TRIAL INTERACTIVE

Trial Interactive v10.4.3 User Guide v1

TRANSPERFECT LIFE SCIENCES

APPROVALS

Product Owner

Name: Jay Smith	Title: Sr. Director, Product
Signature: Reason for signature: Date:	

Quality Assurance

Name: Conor McCabe	Title: Quality Assurance Specialist
Signature: Reason for signature: Date:	

Table of Contents

Trial Interactive 10.4- Overview and Features

Hardware and Software Requirements

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

System Requirements	
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 88 and later • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • NOTE: Microsoft® concluded support of Internet Explorer™ 11 in January 2022. Internet Explorer™ 11 is no longer supported in 10.4.
Client Software	• For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally. • For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred). • 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	• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) • 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

What's New in TI v10.4.3?

eSignatures

TTI-2827: ASSIGN SIGNATURE BLOCKS WITHIN THE DOCUMENT

This improvement allows the user who is creating the document signature request (using MSB as a vendor) to assign specific locations within a document for the signatories' digital signatures to appear. After the user has selected the users who will sign the document, a popup will now appear asking the user to indicate where each signature should be applied within the document to be signed.

Collaborative Review

TTI-2444: TRACK CHANGES TURNED ON BY DEFAULT

Prior to TI v10.4.3, any user who was a part of a team editing session could turn Track Changes on or off. With this improvement, Track Changes for everybody will be turned on by default and control of that lay only with the owner of the review session (normally, this is the user who initiated the session).

Searching

TTI-2984: INCLUDE DELETED DOCUMENTS IN SEARCHES

Administrator level users will now have the ability to include deleted documents in their searches. When performing a search, the user can use the 'Include' dropdown menu to select this feature.

Room-Level KPI Information

TTI-2985: KPI CARDS ARE NOW CLICKABLE

With this improvement in TI v10.4.3, the KPI Cards visible on the room Dashboard that are related to documents will now be clickable. Users can click on them to see additional information regarding collected and missing documents.

Chapter 1. Getting Started

Trial Interactive helps clinical teams build a eTMF for clinical trials and to manage content from author to archive. It all starts with workflow, metadata, and content strategy — define your essential documents, determine your required

metadata, configure your index structure, and manage eTMF health in quality reviews, reports and dashlets. Along the way, Trial Interactive helps you prioritize the eTMF and content workflows, collect the documents required to activate your investigative sites, collaborate with the study teams at the sponsor, CRO, and site, as well as integrate with other Clinical platforms so that you can sync with other teams and other types of data. This online help contains a descriptive overview of the Trial Interactive tool and step-by-step procedures of Trial Interactive functions.

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

Signing in to Trial Interactive for the First Time

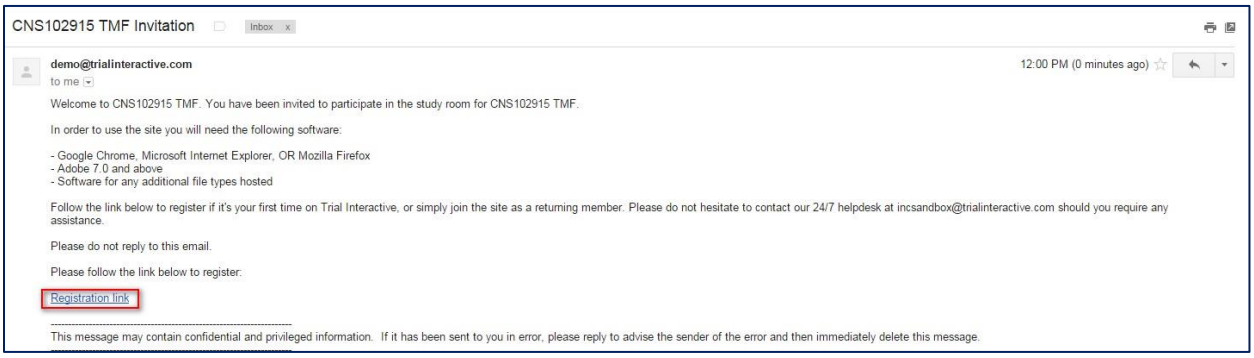
This section includes basic information that will help you get started with Trial Interactive 10.3.

- **Receiving and responding to Room Invitation**
- **User Registration**
- **Multifactor Authentication**
- **Logging in on Subsequent Visits**
- **Requesting a Password Reset during Login**
- **Logging in without access to rooms**
    - **With Trial Interactive 10.3, a user will be logged out if the user is logged on multiple sessions indifferent browsers at the same time. Users cannot be logged in to Trial Interactive on more than one device at a time.**

Receiving and Responding to a Room Invitation

Once a Trial Interactive room Administrator has sent you an invitation, you will receive an email message with a registration link.

Figure: Room Invitation Email



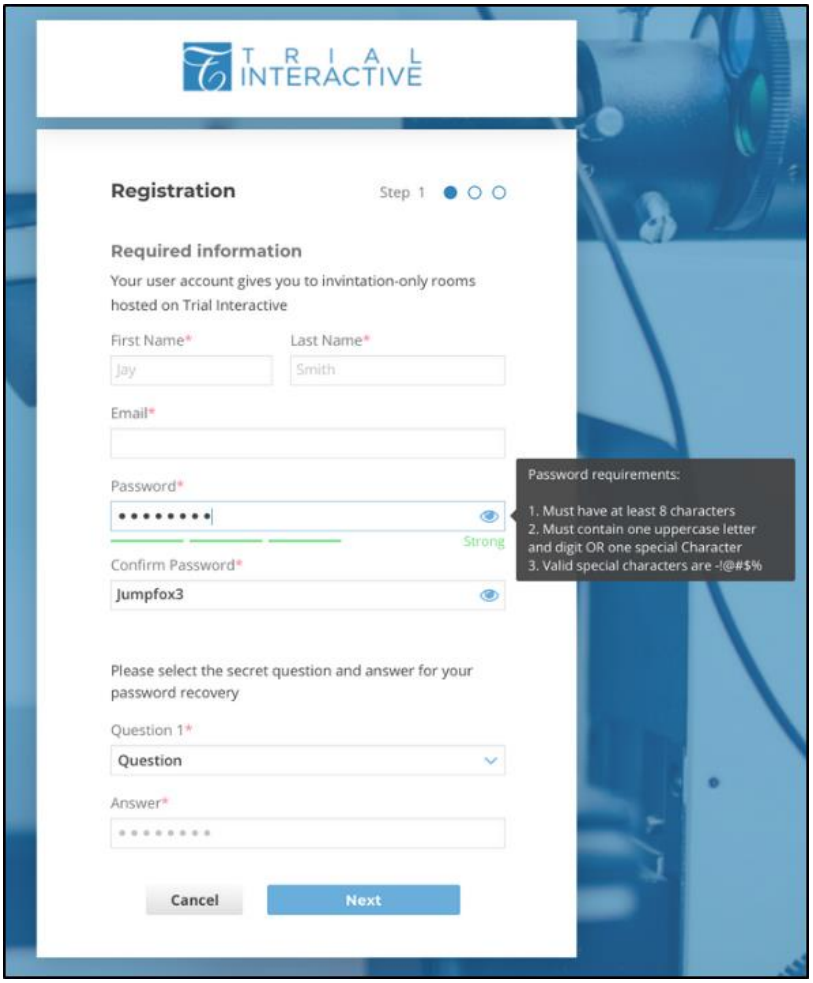
Click the Registration link near the bottom of the message to be directed to the Trial Interactive user account registration page. Complete the registration form to gain access to Trial Interactive.

User Registration

1. **You need to register to the application only once as a first-time user when you are invited to a room via 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. The new room will appear on your Home page on the list of all rooms to which you have been granted access.**
4. **For all subsequent invitations to rooms, you will be notified by emails.**

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

<u>Step 1: Registration - Required Information</u>



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.**

<u>Note:</u> Hover the mouse over the Password field to see the tooltip 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.**

<u>Step 2: Registration - Optional Information</u>

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

Step 3: Registration - Custom Information

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

Signing in on Subsequent Visits

TO LOG IN TO TRIAL INTERACTIVE

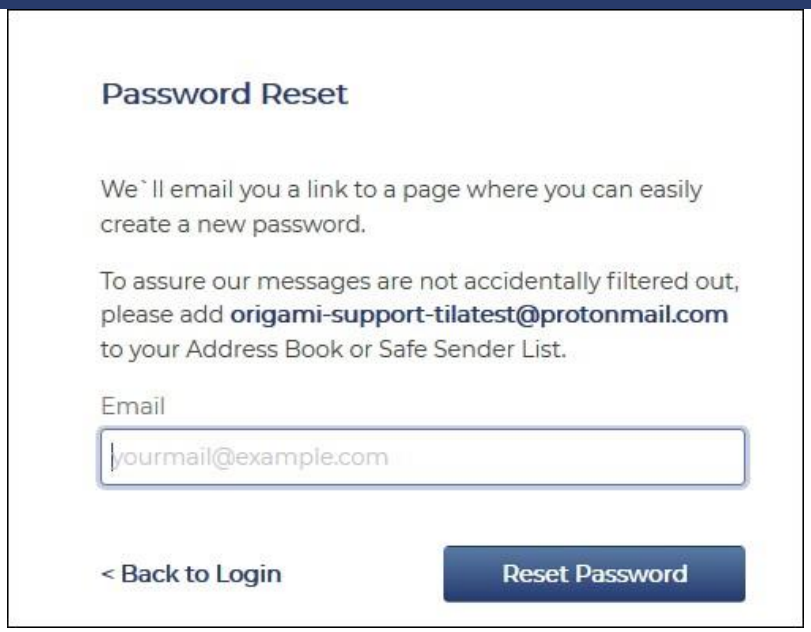
1. **Using your preferred internet browser, navigate to http://www.trialinteractive.com.**
2. **Click the Client Login button located at the top-right corner of the page.**
3. **The Trial Interactive Login page appears.**
4. **Enter your Username and Password. Your Username is the full email address that was submitted by the client-appointed Administrator and is likely the one to which the initial invitation was sent.**
5. **Click Login.**

Requesting a Password Reset

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

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

See the screenshot below:



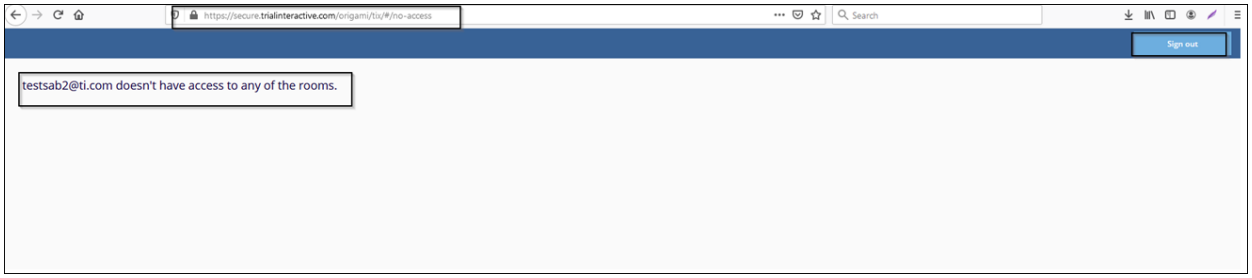
Follow these steps to reset your password:

1. **Enter your email address in the field provided.**
2. **Click Send Request. The next window in the Password reset wizard opens.**
3. **You will receive an email with the Reset Password link.**
4. **Click the link to lead you to the Password Reset page.**
5. **Respond to the security questions and click Next.**
6. **You are taken to the Change Password page. Enter the new password and confirm again.**
7. **Click Set new password.**
8. **The system confirms that the password was successfully reset. Click Back to the login page to login 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 logged off and 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 has been revoked.

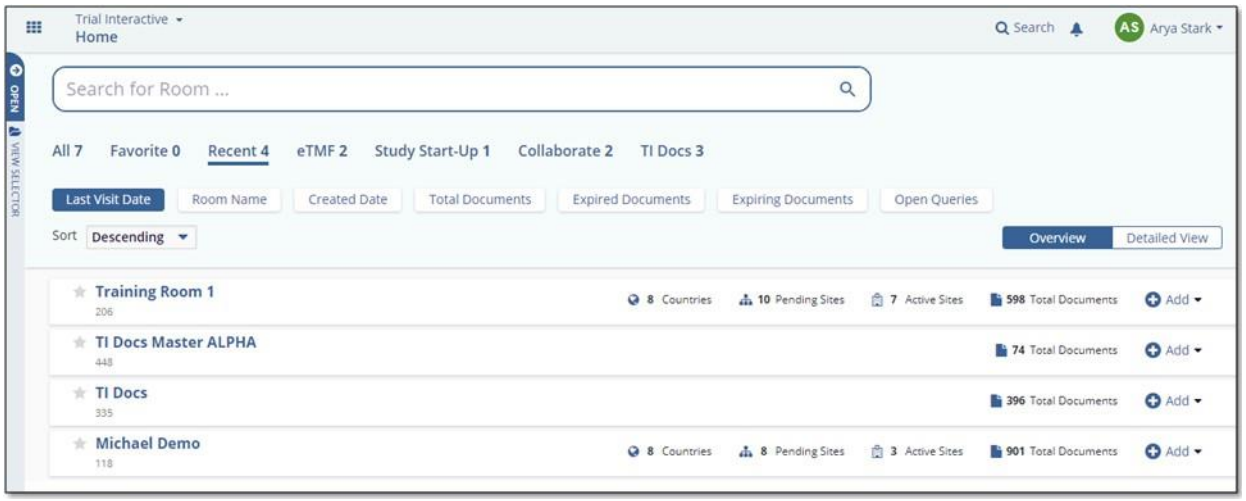
Refer to the screenshot below for a view of a typical advisory page.



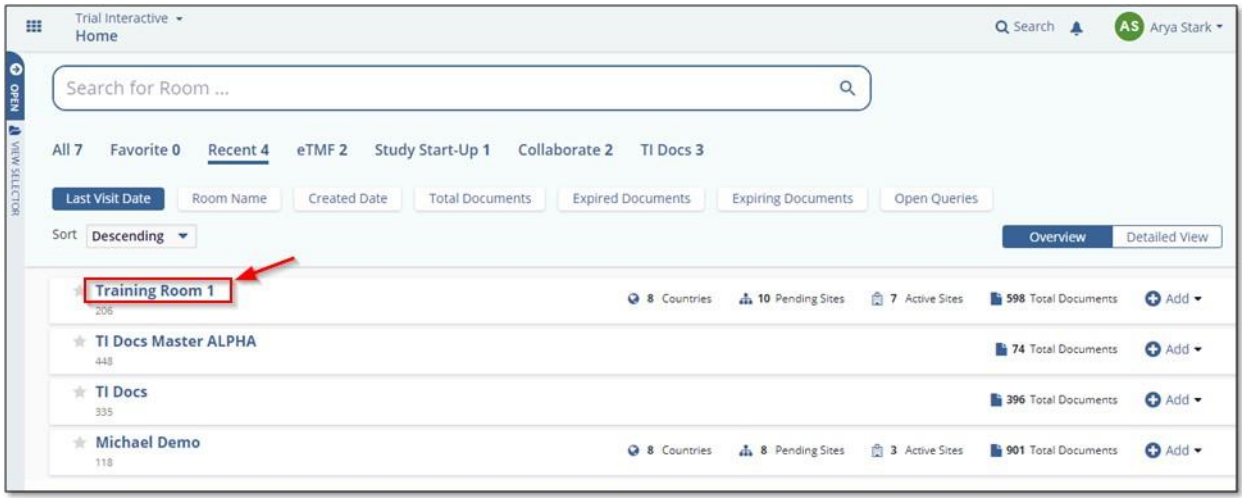
Chapter 2. The Trial Interactive Home Page

This section helps you enter rooms as well as showing Overview and Detailed summary information of rooms to which you have been granted access.

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



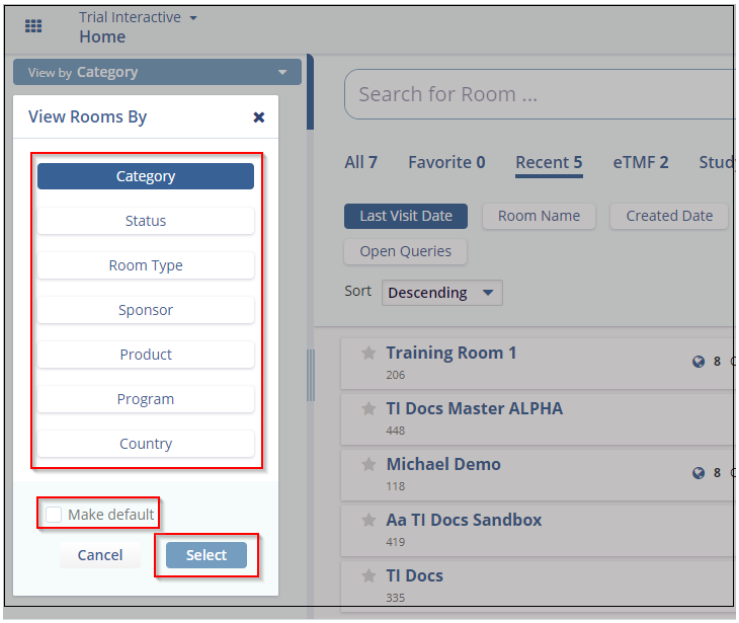
Click the required Room Name to enter a room.



Room Views

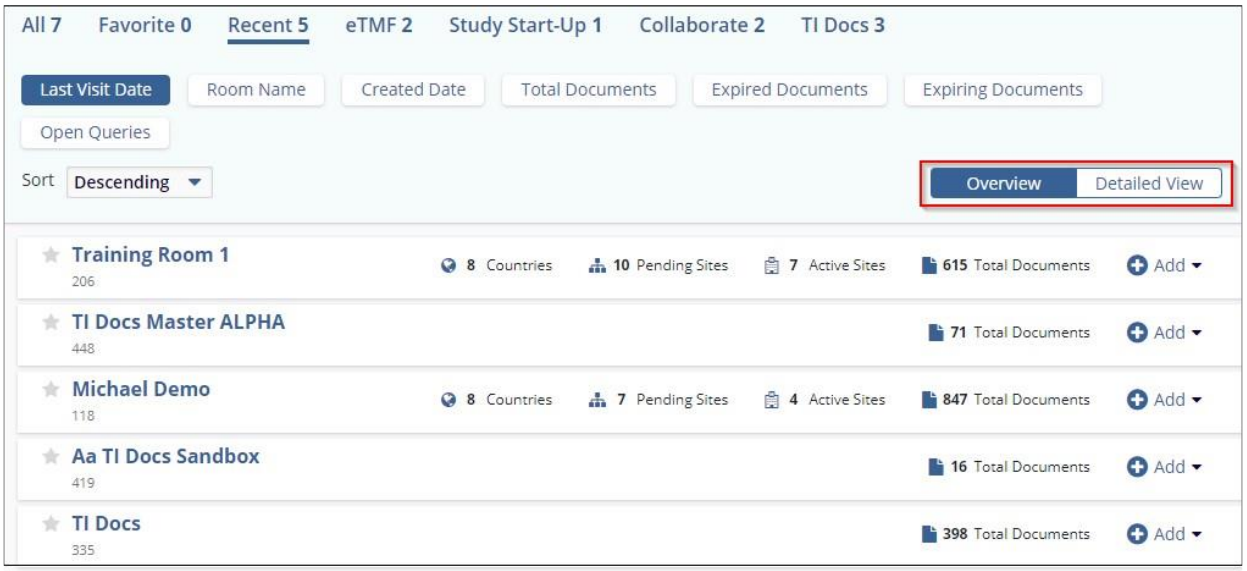
The TI Home page provides you with different views through which you can filter rooms. This is intended to aid users with locating the correct room when there are more than 5 rooms to which the user has been granted access. Users with access to 5 or fewer rooms will simply see a list of all of the rooms to which they have been granted access and will not see the room filtering or searching tools.

Filter categories are placed in the left pane. If it is closed, click on 'Open' to expand the side menu.



Viewing Room Details

You can also view the details of the room and related information by clicking 'Detailed View' to the top-right of the home page. Refer to the screenshot below:



Countries

This is the number of countries in the room. It is available for eTMF or Collaborate rooms. It is not intended to be clickable. Available both in Overview and Detailed View modes.

Pending sites

This is the number of non-active investigative sites. It is available for eTMF or Study Start-Up rooms. It is not intended to be clickable. Available both in Overview and Detailed View modes.

Active sites

The number of active investigative sites. It is available for eTMF or Study Start-Up rooms. It is not intended to be clickable. Available both in Overview and Detailed View modes..

Total documents

The overall number of documents in the room. This number includes only "documents" in all modules in a room, no any deleted, purged or missing document. It is available for all rooms. It is not intended to be clickable. Available both in Overview and Detailed View modes.

Collected documents

The number of collected documents. This number includes all documents marked as required for the eTMF which we

consider to be collected. It is available for eTMF or Study Start-Up rooms. This item is clickable. Available only in Detailed View mode.

Missing documents

The number of missing documents. This number includes all eTMF placeholders which have no document which can be considered as collected. This number represents the difference between the number of all required documents in a room and the number of required documents that we have already collected. It is available for eTMF or Study Start-Up rooms and is clickable. Available only in Detailed View mode.

In the corresponding grid we see all placeholders we still have to submit a document and all submitted documents we do not consider as collected. For one placeholder we may have several submitted documents and that makes difference in number of missing documents we have in KPI dashboard and in the grid.

Required coding

This is the number of non-final documents which are in a workflow. TI does not take into account rejected documents or those documents which have been excluded from the workflow. It is available for eTMF or Study Start-Up rooms with a Workflow enabled and only for Editor and higher level users. It is clickable. Available only in Detailed View mode.

Final documents

This is the number of documents with a status of Final, regardless of whether the document was submitted as Final or is published via the workflow. It is available for eTMF or Study Start-Up rooms with a workflow enabled. It is intended to be clickable. Available only in Detailed View mode.

Expired documents

This is the number of expired documents in the room. A document is considered to be expired when it has an expiration date earlier than today. It is available for eTMF, Study Start-Up, Collaborate and TI Docs rooms and is intended to be clickable. Available only in Detailed View mode.

Expiring documents

This is the number of expiring documents. The expiring period is configurable on a room level via the room settings. It is available for eTMF, Study Start-Up, Collaborate and TI Docs rooms and is clickable. Available only in Detailed View mode.

Open queries

This is the number of "Pending" and "In Progress" queries in the room. It is available for all rooms with queries and is clickable. Available only in Detailed View mode.

eSignature requests

This is the number of documents which were sent to the eSignature workflow stage and have not been signed yet. It is available for Collaborate and TI Docs rooms with eSignature enabled. It is clickable. Available only in Detailed View mode.

eSignature in progress

This is the number of documents which were sent to the eSignature workflow stage and signing is in progress. It is available for Collaborate and TI Docs rooms with eSignature enabled. It is clickable. Available only in Detailed View mode.

Periodic review

This is the number of documents which require periodic review. It is available for Collaborate and TI Docs rooms with eSignature module enabled and only for Editor level users and higher. It is clickable. Available only in Detailed View mode.

Room Search and Accessing a Trial Interactive Room

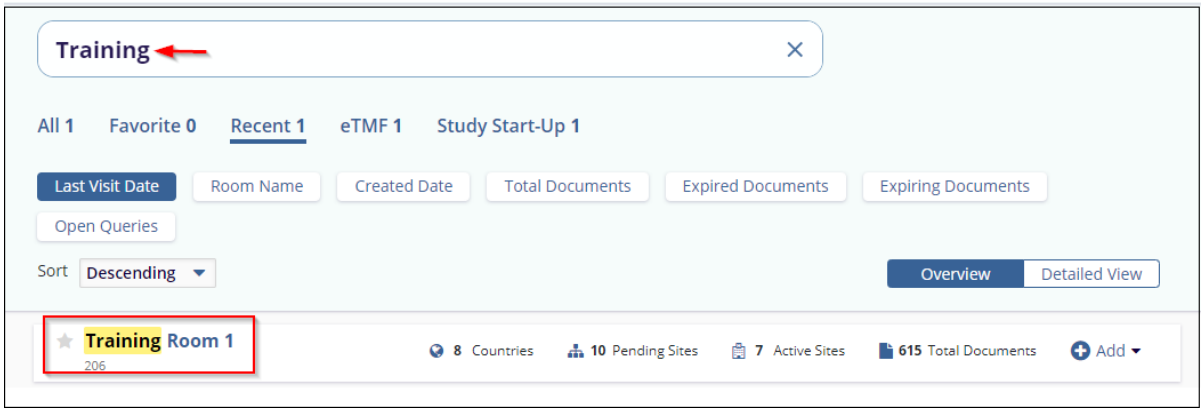
ROOM SEARCH

Trial Interactive allows you to search for rooms easily even when you have access to hundreds of rooms.

To perform a room search:

1. **Enter the required room name in the Search box at the top of the page and press Enter on your keyboard.**
2. **Rooms matching the search criteria are displayed in the panel below the filters, else a message 'No Rooms Found' is displayed.**

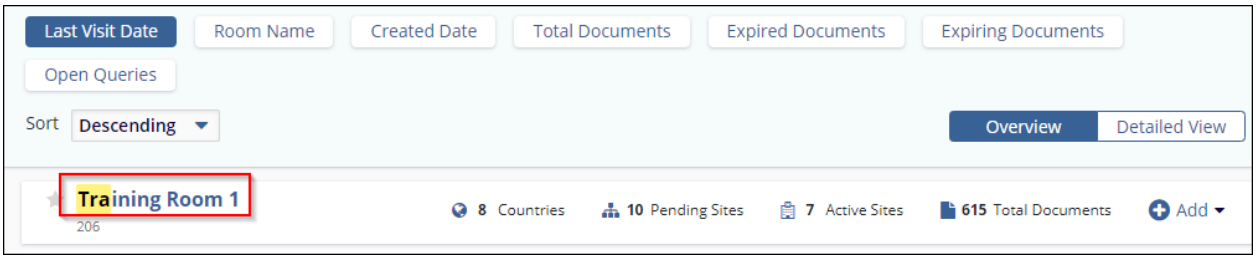
Refer to the screenshot below:



ACCESSING A TRIAL INTERACTIVE ROOM

Click on the room name in the panel to enter the room.

Refer to the screenshot below:

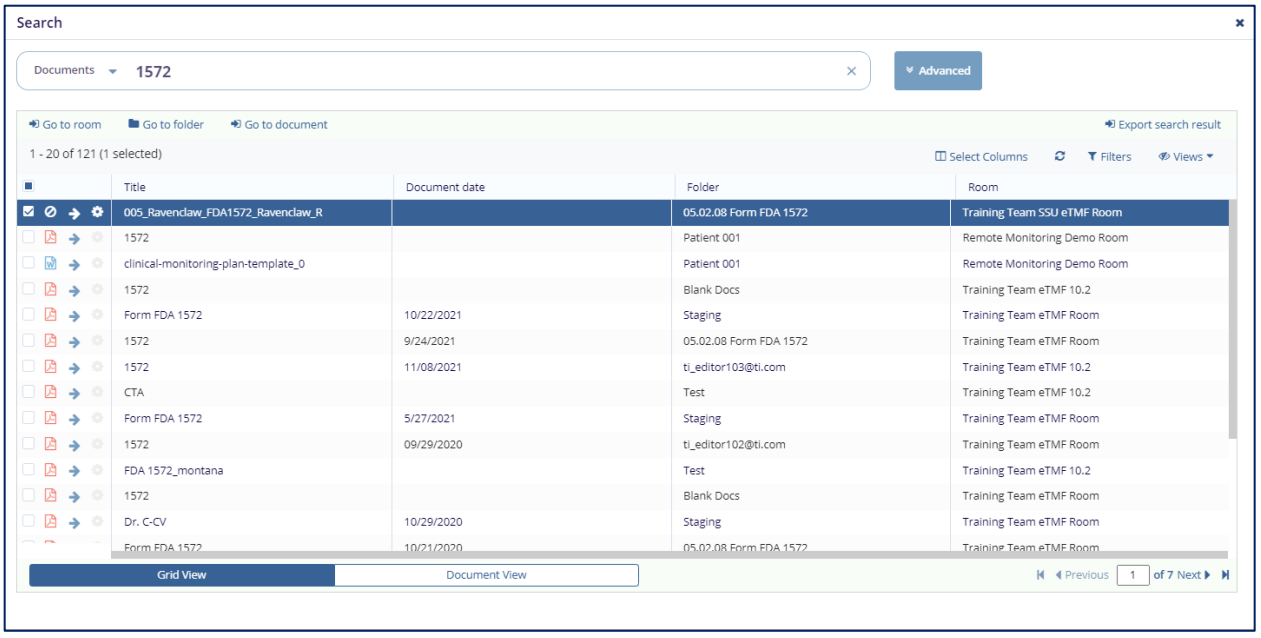


Cross Study Document Search

DOCUMENTS SEARCH

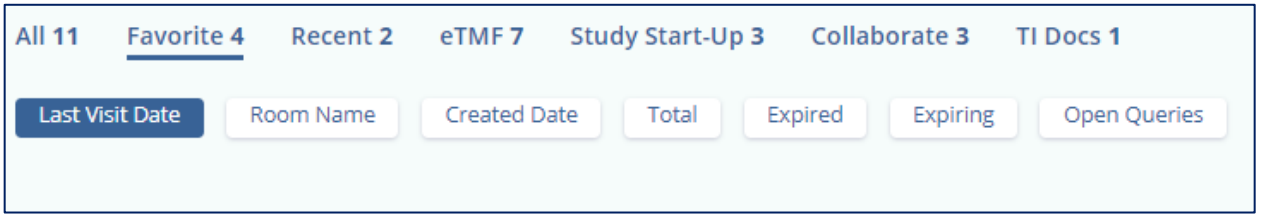
To perform a cross-study documents search, perform the following steps:

1. **From the Home Page, (or from within a room) click the Search icon located at the top-right corner of the screen.**
2. **The Search window appears.**
3. **Type the keywords pertinent to your search into the search field.**
4. **Any related documents will appear in the grid below.**



TI Home Page Filters

The TI Home Page provides a variety of filters through which you can filter the rooms displayed. Refer to thescreenshot below:



The filters consist of the following:

- **All: This link displays all rooms that you have access to.**
- **Favorite: This link displays the list of all rooms that you have marked as favorites.**
- **Recent: This link displays the list of rooms that have been visited recently with the latest visited room at the top.**
- **eTMF: This link displays all eTMF rooms.**
- **Study Start-Up: This link displays all Study Start-Up rooms.**
- **Collaborate: This link displays the list of all TI Collaborate rooms.**

Below these main filters, the TI Home Page provides additional sorting options which allow you to sort the order in which the rooms appear. These options vary with every main filter.

Summarized (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 rooms that you have access to with a count of the following metadata:

- **Countries where sites are located**
- **Active Sites**
- **Pending Sites**
- **Total Documents**

Refer to the screenshot below:

Countries

The number next to Countries shows the total count of the countries where clinical trial sites pertaining to a room are located.

Active Sites

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

Pending Sites

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

Total Documents

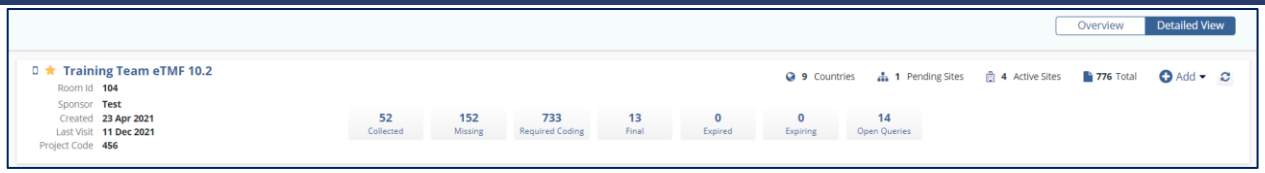
The number next to Total Documents shows the total count of documents pertaining to a room.

Detailed View of Rooms

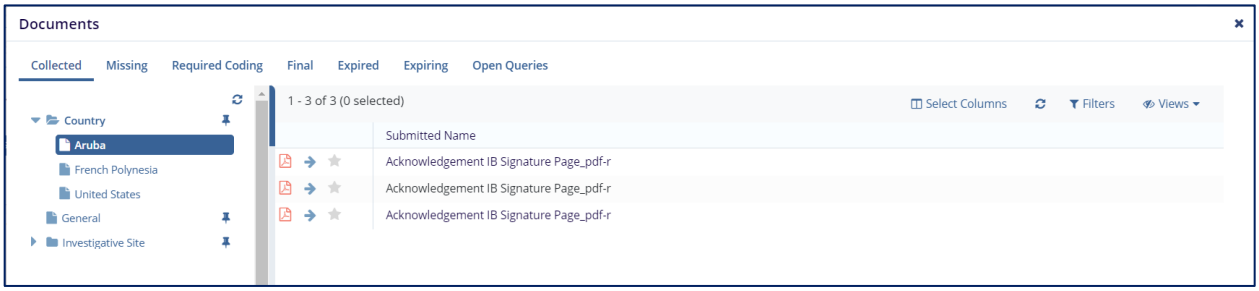
From the Home Page, click the 'Detailed' button located at the top-right corner of the page to view rooms and studies with the following information:

- **Open Queries**
- **Collected Documents**
- **Missing Documents**
- **Expired or Expiring Documents**
- **Require Coding**
- **Final Documents**

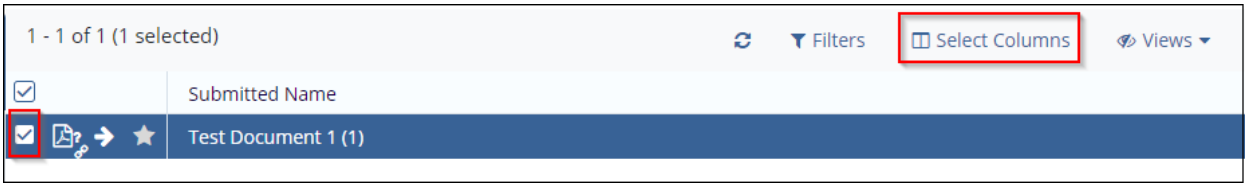
Refer to the screenshot below:



Each of the categories listed above can be clicked. When clicked, the screen will change to display relevant information for the room chosen. The Document window opens which displays the list of documents. The screenshot below shows an example of the expanded view of the Collected Documents tab which displays the list of documents:



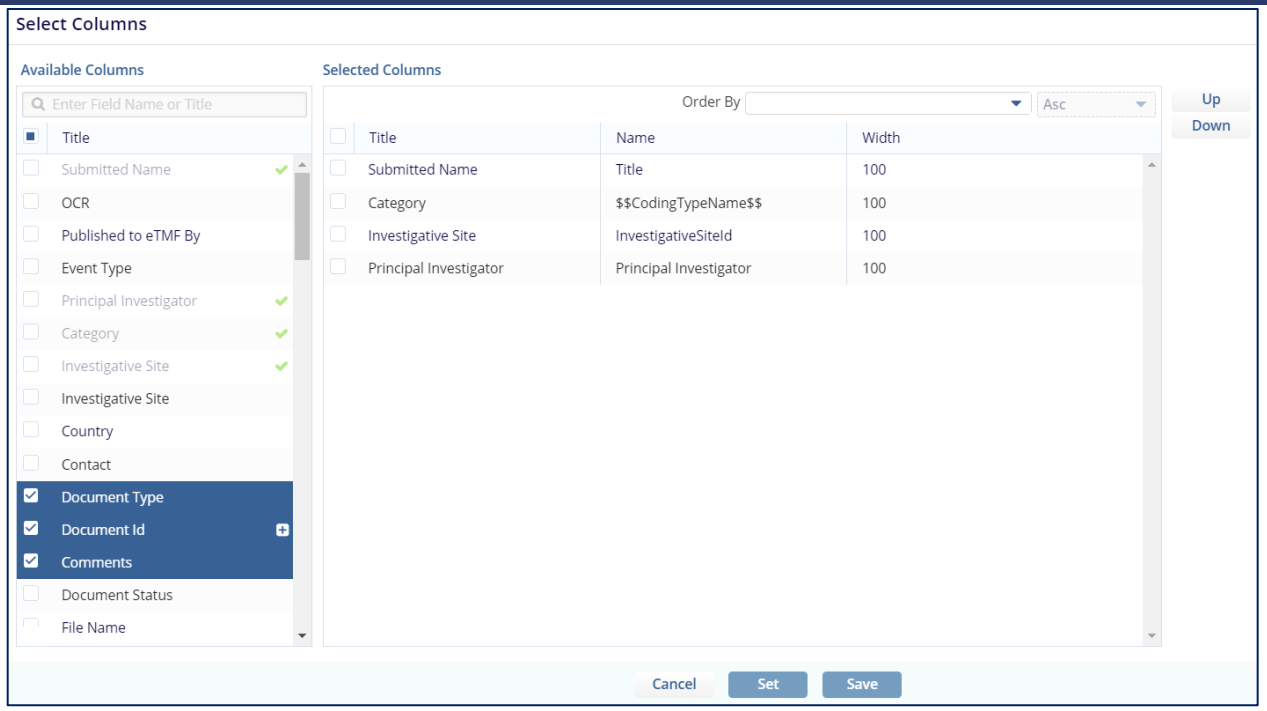
You can drill down the folders in the Index on the left to locate the required document. You can also configure the columns in the document window as required by clicking the
'Select Columns' link at the top-right corner of the window. Refer to the screenshot below:



Clicking the 'Select Columns' link opens the grid configuration window which allows you to configure the columns in the document grid. You can add and remove columns to be displayed for a document in the document grid as required.

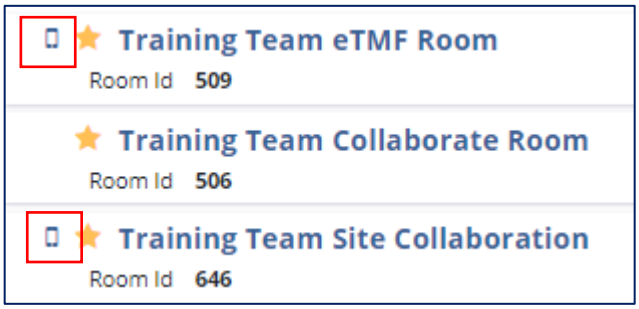
You can also change the order of the selected columns by clicking the Up and Down buttons located to the right of the window. Fields can be dragged to a different location as well.

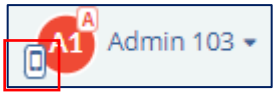
Similarly, you can view the list of documents for Missing Documents, Documents that Require Coding, Final Documents, Expired Documents, and Open Queries.



myTI Enabled Rooms

It can be difficult to remember all of the rooms to which you may have access both via the standard online application and via myTI. To aid in that, an icon will now appear next to any room to which you have been granted access via myTI. The same icon will be available within the room as well, but it will be added to your Username Menu dot.



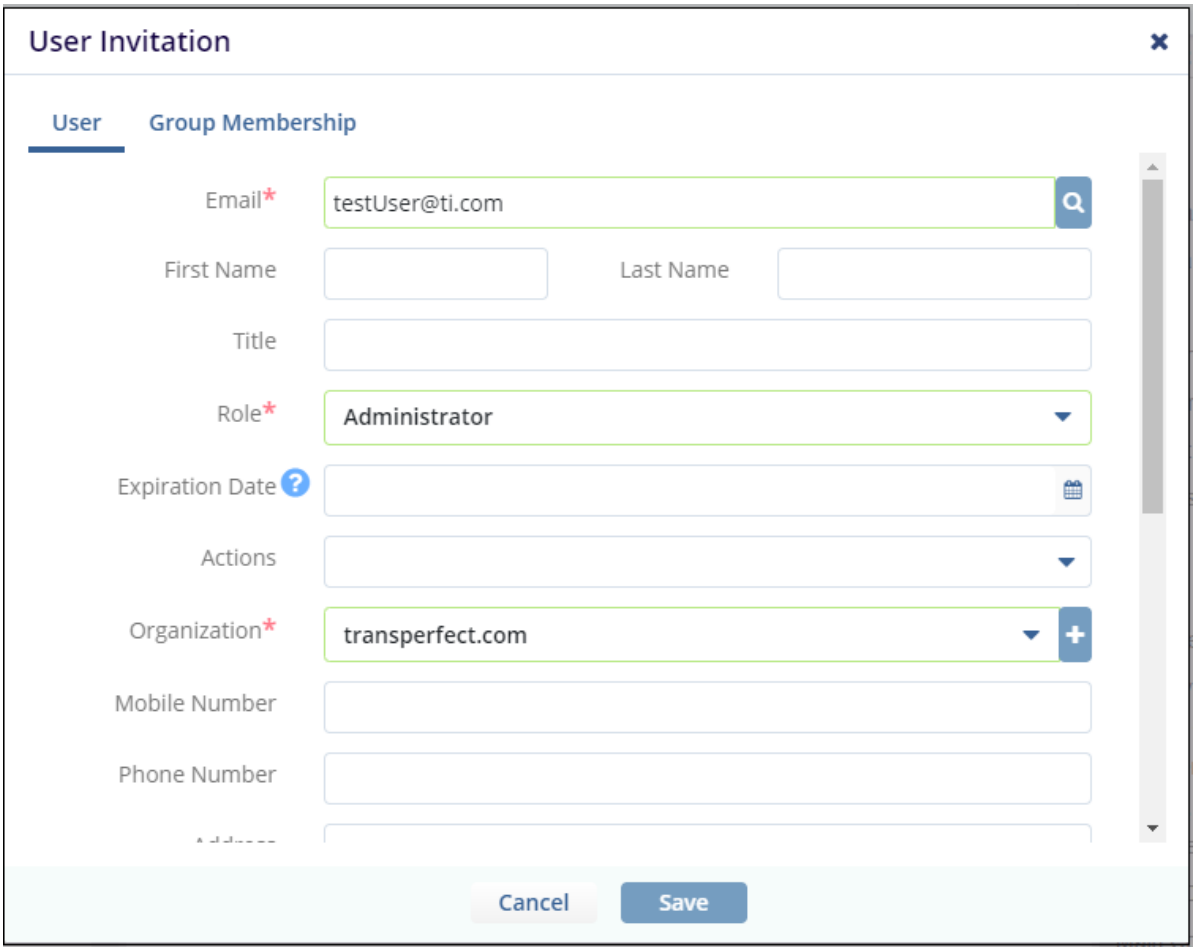


Add Users to a Room

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

1. **Click the 'Add' dropdown 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 will open.**

Refer to the screenshot below:

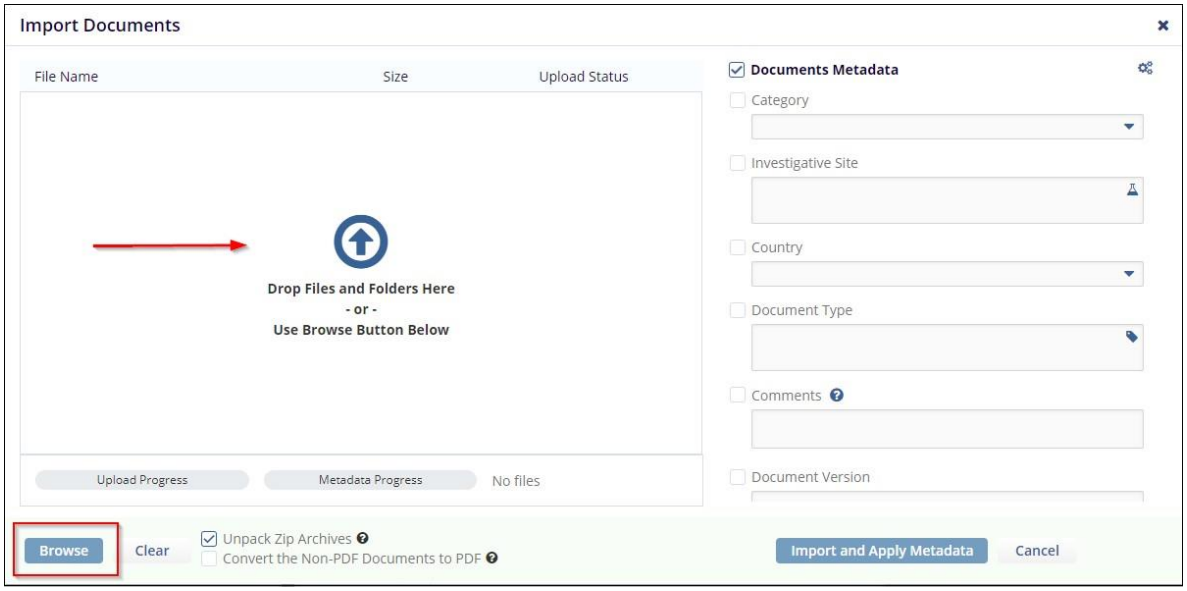


3. **Enter the email address of the user, assign a Role to the user, and select Actions as appropriate.**
4. **Select any Groups to add users to that group.**
5. **Click Save to add the user to the room and send the invitation.**
    a. **If the 'Invite Later' option was chosen, you will need to locate the user's account in the room to send the invitation.**

Upload Documents to a Room

1. **Follow the steps below to upload documents to a room from the Home Page:**
2. **Click the 'Add' button to open the dropdown menu to the right side of the room line on the home page to reveal the options.**
3. **Select the Document option from the dropdown list that appears.**
4. **Drag and drop the files or click 'Browse' at the bottom of the page to navigate to the required document to be uploaded.**

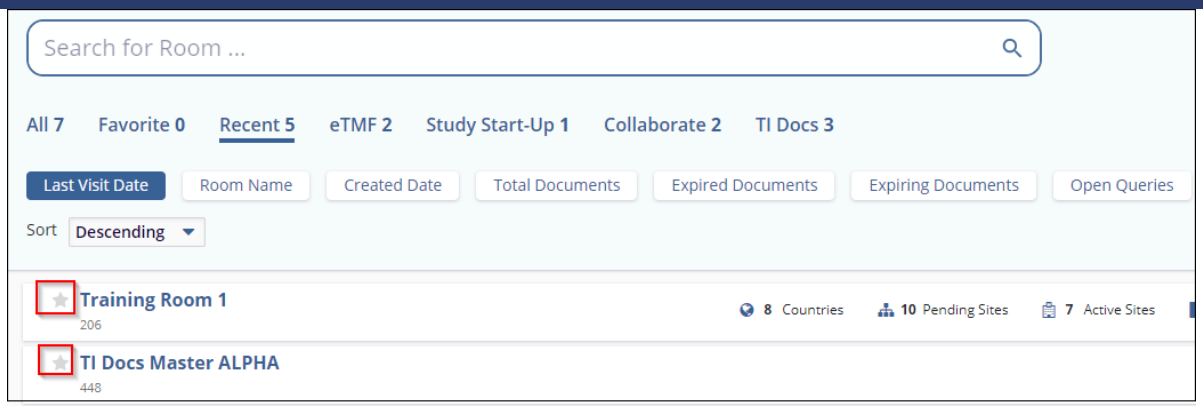
See the screenshots below:



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 the room or rooms as favorites.

On the home page, click the star next to the name of the room you wish to designate as a favorite. The color of the star will change from grey to gold indicating that the room has been successfully marked as a favorite. Refer to the screenshot below:

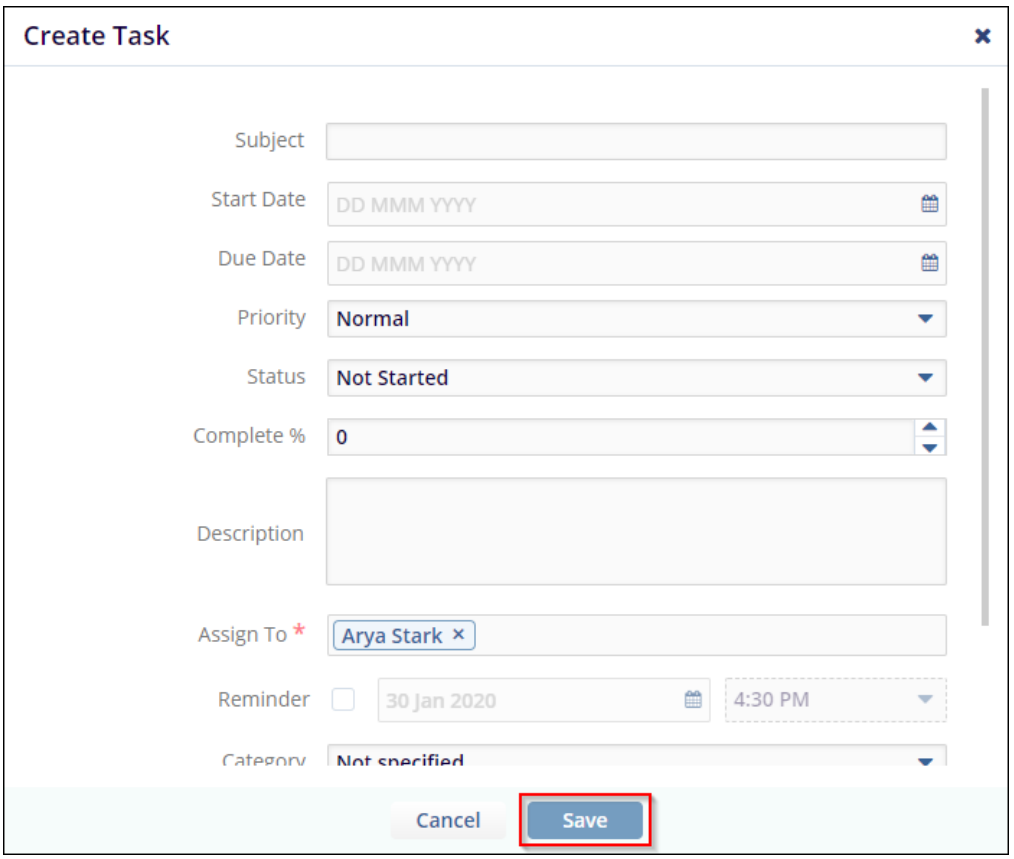


Adding Tasks to a Room

To add tasks 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:**

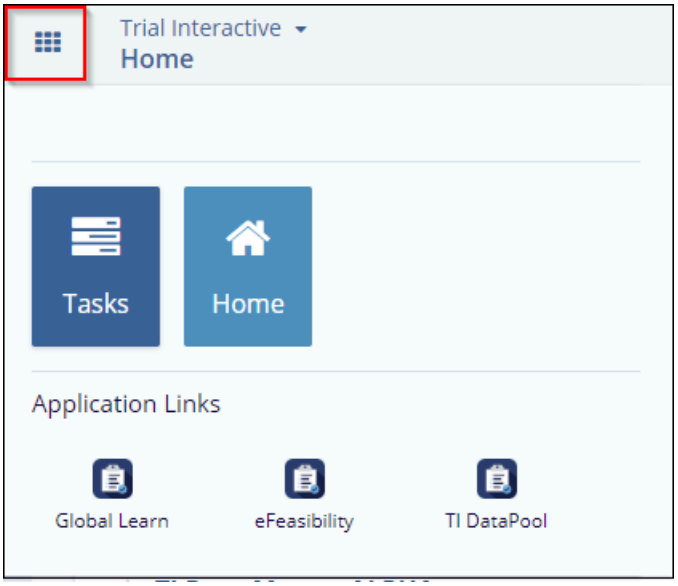
2. **The Create Task window will open.**
3. **Fill in the details as instructed on the screen.**



4. **Click Save when all the information is entered in order to complete the creation of the task.**

Chapter 3. Main Navigation and Inter-Room Navigation

Main Navigation, more commonly referred to as the Navigation Grid or the "Waffle" can be accessed both from the Home Page and from within rooms. The options will be different depending upon context and the user's access rights within each location. From the Home Page, the Navigation Grid can be accessed by clicking the dots located at the top-left corner of the page. See the screenshot below:

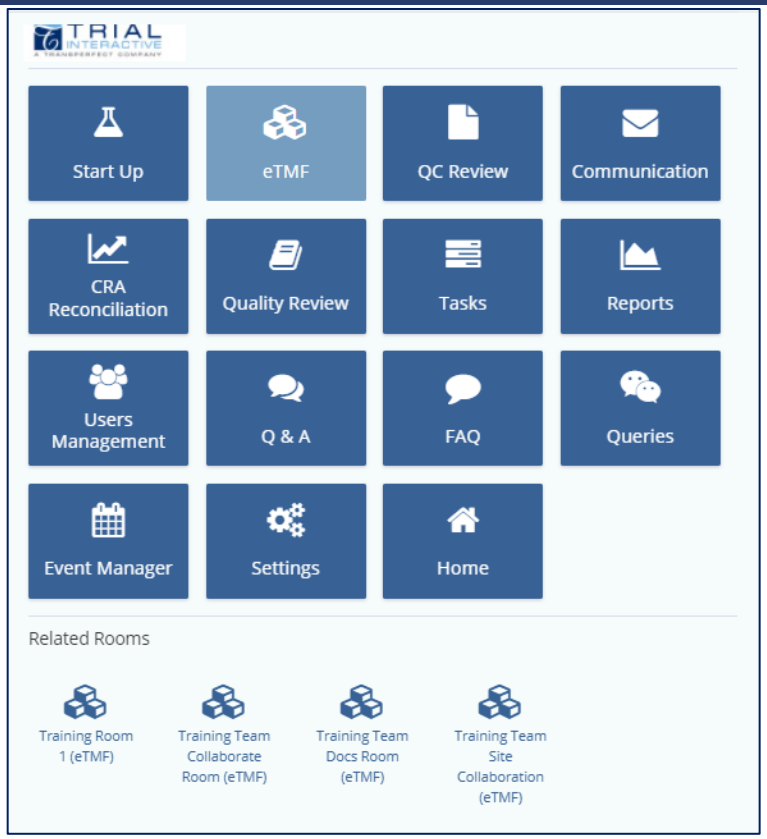


Users can access the Home Page and the Tasks application from the Navigation Grid. Besides applications, you can also access links to other TI products from the 'waffle' on the Home Page. Your options here will depend on your access level to the system. Most users will only see Tasks and Home represented in this menu.

Main Navigation from within a Room

On entering a room, you will be taken either to the room dashboard or to another location identified as your preferred landing spot in your User Profile. To learn more about this, please check out the section on Default Context Configuration. Regardless, once you have entered a room, the Navigation Grid will be accessible from the top-left corner. The options available to any user are dependent on which modules are active in the room as well as what their access level allows.

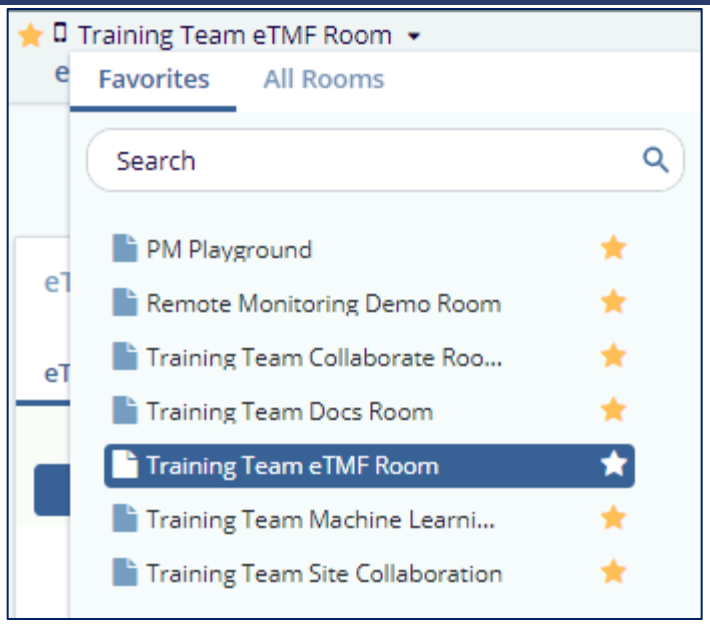
The user whose 'waffle' is displayed below is an Administrator with full access to a room that has several other rooms of varying types linked to it. Clicking on any of the tiles will take you to the related module within the room. Below, we will discuss navigating to different rooms.



Navigating between Rooms

With this version of Trial Interactive, you can seamlessly change rooms from any location within the application without having to navigate back to the home page. Looking at the screenshot above, you can see that several rooms are linked to the user's current room. Clicking on one of those rooms will take the user there.

Another available option is to click the dropdown menu next to the room name to open a menu with the list of all the rooms to which you have been granted access. Refer to the screenshot below:

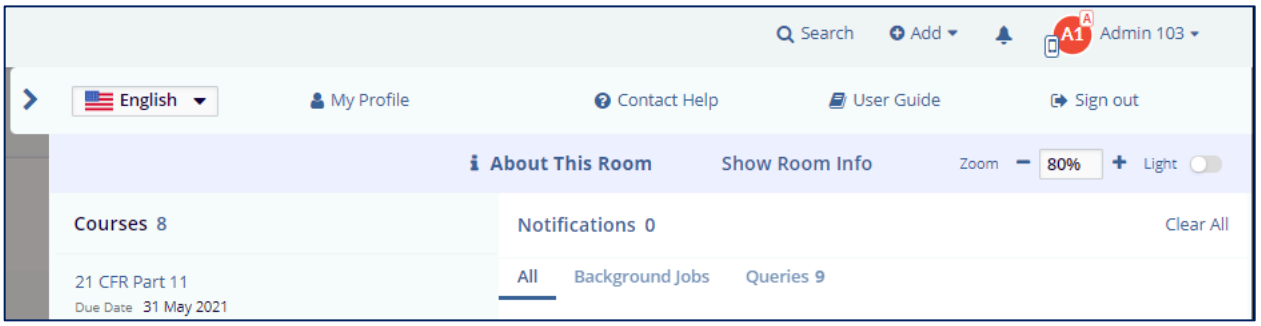


Please note that the menu defaults to showing the user's Favorite rooms as indicated by the gold stars. A room may be designated a favorite or may be removed from this list, by clicking on the star icon wherever it is seen in TI. To navigate to a non-favorite room, click the "All Rooms" option and search through all of the rooms to which you have been granted access.

Chapter 4. Username Menu

Each user has a colored dot at the upper-right corner of the screen with their initials in it. This is somewhat less commonly known as the User Avatar. The color of the dot is dependent upon your access level to the room you are in currently. Also, the dot can be replaced with a picture via the My Profile Settings menu if so desired.

When you click on or near the dot, a menu opens. We call this the Username Menu and it has several functions.



Through the Username Menu, you can access the following:

- **My Profile**
- **About This Room**
- **Language Settings**
- **Help (Contact Support)**
- **User Guide**
- **Notifications**
- **Sign Out**
- **Dark Mode/Light Mode**
- **Zoom**
- **Global Learn Courses**

About This Room

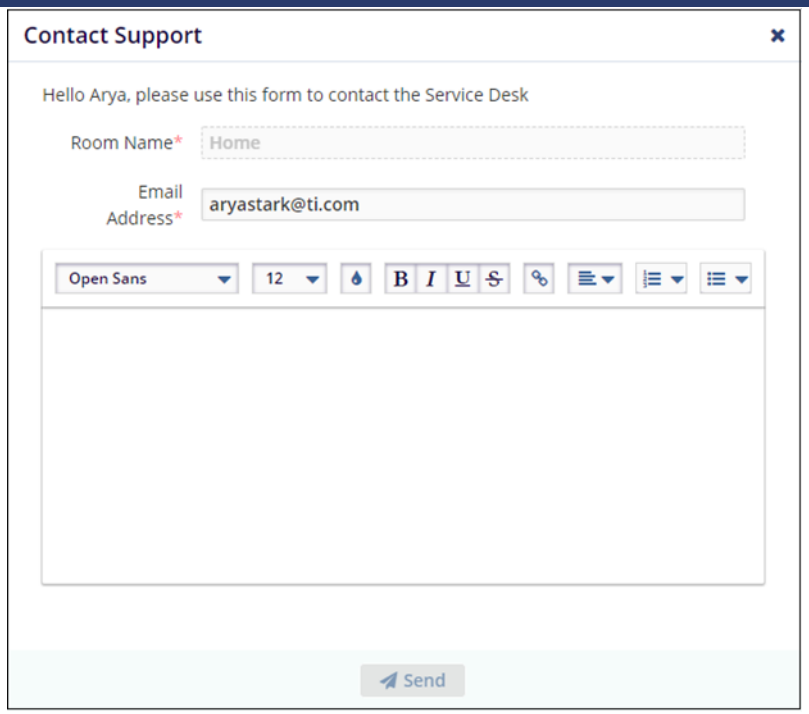
Click the 'Show Room Info' link to reveal the About This Room dashlet. This is typically configured by Administrator level users to welcome new users and provide them with information pertaining to the room. An administrator can also upload any information through the room's settings that is pertinent to the study that they would like to share with users.

Room administrators can either click the 'Edit' link in the About this Room window, use the 'Edit' button in the About the Room dashlet, or use the Settings module to alter the content of this window. The main text can be edited directly. The lower portion of the window, showing contact information and email addresses for the room is managed via the Settings module.

Contact Help

In a scenario where you need any help related to Trial Interactive, you can contact the Service Desk by clicking 'Contact Help' from the Username Menu.

This opens the Contact Support email window to allow you to enter the details for the request needed and send it to the service desk. Refer to the screenshot below:



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 room menus and field labels will change to be displayed in the language of your choosing.**

My Profile

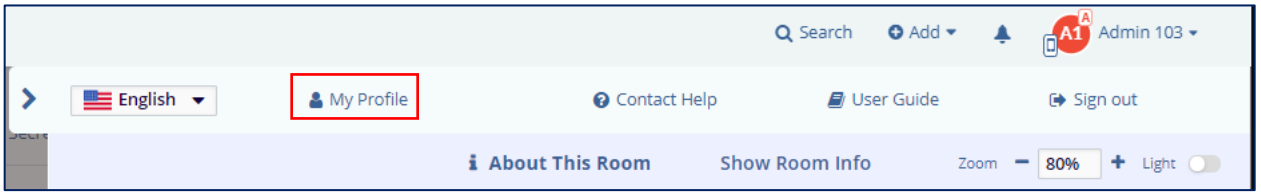
By clicking on the 'My Profile' option, you can manage your profile. Please note that these settings are user-specific and are not room-specific. Any changes made in this area impact the overall user account and are not contained to any

single TI room.

To access My Profile:

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

Refer to the screenshot below:



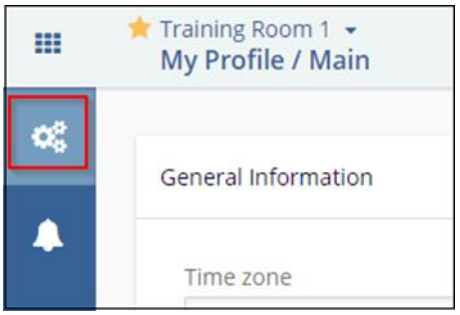
The My Profile area is divided into the following two sections:

- **My Profile Settings (Main)**
- **My Profile Notifications**

Navigate to the vertical menu at the left to choose which area to edit.

MY PROFILE - MAIN SECTION

From the My Profile page, click the Main section from the left panel as indicated by the gearwheels. Refer to the screenshot below:



In this menu, you will find the following User Profile Dashlets.

- **General Information**
- **Password Recovery – Secret Questions**
- **User Avatar**

- **Change Password**
- **Site Filtering Options**
- **Default Context Configuration**

GENERAL INFORMATION - TIME ZONE

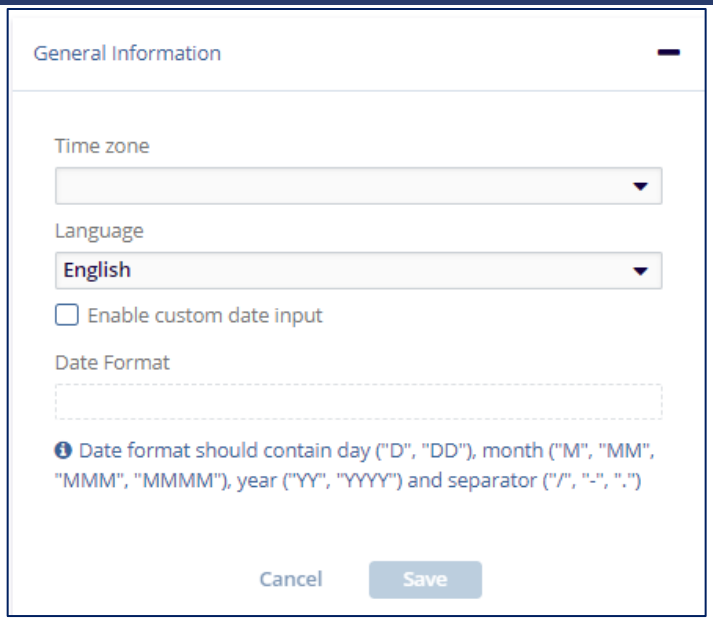
To set the time zone applicable to you:

1. **Click the Time zone dropdown to reveal the popup with the time zones.**
2. **Scroll up or down to locate your time zone and click the applicable time zone to select it.**
3. **The selected time zone displays in the box.**
4. **A popup confirming the same appears. Click the 'x' on the popup to dismiss it.**
5. **Click Save.**

GENERAL INFORMATION - ENABLE CUSTOM DATE INPUT

For users of Editor level or above, when coding a document, in addition to selecting the date from the Calendar Date Picker, you can choose to type in dates in the format preferred by you. The system interprets the date entered and saves it based on your geolocation.

To be able to manually type-in dates, you will need to enable the manual entry of custom dates from this section of the My Profile area. Refer to the screenshot below:



1. **Tick the checkbox Enable custom date input.**
2. **Enter the date format preferred by you. Some of the most common date formats are MM/DD/YY, DD/MM/YY, MM/DD/YYYY, DD-MMM-YY.**
3. **Once done, Save the changes. You will now be able to enter dates manually if you so choose.**

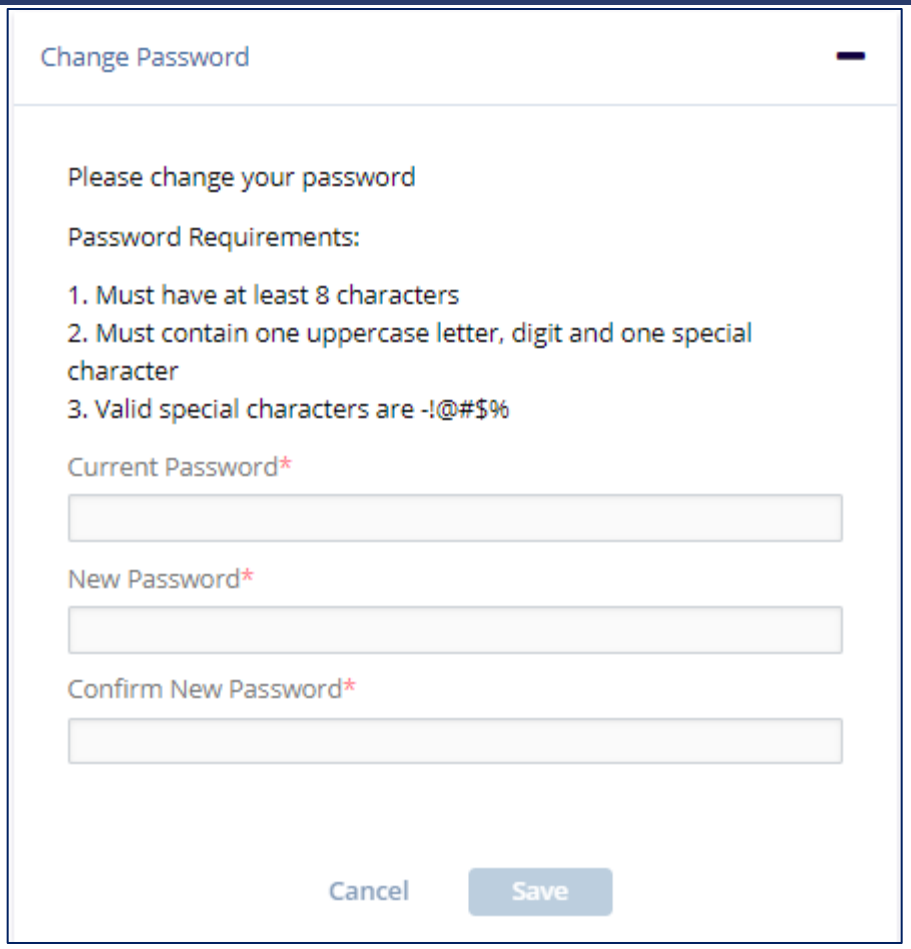
CHANGE PASSWORD

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

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

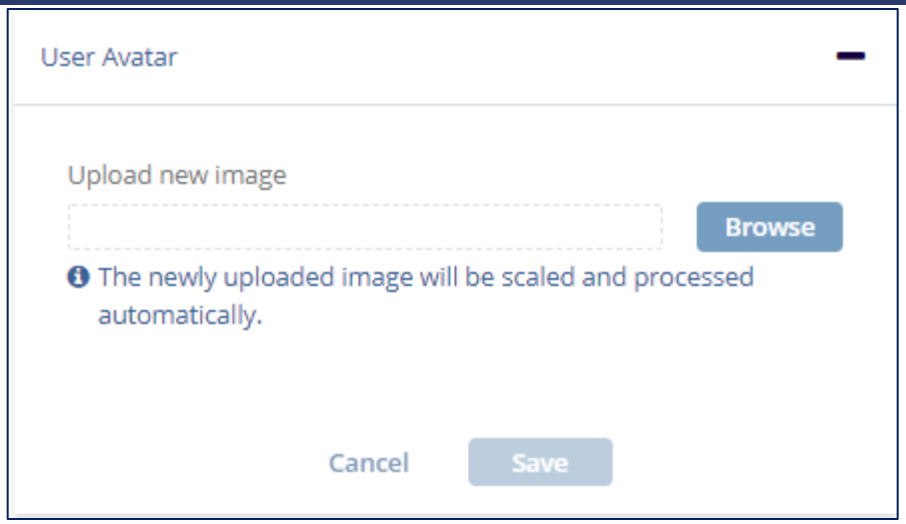
You are required to set the answers to secret questions to help recover your password if you happen to forget it.

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.**

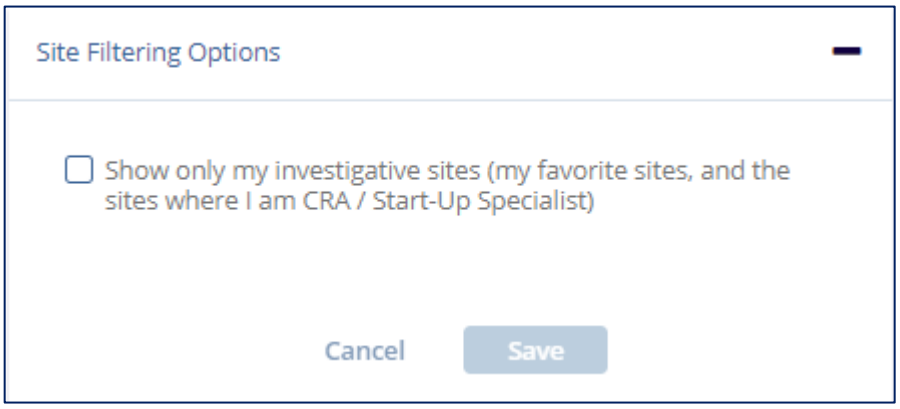
USER AVATAR

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

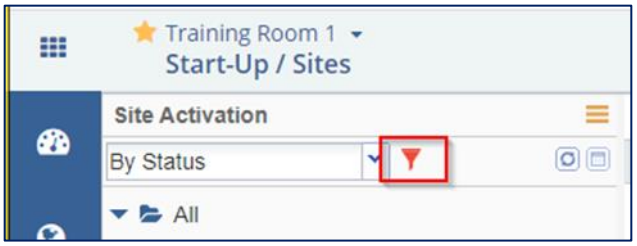


SITES FILTERING OPTIONS

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



On selecting this option, the filter icon in the Sites module appears in red. Refer to the screenshot below:

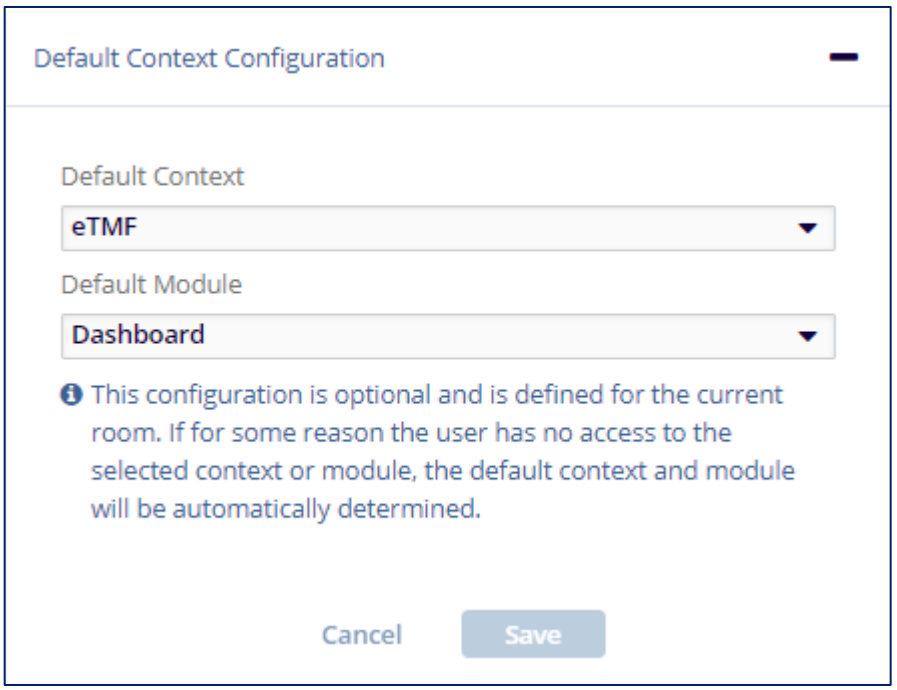


DEFAULT CONTEXT CONFIGURATION

This dashlet allows you to indicate to TI what part of the room should be treated as your initial landing page. This allows you to be taken directly to whichever part of the system you use most.

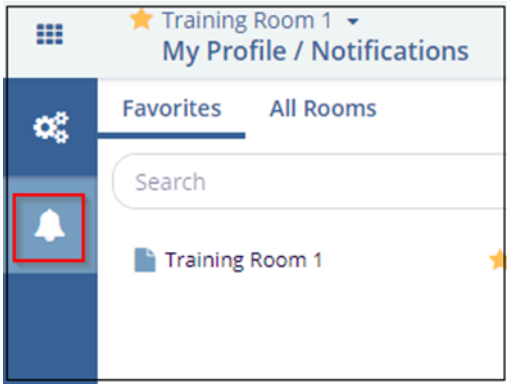
In order to set your landing location, follow the steps below:

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



My Profile Notifications Section

You also have the Notifications section that allows you to specify which email notifications you would like to enable for your account for each of the rooms to which you have access. 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 which notifications are available for you and they can make some choices default or mandatory:

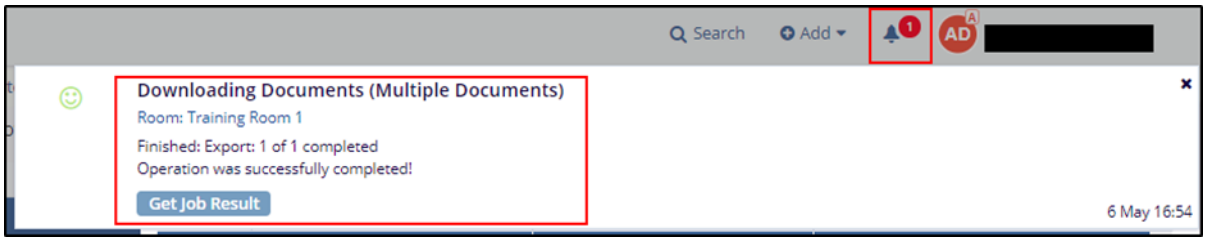
You can elect to receive either a mini summary of notifications or you can choose nightly newsletters recapping all of the new events in the past 24 hours for each of the notification categories. The frequency of mini notifications is selected by the room administrator in the Settings module.

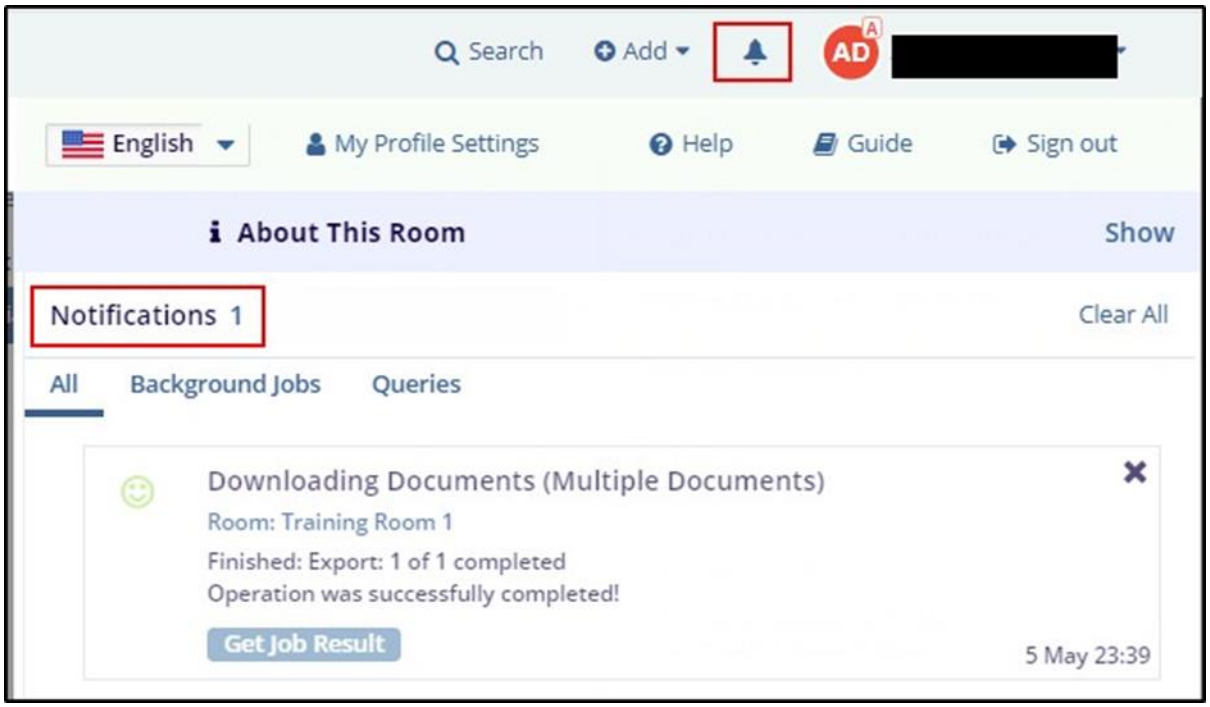
Once you are done selecting which notifications you would like to receive, click Save.

Job Processing Notifications

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

Refer to the screenshots below:



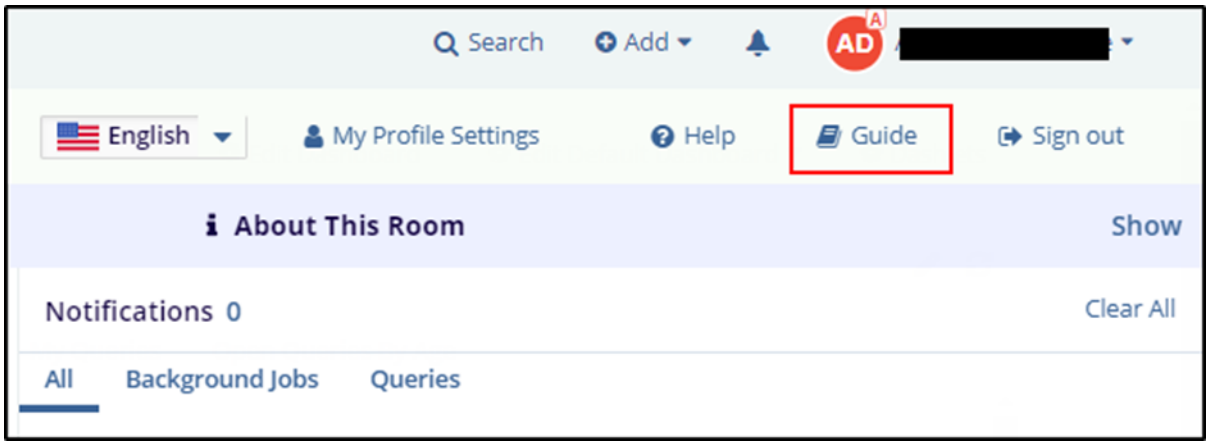


This section displays the following tabs:

- **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.**
- **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.**
- **Background Jobs: Through this tab, you are notified about a background job that is executing or is completed.**
    - **Some messages like downloading/mass coding documents provide the Get Job Result button that you click to get further details on the action like a message or a downloadable file.**

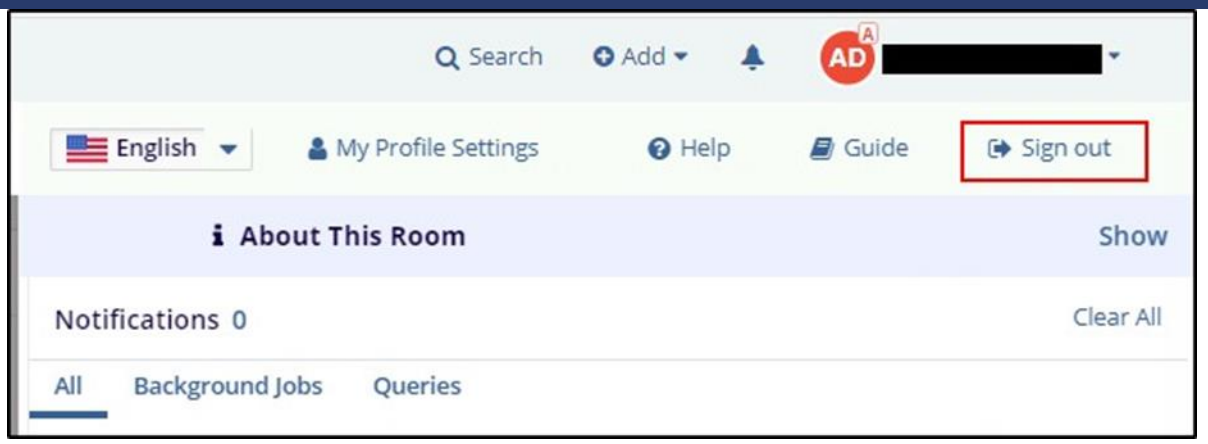
User Guide

This link opens the Online User Guide containing the full contents of this document in addition to job aids and videos designed to help you perform many of the most common tasks in Trial Interactive.



Sign Out

Click 'Sign out' to end your current session. Refer to the screenshot below:

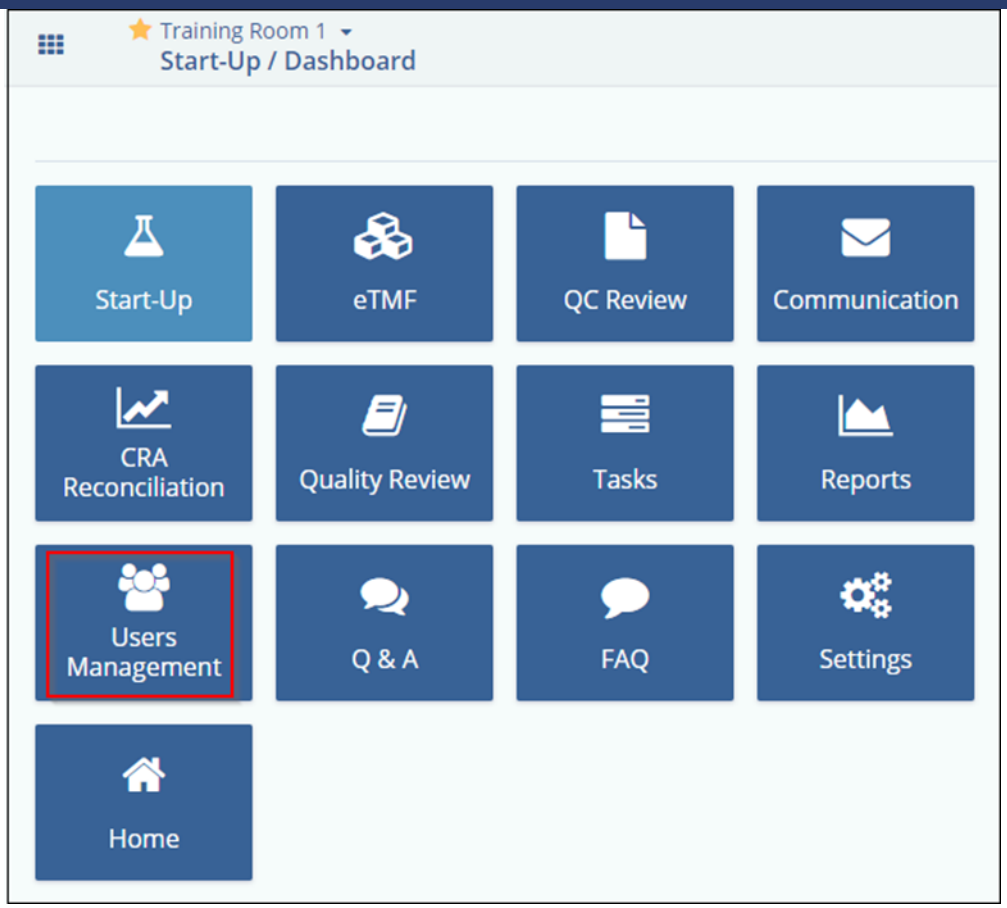


Chapter 5. User Management

Room Administrators can manage Groups, Users, and Contacts through the Users Management module. Administrators can do the following from within this application:

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

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



Users Management - Users

From this page, you can do the following:

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

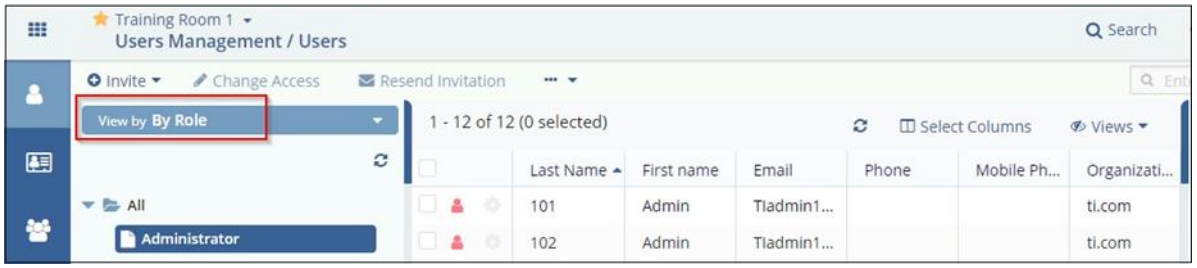
Viewing Users

Users in Trial Interactive are grouped under various categories for easy viewing and access to their information.

Follow the steps as below to choose from the filtering options available:

1. **Click the 'View by' dropdown menu in the left panel.**
2. **This opens the menu with the list of categories available.**

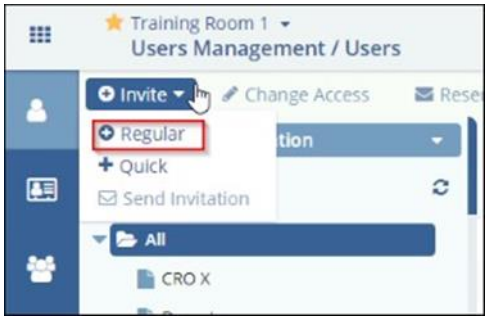
3. **Select the category you want to use while viewing the room's users.**
4. **Click Select located at the bottom of the popup window. You can also make the view your default by selecting the Make Default checkbox below the list of views.**
5. **The category and the list of users grouped under the categories are displayed in the Index Pane. The screenshot below shows the rooms administrator level users with a 'By Role" view applied.**



Inviting New Users via the Regular Invitation

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

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



3. **The User Invitation window will open.**
4. **Complete the required fields on the form.**
5. **If you would like to assign the user to a group upon initial account creation, select the Groups tab at the top of the window and select any appropriate groups.**
6. **When you are done, click Save.**
7. **The user will be created and can be viewed in the list of users.**

USER PROFILE FIELDS

The fields of importance are discussed below:

- **User Email: This is used as a unique identifier to log in to Trial Interactive. This can be typed in or, the case of**

users who are already in the system, 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.**

- **Role:** Choose the role from the dropdown.
- **Actions:** These are tasks that the user would be allowed to perform in addition to the basic rights associated with their user access role.
- **Expiration Date:** Enter this date if you want the user's access to be revoked on a certain date.
- **Organization:** Choose from the dropdown the organization to which the user belongs. The Administrator can also create an organization, if not available from the list, by clicking the '+' sign at the end of the textbox.
- **Invite Later:** Click the toggle bar if you want to create a user for the room but you do not want to send the invitation yet.
- **Regulatory Agency Inspector:** Users who are invited as Regulatory Agency Inspectors will have reduced access to the multiplicity of dashboards and modules that regular TI users need to be trained on prior to granting system access. These users will only have access to the Quality Review module and the FAQ module and will, therefore, require significantly less initial training than a standard room user.

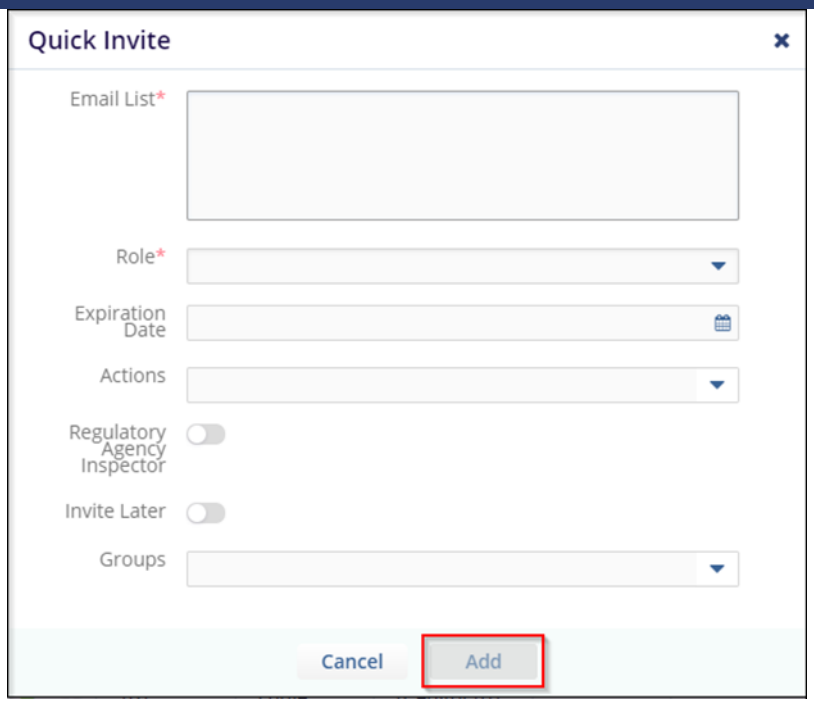
Inviting New Users via the Quick Invitation

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 groups.

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

1. **From Users Management → Users, click the Invite dropdown from the top menu bar and then select Quick from the list of options that appear.**
2. **The Quick Invite page opens.**
3. **Enter the email addresses of all the users to be created.**
4. **Complete the required fields, adding email addresses for each user, and selecting the role they will all have in common.**
5. **Select Invite Later if appropriate.**
6. **Click the Groups textbox to assign the users to any appropriate groups.**
7. **Click Add.**

Refer to the screenshot below:



Users invited via this method will need to fill in information which was not provided during the quick invitation process such as name and organization. As a note, this frequently results in some variation regarding the information entered which the room administrator should review and standardize.

Editing a User's Profile

A user's access can be adjusted at any time from the User's Management module. There are several ways to do so.

- **Double-click on the user in the list of users displayed.**
  - **This will open the user's profile in a new window.**
- **Select the user from the list of users displayed and use the right-panel.**
  - **You may need to open the panel at the right side of the screen if it does not open automatically.**
- **Use the three dots on the user's grid entry to open the menu of actions associated with user accounts.**
- **Select the user from the list of users displayed and click the three-dot menu above the grid to expand the list of menu items.**
  - **Once the menu opens, select "Edit"**
- **Select the user from the list of users displayed and click "Change Access" from the menu ribbon above the grid.**
  - **This does not open the user profile but does provide opportunity to adjust the user's general access privileges and can be used to edit multiple users at once.**

Make whatever changes are required and press "Save" in order to finalize them.

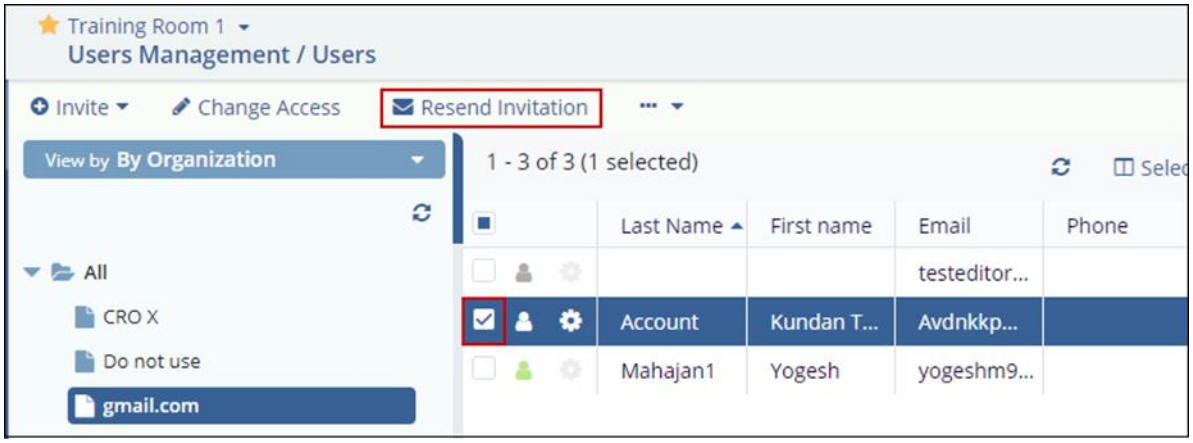
Resending an Invitation

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

To resend an invitation:

1. **From the left pane, select the preferred category to view the users.**
2. **From the list of users displayed in the right pane under the selected category, tick the checkbox for users to whom you want to resend the invitations.**
3. **From the top ribbon bar, click the Resend Invitation icon. A popup window will appear asking you to confirm.**
4. **Click Yes.**
5. **The invitations will be resent to the selected users and a confirmation notification will appear.**

Refer to the screenshots below:



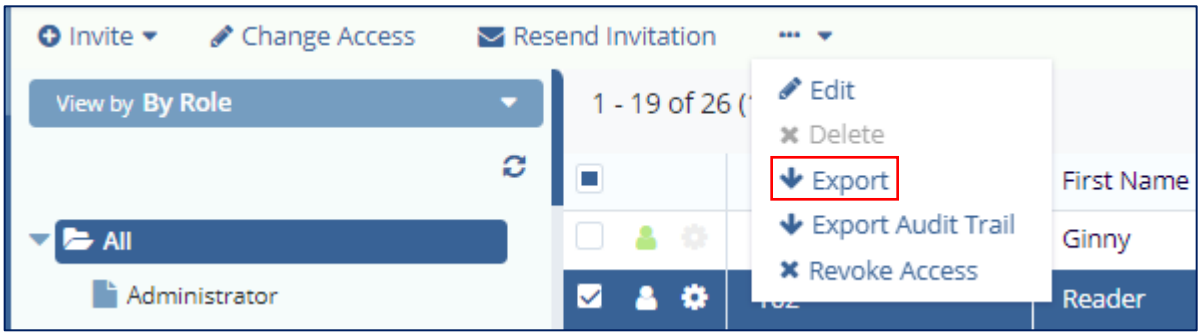
Exporting User Information

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

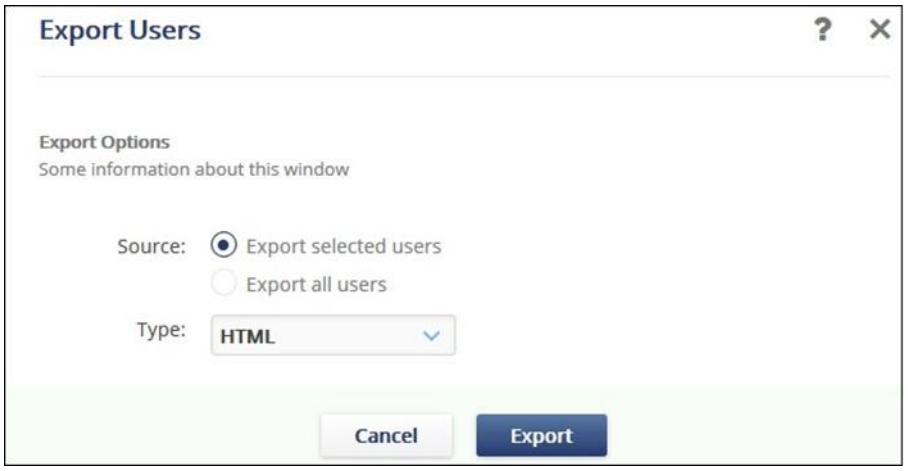
EXPORTING SELECTED USER PROFILE INFORMATION

1. **Navigate to User Management → Users.**

2. **Locate the users whose information you wish to export.**
3. **Tick the checkboxes of the users.**
4. **From the top ribbon bar, click the three dots and then click Export from the options that appear. Refer to the screenshot below:**



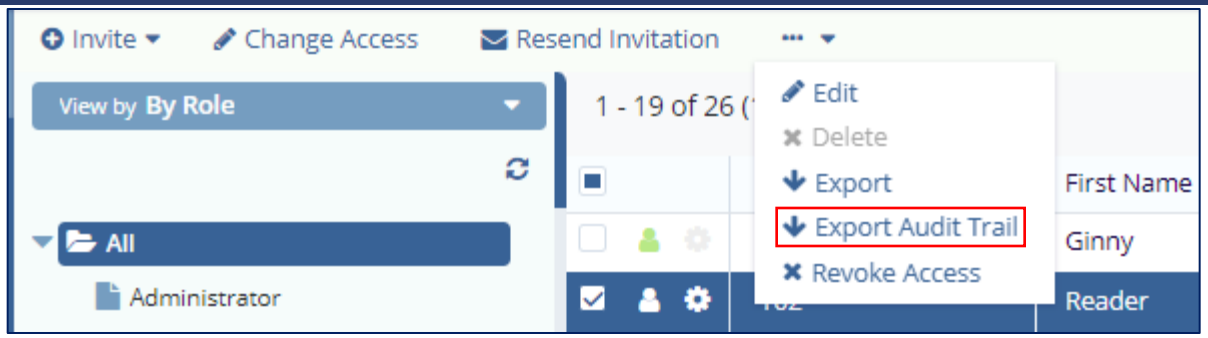
5. **The Export Users popup opens with the Export Selected Users radio button highlighted.**
6. **Select the Type of export file format. You can select either HTML or Microsoft Excel.**
7. **Click Export. Refer to the screenshot below:**



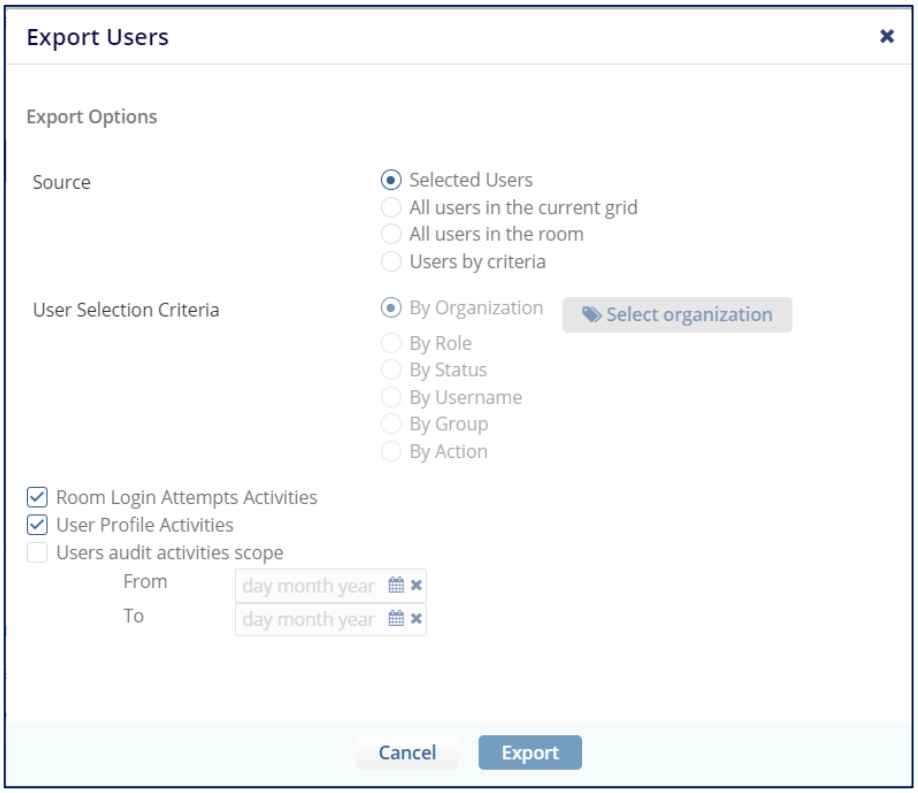
8. **You will receive a notification about the job completion.**
9. **Click Get Job Result to download the document.**

EXPORTING USER AUDIT TRAIL DATA

1. **Navigate to User Management → Users.**
2. **Locate the users whose information you wish to export.**
3. **Tick the checkboxes of the users.**
4. **From the top ribbon bar, click the three dots and then click Export Audit Trail from the options that appear. Refer to the screenshot below:**



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



User Management - Contacts

VIEWING CONTACTS

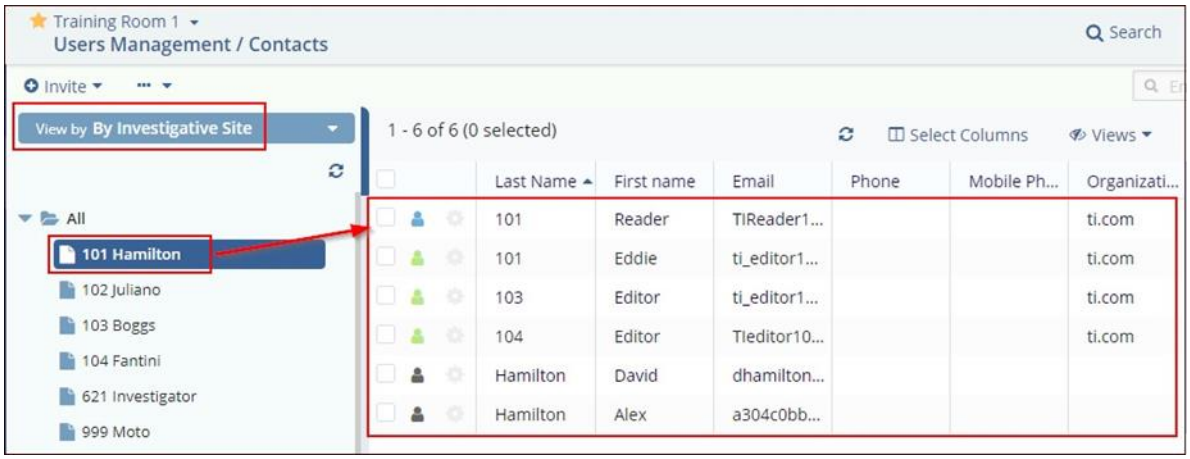
This section allows you to view contacts that are available in the Investigative Sites.

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

1. **From Users Management, click the Contacts icon from the left menu.**
2. **Using the View By dropdown menu to view the list of categories.**

3. **Select the category under which you want to view the contacts.**
4. **Click Select located at the bottom of the popup window.**
5. **This will display the requested list of site contacts.**

See the screenshot below:



User Management - Groups

Administrators can manage the creation, deletion, and assigning of users to Groups. Administrators can manage the following:

- **The names of groups**
- **The descriptions of groups**
- **The security rights of a group**
- **The actions awarded to group members**

Groups are used in granting users access to particular folders, files, and actions.

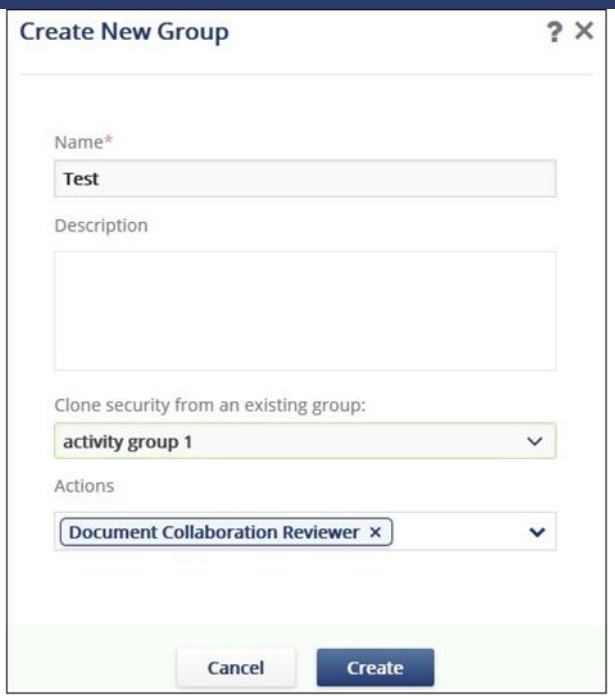
From the Groups area, room administrators can do the following:

- **Adding a new group**
- **Adding a child group**
- **Editing a group**
- **Deleting a group**

ADDING A NEW GROUP

New Groups can be added by clicking the Add Group button.

1. **To add a new group, click the Add Group button from the left pane.**
2. **The Create new group window opens. Refer to the screenshot below:**



3. **Enter the new group's name.**
4. **Add the description of the new group.**

<u>Note:</u> 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. **Assign Actions that members of the group can perform by selecting from the list of actions in the dropdown menu.**
6. **Click Create. The new group appears in the Groups list with no users assigned to it.**

ADDING A CHILD GROUP

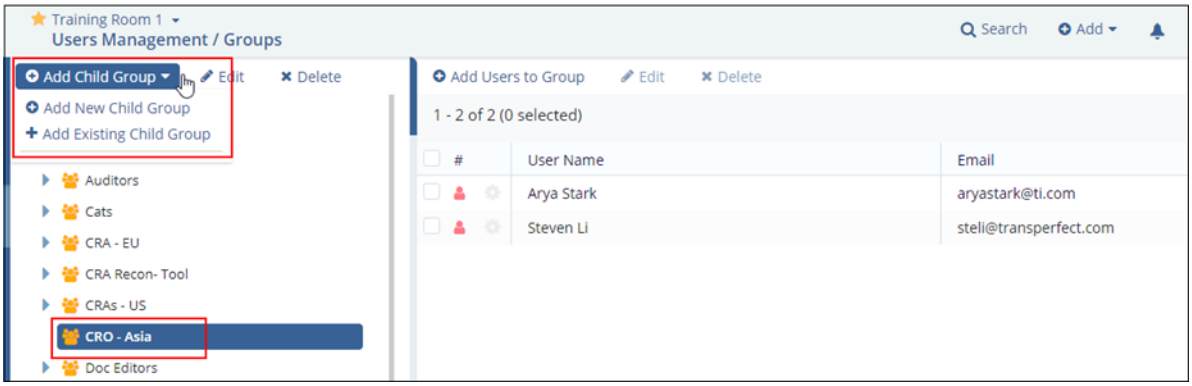
You can reach this page by clicking the Groups icon from the menu bar on the extreme left of the Users Management module.

Follow the steps as below to create child groups:

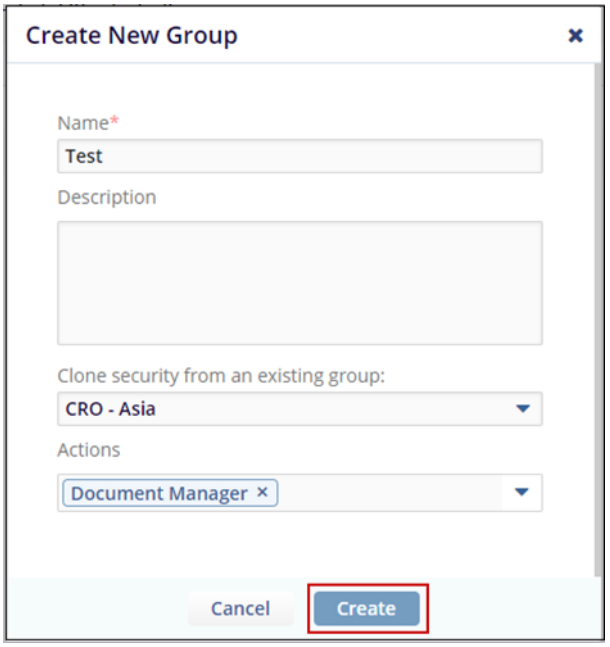
1. **Click the arrow to the left of All Groups to expand groups and select the parent group from the list to which you want to add child group.**
2. **Note that the Add Group button at the top left corner now changes to Add Child Group and the buttons Edit and Delete are also enabled. Refer to the screenshot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

3. **Click Add Child Group from the top menu. There are two options for group addition:**
   a. **Add New Child Group**
   b. **Add Existing Child Group.**

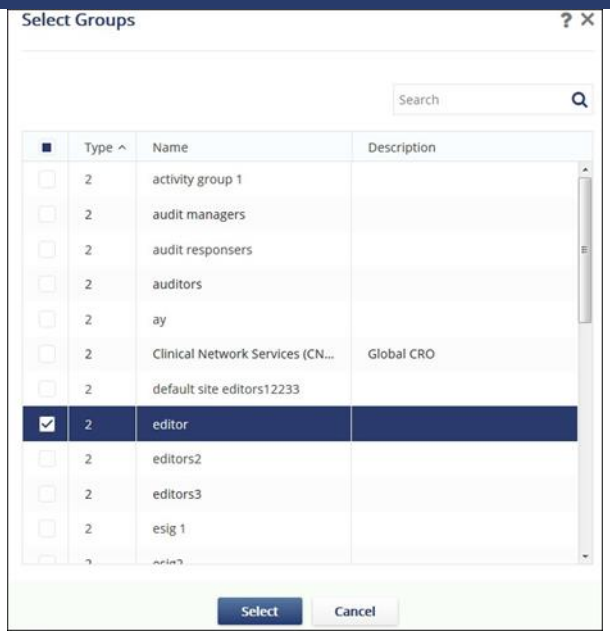
   See the screenshot below:



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



5. **If the option 'Add Existing Child Group' is selected, then the Select Groups popup opens.**
6. **Select the correct group from the list to assign that group as a child group.**
7. **Click Select. Refer to the screenshot below:**



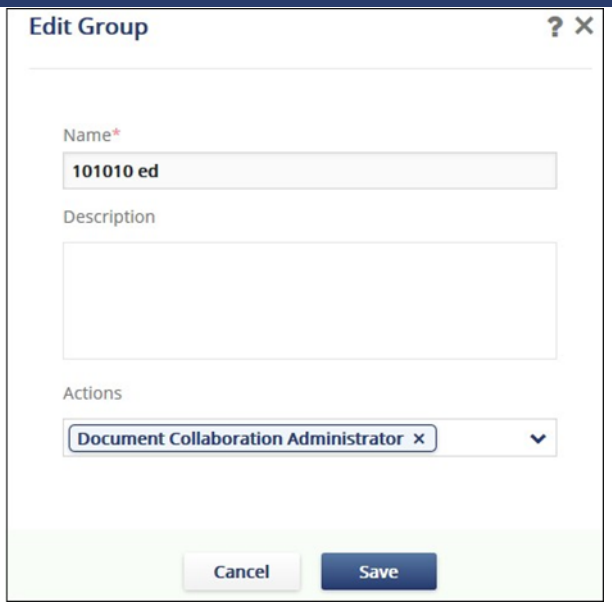
EDITING A GROUP

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

Follow the steps below to edit a 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:

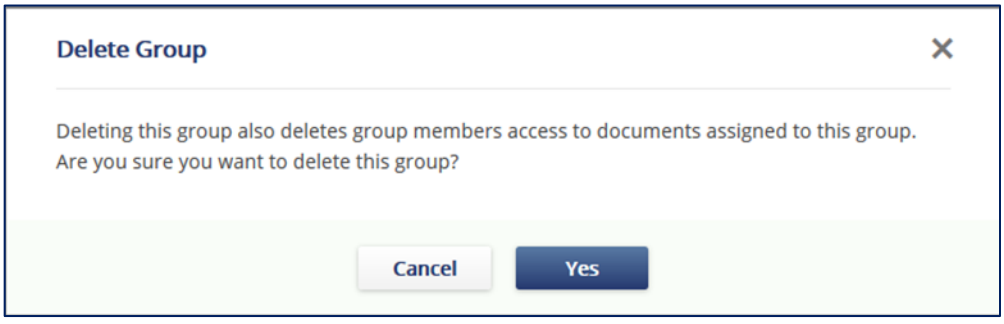


DELETING A GROUP

Groups can be deleted from the list. Deletion of a group does not delete its users, only the group members' access to group privileges is deleted. A Confirmation box will warn you about making a change to the group security settings.

Follow the steps below to delete a group:

1. **Select the required group from the left pane you wish to delete.**
2. **Click 'Delete' from the top menu.**
3. **A confirmation window will open.**
4. **Click 'Yes' to confirm.**

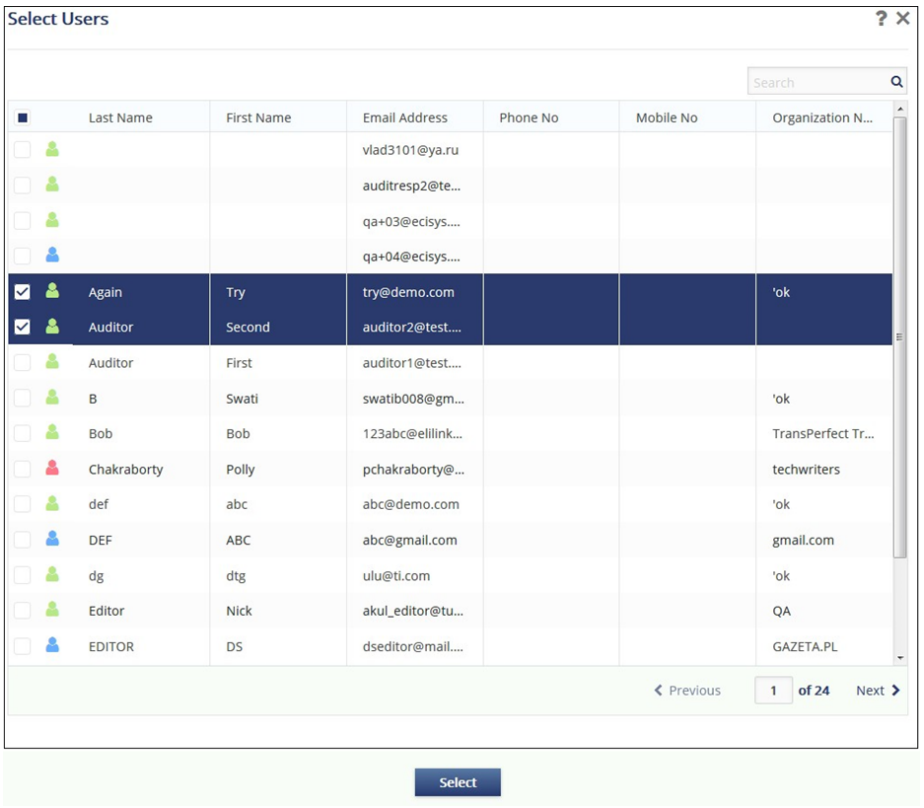


ADDING USERS TO A GROUP

Follow the steps below to add users to a group:

1. **Navigate to Users Management → Groups.**
2. **Select the required group from the Index pane. The list of users appears in the right pane.**
3. **Click 'Add User to Group' from the top menu in the right pane to add the user to the group.**
4. **The Select Users window opens up.**
5. **Select the users you wish to add to a group and click 'Select.' The users will be added to the group.**

Refer to the screenshot below:

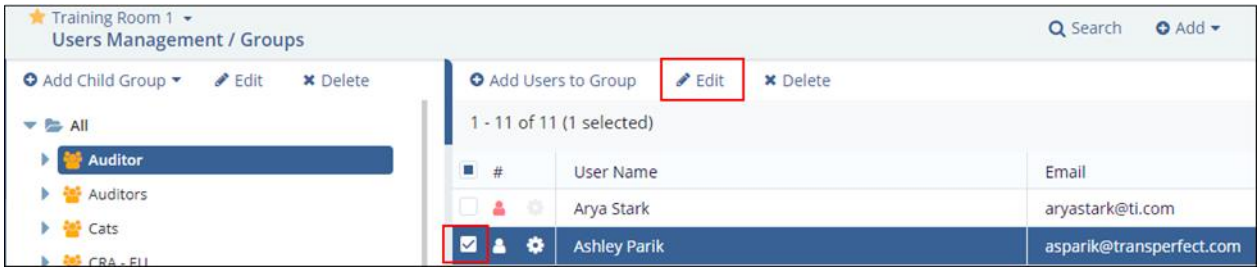


EDITING AND DELETING USERS FROM A GROUP

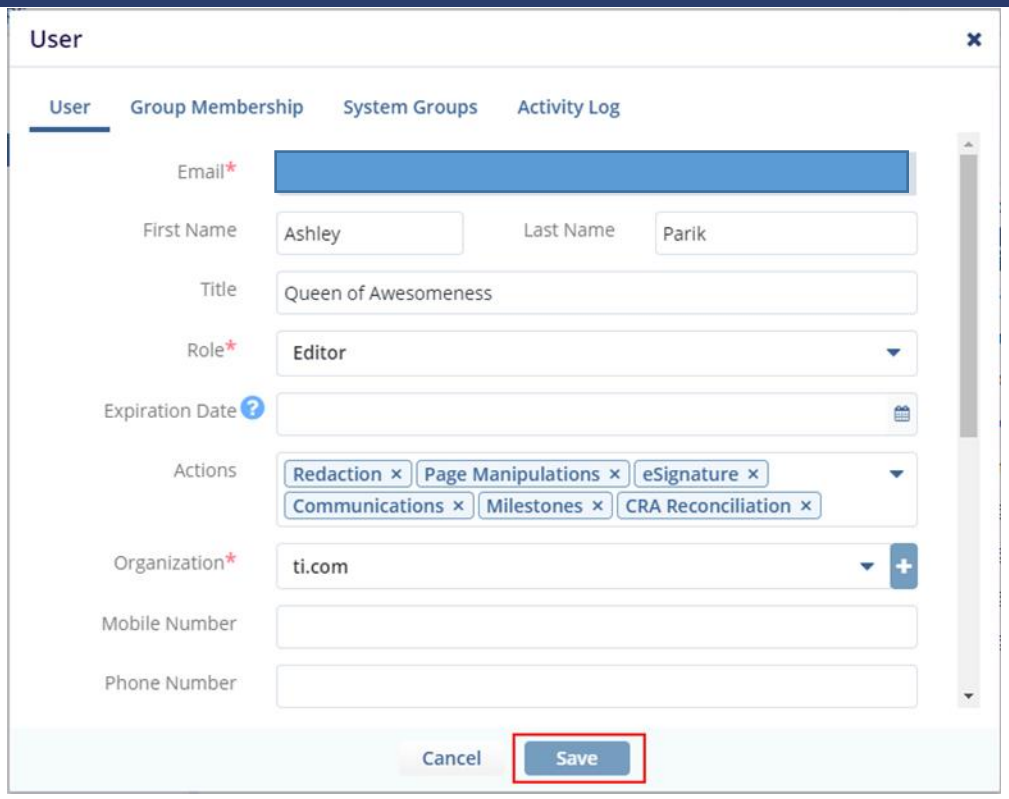
Editing User in a Group

Users in a group can be edited by selecting the user from the list of group members and clicking Edit from the top menu.

Follow the on-screen instructions to edit the user details. Refer to the screenshot below:

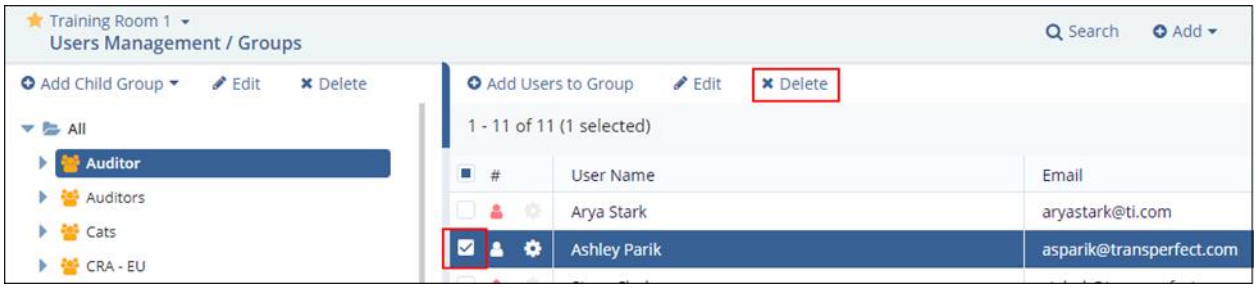


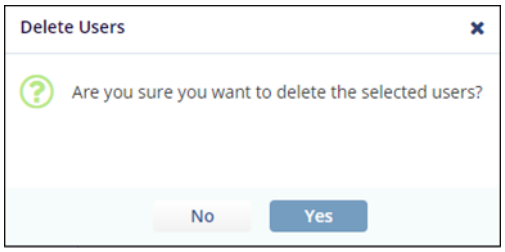
The pop-up screen below appears upon clicking on the Edit button shown in the above image.



DELETING USER FROM A GROUP

Select the user from the group and click Delete from the top menu to delete them from the group. Click 'Yes' on the confirmation window that opens if you wish to delete the user. Refer below screenshots:





ADDING A USER TO THE GENERAL QUERY RESPONDERS GROUP

There is a system generated group called General Query Responders available in the Groups area of the Users

Management module. Administrator level users will be able to add any Editor or Administrator level user to this group. Readers are not eligible for inclusion in this group. Members of this group will be responsible for responding to general queries created by other room users.

Please see the section on adding users to groups for step-by-step instructions.

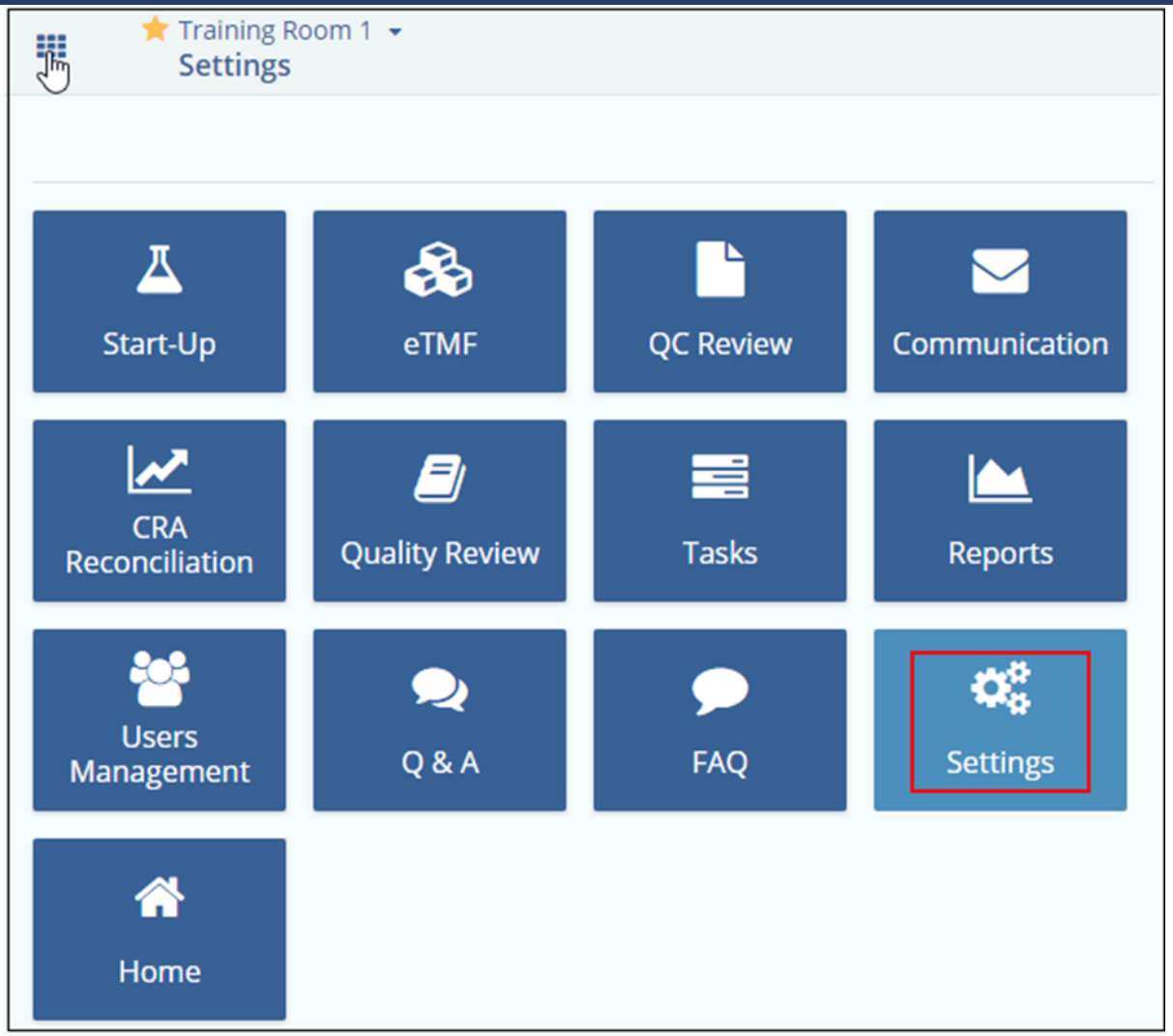
THE QUERY MANAGER GROUP

There is a system generated group called Query Manager. Users added to this group will be able to view and manage all QC Workflow related queries via the Query by Sender and Query by Recipient views in the Documents module or the Queries module. Only Editor and Administrator level users can be added to this group.

Please see the section on adding users to groups for step-by-step instructions.

Chapter 6. Room Settings

Access the Room Settings from the Navigation Grid by clicking the Settings tile. Refer to the screenshot below:

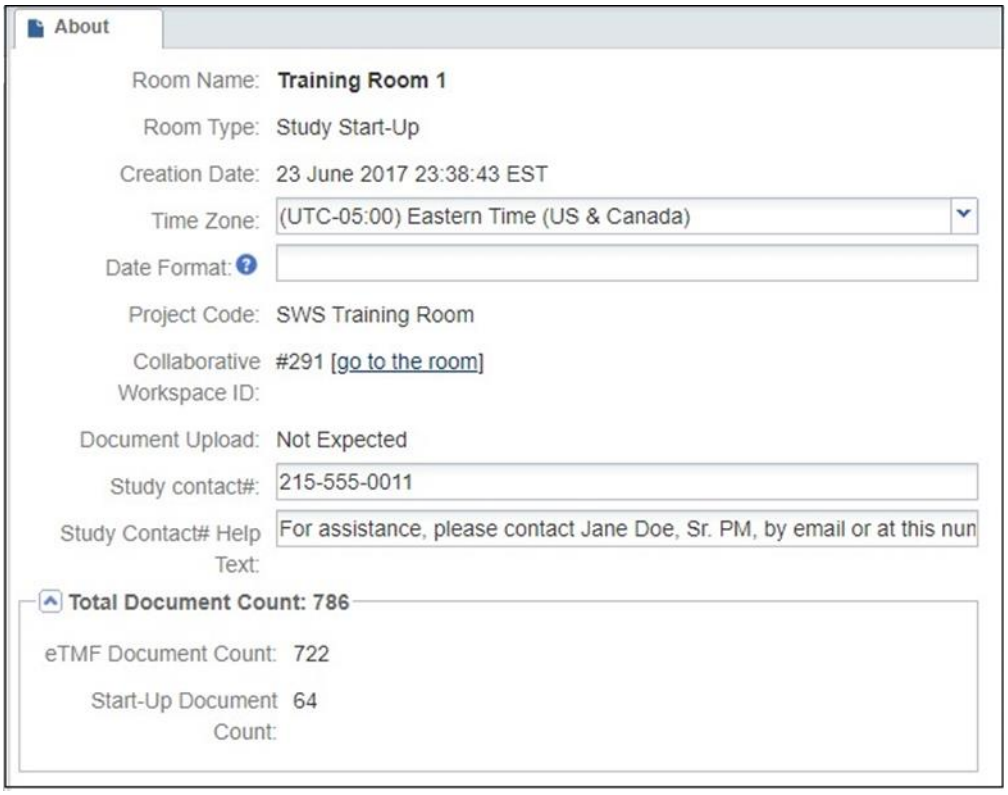


- **Room administrators can access the menus from the left pane of the Room Settings page.**
- **By default, when Administrator users click on Settings, it only displays the first item of the General Settings menu, which is the 'About' page of the study room.**
- **Most room setting menus in the left panel are divided into sub-menus, allowing specific modifications for each defined category.**
- **To view and modify a specific sub-menu in settings, click the arrow to expand the main menu.**
- **When each sub-menu is clicked, it appears as a separate tab on the right side of the screen. If users click multiple sub-sections, separate tabs will be created for each item clicked.**
- **Right-clicking a tab will also provide an option to Close All Tabs and Close Other Tabs. A**
- **For assistance in finding a specific setting, there is a search box at the top of the left panel.**
- **Administrator users can view and change most of the room settings in Trial Interactive.**
- **Typically, the room's settings will be decided upon during room configuration, and the settings will remain mostly unchanged for the duration of the study.**
- **As a general rule, for most menus, there will be a Save button which will need to be pressed in order to retain any changes that were made to the room settings.**

Refer to the screenshot below:

General Settings

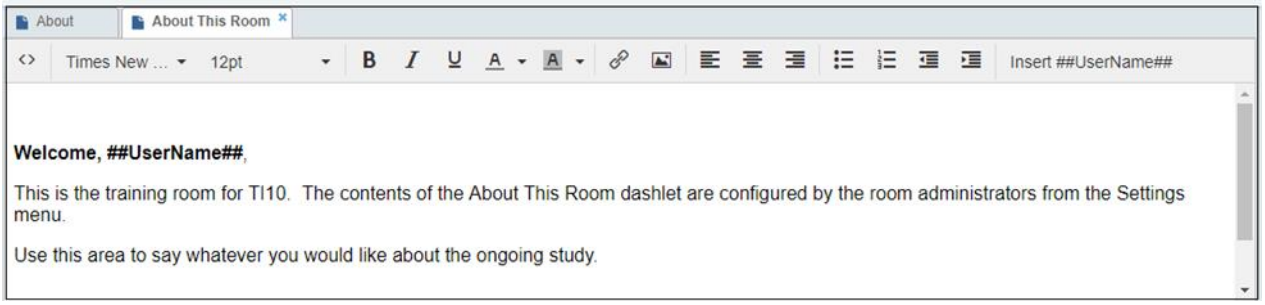
ABOUT



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. You can click on the expand icon to view details. Be sure to save any changes you

wish to keep.

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 first access the room. This space can also be used to share important information about the study once the study is in full swing. 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 can be filled out by administrator-level users. By doing so, this portlet will give 'instructions' to users on their first entry to the room.

ORGANIZATIONS LIST

This menu allows the room administrator to add, edit (rename), or delete organizations. This normally becomes useful when a large number of room users have been invited via the Quick Invitation method because it allows users to specify their own organization. Normally, in instances like this, there are several variations created by the users via acronyms, abbreviations, and misspellings.

Organizations which currently have users assigned to them cannot be deleted. In order to delete an organization, you may have to go to Users Management and reassign any users to another organization before proceeding.

DATA GRID NAVIGATION

The options in this menu vary based on room configuration but can be used as follows:

- **Minimum number of records per page in data grid: This option actually sets the maximum number of records displayed per page in the data grid.**

- **Minimum number of documents in the unread documents grid: This impact the Documents dashlet on the dashboard and shows the maximum number of documents displayed in the unread documents view.**
- **Days to show last registered users: This option also impacts a dashlet. The Users dashlet has a toggle indicating whether it should display 'New' users or 'All' users. This field defines how many days a user appears on the 'New' list.**
- **Start-Up dashboard recent investigative sites number: This indicates how many sites should be displayed on this dashlet.**
- **Start-Up dashboard recent communication log items number: This indicates how many communications should be shown on the related dashlet.**
- **Start-Up dashboard recent tasks number: This indicates how many tasks should be displayed on the related dashlet.**

MACHINE TRANSLATION

This menu allows the user to enable or disable the Machine Translation function and to indicate which languages should be both available and expected as default languages for this function.

Please note: The Machine Translation function only works with .pdf documents which have had OCR (Optical Character Recognition) applied.

Event Manager Settings

EVENT TYPES

This functions as a secondary location for managing event types in a study room. In most cases, the room will come with an approved selection of event types already populated. For additional information on managing event types, please see the related section of the User Guide.

COMMON EVENT CONFIGURATION

From here, the room administrator can indicate how often the room should send reminder notifications for placeholders generated by events. These notifications will be delivered to the members of the Responsible Department associated with the document types of the missing documents.

If Responsible Departments are not set up in your study room, you may use the "Default event reminder recipients" to indicate users who should be notified for all missing event-related documents regardless of department affiliation.

TransPort Integration

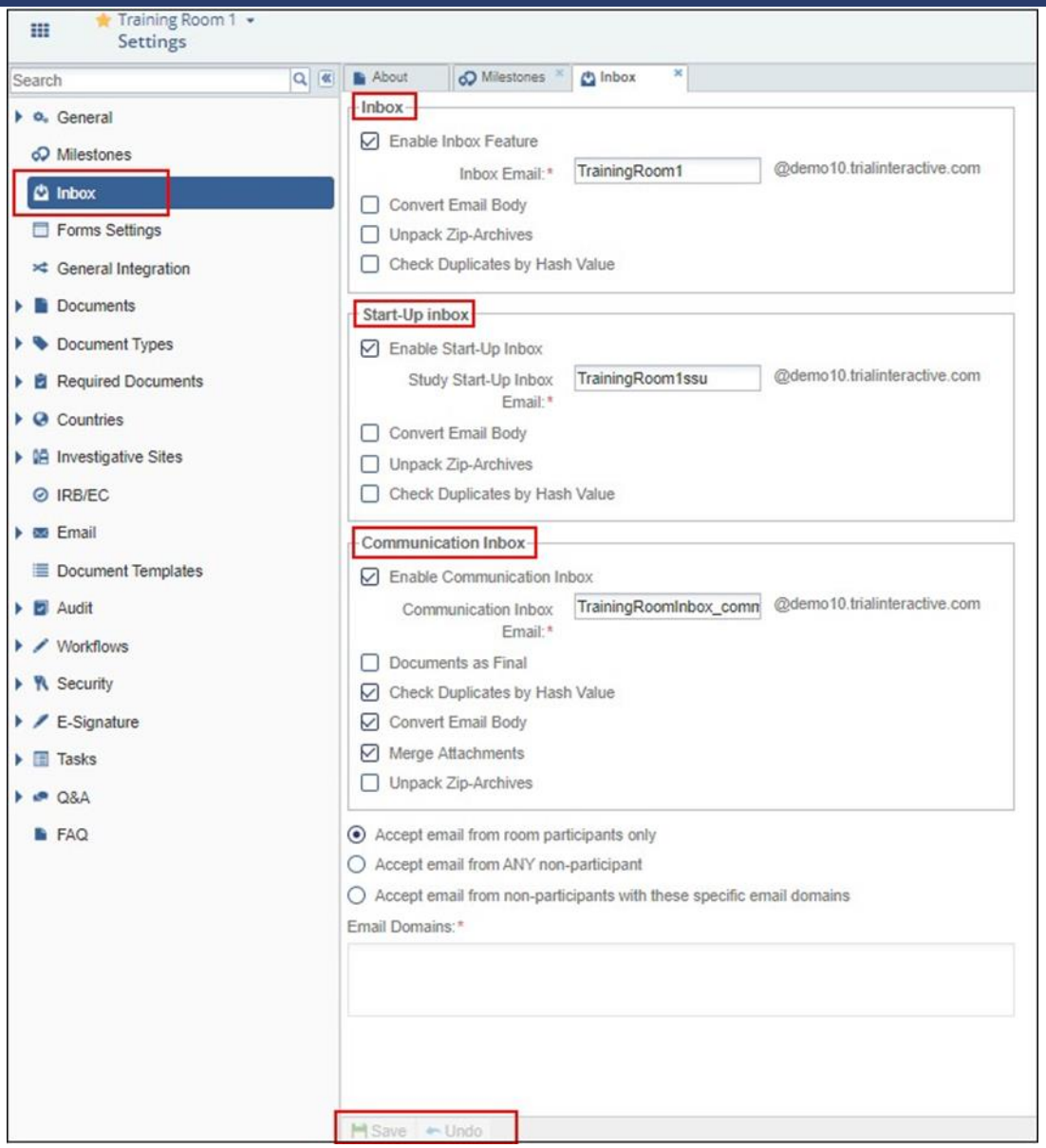
This is normally set up upon room configuration but the room administrator retains the ability to enable or disable this functionality from here. The Organization, Department, and Certificate Document Type must be indicated here before this feature can be enabled successfully.

Inbox Settings

From this page, room administrators can enable the Inbox feature.

- **Navigate to Navigation Grid->Settings->Inbox.**

Refer to the screenshot below:



INBOX AND START-UP INBOX OPTIONS

- **Room administrators can enable the Inbox by ticking the checkbox to make it possible for room participants to send trial documents directly to the room's inbox.**
- **Ticking the checkbox of 'Convert Email Body' option will automatically convert the emails that enter the Inbox into PDFs.**
- **Choose 'Unpack Zip-Archives' to extract files from an attached zip folder.**
- **The 'Enable Inbox Auto Coding' option allows users to send emails into the room with subject lines formatted along certain guidelines so that the document is received with certain metadata already applied to it.**
    a. **Hover over the blue circle "Tool Tip" to see specific requirements.**
- **To prevent duplicate publishing of email converted documents to the room, activate the 'Check for and**

Suppress Duplicates by Hash Value' option.

COMMUNICATION INBOX OPTIONS

- **Room administrators can enable the Inbox by ticking the checkbox to make it possible for room participants to send trial documents directly to the room's inbox.**
- **Ticking the checkbox of 'Convert Email Body' option will automatically convert the emails that enter the Inbox into PDFs.**
- **Choose 'Unpack Zip-Archives' to extract files from an attached zip folder.**
- **The 'Enable Inbox Auto Coding' option allows users to send emails into the room with subject lines formatted along certain guidelines so that the document is received with certain metadata already applied to it.**
    a. **Hover over the blue circle "Tool Tip" to see specific requirements.**
- **To prevent duplicate publishing of email converted documents to the room, activate the 'Check for and Suppress Duplicates by Hash Value' option.**
- **The user can choose to have relevant communications published from the Communication Inbox directly to the eTMF Index as final documents.**

EMAIL SENDER OPTIONS

Besides the above options, you can also enable the following options for the Inbox:

- **Accept email from room participants only: This option, when enabled, indicates that emails from non-room-users will not be accepted.**
- **Accept email from ANY non-participant: This option, when enabled, indicates that al emails will be accepted regardless of who sent them.**
- **Accept email from non-participants with these specific email domains: This option, when enabled, allows the room administrator to define which email domains can successfully send emails to the study room.**

Outbox Settings

This menu only allows the user to enable or disable to room 'Outbox' feature. This feature keeps a running log of all emails sent from the room. One example of an email that would be indicated here is query notifications. The Outbox can be accessed from the room Communications Module.

