TRIAL INTERACTIVE

9.2 Admin Guide, v. 1.0

TRANSPERFECT

Approval Signature: ______________________________ Date: _____________________

Approved By: Abdul Anwer

Title: Senior Director, Application Development

Approval Signature: ______________________________ Date: _____________________

Approved By: Rebecca Maizel

Title: Senior Quality Assurance Specialist

Version History

Author	Version	Date	Change History
Polly Chakraborty	1.0	06June2018	Document Creation

Table of Contents

1. About This Guide

This help guide will assist users with Admin Access in understanding and using the TransPerfect Trial Interactive 9.2 platform, which is used by life science companies to conduct eTMF, Study Start-Up, licensing, due diligence, and clinical trial collaboration activities in a secure online environment. This guide contains a descriptive overview of the Trial Interactive tool and step-by-step procedures for common Admin User level Trial Interactive functions.

This guide is intended solely for the use of clients who have purchased the Trial Interactive platform. This guide and its contents are the intellectual property of TransPerfect Trial Interactive and are not to be distributed without the expressed consent of TransPerfect Trial Interactive.

2. About Trial Interactive

TransPerfect offers global eClinical Solutions through its platform, Trial Interactive. Trial Interactive enables life sciences companies to streamline the execution and commercialization of global clinical trials and collaborate on partnerships while reducing administrative burdens. As a 21 CFR Part 11 solution, Trial Interactive provides users with a completely secure environment in which to complete all required regulatory information, paving the way for paperless global clinical development and commercialization.

Our solutions are used by pharmaceutical, biotechnology, and medical device companies as well as CROs, IRBs/ECs, and leading academic institutions involved in clinical development that stand up to the scrutiny of regulatory authorities globally. As near real-time access becomes even more critical to development and management teams around the world, Trial Interactive provides a hosted SOC 2 Type II certified environment with next-generation encryption and intrusion detection to protect your confidential information. Trial Interactive 9.2 takes a step further by integrating within its system, Mixpanel, a third party service, that allows the client to track user actions, and thereby manage and analyze collected data. Trial Interactive’s configurability allows it to be used in multiple ways to streamline clinical development and has multiple modules that can be used standalone or integrated to streamline study processes. These include:

- Study Start Up Module
- eTMF Module
- e-Feasibility Module
- Safety Notification Letter Distribution and Tracking
- Safety Portal
- Endpoint Adjudication
- myTI

3. Getting Started

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

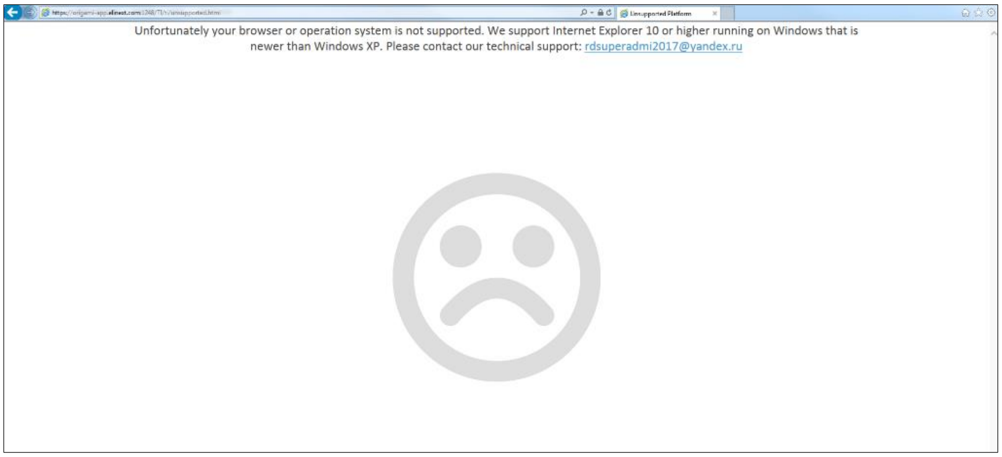
- Browser and Operating System Support
- Receiving and Responding to a Room Invitation
- Logging In on subsequent visits
- Logging in using Multi-Factor Authenticator
- Logging In without access to rooms
- Requesting a password reset
- Accessing a Trial Interactive Room
- Navigating between Rooms
- Marking favorite rooms

3.1. Browser and Operating System Support

Trial Interactive is fully functional in standard browsers including Internet Explorer 10, Internet Explorer 11, Chrome, Firefox, and Safari; it requires Adobe 7.0 or higher and recommends Chrome for PC users and Firefox for Mac users. It is also fully functional in the Windows Operating System.

Trial Interactive 9.2 restricts the usage of versions of Internet Explorer with version number less than 10. It also restricts the usage of Windows operating system with version of Windows XP and earlier.

If Trial Interactive 9.2 is accessed through any of the unsupported browsers, or operating systems mentioned above, a message as shown in the screenshot below is displayed:



With Trial Interactive 9.2, a user will be logged out if the user is logged on multiple sessions in different browsers at the same time. To enable multiple sessions at the same time, the administrator needs to enable it while inviting a user to room.

3.2. Confidentiality Agreement

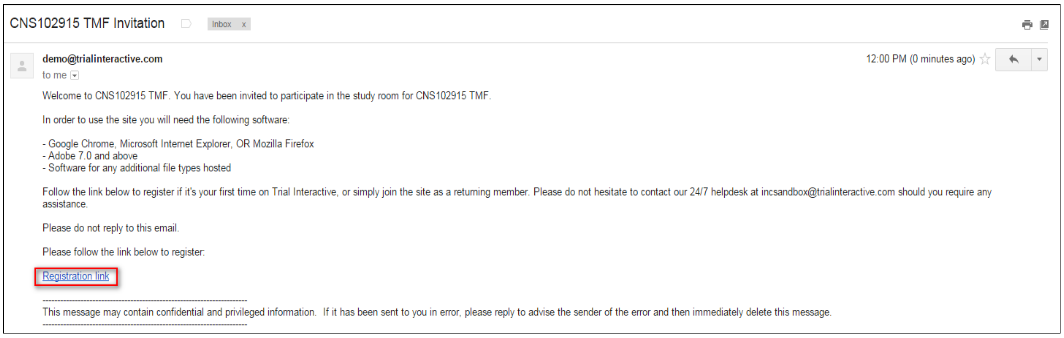
If a Confidentiality Agreement is enabled for your room, the user will be asked to sign the Confidentiality Agreement:

1. When the user logs in the first time and visits the room or accesses the room, or
2. When the user visits the room each time or refreshes the page, or
3. When the user uploads a document from the Home page, or
4. When entering a room through multiple sessions.

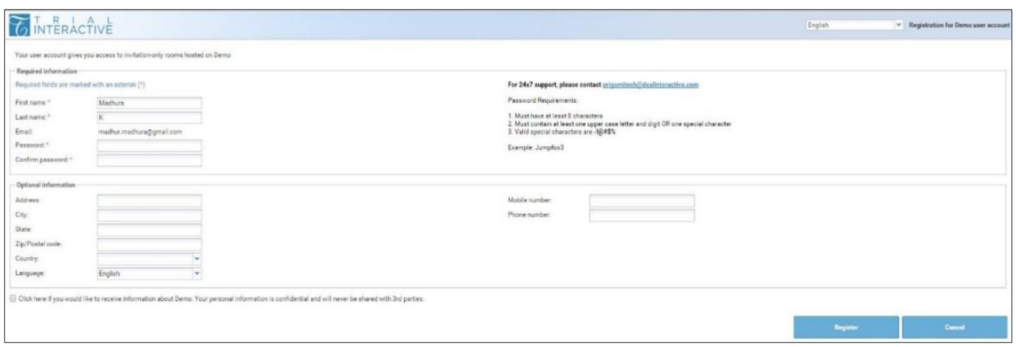
For more details on setting up the Confidentiality Agreement for your room, proceed to section <u>General Security Settings -> Confidentiality Agreement</u>.

3.3. 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 welcome message and a Registration link.



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

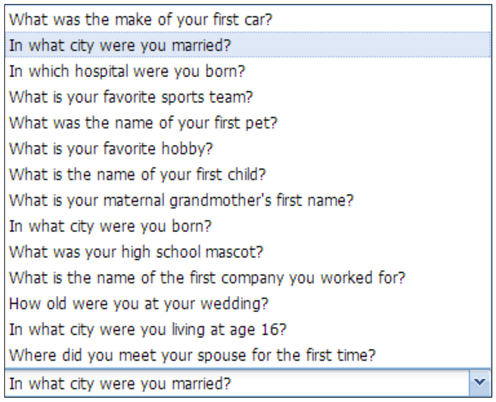


2. Type in your first name, your last name, and your email address as requested on the page in the appropriate fields.
3. Create your secure password, and confirm the password by re-typing it in the **Confirm password** field.

Password requirements:

- ***Must have at least 8 characters***
- ***Must contain at least one upper case letter and digit OR one special character***
- ***Valid special characters are - ! @ $ %***

4. Select your first secret password recovery question from the dropdown list.

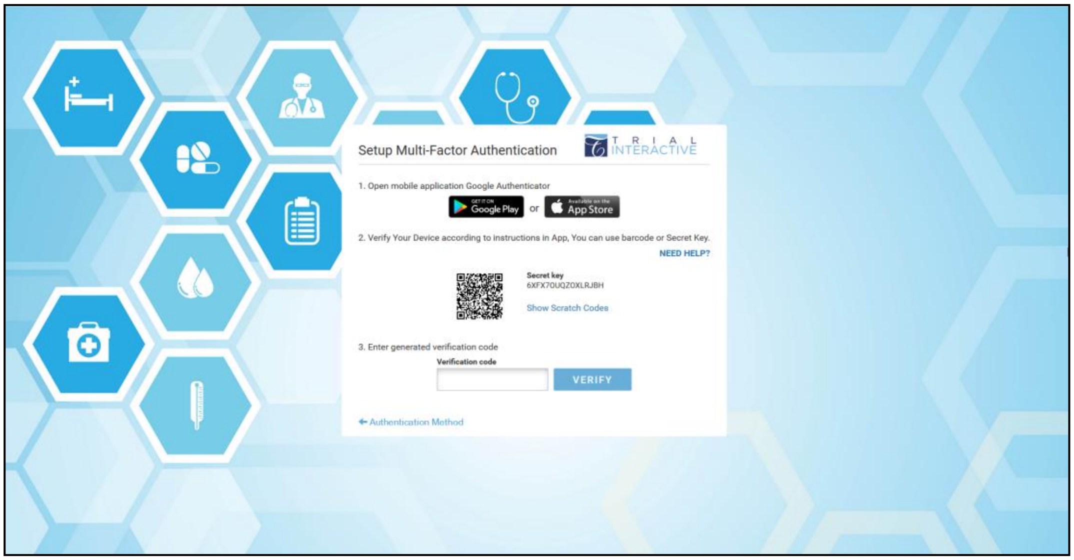


5. Type your answer in the appropriate field. Based on client preference, some rooms have only one password recovery question.
6. Select your second password recovery question.
7. Type the answer to that question.
8. Complete the other fields at the bottom of the registration page as directed by the study sponsor.
9. Click **Register**. You will be directed to a confirmation page.

10. Click the link to the secure Trial Interactive website. From this site you can begin work in the trial room.

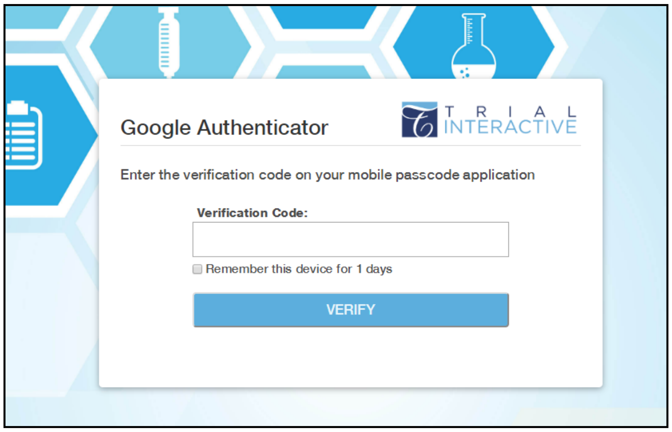
3.4. Logging in using Multi-Factor Authenticator

If your system is enabled for Multi-Factor authentication using Google Authenticator, you will be lead to the **Setup Multi-Factor Authentication** page on logging in with your login credentials. Refer to the screenshot below:



On this page you will need to enter the verification code generated by Google Authenticator. For this you will need to do the following:

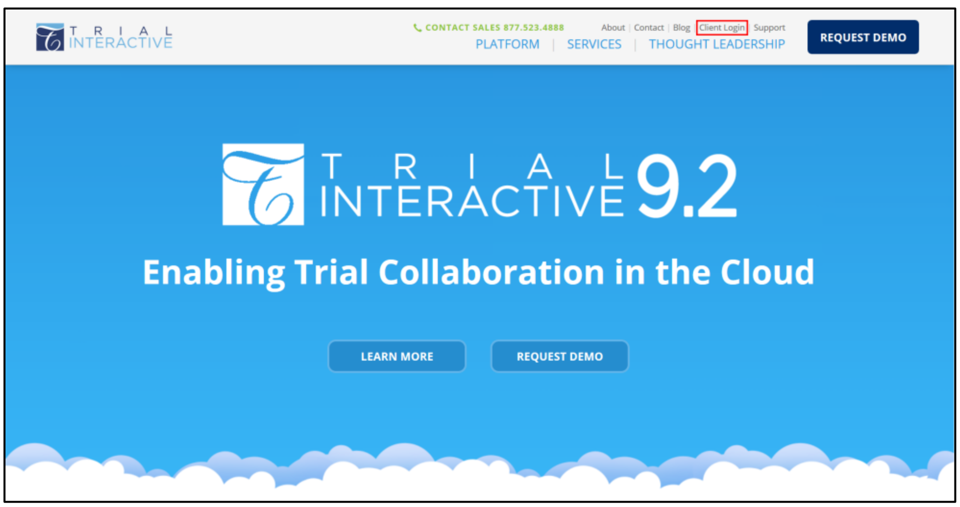
1. From Google Play Store or App Store on your mobile device, install **Google Authenticator**.
2. Add your Trial Interactive account by **scanning the bar code** on your computer's Login screen from your mobile device, or enter the **Secret key** in the field provided by your Authenticator on your mobile device . Refer to the screenshot above.
3. The above step will generate a **verification code** on your mobile device.
4. Enter the verification code on the **Setup Multi-Factor Authentication** page on your computer. Click **Verify**.
5. You will now be logged in.
6. When you log in for a subsequent visit, you will only be asked for the verification code generated by Google Authenticator after you have entered your login credentials. Refer to the screenshot below:



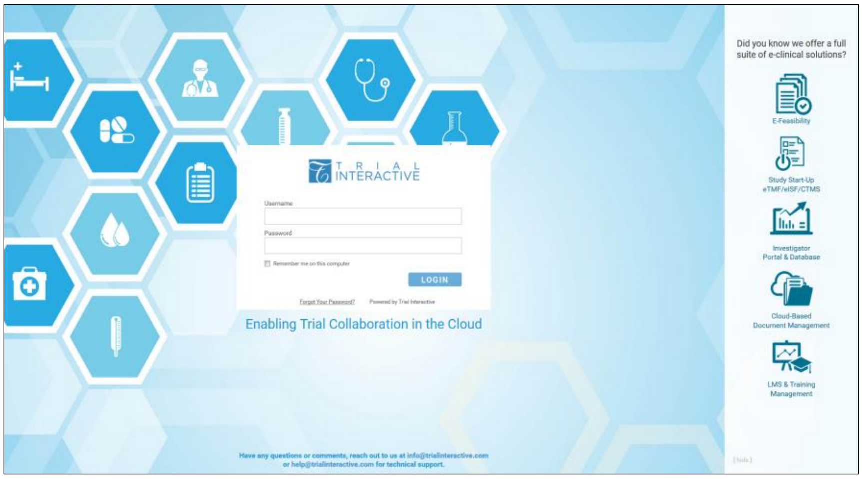
3.5. Logging In on Subsequent Visits

To log in to Trial Interactive:

1. Using your preferred internet browser, navigate to http://www.trialinteractive.com



2. Click the **Client Login** button located at the top right corner of the page.
3. The Trial Interactive Login page with links to a suite of e-clinical solutions offered by TransPerfect Life Sciences appears.



Click the links to delve further into the solutions provided by TransPerfect Life Sciences or login.

4. Enter the **Username** and **Password**. The **Username** is the full email address that was submitted by the client-appointed Administrator.
5. Click **Login**.

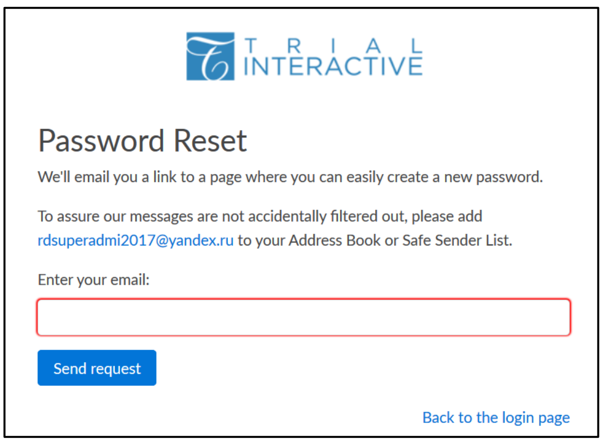
   If you are logging in the first time, the Trial Interactive Homepage for the account associated with the login username appears, else you are redirected to the same location in the application that you were in upon a subsequent login.

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

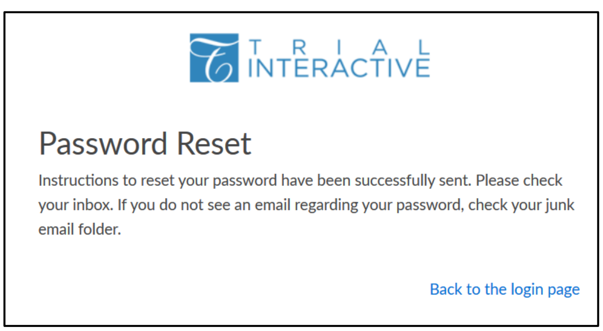
3.6. Requesting a password reset

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 Help Desk. In most cases, the user can perform the Password Reset operations without any outside help.



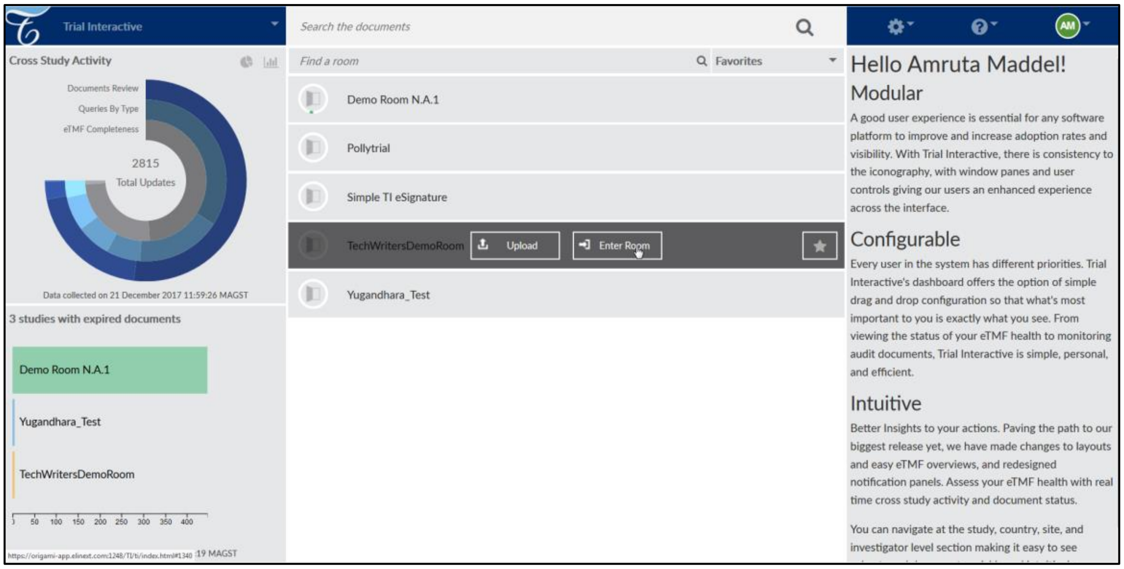
1. **Enter your email** address in the field provided.
2. Click **Send Request**. The next window in the Password reset wizard opens.



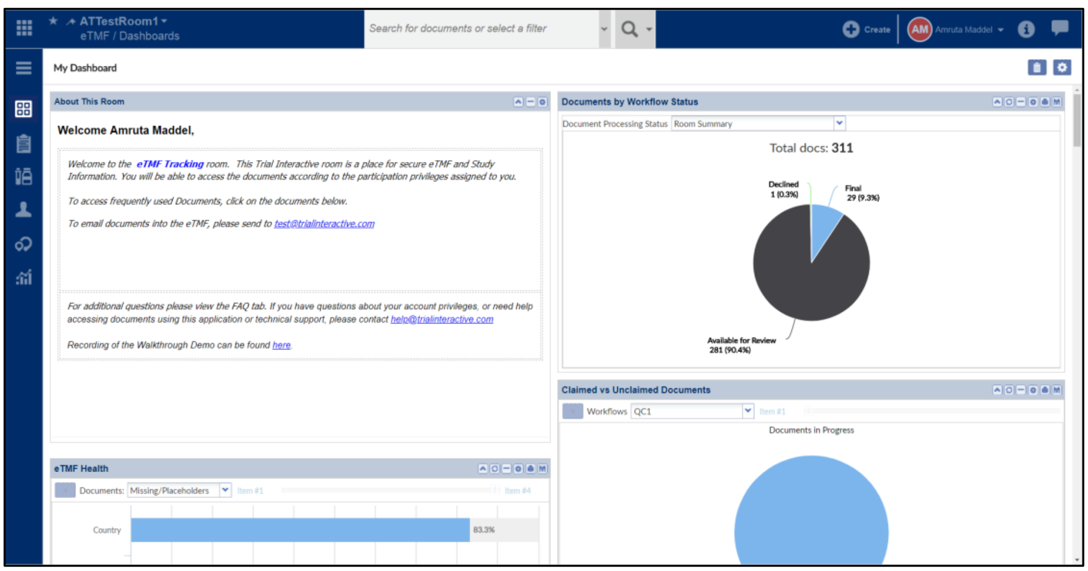
3. You will receive an email with the **Reset Password** link.
4. Click the link to lead you to the **Password Reset** page.
5. Respond to the security questions and click **Next**.
6. You are taken to the **Change Password** page. Enter the new password and confirm again.
7. Click **Set new password**.
8. The system confirms that the password was successfully reset. Click **Back to the login page** to login with your new password.

3.7. Accessing a Trial Interactive Room

After logging in to Trial Interactive, you can access an individual study room from the user homepage. Hover the mouse over the name of the room appearing in the pane at the center and click **Enter Room**.



Your screen opens to the Dashboard view of the selected room. You can find more information in the Main Module View section of this guide.

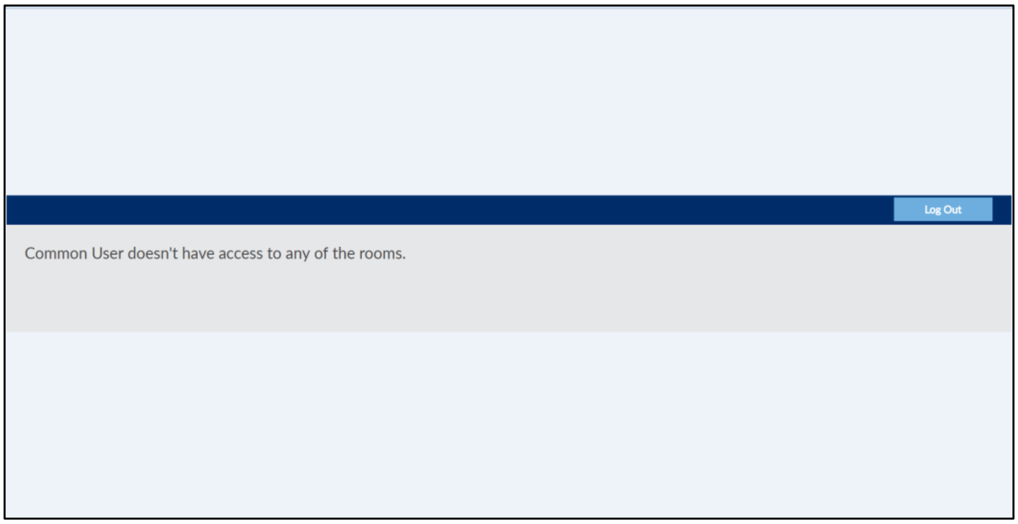


You can set the default view you want to arrive at upon entering a room from your **My Profile Settings -> Default Context Configuration**.

3.8. Logging In without access to rooms

If a user who does not have access to rooms in the system tries to log in, such a 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 have expired or revoked.

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



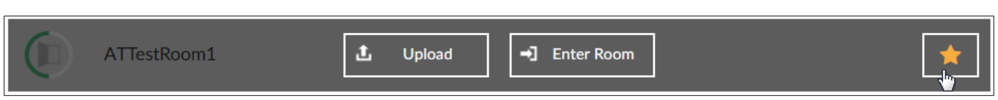
Click the **Logout** button to redirect to the standard login page.

You can contact the helpdesk if you want to configure a different message to be displayed in the advisory page.

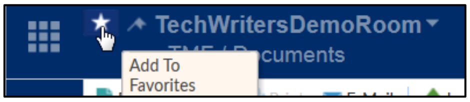
3.9. Marking Favorite Rooms

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. This can be done in two ways.

A. From the home page by hovering the mouse over a room name and clicking the star which changes its color to golden on selection.



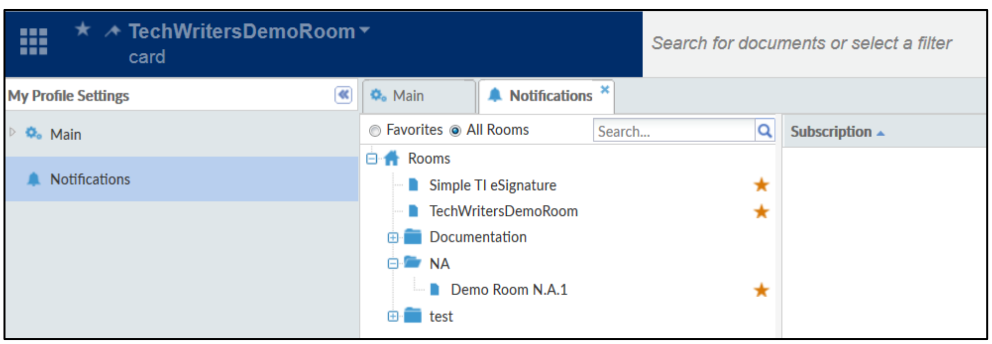
B. On entering a study room, you can add it to Favorites by clicking the star at the top left corner of the page where the room name is displayed. The room can easily be removed from the list by clicking the star again.



C. On entering a study room, you can also add rooms to Favorites from the list of rooms displayed in the popup when you click the dropdown next to the room name. Refer to the screenshot in section 3.10.

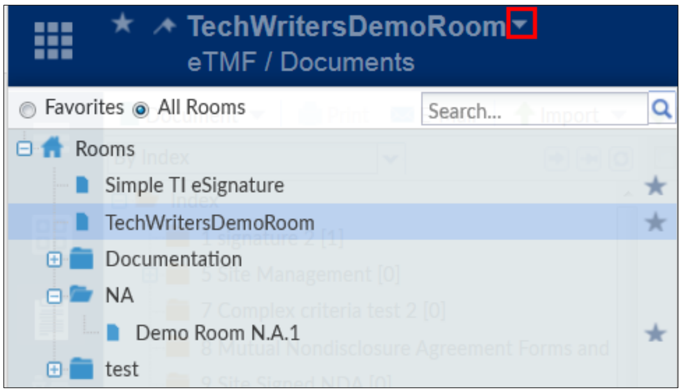
D. The list of all rooms to which you are assigned is also available through the user profile.

1. Click the **username** and then **My Profile** in the upper right corner of the Trial Interactive screen.
2. Select **Notifications** from the menu on the left.
3. Click the golden star to the right of the room names to mark the selected rooms as **Favorites**.



3.10. Navigating between Rooms

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

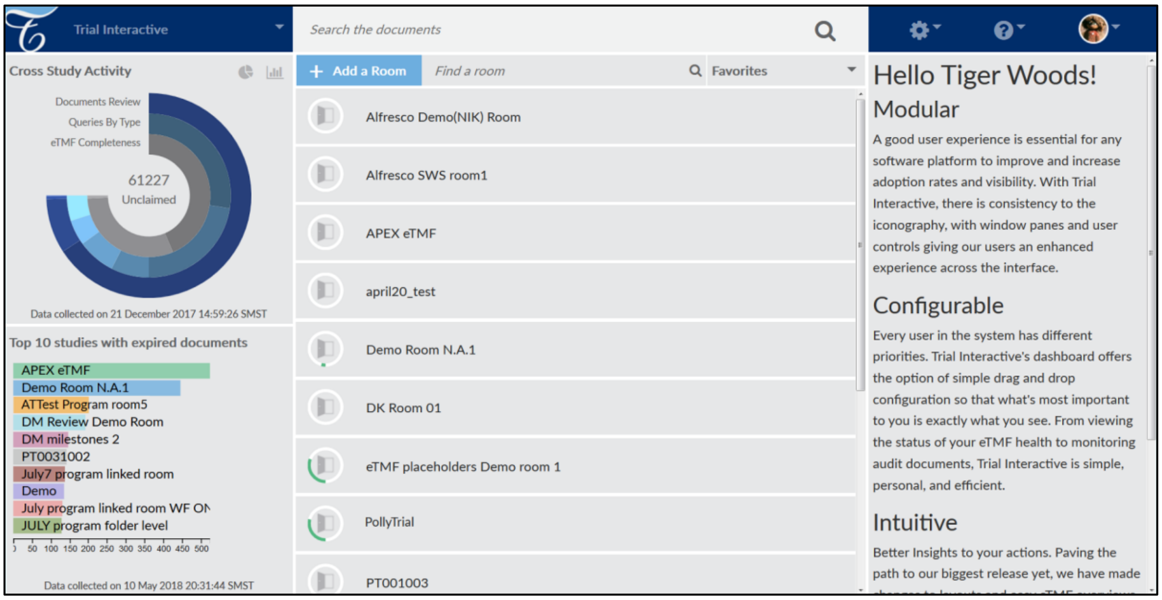


Click a room name from the list and the system will navigate you to the selected room.

4. The Trial Interactive Home Page

The Home Page is the default dashboard of Trial Interactive. It gives you a quick overview of the rooms along with the Cross Study Activity, and Top Studies with Expired Documents.

Refer to the screenshot below to get a view of the Trial Interactive Home Page.



The Trial Interactive Home Page is divided into:

1. The dashlets on the left and right
2. The list of rooms in the center, or the Room Pane, and
3. The toolbars on the top

4.1. The Dashlets

From the Home Page, the administrator can view the following dashlets:

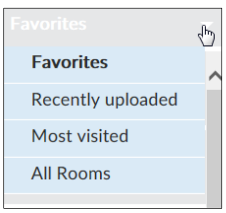
1. Cross Study Activity
2. Top N Studies with Expired Documents and,
3. About

Each dashlet and dashboard is discussed in detail in subsequent sections.

4.2. The Room Pane

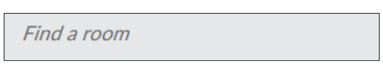
The Room Pane displays the list of rooms in the center of the dashboard. Besides this it allows you to Search for documents across rooms, Find a room in a study and Upload documents into a room.

The user can choose which rooms to view through the filters selected from the dropdown at the top of the room pane. The filters are broadly classified into the following types:



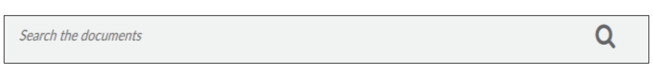
1. Favorite rooms, which is the default filter
2. Recently uploaded rooms
3. Most visited rooms, and
4. All rooms

4.2.1. Finding a Room



Enter the name of the room to search. If the search criteria is met, the room matching the criteria will be displayed, otherwise a message as 'No rooms found' is displayed. Click the cross that appears in the box after the search to dismiss it and return to the original view.

4.2.2. Searching for Documents



This is discussed in detail in section Searching Documents.

4.2.3. Uploading documents to a room from the Home Page

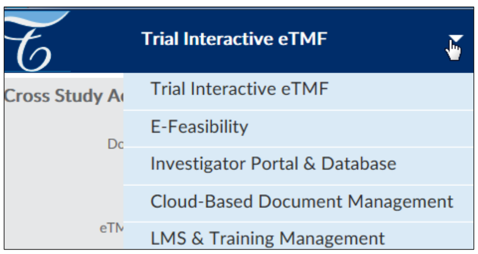
This is discussed in detail in section Adding documents and metadata to a room.

4.3. The toolbars

There are two toolbars that are located on the upper left and upper right of the **Home page**.

4.3.1. The Trial Interactive eTMF dropdown

This toolbar on the left offers links to various services offered by TransPerfect Life Sciences. An example of the same is provided below:



4.3.2. The Help and Language dropdown

As shown in the screenshot below, you can contact the Trial Interactive Support from here and send out your requests to the helpdesk. Besides this, you can also choose the display language of your choice and use throughout your Trial Interactive login.

4.4. The Username dropdown

Through the username dropdown, as shown below, you can access:

- The **Classic Home Page** which is the home page of Trial Interactive 9.0
- The Profile settings of your login through My Profile**.** You can also access this from within a room and is discussed in section 5.2.6, and
- **Logout**

5. Main Module Views

5.1. About the Main Module Views

The Main Module Views in Trial Interactive display a different graphical user interface to carry out various functionalities and processes. Once you enter a room, you are taken to the dashboard of the default main module as configured in your profile settings.

Every Main Module is divided into the **Title Bar** at the top, and the **Main Module Area** in the center.

5.2. Title Bar

The **Title Bar** consists of the *'Navigation Grid'* on the top left hand corner with the name of the room and module next to it, a *'dropdown'* next to the room name to change rooms, the *'Search Box'* and *'Advanced Search'* in the center, the *'+Create'* icon, *'Username'* drop-down, *the 'Study Contact'* information for help, and the *'Notifications'* at the top right hand corner.

5.2.1. Navigation grid

As a user of Trial Interactive, you can choose which module to view in a dashboard by hitting the *'Navigation Grid'* on the top left corner of your dashboard. This is shown in the screenshot below:

The different modules that can be viewed from a particular Main Module depend on the functionality that can be allowed from the particular Main module. Within Trial Interactive, you can view the following Main Modules:

1. Home
2. Tasks

3. eTMF
4. QC Review
5. Start-Up
6. Audit/Quality Review
7. Communication
8. Authoring
9. Q&A
10. FAQ
11. Reports
12. SWS

The Default page of Trial Interactive, on logging in, is the Home Page which is discussed in detail in Section 4 above.

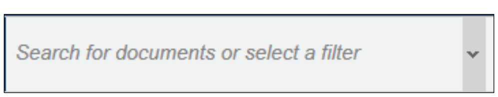
***The Start-Up module Start-Up is available to users who have the Study Start-Up action selected in user profile, who are members of the data room's Study Start-Up Team group, and who are Start-Up Specialists in the data room. A detailed description of this module is out of the scope of this guide, hence the Start-Up will be discussed in a separate guide*.**

5.2.2. The Room Change Dropdown

This is discussed in detail in Navigating between Rooms.

5.2.3. The Search box

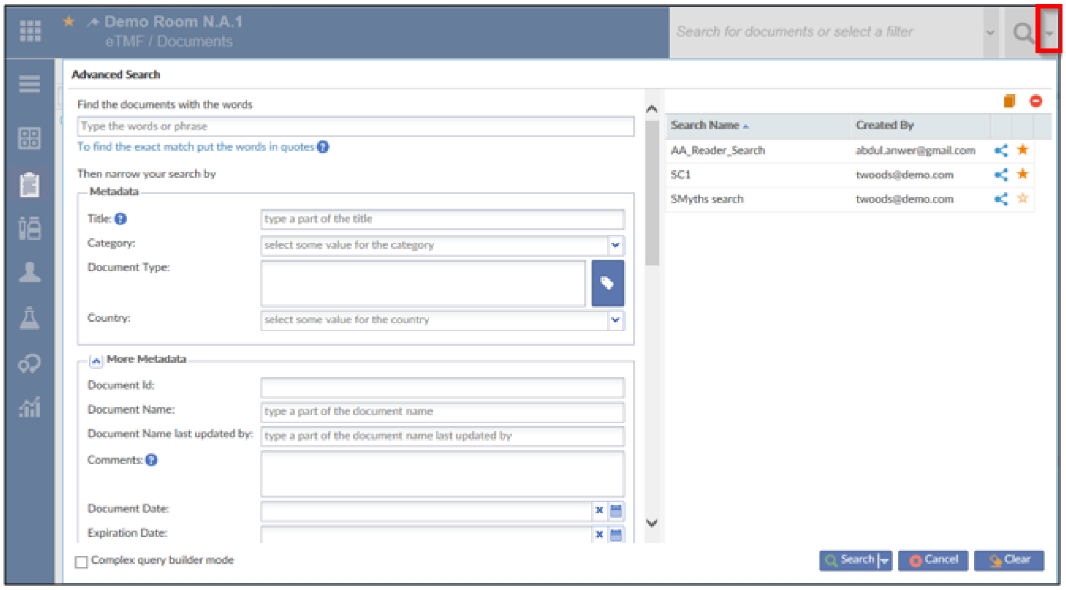
You can search for documents across their studies in Trial Interactive through the **Search Box**. By default the Search Box has the view as shown in the screenshot below:



For further details on Search proceed to the section Searching Documents.

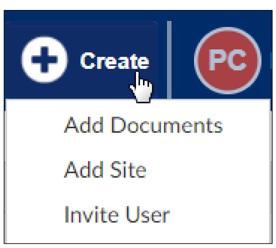
5.2.4. Advanced Search

The Advanced Search can be accessed in a **popup window via the small downward arrow** next to the Magnifying Glass icon. Refer to the screenshot below.



You can define and save searches from the [Advanced Search](). Besides this, you can also perform [Cross-Study Search](). Both of these are discussed in later sections.

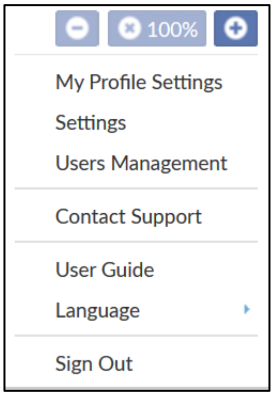
5.2.5. +Create



The **+Create** tool gives a shortcut to options like:

1. **Add Documents**: This is nothing but the Import Documents module.
2. **Add Site**: Instead of navigating to the **Sites** module to add sites, the user can avail this shortcut to **Add Site**.
3. **Invite User**: To invite a user to a room, the administrator does not have to navigate to Settings explicitly. By clicking the **Invite User,** the administrator is directly lead to the [Users Management/User Invitation]() module.

5.2.6. Username Dropdown



This appears as a drop down with the name of the user currently logged on. It allows you to set your account preferences such as language and time zone for your account, contacting support, accessing the room's Settings and the User Guide, Managing Users, and logging out.

My Profile Settings

This discussed in detail in section My Profile.

Settings

This will lead you to the room's Settings. Details of each setting module is discussed in their respective sections as and when they appear.

Users Management

This will lead you to User Invitation module in Settings.

Contact Support

You can also contact the help desk from here and send out your requests.

User Guide

You can access a searchable PDF version of this User Guide.

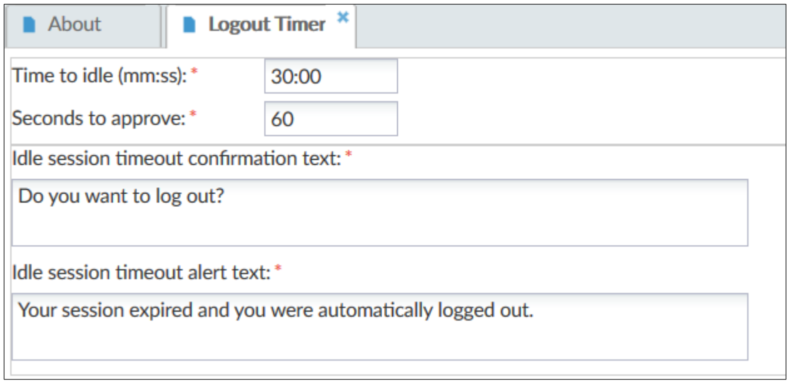
Language

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

Sign out

Sign out/Logout to terminate the session. You may also be logged out of the system automatically due to some of the reasons as session timeout, parallel login if you are not allowed to do so, closing of a browser window without logging out.

You can set a **Logout Timer** from the rooms settings as follows:



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

5.2.7. Study Contact

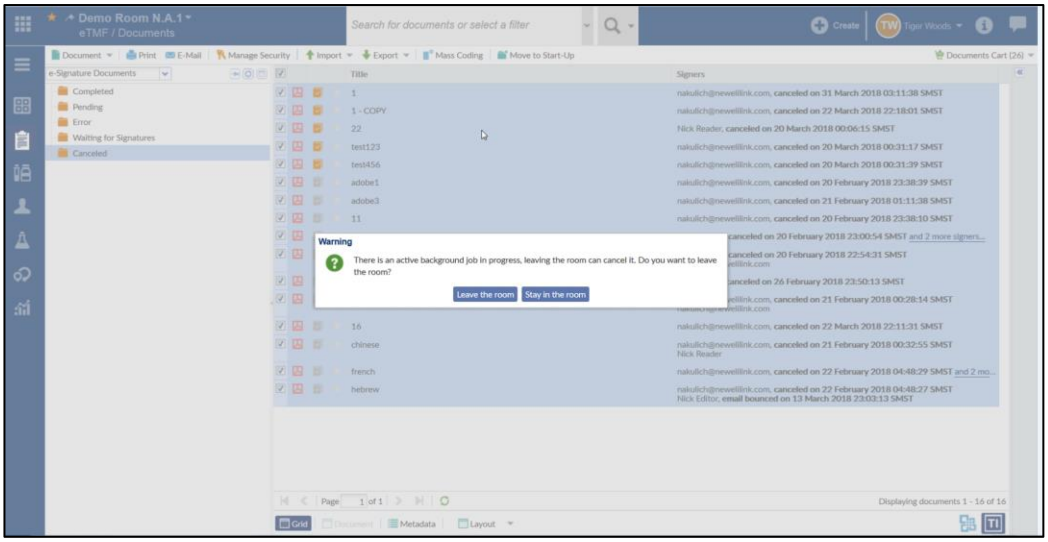
This opens the Study Contact popup with the email addresses of the Study Inbox, and the Start-Up Inbox.

5.2.8. Notifications

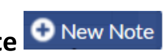
Through **Notifications**, which is located at the extreme top right corner of the dashboard, you can view messages and results of various jobs that you perform in Trial Interactive. This will be discussed through various sections as the need arises.

Background Jobs

You are notified about a background **job** that is executing if you try to leave the room without completing the job as that will pause the job. Refer to the screenshot below:



If you still choose to leave the room in spite of the notification, the system shall resume the job and complete it on your subsequent return to the room.

The Notifications also include a tab for **Sticky Notes**. You can use sticky notes to pin reminders for yourself. To add a sticky note click the **New Note** 

button at the bottom of the Notifications window. A sticky note opens with the current date and time on it. Type in your notes and click the tick to pin it on the Notifications window. You can Maximize/Minimize, unpin a sticky note, or delete it from the buttons located on the top of a sticky note once it is added to the Notifications window .

5.3. Main Module Area

The **Main Module Area** is home for all Trial Interactive dashboards. This area displays the functionality that is selected for a particular module.

5.3.1. Toggling Menu Bar

The modules like the **eTMF**, **QC Review**, **Start-Up**, and **Quality Review (previously Audit)** host the toggling menu bar which allows the user to access several other major functionalities. The functionalities that may be allowed for access from the toggling menu bar depends upon the activities the user might be required to perform from within a module. For example, the **Quality Review Module** allows access to the **Audit** and **Documents** functionality from the toggling menu; whereas the **eTMF** module allows to access many more functionalities like the **Dashboard**, **Documents**, **Sites**, **Contacts**, **Milestones**, **Potential Sites** and **CRA TMF Reconciliation**.

The toggling menu bar can be expanded or collapsed by clicking the three white lines on it.

You can ask the Super Admin to rename the Main Module and views for you.

Two most common functionalities available to the above mentioned modules are the **Dashboard**, and the **Documents.** The other functionalities that are specific to the particular module would be discussed in respective sections.

5.3.2. Dashboard

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

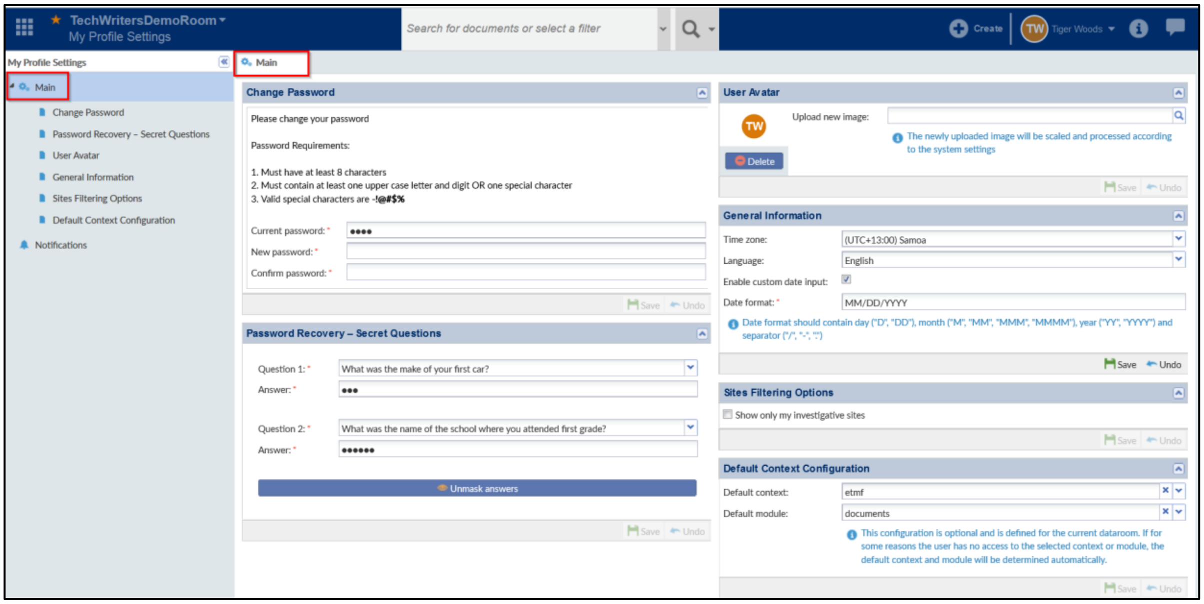
This section is discussed in detail in Chapter Dashboard Dashlet View.

6. My Profile

My Profile can be accessed from the following two locations within the Trial Interactive environment:

1. From the Home Page
2. From within a Trial Interactive Room

From both the locations you will get the view as shown in the screenshot below:

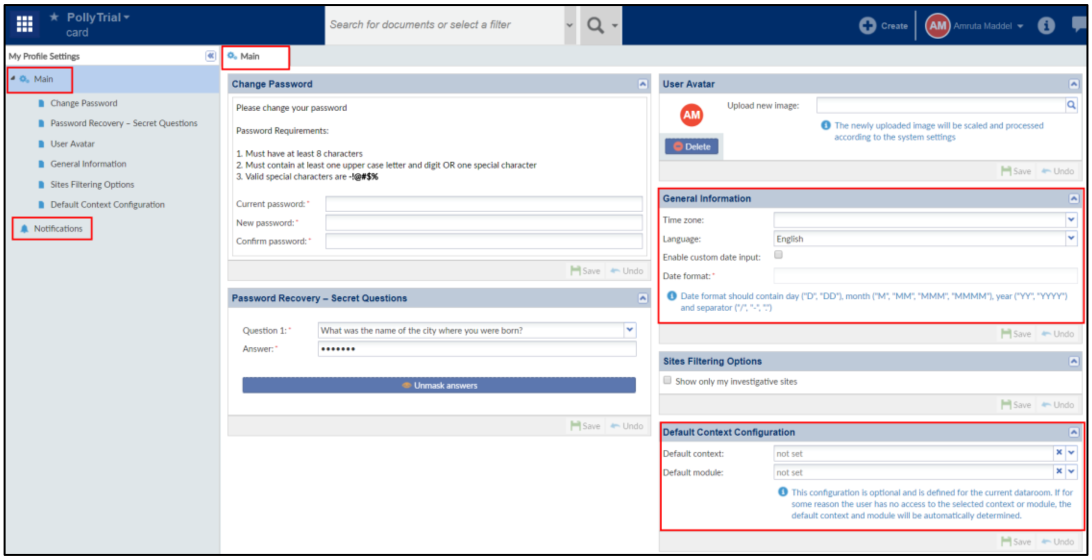


The My Profile Settings is divided into the following two sections:

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

6.1. The My Profile Main Section

Access **Main** section from **My Profile Settings** from the drop down under your profile name. This will open a page as shown in the screenshot below:



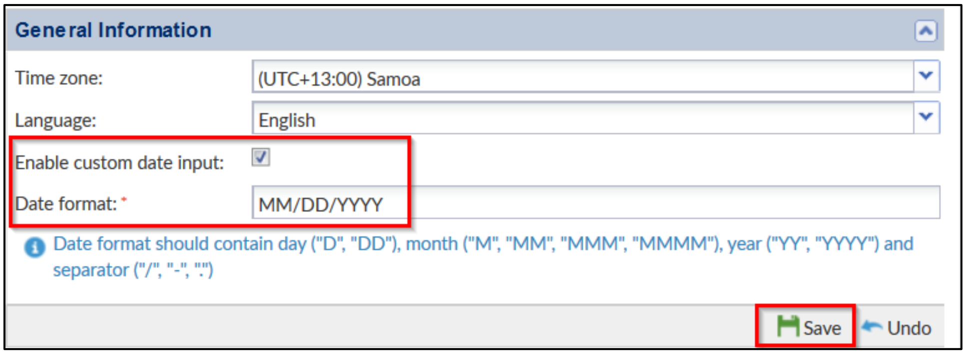
Follow the instructions on the dashboard to configure your profile settings as required. **Some of the important sections are discussed below:**

6.1.1. General Information

From this section of your Profile Settings, you can set your time zone, preferred language, and the custom input date format.

With the Trial Interactive 9.2 release, while coding a document, in addition to selecting the date from the **Calendar Date Picker**, you can **directly type in dates** in the format preferred by you. The system interprets the date entered by you manually and saves it based on your geo location that it is capable of detecting.

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

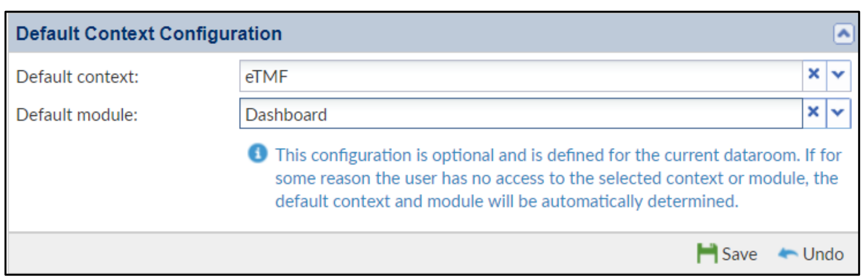


1. Tick the checkbox **Enable custom date input**.
2. The Date format textbox gets active. Enter the date format as preferred by you. Some of the most common date formats are MM/DD/YY, DD/MM/YY, MM/DD/YYYY, DD-MMM-YY.
3. You also have the information text below to help you enter the date format correctly.
4. Once done, **Save** the changes. You will now be able to enter dates manually if you so choose.

6.1.2. Default Context Configuration

You can choose your preferred landing page once you enter your room by selecting your Default Context as shown in the screenshot below:

1. Select the Main Module from the **Default context dropdown**.
2. Select the preferred view from the **Default module**.
3. Click **Save.**



6.2. The My Profile Notifications Section

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

Select the desired room from the list of studies in the left pane of the Notifications panel. Using the options grid on the right of the Subscriptions window, you can select which notifications you would like to receive. Administrators can choose alert systems, depending on which notification systems are enabled for you:

- A new audit query response is submitted
- A New Document is added or updated in eTMF, or Start-Up
- A New Question or Answer is added
- A new user registers within a room, or visits a room for the first time
- Workflows
- A new Workflow Query Response is submitted
- A New Document is submitted, approved, or rejected by the Regulatory Reviewer

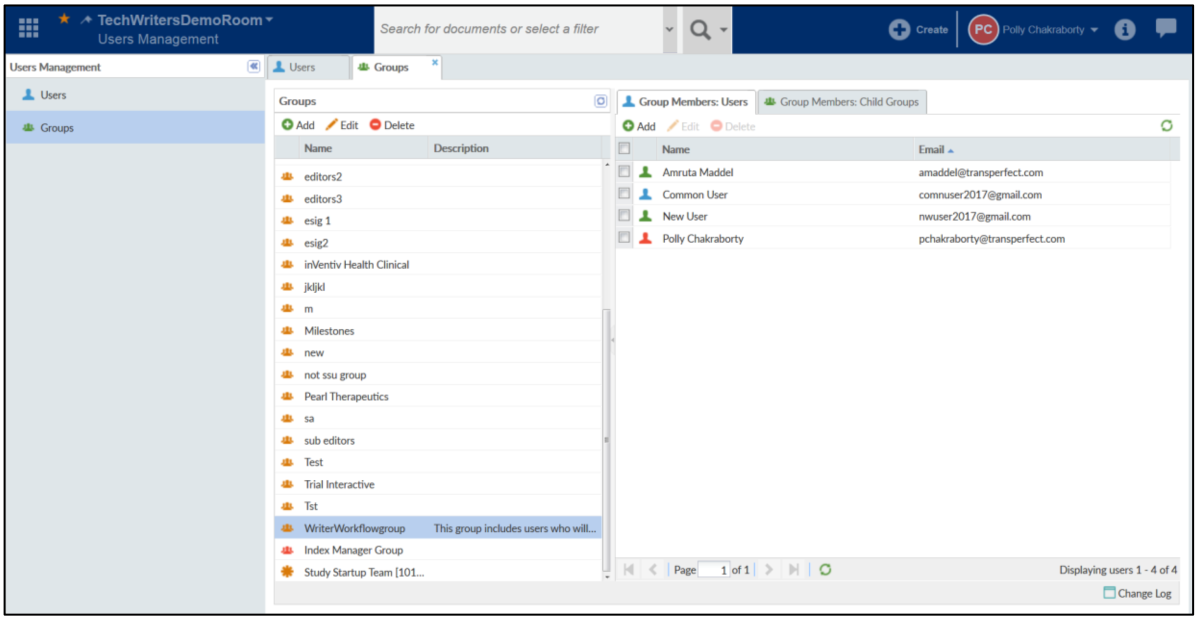
You can elect to receive either a mini summary of notifications or nightly newsletters recapping all of the new events in the past 24 hours for each of the notification categories.
Once you make your Notifications selections, click **Save** in the lower right corner.

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

7. User Management – Groups

This page can be reached from the following three locations in the Trial Interactive environment:

1. Username dropdown -> User Management
2. +Create button -> Invite Users
3. Username dropdown -> Settings -> Security -> Users



From this view, Administrators can manage groups in the following manner:

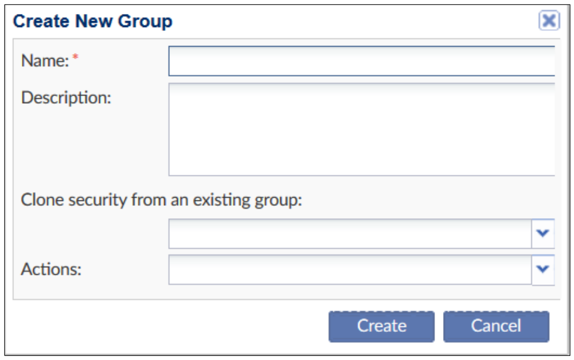
1. The names of groups
2. The Descriptions of groups
3. Clone security from an existing group
4. Assign Actions to groups

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

7.1. Defining New Groups

New Groups can be defined and added by clicking **Add** from the **Groups panel**.

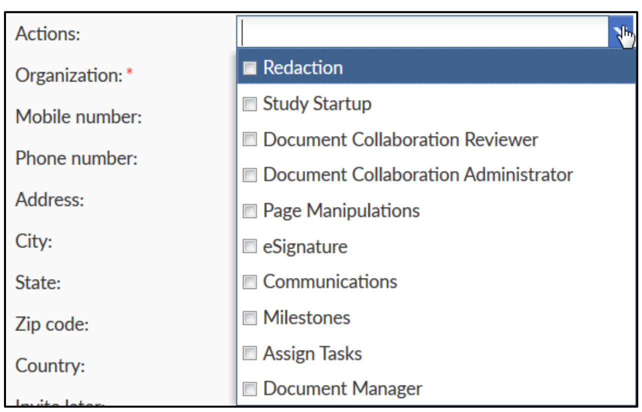
1. The **Create new group** window pops open.



2. Add the new security group's name.
3. Add the description of the new group.

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.

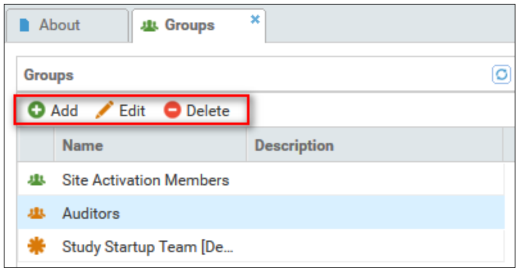
4. Assign **Actions** or tasks that the group of users can perform under the specific role by ticking the checkbox next to the Action name in the dropdown.



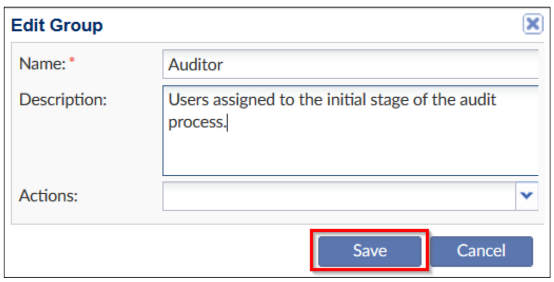
5. The Administrator can also view the actions available in a room along with their purpose from the **Username dropdown -> Settings -> General -> Actions**. This is discussed in Section Actions.
6. Click **Create**. The new security group appears in the Groups list with no users assigned to it.

7.2. Editing Groups

1. To edit, select a group from the list of groups in the **Groups panel**.
2. Click **Edit**.



3. The Edit **Group** window opens to allow you to change the information held there.



4. Click on the field you want to edit and type your change.
5. Click **Save** to confirm your changes.

7.3. Deleting Groups

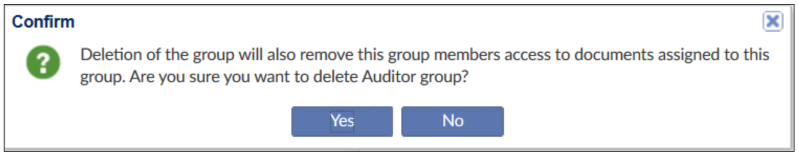
Groups can be deleted from this list. Deletion of a group does not delete its users, only the group members' access to documents assigned to this group is deleted. A **Confirm** box will warn you about making such a change to the group security settings. Any changes to a room's settings need to be cleared with the Project Manager.

To delete a group:

1. Select the name of the group you need to delete from the **Groups panel**.

2. Click **Delete**.

   A confirmation window opens.



3. Click **Yes**.

7.4. Adding Users to a Group

To add user to a group:

1. Select the name of the group to which you need to add members from the **Groups panel**.
2. Select **Add user** from the top menu ribbon in the **Group members: Users** panel.

   A **Select users** window opens.
3. Select the appropriate user(s) from the list of users in the room.
4. Click **Select** in the lower right corner of the window.

   The selected users are added to the group.

> - ***In performing this operation, you can also add entire groups of users to the group that you are modifying. Instead of clicking Add user, click Add group. You will have the option to add entire pre-defined groups to the list for this other group.***
> - ***You can also add users to groups while creating or editing user profiles from the Users panel of the User Management window.***

7.5. Removing Users from a Group

1. Select the name of the group from which you need to delete a user.

   The list of the room's users currently assigned to that group appears in the **Group members** panel.
2. Click the checkbox next to the user (or group) that you need to delete from this group.

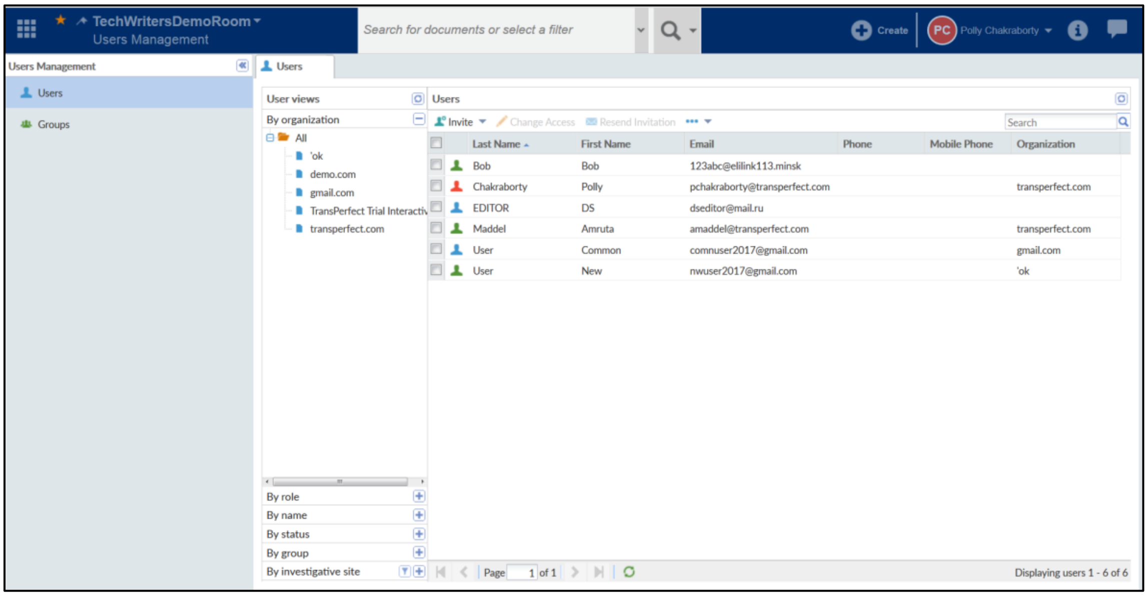
3. Click **Delete** in the top menu ribbon.

   That user is deleted from that security group.

8. User Management - Users

This page can be reached from the following three locations in the Trial Interactive environment:

1. Username dropdown -> User Management
2. +Create button -> Invite Users
3. Username dropdown -> Settings -> Security -> Users

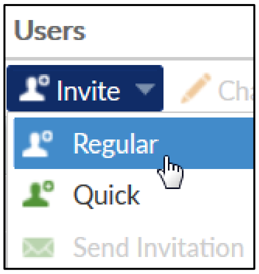


During the course of a study, Administrators can do the following from this page:

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

All of these are discussed in subsequent sections.

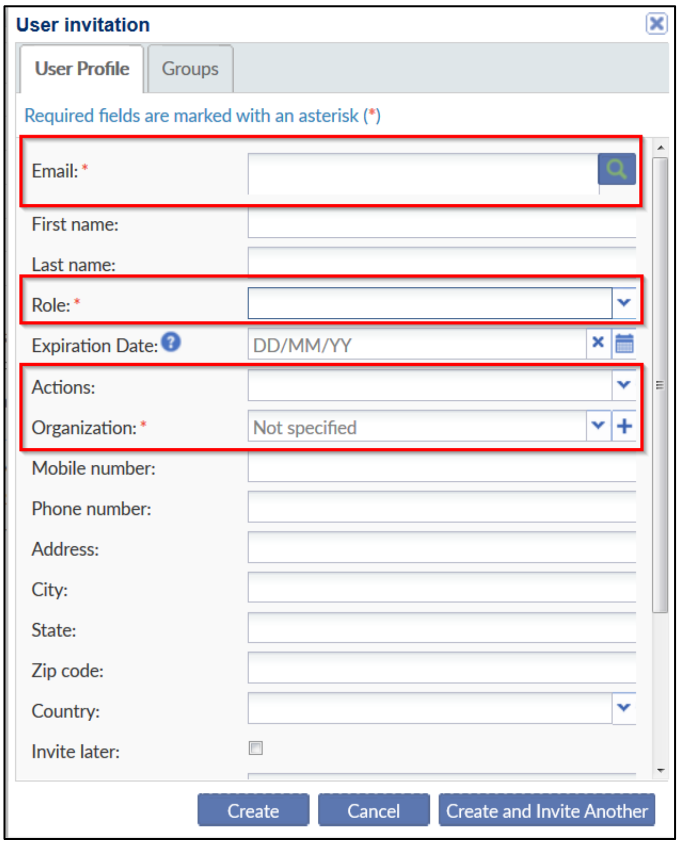
8.1. Invite Users – Regular



From the Users panel:

1. Click **Invite** and select **Regular** from the drop down.

   The **User invitation** window opens.



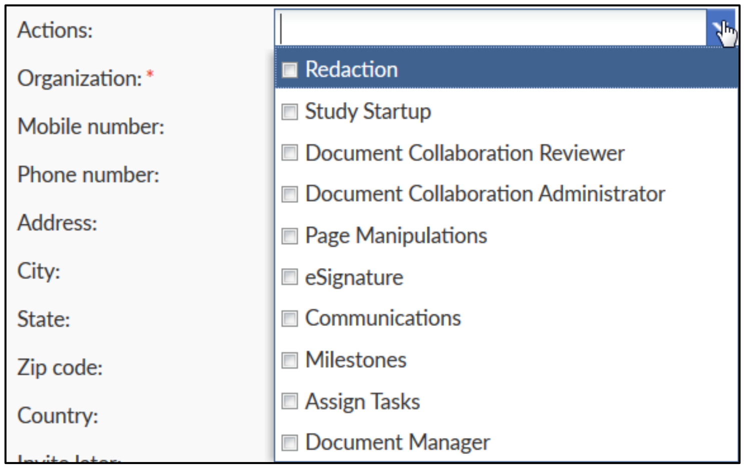
2. Complete the User Profile.

3. The mandatory fields are:

   a. **User Email** which can be typed in or searched by clicking the magnifying lens icon at the end of the field.

b. Role to be assigned to the user. The roles can be either of an **Admin**, **Editor** or **Reader** in a particular room.

c. **Actions** or tasks that the user can perform under the specific role can be assigned by ticking the checkbox next to the Action name in the dropdown.



The Administrator can also view the actions available in a room along with their purpose from the **Username dropdown -> Settings -> General -> Actions**. This is discussed in Section Actions below.

d. **Organization** to which the user belongs to. The Administrator can create an organization by clicking the '+' sign at the end of the textbox, if the organization is not found in the dropdown list.

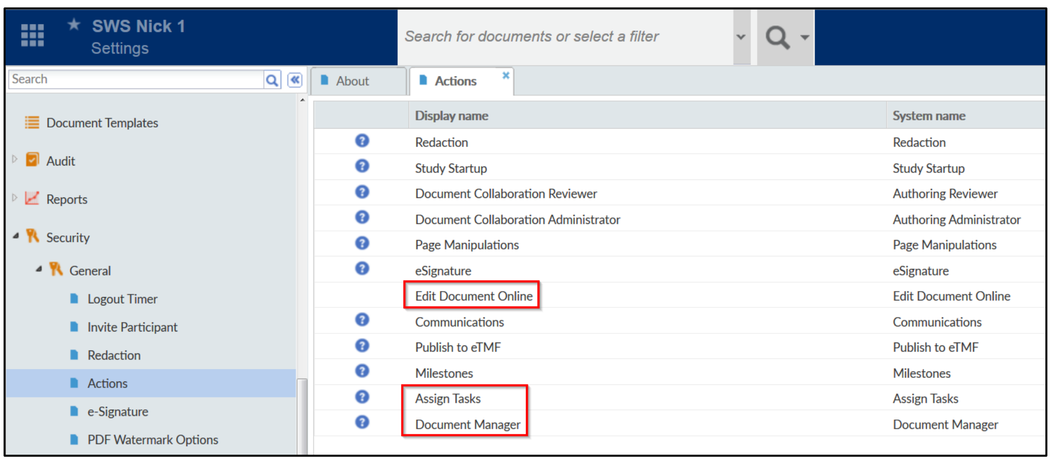
You can also create organizations from the Settings - > General -> Organizations List.

