness** of documents associated with them, and generate **eTMF Completeness Reports**.

Milestone Related Fields Auto Enabling

When a user selects one or more items in the Study Milestones, Investigative Site Milestones, or Country Milestones files in the Document Type Profile, **the system will automatically mark the 'Milestone' and 'Milestone Date' document fields as visible and required**. This will be reflected in the custom form fields list in the **Doc. Type fields window** of the selected Document Type; an information message will also be shown. Refer to the screenshot below:

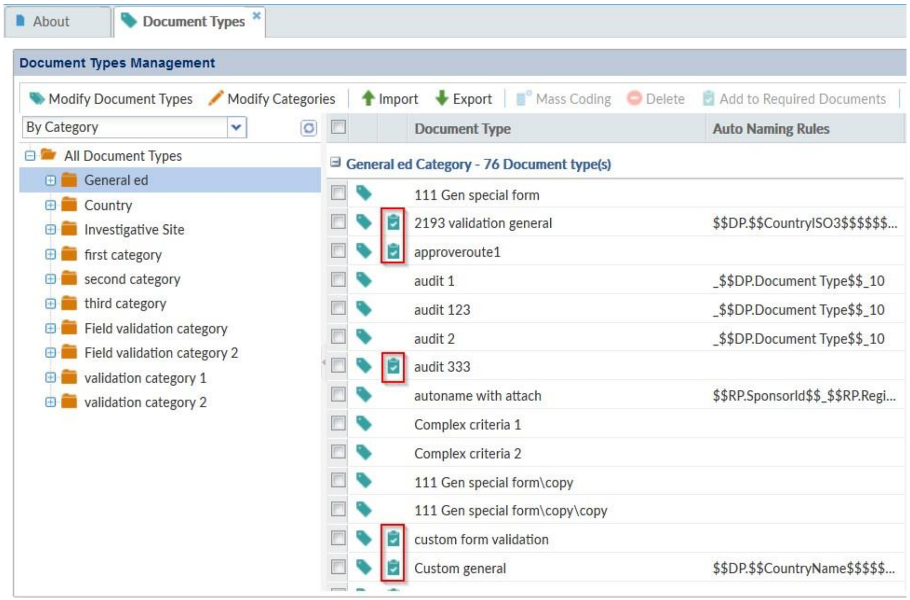


Besides the above, a document type can also be added to a milestone by either of the following ways:

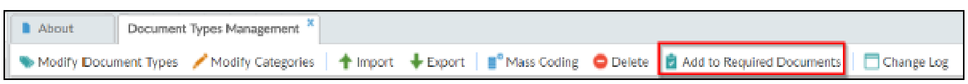
1. From **Required Documents** window
2. From **Sites Profile** window while adding or editing sites

Adding Document Types to Required Documents

You can know if a document type is added to the required documents list from the **Required Documents icon**  that appears in the grid next to the document type category. Refer to the screenshot below:



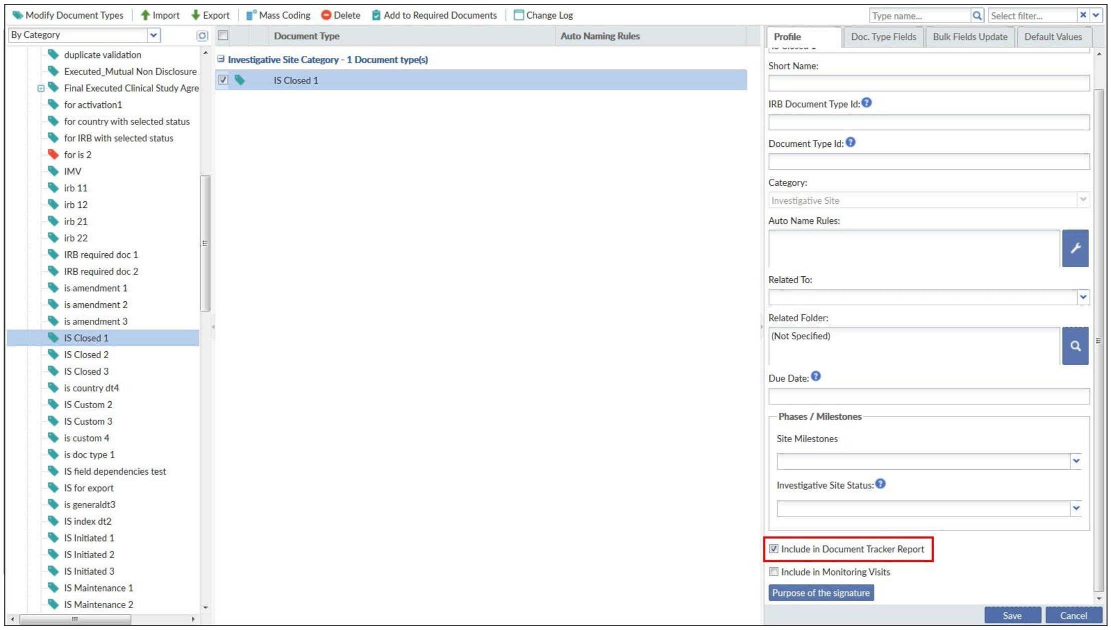
A document type can be added to the required documents list from the **Add to Required Documents** button located on the toolbar above the Document Types Management window. Refer to the screenshot below:



Besides, you can also make a document type a required document from the **Required Documents** window.

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:

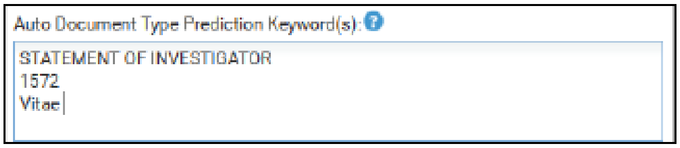


Auto Document Type Prediction Keyword(s)

Out of the hundreds of potential document types that might be present in a study, many of those document types might be auto predicted. For example, Curriculum Vitae, the 1572 form, a financial disclosure form – practically any required regulatory pack document or any document for which a sponsor has a template to send to investigators. A Super

Administrator user needs to activate this option in the room. When this feature is activated, and a document is uploaded, it goes into a queue. The system searches the first page of each document for the keywords entered for all of the document types for which keyword identifiers have been entered.

1. Open the Profile for the document type for which you want to add the Prediction Keywords in the **Document Types Management** settings.
2. Type Keywords into the field, one keyword per line.

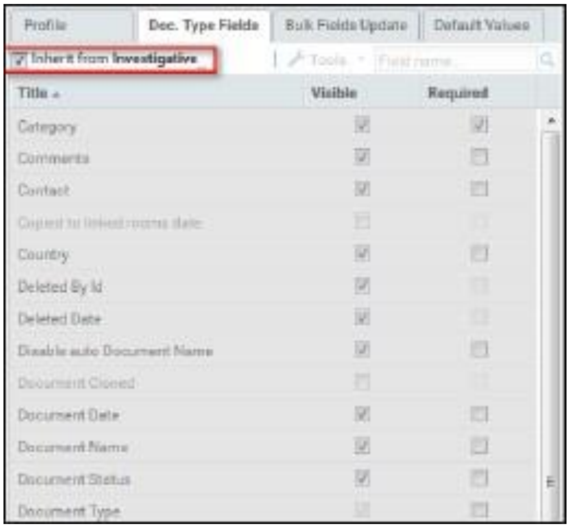


3. When all of the appropriate keywords have been entered, click **Save** at the bottom of the **Profile** panel.

Modifying Document Type Fields

In some cases, you may need to change which metadata fields are available for a particular document type.

1. To initiate a change in the availability of metadata fields, click the **Doc. Type Fields** tab next to the **Profile** tab in the panel on the right.



2. Uncheck the Inherit from {Category Name} box at the top of the pane to break the inheritance. The pane becomes active, no longer grey in appearance.
3. Click the boxes in the columns marked **Visible** and **Required** as dictated by the client request.

   Note: *If you have already established a standard set of metadata fields for the documents, you can use this shortcut:*

   a. *Click Tools.*
   b. *Select Clone Fields from.*

   Then select another document type whose metadata fields are the same.

4. When you have finished making the requested changes, click **Save** at the bottom of the pane.

   Note: *The Search box allows you to type in simple search criteria to help you find particular metadata fields in the list.*

Default Values

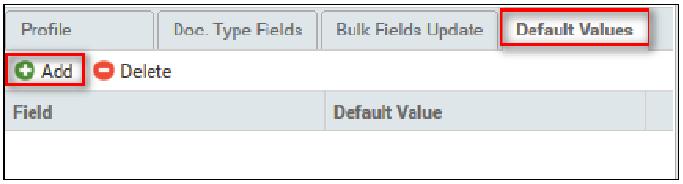
By implementing the **Default Values** options when defining a document type's profile coding, you can set a specific metadata field value to auto-populate based on the document type.

1. 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.
2. Select the specific document type to which you want to add the field that will auto-populate with the default value.
3. Click the **Metadata Fields** tab.
4. Click the necessary checkbox.
5. Click **Save**.
6. Click the **Default Values** tab.
7. Click the **Add** button.

The **Field** textbox activates. Click the dropdown arrow at the right end of the box.

8. Select the necessary custom metadata field from the list.

9. Press **Tab** on your Keyboard.
10. Set the field's default value by typing the value in the textbox.

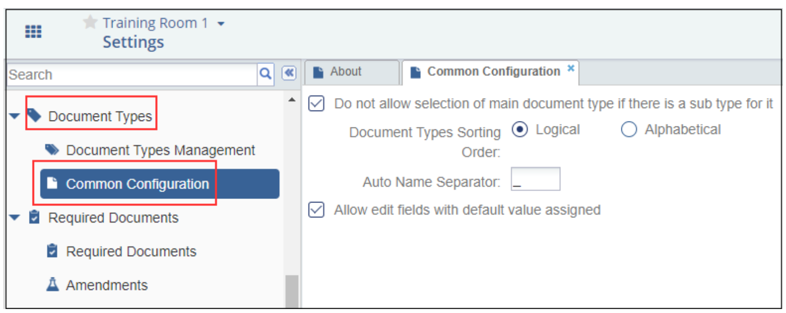


11. Click **Save**.

When any document is assigned to that document type, the custom field will auto-populate with the default value you established.

Common Configuration

Clicking **Document Types Management** opens its dashboard on the right. Refer to the screenshot below:



- In the **Common Configuration** panel, you can make it so that users cannot select a main document type name if one or more sub-types exist for that type.
- In this panel, you also select whether Document Types are sorted by **Logical** order (the order in which they were entered) or sorted **Alphabetically**.
- Here, too, you select the default **Auto Name Separator**; you can choose any character, or you can make the auto separator a blank space.
- On enabling **Allow edit fields with default value assigned**, some document metadata fields will be filled automatically on creating a document and selecting a document type from the configured list.
- If you make any changes in this panel, click **Save** at the bottom of the panel.

Required Documents Settings

With the help of **Required Documents Settings**, Administrators establish and edit the Required Documents for a study. Different document types may be required for all Investigative Sites involved in a study, or there may be documents that are required of investigative sites that are located in particular countries. These settings are typically made at the outset of a study, but they may be modified during the course of a study under certain circumstances.

Once Document Types are set up for a room from Document Types Management, *(page 105)* 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 here. Once Document Types are set up for a room from* ***Document Types Management****, you can set up the Required Documents.*

1. Navigate to **Main Navigation -> Settings Module**
2. Select **Required Documents** from the menus on the left.

   Refer to the screenshot below showing the various options under **Required Documents Settings**:

Required Documents can be defined for the following:

1. All Sites
2. Country-Specific
3. IRB/EC

Each of these is discussed in the separate topics and can be viewed from the left pane of this help.

Required Documents

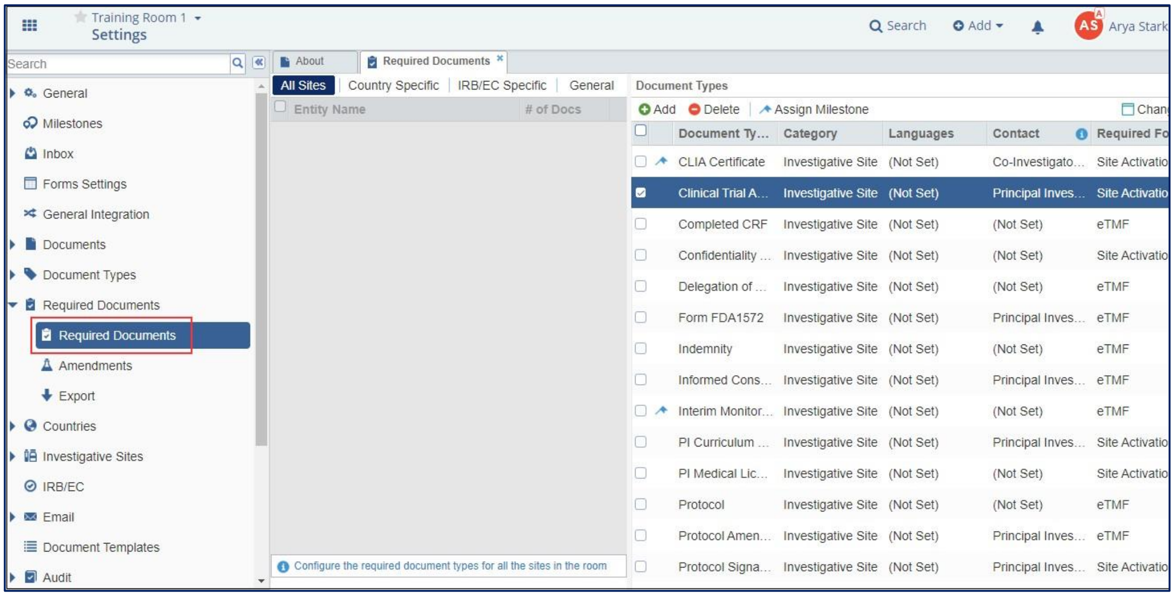
1. From the left section of the panel, you can select the category (**Sites, Country, IRB/EC, and General**) of the Required Documents. By default, the **All Sites** category is chosen.
2. From the right section of the panel, named as Document Types, you can:

   a. **Add** Add or **Delete** Delete a Required Document to the category selected from the left pane.

   b. **Assign Milestones** Assign Milestone to selected Required Document Types.

   c. View the activity log of the selected category from the **Change Log** Change Log.

   d. Once a Required Document is added, it appears in the Document Types Grid.



Each **View Option in the Required Documents** is discussed as below:

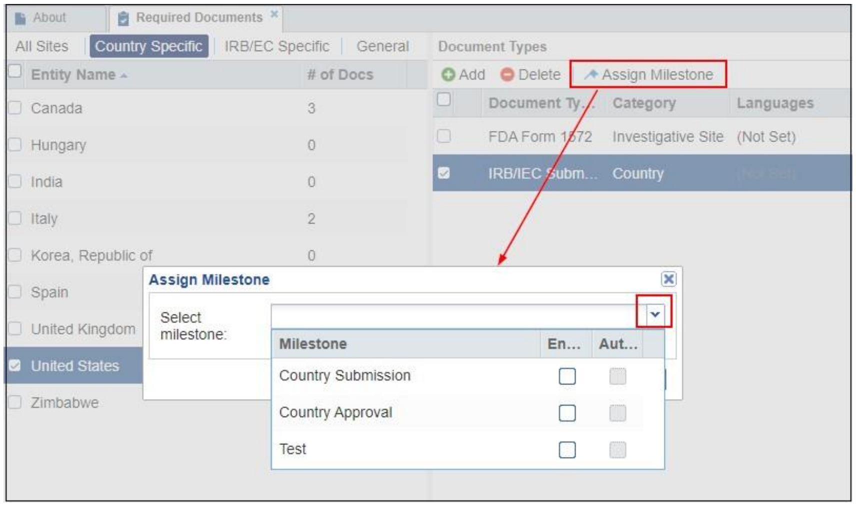
All Sites Country-Specific IRB/EC Specific General

Assigning Milestones to Required Documents

To assign a milestone to a Required Document, follow the steps as below:

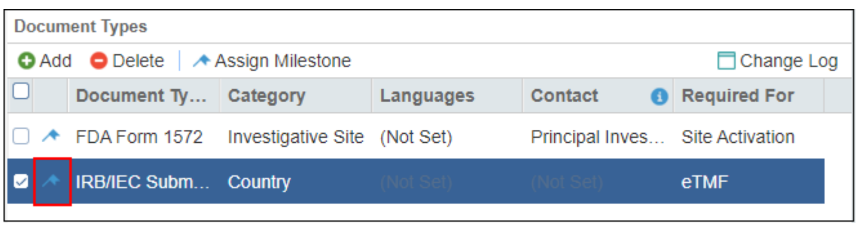
1. Select the category from the left pane.
2. Except for All Sites and General categories, select the Country or IRB/EC from the left pane.
3. Select the Required Documents from the right pane.
4. Click the **Assign Milestone** 

from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:



6. Choose the milestones from the dropdown list
7. Click the **Assign Milestone** button from the popup window.

8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**. Refer to the screenshot below:

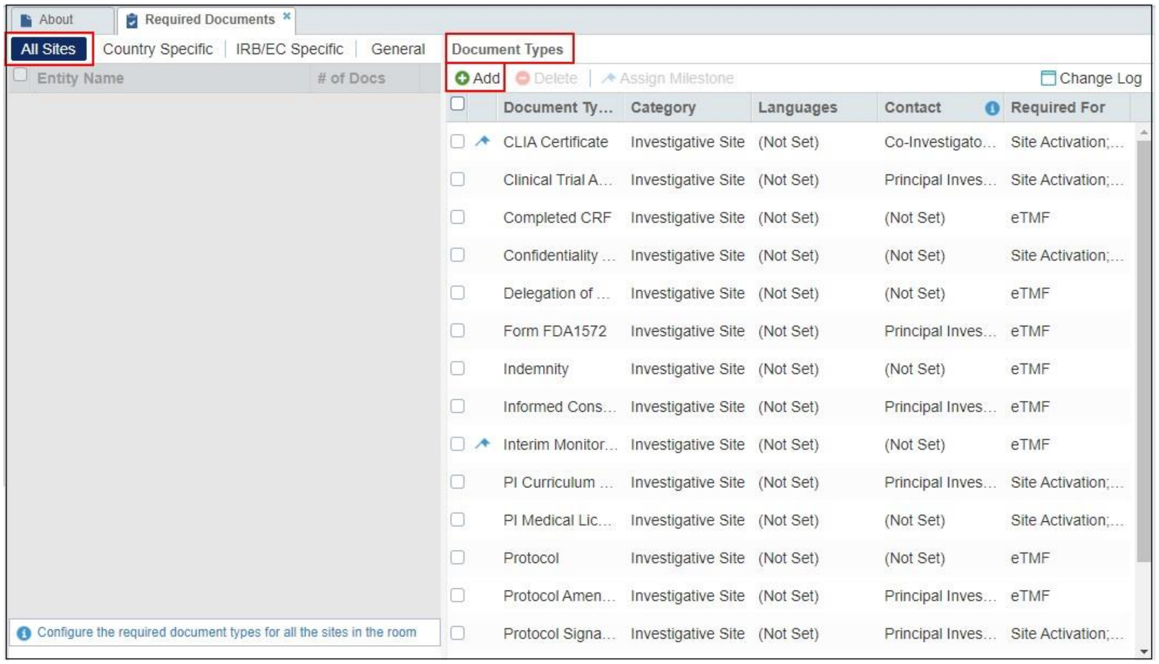


All Sites

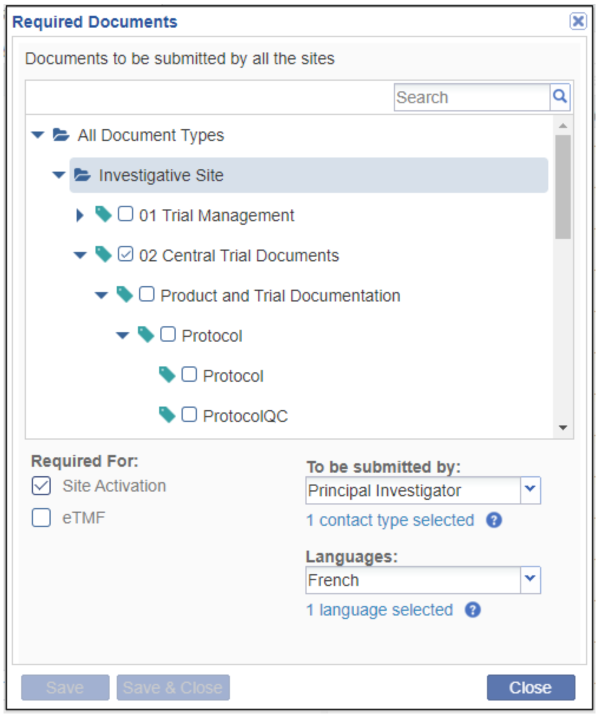
Note: *By default, no documents are Required Documents. Required documents must be defined in this settings view. If the room has been cloned from a previously used room, the Required Documents may already be defined.*

Adding All Sites Required Documents

1. Click the **All Sites** tab from the left panel of the **Required Documents Panel** ***(page 117)***.
2. Click **Add** from the top ribbon bar of the **Document Types** window on the right. Here, you can add document types that will be required by all sites included in the study. Refer to the screenshot below:



3. The **Required Documents** window opens for you to add Required Documents for your sites under specific categories. Refer to the screenshot below:



4. Click the **Category Folder** from which you need to select the Required Documents that you want to add to the list for all sites. The list of the available document types in that category folder appears.
5. Click the checkbox next to one or all of the documents to be required.
6. Select whether the document(s) will be required for **Site Activation** or **eTMF** by clicking the checkbox.
7. From the dropdown menus to the right, select:
   - **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
   - **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.

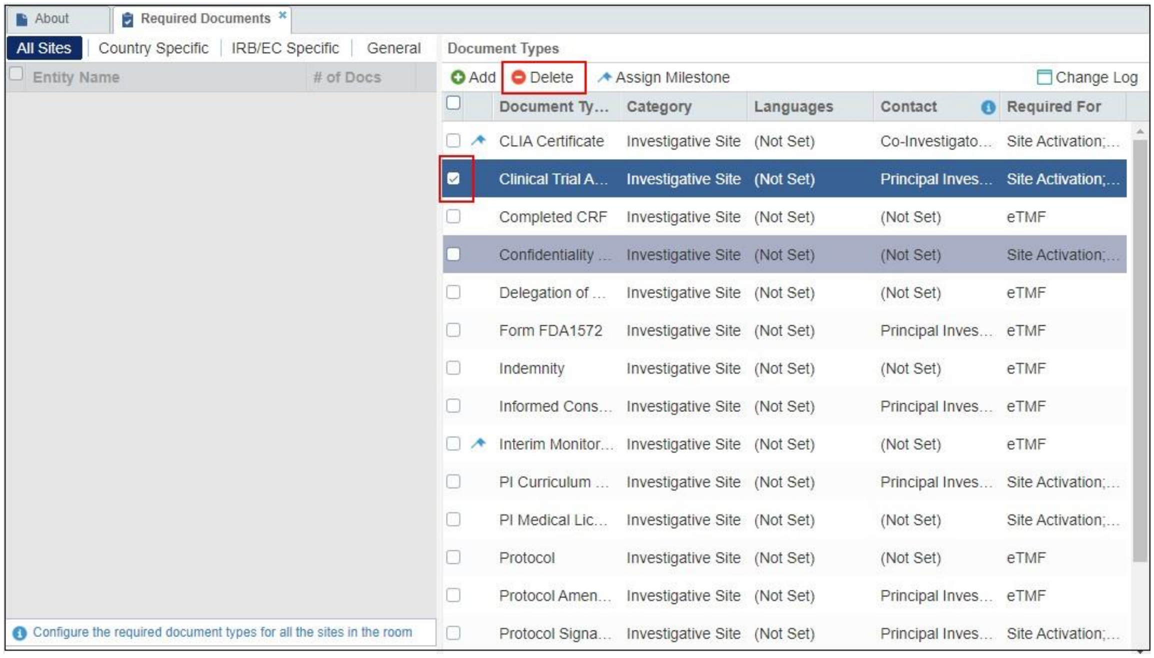
8. Click **Save & Close** if you have documents from only one category folder to add, or click **Save** if you need to add more required documents.

Note: *If documents are to be provided by one study contact and another document or documents are to be provided by a different contact, click **Save**; go back to the documents list; select the next set of documents, again select whether the documents are required for Site Activation or eTMF; select the contact type from the dropdown, and click **Save**. Continue this process until you have finished adding required document types for all contacts and then finally click **Save & Close**.*

Deleting All Sites Required Documents

To delete a Required Document Type for All Sites:

1. Click **All Sites** tab from the left panel of the **Required Documents Panel** ***(page 117)***.
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. Refer to the screenshot below:



4. You will receive a warning asking you to confirm the action.
5. Click **Yes** to confirm and delete it.
6. The Required Document Types are removed from the list.

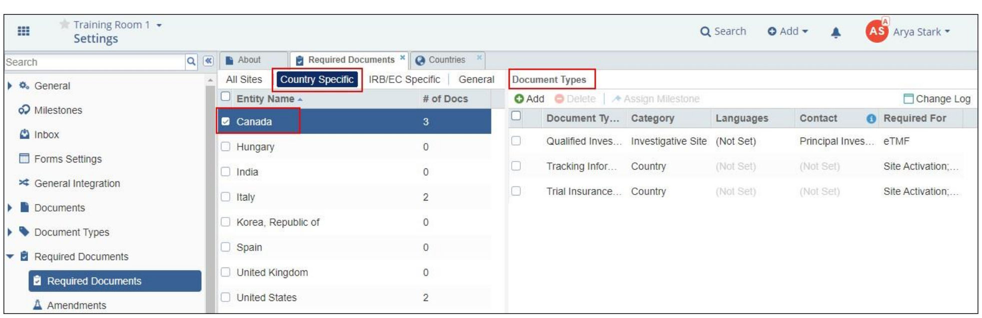
Country Specific

Sometimes, there will also be country-specific document types that will be required.

1. Select the **Country Specific** tab.

> **Note:** *Countries being used for a study are entered during initial Room Configuration. Instructions for* ***Adding Countries*** *can be found in another section of this guide.*

The list of countries will activate in the left pane. Refer to the screenshot below:



2. Select the particular country for which you need to add a required document.
3. The **Document Types** window on the right becomes active.
4. Click **Add** from the top ribbon bar of the Document Types window on the right.

   The **Required Document** ***(page 119)*** window opens, allowing you to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).

5. Selection of the **Investigative Site** radio button activates the list of document types included under Site Management.
6. Selection of the **Study** radio button activates the document types included under the Country document category.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.

   Note: If a specific contact type is made a requirement for document submission, all matching site users will be required to submit that document.

10. Click **Save**.
11. Begin again at the top of the **Required Documents** window.
12. Select the Study documents to be required.
13. Click **Save & Close**.
14. Select the next country in the list to which you need to add required documents, and follow the process steps above.

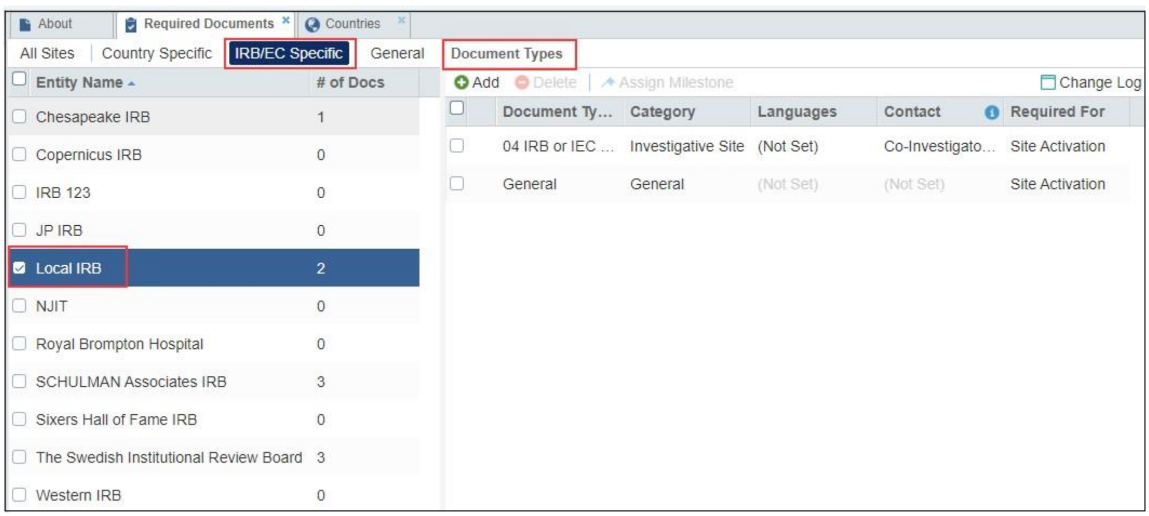
IRB/EC Specific

Sometimes, there will also be IRB/EC-specific document types that will be required.

Adding IRB/EC Specific Required Documents

1. Select the **IRB/EC Specific** tab

   The list of IRB/ECs will activate in the left pane. Refer to the screenshot below:



2. Tick the checkbox to select the particular IRB/EC for which you need to add a required document.
3. The **Document Types** window on the right becomes active.
4. Click **Add** from the top ribbon bar of the Document Types window on the right.

   The **Required Documents** window opens, providing you with the opportunity to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).

5. Selection of the **Investigative Site** radio button activates the list of document types included under **Site Management**.
6. Selection of the **Study** radio button activates the document types included under the **General document category**.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction, if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.
    a. **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
    b. **Languages**- Select the language from the list to apply to the Required Documents.

    Note: If a specific contact type is made a requirement for document submission, all matching site users will be required to submit that document.

10. Click **Save**.
11. Begin again at the top of the Required Documents window to continue adding for different contacts under Investigative Site.
12. Select the **Study** documents to be required.
13. Click **Save & Close**.
14. Select the next **IRB/EC** in the list to which you need to add required documents, and follow the process steps above.

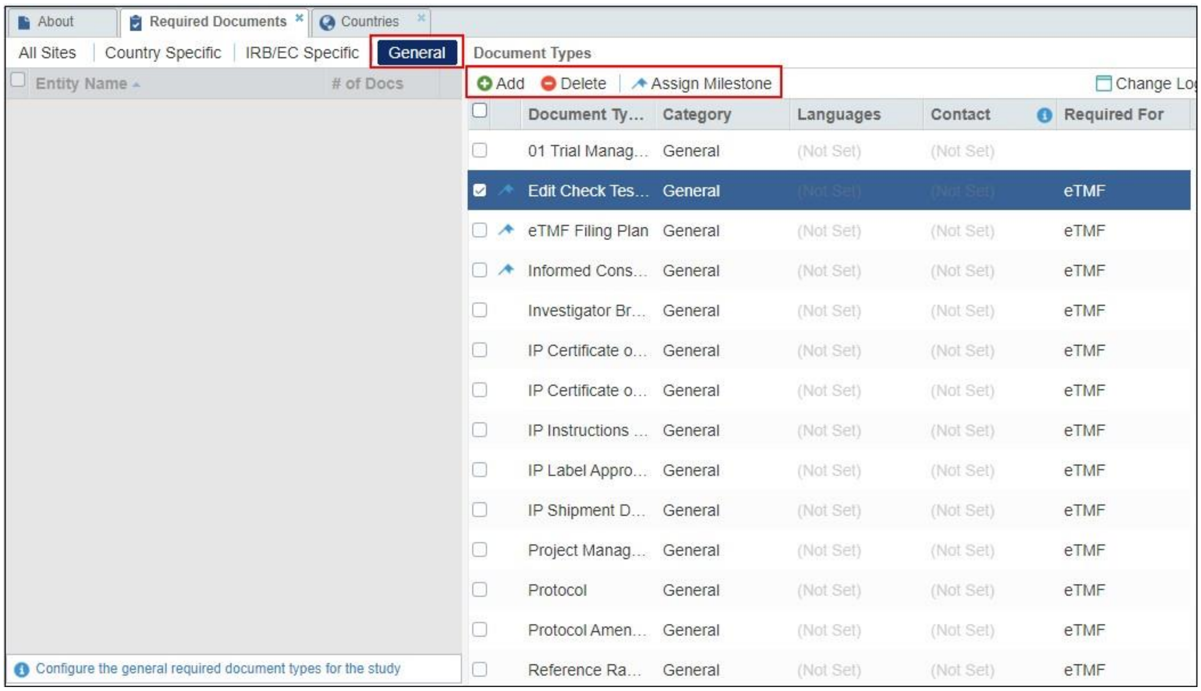
Deleting IRB/EC Specific Required Documents

1. From the IRB/EC tab, tick the checkbox to select the particular IRB/EC.
2. The **Document Types** window on the right becomes active.
3. Select the required **Document Type** you wish to delete and click **Delete** from the top ribbon of the Documents Types window.

General View

Adding General Required Documents

1. Click the **General** tab from the left panel of the Required Documents panel *(page 117)*.
2. The **Document Types** window on the right becomes active.
3. Click **Add** from the top ribbon bar of the **Document Types** window on the right.
4. The **Required Documents** window opens for you to add General Required Documents.
5. Select the particular **General** category for which you need to add a required document. Refer to the screenshot below:



6. Click the category folder from which you need to select the Required Document that you want to add to the list for all sites. The list of the available document types in that category folder appears.
7. Click the checkbox next to one or all of the documents to be required.
8. 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.

Deleting Required Documents

To delete a Required Document Type for All Sites:

1. Click the **General** tab from the left panel of the **Required Documents Panel** ***(page 117)***.
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. You will receive a warning asking you to confirm the action.

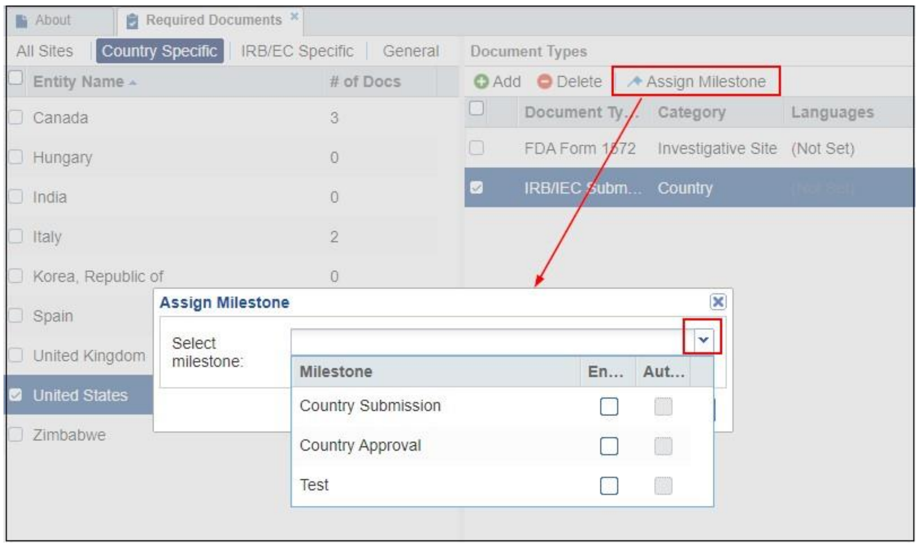
5. Click **Yes** to confirm and delete.
6. The Required Document Types are removed from the list.

Required Documents Milestones Linking

To assign a milestone to a Required Document, follow the steps as below:

1. Select the category from the left pane.
2. Except for **All Sites** and **General** categories, select the **Country** or **IRB/EC** from the left pane.
3. Select the Required Documents from the right pane.
4. Click **Assign Milestone** 

from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:



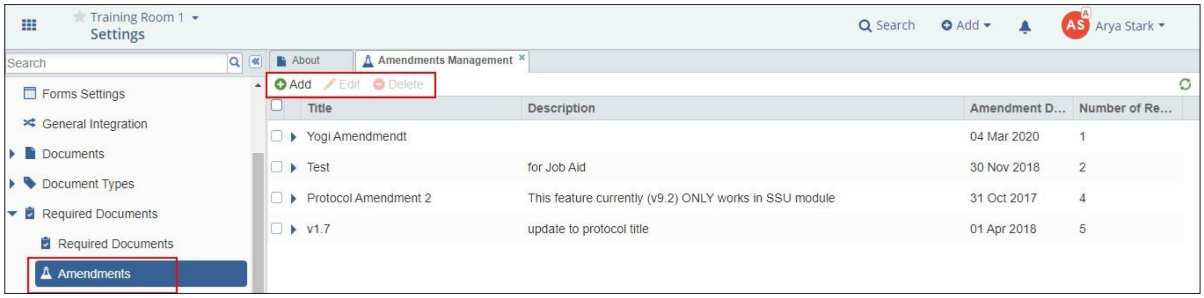
6. Choose the milestones from the dropdown list
7. Click **Assign Milestone** button from the popup window.
8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**.

Amendments

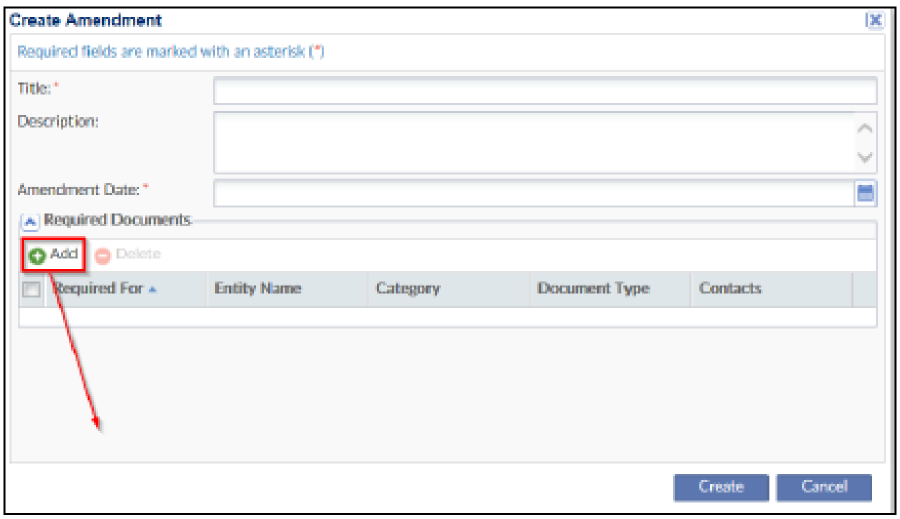
In the Amendments panel, Administrator users can add, edit, and delete amendments.

It will provide a list of documents that need to be collected after the initial set of Required Documents have been set up and rendered. Thus, Administrator users can track the needed documents more conveniently.

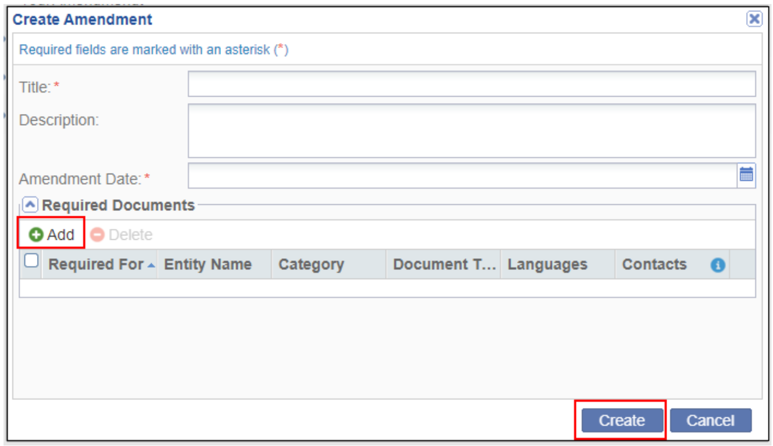
In this dashboard, besides adding amendment required documents, you can adjust your Amendment dashboard view by sorting the columns by ascending or descending order, and also can manage which columns will be shown or hidden. Refer to the screenshot below:



1. Click the **Add** button from the top ribbon bar. **Create Amendment** window opens. Refer to the screenshot below:



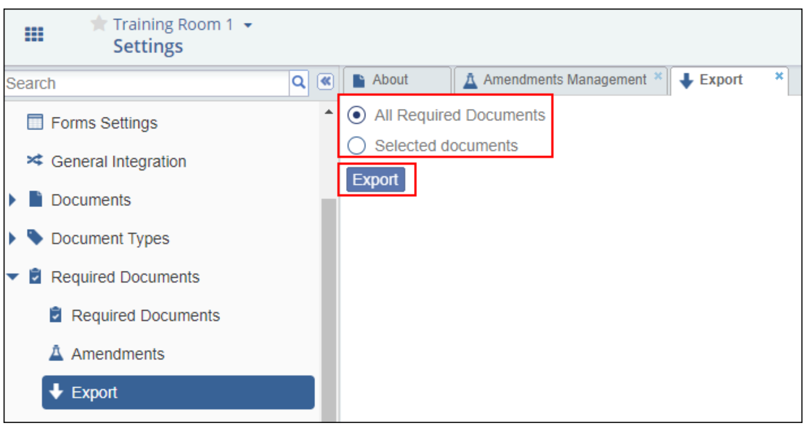
2. Fill in the required details.
3. Click on the **Add** button placed under the **Required Documents** panel. **Required Documents** window opens for you to add the documents that need to be submitted for the specific amendment created. Refer to the screenshot below:



4. Select from the list for **To be submitted by** and **Languages**. Click **Add** to save the amendment made.
5. To edit the amendment, double-click the particular amendment or click the **Edit** button.
6. To delete, click the **Delete** button or right click on the amendment and click **Delete**.

Export Required Documents

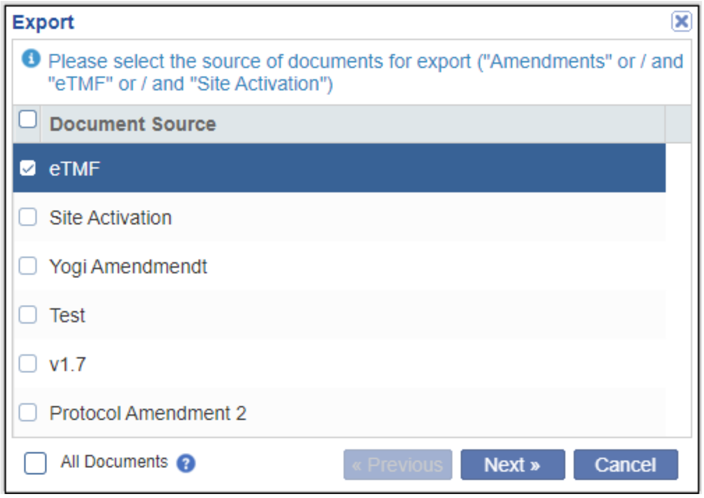
In this panel, Administrator users can export either **All required documents** or **Selected documents**. Refer to the screenshot below:



Required Documents can be exported in two ways:

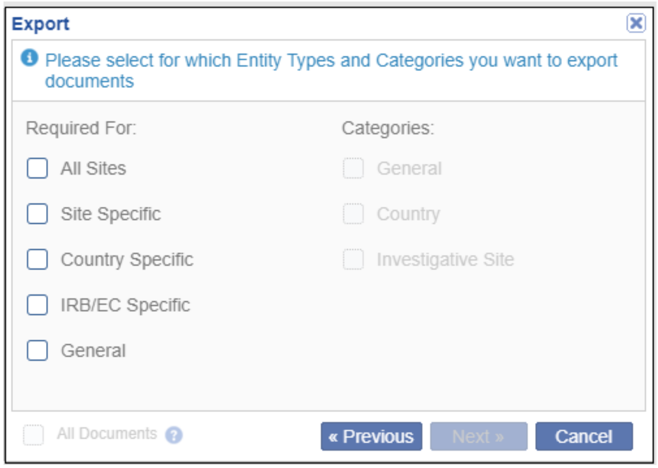
1. Select **All required Document** Option to export documents from all document source categories
2. Select **Selected documents** option.
   a. Export window opens for you to choose from **Amendments or/ and eTMF or/ and Site Activation** sources of documents.

   Refer to the screenshot below:



b. Select the required **Document Source/s** and click **Next**.

c. New Export window opens for you to select required **Entity Types and Categories** to export documents. Refer to the screenshot below:



d. Click **Next.**The final Export window opens to review criteria chosen by you.
Click **Previous** to make changes in the selection or click **Next** to export Required Documents.

e. On successful exporting of Required Documents, you will receive a notification.

f. 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:

Exported Required Documents **Training Room 1**

Required For	Requirement Level	Entity	Category	Document Type	Contact Type	Language
eTMF	All Sites		Investigative Site	02 Central Trial Documents\Subject Documentation\Informed Consent Form\Informed Consent Form	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Initiation\Trial Inititiation Monitoring Report\Site Initiation Visit Report		
eTMF	All Sites		Investigative Site	05 Site Management\Site Management\Monitoring Visit Report\Interim Monitoring Visit Report		
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Form FDA1572\Form FDA1572	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Protocol Amendment Signature Page\Protocol Amendment Signature Page	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Site Signature Sheet\Delegation of Authority		
eTMF	All Sites		Investigative Site	10 Data Management\Data Capture\Final Subject Data\Completed CRF		
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Indemnity\Indemnity		
eTMF	All Sites		Investigative Site	02 Central Trial Documents\Product and Trial Documentation\Protocol \Protocol		
eTMF	All Sites		Investigative Site	01 Trial Management\Trial Oversight\Recruitment Plan\Recruitment Plan		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Site and Staff Qualification Supporting Information\PI Medical License		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Sub-Investigator Curriculum Vitae\SubI Curriculum Vitae	Sub-Investigator	
eTMF, Site Activation	All Sites		Investigative Site	08 Central and Local Testing\Facility Documentation\Certification or Accreditation\CLIA Certificate	Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Protocol Signature Page\Protocol Signature Page	Principal Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Principal Investigator Curriculum Vitae\PI Curriculum Vitae	Principal Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Selection\Confidentiality Agreement\Confidentiality Agreement		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Clinical Trial Agreement\Clinical Trial Agreement	Principal Investigator	

Countries

When a study includes investigative sites located in different countries, scountries need to be added to the room**.** In this way, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents. To set up countries for investigative sites, navigate to:

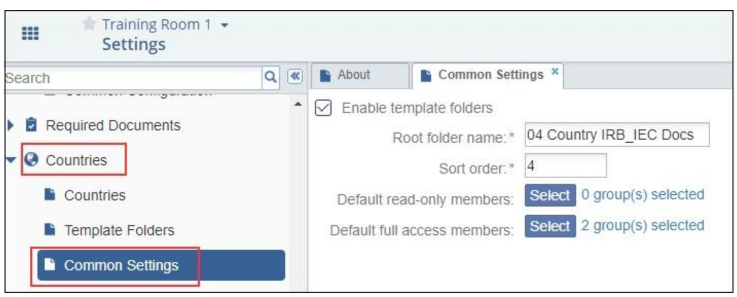
1. The Trial Interactive room for which you want to set up countries.
2. Select the **Settings** option from **Main Navigation**.
3. Select **Countries** from the menu on the left. This option drops down to reveal the following options:
   a. Countries
   b. Template Folders
   c. Common Settings

All of the above options are discussed in separate topics accessible from the left panel of this help.

Common Settings

In the Common Settings window, you can:

1. Enable or disable the Template Folders.
2. Edit the **Root folder name**. Typically the client supplies the preference here.
3. Change the Sort Order, the place in the room's index structure where the Country Management folder (or whatever name the client has specified) appears. This setting, too, is based on client preference.
4. And, as in the **Edit** function in the **Countries** window, you can adjust the **Read-Only** and **Full Access** security settings. Select the users or groups to set access. If you make any changes in this window, click **Save**. Refer to the screenshot below:

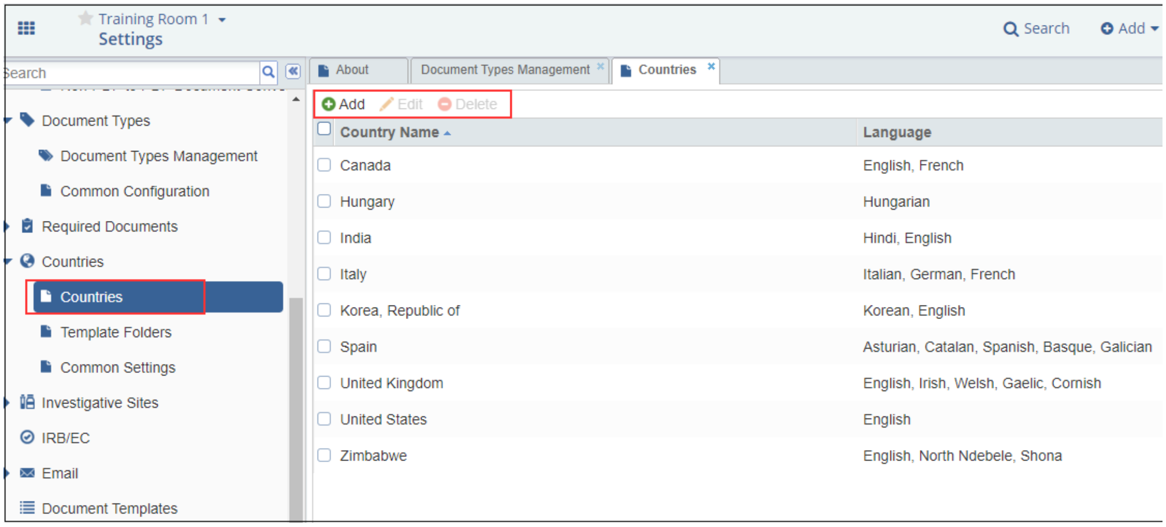


Countries Settings

Trial Interactive allows Admin to perform Countries Settings from this page.

Follow the steps below to perform the country settings:

1. Navigate to the **Main Navigation** -> **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.

Each of these is discussed in separate topics and can be accessed from the left menu of this help.

Add Countries

Follow the steps below to add countries:

1. Click **Add**  from the ribbon above the country listing. The **Create Country** window opens. Refer to the screenshot below:

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.

> **Note:** *You can ease the process of finding the country name in the list by typing the first few characters in the country name. The dropdown list will shorten to include only the countries whose names begin with the characters you have typed.*

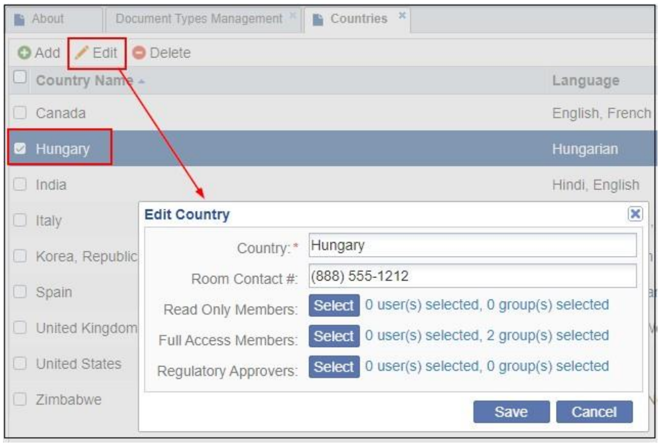
4. If the client has supplied country-specific **Study Contact #**, include the associated number in the field.
5. Click **Create**. The name of the newly added country appears in the alphabetized list.
6. Repeat these steps until you have added all of the countries associated with the study.

Edit Countries

Once a country has been added to the list, you can add or change the study contact #, and you can 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 opens. Refer to the screenshot below:



3. It might be that after you've added the country to the list, you are supplied with the study contact number later.

4. Click **Study Contact#** field to change the information.
5. Click **Select** next to **Read Only Members** or **Full Access Members** or **Regulatory Approvers** to add or delete users or groups of users from the access settings.

   These selections will probably not be available at this early stage of room configuration. Room configuration is not a strictly linear process – you will have to make additions and changes in other areas on the Trial Interactive platform in order to complete the room's configurations.

6. Click **Save**.

> **Note:** *Though you have access to these security settings here, it is not typical that you will make changes using this path.*

Delete Countries

Follow the steps below to delete the countries:

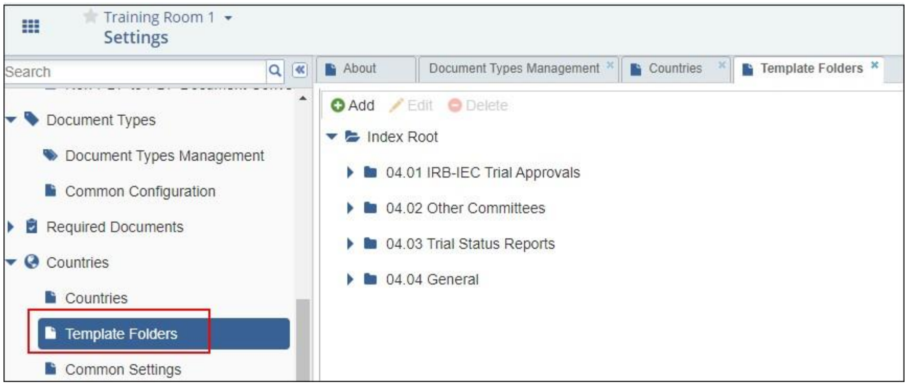
1. Select the country or countries that you need to delete from the list by clicking the checkbox next to the country's name(s).

2. Click **Delete**  at the top of the **Countries** window. The country name(s) will delete automatically, without giving you a warning.

Note: *At a later stage in the study, once documents have begun to populate the room's index folders, you won't be able to delete countries that have associated documents. Adding to and editing the Countries list can go on 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.



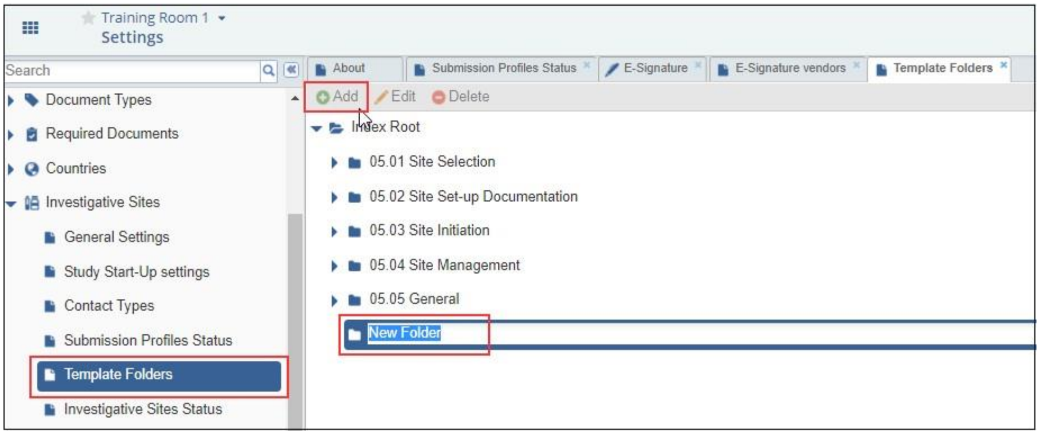
Note: *The details necessary for completing this stage of the room configuration come from the client – the titles and the order of the folders to be included. The folder structure is fairly consistent, but it is always study specific.*

Each of the above topics is discussed in separate topics and can be accessed from the left menu of this help.

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

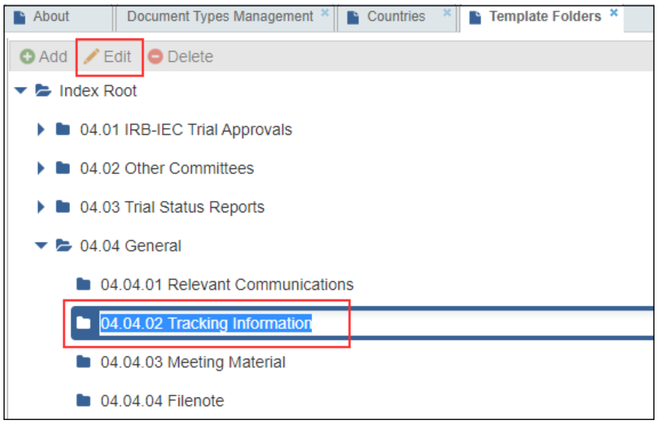
1. To add a folder to the Index Root, first click **Index Root**, marked by a yellow folder icon.
2. Click **Add** near the top of the **Template Folders** window. A new folder naming field opens, temporarily named **New Folder**.
3. Type the name of the new folder name in the highlighted field.
4. Press **Enter**.
5. Repeat this process until you have entered all of the new folder names.



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**.



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 disappears from the index structure.

Note: *Folders that contain subfolders or documents cannot be deleted.*

Investigative Sites

By clicking the **Investigative sites** tab in the menu, the Administrator gains access to panels that control settings related to generic components for each investigative site for the study.

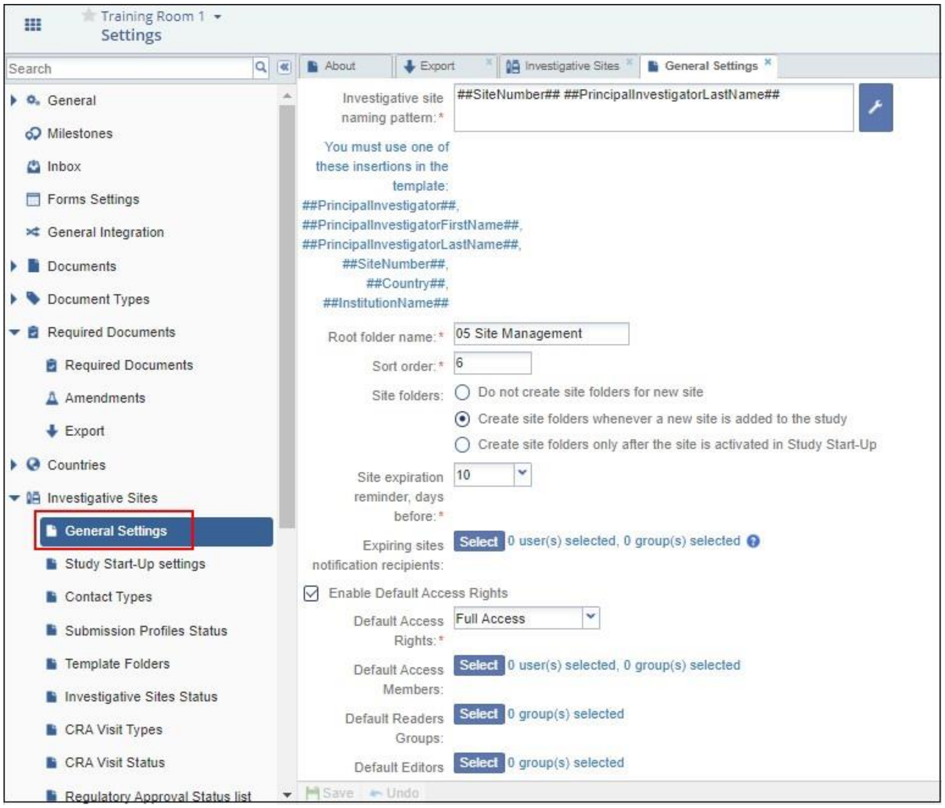
- General settings
- Study Start-Up settings
- Contact Types
- Submission Profiles Status
- Template Folders
- Investigative Sites Status
- CRA Visit Types
- CRA Visit Status
- Regulatory Approval Status list
- Communication Types
- Issues
- Regulatory Packet Options

Each of these is discussed in the separate topics and can be accessed from the left menu of this help.

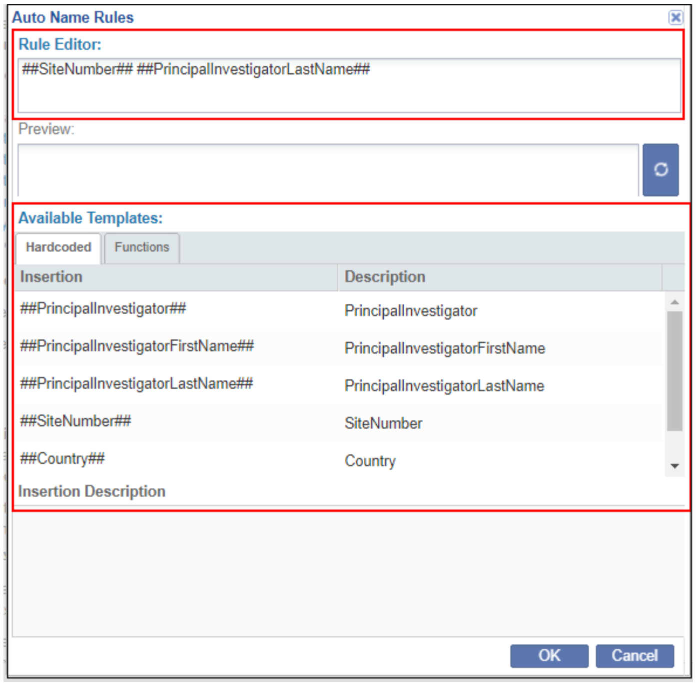
General Settings

This is a very active panel that houses a lot of options. The choices made here are dictated by client preferences. Refer to the screenshot below:

Note: *The entire General Settings panel has only one **Save** button. Be sure that you click **Save** after making any additions, selections, or changes in this panel.*



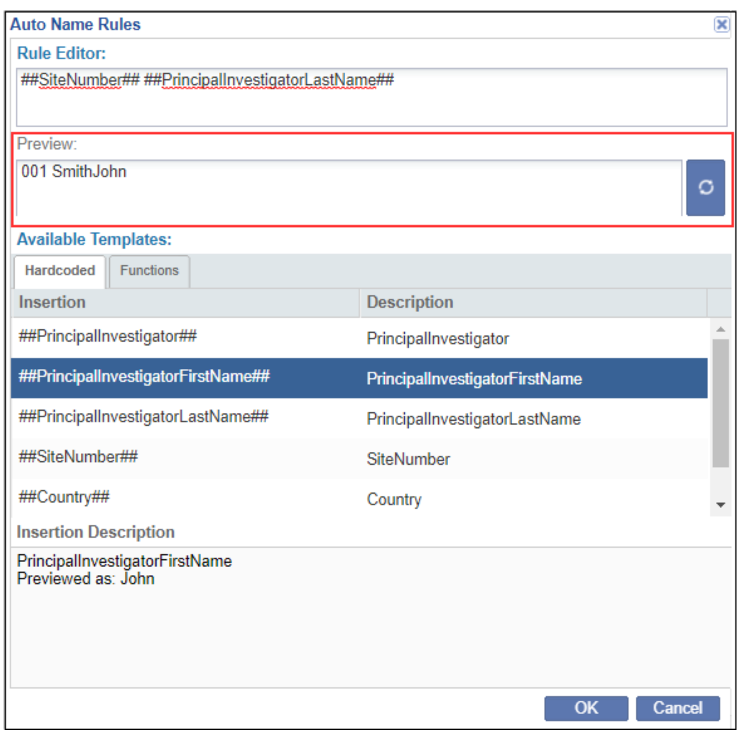
1. Click the wrench icon to the right of the **Investigative Site Naming Pattern** box.
    a. An **Auto Name Rules** window opens. The naming pattern is built and displayed in the **Rule Editor** box. The information that populates in the box is selected from the list of **Available Templates**. You can also hard-type text into the Rule Editor. In the example below, ‘Site’ and ‘[Site Management]’ has been typed into the naming pattern. Refer to the screenshot below:



b. Click in the **Rule Editor** box.

c. Double-click the insertions in the **Available Templates** box in the order in which you want them to appear in the naming pattern.

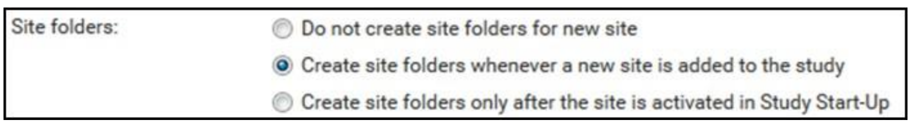
d. Once you have made the selections, click the blue box to the right of the **Preview** box to see how the folder names will appear in the room's index.



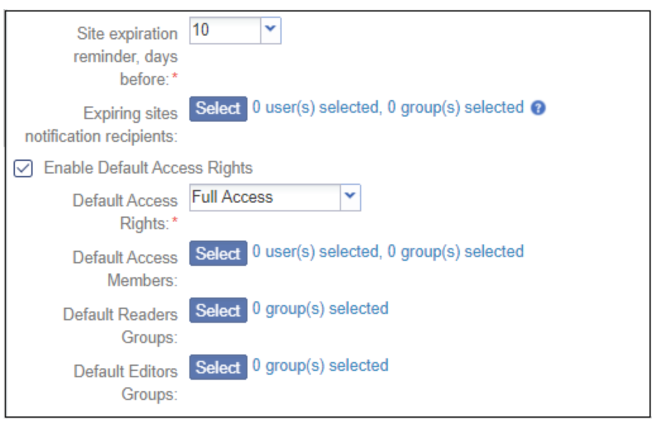
e. Once the naming pattern is set up correctly, click **OK** at the bottom of the window. You return to the **General settings** panel.

2. In the next available field, set the **Root folder name** in compliance with the client's preference. This is the title that is given to the main folder in the room's index that will hold the subfolders for each investigative site involved in the study.
   a. Click in the field.

   b. Type the root folder.
   c. Hit the **Enter** key on the keyboard.
3. 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.
   a. Click in the field.
   b. Type the number of the client's preference.
   c. Hit **Enter** on the keyboard.
4. The next box contains three radio buttons for Site folder creation in the eTMF. Click the option that fits your needs.
5. Like the previously described settings, the rest of the settings in this panel are dictated by client preferences. Closely



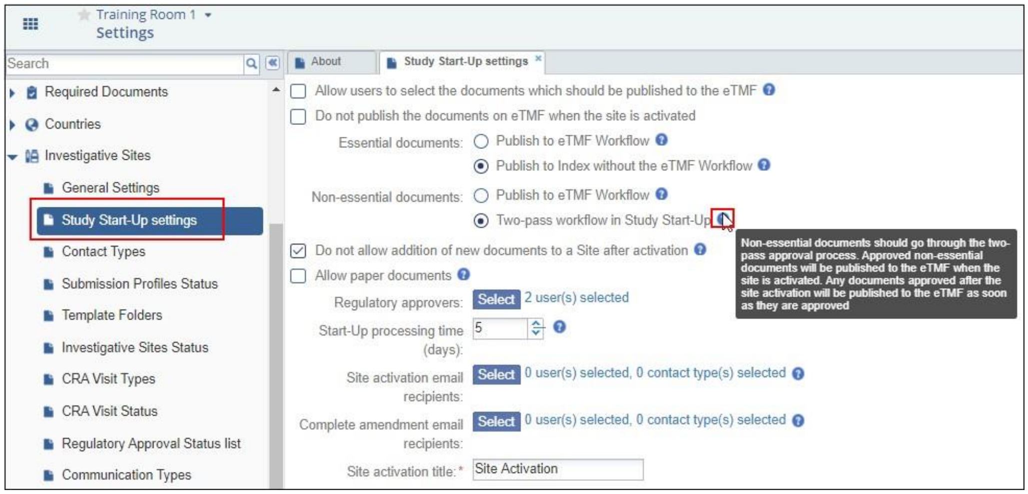
follow all instructions from the client in controlling these settings.
6. Hover the mouse over the question marks in blue circles for more information about specific options on the screen.



7. Click **Save** after making any additions, selections, or changes in the **General Settings** panel.

Study Start-Up Settings

In this panel, Administrator users can manage the study start-up settings for investigative sites. You can place your cursor on the button to receive a further explanation about each option. In this panel, the Site activation title is the only mandatory field.

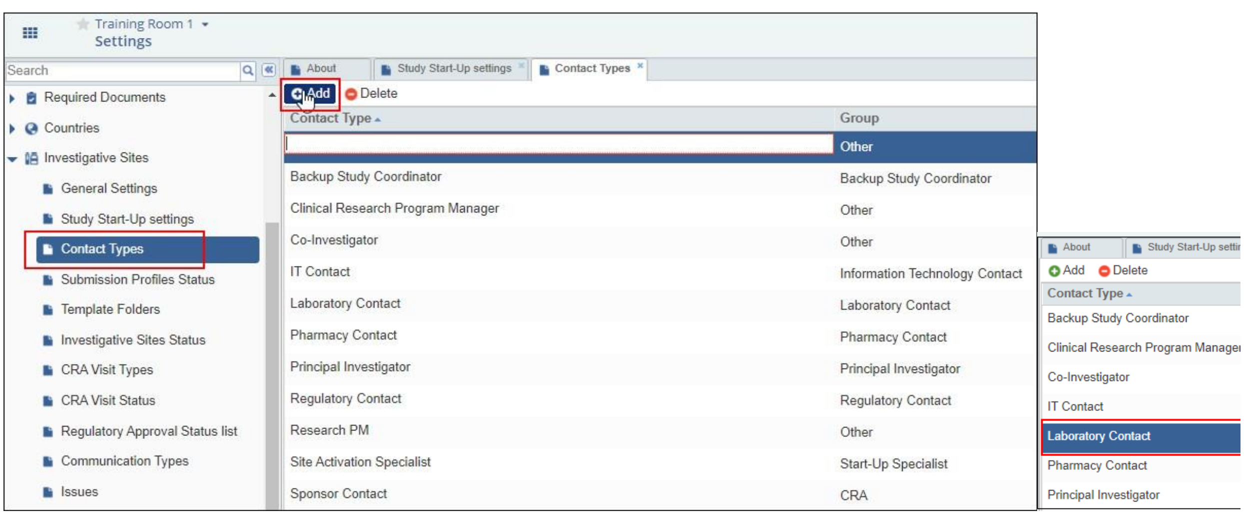


Note: *This is further discussed in detail in* ***Study Start-Up Guide***

Contact Types

In this panel, the list of **Contact Types** provided by the client is linked to Contact Type names that are already stored in the Trial Interactive platform. The **Contact Types** are the contact type names that the client wants to use for the study. The **Group** titles are study contact type names that already exist in Trial Interactive. Completing this process maps the type- names requested by the client to the type names in Trial Interactive.

1. Click **Add**. The **Contact Type** field becomes active.
2. Type the contact name provided by the client.
3. Hit **Tab** or **Enter**.
4. Click the field in the **Group** column to make it active.
5. Click the far-end right edge of the field to activate the dropdown menu.
6. Select the group title from the list that best corresponds to the client-requested Contact Type name. Additions and changes made here are saved automatically.



Note: *Three contact types are required – Principal Investigator, Sponsor Contact, and Site Activation Specialist. Trial Interactive will not allow the setup of any Investigative Sites in the trial room without these contact types having been set up first.*

Submission Profile Status

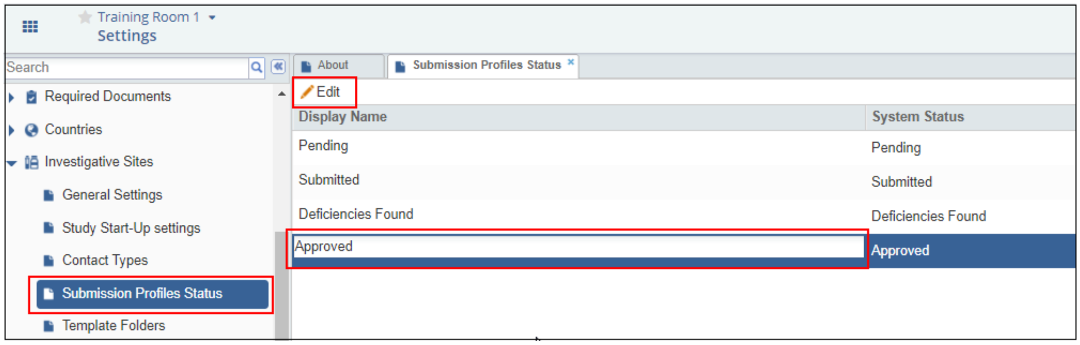
It is common practice to associate health agencies with sites and send submission packages to them for their approval. Sites cannot be activated for the clinical study unless the agency's approval is received. A study may have multiple health agencies located in various countries. These agencies may have more comprehensive site activation submission packages involving hundreds of documents and that need to be reviewed and approved.

This module allows you to prepare submission profiles where the user can provide the details such as agency name, country,the status of submission, documents to be included in the submission profile, date when the package was submitted, and also the status of the submission package.

A submission package can contain documents from the eTMF, SSU, Site, Country, and IRB, or any document from the disk. For instance, the IB and protocol are already filed in the eTMF but are required for the submission package. The clinical trial organization downloads the submission package to perform QC Review as in other documents and then forwards it for regulatory review. All the actions from creating and editing submission profiles to downloading submission packages for health agencies can be performed by an admin or editor.

Through the Agency Submission section in Trial Interactive, the organization can track multiple submission packages for the same country in case one submission package is rejected. Once a site is activated, these documents are not transferred to the eTMF and are left in the submission package.

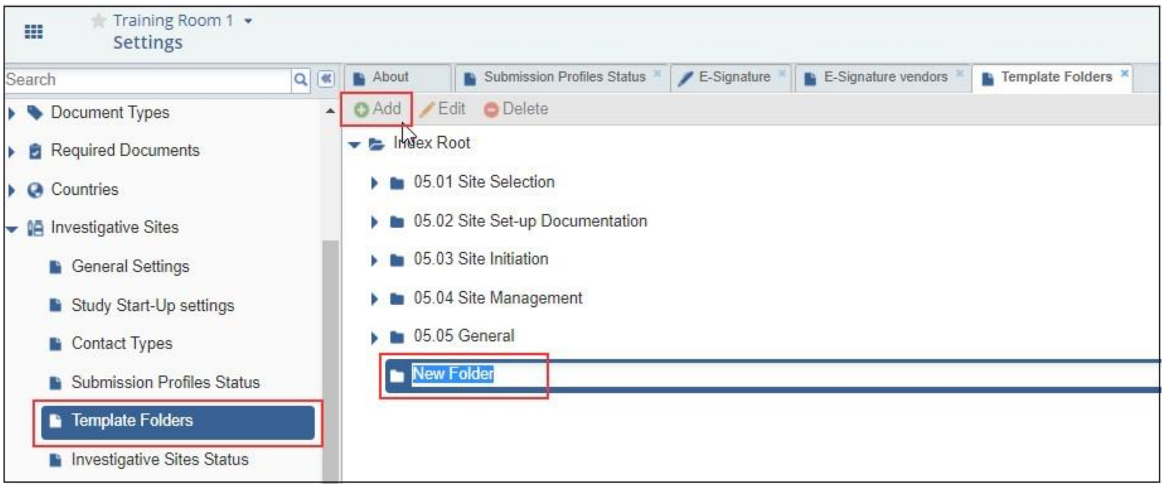
This panel provides the list of Submission Profiles and their System Statuses. The administrator may edit a submission profile by double-clicking the Display Name of a submission profile or by selecting a profile and clicking Edit from the top ribbon bar of the panel.



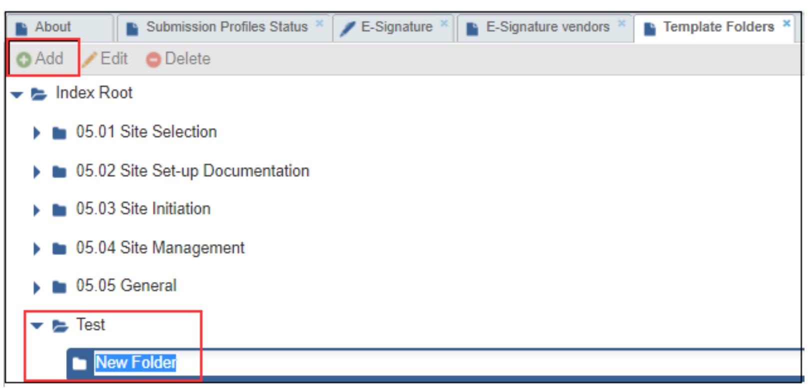
Template Folders

The Template Folders panel is very powerful. It is here that you generate the folder structure into which all Investigative Sites documents will be deposited throughout the course of a study. The structure you build here is supplied by the client.

1. Click **Add** to create the first folder to the Investigative Site index structure.



2. Type the name of the first 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**.

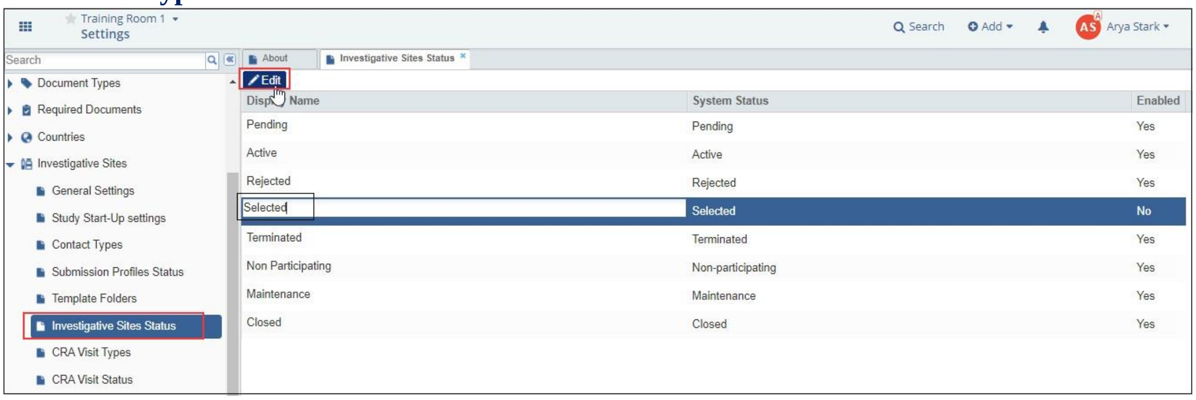


5. Continue adding folders and subfolders until the full Investigative Site Folder Index is complete and in compliance with the client's request.
6. Similarly, **Edit** or **Delete** the folders by selecting them as required.

Investigative Site Status

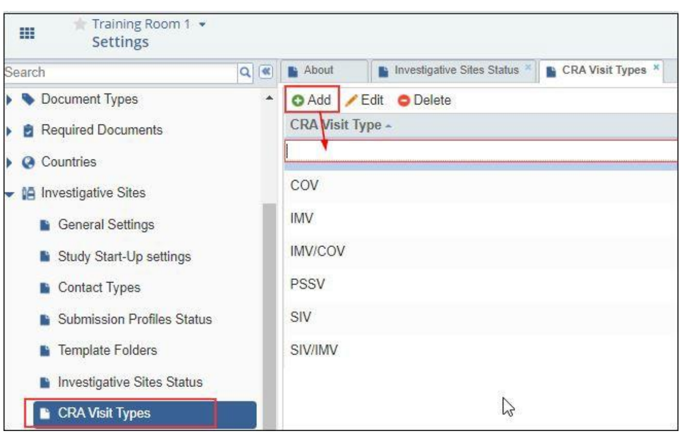
In this panel, Administrator users can edit the Display Name of the investigative site status. Click the **Edit** button on the top or double click on the specific display name to edit. Again, Investigative Site Status will also appear on the Document Types Management section of the settings.

CRA Visit Types



A CRA might need to create a **CRA TMF Reconciliation Report** to reconcile documents during site visits. While creating the report, the visit type must be chosen so that reports generated during two or more site visits can be differentiated with ease. Refer to the screenshot below:

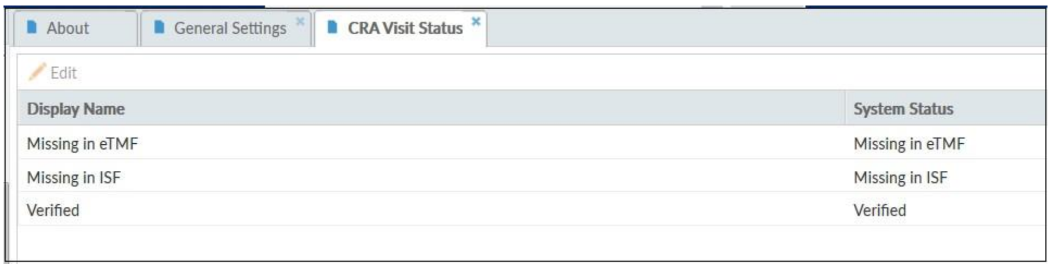
For the visit types to be populated in the dropdown, as shown above, the admin will need to create visit types from this panel.



1. To add a new visit type, click the **Add** button at the top of the portlet window.
2. Type in the desired term and press **Enter**. Changes made here are saved automatically. 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.
4. To delete a visit type, select the visit type and click **Delete** from the toolbar above.

CRA Visit Status

In this panel, Administrator users can set the CRA Visit Status required during the Reconciliation Reports. Refer to the screenshot below:



Regulatory Approval Status List

In the Regulatory Approval Status list panel, Administrators can Add, Edit, and Delete status titles to the list that will be available to users in the regulatory approval document flow. The standard statuses include Pass, Pending, and Rejected.

The terms used to identify and track each document's Regulatory Approval Status are configurable. Based on client request, those terms are added in this portlet.

1. To add a new regulatory approval status, click the **Add** button at the top of the portlet window.
2. Type in the desired term.

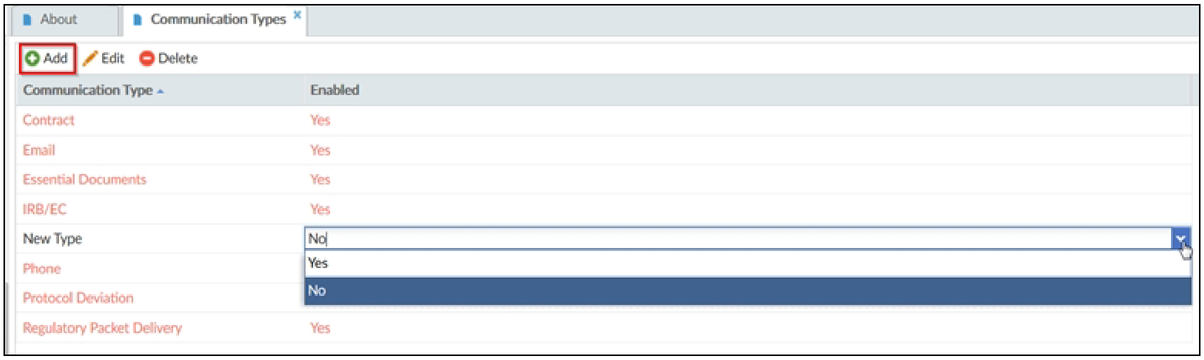
Changes made here are saved automatically. These status terms appear for Investigative Sites Documents as they go through the Study Start Up process.

Communication Types

Communications are tracked in the Study Start Up module. The Communication Type labels that mark individual communications in a study are set up in this portlet by Administrators.

1. To add a new Communications Type label, click the **Add** button. An empty test field opens.

2. Type in the label. By default, the new communication type is not Enabled. Refer to the screenshot below:

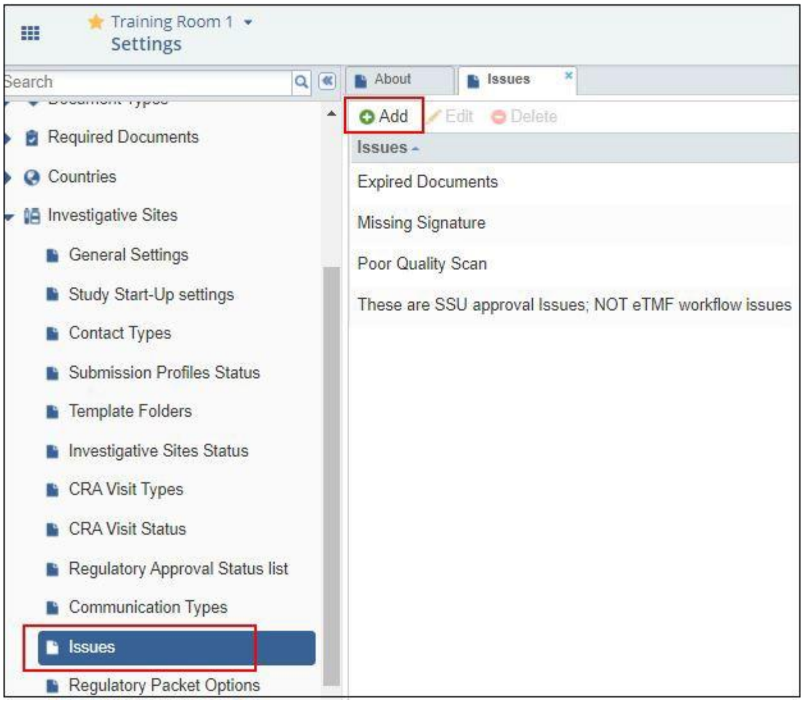


3. To enable the label for use in the study, double-click on **No**.That field becomes active with a dropdown menu.
4. Click **Yes** to enable the use of the new label option. The change saves automatically.

Issues

When a document going through the SSU approval process is rejected, the user who rejects the document must cite a reason for the rejection by choosing a pre-defined and named issue. The issues from which users can choose are established by Administrator users in **Settings** -> **Investigate Site** -> **Issues**.

1. Click **Add**. A text field opens.

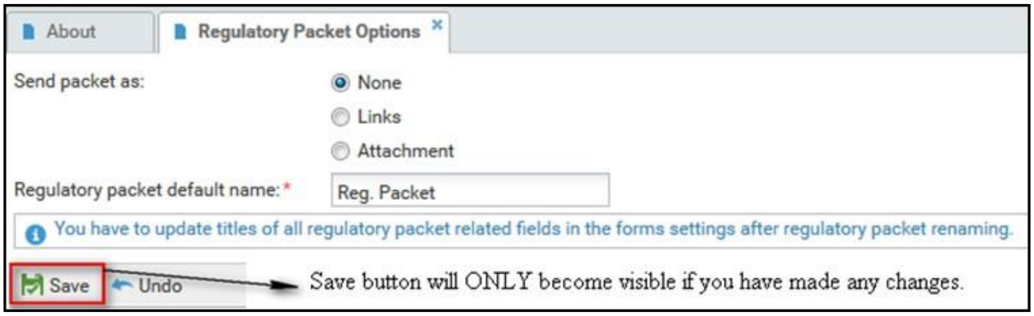


2. Type the description of the issue in the field.
3. Press **Enter**. The changes are saved automatically.

Regulatory Packet Options

In this portlet, Administrators make the setting for the means by which Regulatory Packets will be sent to Investigative Site Administrators. Typically, the template documents are sent either as links to documents stored in the TI room or as attachments to the email messages sent to site administrators. In some cases, documents are sent under a different cover, and are not included as either links or as attachments; in those cases, the Administrator setting up this configuration would select the None radio button. In most cases, the Administrator selects either Links or Attachment.

Email Settings



From here you can perform different Email configuration functions as follows:

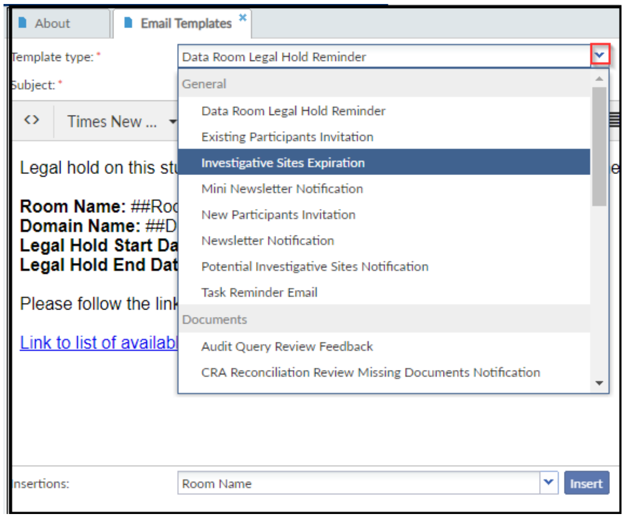
- **From here you can configure email functionality as follows:**
- **Email Templates**
- **Room Legal Hold Notifications**
- **Notification Preferences**
- **Notification Columns**

Each of the options above is discussed in detail in the separate section.

Email Templates Settings

Generic email templates are preloaded for a room when the room has been cloned. To make changes to the templates, follow these instructions.

Refer to the screenshot below:



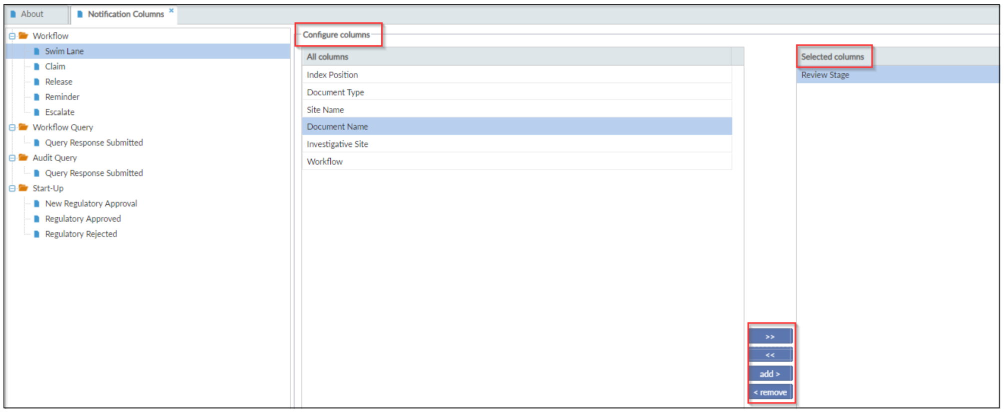
1. Select the **Template type** from the dropdown menu.

2. Edit the fields as appropriate.
3. Click **Save**.

Notification columns

The Notification Columns are related to those lists of fields which will be included in notification emails for notifications that the user wants to receive.

The Notification Columns are available for categories Workflow, Workflow Query, Audit Query, and Start-Up. Refer to the screenshot below:



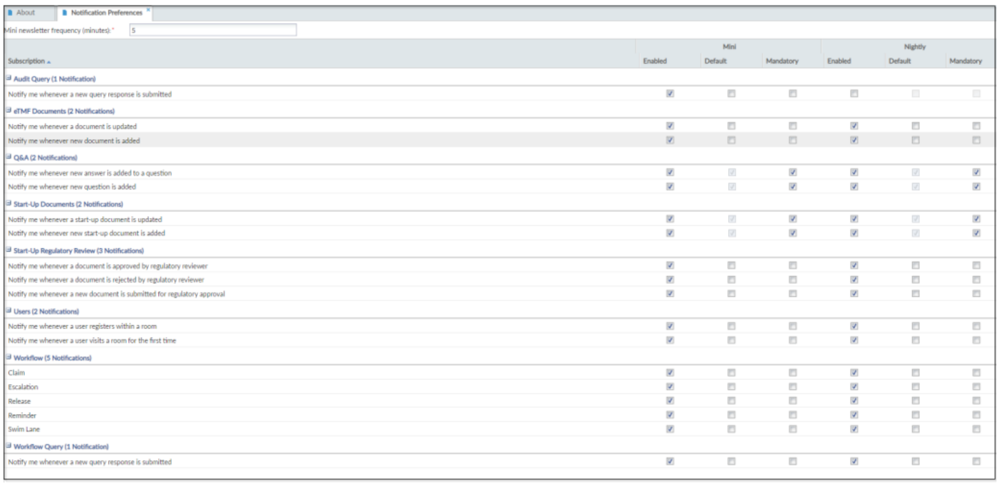
To filter the columns that would appear in the **notification emails**:

1. Select the **Notification Column** category from the left pane.
2. From the **Configure Columns** double-click to add the columns under the **Selected Columns** list.
3. Click **Save**.

Notification Preferences Settings

The Notifications settings section allows users to specify the email notifications they would like to enable for their account for each of the Trial Rooms to which they have access.

1. Enter the **Mini newsletter frequency** with which the Mini newsletters will be sent to subscribers. 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 you would like to receive. Below are the definitions of each notifications type and their use:
     - **Enabled**: This enables the possibility to subscribe to related notifications.
     - **Default**: This enables the user to subscribe by default on the related notification but with the possibility to unsubscribe.
     - **Mandatory**: The user gets automatically subscribed without the possibility to unsubscribe.
   - Administrators can choose alert systems, depending on which notification systems have been enabled by the room's Administrator.
     - A new audit query response is submitted
     - A Document is updated in the eTMF, and/or Start-Up
     - A New Document is added to the eTMF, and/or Start-Up
     - A user visits a room for the first time
     - A user registers within a room
     - A New Question is added
     - A New Answer is added to a question
     - Workflows
     - Workflow Query response submissions

   Note: *If the Study Start-Up module is active in the room, users will also see Start-Up notifications they can opt to receive.*

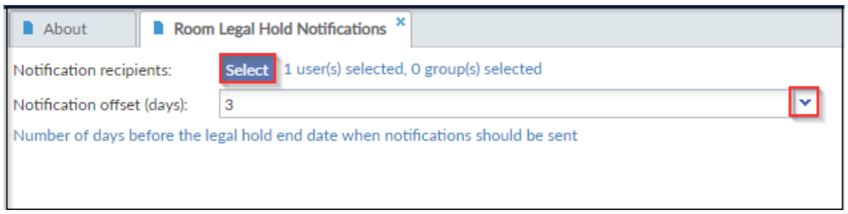
   Tip: *You can elect to receive either a mini summary of notifications or nightly newsletters recapping all of the new events in the past 24 hours for each of the five notification categories.*

3. Once you have made your Notifications selections, click **Save**.

Note: *The availability of the notification option is determined by the client-appointed Administrator in each room. Some notifications may not be enabled and appear dimmed to the user. For example, workflow notifications may not be available to users with Editor or Reader access.*

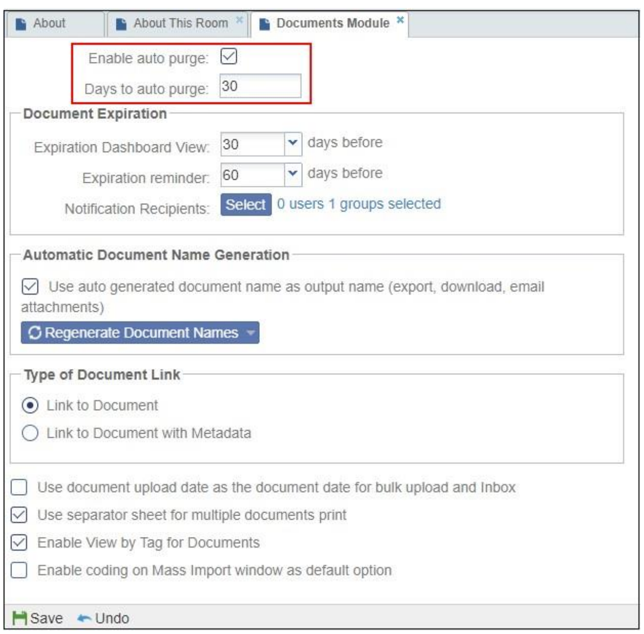
Room Legal Hold Notifications Settings

Note: Super administrator can put a **Legal Hold on Rooms**.



1. Click **Select** to set up the **users** who will be notified when a room is put on legal hold. Refer to the screenshot above.
2. The **Notification recipients** window opens for you to select from the list of **Users**.
3. 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.
4. Click **Save** from the bottom of the grid.

Document Template Settings



In the Document Templates settings, Administrator users can add, edit, and delete document templates. Templates here refer to documents that can be used as a source document. Therefore, users can keep a library of template documents with multiple versions (for example, one version in French and one version in Korean) in this setting.

When you click on Add, a Create Template, a window will open up. Provide a template name, and choose a category to indicate where this document template will be used – General, All Sites, Specific Country, or Specific Site. Submit an attachment and lastly, you can choose to include this document template in the Regulatory Packet. To do so, click on the checkbox on the bottom left corner. Here, please keep in mind that if you put a checkmark here, this document template will be sent in the Regulatory Packet email even if they are not required documents for the investigative site.

Workflow Settings

In Workflow Settings, Admins set up important details like workflow statuses, issues in the workflow, timeline, and members of the workflow group.

All these configuration details need to be previously created by the super-admin and configured to enable the administrator to add them to the workflow. This section will take you through the various configuration details. Changes made here will be applicable to all workflows.

To access the Quality Control Settings:

1. Navigate to the **Main Navigation-> Settings → Workflows**. From **Workflows Settings**, we discuss:
    - **a.** Common Workflow Settings
    - **b.** Creating, Editing, and Deleting Quality Control Review Statuses
    - **c.** Creating, Editing, and Deleting Quality Control Document Statuses
    - **d.** Creating, Editing, and Deleting Quality Control Profiles Each of these is discussed in the separate topics in this help.

Common Settings

The Workflow Common Settings can be accessed from **Room Settings → Workflow → Common Settings.**

Admin can perform the following Common Settings in a Workflow:

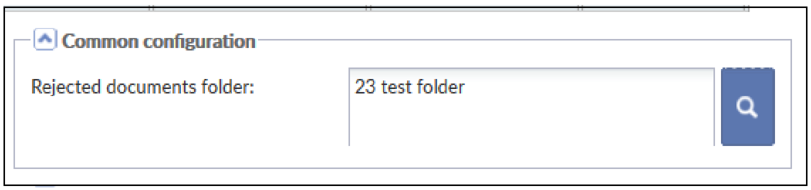
1. Common Configuration
2. Default Ranges Configuration
3. Timeline Configuration
4. Issue Email
5. Rejection Email Configuration
6. Query Reminder Configuration
7. Auto-Claim Configuration

Each of these is discussed in the separate topics and can be accessed from the left of this help.

Workflow Common Configuration

Rejected Documents folder: Here, you specify the folder and its index number that will hold the documents when they are rejected during the review.

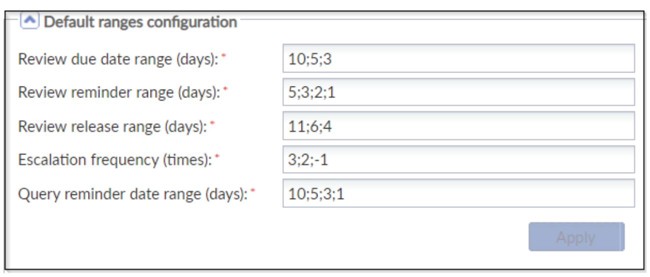
Default ranges configuration



Here you can specify date ranges that would be applicable to your workflow.

- TI acknowledges the fact that various workflows would have different review and submission periods.
- Hence it allows you to specify more than one value separated by semi-colon.
- These values would be populated in the dropdown during workflow creation, and you may choose a value as appropriate.

  Refer to the screenshot below:

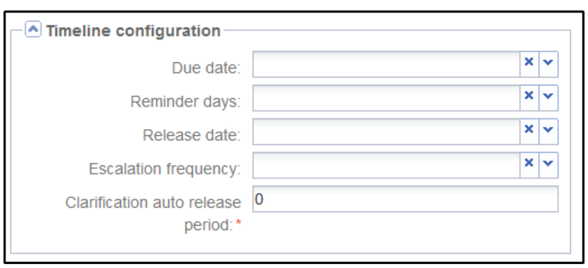


Each field above is editable, you can enter the values separated by a semi-colon. Each option is discussed in separate sections below:

1. **Review due date range (days)**
    - Here you specify the days when the review would be due after claiming the documents for review.
    - You may specify multiple values, all of which will be populated in the dropdown while creating the workflow to enable you to select a value as appropriate.
    - The **Returned Back** is a new system status that can be given to a document when it is routed back to a previous workflow stage.
    - Hence, it is available from Approval Stage 2/QC2 onwards only.
2. **Review reminder range**
    - Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.
    - If multiple values are specified, all of them would be populated in the dropdown during workflow creation, and you may select multiple values as required.
    - In the screenshot above, the Reminder schedule is 5;3;2 which means:
        - the reviewer will receive reminders 5 days before the due date,
        - then 3 days before the due date,
        - and then 2 days before the due date if the reviews are pending.
3. **Review release range days**
    - Here you specify the days after the claim when the documents would be automatically released from the reviewer's claim list.
    - The Auto release date is always greater than the due date.
    - It will not allow you to select a value less than the due date.
4. **Escalation frequency**
    - Escalations are reminders about **not completed reviews**.
    - During workflow creation, an escalation group needs to be specified who will receive notifications about escalations.
    - Here, you specify the timeline for escalation notification frequency.
5. **Query reminder date range**
    - If the user does not respond to a query with a document, reminder emails are sent to the query recipients on the nth days as specified here.
    - So if the setting is 10; 5; 3 reminders will be sent on the 10th day, 5th day, and the 3rd day.

Timeline configuration

Refer to the screenshot below:

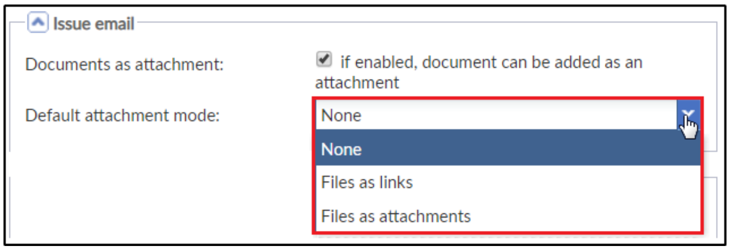


- If you specify values in the timeline, the values will be automatically set for you at the time of workflow creation.
- If you happen to change your mind at the time of creation, you may select values as required as opposed to that set in the timeline configuration.

- 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 period.
- 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

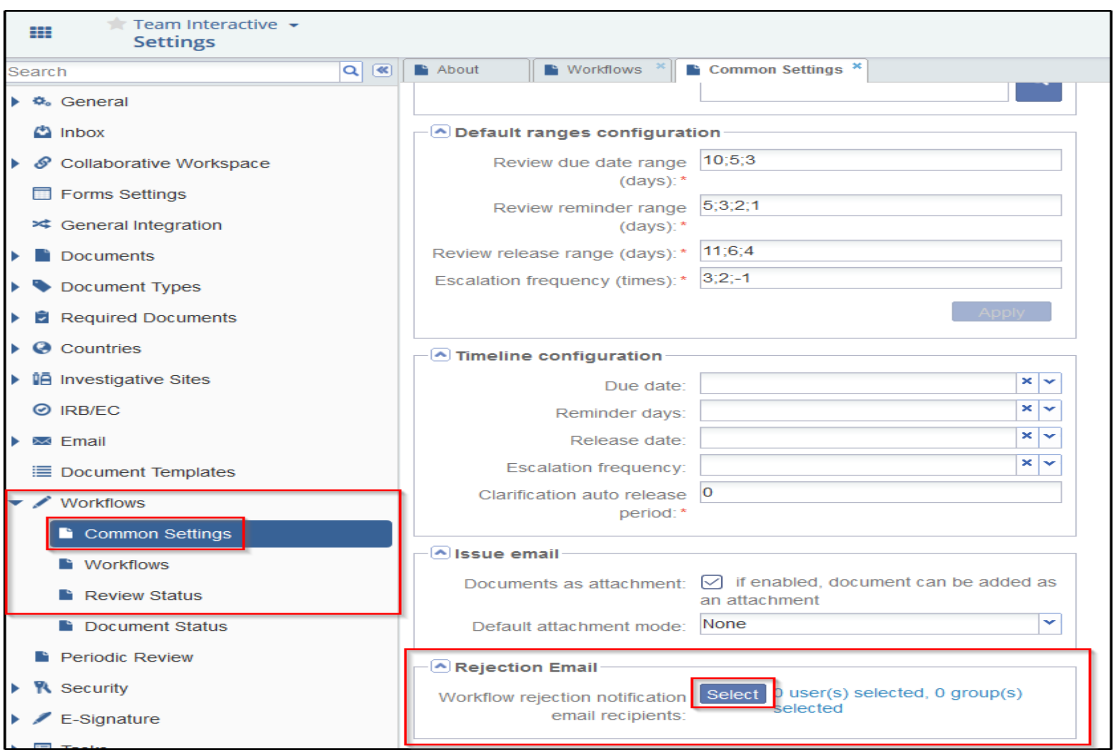
1. From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session. Refer to the screenshot below:



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.

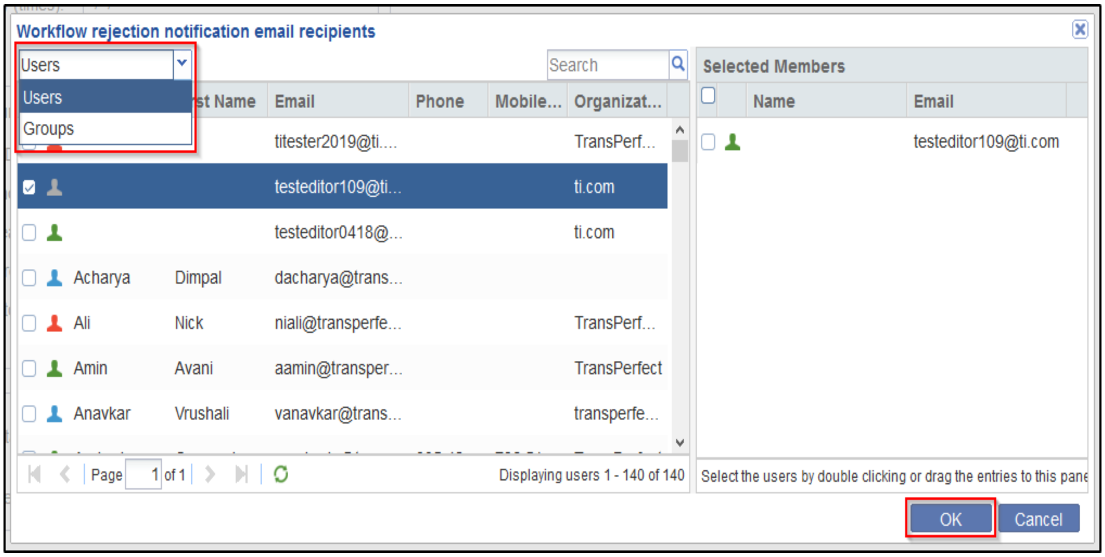
Rejection Email Configuration

When the document is rejected in the Workflow, a rejection email is sent to the document owner plus the users specified in the **Rejection Email** configuration settings. Refer to the screenshot below:

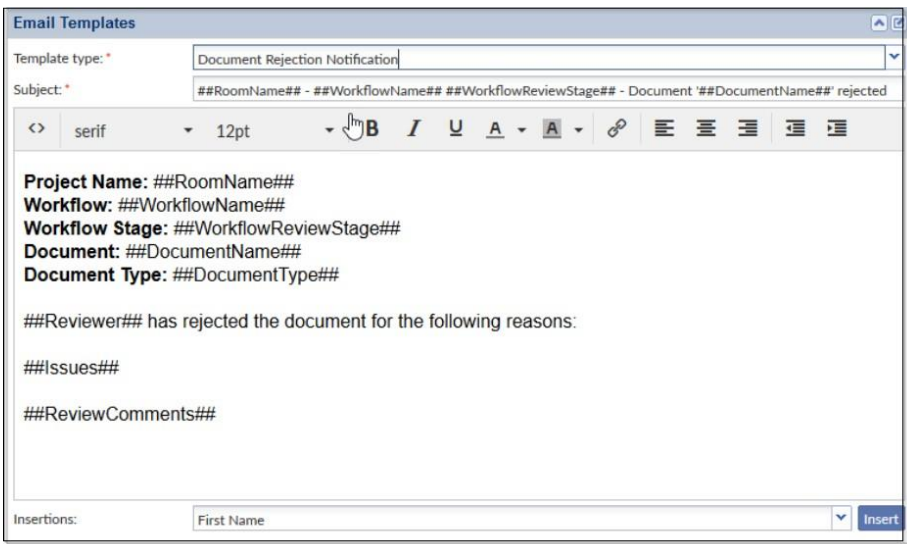


1. Click **Select** from the **Rejection Email** settings.

2. **Workflow rejection notification email recipients** window opens. Refer to the screenshot below:



3. You can choose from **Users or Groups**. Select the users by **double-clicking or drag** the entries to the right pane.
4. Click **OK** to save the selection of the users.

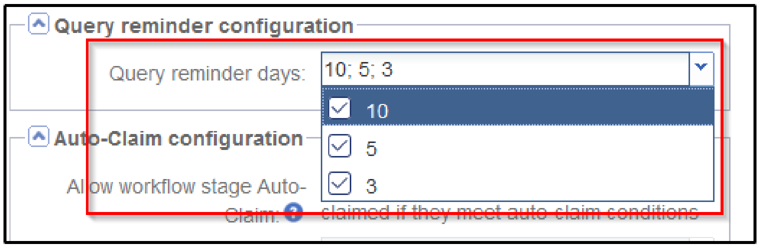


You can change the Rejection Email Template from **Settings-> Email ->Email Template**

Query reminder configuration

From **Query Reminder configuration** Admin can configure reminder emails' schedule. Refer to the screenshot below:

1. As per the above configuration, reminders will be sent on the 10th day, 5th day, and the 3rd day, if the user does not



   respond to a query with a document.
2. You can change the number of days from **Query reminder date range** ***(page 148)*** (days) in Default ranges configuration *(page 148)*.

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.*

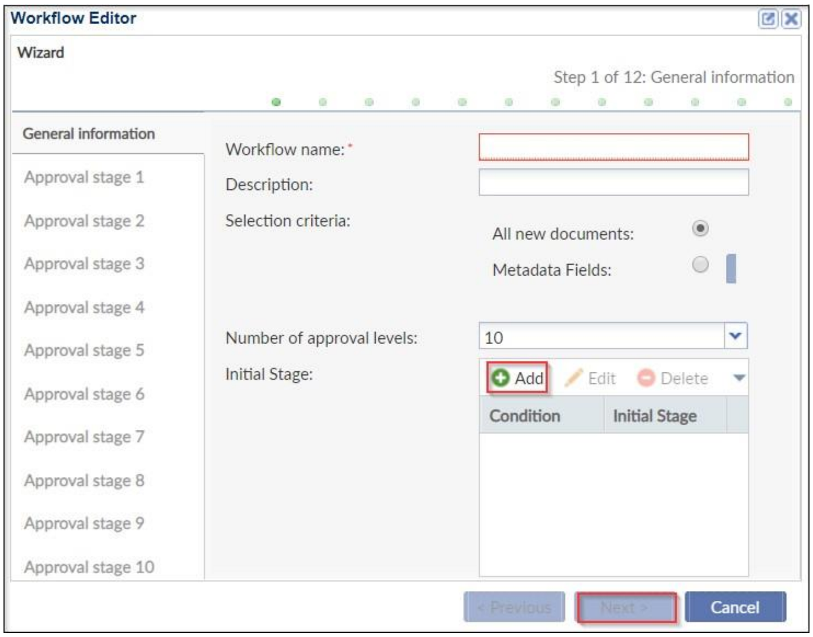
To enable the auto-claiming of a document, the Administrator will need to enable the configuration from this panel. Refer to the screenshot below:

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.

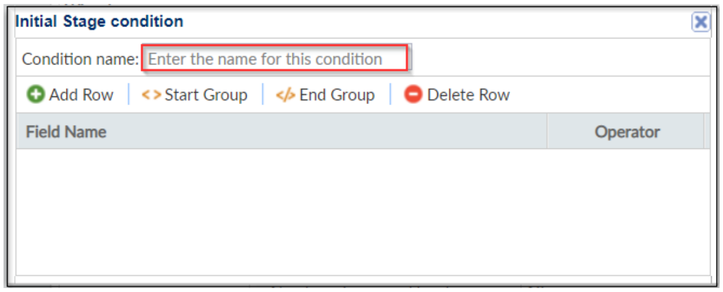
Creating the Quality Control Workflow

To create a Quality Control workflow, follow the procedure below:

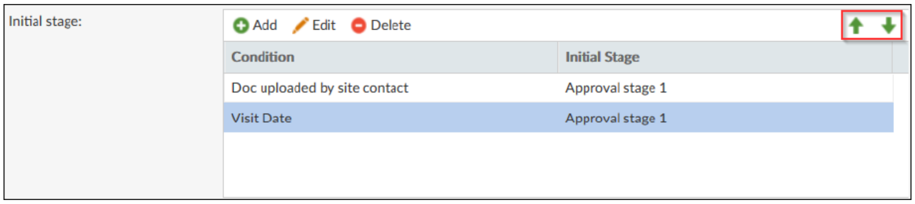
1. From the **Settings** → **Workflows** → **Workflows**, click the **Add** button from the grid. The **Workflow Editor** window opens. Refer to the screenshot below:



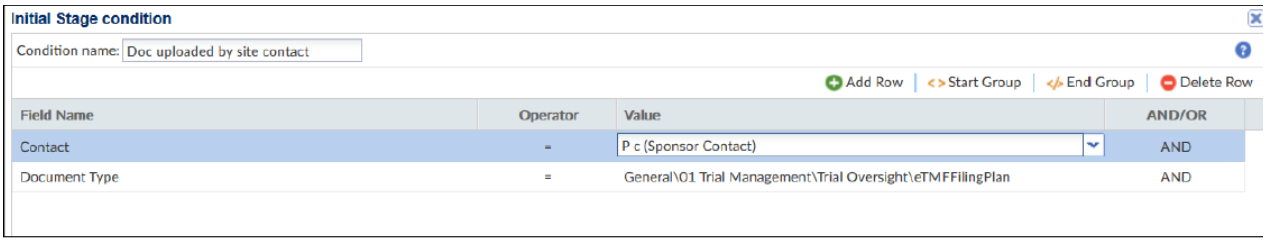
2. Enter the **Quality Control Workflow** name and **Description**.
3. The Selection Criteria could be **All new documents** or only those **Metadata fields** that need to be reviewed. Refer to the screenshot above.
4. Select the workflow levels, i.e. QC1, QC2, etc.
5. You may apply a **condition** to select documents for review as per a particular condition. Click **Add** to add a condition from the **Initial Stage** box. Refer to the screenshot above.
6. The **Initial Stage Condition** window opens. Refer to the screenshot below:

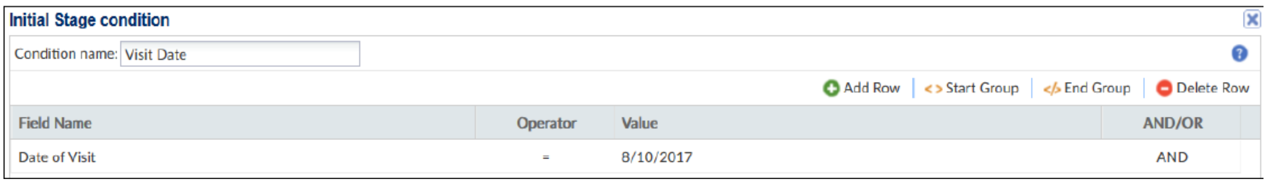


7. You may add multiple conditions and decide their sequence to filter documents with the green arrow keys. Use **And / Or** operators if you want all / either of the conditions to execute. Refer to the screenshot below:

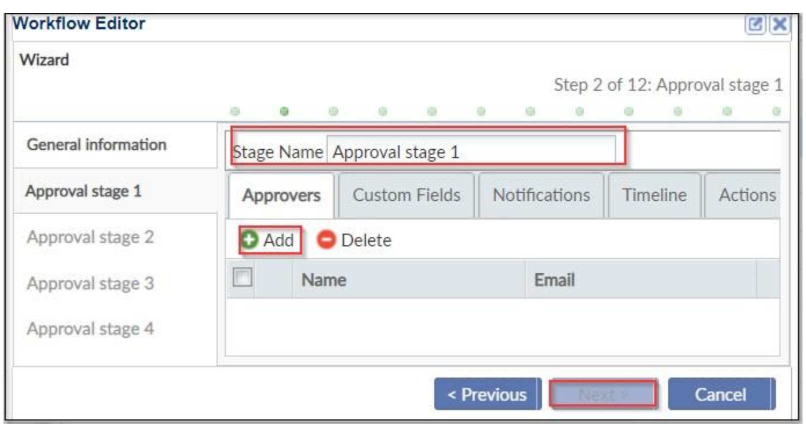


8. As per the screenshot above, documents uploaded by the site contact on a particular site visit date would be added to the workflow. The details of each condition are as below:





9. Thus, as per the above conditions, documents of type **'General\Trial Management\Trial Oversight\eTMFFilingPlan'** uploaded by the site sponsor on the site visit date of 10th of Aug. 2017 would be added to the workflow.
10. Click **Next**. This leads you to the configuration wizard of the **first stage of the workflow**. Refer to the screenshot below:

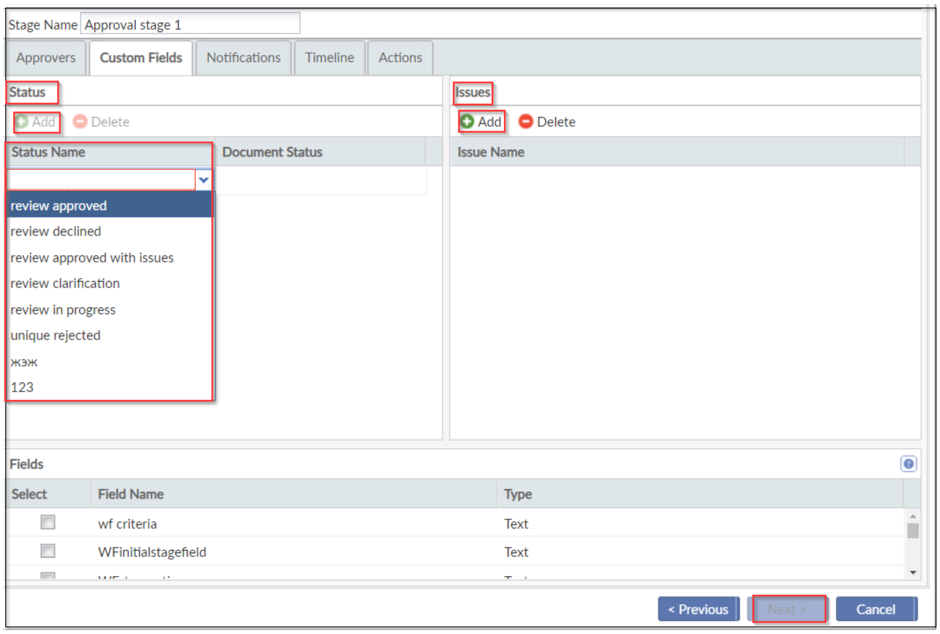


Change the **Stage Name**, if desired. Click the **Approvers** tab. Refer to the screenshot above.

11. This allows you to **add users/groups** as reviewers of the documents for the particular stage in the workflow.

Note: *It is recommended to add a **Group** to save configuration time.*

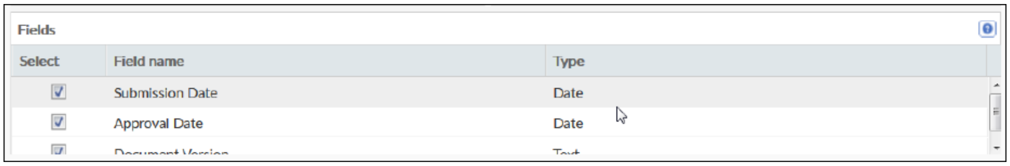
12. Click the **Custom** fields tab. This is a required tab and **Statuses**, and **Issues** must be added. Refer to the screenshot below:



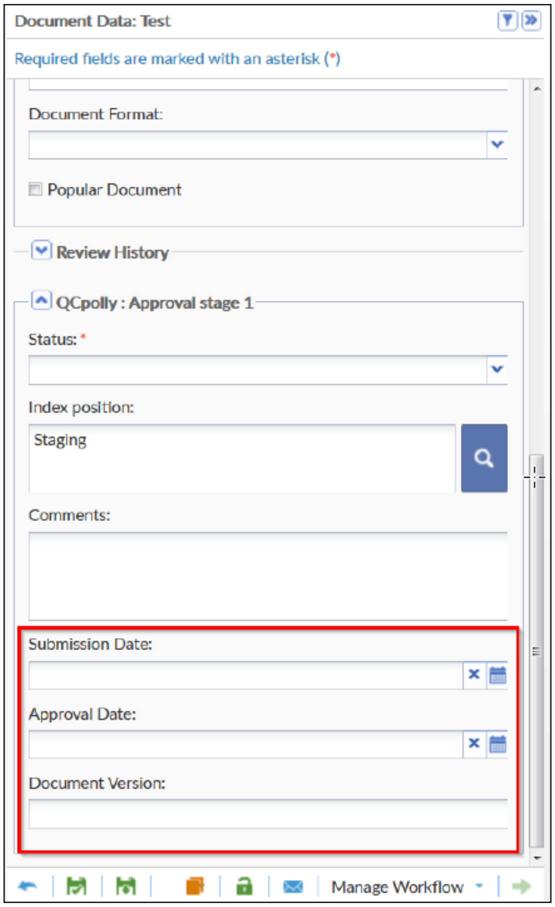
The statuses are the ones previously created under **Review Status** ***(page 158)***. Click **Add** to add the first status and select the document status from the dropdown. Refer to the screenshot above. **Approved** and **Rejected** are the minimum statuses that need to be added to a workflow. You can include more statuses, like **Clarification** and **In Progress**, for better functionality of the workflow.

13. Click the **Issues** section to assign the reasons in case the reviewer rejects a document/asks for clarification. Some of the standard issues could be **Missing Pages, Missing Signature, Blank Pages, Incorrect Study, Poor Scan, Duplicate, and Expired Documents**.

14. 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 **Customs** 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**.



15. Click the **Notifications** tab.
    - Here, you can allow for email notifications to be enabled for the event names listed.
    - For users who want to be notified only in case of **Claim**, **Release**, or **Escalation**, groups can be added accordingly.
16. 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.
17. **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 perform a2nd review on the document.
    - While efficient for complex workflows, it is not required for regular workflows creation.
18. Click **Next**, when all tabs have been reviewed.
    - Repeat similar steps for each stage of approval.
    - Settings may change per approval stage, like **approvers, notifications, and timelines**.
19. When finished, click **Next**.
20. The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If no errors, click **Finish** when done.

Editing an Existing Workflow

Caution: *Editing of existing workflow should be executed with caution because any saved changes require a new and revised workflow to be created*

While editing an existing workflow is quicker than creation, having multiple workflows enabled in the same room is not common and can cause confusion.

1. In the Workflows panel, click the **Name** of the workflow and either click **Edit** from the top menu or double click the required workflow.
2. The **Workflow Editor** window opens. Review the steps of the workflow wizard as before, clicking **Previous** & **Next** to review the settings.
3. If no changes have been made, click **Cancel**.
4. Yet if changes were made, this has become a new and different workflow. Thus, click on **Save as**.
5. Give the revised workflow a new name. A **new workflow** is created with the new name.
6. Click **Ok** when done. A confirmation message appears confirming creation. Click **Ok**.
7. The previous workflow and the newly revised workflow are both by default enabled. If one needs to be disabled, uncheck the associated box. Remember to click **Save**.

Deleting an Existing Workflow

Select a workflow from the list you wish to delete and then click **Delete** from the top menu.

Quality Control Review Status

Here Admin can **create the review statuses** to assign to the document at each stage of the Workflow.

Figure 40: Review Status

- The Display Name' is the name of the status that would be visible on the user interface, whereas the System Status is pre-defined values that you assign to review status.
- Regardless of what the Display Name is, the documents will be routed to one of the workflow folders in QC Review/My Reviews based on the system status.

Figure 41: Adding Review Status

1. Click **Add**.
2. Enter the **Display Name**
3. 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** to be edited and click **Edit**.
2. The **Review Status** field becomes editable. Make the required changes.
3. 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. Click **Delete**.

Security

From here Admin can perform various functions of security configuration.

Note: Most of the room's Security Settings are established at the outset of a study and go unchanged throughout the study. Before making any changes to any Security Settings, confirm the changes with the Project Manager.

Following functions in the Security are discussed in detail in separate sections:

- **General Security Settings**
- **Users Security Settings**
- **Groups Security Settings**

Besides Room Settings, the **Users Security Settings** and **Group Security Settings** can be accessed from the User Management *(page 67)*in the Main Navigation.

General Security Settings

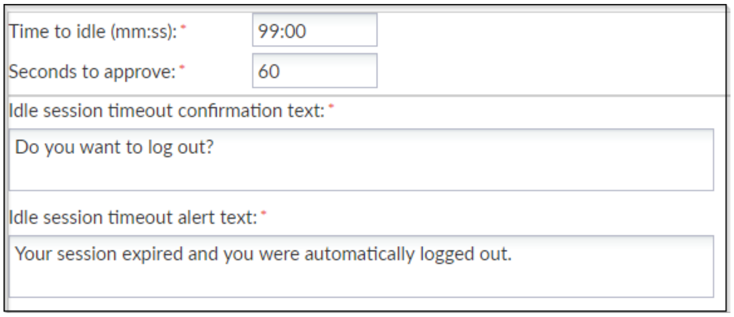
From here you can perform the following functions:

- Logout Timer Configuration
- Invite Participants Settings
- Redaction Settings
- Actions Security Settings
- PDF Watermark Options Settings
- Document Viewers Settings
- Document Encryption Options
- Confidentiality Agreement Settings

All the above topics are discussed in separate sections

Logout Timer Configuration

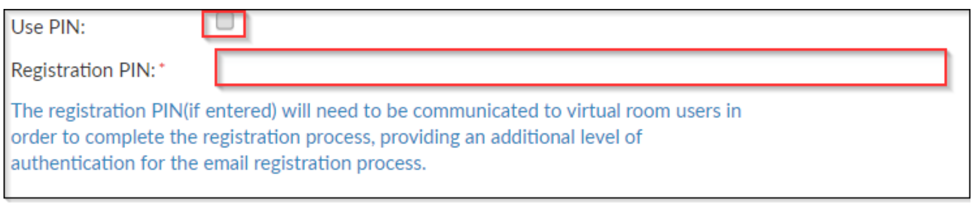
Admin can set a **Logout Timer** from the room settings. Refer to the screenshot below:



1. Navigate to **Main Navigation -> Settings -> Security -> General -> Logout Timer**.
2. Adjust the time a user can remain logged in without being active in the study room.
3. 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.
4. 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**.
5. Click **Save** after any changes or **Undo** to revert back any changes made.

Invite Participant Settings

As an Administrator, you 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**.
3. Click **Save** from the bottom of the grid to save the changes made.

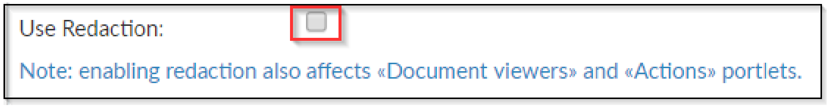
Remember: *You will also need to inform new users of the PIN that you have created. New users will have to enter this PIN before being allowed access to the room's registration process.*

Note: *The Registration PIN (if entered) will need to be communicated to Virtual Data Room Users in order to complete the registration process, providing an additional level of authentication for the email registration process.*

Redaction Settings

Note: *Enabling Redaction also affects Document viewers and Actions portlets.*

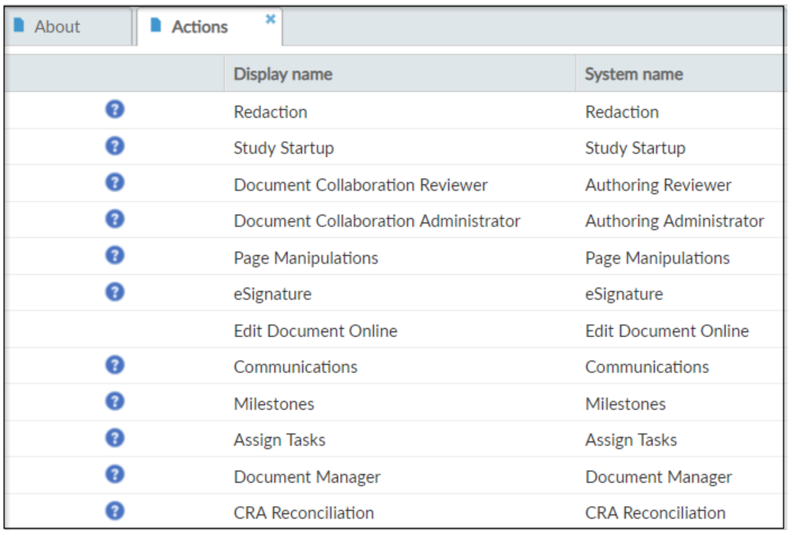
1. Administrators can choose to **enable or disable** the Redaction option in the room. Refer to the screenshot below:



2. Click **Save** from the bottom of the grid.

Actions Security Settings

This pane shows the tasks that are enabled for the user in a particular room. Refer to the screenshot below:



	Display name	System name
?	Redaction	Redaction
?	Study Startup	Study Startup
?	Document Collaboration Reviewer	Authoring Reviewer
?	Document Collaboration Administrator	Authoring Administrator
?	Page Manipulations	Page Manipulations
?	eSignature	eSignature
	Edit Document Online	Edit Document Online
?	Communications	Communications
?	Milestones	Milestones
?	Assign Tasks	Assign Tasks
?	Document Manager	Document Manager
?	CRA Reconciliation	CRA Reconciliation

1. Double-click the **Display name** of the listed action and edit the display.
2. Click **Save** from the bottom of the grid to implement the changes.

Note: *The new actions added to the list of actions are as follows:*

- ***Edit Document Online**- This feature allows a user to open MS Office documents in native office applications to edit them online immediately on upload.*
- ***Assign Task**- This feature denotes that the user is enabled to assign tasks to multiple users.*
- ***Document Manager**- This feature allows the editors to edit, update metadata, and/or change the index locations of documents with **Final** status that are not added by the editor.*

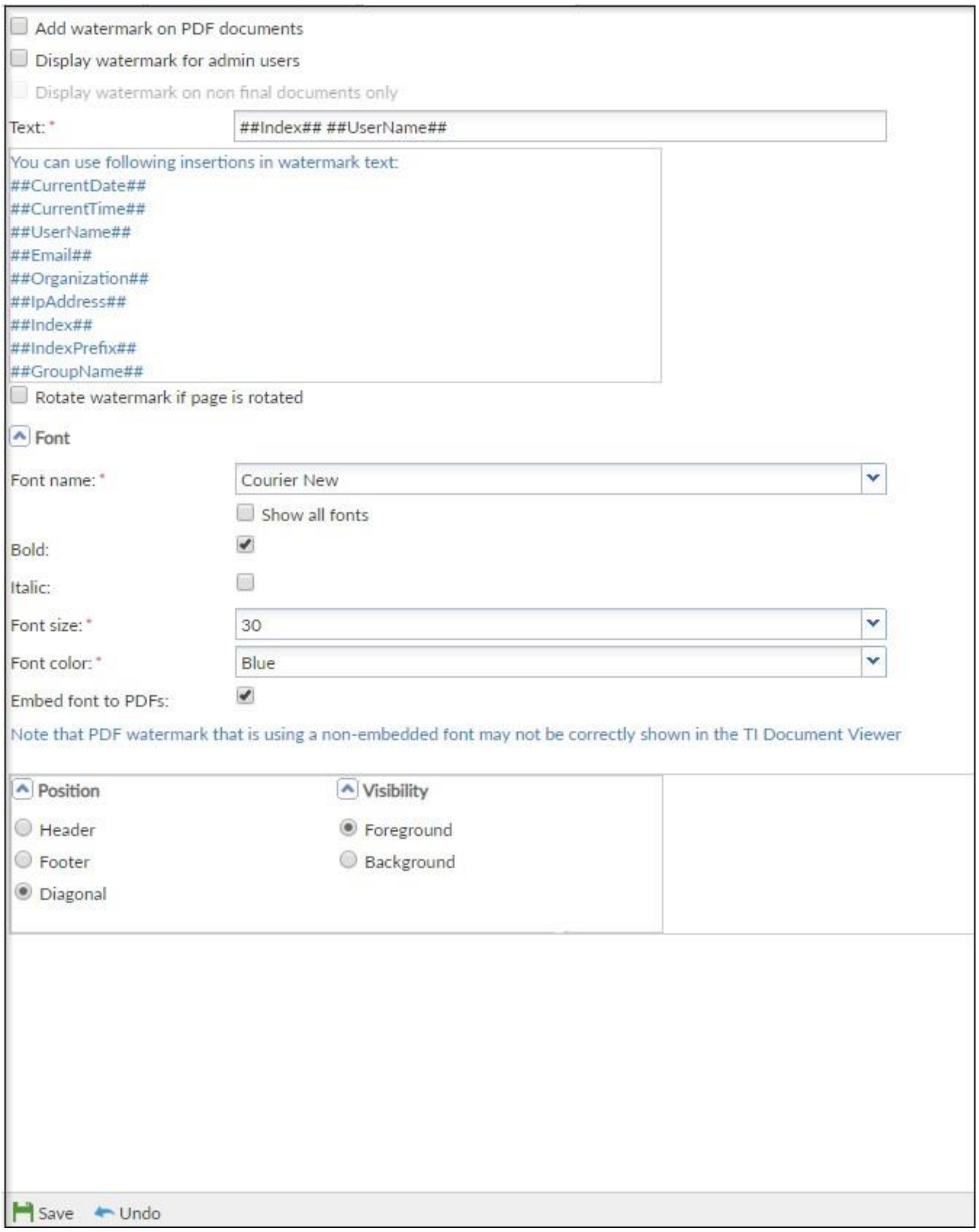
Note: *The editor must be assigned Full Access to the folder having final documents, or to the documents with final status from **View Security**, or **Manage Security** options available in the eTMF/Documents module.*

PDF Watermark Options Settings

Watermarks can be added to documents downloaded or printed from a study room's file index.

- Watermarks are only displayed when a document is not in the **final** workflow status.
- Therefore, once the document becomes final, the watermark will no longer be available on the document; this is an automatic process.

- In this panel, Administrators can select which metadata fields will comprise the watermark, and they can select the appearance and position of the watermark. Refer to the screenshot below:

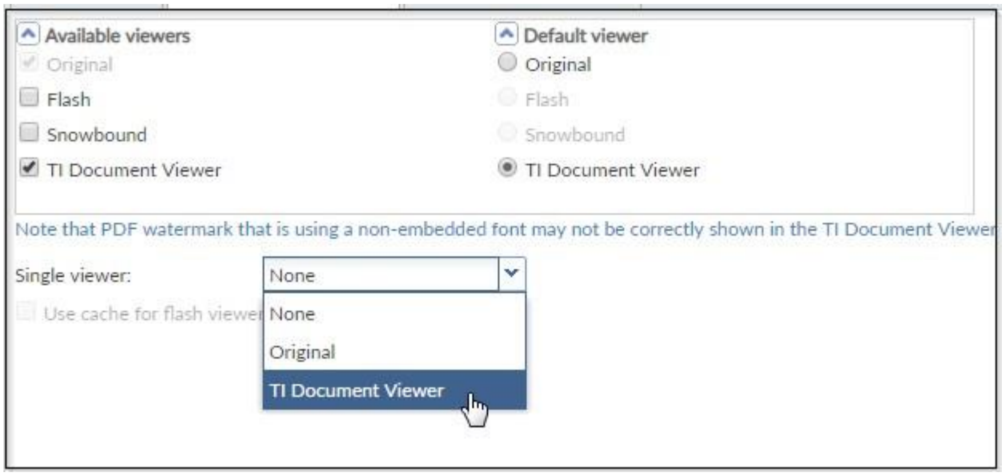


1. Activate or inactivate the **Add Watermark on documents** option by clicking the checkbox.
   - Activation of this option also activates the option of allowing non-PDF documents to be printed or downloaded without watermarks.
2. Tick the checkbox to **Display watermark for Administrator users**.
3. Type in the **Text** of the message to be displayed as the watermark using the text strings from the list provided.
4. Tick the checkbox to **Rotate watermark if page is rotated**.
5. Select the **Font name** from the dropdown.
   - The dropdown list can be extended to include all fonts by clicking the Show all fonts checkbox.

6. Select whether the watermark text will be rendered as **Bold** and/or **Italic** text.
7. Select or confirm the **Font Size** from the dropdown menu.
8. Select the **Font color** from the dropdown menu.
9. Select whether or not to **Embed the font to the PDF**.
10. Select the **Position** of the watermark.
11. Select whether the watermark will appear in the **Foreground** or the **Background** of the document text.
12. Click **Save**.

Document Viewers Settings

Administrators can select which document viewers are available to room users and which of the viewers is marked as the room's default viewer. Refer to the screenshot below:



1. Select the **Available viewers** that will be available to users in the data room.
2. Select whether the **Default viewer** for users in the room will be the **Original** viewer or the selected viewer.
3. Select a **Single viewer** from the dropdown list if you want to restrict the availability for users.
4. Click **Save**.

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:

1. Tick the checkbox to **Enable DRM on documents**.
2. Click **Save**.

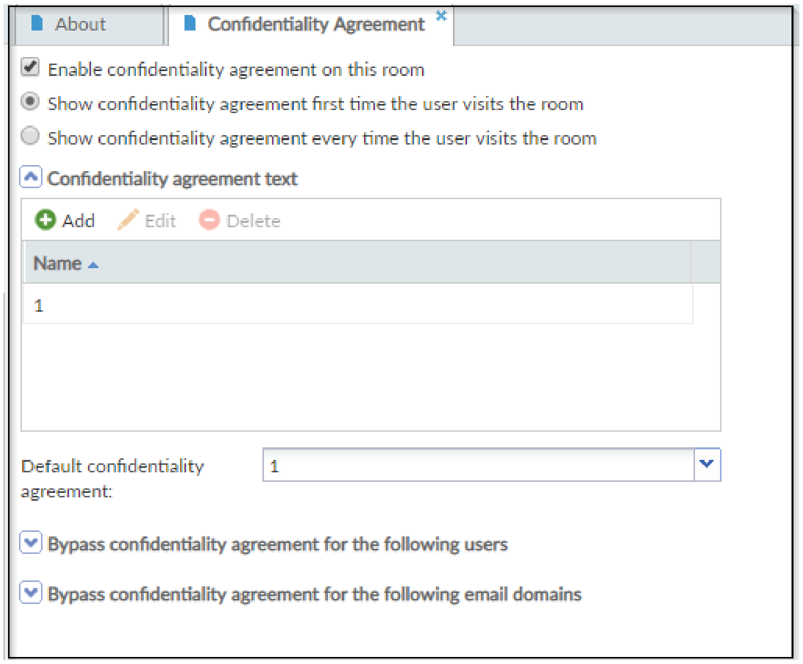
Confidentiality Agreement Settings

Another layer of security that an Administrator can add to a room is a Confidentiality Agreement.

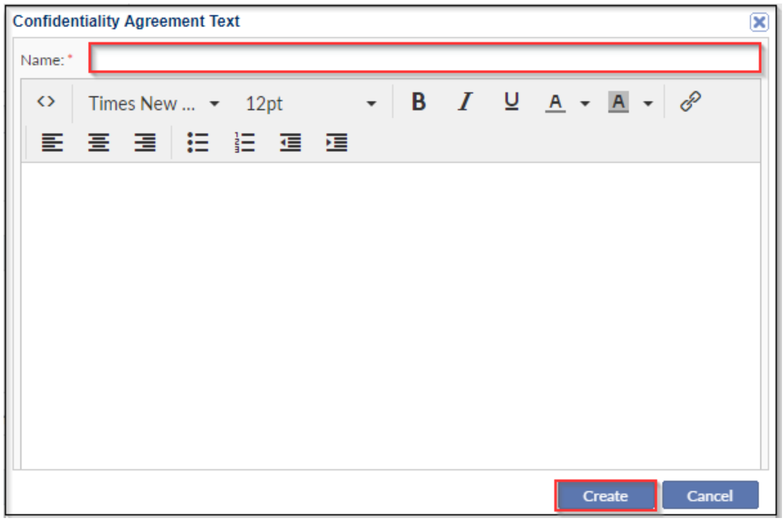
- Once enabled, you choose whether to have the agreement appear only on a user's initial visit to the room, or have the agreement appear each time users log in.
- You also have the option of designating individual users or groups of users whose email addresses share a domain name who would be exempt from clicking the agreement.

Following are the steps to enable the Confidentiality Agreement:

1. Tick the checkbox to enable/disable the **Confidentiality Agreement on this room**. Refer to the screenshot below:



2. If enabled, select whether to have the agreement show only on the **first time a user visits the room** or **every time auser visits the room**.
3. To type in the text of the Confidentiality Agreement, click **Add**. A pop-up window appears. Refer to the screenshot below:



4. Type in the **Name** of the agreement.
5. Click **Create**.

Note: *More than one Confidentiality Agreement can be added*.

User Management - Users

From this page, you can do the following:

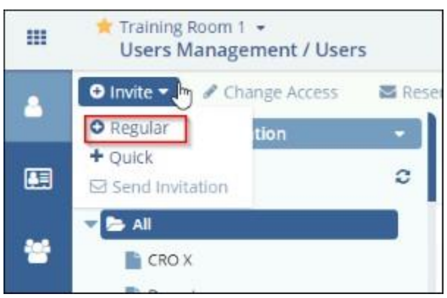
1. Invite users through Regular Invite or Quick Invite.
2. View user accesses to the room under various categories.
3. Edit user access.
4. Change the access to the user by changing the Role or Groups
5. Resend invitation to the room to users
6. Reset Password for a user login
7. Delete a user access
8. Export Users
9. Filter Users
10. Update preferences

Regular Invite

Note: *Users can also be invited from the* ***Room Settings → Security → Users. (page 159)***

Follow the steps as below to create a new user and add the user to a group:

1. Navigate to the **Main Navigation → Users Management → Users.**
2. Click the **Invite** dropdown from the top menu bar and then select **Regular Invite** from the dropdown list that appears. Refer to the screenshot below:



3. The **User Invitation - Edit User** page opens.
4. Complete the form and click **Next.**
5. The **User Invitation - Group Memberships** page opens to allow you to add the user to a group.
6. Complete the details as required and click **Finish**.
7. The user is now created. You can view the user on the dashboard.

Note: The *Edit User* and *Group Memberships* pages are discussed in separate sections below.

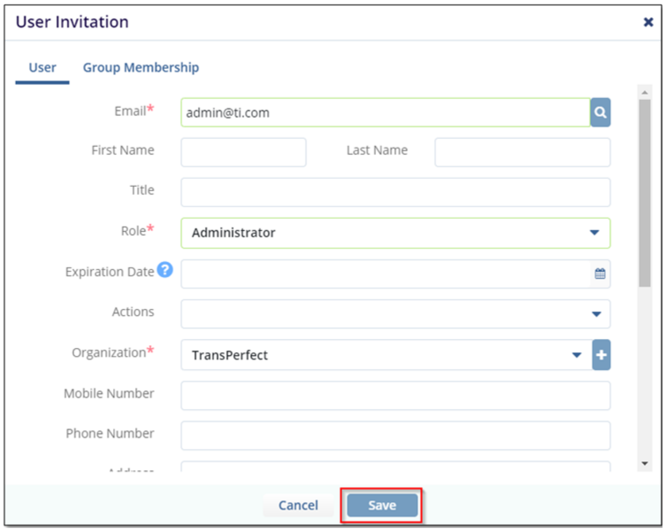
Edit User

1. Complete the User Profile as required.
2. The fields of importance are discussed below:
   a. **User Email**: This is used by the user as a unique identity to log in to Trial Interactive. This can be typed in or searched by clicking the magnifying lens icon at the end of the field. 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.
   b. **Role**: Choose the role from the dropdown to be assigned to the user. The roles can be either of an **Admin**, **Editor** or, **Reader** in a particular room.

c. **Actions**: These are tasks that the user would be allowed to perform under the specific role that can be assigned by selecting the Action name from the Actions dropdown.
d. **Expiration Date**: Enter this date if you want the user access to be revoked after the lapse of a particular period.
e. **Organization**: Choose from the dropdown the organization to which the user belongs to. The Administrator can also create an organization, if not available from the list, by clicking the '+' sign at the end of the textbox.
f. **Allow Multiple Sessions**: Click the toggle bar to **Yes** if you want to allow the user to login through different browsers at the same time.
g. **Invite Later**: Click the toggle bar to **Yes** if you want to prepare a user for the room but not want to send the real invitation. So users will be prepared for invitation sending, and when the time comes, they can be invited later. For example, a user is in training and would be allowed access to the room later.
h. **Silent Invite**: Click this toggle bar to **Yes** if you want to invite the user without sending the invitation email. In such a case, you will need to provide a temporary password in the **Password** field that appears on activating this option.

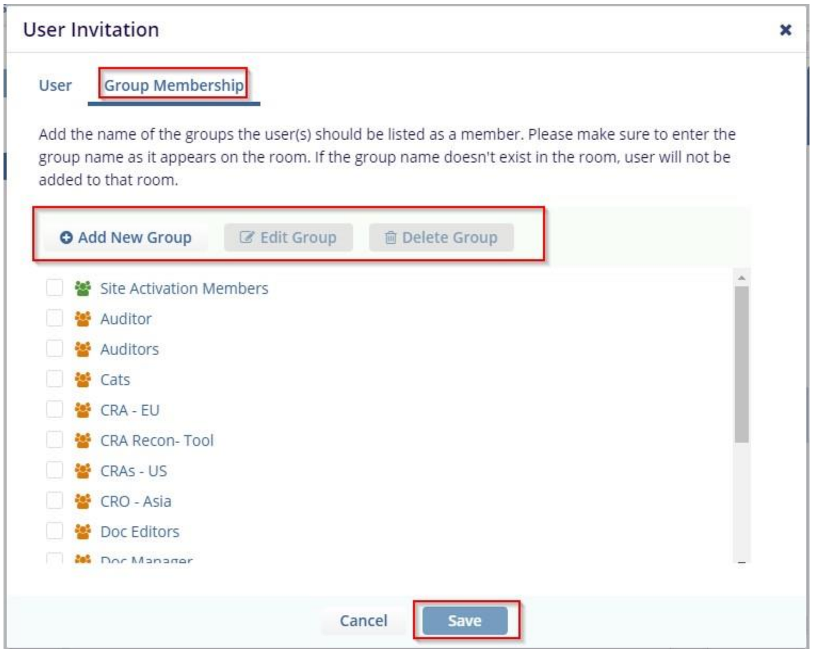
Remember: *<u>You can select either Invite Later or Silent Invite only at a particular point in time.</u>*

3. Click **Next** to proceed to the **Groups memberships** page to add the user to the required group. Refer to the screenshot below:



Groups Memberships

From this page, you can select the required groups from a pre-created list of groups to add the user as a member. If the group does not exist, then you may create the group on the fly through **Add New Group**. Besides, you can also **edit** or **delete** a group. *Note that the **Edit Group** and the **Delete Group** buttons enable on when you select the group from the list*. Refer to the screenshot below:



Click the links below for more details on any of the operations:

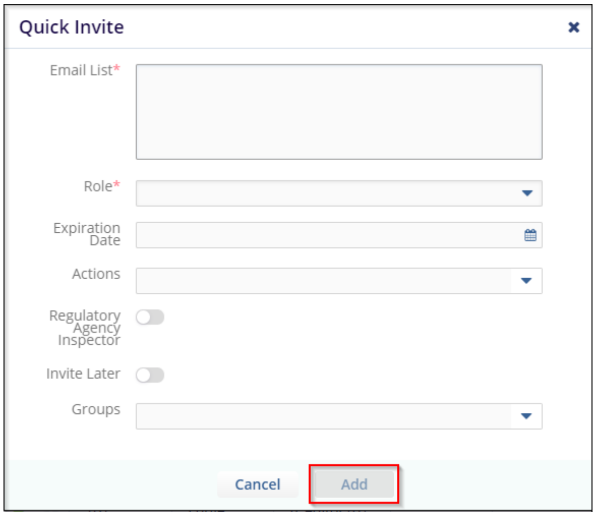
1. Add New Group *(page)*
2. Edit Group *(page 81)*
3. Delete Group *(page 82)*

Quick Invite

You can use the **Quick Invite** when you want to invite, all at once, a set of users with the same role, actions, access period, and belonging to the same group/s.

Follow the steps as below to Quick Invite users:

1. From the **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 you want to send an invitation to.
4. Complete the required fields, adding email addresses, and selecting the role the invitees will be assigned to. ***You can Invite single or multiple Readers or Editors or Administrators at one time.***
5. Select **Invite Later**, **Silent Invite**and , **Invite Later** toggle buttons when appropriate.
6. Click the **Groups** textbox to assign the user to the appropriate group(s).
7. Click **Add**. Refer to the screenshot below:



The invited user(s) will receive an email invitation to register in the Trial Interactive room.

Viewing Users

Users in Trial Interactive are grouped under various categories for easy viewing and access to their information. Follow the steps as below to view users under various categories available in Trial Interactive:

1. Click the **three dots** next to the **View by** from the Index Pane.
2. This opens the **View Users By** popup window with the list of categories for user viewing.
3. Select the category under which you want to view the users.
4. Click **Select** located at the bottom of the popup window. You can also make the view default by selecting the **Make Default** checkbox below the views.
5. The category and the list of users grouped under the categories are displayed in the Index Pane. The screenshot below shows the users by Admin role.

The table below lists out the various user views seen in the popup along with the description:

User Views	Description
By Organization	By Organization view lists the organizations for which there are users in the room. The organization to which the user belongs is specified during user creation *(page 69)*.
By Role	By Role view lists the users belonging to the categories of Admins, Editors and, Readers.
By Status	By Status view lists the users under categories as **Pending** for invitation, **Invited** to the room, **Registered** to the room, users who **Visited** the room, and users with **No Access** to the room.
By Group	By Group view list the groups to which the users belong in the room. The groups are specified during user creation *(page 69)*.
By Action	By Action view list the users according to the actions to which they have permission for.

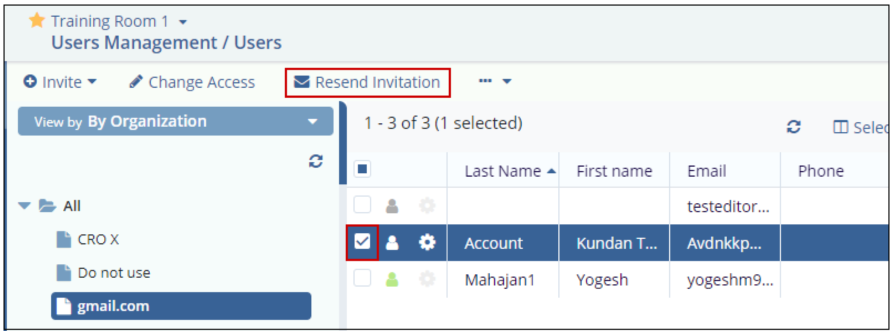
Resending Invitation

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

To re-invite users:

1. From the left pane, select the preferred category to view the users *(page 68)*.
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 appears asking you to confirm. Refer to the screenshot below:



4. Click **Yes**.

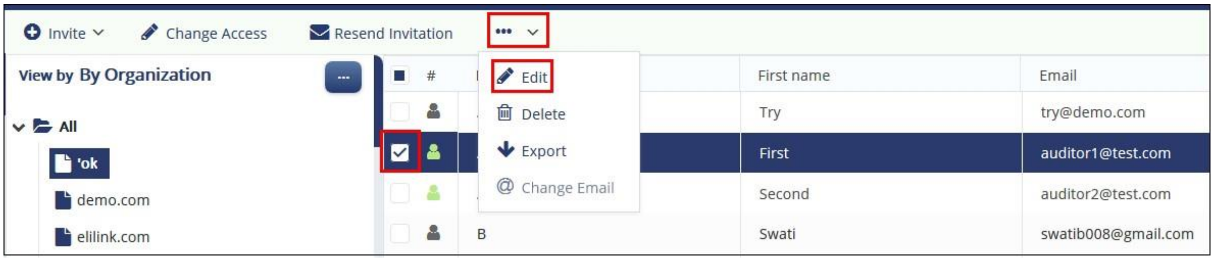
5. Invitations are resent to the selected users, and a confirmation notification appears for the same.

Editing and Deleting Users

Editing Users

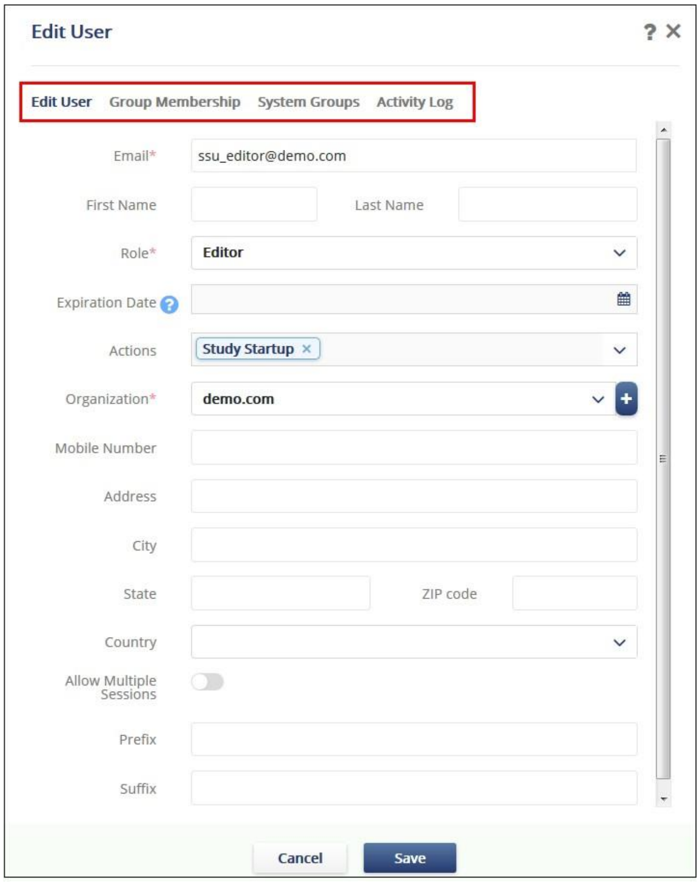
Follow the steps as below to edit user access:

1. Navigate to **Main Navigation → Users Management → Users**.
2. From the left pane **Index View**, select the preferred category to view the users *(page 68)*.
3. From the list of users displayed in the right pane under the selected category, tick the checkbox of the user to edit.
4. From the top ribbon bar, click the **three dots** and then click **Edit** from the options that appear. Refer to the screenshot below:

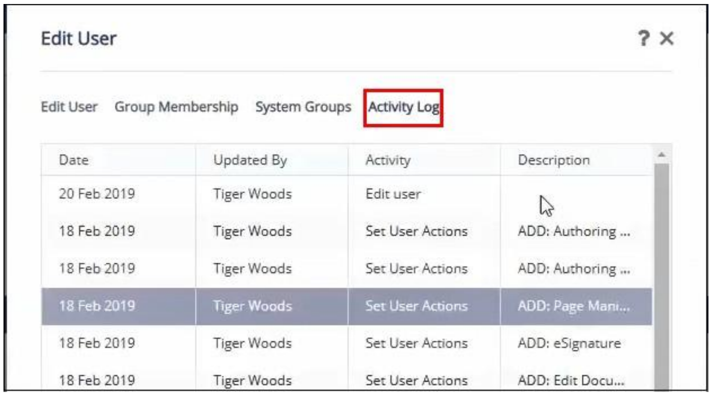


5. The **Edit User** popup opens, which contains the following section:
   a. Edit User
   b. Group Membership
   c. System Groups
   d. Activity Log

   Refer to the screenshot below:



6. Select the **Edit User** section to edit the user details and click **Save**.
7. Select the **Group Membership** section to add, edit, delete groups and click **Save**.
8. Select the **Systems Group** section to manage the assigned security to groups at the system level and click **Save**.
9. Select the **Activity Log** section to view the timestamp of activities for the user and click **Save** to commit the changes. Refer to the screenshot below:

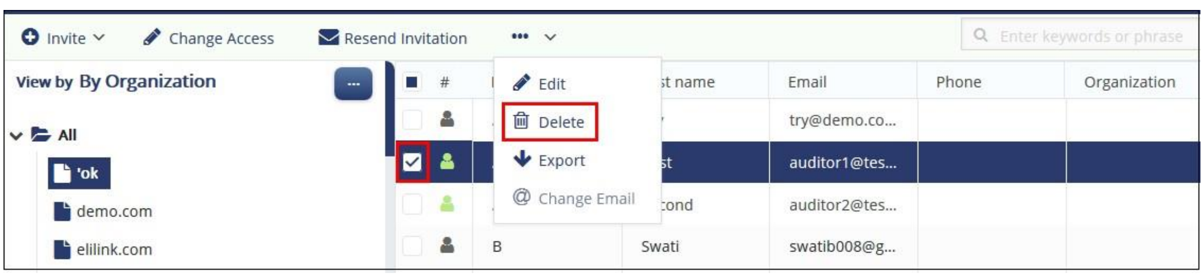


Note: *Follow the same procedure for **editing General Information**, and **Group Membership** as discussed in Invite Users.*

Deleting Users

Follow the steps below to delete users from a room:

1. From the left pane **Index View**, select the preferred category to view the users *(page 68)*.
2. From the list of users displayed in the right pane under the selected category, tick the checkbox of the user to edit.
3. From the top ribbon bar, click the **three dots** and then click **Delete** from the options that appear. Refer to the screenshot below:

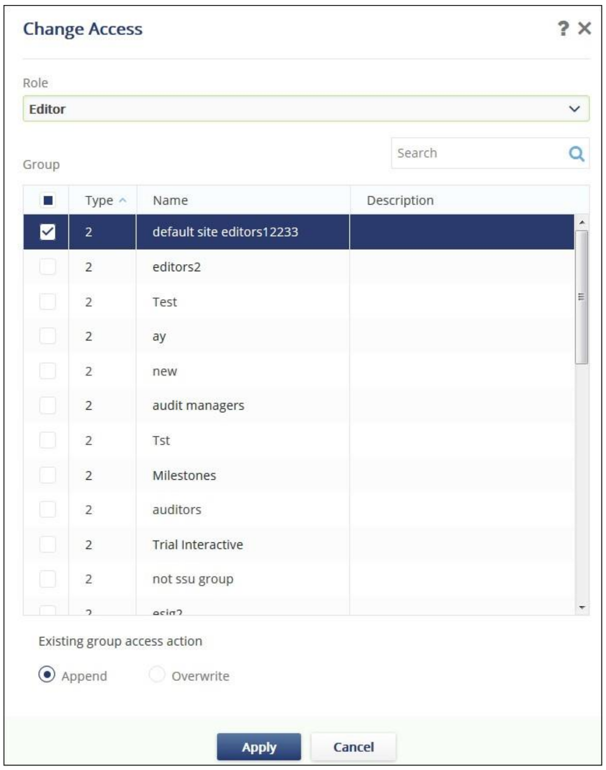


Changing User Access

Follow the steps as below to edit user access:

1. Navigate to **Users Management → Users.**
2. From the left pane **Index View**, select the preferred category to view the users *(page 68)*.
3. From the list of users displayed in the right pane under the selected category, tick the checkbox of the user whose access you want to change.
4. From the top ribbon bar, click the **Change Access** icon.
5. The **Change Access** popup opens.
6. Complete the details as required.
7. Click **Apply**.

Refer to the screenshot below:



The fields of importance are discussed below:

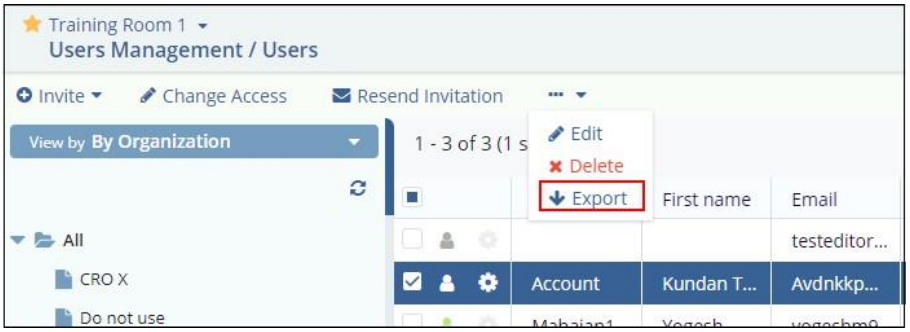
a. **Append** group access will add the user to the new group without removing the user from previous groups.
b. **Overwrite** group access will remove the user from all the previous groups and add the user to the selected group.

Exporting Users

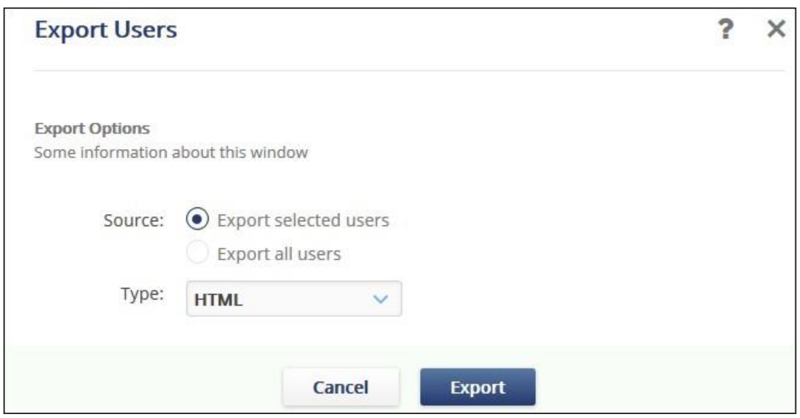
You can either export all the users available in the room, or export only selected users as required. Each of the processes is discussed in separate sections below:

Exporting Selected Users

1. Navigate to **User Management → Users**.
2. From the left pane **Index View**, select the preferred category to view the users *(page 68)*.
3. From the list of users displayed in the right pane under the selected category, tick the checkboxes of the users to export.
4. From the top ribbon bar, click the **three dots** and then click **Export** from the options that appear. Refer to the screenshot below:



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 either HTML, Microsoft Excel, or Microsoft Word.
7. Click **Export**. Refer to the screenshot below:



8. You will receive a notification *(page 64)* about the job completion.
9. Click **Get Job Result** to download the document.