Documents Distribution Settings

Users can be allowed to share documents from one room to another. This function will create a copy of the document in

a target room which is still functionally linked to the source document. This is most commonly utilized when publishing documents from a TI Content Management room. Any versioning of the shared document would be shown in the target room once the new version became effective in the source room.

Users must be granted permission via the associated Action on their user profile before they can use the Documents Distribution function.

COMMON CONFIGURATION

This allows the user to enable or disable the Documents Distribution function as well as to indicate whether shared documents will be published to the target room as final documents or whether they will need to be subjected to the room's QC workflow prior to becoming finalized.

Forms Settings

This menu controls metadata and other form settings throughout the study room. Studies sometimes require custom settings to form fields that appear throughout a study room, such as document metadata fields, question and answer forms, and audit related fields. We recommend partnering with the Trial Interactive Service Desk before making any changes to these settings.

- **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, Document Types settings, and 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:**

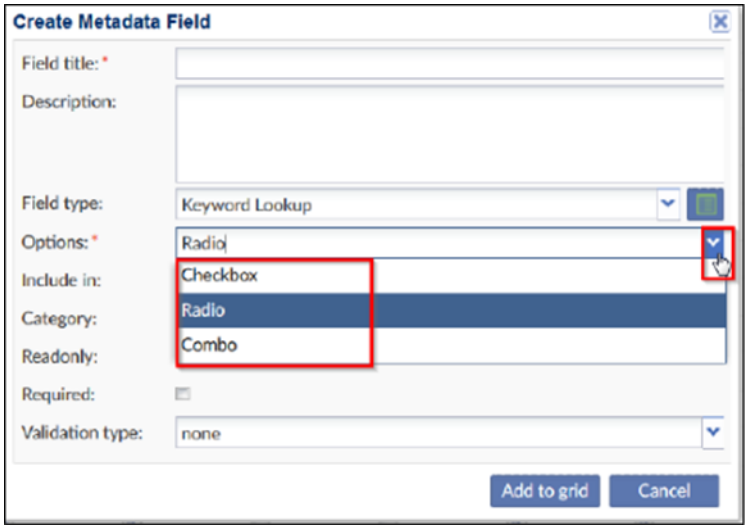
Though the individual fields and field options differ from form to form, the operations to add, to delete, and to edit these settings are consistent across the array of forms. From here you can perform the following settings functions:

- **Adding a Custom Field**
- **Editing a Metadata Field**
- **Deleting a Field**

- **Setting Advanced Validation Fields**

ADDING A CUSTOM FIELD

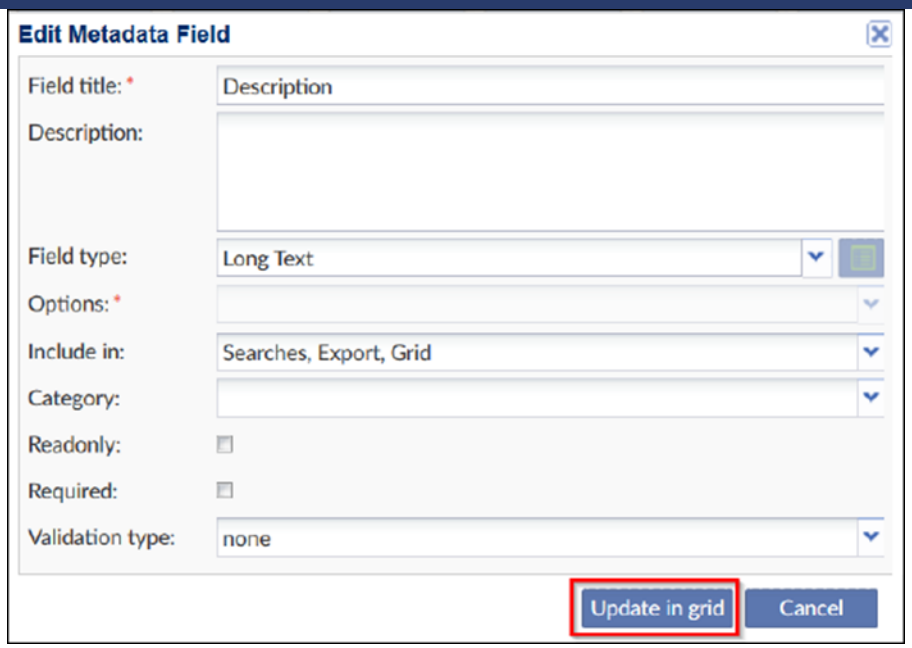
1. **Click Add from the menu bar.**
2. **The Create Metadata Field window opens. Refer to the screenshot below:**



3. **Select the most appropriate option:**
    a. **Checkbox – the values entered display as a list and users can choose one or more**
    b. **Radio – user must choose only one value from the list**
    c. **Combo – users can choose only one value from a dropdown list**
4. **Click the 'Include in' dropdown arrow and select the appropriate option.**
    a. **The options in this menu correspond to the options on the Forms Settings grid.**
5. **Select the Document Type Category or categories in which this new custom field will appear.**
    a. **Click the Read-only checkbox if required.**
    b. **Click the Required checkbox if necessary.**
6. **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.**
7. **Click 'Add to Grid'. The view returns to the full Document Profile Form display.**
8. **Press 'Save' if you wish to keep the new field.**

EDITING A METADATA FIELD

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



2. **Make any required changes in the available fields.**
3. **Click 'Update in grid' at the bottom of the window.**
4. **Press 'Save' to keep any changes.**

DELETING A FIELD

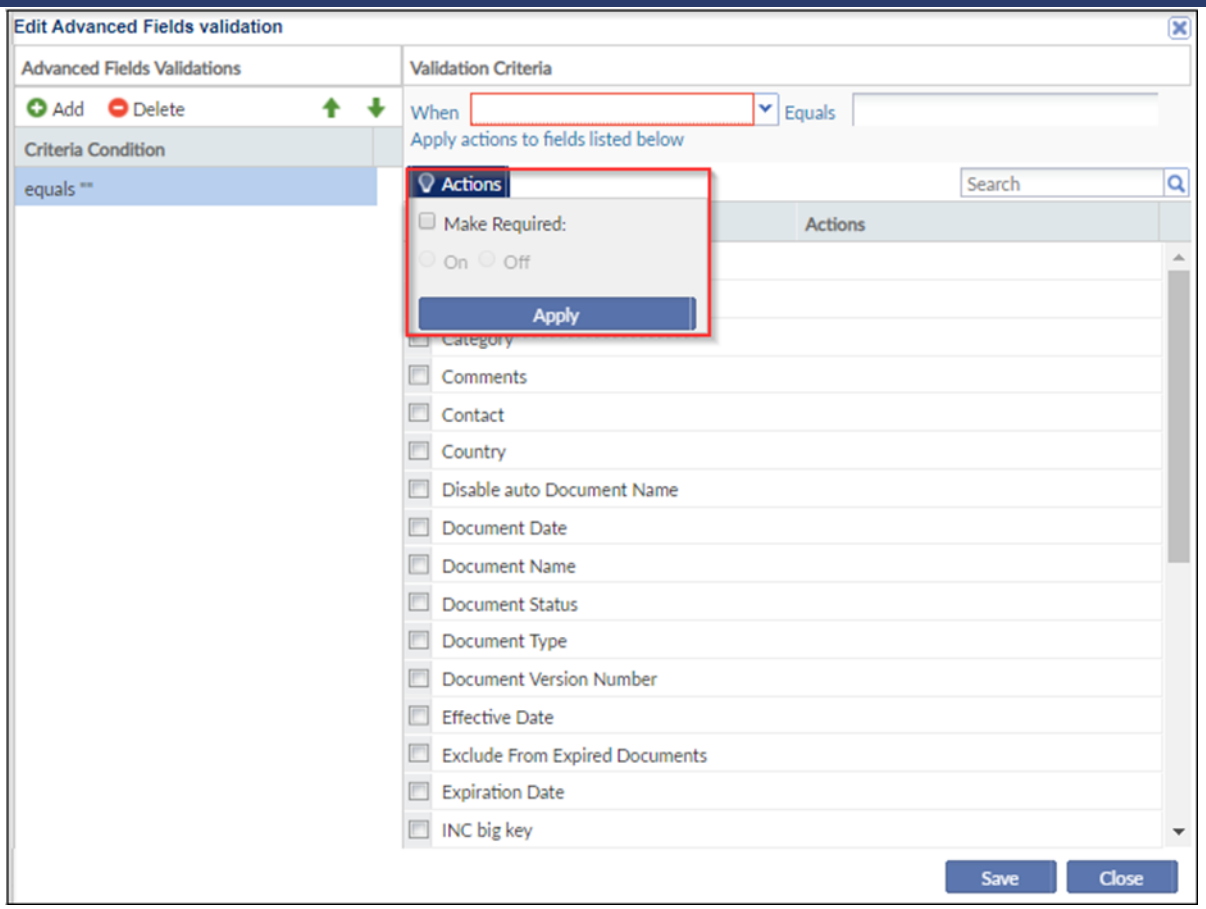
1. **Select the field to be deleted. The row highlights in light blue.**
2. **Click the 'Delete' from the menu ribbon.**
3. **Press 'Save' to keep any changes or use the 'Undo' button if you want to undo the changes.**

Note: The 'Undo' button only works until you press the 'Save' button.

SETTING ADVANCED VALIDATION FIELDS

This advanced function links two or more metadata fields based on specified validation criteria is not generally used by Administrators. We recommend partnering with the Trial Interactive Service Desk before making any changes to these settings.

1. **Click Advanced Validation in the menu 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.**
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 a calendar 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.**

TYPE-AHEAD FIELDS

When faced with a text metadata field, it can be difficult, especially for those new to a team, to decide exactly what should be entered into the field or perhaps the spelling of a particular word might be especially difficult. Trial Interactive has the ability for a metadata field to learn values entered into it and to suggest those words when a user fills in the field for another document.

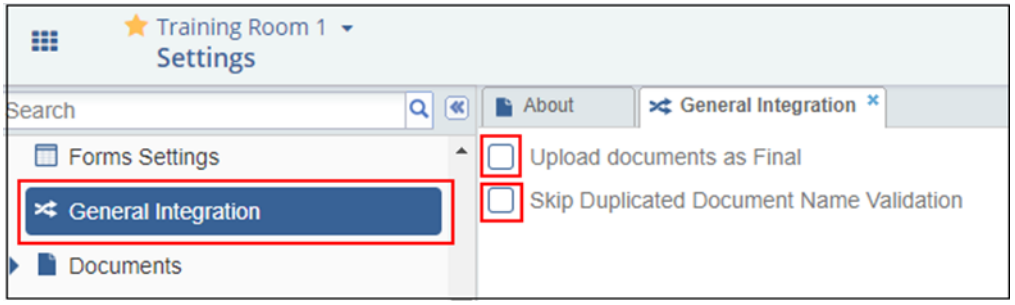
The 'Suggestions' column controls this feature. Once the box is checked, the field will begin learning and suggesting values for future entry.

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.**
    a. **Documents, upon being uploaded, would then move directly to the related folder assigned to their document types and acquire the status as final. Refer to the screenshot below:**
3. **Navigate to the Navigation Grid->Settings--> General Integration.**
4. **Tick the checkbox to upload documents as Final**
5. **Tick the checkbox to skip validation of duplicated document name.**



Documents

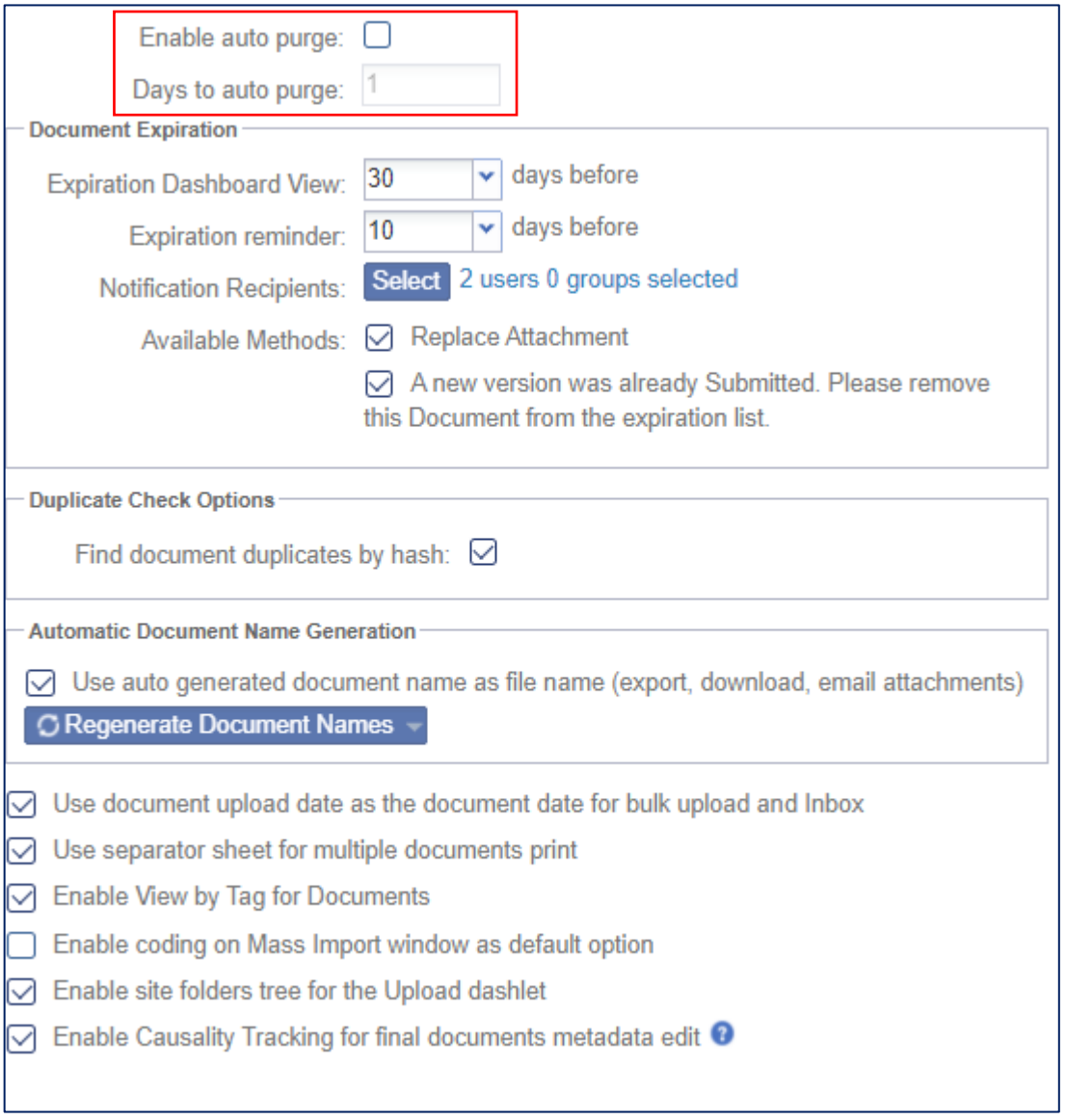
All settings related to documents in a room are made here. You can perform the following document settings from here.

DOCUMENTS MODULE

Auto Purge Settings

Trial Interactive has the ability to purge deleted documents when needed. This can be done manually from the Deleted Documents view in the Documents module or it can be set up as an automatic process. The instructions for setting up the Auto Purge are below.

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

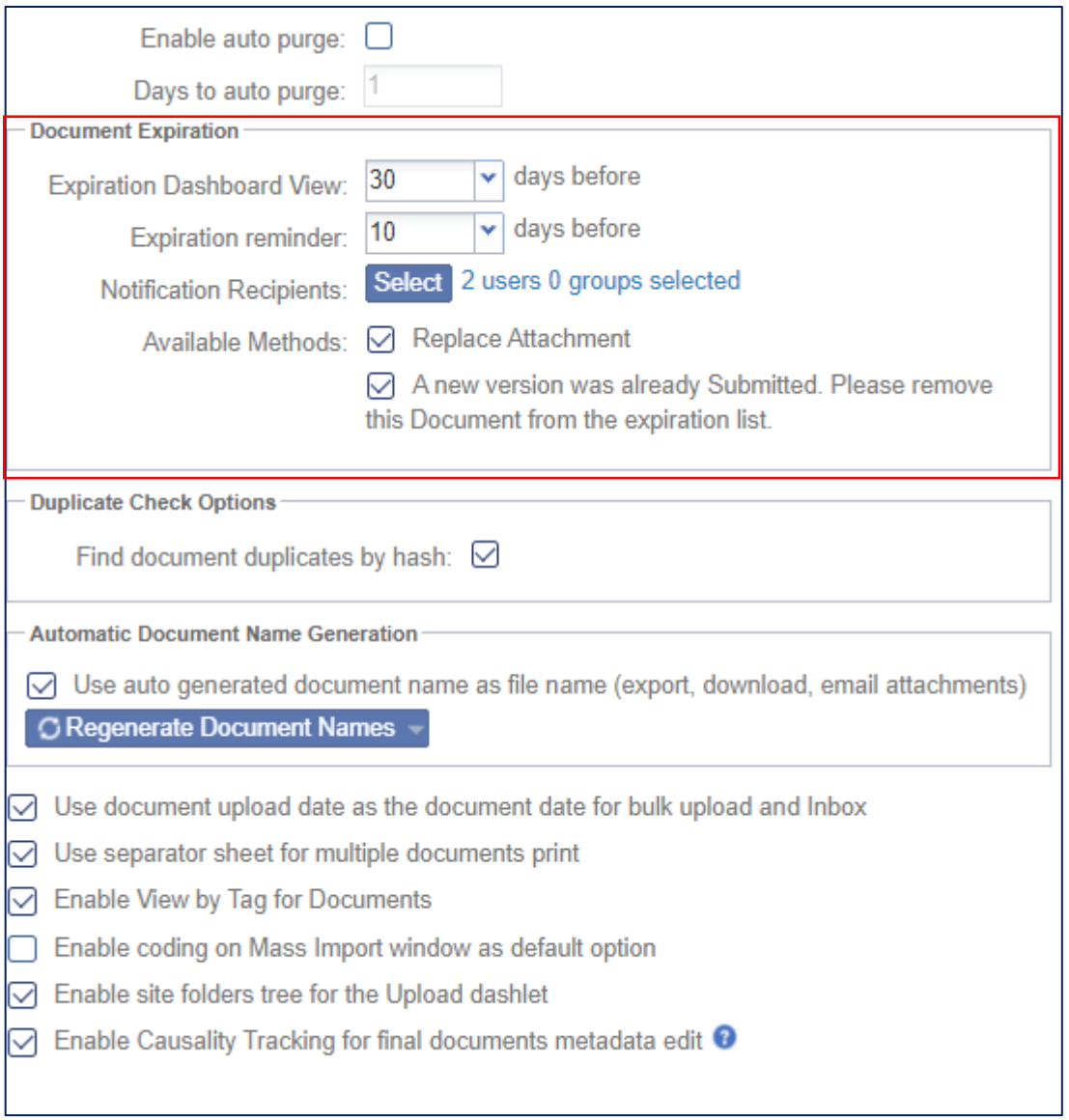


3. **Adjust Days to auto purge by clicking the box and typing the number of days in the box below.**
4. **Click Save.**

Document Expiration Settings

Document types where an expiration date is applied may eventually expire prior to the conclusion of the study. In cases such as this, Trial Interactive has several tools available to users for detection and replacement of expired or expiring documents. The settings for these are discussed here.

1. **Navigate to Navigation Grid -> Settings -> Documents Module**



- **The <u>Expiration dashboard view</u> field controls how much lead time users will have to see and act upon an expiring document prior to its actual expiration date.**
- **The <u>Expiration reminder</u> field controls when reminder emails should be sent regarding documents that will be expiring soon.**
    - **Click Select from the Notification Recipients field to select users/groups who should receive a notification email.**

- **The Available Methods area allows room administrators to choose which options are available to their users in the Expiring Documents dashlet.**
  - **Replace Attachment will allow users to replace the file attached to the existing metadata. All versions of the document will be visible in the 'Versions' tab of the metadata panel.**
  - **The 'A new version was already Submitted. Please remove this Document from the expiration list' option indicates that another version of this document has been submitted to the room as a separate document and that the expiring document should be removed from the list of expired/expiring documents.**

Duplicate Check Options

The methods that the room uses to detect duplicate documents are typically decided upon during room configuration but there is still one option remaining to room administrators which can be altered. Please note that the Service Desk has additional options and should be consulted when seeking to change duplicate detection requirements.

The 'Find document duplicates by hash' option allows the room administrator to enable or disable this particular duplicate check functionality. In short, a document hash is an alphanumeric representation of the qualities of a document.

Duplicate check options are flexible, allowing for the verification of duplicate documents within the staging area and upload folders, an indication of the checksum in the comparison metadata, as well as a more flexible duplicate check that may be triggered in the QC1 stage (instead of Final). Enabling and configuring these options will require the assistance of the Trial Interactive Service Desk.

Automatic Document Name Generation

Room owners can choose to set the auto naming pattern for a document type and generate the document name automatically as per the set pattern. This is typically set up during the room configuration process and is not normally adjusted during the course of the study. Should you need to make any changes to automatic name generation settings, we recommend partnering with the Trial Interactive Service Desk.

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.**

a. **Now, the upload date will automatically be assigned as the document date in the document profile.**

Use Separator Sheet for Multiple Documents Print

This option impacts the "Print" function available in the Documents module. Users can choose to print multiple documents. What the system initially does is to create a .pdf file from all of the chose files which can then be downloaded or printed locally. This option, when enabled, causes a separator sheet to appear between each of the source documents.

Enable View by Tag for Documents

This option, when enabled, provides room users with the option to view documents in the Documents module by the value in the Tag field. This metadata field may be enabled or disabled and may be assigned to certain documents or to all documents just as with any metadata field. The View by Tag option here does not enable to metadata field for use, for that, please reach out to the Trial Interactive Service Desk or set up the field during room configuration.

The View by Tag metadata field allows users to apply tags (similar to the # applied to posts in social media) to documents. This would indicate that any documents with the same tag are related by the tag. One example might be tagging documents submitted in a certain language so that they could all be viewed together regardless of document type. One especially valuable element of this is that multiple tags can be applied to any document, meaning that documents can be cross-referenced by applying several tags.

Enable coding on Mass Import Window as Default Option

When users import documents, there is often a panel on the right-side of the import window which can be enabled or disabled depending on whether or not the user wishes to apply metadata to the documents being uploaded. This option would cause that panel to be activated by default when uploading documents.

Enable Site Folders Tree for the Upload Dashlet

This option, when enabled, allows users to see the site-related folders present in the Documents module and allows the user to choose which folder should house the documents being uploaded.

Enable Causality Tracking for Final Documents Metadata Edit

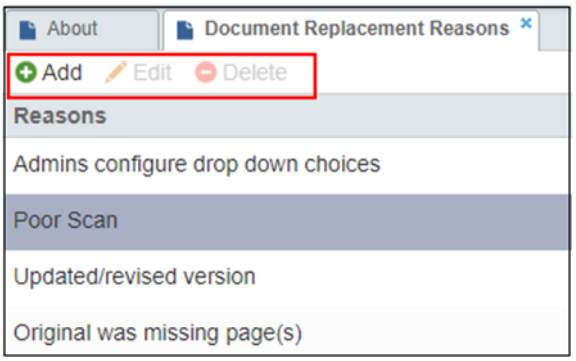
Administrators and Document Manger users have the ability to alter metadata for final documents in a study room. Enabling this option has two effects:

1. **The user, upon changing metadata for a final document, will be requested to provide a reason for making the change.**
2. **Mass Coding will be disabled in the study room.**

DOCUMENT REPLACEMENT REASONS

In this section, an administrator can configure the set of reasons that might be applicable when replacing an attachment to a document. These reasons will appear in the dropdown menu available when users choose to replace a document file.

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



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

QUERY MANAGER OPTIONS

Query Managers in Trial Interactive are a group of users who are assigned permission to see all QC Workflow-related queries in the room and, where necessary, assist. Specifically what a Query Manager can do is determined by the setting here. By checking the boxes on this menu, the room administrator can give the Query Managers permission to resolve queries and/or to respond to queries assigned to any user.

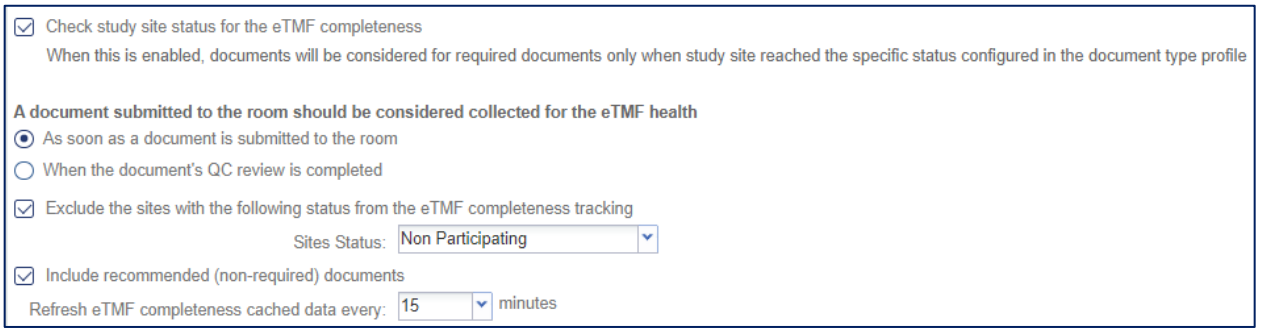
In order to designate a user as a Query Manager, they should be added to the Query Manager group in Users Management.

ETMF HEALTH SETTINGS

- **The 'Check study site status for the eTMF completeness' option can be enabled or disabled here. When enabled, it allows the room to either include or ignore site document requirements based on the specific site status as configured in the document-type profile.**
- **The user can also choose when the system would consider a requirement as having been considered to be collected using the radio buttons on the screen.**

- **'As soon as the document is submitted to the room' would cause the room to indicate that a placeholder was fulfilled successfully as soon as a document was uploaded with the corresponding metadata.**
- **'When the document's QC review is completed' would indicate that missing document placeholders could only be fulfilled by documents marked as 'Final' by the room's QC Workflow.**

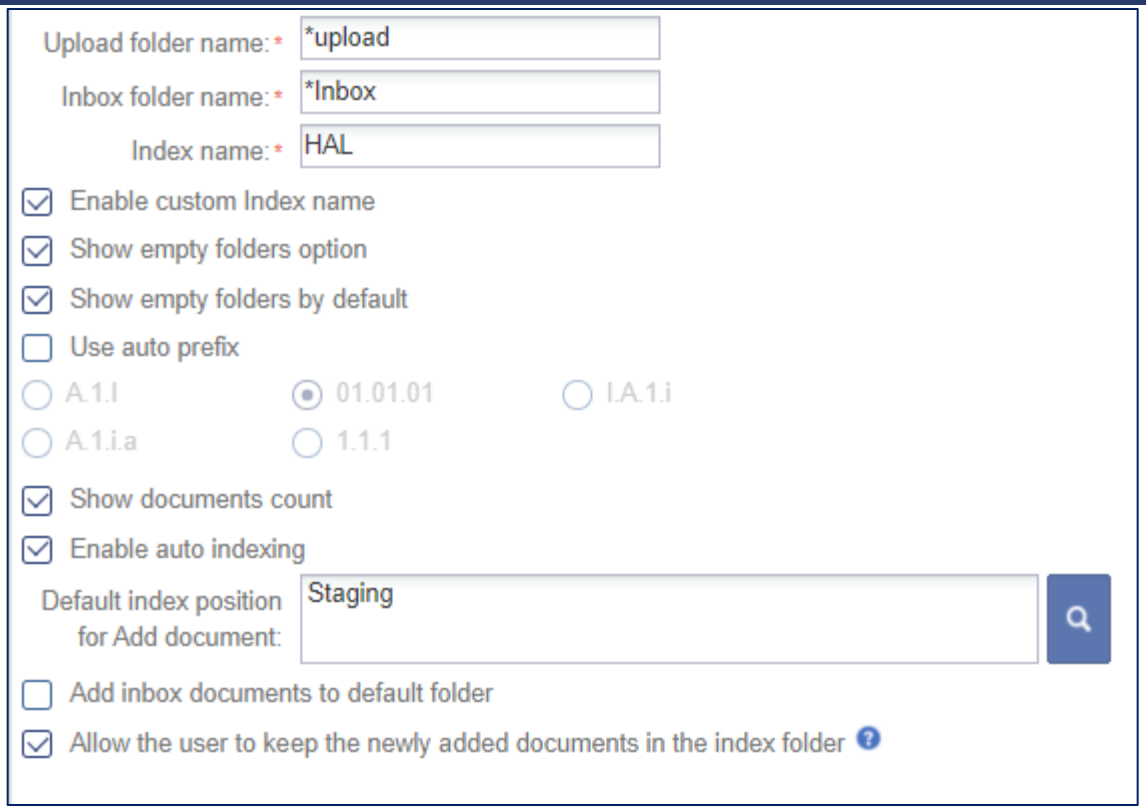
- **The option to 'Exclude the sites with the following status from the eTMF completeness tracking' would indicate that document requirements for sites in the chosen status would not be considered during the calculation of the room's eTMF health.**
- **Administrators can also choose whether or not to include recommended (non-required) documents when calculating the room's eTMF health.**
- **Finally, the user can set the refresh rate for completeness data, indicating how often the room calculates eTMF health.**



INDEX OUTLINE

The administrator can decide on several functions and appearances related to the Trial Interactive room's index. As with any change to room settings, please communicate any alterations to your Trial Interactive representative so that the configuration manual may be maintained correctly.

- **Navigate to Navigation Grid->Settings->Documents->Index Outline**

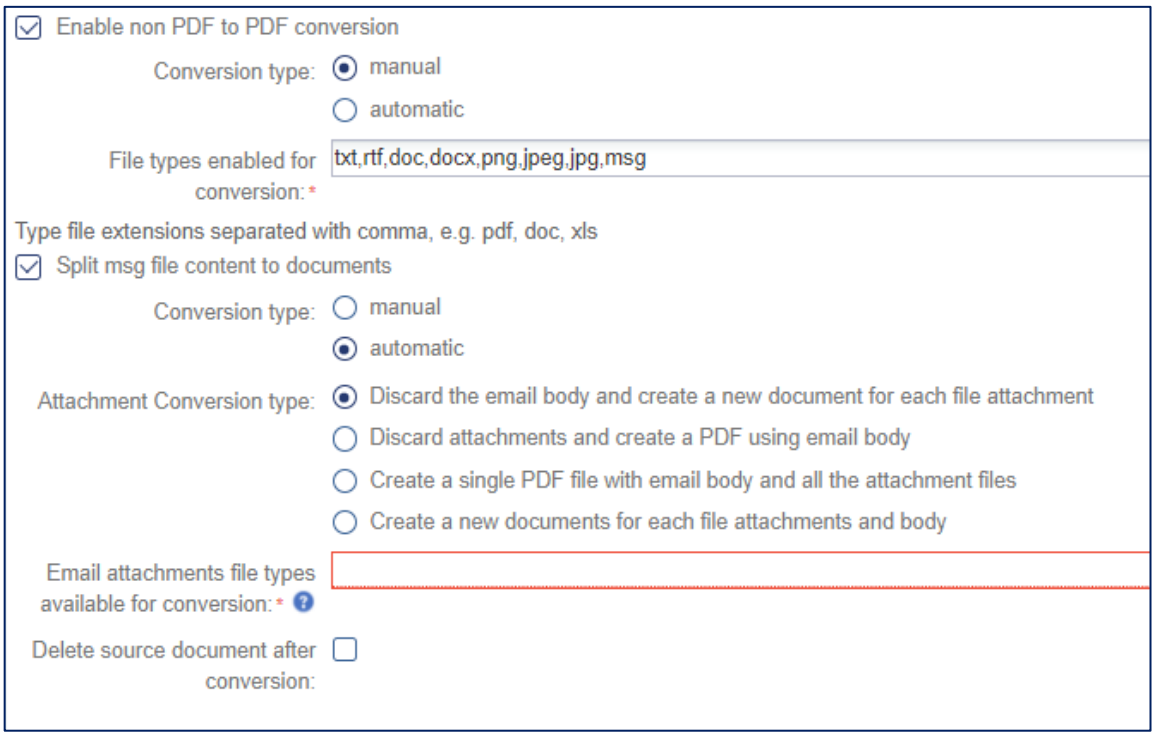


- **All documents imported are populated in the Upload folder unless they have been assigned metadata during upload.**
- **The folders in a room index are numbered, and the subfolders follow a standard numbering system.**
    a. **These folder numbers are called as Folder Prefixes, whose settings can be decided from the Auto Prefix option.**
    b. **Activate or inactivate Auto Prefixing of folders in the room's index by ticking the Use auto prefix checkbox. Refer to the screenshot above.**
    c. **If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index.**
    d. **Auto prefixing inserts the desired prefix of numbers or letters to identify the levels of the folders in the index.**
- **Numbers after the folder names indicate how many documents are available to you in each folder. Check the 'Show Documents Count" option to enable these numbers on the room's documents module.**
- **Enable Auto Indexing determines whether or not documents can be routed automatically to the correct index location as indicated in the related document-type profile.**
- **The default location for documents which have been uploaded with metadata assigned is indicated in the 'Default index position for Add document" field.**
- **Documents which are emailed into the room's inbox are typically stored in each user's Inbox folder, but this can be altered by choosing to enable the 'Add inbox documents to default folder' option which would then route all documents emailed to the room inbox directly to the default folder (Staging, in the screenshot above).**

- **Users can click and drag documents directly to any folder of their choosing depending upon access rights. Whether or not those documents stay in the index folder is determined by the final setting: 'Allow the user to keep the newly added documents in the index folder"**

NON-PDF TO PDF DOCUMENT CONVERSION SETTINGS

1. **Navigate to Navigation Grid -> Settings -> Documents-> Document 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.**



- **The 'Attachment Conversion type:' field instructs the room as to what action should be taken when an email message is dragged from Outlook directly into your Trial Interactive room.**
  - **The settings below clarify which attachment file types can be converted to .pdf as well as what to do with the source document after conversion.**

DOCUMENT CERTIFICATION

Trial Interactive has the ability to allow users to submit certified copies of documents either via the myTI application or directly to the study room. Checking the box in this menu enables the function in the Documents module of the study room.

Document Types and Management

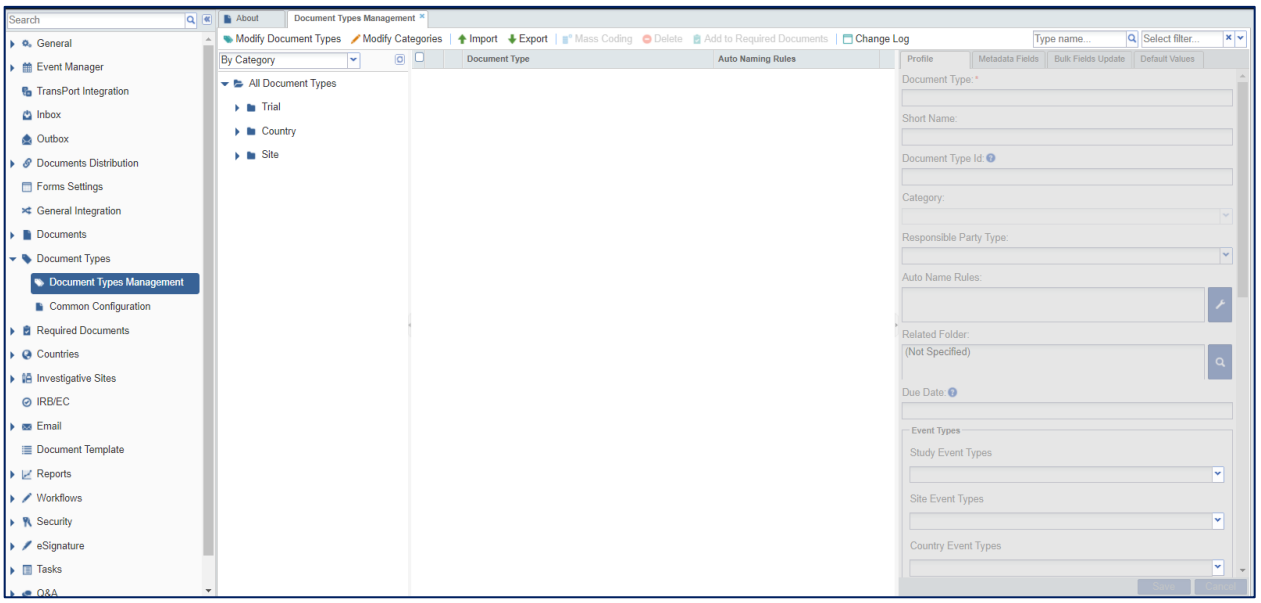
In this section, we discuss creating Document Types and associated functions.

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 Navigation Grid -> Settings.**
2. **Select Document Types from the menu on the left.**
3. **The Document Types option expands to reveal two sub-options:**
    a. **Document Types Management and**
    b. **Common Configuration.**
4. **Click and view each panel separately.**

Refer to the screenshot below:



Click the 'Document Types Management' menu to open its dashboard on the right.

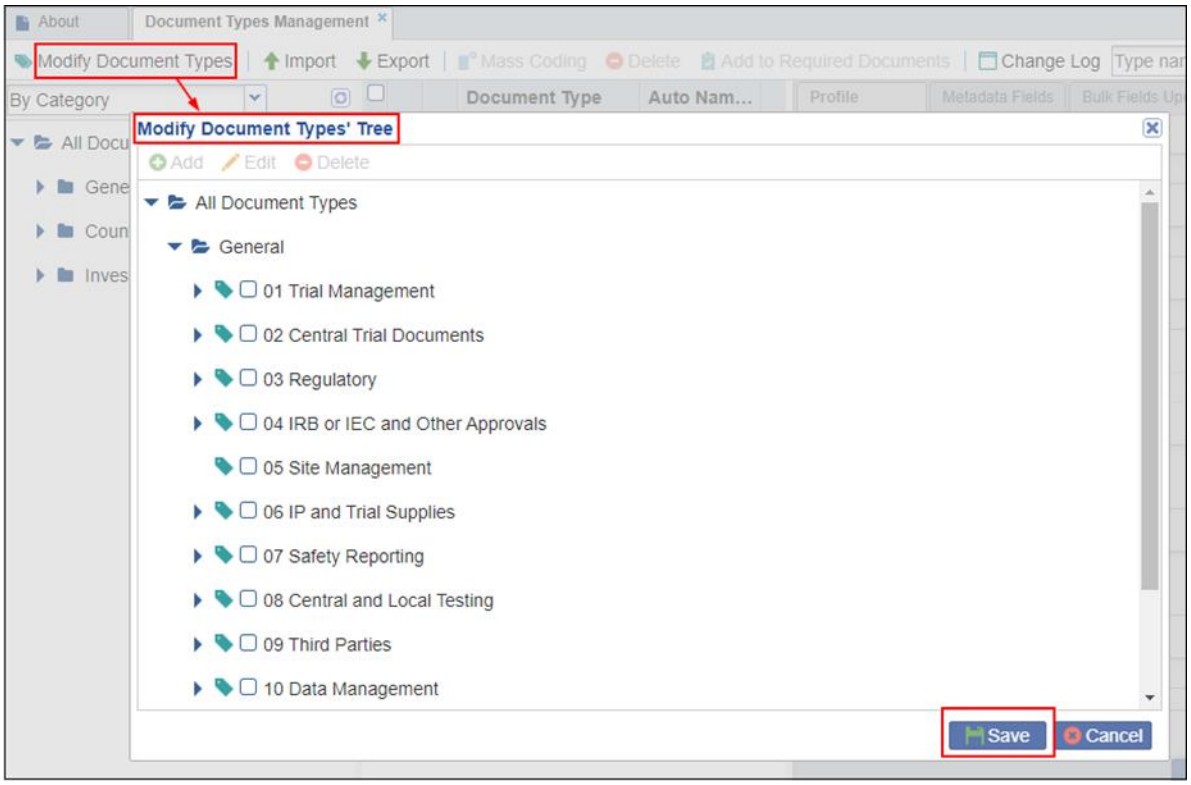
From this page, you can perform the various actions listed below.

- **Modify Document Types**
- **Building the Document Type Profile**
- **Specifying the Related Folder**
- **Include Phases/Milestones**
- **Adding Document Types to Required Documents**

- **Include in Document Tracker Report**
- **Auto Document Type Prediction Keyword(s)**
- **Modifying Document Types Fields**
- **Default Values**

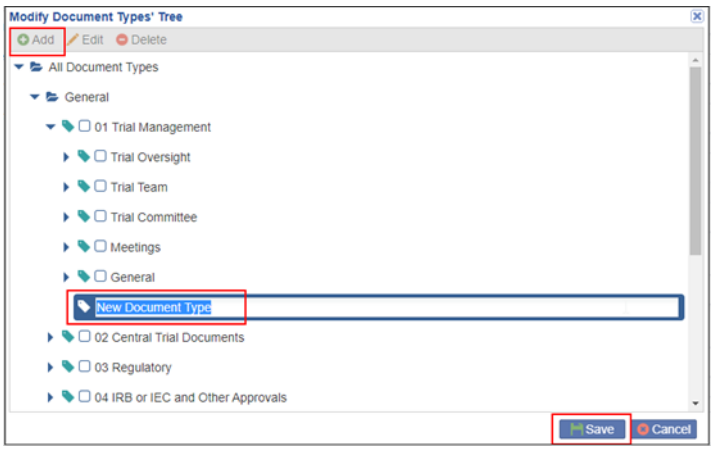
MODIFYING DOCUMENT TYPES

1. **Click the '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.**
    a. **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.**

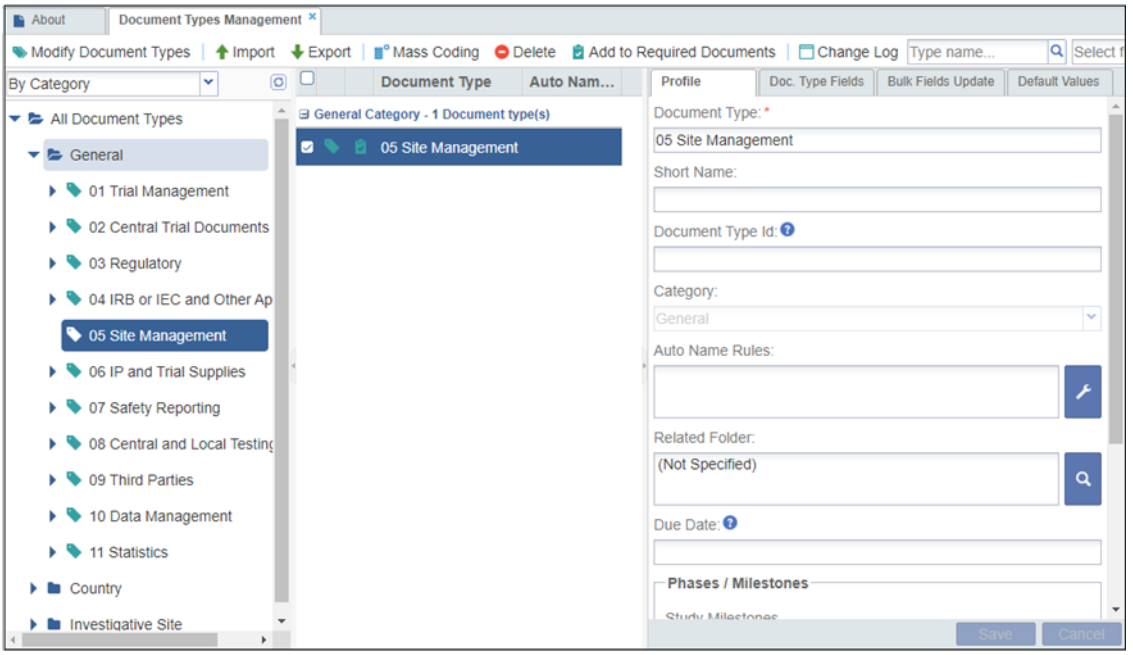


1. **To add a new document type, click the main category into which the new document type is to be assigned. If the folder already contains document types, click the + sign next to the category's folder icon to see the document types already contained in the category.**
2. **Click the 'Add' button near 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**

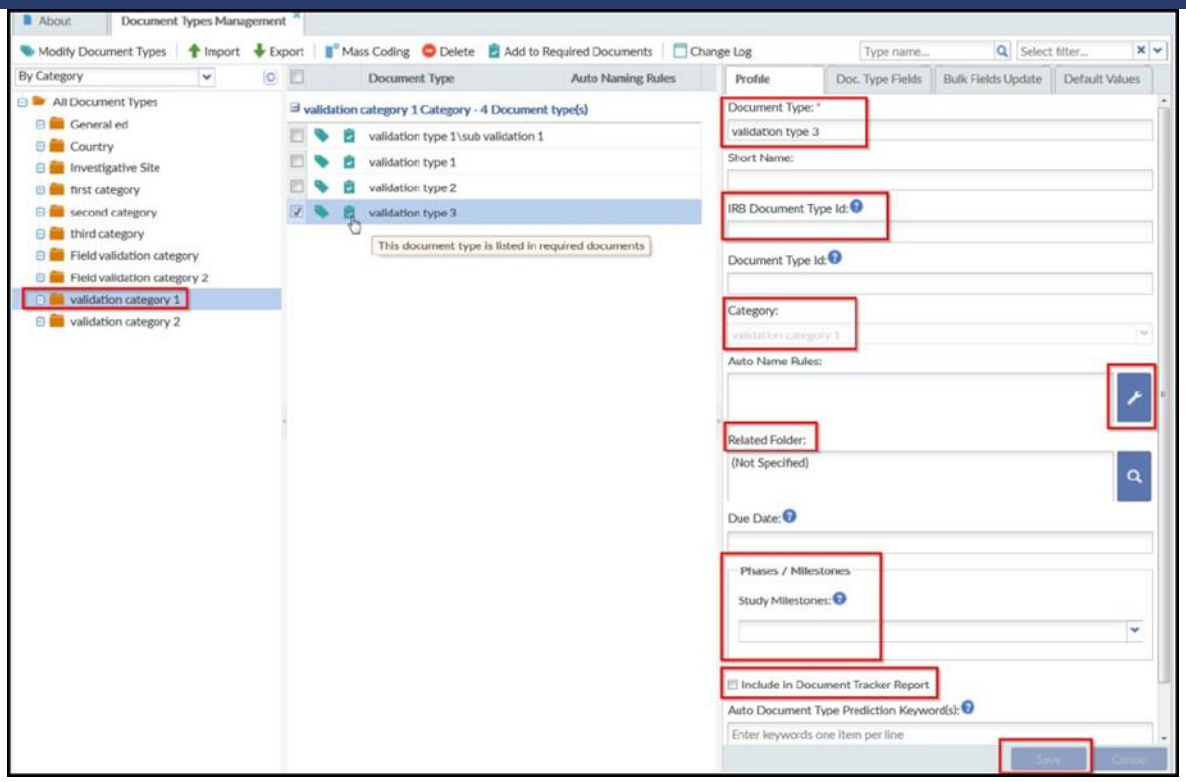
with an editable field that reads New Document Type. Refer to the screenshot below:



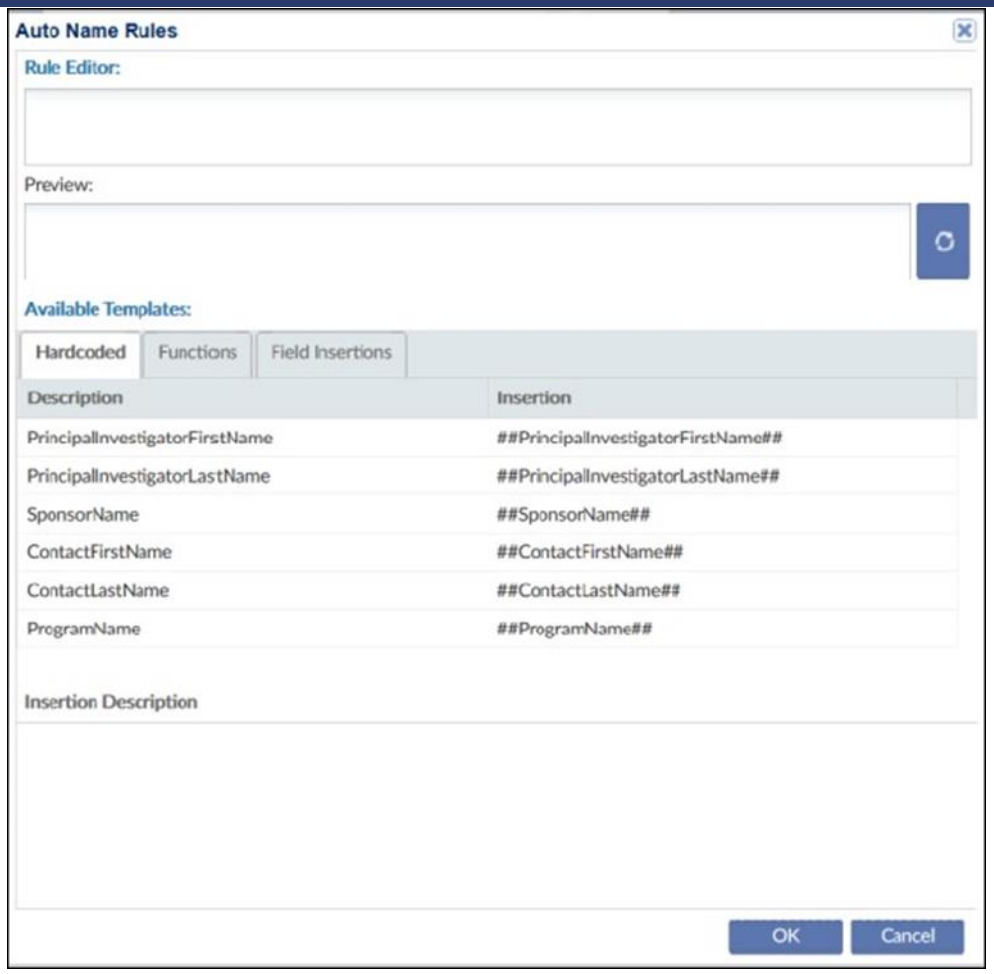
3. **Type the name of the new document type to be added to the category folder.**
4. **Press the Enter key. If you have more document types to add to this or other categories, you can repeat this process.**
5. **When you have added all of the necessary new document types, click 'Save' at the bottom of the window. That window closes, and you return to the primary Document Types view. The document type that you have just created has now been routed to a proper index position. Refer to the screenshot below:**



BUILDING THE DOCUMENT TYPE PROFILE

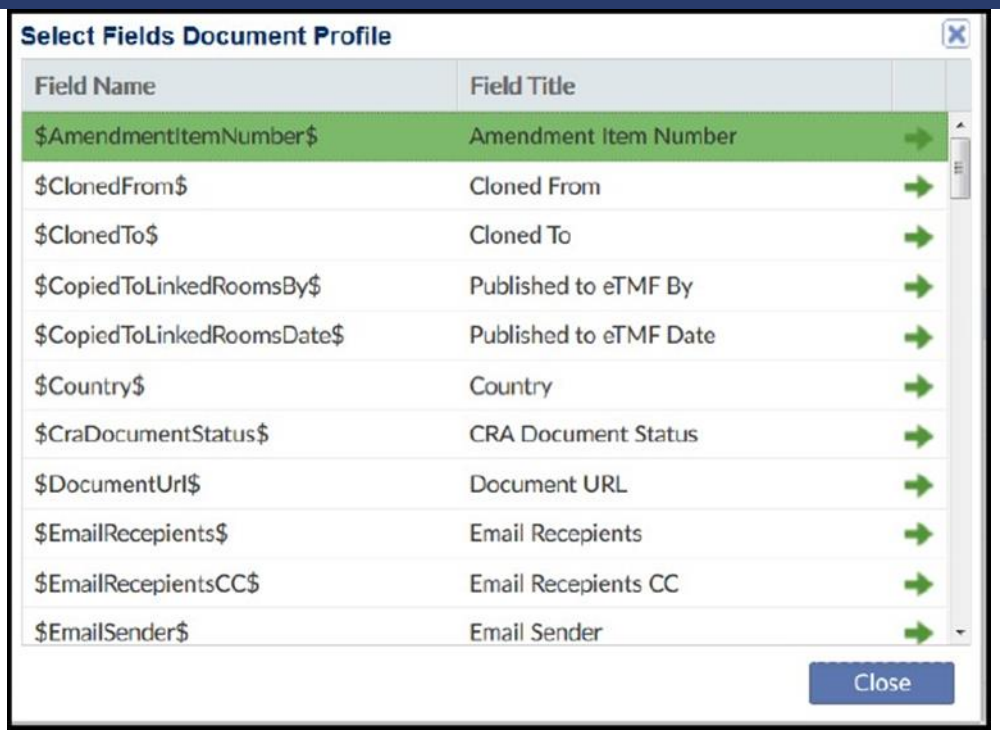


1. **Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.**
2. **In the Profile tab, type in the Short Name for the document type. This can be the same as the Document Type name that you created in the previous steps, 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.**
5. **Click the wrench icon next to the Auto Name Rules field. When the metadata gets filled out for documents of this type, the auto naming rules you set up here will be applied to these documents. All initial document types and auto naming rules are determined by the configuration manual. An Auto Name Rules window opens. Refer to the screenshot below:**



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.

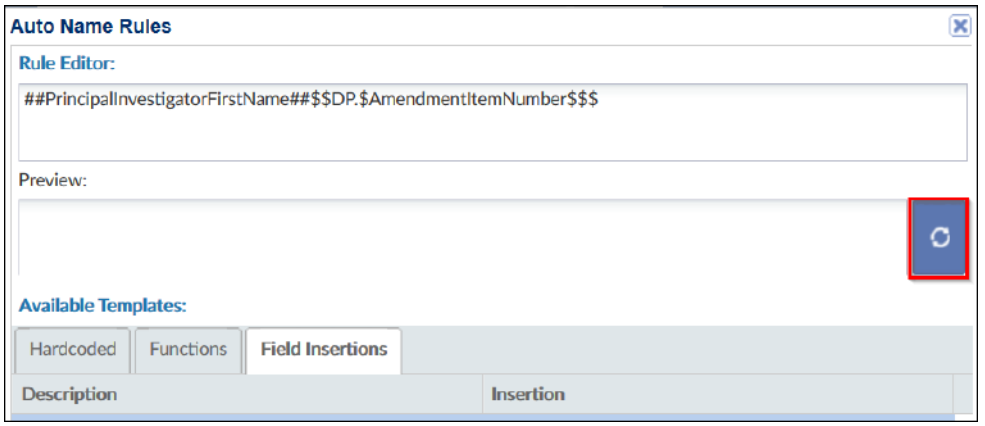
1. **Under the Hardcoded tab, double-click a description to be inserted as auto naming rule. The insertion appears in the Rule Editor.**
2. **If you want to include fields present under the Field Insertion tab, double-click the description, and click the green arrow in the Select Fields Document Profile.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



3. **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.

4. **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.**

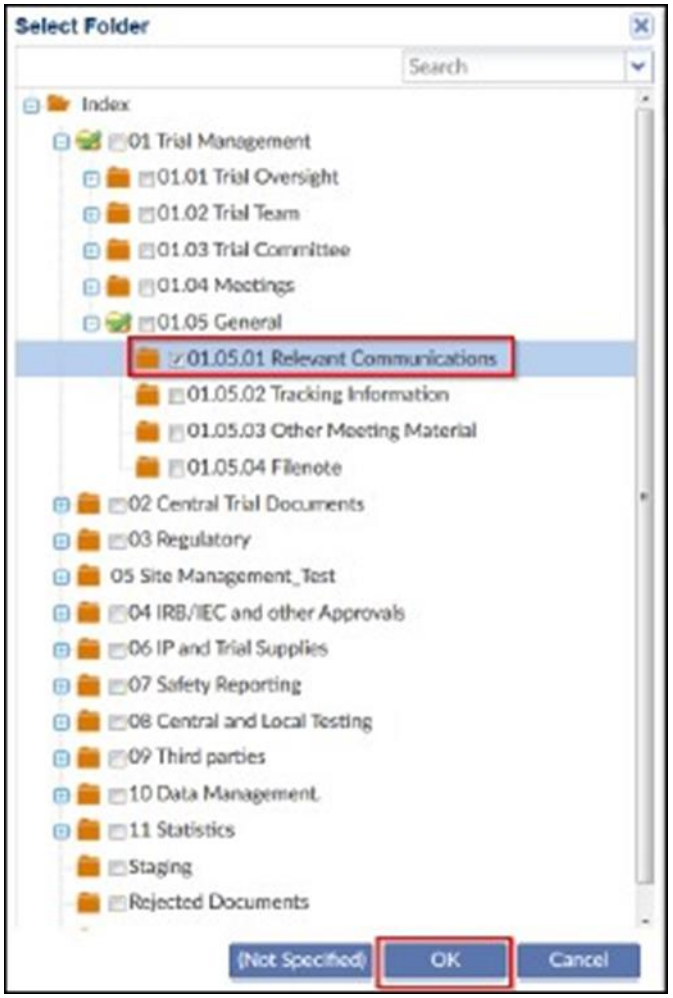


5. **Click OK at the bottom of the window to be returned to the main Document Types view.**
6. **Click 'Save' at the bottom right of the Profile tab window.**

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.**

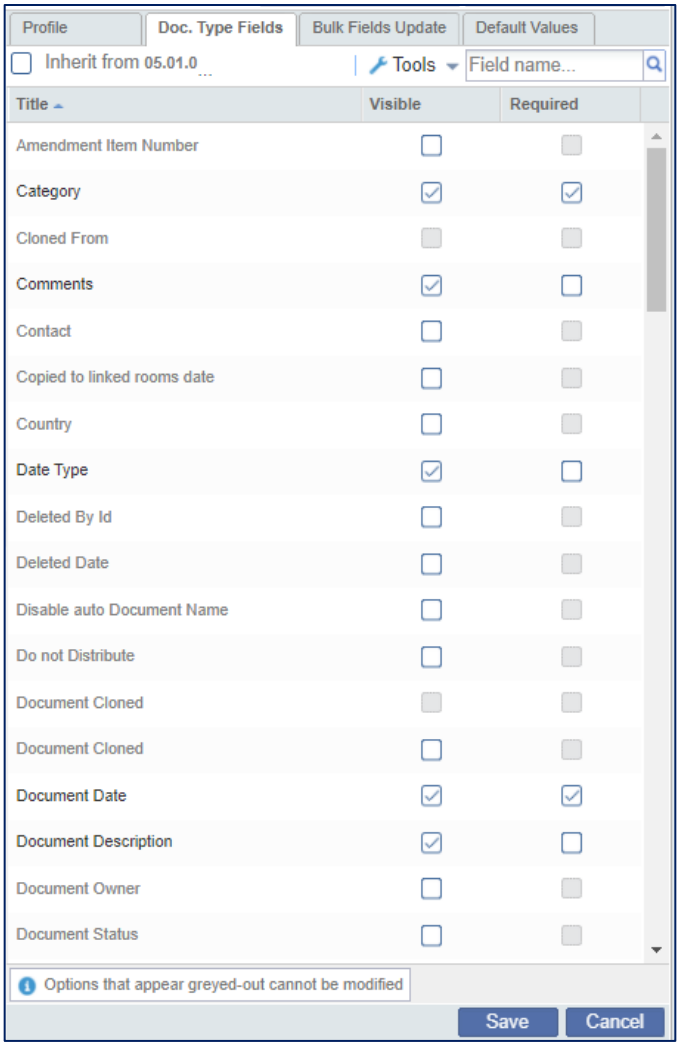


3. **Click OK at the bottom of the window.**
4. **Back on the main Document Types view, click Save at the bottom of the panel on the right.**

DOC TYPE FIELDS

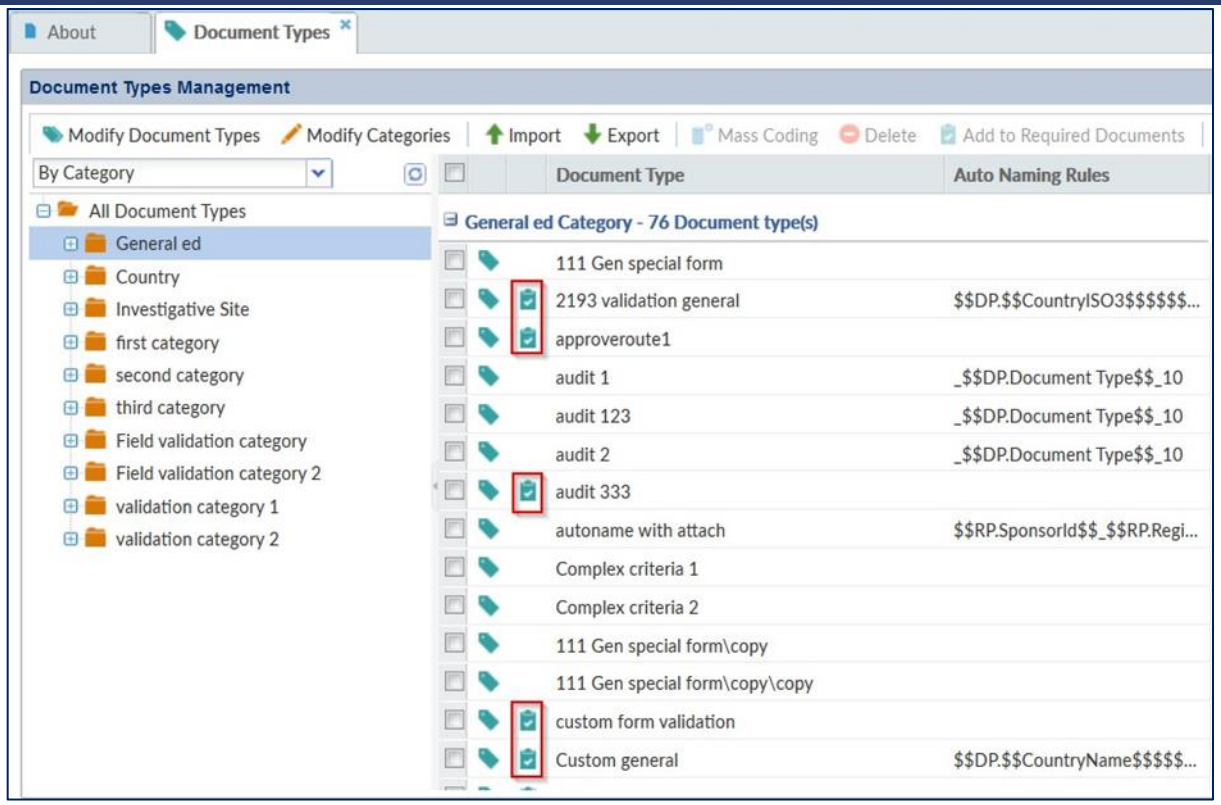
This will allow the user to determine which metadata fields are associated with any given document type. These values can be assigned to a specific document type or they can be inherited from a folder level.

- **If the field is marked as 'Visible' then it will be displayed in the metadata field when the chosen document type is assigned to a file.**
- **If the field is marked as 'Required' (which can only be done for Visible fields) will be required for any document coded as the related document type.**



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:

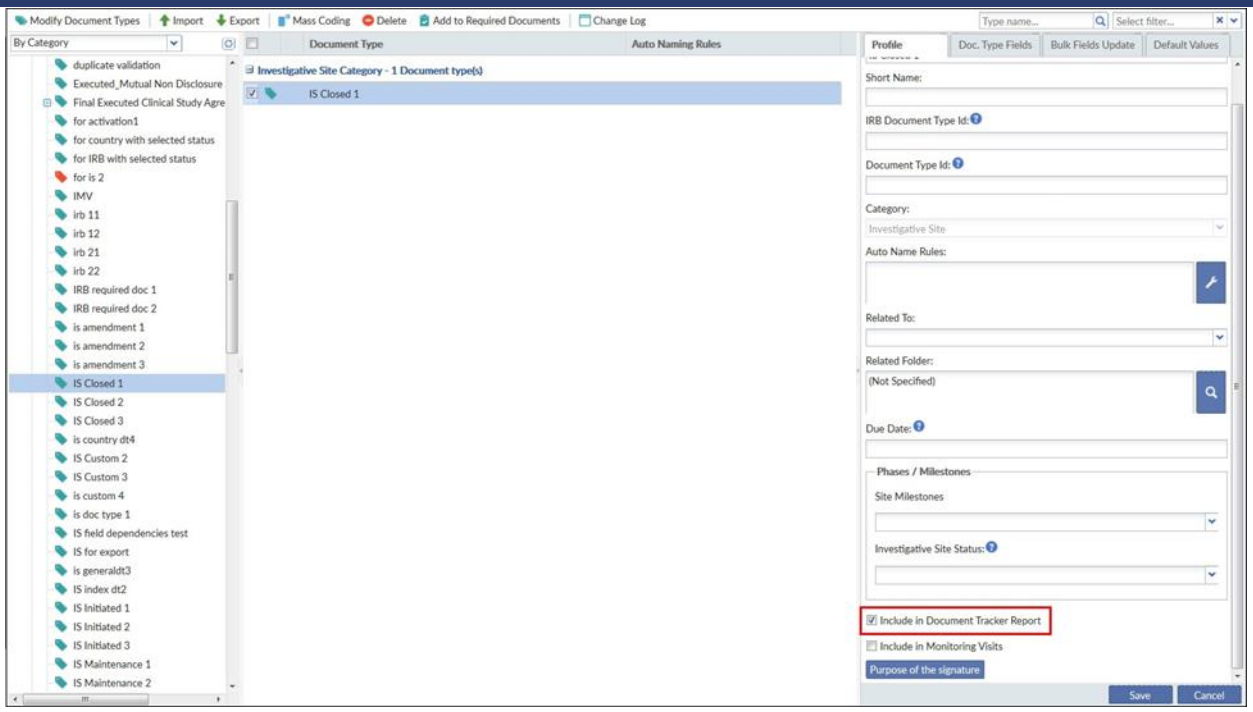


A document type can be added to the required documents list from the Add to Required Documents button located on the toolbar above the Document Types Management window. Refer to the screenshot below:

For additional instructions regarding adding a document to the list of required documents for the study, please see the section on Required Documents.

INCLUDE IN DOCUMENT TRACKER REPORT

To specify that any Document Type will specifically be included in the Document Tracker Report, tick the Include in Document Tracker Report checkbox from the Document Types Profile window. After making any changes, be sure to click Save at the bottom of the window. Refer to the screenshot below:



REFERENCE METADATA

The standard set of TMF metadata is 'mappable' from Trial Interactive document types but it has not been available directly in the User Interface. Providing this information allows for better metadata exports and improves classification.

For eTMF rooms, this metadata is now included with each document type in a set of virtual fields. Fields now include:

- **Zone**
- **Section**
- **Artifact**
- **Sub-Artifact**
- **Index Number**
- **Description**
- **Instructions**

These fields will simplify the full implementation of sub-artifacts, particularly important for the TMF Reference Model v3.2.

Additionally, when selecting a document type, the Instructions field is now made available as flyover help.

Finally, these fields are all fully reportable and are made available in standard views, grid view metadata exports, standard reports, and archives.

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.

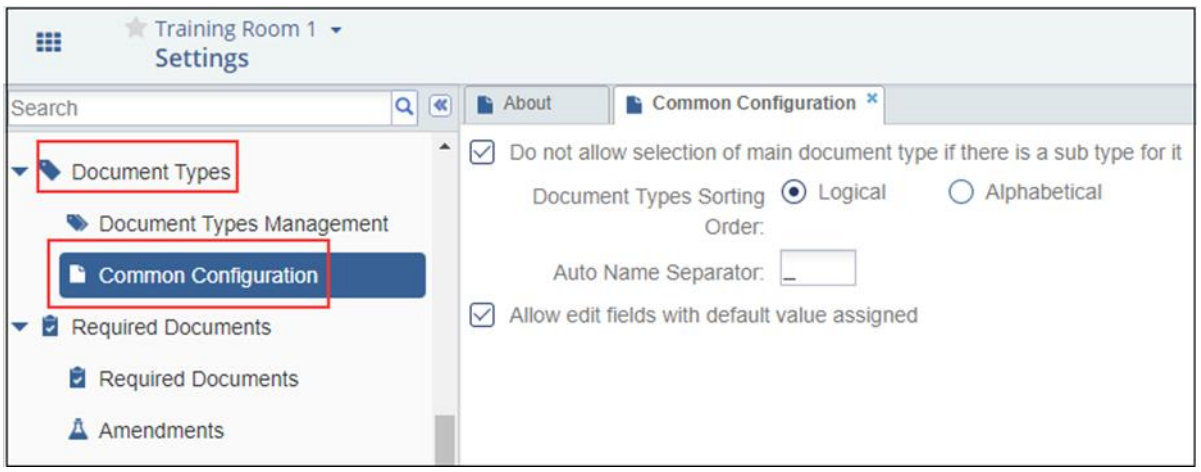
To use these new options, you must first create a custom metadata field in Form Settings. You must be sure to include the custom field in Coding before you save the final changes.

1. **Click the Default Values tab.**
2. **Click the Add button. The Field textbox activates.**
3. **Click the dropdown arrow at the right end of the box.**
4. **Select the necessary custom metadata field from the list.**
5. **Set the field's default value by typing the value in the textbox.**
6. **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

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, 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.**

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

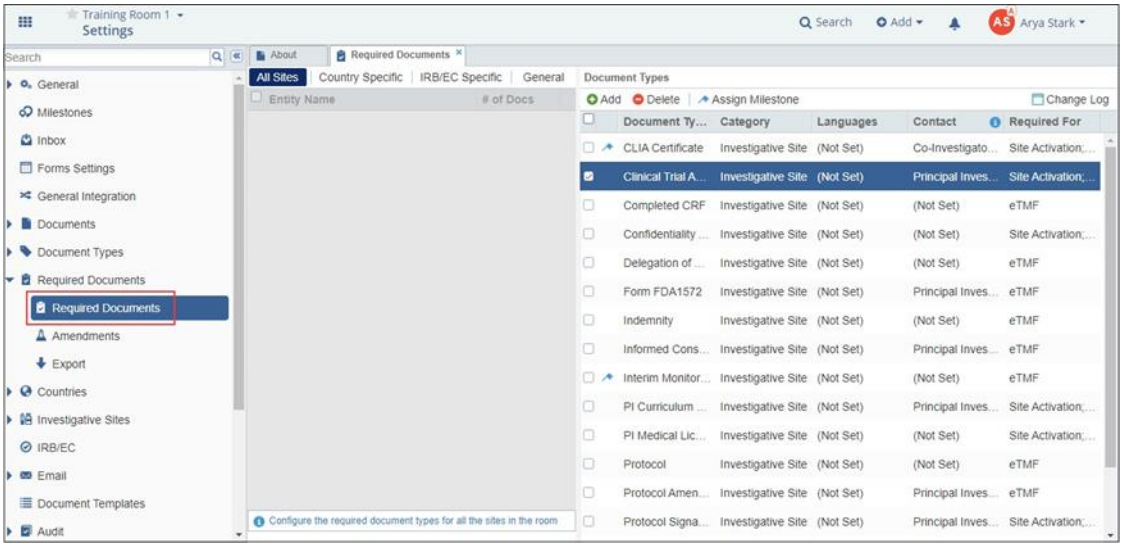
Refer to the screenshot below showing the options under Required Documents:

Required Documents can be defined for the following:

- **All Sites**
- **Country-Specific**
- **IRB/EC**

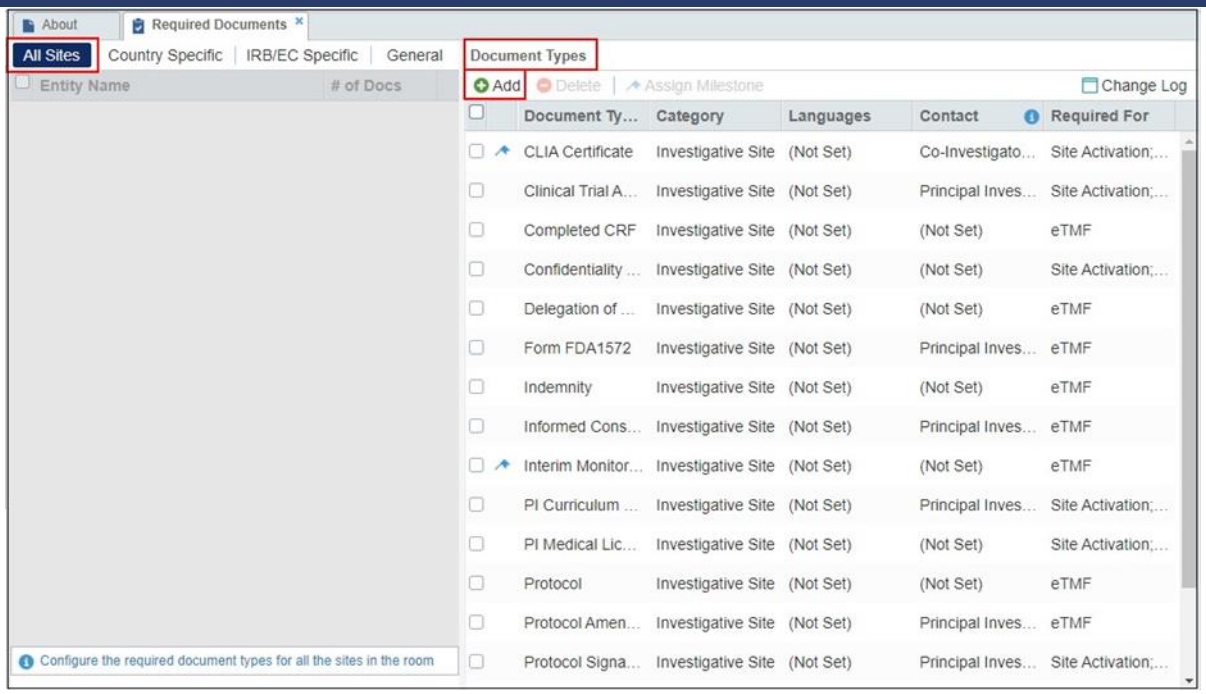
REQUIRED DOCUMENTS

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 or Delete a Required Document to the category selected from the left pane.**
    b. **Assign Milestones to selected Required Document Types.**
    c. **View the activity log of the selected category from the Change Log**
    d. **Once a Required Document is added, it appears in the Document Types Grid.**

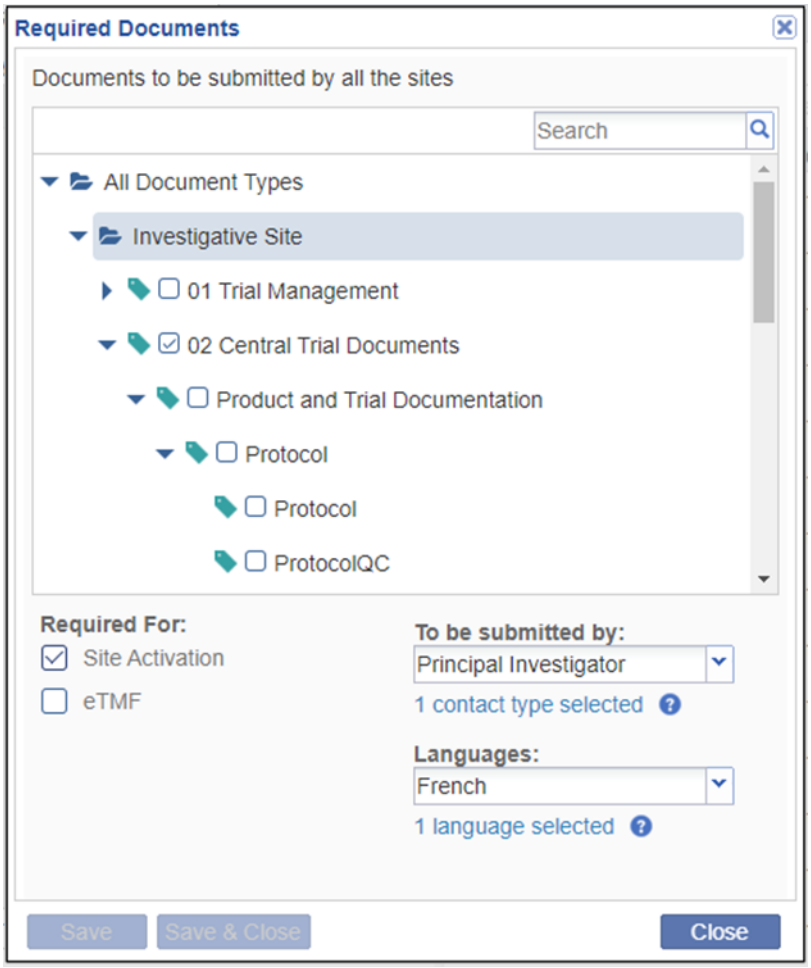


ADDING DOCUMENTS TO THE LIST OF REQUIRED DOCUMENTS

1. **Click the relevant tab from the left panel of the Required Documents menu.**
    a. **For Country and IRB/EC documents, pick the relevant country or IRB/EC.**
2. **Click 'Add' from the top ribbon bar of the Document Types window on the right. Here, 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 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 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, if necessary, select:**
    a. **To be submitted by- This is the Study Contact who is responsible for providing the selected required documents**
    b. **Languages- Select the language from the list to be applicable to the Required Documents.**

- **Note: Document types that need to be submitted by different contact types need to be set up separately.**

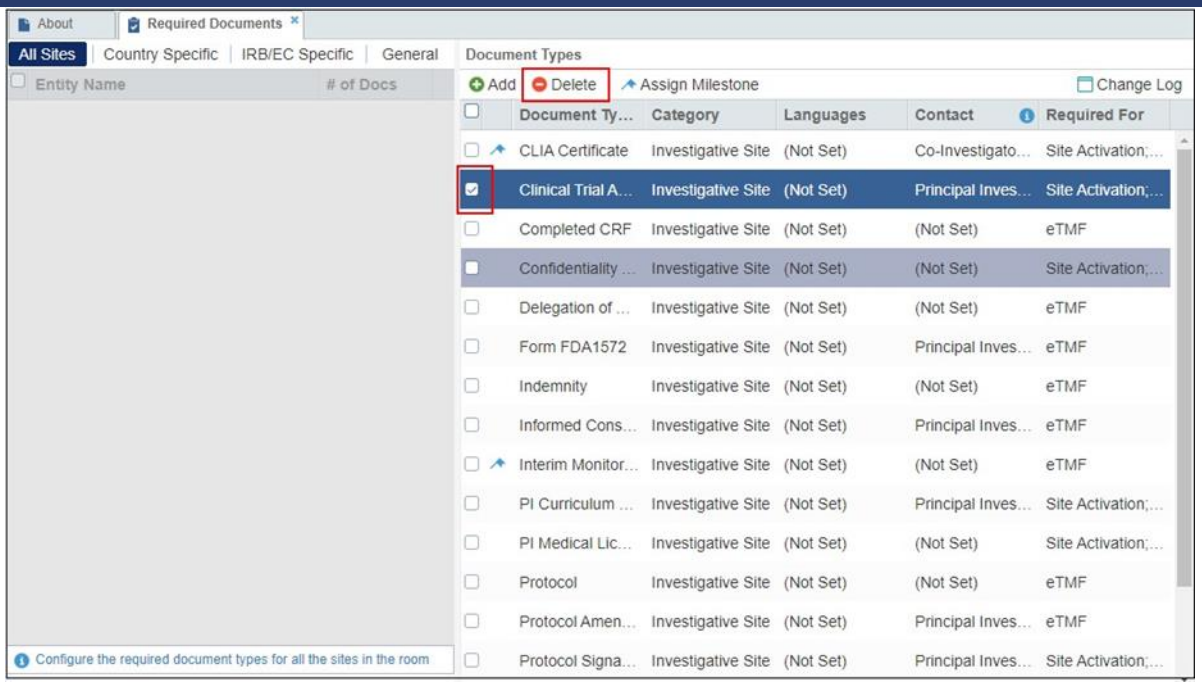
8. **Click 'Save & Close' if you have documents from only one category folder to add or click 'Save' if you need to add more required documents.**

- **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 DOCUMENTS FROM THE LIST OF REQUIRED DOCUMENTS

To delete a Required Document:

1. **Click All Sites tab from the left panel of the Required Documents Panel (page 175).**
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:**

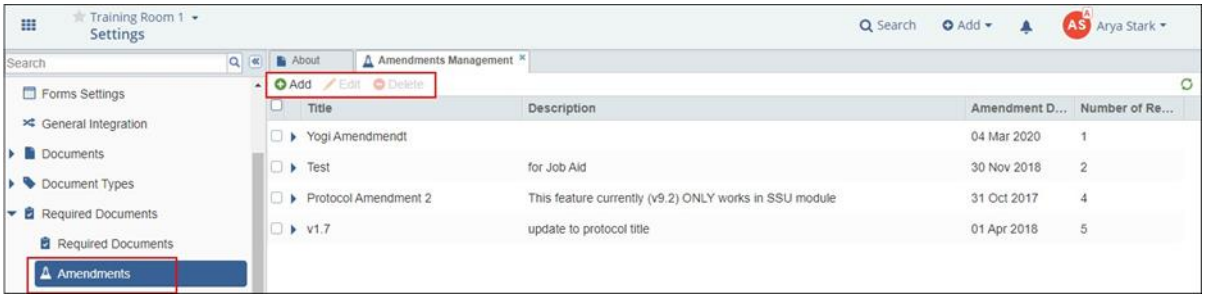


4. **You will receive a warning asking you to confirm the action.**
5. **Click Yes to confirm and delete it.**
6. **The Required Document Types are removed from the list.**

AMENDMENTS (SSU ROOMS ONLY)

In the Amendments panel, Administrators can add, edit, and delete amendments. This functionality is only available in rooms with Study Start Up enabled and these amendments can only be tracked from within Study Start Up. For users with rooms that do not have SSU enabled, we recommend using the Event Manager function if it is enabled in your study room.

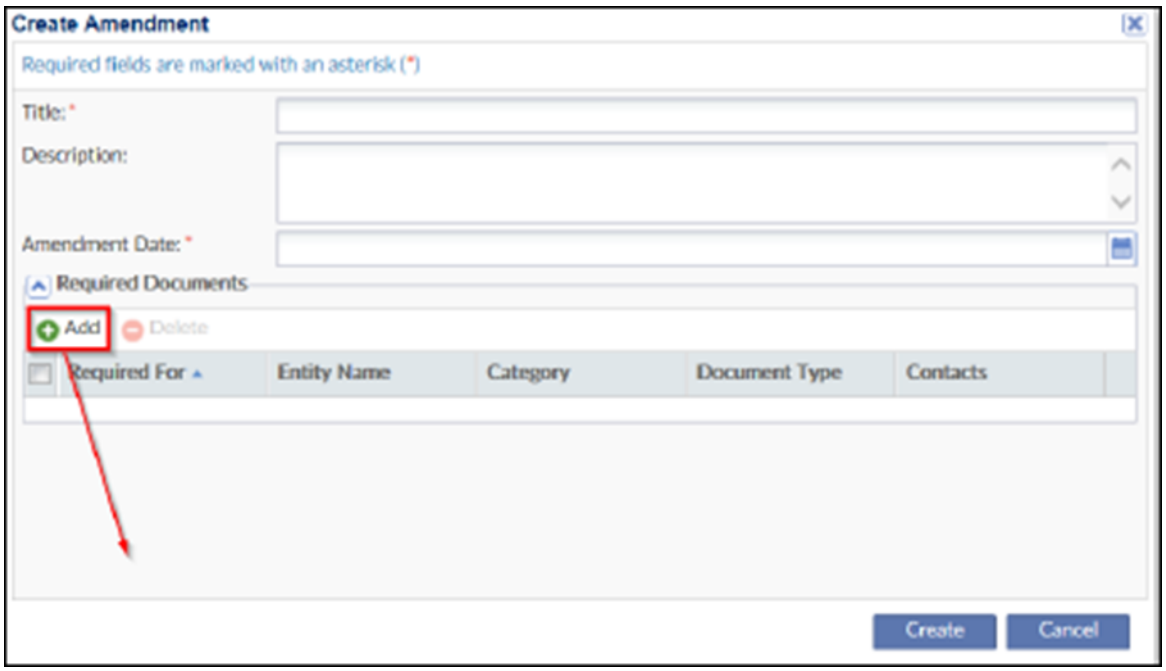
The Amendment function will provide a list of documents associated with the amendment that need to be collected.



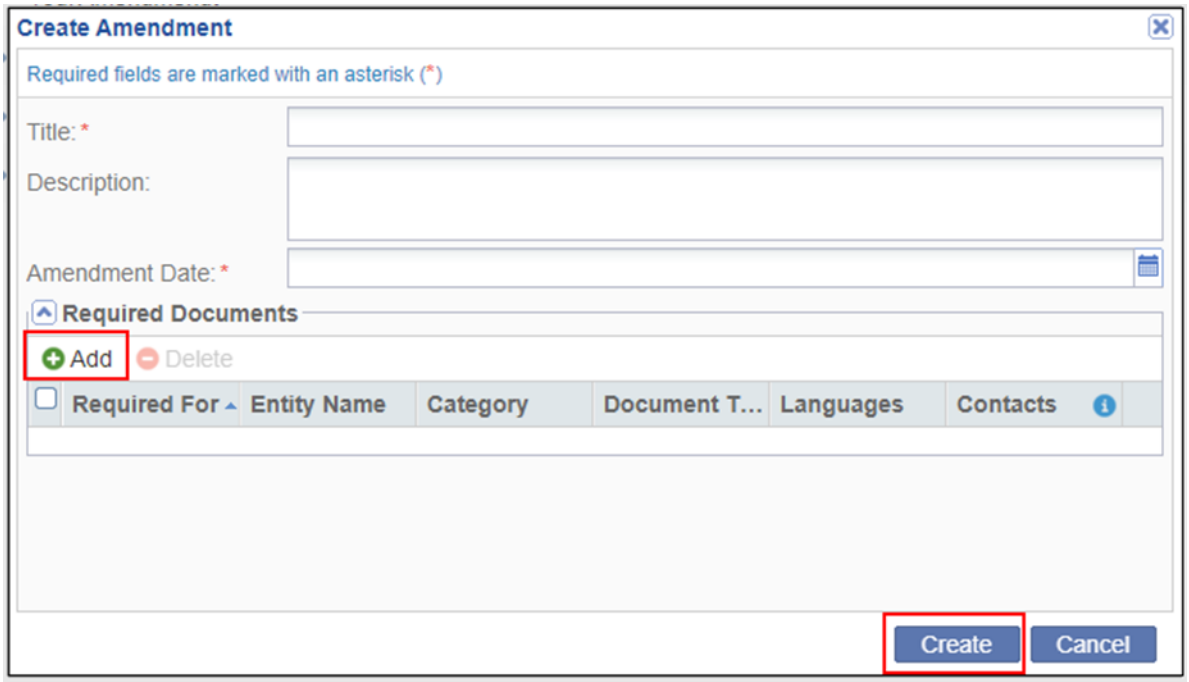
Follow the steps below to add a new amendment:

1. **Click the 'Add' button from the top ribbon bar. The Create Amendment window will open. Refer to the**

screenshot below:



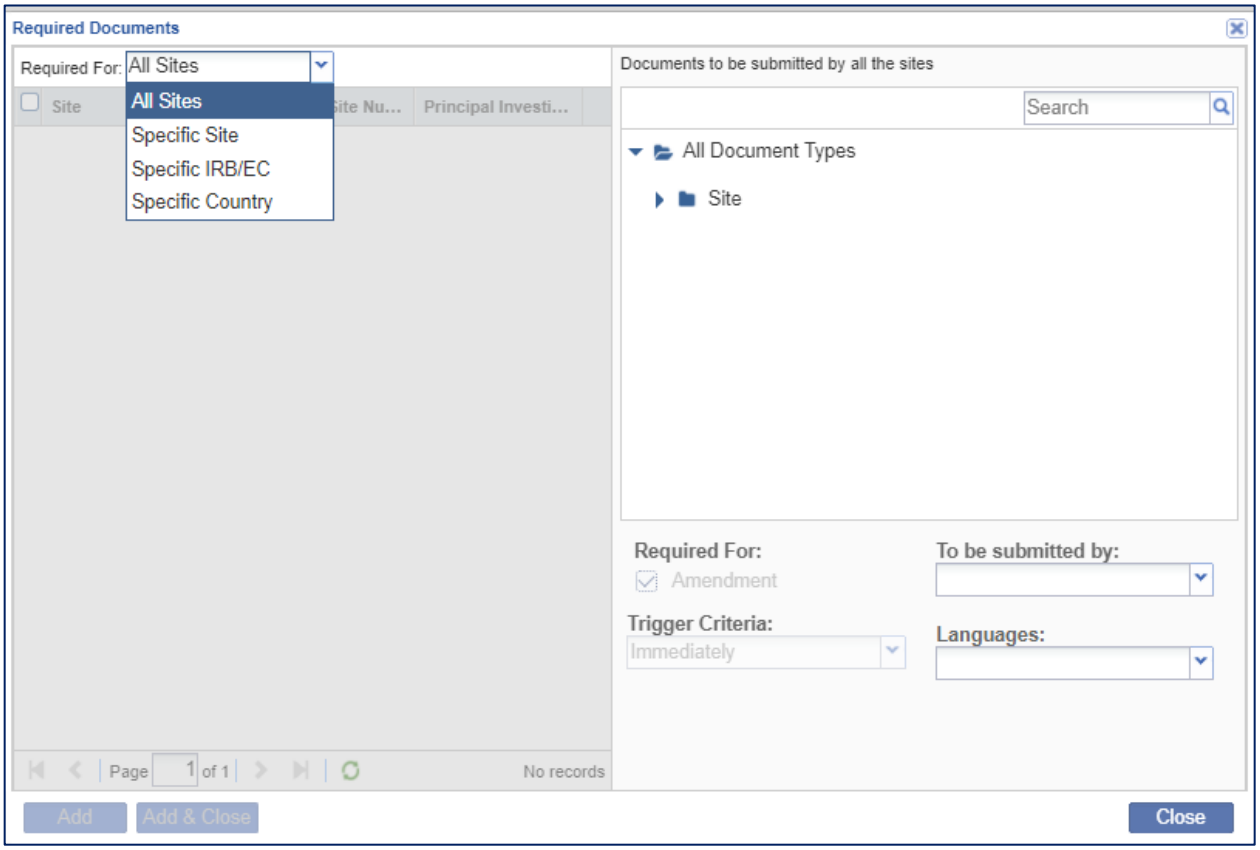
2. **Fill in the required details.**
3. **Click on the 'Add' button under the Required Documents panel.**
    a. **The Required Documents window will open for you to indicate which documents will need to be submitted for the amendment being created. Refer to the screenshot below:**



4. **In the Required Documents window, first use the dropdown menu at the top-left to indicate which group the amendment impacts:**
    a. **All Sites**
    b. **Specific Sites**

c. **Specific IRB/EC**

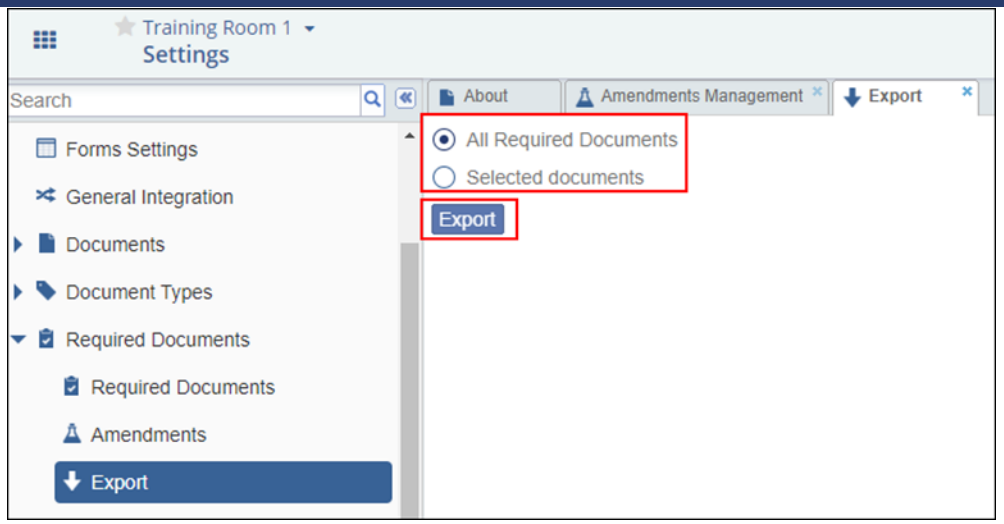
d. **Specific Country**



5. **Select a document type and press either 'Add' if you need to add another document type or press 'Add & Close' if you are done selecting document types to be associated with the amendment.**
6. **The amendment can be edited later on by double-clicking the amendment in the list or by selecting the amendment and pressing the Edit button.**
7. **To delete, click the Delete button or right click on the amendment and click Delete.**

EXPORT REQUIRED DOCUMENTS

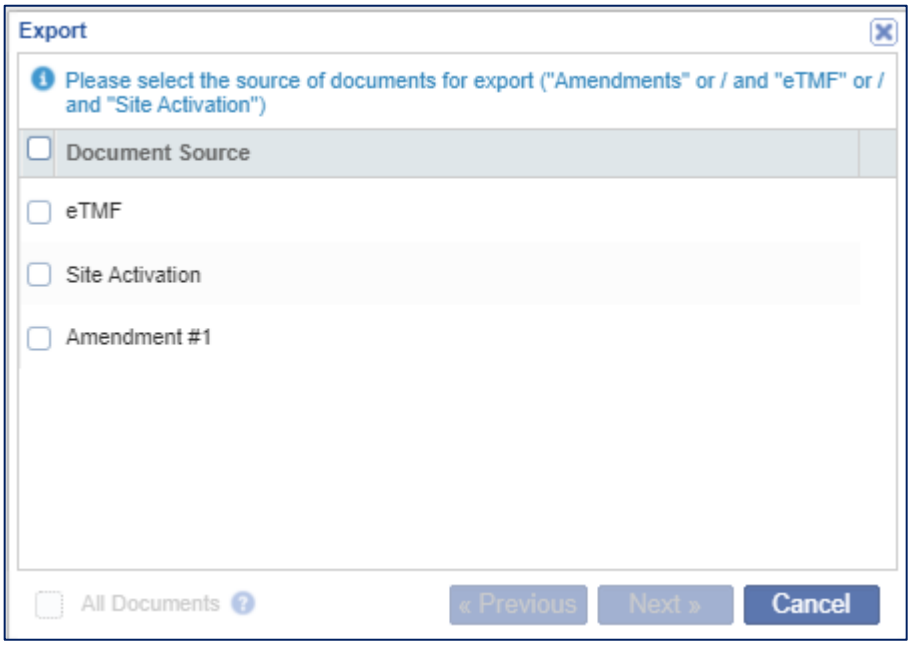
In this menu, Administrator users can export either All Required Documents or Selected documents. Refer to the screenshot below:



Required Documents can be exported in two ways:

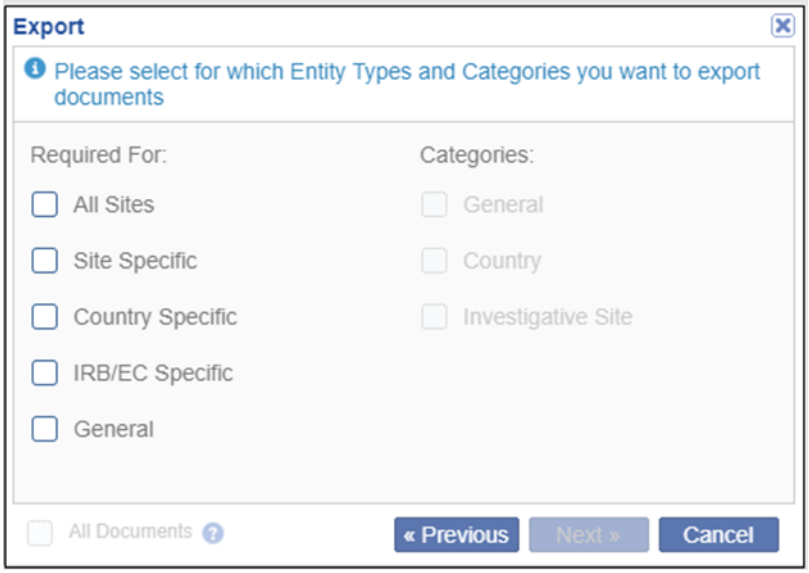
1. **Select the 'All Required Documents' option to export documents from all document source categories.**
2. **Select the 'Selected documents' option to indicate which documents should be exported.**
    a. **The Export window opens for you to choose from Amendments, Site Activation Requirements, or eTMF documents.**

Refer to the screenshot below:



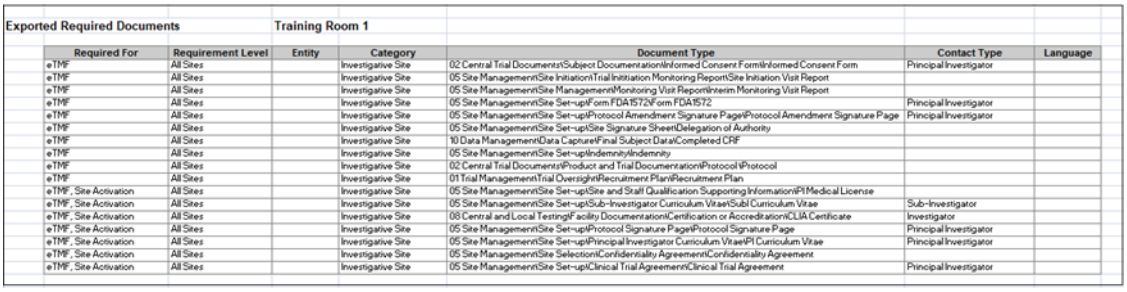
    b. **Select the required Document Source/s and click Next.**
    c. **A new Export window opens for you to select required Entity Types and Categories.**

Refer to the screenshot below:



3. **Click Next.**
    a. **The final Export window will open for you to review the chosen criteria.**
4. **Click 'Previous' to make changes in the selections or click 'Next' to continue.**
5. **Press the 'Export' button to export the list of documents selected.**
6. **A notification will display indicating that the job was completed successfully.**
7. **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 Initiation 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\Subl 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, those countries need to be added to the room. As a result of this, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents and users will be able to choose the appropriate country when setting up new investigative sites in that country.

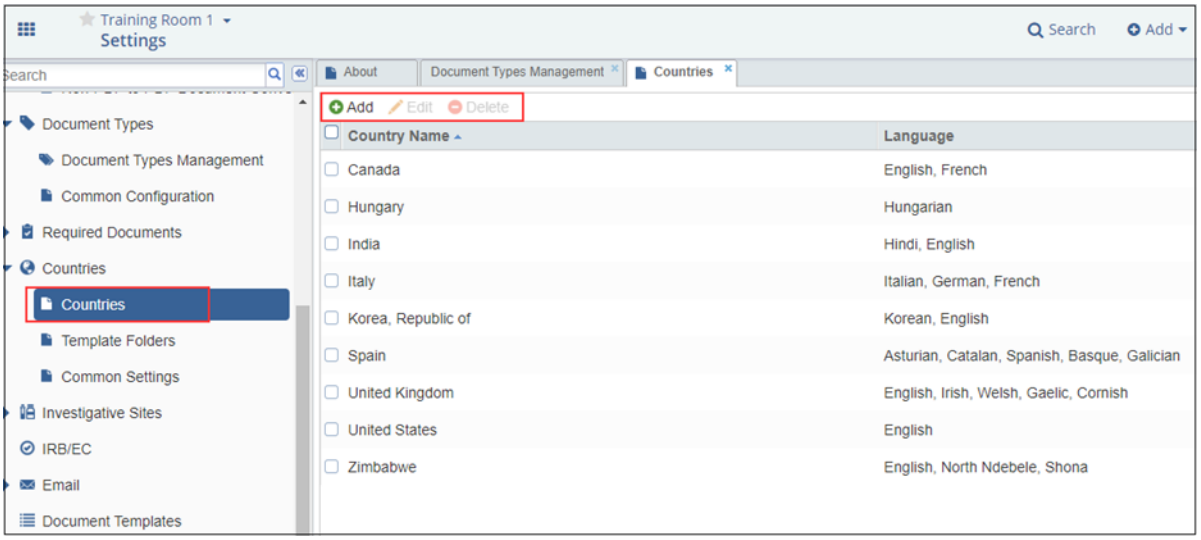
COUNTRIES SETTINGS

Trial Interactive allows administrators to make changes to Countries Settings from this page.

Follow the steps below to make changes to the country settings:

1. **Navigate to the Navigation Grid -> Settings Module**
2. **Go to the Countries settings from the left menu of the settings page.**

Refer to the screenshot below:



Selecting countries will open the option in a tab in the next pane. As shown in the screenshot above, the list of countries where studies are being conducted is displayed. These countries can be added, edited, or deleted from the buttons in the ribbon above the country listing.

<u>Add Countries</u>

Follow the steps below to add countries:

1. **Click Add from the ribbon above the country listing.**
    a. **The Create Country window will open.**

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.**

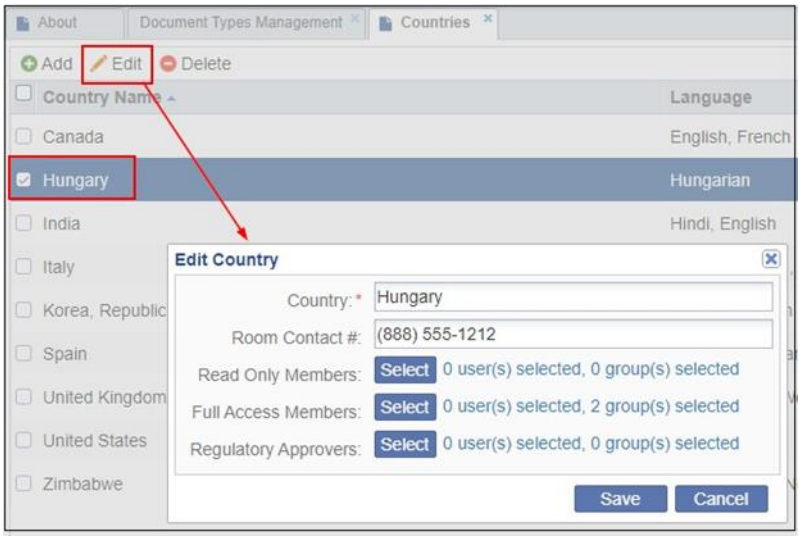
3. **Select the name of the country to be added. The name of the selected country populates the Country field.**
4. **If there is a country-specific Study Contact #, include the associated number in the field.**
5. **Click 'Create.' The name of the newly added country appears in the alphabetized list.**
6. **Repeat these steps until you have added all of the countries associated with the study.**

Edit Countries

Once a country has been added to the list, you can add or change the study contact #, and adjust access to groups or users.

Follow the steps below to edit countries:

1. **Select the required country from the grid to be edited. Click 'Edit' at the top of the Countries window.**
2. **The Edit Country window will open. Refer to the screenshot below:**



3. **Click Study Contact# field to change the information.**
4. **Click Select next to any of the listed groups in order to add members.**
5. **Click Save.**

Delete Countries

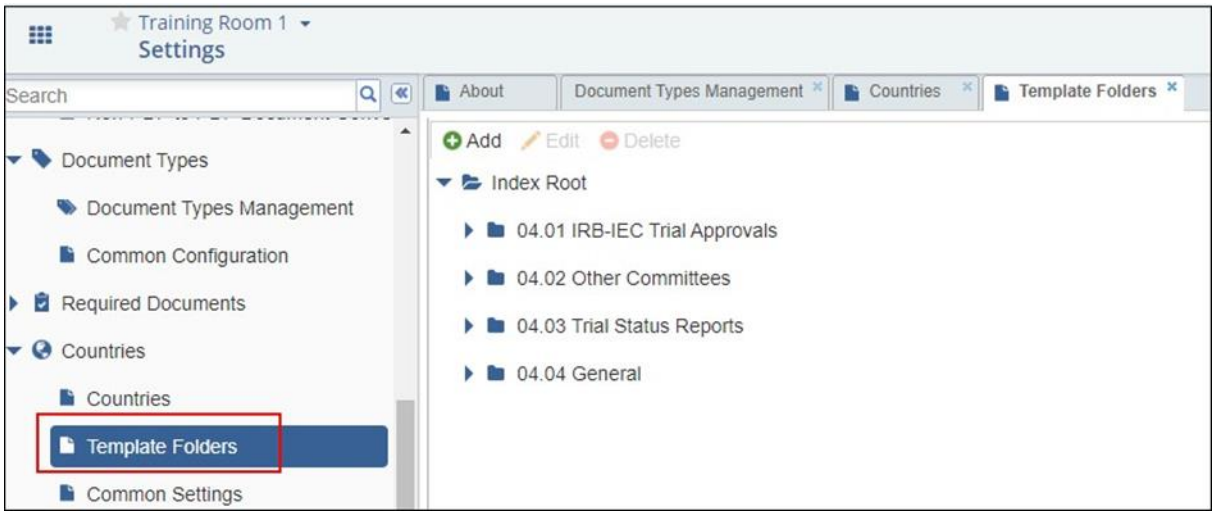
Follow the steps below to delete the countries:

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:** **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.

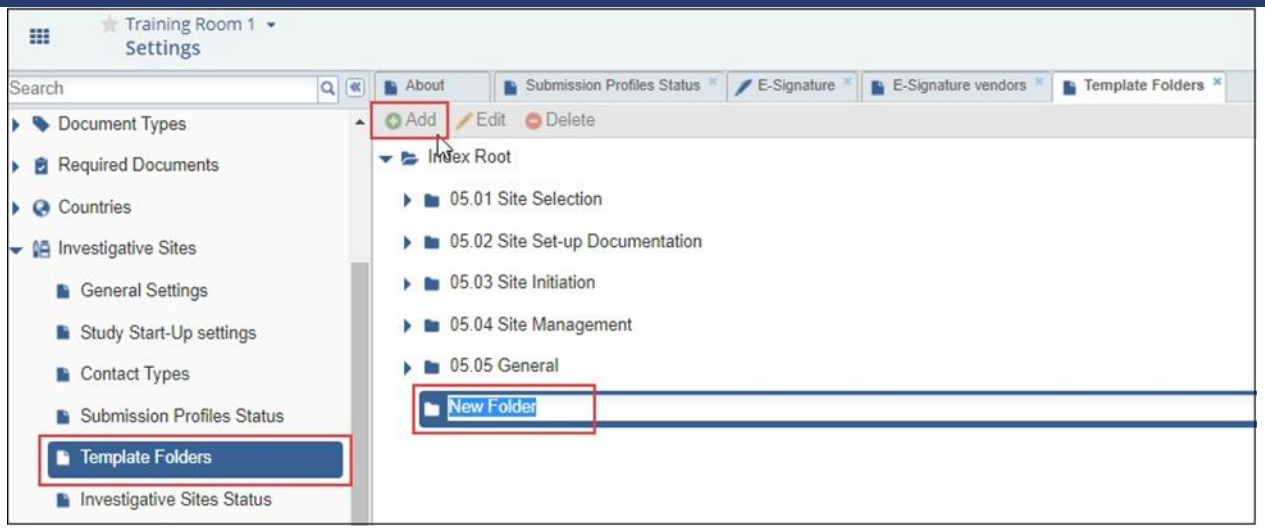


- **Note:** **The details necessary for completing this stage of the room configuration come from the Configuration Manual. The folder structure is often consistent, but it is always study specific.**

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

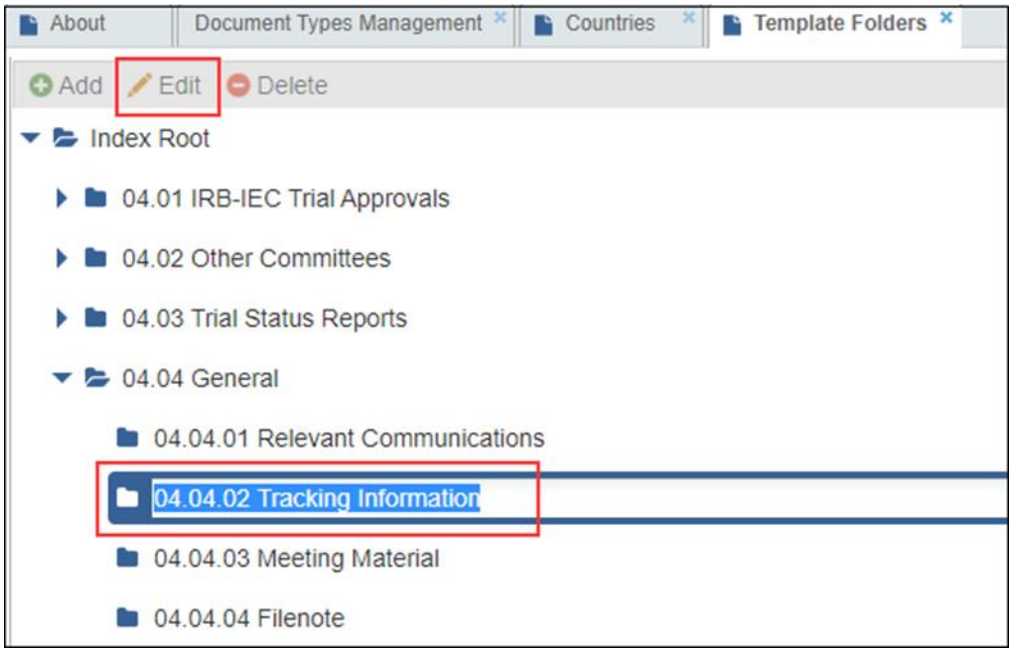
1. **To add a folder to the Index Root, first click Index Root.**
2. **Click the 'Add' button near the top of the Template Folders window. A new folder naming field opens, temporarily named New Folder.**
3. **Type the name of the new folder name in the highlighted field.**
4. **Press Enter.**
5. **Repeat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



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 will disappear from the index structure.**

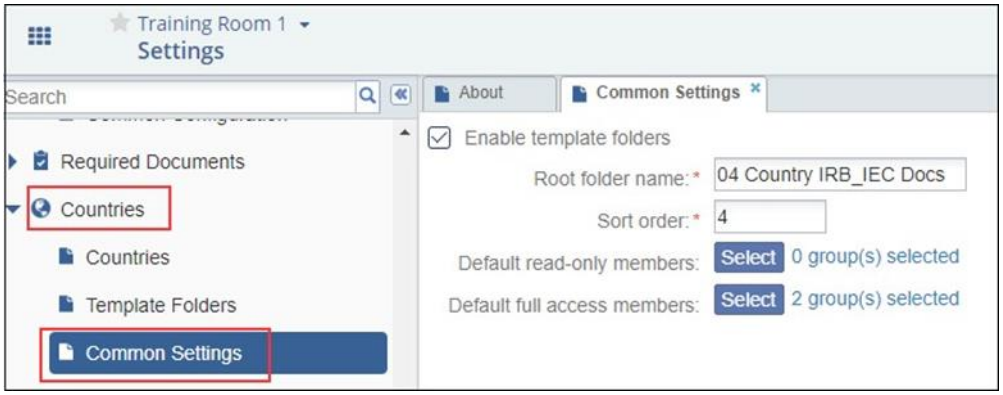
- **Note: Folders that contain subfolders or documents cannot be deleted.**

COMMON SETTINGS

In the Common Settings window, you can:

1. **Enable or disable the Template Folders.**
2. **Edit the Root folder name.**
3. **Change the Sort Order, the place in the room's index structure where the Country Management folder appears.**
4. **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:



Investigative Sites

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

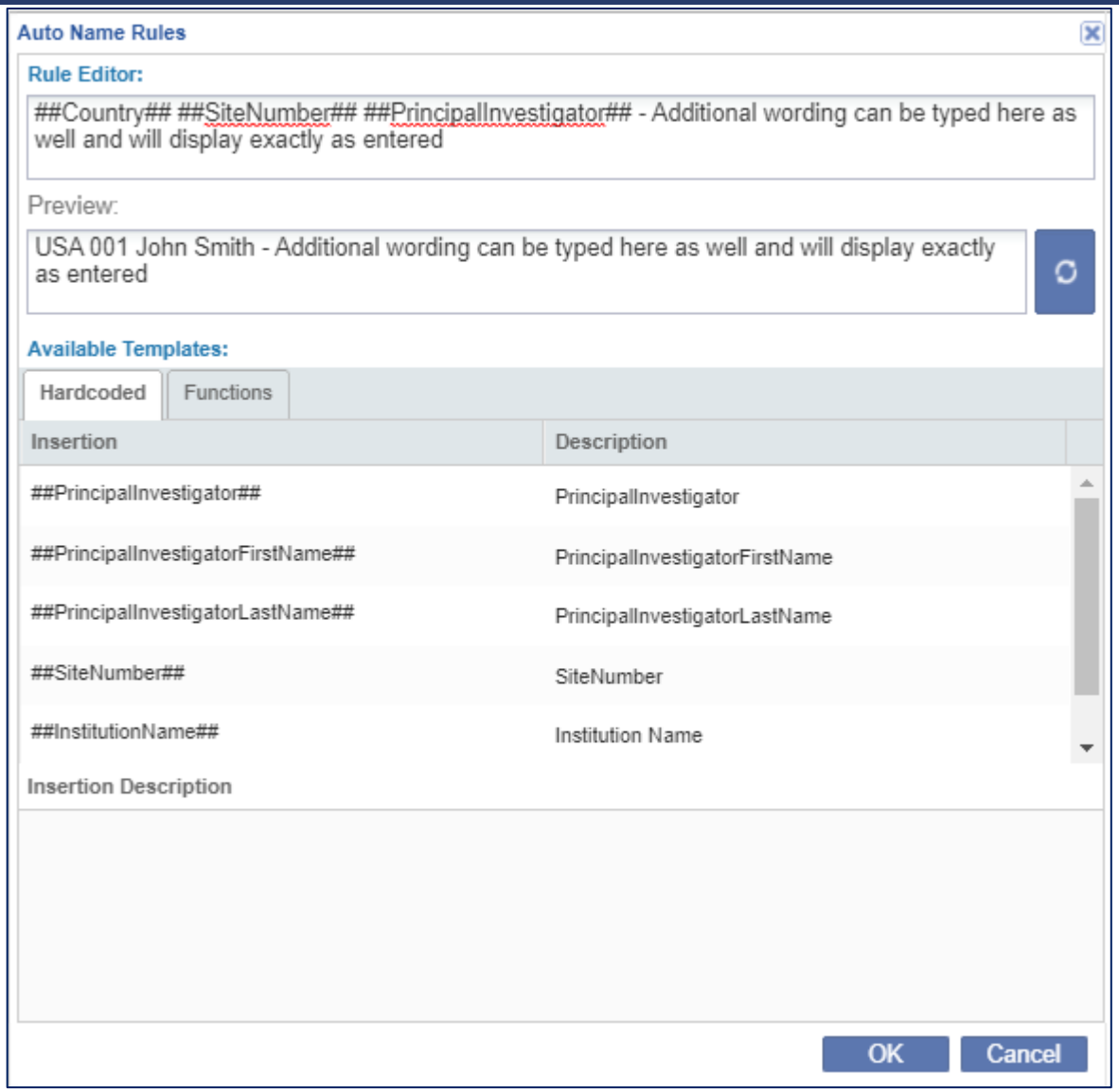
GENERAL SETTINGS

- **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.**

In order to set the general investigative site settings, follow the instructions below:

1. **Click the wrench icon to the right of the Investigative Site Naming Pattern box.**
    a. **An Auto Name Rules window opens.**
    b. **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 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:

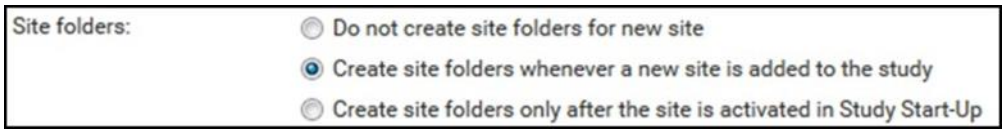


2. **Click in the Rule Editor box.**
3. **Double-click the insertions in the Available Templates box in the order in which you want them to appear in the naming pattern.**
4. **Once you have made the selections, click the blue box to the right of the Preview box to see how the folder names will appear in the room's index.**
5. **Once the naming pattern is set up correctly, click OK at the bottom of the window.**
6. **In the next available field, set the Root folder name. 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.**
7. **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.**

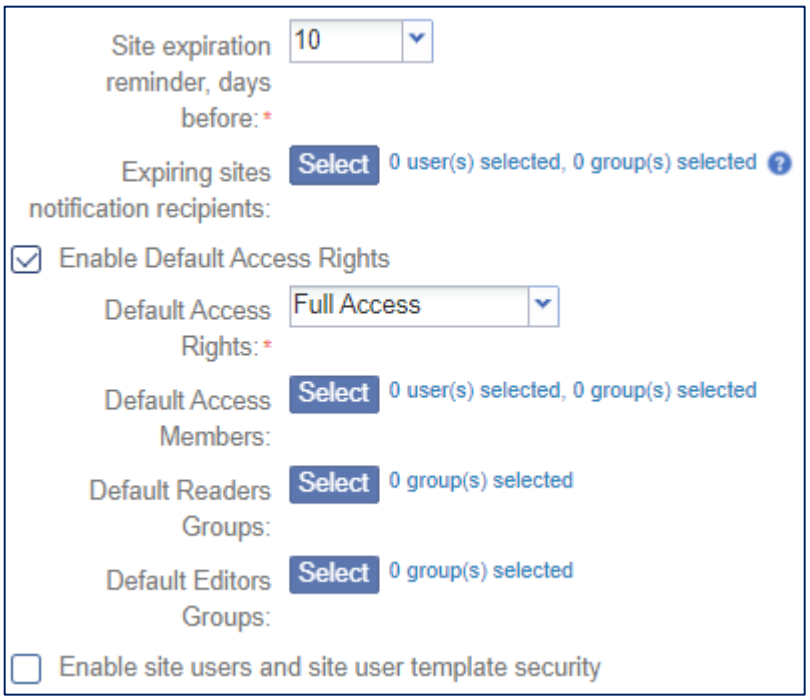
a. **Click in the field.**

b. **Type the number order where it should appear in the index.**

8. **The next area contains three radio buttons for Site folder creation in the eTMF. Click the option that fits your needs.**



- **Note: Hover the mouse over the question marks in blue circles for more information about specific options on the screen.**

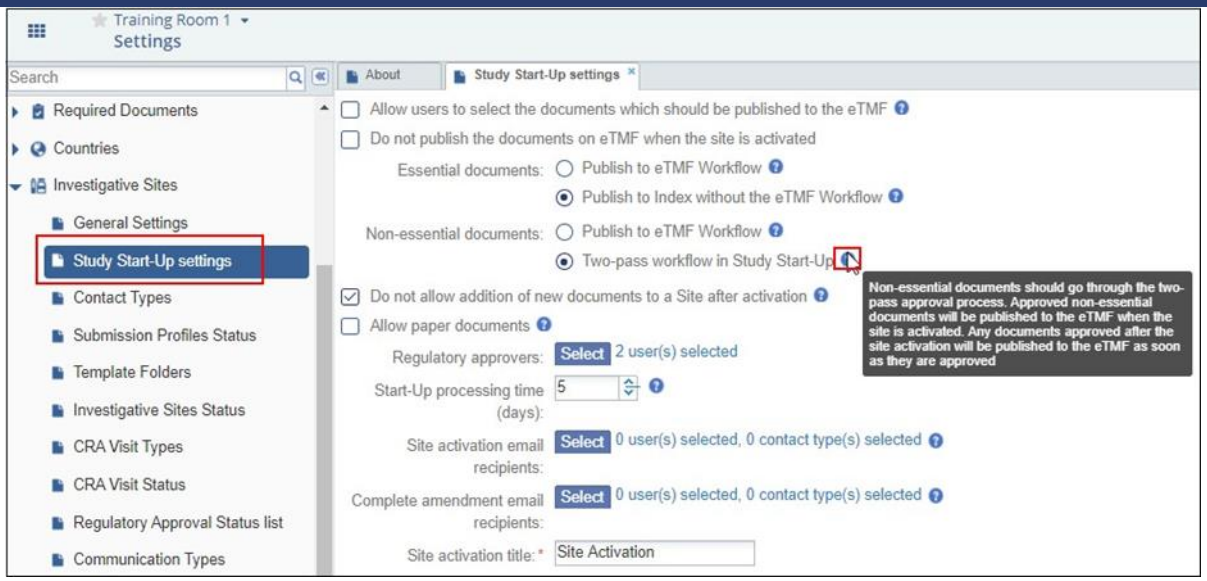


9. **The 'Enable site users and site user template security' option is most typically enabled in eISF rooms where strict site security must be maintained. For additional information on these settings, please see the section on Investigative Site Template Folders.**

10. **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. If your study room does not include Study Start Up, this menu will not appear.

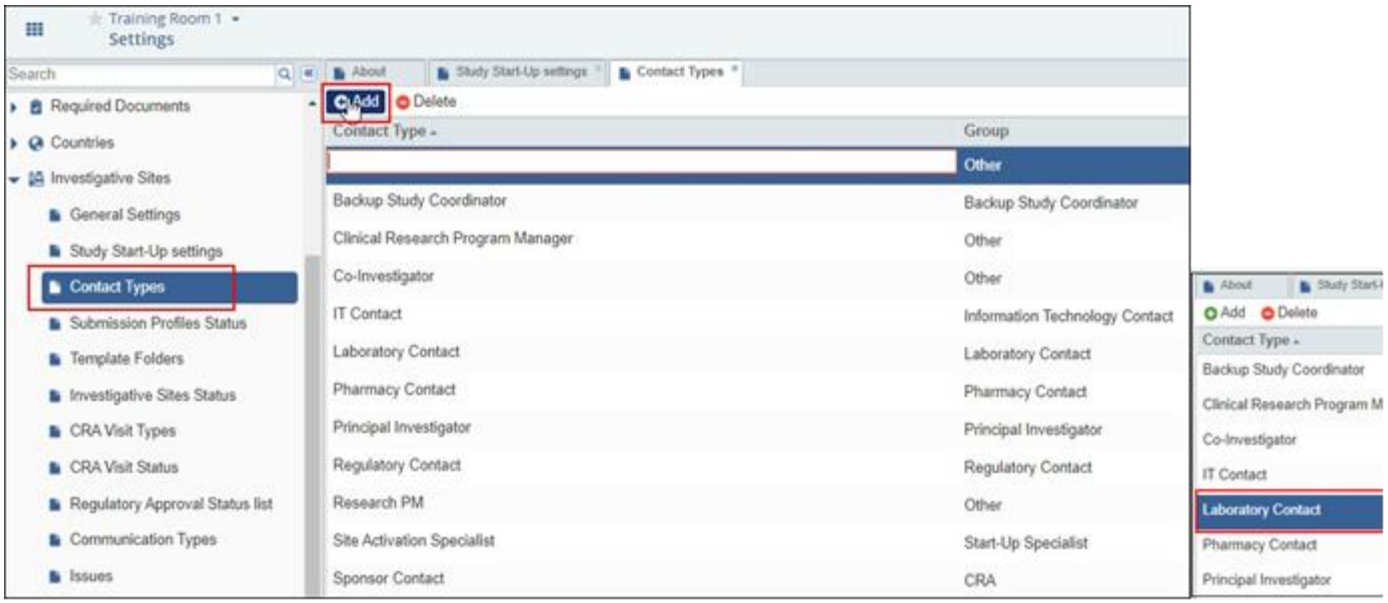


- **Allow users to select the documents which should be published to the eTMF**
  - **When this is disabled, SSU will automatically move all documents over to the eTMF upon site activation.**
  - **When this is enabled, the user who activates a site will be able to choose which documents move to the eTMF upon site activation.**
- **Do not publish the documents to eTMF when the site is activated**
  - **When enabled, SSU will not move any documents to the eTMF.**
- **Essential Documents**
  - **Essential documents are those required for site activation as indicated in the room's Required Documents settings.**
  - **These options tell the system whether or not the essential documents being moved to the eTMF should be subject to the QC Workflow or if they should be brought in as final documents.**
- **Non-Essential Documents**
  - **Non-Essential documents are those not required for site activation as indicated in the room's Required Documents settings.**
  - **These options tell the system whether these documents should be included in the SSU QC Review process or in the eTMF QC Workflow.**
- **Allow Paper Documents**
  - **When enabled, SSU will accept metadata-only entries as acceptable proof of documentation.**
- **The Regulatory Approvers are discussed more in detail in the SSU specific settings but users and groups added to this area will act as global regulatory reviewer users in Study Start Up.**
- **Site activation email recipients will receive an email whenever a site is activated in SSU.**
- **Complete amendment email recipients will receive and email whenever an amendment's documentation requirements are complete.**

CONTACT TYPES

In order to set up the Contact Types for the room, follow these steps:

1. **Click Add. The Contact Type field becomes active.**
2. **Type the contact type name.**
3. **Hit Tab or Enter.**
4. **Click the field in the Group column to make it active.**
5. **Click the far-right edge of the field to activate the dropdown menu.**
6. **Select the group title from the list.**



Additions and changes made here are saved automatically.

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.

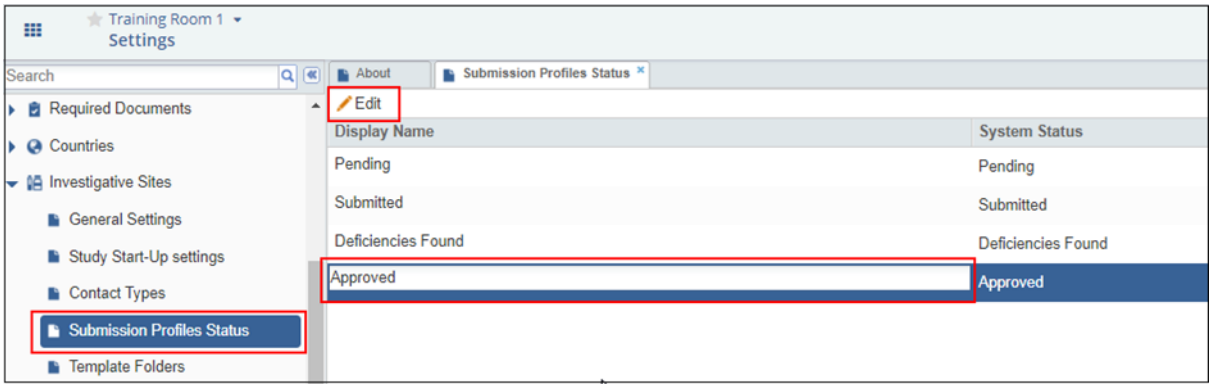
This module allows you to prepare submission profiles where the user can provide the details such as agency name, country, the status of submission, documents to be included in the submission profile, date when the package was submitted, and also the status of the submission package.

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.

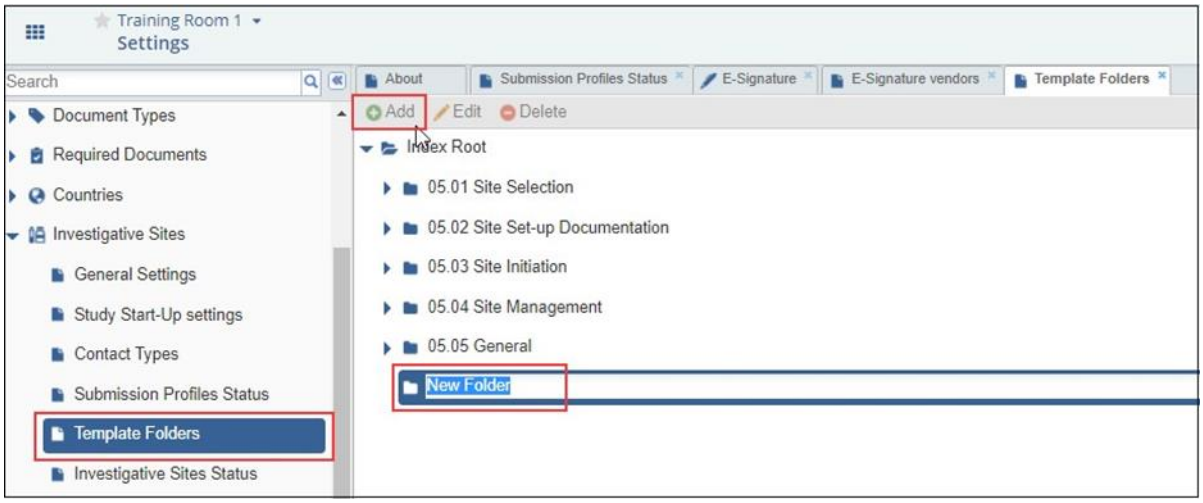
This panel provides the list of Submission Profiles and their System Statuses. The administrator may edit a submission profile by double-clicking the Display Name of a submission profile or by selecting a profile and clicking Edit from the top ribbon bar of the panel.



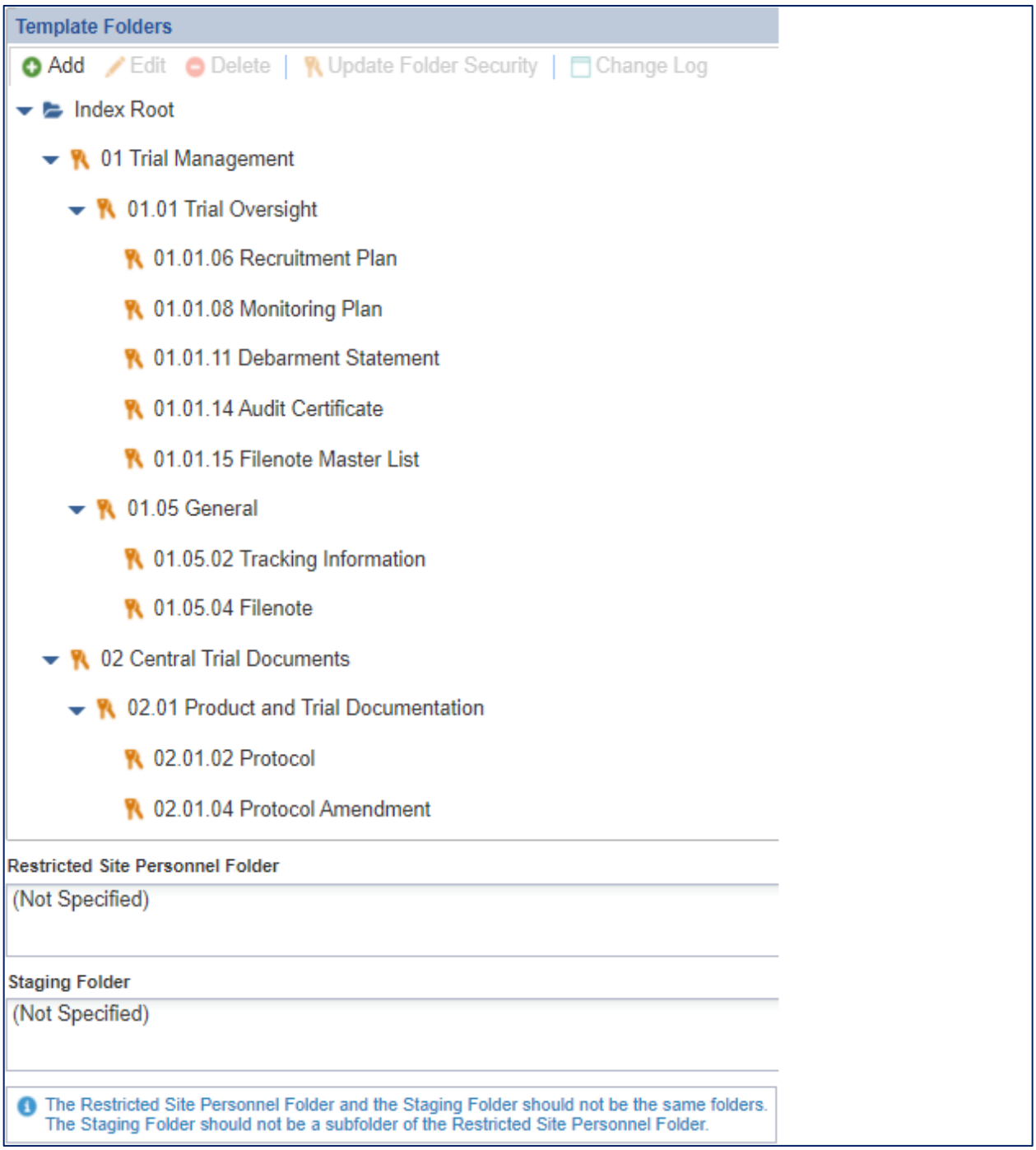
TEMPLATE FOLDERS

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 Configuration Manual.

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.**

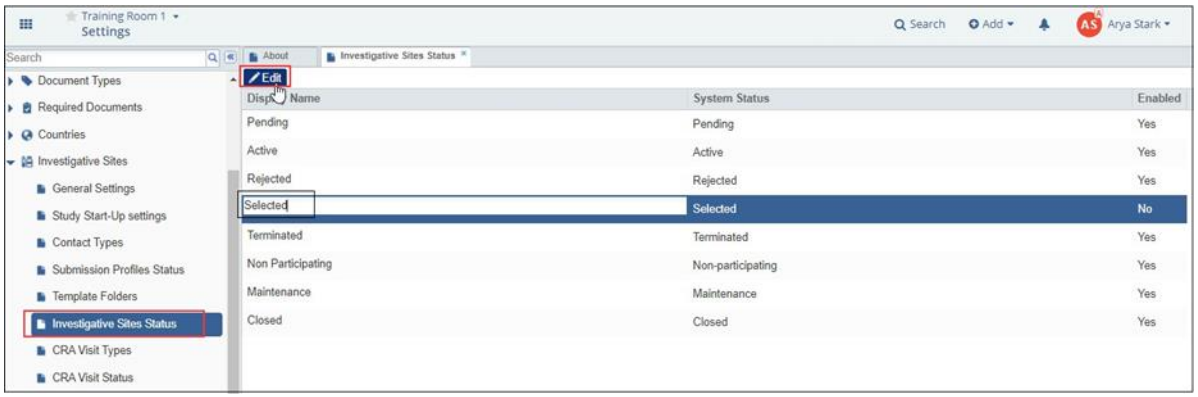


- **In eISF rooms, this is also where site folder security rules are created and maintained. These security rules are laid out in the configuration manual and should be adhered to throughout the study. If changes need to be made, please work with the Trial Interactive Service Desk.**

INVESTIGATIVE SITE STATUS

In this panel, Administrator users can edit the Display Name of the investigative site status.

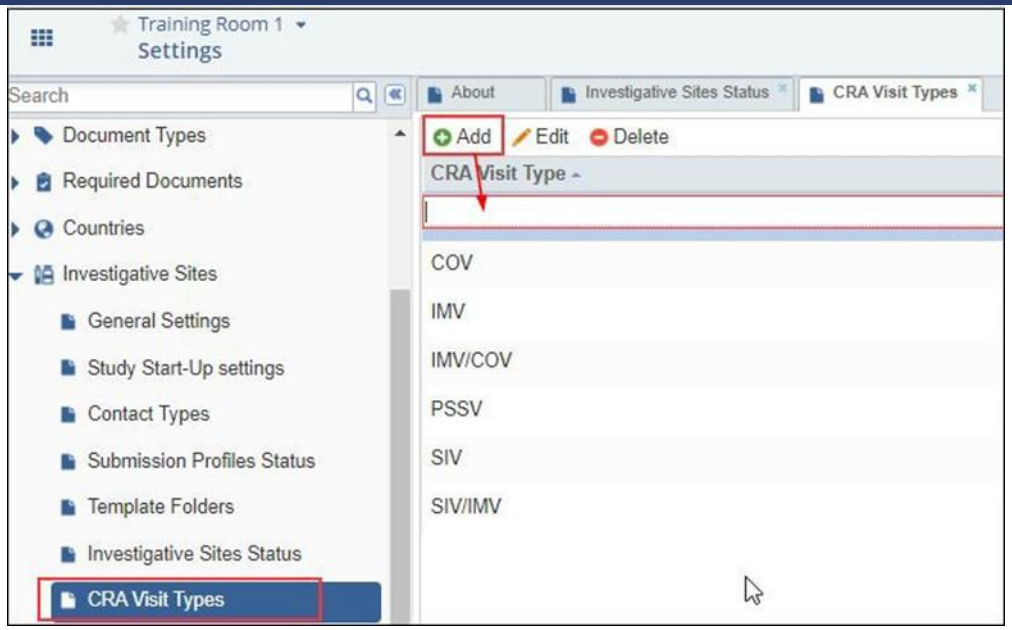
- **Click the 'Edit' button on the top or double click on the specific display name to edit.**
- **Site statuses can be enabled or disabled as well. Double click on the Yes or No entry to change the value.**



CRA VISIT TYPES

The visit types maintained in this area are available to CRA users in the CRA Reconciliation module. 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:

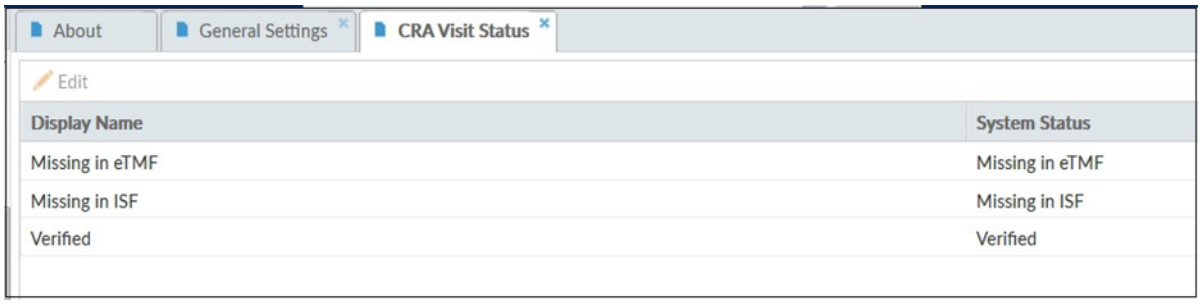
For visit types to be populated in the dropdown, as shown above, the administrator will need to create visit types in this panel.