4. Click the **Groups** tab at the top of the **User invitation** window.
5. Select which group or groups to which the user is to be assigned.
6. Click either **Create** or **Create and Invite Another** at the bottom of the window.

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

- ***Users can be set up with a defined period of access to the trial room. An Administrator can set an Expiration Date for users' access. Click the calendar icon and select the date on which the user's access will expire.***
- ***Users can be set up as a Regulatory Agency Inspector if the user is going to be invited to the room as an Auditor. Such a user can access only the Quality Review and FAQ modules of the study.***

8.2. Actions

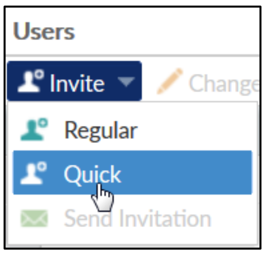


This pane shows the tasks that are enabled for the user in a particular room. You can double-click the Display name of the listed action and edit the display. If you make changes you want to keep, click **Save**.

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

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

8.3. Quick Invite



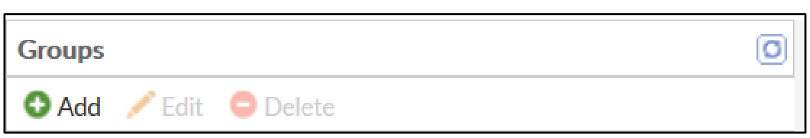
The **Quick invite** feature allows Administrators to invite individual users or groups of users with a minimum of information about the invitees.

1. Click **Invite** and select **Quick invite** from the drop down.

   The **Quick invite** window opens.

2. Complete the required fields, adding email addresses and selecting the role the invitees will be assigned to. Invite any number of Readers or Editors or Administrators at one time.
3. Select the **Invite later** when appropriate.
4. Assign the new invitees to the appropriate group(s) by clicking the checkbox(es) in the Groups panel.

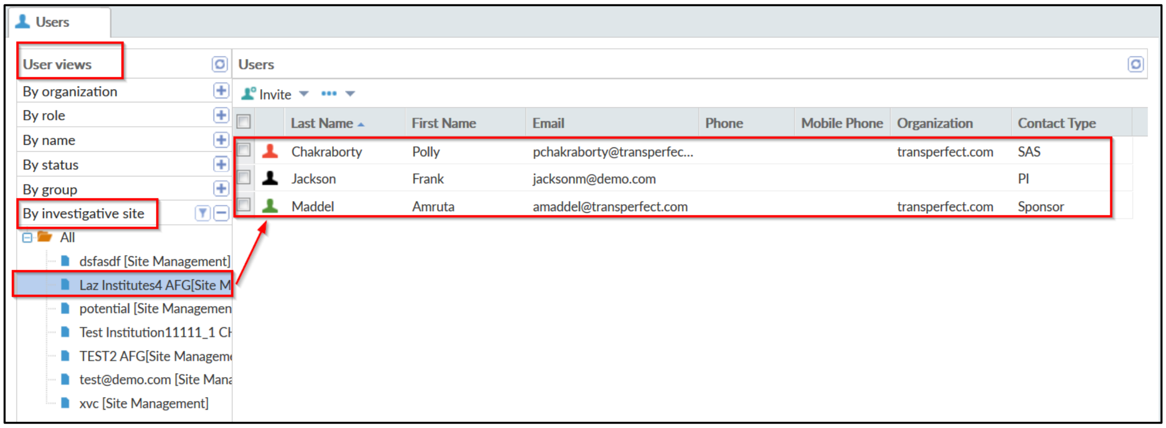
   New Groups can also be added to the room from this access point.

5. Click **Create** at the bottom of the window.

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

8.4. Viewing Users



As an Administrator you can view the users from the **User Views panel** by:

a. Organization

b. Role

c. Name

d. Status

e. Group and

f. Investigative Sites

Click a view to display the users belonging to the view. The screenshot above shows the users added to the investigative sites 'Laz Institutes4 AFG'.

8.5. Change Access

As an Administrator you can change the accesses of user from the **Users panel**:

1. Select a user or users from the list.
2. Click **Change Access** from the menu ribbon. The **Change Access** window opens.

3. Assign the user(s) to a role by selecting the role from the dropdown menu.

4. Select the group or groups for the new assignment.
5. Click the appropriate radio button near the bottom of the window, appending or overwriting the existing group access.
6. Click **Apply** to make the change(s).

8.6. Resend invitation

As an Administrator you can resend an invitation to an user from the **Users panel** if the user has been invited but has not visited the room:

1. Select a user or users from the list.
2. Click **Resend Invitation** in the menu ribbon. A confirmation window opens.

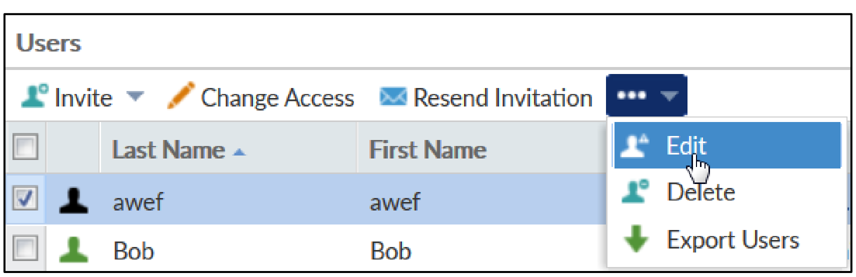
3. Click **Yes** to re-invite the selected user(s).

   The selected user(s) will receive another email invitation

8.7. Edit user

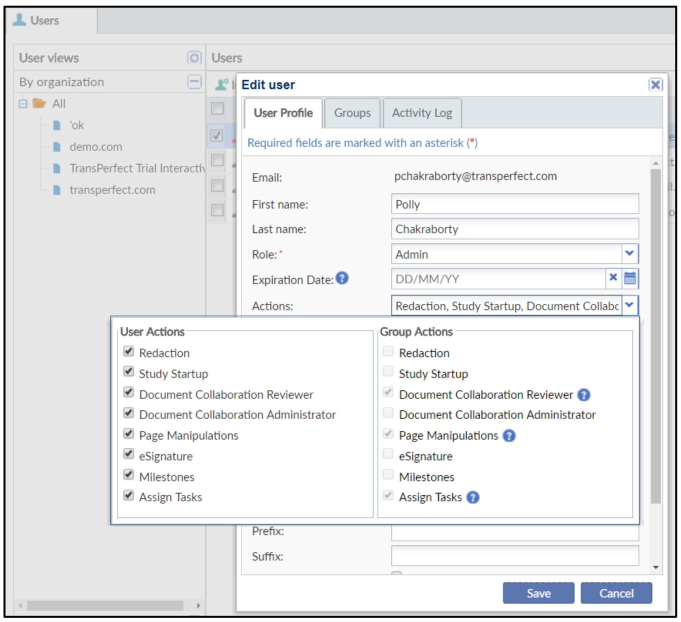
As an Administrator you can edit a user profile from the **Users panel**:

1. Select a single user from the list.
2. Click **Edit** from the dotted drop down on the menu ribbon.

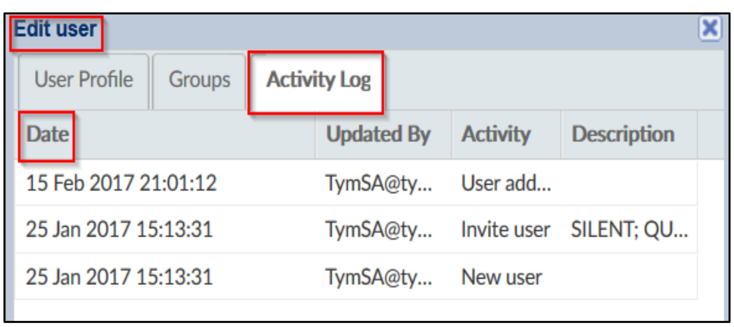


An **Edit user** window opens, revealing the User Profile for the selected user.

3. Edit the data in this view as needed.
4. Click the **Actions** dropdown to reveal a list of actions that can be assigned to the user from the **User Actions** panel. Find new actions in the list named as **Edit Document Online, Assign Tasks**, and **Document Manager** that can be ticked to assign the actions to editors/other users.
5. You can also simultaneously view the actions assigned to the Group to which the user belongs to in the **Group Actions** panel from the **Actions** dropdown.



6. Select the **Groups** tab.
7. Add, Edit, or Delete this user's group access.
8. Select the **Activity Log** tab to view the timestamp of activities for the user.

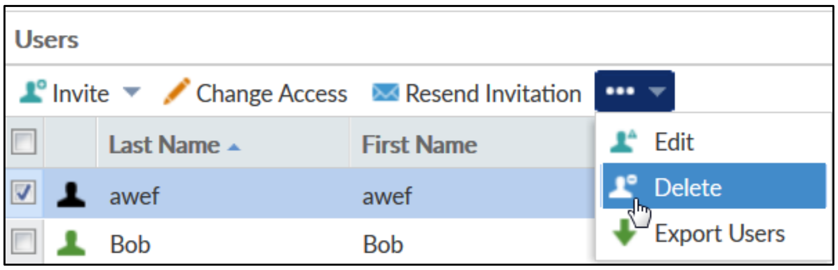


9. Click **Save** at the bottom of the window once editing a user is complete.

8.8. Delete user

As an Administrator you can delete a user profile from the **Users panel**:

1. Select a user or users from the list.
2. Click **Delete** in the dotted drop down on the menu ribbon.



A confirmation window opens.

3. Click **Yes** to delete the user from the room.

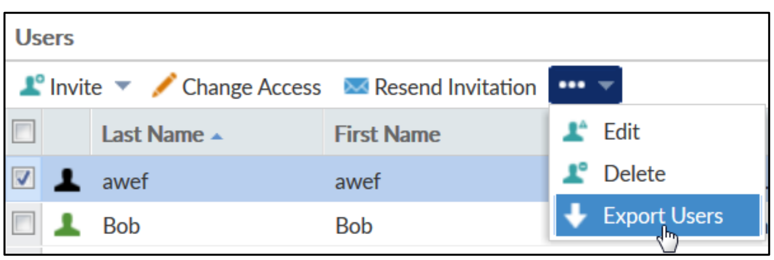
   The name(s) of the selected user(s) will no longer appear in the list of users.

4. If you want to simply remove the user's access and not delete the user altogether, use the **Change Access** option.

8.9. Export users

As an Administrator you can export users from the **Users panel**:

1. Select a user or users from the list.
2. Click **Export Users** in the dotted drop down on the menu ribbon.



An **Export Users** window opens.

Here you can decide to Export the data for all users in the list from your main screen or just the selected user(s) by selecting the appropriate radio button.

3. Select the format of the download from the dropdown menu.
4. Click **Export**.

   A **Background Jobs** window opens.
5. Double-click the panel in the window.

   A new window opens showing the result of your download request.
6. Click **Print** to either print the results or to save the results as a PDF.

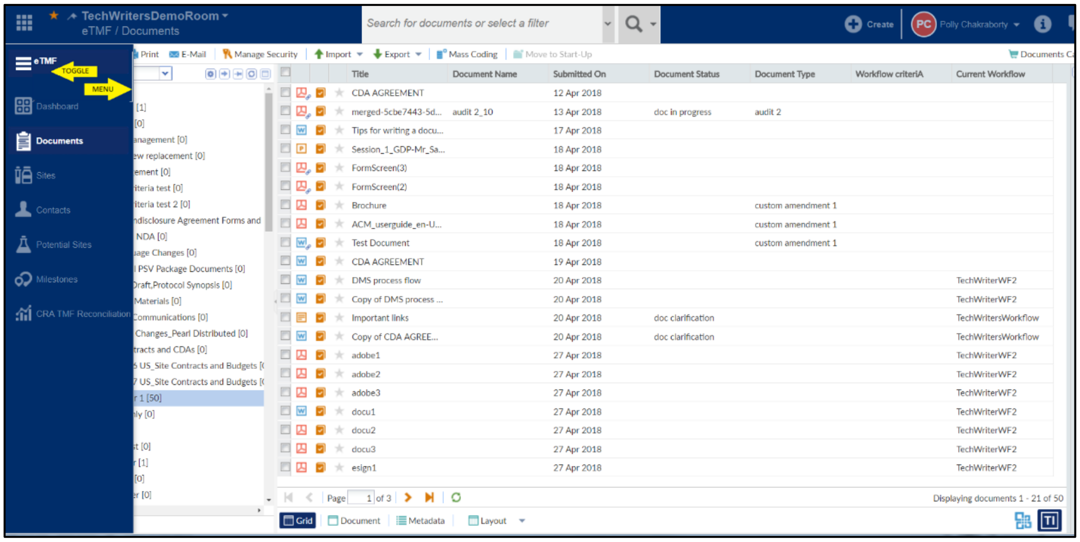
8.10. Search for users

As an Administrator you can search for users from the **Users panel**:

1. Click in the search box.
2. Type in your search criteria and press Enter.

   The results of your search appear in a list in the **Users** grid.

9. The eTMF Module

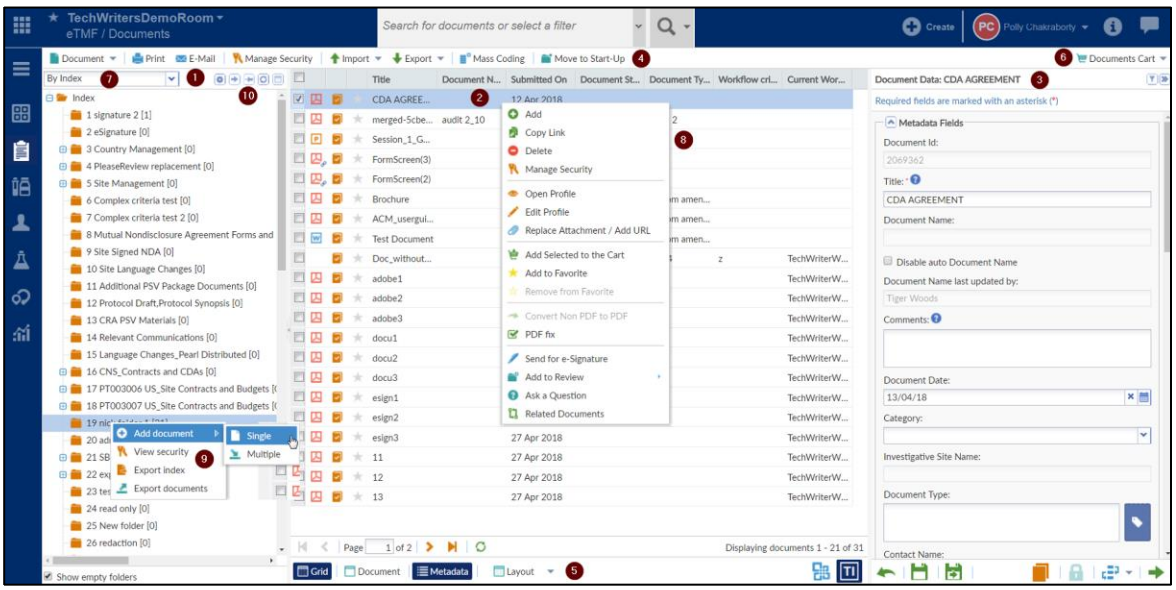


Through the eTMF Module, you can perform a host of activities like reviewing the status of the studies through the dashlets, and accessing the documents available in the room. The menu bar on the left allows you to toggle between the Dashboard Dashlet view, Documents view, Sites view, Contacts view, the Potential Sites view, the Milestones view and the CRA TMF Reconciliation view.

All these views can be enabled for you by the super admin through the Settings, and are discussed in subsequent sections below.

10. Documents view - Introduction

You can access the **Documents** view by clicking **Documents** icon  on the menu bar at the left. The **Documents View** Dashboard is the central repository for all the documents pertaining to a room. From here you can perform various important functions related to a document like viewing and editing documents, managing their security privileges, importing or exporting them, mailing them to other users, besides many others. For further details on the **Documents View,** refer to the screenshot below.



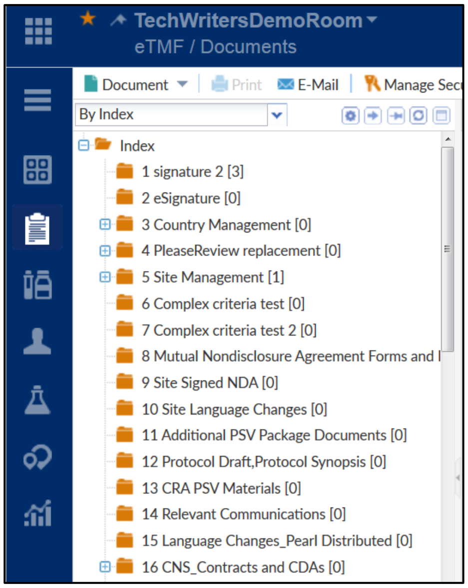
As numbered in the screenshot above, this section is divided into the following parts:

Number	Part
1	The Room’s Index Pane
2	The Document Grid/Viewer Pane
3	The Document Data Pane (that is typically hidden behind the double caret button)
4	The top menu ribbon

5	The lower tool bar, at the bottom of the Document Grid/Viewer Pane
6	Document Cart
7	Current View
8	Right-click popup on Document
9	Right-click popup in Index Pane
10	Buttons on Index pane

11. Documents view - Room's Index Pane

11.1. Creation/Modification



Generally a room index is created while creating a room from another room so that the index of the existing room is also copied into the new room. A client may opt to create a new room without any index, in which case the index structure needs to be created manually, and the documents and its types to be added to it. Creation of an index with its documents includes the following steps:

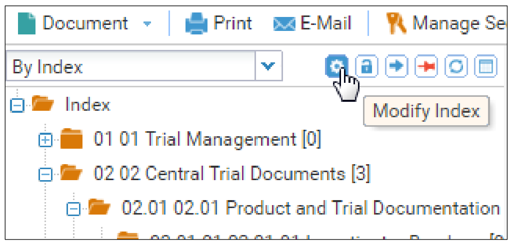
1. Adding main folders and sub-folders under the root folder of **Index** which is available by default.
2. Adding document types to the document categories. **By default**, the system provides three categories for the documents:
   a. General
   b. Country
   c. Investigative site
3. If new categories are required for the documents, the super- administrator will need to add them.

4. Adding documents by importing or uploading and assigning them their categories and document types.

Adding Main Folders

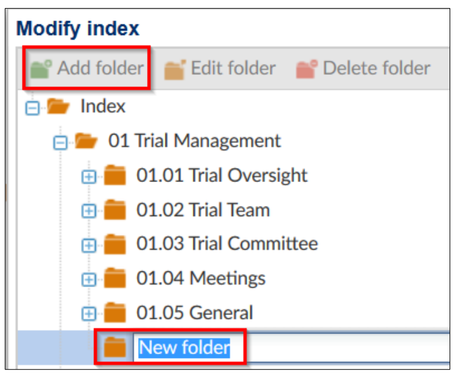
The administrator follows the process below to create the main folder structure:

1. Click the root folder of **Index** in the Documents module.
2. Click the **Modify Index** icon pictured below. The **Modify Index** window opens.



3. Click **Add Folder** 

from the top ribbon on the window to add a new folder. Type in the folder name and hit the **Enter** key.



4. To create another main folder, repeat the above steps.

Adding a Subfolder

1. In the **Modify** index window, click the folder (or subfolder) into which you want to add a subfolder.
2. Click the **Add folder** button at the top left.
3. Type in the name the folder when the New folder text field is available for editing.
4. Press **Enter**. The subfolder takes its place in the index structure.

Editing a Folder Name

1. You can change the name of an existing folder.
2. Click the **Modify index** icon (which looks like a little gear).

3. Click the folder you want to rename.
4. Select **Edit folder** from the menu at the top of the box.

   The selected folder and its name appear in a highlighted box.
5. Make your changes, then press **Enter**.
6. Click **Save**.

Deleting a Folder

1. To delete a folder, click the folder in the Modify index window.
2. Click Delete folder.

   Note: Deleting a folder will delete all of its contents including documents and subfolders.
3. Click **Save**.

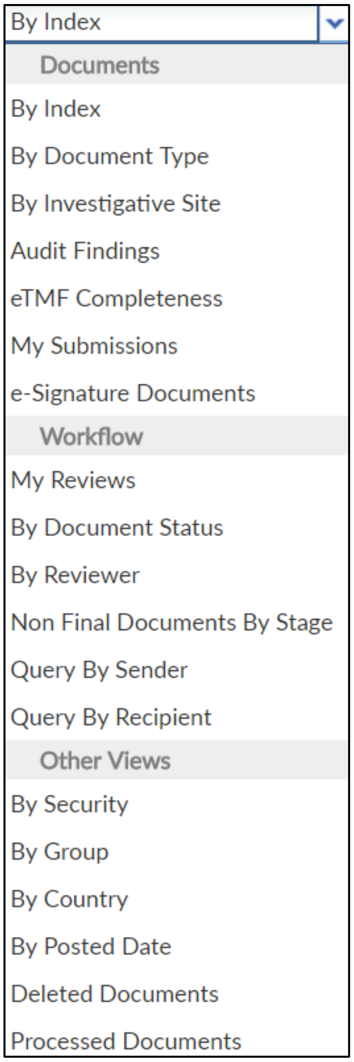
If you have already clicked Delete folder in error, you can still click Cancel in the bottom right corner of the Modify index window. The change will not be saved.

After you have created the index structure, proceed to Document Types under Settings to create documents types that would be required for the study.

After adding the document types, proceed to the Import function to add documents.

11.2. Current Views

A room's index can be viewed from the Index Pane of the room, as shown in the above screenshot, and offers various kinds of views to view the folder structure from the Current view dropdown. The screenshot below shows the various views available to an Admin:



Each of the **Current View** options are discussed in the table below:

Current View option	Feature details
By Index	This is the Index Pane view which
By Document Type	This view groups all the documents by its Category as the parent folder. Each Category folder further holds documents grouped by Document types as sub-folders. These Document types are created from Document Types Management in **Room Settings**.

	Clicking each Document Type displays the documents of that type in the **Document** view.
By Investigative Site	This lists the document type as per the Investigative Sites available in the room.
Audit Findings	This lists the documents as per their audit status.
eTMF Completeness	This lists collected, missing documents and acts as placeholder for missing documents that do not fall under the required documents section.
My Submissions	This will display status for the documents submitted by the current user.
e-Signature Documents	This allows users to view all e-Signature documents with their signers.
My Reviews	This lists out the documents assigned to the user for review as per the stages in a QC workflow process.
By Document Status	This displays the current workflow status of documents.
By Reviewer	This displays the current review stage of the documents.
Non Final Documents By Stage	This allows the users to assign documents to a previous stage in a workflow.
Query By Sender	This displays documents grouped by reviewers who have raised queries on the documents during a QC Review/Quality Review and have sent them for clarification.

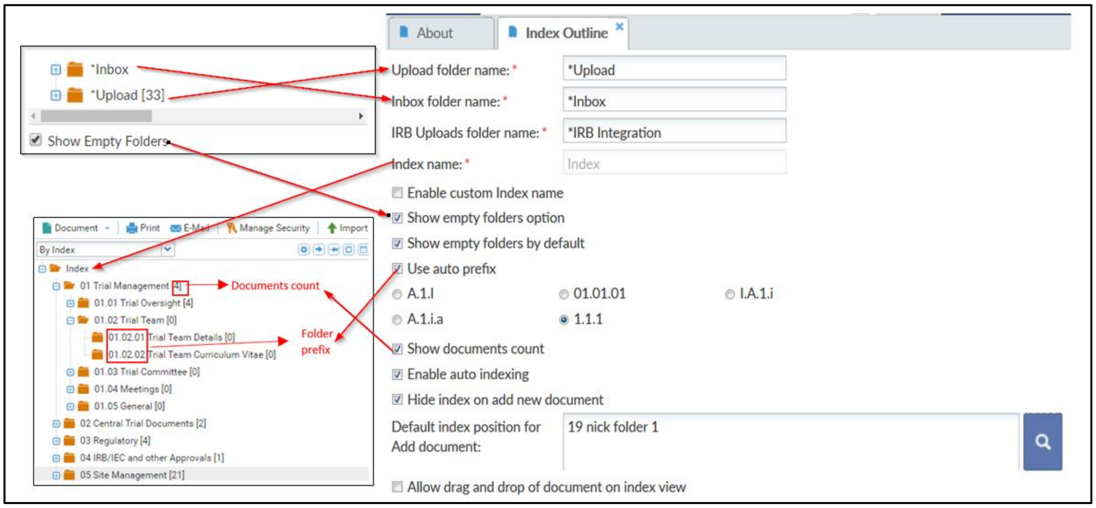
Query By Recipient	This displays documents grouped by the recipients of the queries received by them for clarification from the reviewers in a QC Review/Quality Review.
By Security	This displays the documents by their security accesses.
By Group	This displays the documents under groups of users.
By Country	This displays the documents in each country where the study is being conducted.
By Posted Date	This displays the documents by their posted dates.
Deleted Documents	This displays the documents that were deleted.
Processed Documents	This displays the documents that were processed.

Discussed below is the **By Index** view. The other views are discussed in appropriate sections where they are used.

11.3. Index Outline and By Index view

On creating the index, as an administrator, you can decide on a number of functions and appearances related to the Trial Interactive room's index from the **Username dropdown -> Settings -> Documents Module -> Index Outline**. You can change the names of the Upload folder, the Index folder, and the IRB Uploads folder if so requested by the client.

11.3.1. By Index view

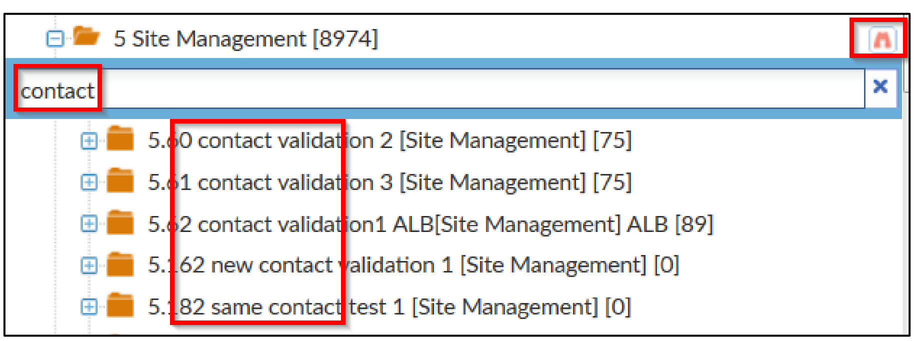


The **By Index View** shows the full folder index of the room with child pages. If a folder contains sub-folders, it can be expanded to list its content by clicking the expand icon.

If a user emails documents to the room, such documents get stored in the **Inbox** folder of the room. Similarly, all documents imported are populated in the **Upload folder.**

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

Some of the folders like **Country Management** and **Site Management** allow you to search for sub-folders under them when you expand the main folder and hover the mouse over the folder name to reveal a Blue Search icon. Click the icon and type in the search criteria to reveal matching contents. Refer to the screenshot below:



Click the cross to delete the search criteria and then the Red Search icon dismiss the textbox.

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

Auto Prefix

The folders in a room index are numbered, and the subfolders follow a standard numbering system. These folder numbers are called as Folder Prefixes, whose settings can be decided from the **Auto Prefix** option in the **Settings -> Documents Module -> Index Outline**.

Activate or inactivate Auto Prefixing of folders in the room's index by ticking the **Use auto prefix** checkbox. If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index. Auto prefixing inserts the client's requested prefix of numbers or letters to identify the levels of the folders in the index. Click the radio-button for the prefix pattern requested by the client.

Documents Count

Numbers in parentheses after the folder names indicate how many documents are available to you in each folder. Click a folder to open the documents contained in it in the Documents Grid.

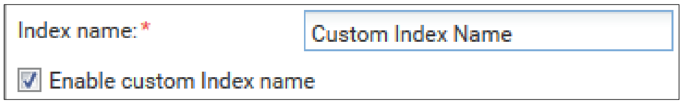
By showing Documents count, by ticking the **Show documents count** checkbox in the settings, users in the room will see a number in brackets that indicates how many documents are in each index folder.

11.3.2. Changing the Index Name

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

1. If the client wants to customize the name of the Index, click the box to activate it.

   The Index Name field then becomes active.



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

11.3.3. Empty Folders Options

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

You can enable or disable the **Show Empty Folders Option**. By showing that option, users in the room will see this checkbox at the bottom of the room's folder index.

Another option sometimes called for by the client is to show empty folders all the time. If that is the case with the room you're configuring, click this box – **Show Empty Folders by default**. Then, the room's full index will always show in the documents view, whether the folders are empty or not.

11.3.4. Hide index on add new document

This setting is used only for non-admin users. If it is enabled:

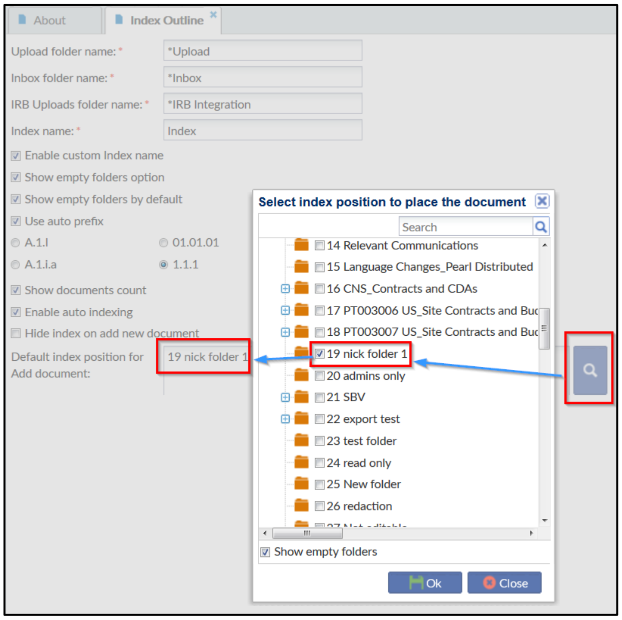
1. index position will be hidden in new document window.
2. But in case if auto routing logic can't determine index position, this control will be displayed, so user will be able to specify index position manually.
3. A document cannot be copied or dragged to a different location/folder by editors.

11.3.5. Auto Indexing

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

1. Click the magnifying glass.

   Full index list appears.



2. Select the folder indicated by the client. In this example, the folder is named **19 nick folder 1**.

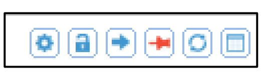
3. Click **OK**.

   The window closes.

4. Click **Save** at the bottom of the **Index Outline** panel.

11.4. Buttons on Index Pane

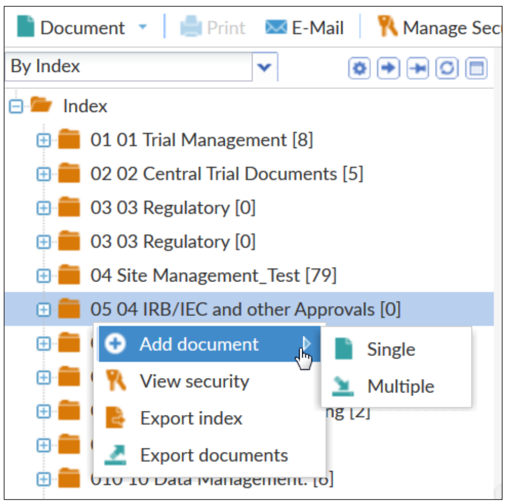
The Index Pane also has a set of icons on the right. Refer to the screenshot below.



Available Icon	Purpose
	To force index unlock when an index is locked.
	To refresh the index
	To export index.

	To modify the index.
	To set default view of index.
	To configure grid.

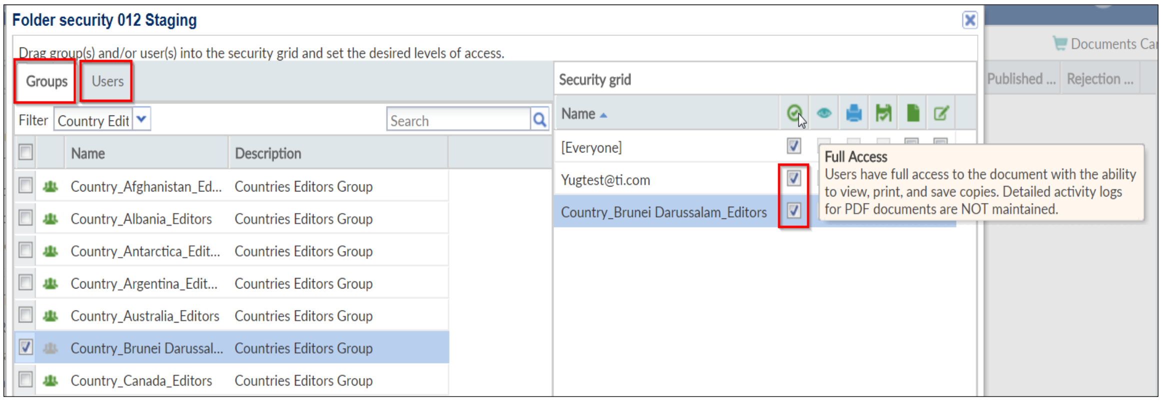
11.5. Right-click popup on Index



As shown in the screenshot above, through the right-click popup in the Index pane for the selected folder, an administrator can:

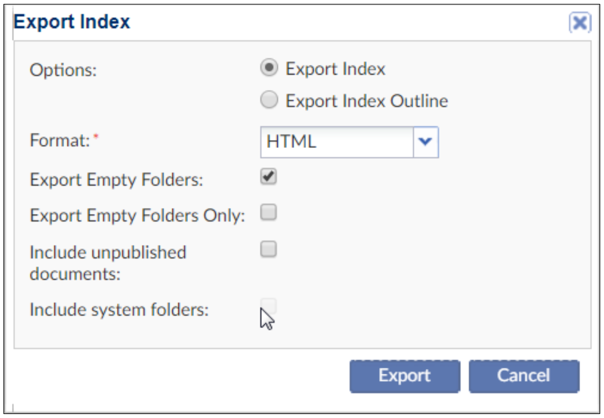
1. Add single or multiple documents
2. View security
3. Export index
4. Export documents

Adding a single document is the same as adding a document from the document dropdown. The **View Security** option can be used to assign privileges to groups/users on selected folder. Refer to the screenshot below:



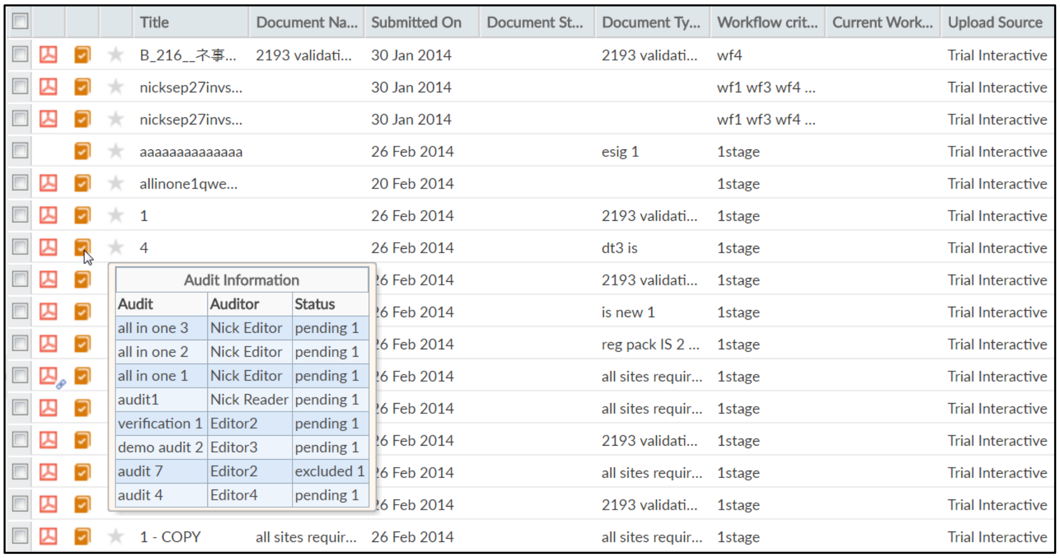
Similarly, adding multiple documents is [importing documents]() using the import icon on the top ribbon; and **exporting documents** as **downloading all the documents** from the chosen folder after a confirmation as opposed to downloading documents from the cart or from the top ribbon bar which allows you to only download/export documents added to the cart or selected respectively.

Export index allows you to export the document structure index of the room. You can choose to export the index for the chosen folder, or only the index outline. The index can be exported in either HTML, or Microsoft Excel, or Microsoft Word formats. Besides these, you may also choose to export empty, or system folder as also documents unpublished to the eTMF.



12. Documents view - Document Grid

When you click a folder on the Index Pane that contains documents, the list of documents contained in that folder appears in the **Document Grid**. Refer to the screenshot below.



Title	Document Na...	Submitted On	Document St...	Document Ty...	Workflow crit...	Current Work...	Upload Source
B_216__ネ事...	2193 validati...	30 Jan 2014		2193 validati...	wf4		Trial Interactive
nicksep27invs...		30 Jan 2014			wf1 wf3 wf4 ...		Trial Interactive
nicksep27invs...		30 Jan 2014			wf1 wf3 wf4 ...		Trial Interactive
aaaaaaaaaaaaaa		26 Feb 2014		esig 1	1stage		Trial Interactive
allinone1qwe...		20 Feb 2014			1stage		Trial Interactive
1		26 Feb 2014		2193 validati...	1stage		Trial Interactive
4		26 Feb 2014		dt3 is	1stage		Trial Interactive
		6 Feb 2014		2193 validati...	1stage		Trial Interactive
		6 Feb 2014		is new 1	1stage		Trial Interactive
		6 Feb 2014		reg pack IS 2 ...	1stage		Trial Interactive
		6 Feb 2014		all sites requir...	1stage		Trial Interactive
		6 Feb 2014		all sites requir...	1stage		Trial Interactive
		6 Feb 2014		2193 validati...	1stage		Trial Interactive
		6 Feb 2014		all sites requir...	1stage		Trial Interactive
		6 Feb 2014		2193 validati...	1stage		Trial Interactive
1 - COPY	all sites requir...	26 Feb 2014		all sites requir...	1stage		Trial Interactive

Audit Information

Audit	Auditor	Status
all in one 3	Nick Editor	pending 1
all in one 2	Nick Editor	pending 1
all in one 1	Nick Editor	pending 1
audit1	Nick Reader	pending 1
verification 1	Editor2	pending 1
demo audit 2	Editor3	pending 1
audit 7	Editor2	excluded 1
audit 4	Editor4	pending 1

The procedure to view a document is:

1. Navigate the folder structure in the Index Pane by clicking the + sign next to the folder icon.
2. Click the folder icon or the name of the folder.
3. The **Document Grid** opens and populates with the documents in the folder.
4. The columns configured for display in the grid pane are selected by the room's Administrator.
5. Click the check box next to the document icon of the document you want to view from the list in the grid.
6. To open the document, click the document icon or click the **Document** button in the lower menu bar below the document grid.

7. The document appears in a new pop-up window.
8. To return to the document grid, click **Grid** at the bottom of the viewing panel.

9. The **Audit Information** icon displays the audit status of the document when you hold the mouse over it.

12.1. Copying or Moving documents

The procedure to copy or move a document is:

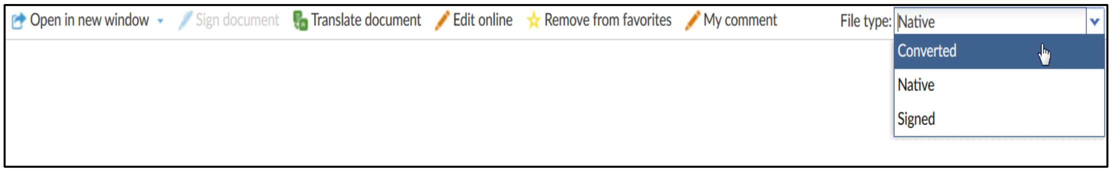
1. Select the document/s to be copied or moved in the grid.
2. To **move** the document/s to another folder, drag the document from the grid and drop it to the destination folder in the Index Pane.
3. To **copy** the document/s to another folder, hold the *Ctrl or Shift key*, and drag and drop the document to the destination folder in the Index Pane.

While copying or moving a document you will be asked to re-code the document profile and will open the **Edit Document Profile** window to enter the details. Follow the instructions to complete the form. You may choose to replace the attachment at this time if required. If you replace the attachment you can view the version history in the document's metadata panel.

> ***Viewing of version history on replacing attachments is available only in Alfresco rooms. For more details follow on to section Replace Document.***

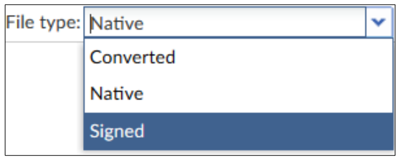
If the **Hide Index on add new document** option is on, editors will not be able to copy or move a document and will receive the warning as below.

12.2. Document Grid View Tool Bar

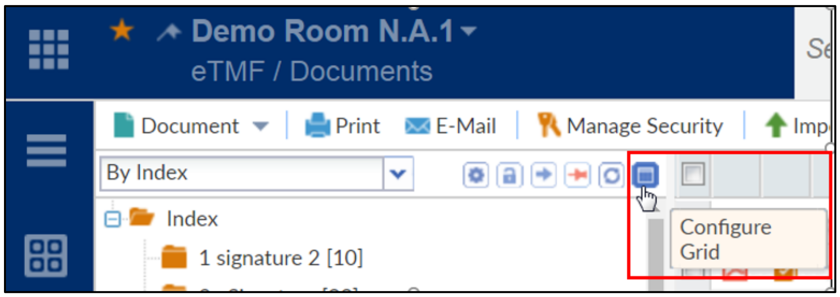


This toolbar is available once you open a document for viewing. The options available here allow you to change what displays on your screen and the arrangement of the material. You can toggle back and forth between viewing a document and seeing the list of the documents in a selected folder by clicking either the **Grid** view or the **Document** view. If you select to view the document itself, other function options become available to you at the top of the viewing pane, depending on the room's configuration.

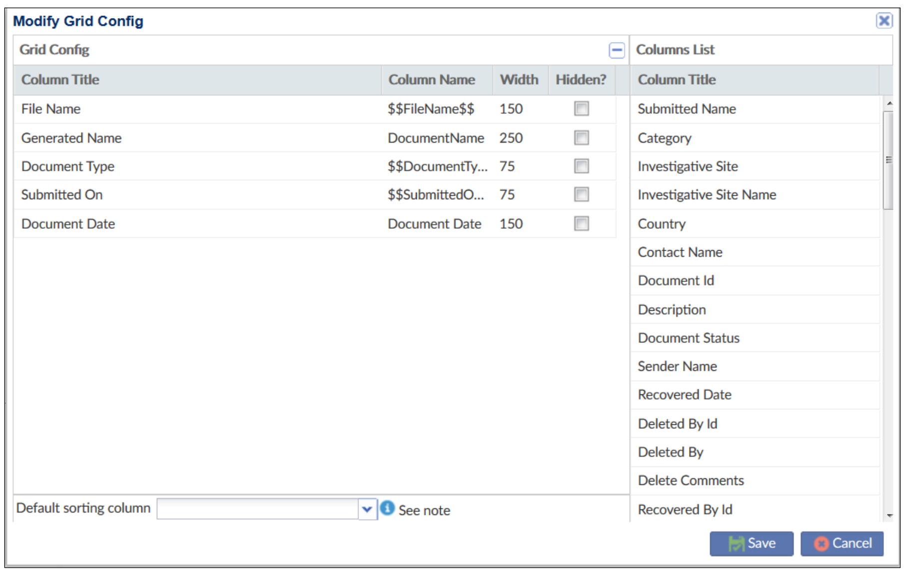
- You can opt to **open** the document in a **new window**. If you click this option, the selected document pops up in a new reader window. This function is available to all users with Administrator level access.
- If the **Machine Translation** option has been activated for your room, the **Translate Document** button is available to you.
- You can **Sign** a **Document** if it is sent for e-Signature.
- Similarly, you can **Add** a document **to favorites** ★ Add to favorites from here. If a document is added to favorites, you will see the **Remove from favorites** icon ☆ Remove from favorites instead.
- Also, you can add comments to a document through **My comment,** which will open an **Edit Comment** window for adding comments.
- You can also **Edit online** a document. For example, if it is a Word document, then clicking this option will open the document in Microsoft Word for editing.
- Besides the above, the **File Type** dropdown at the end of the tool bar will **appear only if a file has more than one version**. It provides options as below:
  - **Native** : To get the original view of the document
  - **Signed**: To view the document with e-Signature on it. This option is available only for e-Signature documents.
  - **Converted**: If a document is converted to PDF, you can view the document as converted.



12.3. Configuring the Document Grid



1. Select the **Configure Grid** icon pictured above. The **Modify Grid Config** window opens.



2. Add metadata fields to the grid display configuration by dragging-and-dropping them from the list of available fields on the left.
3. Delete fields by dragging them out of the **Grid Config** panel on the left.
4. Modify the width of the display columns for each column in the grid configuration by double-clicking the number in the Width column.

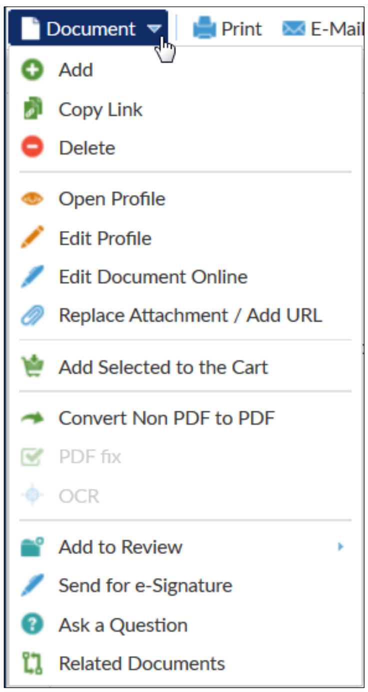
   The field becomes active.

5. Type the appropriate number to set the width that you'd like to see for that column in the grid.
6. Tick a column as **Hidden** if you do not want it to appear in the grid.
7. Click **Save** at the bottom of the window when you have finished making changes.

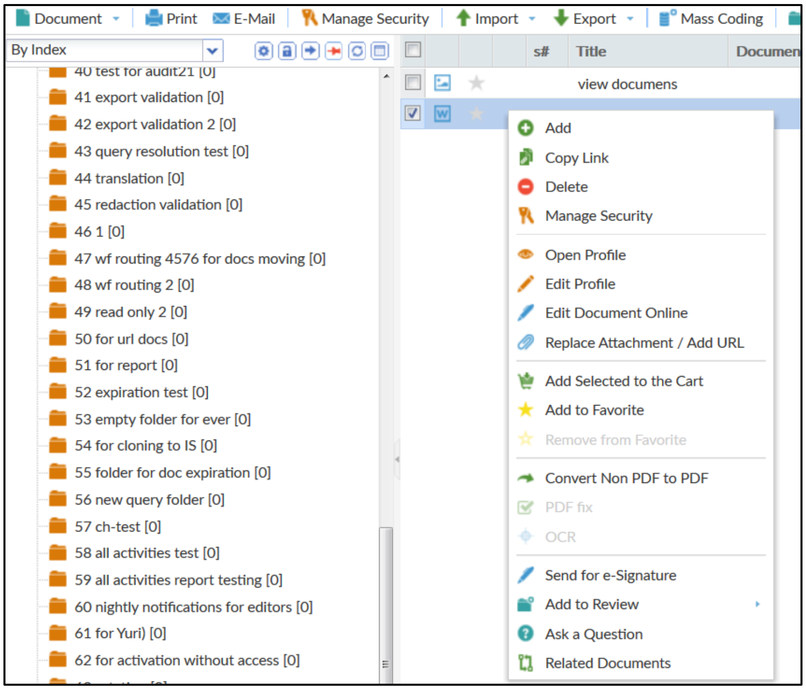
13. Documents view - Top menu ribbon

The Top menu ribbon in the **Document** view offers Administrators access to many important Trial Interactive functionalities.

13.1. Document dropdown/Right-click on a document



This functionality is also available as a right-click popup from the Document Grid. Refer to the screenshot below:



As shown in the screenshots above, a horde of activities can be performed on a Document by right-clicking it or from the Document Dropdown such as Add, Copy Link, Delete, Open Profile, Edit Profile, Edit Document Online, Replace Attachment/Add URL, Add Selected to the Cart, Convert Non PDF to PDF, PDF Fix, Add to Review, Send for e-Signature, Ask a Question, and Related Documents.

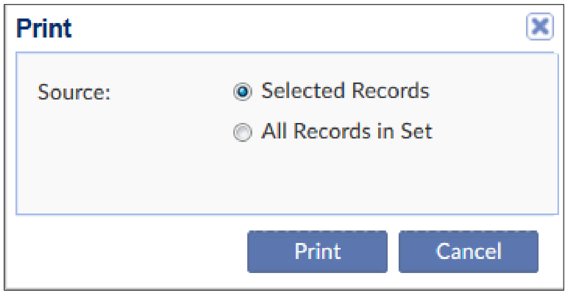
Each of the functionalities are discussed in separate chapters.

13.2. Print

The **Print** function is self-explanatory. You can order a printed hard copy of a document through this menu option.

1. To activate the **Print** function, first click a folder in the index so that documents populate on the document grid.
2. Select one or more documents from the grid that you want to print.
3. Click the **Print** icon in the menu ribbon. The **Print** window opens.

4. Click the appropriate radio button, **Selected Records** or **All Records in Set**.



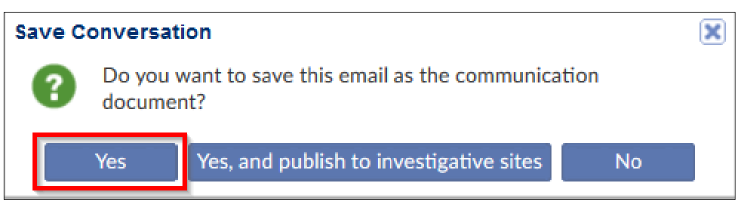
5. Click **Print**.
6. Follow the usual steps of creating a printout from your computer.

   If the user has opened a folder with documents and has not selected a document or particular set of documents from that view, the **Print** option is still available. When the user clicks the option without having selected a document, the default is to print all of the documents in the set. Follow the on-screen instructions to complete this operation.

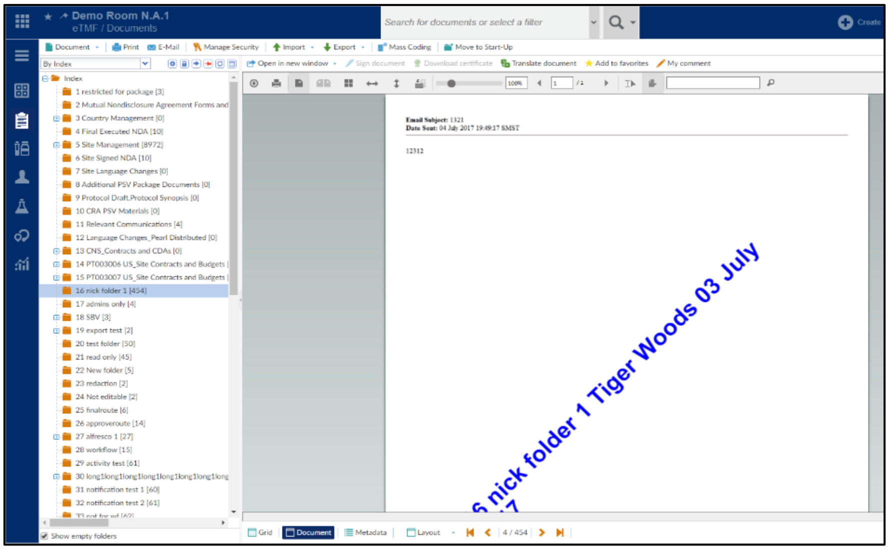
13.3. Email

To email a specific document as an attachment or as a link, click the **Email** option from the top menu ribbon and follow the on-screen instructions.

You can save an outgoing email as a PDF document. On clicking **Send**, the **Save Conversation** dialog box pops up.



If required, you may also opt to save the document as PDF and publish it to investigative sites. Upon selecting your option, the **Document Profile** dialog box pops up. Enter the details and click **Finish**. The email communication is now saved as a PDF document in the folder as mentioned in the **Default index position for Add document** in the **Settings -> Documents -> Index Outline**. The email PDF has only Subject, date sent, and body of the email as its contents. You can view this email sent from the Communications Outbox module.



For further email settings, proceed to **Username Dropdown -> Settings -> Email**.

13.3.1. Email Templates

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

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

13.3.2. Room Legal Hold Notification

This section is discussed under Legal Hold.

13.3.3. Notification Preferences

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

1. Enter the frequency with which the Mini newsletters will be sent to subscribers.

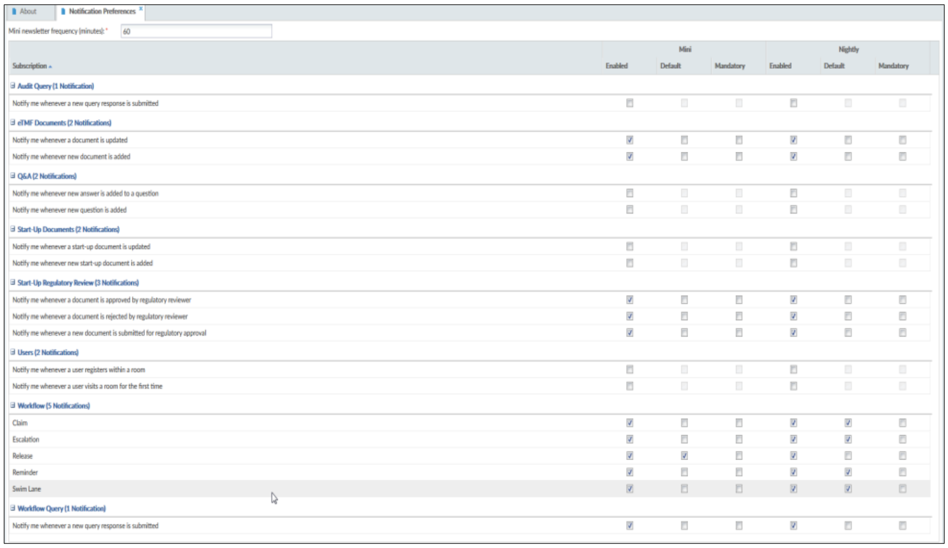
2. In the Subscription panel, enable the appropriate notifications that will be available to the room's users.
3. Click **Save**.

Using the options grid on the right of the **Subscriptions** window, you can select which notifications you would like to receive. Administrators can choose alert systems, depending on which notification systems have been enabled by the room's Administrator:

- A new audit query response is submitted
- A New Document is added to the eTMF, and/or Start-Up
- A Document is updated in the eTMF, and/or Start-Up
- A user visits a room for the first time
- A user registers within a room
- A New Question is added
- A New Answer is added to a question
- Workflows
- Workflow Query response submissions
  If the Study Start-Up module is active in the room, users will also see Start-Up notifications they can opt to receive.

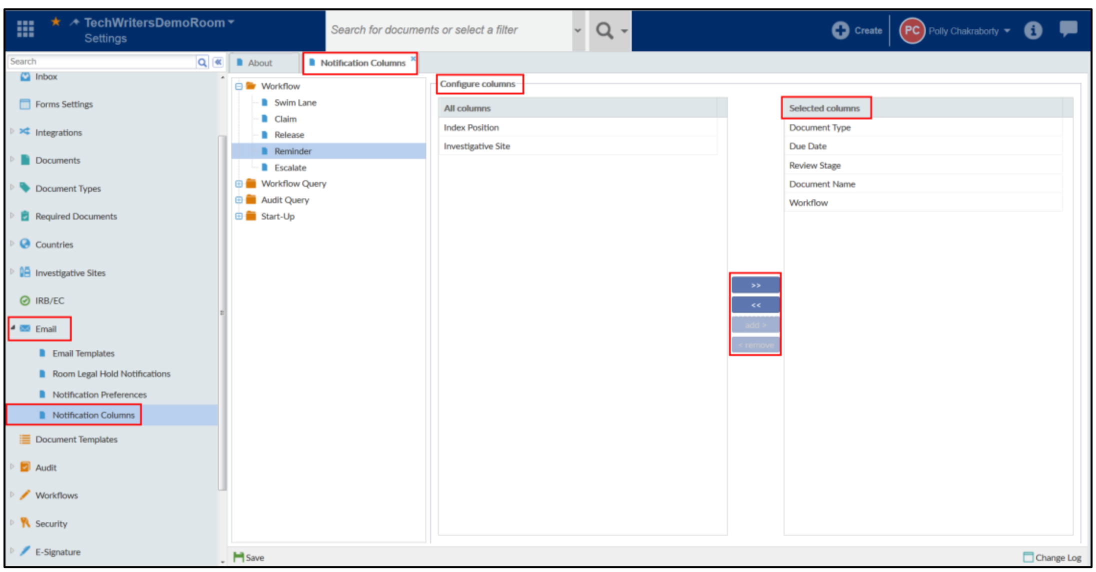
You can elect to receive either a mini summary of notifications or nightly newsletters recapping all of the new events in the past 24 hours for each of the five notification categories.

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



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

13.3.4. Notification columns



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

The Notification Columns are available for categories **Workflow**, **Workflow Query**, **Audit Query**, and **Start-Up**.

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.**

13.4. Manage Security

The Trial Interactive platform allows for two different approaches for defining security rights in the Trial Interactive site. Security can be set on a **folder level** or on a **document level**. At the onset of a Trial Interactive project, the desired security method should be conveyed to the Trial Interactive Project Management team, who will enable the appropriate security module in the site. Modification of these settings is accessed through the **Documents** view.

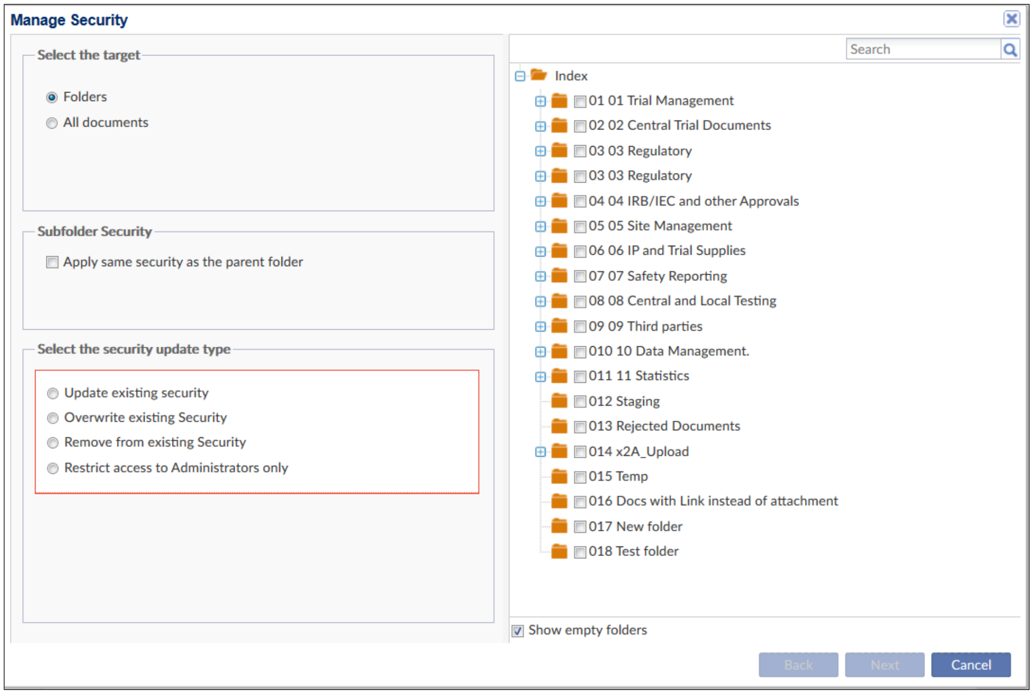
You can also Manage Security for Sites which is different from managing security for documents and is discussed in section Manage Security for Sites.

13.4.1. Folder Level Security

This allows for security definitions to be assigned to the individual folders in the Index Outline of the Trial Interactive room. Once security definitions are assigned for a folder, whenever a document is profiled into that folder, the document automatically inherits the security definitions assigned for the folder. To assign folder level security, follow the steps as below:

1. Click the **Manage Security** button located in the upper toolbar.

   The **Manage Security** tool opens.



2. Select the **Folders** button.

   The panel on the right that displays the Index structure becomes active allowing you to select exactly to which folders you would like to apply the security change. You must select at least one folder from this list.

   By leaving the **Apply same security as the parent folder** checkbox unchecked, you can select specific subfolders on which to modify the security settings. If you check the box, you need only to select the main folders whose security settings you want to modify.

3. Check the boxes next to the folders to be affected.

4. Select the security update type by selecting one of the four available options.

Update Type	Description
Update existing security	This option leaves all current security definitions in place and adds on any new definitions set in step two of the manage

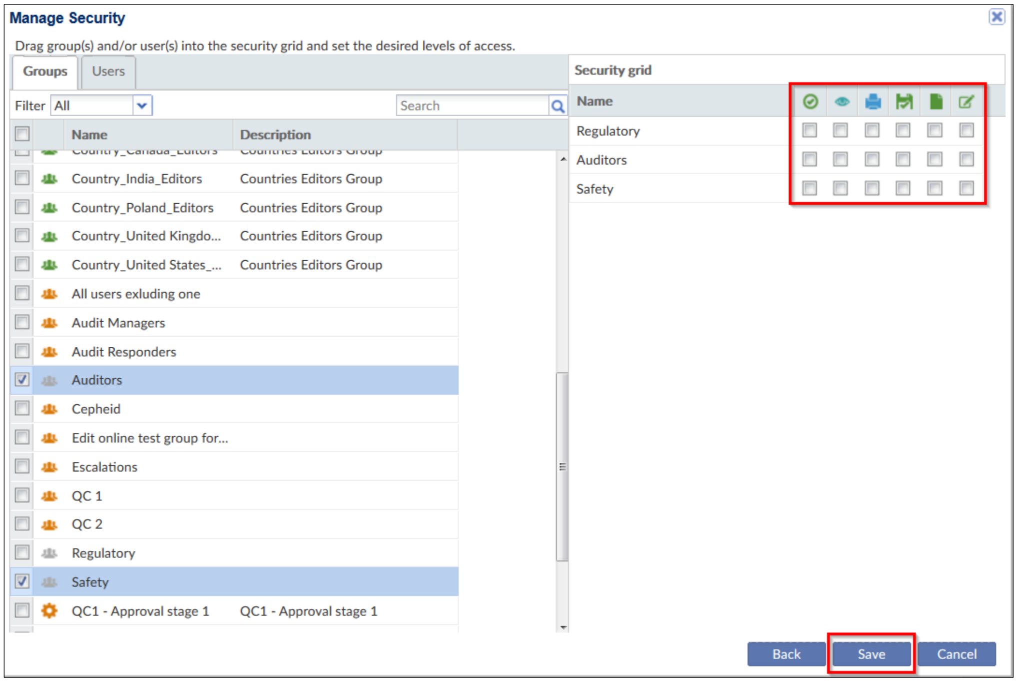
Update Type	Description
	security process.
Overwrite existing security	This option erases all current security definitions and replaces entirely with the definitions set in step two of the manage security process.
Remove from existing security	This option leaves intact any security definitions already assigned, but removes access for any group(s) or user(s) specified in step two of the manage security process.
Restrict access to Administrators only	This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.

5. Click **Next**.

   The second stage of the **Manage Security** tool populates the window.

6. Using the **Groups** and **Users** tabs on the left side of the control window, select the Groups and/or Users to update security rights for by double clicking on the listings. This

moves the Groups and/or Users into the **Security grid** on the right.



7. Select which security definitions you want to update for the selected group/user.

Security option	Description
Full Access	Non Encrypted access allowing for full printing and saving rights
View Only	Allows users to only view the PDF while restricting printing and saving
No Watermark	If the watermark is in use in the site, this access will provide the users access to a non-watermarked version of the PDF file
Redacted	Gives the users access to the redacted version of the file while preventing access to the original (non-redacted) version

8. Click **Save**, and the security definitions are in place.

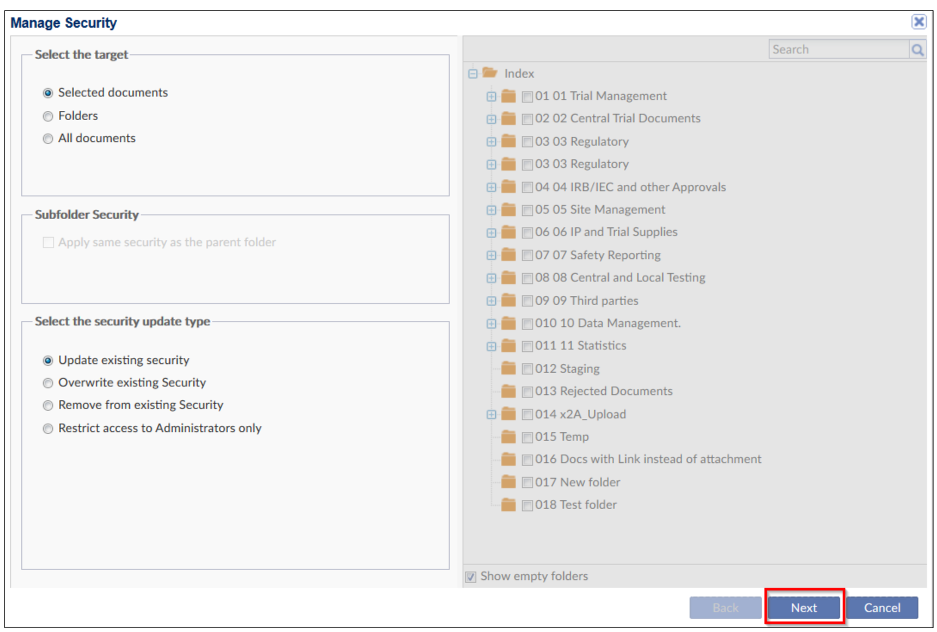
By selecting the target as All documents in the top left panel of the Manage Security tool, you need only to Select the security update type before clicking Next and selecting which groups or users to include in the security modification.

13.4.2. 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**.

Notice that the options to manage the security for specific folders and for All documents is available here, too, just when no specific documents have been selected.

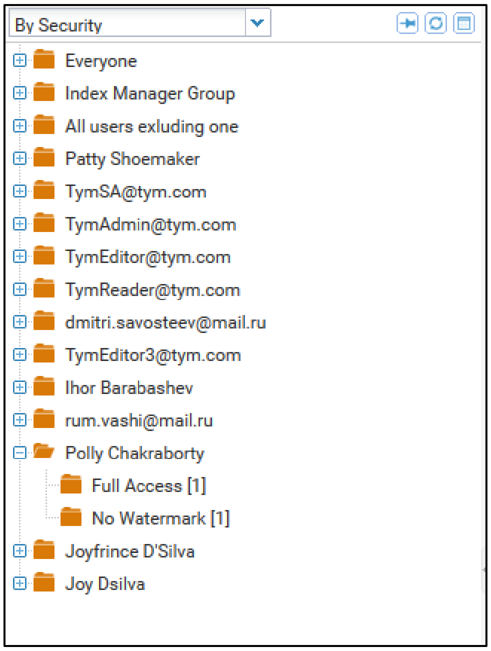
5. Select the security update type by clicking one of the four options, as described in the previous section of this guide.
6. Click **Next**.

   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.

   Click **Save**, and the security definitions are in place.

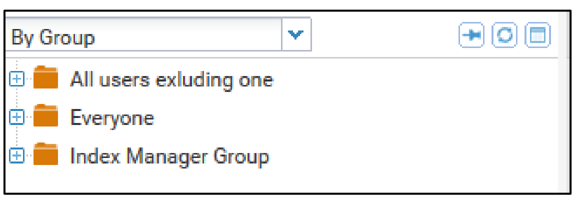
13.4.3. By Security view

Click the **By Security** view from the Index Pane. The **By Security** view shows all the documents based on the security accesses provided to users and group of users. Documents are segregated under folders by the name of users showing the level of their access



13.4.4. By Group

In the **By Group** view, the folders and documents belonging to a particular group can be viewed by clicking the group name in the index pane.