Exporting All Users

1. From the top ribbon bar, click the **three dots** and then click **Export** from the options that appear.
2. The **Export Users** popup opens with the **Export all Users** radio button highlighted.
3. Select the **Type** of export file format. You can select either **HTML**, **Microsoft Excel**, or **Microsoft Word**.
4. Click **Export**.
5. You will receive a notification *(page 64)* about the job completion.
6. Click **Get Job Result** to download the document.

User Management - Groups

Administrators can manage the creation, deletion, and assign of users to Groups. Administrators can manage groups in the following manner:

1. The names of groups
2. The Descriptions of groups

3. Clone security from an existing group
4. Assign Actions to groups

The groups are used in allowing the user access to particular folders, files, activities, and workflow

and audit assignments. You can perform the following activities from Groups:

1. Adding New Group
2. Adding Child Group
3. Editing Group
4. Deleting Group

Each of these is discussed in separate topics. Navigate to the topics from the left menu to access them.

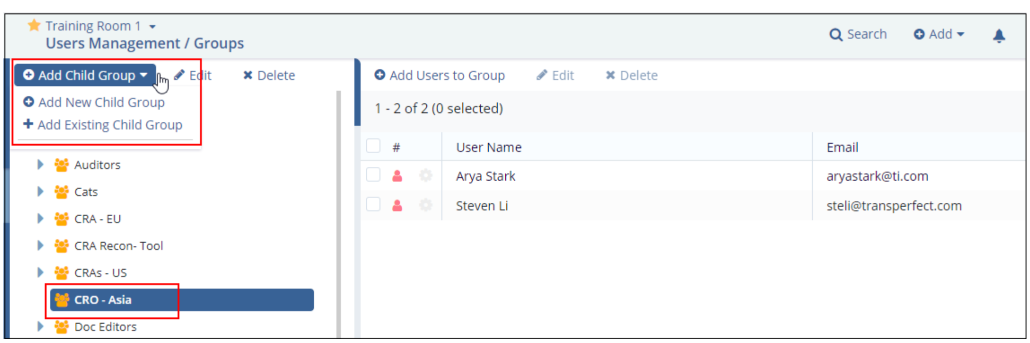
Adding Child Group

You can reach this page by clicking the **Groups** icon from the toggling menu bar on the extreme left of the User Management application.

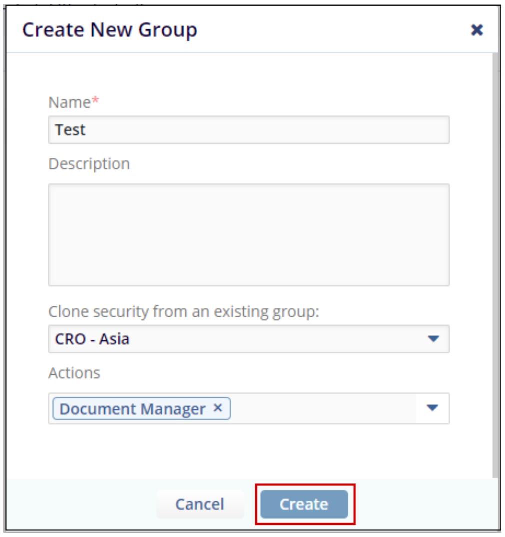
Follow the steps as below to create child groups:

1. Click the arrow to the left of **All Groups** to expand groups and select the required group from the list to which you want to add child group.
2. *Note that the* ***Add Group*** *button at the top left corner now changes to* ***Add Child Group*** *and the buttons* ***Edit*** *and* ***Delete*** *are also enabled.* Refer to the screenshot below:

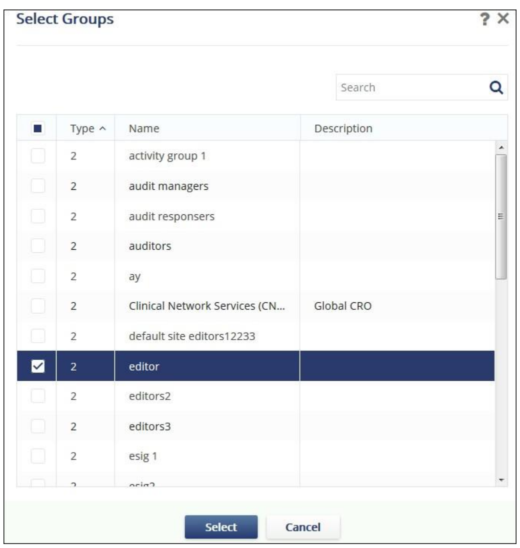
3. Click **Add Child Group** from the top menu. There are two options of group addition: a) **Add New Child Group**, b) **Add Existing Child Group**. See the screenshot below:



4. If **Add New Child Group** is selected, then the below screen appears. Enter the details of the group to be created and click **Create** button.



5. If the option of **Add Existing Child Group** is selected, then the **Select Groups** popup opens.
6. Select the required group from the list to for which you want to create a child group.
7. Click **Select**. Refer to the screenshot below:



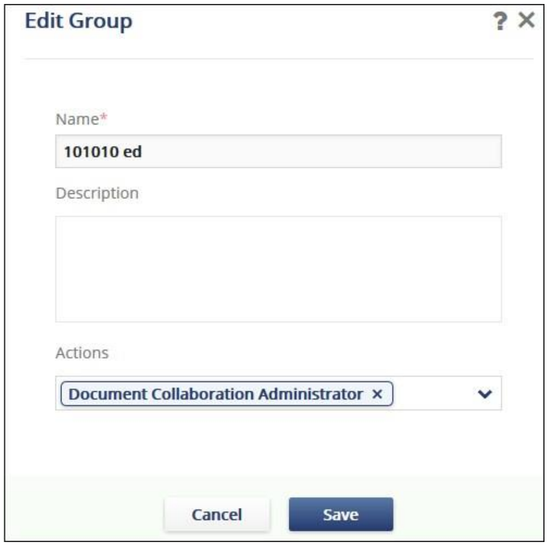
The group gets added to the **Parent Group** to which it is added.

Editing a Group

You can reach this page by clicking the **Groups** icon from the toggling menu bar on the extreme left of the User Management application.

Follow the steps as below to edit a new group:

1. Select the required group you wish to edit from the list of groups in the left pane.
2. Click the edit button from the top ribbon bar.
3. The **Edit Group** popup opens.
4. Fill in the details as required.
5. Click **Save**. Refer to the screenshot below:



eSignature

The client can choose the required e-Signature vendor from **Main Navigation → Settings → e-Signature → Vendors**.

Vendors

The e-Signature vendor available to you depends on the vendor chosen by your organization. This section discusses the following three e-Signature options:

1. DocuSign
2. Adobe Sign
3. TI e-Signature

Follow the steps below to select the e-Signature vendor:

1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Vendors**.
2. Click the **Use E-Signature dropdown** to select the vendor. Refer to the screenshot below:

Note: *The e-Signature vendor available to you depends on the vendor chosen by your organization.*

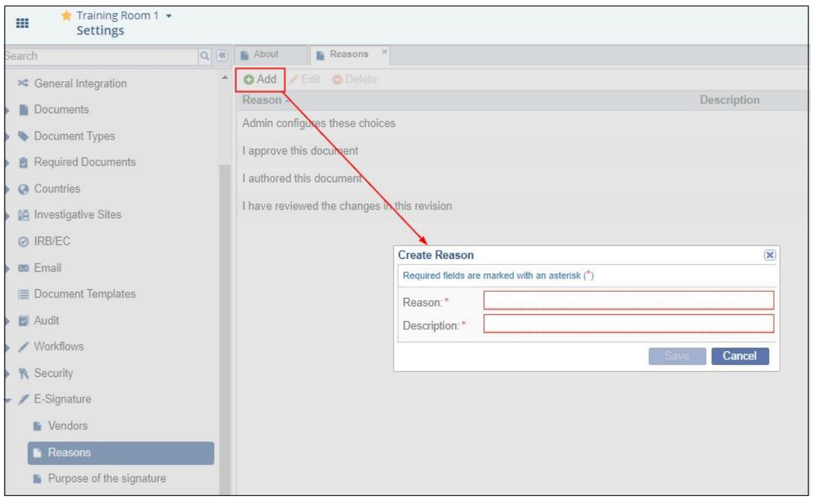
3. An Administrator can choose to enable or disable the use of an e-signature for users in a room by selecting the **None** option from the dropdown.
4. Click **Save** if you make any changes here.

Note: *If the **E-signature** is enabled, the e-Signature Action is automatically added in the **Actions** pane as discussed in* *Edit User (page 72)**. To see the addition, refresh the room in the browser.*

Reasons

While e-signing a document, the e-signers need to specify the reasons for approving or declining a document. Administrators can configure reasons for e-signature from here.

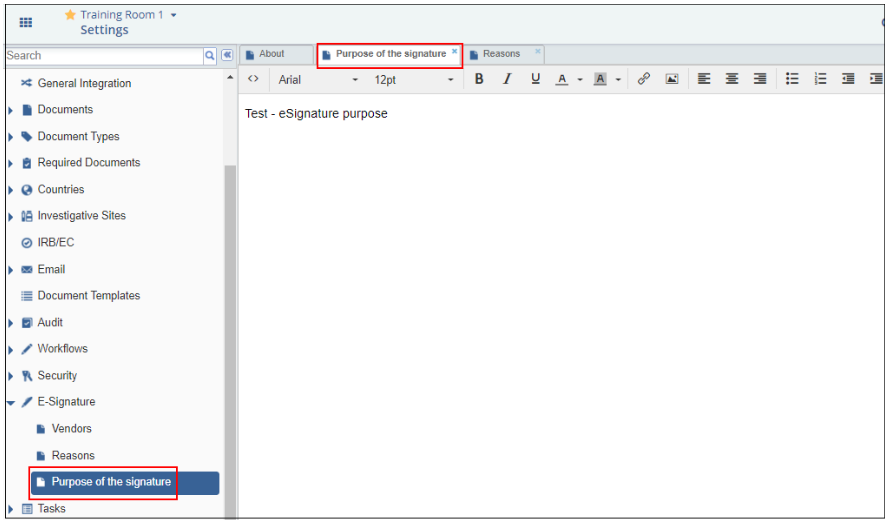
1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Reasons**. Refer to the screenshot below:



2. Click **Add** to create new reasons.
3. Select a reason from the list and click **Edit** to make changes in the existing reason.
4. Select a reason from the list and click **Delete** to delete the existing reason.

Purpose of the e-signature

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:



1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Purpose of the signature**.

2. In the Right Panel, you can write the Purpose of the e-signature.
3. Click **Save**.

Tasks

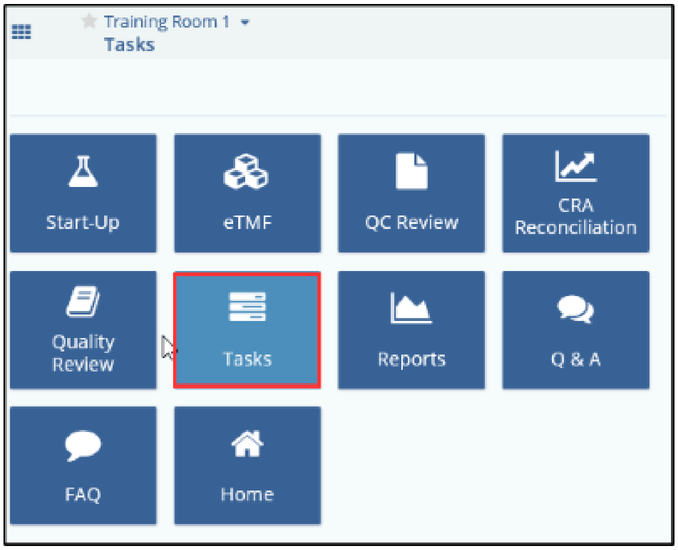
The Administrator would need to set up certain configurations for tasks in a room from **Main Navigation → Room Settings → Tasks.** These configurations are listed below:

1. Tasks
2. Tasks Category

Each of the options above is discussed in separate topics which can be accessed from the left panel of this help.

Tasks

1. Navigate to **Main Navigation->Settings->Tasks->Tasks**
2. Define a number of days from **IRB/EC submission reminder task [field] day(s)** option. Refer to the screenshot below:

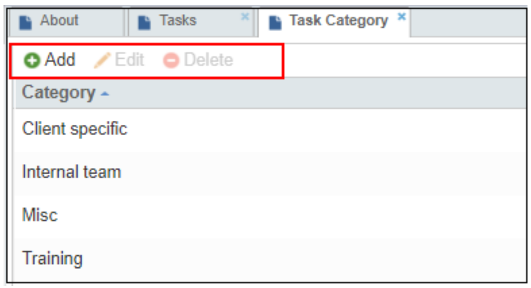


3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.

Task Category

Task categories need to be specified while creating a task. These task categories need to be created so that the user may select the appropriate category from the dropdown of the Task Creation window.

Tasks can be created, edited, or deleted through the buttons on the Task Category dashlet. Refer to the screenshot below:



1. Click **Add** to add a task and press Enter.
2. Double-click a task, or select an existing task and hit the **Edit** button to edit a task. Press Enter after editing.
3. Select a task and hit the **Delete** button to delete it.

General

The **Q&A** functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.

Through the **Q&A settings** view, you can add, edit, or delete **Question Levels**. In the **Q&A** configuration panel, you can enable and disable three Q&A options: the ability to delete questions and answers, the activation of Subject Matter categories, and the activation of questions issue levels.

To access the Q&A Settings:

1. Navigate to the **Main Navigation**-> **Settings Module**
2. Go to **Q&A**

From this section, we discuss :

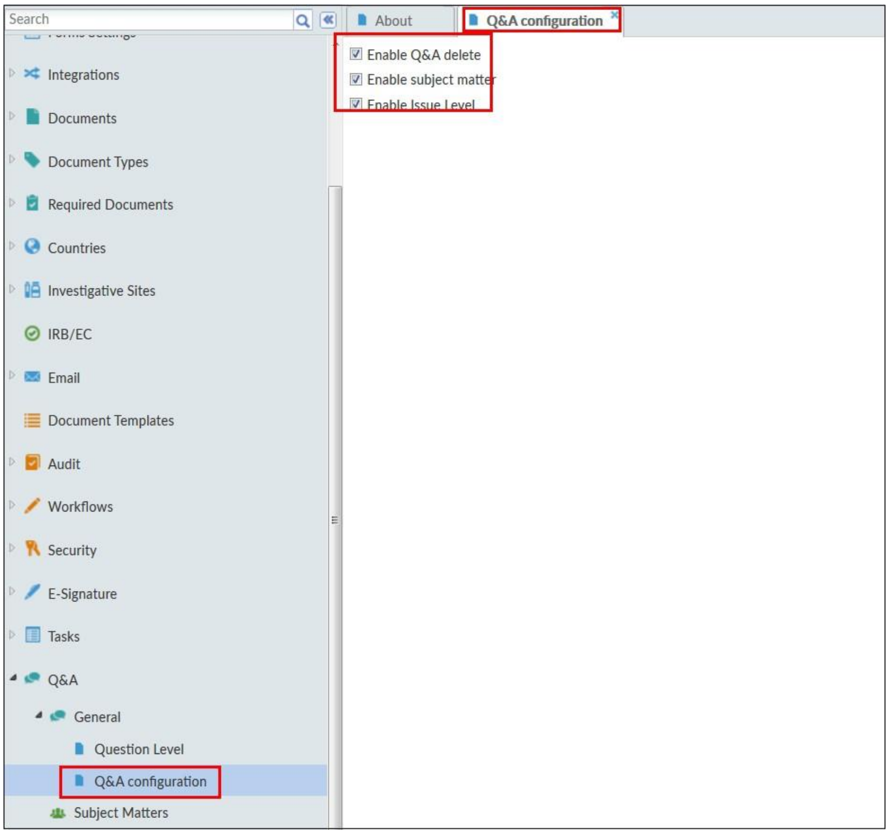
1. Configurations for questions and answers
2. Adding Editing and Deleting Question Levels

All of the above are discussed in separate topics accessible from the left panel of this help.

Q&A Configuration

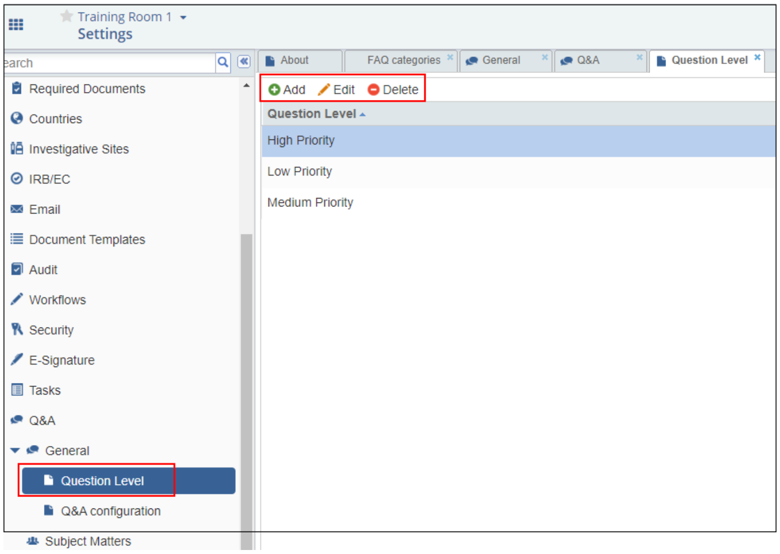
From here, you can enable and disable the following three options:

1. The ability to delete questions and answers.
2. The activation of Subject Matter categories.
3. The activation of question issue levels. Refer to the screenshot below:



Q&A Question Level

From here, you can create a list of issues that are associated with the documents. Administrator can set these issues as per the client request. These issues are then assigned to Subject Matter Experts who can answer the question. Refer to the screenshot below:



From here, you can perform the following:

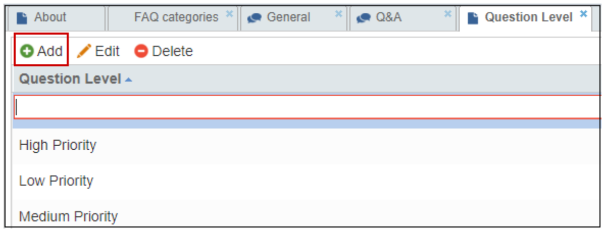
1. Adding New Question Level
2. Editing a Question Level
3. Deleting a Question Level

Each of these is discussed in the sections below:

Adding New Question Level

To add a new question-level:

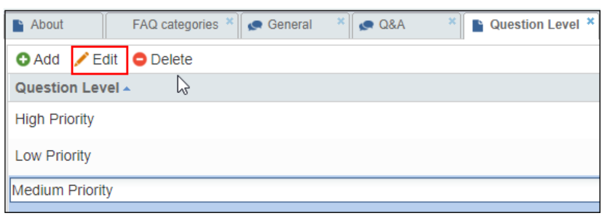
1. Click **Add** from the top ribbon.
2. A new row appears in the grid below.
3. Enter the question level. Refer to the screenshot below:



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.
2. The field becomes editable.
3. Edit the details as required. Refer to the screenshot below:



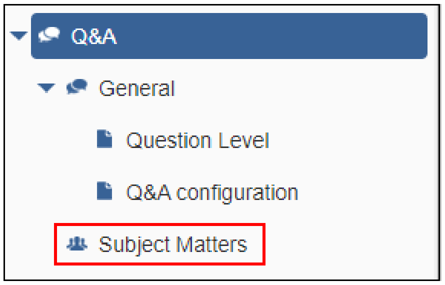
Deleting a Question Level

To delete a question-level:

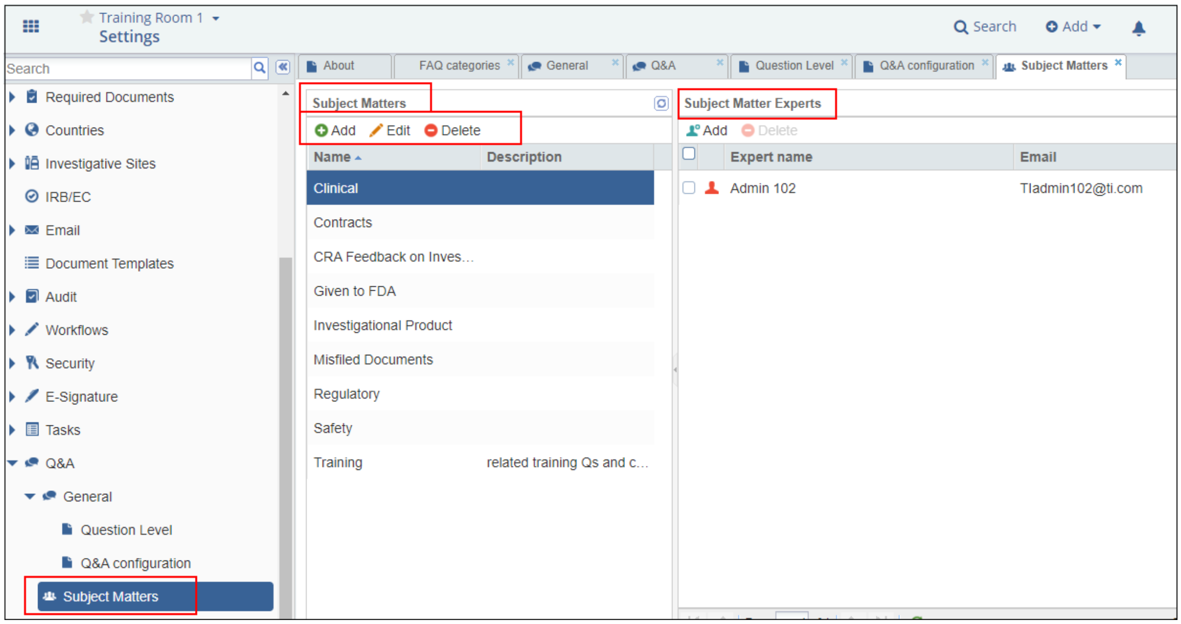
1. Select the level and click **Delete** from the top ribbon to delete it.

Question Subject Matter

If Subject Matter was enabled in the Q&A Configuration *(page 179)*, another set of options for Subject Matters is activated. You can access this option from the Q&A menu in the left panel of the Room Settings *(page 85)*. Refer to the screenshot below:



Clicking **Subject Matters** from the Q&A menu opens the **Subject Matters window** in a separate tab. Refer to the screenshot below:



This window consists of two panels:

1. **Subject Matters panel** from which **Subject matter categories** can be added, edited and deleted.
2. **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 channelled to subject matter experts when the questions are submitted in the room.

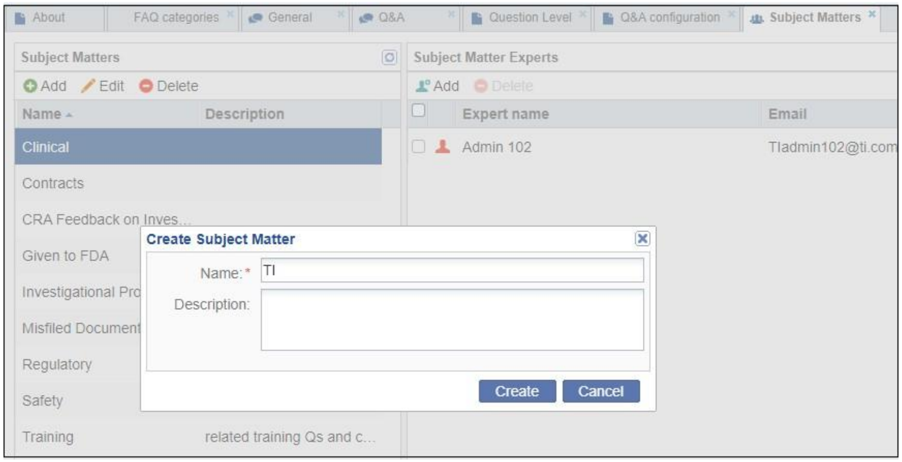
All of the above are discussed in subsequent sections below:

Adding Subject Matters

To create Subject Matters:

1. From the **Subject Matters panel** toolbar, click **Add**.

2. The **Create Subject Matter window** opens. Refer to the screenshot below:

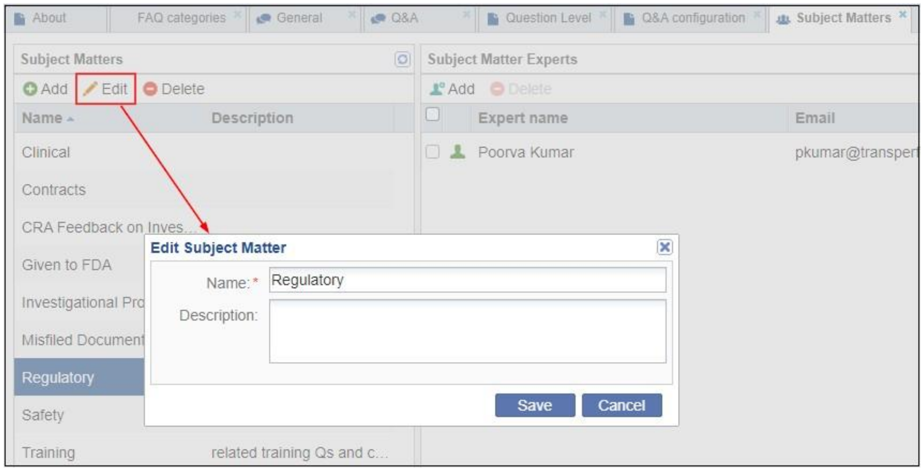


3. Type the name of the Subject matter category in the **Name** field. The **Name** field is required; the **Description** field is optional.
4. Click **Create** at the bottom of the window. The new Subject Matter category is added to the list.

Editing Subject Matters

To edit Subject Matters:

1. From the **Subject Matters panel,** click on a **Subject Matter category** to select it.
2. From the **Subject Matters panel** toolbar, click **Edit**.
3. The **Edit Subject Matter window** opens. Refer to the screenshot below:



4. Edit the **Subject Matter Category name** and **Description**; click **Save**.
5. The changes are committed and visible in the list of categories.

Deleting Subject Matters

To delete a Subject Matter category:

1. From the **Subject Matters panel,** click on a **Subject Matter category** to select it.
2. From the **Subject Matters panel** toolbar, click **Delete**.
3. The **Subject Matter Category** is removed from the list of categories.

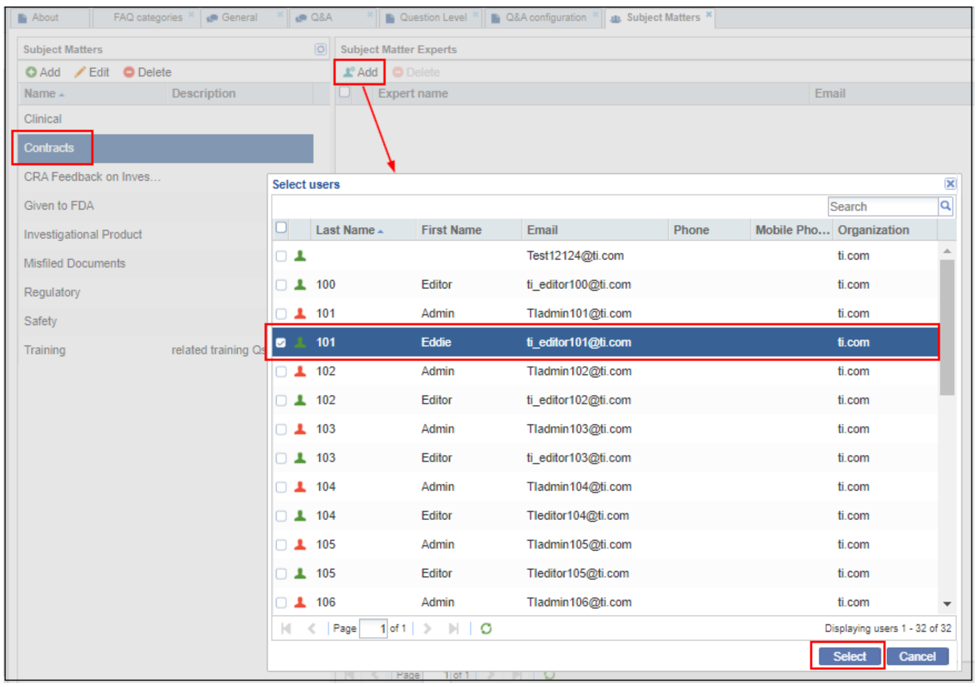
Assigning Subject Matter Experts to Subject Matters

To assign a Subject Matter Expert to a specific subject matter, select a subject matter from the list on the left.

1. Click the Name of the **Subject Matter**. The subject matter category name is highlighted in light blue.
2. Click the **Add** button from the **Subject Matter Experts** panel toolbar.

   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.

3. Click the checkbox next to the name of the user you want to assign to the expert role.
4. Click **Select** at the bottom of the window. The changes are automatically saved. Refer to the screenshot below:



Now, when a user asks a question and assigns it to the Q&A category and the Subject Matter while creating the question, the assigned expert will be notified of the question that needs 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:

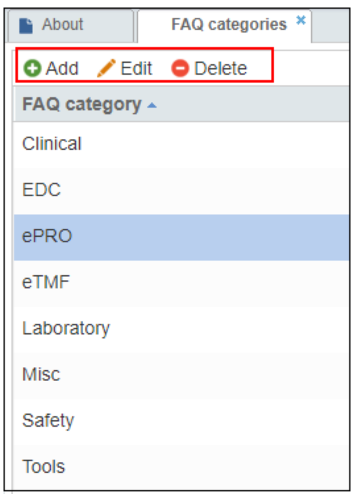
1. Click the Name of the **Subject Matter**. The subject matter category name is highlighted in light blue.
2. The list of **Subject Matter Experts** appears in the Subject Matter Expert Panel.
3. Select the checkbox next to the name(s) of the Subject Matter Expert you want to delete.
4. Click **Delete** from the toolbar. The names of the Subject Matter Experts gets deleted from the list.

FAQ Module

Note: *The FAQ functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.*

Adding FAQ Categories

1. Navigate to **Main Navigation->Settings->FAQ**
2. Click **Add**. Refer to the screenshot below:



3. Click **Save** after making any changes.

Editing FAQ Categories

1. Double-click the FAQ category, or select an existing FAQ category and click **Edit**. Press **Enter** after editing.
2. Click **Save** to save the changes.

Deleting FAQ Categories

1. Select a FAQ and click **Delete**.
2. Click **Save** to save the changes made

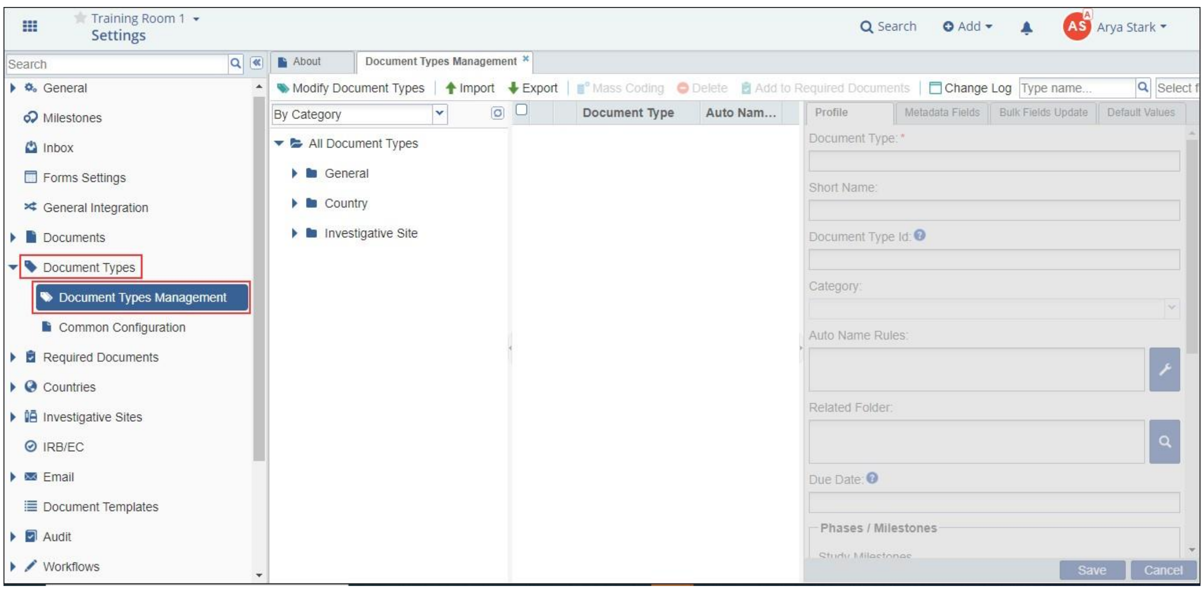
Chapter 7. Document Types and Management

In this section, we discuss creating Document Types and various functionalities related to it.

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.

All of these document types need to be set up and defined in the Trial Interactive room:

1. Navigate to **Main Navigation -> Settings**. The Room Settings page opens.
2. Select **Document Types** from the menu on the left.
3. The **Document Types** option expands to reveal two sub-options:
    a. The **Document Types Management** and
    b. The **Common Configuration.**
4. Click and view each panel separately. Refer to the screenshot below:



The Documents under the Document Types created from here can be viewed under the By Document Type *(page 232)* view.

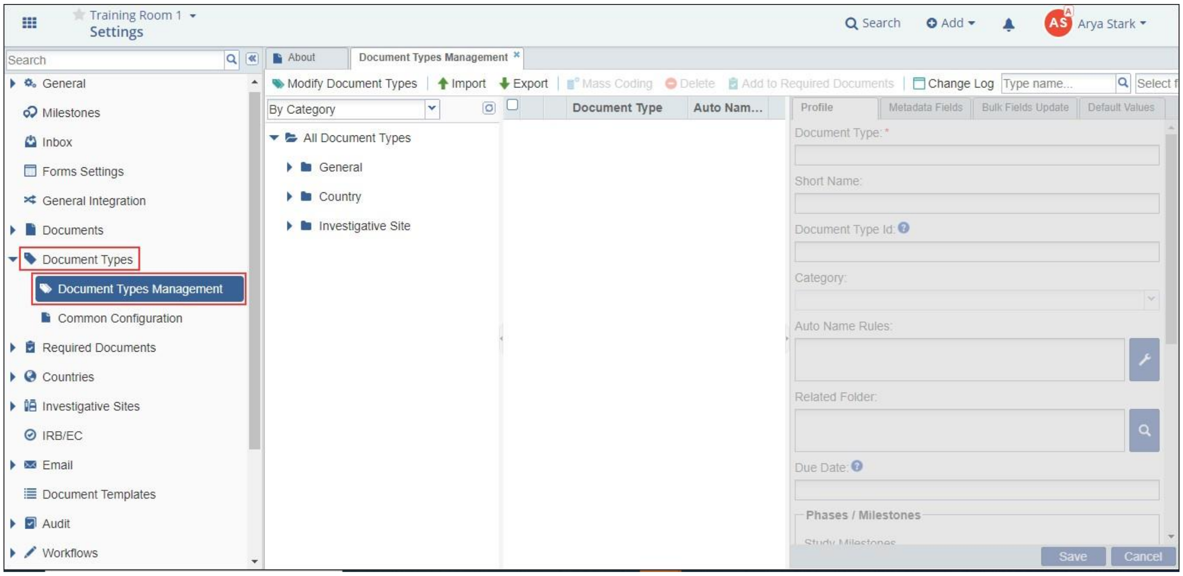
Each view or panel are discussed in separate topics accessible from the left pane of this help:

1. Document Types Management
2. Common Configuration

Document Types Management

Note: *Super Administrator users have the ability to turn On and Off Administrator access to Document Types Management Settings.*

Attention: *This tab may not be available in your data room. The Document Types Management tab, if enabled, for Administrator users, allows access to the auto-naming rules and to linking metadata fields to document types, enabling conditional metadata. Auto-naming settings are complex, and it is preferred that Administrators work with the Trial Interactive*



Click the **Document Types Management** tab to open its dashboard on the right.

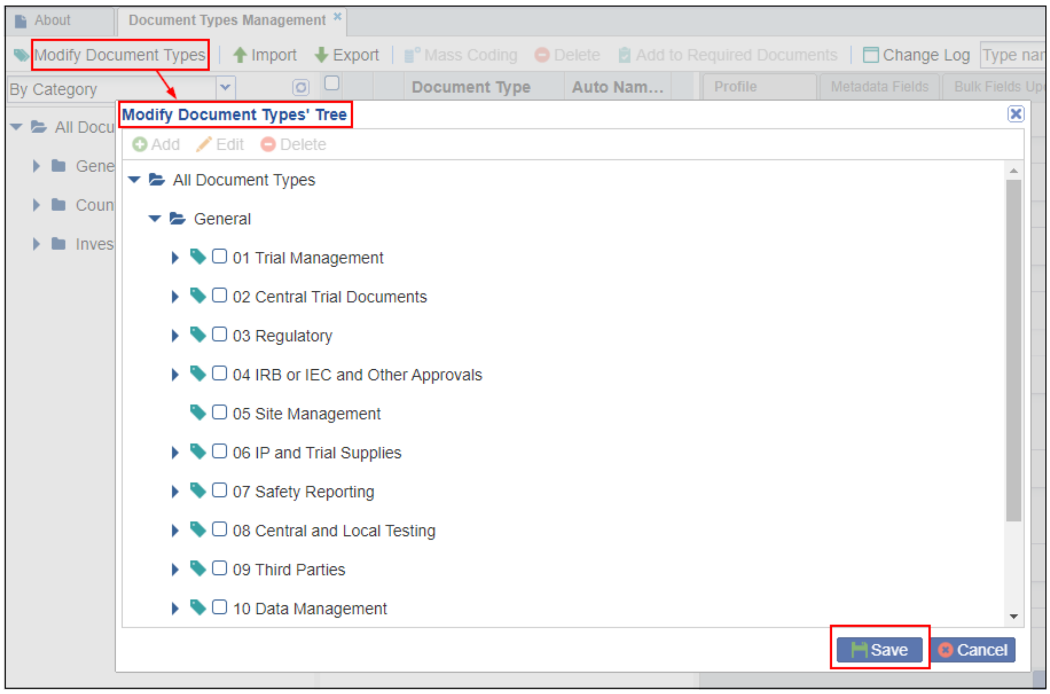
From this page, you can perform various actions as below. All of these are discussed in separate child-topics. Expand this topic from the left pane of this help to reveal the following child-topics:

1. Modify Document Types' Tree
2. Building the Document Type Profile
3. Specifying the Related Folder
4. Include Phases/Milestones
5. Adding Document Types to Required Documents
6. Include in Document Tracker Report
7. Auto Document Type Prediction Keyword(s)
8. Modifying Document Types Fields
9. Default Values

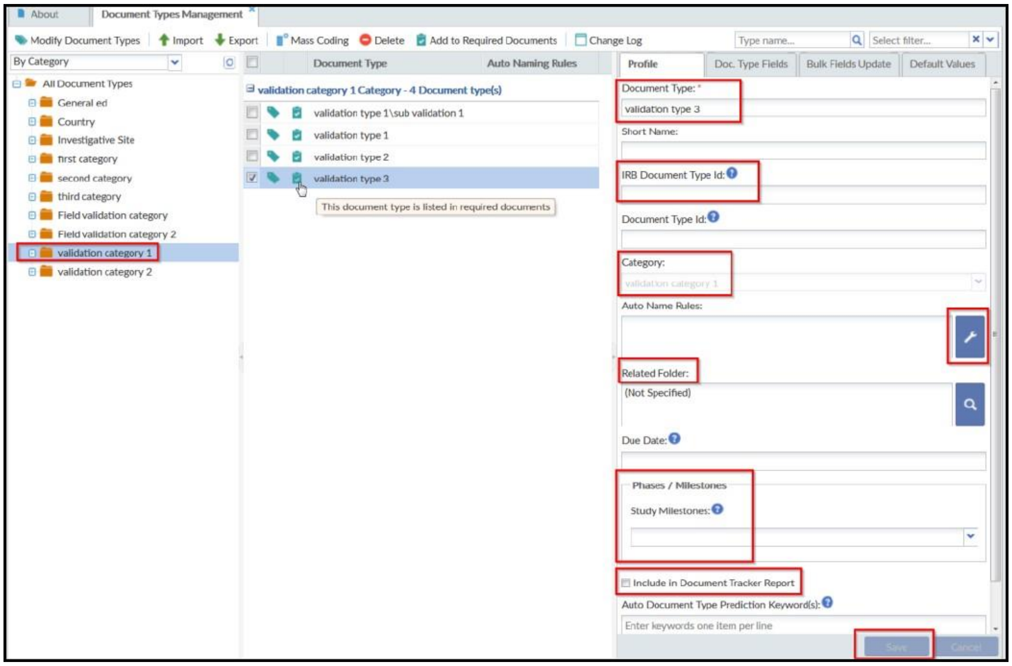
Modify Documents Types

1. Click **Modify Document Types** option from the ribbon above the dashboard.
2. A new **Modify Document Types' Tree** window opens, displaying the folder structure of Document Types in a tree view. Document Types can be added to the category folders, edited in their current positions, and deleted through this view. In the figure below, the **Investigative Site** folder is open, displaying the document types that are added in that category.

Figure 43: Modify Document Types' Tree



   a. To add a new document type, click the main category into which the new document type is to be assigned. If the folder already contains document types, click the + sign next to the category's folder icon to see the document types already contained in the category. The categories are marked by the yellow folder icons and the actual document types by the blue document icon.
   b. Click the **Add** button near the top of the window, or right-click the folder where you want to add the new document type, or right-click the document type under which you want to add a sub-type. A new line appears with an editable field that reads **New Document Type**. Refer to the screenshot below:



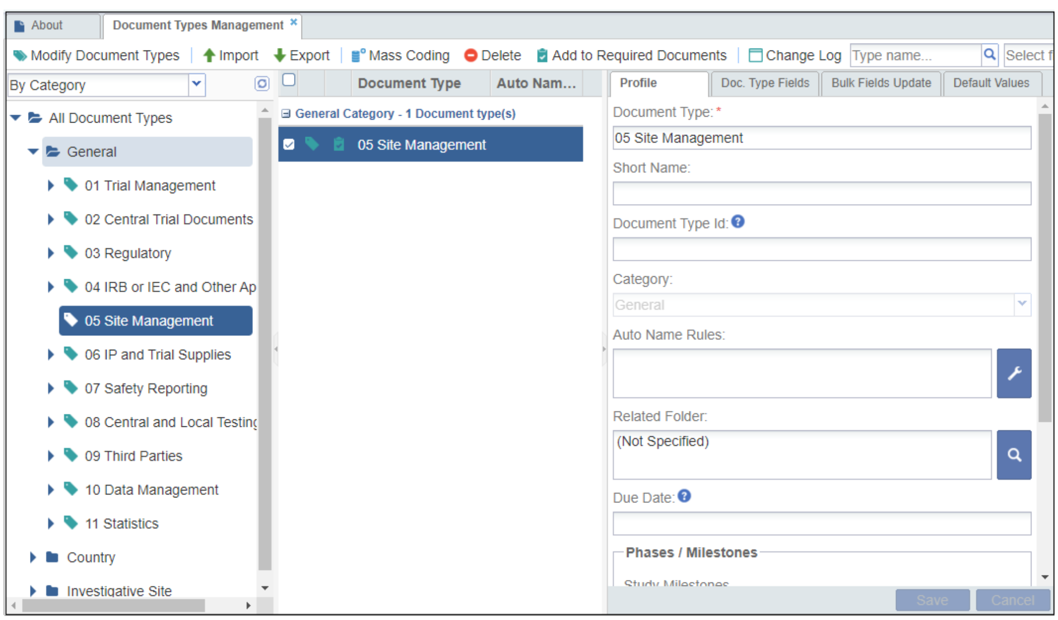
c. Type the name of the new document type to be added to the category folder.

d. Press the **Enter** key. If you have more document types to add to this or other categories, you can repeat this process.

e. When you have added all of the necessary new document types, click **Save** at the bottom of the window. That window closes, and you return to the primary **Document Types** view. The document types that you have just created has not been routed to a proper index position. Refer to the screenshot below:

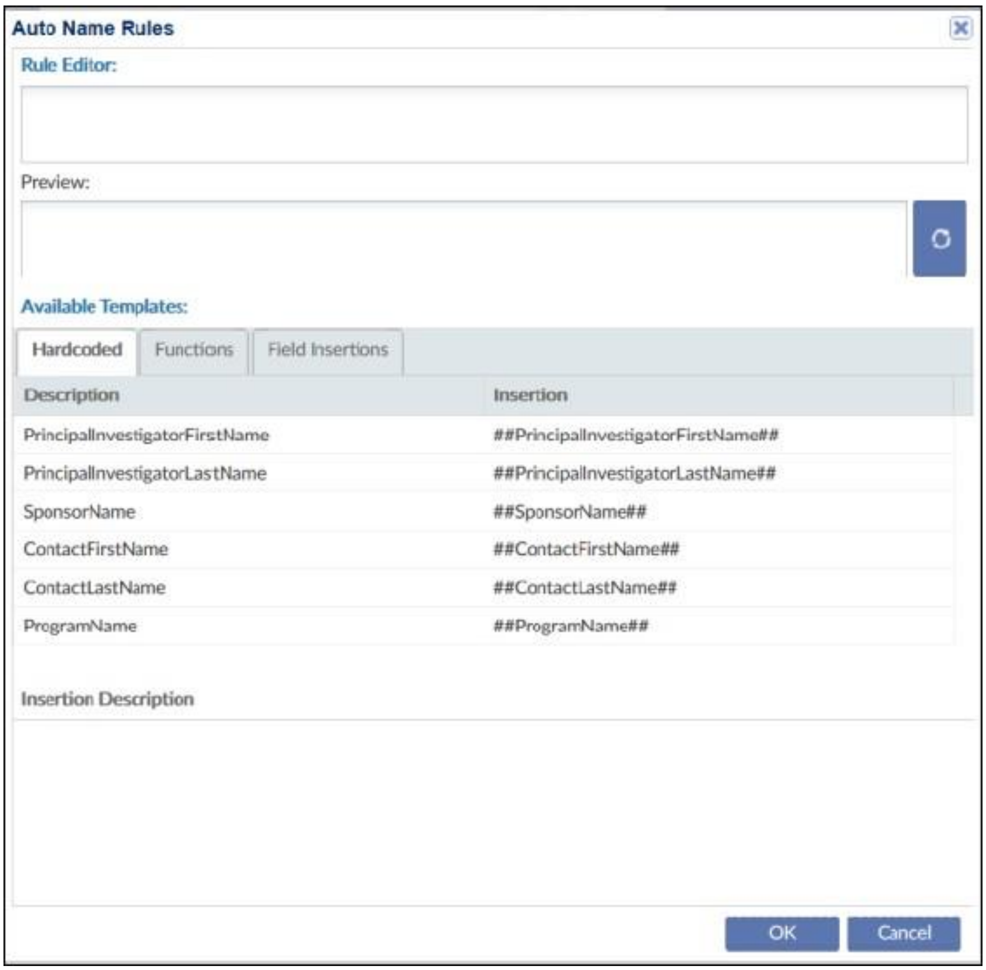
f. Similarly, you can also edit or delete document types.

Building the Document Type Profile



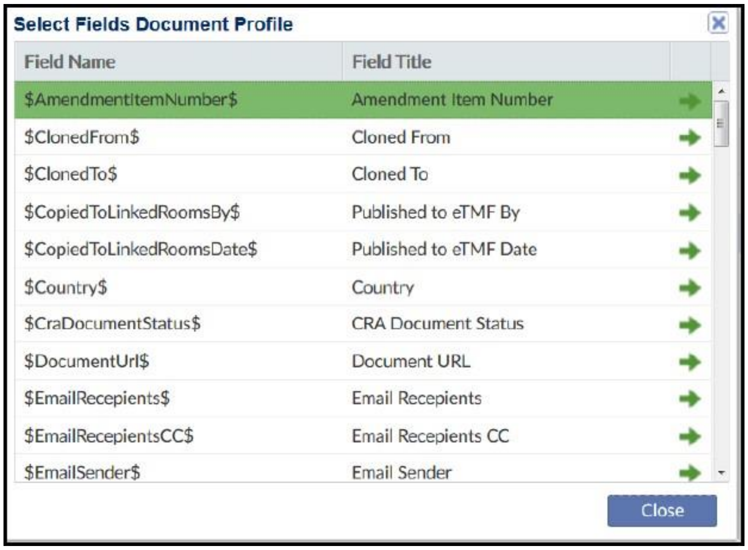
1. Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.
2. In the **Profile** tab, type in the **Short Name** for the document type. This can be the same as the **Document Type** name that you created in the previous steps, or it can be abbreviated if the original name is long.
3. The **IRB Document Type ID** is one of the fields besides 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, so this field is not enabled.
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. The client typically supplies a file with prescribed document types and the auto naming rules that they want to be assigned to the document types. An **Auto Name Rules** window opens. Refer to the screenshot below:



The following set of instructions describes the insertion of a standard set of fields for 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 Sponsor Name.

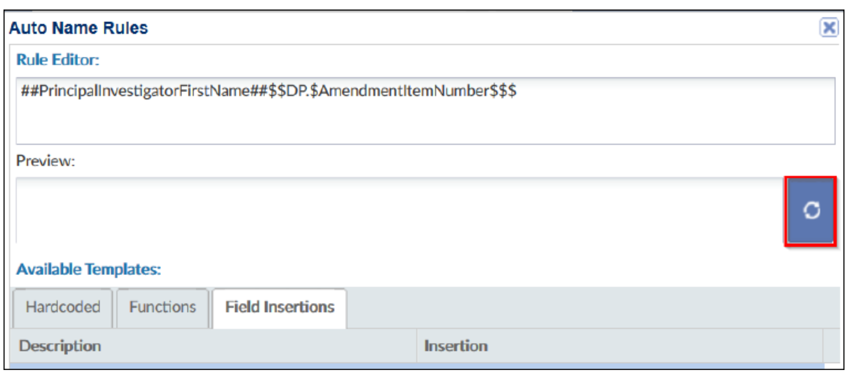
a. Under the **Hardcoded** tab, double-click a description to be inserted as auto naming rule. The insertion appears in the **Rule Editor**.
b. If you want to include fields present under the **Field Insertion** tab, double-click the description and further click the green arrow in the **Select Fields Document Profile**. This too gets appended in the **Rule** Editor. The order in which you select these naming elements is the order in which they will display.



c. 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.*

d. 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.



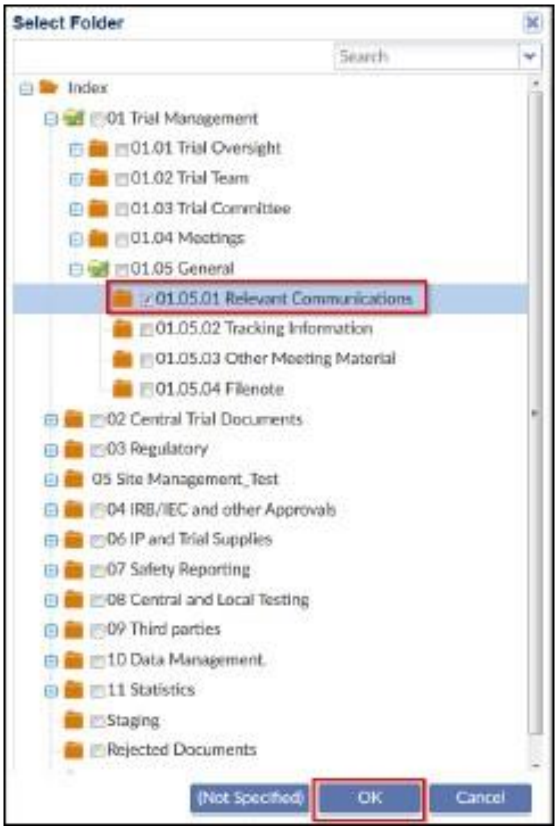
e. Click **OK** at the bottom of the window. You return to the main **Document Types** view.
f. Click **Save** at the bottom right of the **Profile** tab window.

Specifying the Related Folder

1. 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.

2. Select the proper folder or subfolder for the document type.

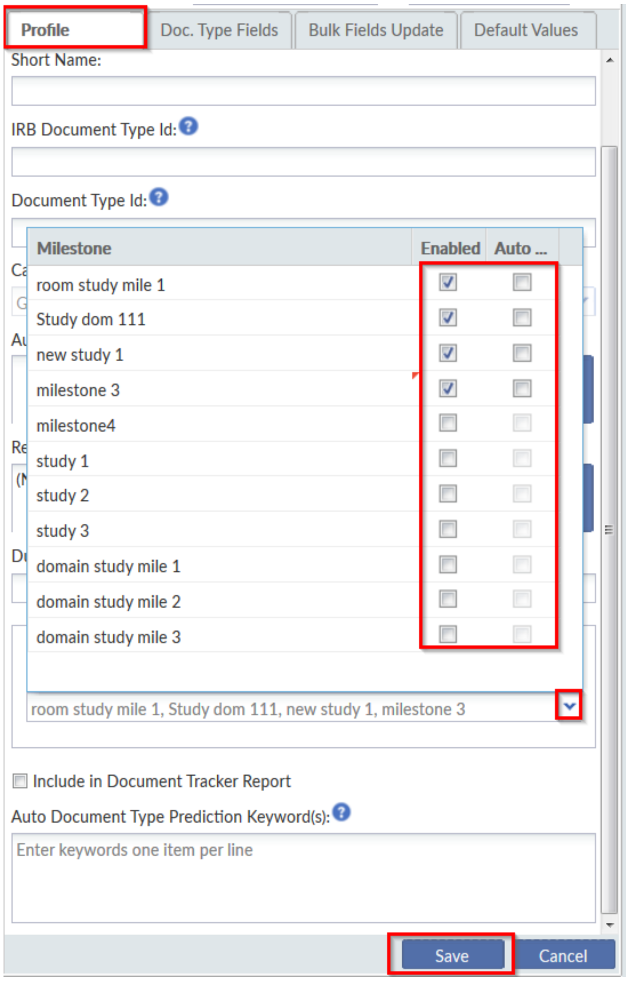


In this example, we have chosen the **Relevant Communications** folder.

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.

Include Phases/Milestones

To add Document Types to Milestones in your room, click the **Study Milestones** dropdown in the **Phases/Milestones section** of the **Document Type Profile window**. Refer to the screenshot below:



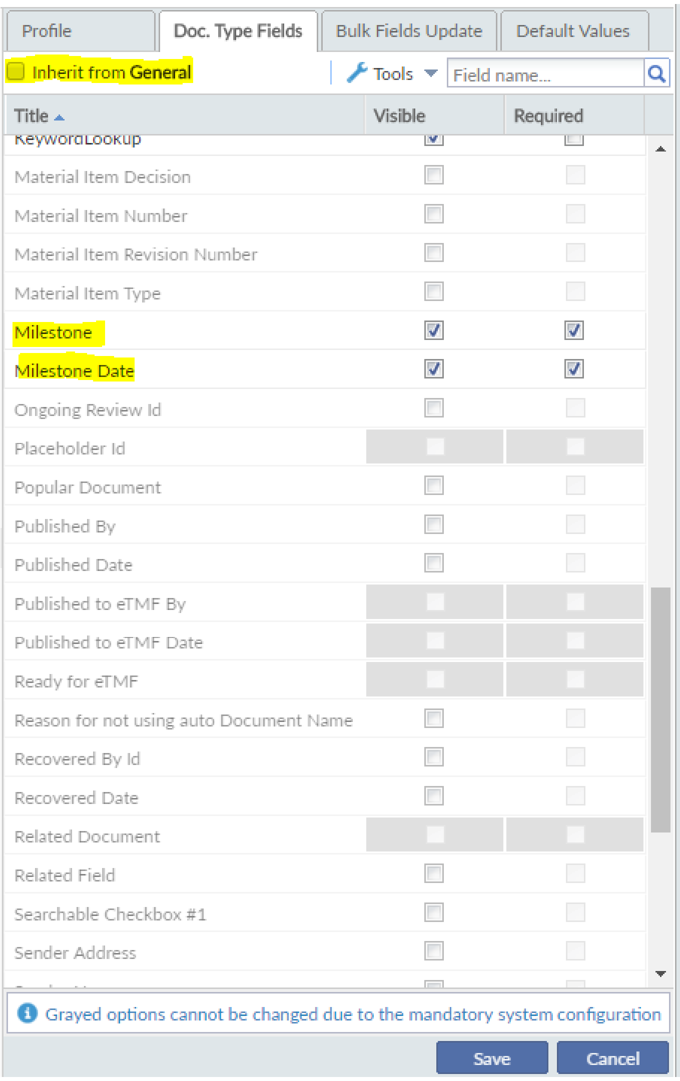
From the list of milestones that appear:

1. Tick the checkboxes to select the milestones that apply to the current document type
2. Click **Save**.

These milestones, when added to the document types, help to track the **eTMF Completeness** of documents associated with them, and generate **eTMF Completeness Reports**.

Milestone Related Fields Auto Enabling

When a user selects one or more items in the Study Milestones, Investigative Site Milestones, or Country Milestones files in the Document Type Profile, **the system will automatically mark the 'Milestone' and 'Milestone Date' document fields as visible and required**. This will be reflected in the custom form fields list in the **Doc. Type fields window** of the selected Document Type; an information message will also be shown. Refer to the screenshot below:

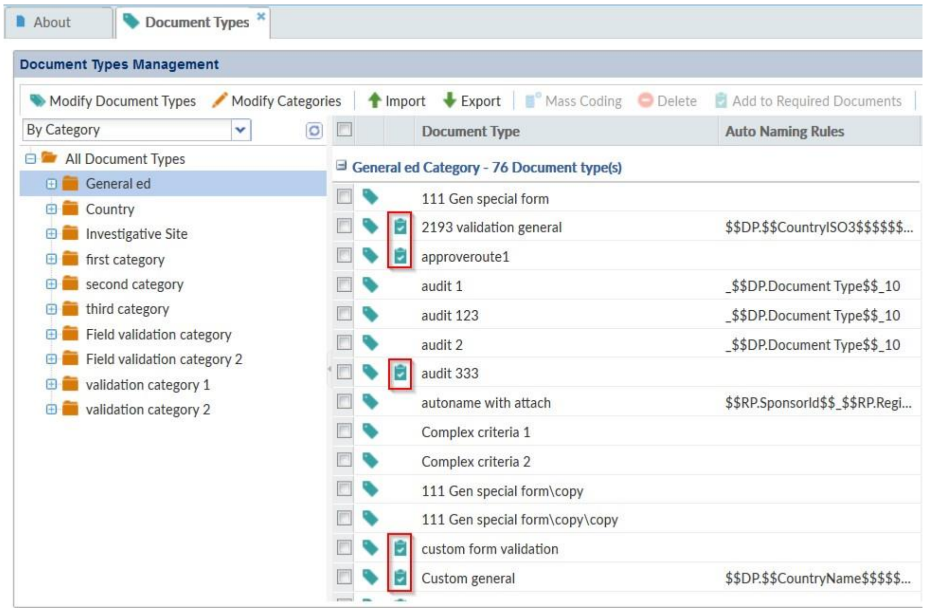


Besides the above, a document type can also be added to a milestone by either of the following ways:

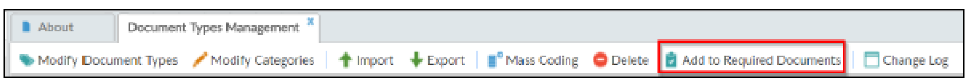
1. From **Required Documents** window
2. From **Sites Profile** window while adding or editing sites

Adding Document Types to Required Documents

You can know if a document type is added to the required documents list from the Required Documents icon that appears in the grid next to the document type category. Refer to the screenshot below:



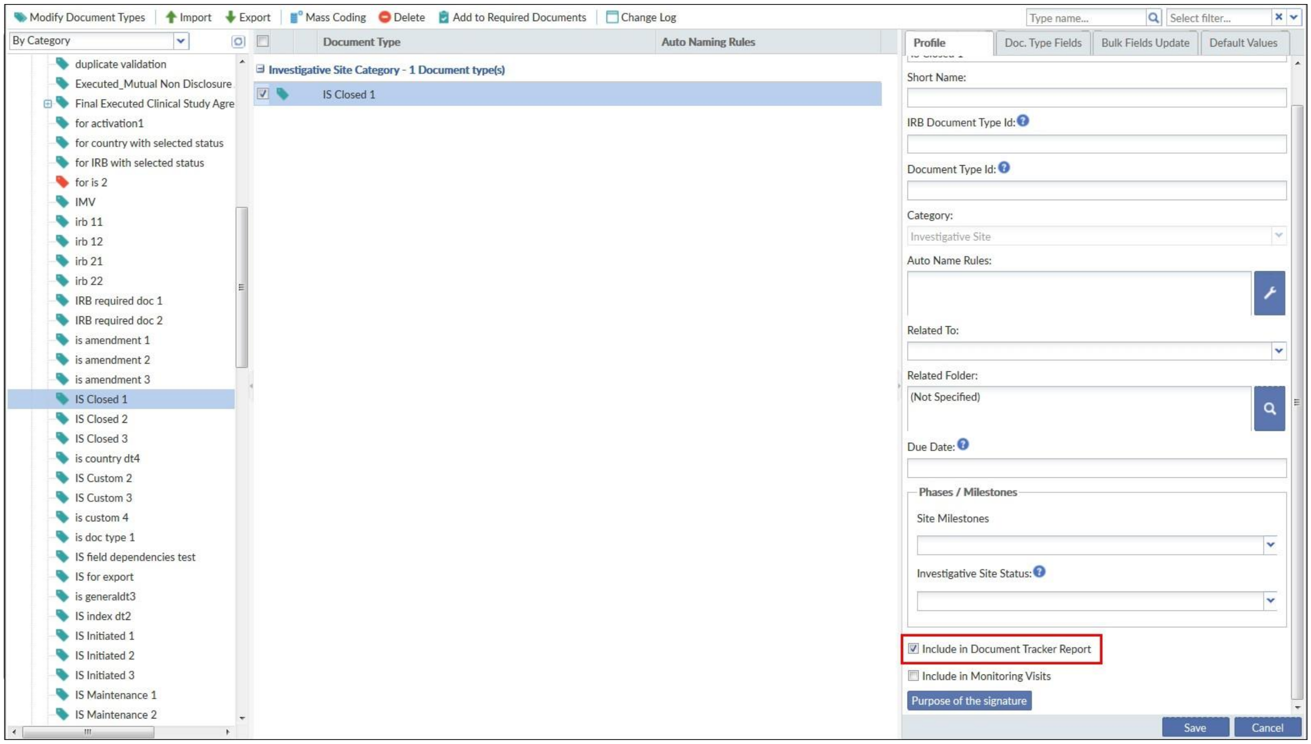
A document type can be added to the required documents list from the Add to Required Documents button located on the toolbar above the Document Types Management window. Refer to the screenshot below:



Besides, you can also make a document type a required document from the Required Documents window.

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:

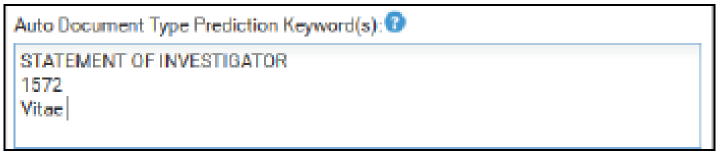


Auto Document Type Prediction Keyword(s)

Out of the hundreds of potential document types that might be present in a study, many of those document types might be auto predicted. For example, Curriculum Vitae, the 1572 form, a financial disclosure form – practically any required regulatory pack document or any document for which a sponsor has a template to send to investigators. A Super

Administrator user needs to activate this option in the room. When this feature is activated, and a document is uploaded, it goes into a queue. The system searches the first page of each document for the keywords entered for all of the document types for which keyword identifiers have been entered.

1. Open the Profile for the document type for which you want to add the Prediction Keywords in the **Document Types Management** settings.
2. Type Keywords into the field, one keyword per line.

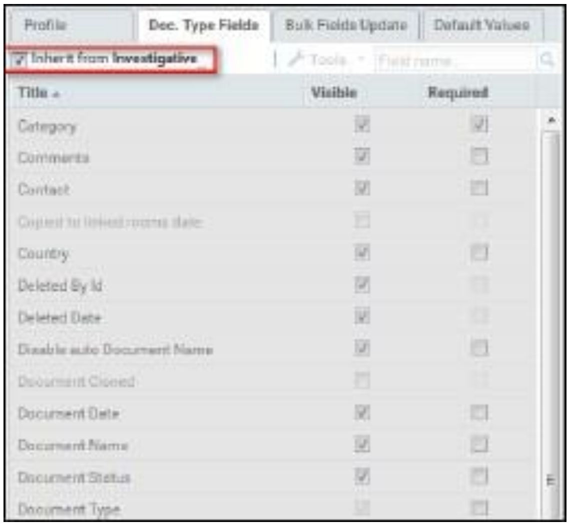


3. When all of the appropriate keywords have been entered, click **Save** at the bottom of the **Profile** panel.

Modifying Document Type Fields

In some cases, you may need to change which metadata fields are available for a particular document type.

1. To initiate a change in the availability of metadata fields, click the **Doc. Type Fields** tab next to the **Profile** tab in the panel on the right.



2. Uncheck the **Inherit from {Category Name}** box at the top of the pane to break the inheritance. The pane becomes active, no longer grey in appearance.
3. Click the boxes in the columns marked **Visible** and **Required** as dictated by the client request.

   Note: *If you have already established a standard set of metadata fields for the documents, you can use this shortcut:*

   a. *Click Tools.*
   b. *Select Clone Fields from.*

   Then select another document type whose metadata fields are the same.

4. When you have finished making the requested changes, click **Save** at the bottom of the pane.

   Note: *The Search box allows you to type in simple search criteria to help you find particular metadata fields in the list.*

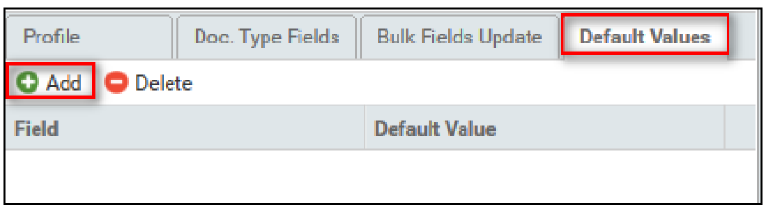
Default Values

By implementing the **Default Values** options when defining a document type's profile coding, you can set a specific metadata field value to auto-populate based on the document type.

1. 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.
2. Select the specific document type to which you want to add the field that will auto-populate with the default value.
3. Click the **Metadata Fields** tab.
4. Click the necessary checkbox.
5. Click **Save**.
6. Click the **Default Values** tab.
7. Click the **Add** button.

   The **Field** textbox activates. Click the dropdown arrow at the right end of the box.

8. Select the necessary custom metadata field from the list.
9. Press **Tab** on your Keyboard.
10. Set the field's default value by typing the value in the textbox.

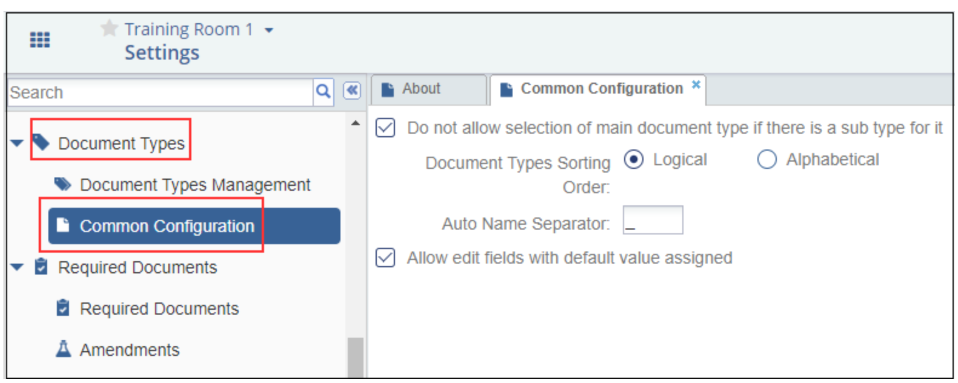


11. Click **Save**.

When any document is assigned to that document type, the custom field will auto-populate with the default value you established.

Common Configuration

Clicking **Document Types Management** opens its dashboard on the right. Refer to the screenshot below:



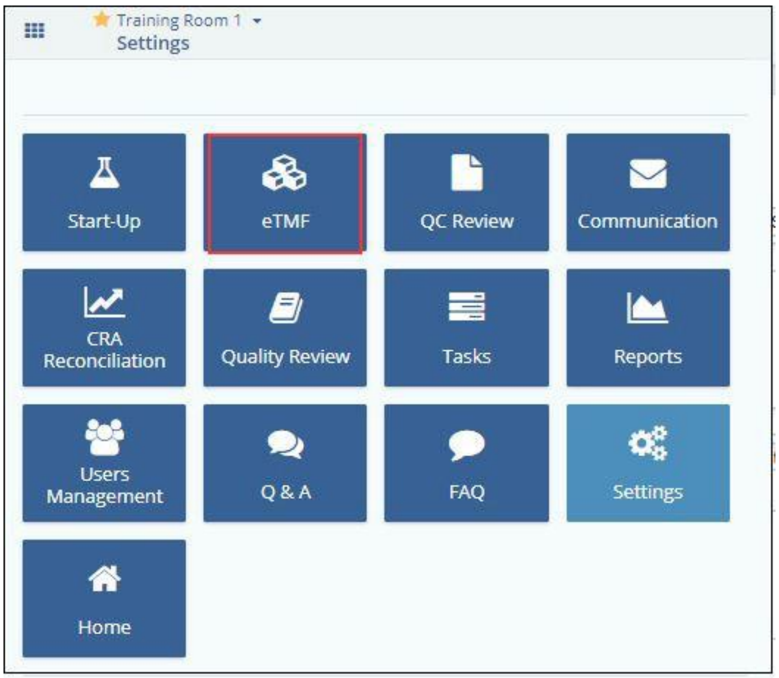
- In the **Common Configuration** panel, you can make it so that users cannot select a main document type name if one or more sub-types exist for that type.
- In this panel, you also select whether Document Types are sorted by **Logical** order (the order in which they were entered) or sorted **Alphabetically**.
- Here, too, you select the default **Auto Name Separator**; you can choose any character, or you can make the auto separator a blank space.
-

- On enabling **Allow edit fields with default value assigned**, some document metadata fields will be filled automatically on creating a document and selecting a document type from the configured list.
- If you make any changes in this panel, click **Save** at the bottom of the panel.

Chapter 8. Trial Interactive eTMF and the Documents Module

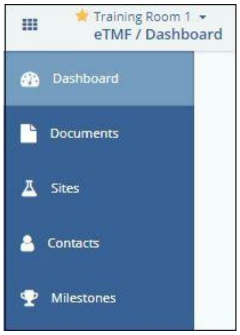
The Trial Interactive eTMF Application acts as a central access point to not only Clinical Trial Documents *(page 222)* but also to eTMF Sites *(page 291)*, Contacts, eTMF Completeness, and CRA Reconciliation Reports *(page 308)*, reports in the form of **Dashlets** for all clinical trial activities, and also to IRB Integration and Potential Sites *(page 291)*.

You can access this module from the Main Navigation *(page 53)*. Refer to the screenshot below.



Once you enter the application, you have access to various modules within it and can toggle between the:

1. Dashboard Dashlet View
2. Documents
3. Sites
4. Contacts
5. Milestones etc. from the menu bar on the left. Refer to the screenshot below:



All these views can be enabled for you by the Super Admin through the Room Settings (page 85), and are discussed in separate topics.

Dashboard Dashlets

Know how to configure the dashboard and dashlets in a room.

All Trial Interactive dashboards are primarily composed of dashlets. As a user, you can configure your dashboards to suit your preferences, views, and convenience for efficient performance.

Individual users in Trial Interactive have the option to arrange their Dashboard views. Arranging your dashboard views include deciding:

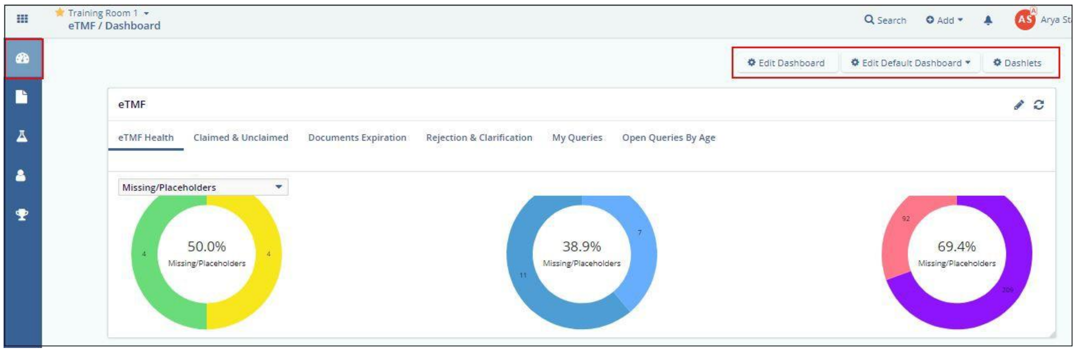
1. The layout of the dashlets on your dashboard by moving them around,
2. The dashlets to view along with their distribution on the dashboard, and
3. The configuration of each dashlet.

Dashlets

A dashlet is a component in a dashboard with functionalities of its own. A dashlet may provide information on a particular feature in the form of a report, a graph, or a description on a particular topic. Dashlets are independent of each other and are contained in a dashboard. In a way of its own, they play a significant role in the look and feel of a dashboard.

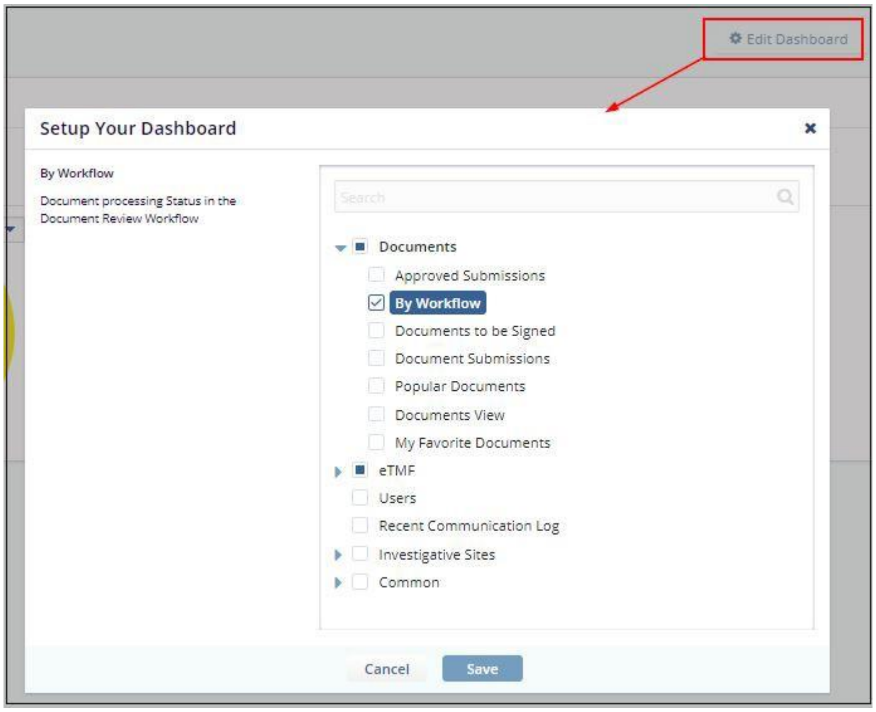
To visit a Room Dashboard, click **Dashboard** from the left menu from the eTMF module. Refer to the screenshot below:

Dashboard Settings



As one of the sub-section of General room setting tabs, the Administrator will see the Dashboard Setup box. An Administrator can change the information that will be available to users in the room when they access their Dashboard.

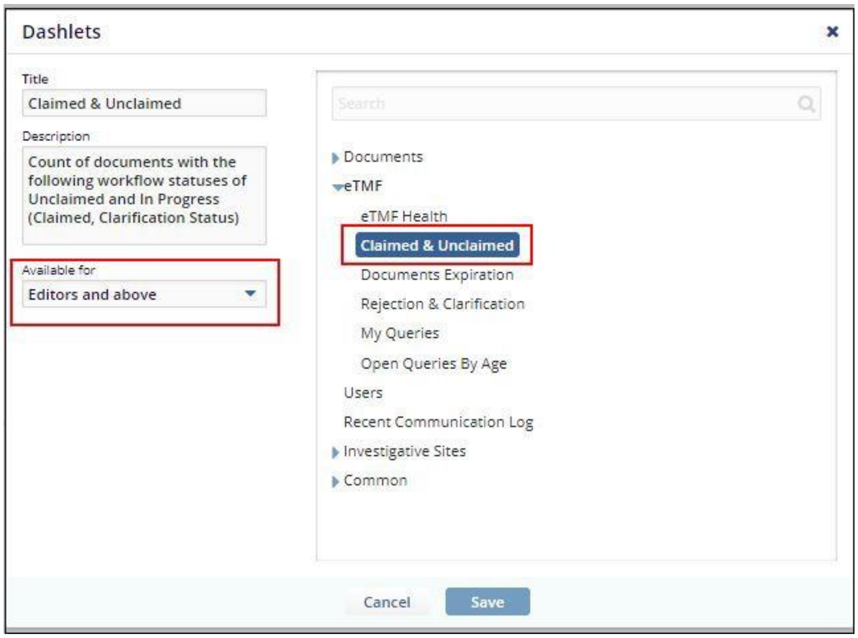
To **modify the availability of dashlets** to users, here are the steps to follow.



1. Navigate to **Main Navigation-> Settings -> General -> Dashboard Setup.**
2. Double-click any of the dashlet lines in the **Available for** column.

   The field becomes active with a dropdown arrow at the right end of the field.

3. Click the dropdown arrow. A set of selections becomes available to the Administrator.



4. Select which users in the room will see any particular dashlet in their **Dashboard** views.
5. Click **Save** if you have made acceptable changes.

From the Dashboard Settings, the following activities are available:

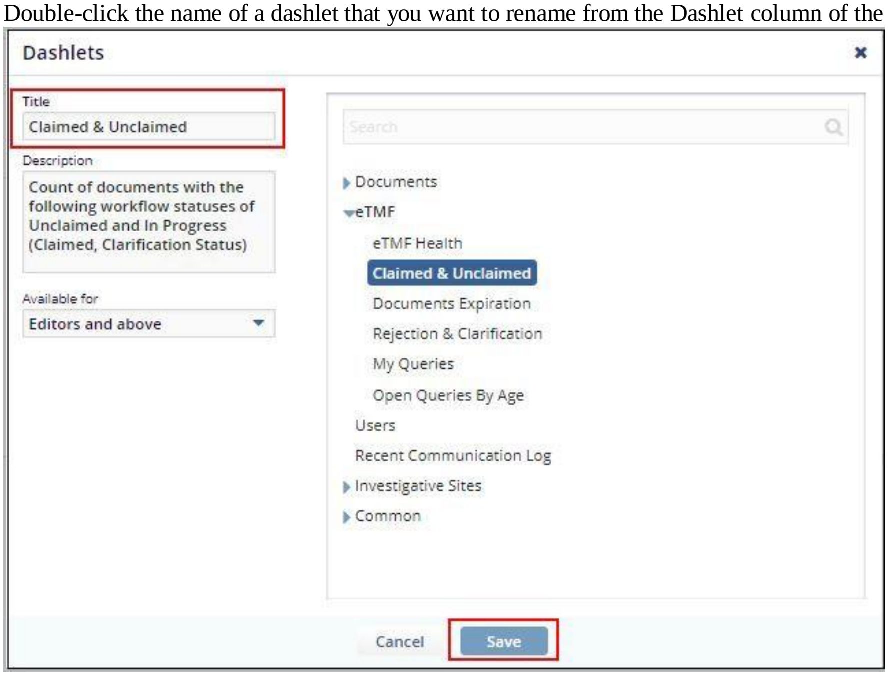
1. Renaming a dashlet
2. Default Dashboard Setup

Above activities are discussed in details in the sections below.

Renaming a dashlet

To **rename a dashlet** follow the steps as below:

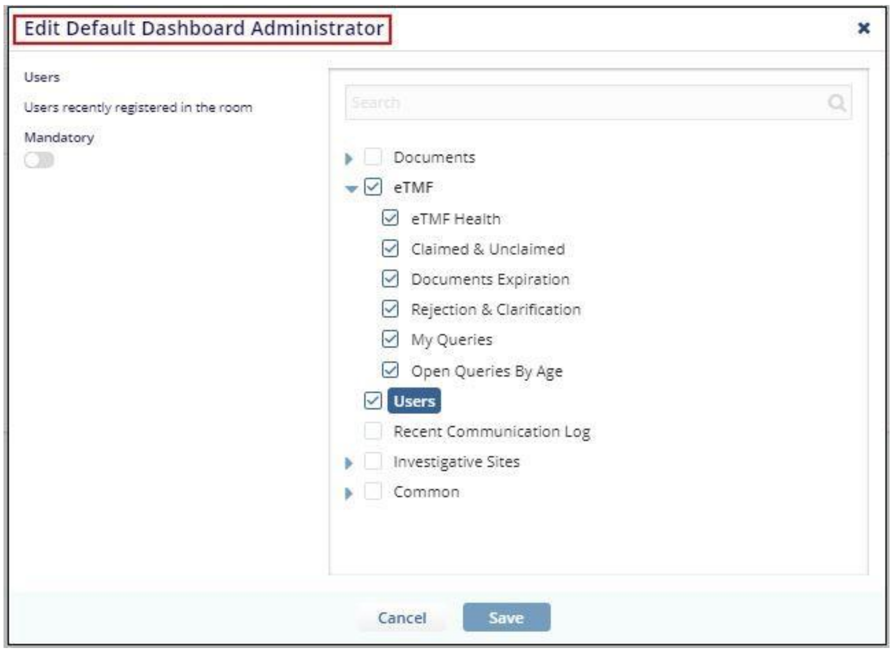
1. Double-click the name of a dashlet that you want to rename from the Dashlet column of the Dashboard Setup window.



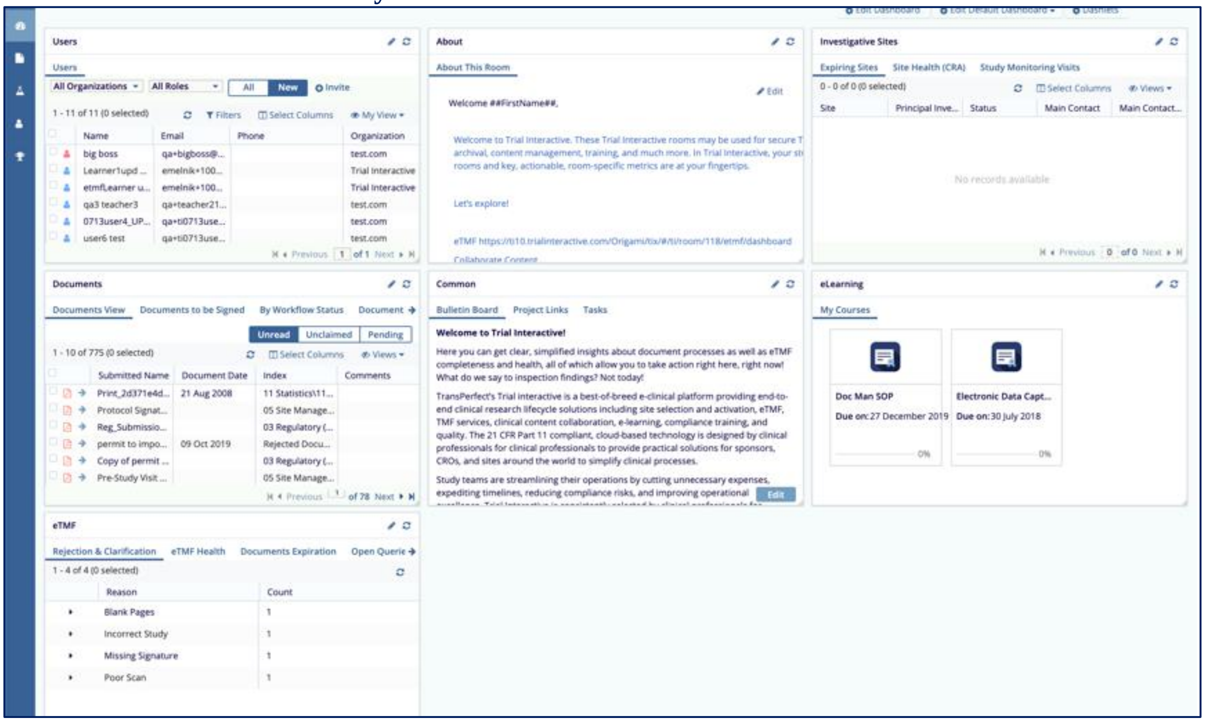
2. Type in the new name into the activated field.
3. Click **Save**.

Default Dashboard Setup

You can set the default dashboard for the minimum level role by clicking the button at the bottom of the Dashboard Setup panel. The Default Dashboard Setup window opens. Make the appropriate choices as required and click OK.



Three-Column Dashboard Layout



Trial Interactive 10.1 brings back the 2 and 3 columns look to the dashboards as well as the single column tabbed view introduced in TI 10. This provides more flexibility, allowing dashlets to be repositioned and configured to fit the needs of your team.

All standard TMF dashlets are available to show in different chart styles, such as donut, horizontal and vertical bar chart layouts.

If project training is required for access it is clearly shown in an eLearning dashlet with courses listed.

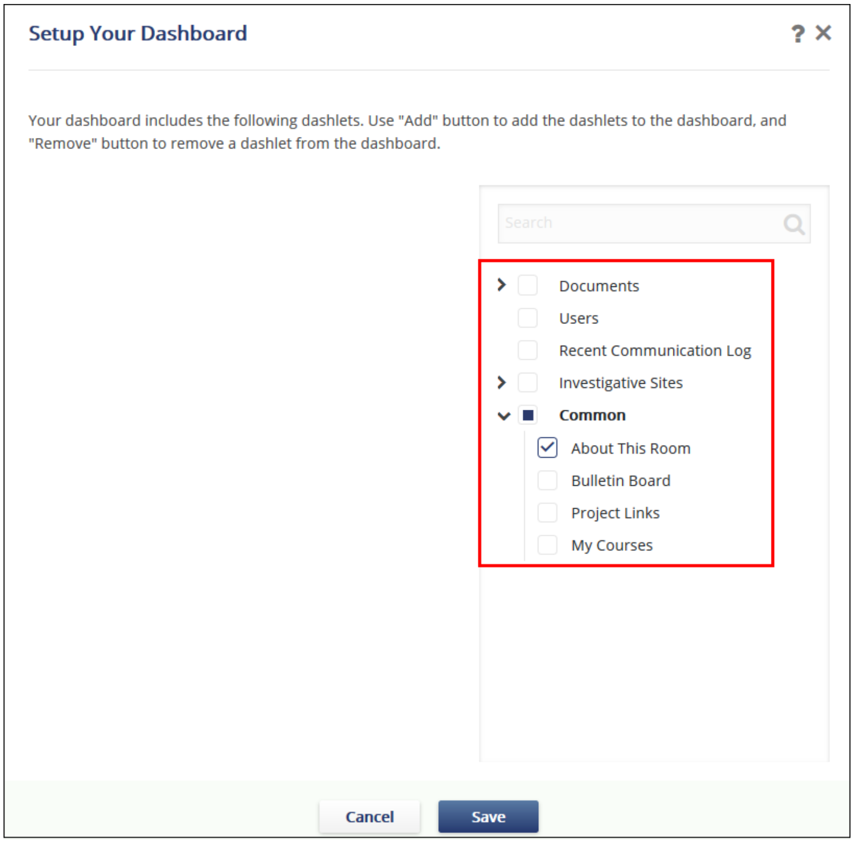
For Content Management customers, the in progress collaborative reviews are shown, as are popular documents, favorites, approvals, and required signatures. Finally, administrators can set the default dashlet layout for each major role directly from this page, defining it for all users of the eTMF or room.

In order to enable the multiple column layout, press the Edit Dashboard button on the dashboard and choose Setup Layout. This will enable you to choose the number of columns visible on the dashboard. This can be customized for each of the available dashboards within TI.

Configure Dashboard

The ***Configure Dashboard*** icon at the top right corner of the Dashboard page opens the **Setup Your Dashboard** window which lists out the dashlets available for a particular dashboard.

Refer to the screenshot below:



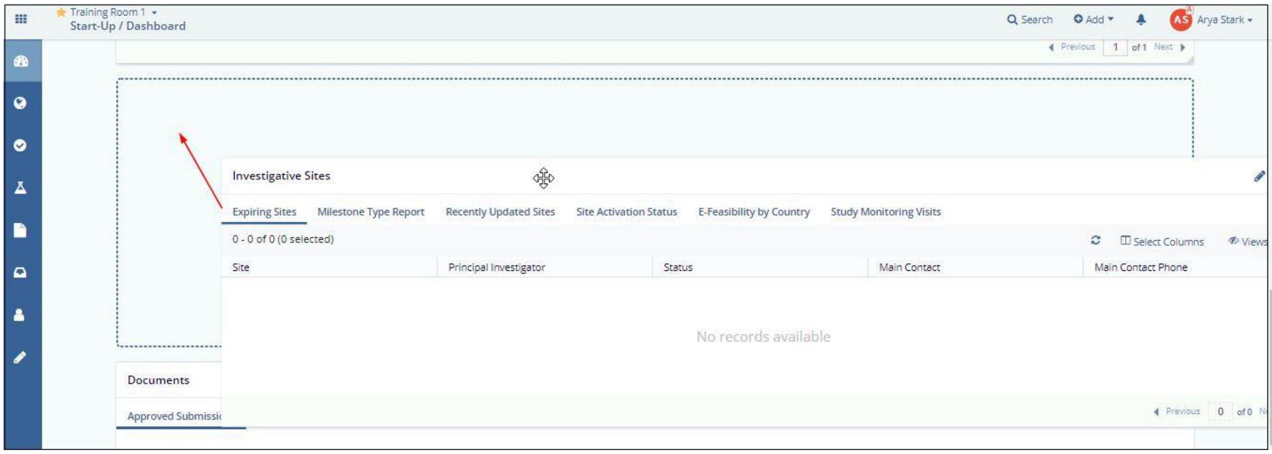
The dashboard is divided into the following parent dashlets which have child dashlets associated with each of them:

1. Documents
2. Users
3. Recent Communication Log
4. Common

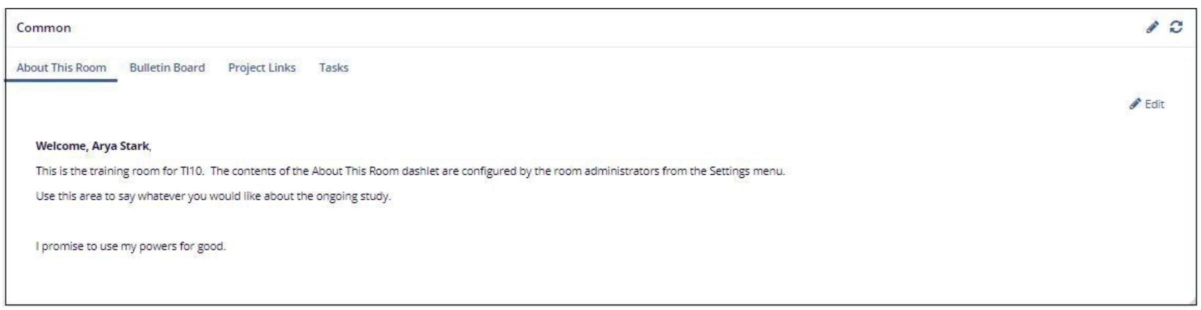
   Click the arrow next to the required parent dashlets to revel the child dashlets to add them to the dashboard as shown in the screenshot above. On selecting the dashlets, click **Save** and the dashlets appear on the dashboard.

Laying Dashlets in your dashboard

To arrange the dashlets, simply drag-and-drop them to a location of your choice on your dashboard. This is demonstrated below:



Dashlet – Common Grouping



The Common Dashlet gives an overview of the room and the related information to the room. Administrators can rename the dashlet by clicking the Edit icon from the top of the right corner of the dashlet and refresh the dashlet by clicking the

Refresh icon.

The following tabs are available in the dashlets:

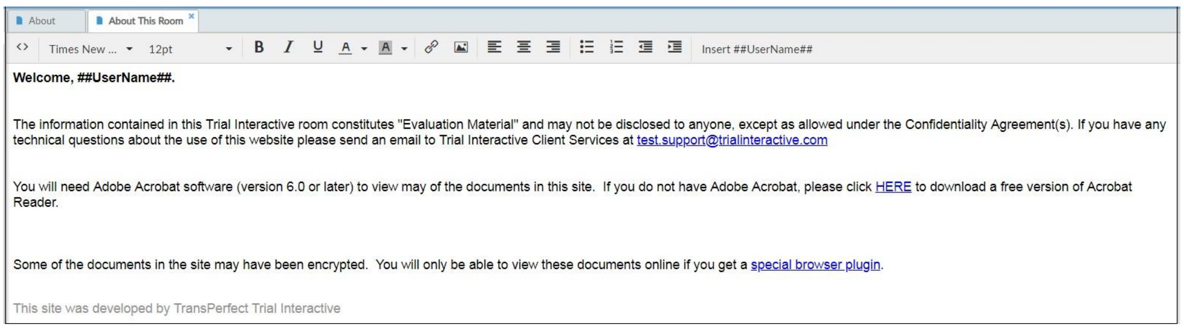
1. About The Room
2. Bulletin Board
3. Project Links
4. Tasks

Each of these is discussed in the separate topics. Click the topics on the left to open the topic.

About This Room

In this window, the user can see and change the information contained in the room's Welcome message, which is the message that all users see when they access the room. This space can be used to share important information about the study once the study is in full swing, and the welcome message is no longer necessary. Once you have made the desired changes, click Save in the lower-left corner of the box.

You can view the Change Log History by using the Change Log button that is directly available on the bottom right corner of the About this Room dashlet.

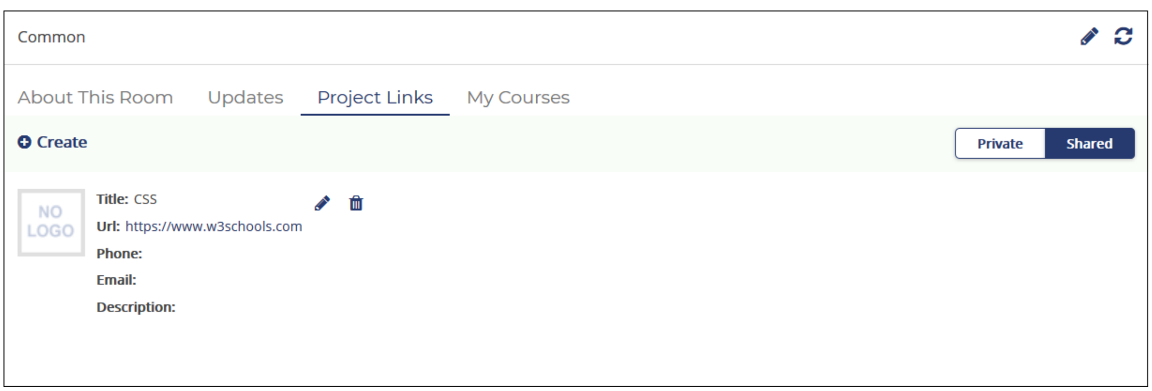


Dashlet Common - Bulletin Board

This is set up by the administrators to provide messages to the team which can be information regarding a room or problems within a study. It can be configured only by the administrators, and the reader can only see the information but could not edit.

Dashlet Common - Project Links

The Project Links tab displays the links to different systems that are used for the study and their contact information.



Note: *The project links are displayed in the tab only when you select the Shared button located at the right of the tab.*

Following activities are available for the administrators in the Project Links tab:

1. Adding a new link
2. Editing a link
3. Deleting a link

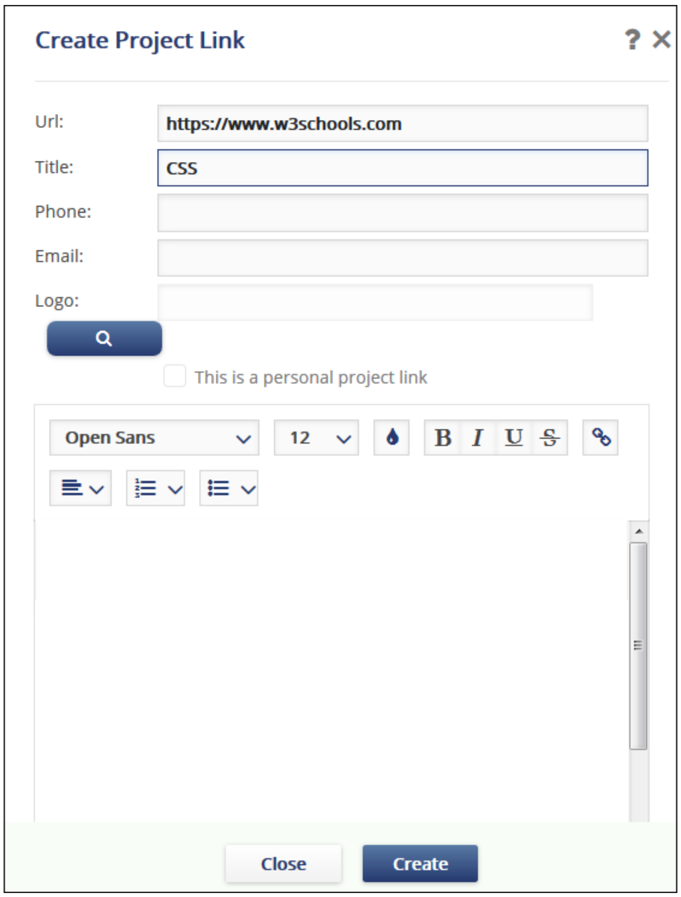
Each of these activities is discussed in the sections below:

Adding a new link

To add a new link:

1. Click the **Create** 

button from the top left corner of the tab.
2. The **Create Project Link** window appears.
3. Enter the URL, Title, Contact details, Email, Logo, and any description.
4. Click **Create** at the bottom of the window. The link is added to the Project List. Refer to the screenshot below:



Editing a link

Click the **Edit** icon next to the link. Follow the on-screen instructions and edit the required details.

Deleting a link

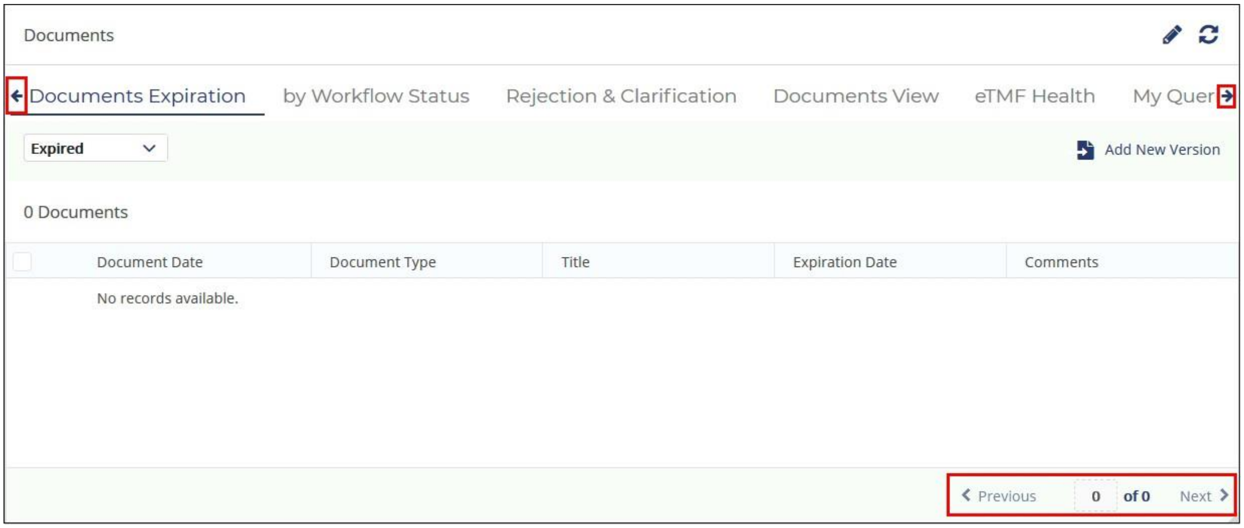
Click the **Delete** icon next to the link. Follow the on-screen instructions to delete the link.

Dashlet Common - My courses

This displays the courses you are assigned to and is configured by the administrator.

Dashlet – Documents Grouping

The Documents Dashlet gives an overview of the all documents and their related activities in a room. Refer to the screenshot below:



The dashlet provides the Right and Left arrows to the extremes of the dashlet to allow you to navigate to the sub-dashlets dashlets contained in the Document Dashlet.

Besides, for every dashlet of the Documents Dashlets, you can also use the Previous and Next arrows to move among the documents in the dashlet as shown in the screenshot above.

The Documents Dashlet contains the following tabs related to documents:

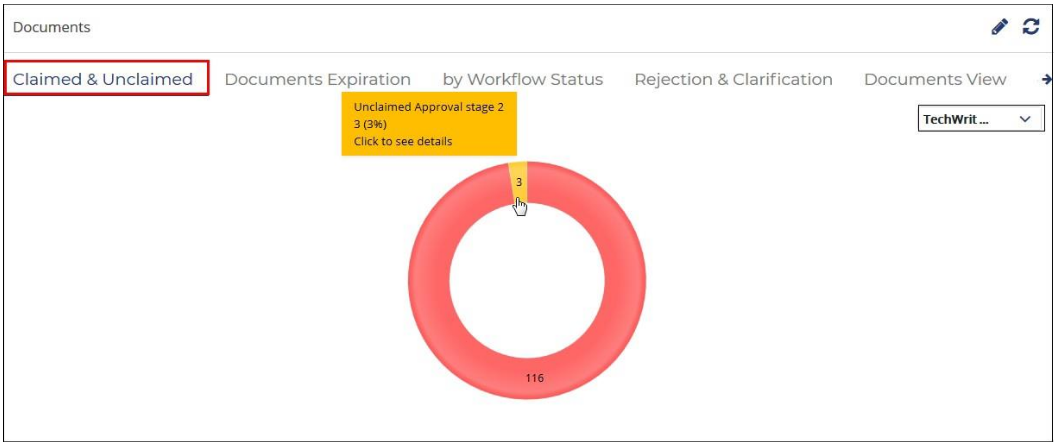
1. Claimed & Unclaimed
2. Documents Expiration
3. By Workflow Status
4. Rejection and Clarification
5. Documents View
6. eTMF Health
7. My Queries
8. Documents Submissions
9. Open Queries by Age
10. Popular Documents
11. Pending Documents Review
12. Unread
13. My Favorite Documents
14. Milestones Timeline
15. Milestone Type Report
16. Tasks

Each of these is discussed in separate topics. Select a topic from the left pane to open it.

Dashlet - Claimed & Unclaimed

The Claimed vs Unclaimed Documents dashlet provides a count of all documents that are in workflow and are either claimed, unclaimed, or in progress. You can further click on each slice of the interactive donut chart to obtain further detailed information.

The dashlet also provides the dropdown to select the workflow as required and displays the Donut Chart as per the selected workflow. Refer to the screenshot below:

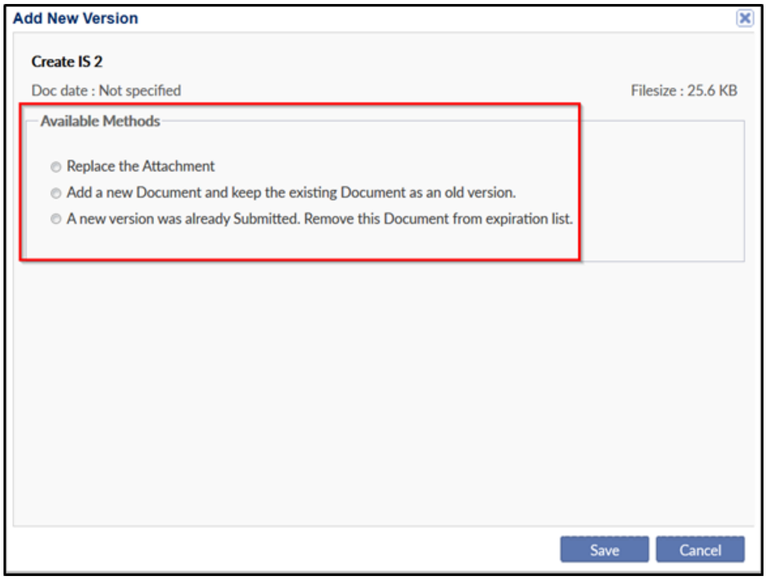


Dashlet - Documents Expiration

The Documents Expiration dashlet lists the expiring and expired documents as specified in the expiration period (N). The dashlet has two views that can be selected through an Expired dropdown. To set the views, click the **Expired** dropdown located on the top left corner. Refer to the screenshot below:

Click the Add New Version button from the top right corner of the dashlet to replace a document.

This opens the Add New Version window which provides the available methods to replace an attachment, or adds a new document and retain it alongside the older version or remove the older version if a new version is already submitted. Refer to the screenshot below:

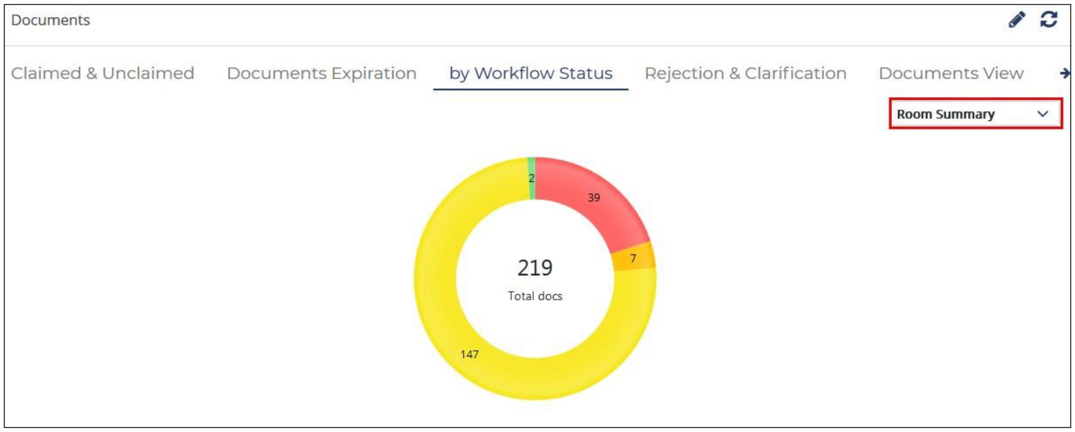


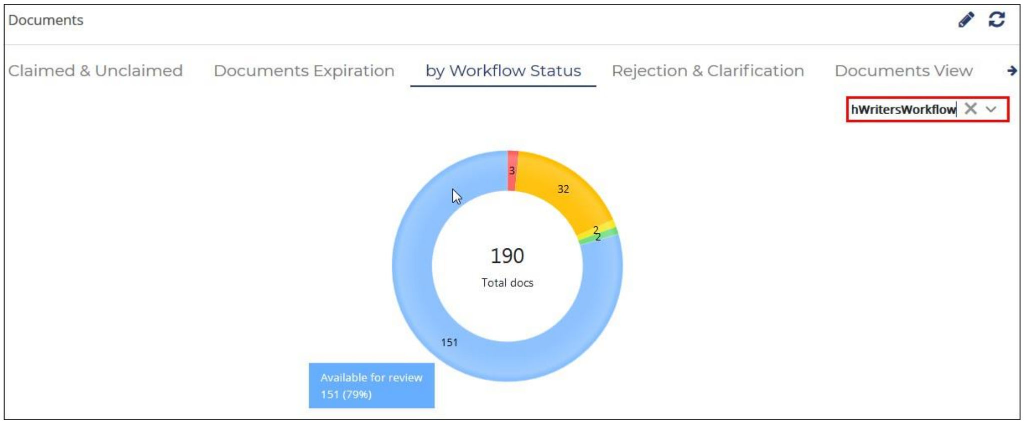
Dashlet - Documents by Workflow Status

The Documents by Workflow Status dashlet displays the document processing status in the document review workflow through a donut chart. By changing the dropdown menu, you can view the document processing status:

1. As a complete Room Summary, or
2. As workflow stages defined.

Refer to the screenshots below:

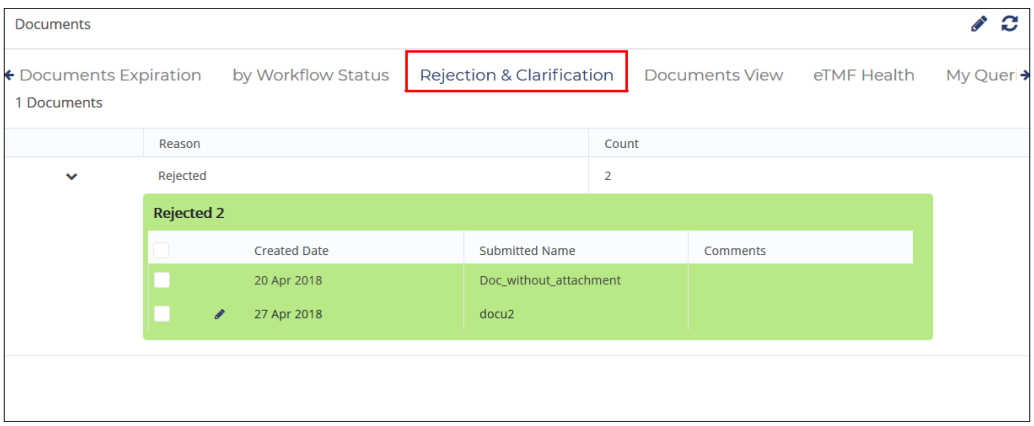




Dashlet - Documents Clarification and Rejection

The Documents Rejection and Clarification dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.

You can further double-click on the count to view the list of documents associated with a particular rejection or clarification reason. Refer to the screenshot below:



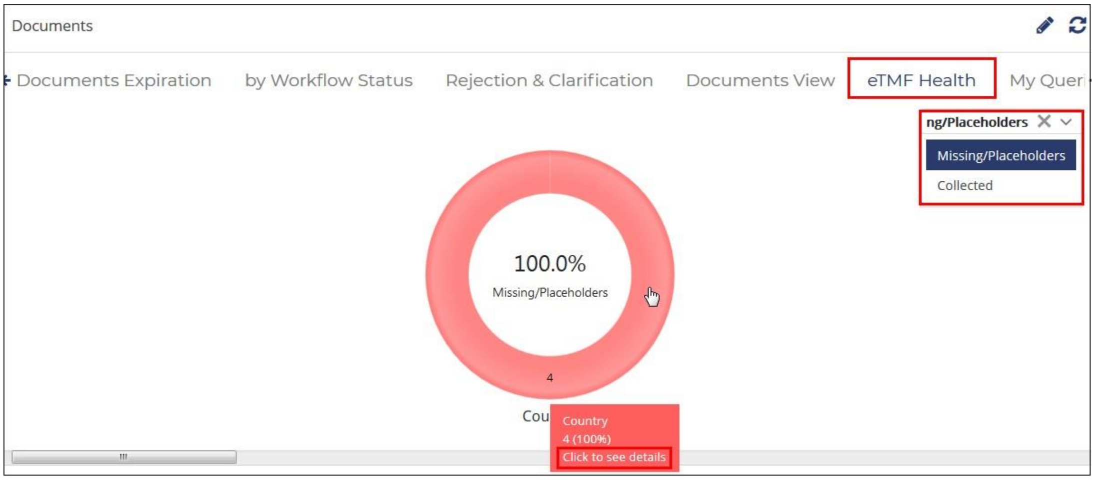
Dashlet - eTMF Health

The eTMF Health dashlet displays a donut chart that indicates what percentage of required eTMF documents are either collected or currently missing. From the top right corner of the donut chart, Administrator users can manually set the chart type to be displayed.

Hovering the mouse over the donut chart shows a popup with a more detailed progress percentage for the category of the documents.

Click a donut to drill down to the lowest level to list the missing/placeholder documents. Additionally, you can use the

Add Placeholder button to conveniently upload a missing document/placeholder or to edit a placeholder right off the dashlet. To view any changes, refresh the chart to update the missing documents list. Refer to the screenshot below:



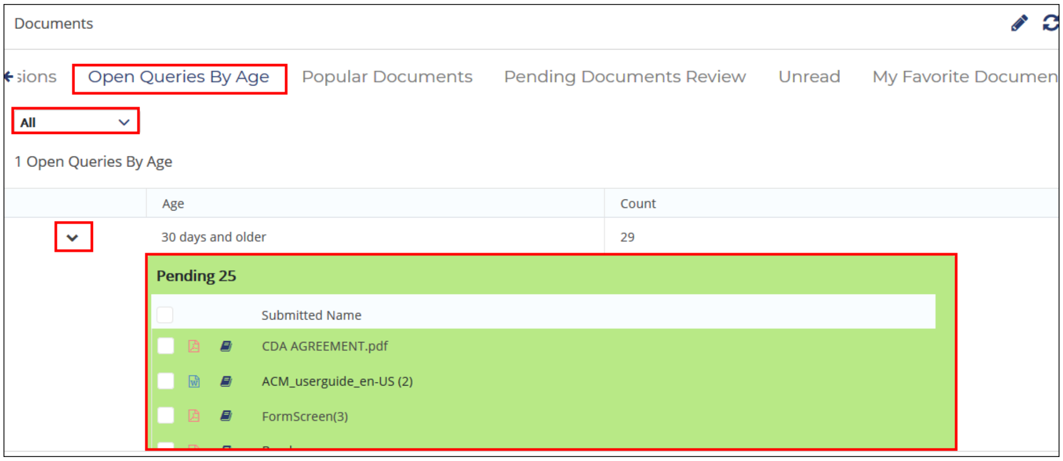
Dashlet - My Queries

The **My Queries** dashlet gives a list of documents based on their query types. The query types could be All, Workflow, or Audit. Refer to the screenshot below:

Click the **All dropdown** to toggle between different views to view the queries.

Dashlet - Open Queries by Age

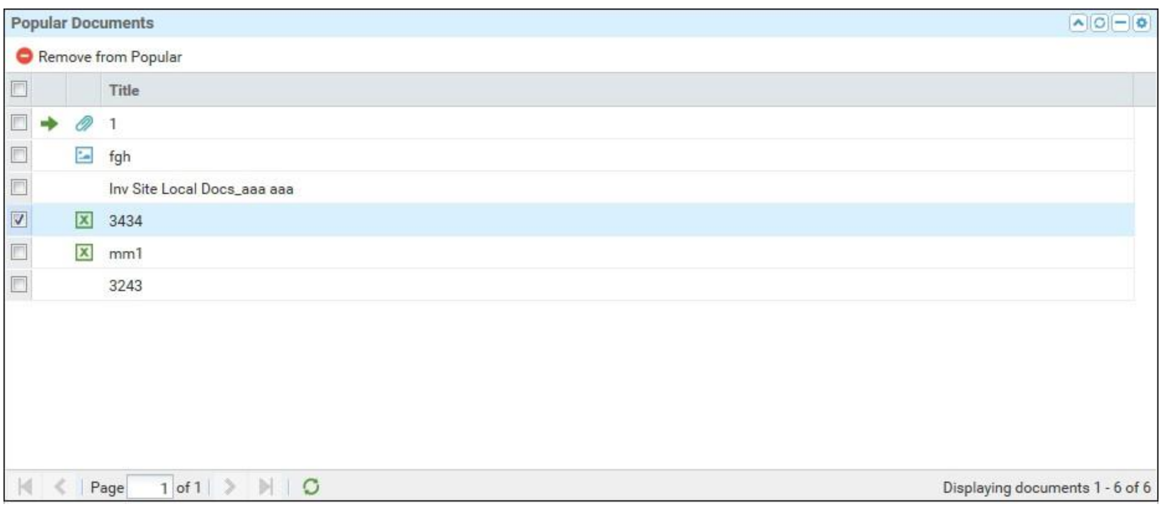
The Queries by Age dashlet conveniently displays those documents that are 30 days and older in age and also provides a documents count. The query types could be All, Workflow, or Audit. Click the arrow next to the age to reveal the queries listed in the query type. Refer to the screenshot below:



Dashlet - Popular

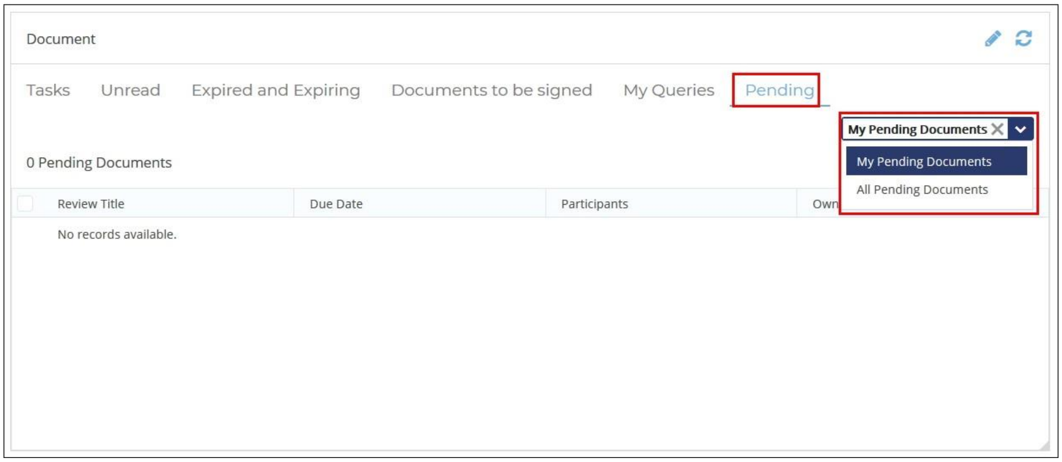
The **IP Release Documents** dashlet displays the list of documents that have been **marked as popular** ***(page 289)*** by an Admin or Editor through the Document Cart and which are used frequently.

To remove a document from the Popular list, click **Remove from Popular** button on the dashlet. To view the document, click the icon. Refer to the screenshot below:



Dashlet - Pending Documents Review

The Pending Documents Review dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for All users, or only for yourself through My Review. Refer to the screenshot below:

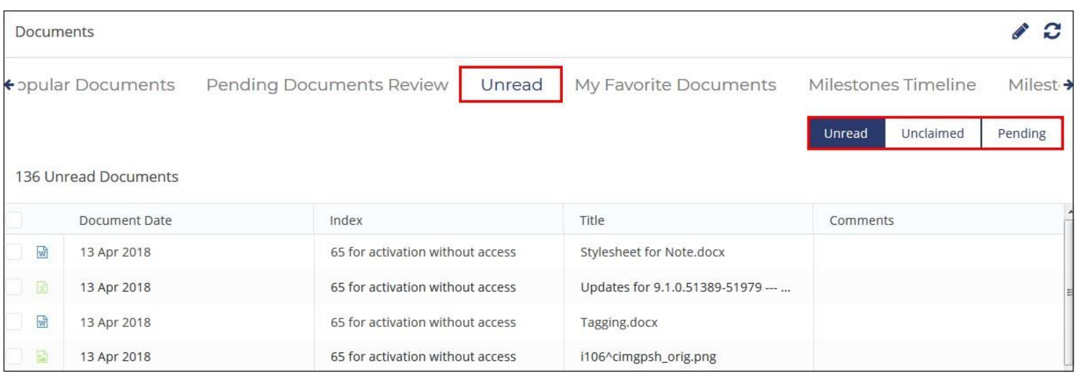


Click the All Pending Documents dropdown from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

1. **My Pending Documents**: This displays the list of all pending documents that are assigned to you for review.
2. **All Pending Documents**: This displays the list of all pending documents that are pending for review in a room.

Dashlet - Unread

The Unread dashlet shows the three different views of documents in eTMF module - Unread, Pending, and Unclaimed. Refer to the screenshot below:

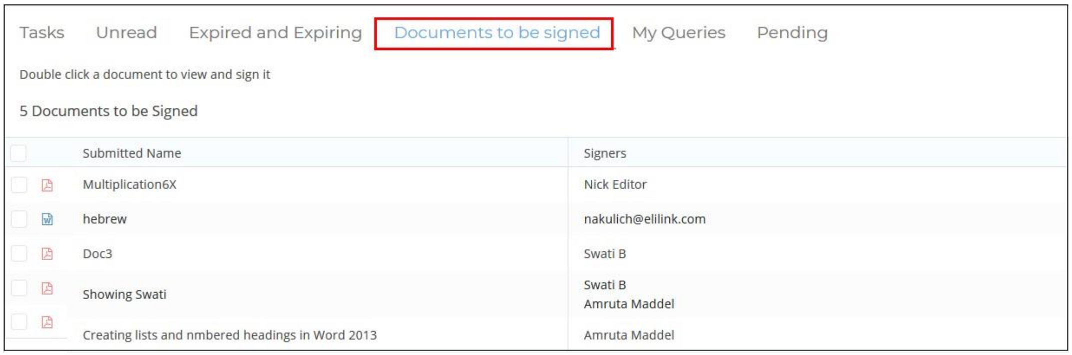


Click the Unread button to list any of the documents posted in the Trial Interactive site that has not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of.

Click the Unclaimed button to get a list of documents that have not been claimed for review. Click the Pending button to get a list of documents that are yet to be reviewed.

Dashlet - Documents to be Signed

The Documents to be Signed dashlet gives a list of document pending for signature. Refer to the screenshot below:



Dashlet - Milestone Type Report

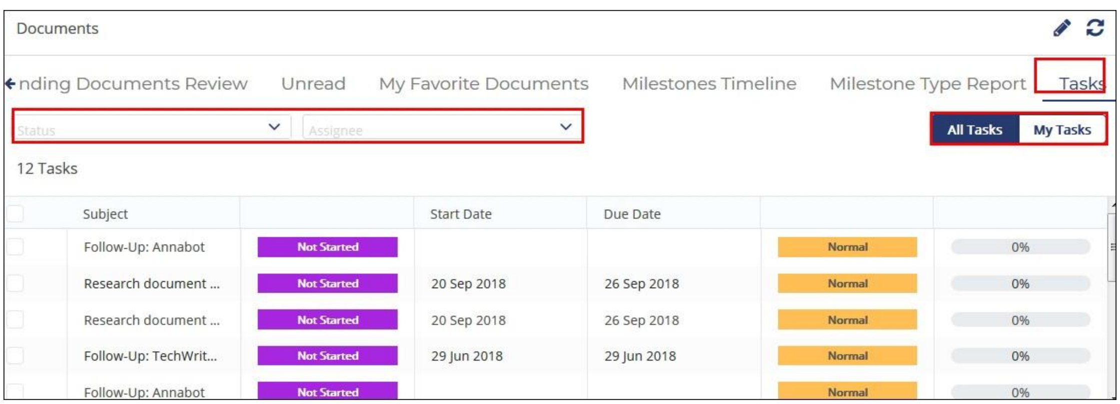
The Milestone Type Report dashlet gives the percentage of missing/placeholder documents or collected documents for a particular milestone type associated with a site in the form of a bar graph.

Dashlet - Tasks

The Tasks dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the Status and the Assignee from their respective drop-downs to get the task details.

All Tasks lists all the tasks belonging to the selected assignee.

My Tasks lists all the tasks pending recently, today, or are overdue.

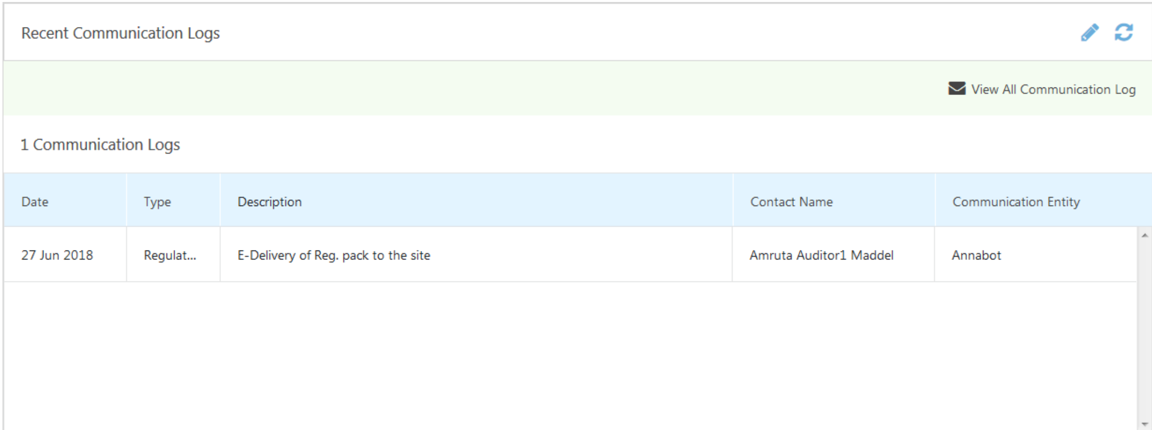


You can also export selected tasks or all tasks in the current grid by clicking the Tasks Export icon located on the top right corner of the dashlet. After the export job is over, you can retrieve the job result from the Notifications (page 64) by clicking Get Job Result which then downloads the export job as a .xlsx file on your hard disk.

Dashlet - Recent Communications Log

The Recent Communication Logs dashlet gives a list of all communications made during the site start-up and activation stage.

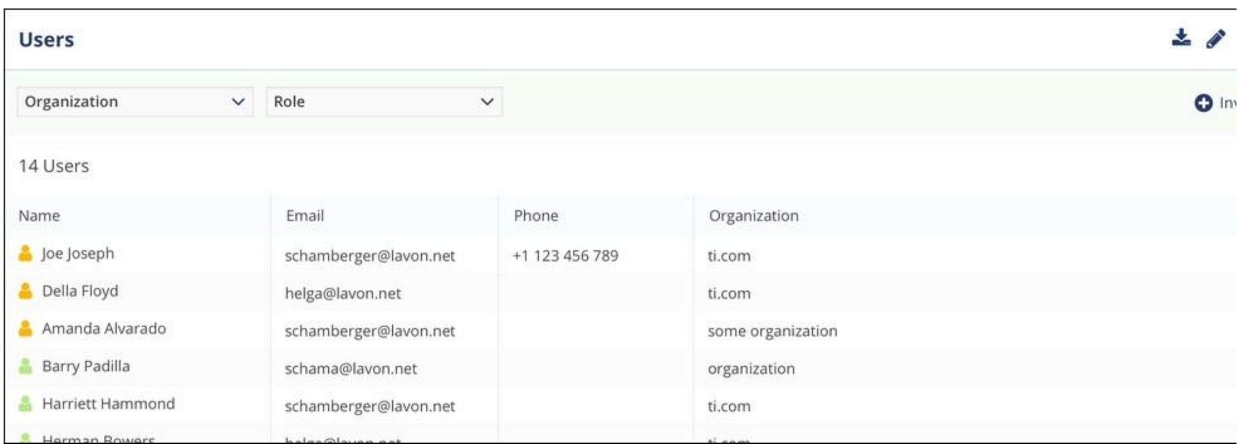
Clicking the View All Communication log link from the top right corner of the dashlet to view the list of all communication log. Refer to the screenshot below:



You can also rename the dashlet by clicking the Pencil icon to the right of the dashlet and refresh the dashlet by clicking the Refresh icon.

Dashlet - Users

The Users dashlet provides a helpful option that lists new users or all users in a study with filters to sort users by organization and by their organization and access level (role). You can also invite a new user here by clicking the Invite button placed in the upper right corner. Double-clicking the icon next to the Last name opens the Edit User popup to allow editing of the user profile. Refer to the screenshot below:



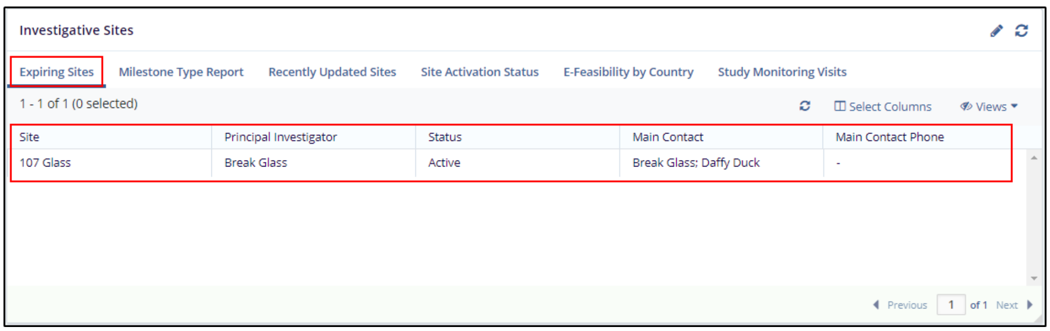
Dashlet - Investigative Sites

The Investigative Sites dashlet display the overview of Sites in the form of Pie Chart. The dashlet contains the following tabs for the related to the sites:

1. **Expiring**: Display the details and count of expired sites in the form of Pie Chart.
2. **E-Feasibility by Country**: Display the count and details of sites based on E-Feasibility by Countries.
3. **Study Monitoring Visits**: Display the count of sites based on the Study Monitoring Visits.
4. **Recently Updated**: Display the count of all recently updated sites.

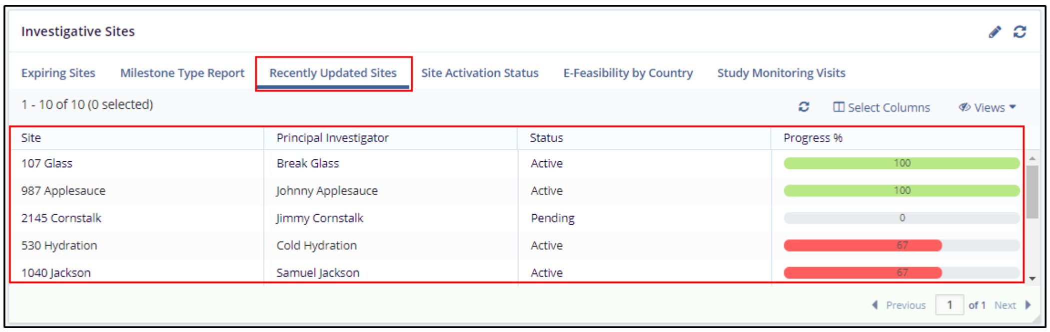
Dashlet - Expiring Sites

The **Expiring Sites** dashlet gives a list of all sites that are expiring in a future date. Refer to the screenshot below:



Dashlet - Recently Updated Sites

The Recently Updated Sites gives the activation progress of all sites in a room. Hover the mouse over the Progress % column to view the list of documents that are missing to complete the site activation. Refer to the screenshot below:

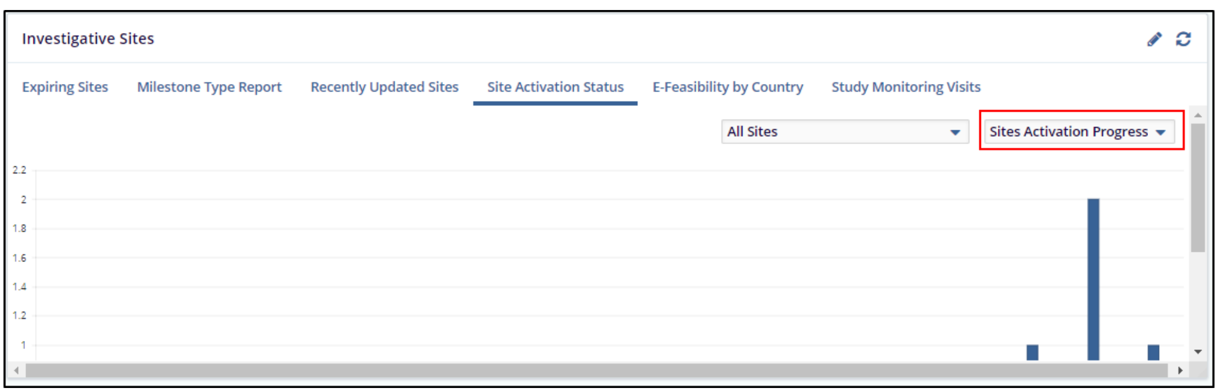


Dashlet - Site Activation Status

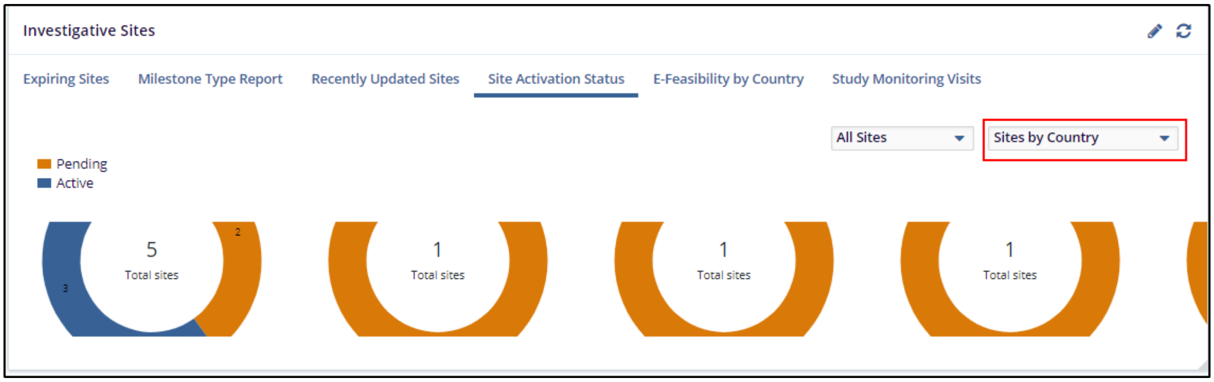
This dashlet offers three views – Sites By Country, e-Feasibility By Country, and Sites Activation Progress.

Select the Site By Country view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshots below:

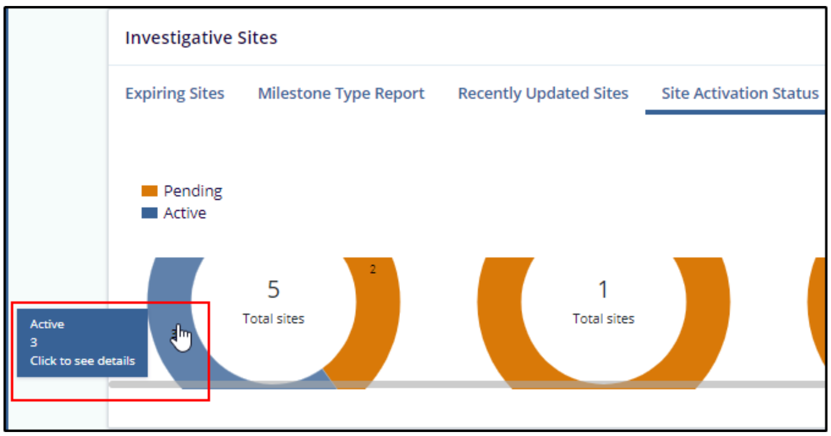
Site Activation Progress Screenshot -



Sites by Country Screenshot -



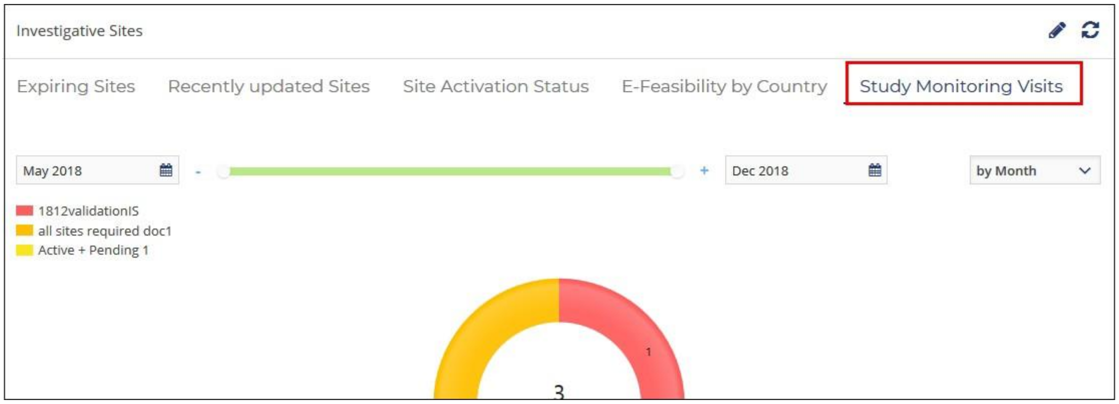
Hover the mouse on any part of the chart to view the details of the site, see below -



Drilldown to the specific site, see below -

Dashlet - Study Monitoring Visits

The dashlet Study Monitoring Visits provides two different views study monitoring visits – Monitoring Visits By Month, and Monitoring Visits By Country, in the form of a donut chart. This dashlet can be configured to display the Visit Date instead of the Created Date through the Configure Dashlet feature as discussed above. Refer to the screenshots below:



The dashlet provides the Date Ranges to filter the sites. Besides selecting dates in the date columns, you can also scroll the bar between the ranges to filter the sites.

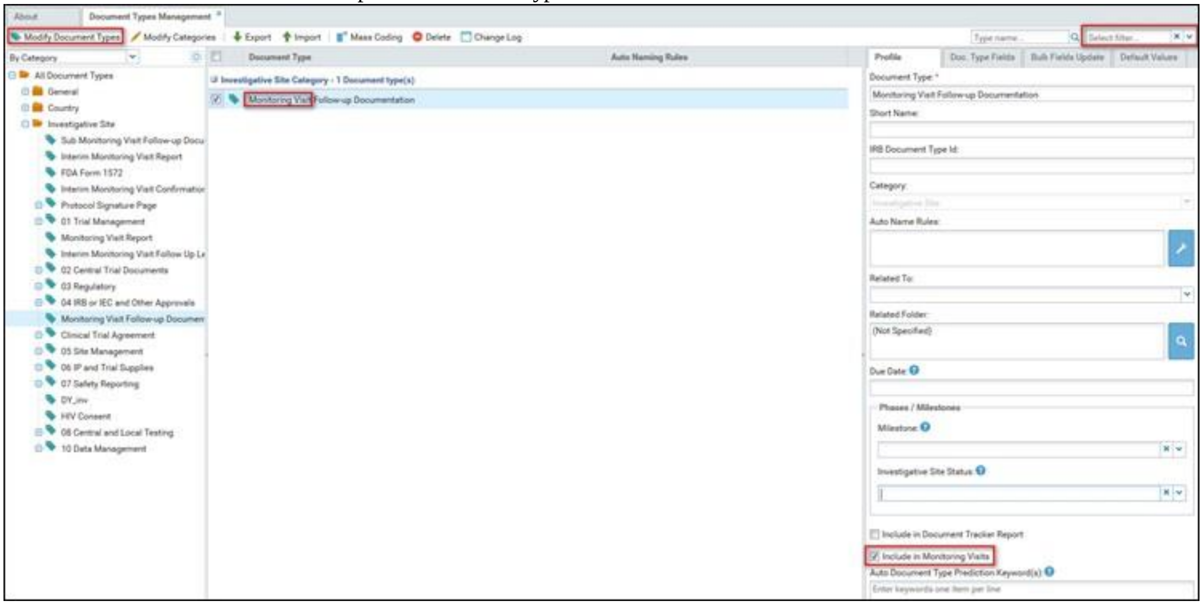
When you select the 'By Country' option from the dropdown at the top right corner, you will finally be able to view the documents for the particular country. Click the section on the donut chart to delve further for the country documents.

The Study Monitoring Visits dashlet is connected to the Document Type Settings. Therefore, Administrator users can go to SettingsàDocumentTypesàDocumentTypesManagement, *(page 105)* and assign or modify document types. Through the configuration box, users can manually specify whether to include the document in the Monitoring Visits or not.

If you choose to include a new document type, the Study Monitoring Visits dashlet will be updated to reflect the change.

For your convenience, a search box and a filter option are also available in the Document Type

Management section in the Settings. These features help users track which documents, and how many documents are needed to be collected for specific document types. Refer to the screenshot below:



Dashlet - CollaborativeReview

The Collaborative Review dashlet gives you an overview of all the documents that are in a Collaborative Review. Refer to the screenshot below:

The following dashlets are available in the Collaborative Dashlet:

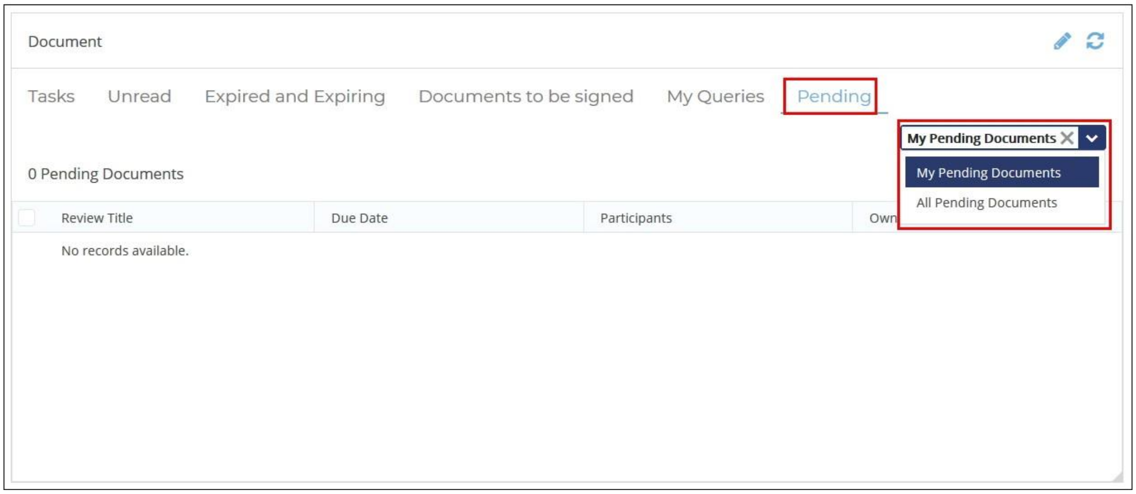
1. Documents to Approve
2. Documents to Sign
3. Pending Documents Review
4. Collaborative Documents

Dashlet - Documents to Approve

This dashlet displays the list of all documents that are pending for approval in TI Collaborative. Click the document to open the document for approval.

Dashlet - Pending Documents Review

The Pending Documents Review dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for All users, or only for yourself through My Review. Refer to the screenshot below:



Click the All Pending Documents dropdown from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

1. **My Pending Documents**: This displays the list of all pending documents that are assigned to you for review.
2. **All Pending Documents**: This displays the list of all pending documents that are pending for review in a room.

Dashlet - Collaborative Documents

The Collaborative Documents dashlet displays the list of all collaborative documents.

From this dashlet, you can also create a new Collaborative Profile by clicking the Create Profile button located at the top right corner of the dashlet.

Documents View

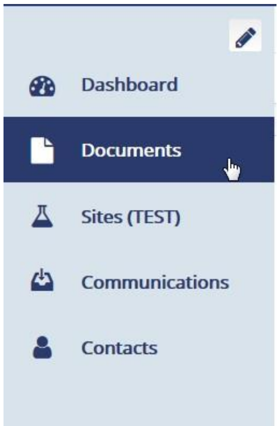
The Trial Interactive eTMF Documents is the central repository for all the clinical trial documents in their original digital format with Digital Signatures *(page 255)* wherever applicable, records, or documents converted from one format to another like paper documents, images converted to PDFs *(page 255)*, besides videos and recordings pertaining to trials.

Here, you can configure and store trial master file 'essential documents' pertaining to clinical trials, view and edit documents attachments, manage security privileges on them, import and export documents and their metadata, mail them to other users besides many others.

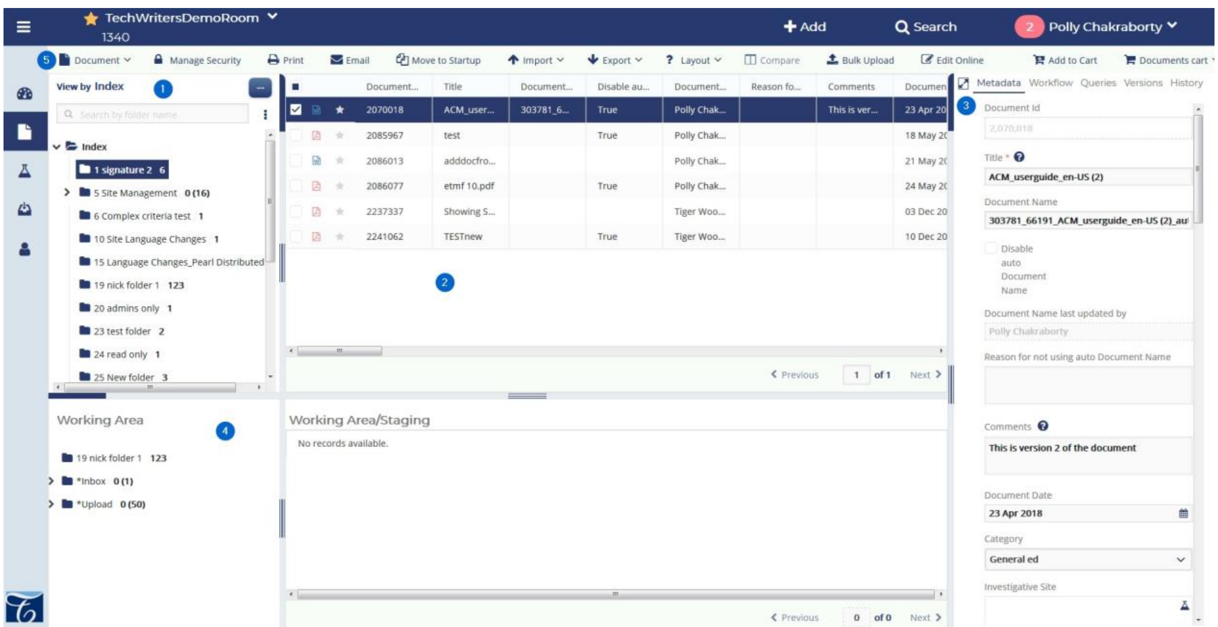
To comply with eTMF Completeness, you can track the progress right from documents collection to the finalization of a document through Milestones and assignments of Tasks to authorized personnel. Besides, this application also provides you with the facility to post Questions and Answers along with the generation of FAQs for further insight.

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

You can access the Documents View by clicking the Documents icon from the menu bar at the left of the dashboard. Refer to the screenshot below:



Clicking the **Documents icon** from the menu bar at the left leads you to the **Documents dashboard**. Refer to the screenshot below:



Refer to the table below for more description on each numbered part.

Table 1: The Documents View

No.	Part Name	Description
1.	The Room Index *(page 224)*	The Room Index consists of folders organized into a tree-like structure starting with **Index** as the root folder.
2.	The Documents Grid *(page 241)*	Select a chid folder from the Index to populate and view its documents in the Documents Grid.
3.	The Document Data Panel *(page 261)*	Tick a checkbox next to a document in the Documents Grid to populate the Document Data Panel.
4.	The Working Area *(page 259)*	Shows the record of the document currently working in.
5.	The Top Ribbon Bar *(page 269)*	Access various functionalities required for eTMF operations from here.

Click the links in the table below for more details on each part or section.

Documents Module Settings

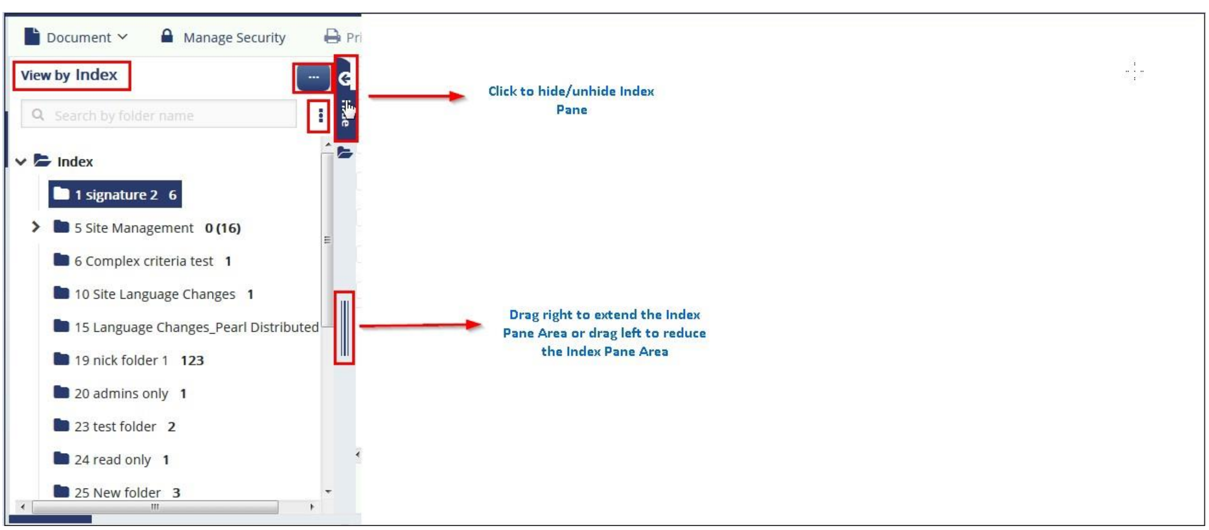
Important:

- *All documents added/imported to a room get populated in the Upload folder by default unless the Default index position is specified in the document settings.*
- *Documents emailed to the room will find its way to the Communication Inbox or the eTMF Inbox as per the room settings.*

  The settings that need to enable for a document are discussed in detail in the Settings → Documents → Documents Module. *(page 97)*

The Room Index

- The Room Index consists of folders organized into a tree-like structure starting with **Index** as the root folder.
- The Index consists of **parent and child folders** and can either be cloned during room creation or created from scratch.
- The Index Folders are categorized as per the **Document Types** specified from the Room Settings and consist of three main categories – **General**, **Country Management**, and **Site Management**.
- **Documents emailed to a room get stored in the room's Inbox folder.**
- **Similarly, all documents imported are populated in the Upload folder.**
- If a folder contains subfolders, you can **expand** it to list its content by clicking the expand arrow icon next to a collapsed folder.
- Similarly, you can **collapse** an Index folder by clicking the collapse arrow icon next to an expanded folder.
- To locate documents in a child folder, you drill down to the last child folder and click on it.
- The documents in the child folder populate in the **Documents Grid**.
- Tick a checkbox in the Documents Grid to view its metadata in the **Metadata tab** of the **Right Panel**.
- Besides the Metadata tab, the **Right Panel** also consists of the **Workflow, Queries, Versions, History, and eSignature tabs**.



From the Index Pane:

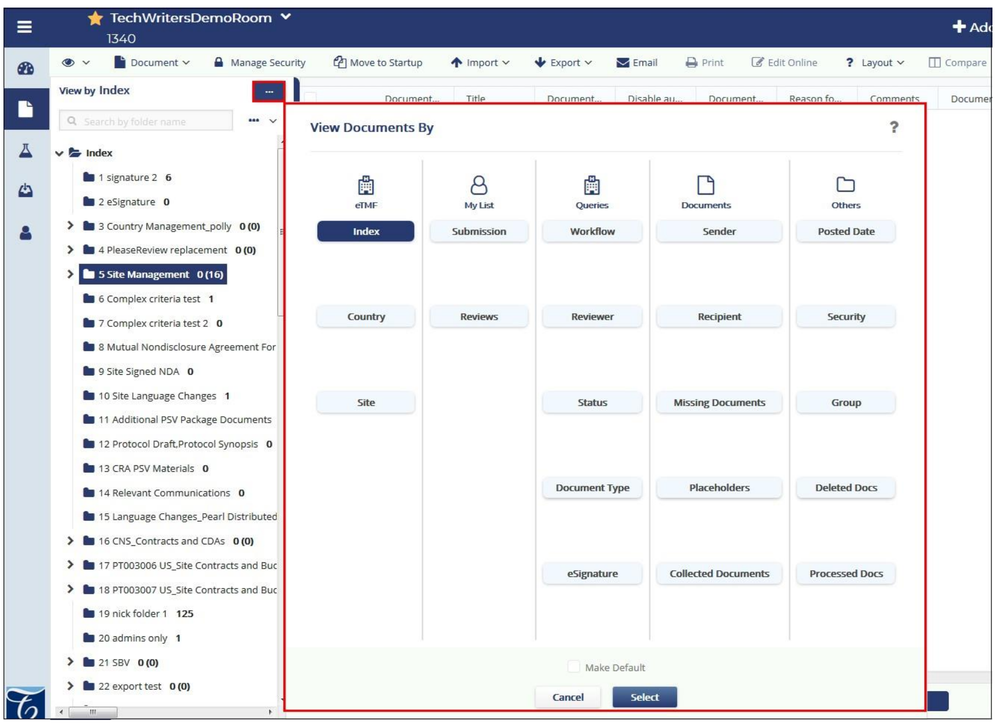
- View the room's folder structure *(page 225)*
- Search and navigate to sub-folders *(page 241)*
- Modify Index Structure *(page 238)*
- Export Index *(page 240)*
- Refresh Index *(page 240)*
- View Security on an Index Folder
- Export documents from an Index Folder
- Add documents to an Index Folder *(page 297)*
- Index Outline Settings and By Index View *(page 101)*

Choose View - Viewing the Room's Index Structure

You can view a room's index and its documents from the Index Pane of the room. From the Index Pane, you have access to various kinds of views to the folder structure. The default view provided by the system is By Index.

To toggle between the various views of the Index Structure:

1. Click the **Choose View** button on the Index Pane.
2. This opens the **View Documents By** popup with various view options. Refer to the screenshot below:



Tip: *Select a view and tick the **Make Default** checkbox to make that view the default view. You will then see the documents sorted and grouped by the view you marked as default every time you visit the room.*

Each of the view options are discussed in separate topics available from the left pane of this help.

By Index and Index Outline Settings

Important: ***Index Outline is a group of settings that Administrators should leave unchanged. The settings here are those chosen by the client during the initial room setup. Before making changes here, consult with the Project***

Manager and/or the Client Services Team.

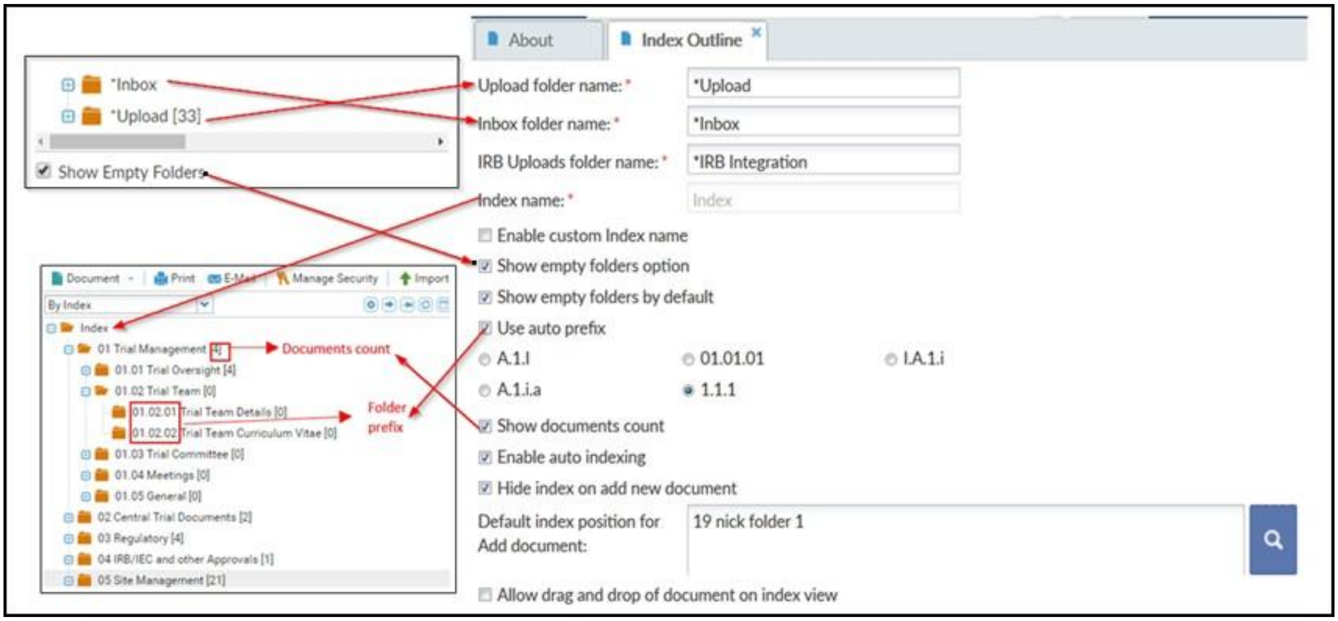
On creating the index, as an administrator, you can decide on a number of functions and appearances related to the Trial Interactive room's index from the Main Navigation ->Settings -> Documents Module -> Index Outline. You can change the names of the Upload folder, the Index folder, and the IRB Uploads folder if so requested by the client.

The following settings are configured from the Index Outline:

- By Index View
- Changing the Index Name
- Empty Folders Options
- Hide Index on add new document
- Auto Indexing

Each of these sections is discussed in detail in the sections below.

By Index View



The All View(By Index) shows the full folder index of the room with child pages. If a folder contains sub-folders, it can be expanded to list its content by clicking the expand icon.

If a user emails documents to the room, such documents get stored in the Inbox folder of the room. Similarly, all documents imported are populated in the Upload folder.

Note: ***A new Index sub-folder inherits the permissions from its parent folder.***

Auto Prefix

The folders in a room index are numbered, and the subfolders follow a standard numbering system. These folder numbers are called as Folder Prefixes, whose settings can be decided from the **Auto Prefix** option in the **Settings -> Documents Module -> Index Outline**.

Activate or inactivate Auto Prefixing of folders in the room's index by ticking the **Use auto prefix** checkbox. If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index. Auto prefixing inserts the client's requested prefix of numbers or letters to identify the levels of the folders in the index. Click the radio button for the prefix pattern requested by the client.

Documents Count

Numbers in parentheses after the folder names indicate how many documents are available to you in each folder. Click a folder to open the documents contained in it in the Document Grid.

By showing Documents count, by ticking the **Show documents count** checkbox in the settings, users in the room will see a number in brackets that indicate how many documents are in each index folder.

Changing the Index Name

If the client has requested some unique name for the room's index besides the standard 'Index', then you have to first enable the custom index name, and then type the custom name in this field.

1. If the client wants to customize the name of the Index, click the box to activate it. The Index Name field then becomes active.

2. Type in the custom name requested by the client.
3. If this is the only change requested for this panel, click **Save** at the bottom of the panel.

Empty Folders Options

In this next section of this panel, you make selections for the client regarding the appearance of Empty Folders.

You can enable or disable the **Show Empty Folders Option**. By showing that option, users in the room will see this checkbox at the bottom of the room's folder index.

Another option sometimes called for by the client is to show empty folders all the time. If that is the case with the room you're configuring, click this box – **Show Empty Folders by default**. Then, the room's full index will always show in the documents view, whether the folders are empty or not.

Hide Index on add new documents

Note: ***This setting is used only for non-admin users***

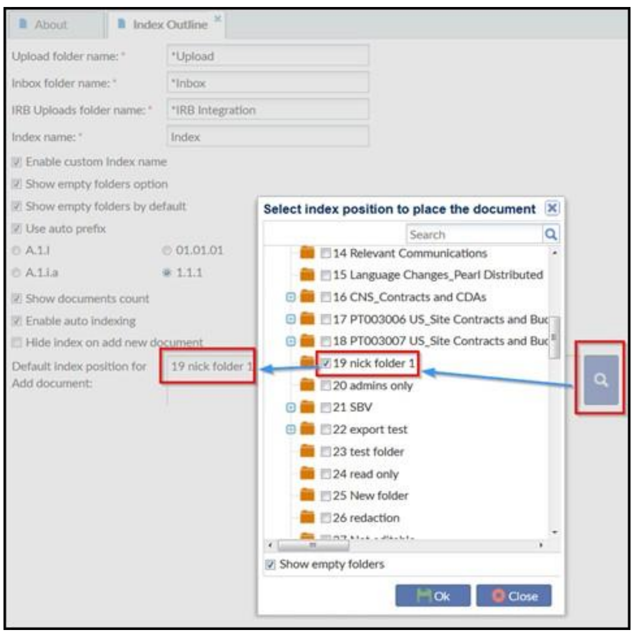
If this setting is enabled:

1. Index position will be hidden in the new document window.
2. But in case if auto-routing logic can't determine index position, this control will be displayed, so the user will be able to specify index position manually.
3. A document cannot be copied or dragged to a different location/folder by editors.