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.**
    a. **Changes made here are saved automatically.**
    b. **These visit types automatically appear in the dropdown while creating the CRA TMF Reconciliation Report.**
3. **To edit a visit type, double-click the visit type, or select it and click the Edit button from the toolbar above.**
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:

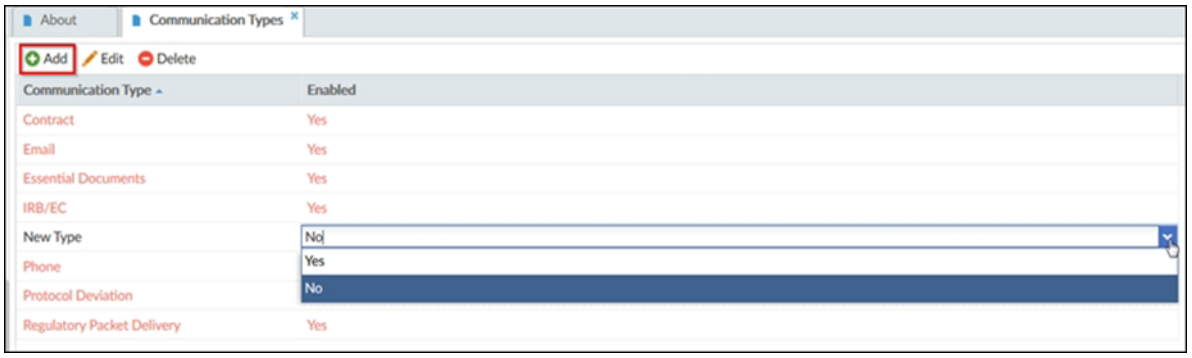


COMMUNICATION TYPES

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 menu 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:**

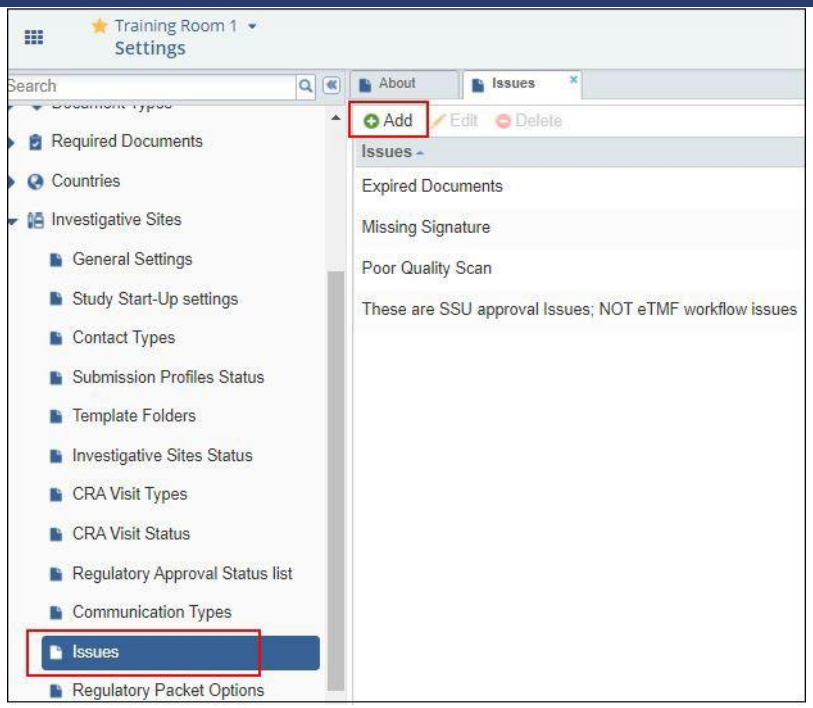


3. **To enable the label for use in the study, double-click on the value in the 'Enabled' column. The field will become active with a dropdown menu.**
4. **Click Yes to enable the use of the new label option. The change saves automatically.**

ISSUES

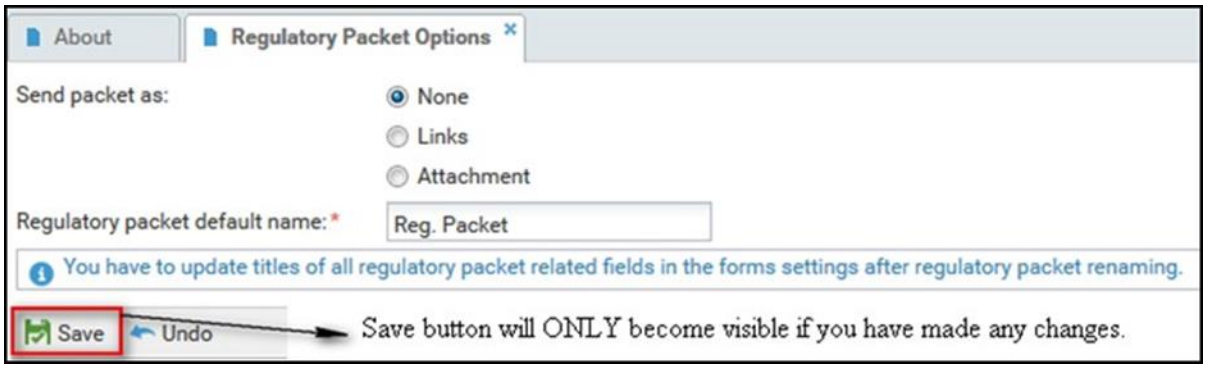
When a document going through the SSU approval process is rejected, the user who rejects the document must cite a reason for the rejection by choosing a pre-defined and named issue. The issues from which users can choose are established by Administrators.

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 menu, 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.



IRB/EC Settings

The IRB/EC organizations associated with the study will normally be identified and configured upon room creation. However, additional IRB/EC organizations can be added, edited, or deleted as needed from this menu.

In order to add a new entry, use either the 'Add' or 'Add existing' buttons. The 'Add Existing' button opens a list of organizations stored at a domain level. Simply locate the appropriate organization and press the OK button to add them to the room list.

The 'Add' button opens an interface for creating a new entry. Complete all required fields, as well as any available optional information, and press OK to create the new record in the room list. Some of the more advanced predictive reporting features of Study Start Up are dependent upon the non-required fields listed in the window as the allow the room to predict site activation based on the approval cycle, buffer time, etc. associated with the approving organization.

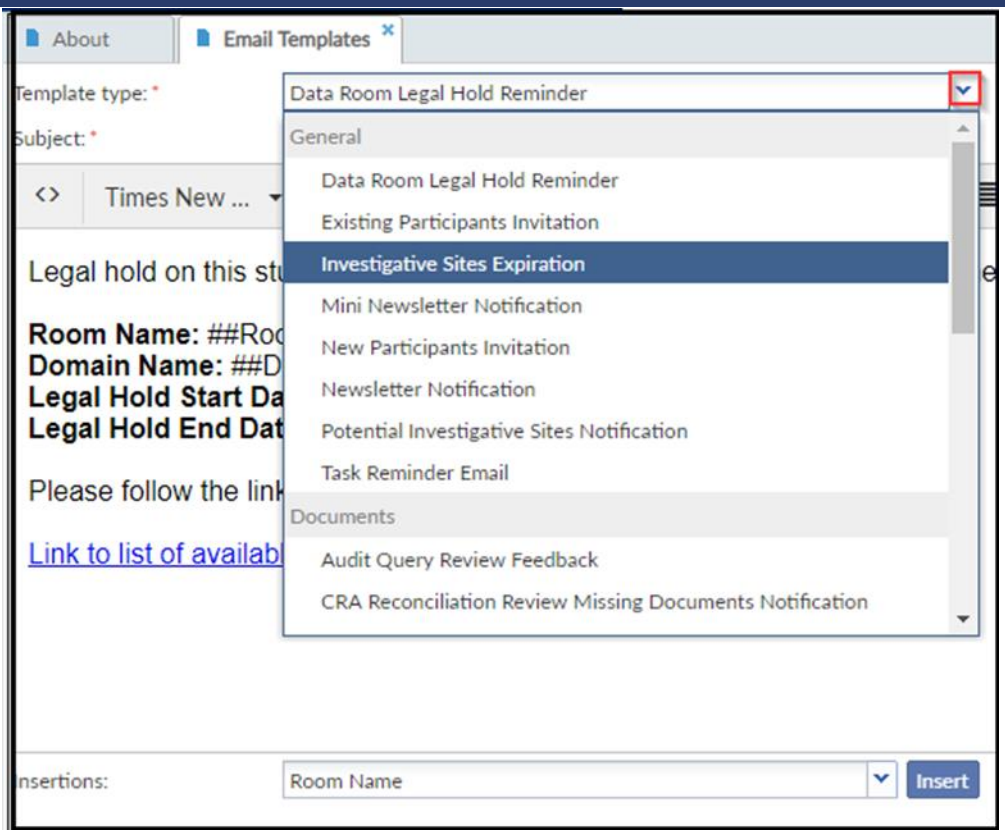
Email Settings

EMAIL TEMPLATES

Generic email templates are preloaded for a room when the room has been cloned. Follow these instructions to make changes to any of the email templates.

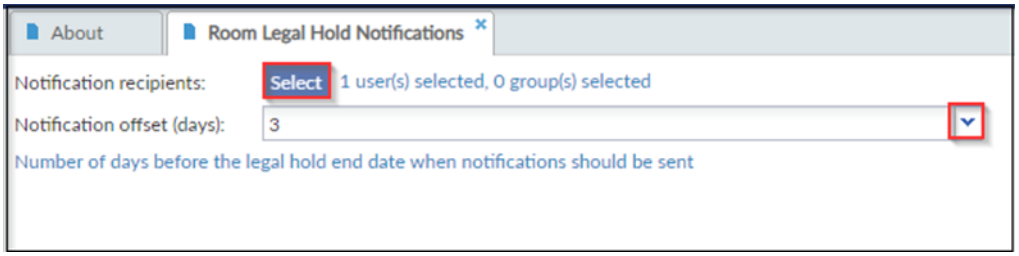
1. **Select the Template type from the dropdown menu.**
2. **Edit the fields as appropriate.**
3. **Click Save.**

Refer to the screenshot below:



ROOM LEGAL HOLD NOTIFICATIONS SETTINGS

- **<u>Note:</u> Super Administrator users from the TI Service Desk can put a Legal Hold on Rooms when required.**

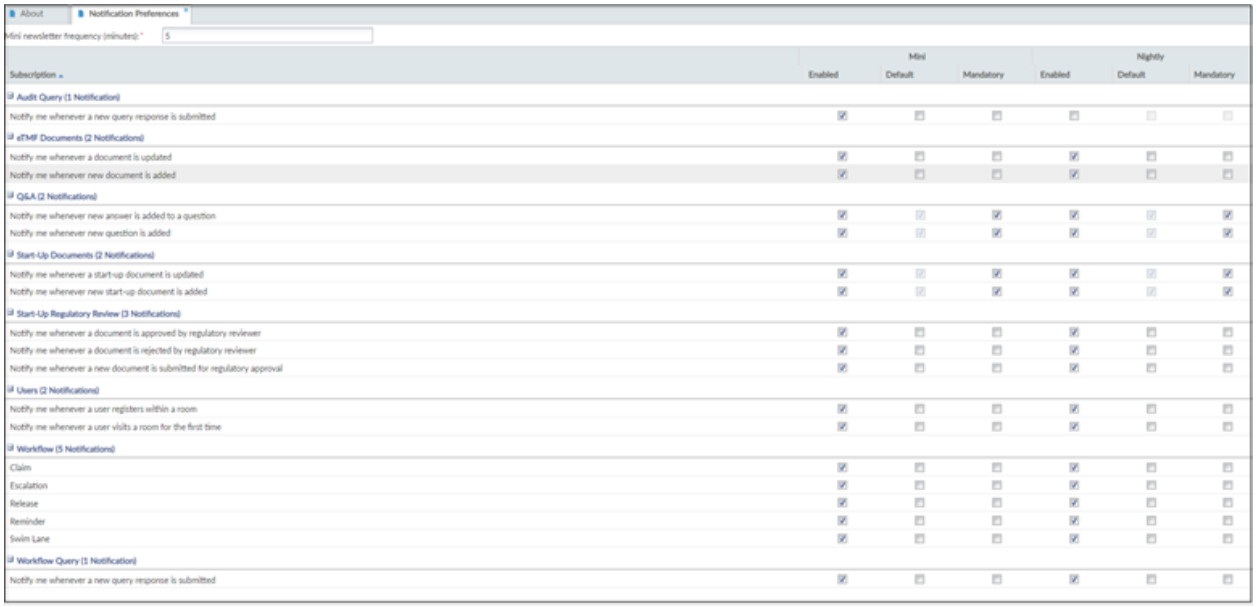


1. **Click Select to set up the users who will be notified when a room is put on legal hold. Refer to the screenshot above.**
2. **The notification recipients window opens for you to select from the list of Users.**
3. **Select the number from the Notification offset (days) dropdown. It will decide the 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.**

NOTIFICATION PREFERENCES SETTINGS

The Notifications settings section allows users to specify the email notifications they would like to enable for the study room.

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:**
  - **<u>Enabled:</u> This enables users to subscribe to related notification.**
  - **<u>Default:</u> This subscribes all users to the related notification by default but with the possibility to unsubscribe.**
  - **<u>Mandatory:</u> All users get automatically subscribed without the possibility to unsubscribe.**

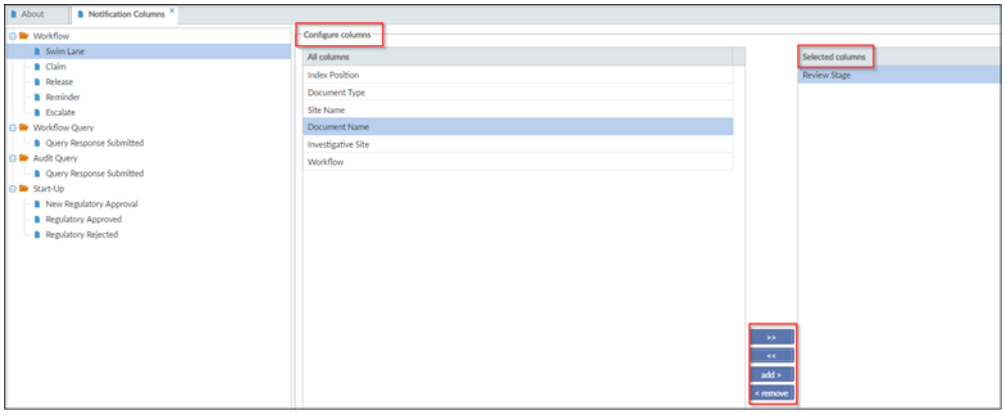
NOTIFICATION COLUMNS

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

The Notification Columns are available for the following categories:

- **Workflow**
- **Workflow Query**
- **Audit Query**
- **Start-Up.**

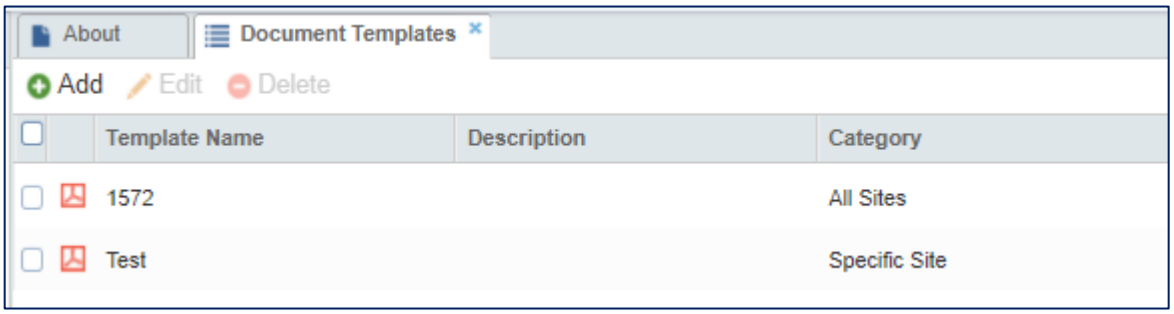
Refer to the screenshot below:



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.**

Document Template Settings

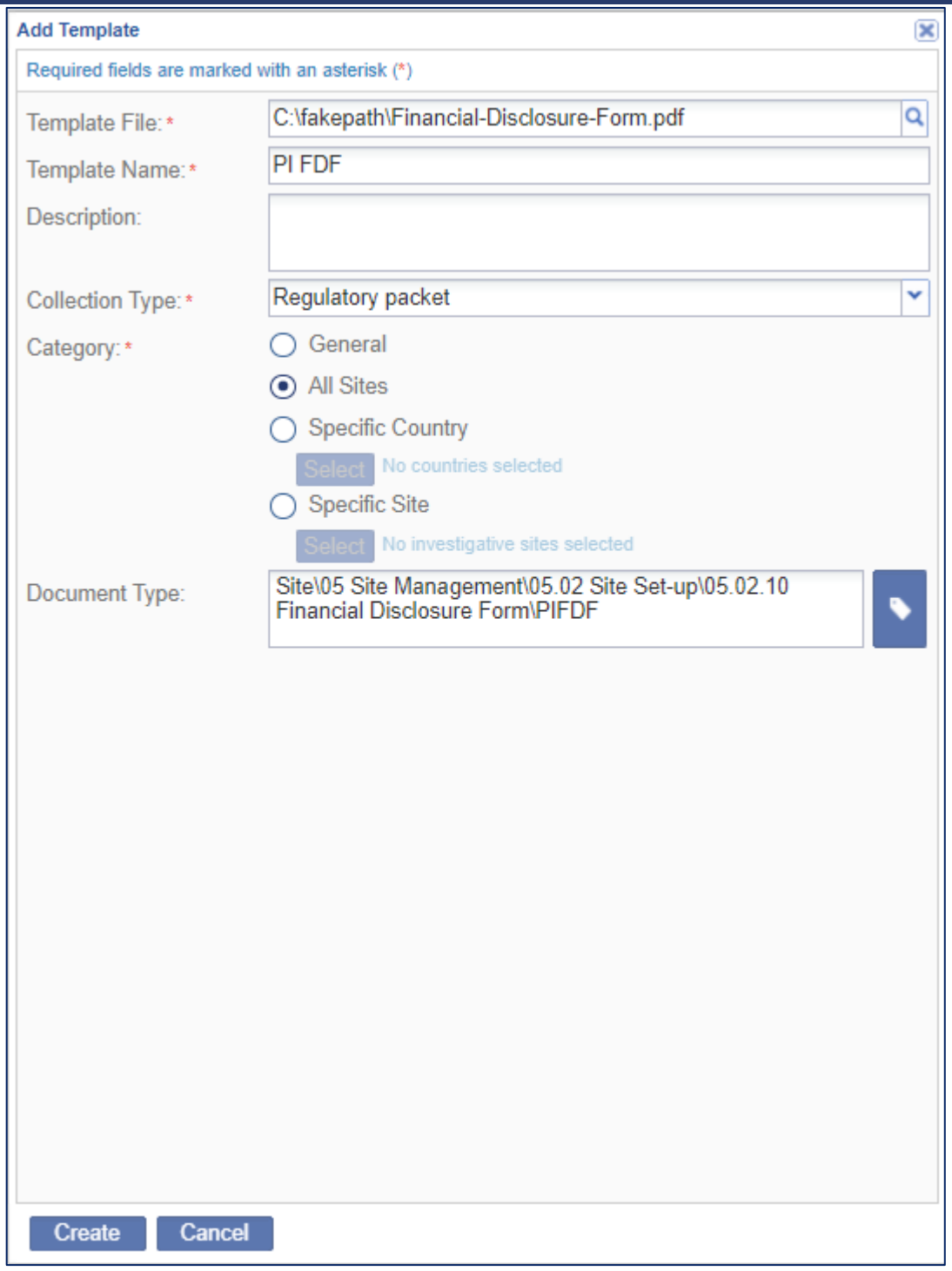


In Document Templates settings, Administrator users can add, edit, and delete document templates. Templates here refer to documents that can be used as a source document. Therefore, users can keep a library of template documents with multiple versions (for example, one version in French and one version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

Follow the instructions below to add a new template document:

1. **Click on the 'Add' button above the grid area.**
    a. **This will open the Add Template window.**
2. **Upload the relevant file.**
3. **Give the template document a name.**

4. **(Optional) Give the template a description.**
5. **Assign a Collection Type to the document using the dropdown menu.**
    a. **<u>General:</u> This is more applicable to Collaborate or Docs type rooms where new SOP documents are created, reviewed, and approved.**
    b. **<u>Regulatory Packets:</u> This is applicable to rooms where SSU is enabled. Choose this option if this document should be sent out with the regulatory packet.**
    c. **<u>Monitoring visits:</u> This option is appropriate for Collaborate rooms integrated with our CTMS solution. These files can be used in generating documents related to monitoring visits as created and planned in the CTMS.**
6. **(Optional) Choose the appropriate document type.**
7. **When you have entered all required information, press the 'Create' button.**



Reports Settings

HEATMAP SETTINGS

Trial Interactive has the ability to display cross-room metrics in the KPI Dashboard, accessible from the Home screen.

The KPI heatmap is color coded so that metrics which are out of the acceptable range are highlighted. The values

associated with those metrics are controlled here. Double click on any setting to edit the value.

Target Period (in days): * 10

Heatmaps	Green		Yellow		Red	
	min	max	min	max	min	max
Under Clarification Documents	0	5	6	10	11	100
Published Documents	95	100	90	94	0	89
Rejected Documents	0	5	6	10	11	100
Resolved Queries	95	100	90	94	0	89
Pending Queries	0	5	6	10	11	100
In-Progress Queries	0	5	6	10	11	100
Deleted Documents	0	2	3	5	6	100
Documents Published within Business days cycle time	90	100	80	89	0	79
Documents Published outside Business days cycle time	0	10	11	20	21	100
Documents Published outside Business days cycle time with Queries raised	0	10	11	20	21	100
All Documents (Published & In-Progress) outside Business days cycle time	0	10	11	20	21	100
Documents Passed In Quality Review	95	100	90	94	0	89

Workflow Settings

In Workflow Settings, Admins set up important details like workflow statuses, issues in the workflow, timeline, and members of the workflow group. The workflow configuration is laid out in the room's configuration manual and is set up upon room creation. It is *highly* recommended that any changes to the room's workflow settings should be done by the Trial Interactive Service Desk.

It should be noted that there are some functions associated with the workflow which are not available to users below the level of Super Administrator (Service Desk Personnel) and that attempts to alter a room's workflow without the appropriate training and access may result in the loss of data and documentation or the unintentional exclusion of documents from the QC workflow.

To access the Quality Control Settings:

Navigate to the Navigation Grid → Settings → Workflows.

COMMON SETTINGS

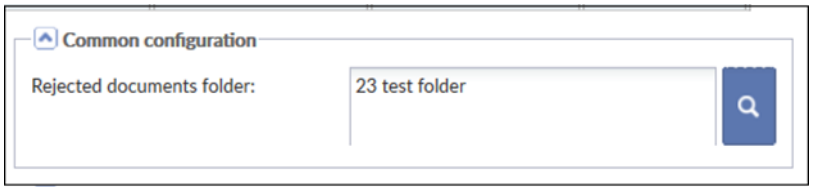
Admin can adjust the following in the Common Settings area:

- **Common Configuration**
- **Default Ranges Configuration**
- **Timeline Configuration**
- **Issue Email**

- **Rejection Email Configuration**
- **Query Reminder Configuration**
- **Auto-Claim Configuration**

Workflow Common Configuration

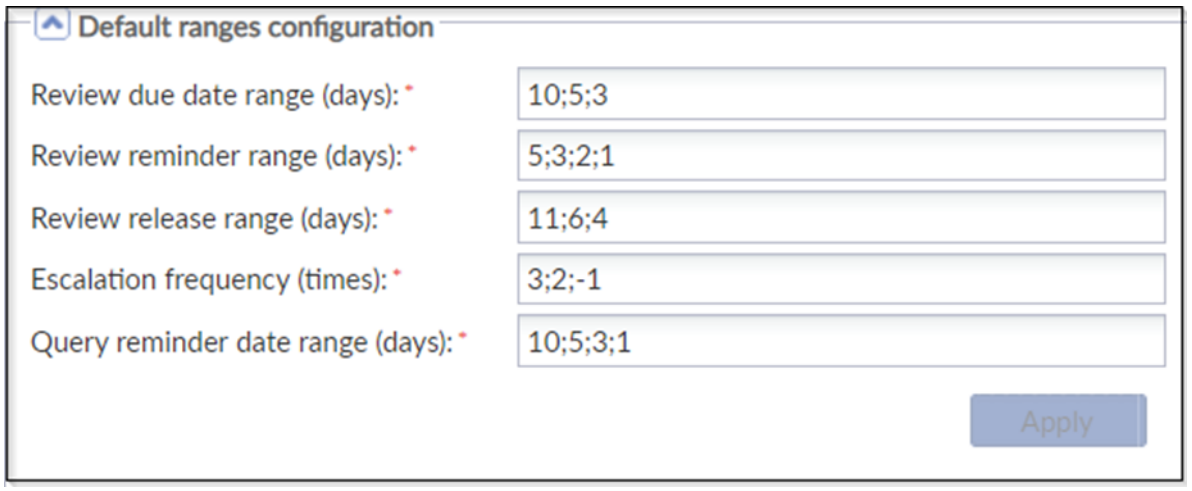
Rejected Documents folder: Here, you specify the folder and its index number that will hold the documents when they are rejected during the review.



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 will serve to populate the related dropdown menu during workflow creation, and you may choose a value as appropriate.**

Refer to the screenshot below:



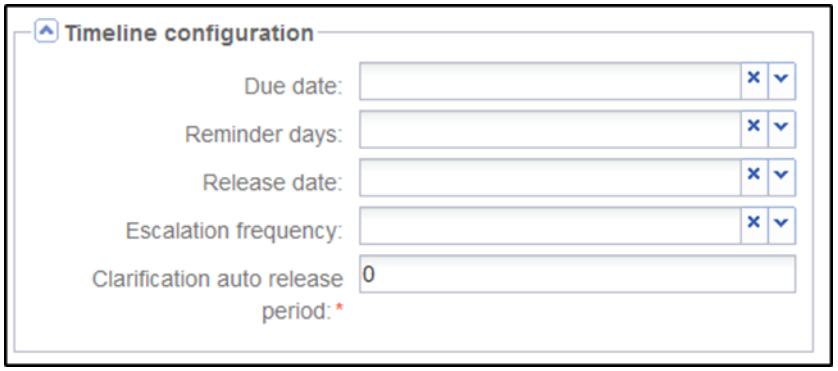
Each field above is editable, you can enter the values separated by a semi-colon.

1. **Review due date range (days).**
    a. **Here you specify the days when the review would be due after claiming the documents for review.**
    b. **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.**

2. **Review reminder range**
    a. **Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.**
    b. **If multiple values are specified, all of them would be populated in the dropdown during workflow creation, and you may select multiple values as required.**
    c. **In the screenshot above, the Reminder schedule is 5;3;2 which means:**
        i. **the reviewer will receive reminders 5 days before the due date,**
        ii. **then 3 days before the due date,**
        iii. **and then 2 days before the due date if the reviews are pending.**
3. **Review release range days**
    a. **Here you specify the days after the claim when the documents would be automatically released from the reviewer's claim list.**
    b. **The Auto release date is always greater than the due date.**
    c. **It will not allow you to select a value less than the due date.**
4. **Escalation frequency**
    a. **Escalations are reminders about not completed reviews.**
    b. **During workflow creation, an escalation group needs to be specified who will receive notifications about escalations.**
    c. **Here, you specify the timeline for escalation notification frequency.**
5. **Query reminder date range**
    a. **If the user does not respond to a query with a document, reminder emails are sent to the query recipients on the nth days as specified here.**
    b. **So, if the setting is 10; 5; 3 reminders will be sent on the 10th day, 5th day, and the 3rd day.**

<u>Timeline configuration:</u>

Refer to the screenshot below:



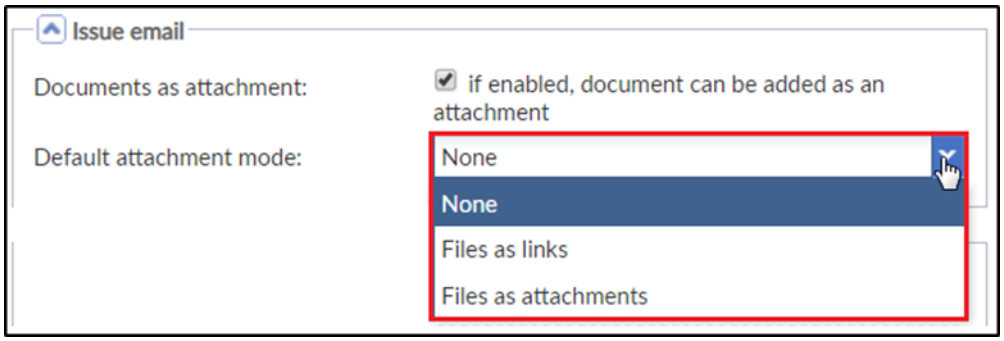
- **If you specify values in the timeline, the values will be automatically set for you at the time of workflow creation.**
- **If you happen to change your mind at the time of creation, you may select values as required as opposed to that**

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:

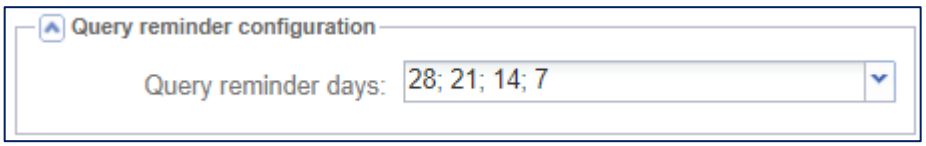
1. **From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session. Refer to the screenshot below:**



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.**

Query reminder configuration:

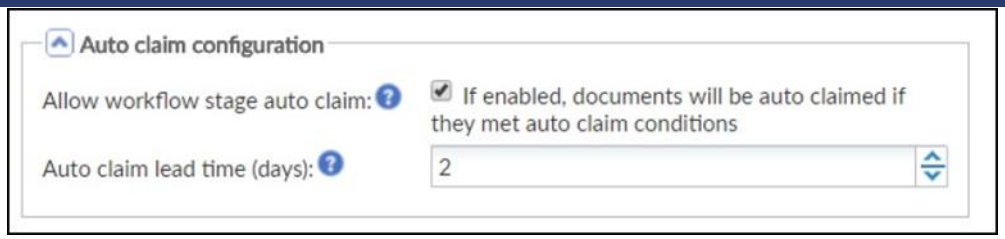
From here, room Administrators can configure a schedule by which reminder emails will be sent. Refer to the screenshot below:



Auto claim configuration:

- **Note: If there is only one reviewer in a workflow the documents will be auto-claimed by the system and assigned to the lone reviewer for review.**

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



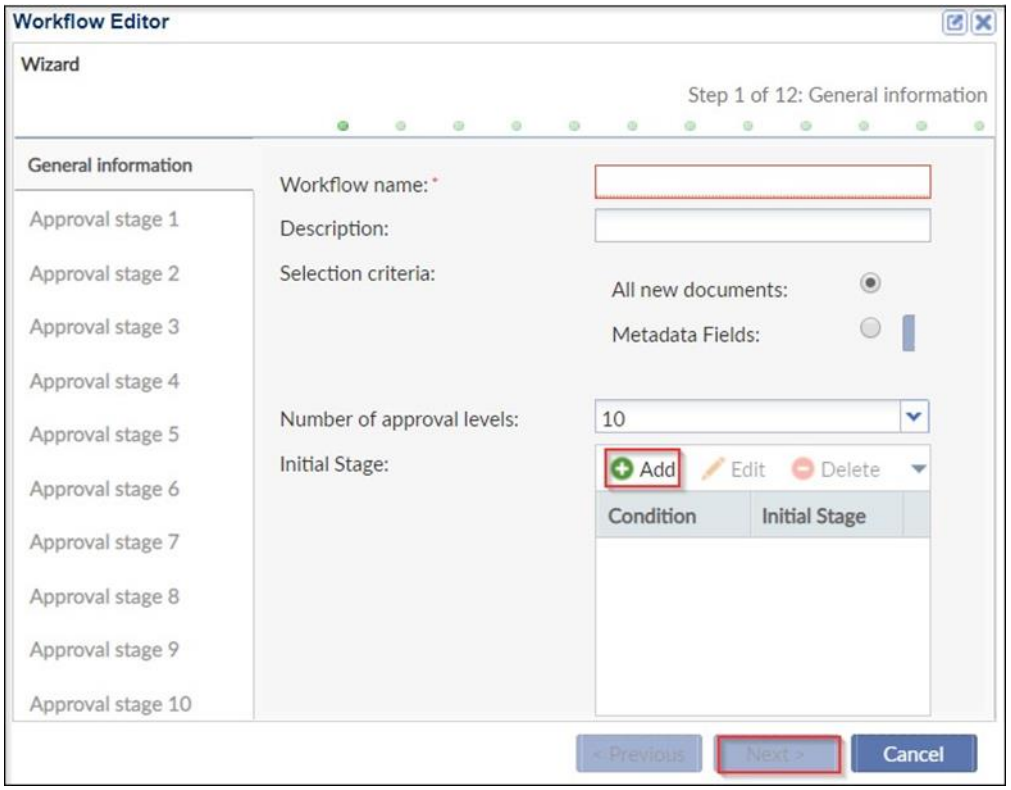
1. **Tick the checkbox next to Allow workflow stage auto claim.**
2. **Enter the number of days after which if the reviewer has not claimed the documents, they will be auto-claimed by the system and assigned to the reviewer.**

CREATING THE QUALITY CONTROL WORKFLOW

To create a Quality Control workflow follow the procedure below:

1. **Click the Add button from the grid.**
    a. **The Workflow Editor window will open.**

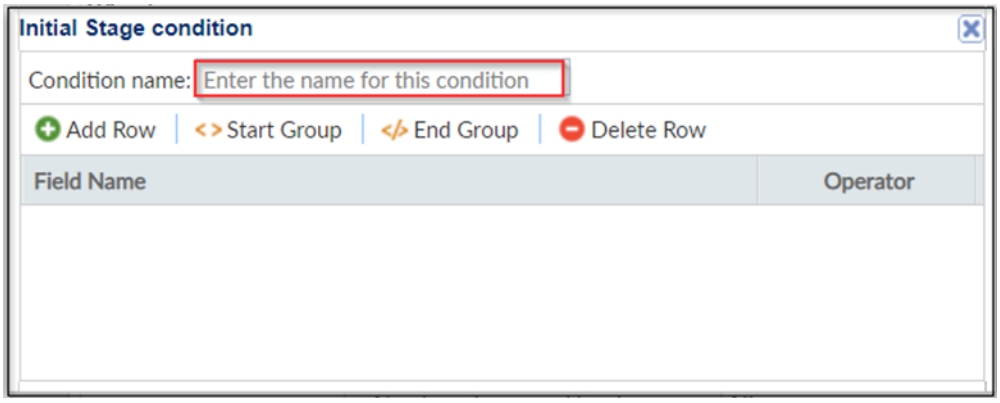
    Refer to the screenshot below:



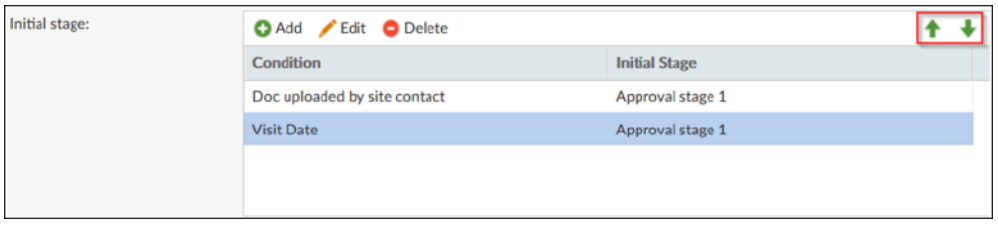
2. **Enter the Quality Control Workflow name and Description.**
3. **The Selection Criteria could be All new documents or only those Metadata fields that need to be reviewed.**

Refer to the screenshot above.

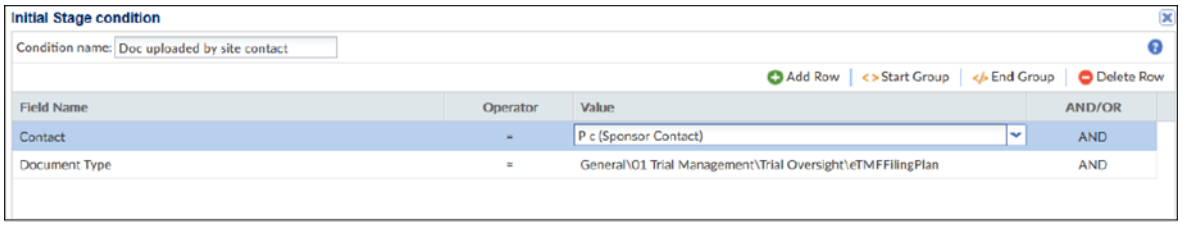
4. **Select the workflow levels, i.e. QC1, QC2, etc.**
5. **You may apply a condition to select documents for review as per a particular condition. Click 'Add' to add a condition from the Initial Stage box. Refer to the screenshot above.**
6. **The Initial Stage Condition window opens. Refer to the screenshot below:**



1. **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:**

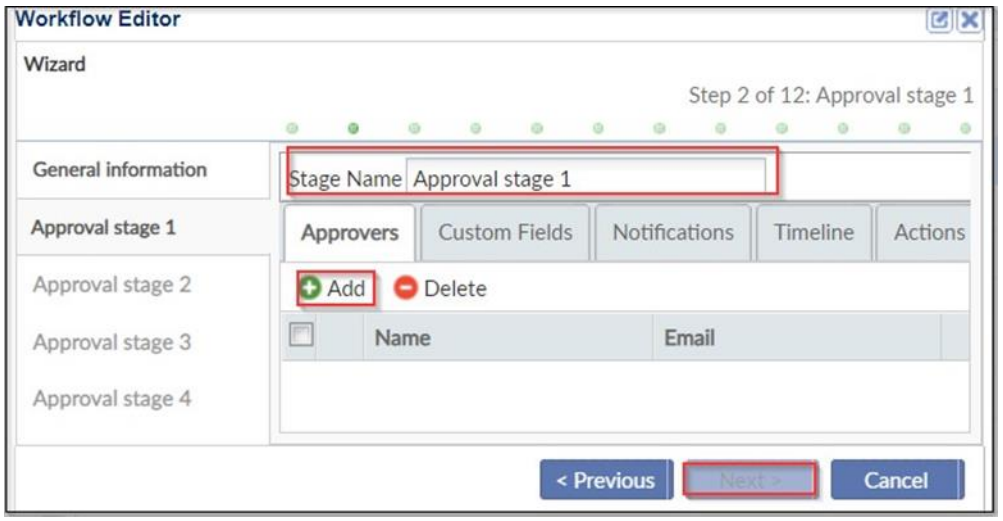


2. **As per the screenshot above, documents uploaded by the site contact on a particular site visit date would be added to the workflow. The details of each condition are as below:**



3. **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.**
4. **Click Next. This leads you to the configuration wizard of the first stage of the workflow. Refer to the screenshot**

below:

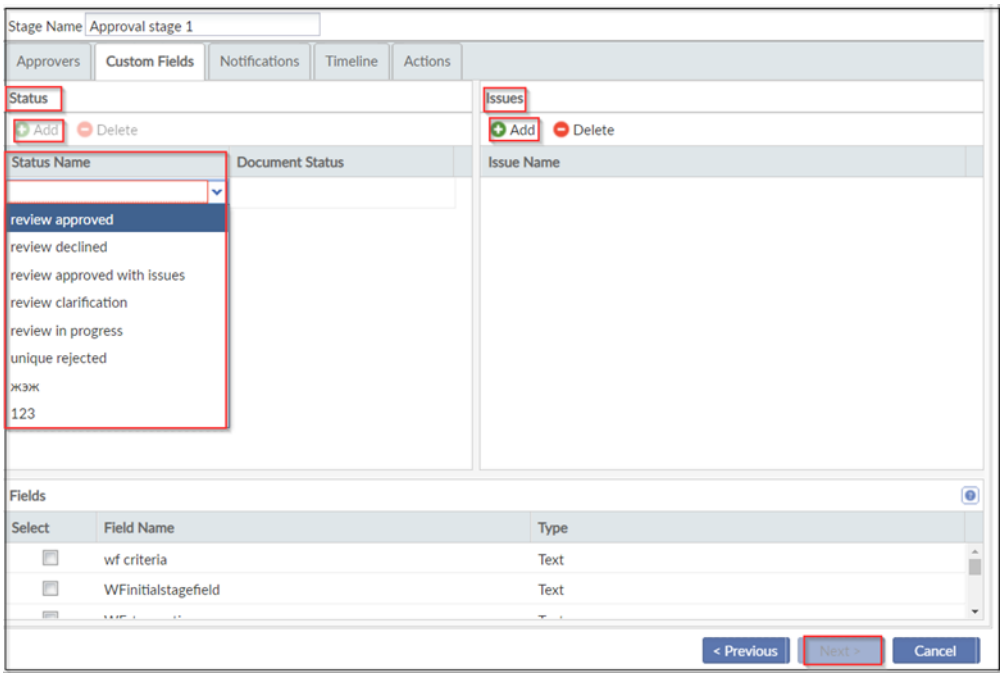


5. **Change the Stage Name, if desired. Click the Approvers tab. Refer to the screenshot above.**

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

- **<u>Note:</u> It is recommended to add a Group to save configuration time.**

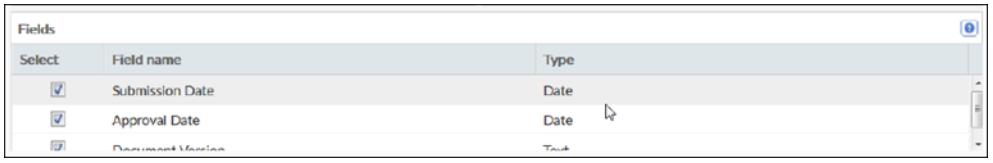
7. **Click the Custom fields tab. This is a required tab and Statuses, and Issues must be added. Refer to the screenshot below:**



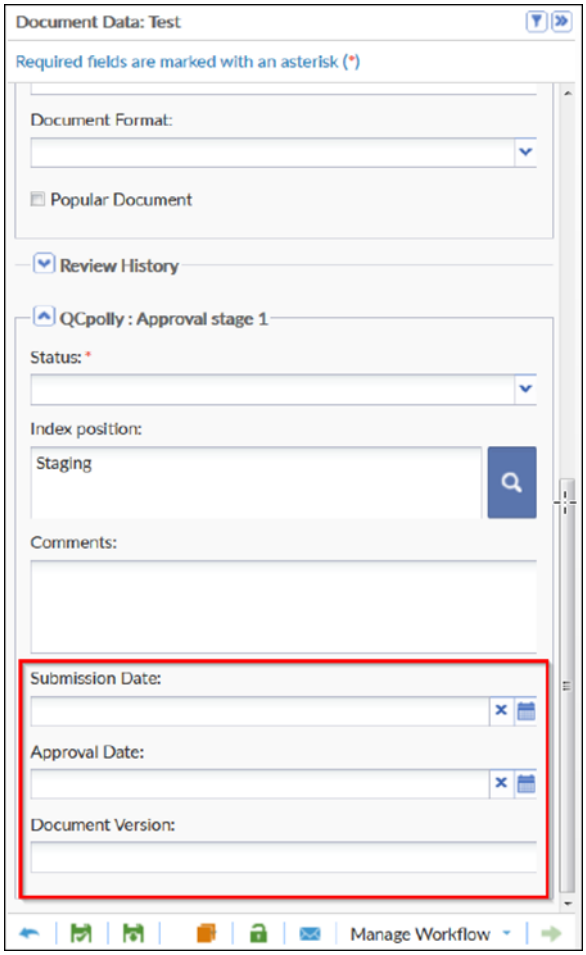
The statuses are the ones previously created. Click 'Add' to add the first status and select the document status from the

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.

8. **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.**
9. **To make metadata fields, as required, available for a workflow configuration, proceed to Forms Settings and select the Workflow Fields, as required.**
    a. **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:**



    b. **These checked fields will appear in the Review panel of a document in the eTMF/ Documents module once a document is claimed for review.**
    c. **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.**



10. **Click the Notifications tab.**
    a. **Here, you can allow for email notifications to be enabled for the event names listed.**
    b. **For users who want to be notified only in case of Claim, Release, or Escalation, groups can be added accordingly.**
11. **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.**
12. **Actions is an optional tab allowing for complex workflow building.**
    c. **It enables a workflow to have a jump. A specific document can jump to a certain stage.**
    d. **For example, a Form FDA 1572 after QC1 review, can jump to a stage 3 review, where Regulatory Affairs perform a 2nd review on the document.**
    e. **While efficient for complex workflows, it is not required for regular workflows creation.**
13. **Click Next when all tabs have been reviewed.**
    f. **Repeat similar steps for each stage of approval.**
    g. **Settings may change per approval stage, like approvers, notifications, and timelines.**
14. **When finished, click Next.**
15. **The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If there are no errors, click Finish when done.**

EDITING AN EXISTING WORKFLOW

- ***CAUTION:*** **Editing of an existing workflow should be executed with caution because any saved changes require a new and revised workflow to be created.**
  - **Because of this, it is effectively impossible for any user below the level of Super Administrator to edit an existing workflow.**
  - **If you require edits to your workflow, please reach out to the TI Service Desk.**

DELETING AN EXISTING WORKFLOW

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

Deleting an existing workflow will result in the removal of any related status from documents previously processed as a part of the deleted workflow.

QUALITY CONTROL REVIEW STATUS

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

- **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.**

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.**
3. **Make the required changes.**
4. **Double click the System Status field, click the dropdown arrow, and select the System Status from the list.**

Deleting Review Status

1. **Select the required Review Status to be deleted.**
2. **Click Delete.**

Security

- **Note: Most of the room's Security Settings are established at the outset of a study and go unchanged throughout the study. When making any changes to a room's Security Settings, please communicate them to the Project Manager for inclusion in the Change Log.**

GENERAL SECURITY SETTINGS

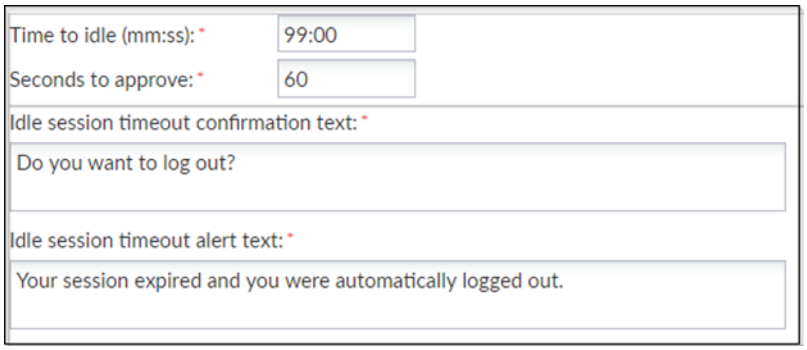
From here you can perform the following functions:

- **Logout Timer Configuration**
- **Invite Participants Settings**
- **Redaction Settings**
- **Actions Settings**

- **PDF Watermark Options Settings**
- **Document Viewers Settings**
- **Document Encryption Options**
- **Confidentiality Agreement Settings**

Logout Timer Configuration

Room administrators can set a Logout Timer from the room settings. Refer to the screenshot below:



1. **Adjust the time a user can remain logged in without being active in the study room.**
2. **You can also adjust the Seconds to approve field. This is the amount of time a user has to respond to the Idle session timeout confirmation message.**
3. **Enter the message that the user sees on the screen when the user is automatically logged out due to an idle session in the Idle session timeout alert text.**
4. **Click Save after any changes or Undo to revert back any changes made.**

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:

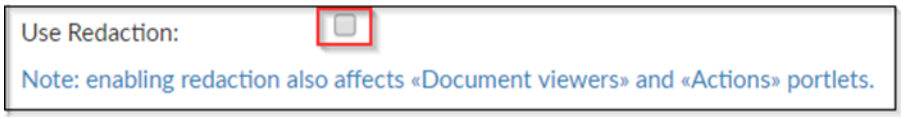
1. **Click the Use PIN checkbox.**
2. **Enter a Registration PIN.**
3. **Click Save from the bottom of the grid to save the changes made.**

- **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.**

Redaction Settings

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

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

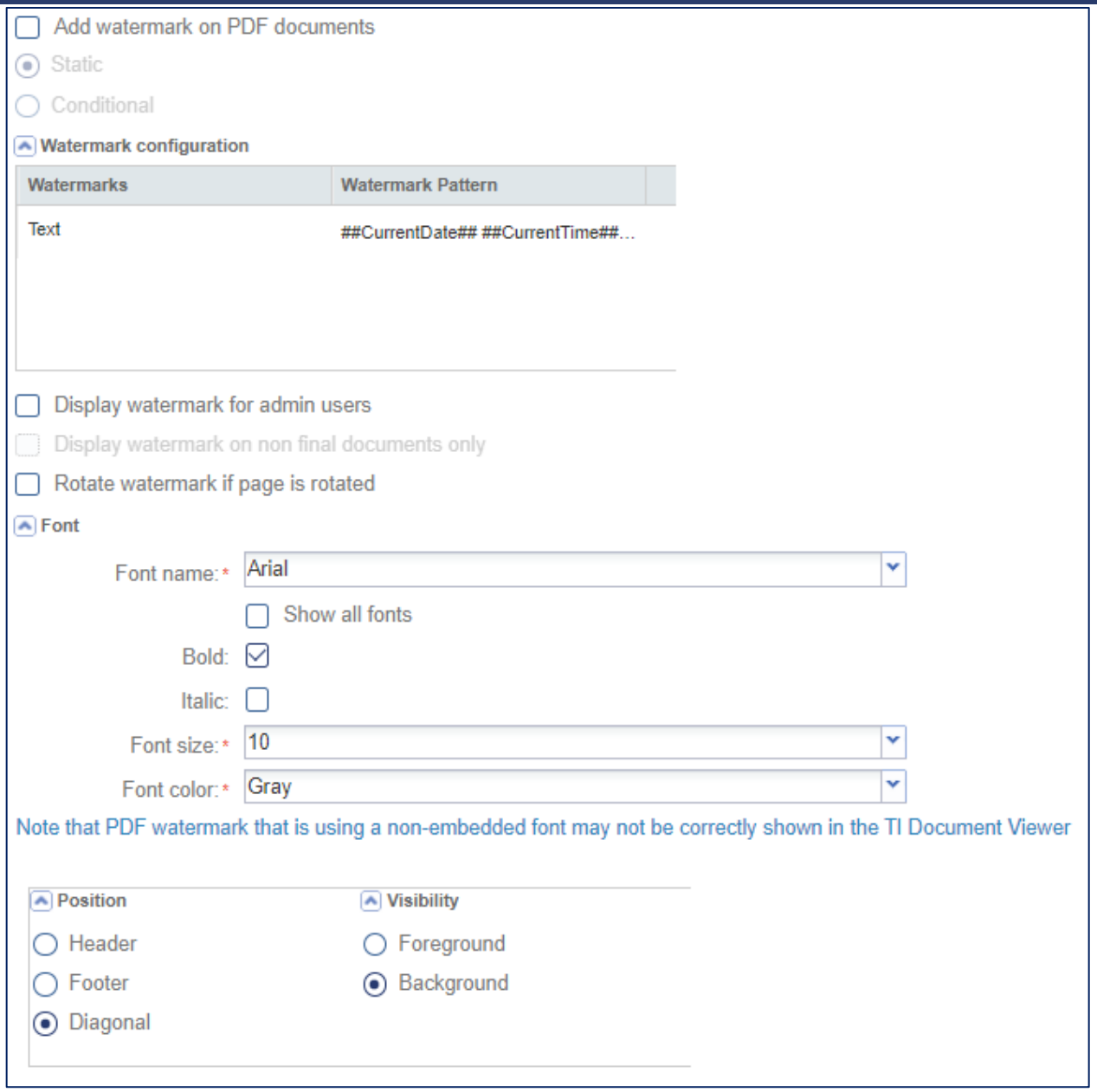
	Display name	System name
	Redaction	Redaction
	Study Startup	Study Startup
	Page Manipulations	Page Manipulations
	eSignature	eSignature
	Communications	Communications
	Document Distribution	Document Distribution
	Event Manager	Event Manager
	Assign Tasks	Assign Tasks
	Document Manager	Document Manager
	CRA Reconciliation	CRA Reconciliation
	Enroll for GL Courses	Enroll for GL Courses
	CRA	CRA

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.**

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:**



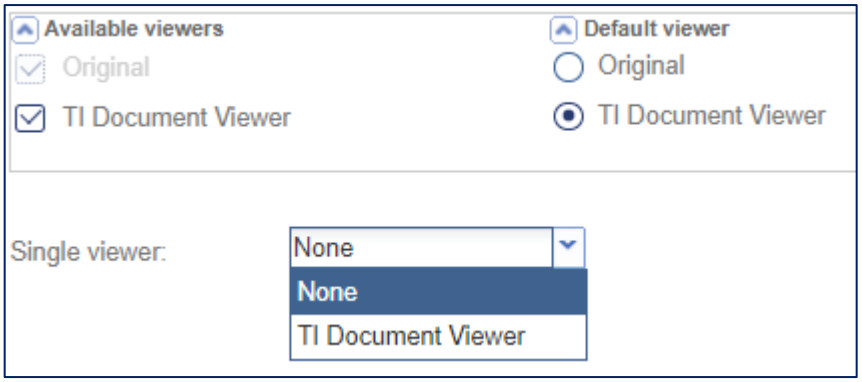
1. **Activate or inactivate the Add Watermark on documents option by clicking the checkbox.**
    a. **Activation of this option also activates the option of allowing non-PDF documents to be printed or downloaded without watermarks.**
2. **Tick the checkbox to Display the watermark for Administrator users.**
3. **Double-click on the Watermark Pattern to enable editing.**
4. **Click on the wrench icon to open the Watermark Pattern window.**
5. **Select from the available insertions in the "Available Templates" portion of the window.**
    a. **To use one of these insertions, select the point in the Rule Editor where the text should appear and**

then double-click on the desired insertion.

6. **Users can also free-type text into the Rule Editor**
7. **When you are satisfied with the pattern, press OK.**
8. **Tick the checkbox to Rotate watermark if page is rotated.**
9. **Select the Font name from the dropdown.**
    a. **The dropdown list can be extended to include all fonts by clicking the Show all fonts checkbox.**
10. **Select whether the watermark text will be rendered as Bold and/or Italic text.**
11. **Select or confirm the Font Size from the dropdown menu.**
12. **Select the Font color from the dropdown menu.**
13. **Select whether or not to Embed the font to the PDF.**
14. **Select the Position of the watermark.**
15. **Select whether the watermark will appear in the Foreground or the Background of the document text.**
16. **Click Save.**

Document Viewers

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 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 TI Document Viewer.**
    a. **It is our recommendation that the TI Document Viewer be the default viewer. Some document functionality depends upon the use of this 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. **Use the checkbox to enable or disable DRM on documents.**
2. **Click Save.**

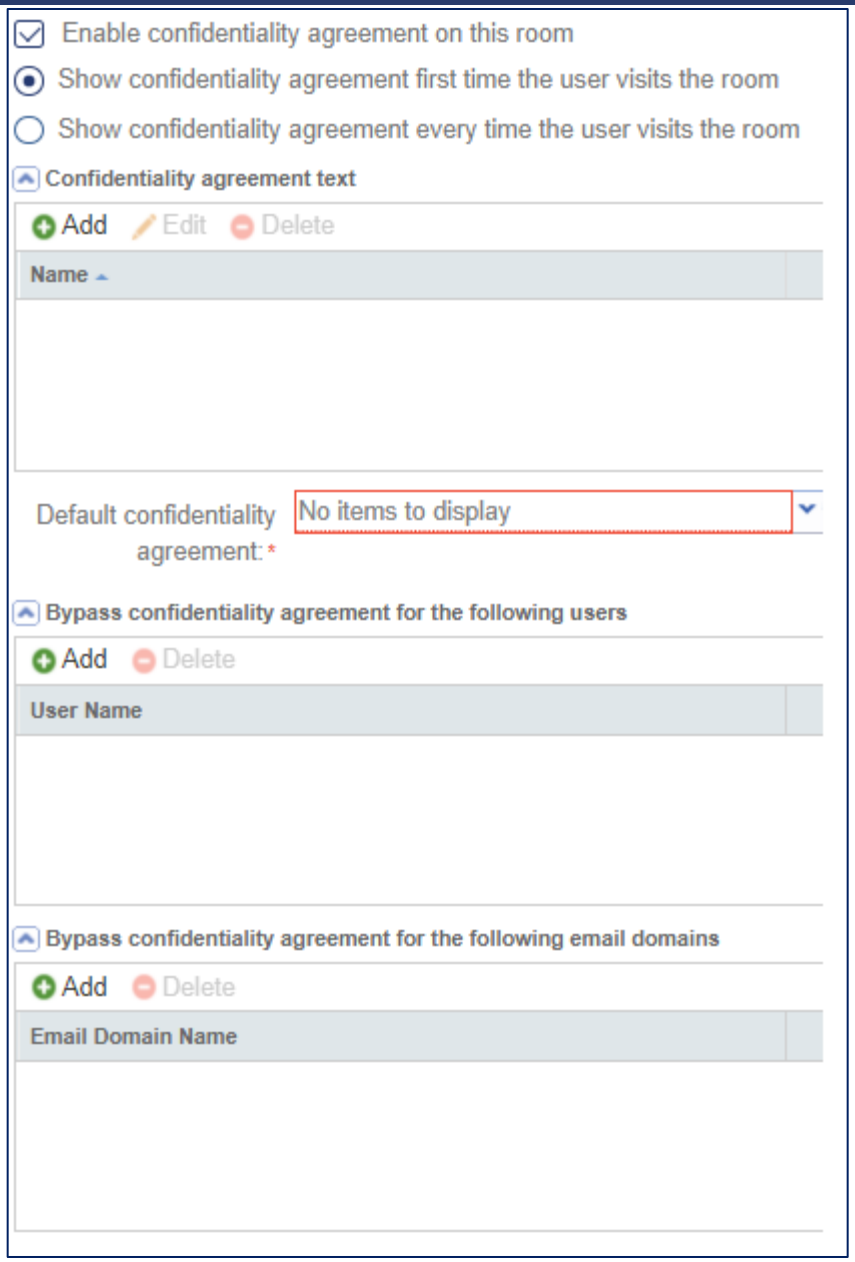
<u>Confidentiality Agreement Settings</u>

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

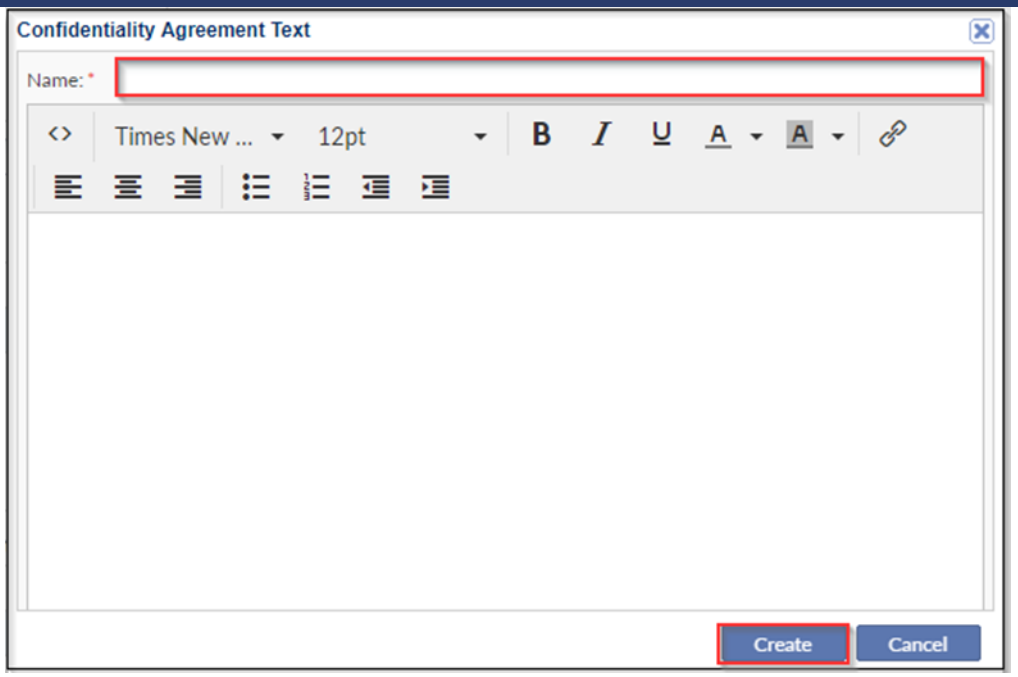
- **Once enabled, you can choose whether to have the agreement appear only on a user's initial visit to the room, or have the agreement appear each time users log in.**
- **You also have the option of designating individual users or groups of users whose email addresses share a domain name who would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

Follow these steps to enable the Confidentiality Agreement:

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



2. **If enabled, select whether to have the agreement show only on the first time a user visits the room or every time a user visits the room.**
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.**

MANAGER ACCESS

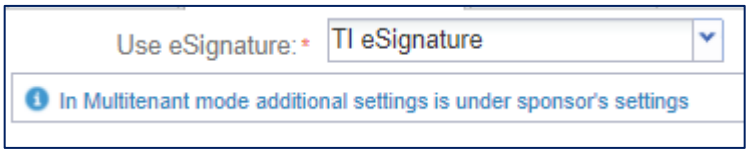
The Manager role is customizable from this menu. The options listed show potential access rights and privileges associated with the Manager role. Use the checkboxes to enable or disable these abilities.

e-Signature

VENDORS

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

- **Click the Use E-Signature dropdown to select the vendor. Refer to the screenshot below:**

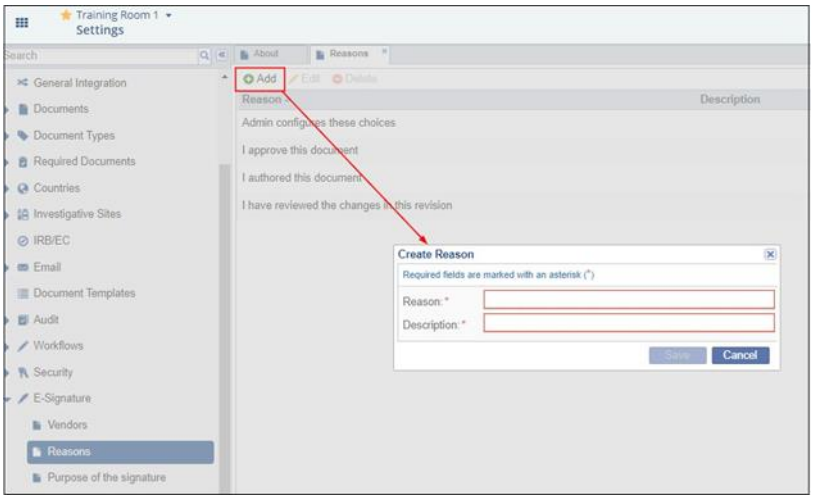


REASONS

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.

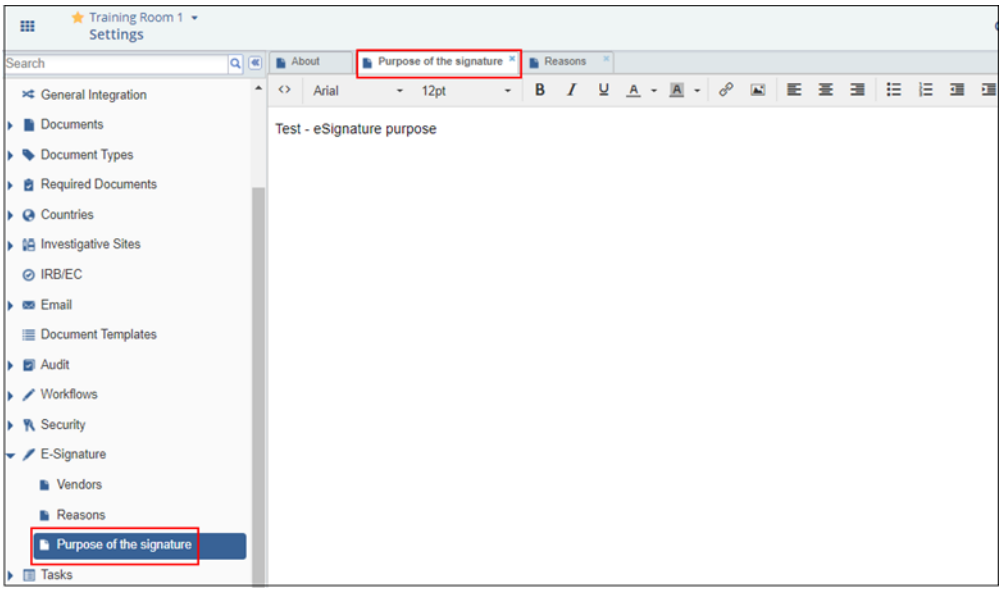
1. **Navigate to Navigation Grid-> Settings-> E-Signature-> Reasons. Refer to the screenshot below:**



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

Tasks

The Administrator may need to set up certain configurations for tasks in a room.

.

TASKS

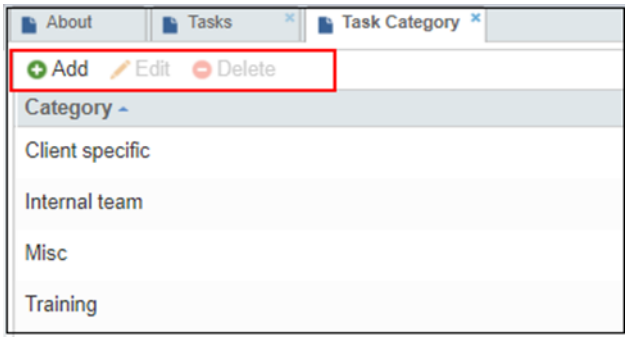
1. **Navigate to Navigation Grid → Settings → Tasks → Tasks**
2. **Define the number of days from IRB/EC submission reminder task option. Refer to the screenshot below:**

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.

Task categories 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 category or select an existing task and hit the Edit button to edit a task. Press Enter after editing.**
3. **Select a category and hit the Delete button to delete it.**

Q&A

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.

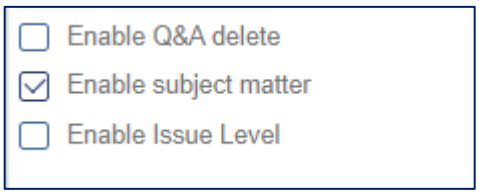
Through the Q&A settings view, you can add, edit, or delete Question Levels. In the Q&A configuration panel, you can enable and disable several Q&A options: the ability to delete questions and answers, the activation of Subject Matter categories, and the activation of questions issue levels.

Q&A Configuration

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

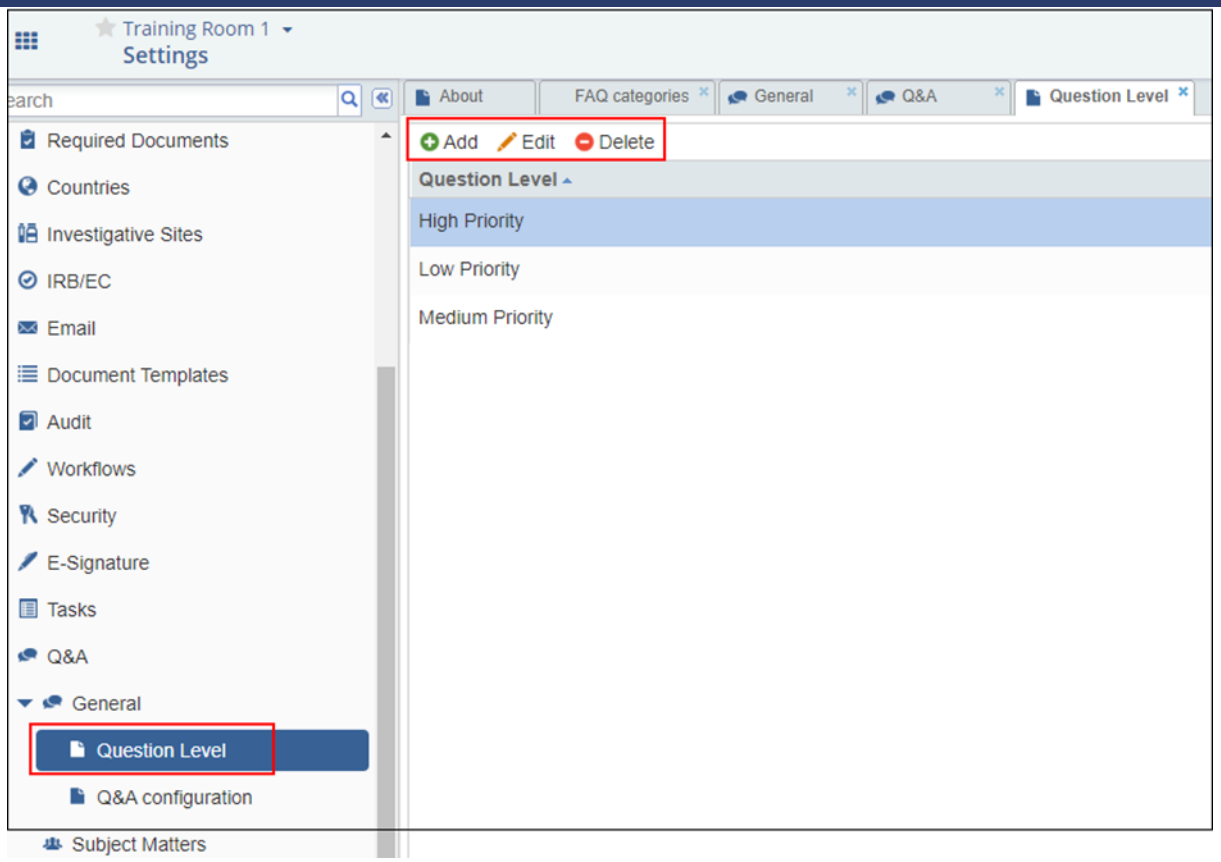
- **The ability to delete questions and answers.**
- **The activation of Subject Matter categories.**
- **The activation of question issue levels.**

Refer to the screenshot below:



Q&A Question Level

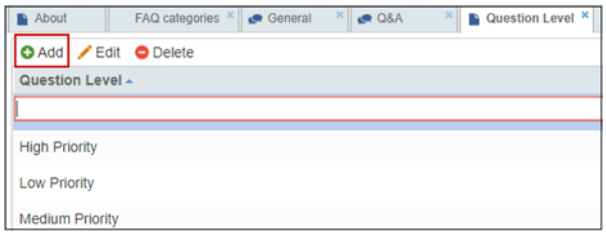
From here, you can create a list of issues that are associated with the documents. These issues are then assigned to Subject Matter Experts who can answer the questions. Refer to the screenshot below:



Adding New Question Level

To add a new question-level:

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



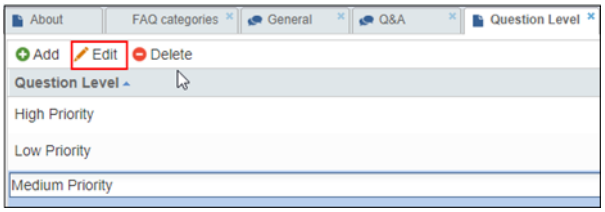
Editing a Question Level

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.**

a. **The field becomes editable.**

2. **Edit the details as required. Refer to the screenshot below:**



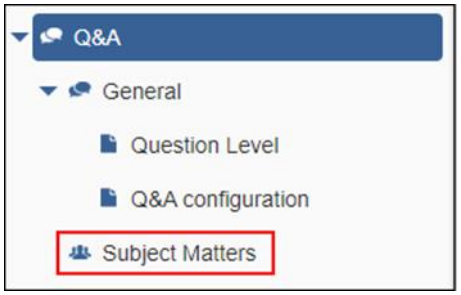
Deleting a Question Level

To delete a question-level:

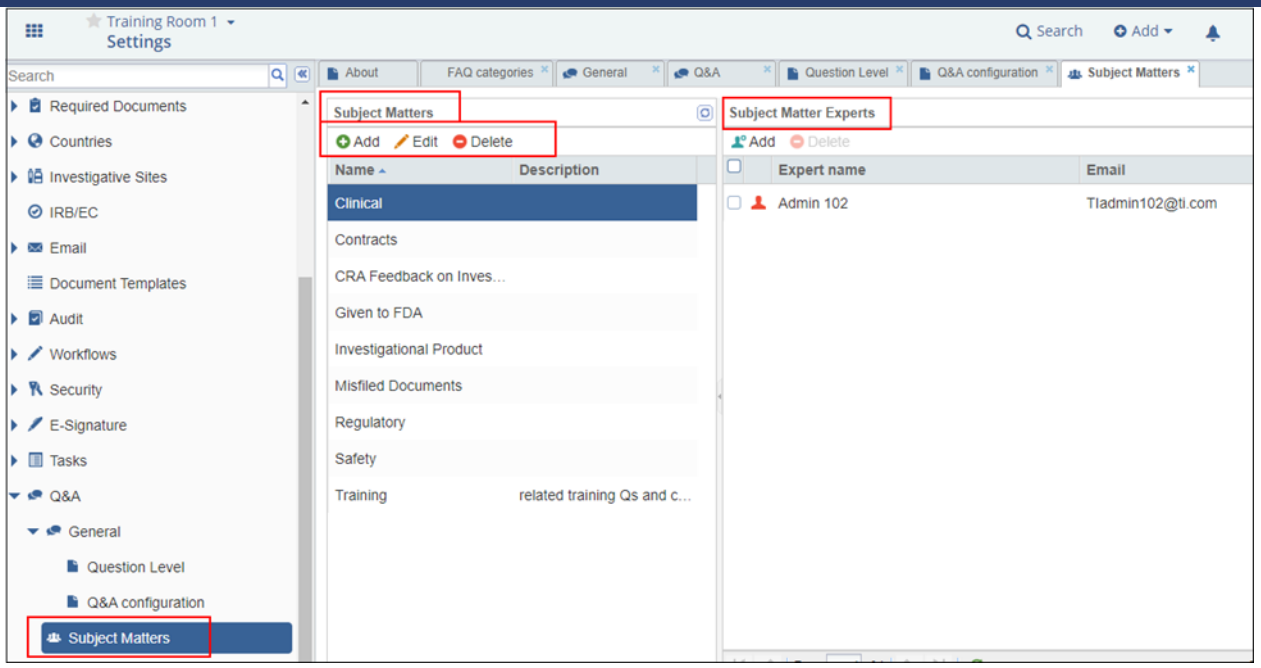
- **Select the level and click 'Delete' from the top menu to delete it.**

QUESTION SUBJECT MATTER

If Subject Matter was enabled in the Q&A Configuration, 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. 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:

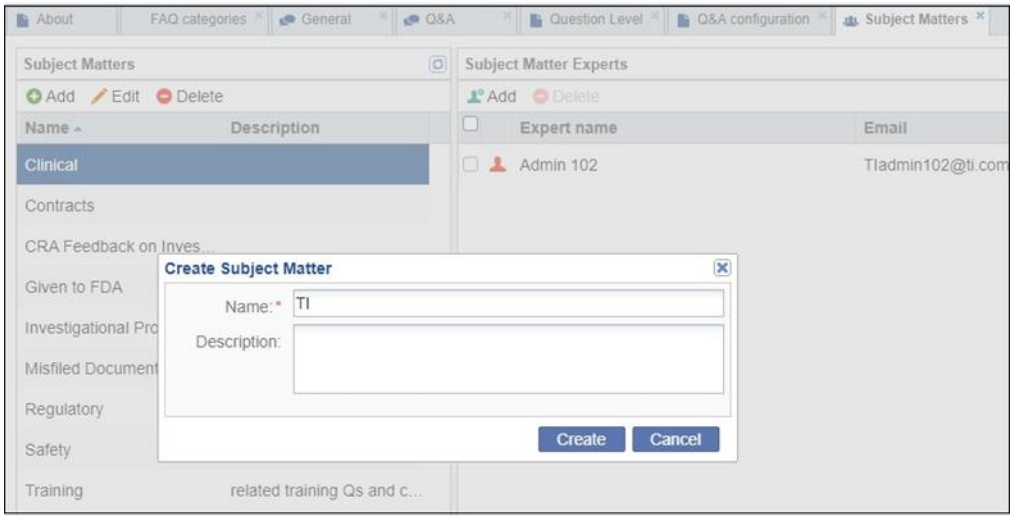


This window consists of two panels:

- **The Subject Matters panel from which subject matter categories can be added, edited, and deleted.**
- **Subject Matter Experts panel from which Subject Matter Experts can be assigned to or unassigned from the specific Subject Matter Categories. In this way, questions from particular categories can automatically be channeled to subject matter experts when the questions are submitted in the room.**

<u>To create Subject Matters:</u>

1. **From the Subject Matters panel toolbar, click Add.**
2. **The Create Subject Matter window opens. Refer to the screenshot below:**

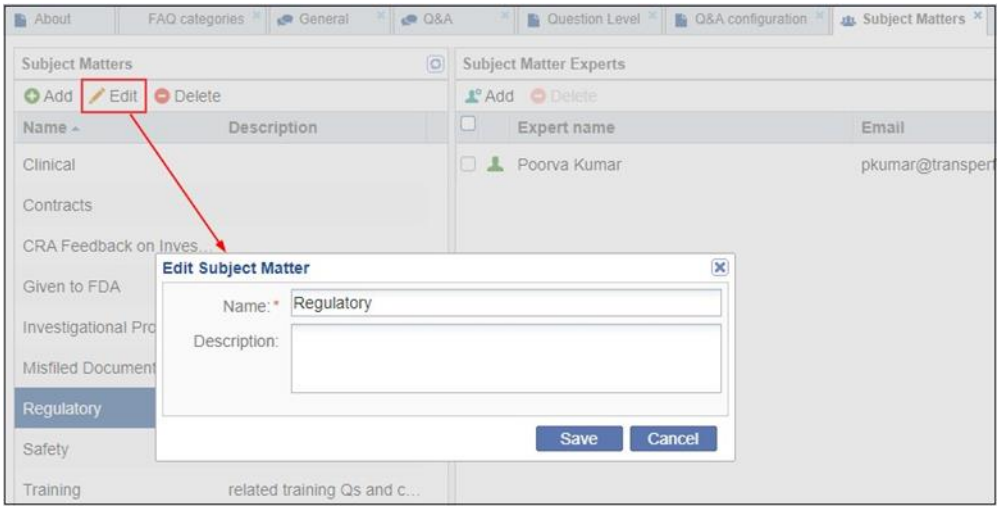


3. **Type the name of the Subject matter category in the Name field. The Name field is required; the Description field is optional.**
4. **Click Create at the bottom of the window. The new Subject Matter category is added to the list.**

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.**
5. **click Save.**
6. **The changes are committed and visible in the list of categories.**

Deleting Subject Matters

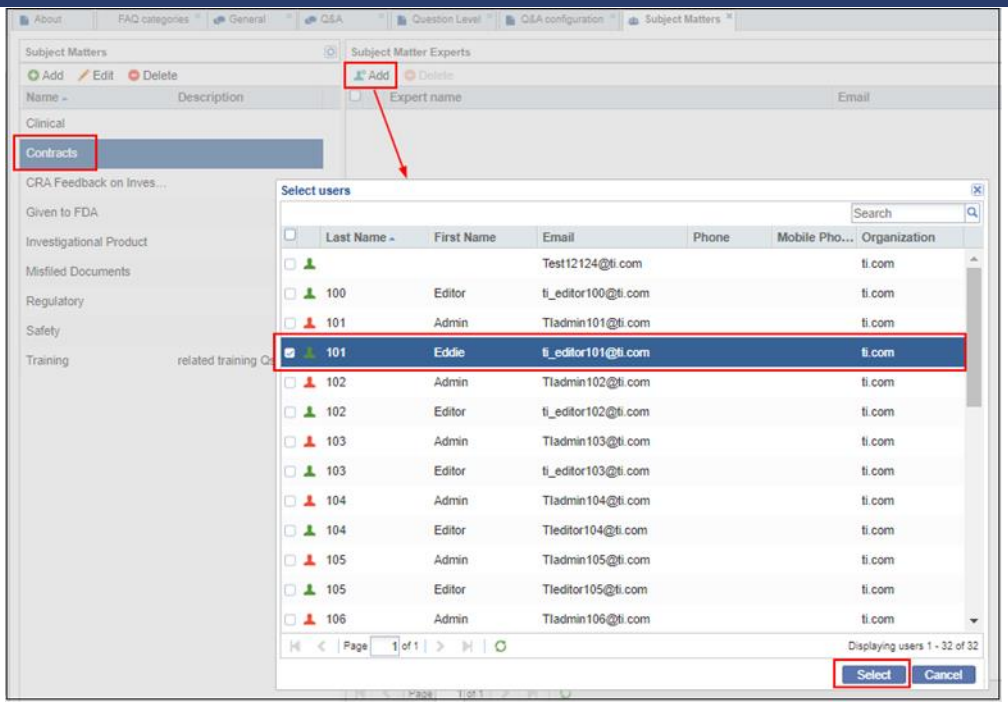
To delete a Subject Matter category:

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 subject matter, select a subject matter from the list on the left.

1. **Click the Name of the Subject Matter.**
2. **Click the Add button from the Subject Matter Experts panel toolbar.**
3. **A Select users window opens, displaying the full list of the room's registered users who are eligible to be assigned the role of Subject Matter Expert – users with Administrator or Editor access to the room.**
4. **Click the checkbox next to the name of the user you want to assign to the expert role.**
5. Click **Select at the bottom of the window. The changes are automatically saved. 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.**
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.**
5. **The names of the Subject Matter Experts is deleted from the list.**

FAQ Module

The Frequently Asked Questions, or FAQ Module of Trial Interactive provides a convenient and readily-available place for your study team to store all commonly-asked questions about your clinical trial. This module may be made easily available to anyone who has access to the eTMF, Site or Study Collaborate rooms as well as a standard Content Management workspace.

During a Clinical Trial, so many questions come up from the team. These questions can range from document naming conventions, instructions on how to classify certain metadata and content, who to contact for specific study

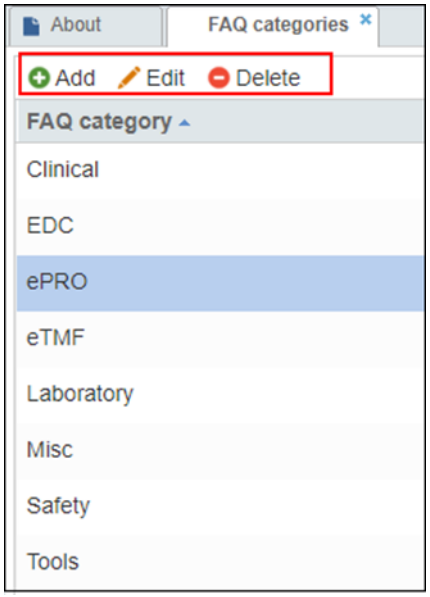
information, all the way to entries for each Investigative Site providing contact information and other critical information. If your CRAs, CTAs, and Clinical Document Specialists have access to the right answers your project can run much more efficiently. Simply click on the FAQ Module and take a look.

How it Works

The FAQ icon in the Navigation Grid allows you to view the list of FAQs. You can reach this page by clicking the FAQ icon from the Navigation Grid. From this page you may search for any FAQ, or simply view the listing and expand the answers you require. You can also view by date or category from the index, and also modify the columns and create your own views as necessary. FAQs, both Questions and Answers, may contain rich text, images, and other information. Finally, FAQs may be emailed to other users in the room.

ADDING FAQ CATEGORIES

1. **Navigate to Navigation Grid → Settings → FAQ**
2. **Click Add. 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.**

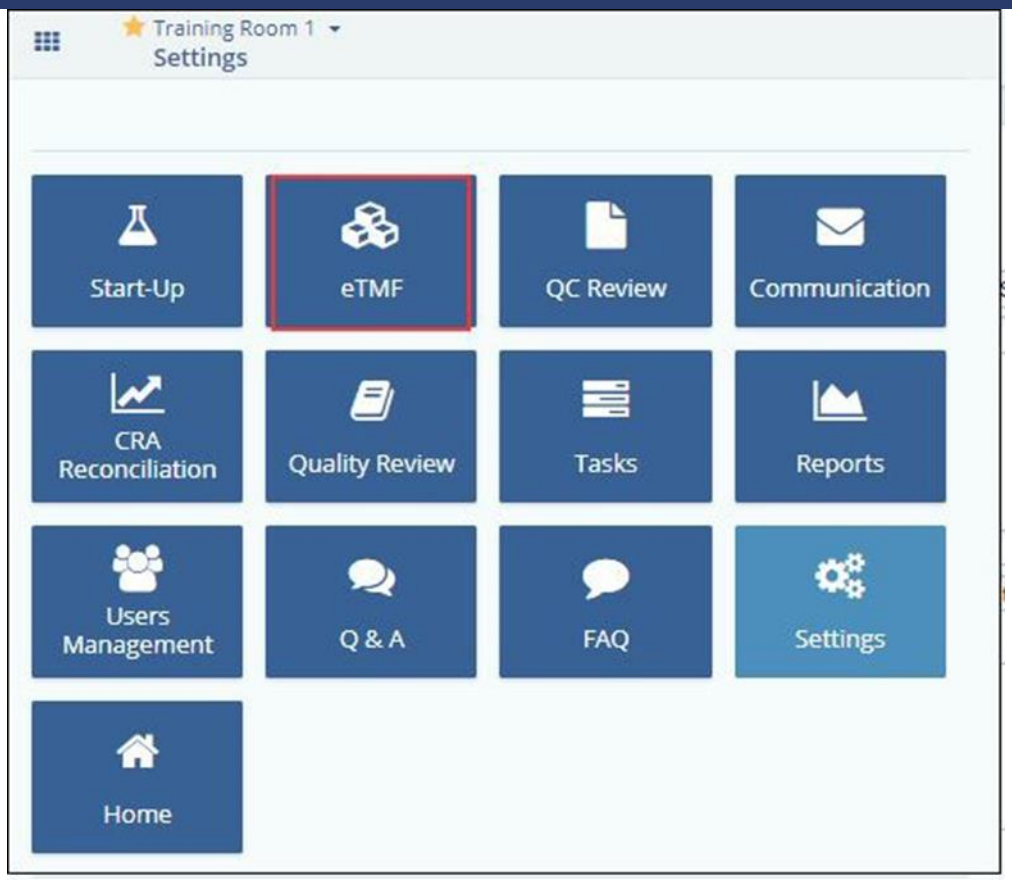
DELETING FAQ CATEGORIES

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

Chapter 7. Trial Interactive eTMF and the Documents Module

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

You can access this module from the Navigation Grid in the upper-left corner of the screen. Refer to the screenshot below.



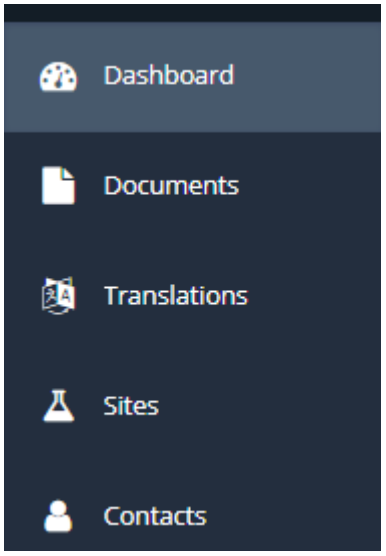
Once you enter the application, you have access to various modules within it and can toggle between them. The following are modules available from this area of the system:

- **Dashboard**
- **Documents**
- **Translations**
- **Sites**
- **Contacts**

The menu at the left side of the screen contains a menu bar with all of these options. Users will only see those options which they have been granted access to see.

Refer to the screenshot below:

If you click on whichever module is already highlighted, the menu will expand to display labels as shown in the screenshot below:



Documents module

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

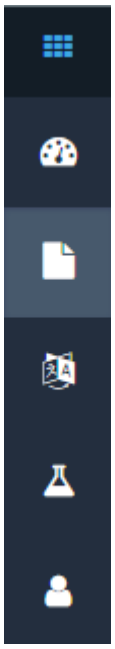
Here, you can configure and store 'essential documents' pertaining to clinical trials, view and edit documents

attachments, manage security privileges on them, import and export documents and their metadata, and mail them to other users in addition to many other functions.

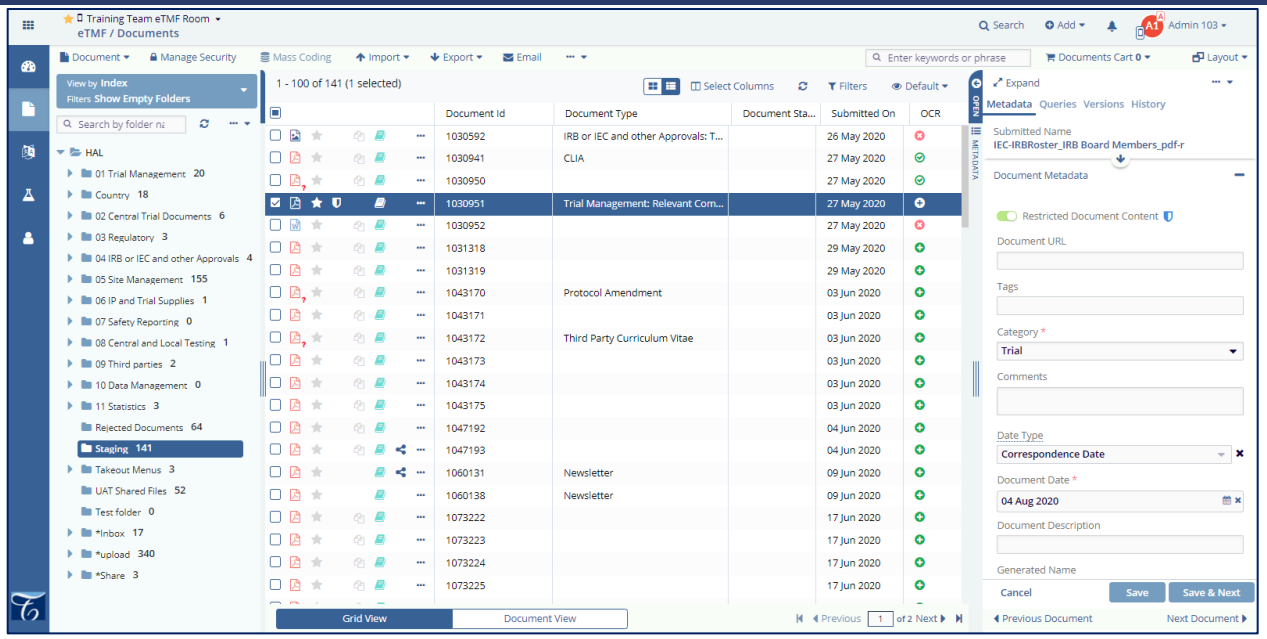
To comply with eTMF Completeness, you can track the progress right from documents collection to the finalization of a document. This application also provides you with the facility to post Questions and Answers along with the generation of FAQs for further insight.

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:



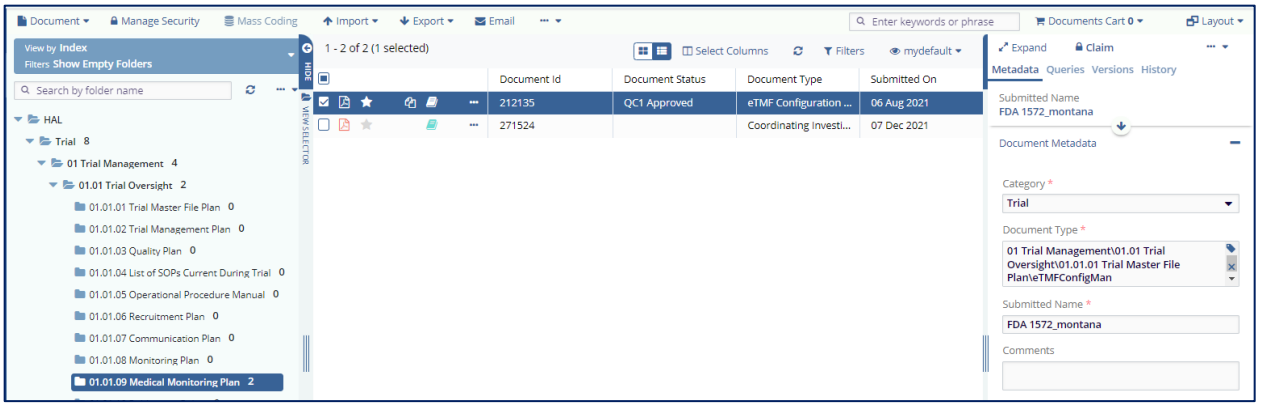
Clicking the Documents icon in the menu bar at the left leads you to the Documents module. Refer to the screenshot below:



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.**
- **No two index structures are necessarily identical and each Trial Interactive room can have a completely customized index structure.**
- **Documents emailed to a room's inbox address are stored in each user's Inbox folder unless the room is configured otherwise.**
- **All documents directly uploaded to the room without any metadata appear in each user's upload folder.**
- **Documents which are uploaded with metadata appear in the default folder location, usually the Staging folder.**
- **Documents can be uploaded directly to other index folders if the room is configured to allow it.**
- **If a folder contains subfolders, you can expand it to by clicking the arrow next to the folder or you can double-click the folder to show the child folders.**
- **Similarly, you can collapse an Index folder by clicking the arrow next to an expanded folder.**
- **To view any documents in a folder, simply click on the folder and any documents stored there will display in the documents grid at the center of the screen.**
- **Selecting a document from the documents grid will cause the document's metadata to load in the Metadata Pane at the right-side of the screen.**
- **Besides the Metadata tab, the Metadata Pane also may contain the Workflow, Queries, Versions, History, and**

eSignature tabs as appropriate.



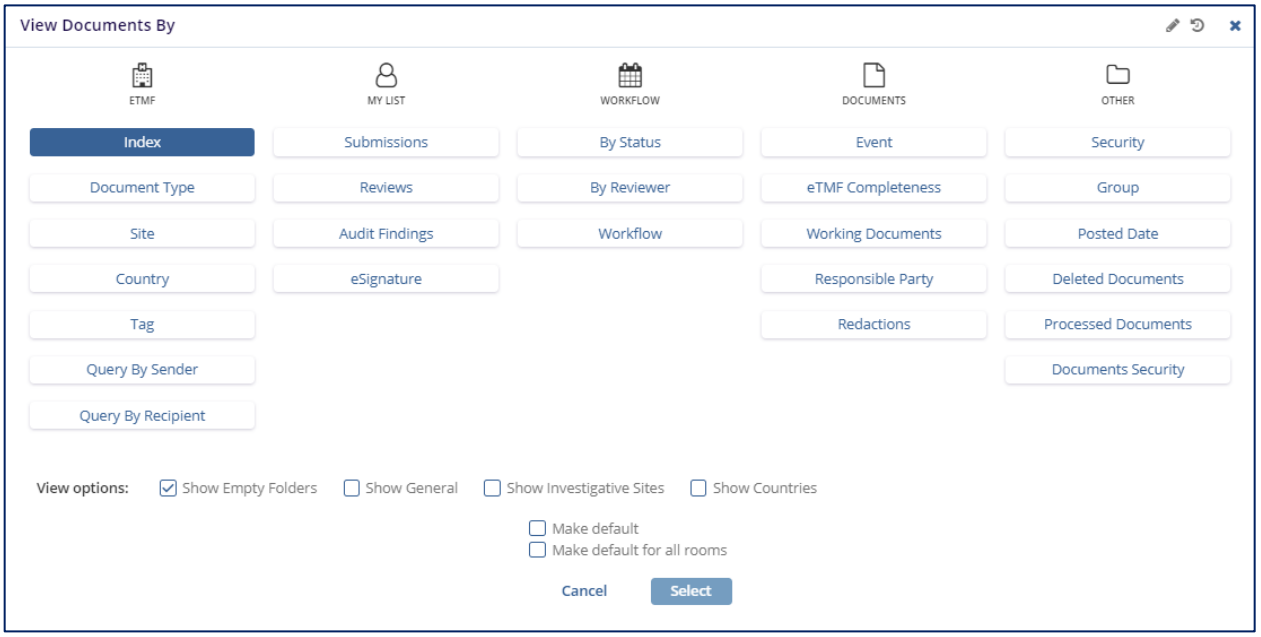
Choose View - Viewing the Room's Index Structure

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 'View by' dropdown menu in the Index Pane.**
2. **This opens the View Documents By popup with various view options.**
   a. **The options visible here will be different depending upon your user access level and other associated user account permissions.**

Refer to the screenshot below:



- **Tip: Select a view and tick the Make Default checkbox to make that view your default view.**

Each of the columns contains options for viewing the documents and placeholders in the room.

- **Index: This view displays all of the room's documents by their index location.**
- **Document Type: This view displays all documents based on their assigned document types.**
- **Site: This view shows all room documents based on their site association.**
- **Country: This view shows all room documents based on their country association.**
- **Tag: Tag is a metadata field by which documents can be linked or associated. This view displays all documents organized by the tags assigned to them. One document may be associated with multiple tags.**
- **Query by Sender: This view shows all queries organized by the query sender.**
    - **Users will see different queries depending upon their user access level.**
        - **Administrator level users will see all queries in the room.**
            - **Administrator users can choose to view only their own queries.**
        - **Other users, unless granted additional privileges, will see only their own queries.**
- **Query by Recipient: This view shows all queries organized by the query recipient.**
    - **Users will see different queries depending upon their user access level.**
        - **Administrator level users will see all queries in the room.**
            - **Administrator users can choose to view only their own queries.**
        - **Other users, unless granted additional privileges, will see only their own queries.**
- **Submissions: This view will display every document ever submitted to the room by the user regardless of status or index location.**
    - **Deleted documents will not display.**
- **Reviews: This view is only available to users who are a part of the room's QC workflow. From this view, users who are a part of the workflow will be able to perform all associated functions.**
    - **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 Control module in the folder with unclaimed documents under the workflow configured by you.**

- **Note: If you are the part of one of the QC groups, you are assigned to the workflow and this view is automatically activated for you. This view mirrors that which is available in the QC Review module located in the Navigation Grid.**

- **Audit Findings: This view is only available to users who have been assigned a role of Audit Responder in an audit in the room.**
  - **From this view, Audit Responders can perform all related functions to correct audit findings.**

- **eSignature: From this view, users can view documents which require eSignature and perform eSignature related functions.**

- **By Status: This view allows users to view all room documents grouped by their QC Workflow status (ex. QC 1 Approved, Final, etc.)**

- **By Reviewer: This view allows users to view all documents currently claimed by QC workflow personnel.**
  - **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.

- **Workflow: This view allows users to view all documents by their workflow association.**

- **Event: This view is only available in rooms where the Event Manager is in use. The view displays documents and placeholders associated with specific events.**

- **eTMF Completeness: This view allows users to view all placeholders and documents organized the related entity (Study, Countries, Sites, or IRB/EC).**

- **Working Documents: This view is focused on missing documents and displays placeholders.**
    - **The Staging, Upload, and Inbox folders are available from the lower panel. Users can drag documents onto placeholders to apply coding to the uploaded document and fulfil the placeholder.**

- **Responsible Party: This view shows all collected and missing documents by their Responsible Party association. This requires that responsible parties are in use in the room.**

- **Redactions: This view shows documents which have been identified as containing protected content organized by the state of their redaction.**

- **Security: This view shows documents organized by their affiliated security access group.**

- **Group: This view shows documents organized by their affiliated group.**

- **Posted Date: This view shows documents organized by the date that they were added to the study room.**

- **Deleted Documents: This view shows all documents that have been deleted. From here, documents can be restored or purged from the system.**

- **Processed Documents: This shows documents which have undergone some form of process in the room. The most common of these would be conversion to PDF or application of OCR.**

- **Documents Security: This view displays all documents which have specific document level security applied.**

CONFIGURING THE INDEX STRUCTURE

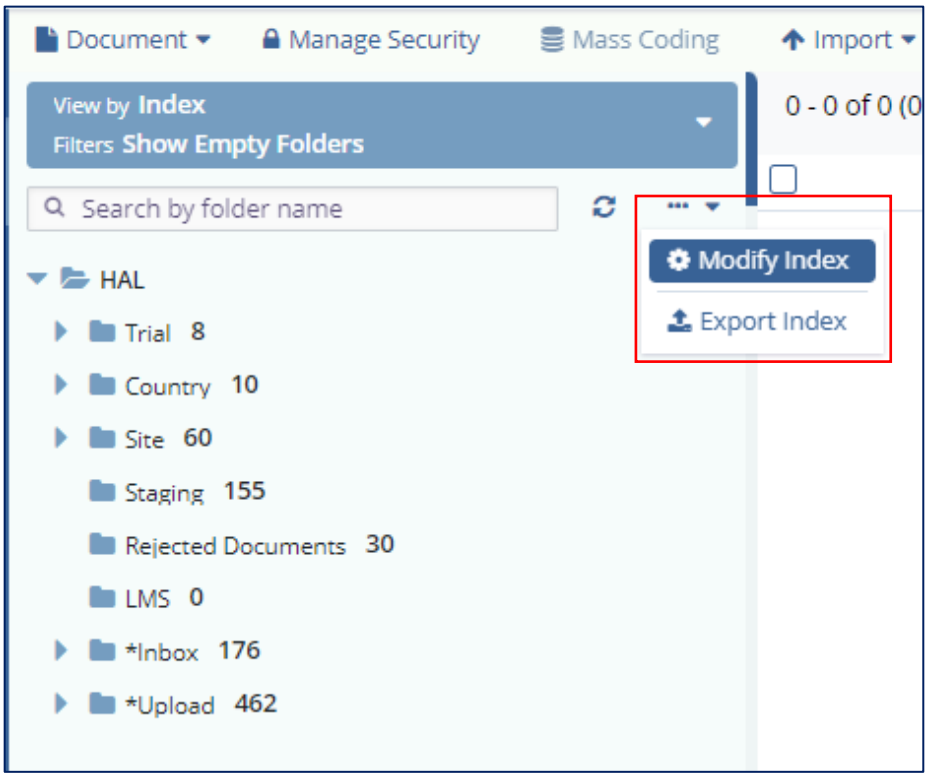
Most commonly, a room's index structure will be cloned from an existing room or a client-specific template room. Normally, any changes to the standard layout would be indicated in your configuration manual and addressed prior to the room being used. However, administrator level users can make changes to a room's index structure. The sections below will cover how this is done.

- **Warning!: This functionality can have dire consequences if used in a live study room. Please be certain that you have been fully trained by a Trial Interactive eClinical Trainer and that you are absolutely sure what changes**

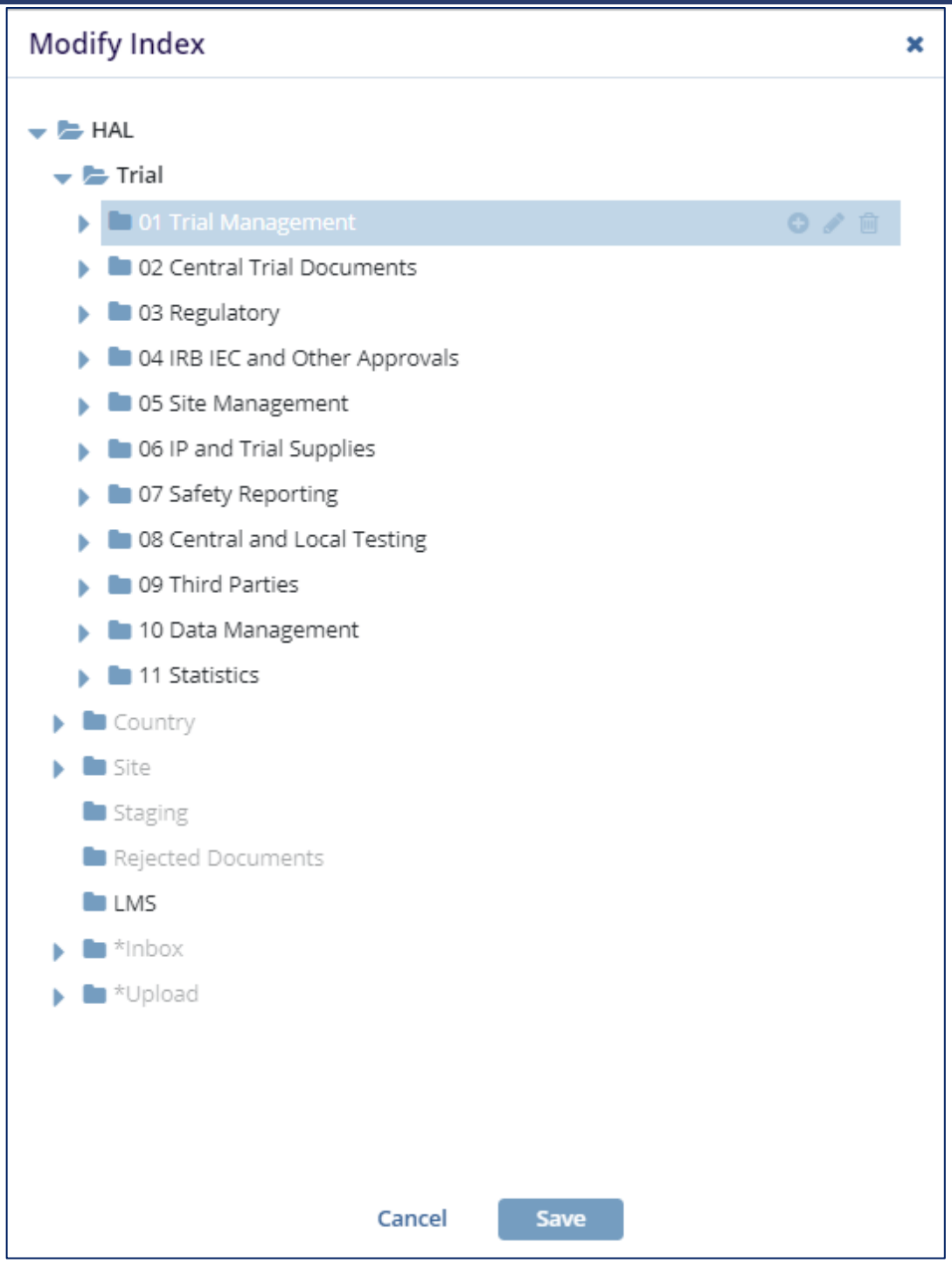
need to be made. Deleting a folder containing documents will immediately delete all of the documents within. It is *highly* recommended that you work with the Trial Interactive Service Desk if you want to make ANY alterations to the index structure of a study room.

Adding New Folders

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



1. **Select the Modify Index option from the dropdown menu.**
    a. **The Modify Index window will open.**
2. **Hover over the parent folder or, to create a new zone-level folder, hover over the index itself. Select the + symbol to create the new folder. See the screenshot below.**
    a. **Because index structures can be customized on a room-by-room basis, your index structure may appear different from the one show.**

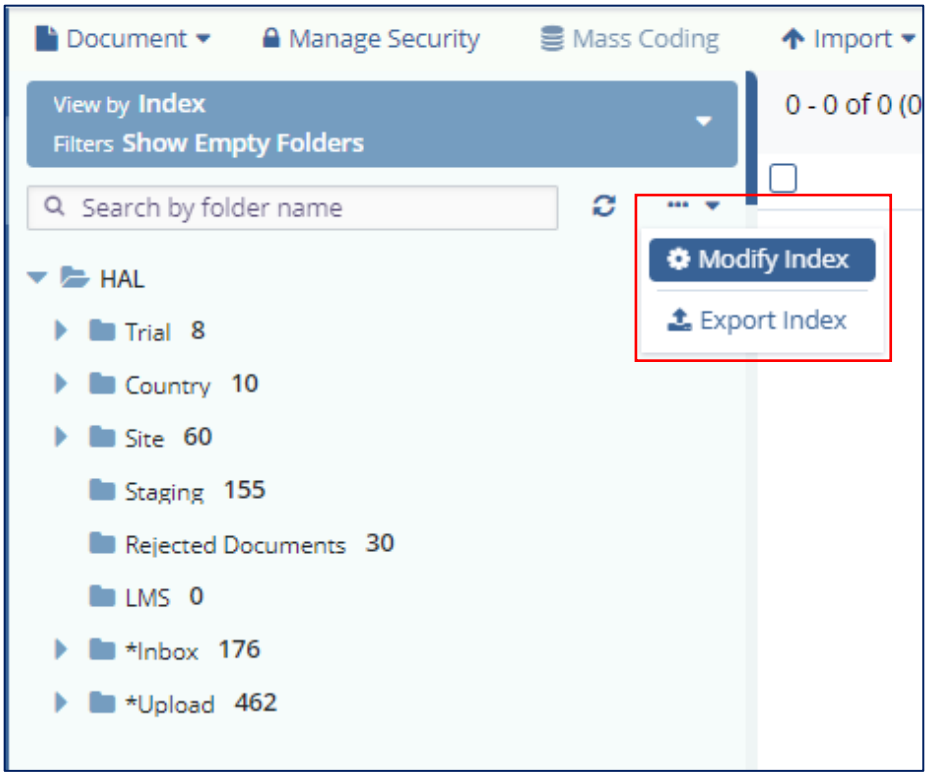


3. **When the folder is created, name the folder and press the 'Enter' Key to save the name.**
4. **Perform any other desired index modifications and press 'Save.'**

Editing or Deleting an Existing Index Folder

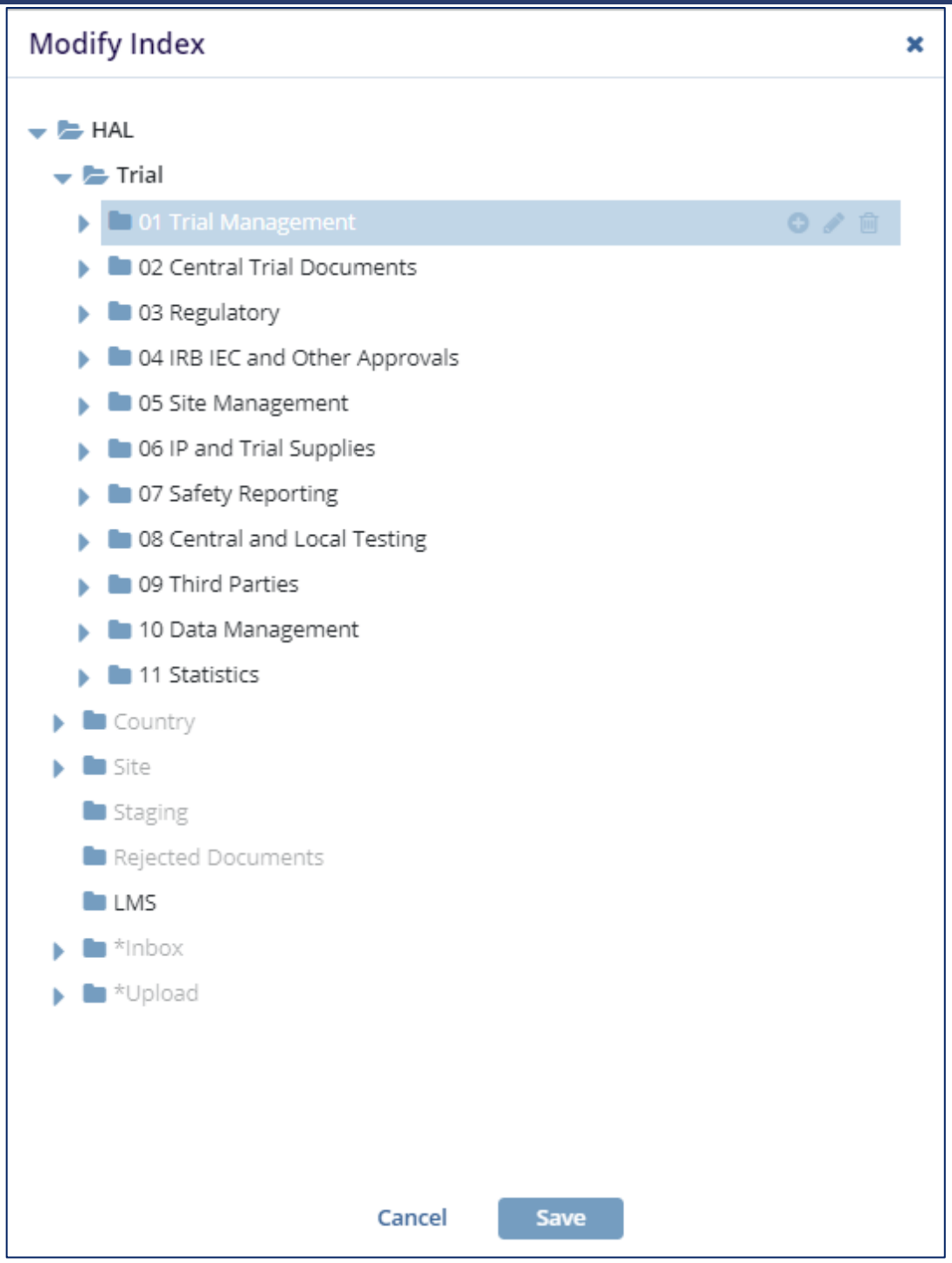
Administrator level users can delete or edit the names of existing folders to the index structure of the documents

module from the Index pane. There is a three-dot menu under the view selector menu. See the screenshot below:



1. **Select the Modify Index option from the dropdown menu.**
    a. **The Modify Index window will open.**
2. **Hover over the parent folder or, to create a new zone-level folder, hover over the index itself. Select the pencil symbol to edit the folder's name or press the trash can icon to delete the folder. See the screenshot below.**
    a. **Because index structures can be customized on a room-by-room basis, your index structure may appear different from the one show.**

- **<u>Warning!:</u> This functionality can have dire consequences if used in a live study room. Please be certain that you have been fully trained by a Trial Interactive eClinical Trainer and that you are absolutely sure what changes need to be made. Deleting a folder containing documents will immediately delete all of the documents within. It is *highly* recommended that you work with the Trial Interactive Service Desk if you want to make ANY alterations to the index structure of a study room.**



3. **Press the 'Enter' Key to save the new name.**
4. **Perform any other desired index modifications and press 'Save.'**

<u>Editing Country and Site Level Folders</u>

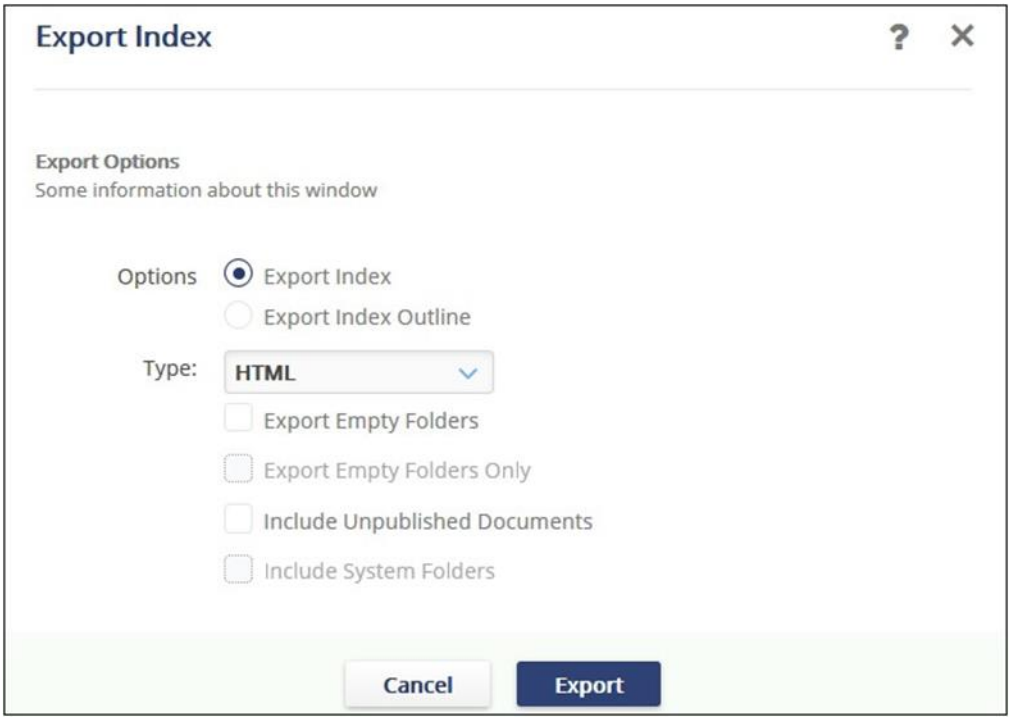
You may notice that country and site level folders are greyed out and are not editable from the Modify Index window. These folders are controlled by the template folder settings. Please see the sections on country and site template folders for more information on making changes to these folders.

EXPORTING THE INDEX STRUCTURE

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 format. Besides these, you may also choose to export empty, or system folder as also documents unpublished to the eTMF.

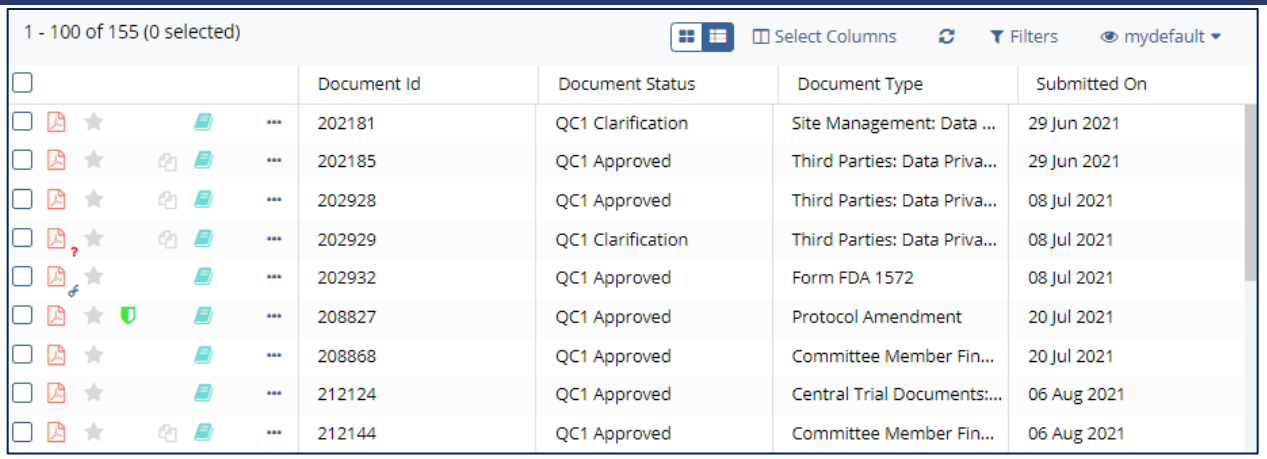
To export the index:

1. **Click Export Index from the three-dot dropdown menu at the top-right of the Index pane.**
    a. **This will open the Export Index window.**
2. **Choose from the available options and press 'Export' when you are ready. See the screenshot below:**



THE DOCUMENTS GRID

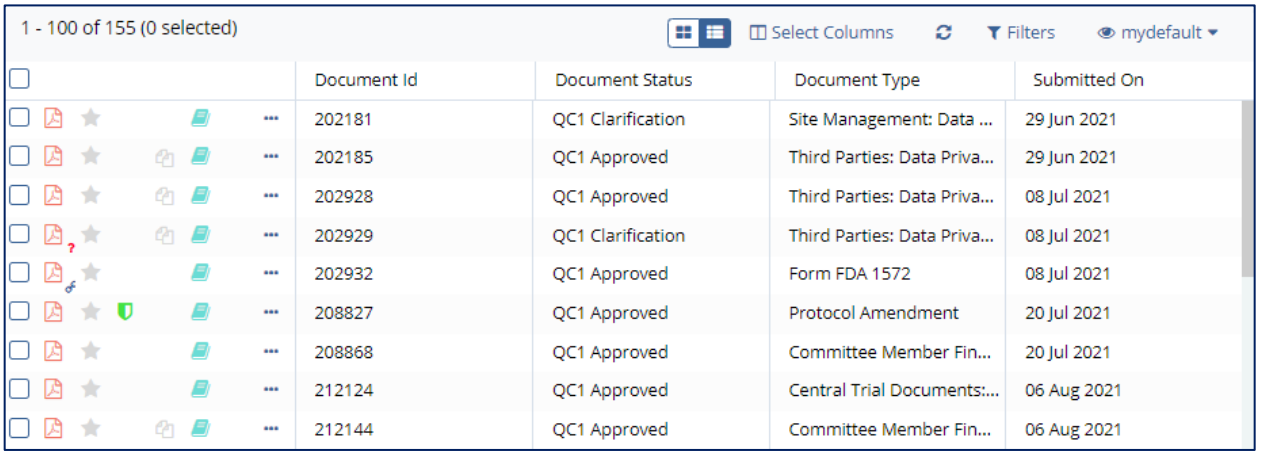
Once you select a folder with documents in it, the documents will be listed in the Documents Grid.



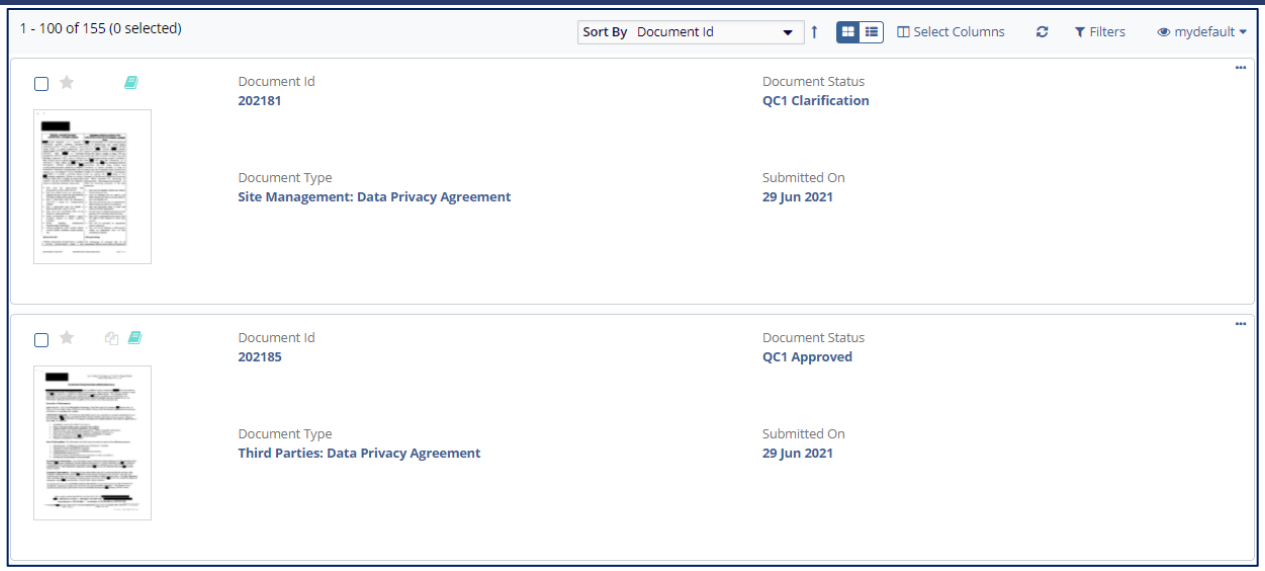
Choosing between the Grid View and the Card View

Immediately above the Documents Grid is a toggle switch which will allow the user to switch between Grid View and Card View. See the screenshots below:

Grid View



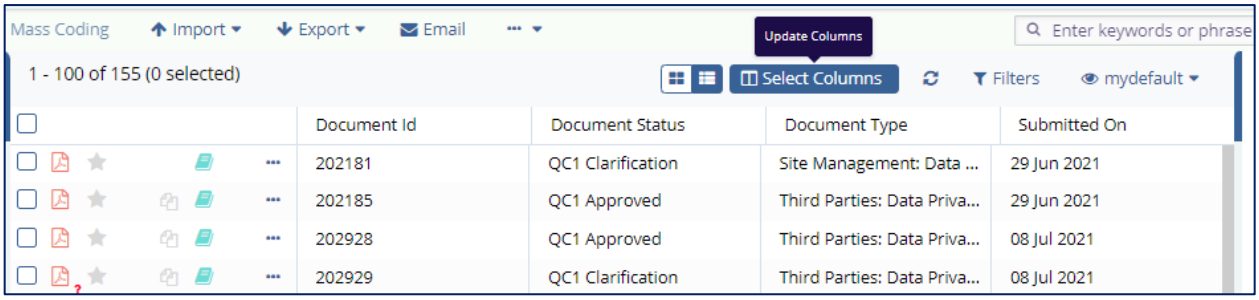
Card View



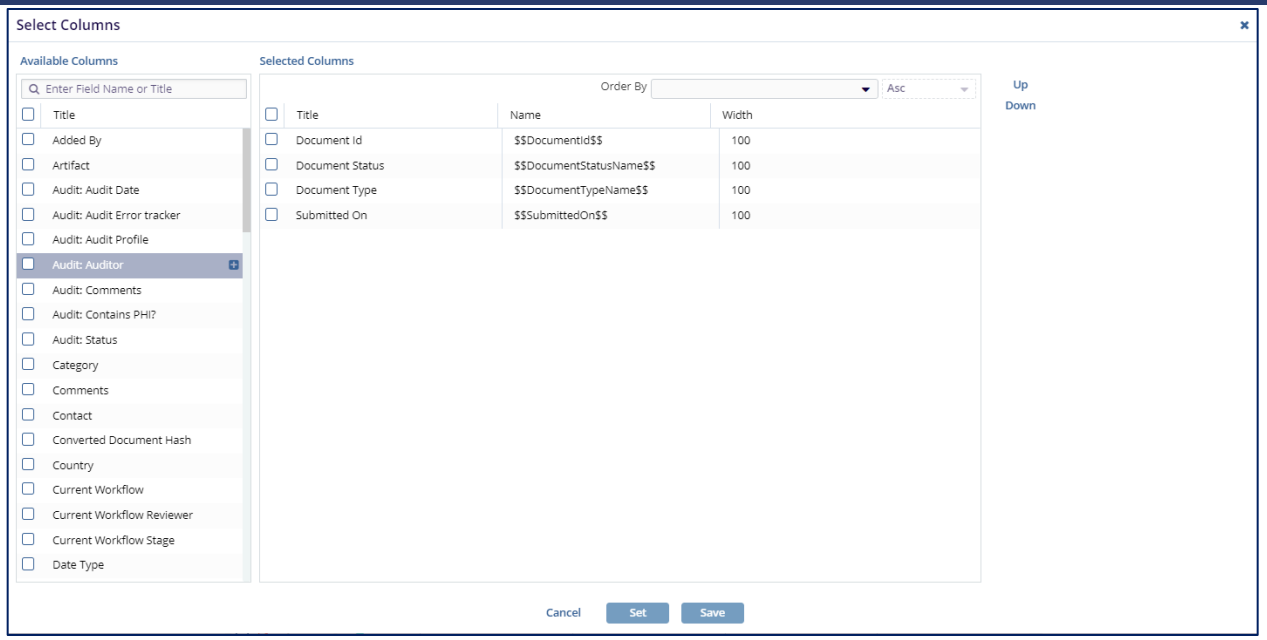
Configuring the Document Grid

Users are able to configure which columns are displayed in the Document Grid. This function is not limited to the Documents module. Very nearly any grid in the system can be configured to the user's preferences.

1. **Click the Select Columns button from the top-right corner of the documents grid. Refer to the screenshot below:**



2. **The Select Columns window will open 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.**
3. **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.**
    a. **A '+' sign appears next to the column name.**
4. **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:**



5. **Alternatively, you can also double-click the columns in the Available Columns to add to the Selected Columns.**
6. **After adding the columns to the Selected list, they are greyed out in the Available Columns list.**
7. **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.**
8. **Besides adding and deleting columns, you can also change the sequence of the columns by**
9. **clicking the Up or Down buttons located at the extreme right of the window.**
10. **Click Save to save to changes.**

Once you have figured out which view will work best for you, you can do the following:

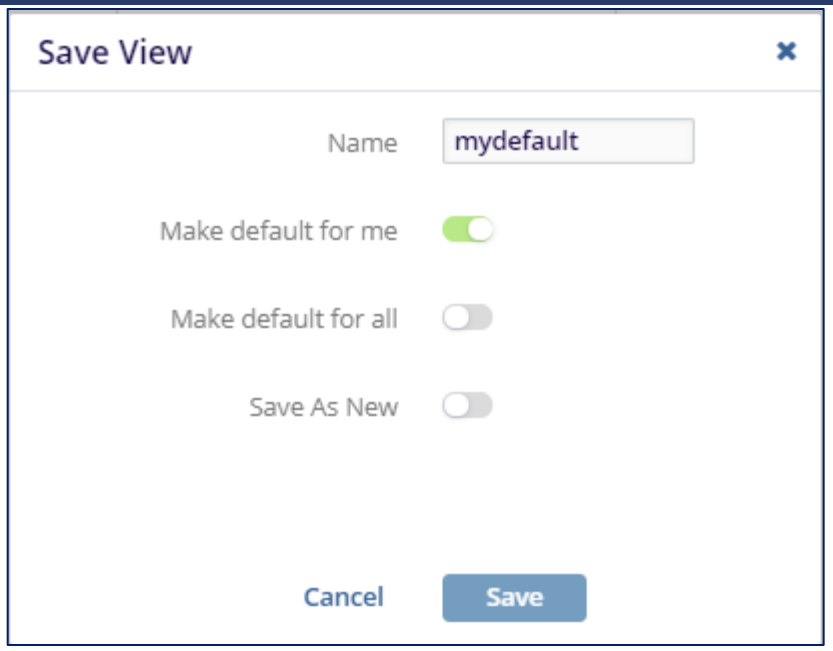
- **Save your view**
- **Set it as the default view**
- **Share your view**

<u>Saving your View</u>

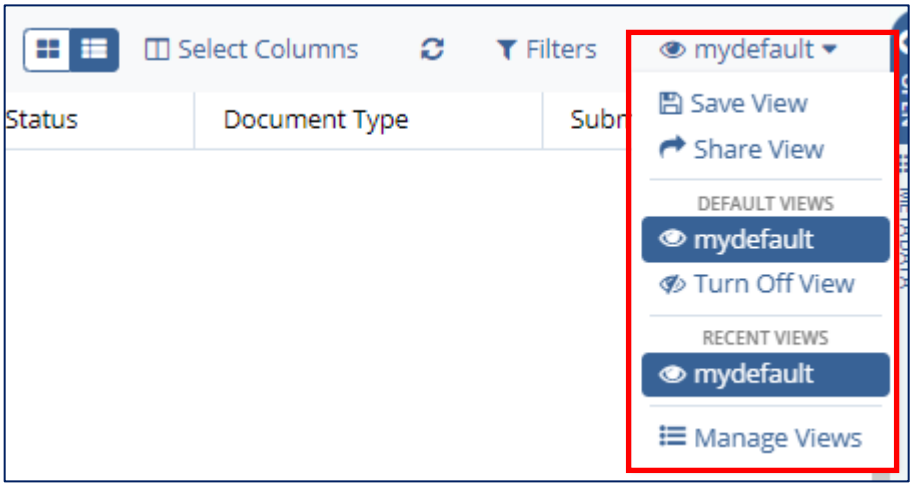
If you used the 'Set' button to test out a view of the Grid and you wind up wanting to keep it, you can go back into the 'Select Columns' window and choose to save your view.

From the Select Columns window:

1. **Press 'Save'**
    a. **This opens the Save View window (see the screenshot below)**



2. **If the view is new, give it a unique name.**
    a. **If you are updating an existing view, you can leave the name as it is.**
3. **Choose whether or not this view should be your default view.**
4. **(Admins Only) – Select whether this view should be the default view for all users in the room.**
    a. **Users will be able to change their default view after this is selected but all users will initially have this view presented to them.**
5. **Choose whether or not you would like to save this view as a new view.**
    a. **If you are editing an existing view, you would not choose to save your selections as a new view.**
6. **Press 'Save'**
7. **Once you have saved your view, it will be available in the list of all views. This list is accessible from the 'view' dropdown menu at the top-right of the Grid. (See the screenshot below)**

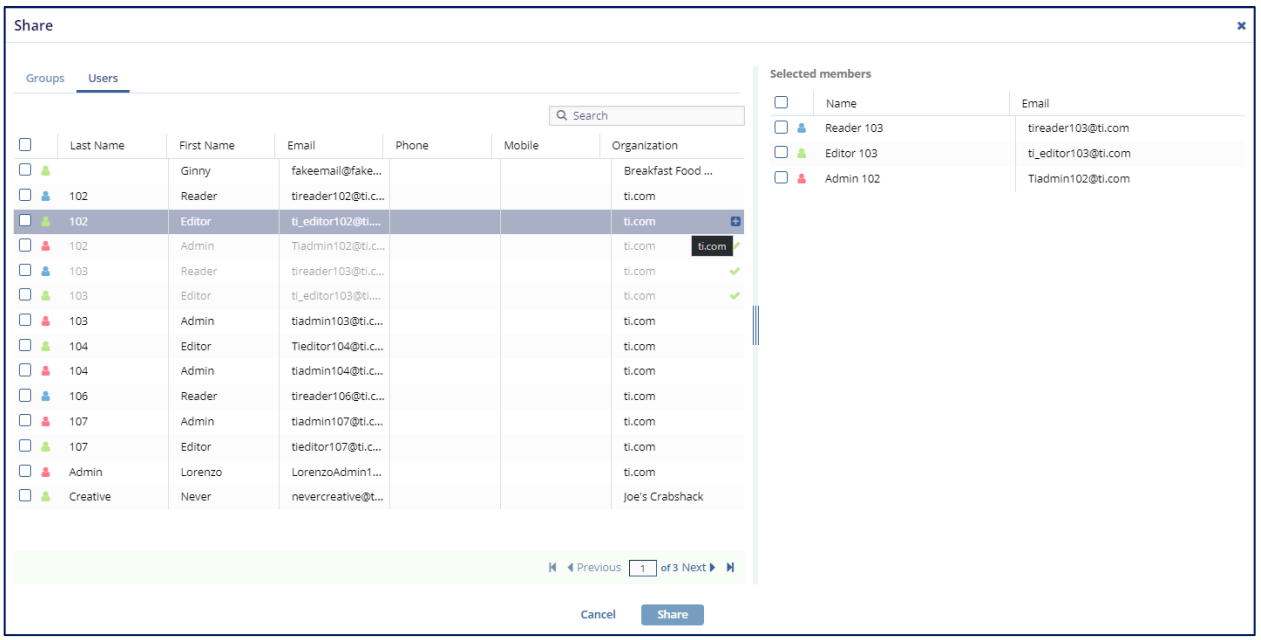


<u>Sharing your View of the Grid</u>

Once you have saved your view, you will be able to share it to any other room user. This is particularly useful when

bringing on a new team member who may not be familiar enough with Trial Interactive to easily find necessary information via the Grid. To share your view, follow the steps below:

1. **Open the View menu at the top-right of the Grid (See the screenshot above).**
2. **Select 'Share View'**
    a. **This will open the 'Share' window. (See the screenshot below)**

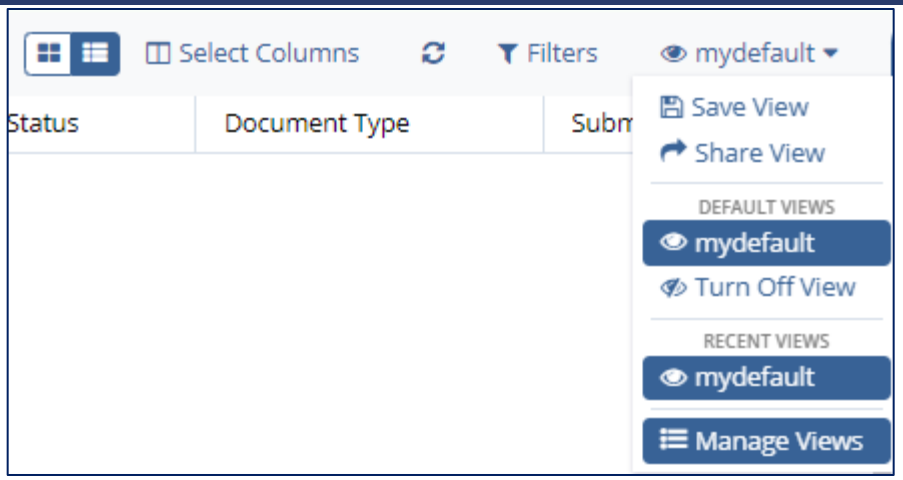


3. **Choose users or groups of users from the list at the left. Move these users to the right-hand panel by clicking and dragging or by hovering over the listing and using the + symbol at the right side of the line.**
4. **Press 'Share'**

Show All views

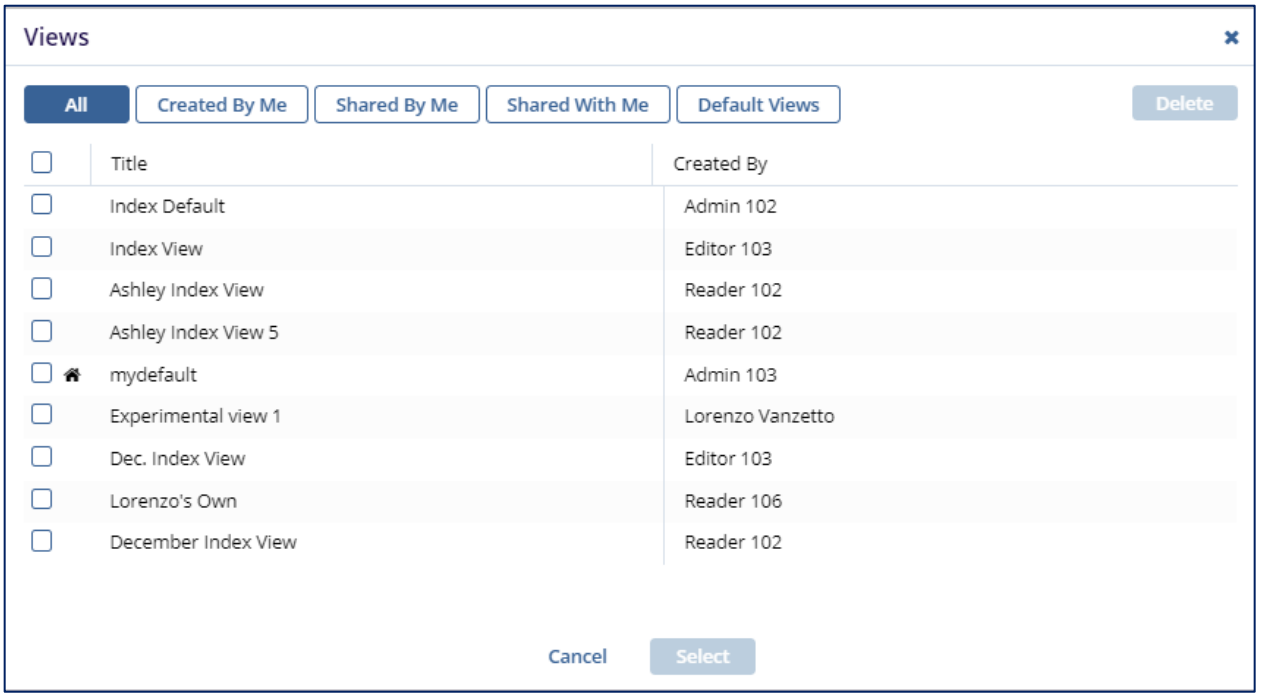
If the room has multiple views created in a room, and if they are visible to all users, you can view all the views in a room. To display all views:

1. **Click Manage 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:



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

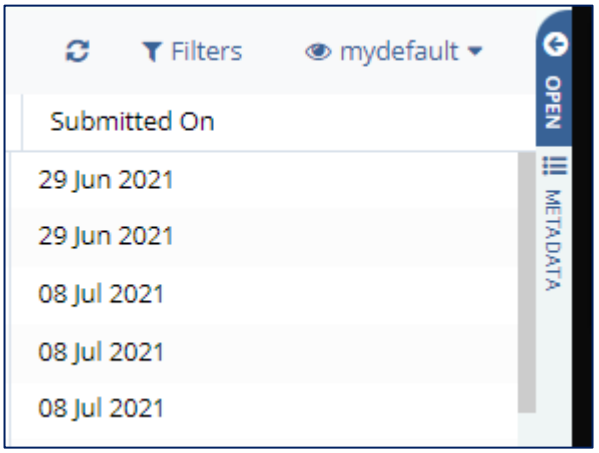
<u>Previewing and Viewing a Document and its Metadata</u>

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:

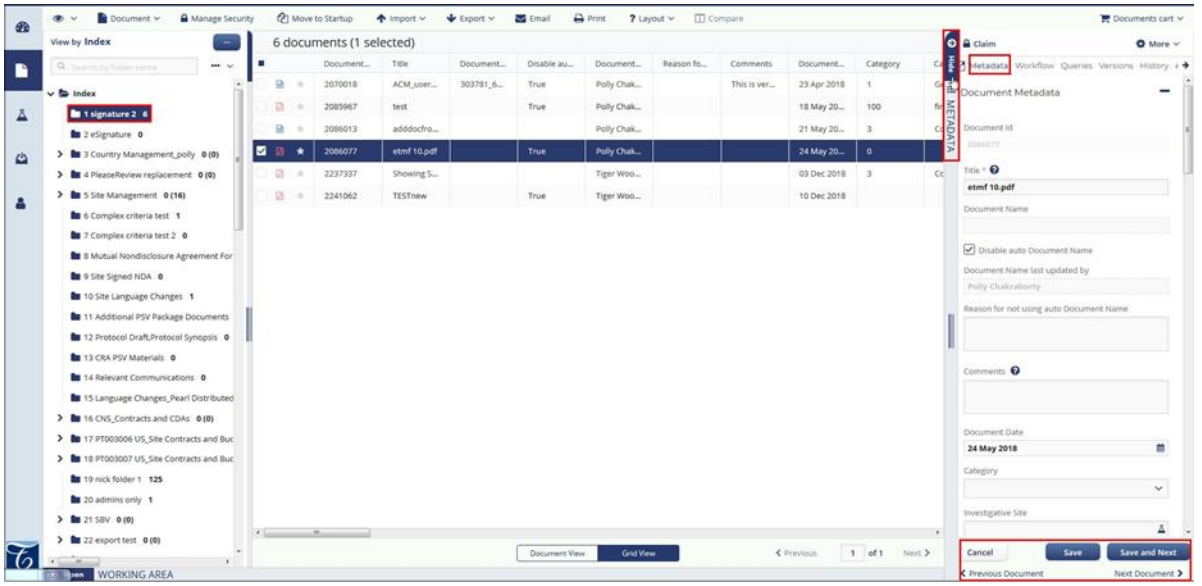
Viewing Document Metadata

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.**



3. **Click the viewer to open the Metadata Panel.**
4. **The Metadata Pane opens which displays the Document Metadata by default. Refer to the screenshot below:**



Editing Document Metadata

Users who have sufficient access can edit document metadata. The following requirements apply:

- **Administrator level users can edit metadata for any document.**
- **Editor level users and Manager users with Document Manager permission can edit metadata for any document.**
- **Editor and Manager users can edit metadata for non-final documents.**

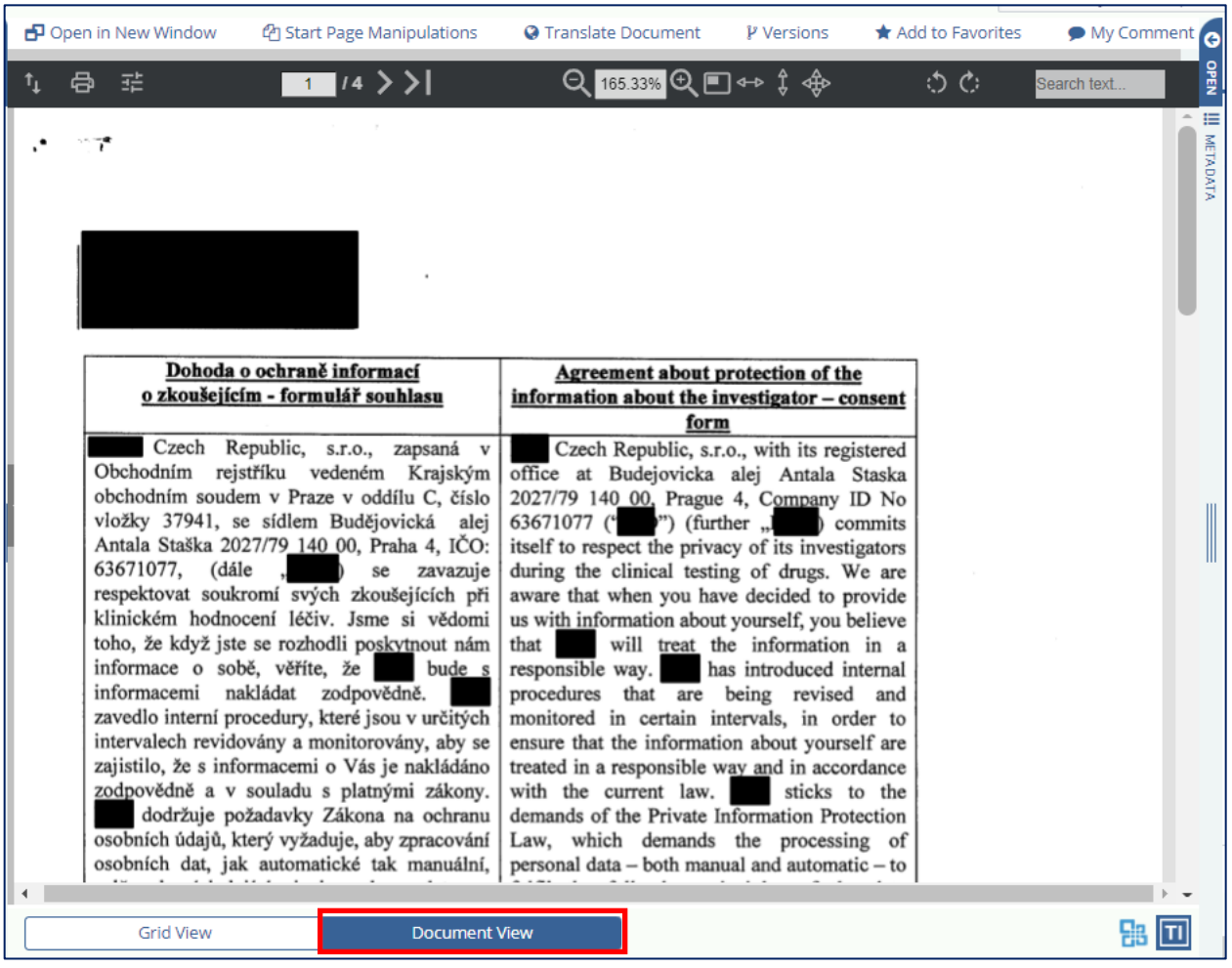
- **Reader level users cannot alter metadata for any document.**

To edit document metadata, simply alter the value present in the field and press the Save or Save and Next buttons at the bottom of the metadata pane.