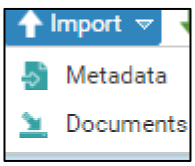
13.5. Import

Administrators have the ability to upload documents into the trial room. For browsers such as Chrome and Firefox, Trial Interactive uses an HTML5 uploader. For browsers such as Internet Explorer 10, Trial Interactive uses a Java uploader by default. Trial Interactive detects whether your browser is HTML5 compatible, and makes the appropriate uploader selection.

Depending on the security settings in your browser and whether your browser supports HTML5, you may be asked to allow Java Software to run in order to perform the upload. If so, authorize the use of the software and proceed. Use of the Java uploader allows the user access to advanced upload features, such as drag-and-drop of entire document folders.

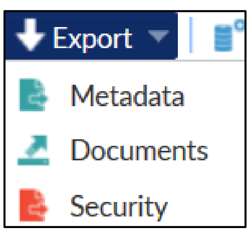
You can add multiple documents at a time to the trial room by using the **Import** tool from the top ribbon bar.

1. Log in to a TI room using one of the browsers listed above that supports HTML5.
2. Go to the **eTMF Documents** module.
3. Click the **Import** Import button in the menu ribbon located above the display grid.
4. Here, you can choose to import **Documents** or **Metadata**.



Each of the import functions are discussed in a Importing Documents and Importing Metadata.

13.6. Export



Three options are available to the Administrator from the **Export** button on the Top menu ribbon – **Metadata**, **Documents**, and **Security**. Each of these options offers you a number of choices regarding the scope of the export. The user chooses the boundaries that define the parameters of the export.

Each of the export functions are discussed in Chapter Export Documents.

13.7. Mass coding

The Mass Coding feature is useful when an Administrator knows of a number of documents in the room that all need the same metadata update. Using this feature saves a lot of time and keystrokes. Contacts and Sites data too can be mass coded. Follow the hyperlinks below to know how to mass code for:

1. Documents
2. Contacts
3. Sites

13.8. Move to Start-up

The **Move to Start-Up** option is available only in rooms in which the **Start-Up Module** is active. In such cases, this option can be used to move documents from the eTMF back to the appropriate Start-Up folder in the case that documents have been delivered and deposited in the eTMF prematurely.

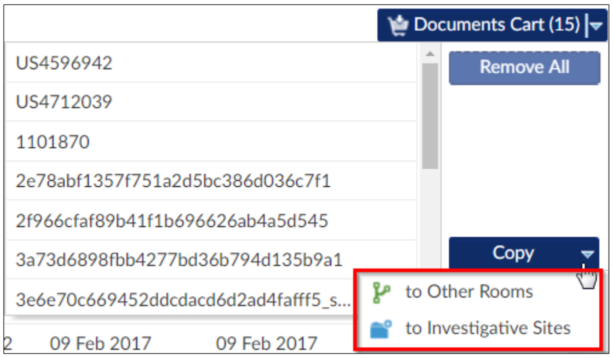
13.9. Document Cart

The **Document Cart** works just like an online shopping cart. Users select documents to add to the Document Cart either from the Documents menu, or from the right-click popup, or by dragging and dropping the documents into the Cart.
Here users are able to perform a variety of functions on the document.

The Document Cart icon 

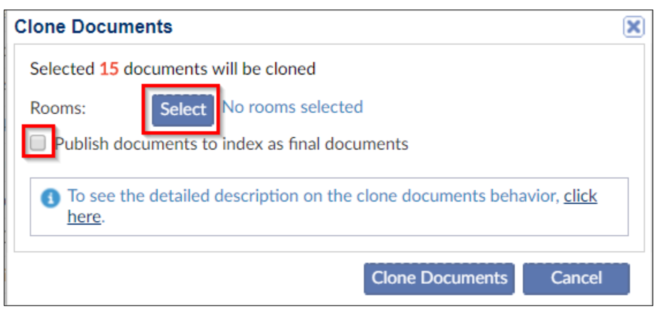
is located on the upper right corner of the document grid. Once a document is added, it will automatically update to reflect the number of documents available in the cart.

After documents are added to the Document Cart, you can remove a document from the cart by clicking the red X button right next to the document name. If you wish to remove all documents, click the **Remove All** button. Additionally, when you hover your mouse over a document's name, it will display a quick summary of the document such as its title, document type, and index.



13.9.1. Document Cart – Copy 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 Document Cart, selected documents as well as their metadata will be copied to other rooms. The **Clone Document** window will open up and prompt you to specify to which study rooms documents shall be copied. If you wish to publish documents to the index as final documents without going through the workflow, put a checkmark next to the given choice. The document type of the destination room will determine the auto-naming rule for the document.



13.9.2. Document Cart – Copy 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 Document Cart.

Once you click **Copy to Investigative Sites**, a **Clone Documents to Investigative Sites** window opens up and asks you to select investigative sites. Click a radio button next to your choice.

- If you choose **All Sites**, click **Next** to select the folder to which the documents will be cloned.
- If you choose **Specific Sites**, just click **Next**, and it will give you site choices on the next section.
- If you choose **By Country**, a dropdown with the list of countries gets activated for you to choose from. Click **Next** folder selection.

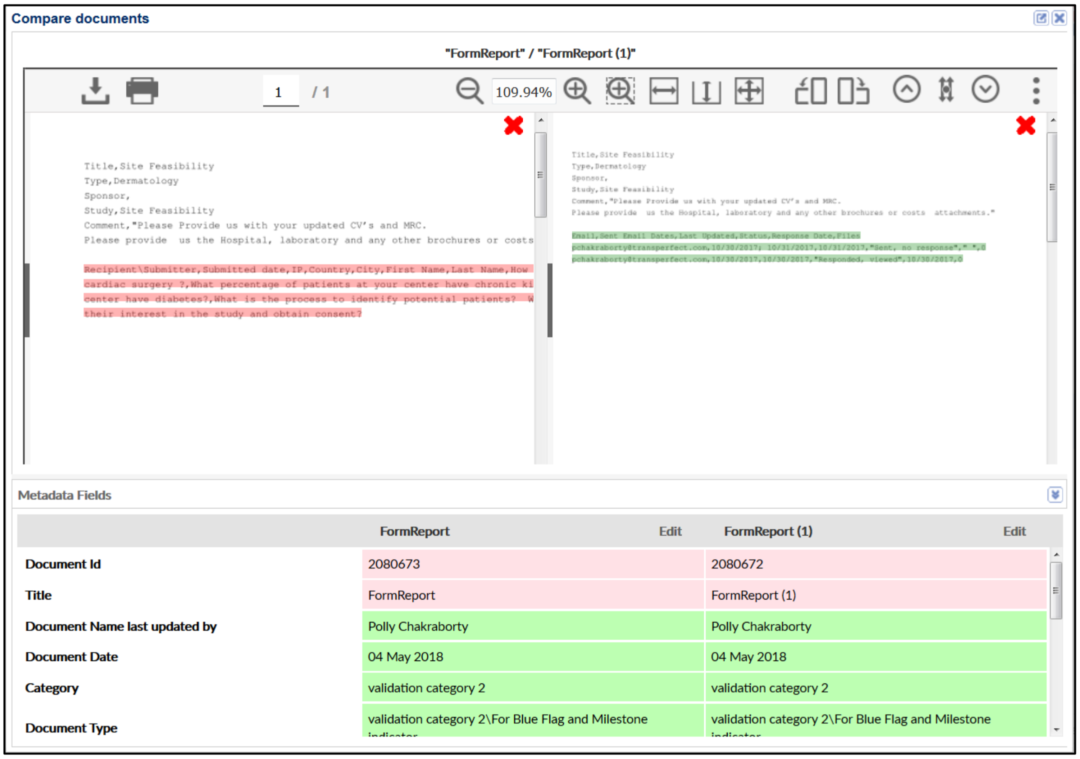
Please refresh the page after any changes.

13.9.3. Document Cart – I want to…Compare Documents

The **Compare Documents** tool in Document Cart lets you view and compare two or three documents at the same time by placing those side by side. You can use the ABBYY Optical Character Recognition (if that is enabled for you) to support the comparison of documents from document scans and images.

After adding documents to the Document Cart, first click the **I want to** option located on the bottom right and then select **Compare Documents**. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the viewer chosen by you. You can also expand the metadata fields on the bottom using the double-caret bar to compare documents' metadata conveniently at once.

Refer to the screenshot below which shows the documents opened using TI Viewer:



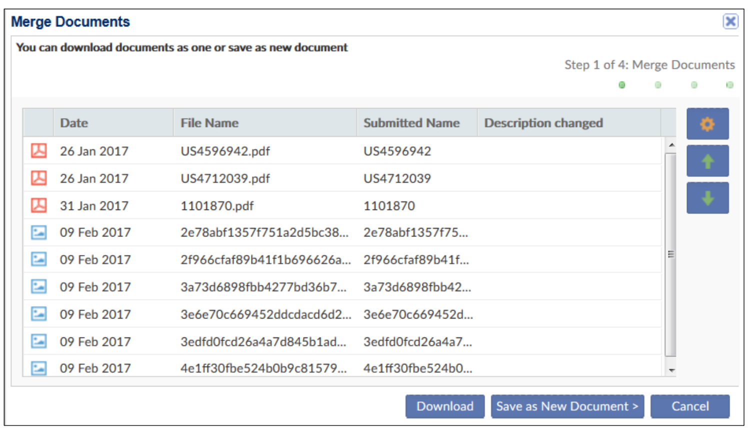
To facilitate easy and seamless comparison of documents:

1. The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
2. The **documents scroll at once in sync** with each other when you drag the scroll bar to facilitate easier viewing and comparison if you have activated the 'Synchronize document scrolling' from the toolbar.
3. The system displays appropriate messages when two documents are identical.
4. The print and download options for comparison are available to you only if you have **Full Access** to the documents.

13.9.4. Document Cart – I want to…Merge Documents

An Administrator user can merge two or more documents into one document. Select the documents you want to merge into one, either to use as a single document in the room or to download and print as a single document. After placing the desired documents in the Document Cart, simply click the **I want to…Merge Documents** tool. Next, on-screen instructions will appear. In total, there are at most four steps involved. You can first decide in which order these documents will be merged into one by selecting the document and clicking the arrows. Click on the **Configure Grid** (gear icon) button to modify the columns to be shown on the merged document. Tick the checkbox if you wish to hide a specific column. Click **Save as New Document** button; you will be given an option to delete documents after merging. At times the original documents cannot be deleted after merging, the reasons of which are as follows:

1. If the user does not have access rights to delete the documents. For example, an Editor may have full access rights to the document, but if the document was not uploaded by this editor, he/she will not have the possibility to delete it.
2. If the documents have been published from SWS to eTMF, they cannot be deleted.



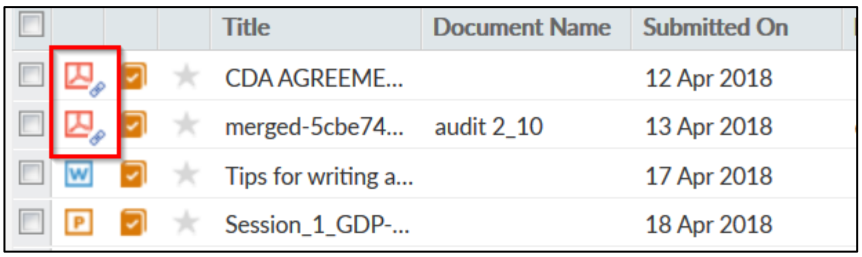
Follow the instructions on screen to download the merged file as PDF file, or save.

Only PDF, HTML, HTM, JPEG, JPG, PNG, and BMP file types can be merged in TI 9.2. The maximum number of files that can be merged at a time need to be specified in Settings -> Documents -> Documents Module by the super-admin. If number of documents are more than the limit set, then only first N matches specified in the settings will be merged.

13.9.5. Document Cart – I want to…Link Documents

Administrator users can link documents together with this option. To link documents placed in the Document Cart, simply click **I want to**…**Link Documents** button. A pop-up message will appear to confirm the documents are successfully linked.

Once complete, the linked documents will be removed from the Document Cart. In the Document Grid, a chain icon will appear next to all the documents that are linked so that you may easily identify the linked documents. Refer to the screenshot below:



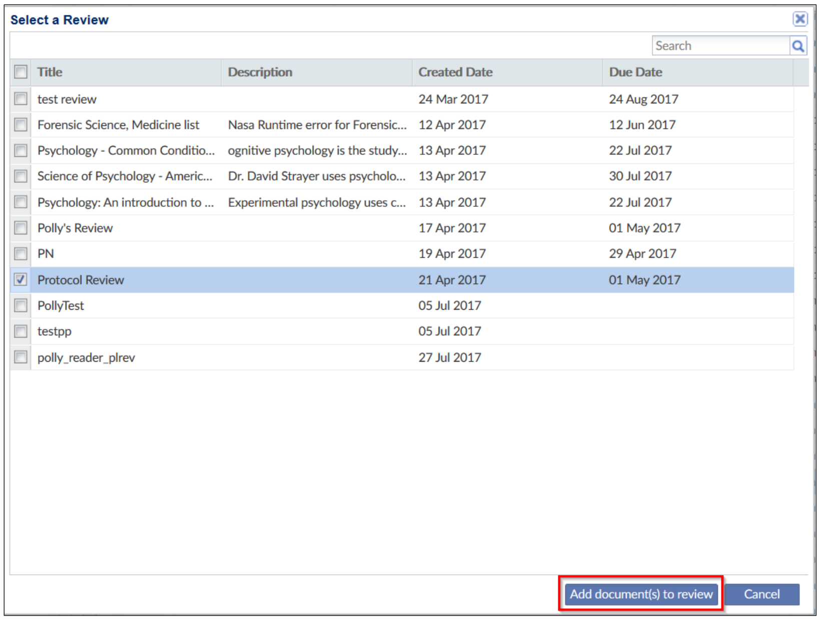
Afterward, whenever you right-click on one of the linked documents and click **Related Documents**, interrelated documents will all be displayed on the screen.

13.9.6. Document Cart – I want to…Add to existing review

This functionality is meant for those users who use Please Review.

As an administrator you can add documents to the cart from the grid and include them in an existing review workflow by using the option **I want to…Add to Existing Review.**

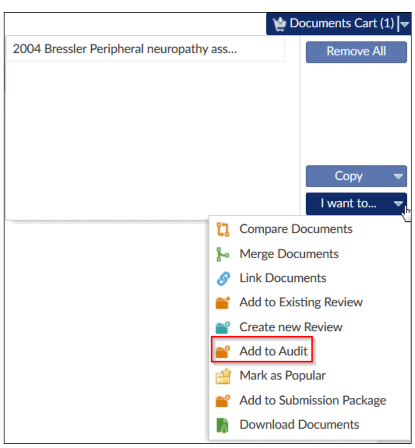
On selecting this option, the **Select Review** popup opens with a list of existing reviews for you to select from. Tick the checkbox next to the review name as required and click **Add document(s) to review**. The review can then be accessed from the **Authoring Module.**



13.9.7. Document Cart – I want to….Create new Review

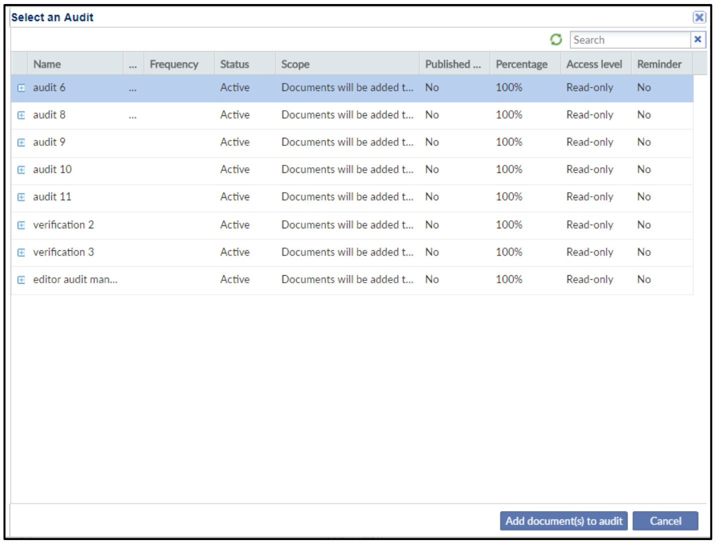
You can also add documents to the cart from the grid to include them in a new review workflow by using the option **I want to…Create new Review.** This opens the **Create Review** popup to create the review. This is discussed in detail under the section Authoring **Dashboard.**

13.9.8. Document Cart – I want to…Add to Audit



The **Add to Audit** feature in Document Cart provides on-demand document publishing for periodic audit review. After selecting documents and placing them in the Document Cart, you can directly add documents to an audit. Therefore, if auditor specifically asks for certain documents, simply click **I want to… Add to Audit** button to move those documents over to an auditor to review.

Upon clicking the **Add to Audit** button, you will be directed to choose to which audit to add the document. Select an audit and click the **Add document(s) to audit button** located on the bottom left corner. A message will pop-up to ensure your decision to publish the selected documents to audit immediately. Click **Yes** to complete.



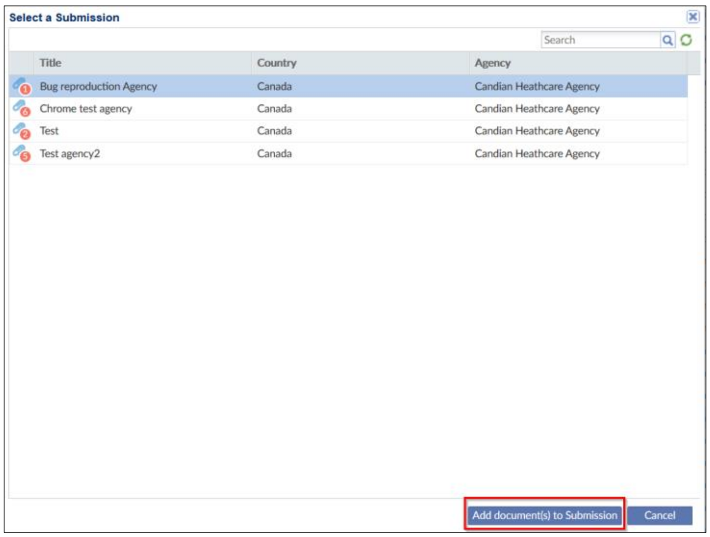
13.9.9. Document Cart – I want to…Mark as Popular

Administrator users can mark certain documents as popular using this option. Choose the document in the Document Cart and click **I want to**…**Mark as Popular**. The selected documents will then appear on the dashboard dashlet, **Popular Documents**. There, you can easily view all popular documents that you have specified.

Please keep in mind that the Popular Documents list is common to all users; however, users who do not have an access to a particular document will not be able to view that document in the Popular Documents list.

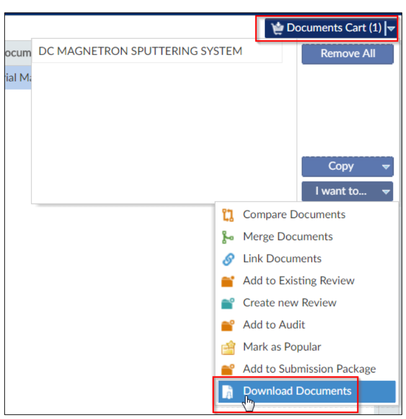
13.9.10. Document Cart – Add to Submission Package

You can add documents to the cart from the grid to include them in a start-up submission package by using the option **I want to…Add to Submission Package**. This opens the **Select a Submission** popup with a list of existing submission packages for you to select from. Select the submission package and click **Add document(s) to Submission**. Refer to the screenshot below.

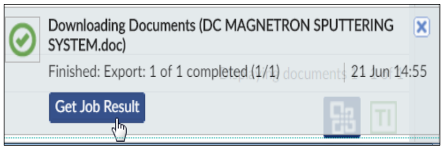


13.9.11. Document Cart – Download Documents

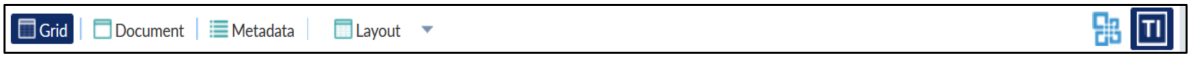
Add documents to the cart and select the option **I want to…Download Documents**.



The documents get downloaded in a .zip format and a notification regarding the same is received. Documents added without attachments cannot be downloaded and the archived zip of downloaded documents will not contain documents without attachments.



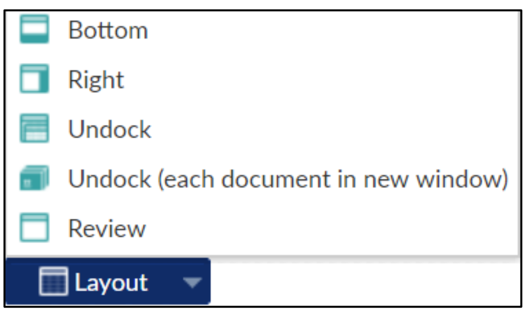
14. Documents view - Lower toolbar



This tool bar lies at the bottom of the document grid, and comes with various functionalities.

1. Click the **Document** button in the lower menu bar below the document grid.

2. The document appears in a new pop-up window. The layout of this window can be selected from **Layout** as show in the screenshot above. Hover the mouse over the Layout button to know your current layout in a popup. The window can be laid out at the **Bottom** of the grid, or at the **Right** of the grid. You can **Undock** to open a separate window displaying the document. In the **Undock** mode, any document that you open will be swapped for viewing in the same window undocked by you. You can choose to open each and every document in a separate window of their own through the **Undock (each document in new window)**. You can also open the document for **Review.**

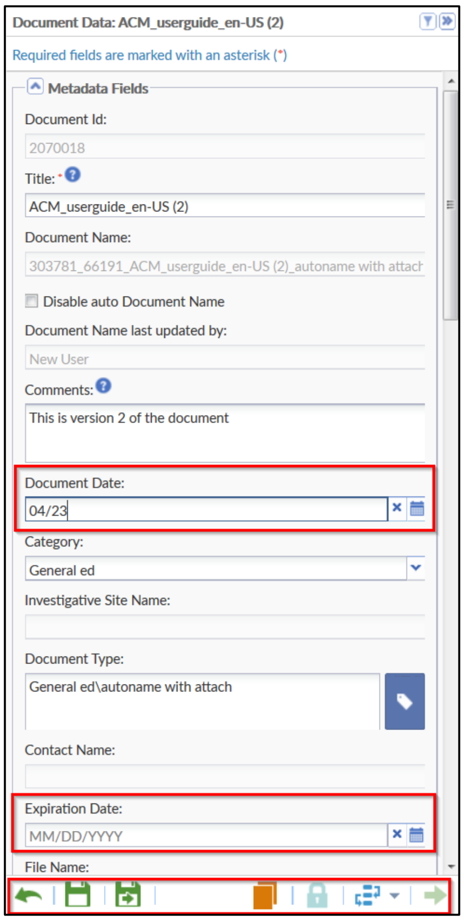


3. To return to the document grid, click **Grid** at the bottom of the viewing panel.

Another viewing option is to open the document in a new window. Click the icon above the document viewing pane.

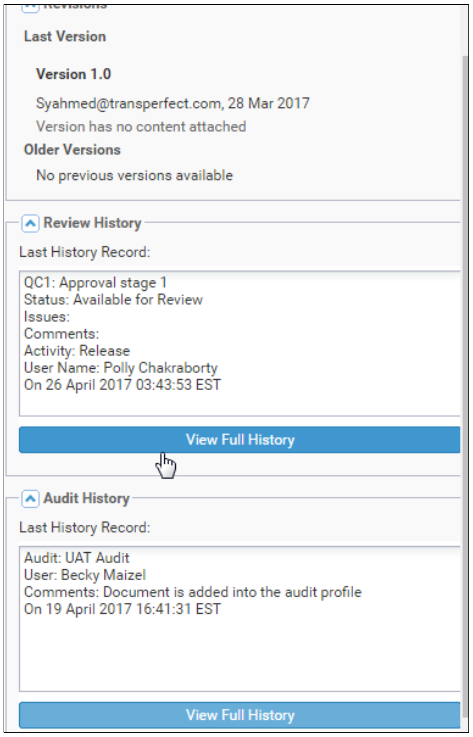
15. Documents view - Document Data/Metadata Pane

You access this pane by clicking the double-arrow on the right side of the screen or by clicking **Metadata** button in the lower toolbar at the bottom of the **Document Grid**. As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The icons at the bottom of the panel provide access to several essential functions, such as saving changes and updates in the metadata panel.



Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings -> General Information section.

Besides these, you can also view document Revisions, Review History, and Audit History.



Click the **View Full History** button to view the complete **review history** or **audit history**. Here you can view the timestamp of the user activities under various workflow stages, or the timestamp of the audit history of the document under various audit profiles respectively.

The functionalities of the buttons at the bottom of the metadata pane are discussed in various sections of the document.

15.1. Forms Settings

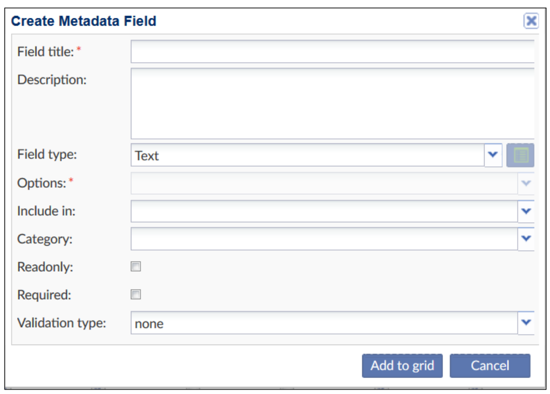
Clients sometimes request custom settings to form fields that appear in a number of forms throughout a TI data room, such as document type metadata fields, question and answer forms, and audit form options. Metadata system fields can be switched off and on from this view. Changes here will affect the fields that users have the availability to view in document profiles for all different document types in a room. Settings here work in conjunction with **Q&A Settings,** with **Document Types** settings, and with **Countries** settings. Custom metadata fields can be created and set up here, too. Making changes to these advanced settings should only be done in close consultation with the Project Manager.

To navigate to these settings, click **Settings** from **My Profile** dropdown from within the room, then select the **Forms settings** tab on the left. 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. For this section of the User Guide, the focus is on the **Document Profile**.

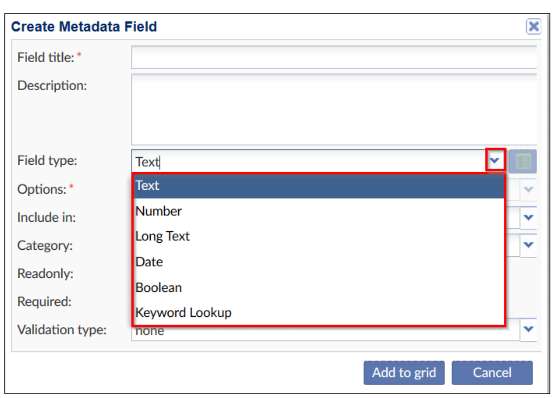
15.1.1. Adding a Custom Field

1. Navigate to **Username dropdown ->Settings -> Form Settings**.
2. Click **Add** Add in the menu ribbon.

   The **Create Metadata Field** window opens.

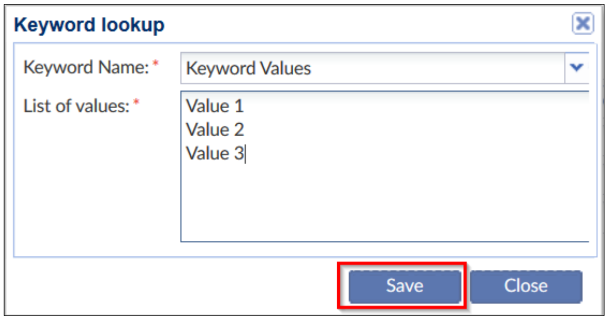
   

   Enter the **Field Title**.
3. Click the dropdown arrow to the right of the **Field Type** field.
4. Select the **Field Type** from the list.

Keyword Lookup is the most complicated Field Type to create, so that will serve as the example.

5. If you have chosen **Keyword Lookup**, a new window opens.

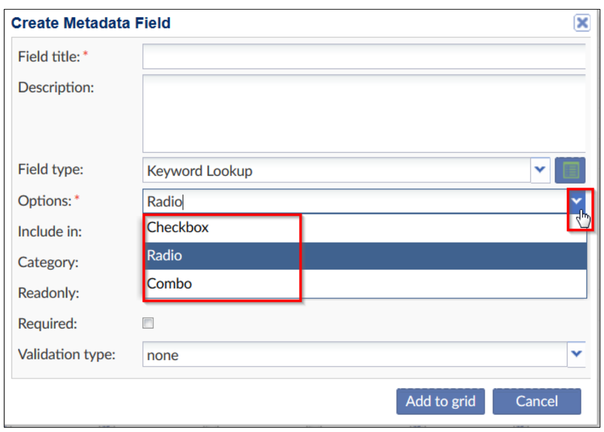


Type in the list of requested Keyword values.

6. Click **Save** at the bottom of the window.

When you return to the previous window, the **Options** field is active. This field becomes active only with the selection of the **Keyword lookup** option.

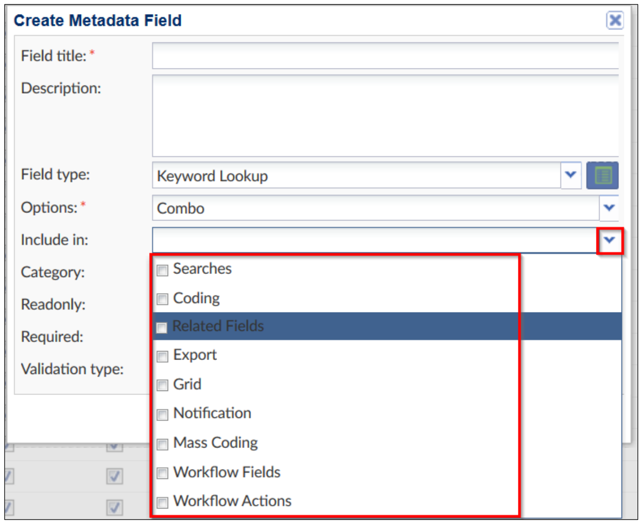
7. Click the dropdown arrow at the right end of the **Options** field.



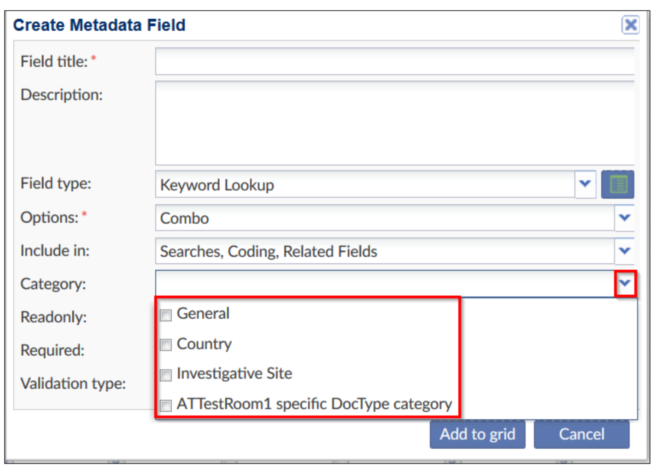
8. Select the appropriate option.

- Checkbox – the values entered display as a list and users can choose one or more
- Radio – user must choose only one value from the list
- Combo – users can choose only one value from a dropdown list

9. Click the dropdown arrow at the right end of the **Include In** field.



10. Select the operations in which this new custom field will appear by clicking the appropriate check boxes.
11. Once you have made that selection, click outside of the list.
12. Click the dropdown arrow at the right end of the **Category** field.



13. Select the Document Type category or categories in which this new custom field will appear.
14. Once you have made that selection, click outside the list.
15. Click the **Read-only** checkbox if that option has been requested by the client.

16. Click the **Required** checkbox if that option has been requested by the client.

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

17. 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.

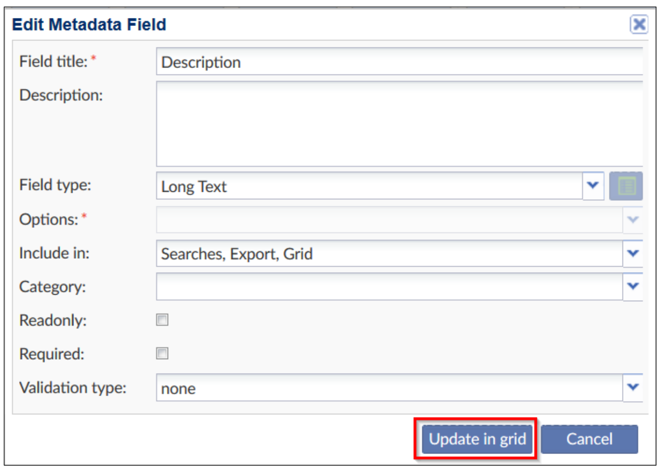
18. Click **Add to Grid**.

    The view returns to the full **Document Profile Form** display.

15.1.2. Editing a Metadata Field

1. Click **Edit** in the menu ribbon.

   The **Edit Metadata Field** window opens.



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

15.1.3. Deleting a Field

1. Click the Field Title of the field to be deleted.

   The row highlights in light blue.

2. Click the **Delete** button in the menu ribbon.

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

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

15.1.4. Setting Advanced Validation Fields

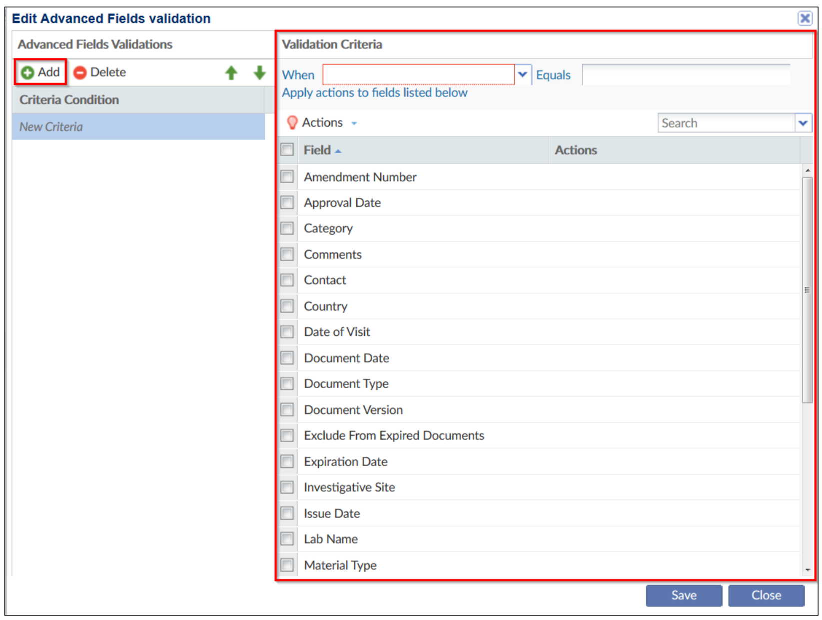
This advanced function that links two or more metadata fields based on specified validation criteria is not generally used by Administrators. Consult closely with the Trial Interactive management team before making any changes here.

1. Click **Advanced validation** in the menu ribbon.

   The **Edit Advanced Fields validation** window opens.

2. Click **Add** in the **Advanced Fields Validations** panel on the left.

   The **Validation Criteria** panel on the right activates.



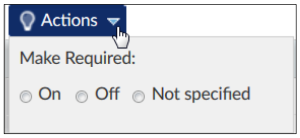
3. From the **When** field dropdown, select the metadata field that will trigger an action in another metadata field or fields.

   Those fields are selected in step 7 of this process.

4. Complete the **Equals** field.

   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.



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

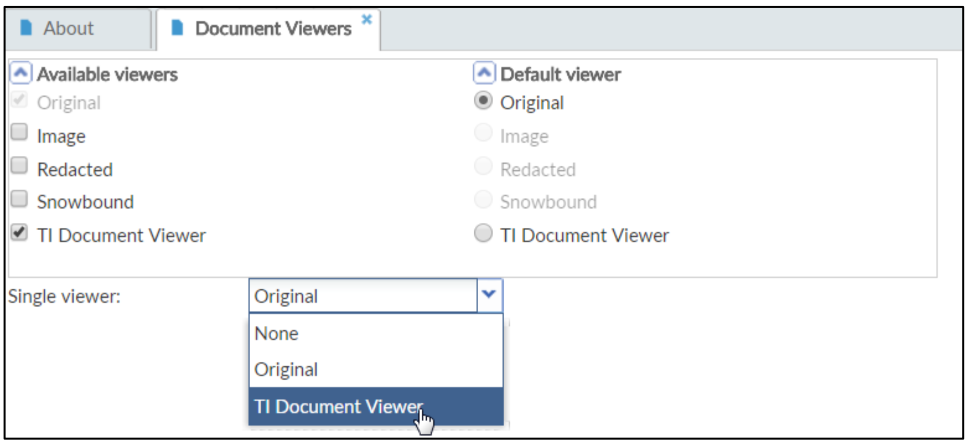
   The selected Action will apply to the selected Fields when the Validation Criteria you have set are met in a particular document's metadata.

16. Document Viewers

At the far end of the lower toolbar of the Document Grid are located two viewers to enable you to view the documents as per your convenience:

1. Original Document Viewer
2. TI Document Viewer

16.1. Document Viewers Settings



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

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

16.2. TI Viewer

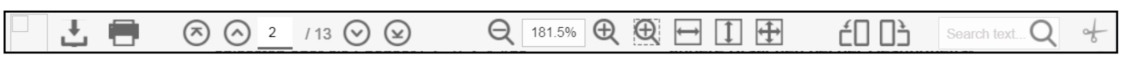
In Trial Interactive 9.2, the TI Viewer is now enhanced with the following features:

1. Viewing 300 + document and major document formats
2. Displaying Zip content
3. Displaying Email Messages
4. Full-text search documents
5. Annotate documents and save it as comments/notes
6. Merge/split/compare and create documents
7. Automatic conversion and downloading of non PDF files to PDF in TI Viewer and retaining the original format in the grid.

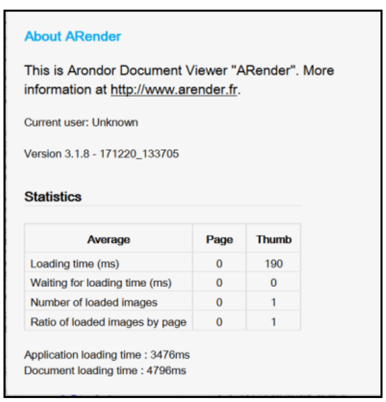
TI Viewer 9.2 Document Comparison allows documents to be compared directly using **Compare Document** option, from the **Document Cart**.

> ***Acrobat X and Adobe Portfolio documents are not supported in TI Viewer. To view these file types, you need to use IE Browser – Original viewer + TI Viewer.***

The TI Viewer comes with a horde of advanced functionalities through its top ribbon bar to ease your viewing of a document.



- Click the **About** option to view the information of the TI Viewer.

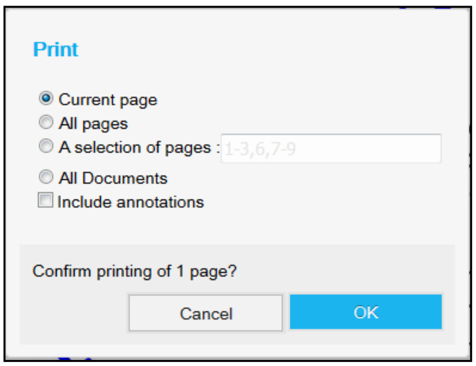


- Click the **Download** icon to download and save the document in your computer's storage. If the document is in a non-PDF format, TI Viewer will automatically download the PDF version of the file but still retain its original format, so when you return back to the grid you will still find the original version instead of the PDF version.

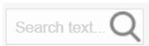
To download the original version of the document, you will need to switch to the Original Viewer.

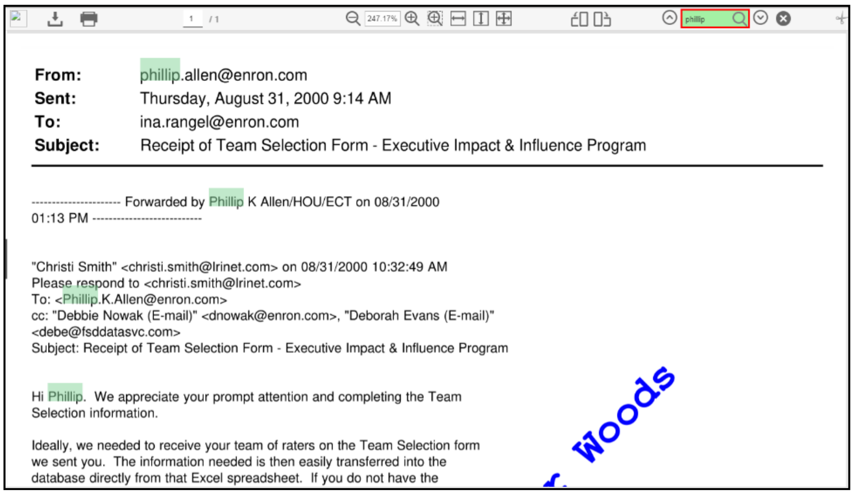
- Click the **Print** icon to print all the pages, or only the current page that is open in the viewer, or range of pages.

For users with View only privilege, Print and Save is disabled from TI Viewer.

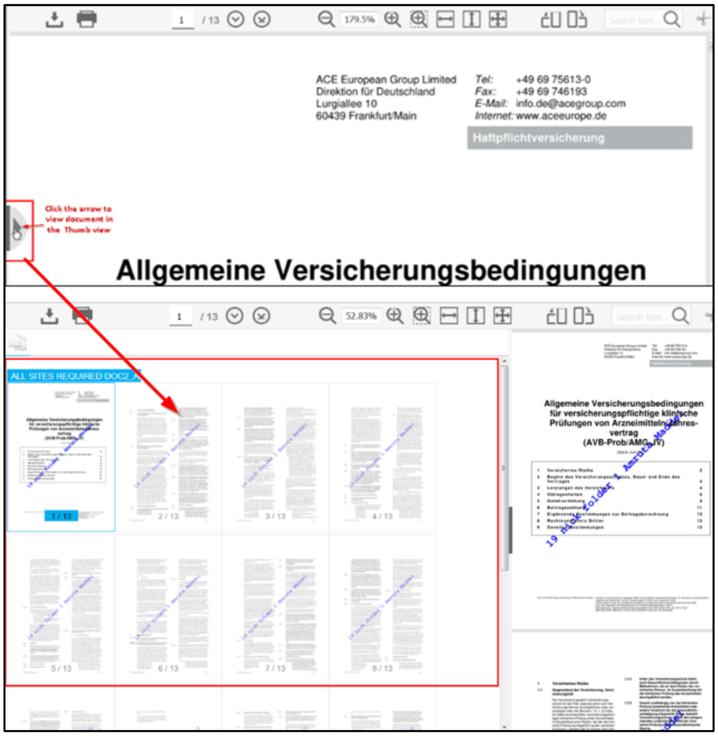


- You can also move to the desired page by entering the page number in the **Current Page** box or scroll to the **Previous Page** or **First Page** and **Next** or **Last Page**. **Note that the Previous Page and First Page options appears when you are on the second and further pages of the document.**
- The **Minus** option and the **Plus** option allows you to Zoom Out and Zoom In the document respectively as per your requirement by clicking the button. Contrary, you can also type in the zoom percent in the box next to the **Minus** option.
- The Zoom in zone option allows you to zoom In the selected area/zone of the page.
- The **Full Width** option allows you to zoom out the document enough to span the entire window.
- The **Full Height** and **Full Page** options allows view the multiple pages of the document at a time in the window.
- The **Turn Page Left** option allows you to rotate the document to the left.

- The **Turn Page Right**  option allows you to rotate the document to the right.
- You can search for a text in the document by entering the search criteria in the **Search box**  and clicking the magnifying lens icon next to it. This will highlight the matching the search criteria across all pages.
- You can delete the search criteria by clicking the **Cross** next to the **Search box.**



- Last but not the least, hover the mouse to the extreme left of the TI Viewer and click the arrow that appears to view **Thumb View** of the document. This is especially helpful if you want to view the formatting of the document before printing it. Refer to the screenshot below:


ACE European Group Limited
Direktion für Deutschland
Lurgiallee 10
60439 Frankfurt/Main
Tel: +49 69 75613-0
Fax: +49 69 746193
E-Mail: info.de@acegroup.com
Internet: www.aceeurope.de
Haftpflichtversicherung
Click the arrow to view document in the Thumb view
Allgemeine Versicherungsbedingungen
ALL SITES REQUIRED DOC2

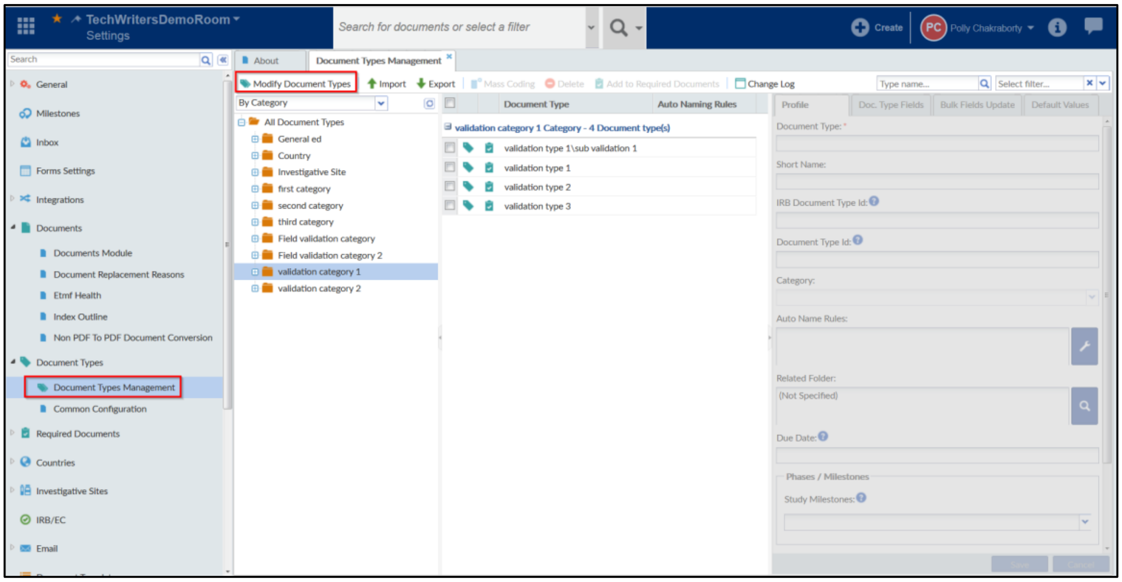
17. Document types and management

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:

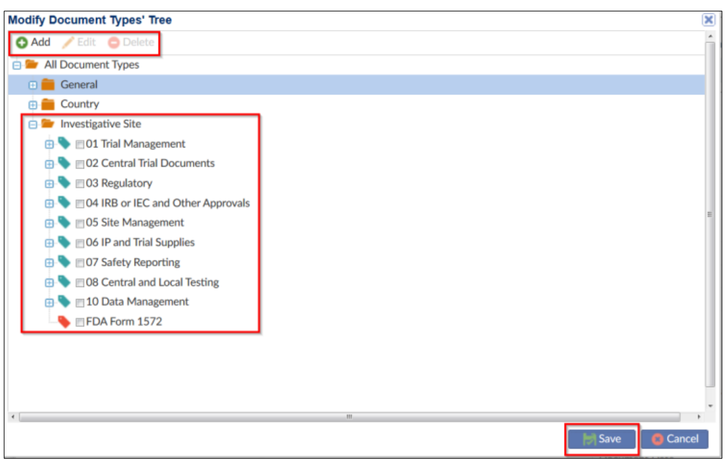
1. Navigate to **Username Dropdown -> Settings**
2. Select **Document Types** from the menu on the left.
3. The **Document Types** option expands to reveal two sub-options, the **Document Types Management a**nd the **Common Configuration**. Click and view each panel separately.

17.1. Document Types Management

Super Administrator users have the ability to turn On and Off Administrator access to Document Types Management Settings. This tab may not be available in your data room. The **Document Types Management** tab, if enabled for Administrator users, allows access to the auto-naming rules and to linking metadata fields to document types, enabling conditional metadata. Auto-naming settings are complex, and it is preferred that Administrators work with the Trial Interactive team to make any changes to these rules.

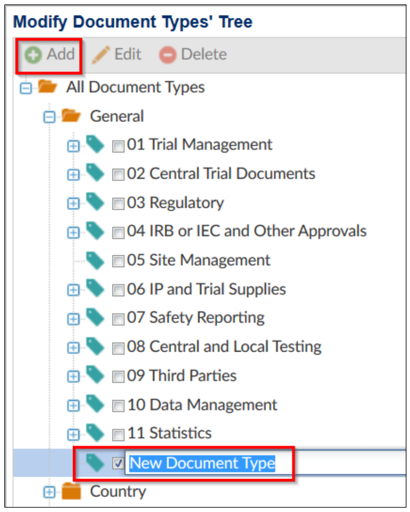


1. Clicking **Document Types Management** opens its dashboard on the right.
2. Click **Modify Document Types** option from the ribbon above the dashboard.
3. A new **Modify Document Types' Tree** window opens, displaying the folder structure of Document Types in a tree view. Document Types can be added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



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

b. Click the **Add** button near the top of the window, or right-click the folder where you want to add the new document type, or right-click the document type under which you want to add a sub-type.



A new line appears with an editable field that reads **New Document Type**.

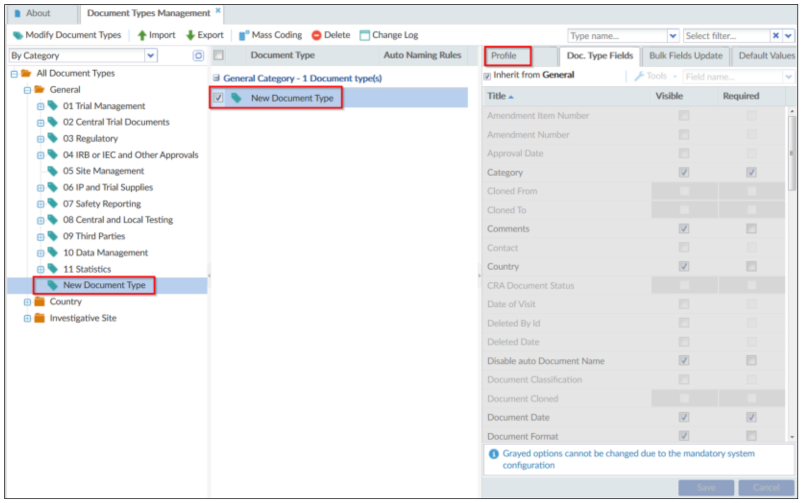
c. Type the name of the new document type to be added to the category folder.

d. Press the **Enter** key.

If you have more document types to add to this or other categories, you can repeat this process.

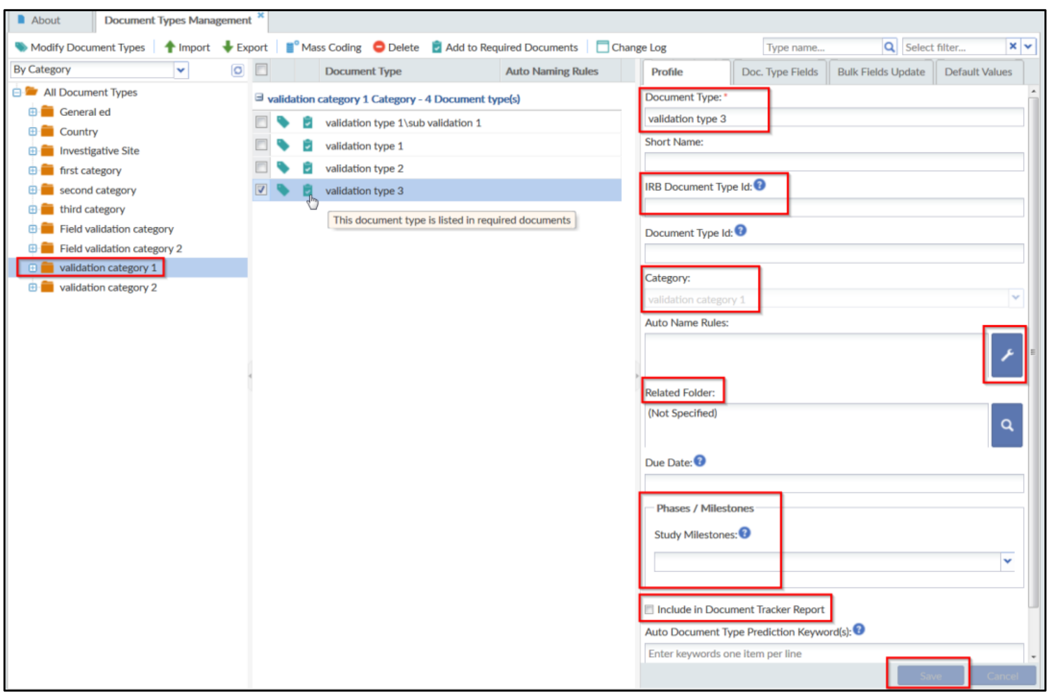
e. When you have added all of the necessary new document types, click **Save** at the bottom of the window.

That window closes and you return to the primary **Document Types** view. The document types that you have just created has not been routed to a proper index position.



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

17.1.1. Building the Document Type Profile



1. Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.

2. In the **Profile** tab, type in the **Short Name** for the document type.

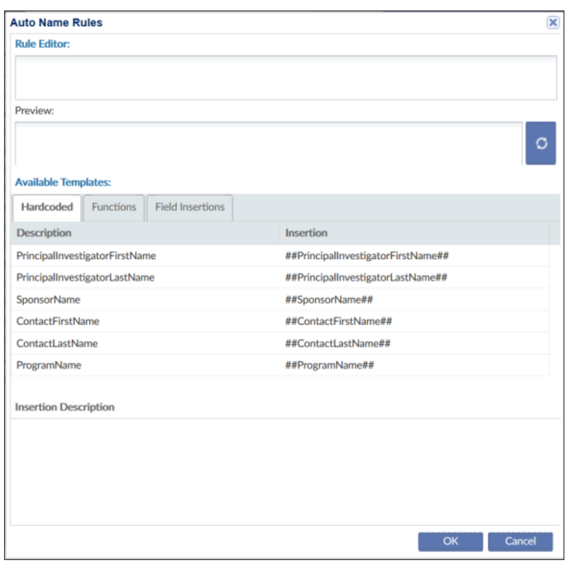
   This can be the same as the **Document Type** name that you created in the previous steps, or it can be abbreviated if the original name is long.

3. The **IRB Document Type ID** is one of the fields besides Site ID and IRB Number that is required by the system for [IRB Integration](). This field will be available only if IRB Integration is enabled in the room.

   This field can accept multiple values separated by semi-colon and should be unique within the document type category.

4. The **Category** has already been assigned by your first steps of creating the new document type, so this field is not enabled.

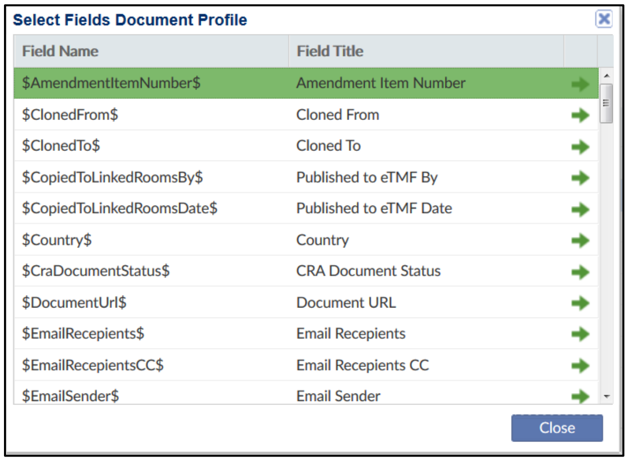
5. Click the wrench icon next to the **Auto Name Rules** field. When the metadata gets filled out for documents of this type, the auto naming rules you set up here will be applied to these documents. The client typically supplies a file with prescribed document types and the auto naming rules that they want assigned to the document types. An **Auto Name Rules** window opens.



   The following set of instructions describes the insertion of a standard set of fields for auto naming of documents of a particular type. For this example, the proposed naming rules include the study Principal Investigator's first and last name, and Sponsor Name.

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

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

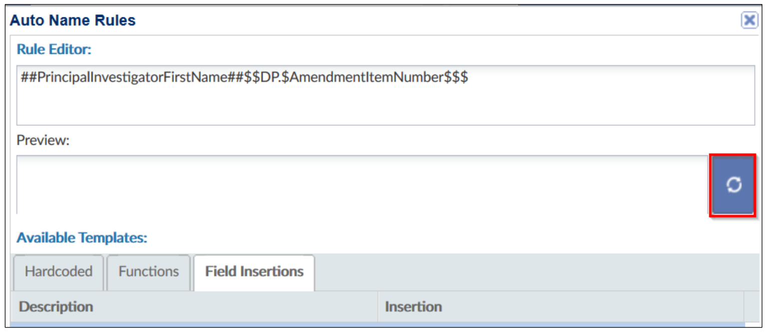


c. Click **Close** when you have included all of the necessary fields.

The fields stored under the Hardcoded tab are fields typically used in building auto naming patterns. To include these, insert your cursor in the spot in the Rule Editor where you want this field to appear, then double-click the Description of the field and it will be inserted into the naming pattern.

d. Back in the **Auto Name Rules** window, click the white arrows icon to the right of the **Preview** box. Refer to the screenshot below.

The box populates with a generic preview of the selected Auto Naming pattern.



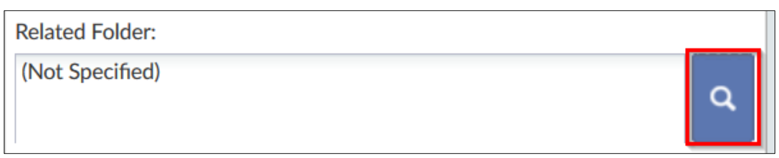
e. Click **OK** at the bottom of the window.

   You return to the main **Document Types** view.

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

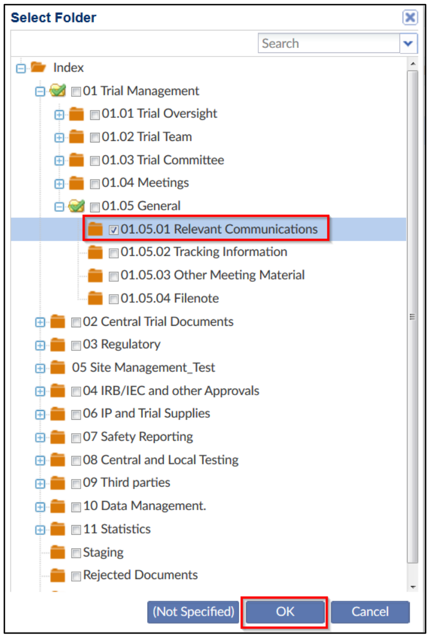
17.1.2. Specifying the Related Folder

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.

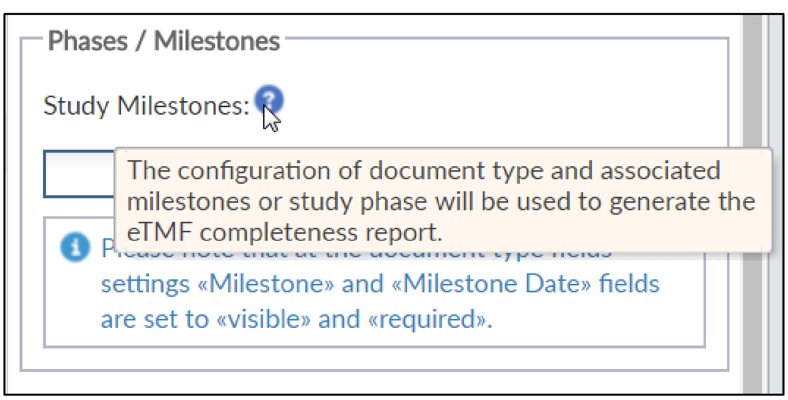


In this example, we have chosen the **Relevant Communications** folder.

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.

17.1.3. Include Phases/Milestones

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



From the list of milestones that appear, select the milestones that are applicable to the current document type. These milestones when added to the document types, help to track the eTMF Completeness of documents associated with them and generate eTMF Completeness Reports.

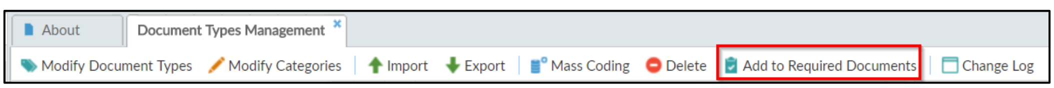
Besides the above, a document type can also be added to a milestone by either of the following ways:

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

17.1.4. Adding Document Types to Required Documents

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

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



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

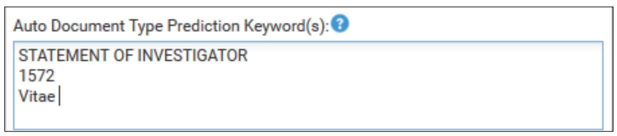
17.1.5. Include in Document Tracker Report

To specify that any Document Type will specifically be included in the Document Tracker Report, click the **Include in Document Tracker Report** checkbox. After making any changes, be sure to click **Save** at the bottom of the window.

17.1.6. Auto Document Type Prediction Keyword(s)

Out of the hundreds of potential document types that might be present in a study, many of those document types might be auto predicted. For example, Curriculum Vitae, the 1572 form, a financial disclosure form – practically any required regulatory pack document or any document for which a sponsor has a template to send to investigators. A Super Administrator user needs to activate this option in the room. When this feature is activated and a document is uploaded, it goes into a queue, and the system searches the first page of each document for the keywords entered for all of the document types for which keyword identifiers have been entered.

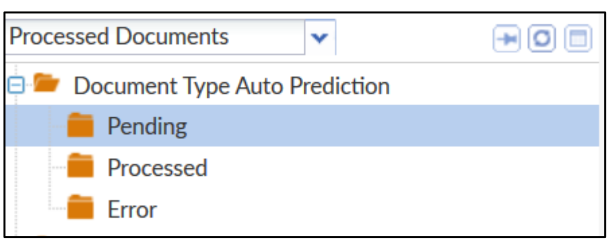
1. Open the Profile for the document type for which you want to add the Prediction Keywords in the Document Types Management settings.
2. Type Keywords into the field, one keyword per line.



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

Processed doc view -> doc type auto prediction

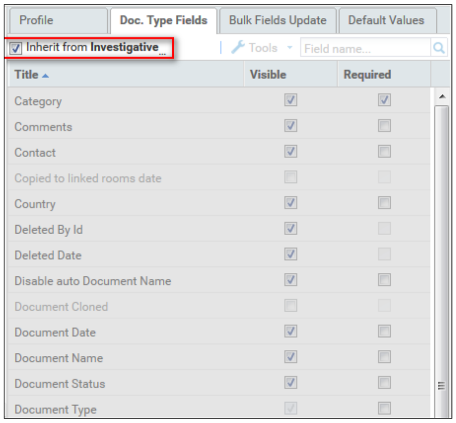
The documents uploaded and waiting for document type auto prediction can be viewed from the **Processed documents view** in the index pane under the **Pending** sub-folder. You can also view the documents whose document types have been successfully predicted under the **Processed** sub-folder whereas those which could not be successfully processed can be viewed under the **Error** sub-folder. Refer to the screenshot below:



17.1.7. Modifying Document Type Fields

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

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



2. Uncheck the **Inherit from {Category Name}** box at the top of the pane to break the inheritance.

   The pane becomes active, no longer grey in appearance.

3. Click the boxes in the columns marked **Visible** and **Required** as dictated by the client request.

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

1. ***Click Tools.***
2. ***Select Clone Fields from.***

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

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

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

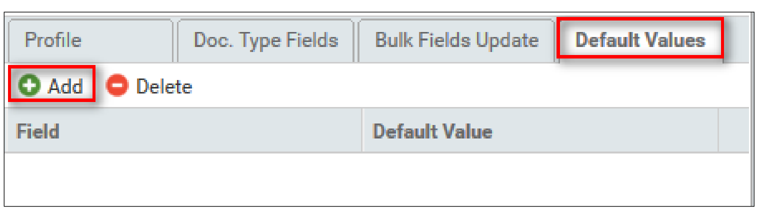
17.1.8. Default Values

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

1. In order to use this new options, you must first create a custom metadata field in [Form Settings.]() You must be sure to include the custom field in **Coding** before you save the final changes.
2. Select the specific document type to which you want to add the field that will auto-populate with the default value.
3. Click the **Metadata Fields** tab.
4. Click the necessary checkbox.
5. Click **Save**.
6. Click the **Default Values** tab.
7. Click the **Add** button.

   The **Field** textbox activates.

   Click the dropdown arrow at the right end of the box.
8. Select the necessary custom metadata field from the list.
9. Press **Tab** on your Keyboard.
10. Set the field's default value by typing the value in the textbox.

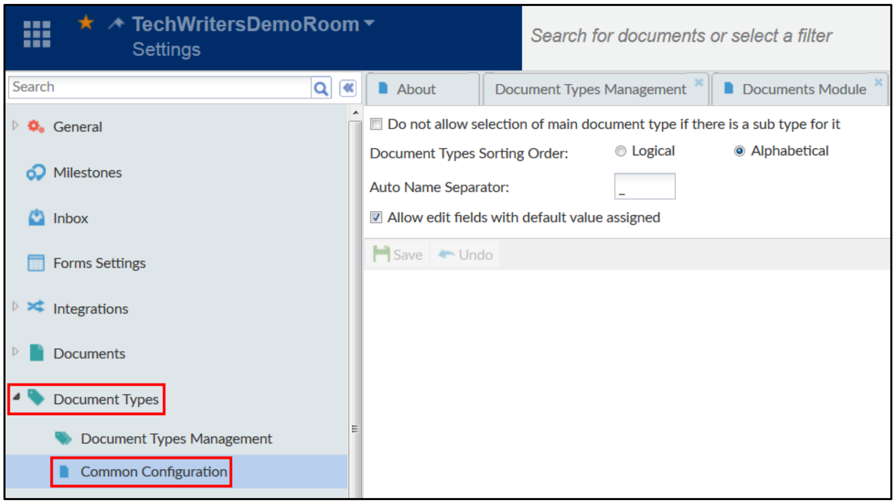


11. Click **Save.**

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

17.2. Common Configuration

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



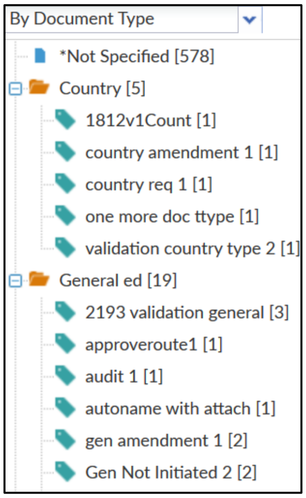
- In the **Common Configuration** panel, you can make it so that users cannot select a main document type name if one or more sub-types exist for that type.
- In this panel, you also select whether Document Types are sorted by Logical order (the order in which they were entered) or sorted alphabetically.
- 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.

17.3. Adding document types from metadata pane

The document types thus created can also be manually added from the metadata panel or in the document profile form while adding/editing a document if they are not set up for auto prediction.

17.4. By document type from index pane

All of the document types set up in a Trial Interactive room and the documents categorized under them can be viewed from the **By Document type** view in the Index pane. Refer to the screenshot below:



As shown in the screenshot above, the categories are marked by the yellow folder icons and the actual document types by the blue document icon. Besides the categories, you can specify the document type in the metadata of the document.