Auto Indexing

In order to activate either of these next two options – **Enable Auto Indexing** or **Hide Index on add new document** – this Default Index Position for Add Document field must be completed.

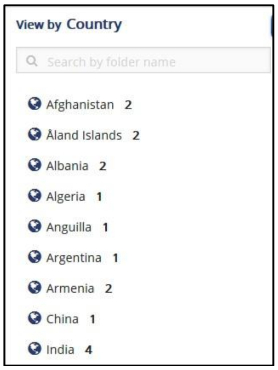
1. Click the magnifying glass. The full index list appears.



2. Select the folder indicated by the client. In this example, the folder is named **19 nick folder 1**.
3. Click **OK**. The window closes.
4. Click **Save** at the bottom of the **Index Outline** panel.

By Country

From this view, you can access all documents and placeholders of the Category Country having a country name metadata specified in its Country Field. When you access this view from within the Documents sub-module, you see all eTMF documents of the category Country. Refer to the screenshot below:



Under each country as a parent folder, the documents are further categorized by its Document Types.

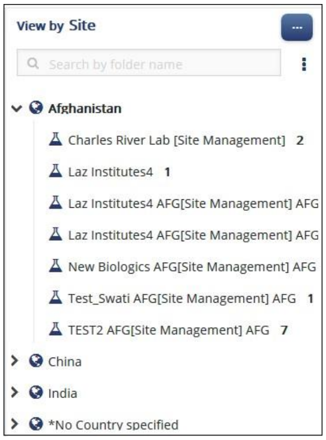
You can also view the category country documents in the By Index (page 225)view under the Country folder (the name that you provide to this folder depends on your room settings).

For more details on how to set up this folder and its hierarchy follow on to Chapter Countries (page 380). To know more about Site-Specific Country Category documents proceed to Site -> By Country view.

By Site

From this view, you can access all documents and placeholders associated with the Investigative Sites. Sites are places where clinical studies are conducted. This view shows the segregation of Investigative Site as located in various countries.

All sites belonging to a particular country are listed under their specific country. Click a site name to list the documents belonging to the site in the Document Grid. Refer to the screenshot below:



The configurations for an Investigative Site can be setup from **Settings -> Investigative Sites** ***(page 133)***. The dashlets related to Investigative Sites are:

1. Expiring Sites
2. Recently updated sites
3. Site Activation Status
4. Site Activation Progress
5. Sites Activation by Country
6. Study Monitoring Visits By Country

By Reviewer

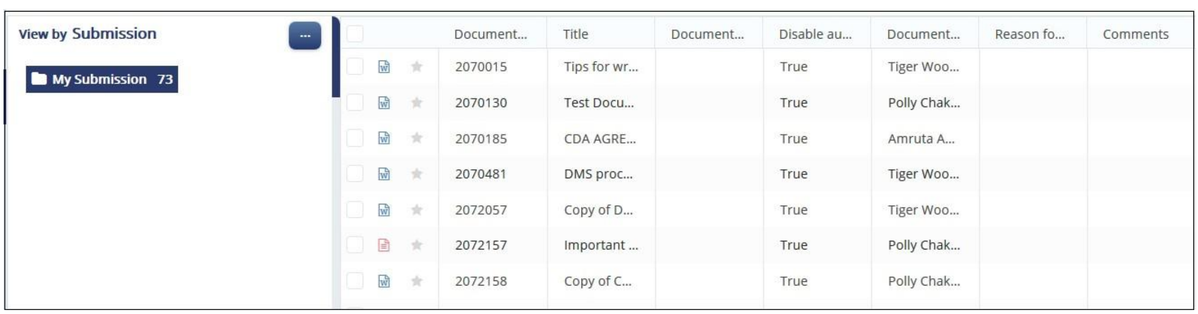
Administrators can reassign documents claimed in the workflow to other reviewers.

1. From the **Documents** view, select **By Reviewer** as the Current view for the index.
2. Open the index folder of the reviewer whose claimed documents you want to reassign.
3. Click the folder holding **claimed document** to reveal its contents. The list of that user's claimed documents populates the document grid.
4. Select the documents from the list that you want to reassign.
5. The **Reassign reviewers** button becomes active in the menu ribbon above the document grid.
6. Click **Reassign reviewers**. A **Reassign reviewers** window opens.
7. From the **Workflow** dropdown, select the workflow you want to adjust.
8. The **Stage** field auto-populates.
9. From the **Reviewer** dropdown, select the reviewer to whom you want to reassign the documents.
10. Click **OK**.

The documents are transferred to the folder for **claimed documents** of the new reviewer.

My Submissions

All the documents that the user imports, emails or adds to the room are populated in the My Submission folder. Refer to the screenshot below:



My Reviews

Note: *If you are the part of the reviewers group which you are assigned to the workflow, the My Reviews in the eTMF Documents module is automatically activated for you. You can have the same reviews as in My Reviews from the Quality Review module as well.*

Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the My Reviews view or the Quality Review module in the folder with unclaimed documents under the workflow configured by you. Refer to the screenshot below:

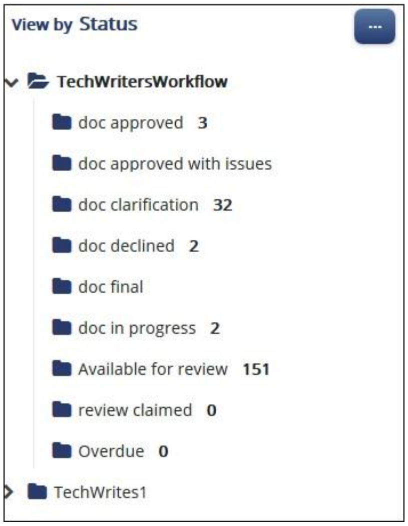
For more details on workflow, refer to chapter **Quality Control.** ***(page)***

By Workflow

From this view, you access the documents available to the user for review in the various stages of workflow. Refer to the screenshot below:

By Status

This view displays the current workflow status of documents. Refer to the screenshot:

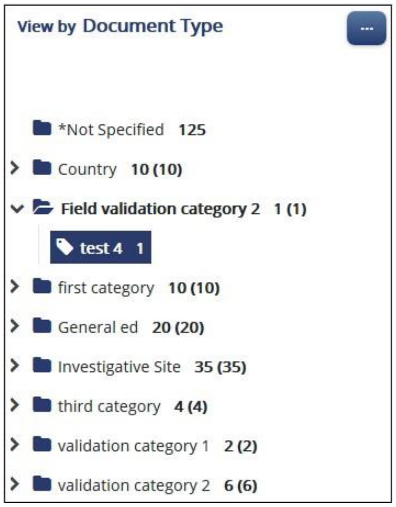


By Document Type

This view groups all documents by its Category as the parent folder. Each Category folder further holds documents grouped by document types as subfolders.

These Document Types are created from Document Types Management (page 105) in Room Settings.

Clicking each document type displays the documents of that type in the Document view. Refer to the screenshot below:



eSignature

This view groups all eSignature documents under Completed, Waiting, and Canceled category. Refer to the screenshot below:

Click the folder to view the required documents.

You can also choose to Cancel eSignature *(page 268)*by selecting a document from the Waiting for eSignatures.

By Sender

This view display documents grouped by reviewers who have raised queries on documents during a **Quality Review** or **Quality Control** and have sent them for clarification. Refer to the screenshot below :

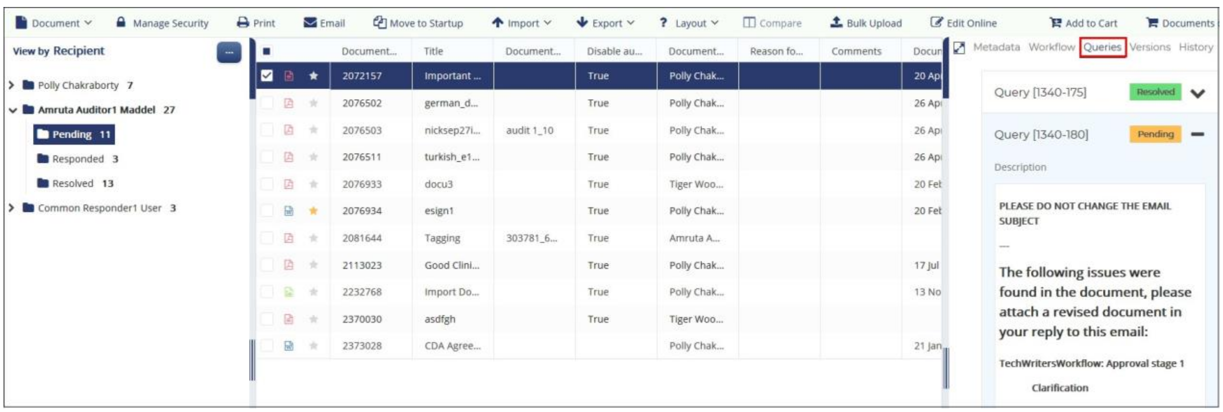
From here the user can:

1. View the query.
2. *Resolve a Query. (page 376)*
3. Respond to a Query.

Click the links above to know more in detail about each topic.

By Recipient

This view display documents grouped by the recipients of the queries received by them for clarification from the reviewers in a **Quality Review/Quality Control.**



From here the user can:

1. View a query.
2. Respond to a query.
3. *Resolve a query. (page 376)*

Click the links above to know more in detail about each topic.

eTMF Completeness

This view lists collected, missing documents and acts as a placeholder for missing documents that do not fall under the required documents section.

From within the Document Grid or from the **Add Placeholder** dropdown on the top ribbon, placeholders can be created, edited, deleted for a document. Documents can be attached to placeholders or missing documents from the **Add Document** located on the top ribbon bar or by dragging and dropping them from the Windows Explorer.

The system:

1. Creates a new document from placeholder and missing documents
2. Does not allow to change the category and related metadata if placeholder ID is present for documents.
3. Allows the user to assign placeholders to milestone histories from the **Create Placeholder** window. Refer to the screenshot below:

By Posted Date

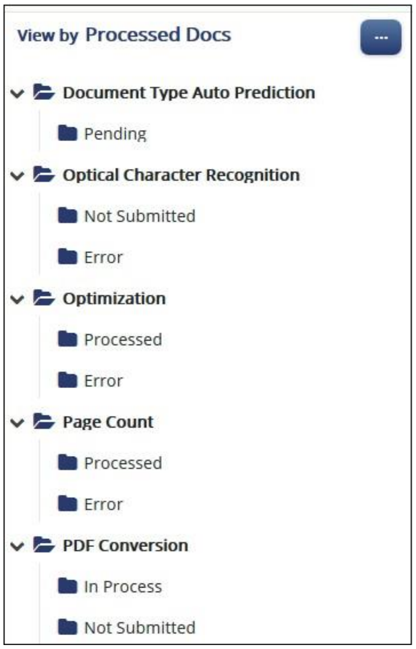
In the **By Posted Date** view, the documents are grouped as per the days they were **posted/imported/added**. Folders by posted dates are created. Clicking each folder displays the documents posted on that particular day. Refer to the screenshot below:

By Security

The **By Security** view shows all the documents based on the security accesses provided to users and group of users. Documents are segregated under folders by the name of users showing the level of their access. Refer to the screenshot below:

Processed Documents

All the documents that traverse through various processes in a study can be viewed from here. Refer to the screenshot below.



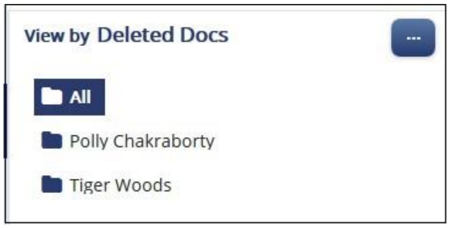
Some examples of processes in a study that the documents need to pass through are **OCR**, **Optimization**, **PageCount**, **PDFConversion**, **PDFFixation**, **PublishtoeTMF**, and **DocumentTypeAutoPrediction**. The documents are listed under each process in this. Under each process, the documents are further categorized into **Not Submitted**, **Pending**, **Processed**, and **Error**.

For example, as a user, you might want to submit documents for PDF Conversion. All the documents that were converted into PDF will appear under the **Processed->PDF Conversion** folder. If some documents could not be converted into PDF due to some error, they will appear under the **Error** folder. The documents that were not submitted for PDF Conversion will appear under the **Not Submitted** folder, and those that are still pending for conversion will appear under the **Pending** folder.

Similarly, all documents that are published from a Shared Workspace to its eTMF room get recorded under **Publish to eTMF** sub-folder in the **Processed** folder.

Deleted Documents

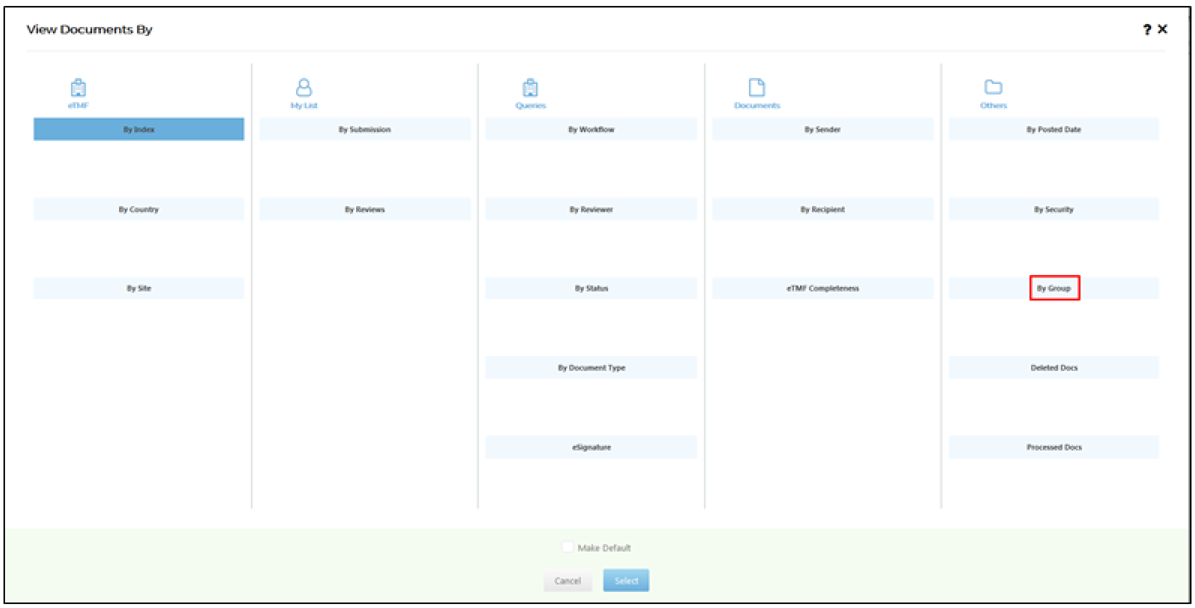
All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.



For more details on deleted documents proceed to Chapter Deleted and Expired Documents. *(page 303)*

By Group

In the **By Group** view, the folders and documents belonging to a particular group can be viewed by clicking the group name in the index pane.



Missing Documents

This view displays the list of all missing documents in a room. Refer to the screenshot below:

Click the folder from the left to view the documents. You can also edit the metadata of the documents from the **Metadata** Panel.

To edit the metadata, select the document from the appropriate folder and edit the metadata. Click Save to commit the changes.

Collected Documents

This view displays the list of all **Collected Documents** in a room. Refer to the screenshot below:

Click the folder from the left to open the list of sites. Select the required site to open the documents in the grid.

Modify Index

Configuring the Index Structure

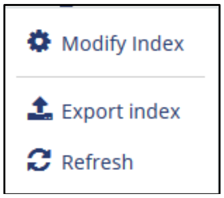
Generally, a room index is created while creating a room from another room so that the index of the existing room is also copied into the new room. A client may opt to create a new room without any index, in which case the index structure needs to be created manually, and the documents and its types to be added to it. Creation of an index with its documents includes the following steps:

1. Adding main folders and sub-folders under the root folder of **Index** which is available by default.
2. Adding document types to the document categories. **By default**, the system provides three categories for the documents:
    a. General
    b. Country
    c. Investigative site
3. If new categories are required for the documents, the super- administrator will need to add them.
4. Adding documents by importing or uploading and assigning them their categories and document types.

Adding Parent Folders / Child Folders

The administrator follows the process below to create the main folder structure:

1. Click the icon next to the View By Index search box. A popup appears. Refer to the screenshot below:



2. Click the **Modify Index** icon.
3. The **Modify Index** popup window opens. Refer to the screenshot below:

4. Select the root folder of **Index** from the popup to add a parent folder, else click a parent folder (or subfolder) into which you want to add a subfolder.
5. Click the '+' icon and type in the folder name in the textbox that appears. Press **Enter**.
6. The new folder appears under the root/parent folder.
7. Repeat the above steps to create another parent/child folder.
8. Click **Save**.

Editing Folder Names

1. You can change the name of an existing folder.
2. Click the **Modify index** icon from the popup.
3. The **Modify Index** popup window opens.
4. Click the folder you want to rename.
5. Select the **pencil** icon.
6. The selected folder and its name appear in a highlighted box.
7. Make your changes, then press **Enter**.
8. Click **Save**.

Deleting Folder Names

1. To delete a folder, click the folder in the **Modify Index window**.
2. Click the **Delete** folder.
3. Click **Save**.

Note: *Deleting a folder will delete all of its contents including documents and subfolders.*

Important: *If you have already clicked the Delete folder in error, you can still click Cancel at the bottom of the Modify Index window. The change will not be saved.*

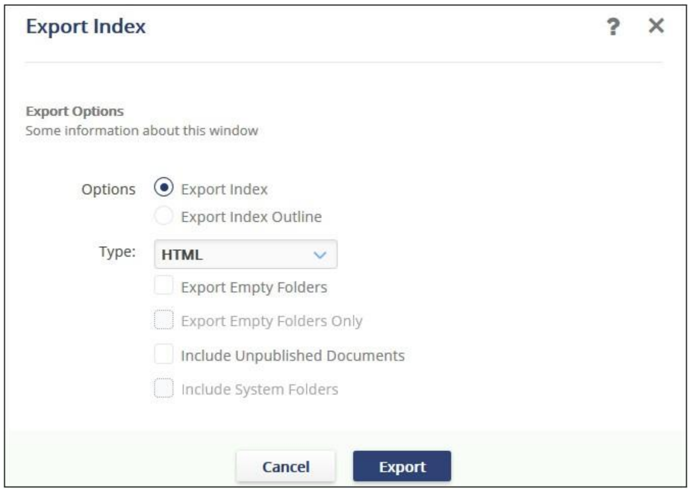
Exporting and Refreshing Index

Exporting Index

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

To export index:

1. Click the **Export Index** Export index from the popup and export the index as per the actions required. Refer to the screenshot below:



Index Search

In the Search box below the View By Index pane, enter the name of the folder you want to search. Press **Enter** or click the magnifying lens icon to reveal matching contents.

Click the Cross next to the right of the search box to delete the search criteria.

The Documents Grid

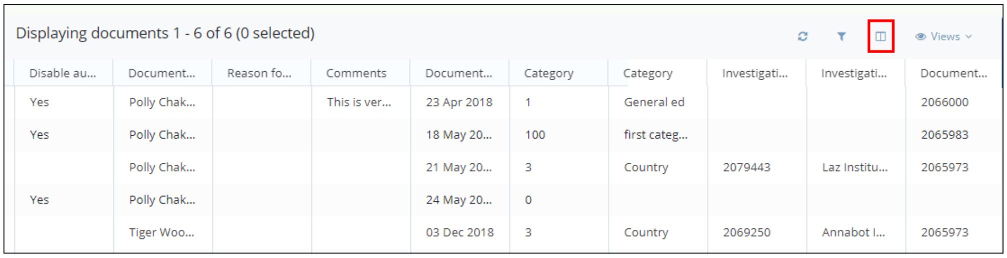
You can perform the following from the Documents Grid.

- Preview and Viewing a document and its metadata *(page 243)*
- Access the Document Context menu on a document by the mouse right-click *(page 249)*
- Configure the Documents Grid *(page 241)*
- Copy or move documents *(page 245)*

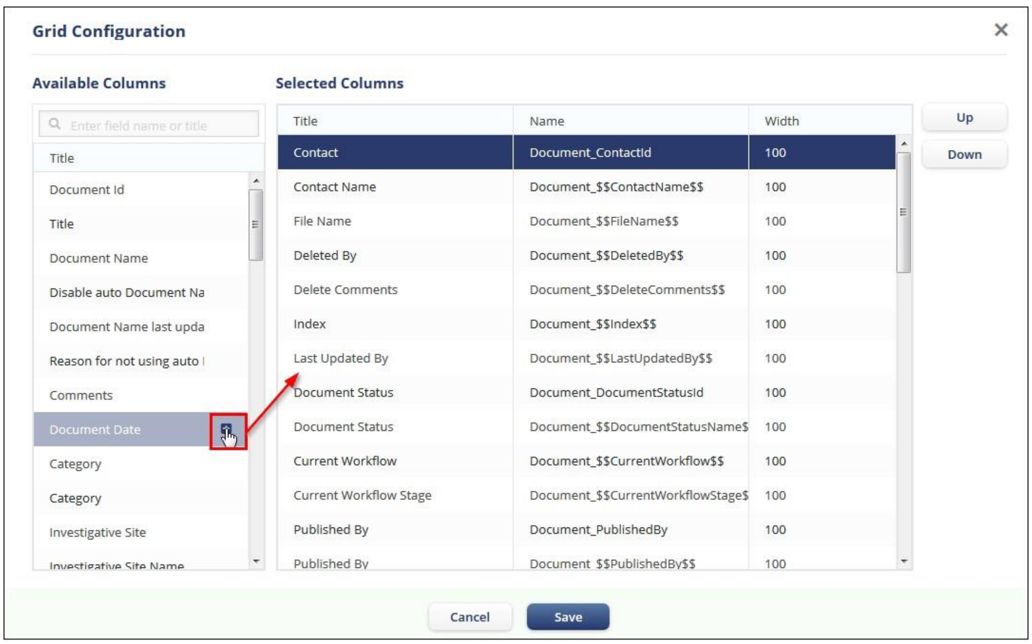
Configuring the Document Grid

Through this option, you can decide which columns to display or hide from the Document, Workflow, or Audits Grid. Thus, you can decide exactly what information you want to see and configure the grids accordingly to suit your view.

1. Navigate to the **eTMF/Documents** module.
2. Click the **Update Columns** icon from the top right corner of the documents grid. Refer to the screenshot below:



3. The **Grid Configuration** window opens which displays the following panels:
   a. **Available Columns Panel**: This panel display 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.
4. To add a column to the **Selected Columns** pane from the **Available Columns** pane, hover the mouse over the column name in the Available Columns. The **+** sign appears next to the column name.
5. Click the **+** sign to add the column to the **Selected Columns.** The column gets added to the list of Selected Columns. Refer to the screenshot below:



6. Alternatively, you can also **double-click** the columns in the Available Columns to add to the Selected Columns.
7. After adding the columns to the Selected list, they are **greyed out** in the Available Columns list and a **small green tick** appears to the next of the column name as shown in the screenshot below:

8. Similarly, you can remove the columns from the Selected Columns list by clicking the **-** icon that appears next to the column name on hovering the mouse over the column OR double-click the column to remove it from the list.
9. Besides adding and deleting columns, you can also change the sequence of the columns by clicking the **Up** or **Down** 

buttons located at the extreme right of the window.
10. Click **Save** to save to changes.

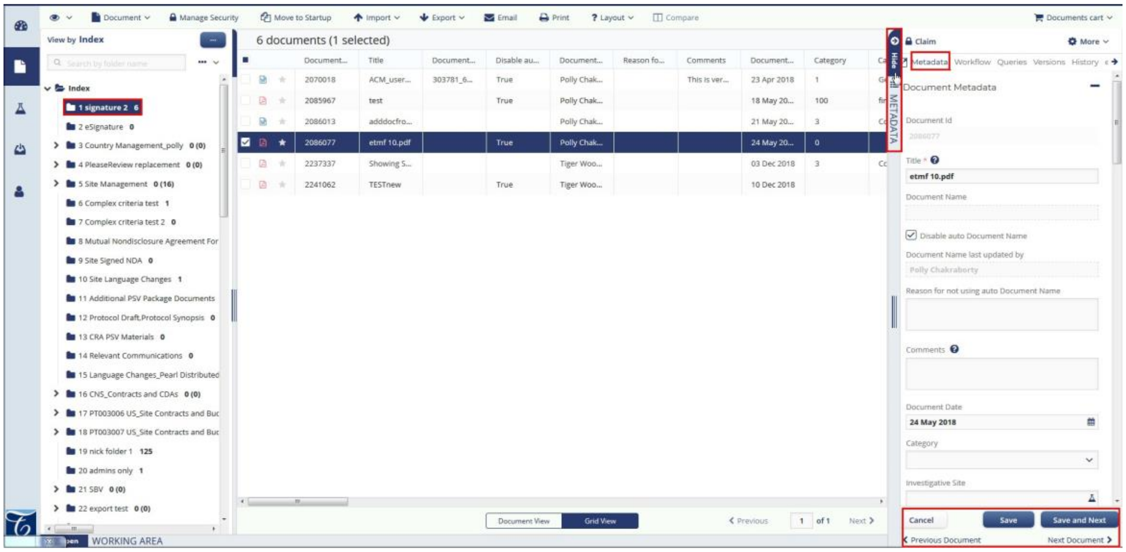
Previewing and Viewing a Document and its Metadata

This allows you to view the document metadata and the document in the separate panels in the eTMF / Documents module. These are discussed in the sections below:

Viewing Document Metadata

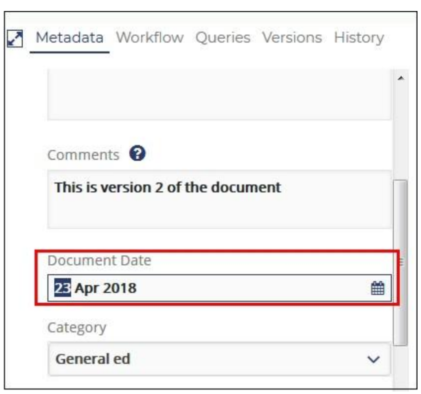
To access the Document Metadata, follow the steps as below:

1. From the **Documents** module, select the document from the grid.
2. Hover the mouse over the bar to the right of the grid. The **Metadata Viewer** display with the **Open** text on it.
3. Click the viewer to open the **Metadata Panel**. *Notice that when you open the metadata panel, the Metadata Viewer bar changes the **Open** text to **Hide** clicking which you can hide the metadata panel*
4. The **Document Data Panel** opens which displays the **Document Metadata** by default. Refer to the screenshot below:



As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The icons at the bottom of the panel provide access to several essential functions, such as saving changes and updates in the metadata panel as shown in the screenshot above.

Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings -> General Information (page 58)section. Refer to the screenshot below:

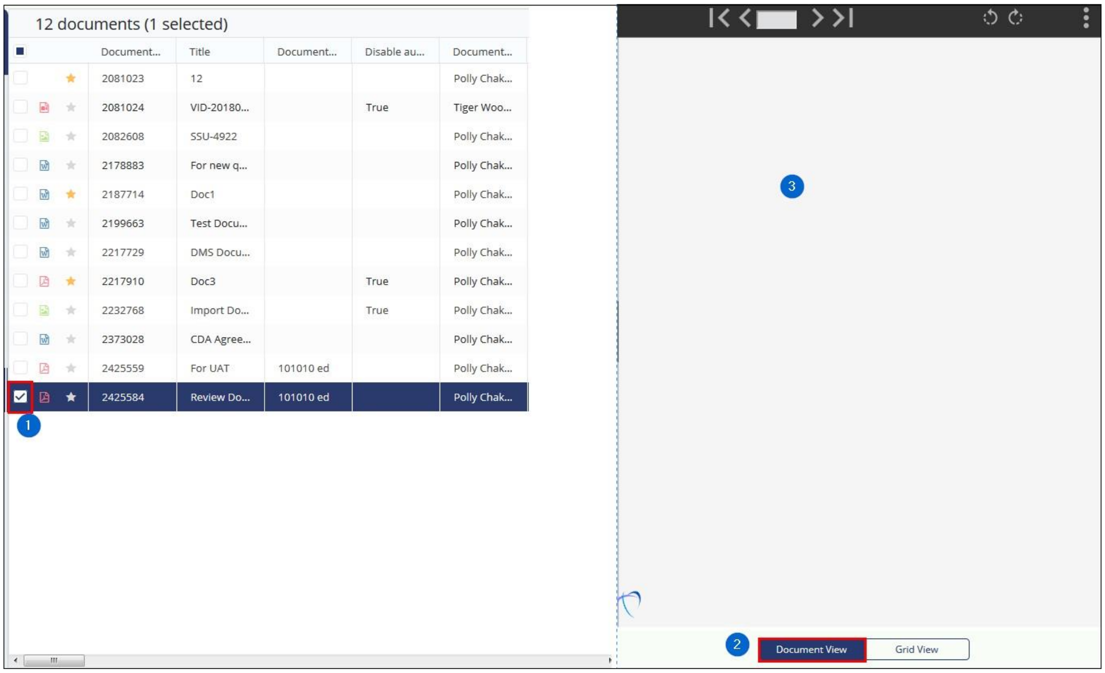


Previewing a document

To preview the selected document:

1. Select the checkbox next to the document.
2. Click the **Document View** button at the bottom of the grid.

3. The document opens in the Arender view. Refer to the screenshot below with the sequence of steps in number denoted:



Copying or Moving Documents

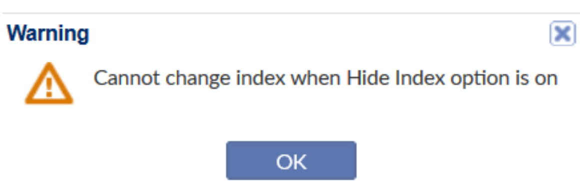
Follow the steps below to copy documents:

1. Select the document(s) to be copied or moved in the grid.
2. To **move** the document(s) to another folder, drag the document from the grid and drop it to the destination folder in the Index Pane.
3. To **copy** the document/s to another folder, hold the *Ctrl or Shift key*, and drag and drop the document to the destination folder in the Index Pane.

While copying or moving a document you will be asked to re-code the document profile and will open the **Edit Document Profile** window to enter the details. Follow the instructions to complete the form. You may choose to replace the attachment at this time if required. If you replace the attachment you can view the version history in the document's metadata panel.

Note: *Viewing of version history on replacing attachments is available only in Alfresco rooms. For more details follow on to section Replace Documents. (page)*

If the **Hide Index on add new document** option is on, editors will not be able to copy or move a document and will receive the warning as below.



Documents Grid Views

While in a specific folder, the user may want to filter the columns and view only the columns that are required. This can be done by customizing the grid view. You can create your own view and set that particular view as a default view so that you can view only that information which is required in the grid.

Besides, you can also apply filters to the grid and save the view for future use. To set and customize a view:

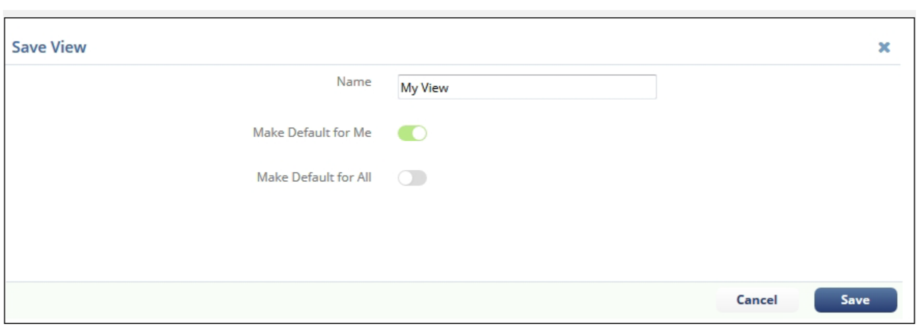
1. Navigate to the **eTMF/ Documents** view.
2. Select the required folder and update the columns *(page 241)* as needed. The documents grid gets updated as required.
3. Click the **Views** dropdown at the top right corner of the grid.
4. The list of options appears. Refer to the screenshot below:

5. You can perform the following actions:
   a. Save View
   b. Set Default View
   c. Show all views
   d. Share the Views

Each of these is discussed in the sections below:

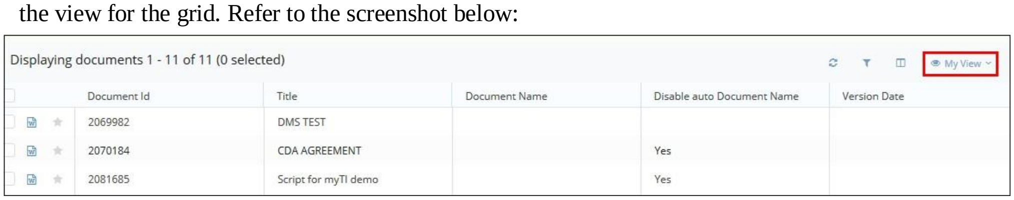
Save Views

After updating the columns in the grid, click **Views** → **Save View**. The **Save View** window opens. Refer to the screenshot below:



Enter the name of the view and enable the options by clicking the toggling buttons below for the default view. You can either make the view default for you or for all the users who accesses the folder to which the view has been set. Click **Save** to save the changes.

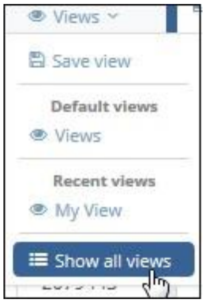
On saving, you can see the name of the view and columns also gets updated. Every time you visit the folder, you can select the view for the grid. Refer to the screenshot below:



Show All views

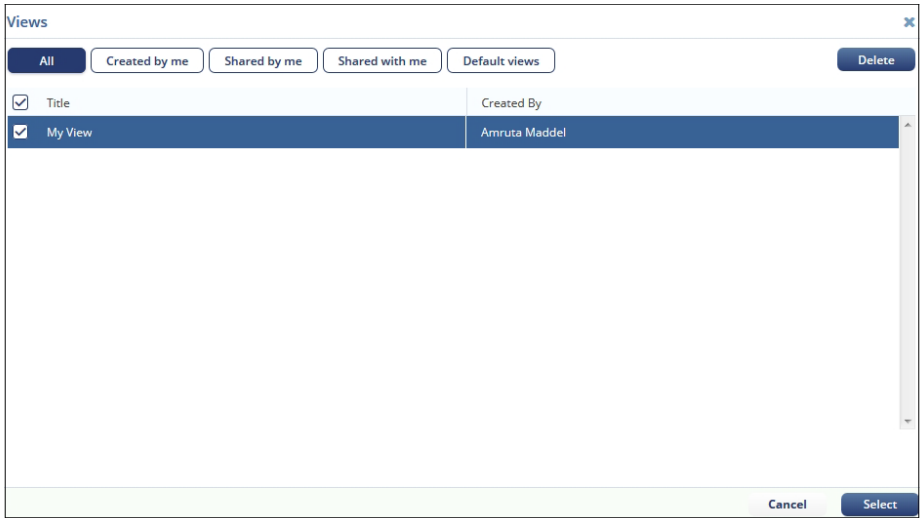
If the room has multiple views created in a room, and if they are visible to all users, you can view all the views in a room. To display all views:

1. Click **Show All Views** from the from the Views dropdown. Refer to the screenshot below:



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 you.
   c. **Shared by me**: This displays the list of all the views that are shared by you to the other users.
   d. **Shared with me**: This displays the list of all the views that are shared with you by the other users.
   e. **Default Views**: This displays the list of all default views.

The screenshot below shows an example of the **All** views:



Note: *The **Delete** and **Select** buttons are enabled only when you select a view from the list.*

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

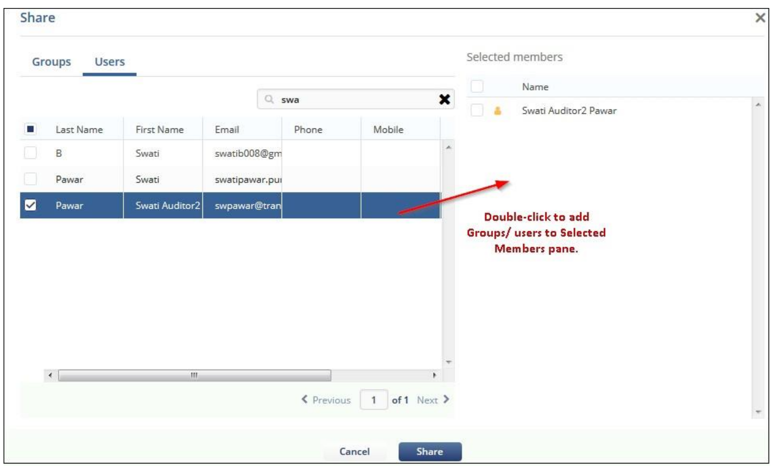
Share Views

Note: *This option is enabled in the Views dropdown only when you select a view created from the list.*

To share view:

1. Select a view you want to share from the list of views. The selected name of the view displays.
2. Now, click the **Views** dropdown. The list of options appears.
3. Click **Share View.** Refer to the screenshot below:

4. The **Share window** opens.
5. Select the **Groups** or **Users** to whom you want to share the view. Double click the user from the left pane to add them to the Selected members pane.
6. After selecting Gorpus/Users, click **Share**. Refer to the screenshot below:

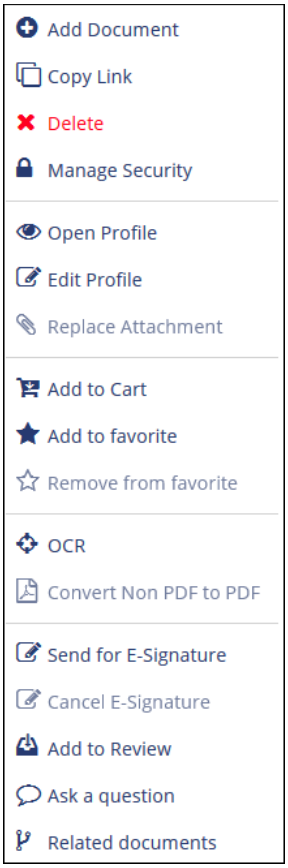


7. This shared view now displays under the list of Shared by me in the Show All Views.

Documents Context Menu

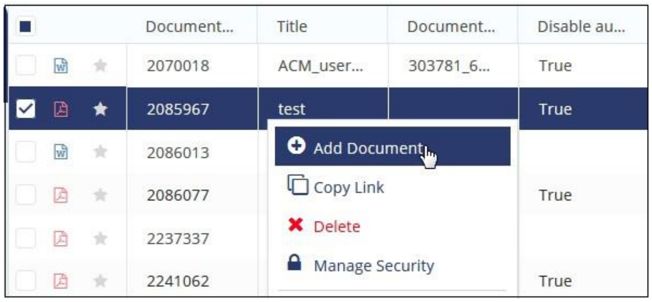
You can perform the horde of activities on a document from the Document Actions (page 269) as well as by right-clicking on a document in the Document Grid.

Refer to the screenshot below to get a list of actions possible from the Documents Context Menu. Each of the functionalities is discussed in separate topics available from the left panel of this topic help.



Adding a Document

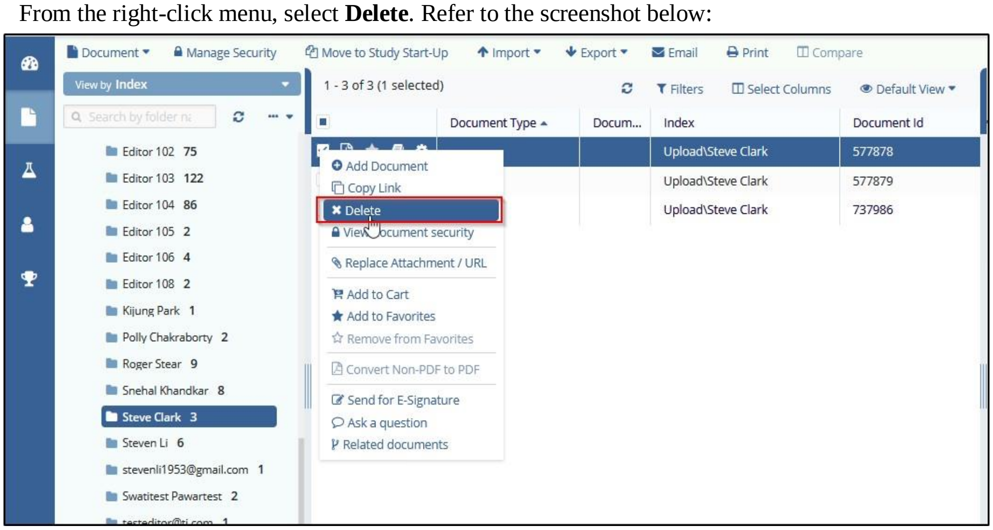
1. From the **Documents** Module, right-click on a document in the Document Grid.
2. Select the **Add Document** option and the **New Document** window opens. Enter the details as required to create a new Document profile. Refer to the screenshot below:



3. Select the appropriate **Category** from the dropdown list: **General**, **Country**, or **Investigative Site.**
4. Depending upon the category selected, the document's Submitted Name field would appear or disappear. Enter the Submitted Name as required.
5. Select the **Document Type**, and **Document Date**. Type in the date if that is configured for you.
6. Add pertinent Comments, if necessary. The Index position will populate automatically, based on the folder you selected from the index.
7. Click the **Add** button at the right end of the Attachment field to attach a document.
8. Click **Save**.

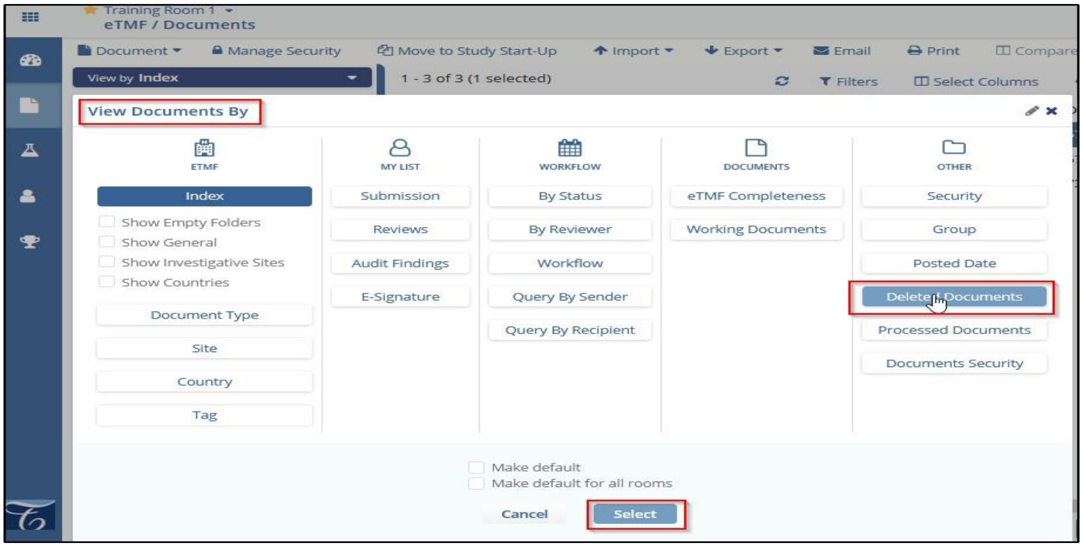
Deleting Documents **Deleting Documents To delete a document:**

1. Navigate to the **Documents** module.
2. Select the document(s) from the documents grid.
3. From the right-click menu, select **Delete**. Refer to the screenshot below:



Deleted Documents View

All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.

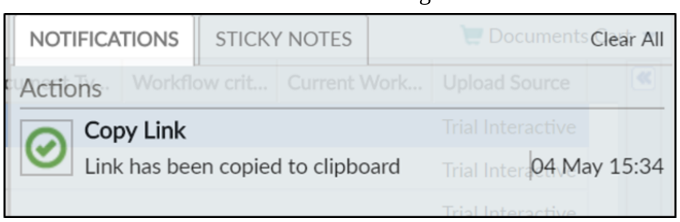


Copy Link

Clients might need to copy a document link through the Document dropdown in the eTMF module. They can choose the type of document link to copy through the**Copy Link Settings** option.

Once the Copy Links settings are made, follow the steps as below to copy a link:

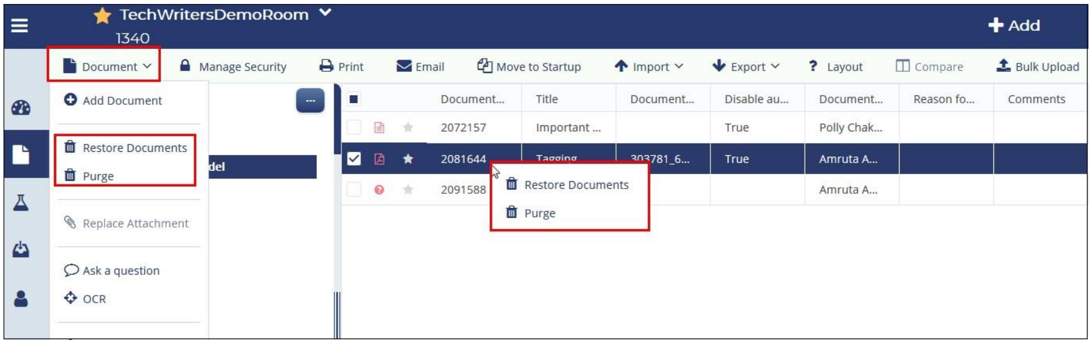
1. Navigate to the **Documents** Module.
2. Select the required document from the grid and right-click on it.
3. Click **Copy Link** to **copy the link to a documen**t, or to **copy the link to a document with metadata** and anotification about the same is received. Refer to the figure below:



Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings, the document will either open up in the browser for you to read, or the link will take you to the eTMF room and open the document and its metadata for you to view. **Copying and pasting the link of an empty document shall display the message 'This document profile does not have an associated document'.**

Purging and Restoring Documents

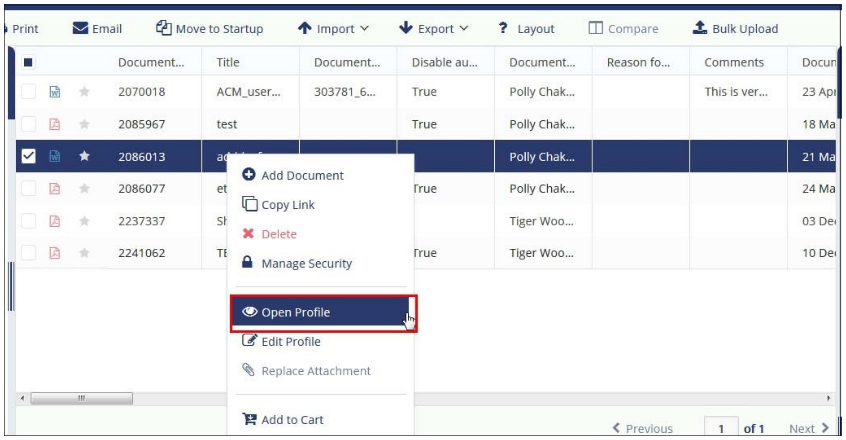
Deleted documents can be restored or purged by clicking the required icon located on the top ribbon from the **Document dropdown** or he **right-click menu** on the document . Restored documents take the same place in the index they were located in before deletion. Refer to the screenshot below:



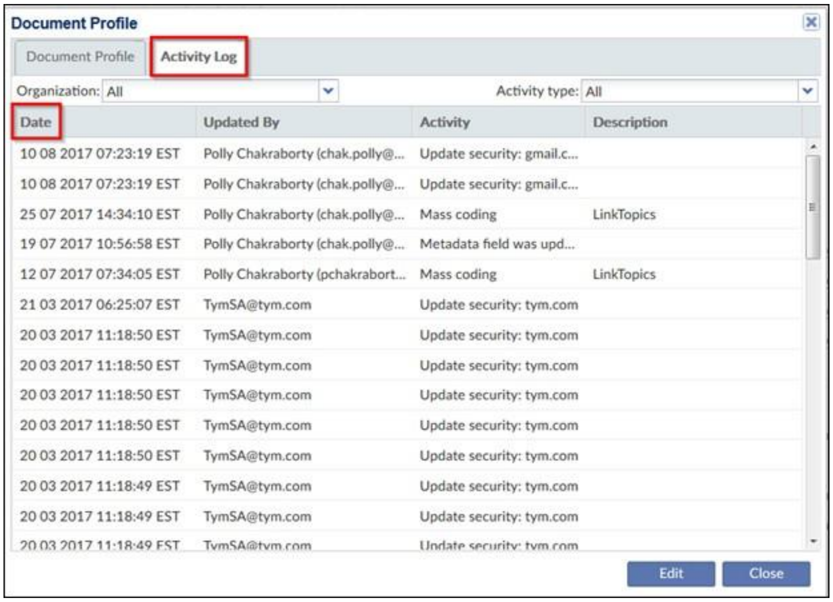
Documents can also be **auto purged** if so required by the client. For such documents, the admin can enable the Auto Purge *(page 97)* from the Room Settings.

Opening Document Profile

In the **Documents** module, select the document and click **Open Profile** from the right-click menu on the document. Refer to the screeshot below:

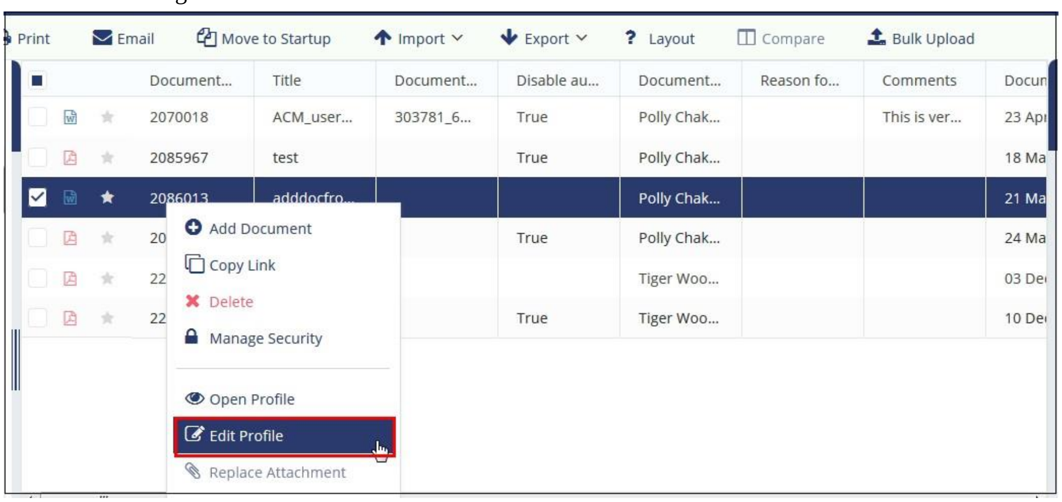


On clicking Open Profile, you will see the Document Profile for the selected document. In this view, the fields are static. Refer to the screenshot below:



Editing Document Profile

In the Documents module, select the document and click **Edit Profile** from the right-click menu on the document and the fields are no longer static. Refer to the screenshot below:



By this route, an Administrator can edit the document profile. Editing profile is also possible from the Metadata Panel. *(page 262)*

Add Selected to Cart

Add Selected Document to Cart

Proceed to section Adding Selected Documents to Cart *(page 282)*for the detailed information.

Adding and Removing Favorites

Adding Favorites

Click **Add to favorite** from the Documents Context Menu menu to mark a document as favorite. Similarly, click **Remove from favorite** from the right-click menu to unmark document as favorite.

Besides, you can also click a **Star** to the left of a document to mark/unmark it as a favorite.

Ask a Question

This allows you to create a question related to a particular subject. Click the link Ask a Question *(page)*to lead you to the topic

Note: You can also perform this action from the **Documents Actions** ***(page 269)*** dropdown on the top menu bar.

Convert Non PDF to PDF

Convert Non PDF to PDF and PDF fix

This allows you to convert the Non PDF documents to PDF. You can view these converted PDF documents under the **Processed view** of the documents.

eSignature

This section discuss the various ways of e-Signature used to sign the documents.

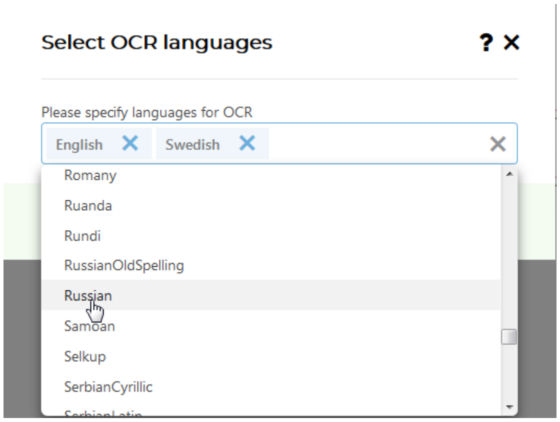
Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

OCR

This allows you to choose the language for OCR.

OCR can also be performed from the **Documents Actions dropdown** *(page 269)* on the top ribbon bar. To specify languages for OCR:

1. Right-click on the required document from the grid. The **Document Context Menu** popup appears.
2. From the Context Menu, select **OCR**.
3. The **Select OCR languages** popup appears.
4. Click the textbox and select the languages as applicable from the dropdown.



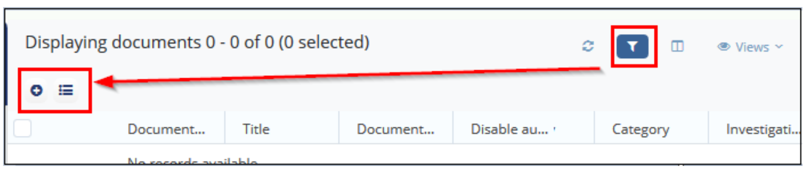
5. Click **Ok.**

PDF Fix

Grid Filters

For a document grid, you can apply and save filters to make the search for the documents easier. To apply filters:

1. Click the **Filter** icon above the document grid.
2. The Filter options are enabled at the top left corner of the documents grid. Refer to the screenshot below:

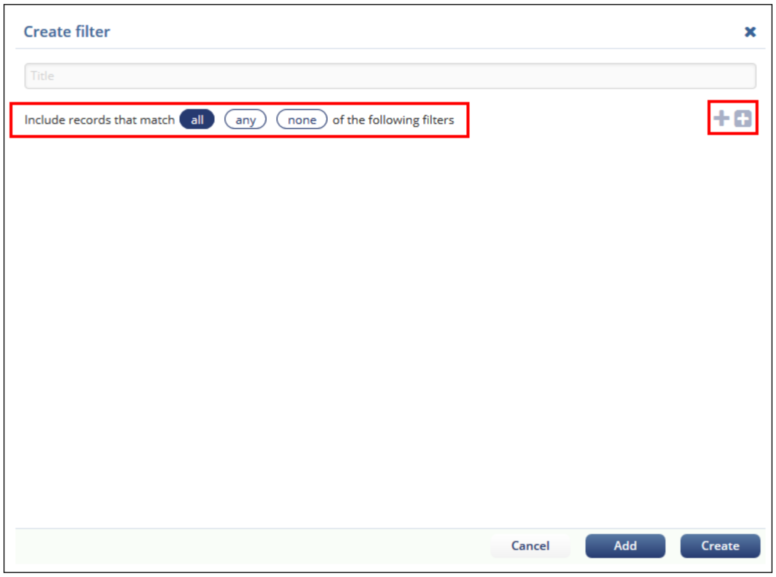


3. From the enabled options, you can perform the following:
   a. Create New Filter
   b. Add Existing Filter/Manage Filter

   Each of these is discussed in the separate sections below:

Creating New Filter

1. Click the + sign above the documents grid.
2. The **Create Filter** window opens. The window displays the following:
   a. A textbox that displays the **Title** for the filter selected.
   b. The options for matching the filter records. Refer to the screenshot below:

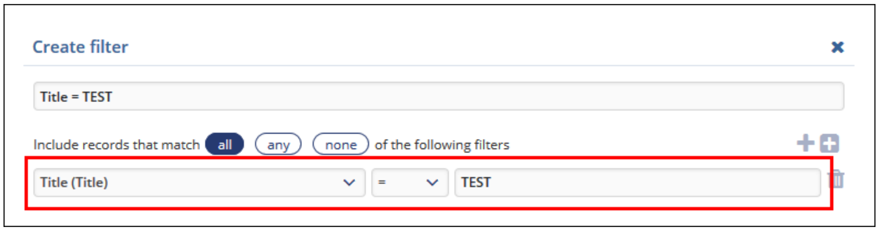


3. Notice that there are two + plus signs to the right of the window which allows you to create a **single filter** and **group of filters.**

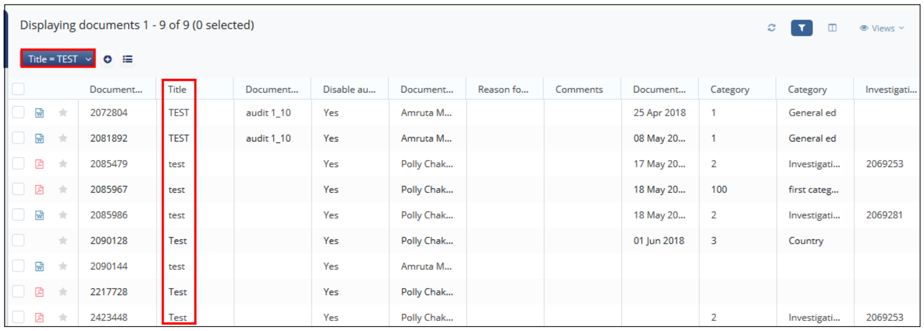
   Adding Single Filter

4. To add a single filter, click the **first +** sign. Refer to the screenshot below:

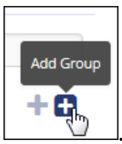
5. A dropdown appears. Click the dropdown and select the fields to which you want to apply filters.
6. Select the operator and enter the value for the selected field. Refer to the screenshot below:



7. Click **Add** if you wish to display the filter in the current view or click **Create** if you want to save the filter and use it later.
8. After creating a filter, when you select the filter and apply it for the document grid, the search results display accordingly. The screenshot below shows an example of the filter result applied for the **Title = Test**.

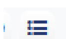


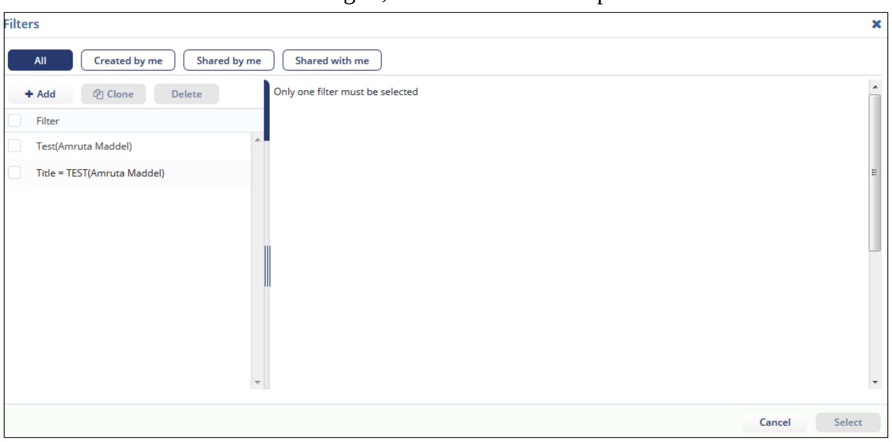
Document...	Title	Document...	Disable au...	Document...	Reason fo...	Comments	Document...	Category	Category	Investigati...
2072804	TEST	audit 1_10	Yes	Amruta M...			25 Apr 2018	1	General ed	
2081892	TEST	audit 1_10	Yes	Amruta M...			08 May 20...	1	General ed	
2085479	test		Yes	Polly Chak...			17 May 20...	2	Investigati...	2069253
2085967	test		Yes	Polly Chak...			18 May 20...	100	first categ...	
2085986	test		Yes	Polly Chak...			18 May 20...	2	Investigati...	2069281
2090128	Test		Yes	Polly Chak...			01 Jun 2018	3	Country	
2090144	test		Yes	Amruta M...						
2217728	Test		Yes	Polly Chak...						
2423448	Test		Yes	Polly Chak...				2	Investigati...	2069253

9. Similarly, you can add group filters to apply for the document grid and search for the results by clicking the second + sign 

. Proceed further as discussed above to add group filters.

Add Existing Filters / Manage Filters

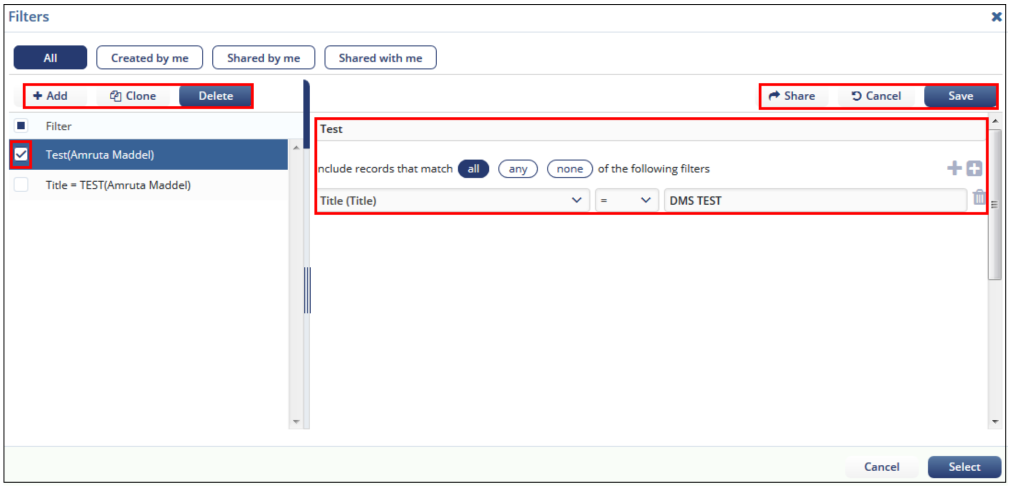
Manage filters allows you to view and share the created filters by you and by others. When you click the Manage Filters  icon above the documents grid, the **Filters** window opens. Refer to the screenshot below:



You can perform the following activities on the filters in Manage Filers window:

1. Share Filters
2. Clone Filters
3. Delete Filters **Sharing Filters** To share a filter:

1. Select the filters from the list of filters in the **Filter** window.
2. The selected filter appears in the right pane of the window and the buttons **Clone**, **Delete**, **Share**, **Cancel**, and **Save** are enabled. Refer to the screenshot below:



3. After selecting a filter, click the **Share** button. The **Share** window opens.
4. Select the **Users / Groups** to whom you want to share the filter and click **Share**. **Deleting Filters**

Similarly, select the filter from the list of filters and click **Delete** to delete the filter.

Viewing Shared Filters

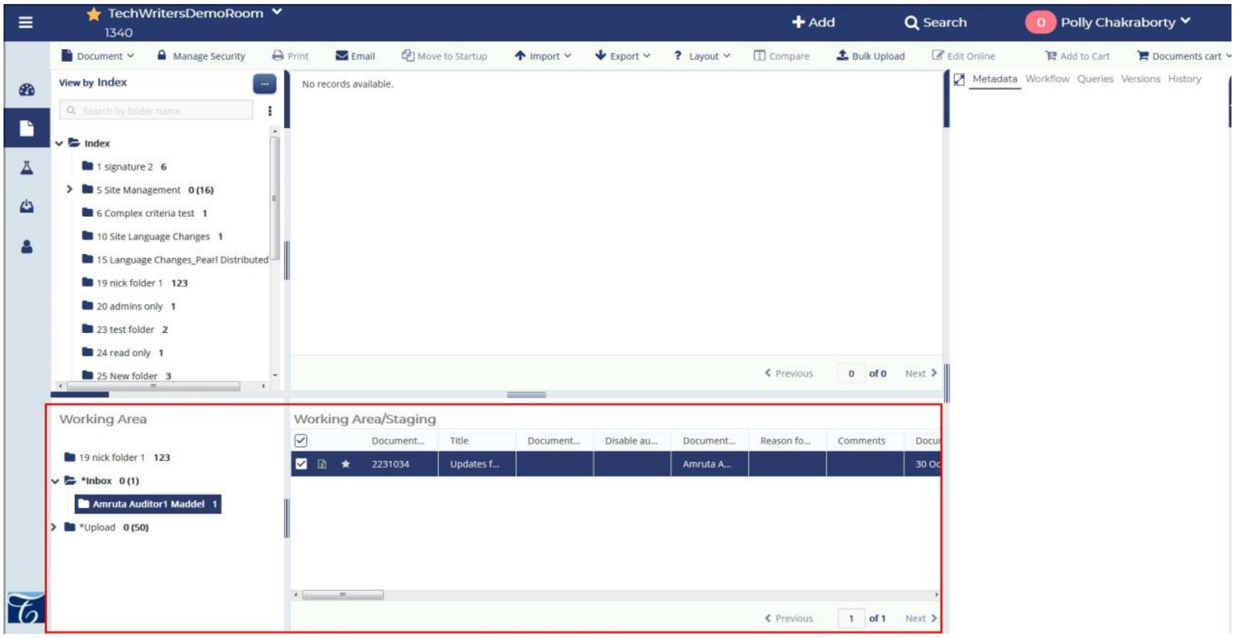
You can view the filters that are **created by you**, **shared by you** and that are **shared with you** by clicking the required tabs in the Filters window.

The Working Area and Grid

When you open the **eTMF/Documents** module, the following appears:

1. The Room Index *(page 224)*
2. The Documents Grid *(page 241)*
3. The Working Area and Grid

In Trial Interactive 10, the eTMF index is separated from the working folders which include Working Documents, Rejected Documents, Uploaded, and Emailed documents. Users can perform various actions like document coding, document replacing and attaching, adding documents to workflow or auditetc. from this Working Area. The folders in the working area are hardcoded and any documents coming in the room, either by uploading or emailing are available for further process or actions from this Working Area. Refer to the screenshot below:

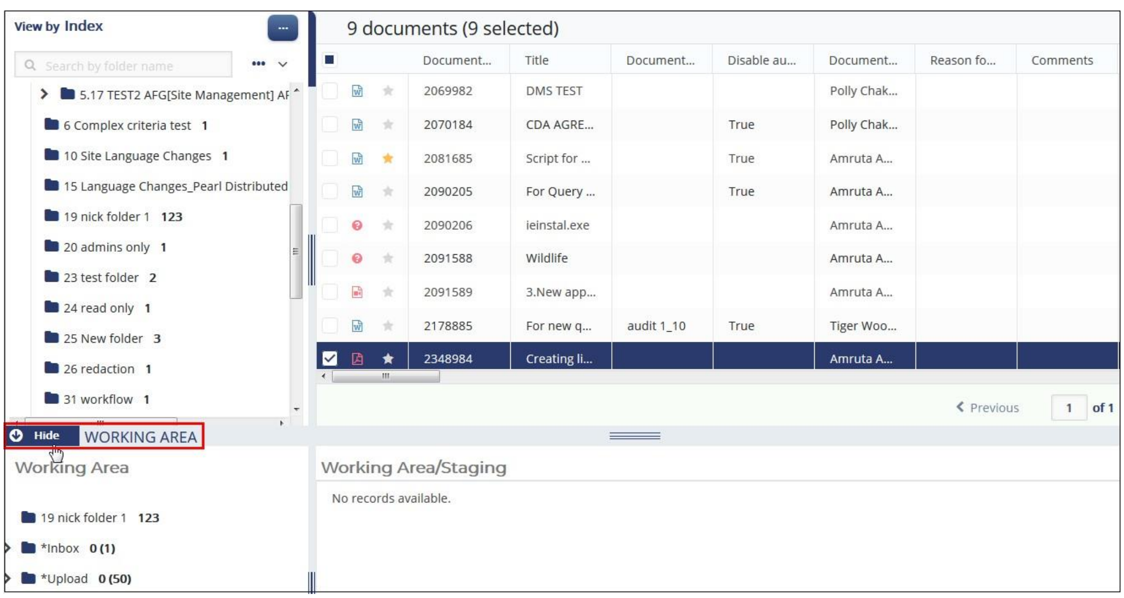


Besides working on documents, you can also drag and drop the documents from the Working Area to the required eTMF folders above like for the **Country** and **Site** views, the user can easily drag and drop documents from the working folders into **missing documents** and **placeholders** in the eTMF.

Note: *Documents can be dragged only out of Working Area but not into the Working Area.*

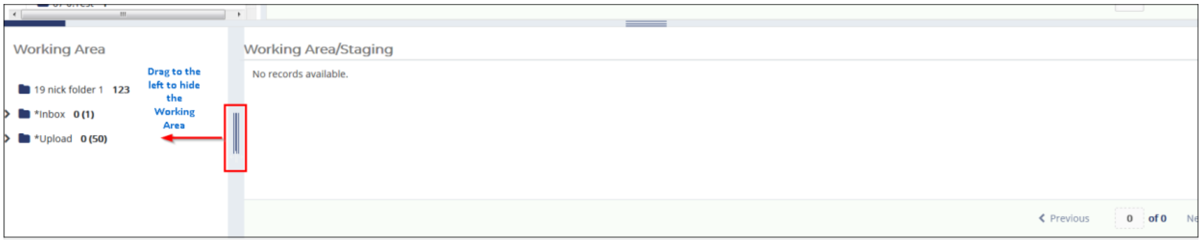
Hiding or Unhiding the Working Area/Staging panel

To hide or unhide the Working Area, hover the mouse over the bar above the Working Area. The Hide - Working Areabar appears. Refer to the screenshot below:



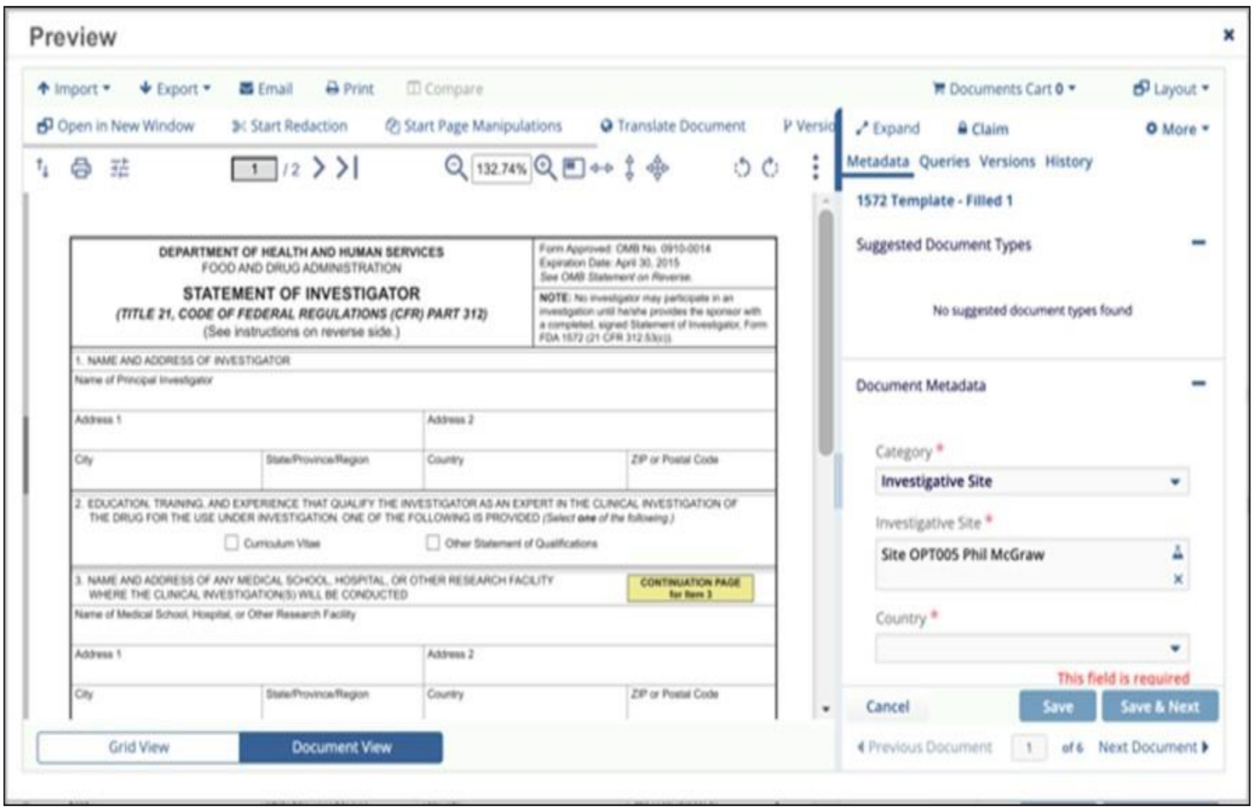
Hiding the Working Area

You can also drag the Working Area/Staging to the extreme left to hide the Work Area. Refer to the screenshot below:



Similarly, you can also drag the Working Area/Staging Area **up** to increase the size of the window and the number of documents count in the grid.

Staging Area Preview



In TI 10, the Working Documents view was introduced to provide a simpler, more comprehensive index for eTMF Completeness, showing not just final documents, but also collected documents, placeholders, and required documents within a standard eTMF index structure. This view also introduced the Staging Area, a separate panel that shows documents waiting to be classified via theeTMF workflow.

TI 10.1 introduces a simpler way to preview these documents. Selecting a document in the Staging Area and double-clicking will open the document in a preview modal window alongside its metadata.Then the document can be dragged and dropped directly into the eTMF index, into a folder or onto a Placeholder, and have Trial Interactive intelligently prompt you for the correct Document Type and other classification metadata.

The Document Data Panel

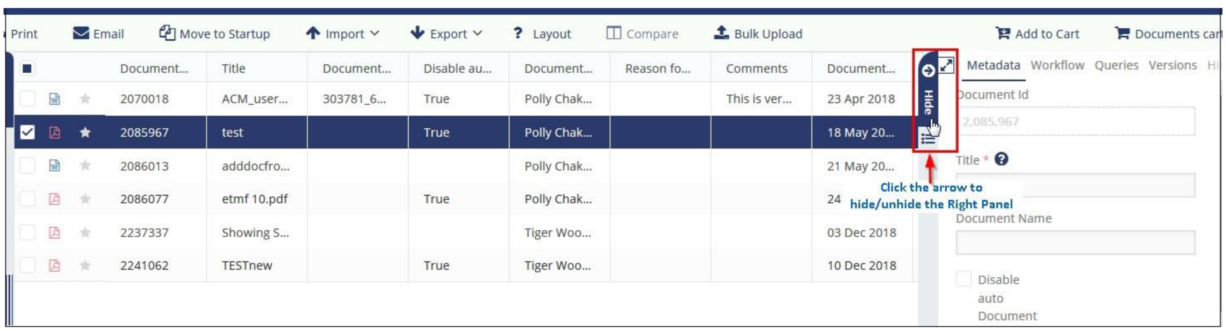
The Right Panel opens by default in the **eTMF Documents Module** when you click **Documents** from the left pane.

From the **Right Panel** located at the right of the documents grid, you can view the following panels after you select a document from the grid:

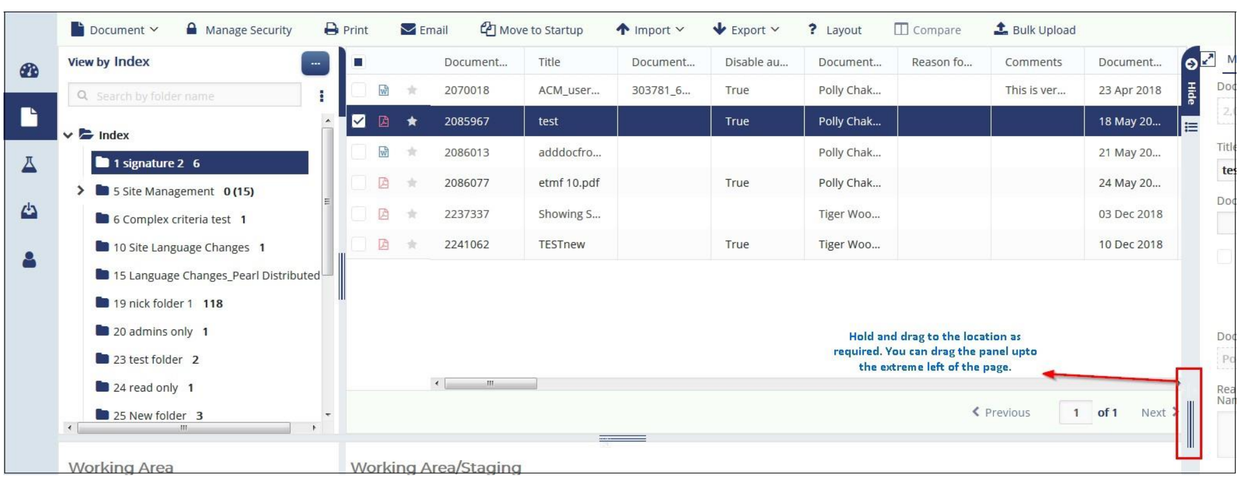
1. Metadata panel
2. Workflow panel
3. Queries panel
4. Versions panel
5. History panel
6. eSignature panel

Each of the functionalities above is discussed in separate topics available from the left panel of this help.

You can **hide** this panel by hovering the mouse to the right of the grid and clicking the **Hide** arrow. Refer to the screenshot below:



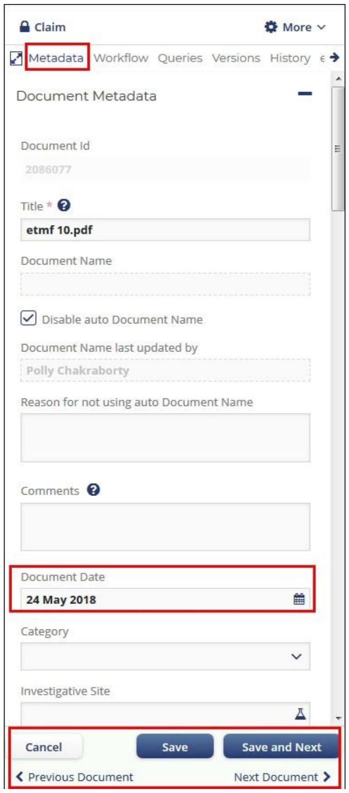
Besides, you can also hold the panel and drag it to the extreme left of the page. Refer to the screenshot below:



Metadata Panel

Metadata Panel is activated by default when you select a document.

As an Administrator, you can not only view a document's metadata, but you 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. Refer to the screenshot below:



Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your *My Profile Settings → General Information (page 60)* *section.*

You 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.

The Metadata Panel also provides the Claim button and the More (Settings) icons at the top of the panel to allow you to claim documents in workflow and perform various actions on the document.

Workflow Panel

You can do the following from the Workflow Panel:

1. Claim Documents in a workflow
2. View the Workflow History
3. Initiate a Query
4. Release a document from a workflow'
5. Reassign Reviewer
6. Exclude document from a workflow

The Workflow panel displays all the details of the document workflow.

Click the **Date** to view from the **Workflow History** section to view the full history of the document in a workflow as shown in the screenshot below:

Queries Panel

From the Queries tab, you can not only view the queries received but also can resolve them. You can view queries in TI by various methods:

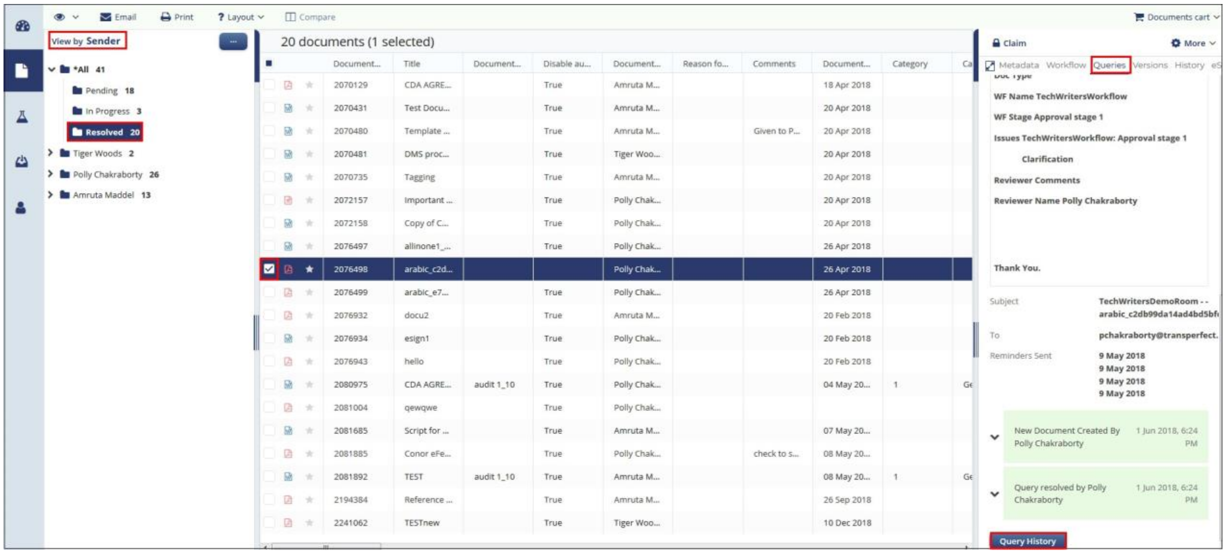
1. **Query Email:** By the Query Responder from the query email received in his/her inbox
2. **By Recipient View**: The Query Responder can view the queries received under the By Recipient view if the said query responder has access to such a TI room and documents related to the query.
3. **By Sender View**: The Reviewer can view the queries from the By Sender view if such a reviewer is the creator and sender of the query.
4. **By Reviewer**: This view is available only for admins and such a user can view the queries sent and responded by all the reviewers. (add to profiling for admins)

5. **By Reviews**: The reviewer can view all the queries from the By Reviews view which he/she has initiated.

Viewing a Query

To view a query, follow the steps as below:

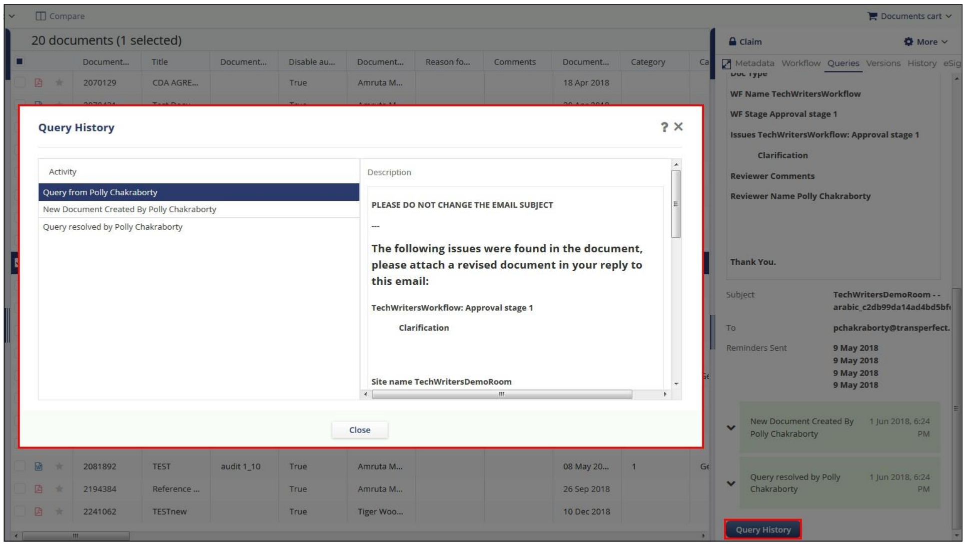
1. From the **eTMF/documents** application, click **Choose View** next to the Index View.
2. The **View Documents By** popup appears.
3. Select the **By Sender** view and click **Select** at the bottom of the page.
4. The folders with the name of reviewers appear.
5. Click the required folder. The following folders are available for the query:
    a. **Pending**: This folder contains all the queries sent and are awaiting the response.
    b. **In Progress**: This folder contains all the queries which are responded.
    c. **Resolved**: This folder contains all the queries which are resolved.
6. Select the required document from the grid and click **Query** tab from the metadata panel.
7. The queries display in the **Queries** panel.
8. Click the query to view the full query history.
9. The query displays the following:
    a. The email body of the query that was initiated.
    b. The responses and attachments to the query displayed by green sections. Refer to the screenshot below:



    c. Expand the required section to view the details for the sections.

Viewing Query History

To view the query history, open the required query and click the **Query History** button at the bottom of the Queries panel. This opens the history of the query in the **Query History** window. Refer to the screenshot below:



From the Query History window, select the required query activity from the left pane and the details of the history displays in the right pane.

Versions Panel

Versions Panel allows you to view and compare the different versions of a document.

Select a document from the grid and click **Versions** tab from the **Right panel**. The different versions of the document are displayed in the versions tab, if applicable. Refer to the screenshot below:

Clicking **More info** next to the version number opens the **Version History** which gives a detailed view of the document version history. Refer to the screenshot above.

History Panel

The History panel gives an overview of a document history. This panel displays the top four entries of the activities performed on the document. Here, you can apply filters to view the history of a document. Refer to the screenshot below:

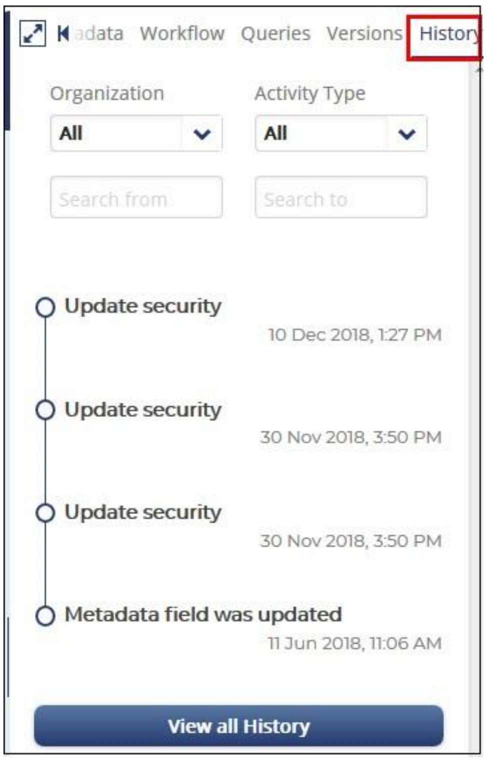
Document History Filters

The History Panel provides the following filters to allow you to view a document history:

1. **By Organization**: Use this filter if you want to view the document history based on the organization.
2. **Activity Type**: Use this filter if you want to view the document history by the activity performed on it.
3. **Date Filter**: Use this filter if you want to view the document history within the set date range.
4. **View All History**: Click this button to view the full history of a document. The full document history opens in a popup. You can also apply the filters from the **All History** popup.

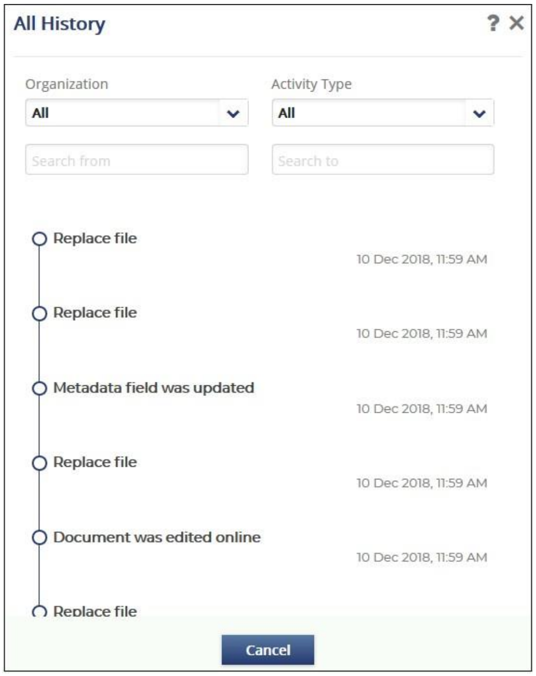
Viewing Document Activity

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. Refer to the screenshot below:



Viewing All History

Clicking the **View All History** button opens the **All History** popup which displays the complete history of a document and also allows you to filter the document history based on the **Organization**, **Activity Type**, and **Duration**. Refer to the screenshot below:



eSignature panel

The eSignature Panel:

1. Allows sending the document for eSignature if it is not initiated for eSignature yet.
2. Display the status of the document eSignature if it is initiated for eSignature.

Besides eSignature Panel, you can also send the documents for eSignature from the **Document Context Menu** ***(page 249)***by right-clicking on a document.

Cancel eSignature

If the document is waiting for eSiganture, the eSignature Panel displays the status of the document as shown in the screenshot below:

Select the eSignature and click the Cancel E-Signature button at the bottom of the eSignature Panel if you wish to cancel the eSignature of any document. Click Yes on the pop-up that appears to confirm the cancellation.

The Top Ribbon Bar

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

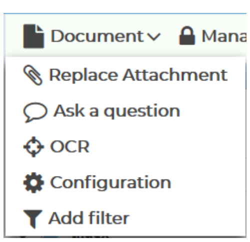
- The Document Actions
- Manage Security on documents
- Print
- Email
- Move to Startup
- Import
- Export
- Comparing Documents
- Documents Cart
- Dashboard Layout

Refer to the screenshot below:

Each of the above functionalities is discussed in separate topics available from the left panel of this help.

Document Actions

You can perform the horde of activities on a document by from the Document Drop down located on the top ribbon bar of the eTMF Documents Dashboard.



Each of the functionalities is discussed in sections below:

Replace Attachment

To replace a document attachment or URL:

1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.
2. The dropdown appears.
3. Select **Replace Attachment / Add URL**.
4. The **Replace Attachment / Add URL** popup window opens.

5. Select the **File** radio button to replace an attachment, or select the **URL** radio button to replace the URL
6. To attach a document click **Browse** and select the required document from the Explorer, whereas to replace a URL ????
7. Enter the reason for replacement.
8. Click **Apply**

1. Click **Ok.**

Manage Security

The Trial Interactive platform allows for two different approaches for defining security rights in the Trial Interactive site. Security can be set on a **folder level** or on a **document level**.

Note: *You can also Manage Security for Sites which is different from managing security for documents and is discussed in topic **Manage Security for Sites**.*

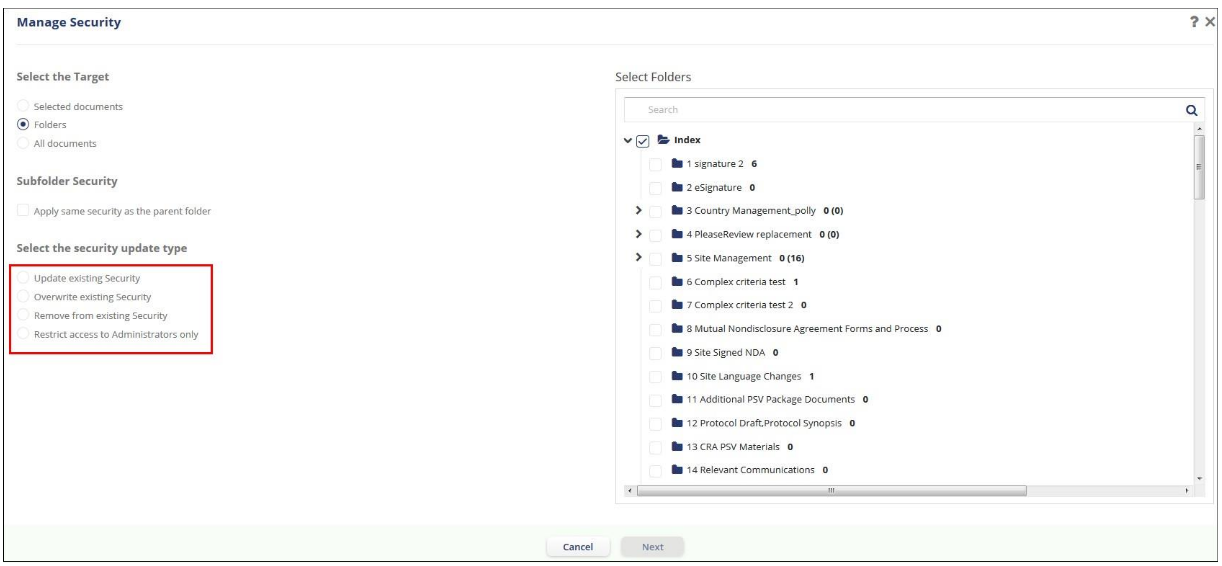
Folder Level Security

This allows to assign security for the individual folders in the Index of the room. This automatically applies the security to the documents when they are uploaded in the assigned security folders.

To assign Folder Level Security:

1. Click **Manage Security** 

from the top ribbon bar. The **Manage Security** window opens. Refer to the screenshot below:



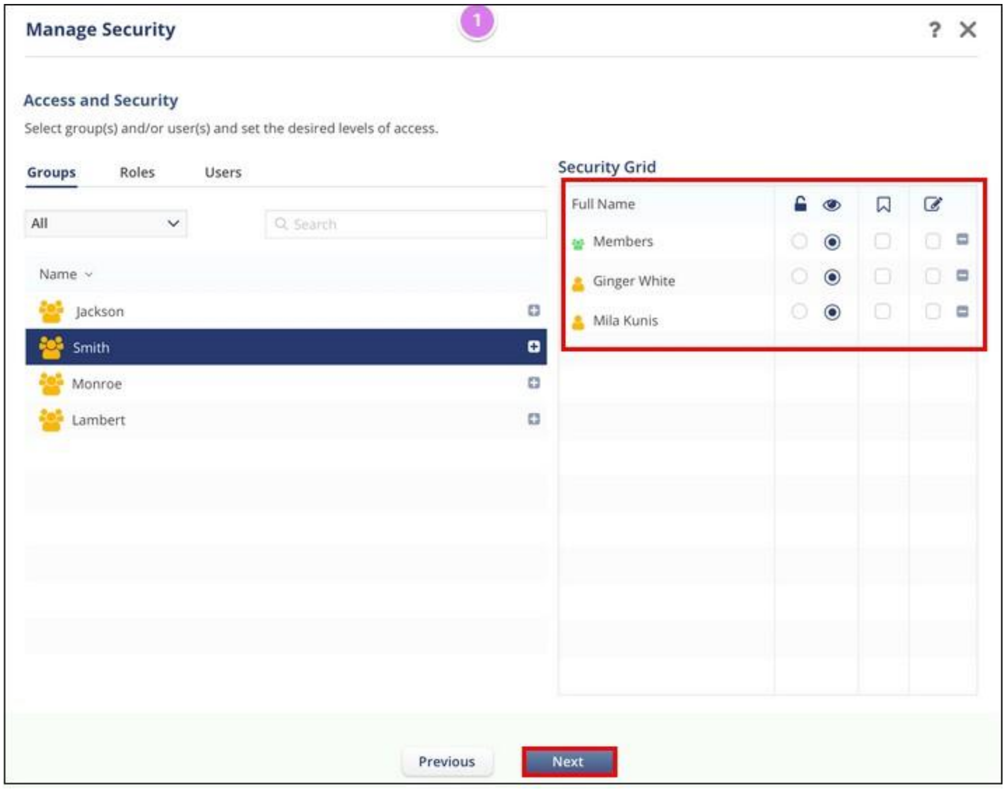
2. Select the **Folders** button from the **Select a Target section** in the left panel of the window. The panel on the right that displays the Index structure becomes active allowing you to select exactly to which folders you would like to apply the security change. You must select at least one folder from this list.

   By leaving the **Apply same security as the parent folder** checkbox unchecked, you can select specific subfolders on which to modify the security settings. If you check the box, you need only to select the main folders whose security settings you want to modify.

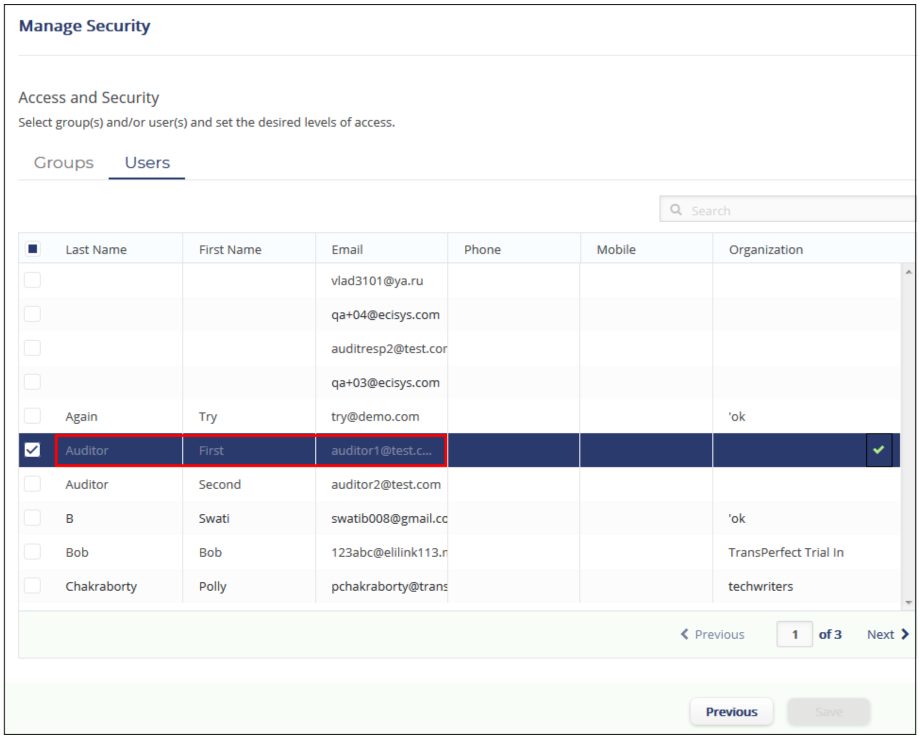
3. Select the checkbox next to the folders to which the security is to be applied.
4. Select the Security Update Type for the folder from the following options.

Security Type	Description
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.
Over write security	This option erases all current security definitions and replaces 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.

5. Click **Next**. The **Access and Security** step of the Manage Security opens.
6. Using the **Groups** and **Users** tabs on the left side of the control window, select the Groups and/or Users to update security rights.Refer to the screenshot below:



7. Hover the mouse over the group/user name in the left pane. The **Plus icon** appears to the right.
8. Click the **Plus icon** to add the group and /or users to the Security Grid to the right pane. *Notice that the group and /or user is grayed out when you add them to the Security Grid and a small green tick appears to the right of the selected group/user.* This moves the Groups and/or Users into the **Security grid** on the right. Refer to the screenshot below:



9. Select the required security definitions that you want to update for the selected group/user.

Security Option	Description
Full Access	Non Encrypted access allowing for full printing and saving rights
View Only	Allows users to only view the PDF while restricting printing and saving
No Watermark	If the watermark is in use in the site, this access will provide the users access to a non-watermarked version of the PDF file
Redacted	Gives the users access to the redacted version of the file while preventing access to the original (non-redacted) version

10. Click **Save**. This applies the security permissions on the folders for the selected groups and/or users.

Note: *By selecting the target as All documents in the top left panel of the Manage Security tool, you need only to Select the security update type before clicking Next and selecting which groups or users to include in the security modification.*

Document Level Security

Note: *To set the document level security, the option for document security needs to be enabled in the room by your Administrator.*

This allows for security definitions to be set at the individual document level, allowing for the greatest control and flexibility on the security definitions as documents within a single folder can have different security/access rights. If document level security is used, each document will maintain its unique security settings, even as it is moved from one folder to another in the index outline, until its security definitions are changed.

1. Open a folder that contains documents from the Index outline.
2. Select one or more documents from the Document Grid whose security setting you want to modify.
3. Click the **Manage Security** button located in the upper toolbar. The Manage Security tool opens.
4. Click the button for **Selected documents**.
5. Select the security update type by clicking one of the four options, as described in the previous section of this guide.
6. Click **Next**. The second stage of the Manage Security tool populates the window.

7. Using the **Groups** and **Users** tabs on the left side of the control window, select the Groups and/or Users to update security rights for by double clicking on the listings. This moves the Groups and/or Users into the **Security grid** on the right.
8. Select which security definitions you want to update for the selected group/user, as described in the previous section of this guide.
9. Click **Save**, and the security definitions are in place.

By Security View

The By Security view shows the list of all the documents based on the security provided to the folders. To view the folders by security:

1. Click the **three dots**  next to **View by Index**. The **View Documents By** pop-up opens.
2. Select the **By Security** view**.**
3. Click **Select**. The Index displays the documents and folders based on the security level.

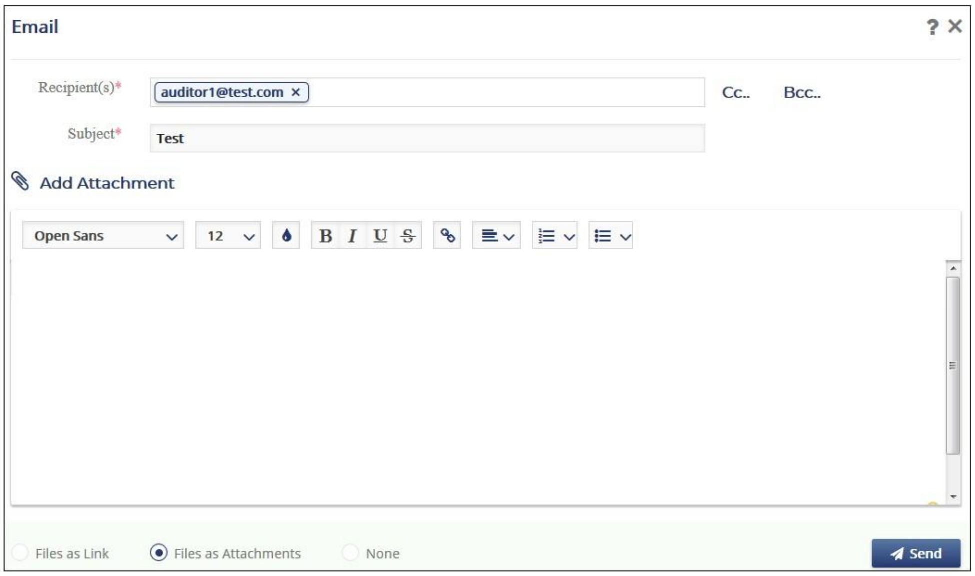
By group

The By Group view shows the list of all the documents and folders belonging to a particular group. To view the folders by group:

1. Click the **three dots**  next to **View by Index**. The **View Documents By** pop-up opens.
2. Select the **By Group** view.
3. Click **Select**. The Index displays the documents and folders based on the security level.

Email

To email a specific document as an attachment or as a link, click the **Email** option from the top ribbon and follow the on-screen instructions. You can save an outgoing email as a PDF document. On clicking **Send**, the **Save Conversation** dialog box opens up. Refer to the screenshot below:



If required, you may also opt to save the document as PDF and publish it to investigative sites. Upon selecting your option, the **Document Profile** dialog box pops up. Enter the details and click **Finish**. The email communication is now saved as a PDF document in the folder as mentioned in the **Default index position for Add document** in the **Settings -> Documents-> Index Outline**. *(page 225)*The email PDF has only Subject, date sent, and body of the email as its contents. You can view this email sent from the **Communications Outbox** module.

Print

The **Print** function is self-explanatory. You can order a printed hard copy of a document through this menu option.

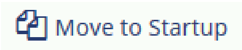
1. To activate the **Print** function, first, click a folder in the index so that documents populate on the document grid.
2. Select one or more documents from the grid that you want to print.
3. Click the **Print**  icon from the top ribbon. The **Print** window opens.
4. Click the appropriate radio button, **Selected Records**, or **All Records in Set**.
5. Click **Print**.
6. Follow the usual steps of creating a printout from your computer.

If the user has opened a folder with documents and has not selected a document or particular set of documents from that view, the **Print** option is still available. When the user clicks the option without having selected a document, the default is to print all of the documents in the set. Follow the on-screen instructions to complete this operation.

Move to Start-Up

Note: *The Move to Start-Up option is available only in rooms in which the Start-Up Module is active.*

Move to the Start-Up option can be used to **move documents from the eTMF back to the appropriate Start-Up folder** in the case that documents have been delivered and deposited in the eTMF prematurely.

1. Navigate to **Main Navigation-> eTMF module**.
2. Select the required document/s from the grid and click the **Move to Start-Up** button 

from the top ribbon bar.

Import

You can import multiple **documents** and **metadata** using just their metadata to a room. Click the **Import**

dropdown to reveal the import options - **Documents** and **Metadata**.

Each of these is discussed in the separate topics and can be accessed from the left of this menu.

Export

Documents can be exported from:

1. The **Export** dropdown from the top ribbon bar
2. The **Documents Cart**
3. The **Download documents** when opening a document in the **Original Viewer**

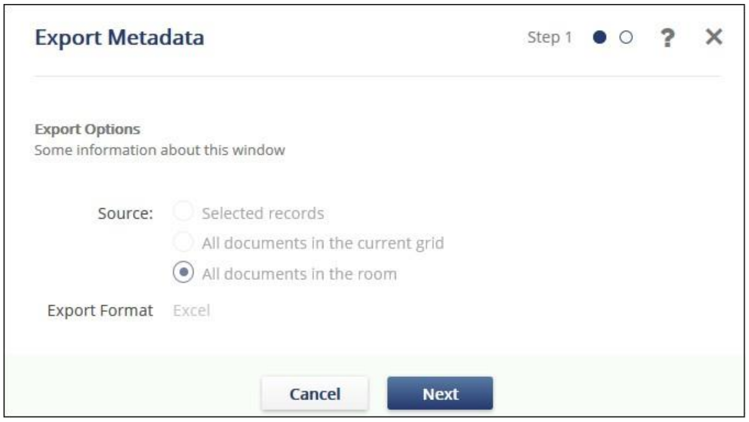
   Three options are available for Administrators from the **Export Dropdown** on the top ribbon bar - **Metadata**, **Documents**, and **Security**. Refer to the screenshot below:

   All of these options are discussed in separate topics accessible from the left panel of this help.

Exporting Metadata

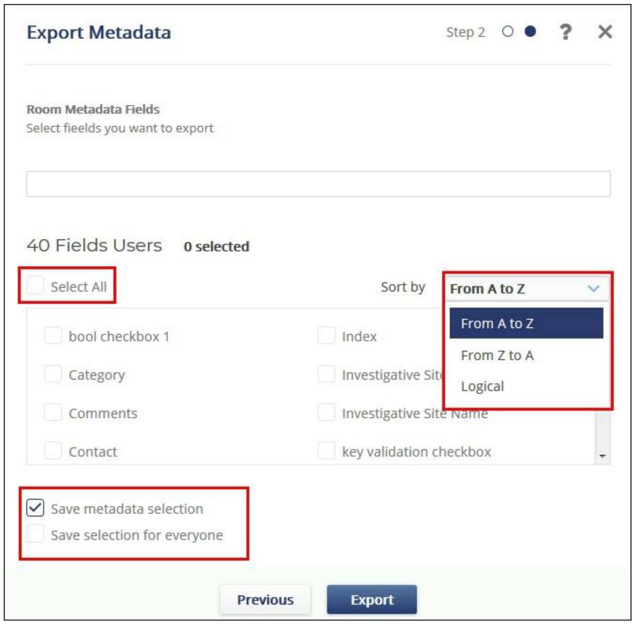
This function gives you a compressed file with the information you requested in XLSX spreadsheet file To export metadata,

1. Click the **Metadata** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:



2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
   a. **Select All**: Tick this checkbox if you wish to select all metadata fields.
   b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.

4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:

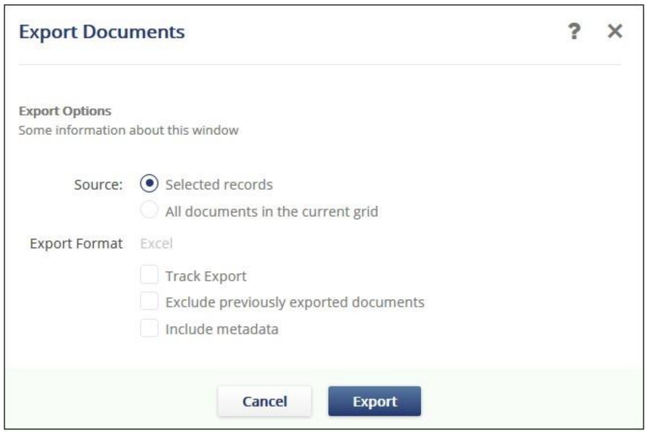


5. Click **Export**.

Exporting Documents

Exporting documents is the same as downloading documents from the **Documents Cart**.

You can **track an export**, **exclude previously exported documents**, or **include metadata during export**. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.



The documents or selected documents get exported in a .zip file. The .zip will include the following:

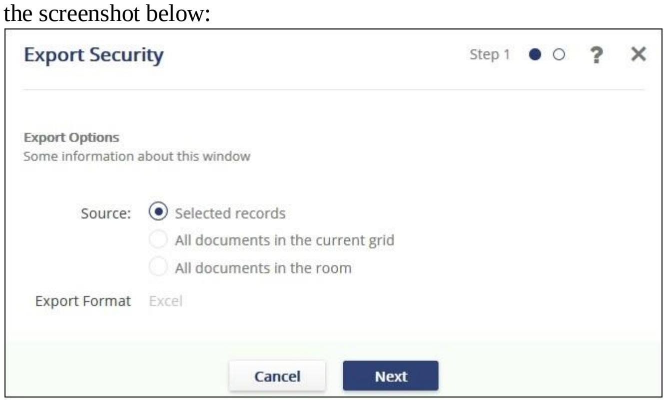
1. A **folder with the exported documents** in it.
2. An **excel worksheet** with the metadata, if you happen to export metadata.
3. A **.log** file which opens in Notepad to give the list of previously exported documents that were excluded during export. Here again, you have to select the option to exclude previously exported documents to enable this.
4. An **ErrorsLog.xml** file that includes details of documents that fail to export. To view the exported file, navigate to the

Notifications *(page 64)*.

Exporting Security

This allows you to export all the security accesses for selected records for all documents in the grid, all documents in the room. The output of the export job is an .xlsx file that can be accessed from the **Notifications.** Follow the steps below to export documents security:

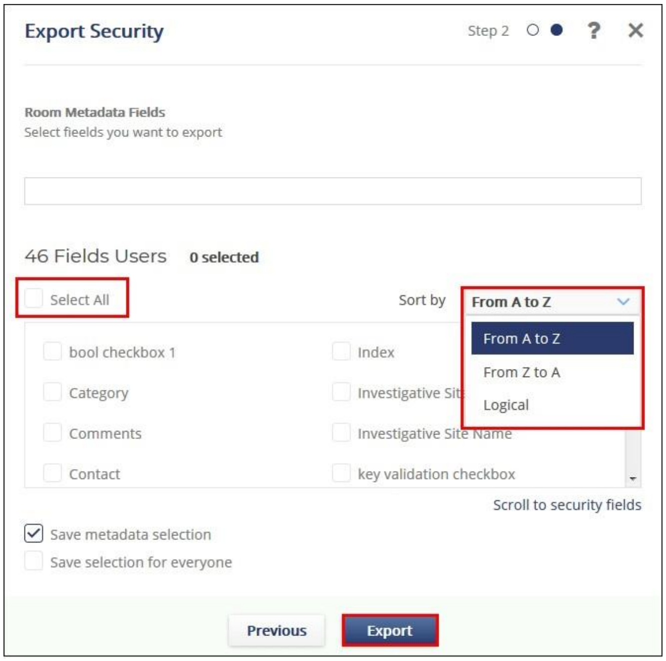
1. Click the **Security** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:



2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:

a. **Select All**: Tick this checkbox if you wish to select all metadata fields.
b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.

4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:

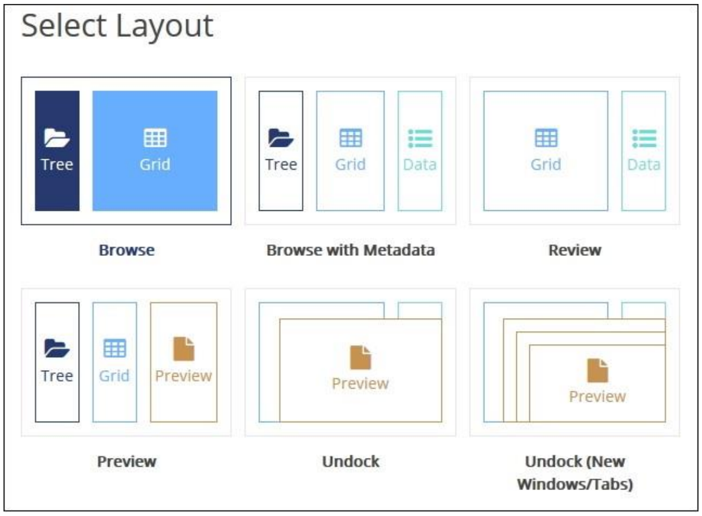


5. Click **Export**.

Layout

You can change the layout view of the grid by clicking the Layout option from the top ribbon bar. Follow the steps below to change the layout of the gird.

1. Navigate to **eTMF Documents module.**
2. Select the **Layout** option from the top ribbon bar. The **Select Layout** popup opens. Refer to the screenshot below:



3. Select the required layout and the document grid sets it layout as selected.

Compare

Documents can be compared from in the following ways:

1. From the top ribbon in the eTMF Documents module.
2. From the Documents Cart *(page 285)*. To compare documents,

1. From the **eTMF Documents** module, select the folder from the Index to open the documents in the grid.
2. Select the required documents to compare and click the **Compare** 

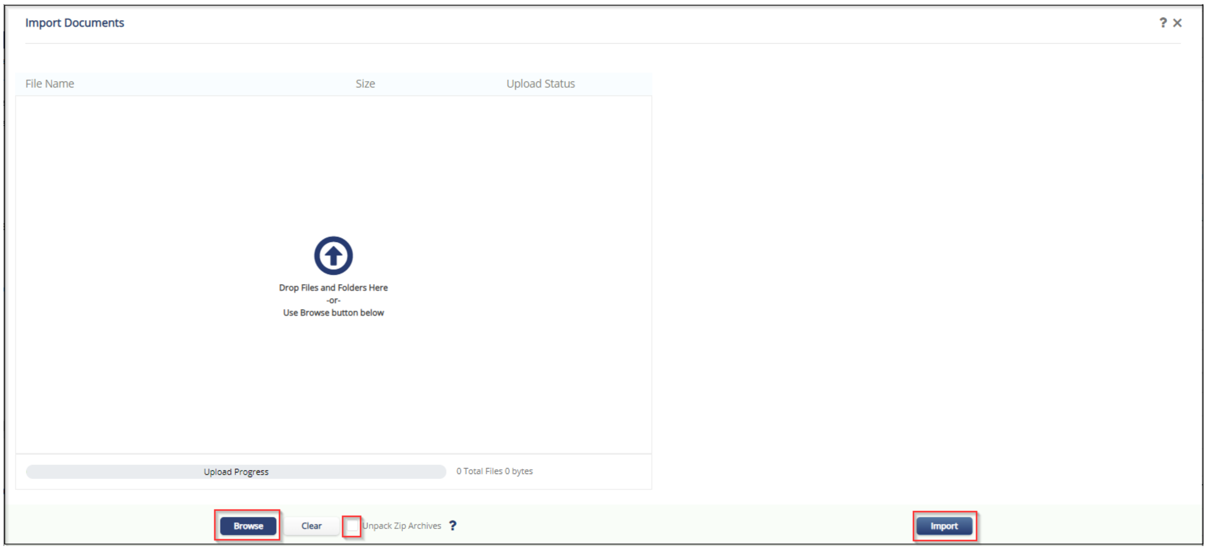
option from the top ribbon bar.
3. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the viewer chosen by you. You can also expand the metadata fields on the bottom using the double-caret bar to compare documents metadata conveniently at once.

Bulk Uploading

Besides Importing documents, you can also upload documents in a bulk to the room. Follow the steps below to bulk upload documents in a room.

1. Navigate to **eTMF Documents** module.
2. Click the **Bulk Upload** 

option from the top ribbon bar. The **Import Documents** window opens.
3. Following the on-screen instructions, either drag-and-drop files from your computer into the upload panel or use the **Browse** button on the window to select documents to upload. Refer to the screenshot below:



4. Choose **Unpack Zip-archives** if you wish to extract files from an attached zip folder.
5. Tick the checkboxes for documents to be uploaded and click **Import.** These documents are uploaded to the upload folder. You can later edit the metadata of these documents from the **Metadata Panel** ***(page 262)***as required.

Documents Cart

Perform various functions from here like **copying documents to rooms or sites, comparing, merging, or linking** documents besides many more.

Users select documents to add to the Document Cart either from the Documents Context Menu *(page 249)* or by selecting documents from the grid and then clicking the **Add to Cart** button from the top ribbon menu.

The **Documents Cart** 

icon is located on the upper right-hand corner of the document grid and works just like a shopping cart.

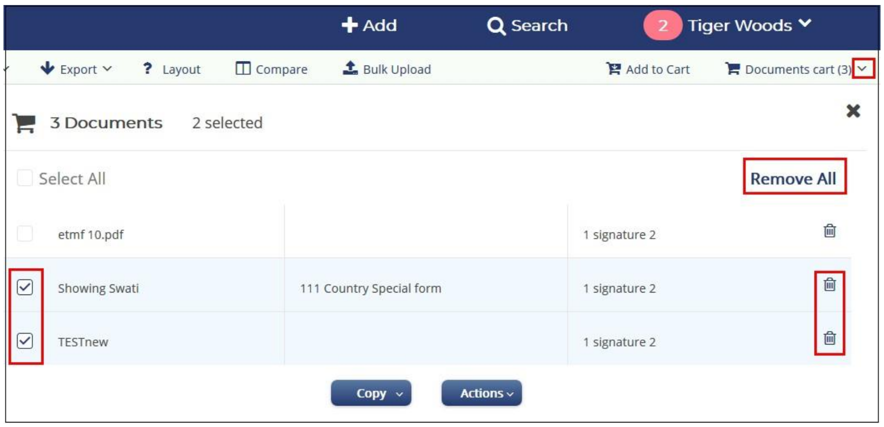
Adding documents to the Documents Cart

1. Locate the document which is to be added to the Document Cart and select the checkbox next to it. Now the process of addition can be done in two ways.
   a. Click **Add to Cart** from the upper right-hand corner.
   b. Right-click and select **Add Selected to the Cart** option.
2. Once a document is added, it will automatically update to reflect the number of documents available in the cart. Refer to the screenshot below:

Removing documents from the Documents Cart

Follow the steps below to remove documents from the Documents Cart:

1. Click the arrow next to the **Documents Cart**. A popup window opens.
2. Select the checkboxes next to the documents and click Delete button to the right of the selected documents.
3. If you wish to remove all the documents, click the **Remove All** button. Refer to the screenshot below:



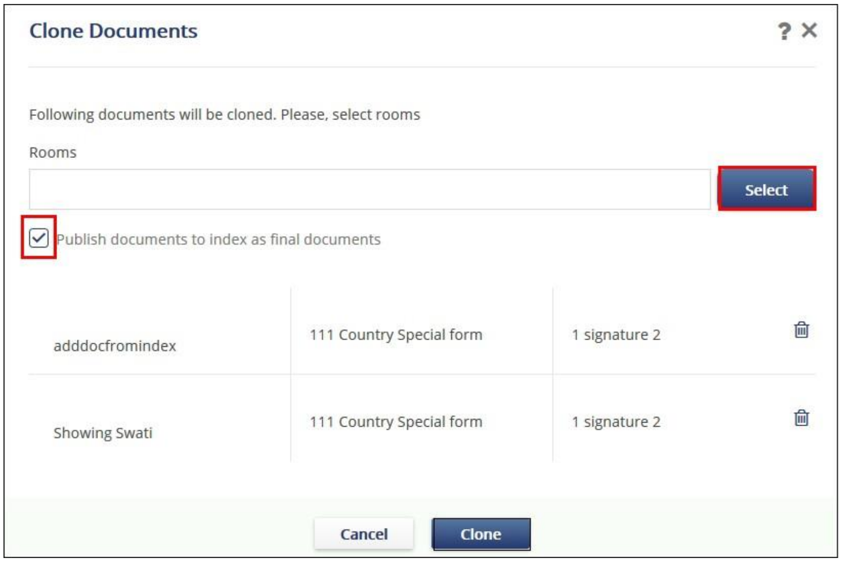
Copying documents to Other Rooms

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.

1. Add the required documents *(page 282)* to the Documents Cart.
2. Click the arrow next to the Documents Cart. A pop-up opens.
3. Select the documents which you wish to copy to other Rooms.
4. Click **Copy** and select **to other Rooms.** Refer to the screenshot below.

5. The **Clone Document** window will open up and prompts you to specify to which study rooms documents shall be copied.
6. Click the **Select** button which opens the **Rooms** window to allow you to select the rooms to copy the documents to.
7. If you wish 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**.
8. Click **Clone**. The document type of the destination room will determine the auto-naming rule for the document. Refer to

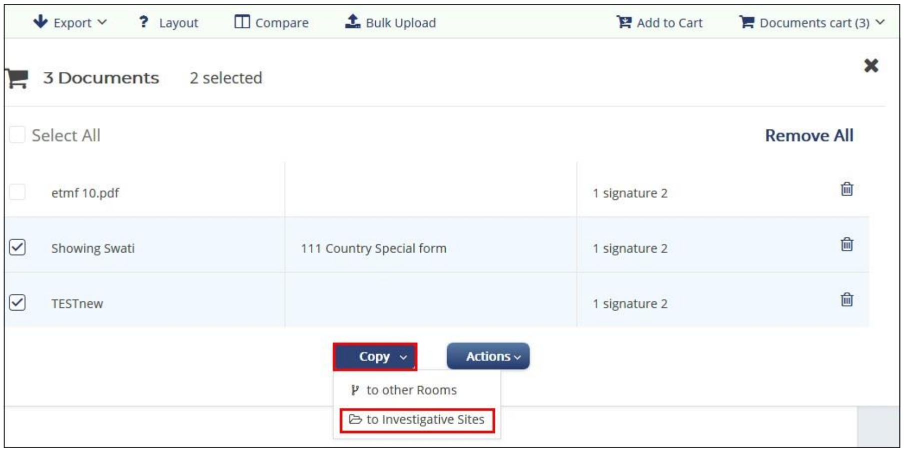
the screenshot below:



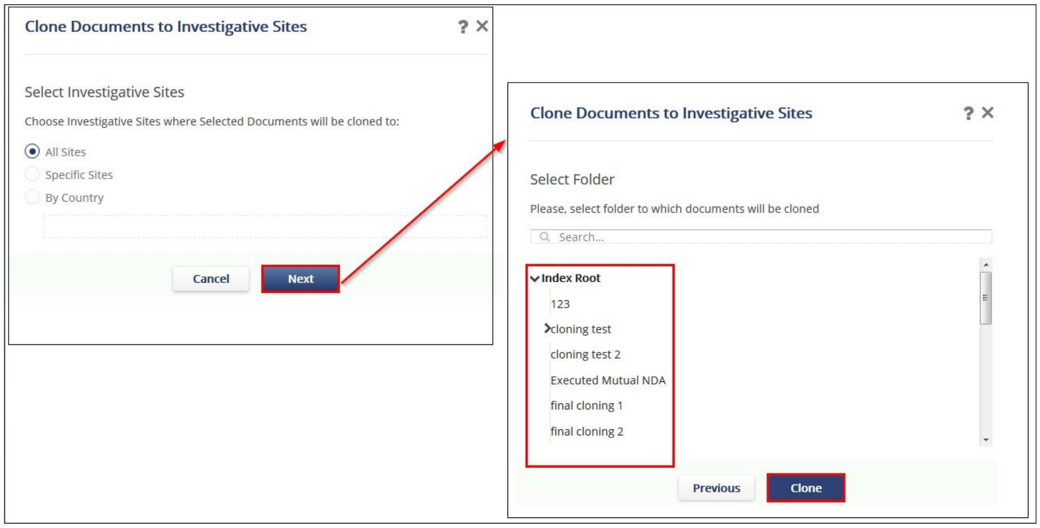
Copying documents to Investigative Sites

This option is helpful when Administrator users wish to distribute the same document, such as training documents, across different investigative sites. To avoid copying these documents one-by-one, you can simply use this option in Documents Cart.

1. Add required documents to the Documents Cart *(page 282)*.
2. Click the arrow next to the Documents Cart. A pop-up opens.
3. Select the documents which you wish to clone to other Investigative Sites.
4. Click **Copy** and select **to Investigative Sites**. Refer to the screenshot below.



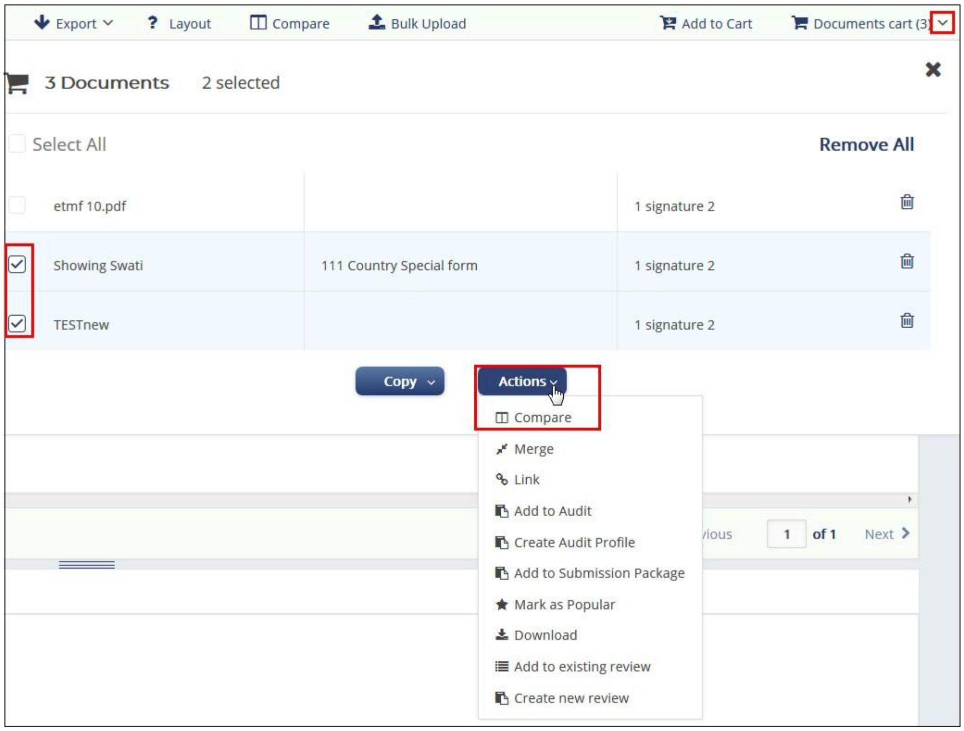
5. The **Clone Documents to Investigative Sites** window opens up and asks you to select investigative sites. Click radio button next to your choices.
   a. If you choose **All Sites**, just click **Next**, to select the folder to which the documents will be cloned.
   b. If you choose **Specific Sites**, just click **Next**, and it will give you site choices on the next section.
   c. If you choose **By Country**, a dropdown with the list of countries gets activated for you to choose from.
6. Click **Next** folder selection.
7. Once the folder is selected, click **Clone**. The documents are copied to the Investigative Site folder. Refer to the screenshot below:



Compare Documents

The **Compare Documents** tool in Documents Cart lets you view and compare two or three documents at the same time by placing those side by side. You can use the **ABBYY Optical Character Recognition** (if that is enabled for you) to support the comparison of documents from document scans and images.

1. Add required documents to the Documents Cart. *(page 282)*A pop-up window opens.
2. Select the documents from the list you wish to compare.
3. Click **Actions** at the bottom of the window and then select **Compare**. Refer to the screenshot below.



4. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the **Arender** view. Refer to the screenshot below:
5. To facilitate easy and seamless comparison of documents:
   a. The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
   b. The **documents scroll at once in sync** with each other when you drag the scroll bar to facilitate easier viewing and comparison if you have activated the 'Synchronize document scrolling' from the toolbar.
   c. The system displays appropriate messages when two documents are identical.
   d. The print and download options for comparison are available to you only if you have **Full Access** to the documents.

Merging documents

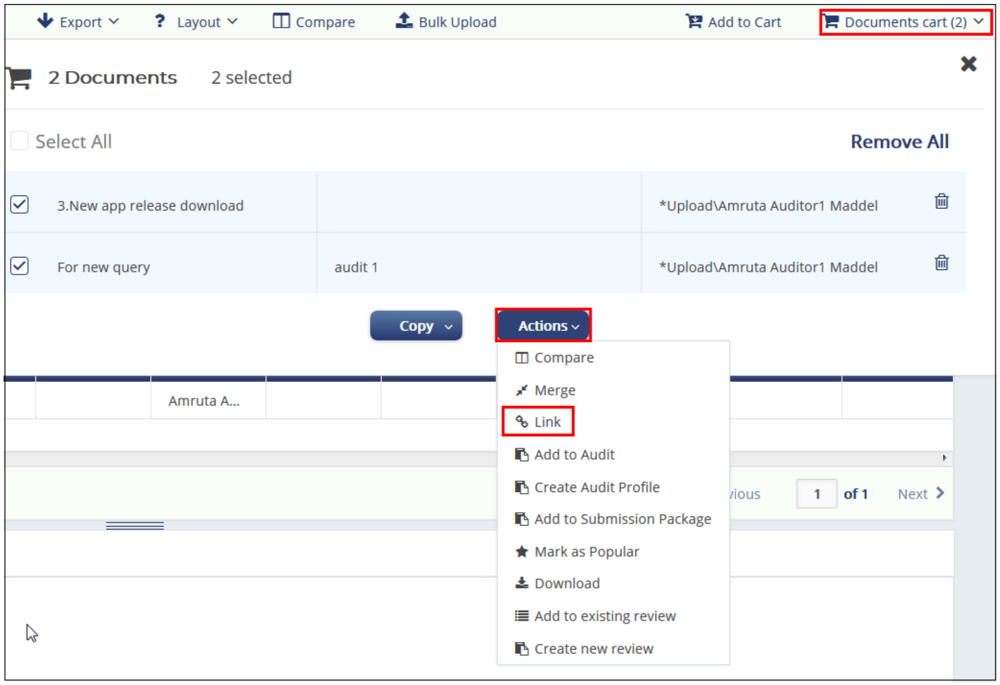
An Administrator user can merge two or more documents into one document.

1. Add required documents to the Documents Cart. *(page 282)*
2. Select the documents from the cart you want to merge into one, either to use as a single document in the room or to download and print as a single document.
3. Click **Actions** and then select **Merge**. Refer to the screenshot below.

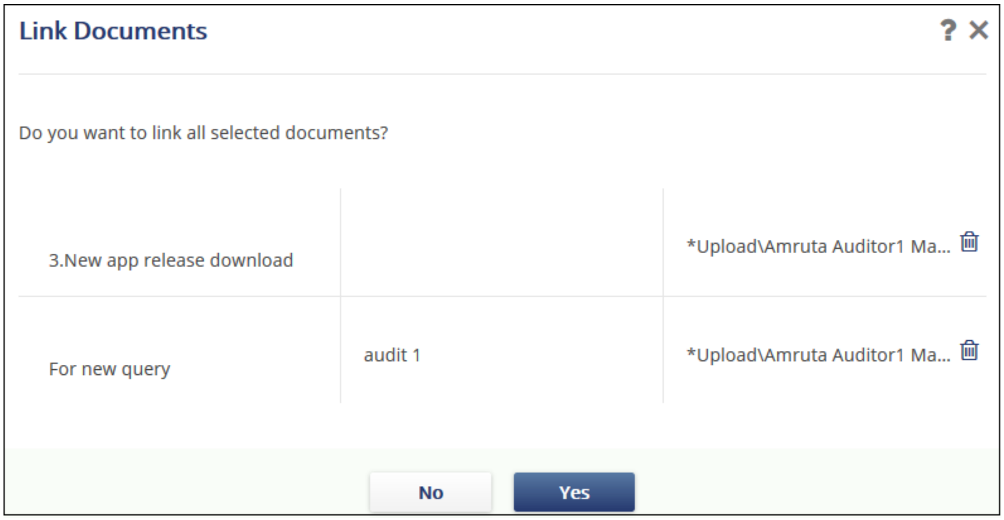
Linking documents

Administrator users can link documents together with this option.

1. Add required documents to the Documents Cart. *(page 282)*
2. Select the documents from the cart.
3. Click **Actions** and then select **Link.** Refer to the screenshot below:



4. The **Link Documents** window opens. Select 2 or more than 2 documents to link and click **Yes**. Refer to the screenshot below:

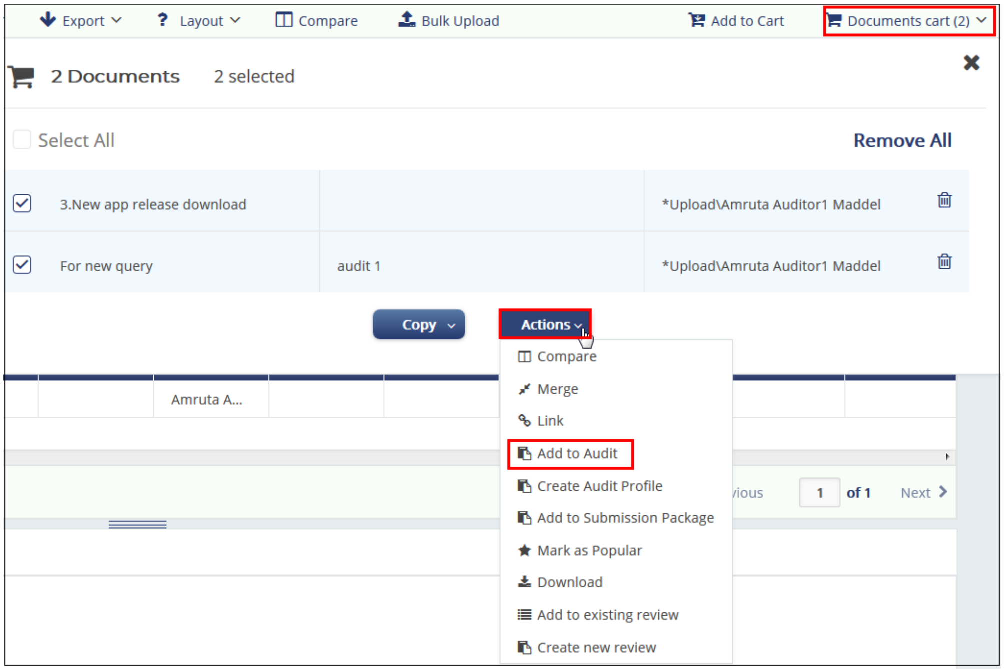


5. A pop-up message appears to confirm the documents are successfully linked.
6. Afterward, whenever you right-click on one of the linked documents and click **Related Documents**, interrelated documents will all be displayed on the screen.

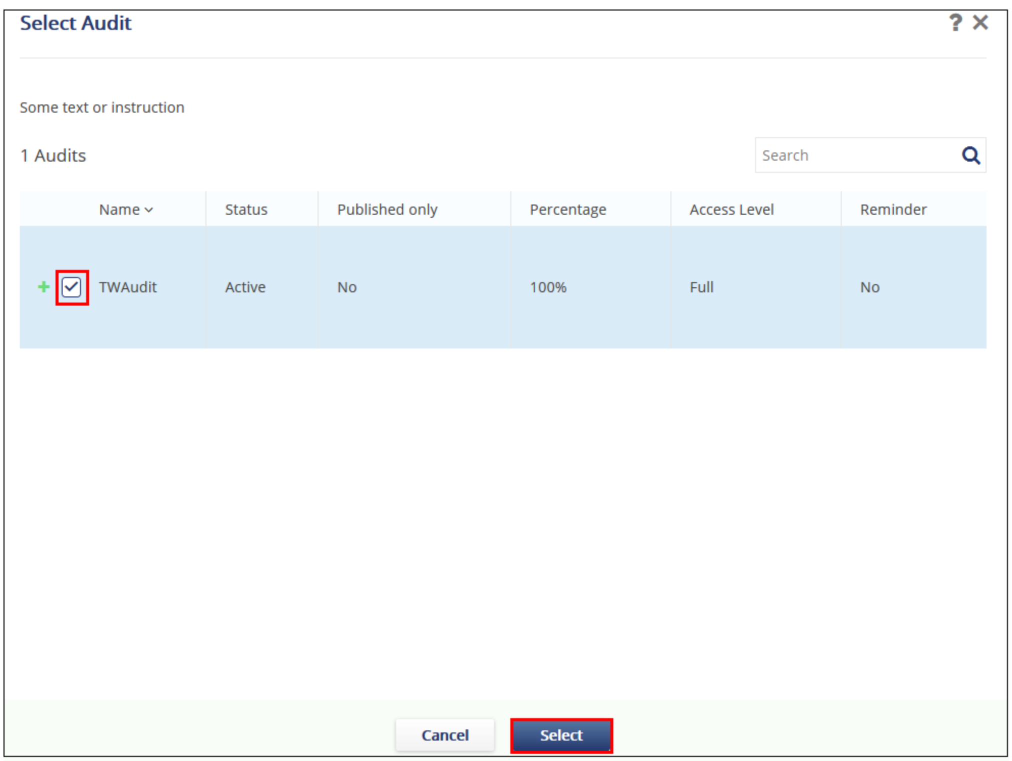
Adding documents to Audit

Admin can add documents to the cart from the grid and include them in an existing audit by using the **Add to Audit** option.

1. Add required documents to the Documents Cart *(page 282)*.
2. From the Documents Cart, select a document.
3. Click **Actions** and then select **Add to Audit**. Refer to the screenshot below:



4. The **Select Audit** window opens.
5. Select the Audit to which you wish to add documents to.
6. Click **Select**. Refer to the screenshot below:

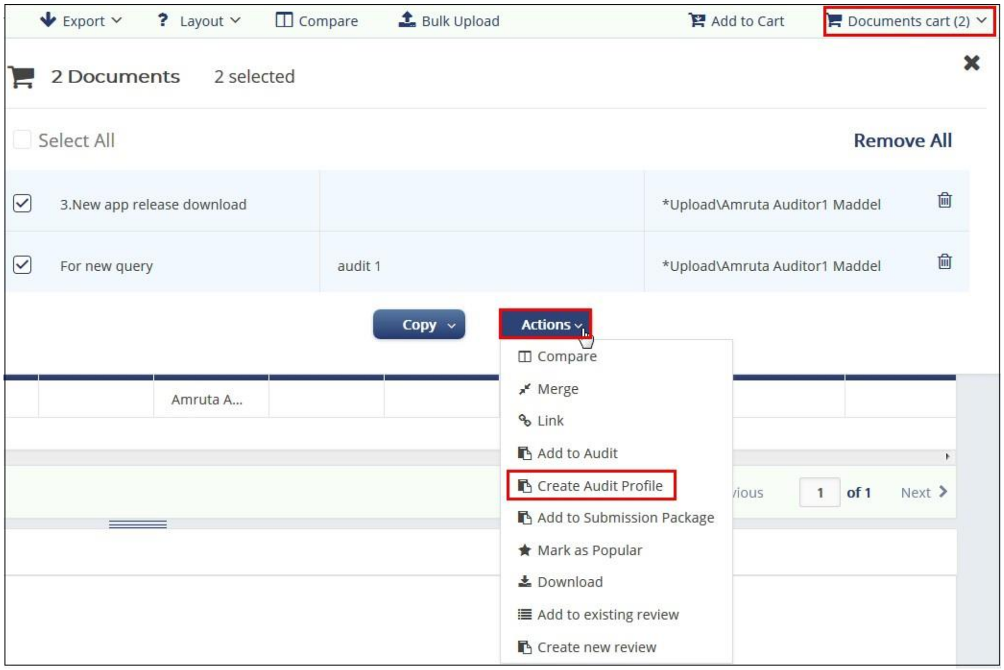


Note: *The Audits in the Select Window are displayed only when you select Add Documents to pool on Demand Basis (page 353) option while creating an Audit profile.*

Create Audit Profile

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

1. Add required documents to the Documents Cart *(page 282)*.
2. From the Documents Cart, select a document.
3. Click **Actions** and then select **Create Audit Profile**. Refer to the screenshot below:



4. The **Create Audit Profile** popup opens.
5. Follow the instructions on the form to create the audit profile as required.

Note: Creating Audit Profiles *(page 351)* are discussed under the Quality Review section in detail.

Adding documents to Submission Package

Admin can add documents to the cart from the grid to include them in a start-up submission package by using this option.

1. Add required documents to the Documents Cart. *(page 282)*.
2. Select the documents from the cart.
3. Click **Actions** and then select **Add to Submission Package**. Refer to the screenshot below:
4. The **Select a Submission** window opens.

Marking documents as Popular

Administrator users can mark certain documents as popular using this option.

1. Add required documents to the Documents Cart.
2. Click **Actions** and then select **Mark as Popular.** Refer to the screenshot below.
3. A pop-up message- **Documents successfully marked as popular** appears.
4. The selected documents now appear on the dashboard- **Popular Documents** dashlet

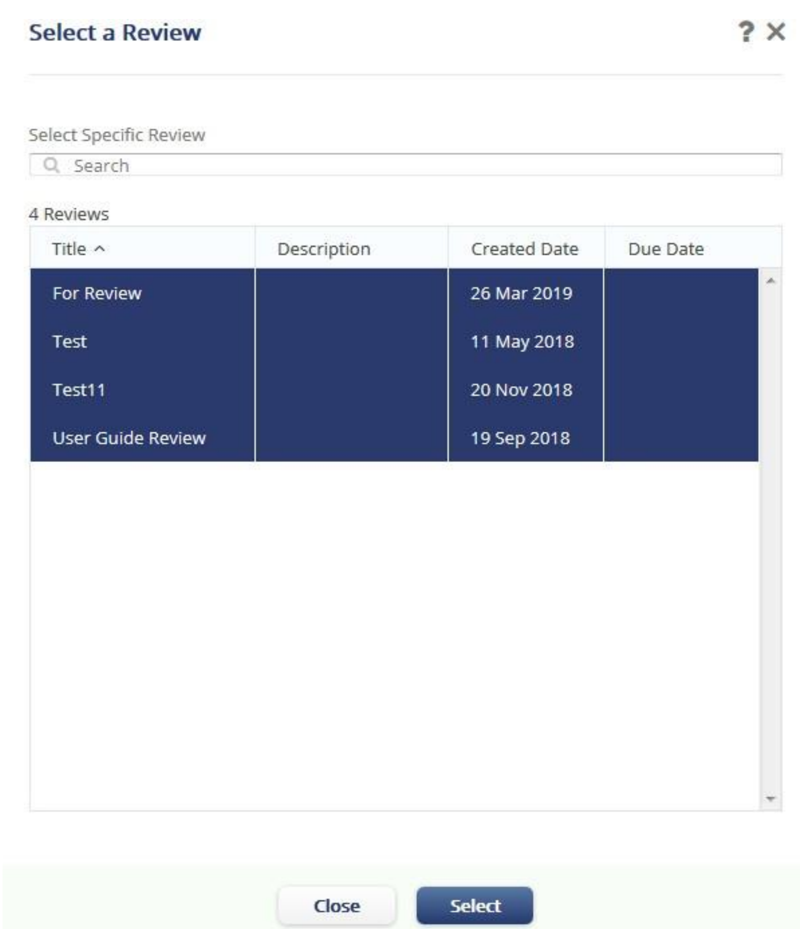
Downloading documents

1. Add required documents to the Documents Cart. *(page 282)*
2. Click **Actions** and then select **Download**. Refer to the screenshot below.

Adding documents to existing review

Admin can add documents to the cart from the grid and include them in an existing review workflow by using the **Add to existing review** option.

1. Add required documents to the Documents Cart *(page 282)*.
2. Click **Actions** and then select **Add to existing review**. Refer to the screenshot below.
3. The **Select a Review** window opens. Select a review from the list of reviews and click **Select.** Refer to the screenshot below:

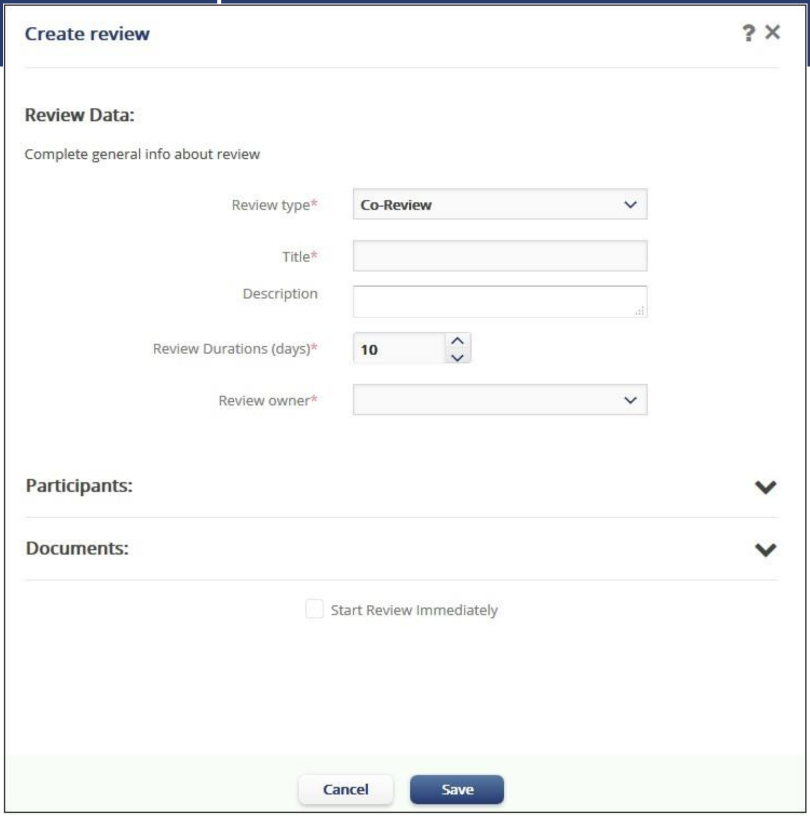


4. **Confirmation** pop-up opens. Select **Yes**.
5. **The review was added successfully** message appears. The review can be accessed from the **Collaborative Authoring** module.

Creating a new review

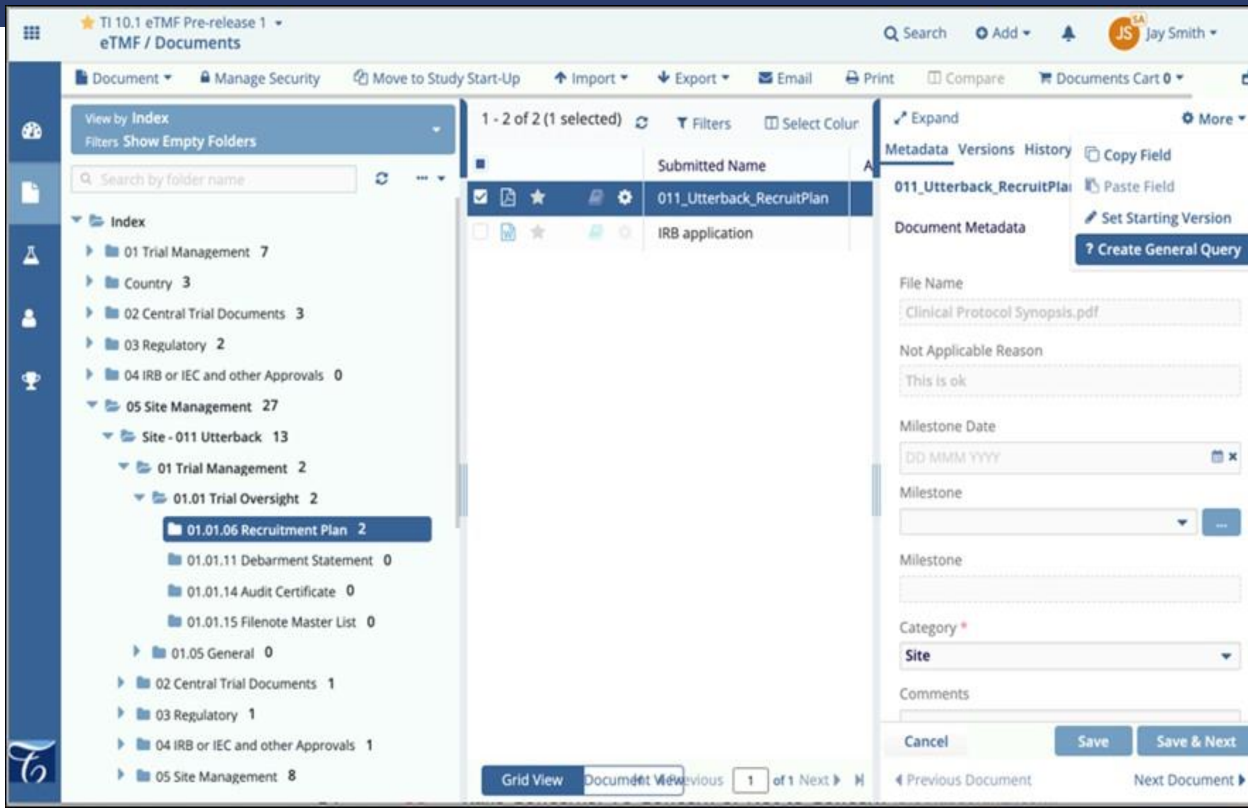
Admin can also add documents to the cart from the grid to include them in a new review workflow by using the **Create new Review** option**.**

1. Add required documents to the Documents Cart. *(page 282)*
2. Click **Actions** and then select **Create new review**. Refer to the screenshot below:



3. The **Create review** window opens. Fill in the details under **New Review Info, Participants,** and **Documents**.
4. Click **Save**. **New review was successfully created** message appears.

Query Any Document



Queries are a critical feature in TI, and in 10.1, Queries will become much more flexible. Currently, queries can only be used as part of eTMF Quality Control or Quality Review, but 10.1 changes all ofthat. Queries can now be opened regarding a document at any time for purposes of clarification or toprompt for document replacement.

A room Admin or Document Manager can raise and resolve a query against a Collected or Final document through a simple right-click. This query may be sent to anyone in the room, including Readers and Editor roles. Once raised, the queries may be viewed by status from an All Queries viewand are assigned by default to the submitter or the person who last progressed the workflow.

The standard query workflow process is then followed, allowing the responder to clarify the query,or respond with updated content. All back-and-forth is captured in the document audit trail as normal. Documents may be emailed in or attached directly to the query response from within TrialInteractive.

Users can see what queries are assigned to them just like they would their tasks, through a notification in the user menu, the query view, or the corresponding dashlet. They may be reminded about their queries through a message or newsletter. Documents with open queries will show with an icon in the index and working views, and queries may be filtered by site, country, issue type, and other configurable filters. Open queries against collected and final documents also show in the 'MyQueries' and 'Queries by Status' dashboards alongside standard workflow and audit queries

Potential Sites and IRB Integration

This allows you to locate the Unique Sites using the combination of Study Name and Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

Note:*If the system finds matching conditions like the site, IRB number and IRB document type in the Study Start- up Site Profile, the documents for the imported site will be uploaded into the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which are discussed below.*

This section includes the following sections:

1. IRB Integration and Settings
2. Potential Sites and Modules

Chapter 9. Searches

In this section we discuss Document and Advanced Search, Cross Study Search, Search for Users, Sites, Clinical Data and Room Search

Each of the searches is discussed in separate topics available in the left panel of this help topic.

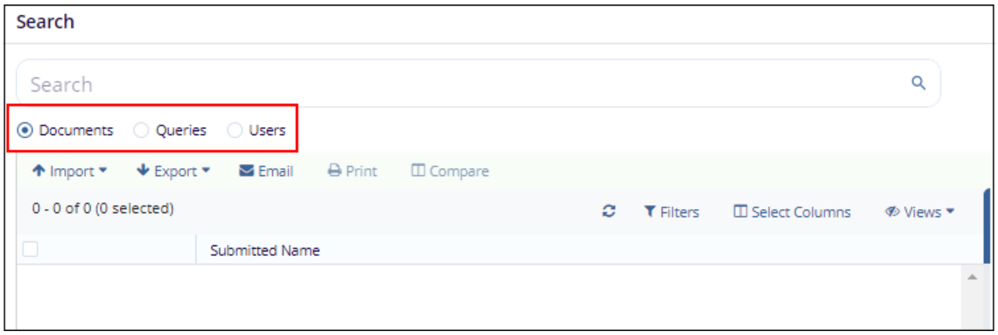
Documents Search

We can perform two types of searches on documents:

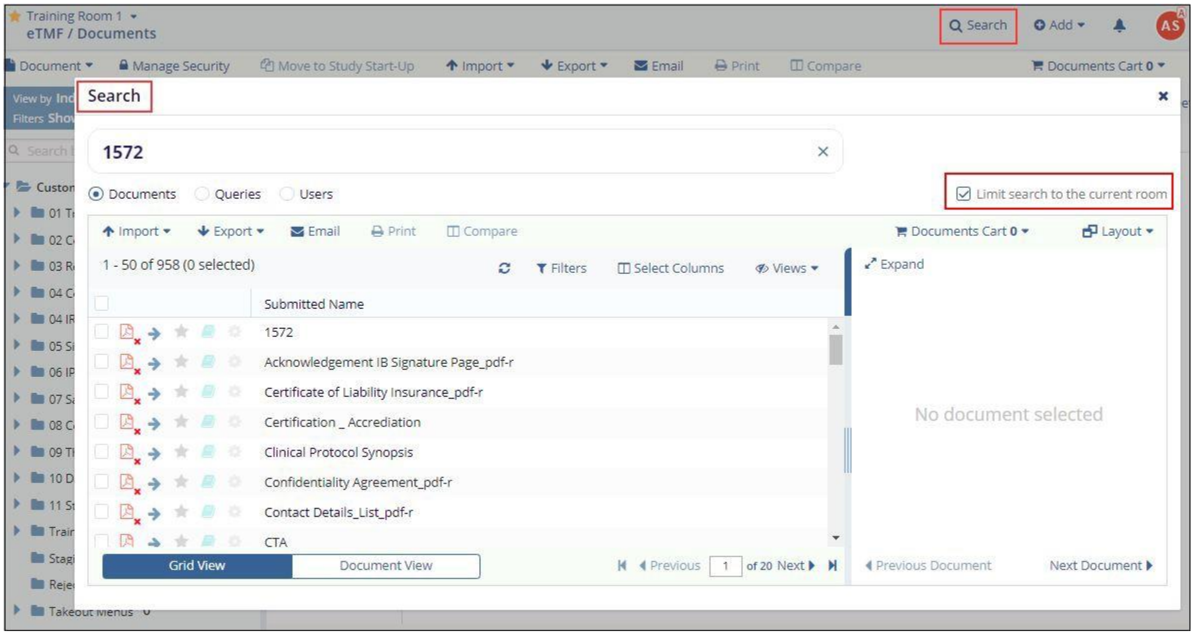
1. **Cross Room Search:** When you search for documents across all studies that you have access to, you are performing a cross-study search. You can execute this search from the **Home Page Search** functionality.
2. **Documents Search:** When you search for documents from within a room or study, check the box **Limit search to the current room**. Refer to the screenshot below:

The process to execute both the types of searches is the same except for the location of executing the search:

1. Navigate to the Home Page or a Trial Interactive room as required.
2. Click the Search icon from the blue bar located on the top of the dashboard.
3. The Search popup appears.
4. Select **Documents** from the options of Documents, Queries, and Users, Refer to the screenshot below:



5. Enter the search criteria in the **Search box**.
6. As soon as the text is entered in the Search box, the search process starts.
7. Documents matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:

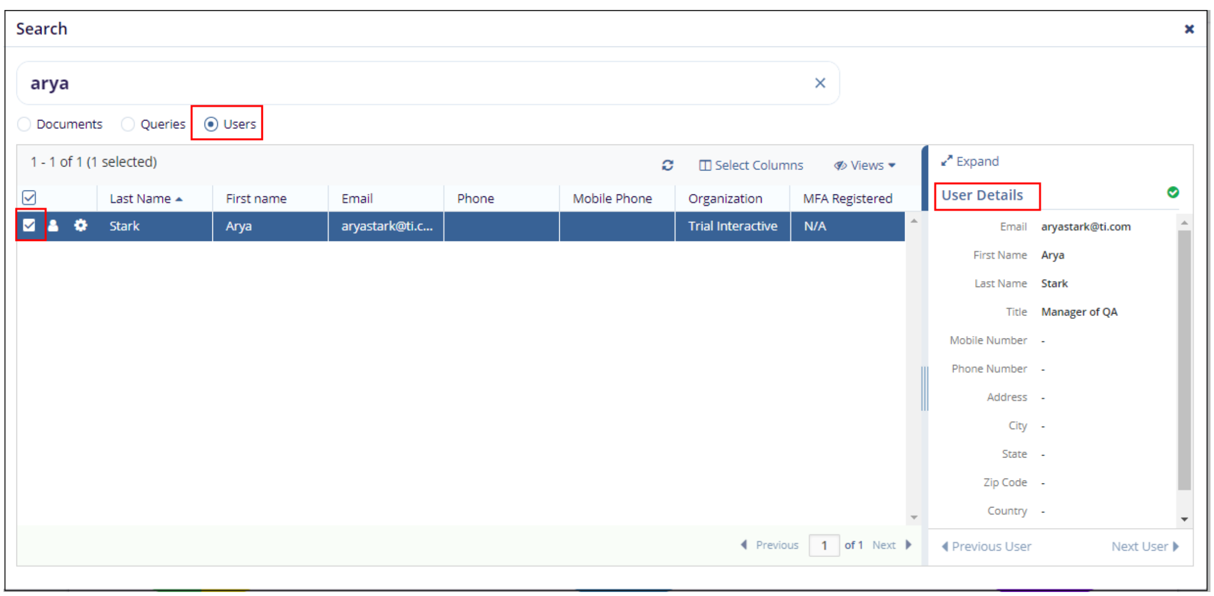


8. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.

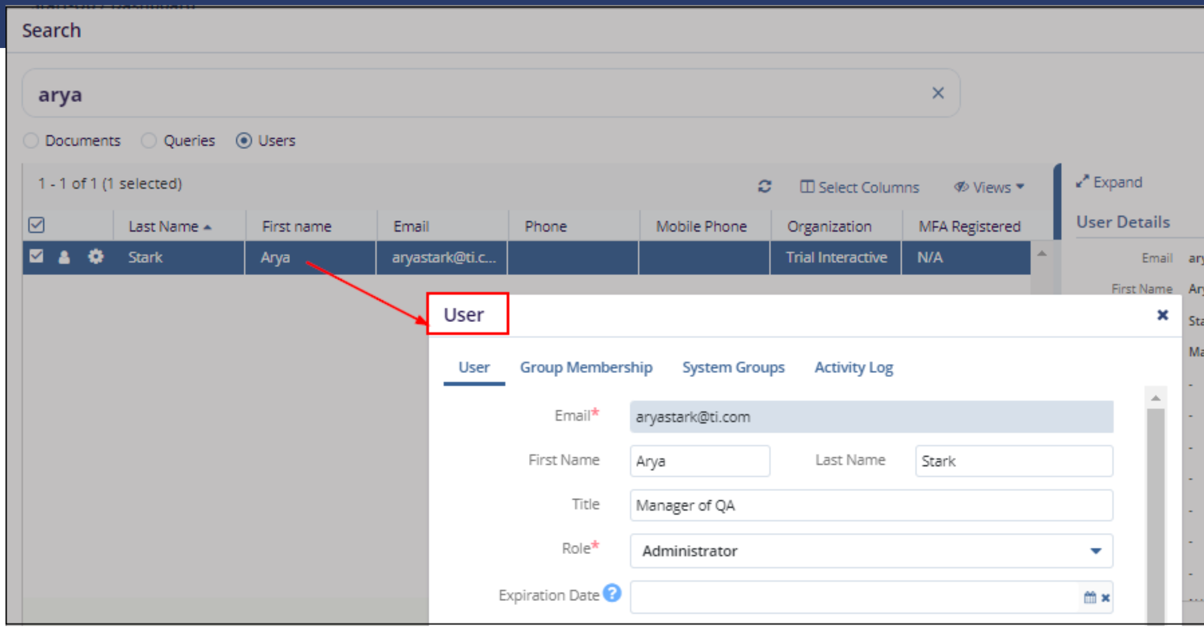
9. Hover the mouse over the **Document icon** to get a preview of the documents.