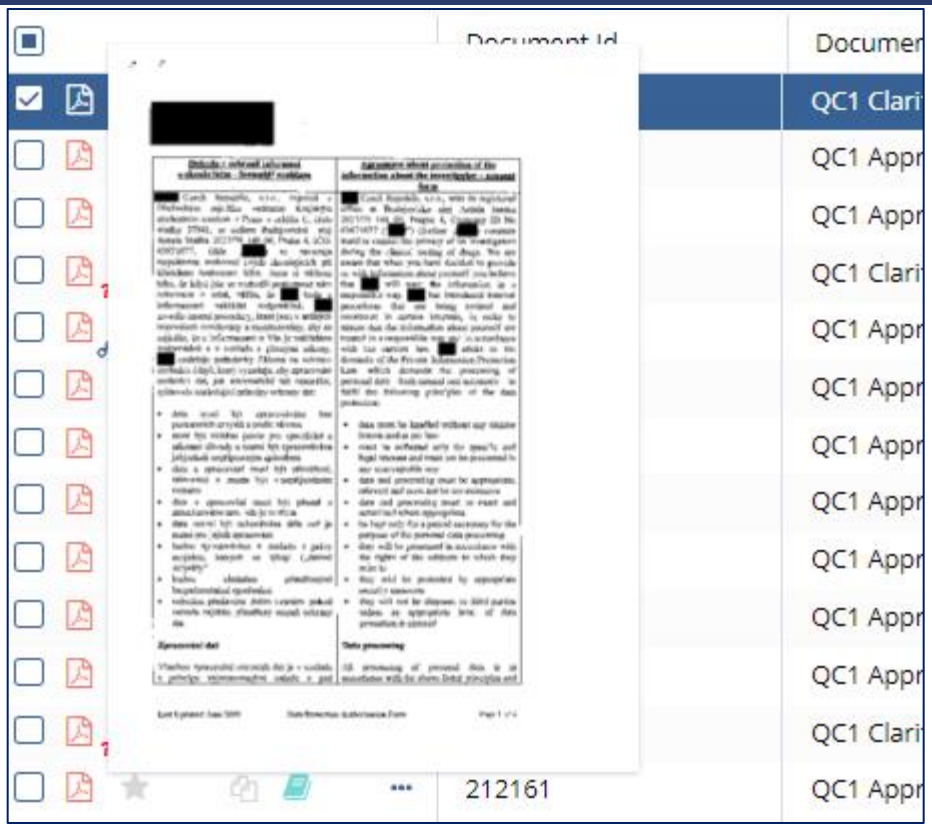
For rooms where Causality Tracking is enabled (see: Document Settings), users who attempt to alter metadata for a document in Final status will be asked to give a reason for altering the value.

Viewing Documents

In order to view documents in the Documents module. Locate the document in the grid and use the Document View button at the bottom of the grid view. The document will open. See the screenshot below:



Documents can also be previewed by hovering over the document icon on the grid as in the screenshot below.



Copying or Moving Documents

Users with sufficient access can click and drag documents from one folder to another. Note, this will not alter the metadata applied to the document. If you move a document manually from one folder to another, you will need to re-code the document.

Follow the steps below to copy documents:

1. **Select the document(s) to be copied or moved in the grid.**
2. **To copy the document/s to another folder, hold the Ctrl key, click, drag and drop the document to the destination folder in the Index Pane.**

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**

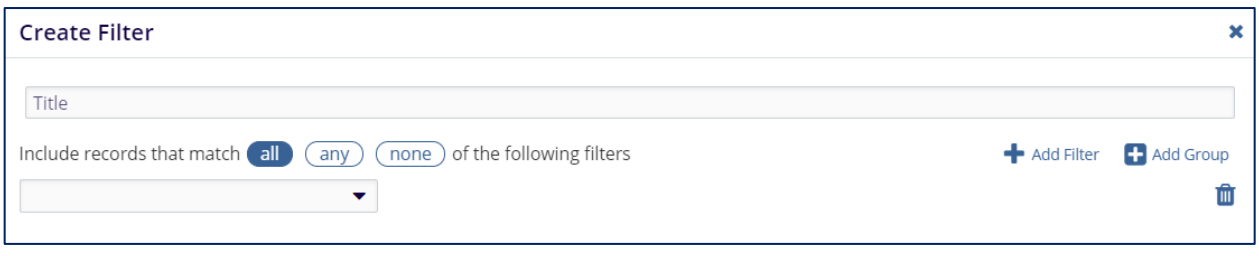
Each of these is discussed in the separate sections below:

Creating a New Filter

1. **Click the '+ Create New Filter' button 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. **Notice that there are two plus signs to the right of the window which allow you to create a single filter or a group of filters.**
    c. **The options for matching the filter records. Refer to the screenshot below:**

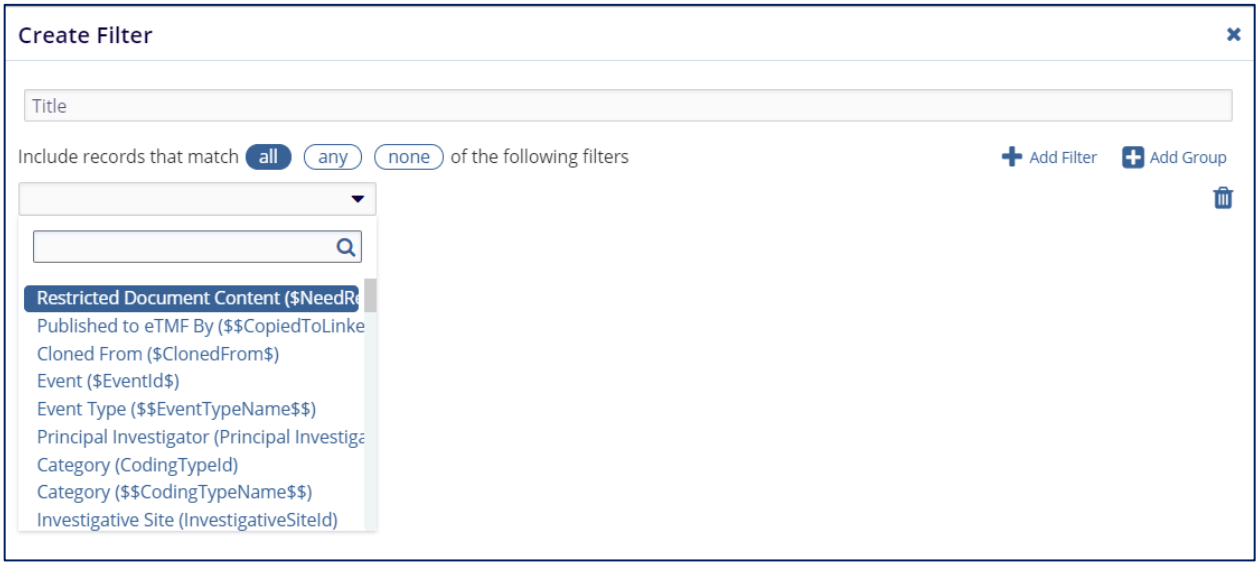
Adding Single Filter

1. **To add a single filter, click the first + sign. Refer to the screenshot below:**

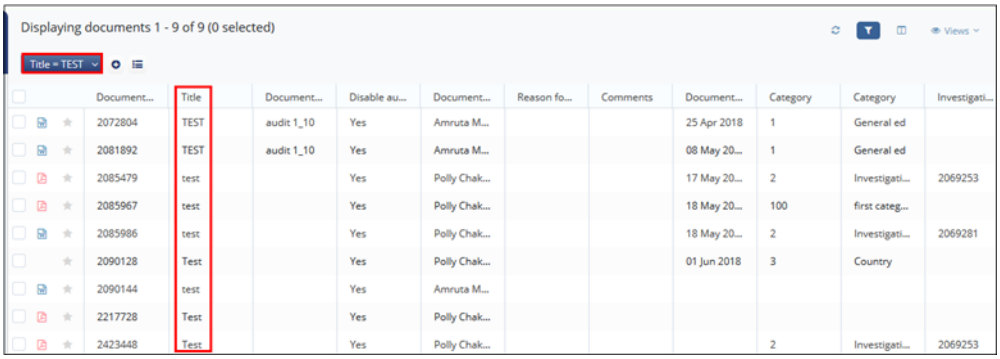


2. **A dropdown appears. Click the dropdown and select the fields to which you want to apply filters.**

3. **Select the operator and enter the value for the selected field. Refer to the screenshot below:**



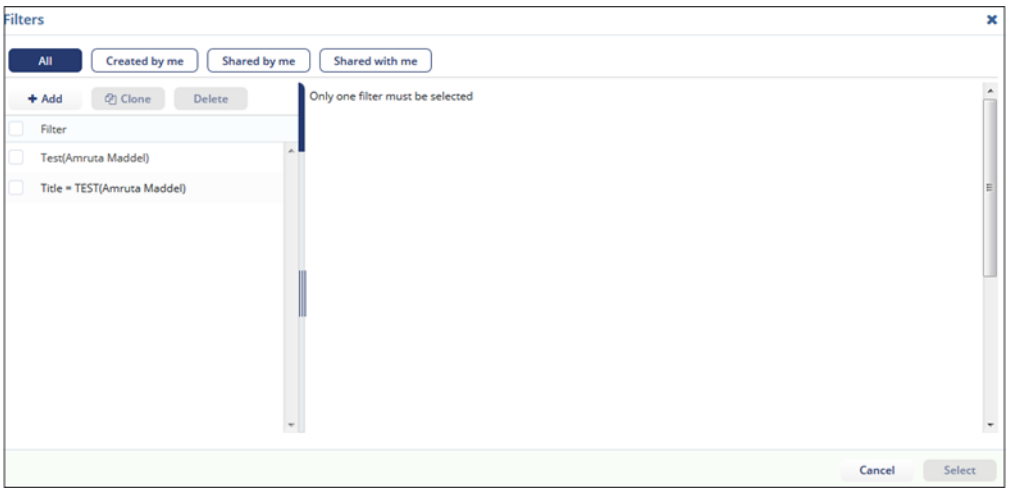
4. **When you have applied all of the applicable filters, press the 'Create' button.**
5. **The filter will appear above the grid, select the filter to apply it to the grid contents. The screenshot below shows an example of the filter result applied for the Title = Test.**



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

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:



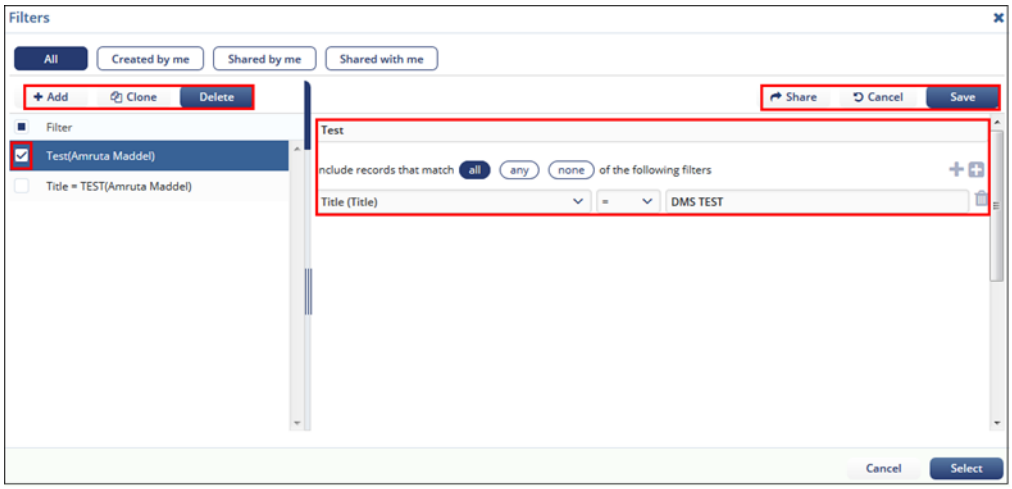
You can perform the following activities on the filters in Manage Filers window:

- **Share Filters**
- **Clone Filters**
- **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.

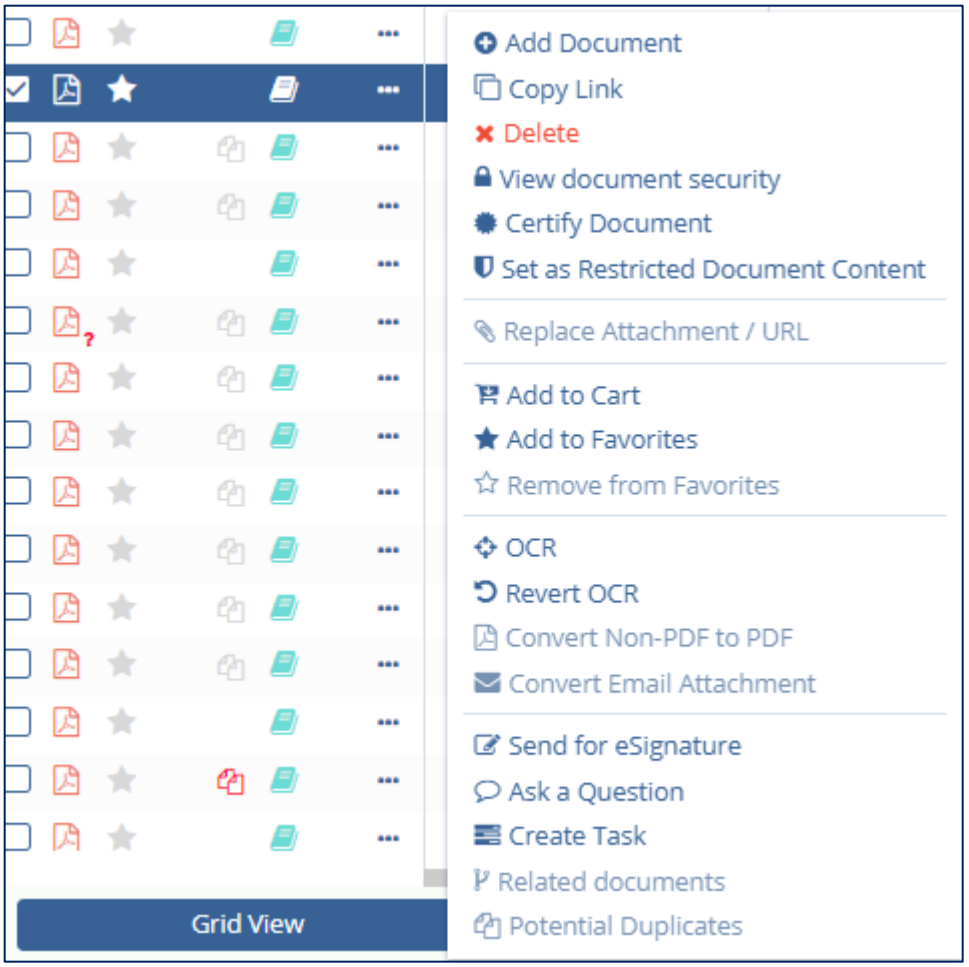
Viewing Shared Filters

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 DOCUMENT ACTIVITIES MENU

Depending upon your user access rights, there are a great many activities that can be performed from the Document

Activities Menu. To open this menu, select a document or a placeholder from the Grid and either right-click or use the three-dot menu. (See the screenshot below)



The view shown is that of a room administrator. The options available to you will depend upon your individual user access rights. We will discuss several of the option shown in the section below. Other options will be discussed in topic-specific sections elsewhere in the User Guide.

<u>Adding a Document via the Document Activities Menu</u>

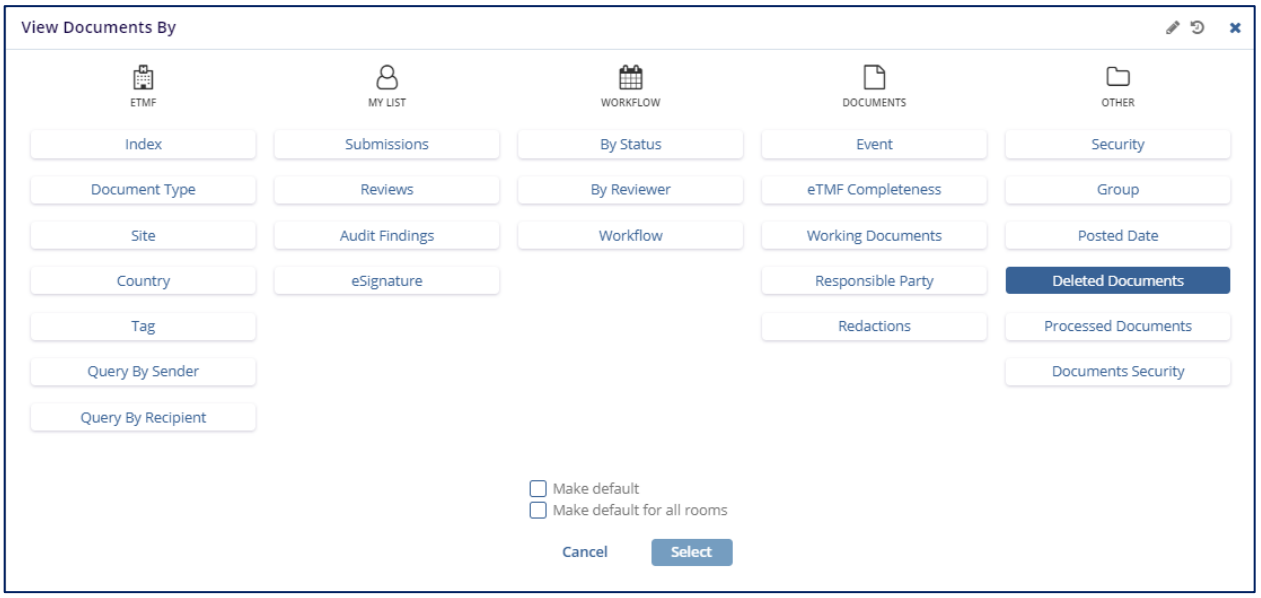
Often, when a placeholder is displayed in the Grid, users with sufficient access (editors and above) can open the Document Activities Menu and select the 'Add Document' option. In locations within Trial Interactive where this is an option, the system will open an import interface which will apply the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

<u>Deleting a Document via the Document Activities Menu</u>

Administrator level users will be able to select 'Delete' from the Document Activities menu for any document in the room except those currently claimed for review in either an Audit Response or the QC Workflow. Editor and Manager level users are able to delete documents so long as the user is the one who uploaded the document and that document

has not been claimed by the QC workflow. Once a document is final, Editor and Manager level users will not be able to delete the document without additional permissions applied to their account.

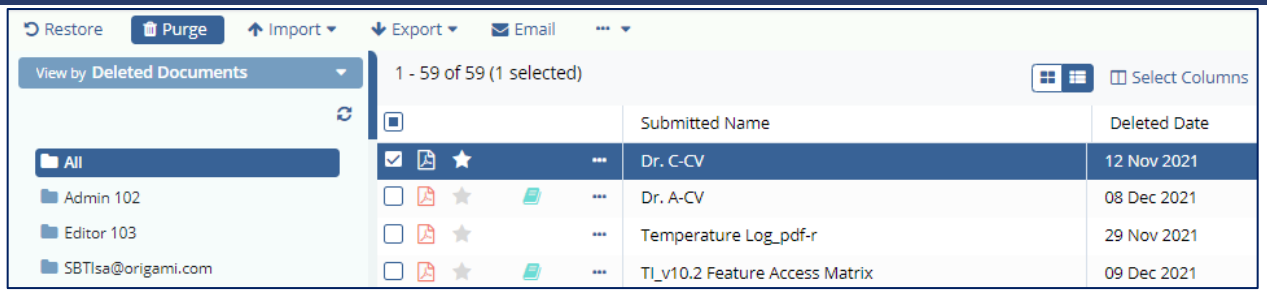
Deleted documents are accessible in the Deleted Documents view of the Documents module. Only Administrators have access to this view. (See the screenshot below)

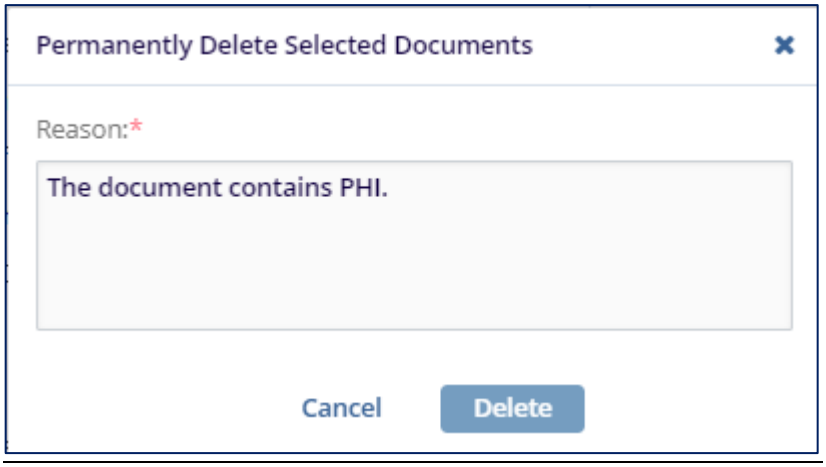


<u>Purging a Deleted Document</u>

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

1. **Navigate to the Deleted Documents view.**
2. **Locate the document that was deleted.**
    a. **Documents are sorted by the user who deleted them and additional column selection and filtering are available as in other areas of the system.**
3. **Use the Purge option.**
4. **Provide a reason.**
5. **Press 'Delete' (See the screenshots below)**





Copying a Link to a Document

It may be that you need to reference a specific document to another room user for review. If that is the case, you can either reference the Document ID Number or you can open the Document Activities menu and select 'Copy Link' which will copy a direct URL link to your clipboard. Anybody attempting to use the link will need to have sufficient access to the study room in order to access the document.

Adding a Document to the Documents Cart

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

Marking a Document as a Favorite

Marking a document as a favorite makes it appear in the My Favorite Documents dashlet on the dashboard and provides a direct link to the document from that dashlet. The easiest way to mark a document as a favorite is to click the gold star on the document line in the grid. However, you can also open the Document Activities menu via right-click or clicking on the three-dot icon and select 'Add to Favorites'.

Similarly, a document may be removed from the list of favorites by selecting 'Remove from Favorites.'

View Document Security

Administrator level users can apply specific document-level security via the Document Activities menu. Selecting 'View Document Security' will open the Document Security window. For a more in-depth discussion of security, please see the related section of the user guide.

Certify Document

For studies in which the document certification option is in use, a user can either choose to indicated that a document is a certified copy upon upload or it can be done via the Document Activities Menu. To certify a document, follow the steps below:

1. **Open the Document Activities menu by right-clicking on a document or using the three-dot icon on the grid.**
2. **Select 'Certify Document'**
3. **Read the criteria and press Finish if the document meets all expectations.**
4. **Use your username and login to complete the process.**

OCR/Revert OCR

Some functions, such as text-specific redaction, require that the document has OCR (Optical Character Recognition) applied. To apply OCR to a document, simply open the Document Activities menu and select OCR. Indicate which language the document is written in and press OK to complete the process. This process is not instantaneous. There is an OCR column that can be added to the grid which will indicate when the process is complete.

Ask a Question

This option allows users to submit a document-specific question directly to the Q&A module of the room. The Q&A module is discussed in greater detail in another section of this guide.

Convert Non-PDF to PDF

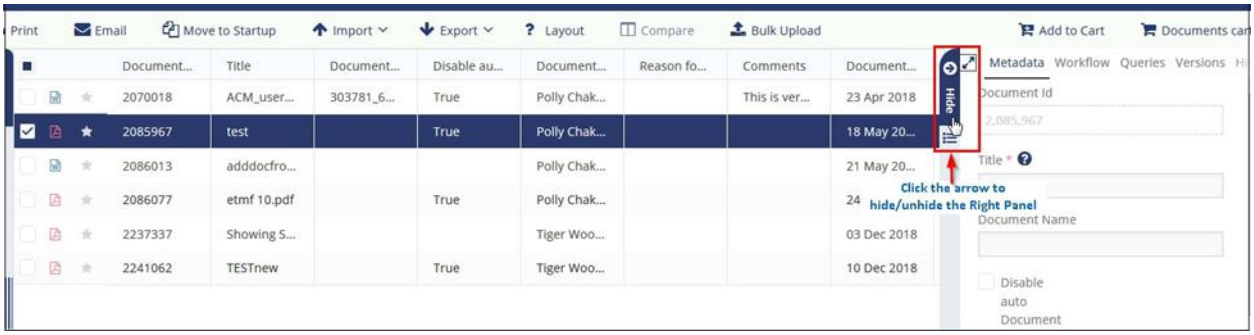
This allows you to convert the Non-PDF documents to PDF. You can view these converted PDF documents under the Processed view of the documents.

THE DOCUMENT METADATA PANEL

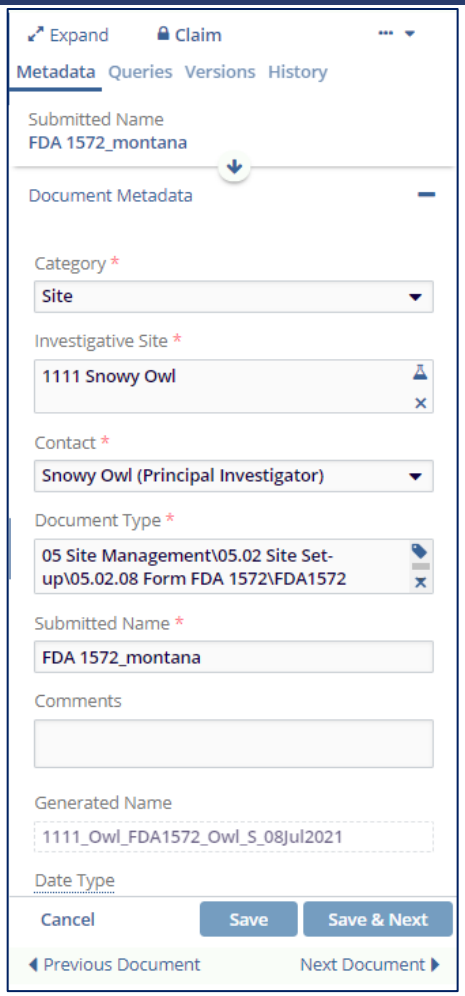
From the Right Panel located at the right of the documents grid, you can view the following panels after you select a document from the grid:

- **Metadata tab**
- **Queries tab**
- **Versions tab**
- **History tab**
- **eSignature tab**

You can expand or hide this panel by hovering the mouse to the right of the grid and clicking the Open/Hide arrow. Refer to the screenshot below:



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



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 three-dot menu icons at the top of the panel to allow you to claim documents in workflow and perform various actions on the document.

<u>Workflow Functions in the Metadata Panel</u>

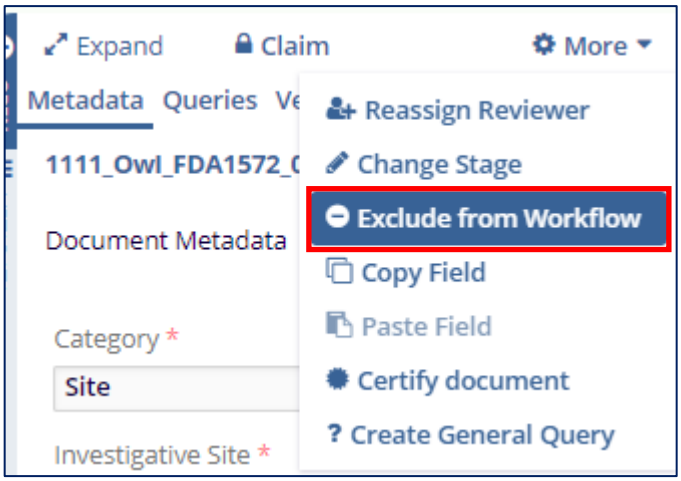
Users can conduct the full document QC Workflow process for a document via the metadata panel, even outside of the normal QC Review area of the system. A more in-depth review of these functions can be found in the related section of this user guide. However, a list of workflow related functions available from the metadata pane is below:

- **Claim and Release documents**
- **Apply metadata coding**
- **Pass/Fail documents**
- **Send an issue notification**
- **Open a workflow query**
- **View all Workflow History**

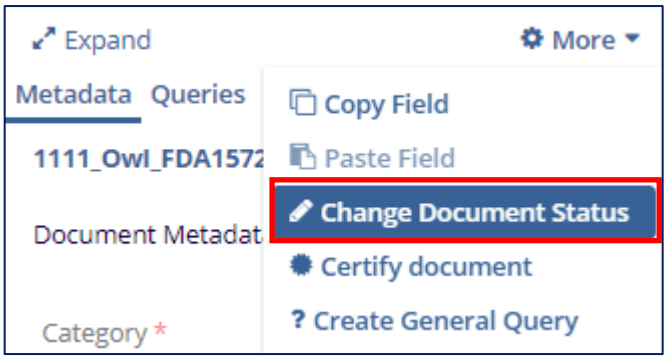
Administrative users can also use the three-dot menu at the top-right of the metadata pane to reassign a document reviewer or to exclude a document from the workflow entirely. Once a document has been excluded from the workflow, room administrators can use the same menu to manually set a document's status in the study room.

An administrator level user will only be able to change the status of a document if it is not a part of a document workflow in the room. For rooms in which all documents are automatically incorporated into a workflow, the administrator will need to first exclude the document from the workflow prior to changing its status. See the screenshots below:

Step 1



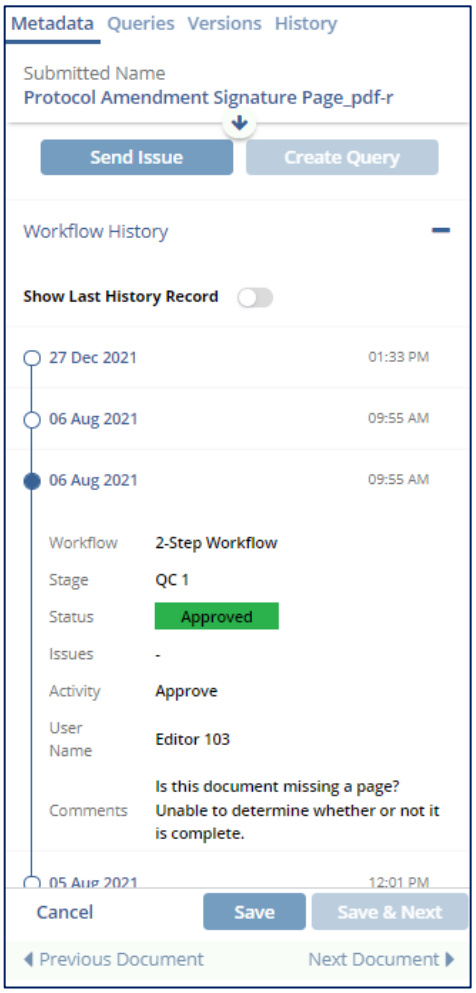
Step 2



Workflow History

At the bottom of the metadata panel, there is an expandable area which displays the document's workflow history. The system defaults to showing the last recorded entry. There is a toggle switch at the top of the section. When this is toggled to it's active (green) setting, it will show only the most recent entry. To see more entries in this area, deactivate this selection using the toggle switch.

When all workflow entries are displayed, click on the date to display more information about the history record. See the screenshot below:



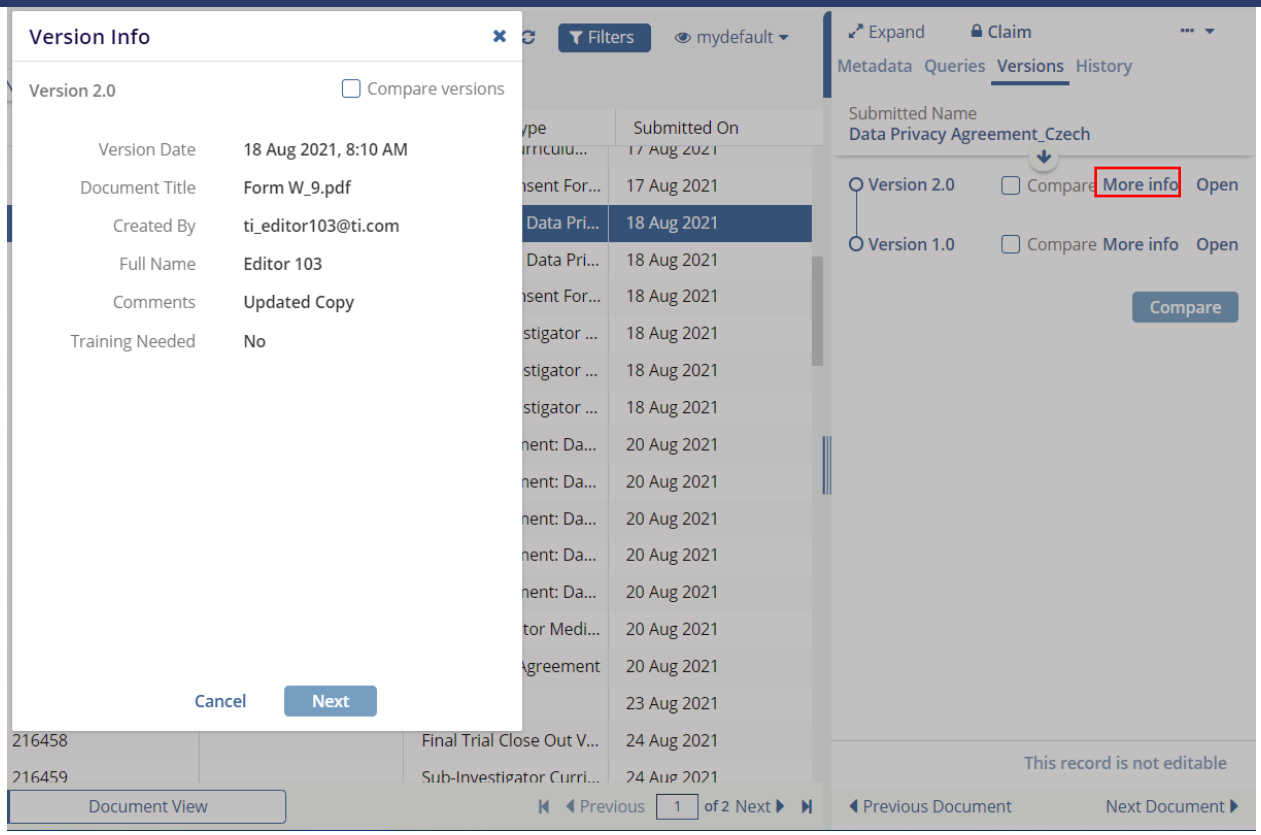
Viewing and Working Queries from the Metadata Panel

Users can perform all query-related activities from the metadata panel. For additional information on viewing and working queries, see the section on queries in this guide.

Versions Tab

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

Select a document from the grid and click Versions tab from the Right panel. The different versions of the document will be displayed in the versions tab, if applicable. Refer to the screenshot below:

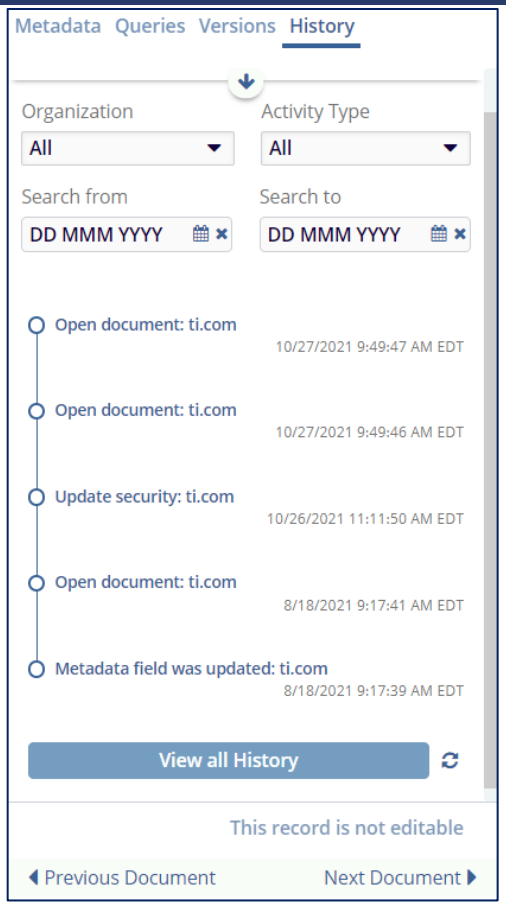


Clicking More info next to the version number opens the Version History which gives a detailed view of the document version history. Refer to the screenshot above.

Users can also check the boxes for two versions and press the 'Compare' button in order to view the versions side by side.

<u>History Tab</u>

The History tab gives an overview of a document history. This panel displays the top five 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:

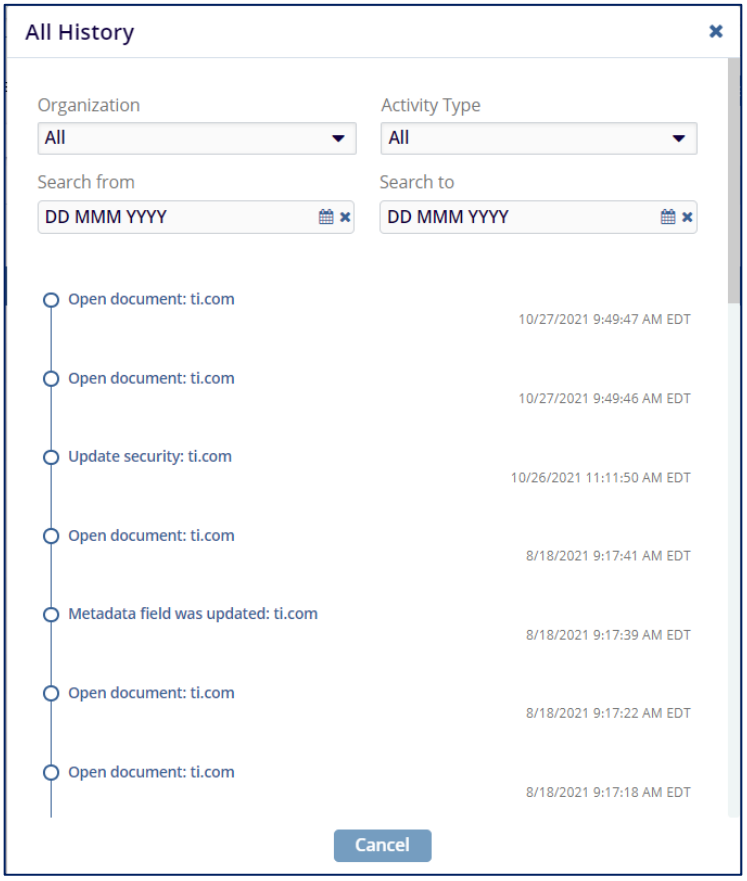
- **By Organization: Use this filter if you want to view the document history based on the organization.**
- **Activity Type: Use this filter if you want to view the document history by the activity performed on it.**
- **Date Filter: Use this filter if you want to view the document history within the set date range.**
- **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.**

<u>Viewing Document Activity</u>

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.

<u>Viewing All History</u>

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:



DOCUMENTS MODULE, TOP MENU RIBBON

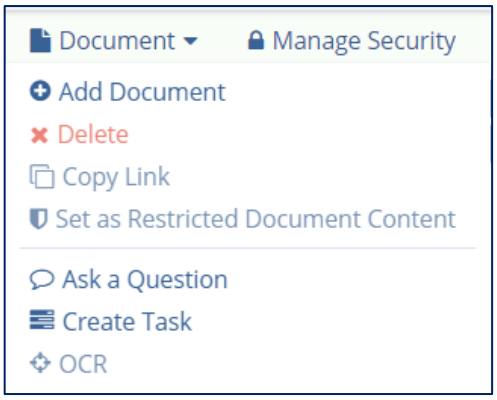
This menu is located at the top of the Documents module and allows access to various functionalities on documents:

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

Refer to the screenshot below:

Document Activities

The options available in this dropdown menu are only available once a document has been selected in the grid and are a subset of the options available in the Document Activities menu mentioned in the section above. Please see that section for a more detailed description of these options. See below for a screenshot of the menu:



Manage Security

This option will open up the Manage Security window from which folder-level security can be managed. For a more detailed description of this process, please see the related section.

Mass Coding

The Mass Coding function, accessible by clicking on the three-dot dropdown menu, allows a user to apply metadata to multiple documents at the same time. If the Causality Tracking feature is enabled in the room then Mass Coding will be disabled.

Email

The email function allows users to send an email to another room user or contact. This could be a document-related email or not. In order to send an email, follow these steps:

1. **If applicable, select the documents related to your email.**
2. **Press the Email button above the grid.**
    a. **This will open the Email window.**
3. **You can either type the email recipients into the appropriate line or use the 'To' and 'CC' buttons to select recipients from the list of users.**
4. **Type your message.**

5. **If applicable, indicate whether or not the documents should be attached to the email using the radio buttons at the lower-left corner of the window.**
6. **Press 'Send' when done.**

Move to Study Start Up

This option is only available in rooms with Study Start Up enabled. Selecting documents from the eTMF (normally from the default or upload folders) and pressing this button will move the documents to the Study Start Up module of the study room.

Print

This function does not actually print the documents. Instead, the 'Print' button will take the selected documents and merge them together into a single PDF file which can then be downloaded or printed by the user.

Compare

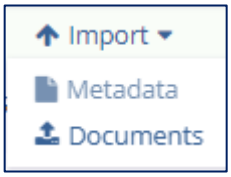
Selecting two documents and pressing the Compare button will cause the chosen documents to appear side-by-side in a pop out window along with any associated metadata.

Local Search

Above the documents grid, next to the documents cart, is a search bar. This is a local search and will search the currently selected index folder for relevant documents. This feature is intended to be a simpler and quicker solution than the creation of filters although a filter may produce more fine-tuned results.

IMPORTING DOCUMENTS AND METADATA

The Import function allows users to bring documents into the room, where permissible, the function also allows for an import of metadata only. If the user has selected a specific target folder in the index pane, the import window will populate with appropriate metadata in anticipation of that folder being the desired final location of the document.



Follow these steps in order to use the Import function to add documents to a room via this function:

1. **Click on the Import button above the documents grid.**
    a. **This will open the Import Documents window.**
2. **Add documents to the area at the left either by dragging them from your desktop or by searching for them on your computer. To open the browsing window either click on the Browse button or on the arrow at the center of the documents area.**

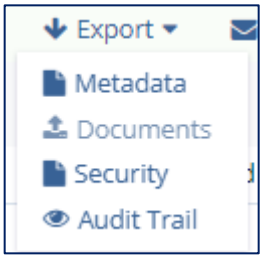
a. When adding .zip files to the room, review the options at the bottom of the window to indicate whether or not these files should be unpacked during upload. Password protected files cannot be unpacked by the system during upload.

3. Indicate whether or not any non-PDF documents should be converted to PDF files during the upload process. The types of files that can be converted are specified in the room's settings.
4. Indicate, via the checkbox at the top of the right side, whether or not any metadata should be applied to the documents.
    a. Metadata can be applied to all documents at once or to a subset of documents. In order to apply metadata to only some of the documents, check the box next to the documents to which the metadata should be added.
5. Press 'Import' or, if you have applied metadata, Press 'Import and Apply Metadata.'
    a. If you have chosen to apply metadata to only a few of the documents, only those documents will be uploaded to the room. Repeat steps 4 and 5 until all documents have been uploaded.

EXPORTING DOCUMENTS AND METADATA

There are two export functions in Trial Interactive. This particular function is related to documents currently visible in the grid. If you would like to export documents from multiple locations at the same time, place them all in the Documents Cart and use the export function in there to complete the process.

Like the Import function, this export has the ability to export documents, metadata, or both. Users with sufficient access will be able to export security and audit trail information.



A metadata-only export is often a faster and more efficient way of gathering information regarding a subset of documents in the study room than running a related report.

To export metadata, follow these steps:

1. Locate the documents whose metadata should be exported.
2. Check the box next to each document to be exported.
3. Click the Export button and choose 'Metadata'
    a. The Export Metadata window will open.
4. Choose from the Source options:

   a. Selected records
   b. All documents in the current grid
   c. All documents in the room
5. Choose whether or not the export should include Quality Review (audit) related Metadata.
   a. If you choose to export Quality Review metadata, indicate whether all information should be provided or only the information from the most recent audit.
6. Press 'Next'
7. Choose which metadata fields should be included in the export
8. Press 'Export'

To Export Documents, follow these steps:

1. Locate the documents to be exported.
2. Check the box next to each document to be exported.
3. Click the Export button and choose 'Documents
   a. The Export Documents window will open.
4. Choose from the Source options:
   a. Selected records
   b. All documents in the current grid
5. Choose from the available options (these options will vary depending upon user access rights)
   a. Track Export
   b. Exclude previously exported documents
   c. Include Metadata
   d. Include Document Versions – This option will export all versions of a document to which the user has access. Reader level users can only export the current effective version.
6. If you have chosen to include metadata, choose whether or not the export should include Quality Review (audit) related Metadata.
   a. If you choose to export Quality Review metadata, indicate whether all information should be provided or only the information from the most recent audit.
7. Press 'Export' or 'Next' depending on whether or not you opted to include metadata.
8. If you opted to include metadata, choose which metadata fields should be included in the export
9. Press 'Export'

To export security information, follow these steps:

1. Locate the documents whose information should be exported.
2. Check the box next to each document to be exported.
3. Click the Export button and choose 'Security'
   a. The Export Security window will open.

4. **Choose from the Source options:**
    a. **Selected records**
    b. **All documents in the current grid**
    c. **All documents in the room**
5. **Press 'Next'**
6. **Choose which metadata fields should be included in the export**
7. **Press 'Export'**

EXPORTING INSTANT AUDIT TRAILS

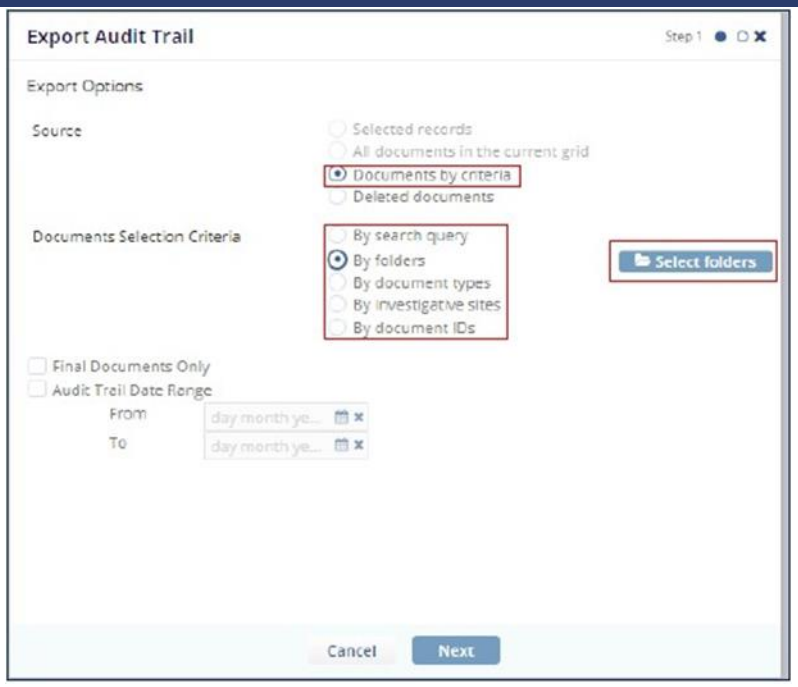
Auditors often ask for immediate access to the audit trail of a specific document or set of documents. It is critical to be able to provide this information immediately and respond to the audit request. This feature is also available to users who are provided with Regulatory Agency Inspector access as well as internal auditors.

To that end, Trial Interactive now provides this capability through an audit trail export feature. This export feature allows for users to report audit information according to the following criteria: All documents in a room, Current list of documents in the grid,

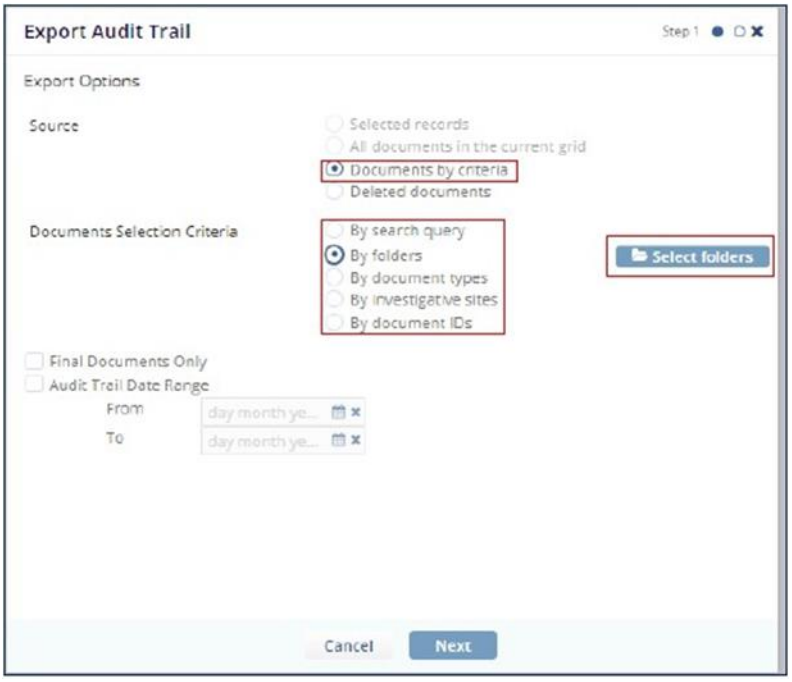
- **A specific search query,**
- **A specific folder, site, document type, or Document ID, or**
- **A range of dates**
- **This feature also provides the flexibility to easily export this information to an Excel spreadsheet for review.**

In order to export an audit trail, follow the steps below:

1. **Navigate to the eTMF Documents module.**
2. **Select the Export dropdown menu from the options above the Grid.**
3. **Select the Audit Trail option as shown in the screenshot below.**



4. **The Export Audit Trail window will open.**
5. **Select the Documents by Criteria option.**
    a. **This will activate the Documents Selection Criteria area of the window.**
6. **Select which option you would like using the radio buttons.**
7. **If you have chosen the By document IDs option, you can enter the document ID numbers in the field below. For all other options, press the associated blue button to the right of the chosen option to continue and select specific criteria as shown in the screenshot below.**



8. **Choose the appropriate criteria and press the Select button.**
9. **When you have indicated all necessary criteria, press Next to continue.**

a. **A confirmation window will open showing you the selected criteria.**

10. **Review the selected criteria and, if they are correct, press Export.**
11. **A message will be displayed when the export is ready for download.**
12. **Press Get Job Results to download the file.**

THE DOCUMENTS CART

The functions available to a user via the documents cart will vary based on access level.

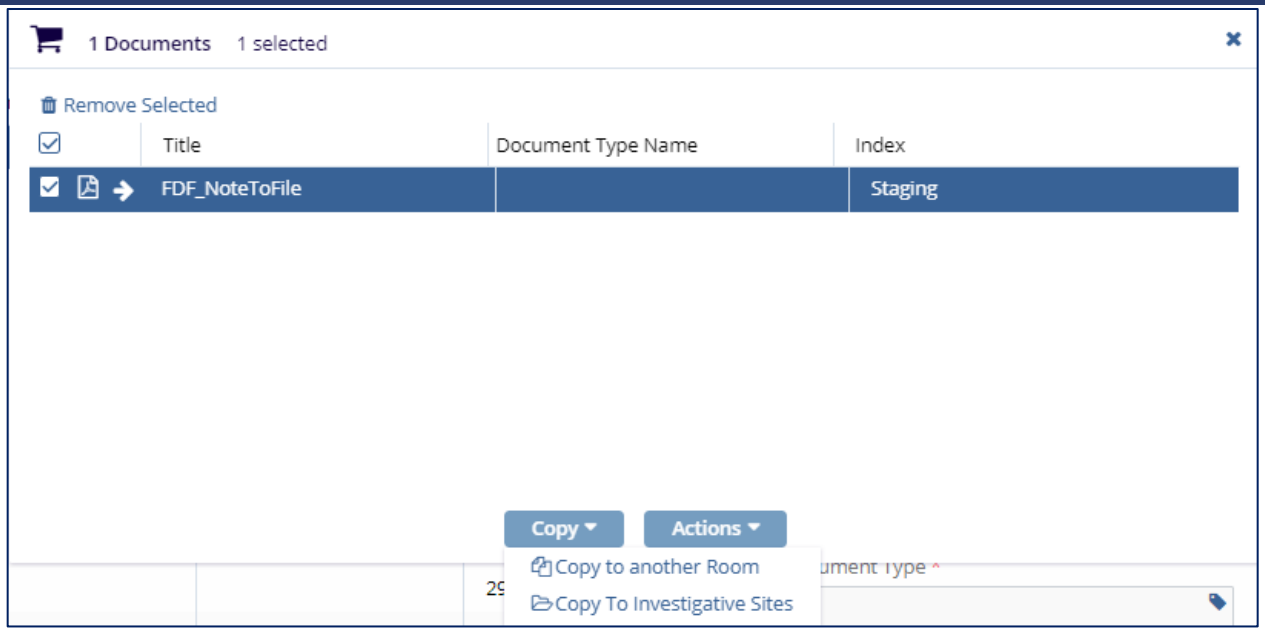
Adding documents to the Documents Cart

1. **Locate the document which is to be added to the Document Cart and select the checkbox next to it.**
2. **Right-click and select Add Selected to the Cart option or simply click and drag the document to the documents cart.**
3. **Once a document is added, it will automatically update to reflect the number of documents available in the cart. Refer to the screenshot below:**

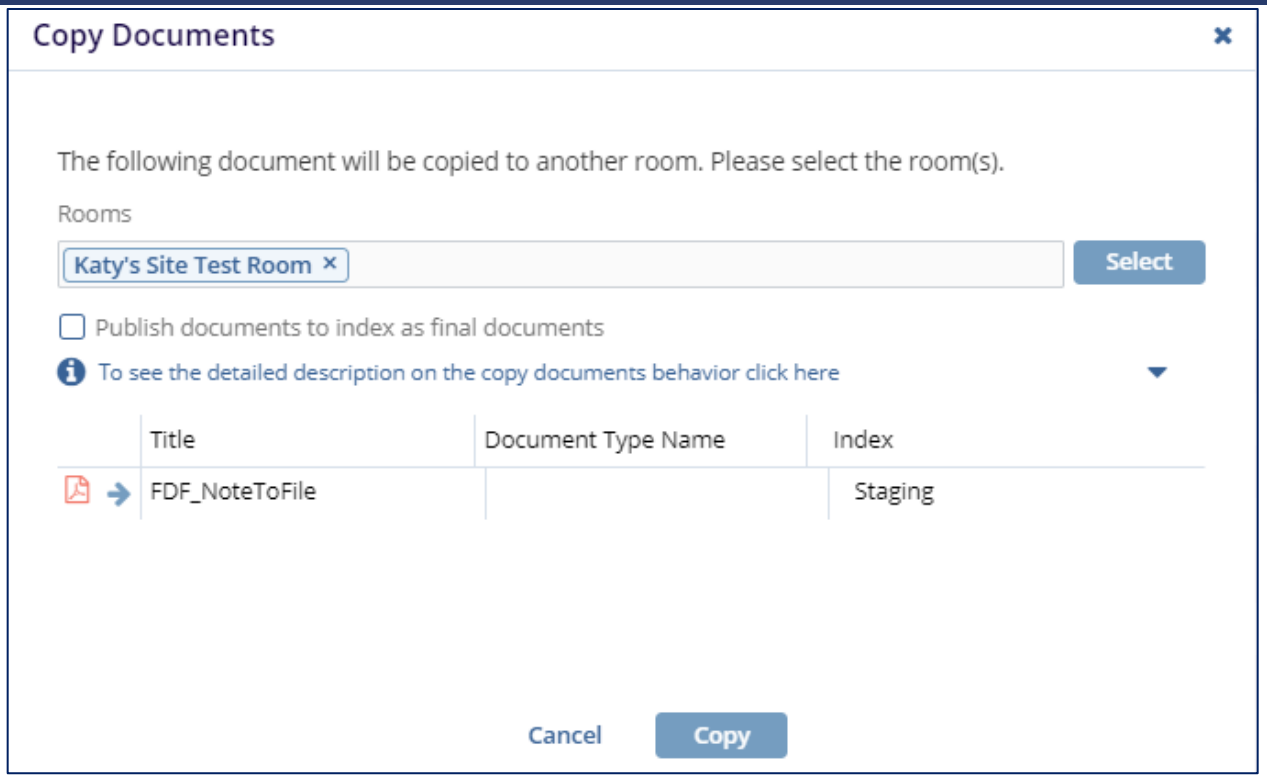
Copying documents to Other Rooms

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 to the Documents Cart.**
2. **Click the arrow next to the Documents Cart to open the cart window.**
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.**



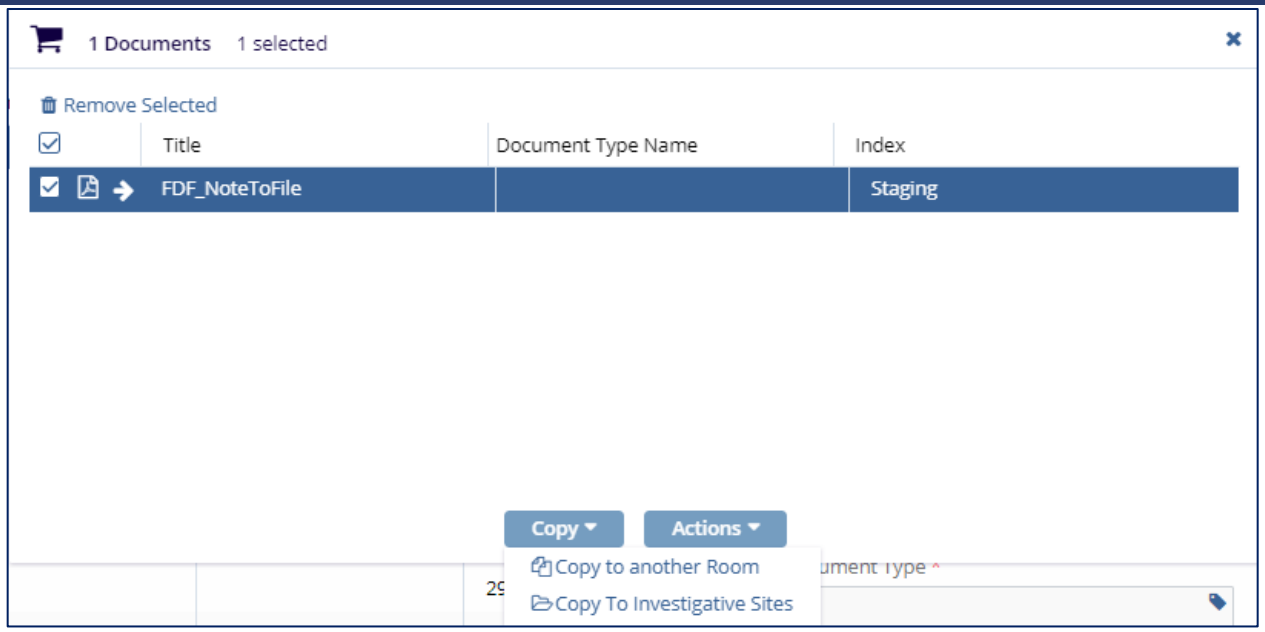
5. **The Clone Document window will open up and prompts you to specify to which study rooms documents the documents should be copied to.**
6. **Click the Select button which opens the Rooms window to allow you to select the rooms to copy the documents to.**
7. **If you wish to publish documents to the index as final documents without going through the workflow, select the checkbox next to publish documents to the index as final documents.**
8. **Click Copy. 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

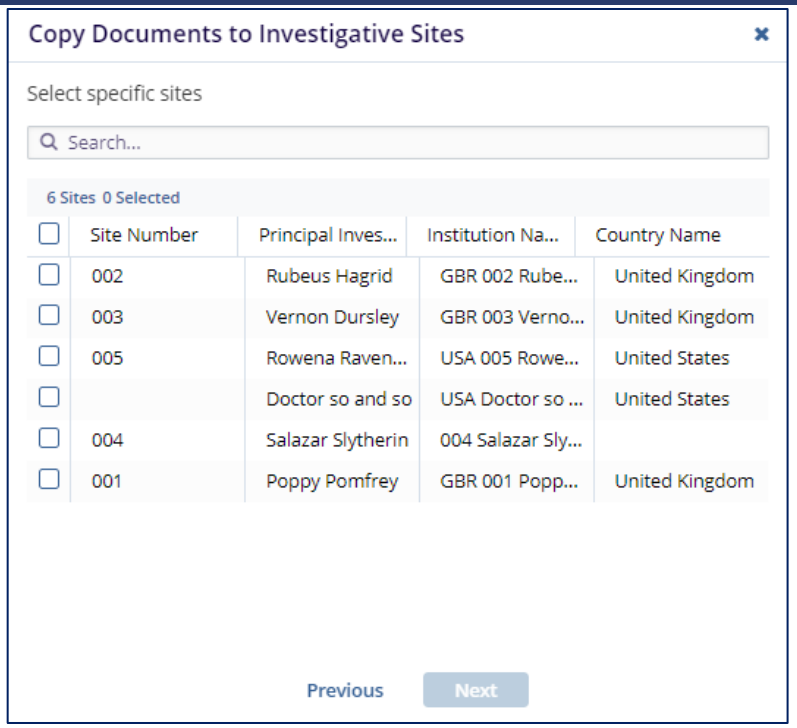
This option is helpful when Administrator users wish to distribute the same document, such as training documents, across different investigative sites. To avoid copying these documents one-by-one, you can simply use this option in Documents Cart.

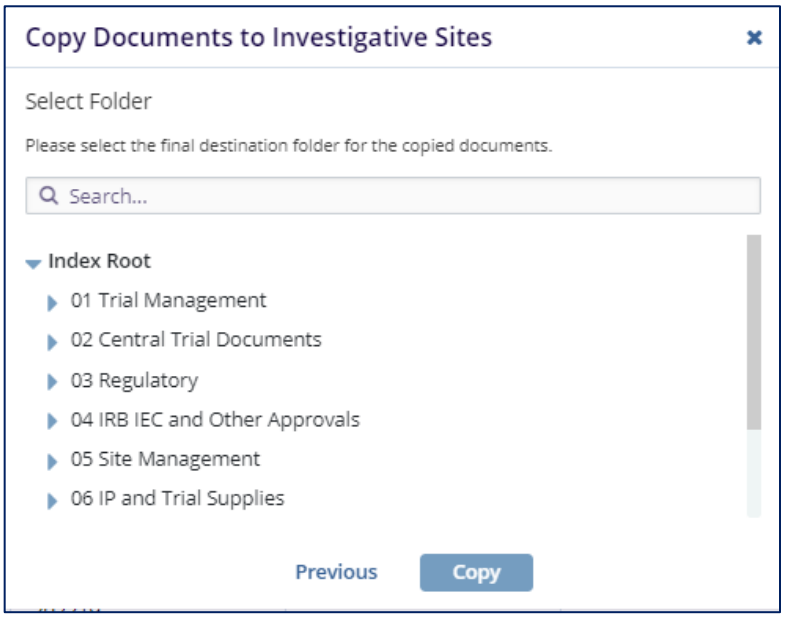
1. **Add required documents to the Documents Cart**
2. **Click the arrow next to the Documents Cart. A pop-up opens.**
3. **Select the documents which you wish to clone to other Investigative Sites.**
4. **Click Copy and select to Investigative Sites. Refer to the screenshot below.**



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 Copy. The documents are copied to the Investigative Site folder. Refer to the screenshot below:**

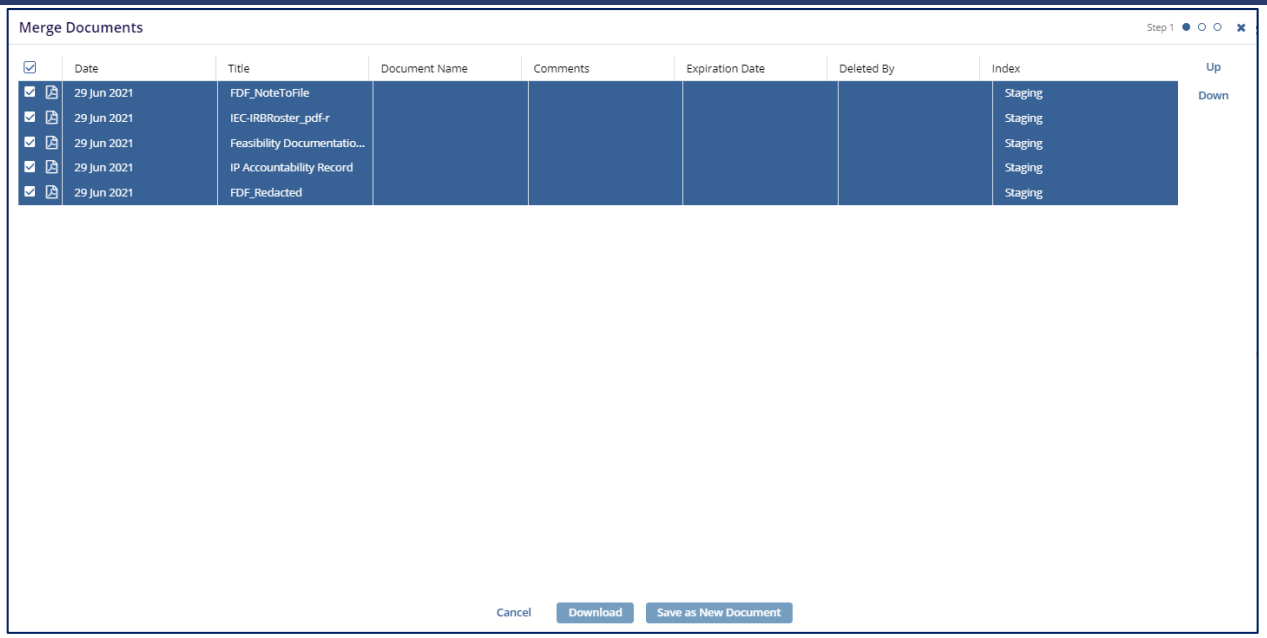




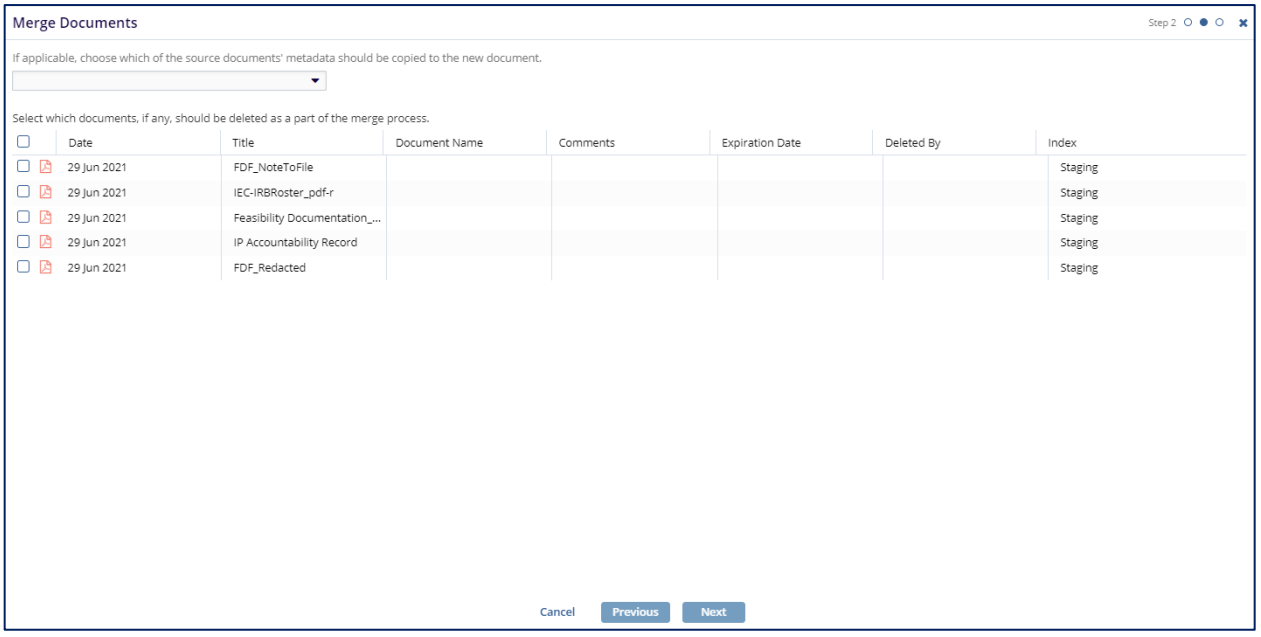
Merging documents

Administrator, Manager, and Editor users can merge two or more documents into one document.

1. **Add required documents to the Documents Cart.**
2. **Select the documents from the cart you want to merge.**
3. **Click Actions and then select Merge.**
    a. **The Merge Documents window will open.**



4. **Confirm that all of the documents present are to be merged.**
5. **Use the Up and Down buttons on the right side to place them in the correct order of appearance in the final document.**
6. **Press either Download or Save as New Document.**
    a. **Save as New Document will create the merged file as a new document in the study room. All additional steps refer to this process.**
    b. **The screenshot below shows the next screen that appears after pressing 'Save as New Document.'**



7. **The dropdown menu at the top of the screen allows you to clone the metadata from any of the source documents.**
8. **The lower area, listing the source documents, is there in case the user wishes to delete any of the source documents as a part of the merge process.**

a. **The source documents will only appear here if the user has the appropriate access rights to the documents to delete them.**

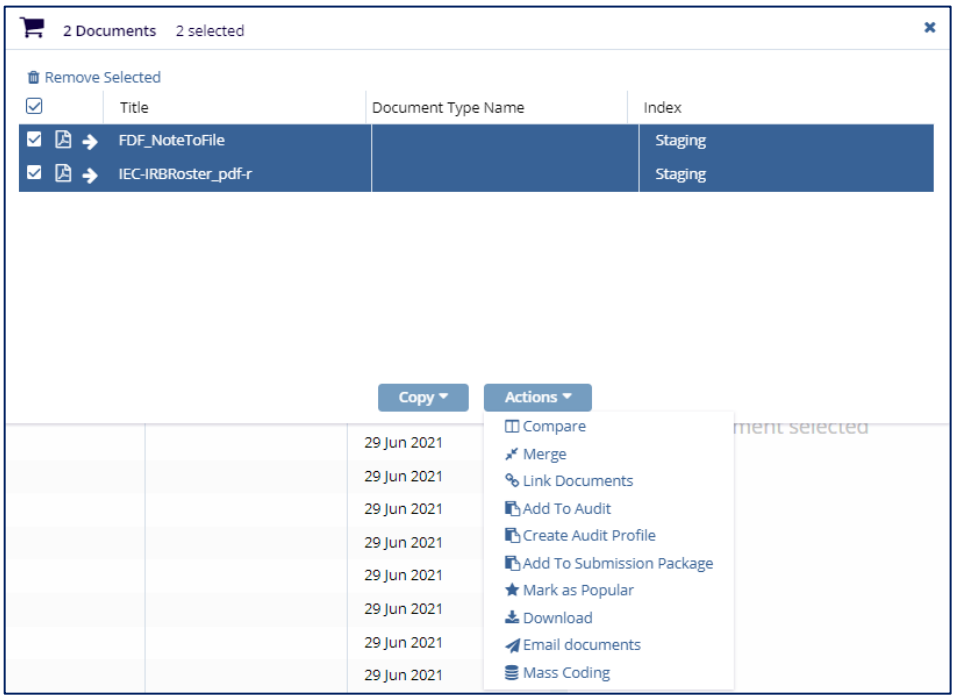
b. **Any document selected will be deleted as a part of the merge process.**

9. **Press 'Next'**
10. **Confirm the metadata for the merged document and press 'Finish'**

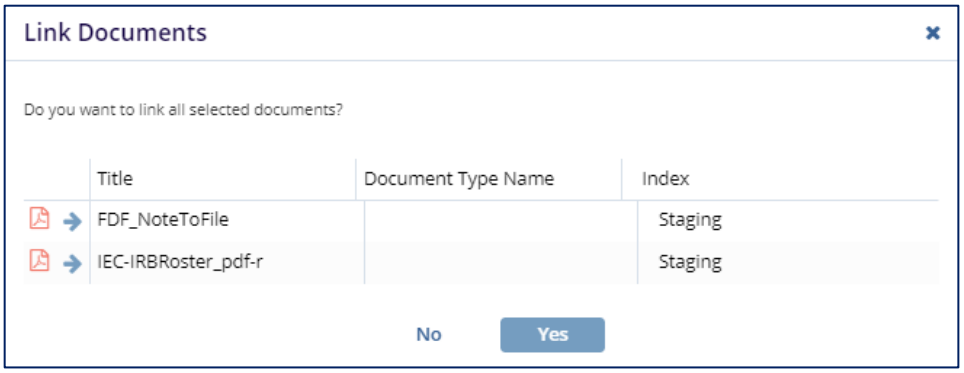
Linking documents

Editor and Administrator level users can link documents together with this option.

1. **Add required documents to the Documents Cart.**
2. **Select the documents from the cart.**
3. **Click Actions and then select Link. Refer to the screenshot below:**



4. **The Link Documents window will open. See the screenshot below:**

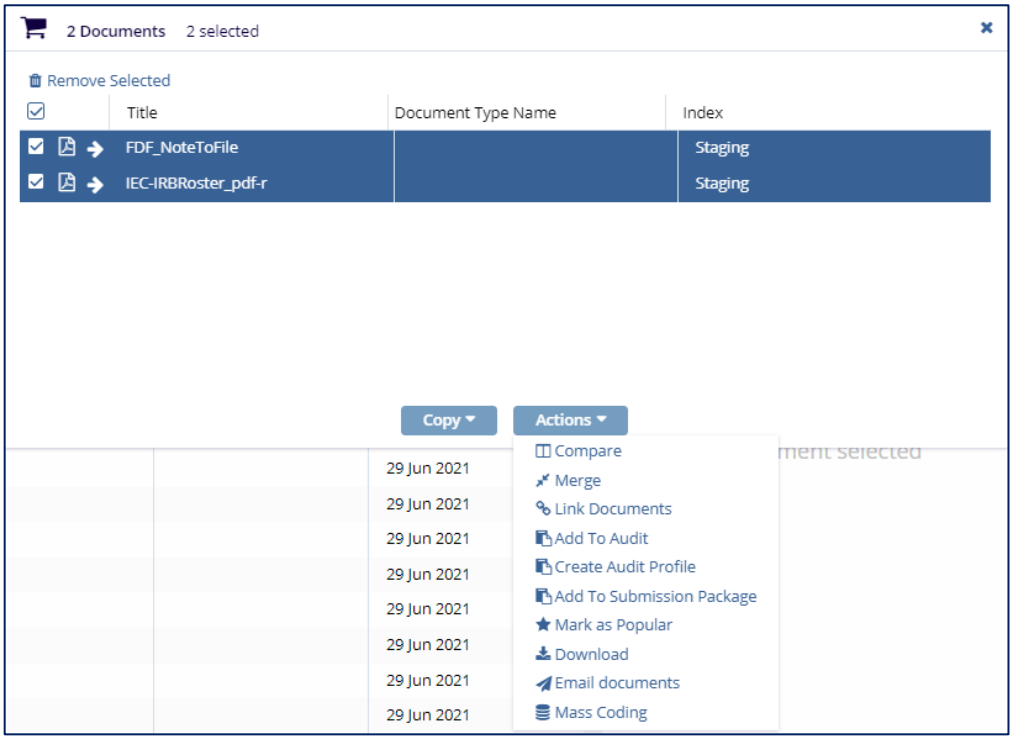


5. **Press Yes to complete the linking process.**

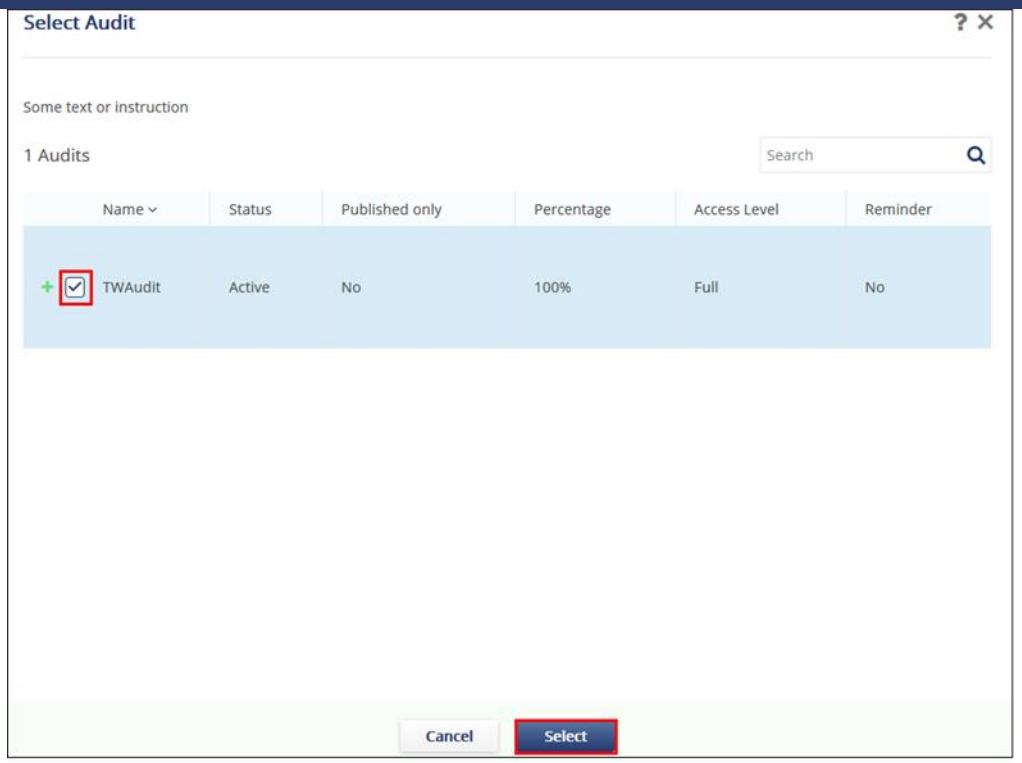
Adding documents to an Audit

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

1. **Add required documents to the Documents Cart.**
2. **From the Documents Cart, select the appropriate documents.**
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:**

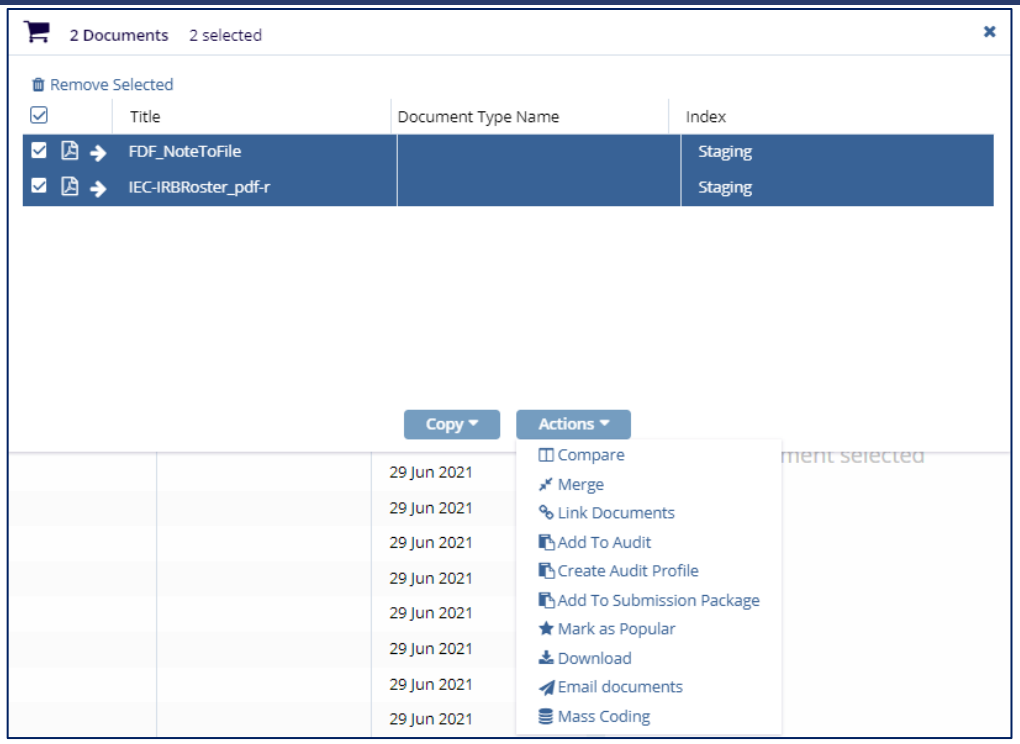


- **Note:** **The audits displayed are those which have been created in the Quality Review module specifically to have documents added to them in this manner. For additional information on creating the appropriate type of audit, please see the chapter on Quality Reviews.**

Create an 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 343).**
2. **From the Documents Cart, select a document.**
3. **Click Actions and then select Create Audit Profile. Refer to the screenshot below:**



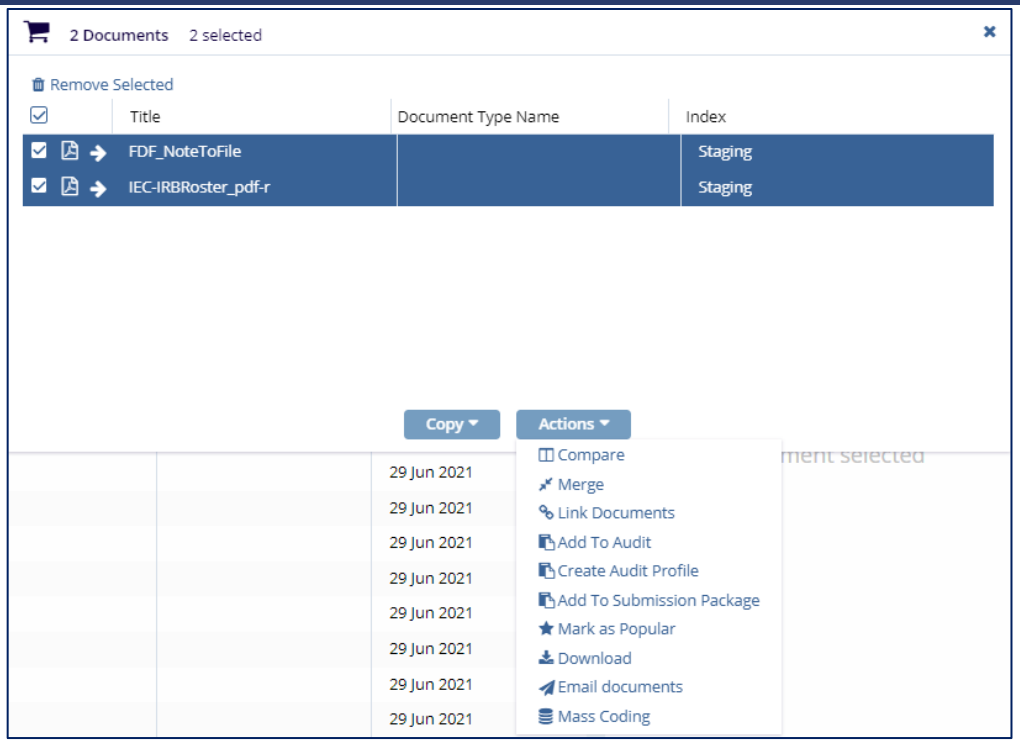
4. **The Create Audit Profile popup opens.**
5. **Follow the instructions on the form to create the audit profile as required.**

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

<u>Adding Documents to a Submission Package</u>

Administrators, managers, and editors can add documents to the cart from the grid to include them in a start-up submission package by using this option. Please note that this option will only be available in rooms in which Study Start Up has been enabled.

1. **Add required documents to the Documents Cart.**
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.**
5. **Choose the Submission Package and press 'Select'**

Downloading documents

1. **Add required documents to the Documents Cart.**
2. **Click Actions and then select Download. Refer to the screenshot below.**

Mass Coding

The Mass Coding function, accessible by clicking on the three-dot dropdown menu, allows a user to apply metadata to multiple documents at the same time. If the Causality Tracking feature is enabled in the room then Mass Coding will be disabled.

Email

The email function allows users to send an email to another room user or contact. This could be a document-related email or not. In order to send an email, follow these steps:

1. **If applicable, select the documents related to your email.**
2. **Press the Email button above the grid.**
    a. **This will open the Email window.**
3. **You can either type the email recipients into the appropriate line or use the 'To' and 'CC' buttons to select recipients from the list of users.**
4. **Type your message.**

5. **If applicable, indicate whether or not the documents should be attached to the email using the radio buttons at the lower-left corner of the window.**
6. **Press 'Send' when done.**

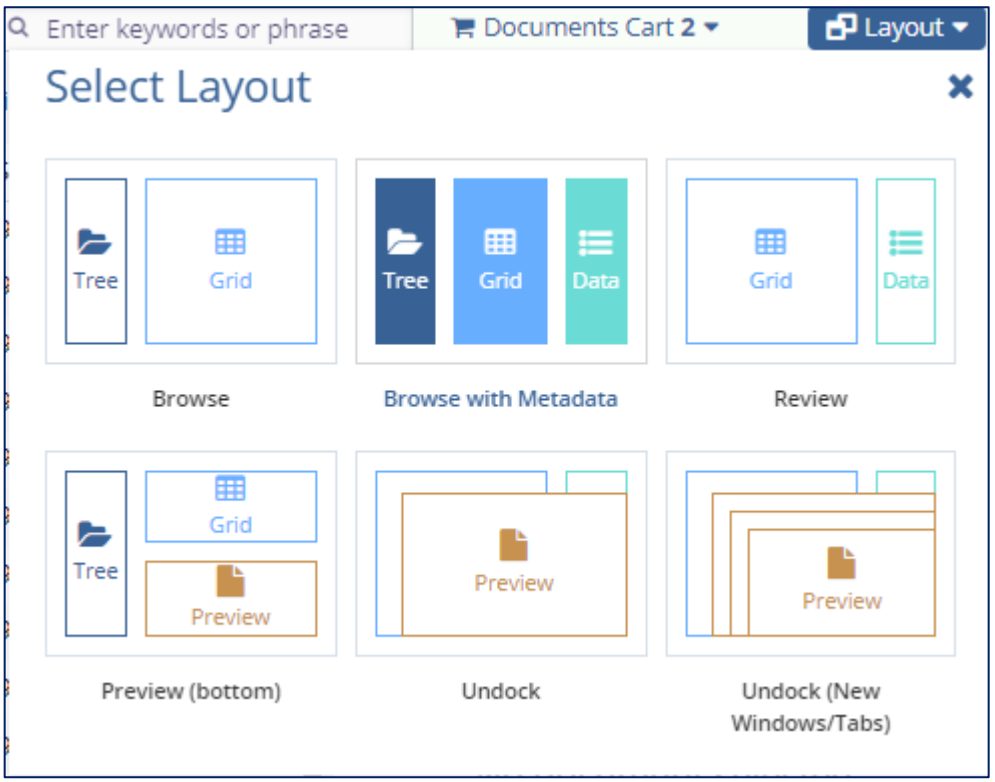
Marking documents as Popular

Administrator, Manager, and Editor 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**

Layout

The layout menu, located above the metadata pane, allows the user to choose from a number of page potential layouts. (See the screenshot below)



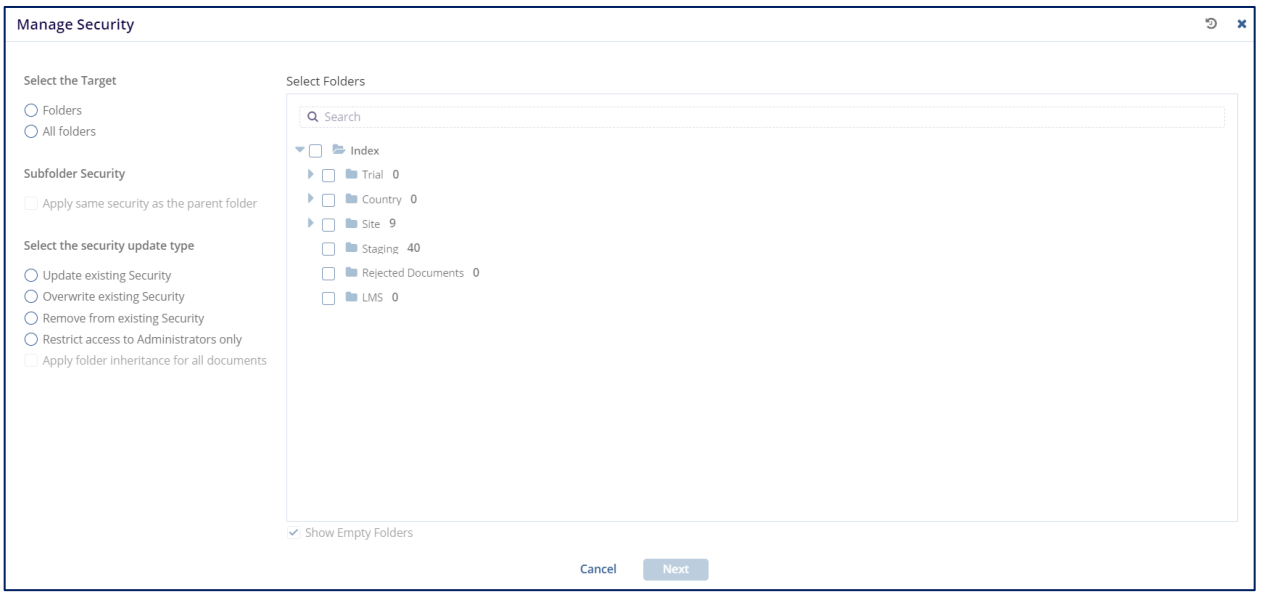
MANAGING FOLDER SECURITY

Administrator users can manage folder security. This section discusses the major interface for doing so but the user can also right-click on index folders to view and edit that specific folder's security. As the same can be done via this interface, the folder-specific method will not be discussed in depth here. Some rooms, such as eISF rooms have separate

security controls for site folders. Those are controlled from the Settings menu. Please see Site Template Folder Security for more information.

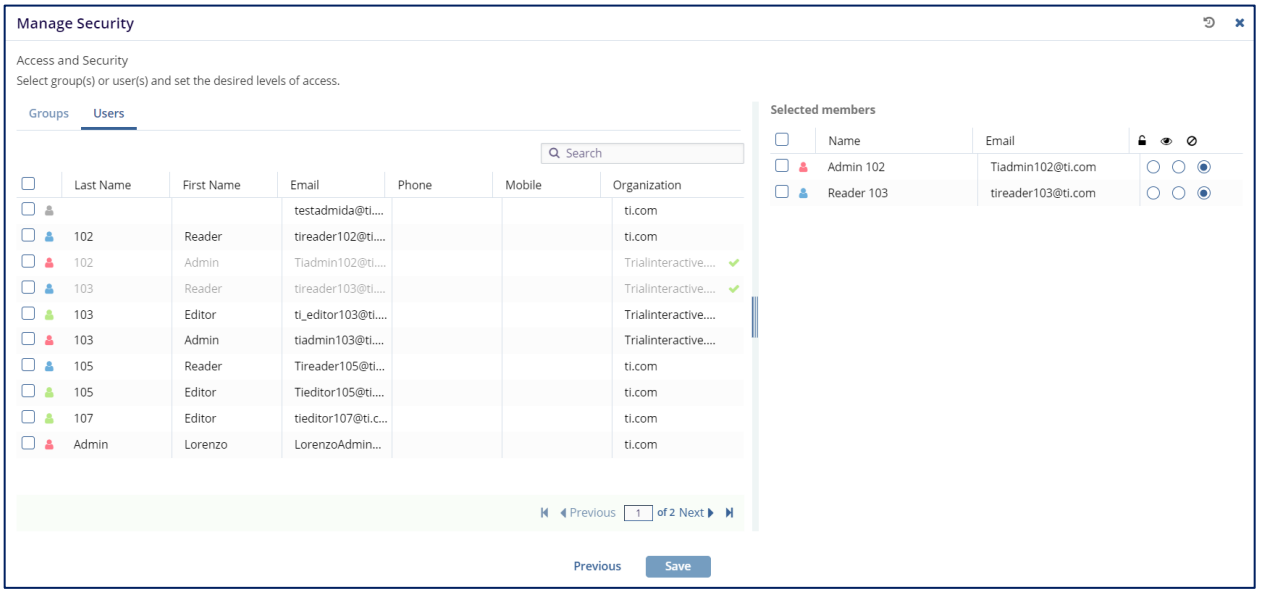
To assign Folder Level Security:

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 the 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 security. You must select at least one folder from this list.**
    a. **If you select the 'All Folders' option, the changes will automatically be applied to all folders whose security can be managed from this interface.**
3. **Select whether or not the changes should apply to all subfolders or only to the folders specifically chosen.**
4. **Click the checkboxes next to the folders whose security should be changed or, if you chose to include all subfolders then choose only the relevant parent folders.**
5. **Choose the type of security update**
    a. **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.**
    b. **Overwrite existing security: This option erases all current security definitions and replaces entirely with the definitions set in step two of the manage security process.**
    c. **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.**
    d. **Restrict access to administrators only: This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.**
6. **Click 'Next'**

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. Refer to the screenshot below:**



8. **Hover the mouse over the group/user name in the left pane. The Plus icon appears to the right.**
9. **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:**
10. **Once the users or groups are moved to the right side of the window, you will need to define their security access rights.**
    a. **Full Access – Users have unhindered access-level-appropriate access to the documents.**
    b. **Read-Only Access – Users can only view the documents.**
    c. **No Access – These users will not even see this folder on their room index and cannot access any associated files.**
    d. **No Watermark – This option will only appear for rooms in which the watermark option is enabled. It allows the selected user to view the documents in the chosen folders without the watermark.**
    e. **(Collaborate rooms only) Proxy Document Owner – This allows the specified user to act as a document owner for any documents contained in the selected folders.**
11. **Click Save**

MANAGING DOCUMENT LEVEL SECURITY

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.**

RESTRICTED CONTENT

With new regulations that limit exposure to Personalized Health and Identity Information, as well as the constant concern about exposure to unblinded data, it is often difficult to indicate that a document must be redacted within a trial while preventing unauthorized individuals from seeing this document in the interim.

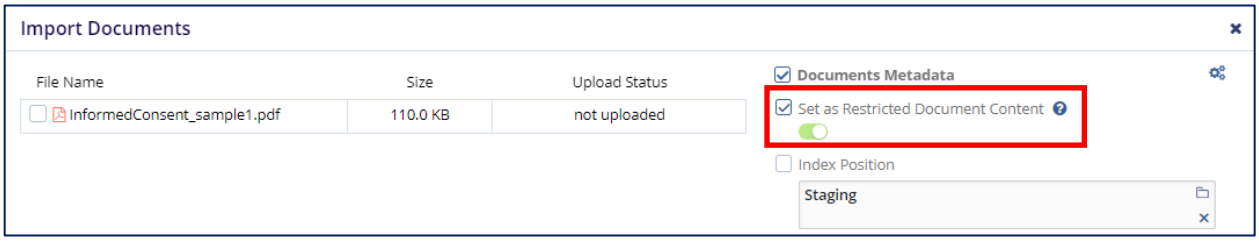
To that end, we have a Restricted Content feature. This feature allows users to indicate that a document is a 'Restrict Document.' Once restricted, only Administrator-level users or users with the redaction action on their user profile may see the unredacted copy (also referred to as the 'native' copy or 'native' version) no matter where the document moves within the room. These restricted documents will show in a new Redaction view and Redacted dashlet which shows the current queue. Users with redaction permission may then process unblinded data or documents with PII/PHI in them. Until unrestricted by a user with redaction permissions, the content will be unavailable for any purpose within TI.

<u>In order to designate a document as containing restricted content, see the section below:</u>

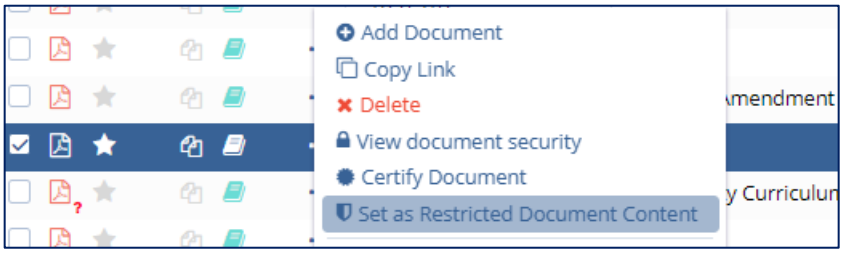
A document may be designated as 'Restricted' either during or after upload. As a best practice recommendation, we suggest that documents requiring this level of protection are designated as 'Restricted' upon upload in order to help ensure that the restricted content is not viewed by any unauthorized personnel.

During the upload (or import) process, there will be a toggle switch which, when enabled, will designate all selected documents as 'Restricted' during the upload process. The user will need to enable Documents Metadata during upload in order to activate the "Set as Restricted Document Content" option.

Please see the screenshot below.



For documents that are already in the room, users can right-click on the document or open the document action menu with the gearwheel icon on the grid. Once the menu opens, select the "Select as Restricted Document Content" option in order to designate the document as 'Restricted.' For users with the ability to edit a document's metadata, the "Restricted Document Content" toggle switch will also appear in the metadata pane.



Regardless of which method is used to designate the document as 'Restricted,' a shield icon will appear on the grid as a visual reference that the document cannot be viewed prior to being redacted unless the user has sufficient privileges.

Chapter 8. Events

Event Manager

The Event Manager was created as a new way to manage amendments, milestones, visits, and other events that occur during a Clinical Trial. It is important to have a simple way to recognize clinical events as they happen in order to get the

most accurate picture of eTMF Health. That way, as amendments, visits, and other activities occur, the eTMF 'knows' what documents are needed in association with those events and can even plan them, including the responsible party and due date.

Events may be applied to the eTMF Required Document and Placeholder definitions, providing a simple way to manage the milestones of a study, applying the planned documents automatically, and improving the quality of the measurement of eTMF Health. Placeholders are defined and applied as a part of amendments, milestones, visits, and other trial activities. Sites and countries may be included or removed as necessary.

PRIOR TO CREATING EVENTS

Prior to creating events, users will need to ensure that their required documents are set up appropriately. It is recommended to make any required changes in the room's Configuration Manual and to work with the Trial Interactive Service Desk to ensure that all changes are made correctly. For more advanced users, please see the section about updating required documents for instructions on how to adjust these requirements.

Users will have the choice to indicate whether a document type is to be required "Immediately" or upon "Event Completion." A placeholder will be created automatically for any document which is indicated as being required immediately. Documents which are intended to be associated with events will not necessarily be due right away and, in order to allow users to get a better sense of the current state of the eTMF, placeholders for these documents will not be generated until the associated event has been created and placed into a status of "Completed." Once the event is marked as completed, the placeholders will be visible in the room at large and will impact eTMF completeness, but not before then.

CREATING AN EVENT TYPE

Prior to creating a specific event in the system, we must first ensure that the type of event has been created. If your room has come prepopulated with event types based on those created by default in the system or milestones cloned from another room, you can certainly use those. However, there will sometimes be an occasion where a custom event may be of use. In order to create an event, follow the steps below:

1. **Select the Event Types area of the Event Manager. This is indicated by a gearwheel icon on the far left of the screen.**
2. **Click on the "Add" button in the menu bar above the list of events already in the room. The "Create New Event Type" window will open.**
3. **Fill out the required fields.**
   a. **The Event Type field allows you to name the new event.**
   b. **Category indicates whether this is related to a Study, Country, or Site level event.**

c. **The Due Date Period field allows you to indicate how much time users have to submit the documents after the event has taken place.**
d. **Please note that the 'Description' field is not required but, should you have several Event Types that are similar, this field can help users differentiate between them as this description will be visible to users when creating an Event based on the Event Type.**

4. **Use the "Add" button above the Document Type Name field in order to open the Select Document Type window.**
5. **You can search for the document type via the search bar at the top of the window or by drilling down in the index structure until the correct document type entry is shown.**
6. **Check the box next to the correct document type(s) and click Select to add the selected document type(s) to the event being created.**
7. **Once all document types have been added, press the Create button to create the event type.**

CREATING AN EVENT

Once an appropriate event type has been created, specific events can be planned using that event type. Events that have been created can be updated at any time by the eTMF team to reflect the latest content. Each event will show with its own eTMF Health measurement at the study, country, and site levels.

Events can be created using the following steps:

1. **Access the Events module. Any previously created events should be displayed in the window.**
2. **Click on the "Add" button in the menu bar above the list of events. The "New Event" window will open.**
3. **Using the Category field, indicate whether the event being planned is a Study, Country, or Site level event.**
4. **Choose the Event Type from the dropdown menu.**
5. **Give the event a name and fill out any other fields as desired.**
    a. **The planned date field will be critical to tracking the timeliness of event document submissions.**
    b. **The Due Date Period should be automatically populated based on the value entered during the creation of the Event Type.**
    c. **The Status field can be used to indicate whether an event is being planned or has already been completed. Most events will be created with a status of "Planned."**
6. **Press "Next"**
7. **The next screen allows the user to confirm whether all required document types for this event are displayed. The list will be populated based on the values chosen during the creation of the Event Type.**
    a. **If another document type is required, the user can press the "Add" button in the menu bar above the right panel. This will open the "Add Required Document Types" window.**
        i. **Use the Search bar or manually drill down in the folder structure to locate the required document type and press "Add".**

8. **Once all required document types have been added to the event, press "Finish" to complete the event creation process. The event will be displayed in the list of created events.**

MODIFYING AN EVENT

Follow these steps in order to modify an existing event:

1. **Access the Events module. Any previously created events should be displayed in the window.**
2. **Select the event to be modified and, using the toggle switch at the bottom of the screen, press "Profile." The event profile will open.**
3. **The event profile has three tabs:**
    a. **General Info: This tab includes the name of the event, any impacted sites or countries, the due date, etc.**
    b. **Requirements: This tab allows the user to adjust the required documents associated with the event.**
    c. **Documents: This tab allows the user to see which documents have been collected or are still outstanding.**
4. **Only the General Info tab has a save button. Be sure to save any changes made to this tab prior to exiting the view or else the changes will be lost.**

ASSIGNING DOCUMENTS TO EVENT PLACEHOLDERS

Once an event has been created, documents which have been submitted to the room can be assigned to the placeholders generated by the creation of the event so that they can count toward event completion and eTMF health. In order to assign a document to an event placeholder, follow the steps below:

1. **Select the Documents area of the Event Manager. This is indicated by a page icon.**
2. **The user can change their view of the Documents area using the "View by" dropdown menu. The available completeness views are the same as those available in the eTMF Documents module with the exception of "View by Event." We will be addressing the "View by Event" view in these instructions.**
3. **Using the index pane at the left side of the screen, drill down to the Event in question and click on it in order to show the missing and collected documents in the central "Grid" pane.**
4. **If it is not already expanded, click on the "Open Staging Area" button at the bottom of the screen in order to access those documents currently housed in the Staging, Inbox, and Upload folders.**
5. **Click on the document location and locate the document which applies to the placeholder displayed in the upper portion of the screen.**
6. **Click and drag the appropriate document from the lower panel onto the document placeholder in the upper**

panel.

7. **The document will be coded based on the placeholder metadata.**
8. **Press the Refresh button above the Grid or in the Index pane in order to see the selected document in place of the Placeholder that was filled.**

Chapter 9. Dashboard

Study Room Dashlet Settings

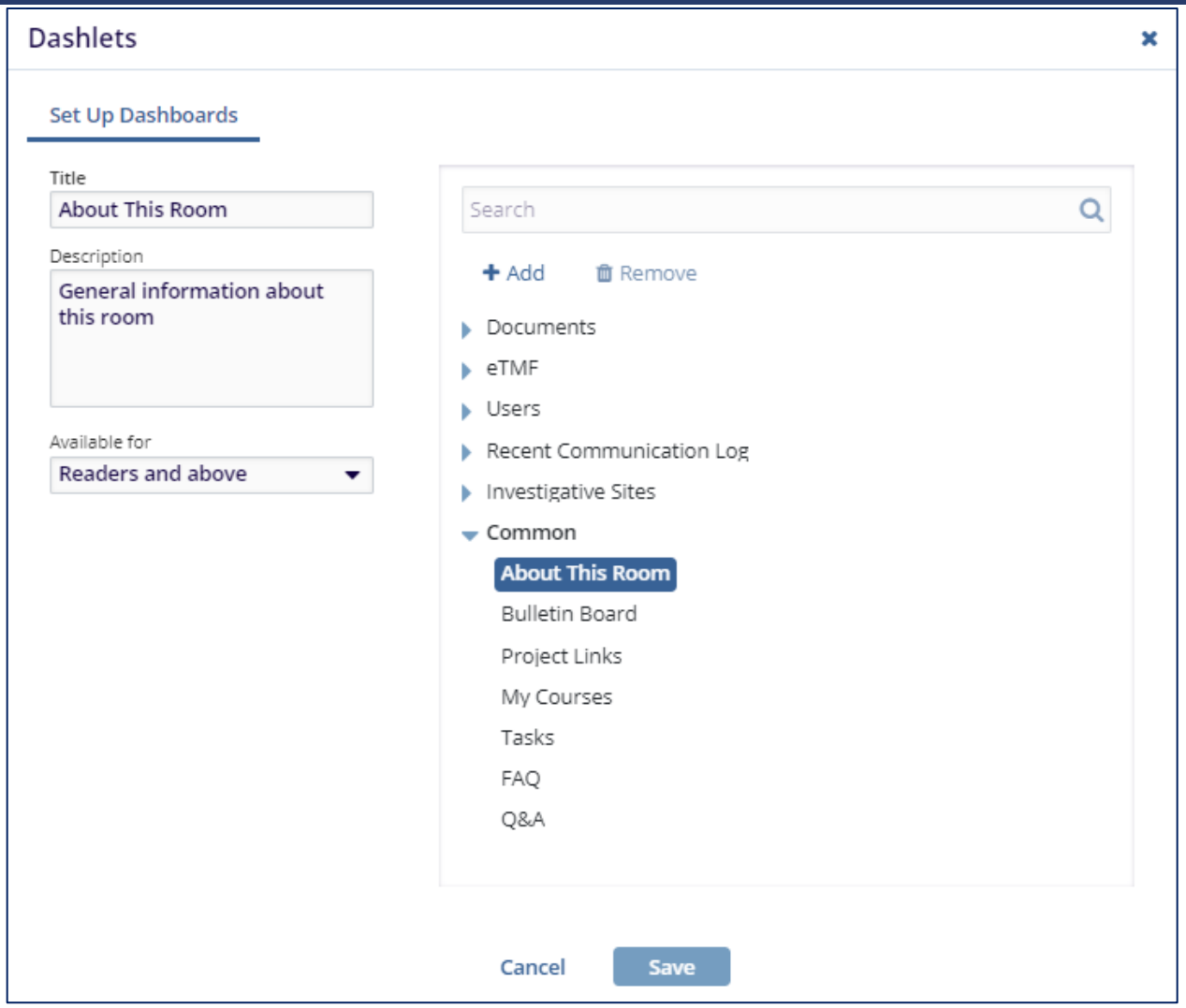
Administrator users can set up a default dashboard for each level of user access. However, unless specifically forbidden from adding or removing a particular dashlet, users have control over the dashlets that are displayed on their individual dashboard.

MODIFYING A DASHLET'S SETTINGS FOR ALL ROOM USERS

To modify a dashlet's settings, follow these steps:

1. **Navigate to the dashboard.**
2. **Click on the 'Dashlets' button at the top-right of the screen.**
    a. **This will open the Dashlets window.**

3. **Locate the dashlet whose settings need to be altered.**
4. **Click on the name of the dashlet**
    a. **This will cause the dashlet's properties to be populated in the left side of the window.**



5. **Any of the following may be adjusted:**
    a. **<u>Dashlet Title:</u> Any name entered here will be displayed to all users.**
    b. **<u>Description:</u> Anything entered here will be displayed to all users when they select dashlets for their dashboard.**
    c. **<u>Available for:</u> This field controls which user levels have the ability to add this dashlet to their dashboard.**
6. **Press 'Save'**

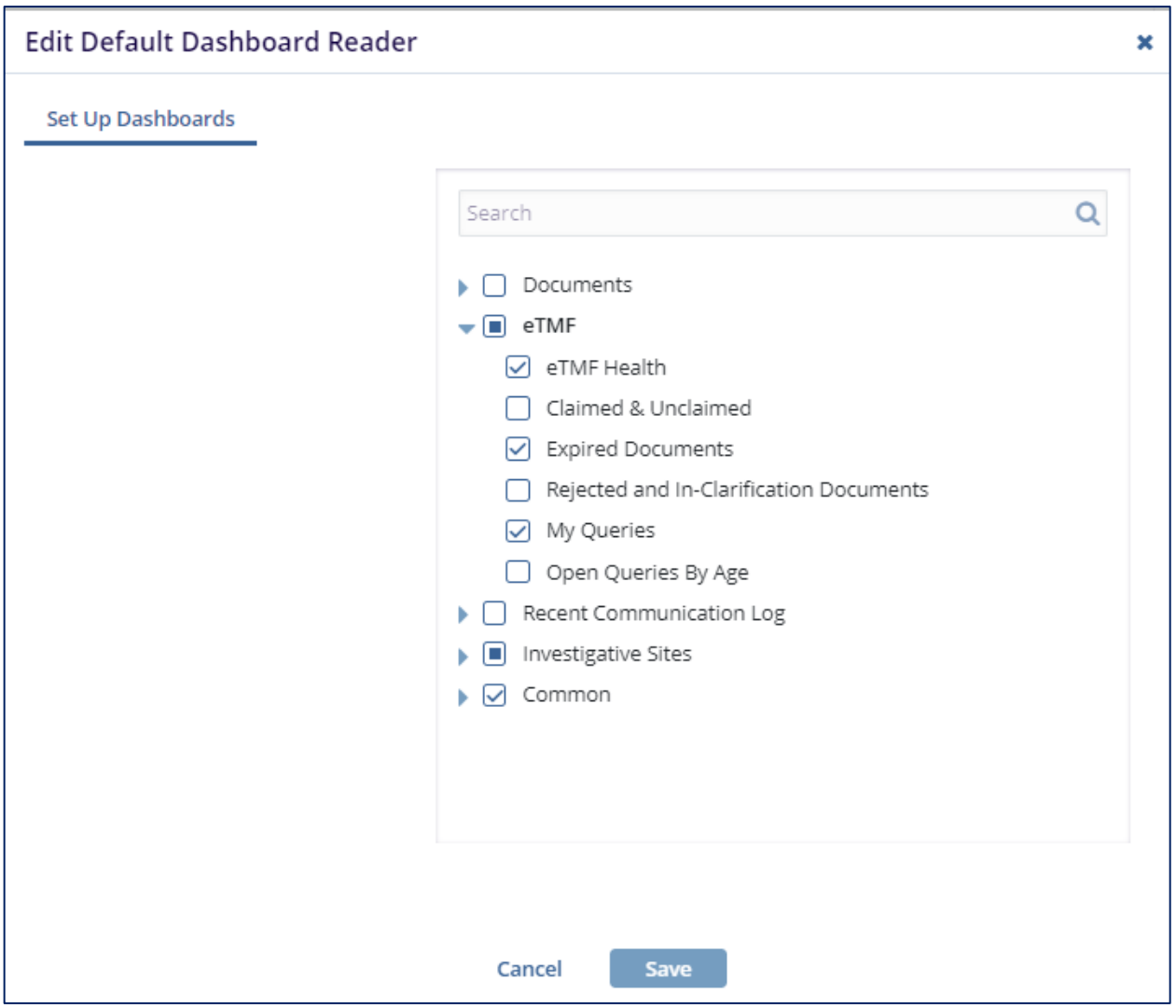
DEFAULT DASHBOARD SETUP

Administrator level users can set up default dashboards for users based on their access level. Unless otherwise forbidden, users can alter their dashboards to be different than the default.

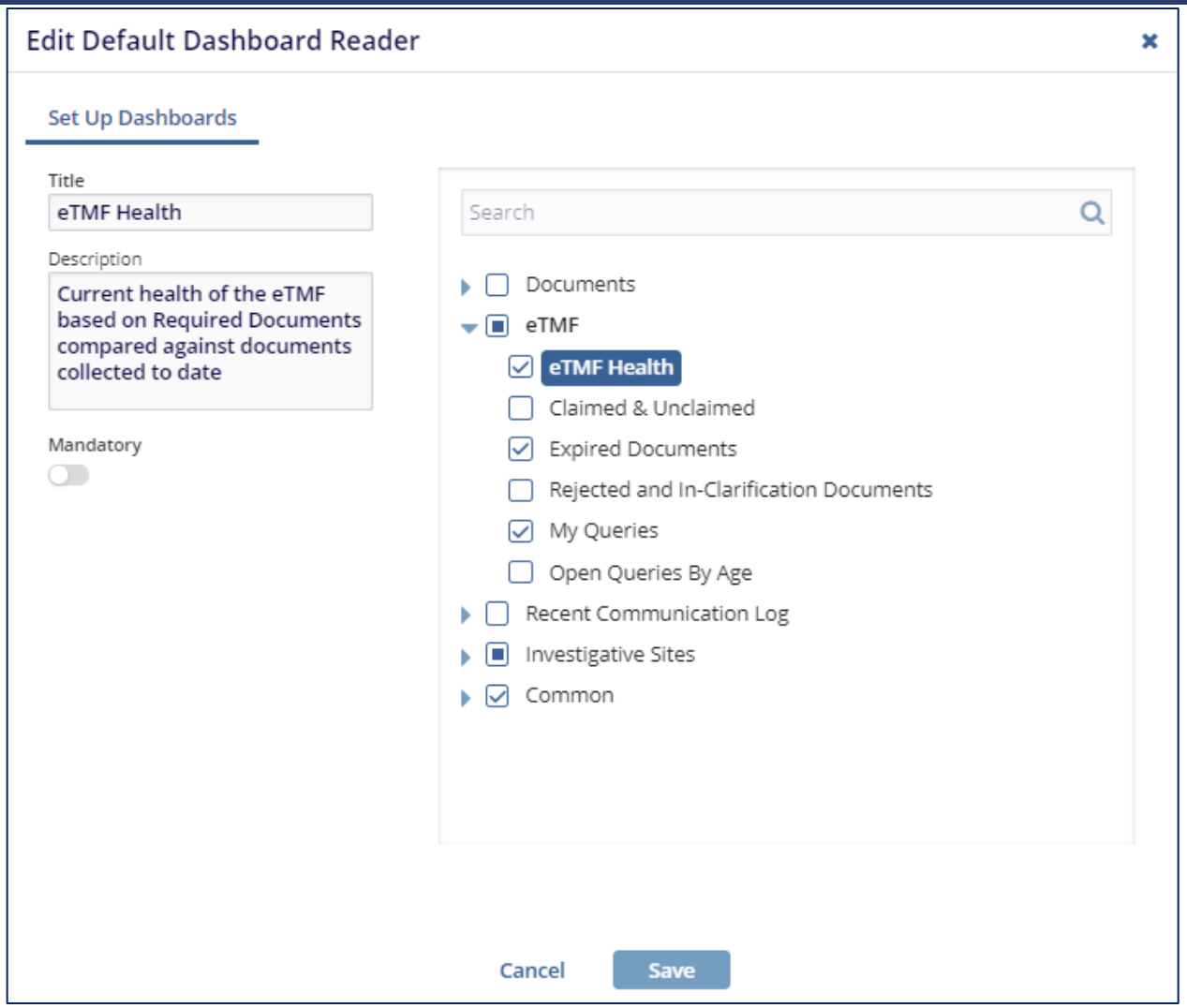
Follow these steps to set up default dashboards:

1. **Click on the 'Edit Default Dashboard' button at the top-right of the screen.**
    a. **This will open the Edit Default Dashboard window.**

2. **Click the checkboxes next to the dashlets which should be displayed by default.**



3. **Click on the name of the dashlet to populate the dashlet properties on the left side of the window.**



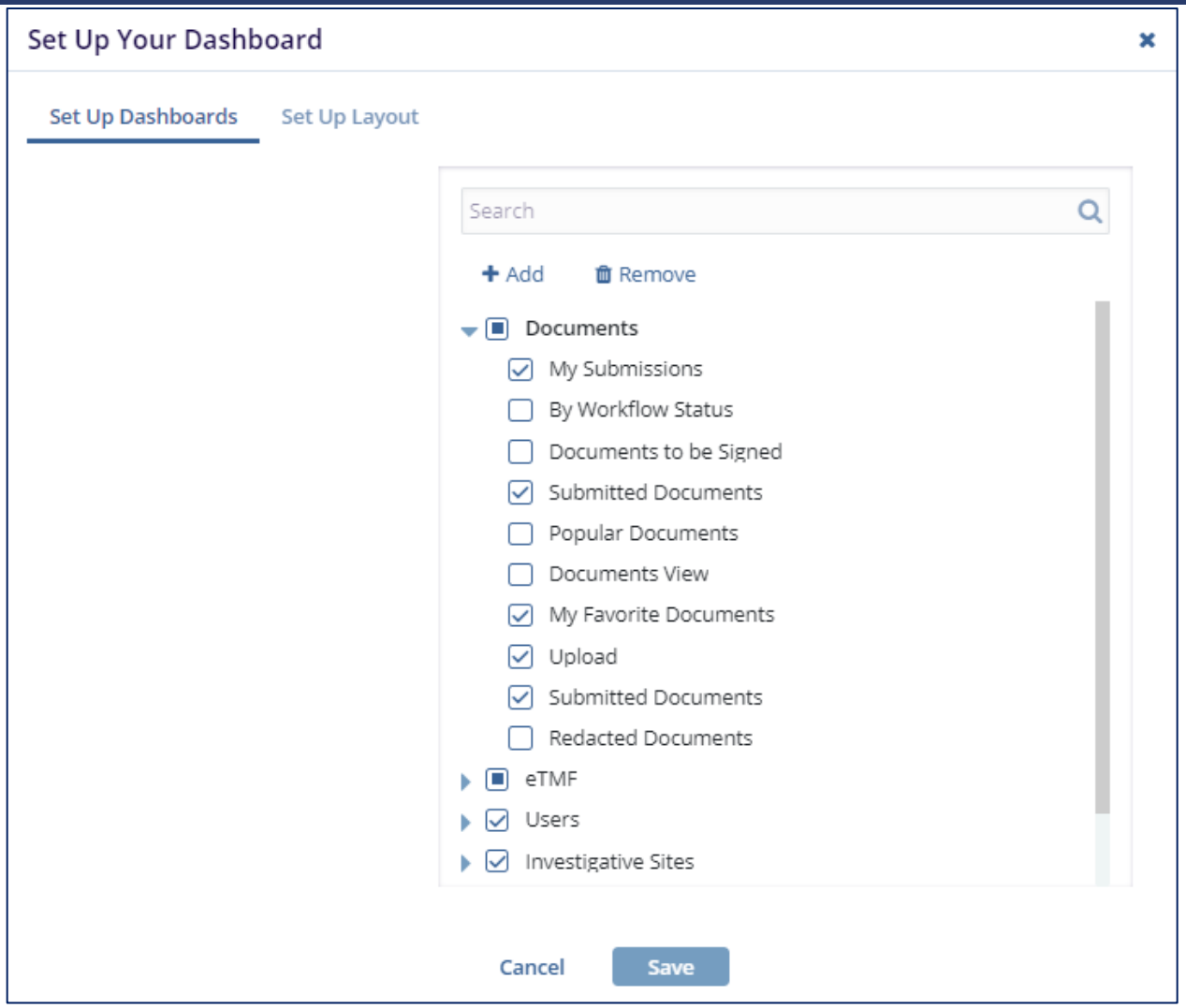
4. **Make any desired changes to the available fields.**
    a. **Title: The chosen user access level will see this custom title.**
    b. **Description: The chosen user access level will see the custom description.**
    c. **Mandatory: Toggling this on will prevent users at the chosen access level from removing the selected dashlet.**
5. **Press 'Save' when done.**

SETTING UP YOUR INDIVIDUAL DASHBOARD

Unless otherwise restricted by room administrators, each user can control the appearance of their own dashboard.

Follow the steps below to customize your dashboard:

1. **Click the 'Edit Dashboard' button at the top-right of the dashboard.**
    a. **This will open the 'Set up your Dashboard' window**



2. **Check the box next to each dashlet which should be displayed on your dashboard.**
    a. **You can also check the entire category to select all related dashlets.**
3. **Once you know what dashlets you use most frequently, you may want to press the '+Add' button to create a custom dashlet category.**
    a. **If you choose to do this, you can click on the name of a dashlet and drag it from its home category into your custom category. Once done, the dashlet will be displayed on the dashboard in your custom category.**
4. **If you would like to change the number of columns showing on the dashboard, click on the 'Set Up Layout' tab and choose the desired number of columns.**
5. **Press 'Save' when done.**
6. **Each category of dashlet can be adjusted by doing the following:**
    a. **Press the Pencil icon at the right side of the dashlet category to rename the category.**
    b. **Click on the lower-right corner of the category to alter the height of the category window.**
    c. **Click on the category header to drag the window to a new position on the dashboard.**

Dashlet Descriptions – Common Grouping

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. Administrator and Manager level users can make changes to this dashlet by pressing the 'Edit' button. Once you have made the desired changes, click Save. Any changes made will be immediately visible to all room users.

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 edited by administrators and managers.

PROJECT LINKS

The Project Links dashlet displays the links to different websites that are used for the study. Editor level users and above may create links by pressing the 'Create' button. The toggle switch allows users to switch between private links and those shared with the rest of the users in the room.

MY COURSES

Some study rooms are integrated with Global Learn in order to conduct appropriate study-related training. This displays your courses. Each course displayed serves as a link which, when clicked, will take the user to that course in Global Learn.

THE FAQ DASHLET

The FAQ dashlet will display a list of frequently asked questions to help users find important information even more easily. The questions will be displayed in a grid-style and the user can choose to view the answer to the question by clicking on the arrow next to the checkbox.

THE Q&A DASHLET

The Q&A dashlet will make it easier for users to view answers to their important study-related questions. Users below Administrator level access will only see their own questions posted here. Users who have been designated as Subject Matter experts will also see questions related to their area of expertise.

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 dropdown menus 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 by clicking Get Job Result which then downloads the export job as a .xlsx file.

Dashlet Descriptions – Documents Grouping

UPLOAD

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

In order to use the Upload dashlet, simply drag a file from your computer desktop into the dashlet and press Import. In rooms where it has been enabled, users will be able to see the index folders associated with sites and can upload documents directly to a specific folder.

MY SUBMISSION

The My Submission dashlet will allow users to view the files they have uploaded right from their dashboard.

This operates very much like the already familiar Favorite Documents and Popular Documents dashlets. Users can click on the document type icon (PDF, Word, etc.) in order to launch a preview of the document in a separate window or click on the blue arrow to be taken directly to the document within the room's index structure.

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.

EXPIRED DOCUMENTS

The Expired Documents dashlet lists the expiring and expired documents as specified in the expiration period. 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.

Users can also use the Expiring Document to replace expired or expiring versions of a document.

To deal with an expired or expiring document, follow these steps:

1. **Locate the document in the dashlet.**
2. **Check the box next to the document.**
3. **Click the '+Add New Version' button at the top-right of the dashlet.**
    a. **This opens the 'Add New Version' window.**
4. **Select the appropriate replacement option.**
    a. **The options available are configurable by the room administrator in the Settings area.**
5. **If 'Replace the Attachment' is chosen,**
    a. **Press the 'Browse' button and locate the new version of the file.**
    b. **Set the new expiration date**
    c. **Indicate the reason for the replacement**
6. **If the 'A new version was already submitted. Remove this document from the list' option is chosen nothing else needs to be done. The document will be removed from the list of expiring documents.**
7. **Press 'Save'**

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:

- **As a complete Room Summary, or**
- **As workflow stages defined.**

REJECTED AND IN-CLARIFICATION DOCUMENTS

This 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 double-click on the count to view the list of documents associated with a particular rejection or clarification

reason.

ETMF HEALTH

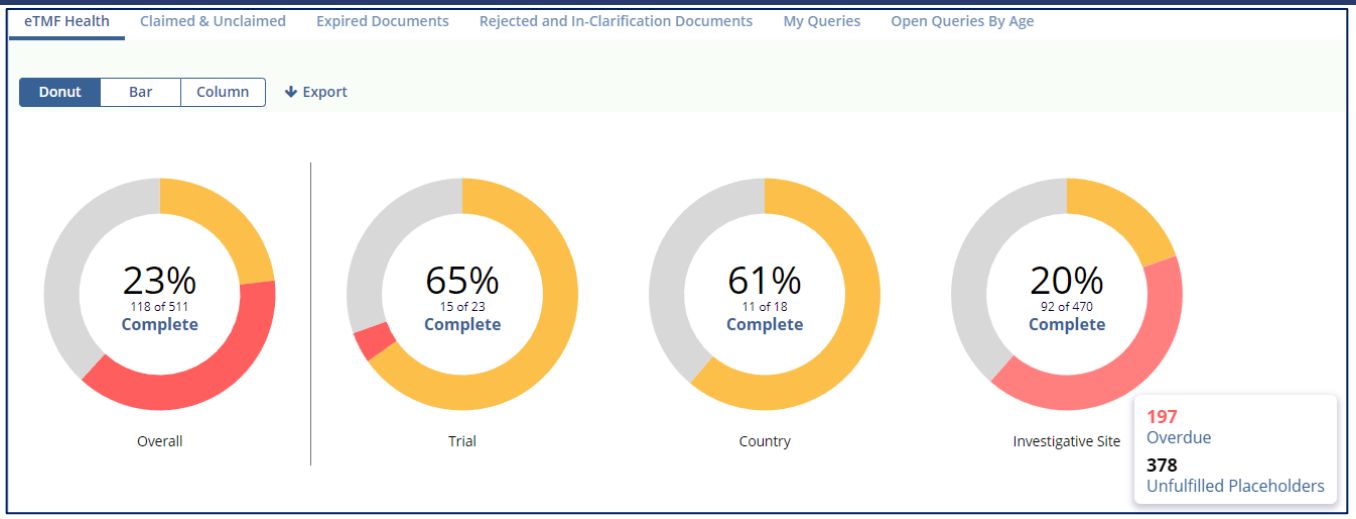
This dashlet shows a summary of the percentage of missing and collected documents as defined by the room's configuration. Each category of documents is listed and has its own chart. To view the missing documents at each category level, click on the appropriate 'donut' chart to drill down if required (ex. To locate a specific site's entries).

When viewing a list of placeholders (missing required documents) for a site or other entity, Editor and above level users will be able to press the +Add Document button to attach the necessary document to the placeholder. The primary benefit of uploading a document this way is that it will come into the room already coded with the necessary metadata to fulfill the placeholder. Whether the placeholder is filled right away or after the document passes the QC review process is determined by the room settings.

Users can also generate a new placeholder directly via this dashlet. Once the proper entity is located, the user can press the +Add Placeholder button, select the document type and fill in any other required metadata to create the placeholder.

This dashlet follows the following definitions:

- **Unfulfilled Placeholders / Missing: This is the count of placeholders that have been set up as required in the eTMF but are still waiting to be collected or marked as final. These are also referred to as Missing Required Documents, or just 'Missing'.**
- **Fulfilled Placeholders: This is the count of placeholders that have been collected, indexed, QC'd, and marked as final in the eTMF.**
- **Collected: This is the total count of final, collected documents in the eTMF, which represent not just a count of fulfilled placeholders, but also additional documents and versions collected where more than one document has fulfilled a particular placeholder or eTMF requirement. For non-TMF rooms, this metric may represent non-final documents as well depending on room configuration.**
- **Overdue: This is the total count of unfulfilled placeholders that are now past the due date set by a completed Event or milestone in the eTMF. When an Event or milestone is marked complete, the unfulfilled placeholders required by this Event are marked as due to be collected based on the Event completion date. A Due Date Period is generally added to provide time to collect and mark the documents as final, and this period is added to the completion date to determine each document's due date.**
- **Overall: This dashlet also now shows an Overall measure that sums up the entire eTMF.**



MY QUERIES

The My Queries dashlet gives a list of documents based on their query types. The user can use the dropdown menus to narrow down the queries displayed.

Responding to queries is covered more in-depth in the Queries chapter of this guide but this dashlet can also serve as a portal for responding to queries. To respond to a query via the My Queries dashlet, locate the Pending query and press the 'Respond to query' button.

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 document 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.

POPULAR DOCUMENTS

The IP Release Documents dashlet displays the list of documents that have been marked as popular by an Administrator, Manager, or Editor through the Documents 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 or click on the blue arrow to be taken to the document in the Documents module.

DOCUMENTS TO BE SIGNED

The Documents to be Signed dashlet gives a list of documents waiting for signature.

RECENT COMMUNICATION 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 Communication Log to go the Communications module of Start-Up dashboard.

USERS (ADMINISTRATORS ONLY)

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.

Dashlet Descriptions – Investigative Sites

EXPIRING SITES

The Expiring Sites dashlet gives a list of all sites that are expiring in a future date

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

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.

Chapter 10. Document Queries

Document queries have several different uses in Trial Interactive but, generally speaking they provide users with a

method of asking questions about documents. The specific use of queries in a study room may be guided by internal SOPs specific to the study.

Workflow Queries

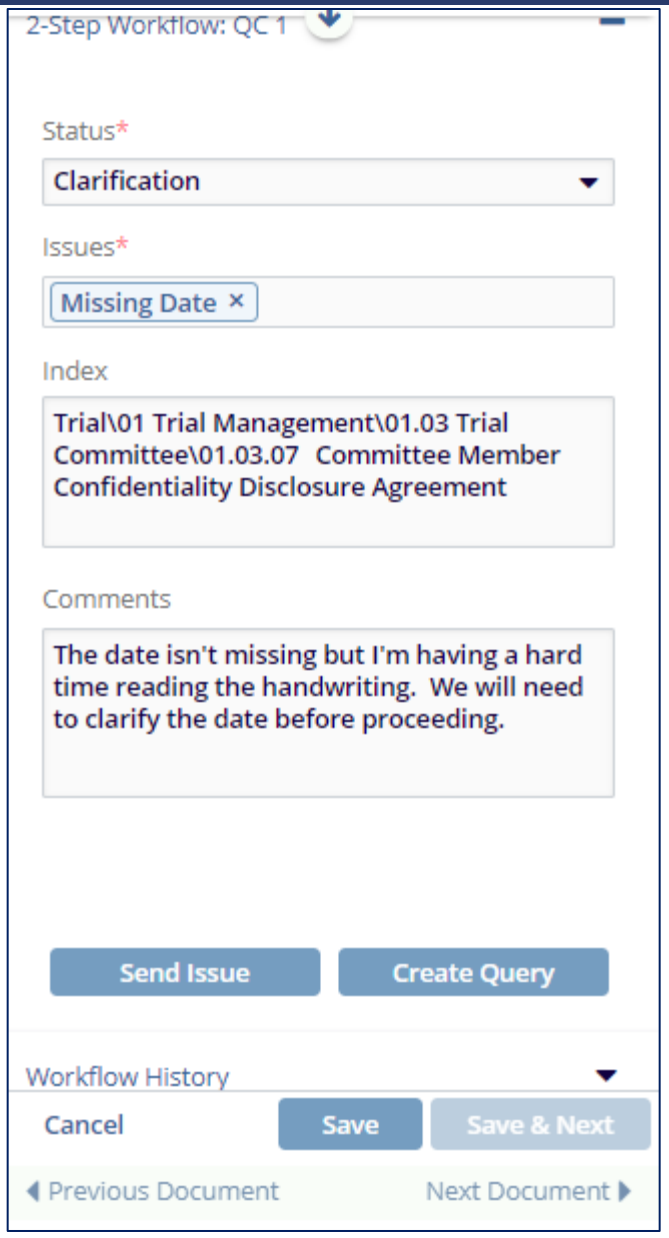
Workflow queries are primarily intended to assist users in seeking clarification about a document while deciding whether it should be approved or rejected. In some instances, these queries may be used to allow the submitted a chance to correct a minor issue by providing updated information or a corrected copy.