18. Adding documents and metadata to a room

Documents can be added to a room by several means such as:

1. Uploading documents from the Home page
2. Adding a document from the Documents module using:
    a. The Add document -> Single option on an index folder in the index pane
    b. The Document dropdown
    c. The right-click from the document grid
3. Importing documents using:
    a. The Import dropdown in the Document module
    b. The Add document -> Multiple option on an index folder in the index pane
    c. The +Create -> Add documents button
4. By emailing and faxing documents to a room
5. By dragging and dropping a document to the document grid

18.1. Add new document settings

- ***All documents added/imported to a room get populated in the Upload folder by default unless the Default index position is specified in the document settings.***
- ***Documents emailed to the room will find its way to the Communication Inbox or the eTMF Inbox as per the room settings.***

The following settings need to be enabled from the **Settings -> Documents -> Index outline** option of a room:

1. Specifying the Upload folder
2. Specifying the Inbox and eFax folder
3. Specifying the default index position for add document

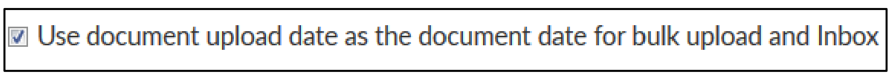
For more details on the Index Outline and other settings to add a document, proceed to chapter Index Outline and By Index view.

Following are some of the other options that need to be set up from the Settings -> Documents -> Documents Module:

18.1.1. Document Upload Date as Document Date

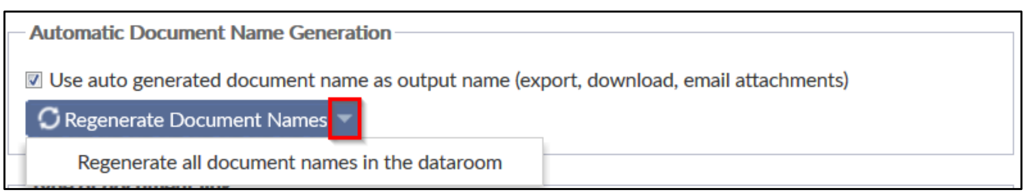
Even though it is not advised to do so, an Administrator can change the naming and dating conventions used for documents that are bulk uploaded or delivered to the room through the Inbox.

Use document upload date as the document date for bulk upload and Inbox: On ticking this checkbox and clicking **Save**, the upload date will automatically be assigned as the document date in the document profile.

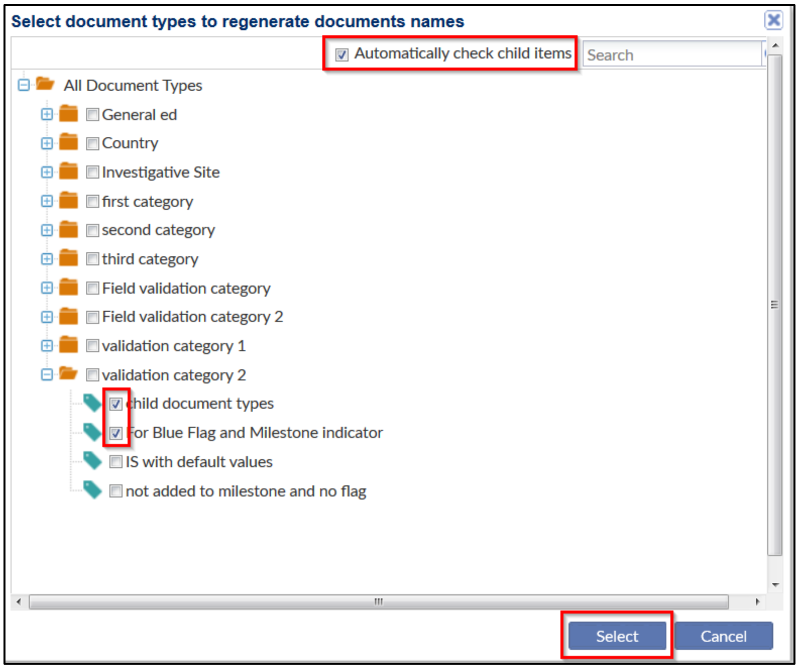


18.1.2. Automatic Document Name Generation

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



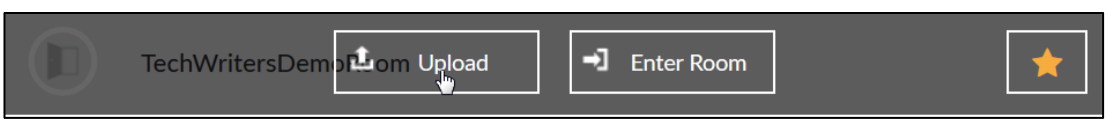
- Regenerate document names of selected document types by clicking the **Regenerate Document Names** button. This will open the **Document Types** window allowing you to select the document types and their categories for which you want to regenerate document names. Refer to the screenshot below:



- You can also choose to regenerate the document names for all the documents in the dataroom by clicking the dropdown option **Regenerate all document names in the dataroom.** Confirm the popup by clicking **Yes** to proceed further.

For either of the options mentioned above, a background job starts which then exports the document names in an .xlsx file. On receiving a notification about completion of the job, click **Job Result** to retrieve the file.

18.2. Uploading documents to a room from the Home Page



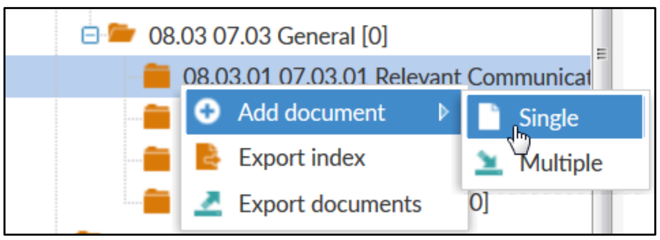
1. Navigate to the Home page.
2. Hover the mouse over the room into which you want to upload documents.
3. Click the **Upload** button to open the Windows Explorer.
4. Select the document(s) to upload and click **Open**. Alternatively, drag and drop selected documents over the grey bar.
5. This opens the **Import Documents** window.

6. Select the document type and click the **Import Documents** button at the bottom of the window.
7. The document(s) will find its way to the **Upload** folder of the room, or the folder set as default in the room settings.

18.3. Adding documents 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 document -> Single**.

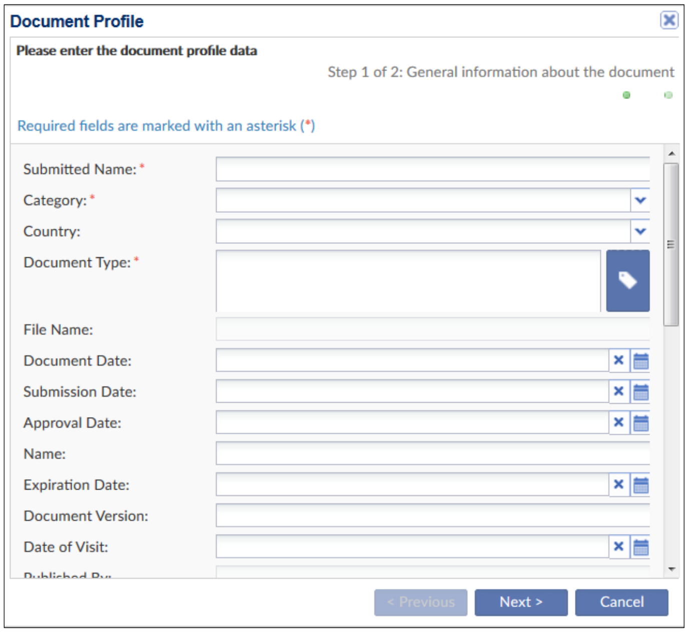


4. This will open the **Document Profile** form for you to add the details and save. This adds documents directly to the selected folder and such an added document does not appear in the default index folder or Upload folder.

18.4. Adding documents from Document Dropdown or right-click

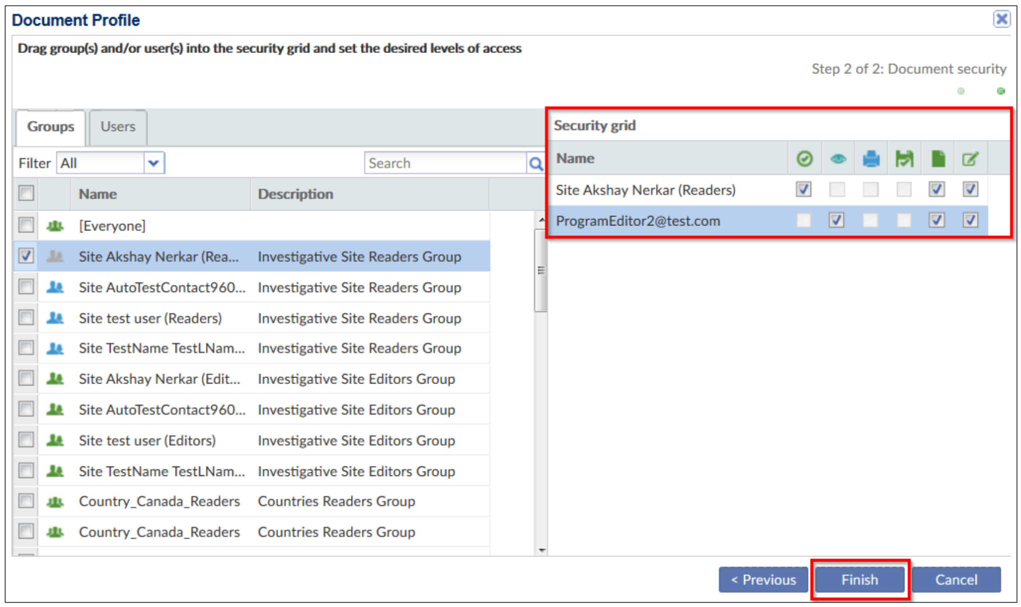
1. From the **Documents** Module, click the Document dropdown or right-click on a document in the Document Grid.

2. Select **Add** and the **Document profile** window opens. Enter the details as required to create a new Document profile.



- Select the appropriate **Category** from the dropdown list; **General**, **Country**, or **Investigative Site**.
- Depending upon the category selected, the document's **Submitted Name** field would appear or disappear. Enter the Submitted Name as required.
- Select the **Document Type**, and **Document Date.** Type in the date if that is configured for you.
- Add pertinent **Comments,** if necessary. The Index position will populate automatically, based on the folder you selected from the index.
- Click the magnifying glass icon at the right end of the **Attachment** field to attach a document, or click the dots to provide URL i.e. the link to an external document.
- Assign milestone histories from the milestone field. This is discussed in detail in Assigning Milestone histories to Documents section.

- Complete other fields as necessary and click **Next** to take you to the Document security popup. Here you can drag group(s) and/or users(s) who would access the documents into the security grid and set the desired levels of access. A detailed description of each security access is given in *Manage Security*. Refer to the screenshot below:



- Click **Finish** for the new document to take its place in the default index folder or the Upload folder as set in the room settings.

> ***You can also add/import documents by dragging and dropping them from the Windows Explorer to their relevant index folders. Upon dragging and dropping the document, the Document Profile window opens for you to code the document. The Title, Document type, and Category fields are automatically coded for you. The dragged document can be found in the Attachment/URL field of the Document Profile.***

18.5. Importing documents

You can add multiple documents at a time to the trial room by importing documents in bulk.

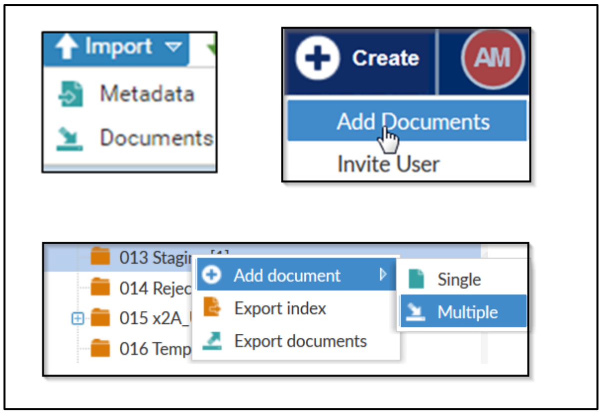
1. Log in to a TI room using one of the browsers listed above that supports HTML5.
2. Go to the **eTMF Documents** module.

3. Click the:

   a. **Import** Import button in the menu ribbon located above the display grid, or

   b. Add documents from the **+Create** button, or

   c. Right-click on an index folder in the index pane and click **Multiple**.

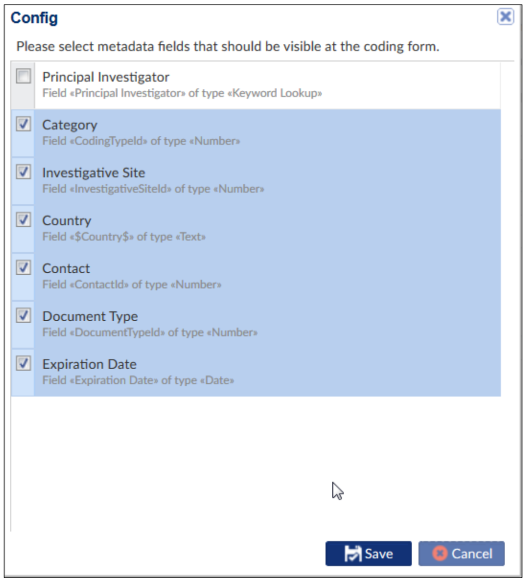


4. The **Import Documents** window opens.

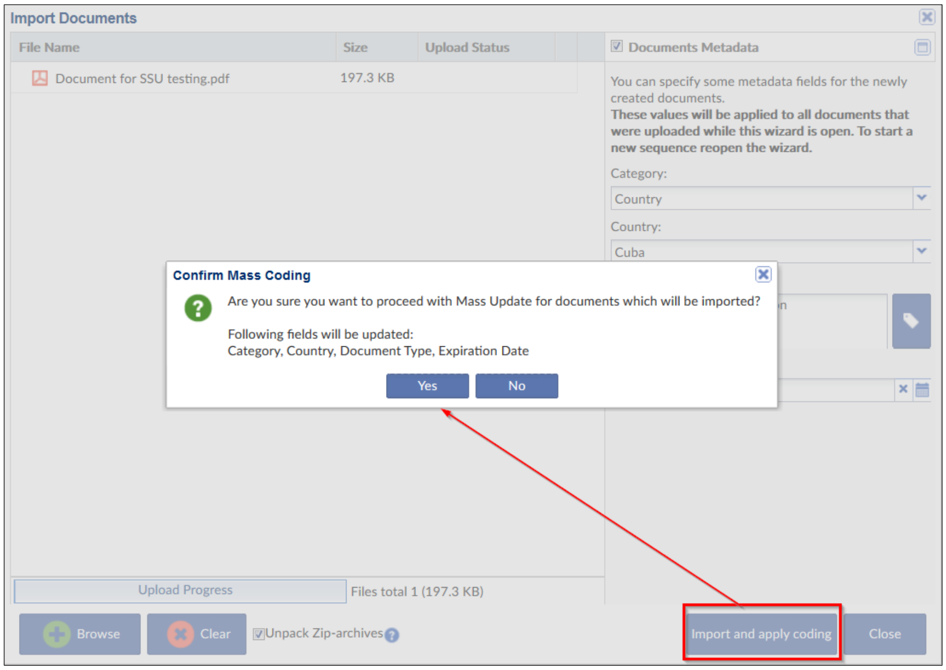
   Following the on-screen instructions, either drag-and-drop files from your own computer into the upload panel or use the **Browse** button on the window to select documents to upload.

5. After selecting documents to be uploaded, you can select the **Documents Metadata** checkbox on the right pane of the window to quickly code select metadata for these documents while the system is carrying out bulk-uploading. Therefore, if you are importing documents that are from the same investigative sites, are related to particular contact person, or belong to same document type, you can assign those at one go. This is also [Mass Coding]() while importing documents.

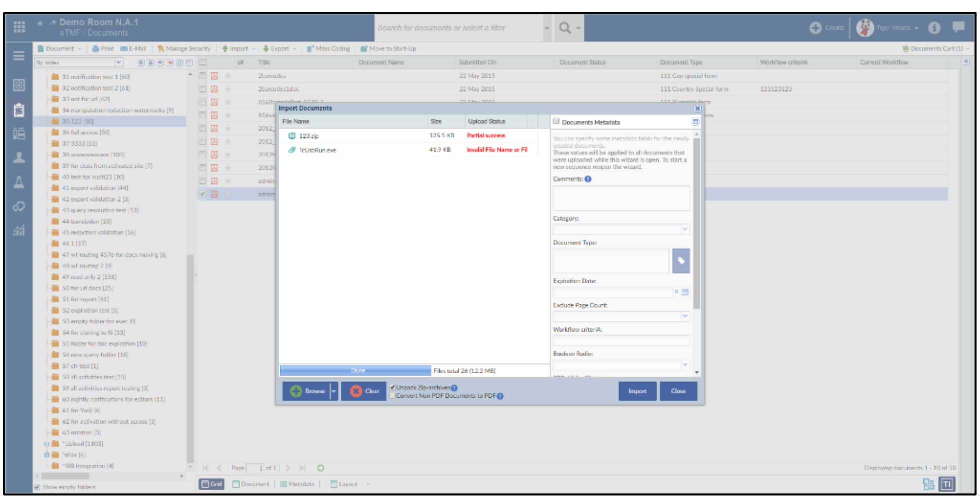
6. Click the **Config** button at the right hand top corner to open the **Config** window. Through this window, you can decide the fields to be included in the metadata of the documents.



7. While the documents are uploading, the user can monitor the Upload Status column in the display panel and view the progress of the upload in the progress bar at the bottom of the window. When the upload is complete, each document will display an **Upload Status** and the progress bar at the bottom of the window will read **Done**.
8. If you have specified the **Documents metadata** then click **Import and Apply coding,** and **close** button placed on the bottom right corner. A confirm Mass Coding message will pop-up. Click **Yes** to confirm.



9. If you have not specified anything on **Documents Metadata**, then after the upload is finished, simply click the **Import** for the process to begin.
10. The **Import** functionality will not allow the import of erroneous files. During import of several files, the files that were uploaded successfully will be removed from the list of files in the Import Document dialog box, but some documents will remain in the grid due to some errors while uploading. The user can try to import the left out documents again. This will not re-import the already uploaded documents but will try to import the documents remaining in the grid only. Refer to the screenshot below:



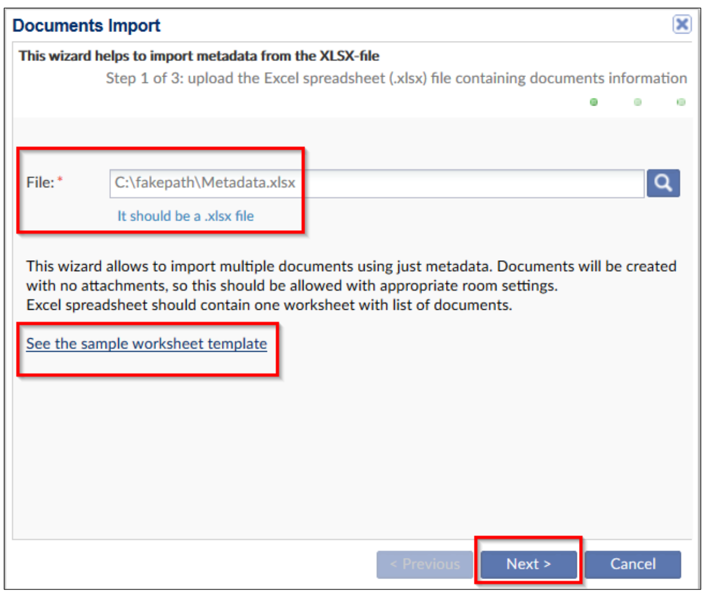
11. Once importing documents is over, click the **Close** button in the bottom right corner of the **Import Documents** window.

    The uploaded documents can then be found in the user's **Upload** folder in the folder index or the default index folder as specified in your room settings.

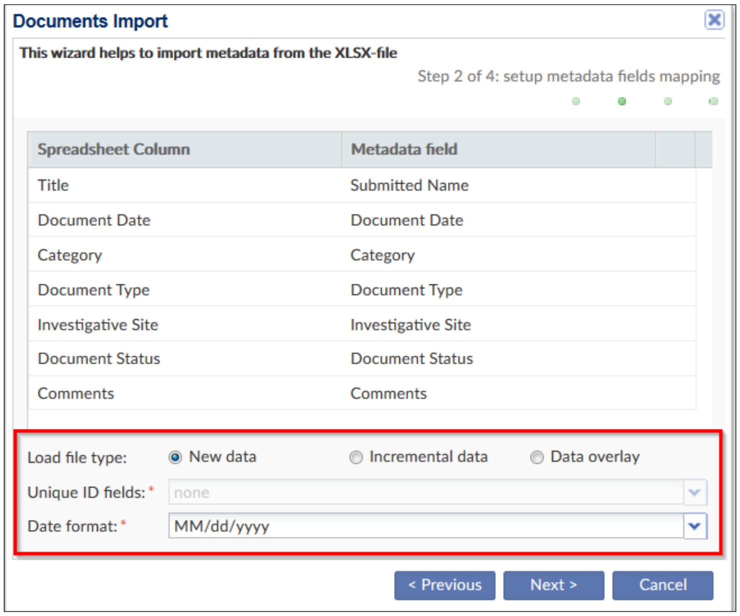
18.6. Importing metadata

To import document metadata:

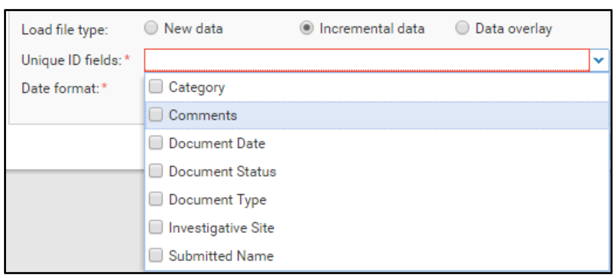
1. Select **Metadata** from the **Import** dropdown. The **Documents import** window opens.
2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import multiple documents using just metadata. The wizard offers a link to the sample worksheet so user can download it and fill with actual data. Click **Next.**



3. Setup the mapping between metadata fields and uploaded file columns. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.**



4. You may choose **incremental data** or **data overlay** options for import of metadata. Here, you will need to mention the **Unique ID fields** for incremental import or data overlay. Click **Next.**



5. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.
6. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.

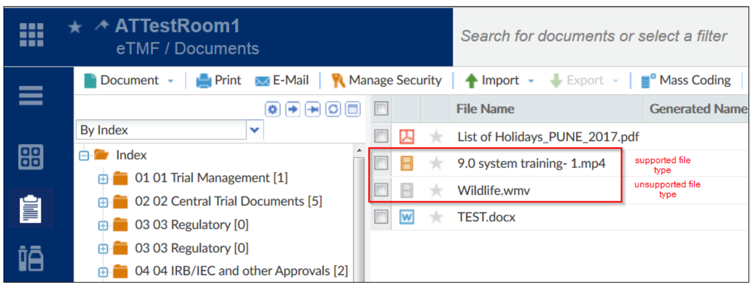
18.7. Uploading videos

Trial Interactive supports the following types of video files as attachments to documents in the below mentioned browsers:

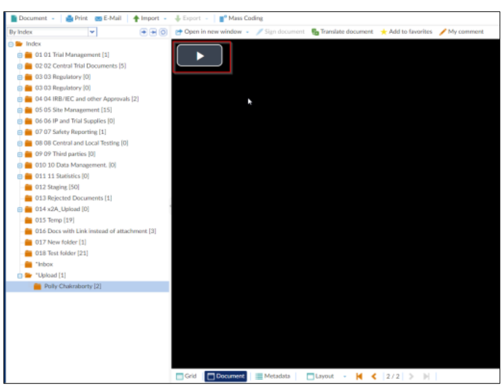
Browser Name	File Type

Browser Name	File Type
Internet Explorer	.mp4
Chrome	.mp4, .webm, .ogg
Firefox	.mp4, .webm, .ogg
Safari	.mp4
Opera	.mp4 (from Opera 25), .webm, .ogg

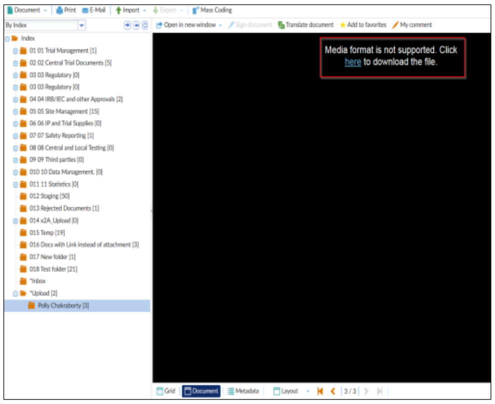
On uploading, a supported video file appears in the grid with a brown icon next to it; whereas an unsupported video file appears in the grid with a grey icon next to it.



To play a video file, select the document in the grid and click the **Document** tab at the bottom of the grid, or simply double-click it. The document opens in the viewer with the **Play Video** button on it.



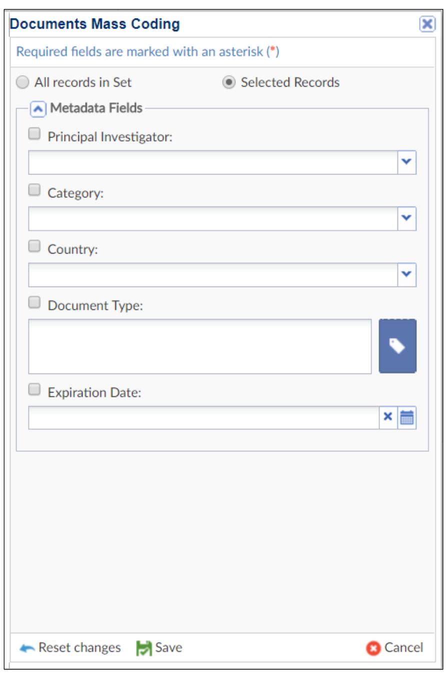
It is possible to start/pause the video, control the sound, seek through the timeline, and switch to full screen mode or back. Unsupported video files open in the viewer with the message **Media format is not supported. Click here to download the file.**



18.8. Emailing documents to room

This is discussed in detail in Communications Inbox.

18.9. Mass coding for Documents



To mass code documents:

1. Select the documents to be coded in your document grid.

2. Click the **Mass Coding** Mass Coding option from the top ribbon bar and the **Documents Mass Coding** window opens. You can also mass code while importing documents in bulk. This is already discussed in the **Importing documents** section.
3. Make your **Source** selection by clicking the appropriate radio button at the top of the window, either everything in set of records on the document grid or only the selected records from the grid.
4. Click the dropdown arrow.
5. Select the values appropriate for the mass coding operation.
6. Click the **Save** icon at the bottom of the window.

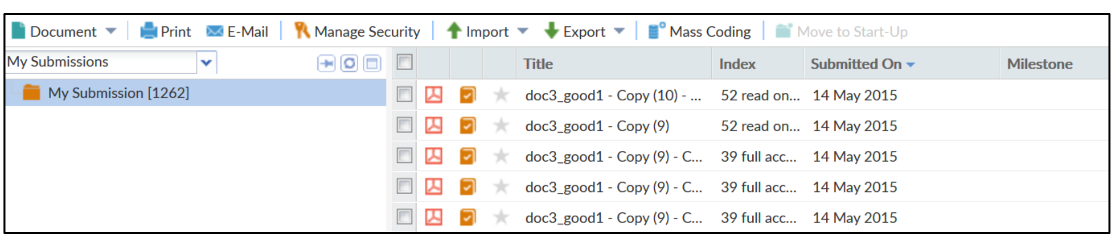
   The documents that you have selected for the operation will be coded according to your choices.

> ***You can also mass code documents while importing them. Follow to [Importing documents](#) for further details on this.***

18.10. Views for added documents

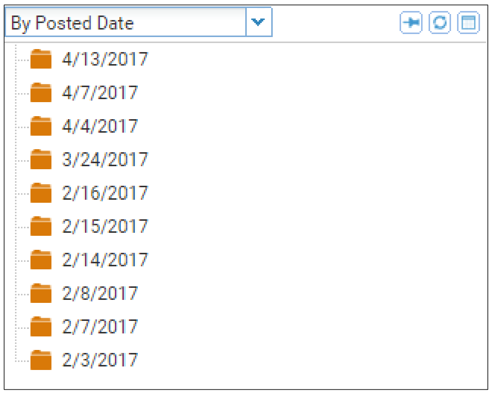
18.10.1. My Submissions

All the documents that the user imports, emails or adds into the room are populated in the **My Submissions** folder. The documents can be imported through **Import** icon on the top ribbon bar.



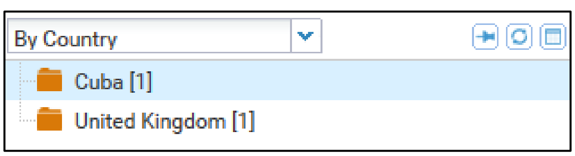
18.10.2. By Posted Date

In the **By Posted Date** view, the documents are grouped as per the days they were posted/imported/added. Folders by posted dates are created. Clicking each folder displays the documents for the particular posted date.



18.10.3. By country

In the **By Country** view, the documents pertaining to studies in each country are listed. Folder by the names of countries are created with each folder having the documents associated with it.

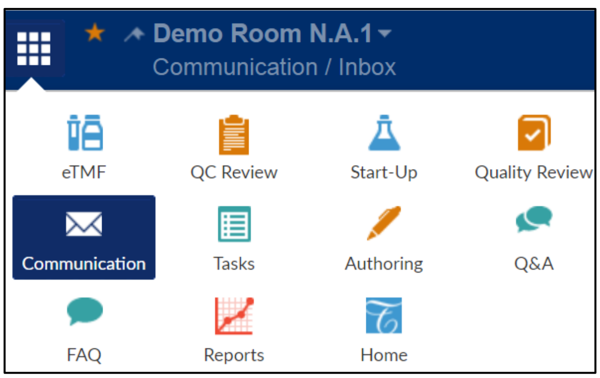


19. Communications

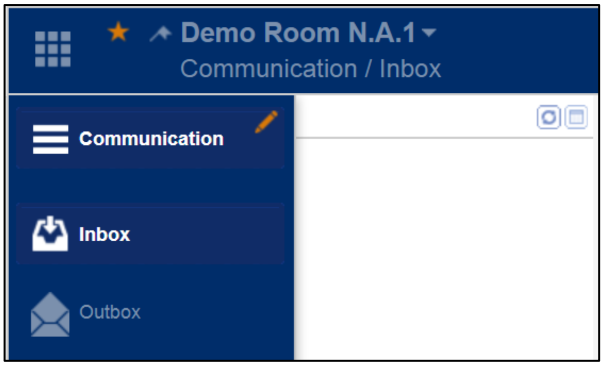
The **Outbox** module in TI 9.1 is now renamed to **Communications** module in TI 9.2. The **Communications** module was introduced to cater to issues related to managing of emails in the Outlook mailbox that required teams with dedicated people to sift through the mailbox, pick out relevant mails, download them, convert them to PDF and then file them to the TMF.

The **Communications** module looks to automatize the manual process of managing emails and thereby reduce unnecessary workload. It incorporates the features of both the Inbox and the Outbox and comes with two views – **Outbox** and **Inbox**. You will have access to this module if it is activated for you.

You can access it from the **Navigations Grid** by clicking the **Communication** icon. Refer to the screenshot below:



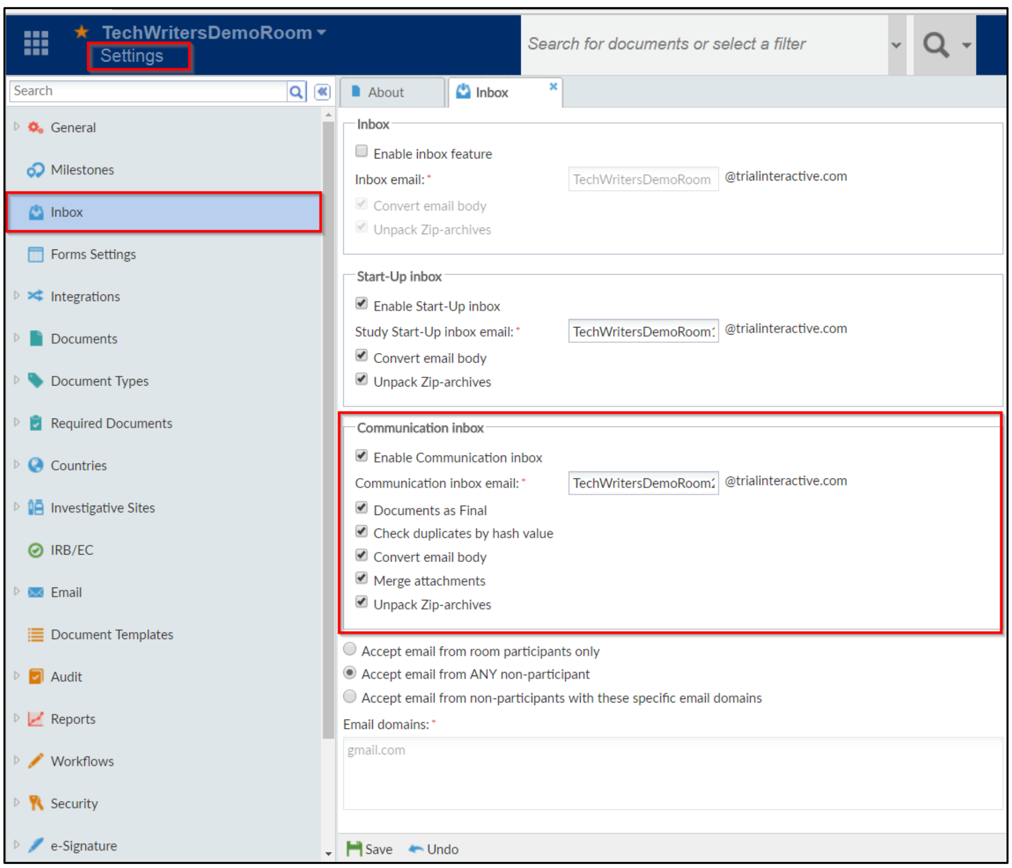
Once you enter the **Communications** Dashboard, you will have access to both the **Inbox** and the **Outbox** from the toggling menu located at the extreme left of the dashboard. Refer to the screenshot below:



19.1. The Communications Inbox

19.1.1. The Inbox Settings

To enable the Communications Inbox feature, navigate to **Username dropdown -> Settings -> Communication Inbox**. Refer to the screenshot below.



Typically, the **Inbox** feature is enabled, making it possible for room participants to send trial documents directly to the room's inbox. Here, the Administrator has the ability to disable the inbox feature or to allow non-participants in the room to send documents to the room's inbox.

To enable the **Communications Inbox**, tick the checkbox next to it. If you choose to file email converted documents to the eTMF as Final, tick the checkbox **Documents as Final** next to it. Similarly, to prevent duplicate publishing of email converted documents to the room activate the **Check duplicates by hash value**. Ticking the **Convert email body** will automatically convert the emails that enter the Inbox into PDFs and **Merge attachments** will merge them into one document. Choose **Unpack Zip-archives** to extract files from an attached zip folder.

To commit the changes, click **Save**.

19.1.2. The Process

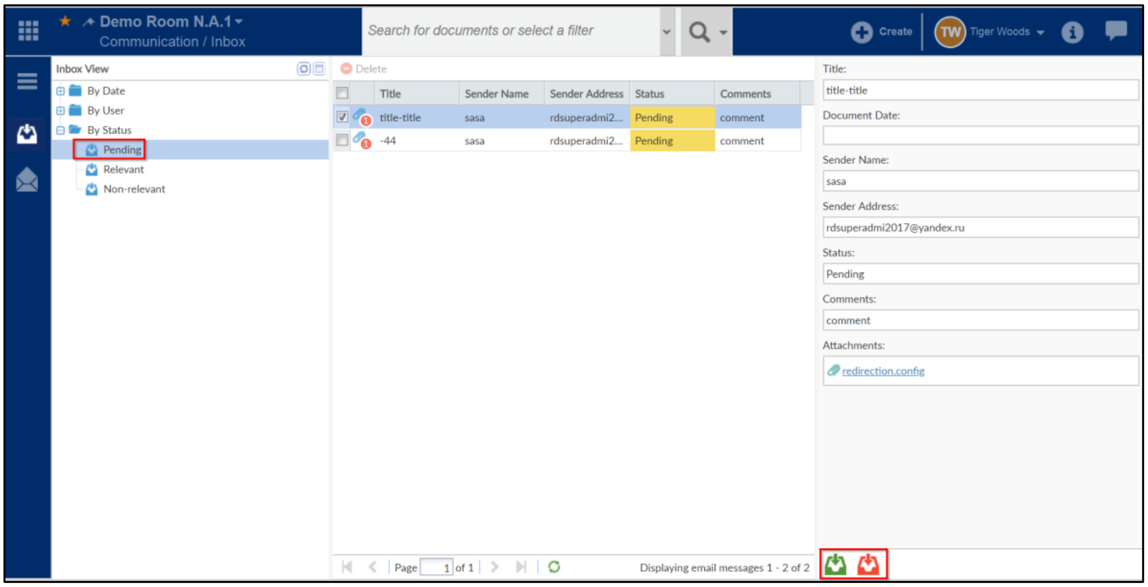
1. After enabling the feature from the Settings -> Inbox module, all the emails sent to the Communications Inbox are deposited here whereas emails sent to the eTMF inbox proceed as before.
2. Depending on the settings of the **Communications Inbox**, the email processing service converts the email into a PDF file; the Subject and date of the email are used to form the **Submitted Name** of the file.

The settings that needs to be activated to convert an email to PDF is Convert email body.

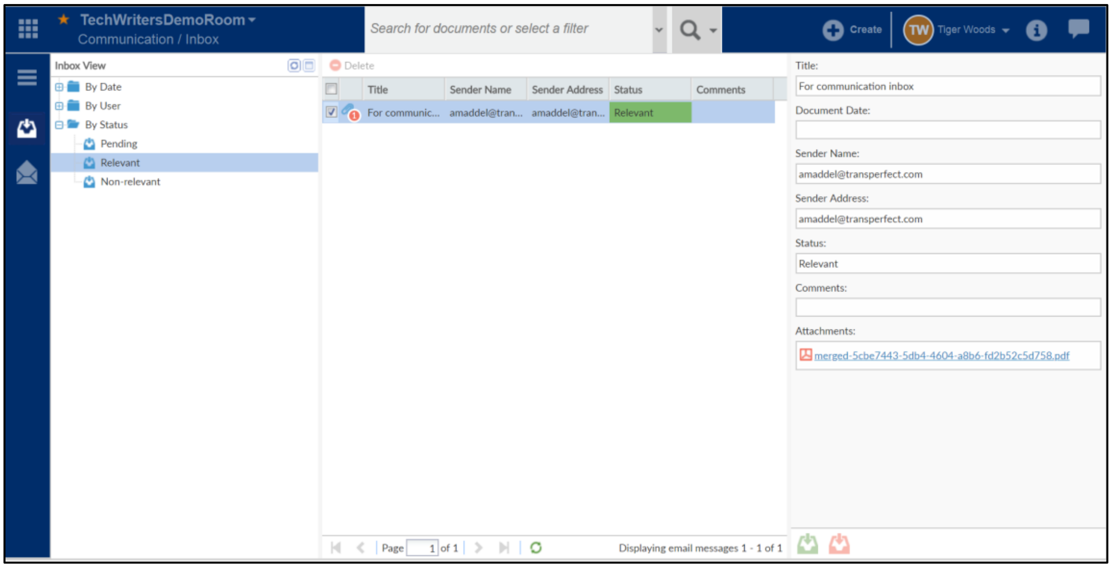
3. If there are any attachments to the email. They are also converted into PDF files (based on room settings) and automatically linked to the email PDF.

The settings that needs to be activated to link attachments to the email PDF is Merge attachments.

4. Any attachment that cannot be rendered into PDF is left in its original format.
5. The email PDF file, along with its attachment(s), if any, are stored in the **Communications Inbox** folder.
6. In the Communications Inbox, the email document is stored in **Pending** sub-folder from where the editor can mark them as **Relevant** or **Non-Relevant**. Refer to the screenshot below:



7. The documents that are marked as **Relevant** are coded by the editor in the **Document Profile** form with data such as category, document type, site and other relevant data based on the document type selection.
8. Once the editor codes the document and saves it, the document will move to the **Relevant** folder in the Inbox View. The Metadata fields are now non-editable. Refer to the screenshot below:



9. Based on the room settings, the document will be published as final or will go to the default folder and the QC Review Workflow where the reviewers will claim the documents, approve them, and file them to the eTMF.
10. The documents that are marked as **Non-Relevant** are moved to the **Non-Relevant folder** of the Communications Inbox module and can be deleted by Administrators, if required.

19.2. The Communications Outbox

Documents or messages emailed from a Trial Interactive room are stored in the **Communication Outbox.** Details on how to email is discussed in detail in section Email.

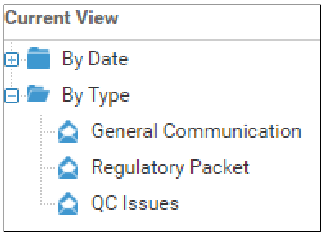
The Outbox is the former Outbox module from Trial Interactive now incorporated with the Communications module. It is the holding area of messages or emails that are sent out from a Trial Interactive room. The left pane of the **Outbox** module gives the **Current View** of the emails **By Date** and **By Type.**

19.2.1. By Type

This section provides the segregation of mails by their types:

1. General Communication

2. Regulatory Packet
3. QC Issues

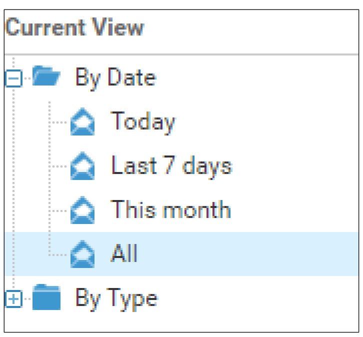


Click a type to view the mails of that type in the right pane.

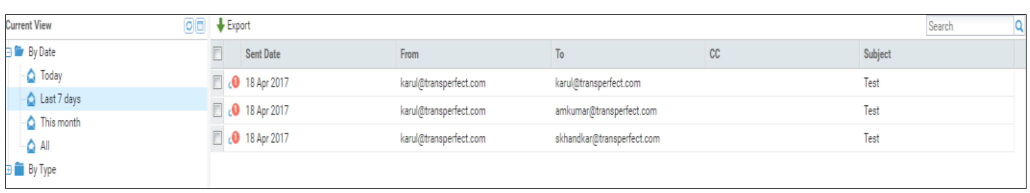
19.2.2. By Date

This section provides the segregation of mails by the period of:

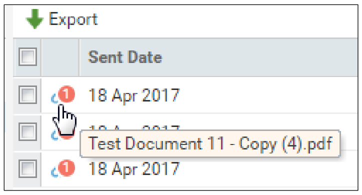
1. Today
2. Last 7 days
3. This month, and
4. All mails.



Click a period to view the communications for that period in the right pane of the dashboard. The screenshot below shows all the communication of the **Last 7 days.**

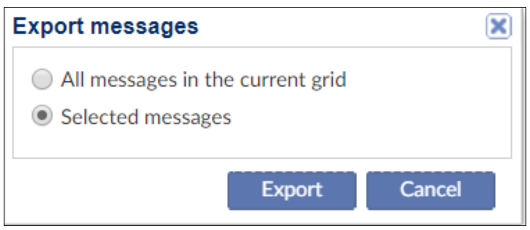


The red icon with a number next to the **Sent Date** shows the number of attachments in the mail. Hover the mouse on the icon to view the attachment name.



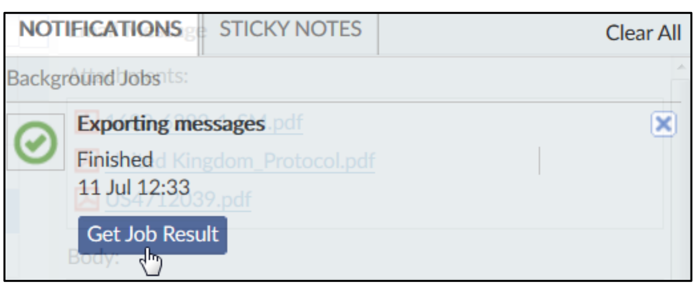
19.2.3. Export of Mails

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.



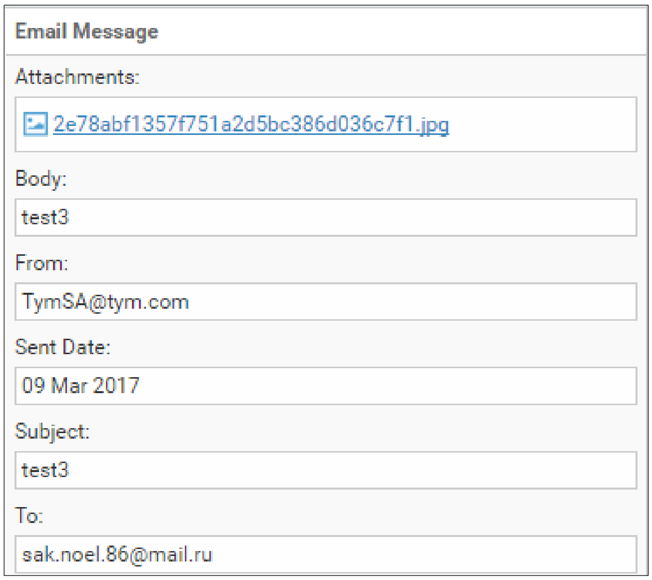
The confirmation of the export job is displayed in a popup at the bottom of the grid. Refer to the screenshot below.

You can **Get Job Result** from the **Notifications.** The export job result is saved as an .xlsx file. Refer to the screenshot below.



19.2.4. The Outbox Email Message Window

Double click a message in the grid, or check the checkbox to display the **Email Message** window at the extreme right of the dashboard. This window gives the complete metadata of a message including its body, sender, receiver, subject, sent date, and attachments. Refer to the screenshot below.



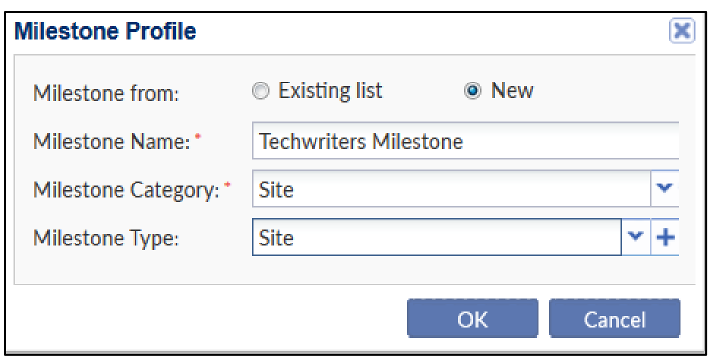
20. Milestones

Milestones is the 'objective-to-reach' for a particular study room, and this function displays the list of milestones that will be used for the current study room. Administrator users can add existing or new milestones, or edit the added milestone names. You can also choose to either enable or disable the added milestones. You can inherit milestones from the domain level settings, or add a new milestone added to the room specifically. Added milestones can also be updated on the Document Types Management section of the settings. You can also use the **Milestone** section to define the current milestone, and to track which documents are needed.

20.1. Configuring Milestones

Follow the steps as below:

1. Enter the room for which you want to set milestones.
2. Navigate to **Username dropdown -> Settings -> Milestones**.
3. The Milestones window opens with the list of milestones.
4. To add milestone, click **Add** Add on the **Milestones** window.
5. The **Milestone Profile** window opens.



6. Choose from the **Existing** list of milestones to enable that milestone for your room

   or

   Enter the milestone name to create **New** milestone.

   a. Select the category as **Study, Site, or Country**.
   b. Select the milestone type from the dropdown and click **Ok**.
   c. To select milestone type of your choice, you will need to add milestone types.

- You can create milestones type on the fly by clicking the '+' icon in the **Milestone Type** field.
- Once a milestone type is created, it will not automatically populate in the textbox. Select the milestone type from the dropdown.

7. The milestone thus created is enabled by default.
8. Similarly, you can **Edit** Edit or **Delete** Delete a milestone after selecting it from the list.

20.2. Adding Milestones to Document Types

You can add a milestone thus created to Document Types to track the eTMF Completeness of the documents associated with such document types. This is discussed in detail in Include Phases/Milestones section under Document Types Management.

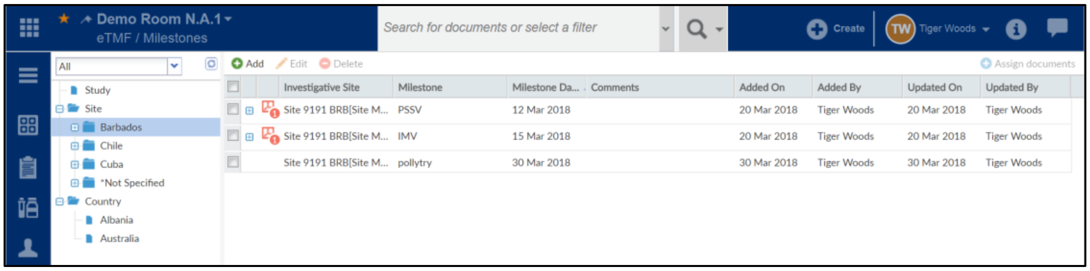
20.3. Milestones module

The administrator can monitor a milestone progress from the **Milestone module** that can be selected from the toggling menu bar.

From the Milestones module, the administrator can add milestone histories, edit or delete them.

Before starting to monitor milestone progress, administrators need to add new or existing milestones, or edit the added milestone names from the Settings -> Milestones.

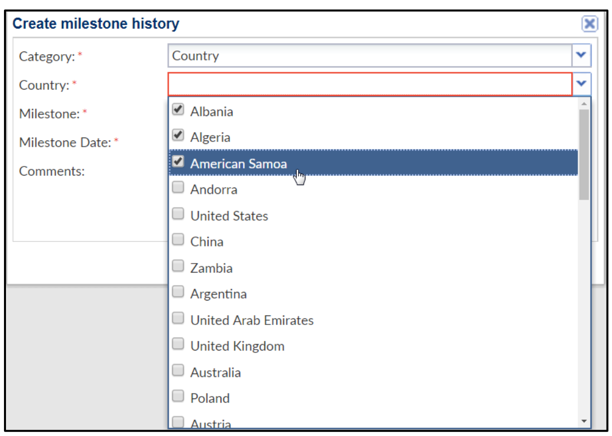
On entering the dashboard, the administrator can see the list of milestone histories, if they were created.



As milestones are applicable to multiple countries and sites, with Trial Interactive 9.2 you have the ability to add milestones to multiple countries and sites.

20.3.1. Adding Milestones to Countries

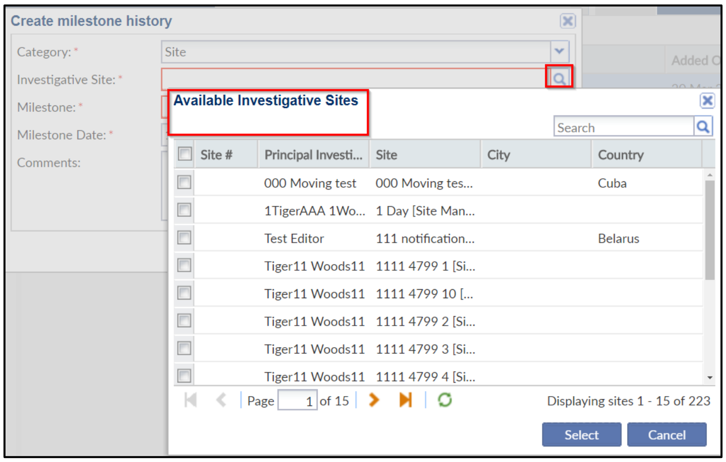
1. Click **Add** from the top menu bar in the **Milestone** module. The **Create** milestone history window opens.
2. Select the **Category** as **Country**. The **Country** dropdown appears.
3. Select all the countries to which the milestone event is applicable.



4. Select the **Milestone**.
5. You can either choose the date from the **Calendar Date Picker**, or enter the **date manually**.
6. Enter the **Comments** and click **Create** to create and add the milestone history in the grid.

20.3.2. Adding Milestones to Sites

1. Click **Add** from the top menu bar in the **Milestone** module. The **Create** milestone history window opens.
2. Select the **Category** as **Site**. The **Available Investigative Sites** window appears.
3. Select all the sites to which the milestone event is applicable.



4. Select the **Milestone**.
5. You can either choose the date from the **Calendar Date Picker**, or enter the **date manually**.
6. Enter the **Comments** and click **Create** to create and add the milestone history in the grid.

20.3.3. Adding Milestones to Studies

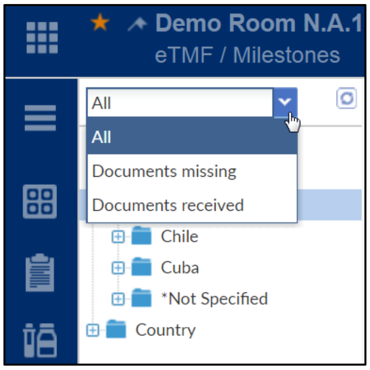
Follow the same procedure as above to add milestone events to a Study.

20.3.4. Editing and Deleting Milestones

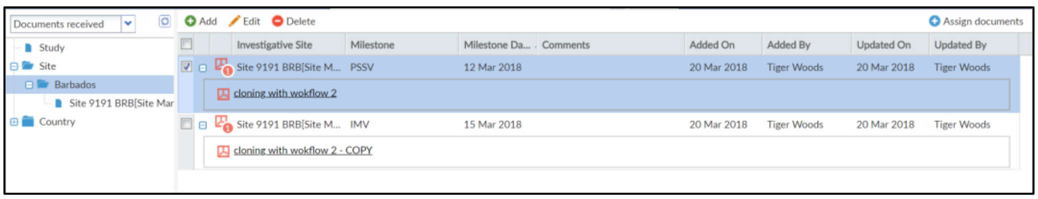
1. To edit a milestone history, click **Edit** Edit from the top ribbon bar.
2. To delete a milestone history, click **Delete** Delete from the top ribbon bar.

20.3.5. Milestone History Grid and Filters

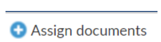
Besides categorizing milestones by the Study, Site, and Country, the milestone module also allows you to filter milestone events by **Documents Received** vs. **Documents Missing**. Refer to the screenshot below:



Select a filter of your choice to display the milestone history and its associated documents in the neighboring grid. Refer to the screenshot below:



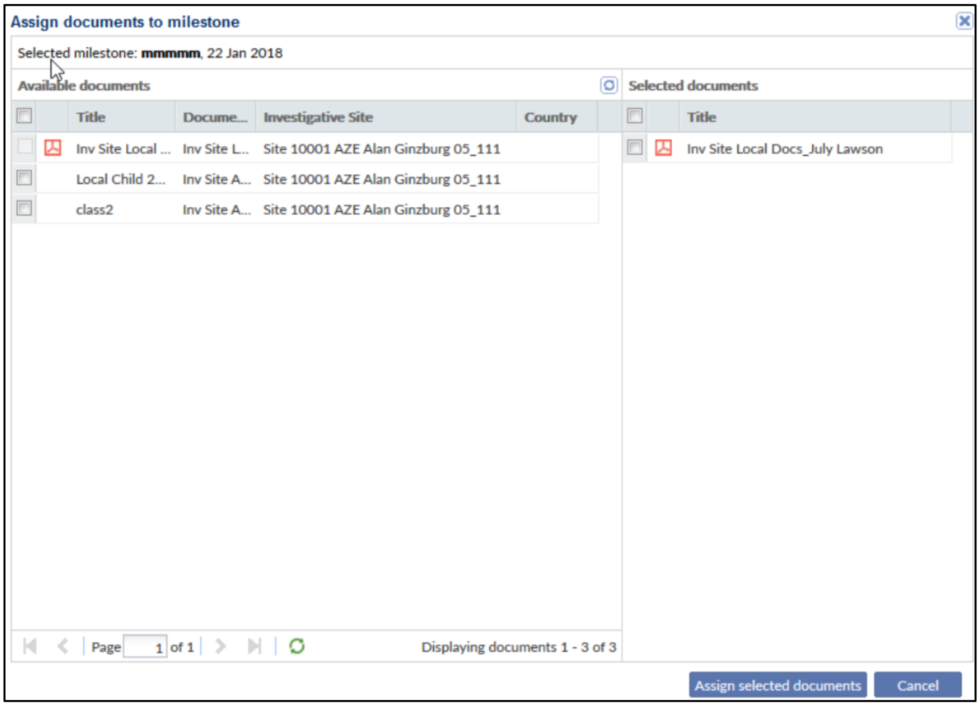
20.3.6. Assigning Milestone histories to Documents

1. You can assign documents available in the eTMF to a milestone history by clicking the **Assign documents** 

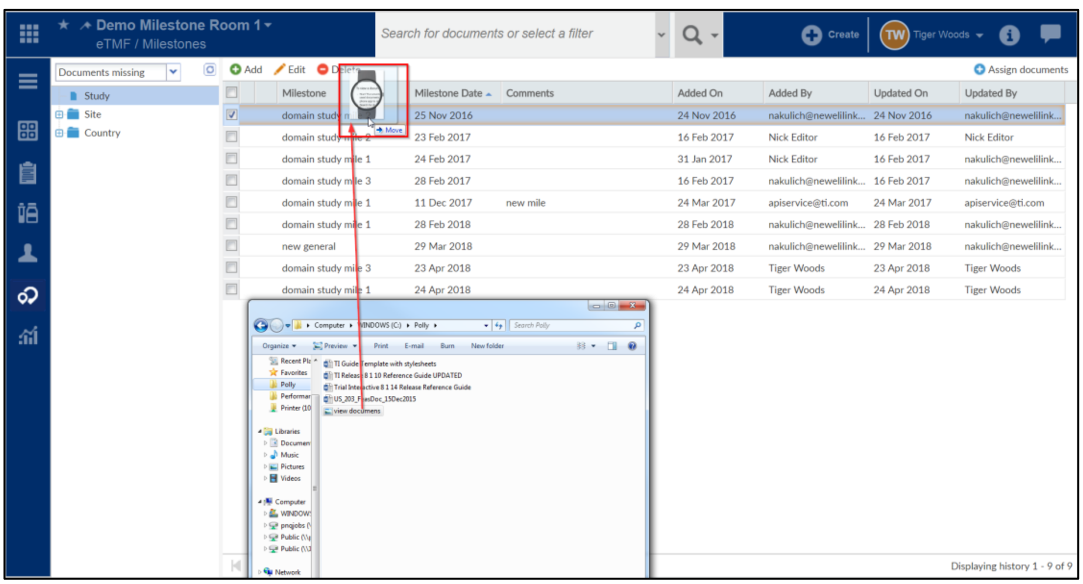
icon located at the top right corner of the grid. This opens the **Assign Documents to milestone window** for you to select and assign documents to the selected milestone event.

   Documents will appear in this window only if they have document types which are associated with milestones.

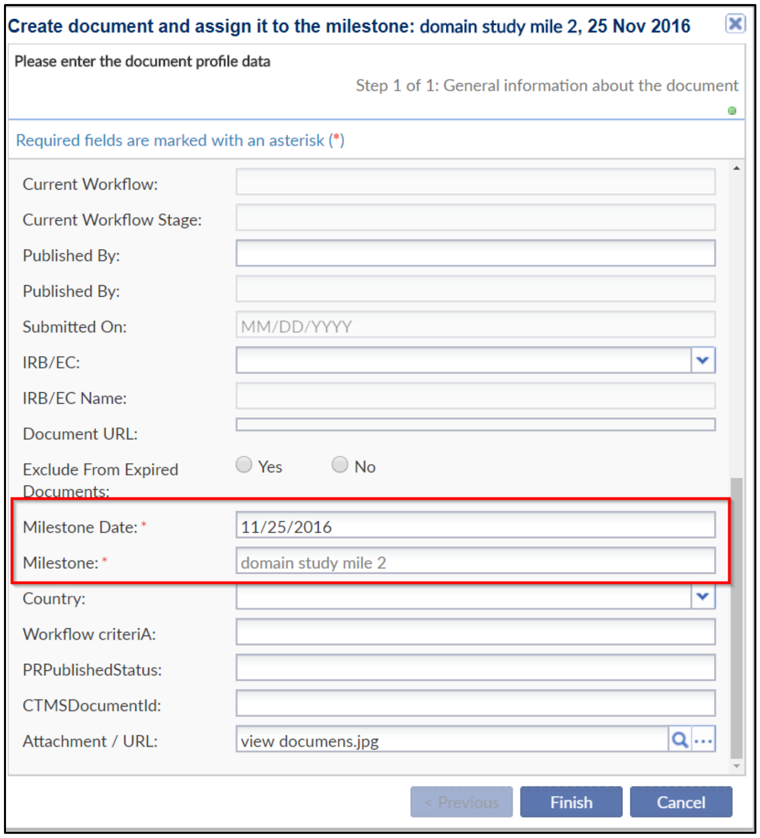
   Refer to the screenshot below:



2. You can also drag and drop a document from the Windows Explorer and assign it to a milestone history. Refer to the screenshot below:



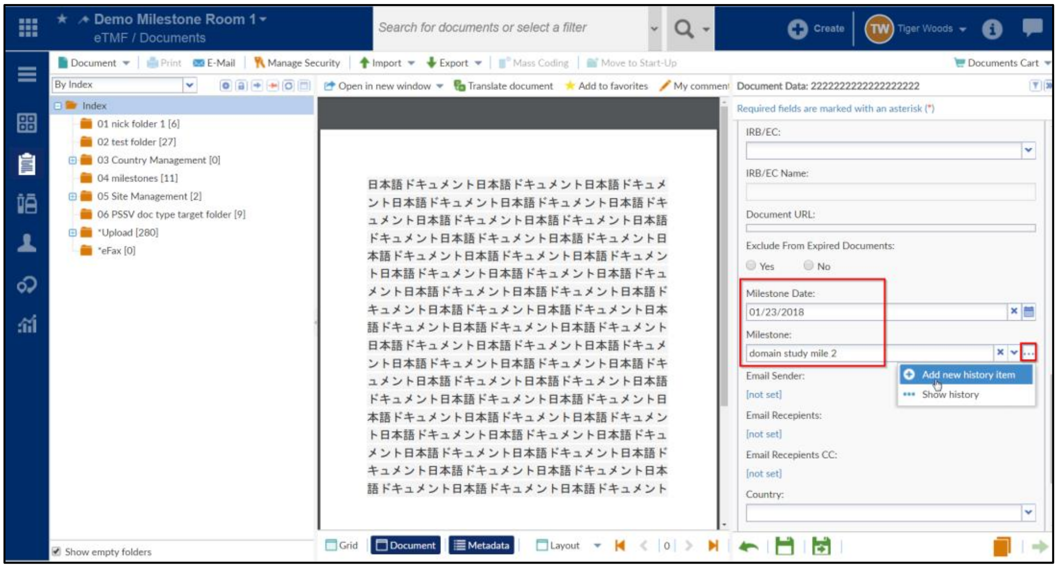
a. When you have dropped the document to the selected milestone event, the Document Profile opens in **Create and assign it to the milestone** window. Refer to the screenshot below:



b. Code the document and click **Finish** to complete the process.

c. Accept the message **Document is successfully created and assigned to the milestone**. The counter in the milestone history grid goes up by one after a successful addition.

3. To view a document associated with a milestone history in the **eTMF -> Documents** module click the document icon in the Milestone history grid to navigate you to the Documents module. Refer to the screenshot below.



a. Click the **3 dots** to **Add new milestone history** directly from the Metadata panel and assign it to the document or to **Show** the **Milestone history** and select a history from the list. Refer to the screenshot above, **or**

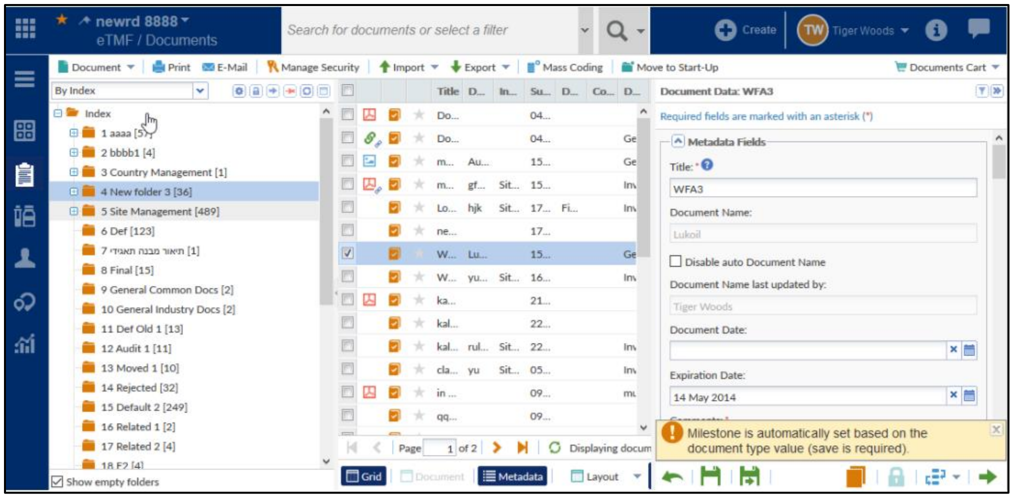
b. Click the dropdown to select from a list of other milestone histories created previously.

20.3.7. Assigning Milestone to Document Types

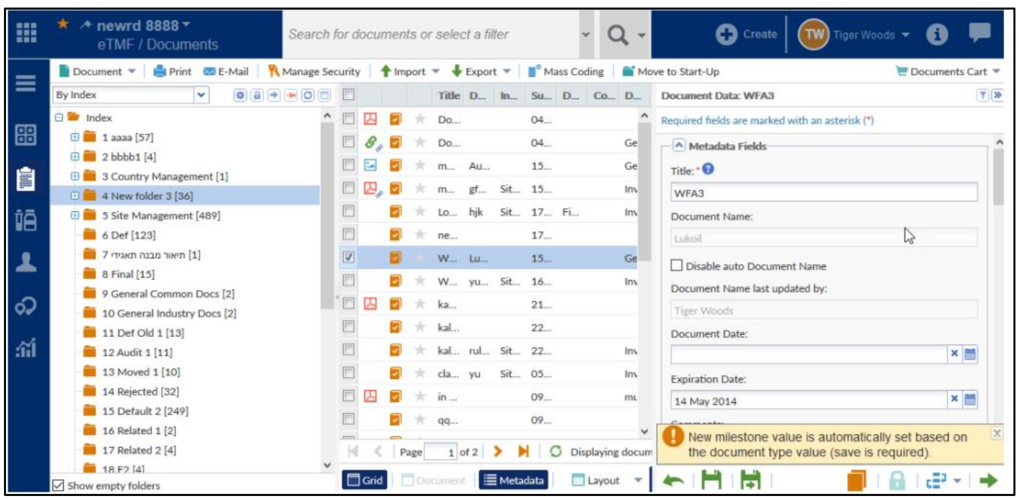
You can assign milestones to document types from the Phases/Milestones section in the Document Type Management Profile window. To enable milestone association with a document, the **Milestone** and **Milestone Date** fields are marked as **Required** and **Visible** in the Document Type Fields in Document Types Management.

20.3.8. Automatic association of document types to milestones on the Metadata panel

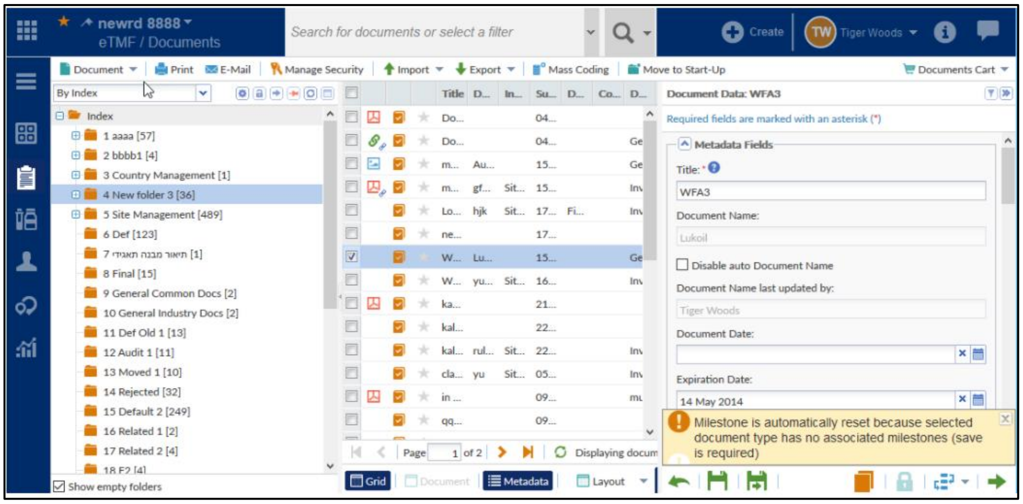
1. If, while coding a document, there exists only one milestone history, then the milestone date and record is automatically assigned to the document and appropriate message displayed accordingly.