10. Click the document icon. The document **Metadata** panel opens in the right pane.

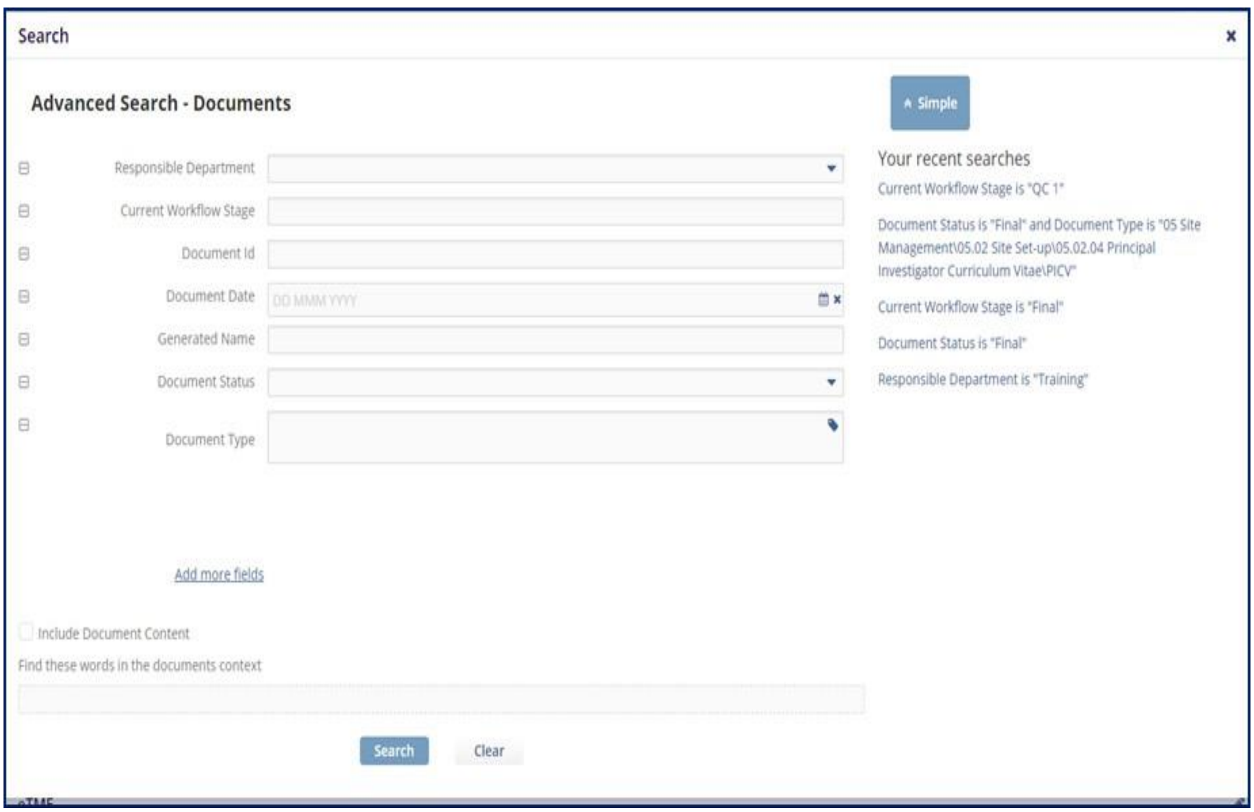
11. Similarly, select the **User** option to perform the user search. When the results are displayed and the user selects any record, User Details are displayed in the right pane.



If more details are required then double click the record and **User** popup screen appears in which more **User Details**, **Group Membership**, **System Groups**, and **Activity Log** details are available.



Improved Metadata Search



In 10.1, additional items may be searched that go beyond documents, including queries, tasks, andusers. These may be selected using a simple dropdown next to the search box.

A more advanced metadata search is also available that provides the ability to search on key fields that are most common. Rooms may still be configured to limit the global search to just a few metadata fields. This improvement provides more fine- grained control to a user. For Example, a usermay search against all 1572 forms in a specific Country containing a specific piece of text. Other available search fields may include:

- Document ID
- Name
- Title / Submitted Name
- Submitted Date
- Investigative Site
- Country
- Within the text of the document
- Any other metadata field needed, configured in the search panel by each user.

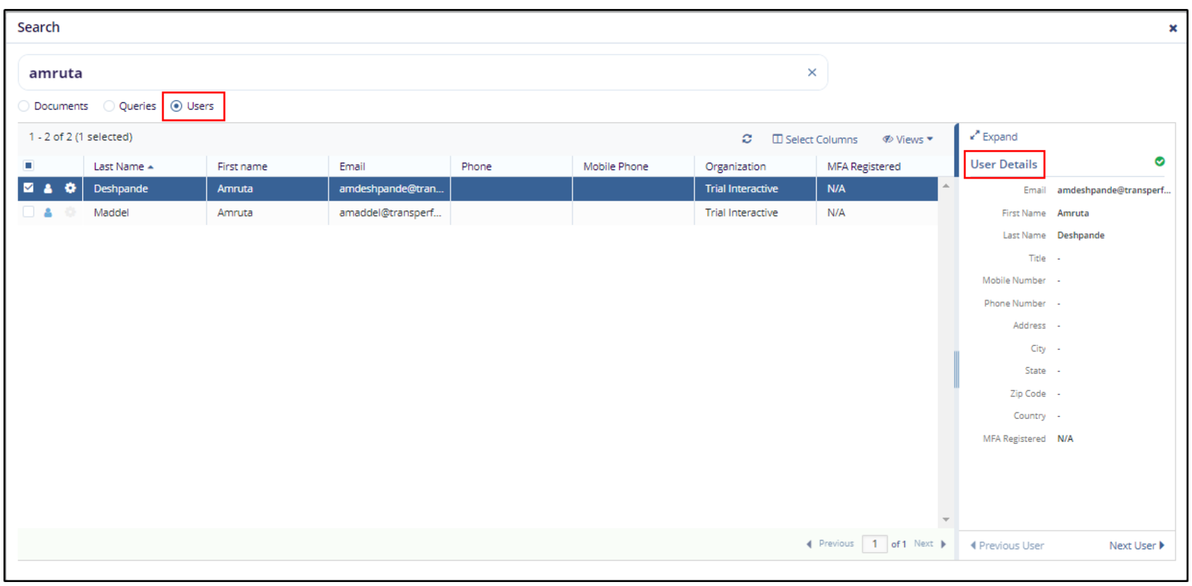
In order to perform an Advanced search, the user would open the regular search function and pressthe Advanced button at the right of the search field.

In the Advanced Search window, the user can then refine their search by adding specific metadata fields.

Searching Users

To search for users, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
2. The **Search** window appears. Select **Users** from the options given.
3. Enter the user name in the **Search** textbox at the top of the window. This displays the user in the **Records** section if available. Refer to the screenshot below:



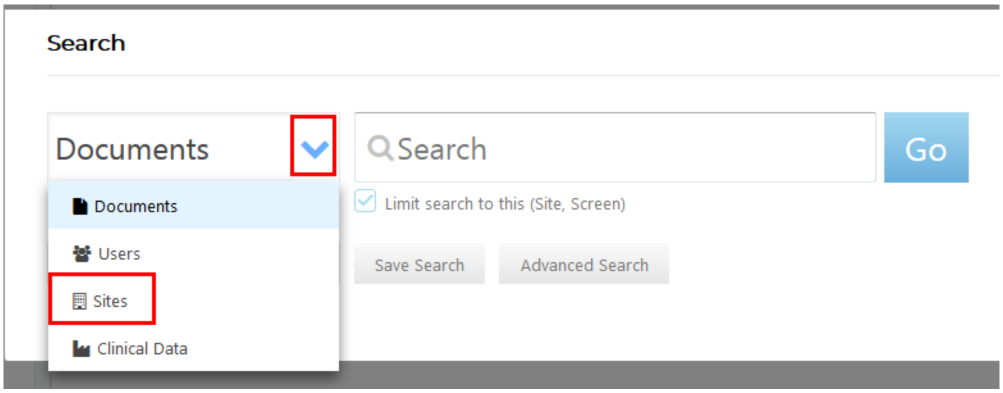
4. Upon selecting a required user from the results grid, details of that user will be displayed in the **User Details** section in the right pane.

Searching Sites

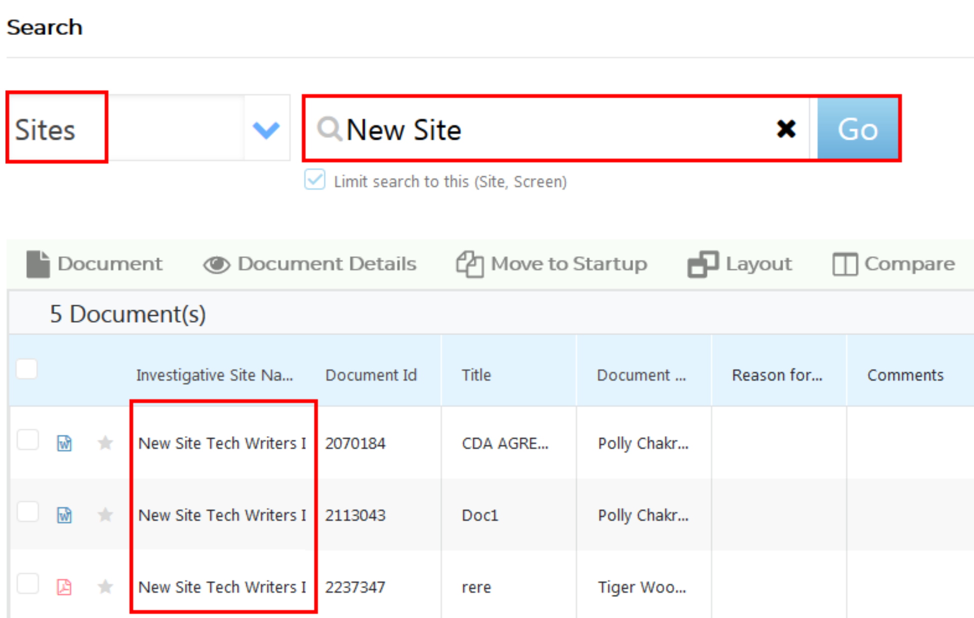
To search for sites, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located on the blue bar.

2. The **Search** popup appears.
3. From the **Documents** dropdown, click **Sites**. Refer to the screenshot below:



4. Enter the site name in the **Search box** next to the dropdown and click **Go** or press **Enter**.
5. The sites matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:



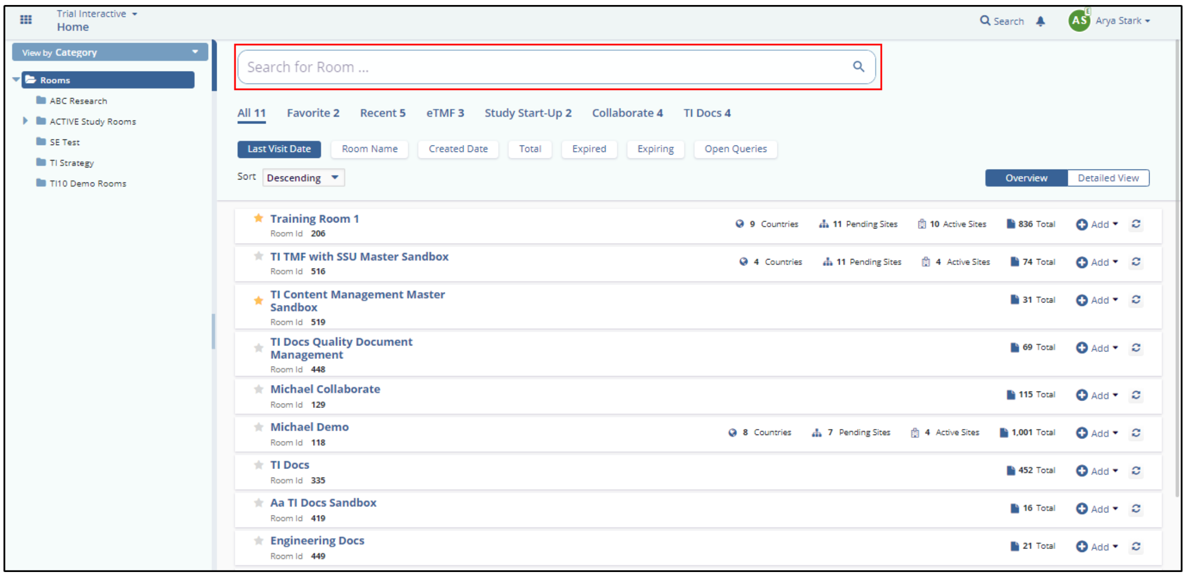
6. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
7. Notice that the top ribbon bar is also available above the Grid which provides the functionalities like **Document**, **Document Details**, **Move to Startup**, **Layout**, **Compare**, and **Add to Cart**.

Each of these functionalities is discussed in the respective sections.

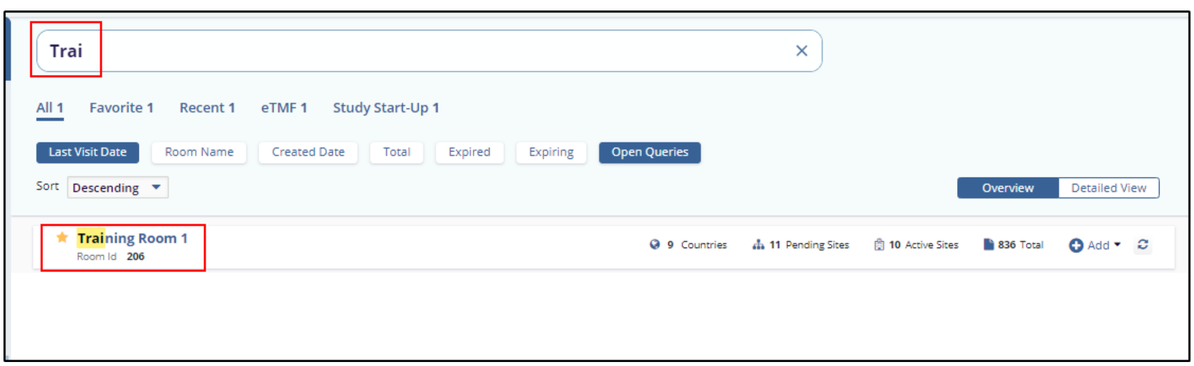
Room Search

To search for a room, follow the steps as below:

1. The **Search** textbox is located on the home page to perform the room search. Refer to the screenshot below:



2. On the home page of the application, all the rooms are displayed and the user can use this search functionality to easily search for the desired room.
3. Enter the room name in the search textbox and search starts automatically as and when the text gets entered in it. Refer to the screenshot below:



Chapter 10. Importing Documents and Metadata

Following are the various ways to add documents to a study room. Documents can be added to a room by several means such as:

1. Uploading documents from the **Home page**
2. Adding a document from the Documents module using:
   a. The **Document Action dropdown**
   b. The **Context Menu** from the document grid
3. Importing documents using:
   a. The **Import dropdown** in the Document module
4. By emailing and faxing documents to a room

Each of these is discussed in a separate topic and can be accessed from the left menu of this help.

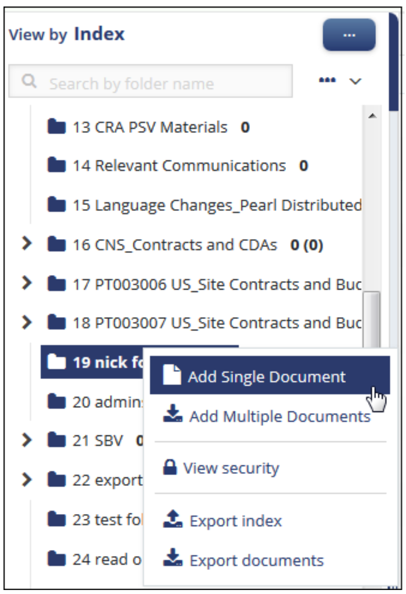
Adding Documents to Index Folder

You can add Single or Multiple documents to an index folder. Each of these is discussed in the sections below.

Adding Single Document to Index Folder

To add a document directly to an index folder:

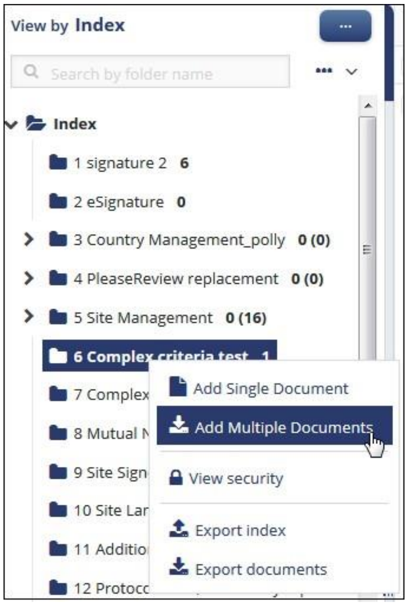
1. Navigate to the **Documents** module.
2. Select the folder from the index pane into which to add documents and right-click on it.
3. From the right-click popup, select **Add Single Document**. Refer to the screenshot below:



4. This will open the **Document Profile** form for you to add the details and save. This adds documents directly to the selected folder and such an added document does not appear in the default index folder or Upload folder.

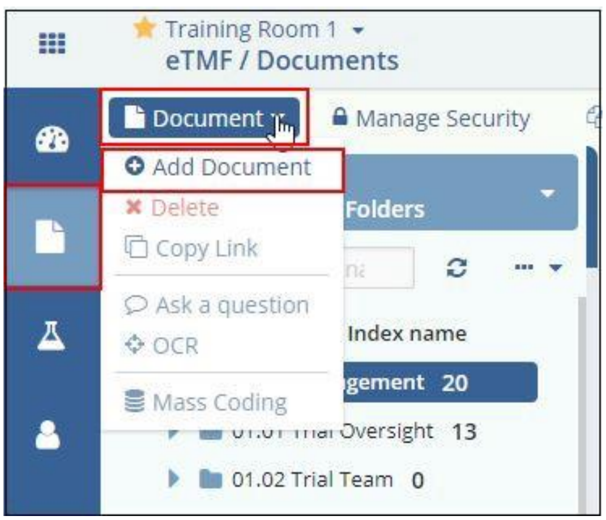
Adding Multiple Documents to Index Folder

1. From the Documents Module, select a folder in the index.
2. From the right-click popup, select **Add Multiple Document**. Refer to the screenshot below:



Adding Documents from the Documents Action or Context Menu

1. From the **Documents** Module, click the **Document** dropdown.



2. Select **Add Document** and the **New Document** window opens. Enter the details as required to create a new Document profile. Refer to the screenshot below:
3. Select the appropriate **Category** from the dropdown list; **General**, **Country**, or **Investigative Site**.

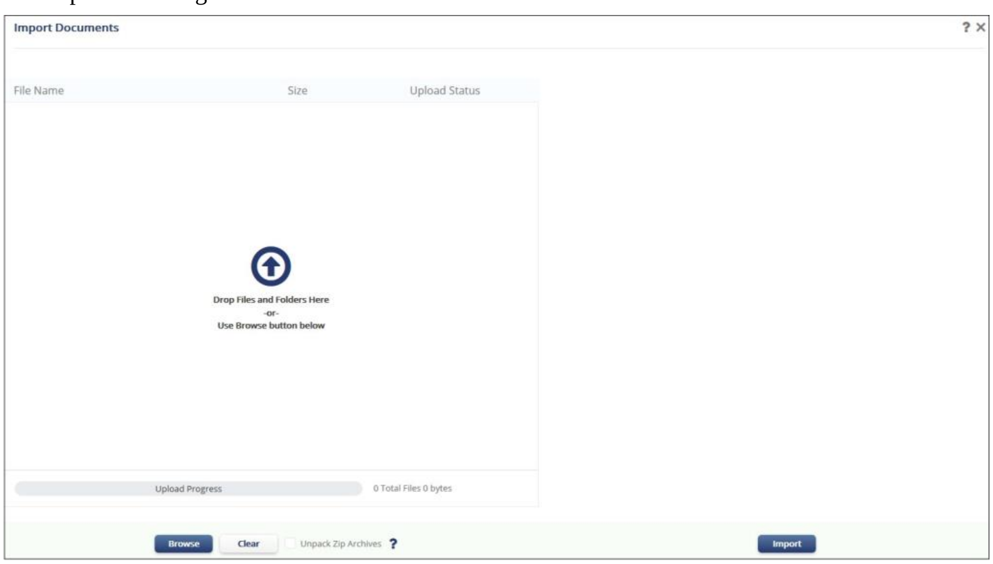
4. Depending upon the category selected, the document's **Submitted Name** field would appear or disappear. Enter the Submitted Name as required.
5. Select the **Document Type**, and **Document Date.** Type in the date if that is configured for you.
6. Add pertinent **Comments,** if necessary. The Index position will populate automatically, based on the folder you selected from the index.
7. Click the **Browse** button next to the Attachment field to attach a document.
8. Complete other fields as necessary and click **Next** to take you to the **Document Security popup**. Here you can add group(s) and/or users(s) who would access the documents into the security grid and set the desired levels of access. Adetailed description of each security access is given in *Manage Security (page 270)*.
9. Click **Finish** for the new document to take its place in the default index folder or the Upload folder as set in the room settings.

Note: *You can also add/import documents by dragging and dropping them from the Windows Explorer to their relevant index folders. Upon dragging and dropping the document, the Document Profile window opens for you to code the document. The Title, Document type, and Category fields are automatically coded for you. The dragged document can be found in the Attachment/URL field of the Document Profile.*

Importing Documents

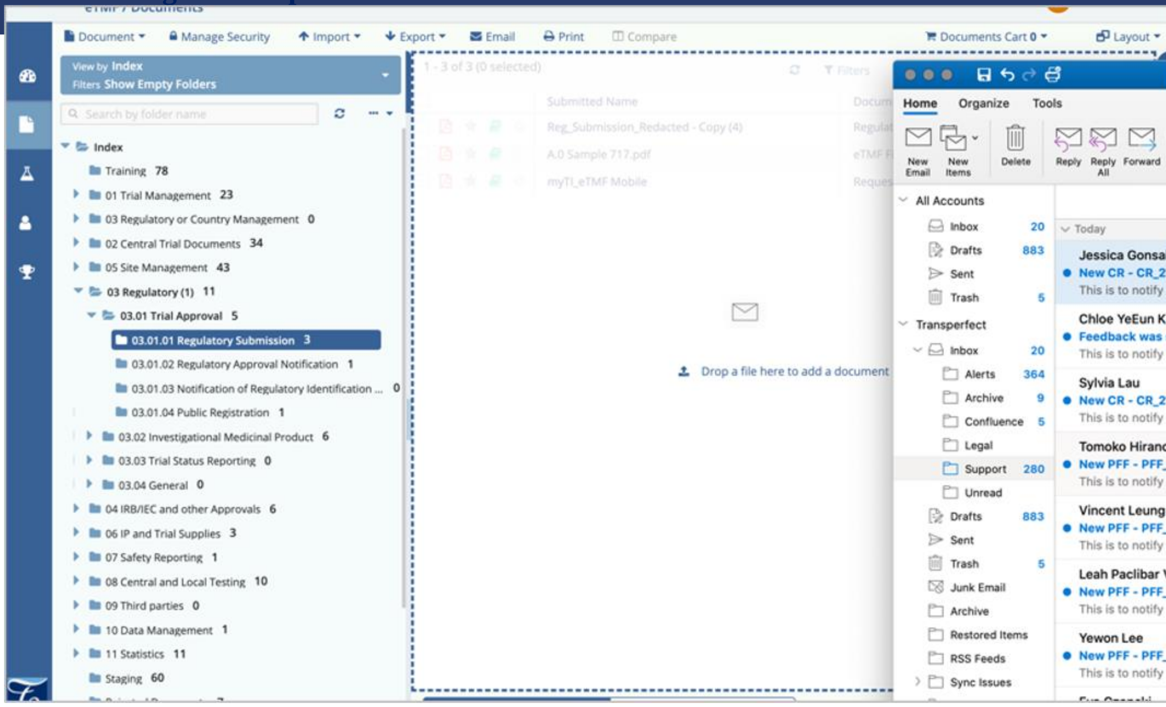
Follow the steps below to import documents metadata to a room:

1. Navigate to the **eTMF Documents** module and select **Documents** from Import dropdown.
2. The **Import Documents** window opens. Refer to the screenshot below:
3. Following the on-screen instructions, either drag-and-drop files from your own computer into the upload panel or use the **Browse** button on the window to select documents to upload.
4. After selecting documents to be uploaded, you can select the **Documents Metadata** checkbox on the right pane of the window to quickly code select metadata for these documents while the system is carrying out bulk-uploading. Therefore, if you are importing documents that are from the same investigative sites, are related to a particular contact person, or belong to the same document type, you can assign those at one go. This is also **Mass Coding** while importing documents.
5. While the documents are uploading, the user can monitor the **Upload Status** column in the display panel and view the progress of the upload in the progress bar at the bottom of the window. When the upload is complete, each document will display an **Upload Status** and the progress bar at the bottom of the window will read **Done**.
6. If you have specified the Documents metadata then click Import and Apply coding, and Close button placed on the bottom right corner. A confirm Mass Coding message will pop-up. Click Yes to confirm.
7. If you have not specified anything on **Documents Metadata**, then after the upload is finished, simply click the **Import** for the process to begin.



8. The **Import** functionality will not allow the import of erroneous files. During the import of several files, the files that were uploaded successfully will be removed from the list of files in the Import Document dialog box, but some documents will remain in the grid due to some errors while uploading. The user can try to import the left out documents again. This will not re-import the already uploaded documents but will try to import the documents remaining in the grid only.
9. Once importing documents is over, click the **Close** button in the bottom right corner of the **Import Documents** window. The uploaded documents can then be found in the user's **Upload** folder in the folder index or the default index folder as specified in your room settings.

Outlook Drag and Drop



10.1 now supports Microsoft Outlook™ interoperability, fully supporting drag and drop of documents and mail messages in Windows 10™. This provides the following:

- You can drag and drop email messages from MS Outlook into TI and the email will import along with all document attachments. Once in TI, MSG files may be converted to PDF.
- You can drag and drop individual document attachments from an email into TI and the documents will import.
- You can drag and drop a single document or email message onto a folder or placeholder and it will auto-classify.
- You can drag and drop many documents or email messages into the import modal in TI and they will all load into the import box.

Certain browsers such as Mozilla Firefox™ require an Outlook plug-in to fully support this feature. Chrome, Edge, and IE 11 do not require a plug-in. Links to download the required plug-ins will be provided in the online help.

Outlook File Drag

Drag and drop Outlook items as files into any application

Read This First!

Microsoft Edge (as of Windows 10 1709) and Google Chrome (as of version 76) natively support drag and drop from Outlook on Windows. If you use one of these browsers, then this plugin is not necessary.

Overview

Outlook File Drag is an add-in for Outlook 2013 and 2016 that allows you to drag and drop Outlook items (messages, attachments, contacts, tasks, appointments, meetings, etc.) to applications that allow physical files to be dropped, such as web browsers.

How Does it Work?

When you try to drag and drop from Outlook, Outlook correctly identifies the format as virtual files (CFSTR_FILEDESCRIPTORW) since the files do not exist directly on disk. Instead, they are contained in a PST file, OST file, or on an Exchange server.

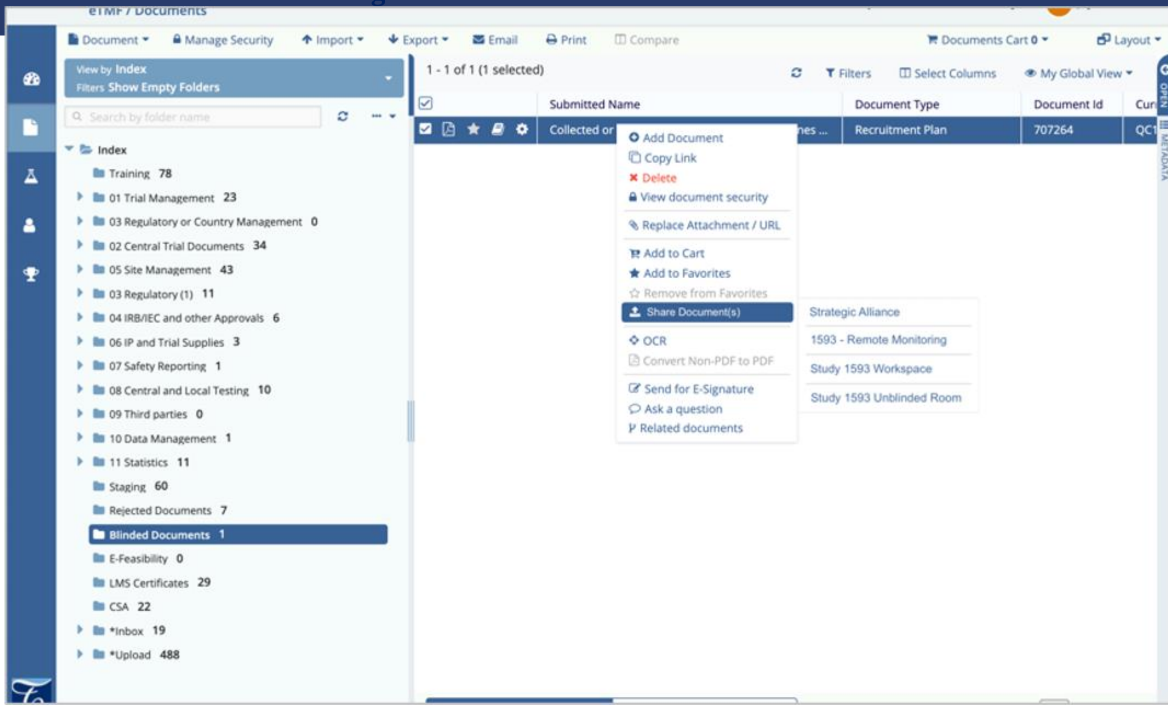
However, many applications do not support this format, such as web browsers and most .NET/Java applications.

To work around this issue, Outlook File Drag hooks the Outlook drag and drop process and adds support for physical files (CF_HDROP). When the receiving application asks for the physical files, the files are saved to a temp folder and those filenames are returned to the application. The application processes the files (such as uploading them). Outlook File Drag deletes the temp files later in a cleanup process.

Features

- Works with Chrome, Firefox, Internet Explorer, Edge, and other applications that accept files to be dropped
- Allows drag and drop into HTML5-based web applications
- Drag e-mails, attachments, contacts, calendar items, and more
- Drag multiple items at once
- Supports Unicode characters

Cross-room document sharing



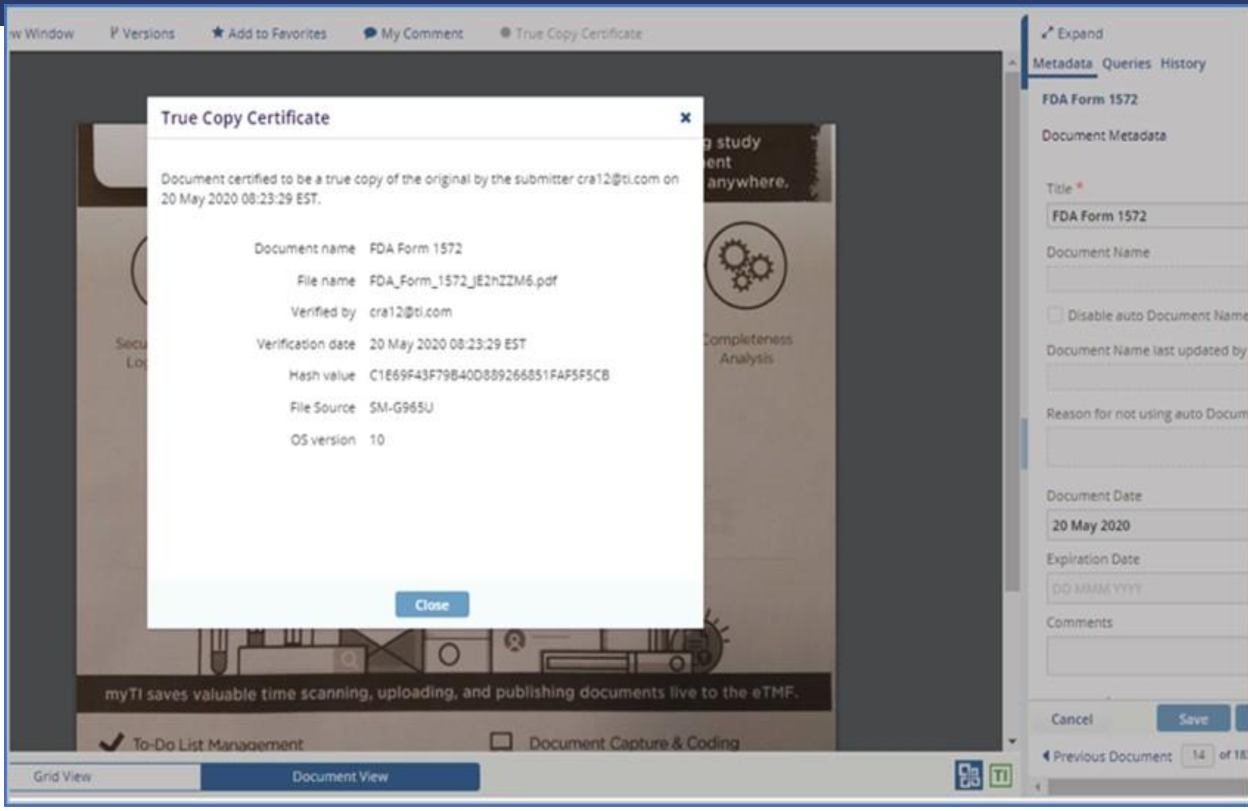
Content Management in life sciences is a very complex set of relationships that happen across multiple repositories of content, owned by different business units. Clinical needs content management and a TMF system that authors and captures content generated during the planning and execution of a Clinical Trial. Other repositories exist that are owned by Quality, Regulatory, R&D, Commercial, Training, Medical Writing, and many others. Finally, quite often, Clinical needs to keep unblinded content in a separate repository as well as the ability to access site documents from remote monitoring workspaces.

Each of these units broadly has its own workflows, approval cycles, and policies for the management of content. They also have separate owners who want control of the content management and metadata policies within. When it comes to a Clinical Trial, much of this content is archived and ends up in the Trial Master File.

10.1 introduces the capability to share documents easily, in a controlled fashion, between TI repositories called Rooms. This sharing is configured by room and may be enabled to many rooms, to allow for multiple content sharing scenarios, including: Sharing a single document to many eTMFs, sharing from many sites to a single eTMF, and sharing from an eTMF to other groups.

The 'chain of custody' of these documents is very important to maintain. As approved document versions are shared between rooms, the document source location and destination are tracked and can be viewed. Metadata that is common between two rooms will be shared along with the content, and only users with permission may share content. However, users may not share content to rooms to which they do not have access, like the eTMF for example, to enforce a controlled document workflow between repositories.

Certified Copy



For situations where the original paper copy of a document may be destroyed or unavailable, TI 10.1 introduces the capability to ensure a certified copy workflow from eTMF, Collaborate, Remote Monitoring, and other room types in TI. With this feature:

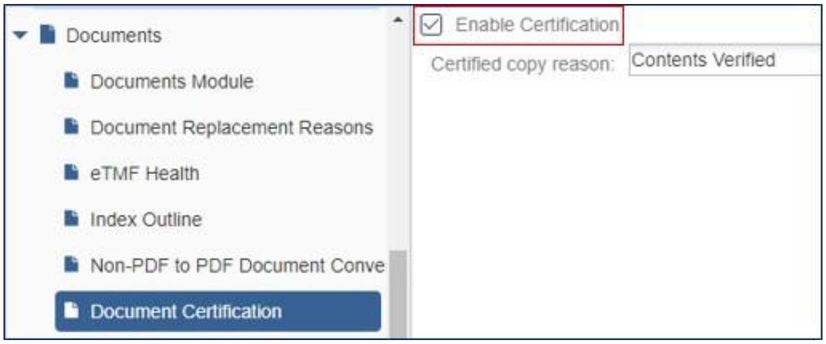
- You can upload a document in a room that has enabled certified copy, and you can verify the document uploaded and review copy certification text before providing credentials to certify the document.
- You can review a certified document and view the details related to that certification.

- If you edit a certified document, the document will no longer be a certified copy.
- The text used as the certification criteria is configurable by room, as well as the ability to define a default reason.
- This feature also works in the myTI mobile app.

Enabling Certified Copy

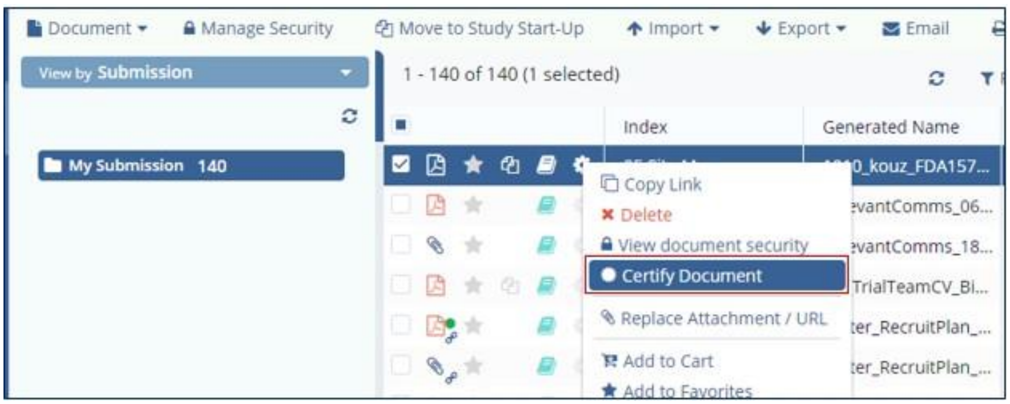
In order to enable detection of potential duplicates, an Administrator level user will need to go to theSettings menu and go to the Documents Module area of the Document Certification sub-menu.

From here, the user can check the box labeled "Enable Certification."

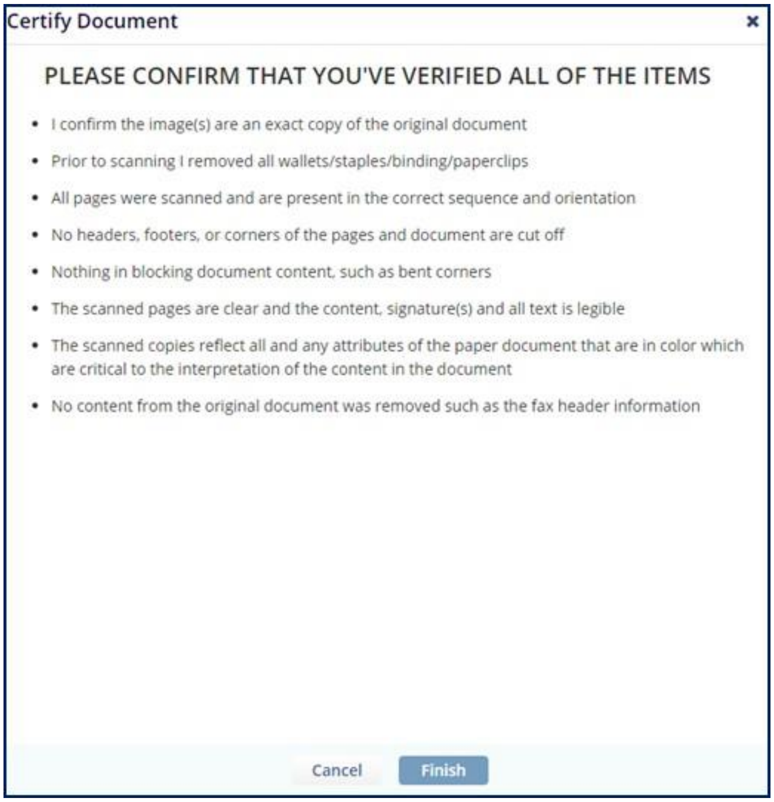


Marking a Document as Certified

Once the document has been uploaded, proceed to the Documents Module or Documents Library module and choose the Submission view under the My List column. Choose the document from the grid and open the Document Menu by clicking on the gearwheel icon or by right-clicking on the lineitem in the Grid.

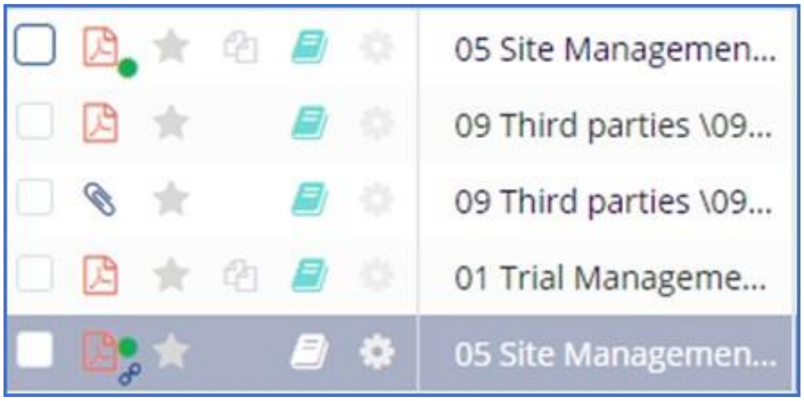


Choose Certify Document from the menu that opens. This will open the Certify Document window



The user will need to read and agree to the conditions shown. If the document meets all of the displayed criteria, they can press the Finish button. The user will be required to confirm their identityby entering their Username and Password.

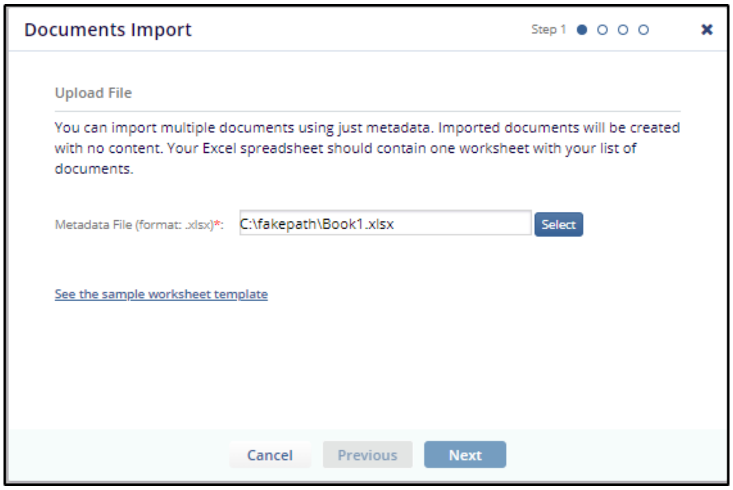
Once this is done, the document will be given the status of Certified. This is indicated in the Grid bya green dot next to the file-type icon.



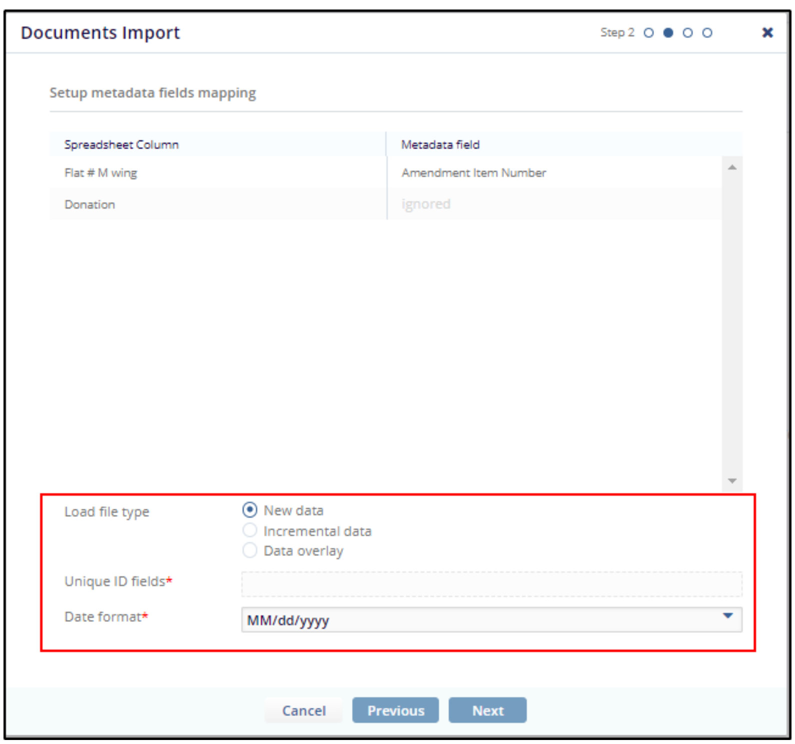
Importing Metadata

To import document metadata:

1. Select **Metadata** from the **Import** dropdown. The **Documents Import** popup opens.
2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import multiple documents using just metadata. The wizard offers a link to the sample worksheet so the user can download it and fill it with actual data. Click **Next.** Refer to the screenshot below:
3. Setup the mapping between metadata fields and uploaded file columns. It is possible to skip sheet selection in case you



do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.** Refer to the screenshot below:



4. You may choose **incremental data** or **data overlay** options for the import of metadata. Here, you will need to mention the **Unique ID fields** for incremental import or data overlay.

   Click **Next.**

5. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.
6. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.

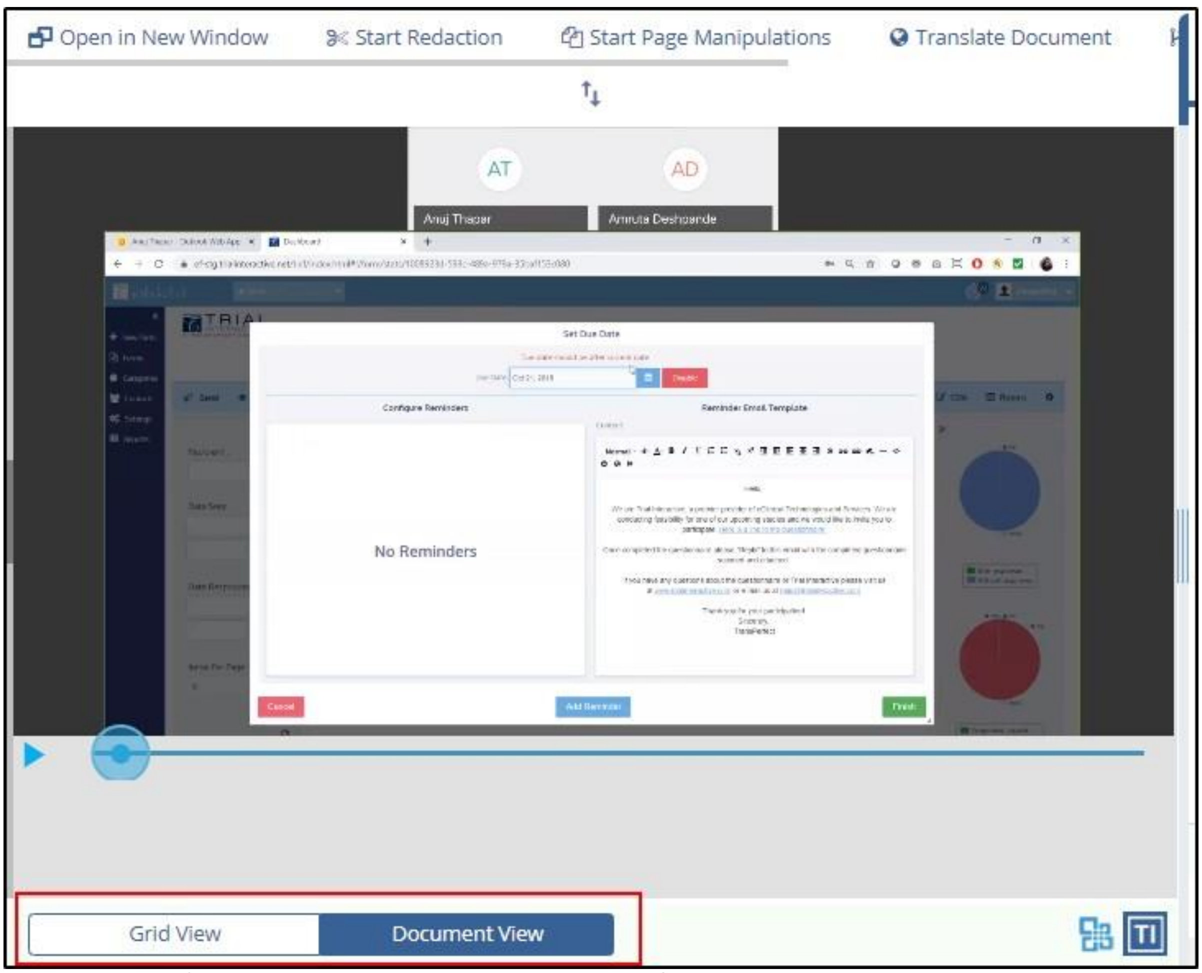
Uploading Videos

Trial Interactive supports the following types of video files as attachments to documents in the below mentioned browsers:

Browser Name	File Type
Internet Explorer	.mp4
Chrome	.mp4, .webm, .ogg
Firefox	.mp4, .webm, .ogg
Safari	.mp4
Opera	.mp4 (from Opera 25), .webm, .ogg

To play a video file, select the document in the grid and click the **Document** tab at the bottom of the grid, or simply double-click it. The document opens in the viewer with the **PlayVideo** button on it. Refer to the screenshot below:

It is possible to start/pause the video, control the sound, seek through the timeline, and switch to full-screen mode or back.



Unsupported video files open in the viewer with the message **Media format is not supported. Click here to download the file.**

Chapter 11. Deleted and Expired Documents

This explains the places where deleted and expired documents are stored. This section includes the following:

1. Deleting and Viewing Deleted Documents
2. Expired Documents
3. Deleting Queried Documents

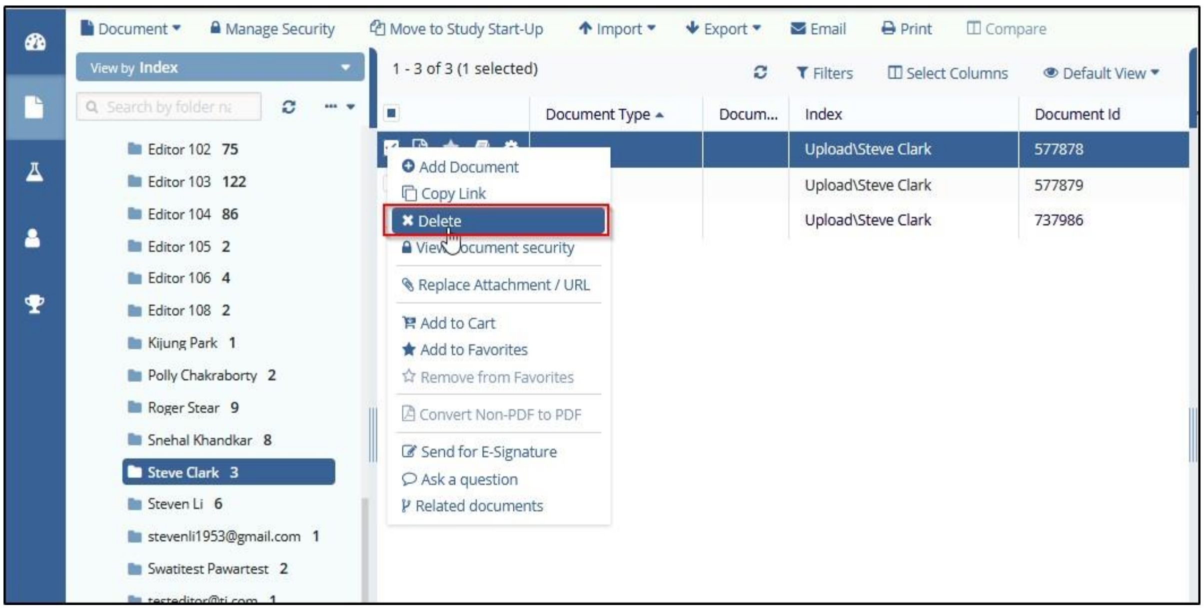
The above is discussed in separate topics accessible from the left panel of this help.

Deleting Documents and Viewing Deleted Documents

Deleting Documents

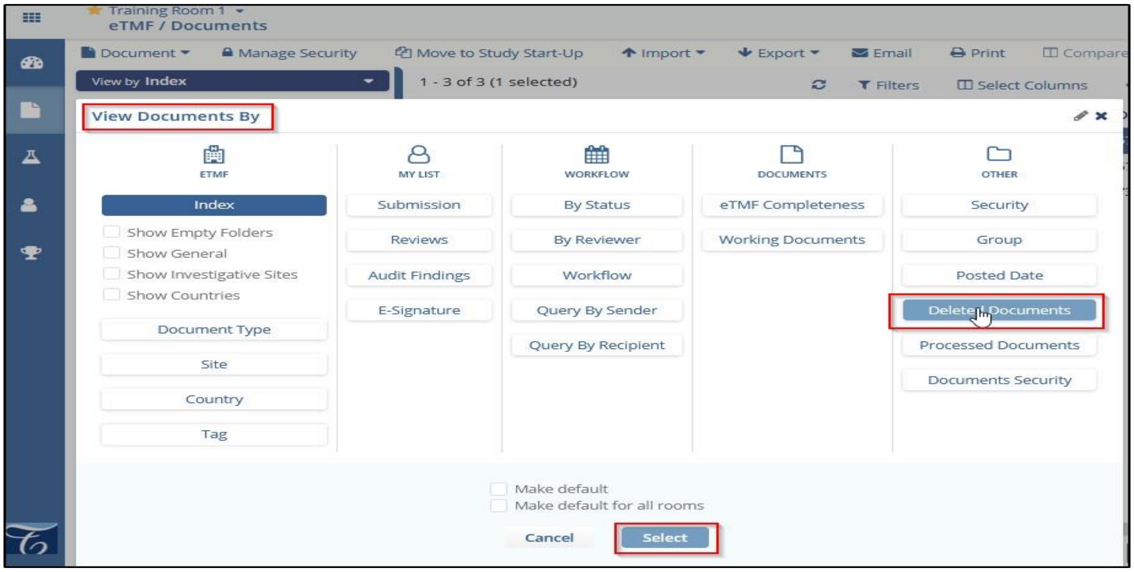
To delete a document:

1. Navigate to the **Documents** module.
2. Select the document(s) from the documents grid.
3. From the right-click menu, select **Delete**. Refer to the screenshot below:



Deleted Documents View

All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.



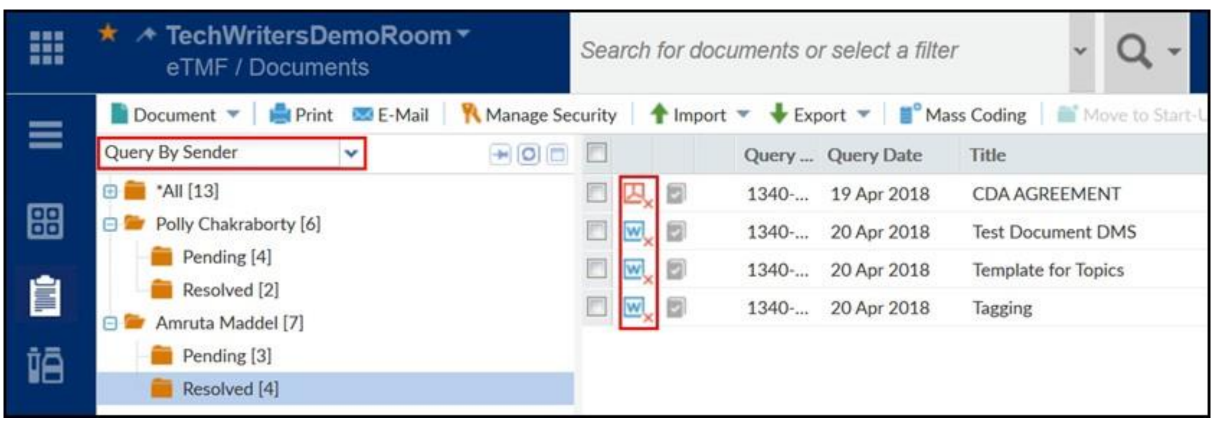
Expired Documents

As an Administrator, you might want to specify the time by which a document will expire and require a new version. You can set up the settings of expired documents from the **Main Navigation -> Settings -> Documents -> Documents Module.**

You can view the expired documents from the **Expired and Expiring Documents** *(page 210)* dashlet.

Deleting Queried Documents

Queried documents deleted by a user can be viewed by the Administrator under the **By Sender** and **By Recipient** views also besides the **Deleted Documents view.** Such documents appear in the mentioned views with a cross colored red next to the document name in the grid. Refer to the screenshot below:



Documents which were in query and were later deleted retain their query history and are also included in query-related reports. The Query History can be viewed from the **Queries** ***(page 264)*** panel in the **Right panel**.

Chapter 12. Potential Sites and IRB Integration

This allows you to locate the Unique Sites using the combination of Study Name and Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

> **Note:** *If the system finds matching conditions like the site, IRB number and IRB document type in the Study Start-up Site Profile, the documents for the imported site will be uploaded into the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which are discussed below.*

This section includes the following sections:

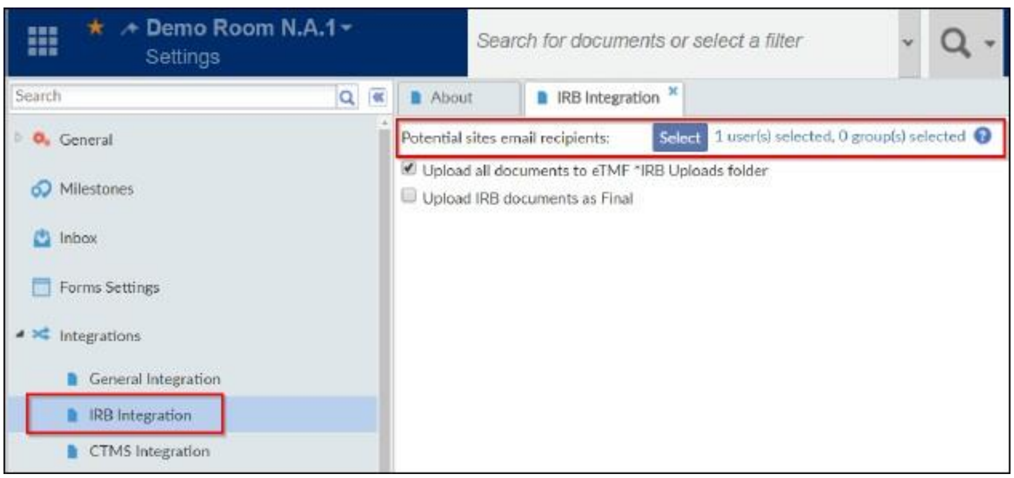
1. IRB Integration and Settings
2. Potential Sites and Modules

Potential Sites Module and Settings

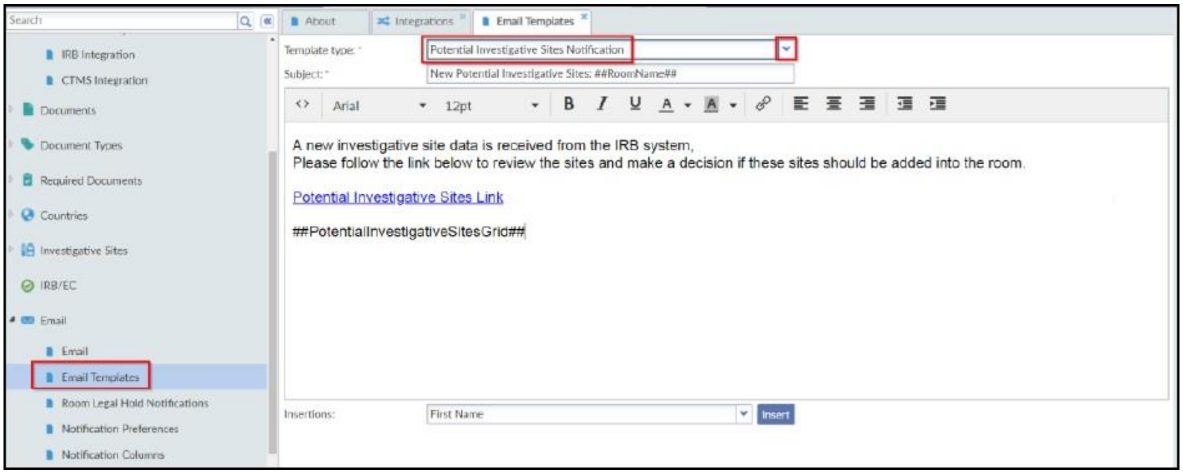
There can be cases where multiple sites are found during IRB Integration, or a site could not be identified, or sites are incorrectly imported.

Under the circumstances, the system creates a list of **Potential Investigative Sites** and notifies appropriate groups about the potential sites.

1. To configure the Potential sites email recipients navigate to **Settings->Integrations->IRB Integrations**. Refer to the screenshot below:



2. Click **Select** next to the Potential sites email recipient and select the email recipients as instructed. The email template for the emails to be received by potential sites email recipients can be set up from the **Email Templates** ***(page 144)*** in the room **Settings -> Email section**. A screenshot of the system provided email template is shown below:



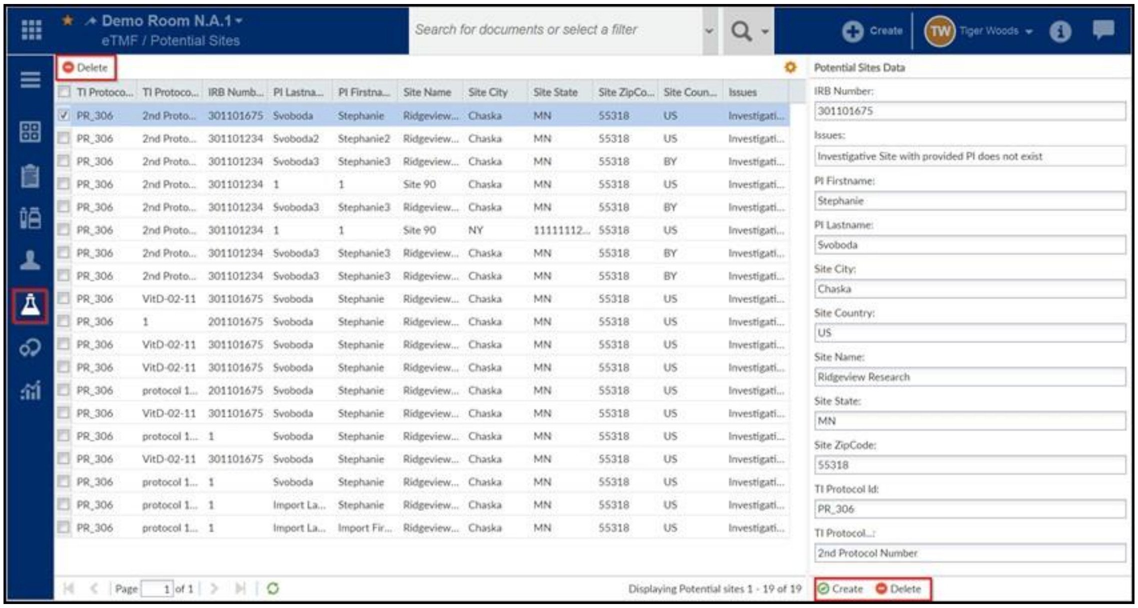
3. With Trial Interactive, you can manage potential investigative sites from the Potential Sites *(page 291)*module if IRB Integration is enabled for you.

4. The module is accessible by clicking the Potential Sites icon from the toggling menu in the eTMF module. Refer to the screenshot below showing the **eTMF/Potential Sites** module.

Note: *As an Administrator, you can create sites from potential sites or delete the ones that cannot be converted into sites.*

Potential Sites Module

With Trial Interactive, you can manage potential investigative sites from the Potential Sites module if IRB Integration is enabled for you. The module is accessible by clicking the Potential Sites icon from the toggling menu in the eTMF module. Refer to the screenshot below showing the eTMF/Potential Sites module. Refer to the screenshot below:



As an Administrator, you can create sites from potential sites or delete the ones that cannot be converted into sites.

To create a site:

1. Select a potential site from the grid as required.
2. From the Potential Site Metadata panel, click the **Create** icon to create a site. The **New Investigative Site** window opens.
3. Fill in the details to create a site from a potential one. The process to create a site is discussed in detail in section **Adding, Editing, and Deleting Sites.**

To delete a site click **Delete** from the Potential Sites Metadata panel.

Chapter 13. Milestones and eTMF Completeness

Here, we discuss all the aspects of Milestones and its use in eTMF Completeness. Through various topics under this section, we discuss:

1. Milestone Configuration
2. The Milestone Application
3. eTMF Completeness and Health
4. CRA TMF Reconciliation Report

Milestones

Milestone is the 'objective-to-reach' for a particular study room, and this function displays the list of milestones that will be used for the current study room. Administrator users can add existing or new milestones, or edit the added milestone names. You can also choose to either enable or disable the added milestones. You can inherit milestones from the domain level settings, or add a new milestone added to the room specifically. Added milestones can also be updated on the Document Types Management (page 110) section of the settings. You can also use the Milestone section to define the current milestone and to track which documents are needed. Besides, you can also Assign Milestones to Required Documents (page 125).

As an Administrator, you can monitor milestone progress from the Milestone application that can be selected.

From the Milestones module, the administrator can add milestone histories, edit or delete them.

Note: *Before starting to monitor milestone progress, administrators need to add new or existing milestones, or edit the added milestone names from the* ***Room Settings -> Milestones****.*

From this section, we discuss under subsequent topics on:

1. Configuring Milestones
2. Adding Milestones to Document Types and Required Documents
3. Viewing Milestones
4. Adding, Editing, and Deleting Milestones
5. Milestone History Grid and Filters
6. Assigning Milestone Histories to Documents
7. Automatic association of Document Types to Milestones from the Metadata Panel

Adding Milestones to Document Types

You can add a milestone thus created to Document Types to track the **eTMF Completeness** of the documents associated with such document types. This is discussed in detail in **Include Phases/Milestones** section under Document Types Management.

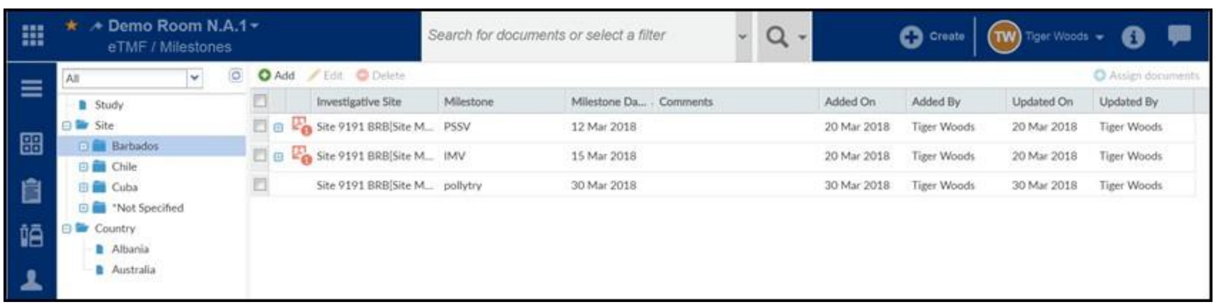
Milestones Module

The administrator can monitor a milestone progress from the **Milestone module** that can be selected from the toggling menu bar.

From the Milestones module, the administrator can add milestone histories, edit or delete them.

Note: *Before starting to monitor milestone progress, administrators need to add new or existing milestones, or edit the added milestone names from the* *Settings -> Milestones (page 90).*

On entering the dashboard, the administrator can see the list of milestone histories, if they were created. Refer to the screenshot below:



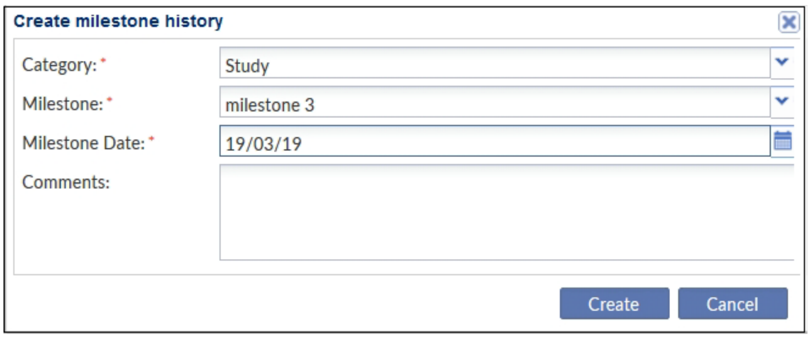
From here, you can perform the following:

1. Adding Milestones to Countries
2. Adding Milestones to Sites
3. Adding Milestones to Studies
4. Editing and Deleting Milestones
5. Milestone History Grid and Filters
6. Assigning Milestones Histories to Documents
7. Assigning Milestones to Document Types
8. Automatic Association of Document Types to Milestones on the Metadata Panel

Adding Milestones to Studies

Follow the steps below to add milestones to studies:

1. Click **Add** from the top menu bar in the **Milestone** module. The **Create** milestone history window opens.
2. Select the **Category** as **Study**. Refer to the screenshot below:

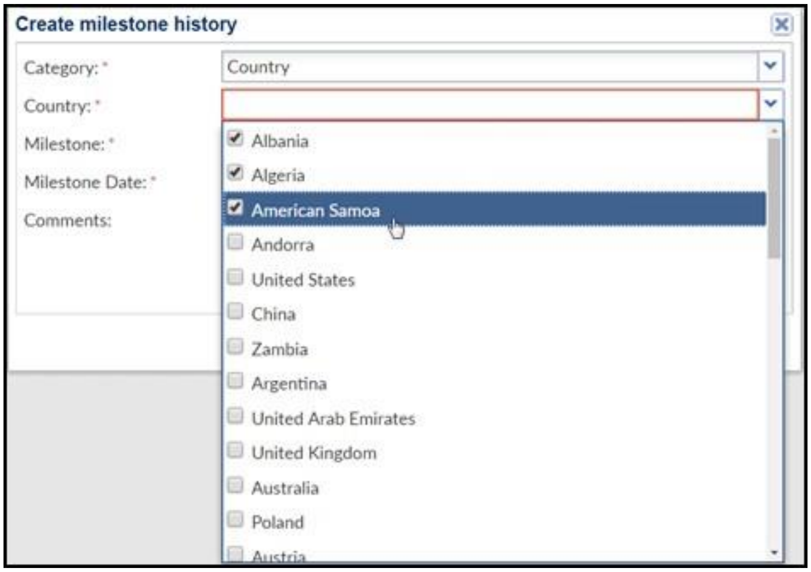


3. Select the **Milestone.**
4. You can either choose the date from the **Calendar Date Picker** or enter the **date manually**.
5. Enter the **Comments** and click **Create** to create and add the milestone history in the grid.

Adding Milestones to Countries

Follow the steps below to add milestones to countries:

1. Click **Add** from the top menu bar in the **Milestone** module. The **Create** milestone history window opens.
2. Select the **Category** as **Country**. The **Country** dropdown appears.
3. Select all the countries to which the milestone event is applicable. Refer to the screenshot below:



4. Select the **Milestone.**
5. You can either choose the date from the **Calendar Date Picker**, or enter the **date manually**.
6. Enter the **Comments** and click **Create** to create and add the milestone history in the grid.

Editing and Deleting Milestones

1. To edit a milestone history, click **Edit** from the top ribbon bar.
2. To delete a milestone history, click **Delete** from the top ribbon bar.

Milestone History Grid and Filters

Besides categorizing milestones by the Study, Site, and Country, the milestone module also allows you to filter milestone events by **Documents Received** vs. **Documents Missing**. Refer to the screenshot below:

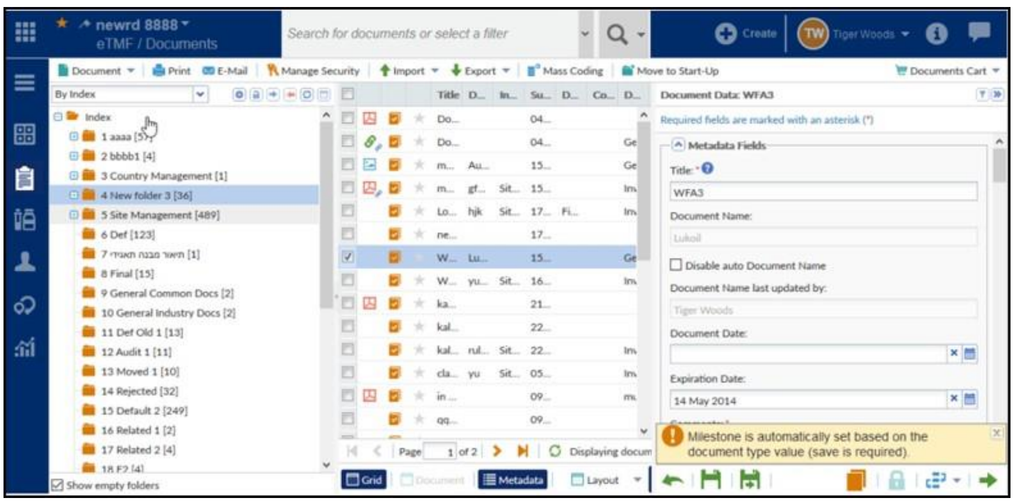
Select a filter of your choice to display the milestone history and its associated documents in the neighboring grid. Refer to the screenshot below:

Assigning Milestone to Document Types

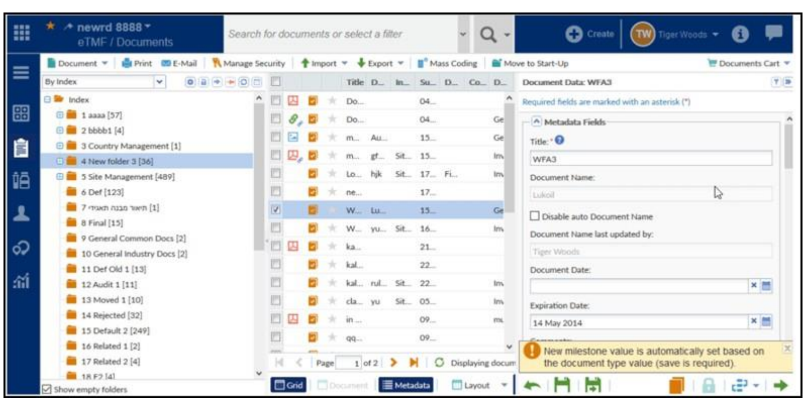
You can assign milestones to document types from the Phases/Milestones section in the Document Type Management *(page 105)* Profile window. To enable milestone association with a document, the **Milestone** and **Milestone Date** fields are marked as **Required** and **Visible** in the Document Type Fields *(page 114)*in Document Types Management.

Automatic association of document types to milestones on the Metadata panel

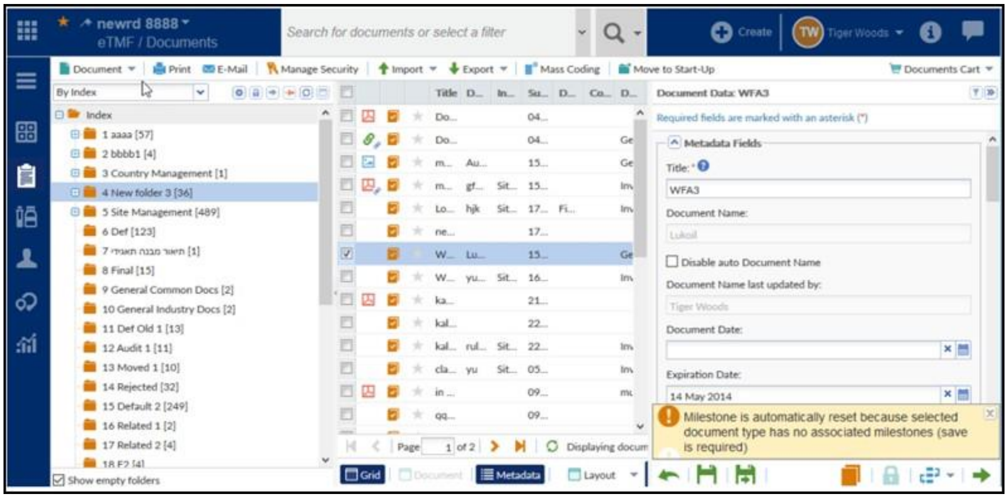
1. If, while coding a document, there exists only one milestone history, then the milestone date and record is automatically assigned to the document and appropriate message displayed accordingly. Refer to the screenshot below:



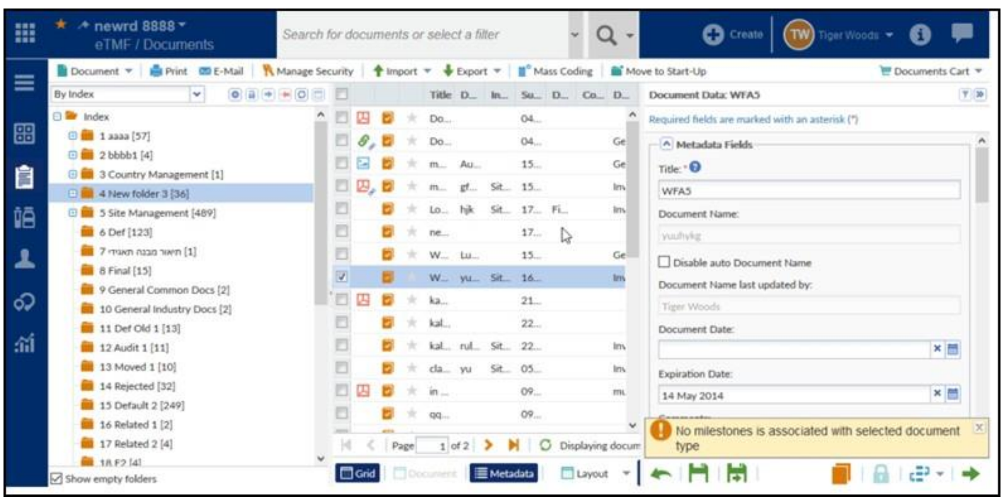
2. If, you change happen to change the document type of a document and a new milestone data is found, the system automatically updates the values and displays a message accordingly. Refer to the screenshot below:



3. If, you change happen to change the document type of a document and no new milestone data is found, the system automatically updates the values and displays a message accordingly. Refer to the screenshot below:



4. If a document is coded with a document type that has no milestone associated with it, then the following message is displayed. Refer to the screenshot below:



eTMF Completeness

eTMF Completeness is a milestone indicator of a clinical study process based on the status of the documents required for the study. The eTMF Completeness view lists the collected, missed, and placeholder documents required to complete a study along with the milestones linked with each document and its placeholder. Therefore, through this module, the Administrator can understand the quality and health of the TMF thereby enabling the Administrator to define controls to set placeholders required to collect documents to complete the clinical trial.

Controls can be set in the form of Milestones (page 308) that are linked at each stage of eTMF completeness to measure the progress percent of documents collected at each stage of the eTMF completeness. For example, the Administrator can set up a milestone for a Site Visit event to include documents for a Confirmation letter sent by the CRA for a site visit, a Site Visit Report, and Follow-up Letter. Each of these documents and their types (page 105) which are defined in the eTMF room can be linked to a milestone, milestone events defined for the same, and placeholders set up in the eTMF. To be able to set up the complete process and make tracking of eTMF Completeness seamless, the Administrator needs set up:

1. The eTMF Completeness metrics from the **eTMF health** in the room settings
2. The Milestones for complete integration of documents
3. Creation of document types and their linking to milestones
4. Creation of Visit types to generate Site Reports

Important:

- *For more details on eTMF Health Settings, proceed to section **eTMF Health Settings***
- *For more details on CRA Visit types, proceed to section **CRA Visit Types***
- *For more details on the creation of milestones proceed to section **Milestones**.*
- For more details to link milestones with document types to track eTMF completeness proceed to section ***Include Phases/ Milestones***.
- *For more details on creating milestone events/history proceed to section **Milestones**.*

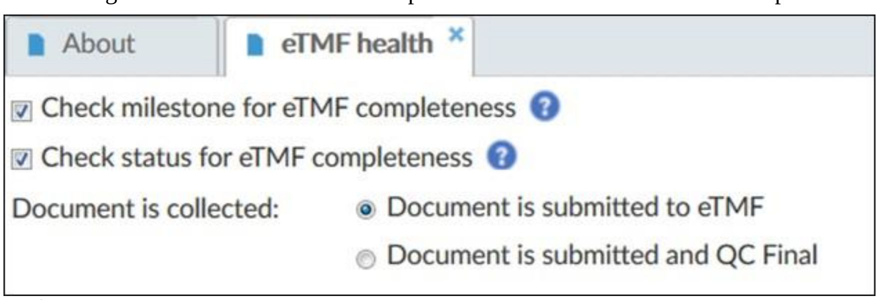
eTMF Health Settings

The eTMF Health dashlet provides information regarding the current health of the eTMF system by indicating what percentage of required eTMF documents are collected/missed so far. The document types of required documents can be linked with milestones to keep track of their progress report.

The eTMF Health functionality under **Settings -> Documents Module -> eTMF Health**, if enabled, checks for:

1. The configurations and current status of milestones
2. The status configurations and current status of a document. This check helps to leverage the eTMF completeness reports and the eTMF Health dashlet to reflect the correct health of the eTMF system. Refer to the screenshot below:

These settings will affect all dashlets and reports related to eTMF Health and completeness. Moreover, clients can also choose



to reflect in the report's documents collected and submitted to **eTMF** or **QC Final** by choosing one of the **radio options** as shown above.

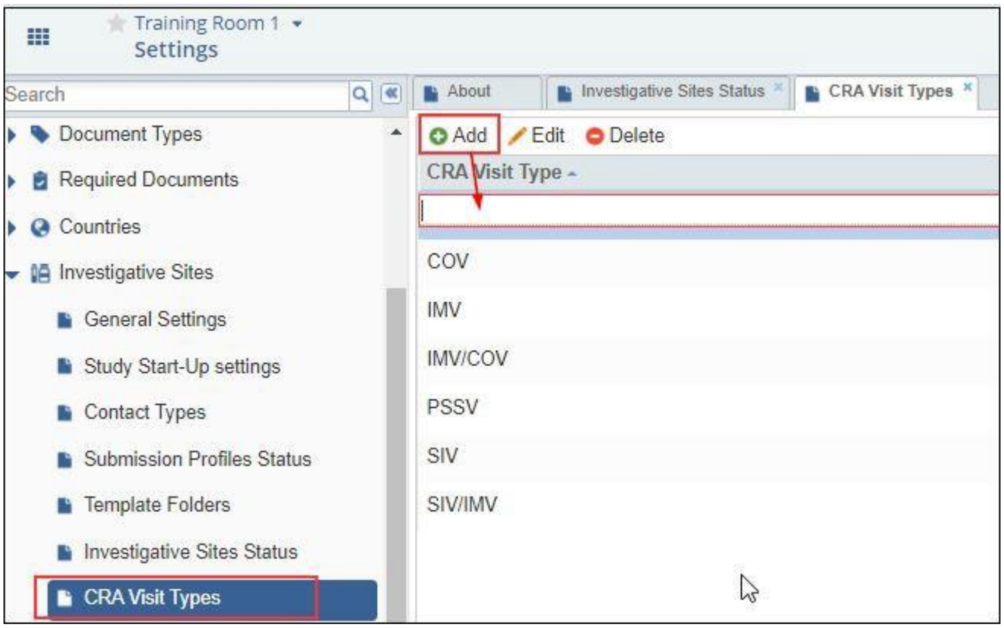
Click **Save** to commit the changes made.

CRA Visit Types

A CRA might need to create a **CRA TMF Reconciliation Report** to reconcile documents during site visits. While creating

the report, the visit type must be chosen so that reports generated during two or more site visits can be differentiated with ease. Refer to the screenshot below:

For the visit types to be populated in the dropdown, as shown above, the admin will need to create visit types from this panel.



1. To add a new visit type, click the **Add** button at the top of the portlet window.
2. Type in the desired term and press **Enter**. Changes made here are saved automatically. 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.
4. To delete a visit type, select the visit type and click **Delete** from the toolbar above.

Chapter 14. CRA Reconciliation

This section helps you find the details about the CRA Reconciliation Reports that allows CRA to take decisions regarding further site visits.

Trial Interactive 10.1 helps the CRA to reconcile documents during their site visits through the Site Report. You can reach this page from **Main Navigation → CRA Reconciliation.** Refer to the screenshot below: The module has the following sections:

1. **Documents:** This module 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 module allows the CRA to create CRA Report which will include all the documents reviewed by the CRA since the last report created by him/her.

   Each of the above modules is discussed in separate topics and can be accessed from the left pane of this help.

Documents Reconciliation

For performing Site Visits, CRAs needs to take some important decisions regarding documents for sites:

1. Which documents need to be added to both eTMF and site binder
2. Which documents need to be added to site binder from eTMF
3. Which documents need to be added from site binder to eTMF

CRAs can avail of this information from the **Site Report** so that they can verify the outstanding documents during their next site visit.

Note: *Only **Pending** and **Active** sites are available for the reconciliation process*

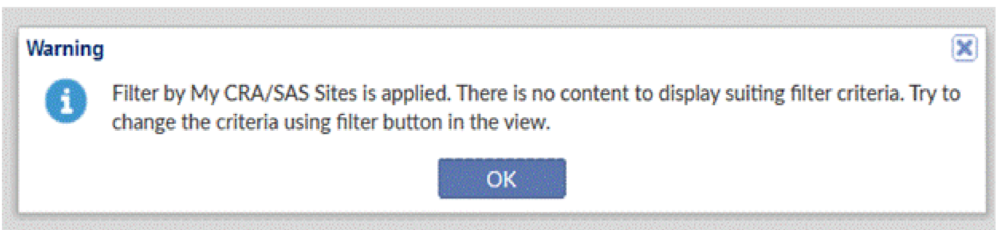
Important:

- *Missing documents cannot be marked as reviewed.*
- *Only CRAs can perform this step. Admin users will not be able to mark documents as Reviewed.*
- *The CRA needs to have **CRA Reconciliation Action** enabled under the user profile.*

Follow the steps below to reconcile documents:

1. Navigate to **Main Navigation → CRA Reconciliation** Refer to the screenshot below:
2. The **Document View** opens as shown in the screenshot below:

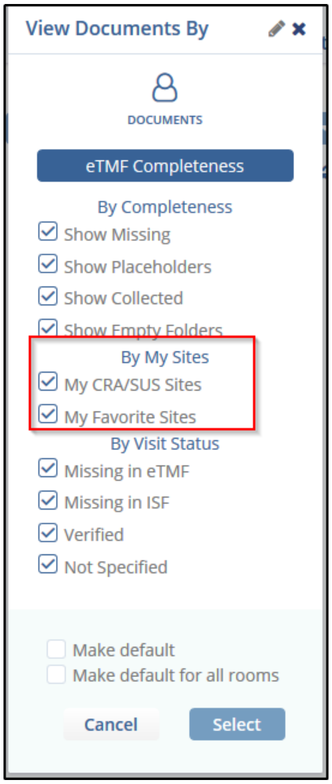
3. Notice if you receive warning as shown in the screenshot below:



4. If the warning is displayed, click the **Filter** icon below the view and uncheck **My CRA/SAS Sites** or **My favorite sites**

from the filter. Refer to the screenshot below:

5. Click **Apply**.



6. The list of folders appears in the view.

7. Click the appropriate folder to display the list of sites.
8. Select the appropriate site from the selected folder to get the list of **missing**, **collected**, and **placeholder documents** in the grid.
9. while reconciliation, each document will fall into one of the three scenarios as below:

   a. ***If the document is in the ISF but not showing in the eTMF:***

      a. Click **Add Placeholder** (or if applicable, upload/email the document to the eTMF).
      b. Complete the known required fields and click **Finish** (metadata can be added/edited once the document is collected).
      c. Once all the actions are done, click the **Reconcile** button and proceed to step 11.

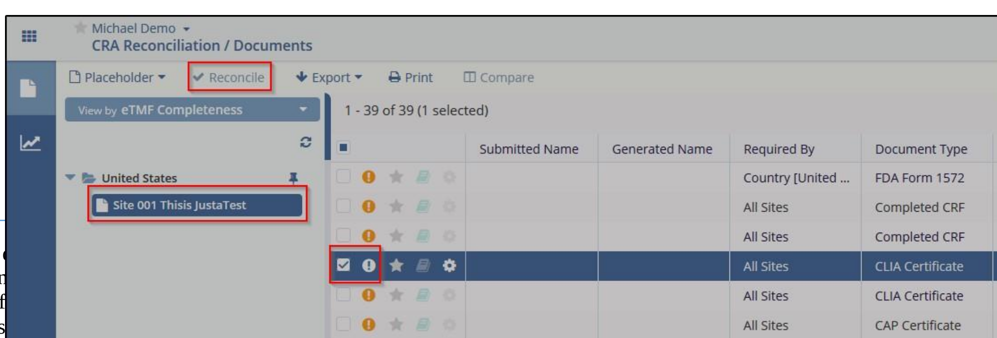
   b. ***If a document is in the eTMF not present in the ISF:***

      a. Click the document(s) and click the **Reconcile** button.

   c. ***When the document is in both eTMF and the ISF***

      a. Click the document and then click the **Reconcile** button.

10. Click the **Reconcile** button from the top ribbon bar to change the status of the document. The **Change Status** pop-up opens. Refer to the screenshot below:



11. Choose the required status and click **Select**. **Note:**

- **Missing in ISF**: Select this status to indicate the document is missing in the site binder (ISF) but present in the eTMF.
- **Verified**: Select this status to indicate the document is in both the eTMF & ISF.
- **Not specified** Select this status to clear a previously assigned status.

12. Once the **Reconcile** process is complete, you can see the status of the document with the date. Refer to the screenshot below:

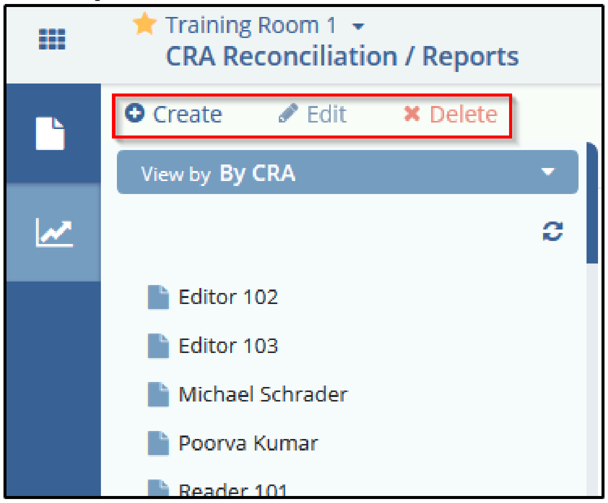
13. This site is then available for the creation of the CRA TMF Reconciliation Report in the **Report** view.

Creating and Viewing the CRA TMF Reconciliation Report

CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. You can access this page from Main Navigation → CRA Reconciliation → Reports View. On entering the dashboard, you can find the list of reports generated displayed in the grid. You can choose to view the reports By Site, By Visit Type, or By CRA from the current view panel on the left. Clicking a report from the grid populates the report metadata in Reconciliation Data panel located at the extreme right of the dashboard. You also have the option to Create edit, or delete a CRA Reconciliation TMF Report from the Create, Edit, or Delete icons located on the top ribbon. Refer to the screenshot below:

Creating CRA TMF Reconciliation Report

1. Once the **Reconciliation** process is complete, you can create the CRA TMF Reconciliation report from the **Reconciliation Report** module.
2. Select the appropriate filter from the Current View. The Previous reports will populate in the grid.
3. Select the appropriate site and click **Create** from the top ribbon bar to run a new report.
4. The **Create CRA TMF Reconciliation**window populates with documents from the latest reconciliation. Complete the required fields.



Note: *The Visit Type will be populated in the dropdown only if it is created from Settings → Investigative Sites → CRA Visit Types. (page 140)* Refer to the screenshot below:

5. Fill in the appropriate details and click **Create.**
6. You will receive a **notification** that the **Site Report** is created successfully and displayed in the grid.

Editing CRA TMF Reconciliation Report

1. Select the required **site** from the **Reports** module and click the **Edit** button on the top ribbon bar.
2. The **Modify CRA TMF Reconciliation** popup opens.
3. Edit the required details and click **Save** when finished.

Deleting CRA TMF Reconciliation Report

1. Select the required **site** from the Current View and click the **Delete** button on the top menu bar.
2. Click **Yes** on the confirmation popup that appears if you wish to delete the report from the list.

Chapter 15. Quality Control

This section involves the quality check of the submitted documents in a room by Quality Reviewers who are the members of the Quality Control group.

Workflow Settings

In Workflow Settings, Admins set up important details like workflow statuses, issues in the workflow, timeline, and members of the workflow group.

All these configuration details need to be previously created by the super-admin and configured to enable the administrator to add them to the workflow. This section will take you through the various configuration details. Changes made here will be applicable to all workflows.

To access the Quality Control Settings:

1. Navigate to the **Main Navigation-> Settings → Workflows**. From **Workflows Settings**, we discuss :
    a. Common Workflow Settings
    b. Creating, Editing, and Deleting Quality Control Review Statuses
    c. Creating, Editing, and Deleting Quality Control Document Statuses
    d. Creating, Editing, and Deleting Quality Control Profiles Each of these is discussed in the separate topics in this help.

Common Settings

The Workflow Common Settings can be accessed from **Room Settings → Workflow → Common Settings.**

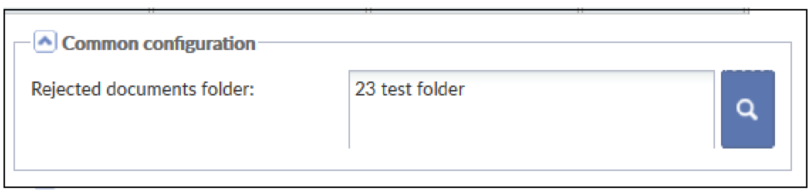
Admin can perform the following Common Settings in a Workflow:

1. Common Configuration
2. Default Ranges Configuration
3. Timeline Configuration
4. Issue Email
5. Rejection Email Configuration
6. Query Reminder Configuration
7. Auto-Claim Configuration

Each of these is discussed in the separate topics and can be accessed from the left of this help.

Workflow Common Configuration

Rejected Documents folder: Here, you specify the folder and its index number that will hold the documents when they are rejected during the review.

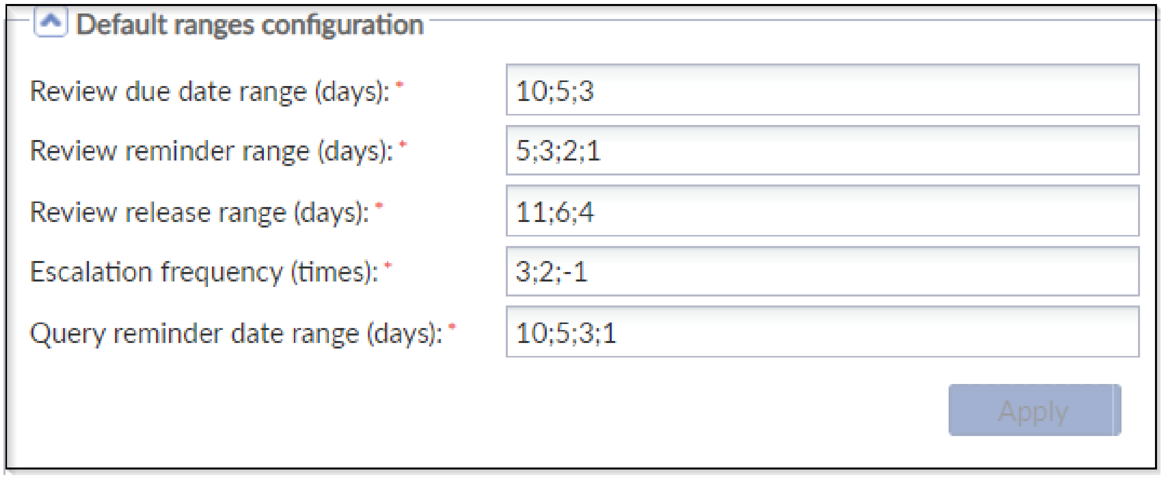


Default ranges configuration

Here you can specify date ranges that would be applicable to your workflow.

- TI acknowledges the fact that various workflows would have different review and submission periods.
- Hence it allows you to specify more than one value separated by semi-colon.
- These values would be populated in the dropdown during workflow creation, and you may choose a value as appropriate.

Refer to the screenshot below:

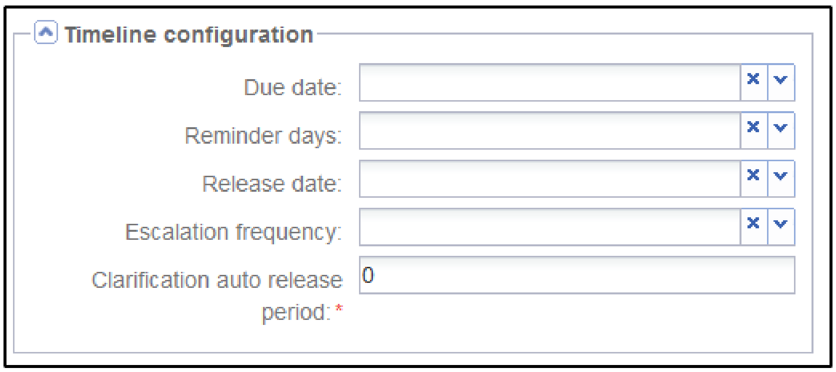


Each field above is editable, you can enter the values separated by a semi-colon. Each option is discussed in separate sections below:

1. **Review due date range (days)**
    - Here you specify the days when the review would be due after claiming the documents for review.
    - You may specify multiple values, all of which will be populated in the dropdown while creating the workflow to enable you to select a value as appropriate.
    - The **Returned Back** is a new system status that can be given to a document when it is routed back to a previous workflow stage.
    - Hence, it is available from Approval Stage 2/QC2 onwards only.
2. **Review reminder range**
    - Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.
    - If multiple values are specified, all of them would be populated in the dropdown during workflow creation, and you may select multiple values as required.
    - In the screenshot above, the Reminder schedule is 5;3;2 which means:
        - the reviewer will receive reminders 5 days before the due date,
        - then 3 days before the due date,
        - and then 2 days before the due date if the reviews are pending.
3. **Review release range days**
    - Here you specify the days after the claim when the documents would be automatically released from the reviewer's claim list.
    - The Auto release date is always greater than the due date.
    - It will not allow you to select a value less than the due date.
4. **Escalation frequency**
    - Escalations are reminders about **not completed reviews**.
    - During workflow creation, an escalation group needs to be specified who will receive notifications about escalations.
    - Here, you specify the timeline for escalation notification frequency.
5. **Query reminder date range**
    - If the user does not respond to a query with a document, reminder emails are sent to the query recipients on the nth days as specified here.
    - So if the setting is 10; 5; 3 reminders will be sent on the 10th day, 5th day, and the 3rd day.

Timeline configuration

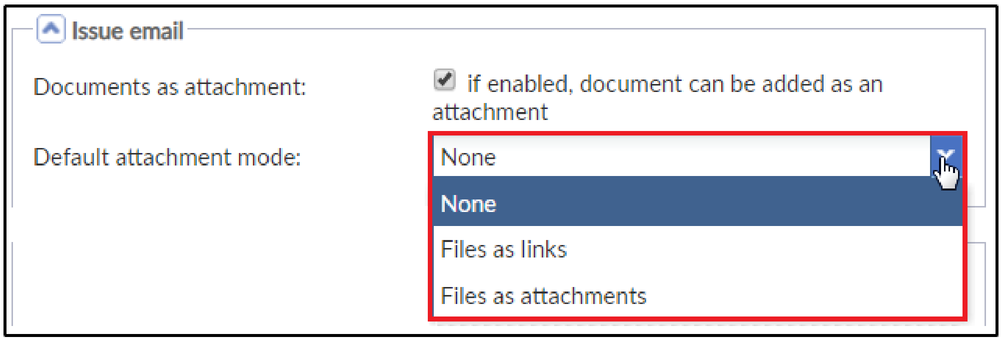
Refer to the screenshot below:



- If you specify values in the timeline, the values will be automatically set for you at the time of workflow creation.
- If you happen to change your mind at the time of creation, you may select values as required as opposed to that 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 period.
- 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

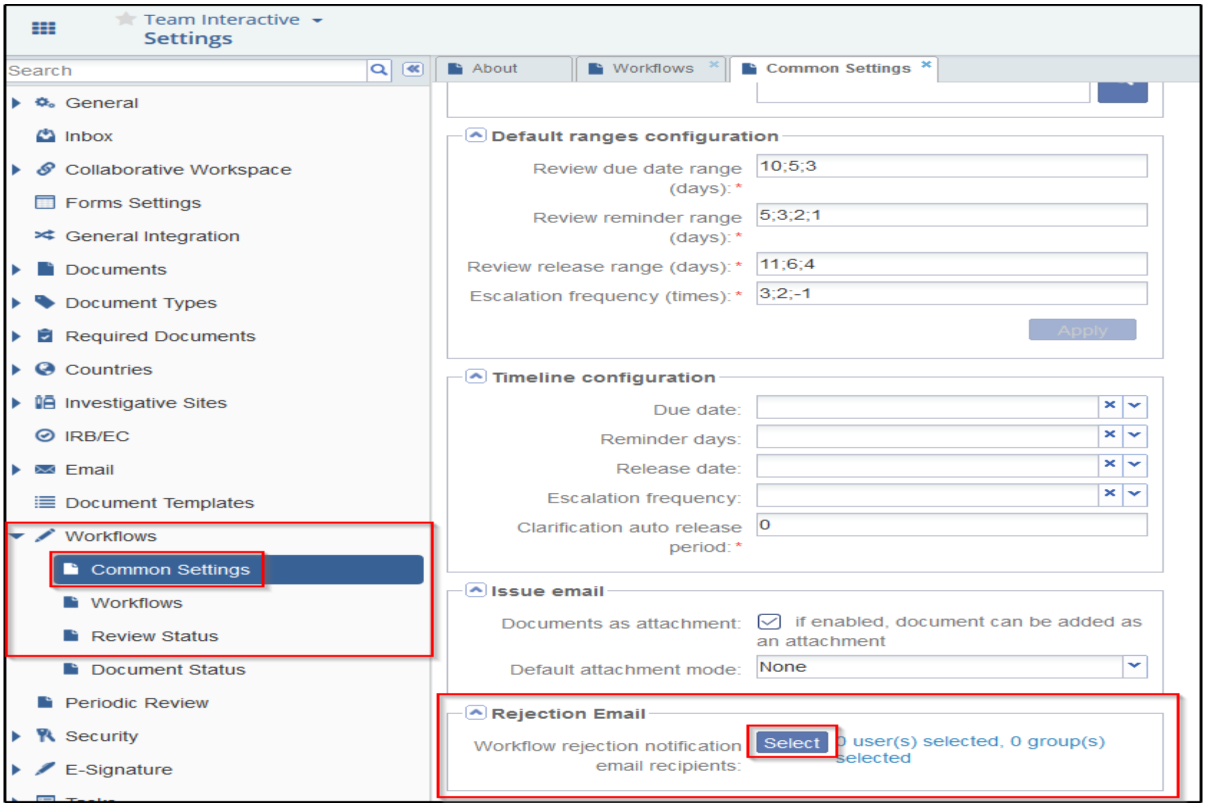
1. From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session. Refer to the screenshot below:



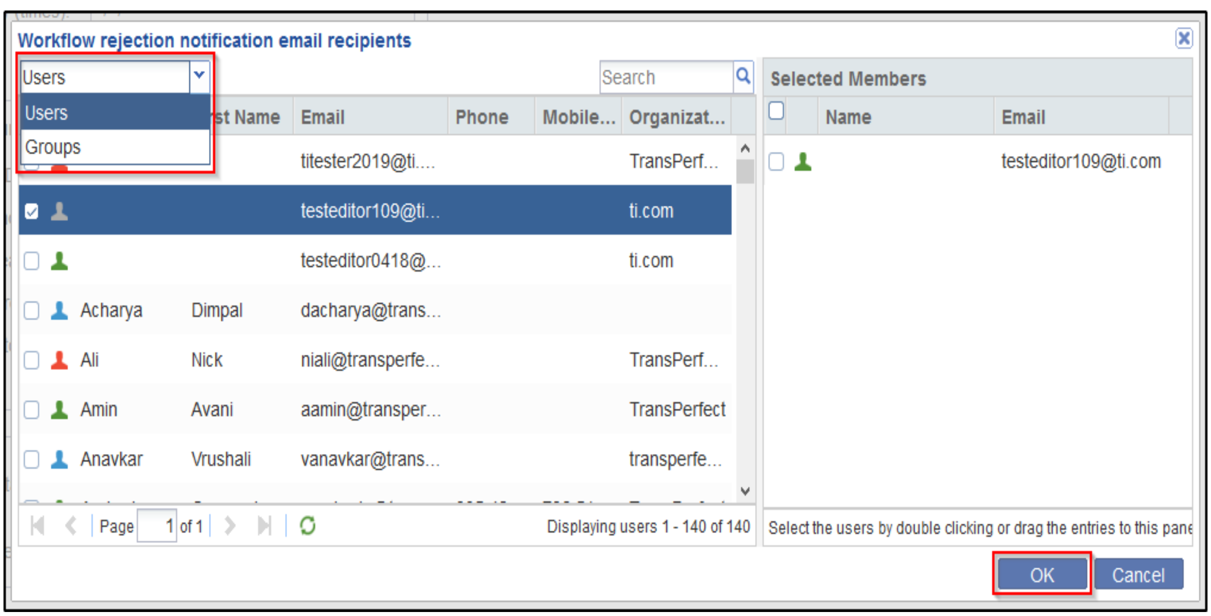
2. Click the dropdown arrow to choose the attachment mode to be either **Files as links or Files as attachments**. Refer to the screenshot above.
3. Click **Save** from the bottom of the grid.

Rejection Email Configuration

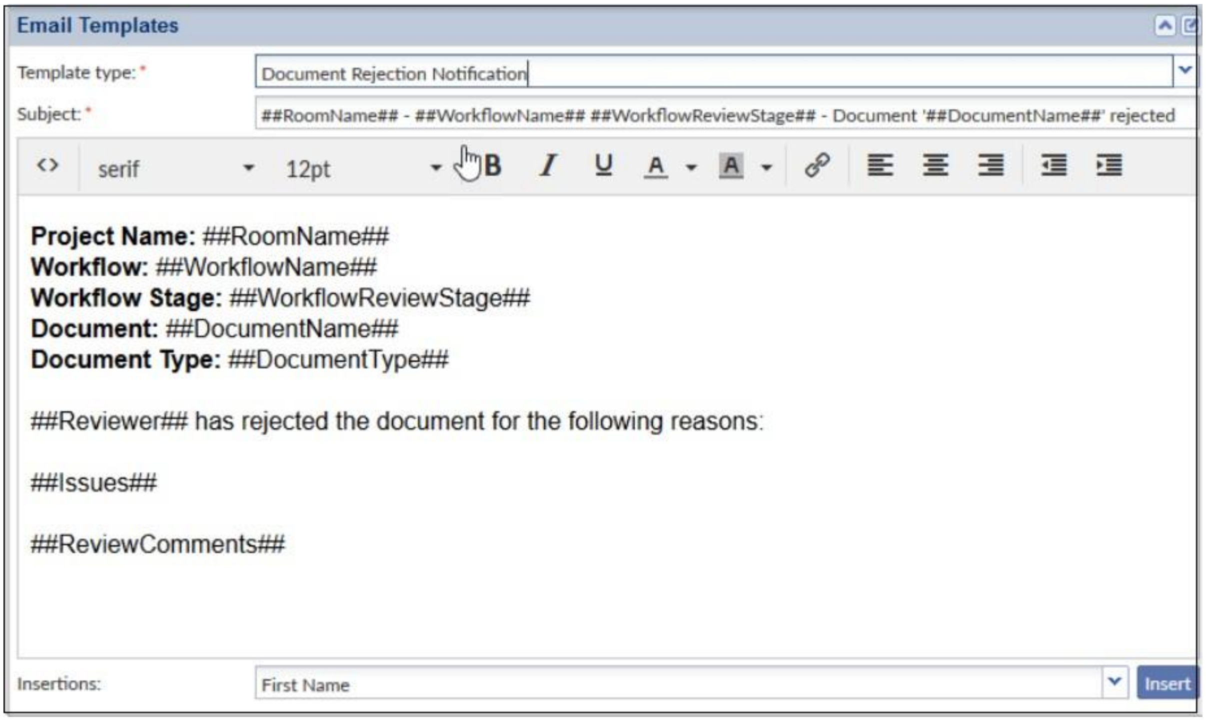
When the document is rejected in the Workflow, a rejection email is sent to the document owner plus the users specified in the **Rejection Email** configuration settings. Refer to the screenshot below:



1. Click **Select** from the **Rejection Email** settings.
2. **Workflow rejection notification email recipients** window opens. Refer to the screenshot below:



3. You can choose from **Users or Groups**. Select the users by **double-clicking or drag** the entries to the right pane.
4. Click **OK** to save the selection of the users.

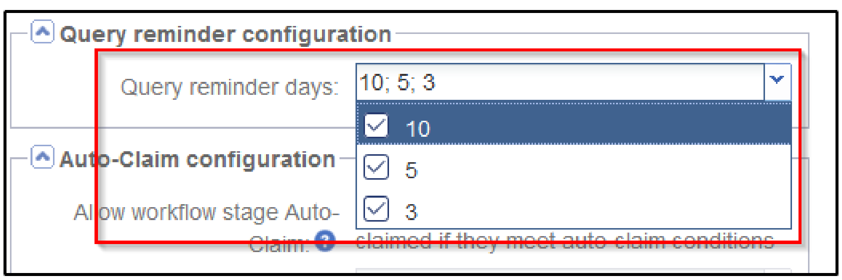


You can change the Rejection Email Template from **Settings-> Email ->Email Template**

Query reminder configuration

From **Query Reminder configuration** Admin can configure reminder emails' schedule. Refer to the screenshot below:

1. As per the above configuration, reminders will be sent on the 10th day, 5th day, and the 3rd day, if the user does not

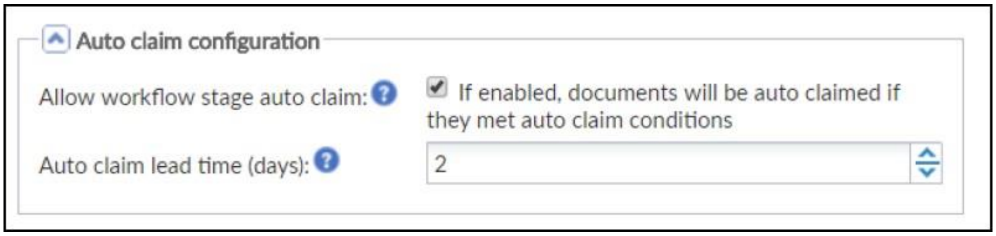


   respond to a query with a document.
2. You can change the number of days from **Query reminder date range *(page 148)*** (days) in Default ranges configuration *(page 148)*.

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. Refer to the screenshot below:



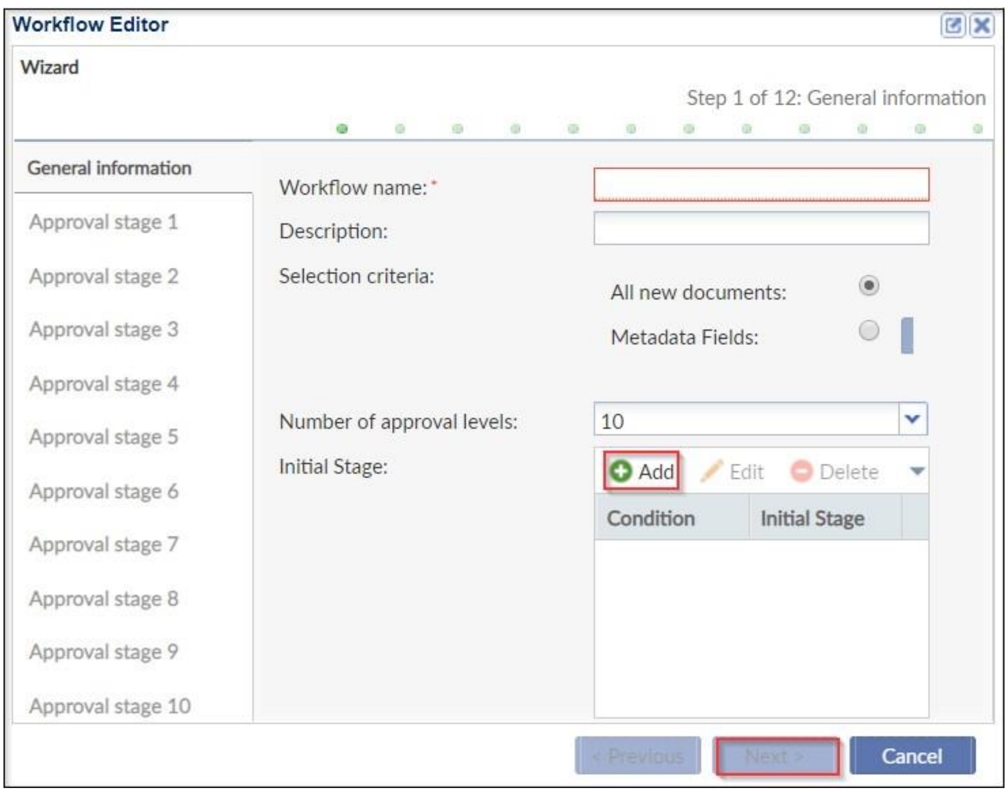
1. Tick the checkbox next to **Allow workflow stage auto claim**.
2. Enter the number of days after which **if the reviewer has not claimed the documents**, they will be **auto-claimed** by the system and assigned to the reviewer.

Creating the Quality Control Workflow

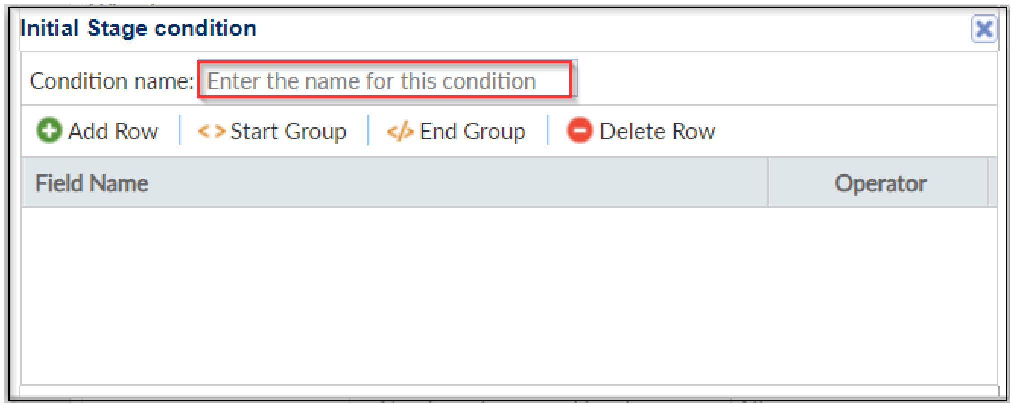
To create a Quality Control workflow follow the procedure below:

1. From the **Settings** → **Workflows** → **Workflows**, click the **Add** button from the grid. The **Workflow Editor** window opens.

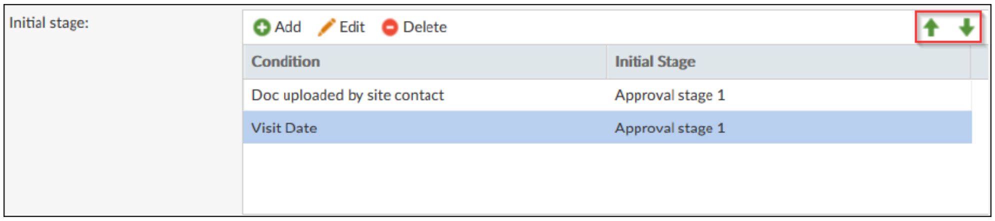
   Refer to the screenshot below:



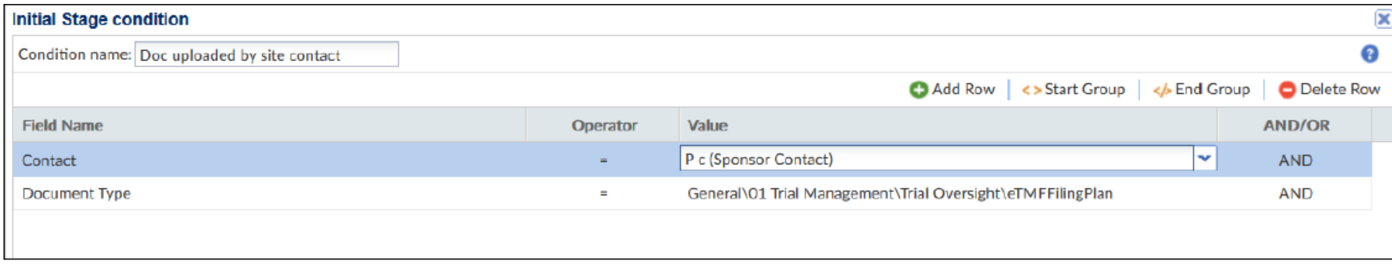
2. Enter the **Quality Control Workflow** name and **Description**.
3. The Selection Criteria could be **All new documents** or only those **Metadata fields** that need to be reviewed. Refer to the screenshot above.
4. Select the workflow levels, i.e. QC1, QC2, etc.
5. You may apply a **condition** to select documents for review as per a particular condition. Click **Add** to add a condition from the **Initial Stage** box. Refer to the screenshot above.
6. The **Initial Stage Condition** window opens. Refer to the screenshot below:

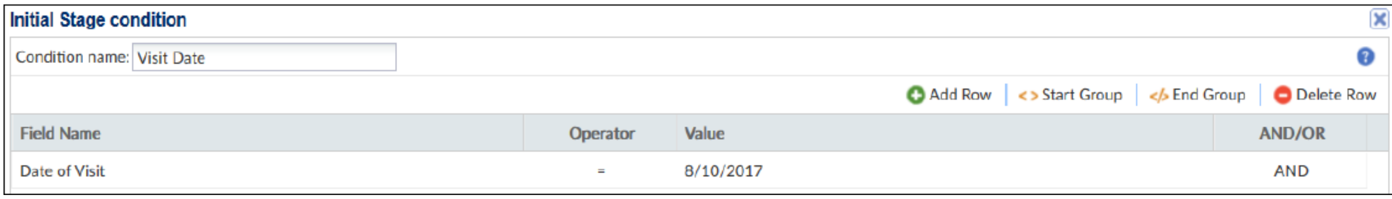


7. You may add multiple conditions and decide their sequence to filter documents with the green arrow keys. Use **And / Or** operators if you want all / either of the conditions to execute. Refer to the screenshot below:



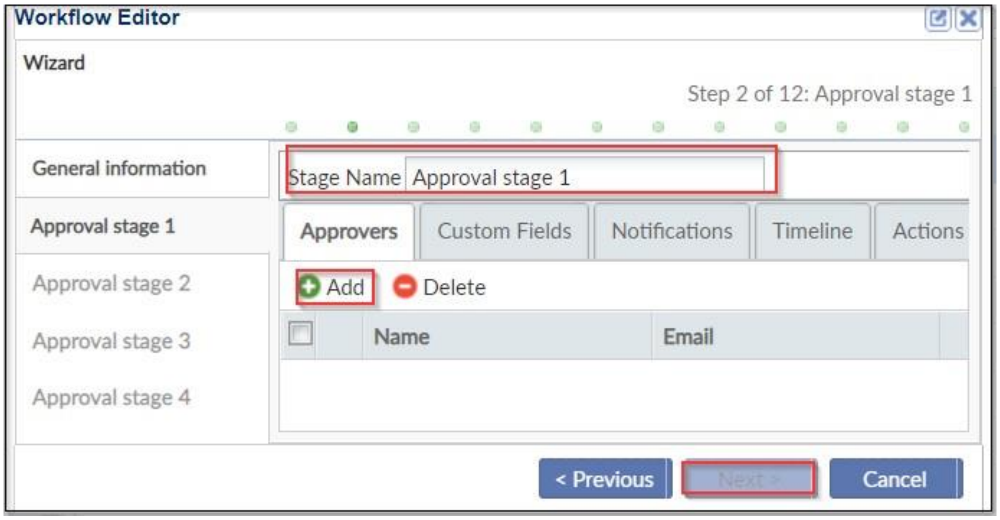
8. As per the screenshot above, documents uploaded by the site contact on a particular site visit date would be added to the workflow. The details of each condition are as below:





9. Thus, as per the above conditions, documents of type **'General\Trial Management\Trial Oversight\eTMFFilingPlan'** uploaded by the site sponsor on the site visit date of 10th of Aug. 2017 would be added to the workflow.

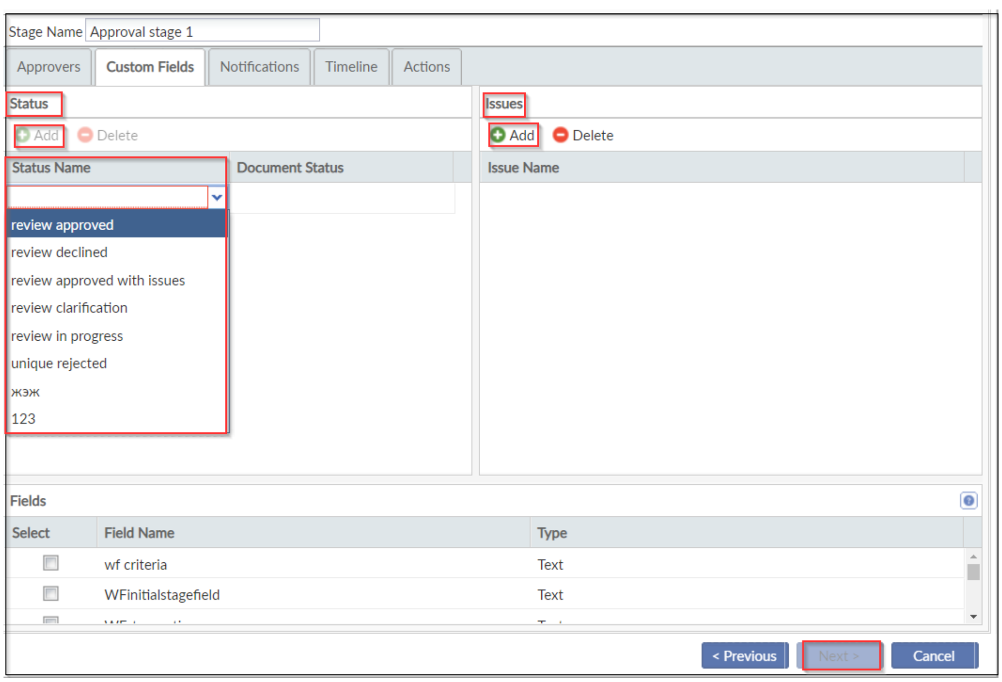
10. Click **Next**. This leads you to the configuration wizard of the **first stage of the workflow**. Refer to the screenshot below:



11. Change the **Stage Name**, if desired. Click the **Approvers** tab. Refer to the screenshot above.
12. This allows you to add **users/groups** as reviewers of the documents for the particular stage in the workflow.

Note: *It is recommended to add a* ***Group*** *to save configuration time.*

13. Click the **Custom** fields tab. This is a required tab and **Statuses**, and **Issues** must be added. Refer to the screenshot below:

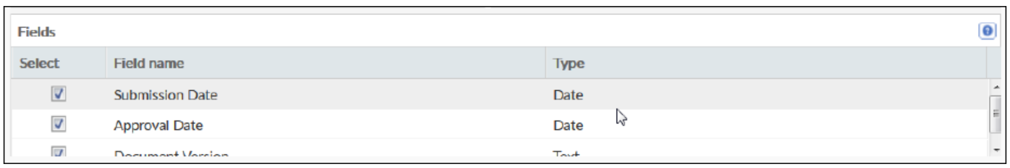


The statuses are the ones previously created under **Review Status *(page 158)***. Click **Add** to add the first status and select the document status from the dropdown. Refer to the screenshot above. **Approved** and **Rejected** are the minimum statuses that need to be added to a workflow. You can include more statuses, like **Clarification** and **In Progress**, for better functionality of the workflow.

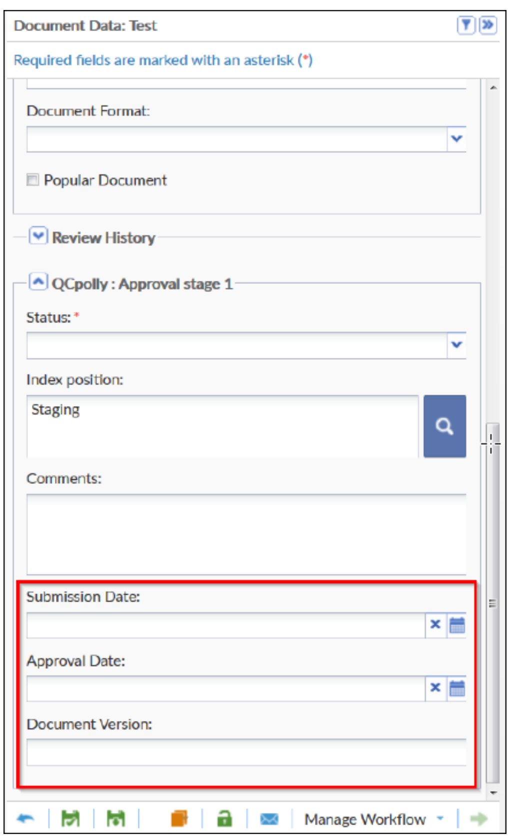
14. Click the **Issues** section to assign the reasons in case the reviewer rejects a document/asks for clarification. Some of the standard issues could be **Missing Pages, Missing Signature, Blank**

Pages, Incorrect Study, Poor Scan, Duplicate, and Expired Documents.

15. 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 **Customs** 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**.



16. Click the **Notifications** tab.
    - Here, you can allow for email notifications to be enabled for the event names listed.
    - For users who want to be notified only in case of **Claim**, **Release**, or **Escalation**, groups can be added accordingly.
17. 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.

18. **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 perform a2nd review on the document.
    - While efficient for complex workflows, it is not required for regular workflows creation.
19. Click **Next**, when all tabs have been reviewed.
    - Repeat similar steps for each stage of approval.
    - Settings may change per approval stage, like **approvers, notifications, and timelines**.
20. When finished, click **Next**.
21. The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If no errors, click **Finish** when done.

Editing an Existing Workflow

Caution: *Editing of existing workflow should be executed with caution because any saved changes require a new and revised workflow to be created*

While editing an existing workflow is quicker than creation, having multiple workflows enabled in the same room is not common and can cause confusion.

1. In the Workflows panel, click the **Name** of the workflow and either click **Edit** from the top menu or double click the required workflow.
2. The **Workflow Editor** window opens. Review the steps of the workflow wizard as before, clicking **Previous** & **Next** to review the settings.
3. If no changes have been made, click **Cancel**.
4. Yet if changes were made, this has become a new and different workflow. Thus, click on **Save as**.
5. Give the revised workflow a new name. A **new workflow** is created with the new name.
6. Click **Ok** when done. A confirmation message appears confirming creation. Click **Ok**.
7. The previous workflow and the newly revised workflow are both by default enabled. If one needs to be disabled, uncheck the associated box. Remember to click **Save**.

Deleting an Existing Workflow

Select a workflow from the list you wish to delete and then click **Delete** Delete from the top menu.

Quality Control Review Status

Here Admin can **create the review statuses** to assign to the document at each stage of the Workflow.

Review Status

- The Display Name' is the name of the status that would be visible on the user interface, whereas the System Status is pre-defined values that you assign to review status.
- Regardless of what the Display Name is, the documents will be routed to one of the workflow folders in QC Review/My Reviews based on the system status.

Adding Review Status

1. Click **Add**.
2. Enter the **Display Name**
3. 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** to be edited and click **Edit**.
2. The **Review Status** field becomes editable. Make the required changes.
3. 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. Click **Delete**.

Quality Control Process

This section gives the complete process of the Quality Control Workflow.

Assigning a Group of Users to the Quality Control

To assign a group of users to a workflow follow the procedure below:

1. Navigate to **Main Navigation ->Settings -> Security -> Groups** or to **Main Navigation -> User Management**.
2. Create a **Group**.
3. **Add users** to the group. The users in this group would be the reviewers who would review the documents.
4. Now navigate to the Settings-> Quality Control-> Workflows *(page 154)* and create a workflow.
5. In the Workflow Editor click **Next**.
6. Click **Approvers->Groups**. The group name to select would be the one you created in step 2 above.
7. Save the changes. This would have assigned the group of reviewers to the workflow.

Activating My Reviews

If you are part of the reviewers group which you assigned to the workflow, the Reviews view in the eTMF Documents module is automatically activated for you. You can have the same view as in My Reviews from the Quality Control Review application as well.

Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the Reviews view or the Quality Control module in the folder with unclaimed documents under the workflow configured by you. Refer to the screenshot below:

Claiming a Document

To claim a document for review, click folder holding **unclaimed documents** under **Reviews** or the **By Document Status view** from within your eTMF room. This will list the documents on the right pane.

Select the document you want to claim for review and navigate to the right panel.

If Workflows have been activated in your trial room and you are a member of a **Reviewers** or **Approvers** Group, you will see a **padlock icon** at the top of the metadata panel.

1. Click the **padlock icon** to claim the document for workflow review.
2. Then click **Save**.
3. Click the **Next Document** link at the bottom of the right panel to move to the next document in the current data grid. The process can be repeated as long as there are more documents available to be claimed. You may also select documents in bulk in the Documents Grid and claim them altogether.
4. All the claimed documents move to the **folder for holding documents claimed for review** in the **Index Pane**. Click the folder to view the claimed documents in the Documents Grid.

> **Note:** *Once you claim a document for review, the padlock icon appears to be unlocked and changes its text to **Release** which allows you to release the claimed document.*

5. Select the document from the grid and navigate to the **Workflow** panel to the right. From the Workflow panel, you can add the appropriate workflow status to the document.

Auto-Claiming a Document

In certain business scenarios, there can be only one reviewer assigned to a Quality Control stage. Under such circumstances, documents will be auto-claimed by the system and assigned to the lone reviewer for review. To enable auto-claiming of a document, the Administrator will need to enable the configuration from the Main Navigation ->Settings -> Workflows ->

Common Settings -> Auto claim configuration. *(page 153)*

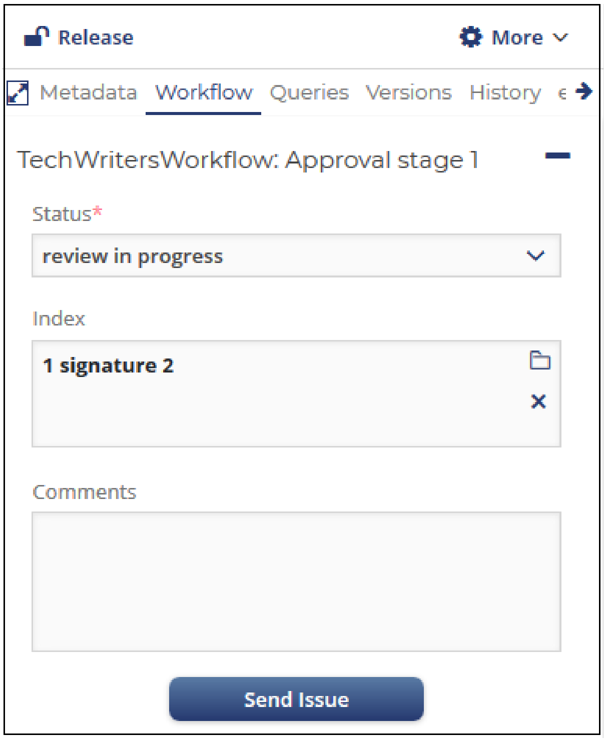
Note: *If documents are present in the same stage of more than one Quality Review, and the Reviews have only one reviewer assigned to them, the documents will not be auto-claimed.*

Assigning Quality Control Status

If you have been assigned to a Quality Review role, additional fields are available to you in the Metadata panel for documents in the Quality Control. Part of your assignment is to assign each document a Workflow Status.

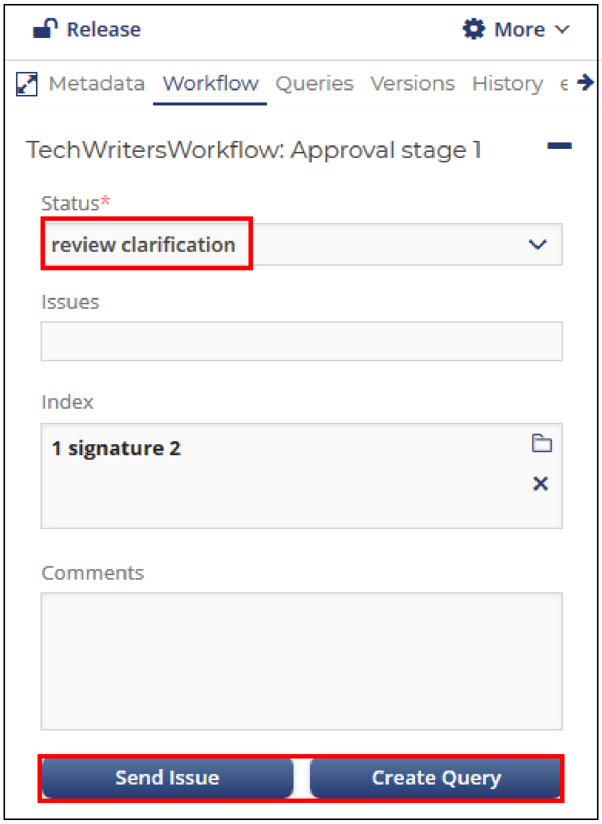
1. Click **Documents** from the left menu.
2. Select **Reviews** or **Status** view from the views. Alternatively, you can also navigate to the Quality Control module from the Main Navigation.

3. Open the **folder holding document claimed** for the review by clicking the folder icon next to the folder name. A list of your claimed documents will populate the document grid.
4. Select a document.
5. View the document's contents by clicking the document's icon in the grid or by clicking the **Document View** button at the bottom of the grid.
6. Inspect the document.
7. From the **Metadata** panel, code the document as required.
8. Navigate to the **Workflow** panel. Refer to the screenshot below:



9. Click the dropdown arrow to the right of the **Status** field to reveal the available Status selections.
10. Select the appropriate status based on your review of the document's contents.
11. Select the issue from the **Issues** field and select the **Index Position** for the document.
12. Add comments to the **Comments** field if appropriate.

Note: *When you select the **Review Clarification** or **Review Declined** status, the **Create Query** button appears along with the **Send Issue button** as shown in the screenshot below.*



13. Click the **Save** button at the bottom of the Workflow panel to save the workflow status you have assigned to the document, or click the **Save and Next** to continue reviewing the next document in the claimed documents queue.
14. Depending upon the status selected, the document moves to a corresponding folder under the Index Pane. For example, approved documents will move to the folder for holding documents **approved** in the workflow, rejected documents will move to the folder for holding **declined** documents, documents in progress will move to the folder for holding documents **in progress**, and so on.
15. You can also view the review history in the **Workflow History** section in the Workflow panel.

Releasing Claimed Documents Back

As a user with the Administrator role, you might find that you have claimed more documents for Quality Review than you can handle. If such a situation arises, you can release some or all of your claimed documents back into the Quality Review.

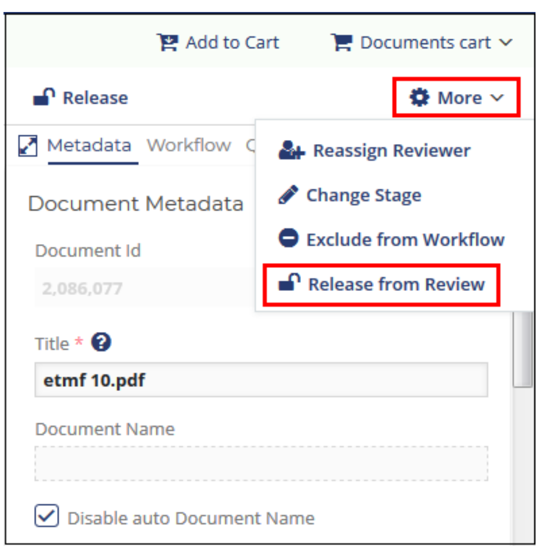
1. Click **Documents** from the left menu of the screen.
2. From the views, select **Reviews** or By **Status**, or navigate to **Quality Control** module.

All of the folders related to the Workflows in which you are an active reviewer populate the **Current view** index structure of the **eTMF/Documents Reviews view**.

3. Click the **folder holding claimed documents** from which you want to release documents. The list of documents in that folder populates the document grid.
4. Click the checkbox above the list to select all of the items in the folder, or select individual documents by clicking the checkboxes for those individual documents.
5. Click the **Release** button from the Right Panel. Refer to the screenshot below:

6. A window opens asking for document release confirmation.
7. Click **Release** if you are sure you want to release the document or documents.

8. Alternatively, you can also release the document by clicking **More**  dropdown at the top right corner of the Right Panel. From the dropdown options, click the **Release from Workflow** option to release the document. Refer to the screenshot below:

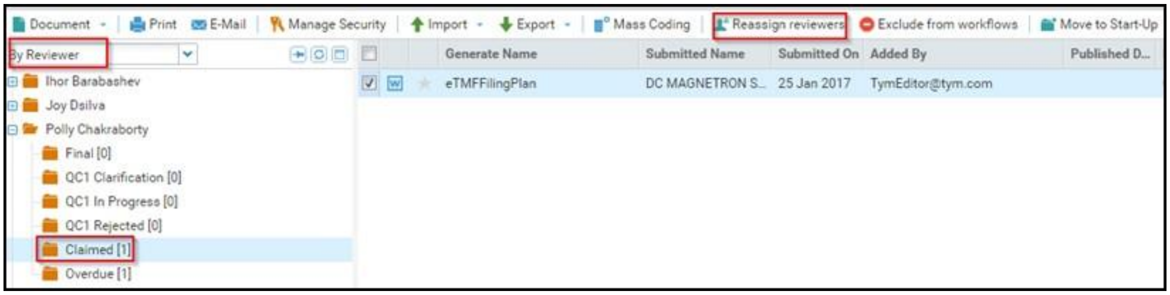


That document or those documents return to the folder designated to hold **review unclaimed** documents. The documents are now available for other reviewers to claim.

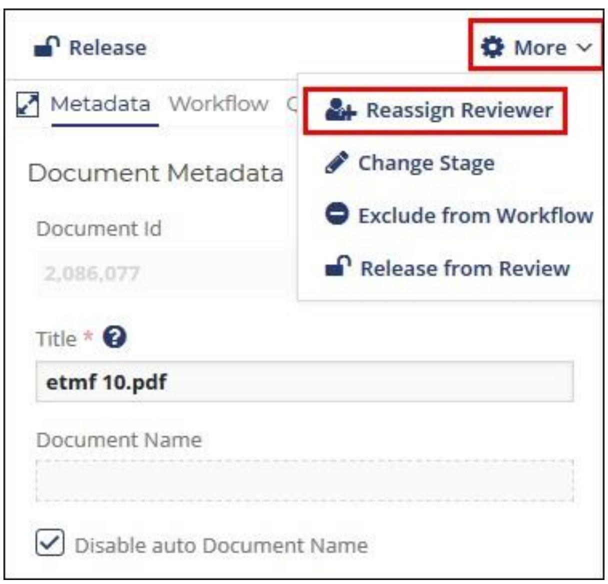
Reassigning a Reviewer

Administrators can reassign documents claimed in the workflow to other reviewers.

1. From the **Documents** view, select the **Reviewer** view.
2. Open the index folder of the reviewer whose claimed documents you want to reassign.
3. Click the folder holding **claimed document** to reveal its contents. The list of that user's claimed documents populates the document grid.



4. Select the documents from the list that you want to reassign.
5. Click the **More** dropdown located at the top right corner of the Right Panel to reveal the options.
6. Select the **Reassign Reviewer** option from the list. Refer to the screenshot below:



7. A **Reassign Reviewer** window opens.
8. From the **Workflow** dropdown, select the workflow you want to adjust. The **Stage** field auto-populates.
9. From the **Reviewer** dropdown, select the reviewer to whom you want to reassign the documents.

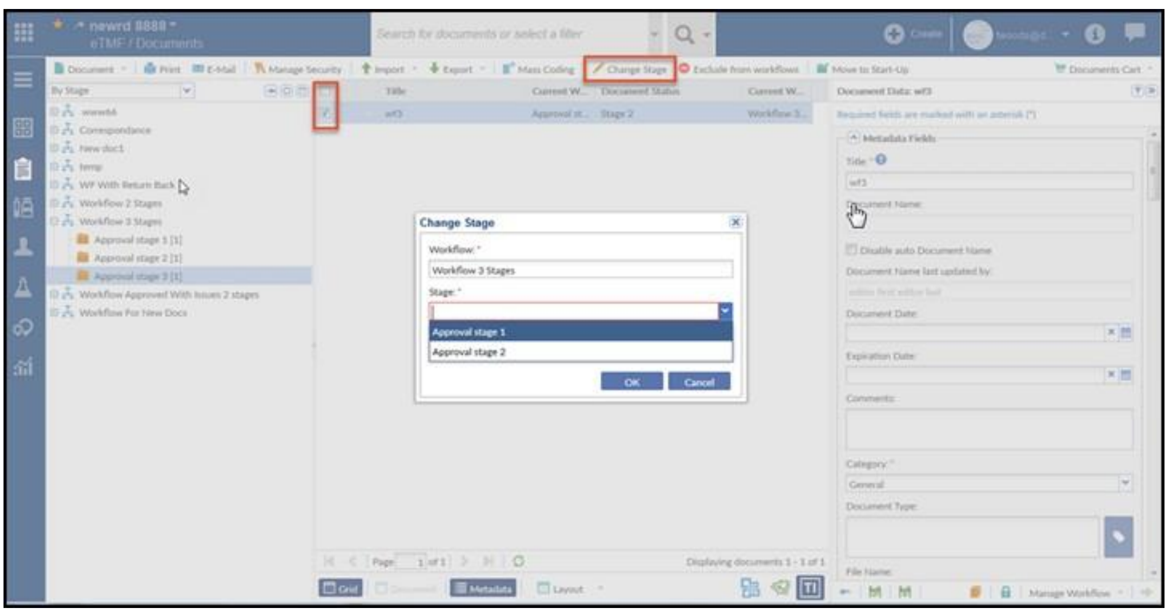
10. Click the **Change Reviewer** button.

    The documents are transferred to the folder for **claimed documents** of the new reviewer.

Reassigning Documents to a Different Stage in the Quality Review

Note: *Documents with Final status cannot be re-assigned to workflow stages. They will not be shown on the view.*

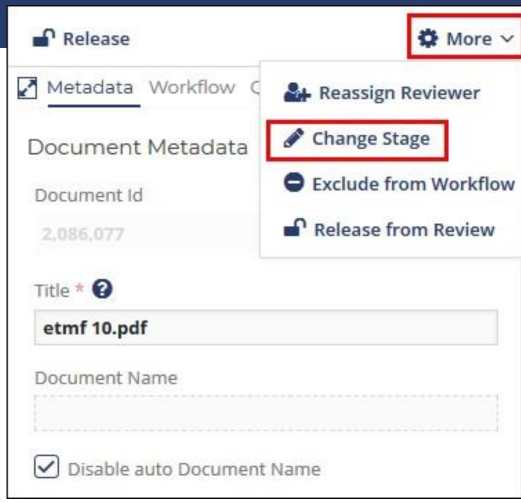
Documents can be reassigned by Administrators and Editors with **Document Manager** action to a previous stage in a workflow from the **Non-Final Documents By Stage** view in the



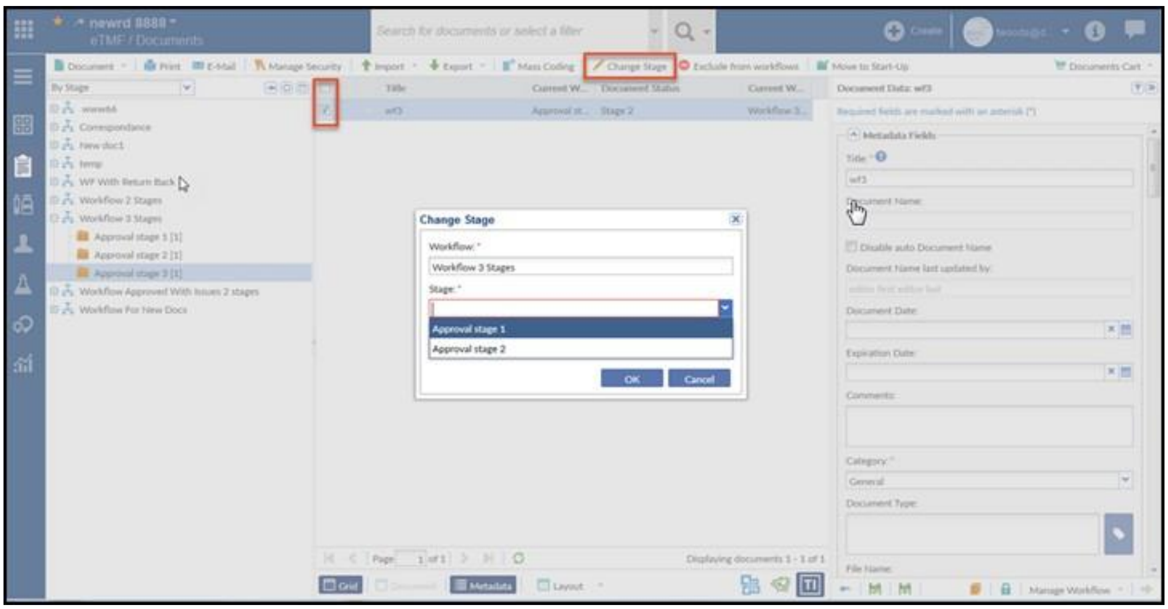
eTMF/Documents module. Refer to the screenshot below:

To Change Stage of documents in bulk or individually:

1. Select the Workflow Stage of the document above the current stage.
2. Select the documents in the stage from the Documents Grid.
3. Select the **Change Stage** option from the **More**dropdown from the Right Panel as shown in the screenshot below:

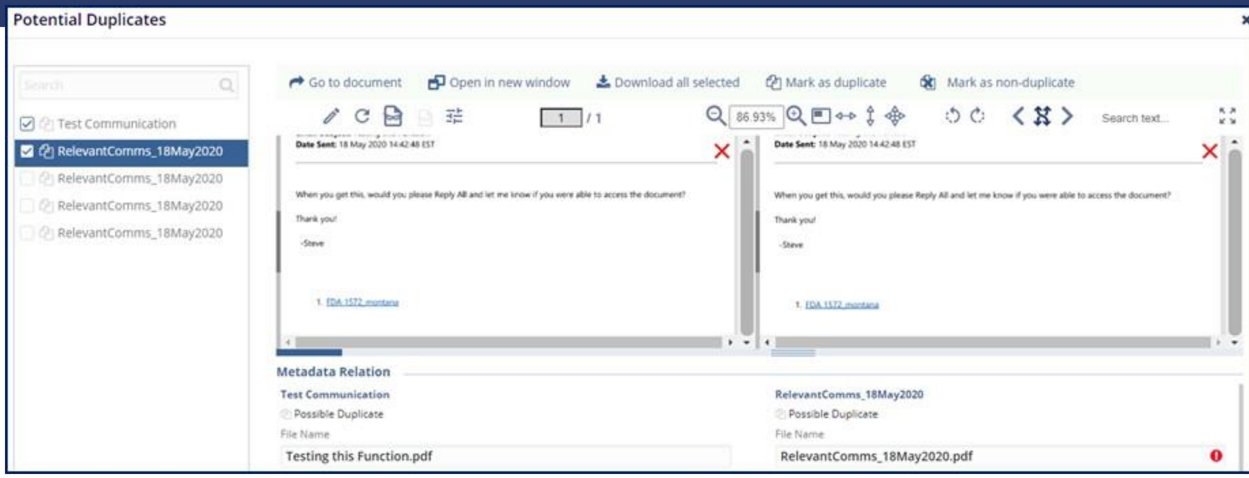


4. The **Change Stage** window opens.
5. Select the Stage and click **OK**. Only stages below the current stage will be available for selection.



6. The change stage operation for bulk documents is performed in a background process and the user is notified about the same in the Notifications panel once the job is completed.
7. Once the stage is changed, the documents move to the **folder for unclaimed documents** of the selected stage.

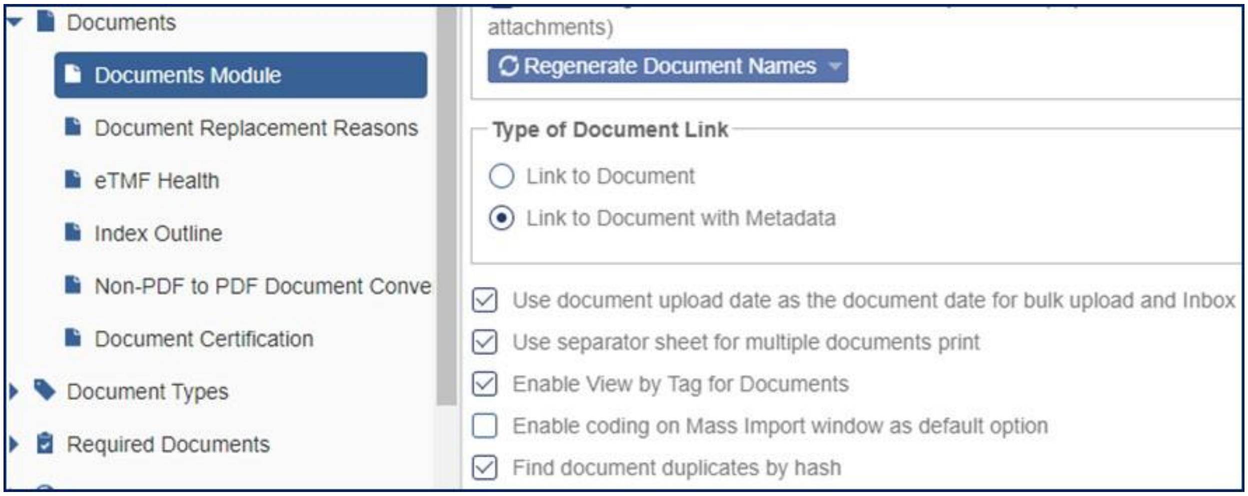
Duplicate Checks



TI10 introduces more flexibility around duplicate checks, improving the process in the followingways:

- Documents are now flagged as a possible duplicate if they are identical in every way to a document that already exists in the eTMF room (they have the same hash value which means the content is identical).
- Documents are now flagged as a possible duplicate if there is a document with an identical Generated Name at any step in the QC workflow process.
- These flagged documents can be identified through an icon. Once they are claimed, the user will be prompted to compare them. Note that the user may opt to ignore the flag, for example, if the document is known to be a duplicated site document.

Enabling Detection of Potential Duplicates



In order to enable detection of potential duplicates, an Administrator level user will need to go to the Settings menu and go to the Documents Module area of the Documents sub-menu.

From here, the user can check the box labeled "Find document duplicates by hash."

Once this setting is enabled, the room will be able to detect potential duplicates by hash value.

Reviewing Potential Duplicates

When a potential duplicate is detected, it will be indicated by a gray, Potential Duplicate icon. Clicking on that icon will open the window shown at the beginning of this section wherein the usercan compare potential duplicate documents and indicate whether or not they are duplicates.

Documents which have been marked as duplicates will be indicated by a red version of the potential duplicate icon.

Quality Control Query

The Workflow Query Resolution module must be enabled by a user who has Super Administrator access in Trial Interactive. When Query Resolution module is enabled, Query Reminder configuration is present in **Notification Preferences** and **Notification Columns** portlets in Email settings.

Quality Control Query involves the following processes:

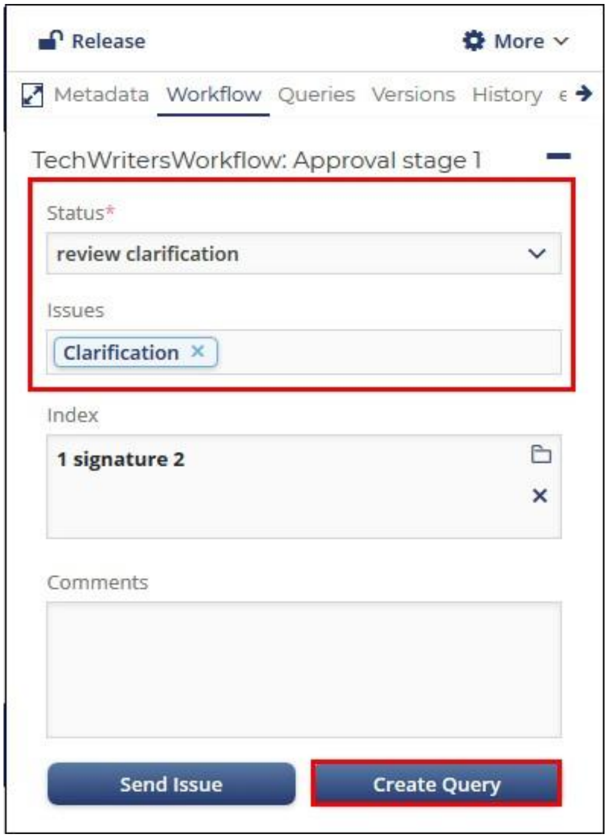
1. Quality Control Query Initiation by a Reviewer
2. Quality Control Response by a Responder
3. Quality Review Query Resolution by Reviewer for Query Response without attachment
4. Quality Review Query Resolution by Reviewer for Query Response with attachment
5. Tracking Quality Control Queries
6. Excluding Documents from a Quality Review

Each of these processes are discussed in seperate topics. Click the topic from the left pane to view it.

Quality Control Query Initiation by a Reviewer

1. As a user with **Quality Control Reviewer** assignment, go to the **Documents** module.
2. Select the **Reviews** view in the index panel on the left side of the screen, or navigate to **Quality Control** module.
3. Select an active **Workflow** main folder.The related subfolders open in the index view.
4. Select a document from the folder having **unclaimed documents**.
5. Claim the document by clicking the **Claim** button located at the top of the right panel. The document moves to the **folder containing claimed documents.**
6. Navigate to the folder that contains documents claimed for workflow and select a document from the grid.
7. Navigate to the **Workflow** panel in the right.
8. Select either **Rejected** or **Clarification** as the workflow status.
9. Select one or more **Issue** from the Issue field.

10. Click the **Create Query** below the **Comments** field. Refer to the screenshot below:



An email window opens. Click **Yes** to the question **Are you sending a Query?** (add image)

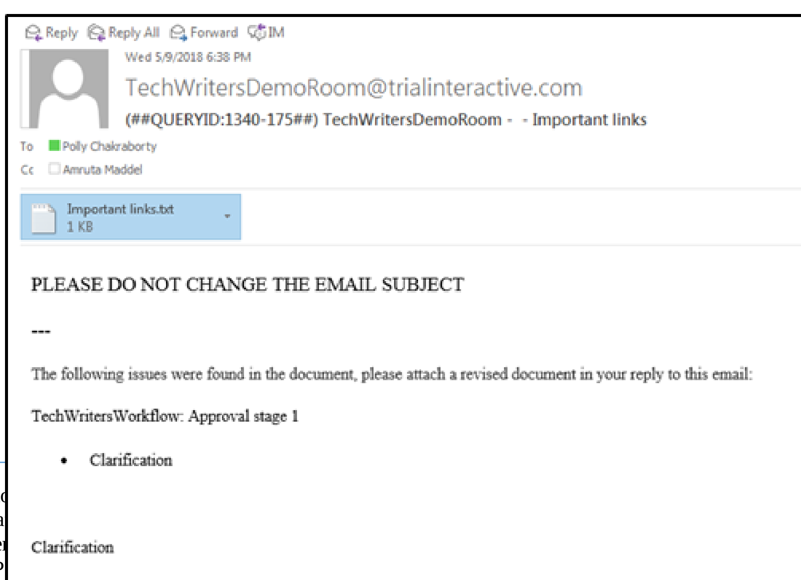
11. Click the ‘To’ and/ or the ‘CC’ button at the top of the message to add recipient of the Query notification email message.

    The party responsible for having sent the document to the room is an automatic recipient of the outgoing message. Only room participants can be added to the ‘To’ and ‘CC’ fields. Other email addresses cannot be added.

    The sender can include the associated workflow query document as an attachment or as a link.

12. Once all appropriate selections are made, click **Send Query**.

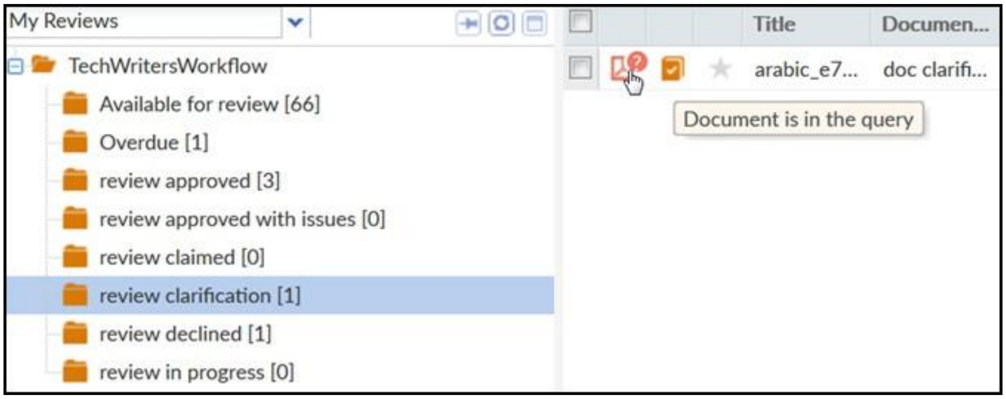
    The email message will go out to all recipients indicated in the fields at the top. Recipients receive an email message like this:



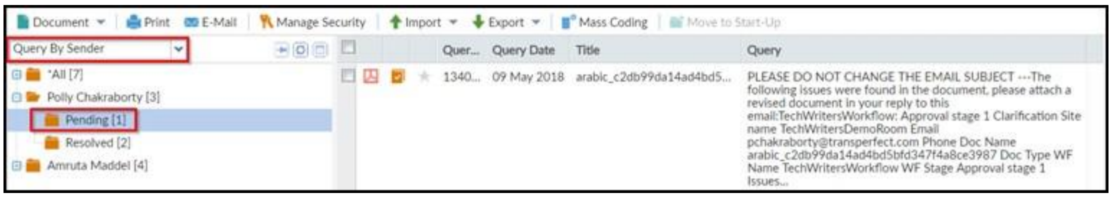
Each Query is assigned a unique **Query ID** number for easy tracking.

Note: *A Query ID consists of the of the Room ID where the query was generated and the Query ID separated by a dash. For example, in the above screenshot, in the Query ID 1340-175, 1340 is the Room ID and 175 is the Query ID.*

13. Click **Save**.
14. The **Reviewer** can also view the queries sent under two other views:
    a. In the folder designated to hold documents sent for clarification under **My Review** view or **Quality Control Reviews** module where the document acquires a question mark to indicate that it is in query.



b. In the **Pending** folder under **Query By Sender** view from the eTMF/Documents module.



Quality Control Response by a Responder

The Quality Control Responder can do the following to respond to the query email received in his/her email inbox:

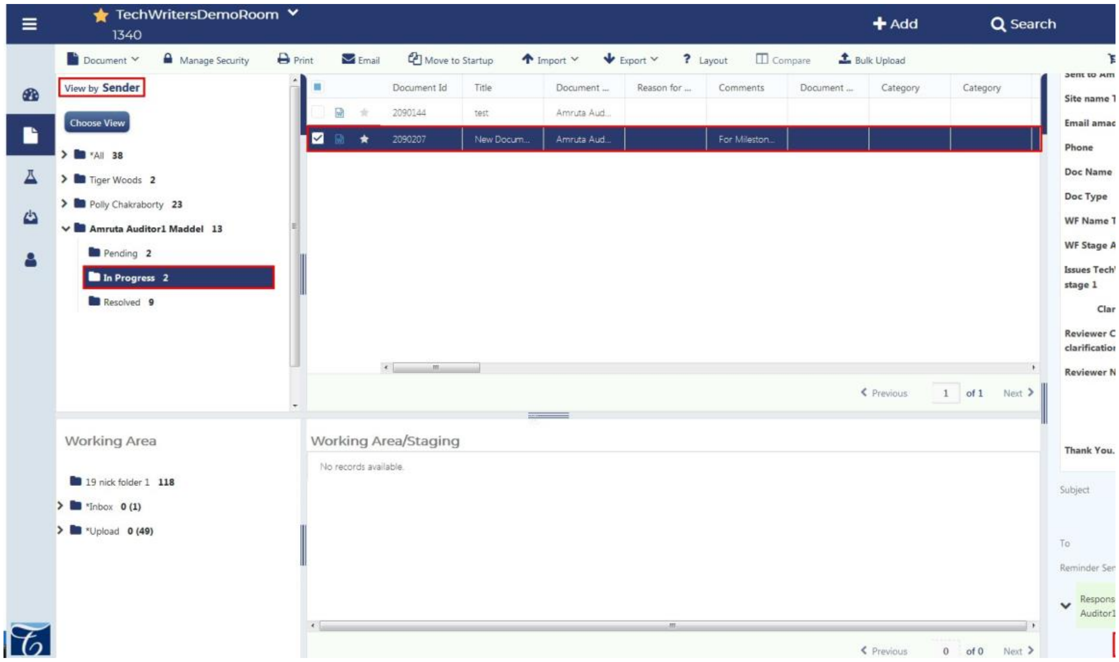
1. The responder can view the query email in the **By Recipient** view under the **Pending** folder.
2. The responder replies to the email query **with/without attachments** or **links** after examining the query closely.
3. Once the **Responder** replies to the query email, the query automatically moves to the **Responded** folder in the responder's room under the **By Recipient** view.
4. The *Responder may also choose to resolve the query* by clicking the **Resolve** button in the Queries panel in the **Pending** folder. Under such circumstances, the document moves to the **Resolved** folder of the **By Recipient view of the responder** and in the **By Sender view of the reviewer**.