OPENING A WORKFLOW QUERY

It is assumed that the user is already a part of the workflow in the room and has already claimed the document for review. Also, the statuses for each workflow are configurable. For these instructions, we are using the default or most commonly used statuses but the statuses available in your study room may be different.

To open a workflow query, follow these steps:

1. **Apply metadata to the document as accurately as possible.**
    a. **Some fields will be required even if the point of the query is to clarify the required value. Fill in the field to the best of your ability.**
2. **Apply a status of "Clarification" to the document and indicate the issue.**
    a. **It is not required to add comments to a document when applying a status of 'Clarification' but it is highly recommended that you be as specific as possible in order to give the query recipient enough detail to correctly and quickly answer your question.**
3. **Press the 'Save' button.**
    a. **If you inadvertently press the 'Save & Next' button, you will need to go get your document from the 'Clarification' folder at the left side of the screen before continuing.**
4. **Press the 'Create Query' button.**



a. **This will open the email window.**

5. **The email window will automatically populate with the submitter as the recipient, the template email, the issues chosen, and any comments that you provided. Customize the email and add any additional recipients as necessary.**
6. **Press 'Send Query'**

RESPONDING TO A WORKFLOW QUERY

The recipient of a query will receive an email as shown in the steps for sending a workflow query. The easiest way to respond to the query is to simply reply to the email. Other options are discussed below:

Responding to a query can happen from multiple locations in the system:

- **Email**

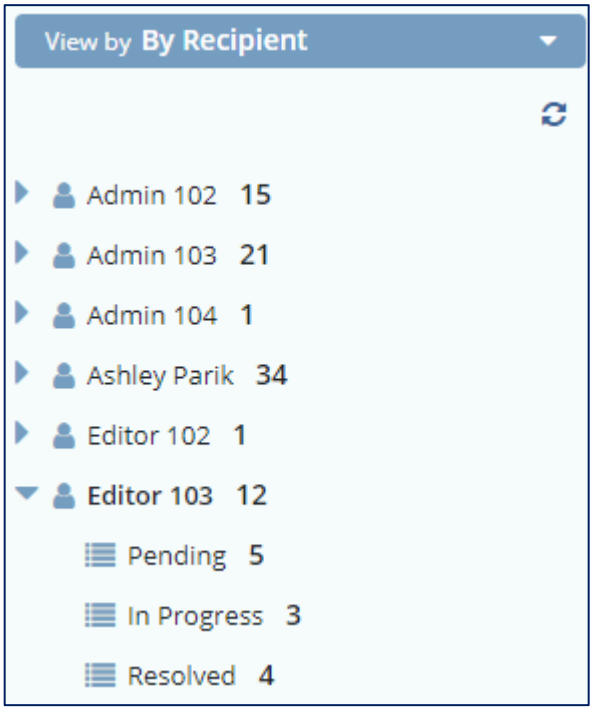
- Replying to the query email will add a response to the query in the system.

- The Documents Module
  - Query by Sender view
  - Query by Recipient view
  - Any other view where the document can be chosen and the metadata panel can be accessed
- The Queries Module
- The My Queries Dashlet

These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To respond to a query from inside the system:

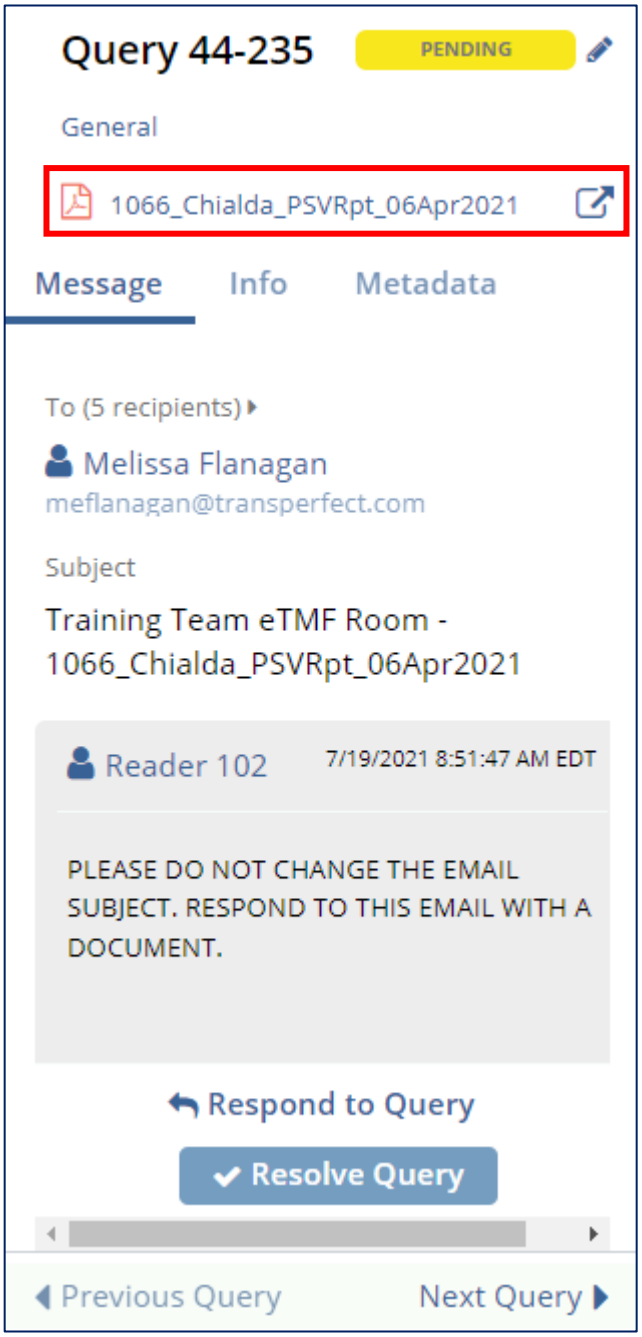
1. Navigate to the Queries Module via the Navigation Grid at the top-left corner of the screen.
   a. This will open a view that defaults to 'My Queries' which are queries in which you are listed as either the sender or the recipient.
2. Choose the 'By Recipient' view from the dropdown menu at the top-left.
   a. Users who have access to view queries for multiple users will need to expand their own list by clicking on the arrow next to their username.



3. Select your Pending queries.
   a. This will cause the documents grid to populate.
4. Select the document whose query you wish to review and respond to.
   a. The metadata panel will populate with the query information.
   b. For other areas of the system, choosing the document will also cause the metadata panel to load but

the user may be required to select the Queries tab of the metadata panel to continue.

5. **Read the query email, review the document.**
    a. **There is a link to the document at the top of the metadata panel. See the screenshot below.**



6. **When you are ready to respond to the query, press the 'Respond to Query' button.**
    a. **This will cause a response area to appear.**
7. **Type in your response and, if necessary, attach any required documents.**
8. **Press 'Save'**

RESOLVING A WORKFLOW QUERY

When a query is first created, it appears in 'Pending' status to indicate that the system has not received a response from the recipient. When the query changes to 'In Progress' status, the system has received a response. This will happen whether the system receives an actual response or if it receives an out of office message. If that happens, the user may want to use the 'Return to Pending' option in the Info area of the Queries module metadata panel.

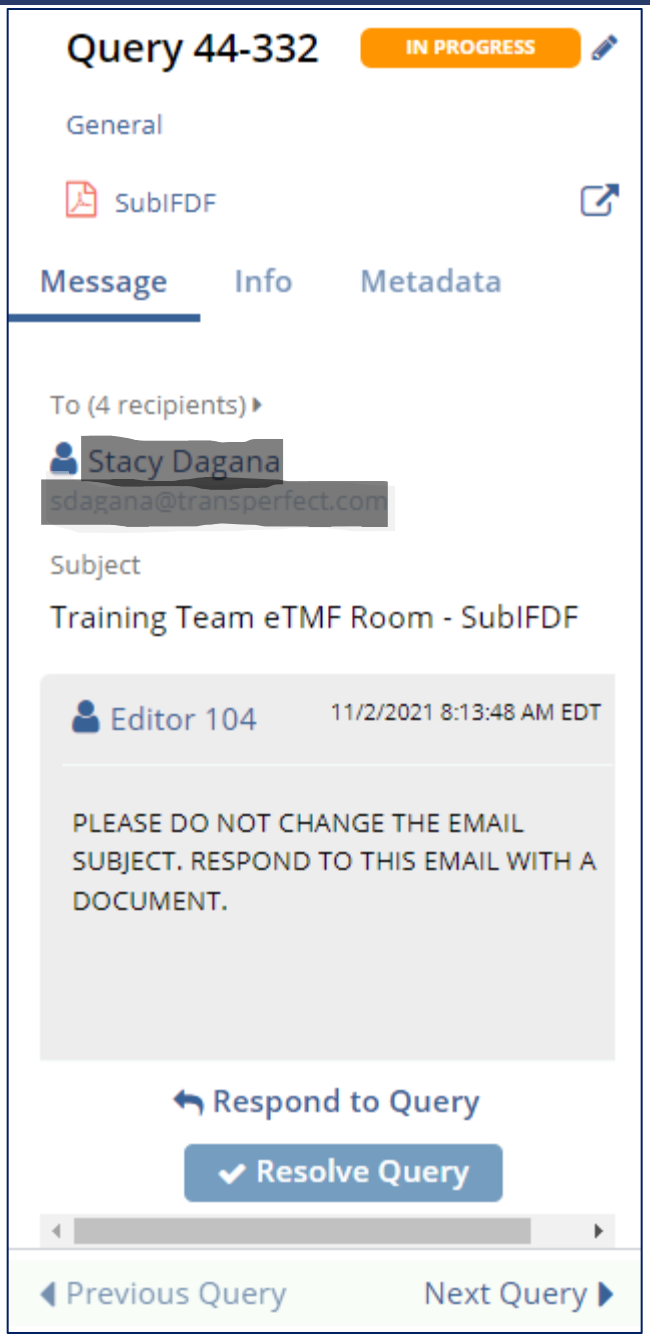
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

- **The Documents Module**
  - **The Reviews view**
  - **Query by Sender view**
  - **Query by Recipient view**
  - **Any other view where the document can be chosen and the metadata panel can be accessed**
- **The Queries Module**
- **The My Queries Dashlet**
- **The QC Workflow module**

These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To resolve a query, follow these steps:

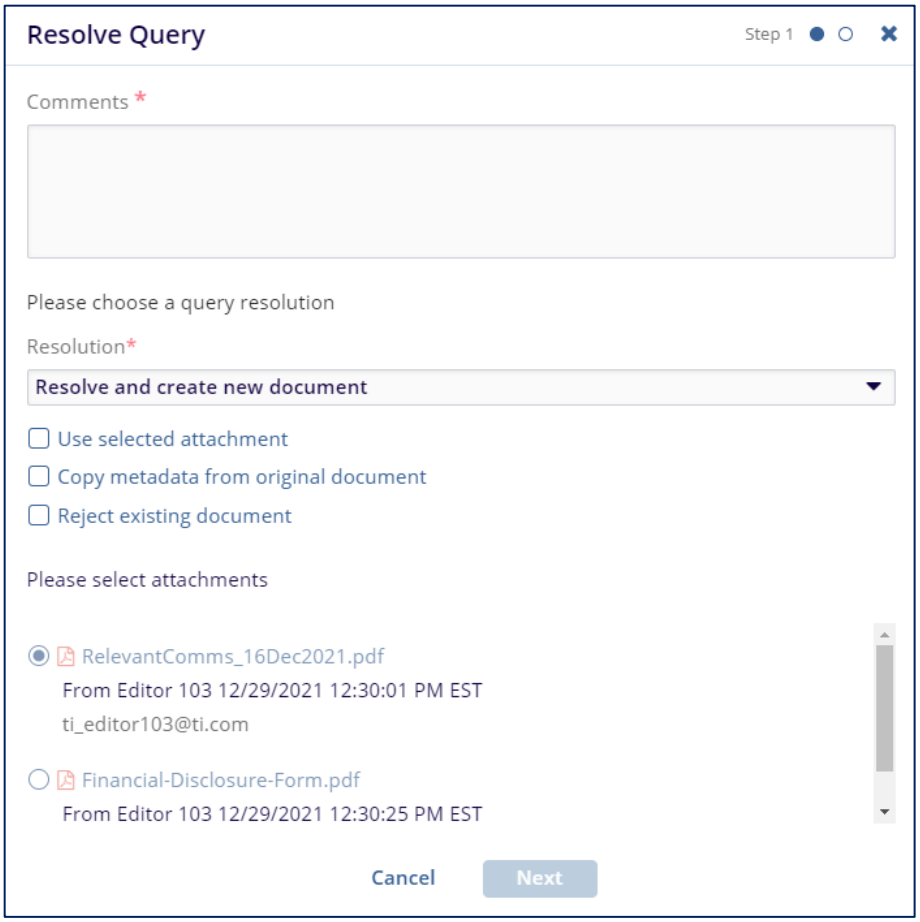
1. **Locate the 'In Progress' query**
   a. **Pending queries can be resolved too but the status indicates that no response has been received.**
2. **Click on the query in the grid.**
   a. **The metadata panel will load**
   b. **For users who opt to perform these steps from other locations in the system, you may have to select the Query tab of the metadata panel.**



c. **The query response will appear lower down in the panel and is usually colored green or blue depending upon your system settings.**

3. **Read the response and, if it answers your question, press 'Resolve Query'**
   a. **The 'Resolve Query' window will open.**
4. **Add a comment indicating why the query is being resolved.**
5. **Choose your Resolution type using the dropdown menu.**
   a. **Resolve – This option would be used if no replacement document was received during the query process.**
   b. **Resolve and Replace using selected attachment – This option would be used if the user wants to replace the attached file.**

c. **Resolve and create new document – This is primarily used when the document received in the query response should be used but is significantly different from the one received.**



i. **Please note that the checkboxes become active asking the user to clarify what action is to be taken next:**

1. **Use selected attachment**
2. **Copy metadata from original document**
3. **Reject existing document**

6. **If appropriate, choose the file to move forward with.**
7. **Press 'Next' or 'Resolve'**
   a. **If you have chosen either the 'Resolve' or 'Resolve and replace using selected attachment' option then this is the last step.**
   b. **If you have chosen to reject the existing document and use a replacement attachment, press 'Next'**
8. **Apply the correct metadata to the new document.**
9. **Press 'Resolve'**

Audit Queries

Audit queries can be opened at two different points during the quality review process. In the first case, the Auditor can open a query against a document if they need assistance determining if the document should be passed or failed. The

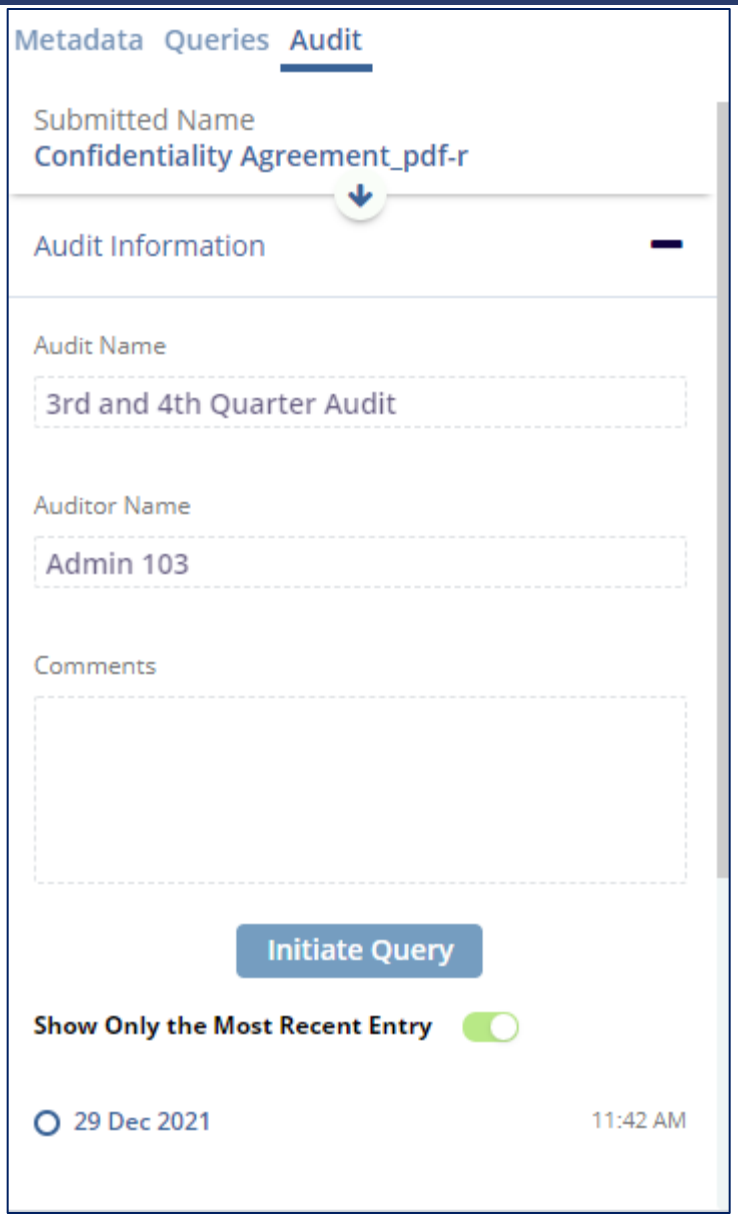
second, and likely more common usage, would be when the document has been failed and the Audit Responder needs to correct any audit findings.

OPENING AN AUDIT QUERY

It is assumed that the user is already a part of the audit and has already either been assigned the document for review or claimed the audit finding for review. For these instructions, we are focusing no the Audit Responder role but the general instructions are the same.

To open an audit query, follow these steps:

1. **Select the document from the documents grid.**
    a. **Once again, we are assuming that the user has already claimed the finding for response. For additional instructions, please see the chapter on performing quality review related activities.**
2. **If necessary, expand the Audit Information area of the metadata panel.**
3. **Press the 'Initiate Query' button. See the screenshot below**



a. **This will open the email window.**

4. **The email window will automatically populate with the template email. Customize the email and add recipients.**
5. **Press 'Send Query'**

RESPONDING TO AN AUDIT QUERY

The recipient of a query will receive an email as shown in the steps for sending an audit query. The easiest way to respond to the query is to simply reply to the email. Other options are discussed below:

Responding to a query can happen from multiple locations in the system:

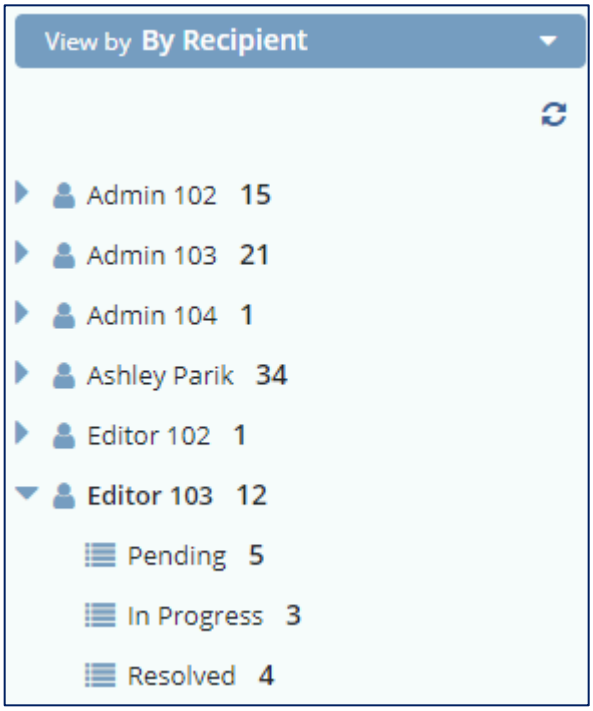
- **Email**
  - **Replying to the query email will add a response to the query in the system.**

- **The Documents Module**
  - **Query by Sender view**
  - **Query by Recipient view**
  - **Any other view where the document can be chosen and the metadata panel can be accessed**
- **The Queries Module**
- **The My Queries Dashlet**

These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

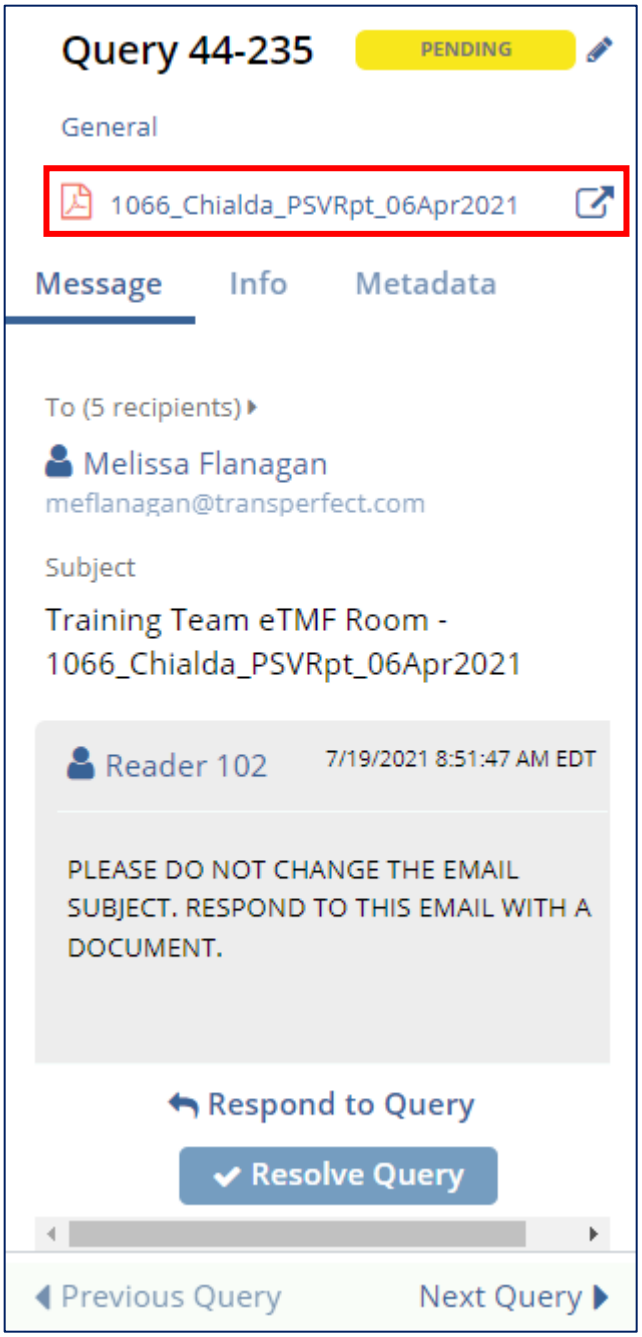
To respond to a query from inside the system:

1. **Navigate to the Queries Module via the Navigation Grid at the top-left corner of the screen.**
   a. **This will open a view that defaults to 'My Queries' which are queries in which you are listed as either the sender or the recipient.**
2. **Choose the 'By Recipient' view from the dropdown menu at the top-left.**
   a. **Users who have access to view queries for multiple users will need to expand their own list by clicking on the arrow next to their username.**



3. **Select your Pending queries.**
   a. **This will cause the documents grid to populate.**
4. **Select the document whose query you wish to review and respond to.**
   a. **The metadata panel will populate with the query information.**
   b. **For other areas of the system, choosing the document will also cause the metadata panel to load but the user may be required to select the Queries tab of the metadata panel to continue.**

5. **Read the query email, review the document.**
    a. **There is a link to the document at the top of the metadata panel. See the screenshot below.**



6. **When you are ready to respond to the query, press the 'Respond to Query' button.**
    a. **This will cause a response area to appear.**
7. **Type in your response and, if necessary, attach any required documents.**
8. **Press 'Save'**

RESOLVING AN AUDIT QUERY

When a query is first created, it appears in 'Pending' status to indicate that the system has not received a response from

the recipient. When the query changes to 'In Progress' status, the system has received a response. This will happen whether the system receives an actual response or if it receives an out of office message. If that happens, the user may want to use the 'Return to Pending' option in the Info area of the Queries module metadata panel.

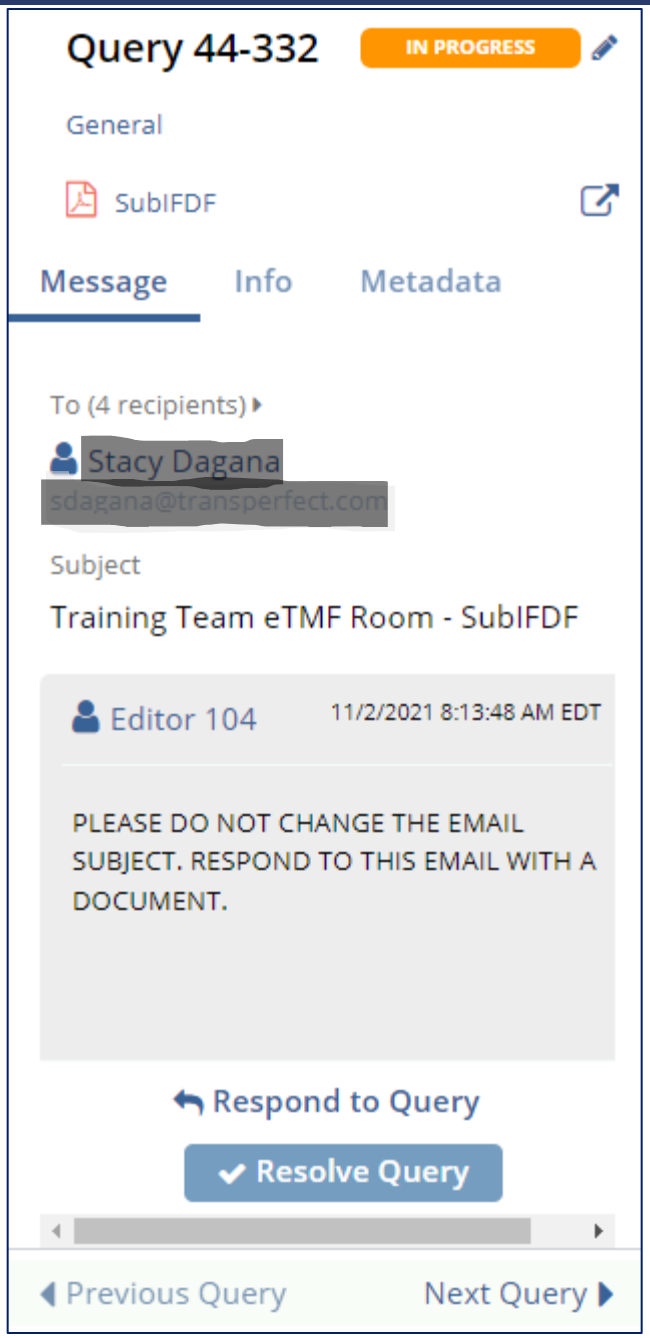
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

- **The Documents Module**
  - **Query by Sender view**
  - **Query by Recipient view**
  - **Any other view where the document can be chosen and the metadata panel can be accessed**
- **The Queries Module**
- **The My Queries Dashlet**

These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To resolve a query, follow these steps:

1. **Locate the 'In Progress' query**
   a. **Pending queries can be resolved too but the status indicates that no response has been received.**
2. **Click on the query in the grid.**
   a. **The metadata panel will load**
   b. **For users who opt to perform these steps from other locations in the system, you may have to select the Query tab of the metadata panel.**



c. **The query response will appear lower down in the panel and is usually colored green or blue depending upon your system settings.**

3. **Read the response and, if it answers your question, press 'Resolve Query'**
   a. **The 'Resolve Query' window will open.**
4. **Add a comment indicating why the query is being resolved.**
5. **Press 'Resolve'**

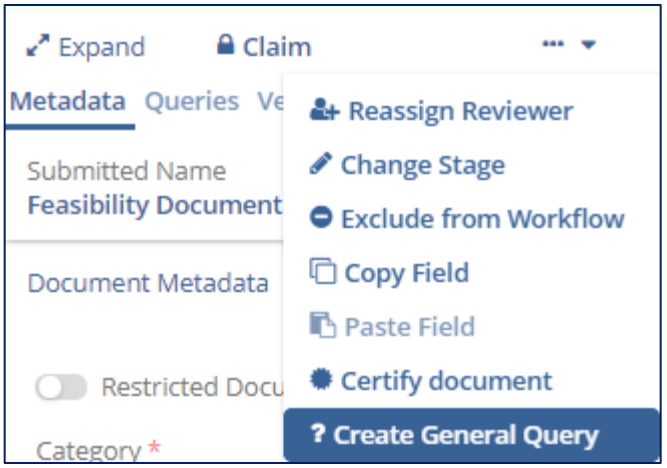
General Queries

General queries are somewhat more flexible in terms of their use case. Whereas QC Workflow and Audit queries are specifically intended to address concerns encountered when performing actions related to those processes, a General Query can be opened against any document and by any user.

OPENING A GENERAL QUERY

All Trial Interactive users can issue general queries against any document or document placeholder in the eTMF. In order to open a general query on a document, follow the steps below:

1. **Login to the room and navigate to the eTMF Documents module.**
2. **Locate the document in question either using the search function or by drilling down in the index panel to select the appropriate index location for the document.**
3. **Click on the document in the grid and open the Metadata Pane at the right side of the screen.**
4. **Once the Metadata Pane has loaded, click on the three-dot menu at the top-right corner of the pane to display additional document actions.**
    a. **Please note that administrators and editors may have additional functions in this area.**



5. **Select the "Create General Query" option. This will open the Email window.**
6. **Readers and Editors will not be able to select an individual recipient of their query. Instead, the General Query Responder group will be the dedicated recipients of these queries. At this point, Administrators will be able to select a recipient.**
7. **Compose the email and, when done, press "Create Query" to send the message to the selected recipients.**
    a. **These queries can be tracked using the Queries Module, the Query by Sender or Query by Recipient views, or via the My Queries dashlet on the dashboard.**

RESPONDING TO A GENERAL QUERY

The recipient of a query will receive an email as shown in the steps for sending a general query. If the sender was a Reader or Editor, they will not have been able to designate a specific responder. In cases like these, the members of the

General Query Responders group would be able to respond to the query from within the system.

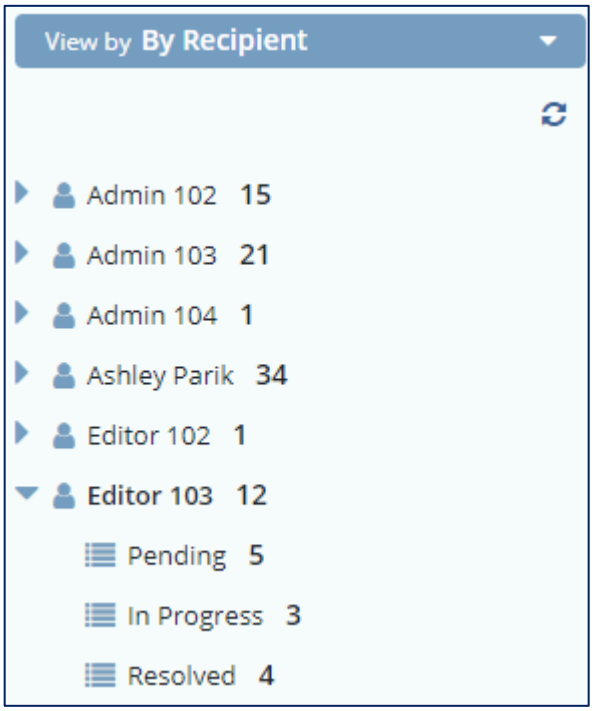
Responding to a query can happen from multiple locations in the system:

- **The Documents Module**
  - **Query by Sender view**
  - **Query by Recipient view**
  - **Any other view where the document can be chosen and the metadata panel can be accessed**
- **The Queries Module**
- **The My Queries Dashlet**

These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To respond to a query from inside the system:

9. **Navigate to the Queries Module via the Navigation Grid at the top-left corner of the screen.**
   a. **This will open a view that defaults to 'My Queries' which are queries in which you are listed as either the sender or the recipient.**
10. **Choose the 'By Recipient' view from the dropdown menu at the top-left.**
    a. **Users who have access to view queries for multiple users will need to expand their own list by clicking on the arrow next to their username.**



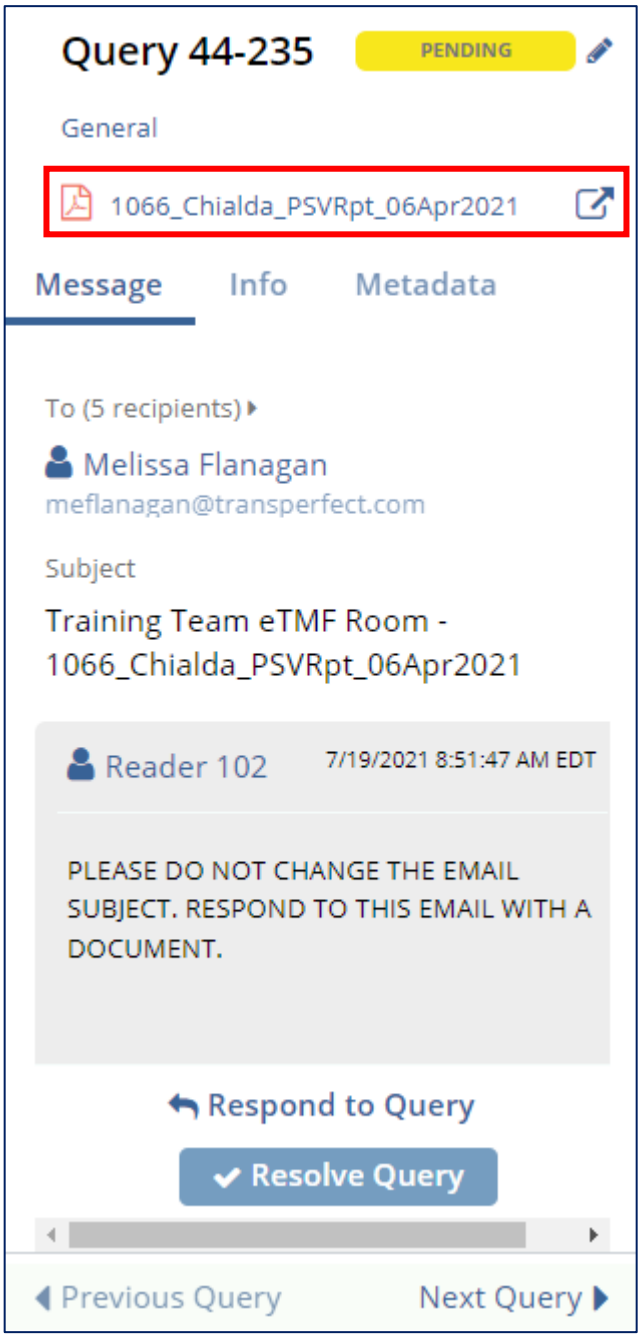
11. **Select your Pending queries.**
    a. **This will cause the documents grid to populate.**
12. **Select the document whose query you wish to review and respond to.**

a. **The metadata panel will populate with the query information.**

b. **For other areas of the system, choosing the document will also cause the metadata panel to load but the user may be required to select the Queries tab of the metadata panel to continue.**

13. **Read the query email, review the document.**

    a. **There is a link to the document at the top of the metadata panel. See the screenshot below.**



14. **When you are ready to respond to the query, press the 'Respond to Query' button.**

    a. **This will cause a response area to appear.**

15. **Type in your response and, if necessary, attach any required documents.**

16. **Press 'Save'**

RESOLVING A GENERAL QUERY

When a query is first created, it appears in 'Pending' status to indicate that the system has not received a response from the recipient. When the query changes to 'In Progress' status, the system has received a response. This will happen whether the system receives an actual response or if it receives an out of office message. If that happens, the user may want to use the 'Return to Pending' option in the Info area of the Queries module metadata panel.

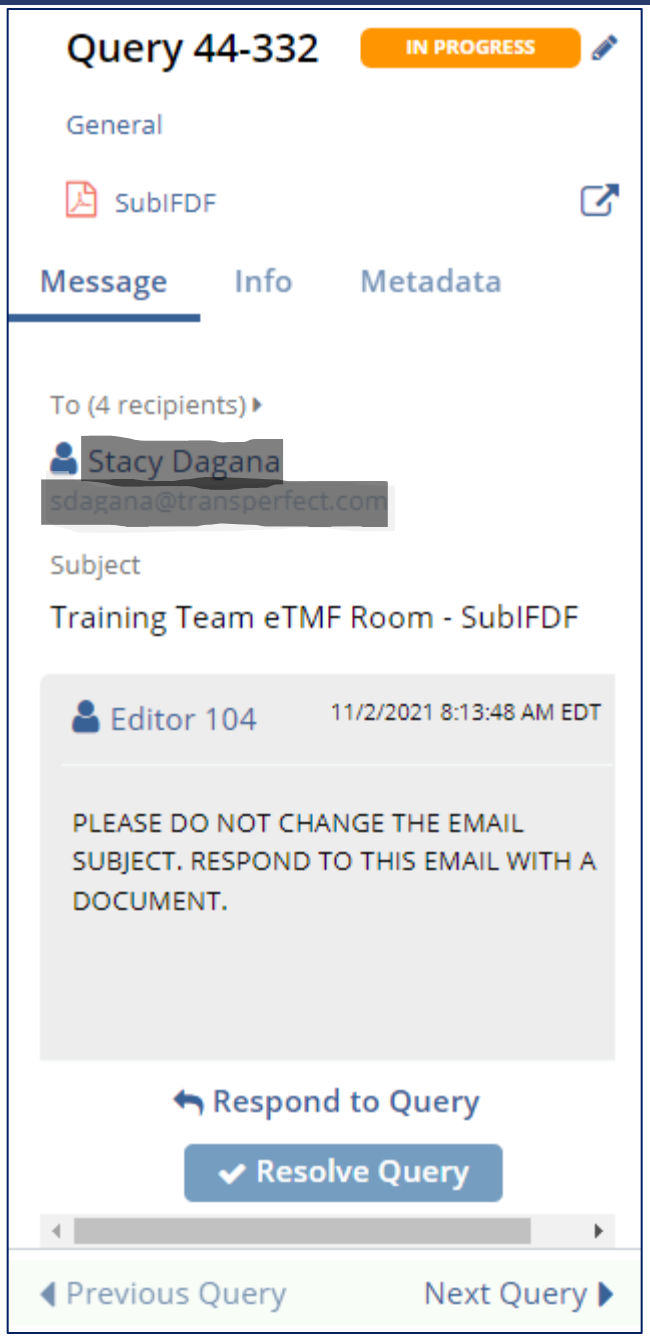
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

- **The Documents Module**
  - **Query by Sender view**
  - **Query by Recipient view**
  - **Any other view where the document can be chosen and the metadata panel can be accessed**
- **The Queries Module**
- **The My Queries Dashlet**

These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To resolve a query, follow these steps:

6. **Locate the 'In Progress' query**
   a. **Pending queries can be resolved too but the status indicates that no response has been received.**
7. **Click on the query in the grid.**
   a. **The metadata panel will load**
   b. **For users who opt to perform these steps from other locations in the system, you may have to select the Query tab of the metadata panel.**



c. **The query response will appear lower down in the panel and is usually colored green or blue depending upon your system settings.**

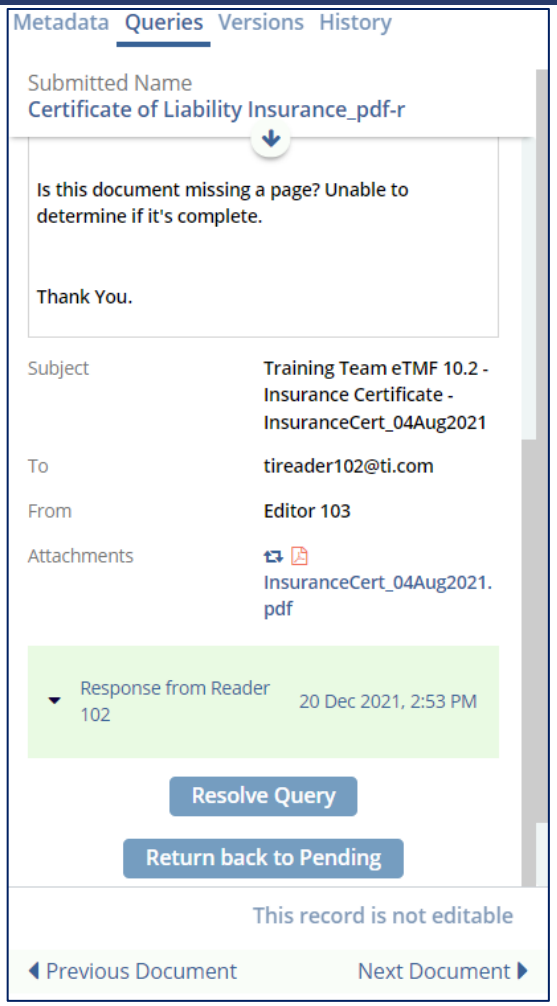
8. **Read the response and, if it answers your question, press 'Resolve Query'**
    a. **The 'Resolve Query' window will open.**
9. **Add a comment indicating why the query is being resolved.**
10. **Press 'Resolve'**

The Queries Module

VIEWING A QUERY

To view a query, follow the steps as below:

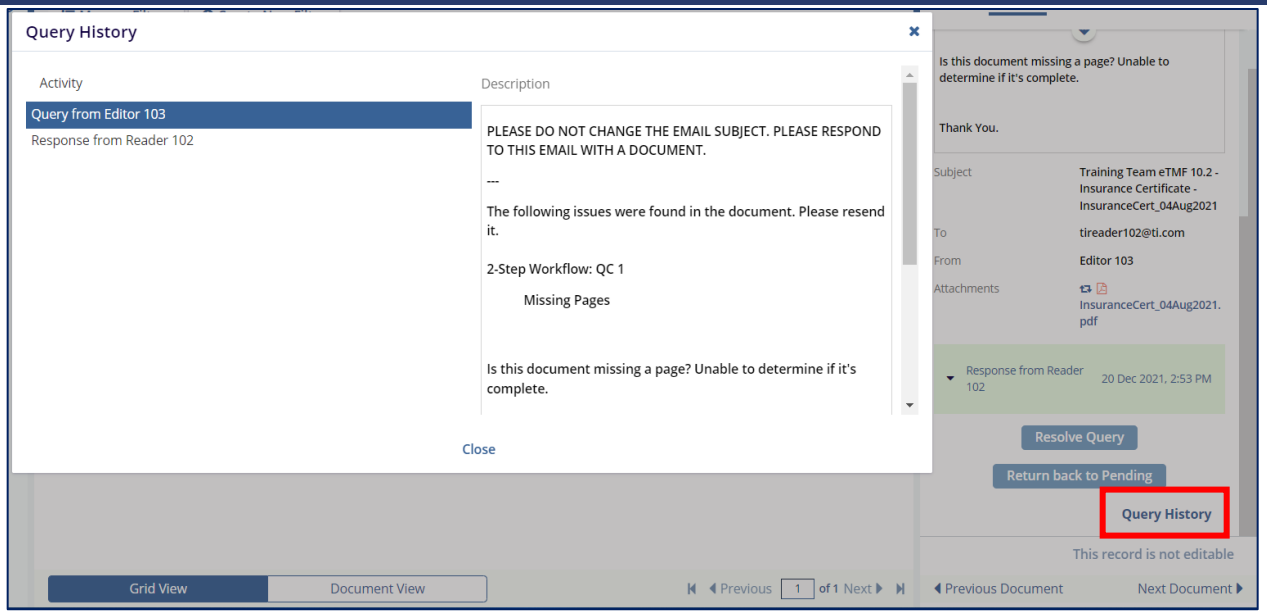
1. **In the Queries module, click Choose View next to the Index View.**
2. **The View Documents By popup appears.**
3. **Select the By Sender view and click Select at the bottom of the page.**
4. **The folders with the name of reviewers appear.**
5. **Click the required folder. The following folders 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

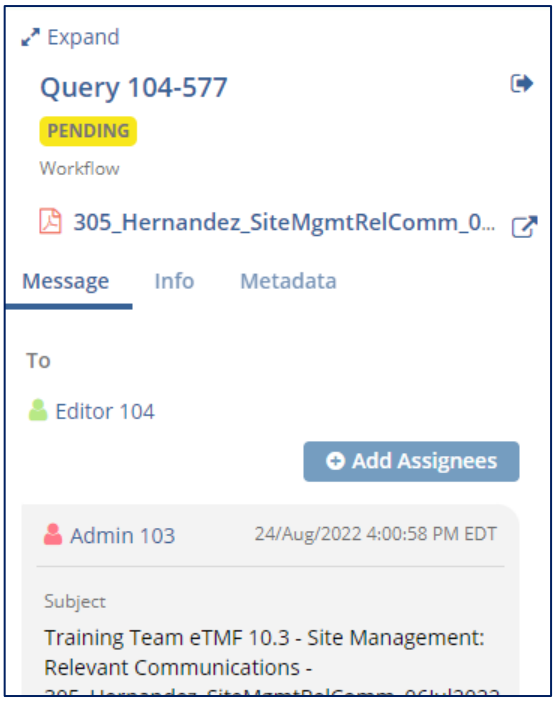
To view the query history, open the required query and click the Query History button at the bottom of the Queries panel. This opens the history of the query in the Query History window. Refer to the screenshot below:



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.

REASSIGNING A QUERY TO A NEW RECIPIENT

Administrator users and those users who are added to the Query Managers group can add an additional recipient to a query. Users can perform this action by locating the query in the Queries module and pressing the Add Assignees button in the metadata panel on the right.



Chapter 11. Searching

Documents Search

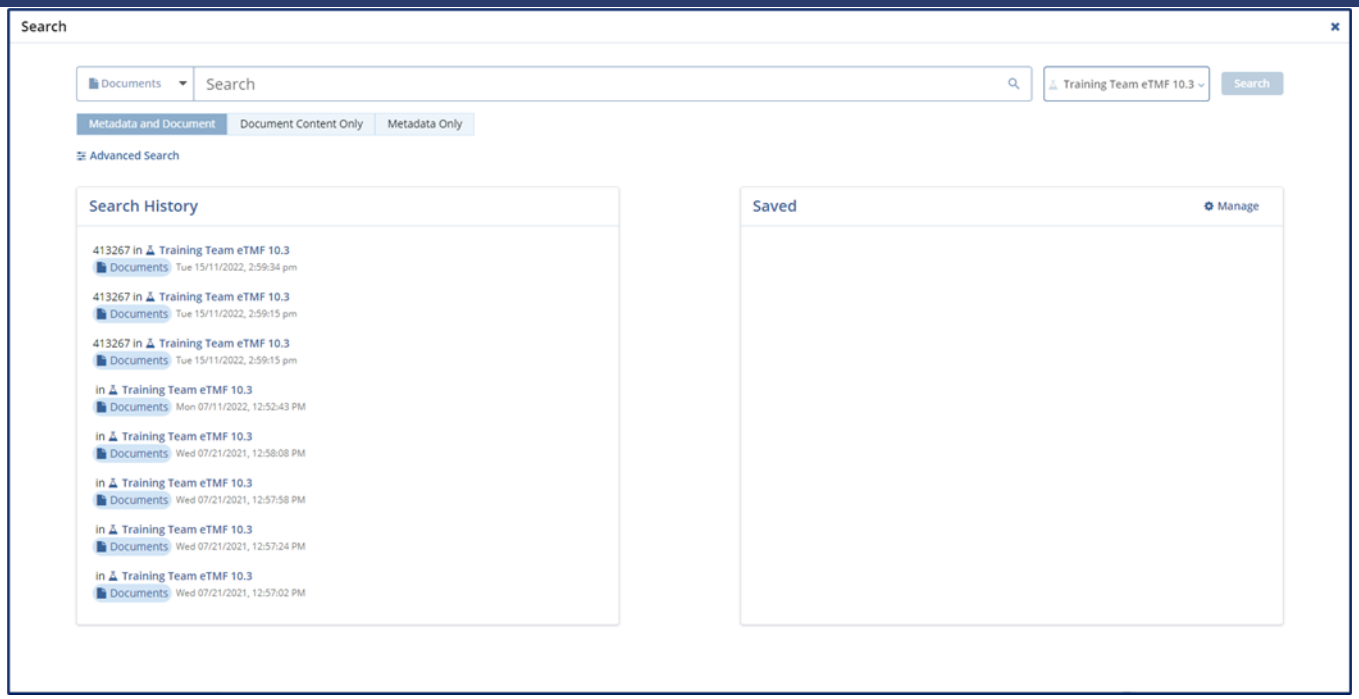
We can perform two types of searches for documents:

- **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.**

- **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:

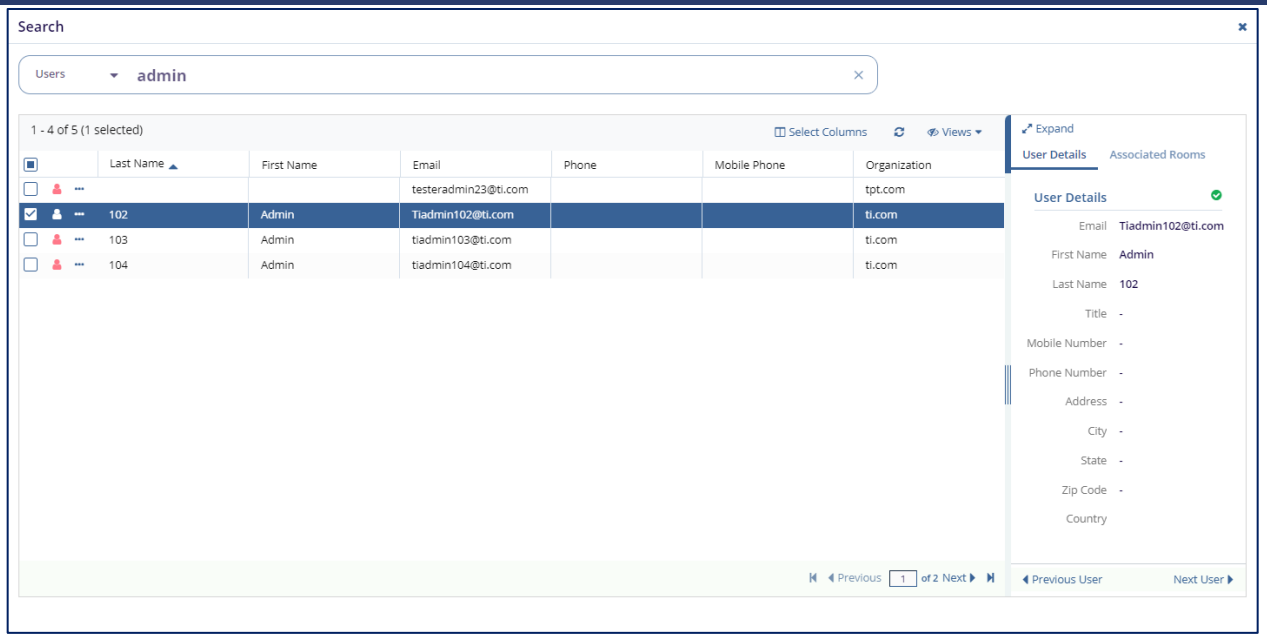
1. **Navigate to the Home Page or a Trial Interactive room as required.**
2. **Click the Search icon next to the username menu.**
3. **The Search popup appears.**
4. **Select Documents from the dropdown of the following options:**
    a. **Documents**
    b. **Queries**
    c. **Users**
    - **Note: Only Administrator users will be able to view all of these options.**
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. **Items matching the search criteria are displayed in the Grid below the Search box or else a message No records available is displayed.**
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.**



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:**

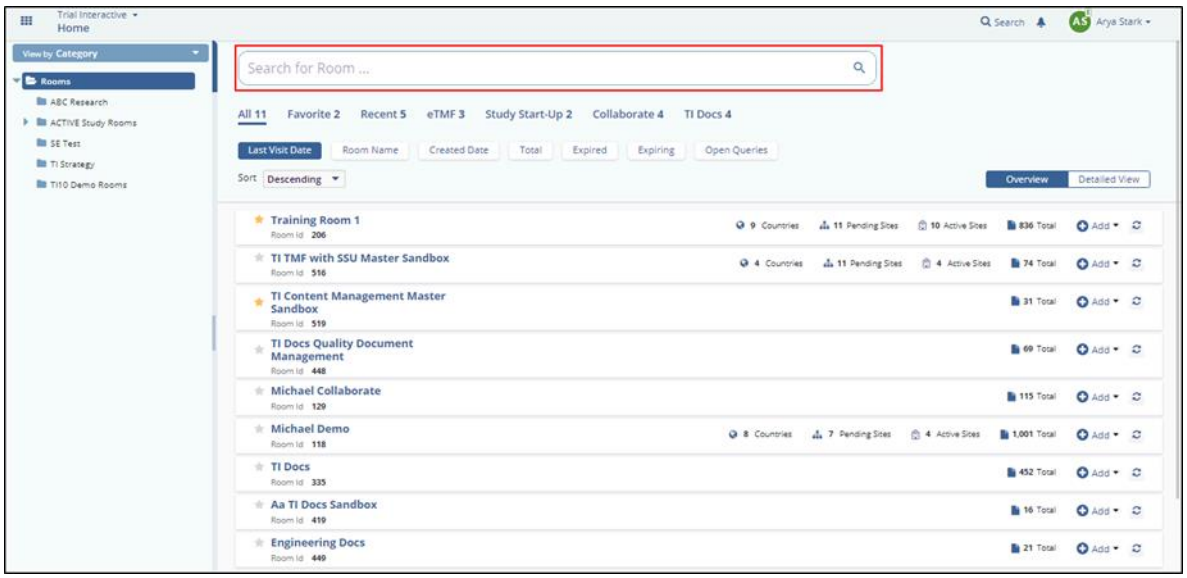


4. **Upon selecting a required user from the results grid, details of that user will be displayed in the User Details section in the right pane.**

Room Search

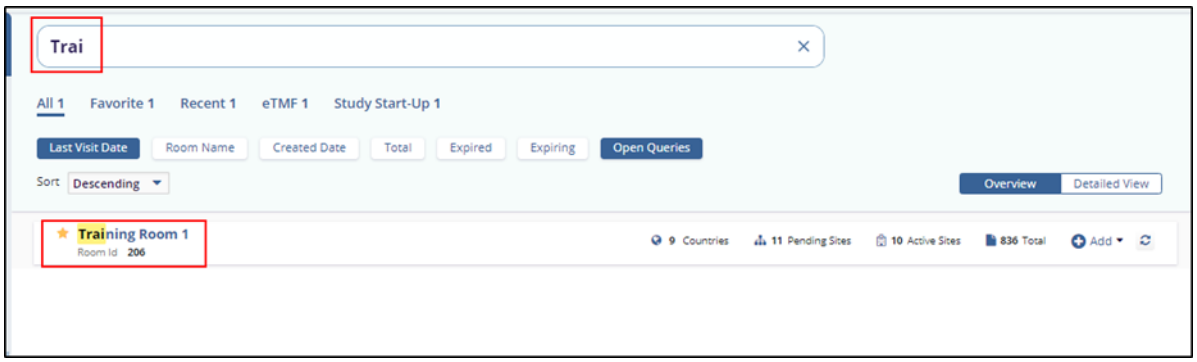
To search for a room, follow the steps as below:

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 12. Importing Documents and Metadata

There are a large number of ways that Documents can be added to a room. This chapter will not be an exhaustive discussion of every possible method. Other methods are mentioned in relevant chapters of the user guide.

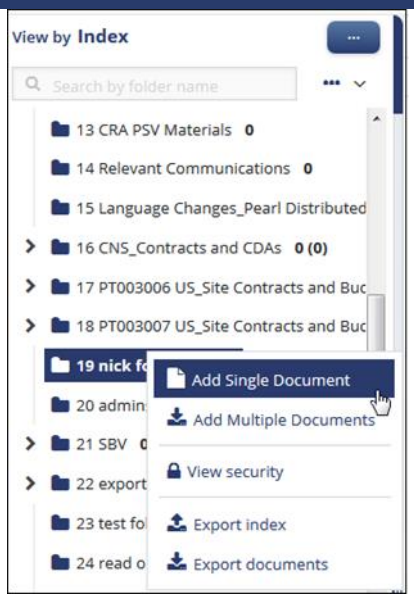
Adding Documents Directly to an Index Folder

You can add Single or Multiple documents to an index folder. Each of these is discussed in the sections below.

ADDING A SINGLE DOCUMENT TO INDEX FOLDER

To add a document directly to an index folder:

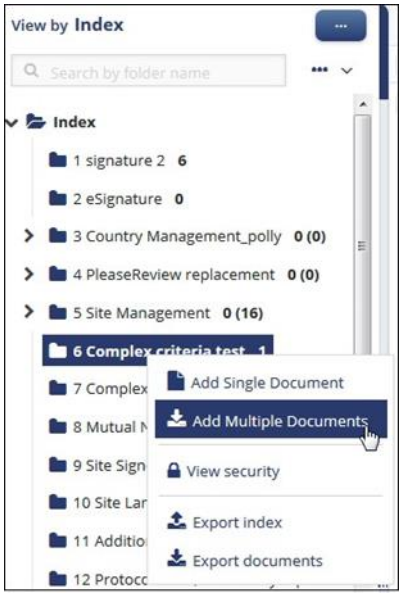
1. **Navigate to the Documents module.**
2. **Select the folder from the index pane into which to add documents and right-click on it.**
3. **From the right-click popup, select Add Single Document. Refer to the screenshot below:**



4. **This will open the Document Profile form for you to add the details and save.**
    a. **This adds documents directly to the selected folder but, depending upon room settings, the document may be redirected to the default (staging) folder.**

ADDING MULTIPLE DOCUMENTS TO AN INDEX FOLDER

1. **From the Documents Module, select a folder in the index.**
2. **From the right-click popup, select Add Multiple Documents. Refer to the screenshot below:**

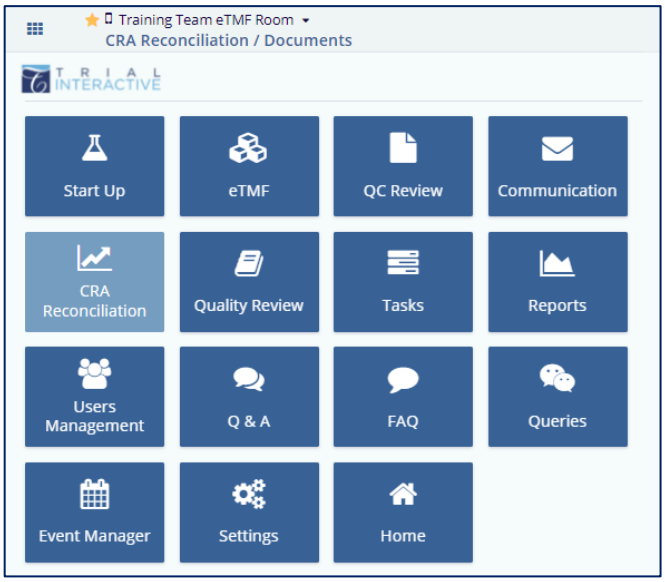


3. **This opens the Import Documents window. Add documents to the window and press 'Import.' A more in-depth discussion of this import window can be found in the section on importing documents and metadata.**

Chapter 13. 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 helps the CRA to reconcile documents during their site visits through the Site Report. You can reach this page from the navigation grid in the upper-left corner of the screen. Users will need to have the CRA Reconciliation action on their user profile to see this module. Refer to the screenshot below:



The module has the following sections:

1. **<u>Documents</u>: 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. **<u>Reports</u>: 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.

- **<u>Note:</u> Any user can be granted access to the CRA Reconciliation module but the reconciliation and reporting functions will only be available to users who have been designated as a CRA for a site. This designation is not available to room administrators.**
    - **In rooms with Study Start Up enabled, this module can also be used to track sites to which the user has been assigned as a Site Activation Specialist.**

Documents Reconciliation

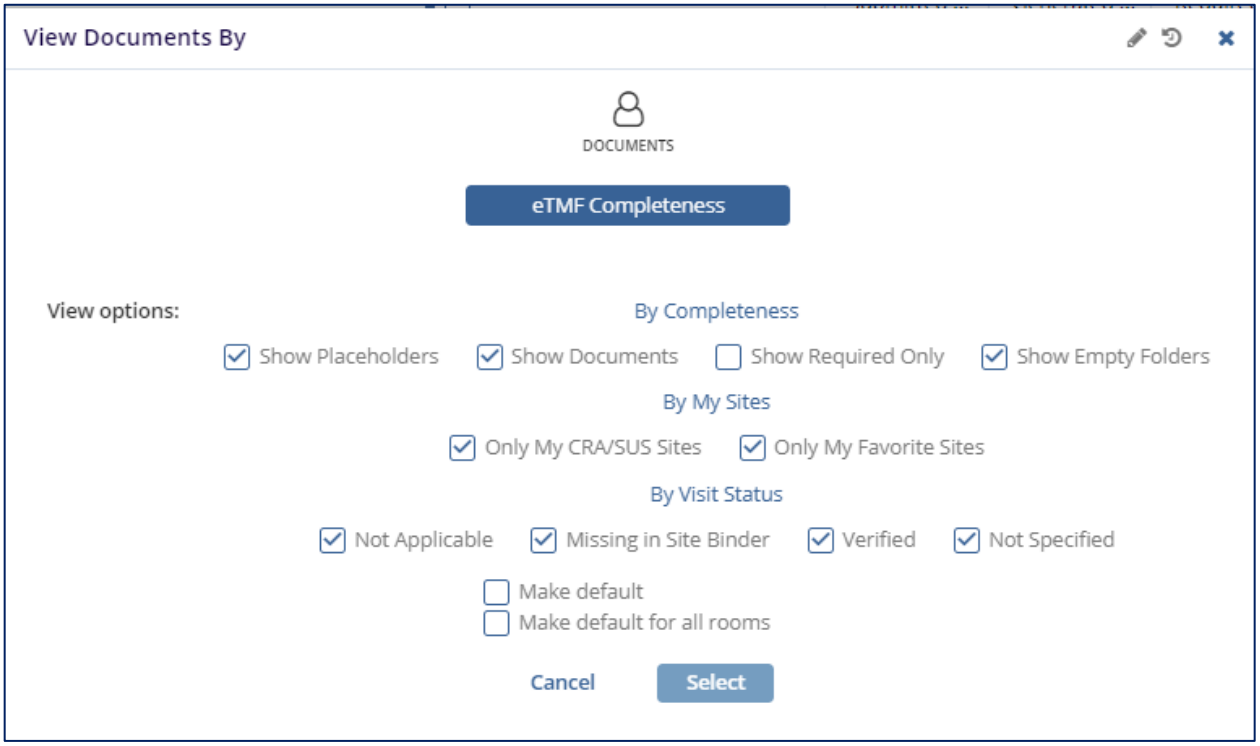
For performing Site Visits, CRAs needs to make some important decisions regarding documents for sites:

- **Which documents need to be added to both eTMF and site binder**
- **Which documents need to be added to site binder from eTMF**
- **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.

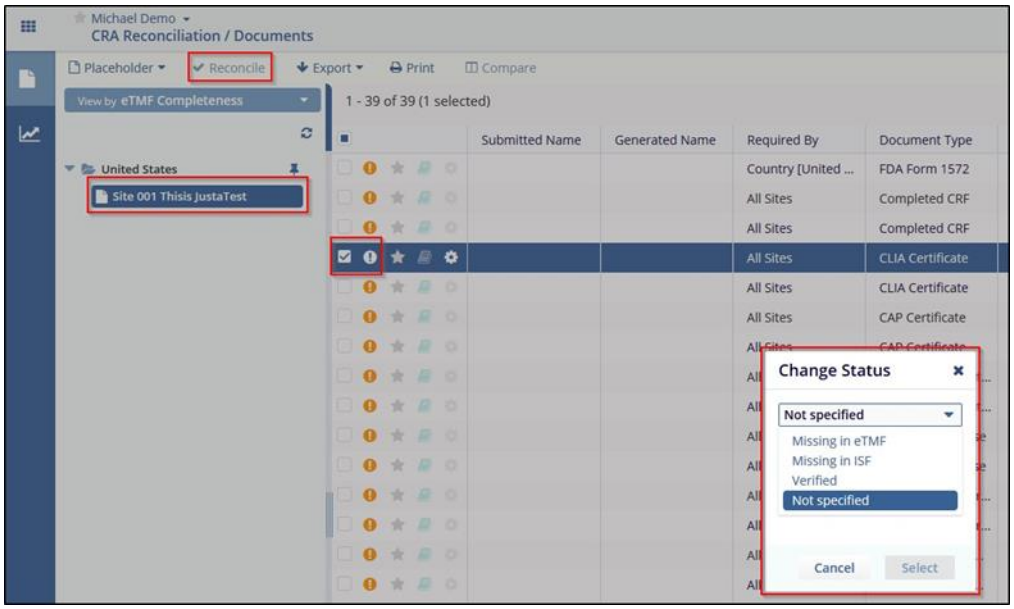
Follow the steps below to reconcile documents:

1. **Navigate to the CRA Reconciliation Module.**
    a. **Note: If you are not a CRA and have not set up a personalized default view, you will receive a warning message indicating that you will need to disable the 'My CRA/SAS sites' filter in order to see the study sites.**
2. **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:**



3. **Click Apply.**
4. **The list of folders appears in the view.**
5. **Click the appropriate folder to display the list of sites.**

6. **Select the appropriate site from the selected folder to get the list of missing, collected, and placeholder documents in the grid.**
7. **Click the document and then click the Reconcile button.**
8. **Select the appropriate status from the dropdown menu.**
9. **Press 'Select'**

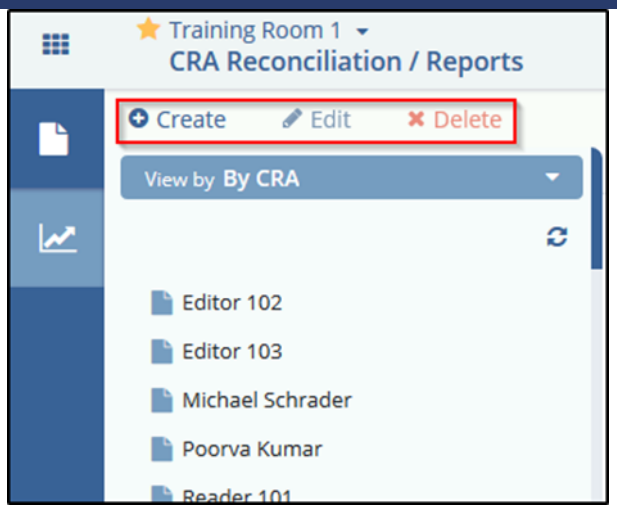


Creating and Viewing CRA TMF Reconciliation Reports

The 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 the Navigation Grid. On entering the reports area via the link on the left-side of the screen, you can find the list of reports displayed in the grid.

You can choose to view the reports By Site, By Visit Type, or By CRA from the view dropdown menu on the left. Clicking a report from the grid populates the report information in the metadata panel to the right side of the screen.

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 A CRA TMF RECONCILIATION REPORT

1. **Once the Reconciliation process is complete, you can create the CRA TMF Reconciliation report from the Reconciliation Report area.**
2. **Select the appropriate filter from the Current View. Any 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.**
    a. **If this is the first report being created for the site, simply click the 'Create' button and then manually enter the site information the form that opens.**
4. **The Create CRA TMF Reconciliation window populates with documents from the latest reconciliation. Complete the required fields.**
5. **Fill in the appropriate details and click 'Create.'**
6. **You will receive a notification that the Site Report is created successfully. The report will then be displayed in the grid.**

EDITING A CRA TMF RECONCILIATION REPORT

1. **Select the required site from the Reports 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.**
    a. **You will only be able to delete reports which you generated.**

2. **Click Yes on the confirmation popup that appears if you wish to delete the report from the list.**

Chapter 14. Quality Review

The Quality Review module of Trial Interactive tends to be used in a variety of ways depending upon individual study needs and internal SOP requirements. However, the most common usage of this is as a post-QC review of document and information quality and accuracy. These audits can be conducted internally or an audit can be set up specifically for an external auditor or inspector to come in and review your study room.

In cases where an external auditor will be conducting the review, you may want to grant them specific access as a Regulatory Agency Inspector so that they can be adequately trained in a limited amount of time. For additional information regarding user management, please see the related section of the user guide.

The Quality Review module can be found in the Navigation Grid. Room administrators will always be able to see the Quality Review tile but other user access levels will need to first be indicated as an active participant in an audit as an Auditor or an Audit Manager before the tile will appear. Audit Responders conduct their document corrections from the Documents module and will not see the Quality Review tile unless they also have one of the other roles.

Quality Review Settings

Once you enter the Quality Review module, all Administrators and Editor or Manager users who have been designated as Audit Managers will see a gearwheel icon in the menu to the left side of the screen. Clicking on this will open the Quality Review Settings area. See the screenshot below.

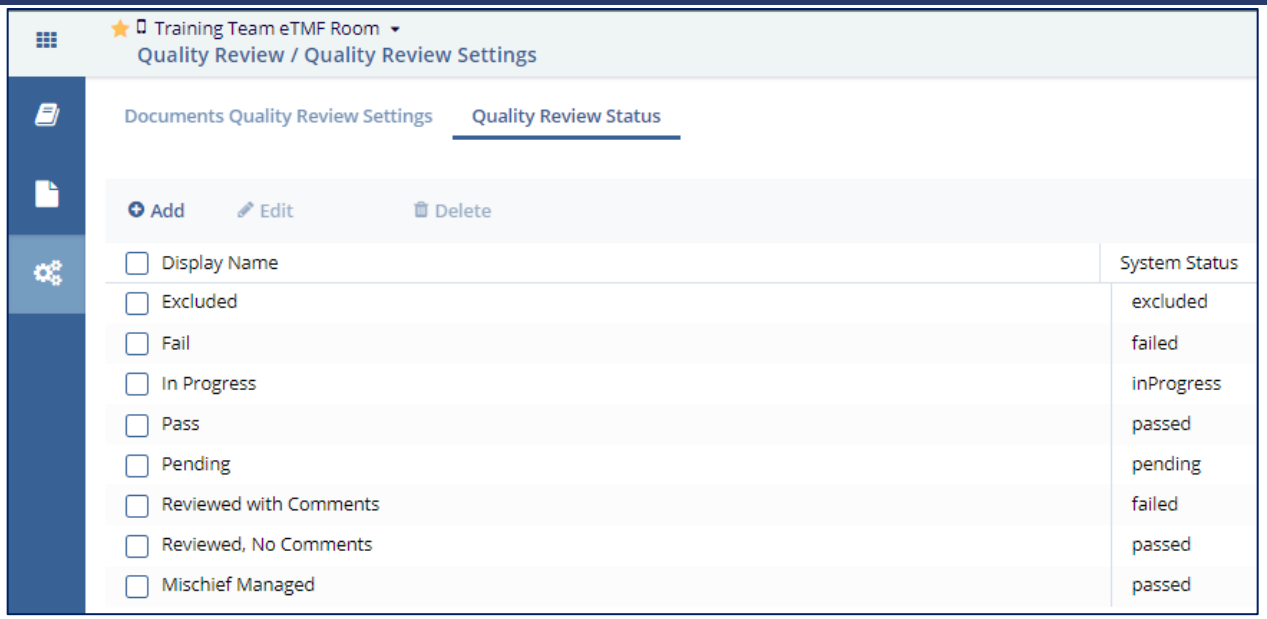
From here, Administrators can create new audit profiles as well as made changes to any audit profile in the room. Additionally, they can create and edit the statuses which will be available for use in the creation of audit profiles. Audit Managers who are not administrators will be able to edit any audit in which they are designated as an Audit Manager.

MANAGING QUALITY REVIEW STATUSES

Every status which can be assigned to a document during an audit has to be added into the Audit Status window before the related audit is built. The system allows users to create custom statuses but each one will represent one of the basic 5 system statuses:

The 5 basic system statuses are:

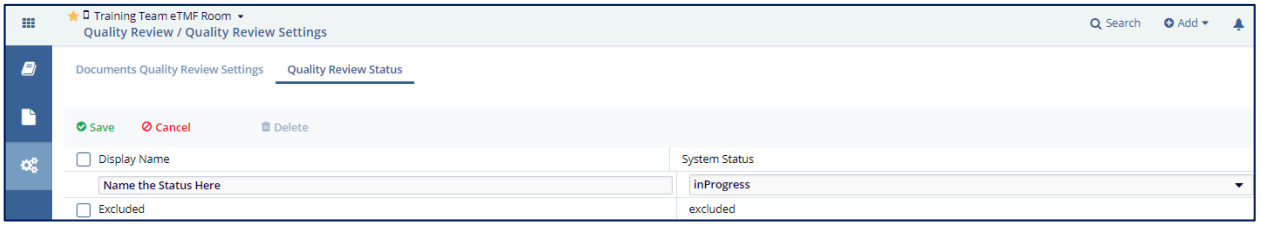
- **Passed – There are no findings associated with the document.**
- **Failed – Assigning a status which means that the document has failed generates an audit finding which will then need to be reviewed and, if possible, corrected by the Audit Responders.**
- **Pending – Documents in Pending status are those which still require review by an auditor.**
- **In Progress – This status can mean whatever it needs to and serves as a placeholder between passed and failed statuses.**
- **Excluded – Users are not able to manually apply a status of 'Excluded' to documents in the audit but, in specific circumstances, the system may apply this status.**



Adding an Audit Status

Follow the steps below to add audit statuses:

1. **Click the Add button on the Quality Review Status tab.**
2. **The fields under the Display Name and System Status fields are activated.**
3. **Type in the Display Name.**
4. **Click the dropdown arrow from the System Status field and select the established System Status term to associate with the newly added Display Name.**
5. **The 'Add' button is replaced with 'Save' and 'Cancel' buttons during this process. Press 'Save' when you are done.**
    a. **The status will be saved and added to the list.**

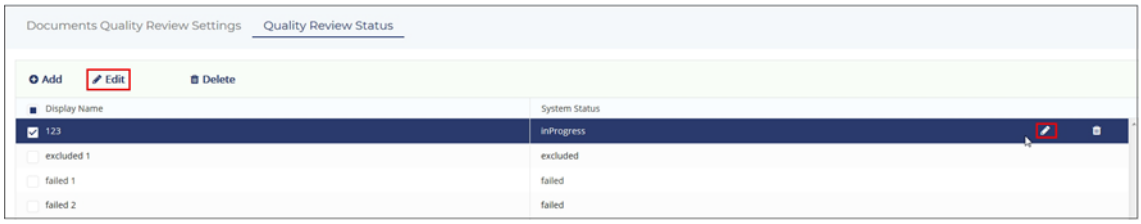


Editing an Audit Status

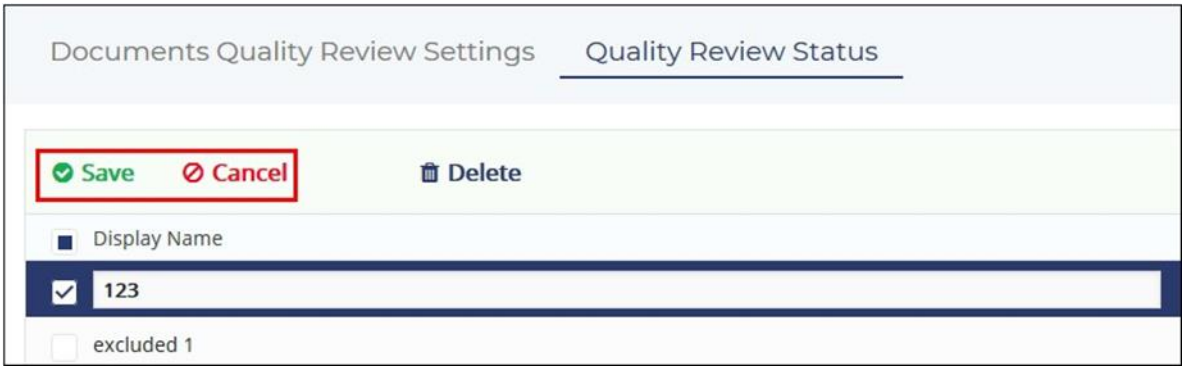
Follow the steps below to edit audit statuses:

- **Select the audit status from list in the Quality Review Statuses window.**

- **You can edit the audit in the following by:**
  a. **Pressing the 'Edit' button from the top ribbon bar or,**
  b. **Clicking the Edit button that appears while hovering the mouse over the status.**



- **Notice that the Add and Edit buttons changes to Save and Cancel when the audit is activated for editing. Refer to the screenshot below:**



- **Make the required changes and click Save.**

Deleting an Audit Status

Follow the steps below to delete an audit status:

1. **Select the status from the list in the Quality Review Status window.**
2. **Either click 'Delete' from the top ribbon bar or click the trash can icon that appears on hovering the mouse over the status.**

CREATING A NEW AUDIT

In Trial Interactive, before creating an Audit Profile, it may be helpful to understand the various roles that are assigned to users as a part of creating the audit:

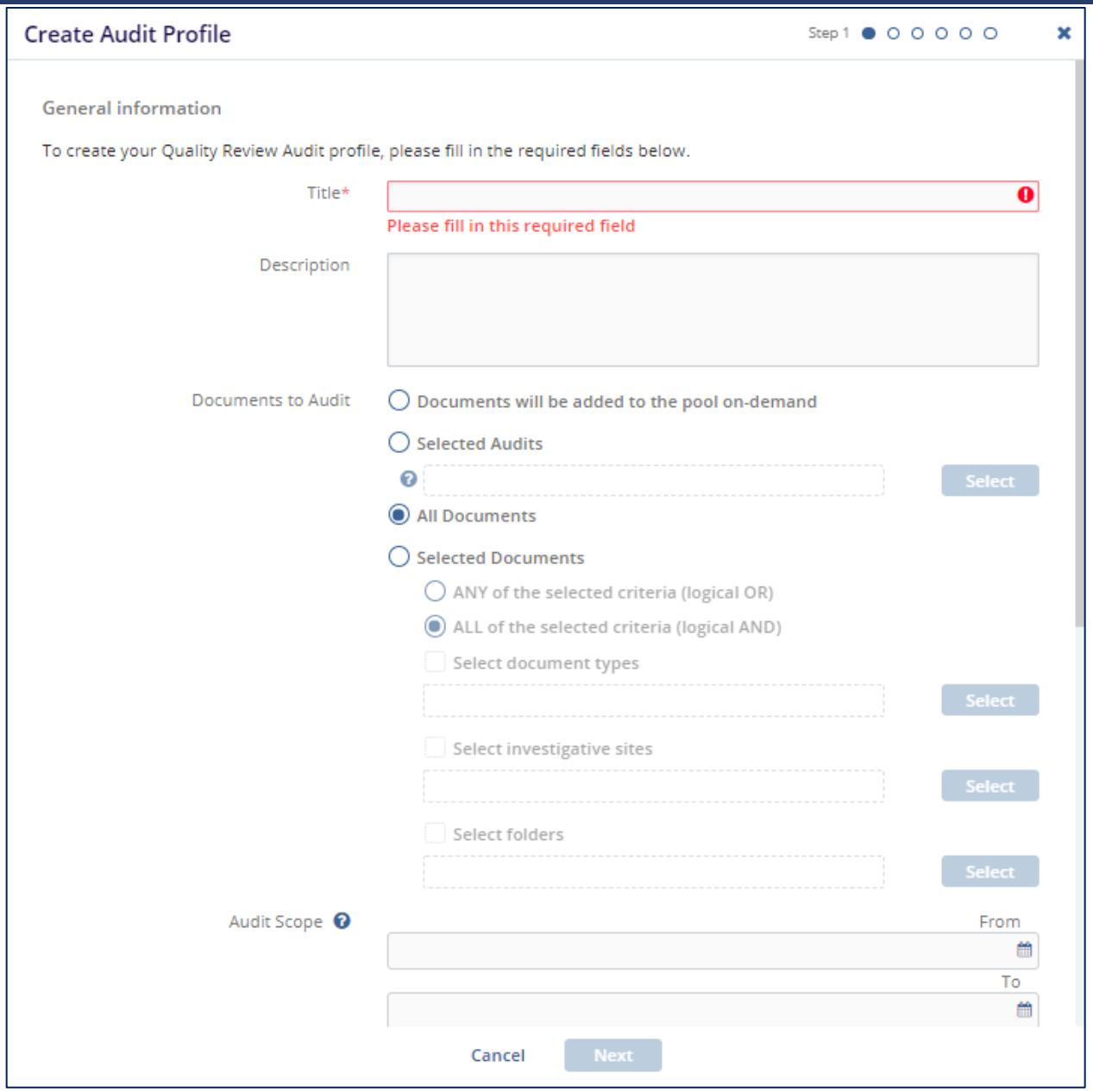
- **Auditor: Users assigned to this role are responsible for reviewing documents and assigning them a status of passed or failed. Any level of user can be assigned to this role.**
- **Audit Manager: Users assigned to this role can see audit results, create an audit export, reassign documents to other auditors, release audit findings from review, and make changes to the audit profile. Only editors and higher-level users may be assigned to this role.**

- **<u>Audit Responder</u>: Users assigned to this role are responsible for taking action to rectify audit findings generated by the auditors during their review of the documents. Only editors and higher-level users can be assigned to this role.**

The process for creating a new audit profile is discussed below:

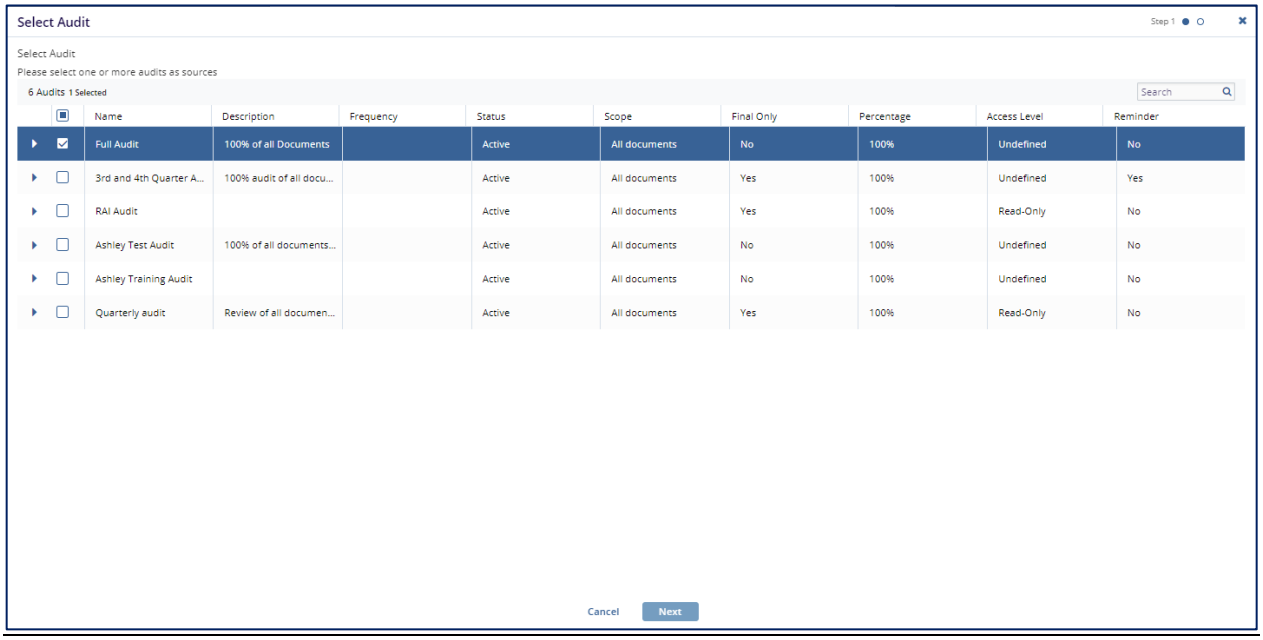
- **Prior to beginning this process, it is crucial that you ensure that all applicable Quality Review Statuses should have already been created.**

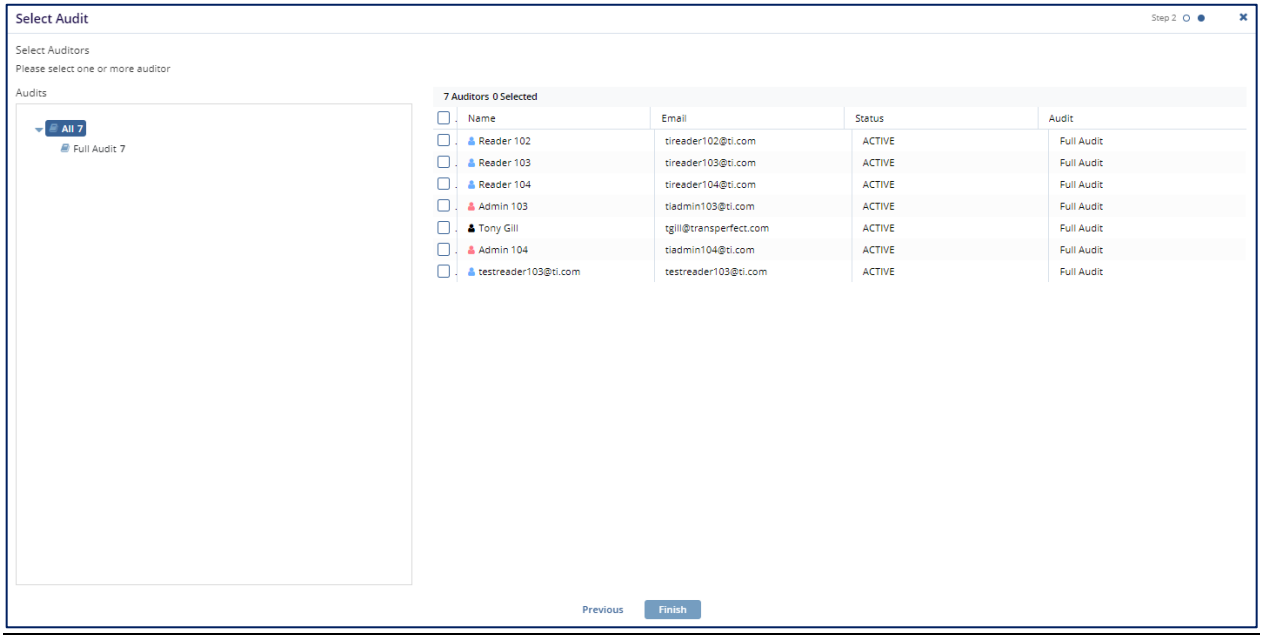
1. **Navigate to the Quality Review Settings area of the Quality Review module.**
2. **Press 'Add' button in the menu bar above the grid.**
    a. **This will open the Create Audit Profile window.**



3. **Enter a title for the audit profile.**
    a. **It is generally best to be as specific as possible here. For example: 2nd Quarter 2021 Final Documents Review**
4. **The description field is not required but it is highly recommended as it serves as a mission statement of sorts for the audit and will assist in choosing the correct audit settings in the remainder of the fields.**
    a. **For example: "This audit will review a random 20% of all documents that were published to the eTMF during the 2nd quarter of 2021."**
5. **The 'Documents to Audit' area has several options to choose from:**
    a. **<u>Documents will be added to the pool on-demand:</u> This option will create a blank audit with no documents in it. Editor, manager, and administrator users can then add documents to the audit manually via the Documents Cart.**

b. <u>Selected Audits:</u> This option indicates that the audit will be reviewing the work done in a prior audit or set of audits. If you select this option, you will be asked to specify which audit and which auditor(s) you wish to review.





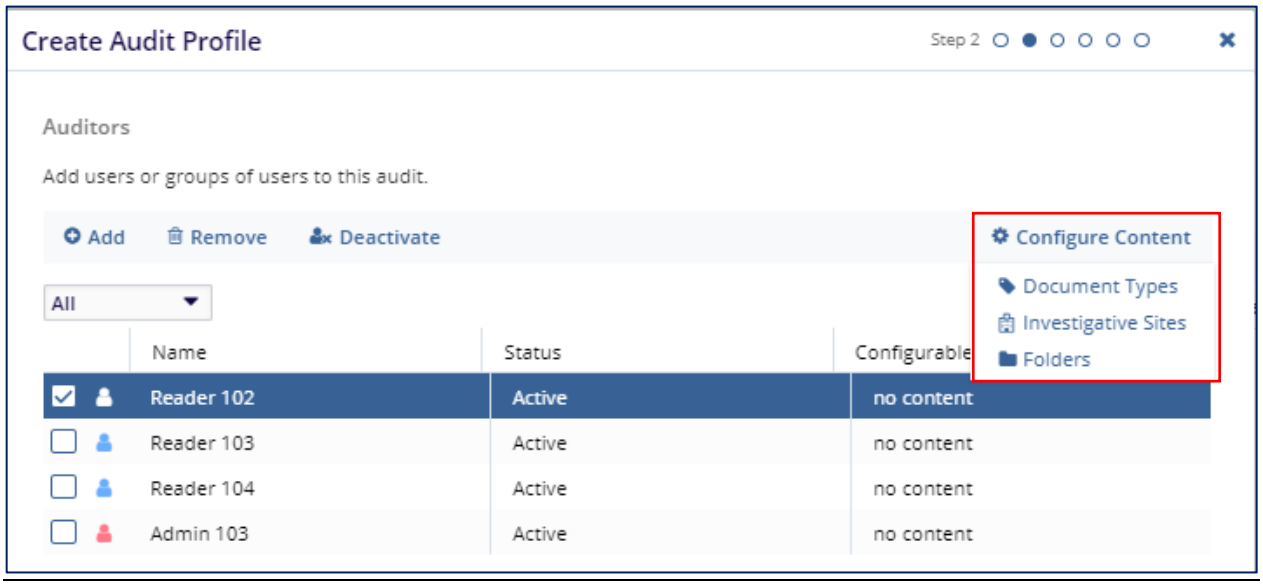
c. <u>All Documents:</u> This option will cause the system to gather all documents which meet the criteria chosen below.

d. <u>Selected Documents:</u> This option allows the user to specify the criteria which the room will use in gathering documents for review.

i. The user will first need to specify whether the room should take in to account ANY or ALL of the criteria specified.

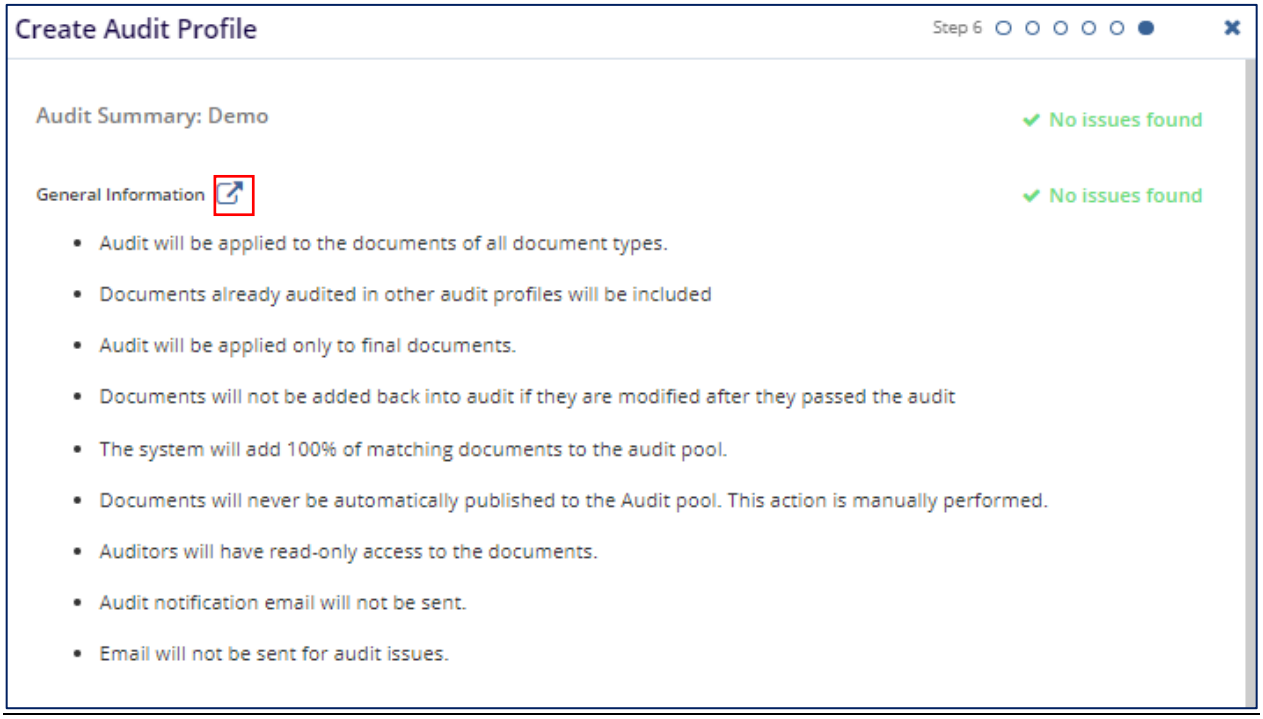
6. **The Audit Scope is only applicable to audits which are reviewing documents from a specific timeframe.**
    a. **In the example from above (2nd Quarter 2021 Final Documents Review), the user would specify the beginning and end dates for the 2nd Quarter of 2021.**
7. **The 'Submitted' and 'Final' radio buttons are asking the user to specify which date should be used when determining whether or not the document falls into the Audit Scope designated in step 6.**
    a. **Submitted: The date that the document was submitted to the room.**
    b. **Final: The date that the document was made 'Final' and published to the index.**
8. **Indicate whether or not the system should include documents which were already included as a part of another audit.**
9. **Indicate whether the system should include only documents which are in a 'Final' status.**
    a. **If this option is not checked, it is possible that a document may go through the QC Workflow and the Quality Review Audit at the same time. This may cause some confusion and is not recommended.**
10. **Sometimes, when the Audit Responder is addressing an Audit Finding, a document's metadata may be updated. The 'Add modified documents back into the audit pool' option tells the system that, if any of the following metadata fields were updated as a part of the correction, the document should be re-added to the audit for another review.**
    a. **Index**
    b. **Category**
    c. **Document Type**
    d. **Investigative Site**
    e. **Document Date**
11. **The 'Percentage of new documents' tells the system that, whenever it gathers documents matching the criteria above, it needs to take a random sampling matching the designated percentage.**
12. **The 'Update Interval/Frequency' field is for use in ongoing audits which will need to be updated at regular intervals. The system will go out and gather new documents matching the specified criteria at the indicated interval.**
13. **Indicate the auditor access level.**
    a. **View Only, no download: This restricts the auditor to viewing documents.**
    b. **Full Access: This allows the auditor to download or modify documents based on their user access level rights. This is most commonly applied to internal audits.**
14. **Indicate whether the auditors should have access to the 'Contains PHI' function.**
    a. **This function allows an auditor who discovers PHI in the room to immediately delete the attached file. This will move the file record (metadata only) to the Audit Responder so that they can upload a redacted version of the document.**
15. **There are two types of audit notification that can be sent. Indicate whether or not the room should send audit notifications.**
16. **Press 'Next'**

17. **The next step is to assign the users who will be Auditors in the audit.**
18. **Press the 'Add' button.**
    a. **This will open the 'Add Users and Groups' window.**
19. **Move any applicable users and/or groups to the right panel by clicking and dragging, double clicking, or by pressing the + sign that appears at the right side of the user's line.**
20. **If multiple auditors have been added, the 'Configure Content' option may be used. It is optional.**
    a. **This option is most useful when you have chosen specific criteria such as document types or investigative sites and you would like a specific auditor to review a specific document type or all documents associated with a specific site.**
    b. **Select the auditor and press 'Configure Content.'**
    c. **Choose which criteria will be used in assigning documents to this auditor:**
        i. **Document Types**
        ii. **Investigative Sites**
        iii. **Folders**



    d. **Once selected, another window will open in which you will be able to specify which document types, sites, or folders apply to the specified user.**
21. **When you are done adding auditors and, if necessary, configuring content, press 'Next.'**
22. **The next step is to assign the users who will be Audit Managers in the audit.**
23. **Press the 'Add' button.**
    a. **This will open the 'Add Users and Groups' window.**
24. **Move any applicable users and/or groups to the right panel by clicking and dragging, double clicking, or by pressing the + sign that appears at the right side of the user's line.**
25. **Press 'Next' when done.**
26. **The next step is to assign the users who will be Audit Responders in the audit.**
    a. **These users cannot be the same as those who are added as Auditors.**

27. **Press the 'Add' button.**
    a. **This will open the 'Add Users and Groups' window.**
28. **Move any applicable users and/or groups to the right panel by clicking and dragging, double clicking, or by pressing the + sign that appears at the right side of the user's line.**
29. **Press 'Next' when done.**
30. **In the next window, you will be required to choose the document statuses for use in the audit.**
    a. **These must have been created prior to beginning the audit.**
    b. **You will be required to include at least one status for each of the basic 5 system statuses:**
        i. **Passed**
        ii. **Failed**
        iii. **Pending**
        iv. **In Progress**
        v. **Excluded**
31. **Press 'Next' when done.**
32. **The final screen indicates if there are any errors detected.**
    a. **The most common of these would be if you had a user added as both an Auditor and an Audit Responder.**
33. **If there are any errors, use the section link to go back and correct the error.**



34. **When you are done, press 'Finish.'**
35. **A window will open asking you if you want to activate the audit.**
    a. **If you press 'No' the window will close and the audit will be added to the list in an 'Inactive' status.**
    b. **If you press 'Yes' the window will close and the audit will be added to the list in an 'Active' status.**

COPYING AN EXISTING AUDIT

Users of Trial Interactive often need to run the same quality review audit multiple times, changing a few details such as the participating auditors. You may also need to change the audit scope after an audit has started, but do not wish to impact the current audit.

There are now two options:

- **<u>Duplicate an Existing Audit:</u> Use this option when you wish to duplicate an existing audit, running the same scope again but with different users involved. You may update the scope in the new audit if you need, but once it is published, no further scope changes can be made.**
    - **To duplicate an existing audit, select the audit from the list of existing audits and press the 'Duplicate' button in the menu bar above the list.**

- **<u>Documents from Selected Audits:</u> Use this option when you want to create a new audit that contains the documents from prior audits. This allows you to choose from the existing users involved in those audits, and**

merge and include all the same sets of documents from those prior audits.

Additionally, this improvement:

- **Simplifies the duplication of existing audits, providing an option to easily do this so that audits may be managed through a regular maintenance cycle.**
- **Corrects the audit scope for audits using the 'Do not include already audited documents' feature, limiting this scope to only Active and Completed audits, and ignoring Disabled audits.**
- **Adds 'Disabled' and 'Completed' statuses for audits, allowing an improved tracking of audit statuses.**
- **Restricts updates to the Audit Scope for existing active audits, requiring duplication of the current audit instead.**
- **Improves the descriptions and tooltips on the Audit Scope page.**

EDITING AUDITS

Existing audits can be edited by any room administrator or any user who is indicated as one of the Audit Managers for the audit in question. For example, an Editor or Manager level user who is designated as an Audit Manager for one of several quality review audits in the room will be able to navigate to the Quality Review Settings menu. The difference between their view and the Administrator view will be that the Administrator will see all audits whereas the Editor or Manager user will only see the audit in which they are indicated as the Audit Manager.

Follow the steps below to edit an existing audit:

1. **Select the audit from the list.**
2. **Click the Edit button from the top ribbon bar.**
3. **The Edit Audit Profile window opens.**
4. **Follow on to the steps and make any required changes to the audit profile.**

<u>Deactivating an Auditor</u>

- **While you are editing an audit, you will have the option to remove an auditor from the audit. In order to do that, please follow the steps below:**

1. **Open the audit profile for editing and to the auditors page.**
2. **Select the auditor who needs to be removed from the audit.**
3. **Press the 'Deactivate' button.**
    a. **This will open the 'Documents Reassignments' window.**
4. **Choose what to do with the user's remaining documents.**
    a. **Leaving the 'Automatically reassign all documents randomly between existing auditors' box checked**

will do just that. The auditor's remaining documents will be reassigned randomly.

b. If the box is unchecked, you will be able to choose an auditor to reassign the documents to. Move the selected recipient from the left side of the window to the right side.

5. Press 'Add'
6. Proceed through the remainder of the Edit Audit wizard and press 'Finish' to save your changes.

DELETING AN AUDIT

Deleting an audit can only be done until a document has been reviewed. Once a document has been reviewed as a part of the audit, the audit can only be stopped.

1. Select the audit.
2. Press the 'Delete' button at the top of the grid.
3. The audit will be removed from the list.

STOPPING AN AUDIT

Stopping an audit can be done at any time but it is recommended that you wait until all documents have been reviewed and all audit findings have been corrected. Once an audit has been stopped, Auditors will lose access to any unreviewed documents and Audit Responders will lose access to any un-corrected findings. If this is done too soon, an audit can be re-started and the users will be able to pick up where they left off.

To stop an ongoing audit:

1. Select the audit from the list.
2. Press the 'Stop' button at the top-right of the grid.
    a. The 'Stop' button becomes a 'Start' button in case the audit needs to be re-started.

PUBLISHING DOCUMENTS TO AN AUDIT

Sometimes, users will keep an audit profile in a study room which needs to be deactivated and reactivated. If an audit is reactivated and new documents need to be added to the audit you can select the audit and then press the 'Publish Documents' button.

Performing Audit Functions

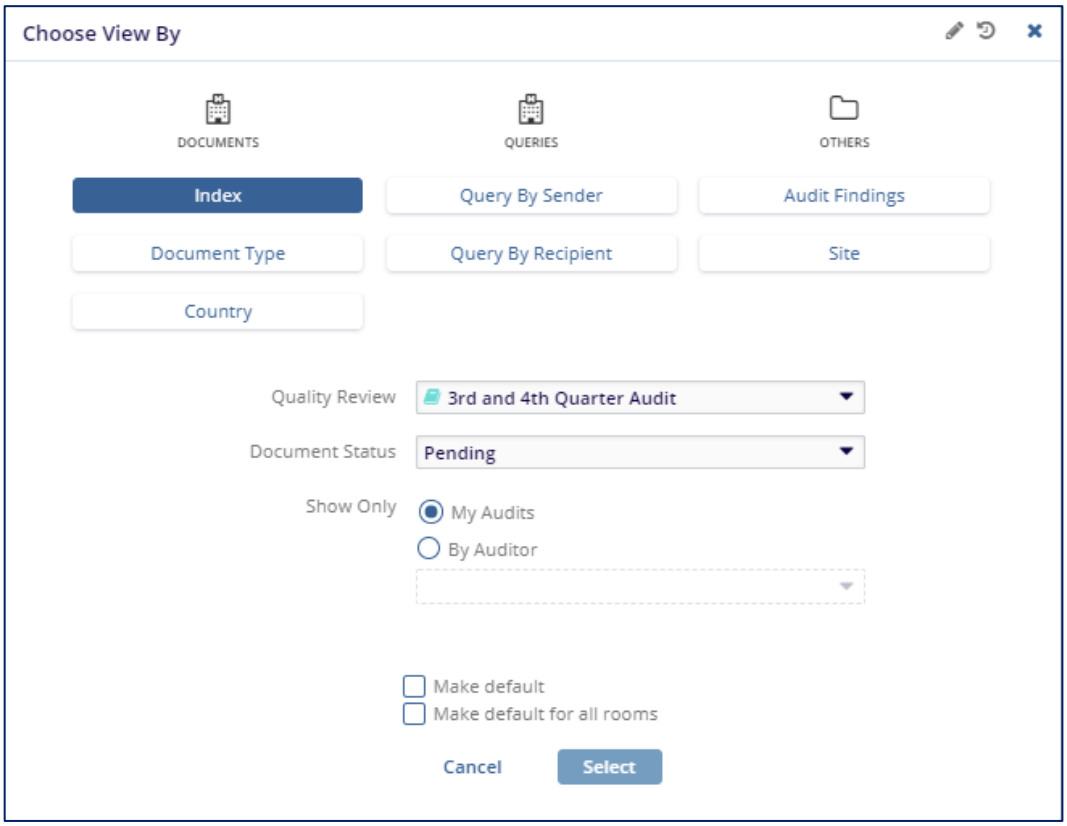
If you are assigned as an Auditor or Audit Manager in your trial room, the Quality Review module is available to you in the Navigation Grid at the top-left of the screen.

The Quality Review module has the following views available in the vertical menu at the left side of the screen:

- **Audit: This view allows you to select an audit and perform audit-related functions.**
- **Documents: This is the standard Documents module and allows the user access to search for documents within the index.**
- **Settings: This allows you to configure settings for Quality Review**

SELECTING AN AUDIT

Much like the Documents module, the Quality Review module has a view selection dropdown menu at the top of the index pane. Use this menu to select your preferred view of the documents in the audit. See the screenshot below:



The Quality Review dropdown menu allows Reader, Editor, and Manager level users to see the audits that they are currently a part of in either the Auditor or Audit Manager role. Administrators can see all audits here.

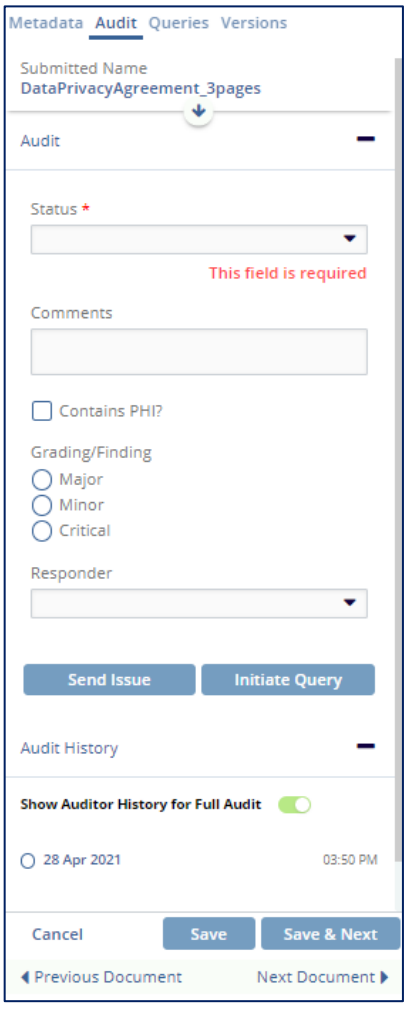
Audit Managers will also have an option to view either their own audits (if they are also acting as an auditor for the audit) or they can check up on the progress of other auditors in the selected audit.

When you have made your choice, press 'Select' to be taken to the audit.

REVIEWING A DOCUMENT

Follow these steps to review a document in an ongoing audit:

1. **Select an audit in which to work.**
2. **Drill down in the index to locate a document in need of review.**
3. **Select the document from the grid.**
4. **Open and review the document per internal standards.**
5. **In the metadata panel, choose the Audit tab.**
6. **Assign a status to the document.**
    a. **The available statuses may vary from audit to audit.**
    b. **If you have assigned the document a status indicating that the document failed, it is highly recommended that you add comments in the box below in order to explain to the Audit responder why the document failed the audit.**
7. **The audit fields are customizable. Fill in values for any other required fields. See the screenshot below:**



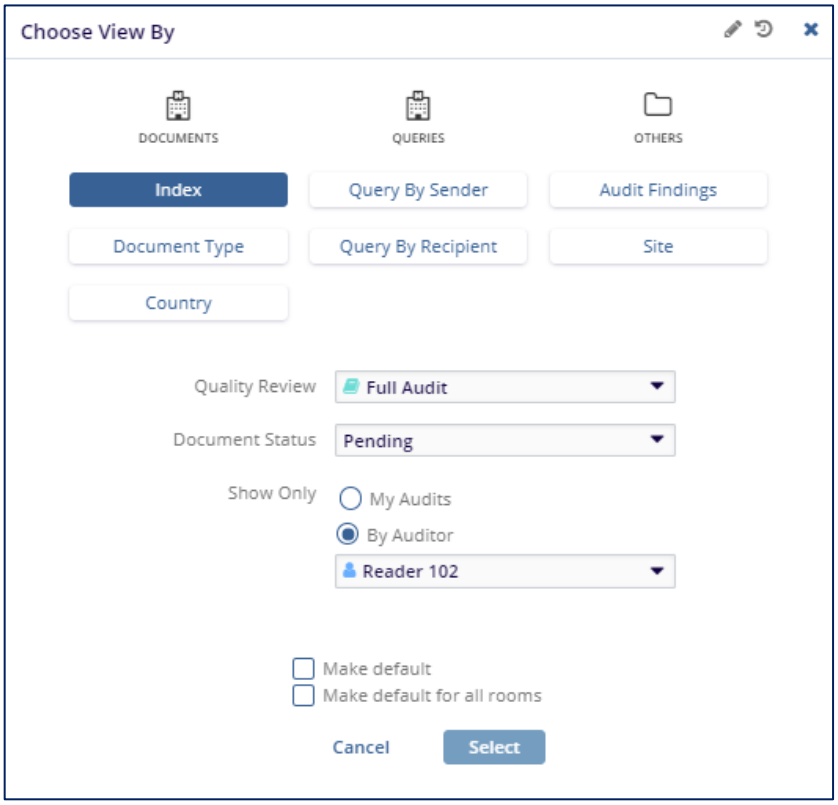
8. **Press 'Save' or 'Save & Next'**

- **Note: Auditors can also send audit queries. For more information on this, please see the chapter on Queries.**

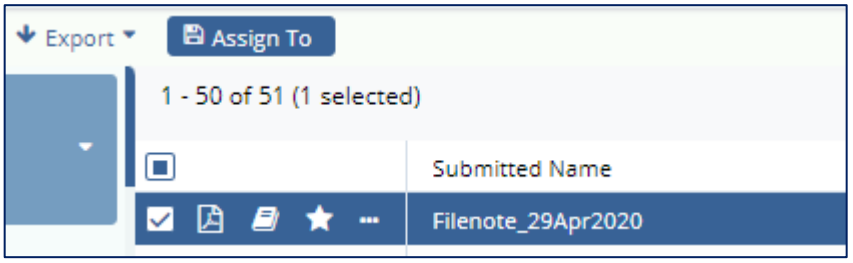
REASSIGNING A DOCUMENT TO ANOTHER AUDITOR

Sometimes an Audit Manager need to reassign a document to another auditor. Please follow the steps below to perform this action.

1. **Select the audit and choose to view Pending documents for the currently assigned auditor. See the screenshot below:**



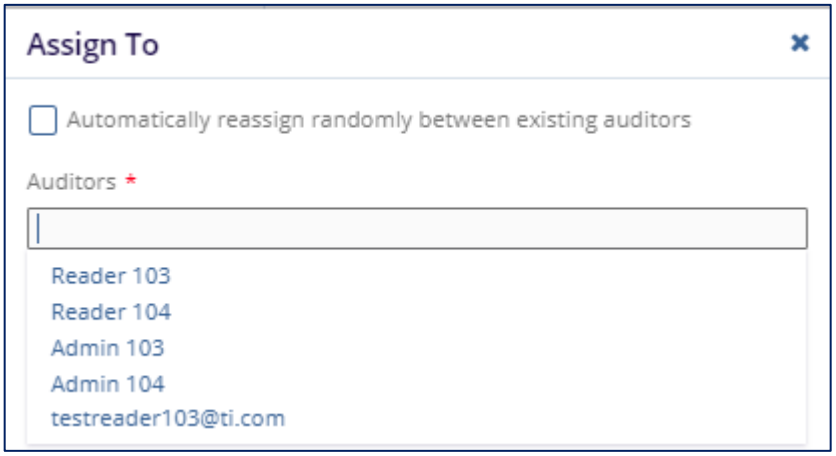
2. **Press 'Select'**
3. **Locate the document to be reassigned and check the box for the document on the Grid.**
4. **Press the 'Assign To' button above the Grid.**



   a. **The 'Assign To' window will open.**

5. **You may leave the box checked to allow the system to randomly reassign the reviewer or you may uncheck the**

box and manually pick a new reviewer.

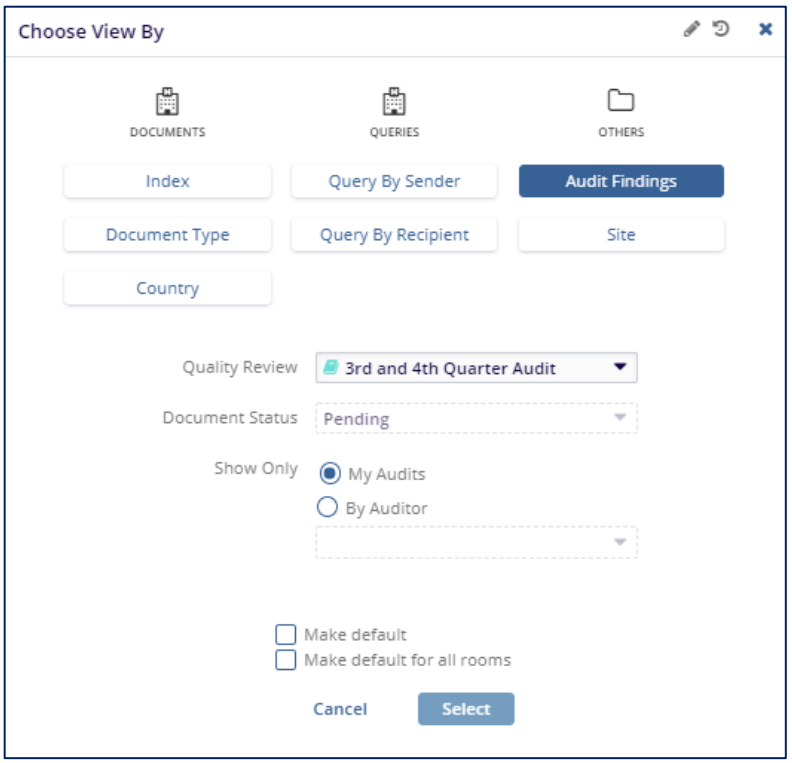


6. **When you have chosen, press the 'Assign' button.**

RELEASING AN AUDIT FINDING FROM AN AUDIT RESPONDER

An Audit Manager can release a document currently claimed for correction by an Audit Responder. To do so, follow the steps below.

1. **Navigate to the Quality Review module and use the dropdown menu above the index to select the correct audit and the 'Audit Findings' view. See the screenshot below:**



2. **Press 'Select'**
3. **The audit findings will display in the index panel organized by who currently has them claimed.**

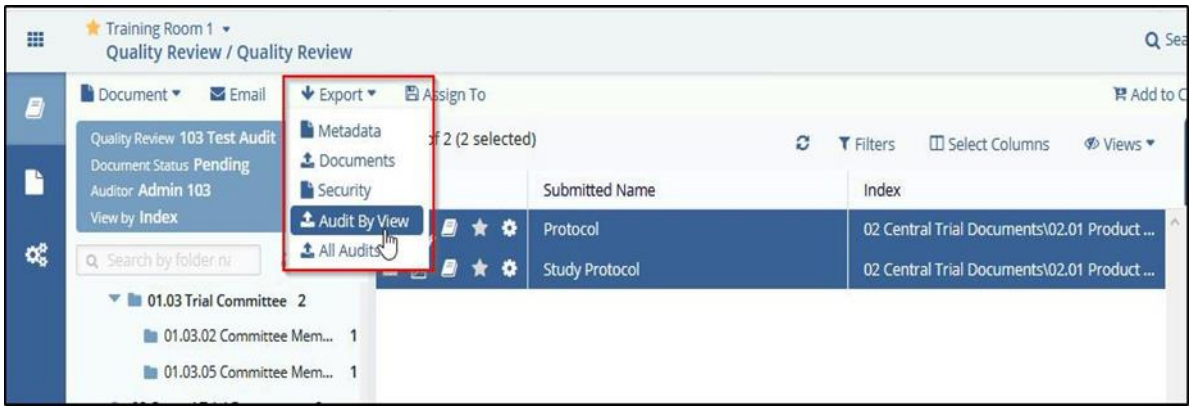
4. **Select the correct finding on the Grid.**
    a. **The metadata panel will populate.**
5. **Press the 'Release' button at the top of the metadata panel.**

EXPORTING AUDIT DATA

An Audit Manager can export a report related to the documents assigned to any particular audit.

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.**

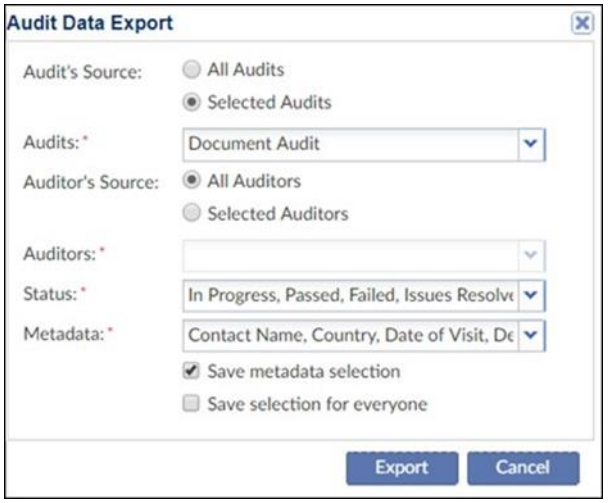
<u>Exporting Audit by View</u>

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.

Exporting Data from 'All Audits'

This option, contrary to how it sounds, just allows the user to select from all audits in the room. It is not an automatic export of all audit data in the room. Select All Audits from the dropdown menu. The Audit Data Export window opens.



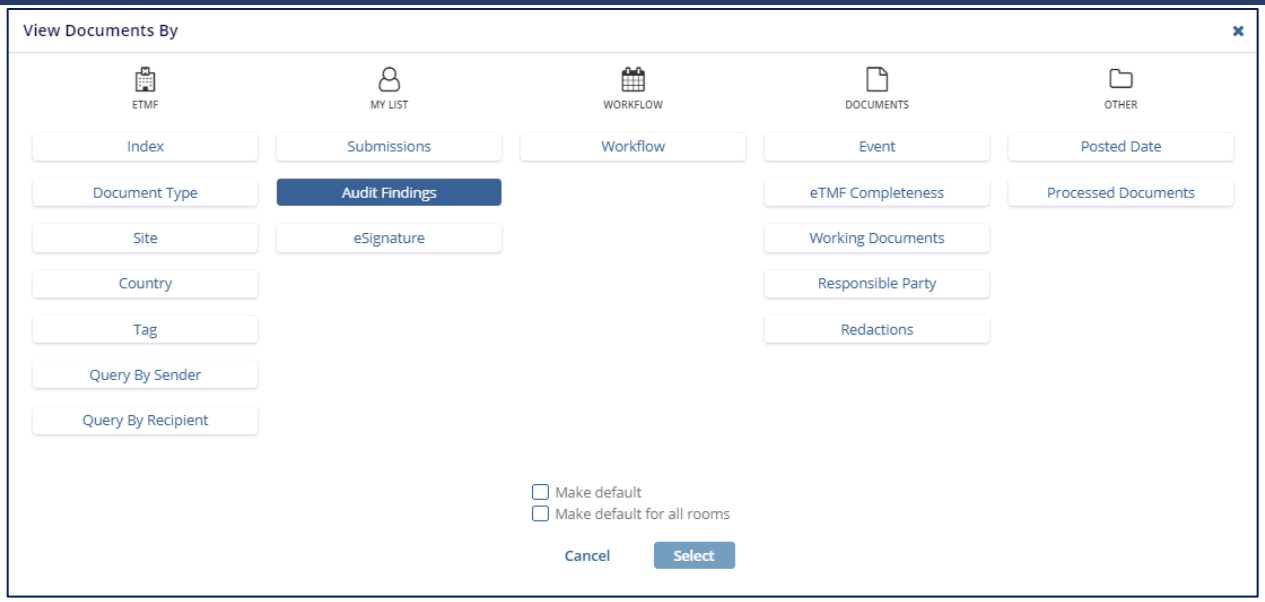
Follow the on-screen instructions to generate the audit report.

RESPONDING TO AUDIT FINDINGS

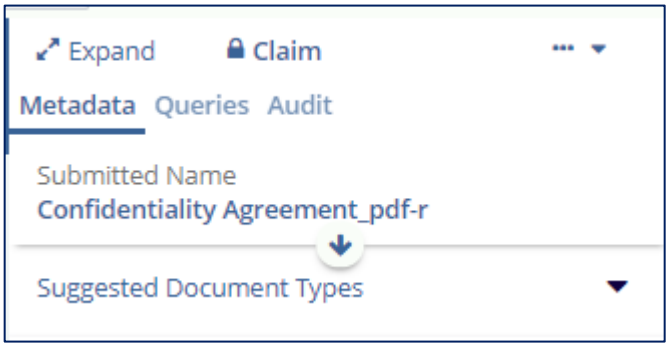
The Audit Responder is designated during the creation of the audit. There can be multiple audit responders for an audit.

In order to respond to audit findings, follow the steps below:

1. **Navigate to the Documents module.**
2. **Select the Audit Findings view from the dropdown at the top of the Index panel on the left.**

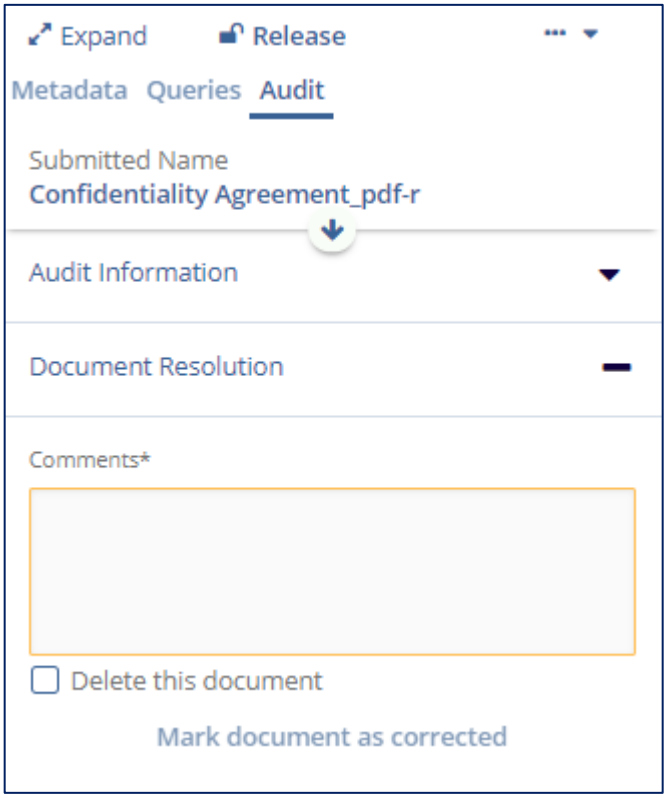


3. **The index panel will populate with audit findings organized by their respective audit.**
4. **Drill down to locate a audit finding.**
5. **Select the finding in the grid**
6. **Press the 'Claim' button at the top of the metadata panel.**



7. **If the audit finding has already been claimed by another user, you will not be able to claim the finding for review.**
8. **Select the Audit tab of the Metadata panel.**
9. **If necessary, expand the 'Audit Information' section to view the reviewer's comments indicating why the document was failed.**
    a. **The Audit Comments field can also be brought into the user's grid column layout. For more information, please see the section on customizing your grid view.**
10. **Make any necessary corrections based on the comments.**
    a. **This may require the user to initiate an audit query. For more information on this, please see the chapter on Queries.**
11. **Once all corrections have been made, return to the Audit tab of the metadata panel and expand the 'Document Resolution' section.**
12. **Make any comments necessary.**
13. **If the appropriate resolution requires that the document should be deleted, check the box under the comments**

field:



14. **Press 'Mark Document as Corrected'**

Chapter 15. Quality Control

This quality control section will be focused primarily on workflows in reference to eTMF rooms. However, the same processes are utilized in many TI Content Management room types as well. eTMF rooms tend to have a more standardized 1 or 2 step QC review workflow whereas Content Management rooms can have multiple workflows depending upon site, sponsor, or other SOP requirements.

Because of the potential issues that can be encountered when designing and implementing workflows, we recommend always working with the TI Support Desk with regard to workflows. Workflows are created and maintained in the Settings area of Trial Interactive. For additional information on this process, please see that section.

Performing eTMF Quality Control Functions

Editor, manager, and administrator level users can all perform Quality Control functions. Reader level users cannot perform these tasks.

In order to be a part of the quality control workflow, the user must be added to at least one of the QC related groups in the Users Management area. For more information on how to add users to a group, please see the related section of this guide. In Content Management rooms, a user's group is likely related to their job function and then that department or other group would be selected for inclusion in the approval workflow.

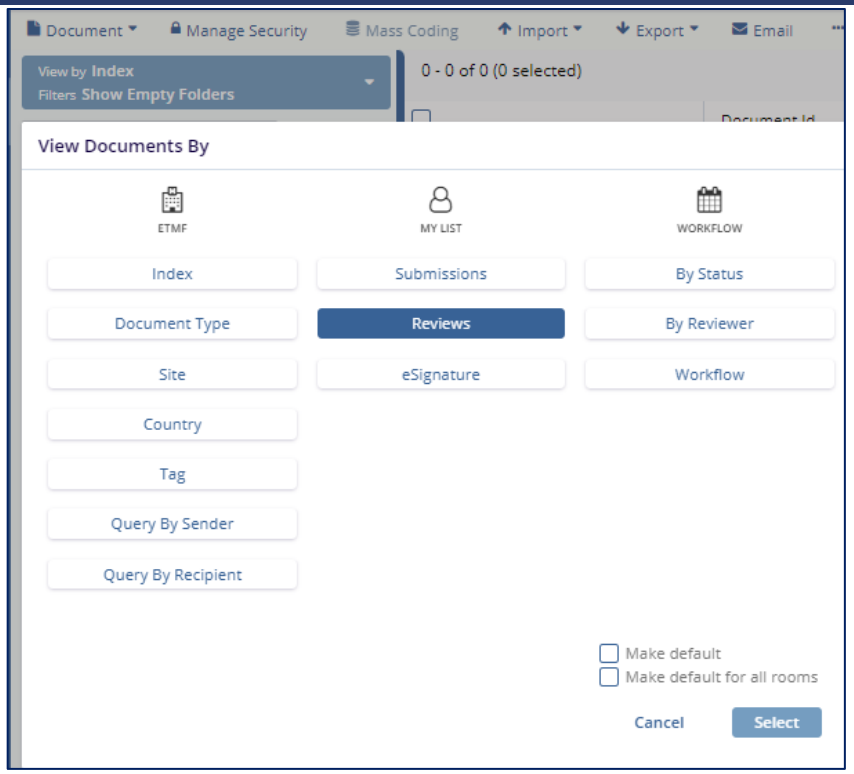
For more information on approving a document in a collaborate room, please see the section on versioning a controlled document.

CLAIMING A DOCUMENT FOR REVIEW

Once a user has been added to a QC workflow, the first step is to claim a document for review. The user must first claim the document because all newly added documents come into the workflow in a pool of documents normally referred to a 'Available for Review.'

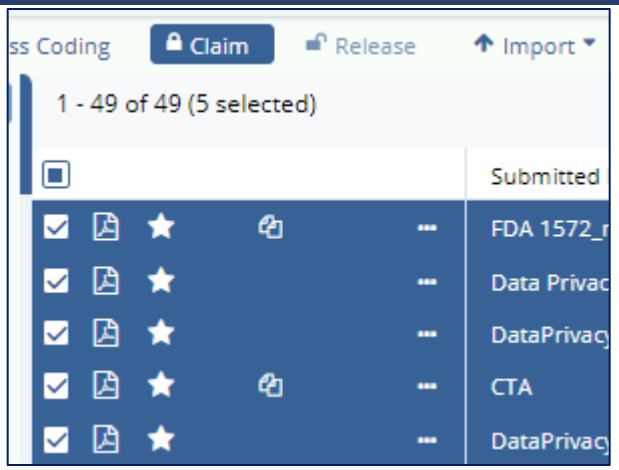
To claim a document for review, please follow these steps:

1. **Navigate to the Documents module.**
2. **Select the 'Reviews' view from the dropdown menu above the index pane.**
    a. **This view will only appear in the list if you have been added to the workflow.**



3. **When the screen loads, the index pane will load with all of the workflows in which the user is a participant. This will normally be just one workflow. Expand the workflow to see the status folders.**

4. **Select the 'Available for Review' folder.**
    a. **The documents grid will populate with a list of documents which could potentially be claimed by the user. The list of documents may not be the same for any two users depending upon what step of the workflow they are assigned to and whether or not they have already reviewed the document.**
        i. **Users who have reviewed a document in step 1 of a multi-step QC workflow will not be able to claim the document in any later step.**
5. **Check the boxes in front of the documents to be claimed. The user could claim one document at a time but selecting multiple documents is far more efficient.**
6. **Click the 'Claim' button above the documents grid.**

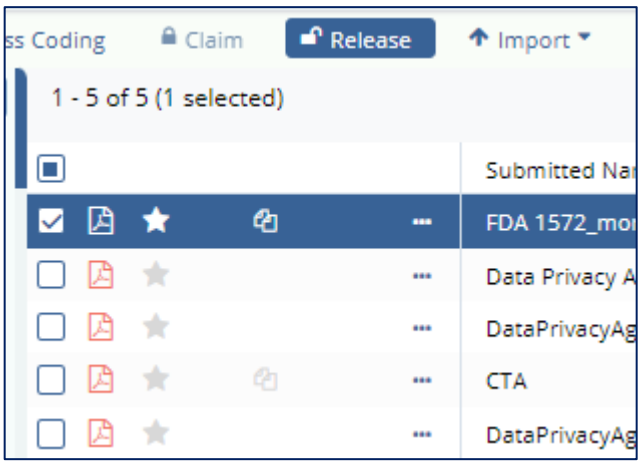


7. **Once the documents have been claimed, they are moved to the 'Claimed' folder and are no longer visible in the 'Available for Review' folder.**

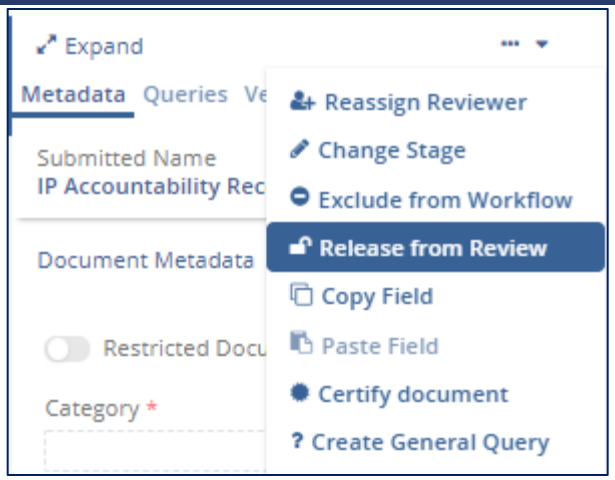
RELEASING A CLAIMED DOCUMENT

Sometimes a user will have claimed documents that need to be returned to the pool of 'Available for Review' documents so that someone else may claim them for review. Follow the steps below to release a document.

1. **Click on your 'Claimed' folder.**
    a. **All of the documents you currently have claimed will populate to the grid.**
2. **Check the box to indicate which documents should be released.**
3. **Press the 'Release' button above the grid.**



4. **Once released, the documents will be removed from your 'Claimed' folder and returned to the 'Available for Review' folder.**
5. **Alternately, this may be done by a room administrator using the three-dot menu at the top-right of the metadata pane.**

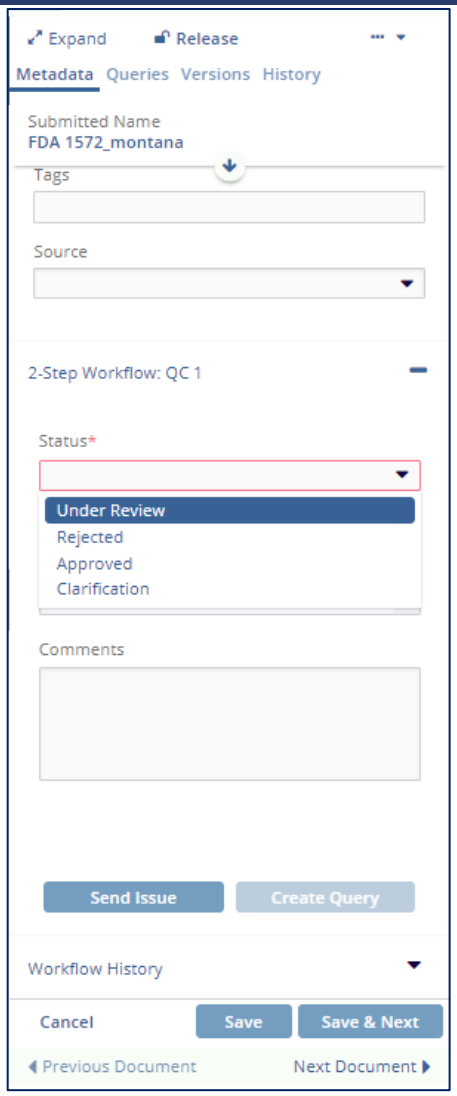


REVIEWING A DOCUMENT

Once a document has been claimed, the reviewer will need to check the document against established quality control guidelines, apply any necessary metadata, and indicate whether the document has been approved or has been rejected. QC reviewers also have the ability to launch a query in order to get assistance with reviewing a document. For more information regarding launching a QC Workflow Query, please see the chapter on Queries.