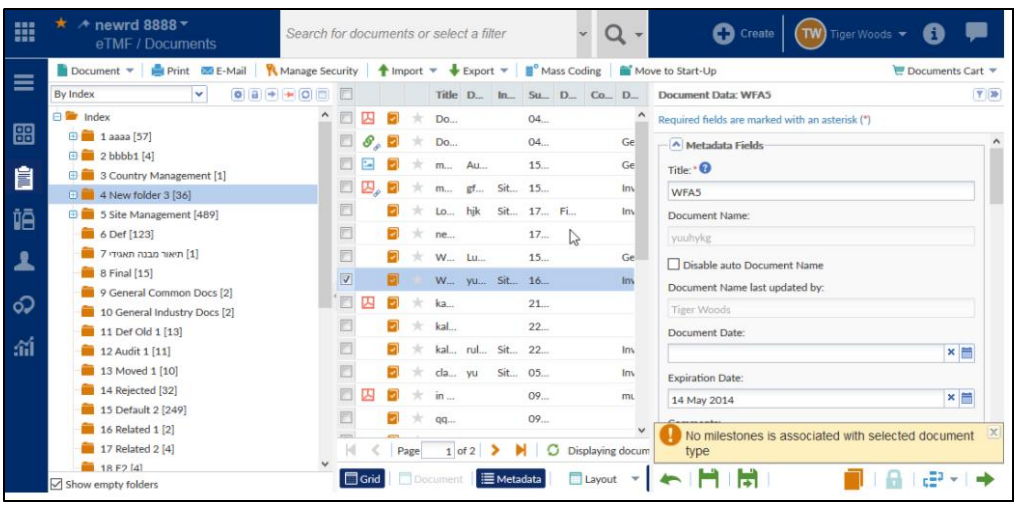
2. If, you change happen to change the document type of a document and a new milestone data is found, the system automatically updates the values and displays a message accordingly.



3. If, you change happen to change the document type of a document and no new milestone data is found, the system automatically updates the values and displays a message accordingly.



4. If a document is coded with a document type that has no milestone associated with it, then the following message is displayed.



21. QC Review and Workflow

21.1. Workflow Settings

To create a workflow, you would need to specify important details, some of which are the workflow statuses, issues in the workflow, timeline, and members of the workflow group. All these configuration details need to be previously created by the super-admin and configured to enable the administrator to add them to the workflow. This section will take you through the various configuration details. Changes made here will be applicable to all workflows.

21.1.1. Common Settings

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-colons. These values would be populated in the dropdown during workflow creation, and you may choose a value as appropriate.

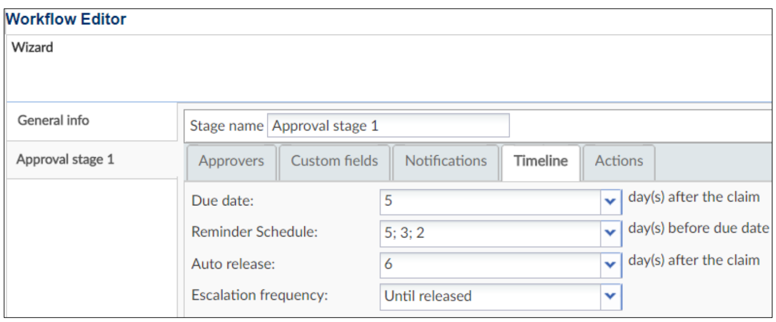
Review due date range (days): Here you specify the days when the review would be due after claiming the documents for review. You may specify multiple values, all of which will be populated in the dropdown while creating the workflow to enable you to select a value as appropriate. The **Returned Back** is a new system status that can be given to a document when it is routed back to a previous workflow stage. Hence, it is available from Approval Stage 2/QC2 onwards only.

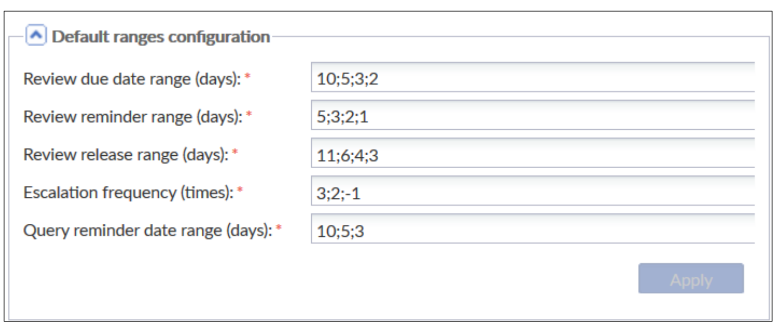
Review reminder range: Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review. If multiple values are specified, all of them would be populated in the dropdown during workflow creation, and you may select multiple values as required. In the screenshot below, the

Reminder schedule is 5;3;2 which means the reviewer will receive reminders 5 days before due date, then 3 days before due date, and then 2 days before due date if the reviews are pending.

Review release range days: Here you specify the days after the claim when the documents would be automatically released from the reviewer's claim list. The Auto release date is always greater than the due date. It will not allow you to select a value less than the due date.

Escalation frequency: Escalations are reminders about not completed reviews. During workflow creation, an escalation group needs to be specified who will receive notifications about escalations. Here, you specify the timeline for escalation notification frequency.





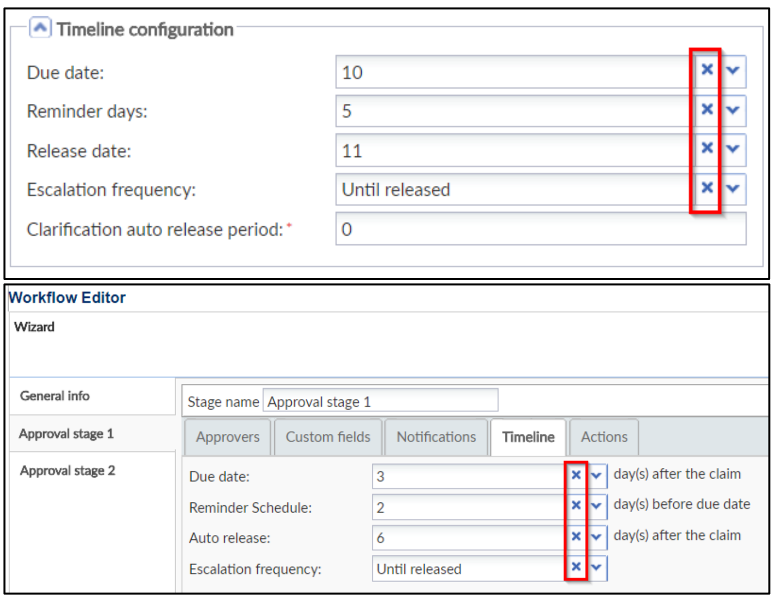
Query reminder date range

If the user does not respond to a query with a document, reminder emails are sent to the query recipients on the nth days as specified here. So if the setting is 10; 5; 3 reminders will be sent on the 10th day, 5th day, and the 3rd day.

Timeline configuration and Query reminder configuration

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**.

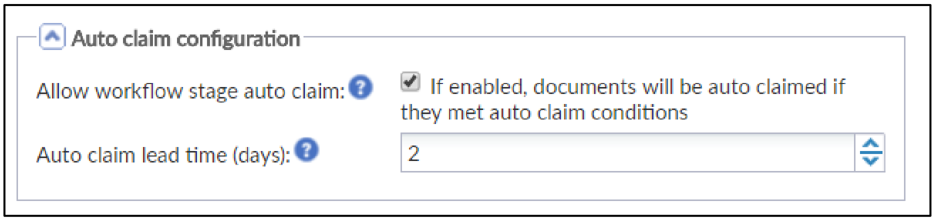


Issue email

From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session and can also choose the attachment mode to be either **Files as links** or **Files as attachments**.

Auto claim configuration

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



The Administrator should tick the checkbox for **Allow workflow stage auto claim** and set 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. In the above image, the claim time is two days.

21.1.2. **Review Status**

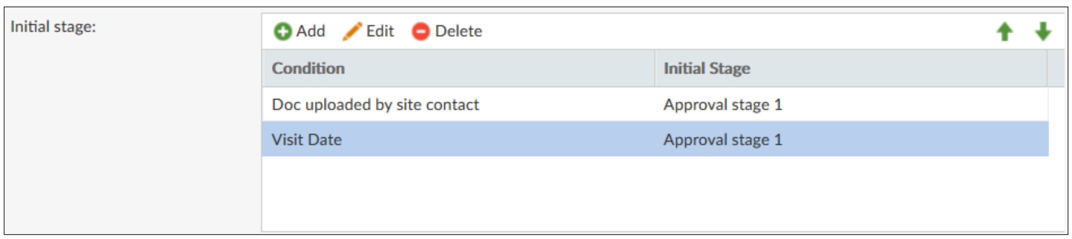
Here you create the review statuses that you would like to assign to the document at each stage of a workflow. The **Display Name** is the name of the status that would be visible on the user interface, whereas the **System Status** are pre-defined values that you assign to a review status. Regardless 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**.

21.1.3. **Document Status**

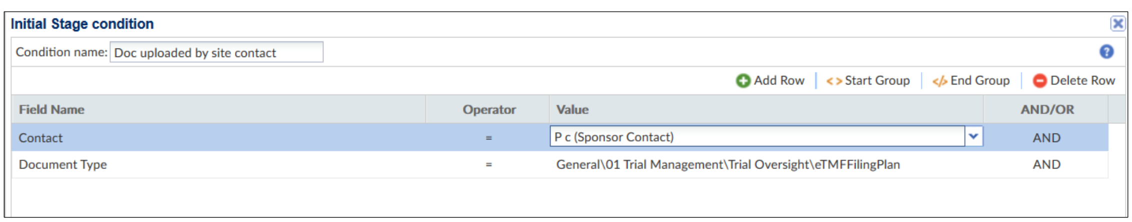
During review, a document is assigned a status by the reviewer, upon which the document is automatically moved to the respective folder in **My Reviews/QC Reviews**. These statuses need to be created for them to be available in the workflow. During workflow creation, each document status is assigned a corresponding review status. **Approved**, and **Rejected** are statuses required at minimum. You can consider creating **Clarification** for document queries, and **In Progress** for a temporary status for the document reviewer. Choose the **Final** status of a document in the bottom field. Any document status could be selected as Final. Usually, **Approved** status is selected as Final status. This is the status that will move a document to the filing index.

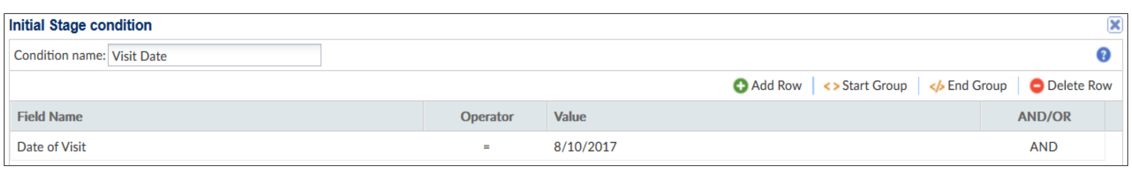
21.1.4. How to Create a Workflow

1. Click **Add**.
2. Enter the workflow name and description.
3. The Selection Criteria could be **All new documents**, or only those **Metadata fields** that need to be reviewed.
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. 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:



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:

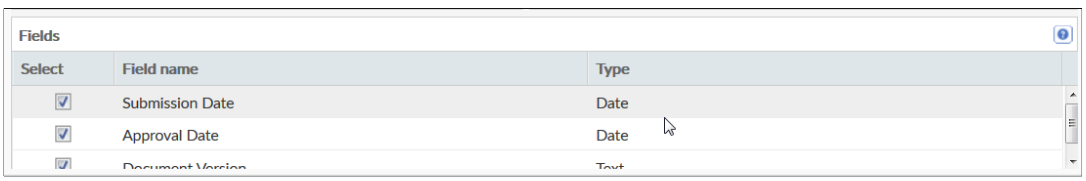




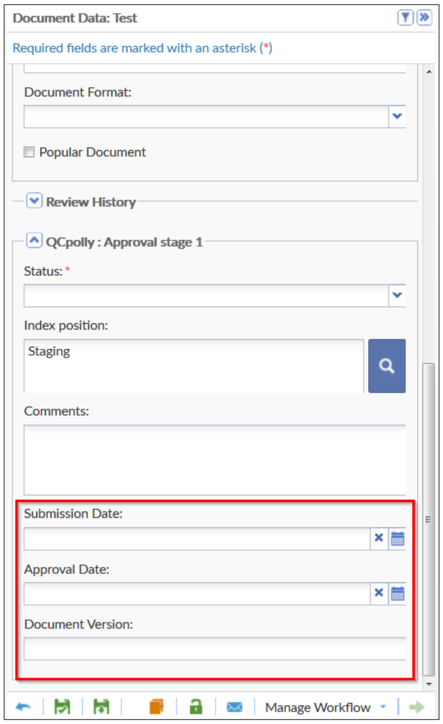
Thus, as per the above conditions, documents of type 'General\Trial Management\Trial Oversight\eTMFFilingPlan' uploaded by the site sponsor on the site visit date of 10th of Aug. 2017 would be added to the workflow.

6. Click **Next**.

7. This leads you to the configuration wizard of the first stage of the workflow.
8. Change the **Stage name**, if desired. Click the **Approvers** tab.
9. This allows you to add users/groups as reviewers of the documents for the particular stage in the workflow. It is recommended to add a **Group** to save configuration time.
10. Click the **Custom fields** tab. This is a required tab and **Statuses** and **Issues** must be added. The statuses are the ones previously created under **Review Status**. Click **Add** to add the first status and select the document status from the dropdown. **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.
11. 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.
12. To make metadata **fields**, as required, available for a workflow configuration, proceed to **Forms Settings** and select the **Workflow Fields**, as required. These fields will appear in the **Fields** panel at the bottom of the **Customs** tab. Check the fields as required for the review.



These checked fields will appear in the **Review** panel of a document in the **eTMF/Documents** module once a document is claimed for review. As shown in the screenshots, the **Submission Date**, **Approval Date**, and **Document Version** fields checked in the workflow configuration appear in the **Review panel** of the **document metadata window**.



13. Click the **Notifications** tab. Here, you can allow for email notifications to be enabled for the event names listed. For example, users in Swim Lane can be configured to receive emails at every stage of the workflow. For users who want to be notified only in case of **Claim**, **Release**, or **Escalation**, groups can be added accordingly.
14. 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.
15. **Actions** is an optional tab allowing for complex workflow building. It enables a workflow to have a jump. A specific document can jump to a certain stage. For example, a Form FDA 1572 after QC1 review, can jump to a stage 3 review, where Regulatory Affairs perform a 2nd review on the document. While efficient for complex workflows, it is not required for regular workflows creation.
16. Click **Next** when all tabs have been reviewed. Repeat the similar steps for each stage of approval. Settings may change per approval stage, like approvers, notifications, and timelines. When finished, click **Next**.

17. The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If no errors, click **Finish** when done.

21.1.5. How to edit an existing workflow

There may be a need to edit an existing workflow. This should be executed with caution because any saved changes require a new and revised workflow to be created. While editing an existing workflow is quicker than creation, having multiple workflows enabled in the same room is not common and can cause confusion.

In the Workflows panel, click the **Name** of the workflow. Click **Edit**.

Review the steps of the workflow wizard as before, clicking **Previous** & **Next** to review the settings. If no changes have been made, click **Cancel**. Yet if changes *were* made, this has become a new and different workflow. Thus, click on **Save as**.

Give the revised workflow a new name. An error message will appear if the entered name matches an existing workflow. Click **Ok** when done. A confirmation message appears confirming creation. Click **Ok**.

The previous workflow and the new revised workflow are both by default enabled. If one needs to be disabled, uncheck the associated box. Remember to click **Save**.

21.2. Workflow Process

21.2.1. Assigning a Group of users to the workflow

To assign a group of users to the workflow follow the procedure as below:

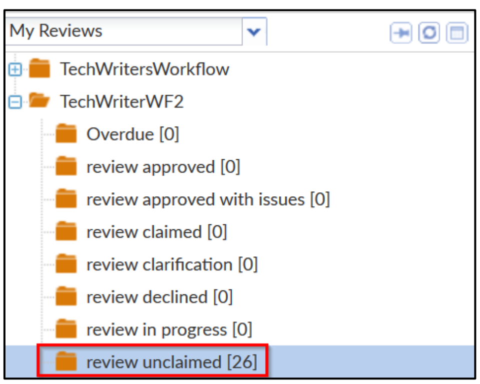
1. Navigate to **Settings -> Security -> Groups** or to **Username dropdown -> User Management.**
2. Create a **Group**.
3. **Add users** to the group. The users in this group would be the reviewers who would review the documents.
4. Now, navigate to **Settings -> Workflows -> Workflows** and create a workflow.
5. In the **Workflow Editor** click **Next.**

6. Click **Approvers -> Groups.** The group name to select would be the one you created in step 2 above.
7. Save the changes. This would have assigned the group of reviewers to the workflow.

21.2.2. Activating My Reviews

If you are part of the reviewers group which you assigned to the workflow above, the **My Reviews** in the eTMF Documents module is automatically activated for you. You can have the same view as in My Reviews from the **QC Review** module as well.

Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the **My Reviews** view or the QC Review module in the **folder with unclaimed documents** under the workflow configured by you. Refer to the screenshot below:



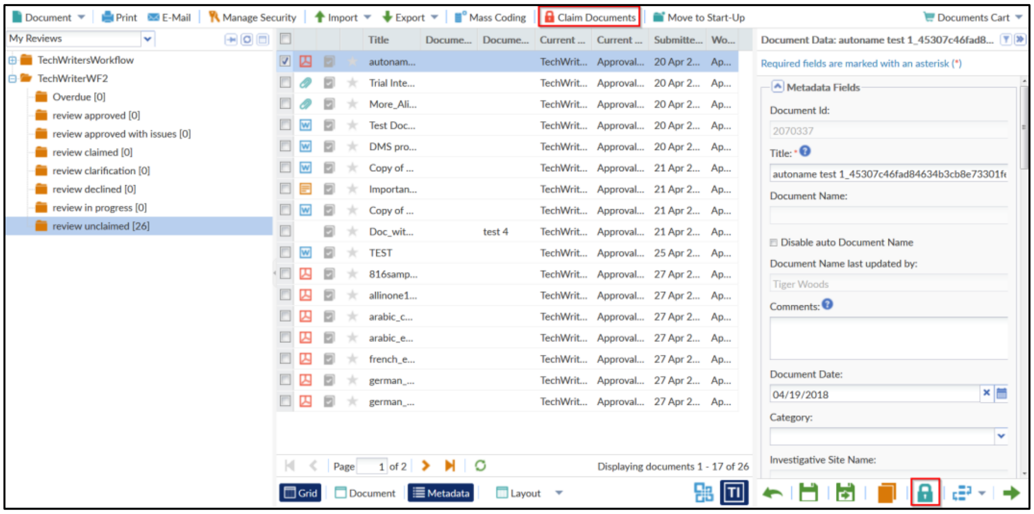
21.2.3. Claiming a Document in the Workflow

To claim a document for review, click folder holding **unclaimed documents** under **My Reviews** or the **By Document Status view** from within your eTMF room. This will list the documents on the right pane.

Select the document you want to claim for review and navigate to the Document Data panel.

If Workflows have been activated in your trial room and you are a member of a Reviewers or Approvers Group, you will see a padlock icon at the bottom of the Document Data panel. You will also see the same icon 

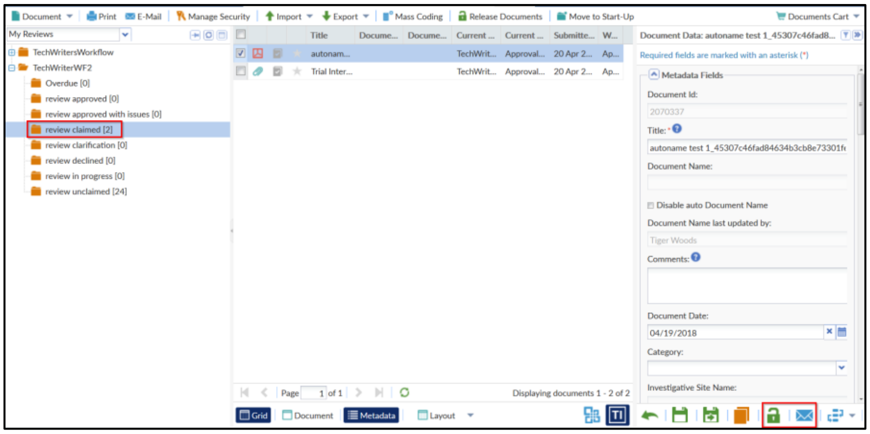
colored red located on the toolbar above the Document Grid to claim multiple documents all at once. Refer to the screenshot below:



1. Click the padlock icon to claim the document for workflow review.

2. Click the green arrow icon  to move to the next document in the current data grid. The process can be repeated as long as there are more documents available to be claimed. You may also select documents in bulk in the Documents Grid and claim them altogether.

3. All the claimed documents move to the **folder for holding documents claimed for review** in the **Index Pane**. Click the folder to view the claimed documents in the Documents Grid. Refer to the screenshot below:



A new set of icons  appears in that corner of the **Document Data** panel. The padlock now appears to be unlocked, and an envelope icon appears.

4. By clicking the envelope icon, the user can send a Query to room administrators about issues you might find with the document.
5. To release a claimed document back into the workflow for others to claim, simply click the unlocked padlock icon. The document will move back to the '**review unclaimed**' folder.

21.2.4. Auto-claiming a document

In certain business scenarios, there can be only one reviewer assigned to a workflow stage. Under such circumstances documents will be auto-claimed by the system and assigned to the lone reviewer for review. To enable auto-claiming of a document, the Administrator will need to enable the configuration from the Settings -> Workflows -> Common Settings -> Auto claim configuration.

If documents are present in the same stage of more than one workflow, and the workflows have only one reviewer assigned to them, the documents will not be auto-claimed.

21.2.5. Assigning Workflow Status

If you have been assigned to a Workflow role, additional fields are available to you in the Document Data panel for documents in the Workflow. Part of your assignment is to assign each document a Workflow Status.

1. Click **Documents** from the toggling menu bar.
2. Select **My Reviews** or **By Document Status** view from the Current view dropdown above the index on the left side of the screen.

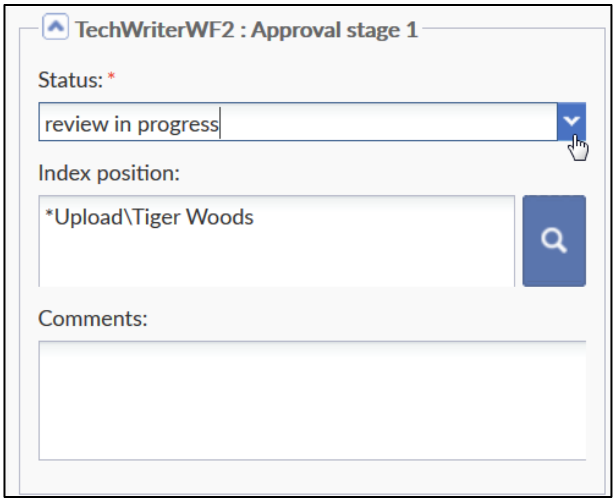
   Alternatively, you may also navigate to the **QC Review module** from the Navigations Grid.

3. Open the **folder holding document claimed** for review by clicking the folder icon next to the folder name.

   A list of your claimed documents will populate the document grid.
4. Select a document.
5. View the document's contents by clicking the document's icon in the grid or by clicking the Document button at the bottom of the grid.
6. Inspect the document.
7. Open the Document Data panel by clicking the **Metadata** button at the bottom of the document grid or by clicking the double-arrows at the top right of the document grid.

8. Code the document as required. Scroll down in the Document Data panel to find the **Status field** in the Workflow section.

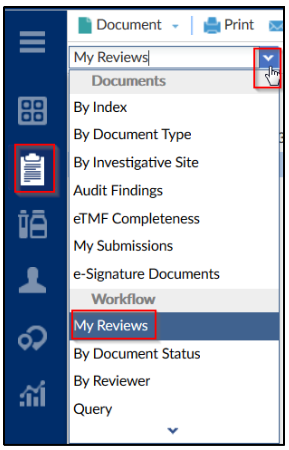


9. Click the dropdown arrow to the right of the **Document Status** field to reveal the available Status selections.
10. Select the appropriate status based on your review of the document's contents.
11. Add comments to the Comments field if appropriate.
12. Click the **Save** icon at the bottom of the Document Data panel to save the workflow status you have assigned to the document, or alternatively click the **Save and select next document** to continue reviewing the next document in the claimed documents queue.
13. Depending upon the status selected, the document moves to a corresponding folder under the Index Pane. For example, approved documents will move to the folder for holding documents **approved** in the workflow, rejected documents will move to the folder for holding **declined** document, documents in progress will move to the folder for holding documents **in progress** and so on.
14. You can also view the review history in the **Review History** panel in the Metadata panel.

21.2.6. Releasing Claimed Documents Back into the Workflow

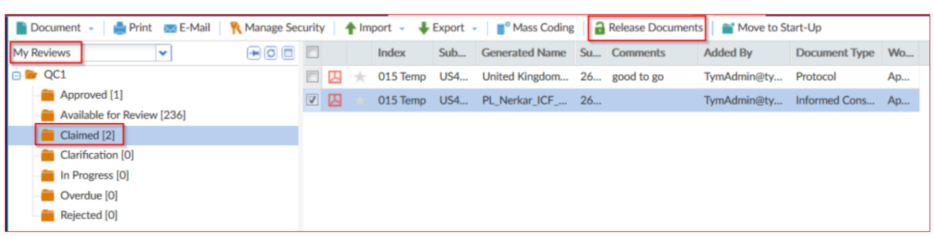
As a user with the Administrator role, you might find that you have claimed more documents for Workflow review than you can handle. If such a situation arises, you can release some or all of your claimed documents back into the Workflow.

1. Click **Documents** in the menu bar at the side of the screen.
2. From the **Current view** dropdown, select **My Reviews** or **By Document Status**, or Navigate to **QC Review/My Reviews** module.



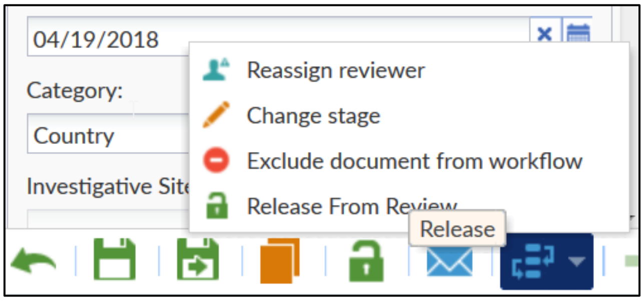
All of the folders related to the Workflows in which you are an active reviewer populate the **Current view** index structure of the **eTMF/Documents My Reviews view**.

3. Click the **folder holding claimed documents** from which you want to release documents. The list of documents in that folder populates the document grid.
4. Click the checkbox above the list to select all of the items in the folder, or select individual documents by clicking the checkboxes for those individual documents. The **Release Documents** button in the top menu ribbon becomes active.



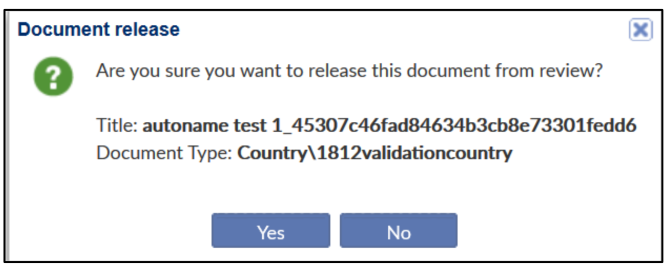
5. Click the **Release Documents** 

button. Alternatively, select **Release from Review** option from the dropdown located at the bottom right corner of the Metadata panel. Refer to the screenshot below:



6. A confirmation window opens.

Or



7. Click **Yes** if you are sure you want to release the document or documents.

   That document or those documents return to the folder designated to hold **review unclaimed** documents. The documents are now available for other reviewers to claim.

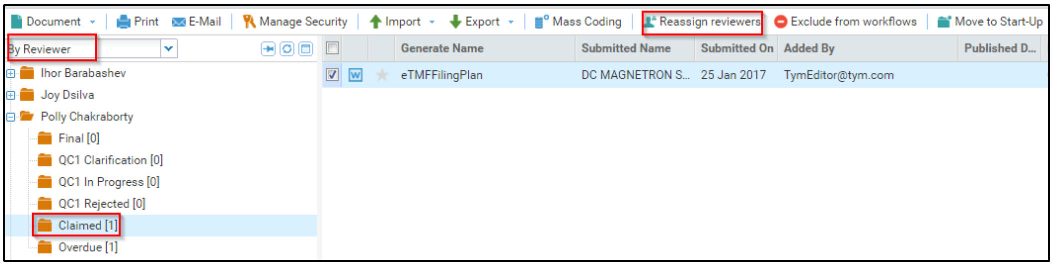
21.2.7. Reassigning Workflow Reviewer

Administrators can reassign documents claimed in the workflow to other reviewers.

1. From the **Documents** view, select **By Reviewer** as the Current view for the index.
2. Open the index folder of the reviewer whose claimed documents you want to reassign.

3. Click the folder holding **claimed document** to reveal its contents.

   The list of that user's claimed documents populates the document grid.



4. Select the documents from the list that you want to reassign.

   The **Reassign reviewers** button becomes active in the menu ribbon above the document grid.

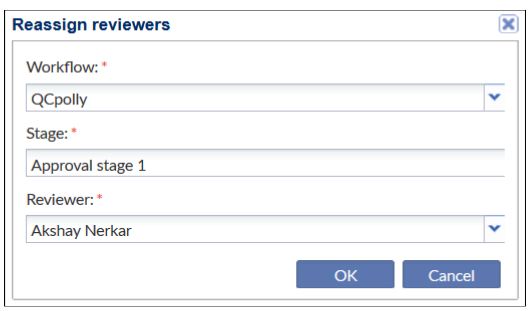
5. Click **Reassign reviewers**.

   A **Reassign reviewers** window opens.

6. From the **Workflow** dropdown, select the workflow you want to adjust.

   The **Stage** field auto-populates.

7. From the **Reviewer** dropdown, select the reviewer to whom you want to reassign the documents.



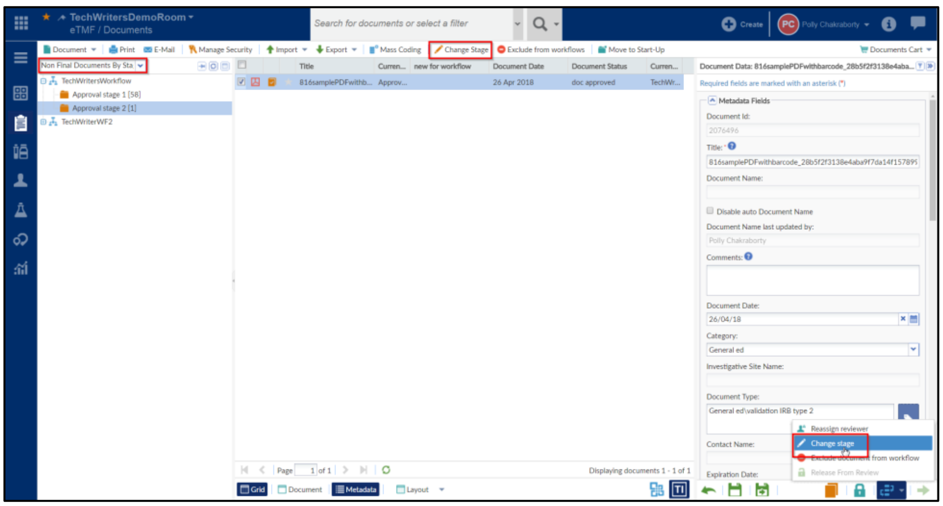
8. Click **OK**.

   The documents are transferred to the folder for **claimed documents** of the new reviewer.

21.2.8. Reassigning documents to a different stage in a Workflow

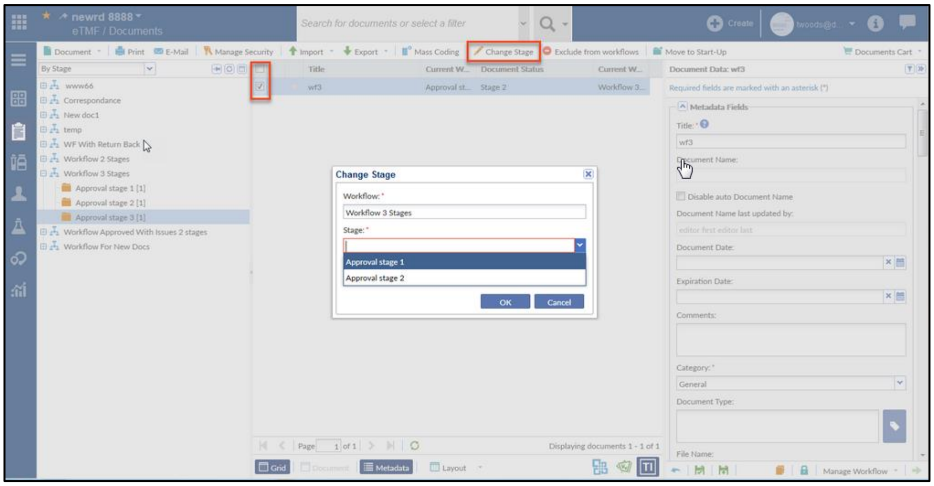
Documents with Final status cannot be re-assigned to workflow stages. They will not be shown on the view.

Documents can be reassigned by Administrators and Editors with **Document Manager** action to a previous stage in a workflow from the **Non Final Documents By Stage** view in the **eTMF/Documents** module. Refer to the screenshot below:



To Change Stage of documents in bulk or individually:

1. Select the Workflow Stage of the document above the current stage.
2. Select the documents in the stage from the Documents Grid.
3. Click the **Change Stage** icon from the top ribbon bar to assign to a different stage in bulk, or select **Change Stage** from the Metadata panel.
4. The **Change Stage** window opens.
5. Select the Stage and click **OK**. Only stages below the current stage will be available for selection.



6. The change stage operation for bulk documents is performed in a background process and the user is notified about the same in the Notifications panel once the job is completed.
7. Once the stage is changed, the documents move to the **folder for unclaimed documents** of the selected stage.

21.2.9. Workflow Query

The Workflow Query Resolution module must be enabled by a user with Super Administrator access in Trial Interactive. When Query Resolution module is enabled Query Reminder configuration is present in Notification Preferences and Notification Columns portlets in Email settings.

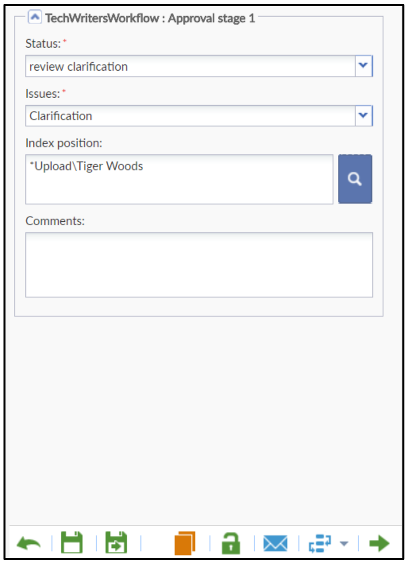
Workflow Query Initiation by Workflow Reviewer

1. As a user with **Workflow Reviewer** assignment, go to the **Documents** module.
2. Activate the **My Reviews** view in the index panel on the left side of the screen, or navigate to **QC Reviews** module.
3. Select an active Workflow main folder.

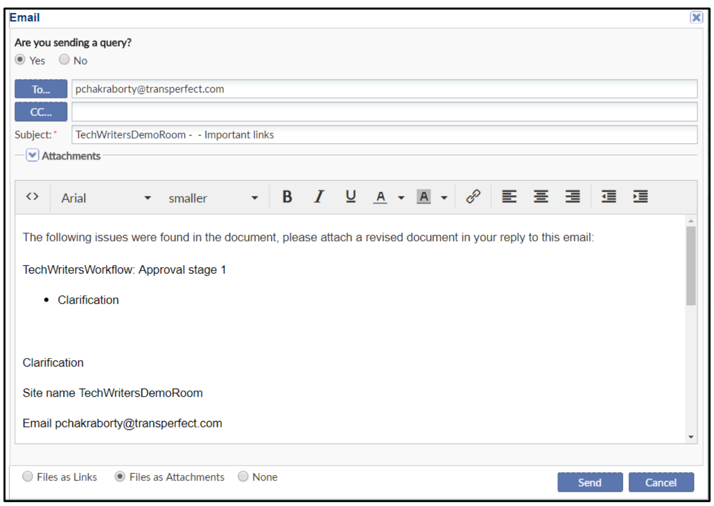
   The related subfolders open in the index view.
4. Select a document from the folder having **unclaimed documents** and open the **Document Data panel** for that document.
5. Claim the document by clicking the padlock icon at the bottom of the data panel.
6. Select either **Rejected** or **Clarification** as the workflow status.

7. Select one or more Issue from the dropdown menu.

8. Click the **envelope** icon next to the padlock icon at the bottom of the data panel.



An **Email** window opens. Click **Yes** to the question **Are you sending a query?**



The initiator of the Query will make several choices at this point.

9. Click the ‘To’ and/ or the ‘CC’ button at the top of the message to add recipient of the Query notification email message.

   The party responsible for having sent the document to the room is an automatic recipient of the outgoing message.

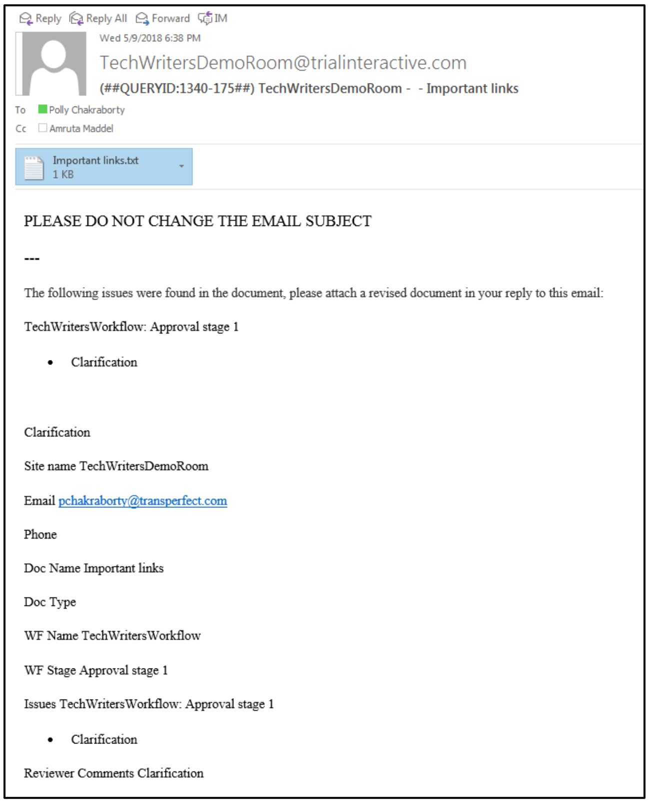
   Only room participants can be added to the ‘To’ and ‘CC’ fields. Other email addresses cannot be added.

The sender can include the associated workflow query document as an attachment or as a link.

10. Once all appropriate selections are made, click **Send**.

    The email message will go out to all recipients indicated in the fields at the top.

    Recipients receive an email message like this:



Reply Reply All Forward IM

Wed 5/9/2018 6:38 PM

TechWritersDemoRoom@trialinteractive.com

(##QUERYID:1340-175##) TechWritersDemoRoom - - Important links

To Polly Chakraborty

Cc Amruta Maddel

Important links.txt
1 KB

PLEASE DO NOT CHANGE THE EMAIL SUBJECT

The following issues were found in the document, please attach a revised document in your reply to this email:

TechWritersWorkflow: Approval stage 1

- Clarification

Clarification

Site name TechWritersDemoRoom

Email pchakraborty@transperfect.com

Phone

Doc Name Important links

Doc Type

WF Name TechWritersWorkflow

WF Stage Approval stage 1

Issues TechWritersWorkflow: Approval stage 1

- Clarification

Reviewer Comments Clarification

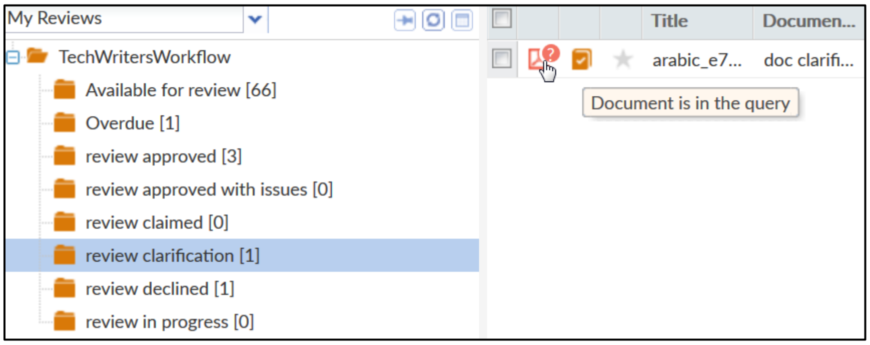
Each Query is assigned a unique **Query ID** number for easy tracking.

A Query ID consists of the of the Room ID where the query was generated and the Query ID separated by a dash. For example, in the above screenshot, in the Query ID 1340-175, 1340 is the Room ID and 175 is the Query ID.

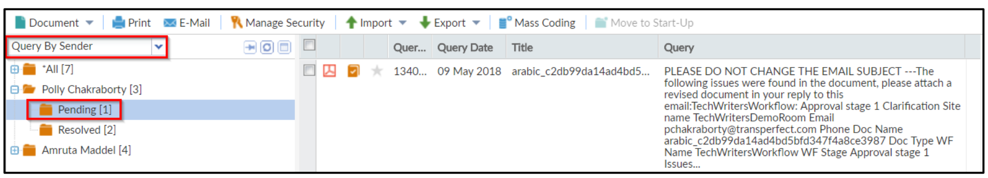
These outgoing messages are tracked in the room's **Communication/Outbox** module.

11. Click **Save.**

12. The **Reviewer** can also view the queries sent under two other views:
    a. In the folder designated to hold documents sent for clarification under **My Review** view or **QC Reviews** module where the document acquires a question mark to indicate that it is in query.



    b. In the **Pending** folder under **Query By Sender** view from the eTMF/Documents module.



Workflow Query Response by the Responder

The Workflow Responder can do the following to respond to the query email received in his/her email inbox:

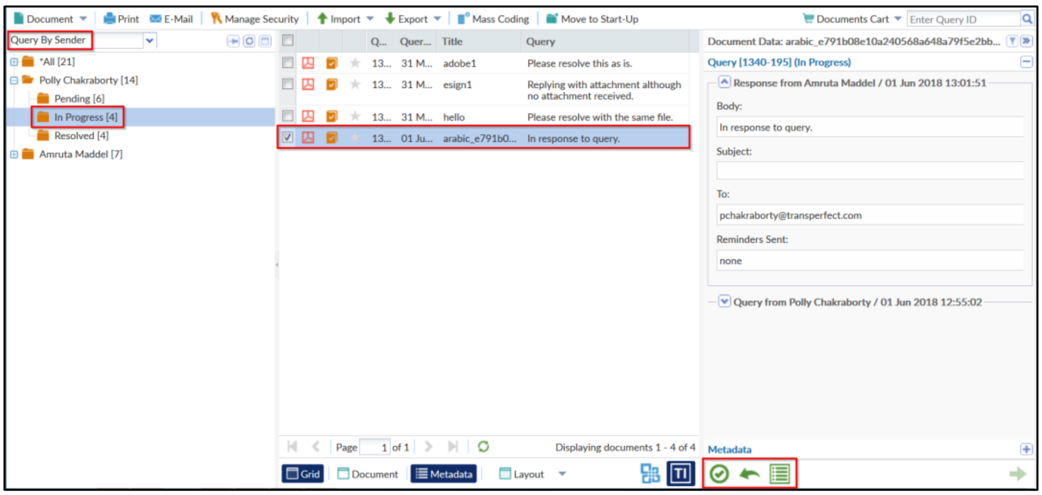
1. The responder can view the query email in the **Query By Recipient** view under the **Pending** folder.
2. The responder replies to the email query **with/without attachments** or **links** after examining the query closely.
3. Once the **Responder** replies to the query email, the query automatically moves to the **Responded** folder in the responder's room under the **Query by Recipient** view.
4. The *Responder may also choose to resolve the query* by clicking the **Resolve** button in the document's metadata panel in the **Pending** folder. Under such circumstances, the document moves to the **Resolved** folder of the **Query By Recipient view of the responder** and in the **Query By Sender view of the reviewer**.

Workflow Query Resolution by reviewer for query responses without attachment

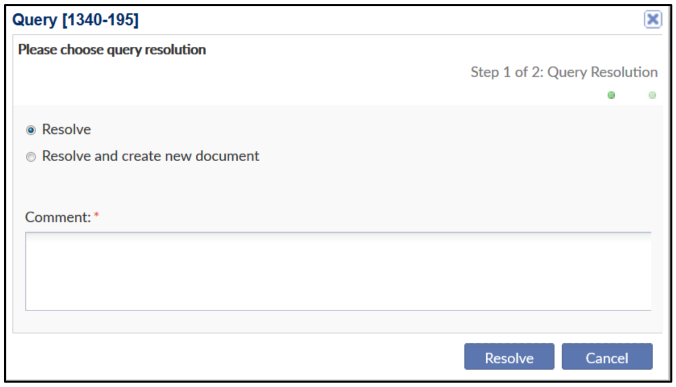
Once the responder replies to the query email, the reviewer can view the responded message in the room in **Query By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

1. From the **In Progress** folder, click the document and activate the Metadata panel.
2. At the bottom of the metadata panel, three buttons are visible – Resolve, Return back to Pending, and Query History. Refer to the screenshot below:



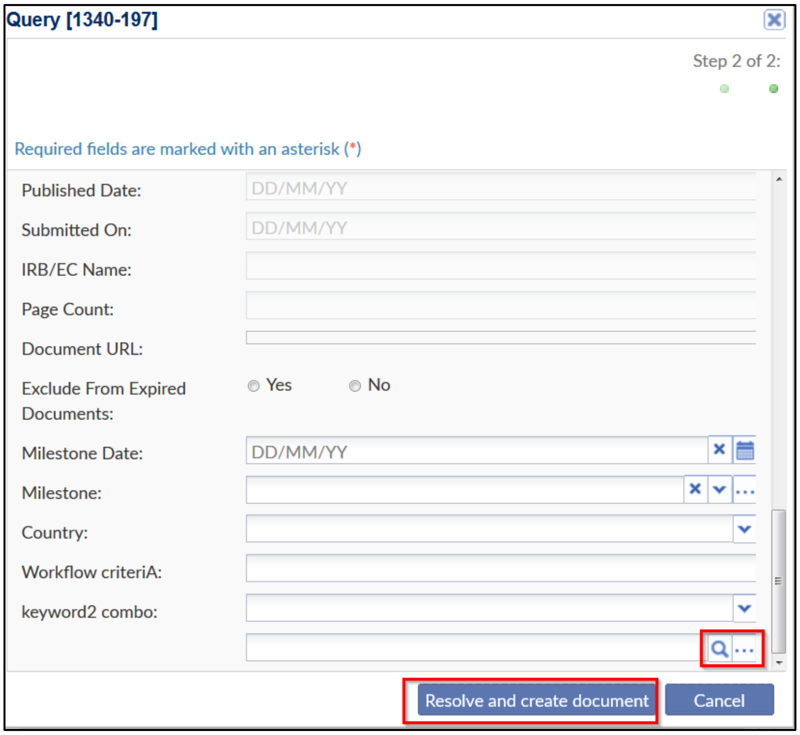
3. Click the **Resolve** button for query resolution else click the **Return back to Pending** button from the metadata panel.
4. On clicking the **Resolve** button from the metadata panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries without attachments:



- ***On clicking the Return back to Pending button, the document returns back and is available for review again. It will then need to re-start the query process from the beginning. This can be used, for example, if the responder is Out of office and an automatic reply is sent from his/her email inbox due to which the document moves to the In Progress folder.***
- ***The reviewer can also click the Resolve button from the Query window in Pending folder to mark a query as resolved without any additional actions or waiting for the responder to respond to the query email. This can be used if the reviewer decides that a response is not required or the documents will be received in some other way. For example, if a query was created by mistake and the reviewer decides to cancel the query thereby resolving it.***

5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the Query by Sender view for the reviewer and in the **Resolved** folder under the **Query By Recipient** view for the responder. In this view the user can **only see the Query History button**.

   It also moves back to the folder holding documents available for review and needs to follow the review process again.
6. On clicking the **Resolve and create new document button** and entering the **Comments**, the reviewer clicks the **Next** button to arrive at the **Document Profile** form. Refer to the screenshot below:



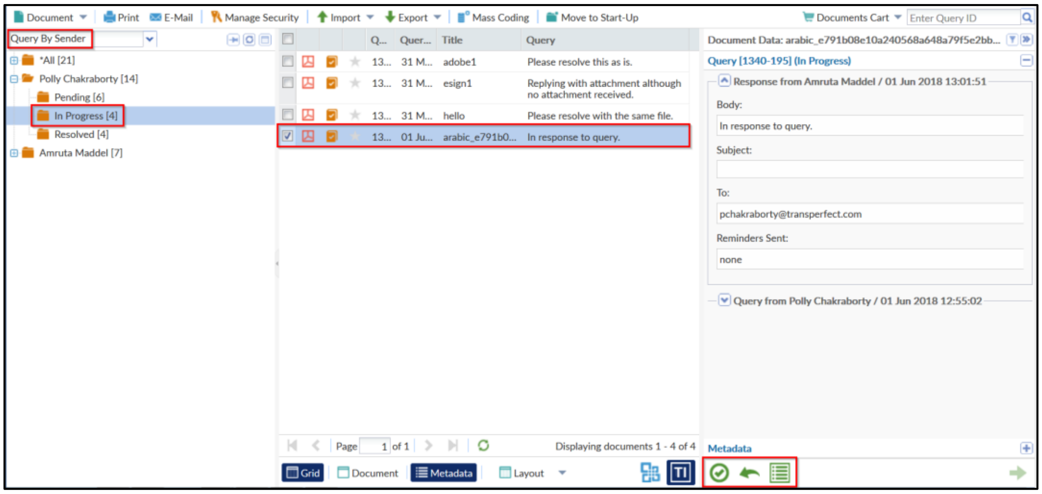
7. Enter the document metadata details and provide the attachment.
8. Click the **Resolve and create document** button.
9. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **Query by Sender/Query by Recipient** view.

Workflow Query Resolution by reviewer for query responses with attachment

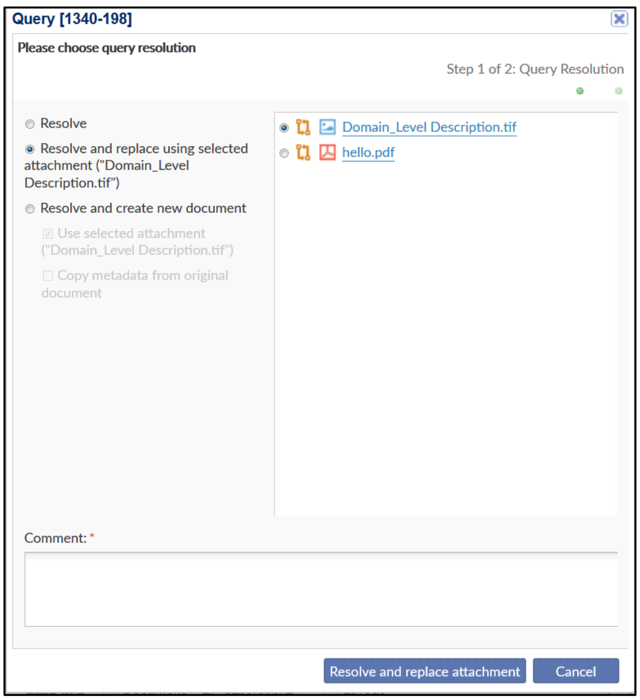
Once the responder replies to the query email, the reviewer can view the responded message in the room in **Query By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

1. From the **In Progress** folder, click the document and activate the Metadata panel.
2. At the bottom of the metadata panel, three buttons are visible – Resolve, Return back to Pending, and Query History. Refer to the screenshot below:



3. Click the **Resolve** button for query resolution else click the **Return back to Pending** button from the metadata panel.
4. On clicking the **Resolve** button from the metadata panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries with attachments:



- ***On clicking the Return back to Pending button, the document returns back and is available for review again. It will then need to re-start the query process from the beginning. This can be used, for example, if the responder is Out of office and an automatic reply is sent from his/her email inbox due to which the document moves to the In Progress folder.***
- ***The reviewer can also click the Resolve button from the Query window in Pending/In Progress folder to mark a query as resolved without any additional actions or waiting for the responder to respond to the query email. This can be used, for example, if a query was created by mistake to cancel the query.***

5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the Query by Sender view for the reviewer and in the **Resolved** folder under the **Query By Recipient** view for the responder. In this view the user can **only see the Query History button**.

   It also moves back to the folder holding documents available for review and needs to follow the review process again.
6. On clicking **Resolve and replace using selected attachment**:
   a. The reviewer can choose from the right pane, the document as deemed fit. The right pane shows two attachment – (1) that was sent as an attachment by responder to allow the reviewer to resolve the query and (2) the document that is in the review process.
   b. Before taking a decision, the reviewer can click the **Compare** icon from the right pane to compare between the document under review and the attachment sent by the responder in the **Compare documents** window, or click the attachment icon to open and view the attachment in the viewer.
   c. Once done, the reviewer clicks the **Close** button on the Compare documents window and clicks the **Resolve and replace attachment** button after entering the **Comments**.

d. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **Query by Sender/Query by Recipient** view. In this view the user can **only see the Query History button**.

e. The original document is still seen in the grid but the attachment from the query resolution can be seen under the Query History window.

7. On clicking the **Resolve and create new document button** and entering the **Comments**, the reviewer:

    a. Can choose whether to **Use selected attachment** from the right pane *(that shows two attachments – the one in review and the other received from the responder)* by ticking the checkbox next to it and also use **Copy the metadata from the original document** to create a new document, ***or***

    b. Untick both the above checkboxes and proceed to ignore the attachment and create a new document by providing another attachment.

    c. Either ways, the reviewer clicks the **Next** button to arrive at the **Document Profile** form.

    d. If the reviewer proceeds with option **7a**, then he/she enters the metadata and clicks **Resolve and create document** button.

    e. If the reviewer proceeds with option **7b**, then he/she enters the metadata, provides the attachment and clicks **Resolve and create document** button.

    f. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **Query by Sender/Query by Recipient** view. In this view the user can **only see the Query History button**.

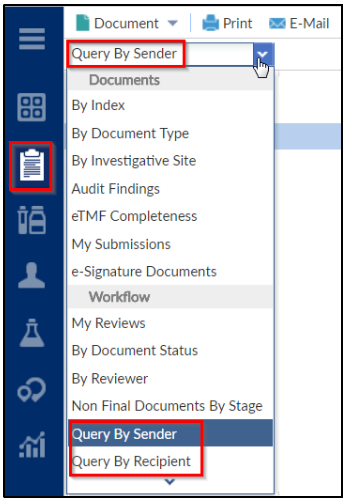
    g. The original document is still seen in the grid but the attachment from the query resolution can be seen under the **Query History** window.

Tracking Workflow Queries

Users with Administrator access in a trial room can check the status of Workflow Queries.

1. Navigate to the **Documents** module.

2. In the index panel of the left, activate the dropdown.



3. Select **Query By Sender** or **Query By Recipient** view from the list.

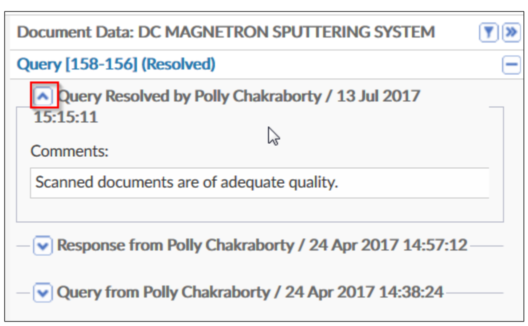
   The Index panel populates with folders that contain the Workflow Queries at their various stages of progress.

   Select a specific folder and the contents of the folder populates the document grid.

4. Select a specific query from the grid and open the metadata panel.

   The history of the selected query is available by clicking the **Query History** icon at the bottom of the Metadata Panel.

   The stages of the query history populate the metadata panel.

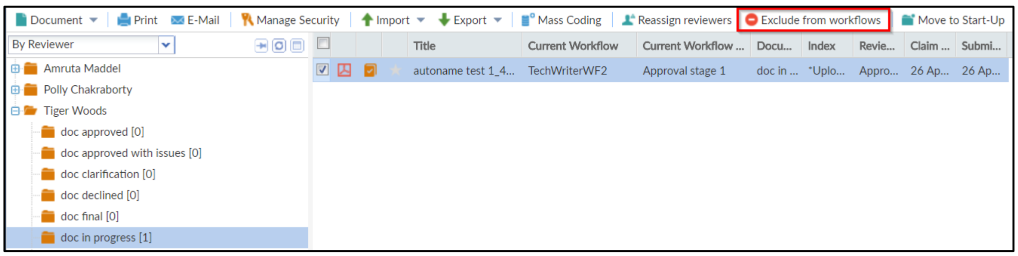


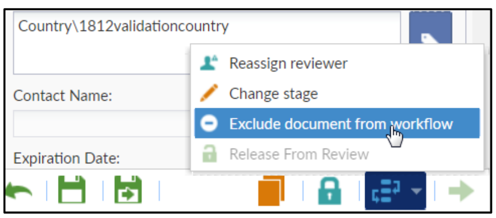
5. Click the arrows to the left of stage description to see the details of each query stage.

   If the user decides it is appropriate to create a new document in order to resolve the query, the user is required to complete the document profile, including uploading a new attached document.

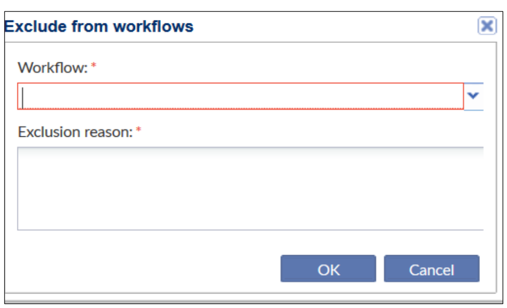
Excluding documents from workflow

An administrator can exclude one or more documents from the workflow by selecting the documents and clicking the **Exclude from workflows** Exclude from workflows button located on the top ribbon bar in the **By Reviewer** view, or by selecting the **Exclude document from workflow** button from the **Manage Workflow** dropdown at the bottom of the metadata panel for individual documents.

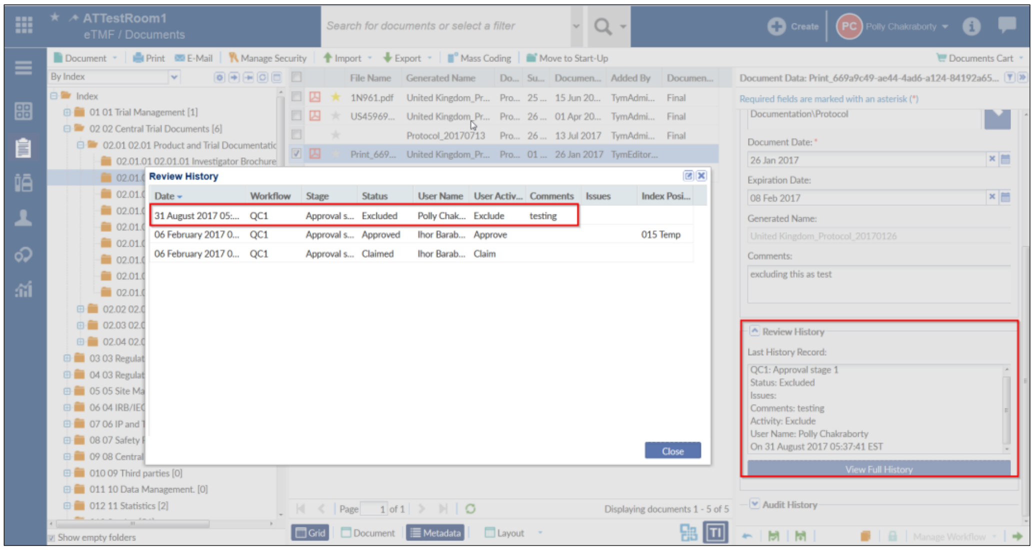




On clicking the button, the Exclude from workflows window pops up.



If the room has multiple workflows, the administrator can select the workflows from which to remove the document/s by clicking the dropdown arrow in the dialog box. It is mandatory to provide the reason for exclusion which gets recorded in the review history of the document. By removing a document from a workflow, the document can be found in the index where it is originally placed.



Documents moved to the Start-Up are automatically excluded from the workflow and the eTMF.

To know how to view a deleted queried document, proceed to section Deleted Queried Documents.

22. eTMF Completeness and CRA TMF Reconciliation Report

eTMF Completeness is a milestone indicator of a clinical study process based on the status of the documents required for the study. The eTMF Completeness view lists the collected, missed, and placeholder documents required to complete a study along with the milestones linked with each document and its placeholder. Therefore, through this module the Administrator can understand the quality and health of the TMF thereby enabling the Administrator to define controls to set placeholders required to collect documents to complete the clinical trial.

Controls can be set in the form of Milestones which are linked at each stage of eTMF completeness to measure the progress percent of documents collected at each stage of the eTMF completeness. For example, the Administrator can set up a milestone for a Site Visit event to include documents for a Confirmation letter sent by the CRA for a site visit, a Site Visit Report, and Follow-up Letter. Each of these documents and their types which are defined in the eTMF room can be linked to a milestone, milestone events defined for the same, and placeholders set up in the eTMF. To be able to set up the complete process and make tracking of eTMF Completeness seamless, the Administrator needs set up:

1. The eTMF Completeness metrics from the eTMF health in the room settings
2. The Milestones for a complete integration of documents
3. Creation of document types and their linking to milestones
4. Creation of Visit types to generate Site Reports

- ***For more details on eTMF Health Settings, proceed to section eTMF Health Settings***
- ***For more details on CRA Visit types, proceed to section CRA Visit Types***
- ***For more details on creation of milestones proceed to section Milestones.***
- ***For more details to link milestones with document types to track eTMF completeness proceed to section Include Phases/Milestones.***
- ***For more details on creating milestone events/history proceed to section Milestones.***

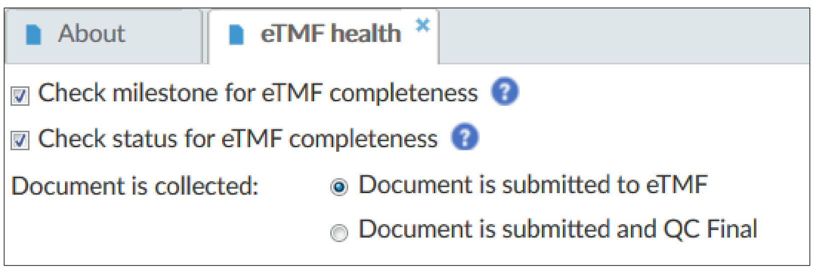
22.1. eTMF Health Settings

The eTMF Health dashlet provides information regarding the current health of the eTMF system by indicating what percentage of required eTMF documents are collected/missed so far. The document types of required documents can be linked with milestones to keep a track on their progress report.

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

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

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

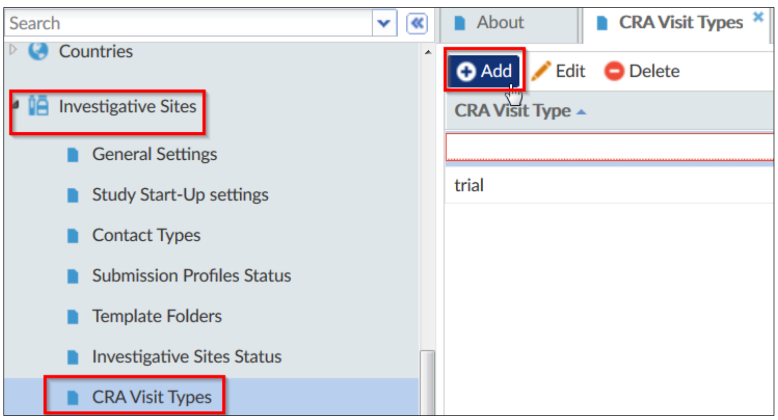
   These settings will affect all dashlets and reports related to eTMF Health and completeness. Moreover, clients can also choose to reflect in the reports documents collected and submitted to **eTMF** or **QC Final** by choosing one of the **radio options** as shown above.

   Click **Save** to commit the changes made.

22.2. CRA Visit Types

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

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



1. To add a new visit type, click the **Add** button at the top of the portlet window.
2. Type in the desired term and press **Enter**.

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

22.3. eTMF Completeness

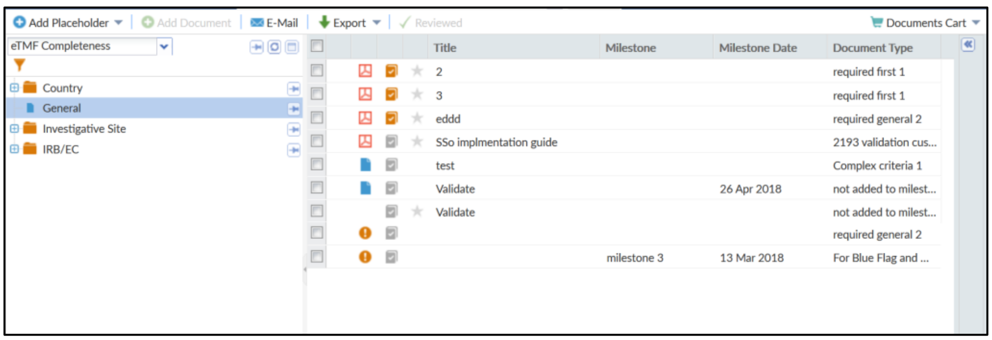
In the Documents module, select eTMF Completeness as the current view in the index pane.

From within the Document Grid or from the **Add Placeholder** dropdown 

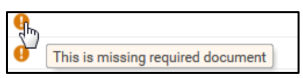
on the top ribbon, placeholders can be created, edited, deleted for a document. Documents can be attached to placeholders or missing documents from the **Add Document** 

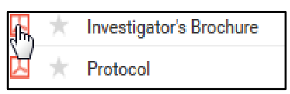
located on the top ribbon bar or by dragging and dropping them from the Windows Explorer. The system:

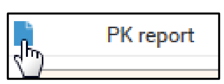
1. Creates a new document from placeholder and missing documents
2. Does not allow to change the category and related metadata if placeholder ID is present for documents.
3. Allows the user to assign placeholders to milestone histories from the **Create Placeholder** window. Refer to the screenshot below:



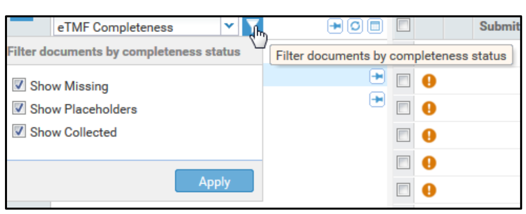
Read the components in the screenshot as below:

1. **Missing Documents:** 

2. **Collected Documents:** 

3. **Placeholder Documents:** 

4. **Filter for Documents:** This allows us to filter documents based on their completeness status.



Select the filter you would like to have and click **Apply**.

22.4. Creating the CRA TM Reconciliation Report

Trial Interactive 9.2 helps the CRA to reconcile documents during their site visits through the Site Report. CRAs needs to take some important decisions regarding documents for sites:

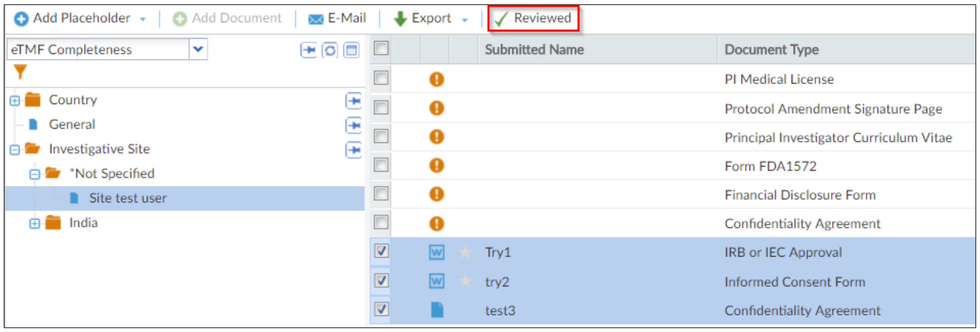
1. Which documents need to be added to both eTMF and site binder
2. Which documents need to be added to site binder from eTMF
3. Which documents need to be added from site binder to eTMF

CRAs can avail this information from the **Site Report** so that they can verify the outstanding documents during their next site visit.