Quality Control Query Resolution by Reviewer for Query Responses without Attachments

Once the responder replies to the query email, the reviewer can view the responded message in the room in **By Sender** view under the **In Progress** folder.

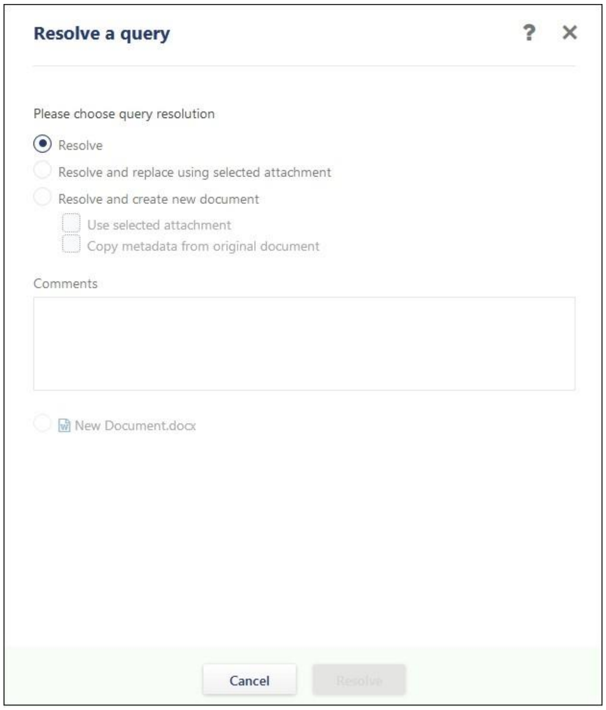
The reviewer needs to do the following to resolve the query:

1. From the **In Progress** folder, click the document and select the **Query Panel** from the right of the page.
2. At the bottom of the Query panel, two buttons are visible – **Respond to Query** and **Resolve Query.** Refer to the screenshot below:



3. Click the **Resolve Query** button.

4. On clicking the **Resolve Query** button from the Query panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries without attachments:



Note:

- *On clicking the <u>Return back to Pending</u> button, the document returns back and is available for review again. It will then need to re-start the query process from the beginning. This can be used, for example, if the responder is Out of office and an automatic reply is sent from his/her email inbox due to which the document moves to the In Progress folder.*
- *The reviewer can also click the <u>Resolve</u> button from the <u>Query window</u> in <u>Pending</u> folder to mark a query as resolved without any additional actions or waiting for the responder to respond to the query email. This can be used if the reviewer decides that a response is not required or the documents will be received in some other way. For example, if a query was created by mistake and the reviewer decides to cancel the query thereby resolving it.*

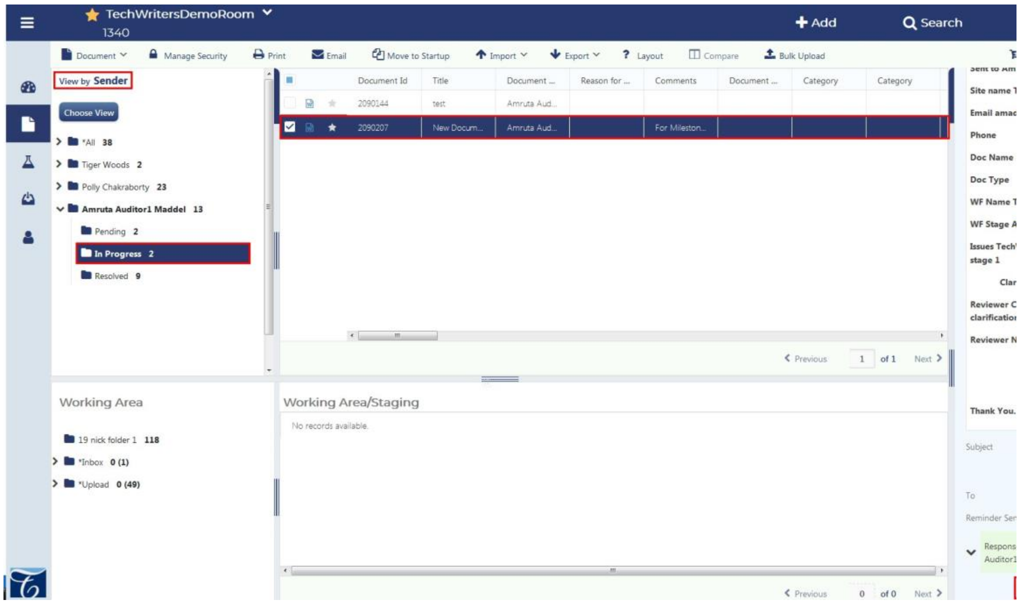
5. On clicking the **Resolve** button from the **Query** window, the query moves to the **Resolved** folder under the **By Sender** view for the reviewer and in the Resolved folder under the **By Recipient** view of the responder. The user can see the **Query History** in the **History** Panel to the right of the page.
6. On clicking the **Resolve and create new document button** and entering the **Comments**, the reviewer clicks the **Next** button to arrive at the **Document Profile** form. Refer to the screenshot below: (add image)
7. Enter the document metadata details and provide the attachment.
8. Click the **Resolve and create document** button.
9. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.

Quality Control Query Resolution by Reviewer for Query Responses with Attachments

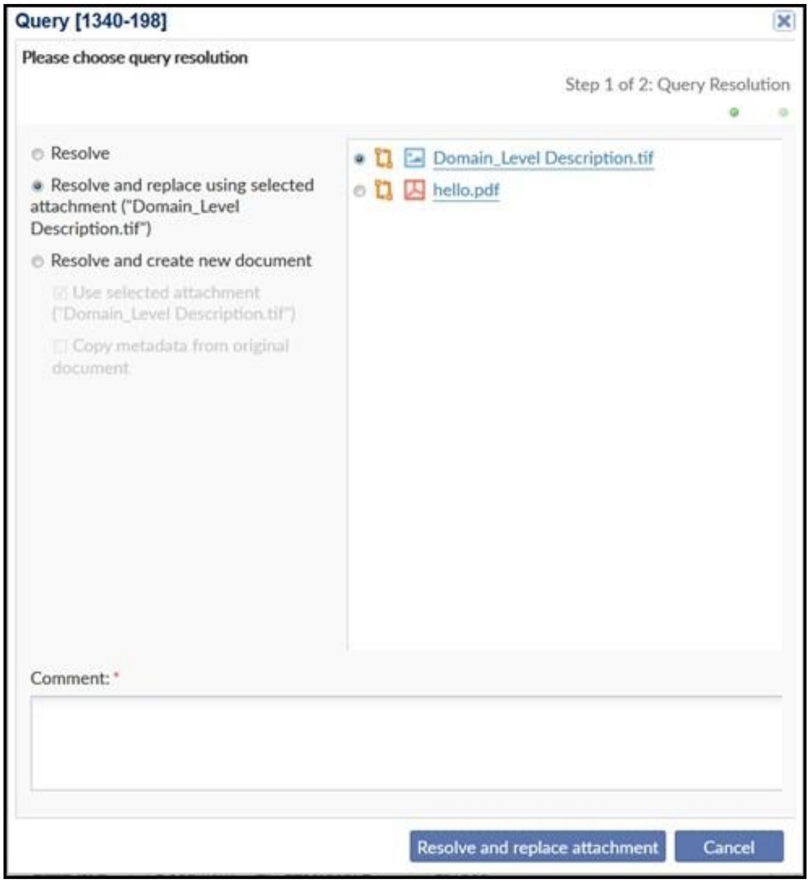
Once the responder replies to the query email, the reviewer can view the responded message in the room in **By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

1. From the **In Progress** folder, click the document and select the **Query Panel** from the right of the page.
2. At the bottom of the Query panel, two buttons are visible – **Respond to Query** and **Resolve Query.** Refer to the screenshot below:



3. Click the **Resolve Query** button.
4. On clicking the **Resolve Query** button from the Query panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries with attachments:



5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the Query by Sender view for the reviewer and in the **Resolved** folder under the **Recipient** view for the responder. The user can view the Query History in the **Query** Panel from the right panel. It also moves back to the folder holding documents available for review and needs to follow the review process again. The following options are available for sending response with attachment:

Resolve and replace using selected attachment

On clicking Resolve and replace using selected attachment option:

1. The reviwer can choose from the right pane, the document as deemed fit. Two attachments are displayed at the bottom of the window – (1) that was sent as an attachment by responder to allow the reviewer to resolve the query and (2) the document that is in the review process.
2. Before taking a decision, the reviewer can click the **Compare** icon from the right pane to compare between the document under review and the attachment sent by the responder in the **Compare documents** window, or click the attachment icon to open and view the attachment in the viewer.
3. Once done, the reviewer clicks the **Close** button on the Compare documents window and clicks the **Resolve and replace attachment** button after entering the **Comments**.

4. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.
5. The original document is still seen in the grid but the attachment from the query resolution can be seen under the Query History window.

Resolve and create new document

1. Can choose whether to **Use selected attachment** below the option by ticking the checkbox next to it and also use **Copy the metadata from the original document** to create a new document, ***or***
2. Untick both the above checkboxes and proceed to ignore the attachment and create a new document by providing another attachment.
3. Either ways, the reviewer clicks the **Next** button to arrive at the **Document Profile** form.
4. If the reviewer proceeds with option **Use selected attachment** , then he/she enters the metadata and clicks **Resolve and create document** button.

1. If the reviewer proceeds **with no option selected,** then he/she enters the metadata, provides the attachment and clicks **Resolve and create document** button.
2. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.
3. The original document is still seen in the grid but the attachment from the query resolution can be seen under the **History** panel.

Tracking Quality Control Queries

Users with Administrator access in a trial room can check the status of Quality Query Queries.

1. Navigate to the **Documents** module. (add image)
2. Click the Choose View button and select **By Sender** or **By Recipient** view from the list. The Index panel populates with folders that contain the Quality Control Queries at their various stages of progress.

   Select a specific folder and the contents of the folder populates the document grid.

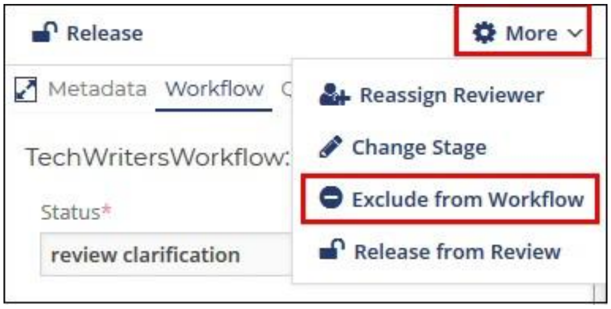
3. Select a specific query from the grid and open the Right panel. The history of the selected query is available by clicking the **Query** panel. The stages of the query history populate the metadata panel.
4. Click the arrows to the left of stage description to see the details of each query stage.

   If the user decides it is appropriate to create a new document in order to resolve the query, the user is required to complete the document profile, including uploading a new attached document.

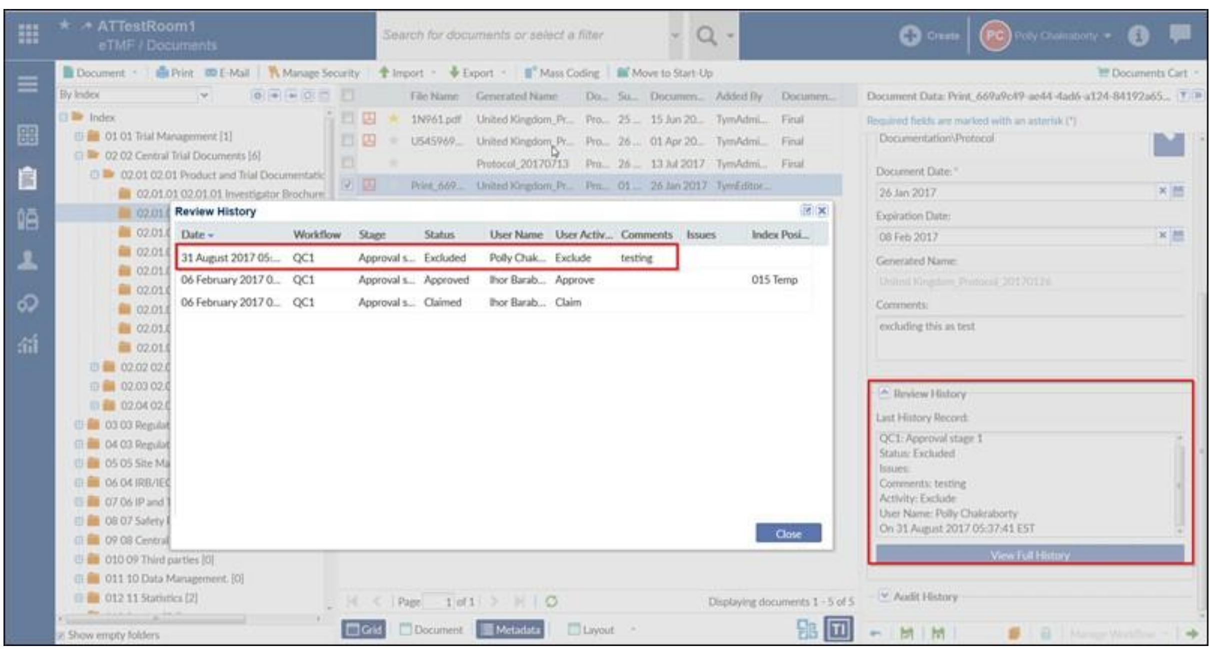
Excluding Documents from a Quality Control

An administrator can exclude one or more documents from the workflow by selecting the documents and clicking the Exclude from workflows option from the More dropdown located at the top right corner of the Right Panel. Refer to the screenshot below:

On clicking the button, the **Exclude from workflows window** pops up.



If the room has multiple workflows, the administrator can select the workflows from which to remove the document/s by clicking the dropdown arrow in the dialog box. It is mandatory to provide the reason for exclusion which gets recorded in the review history of the document. By removing a document from a workflow, the document can be found in the index where it is originally placed.



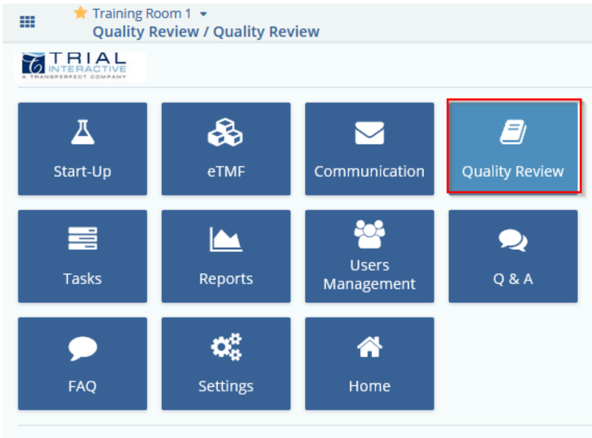
Documents moved to the Start-Up are automatically excluded from the workflow and the eTMF.

Note: *To know how to view a deleted queried document, proceed to section Deleted Queried Documents.*

Chapter 16. Quality Review

This section helps you understand the Quality Review/Audit application in Trial Interactive that allows creating Quality Review profile, recording auditor’s review and comments on various documents added for audit in a trial.

As a Trial Interactive Administrator, you can access the **Quality Review Application** from the **Main Navigation**:



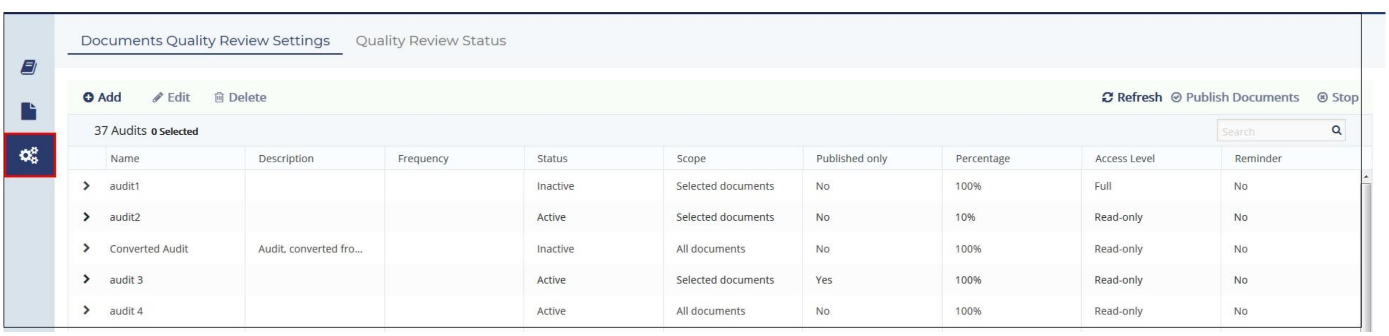
From here we discuss the following:

1. Quality Review Settings
2. Creating a Quality Profile
3. Performing Quality Review
4. Performing Quality Review Response
5. Responding to Quality Review Queries
6. Resolving Queries Raised during Quality Review

Quality Review Settings

Initial Audit functionality in a Trial Interactive room must be triggered by a user with Super Administrator access to the room. Once that setting has been activated, an Administrator can set up and edit audits on sets of documents in a room.

Once you enter the **Quality Review Application dashboard**, you can reach the **Quality Review Settings** page from **Quality Review Application -> Audit Settings.** Refer to the screenshot below:



The screenshot above shows a room that already has audits set up. The Audit Settings page includes the following sections:

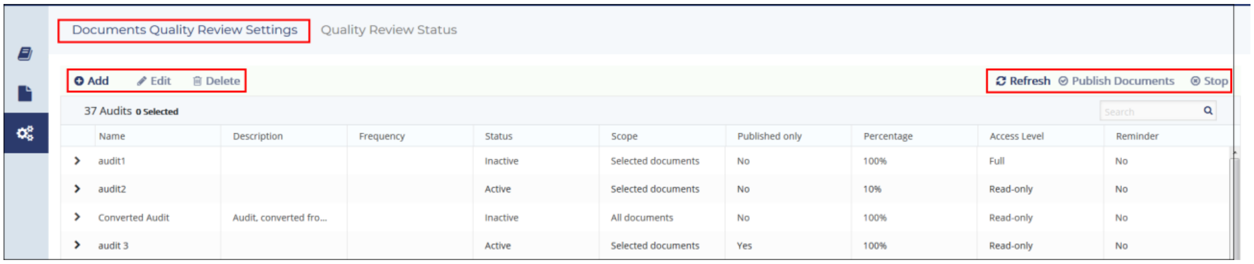
1. **The Documents Quality Review Settings:** From here Create, Edit, or Delete Audit profiles, Refresh Audit profiles, Publish Documents to Audit Profiles, and Activate/Deactivate Audits.

2. **The Quality Review Status:** From here Create Quality Review Profiles.

The above is discussed in separate topics accessible from the left panel of this help.

The Documents Quality Review Settings

This section displays the list of all active and inactive audits that are set up in the room. Refer to the screenshot below:



From here you can do the following:

1. Adding or Creating Audits
2. Editing Audits
3. Deleting Audits
4. Refreshing Audits
5. Publishing Documents to an Audit
6. Deactivating and Reactivating Audits

Adding or Creating Audits

From the Audit Settings, click the **Add** button on the top ribbon bar and follow the procedure as discussed in the topic Creating an Audit Profile *(page 351)*.

Editing Audits

Note: *The Edit button is enabled only when you select the audit.*

Follow the steps below to edit an existing audit:

1. Select the required audit from the list.
2. Click the **Edit** 

button from the top ribbon bar.
3. The **Create an Audit Profile** window opens.
4. Follow on to the steps and complete the audit profile.
5. The created audit profile then appears in the list of audits.

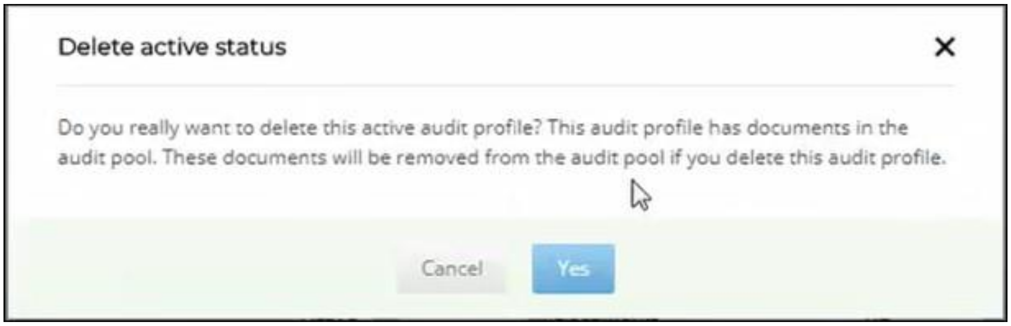
Deleting Audits

Note: *The Delete button is enabled only when you select the audit.*

Follow the steps below to delete an existing audit:

1. Select the required audit from the list in the **Documents Quality Review Settings** window.
2. Click the **Delete** 

button from the menu bar.
3. You are asked for the delete confirmation.
4. Click **Yes** if you are sure to delete the audit. Refer to the screenshot below:



Refreshing Audits

Click the **Refresh** 

button to reset the audit list.

Publishing Documents to Audit

Documents can be either be added manually or automatically to an audit. When you select the option **Documents will be added to the pool on demand basis** ***(page 353)***while creating an audit profile, you will have to add documents manually to an audit by clicking the **Publish Documents** button.

To publish documents:

1. Select the audit from the list of audits.
2. Click the **Publish Documents** 

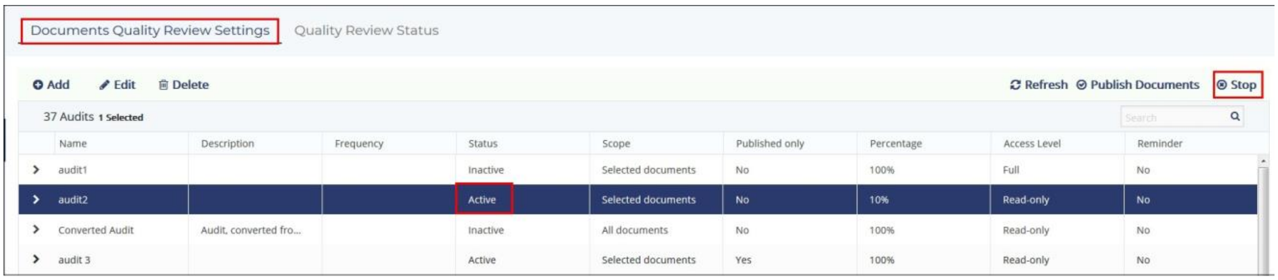
button in the **Documents Quality Review Settings** window.
3. Click **Yes** on the confirmation window that appears, if you are sure to publish documents. Refer to the screenshot below:

All documents are now available in the audit for review.

Deactivating and Reactivating Audits

Room Administrators can stop and start audits that have been added to a room. Follow the steps below to inactivate an audit that is currently active:

1. Click the name of the audit in the list in **The Document Quality Review Settings** window.
2. If the audit is **Active**, click the **Stop** button from the top ribbon bar. Refer to the screenshot below:



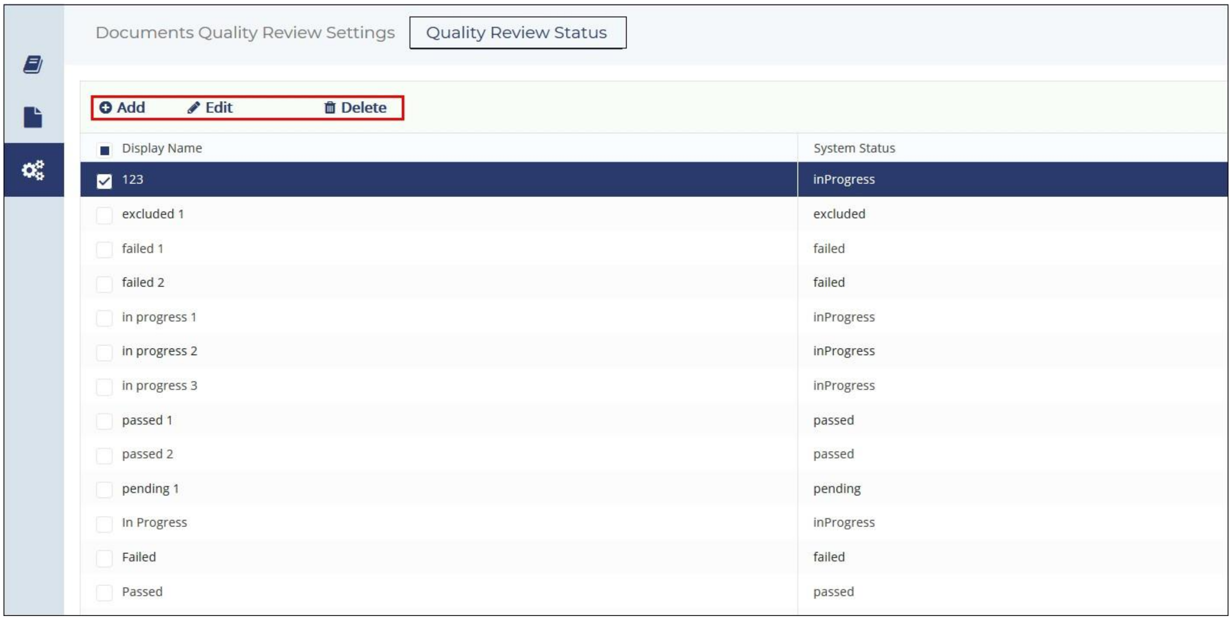
The status of the audit changes from **Active** to **Inactive** in the Status column.

3. Similarly, you can activate the **Inactive** Audit by clicking the **Start** button on the top ribbon bar and the status changes to **Active**.

Note: *The* ***Start*** *and* ***Stop*** *buttons on the top ribbon bar change their text as per the* ***Audit Status*** *for reactivating or deactivating them*

The Quality Review Status

Every system audit status has to be added into the **Audit Status** window before an audit can be built. The system statuses are **Passed**, **Failed**, **Pending**, **In Progress**, and **Excluded**. Each of these statuses must be mapped to a Display Name.



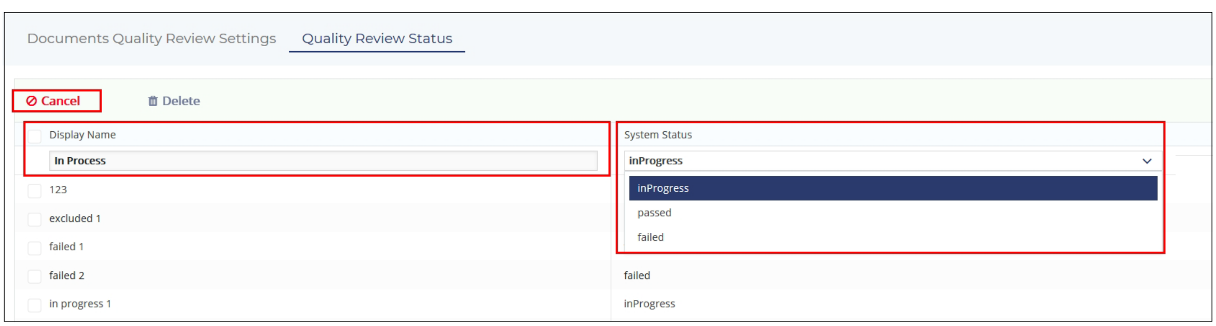
From here you can do the following:

1. Adding Statuses
2. Editing Statuses
3. Removing Statuses Each of these are discussed in the sections below:

Adding Audit Status

Follow the steps below to add audit statuses:

1. Click the **Add**  from the **Quality Review Status** tab.
2. The field under the **Display Name** and **System Status** fields gets activated.
3. Type in the **Display Name**.
4. Click the drop down arrow from the **System Status** field and select the established **System Status** term to associate with the newly added **Display Name**.
5. Click the **Add** in the Command columns to save the changes. The status gets saved to the list. Refer to the screenshot below:



6. Notice that when you click the **Add** button and the fields get activated, the Add button changes to **Cancel**.

Editing Audit Status

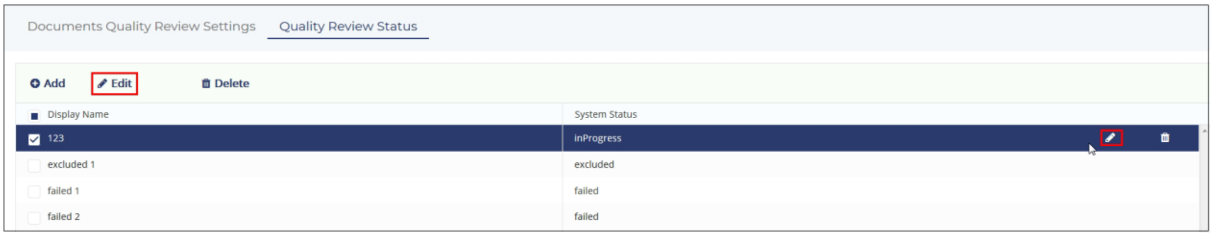
Follow the steps below to edit audit statuses:

1. Select the audit status from list in the **Quality Review Statuses** window.
2. You can edit the audit in the following by:

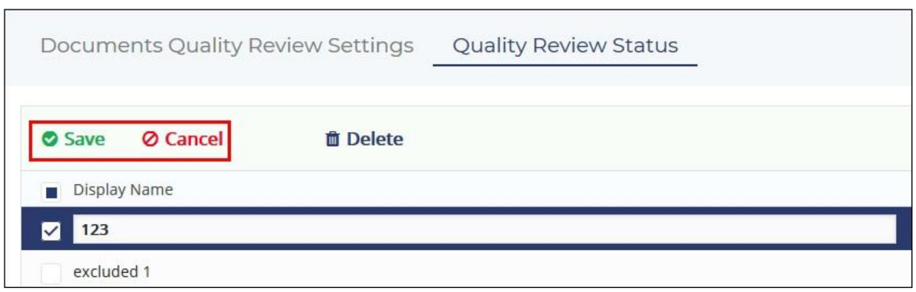
   a. Selecting the audit from the list and then the **Edit** 

 button from the top ribbon bar OR,

   b. Clicking the **Edit** icon that appears on hovering the mouse over the audit. Refer to the screenshot below:



3. Notice that the **Add** and **Edit** buttons changes to **Save** and **Cancel** when the audit is activated for editing. Refer to the screenshot below:



4. Make the required changes and click **Save**.

Removing Audit Status

Follow the steps below to remove audit statuses:

1. Select the audit status from the list in the **Quality Review Status** window.
2. Either click the **Delete** 

 from the top ribbon bar or click the **Delete** icon that appears on hovering the mouse over the audit.

Creating an Audit Profile

In Trial Interactive, before creating an Audit Profile, we would need to know the various roles that need to be assigned to users to perform audits:

1. **Auditor**: Users under this role can see only the documents they audit.
2. **Auditor manager**: Users under this role can see audit results of all auditors and can provide their own review comments to documents. Only editors and higher level users fit this role.
3. **Audit Responder**: Users under this role are responsible to take actions on issues cited by auditors in the documents. Only editors and higher level users fit this role.

Note: Quality Review Profiles can be created from either the Documents Cart *(page 287)* or from the Documents Quality Review Settings module *(page 347)*.

Creating an Audit Profile involves the following steps in sequence:

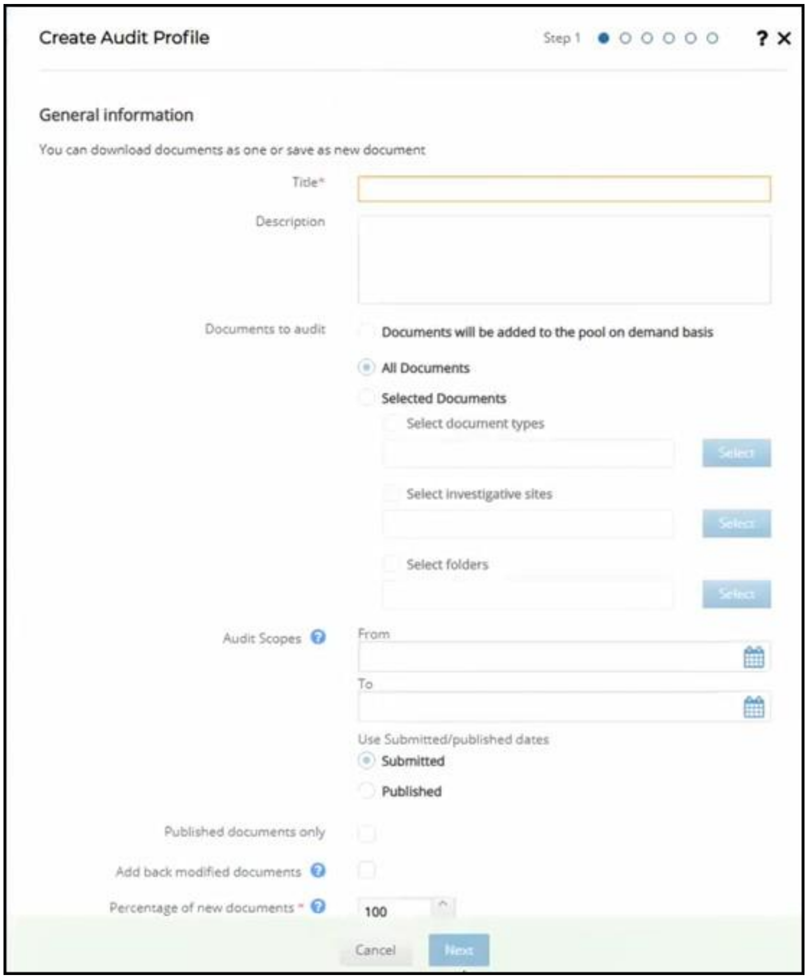
1. Filling the General Information
2. Selecting Auditors
3. Selecting Audit Managers
4. Selecting Audit Responders
5. Selecting Statuses
6. Viewing Audit Summary

Each of the above is discussed in separate topics available from the left panel of this topic help.

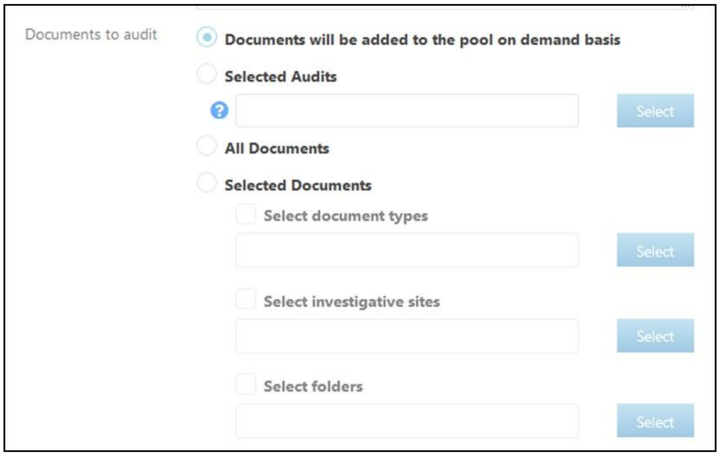
Creating an Audit Profile - General Information

Follow the steps below to enter the general information for Audit Profile:

1. Navigate to **Quality Review → Documents** module.
2. Navigate to the required folder to display the documents in the grid.
3. Right-click on the required documents and select the **Add to Cart** options. The documents get added to the **Documents Cart.**
4. From the Documents Cart, select the documents and click **Actions → Create Audit Profile**.
5. The **Create Audit Profile** window opens. Refer to the screenshot below:

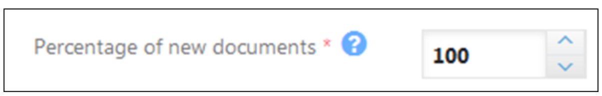


6. Enter the **Title** of the Audit in the title field.
7. Select the **Documents to audit** from the various radio button options available in this section. Each of the options in the Documents to Audit is discussed in detail in the topic ***Documents to Audit*** *(page 353)*.
8. Enter **Audit Scopes**. Documents submitted/published within the selected date range will be published to the audit pool. The Audit scope will be disabled if the documents are added to the pool on demand basis, or from selected audits.
   a. ***From Date***: The day from which the audit is to start. It is not possible to select future dates as 'From Date'.
   b. ***To Date***: The day till which the audit is to be completed.
9. Select **Submitted/ published dates**. Audit will be applied only to submitted or published



documents as per selection. Submitted documents are documents just added to the room, whereas published documents are documents added to the room as final.

10. Select **Published documents only**: If selected, documents added to the room as Final documents will be added to the audit pool. The user can choose to select Submitted from step c and check the **published documents only** checkbox. In this case, the audit pool will receive only documents that are just published to the room as final.
11. Select **Add reworked documents back to the audit pool**: Changing document metadata, or replacing the document attachment will add the document back to the audit profile with open status, irrespective of the fact that the document was passed/approved during the audit in the same audit profile. Currently supported metadata changes are Index, Category, Document Type, Investigative Site, and Document Date.
12. Select **% of new documents**: This defines the percentage of documents to be included in the audit pool as per the frequency, or audit scope. The percentage of documents is calculated from each intersection of selected investigative sites, document types, and folders. Refer to the screenshots below:



13. Select **Frequency:** When set, the system will move the documents to the audit pool based on the period set in the interval. This will be disabled if the audit scope date range is selected.
14. Select**Auditors' access level**: This defines the security that the auditor receives on a document. The access level can be **Full** or **Read-only**.
15. Select **Contains PHI**: The client may allow auditors to delete documents containing PHI, under which case the administrator will need to enable the **Contains PHI** functionality by ticking the checkbox next to it. To activate this checkbox, the **Auditor's access level** has to be set to **Full**.
16. Select **Send audit notification**: When checked, the auditor will receive an email notifying that new documents are added to the audit pool.
17. Once you have made the selections, click **Next** at the bottom of the window. You are taken to the next step of the Audit Profile to add **Auditors** ***(page 358)***.

Documents to Audit

You can add audits and documents to the current audit profile from the various radio button options available as shown in the screenshot below:

Documents will be added to the pool on demand basis

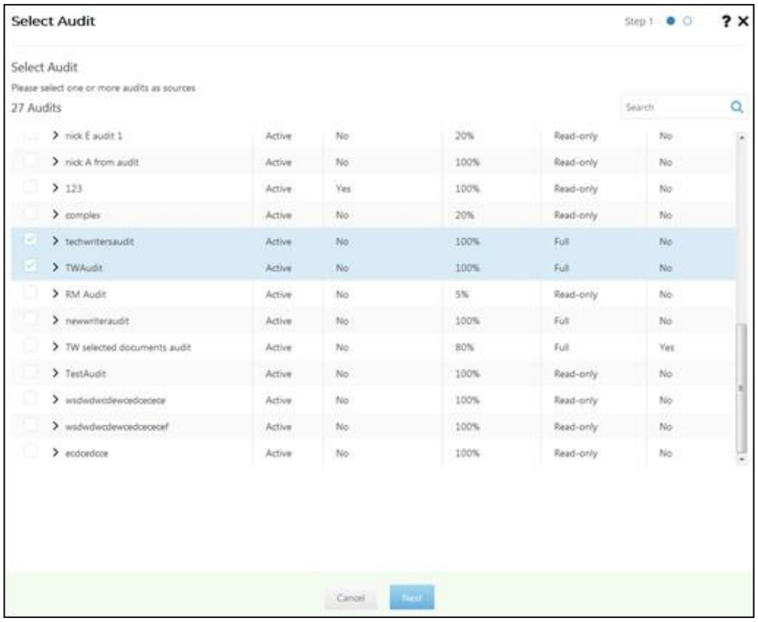
If selected, documents will not be added to the audit pool automatically. Instead, the user have to

add documents manually to the audit pool from the Documents Cart. *(page 287)*

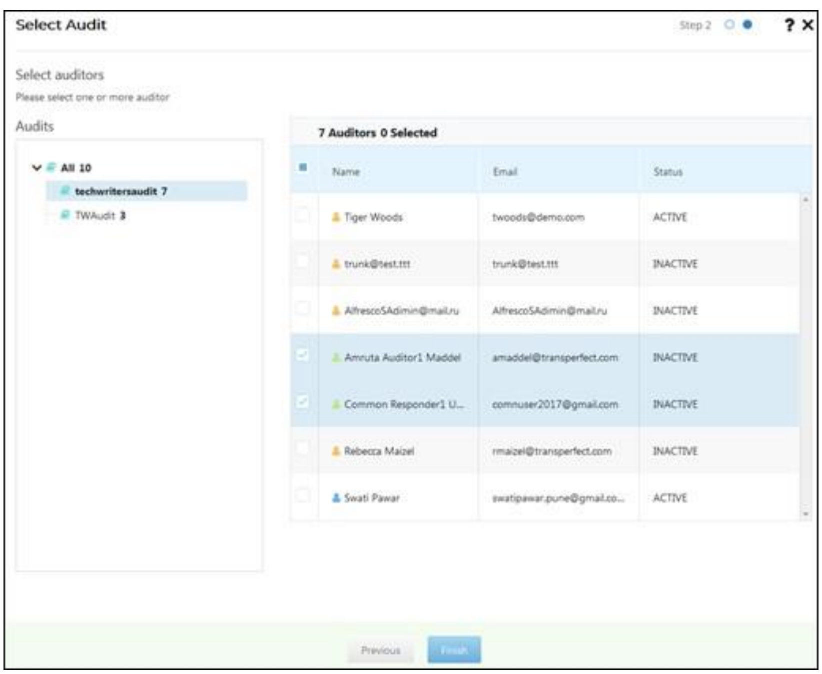
Selected Audits

If selected, documents passed in the selected audit profiles will be added to the current audit profile. Follow the steps below to add audits to the current audit profile:

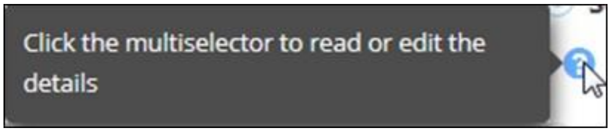
1. Click **Select**. The **Select Audit** window opens.
2. Select audits from the list of audits and click **Next** at the bottom of the window. Refer to the screenshot below:



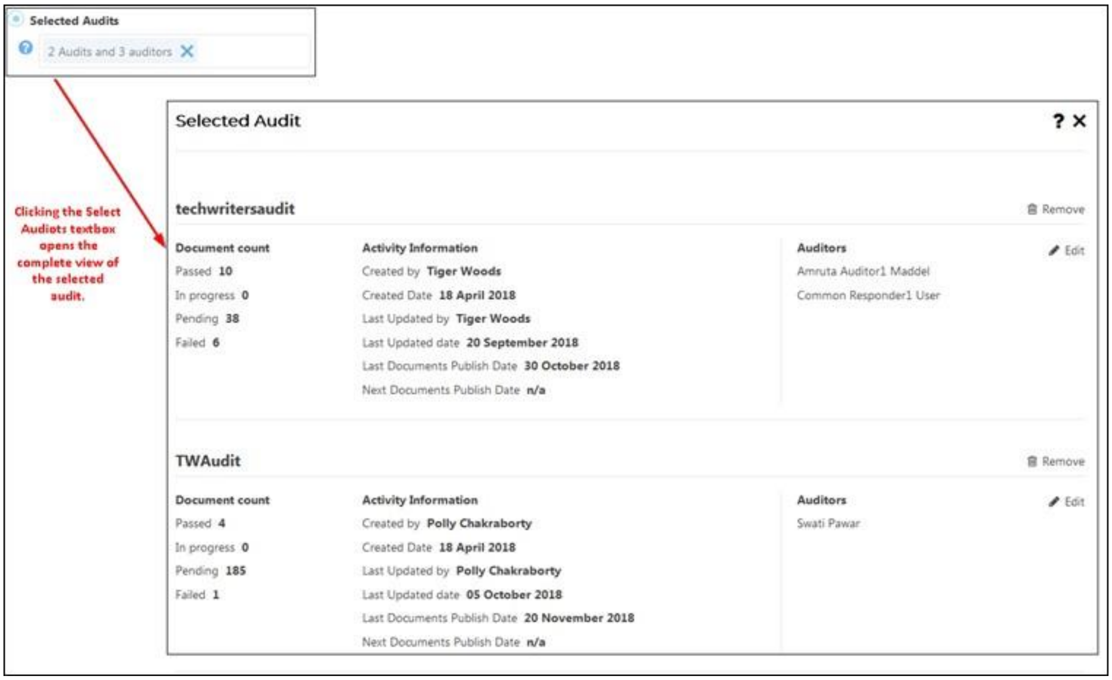
3. Select auditors from the selected audit profiles and click **Finish** at the bottom of the window.



4. The number of audits and auditors selected appears in the **Selected audit** text box. Hold the mouse over the help icon to reveal the details of the audits and auditors selected.



5. Clicking the multi-selector (textbox) opens the complete view of the audits and auditors selected. Refer to the screenshot below:



All documents

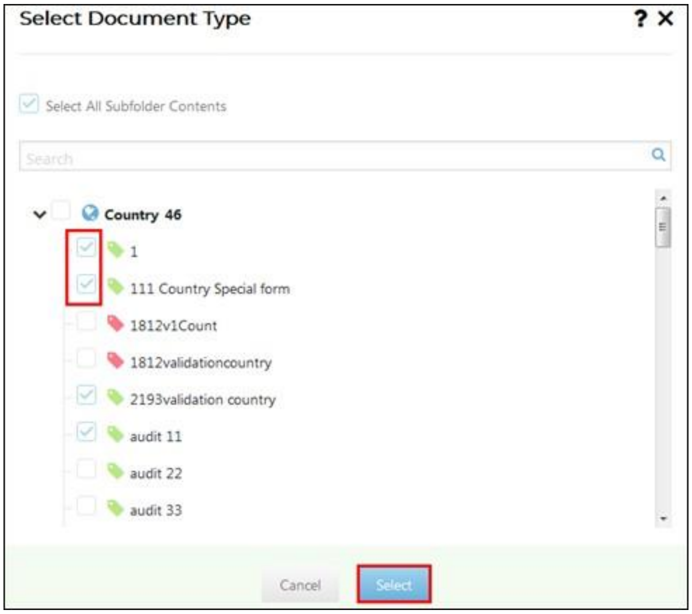
If selected, the documents of all document types will be added to the audit pool for audit.

Selected Documets - Selected document types

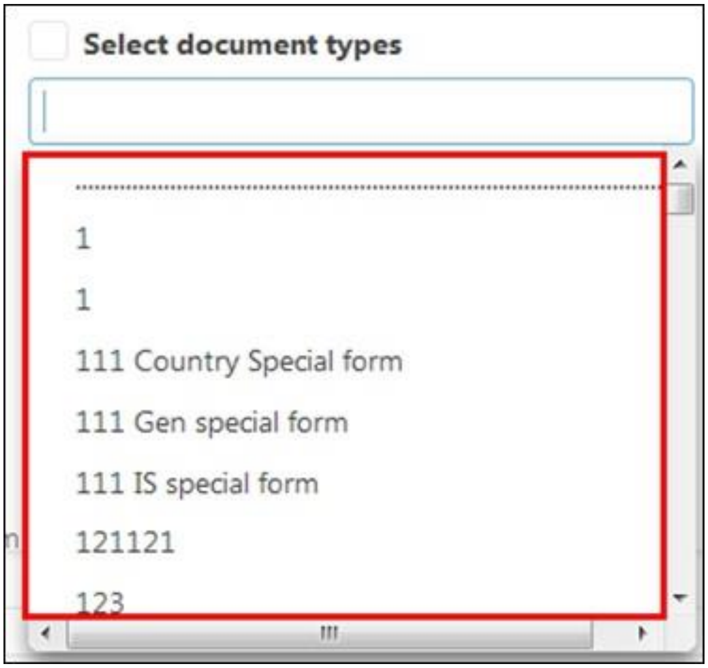
If selected, documents for audit will be selected from the chosen document types.

1. Click **Select** 

. The **Select Document Types** window opens.
2. Click the arrow next to the document type to navigate to the sub-types and select the checkbox next to the required document type.
3. Click **Select** at the bottom of the window. Refer to the screenshot below:



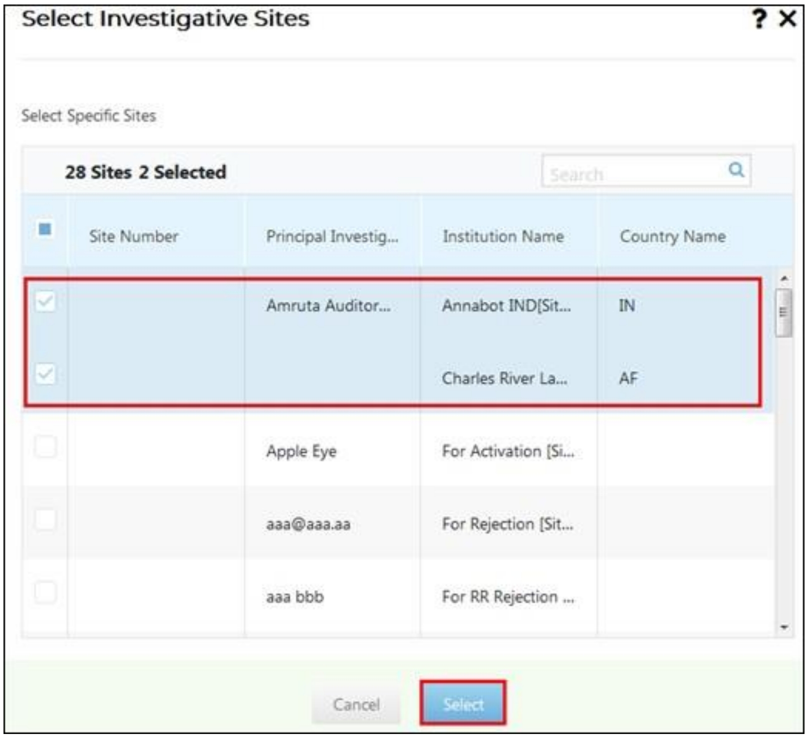
4. Besides, you can also click the textbox and select the document types from the dropdown that appears. Refer to the screenshot below:



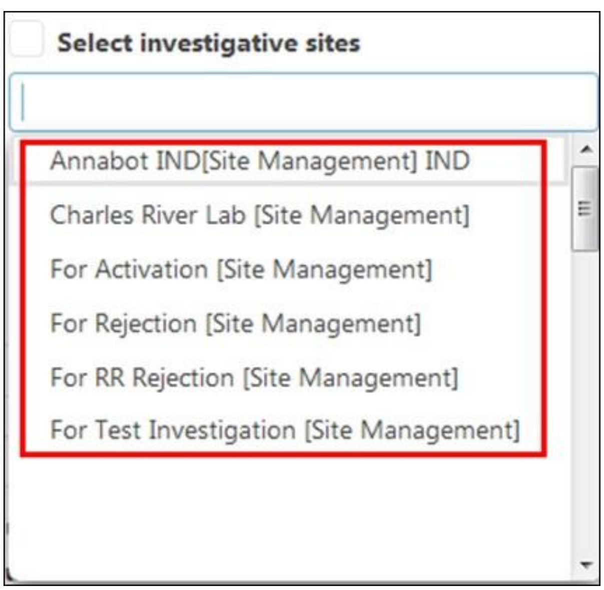
Selected Documents - Selected Investigative Sites
If selected, documents for audit will be selected from the chosen investigative sites.

1. Click **Select** 

. The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites get highlighted.
3. Click **Select** at the bottom of the window. Refer to the screenshot below:



4. Besides, you can also click the textbox and select the investigative sites from the dropdown that appears. Refer to the

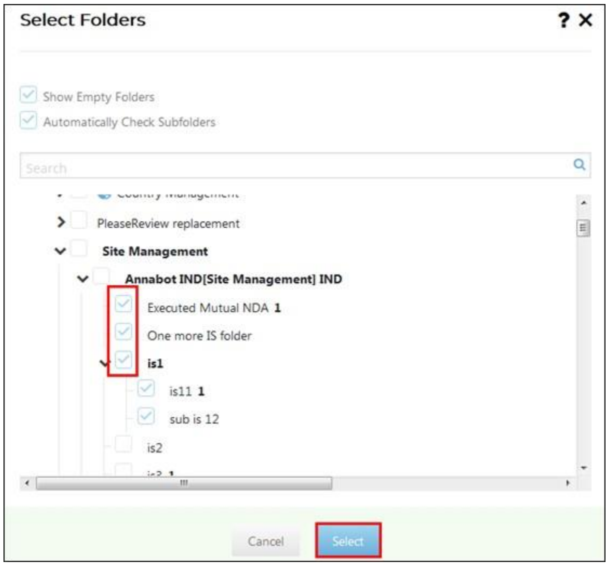


screenshot below:

Selected Documents - Select Folders

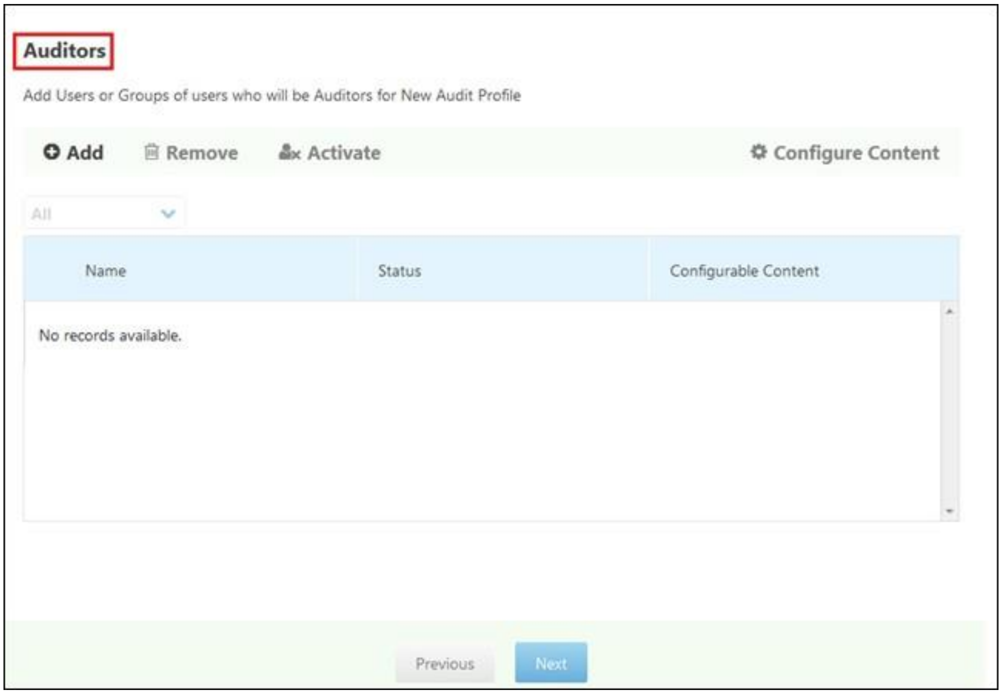
If selected, documents for audit will be selected from the chosen folders.

1. Click **Select** . The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites get highlighted.
3. Click **Select**. Refer to the screenshot below:

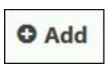


Creating an Audit Profile - Adding Auditors

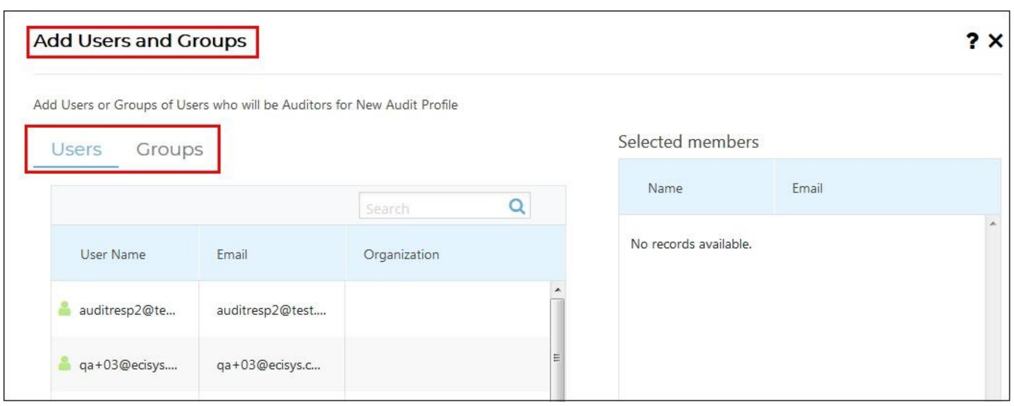
After adding all the general information, you are landed on the **Auditors** step. Refer to the screenshot below:



Follow the steps below to add auditors to the current audit profile:

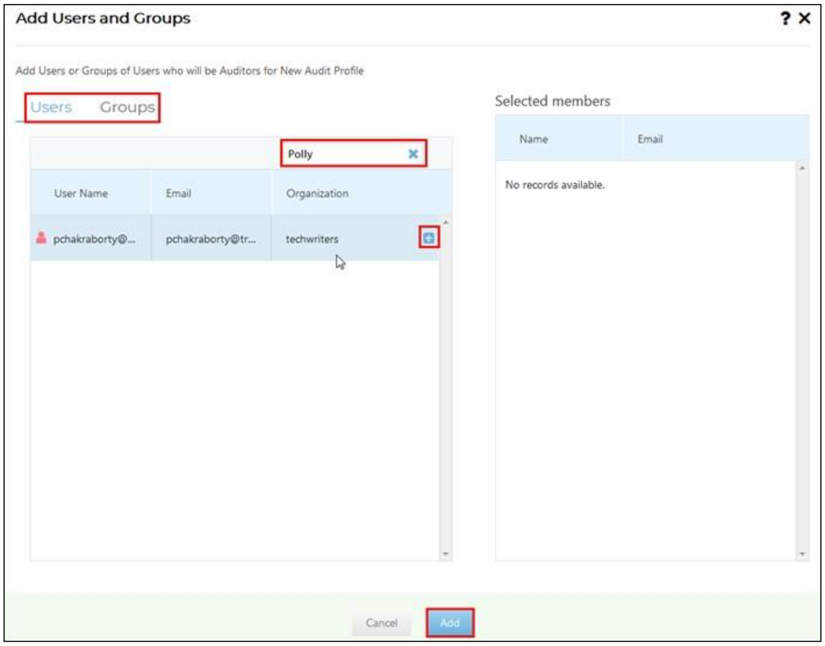
1. Click **+Add** 

 from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:



   a. Hover the mouse over the required user/group and click **+** icon that appears to the right of the selected user/ group or double click the user/group to add them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to the audit.
   b. You can also search for the user/group by entering the name in the Search box above the grid and then click the

Magnifying icon to the right. Refer to the screenshot below:



c. Click **Add** from the bottom of the **Add Users and Groups** window.

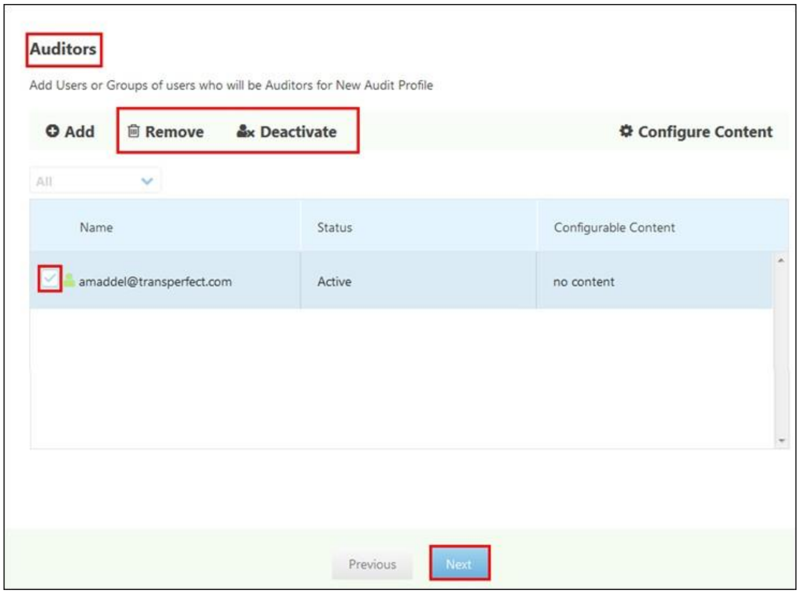
d. You are taken back to the **Auditors** window and the selected members appear in the grid.

3. Click **Next** at the bottom of the **Auditors** window.
4. You can also choose specific documents types, investigative sites, and folders to be available to the auditors for audit by clicking **Configure Content** ***(page 360)*** in the Auditors section.
5. During the process of creating an audit profile you may choose to remove, activate/deactivate auditors:

   a. Tick the checkboxes next to the auditor names and click **Remove** to remove them from the list.

   b. Tick the checkboxes next to the auditor names and click **Deactivate** to deactivate auditors.

   Alternatively, select a deactivated auditor and click the **Activate** button to activate an auditor. Refer to the screenshot below:



6. Click **Next** at the bottom of the **Auditors** window.

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Managers**.

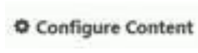
Configure Content

Besides adding documents for the current audit profile from the General Information step, you can also configure the content for the auditors using Configure Content from the Auditors step.

Note: *This feature is enabled only if you choose **Add documents to pool on demand basis** option disabled when you choose **Selected Audits** from the General Information step.*

Follow the steps below to configure content:

1. Select the user/group from the list of auditors.

2. Click the **Configure Content** 

icon located to the extreme right of the menu bar. A popup appears displaying the options as shown in the screenshot below:

3. Click the required option to configure the content for the selected audit user/group.

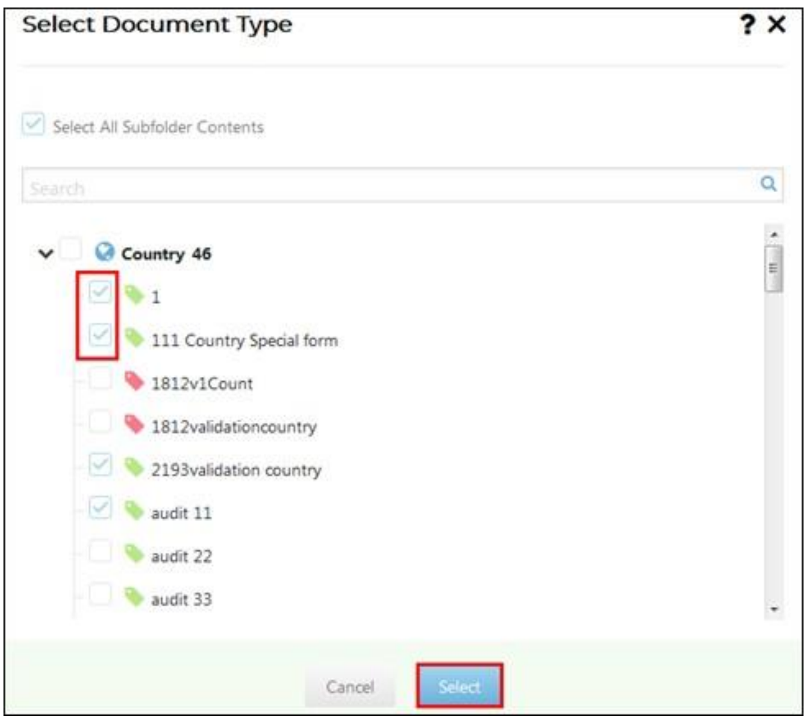
Follow the steps below to configure Document Types:

a. Click **Select** 

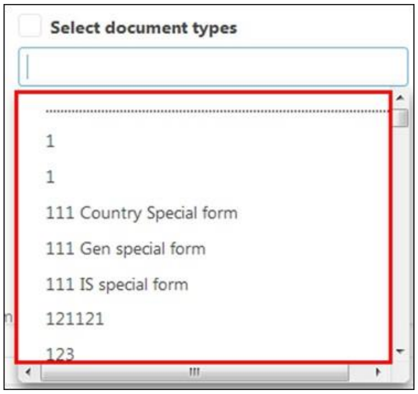
. The **Select Document Types** window opens.

b. Click the arrow next to the document type to navigate to the sub-types and select the checkbox next to the required document type.

c. Click **Select** at the bottom of the window. Refer to the screenshot below:



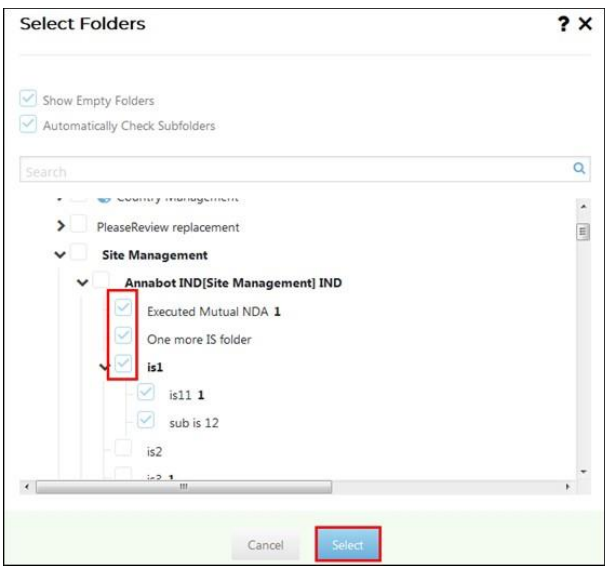
d. Besides, you can also click the textbox and select the document types from the dropdown that appears. Refer to the screenshot below:



Follow the steps below to configure Investigative Sites:

a. Click **Select** 

. The **Select Investigative Sites** window opens.
b. Select the checkbox next to the required investigative sites. The selected sites get highlighted.
c. Click **Select**. Refer to the screenshot below:



Follow the steps below to configure folders:

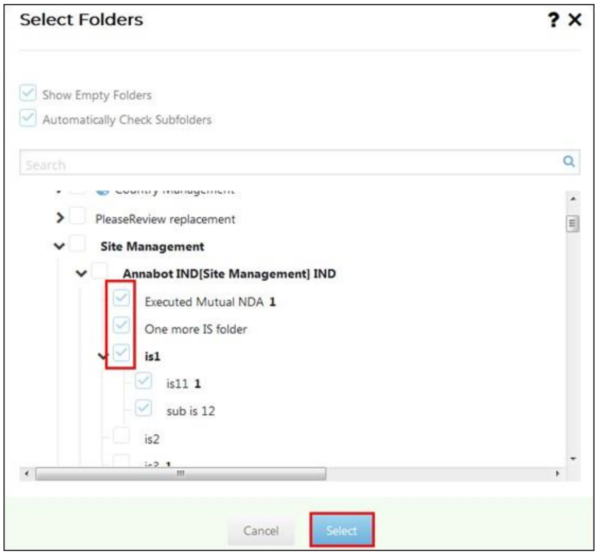
Selected Documents - Select Folders

If selected, documents for audit will be selected from the chosen folders.

1. Click **Select** 

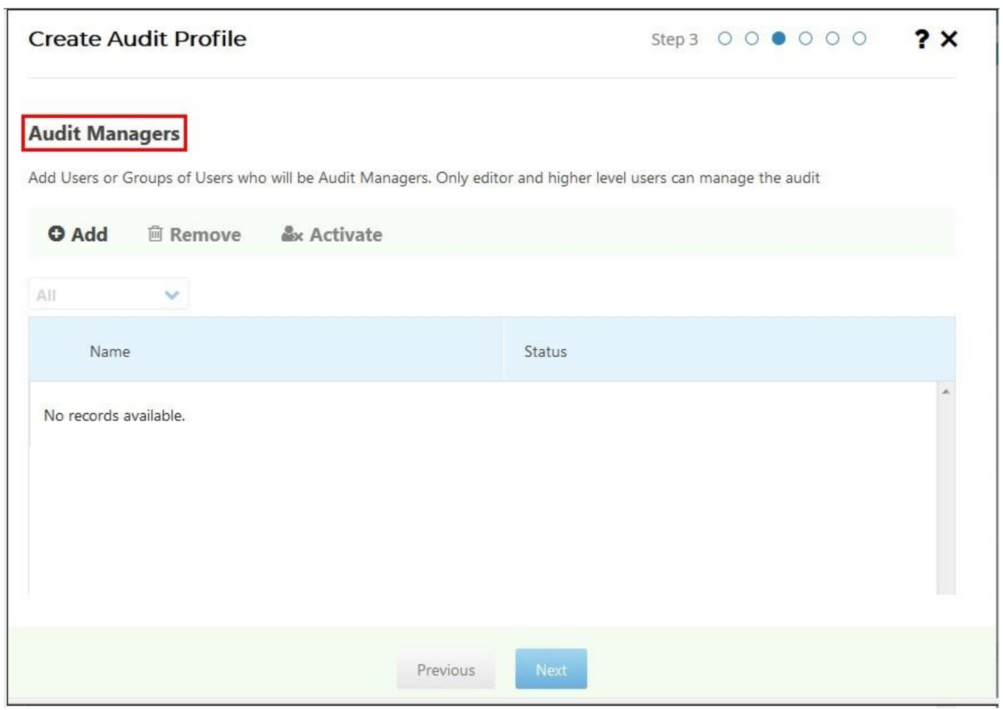
. The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites get highlighted.

3. Click **Select**. Refer to the screenshot below:

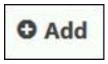


Creating an Audit Profile - Adding Audit Managers

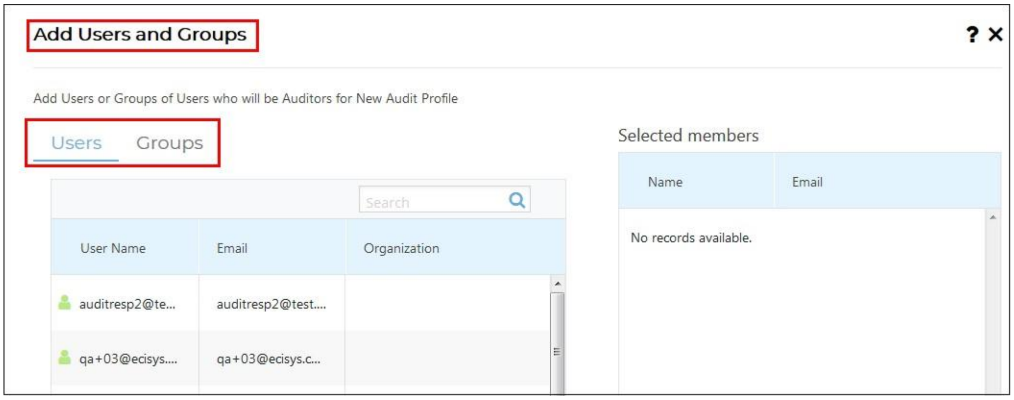
After adding Auditors, you are moved to the next step to add **Audit Managers**. Refer to the screenshot below:



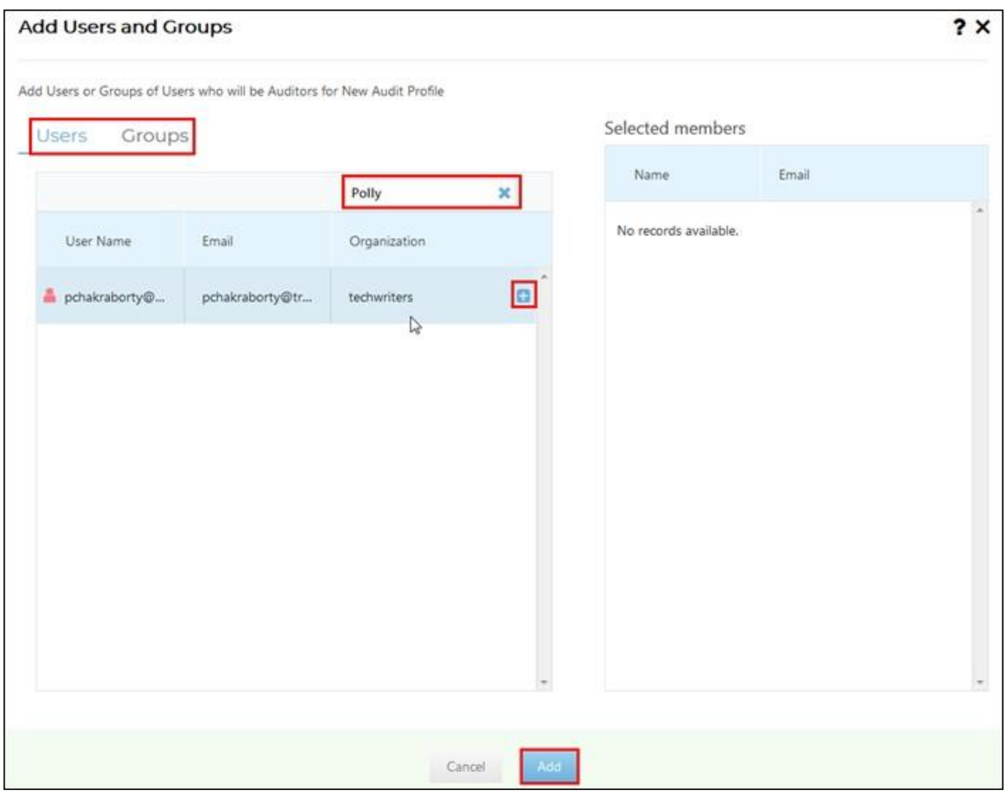
Follow the steps below to add audit managers to the current audit profile:

1. Click **+Add** 

from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:

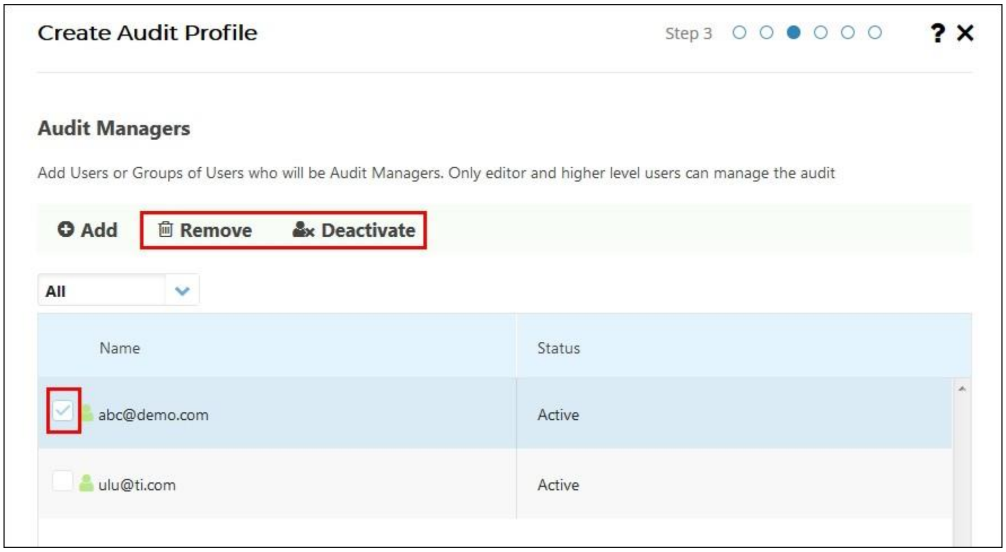


3. Hover the mouse over the required user/group and click **+** icon that appears to the right of the selected user/group or double click the user/group to add them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to the audit.
4. You can also search for the user/group by entering the name in the Search box above the grid and then clicking the **Magnifying icon** to the right. Refer to the screenshot below:



5. Click **Add** from the bottom of the window.
6. You are taken back to the **Audit Managers** window and the selected members appear in the grid.

7. You can also **Remove** Audit Managers by clicking Remove button or **Deactivate** them by clicking button from the Deactivate menu bar. Refer to the screenshot below:



8. Select the appropriate users/groups from the grid, click **Next** at the bottom of the window.

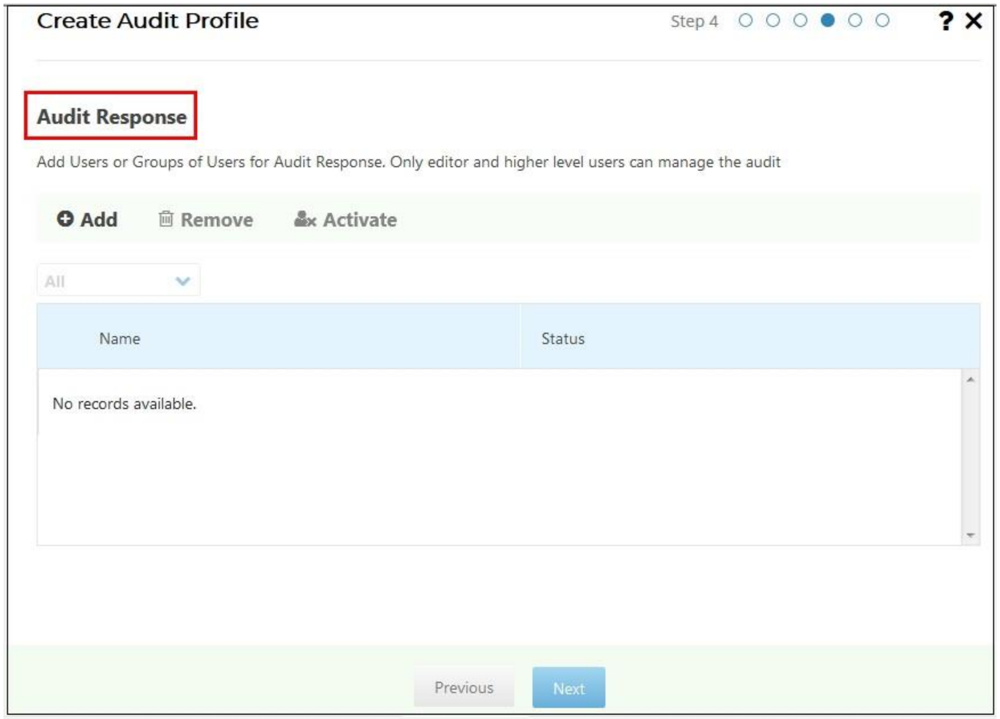
Note:

- *The **Remove** and **Deactivate** buttons enable only when you select the auditor from the grid.*
- *The **Deactivate** button toggle to **Activate** when no auditor is selected from the grid.*

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Response** *(page 365)*.

Creating an Audit Profile - Adding Audit Responders

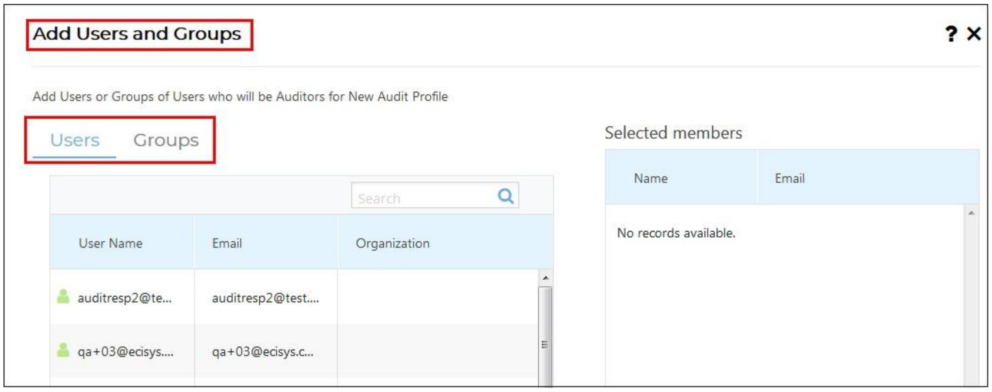
After adding Audit Managers, you are moved to the next step to add **Audit Responders**. Refer to the screenshot below:



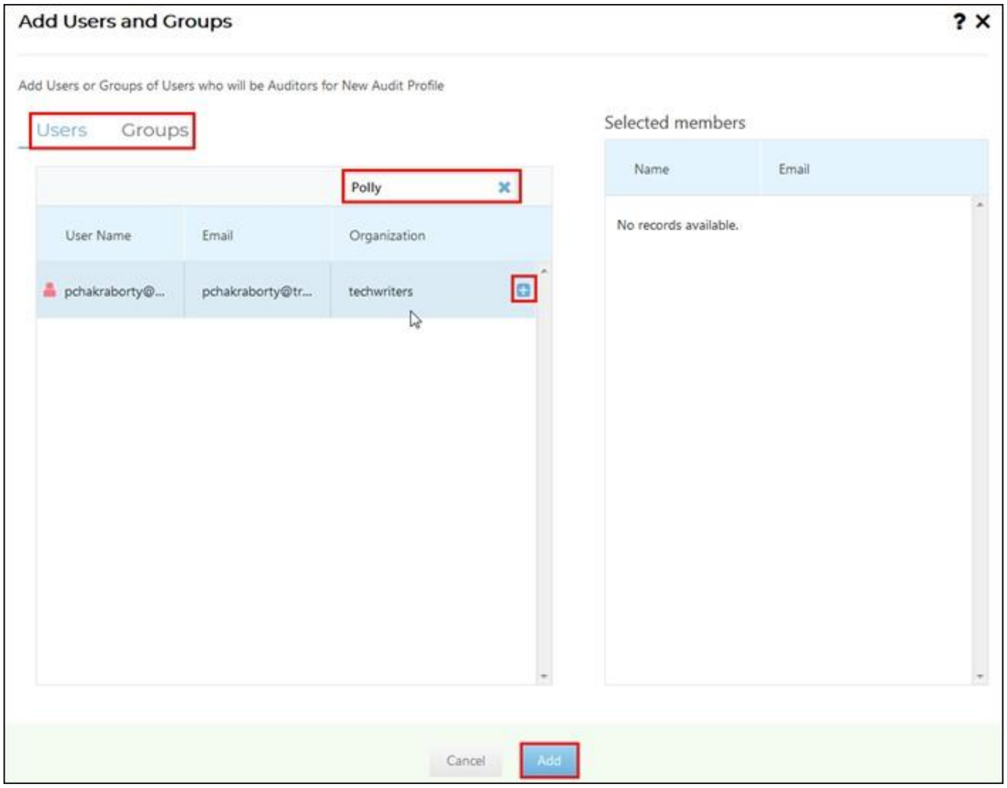
Follow the steps below to add audit responders to the current audit profile:

1. Click **+Add**  from the menu bar of the window. The **Add Users and Groups** window appears.

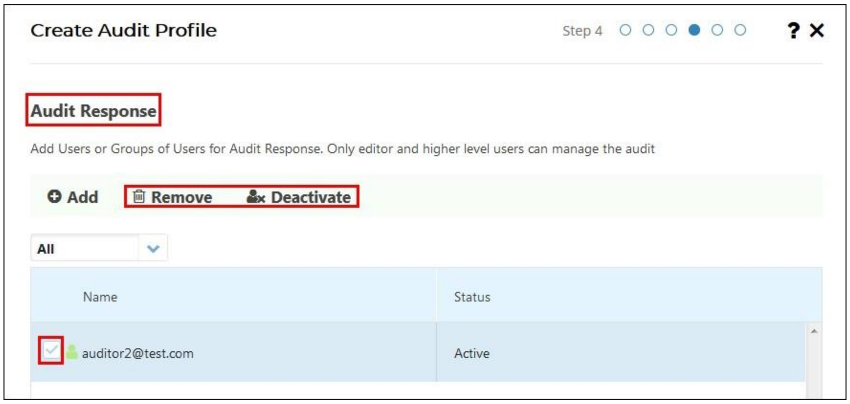
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:



3. Hover the mouse over the required user/group and click **+** icon that appears to the right of the selected user/group or double click the user/group to add them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to the audit.
4. You can also search for the user/group by entering the name in the Search box above the grid and then clicking the **Magnifying icon** to the right. Refer to the screenshot below:



5. Click **Add** from the bottom of the window.
6. You are taken back to the **Audit Responders** window and the selected members appear in the grid.
7. Select the appropriate users/groups from the grid, click **Next** at the bottom of the window.
8. You can also **Remove** auditors by clicking Add button or **Deactivate** them by clicking Deactivate button from the menu bar. Refer to the screenshot below:



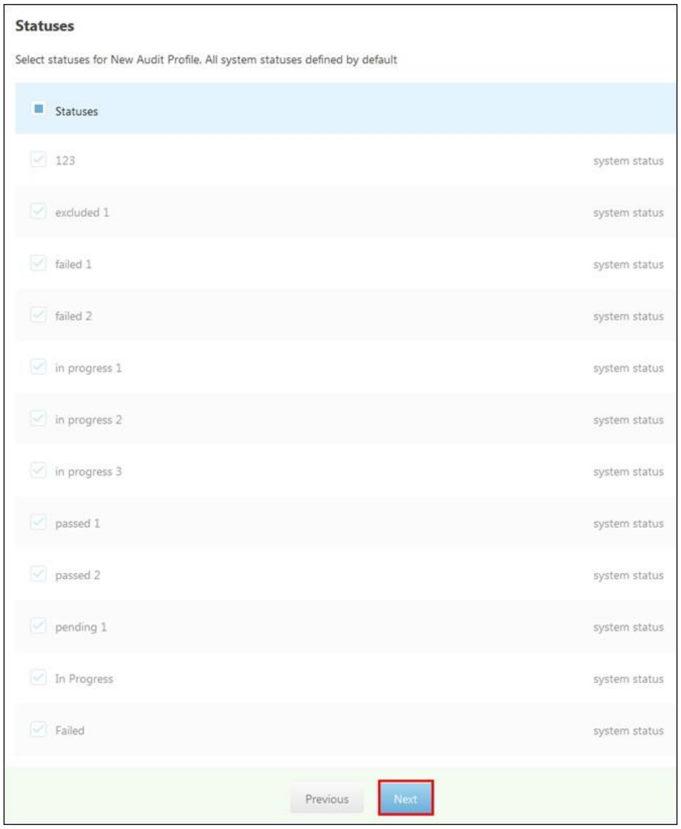
Note:

- *The **Remove** and **Deactivate** buttons enable only when you select the auditor from the grid.*
- *The **Deactivate** button toggle to **Activate** when no auditor is selected from the grid.*
- *Only **Editors** and **higher-level** users can be allotted the **Audit Managers** and **Audit Responders** role. A user cannot be allotted both the Auditor and Audit Responder role for the same Audit profile.*

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Statuses** ***(page 367)***.

Creating an Audit Profile - Adding Statuses

After adding Audit Responders, you are moved to the next step to add **Audit Statuses**. Refer to the screenshot below:

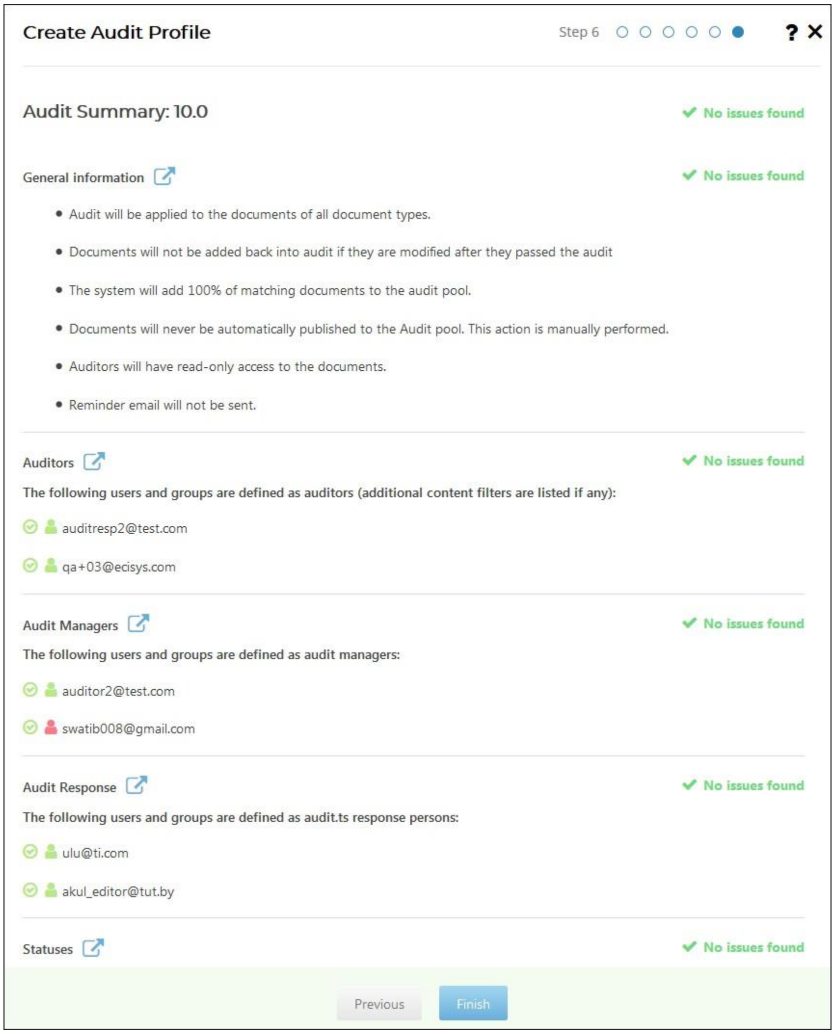


To add the statuses:

1. Select the required audit statuses from the **Statuses** window.
2. Click **Next**. You are taken to the next step of the audit profile which displays the **Audit Summary** *(page 368)*.

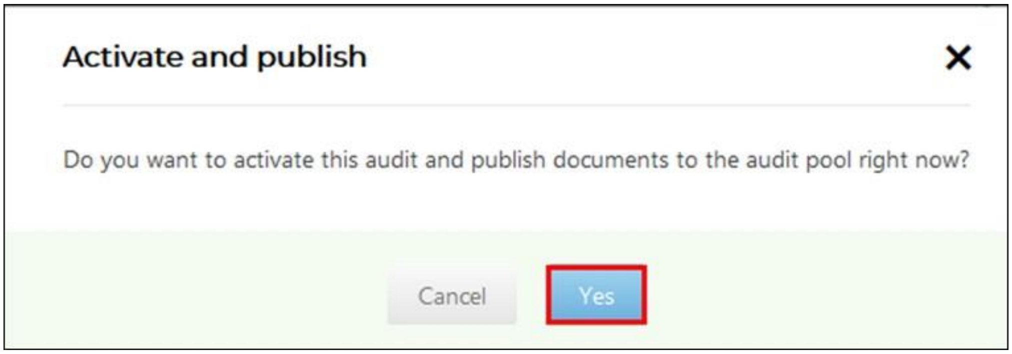
Creating an Audit Profile - Viewing Summary

After adding Audit Statuses, you are moved to the next step to view **Audit Summary**. Refer to the screenshot below:


Create Audit Profile
Step 6
Audit Summary: 10.0
No issues found
General information
No issues found
Audit will be applied to the documents of all document types.
Documents will not be added back into audit if they are modified after they passed the audit
The system will add 100% of matching documents to the audit pool.
Documents will never be automatically published to the Audit pool. This action is manually performed.
Auditors will have read-only access to the documents.
Reminder email will not be sent.
Auditors
No issues found
The following users and groups are defined as auditors (additional content filters are listed if any):
auditresp2@test.com
qa+03@ecisys.com
Audit Managers
No issues found
The following users and groups are defined as audit managers:
auditor2@test.com
swatib008@gmail.com
Audit Response
No issues found
The following users and groups are defined as audit.ts response persons:
ulu@ti.com
akul_editor@tut.by
Statuses
No issues found
Previous
Finish

The **Audit Summary** warns for any issues found in the Audit Profile. If Issues are cited:

1. Follow the directions in the fields showing explanations, and click the arrow next to the field to navigate to the page of the building of the audit profile where the issue has been cited.
2. Correct the details that have led to the issue.
3. Click **Go Back to Summary Page** and then click **Finish**. If you are sure the audit profile has been set up correctly, click **Yes** to activate the audit. Refer to the screenshot below:



4. The newly activated audit appears on the display list.

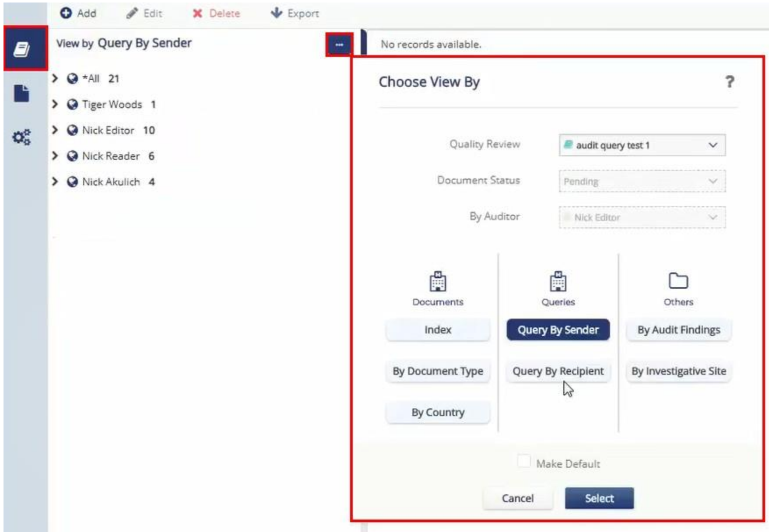
Performing Audits

If you are assigned the Auditor or Audit Manager action in your trial room, the audit feature is available to you when you click the **Quality Review** module in the toggling menu bar.

The Quality Review module has the following views:

- **Audit**: This allows you to perform audits
- **Documents**: This allows you to assign documents for audits
- **Settings**: This allows you to configure settings for Quality Review Follow the steps below to perform audits:

1. As a user with Auditor duties, log in to a room and click the **Quality Review** icon from the Main Navigation. The user can access **Audits**, **Audit Documents**, and **Audit Settings** through the panel on the left.
2. Click the **Audit** view from the left panel. The Audit view opens.
3. Click **three dots** from the left pane. The **Choose View By** popup appears as shown in the screenshot below:

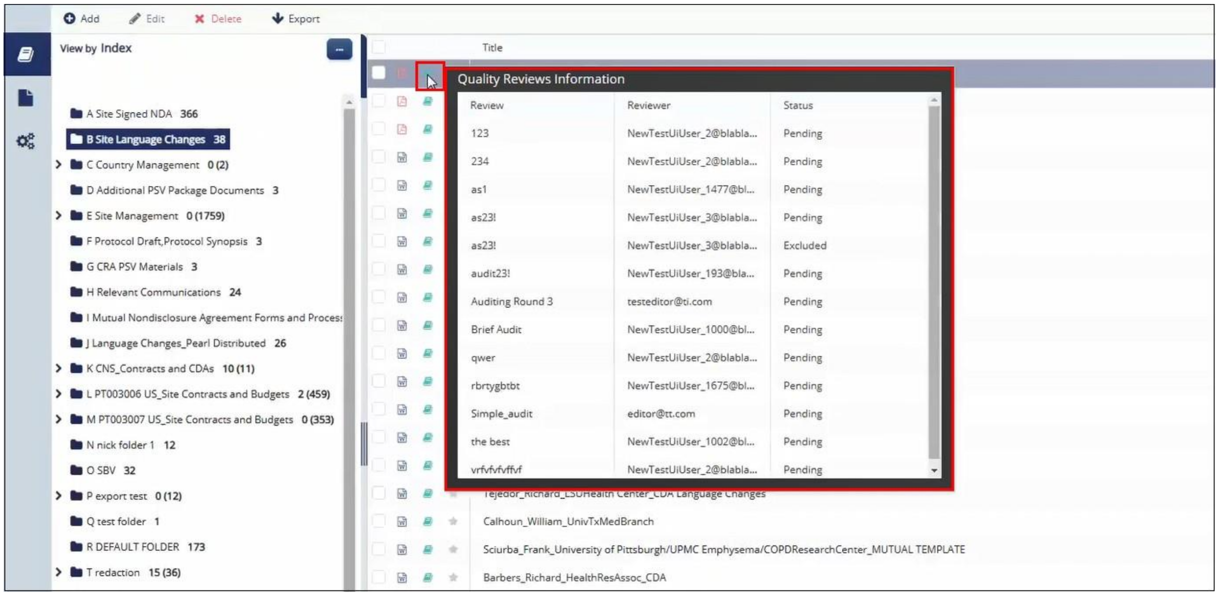


4. Click the **Quality Review** dropdown to select an active audit from the list.
5. The user can also choose to view the available audit documents *By Document Type, By Country, and By Investigative Site, Audit Findings, Query By Sender, and Query By Recipient*. Select views to be displayed.
6. The corresponding folders display based on the selection made by the user. Drill down and select the available folders.

   Available documents will be displayed in the grid.

<u>The Auditor has another means to filter the audit documents.</u>

1. Once the Audit is chosen, click the **Document Status** dropdown.
2. Select **Pending** from the list.
3. Select the auditor from the **By Auditor** dropdown.
4. Click the **Select** button. Index folder containing documents **Pending Audit** populate in the Index View. Refer to the screenshot below:
5. Open folders to locate documents published and assigned for audit.
6. Notice the **Quality Review Information** icon next to the document icon in the document grid.
7. Click the icon to open the Audit Panel in the Metadata Panel. Also, notice that the **Quality Review Information popup** displaying the audit status of the selected document. Refer to the screenshot below:



8. Open the document in the viewing panel.
9. Examine the document and its metadata to determine if it meets the established audit criteria.
10. From the **Metadata panel** to the right, click the dropdown arrow at the right end of the **Status** field. The status options appear.
11. Click the appropriate **Status**.

    If the document contains **Protected Health Information** (PHI) and you want to delete and fail the document attachment for audit, tick the **Contains PHI?** checkbox.

    Note: *To enable the Contains PHI? field, you will need to enable the feature when setting up the Audit under* *Document Audit Settings (page 347)*

    On ticking this, the document automatically acquires a **failed** status and displays a warning regarding the removal of the attachment from the document.

    Click **Remove file** to proceed. The system deletes the attachment in the backend and displays the **Refresh** icon next to the document in the grid.

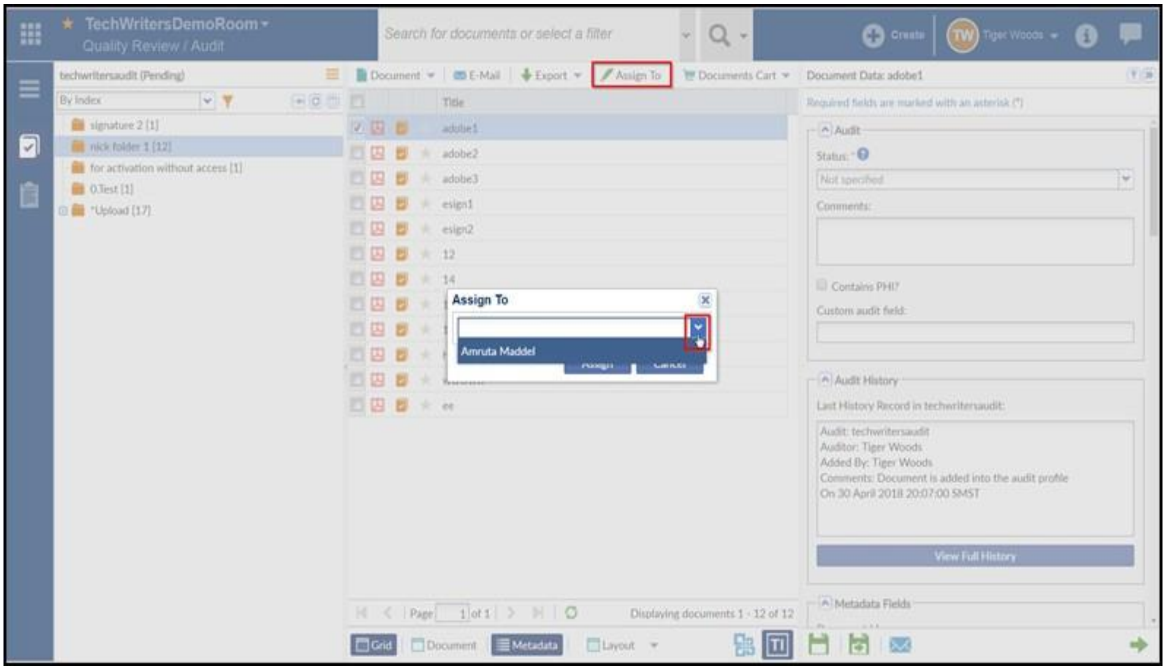
    On clicking the **Refresh** icon, the document disappears from the grid and moves to the **Audited** folder.
12. Insert comments as appropriate.
13. Click the **Save** button, or the **Save and select next button** in the lower toolbar of the window.

Note: *Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your Audit Criteria*

14. To view audited documents, filter the documents by Audited from the panel on the left.
15. The audited documents appear in the grid with their respective statuses. Documents failed due to the content of PHI appear in the grid without the attachment and acquire a failed status.

Reassigning documents for audit to another auditor

As an Administrator or Audit Manager, you can choose to assign a document to another auditor for audit by selecting the documents from the document grid and clicking the **Assign To** icon from the top ribbon bar. Refer to the screenshot below:



Here, you can reassign the auditors in either of the following ways by:

1. Clicking the **Automatically reassign randomly between existing auditors checkbox** from the **Assign to dialog** box if you wish to assign documents randomly to existing auditors, OR
2. Unchecking the **Automatically reassign randomly between existing auditors checkbox** and selecting the auditors by clicking in the textbox and then assigning auditors.

Exporting Audits

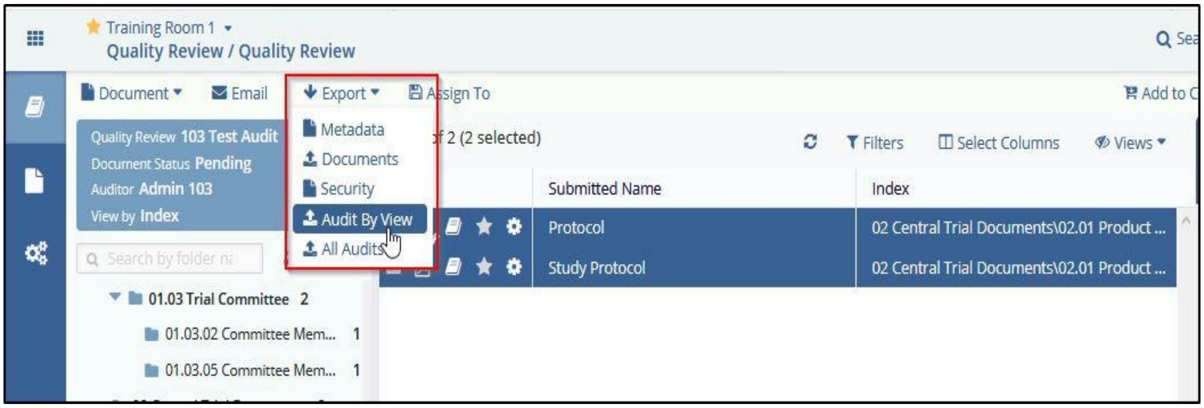
An Auditor or Audit Manager can export a report of the following directly related to the documents assigned to any particular audit:

1. Metadata
2. Documents
3. Security
4. Audit By View
5. All Audits

To export an audit report:

1. From the **Quality Review** module, click **Audit** from the left menu bar.
2. Select the audit on which you would like to run the audit report from the list of active audits.

3. Select the documents from the list and click **Export** on the top ribbon bar.



4. From the Export Dropdown, click the required option to generate an audit report.
5. Click the **Export** button. A **Background Jobs** window opens with the initial export results.
6. As instructed on the screen, click to get the export results. A zipped file downloads to your computer.
7. Follow the on-screen instructions to open the XLSX file.

Each option in the Export dropdown is discussed as below:

Metadata

This is the same as discussed in **Exporting Metadata** in chapter **Exporting Metadata** ***(page 275)***.

Documents

This is the same as discussed in **Exporting Documents** in chapter **Exporting Documents** ***(page 277)***.

Security

This is the same as discussed in **Exporting Security** in chapter **Exporting Security** *(page 278)*.

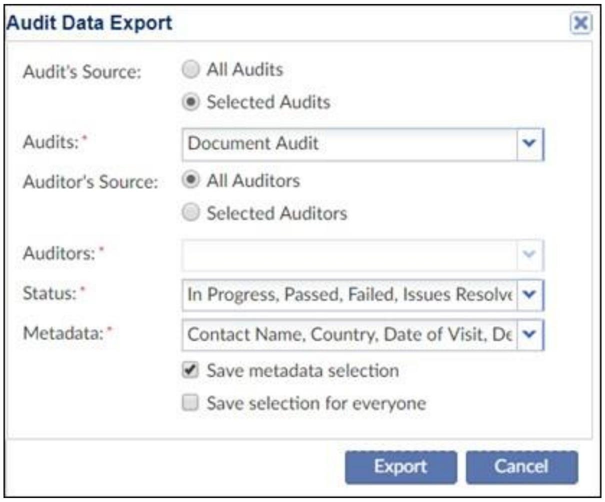
Audit by View

Select **Audit by View** from the Export dropdown menu. The **Audit Data Export** window opens.

Follow the on-screen instructions to generate the audit report.

All Audits

Select **All Audits** from the dropdown menu. The **Audit Data Export** window opens.

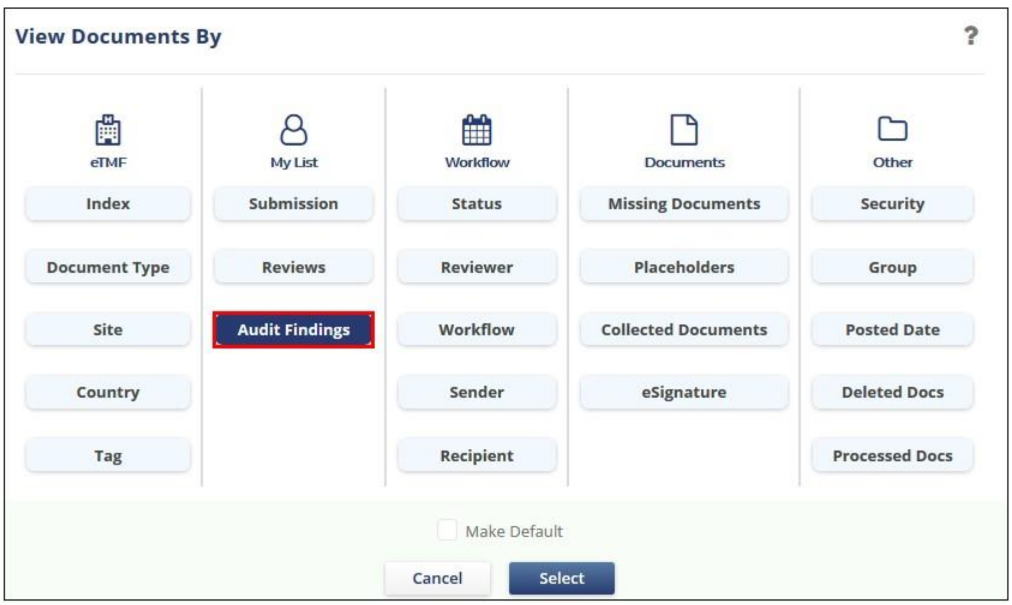


Follow the on-screen instructions to generate the audit report.

Performing Audit Response

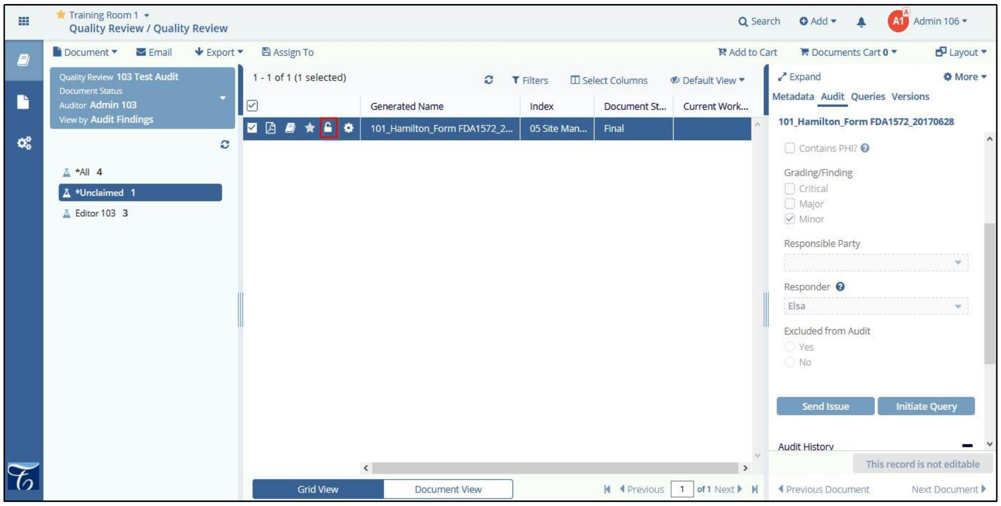
To perform an audit response, you must be logged in the room as an Audit Responder.

1. Navigate to the **eTMF/Documents** module or the **Quality Review/ Audit module**.
2. If you are in the eTMF Documents module, select **Documents** from the menu icons at the top of the screen.
3. From either of the modules, select **Audit Findings** view.

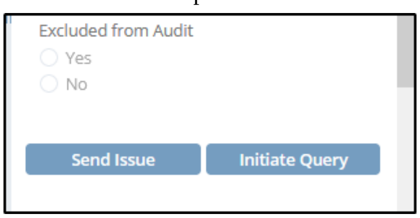


The active audits to which you are assigned that have audits with findings populate the Index panel.

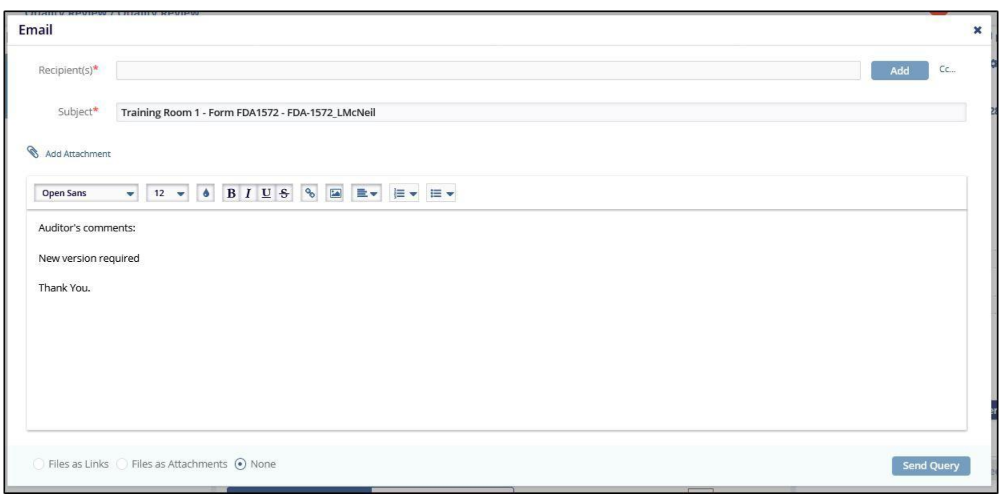
4. Click the folder for one of the audits. The documents with audit findings populate the document grid. Documents in the list that are available for **Audit Response** show a padlock icon that is unlocked.
5. Select the document by clicking the checkbox.
6. Open the metadata panel for the document by clicking the **Metadata** button at the bottom of the document grid.
7. At the bottom of the Metadata panel, click the **Audit** button.



8. From the available options, click **Claim document for Audit Correction**.
9. Click **Document** at the bottom of the document grid to open the contents of the document for inspection.
10. From the Audit History panel, click **View Full History** button to view the comments included by the Auditor.
11. Appropriate actions on the part of an Audit Responder are based on the nature of the failure of the audit.
12. If the cause of the document's audit failure can be remedied by the Audit Responder, that action can be carried out.
13. In such cases, the Audit Responder then goes to the **Audit** button at the bottom of the metadata panel again and selects **Mark document as corrected**.
14. If the cause of the document's audit failure cannot be remedied by the Audit Responder, the Audit Responder clicks **Email** from the top ribbon bar or **Initiate Query** from the bottom of the Metadata panel.



15. The **Email** popup window opens. Click **Yes** to the question **Are you sending a query?**
16. Click **To** and select the appropriate party or parties from the room's users to notify about the discrepancy discovered in the audit.



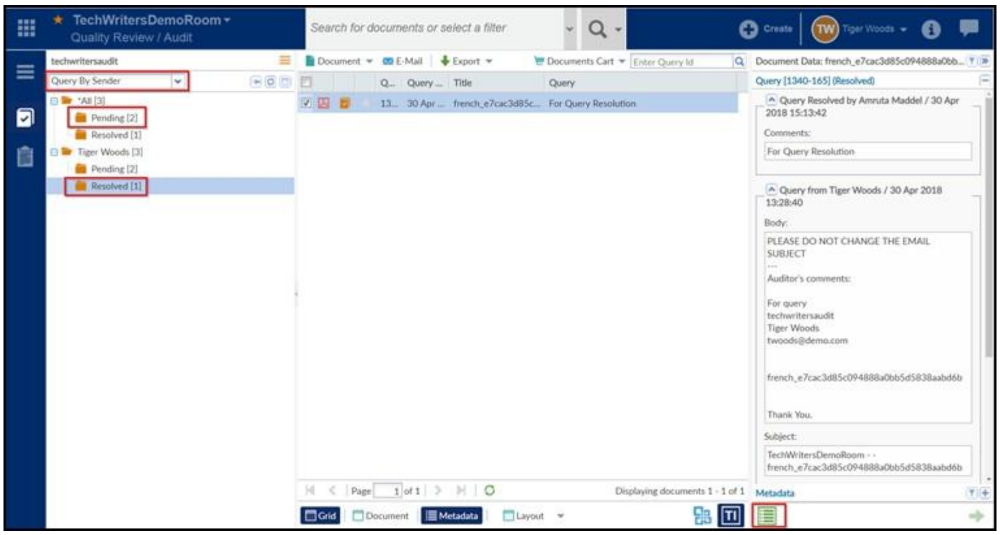
17. Include something in the Subject line and enter the text of message to alert the recipients as to what action they need to take.

18. Select **Files as Links** at the bottom of the Email window to send the document along with the email message. Documents can also be sent as attachments.

Click **Send**.

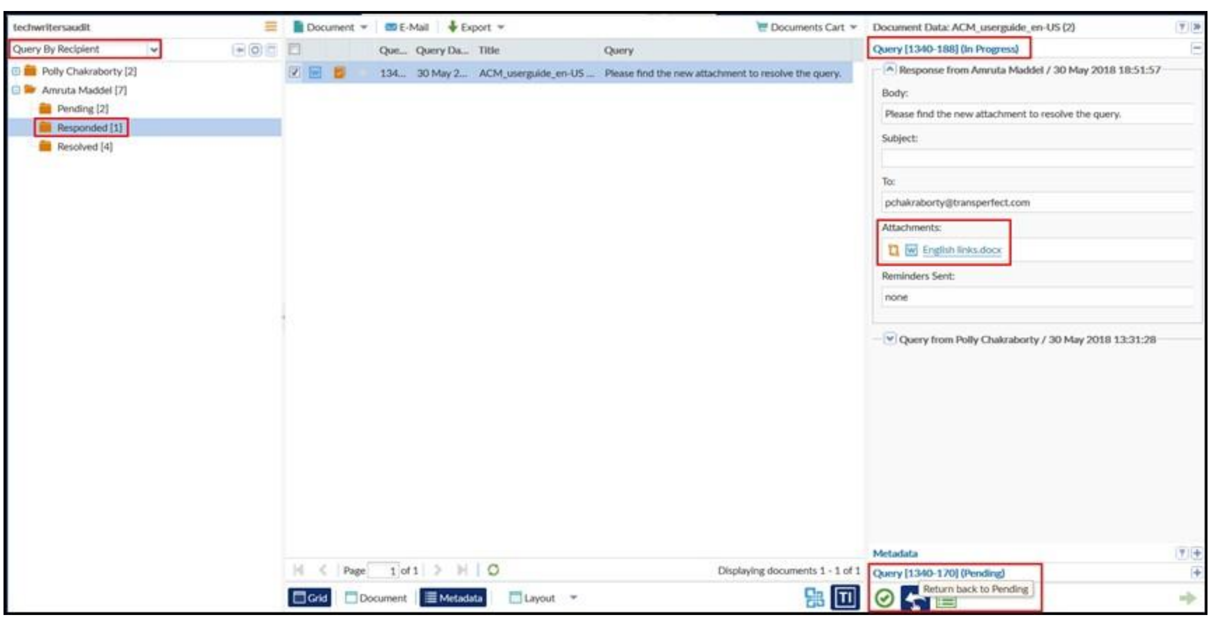
The selected users will receive the email message regarding the Query raised.

19. Click **Audit** sub-module from the left menu bar. The queries raised during audit can be viewed from the **Query By Sender** current viewing the left index pane if you have sent queries to be resolved during audit. Refer to the screenshot below:



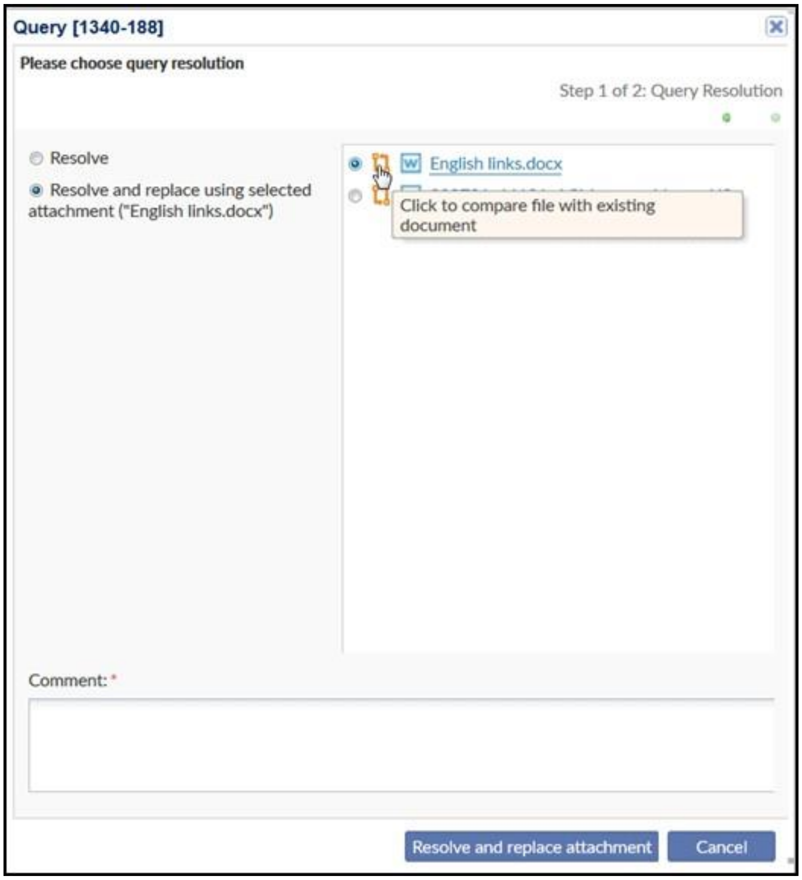
Resolving Queries Raised during Audit

The user who receives the email responds back with an attachment to resolve the query. You can view the responded query in the **Responded** folder of **Query By Recipient** view under the selected audit. Refer to the screenshot below:



To resolve queries raised during audit:

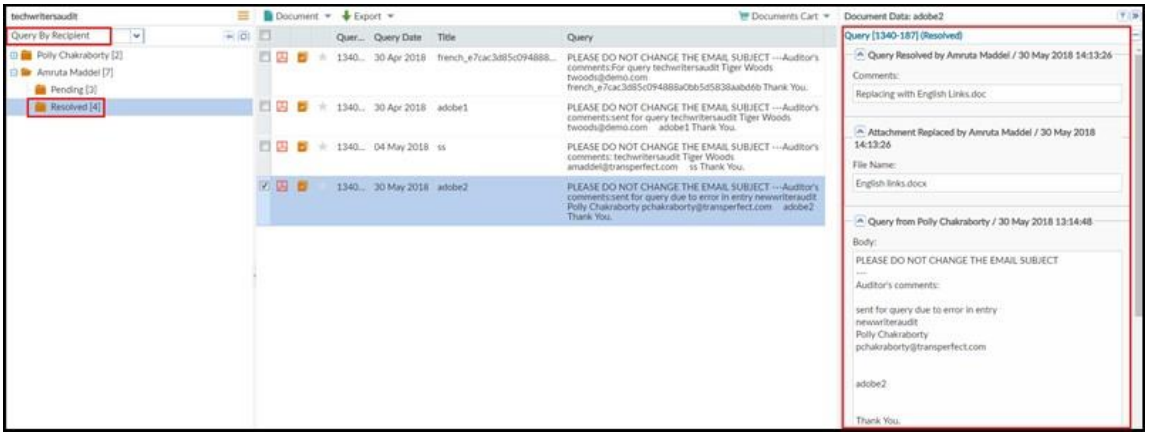
1. Navigate to the **Query By Recipient** view.
2. Select a query from the grid on the right.
3. Click the **Metadata** button from the bottom of the grid. This will open the Document Data Panel.
4. Click the **Resolve** button from the bottom of the **Document Data Panel**. If the resolution is not acceptable, you can click the **Return to Pending**button from the bottom of the metadata panel. The document returns back to the **Pending** folder and can be resent for query again.
5. This will open the **Query** window to comment and resolve the query.
6. Enter the **comments** and click the **Resolve** button or **Resolve and replace attachment** button on the window as per your selection. Refer to the screenshot below:



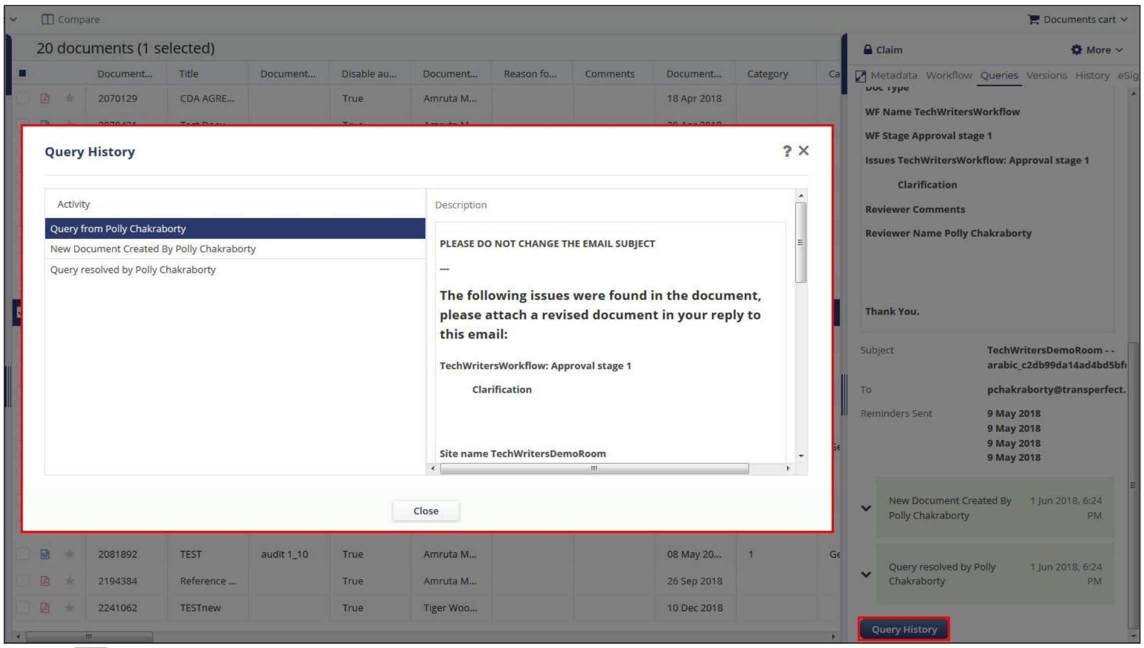
   a. **Resolve**: This option will just mark the query as resolved without any additional actions.
   b. **Resolve and replace using selected attachment**: This option allows you to replace the existing attachment with the one which is received as a part of the query response. Select the document from the right pane and click the **Compare** icon to compare the attachment received with the document in audit.

      If you are satisfied with the response received, enter your comments and click Resolve and replace attachment button.

7. This will resolve the query and the query will now move automatically to the **Resolved** folder under the name of the auditor.
8. Click the **Resolved** folder from the **Index Pane** to view the resolved query. Refer to the screenshot below:



9. You can click the Query History icon at the bottom of the Document Data Pane for a query to view the Query History in a window that pops up.

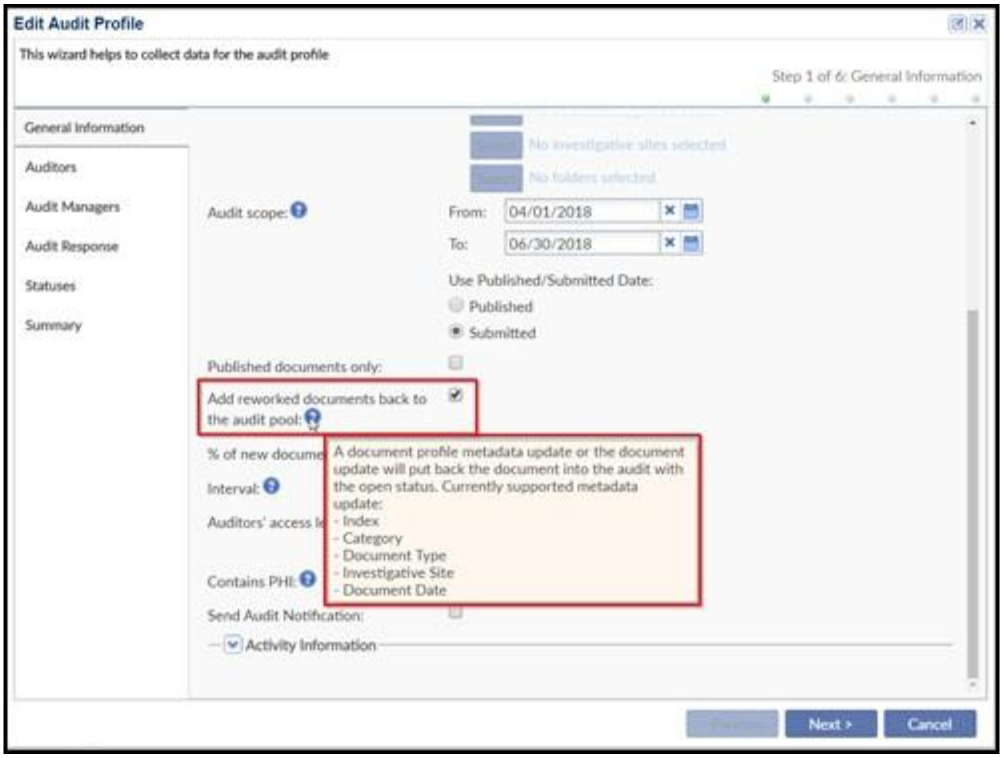


Note: *To know how to view a deleted queried document, proceed to section Deleted Queried Documents.*

Adding modified document back to Audit Profile

To allow for a modified document to be added back to the Audit Profile, follow the steps as below:

1. Navigate to **Username dropdown -> Settings -> Audit -> Quality Review Settings.**
2. Select the Audit Profile as required and click **Edit** from the top ribbon bar.
3. Select the checkbox next to **Add reworked documents back to the audit pool.** Refer to the screenshot below:



4. Click **Next** and complete the remaining steps to modify the Audit Profile.

Chapter 17. Sites, Required Documents, Countries and Contacts

In this section, we discuss the Sites, Required Documents that are required for site activation, Country Documents, and Contacts.

Sites

You can access the Sites module by clicking Sites icon on the left menu bar in the eTMF/Documents module. The Sites module is used for site management purposes and allows the administrator to track the progress of the sites. It gives detailed information on all investigation sites available in a room **By Status**, **By CRA**, **By Country**.

You can perform various other activities associated with a site, such as:

1. Retrieving Site Details
2. Adding, Editing, and Deleting sites
3. Importing, and Exporting Sites
4. Mass Coding metadata for sites
5. Managing Security.

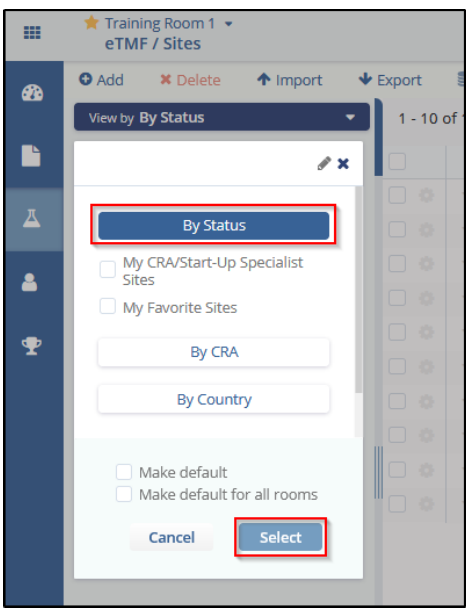
Each of the above is discussed in the separate topics and can be accessed from the left pane of this help.

Site Views

This section discusses about the various views of the Sites module.

By Status

Select **By Status** from the dropdown in the Index Pane of Sites Dashboard. Refer to the screenshot below:
This will populate the data of all the sites available in the room based on their progress report in the right pane of the

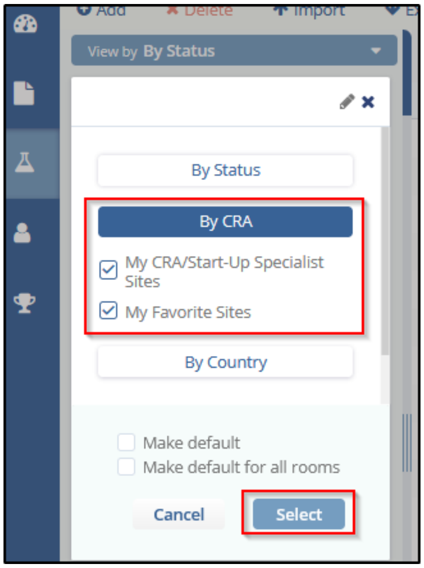


dashboard.

By CRA

Select **By CRA** from the dropdown in the Index Pane of Sites Dashboard. Refer to the screenshot below:

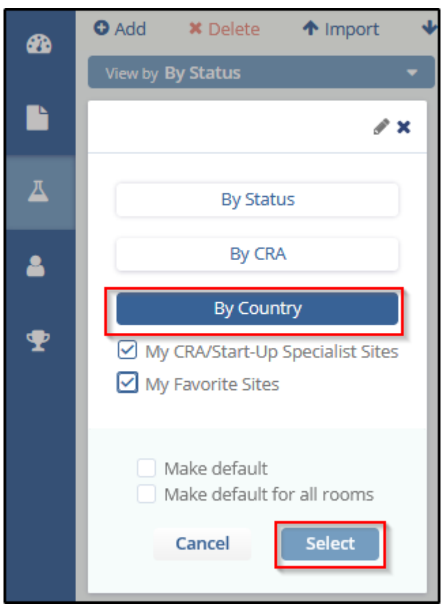
This will populate the Clinical Research Associate (CRA) for the available sites in the Index Pane on the left. Click the name



of a CRA to populate the site details associated with that particular CRA in the right pane.

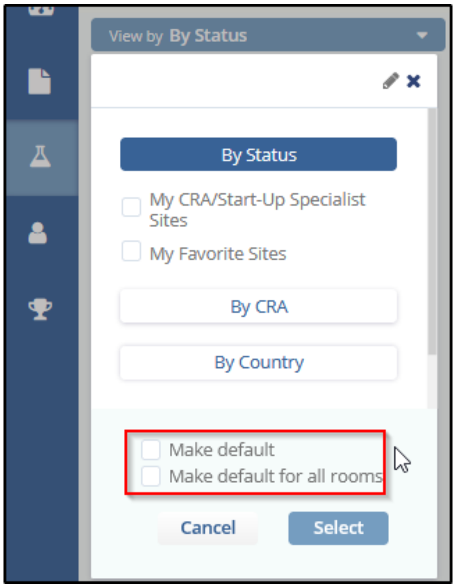
By Country

Select **By Country** from the dropdown in the Index Pane of Sites Dashboard. This will populate the countries where the studies are being conducted in the Index Pane on the left. Click the name of a country to populate the site details associated with that particular country in the right pane. Refer to the screenshot below.



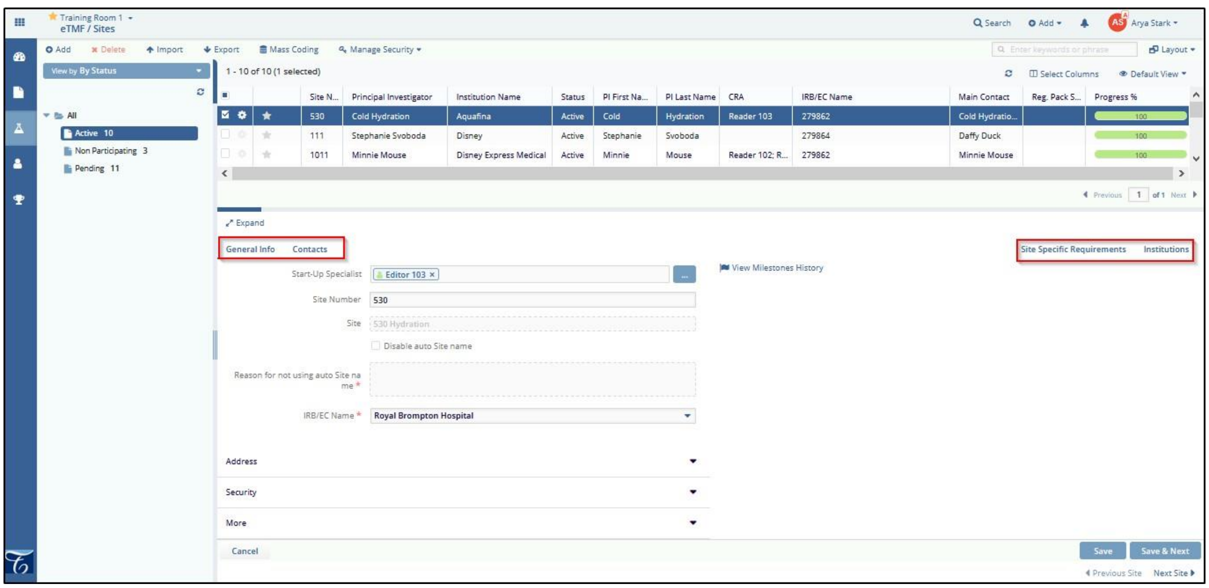
Make a view default

To make any site view default and default for all rooms check one of the two options available in the index dropdown. Refer to the screenshot below.



Site Profile

Select a site from the grid and the Site Profile is displayed at the bottom of the grid. This will allow you to fill all the metadata related to the selected sites. Refer to the screenshot below:



The Site Profile window provides the following:

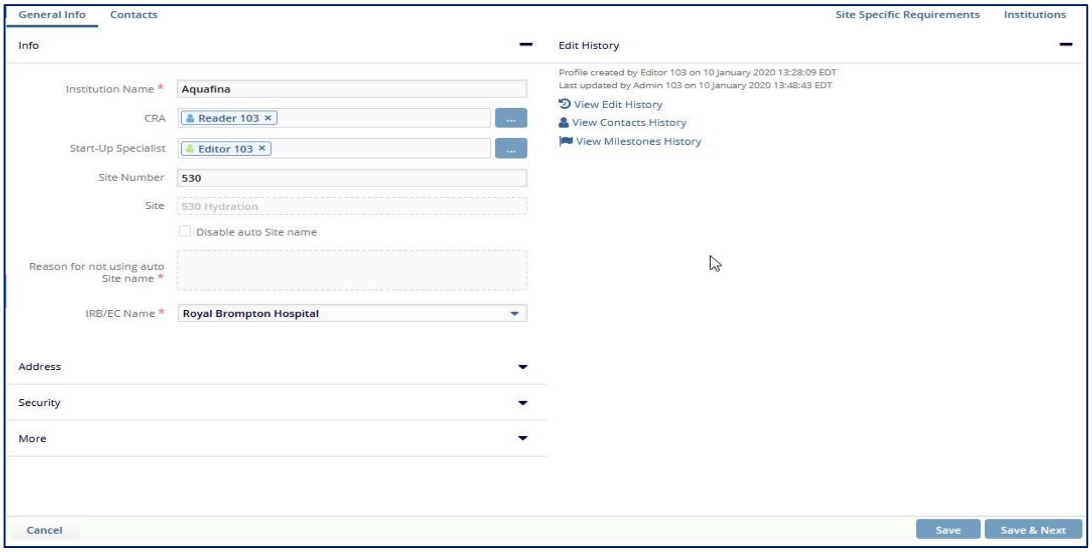
1. General Info tab
2. Contacts tab
3. Specific Requirements tab
4. Institutions

Each of the tabs is discussed in the separate topics.

Site Profile - General Info

This tab displays the general information of the site.

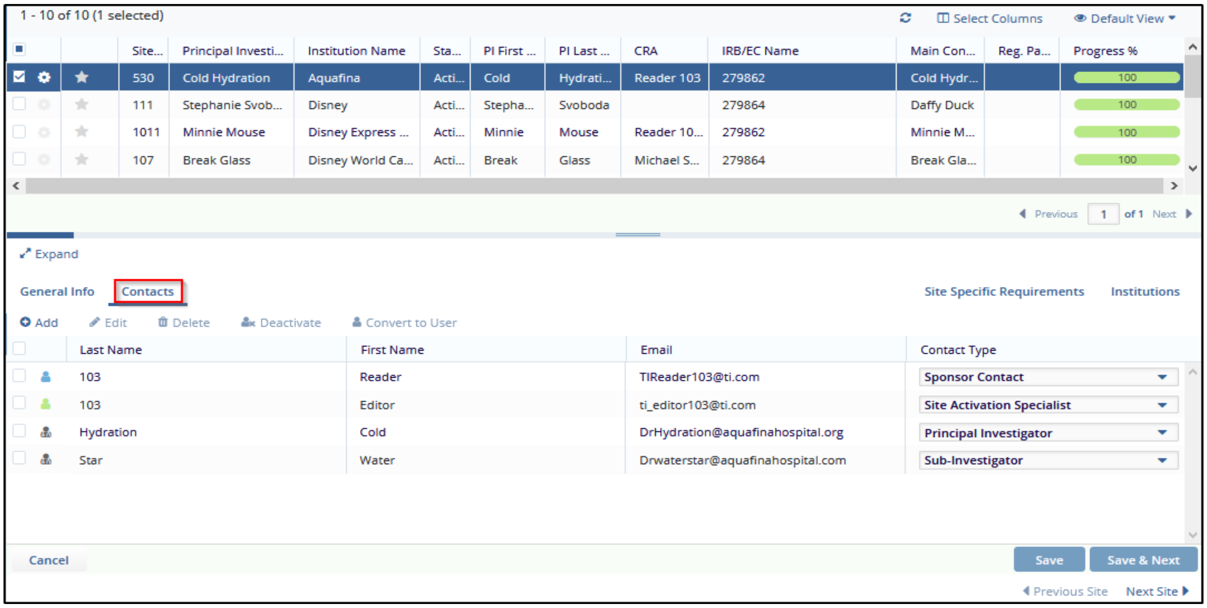
After selecting a site, click the General Info tab to edit the general details of the site. Click the arrow next to the required section of the General Info to update. Refer to the screenshot below:



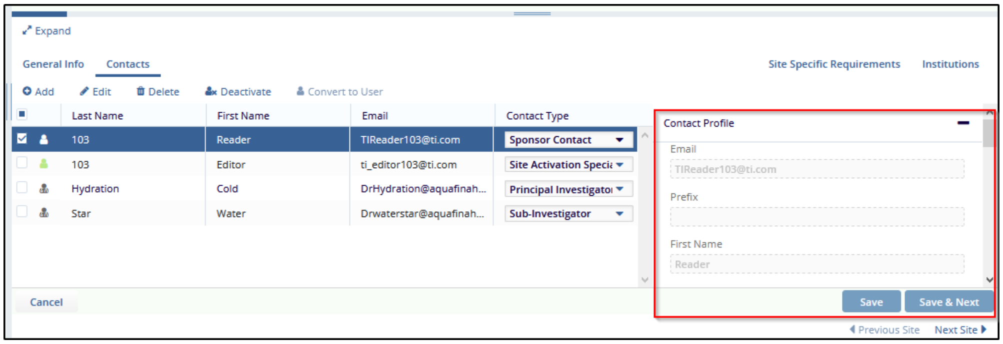
When you click the arrow, the section fields get enabled and the arrow turns to - sign as shown in the screenshot below. Similarly, you can update the fields in the other sections of your choice.

Site Profile - Contacts

This section displays the list of contacts that are added to a site. From here, you can add, edit, delete, deactivate contacts and also change the contact to another level. Refer to the screenshot below:



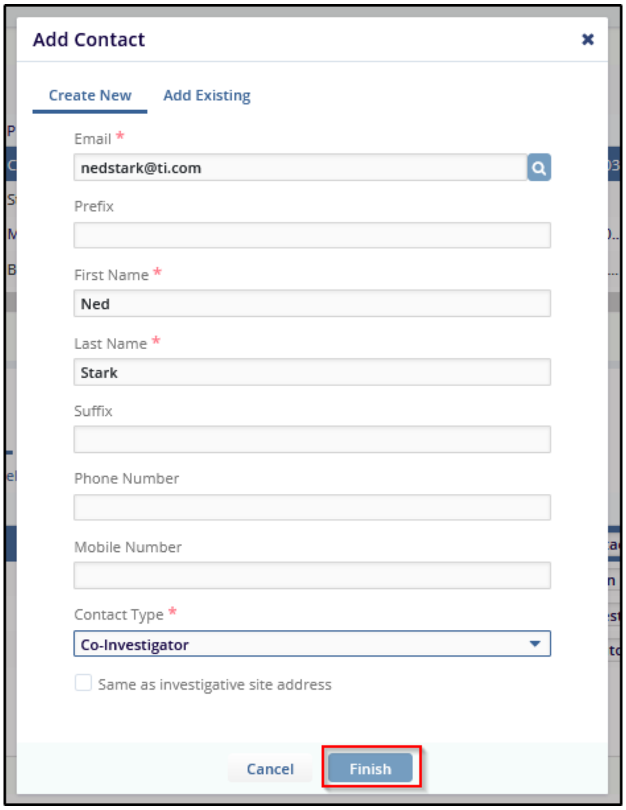
Double click the user to open the **Contact Profile** to the right of the contacts tab. This allows you to edit the contact details of the user. Once all the details are updated, click **Save** to save the changes. Refer to the screenshot below:



Adding a Contact

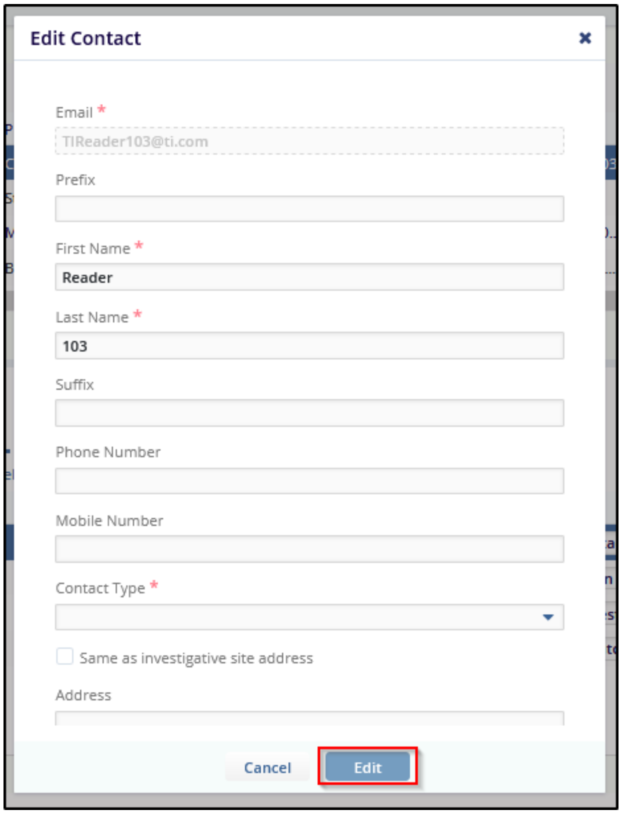
1. Click **Add** from the menu bar of the Contacts tab.
2. The **Add Contact** window opens.

3. Fill in the required details and click **Finish**. Refer to the screenshot below



Editing a Contact

Select an added contact and click Edit in the Contacts tab to edit the contact information entered as above. Refer to the screenshot below.



Deleting a Contact
Select an added contact and click **Delete** in the Contacts tab to delete a contact information.

Deactivating a Contact
Select an added contact and click **Deactivate** in the Contacts tab to deactivate the contact.

Convert to User(s)

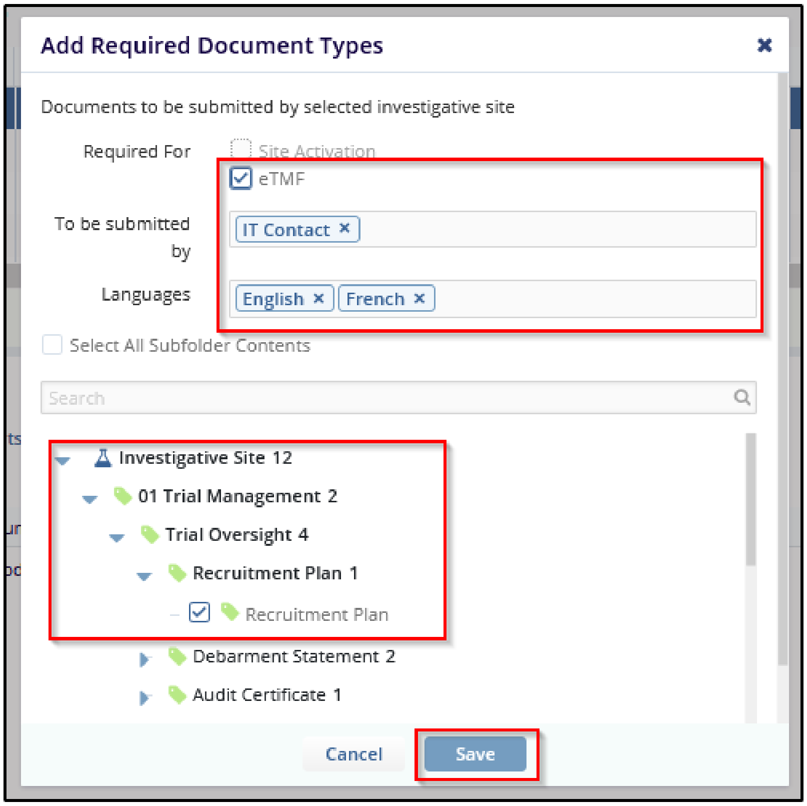
You can assign a site contact the role of editor or reader and assign actions as appropriate from the **Convert to User(s)** utility in the **Contacts** tab.

Site Profile - Site Specific Requirements

This section displays the list of all the Site Specific Required documents. From here, you can **Add** required documents to a site, **delete** the documents, **Assign Milestones** to the documents, and view the **Change Log History** of the selected documents.

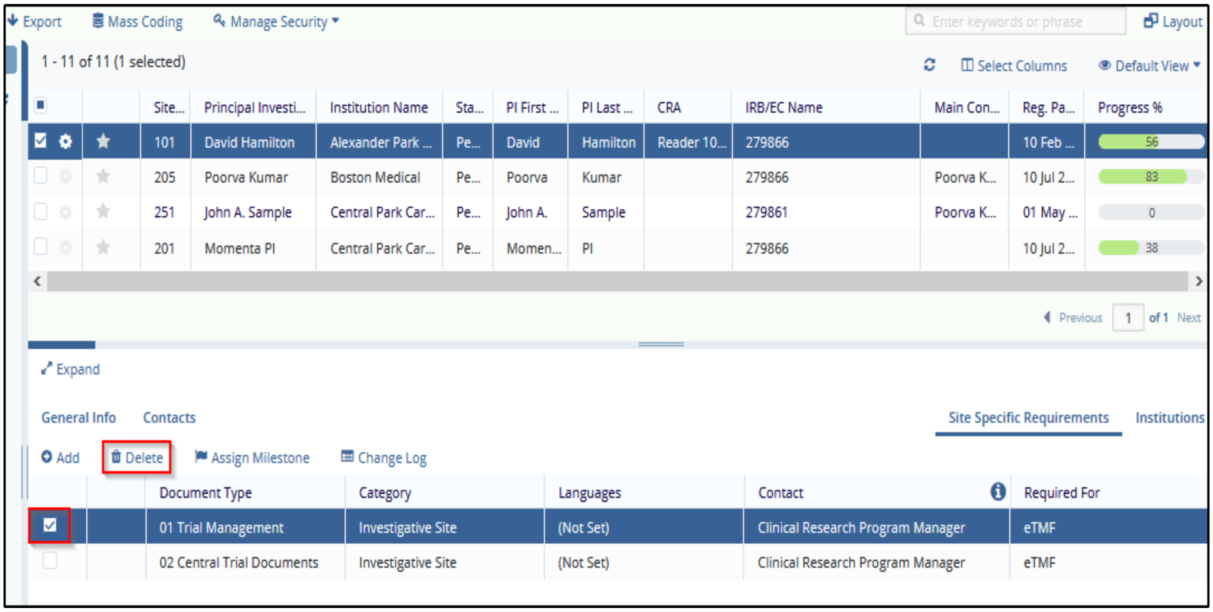
Adding Required Documents

To add required documents to a site click the add button that opens Add Required Document Types popup. Fill up all the required information and click Save button to add required documents to a site. Refer to the screenshot below:



Deleting a site-specific requirement

Delete a site-specific requirement that can be performed with the Pending and Non Participating sites only. To delete a site-specific requirement, tick the checkbox to activate the **Delete** button. Refer to the screenshot below.



Note: Site-specific requirements in the Active Sites can not be deleted.

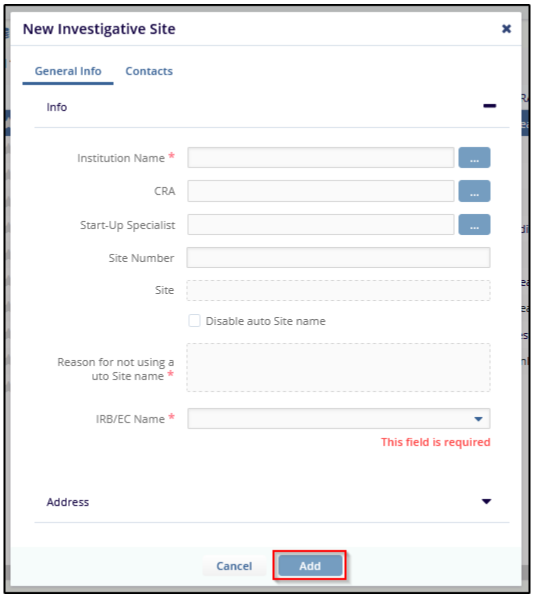
Adding , Editing and Deleting Sites

Important: *The following description is for adding Investigative Sites in an eTMF:*

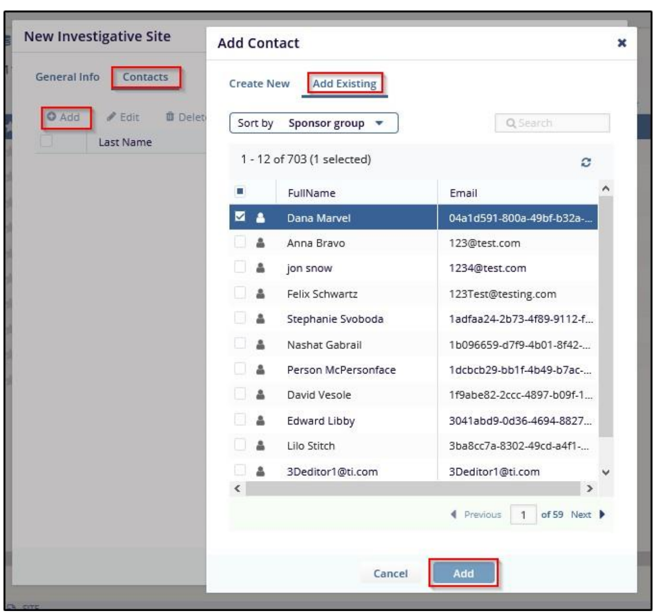
- *Sites are added to the Study Start Up module by a slightly different method. If SSU has been enabled for the study, the user first clicks the Study Start Up icon at the top, then selects the Sites tab. The rest of the process of adding Investigative Sites is the same as the process described below.*
- *Sites added from the eTMF/Sites module also appear in the Study Start-Up, if that is enabled for you***.**

Adding a Site

1. Click the **Add**  button from the top ribbon bar. The New Investigative Site window opens. Refer to the screenshot below:



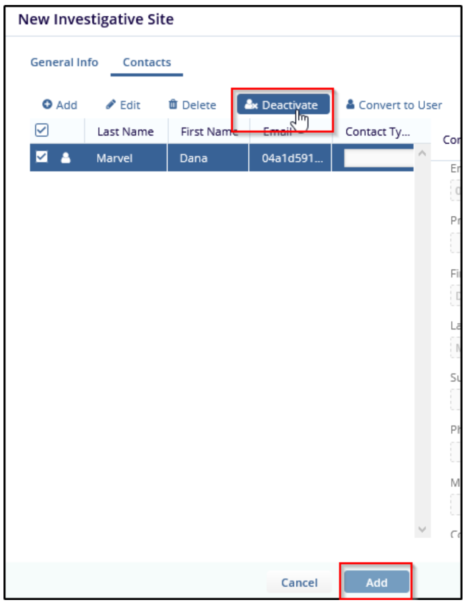
2. Either type the **Institution Name** in the available field or click the search icon to view the list of **Available Investigative Sites**. Investigative site information is stored in Trial Interactive's database. If a client has used an investigative site in a previous study, the site's information will be stored and easily accessed through this option.
3. **Create** or **Add existing** contacts from the **Contacts** panel in the window. This information will be supplied by the client and can be created under **Contact Types** in Investigative Site Settings. You can also add the Contact Type by clicking the contact type field which will then reveal the dropdown list to select your choice. Refer to the screenshot below:



To make the Sponsor Contact ID a Required field proceed to **Settings -> Form Settings -> Investigative Site Profile**. Select the **Sponsor Site ID Field title** from the list **of System Fields** and tick the checkboxes under the **Coding** and **Required** column.

> **Note:** *The Sponsor Contact ID is used by the system as the unique identifier of sites used by third parties to enable their integration with Trial Interactive. Hence, the Sponsor Contact ID will need to be a Required field so that it can be passed to Trial Interactive. Similarly, to detect duplicate entries of site contacts, the email-id field is now case-insensitive.*

4. Select an added contact and click **Edit** in the Contacts panel to edit the contact information entered above, or **Delete** to delete a contact information. You can also edit a contact by double-clicking the contact in the Contacts panel.
5. Click **Activate** or **Deactivate** to activate or deactivate a contact. This will either check or uncheck the **Active Contact** checkbox in the **Edit contact** window. Refer to the screenshot below.



6. You can assign a site contact the role of editor or reader and assign actions as appropriate from the **Convert to User(s) utility** ***(page 386)*** in the **Contacts** panel.

7. Click **Address** to reveal the fields to enter the site location details. Based on the address entered the system shall calculate the Geo Code of the site and populate it in the new field **Geo Code**.

   Click **More** to open another array of data fields. Enter the investigative site information provided by the client. Refer to the screenshot below:

> **Note:** *The Geo Code needs to be enabled from the Settings → Form Settings → Investigative Site Profile → Geo Code. This is an important field for myTI mobile app to detect site location*

8. Click **Create** at the bottom of the window.
9. Repeat this process until all investigative sites have been created for the room.

Editing a Site

Similarly, you can **Edit** a site by first selecting the site from the right pane and then clicking the **Edit** button from the top ribbon bar. You can also edit a site from the **Site Profile** window also. This is discussed under the **Site Profile.**

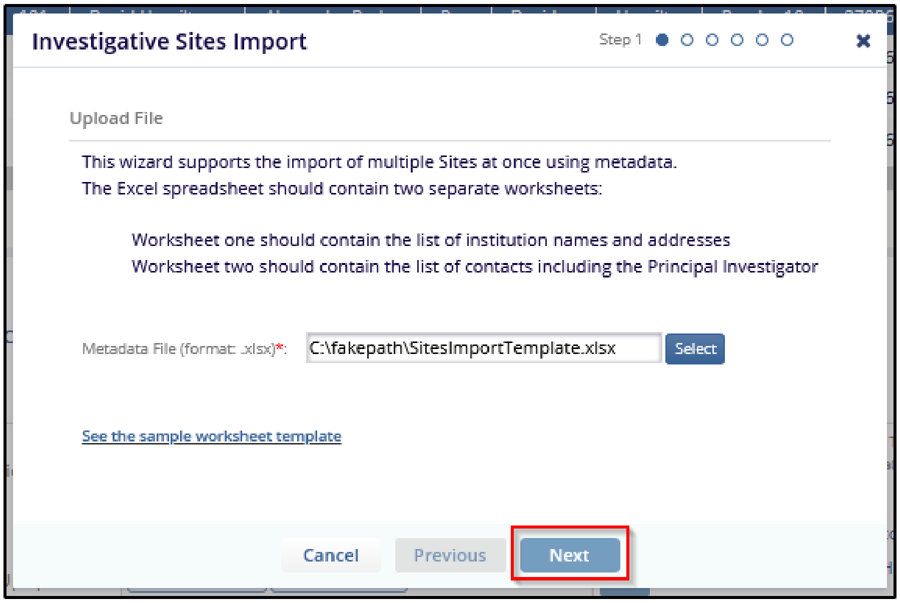
Deleting a Site

Select a site first and then click the **Delete** button from the top ribbon bar to delete a site.

Importing Sites

The metadata and contact information for an investigative site can be imported by using the **Import** icon located on the top ribbon bar. It runs the metadata import wizard where the user can upload a .xlsx spreadsheet, set up columns and metadata fields mapping, perform actual import, and observe the result.

1. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import just contacts so they will be mapped to existing investigative sites. The wizard offers a link to the sample worksheet so the user can download it and fill it with actual data. Click **Next.** Refer to the screenshot below:



2. Setup the mapping between metadata fields and uploaded file columns for Investigative Sites. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.**
3. Setup the Contacts related metadata. Click **Next**.
4. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.

5. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.
6. It is also possible to download the full report as a text file. The import operation can be aborted at any time.