In order to review a document and assign a status to it, please follow the steps below:

1. **Locate the document in your 'Claimed' folder.**
    a. **If the document has not been claimed, please see the section on claiming a document for review.**
2. **Open the document and review it according to any established guidelines for the document type.**
3. **If the document is in good order and can be accepted, review the metadata associated with the document and make any corrections or fill in any required fields.**
4. **Beneath the metadata is a workflow status area. The section is named for the workflow you are working in as well as the step in the workflow that you are completing. Please see the screenshot below:**



5. **Assign the appropriate status to the document.**
    a. **Note: The available statuses are assigned when the workflow is created and may vary from those show above.**
    b. **Approved: This indicates that the document is correct and that it can either move on to the next step of the workflow or, if appropriate, be published as 'Final' to the room's index.**
    c. **Rejected: This indicates that the document has some feature which is incorrect and which will need to be rectified prior to the document being accepted into the room's index as 'Final.'**
        i. **If this value is selected, the user does not need to fill in all of the metadata first.**
        ii. **Also, if this value is selected, the user will be required to indicate a reason why the document was rejected. The list of available issues is created along with the workflow and so may not contain exactly what is needed. It is strongly recommended that you also provide a comment in the box below to clarify the reason for your rejection of the document.**
        iii. **Depending upon internal process requirements, the user may be asked to send the submitter a notification that their document has been rejected. For additional steps on how to do that, see the section below.**

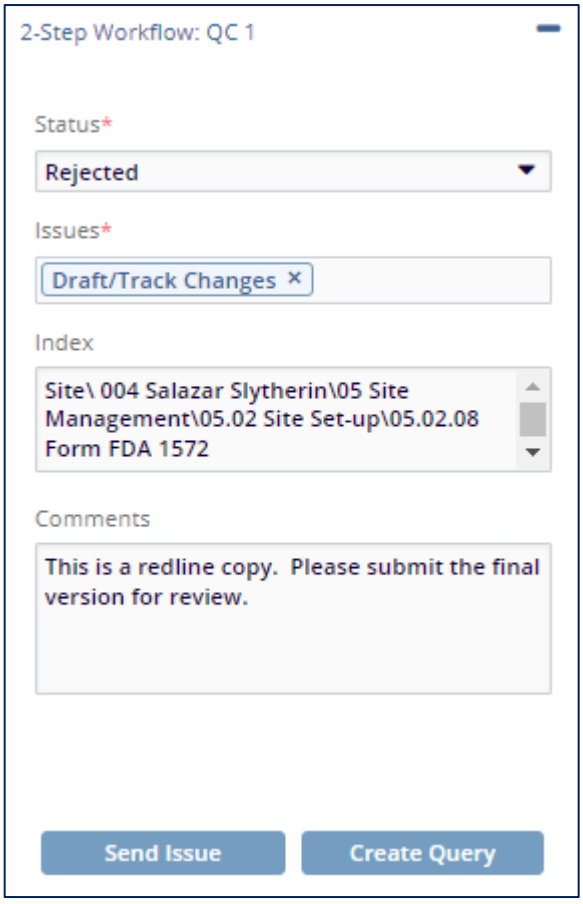
d. **Clarification: This indicates that the QC Workflow reviewer (you) has a question about a document.**
   i. **If this option is selected, the user will also need to indicate the reason for the inquiry (issue). The list of available issues is created along with the workflow and so may not contain exactly what is needed. It is strongly recommended that you also provide a comment in the box below to clarify the reason for your inquiry regarding the document.**
   ii. **The status indicates that the reviewer intends to launch a query. For more information regarding that process, please see the chapter on Queries.**

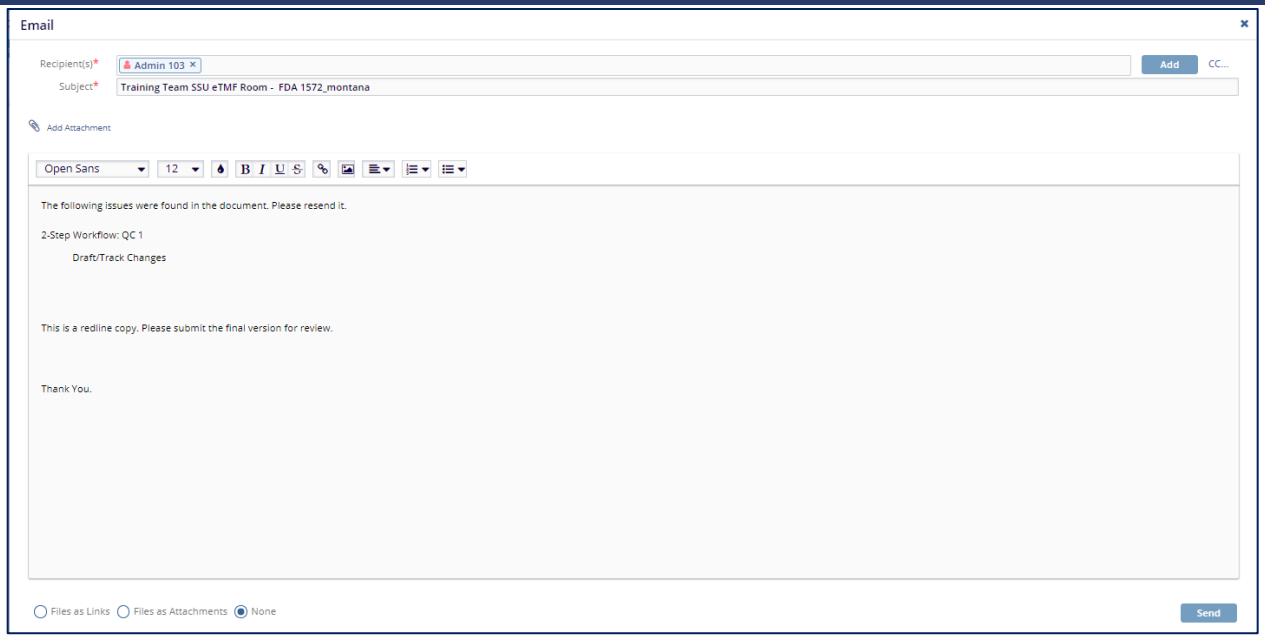
6. **Once the appropriate status has been assigned, press 'Save' or 'Save & Next.'**

SENDING A REJECTION NOTIFICATION

Depending upon the SOP requirements for your organization, you may be required to send a notification to the document submitter that their document was rejected. To do so, follow the steps below:

1. **Below the workflow comments box are two buttons 'Send Issue' and 'Create Query.' Once the status has been assigned and the issues have been noted in the comments, press the 'Send Issue' button.**
   a. **An email window will open.**



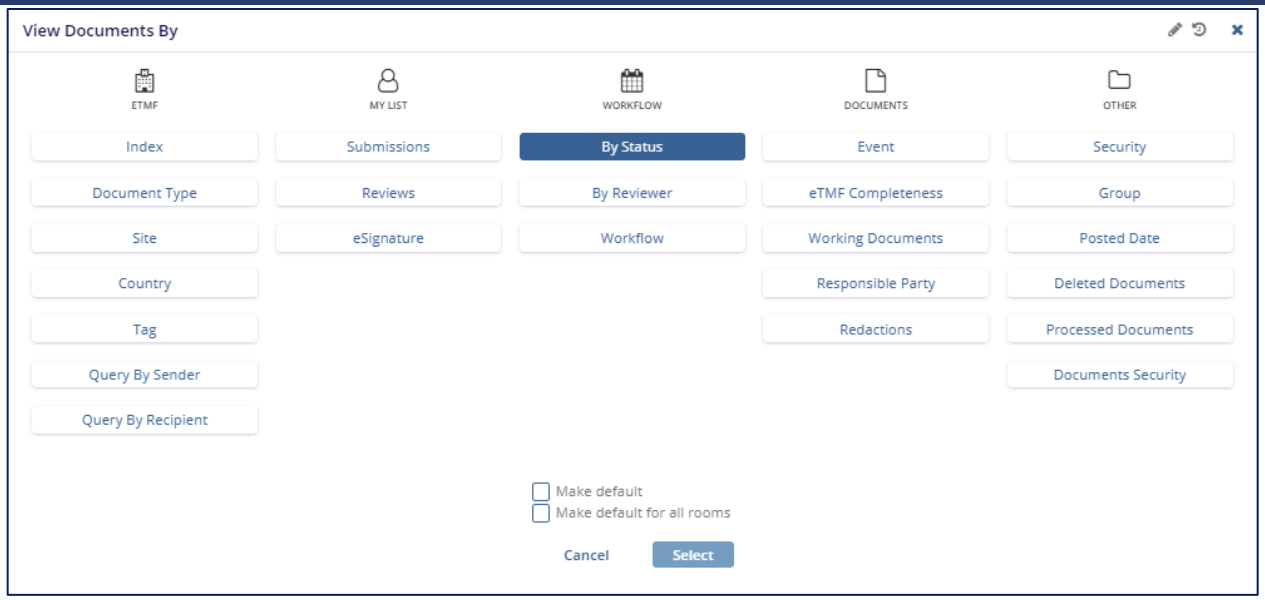


2. **The submitter of the document is populated by default in the Recipients area. Add any additional recipients as appropriate.**
3. **The text that populates comes from both a standard email template and from any comments/issues indicated. Make any necessary additions or changes to the displayed text.**
4. **Indicate, using the radio buttons at the lower-left whether or not the document should be supplied to the recipient and, if so, in what manner.**
5. **Press 'Save'**

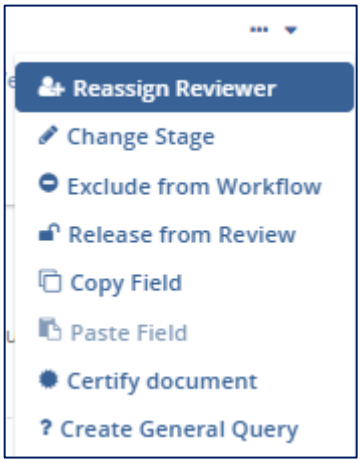
REASSIGNING A REVIEWER

Occasionally, a room administrator may need to reassign a document's reviewer. In order to do that, follow the steps below:

1. **Navigate to the Documents module.**
2. **Select the 'By Status' view from the dropdown menu above the index pane.**



3. **Select the 'Claimed' folder from the index pane.**
4. **Locate the document which needs to be reassigned.**
    a. **If necessary, expand the metadata pane.**
5. **Click the three-dot dropdown menu at the top-right of the metadata pane.**



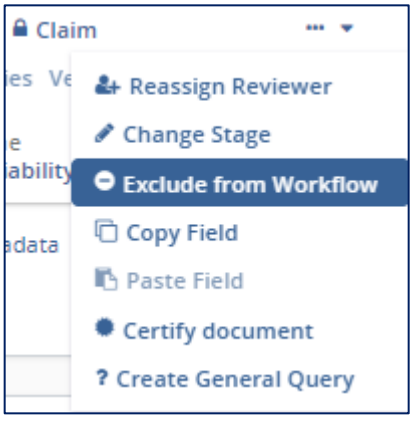
6. **Click 'Reassign Reviewer'**
    a. **The Reassign Reviewer window will open.**

7. **Choose the appropriate reviewer and press 'Change Reviewer'**
8. **A popup will display asking if you are sure. Press 'Yes' if appropriate.**

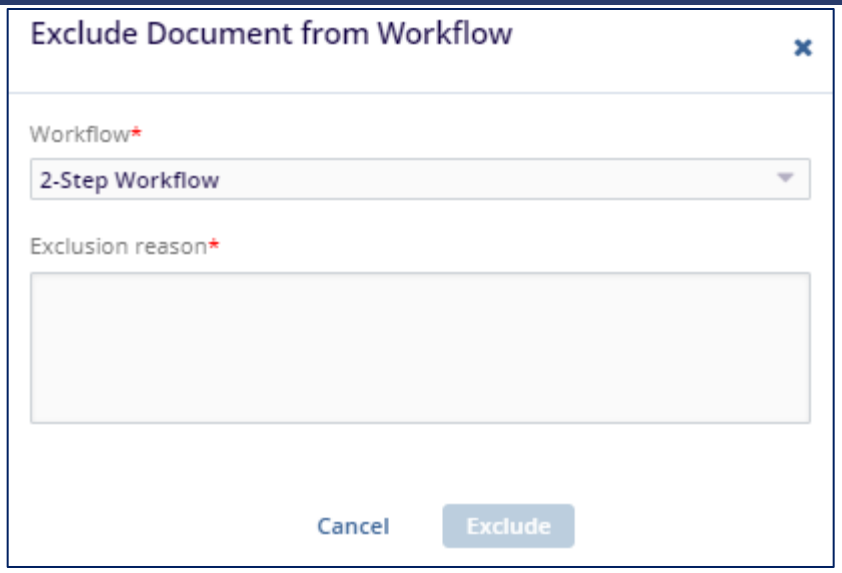
EXCLUDING A DOCUMENT FROM THE WORKFLOW

Documents can be manually excluded from the workflow if necessary. To do so, follow the steps below:

1. **Locate the document.**
2. **Select the document in the grid.**
    a. **If necessary, expand the metadata pane.**
3. **Using the three-dot menu at the top of the metadata pane, choose 'Exclude from Workflow.'**
    a. **This will cause the Exclude Document from Workflow window to open.**



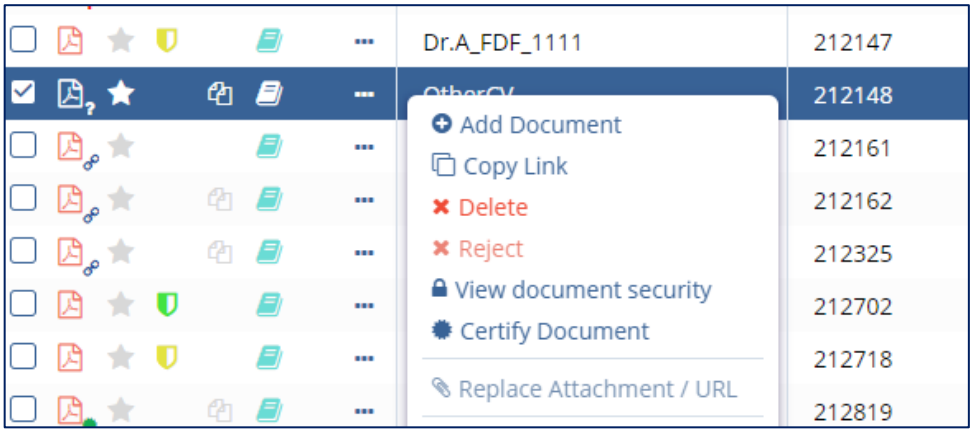
4. **Indicate a reason for the exclusion.**



5. **Press 'Exclude'**

THE 'REJECTED' FOLDER

- **There is a setting available to support a Rejected folder within the eTMF for Room Administrators, and a new Document Rejection function is now available to Admins, Document Managers, and Room Managers. Any documents in Upload, Inbox, Staging, and Rejected Folders are not considered to be Final. This setting makes a 'Reason for Rejection' dropdown available for workflow documents and documents in the rejected folder/status would then be excluded from eTMF health calculations.**
- **<u>NOTE:</u> Users will not be able to drag and drop documents into this folder in order to prevent awarding an erroneous status should a non-rejected document be placed in this folder.**

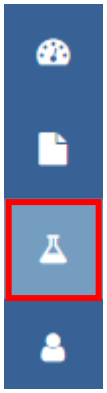


In order to reject a document outside of the standard workflow steps, the user must either be an administrator or they must have the Document Manager action enabled on their user account. For users who meet these requirements, rejecting a document can be accomplished by right-clicking on the document or by clicking on the three-dot menu in the grid and selecting the 'Reject' option from the document actions menu.

Chapter 16. Sites, Required Documents, Countries and Contacts

Sites

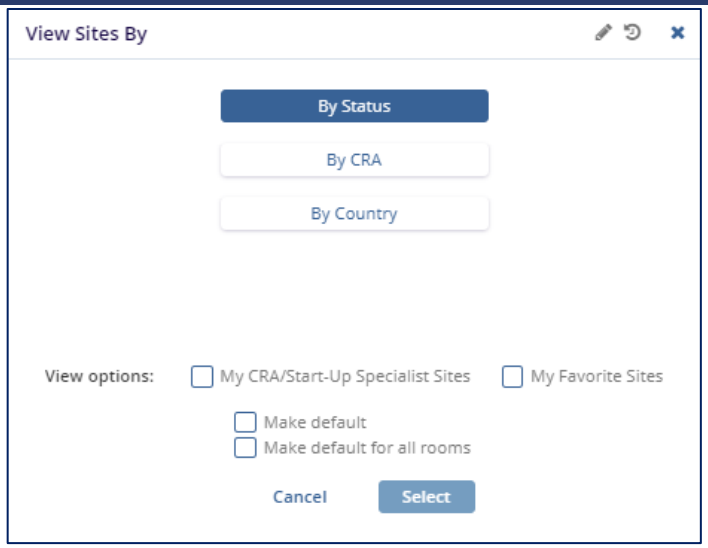
You can access the Sites module by clicking Sites icon on the left menu bar in the eTMF/ Documents module. In order for users to access the sites module, they will need to be added to the Sites Team group in Users Management. Please note that the name of this group may vary based on your instance but this is a system group.



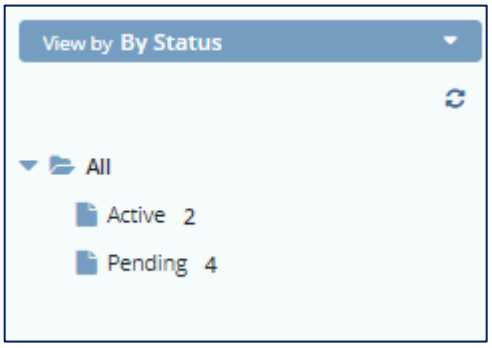
The Sites module is used for site management purposes and allows users to track the progress of the sites. It gives detailed information on all investigation sites available in a room By Status, By CRA, By Country.

SITE VIEWS

Once you click on the Sites module, all of the sites in the room will load up and will appear organized by one of three factors: By Status, By CRS, or By Country. As with the Documents module, you can set your default options for this room or for all rooms to which you have access. You can also choose to apply filters which will display only the sites which are your favorites or to which you have been assigned as a CRA.



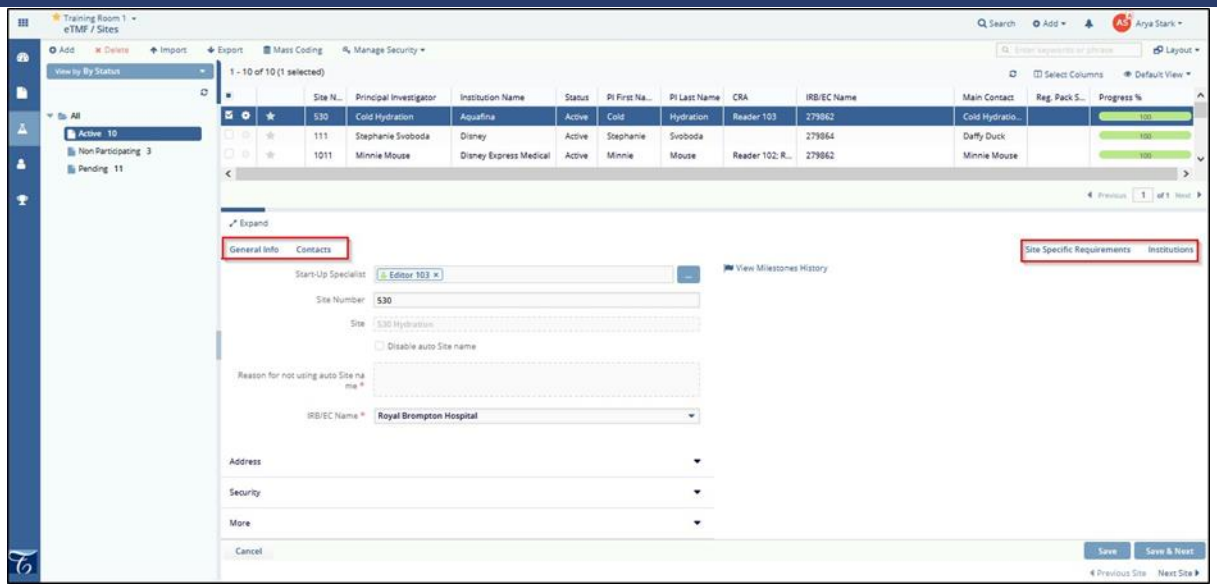
When you have chosen your view, the sites will be displayed in a related folder structure in the index pane on the left side of the screen.



SITE PROFILE

Select a site from the grid and the Site Profile is displayed at the bottom of the grid. If the site profile area is not visible, click 'Open' at the bottom of the screen. This will allow you to view and manage all metadata related to the selected sites.

Refer to the screenshot below:



The Site Profile window provides the following:

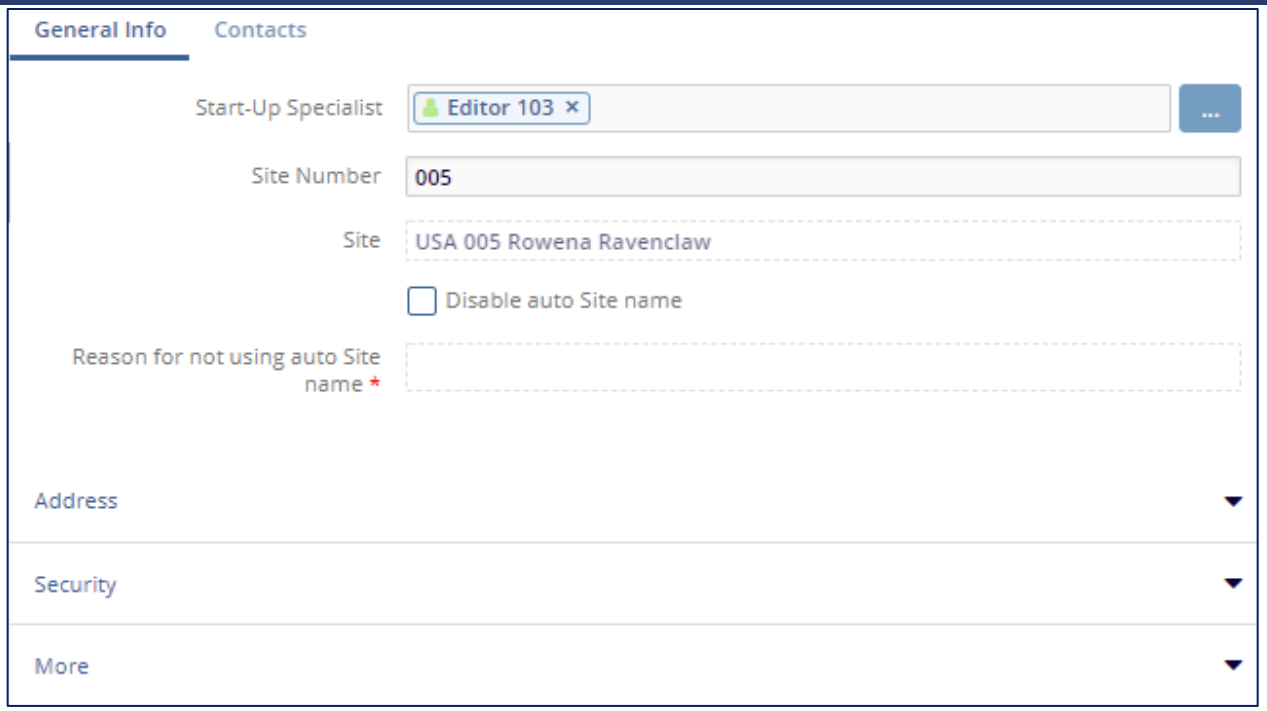
- **General Info tab**
- **Contacts tab**
- **Specific Requirements tab**
- **Institutions**

Each of the tabs is discussed in the separate topics.

<u>Site Profile - General Info</u>

This tab displays the general information for the site.

After selecting a site, click the General Info tab to edit the general details of the site. The sections (Info, Address, Security, and More) are collapsed initially. Click the arrow to expand the section and edit related information. Refer to the screenshot below:

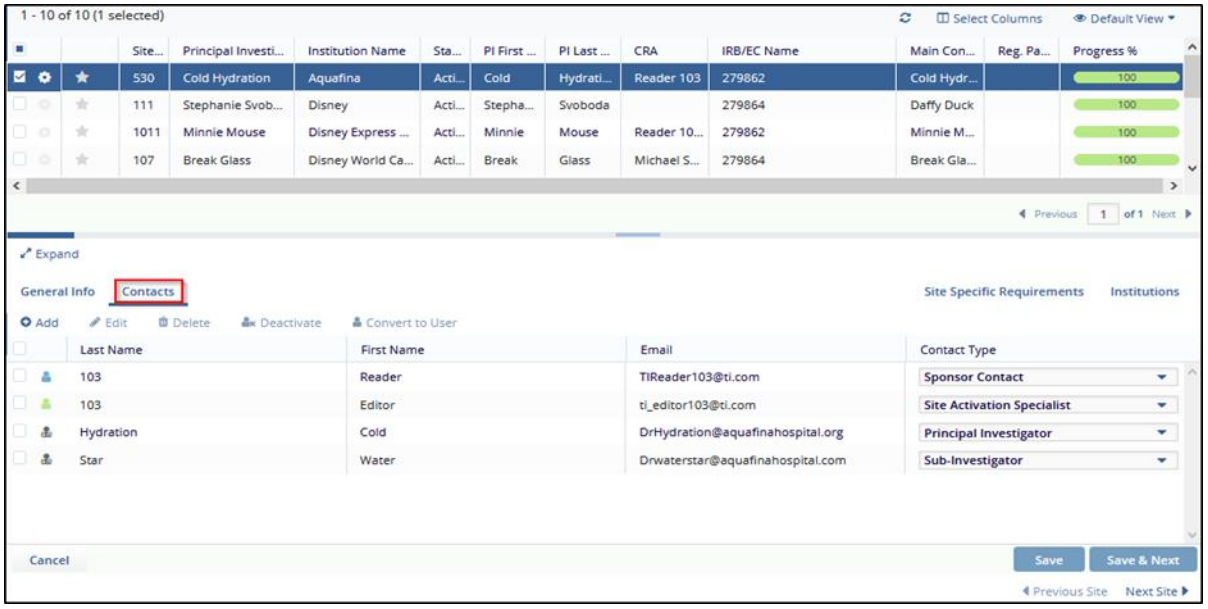


When you click the arrow, the section fields get enabled and the arrow turns to - sign as shown in the screenshot below. Similarly, you can update the fields in the other sections of your choice.

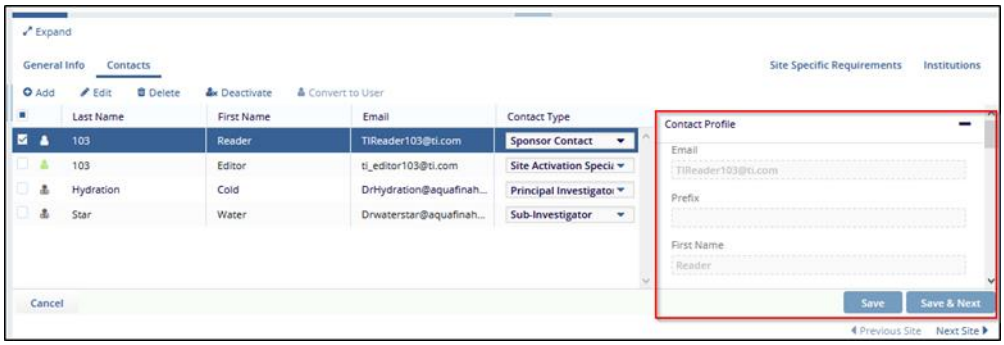
- **<u>Note</u>: Only room administrators can access the Security area of the site profile.**

<u>Site Profile - Contacts</u>

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:

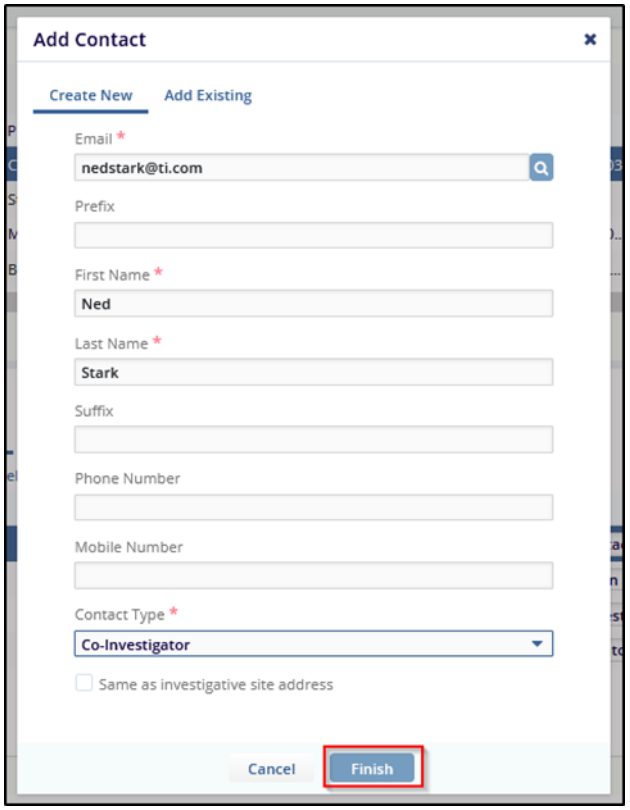


Double click the user to open the Contact Profile to the right of the contacts tab. This allows you to edit the contact details of the user. Once all the details are updated, click Save to save the changes. Refer to the screenshot below:



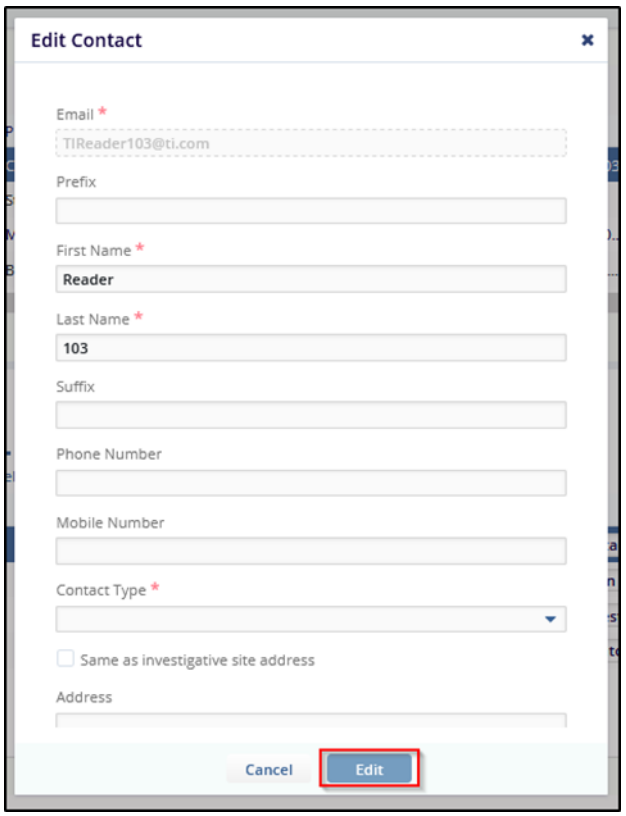
Adding a Contact

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's information.

Deactivating a Contact

Select an added contact and click Deactivate in the Contacts tab to deactivate the contact.

Convert to User(s)

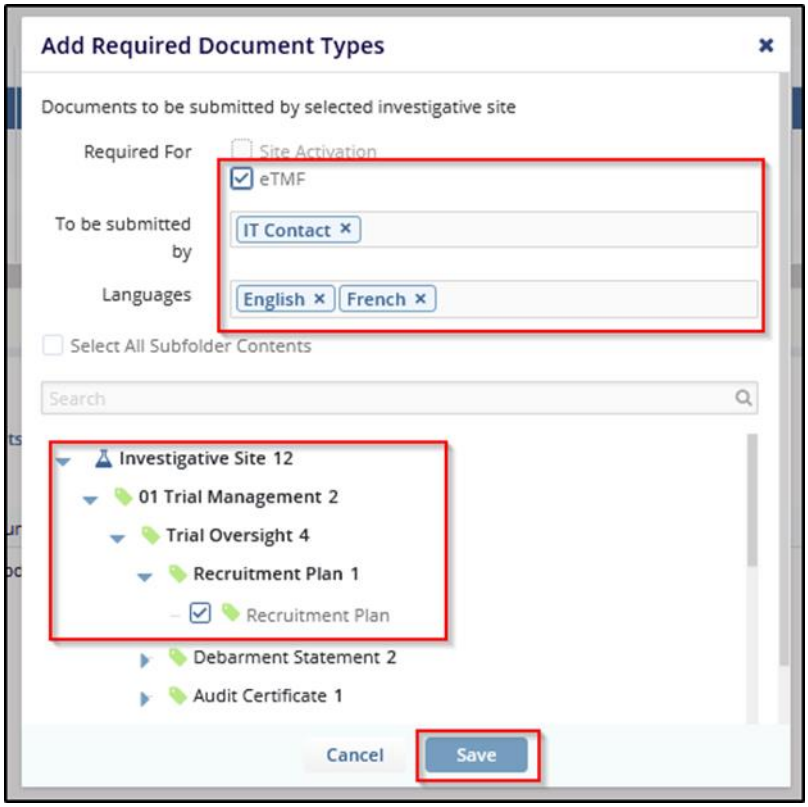
You can assign a site contact the role of editor or reader and assign actions as appropriate from the Convert to User(s) utility in the Contacts tab.

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.

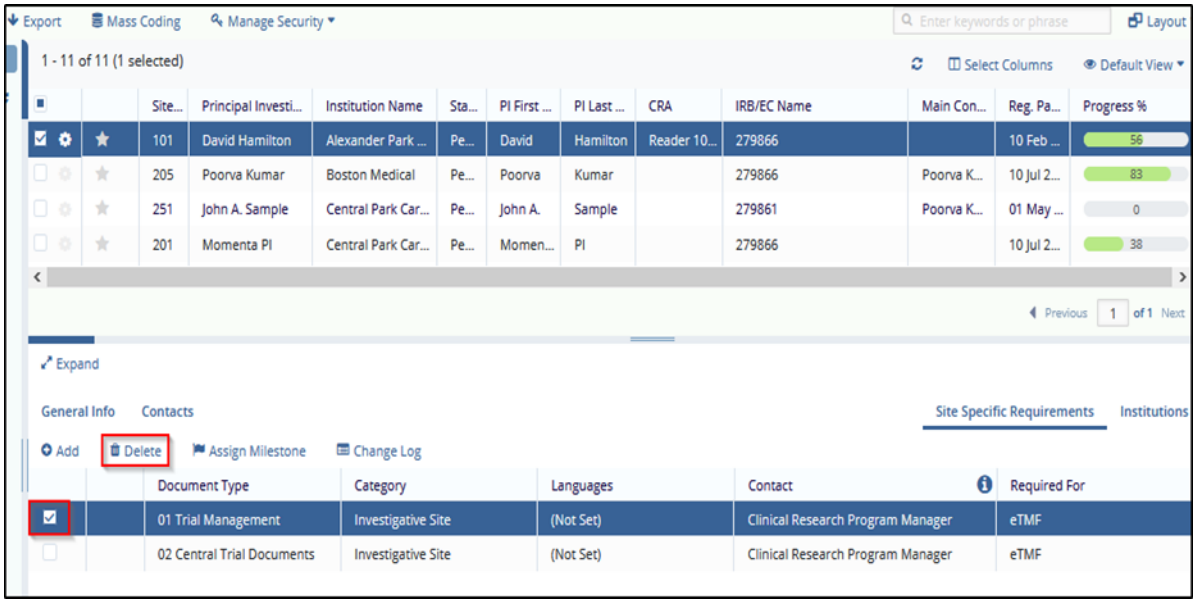
Adding Required Documents

To add required documents to a site click the 'Add' button. That opens the Add Required Document Types popup. Fill in 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

Deleting a site-specific requirement can be done for 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.

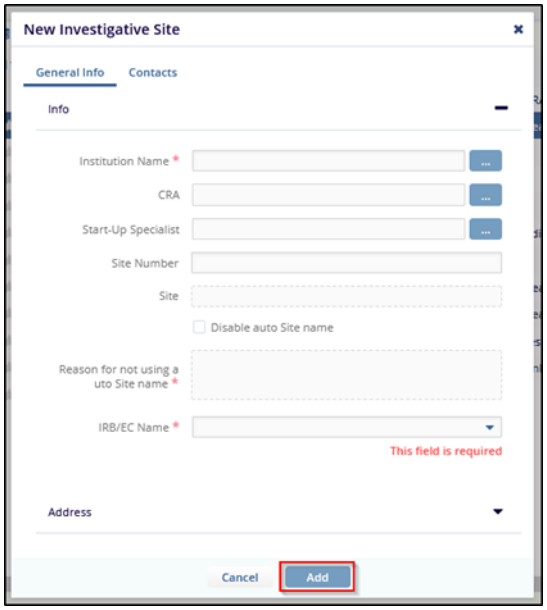


ADDING, EDITING AND DELETING SITES

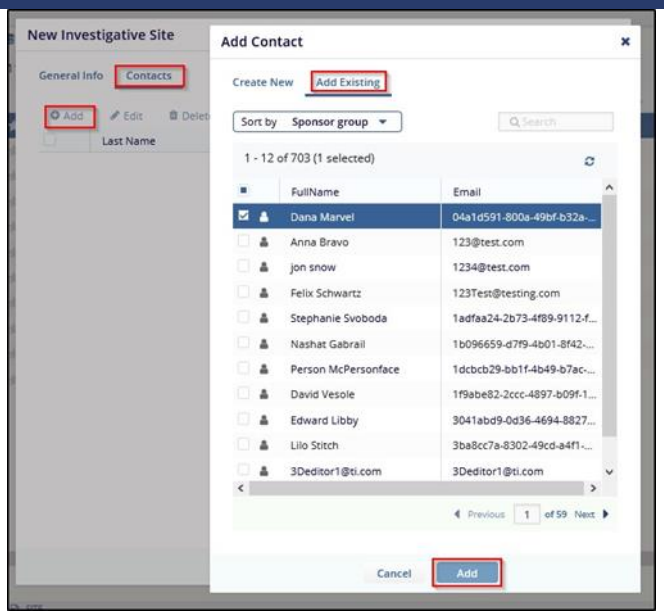
- **<u>Important</u>: The following description is for adding Investigative Sites in an eTMF:**

<u>Adding a Site</u>

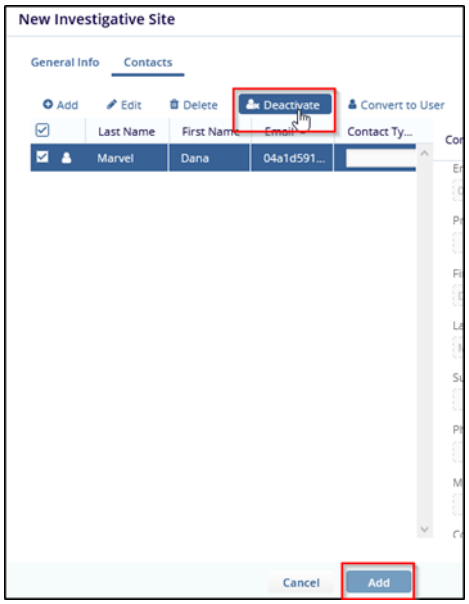
1. **Click the Add button from the top ribbon bar. The New Investigative Site window opens. Refer to the screenshot below:**



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.**
    a. **If you have 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.**
    a. **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:**



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 Contacts panel.**
7. **Click 'Address' to reveal the fields to enter the site location details.**
8. **Click 'More' to open another array of data fields. Enter the investigative site information.**
9. **Click 'Create' at the bottom of the window.**

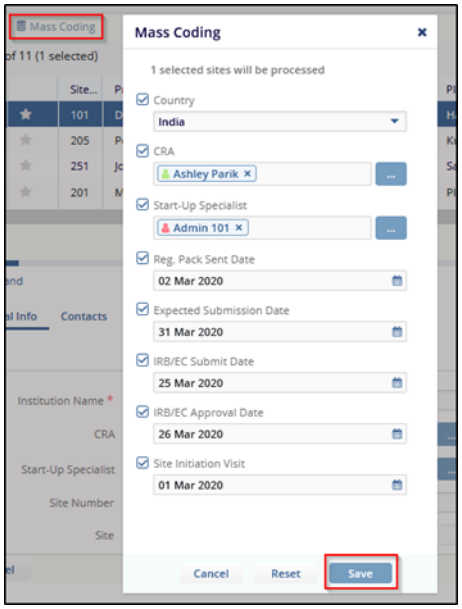
Editing a Site

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. This is discussed in the section regarding the Site Profile.

Mass Coding for Sites

Users are sometimes called upon to fill in or update information of a number of sites in a room at the same time. When these 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 will open.**
3. **Fill in the details by double-clicking the fields.**
4. **Click Save to proceed with mass update of the sites' information. You can select multiple CRAs and Start-Up Specialists if required. Refer to the screenshot below.**



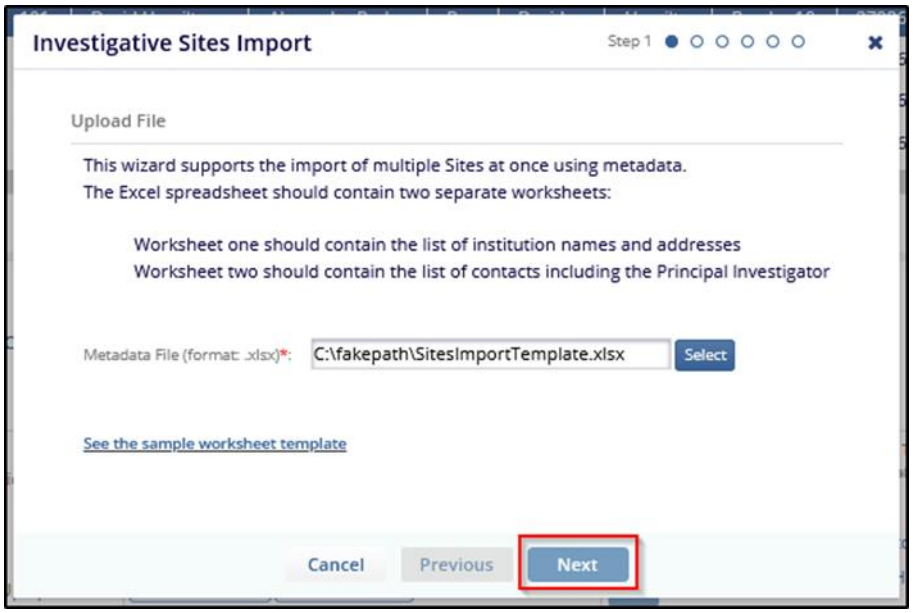
Deleting a Site

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. There is also a link to download the sample worksheet template.

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:**

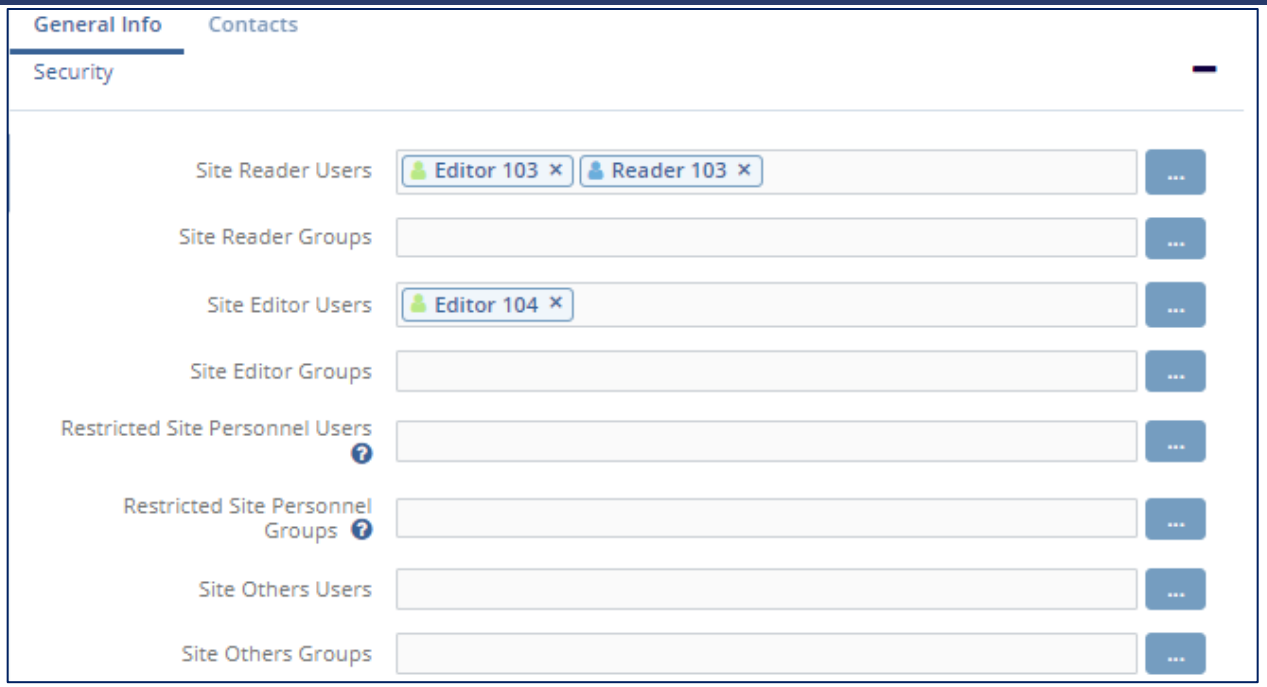


2. **Setup the mapping between metadata fields and uploaded file columns for Investigative Sites.**
3. **Setup the Contacts related metadata. Click Next.**
4. **Review the entries made and, when ready, click Next to confirm.**
5. **This will begin the actual import process. Upon completion, the user will get a short report on any issues that 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.**

MANAGING SECURITY FOR SITES

As mentioned in the Site Profile section, in each site profile are security groups for users. eISF rooms take especial care about who gets added to each group and, for the most part, we recommend working with the TI Service Desk to set up individual site security for those rooms. In addition to site-profile-level security, there are site-folder security setting which are discussed in the chapter on settings. These are normally set up during room configuration and specify which users or groups of users have access (and what kind of access) to each of the site folders.

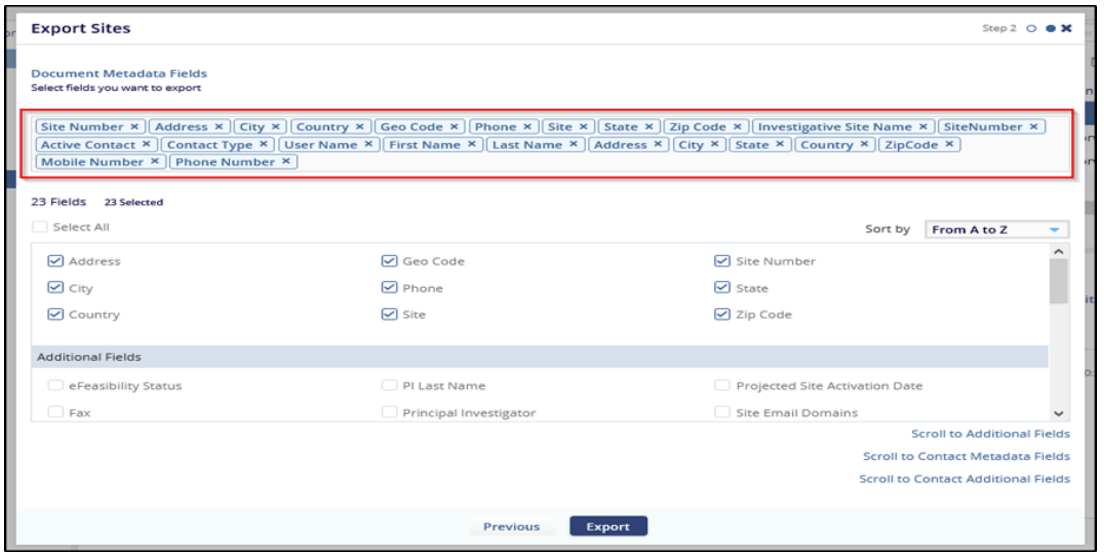
If you do choose to manually add and remove users via the site profile, you will want to expand the security section as shown below (Administrators only):



Clicking in the field or on the three-dot icon will allow you to add new members or groups to the security groups listed. Reader groups are those who can only view site related information whereas Editor groups are allowed to make changes to the fields to which they have access.

EXPORTING SITE INFORMATION

You can also export site metadata by clicking the 'Export' button on the ribbon. Select the Site Metadata Fields to be exported as shown below:



Contacts

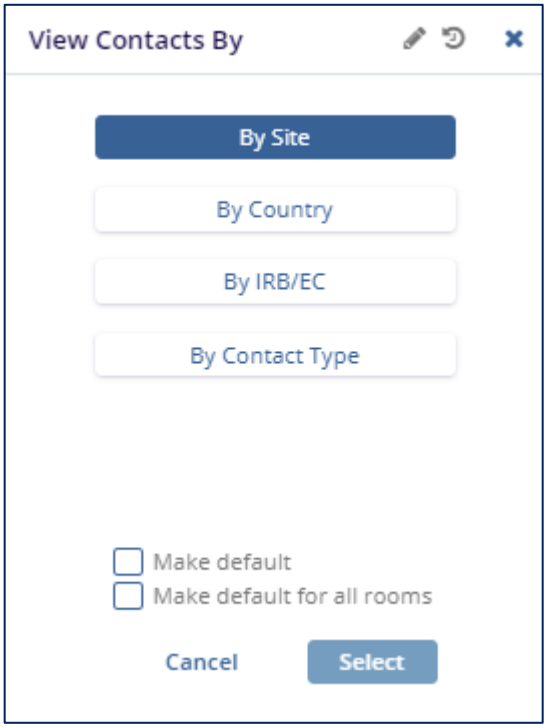
A clinical trial includes a varied range of people with different profiles, who are a part of the study. Trial Interactive helps to maintain the detailed profile of these people as Contacts for a study. Some examples of contacts could be the Principal Investigator, Sponsor, Sub-Investigator, regulatory authorities, and 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:

- **View Contacts**
- **Mass Coding for Contacts**
- **Convert Contacts to Users**

VIEW CONTACTS



By Site

Selecting 'By Site' from the dropdown in the Index Pane on the left of the Contacts Module will reveal all the contacts in the room sorted by the site to which they are associated. Clicking a site in the index pane will populate the grid with the contacts associated with that site.

By Country

Selecting 'By Country' from the dropdown in the Index Pane of the Contacts Dashboard will list all the contacts in the room sorted by the country to which they are associated.

By IRB/EC

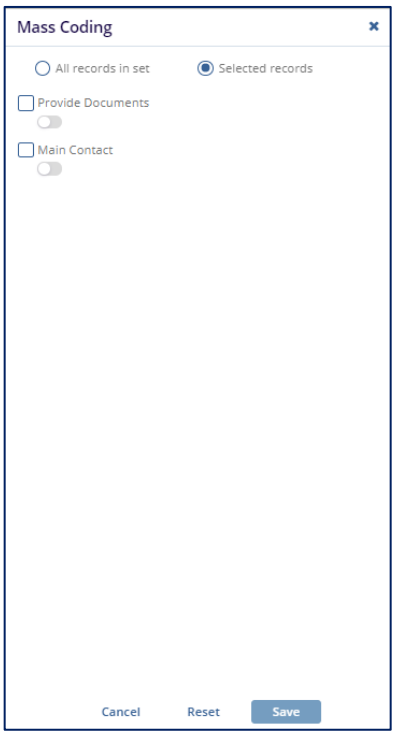
Selecting 'By IRB/EC' from the dropdown in the Index Pane of the Contacts Dashboard will list all the contacts in the room sorted by the IRB/EC to which they are associated.

By Contact Type

Selecting 'Contact Type' from the dropdown in the Index Pane of the Contacts Dashboard will list all the contacts in the room sorted by their contact type.

MASS CODING FOR CONTACTS

1. **Click the Mass Coding tool from the top ribbon bar. The Contacts Mass Coding**
2. **window opens. Refer to the screenshot below:**

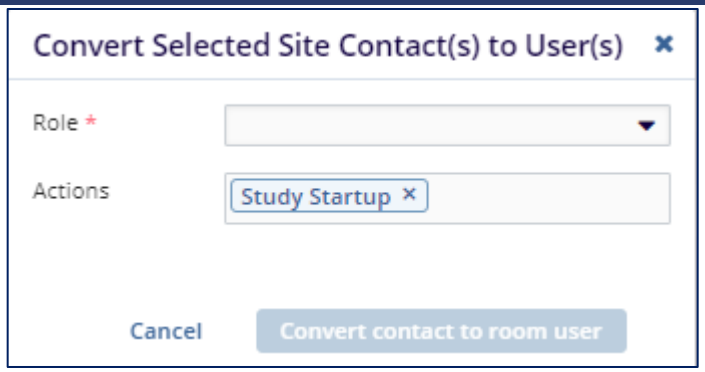


3. **You can choose to mass code for all the records in the grid, or a selected set of records.**
4. **Indicate whether the users will be required to provide documents and whether or not they should be marked as main contacts for their sites.**
5. **Click Save.**

CONVERTING CONTACTS TO USERS

As an administrator, you might want to give Editor or Reader access to one or more contacts for a site. This can be achieved proceed by the following steps:

1. **Click the 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 user's access role.**
4. **Select any appropriate actions the from the Actions field as required.**
    a. **Click in the Actions field to display the list.**
5. **Click Convert to user(s) button in the window.**

Chapter 17. eSigning Documents

Electronic signatures may be applied in all TI room types. However, we normally would expect this to be done prior to a document being submitted to the eTMF. Trial Interactive has a native electronic signature called TI Sign but your Trial Interactive rooms can also be configured to work with other electronic signature software. Additional information on the electronic signature settings is available in the chapter on Settings.

Any user who should be able to send a document for signature or sign a document should have the eSignature action assigned to their user profile. For additional information regarding adding actions to user accounts, please see the section on User Management.

Initiating the eSignature Process

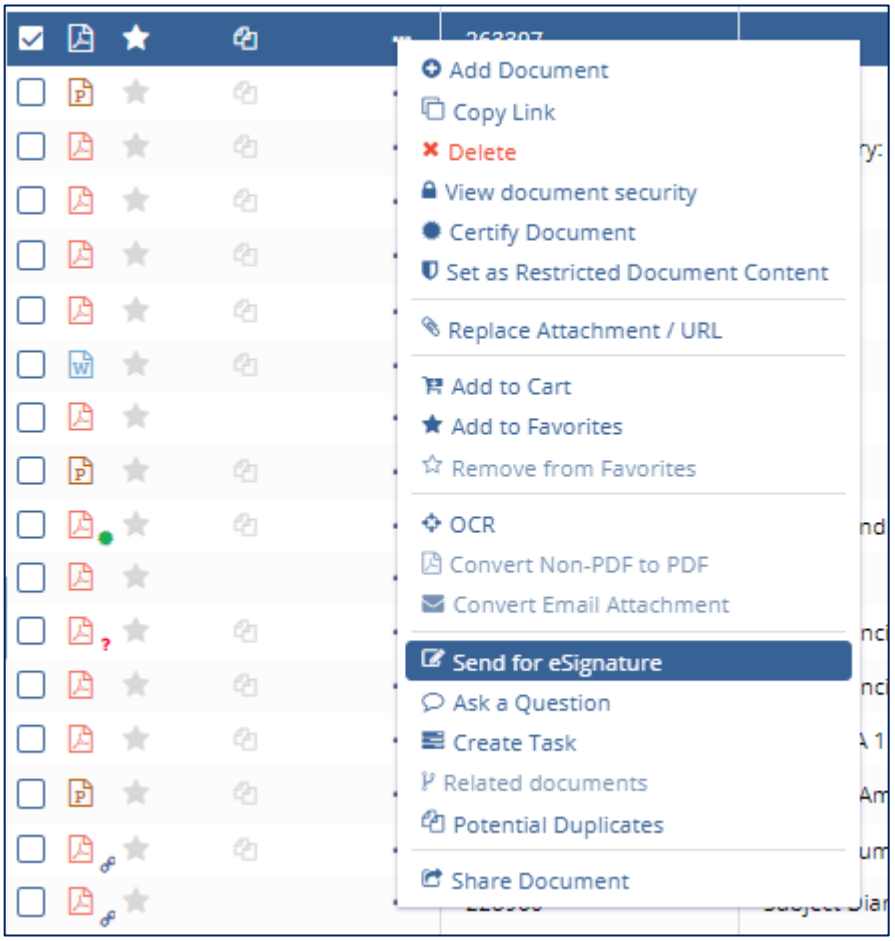
Depending upon which vendor is selected (see the eSignature settings section for additional details), this process can vary. For signature vendors other than TI Sign, a popup window will open, allowing the user to finalize the signature request from within the vendor's system.

In order to send a document for signature, please follow these steps:

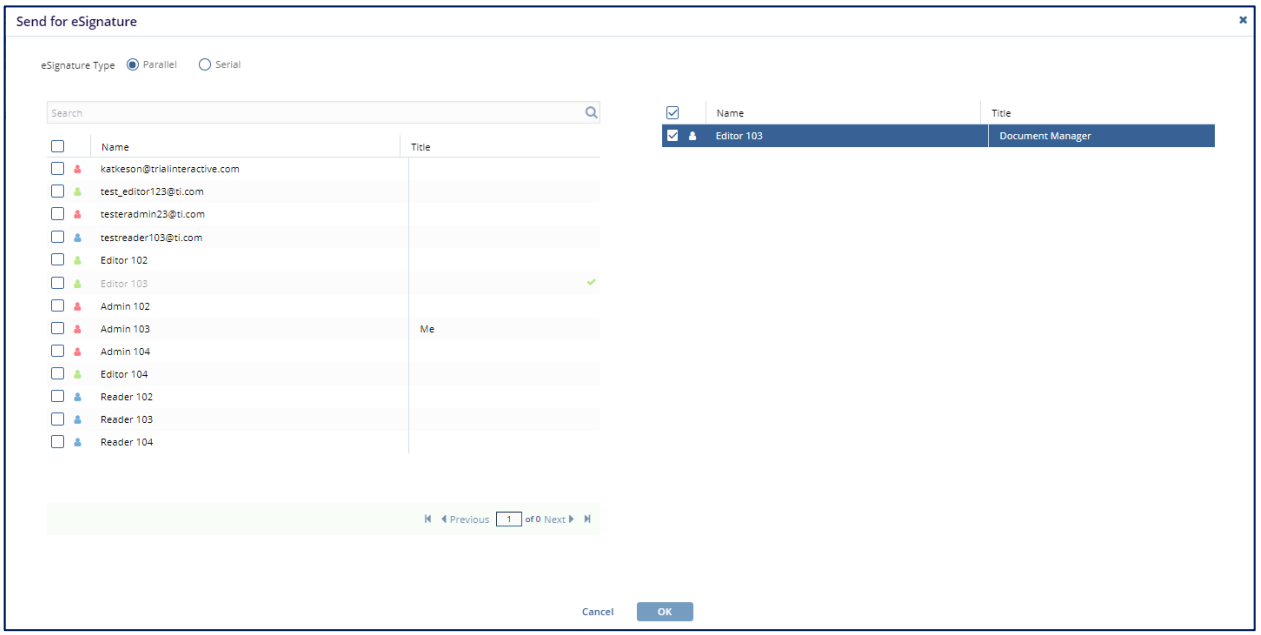
1. **Locate the document in the Documents module/Documents library**
2. **Open the Document Activities menu by right-clicking on the document or by clicking on the three-dot icon on**

the document line in the grid.

3. **Select the 'Send for eSignature' option.**
    a. **This will open the 'Send for eSignature' window.**



4. **Choose the user or users who will need to sign the document by moving them from the left side to the right side.**



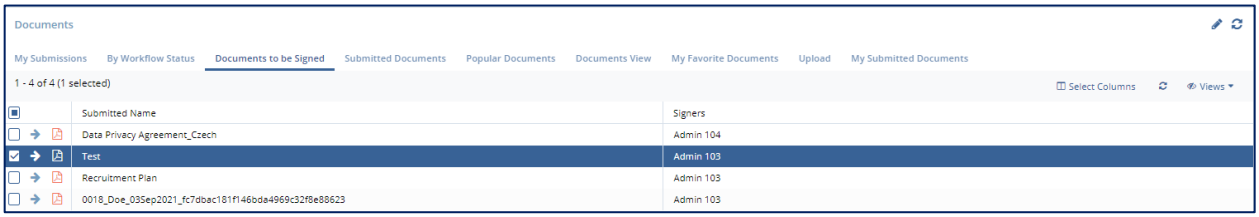
5. **Using the radio buttons at the top-left, indicate whether the signatories (assuming that there is more than one signature required) should sign in parallel or if they need to be completed one at a time.**
6. **Press 'OK'**
    a. **From this point on, the steps will vary depending upon which signature vendor your study room is using. For all but TI Sign, the system interface will open and the user can complete the process using the assigned vendor.**
        i. **See the steps below for signing documents with TI Sign.**

SIGNING A DOCUMENT WITH TI SIGN

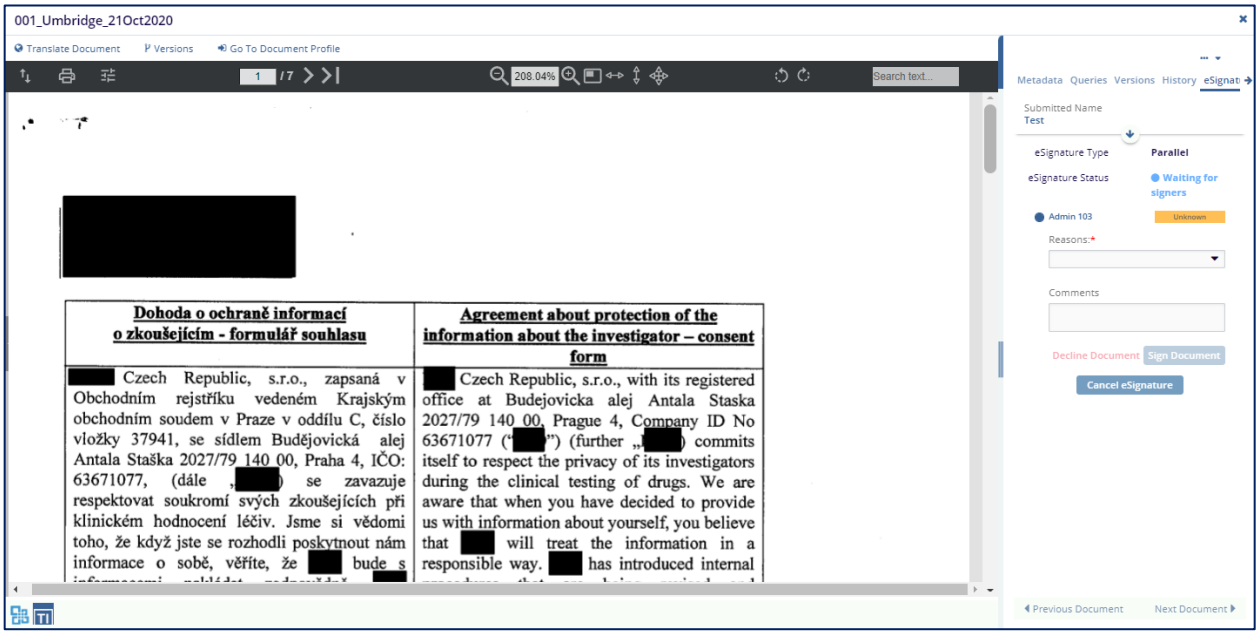
A user who has been assigned a document to review and sign can do so either via the related dashlet or directly from the Documents module.

<u>Signing a document via the 'Documents to be Signed' dashlet</u>

1. **Navigate to the Dashboard and locate the 'Documents to be Signed' dashlet**



2. **Double-click on the document to be signed.**
    a. **This will open the document and the eSignature tab of the metadata panel in a popup window.**

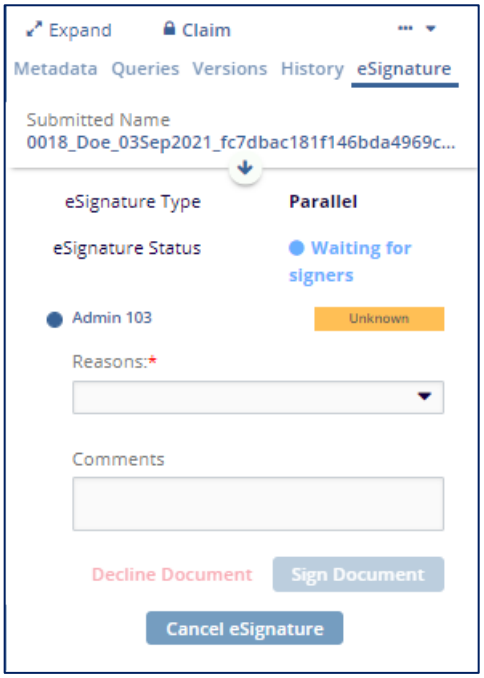


3. **Indicate your reason (either for signing or for rejecting the document) using the dropdown menu.**
    a. **The reasons are populated from the Settings area and are usually set up during room configuration. Please see the chapter on Settings for additional information.**

4. **Make any necessary comments.**
5. **Press the button for the appropriate action (Signing or Declining).**
6. **Use your Username and Password to verify your identity and complete the signature process.**

Signing a document via the Documents module

1. **Navigate to the document in the Documents module.**
2. **Select the document to be signed.**
    a. **This will cause the document's metadata panel to populate. If necessary, expand the metadata panel.**
3. **Select the eSignature tab of the metadata panel.**



4. **Indicate your reason (either for signing or for rejecting the document) using the dropdown menu.**
    a. **The reasons are populated from the Settings area and are usually set up during room configuration. Please see the chapter on Settings for additional information.**
5. **Make any necessary comments.**
6. **Press the button for the appropriate action (Signing or Declining).**
7. **Use your Username and Password to verify your identity and complete the signature process.**

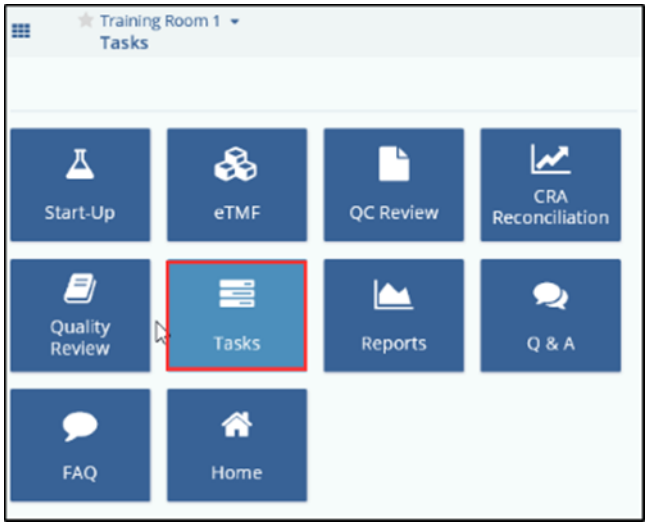
Chapter 18. Tasks

This section explains the tasks application that allow users to manage their tasks for their rooms.

Users are given an option to add, edit, delete, or export tasks. Additionally, users with appropriate actions on user profile 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 set up the reminders from the Reminder section of the metadata panel of a task.

You can access Tasks as mentioned below:

1. **Enter the room for which you want to create tasks**
2. **Click the Navigation Grid**
3. **Click the Tasks icon.**
4. **You are taken to the Tasks page. Refer to the screenshot below:**

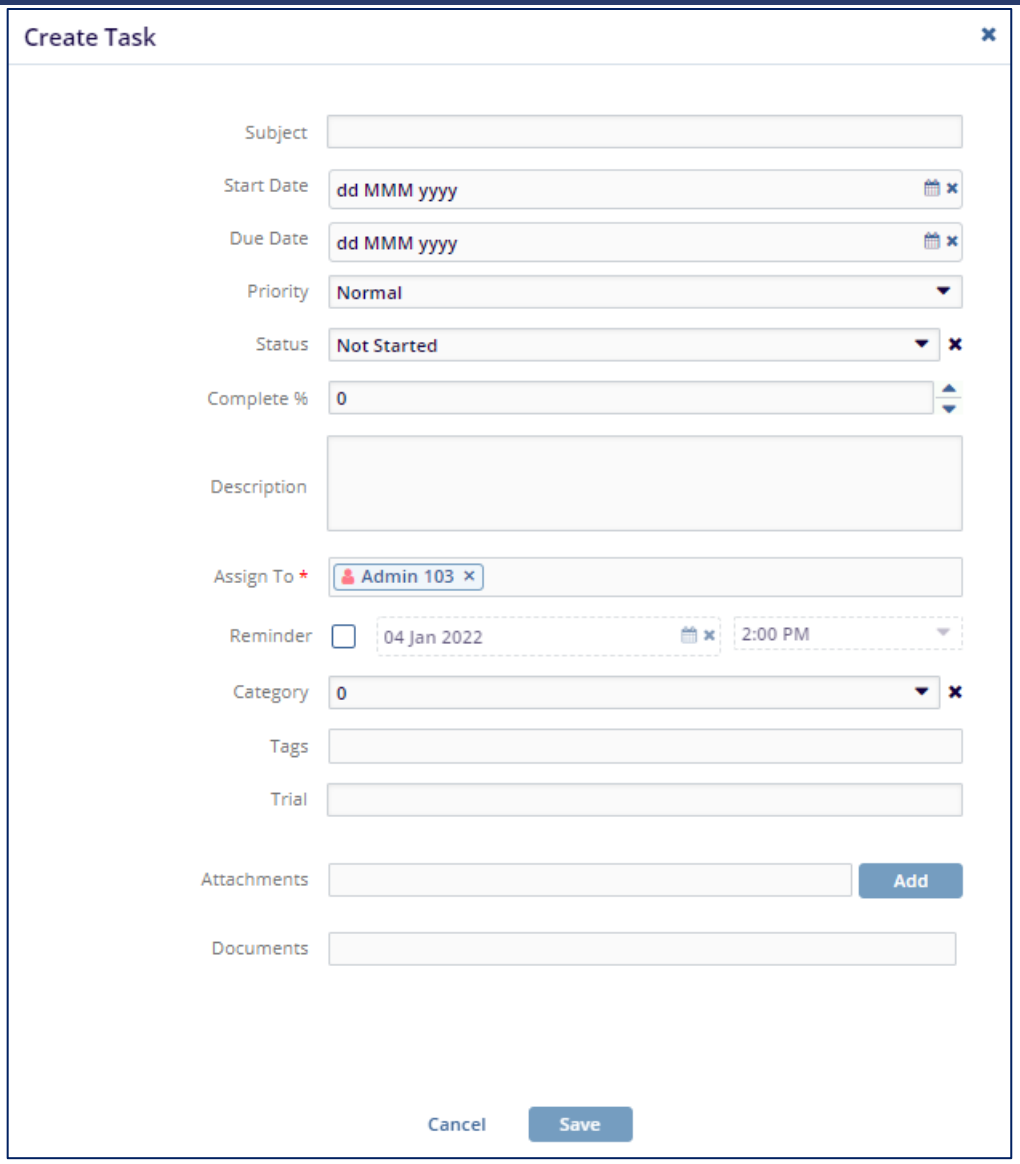


Creating Tasks

Tasks are a way to set reminders for yourself and your team and for tracking the completion of study-related activities. Users who have the Assign Tasks action on their user profile can assign tasks to other users in the room.

To create a task, follow these steps:

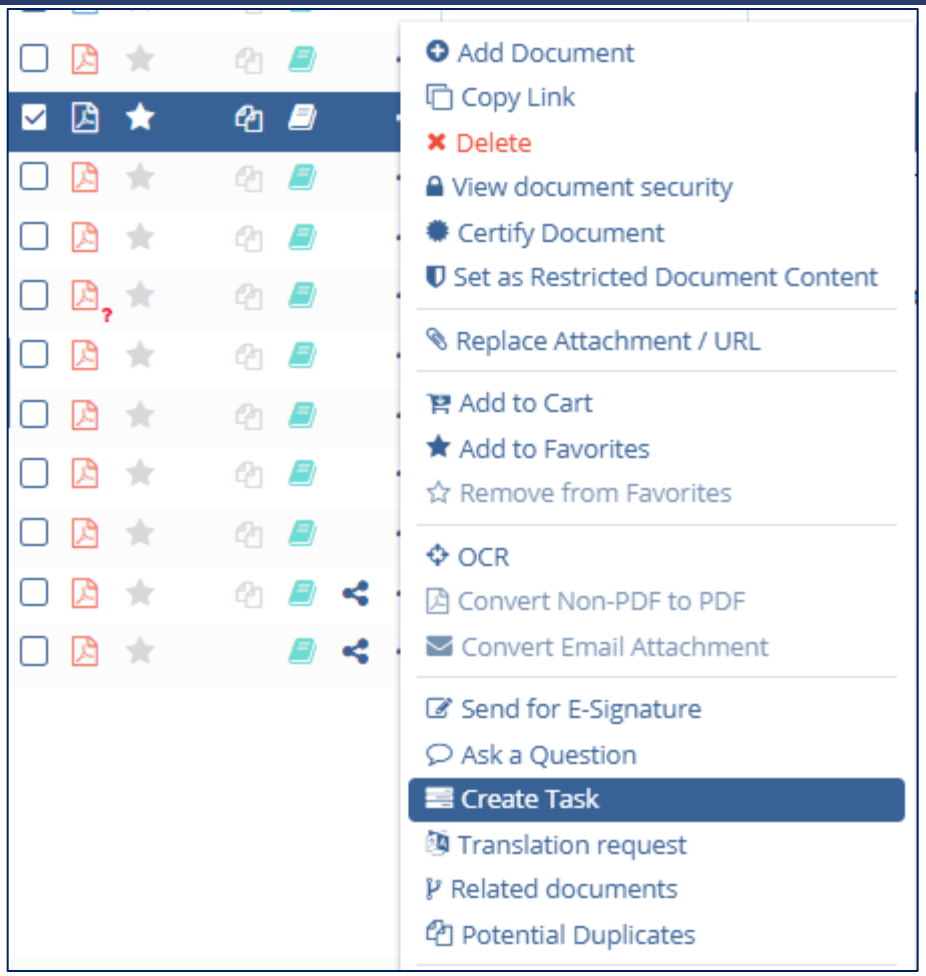
1. **Navigate to the Tasks module via the Navigation Grid in the top-left corner of the screen.**
    a. **Any previously created tasks will appear in the index panel.**
2. **Press the 'Add' button above the index pane.**
    a. **This will open the 'Create Task' window.**



3. **Fill in any relevant information.**
    a. **Most tasks will be created with a 0% completion but the field is editable in case you need to create a task for an activity that is already in progress.**
    b. **If necessary and you have the action on your user profile, assign the task to the correct room user(s).**
4. **Press 'Save' when done.**

DOCUMENT-BASED TASKS

In order to create a task associated with a document, open the document menu either by right-clicking on the document in the grid or by clicking on the three dots on the item line in the grid. When the window opens, choose the "Create Task" option.

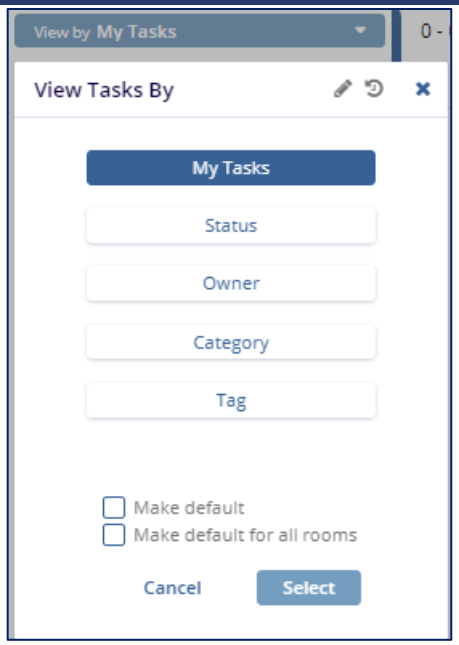


The Create Task window will open, and it will indicate that the task is being created in association with the chosen document. Fill in any required information as well as any necessary additional fields and then press "Save" in order to complete the process and create the task. Users with the "Assign Task" action on their user account can create tasks and assign them to other users in the room.

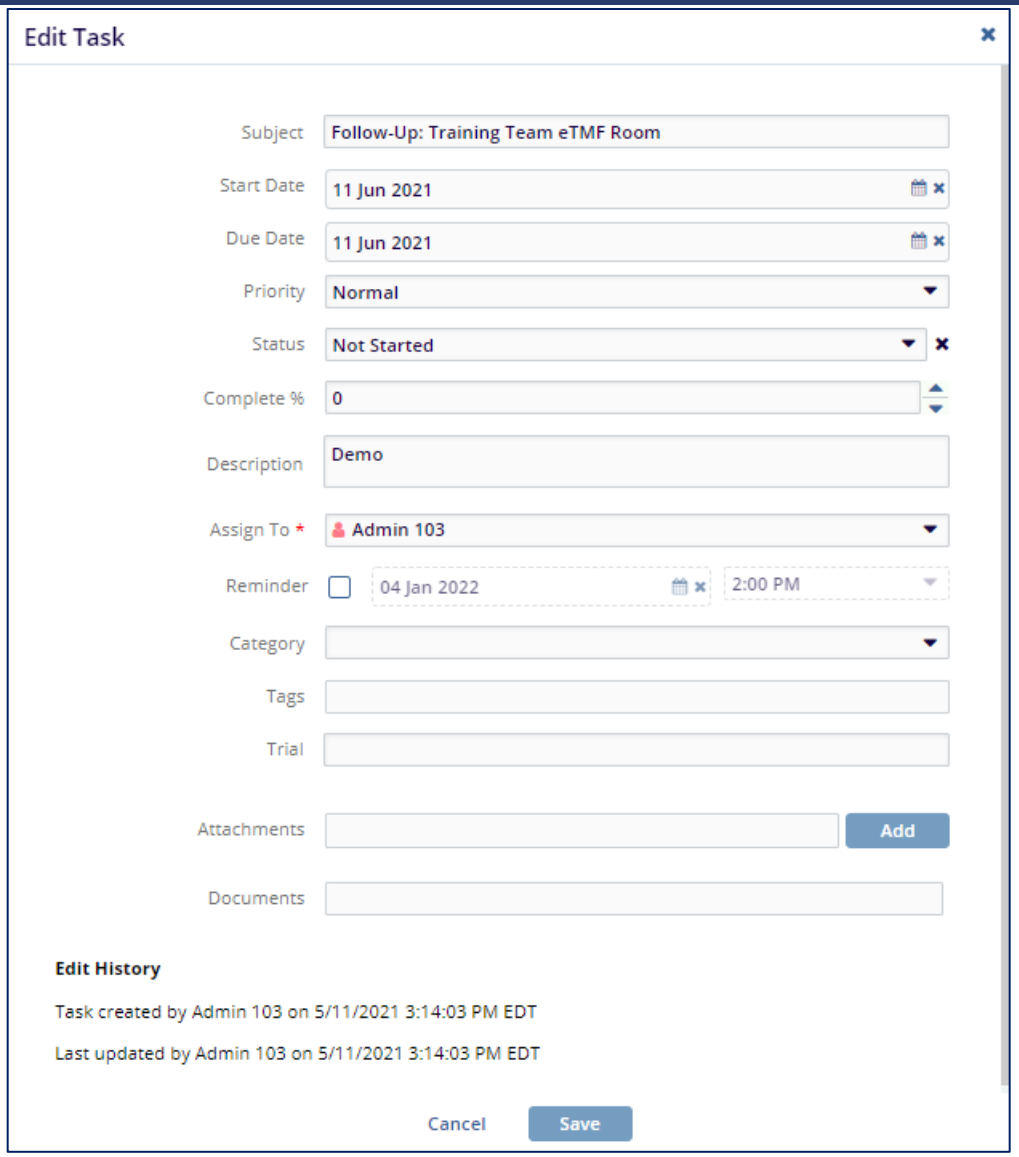
Editing Tasks

To edit a task, follow these steps:

1. **Navigate to the Tasks module via the Navigation Grid in the top-left corner of the screen.**
    a. **Any previously created tasks will appear in the index panel.**
2. **If necessary, change your view of the tasks to sort them in a different way.**



3. **Locate the task to be edited and select it from the grid.**
4. **Press the 'Edit' button above the index pane.**
    a. **This will open the 'Edit Task' window.**

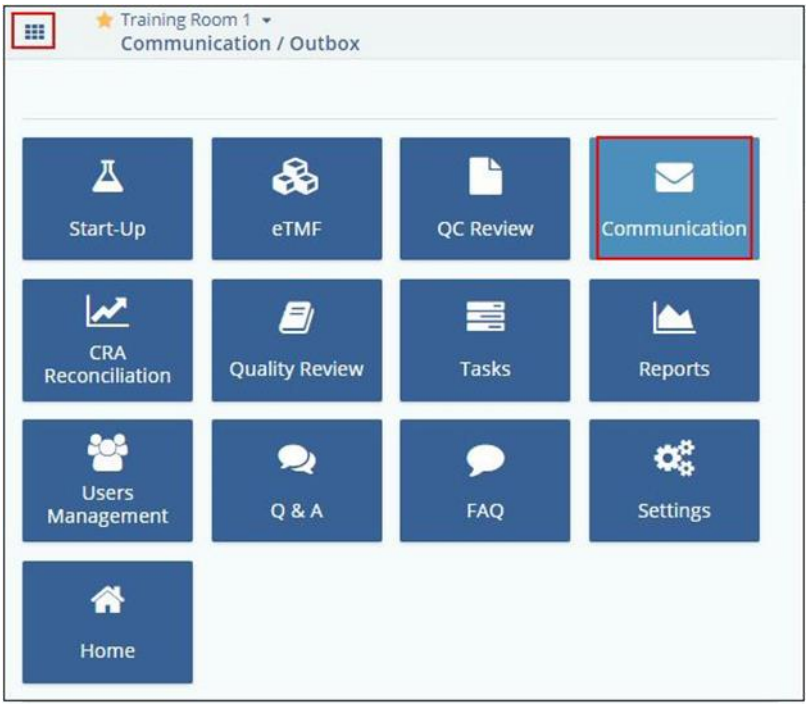


5. **Make any necessary changes**
6. **Press 'Save' when done.**

Chapter 19. Communications

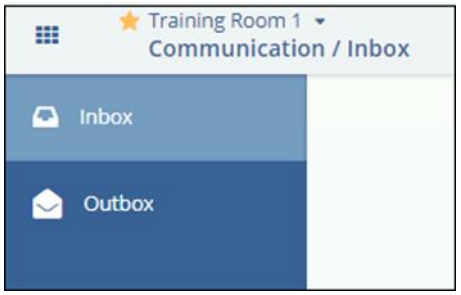
The communications module is intended to capture study-relevant communications. Emails that are sent to the Communications Inbox are automatically converted to PDF format. Messages received to the Communications Inbox need to be reviewed by study room users to determine whether or not they are relevant to the study prior to their being added to the room's QC workflow.

The Communications module can be accessed via the Navigation Grid at the upper-left corner of the screen.



Communications Module

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

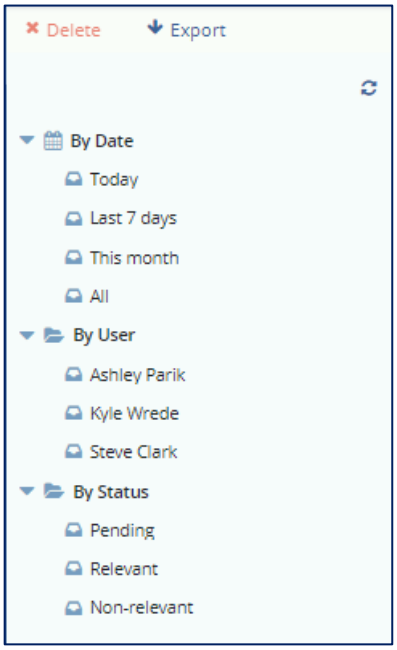
From this area, you can perform the following functions:

- **The Inbox Settings**
- **The Inbox Process**

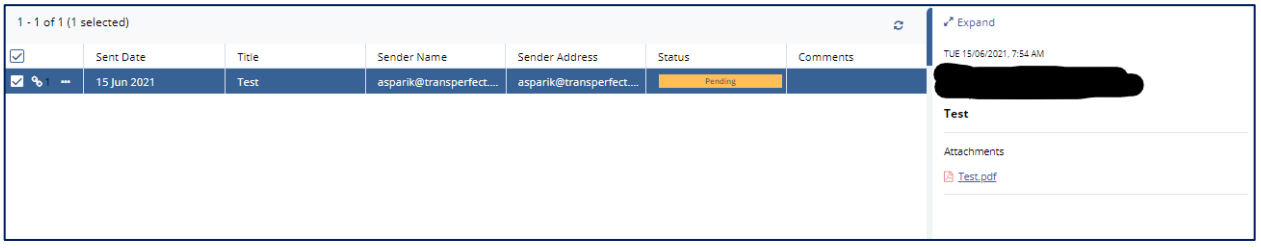
REVIEWING COMMUNICATIONS

Follow the steps below to review communications and mark them as relevant or non-relevant.

1. **Navigate to the Communications module.**
    a. **The communications will be displayed in the following categories:**
        i. **By Date**
        ii. **By User**
        iii. **By Status**

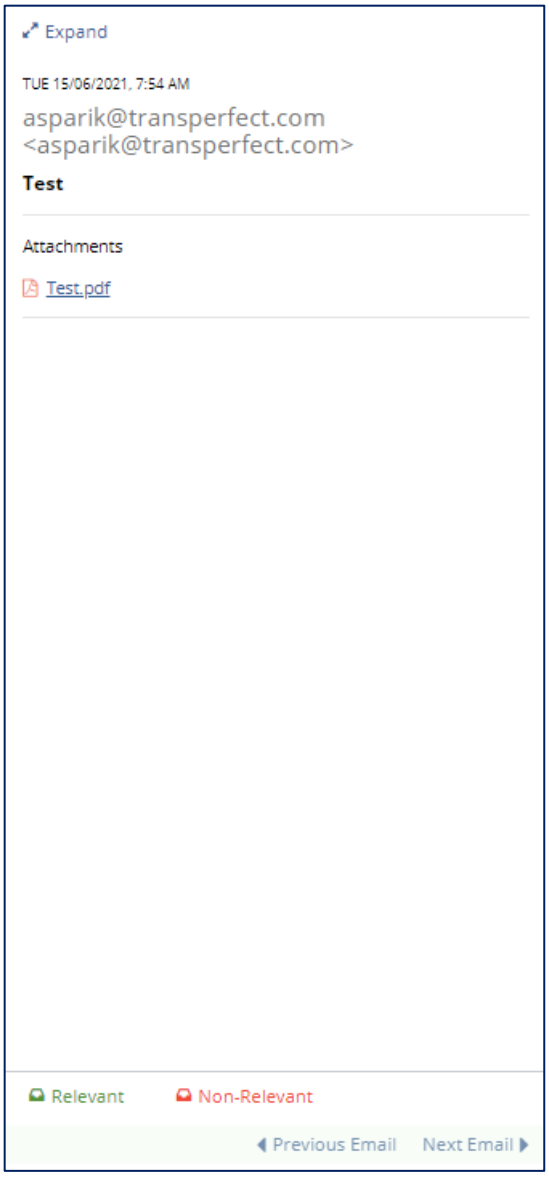


2. **Choose whichever category you would like (By Status is recommended for this process).**
    a. **The communications will load in the grid.**
3. **Select a communication in Pending status.**
    a. **The communication's details will load in the metadata pane.**

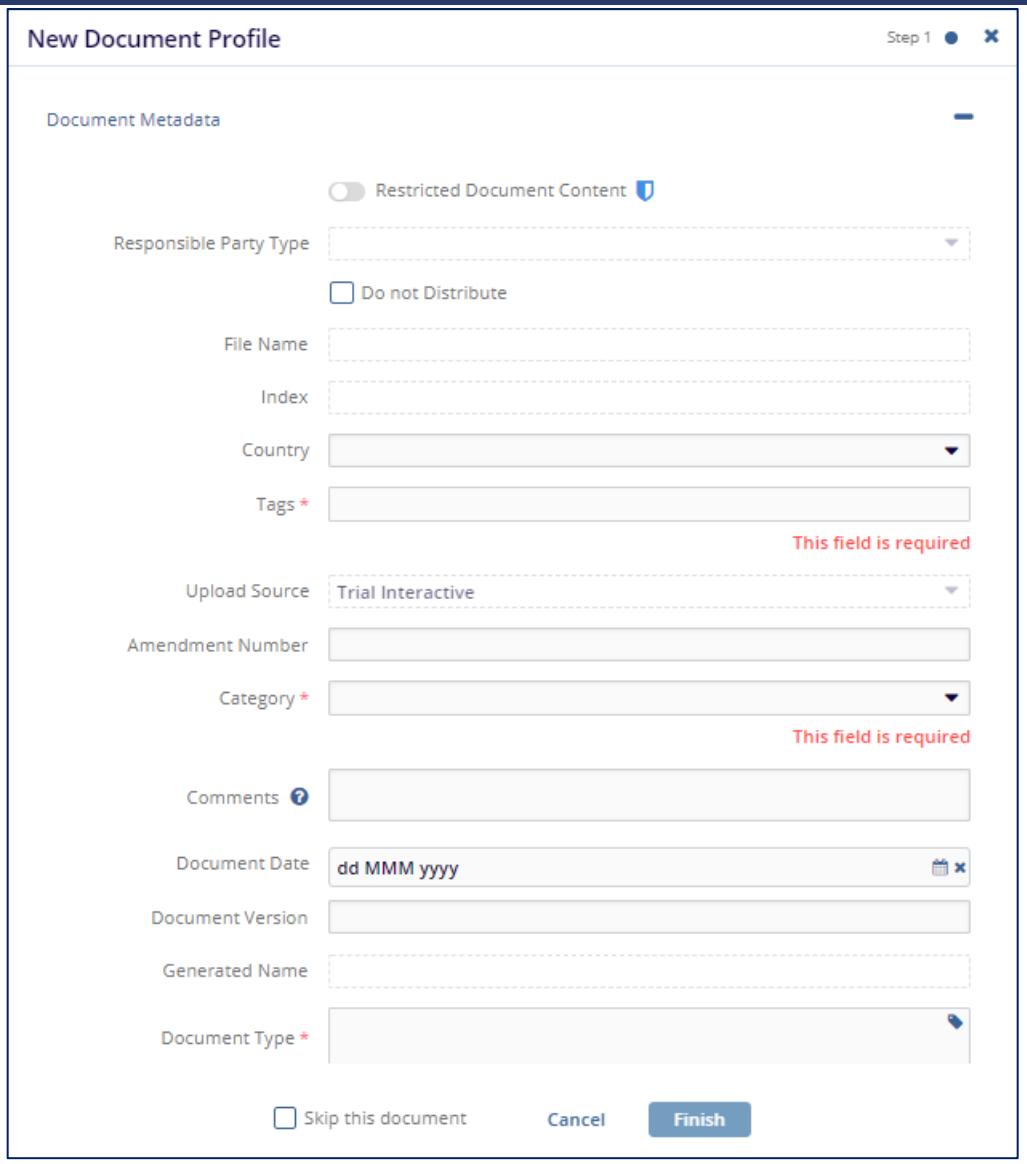


4. **Click on the pdf file shown in the metadata pane to review the communication.**

5. Press either the Relevant or Non-Relevant button at the bottom of the metadata pane as appropriate. See the screenshot below.



6. If you choose 'Relevant' you are indicating that the system should generate a new document for the study room using this file. As such, you will be required to apply required metadata in the 'New Document Profile' window.



7. When you are done applying metadata to the document, press 'Finish.'

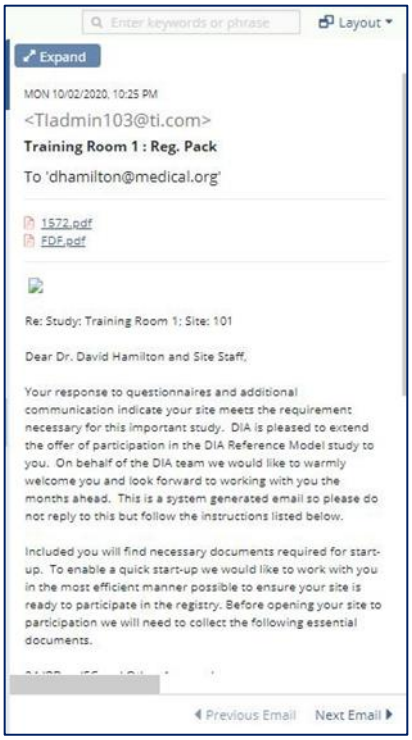
Communication Outbox

Documents or messages emailed from a Trial Interactive room are stored in the Communication Outbox. 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. You can also export communication emails.

VIEWING OUTBOX MESSAGE INFORMATION

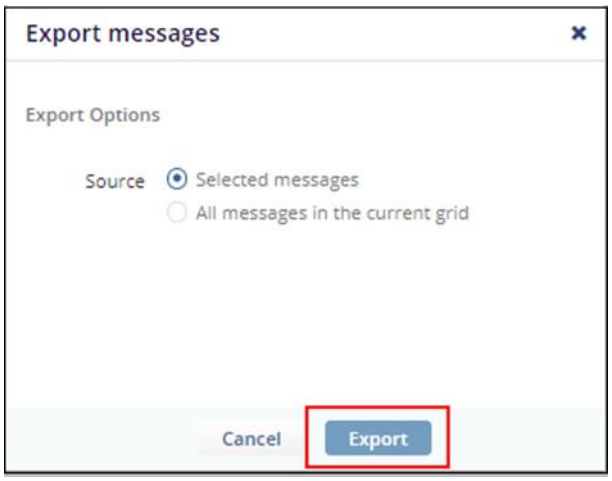
Double-click a message in the grid or check the checkbox to display the Email Message in the metadata pane. This

window gives the complete metadata of a message including its body, sender, receiver, subject, sent date, and attachments. Refer to the screenshot below:



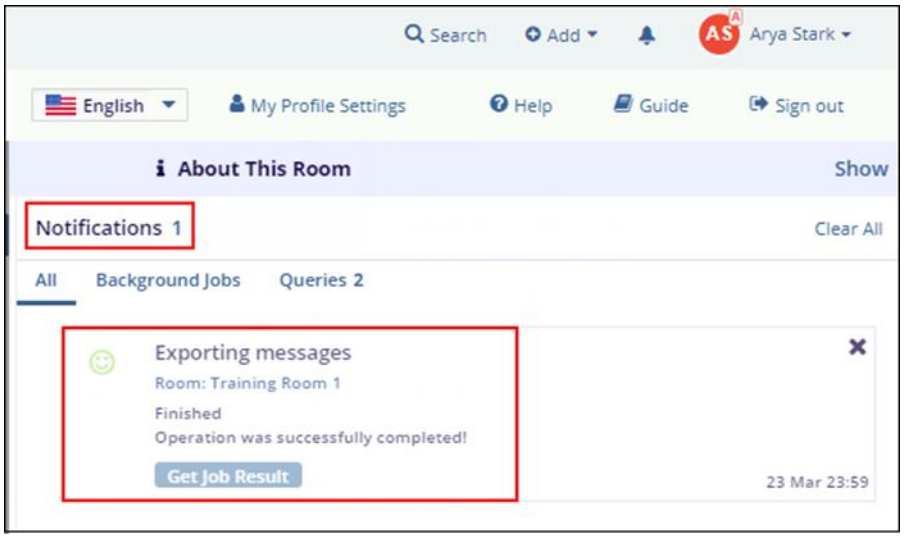
EXPORT COMMUNICATION EMAILS

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 screenshots below:



The confirmation of the export job is displayed in a popup at the top of the grid.

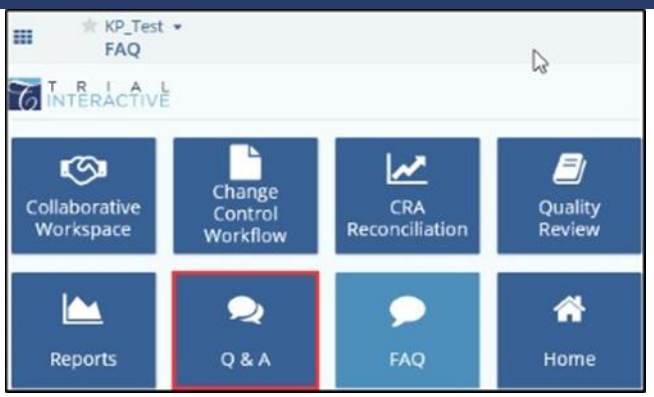
You can Get Job Result from the Notifications area of the Username menu. Refer to the screenshot below.



Chapter 20. Q&A

This section enables you to view the list of questions asked and answers given by users in a room.

From the Navigation Grid select Q&A to reach this dashboard. Refer to the screenshot below:



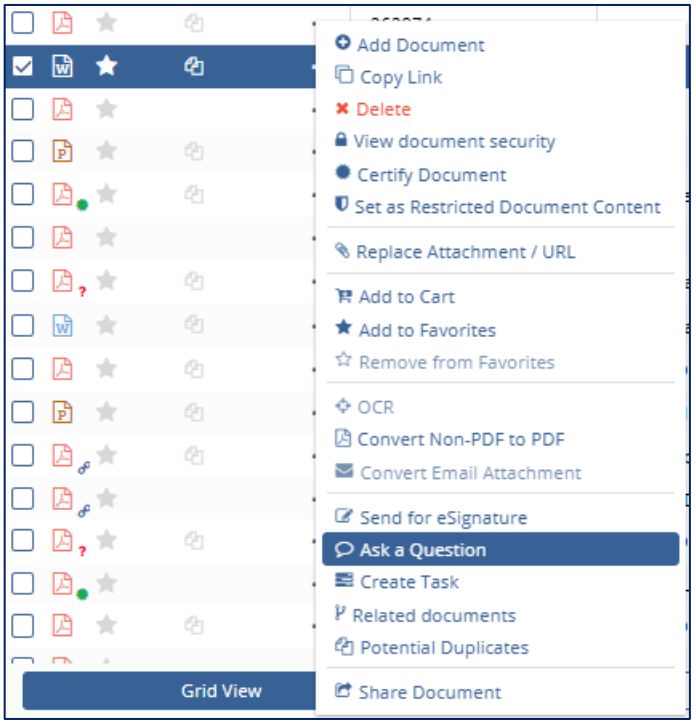
Creating a Question

Creating a question may be done from either the Document Activities menu in the Documents module or directly from the Q&A module.

CREATING A DOCUMENT-SPECIFIC QUESTION

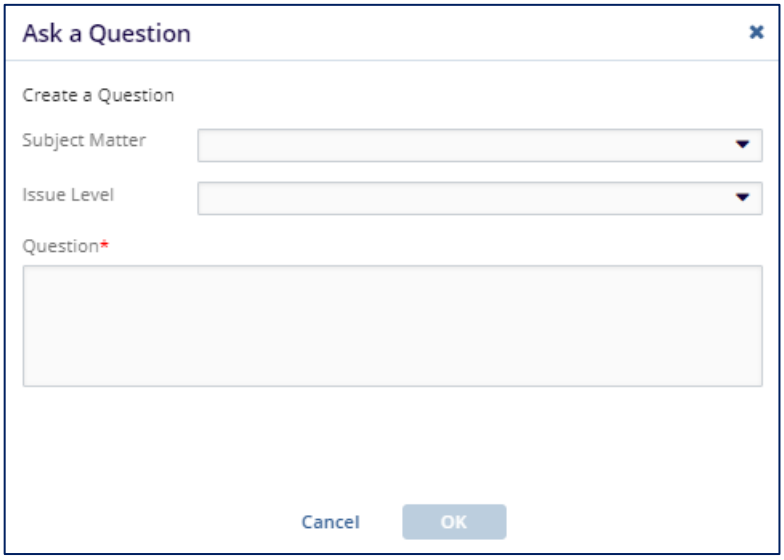
Questions that are related to a specific document should be created by the following process:

1. **Navigate to the document about which you have a question.**
2. **Open the Document Activities menu for that specific document by either right-clicking on it or by clicking on the three-dot menu on the grid entry.**



3. **Click 'Ask a Question.'**

a. **The Ask a Question window will open.**



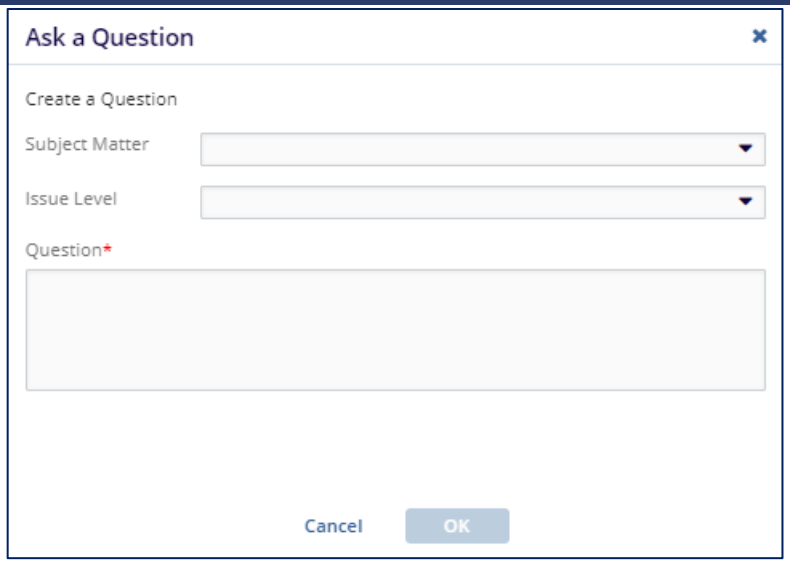
b. **The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.**

4. **If necessary, indicate the applicable subject matter and issue level.**
5. **Type your question into the box.**
6. **When you are done, press 'OK.'**
7. **The question will appear in the Q&A module.**

CREATING A GENERAL QUESTION

More general questions can be created from the Q&A module itself. In order to create a general question, follow the steps below:

1. **Navigate to the Q&A module.**
2. **Click the 'Ask a Question' button in the menu bar above the index panel.**
   a. **The Ask a Question window will open.**



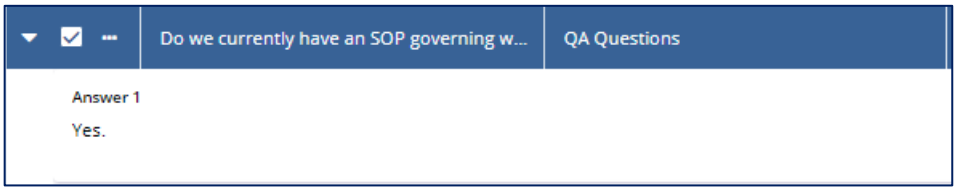
b. **The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.**

3. **If necessary, indicate the applicable subject matter and issue level.**
4. **Type your question into the box.**
5. **When you are done, press 'OK.'**
6. **The question will appear in the Q&A module.**

Viewing the Answer to a Question

Follow the steps below to view the answer to a question:

1. **Navigate to the Q&A module.**
2. **Locate the question in the Grid.**
3. **Click on the arrow next to the question to display the answer. In some cases, there may be multiple answers.**

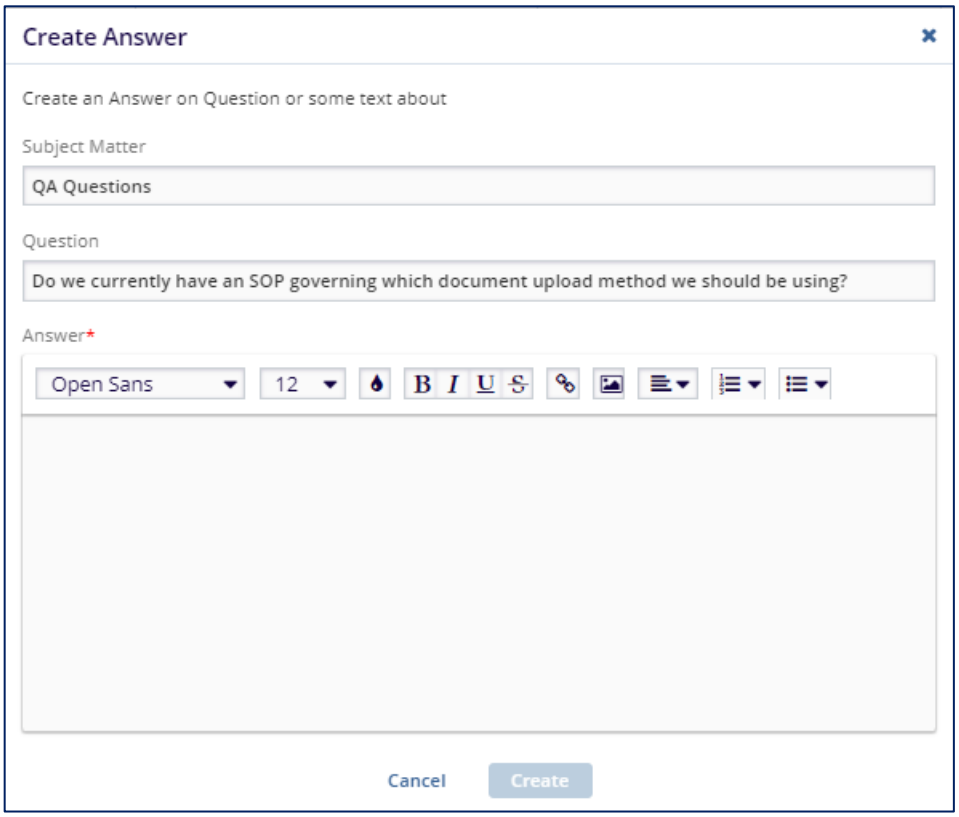


Answering a Question

Administrator users and those users indicated as Subject Matter Experts may create answers to questions in the Q&A module.

Follow these steps to answer a question in the Q&A module:

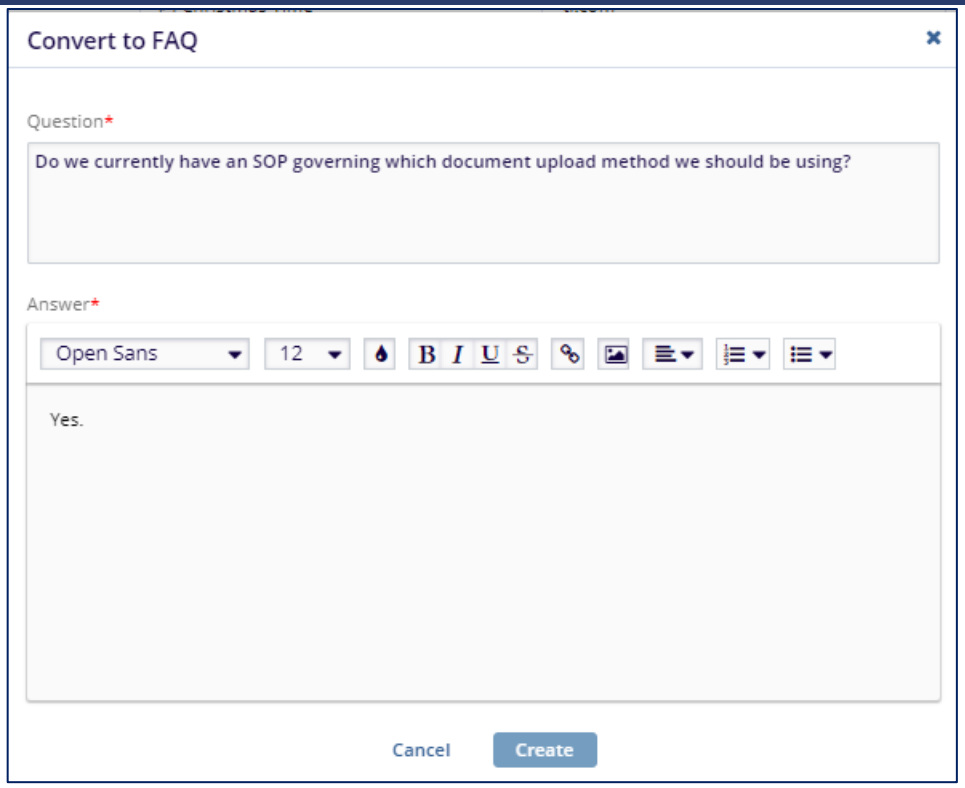
1. **Navigate to the Q&A module.**
2. **Locate the question to be answered.**
3. **Click the 'Create Answer' button in the menu ribbon above the index panel.**
    a. **This will open the 'Create Answer' window.**



4. **Type your answer in the box and press 'Create.'**

Converting a Question into an FAQ Entry

1. **Locate the question which needs to be converted to an FAQ entry.**
2. **Click on the arrow to expand the line and view the available answers.**
    a. **Only answered questions can be converted.**
3. **Click on the answer to the question. If there are multiple answers, you will need to pick one – it can be edited in the next step.**
4. **Click the 'Convert to FAQ' button**
    a. **This will open**

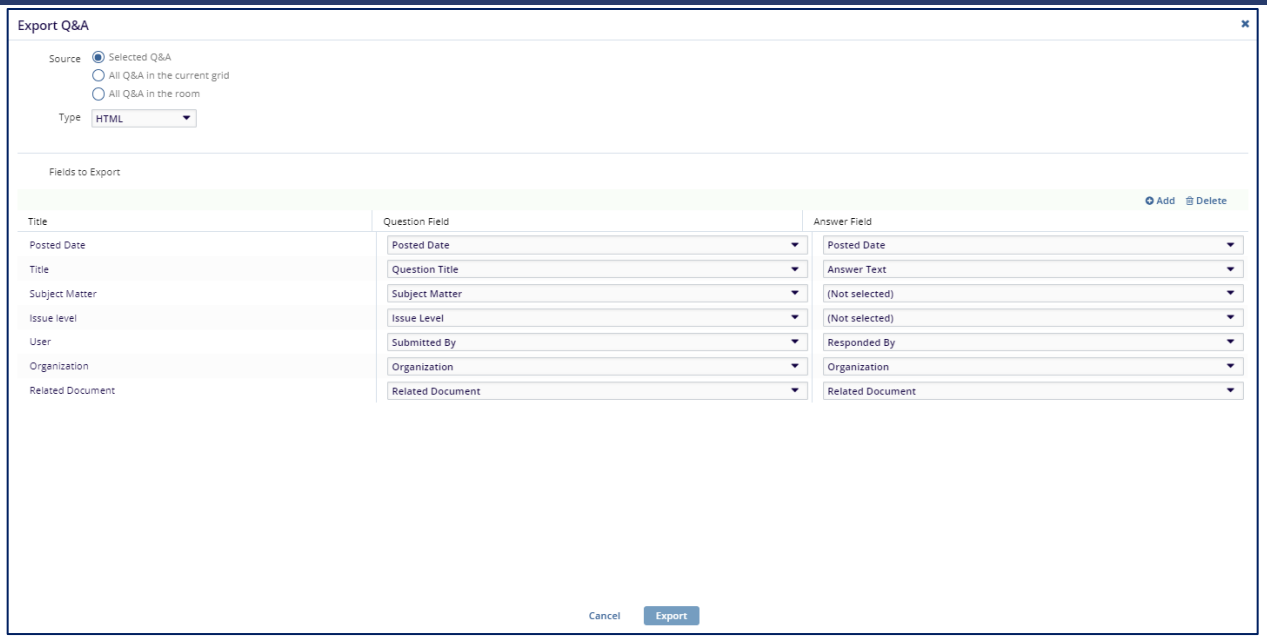


5. **Make any required edits to the Question and/or the Answer.**
6. **When you are done, press 'Create.'**

Exporting Questions and Answers

Administrator level users can export questions and answers. To do so, follow the steps below:

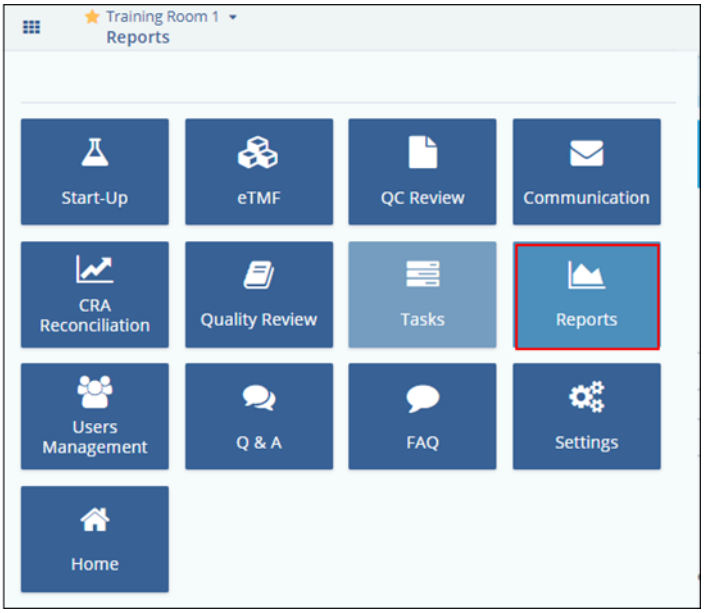
1. **Where applicable, select the question to be exported.**
2. **Press the Export Q&A button.**
    a. **The Export Q&A window will open.**



3. **Select the Q&A Source and the export Type.**
4. **Indicate which fields should be exported.**
5. **Press 'Export'**

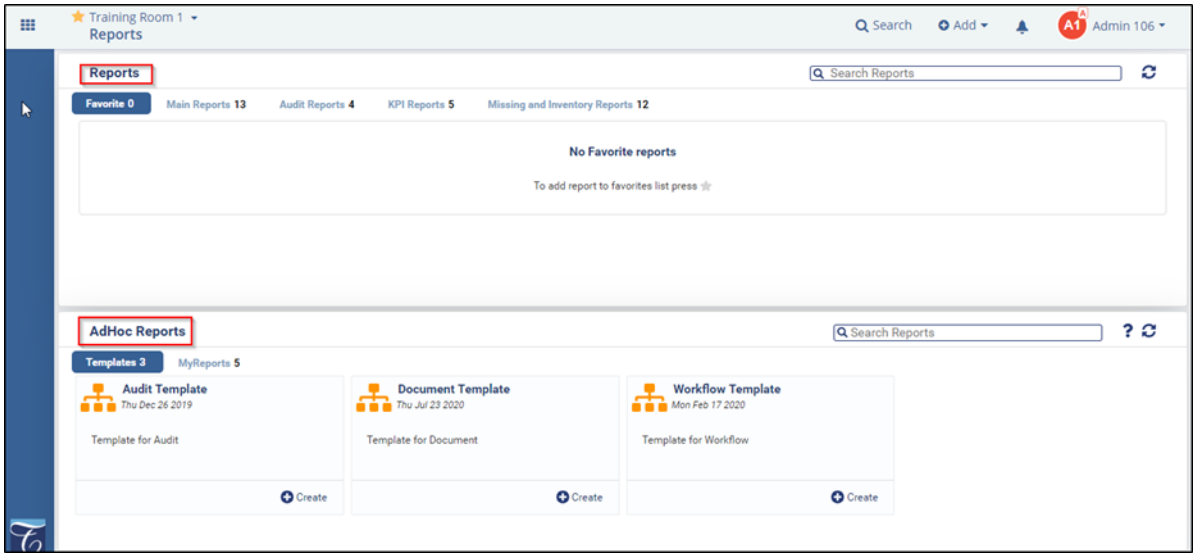
Chapter 21. Reports

The Reports module can be accessed by clicking the Reports application from the Navigation Grid. Refer to the screenshot below:



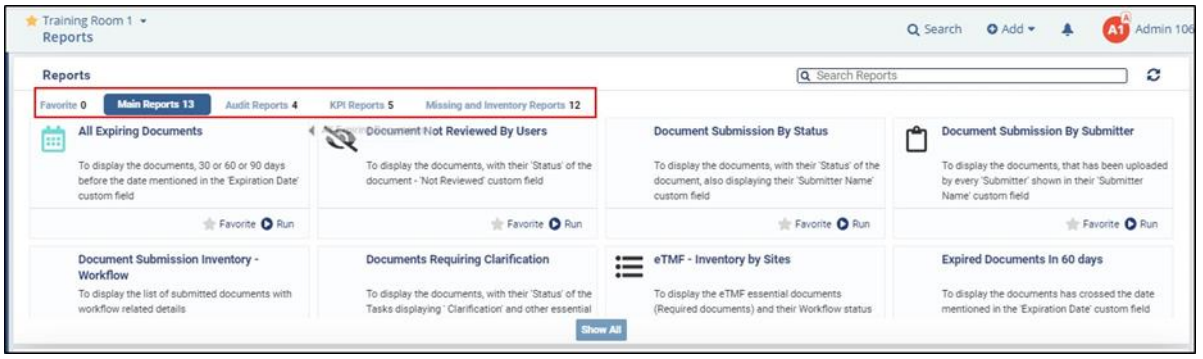
The Reports Dashboard consists of the various dashlets which gives a summary of the reports of the room. Refer to the

screenshot below:



Viewing Reports from the Report List

From the Reports Dashboard, click the reports category marked in red in below screenshot. The below list of reports are from the Main Reports category.



Select any report and click on Run button to view the desired report.

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 astudy 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 toshare 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 capabilityof 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 sametime, 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

1. TI Docs
2. 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 Collaborate asks 'Is this a TMF document?' while publishing the documents. With TI Collaborate the users can also publish the documents to anyother room that is not associated to Collaborative Workspace.

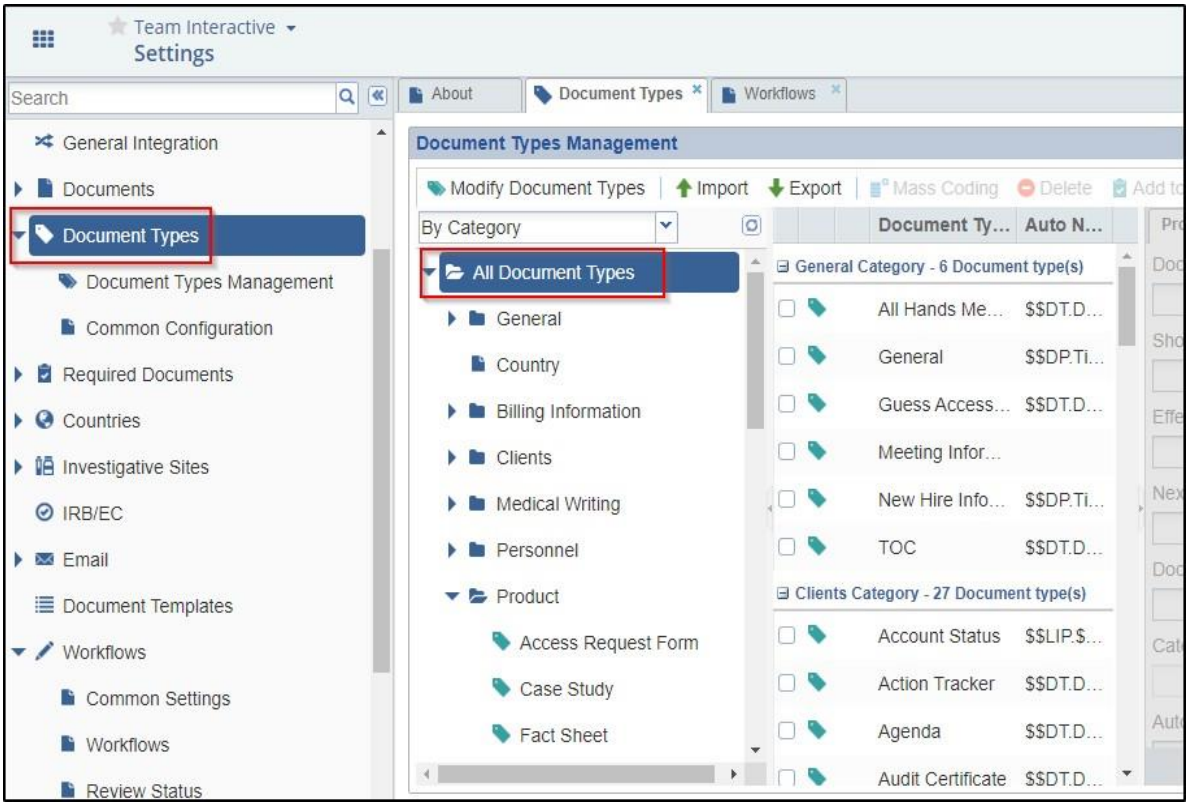
While TI Docs doesn't have any link to TMF, nor it can publish the same to any other room.However, the documents can be copied to other rooms.

Important: *To enable Collaborative Workspace room, contact the Service Desk.*

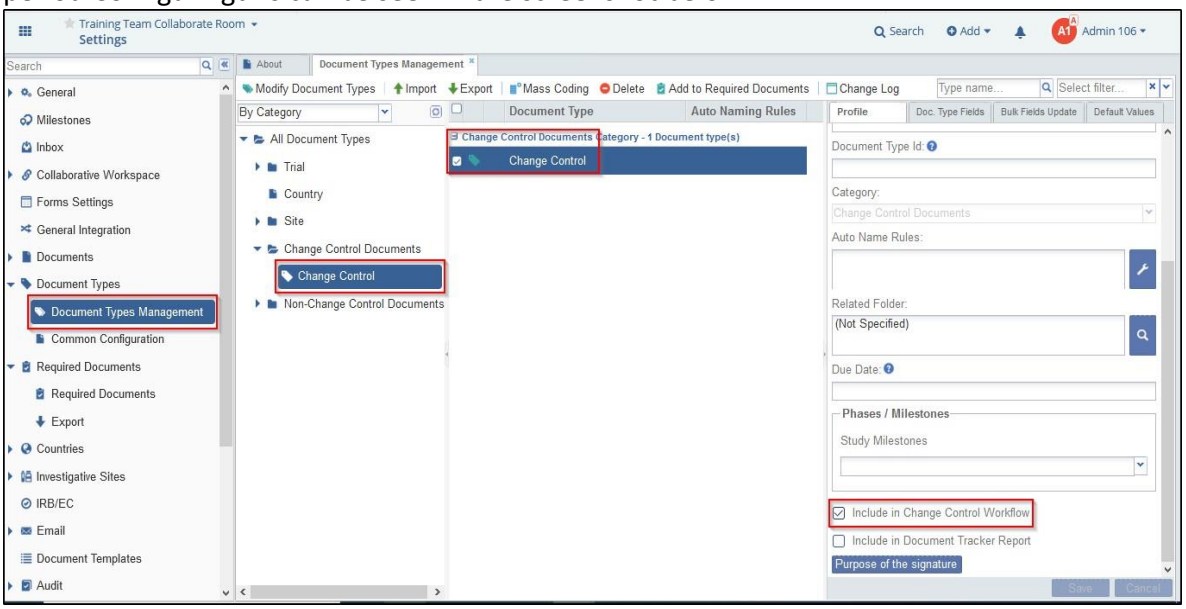
Room Configurations that impact Room Types

The room configrations that impact the room types TI Docs and TI Collaborate are described below.

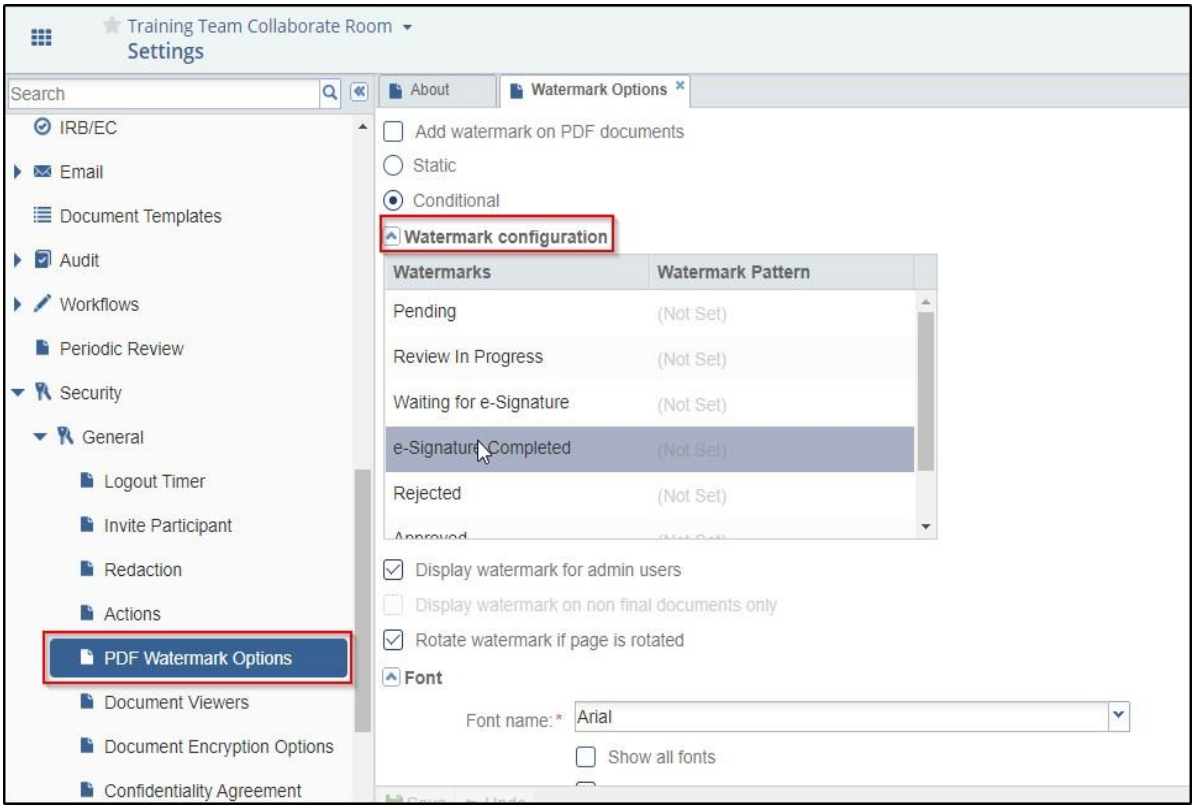
1. Document Type - The document types settings can be configured via Settings>DocumentTypes>All Document Types>. Refer the screenshot below



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.Configuringthis can be seen in the screenshot below.

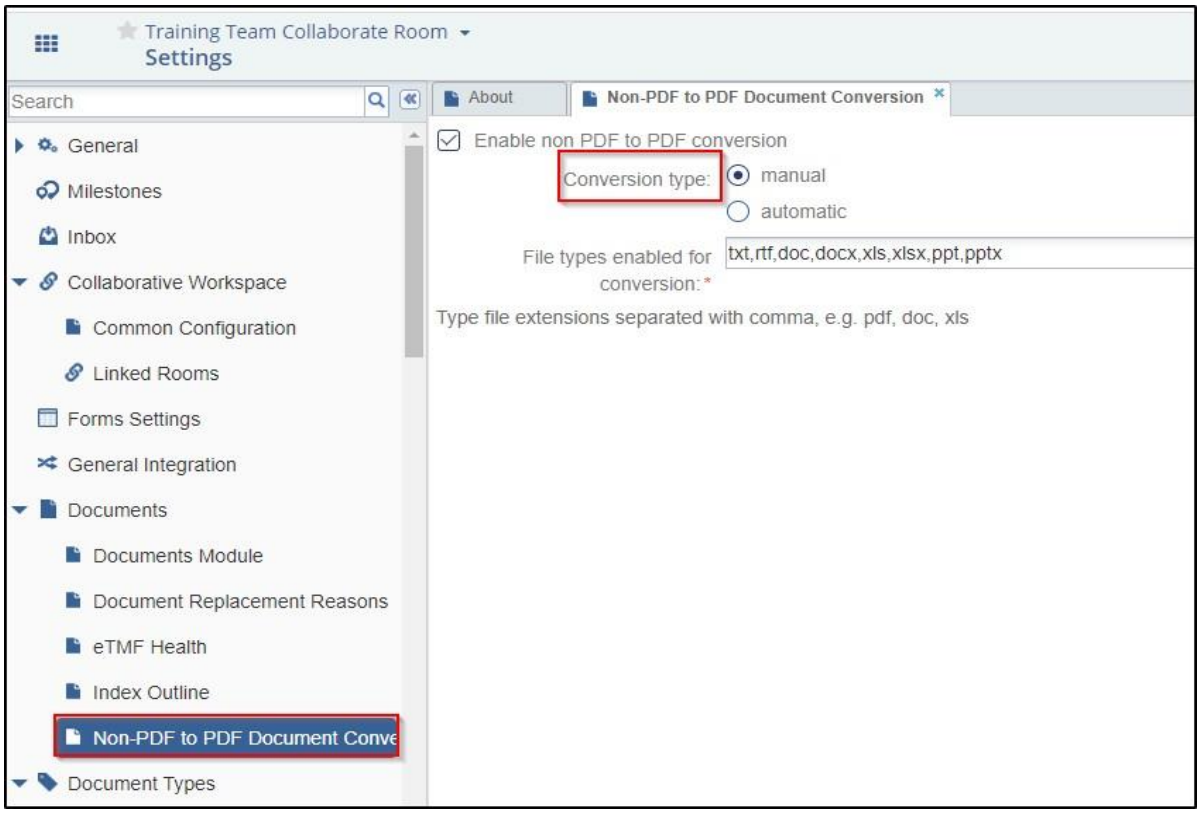


3. PDF Watermark- To insert a PDF watermark, go to Settings> Security>General> PDF Watermark Options and select the Watermark Configuration. Refer the screenshot

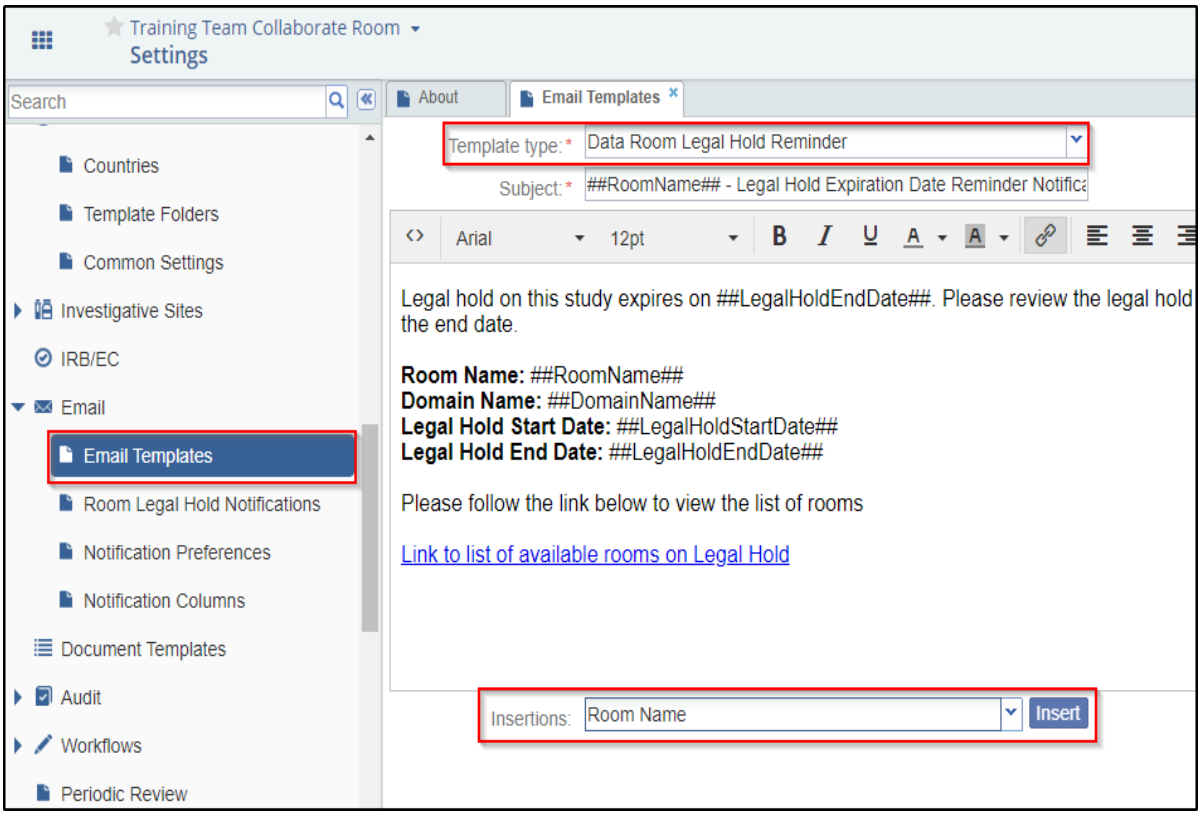


below.

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. Refer the screenshot below

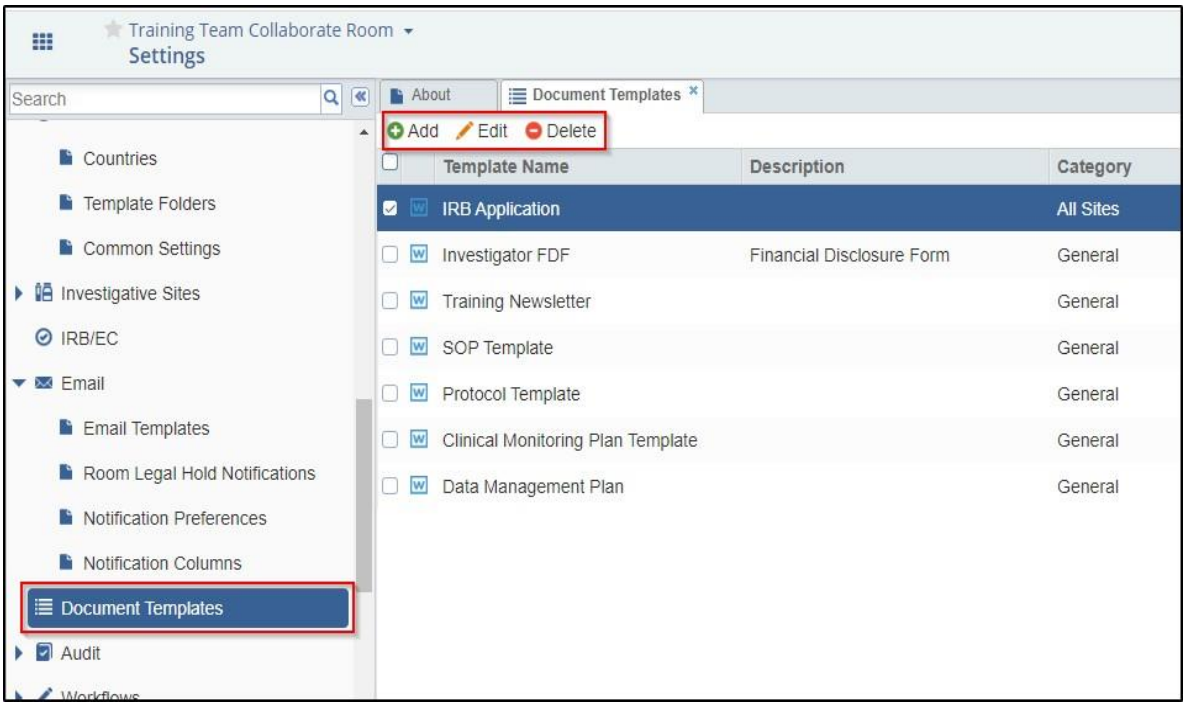


5. Email Templates- To define Email templates, go to Settings>Email>Email Templates. Select the Template Type from the dropdown list available. You can also select email template insertions from the insertions dropdown and click Insert. Refer the screenshot below.



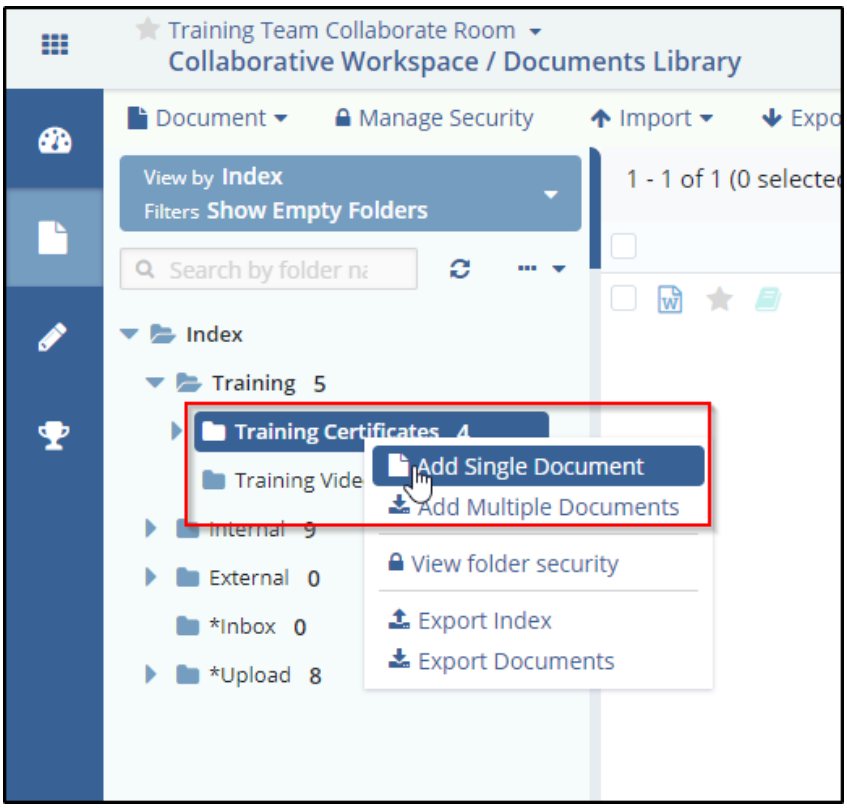
6. Document Templates- To define document templates, go to Settings>Document Templates.

Click Add **button to add a new document template. You can also edit or delete an existing document template. Refer the screenshot below.**

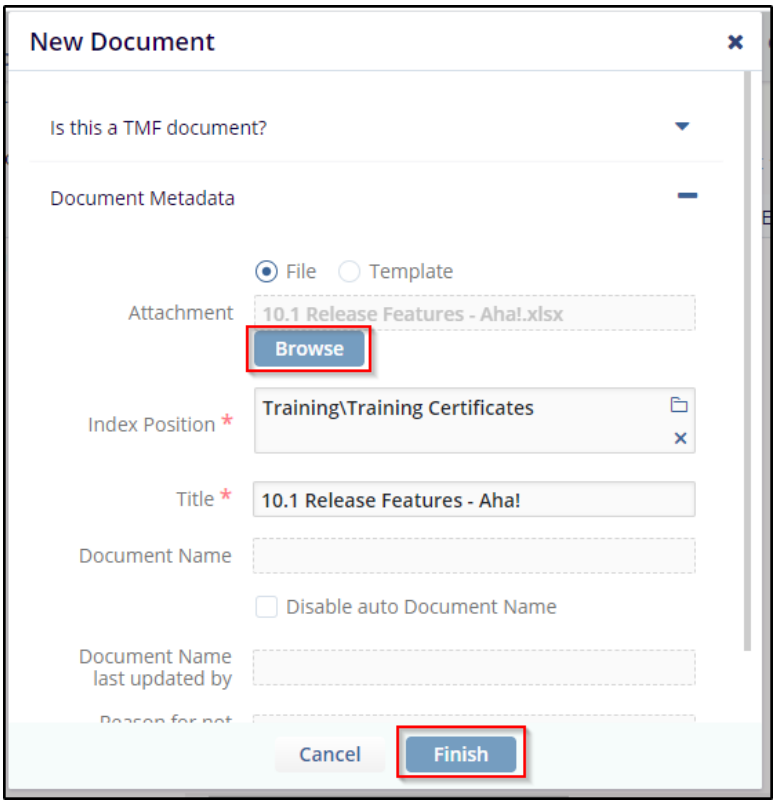


Document Upload

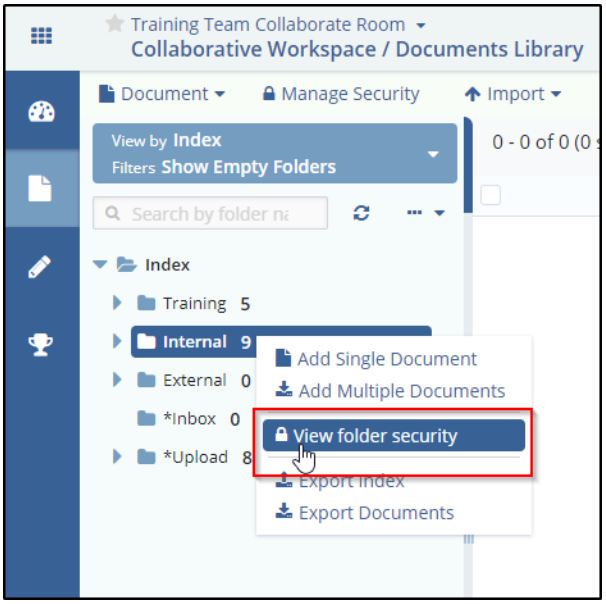
A document or template can be uploaded in the Collaborative Workspace. Choose the desired folderfrom the index view and right click to add a document. Refer to the screenshot below.



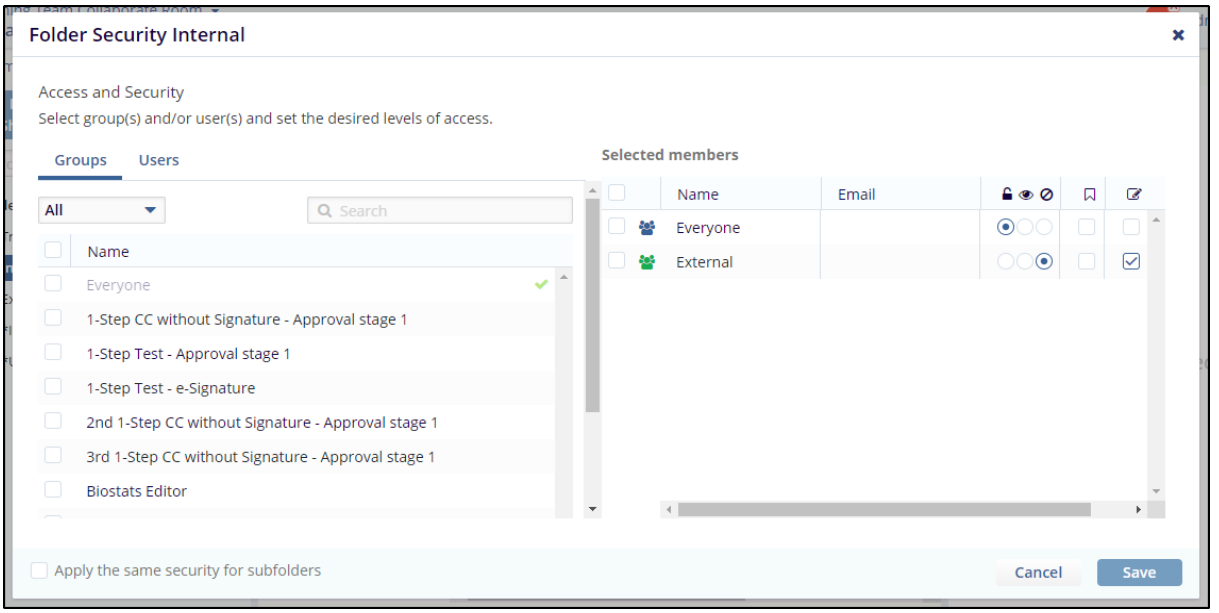
Clicking 'Add single document' tab will open a 'New Document' pop up. Select the option for thequestion 'Is this a TMF document?', attach a document or a template, fill the essential metadata fields, and click 'Finish' to complete the upload. Refer to the screenshot below



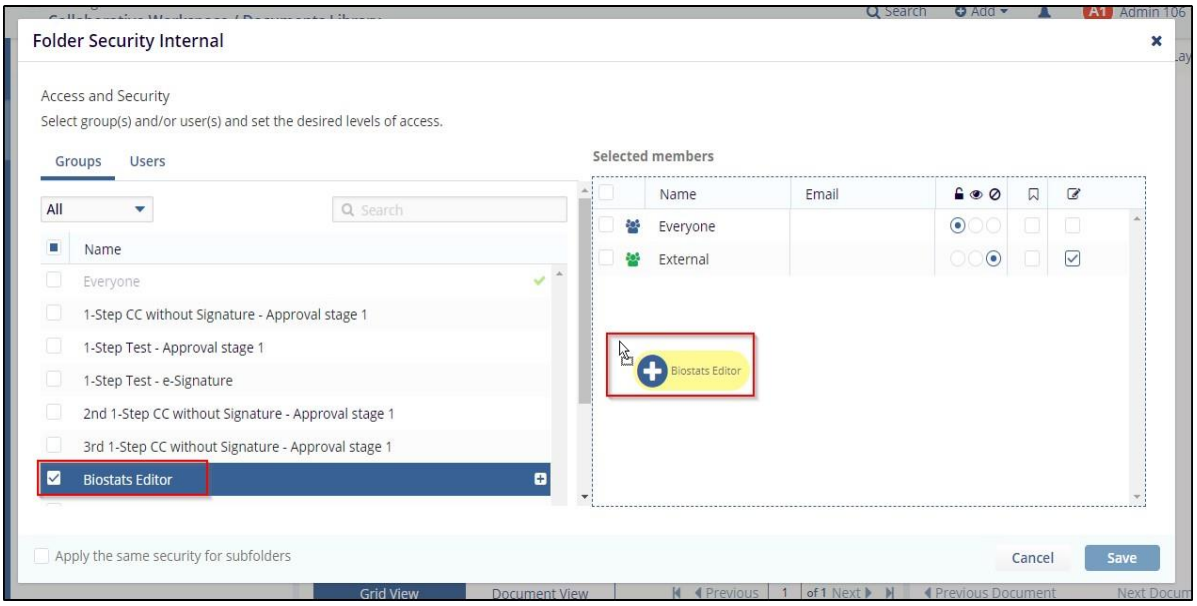
Folder Level Security- To view and edit folder level security, right click a folder available in theindex view and choose the option 'View Folder Security'. Refer the sccreenshot below.