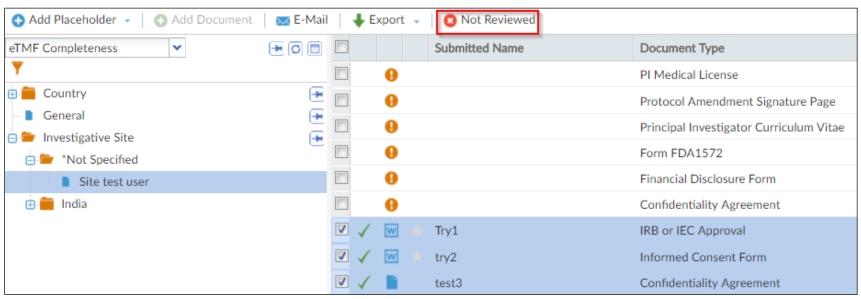
The procedure to create a **Site Report** is detailed below:

1. Select **eTMF Completeness** from the **Current View**.
2. Set the **filter** for eTMF Completeness for all the three options as shown above, and click **Apply**.
3. Select a **site** from the **Current View** so that it shows the list of **missing, collected, and placeholder documents** in the grid.
4. You can **mark the documents as reviewed** for the document types which have documents attached to them.
5. To mark the documents as present, select a document from the grid and click the icon **Reviewed** ✓ Reviewed from the top ribbon bar.

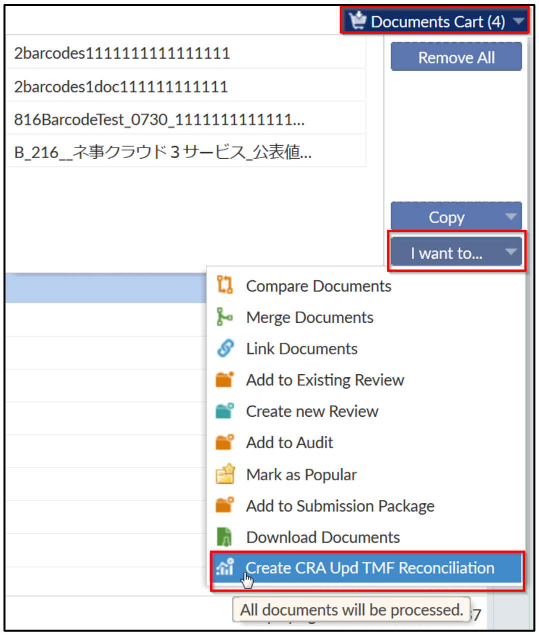
- ***Missing documents cannot be marked as reviewed.***
- ***Only CRAs can perform this step. Admin users will not be able to mark documents as Reviewed.***



6. The documents now acquires a green tick next to it.
7. Similarly mark all the documents which need to be included in the **Site Report**.
8. Once the documents are marked as reviewed, the **Reviewed** ✓ Reviewed icon changes to **Not Reviewed** Not Reviewed.
9. You can click the **Not Reviewed** Not Reviewed icon to **unmark** the documents.

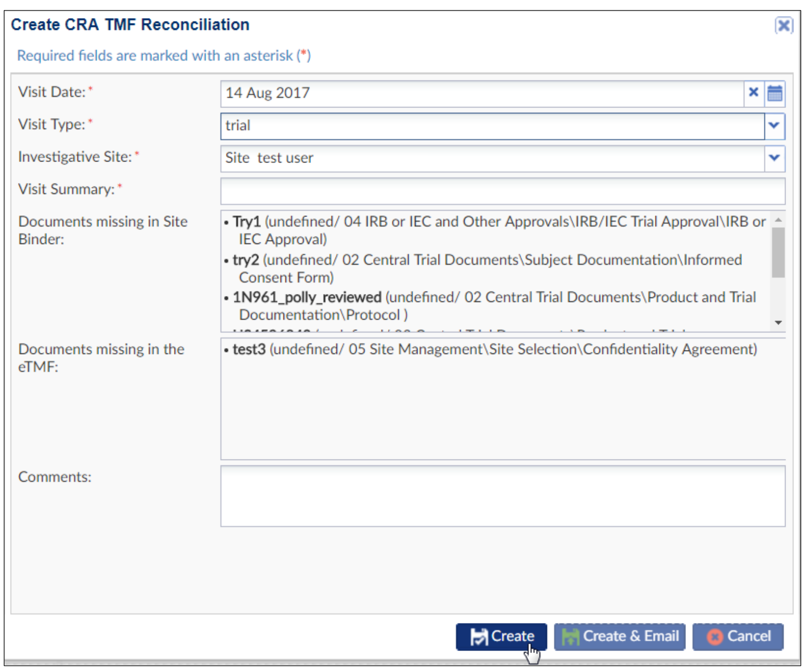


10. Once the documents are marked as reviewed, select them from the grid and **add them to the cart.**
11. Now click the **Documents Cart dropdown** and select **I want to -> Create CRA TM Reconciliation.**



12. The **Create CRA TMF Reconciliation** window opens.
13. Fill in the details and click **Create**.

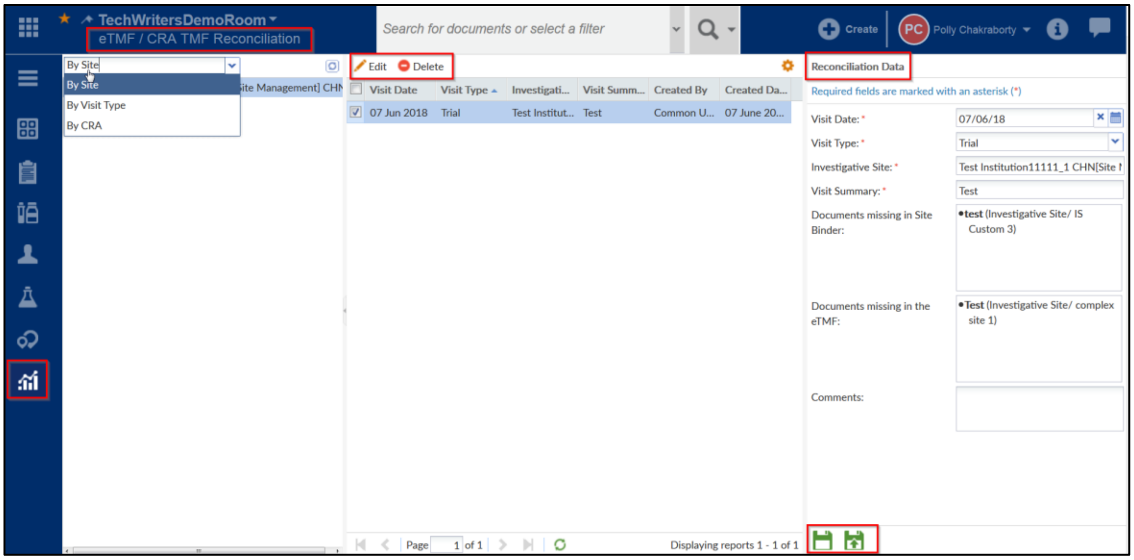
    The **Visit Type** will be populated in the dropdown only if it is created from **Settings -> Investigative Sites -> CRA Visit Types.**



14. You receive a **notification** that the **Site Report** is created successfully.
15. Notice that the documents that are **missing in the Site Binder and eTMF are now marked with yellow ticks,** and those that are **present in the Site Binder and eTMF are marked with green ticks.**
16. The CRA will now only review the documents with yellow ticks on his/her next visit.
17. The Site Report can also be viewed from the CRA TM Reconciliation module located on the toggling menu bar.

22.5. Viewing the CRA TMF Reconciliation Report

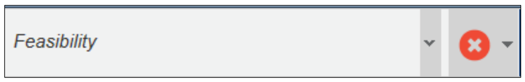
CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. If you are also a CRA in a site, you can access this module from the toggling menu bar by clicking the **CRA TMF Reconciliation** icon. On entering the dashboard, you can find the list of reports generated displayed in the grid. You can choose to view the reports **By Site, By Visit Type**, or **By CRA** from the current view panel on the left. Clicking a report from the grid populates the report metadata in **Reconciliation Data panel** located at the extreme right of the dashboard. You also have the option to edit, or delete a CRA Reconciliation TMF Report from the **Edit** Edit , or **Delete** Delete icons located on the top ribbon bar.



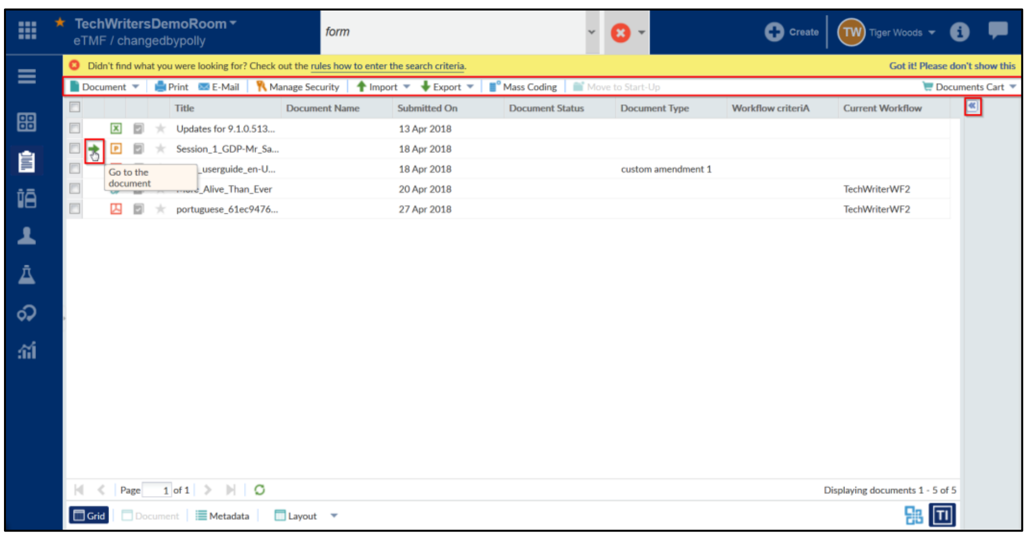
23. Searching Documents

To start a search:

1) Enter the name of the document you want to locate in the Search Box.
2) Click the magnifying glass icon next to the search box or hit **Enter**.
3) Note that on entering the name of the document, the magnifying glass icon is replaced by the Cross icon. This is demonstrated in the screenshot below. You can dismiss the search by hitting the cross.



4) Documents matching the search criteria are displayed in the Grid below the Search box else a message **No documents found** is displayed.
5) Hover the mouse over the documents in the Search Results window to reveal the green arrow with the tooltip **Go to the document**. Refer to the screenshot below:



6) Click the arrow. The document and its **Metadata** opens in the **Document Grid** along with its containing folder for you to view.

   If you want to access the document metadata only without navigating to the document, directly click the double-arrows in the pane located at the extreme right of the Document Grid window.

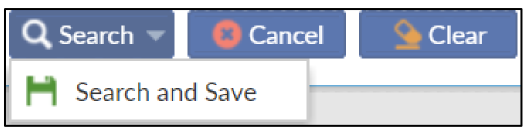
7) The **Top Menu Ribbon** is still accessible from the **Search Results** window and you may use the functionalities for the searched documents as required. You may mass code documents selected from the Search Results window, print or email documents searched, manage their security, add documents to the cart, move them to the Start-Up besides many more.
8) Besides the above, the system also displays a **Help Text link** in the Search Results window to take you to a page in a separate tab with detailed information on syntaxes to create complex search queries to streamline your search further. Refer to the screenshot below:

24. Advanced Search

24.1. Defining and Saving Searches

To define and save your favorite searches, follow the steps below:

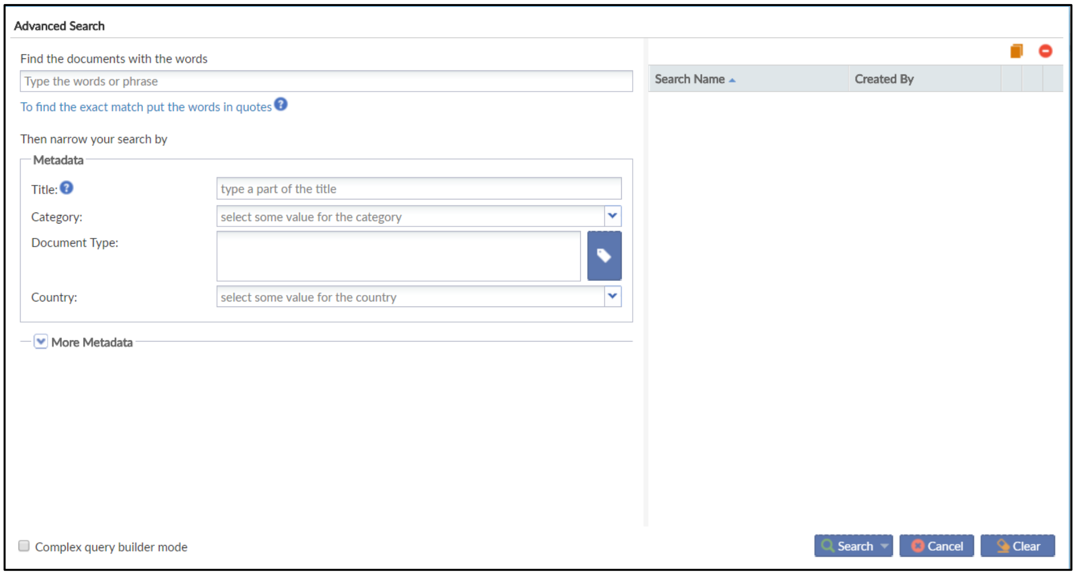
1. Navigate to Advanced Search popup window as mentioned above.
2. Enter your search criteria in the textbox under ***Find the documents with the words***.
3. Click the down-arrow in **Search** button at the right hand bottom of the **Advanced Search** popup window.
4. Click **Search and Save.** Refer to the screenshot below.



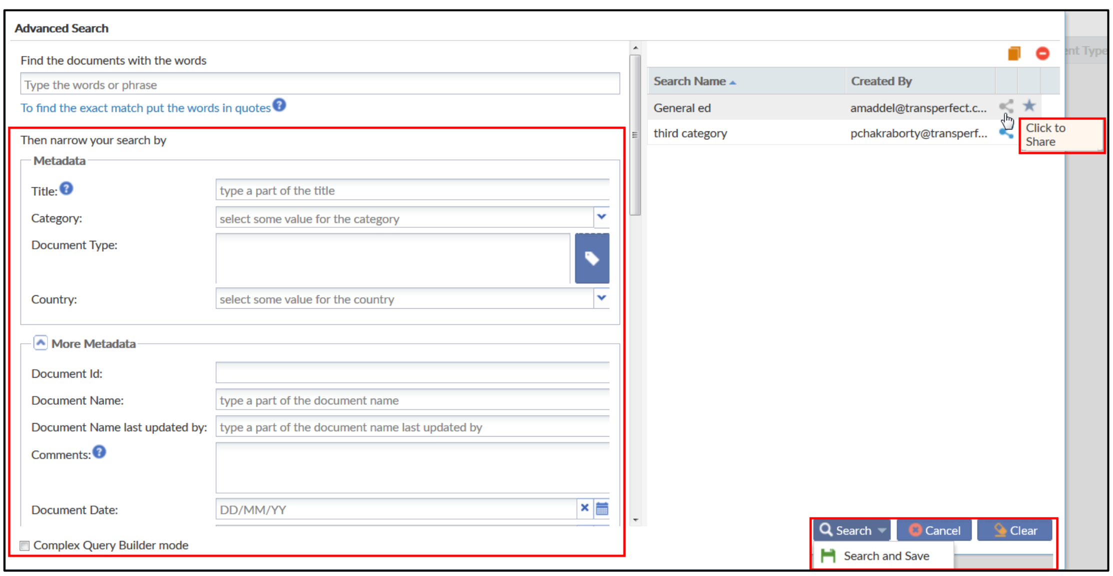
5. This will open the **Search Name** dialog box. Enter the name of the search in the box and click **Ok**.
6. This will initiate the search and will also save it.
7. The search thus created can now be re-used by clicking the down arrow in the **Search Box.**
8. You can share a search by clicking the **share** icon or mark it as your favorite search by clicking the **star** from the **Search Box** drop-down.

24.2. Advanced Functionalities of Advanced Search

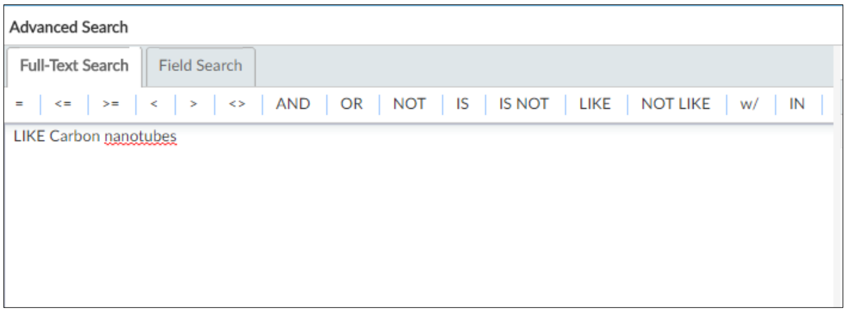
By initiating an **Advanced search**, you can search the full-text of the room's documents or you can choose to search the metadata fields for the room's documents through the **Field Search** tab. Click the arrow to bring up a window to build your advanced search.



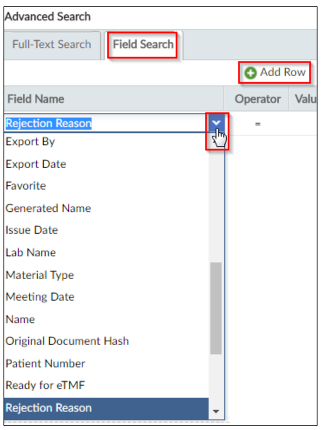
You can further narrow down search results by utilizing the Advanced Search function. In addition to entering general search terms, users can enter metadata information such as the Investigative Site Name, or the Category to which the desirable document might belong. Click **Search** when you are done filling out the additional information. You can save the search terms here as well.



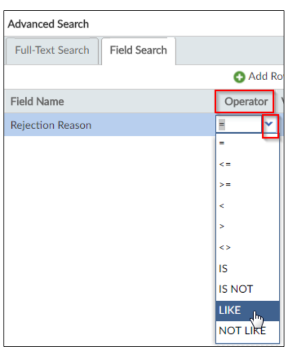
You can also use the **Complex query builder** to refine the search further to match exact text from documents or to match metadata fields. Tick the **Complex query builder mode checkbox**. This will open the **Full-Text Search** and **Field Search** tabs in Advanced Search. Enter your search criteria and click the **Search** button. An example of full text search is shown below:



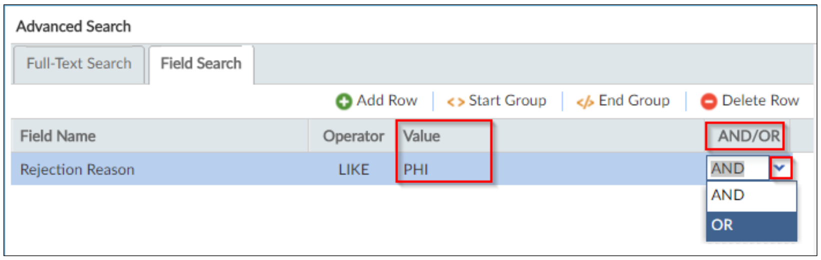
For a field search, click the **Field Search** tab. Click **Add Row** to add fields. Click the added field to select the **Field Name** from the dropdown.



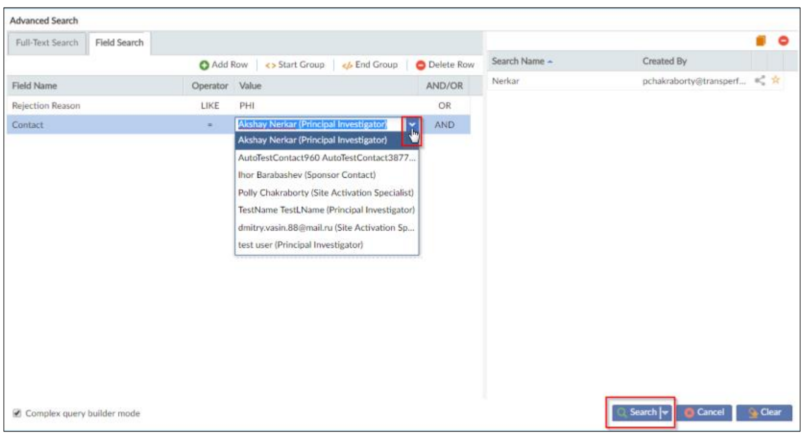
Click the **Operator** field and select the operator as required from the dropdown.

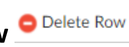


Click the **Value** field and enter the value, or select from the dropdown as required. Now click the **AND/OR** field and select the logical operator as required.



You can proceed in the similar fashion to add another row and enter your search criteria. Once you are done with forming your search criteria, click **Search** to produce the documents matching the search criteria. Refer to the screenshot below:



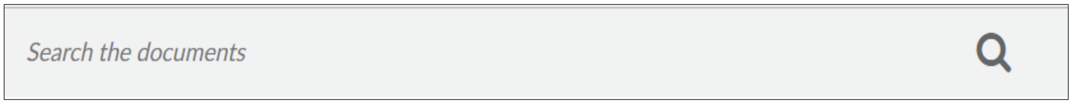
You can **Clear** a search or remove a row by selecting the row and clicking **Delete Row** 

ribbon bar.

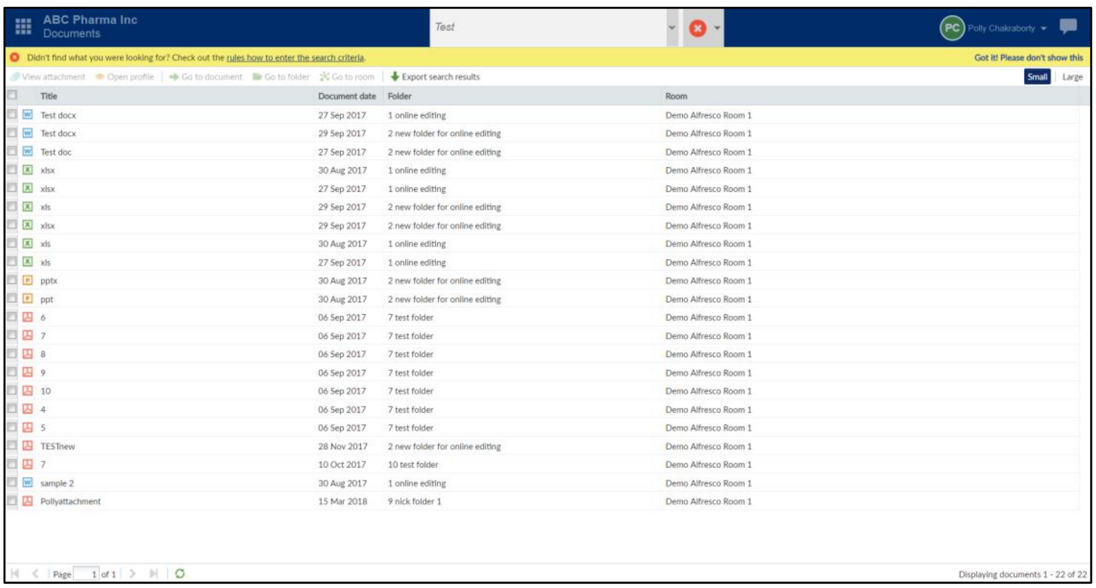
25. Cross Study Search

The **Cross-Study Search** box allows users to search documents across their studies in the TI Interface. To start a search:

1. Navigate to the Home page and enter the name of the document that you want to search in the Search box located at the top of the page.

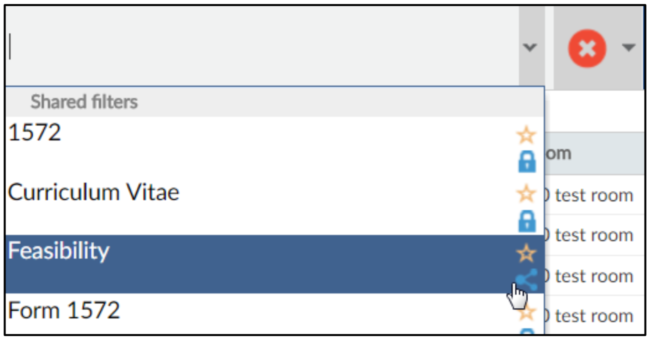


2. Click the magnifying icon next to the search box or hit Enter.
3. The search system then returns a list of all files in the rooms that have that search term in the document title, along with the document date and the room and folder where it is located.



By directly placing your cursor on the document icon, you can preview the document before you actually open the document.

If you wish to export and download the search results, click the Export search results button on the top ribbon bar.

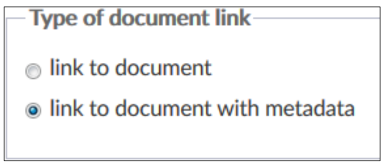


If you click on the down arrow icon of the Cross-Study search box, you can conveniently view your search terms. Therefore, if you want to re-use these search terms later, they are readily available.

26. Copy Link

26.1. Copy link settings/Type of document link

Clients might need to copy a document link through the Document dropdown in the eTMF module. They can choose the type of document link to copy through this option.



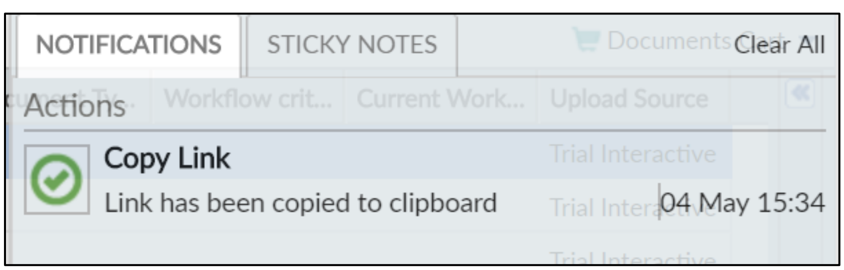
1. Select the **link to document** option when you want to only copy the link and simply view the document in a supported browser.
2. Select the **link to document with metadata** when you also want to view the document metadata along with the document for the document link that you have copied.
3. Click **Save** if you have made a change.

26.2. Copying a document link

After the above options are set, to copy a link navigate to the Documents module.

- Select a document from the grid. Click **Copy Link** to **copy the link to a document**, or to **copy the link to a document with metadata.**

  Once the Copy Link option is selected, the document URL gets copied to the clipboard and a notification about the same is received.



  Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings, the document will either open up in the browser for you to read, or the link will take you to the eTMF room and open the document and its metadata for you to view.

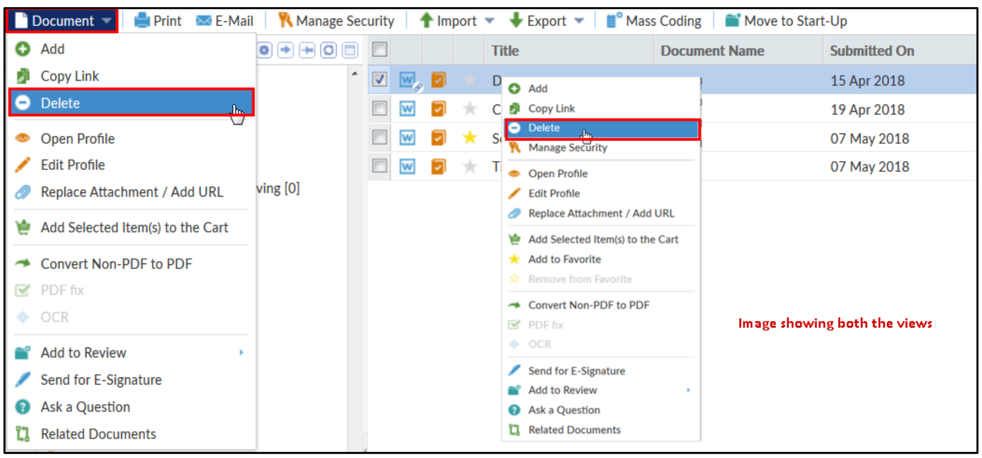
Copying and pasting the link of an empty document shall display the message 'This document profile does not have an associated document'.

27. Deleted and Expired documents

27.1. Deleting Documents

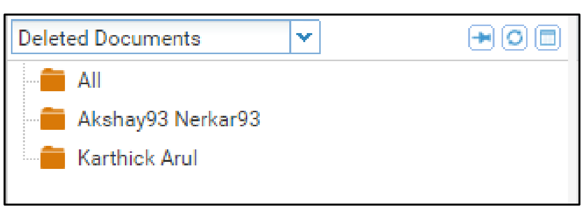
To delete a document:

1. Navigate to the **Documents module**.
2. Select the document(s) from the document grid.
3. From the **Document Dropdown** or **right-click menu**, select **Delete**.



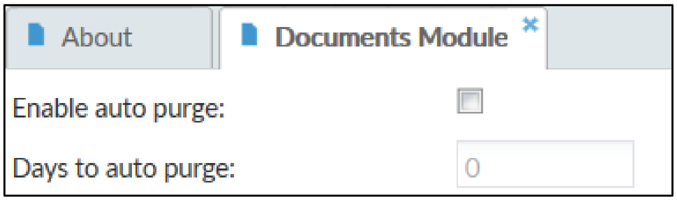
27.2. Deleted Documents view

All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.



27.3. Auto Purging/Restoring Documents

27.3.1. Auto Purge Settings

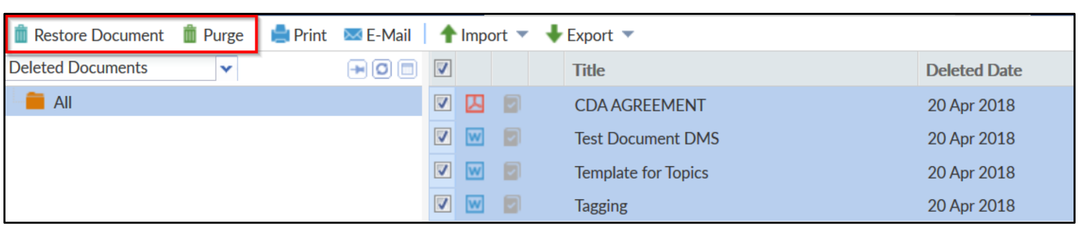


Clients might ask that documents that have, for some reason, been uploaded or sent to the room and then deleted, be purged completely from the room – documents that have been rejected from the room's workflow, for instance. If the client has made such a request, activate this function.

1. Navigate to **Username dropdown -> Settings -> Documents Module -> Auto Purge**.
2. Click the checkbox next to **Enable auto purge**.
3. Adjust **Days to auto purge** by clicking the box and typing the number requested by the client.
4. If that is the only requested change to the settings in this module, click **Save**.

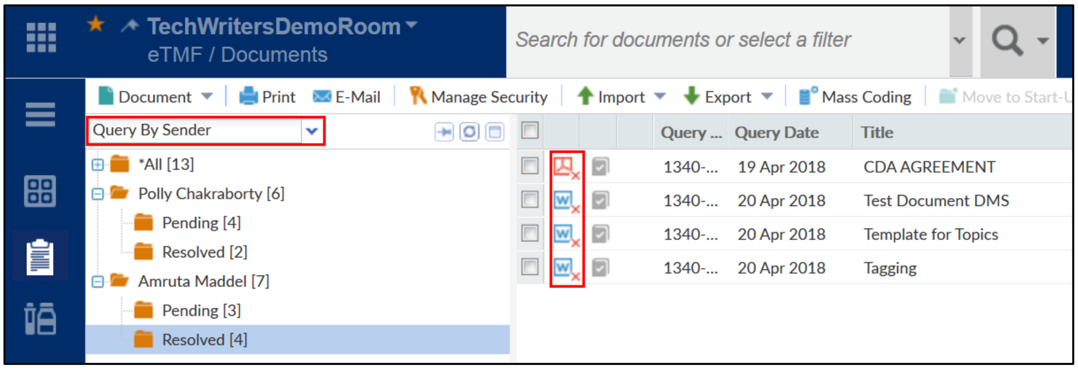
27.3.2. Purging or Restoring deleted documents

Deleted documents can be restored Restore Document or purged Purge by clicking the required icon located on the top ribbon in the Documents module. Restored documents take the same place in the index they were located in before deletion. Refer to the screenshot below:

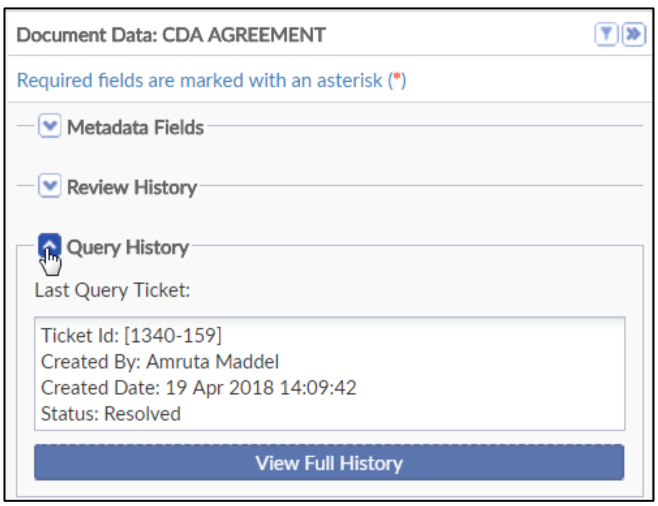


27.4. Deleting Queried documents

Queried documents deleted by a user can be viewed by the Administrator under the **Query By Sender** and **Query By Recipient** views also besides the **Deleted Documents view.** Such documents appear in the mentioned views with a cross colored red next to the document name in the grid.

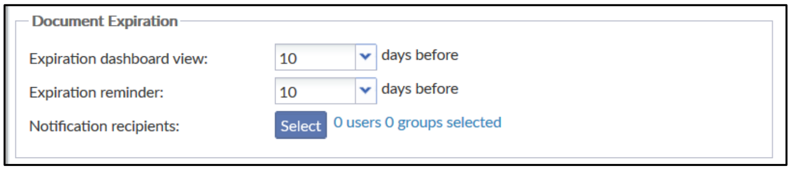


Documents which were in query and were later deleted retain their query history and are also included in query-related reports. The Query History can be viewed from the **Query History** panel in the **Metadata panel.** Click the **View Full History** button to get a complete view of the details.



27.5. Expired Documents

As an Administrator, you might want to specify the time by which a document will expire and require a new version. You can set up the settings of expired documents from the **Username dropdown -> Settings -> Documents -> Documents Module.** Refer to the screenshot below.



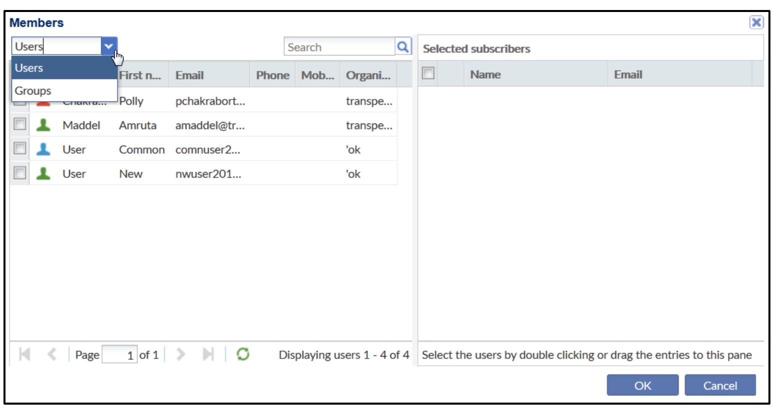
The **Expiration dashboard view** field controls how long before a document expires that it will appear in the **Expiring Documents list** in users' Dashboard view. Insert the **number of days** requested by the client.

The **Expiration reminder** field controls how many days before expiration, a reminder email will be sent to users and groups selected in the option below to receive this reminder. Insert the number of days requested by the client. By default the value of both the fields is 10 days before.

The **Document Expiration Notification** email template can be used to send emails to designated users.

To select user/groups to receive notification email:

1. Click **Select** from the **Notification Recipients** field. A new window opens.

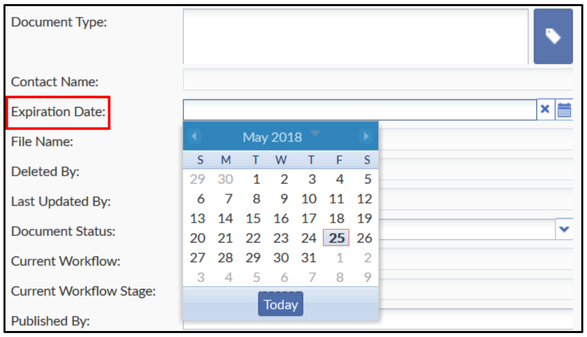


2. Select Users and/or Groups to be affected by these expiration settings by dragging and dropping them, or by double-clicking them to transfer them into the **Selected Subscribers** list on the right.

3. Click **Save** when you have completed this operation.

   The numbers of users and groups that you have selected will appear next to the **Select** button.

You can specify the **Document Expiration Date** in the Document profile while adding/editing a document.



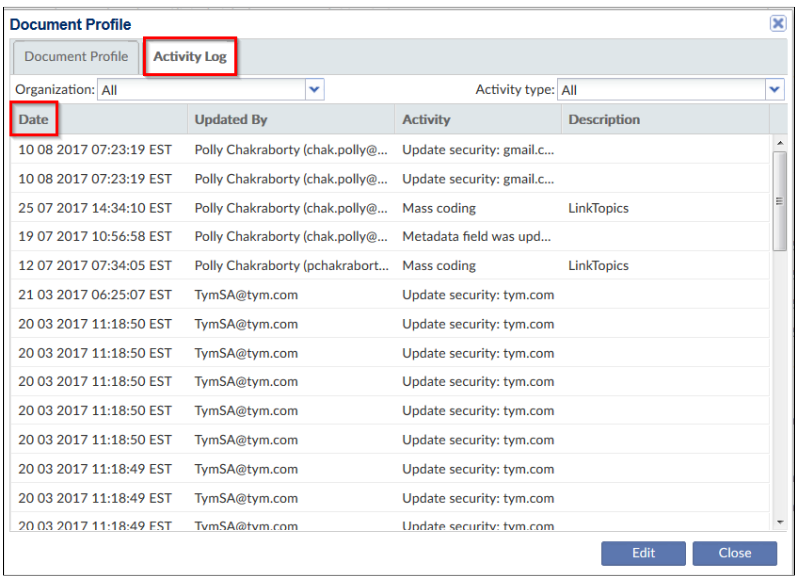
> ***You can view expired documents from the following dashlets :***
>
> ***1. Top N Studies with Expired Documents***
>
> ***2. Documents Expiring in N Days/Expired Documents***

28. Viewing and Editing Document Profile

28.1. Opening Document Profile

In the **Documents** module, select the document and click **Open Profile** from the Document dropdown or right-click menu on the document, and you see the **Document Profile** for the selected document. In this view, the fields are static.

Click the **Activity Log** tab to view the timestamp of the activities performed by various users on the document.



28.2. Editing Document profile

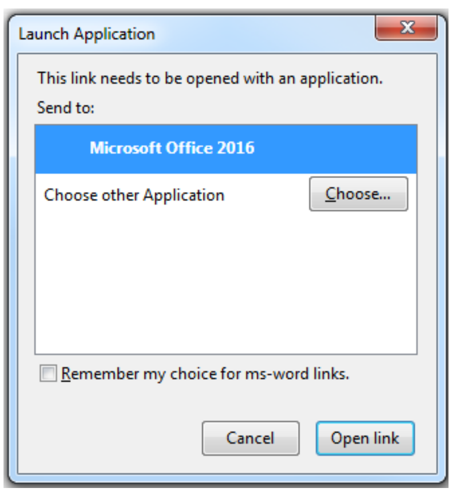
In the Documents module, select the document and click **Edit Profile** from the Document dropdown or right-click menu on the document and the fields are no longer static. By this route, an Administrator can edit the document profile. Editing profile is also possible from the metadata pane.

29. Replace attachments and Edit Document Online

- ***Edit online and is applicable only to Alfresco Rooms.***
- ***Edit Document Online action can be assigned to the user to allow the user to edit a document online. To know more about this, proceed to Settings -> Security -> General -> Actions, and then to Security -> Users -> Invite Users or Security -> Users -> Edit.***

29.1. Editing a Document Online

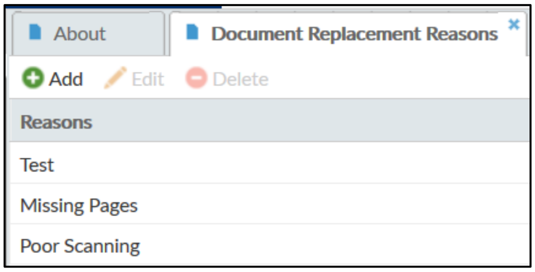
Select **Edit Document Online** to open a MS Office document in its native office application as Word, Excel, etc. to edit it online immediately on its upload. Selecting this feature will open a dialog with a message to **open the document in the applicable protocol**. Refer to the screenshot below.



Once the document is edited in its applicable application, saved and closed, the changes will be saved to the server by the system automatically.

29.2. Replace Document

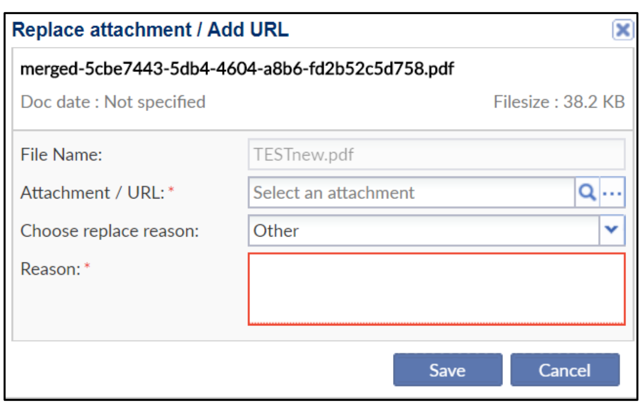
By selecting **Replace Attachment/Add URL**, the user can delete a previous attachment/URL of a particular document and add a new attachment or URL. While replacing an attachment, you will need to specify the reasons as to why the document is replaced. The reasons can be chosen from a configured list of reasons set up from the room **Settings -> Document -> Document Replacement Reasons**. Refer to the screenshot below.



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

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

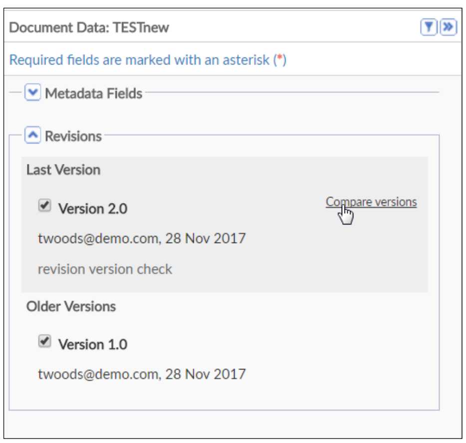
If there are no reasons configured for your room or you do not find the appropriate reason from the list, you will need to select the 'Other' option from the list of reasons and enter the reason in the textbox below. Refer to the screenshot below:



All such changes are tracked within the trial room and different versions of the documents are maintained by the system. *Once the attachment or URL is changed, the document's metadata will need to be changed as per the new attachment/URL*.

> ***Viewing of version history on replacing attachments is available only in Alfresco rooms.***

Users with editor and above access can now view the different versions of a document from its Metadata panel by collapsing the Metadata Fields section which then reveals the Revisions section. The number of version changes will be revealed on expanding the section by clicking the arrow next to the section name. Refer to the screenshot below:

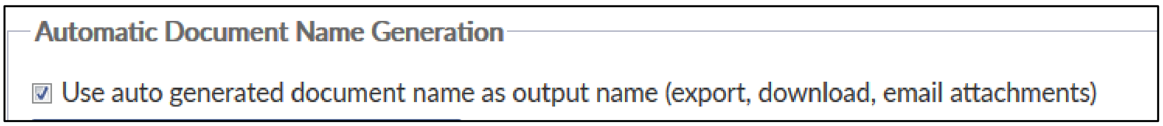


Besides being able to view different versions of a replaced document, you can view the reasons for a document replacement from the **Activity Log** of the Document Profile window.

30. Export/Download Documents, Metadata and Security

30.1. Export Documents Settings

The administrator can use a document name generated automatically as output name for exports, downloads, and email attachments by ticking the checkbox under the Automatic Document Name Generation section in the room settings.



Documents can be exported or downloaded from the following options:

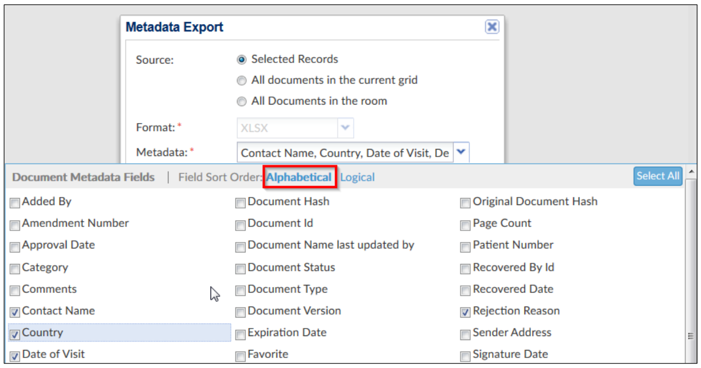
1. The **Export dropdown** from the top menu bar
2. From the Documents Cart
3. Download documents when opening a document in the **Original Viewer**

30.2. The Export Dropdown

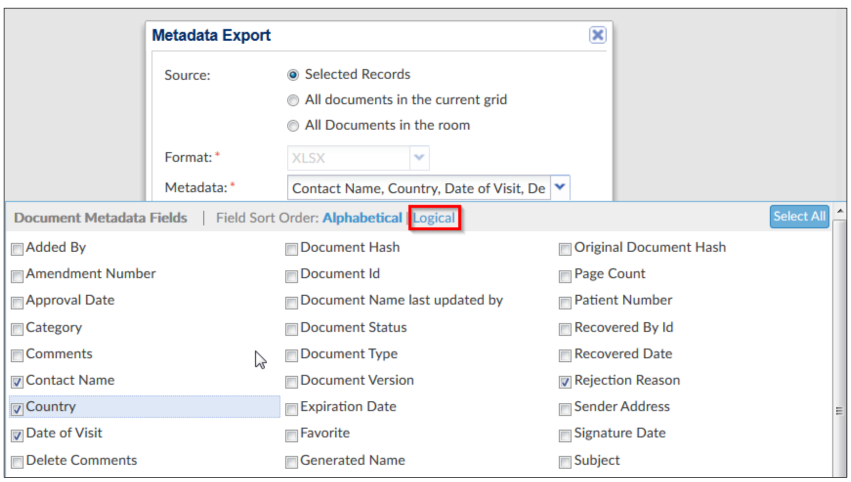
Three options are available to the Administrator from the Export dropdown on the top menu ribbon – **Metadata**, **Documents**, and **Security**.

30.2.1. Exporting Metadata

To export metadata, click the **Metadata** option from the **Export dropdown** located on the top menu ribbon. This opens the **Metadata Export** window. Refer to the screenshot below.



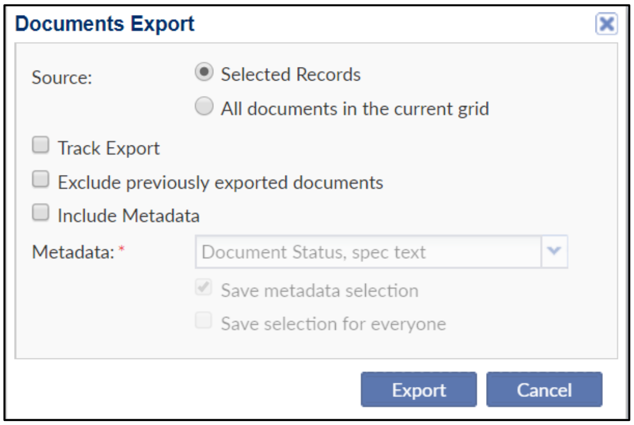
This function gives you a compressed file with the information you requested in XLSX spreadsheet file. As shown in the picture above, by default, the metadata fields are listed in **Alphabetical** order for export. But if you so wish, you may select the **Logical** order for exporting metadata. Your super admin can set the default display of the metadata fields to **Logical**, if required.



If you click the radio button to export All Documents in the data room, that's exactly how the download will perform. If the room has thousands of documents, you will download thousands of documents and all of the associated metadata fields chosen from the Metadata dropdown.

30.2.2. Exporting Documents

Exporting documents is the same as downloading documents from the cart, but with the Export Documents option from the Export dropdown you can avail many other functionalities as discussed below:

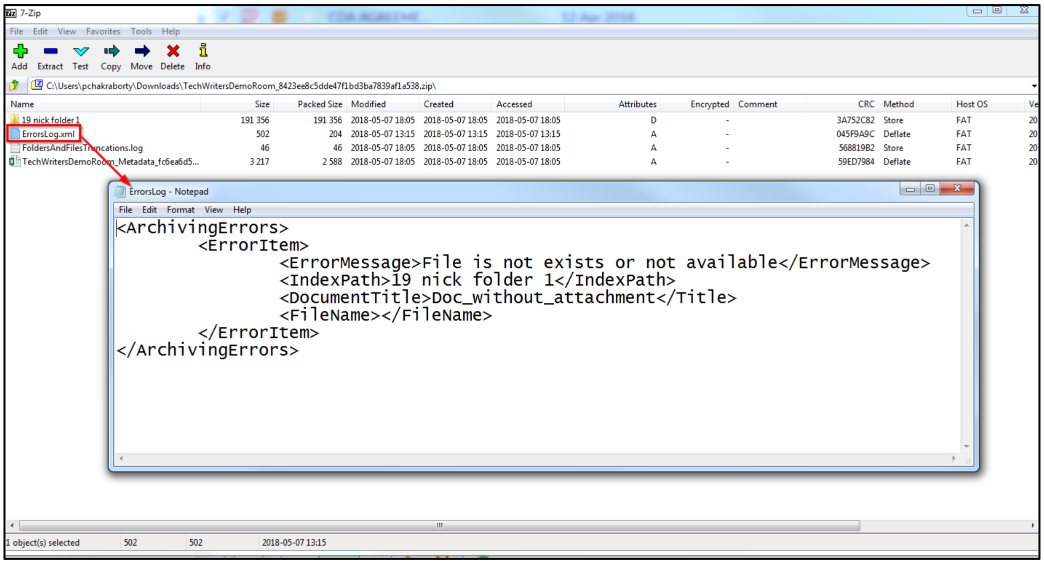


You can track an export, exclude previously exported documents, or include metadata during export. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.

The documents or selected documents get exported in a .zip file. The .zip will include the following:

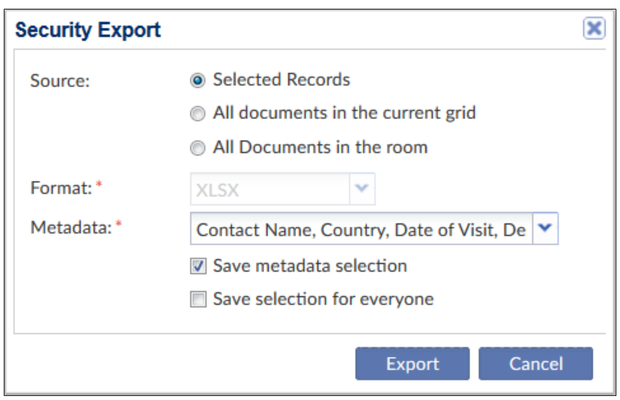
1. A **folder with the exported documents** in it.
2. An **excel worksheet** with the metadata, if you happen to export metadata.
3. A **.log** file which opens in Notepad to give the list of previously exported documents that were excluded during export. Here again, you have to select the option to exclude previously exported documents to enable this.
4. An **ErrorsLog.xml** file that includes details of documents that fail to export.

Refer to the screenshot below:



To view the exported file, navigate to the **Notifications** .

30.2.3. Exporting Security

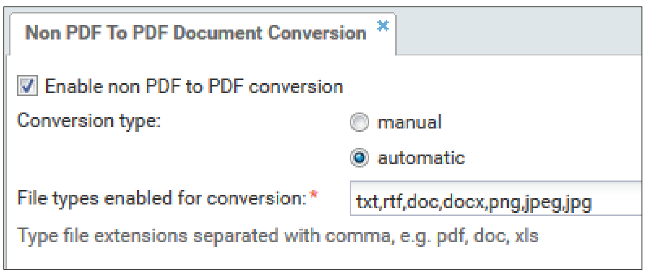


This will allow you to export all the security accesses for selected records, or for all documents in the grid, or for all documents in the room as per your choice. The output of the export job is an .xlsx file that can be accessed from the **Notifications** .

31. PDFs, OCRs and other processes

31.1. Non PDF to PDF Conversion Settings

Navigate to **Username dropdown -> Settings -> Non PDF to PDF Conversion**. From this window, you can choose to enable or disable the PDF Conversion option. You can select to make the conversion, if enabled, Manual or Automatic by clicking the appropriate radio button. You can edit the list of file types that can be converted.

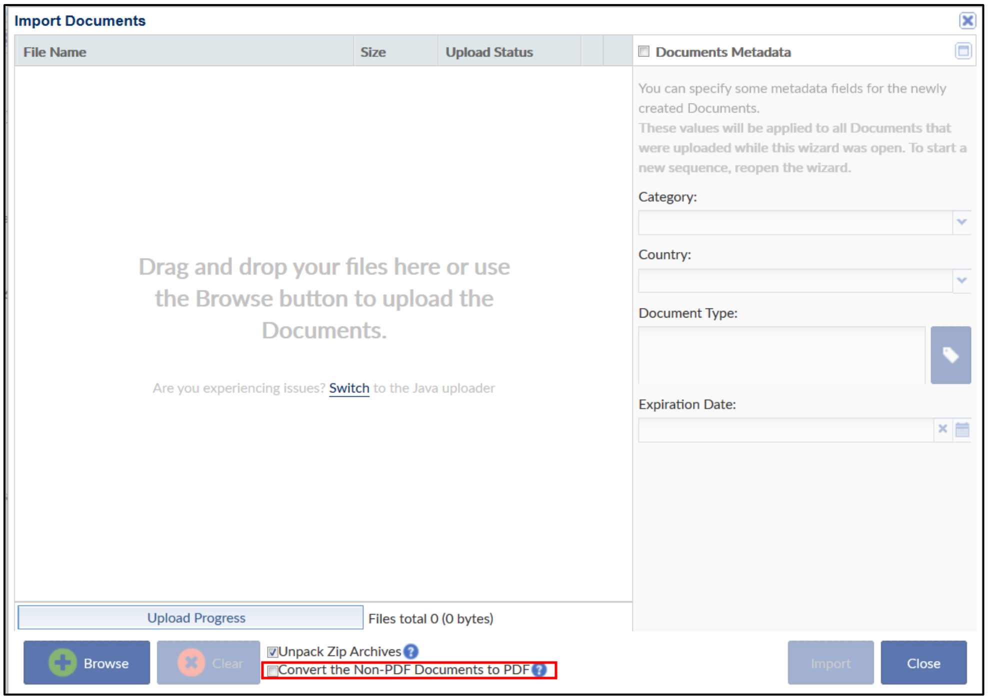


Click **Save** if you have made acceptable changes.

31.1.1. Manual Conversion to PDF during Import

To convert documents from a non-pdf format to pdf while importing, follow the below procedure:

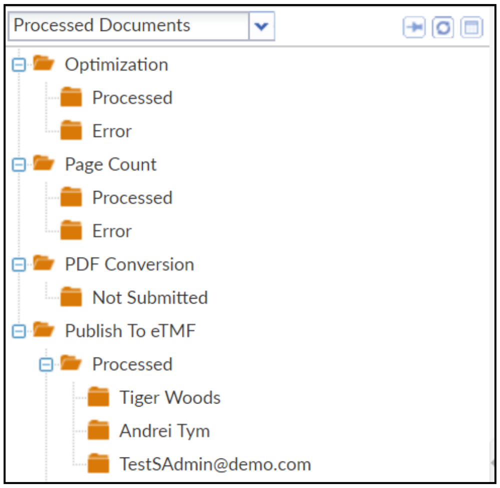
1. From the **Non PDF to PDF Conversion settings** window, select **Conversion Type** as **Manual**. Refer to the screenshot above.
2. Navigate to the **Documents module -> Import -> Documents**. The Import Document window opens.
3. Upload a document and enter the document metadata.
4. Check that the option **Convert the Non-PDF Documents to PDF** is available in the window.
5. Select the option if you want to convert the non-pdf document to pdf manually and import the document. Refer to the screenshot below.



You can view these non-pdf to pdf converted documents under the Processed Documents View -> PDF Conversion -> Processed folder.

31.2. Processed Documents View

All the documents that traverse through various processes in a study can be viewed from here. Refer to the screenshot below.



Some examples of processes in a study that the documents need to pass through are **OCR**, **Optimization**, **Page Count**, **PDF Conversion**, **PDF Fixation**, **Publish to eTMF**, and **Document Type Auto Prediction**. The documents are listed under each process in this. Under each process, the documents are further categorized into **Not Submitted**, **Pending**, **Processed**, and **Error**.

For example, as a user, you might want to submit documents for PDF Conversion. All the documents that were converted into PDF will appear under the **Processed** folder. If some documents could not be converted into PDF due to some error, they will appear under the **Error** folder. The documents that were not submitted for PDF Conversion will appear under the **Not Submitted** folder, and those that are still pending for conversion will appear under the **Pending** folder.

Similarly, all documents that are published from a Shared Workspace to its eTMF room get recorded under various sub-folders in the **Processed** folder. For further details on this proceed to Shared Workspace section.

32. Sites, Required Documents, Countries and Contacts

32.1. Investigative Sites Settings

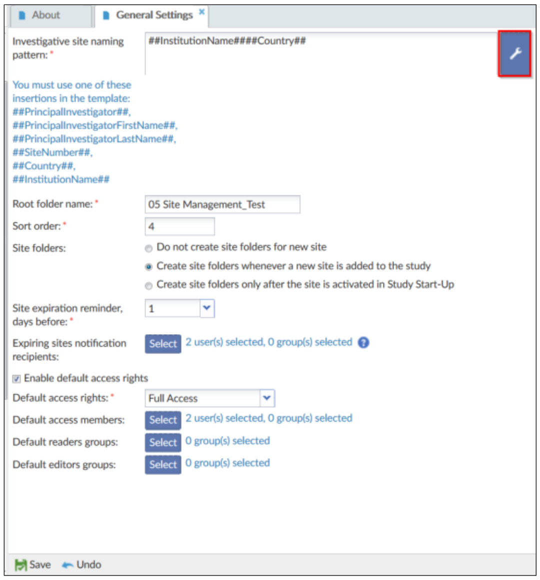
By clicking the **Investigative sites** tab in the menu, the Administrator gains access to panels that control settings related to generic components for each investigative site for the study.

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

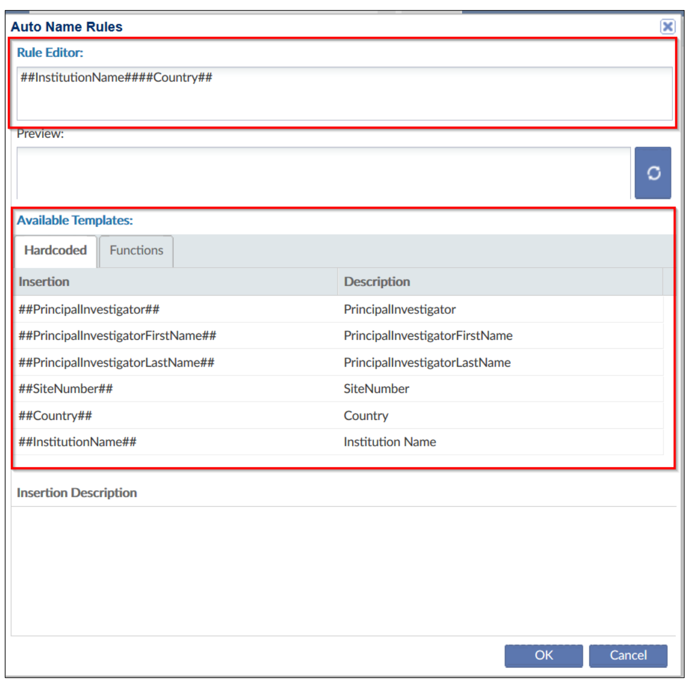
32.1.1. General Settings

This is a very active panel that houses a lot of options. The choices made here are dictated by client preferences.

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



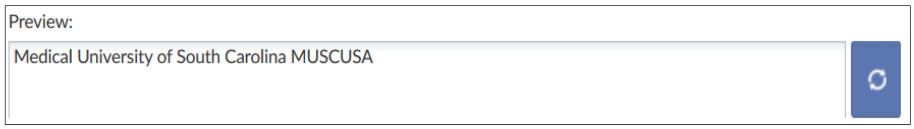
1. Click the wrench icon to the right of the **Investigative Site Naming Pattern** box.
   a. An **Auto Name Rules** window opens. The naming pattern is built and displayed in the **Rule Editor** box. The information that populates in the box is selected from the list of **Available Templates**. You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



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

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

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



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

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

   a. Click in the field.

   b. Type the root folder name.

   c. Hit the **Enter** key on the keyboard.

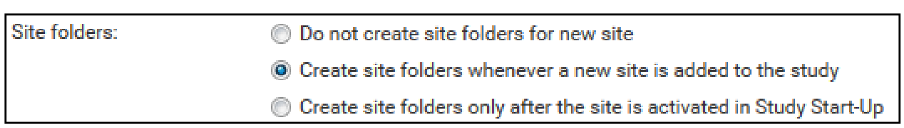
3. Selection of the **Sort Order** for the Site Management folder is made in the next field. This dictates where the folder appears in the room's folder index.

   b. Click in the field.

   c. Type the number of the client's preference.

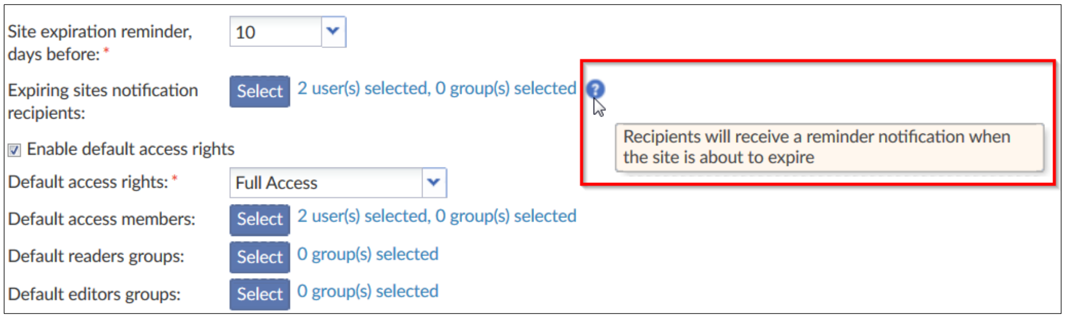
   d. Hit **Enter** on the keyboard.

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



5. Like the previously described settings, the rest of the settings in this panel are dictated by client preferences. Closely follow any and all instructions from the client in controlling these settings.

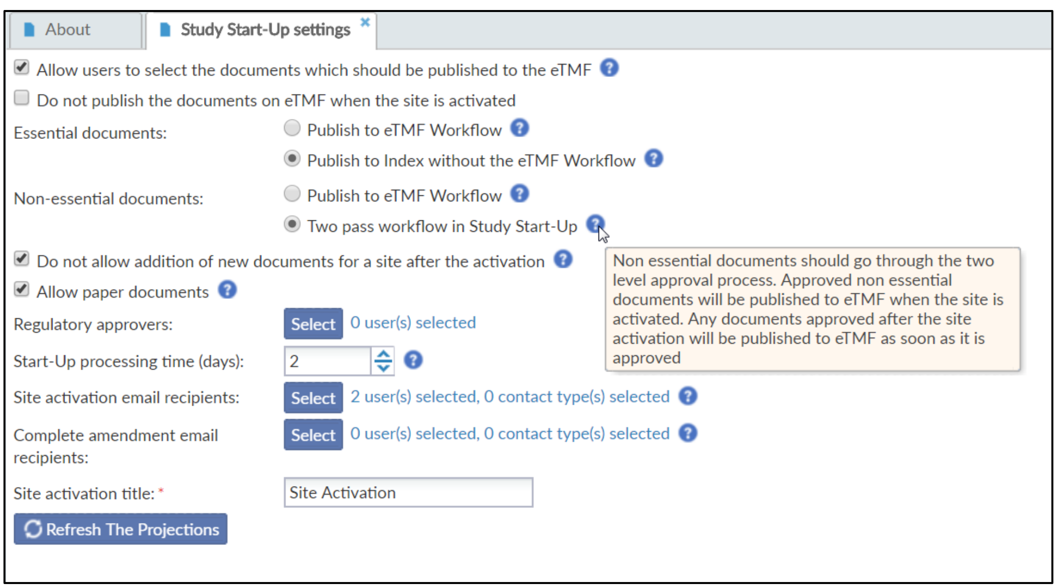
6. Hover the mouse over the question marks in blue circles for more information about specific options on the screen.



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

32.1.2. Study Start-Up settings

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

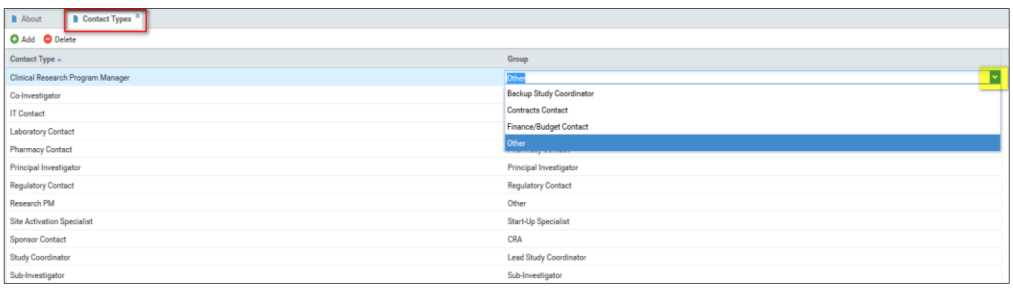


This is further discussed in detail in Study Start-up Guide.

32.1.3. Contact Types

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

1. Click **Add**. The **Contact Type** field becomes active.
2. Type the contact name provided by the client.
3. Hit **Tab** or **Enter**.
4. Click the field in the **Group** column to make it active.
5. Click the far-end right edge of the field to activate the dropdown menu.



6. Select the group title from the list that best corresponds to the client-requested Contact Type name.

   Additions and changes made here are saved automatically.

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

32.1.4. Submission Profiles Status

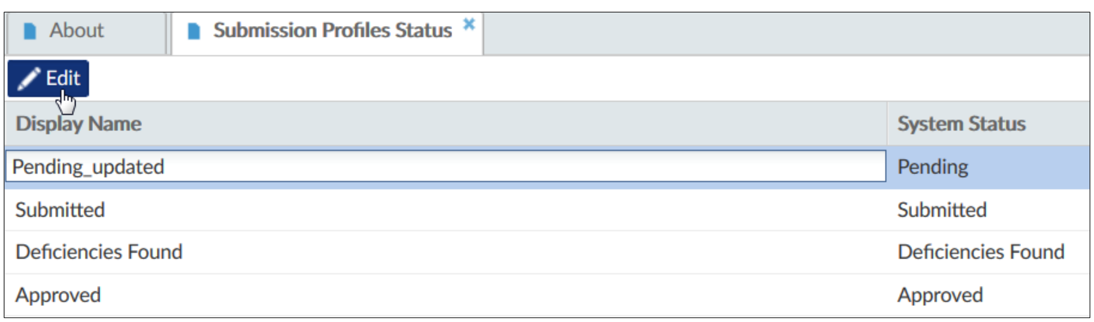
It is common practice to associate health agencies with sites and send submission packages to them for their approval. Sites can't be activated for the clinical study unless the agency approval is received. A study may have multiple health agencies located in various countries. These agencies may have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

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

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

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

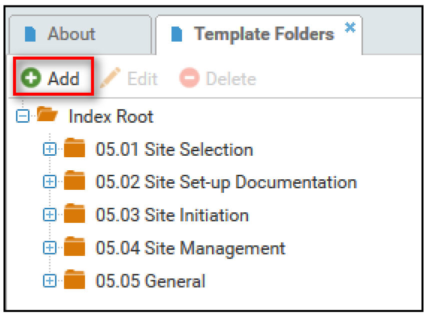
This panel provides the list of Submission Profiles and their System Statuses. The administrator may edit a submission profile by double-clicking the Display Name of a submission profile or by selecting a profile and clicking Edit from the top ribbon bar of the panel.