Manage Security for Sites

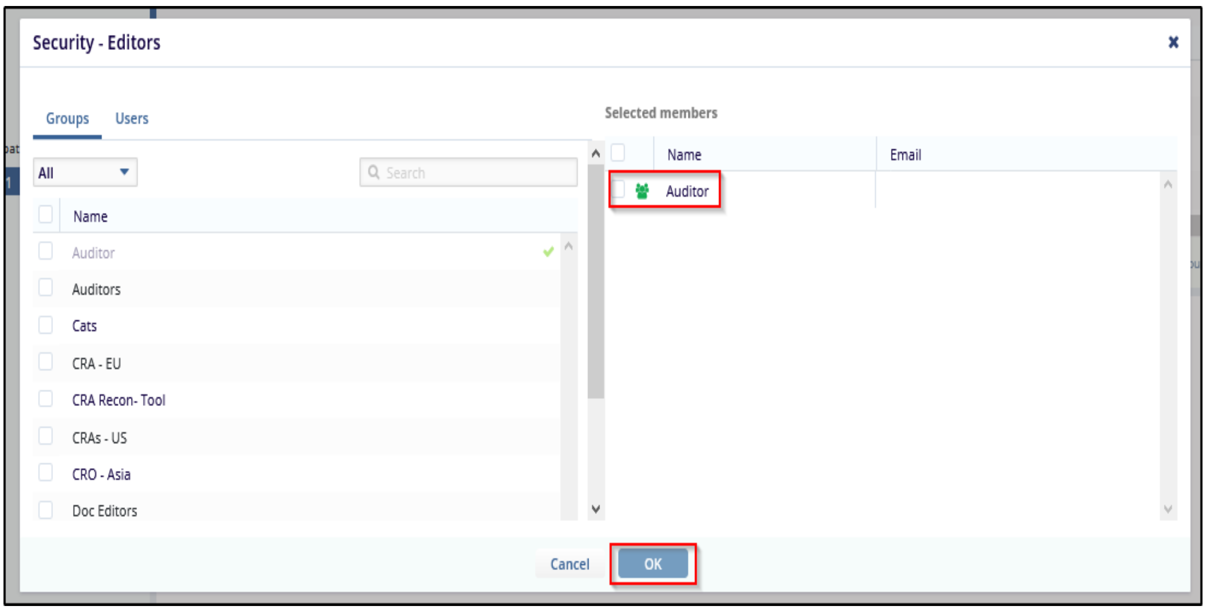
There are two site-level securities available for sites:

1. Editor
2. Reader

Administrators can use **Manage Security** to include users to any one of these groups:

1. Select the sites from the grid and click **Manage Security** dropdown from the top ribbon bar.
2. Select the type of users to add to the security groups. You can add either **Editors** or **Readers**. Refer to the screenshot below:

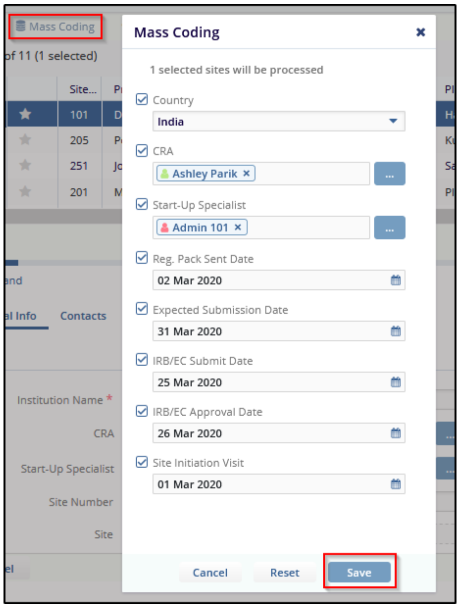
3. This will open either the **Security – Editors** or **Security – Readers** window as per your choice.
4. Select the users in the **Users** tab to add to the security group, or/and click the **Groups** tab to select a group of users to be added to the security group. Click **OK**. An example of adding editors is shown below. The readers too would be added in a similar manner.



Mass Coding for Sites

Administrators are sometimes called upon to fill in or update the metadata of a number of sites in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Select the sites to be coded in your grid.
2. Click the **Mass Coding** tool from the top ribbon bar. The **Mass Coding** window opens.
3. Fill in the details by double-clicking the fields, and click **Save** to proceed with mass update of the sites' metadata. You can select multiple CRAs and Start-Up Specialists if required. Refer to the screenshot below.

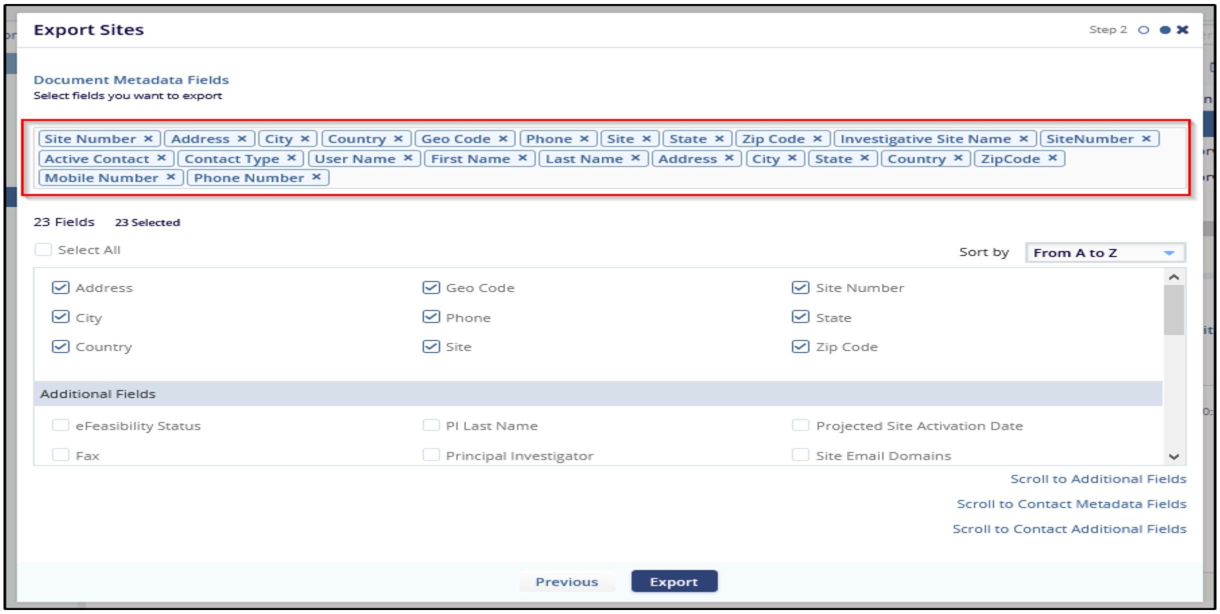


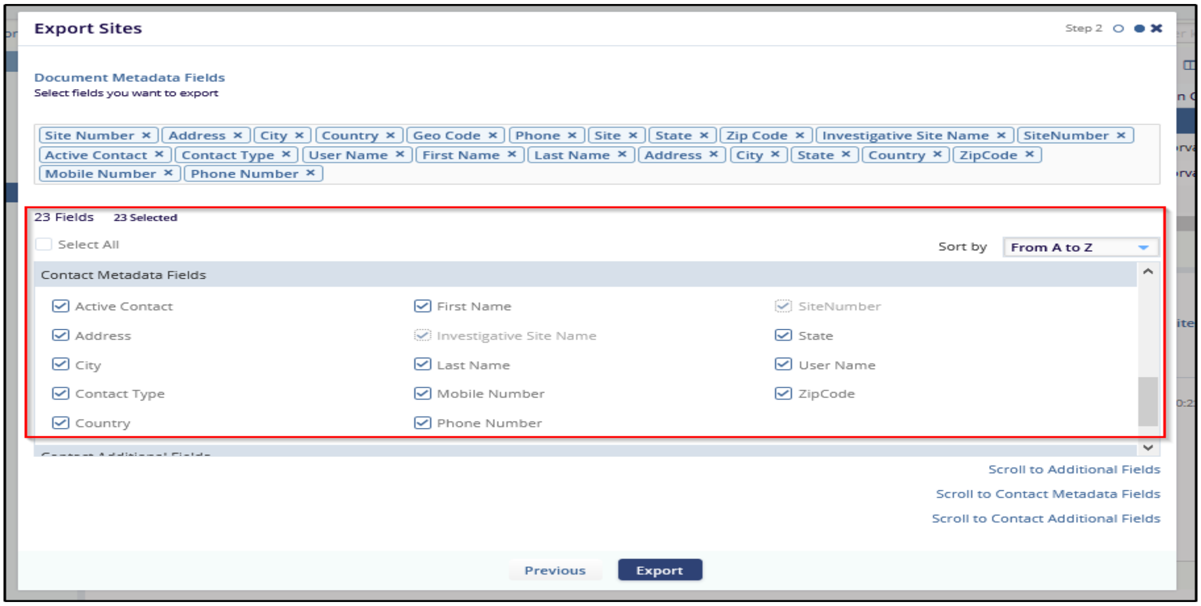
Exporting Sites

You can also export site metadata through the Export window that appears on clicking the Export icon on the ribbon. You may export sites selected from the right panel, or all the sites in the current grid or room. To export site data, it is mandatory to select the **Site Metadata Fields** as shown below:

You can export the additional fields in either alphabetical or logical order of selection.

Similarly, to export site contact data, you need to select **Contact Metadata** fields as shown below:





The export result is also populated in the **Notifications.** Click **GetJob Result** to view the excel file.

Required Documents

When creating a Site, it is mandatory that you submit all the essential and required documents for **Site Activation**. These Required Documents can be among the following depending upon the requirement of site activation:

1. Site Documents
2. Country-Specific Documents
3. IRB/EC Specific Documents

Note: *A site cannot be activated unless all the required documents are submitted during site creation.*

Required Documents Settings

With the help of Required Documents Settings, Administrators establish and edit the Required Documents for a study. Different document types may be required for all Investigative Sites involved in a study, or there may be documents that are required of investigative sites that are located in particular countries. These settings are typically made at the outset of a study, but they may be modified during the course of a study under certain circumstances.

Once Document Types are set up for a room from Document Types Management, (page 105) 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 here. Once Document Types are set up for a room from* ***Document Types Management****, you can set up the Required Documents.*

1. Navigate to **Main Navigation** -> **Settings Module**
2. Select **Required Documents** from the menus on the left.

   Refer to the screenshot below showing the various options under **Required Documents Settings**:

Required Documents can be defined for the following:

1. All Sites
2. Country-Specific
3. IRB/EC

   Each of these is discussed in the separate topics and can be viewed from the left pane of this help.

Required Documents

1. From the left section of the panel, you 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, you can:

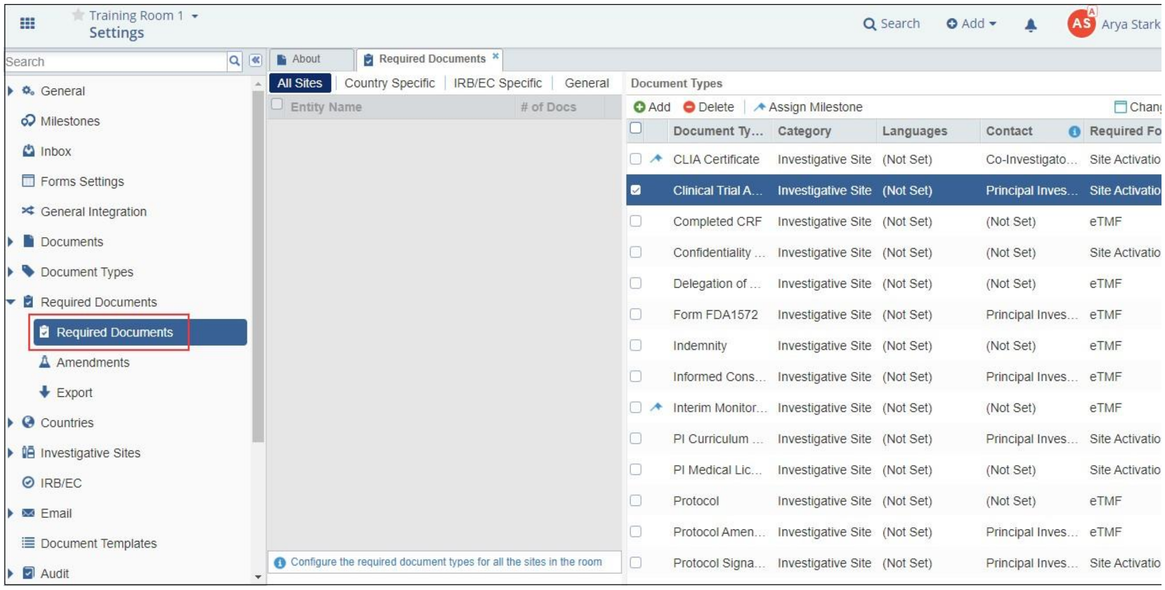
   a. **Add** Add or **Delete** Delete a Required Document to the category selected from the left pane.

   b. **Assign Milestones** Assign Milestone to selected Required Document Types.

   c. View the activity log of the selected category from the **Change Log** Change Log.

   d. Once a Required Document is added, it appears in the Document Types Grid.

Each **View Option in the Required Documents** is discussed as below:

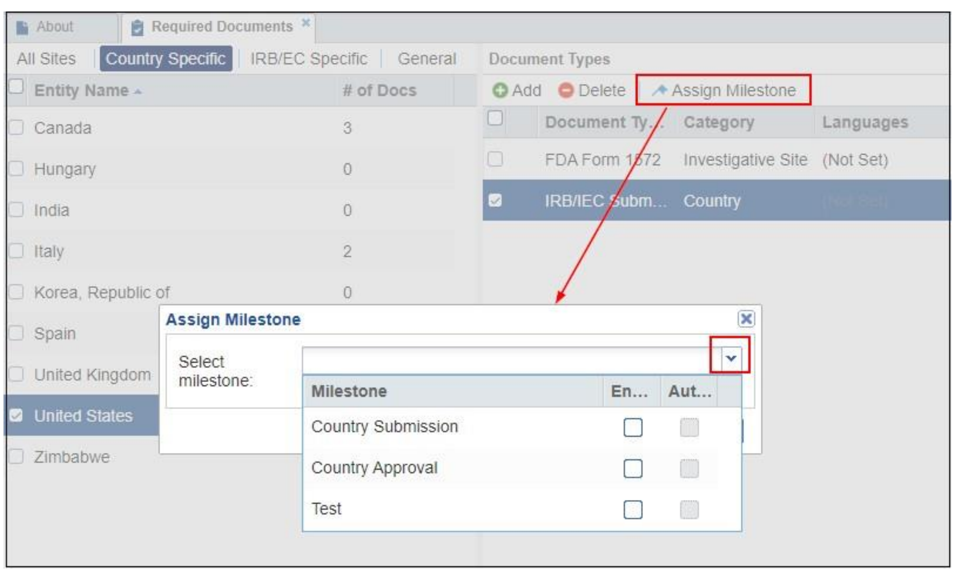


All Sites Country-Specific IRB/EC Specific General

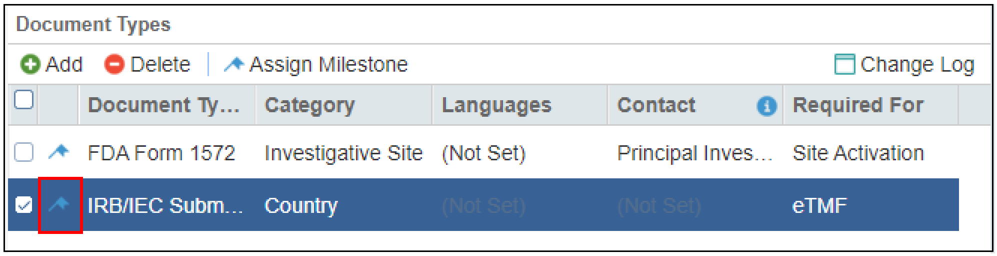
Assigning Milestones to Required Documents

To assign a milestone to a Required Document, follow the steps as below:

1. Select the category from the left pane.
2. Except for All Sites and General categories, select the Country or IRB/EC from the left pane.
3. Select the Required Documents from the right pane.
4. Click the **Assign Milestone**  from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:



6. Choose the milestones from the dropdown list
7. Click the **Assign Milestone** button from the popup window.
8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**. Refer to the screenshot below:

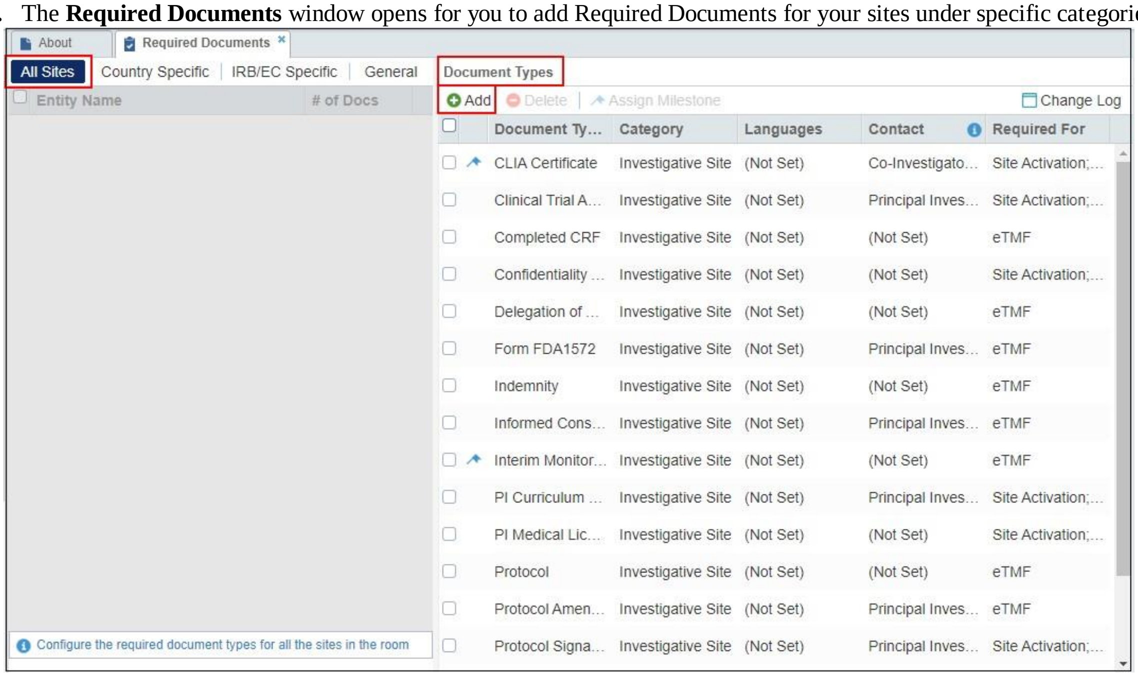


All Sites

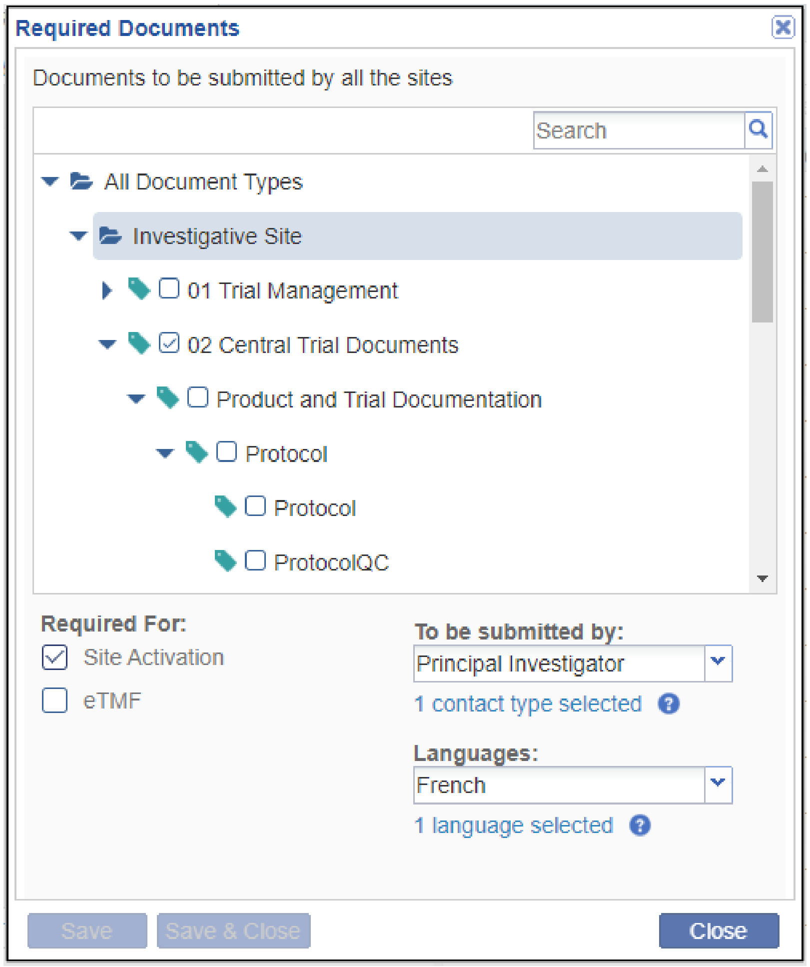
Note: *By default, no documents are Required Documents. Required documents must be defined in this settings view. If the room has been cloned from a previously used room, the Required Documents may already be defined.*

Adding All Sites Required Documents

1. Click the **All Sites** tab from the left panel of the **Required Documents Panel** ***(page 117)***.
2. Click **Add** from the top ribbon bar of the **Document Types** window on the right. Here, you can add document types that will be required by all sites included in the study. Refer to the screenshot below:
3. The **Required Documents** window opens for you to add Required Documents for your sites under specific categories.



Refer to the screenshot below:



4. Click the **Category Folder** from which you need to select the Required Documents that you want to add to the list for all sites. The list of the available document types in that category folder appears.
5. Click the checkbox next to one or all of the documents to be required.
6. Select whether the document(s) will be required for **Site Activation** or **eTMF** by clicking the checkbox.
7. From the dropdown menus to the right, select:
   - **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
   - **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.

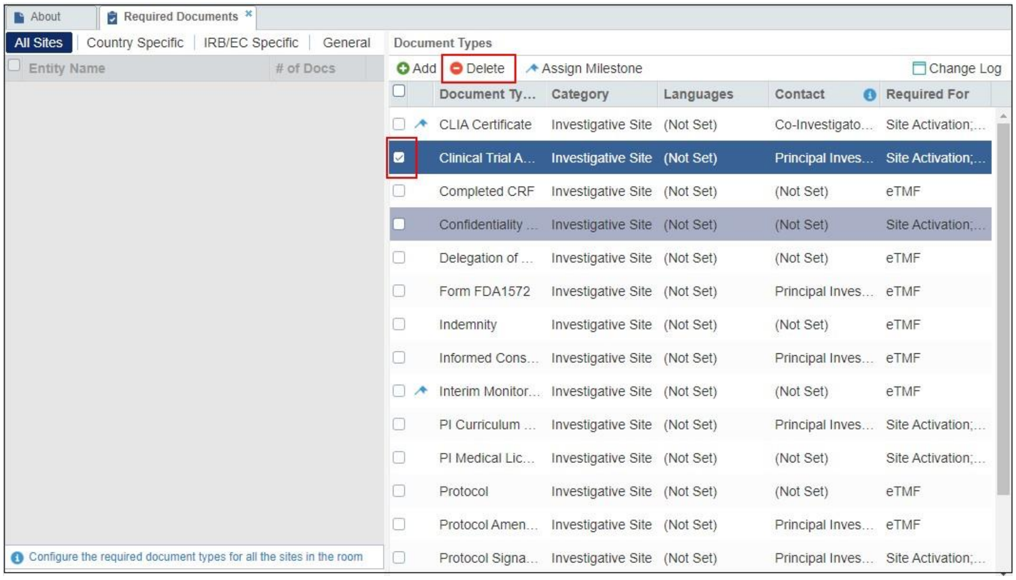
Click **Save & Close** if you have documents from only one category folder to add, or click **Save** if you need to add more required documents.

Note: *If documents are to be provided by one study contact and another document or documents are to be provided by a different contact, click **Save**; go back to the documents list; select the next set of documents, again select whether the documents are required for Site Activation or eTMF; select the contact type from the dropdown, and click **Save**. Continue this process until you have finished adding required document types for all contacts and then finally click **Save & Close**.*

Deleting All Sites Required Documents

To delete a Required Document Type for All Sites:

1. Click **All Sites** tab from the left panel of the **Required Documents Panel *(page 117)***.
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. Refer to the screenshot below:



4. You will receive a warning asking you to confirm the action.
5. Click **Yes** to confirm and delete it.
6. The Required Document Types are removed from the list.

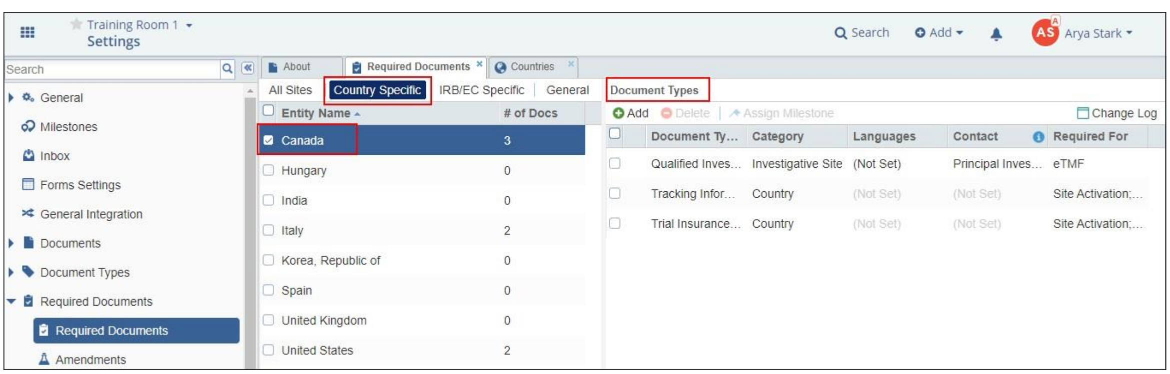
Country Specific

Sometimes, there will also be country-specific document types that will be required.

1. Select the **Country Specific** tab.

Note: *Countries being used for a study are entered during initial Room Configuration. Instructions for* ***Adding Countries*** *can be found in another section of this guide.*

The list of countries will activate in the left pane. Refer to the screenshot below:



2. Select the particular country for which you need to add a required document.
3. The **Document Types** window on the right becomes active.
4. Click **Add** from the top ribbon bar of the Document Types window on the right.

   The **Required Document** ***(page 119)*** window opens, allowing you to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).

5. Selection of the **Investigative Site** radio button activates the list of document types included under Site Management.
6. Selection of the **Study** radio button activates the document types included under the Country document category.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.

   Note: If a specific contact type is made a requirement for document submission, all matching site users will be required to submit that document.

10. Click **Save**.
11. Begin again at the top of the **Required Documents** window.
12. Select the Study documents to be required.
13. Click **Save & Close**.
14. Select the next country in the list to which you need to add required documents, and follow the process steps above.

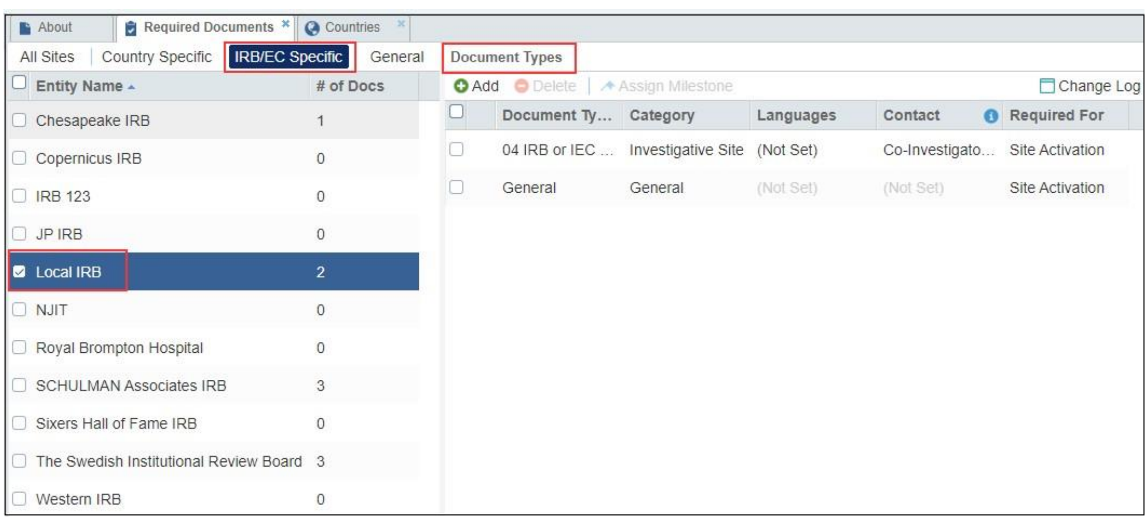
IRB/EC Specific

Sometimes, there will also be IRB/EC-specific document types that will be required.

Adding IRB/EC Specific Required Documents

1. Select the **IRB/EC Specific** tab

   The list of IRB/ECs will activate in the left pane. Refer to the screenshot below:



2. Tick the checkbox to select the particular IRB/EC for which you need to add a required document.
3. The **Document Types** window on the right becomes active.
4. Click **Add** from the top ribbon bar of the Document Types window on the right.

   The **Required Documents** window opens, providing you with the opportunity to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).

5. Selection of the **Investigative Site** radio button activates the list of document types included under **Site Management**.

6. Selection of the **Study** radio button activates the document types included under the **General document category**.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction, if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.
   a. **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
   b. **Languages**- Select the language from the list to apply to the Required Documents.

   Note: If a specific contact type is made a requirement for document submission, all matching site users will be required to submit that document.
10. Click **Save**.
11. Begin again at the top of the Required Documents window to continue adding for different contacts under Investigative Site.
12. Select the **Study** documents to be required.
13. Click **Save & Close**.
14. Select the next **IRB/EC** in the list to which you need to add required documents, and follow the process steps above.

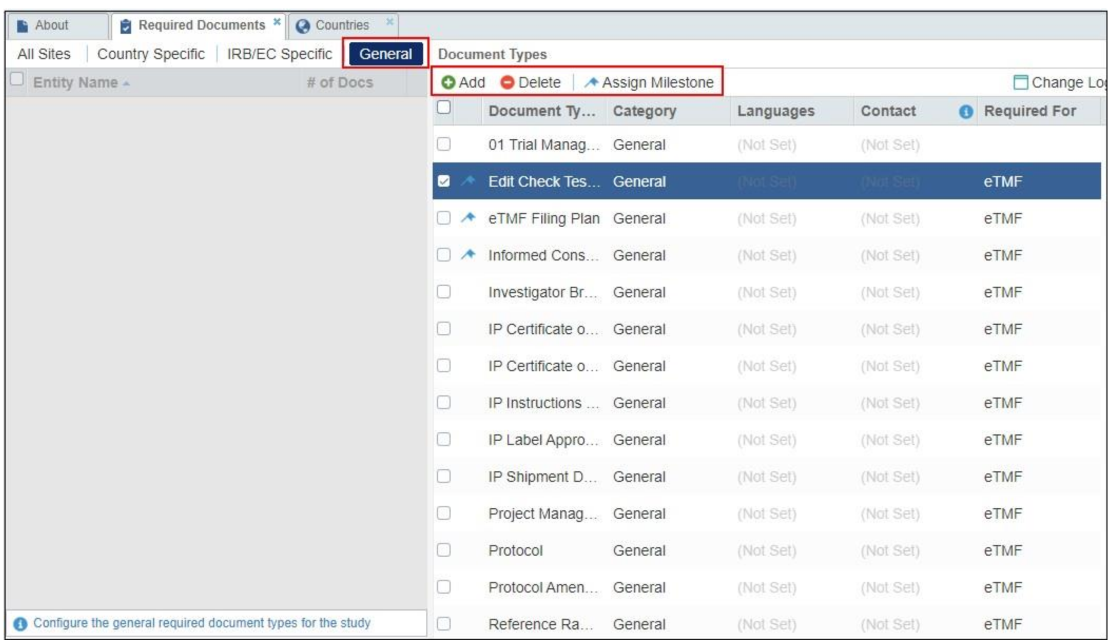
Deleting IRB/EC Specific Required Documents

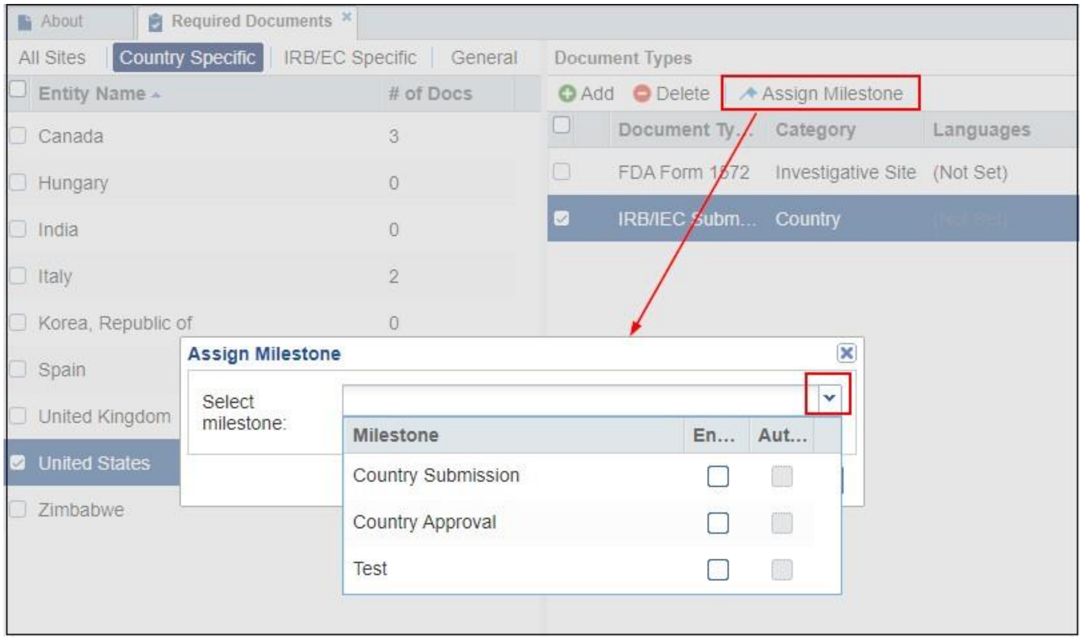
1. From the IRB/EC tab, tick the checkbox to select the particular IRB/EC.
2. The **Document Types** window on the right becomes active.
3. Select the required **Document Type** you wish to delete and click **Delete** from the top ribbon of the Documents Types window.

General View

Adding General Required Documents

1. Click the **General** tab from the left panel of the Required Documents panel *(page 117)*.
2. The **Document Types** window on the right becomes active.
3. Click **Add** from the top ribbon bar of the **Document Types** window on the right.
4. The **Required Documents** window opens for you to add General Required Documents.
5. Select the particular **General** category for which you need to add a required document. Refer to the screenshot below:





6. Click the category folder from which you need to select the Required Document that you want to add to the list for all sites. The list of the available document types in that category folder appears.
7. Click the checkbox next to one or all of the documents to be required.
8. 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.

Deleting Required Documents

To delete a Required Document Type for All Sites:

1. Click the **General** tab from the left panel of the **Required Documents Panel** ***(page 117)***.
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. Refer to the screenshot below:
4. You will receive a warning asking you to confirm the action.
5. Click **Yes** to confirm and delete.
6. The Required Document Types are removed from the list.

Required Documents Milestones Linking

To assign a milestone to a Required Document, follow the steps as below:

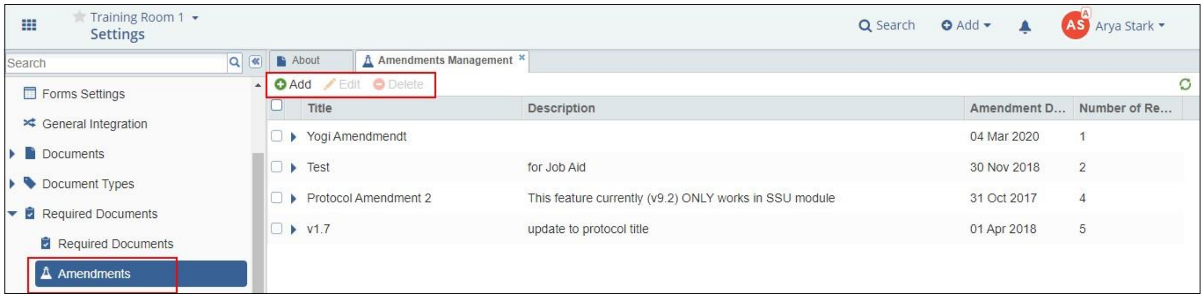
1. Select the category from the left pane.
2. Except for **All Sites** and **General** categories, select the **Country** or **IRB/EC** from the left pane.
3. Select the Required Documents from the right pane.
4. Click **Assign Milestone**  from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:
6. Choose the milestones from the dropdown list
7. Click **Assign Milestone** button from the popup window.
8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**.

Amendments

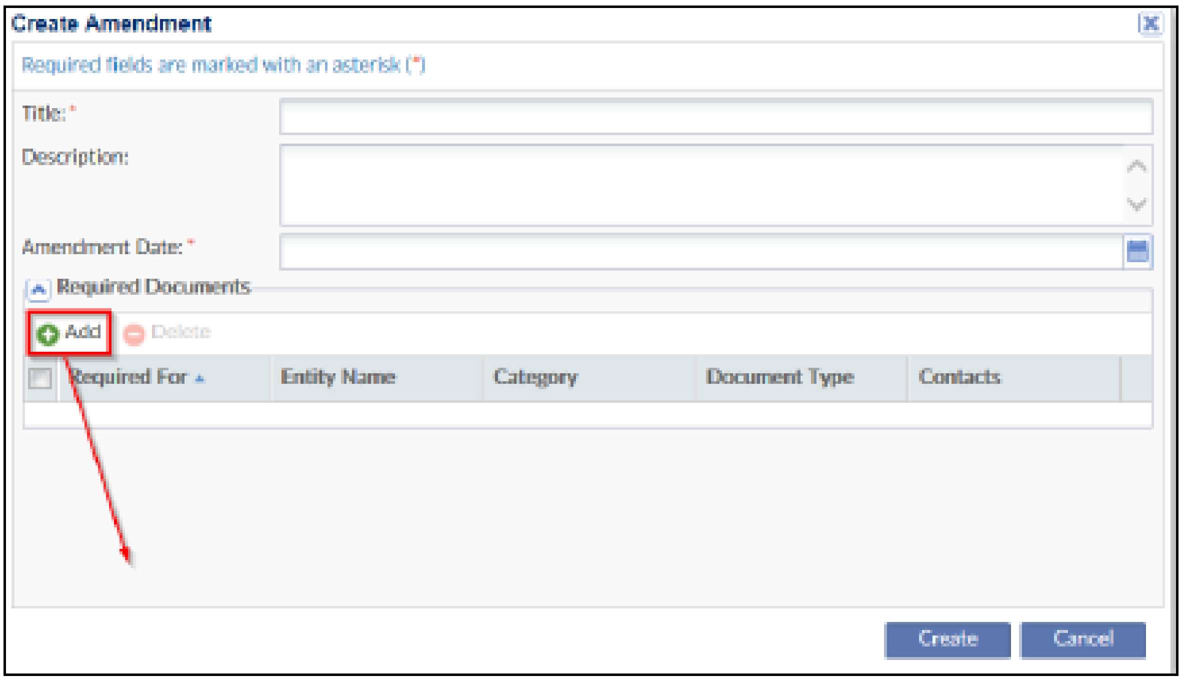
In the Amendments panel, Administrator users can add, edit, and delete amendments.

It will provide a list of documents that need to be collected after the initial set of Required Documents have been set up and rendered. Thus Administrator users can track the needed documents more conveniently.

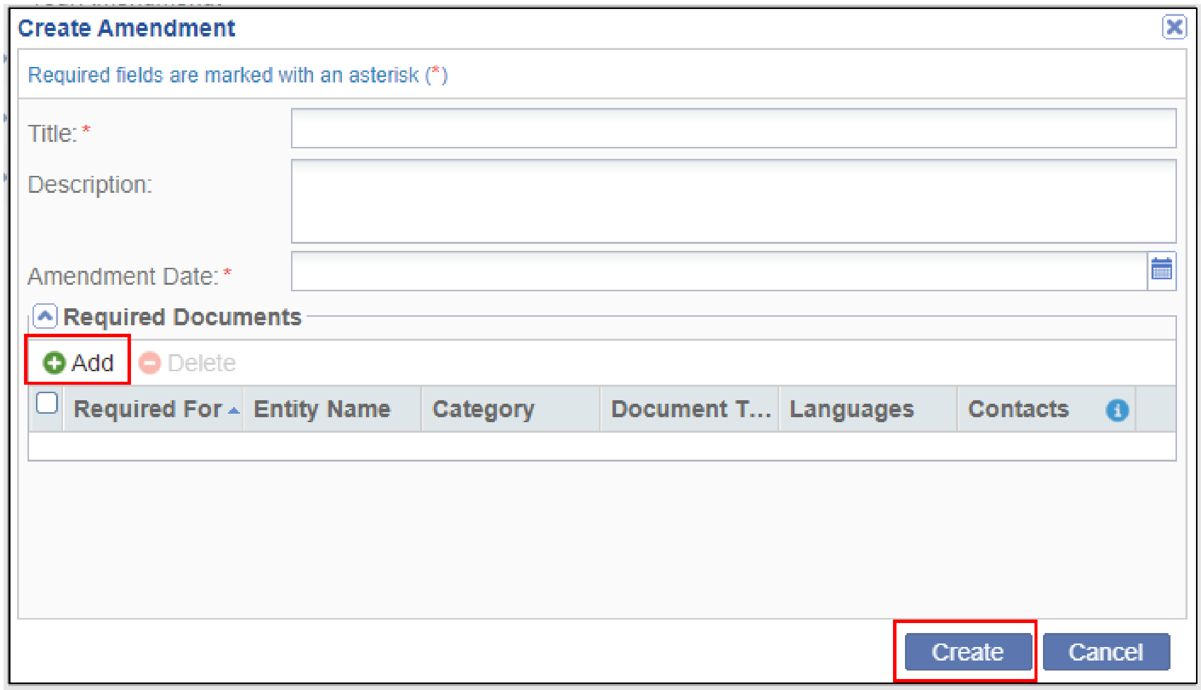
In this dashboard, besides adding amendment required documents, you can adjust your Amendment dashboard view by sorting the columns by ascending or descending order, and also can manage which columns will be shown or hidden. Refer to the screenshot below:



1. Click the **Add** button from the top ribbon bar. **Create Amendment** window opens. Refer to the screenshot below:



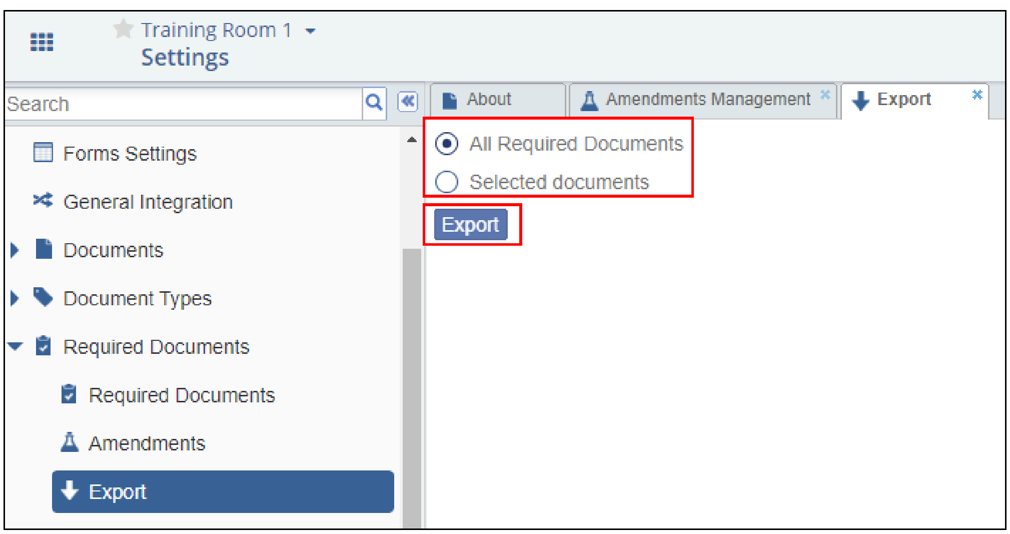
2. Fill in the required details.
3. Click on the **Add** button placed under the **Required Documents** panel. **Required Documents** window opens for you to add the documents that need to be submitted for the specific amendment created. Refer to the screenshot below:



4. Select from the list for **To be submitted by** and **Languages**. Click **Add** to save the amendment made.
5. To edit the amendment, double-click the particular amendment or click the **Edit** button.
6. To delete, click the **Delete** button or right click on the amendment and click **Delete**.

Export Required Documents

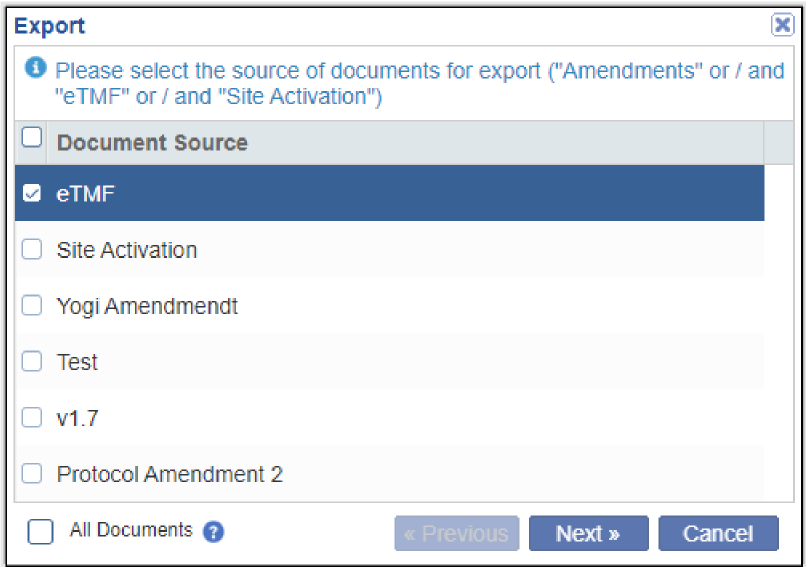
In this panel, Administrator users can export either **All required documents** or **Selected documents**. Refer to the screenshot below:



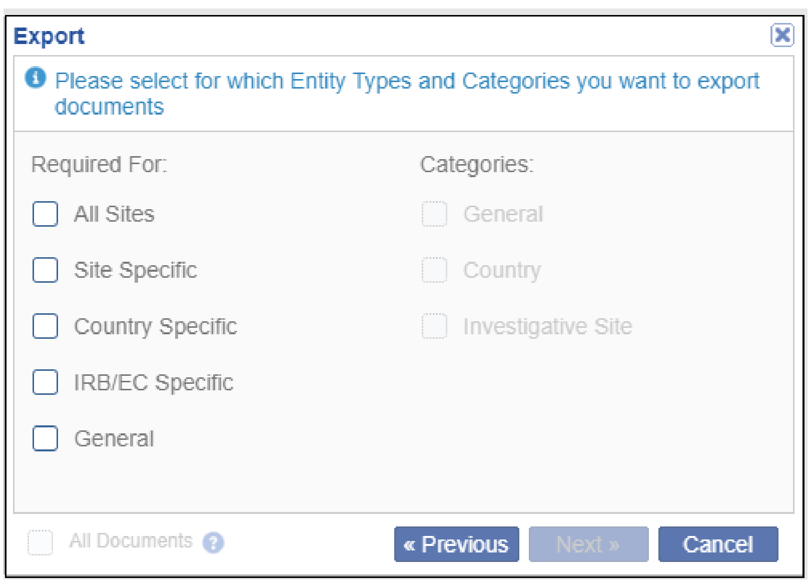
Required Documents can be exported in two ways:

1. Select **All required Document** Option to export documents from all document source categories
2. Select **Selected documents** option.
    a. Export window opens for you to choose from **Amendments or/ and eTMF or/ and Site Activation** sources of documents.

    Refer to the screenshot below:



    b. Select the required **Document Source/s** and click **Next**.
    c. New Export window opens for you to select required **Entity Types and Categories** to export documents. Refer to the screenshot below:



    d. Click **Next.**The final Export window opens to review criteria chosen by you.

    Click **Previous** to make changes in the selection or click **Next** to export Required Documents.

e. On successful exporting of Required Documents, you will receive a notification.

f. 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:

Exported Required Documents **Training Room 1**

Required For	Requirement Level	Entity	Category	Document Type	Contact Type	Language
eTMF	All Sites		Investigative Site	02 Central Trial Documents\Subject Documentation\Informed Consent Form\Informed Consent Form	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Initiation\Trial Inititiation Monitoring Report\Site Initiation Visit Report		
eTMF	All Sites		Investigative Site	05 Site Management\Site Management\Monitoring Visit Report\Interim Monitoring Visit Report		
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Form FDA1572\Form FDA1572	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Protocol Amendment Signature Page\Protocol Amendment Signature Page	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Site Signature Sheet\Delegation of Authority		
eTMF	All Sites		Investigative Site	10 Data Management\Data Capture\Final Subject Data\Completed CRF		
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Indemnity\Indemnity		
eTMF	All Sites		Investigative Site	02 Central Trial Documents\Product and Trial Documentation\Protocol \Protocol		
eTMF	All Sites		Investigative Site	01 Trial Management\Trial Oversight\Recruitment Plan\Recruitment Plan		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Site and Staff Qualification Supporting Information\PI Medical License		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Sub-Investigator Curriculum Vitae\SubI Curriculum Vitae	Sub-Investigator	
eTMF, Site Activation	All Sites		Investigative Site	08 Central and Local Testing\Facility Documentation\Certification or Accreditation\CLIA Certificate	Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Protocol Signature Page\Protocol Signature Page	Principal Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Principal Investigator Curriculum Vitae\PI Curriculum Vitae	Principal Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Selection\Confidentiality Agreement\Confidentiality Agreement		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Clinical Trial Agreement\Clinical Trial Agreement	Principal Investigator	

Contacts

A clinical trial includes a varied range of people with different profiles, who are a part of the study. Such people are a valuable source of information and are required at various stages of the study. Trial Interactive helps to maintain the detailed profile of such people as Contacts for a study. Some examples of contacts could be the Principal Investigator, Sponsor, Co-Investigator, regulatory authorities, authorities in the IRB.

You can access the **Contacts** module by clicking the **Contacts** icon on the menu bar at the left. The **Contacts module** gives detailed information on all contacts available in a room **By Site**, **By IRB/EC**, **By Country**, and **By Contact Type**.

From this section you can do the following:

1. View Contacts
2. Mass Coding for Contacts
3. Convert to Users
4. Contact Data

Each of the above topics are discussed in seperate topics and can be accessed from the left menu of this help.

View Contacts

This section gives you an overview of the different types of contacts:

By Site

Select **By Site** from the dropdown in the Index Pane on the left of the Contacts Module. This will reveal all the sites available in the room.

Click a site. This will populate the data of all the contacts available for the particular site in a room in the right pane of the dashboard.

By Country

Select By Country from the dropdown in the Index Pane of the Contacts Dashboard.

This will list all the countries with the sites where the studies are being conducted in the Index Pane on the left. Clicking a country to expand the dropdown will reveal the sites under it. Click a site to populate the contact details associated with the site in the right pane.

By IRB/EC

Select By IRB/EC from the dropdown in the Index Pane of Contacts Dashboard. This will populate the IRBs associated with the sites in the Index Pane on the left. Clicking an IRB will expand the dropdown to reveal the sites associated with it.

Click a site to populate the contact details associated with the site in the right pane.

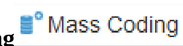
By Contact Type

Select By Contact Type from the dropdown in the Index Pane of Contacts Dashboard. This will populate the contact types associated in the room in the Index Pane on the left.

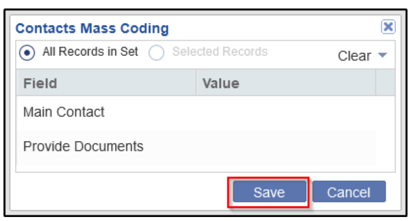
Clicking a contact will list the contact details associated with a particular site in the right pane of the dashboard.

Mass Coding for Contacts

Administrators are sometimes called upon to fill in or update the metadata of a number of contacts in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Click the **Mass Coding** 

tool from the top ribbon bar. The **Contacts Mass Coding** window opens. Refer to the screenshot below:

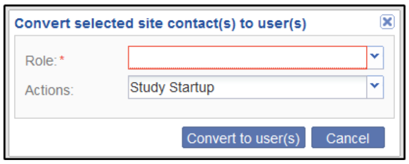


2. You can choose to mass code for **all the records** in the grid, or a **selected set of records**.
3. Either way, double-click and select yes/no from the dropdown in the **Value** field for the required metadata to be mass coded.
4. Click **Save**.
5. Confirm the message to proceed with mass coding. You will receive a confirmation about the job result which can also be retrieved from the Notifications.

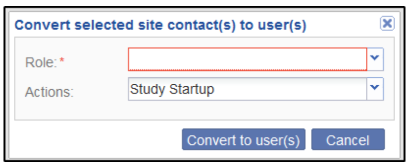
Convert to User(s)

As an administrator, you might want to give **Editor** or **Reader** access on some or all modules to contacts in a site. This can be achieved proceed with the following:

1. Click the **Convert to User(s)** Convert to user(s) icon on the top ribbon bar.
2. This will open the **Convert selected site contact(s) to user(s)** window. Refer to the screenshot below.



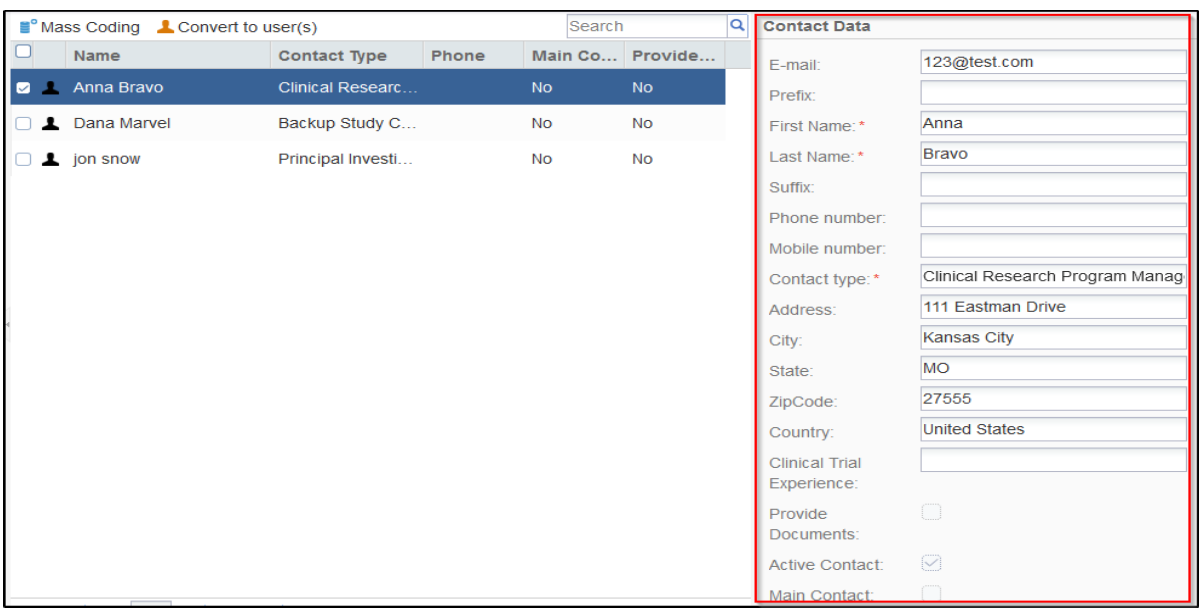
3. Select the role as Editor or Reader as required. Refer to the screenshot Below.



4. Select the modules from the Actions as required.
5. Click **Convert to user(s)** button in the window.

Contact Data

Selecting a contact in the grid will highlight the **Contact Data** window at the extreme right of the grid in the right pane. You can view the details of the contact here. Refer to the screenshot below.



Note: *Contacts can be added through the Sites Dashboard. They can also be added from the Documents Panel*.

Countries

When a study includes investigative sites located in different countries, scountries need to be added to the room. In this way, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents. To set up countries for investigative sites, navigate to:

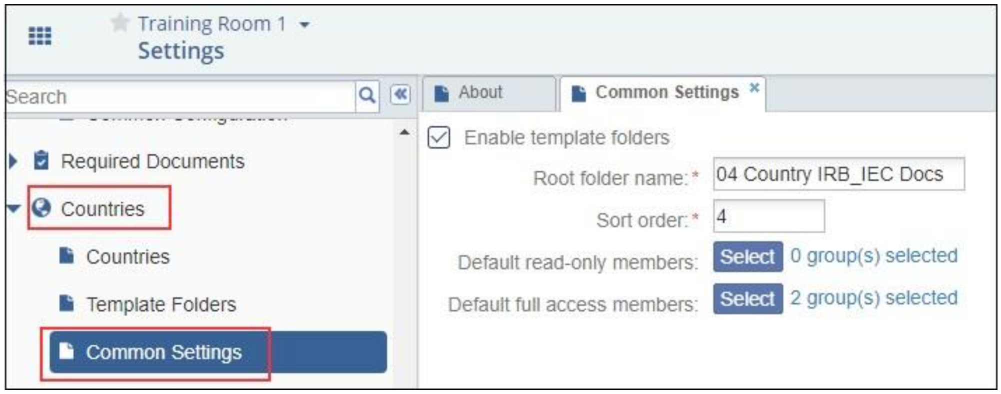
1. The Trial Interactive room for which you want to set up countries.
2. Select the **Settings** option from **Main Navigation**.
3. Select **Countries** from the menu on the left. This option drops down to reveal the following options:
    a. Countries
    b. Template Folders
    c. Common Settings

All of the above options are discussed in separate topics accessible from the left panel of this help.

Common Settings

In the Common Settings window, you can:

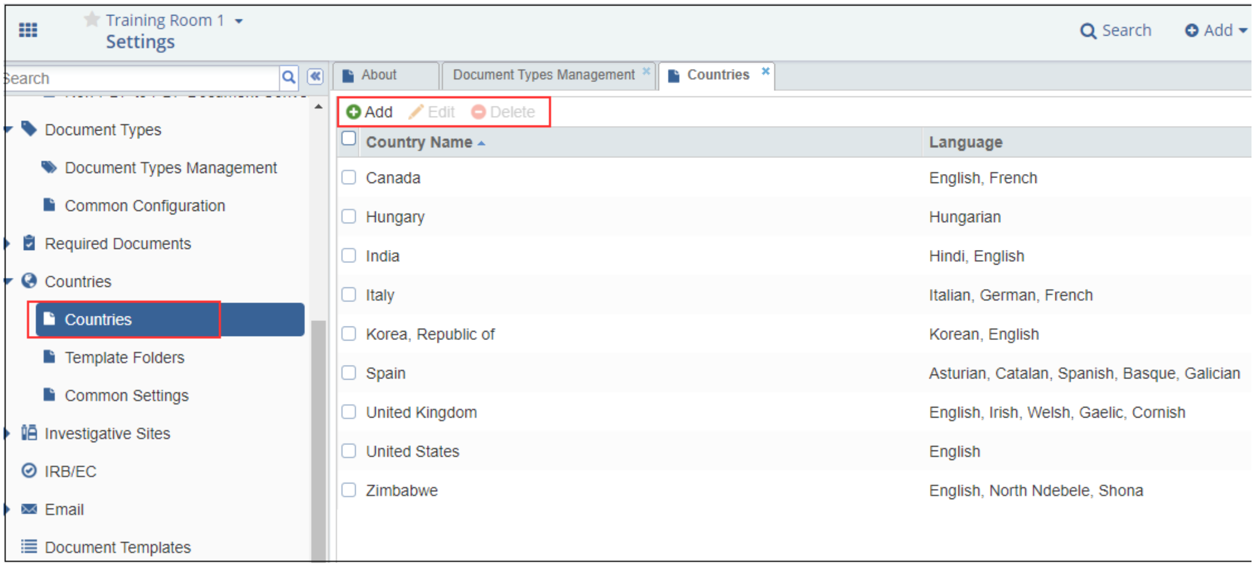
1. Enable or disable the Template Folders.
2. Edit the **Root folder name**. Typically the client supplies the preference here.
3. Change the Sort Order, the place in the room's index structure where the Country Management folder (or whatever name the client has specified) appears. This setting, too, is based on client preference.
4. And, as in the **Edit** function in the **Countries** window, you can adjust the **Read-Only** and **Full Access** security settings. Select the users or groups to set access. If you make any changes in this window, click **Save**. Refer to the screenshot below:



Countries Settings

Trial Interactive allows Admin to perform Countries Settings from this page. Follow the steps below to perform the country settings:

1. Navigate to the **Main Navigation** -> **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.

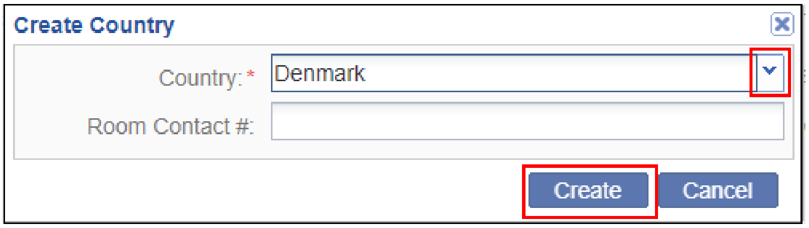
Each of these is discussed in separate topics and can be accessed from the left menu of this help.

Add Countries

Follow the steps below to add countries:

1. Click **Add** 

from the ribbon above the country listing. The **Create Country** window opens. Refer to the screenshot below:



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.

> **Note:** *You can ease the process of finding the country name in the list by typing the first few characters in the country name. The dropdown list will shorten to include only the countries whose names begin with the characters you have typed.*

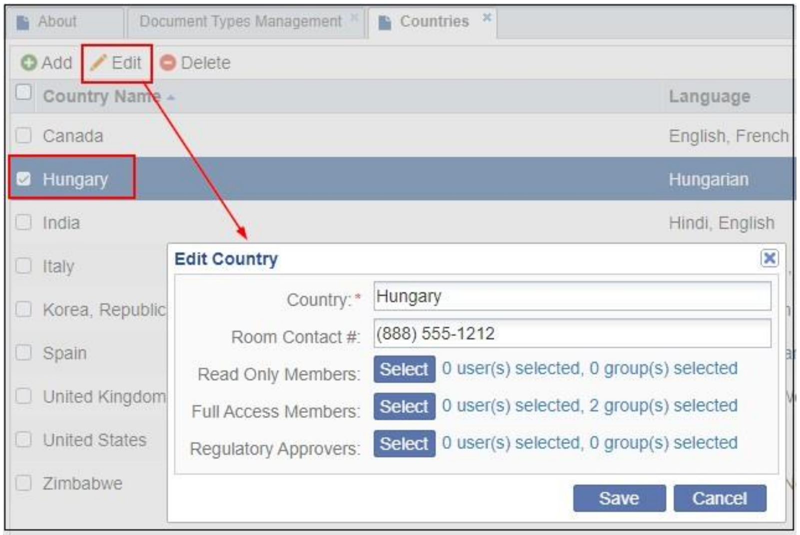
4. If the client has supplied country-specific **Study Contact #**, include the associated number in the field.
5. Click **Create**. The name of the newly added country appears in the alphabetized list.
6. Repeat these steps until you have added all of the countries associated with the study.

Edit Countries

Once a country has been added to the list, you can add or change the study contact #, and you can 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 opens. Refer to the screenshot below:



3. It might be that after you've added the country to the list, you are supplied with the study contact number later.
4. Click **Study Contact#** field to change the information.
5. Click **Select** next to **Read Only Members** or **Full Access Members** or **Regulatory Approvers** to add or delete users or groups of users from the access settings.

   These selections will probably not be available at this early stage of room configuration. Room configuration is not a strictly linear process – you will have to make additions and changes in other areas on the Trial Interactive platform in order to complete the room's configurations.

6. Click **Save.**

Note: *Though you have access to these security settings here, it is not typical that you will make changes using this path.*

Delete Countries

Follow the steps below to delete the countries:

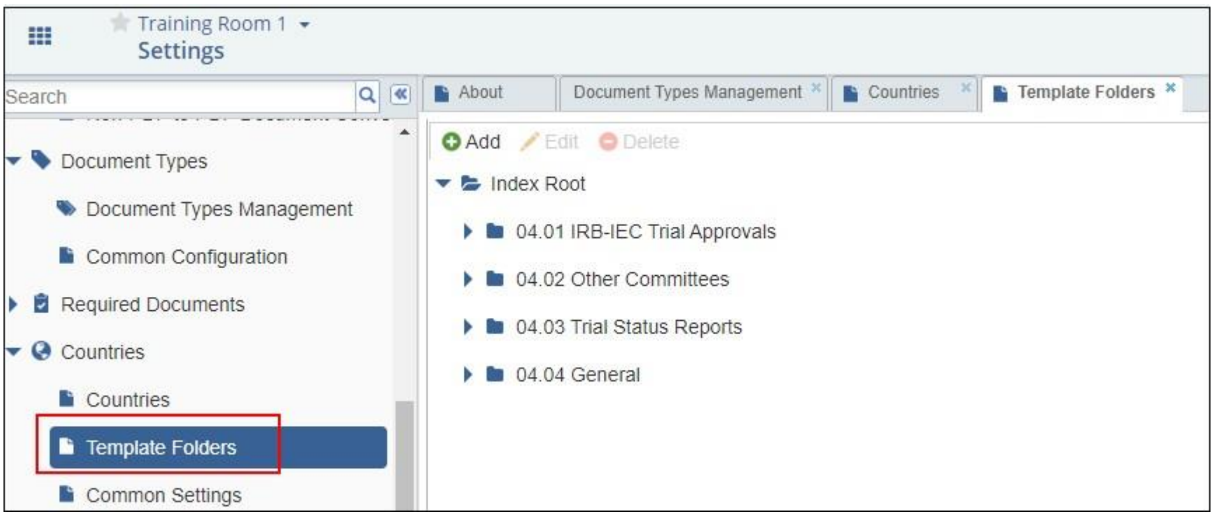
1. Select the country or countries that you need to delete from the list by clicking the checkbox next to the country's name(s).
2. Click **Delete** 

at the top of the **Countries** window. The country name(s) will delete automatically, without giving you a warning.

Note: *At a later stage in the study, once documents have begun to populate the room's index folders, you won't be able to delete countries that have associated documents. Adding to and editing the Countries list can go on 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 necessary for completing this stage of the room configuration come from the client – the titles and the order of the folders to be included. The folder structure is fairly consistent, but it is always study specific.*

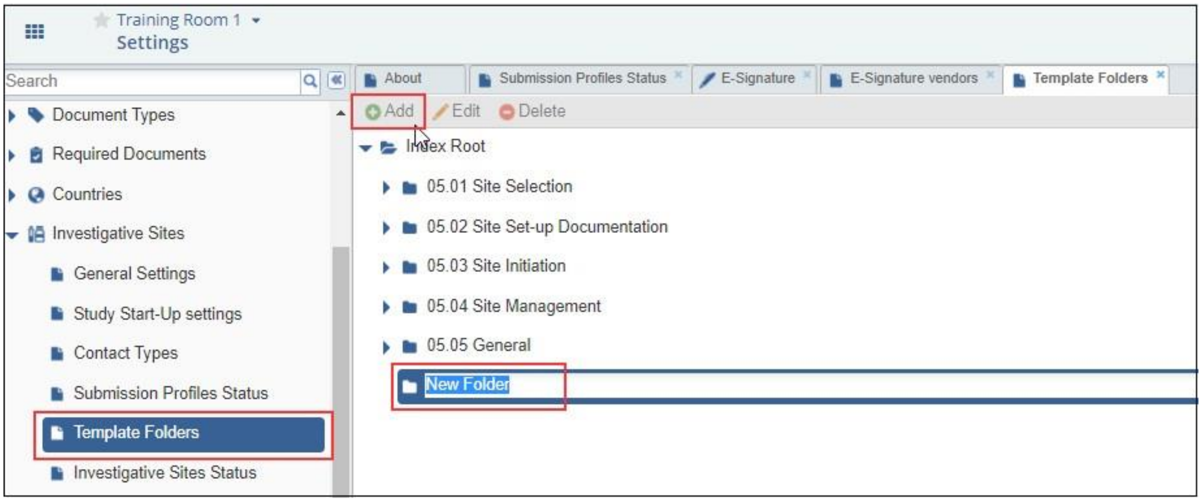
Each of the above topics is discussed in separate topics and can be accessed from the left menu of this help.

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

1. To add a folder to the Index Root, first click **Index Root**, marked by a yellow folder icon.
2. Click **Add** 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**.

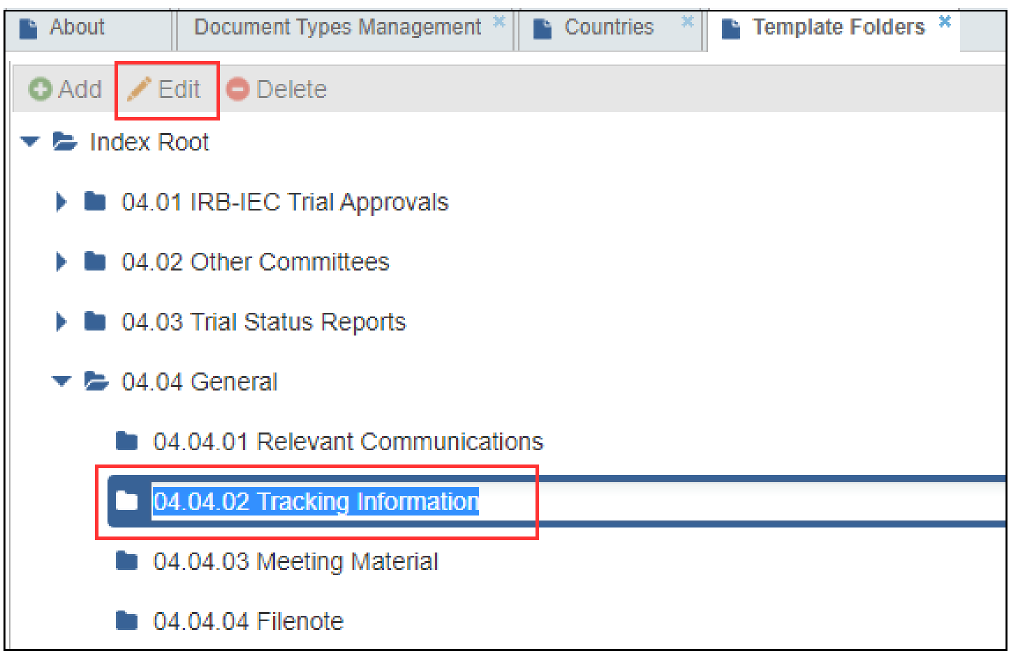
5. Repeat this process until you have entered all of the new folder names.



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**.



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 disappears from the index structure.

Note: *Folders that contain subfolders or documents cannot be deleted.*

Chapter 18. e-Signature

This section discuss the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

eSignature

The client can choose the required e-Signature vendor from **Main Navigation** → **Settings** → **e-Signature** → **Vendors**.

Vendors

The e-Signature vendor available to you depends on the vendor chosen by your organization. This section discusses the following three e-Signature options:

1. DocuSign
2. Adobe Sign
3. TI e-Signature

Follow the steps below to select the e-Signature vendor:

1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Vendors**.
2. Click the **Use E-Signature dropdown** to select the vendor. Refer to the screenshot below:

Note: *The e-Signature vendor available to you depends on the vendor chosen by your organization.*

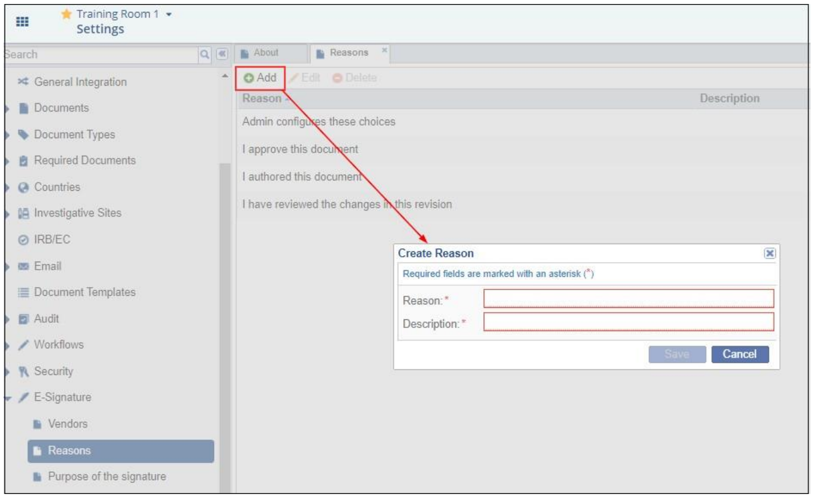
3. An Administrator can choose to enable or disable the use of an e-signature for users in a room by selecting the **None** option from the dropdown.
4. Click **Save** if you make any changes here.

Note: *If the **E-signature** is enabled, the e-Signature Action is automatically added in the **Actions** pane as discussed in Edit User (page 72). To see the addition, refresh the room in the browser.*

Reasons

While e-signing a document, the e-signers need to specify the reasons for approving or declining a document. Administrators can configure reasons for e-signature from here.

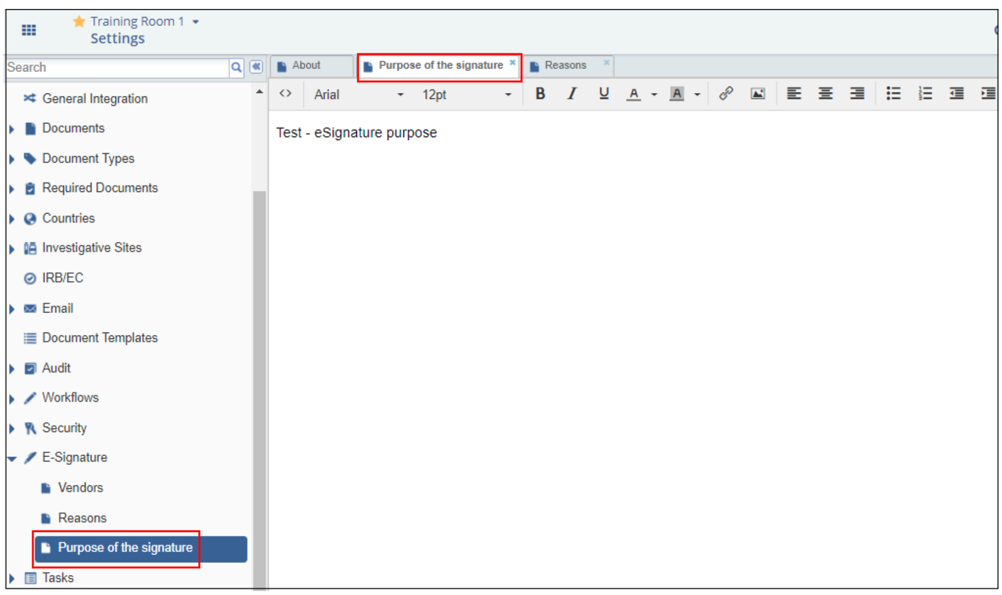
1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Reasons**. Refer to the screenshot below:



2. Click **Add** to create new reasons.
3. Select a reason from the list and click **Edit** to make changes in the existing reason.
4. Select a reason from the list and click **Delete** to delete the existing reason.

Purpose of the e-signature

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:



1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Purpose of the signature**.
2. In the Right Panel, you can write the Purpose of the e-signature.
3. Click **Save**.

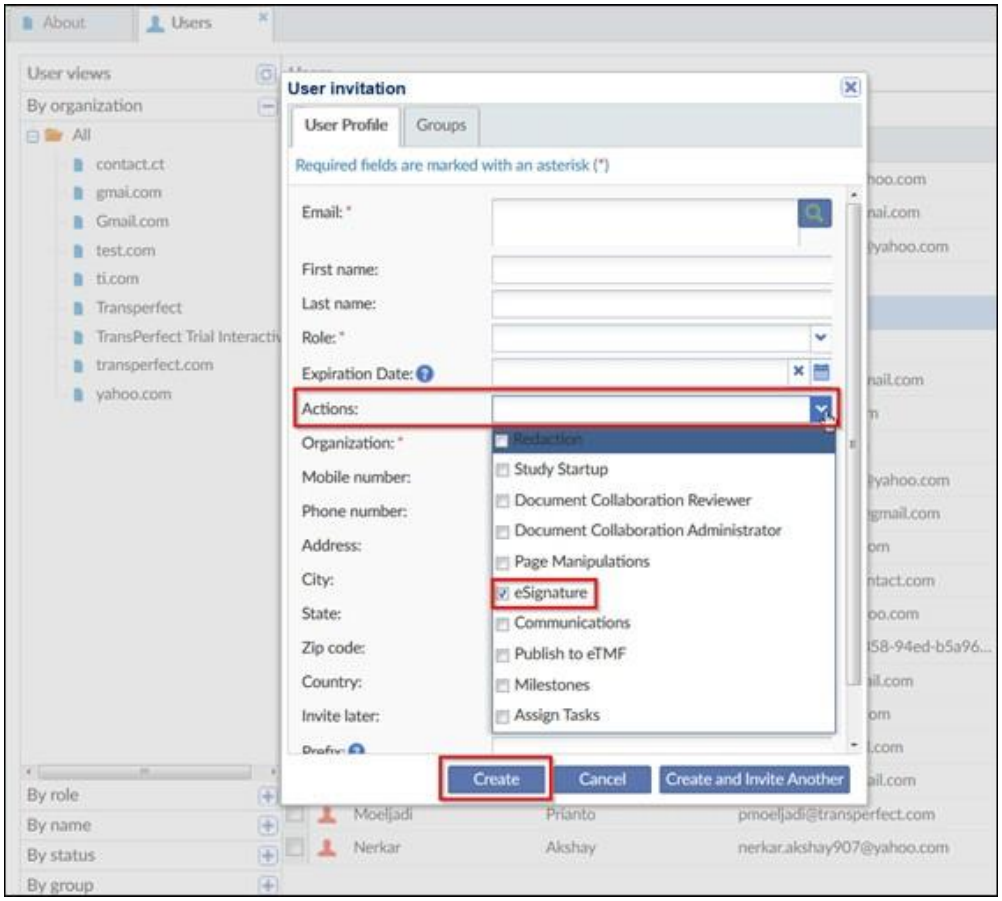
Assigning Users to prepare an e-Signature Envelope

1. Click the desired room in your TI session. Click **Settings** from the Main Navigation to populate the room settings.
2. Navigate to **Settings -> Security-> Users**. A panel listing all users will be displayed in the right pane. Alternatively, you may arrive on the same page from the **Main Navigation -> Users management**.
3. Click the **Invite** dropdown located on the top left corner of the user list pane. Select the invite option from the list. A

User Invitation form will be populated.

Fill in the fields marked with an asterisk (*), at minimum, to invite the desired user.

From the **User Profile** tab click the **Actions** dropdown menu to select the **eSignature** option and click **Create** to assign your user to prepare the eSignature package. Refer to the screenshot below:



4. For existing users, select the user from the user list by clicking the checkbox adjacent to the list populated in the right pane.
5. Click the dropdown next to the dots and click **Edit** option. An **Edit User** form will populate. Refer to the screenshot below:

6. Click the **Actions** dropdown menu and select the **eSignature** option by ticking the checkbox.
7. Click **Save** to prepare the existing user for the e Signature package.

The user added will receive an email from Trial Interactive asking them to register in order to comply with e Signature feature.

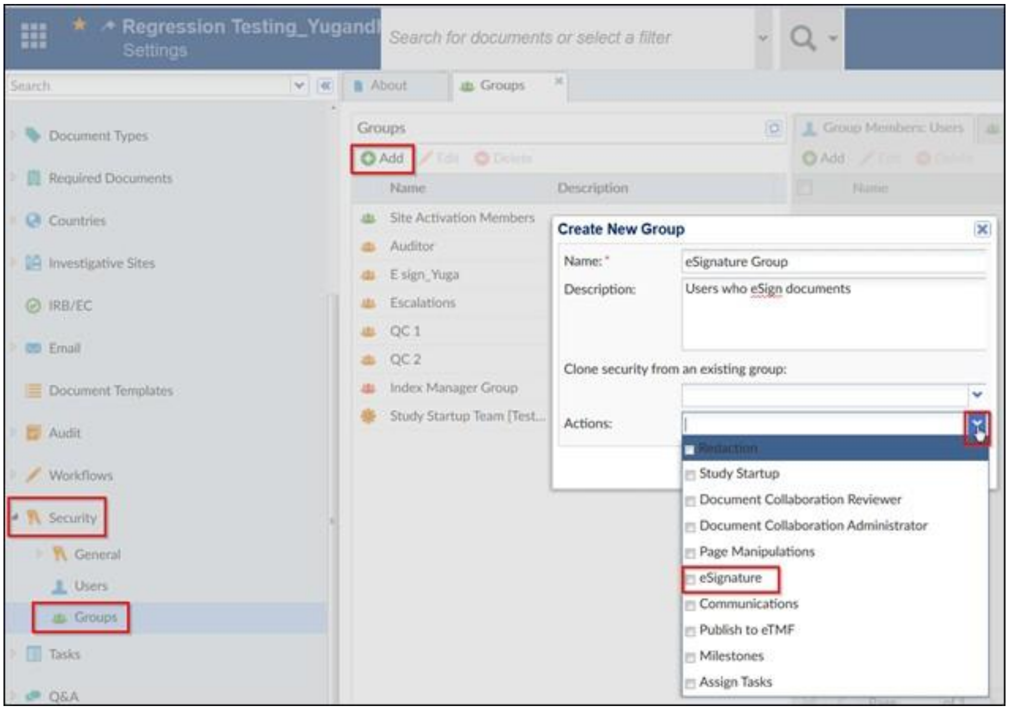
Adding Groups with the eSignature Actions

Add Groups and activate the eSignature Action for the specified groups.

1. Navigate to **Settings -> Security -> Groups**. The Groups Panel opens.
2. From the **Groups** tab, click **Add**. The **Create New Group** window opens.
3. Name the group by typing its title into the **Name** field.
4. Add a **Description**.

   The user making these additions or changes can choose to clone the security parameters already defined for another user group that has been established in the room. This cloning designation is not required.

5. Click the **Actions** dropdown. Refer to the screenshot below:



6. Click the checkbox for **eSignature** and click **Create**.

   The new user group displays in the list of **Groups** in the panel on the left.

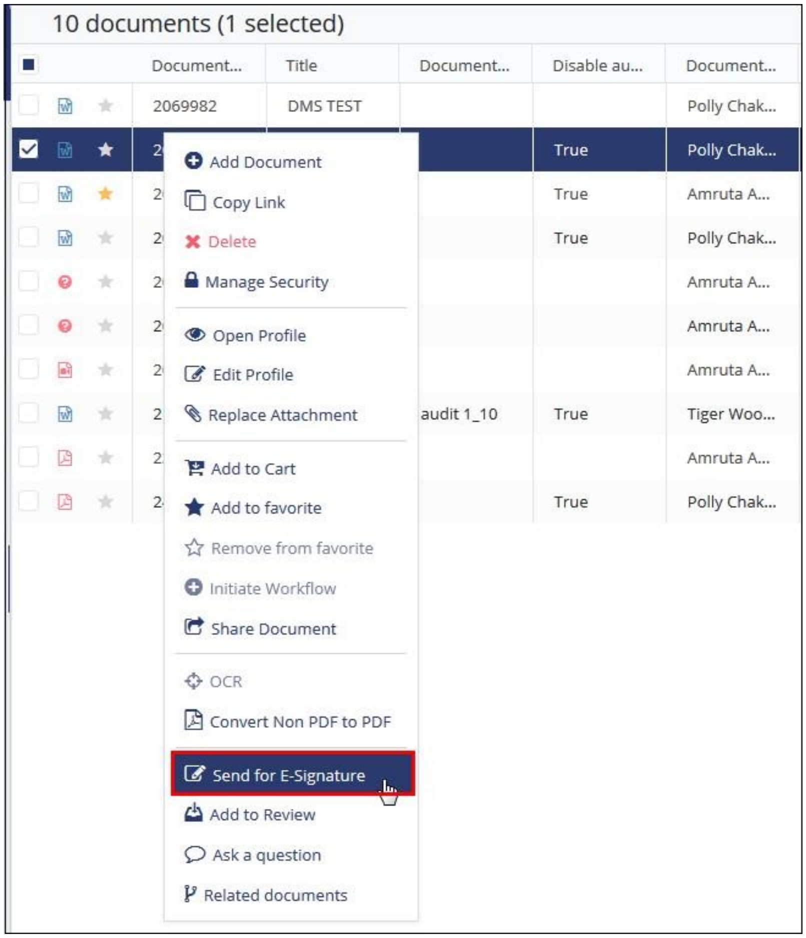
TI eSignature

For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) to sign the documents.

This section includes the following sections:

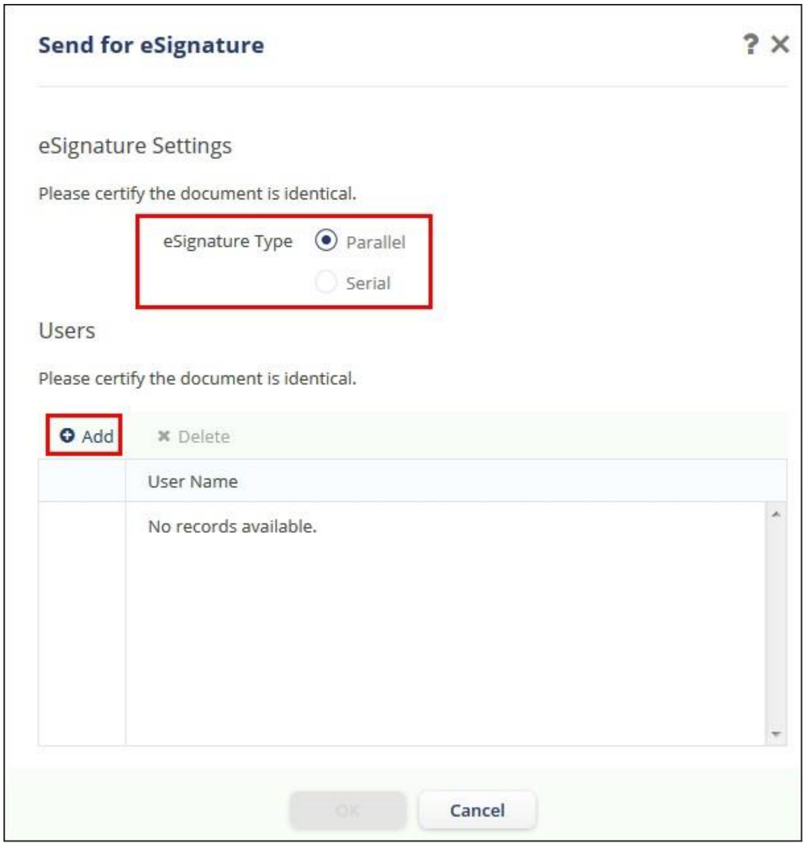
TI eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right-click the desired document and click **Send for e-signature**. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel *(page 268)* to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. Refer to the screenshot below:



Signing the documents in TI - eSignature

If you are assigned to electronically sign a document, you can sign the documents in the following ways:

- From the Documents to be signed dashlet
- From the eTMF/Documents view

Each of the ways is discussed in the sections below:

Signing Documents from the Documents to be Signed Dashlet

1. When you are assigned a document for eSignature, navigate to the room **Dashboard** and scroll to find the **Documents to be signed** ***(page 215)*** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display. Refer to the screenshot below:

   You can also proceed to the **eTMF/Documents** module or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane.

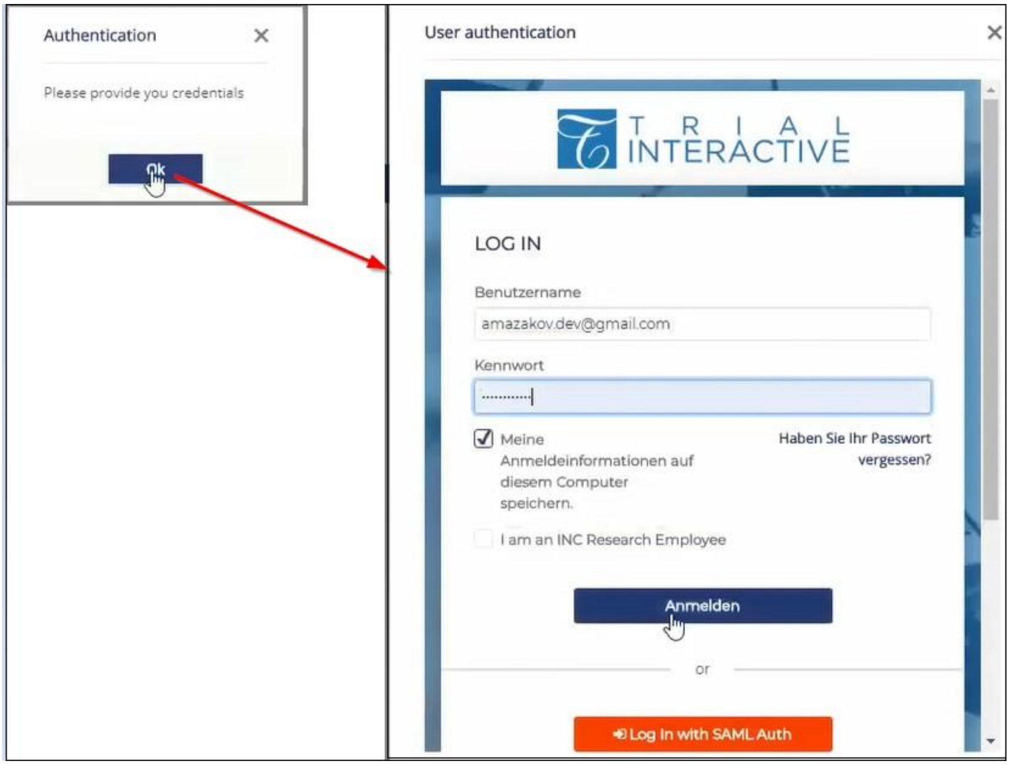
Note:

- *Completed signatures cannot be canceled.*
- *Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.*
- *Once a document is canceled from e-signature, no one can sign the document until it is resent again.*

Signing Documents from the eTMF/Documents view

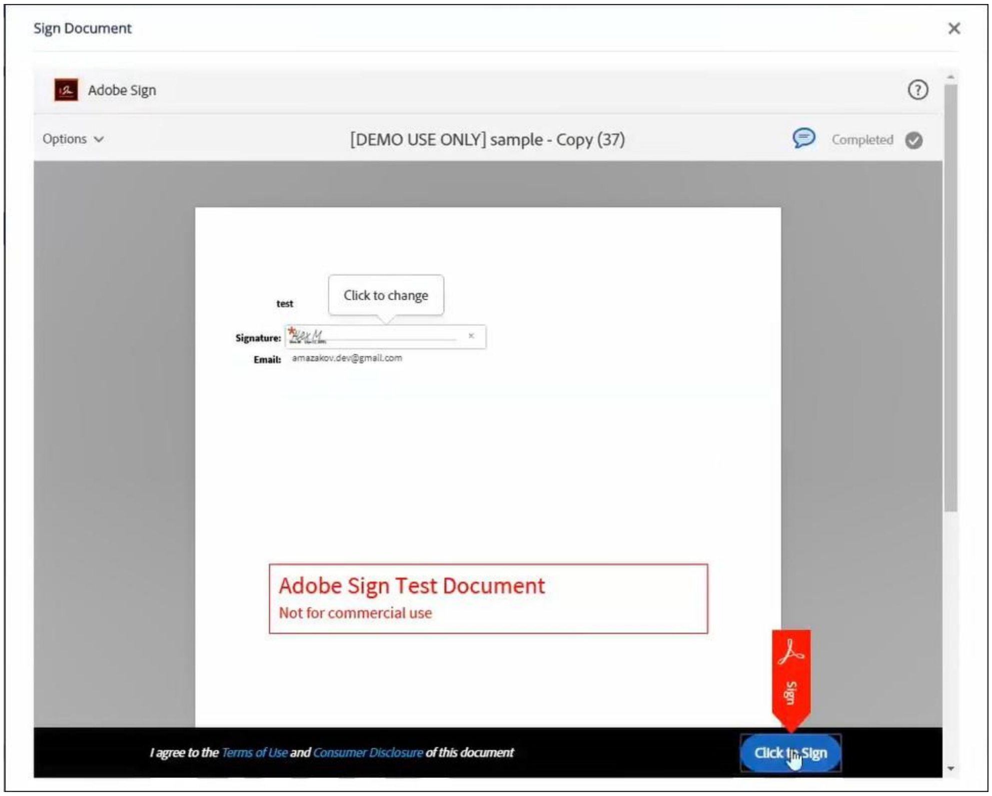
1. Navigate to the **eSignature view** and click the **Waiting for Signature** folder to locate the document to be signed as shown in the screenshot above section.
2. Select a document and open the **eSignature Panel** to the right. The Waiting for eSignature status appears next to your name.
3. Click the username to expand the details. Refer to the screenshot below:

4. Enter all the required details and click **Sign Document** button.
5. A window opens asking you for Authenticating your credentials opens.
6. Click **OK** to authenticate your credentials. Refer to the screenshot below:



7. Once you are authenticated, you are directed to the confirmation dialog box asking for signing.
8. Click **OK**.

9. The **Sign Document** window opens which allows you to sign the document. Refer to the screenshot below:



10. Click the Blue button at the bottom right corner of the window to sign the document.
11. If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all the signers have finished signing. Refer to the screenshot below:

12. Open the signed document to find that a page with the signer's name and contact details, date of e-signing the document is appended as the last page to the document. In the case of multiple e-signers, a page for every signer is appended.

    Note: *Signature Page will be added to PDF documents only after all signers have finished signing the document.*

13. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under **e-Signature Documents** view. You can see the status of the eSignature as **Completed** in the eSignature Panel.

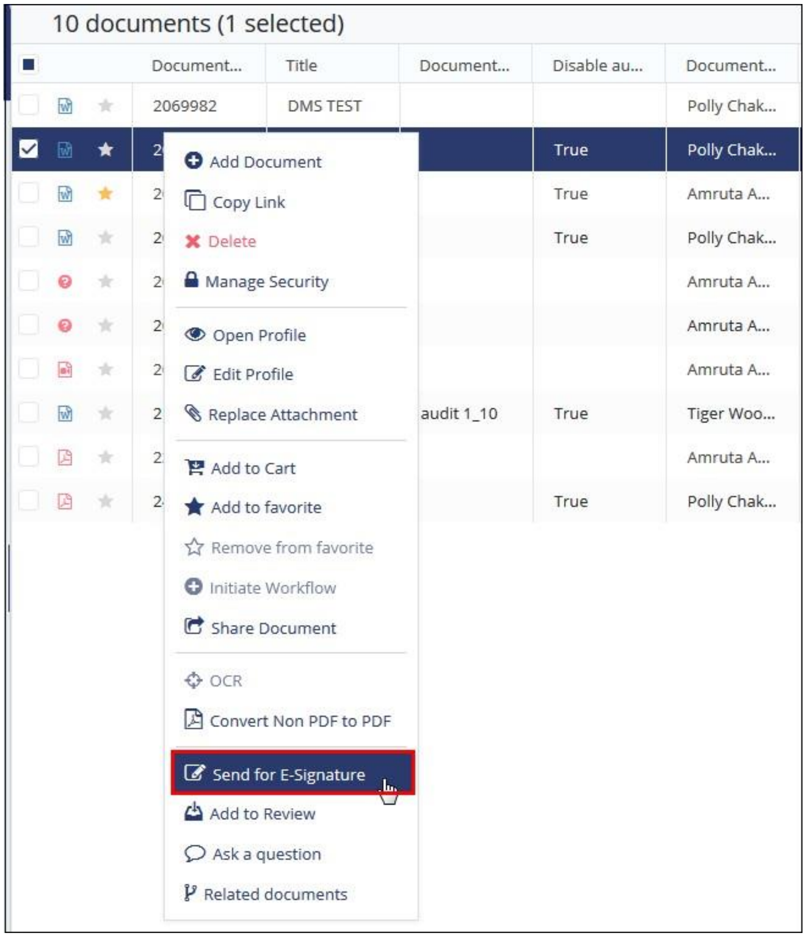
Adobe eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

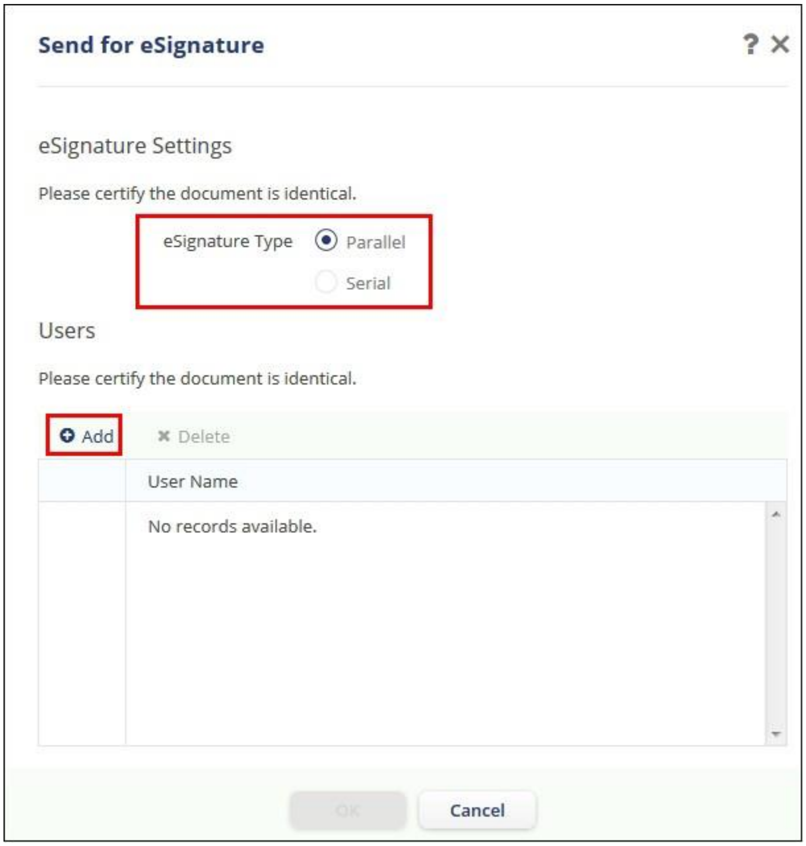
Adobe eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right-click the desired document and click **Send for e-signature**. Refer to the screenshot below:



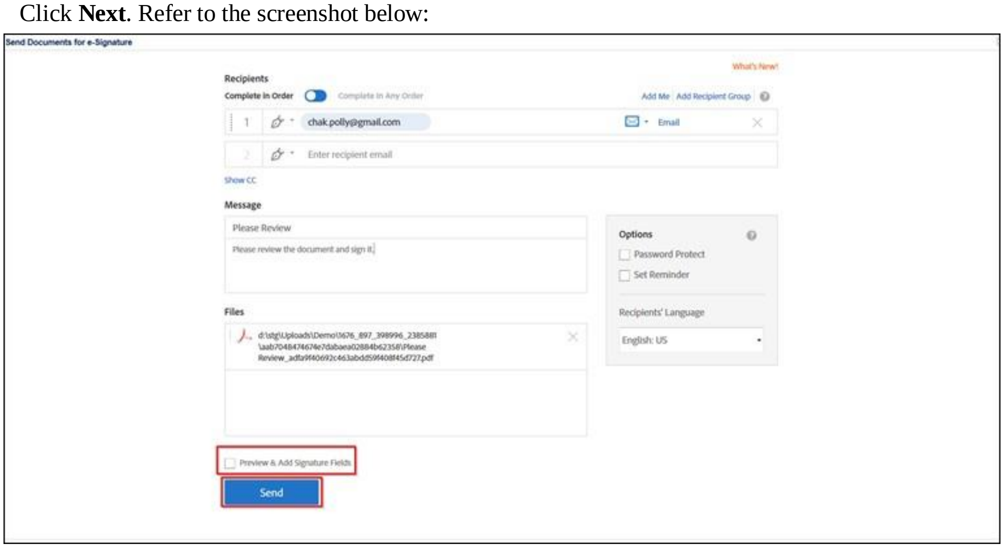
Alternatively, you can also send the document for eSignature from the eSignature Panel *(page 268)* to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:



If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

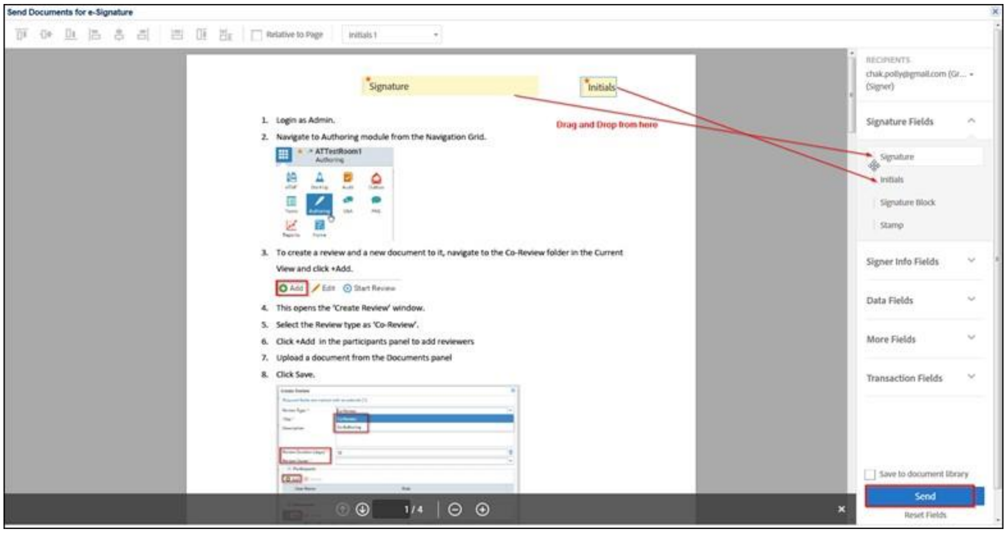
5. Click the **OK** button after adding the desired signers.
6. Recipient window with the list of email ids of signers enlisted opens.
7. Tick the **Preview & Add Signature Fields** checkbox located at the end of the page to determine the placement of signatures on the document.
8. Click **Next**. Refer to the screenshot below:



9. From the Recipients field select the signer and, drag and drop the fields on your document from the right menu option

that you wish to include in the signature.

10. Repeat the above step for every e-signer.



11. Click the **Send** button located on the bottom right corner of the window to complete the signer assignment process. The system will trigger an email to the signers designated by you with a link to the document for eSignature.

    You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

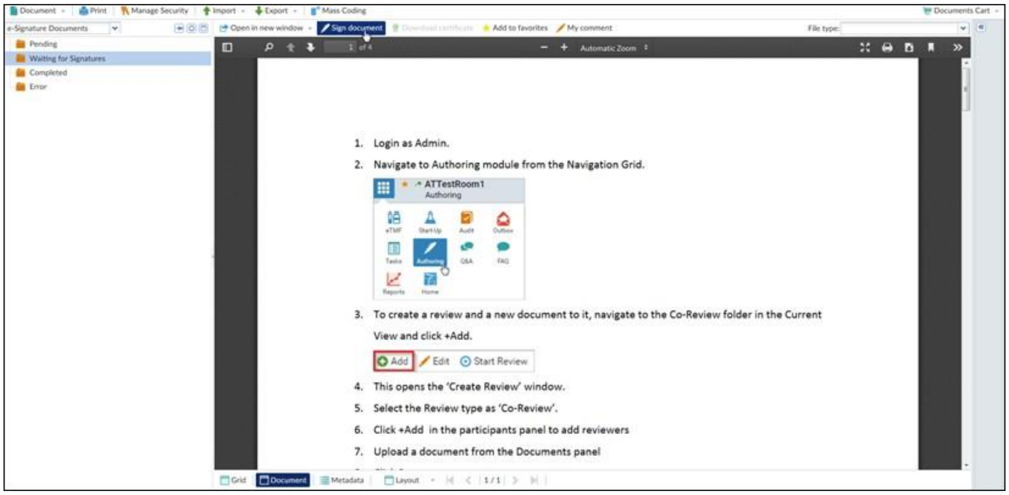
Signing the documents in Adobe Sign

If you are assigned to electronically sign a document, follow the steps mentioned here:

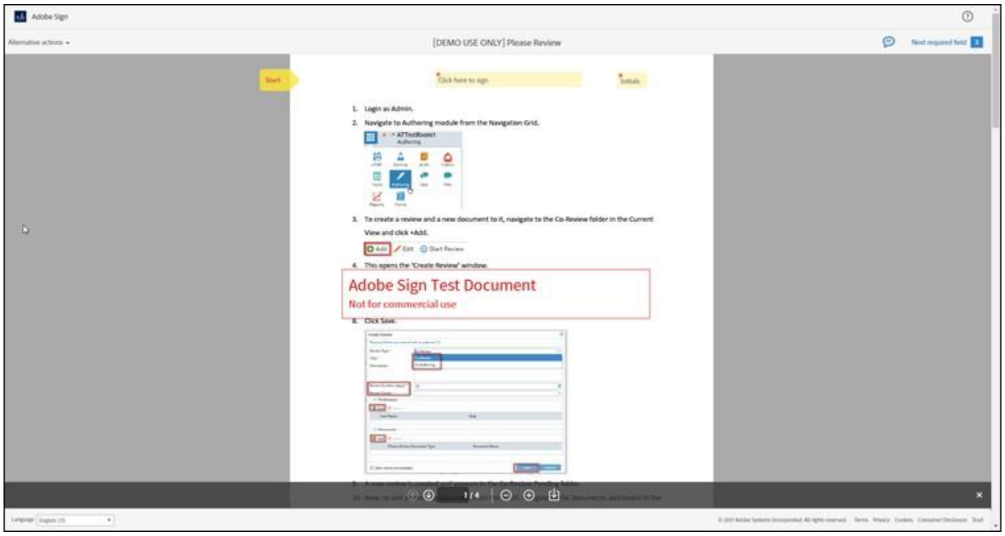
1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document. Alternatively, click the **Dashboard** tab and navigate to the **Documents to be signed** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

   You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature**view in the Index pane. Either way, click **Sign Document** to begin the review and signing process.

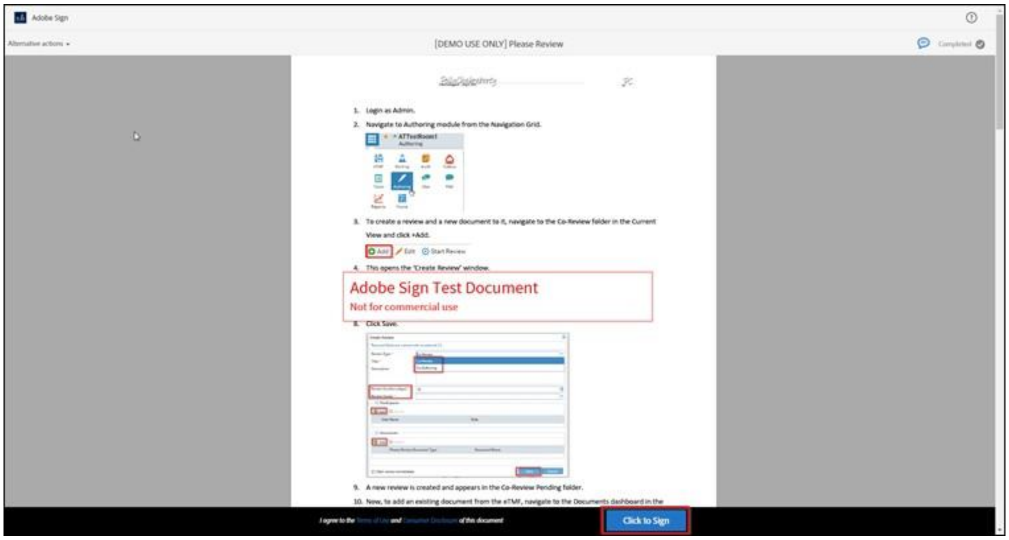
   If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Refer to the screenshot below:



3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.
4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document. Refer to the screenshot below:



5. Hit **Click here to sign** box. You will be prompted to choose your style for the signature (font, size, etc.)
6. Enter your signature and other details as required. Click **Apply.**
7. This will insert your signature. Hit **Click to Sign**. Refer to the screenshot below:



8. The document will move to the **Completed** folder under **e-Signature Documents**.

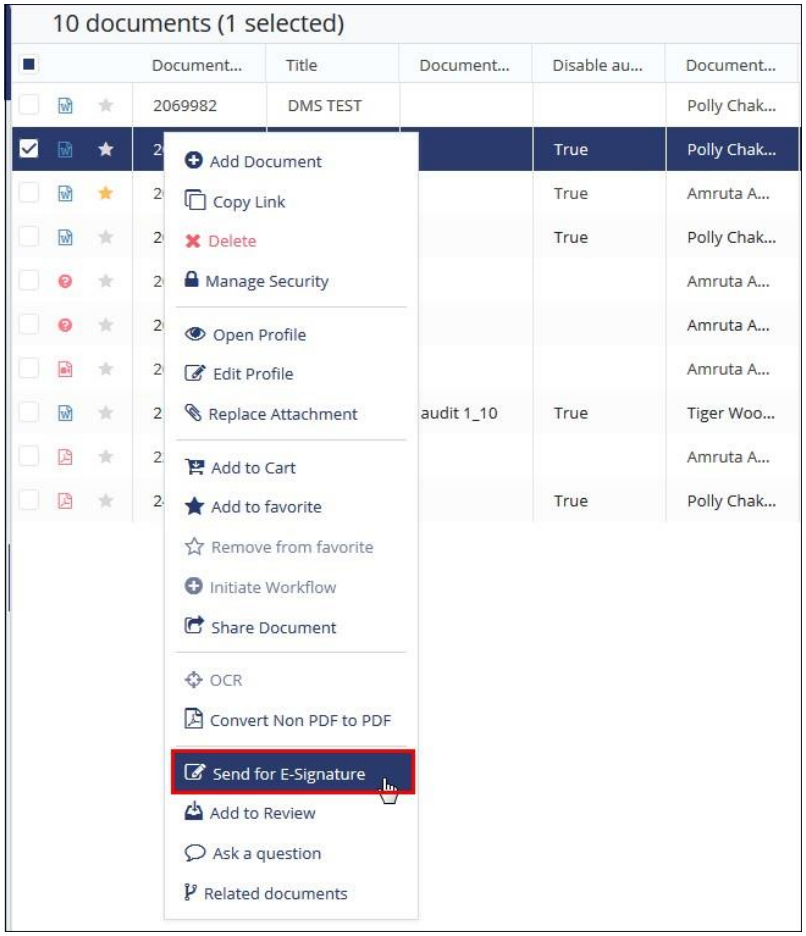
DocuSign eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

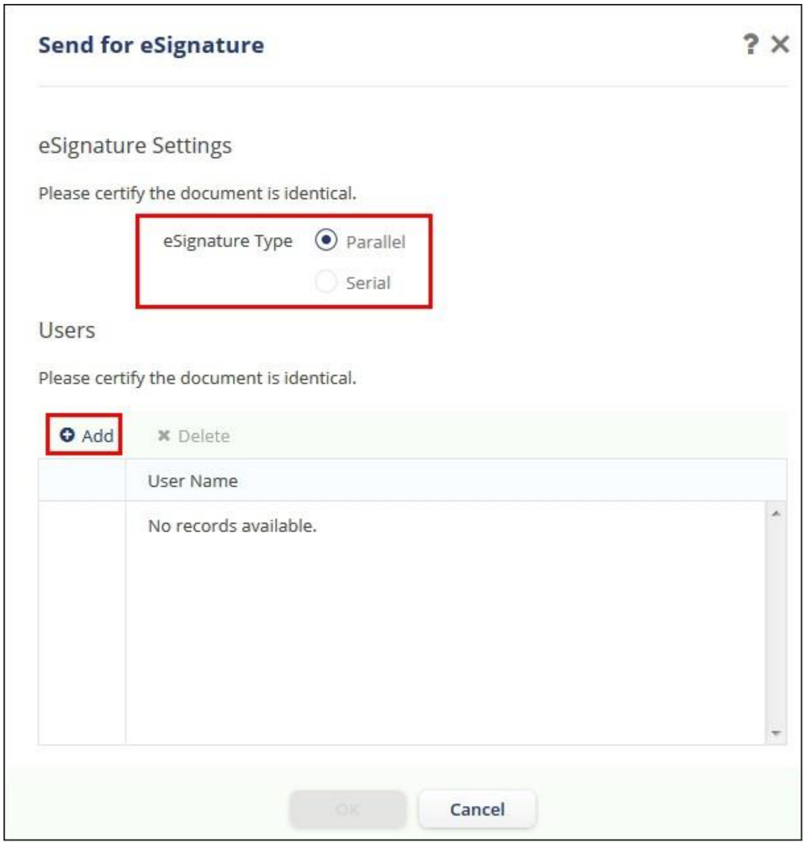
DocuSign - Assiging Signers to the Documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right-click the desired document and click **Send for e-signature**. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel *(page 268)* to the right.

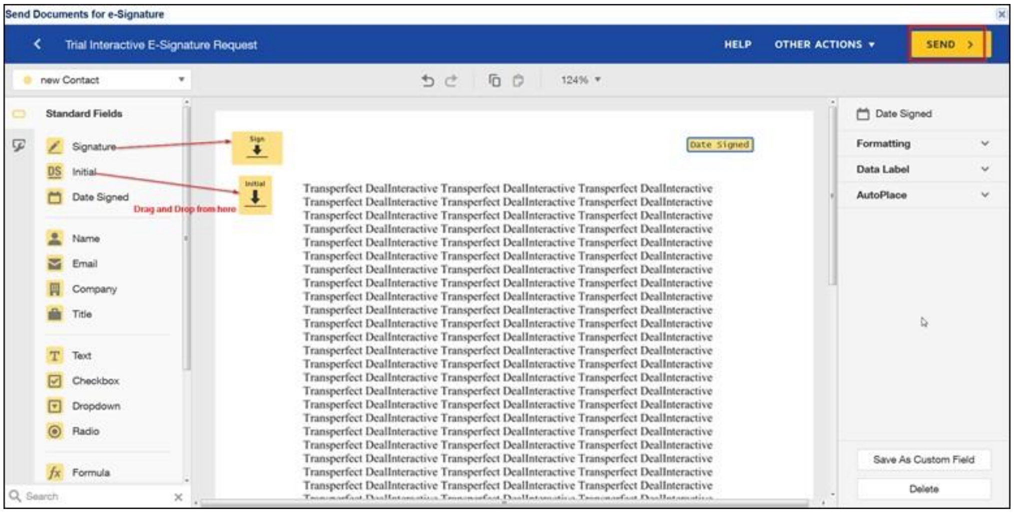
3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:



If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. A document preview window to determine the placement of the signatures with the designated recipient list on the left will display.

Select the desired recipient. Then drag and drop the fields on your document from the left menu option that you wish to be included in the signature. Repeat the above step for every e-signer. Refer to the screenshot below:



Click the **Send** button located on the top right corner of the window to complete the signer assignment process.

The system will trigger an email to the signers designated by you with a link to the document for eSignature.

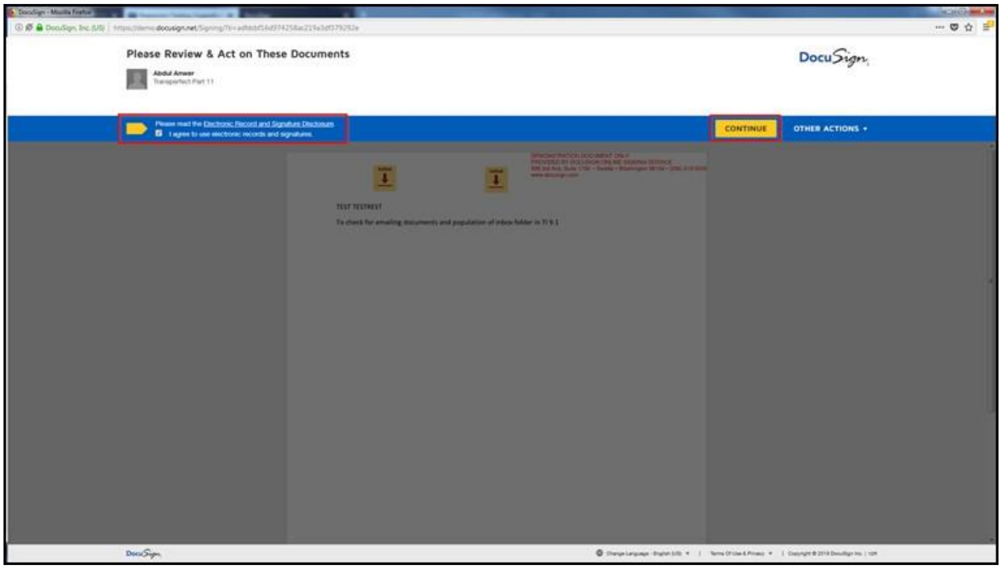
You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

Signing the Documents in DocuSign

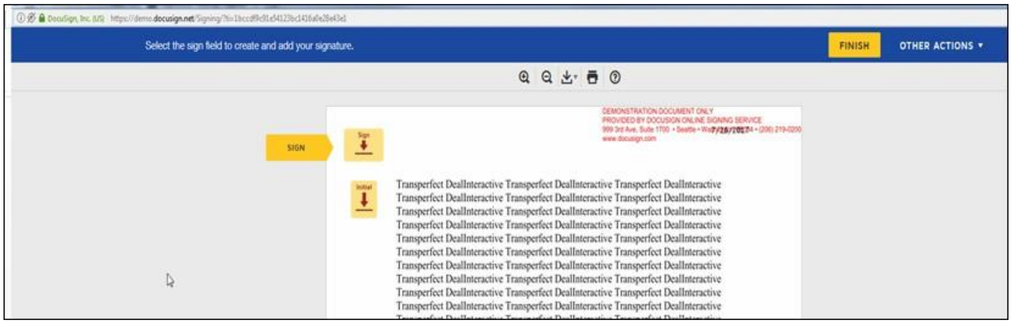
If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room. Alternatively, click the **Dashboard** tab in the eTMF module and scroll down to find the **Documents to be signed** dashlet.
2. Click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.
3. You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature**

Documents view in the Index pane. Either way, click **Sign Document** to begin the review and signing process. Refer to the screenshot below:



Click **Continue.** If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Click the **sign** icon. You will be prompted to choose your style for the signature (font, size, etc.). Refer to the screenshot below:



Click **Finish** to complete the eSignature process.

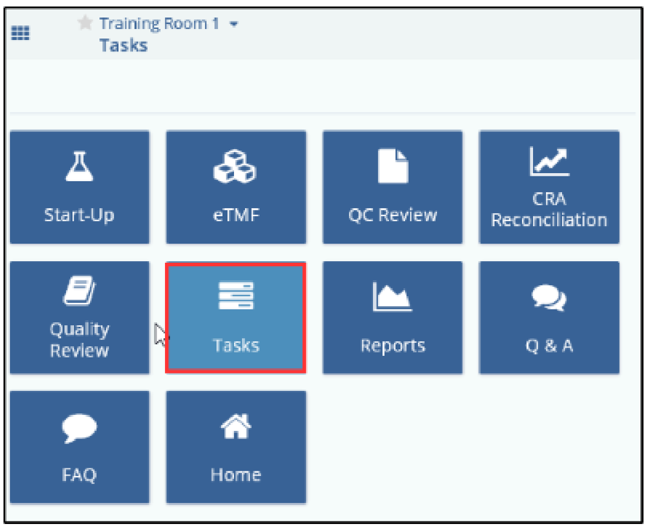
Chapter 19. Tasks

This section explains the tasks application that allow users to manage their Trial Interactive tasks for their rooms.

They are given an option to add, edit, delete, and export tasks. Additionally, administrators can adjust the number of days before a task's deadline for a user to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task.

As a Trial Interactive administrator, you can access Tasks as mentioned below:

1. **Enter the room** for which you want to create tasks from the **Home** page
2. Click the **Main Navigation – >App switcher**.
3. The popup with all the applications appear
4. Click **Tasks** icon.
5. You are taken to the **Tasks** page. Refer to the screenshot below:



The **Task Module** is explained in detail in separate section.

Tasks

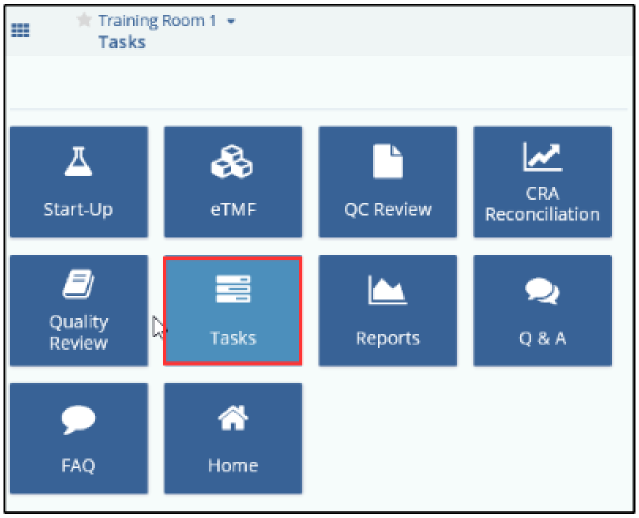
The Administrator would need to set up certain configurations for tasks in a room from **Main Navigation → Room Settings → Tasks.** These configurations are listed below:

1. Tasks
2. Tasks Category

Each of the options above is discussed in separate topics which can be accessed from the left panel of this help.

Tasks

1. Navigate to **Main Navigation->Settings->Tasks->Tasks**
2. Define a number of days from **IRB/EC submission reminder task [field] day(s)** option. Refer to the screenshot below:

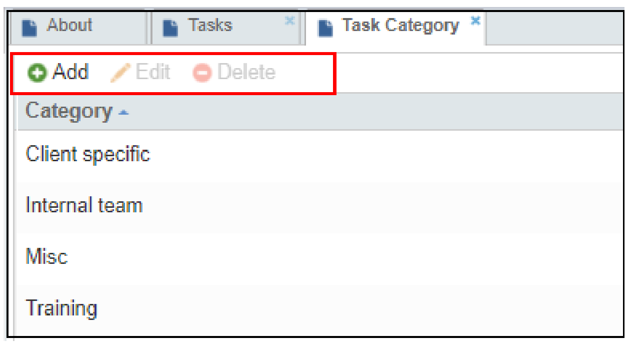


3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.

Task Category

Task categories need to be specified while creating a task. These task categories need to be created so that the user may select the appropriate category from the dropdown of the **Task Creation** window.

Tasks can be created, edited, or deleted through the buttons on the Task Category dashlet. Refer to the screenshot below:



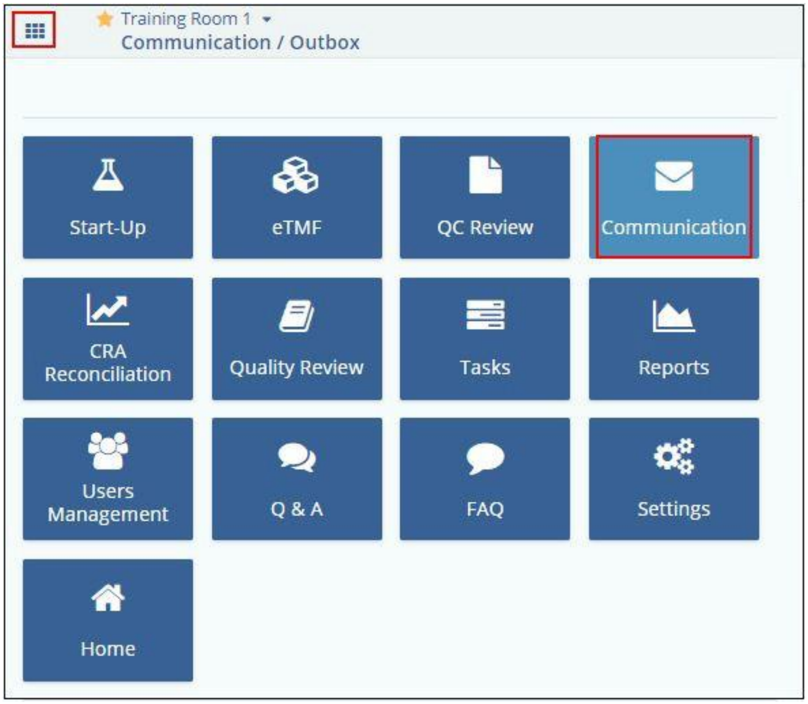
1. Click **Add** to add a task and press Enter.
2. Double-click a task, or select an existing task and hit the **Edit** button to edit a task. Press Enter after editing.
3. Select a task and hit the **Delete** button to delete it.

Chapter 20. Communications

This section explains the Communications module that automatize the manual process of managing emails and thereby reduce unnecessary workload.

The **Communications** module was introduced to cater to issues related to managing of emails in the Outlook mailbox that required teams with dedicated people to sift through the mailbox, pick out relevant mails, download them, convert them to PDF and then file them to the TMF. It incorporates the features of both the *Inbox* and the *Outbox* and comes with two views – **Outbox** and **Inbox**. You will have access to this module if it is activated for you.

You can access the Communications Dashboard from the Main Navigation by clicking the **Communications** icon. Refer to screenshot below:

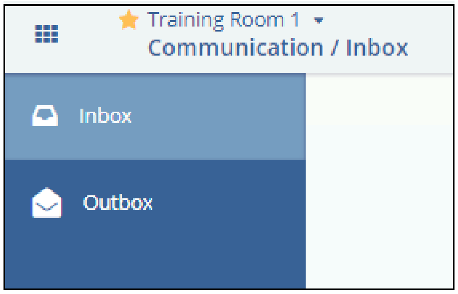


Click the links below for more details on each topic:

1. The Communications Dashboard
2. The Communications Inbox
3. The Communications Outbox
4. Exporting Mails

Communications Dashboard

Once you enter the **Communications** Dashboard, you will have access to both the **Inbox** and the **Outbox** views from the left menu. Refer to the screenshot below:



Communication Inbox

From this section, you can perform the following:

1. The Inbox Settings
2. The Inbox Process

   Each of the above topics is discussed in the separate topic and can be accessed from the left menu of this help.

Communication Inbox Process

Below is the process for communication inbox:

1. After enabling the feature from the Inbox Settings *(page 93)*, all the emails sent to the Communications Inbox are deposited here whereas emails sent to the eTMF inbox will be deposited to inbox.
2. Depending on the settings of the **Communications Inbox**, the email processing service converts the email into a PDF file; the Subject and date of the email are used to form the **Submitted Name** of the file.

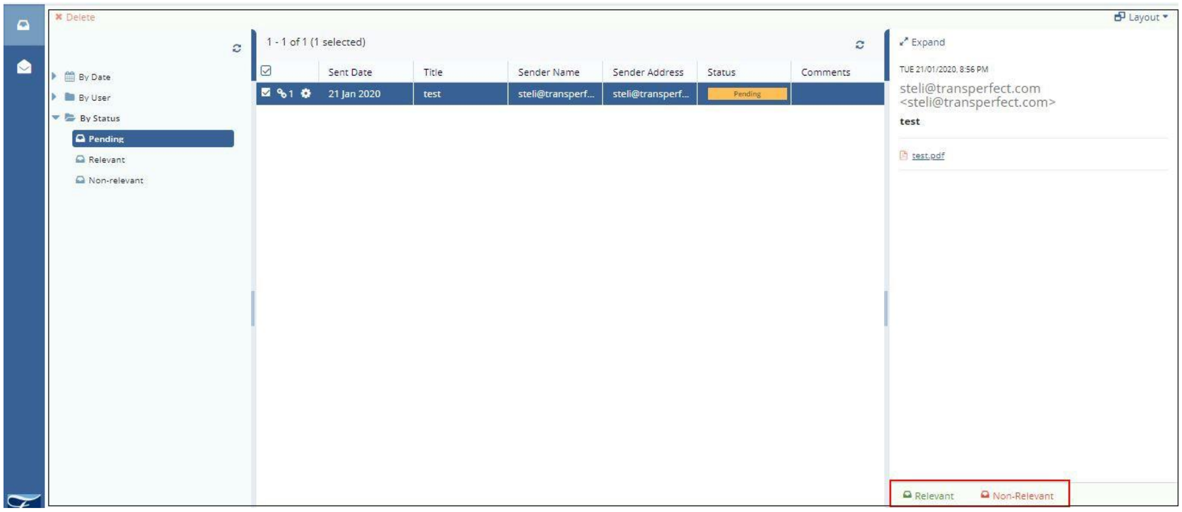
   Note: *The settings that need to be activated to convert an email to PDF is Convert email body*.

3. If there are any attachments to the email. They are also converted into PDF files (based on room settings) and automatically linked to the email PDF.

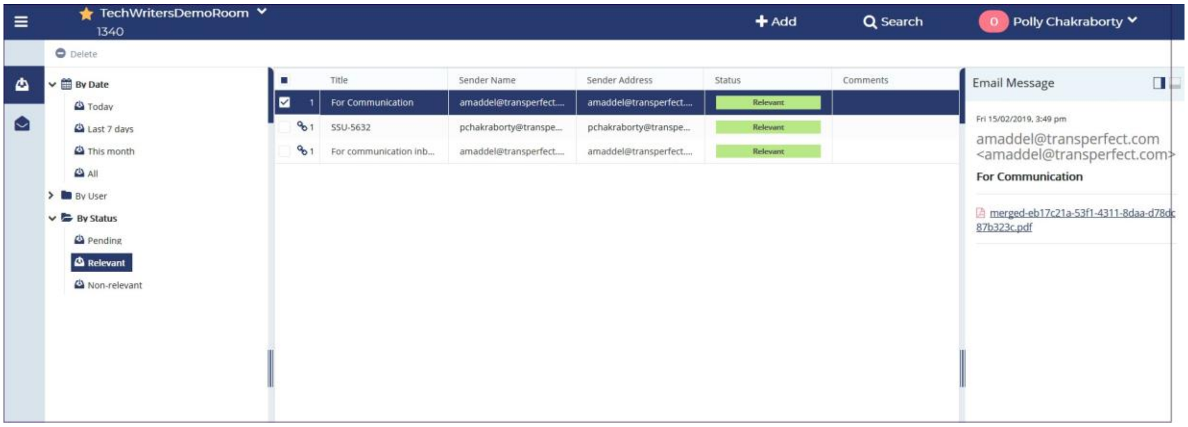
   Note: *The Settings that need to be activated to link attachments to the email PDF is Merge attachments*.

4. Any attachment that cannot be rendered into PDF is left in its original format.
5. The email PDF file, along with its attachment(s), if any, are stored in the **Communications Inbox** folder.

6. In the Communications Inbox, the email document is stored in the **Pending** sub-folder from where the editor can mark them as **Relevant** or **Non-Relevant**. Refer to the screenshot below:



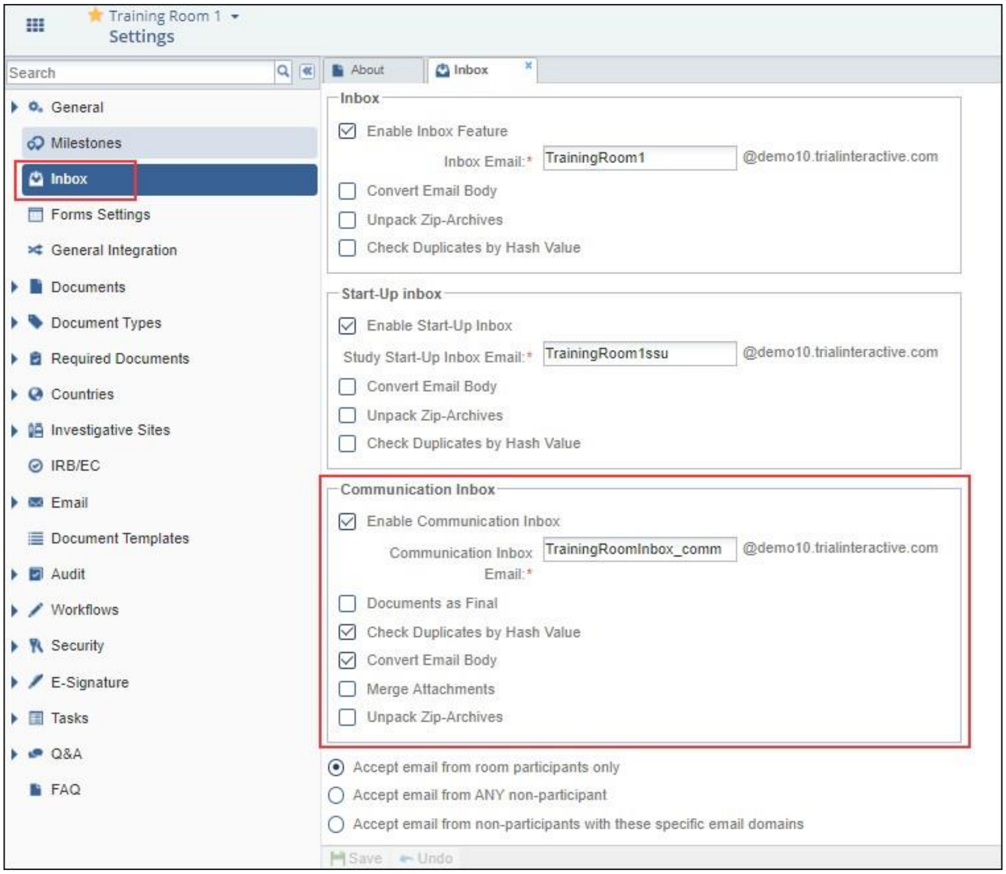
7. The documents that are marked as **Relevant** are coded by the editor in the **Document Profile** form with data such as category, document type, site, and other relevant data based on the document type selection.
8. Once the editor codes the document and saves it, the document will move to the **Relevant** folder in the Inbox View. The Metadata fields are now non-editable. Refer to the screenshot below:



9. Based on the room settings, the document will be published as final or will go to the default folder and the Quality Review Workflow where the reviewers will claim the documents, approve them, and file them to the eTMF.
10. The documents that are marked as **Non-Relevant** are moved to the **Non-Relevant folder** of the Communications Inbox module and can be deleted by the Administrators, if required.

Communication Inbox Settings

To enable the Communications Inbox feature, navigate to **Main Navigation → Settings → Communication Inbox**. Refer to the screenshot below:



1. To enable the **Communications Inbox**, tick the checkbox next to it. These emails can be located in the Inbox from the **Communications Module.**
2. If you choose to file email converted documents to the eTMF as Final, tick the checkbox **Documents as Final next to it**.
3. Enable the **Merge Attachment** option to merge attachment into one document. To commit the changes, click **Save**.

Communication Outbox

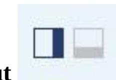
Documents or messages emailed from a Trial Interactive room are stored in the **Communication Outbox.** Details on how to email is discussed in detail in section **Email *(page 143)***

The Communication Outbox is the holding area of messages or emails that are sent out from a Trial Interactive room. The left pane of the **Outbox** module gives the **views** of the emails **By Date** and **By Type.**

Besides, you can also export communication emials.

Communication Outbox Email Message Window

Double click a message in the grid, or check the checkbox to display the **Email Message** window at the extreme right of the dashboard. This window gives the complete metadata of a message including its body, sender, receiver, subject, sent date, and attachments. Refer to the screenshot below:

You can also change the layout of the email message window by clicking the **layout**  buttons at the top right corner

of the message window.

Communications Outbox Views

You can sort the emails in the following ways:

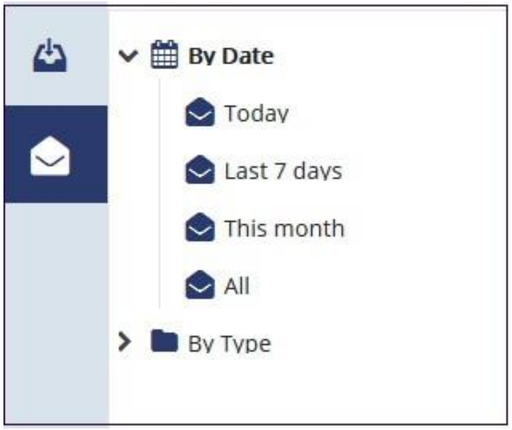
1. By Date
2. By Type

Each of these is discussed in the sections below:

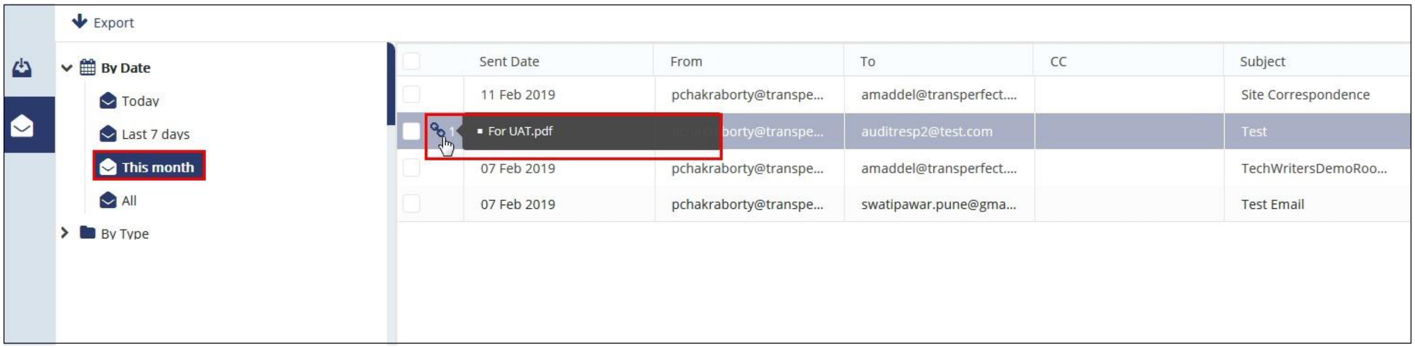
By Date

This section provides the segregation of mails by the period of:

1. Today
2. Last 7 days
3. This month, and
4. All mails.



Click a period to view the communications for that period in the right pane of the dashboard. The screenshot below shows all the communication for the current month.

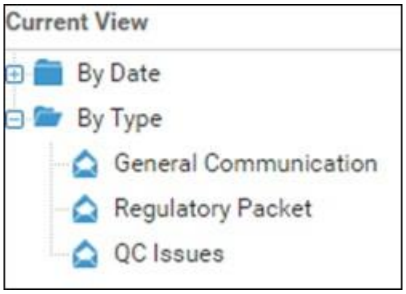


The **link** icon  with a number next to the **Sent Date** shows the number of attachments in the mail. Hover the mouse on the icon to view the attachment name.

By Type

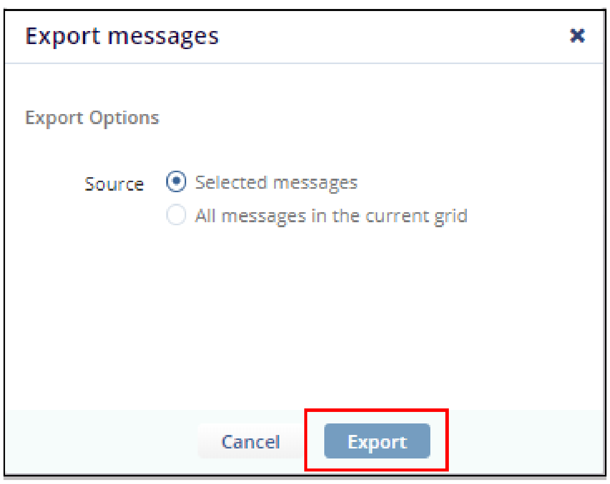
This section provides the segregation of mails by their types:

1. General Communication
2. Regulatory Packet
3. QC Issues



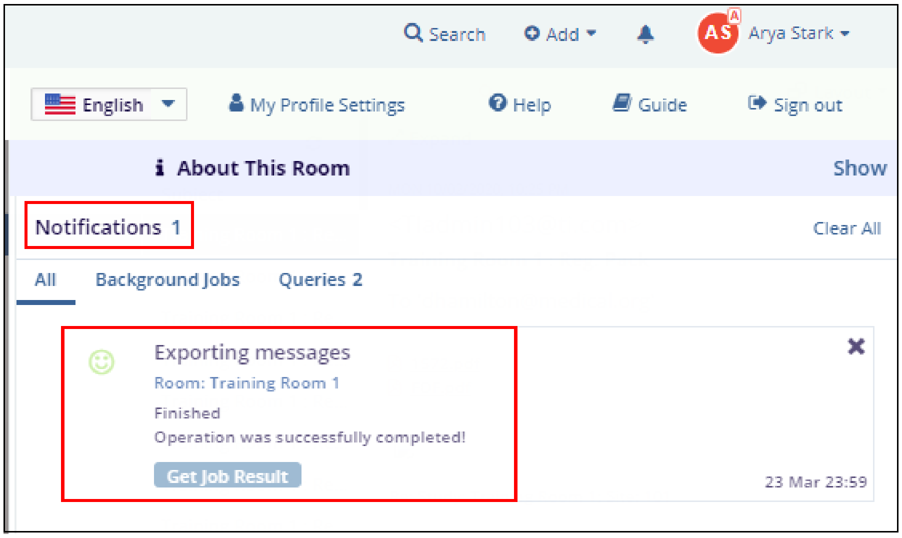
Export Communication Emails

You can export mails by clicking the **Export** icon on the top ribbon bar. This will open the **Export messages** window. You can export all messages in the current grid, or only selected messages. Refer to the screenshot below:



The confirmation of the export job is displayed in a popup at the top of the grid.

You can **GetJob Result** from the **Notifications.** *(page 64)* The export job result is saved as a .xlsx file. Refer to the screenshot below.

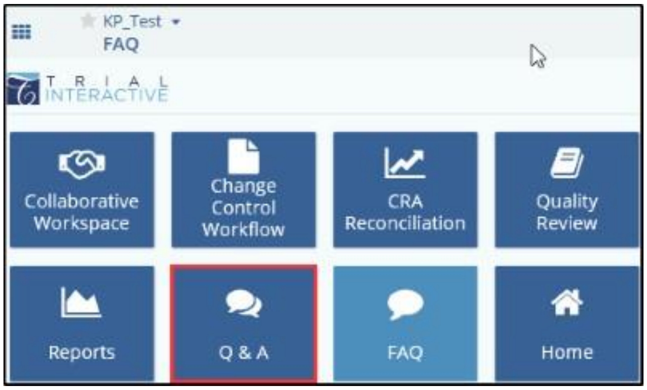

Search
Add
Arya Stark
English
My Profile Settings
Help
Guide
Sign out
About This Room
Show
Notifications 1
Clear All
All
Background Jobs
Queries 2
Exporting messages
Room: Training Room 1
Finished
Operation was successfully completed!
Get Job Result
23 Mar 23:59

Chapter 21. Q&A

This section enables you to view the list of questions asked and answers given by users in a room besides creating them.

Remember: The Q&A functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.

From the Main Navigation select **Q&A** to reach this dashboard. Refer to the screenshot below:



From within the _Q&A_ dashboard, you can:

1. Viewing Questions and Answers
2. Create questions
3. Create answers
4. Convert them to FAQ
5. Export Q&A
6. Delete questions and answers

General

The **Q&A** functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.

Through the **Q&A settings** view, you can add, edit, or delete **Question Levels**. In the **Q&A** configuration panel, you can enable and disable three Q&A options: the ability to delete questions and answers, the activation of Subject Matter categories, and the activation of questions issue levels.

To access the Q&A Settings:

1. Navigate to the **Main Navigation**-> **Settings Module**
2. Go to **Q&A**

From this section, we discuss :

1. Configurations for questions and answers
2. Adding Editing and Deleting Question Levels

   All of the above are discussed in separate topics accessible from the left panel of this help.

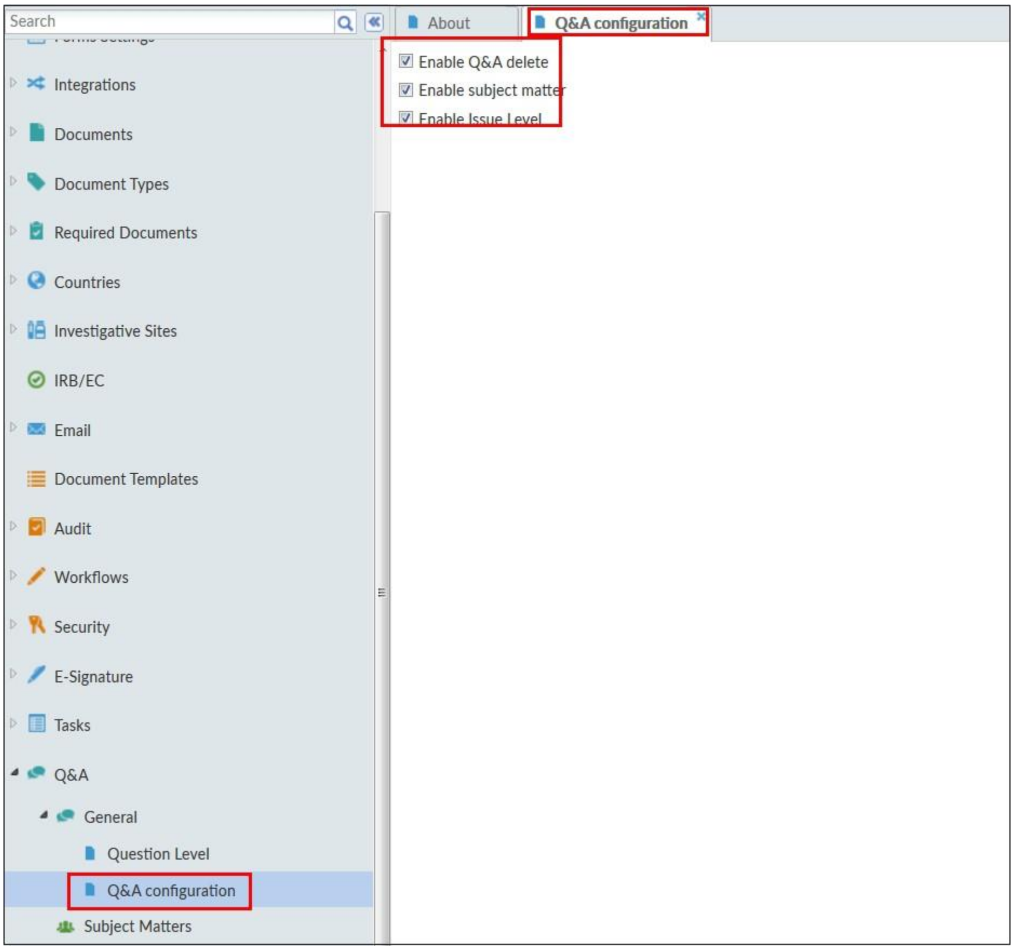
Q&A Configuration

From here, you can enable and disable the following three options:

1. The ability to delete questions and answers.

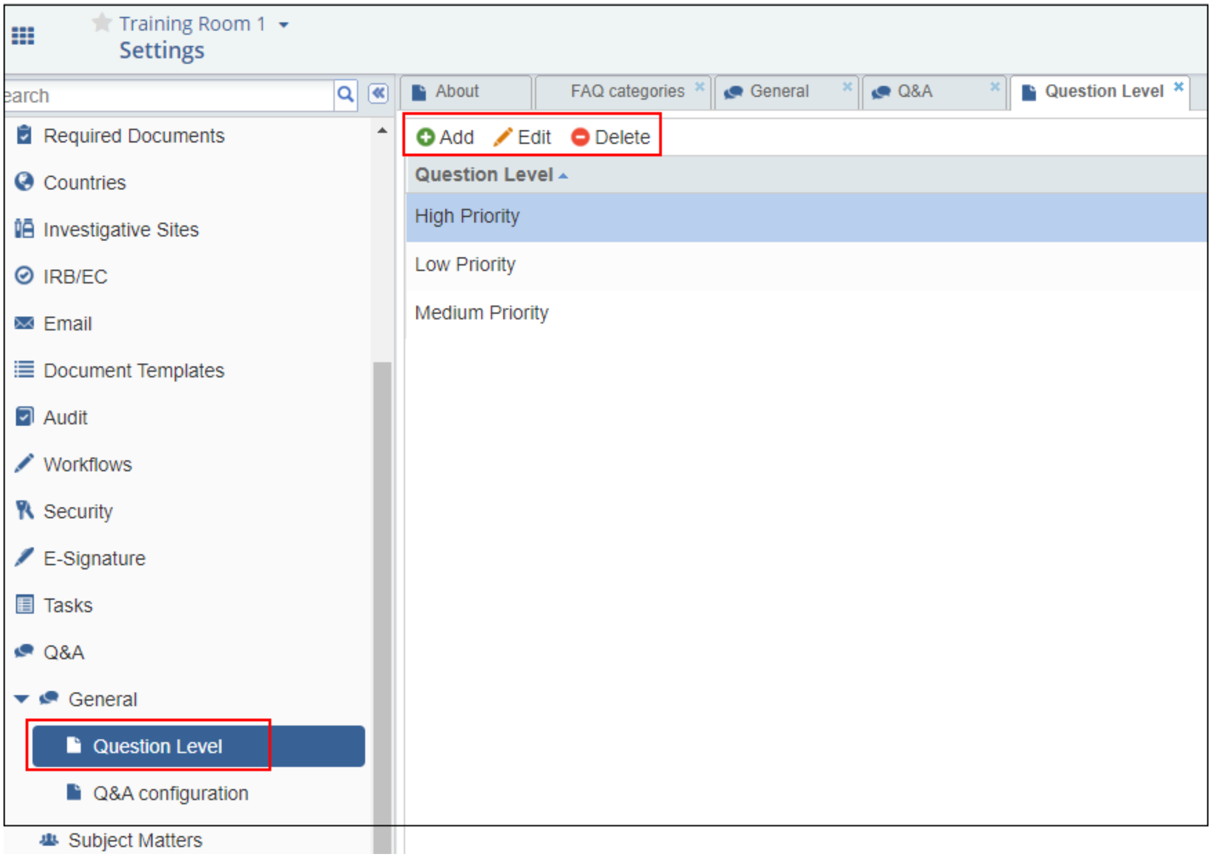
2. The activation of Subject Matter categories.
3. The activation of question issue levels.

Refer to the screenshot below:



Q&A Question Level

From here, you can create a list of issues that are associated with the documents. Administrator can set these issues as per the client request. These issues are then assigned to **Subject Matter Experts** who can answer the question. Refer to the screenshot below:



From here, you can perform the following:

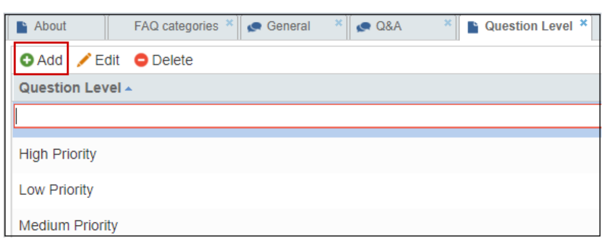
1. Adding New Question Level
2. Editing a Question Level
3. Deleting a Question Level

Each of these is discussed in the sections below:

Adding New Question Level

To add a new question-level:

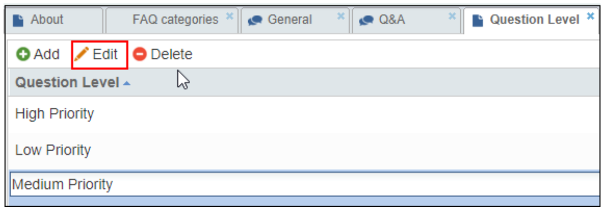
1. Click **Add** from the top ribbon.
2. A new row appears in the grid below.
3. Enter the question level. Refer to the screenshot below:



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.
2. The field becomes editable.
3. Edit the details as required. Refer to the screenshot below:



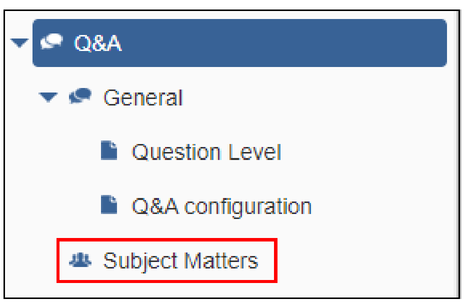
Deleting a Question Level

To delete a question-level:

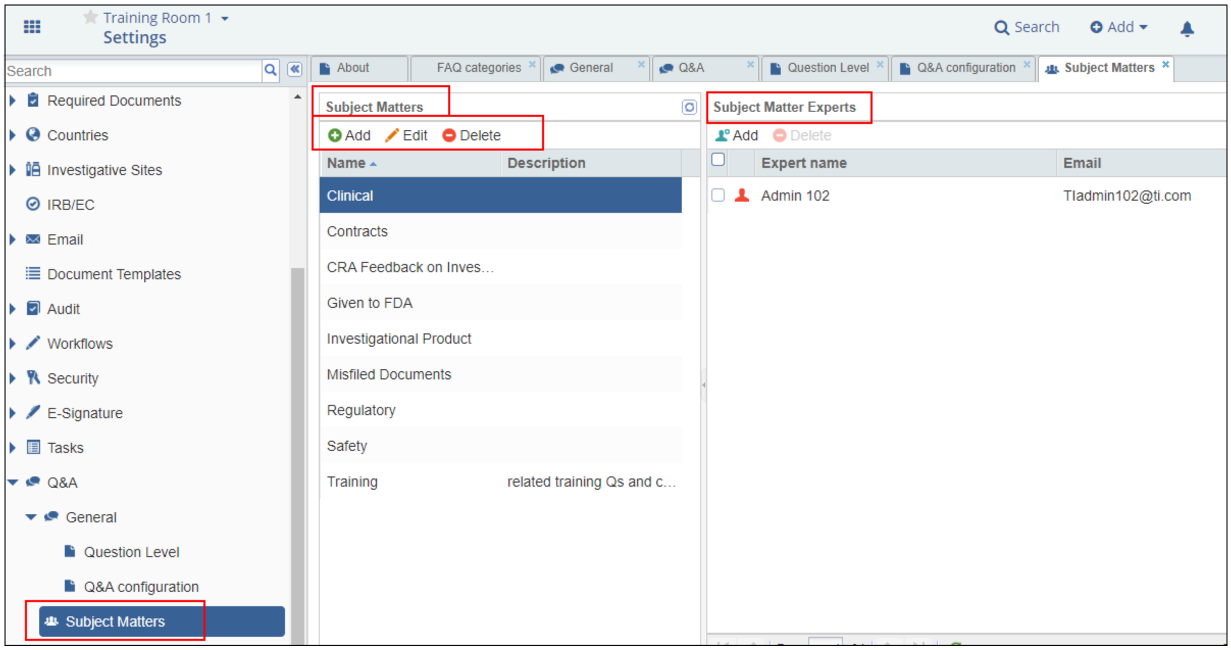
1. Select the level and click **Delete** Delete from the top ribbon to delete it.

Question Subject Matter

If **Subject Matter** was enabled in the Q&A Configuration *(page 179)*, another set of options for **Subject Matters** is activated. You can access this option from the Q&A menu in the left panel of the Room Settings *(page 85)*. Refer to the screenshot below:



Clicking **Subject Matters** from the Q&A menu opens the **Subject Matters window** in a separate tab. Refer to the screenshot below:



This window consists of two panels:

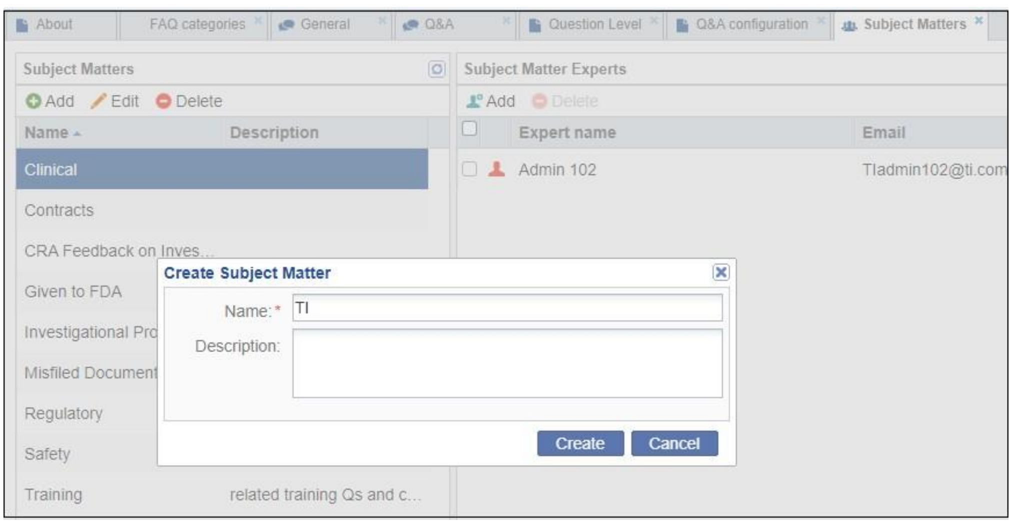
1. **Subject Matters panel** from which **Subject matter categories** can be added, edited and deleted.
2. **Subject Matter Experts panel** from which **Subject Matter Experts** can be **assigned to** or **unassigned from** the specific Subject Matter Categories. In this way, questions from particular categories can automatically be channelled to subject matter experts when the questions are submitted in the room.

All of the above are discussed in subsequent sections below:

Adding Subject Matters

To create Subject Matters:

1. From the **Subject Matters panel** toolbar, click **Add**.
2. The **Create Subject Matter window** opens. Refer to the screenshot below:

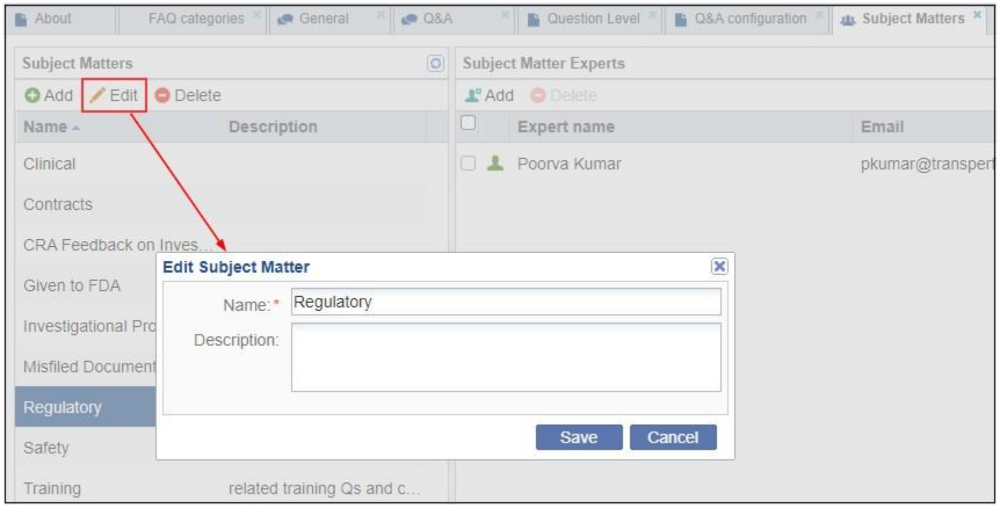


3. Type the name of the Subject matter category in the **Name** field. The **Name** field is required; the **Description** field is optional.
4. Click **Create** at the bottom of the window. The new Subject Matter category is added to the list.

Editing Subject Matters

To edit Subject Matters:

1. From the **Subject Matters panel,** click on a **Subject Matter category** to select it.
2. From the **Subject Matters panel** toolbar, click **Edit**.
3. The **Edit Subject Matter window** opens. Refer to the screenshot below:



4. Edit the **Subject Matter Category name** and **Description**; click **Save**.
5. The changes are committed and visible in the list of categories.

Deleting Subject Matters

To delete a Subject Matter category:

1. From the **Subject Matters panel,** click on a **Subject Matter category** to select it.
2. From the **Subject Matters panel** toolbar, click **Delete**.
3. The **Subject Matter Category** is removed from the list of categories.

Assigning Subject Matter Experts to Subject Matters

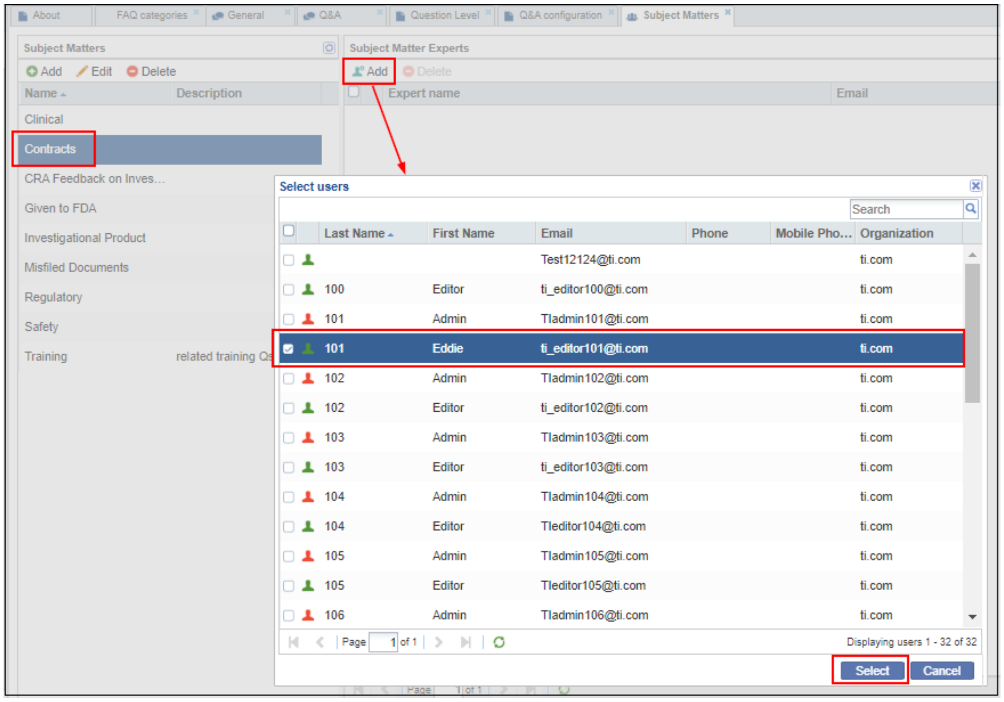
To assign a Subject Matter Expert to a specific subject matter, select a subject matter from the list on the left.