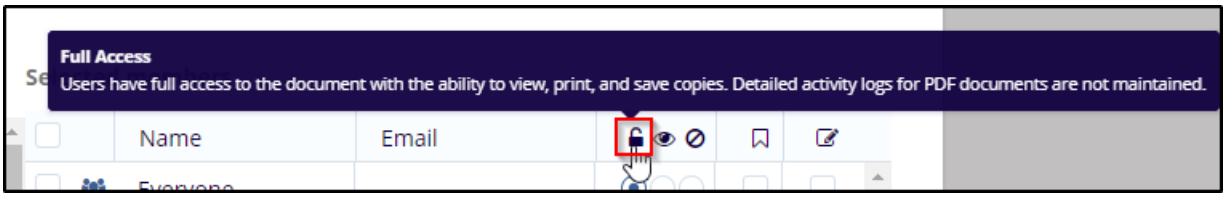
Clicking the option 'View folder security' will open a popup window titled 'Folder SecurityInternal' .Refer the screenshot below.

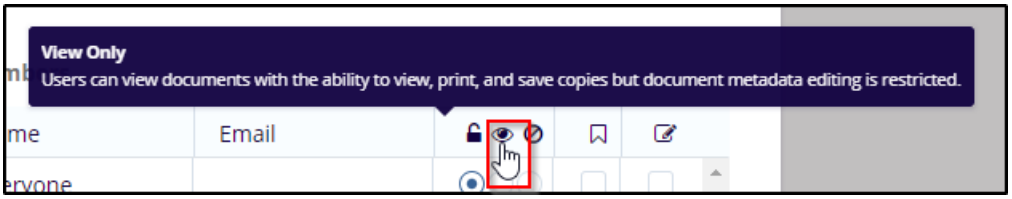


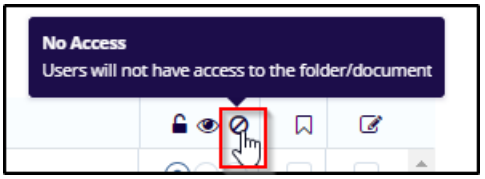
Managing folder security- You can manage group folder security and Users security. To manage the group security, select a group from the available list by checking the checkbox. Drag and drop the group to the selected members ist available at the right side of the screen. Refer the screenshot below

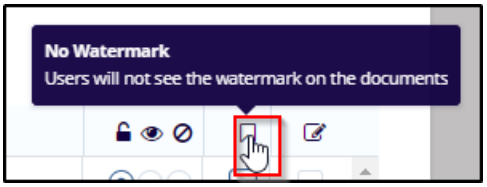


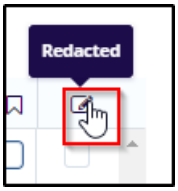
In the selected members section, you can define the access level to the selected groups by checkingthe radio buttons available under the icons. Each icon has its access defined. Hover over the icon tosee the access as shown in below screenshots



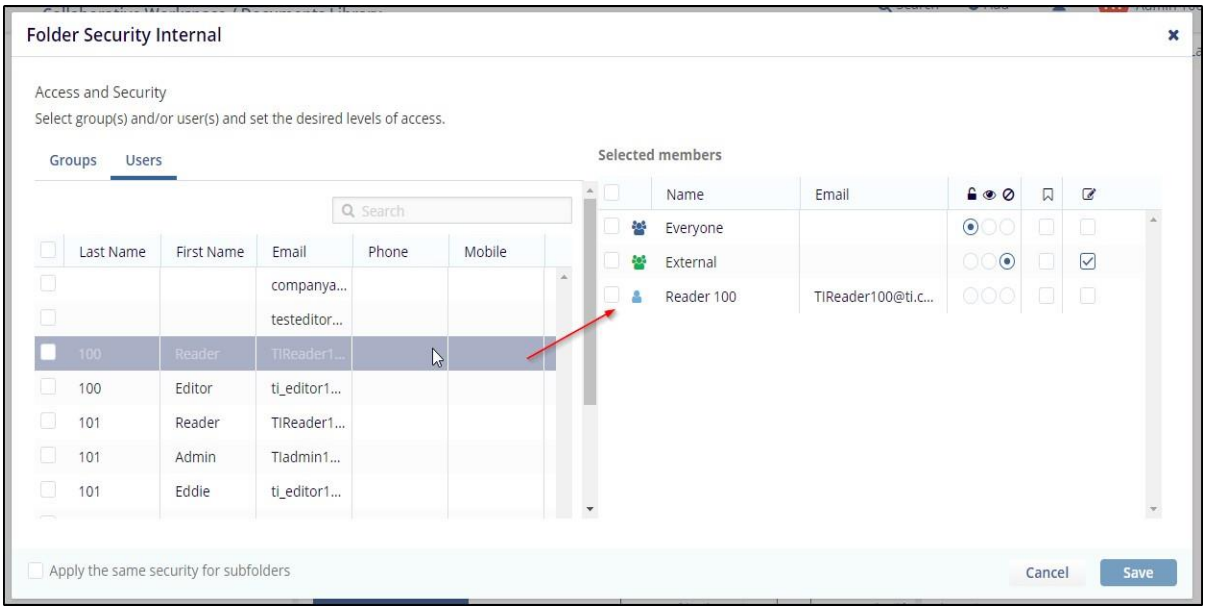








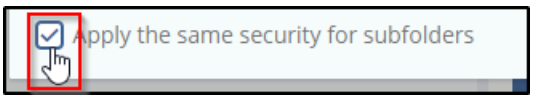
Manage user security- To manage user security, go to Users, drag and drop a user from the list toselected members section. Refer the screenshot below.



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 clickingthe 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 thesame security for subfolders' as shown in the screenshot below



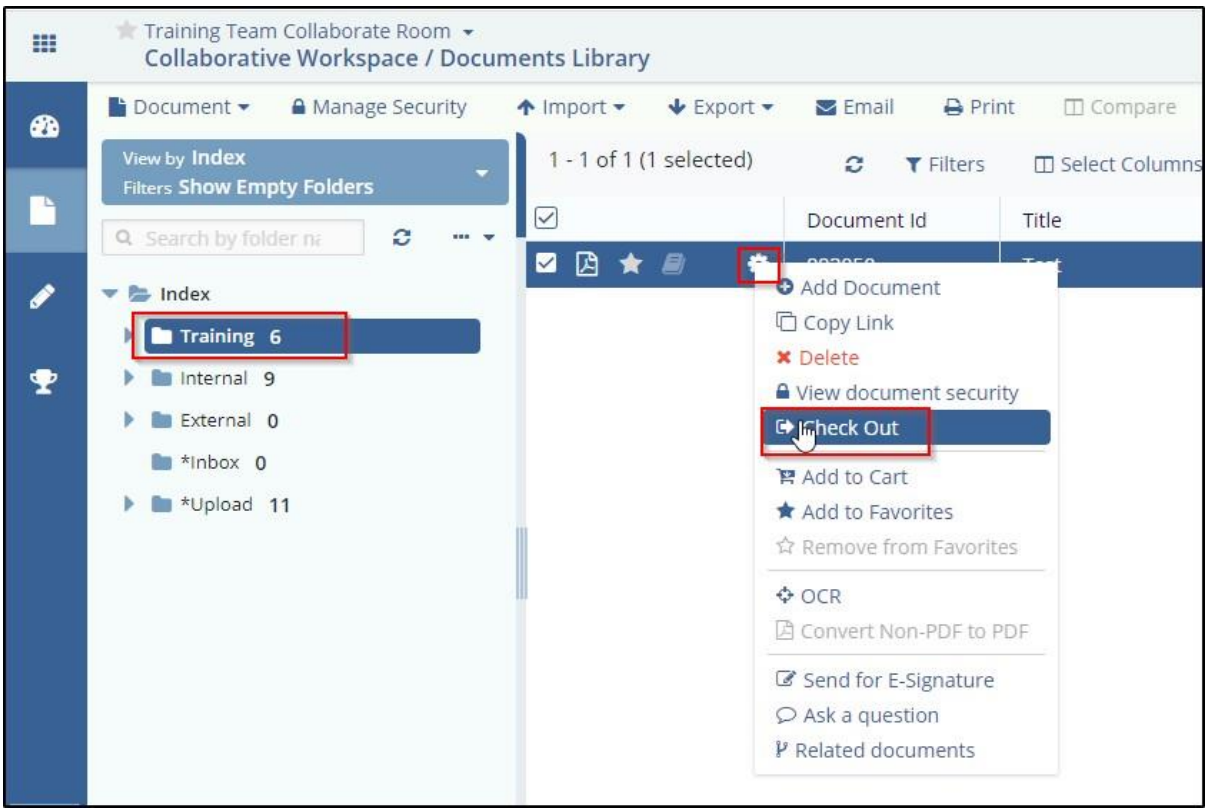
Content Editing and Versioning

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 simultaneouslywork 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 seamlesslyback to the Shared Workspace.

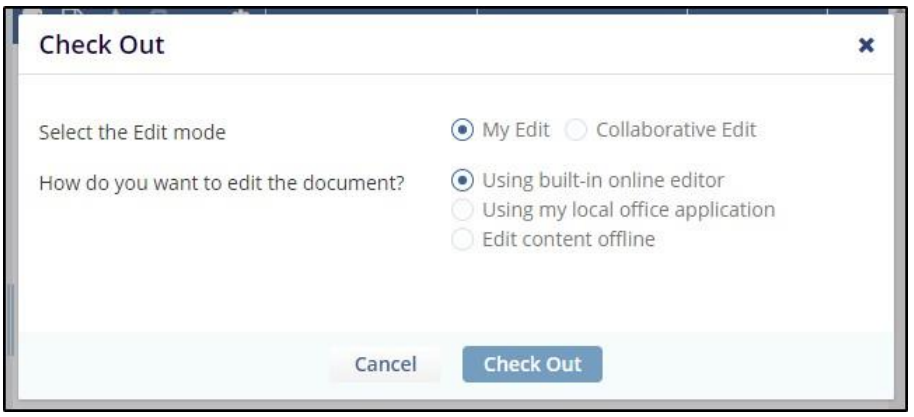
The content editing is performed with check-in and check-out with the documents available in a collaborative room. The detailed process is explained in the subsequent topics.

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.



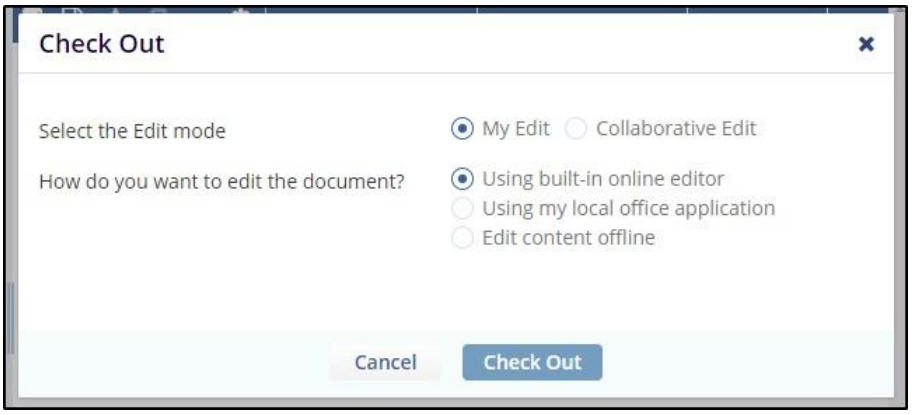
Clicking the Check out option will populate a checkout window as shown in the screenshot below.



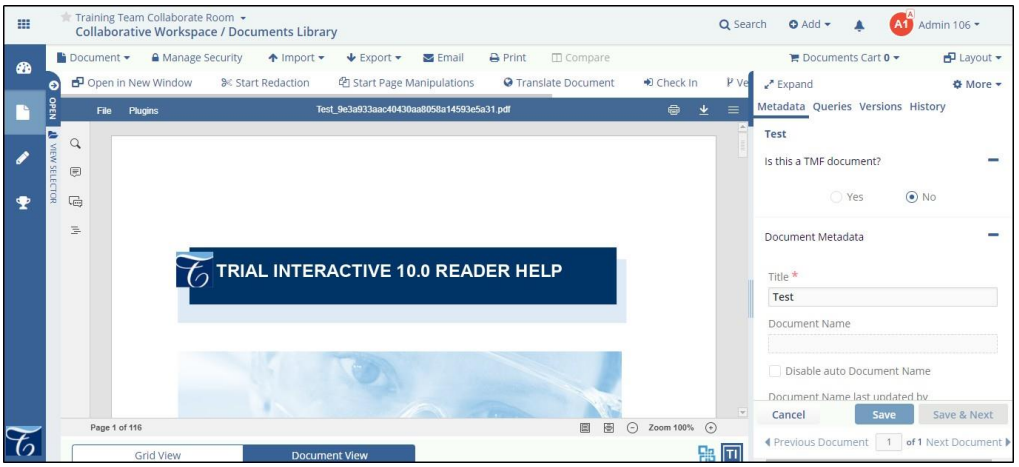
From here, you can initiate My Edit and Collaborative Edit choosing the editor options like Using built in editor, using local office application, and editing content offline. The edit mode 'My Edit' isexplained in the subsequent topics.

My Edit

My Edit is performed under Check out. Click My Edit Rdio button and choose Using built-in onlineeditor as shown in the screenshot below

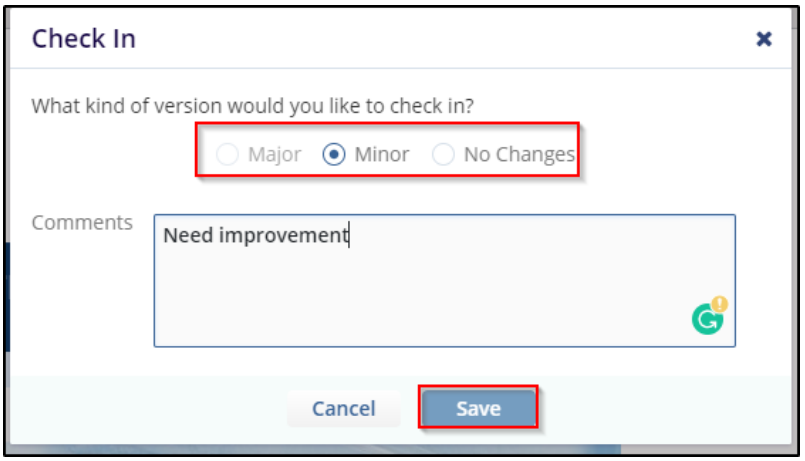


Clicking the check out button with using built-in online editor will open the document editor asshown in the screenshot below.



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. Onceyou make the cdits, the system will poulate a Check in window as shown in the screenshot below.



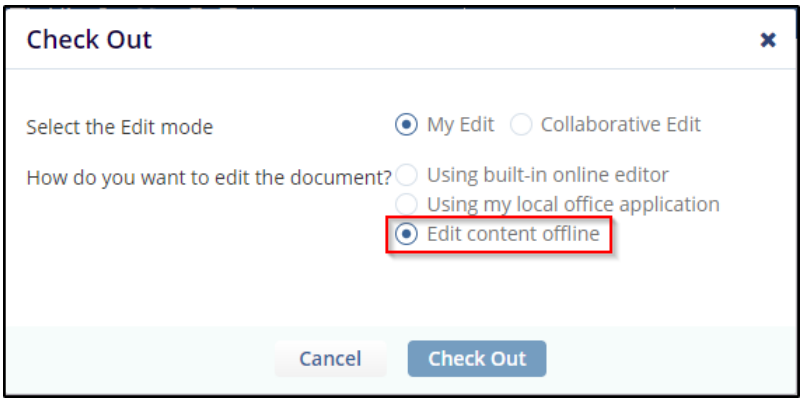
The edited document gets its version up in the metadata.The versioning can be seen in under theVesrions button in the Metadata pane.

Note: Editing a document offline is explained in the subsequent topic.

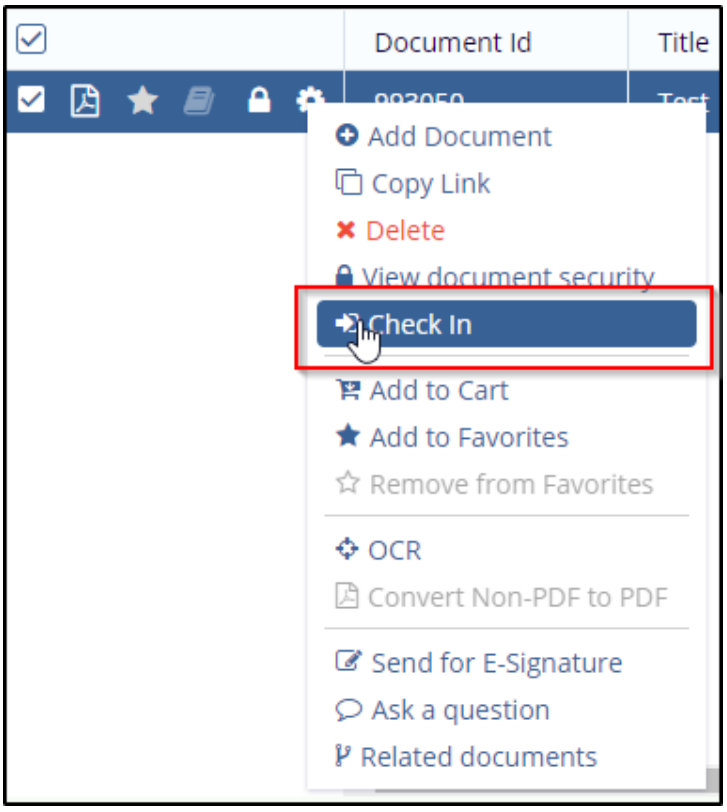
Offline Edit

To edit a document offline,the system prompts you to download the document.

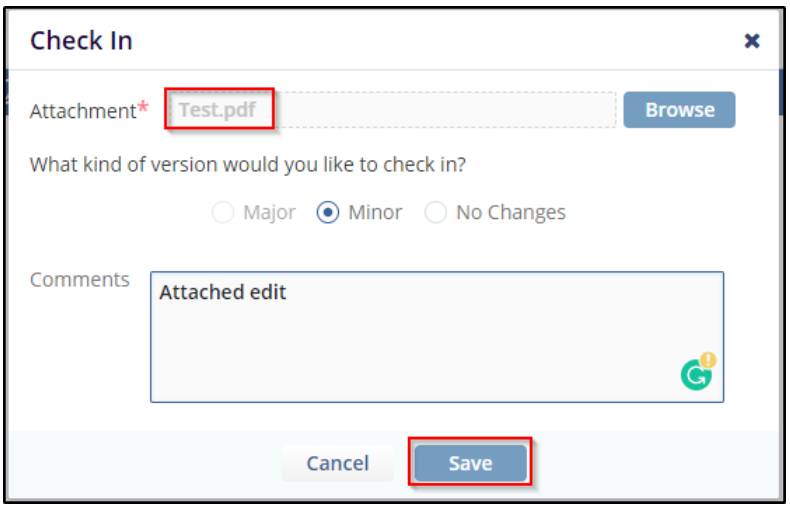
Select the edit mode to My Edit and check the 'Edit Content Online'button as shown in the screenshotbelow



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 thescreenshot below.

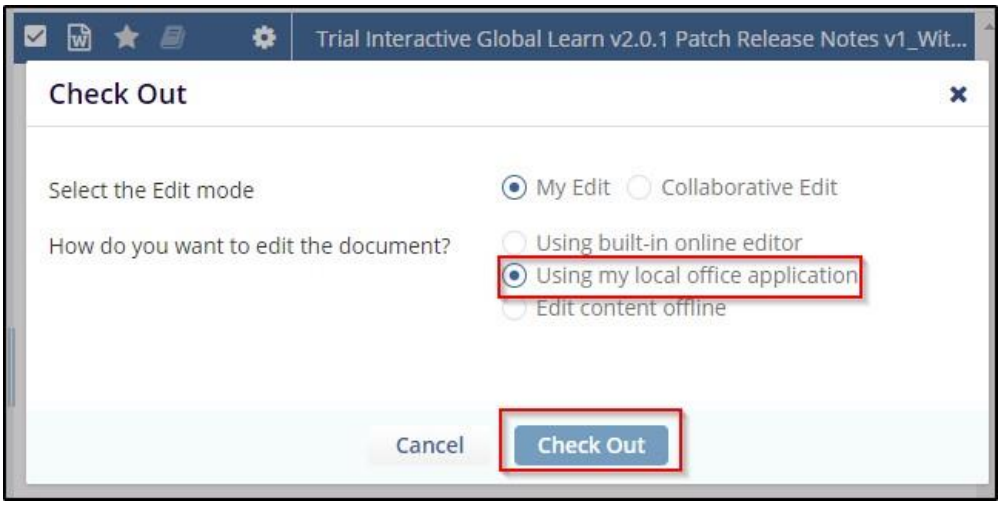


The check in button opens up a Check In pop up that prompts you to attach the edited document. Make your comment in the comment box to save the edit. The edit will be vesrioned up same as theonline edit.

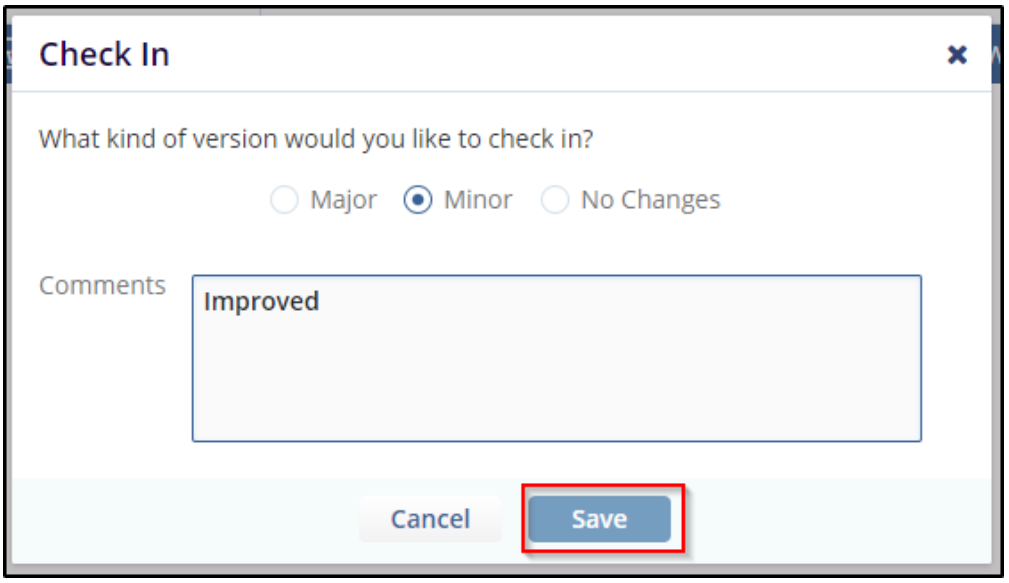


Using My Local Office Application

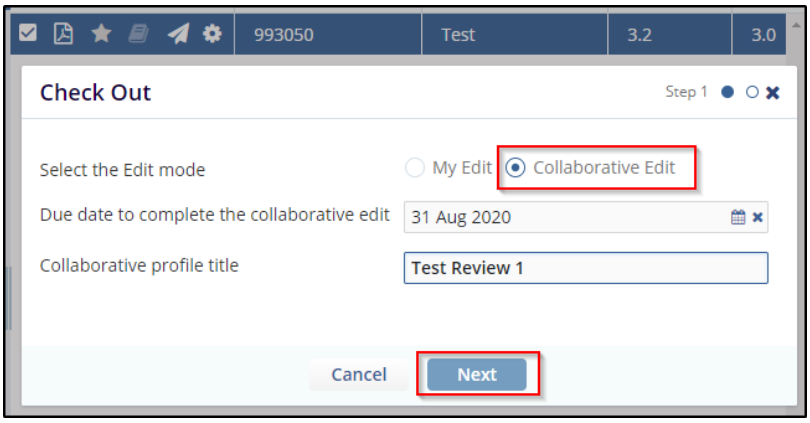
Editing a socument using local office application is same like editing content offline.Here too,thesystem prompts the document download. You can edit the document using your local office application and perform the check in process. Refer to the screenshots below.



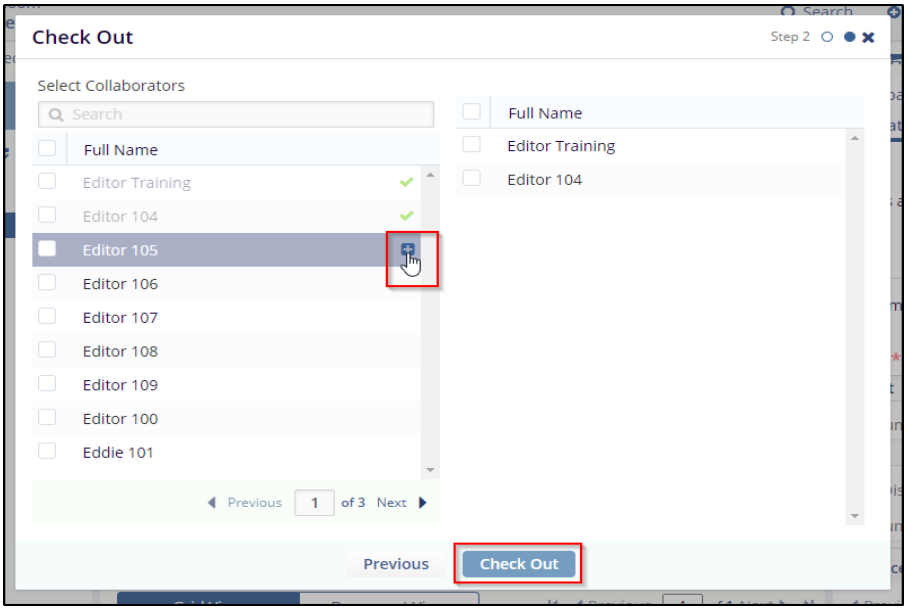
Once you click check out, the system prompts to open the local office to perform the edit. The editedversion then can be cheked in the system with your comments for version up. Refer the chek in screenshot shown below.



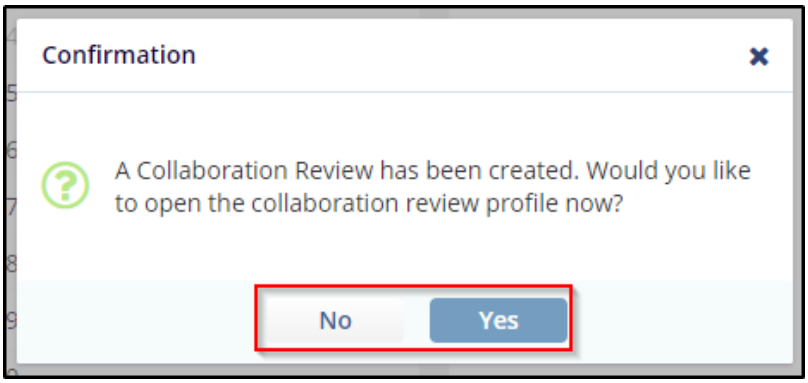
Collaborative edit is performed within a team of editors. The edit initiator can include the editors from this operation. The users can also set the due date to complete the collaborative edit. To initiate a collaborative edit, click the gear icon available in the document grid and click check out. The checkout 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.



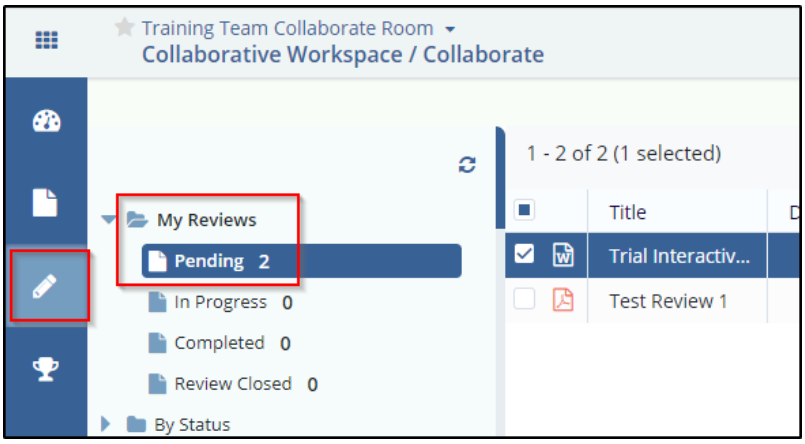
Once you click the Next button, the system takes you to the Step 2 window. This allows you to select the collaborators. To select a collaborator click the 'plus' icon available near the name of thecollaborator. The selected collaborators will be displayed in the right side of the window. Also a green tick is seen in the list available at the left side.



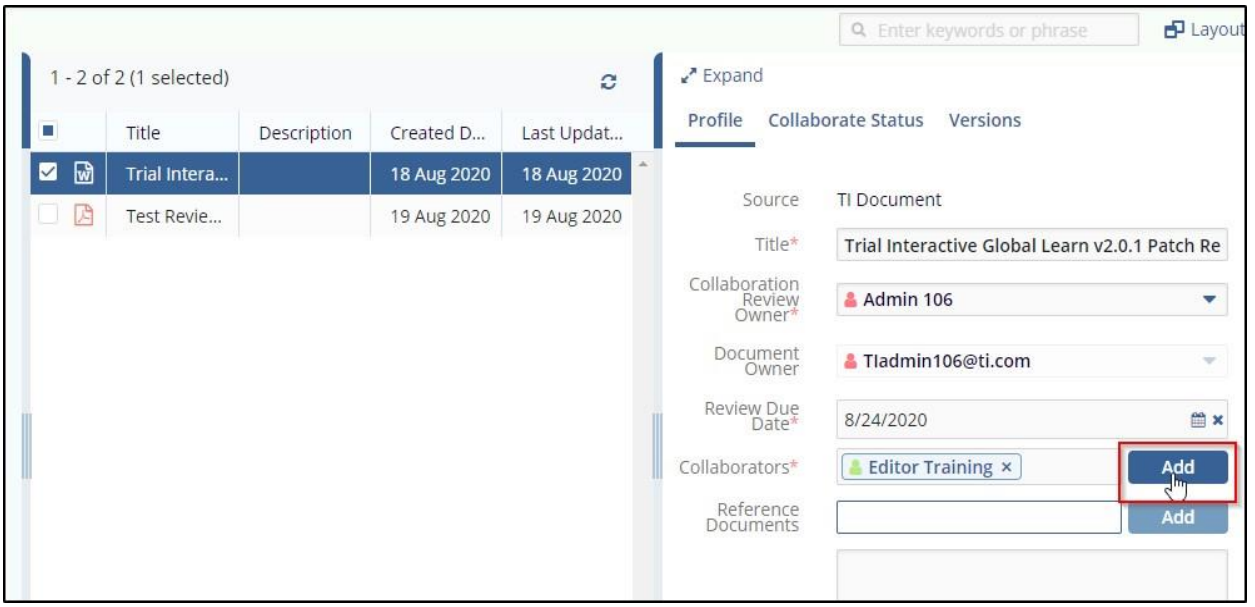
Once you select all the collaborators, click Check out. The system will prompt you for a confirmationwith a question 'A Collaboration Review has been created. Would you like to open the collaboration review profile now?' Select the appropriate option to proceed further.



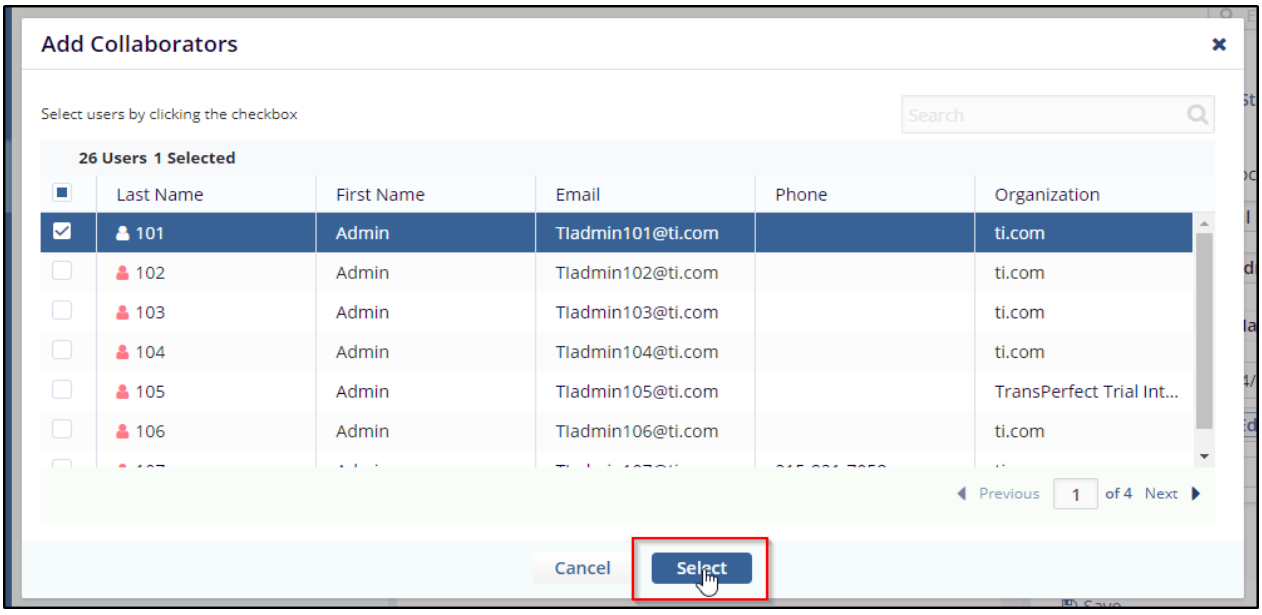
The initiated collaborative edit is seen under my reviews folder under the subfolder 'Pending'. Referthe screenshot below



The collaborators can be added to the review via add button under the profile tab of metadatapane. Refer the screenshots below.

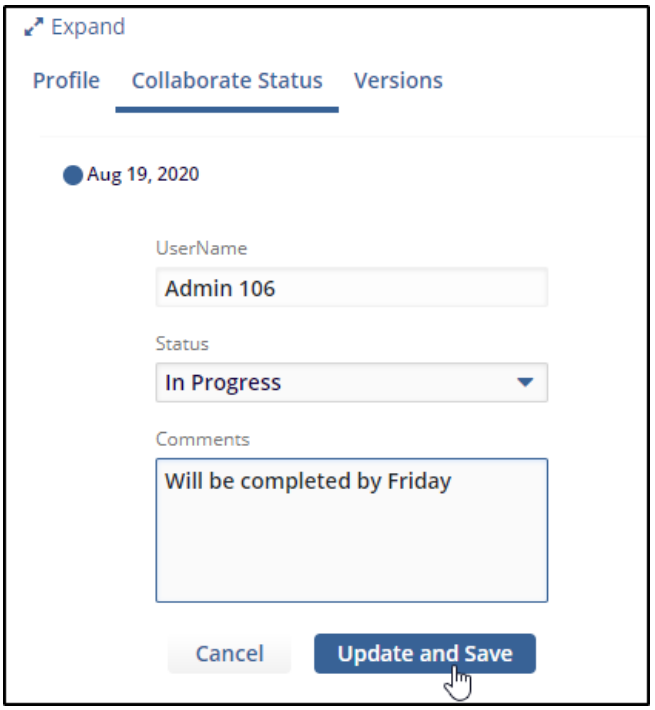


Clicking the Add button will open the Add Collaborators popup. Here you can select collaboratorsavailable from the list. Refer the screenshot below.

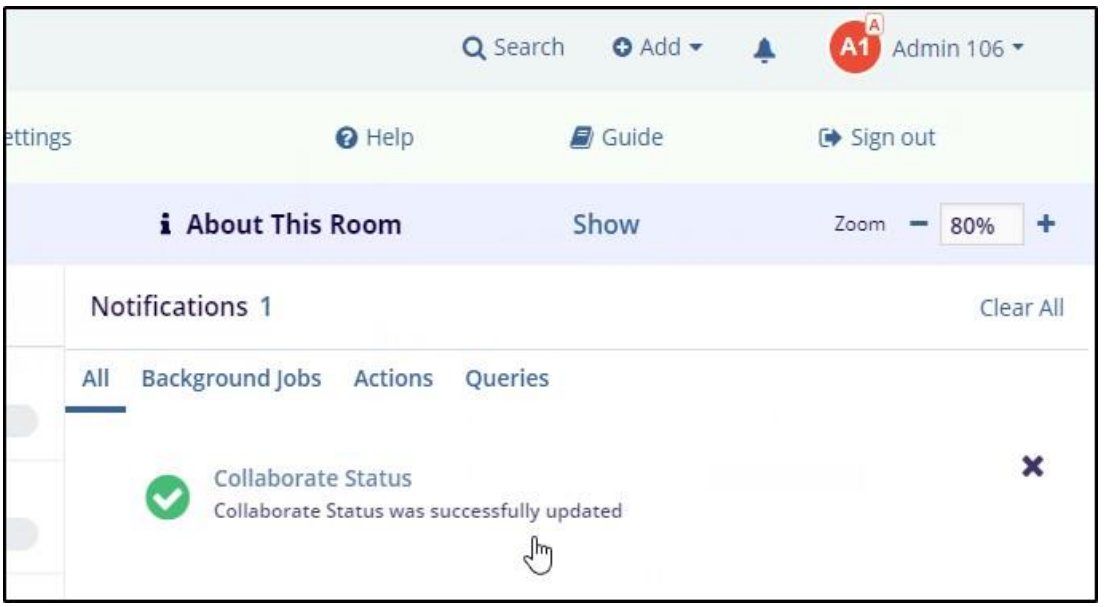


A collaborator can add status by clicking the 

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 putin the comments to update and save the collaorate status. Refer the screenshot below.



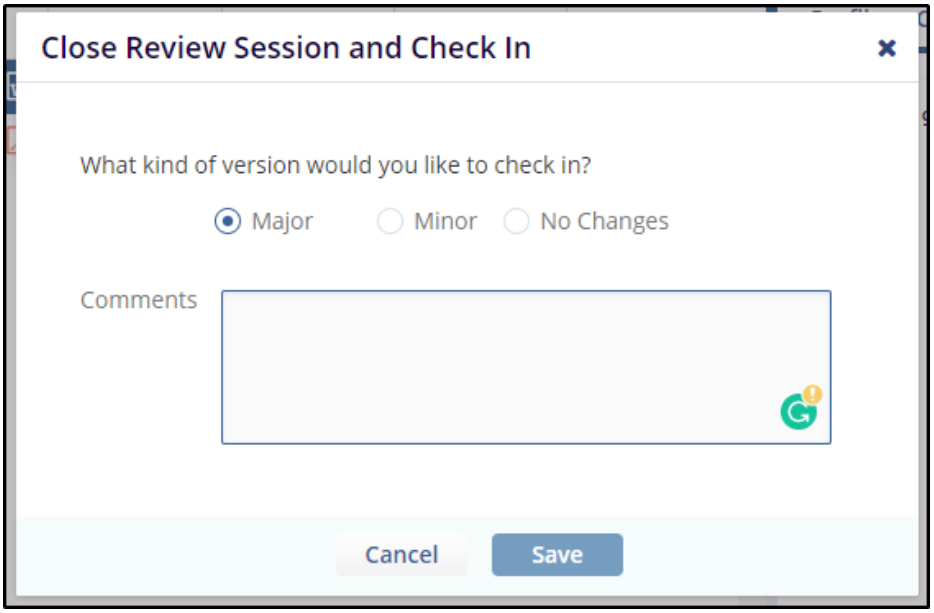
A notification will be available for the executed update



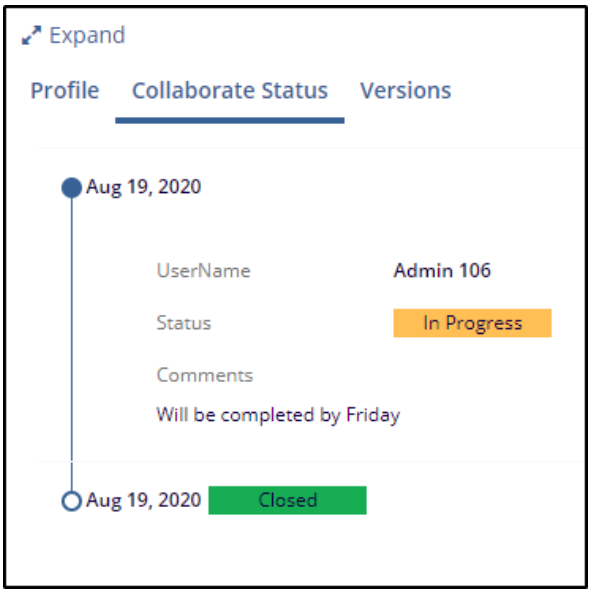
Close Review Session and Check In

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 Close Review Session and Check In button available under the Collaborate status tab in

the metadata pane. Clicking the Close Review Session and Check In button will open the followingpopup 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.



Simplified Site Security

When providing site users access to a study, it is important that security is automatically assignedto ensure that users can complete their tasks, such as document upload, certification, redaction, indexing, reconciliation with the regulatory binder, and sharing to the eTMF while preventing accessto material that they are not authorized to see.

Upon creation of a new user, a designation of Site User can be made along with the assignment of thesite. Specific permissions are assigned to these users based on a predetermined sitetemplate-folder security configuration. This will allow users to be provide the correct security profile right away to provide them immediate access to the Site Collaborate room.

Given the security required in a Site Collaboration room, the creation of new users in this room will be handled by the Trial Interactive Service Desk in accordance with your previously defined securitysetup. To have a site-specific user added to a Site Collaboration room, please reach out to your Trial Interactive representative or directly to the Service Desk.

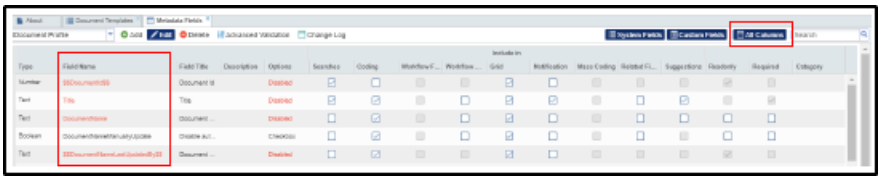
Site User Identity Verification

In order to prevent unauthorized users requesting and gaining access to a site's data, site users are assigned to their site, and a secure PIN code can also be optionally required as part of the request foraccess. Site administrators that are part of a restricted site group can view the PIN code and include the PIN as part of a new user access request. Trial Interactive Service Desk personnel always verify the PIN code as part of granting access to the site.

Headers Footers and Watermarks

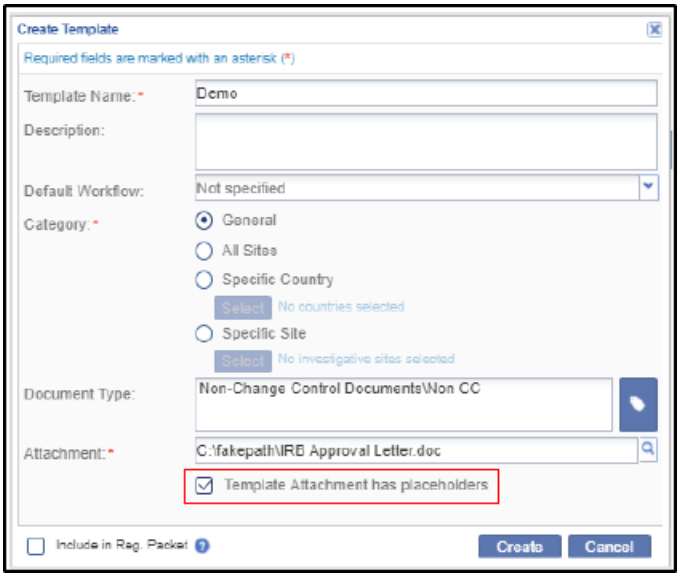
Controlled document workflows often require that headers, footers, watermarks, and other fields to be filled in automatically when the document moves to an effective status. Users can now selectdocument templates that have defined form fields that will automatically populate with metadata information from the document profile.

These template documents can be created in Microsoft Word™ using the Content Control options inthe Developer menu tab. Values for these fields can be located in the Settings module by navigatingto the Forms Settings menu. Select the All Columns option as shown in the screenshot below. The Field Name column will contain the necessary values in order to create the data injection field in Word™.



Once a template document has been created, it can be uploaded to the Document Template menu in the room's Settings module. The process follows the directions laid out in the User Guide section on

Settings with one exception. As shown in the screenshot below, the Create Template window nowhas a field labeled "Template Attachment has Placeholders" which will need to be checked upon uploading a document intended containing data injection fields.



Controlled documents can populate values such as document name, document identifier and other document specific values into the document itself, ensuring that the document and the document's information match. These may be applied in the header, the footer, another location on the document,or the watermark itself. This streamlines the document finalization process as users do not have to manually populate key document information. Templates with the metadata values added as controlled fields will allow for the metadata injection.

Once a document has been created in the Content Management room (see the related section in the Content Management User Guide), the document will have to be checked out or otherwise opened ina content review session in order for the fields to be automatically filled.

Improved Document Owner Privileges

In many cases, the user listed as the Document Owner will not be the only one who needs to have permission to send a document for review and initiate a workflow. To that end, we are introducing anew folder security feature called Proxy Document Owner. Any user indicated as a proxy document owner via the folder security settings can then perform document owner functions for the documentsin that folder.

In order to assign a user as a Proxy Document Owner, follow the steps below:

1. Navigate to the Documents Library in your Content Management room.

2. Locate the folder whose security settings you wish to adjust.

3. Right-click on the folder and select View Folder Security.

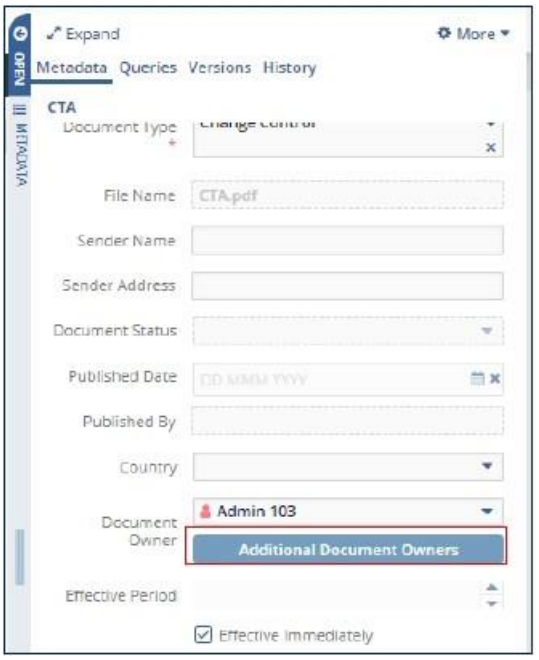
4. Select the Group or User who should be added to the folder security and move them to theright side of the window.

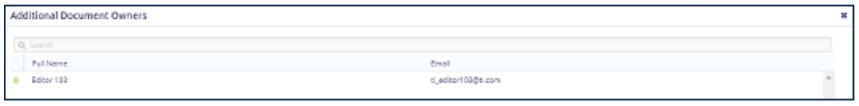
5. Once they are there, you will need to give the Group or User the Proxy Document Ownerpermission as shown in the screenshot below.

6. Press Save to complete the process.

For a more detailed discussion of folder security, please see the related section in the User Guide.

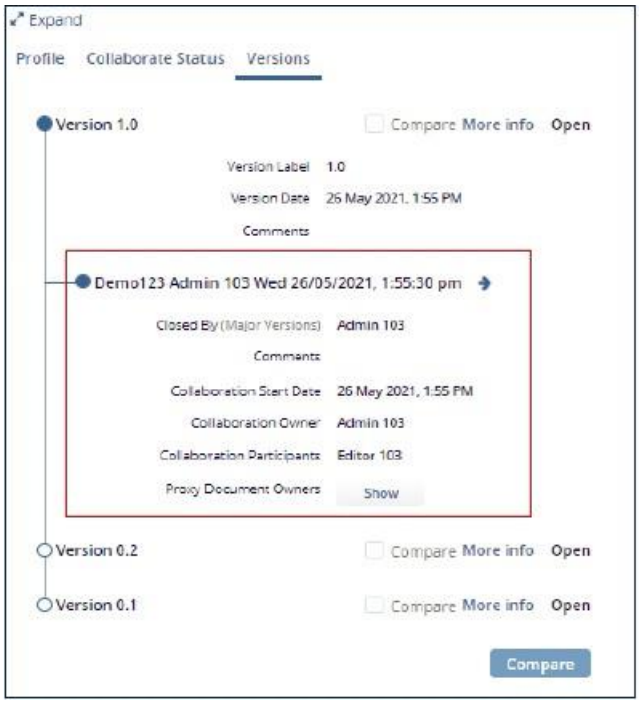
Once a user has been assigned as a Proxy Document Owner, they will appear on the list of AdditionalDocument Owners found in the Metadata Pane for any document in the folder. Please see the screenshots below:


Expand
More
Metadata
Queries
Versions
History
CTA
Document Type
File Name
CTA.pdf
Sender Name
Sender Address
Document Status
Published Date
Published By
Country
Admin 103
Document Owner
Additional Document Owners
Effective Period
Effective Immediately


Additional Document Owners

Improved Document Collaboration Visibility

When viewing the document library, it is important that any collaborative review session that is currently active on a document is easily seen. Now, information from a closed collaborative reviewwill now be displayed as a part of the Versions tab in the document's metadata panel.



Users can see what version was created, who participated in the review and when the collaborative review occurred with the Collaborative review information, putting all of the document history in oneplace.

Additionally, we have introduced the ability to mark a change-controlled document as Obsolete witha simple right-click on the document in the Grid. The document will be moved from the Index view of the Documents Library and will be stored in the new Obsolete Documents view.

Documents which are checked out or undergoing a workflow review cannot be either deleted ormarked as Obsolete.

Administrative Workflows

Effective versions of controlled documents will often require a minor housekeeping change after approval. These changes should not impact the effectiveness of the document. An example of this type of change would be the correction of a minor typo. It would be inconvenient to use the full versioning workflow in correcting such a trivial error and so we have introduced the AdministrativeWorkflow.

For a more detailed discussion of workflow creation, please see the related area of the User Guide.However, it is our recommendation that users should, where possible, reach out to the Trial Interactive Service Desk whenever assistance is needed in workflow creation or maintenance.

The key difference between an Administrative Workflow and a standard Approval Workflow is that the Administrative workflow will appear as a minor version change but the Effective date andPeriodic Review timeframe will remain unchanged from the current effective version

Dashlet - Collaborative Review

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.

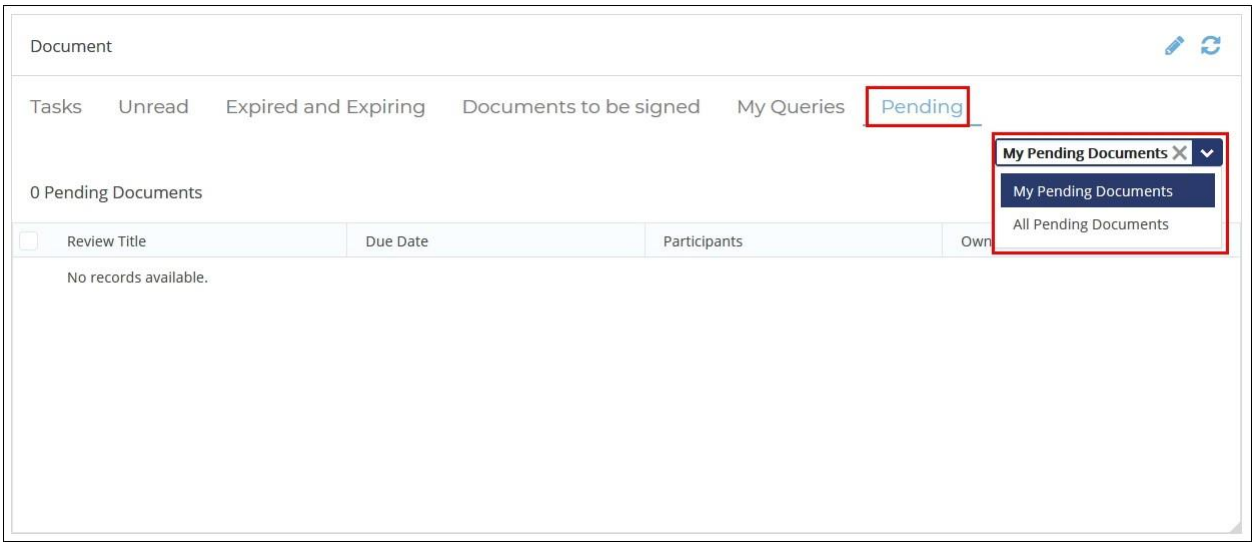
Dashlet - Collaborative Documents

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.**

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.

Chapter 23. 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 inthe 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 followedwithin 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 roleteam 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 Service Desk 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 activationprocess. 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

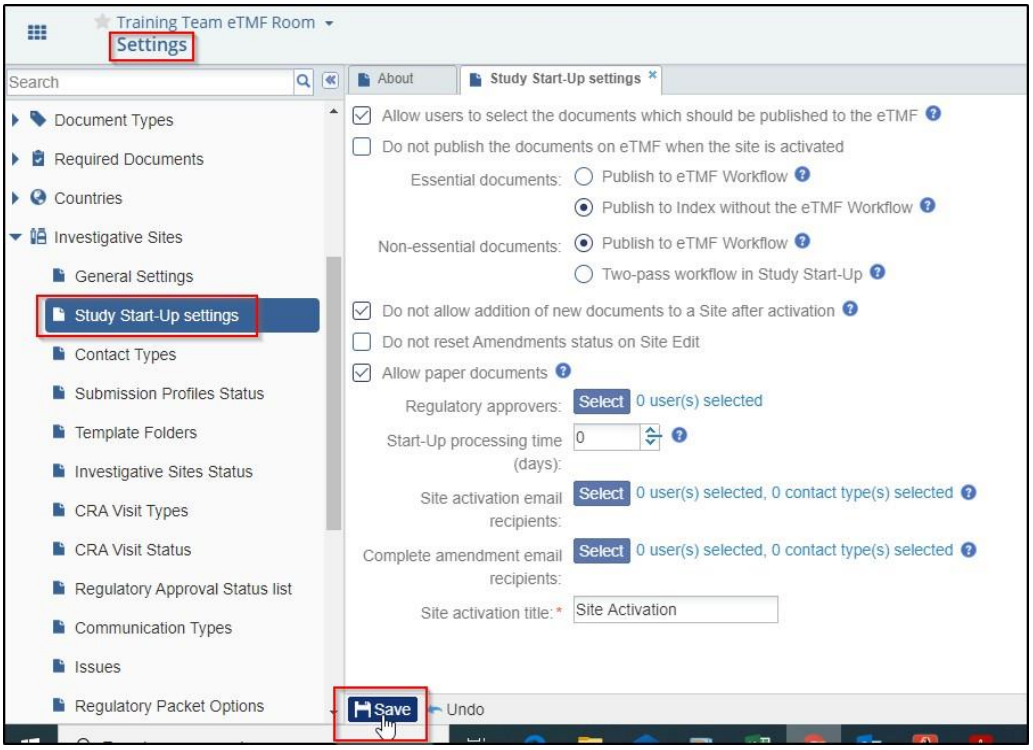
2. Click the arrow next to Investigative Sites in the left pane of the Settings window

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



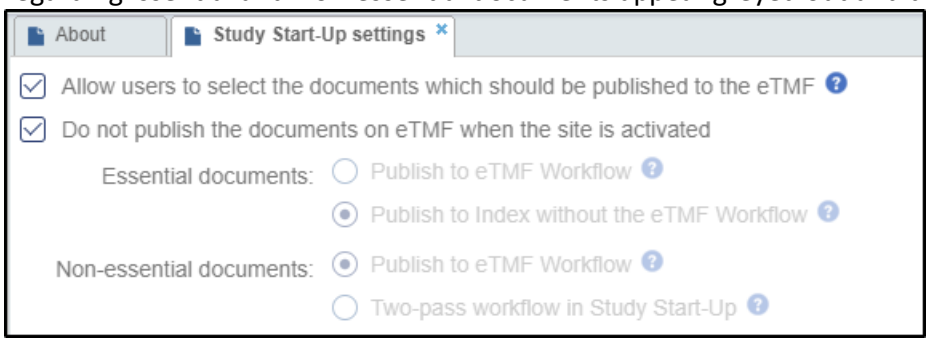
Referring to the screenshot above, the SSU settings window can be divided into two sections:

1. Settings regarding essential and non-essential documents on site activation

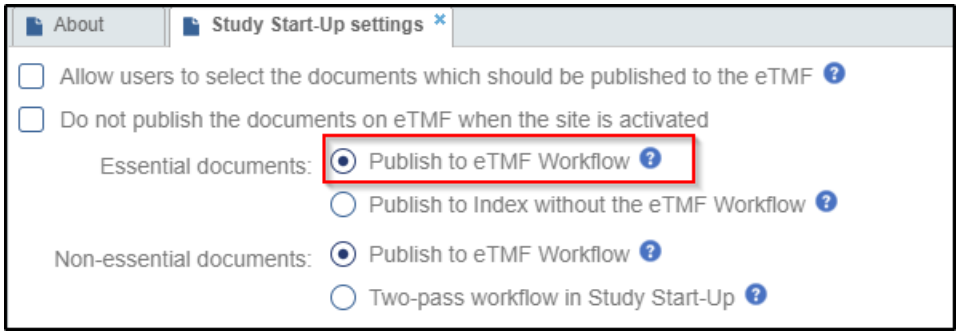
2. Other settings

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 regardingEssential and Non-essential documents appear greyed out and disabled.

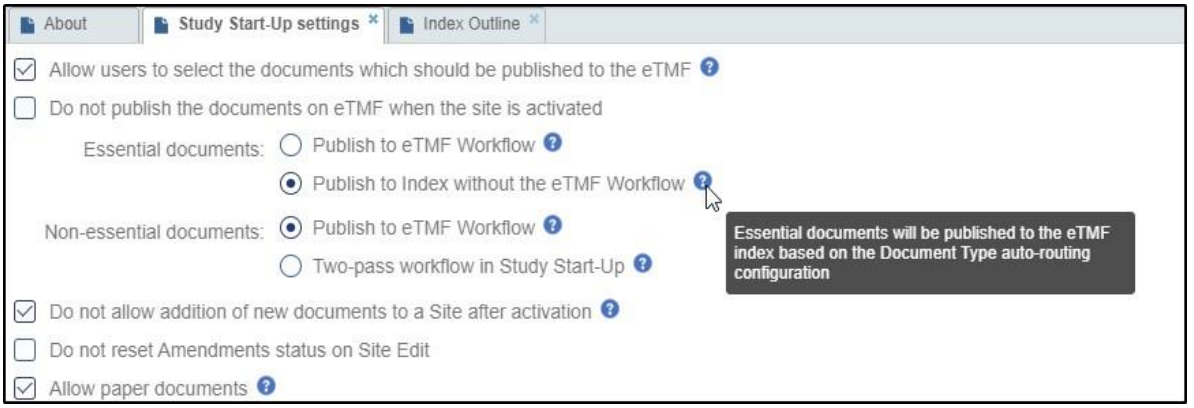


- If you wish to publish the essential and non-essential documents on the eTMF Workflow, selectthe radio button next to the option. These documents will be added to the workflow specified
in your system on site activation and will be taken up for QC Review as per the process. Onpublishing the documents will be added to the default folder as specified in the Documents section under the room settings.



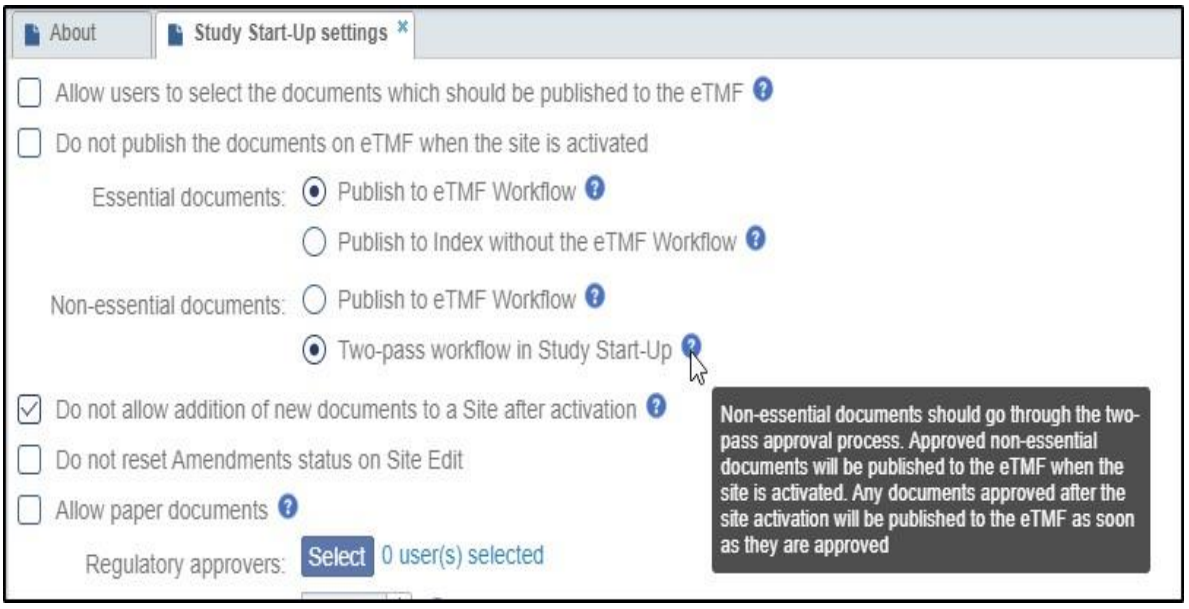
Note: *To be added to the workflow, documents should match workflow conditions. If the document is not matched to workflow conditions, it will be just placed to the default index position.*

- 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

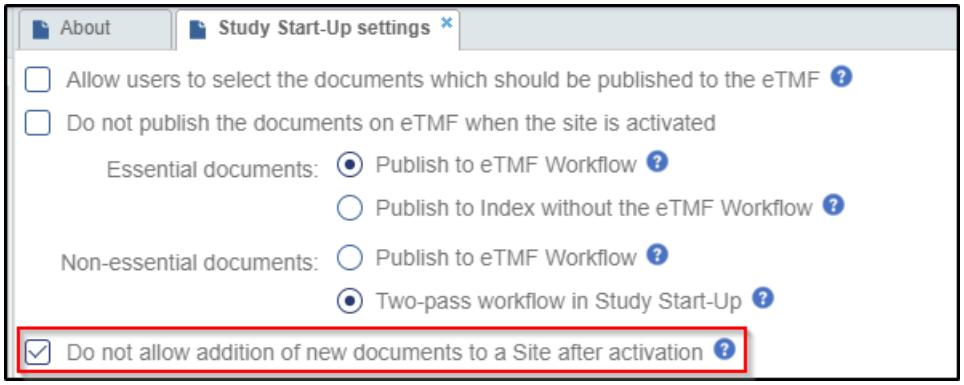


to in the eTMFon site activation.

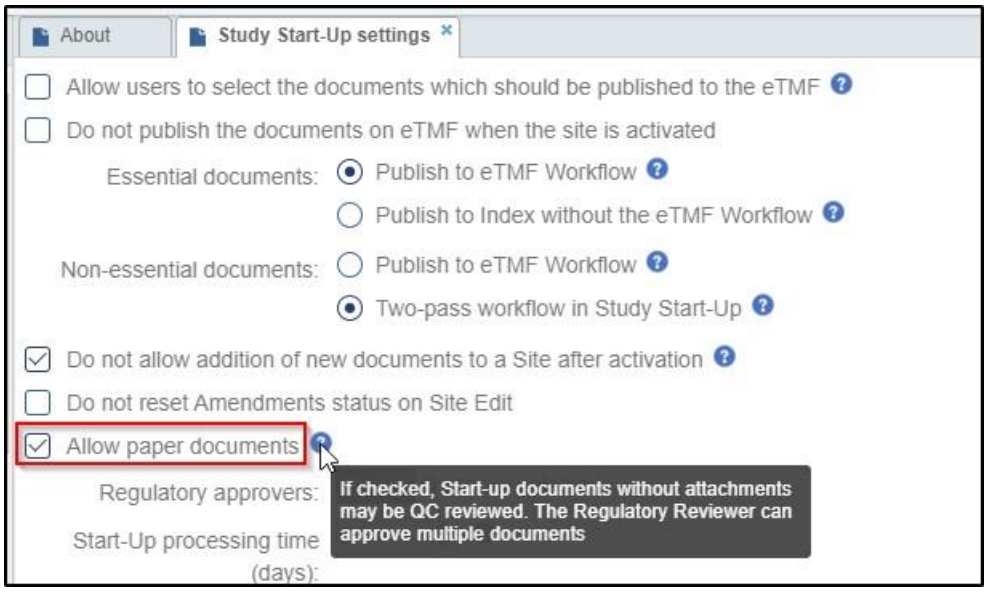
- If you wish the non-essential documents to pass through the two level approval process in SSU,select the radio button next to the option. These documents will need to be approved through QC Review, and Regulatory Review, and will be published on the eTMF with Final status on site activation. If documents are approved after site activation, they will be need to be publishedto the eTMF manually. Position in the eTMF index for these documents will be provided by thesystem as per the Auto-Indexing rules. You will need to enable auto indexing in the Documentssection 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 asshown below:

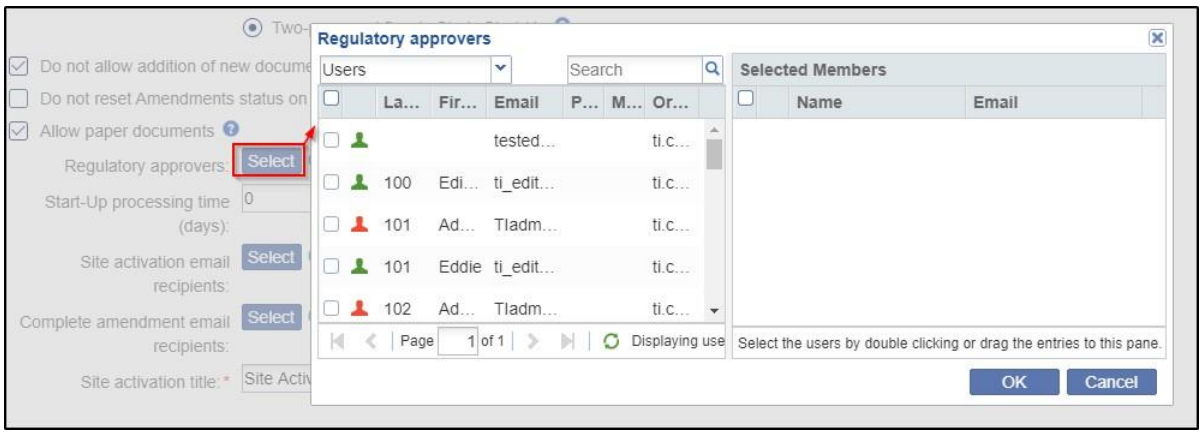


- If you need to submit paper documents instead of their soft copies, you may choose 'Allowpaper documents' option as shown below. Such documents can be uploaded without attachments and can pass through QC Review, and Regulatory Review.

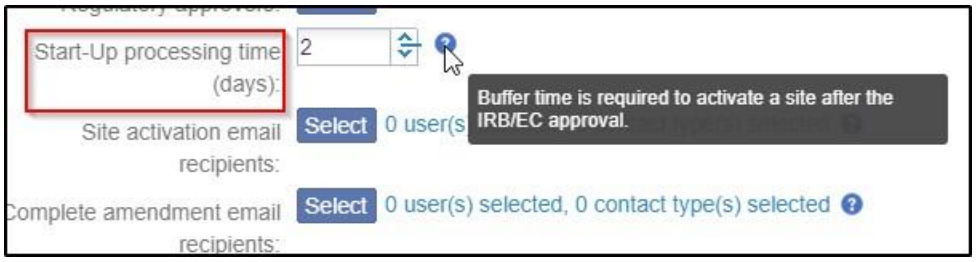


Other Settings

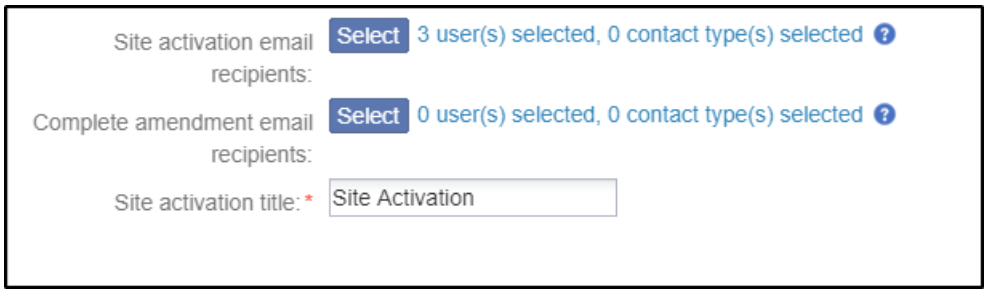
- From this section, you can add Regulatory Approvers globally for all sites in the room. This is discussed in section Adding Regulatory Approvers.



- 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 onsite activation, and on completion of amendment documents (documents added to the site after its activation), and the title for site activation.

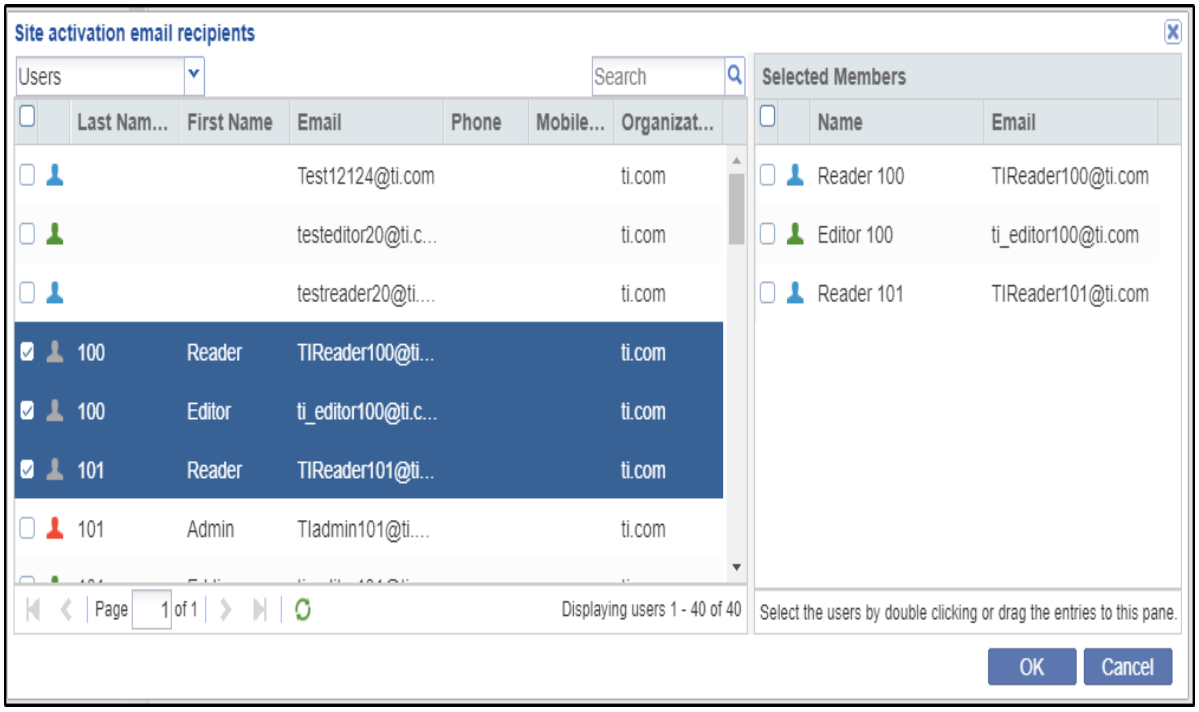


Click the Select button to select the users/contacts who should receive email notifications on site activation. This will open the Site activation email recipients/Complete amendment emailrecipients window as per your selection:

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 bydragging 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. Thesesettings 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

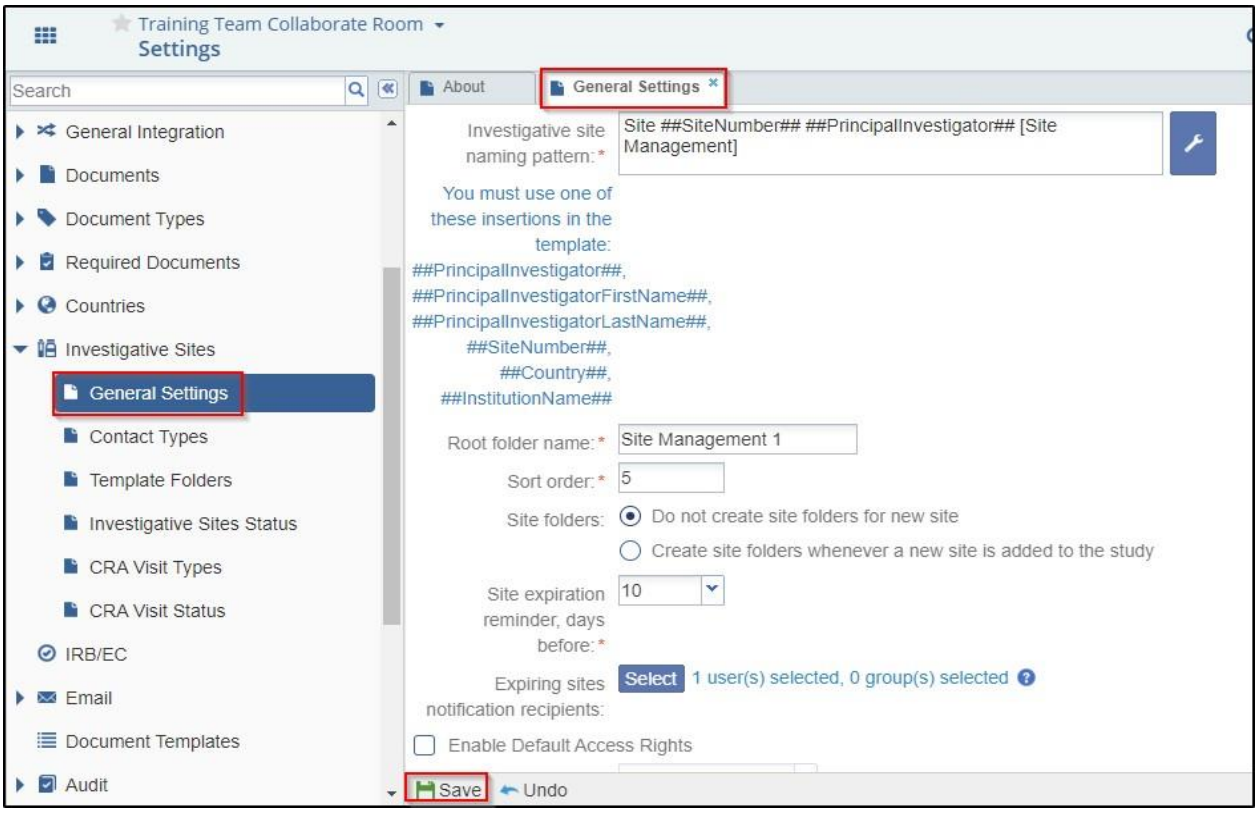
2. Click the arrow next to Investigative Sites in the left pane of the Settings window

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.



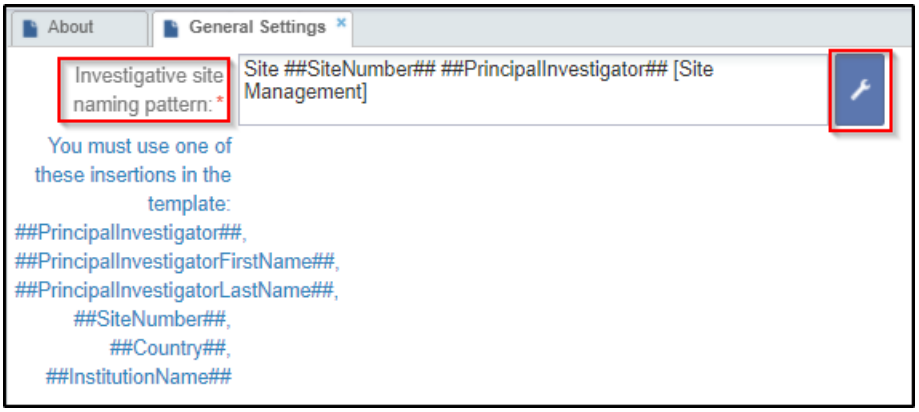
Referring to the screenshot above, the General settings window allows the following to be defined:

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

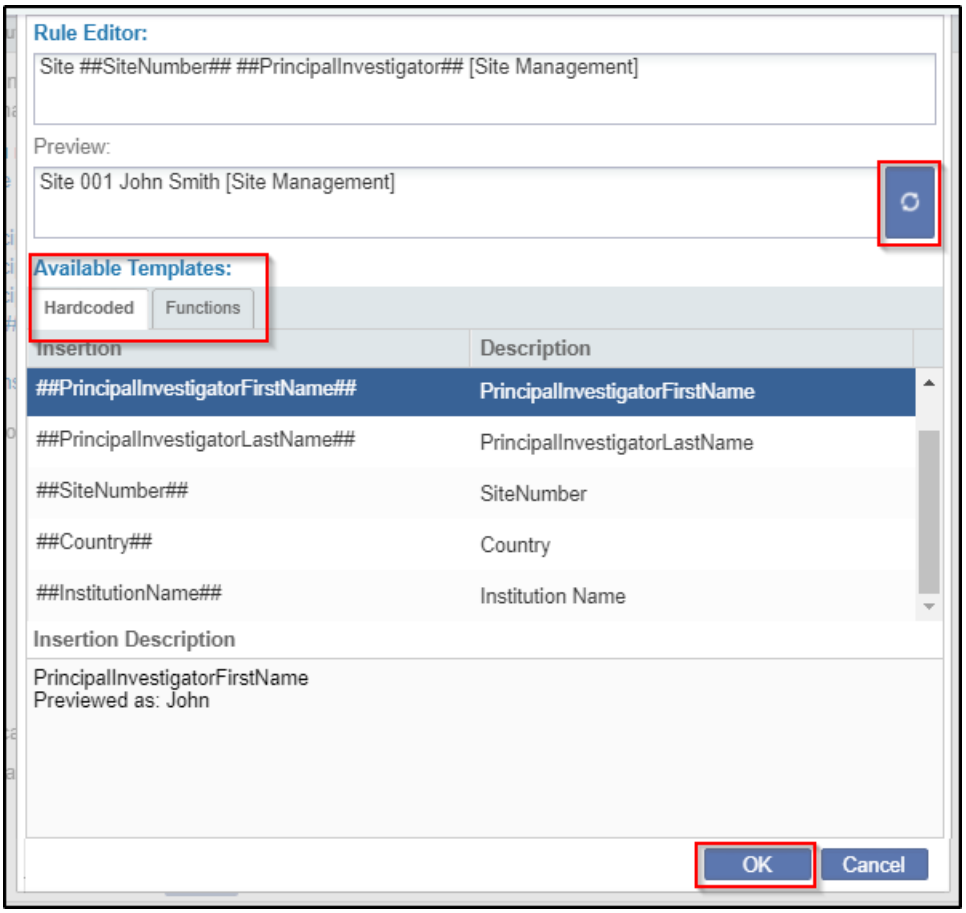
1. Site Naming Pattern

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 NamingPattern.

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 refreshicon 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.



2. Root Folder Name

The Root folder name is set in compliance with the organization's preference. This is the title that isgiven 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.

3. The Sort Order

Selection of the Sort Order for the Site Management folder is made in the next field. This dictateswhere the folder appears in the room's folder index.

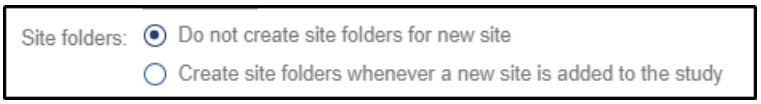
a. Click in the field.

b. Type the number of the client's preference.

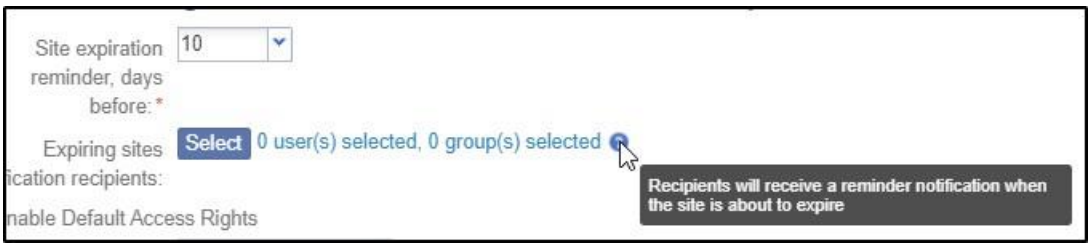
c. Hit Enter on the keyboard.

4. Creation of site folders

The options listed here decide when site folders are created for a new site. The box contains threeradio buttons for Site folder options. Click on the option that fits your needs.



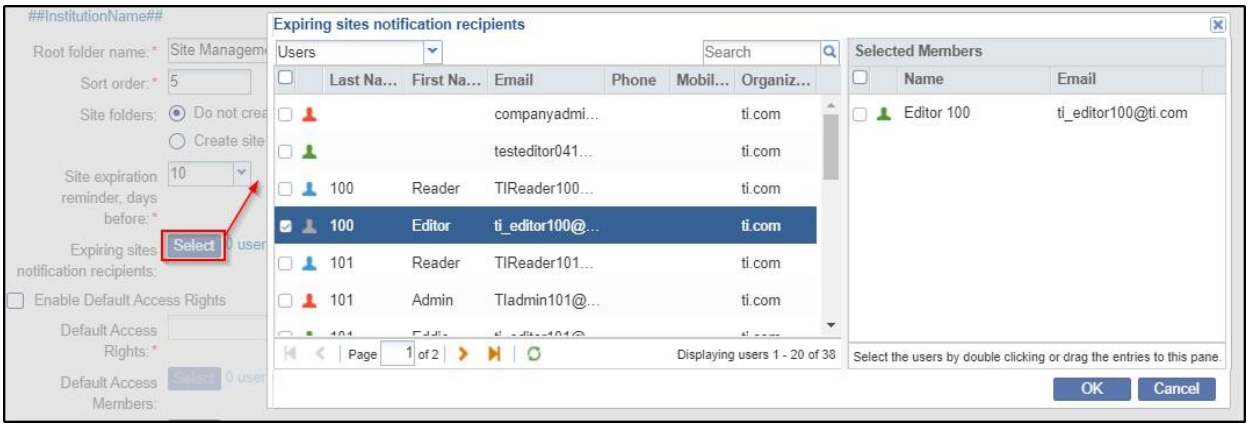
5. Site expiration reminder period



The options here allow you to set the number of days before a site's expiration and when notificationswill be sent out to the users who are selected as the 'Expiring sites notification recipients'.

6. 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.



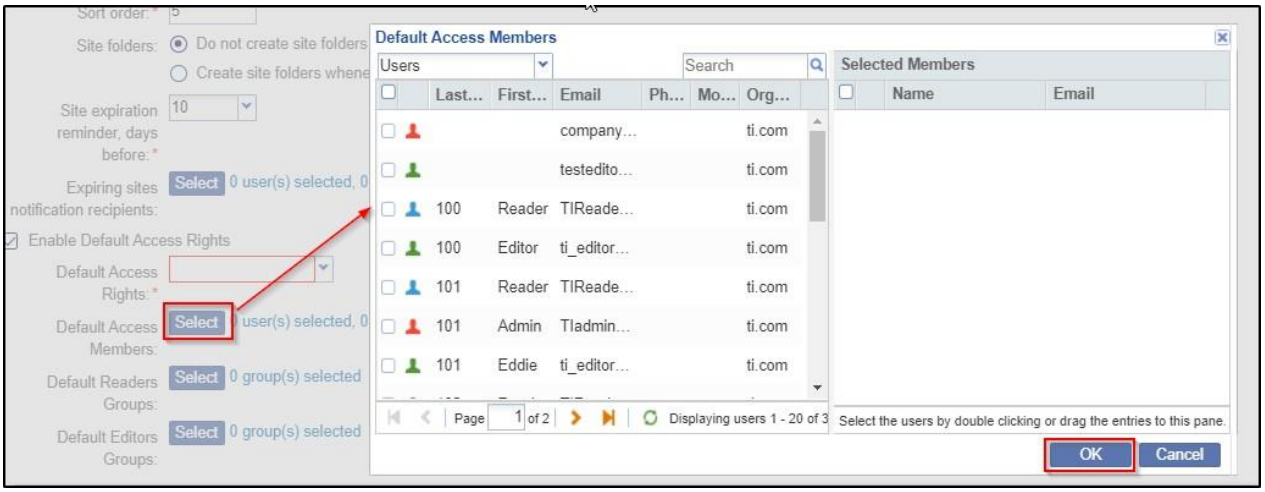
7. Site default access rights and members

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 Accessoption.

To define the default acess rights select any one from the dropdown available with the DefaultAccess

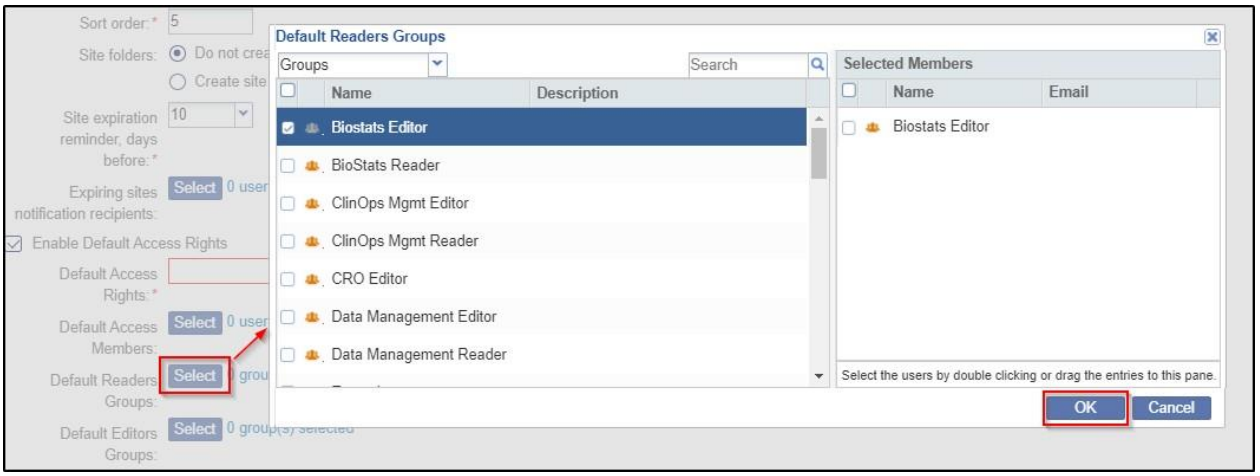
Rights option.

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 Okbutton at the bottom of the popup to save the changes.



8. 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 themto 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.



Adding Countries to Data Rooms

To add countries from where the sites will be enrolling to the study, the administrator needs to do thefollowing:

1. From the Settings section, click the arrow next to Countries from the left panel to collapse itsdropdown.

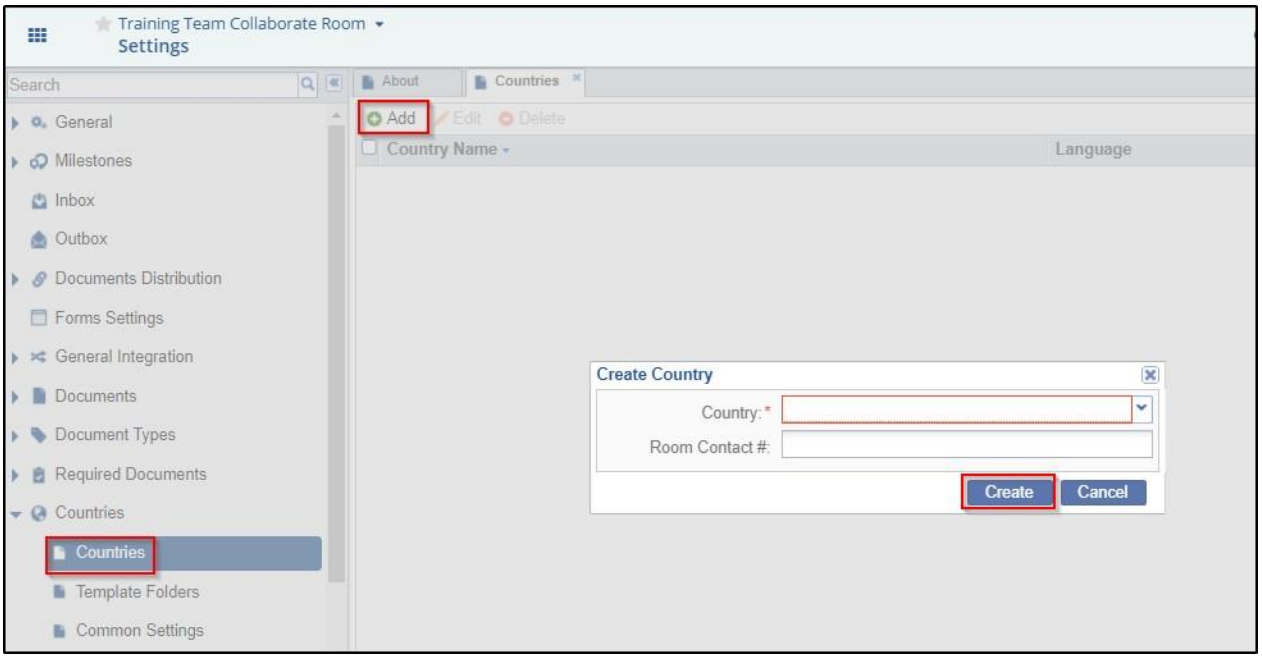
2. Click the sub-option Countries from the collapsed options to reveal the Countries window in theright.

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 theIRB Meeting Date.

b. Click the Committee tab in the popup. This allows you to add the details of Ethics Committeeassociated with the IRB.

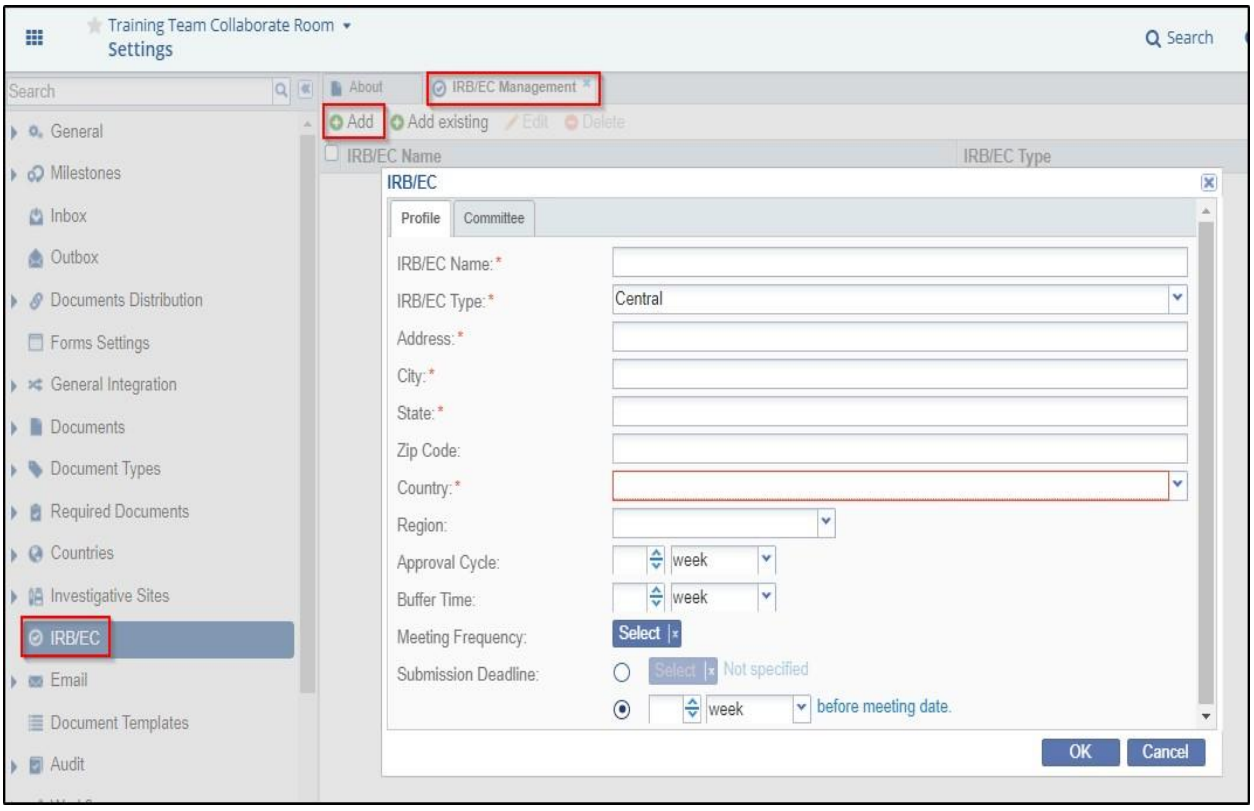
c. Click Add in the Committee tab. This will add a new row to add an ethics committee by the nameof 'New Committee'.

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.

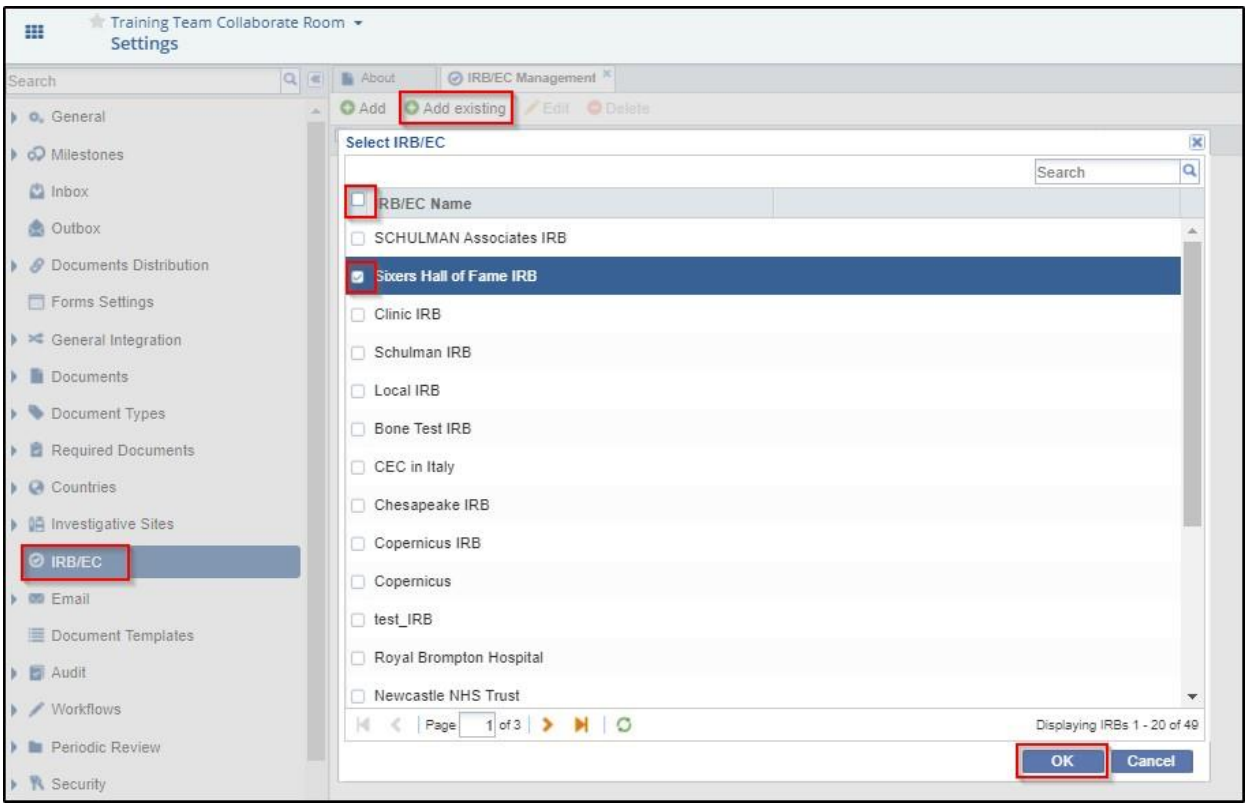
5. Repeat the process for as many IRB/ECs as required. Refer to the screenshot below:



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 listingthe 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:



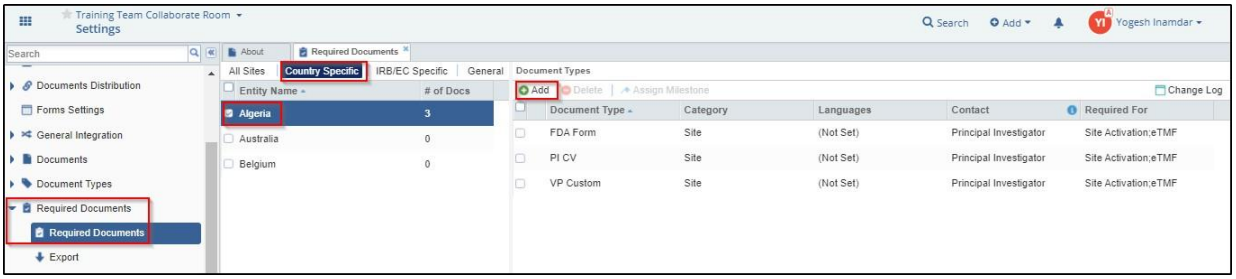
Setting up Required Documents for Countries

For the user to upload collected essential documents for countries, the document types for the sameneeds 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 RequiredDocuments window in the right.

3. Click the Country Specific tab from the top menu options of the window. Refer to the screenshotbelow:



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.

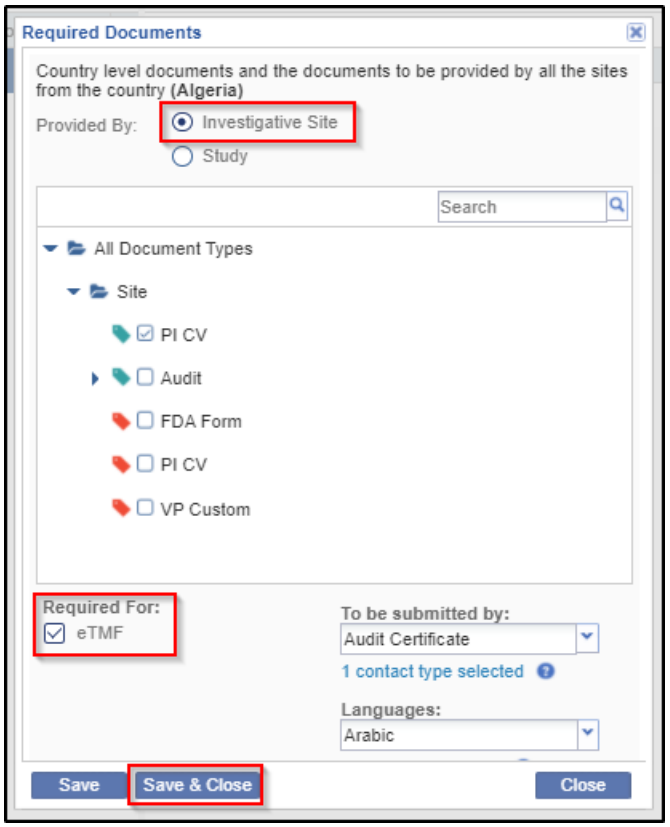
7. Select documents as required from the collapsible tree structure listing the documents.

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:


Required Documents
Country level documents and the documents to be provided by all the sites from the country (Algeria)
Provided By:
Investigative Site
Study
Search
All Document Types
Site
PI CV
Audit
FDA Form
PI CV
VP Custom
Required For:
eTMF
To be submitted by:
Audit Certificate
1 contact type selected
Languages:
Arabic
Save
Save & Close
Close

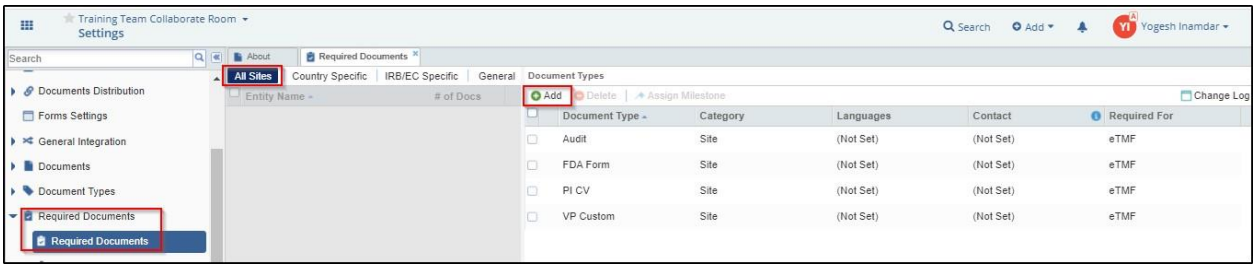
Setting up Required Documents for All Sites

For the user to add essential documents for sites, the document types for the same need to be setup bythe 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 RequiredDocuments option in the left panel.

2. Click the sub-option Required Documents from the collapsed options to reveal the RequiredDocuments window in the right.

3. Click the All Sites tab. Refer to the screenshot below:



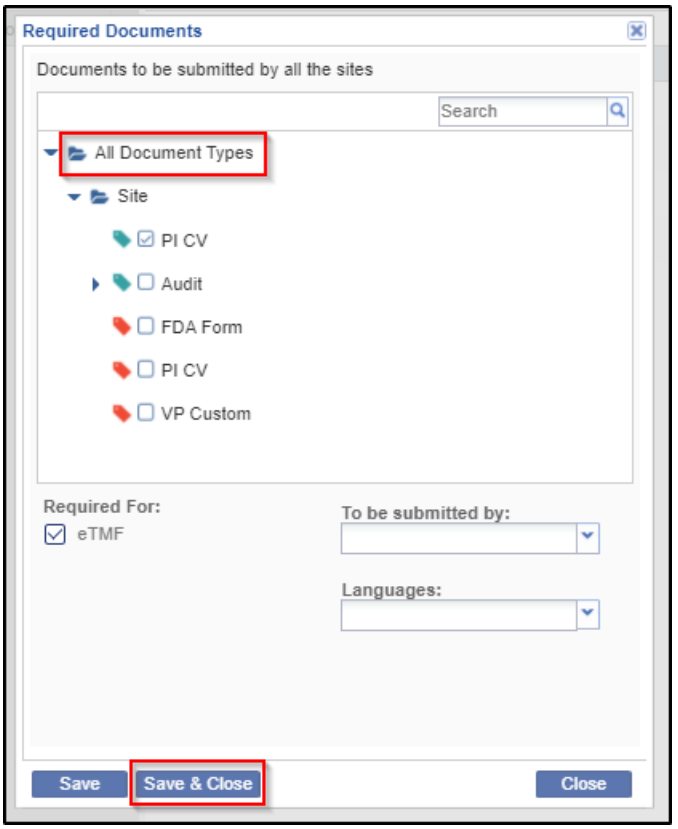
4. Click Add from the menu bar on top of the Document Types panel.

5. This will open the Required Documents window. Select documents as required from thecollapsible 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 canbe 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 RegulatoryReview as follows:

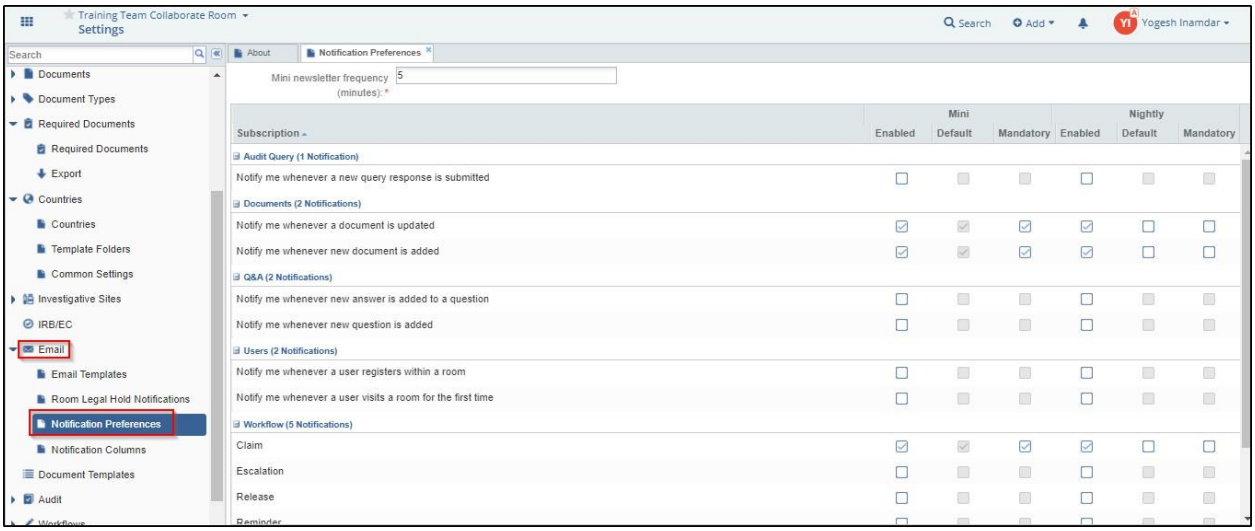
1. Navigate to Username dropdown -> Settings

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/RequiredDocuments 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 functionslike 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 aCRA 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 Specialistwill 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 notificationscan 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 createdwithout 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 variousintricate and complex procedures to users who only review and sign documents in a site. To enablethem 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 toa 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 specificroles in a site?

3. Does the user need to oversee the complete site activities, or is it enough for the user to only be acontact 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 membersto 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 laterin this

2. These security privileges can be assigned at two levels:

a. At room level:

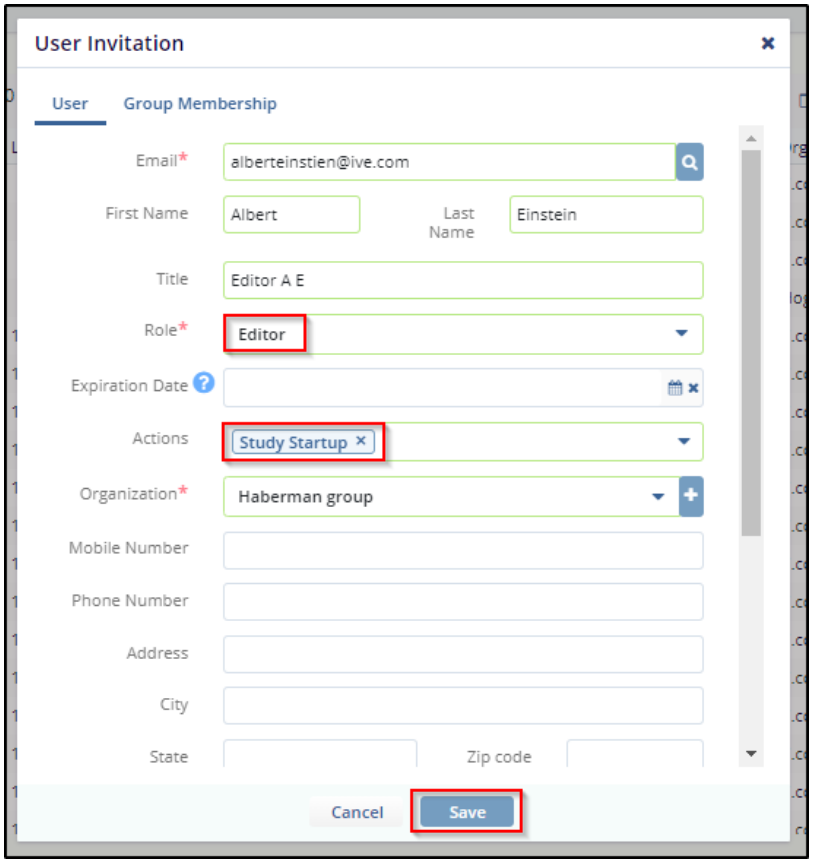
If users are already registered in the room skip the below mentioned process.

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 jointhe 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 socreated 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 beadded 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 theuser 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 sitesthe 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.*

The Study Start Up Module

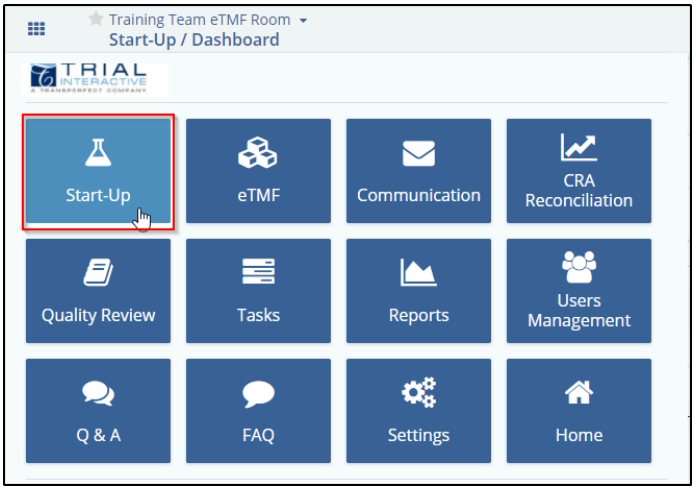
Once you set up the basic configurations and contacts for Study Start Up, you can now move forwardto operate the module. The Study Start Up Module comprises of the following topics.

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

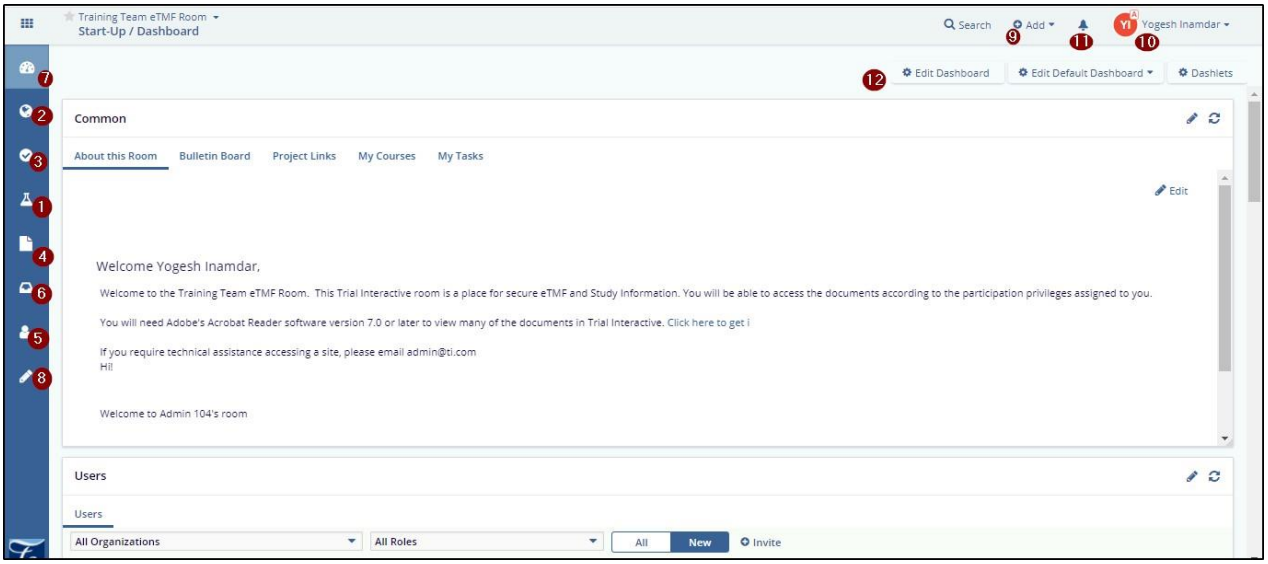
To access the Start-Up Module (SSU), click the Navigation Grid and then the Start-Up icon. Thiswill lead you to the Study Start-Up dashboard. Refer to the screenshot below:



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, andkeep 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 belowfor 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.

Sr. No.	Part	Description
07	Dashboard	Here the users can view variuos dashlets.
08	Regulatory Review	Allows the users with an aceess as a regulatory reviewer to review the documents assigned to them.
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

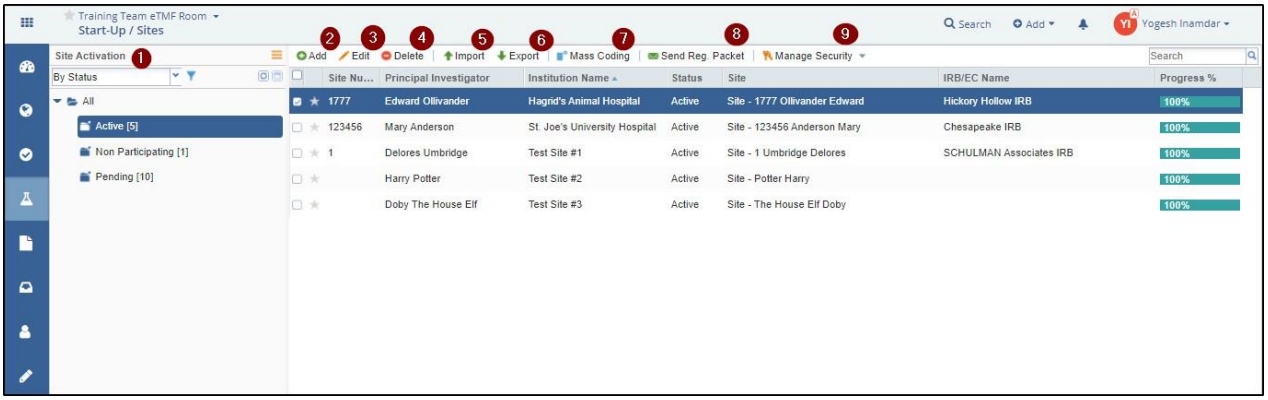
The Sites tab comprises of the following functionalities in Study Start Up

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 andapprove 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 listof 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 aparticular 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

Importing Sites and Site Contacts

This feature is especially helpful if you want to create many sites at once. This is done by enteringthe 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 twosheets – 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 sitesand 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 siteswill not be imported.

3. Start-Up Specialists and CRA cannot be imported. You will need to add these later and can useMass 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 regulatorypackets are sent.

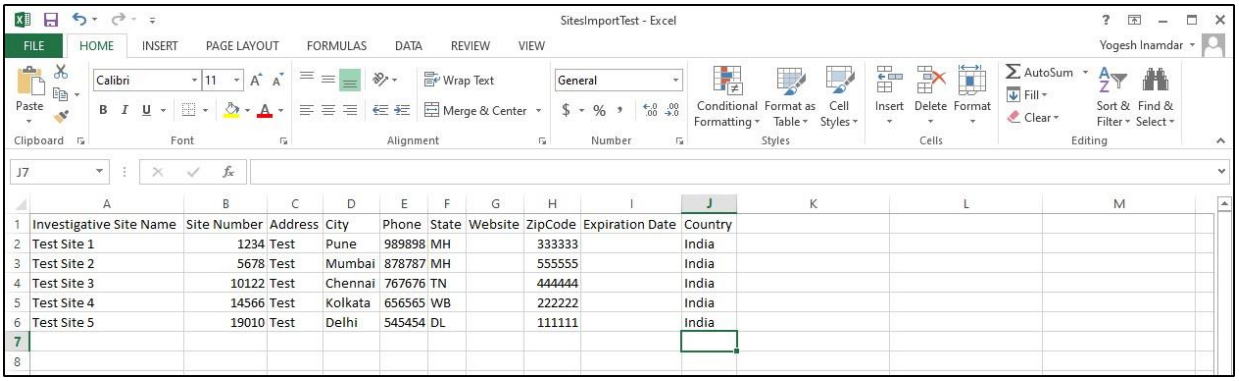
7. If you want a contact to be an Active Contact, Main Contact, or Provide Documents, enter numerical '1' in the Contacts sheet for the fields. The system will automatically map the data andset the actions allowed for the user. On editing the contact from the site profile, you will find the checkboxes 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 onlymanually or through the API.

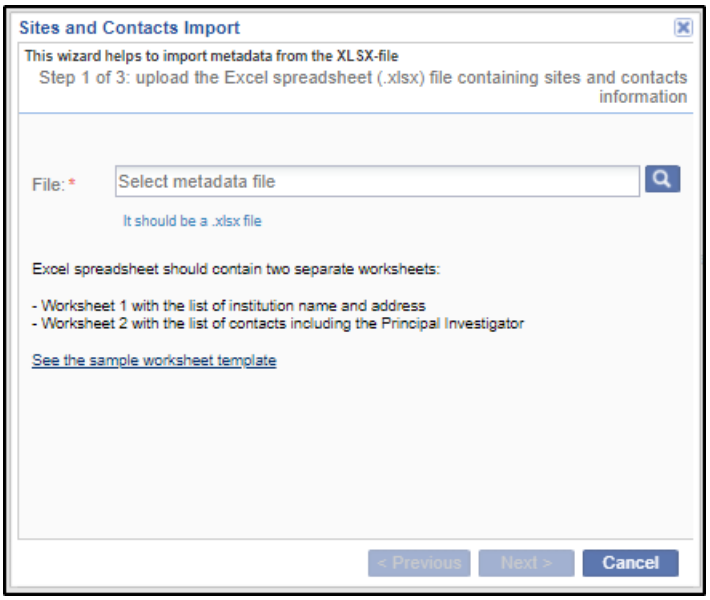
10. Data that was not imported can be mass coded for multiple sites later (follow on to Mass Coding of Sites for further details).

Given below, is an example of the worksheet as guidelines to the import process:



	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Investigative Site Name	Site Number	Address	City	Phone	State	Website	ZipCode	Expiration Date	Country			
2	Test Site 1	1234	Test	Pune	989898	MH		333333		India			
3	Test Site 2	5678	Test	Mumbai	878787	MH		555555		India			
4	Test Site 3	10122	Test	Chennai	767676	TN		444444		India			
5	Test Site 4	14566	Test	Kolkata	656565	WB		222222		India			
6	Test Site 5	19010	Test	Delhi	545454	DL		111111		India			
7													
8													

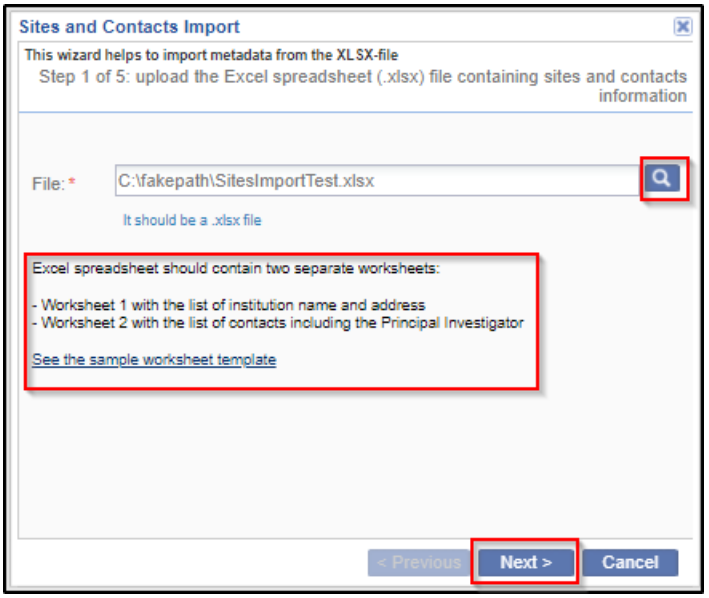
1. Click Import from the menu bar. The Sites and Contacts import window opens.



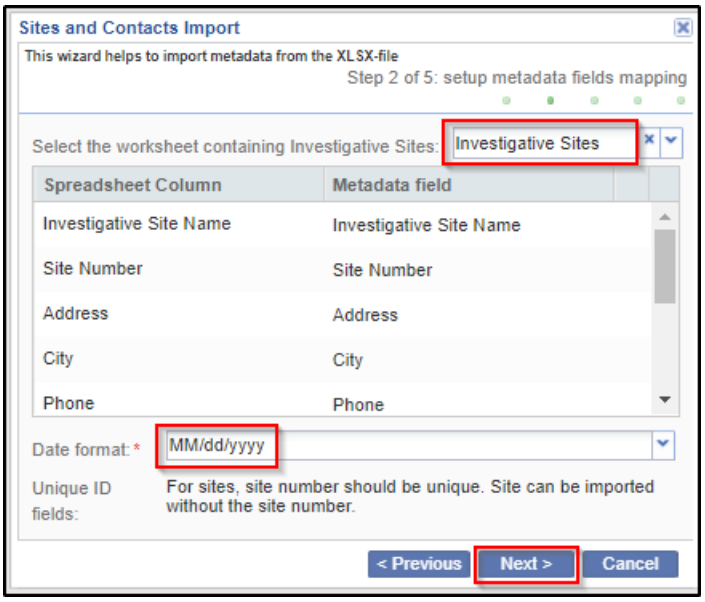
2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon.

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 PrincipalInvestigator.

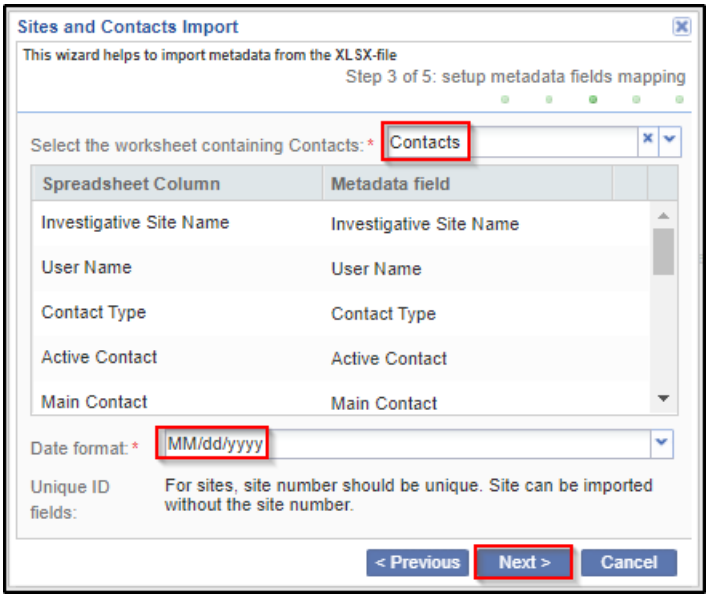
3. Click **Next**.



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 filecolumns. Click **Next**.



6. Observe the settings that were done during previous steps and probably return back and correctsomething. Click **Next** to confirm.

7. This will begin the actual import process. Upon completion, the Administrator will get a shortreport on the issues that were occurred during import.

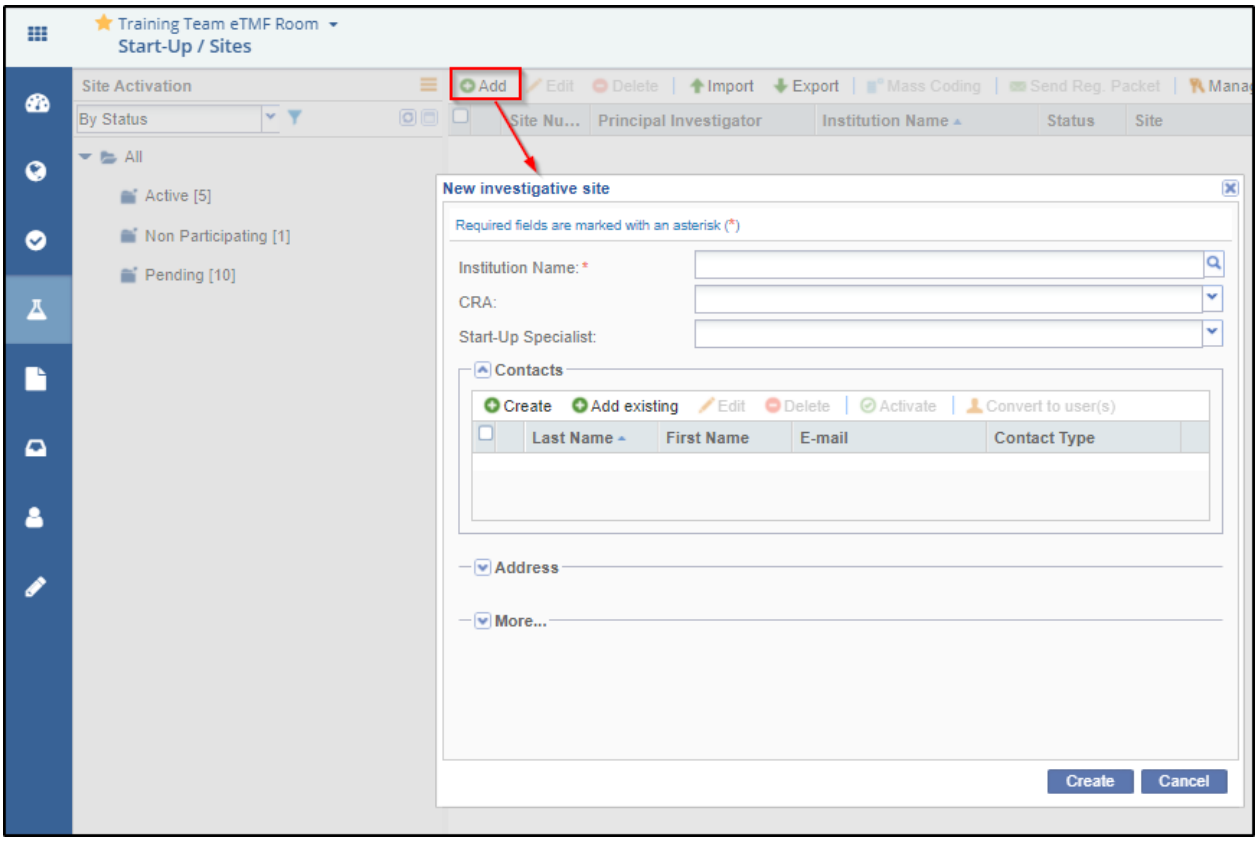
2. Adding each site and its contacts individually

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 andavailable.

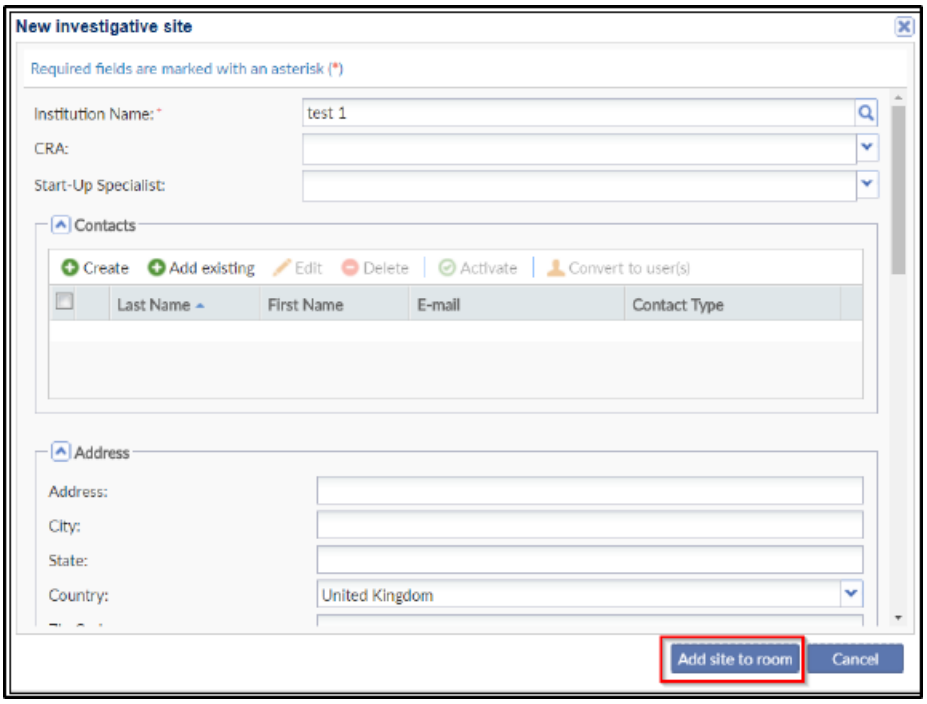
To create sites follow the procedure below:

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 'Newinvestigative site' window is replaced by the 'Add site to room' button. Refer to the screenshot below:

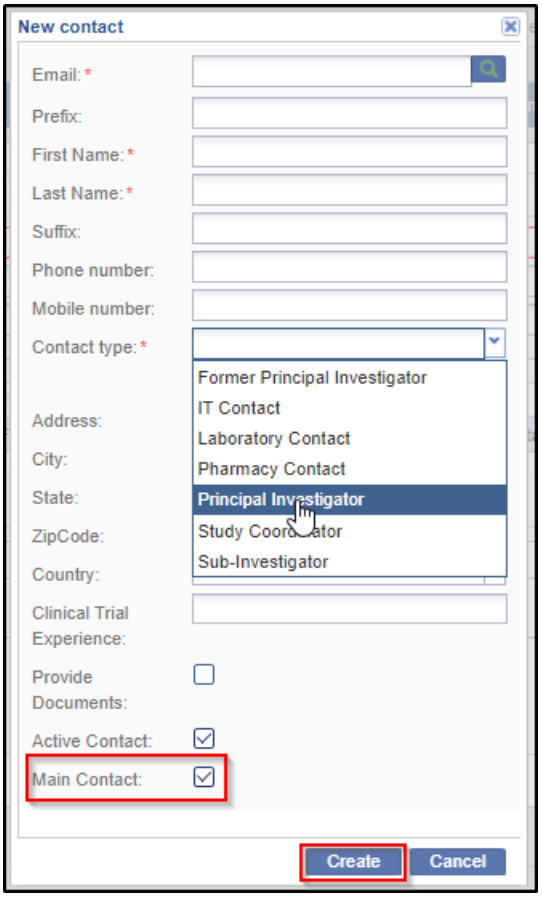


3. Select the CRA from the field's dropdown menu.

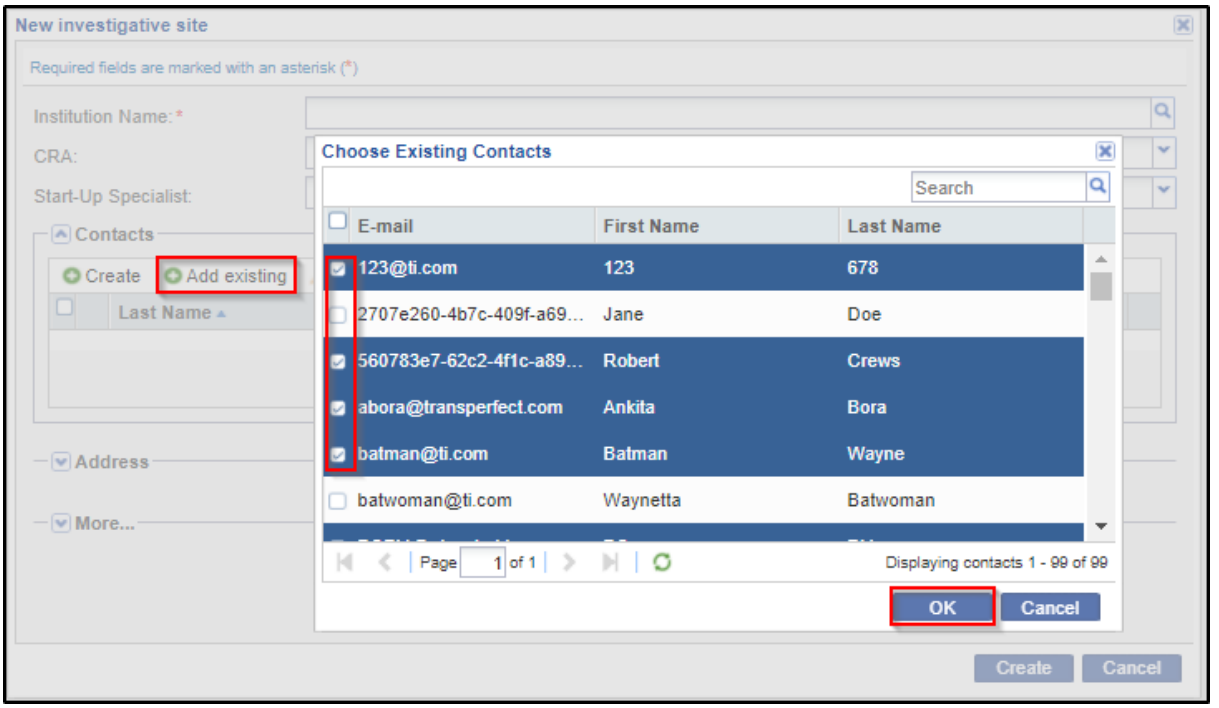
4. Select the Start-Up Specialist from the field's dropdown menu.

5. From the Contact panel of the Site Profile window, the administrator can either create, or addexisting 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 timeand 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. Thisicon 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 reasonof 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 theContacts 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 theeFeasibility 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 byclicking 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.

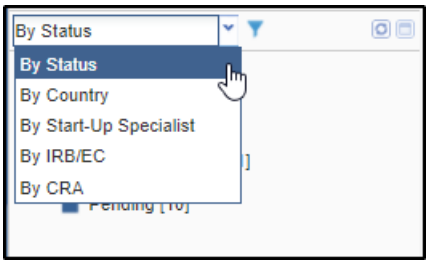
8. Click Create or Add site to room at the bottom of the window as per the process.

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 thesites 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:

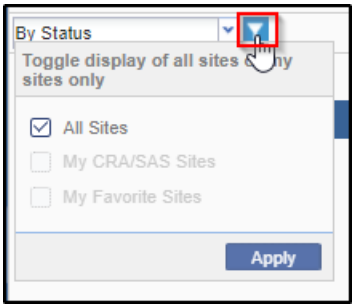
- **By Status**: The Site status could be Not Specified, Active, Pending, Rejected. When an investigative site is added to a data room, it has Pending status. After all documents for the Investigative site are collected, and appropriate country and IRB documents are approved by thestart-up specialist 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 acountry 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 selecta 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 intheir profiles.

Buttons on the Current View

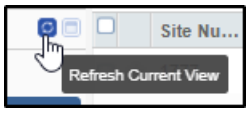
Some studies require that a data room house hundreds of sites. The user can toggle the displaybetween the sites where the user is a CRA or a Start-Up Specialist, or All Sites.

The user can refresh the current view by clicking the Refresh Current View button. Through theConfigure Grid button, the room administrator can decide the columns that team members needto 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.

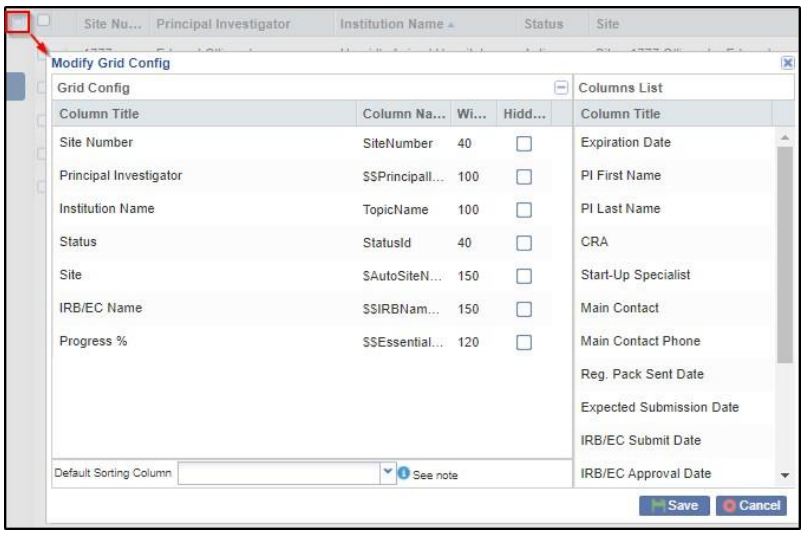
1. Toggle Display Button.



2. Refresh Current View Button.



3. Configure Grid.



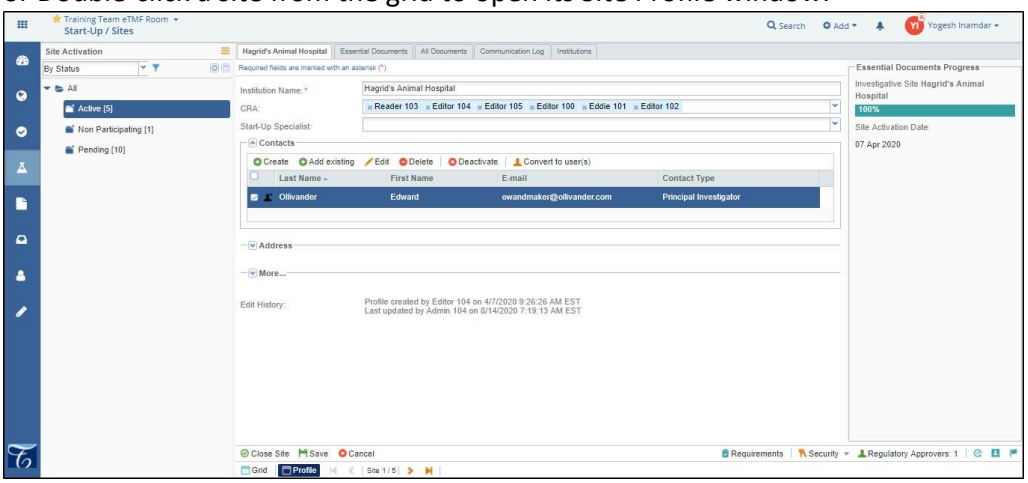
Viewing or Editing Site Profiles

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.