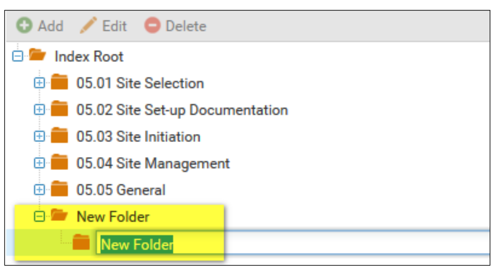
32.1.5. Template Folders

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

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



2. Type the name of the first folder in the available field.
3. To add another folder at the same index level, click the **Index Root** folder and click **Add**.
4. To add a subfolder inside a folder you have already created, click the name of the new folder and click **Add**.



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

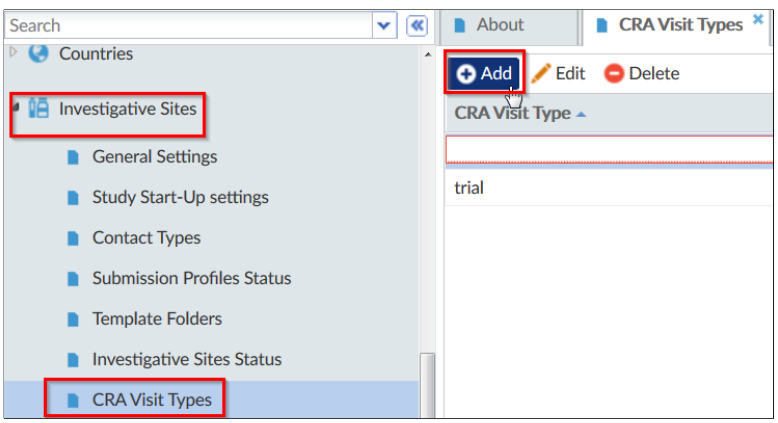
32.1.6. Investigative Sites Status

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

32.1.7. CRA Visit Types

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

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



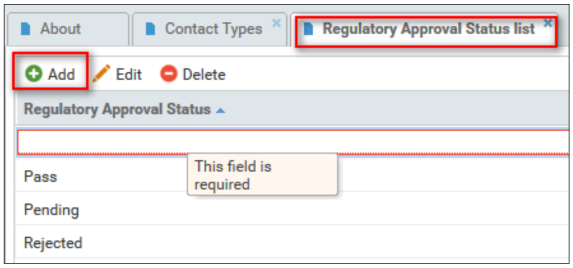
1. To add a new visit type, click the **Add** button at the top of the portlet window.
2. Type in the desired term and press **Enter**.

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

32.1.8. Regulatory Approval Status list

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

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



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

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

32.1.9. Communication Types

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

1. To add a new Communications Type label, click the **Add** button.

   An empty test field opens.
2. Type in the label. By default, the new communication type is not Enabled.

3. To enable the label for use in the study, double-click on **No**.

   That field becomes active with a dropdown menu.

4. Click **Yes** to enable the use of the new label option.

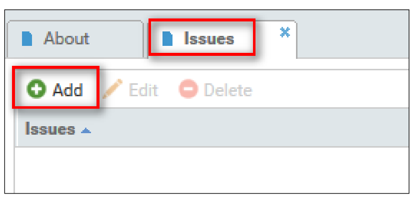
   The change saves automatically.

32.1.10. Issues

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

1. Click **Add**.

   A text field opens.



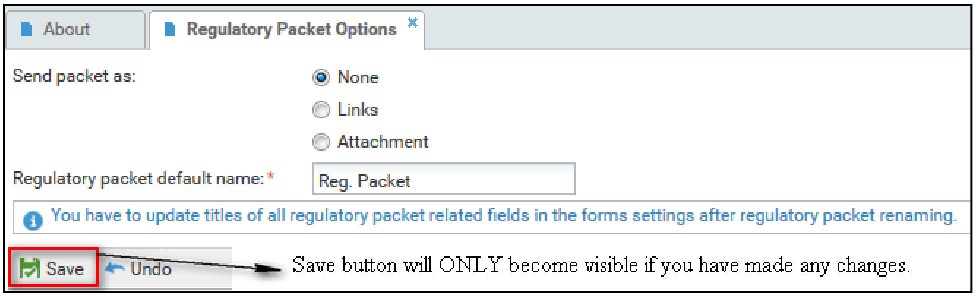
2. Type the description of the issue in the field.

3. Press **Enter**.

   The changes are saved automatically.

32.1.11. Regulatory Packet Options

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



The name associated with the Regulatory Packet is also configurable. The user can edit the name in the available text field.

The Administrator user confirms any changes in this portlet by clicking **Save** at the bottom of the panel after making changes.

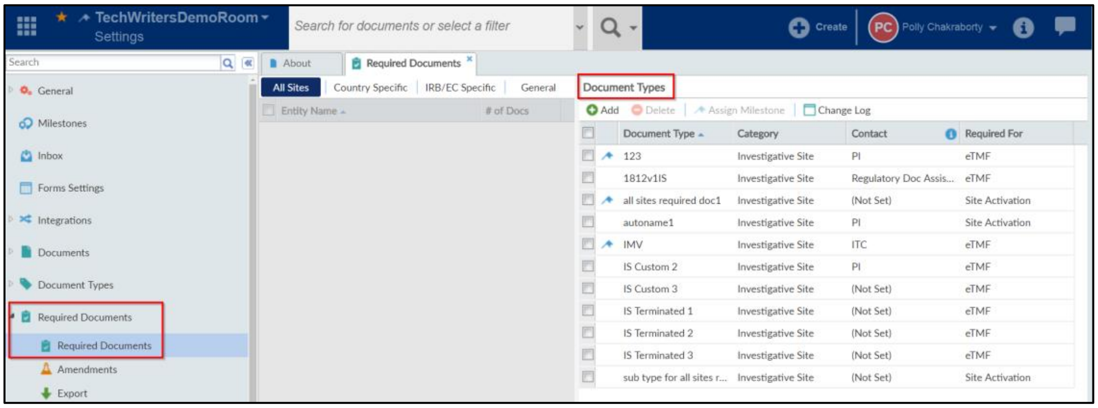
32.2. Required Documents Settings

Through this **Settings** tab, 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. It is recommended that administrators contact the Trial Interactive Project Management Team if any changes or additions are needed here. Once Document Types are set up for a room from Document Types Management, you can set up the Required Documents.

Refer to the screenshot below showing the **Required Documents panel**.

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, **All Sites** category is chosen.
2. From the right section of the panel, named as **Document Types**, you can:
   a. **Add** Add or **Delete** Delete a Required Document to the category selected from the left pane.
   b. **Assign Milestones** Assign Milestone to selected Required Document Types.
   c. View the activity log of the selected category from the **Change Log** Change Log.

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



32.2.1. For All Sites

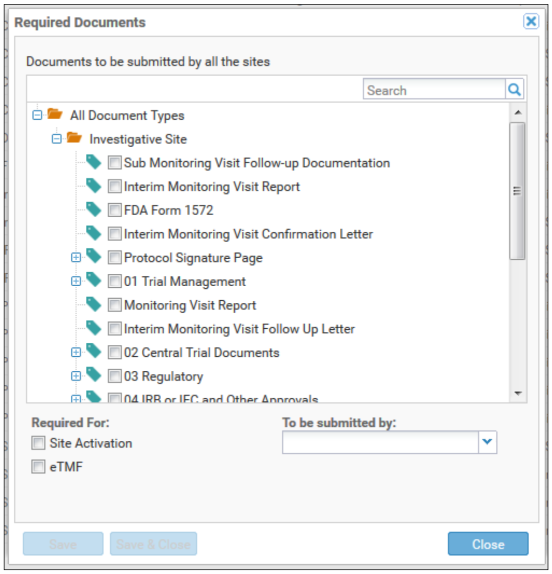
By default, no documents are required. Required documents must be defined in this settings view.

> ***If the room has been cloned from a previously used room, the Required Documents may already be defined.***

1. Select **All Sites** from the left panel.
2. Click **Add** from the top ribbon bar of the **Document Types** window on the right.

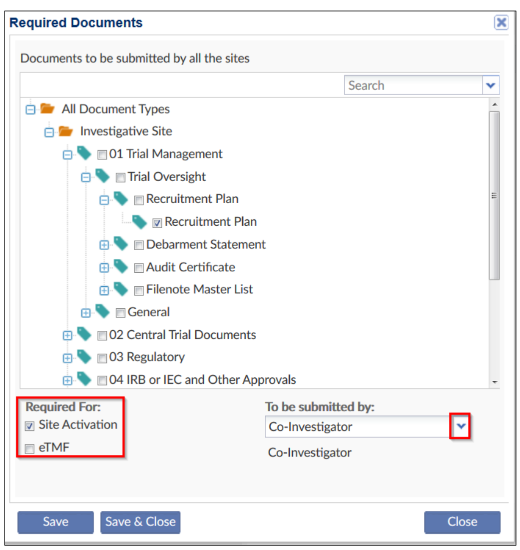
   Here, you can add document types that will be required by all sites included in the study. Refer to the screenshot above.

3. The **Required Documents** window opens.



4. Click the category folder from which you need to select the Required Document that you want to add to the list for all sites.

   The list of the available document types in that category folder appears.



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 menu to the right, select which study contact is responsible for providing the selected required documents.

   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.

> ***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.***

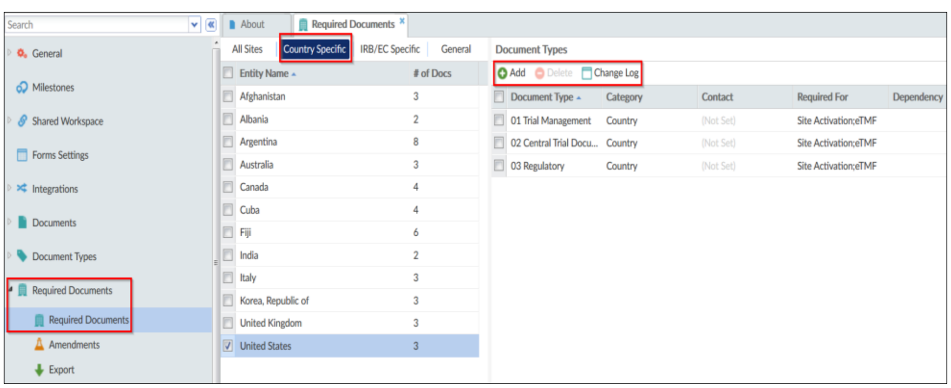
32.2.2. Country Specific

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

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

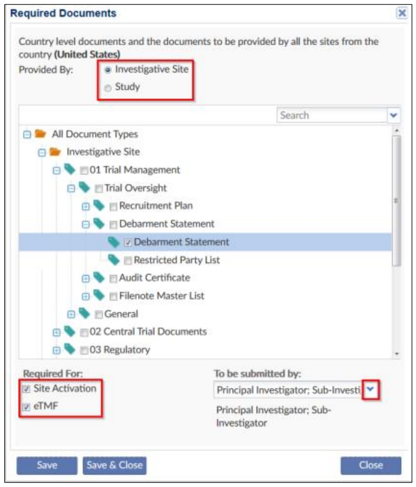
> ***Countries being used for a study are entered during initial Room Configuration. Instructions for [Adding Countries](#) can be found in another section of this guide.***

The list of countries will activate in the left pane.



2. Select the particular country for which you need to add a required document.
3. The **Document Types** window on the right becomes active.

4. Click **Add** from the top ribbon bar of the **Document Types** window on the right.



A new window opens, affording you the opportunity to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).

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

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

10. Click **Save**.
11. Begin again at the top of the Required Documents window.
12. Select the Study documents to be required.
13. Click the appropriate checkboxes for eTMF and/or Site Activation.

14. Click **Save & Close**.
15. Select the next country in the list to which you need to add required documents, and follow the process steps above.

32.2.3. IRB/EC and General

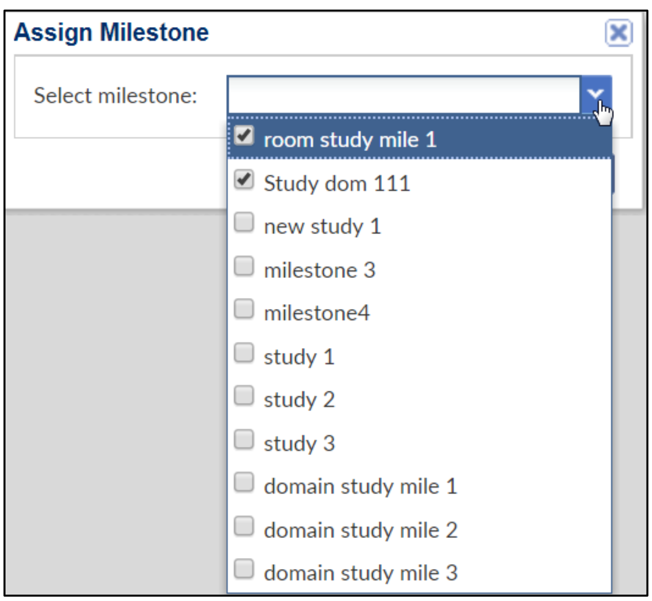
Similarly, as discussed above, you can add the document types for **IRB/EC** and **General**

32.2.4. Assigning Milestones to Required Documents

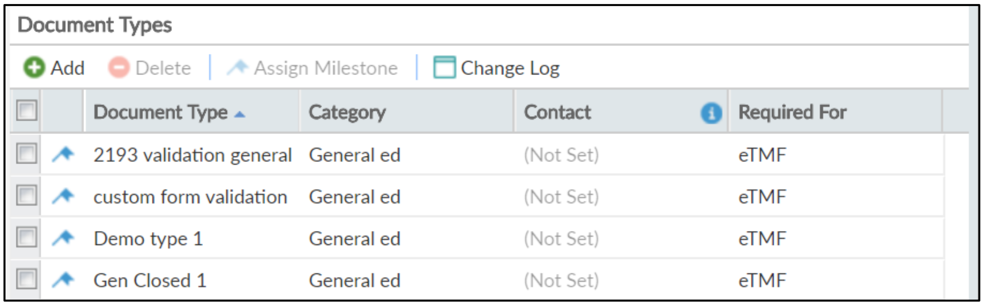
To assign a milestone to a Required Document, follow the steps as below:

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

from the top ribbon bar.
5. The **Assign Milestone** window opens.
6. Choose the milestones from the dropdown list



7. Click **Assign Milestone** button from the popup window.
8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**. Refer to the screenshot below:


Document Types

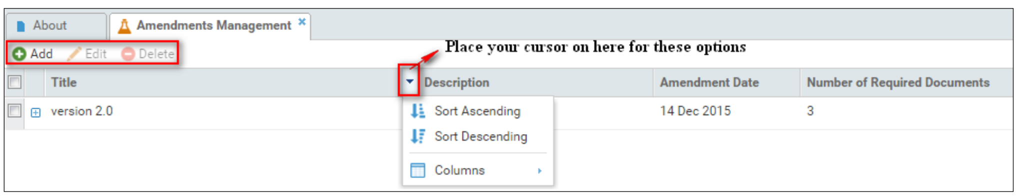
Add | Delete | Assign Milestone | Change Log

Document Type	Category	Contact	Required For
2193 validation general	General ed	(Not Set)	eTMF
custom form validation	General ed	(Not Set)	eTMF
Demo type 1	General ed	(Not Set)	eTMF
Gen Closed 1	General ed	(Not Set)	eTMF

32.2.5. Amendments

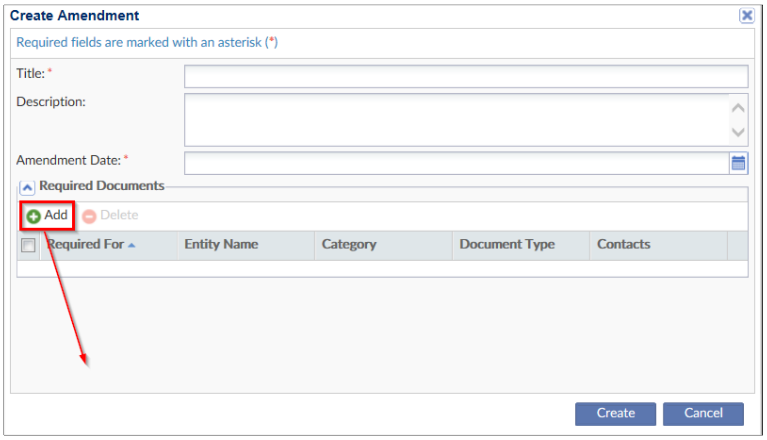
In the **Amendments** panel, Administrator users can add, edit, and delete amendments. It will provide a list of documents that need to be collected and thus Administrator users can track the needed documents more conveniently.

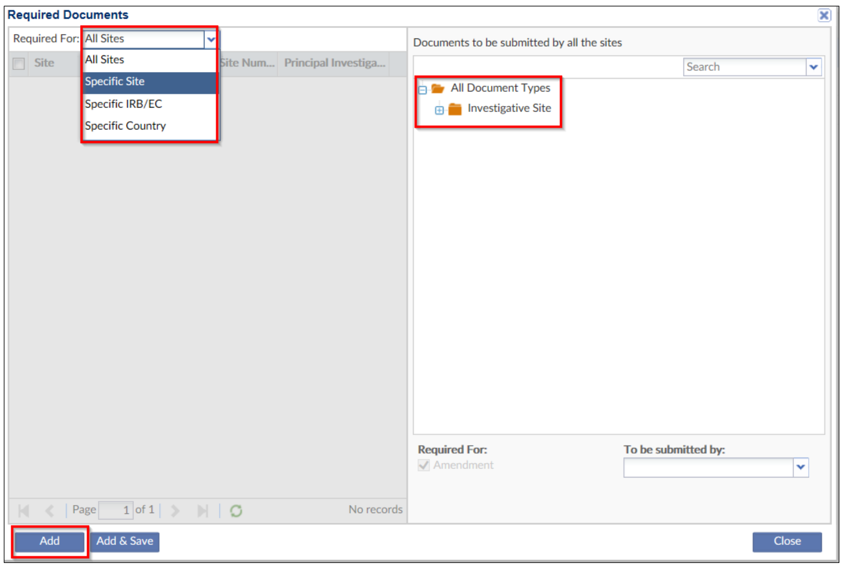
You can sort the columns by ascending or descending order, and also can manage which columns will be shown or hidden.



Adding a new amendment:

1. Simply click the **Add** button from the top ribbon bar
2. Specify the title and the amendment date, which are mandatory fields.
3. You are also given an option to provide a description.
4. Then, click on the **Add** button placed under the **Required Documents** panel, and add the documents that need to be submitted for the specific amendment created. Refer to the screenshots below:

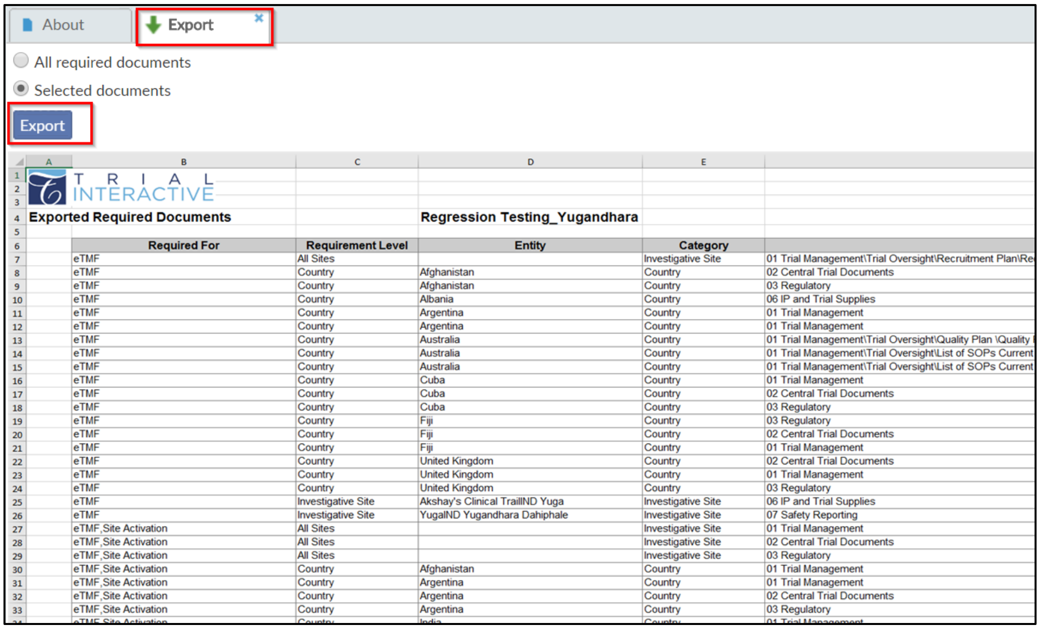




To edit the amendment, double-click the particular amendment or click the **Edit** button under the tab. To delete, use the **Delete** button or right click on the amendment and click delete.

32.2.6. Export

In this panel, Administrator users can export either all required documents or selected required documents. Select one option and click the **Export** button. 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 — Regression Testing_Yugandhara

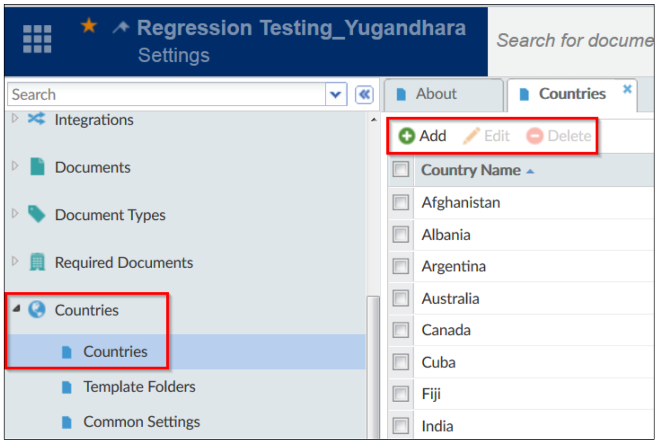
Required For	Requirement Level	Entity	Category	
eTMF	All Sites		Investigative Site	01 Trial Management\Trial Oversight\Recruitment Plan\Re
eTMF	Country	Afghanistan	Country	02 Central Trial Documents
eTMF	Country	Afghanistan	Country	03 Regulatory
eTMF	Country	Albania	Country	06 IP and Trial Supplies
eTMF	Country	Argentina	Country	01 Trial Management
eTMF	Country	Argentina	Country	01 Trial Management
eTMF	Country	Australia	Country	01 Trial Management\Trial Oversight\Quality Plan \Quality
eTMF	Country	Australia	Country	01 Trial Management\Trial Oversight\List of SOPs Current
eTMF	Country	Australia	Country	01 Trial Management\Trial Oversight\List of SOPs Current
eTMF	Country	Cuba	Country	01 Trial Management
eTMF	Country	Cuba	Country	02 Central Trial Documents
eTMF	Country	Cuba	Country	03 Regulatory
eTMF	Country	Fiji	Country	03 Regulatory
eTMF	Country	Fiji	Country	02 Central Trial Documents
eTMF	Country	Fiji	Country	01 Trial Management
eTMF	Country	United Kingdom	Country	02 Central Trial Documents
eTMF	Country	United Kingdom	Country	01 Trial Management
eTMF	Country	United Kingdom	Country	03 Regulatory
eTMF	Investigative Site	Akshay's Clinical TrailND Yuga	Investigative Site	06 IP and Trial Supplies
eTMF	Investigative Site	YugaIND Yugandhara Dahiphale	Investigative Site	07 Safety Reporting
eTMF,Site Activation	All Sites		Investigative Site	01 Trial Management
eTMF,Site Activation	All Sites		Investigative Site	02 Central Trial Documents
eTMF,Site Activation	All Sites		Investigative Site	03 Regulatory
eTMF,Site Activation	Country	Afghanistan	Country	01 Trial Management
eTMF,Site Activation	Country	Argentina	Country	01 Trial Management
eTMF,Site Activation	Country	Argentina	Country	02 Central Trial Documents
eTMF,Site Activation	Country	Argentina	Country	03 Regulatory

32.3. Countries Settings

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

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

32.3.1. Countries



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 are displayed. These countries can be added, edited or deleted from the buttons in the ribbon above the country listing.

Add Countries

1. Click **Add** Add from the ribbon above the country listing. The **Create country** window opens.
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.

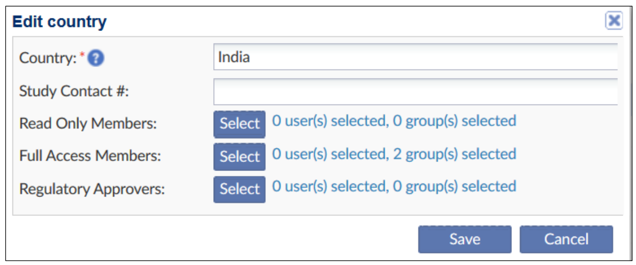
> ***You can ease the process of finding the country name in the list by typing the first few characters in the country name. The dropdown list will shorten to include only the countries whose names begin with the characters you have typed.***

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

Edit Countries

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

1. Click **Edit** Edit at the top of the **Countries** window. The **Edit country** window opens.
2. It might be that after you've added the country to the list you are supplied with the study contact phone number later.



3. Click in the **Study Contact#** field to change the information there.
4. Click **Select** next to **Read Only Members** or **Full Access Members** or **Regulatory Approvers** to add or delete users or groups of users from these access settings.
   These selections will probably not be available at this early stage of room configuration. Room configuration is not a strictly linear process – you will have to make additions and changes in other areas on the Trial Interactive platform in order to complete the room's configurations.
5. Click **Save**.

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

Delete 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** Delete near the top of the **Countries** window. The country name(s) will delete automatically, without giving you a warning.
3. At a later stage in the study, once documents have begun to populate the room's index folders, you won't be able to delete countries that have associated documents.
   Adding to and editing the Countries list can go on as the study progresses.

32.3.2. Template Folders

In this window, you can **Add**, **Edit**, or **Delete** template folders and subfolders in the root folder for managing country-specific documents. The details necessary for completing this stage of the room configuration come from the client – the titles and the order of the folders to be included. The folder structure is fairly consistent, but it is always study specific.

Adding Folders and Subfolders to the Country Index Structure

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

Editing Names of Folders and Subfolders in the Country Index Structure

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 from the Country Index Structure

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 D**elete** from the available options. The folder disappears from the index structure.

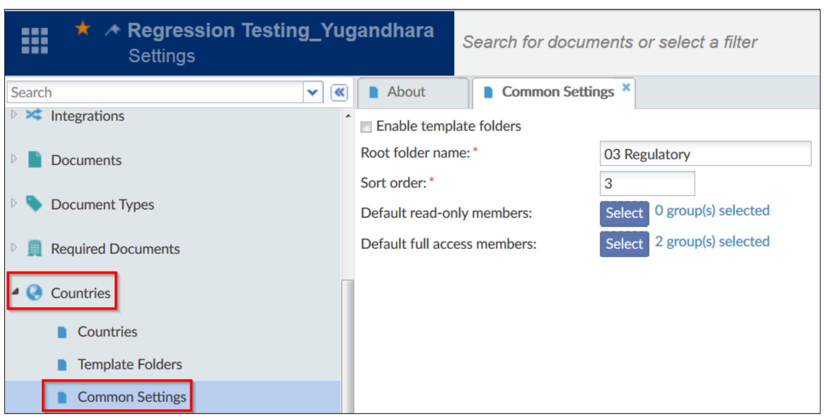
Folders that contain subfolders or documents cannot be deleted.

32.3.3. Common Settings

In the **Common Settings** window, you can:

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

   Refer to the screenshot below:

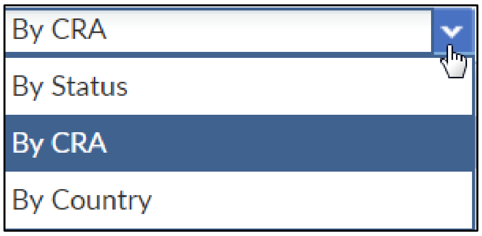


32.4. Sites

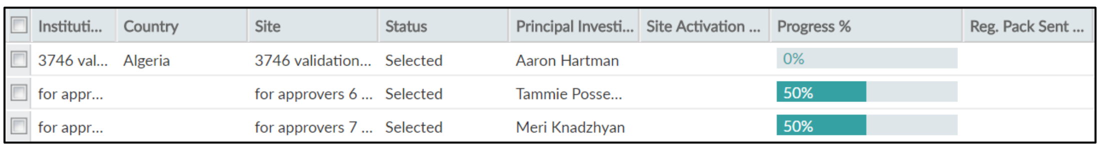
You can access the **Sites** module by clicking **Sites** icon  on the menu bar at the left. The **Sites Module** is used for site management purposes and allows the administrator to track the progress of the sites. It gives detailed information on all investigative sites available in a room **By Status**, **By CRA**, and **By Country**.

32.4.1. By Status

Select **By Status** from the dropdown in the Index Pane of Sites Dashboard.



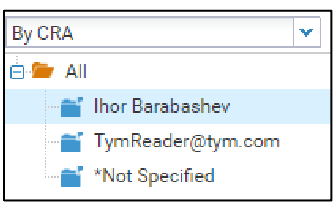
This will populate the data of all the sites available in the room based on their progress report in the right pane of the dashboard.



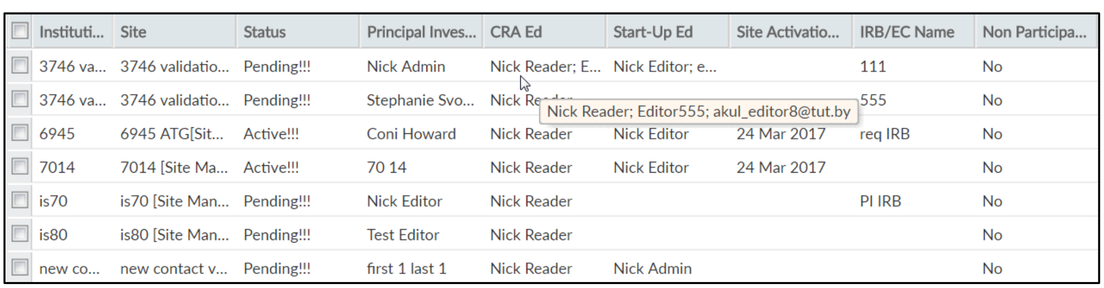
Instituti...	Country	Site	Status	Principal Investi...	Site Activation ...	Progress %	Reg. Pack Sent ...
3746 val...	Algeria	3746 validation...	Selected	Aaron Hartman		0%	
for appr...		for approvers 6 ...	Selected	Tammie Posse...		50%	
for appr...		for approvers 7 ...	Selected	Meri Knadzhyan		50%	

32.4.2. By CRA

Select **By CRA** from the dropdown in the Index Pane of Sites Dashboard.



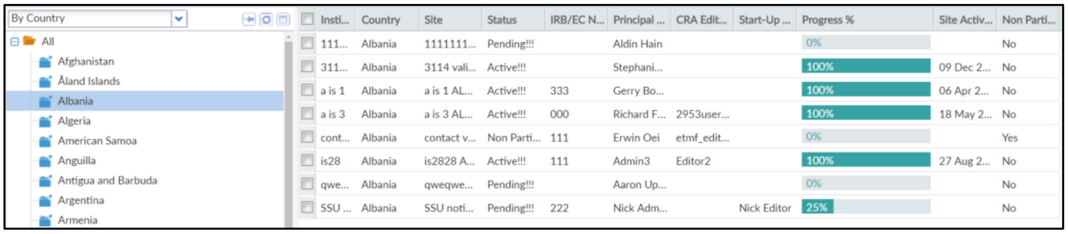
This will populate the Clinical Research Associate (CRA) for the available sites in the Index Pane on the left. Click the name of a CRA to populate the site details associated with that particular CRA in the right pane.



Instituti...	Site	Status	Principal Inves...	CRA Ed	Start-Up Ed	Site Activatio...	IRB/EC Name	Non Participa...
3746 va...	3746 validatio...	Pending!!!	Nick Admin	Nick Reader; E...	Nick Editor; e...		111	No
3746 va...	3746 validatio...	Pending!!!	Stephanie Svo...	Nick Reader; Editor555; akul_editor8@tut.by			555	No
6945	6945 ATG[Sit...	Active!!!	Coni Howard	Nick Reader	Nick Editor	24 Mar 2017	req IRB	No
7014	7014 [Site Ma...	Active!!!	70 14	Nick Reader	Nick Editor	24 Mar 2017		No
is70	is70 [Site Man...	Pending!!!	Nick Editor	Nick Reader			PI IRB	No
is80	is80 [Site Man...	Pending!!!	Test Editor	Nick Reader				No
new co...	new contact v...	Pending!!!	first 1 last 1	Nick Reader	Nick Admin			No

32.4.3. By Country

Select **By Country** from the dropdown in the Index Pane of Sites Dashboard. This will populate the countries where the studies are being conducted in the Index Pane on the left. Click the name of a country to populate the site details associated with that particular country in the right pane. Refer to the screenshot below.

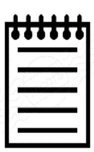


Besides retrieving site details, you can perform various other activities associated with a site, such as:

1. Adding, Editing, and Deleting sites
2. Importing, and Exporting Sites
3. Mass Coding metadata for sites
4. Managing Security.

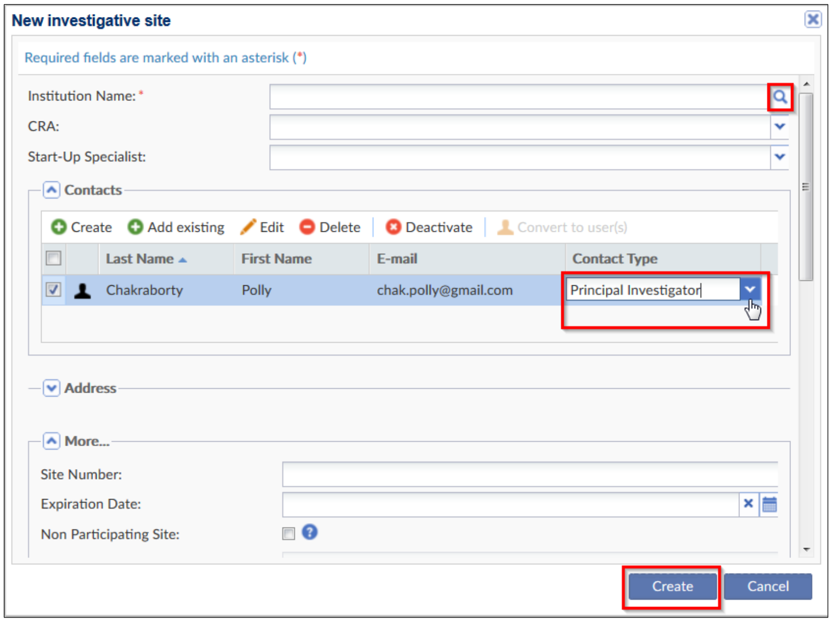
All the above activities can be performed by accessing the icons located on the top ribbon bar.

32.4.4. Adding, Editing, and Deleting Sites



- ***The following description is for adding Investigative Sites in an eTMF. Sites are added to the Study Start Up module by a slightly different method. If SSU has been enabled for the study, the user first clicks the Study Start Up icon at the top, then selects the Sites tab. The rest of the process of adding Investigative Sites is the same as the process described below.***
- ***Sites added from the eTMF/Sites module also appear in the Study Start-Up, if that is enabled for you.***

1. Click **Add** Add icon from the top ribbon bar. The **New investigative site** window opens.



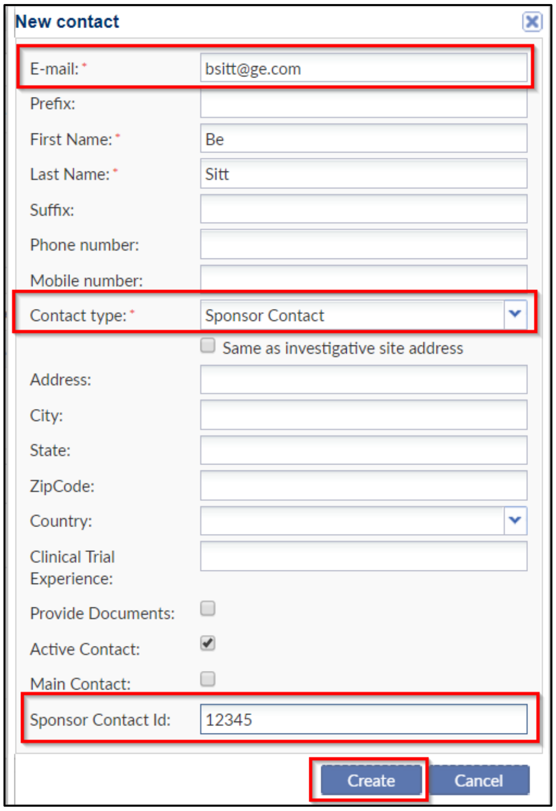
2. Either type the Institution Name in the available field or click the search icon to view the list of **Available Investigative Sites**.

   Investigative site information is stored in Trial Interactive's database. If a client has used an investigative site in a previous study, the site's information will be stored and easily accessed through this option.

> ***With Trial Interactive 9.2, you can add multiple investigative sites with the same institution name. Only the Principal Investigator needs to be different if institution names are the same.***
>
> ***The Site number is an optional field and can be left blank. But if it is filled, it should be different between two or more investigative sites.***

3. **Create** Create or **Add existing** Add existing contacts from the **Contacts** panel in the window. This information will be supplied by the client and can be created under Contact Types in Investigative Site Settings.

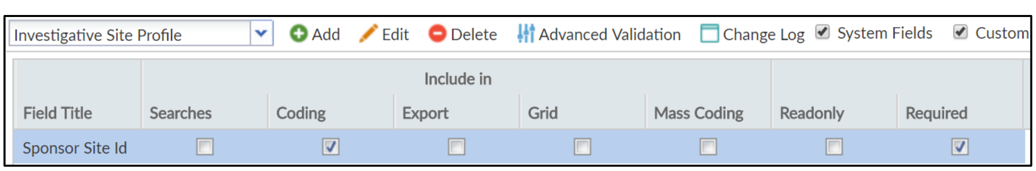
   You can also add the Contact Type by clicking the contact type field which will then reveal the dropdown list to select your choice. Refer to the screenshot below:



The Sponsor Contact ID is used by the system as the unique identifier of sites used by third parties to enable their integration with Trial Interactive. Hence, the Sponsor Contact ID will need to be a Required field so that it can be passed to Trial Interactive.

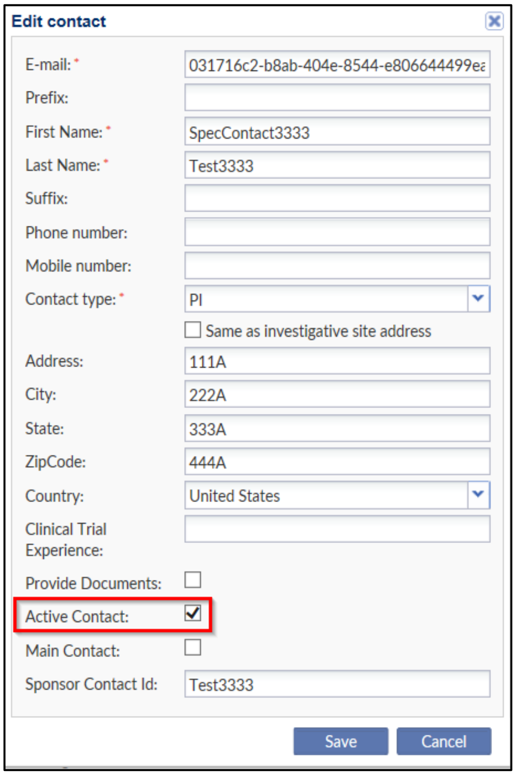
Similarly, to detect duplicate entries of site contacts, the email-id field is now case-insensitive.

To make the Sponsor Contact ID a Required field proceed to **Settings -> Form Settings -> Investigative Site Profile**. Select the **Sponsor Site ID Field title** from the list **of System Fields** and tick the checkboxes under the **Coding** and **Required** column.



Field Title	Searches	Coding	Include in Export	Grid	Mass Coding	Readonly	Required
Sponsor Site Id	☐	☑	☐	☐	☐	☐	☑

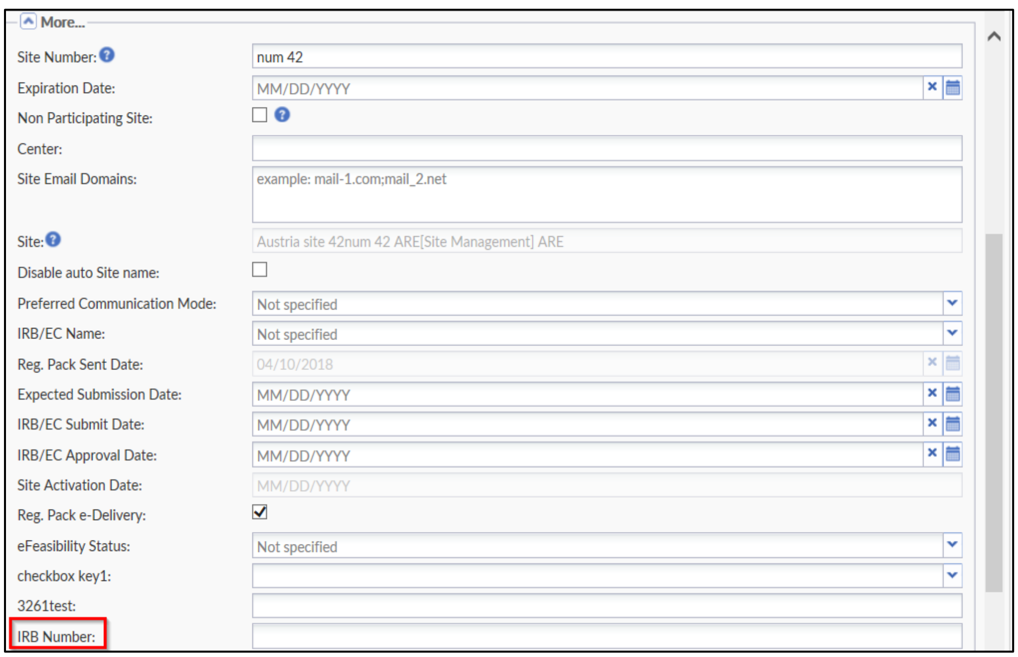
4. Select an added contact and click **Edit** Edit in the Contacts panel to edit the contact information entered above, or **Delete** Delete to delete a contact information.
   You can also edit a contact by double-clicking the contact in the Contacts panel.
5. Click **Activate** or **Deactivate** to activate or deactivate a contact. This will either check or uncheck the **Active Contact** checkbox in the **Edit contact** window. Refer to the screenshot below.



6. You can assign a site contact the role of editor or reader and assign actions as appropriate from the [Convert to User(s)]() Convert to user(s) utility in the **Contacts** panel.
7. Click **Address** to reveal the fields to enter the site location details. Based on the address entered the system shall calculate the Geo Code of the site and populate it in the new field **Geo Code**. Refer to the screenshot below:

The Geo Code field too needs to be activated from Settings -> Form Settings -> Investigative Site Profile -> Geocode. This is an important field for the myTI mobile app to detect site

Click **More** to open another array of data fields. Enter the investigative site information provided by the client. Refer to the screenshot below:



The IRB Number field is used for [IRB Integration](#) if this is enabled for you.

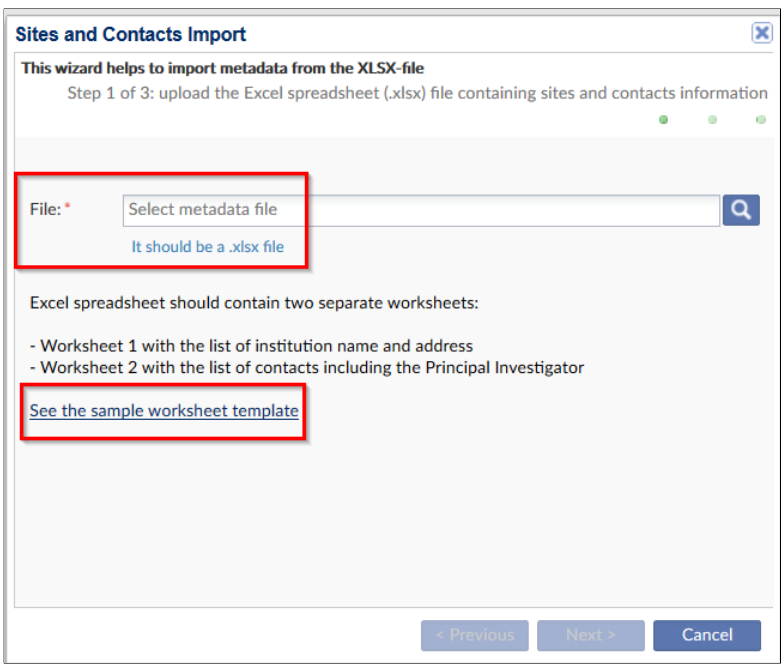
8. Click **Create** at the bottom of the window.

9. Repeat this process until all investigative sites have been created for the room.
10. Similarly, you can **Edit** or **Delete** a site by first selecting the site from the right pane and then clicking **Edit** Edit or **Delete** Delete buttons from the top ribbon bar. You can also edit a site from the **Site Profile** window also. This is discussed under Site Profile.

32.4.5. Importing Sites

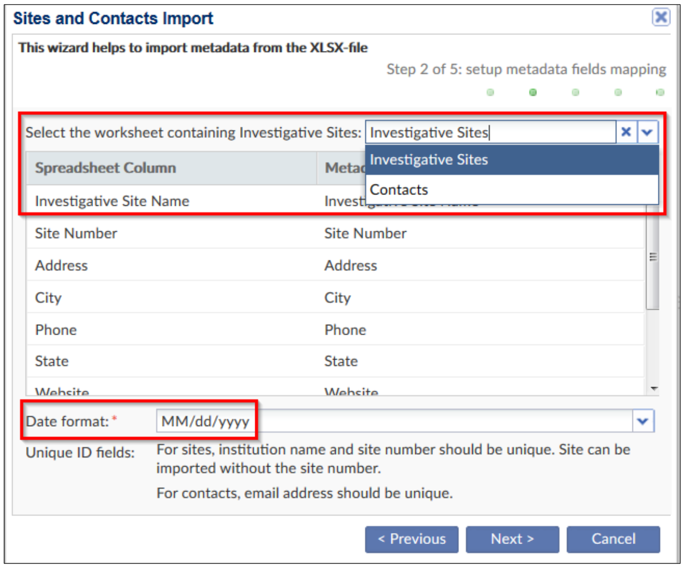
The metadata and contact information for an investigative site can be imported by using the Import icon Import located on the top ribbon bar. It runs the metadata import wizard where the user can upload an .xlsx spreadsheet, setup columns and metadata fields mapping, perform actual import and observe the result.

1. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import just contacts so they will be mapped to existing investigative sites. The wizard offers a link to the sample worksheet so user can download it and fill with actual data. Click **Next.**



2. Setup the mapping between metadata fields and uploaded file columns for Investigative Sites. It is possible to skip sheet selection in case you do not want to import

investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.**

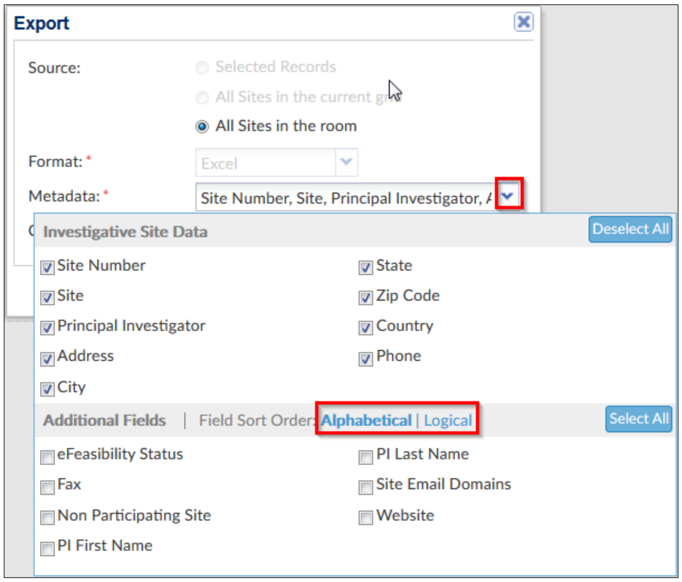


3. Setup the Contacts related metadata. Click **Next**.
4. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.
5. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.
6. It is also possible to download the full report as a text file. The import operation can be aborted any time.

32.4.6. Exporting Sites

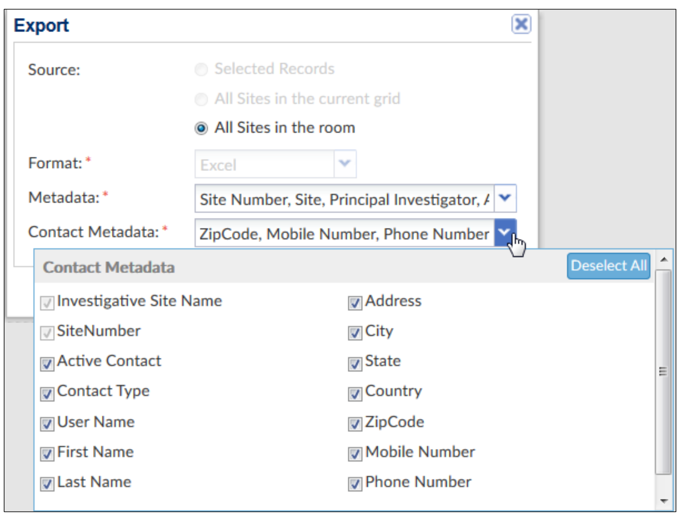
You can also export site metadata through the **Export** window that appears on clicking the **Export** icon 

on the ribbon. Refer to the screenshot above. You may export sites selected from the right panel, or all the sites in the current grid or room. To export site data, it is mandatory to select the **Site Metadata Fields** as shown below:



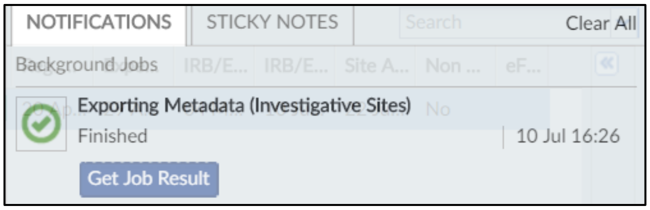
You can export the additional fields in either alphabetical or logical order of selection.

Similarly, to export site contact data, you need to select **Contact Metadata** fields as shown below:



The export job result will be saved as an excel file. During export, a popup showing the status of the export job is shown. Refer to the screenshot below.

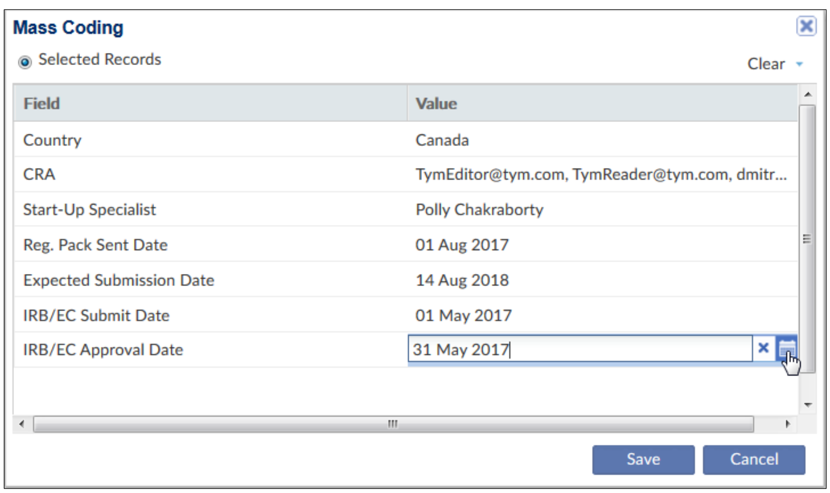
The export result are also populated in the **Notifications.** Click **Get Job Result** to view the excel file.



32.4.7. Mass Coding For Sites

Administrators are sometimes called upon to fill in or update the metadata of a number of sites in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Select the sites to be coded in your grid.
2. Click the **Mass Coding** Mass Coding tool from the top ribbon bar. The **Mass Coding** window opens.



3. Fill in the details by double-clicking the fields, and click **Save** to proceed with mass update of the sites' metadata.

   You can select multiple CRAs and Start-Up Specialists, if required.

32.4.8. Manage Security for Sites

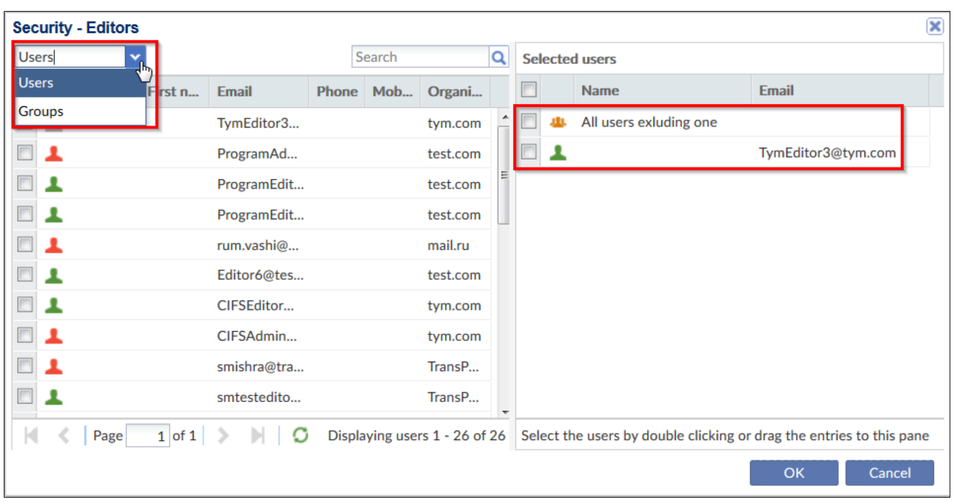
There are two site level securities available for sites:

1. Editor
2. Reader

Administrators can use **Manage Security** to include users to any one of these groups:

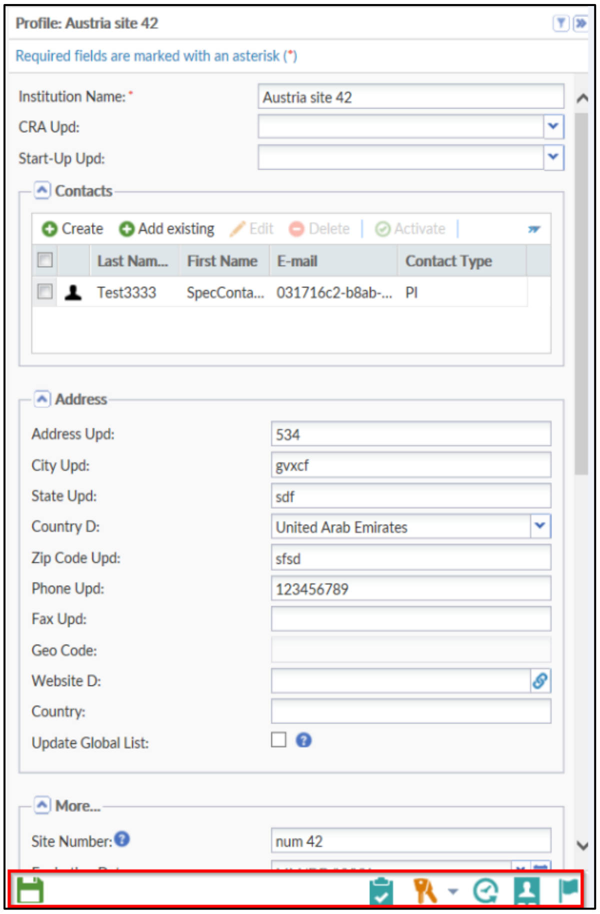
1. Select the sites from the grid and click **Manage Security** dropdown from the top ribbon bar.
2. Select the type of users to add to the security groups. You can add either **Editors** or **Readers**. Refer to the screenshot below:

3. This will open either the **Security – Editors** or **Security – Readers** window as per your choice.
4. Select the users in the **Users** tab to add to the security group, or/and click the **Groups** tab to select a group of users to be added to the security group. Click **Ok**. An example for adding editors is shown below. The readers too would be added in a similar manner.



32.4.9. Site Profile

Open the **Site Profile** window by clicking the caret symbols  at the top right corner of the dashboard. This will allow you to fill all the metadata related to the selected sites. Refer to the screenshot below.

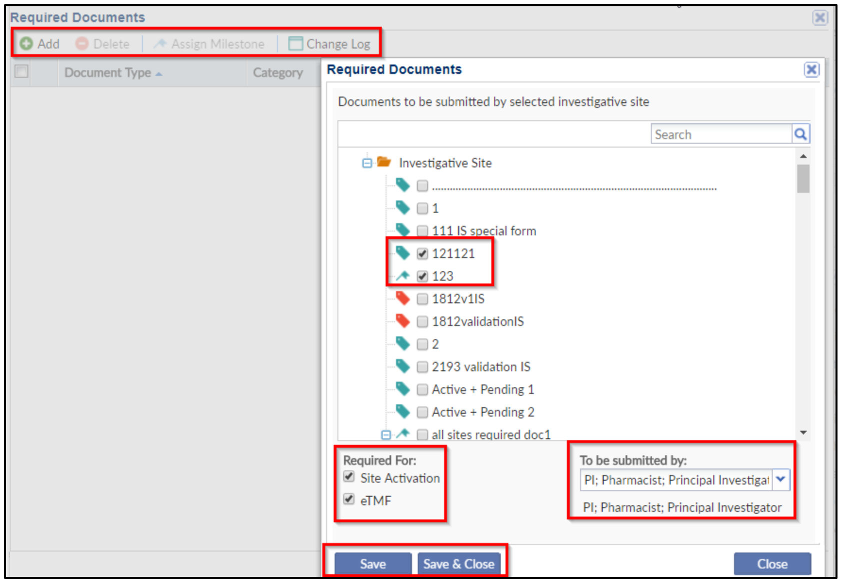


Through the ribbon at the bottom of the Site Profile window, you can:

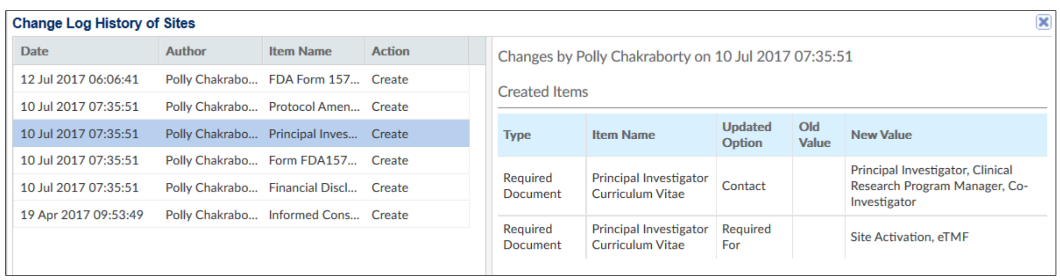
1. Save the site profile data entered.
2. Add **Required Documents** by clicking the icon. This will open the Required Documents window. You can also add required document from the **Edit Investigative site** window.
   - Click **+Add** Add to add documents. Drilldown the index to select documents required for **Site Activation** and/or **eTMF**.

     Select the **authority** who are required to submit the documents.

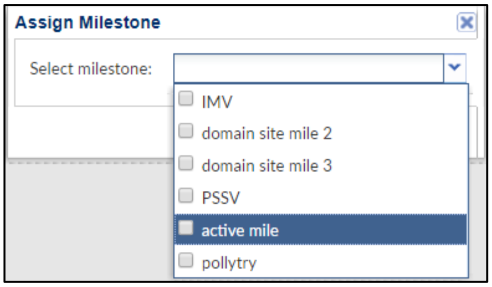
     Click **Save** or **Save & Close**. Refer to the screenshot below.



- Similarly, click **Delete** in the Required Documents window to delete a selected required document from the added list.
- You can also view the Change Log History of selected documents by clicking the **Change Log** from the **Required Documents** window. This will open the change log history in a separate popup. Refer to the screenshot below:



- Add milestones to track the eTMF Completeness of the Required Documents by clicking the **Assign Milestone** icon on the Required Documents window toolbar. Refer to the screenshot below:



More details of Document type association with a milestone in [Documents Type Management](#).

3. **Manage Security** by clicking this icon.

   This functionality is the same as discussed above with the only difference that invoking the function from the metadata panel will allow you to add users to the security groups only for the selected site, and not for multiple sites together as above.

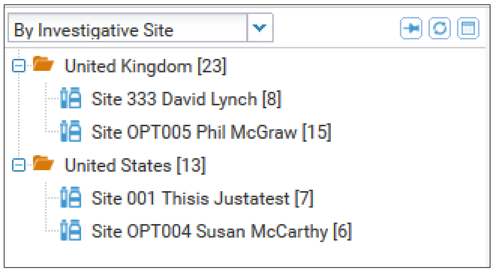
4. View the **Investigative Site Edit History** by clicking this icon.

5. Get the **list of activities** made by the contacts of the site.

6. View **Milestone History** by clicking this icon. You can also **add**, **edit**, or **delete** milestone history from here. This functionality is discussed in detail in the **Milestone Module**.

32.5. By Investigative Site

This lists the current view of the documents based on Investigative Sites. Investigative Sites are places where the clinical studies are conducted. This view shows the segregation of Investigative Sites as located in different countries. All sites belonging to a particular country are listed under its specific country. Click a site name to list the documents belonging to the site in the Document Grid. Refer to the screenshot below:



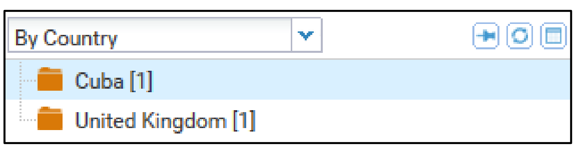
The configurations for an Investigative Site can be setup from Settings -> Investigative Sites.

The dashlets related to Investigative Sites are:

1. Expiring Sites
2. Recently updated sites
3. Site Activation Status
4. Site Activation Progress
5. Sites Activation by Country
6. Study Monitoring Visits By Country

32.6. By Country

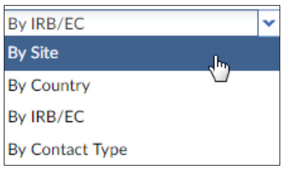
In the **By Country** view, the documents pertaining to studies in each country are listed. Folder by the names of countries are created with each folder having the documents associated with it.



32.7. Contacts

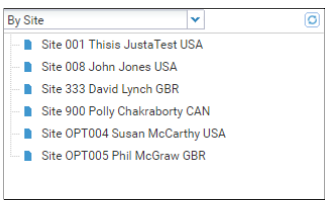
A clinical trial includes a varied range of people with different profiles, who are a part of the study. Such people are a valuable source of information and are required at various stages of the study. Trial Interactive helps to maintain the detailed profile of such people as Contacts for a study. Some examples of contacts could be the Principal Investigator, Sponsor, Co-Investigator, regulatory authorities, authorities in the IRB.

You can access the **Contacts** module by clicking **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**.

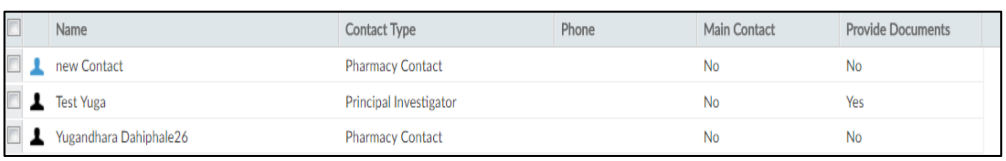


32.7.1. By Site

Select **By Site** from the dropdown in the Index Pane on the left of the Contacts Module. This will reveal all the sites available in the room.



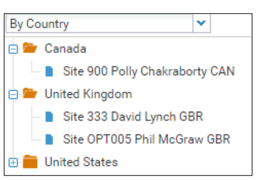
Click a site. This will populate the data of all the contacts available for the particular site in a room in the right pane of the dashboard.



Name	Contact Type	Phone	Main Contact	Provide Documents
new Contact	Pharmacy Contact		No	No
Test Yuga	Principal Investigator		No	Yes
Yugandhara Dahiphale26	Pharmacy Contact		No	No

32.7.2. By Country

Select **By Country** from the dropdown in the Index Pane of the Contacts Dashboard.

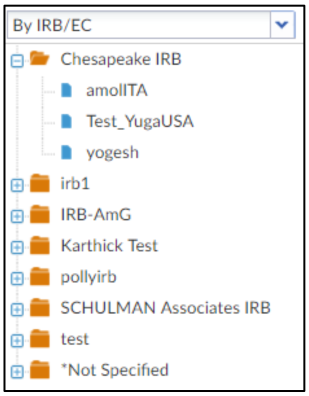


This will list all the countries with the sites where the studies are being conducted in the Index Pane on the left. Clicking a country to expand the dropdown will reveal the sites under it. Click a site to populate the contact details associated with the site in the right pane.

	Name	Contact Type	Phone	Main Contact	Provide Documents
	new Contact	Pharmacy Contact		No	No
	Test Yuga	Principal Investigator		No	Yes
	Yugandhara Dahiphale26	Pharmacy Contact		No	No

32.7.3. By IRB/EC

Select **By IRB/EC** from the dropdown in the Index Pane of Contacts Dashboard. This will populate the IRBs associated with the sites in the Index Pane on the left. Clicking an IRB will expand the dropdown to reveal the sites associated with it.



Click a site to populate the contact details associated with the site in the right pane.

32.7.4. By Contact Type

Select **By Contact Type** from the dropdown in the Index Pane of Contacts Dashboard. This will populate the contact types associated in the room in the Index Pane on the left.

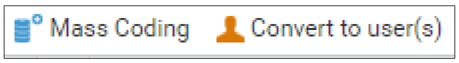
Clicking a contact will list the contact details associated with a particular site in the right pane of the dashboard.

	Name	Investigative Site	Phone	Main Contact	Provide Documents
	David Lynch	NewSIte		No	Yes
	John Jones	Elaine Center of Psychology		No	Yes
	Phil McGraw	Paris Cancer Research Institute		No	Yes
	Polly Chakraborty	Queen Elizabeth II Health Sciences Centre		Yes	Yes
	Susan McCarthy	John Hopkins University Hospital		No	Yes
	Thisis JustaTest	TESTSite		No	Yes

Besides retrieving site details, you can perform various other activities associated with a contact, such as:

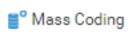
1. Mass Coding metadata for contact
2. Convert to user(s)

All the above activities can be performed by accessing the icons located on the top ribbon bar.