1. Click the Name of the **Subject Matter**. The subject matter category name is highlighted in light blue.
2. Click the **Add** button from the **Subject Matter Experts** panel toolbar.

   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.

3. Click the checkbox next to the name of the user you want to assign to the expert role.

4. Click **Select** at the bottom of the window. The changes are automatically saved. Refer to the screenshot below:



Now, when a user asks a question and assigns it to the Q&A category and the Subject Matter while creating the question, the assigned expert will be notified of the question that needs 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**. The subject matter category name is highlighted in light blue.
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.
4. Click **Delete** from the toolbar. The names of the Subject Matter Experts gets deleted from the list.

Chapter 22. Collaborative Workspace

Collaborative Workspace is repository for the project management related documents, some of the documents in this room will be moved to eTMF room. Collaborative workspace have a reference to a study room.

The Trial Interactive Collaborate solution, also known as Shared Workspace, is a Clinical Collaborative Workspace Solution for clinical teams to provide Sponsors, CROs, and Sites a place to share and author documentation to be used in the Clinical Trial and ultimately archived in the eTMF.

An integral part of TI Collaborate, TI Collaborative Authoring will provide end-users the capability of directly editing MS Word, Excel, and Powerpoint documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

There are two types of rooms associated with Collaborative Workspace

TI Docs

TI Collaborate

TI Docs and TI Collaborate both have the ability to edit the documents online. TI Collaborate acts as Content management tool that is linked to the TMF . TI Collaboarate asks 'Is this a TMF document?' while publishing the documents. With TI Collanorate the users can also publish the documents to any other room that is not associated to Collaborative Workspace.

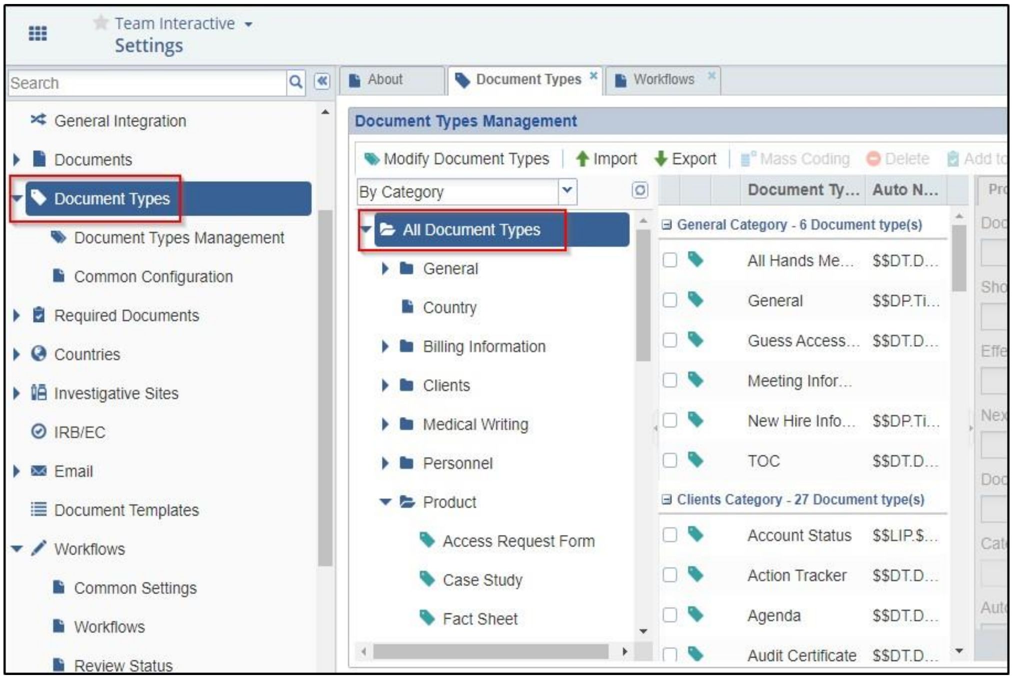
While TI Docs doesn't have any link to TMF, nor it can publish the same to any other room. However, the documents can be copied to other rooms.

Important: *To enable Collaborative Workspace room, contact the Helpdesk.*

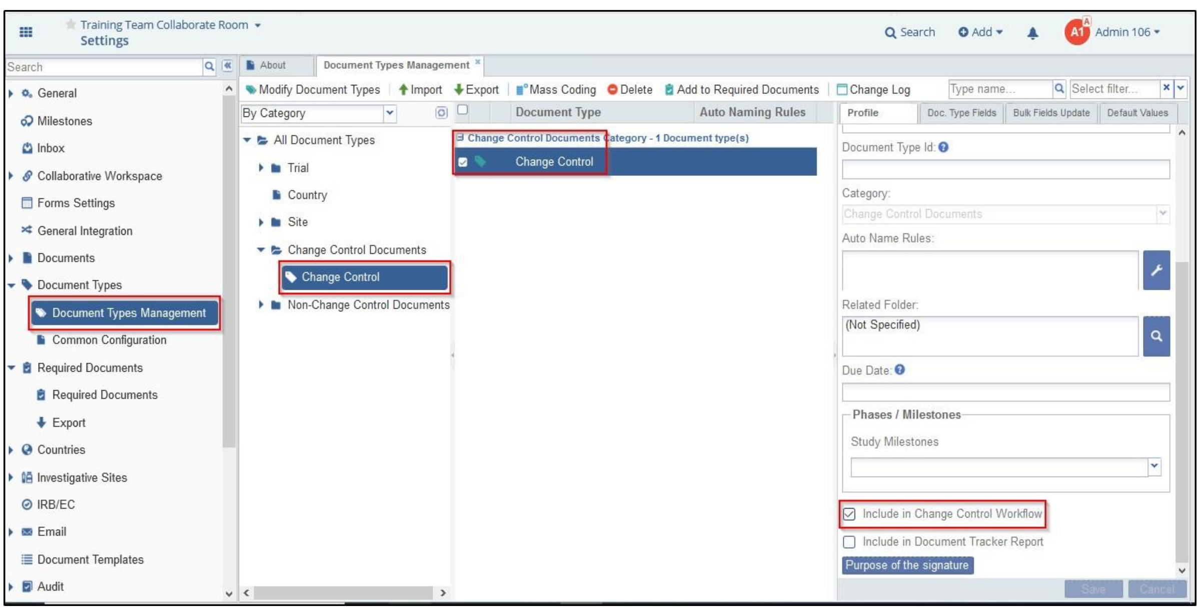
Room Configurations that impact Room Types

The room configrations that impact the room types TI Docs and TI Collaborate are described below.

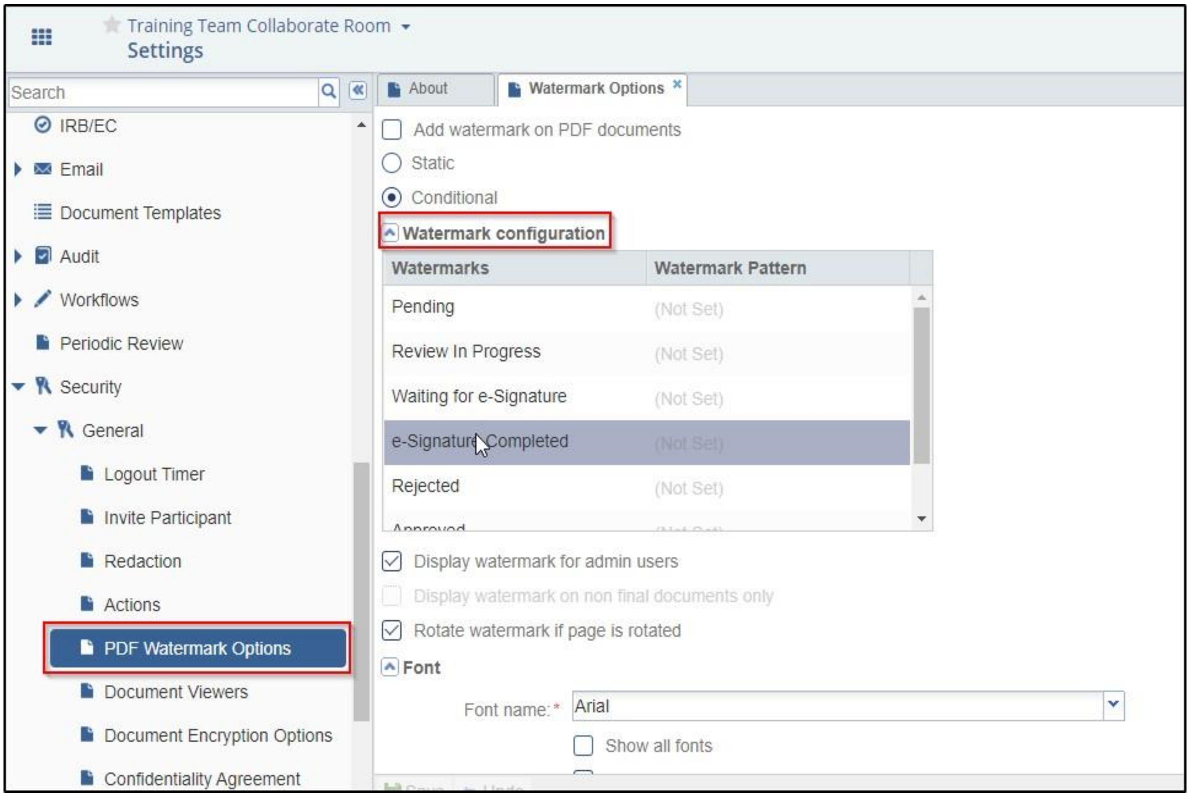
1. Document Type - The document types settings can be configured via Settings>Document Types>All Document Types>. Refer the screenshot below:



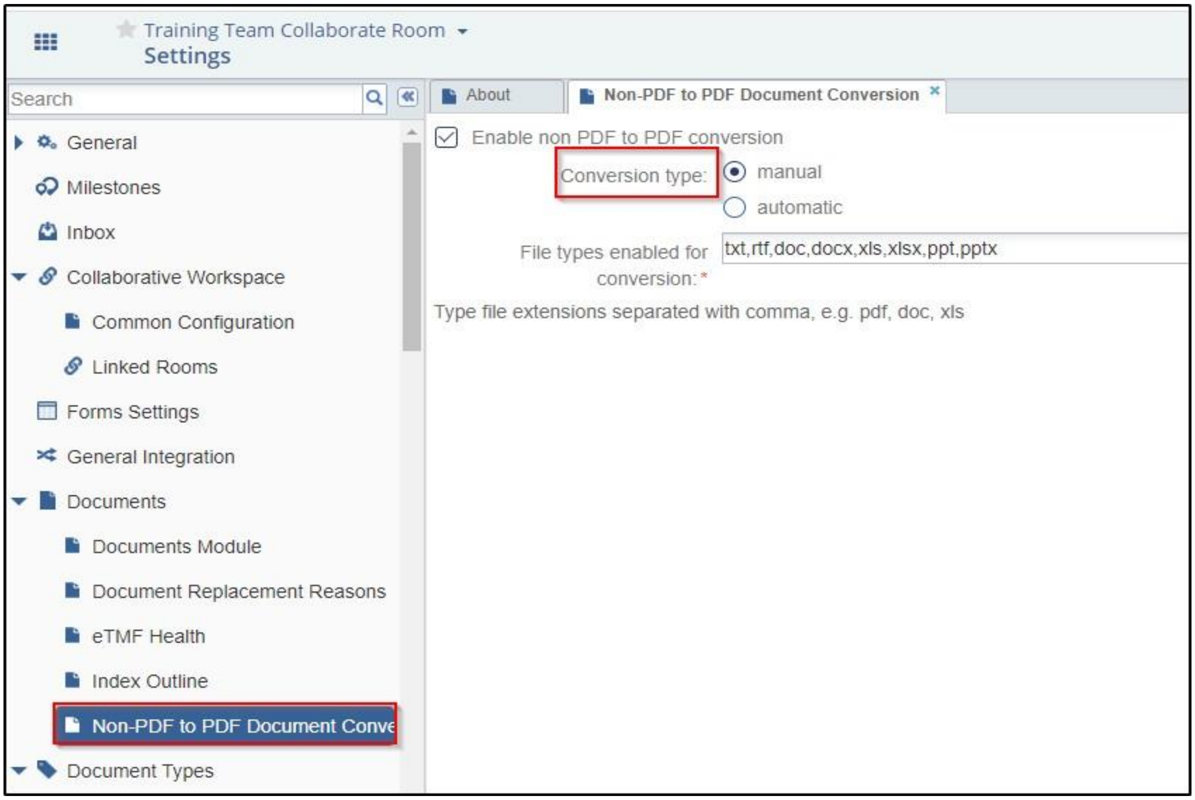
2. Change Control workflow- The checkbox says this doc type can be initiated in the change control workflow. Change control workflow only allows the versions up of the documents. In the profile tab, the users can define the periodic review period and effective period.Configuring this can be seen in the screenshot below.



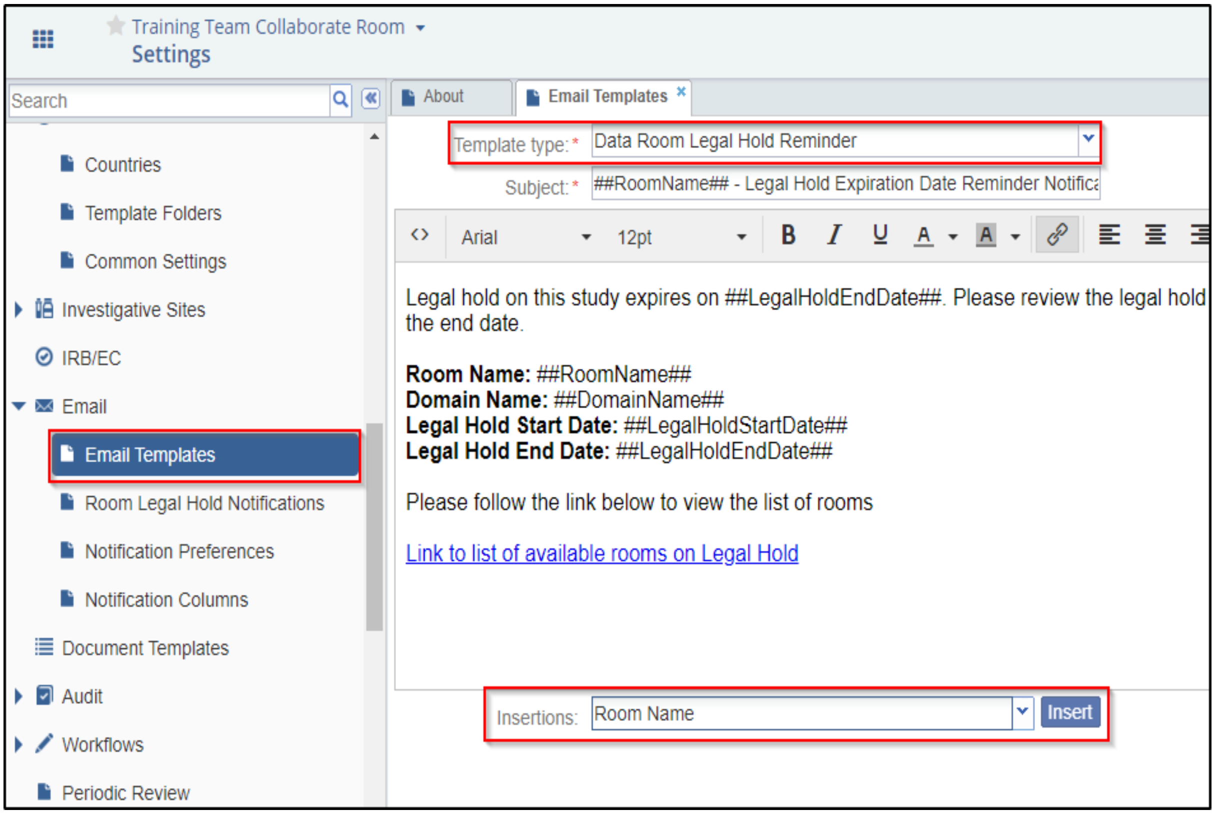
3. PDF Watermark- To insert a PDF watermark, go to Settings> Security>General> PDF Watermark Options and select the Watermark Configuration. Refer the screenshot below.



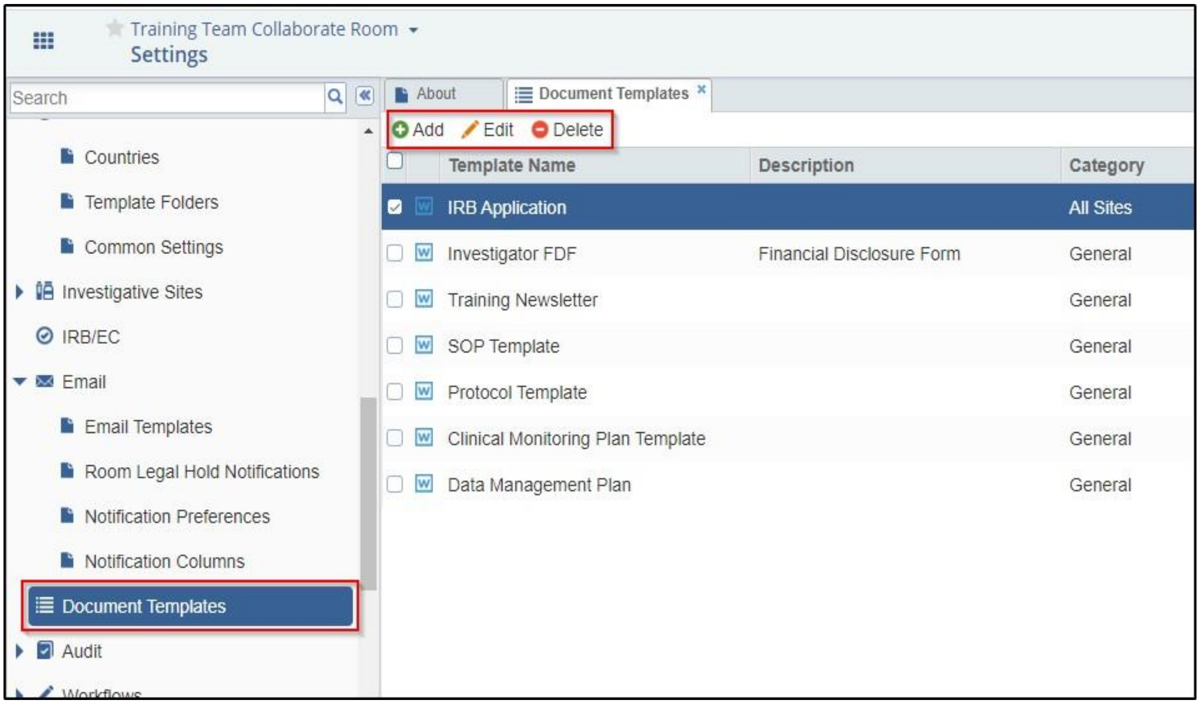
4. Converting Documents -Non PDF to PDF- To convert non PDF documents to PDF, go to Settings>Documents>Non PDF to PDF Document Conversion and select the coversion type.



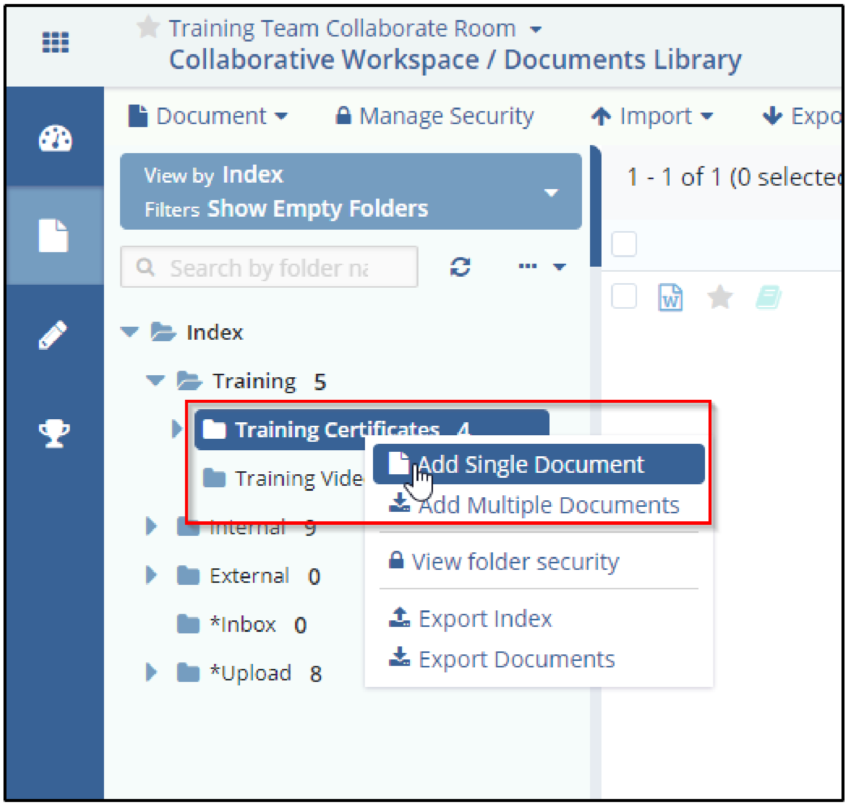
5. Email Templates- To define Email templates, go to Settings>Email>Email Templates. Select the Template Type from the dropdown list available. You can also select email template insertions from the insertions dropdown and click Insert. Refer the screenshot below.



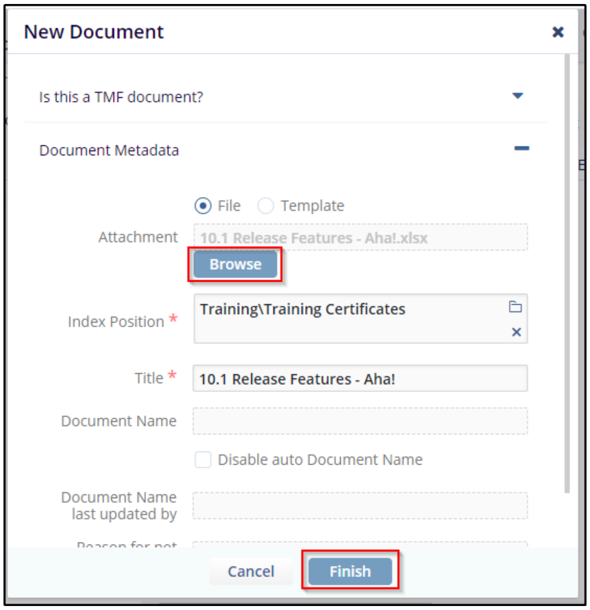
6. Document Templates- To define document templates, go to Settings>Document Templates. Click Add button to add a new document template. You can also edit or delete an existing document template. Refer the screenshot below.


Training Team Collaborate Room
Settings
Search
Countries
Template Folders
Common Settings
Investigative Sites
IRB/EC
Email
Email Templates
Room Legal Hold Notifications
Notification Preferences
Notification Columns
Document Templates
Audit
About
Document Templates
Add
Edit
Delete
Template Name
Description
Category
IRB Application
All Sites
Investigator FDF
Financial Disclosure Form
General
Training Newsletter
General
SOP Template
General
Protocol Template
General
Clinical Monitoring Plan Template
General
Data Management Plan
General

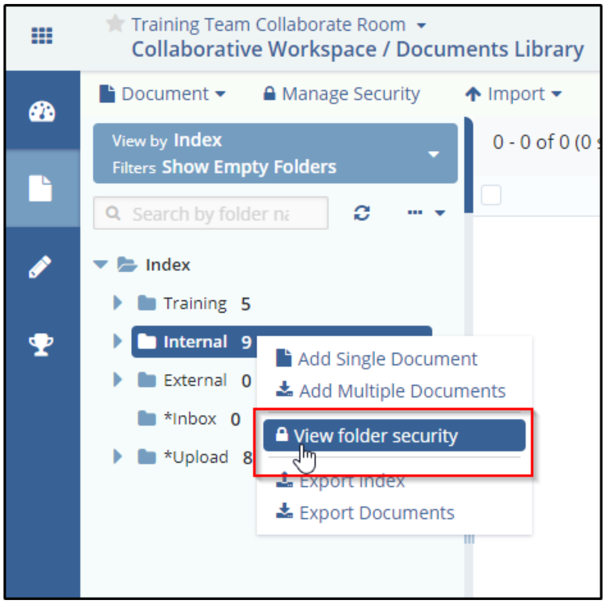
Document Upload-A document or template can be uploaded in the Collaborative Workspace. Choose the desired folder from the index view and right click to add a document. Refer to the screenshot below.

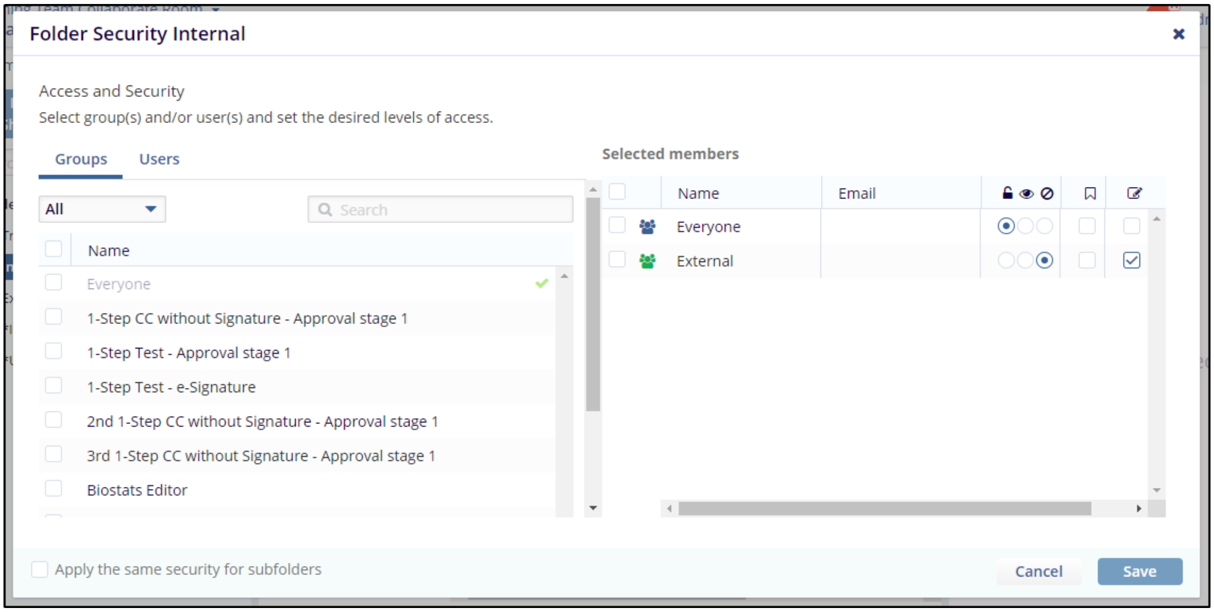


Clicking 'Add single document' tab will open a 'New Document' pop up. Select the option for the question 'Is this a TMF document?', attach a document or a template, fill the essential metadata fields, and click 'Finish' to complete the upload. Refer to the screenshot below:

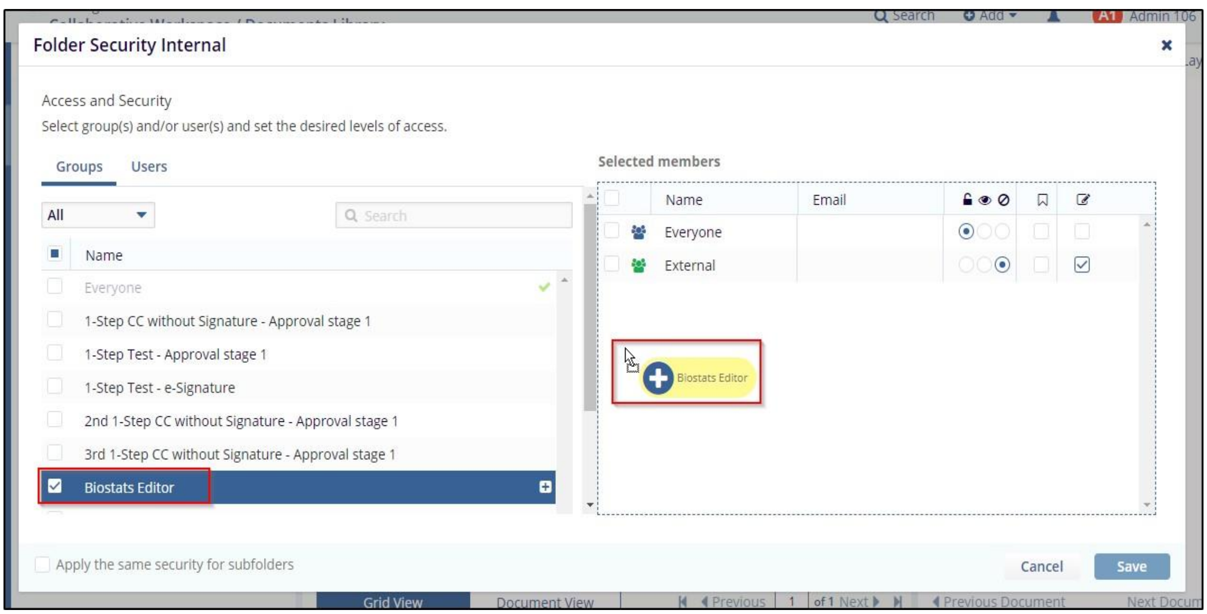

New Document
Is this a TMF document?
Document Metadata
File
Template
Attachment
10.1 Release Features - Aha!.xlsx
Browse
Index Position *
Training\Training Certificates
Title *
10.1 Release Features - Aha!
Document Name
Disable auto Document Name
Document Name last updated by
Cancel
Finish

Folder Level Security- To view and edit folder level security, right click a folder available in the index view and choose the option 'View Folder Security'.
Clicking the option 'View folder security' will open a popup window titled 'Folder Security Internal'. Refer the screenshot below.

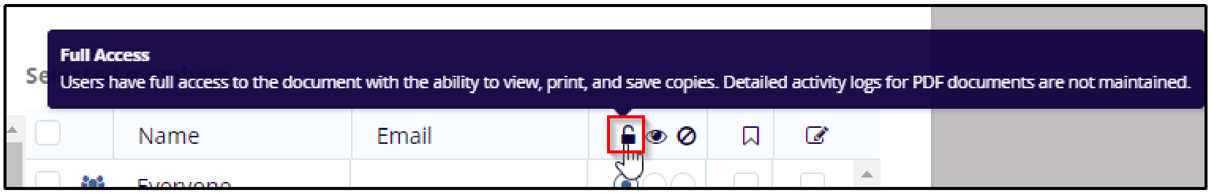




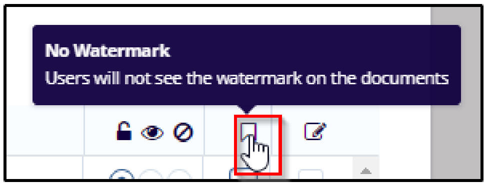
Managing folder security- You can manage group folder security and Users security. To manage the group security, select a group from the available list by checking the checkbox. Drag and drop the group to the selected members ist available at the right side of the screen. Refer the screenshot below

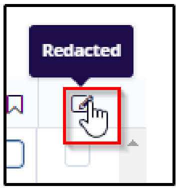


In the selected members section, you can define the access level to the selected groups by checking the radio buttons available under the icons. Each icon has its access defined. Hover over the icon to see the access as shown in below



screenshots



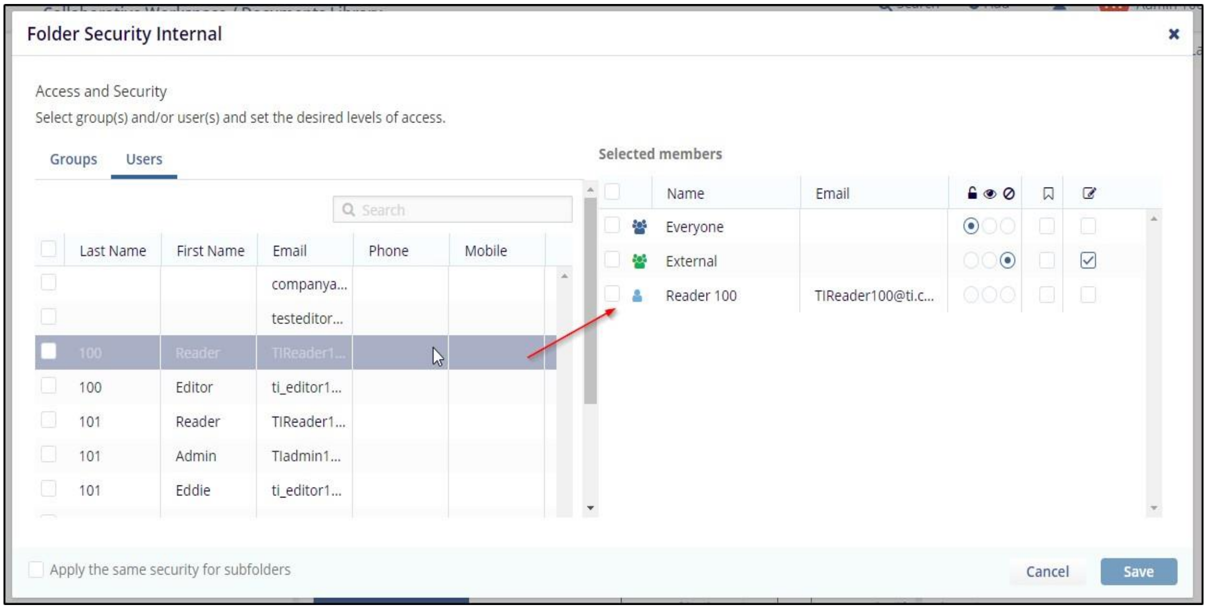


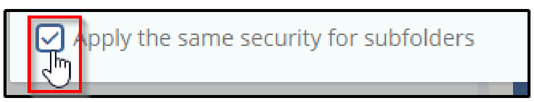
Manage user security- To manage user security, go to Users, drag and drop a user from the list to selected members section.

Managing the access for the selected users is same as per the groups.

Once you have managed the groups/users and the access levels you can save the security by clicking the save button available at the right-hand side bottom of the popup.

Note: To apply the same security for subfolders, click the checkbox before the note 'Apply the same security for subfolders' as shown in the screenshot below





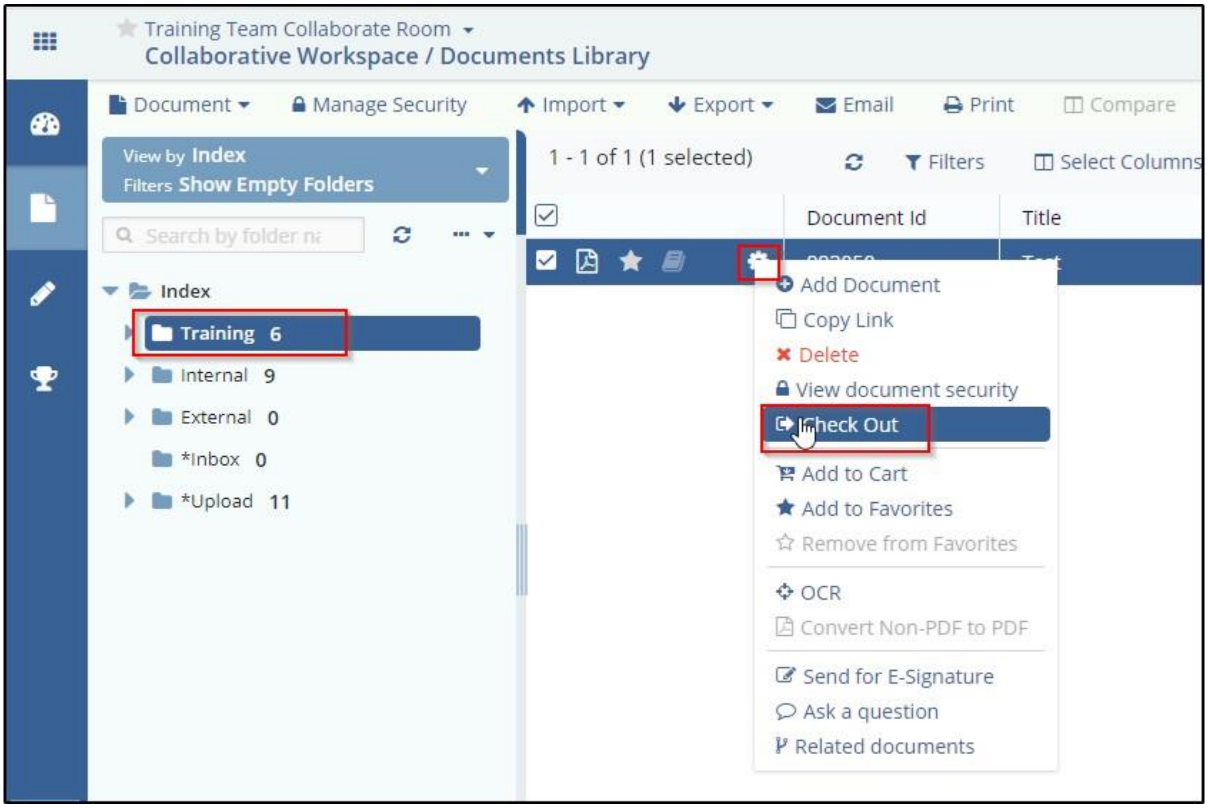
Content Editing and Versioning

Content editing and versioning helps the users with the the capability of directly editing MS Word, Excel, and Powerpoint documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

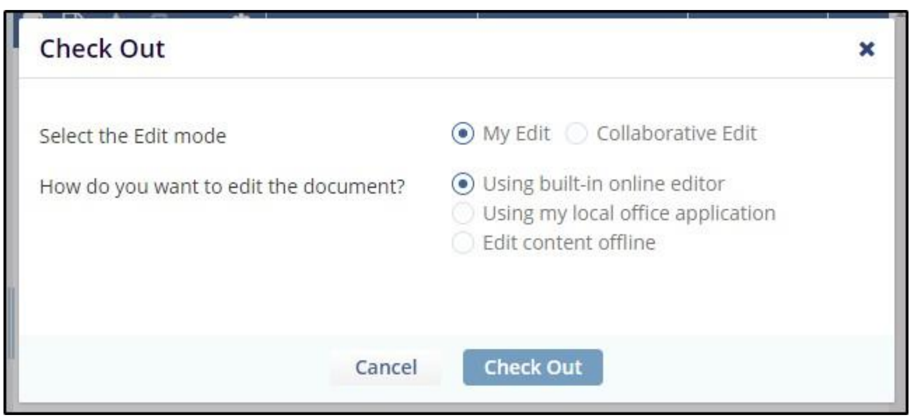
The content editing is performed with check-in and check-out with the documents available in a collaborative room. The detailed process is explained in the subsequent topics.

Check Out

The editing of a document initiates with the check out process. To check out a document, go to the collaborative room and open the document index. Click the gear icon available in the document grid.This will open a dropdown as shown in the screenshot below.



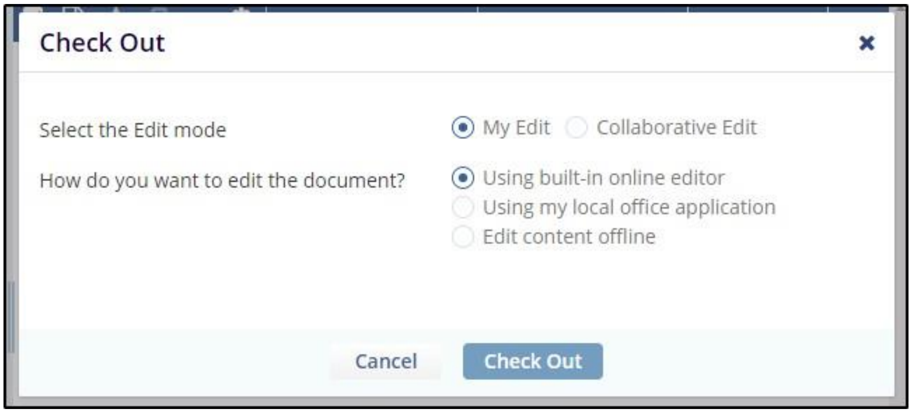
Clicking the Check out option will populate a checkout window as shown in the screenshot below.



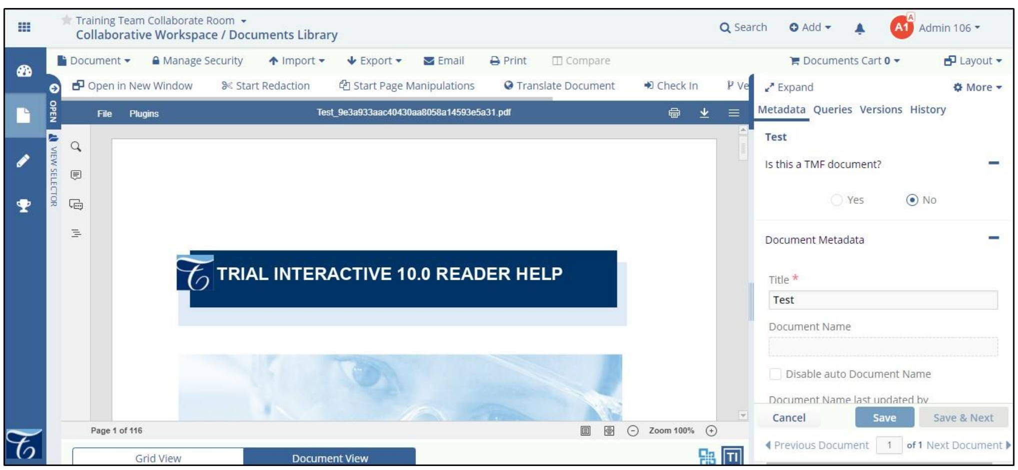
From here, you can initiate My Edit and Collaborative Edit choosing the editor options like Using built in editor, using local office application, and editing content offline. The edit mode 'My Edit' is explained in the subsequent topics.

My Edit

My Edit is performed under Check out. Click My Edit Rdio button and choose Using built-in online editor as shown in the screenshot below

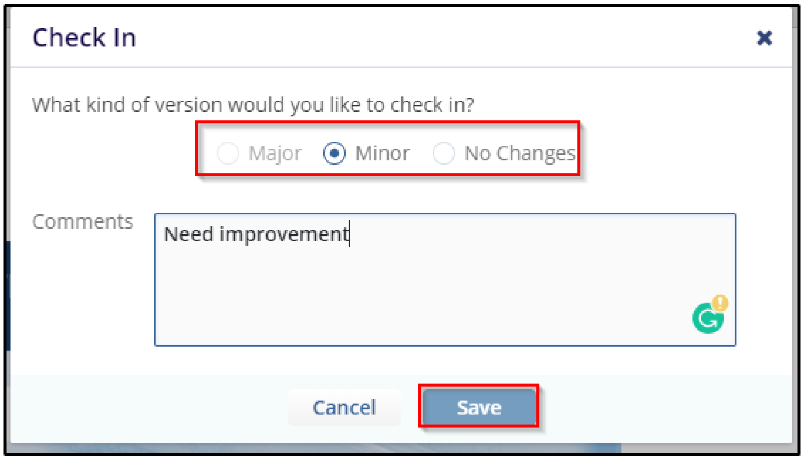


Clicking the check ou button with using built-in online editor will open the document editor as shown in the screenshot below.



The document can be edited by clicking Checkin button available in the ribbon bar. 

This allows you to edit the document online with the things like comments and track changes. Once you make the cdits, the system will poulate a Check in window as shown in the screenshot below.



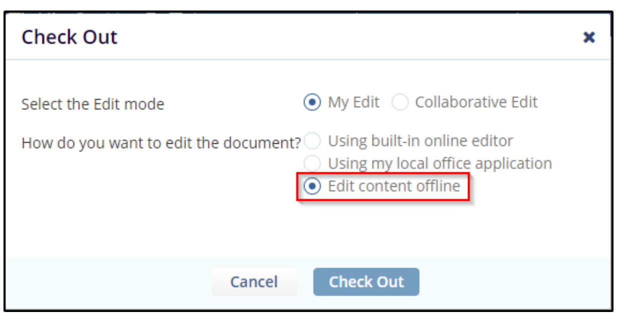
The edited document gets its version up in the metadata.The versioning can be seen in under the Vesrions button in the Metadata pane.

Note: Editing a document offline is explained in the subsequent topic.

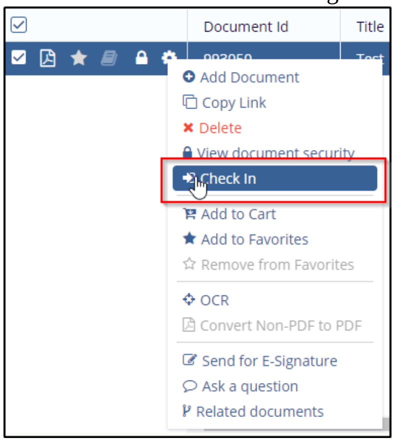
Offline Edit

To edit a document offline,the system prompts you to download the document.

Select the edit mode to My Edit and check the 'Edit Content Online'button as shown in the screenshot below



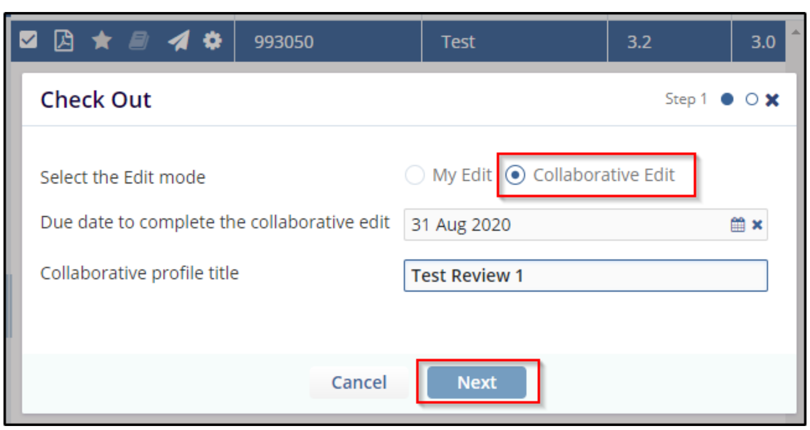
Clicking the Check out button will download the document to your machine. Make the edits in the document and click Check in from the gear icon dropdown from the documents grid as shown in the screenshot below.



The check in button opens up a Check In pop up that prompts you to attach the edited document. Make your comment in the comment box to save the edit. The edit will be vesrioned up same as the online edit.

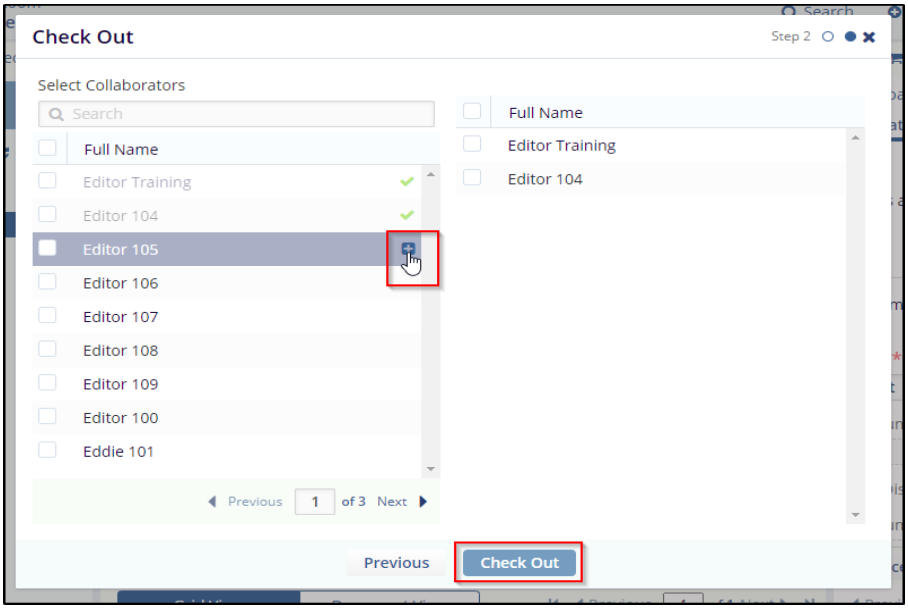
Collaborative Edit

Collaborative edit is performed within a team of editors. The edit initiator can include the editors from this operation. The users can also set the due date to complete the collaborative edit. To initiate a collaborative edit, click the gear icon available in the document grid and click check out. The check out po up has the selection option 'Collaborative edit'. Enter the due date and collaborative edit title to proceed. Refer the screenshots below for the steps to initiate a collaborative edit.



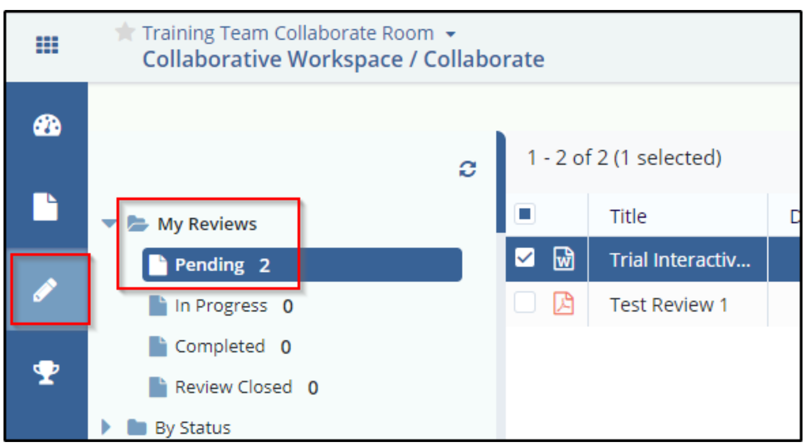
Once you click the Next button, the system takes you to the Step 2 window. This allows you to select the collaborators. To select a collaborator click the 'plus' icon available near the name of the collaborator. The selected collaborators will be displayed in the right side of the window. Also a green tick is seen in the list available at the left side.

.



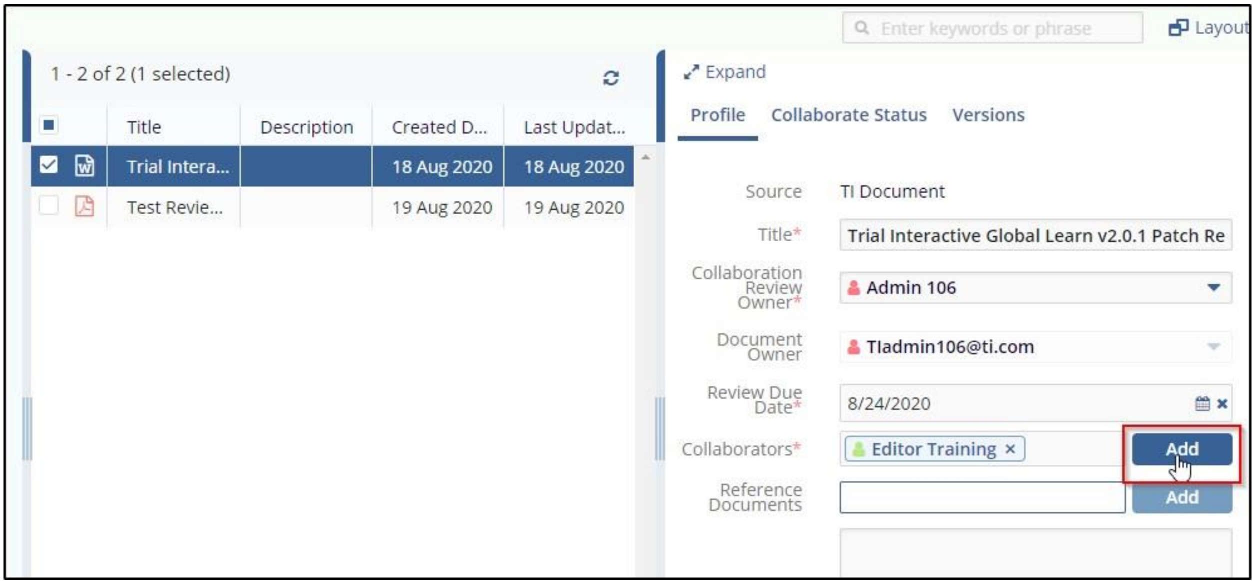
Once you select all the collaborators, click Check out. The system will prompt you for a confirmation with a question 'A Collaboration Review has been created. Would you like to open the collaboration review profile now?' Select the appropriate option to proceed further.

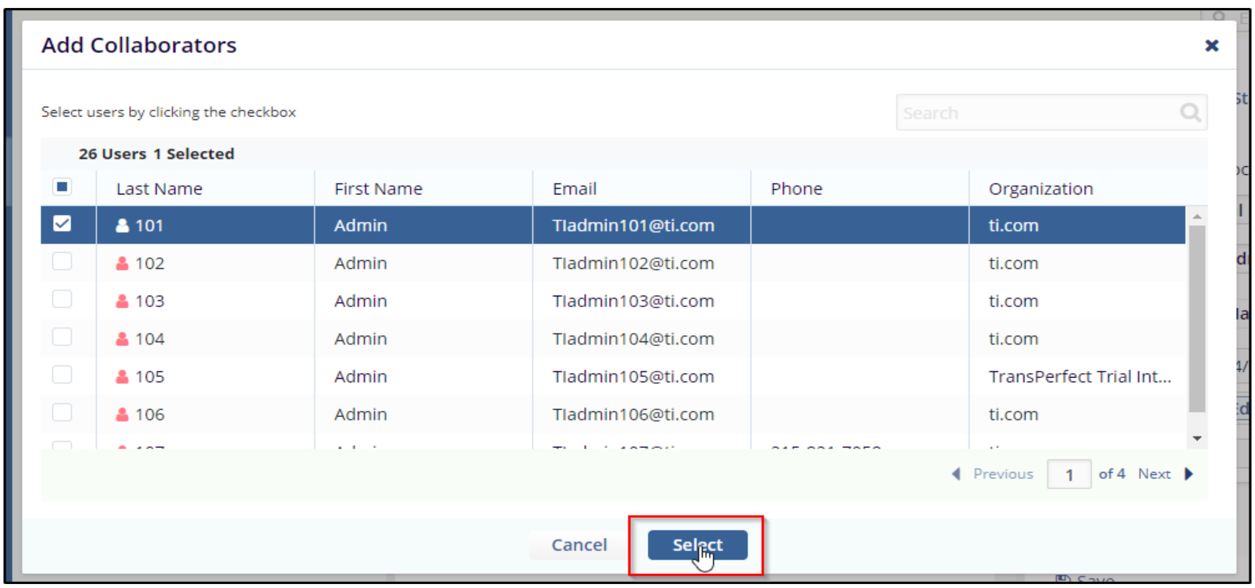
The initiated collaborative edit is seen under my reviews folder under the subfolder 'Pending'. Refer the screenshot below



The collaborators can be added to the review via add button under the profile tab of metadata pane. Refer the screenshots below.

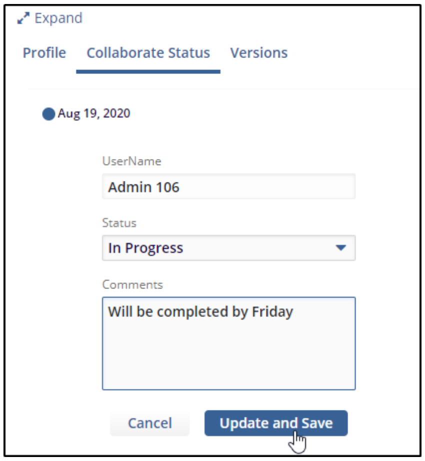
Clicking the Add button will open the Add Collaborators popup. Here you can select collaborators available from the list. Refer the screenshot below

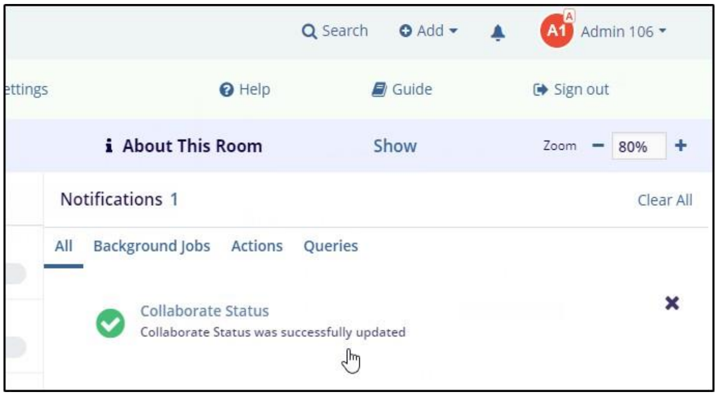

Enter keywords or phrase
Layout
1 - 2 of 2 (1 selected)
Title
Description
Created D...
Last Updat...
Trial Intera...
18 Aug 2020
18 Aug 2020
Test Revie...
19 Aug 2020
19 Aug 2020
Expand
Profile
Collaborate Status
Versions
Source
TI Document
Title*
Trial Interactive Global Learn v2.0.1 Patch Re
Collaboration Review Owner*
Admin 106
Document Owner
TIadmin106@ti.com
Review Due Date*
8/24/2020
Collaborators*
Editor Training
Add
Reference Documents
Add


Add Collaborators
Select users by clicking the checkbox
Search
26 Users 1 Selected
Last Name
First Name
Email
Phone
Organization
101
Admin
TIadmin101@ti.com
ti.com
102
Admin
TIadmin102@ti.com
ti.com
103
Admin
TIadmin103@ti.com
ti.com
104
Admin
TIadmin104@ti.com
ti.com
105
Admin
TIadmin105@ti.com
TransPerfect Trial Int...
106
Admin
TIadmin106@ti.com
ti.com
Previous
1
of 4
Next
Cancel
Select

A collaborator can add status by clicking the button available under Collaborate Status tab in the metadata pane. Clicking Add Status button will open the add status window. Here the collaborate can choose the status as Pending/In Progress/ Completed and put in the comments to update and save the collaorate status. Refer the screenshot below.

A notification will be available for the executed update



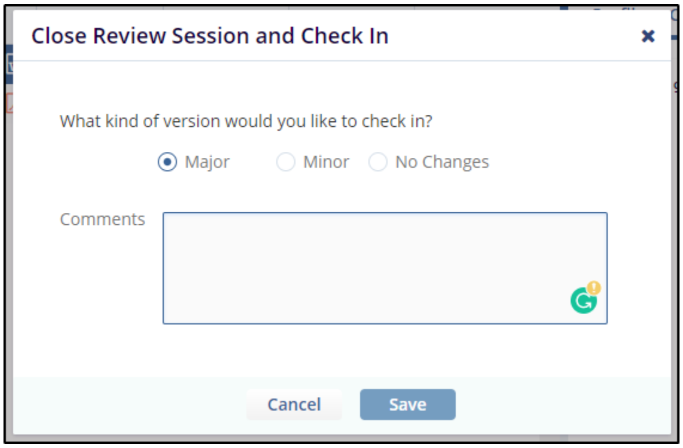


Close Review Session and Check In

Once you are done with the check out process with all the collaborators updates and edits, you can close the review and check in the collaborative edit. To close the review session and check in. click the button available under the Collaborate status tab in the metadata pane.

Clicking the Close Review Session and Check In button will open the following popup window.

Choose the kind of version from the options (Major/Minor/ No changes) and insert your comments to save the review. The closed review notification will be seen in the notifications. The collaborate status will be upadated with the closed status in the metadata pane as shown in the screenshot below.


Close Review Session and Check In
What kind of version would you like to check in?
Major
Minor
No Changes
Comments
Cancel
Save

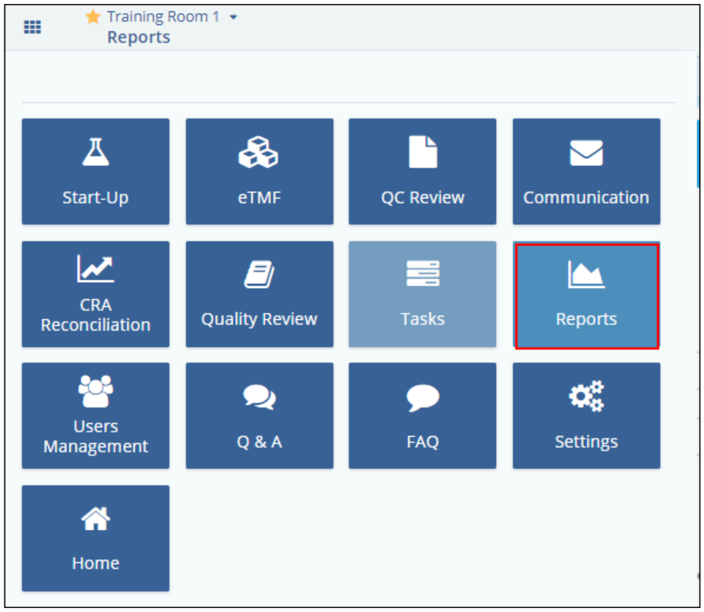
Chapter 23. Reports

This section helps you know about getting the Reports for the room activities.

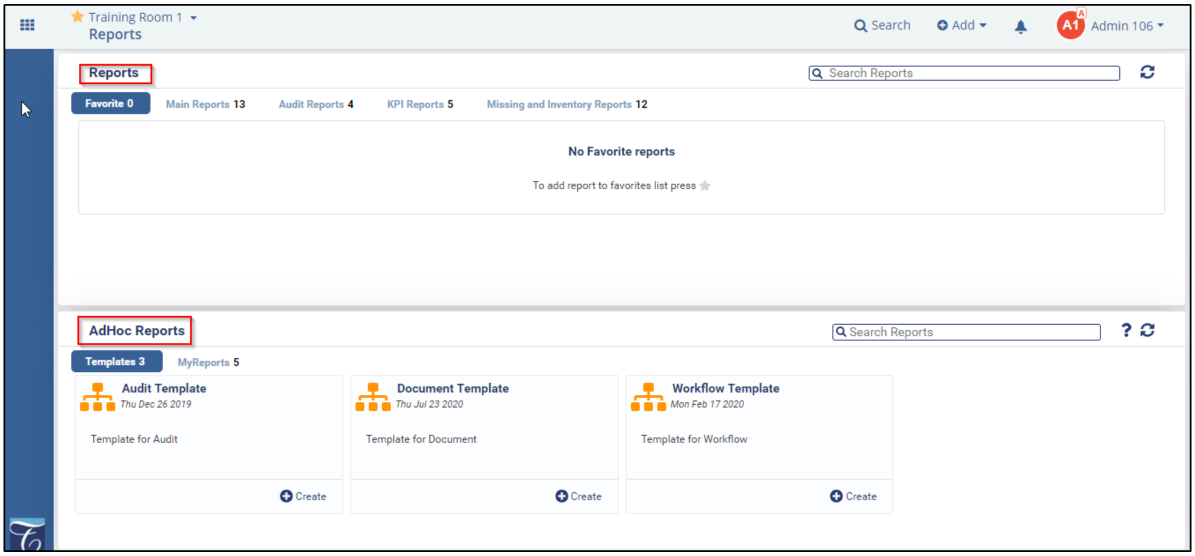
Room Administrators have the option to turn on **Reports** and make them available to other users. If Reports are activated, you will see an icon in the Navigation Grid.

Reports Dashboard

As an Administrator user, you have an option to turn on Reports for other level users to access and view. You can reach this page by clicking the **Reports** application from the Main Navigation. Refer to the screenshot below:



The Reports Dashboard consists of the various dashlets which gives a summary of the reports of the room. Refer to the screenshot below:



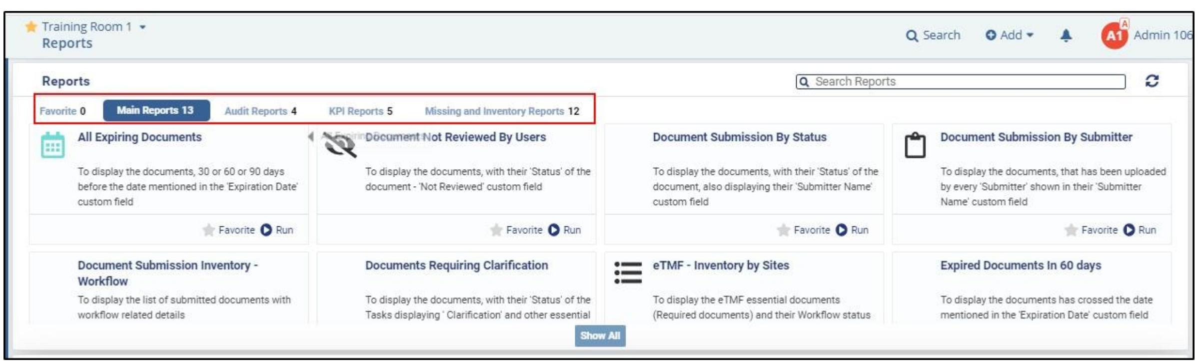
From the Reports Dashboard you can do the following:

1. Generate Reports from the Reports List.
2. Export the Reports.
3. Design a new dashboard
4. Update Results

Each of these is discussed in the seperate topics in this help.

Viewing Reports from the Report List

From the Reports Dashboard, click the reports category marked in red in below screenshot. The below list of the reports are from the **Main Reports** category.



Select any report and click on **Run** button to view the desired report.

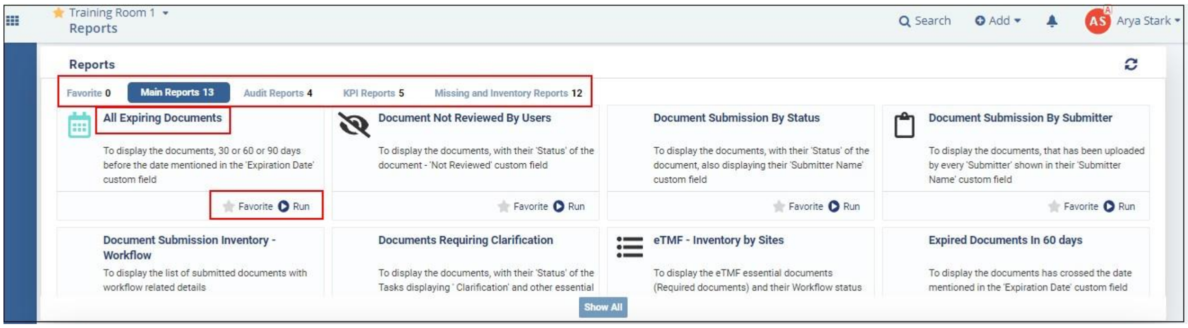
Typically, report builds are based on specific sponsor requests.

Note: *For further assistance on other features of reports, please get in touch with the Support team of Trial Interactive.*

Generating Reports

Reports are categorized by their types at the top and users can choose the category to view the list of reports available in that category. Below screenshot shows an example of **Main Reports**. From the Reports List page, choose the report to be run and click on the **Run** button to open it.

Any report can also be made favorite by clicking on the **Favorite** button.



For a particular report, you can do the following:

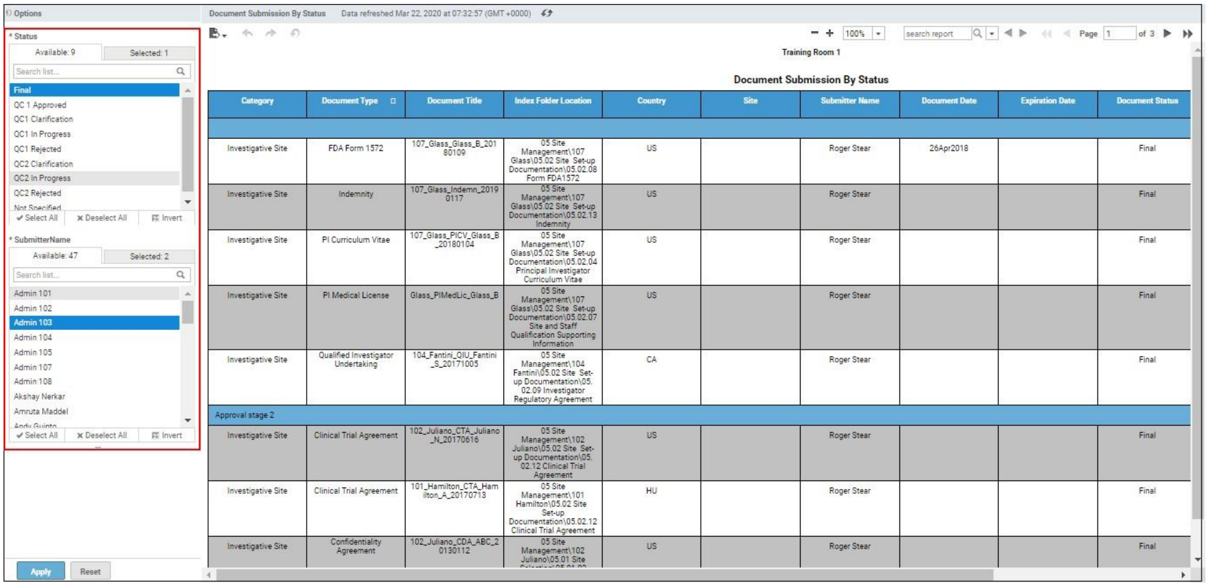
1. Apply Filters
2. Adding and deleting fields in a report
3. Print Reports
4. Download Reports

Each of these is discussed in the sections below.

Applying Filters

You can apply filters for a report if you wish to view and generate the report with only specific information. You can apply filters for a report by clicking the **Show Filters** button in the menu bar. This enables the **Filter Field, Operator**, and **Value(s), Blank** fields to allow you to select the filters for a report.

Select the single or multiple filter fields for which you want to get the reports. An example below shows a filter applied for generating a report for the open queries of a particular **Status** and **Submitter:**



You can also apply multiple filters as well by using the operator conditions to view the required results.

Exporting Reports

You can export the reports in the following formats:

1. CSV
2. Microsoft Excel
3. Microsoft Word
4. XML
5. Open Office Document
6. Rich Text Format (RTF)

Chapter 24. Study Start Up

The Start-up module is available to users who have the Study Start-up action selected in user profile, who are members of the data room's Study Start-up Team group, and who are Start-up Specialists in the data room.

The Study Start Up Process in Trial Interactive

The Study Start Up Process in Trial Interactive

The sequence of steps enlisted below gives you a glimpse of the study start-up process followed within Trial Interactive:

1. Setting up the configurations

a. Configuring Study Start-Up Settings

b. Adding Countries

c. Adding IRB/ECs

d. Setting Required/Essential Documents for Countries

e. Setting Required/Essential Documents for IRB/ECs

f. Setting Required/Essential Documents for all sites in a study

2. Inviting users to the study room

3. Creating/Editing/Viewing/Deleting Sites

4. Adding contacts to sites. This includes adding:

a. Principal Investigator and other contacts

b. Start-Up Specialists

c. Regulatory Approvers

d. Site Activation Specialists

5. Sending Regulatory Packets and Submission Packages submit to IEC

6. Collecting Essential/Required documents for sites, countries, and IRB/ECs

7. Review of documents by a Start-up Specialist

8. Review of documents by Regulatory Approver

9. Site Activation and publishing documents to the eTMF

10. Adding essential/required documents after site activation through amendments Each of the processes mentioned above are discussed in detail in subsequent sections.

Basic Configurations for SSU

Setting up the basic configuration for a Study Start-up (SSU) includes specifying details like adding countries, IRB/ECs, essential/required documents, creating sites and adding contacts to them. All these are the jobs of the data room administrator and needs to be performed by an Administrator role team member or by your TI implementation team.

To perform these activities, the administrator needs to:

1. Login into Trial Interactive.

2. Check that the room is created; else contact the helpdesk for the same.

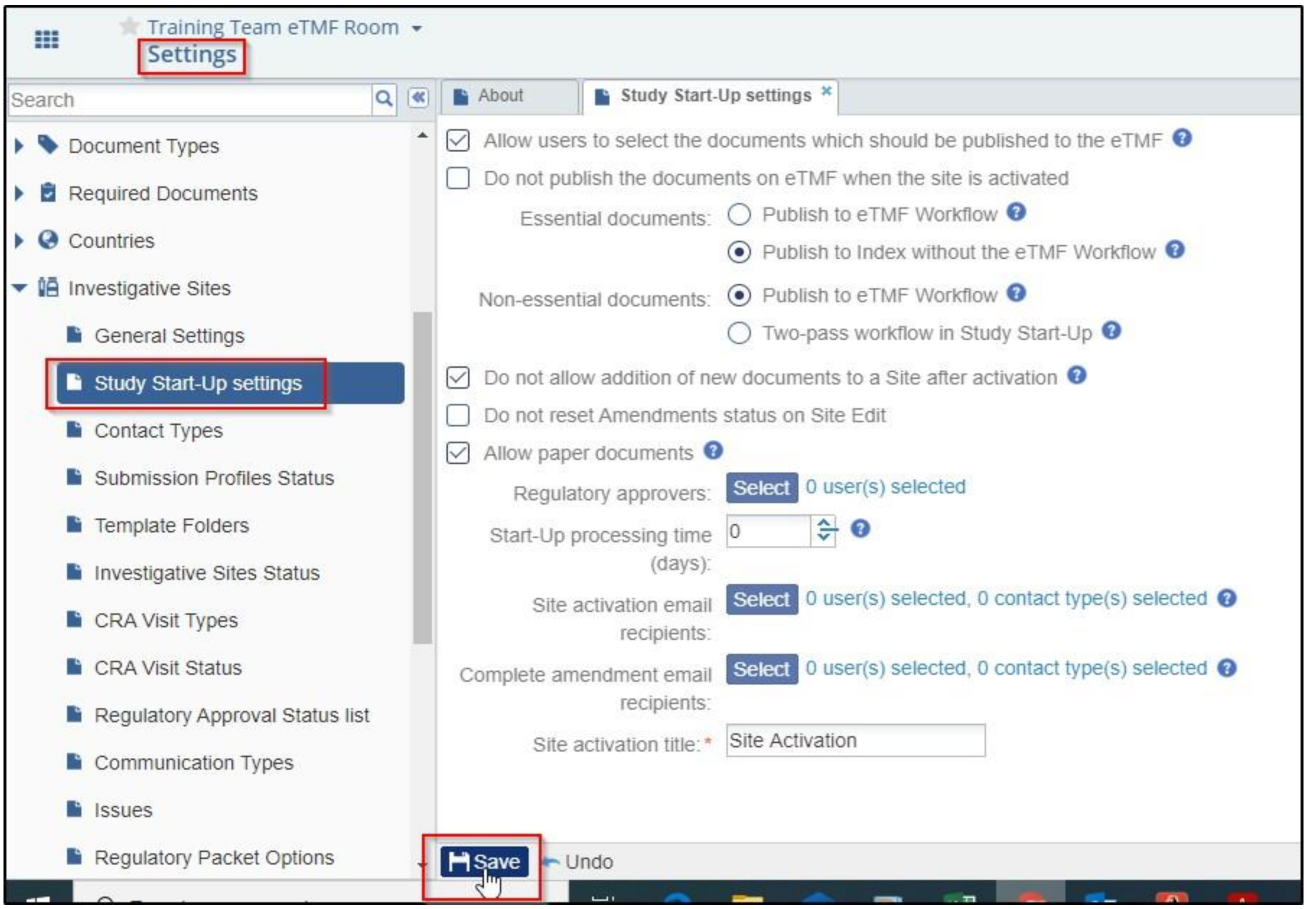
3. If the room is created, enter the room and navigate to - Settings.

Study Start-Up Settings

The Study Start-Up Settings allows you to set up rules that would be critical for a site activation process. These settings are global and are applicable to all sites in the room.

To set up the SSU Settings, the administrator needs to:

1. Navigate to Settings via the navigation grid
2. Click the arrow next to Investigative Sites in the left pane of the Settings window
3. From the collapsed dropdown, click Study Start-Up Settings
4. The Study Start-Up Settings window opens to the right
5. Select the options as required
6. Click **Save** at the bottom of the window to commit the changes Refer to the screenshot below



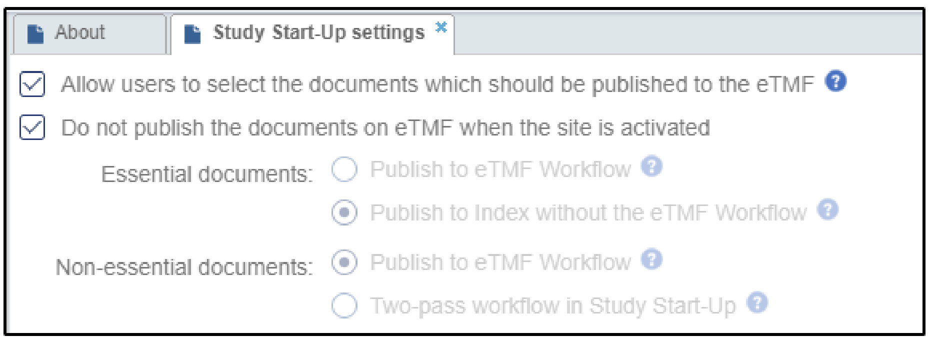
Referring to the screenshot above, the SSU settings window can be divided into two sections:

1. Settings regarding essential and non-essential documents on site activation

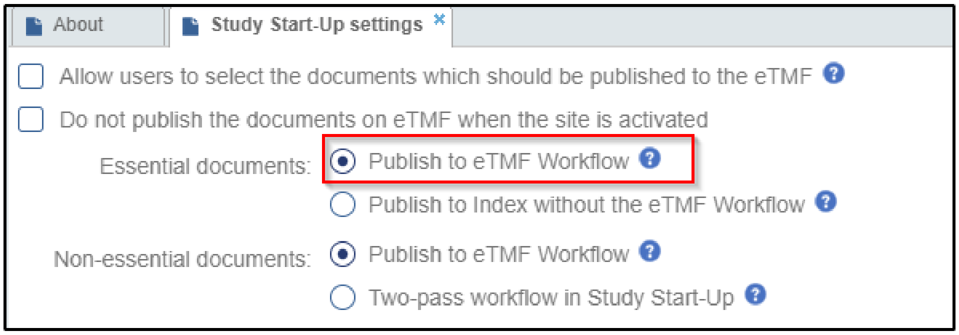
2. Other settings

Settings regarding essential and non-essential documents on site activation

- If you do not wish to publish the documents on the eTMF when a site is activated, select the checkbox next to the option. On selecting the checkbox, the next two options regarding Essential and Non-essential documents appear greyed out and disabled.
-

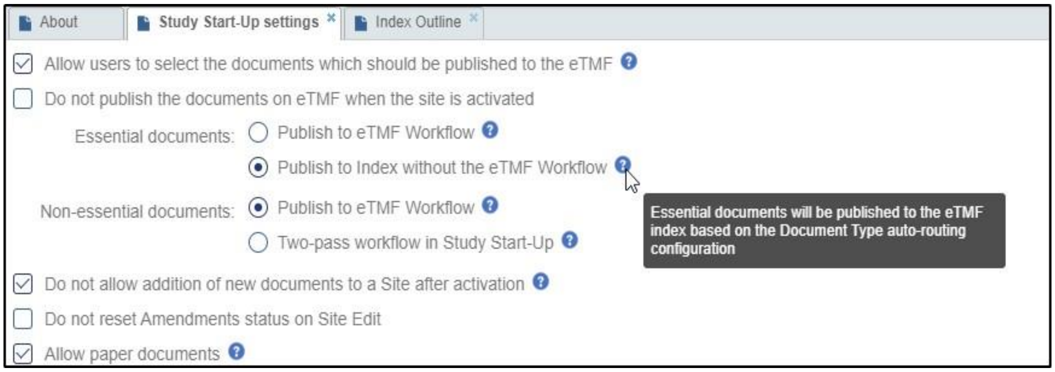


- If you wish to publish the essential and non-essential documents on the eTMF Workflow, select the radio button next to the option. These documents will be added to the workflow specified in your system on site activation and will be taken up for QC Review as per the process. On publishing the documents will be added to the default folder as specified in the Documents section under the room settings.

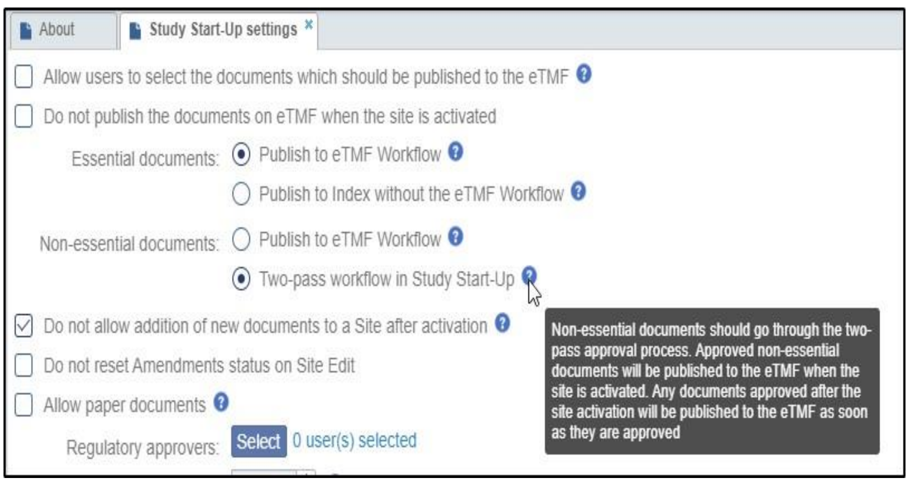


Note: *To be added to the workflow, documents should match workflow conditions. If the document is not matched to workflow conditions, it will be just placed to the default index position.*

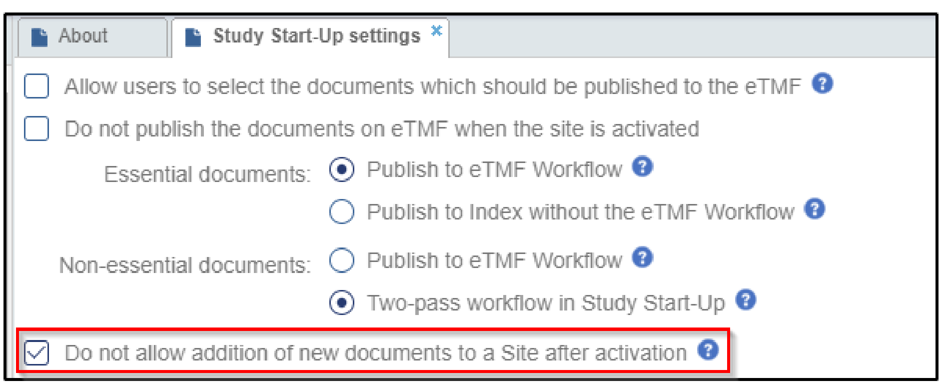
- If you wish to publish the essential documents directly to the Index without the eTMF Workflow, select the radio button next to the option. These documents will be automatically routed to the appropriate eTMF index based on the document type auto routing configuration specified in the Related Folder panel of Document Types section in the room settings. The screenshot below shows where a Tracking Information document will be routed to in the eTMF on site activation.
- If you wish the non-essential documents to pass through the two level approval process in SSU, select the radio button next to the option. These documents will need to be approved through QC Review, and Regulatory Review, and will be



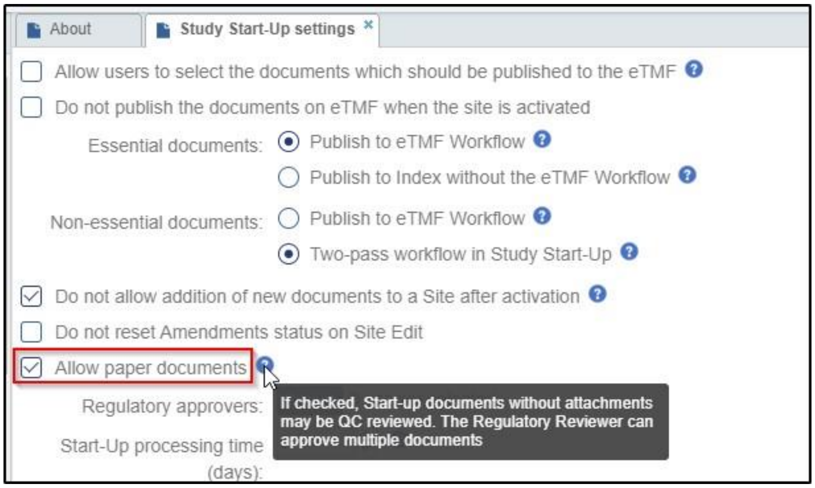
published on the eTMF with Final status on site activation. If documents are approved after site activation, they will be need to be published to the eTMF manually. Position in the eTMF index for these documents will be provided by the system as per the Auto-Indexing rules. You will need to enable auto indexing in the Documents section in the room settings for this to happen.



- If you wish to lock down the site for any new documents after the activation, select the option as shown below:
- If you need to submit paper documents instead of their soft copies, you may choose 'Allow paper documents' option as

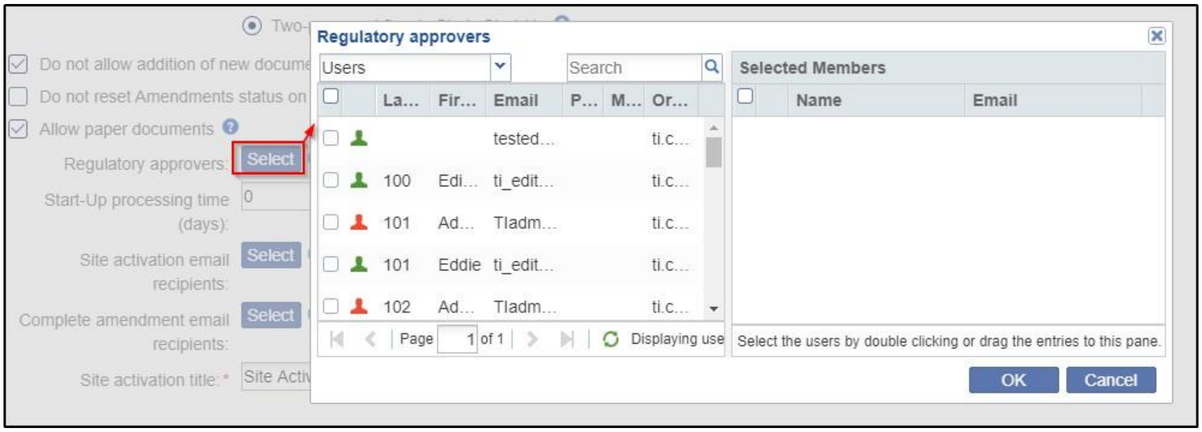


shown below. Such documents can be uploaded without attachments and can pass through QC Review, and Regulatory Review.



Other Settings

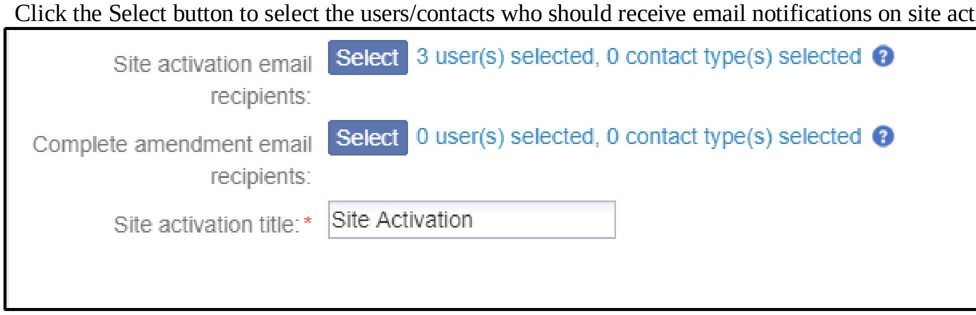
- From this section, you can add Regulatory Approvers globally for all sites in the room. This is discussed in section Adding Regulatory Approvers.



- To specify buffer time in days for site activation after IRB/EC approval, enter the number of days in the textbox next to the option.

- Besides the above, you can also specify the contacts types and users who will receive emails on site activation, and on completion of amendment documents (documents added to the site after its activation), and the title for site activation.

  Click the Select button to select the users/contacts who should receive email notifications on site activation. This will

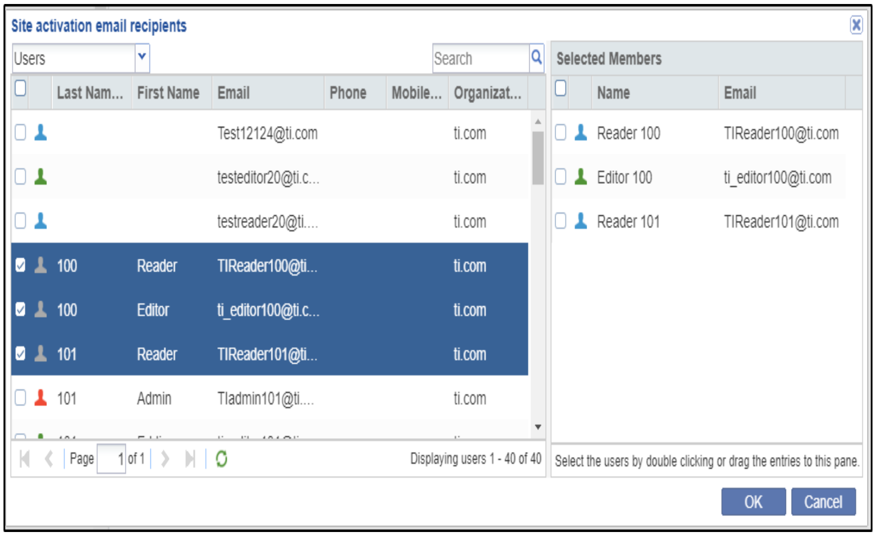


  open the Site activation email recipients/Complete amendment email recipients window as per your selection:

  a. Select Users/Contact Types from the dropdown.

  b. Select the user to transfer them to the right panel by either double-clicking them, or by dragging and dropping them in the right pane.

  c. Once Users/Contact type is selected, they will appear greyed out in the left pane.

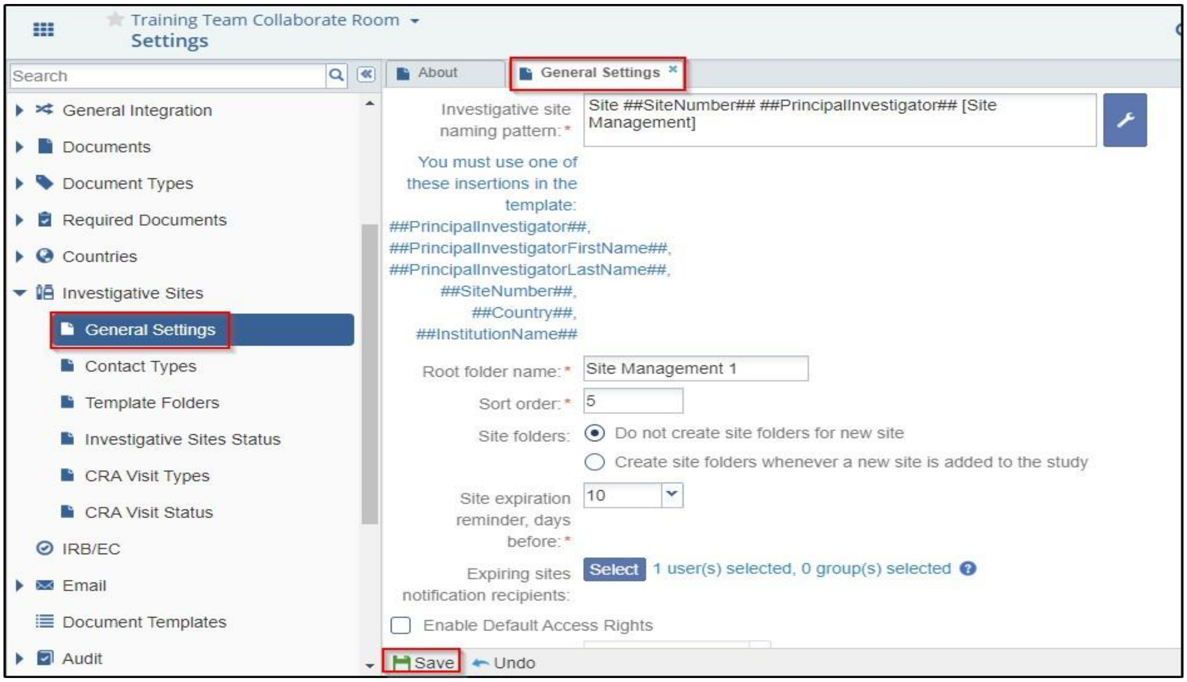


General Investigative Sites Settings

The General Settings allow you to set up rules that would be critical for a site creation process. These settings are global and are applicable to all sites in the room. The choices made here are dictated by client preferences.

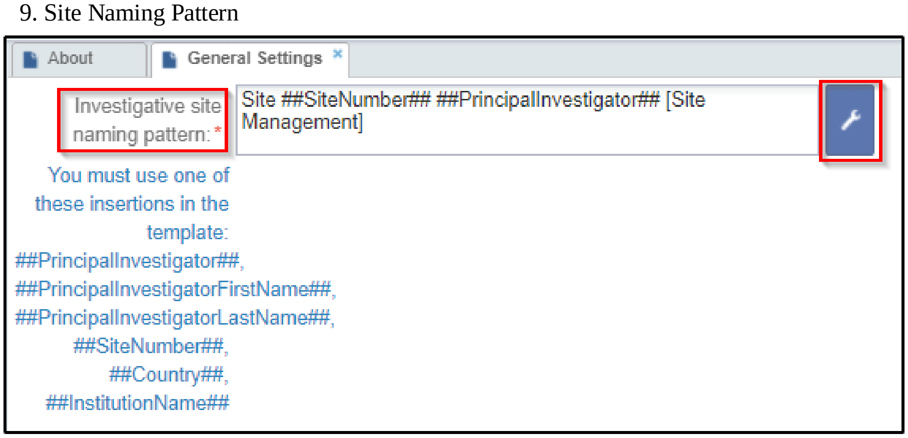
To set up the General Settings, the administrator needs to:

1. Navigate to Settings
2. Click the arrow next to Investigative Sites in the left pane of the Settings window
3. From the collapsed dropdown, click General Settings
4. The General Settings window opens to the right
5. Select the options as required
6. Click Save at the bottom of the window to commit the changes.



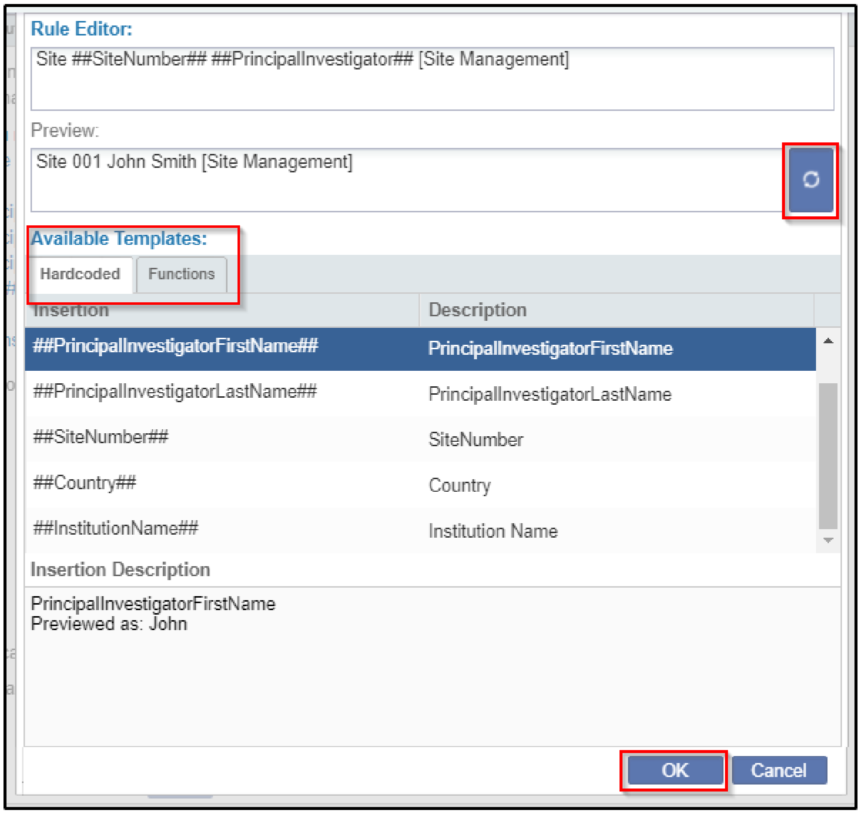
Referring to the screenshot above, the General settings window allows the following to be defined:

1. Site naming pattern
2. The root folder name
3. The sort order
4. Creation of site folders
5. Site expiration reminder period
6. Site expiration notification recipients list
7. Site default access rights and members
8. Site default access editors and readers groups
9. Site Naming Pattern



The investigative site naming pattern is set as per the prescribed pattern of the organization. To set the naming pattern, click the wernch icon available at the end of the Investigative Site Naming Pattern.

This will open a new window pop up of the Rule Editor. Here you can define the rule for naming the investigative sites. Once you set the naming pattern, you can review the same by clicking the refresh icon available after the preview box. Fill the essential details from the available templates (choose Hardcoded/Functions by toggle screen) and click OK button at the button to save and execute the naming pattern. Refer to the screenshot below.



1. Root Folder Name

The Root folder name is set in compliance with the organization's preference. This is the title that is given to the main folder in the room's index that will hold the subfolders for each investigative site involved in the study.

a. Click in the field.

b. Type the root folder name.

c. Hit the Enter key on the keyboard.

2. The Sort Order

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.

a. Click in the field.

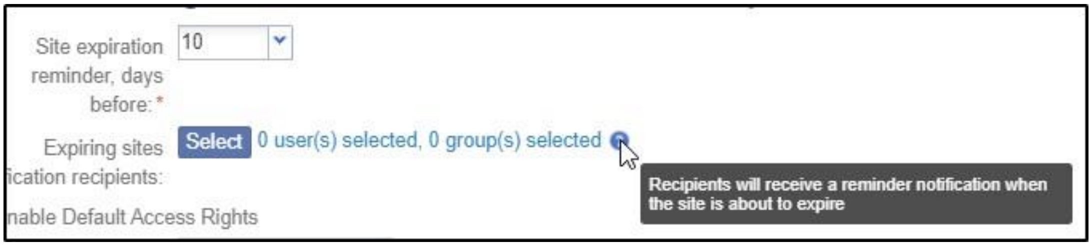
b. Type the number of the client's preference.

c. Hit Enter on the keyboard.

3. Creation of site folders

The options listed here decide when site folders are created for a new site. The box contains three radio buttons for Site folder options. Click on the option that fits your needs.

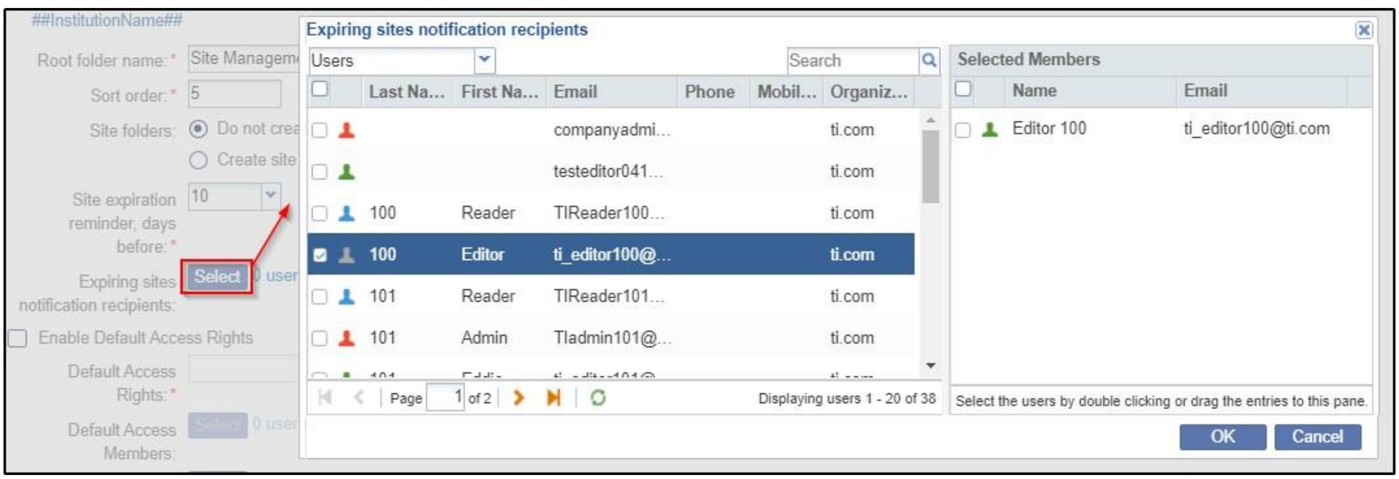
4. Site expiration reminder period



The options here allow you to set the number of days before a site's expiration and when notifications will be sent out to the users who are selected as the ‘Expiring sites notification recipients’.

5. Site expiration notification recipients list

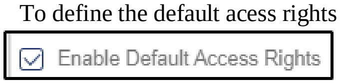
Click the Select button to select the users/groups who will receive the notification reminder email. Either double-click the users, or drag and drop them to the right pane to add them to the recipients’ list.

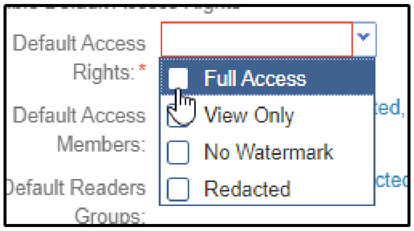


6. Site default access rights and members

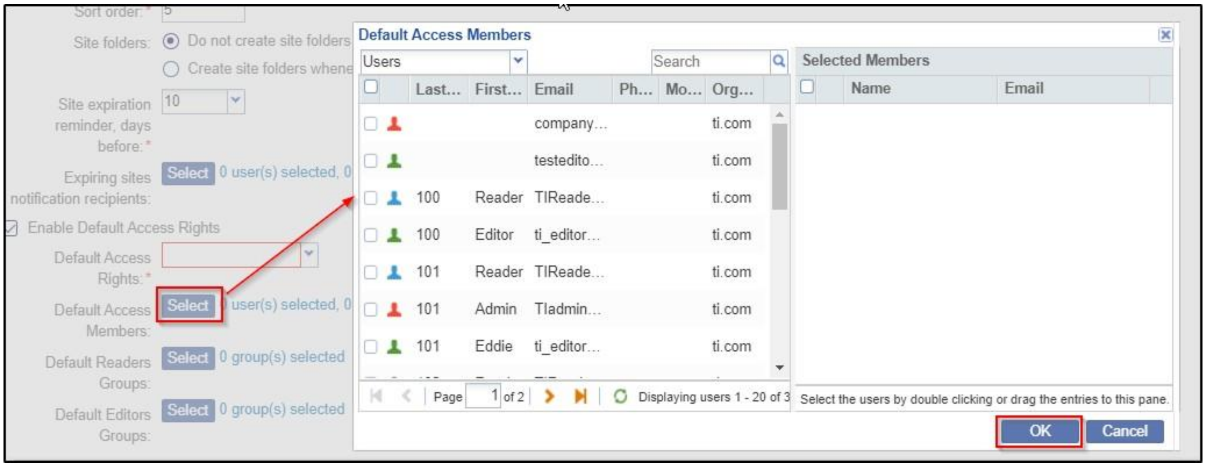
This option alloaws you to enable default access rights and the members who possess them. To enable the default access rights click the checkbox available before the Enable Default Right Access option.

To define the default acess rights select any one from the dropdown available with the Default Access Rights option.





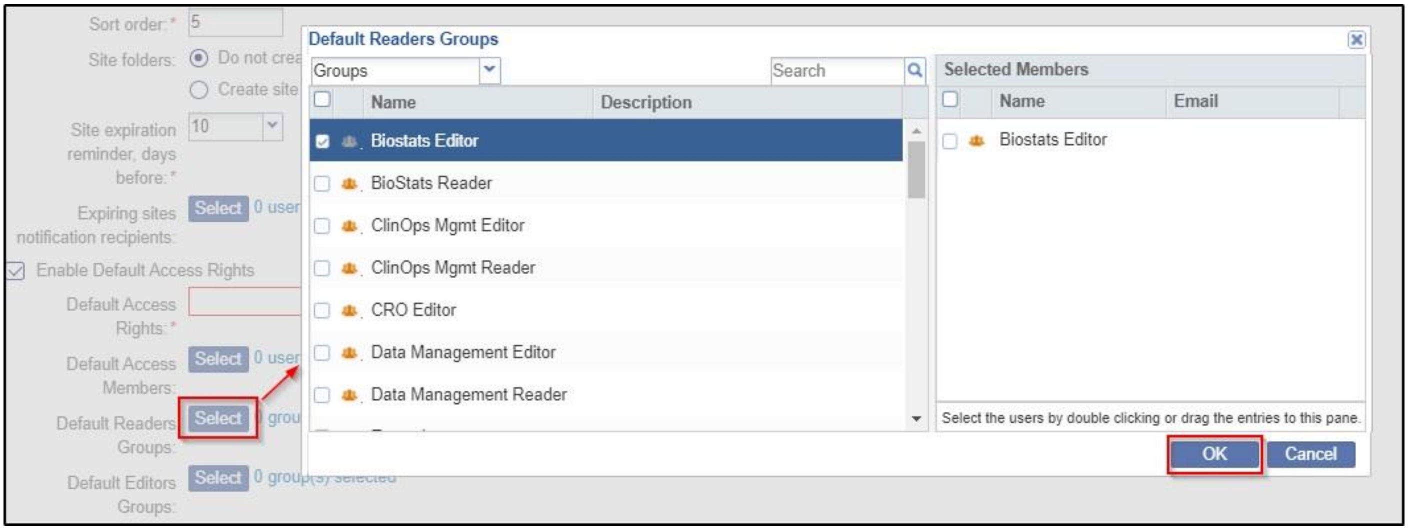
To add the members with default access, click the Select button that opens the Default Access Members popup where you can select the members/groups from the available list and drag them to the selected members list at the righ side of the popup. Once you select all the members, click the Ok button at the bottom of the popup to save the changes.



7. Site default access editors and readers groups

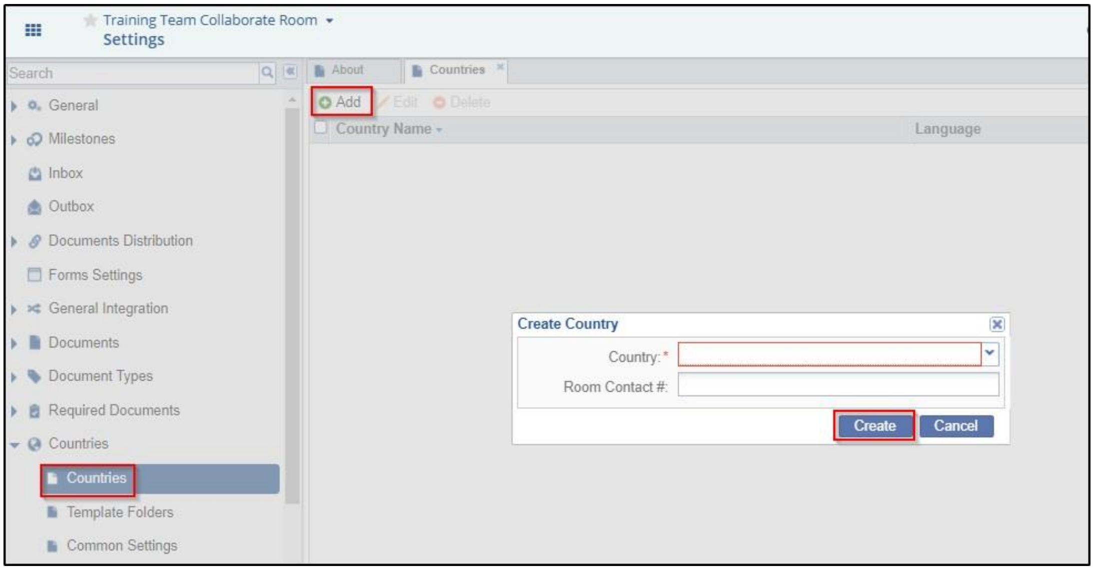
These options allow you to set the the default access to readers and editors group. To add the default readers/editors group click the Select button available after the options Default Redaers/Editors Groups. This will open a popup where you can select the groups from the available list and drag them to the selected members list at the right side of the popup. Once you select all the members, click the Ok button at the bottom of the popup to save the changes.

Adding Countries to Data Rooms



To add countries from where the sites will be enrolling to the study, the administrator needs to do the following:

1. From the Settings section, click the arrow next to Countries from the left panel to collapse its dropdown.
2. Click the sub-option Countries from the collapsed options to reveal the Countries window in the right.
3. Click Add in the menu bar from the Countries window. This opens the Create Country popup.
4. Select from the list of countries from the dropdown as required for your sites.
5. Enter the Room Contact and click Create. This will add the country to the data room.
6. Repeat the process for as many countries as required.



Adding or Creating New IRB/ECs

To add IRB/ECs as required by sites, the administrator needs to do the following:

1. Assuming that you are in the room Settings section, click IRB/EC from the left panel.

2. The IRB/EC Management window opens in the right.

3. Click Add in the menu bar from the IRB/EC Management window.

a. This opens a blank IRB/EC Profile form to fill in the data. Enter all the details as applicable. Some of the important fields are discussed below:

i. Approval Cycle: This is the IRB/EC's processing time and can be denoted in days/weeks/months.

ii. Buffer Time: This is the extra time IRB/EC may need to approve the documents.

iii. Meeting Frequency: This denotes the meeting frequency of the IRB/EC which could be daily/weekly/monthly/yearly.

iv. Submission Deadline: This denotes the submission deadline in day/week/month/year before the IRB Meeting Date.

b. Click the Committee tab in the popup. This allows you to add the details of Ethics Committee associated with the IRB.

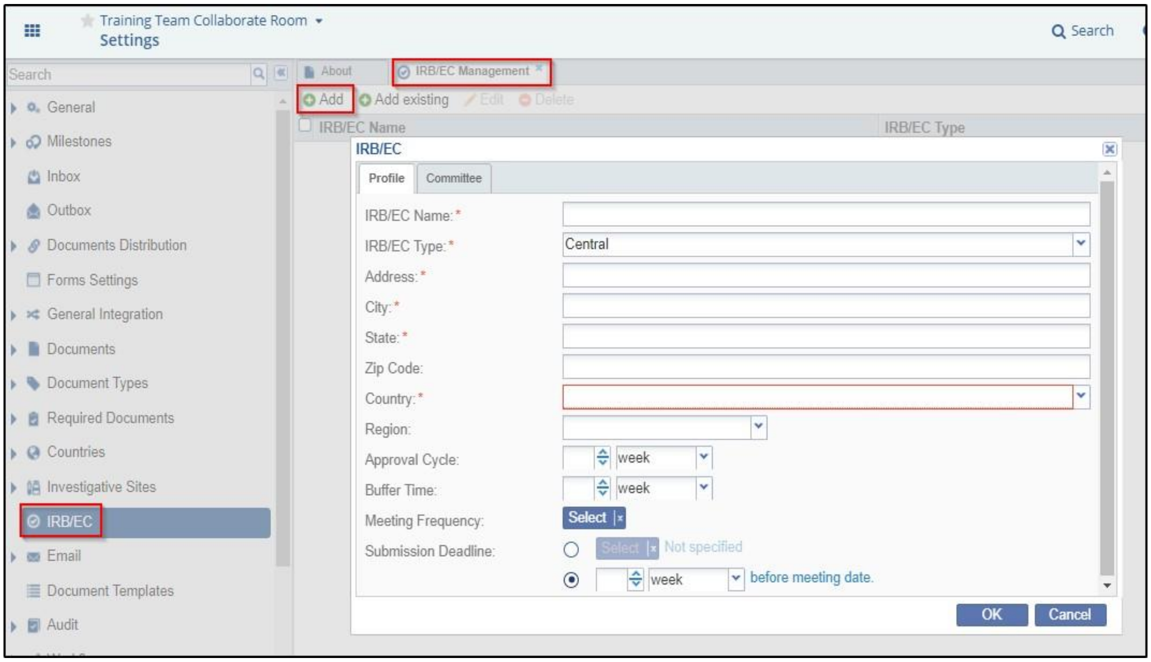
c. Click Add in the Committee tab. This will add a new row to add an ethics committee by the name of 'New Committee'.

d. Double-click each field in the row to enter the details for the committee.

e. Click Ok.

4. This will add the IRB/EC to the study and also to the centralized IRB library.

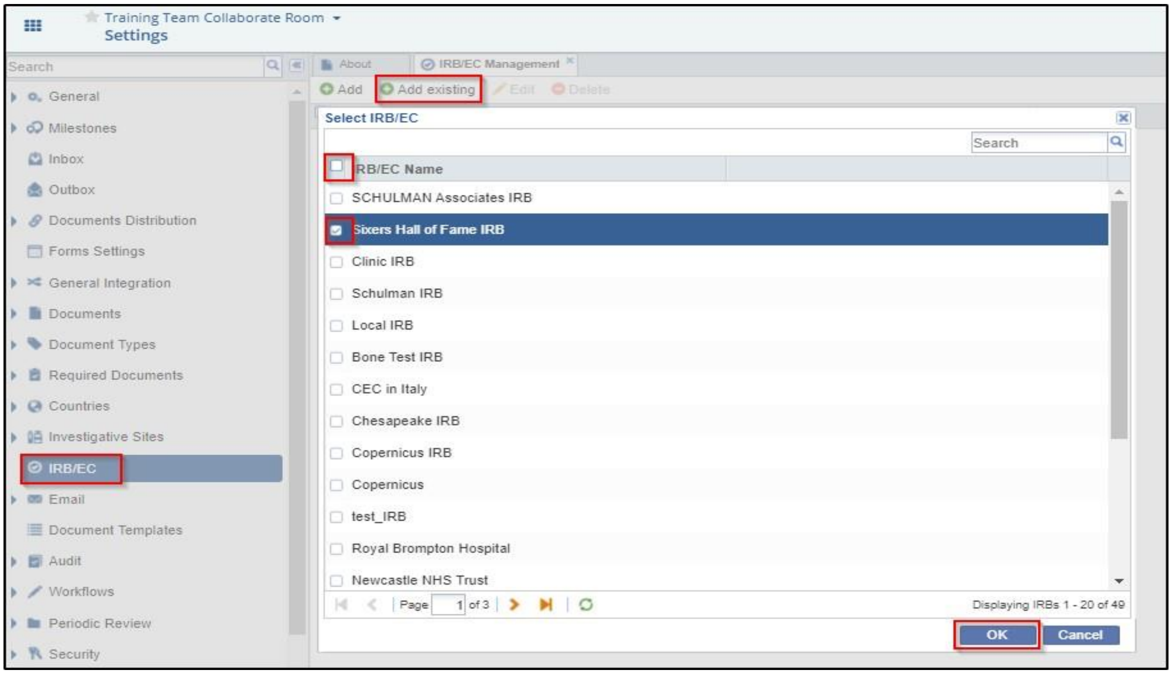
5. Repeat the process for as many IRB/ECs as required. Refer to the screenshot below:



Adding Existing IRB/ECs to Data Rooms

You can add IRB/ECs from the centralized IRB library to your data room by clicking the Add Existing option in the menu bar of the IRB/EC Management window. IRB/ECs specified in the domain level are available to all studies in the domain and can be added to your room specifically.

Clicking the Add Existing button from the menu bar will open the Select IRB/EC window listing the IRB/ECs available in the domain. You can select multiple IRB/ECs as required from the list by ticking the checkbox next to the IRB/EC names and clicking OK on completion. Refer to the screenshot below:



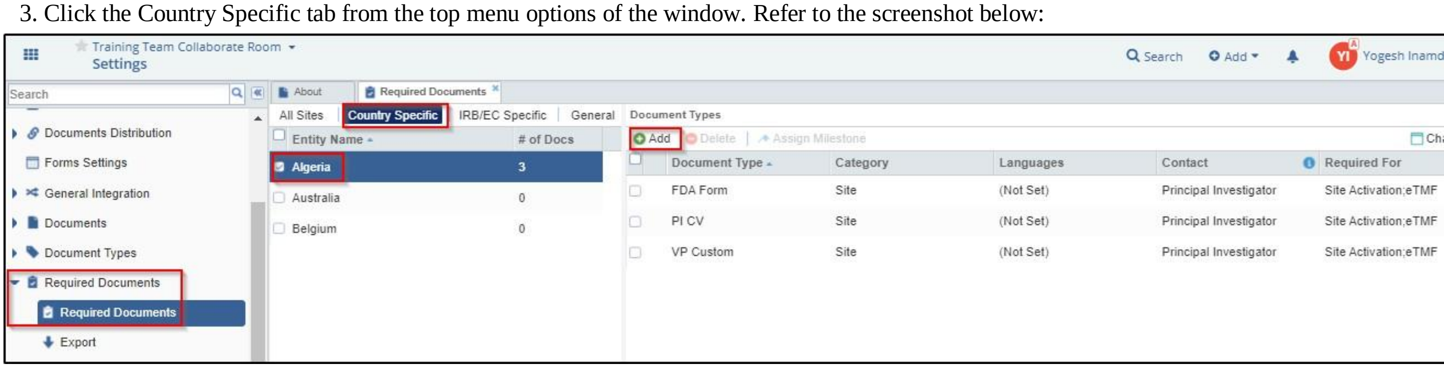
Setting up Required Documents for Countries

For the user to upload collected essential documents for countries, the document types for the same needs to be setup by the administrator. The procedure to add Required Documents is mentioned below:

1. From the Settings section, click the arrow next to the Required Documents option in the left panel.

2. Click the sub-option Required Documents from the collapsed options to reveal the Required Documents window in the right.

3. Click the Country Specific tab from the top menu options of the window. Refer to the screenshot below:



4. Select the checkbox next to the country for which you want to specify the Essential Documents. This activates the Documents Types panel to allow you to add the required documents.

5. Click Add from the menu bar on top of the Document Types window.

6. This will open the Required Documents window offering you two choices – Study, and Investigative Sites -

Choose Investigative Sites if -You wish to submit investigative site documents specific to countries. Choose Study if- You wish to submit government approval documents of the country.

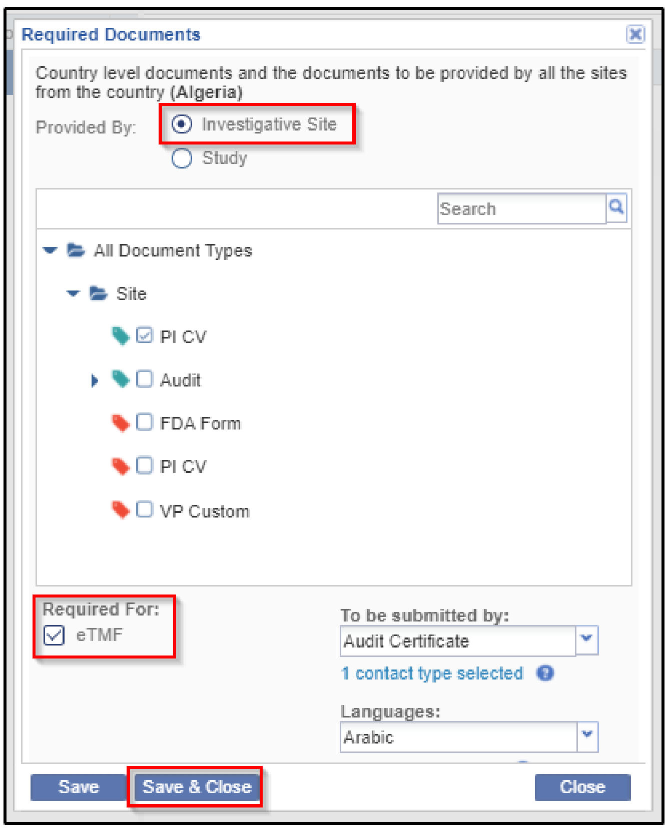
7. Select documents as required from the collapsible tree structure listing the documents.

8. Select Site Activation checkbox.

Note: *To select the contacts who will submit the documents from the 'To Be submitted by' dropdown if you choose the 'Investigative site' option from above.*

9. Click Save & Close.

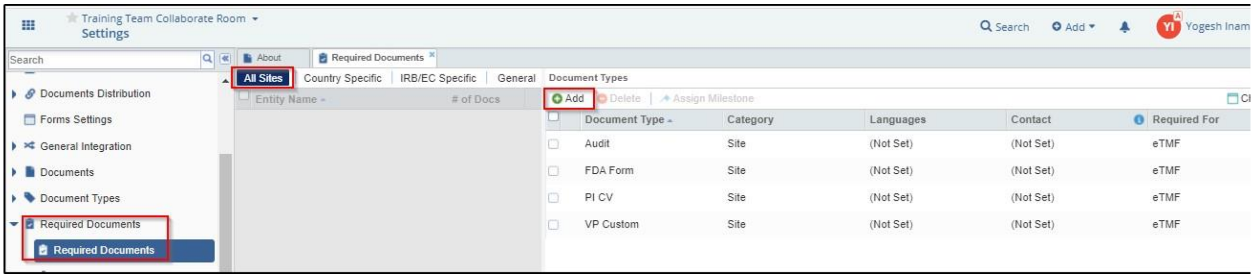
10. Refer to the screenshot below:



Setting up Required Documents for All Sites

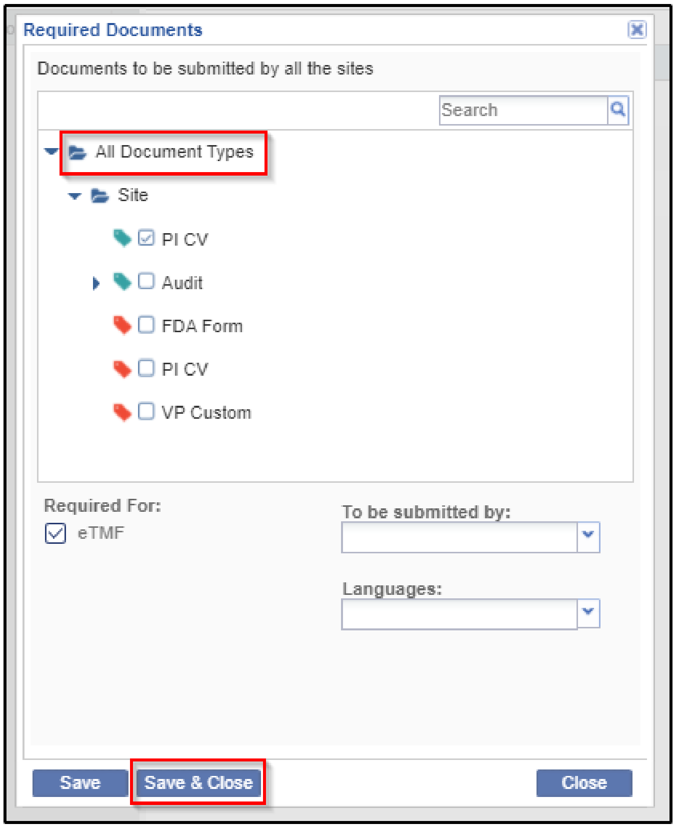
For the user to add essential documents for sites, the document types for the same need to be setup by the administrator. Required Documents for Sites can also be set up from the Settings. The procedure to add Required Documents though Settings is mentioned below:

1. Assuming that you are in the room Settings section, click the arrow next to the Required Documents option in the left panel.



4. Click Add from the menu bar on top of the Document Types panel.
5. This will open the Required Documents window. Select documents as required from the collapsible tree structure listing the documents.
6. Select Site Activation checkbox.
7. Select the contact list from the 'To be submitted by' dropdown as required. Multiple contacts can be selected.

8. Click Save & Close to commit. Refer to the screenshot below:

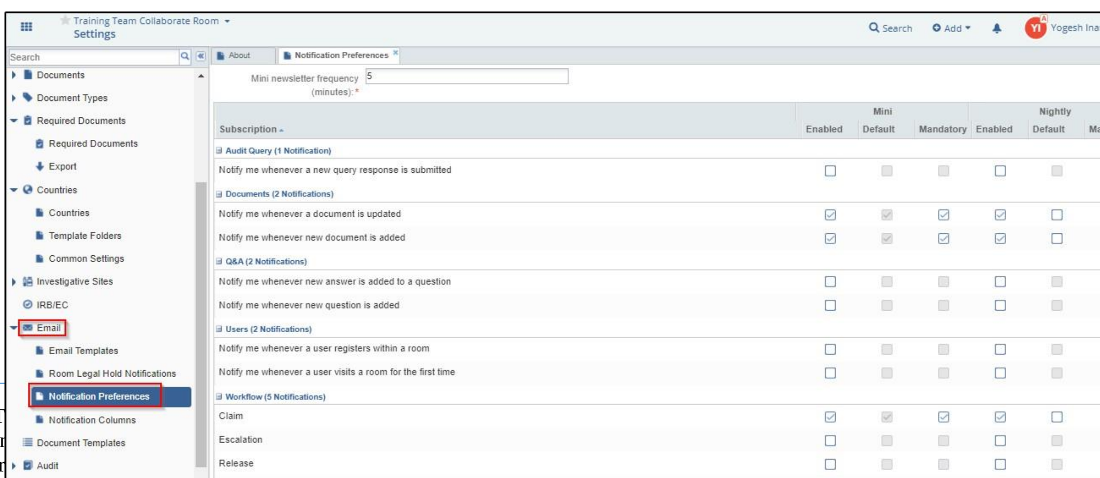


Setting up Notifications

Contacts in SSU can receive notifications via emails for the regulatory packets sent out, for documents collected, approved, and for a site activation.

The administrator can set up notification preferences for Start-Up Documents and Regulatory Review as follows:

1. Navigate to Username dropdown -> Settings
2. Click the arrow next to Email in the left panel
3. Select Notification Preferences from the dropdown.
4. The Notification Preferences window opens in the right.
5. Enable the options as required by your organization.



Study Start-Up Contacts

This section describes in detail the various user roles available in SSU module:

- Clinical Research Associate (CRA)
- Start-Up Specialist
- Regulatory Approver
- Site Activation Member
- Other Site Contacts
- Site Activation Member

After site information is entered in TI, the regulatory packet is subsequently sent out to the site members. If you are added to the Site Activation Member group, you are able to submit Essential/Required Documents to the SSU module for the Start-Up Specialist and Regulatory Reviewer

to review. As a Site Activation Member, you can see and track the progress of Essential/Required Documents collection, and activate the site when required.

Clinical Research Associate (CRA)

A CRA is responsible to conduct a clinical trial, and oversee various important site related functions like initiation, compliance with protocols, site visits, adherence to good clinical practices, integrity of the data collected, and protection and safety of the human subjects of the study. A CRA adds documents to a site as a part of site visits. A CRA needs to be an editor in the room to be added as a CRA in a site.

Start-Up Specialist

The Start-Up Specialist is a part of the Site Activation Member group and is the first reviewer of the SSU documents. Documents can be mailed into the specific SSU email address, imported, or attached individually in Trial Interactive. The Start-Up Specialist will review and approve, or reject the document(s) and push them to the Regulatory Reviewer for final review. The Start-Up Specialist will also activate the site after the Regulatory Reviewer approves all Essential/Required Documents at each site. A Start-Up Specialist can be an Editor, or Admin in the room.

Regulatory Approver

The Regulatory Approver is the second and last reviewer of the SSU documents. (Email notifications can be set up to notify the Regulatory Approver that there are documents pending for review). The Regulatory Approver will review and approve or reject the document(s) in the Regulatory Review section in the SSU module.

Other Site Contacts

Besides the ones mentioned above, there are various other site contacts that can be added to a site. Some of them are mentioned below:

1. Principal Investigator

2. Sub-Investigator

3. Pharmacy Contact
4. Laboratory Contact
5. Contracts Contact
6. Finance/Budget Contacts
7. Co-Investigator
8. Research Specialist

> **Note:** A Principal Investigator is the most important contact for a site as sites cannot be created without a Principal Investigator.

Note: *A SSU specialist cannot be a site contact and a SSU specialist at the same time. Except for the CRA, all the contacts discussed in this section can be viewed from the Contacts module. You can view sites in the By CRA view from the Sites module.*

Inviting contacts and Managing Security

The world of clinical trial involves many users whose responsibilities range from handling various intricate and complex procedures to users who only review and sign documents in a site. To enable them to carry out their duties, the users need to be given proper accesses and privileges in a site.

To facilitate the above, Trial Interactive (TI) implements a process that can be seamlessly aligned to a real world scenario. It caters to various questions in a clinical trial to define the role of a user like ---

1. What is the size of the organization?

2. Does the organization involve users who handle multiple roles, or users who are assigned specific roles in a site?

3. Does the user need to oversee the complete site activities, or is it enough for the user to only be a contact point in the site?

Depending on the functionalities assigned to site users by answering the above questions, the administrator can choose the right combination of rights and privileges.

TI implements the following process to assign a combination of rights and privileges to site members to enable them to carry out their responsibilities:

1. It allows two security privileges to be assigned to users – Editor, and Reader.

A reader is allowed read-only access whereas an editor can perform various other advanced functionalities like adding documents, sending documents for review to activating sites.

To note, an Admin is a privileged role and are assigned to users only in specific cases discussed later in this guide.

2. These security privileges can be assigned at two levels:

a. At room level:

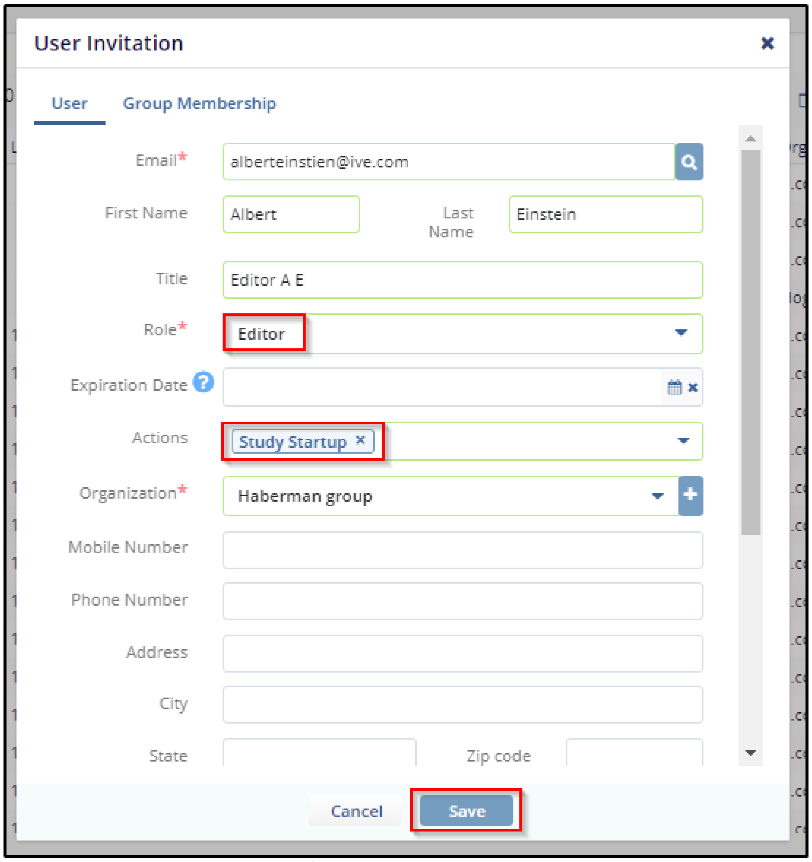
If users are already registered in the room skip the below mentioned process.

To assign privileges to a user in a room, the Admin has to provide access to the user by inviting the user to the room. On inviting, the user receives an invitation mail in his/her registered email id to join the room. The Admin has to follow the process below: -

- Login into TI and enter the room.
- Navigate to Username dropdown -> User Management
- Click Invite, choose Regular. Fill out the required information.
- Assign them appropriate roles as defined within Trial Interactive

Note: For Study Start-Up roles, the user needs to at least be an Editor in the room.

- Enable Study Start-Up as action. Click Create. Refer to the screenshot below:



New users can also be added from within a site by the admin directly. In this case the user so created receives an invitation mail to join the room.

b. At site level:

Within a site, following types of users can be added as site contacts:

1. Users belonging to a room to which the site belongs to.

2. Users belonging to a room to which the site does not belong to.

3. Contacts of one site can be added as contacts to another site.

Examples of the first case could be CRAs and Start-Up Specialists. In the second case, a user could have been invited to say Room1, but user is directly added to a site of Room 2 using his/her email id. In the third case, a Pharmacy Contact might not be required to access a room but just need to be in the list of contacts of the site and hence can be directly added as a site contact.

3. It provides a group, named as Site Activation Member that is pre-defined by the system. This is a privileged group almost equivalent to that of an Admin. Users handling multiple roles in a site can be added to this group. This need arises from the fact that certain users might need access to

all the sites, even if they are not contacts in a site. To make things easy, you can directly add the user to this group without

having to add them to each individual site.

Note: If a user is added to Site Activation Members group but at the same time if for some sites the user is added as Reader, then for those specific sites, system will restrict the user's permissions down to Reader (minimal access)

Note: *Not all contacts need to be added to this group compulsorily. To add a contact to the Site Activation Member group, click Groups tab in the User Invitation window.*

Accessible functionalities for SSU Users

After receiving access to the rooms and sites respectively, the users can start carrying out their responsibilities in the module. To note, each and every contact within a site, are allowed access to the functionalities as per the security privileges assigned to them permits.

Contact Type as Site Access	Room access	Site Access	Functionalities							
			Add Documents	Add/Edit /Delete sites	Manage Security	Add/Edit /Delete Contacts	Regulatory Review tab	Add Country/ IRB	Approve/ Reject Documents	Requirem-ents
SSU Specialist	Reader	Can't be added as SSU Specialist	NA	NA	NA	NA	NA	NA	NA	NA
	Editor	Editor(by default)	✓	✓	×	×	×	✓	✓	✓
	Admin	Editor(by default)	✓	✓	✓	✓	✓	✓	✓	✓
CRA (continued to the next page)	Reader	Reader (by default)	×	×	×	×	×	×	×	×
	Editor	Reader (by default)	×	✓	✓	✓	×	✓	✓	×

Type as Site Access	access		Functionalities							
			Add Documents	Add/Edit /Delete sites	Manage Security	Add/Edit /Delete Contacts	Regulatory Review tab	Add Country/ IRB	Approve/ Reject Documents	Requirem-ents
CRA	Admin	Can't be added as CRA	NA	NA	NA	NA	NA	NA	NA	NA
Regulatory Reviewer	Reader	Can't be added as Regulatory Reviewer	NA	NA	NA	NA	NA	NA	NA	NA
	Editor	Reader(by default)	✓	×	×	×	✓	✓	✓	×
	Admin	Reader (by default)	✓	×	✓	×	✓	✓	✓	×
Other Contacts	Reader	Reader (by default)	×	×	×	×	×	✓	×	×
	Editor	Reader (by default)	✓	×	×	×	×	✓	✓	×
	Admin	Reader (by default)	×	×	✓	×	✓	✓	✓	×

The Study Start Up Module

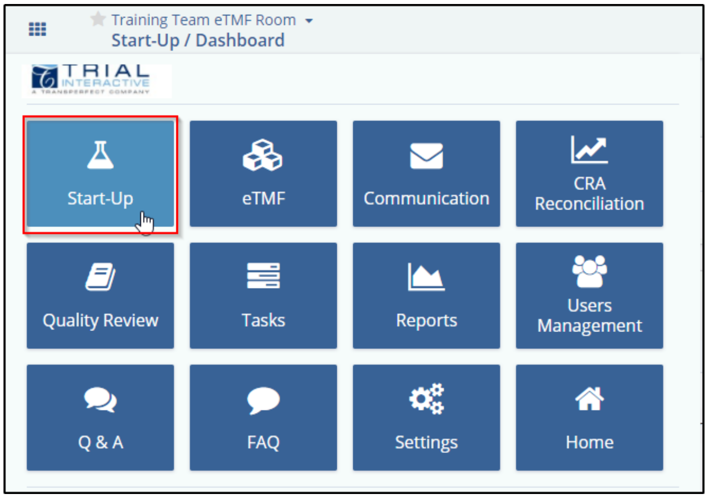
Once you set up the basic configurations and contacts for Study Start Up, you can now move forward to operate the module. The Study Start Up Module comprises of the following topics.

1. Accessing the Study Start Up Module
2. The SSU Interface
3. Sites
4. Countries
5. IRB/EC
6. Regulatory Packets
7. Collecting Essential and non-Essential Documents
8. Documents
9. Regulatory Review
10. Communication
11. Contacts
12. Steps to Site Activation
13. Amendments
14. Overview Dashboard
15. Reports

Each of these topics with their subtopics is described in details in the subsequents.

Accessing the Study Start-Up Module

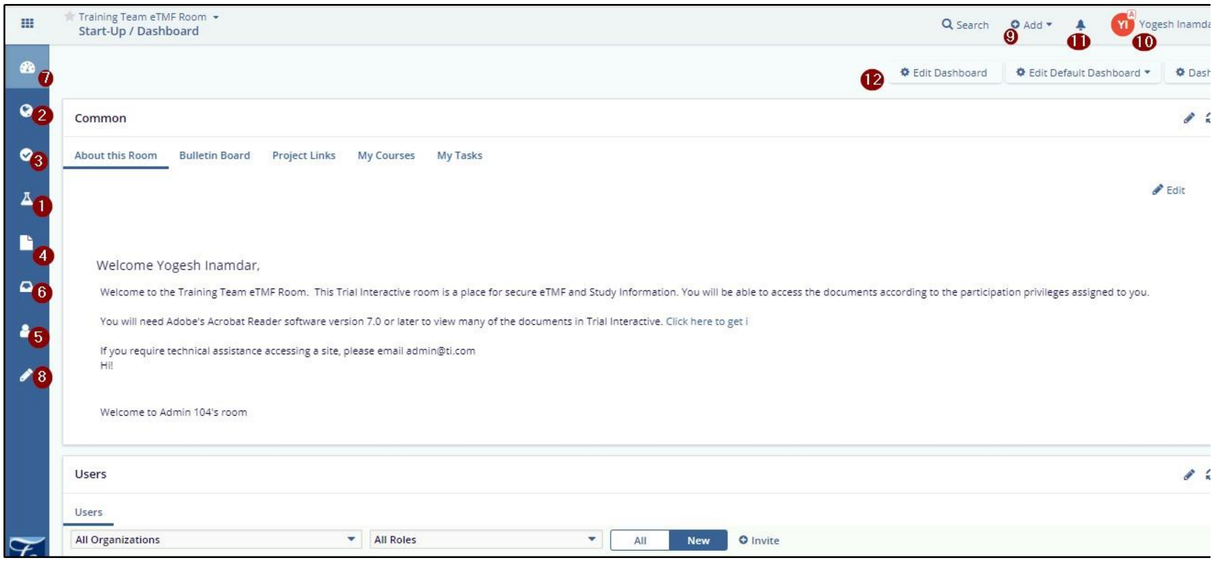
To access the Start-Up Module (SSU), click the Navigation Grid and then the Start-Up icon. This will lead you to the Study Start-Up dashboard. Refer to the screenshot below:



The SSU User Interface

The SSU Module is a platform in Trial Interactive (TI) which allows users to Create, Monitor and Activate sites required for Clinical Trial purposes. Through this interface users can add, upload, and keep track of the progress of the documents collected for site activation, besides reviewing them.

Log in to the Trial Interactive and select the Study Startup room. You'll be taken directly to the Start-Up Overview. This room dashboard has a toggling menu bar on the left with access to various modules and the dashlets on the right. It also has a title bar on the top. Refer to the screenshot below for further insight into functionalities allowed from within the SSU:



The table below describes each numbered section in the screenshot:

Sr. No.	Part	Description
01	Sites	Here the users can create sites and contacts; view them based on status, country, start-up specialist, IRB/EC, CRA. It also allows to export, import, delete, and edit sites, Mass code metadata for sites, add documents, send regulatory packets, and manage security for the contacts in the sites.
02	Countries	Here the users can view and edit the country profile, collecting and reviewing documents for countries.
03	IRB/EC	Here the users can view and edit the IRB/ECs profile, collecting and reviewing documents for IRB/ECs.
04	Documents	Here the users can view, add and keep the track of all the documents collected in the SSU site.
05	Contacts	Here the users can view the contact details based on the User access level in the site.
06	Communication	Here the users can view, add, delete and edit the communication log based on SSU User Access level in the site.
07	Dashboard	Here the users can view variuos dashlets.
08	Regulatory	Allows the users with an aceess as a regulatory reviewer to review the documents assigned to them.

	Review	
09	Add	From this tab the users can add Documents/ Users/Task/ Sites.
10	Username Dropdown	The users can manage user settings, language, can redirect to the guide and so on.
11	Notifications	The users can view the notifications here.
12	Edit Dashboard	The users can manage and edit the dashboad by this button.

Sites

The Sites tab comprises of the following functionalities in Study Start Up

1. Create Sites and adding contacts to them
2. Viewing sites
3. Editing site profile and deleting sites
4. Adding additional IRB/ECs
5. Exporting Site Metadata
6. Mass Coding for sites
7. Managing Security

Clicking the Sites tab from the toggling menu bar leads you to the Sites section. This is where the Start-up Specialists will perform their functions and the users of the sites are allowed to submit and approve documents specific to sites.

The Sites section consists of the Current view on the left and the Grid pane on the right. Besides these, it also allows you to perform various functionalities from the menu bar on the top of the grid pane, and the buttons on the Current View window. Clicking a folder in the current view opens a list of sites in the grid pane. Refer to the screenshot below.

Besides the above, you can also add essential documents, or regulatory approvers specific only to a particular site, and add room users to sites by providing them appropriate security accesses. These will be discussed in subsequent sections.

Sr No	Part	Description
01	Site Activation	Here the user can choose the current view.
02	Add	Allows to add New Investigative Site and Contacts one at a time.
03	Edit	Allows to edit the sites.
04	Delete	Allows to delete the Investigative Site.
05	Import	Allows to import multiple Sites and Contacts at once in the room.
06	Export	Allows to export the sites in the room.
07	Mass Coding	Allows to add Metadata to the multiple selected sites.
08	Sending Regulatory Packet	Allows to send the regulatory packets to the specific sites.
09	Manage Security	Allows to provide security roles to users in the site.

Creating Sites and Adding Contacts

You can create sites by either of the methods:

1. Importing Sites and Site Contacts

2. Adding each site and its contacts individually

1 Importing Sites and Site Contacts

This feature is especially helpful if you want to create many sites at once. This is done by entering the site details in an excel worksheet and uploading them during the import process. A sample worksheet is provided by the system on clicking the Import button. The worksheet consists of two sheets – Investigative Sites, and Contacts. You can download the worksheet, fill it with the site metadata and upload it. Once the worksheet is uploaded, the system will map the metadata of sites and its contacts, and create the sites. The sites thus created appear in the grid for you to view.

Note: *For sites to be imported, the following rules should be adhered to:*

1. The Investigative Sites sheet cannot be left blank.

2. While importing sites, it is compulsory to specify the Principal Investigator without which sites will not be imported.

3. Start-Up Specialists and CRA cannot be imported. You will need to add these later and can use Mass Coding for the same.

4. Sites with same names cannot be imported.

5. Fields such as First Name and Last Name in the Contacts sheet cannot be left blank, as the system will verify the email id of the user with the user's credentials from the database. If they do not match an error will be thrown.

6. Main contact/s should be specified as they are the ones to receive the email when the regulatory packets are sent.

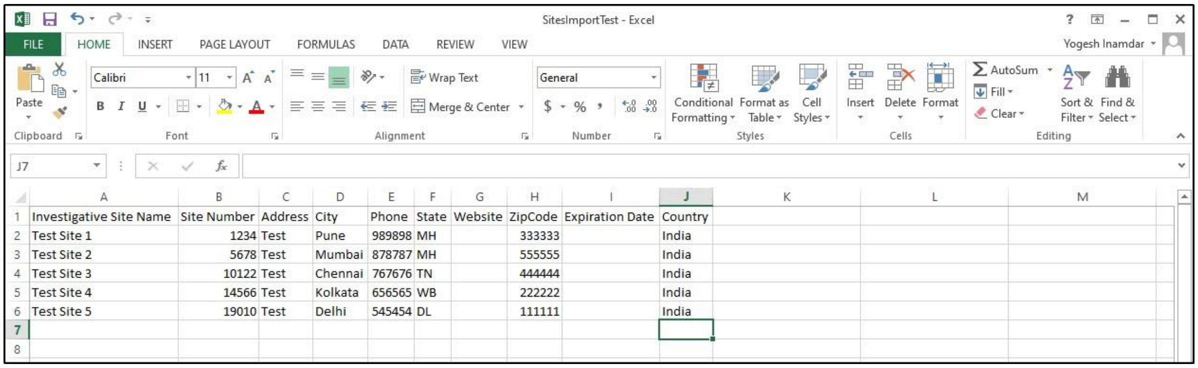
7. If you want a contact to be an Active Contact, Main Contact, or Provide Documents, enter numerical '1' in the Contacts sheet for the fields. The system will automatically map the data and set the actions allowed for the user. On editing the contact from the site profile, you will find the checkboxes for these actions ticked (find more on this in the next section).

8. If 'Active Contact' field is left blank, the contact will be deactivated by the system. You may choose to activate the contact later if, required.

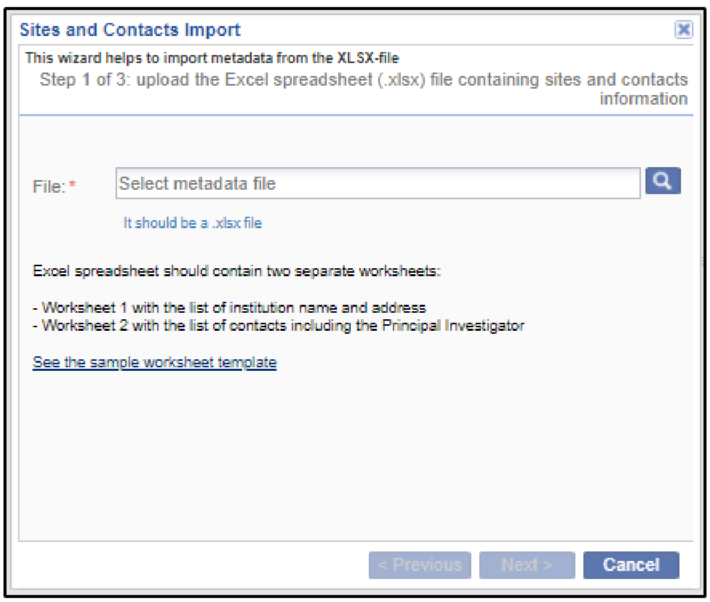
9. If a site and its contacts are already imported, then more contacts can be added to the site only manually or through the API.

10. Data that was not imported can be mass coded for multiple sites later (follow on to Mass Coding of Sites for further details).

Given below, is an example of the worksheet as guidelines to the import process:



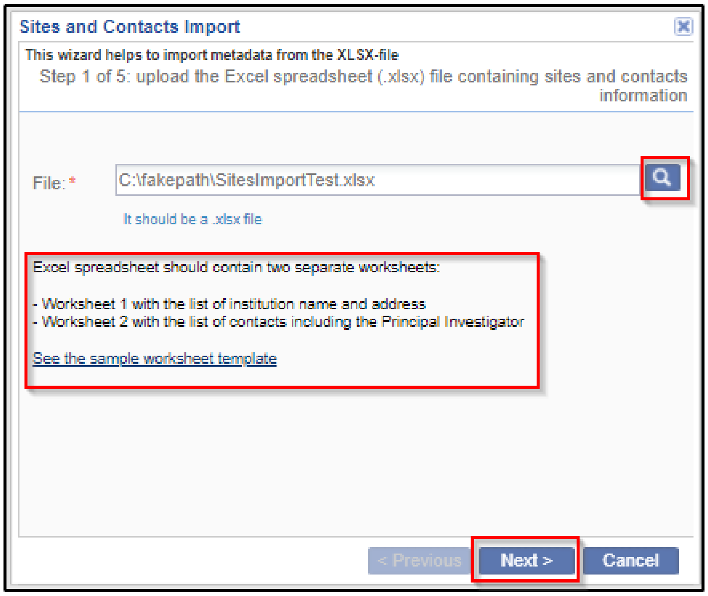
1. Click Import from the menu bar. The Sites and Contacts import window opens.



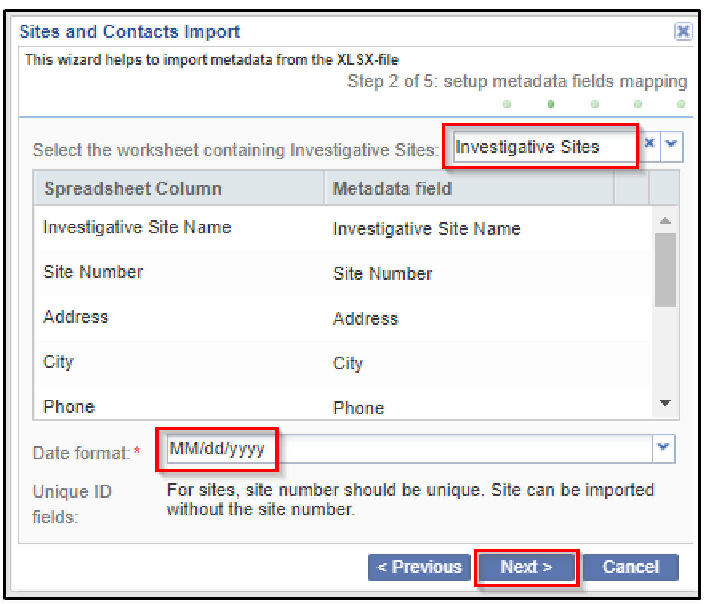
2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon.

a. The excel document should contain two separate worksheets – Worksheet1 with the list of institution name and address, and Worksheet 2 with the list of contacts including the Principal Investigator.

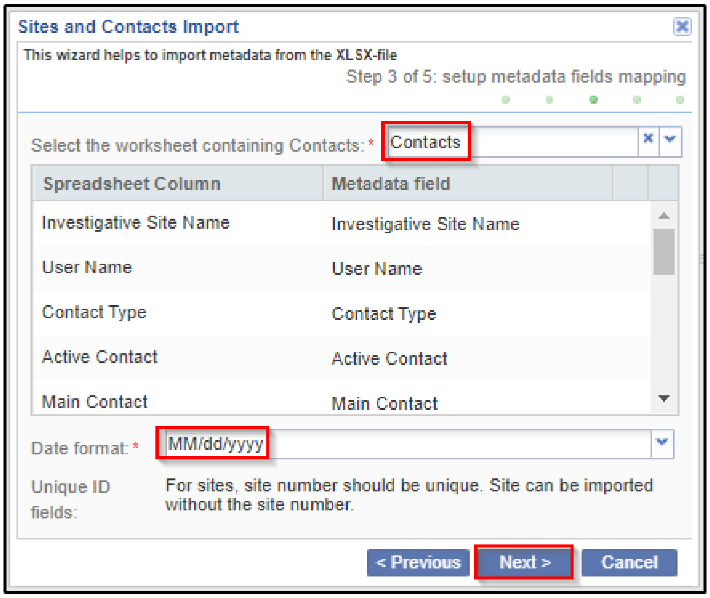
3. Click **Next**.



4. Setup the mapping between metadata fields for Investigative Sites and uploaded file columns. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next**.



5. As in the above step, setup the mapping between metadata fields for Contacts and uploaded file columns. Click Next.



6. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.

7. This will begin the actual import process. Upon completion, the Administrator will get a short report on the issues that were occurred during import.

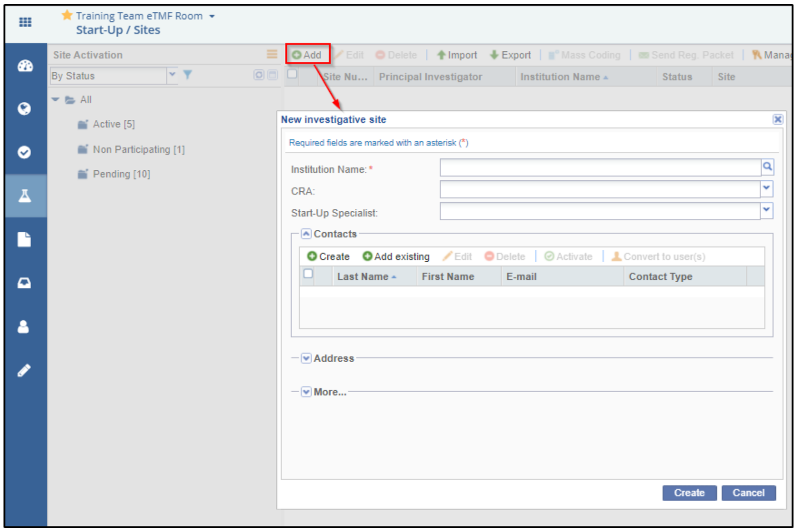
2. Adding each site and its contacts individually

Sites can be created afresh, or added from a list of previously created sites in other rooms related to the same sponsor in a domain. This is especially helpful if the sites are located in multiple locations. So you might want to create sites with the same name but different metadata like contacts, address, IRB/EC, and other details. It can also happen that a site is

conducting different types of clinical trials, hence you might want to keep the same name but the rest of the data can differ. Metadata such as the country, and IRB/EC will be added to the new site only if the room has them configured and available.

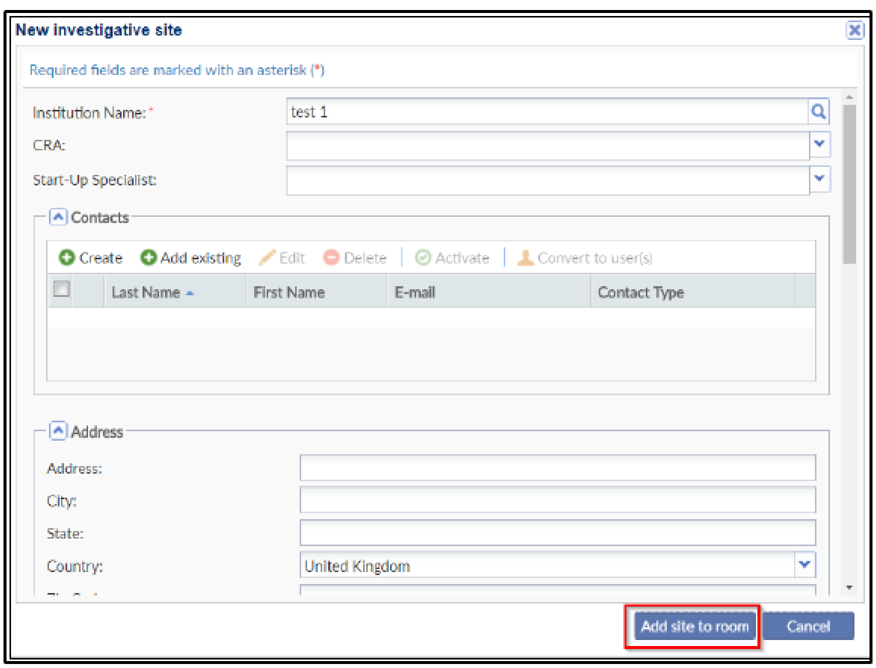
To create sites, follow the procedure below:

1. Click Add from the menu bar. The New investigative site window opens.



2. Either type the Institution Name in the available field or activate the 'Available Investigative sites' window by clicking the magnifying lens at the right end of the field.

Investigative site information is stored in Trial Interactive's database. If a client has used an investigative site in a previous study, the site's information will be stored and easily accessed through this window. If you choose from an existing list of sites, the 'Create' button in the 'New investigative site' window is replaced by the 'Add site to room' button. Refer to the screenshot below:

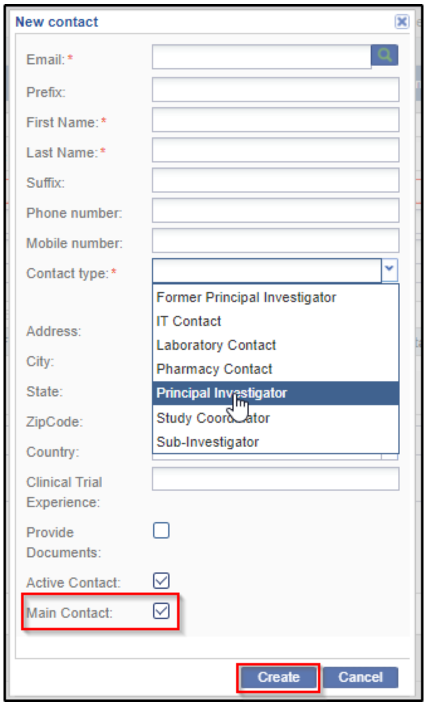


3. Select the CRA from the field's dropdown menu.

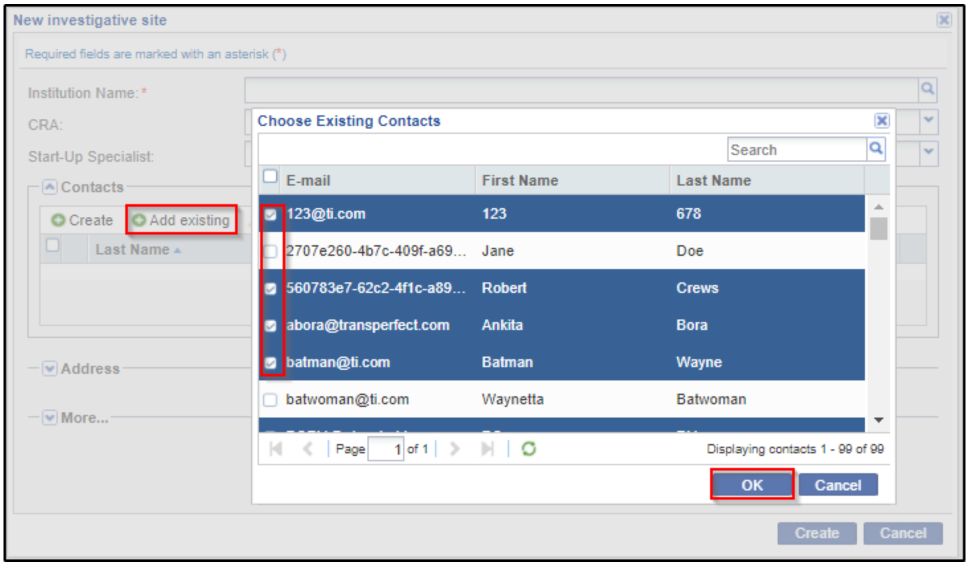
4. Select the Start-Up Specialist from the field's dropdown menu.

5. From the Contact panel of the Site Profile window, the administrator can either create, or add existing contacts, edit/delete contacts, activate/deactivate them, or convert them to room users:

a. Click Create in the Contacts panel to add a new contact to the site. This information, too, is supplied by the client. At minimum, a site must have a contact designated as the Principal Investigator and one of the contacts must be designated as the Main Contact by selecting the Main contact checkbox for the site. If a contact would be responsible to add documents to the site then tick the ‘Provide Documents’ checkbox. Refer to the screenshot below:



b. Click the **Add existing** button to add contacts from a list of existing contacts. Tick the checkboxes next to the contact names to add them to the site. Refer to the screenshot below:



c. You might want to deactivate a contact, if a contact is unavailable for a considerable period of time and assign the role to another user, or would be of use at a later time. You can activate or deactivate a user by clicking the Activate / Deactivate icon in the Contacts panel after selecting the user. This icon toggles from Activate to deactivate state and vice versa depending upon its state.

d. You can edit the profile of a contact by clicking the Edit icon on the Contacts panel.

e. Similarly, you can also delete a contact by clicking the Delete icon on the Contacts panel. A reason of deleting a contact could be that the user is no longer attached to the organization.

If a contact who has added documents, is later deleted, the contact name will be appended with '(undefined)' in the metadata of the documents added by the contact.

f. Contacts can also be converted to Editors or Readers by clicking the Convert to user(s) icon on the Contacts panel. This functionality is available from the Contacts section and is discussed in detail there.

6. Click Address to open the array of data fields for entering the address where the site is located. Here, you can specify the Country which is important when filtering for a site.