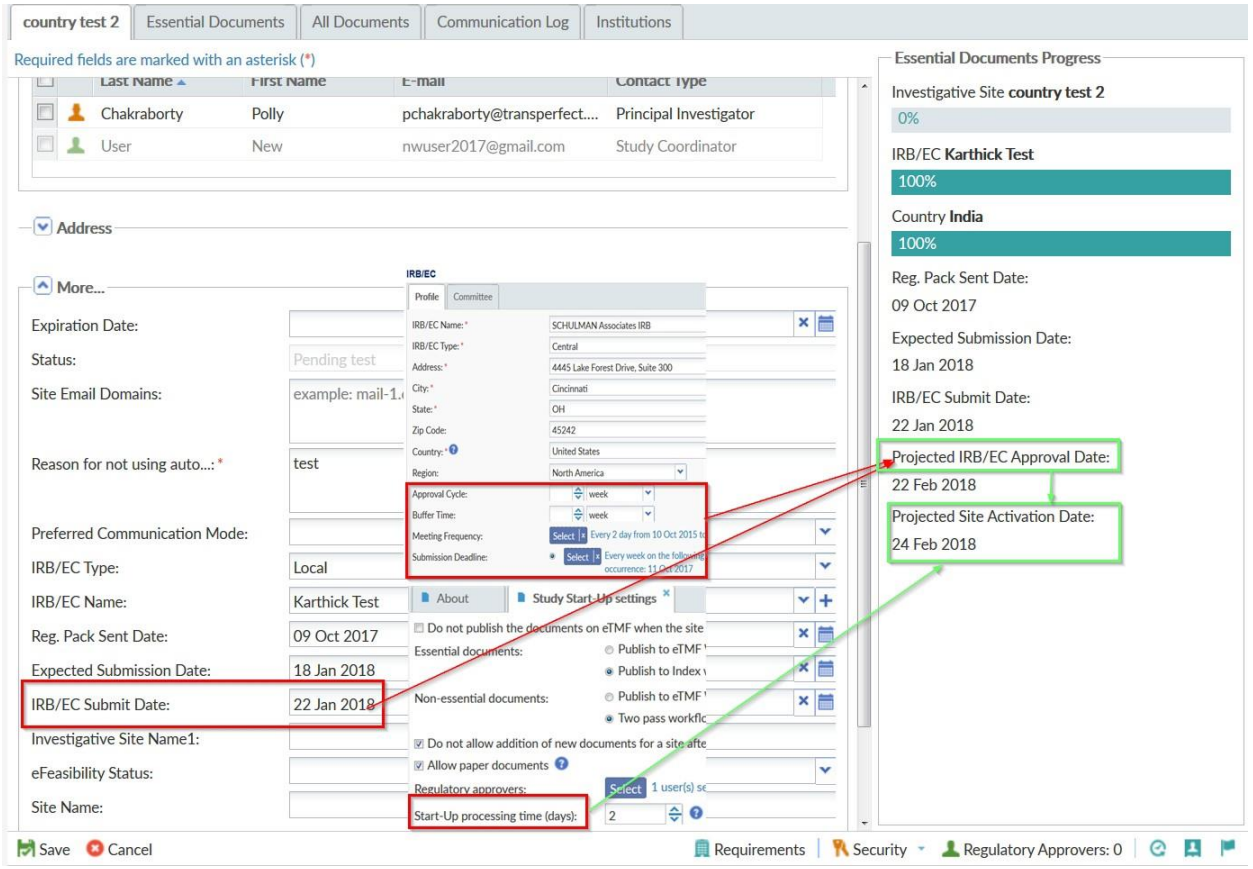


3. The Essential Documents Progress panel shows the Progress percentage bar to track the sitecompleteness as the essential/required documents collected and reviewed.

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 ActivationDate 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 nextto the Expected Submission Date field.

6. Make necessary additions or changes to the data fields in the profile. Refer to Adding sites andsites 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

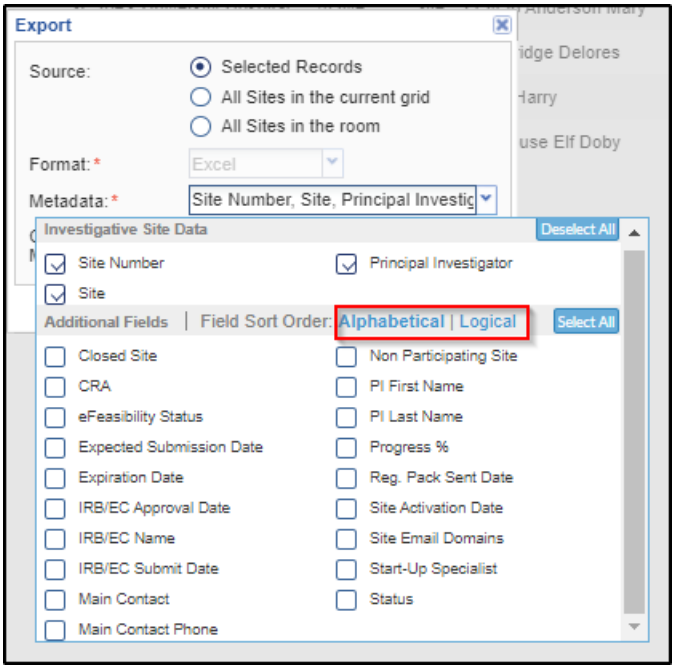
1. To Export a single site or a specific set of selected sites, select the site or sites by clicking thecheck box or boxes at the left side of the grid.

2. Click **Export** in the menu ribbon above the site grid. The Export window opens.

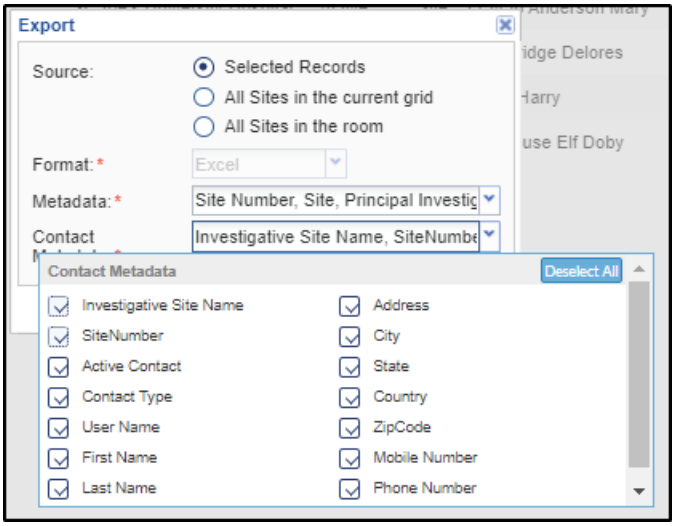
3. Choose the Source from the radio buttons. The export Format is preselected as Excel and cannotbe altered.

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 dataexport.



7. Once you have made the appropriate selections, click Export. When the export is complete, youare notified about the Get Job Result in a popup.

8. To view the exported file, navigate to the Notifications .

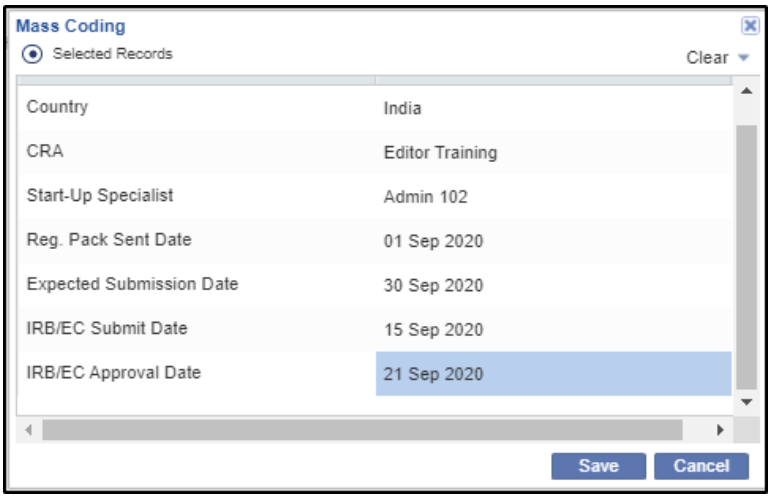
Mass Coding for Sites

During the initial room configuration, the metadata fields that are available for mass coding are marked in the room's Form Settings *(page 145)*by the room's administrators. Once that process isdone, 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 tobe 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 withcalendar selections and some with dropdown menus.

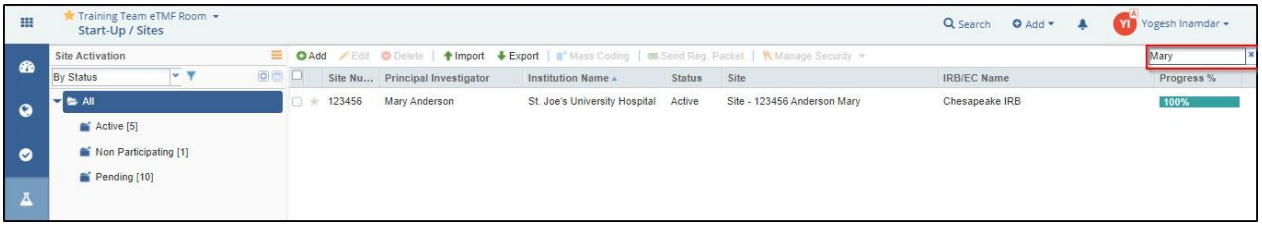
5. When you have completed entering the common metadata, click Save at the bottom of thewindow. A Confirm? Window opens.

6. The coding changes will be added to the site profiles. Note that if the requested coding additionsor 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 Editfunction 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 bedisplayed. The system will not only select sites that match the pattern from the columns in the GridPane, 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.



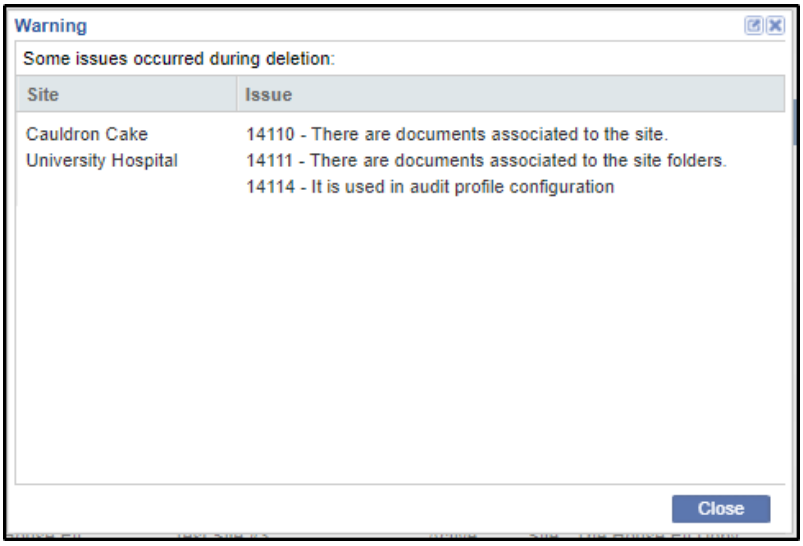
Deleting Sites

1. Select a site from the list.

2. Click Delete in the menu ribbon. A window pops up, asking for confirmation that you want todelete 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 messagewarning 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 opensthe 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 addand exit the window.

Institutions or Additional IRB/ECs

Although clinical trial organizations today adhere to protocols from a central IRB/EC, at times itmight be required to adhere to protocols of more than one IRB/EC. For example, an organizationmay 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 toprovide 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 369)* and Adding Existing IRB/ECs to Data Rooms *(page 370)*

6. The procedure to add from existing IRB/ECs is also the same, with the only difference that fromwithin a site, the Add Existing functionality will only display the IRB/ECs available in the data room.

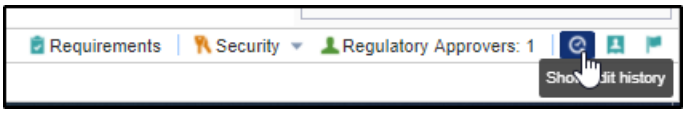
Viewing History

From a site profile window, you can also view histories related to site edit, contact activities, andmilestone.

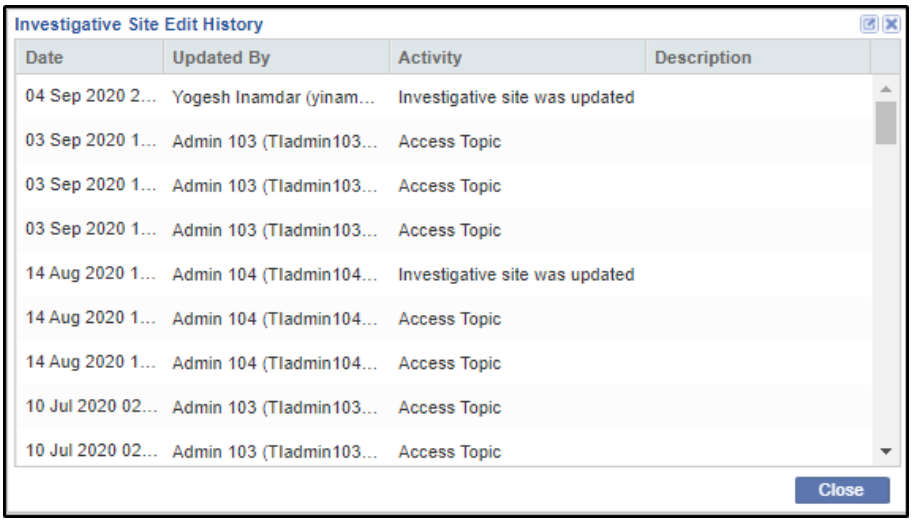
Site Edit History

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 sitecreator and also the last updated by user.



4. The information here cannot be edited. Click **Close** when you are done with viewing.

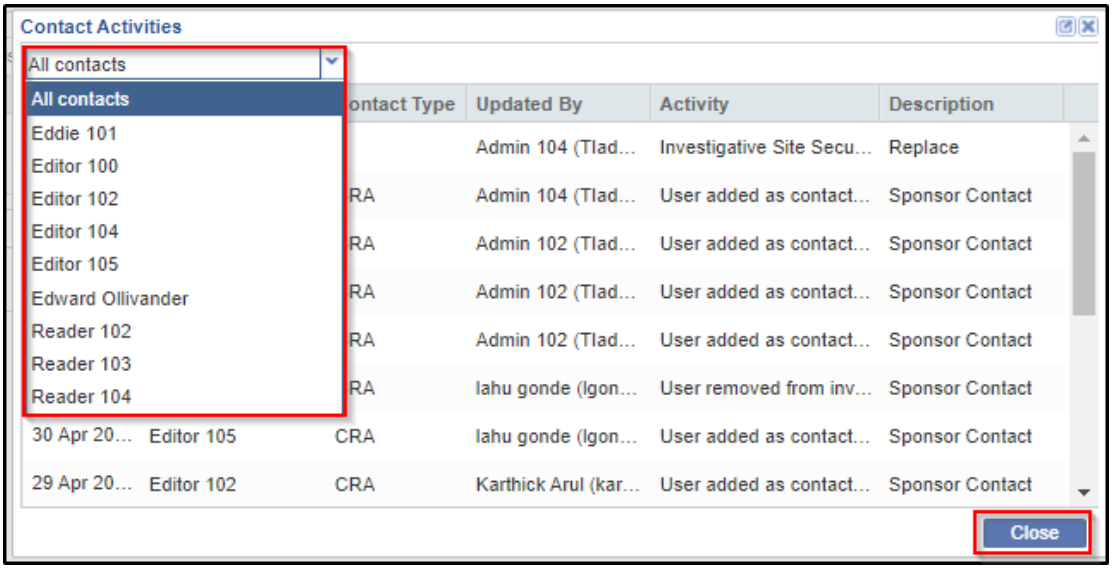
Site Contact Activities History

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 alsotheir activities.

4. Select All contacts, or a specific contact from the dropdown to retrieve the details of only thatcontact.



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 379)* the types

of security privileges provided by Trial Interactive system to the users and contacts of investigativesites. The security privileges can be provided for all sites in a data room, as well as from within theStudy Start-Up Sites section.

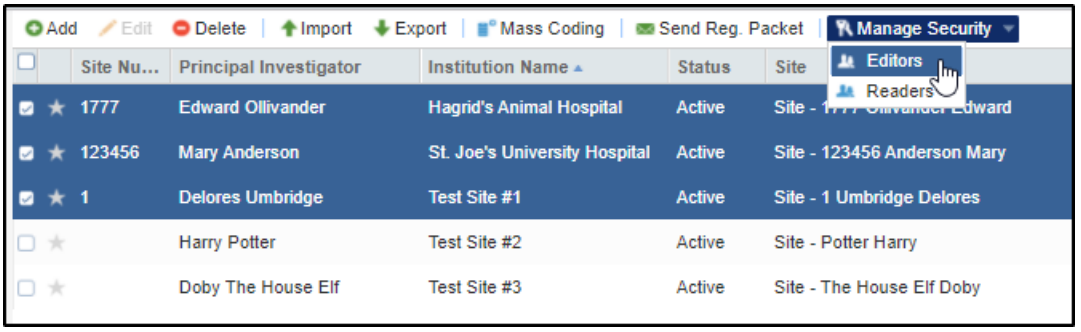
Access to users for all sites can be provided by adding the site users to Default editors/readers group,or by making them Default access members of sites.

From within the SSU Sites section, the administrator can view and provide security privileges tousers 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:

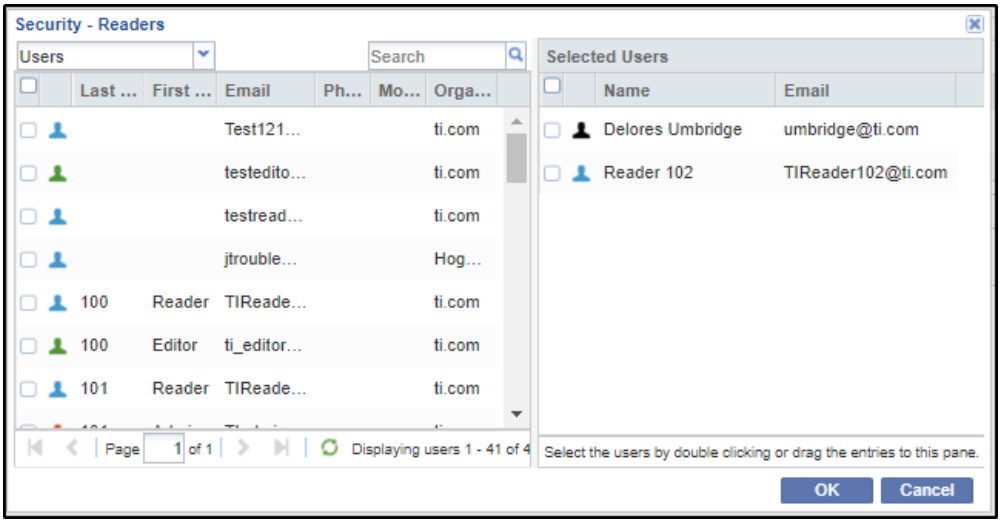
From the Grid Pane the administrator can assign Editor and Reader accesses to users/group of users, thereby making them contacts of multiple sites. By selecting the checkboxes next to the site names inthe grid the administrator can make the selected users/groups member to multiple sites at one time. 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 ofusers 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 theUser Management *(page 115)*section .

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 locatedin the country during its initial setup and configuration. The following section discusses:

1. Viewing and editing country profiles

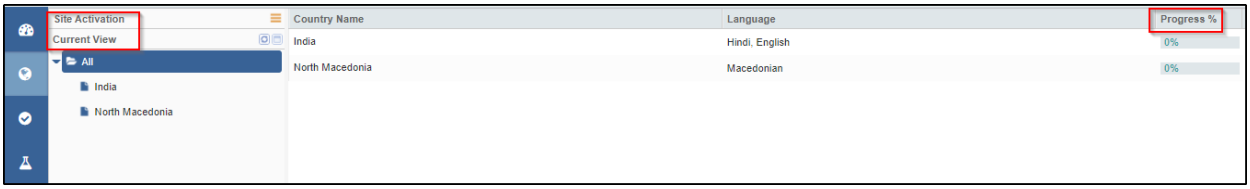
2. Viewing documents

Note: Adding countries, and essential/required documents to countries are discussed in sectionsAdding Countries to Data Rooms *(page 368)*, and Setting up Required Documents for Countries *(page 371)* respectively

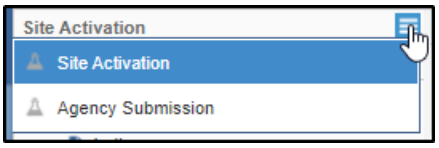
The Start-Up Countries  **tab accessed from the toggling menu bar on the left, allows you to setup documents for countries associated with sites. The Countries dashboard consists of the Current view on the left and the Grid pane on the right.**

Viewing Countries

Countries in which the sites are located can be viewed from the list of countries appearing in the gridpane. 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 Countries Current View



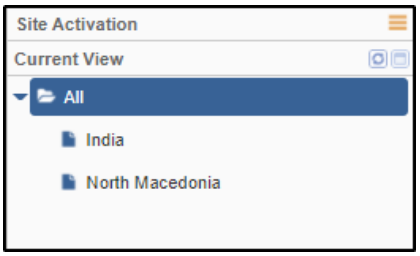
The Current View of the Countries associated with sites is based on:

1. Site Activation

2. Agency Submission (this section is used for Submission Packages)

Site Activation

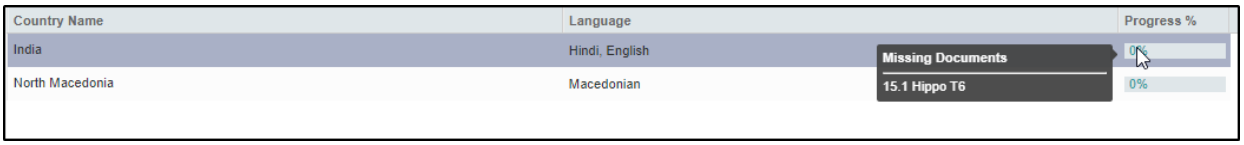
Choose Site Activation as your Current View. This view reveals a list of countries for which specificdocuments need to be submitted and approved. Refer to the screenshot below.



A country name will be visible in the Current View listing only if the essential documents requiredfor site activation for that country have been set up.

The Countries Grid Pane

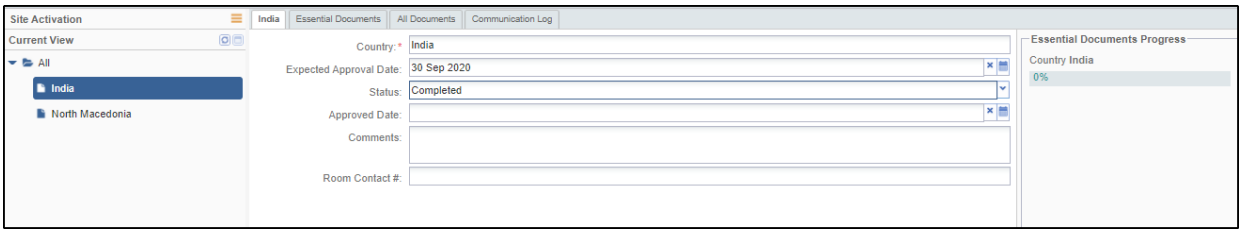
The Grid Pane on the right provides a list of countries for which documents are required along with the Progress % bar to the extreme right showing the percentage of the essential documents submission progress. Hover the mouse pointer over the Progress % bar to get a popup with a list ofMissing Documents. Refer to the screenshot below.



Viewing or Editing Country Profiles

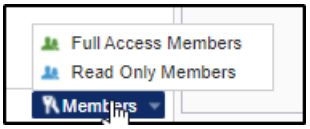
1. Click the country name in the Current View panel, or double-click the name of the country in thedisplay grid in the middle of the screen.

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 singlecountry.



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 canselect 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** afteryou 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 theright 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 changesyou 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 isreceived. A study may have multiple health agencies located in various countries. These agencies may have more comprehensive site activation submission packages involving hundreds of documentsand 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 asagency name, country, status of submission, documents to be included in the submission profile, datewhen 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. Allthe 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 isactivated, these documents are not transferred to the eTMF and are left in the submission package.

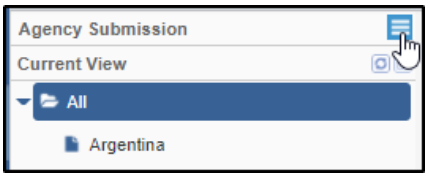
Defining Health Agencies

Before adding submission profiles and downloading packages, it is essential to define health agenciesto be associated with sites. Health agencies need to be defined at domain level.

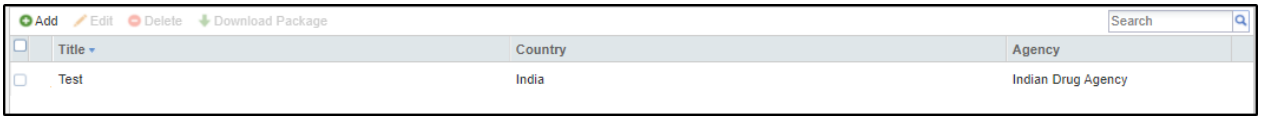
Note: *Contact the Service Desk to create Health Agencies, if they are not already created.*

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 tothe 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 theagencies. 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:



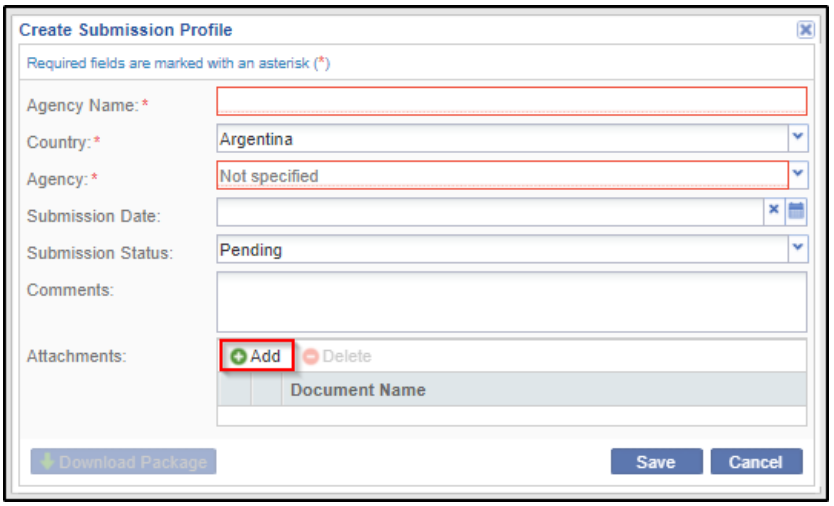
Adding or Creating Submission Profiles

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 arecreating. 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.

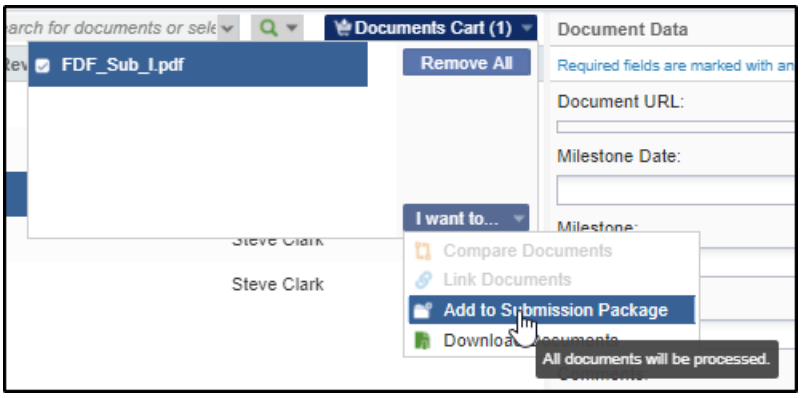
5. This will list all essential/required documents, as well as non-essential documents in the GridPane.

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 tothe Document Cart.

8. You can continue adding documents to the cart from as many filters in the Current Viewdropdown.

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 tothe 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 tothe 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 processesdescribed above, you can also add documents from the eTMF.

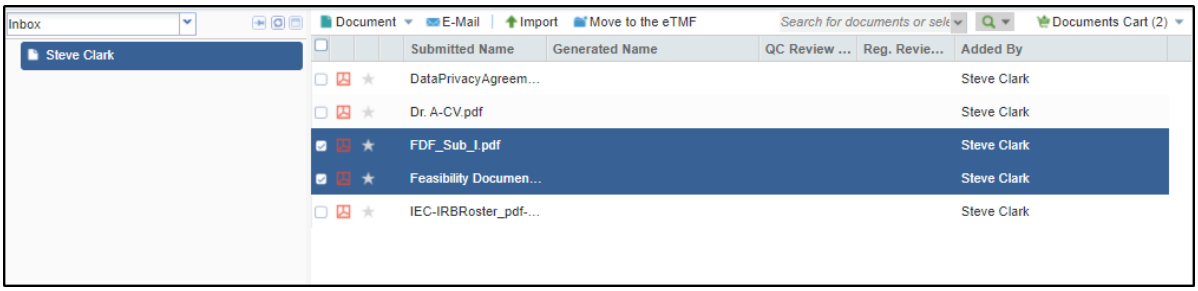
To add documents to a submission package from the eTMF, follow the steps as below:

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 tothe 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 thepackage for further processing.

To download a package:

1. Select the required profile from the Grid Pane.

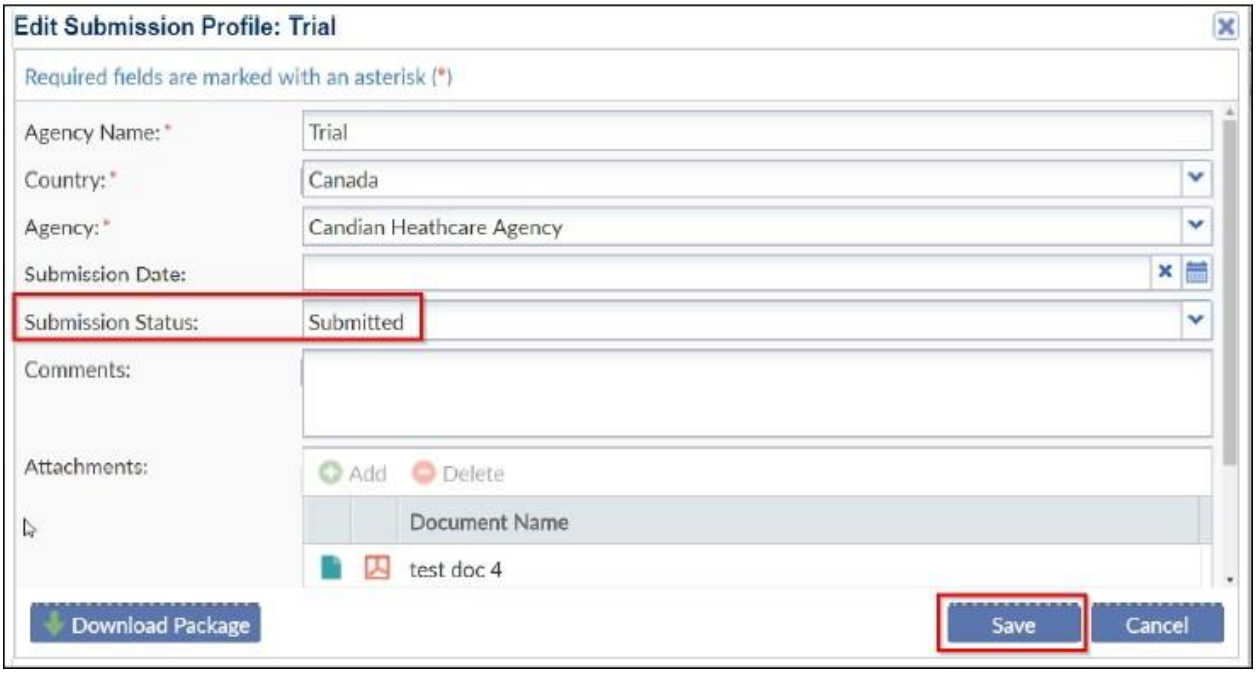
2. Click Download Package from the menu bar on the top of the Grid Pane, or

3. Click Edit from the menu bar and click Download Package.

4. You will receive a notification regarding the documents downloaded. The documents aredownloaded in a .zip format.

Editing a Submission Profile

Once the documents are downloaded, you can edit the submission profile and change the SubmissionStatus to Submitted and click Save. Refer to the screenshot below:

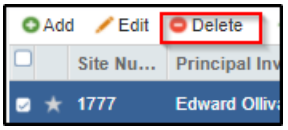


After the Submission Status is changed to Submitted, the profile is locked from further additions ofdocuments to it. Notice that the +Add and –Delete buttons are now disabled, which means further additions to/deletions from the submission package is now prohibited.

To add further documents you have to create another submission profile. Kindly note that you canuse 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 Deletebutton 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 centralIRBs 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 Interactivenot 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

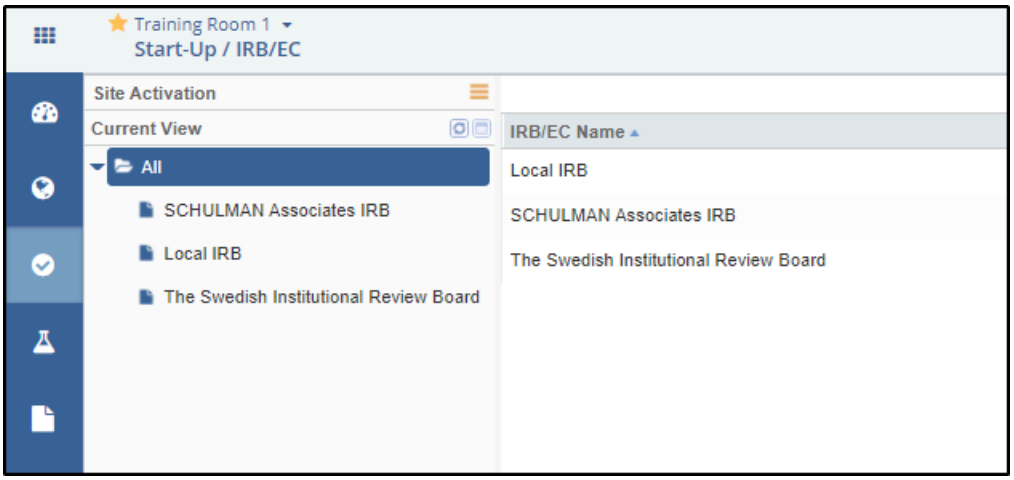
3. Editing IRB/EC profile

Adding additional IRB/ECs

You can specify more than one IRB/EC for a site from within the Sites module of SSU. Proceed tosection Institutions or Additional IRB/ECs *(page 400)*for more details on this.

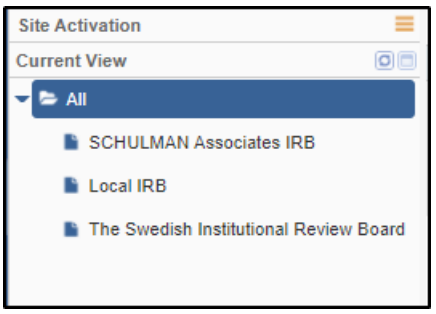
Viewing IRB/ECs

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 aSearch 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 theessential 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 alongwith 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 EssentialDocuments 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 changesyou have made.

Regulatory Packets

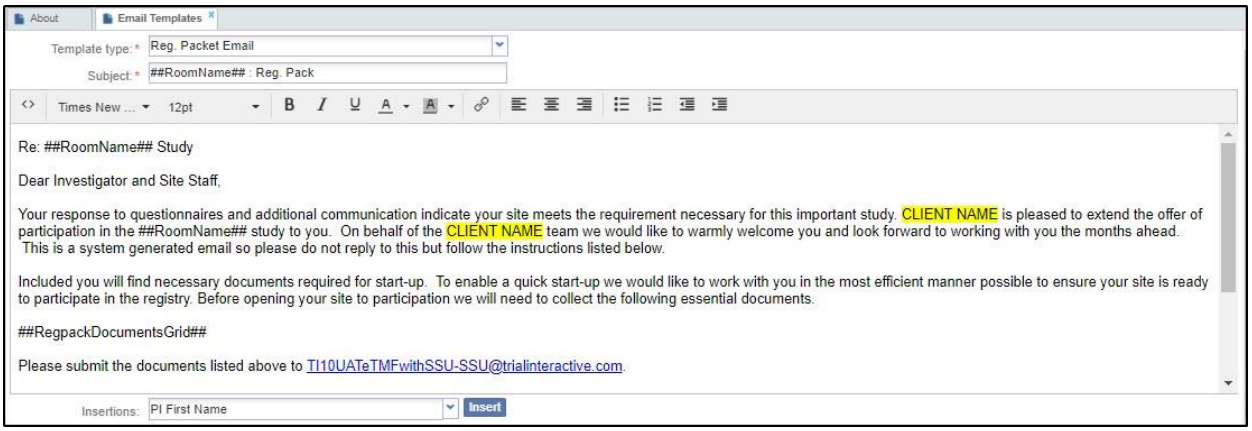
When all required documents are collected, the Start-Up Specialists, or the sponsor, or CRO forwardsan initial regulatory documents packet for collecting the documents from various contacts in the site. Main contacts receive emails with a list of regulatory documents required. If no main contacts are specified for a site, then the Principal Investigator of the site will receive the email. The administratorcan 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 intothe 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 asrequired.

Setting Up Email Templates

The administrator can set up the body of the email template from the room's settings. By default, thesystem 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, proceedas 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.

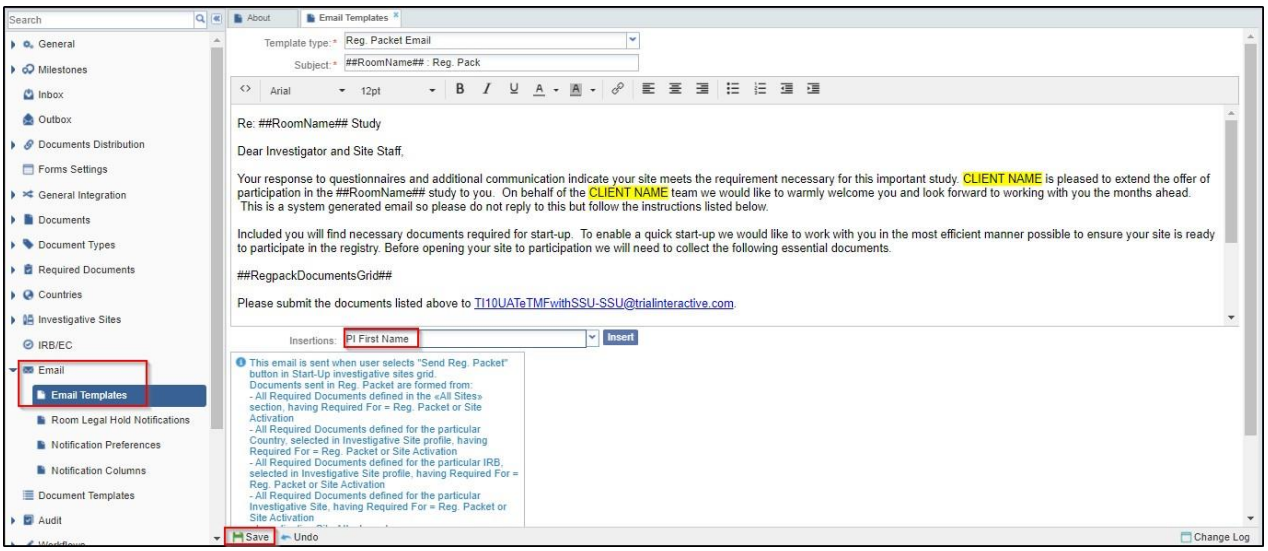
5. Select **Reg. Packet Email** from the Template type dropdown.

6. The default template populates itself.

7. Click the appropriate location in the editor and insert the email body as per the format provided byyour 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.

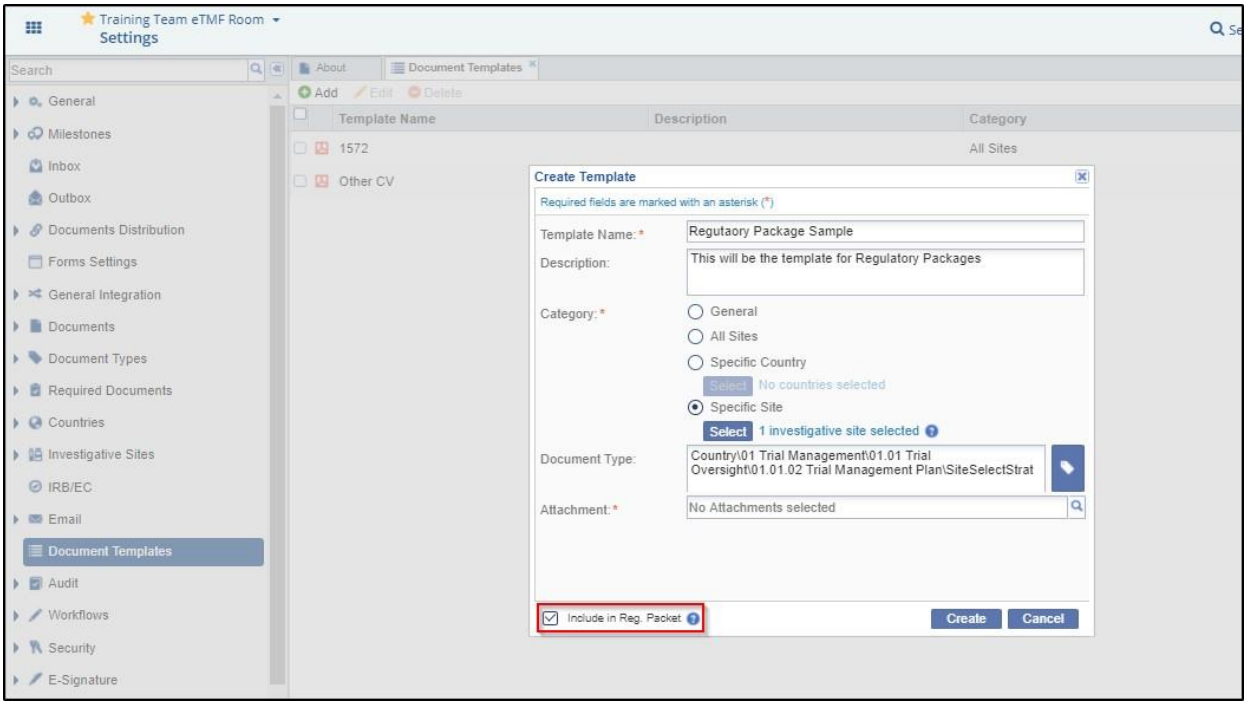
5. The Create Template window opens.

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 asrequired.

7. Select the Document type and provide the attachment specifying document template for thedocument type.

8. To include the template in regulatory packets, tick the Include In Reg. Packet checkbox. Documenttemplates 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

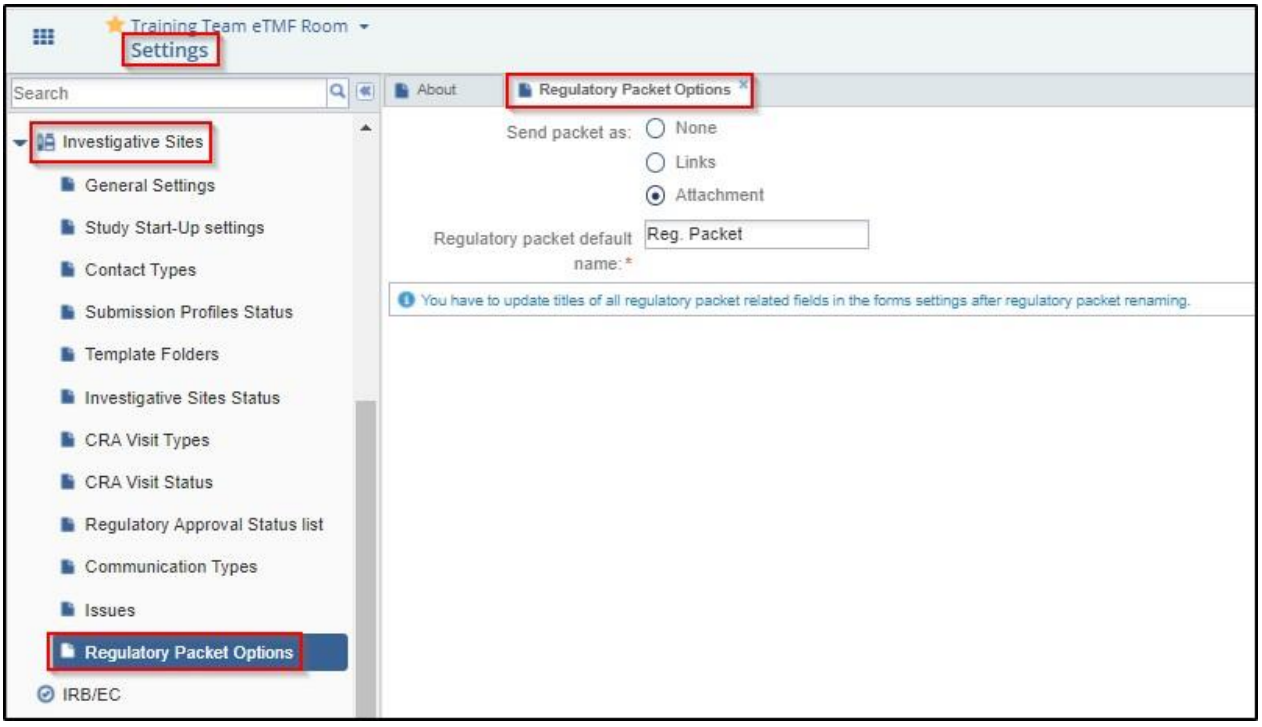
It is possible to send docs within a regulatory pack with the following options:

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:



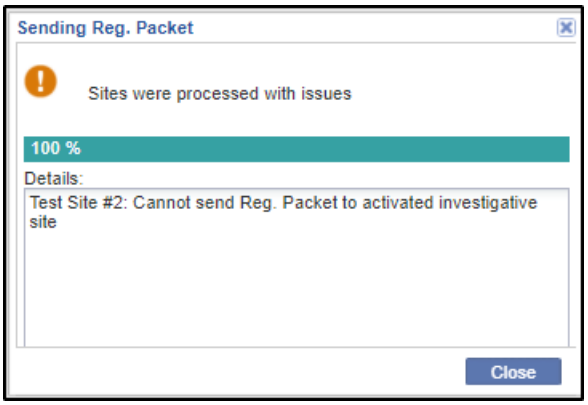
To send regulatory packets follow as below:

1. Select the site/s for which you want to send regulatory packets from the Grid Pane.

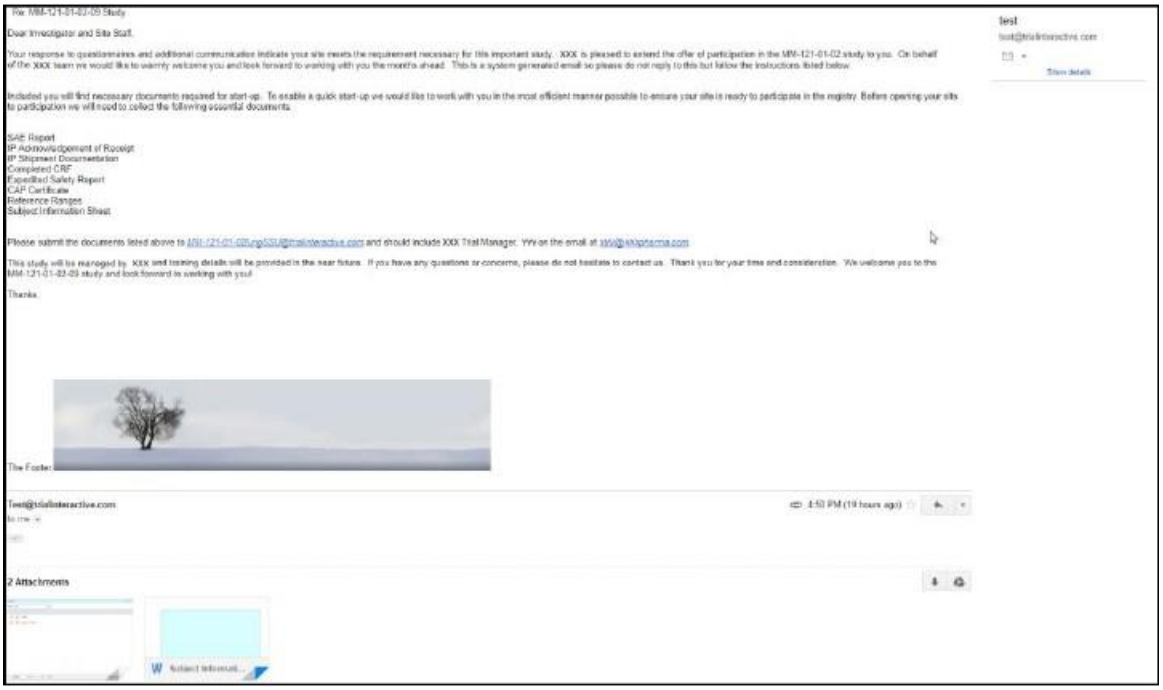
2. Click the Send Reg. Packet button from the top menu bar in the Grid Pane.

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 statusmessage 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 asattachments 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 beviewed 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-essentialdocuments, and add / edit communication logs. The procedure to add documents is the same for sites,countries, and IRB/ECs, and is discussed below.

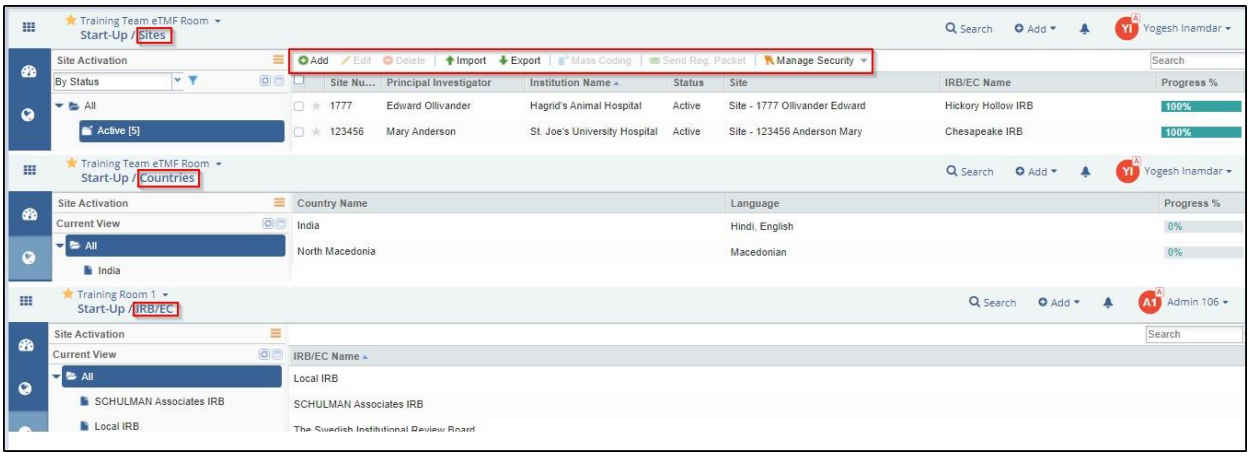
Essential Documents

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 barslocated 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 enabledfor them, and specified as contacts in the essential documents from room settings for site specificdocuments.

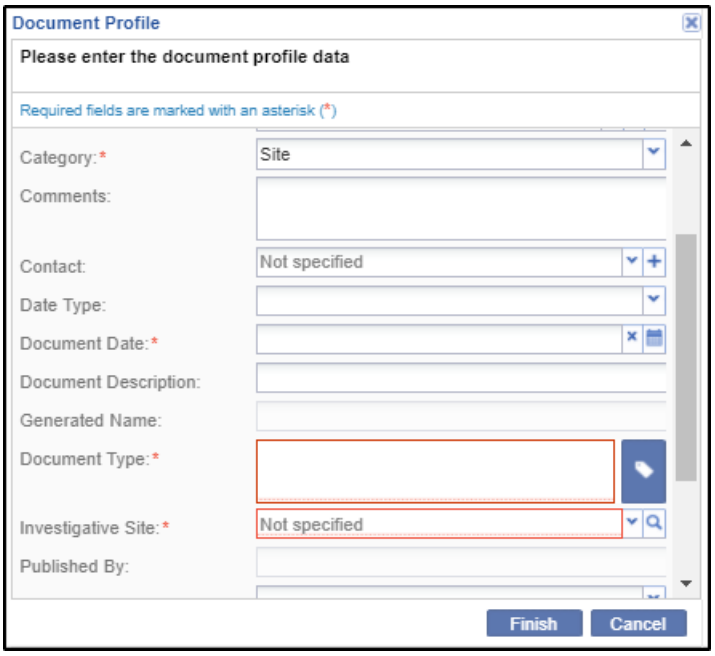
1. Navigate to the module to which you want to add documents as required. The modules here areSites, Countries, or IRB/EC.

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 Pendingstatus.

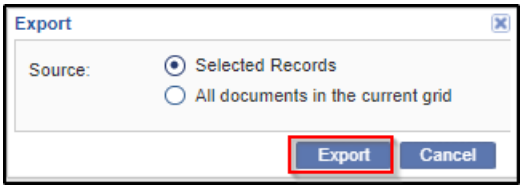
You can also add documents by double clicking the Attachment field in the grid for the required document type for which you want to attach a file. This will activate the magnifying lens and dots toupload attachments. Refer to the screenshot below:

Once the documents are uploaded, click the Save button, without which the document would appearin 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. ClickFinish on completing. The warning symbol now disappears.

Export documents

1. Click the **Export** 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 aredelivered 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 TIcan 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 Documentswindow 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 asselected 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 tothe 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 Documentswindow 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 besubmitted to review.

1. Select the approved document or documents to be submitted to review by clicking the appropriatecheck 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 sameway as mentioned above.

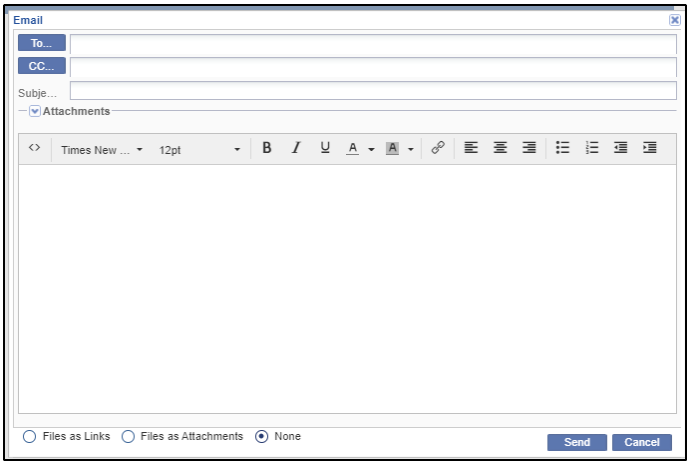
Not Applicable

A document type can be marked Not Applicable if such a document is not required for the studystart-up.

E-Mail

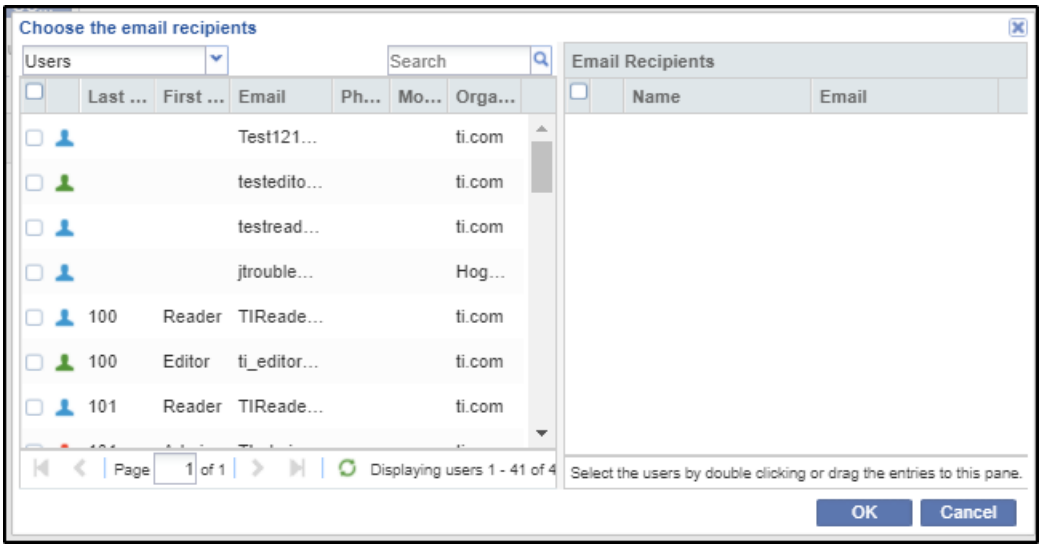
1. To send an Email message about a particular document to another party associated with the study,the site, the country, or the document, select the document in question from the grid by clicking the appropriate check box.

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 therecipients' 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 filesattached.

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 edita document:

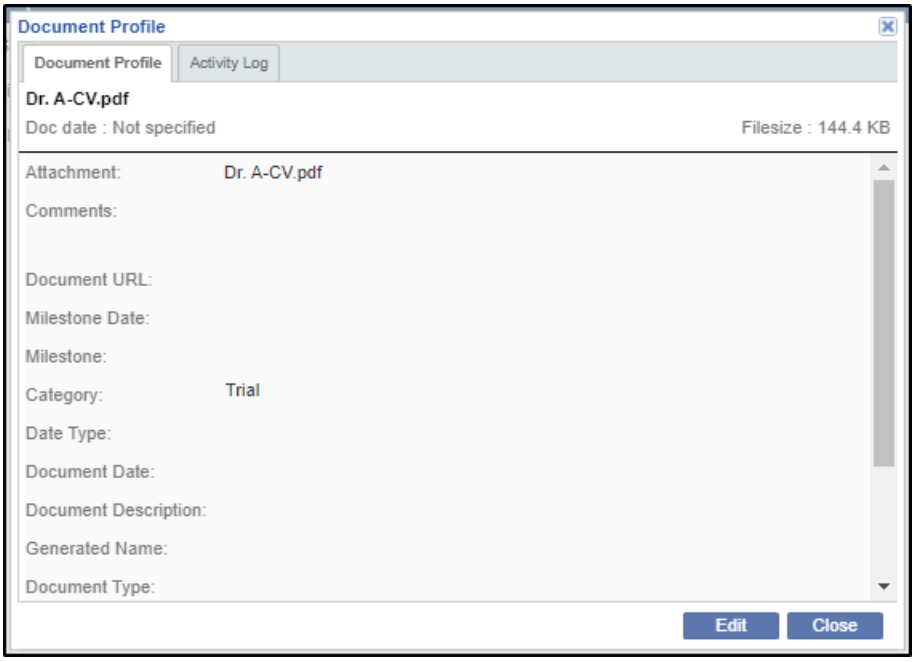
1. Select a document from the grid

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

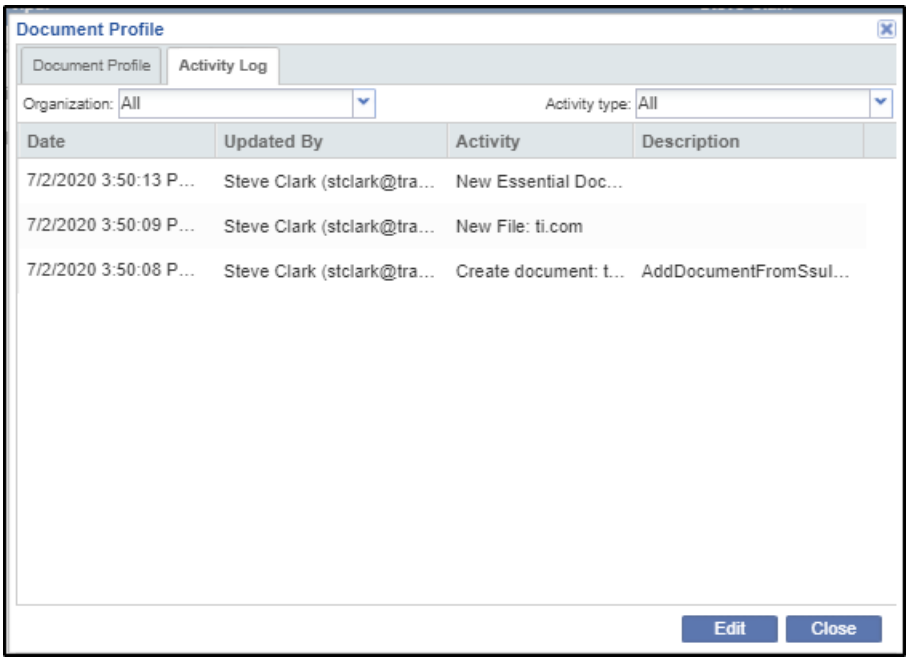
To view the profile of a document you can click the Open Profile button from the menu bar. Thisopens the Document Profile window. Refer to the screenshot below:



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.

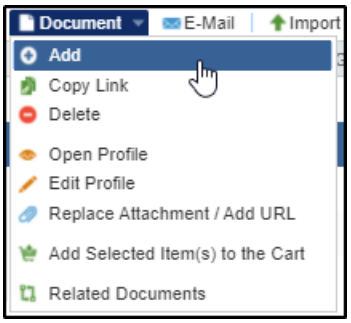
The Activity Log tab shows all the activities performed by users on the document. Refer to thescreenshot below:



All Documents

The view presented to users in the All Documents tab for each site, country, and IRB/EC shows boththe 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 bereferred there.

Review of Non Essential Documents

If the Study Start-Up Settings specify that the documents will need to be approved through the 'Twopass 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 forRegulatory 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.

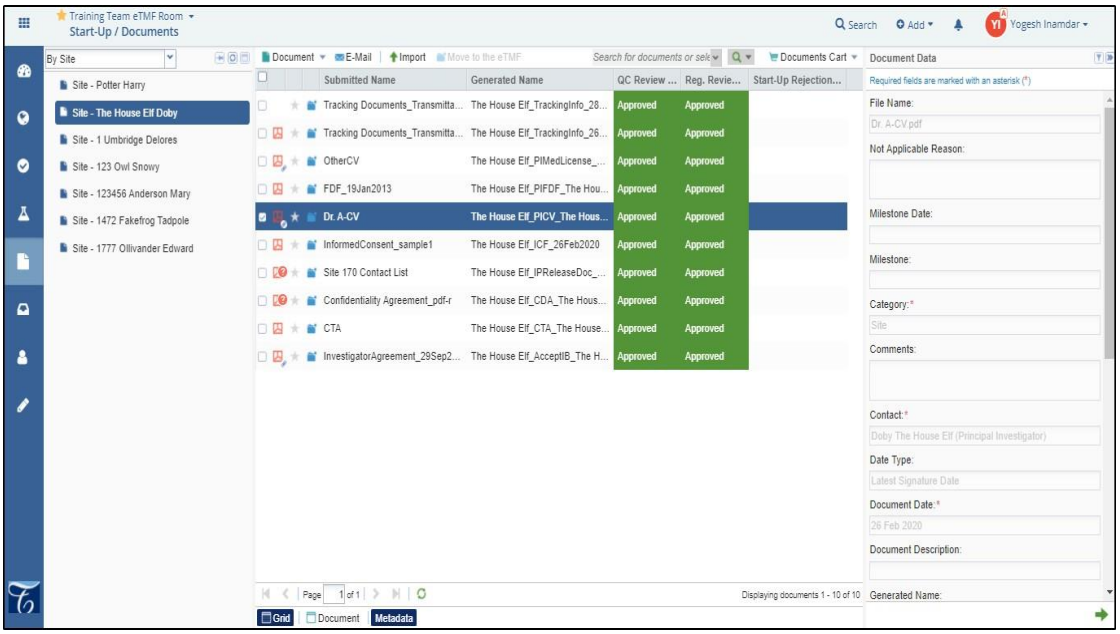
2. From the menu bar on the top of the grid, click the Approve/Reject button.

3. Once the document is approved, the Submit To Review button is activated; clicking which you cansubmit the document for QC Review. A document that is rejected by the SSU Specialist cannot be submitted for Regulatory Review.

Documents

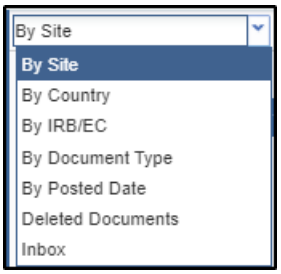
Clicking the Document tab from the toggling menu bar leads you to the Documents dashboard. Typically, the Documents module is the route through which most Editors will access and view documents for a Start-Up study. This module acts as a central repository for all documents added tothe various components of a study start-up.

The Documents dashboard consists of the Current view on the left and the Grid pane on



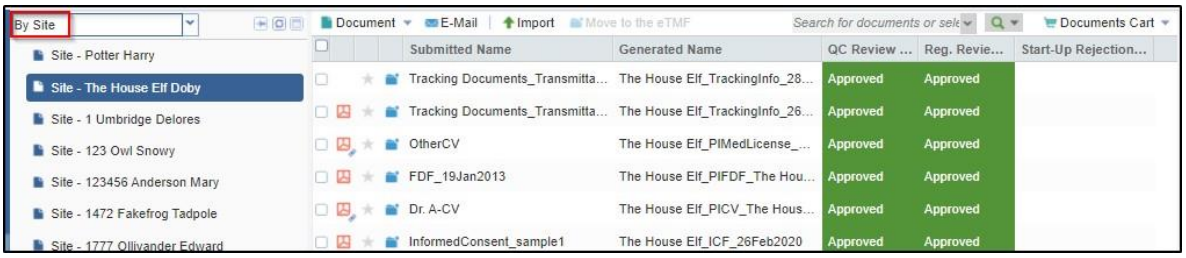
the right. Besides these, it also allows you to perform various functionalities from the menu bar on the top of the grid pane, and the buttons on the Current View window. Clicking a current view opens a list ofdocuments in the grid pane. Refer to the screenshot below.

Current View

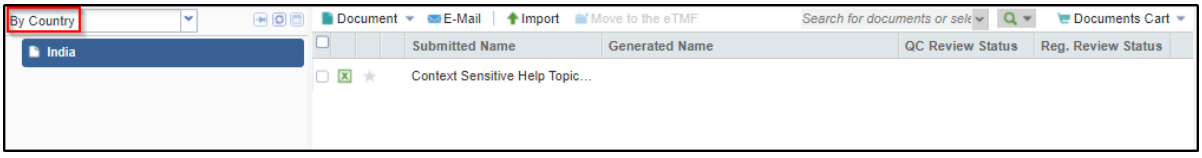


The Current View Dropdown offers five views:

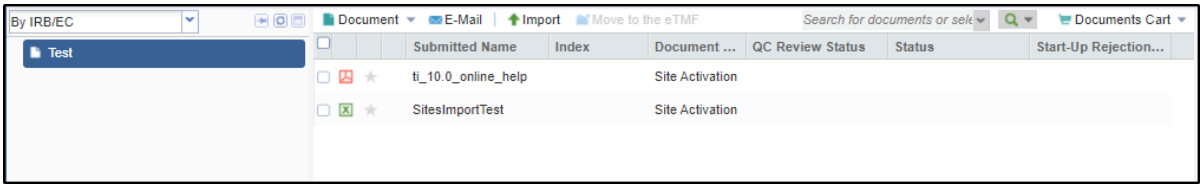
- **By Site**: Selecting the By Site option lists out the sites to which documents have been added. Clicking a site will display the documents submitted to the site along with their review status inthe grid pane. Refer to the screenshot below:



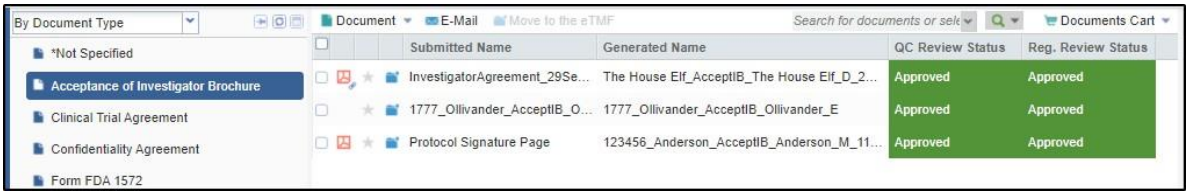
- **By Country**: Selecting the By Country option lists out the countries to which documents have been added. Documents added through the Countries tab can be located here. Clicking a countrywill display the documents submitted to the country along with their review status in the grid pane. Refer to the screenshot below:



- **By IRB/EC**: Selecting the By IRB/EC option lists out the IRB/ECs to which documents havebeen added. Clicking an IRB/EC will display the documents submitted to the institution alongwith 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 documentssubmitted 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.**

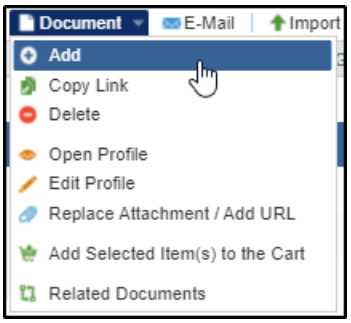
The Documents Grid Pane

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 thepanel.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the screenshotbelow:

Document Dropdown



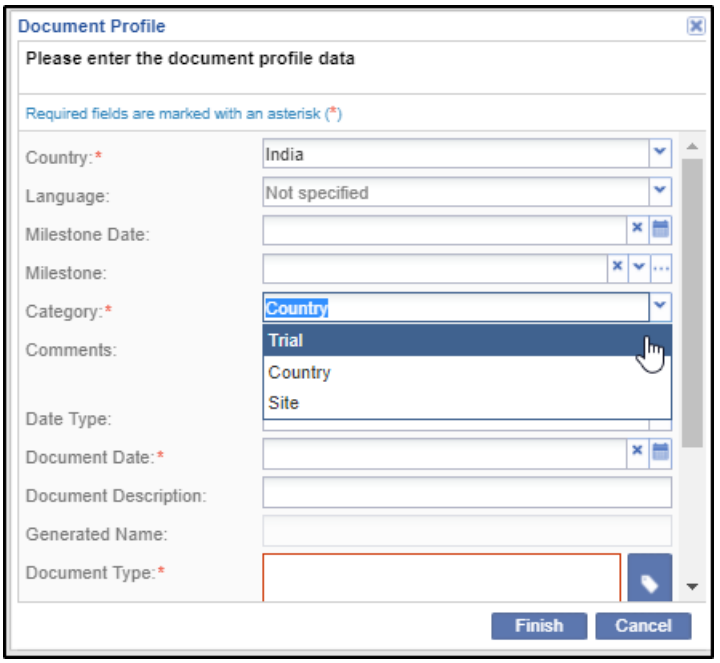
Add documents

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 redasterisk (*) are required – Title, Category, Index Position, Document Type, Document Date, and Name.

3. The Category could be General, Country, or Investigative Site.

If you select Investigative Site as Category, the document added will be available from the Site towhich 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.



4. Click Finish.

Copy Link

Using this option you can copy the link of a document, or copy the link of the document with itsmetadata.

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'.

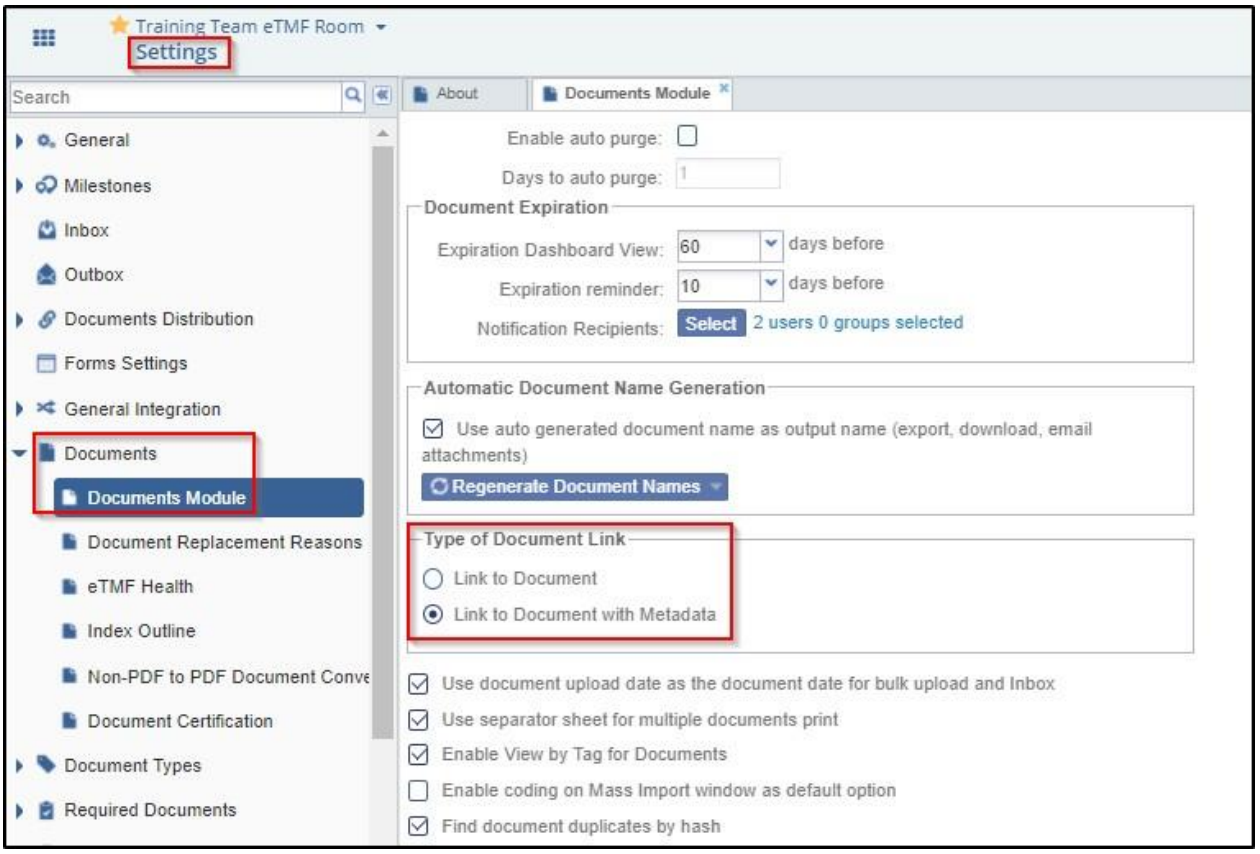
5. Observe that there a two options:

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 Sitessection.

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.

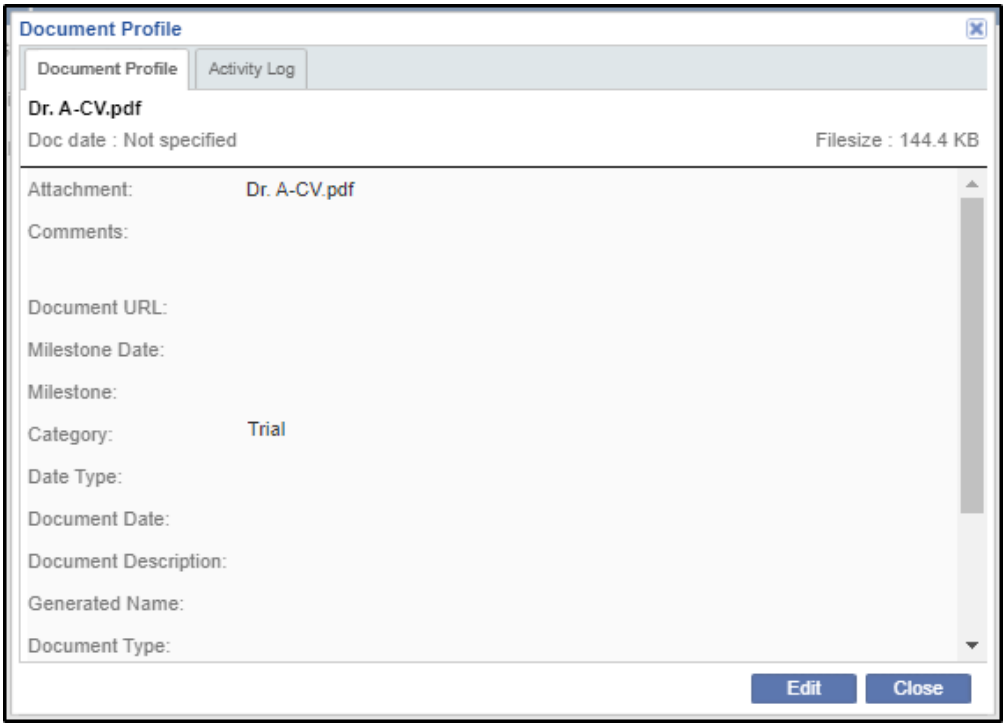
2. Activate the Document dropdown menu and click **Edit Profile**. The **Edit Document Profile window opens.**

3. Make the necessary changes to the profile data fields as required.

4. Click **Finish**.

Open Profiile

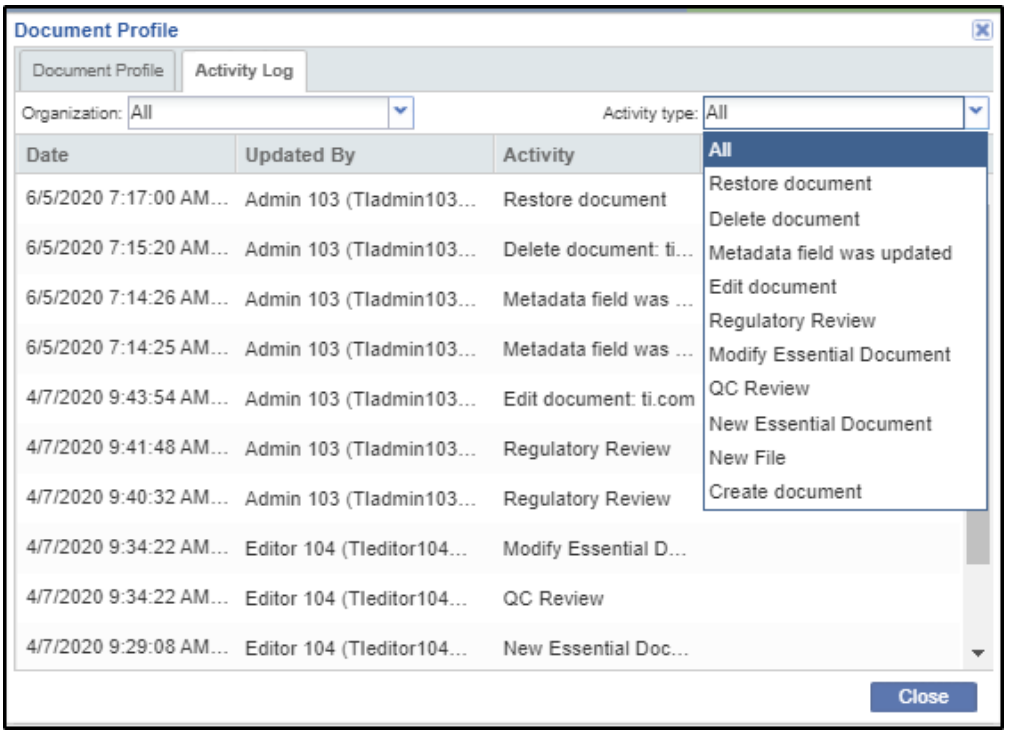
To view the profile of a document, activate the Document dropdown and click the Open Profile button from the menu bar. This opens the Document Profile window. Refer to the screenshot below:



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 screenshotbelow:



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

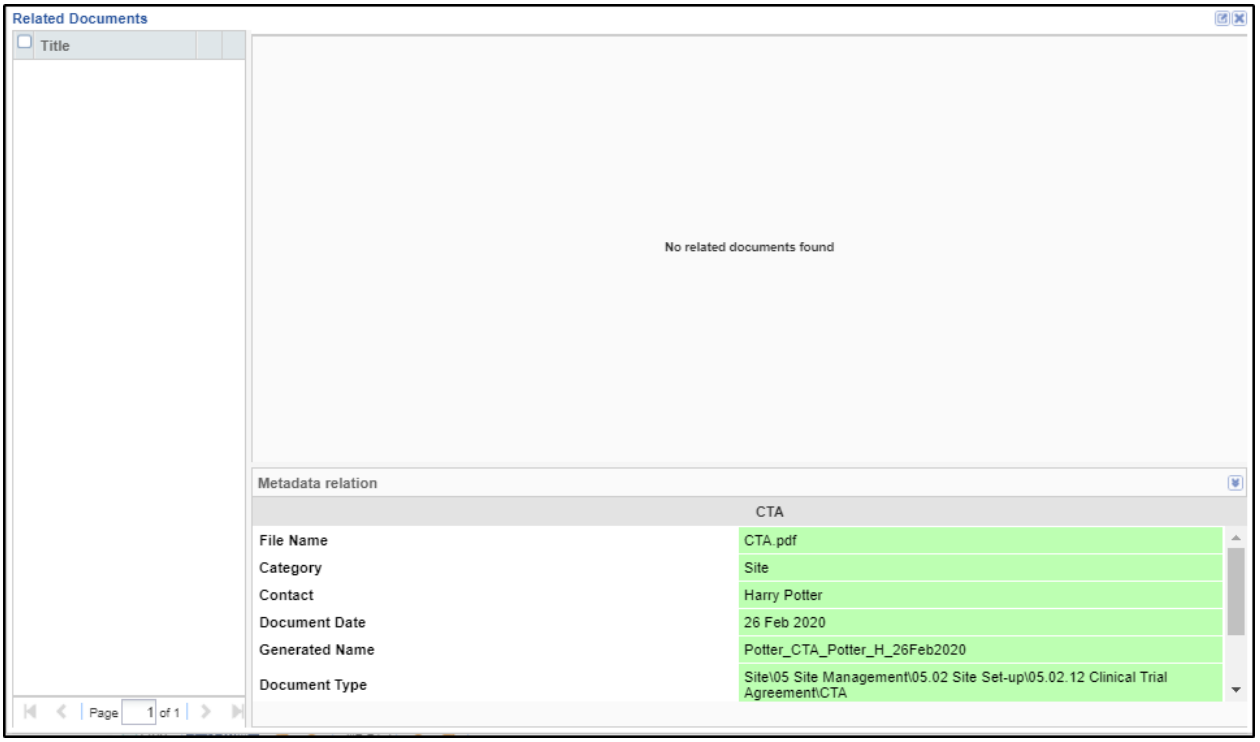
You can add a document selected from the grid to the cart to compare documents, link them, addthem to the submission package, or download documents.

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 defaultviewer. 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.

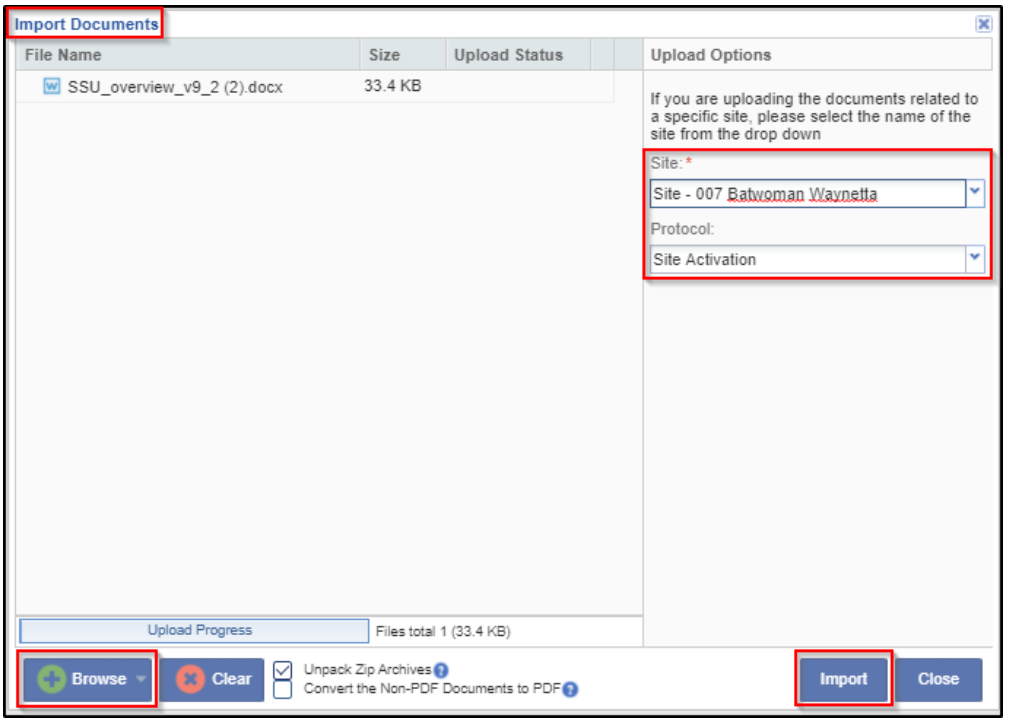
2. The Upload Options depend upon the view selected – By Site, By Country, or By IRB/EC.

3. Select your choice from the dropdown menu in the field in the 'Upload Options' panel.

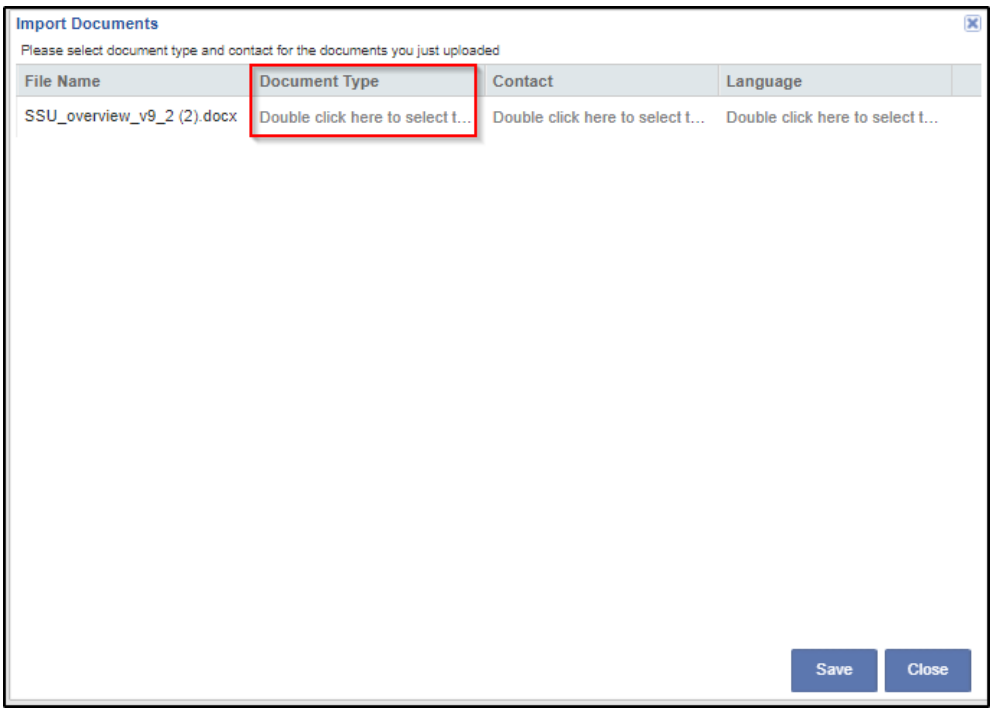
4. You can add documents to the window by using Browse and selecting the appropriate files for upload, or the user can drag-and-drop appropriate files, en masse, directly from a document library.

You can tick the 'Unpack Zip-archives' if you have uploaded a zip file and want to import thedocuments in the zip as separate documents.

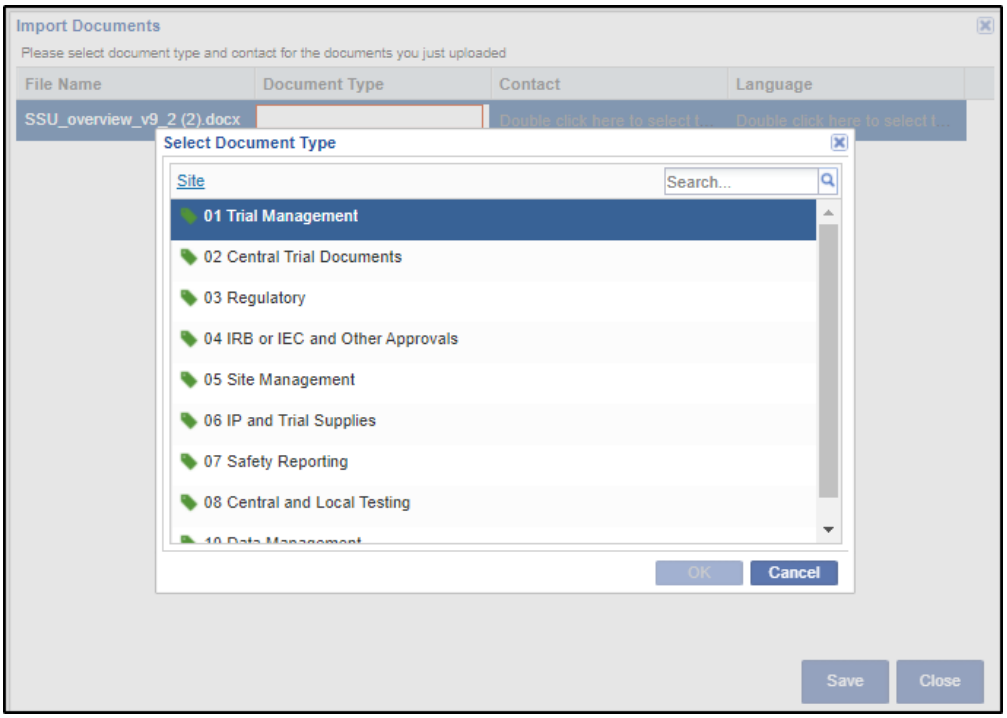
5. Once you have deposited all of the desired files into the Import Documents window, click **Import**.



6. The tool moves to the next stage of the document upload.



7. Following the on-screen instructions, double-click the Document Type field

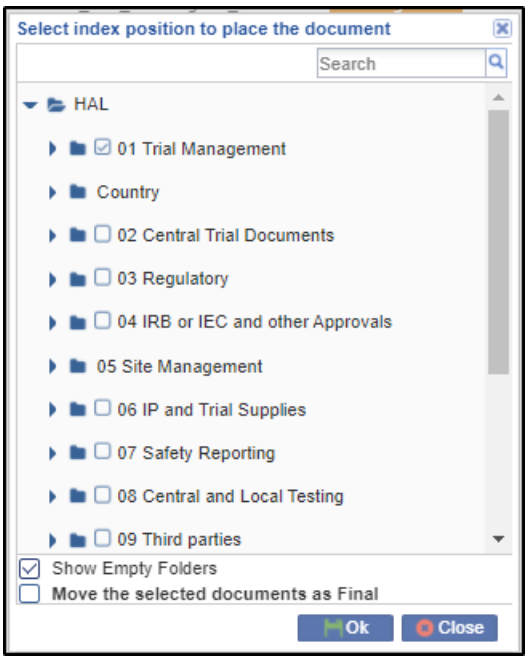


8. Select the document type that matches the actual document for each uploaded document.

9. Click **Save**. You return to the Documents view.

Move to eTMF

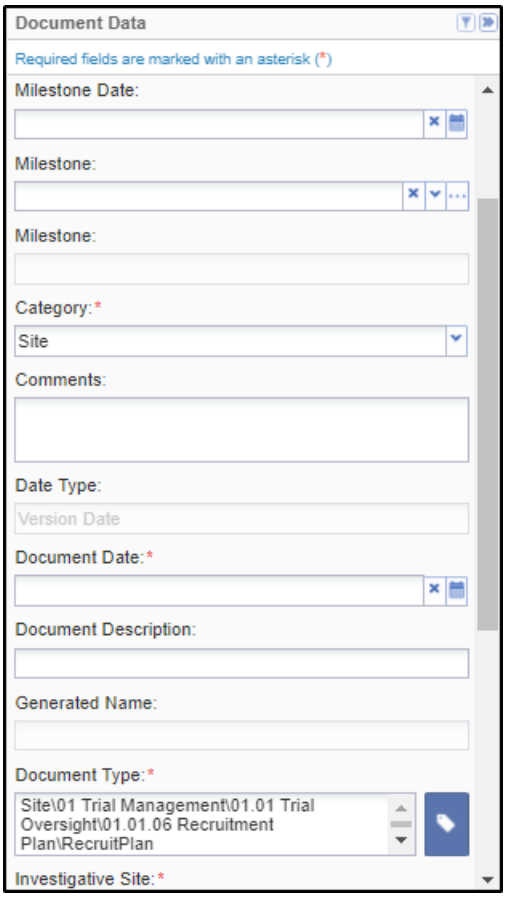
You can move a document selected from the grid in the eTMF by clicking the Move to eTMF buttonon the menu bar. This opens the Select index position to place the document window. Refer to the screenshot below.



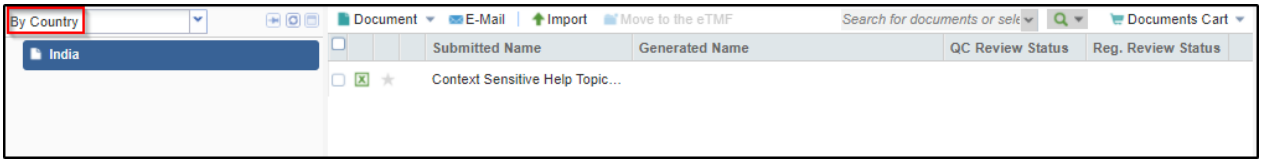
Select the appropriate folder to move the document to and click Ok.

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 **DocumentData Panel**. A screenshot of the panel is provided below:



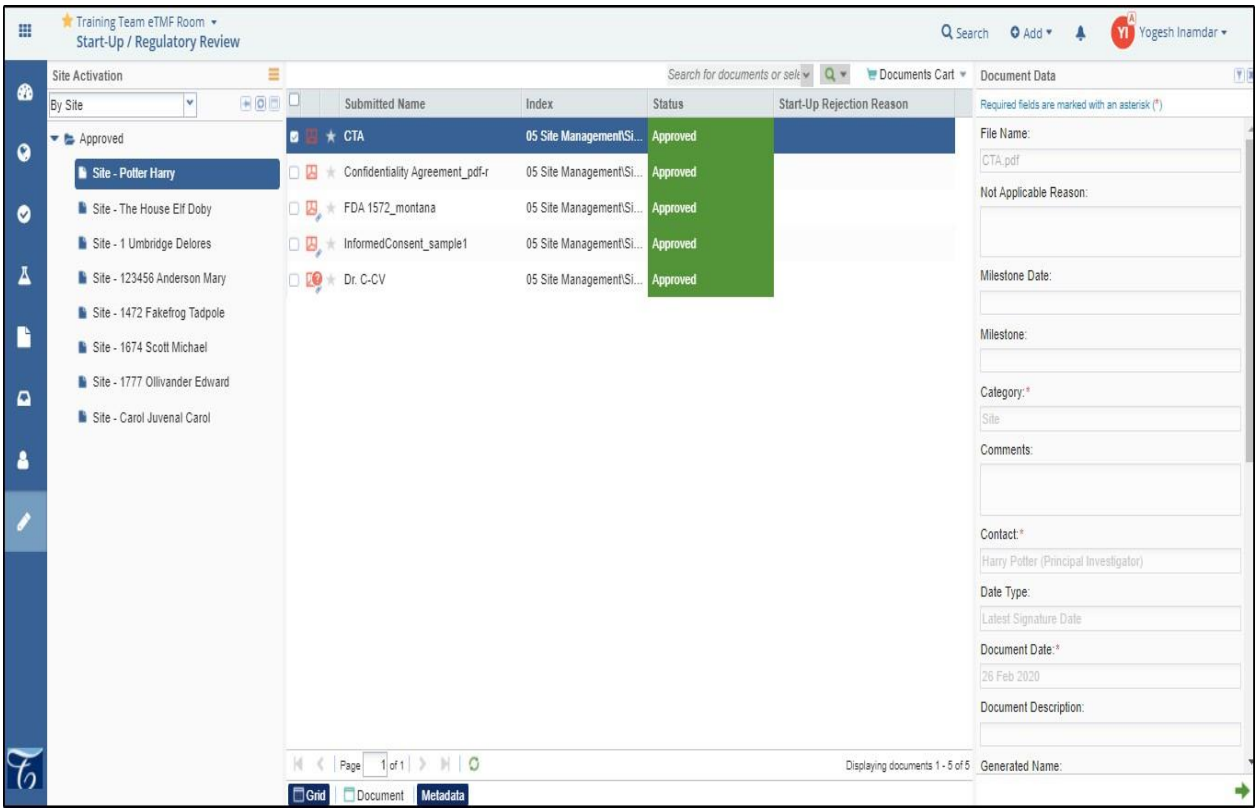
The contact of the documents is the username of the login that was used to upload the documents. Asshown in the screenshot below, documents for country India were uploaded. These documents now appear in the By Country view for India. Refer to the screenshot below:



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 procedureto 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

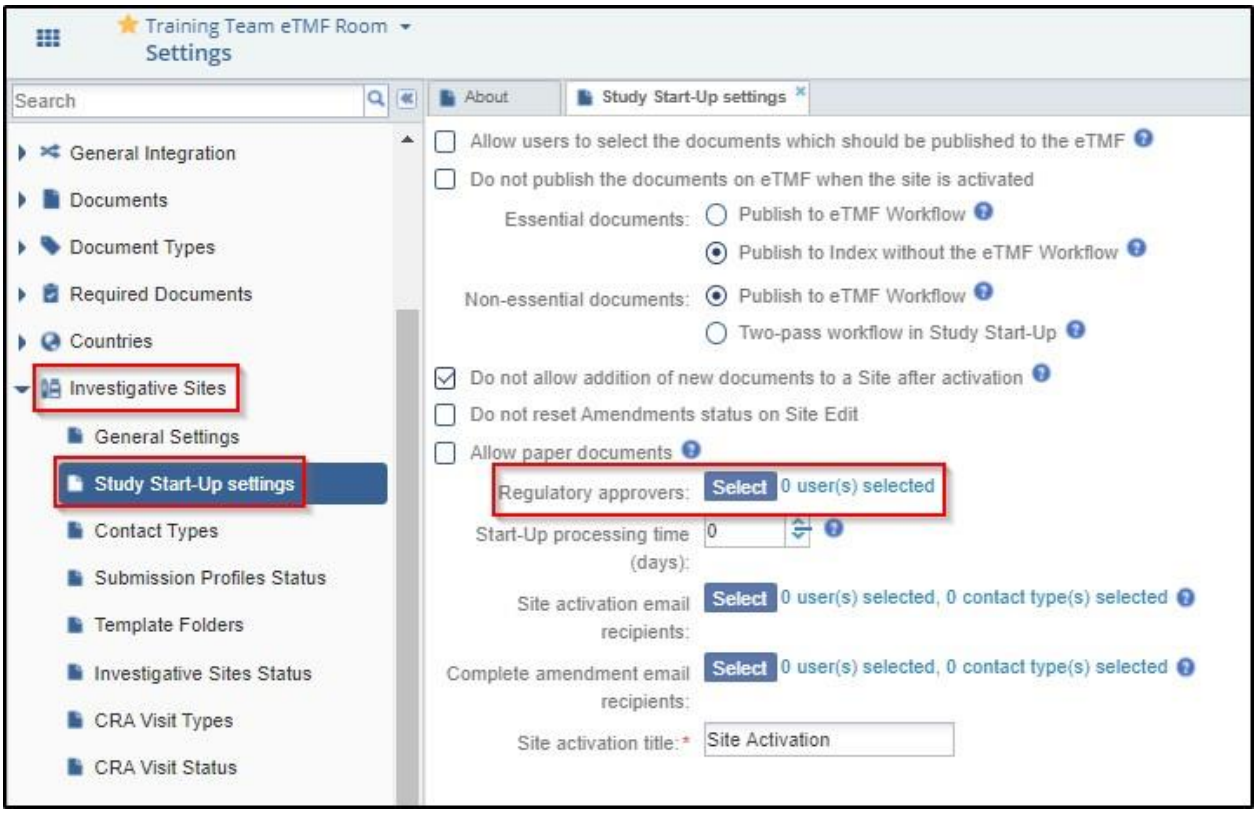
A Regulatory Approver can be a Global Regulatory Approver, Country, or Site Regulatory Approver. As a Global Regulatory Approver, you are able to perform the functions at all sites withina study room. As a Country Regulatory Approver, you are able to perform the functions at all sites in a specific country (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 toall the sites in the room.

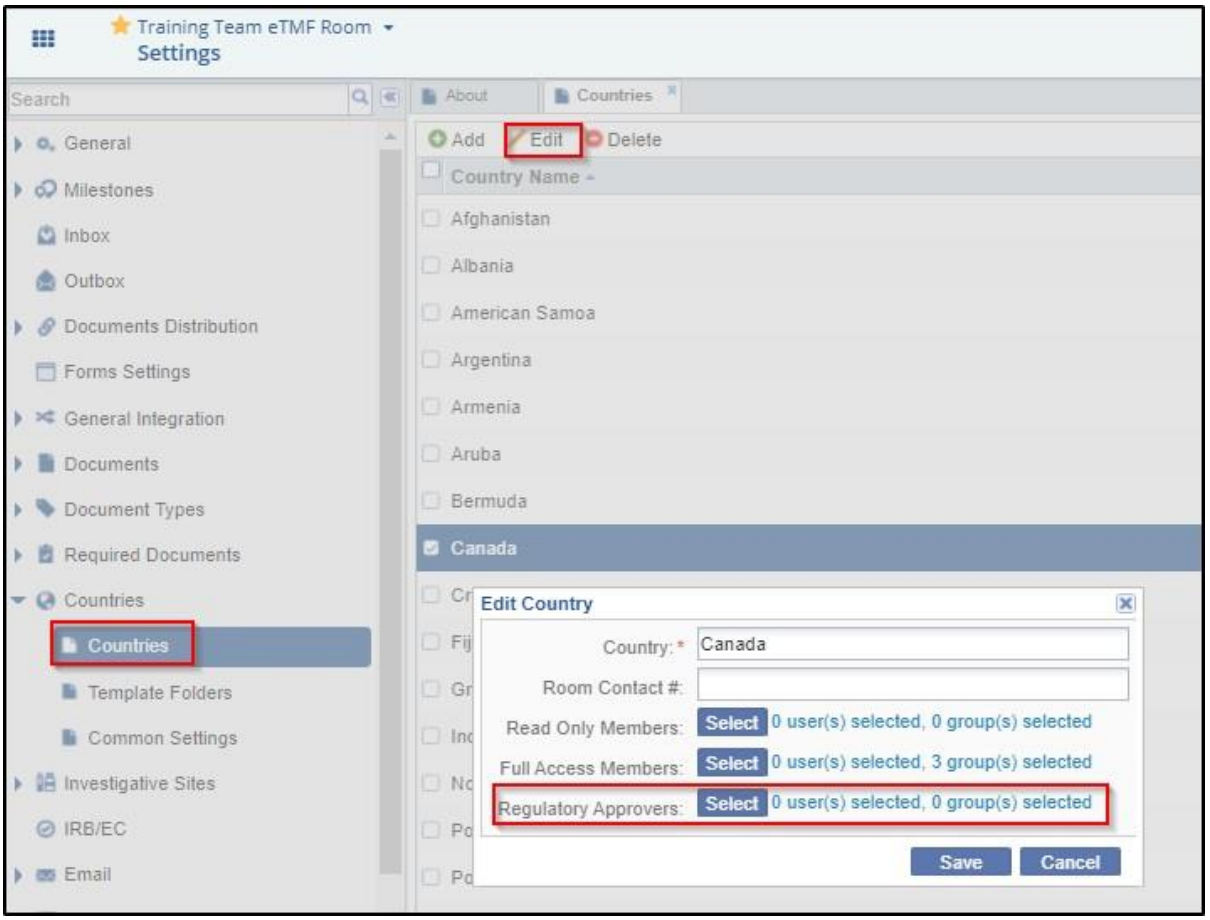
To add a Country Regulatory Approver follow the steps as below:

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**.

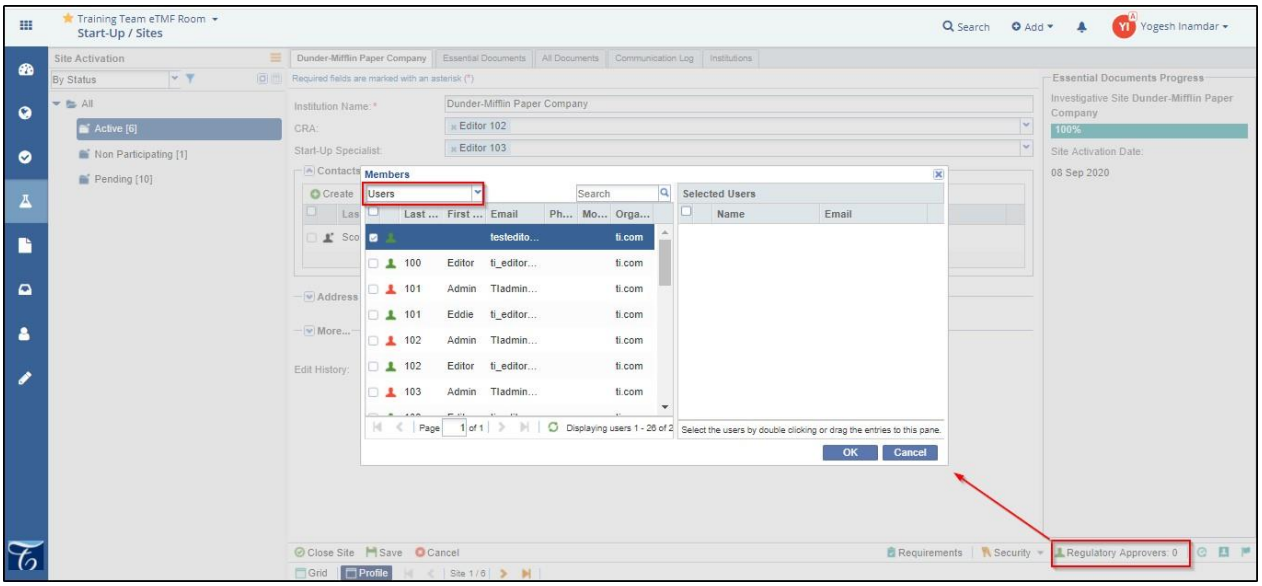
To add a Site Regulatory Approver follow the steps as below:

1. Navigate to the **SSU module** ◊ **Sites**.

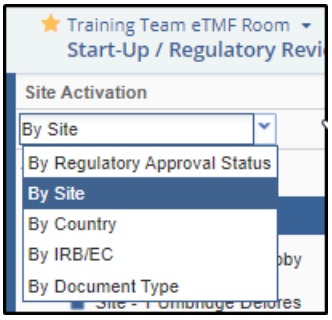
2. Double click on the site you wish to add a Site Global Regulatory Approver.

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 ordragging and dropping the user from the left-hand side to the **Selected Members** on the right-hand side.

4. Click **Save**.

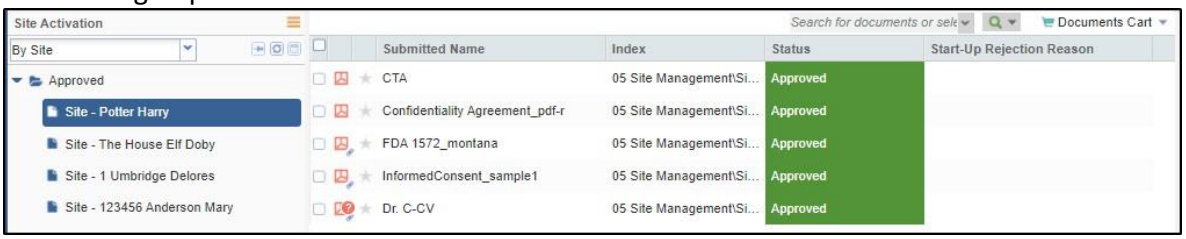


Current View



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. Thereview 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 alongwith their review status in the grid pane.

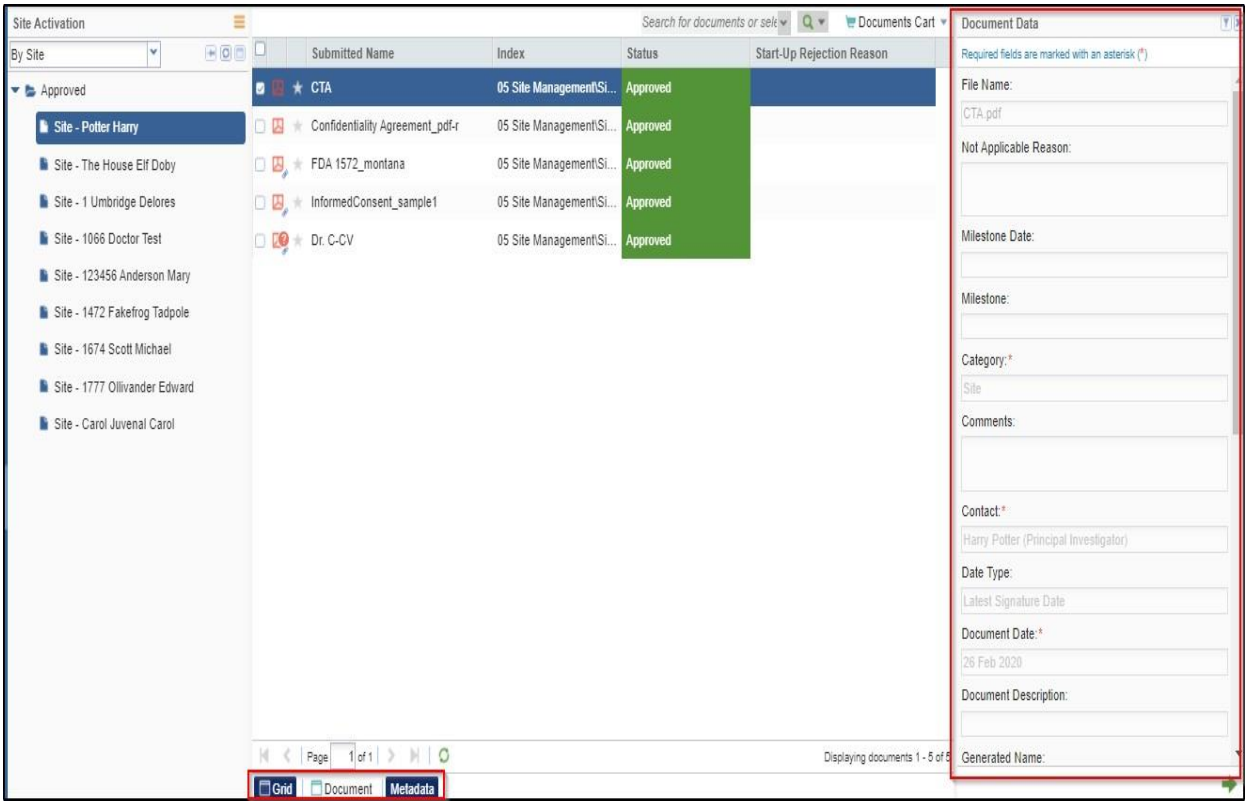
- **By Regulatory Approval Status**: The By Regulatory Approval Status groups all the documentsas per their review status i.e. Approved, Rejected and Pending. Clicking a review status group from the left panel will display the documents belonging to the particular review status group in the grid pane.

- **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.

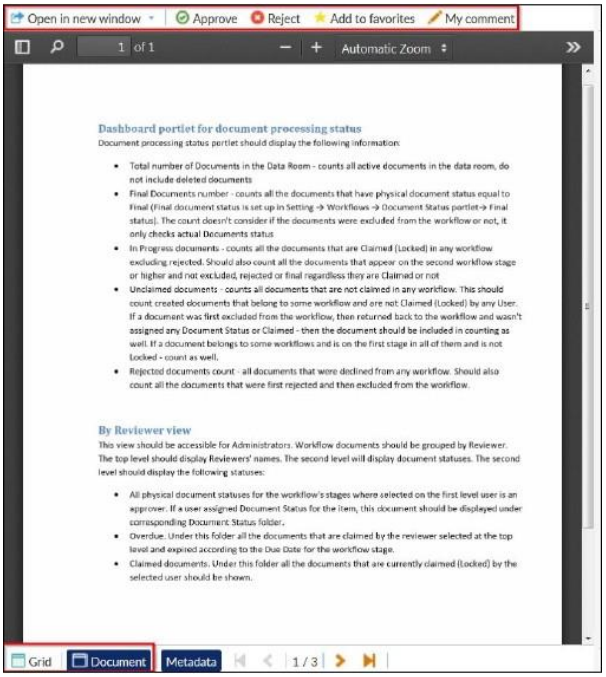


In the screenshot above, observe that the fields are non-editable. The user can switch between the Grid and the Document Data Panel by clicking any of the buttons located at the bottom of the Gridpane.

How to Regulatory Review a Document with Attachments

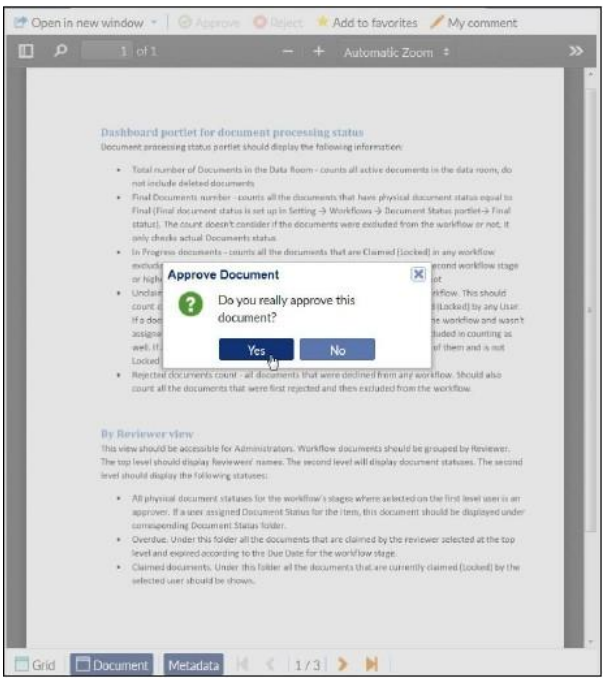
Once the regulatory reviewer receives an email stating about a pending review, he/she logs into TI to locate the documents waiting for review in the Regulatory Review section. The easiest way to find out all the documents in the study start-up waiting for regulatory review is to activate the By Regulatory Approval Status view from the left panel which lists out all the documents in the SSUpending 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.


Open in new window
Add to favorites
My comment
Automatic Zoom
Approve Document
Do you really approve this document?
Yes
No
Grid
Document
Metadata

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 toApproved, 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 CommunicationData.

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 thegrid.**
- **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 sitewill 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 thepeople under the contact type.

The Contacts Grid Pane

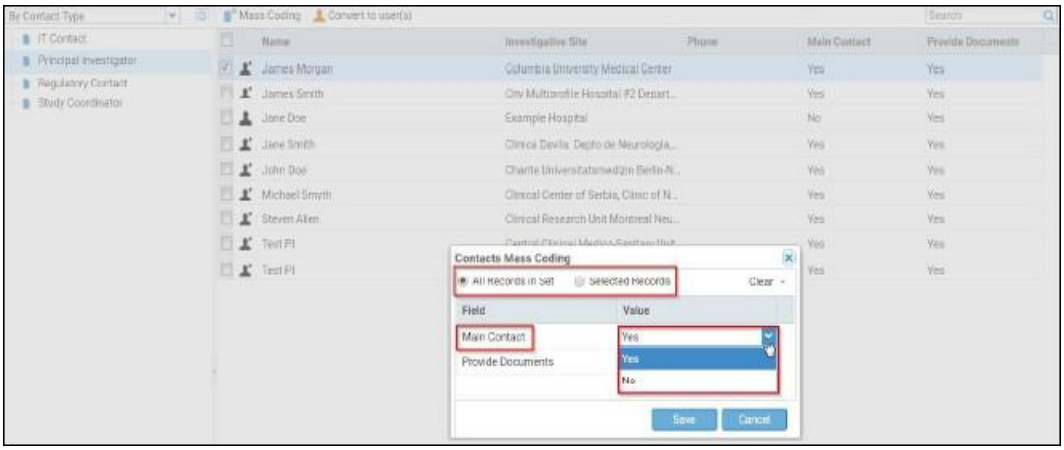
The Grid Pane displays the details of the contacts and provides various other functionalities throughthe Menu Bar on the top.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the screenshotbelow:

Mass Coding Contacts Metadata

Clicking the Mass Coding option from the top menu bar will enable you to set the all contacts in thegrid pane, or only selected contacts in the grid pane as Main Contact at one go for all the sites in thestudy start-up. Refer to the screenshot below:



You can also decide whether the contacts can be mass coded to provide documentsClick

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 theConvert to user(s) button from the menu bar. Refer to the screenshot below:

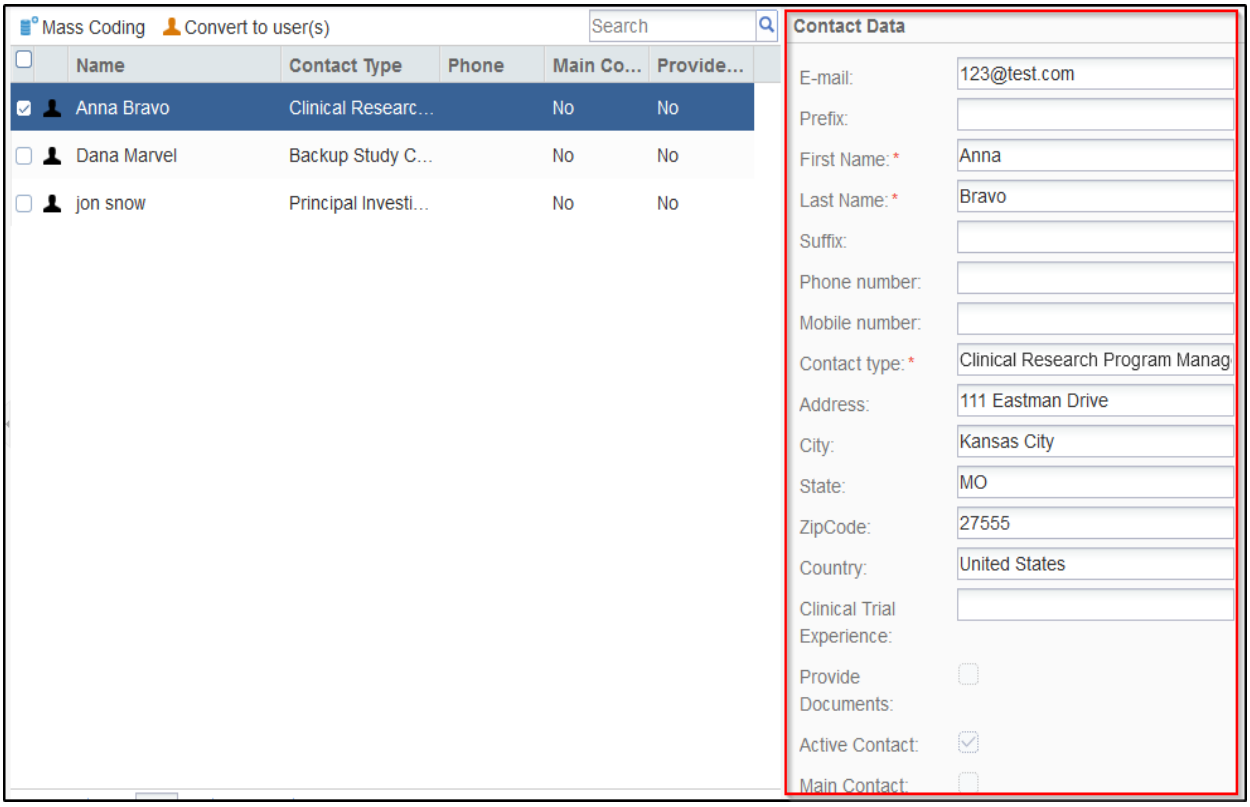
Click the Convert to user(s) button at the bottom of the popup to commit the changes. Refer to the screenshot below:

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 notbelonging 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 Accessiblefunctionalities for SSU contacts.

Contact Data

You can view the contact metadata in this panel. The contacts cannot be edited from here. To editcontact 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

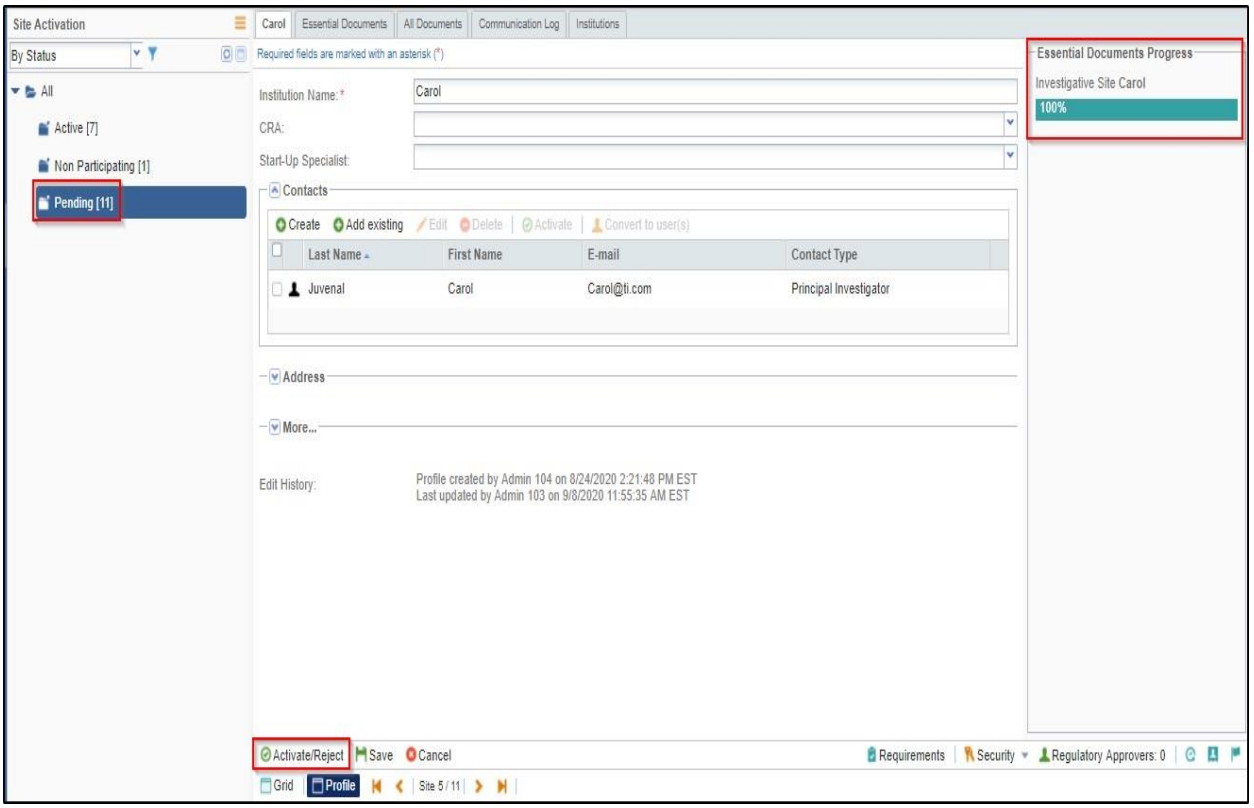
To activate a site in the Trial Interactive Study Start-Up module a series of steps must be followed.

The site information and users specific to the SSU site can be imported by TI if information isprovided 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 siteprofile 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:

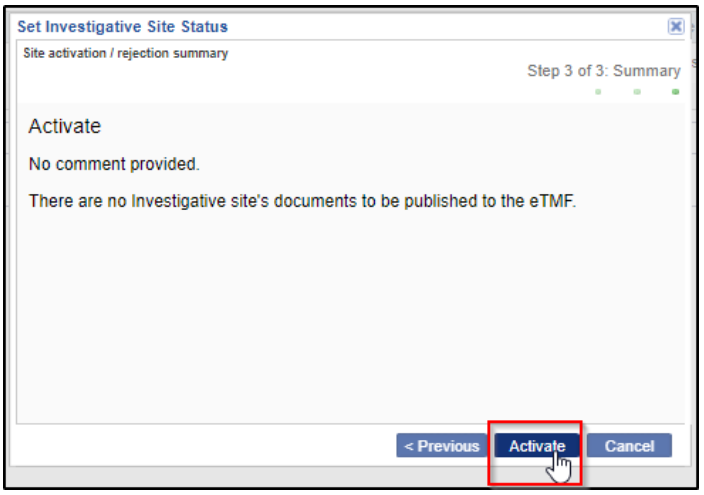
1. Click the Activate/Reject button.

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

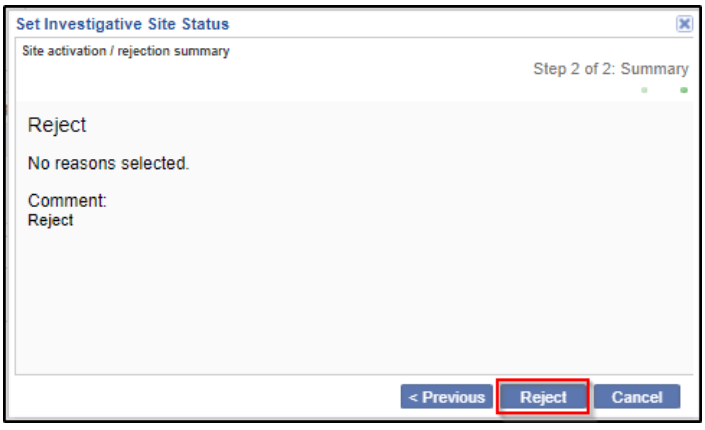
2. The Set Investigative Site Status window opens

3. Select the Status as Rejected.

4. Select the reason for rejection.

5. Enter the comments.

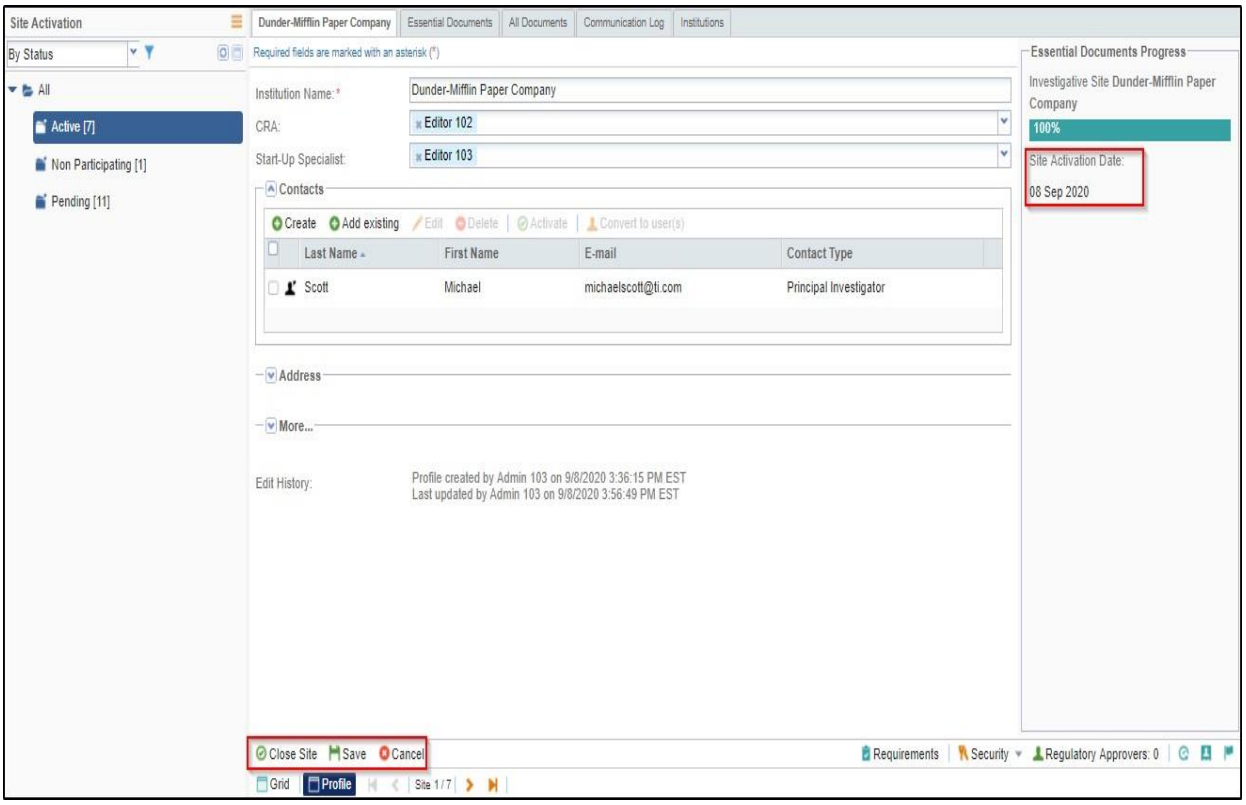
6. Click the **Reject** button.



The site will then be activated and the documents will be published to the eTMF or workflow as peryour 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 Activefolder 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 documentsneeds 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

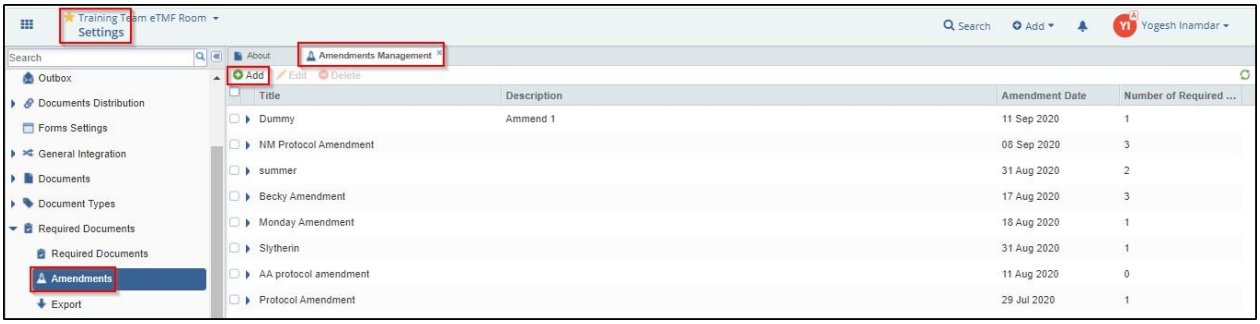
To create amendments, the administrator needs to do the following:

1. Navigate to Settings.

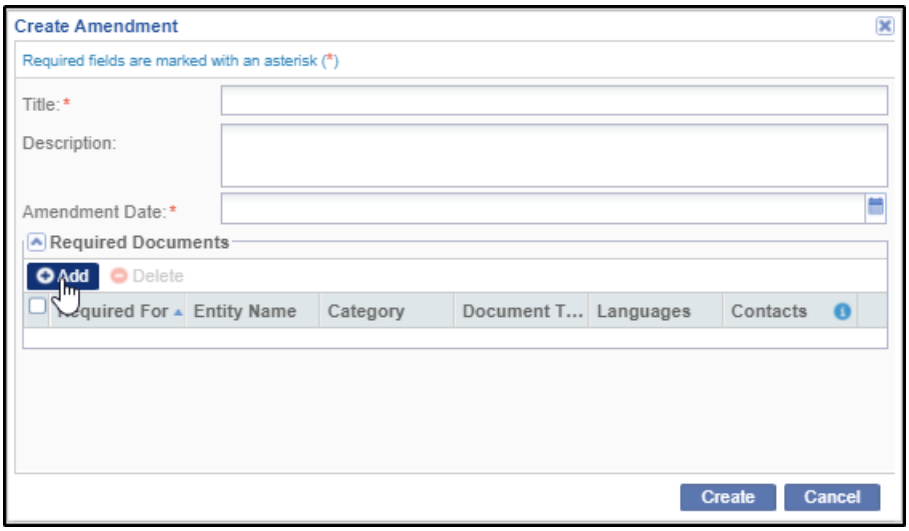
2. Click the arrow next to Required Documents in the left panel.

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, SpecificSite, Specific IRB/EC, or Specific Country).

e) From the right panel select the essential/required documents that are needed after the siteactivation.

f) The procedure to add the documents is same as described in earlier section Basic Configurationsfor SSU *(page 357)*

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 Amendmentdropdown. 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 thesame as described in section Collecting Essential and Non-Essential Documents *(page 417)*

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 Reviewand Regulatory Approval.

The non-essential documents will need to pass through the approval process only if it is specified inthe 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 inearlier sections.

To Regulatory Review the documents, the Regulatory Approver will need to log in to the systemand enter the Regulatory Review section. Here too, the Regulatory Approver selects the requiredamendment 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 onclicking 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 receivea 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 selectedthrough two buttons, Expiring and Expired on the top left corner. To set the views click the Dashleticon 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:

Add Any Sites to Amendments

Previously in TI, when a new site was created, it would automatically be added to the most recent amendment but not to prior amendments. Now, room administrators will have the ability to add anewly created site to any amendment, making it easier to ensure that all required documents are accounted for and collected in a timely manner.

Improved Site Activation Date Tracking

Routinely, a site's activation date may have to be recorded after the fact. In prior versions of TI, siteshave been tied to an automatically generated activation date which was not always representative of the date that the site came online. Trial Interactive now allows a Start-Up Specialist to track the site activation date by setting it manually, overriding the default date set automatically by the system.
This will help provide consistent metrics for cycle time and allow for accurate reporting.

For a more detailed discussion of the site activation process, please see the site activation sectionof the users guide. The ability to manually indicate a site's activation date is added to the Set Investigative Site Status window underneath the Comment field.

Updated Progress for Essential Documents

It is critical to have an accurate idea of how close a site is to activation and key to that is knowingexactly how many documents are still outstanding or may still require review for final approval.

To that end, SSU will now differentiate between documents which have been reviewed and those which are still pending approval. This will allow for users to have a more accurate understanding ofhow close each site is to submitting all of the documentation required for site activation.

When viewing Pending sites in Study Start Up, the Progress % column shows the site's progress towards activation. For more information, hover over the progress bar. The following informationwill be displayed:

- % of documents approved by QC Review (Study Start Up Specialist)
- % of documents approved by the Regulatory Reviewer
- A list of any documents still waiting to be collected.

Email Preview, CC, and Reply to Regulatory Packages

Easy and effective communication with sites is important to the site activation process. In order to help maximize efficiency in these communications, we have made a number of alterations in the emailing of regulatory packages to sites and in how those documents may be returned for processing.Trial Interactive now allows Start-Up Specialists to preview regulatory packet emails in order to see if any edits are required. Users can edit these emails prior to sending to them and to copy additional contacts if necessary.

Also, new to SSU in this release is the ability of sites to submit these documents simply by replying to the regulatory packet email that they received. This will facilitate timely receipt of documents andhelp ensure that the site activation process goes as smoothly as possible.

A more detailed discussion of the process for sending the Regulatory Packet to a site is contained inthe Study Start Up User Guide but the following, abbreviated, discussion may be of assistance.

In order to Preview a Regulatory Packet Email, follow these steps:

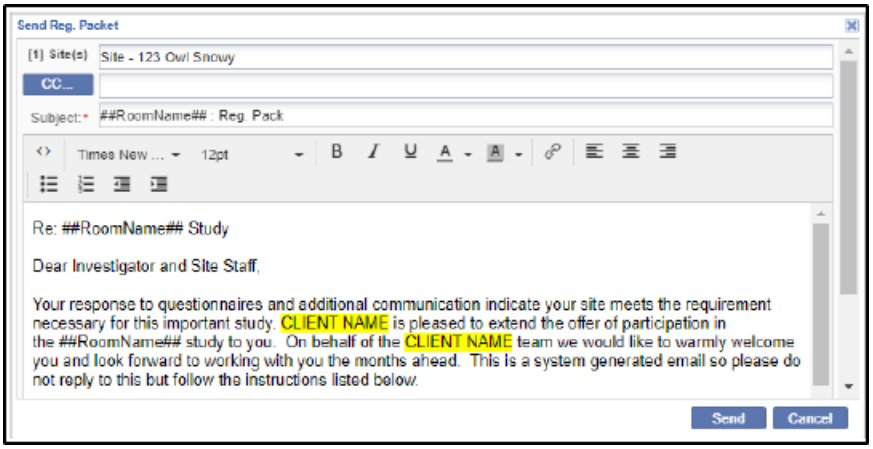
1. From the Grid in the SSU Sites module, select a site.

2. Press the Send Reg Packet button located above the Grid.

3. A preview window will now open allowing the user to confirm the body of the email and makeany edits as necessary.

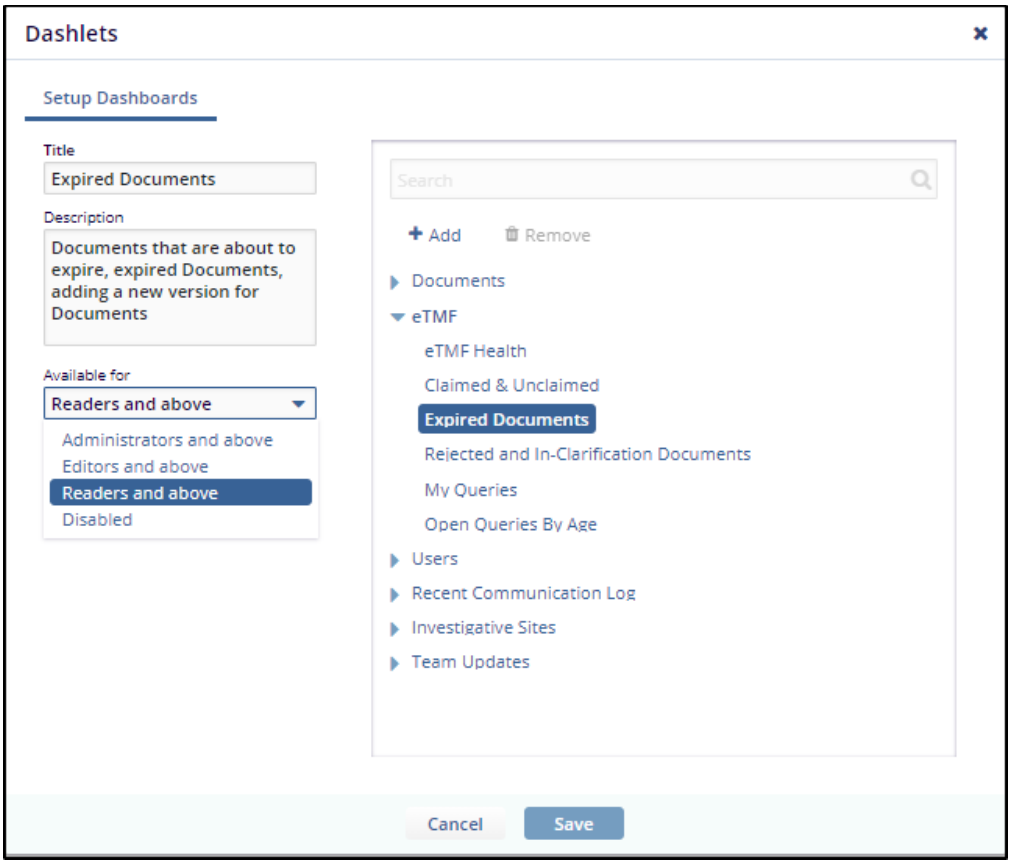
a. This includes adding another recipient by pressing the CC button and selecting from the listshown.

See the screenshot below:



4. When you have completed any required changes to the email template, press Send tosend the email to the site.

Of additional interest with regard to the Regulatory Packet email is that, in prior versions of Trial Interactive, site contacts would be required to send any completed documents to the Study Start Up Inbox in order for them to be received by the system. Now, in TI v10.2, the site will be able toreply directly to the Regulatory Packet email in order to submit their documents.



The columns can be selected from the Expiring or Expired button in the above screen and alsothrough Modify Grid Config.

To view Expiring or Expired documents, click the Expiring `button or Expired button from thedropdown on the dashlet. Refer to the screenshot below:

Dashlet-Recent Communication 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 viewthe 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 thescreenshot 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 theline 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.