7. Click More to open another array of data fields. Here you enter important site information like the site expiration date, status of the site, its email domains, preferred communication mode, and the eFeasibility Status.

a. Besides the above, you also specify the IRB/EC details here. Select the IRB/EC Type from the dropdown. The IRB/EC type could be Any, Local, or Central.

b. Select the IRB/EC Name from the dropdown. This dropdown will list the IRB/ECs that have been added to the room, or domain.

If the required IRB/EC does not appear in the dropdown, you can create/add an IRB/EC on the fly by clicking the plus sign at the right end of the field.

c. You may enter the Expected Submission Date, and IRB/EC Submit Date for the submission of essential/required documents of the IRB/EC.

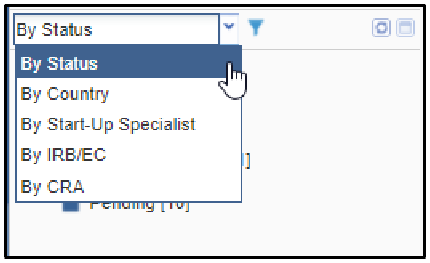
8. Click Create or Add site to room at the bottom of the window as per the process.

9. Repeat until all investigative sites have been created for the room.

Viewing Sites

Sites can be viewed from the list of sites appearing in the grid pane. The user can choose to filter the sites appearing in the grid by selecting the filters from the current view dropdown as shown below.

The Sites Current View



The Current View Dropdown offers five views:

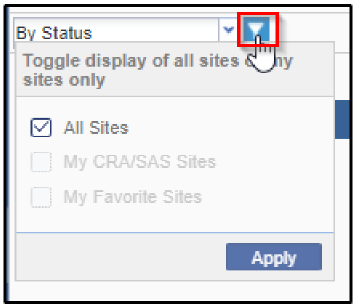
- **By Status**: The Site status could be Not Specified, Active, Pending, Rejected. When an investigative site is added to a data room, it has Pending status. After all documents for the Investigative site are collected, and appropriate country and IRB documents are approved by the start-up specialist and by regulatory approvers, the site can be activated and it moves to Active status. If the site is rejected during activation process, it is assigned Rejected status.
- **By Country**: This view reveals a list of countries, and when you select a particular country from the list, you see all investigative sites related to this country. Not Specified status indicates that a country is not specified in investigative site's profile.
- **By Start-Up Specialist**: This view displays a list of data room users with Start-Up Specialist designation. When you select a particular user from this list, you will see all sites where this user is set as start-up specialist. If you select Not Specified status you will see the list of investigative sites that have no start-up specialist specified in their profiles.
- **By IRB/EC**: IRBs can be of two types: Central or Local. Central type will show you all investigative sites with a central IRB specified in their profiles. Local type will show you all investigative sites with local IRB specified in their profiles.
- **By CRA**: This view displays a list of data room users with CRA designation. When you select a particular user from this list, you will see all sites where this user is set as CRA. If you select Not Specified status you will see the list of investigative sites that have no CRA specified in their profiles.

Buttons on the Current View

Some studies require that a data room house hundreds of sites. The user can toggle the display between the sites where the user is a CRA or a Start-Up Specialist, or All Sites.

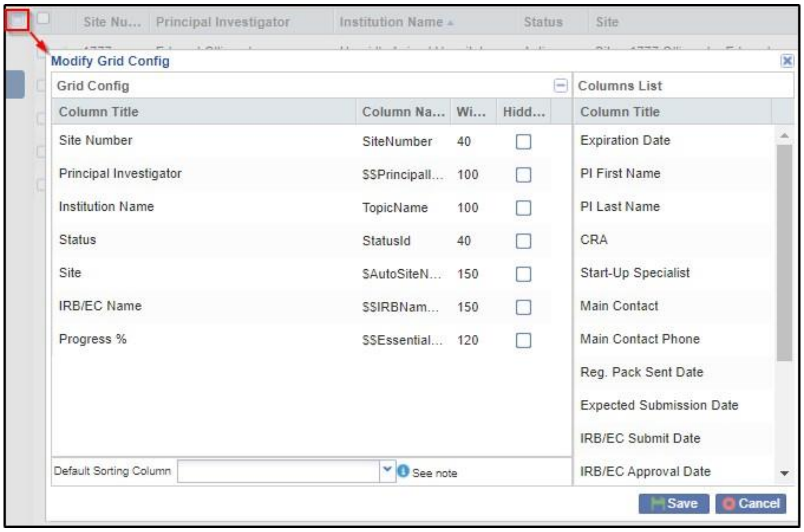
The user can refresh the current view by clicking the Refresh Current View button. Through the Configure Grid button, the room administrator can decide the columns that team members need to display in the grid on the right, or choose the default sorting column. Users can show or hide columns in the grid, but only room administrator can make additional columns available for viewing.

1. Toggle Display Button.



2. Refresh Current View Button.

3. Configure Grid.



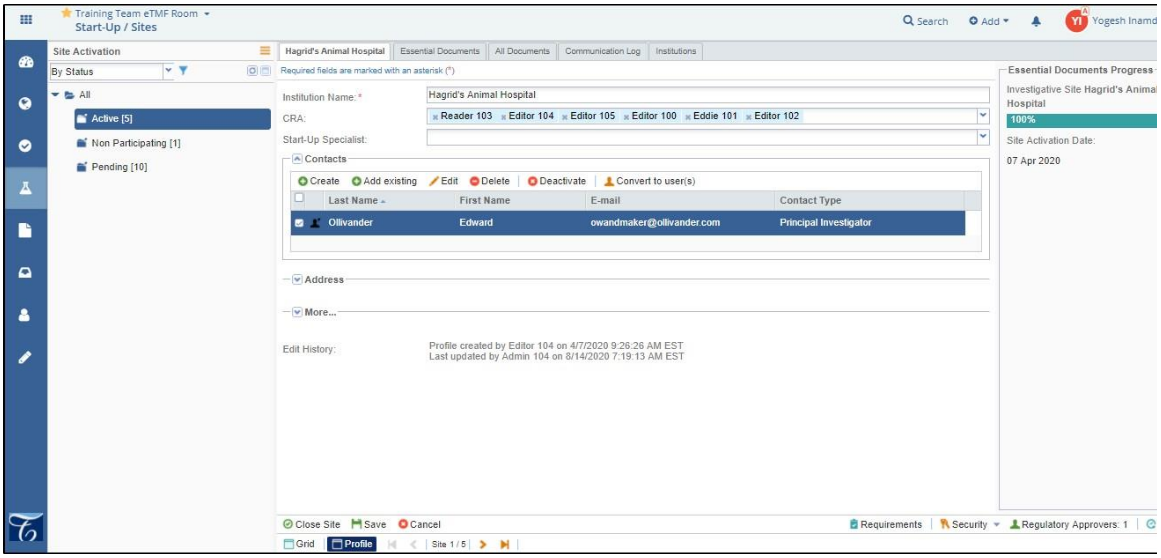
Viewing or Editing Site Profiles

After selecting the required view as shown above, the user can edit a site profile as follows:

1. Select a site from the grid.

2. Click Edit in the menu ribbon to open Site Profile of the site selected. The site profile opens, or

Double-click a site from the grid to open its Site Profile window.

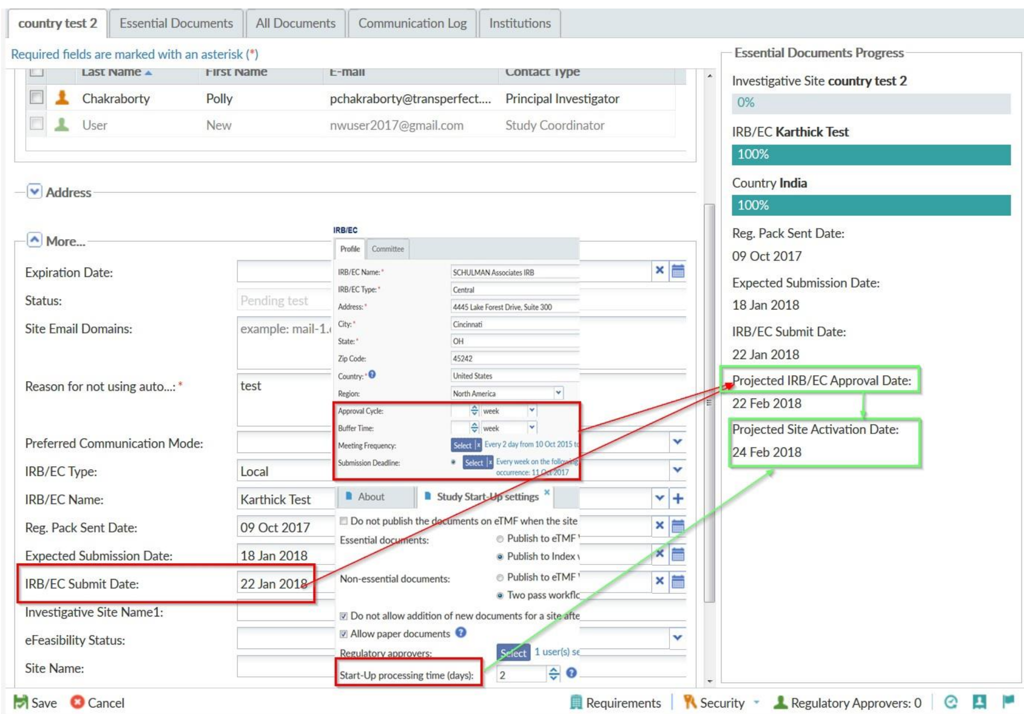


3. The Essential Documents Progress panel shows the Progress percentage bar to track the site completeness as the essential/ required documents collected and reviewed.

4. Below the Essential Documents Progress Bar, the Regulatory Pack Sent Date, IRB/EC Submission Date, and Site Activation Date are automatically displayed as per their entries in the database.

5. Based on the IRB/EC Submission Date, Next Meeting Frequency and Date, Approval cycle, and Buffer time, the system will predict the Projected IRB/EC Approval Date and display it on the right panel of the site profile window. If, for some reason the IRB/EC did not approve the documents, the system will automatically project the Next Approval Time.

Besides these, based on the Projected IRB/EC Approval Date and Start-Up Processing time (specified in the Study Start-Up Settings), the system will also display the Projected Site Activation Date on the right panel. Refer to the screenshot below:



But if there are no IRB/EC Submit Date and Expected Submission Date specified in the site profile, the system will not display them in the right panel. Instead it will project the Next Pre-Submission Deadline Date based on the meeting schedule specified in the IRB/EC profile. To display the Projected IRB/EC Approval Date, the system will use the Next Pre-Submission Deadline Date. The process to project the Projected Site Activation Date remains the same as mentioned above. The projected Next Pre-Submission Deadline Dates can be viewed by clicking the last calendar icon next to the Expected Submission Date field.

6. Make necessary additions or changes to the data fields in the profile. Refer to Adding sites and sites contacts in case of clarifications.

7. Click Save at the bottom of the panel.

Exporting Sites

Here the users can export

- Selected Records
- All Sites in the current grid
- All Sites in the data room

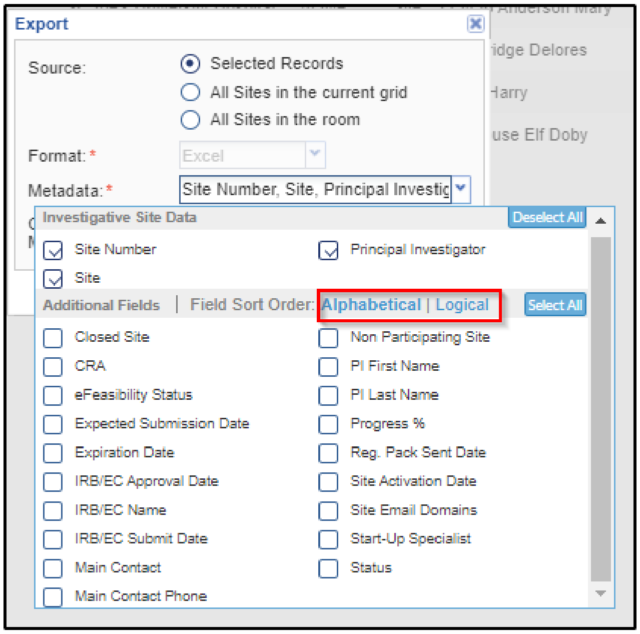
1. To Export a single site or a specific set of selected sites, select the site or sites by clicking the check box or boxes at the left side of the grid.

2. Click **Export** in the menu ribbon above the site grid. The Export window opens.

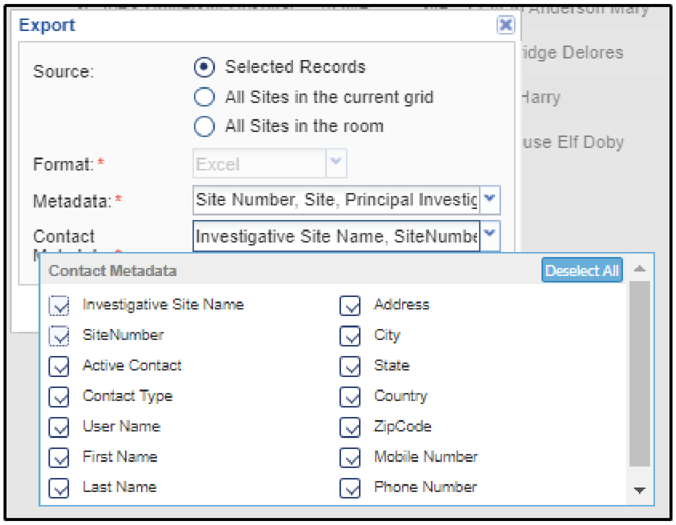
3. Choose the Source from the radio buttons. The export Format is preselected as Excel and cannot be altered.

4. Activate the Metadata dropdown menu to the right of the metadata field.

5. Select which metadata fields you want to include in the export. By not activating the dropdown, you will leave all metadata fields active and the export will include all fields.



6. By the same method, select which contact metadata fields you would like to include in the data export.



7. Once you have made the appropriate selections, click Export. When the export is complete, you are notified about the Get Job Result in a popup.

8. To view the exported file, navigate to the Notifications .

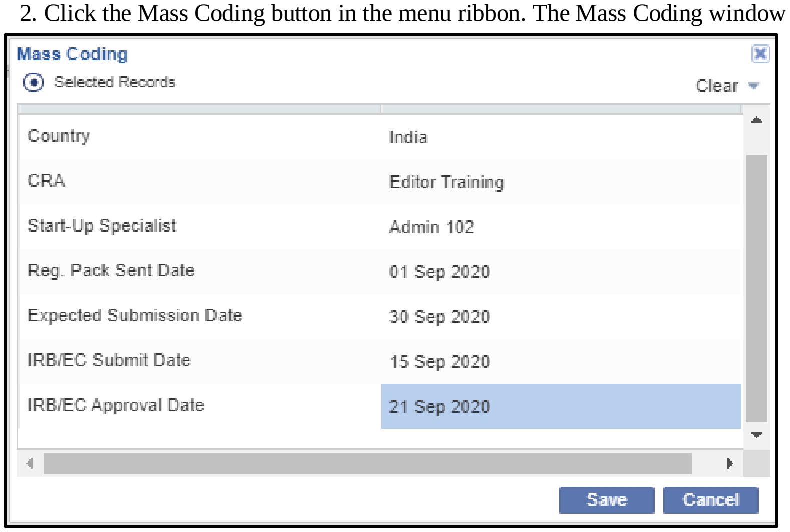
Mass Coding for Sites

During the initial room configuration, the metadata fields that are available for mass coding are marked in the room's Form Settings *(page 93)*by the room's administrators. Once that process is done, it is possible to use mass coding for metadata fields of Investigative sites.

To mass code sites:

1. Select the investigative sites from the list in the grid that have common metadata fields that need to be coded by clicking the check boxes to the left of the Investigative sites grid.

2. Click the Mass Coding button in the menu ribbon. The Mass Coding window opens.



3. Double-click the fields in the Value column that you intend to code for all of the selected sites. The field becomes active.

4. Fill in the data that is common to all of the selected sites. Some of the fields are associated with calendar selections and some with dropdown menus.

5. When you have completed entering the common metadata, click Save at the bottom of the window. A Confirm? Window opens.

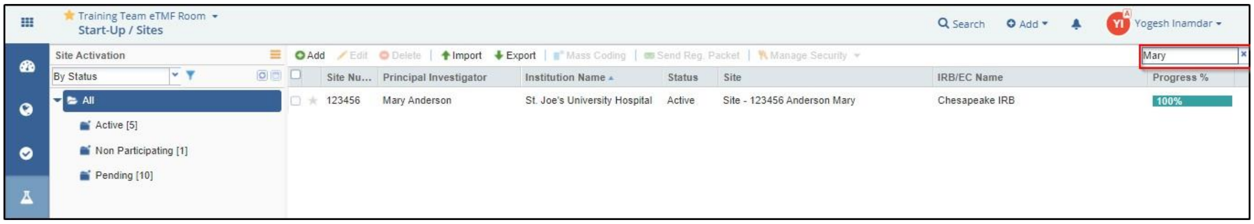
6. The coding changes will be added to the site profiles. Note that if the requested coding additions or changes conflict with existing Investigative site profile metadata, the user will see a warning message.

In such cases, the coding requests will not be completed. The previously existing metadata will remain as part of the site profile. To make such changes to the site profile, the user must use the Edit function described earlier in this guide.

Searching for Sites

To search for sites from the grid pane, enter the search pattern in the Search textbox in the top ribbon bar and click the magnifying lens icon or hit Enter. Sites matching the search pattern will be displayed. The system will not only select sites that match the pattern from the columns in the Grid Pane, it will also display sites that have matching searches from the site profiles. For example, if a site has a contact that matches the search pattern, it will be displayed.

Deleting Sites

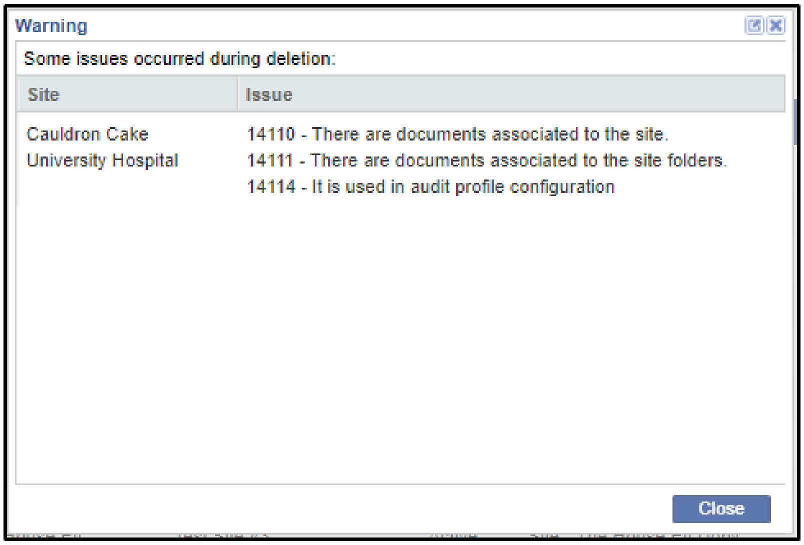


1. Select a site from the list.

2. Click Delete in the menu ribbon. A window pops up, asking for confirmation that you want to delete the site. It also prompts you to enter the reason for deletion.

3. Enter the reason and click Delete.

4. Sites cannot be deleted if they have already collected documents and you will receive a message warning you about the same in a popup.



Note: ***To delete a site, its documents must first be deleted.***

Setting up Site Specific Required Documents

The required / essential documents specific only for a particular site can be set up through the Requirements button located at the bottom of the Sites Profile dashboard. This is discussed as below:

1. Double-click the site from the Grid Pane to open the Sites Profile window.

2. Click the Requirements button located in the lower toolbar of the Sites Profile window. This opens the Required Documents window.

3. Click Add from the menu bar in the window.

4. Select the document types as required from the collapsible tree.

5. Tick the checkbox for ‘Site Activation’ and select the contacts from ‘To be submitted by’ dropdown.

6. Click Save to add the required document type and continue adding, else click Save & Close to add and exit the window.

Institutions or Additional IRB/ECs

Although clinical trial organizations today adhere to protocols from a central IRB/EC, at times it might be required to adhere to protocols of more than one IRB/EC. For example, an organization may have one central IRB/EC, and one or more local IRB/ECs.

In the Site profile, you will be able to specify only one IRB/EC of any type. In case you need to provide additional IRB/ECs, proceed with the steps as below:

1. From the Grid Pane, double-click the site for which you want to specify additional IRB/ECs

2. The Site Profile window opens.

3. Click the Institutions tab.

4. Click Add from the top menu bar.

5. The rest of the procedure is the same as specified in sections Adding or Creating New IRB/ECs *(page 512)* and Adding Existing IRB/ECs to Data Rooms *(page 513)*

6. The procedure to add from existing IRB/ECs is also the same, with the only difference that from within a site, the Add Existing functionality will only display the IRB/ECs available in the data room.

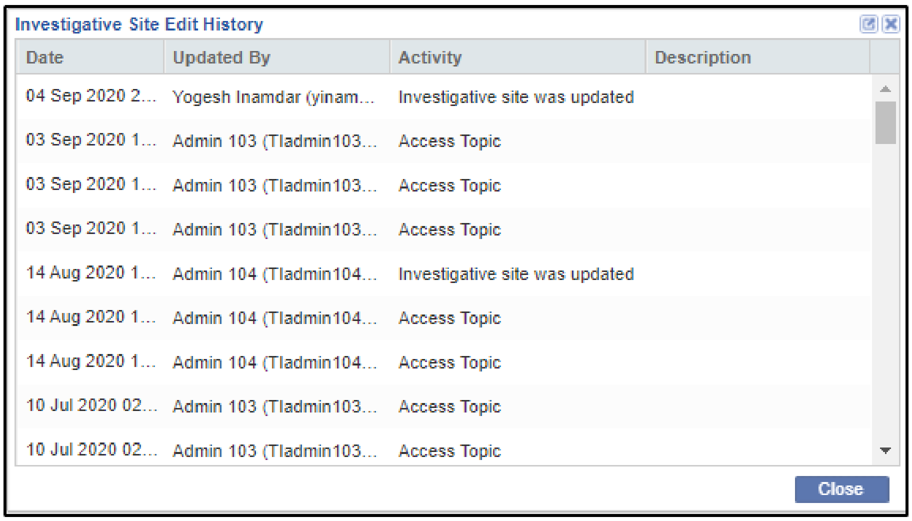
Viewing History

From a site profile window, you can also view histories related to site edit, contact activities, and milestone.

Site Edit History

1. Double-click a site name from the Grid Pane to open the site profile.
2. Click the Show Edit History icon located on the toolbar at the bottom.

3. This opens the Investigative Site Edit History window which contains information on the site creator and also the last updated by user.

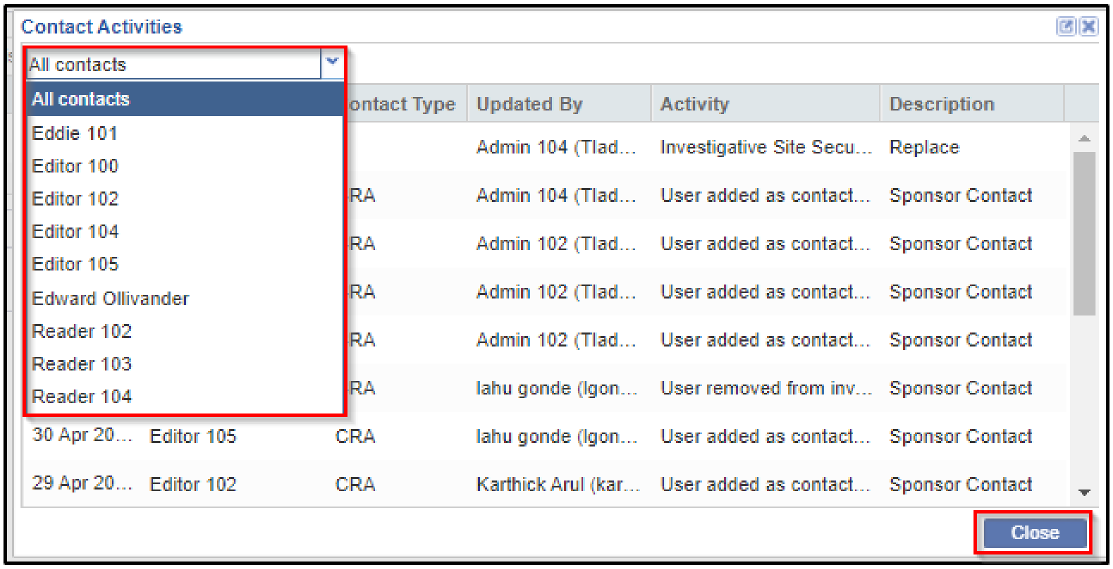


4. The information here cannot be edited. Click **Close** when you are done with viewing.

Site Contact Activities History

1. Double-click a site name from the Grid Pane to open the site profile.
2. Click the Show contacts history icon located on the toolbar at the bottom.

3. This opens the Contact Activities window which contains information on the site contacts and also their activities.
4. Select All contacts, or a specific contact from the dropdown to retrieve the details of only that contact.



5. The information here cannot be edited. Click **Close** when you are done with viewing.

Managing Security

We have already seen in section Accessible functionalities for SSU Users *(page 520)* the types of security privileges provided by Trial Interactive system to the users and contacts of investigative sites. The security privileges can be provided for all sites in a data room, as well as from within the Study Start-Up Sites section.

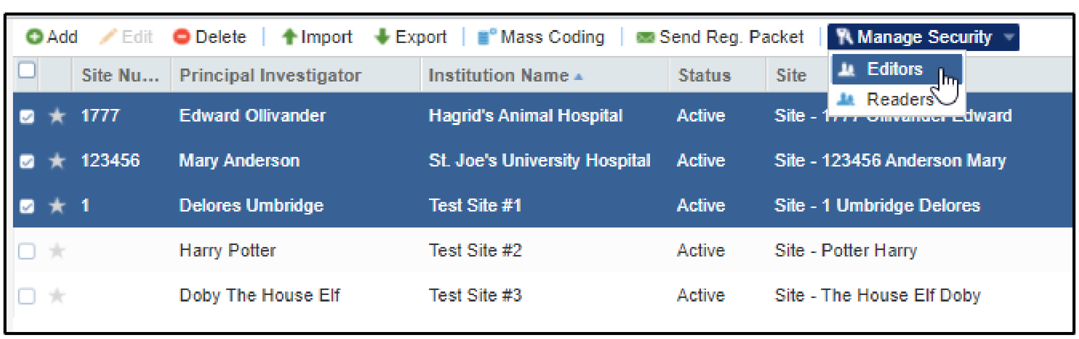
Access to users for all sites can be provided by adding the site users to Default editors/readers group, or by making them Default access members of sites.

From within the SSU Sites section, the administrator can view and provide security privileges to users for site/s from two locations:

> **Note:** *The administrator has to be site members like a SSU Specialist, or Co-Investigator, or Site Activation Member to be able to manage security of sites from within the SSU Sites section.*

1. The **Manage Security** dropdown on menu bar above the Grid Pane:

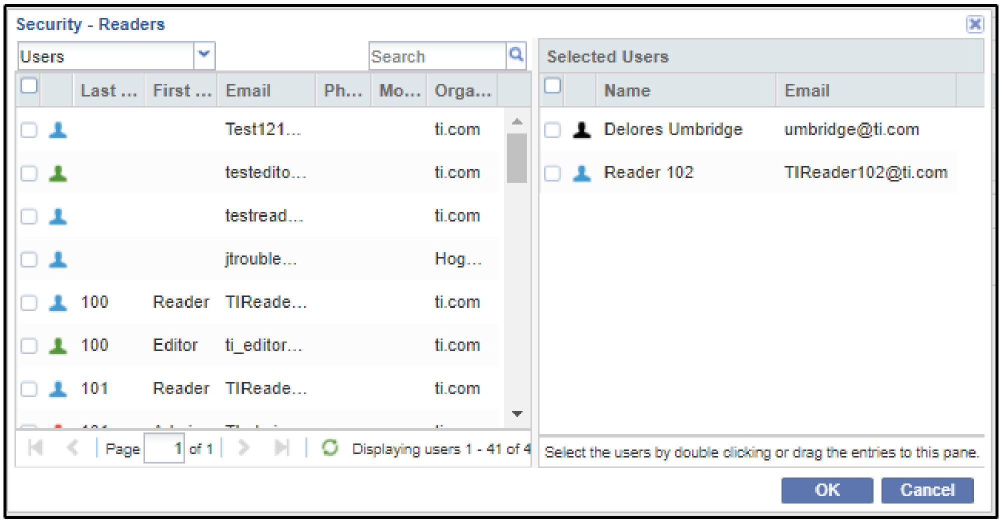
From the Grid Pane the administrator can assign Editor and Reader accesses to users/group of users, thereby making them contacts of multiple sites. By selecting the checkboxes next to the site names in the grid the administrator can make the selected users/groups member to multiple sites at one time. This is helpful if contacts will have same privileges in multiple sites.



2. The **Security** 

dropdown from within a site profile window:

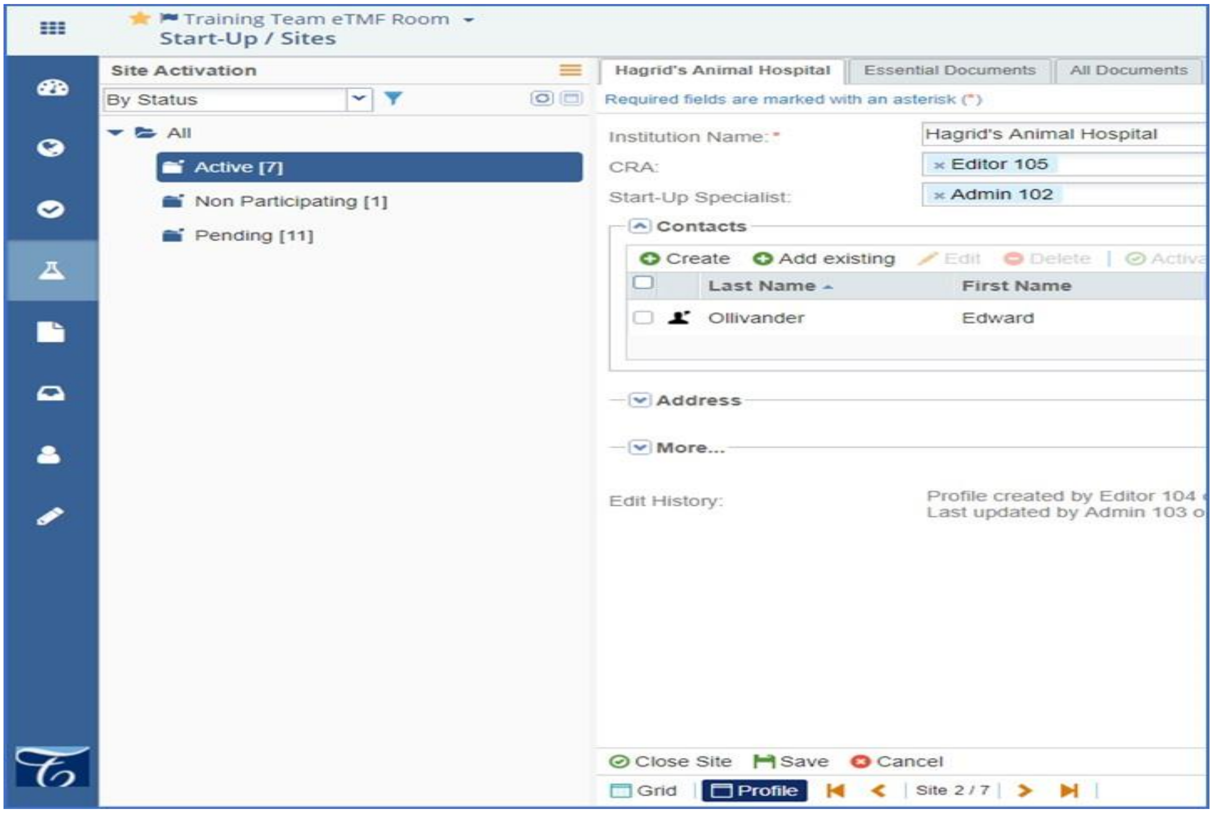
From within a Site Profile, the administrator can assign Editor, and Reader accesses to users/group of users for only the particular site whose profile he/she is accessing at the moment.



Besides these, the administrator can also view the contacts who are assigned Editor, and Reader privileges in the site/s, from the right pane of the Security dialog box. Refer to the screenshot above.

Note: The procedure to add users to default editors/readers groups is described in details in the User Management *(page 67)*section.

Ability to Mark Sites as Closed



As a Clinical Trial is completing, the investigative Sites must ultimately be closed. While not typically part of Study Start-Up, this process is very much a part of the Clinical Trial lifecycle. WithTrial Interactive 10.1 the system shall have the ability to mark Sites as closed once the trials are completed for the Sites. Once closed, these Sites will be moved to a separate folder for closed sites. Advanced Validation for metadata fields is still available when Sites are marked as Closed.

Sites marked as Closed will still appear on eTMF completeness reports but documents from thesesites will not be shown on expired/expiring documents reports or dashlets. Additionally, new amendments will not be applied to Closed sites.

Marking a Site as Closed

If Study Start Up has been enabled in a room, any changes to a site's status must be made from the Study Start Up module. To do so, simply navigate to SSU in the Navigation Grid and open the Sitesarea.

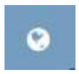
Select a site from the list of Active sites and double-click or select the site and click Edit in the menu-ribbon above the grid. This will open the site profile. As seen in the screen shot above, a userwith sufficient privileges to edit the site (Editor or Admin) will be able to mark the site as closed.

Countries

Since studies can be conducted in multiple countries across the globe, it is important for the administrator to add the countries where the clinical trial is taking, and the investigative sites located in the country during its initial setup and configuration. The following section discusses:

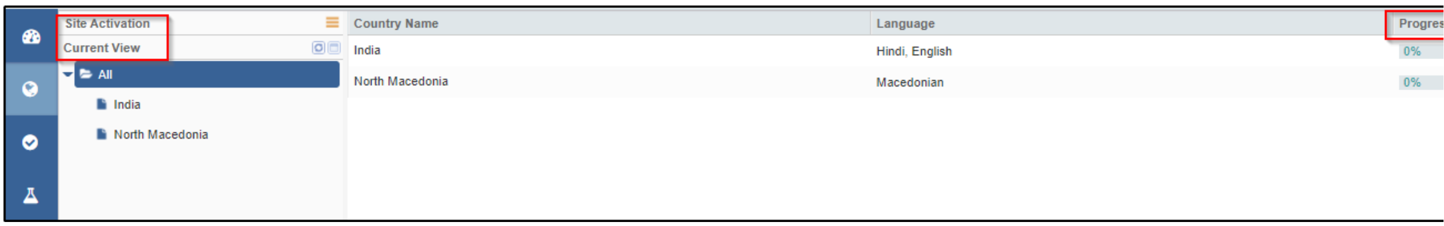
1. Viewing and editing country profiles
2. Viewing documents

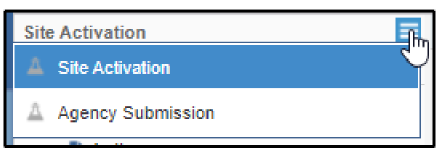
Note: Adding countries, and essential/required documents to countries are discussed in sections Adding Countries to Data Rooms *(page 511)*, and Setting up Required Documents for Countries *(page 514)* respectively

The Start-Up **Countries**  tab accessed from the toggling menu bar on the left, allows you to set up documents for countries associated with sites. The Countries dashboard consists of the Current view on the left and the Grid pane on the right.

Viewing Countries

Countries in which the sites are located can be viewed from the list of countries appearing in the grid pane. The list of countries appearing in the grid and current view pane depends on the filter selected by the user in the current view panel. Refer to the screenshot below.



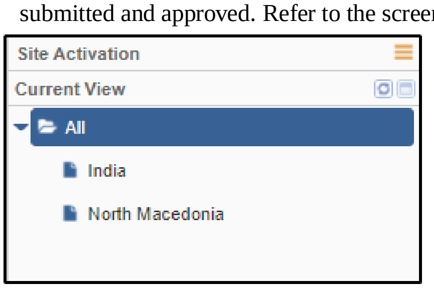


The Current View of the Countries associated with sites is based on:

1. Site Activation
2. Agency Submission (this section is used for Submission Packages)

Site Activation

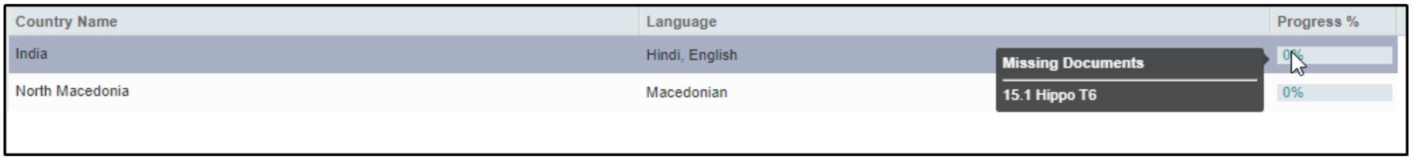
Choose **Site Activation** as your Current View. This view reveals a list of countries for which specific documents need to be submitted and approved. Refer to the screenshot below.



A country name will be visible in the Current View listing only if the **essential documents** required for site activation for that country have been set up.

The Countries Grid Pane

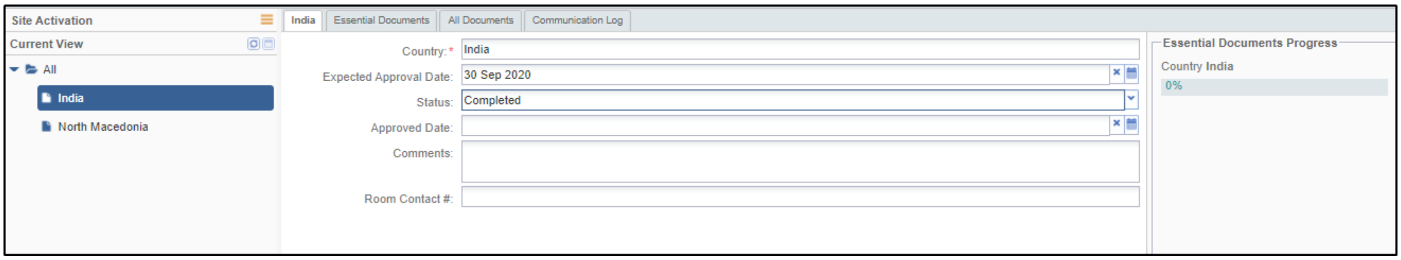
The Grid Pane on the right provides a list of countries for which documents are required along with the Progress % bar to the extreme right showing the percentage of the essential documents submission progress. Hover the mouse pointer over the Progress % bar to get a popup with a list of Missing Documents. Refer to the screenshot below.



Viewing or Editing Country Profiles

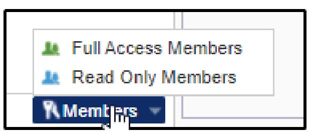
1. Click the country name in the Current View panel, or double-click the name of the country in the display grid in the middle of the screen.

2. The editable fields of the country profile become available in the center of the screen. The Essential Documents Progress graph also appears on the right side of the screen for that single country.



3. Click the data fields in the profile to add or edit profile information.

4. Click the Members dropdown at the bottom right corner of the Profile window. From here you can select users who will have Full Access, or Read Only access to the sites under the specified country.



5. Click one of the options from the Members dropdown. This will either open the Full Access Members window, or the Read Only Members window for you to select the members. Click **Ok** after you are done.

6. Select **Users/Groups** from the dropdown.

7. You can select the users/groups by double-clicking them from the left panel to transfer them to the right pane, or dragging a user/group from the left pane to the right pane.

8. Click **Save** at the bottom of the panel to save your changes, or click Cancel to reset the changes you have made.

Submission Packages

It is common practice to associate health agencies with sites and send submission packages to them for their approval. Sites can't be activated for the clinical study unless the agency approval is received. A study may have multiple health agencies located in various countries. These agencies may have more comprehensive site activation submission packages involving hundreds of documents and that need to be reviewed and approved. Since the agencies are related to countries, submission profiles and packages for them are accessed from the **Countries** Section.

This module allows you to prepare submission profiles where the user can provide the details such as agency name, country, status of submission, documents to be included in the submission profile, date when the package was submitted, and also the status of the submission package.

A submission package can contain documents from the eTMF, SSU, Site, Country, and IRB, or any document from the disk. For instance, the IB and protocol are already filed in the eTMF but are required for the submission package. The clinical trial organization downloads the submission package to perform QC Review as in other documents and then forwards it for regulatory review. All the actions from creating, and editing submission profiles to downloading submission packages for health agencies can be performed by an **admin or editor**.

Through the Agency Submission section in Trial Interactive, the organization can track multiple submission packages for the same country in case one submission package is rejected. Once a site is activated, these documents are not transferred to the eTMF and are left in the submission package.

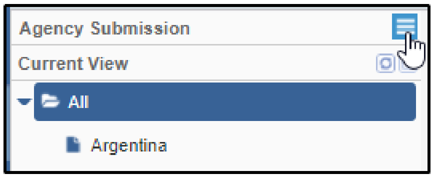
Defining Health Agencies

Before adding submission profiles and downloading packages, it is essential to define health agencies to be associated with sites. Health agencies need to be defined at domain level.

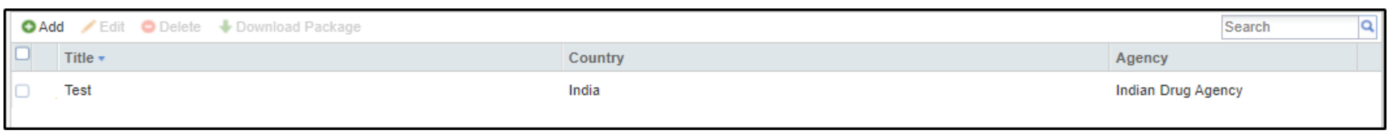
Note: *Contact the helpdesk to create Health Agencies, if they are not already created*.

Agency Submission

Select Countries from the toggling menu bar. Choose Agency Submission as your Current View. This view reveals a list of countries where health agencies are available with their details. Refer to the screenshot below, which shows the view of the left pane.



The Grid pane on the right reveals the country-wise submission profiles that are submitted to the agencies. Through this pane you can Add, Edit, Delete submission profiles, add packages to the profiles, and download them for further processing. Refer to the screenshot below:



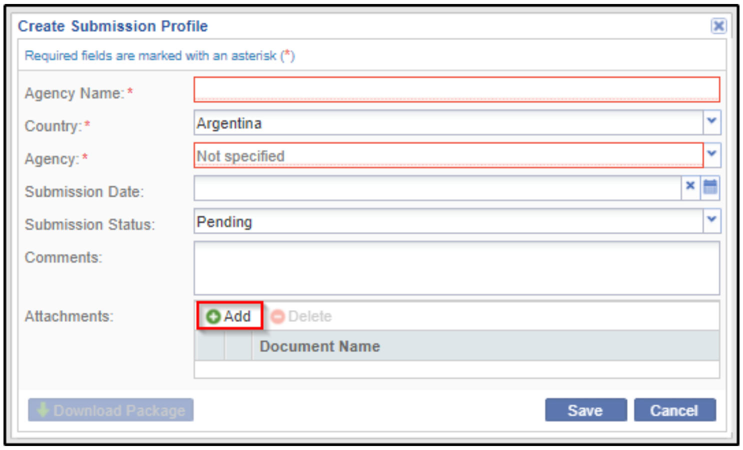
Adding or Creating Submission Profiles

To create a submission profile, follow the steps below:

1. Select **Agency Submission** as your **Current View**.

2. Select the **Country** where you want to add submission profiles.

3. Click +**Add** from the menu bar located on top of the Grid Pane. The **Create Submission Profile** window opens. Refer to the screenshot below:



4. Enter the Agency Name, Country of its location, and other details as asked in the form.

5. Click +**Add** , to upload documents as a part of the submission package of the profile you are creating. Kindly note that the Submission Status has to be Pending to submit documents.

6. Click **Save**.

Adding Site/Country/IRB Documents to Submission Packages

To add site, country, or IRB/EC documents to a submission package, follow the steps as below:

1. Navigate to Documents section from within the SSU module.

2. From the Current View, select 'By Site' for adding site related documents, 'By Country' for adding country related documents, and 'By IRB/EC' for adding IRB/EC related documents to a submission package.

3. Selecting an option, will list the sites, countries, or IRB/ECs in the Current View pane as per your choice.

4. Select a site, country, or IRB/EC as required.

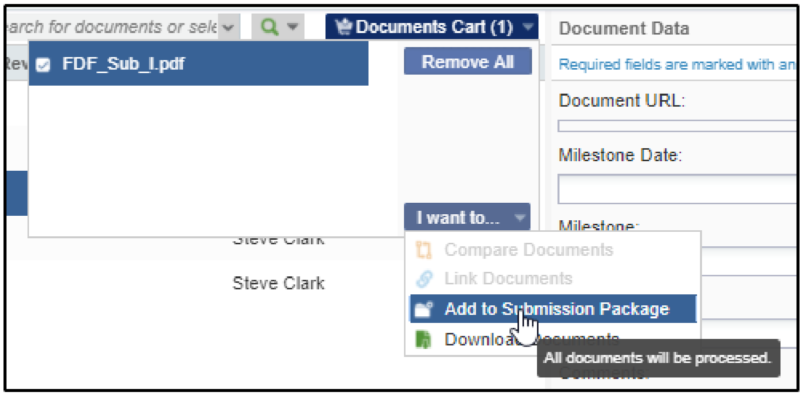
5. This will list all essential/required documents, as well as non-essential documents in the Grid Pane.

6. Select the document/s as required for adding to a submission package.

7. Add the documents to the Documents Cart by selecting Add Selected to the Cart option from the right-click menu, or Documents dropdown, or by dragging and dropping the selected documents to the Document Cart.

8. You can continue adding documents to the cart from as many filters in the Current View dropdown.

9. Once you have completed adding documents to the cart, click Documents Cart -> I want to...Add to Submission Package to add documents to add them to the required submission package. Refer to the screenshot below:



10. The Select a Submission window opens. Select a submission package as required from the list and click Add document(s) to Submission. The number in a red circle with a blue link is the number of attachments already uploaded to the submission package/profile. Refer to the screenshot below.

11. Navigate to Start-up -> Countries. Reload the page for the uploaded documents to be updated to the package.

12. Open the country under Agency Submission from Current View pane on the left and notice the change in the number of attachments besides the profile name on the Grid pane.

Adding Documents to Submission Packages from the eTMF

As an admin or editor, besides adding documents to submission packages through the processes described above, you can also add documents from the eTMF.

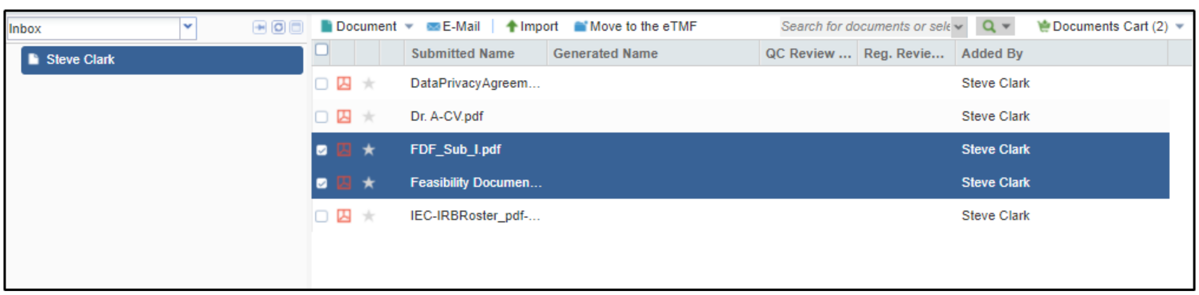
To add documents to a submission package from the eTMF, follow the steps as below:

1. Navigate to eTMF -> Documents.

2. Select the folder which contains the document you want to upload from the left pane.

3. Select the documents to be uploaded from the right pane.

4. Add the documents to the Documents Cart by selecting Add Selected to the Cart option from the right-click menu, or Documents dropdown, or by dragging and dropping the selected documents to the Document Cart. Refer to the screenshot below:



5. Add the documents to the submission package by clicking Documents Cart -> I want to…Add to Submission Package, and select the submission package as required from the 'Select a Submission' window.

6. The rest of the procedure is the same as described in earlier section.

Downloading Submission Package

Once the documents are uploaded to the required submission package, you may download the package for further processing.

To download a package:

1. Select the required profile from the Grid Pane.

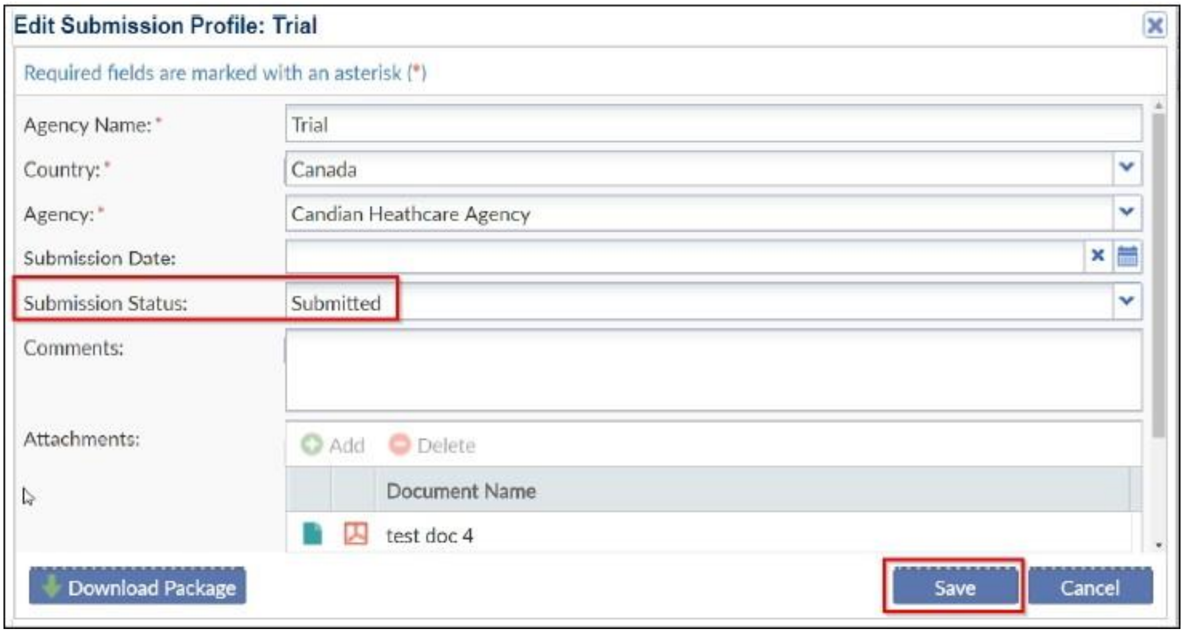
2. Click Download Package from the menu bar on the top of the Grid Pane, or

3. Click Edit from the menu bar and click Download Package.

4. You will receive a notification regarding the documents downloaded. The documents are downloaded in a .zip format.

Editing a Submission Profile

Once the documents are downloaded, you can edit the submission profile and change the Submission Status to Submitted and click Save. Refer to the screenshot below:

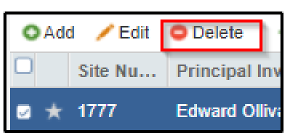


After the Submission Status is changed to Submitted, the profile is locked from further additions of documents to it. Notice that the +**Add** and –**Delete** buttons are now disabled, which means further additions to/deletions from the submission package is now prohibited.

To add further documents you have to create another submission profile. Kindly note that you can use **Edit** to also make other changes in a submission profile as required.

Deleting a Submission Profile

To delete a submission profile, select the required profile from the Grid Pane and click the Delete button from the top menu bar.



A message asking you to confirm the deletion appears in a popup. Click Yes to delete the profile. Refer to the screenshot below:

IRB/EC

It is essential for sites to adhere to the protocols as set by the IRB/ECs for more efficient and effective performance of clinical trial operations. Today organizations are encouraged to use central IRBs as opposed to multiple local IRBs. But the decision to use central or local IRBs or more than one IRB of any type for a clinical trial depends upon the clinical research enterprise, especially if it intends conducting multi-site trials.

Trial Interactive supports the use of both central and local IRBs. Although it is advisable to use a single central IRB for multi-site trials, sites may need to use more than one IRB/EC. Trial Interactive not only allows you add IRB/ECs as required, it also allows you to specify additional IRB/ECs. In this section we will discuss the following:

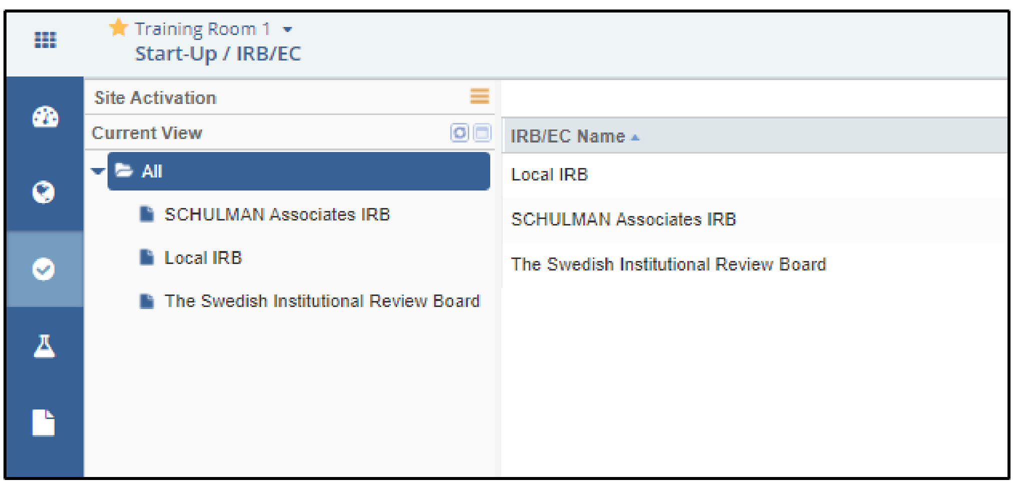
1. Adding additional IRB/ECs to data rooms
2. Viewing IRB/ECs
3. Editing IRB/EC profile

Adding additional IRB/ECs

You can specify more than one IRB/EC for a site from within the Sites module of SSU. Proceed to section Institutions or Additional IRB/ECs *(page 538)*for more details on this.

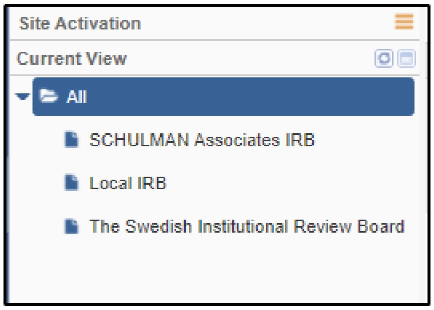
Viewing IRB/ECs

Clicking the IRB/EC tab from the toggling menu bar on the left, will list IRB/ECs available to the room. The IRB/EC dashboard consists of the Current view on the left and the Grid pane on the right with the progress bar showing the percent of essential documents collected for each IRB. It also has a Search textbox in the top right corner to search for IRB/ECs. Refer to the screenshot below.



The IRB/EC Current View

The Current View panel on left lists the IRBs that have accumulated one or more of the essential IRB documents for the study. An IRB/EC name will be visible in the Current View listing only if the essential documents required for site activation for that IRB/EC have been set up.



The IRB/EC Grid Pane

The IRB/EC Grid Pane on the right provides a list of IRBs for which documents are required along with the Progress % bar to the extreme right showing the percentage of the essential documents collected. Hover the mouse pointer over the Progress % bar to get a popup with a list of Missing Documents.

Viewing and Editing IRB/EC Profile

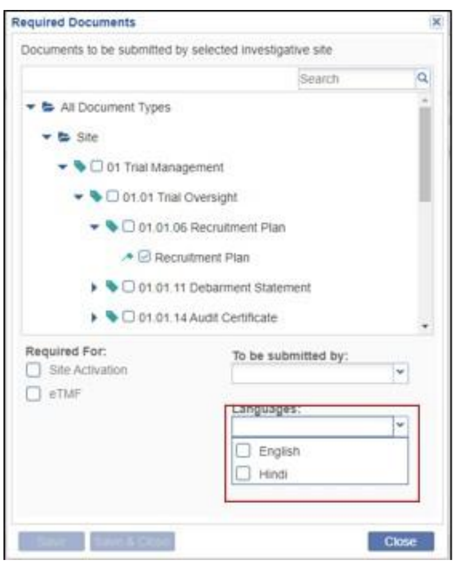
1. Click the IRB name in the Current View panel, or double-click the name of the IRB in the Grid Pane.

2. The editable fields of the IRB profile become available in the center of the screen. The Essential Documents Progress graph also appears on the extreme right of the screen for that single IRB.

3. Click the data fields in the profile to add or edit profile information.

4. Click Save at the bottom of the panel to save your changes, or click Cancel to reset the changes you have made.

Support for Multiple Translations and Multiple IRB/EC Approvals



Quite often, the same Document Type requires a translated version, for example, a regulatory authority may require the document in French, German, and English. Additionally, there may be multiple IRB/ECs required in the regulatory approval workflow, and so the same Document Typemay need to be recorded for each of these separate organizations.

For this reason, in SSU 10.1 a document type may now be set up as required document multiple times. They can now be set up as required documents more than once based on:

- Language
- IRB/EC

This improves support for European agencies, as well as supporting the process where more than oneEthics Committee may be required for a specific Country or Site's activation.

In order to perform this task, follow the standard procedure for designating a document as required. Simply select multiple languages from the drop-down menu in the Required Documents window where possible.

Regulatory Packets

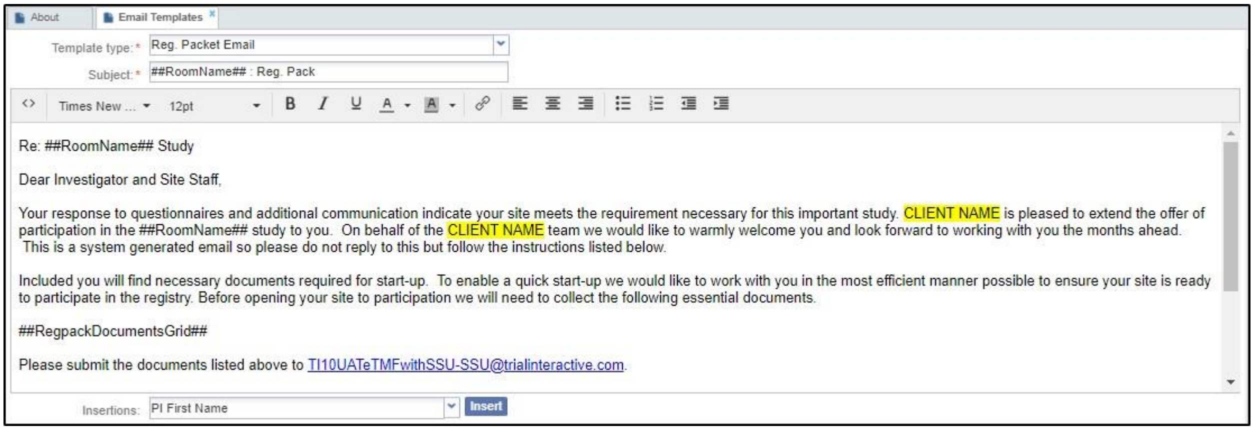
When all required documents are collected, the Start-Up Specialists, or the sponsor, or CRO forwards an initial regulatory documents packet for collecting the documents from various contacts in the site. Main contacts receive emails with a list of regulatory documents required. If no main contacts are specified for a site, then the Principal Investigator of the site will receive the email. The administrator can set up the email template that would be sent out with regulatory packets. The email can also include document templates as attachments for specific document types if the clinical research

enterprise wants to adhere to specific formats for the documents. The Main contacts, on receiving the email, go about the task of collecting the documents, getting them approved from the Principal Investigator, and submitting them to the site. They can submit documents to the site by logging into the site and adding them, or by emailing them to the room. If the documents are emailed into the room, it is the SSU Specialists' responsibility to add them to the sites.

You can choose to send regulatory packets for one or multiple sites. Before sending regulatory packets, admins can set up email templates and document templates for specific document types as required.

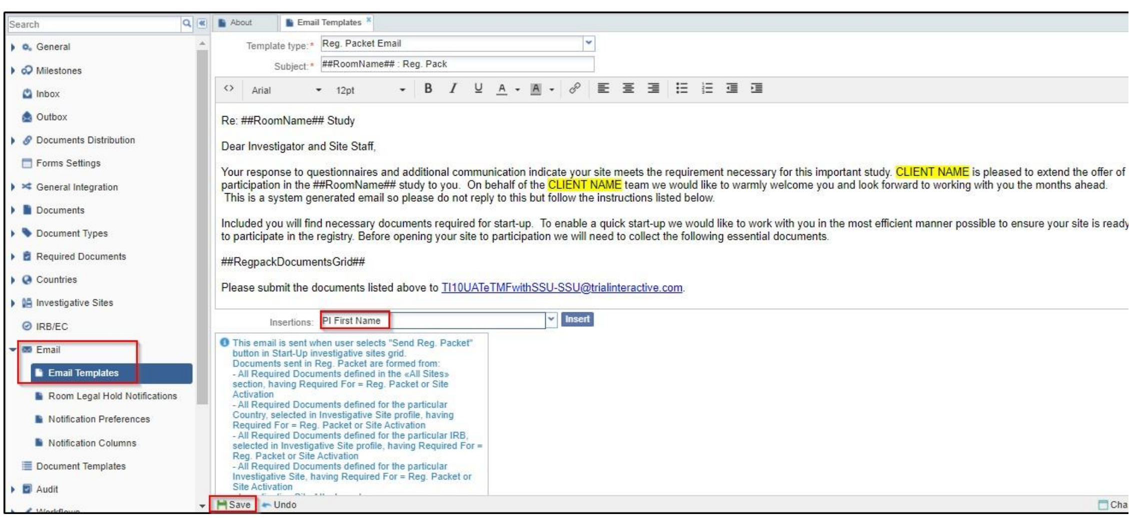
Setting Up Email Templates

The administrator can set up the body of the email template from the room's settings. By default, the system provides a template body with the insertions needed to tell the system to send the names of essential/required documents, and the name and contact details of the SSU Specialist.



All the administrator needs to do is insert the email text description. To set up the template, proceed as follows:

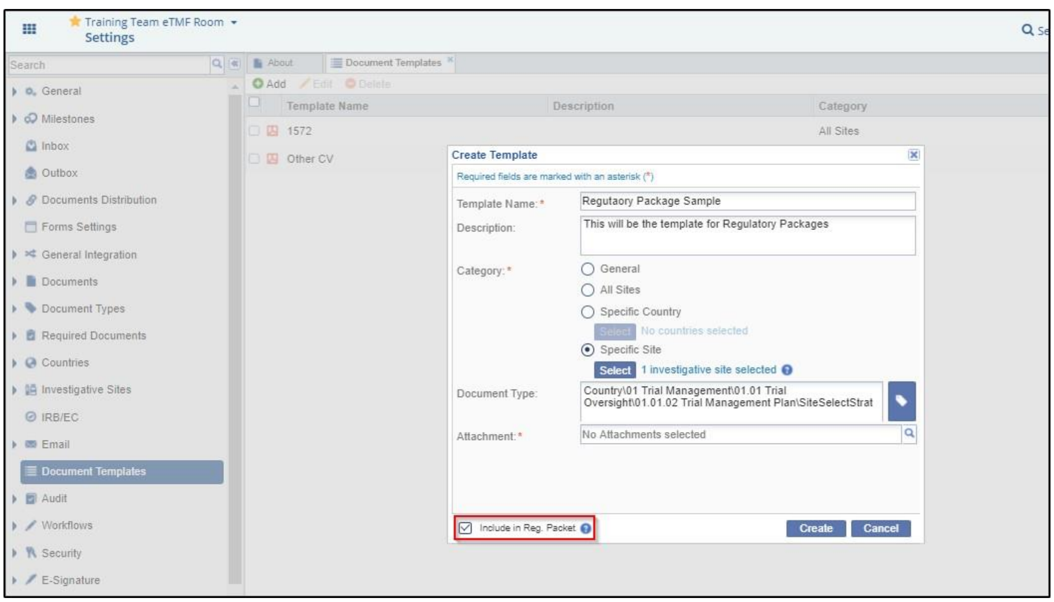
1. Navigate to **Settings**.
2. Select **Email** from the left panel and click the arrow next to it.
3. Select **Email Templates** from the collapsed dropdown.
4. The Email Templates window opens in the right.
5. Select **Reg. Packet Email** from the Template type dropdown.
6. The default template populates itself.
7. Click the appropriate location in the editor and insert the email body as per the format provided by your organization.
8. Besides the insertions already provided by default, you can insert your own insertions in the email body for the PI name, Domain Name, Room Name, and Investigative Site details by choosing appropriate options from the Insertions dropdown and clicking Insert next to the dropdown.
9. Click **Save** to commit the changes.



Setting up Document Templates

To set up document templates, follow the procedure as below:

1. Navigate to Settings.
2. Select Document Templates from the left panel.
3. The Document Templates window opens in the right.
4. Click Add from the top menu of the window to create a template.
5. The Create Template window opens.
6. Enter the details as required. You can choose to create templates for General category documents, for All Sites, or for specific country or site from the Category section of the window. One document template can be created for any one of the categories mentioned above. Hence select a radio button as required.
7. Select the Document type and provide the attachment specifying document template for the document type.
8. To include the template in regulatory packets, tick the Include In Reg. Packet checkbox. Document templates included in regulatory packets will be sent even for non-essential/required documents for the selected investigative sites. Refer to the screenshot below:

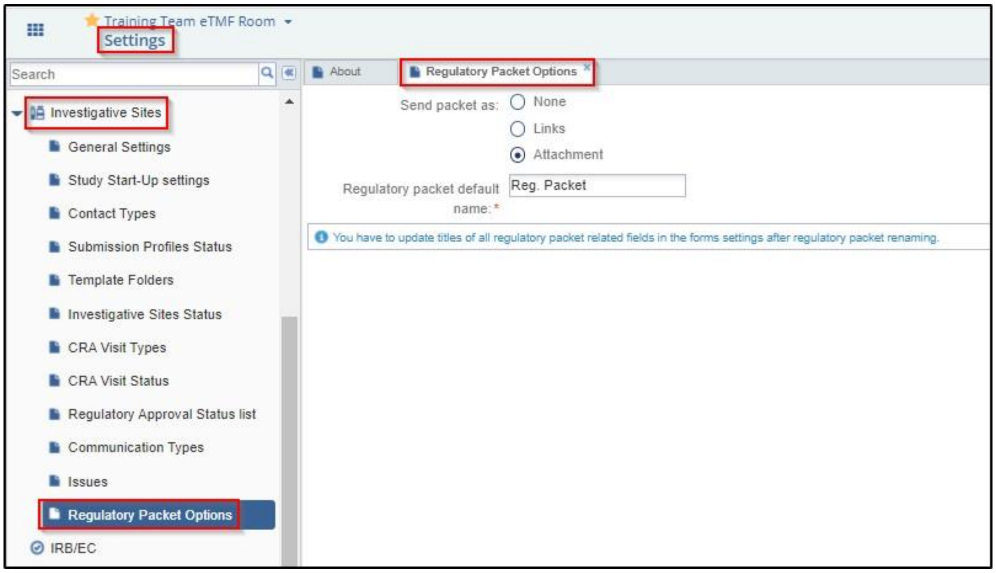


Sending Regulatory Packets

It is possible to send docs within a regulatory pack with the following options:

1. None
2. Links
3. Attachments.

This is similar to the Email documents functionality and can be configured from Settings -> Investigative Sites -> Regulatory packet Options. Refer to the screenshot below:



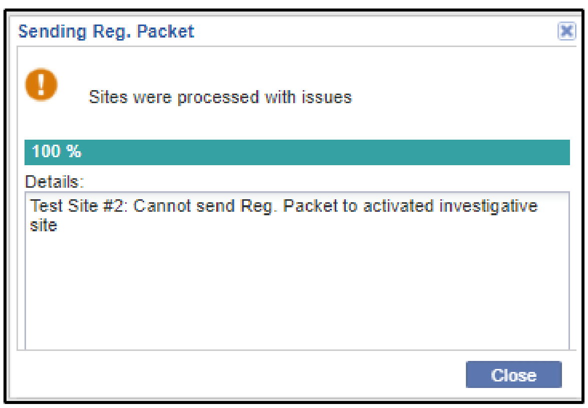
To send regulatory packets follow as below:

1. Select the site/s for which you want to send regulatory packets from the Grid Pane.

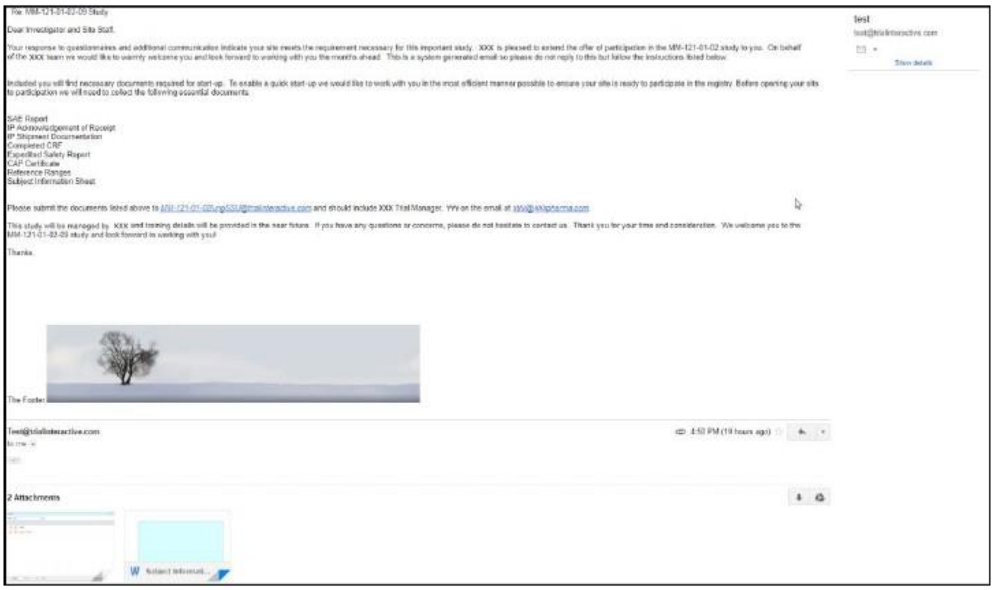
2. Click the Send Reg. Packet button from the top menu bar in the Grid Pane.

3. A Confirmation needed pop up opens asking you to confirm your action. Click Yes to continue.

4. Once the regulatory packet emails are sent to the main contacts in the site, you will receive a status message stating the issues faced by the system while sending the emails, or stating that the process was completed successfully.



5. The document templates, if created and specified for the selected sites, will be included as attachments in the emails. Below is the screenshot of a sample email:



When the regulatory packet is sent, and the site status is 'Pending', the system will automatically create a task for the SSU Specialist for the next submission deadline. The task thus created can be viewed in the Tasks module accessible from the Navigation Grid.

Collecting Essential and Non-Essential Documents

Once the document requirements are configured, documents can enter the room through three methods depending on preference and access:

1) Via a unique SSU email address

2) Via mass Import (follow to Documents section for import of documents).

3) Via individual document attachment

As mentioned earlier, all the sites, countries, and IRB/ECs require addition of essential and non-essential documents to them.

The Grid Panes of sites, countries, and IRB/ECs allow you to add Essential Documents, non-essential documents, and add / edit communication logs. The procedure to add documents is the same for sites, countries, and IRB/ECs, and is discussed below.

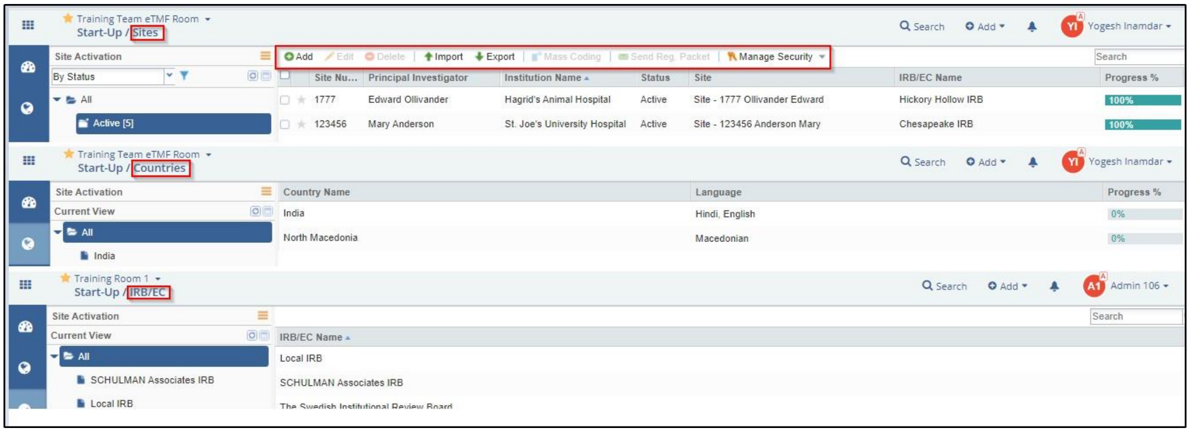
Essential Documents

Setting up of Essential Documents for Sites, Countries, and IRB/ECs involve the following steps:

1) Adding Required/Essential Documents from Settings for Sites, Countries, and IRB/ECs.

2) Adding, editing, and reviewing documents of each Essential Document type from the menu bar.

The Top Menu Bar



Refer to the screenshot above:

Notice that documents for sites, countries, and IRB/ECs can be added and edited from the menu bars located on top of the Grid Panes of Sites, Countries, and IRB/ECs. You can also add documents as attachments. The procedure is the same for all and is described below.

Add Essential/Required documents

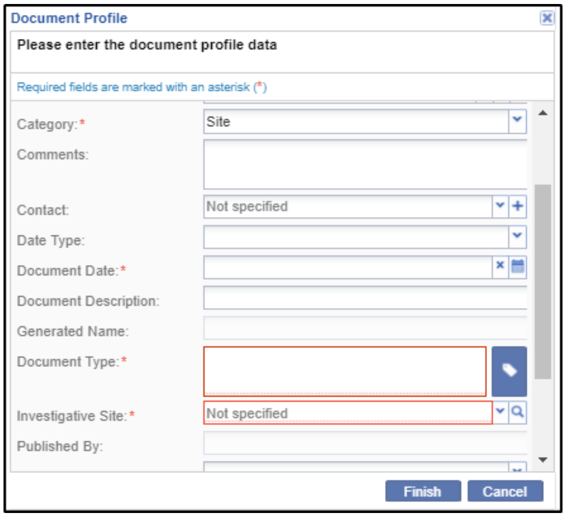
Note: Documents can be added for contacts such as Sub-Investigator or Study Coordinator only if they are added as contacts to the site, have the 'Provide Documents' functionality enabled for them, and specified as contacts in the essential documents from room settings for site specific documents.

1. Navigate to the module to which you want to add documents as required. The modules here are Sites, Countries, or IRB/EC.

2. Select the document type to which you want to add the document from the Grid Pane.

3. Click Add from the menu ribbon above the documents grid. The Document Profile window opens. Complete the required fields, marked by a red asterisk *, including the attached file.

4. Screenshots for each module are provided as below:

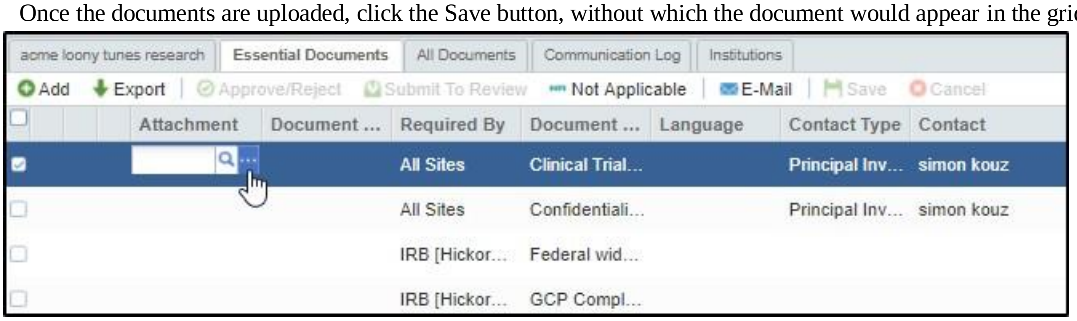


5. You can either attach a file to a document type by clicking the magnifying lens at the end to

6. Click Finish at the bottom of the window. The document takes its place in the grid with a Pending status.

You can also add documents by double clicking the Attachment field in the grid for the required document type for which you want to attach a file. This will activate the magnifying lens and dots to upload attachments. Refer to the screenshot below:

Once the documents are uploaded, click the Save button, without which the document would appear in the grid with a red



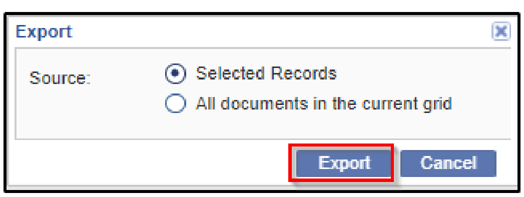
mark but will not acquire the Pending Status.

A document uploaded by this method is not complete in its profile unlike uploading it through the Add button and acquires the warning symbol next to it. Refer to the screenshot above. Clicking the warning symbol will open the Edit Document Profile window for you to complete the details. Click Finish on completing. The warning symbol now disappears.

Export documents

1. Click the **Export** 

button in the menu above the grid. The Export window opens.



2. You can either export selected documents from the grid, or all documents from the current grid.

3. Click **Export** at the bottom of the window. An Exporting Documents window opens.

4. Following the on-screen instructions, click the **Get Job Result** button to get the results that are delivered in a zipped folder.

QC Review by SSU Specialist

The documents are reviewed and approved by the Start-Up Specialists and then by the Regulatory Reviewer. Both these roles are assigned to users within the TI SSU module. Notifications within TI can be sent out to notify both these roles when they have pending tasks to complete.

A Start-up Specialist can approve documents only for his or her own sites. To approve documents:

1. Select a document from the grid.

2. Select the Approve button from the menu ribbon above the grid. The Approve / Reject Documents window opens.

3. You can select the Status to be Approved or Rejected as you deem fit.

4. Select the appropriate approval date.

5. Click Approve to save changes. The document's status changes to Approved or Rejected as selected by you.

You can also approve the documents by double-clicking the Status field in the grid for the required document. This will activate the Status dropdown. Select a status as appropriate. Click Save. Refer to the screenshot below:

You can approve several documents simultaneously.

1. Select several documents from the grid.

2. Select the Approve button from the menu ribbon above the grid. The Approved/Reject Documents window opens.

3. Click Approve/Reject at the bottom of the window to save changes.

4. The Attachment field or Attach URL by clicking the dots.

Submitting documents for Regulatory Review

Once documents are collected and approved by a start-up specialist, the documents should be submitted for regulatory review. Rejected documents or documents in pending status cannot be submitted to review.

1. Select the approved document or documents to be submitted to review by clicking the appropriate check boxes in the Essential Documents grid.

2. Click the Submit To Review button in the menu ribbon directly above the grid.

Note: Rejected documents cannot be submitted for Regulatory Review and need to be re-submitted again, if required. Paper documents are also submitted for Regulatory Review in the same way as mentioned above.

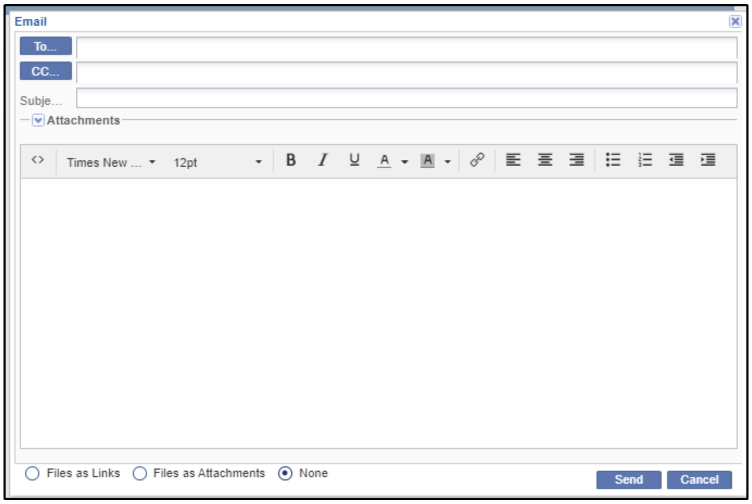
Not Applicable

A document type can be marked Not Applicable if such a document is not required for the study start-up.

E-Mail

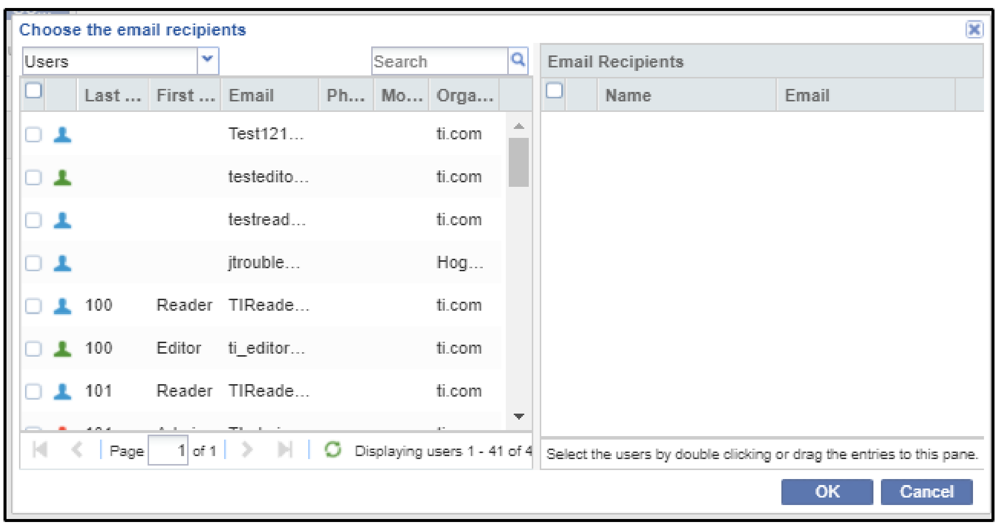
1. To send an Email message about a particular document to another party associated with the study, the site, the country, or the document, select the document in question from the grid by clicking the appropriate check box.

2. Click the E-Mail button in the menu ribbon directly above the grid. An Email window opens.



Files can be sent either as links or as attachments as shown in the screenshots above.

3. Click the To / CC button to activate the list of room users to whom you can send the message.



4. Select the users or groups you want to send the message to by dragging and dropping the recipients' names into the Email recipient's grid or by double-clicking the names.

5. Click OK. The view returns to the Email window.

6. Complete the required Subject field.

7. Either add attachments to the message or click the Files as Links radio button at the bottom of the window. Note that the user can also select the None radio button to send a message without files attached.

8. Add a custom message in the message field.

9. Click Send. The designated recipients receive the email message.

Editing Essential/Required Documents

Once a document is added to a document type, its profile is available for editing, if required. To edit a document:

1. Select a document from the grid

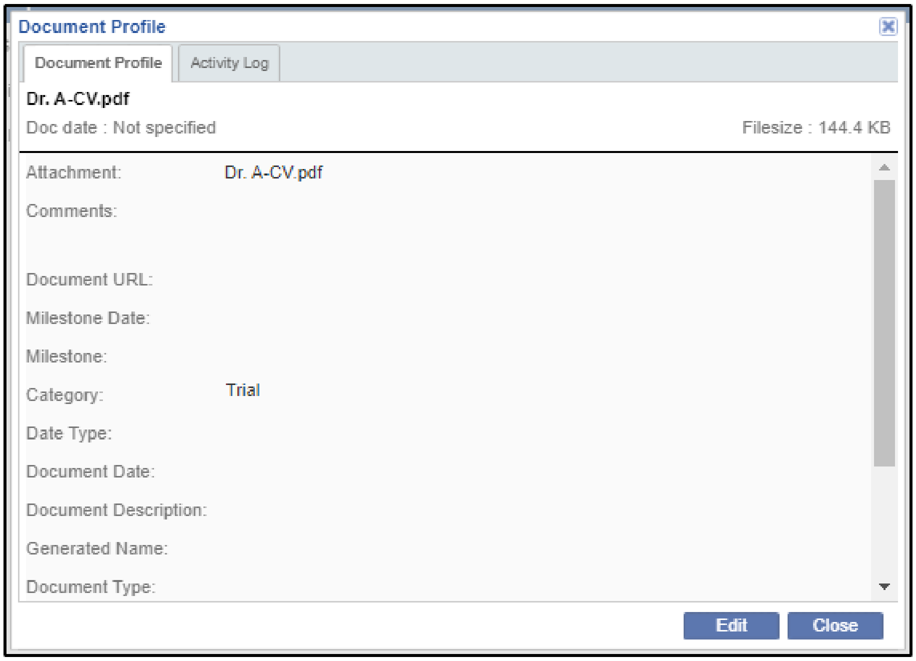
2. Click the Edit button from the menu bar.

3. The Edit Document Profile window opens. Make changes and click Finish to commit the changes made to the document profile.

Viewing Document Profile

To view the profile of a document you can click the Open Profile button from the menu bar. This opens the Document Profile window. Refer to the screenshot below:

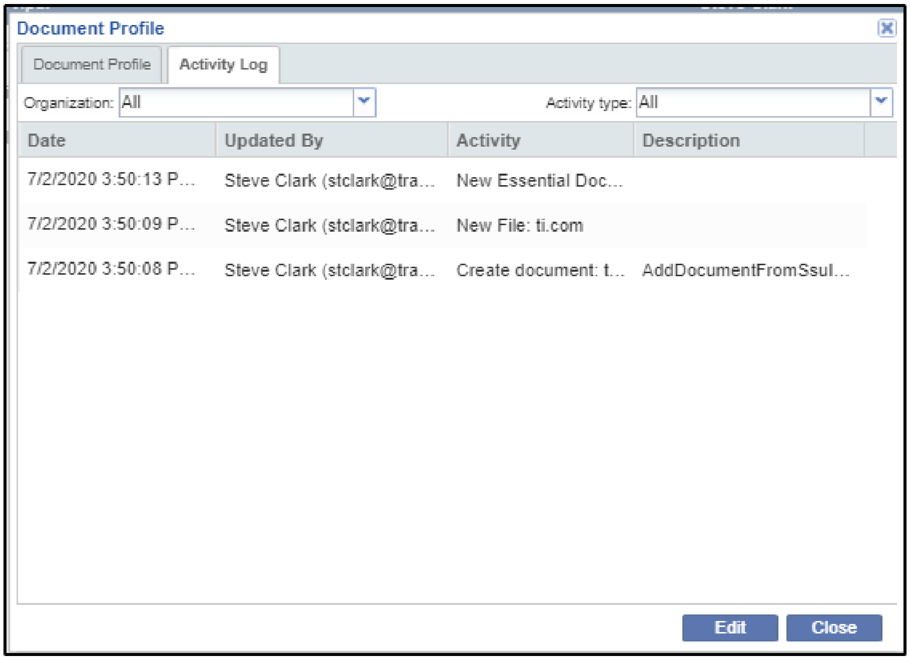
:



This window consists of two tabs: Document Profile and Activity Log.

The Document Profile tab shows the profile of the document. Refer to the screenshot above.

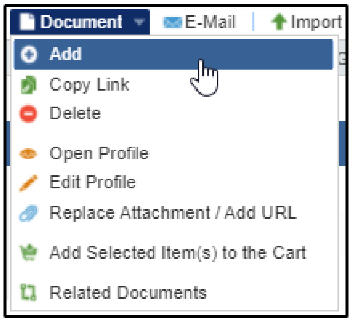
The Activity Log tab shows all the activities performed by users on the document. Refer to the screenshot below:



All Documents

The view presented to users in the All Documents tab for each site, country, and IRB/EC shows both the Essential Documents and the non-Essential Documents associated with the site, country or IRB/EC selected.

The All Documents tab for each of the modules consists of a menu bar which allows various functionalities. Refer to the screenshot below:



The functionalities of this menu bar are the same as in the Documents section of the SSU and can be referred there.

Review of Non Essential Documents

If the Study Start-Up Settings specify that the documents will need to be approved through the ‘Two pass workflow in Study Start-Up’ the documents automatically acquire the Pending status under QC Review. The documents will then have to be approved under QC Review and submitted for Regulatory Review.

The process for reviewing and approving the documents is as follows:

1. From the Grid Pane select the non-essential document to approve/reject.

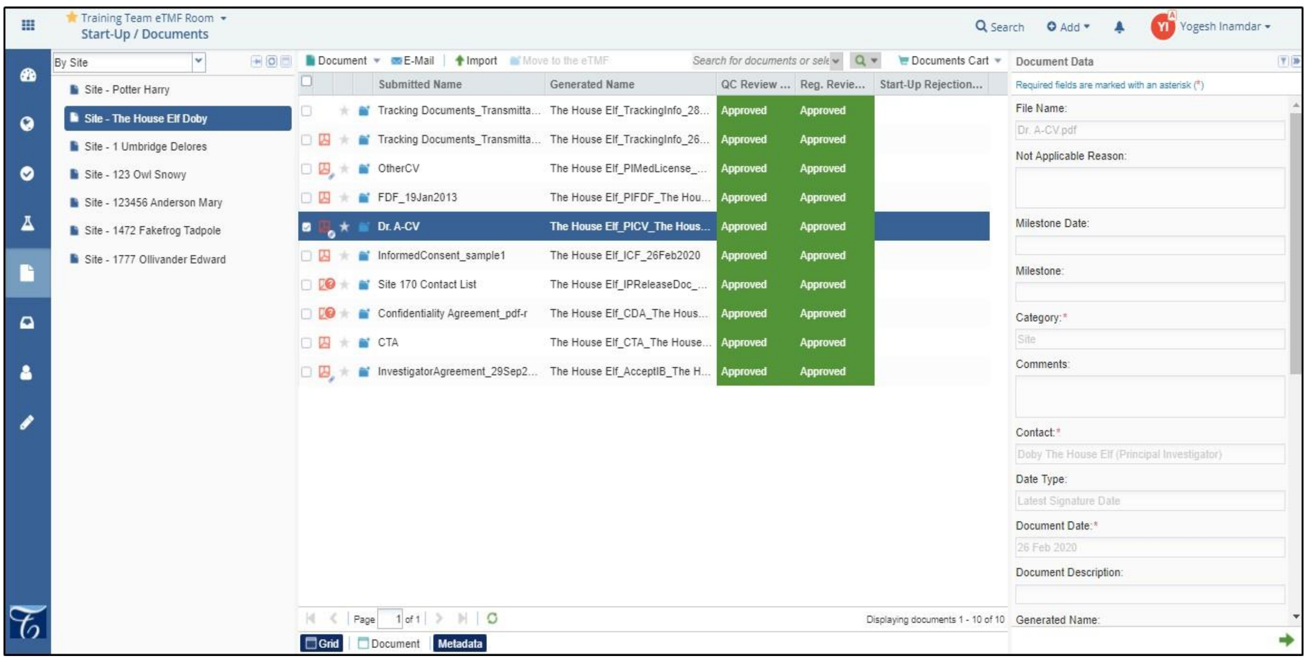
2. From the menu bar on the top of the grid, click the Approve/Reject button.

3. Once the document is approved, the Submit To Review button is activated; clicking which you can submit the document for QC Review. A document that is rejected by the SSU Specialist cannot be submitted for Regulatory Review.

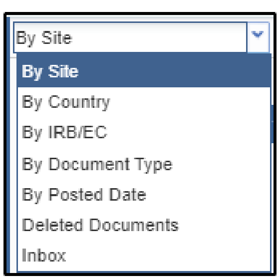
Documents

Clicking the Document tab from the toggling menu bar leads you to the Documents dashboard. Typically, the Documents module is the route through which most Editors will access and view documents for a Start-Up study. This module acts as a central repository for all documents added to the various components of a study start-up.

The Documents dashboard consists of the Current view on the left and the Grid pane on the right. Besides these, it also allows you to perform various functionalities from the menu bar on the top of the grid pane, and the buttons on the Current View window. Clicking a current view opens a list of documents in the grid pane. Refer to the screenshot below.

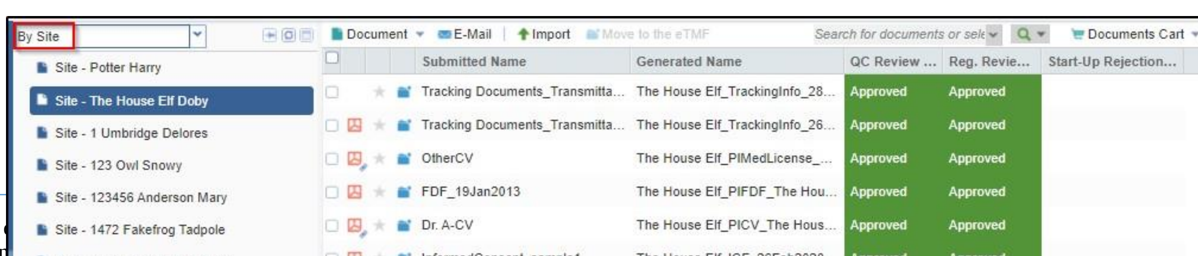


Current View

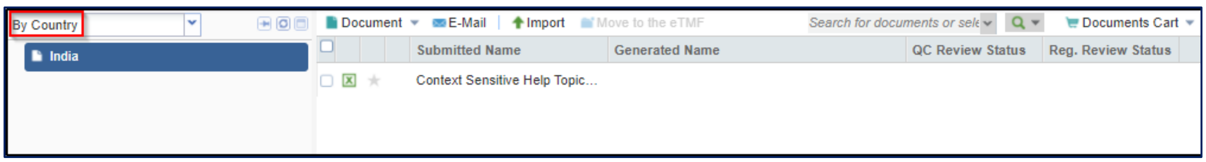


The Current View Dropdown offers five views:

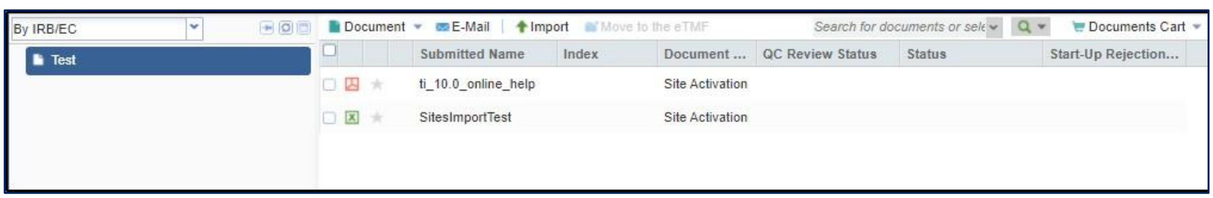
- **By Site**: Selecting the By Site option lists out the sites to which documents have been added. Clicking a site will display the documents submitted to the site along with their review status in the grid pane. Refer to the screenshot below:



- **By Country**: Selecting the By Country option lists out the countries to which documents have been added. Documents added through the Countries tab can be located here. Clicking a country will display the documents submitted to the country along with their review status in the grid pane. Refer to the screenshot below:



- **By IRB/EC**: Selecting the By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC will display the documents submitted to the institution along with their review status in the grid pane. Refer to the screenshot below:



- **By Document Type:** Selecting the By Document Type options lists out the various document types available to the study start-up. Clicking a document type will display the documents submitted by that type along with their review status in the grid pane. Refer to the screenshot below:

- **By Posted Date**: Selecting the By Posted Date option lists out the dates on which documents were submitted to the sites, countries, and IRB/ECs. Clicking a date will display the documents submitted on that day along with their review status in the grid pane. Refer to the screenshot below:

Note: Apart from the above mentoned views you can also view the **deleted documents** and **inbox** documents if the room has set these documents attributes.

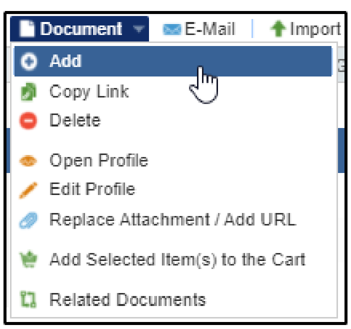
The Documents Grid Pane

The Grid Pane displays the details of the documents and provides various other functionalities through the Menu Bar on the top, the Document Data Panel, and the Selections at the bottom of the panel.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the screenshot below:

Document Dropdown



Add documents

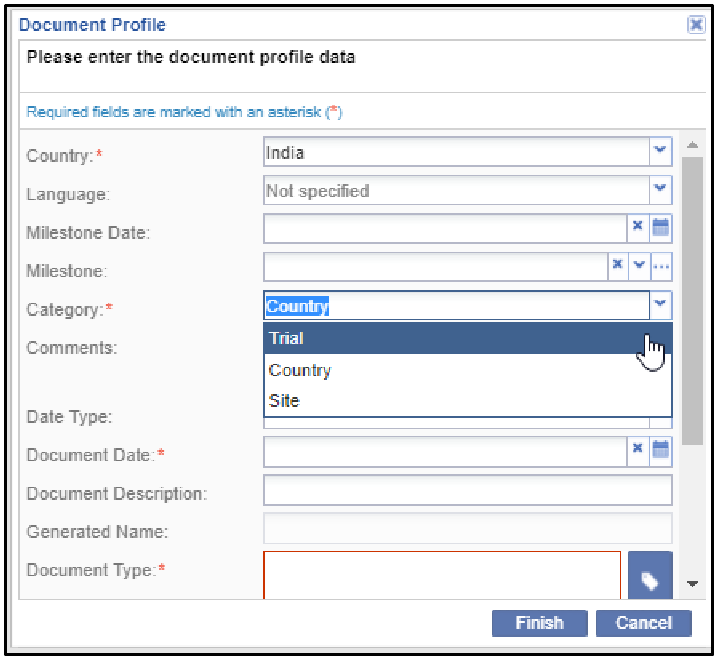
1. Select Add from the dropdown menu. The Document profile window opens.

2. Complete as many of the fields in the Document profile as you can. The fields marked with a red asterisk (*) are required – Title, Category, Index Position, Document Type, Document Date, and Name.

3. The Category could be General, Country, or Investigative Site.

4. If you select Investigative Site as Category, the document added will be available from the Site to which it has been added. Such a document can be viewed from the By Site Current View in the Document Tab or from the Sites Tab.

5. Click Finish.



Copy Link

Using this option you can copy the link of a document, or copy the link of the document with its metadata.

The administrator needs to configure the option that the users would like to use:

1. Navigate to **Settings**

2. Click **Documents** from the left pane.

3. Click **Documents** Module from the dropdown.

4. Go to the tab ‘Type of document link’.

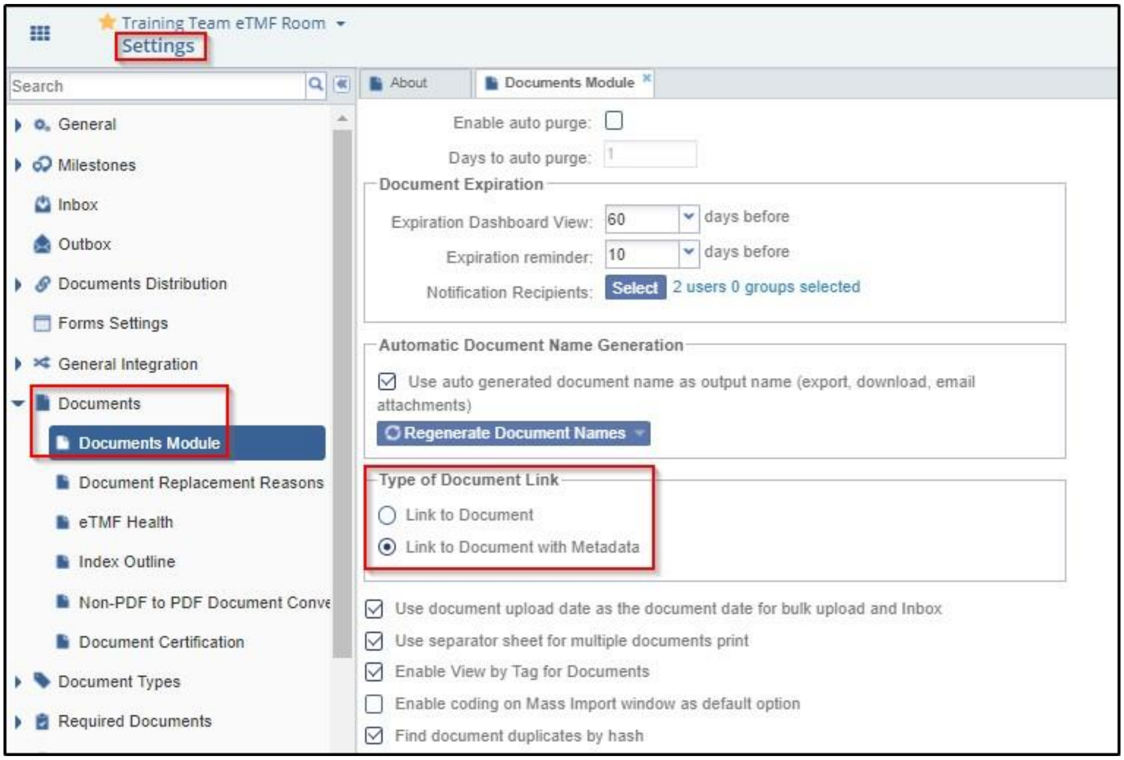
5. Observe that there two options:

a. Link to document

b. Link to document with metadata

2. Select the option as required.

3. Click **Save**.



To copy the link of a document:

1. Select a document from the grid of the Documents section, or from the All Documents tab in Sites section.
2. Right click the document or activate the Document dropdown.
3. Select option Copy Link.
4. The document URL gets copied to the clipboard.
5. A notification about the same is received.

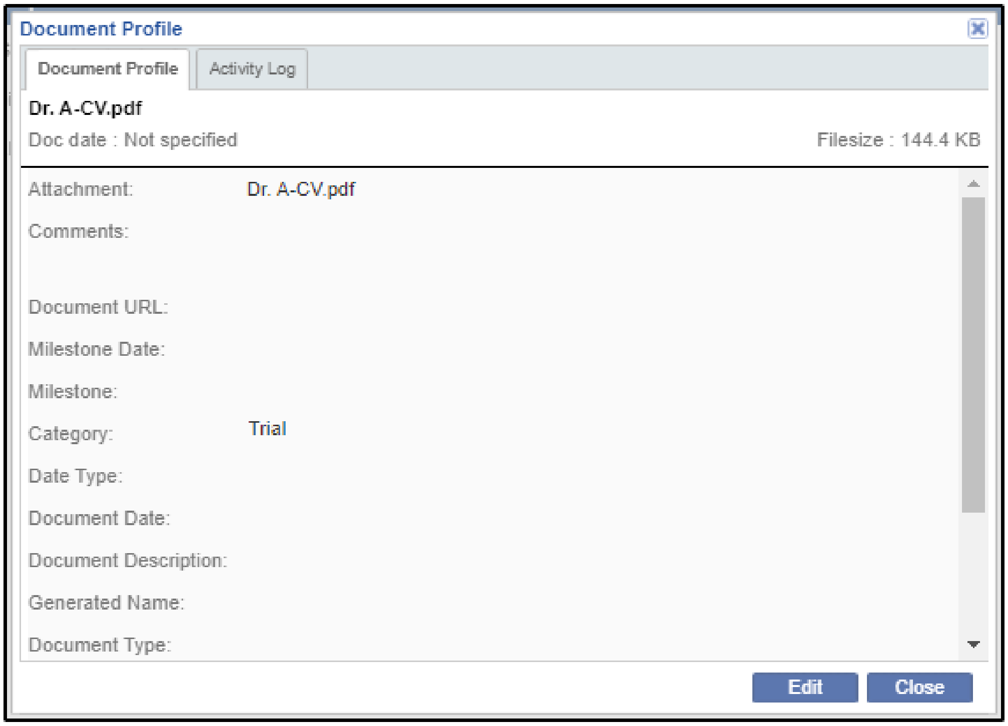
6. Paste the copied URL in a browser tab.
7. The document opens in the browser for you to read.

Edit Profile

1. Select a document from the grid.
2. Activate the Document dropdown menu and click **Edit Profile**. The **Edit Document Profile** window opens.
3. Make the necessary changes to the profile data fields as required.
4. Click **Finish**.

Open Profiile

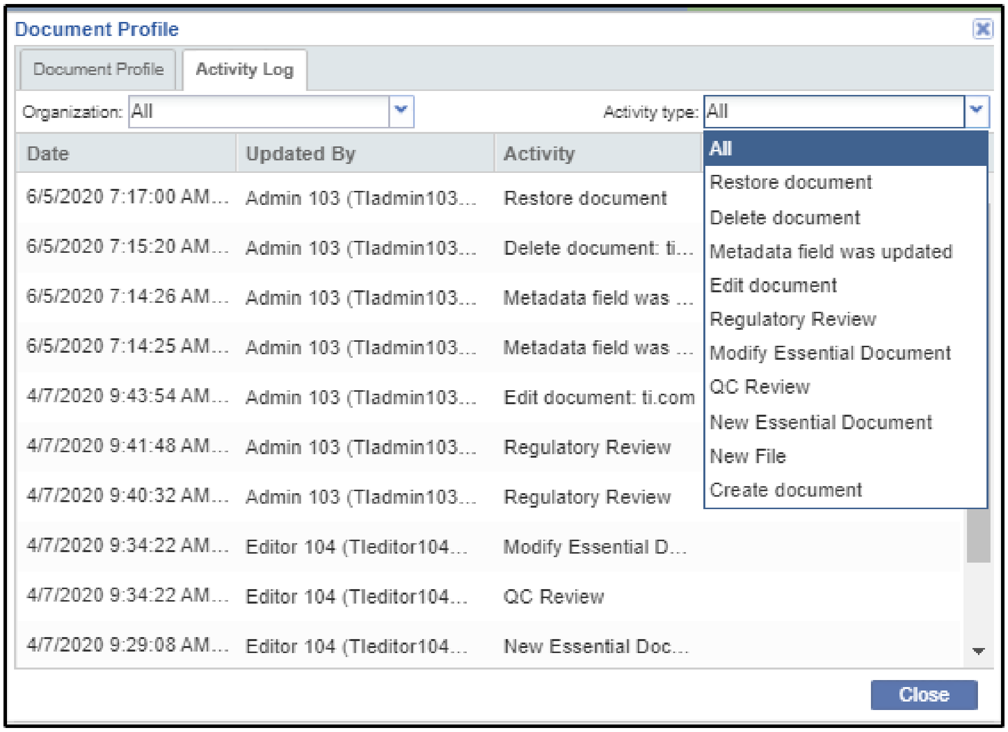
To view the profile of a document, activate the Document dropdown and click the Open Profile button from the menu bar. This opens the Document Profile window. Refer to the screenshot below:



This window consists of two tabs: **Document Profile**, and **Activity Log**.

The Document Profile tab shows the profile of the document. Refer to the screenshot above.

The Activity Log tab shows all the activities performed by users on the document. It allows you to select the Organization, and the Activity Type as filters to view the log. Refer to the screenshot below:



Clicking the **Edit** button leads you to the **Edit Document Profile** window.

Replace Attachment / Add URL

You can replace the attachment to a document type if it is not approved by using this feature.

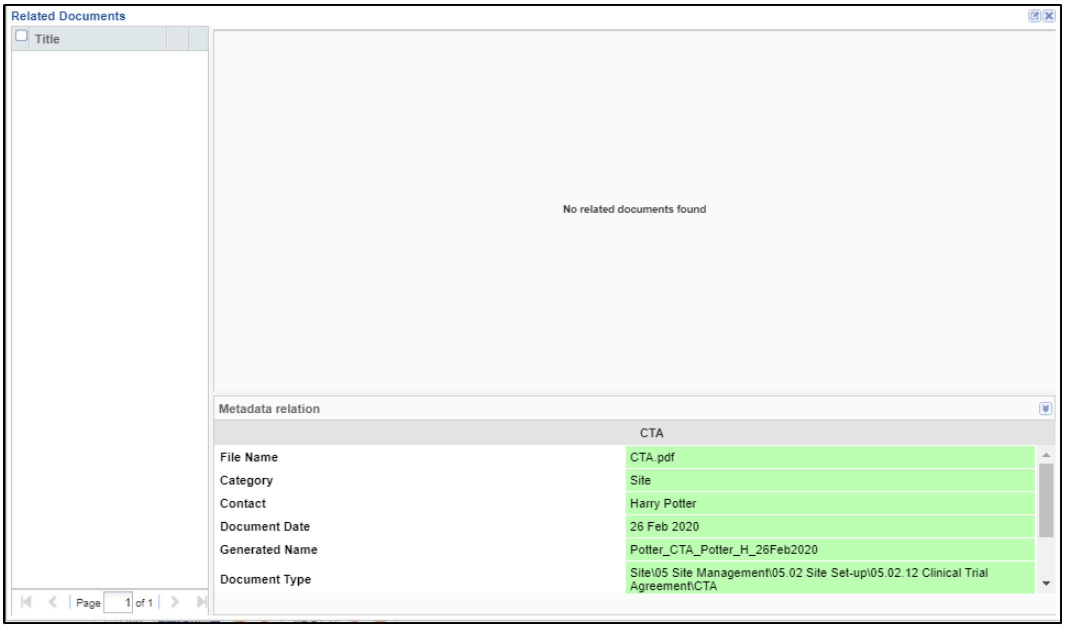
1. Select the document from the grid.
2. Activate the Document dropdown.
3. Click the option Replace Attachment / Add URL.
4. The Replace Attachment / Add URL window opens.
5. Change the attachment as required and provide the reason for the same.
6. Click Save.

Add Selected to the Cart

You can add a document selected from the grid to the cart to compare documents, link them, add them to the submission package, or download documents.

Related Documents

1. Select a single document in the Document Grid.
2. Click the Document dropdown menu.
3. Select Related Documents from the available options. A Related Documents window opens.



The top part of this window shows the documents located in the search through the room's default viewer. The left panel lists the related documents by title. The right portion of the window carries the Metadata Fields of the related documents. The metadata fields that have common content are highlighted in green.

E-Mail

The procedure to send out emails is the same as described under **Essential Documents**.

Import

1. Click **Import**

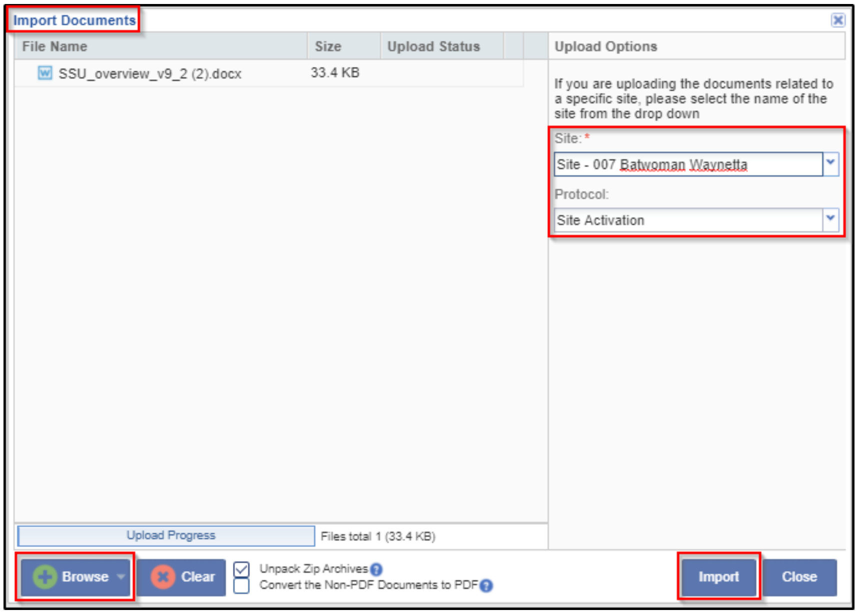
from the menu ribbon. An Import Documents window opens.

2. The Upload Options depend upon the view selected – By Site, By Country, or By IRB/EC.

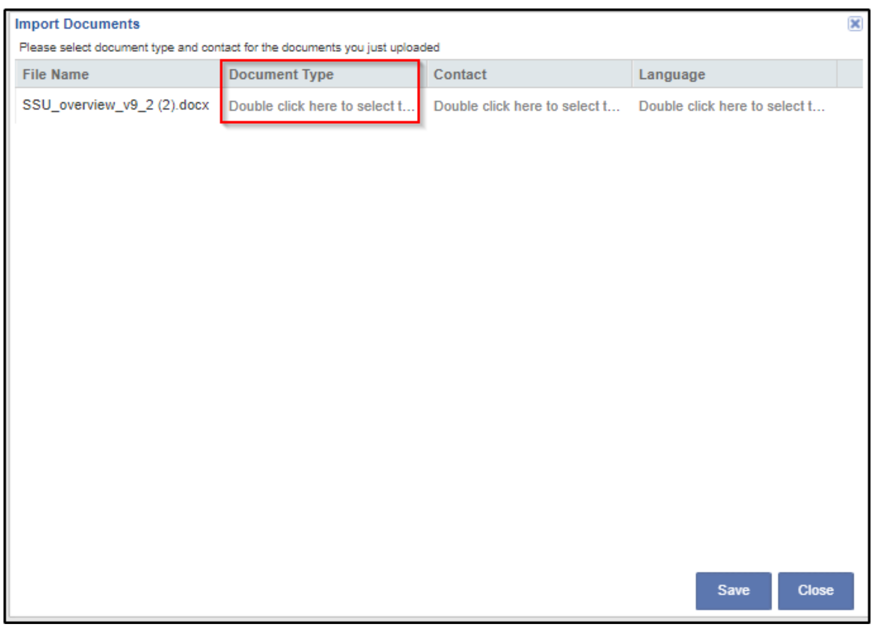
3. Select your choice from the dropdown menu in the field in the 'Upload Options' panel.

4. You can add documents to the window by using Browse and selecting the appropriate files for upload, or the user can drag-and-drop appropriate files, en masse, directly from a document library. You can tick the 'Unpack Zip-archives' if you have uploaded a zip file and want to import the documents in the zip as separate documents.

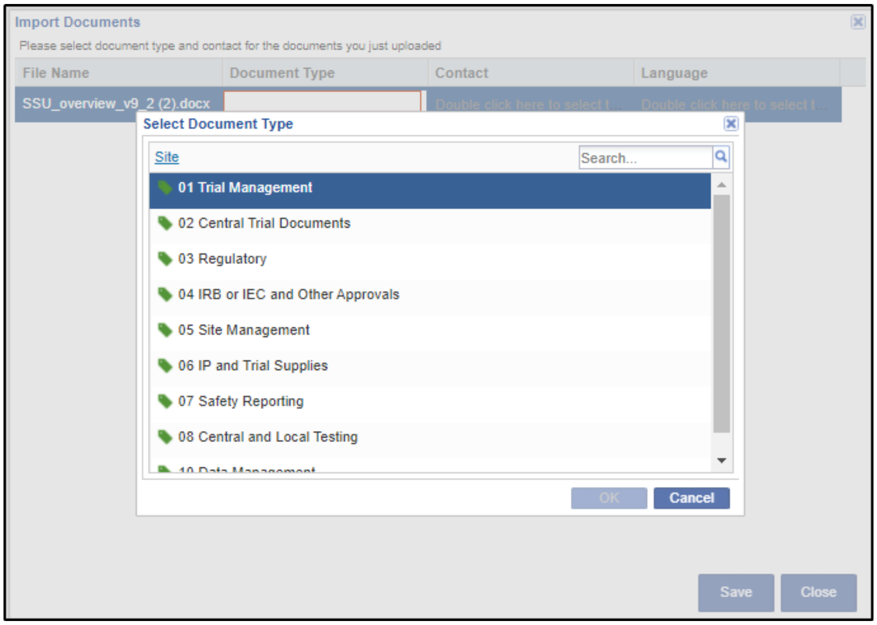
5. Once you have deposited all of the desired files into the Import Documents window, click **Import**.



6. The tool moves to the next stage of the document upload.



7. Following the on-screen instructions, double-click the Document Type field

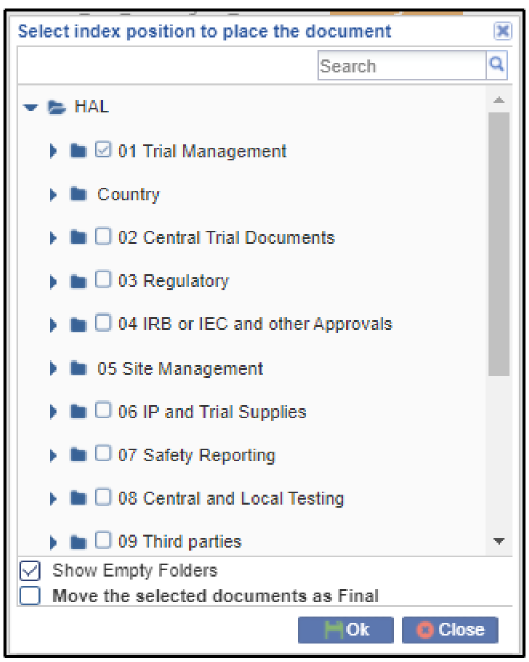


8. Select the document type that matches the actual document for each uploaded document.

9. Click **Save**. You return to the Documents view.

Move to eTMF

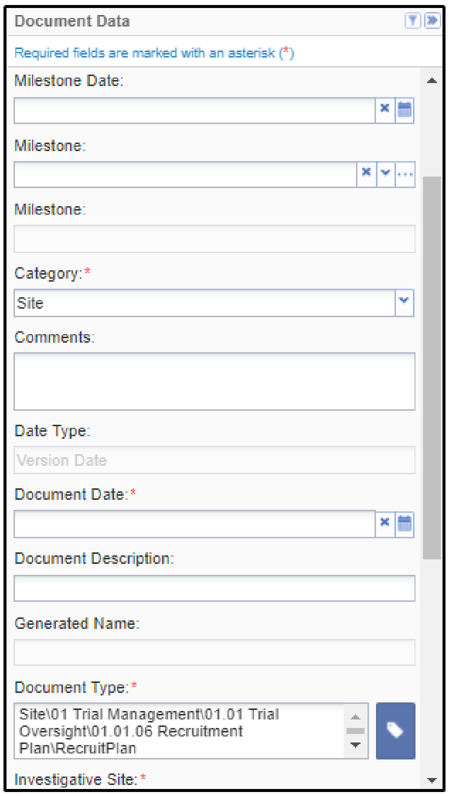
You can move a document selected from the grid in the eTMF by clicking the Move to eTMF button on the menu bar. This opens the Select index position to place the document window. Refer to the screenshot below.



Select the appropriate folder to move the document to and click **Ok**.

Document Data Panel

The **Document Data Panel** at the extreme left lists out the metadata of the document that was entered in the **Document Profile** at the time of adding the document. Instead of opening the **Edit Document Profile** window, you can also edit the profile of a selected document from its **Document**



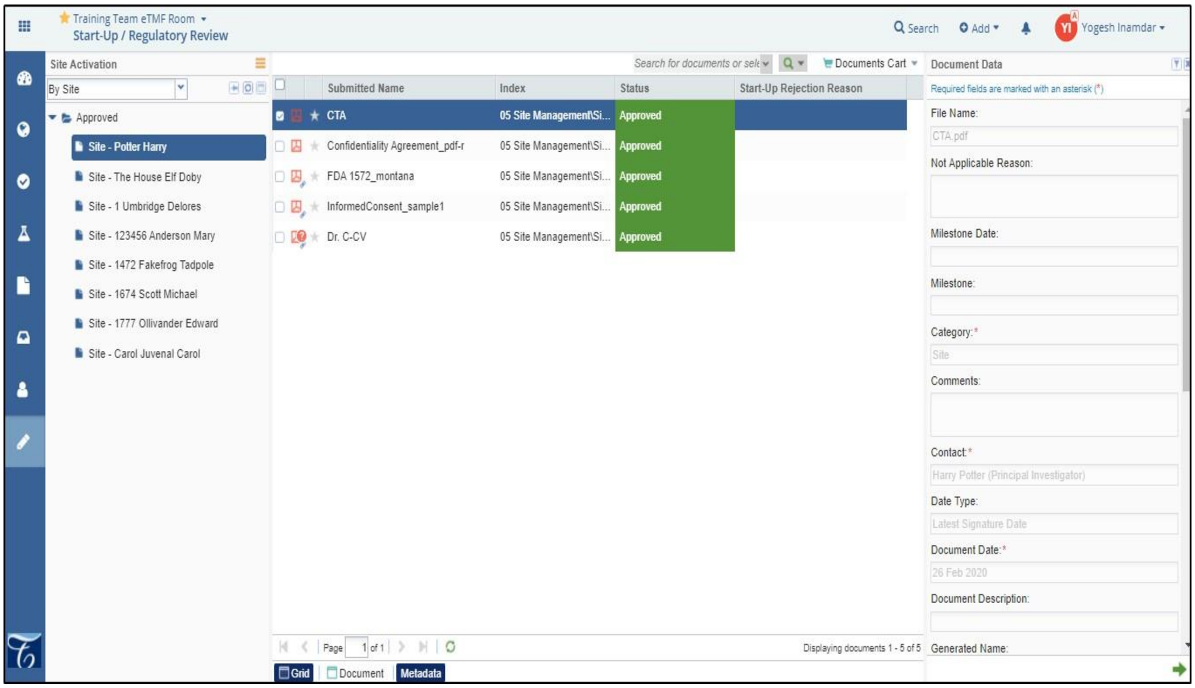
Data Panel. A screenshot of the panel is provided below:

The contact of the documents is the username of the login that was used to upload the documents. As shown in the screenshot below, documents for country **India** were uploaded. These documents now appear in the **By Country view** for **India**. Refer to the screenshot below:

Regulatory Review

Clicking the **Regulatory Review** tab from the toggling menu bar leads you to the **Regulatory Review** dashboard. From this module the regulatory reviewer can view the review statuses of the documents put up for regulatory review as well as review and approve the documents. The procedure to approve the documents by the regulatory reviewer is discussed after a brief summarization of the dashboard.

The **Regulatory Review** dashboard consists of the **Current view** on the left, the Grid pane in the center, and **Document Data** panel on the right. Refer to the screenshot below.



Adding Regulatory Approvers

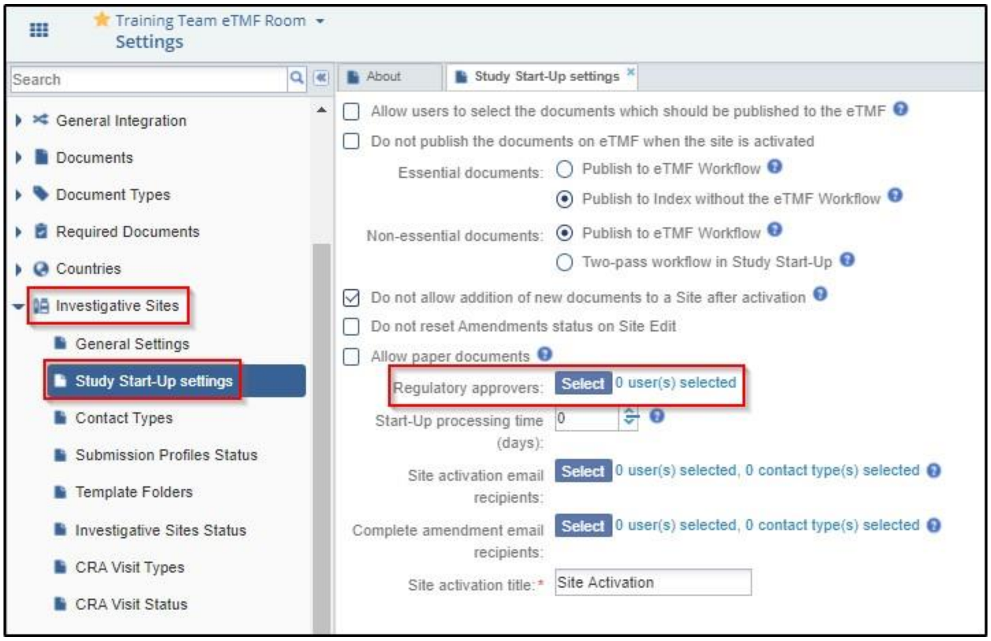
A Regulatory Approver can be a Global Regulatory Approver, Country, or Site Regulatory Approver. As a Global Regulatory Approver, you are able to perform the functions at all sites within a study room. As a Country Regulatory Approver, you are able to perform the functions at all sites in a specific country (ies). Lastly, as a Site Regulatory Approver, you are able to only perform the functions at the site(s) a room Administrator assigns.

To add Global Regulatory Approver, follow the steps as below:

1. Navigate to **Settings**.

2. On the left-side panel, navigate to **Investigative Sites** ◊ **Study Start-Up settings.**

3. Next to **Regulatory approvers**, click on **Select**. Add user(s) by either double clicking on the user on the left-hand side to move to the Selected Members on the right-hand side, or by dragging and dropping the user from the left-hand side to the Selected Members on the right-hand side.



Users added as Regulatory Approvers added from here will be available as Regulatory Approvers to all the sites in the room.

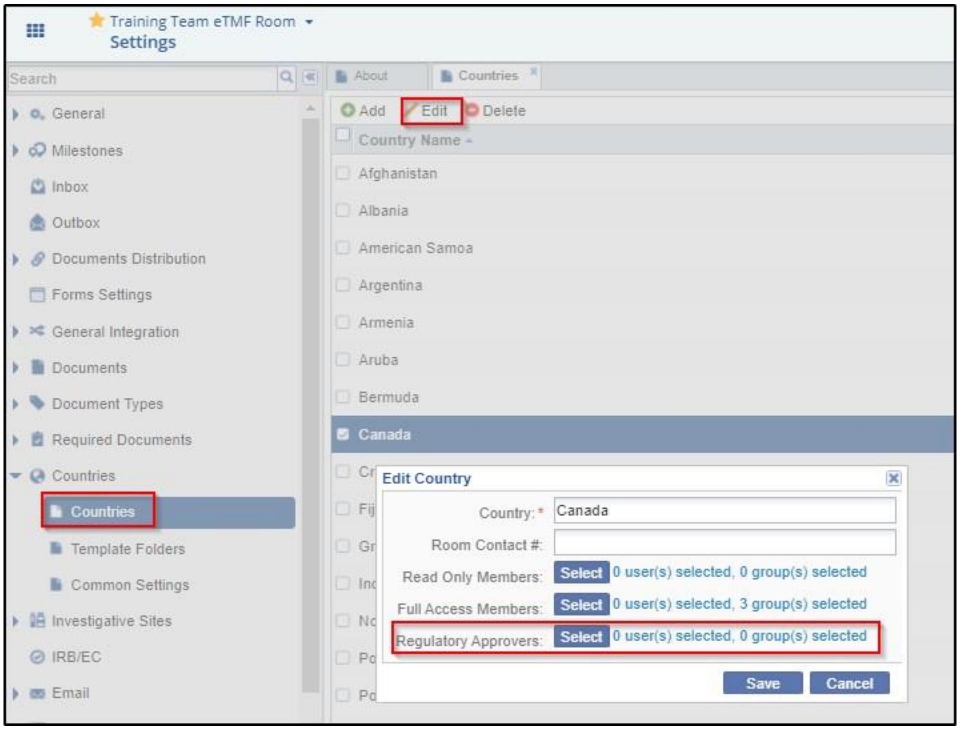
To add a Country Regulatory Approver, follow the steps as below:

1. Navigate to **Settings -> Countries -> Countries**.

2. Check the box next to the country and then click **Edit**. (If the Country is not listed, click **Add** to create a new country).

3. Next to **Regulatory Approvers**, click **Select**. Add user(s) by either double clicking on the user on the left-hand side to move to the **Selected Members** on the right-hand side or dragging and dropping the user from the left-hand side to the **Selected Members** on the right-hand side.

4. Click **Save**.



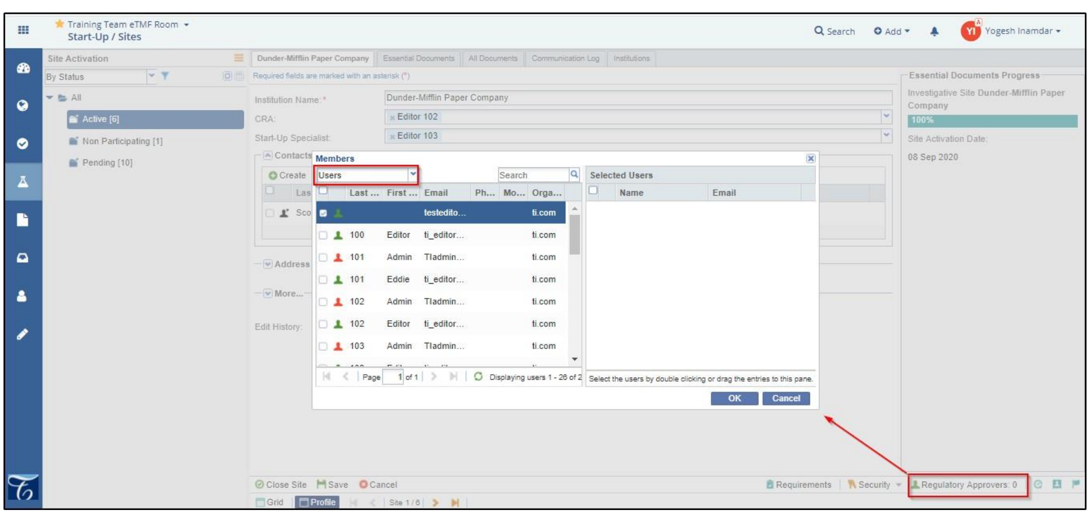
5.Click **Select** to open the Regulatory Approvers windows and add the users. Click **OK**. **To add a Site Regulatory Approver, follow the steps as below:**

1. Navigate to the **SSU module** ◊ **Sites**.

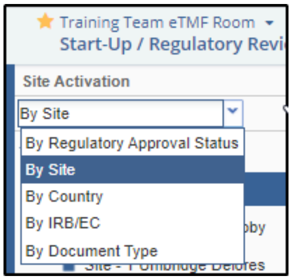
2. Double click on the site you wish to add a Site Global Regulatory Approver.

3. At the bottom right-hand corner, click on **Regulatory Approvers**. Add user(s) by either double clicking on the user on the left-hand side to move to the **Selected Members** on the right-hand side or dragging and dropping the user from the left- hand side to the **Selected Members** on the right-hand side.

4. Click **Save**.



Current View



The Current View Dropdown offers five views:

- **By Site**: The 'By Site option' groups all the sites based on the review status of its documents. The review statuses of the documents could be Pending, Rejected, and Approved. Clicking a site under a particular review status will display the documents with that review status in the site in the grid pane. Refer to the screenshot below:

- **By Country**: The 'By Country' option lists out the countries to which documents are added. Clicking a country from the left pane will display the documents submitted to the country along with their review status in the grid pane.
- **By Regulatory Approval Status**: The 'By Regulatory Approval Status' groups all the documents as per their review status i.e. Approved, Rejected and Pending. Clicking a review status group from the left panel will display the documents belonging to the particular review status group in the grid pane.

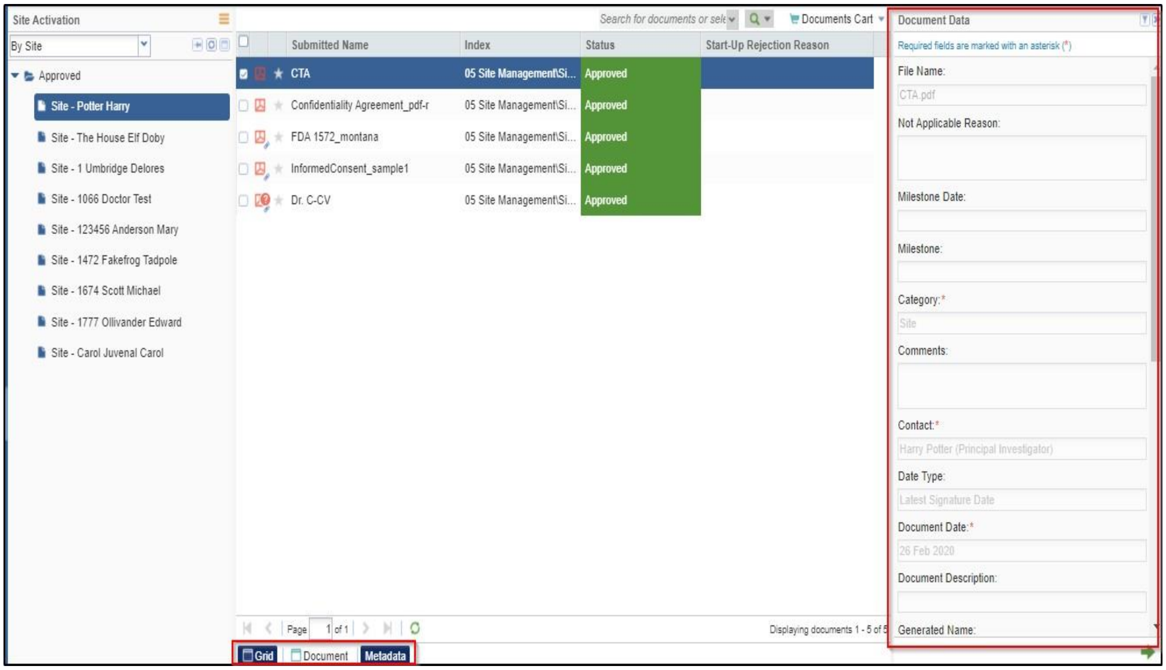
- **By Document Type**: The 'By Document Type' options lists out the various document types available to the study start-up. Clicking a document type will display the documents submitted under that type along with their review statuses in the grid pane. Refer to the screenshot below:

- **By IRB/EC:** The By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC from the left pane will display the documents submitted to the institution along with their review status in the grid pane. Refer to the screenshot below:

Document Data Panel

The Document Data Panel is located on the extreme right of the dashboard and can be activated by clicking a document from the grid pane. Depending on the user's security settings and access rights and roles, this panel might be static to a user. If the user is given appropriate SSU User access rights, the data fields are editable and all changes made here must be saved.

In the screenshot above, observe that the fields are non-editable. The user can switch between the Grid and the Document

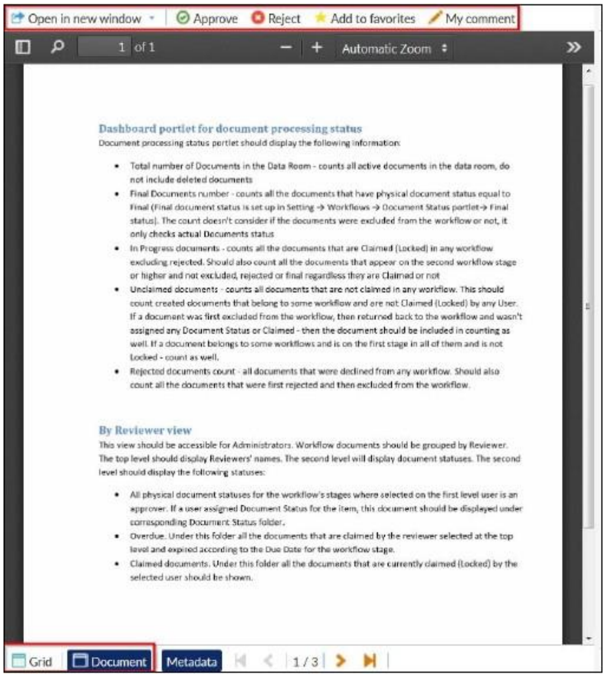


Data Panel by clicking any of the buttons located at the bottom of the Grid pane.

How to Regulatory Review a Document with Attachments

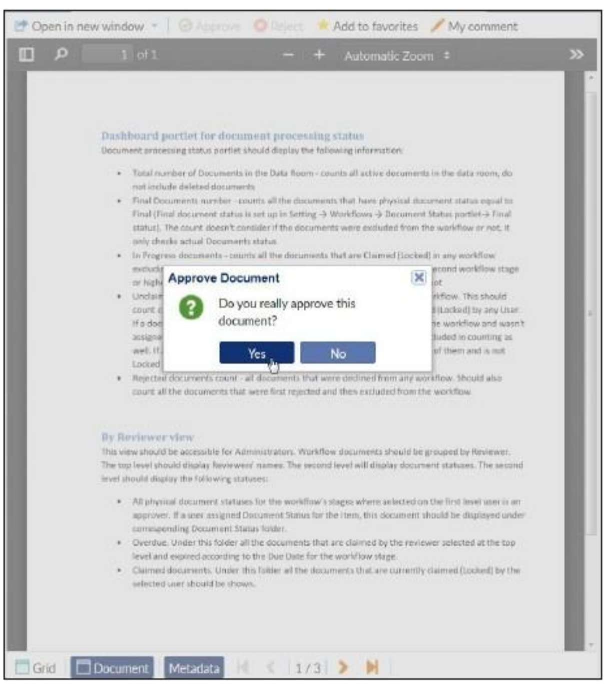
Once the regulatory reviewer receives an email stating about a pending review, he/she logs into TI to locate the documents waiting for review in the Regulatory Review section. The easiest way to find out all the documents in the study start-up waiting for regulatory review is to activate the **By Regulatory Approval Status** view from the left panel which lists out all the documents in the SSU pending for approval.

To review a document, the regulatory reviewer selects a document with pending status and clicks the Document button at the bottom of the Grid Pane, or the icon next to the document name. The Grid Pane will disappear and the document will open for review in the center of dashboard. Refer to the screenshot below:



The regulatory reviewer reads the documents for review. If he/she finds a document appropriate, the reviewer clicks the **Approve** button from the top ribbon bar, else he/she clicks the **Reject** button.

If the reviewer approves a document, a popup appears asking the reviewer to confirm the same. Click **Yes** to confirm the same.



If the reviewer rejects a document, a popup appears asking the reviewer to state the reason for rejection. Fill in the reason and click **Reject** to commit.

Depending upon the decision taken, a message will pop up indicating that the change is now committed to the database.

The document is now locked and cannot be opened for review again. The Regulatory Approval Status of the documents throughout the SSU will now reflect the appropriate status from Pending to Approved, or Rejected. The Document button at the bottom of the dashboard, and the Approve or Reject buttons are now disabled to prevent further changes.

Regulatory Review of Paper Documents/Documents without attachments

As discussed in earlier sections, paper documents go without attachments. In such a case, the Approve, and Reject buttons will be placed above the Regulatory Review documents grid, so it will not be required to open the document in a viewer to approve/reject it. The rest of the approval/rejection process remains the same.

Communication

Note: *The Communication Log section from Sites, Countries, and IRB/EC provides the same functionality as that available in the Communication section.*

The **Communication** tab, accessed from the toggling menu bar on the left, holds all the messages sent and received with a study start-up for the purpose of activating a site. Opening the Communication tab, the user can see three panels: **Current View, Grid Pane,** and **Communication Data.**

Current View

The Current View Dropdown offers four views:

- **By Site**: Selecting the By Site option lists out the contacts added to the sites. Clicking a site will display the contacts of the particular site in the grid pane. If a Principal Investigator (PI) was deleted, and a new one added, the previous PI will appear greyed out. Similarly, if a contact is deactivated, it too will appear greyed out, but if a contact is deleted, it will not appear in the grid.
- **By Country**: Selecting the By Country option lists out the countries which have sites added to them. Sites for which countries are not added will appear under the Not Specified category. Clicking the + next to a country will display the sites belonging to the country. Clicking the site will list the contacts of that site in the grid pane.

- **By IRB/EC**: Selecting the By IRB/EC option lists out the sites by IRB/ECs. The sites for which IRB/ECs are not specified get listed under Not Specified category. Clicking a site will display the contacts of the particular site in the grid pane.
- **By Contact Type**: Selecting the By Contact Type option lists out the various contact types added to the sites in a study start-up. Clicking a contact type will display the names of all the people under the contact type.

The Contacts Grid Pane

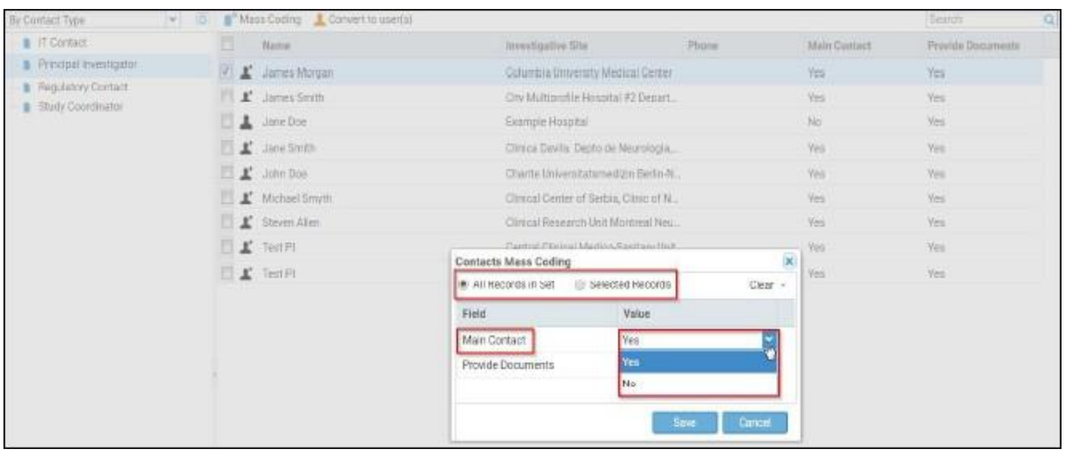
The Grid Pane displays the details of the contacts and provides various other functionalities through the Menu Bar on the top.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the screenshot below:

Mass Coding Contacts Metadata

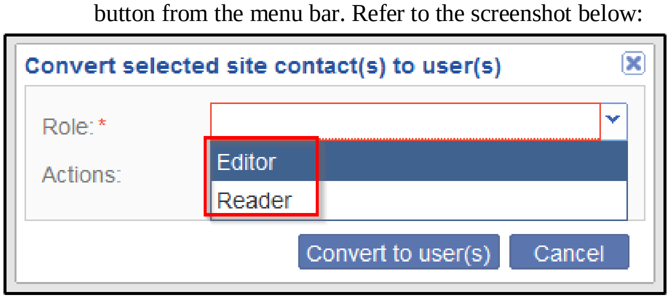
Clicking the Mass Coding option from the top menu bar will enable you to set the all contacts in the grid pane, or only selected contacts in the grid pane as Main Contact at one go for all the sites in the study start-up. Refer to the screenshot below:



You can also decide whether the contacts can be mass coded to provide documents Click Save to commit the changes.

Convert to user(s)

You can choose to assign selected contacts the roles of Editors, or Readers in a site by clicking the Convert to user(s) button from the menu bar. Refer to the screenshot below:



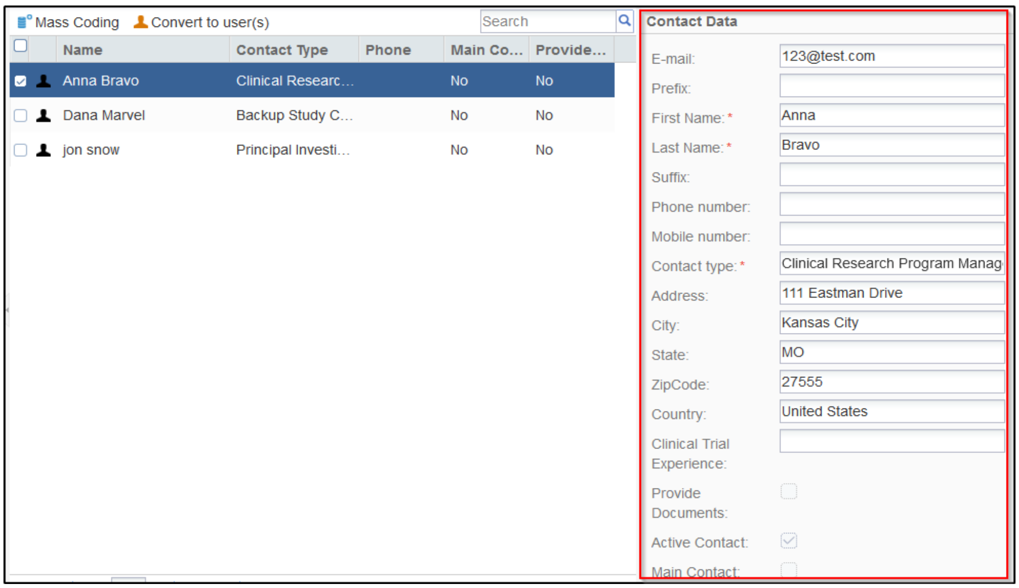
Click the Convert to user(s) button at the bottom of the popup to commit the changes. Refer to the screenshot below:

The user will receive an invitation email to register and access the room with the role and actions ticked by the administrator enabled for him/her. This feature can be used in conjunction with Create/Add existing functionality in the Contacts panel of the Site profile to add a new contact not belonging to any room/site, or to add a contact who belongs to a site, or a room respectively. To know the functionalities that would be accessible to such a user proceed to the table for Accessible functionalities for SSU contacts.

Contact Data

You can view the contact metadata in this panel. The contacts cannot be edited from here. To edit contact information you will need to navigate to the Sites tab.

Select a contact from the grid to activate the Contact Data panel located to the extreme right of the dashboard and view contact information.



Steps to Site Activation

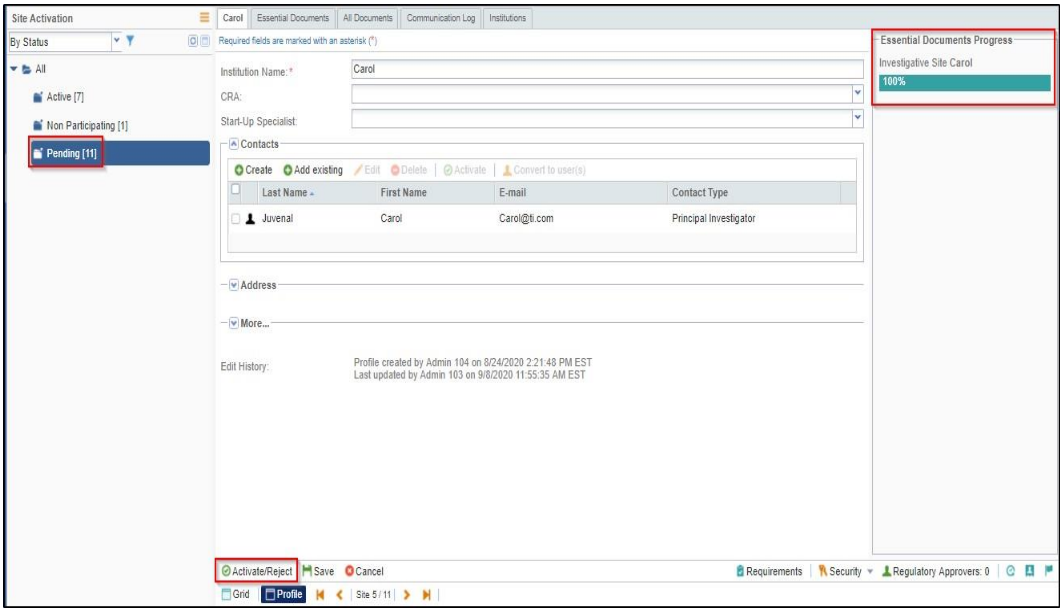
To activate a site in the Trial Interactive Study Start-Up module a series of steps must be followed.

The site information and users specific to the SSU site can be imported by TI if information is provided in a formatted excel. In addition, sites and users can be added in the site grid.

Activating a Site

Once all essential/required documents are sent by the sites to the trial room and approved by appropriate authorities, the site can be activated. Only Site Activation Members will access the site profile to activate the site. Upon site activation, documents can be auto-named, auto-routed, and auto-filed to the appropriate location within the finalized eTMF. To note, Administrator role can place preference on these automated setting features from the Study Start-Up settings.

Once all the required documents are approved by both the Start-Up Specialist and the Regulatory Reviewer, the Essential Documents Progress bar shows as 100% in the Site Profile and the Activate/Reject button at the bottom of the Site Profile dashboard appears.

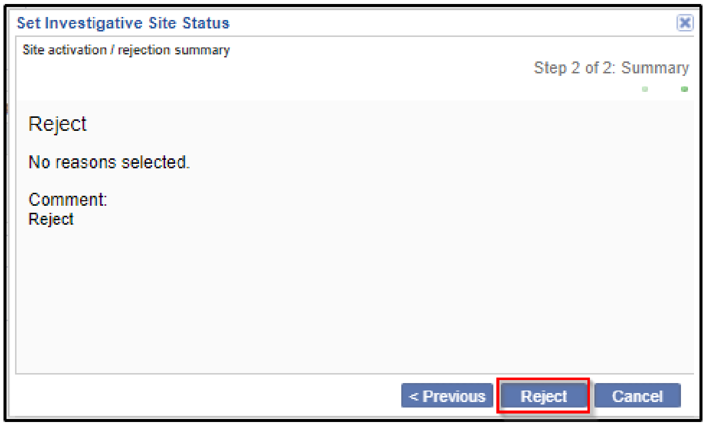


To activate the site:

1. Click the Activate/Reject button.
2. The Set Investigative Site Status window opens
3. Select the Status as Active.
4. Enter the comments
5. Click the **Activate** button

To reject the site:

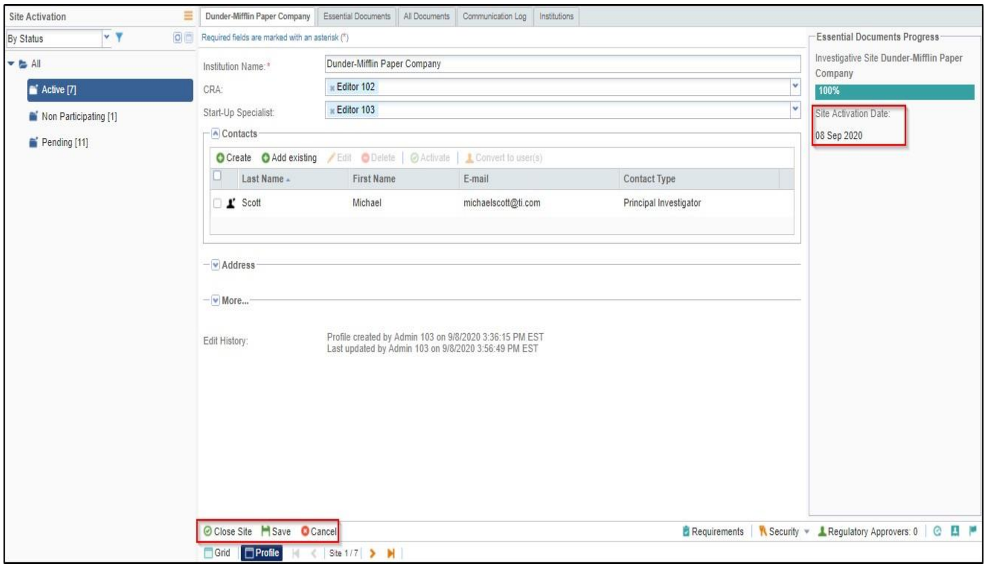
1. Click the Activate/Reject button
2. The Set Investigative Site Status window opens
3. Select the Status as Rejected.
4. Select the reason for rejection.
5. Enter the comments.
6. Click the **Reject** button.



The site will then be activated and the documents will be published to the eTMF or workflow as per your settings. You will receive a confirmation about the same. You can also specify the users, and contacts who will receive email confirmation on site activation from Study Start-Up settings.

The Activate/Reject button will then disappear, and the site name will now appear under the Active folder in the Current window. Refer to the screenshot below:

Note: If during site activation system cannot move the documents to eTMF for some reason, such documents will not be moved and user will be warned about it. In that case site will not be activated. The reasons of why docs cannot be moved to eTMF are: duplications found, cannot determine Index position.



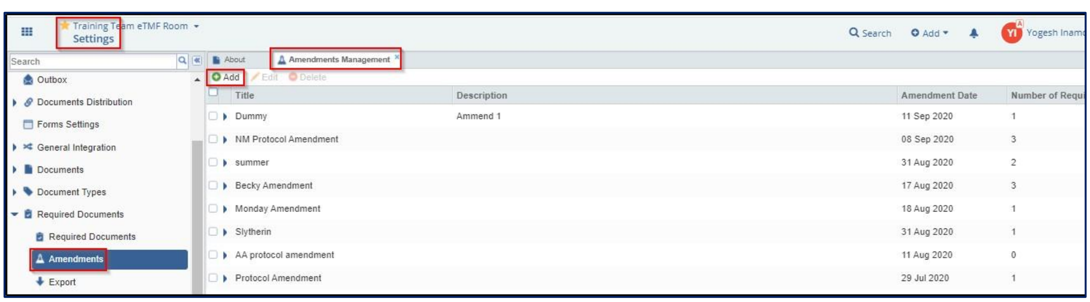
Amendments

After a site is activated and the clinical trial begins, it is very common to have amendments to the study protocol, depending on the nature of the amendments many more essential/required documents needs to be submitted by the sites. Such documents cannot be added to the site directly and can be specified only through Amendments. Amendments can be created for Investigative Sites,Country Amendments, and IRB/EC.

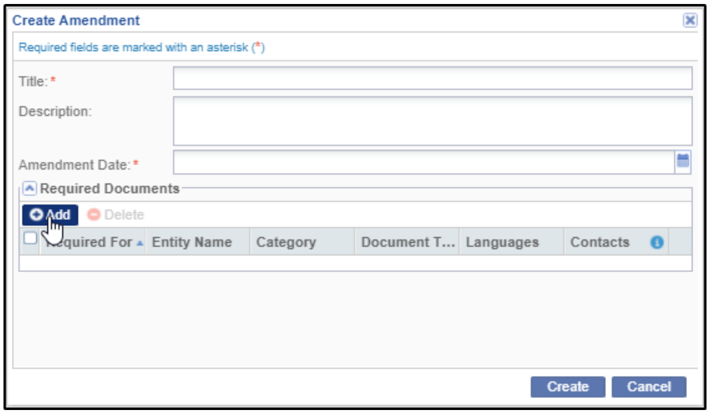
Creating Amendments

To create amendments, the administrator needs to do the following:

1. Navigate to Settings.
2. Click the arrow next to Required Documents in the left panel.
3. Select Amendments from the dropdown.
4. The Amendments Management window opens in the right panel.



5. The Create Amendment window opens.



a) Fill in the details as required.

b) Click Add in the Required Documents panel in this window.

c) The Required Documents window opens.

d) From the Required For dropdown in the left panel select an option as required (All Sites, Specific Site, Specific IRB/EC, or Specific Country).

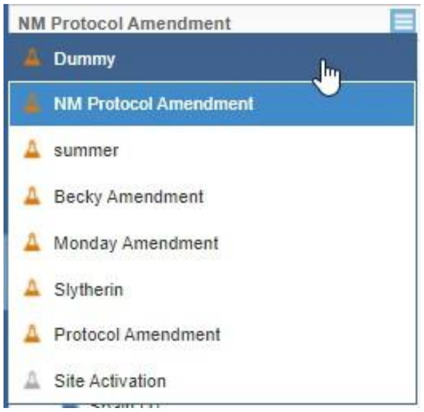
e) From the right panel select the essential/required documents that are needed after the site activation.

f) The procedure to add the documents is same as described in earlier section Basic Configurations for SSU *(page 502)*

6. Click **Create** to create the amendment.

Viewing Amendments and Adding Documents

To view amendments for a site/s and countries, navigate to the Sites section. From the Current View in the left, click the three yellow bars above the panel to activate the Filter By Amendment dropdown. Choose the amendment as required. Refer to the screenshot below:



Double-click a site name from the Grid Pane to open the site profile window for amendments. Like the Sites, and Country section, this window also has three tabs – Essential Documents, All Documents, and Communication Log. The procedure to add documents and communications are the same as described in section Collecting Essential and Non-Essential Documents *(page 552)*

Amendments for IRB/ECs can be viewed from the IRB/EC section. Here too, you will be able to select the required amendment from the Filter By Amendment dropdown in the Current View panel. The rest of the procedure is the same for Sites and Countries as described above.

QC Review and Regulatory Approval of Amendments

After the documents for amendment are added, essential documents will need to pass the QC Review and Regulatory Approval.

The non-essential documents will need to pass through the approval process only if it is specified in the Study Start-Up settings. The settings in this section also apply to the amendments.

The process to review and approve the documents for both the processes is the same as described in earlier sections.

To Regulatory Review the documents, the Regulatory Approver will need to log in to the system and enter the Regulatory Review section. Here too, the Regulatory Approver selects the required amendment from the Filter By Amendment dropdown in the Current View panel and selects the documents to approve/reject them from the Grid Pane.

Completing an Amendment

Once all the documents (essential and non-essential) are approved, the amendment profile window acquires the **Complete Amendment** button at the bottom. Click the button to complete the amendment. You will need to confirm the process by clicking Yes on the dialog box that appears on clicking the button.

On clicking 'Yes', the amendment will be completed and the documents will be published on the eTMF. Whether they will take the place in the default folder to be picked up for the workflow process, or they will be auto-routed to their respective positions in the eTMF index depends once again on your settings in the Study Start-Up section. On completing the amendment, you will receive a confirmation for the same. Click Ok to accept the confirmation.

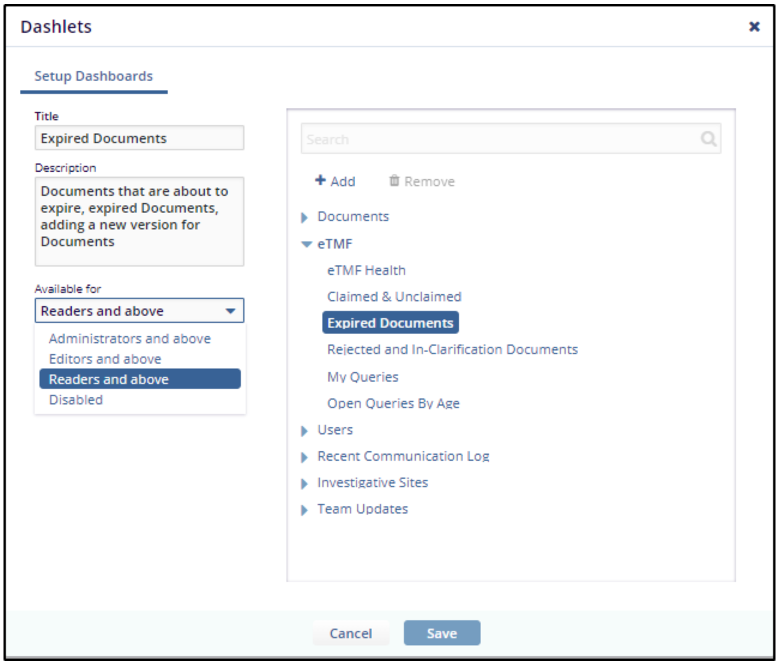
Overview Dashboard

The Overview Dashboard, which consists of a number of different dashlets, can be made available to users by room Administrators, depending on the needs of the client and the particular study room.

The dashlets are described here in the subsequent topics.

Dashlet-Documents Expiring in N Days/Expired Documents

The Documents expiring in N days/expired documents dashlet lists the expiring and expired documents as specified in the expiration period (N). The dashlet has two views that can be selected through two buttons, Expiring and Expired on the top left corner. To set the views click the Dashlet icon located on the top right corner. The header of the dashlet changes as per the view selected. To set the expiration period for the documents, click the configure icon on the top right corner of the dashlet. Refer to the screenshot below:



The columns can be selected from the Expiring or Expired button in the above screen and also through Modify Grid Config.

To view Expiring or Expired documents, click the Expiring `button or Expired button from the dropdown on the dashlet. Refer to the screenshot below:

Dashlet-Recent Commmunication Logs

The **Recent Communication Logs** dashlet gives a list of all communications made during the site start-up and activation stage. Click the **View All Comunication Log** to go the Communications module of **Start-Up dashboard.**

Dashlet – Recently Updated Sites

The Recently Updated Sites dashlet is available under the **Investigative sites dashlet**. This gives the activation progress report of all sites in a room. Hover the mouse over the Progress% column to view the list of documents that are missing to complete the site activation.

Dashlet – Site Activation Status

This dashlet offers two views – Sites By Country and Sites Activation Progress.Select the Site By Country view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshot below.

Select the Site Activation Status view to reveal the number of sites activated per month. Drag the bar further to scroll down the chart.

By default, the charts reflect results from all sites; however, if you wish to view only your own sites, click the All Sites button next to the chart type to change it to My Sites. Clicking a high point on the line graph or a bar in the bar graphs reveal the sites for the particular status.

Double-clicking a site name will open the Edit investigative site popup to allow you to edit the details of the site.