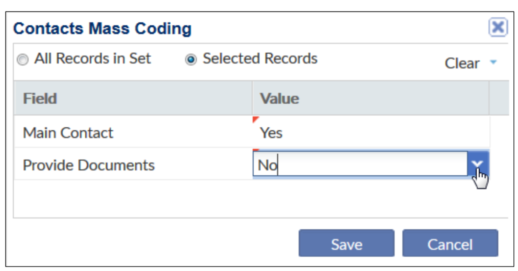


32.7.5. Mass Coding for Contacts

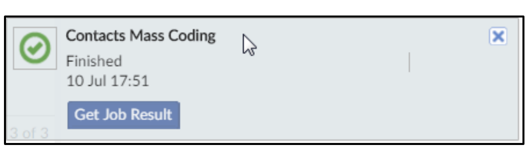
Administrators are sometimes called upon to fill in or update the metadata of a number of contacts in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

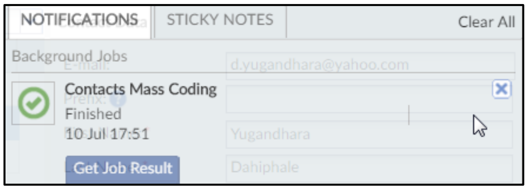
1. Click the **Mass Coding** 

tool from the top ribbon bar. The **Contacts Mass Coding** window opens.
2. You can choose to mass code for **all the records** in the grid, or for a **selected set of records**.
3. Either way, double-click and select yes/no from the dropdown in the **Value** field for the required metadata to be mass coded.
4. Click **Save.**



5. Confirm the message to proceed with mass coding.
6. You will receive a confirmation about the job result which can also be retrieved from the **Notifications.** Refer to the screenshots below.





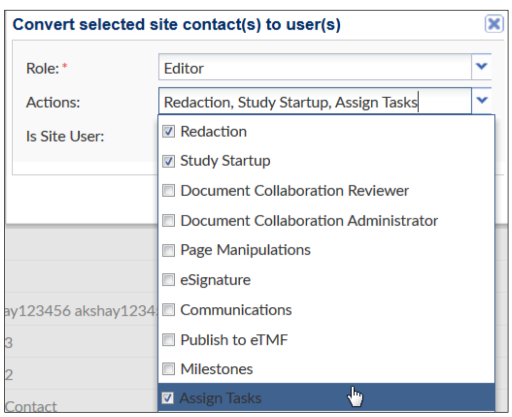
32.7.6. Convert to User(s)

As an administrator, you might want to give **Editor** or **Reader** access on some or all modules to contacts in a site. This can be achieved proceed with the following:

1. Click the **Convert to User(s)**  icon on the top ribbon bar.

2. This will open the **Convert selected site contact(s) to user(s)** window.
3. Select the role as Editor or Reader as required.

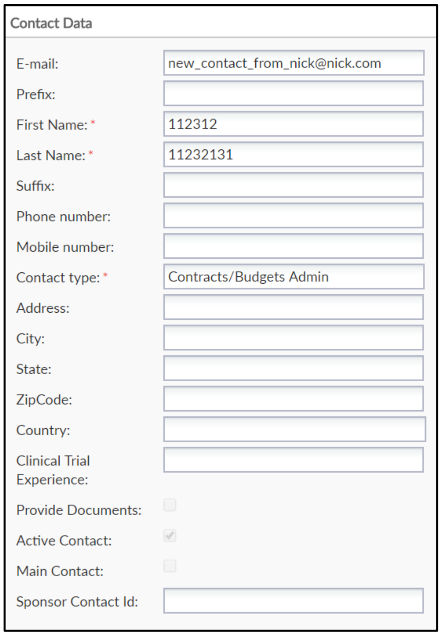
4. Select the modules from the Actions as required.



5. Click **Convert to user(s)** button in the window.

32.7.7. Contact Data

Selecting a contact in the grid will highlight the **Contact Data** window at the extreme right of the grid in the right pane. You can view details of the contact here.



Contacts can be added through the Sites Dashboard. This is discussed in the previous section. They can also be added from the Document Data Panel.

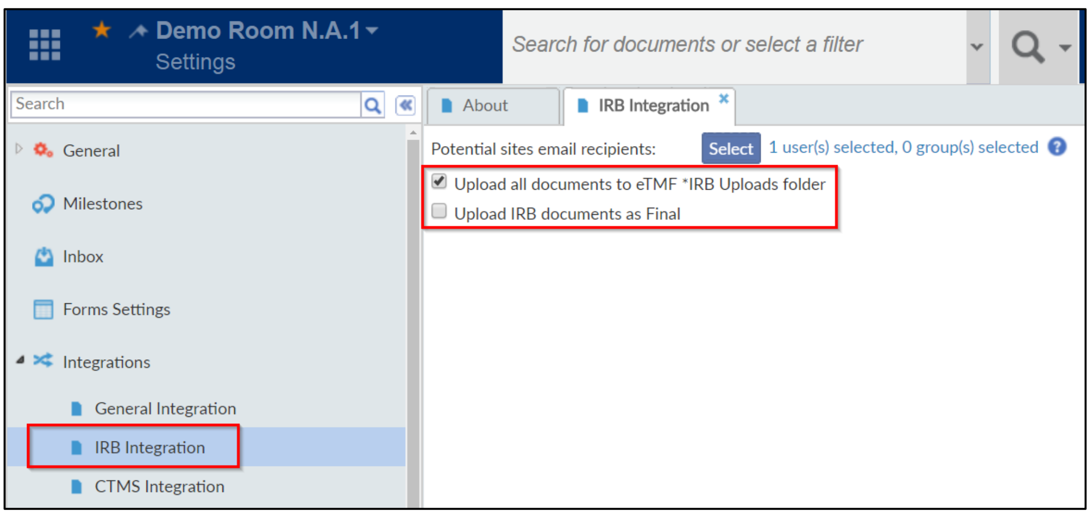
33. IRB Integration and Potential Sites

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

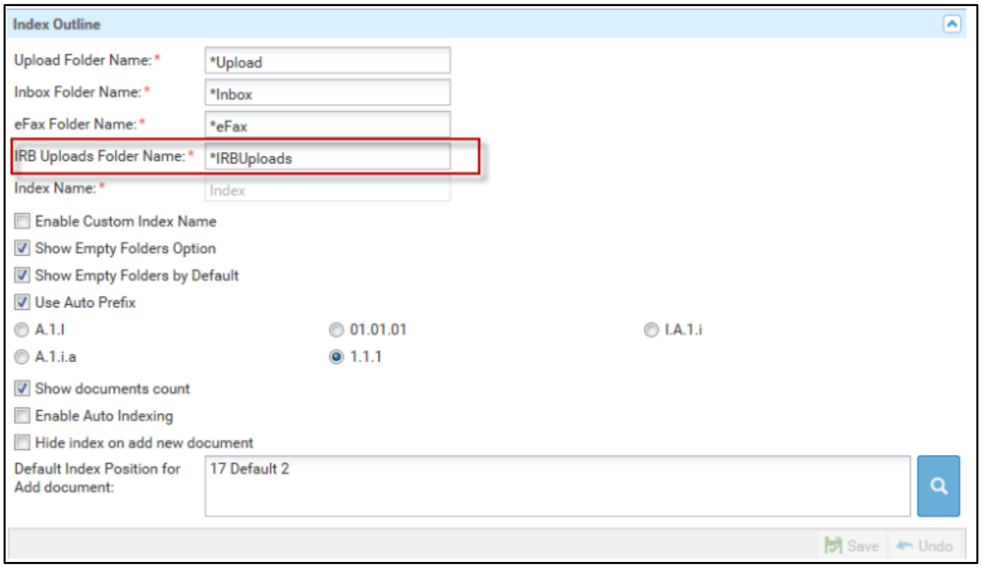
If the system finds matching conditions like site, IRB number and IRB document type in the Study Start-up Site Profile, the documents for the imported site will be uploaded into the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which is discussed below.

33.1. IRB Integration and Settings

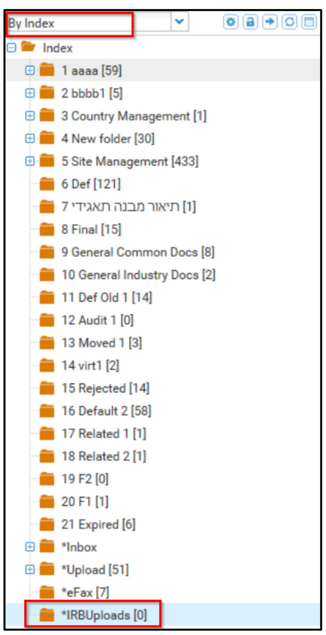
From the room **Settings -> Integrations -> IRB Integration** you can decide the location and the status of the IRB documents in the eTMF.



Trial Interactive introduces a new **IRB Uploads folder** the name of which can be configured from the **Settings -> Documents -> Index Outline**.



If only **Upload all documents to eTMF *IRB Uploads folder** is enabled, the system does not check for matching conditions in the Study Start-up and directly uploads all non-final documents to this folder in the eTMF. Refer to the screenshot below:



If only **Upload IRB documents as Final** is enabled, the system will check for matching conditions in the Study Start-Up.

a. The documents are added as final documents to the Study Start-Up if there is a matching sites and document types. If the document is an essential document, it will be added with the status QC approved and Regulatory Review approved.

b. The documents are added as final documents to the eTMF only if:

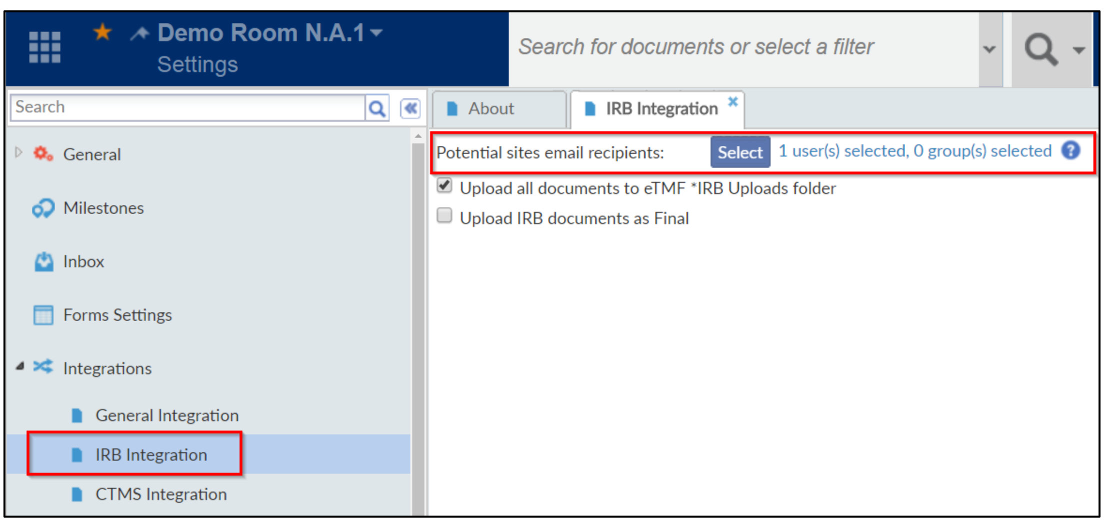
   i. No matching site and document type is found in Study Start-up and

   ii. There is a related folder configuration (index position) defined in the document type. The documents will be placed in that folder, document statuses will be final, and the documents will not be added to the workflow.

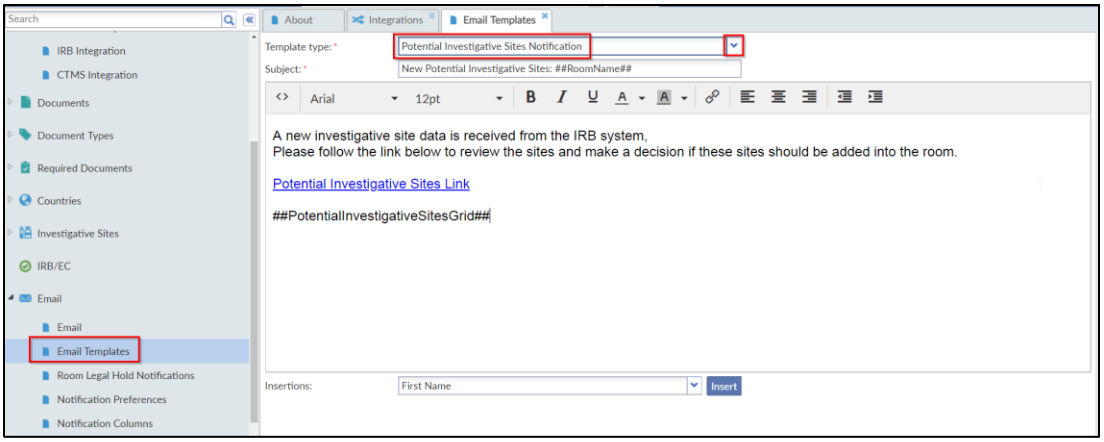
If both the options are checked, then the system shall ignore matching conditions in SSU and upload the documents as final to the indexed folder directly in the eTMF.

33.1.1. Potential Sites module and Settings

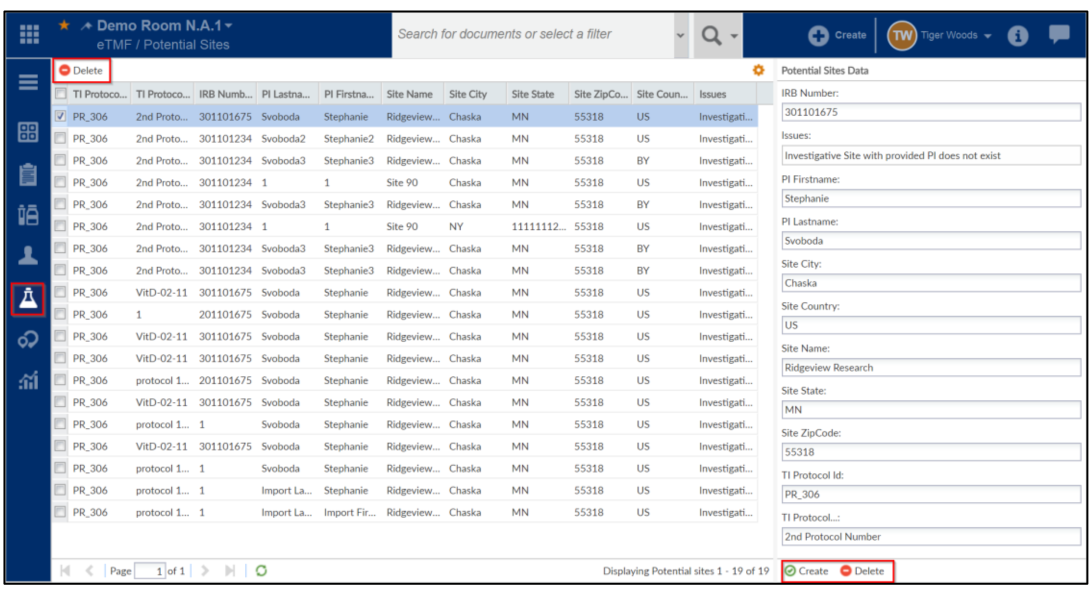
There can be cases where multiple sites are found during IRB Integration, or a site could not be identified, or sites are incorrectly imported. Under the circumstances, the system creates a list of **Potential Investigative Sites** and notifies appropriate groups about the potential sites. Potential sites email recipients can be configured from the **Settings -> Integrations -> IRB Integration**.



The email template for the emails to be received by potential sites email recipients can be setup from the **Email Templates** in the room **Settings -> Email** section. A screenshot of the system provided email template is shown below:



With Trial Interactive, you can manage potential investigative sites from the **Potential Sites module** if IRB Integration is enabled for you. The module is accessible by clicking the Potential Sites icon from the toggling menu in the eTMF module. Refer to the screenshot below showing the **eTMF/Potential Sites module**.



As an Administrator, you can create sites from potential sites or delete the ones that cannot be converted into sites.

To create a site:

1. Select a potential site from the grid as required.
2. From the Potential Site Metadata panel, click the **Create** Create icon to create a site. The **New Investigative Site** window opens.
3. Fill in the details to create a site from a potential one. The process to create a site is discussed in detail in section Adding, Editing, and Deleting Sites.

To delete a site click **Delete** Delete from the Potential Sites Metadata panel.

34. E-signature

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

34.1. e-Signature Settings

The client can choose the required e-signature vendor from **Username dropdown -> Settings -> e-Signature -> Vendors**. The e-Signature vendor available to you depends on the vendor chosen by your organization. This section discusses the following three e-Signature options:

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

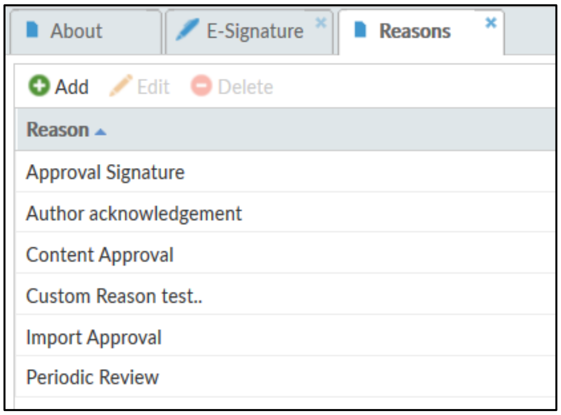
An Administrator can choose to enable or disable the use of an e-signature for users in a room by choosing the **None** option from the dropdown.

Click **Save** if you make any changes here.

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

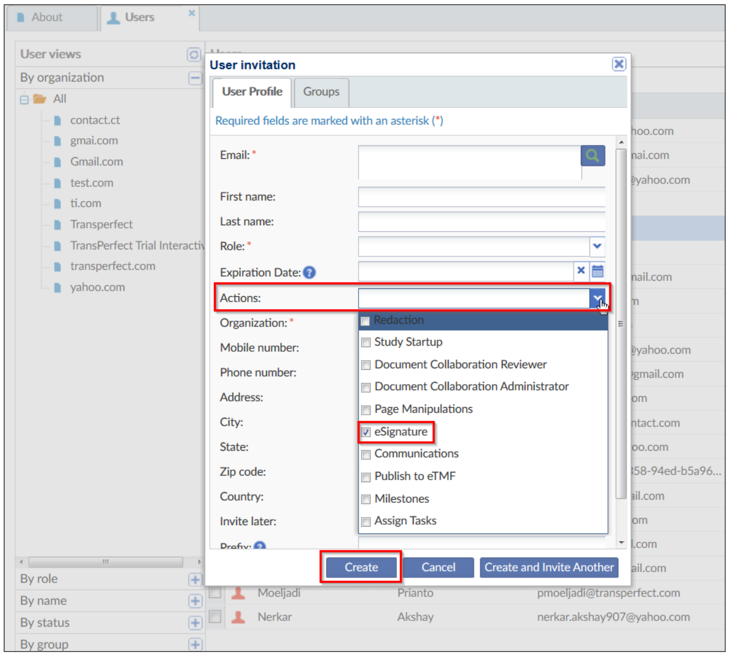
34.1.1. Configuring Reasons for e-Signature

While e-signing a document, the e-signers need to specify the reasons for approving or declining a document. The reasons for the same can be configured from the **Reasons** panel by clicking **Add** from the toolbar of the **Reasons** panel.

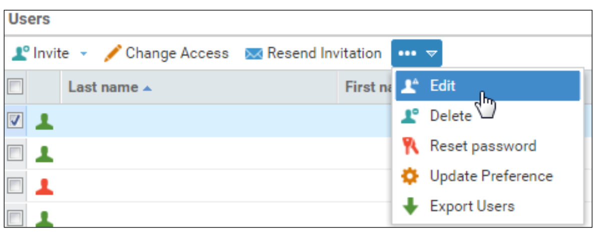


34.1.2. How to Assign Users to prepare an eSignature Envelope

1. Click the desired room in your TI session. Click the **Settings** from the Username dropdown to populate the room settings.
2. Navigate to **Settings -> Security-> Users**. A panel listing all users will be displayed in the right pane. Alternatively, you may arrive to the same page from the **Username dropdown -> Users management**.
3. Click the **Invite** dropdown located on the top left corner of the user list pane. Select the invite option from the list. A **User Invitation** form will be populated.
   Fill in the fields marked with an asterisk (*), at minimum, to invite the desired user.
   From the **User Profile** tab click the **Actions** dropdown menu to select the **eSignature** option and click **Create** to assign your user to prepare the eSignature package.



4. For existing users, select the user from the user list by clicking the checkbox adjacent to list populated in the right pane.
5. Click the dropdown next to the dots and click **Edit** option.



An **Edit User** form will populate.

6. Click the **Actions** dropdown menu and select the **eSignature** option by ticking the checkbox.

   Click **Save** to prepare the existing user for the eSignature package.

   The user added will receive an email from Trial Interactive asking them to register in order to comply with eSignature feature.

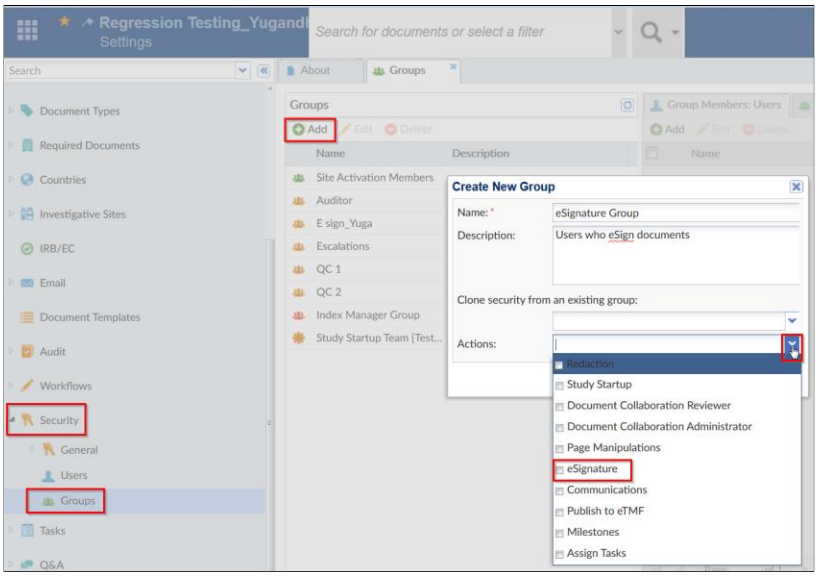
34.1.3. Adding Groups with the eSignature Action

Add Groups and activate the eSignature Action for the specified groups.

1. Navigate to **Settings -> Security -> Groups**. The Groups Panel opens.

2. From the **Groups** tab, click **Add**. The **Create New Group** window opens.
3. Name the group by typing its title into the **Name** field.
4. Add a **Description**.

   The user making these additions or changes can choose to clone the security parameters already defined for another user group that has been established in the room. This cloning designation is not required.
5. Click the **Actions** dropdown.



6. Click the checkbox for **eSignature**. Click **Create**.

   The new user group displays in the list of **Groups** in the panel on the left.

To use TI e-Sign , DocuSign and Adobe Sign to e-sign documents, the administrator must enable the feature at room level, configure the reasons for e-signing a document, and also the eSignature action for the required users/groups. For further details on this proceed to <u>Username - > Settings -> e-Signature Settings.</u>

34.2. TI e-Signature

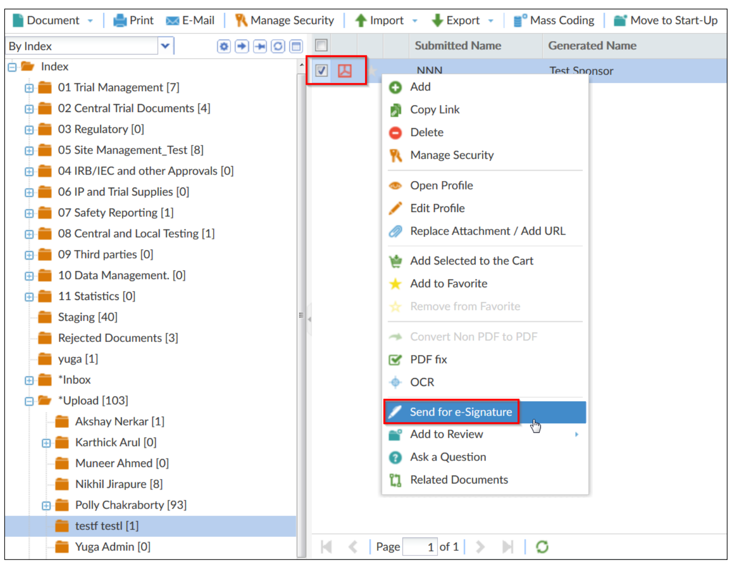
For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) which is now back with some modifications from the TI version 8.13.

34.2.1. Assigning signers to the documents

1. Visit the desired room in Trial Interactive.

   Click the **Documents** tab. If you have recently uploaded the document, click the **Upload** tab and navigate to open the desired folder within the Upload tab. The list of documents will be displayed in the right pane.

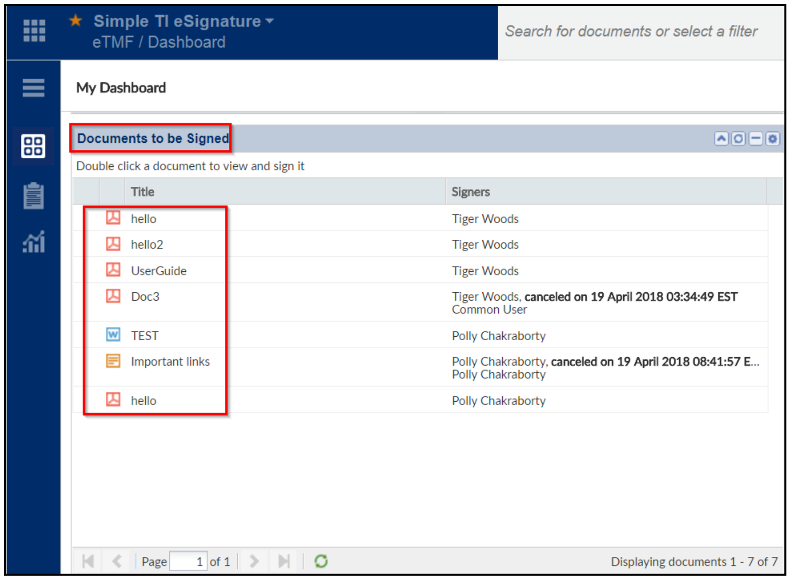
2. Right click the desired document and click **Send for e-signature**.



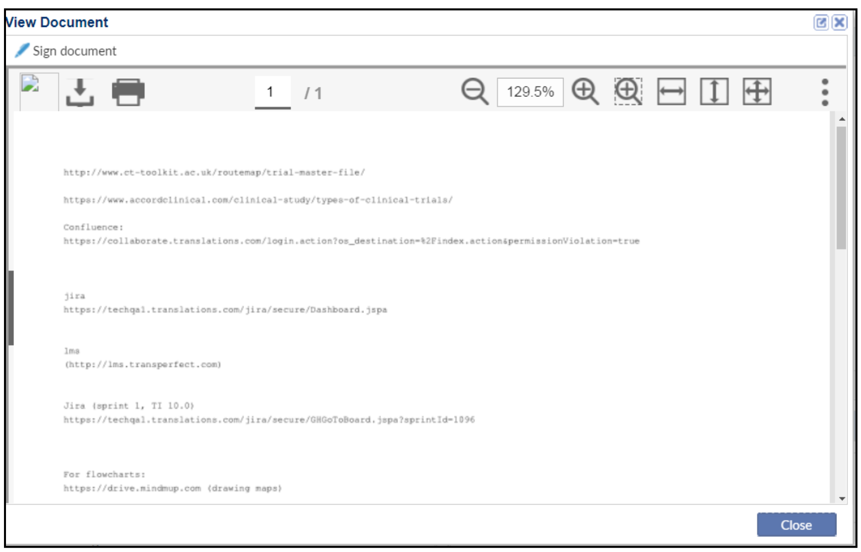
34.2.2. Signing the documents in TI – eSignature if you are a signer

If you are assigned to electronically sign a document, follow the steps mentioned here:

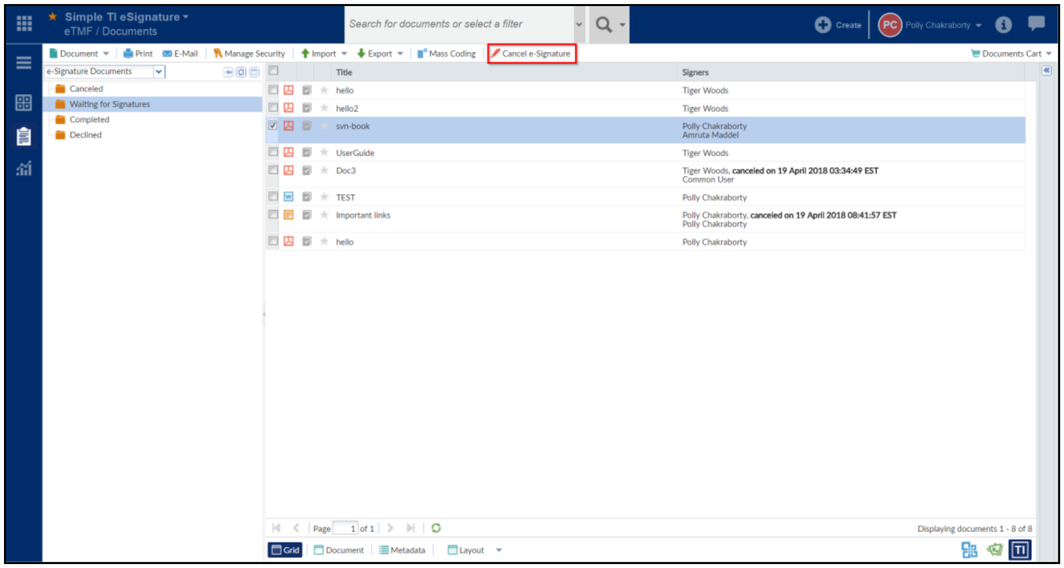
1. When you are assigned a document for eSignature, navigate to the room **Dashboard** and scroll down to find the **Documents to be signed** dashlet.



2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.



You can also proceed to the **eTMF/Documents** module or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane.

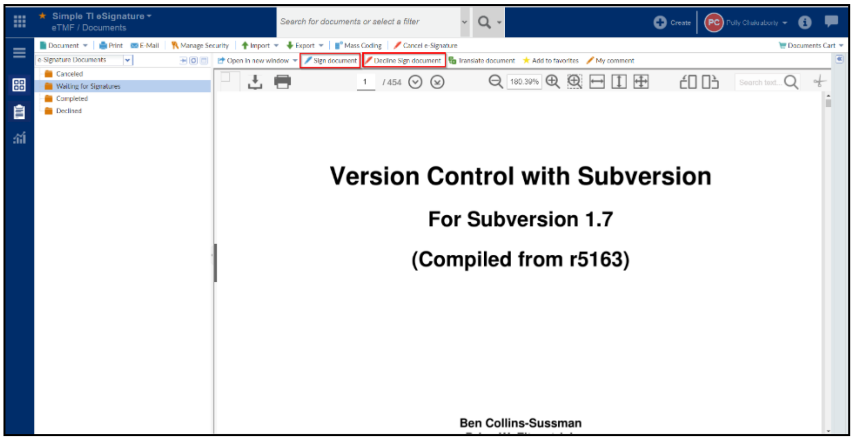


If you do not want to sign the document, directly click the **Cancel e-Signature** button from the top ribbon bar and confirm the cancellation. The document will move to the **Declined** folder under **e-Signature Documents** view.

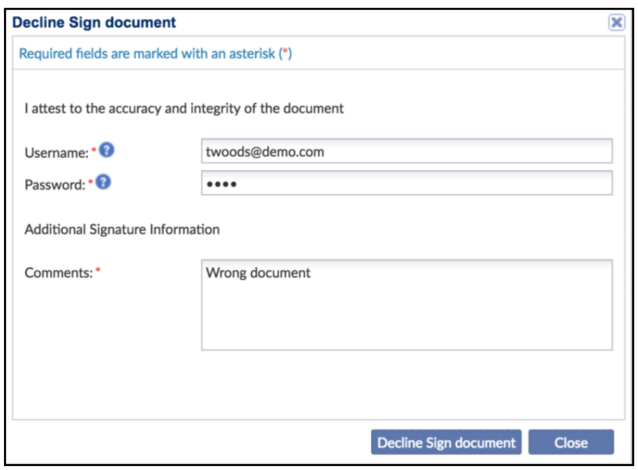
- ***Completed signatures cannot be cancelled.***
- ***Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.***
- ***Once a document is cancelled from e-signature, no one can sign the document until it is resent again.***

Either ways, to e-sign the document:

1. Open the document in the viewer and click **Sign Document** from the toolbar to begin the review and signing process. Refer to the screenshot below:



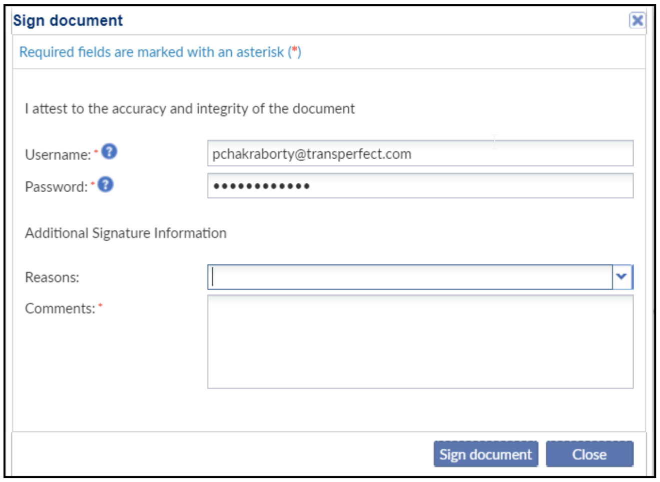
From here too, you may choose to decline to e-Sign by clicking the **Decline Sign document** button. Validate with your login credentials and enter the comments to decline. **Here too, the same rules as mentioned above apply for declining to sign a document**. Refer to the screenshot below.



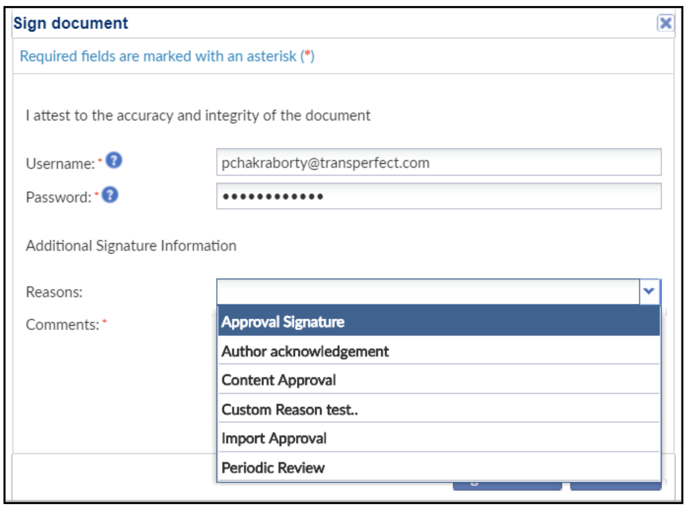
The document moves to the **Declined** folder under **e-Signature Documents** view.

3. Else click the **Sign document** button to proceed with.

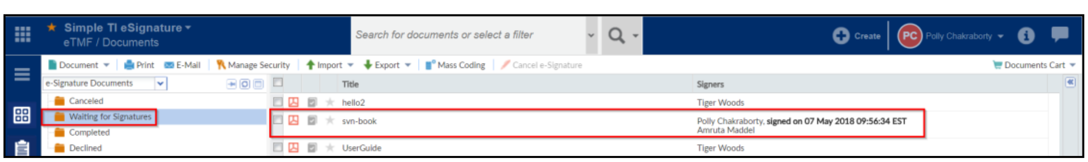
   You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive.



4. Select the reasons applicable to e-sign the document and enter your comments.



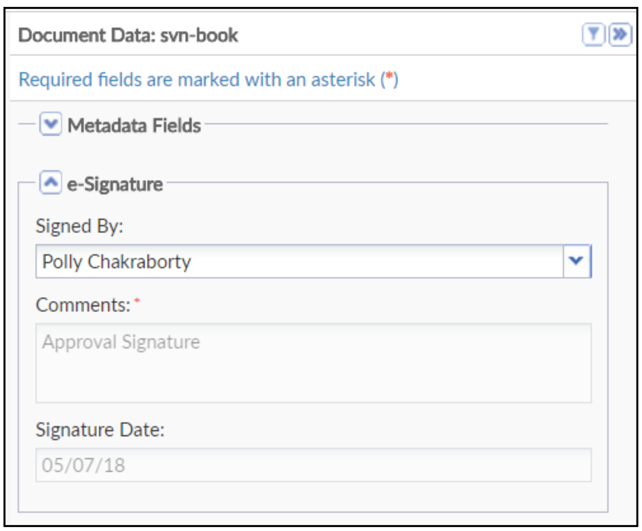
5. Click **Sign document** button.
6. You will receive a message saying that the document was successfully signed. Click **OK**.
7. If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all the signers have finished signing. Refer to the screenshot below:



8. Open the signed document to find that a page with the signer's name and contact details, date of e-signing the document, reason and approval signature is appended as the last page to the document. In case of multiple e-signers, a page for very signer is appended.

> ***Signature Page will be added to PDF documents only after all signers have finished signing the document.***

9. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under **e-Signature Documents** view.
10. Besides the **Completed** folder, you can view the e-signature history of a document in the metadata panel under the e-signature panel.



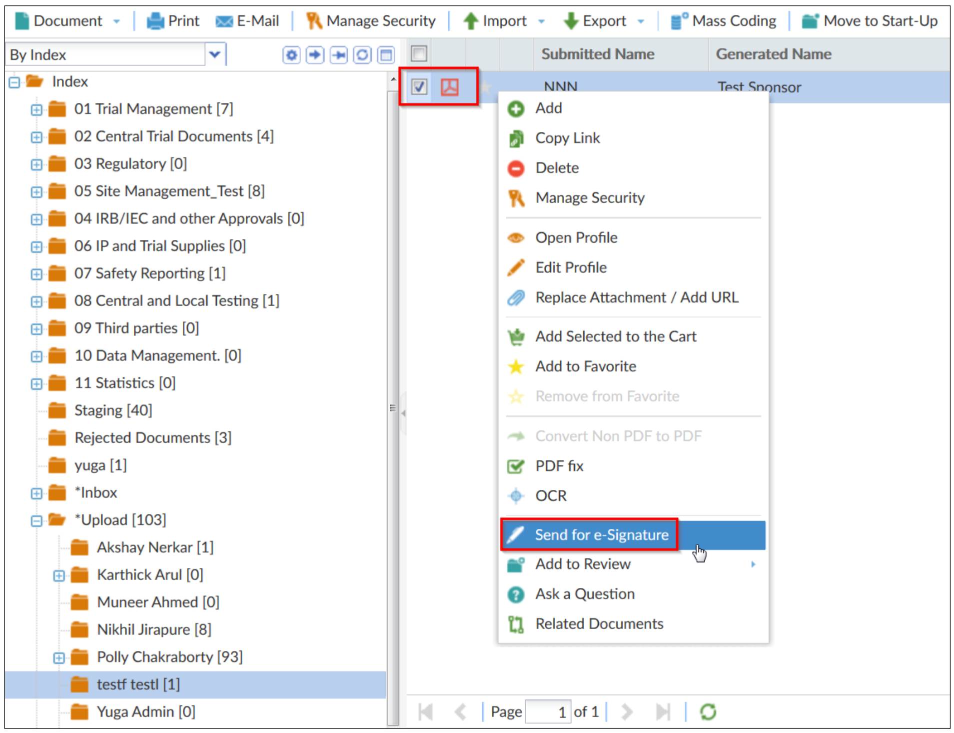
34.3. Adobe e-Signature

34.3.1. Assigning signers to the documents

1. Visit the desired room in Trial Interactive by clicking the room.

Click the **Documents** tab. If you have recently uploaded the document, click the **Upload** tab and navigate to open the desired folder within the Upload tab. The list of documents will be displayed in the right pane.

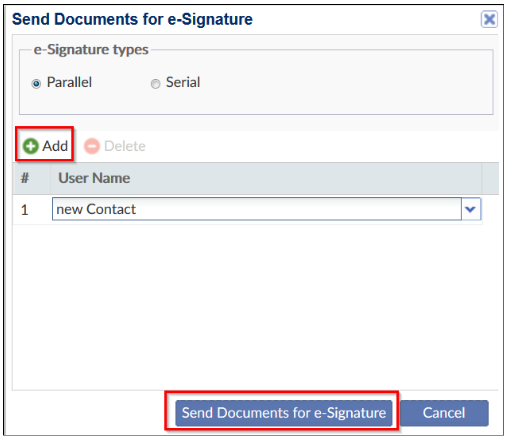
2. Right click the desired document and click **Send for e-signature**.



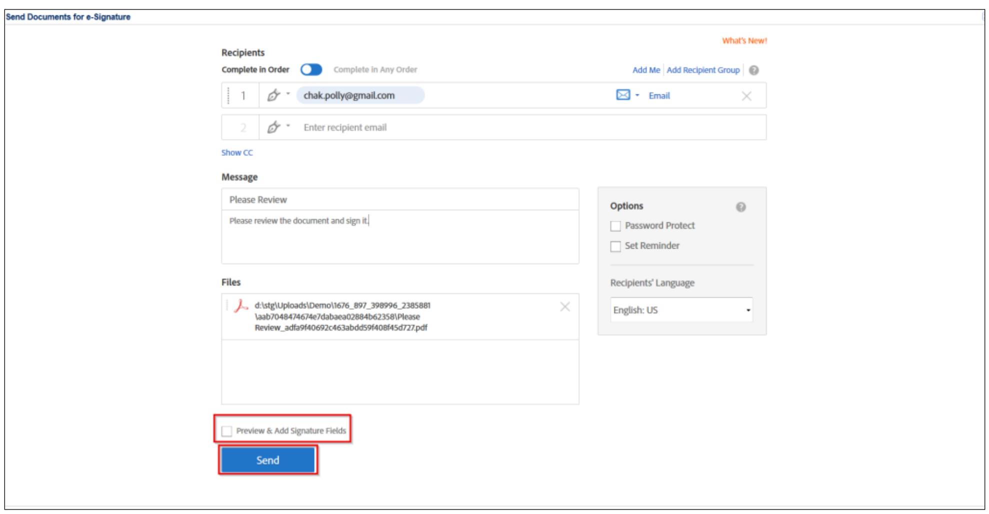
A new pop-up window to add signers for the documents will display. Add the users you wish to assign as the signers by clicking the **Add** button. You may add one or more signers to the document.

If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

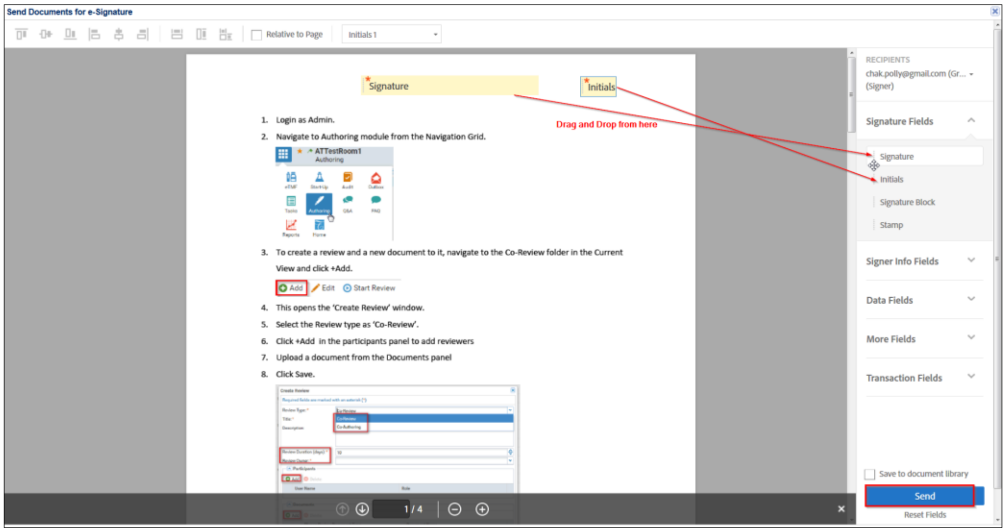
Click the **Send documents for e-signature** button after adding the desired signers.



3. A Recipients window with the list of email ids of signers enlisted opens.
4. Tick the **Preview & Add Signature Fields** checkbox located at the end of the page to determine the placement of signatures on the document.
5. Click **Next**. Refer to the screenshot below:



6. From the Recipients field select the signer and, drag and drop the fields on your document from the right menu option that you wish to include in the signature.
7. Repeat the above step for every e-signer.



8. Click the **Send** button located on the bottom right corner of the window to complete the signer assignment process.

   The system will trigger an email to the signers designated by you with a link to the document for eSignature.

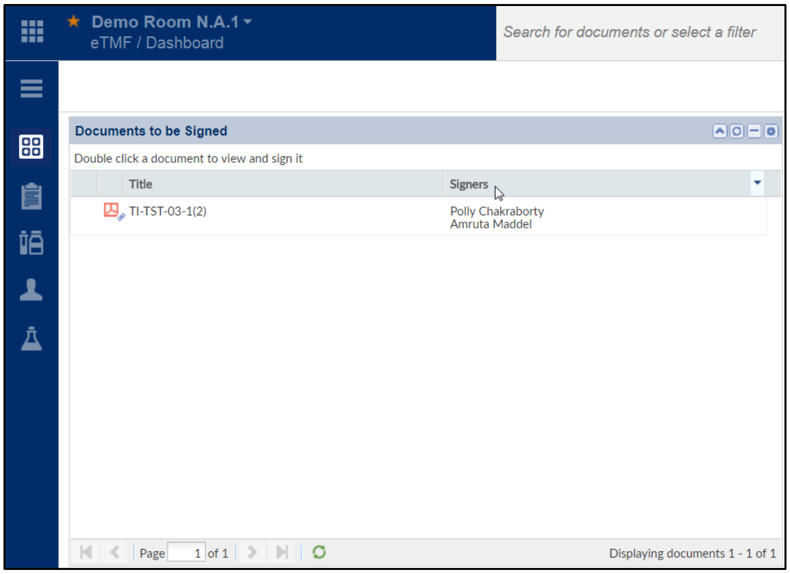
   You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

34.3.2. Signing the Documents in Adobe Sign if you are a Signer

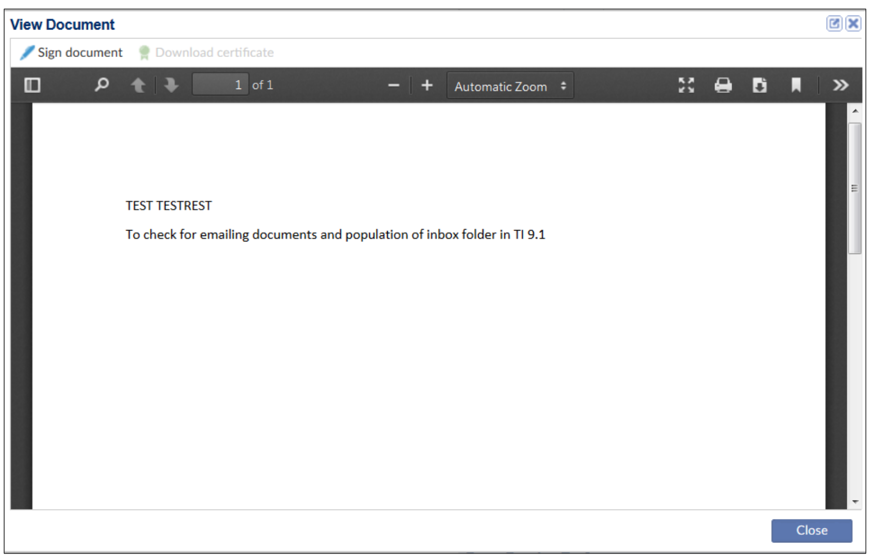
If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document.

   Alternatively, click the **Dashboard** tab and scroll down to find the **Documents to be signed** dashlet.

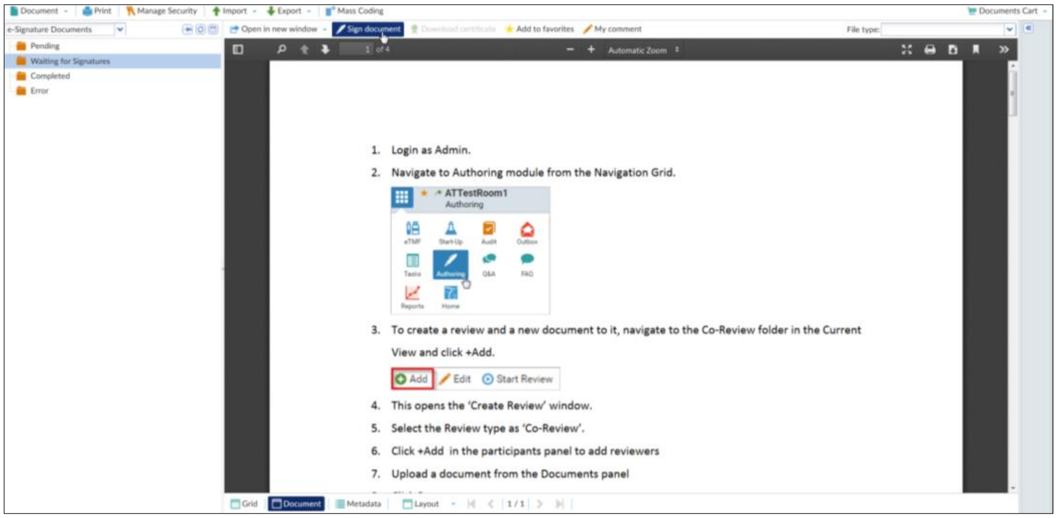


2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

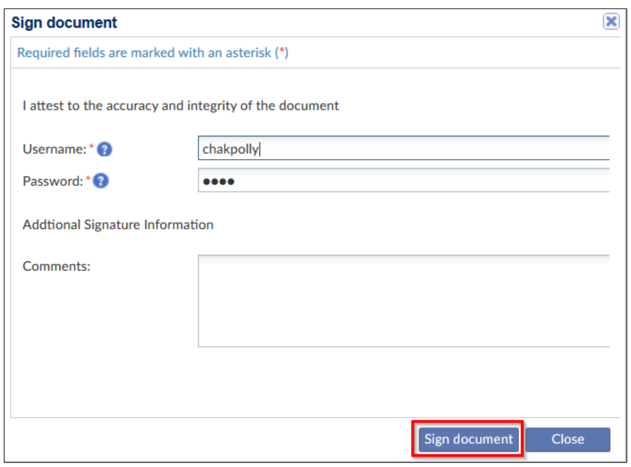


You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process.

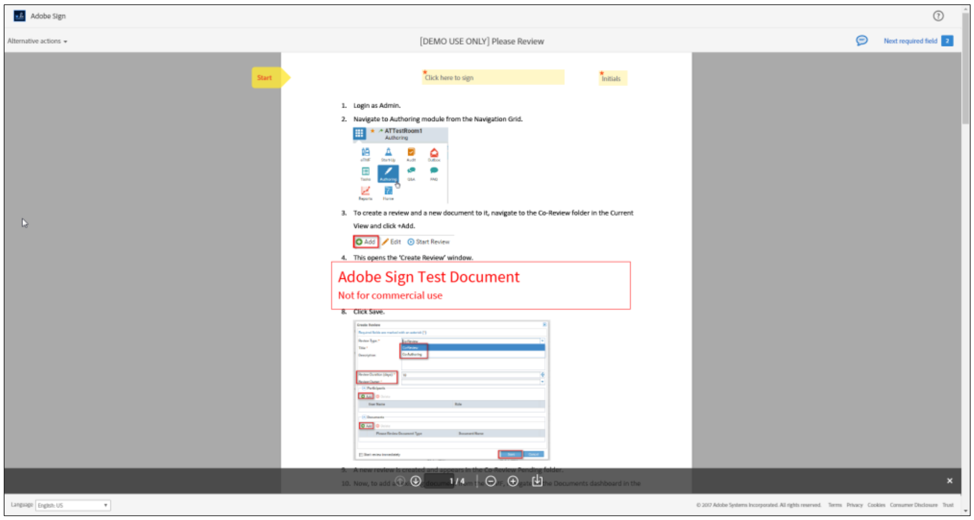
If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document.



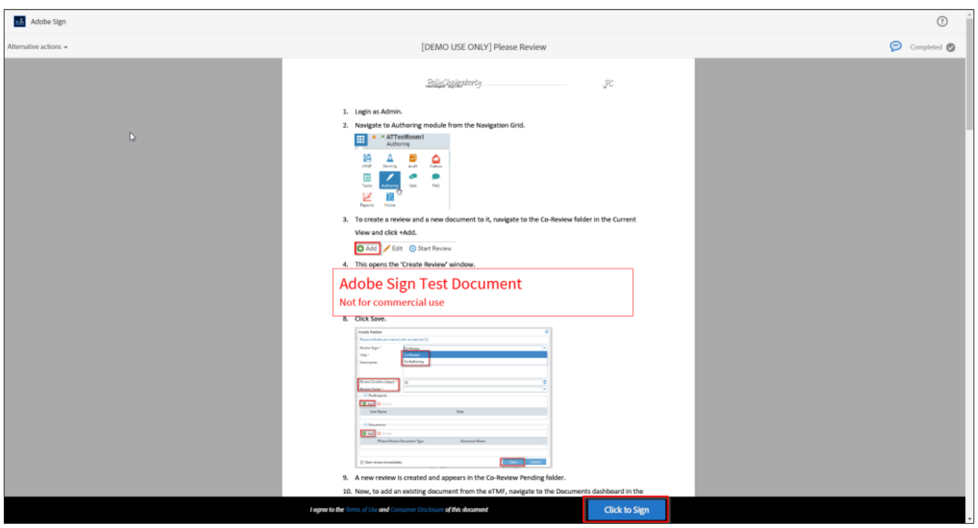
3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.



4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document.



5. Hit **Click here to sign** box. You will be prompted to choose your style for the signature (font, size, etc.)
6. Enter your signature and other details as required. Click **Apply.**
7. This will insert your signature. Hit **Click to Sign**

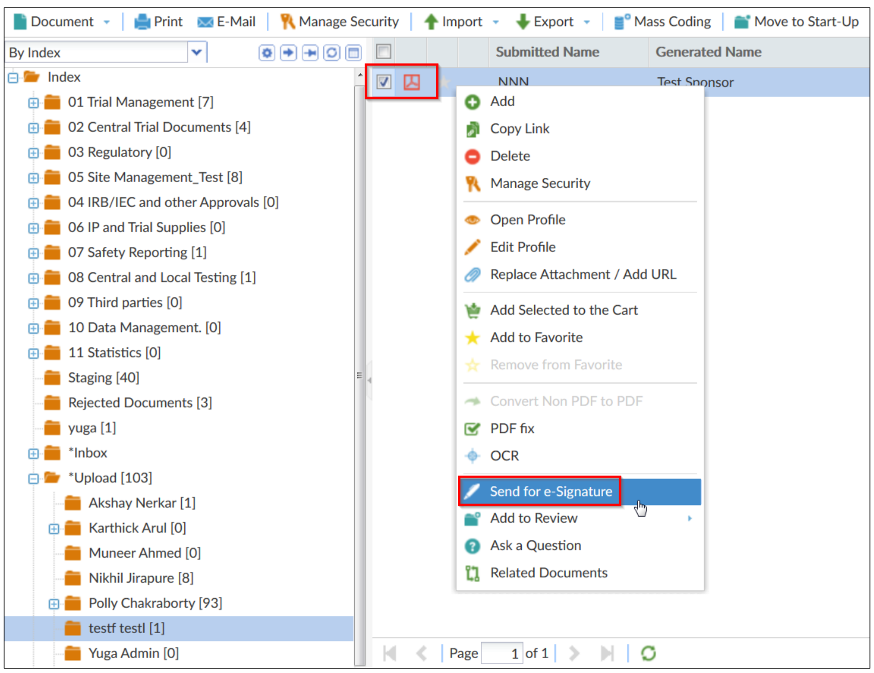


8. The document will move to the **Completed** folder under **e-Signature Documents**.

34.4. DocuSign e-Signature

34.4.1. Assigning Signers to the Documents

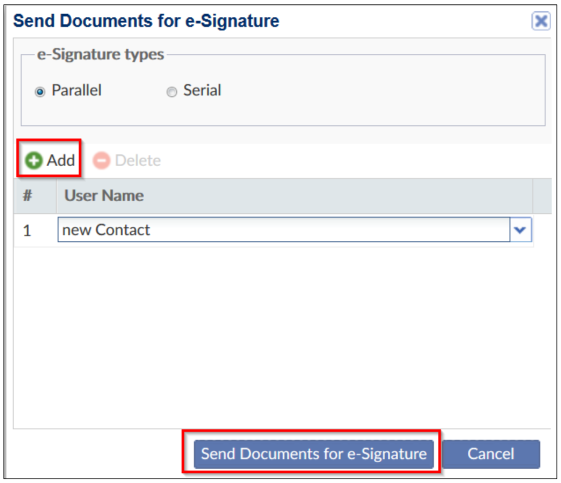
1. Visit the desired room in Trial Interactive by clicking the room.
2. Click the **Documents** tab. If you have recently uploaded the document, click the **Upload** tab and navigate to open the desired folder within the Upload tab. The list of documents will be displayed in the right pane.
3. Right click the desired document and click **Send for e-signature**.



A new pop-up window to add signers for the documents will display. Add the users you wish to assign as the signers by clicking the **Add** button. You may add one or more signers to the document.

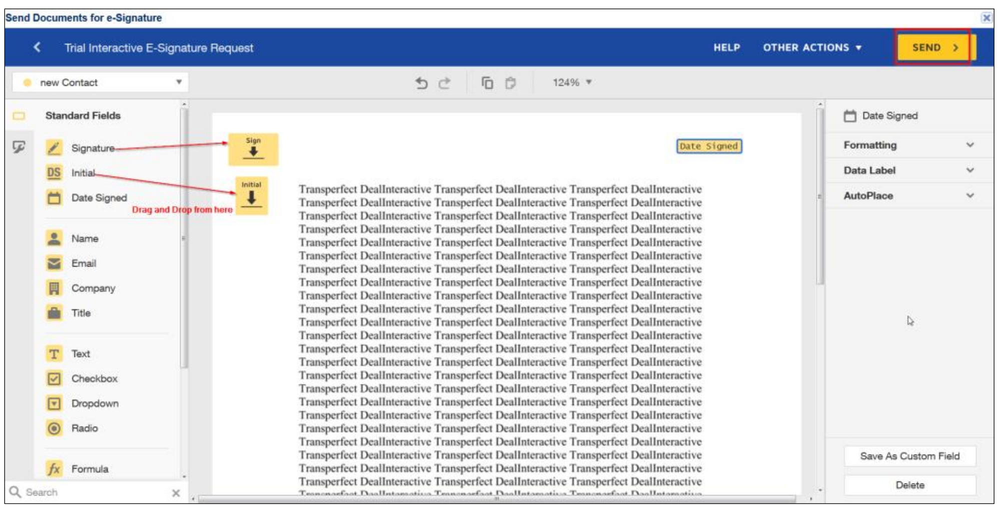
If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

Click the **Send documents for e-signature** button after adding the desired signers.



4. A document preview window to determine the placement of the signatures with the designated recipient list on the left will display.

   Select the desired recipient. Then drag and drop the fields on your document from the left menu option that you wish to be included in the signature. Repeat the above step for every e-signer.



Click the **Send** button located on the top right corner of the window to complete the signer assignment process.

The system will trigger an email to the signers designated by you with a link to the document for eSignature.

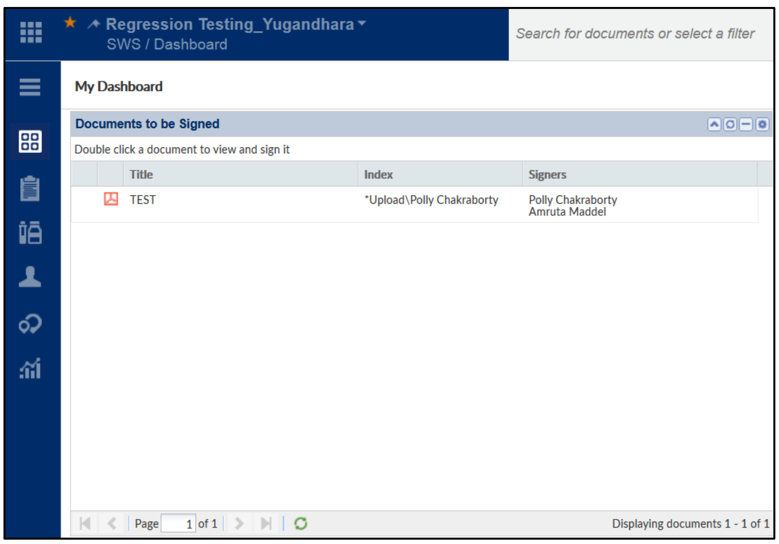
You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

34.4.2. Signing the Documents in DocuSign if you are a Signer

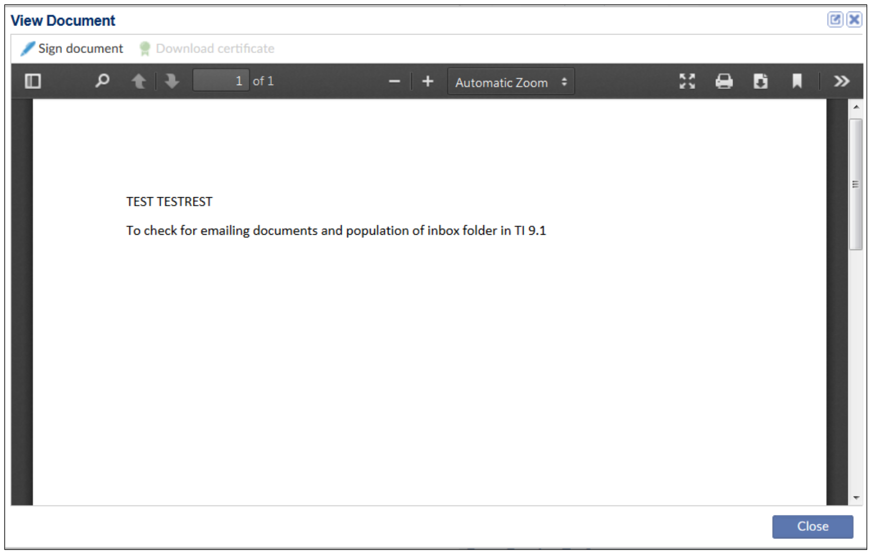
If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room.

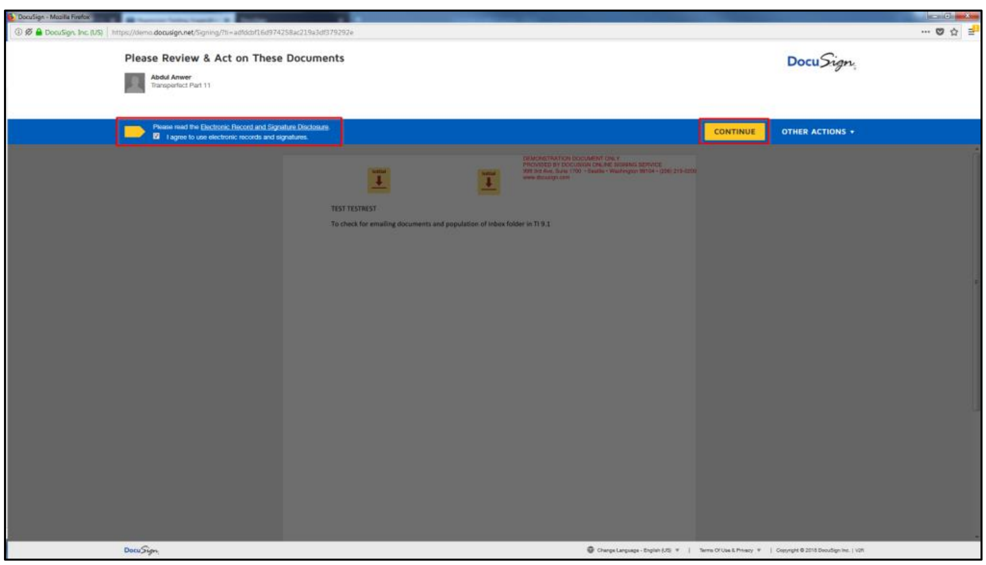
   Alternatively, click the **Dashboard** tab in the eTMF module and scroll down to find the **Documents to be signed** dashlet.

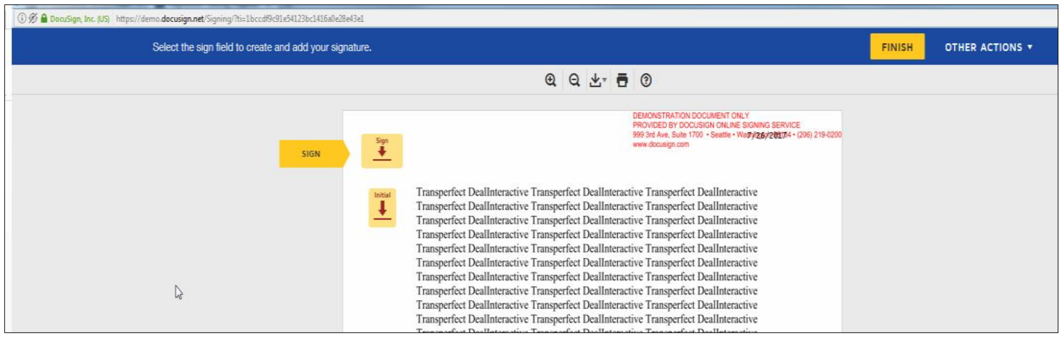
2. Click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.



You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process.



Click **Continue.** If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Click the **sign** icon. You will be prompted to choose your style for the signature (font, size, etc.)

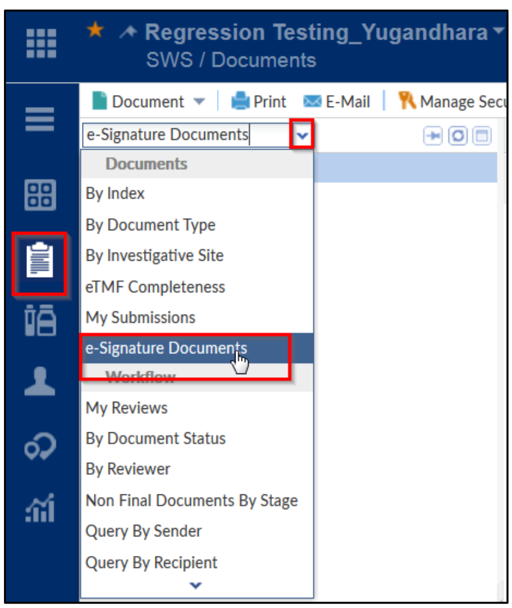


Click **Finish** to complete the eSignature process.

34.5. Accessing the eSignature Documents

Trial Interactive facilitates users with an option to view all the eSignature documents with statuses pending, waiting for signature, and completed.

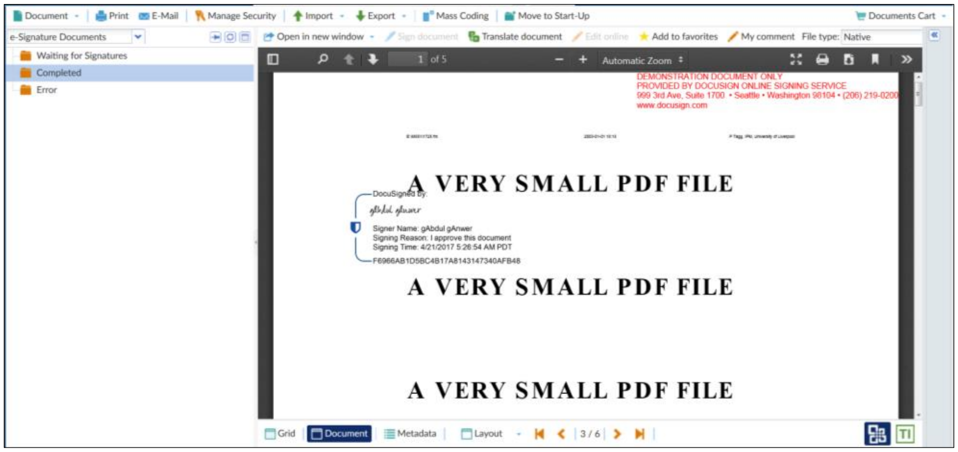
1. Visit the room to which you have sent documents for eSignature. Click the **Documents** tab.
2. Select the **e-Signature Documents** from the dropdown list located on top left panel.



3. The folders with document statuses **Pending**, **Waiting for Signatures**, and **Completed** will be displayed in the left panel. Click on the requisite folder to view the documents

that will be displayed in the right window pane. If you wish to open the document, click the icon.

The signed documents will be displayed in the right pane.



35. Quality Review/Audit

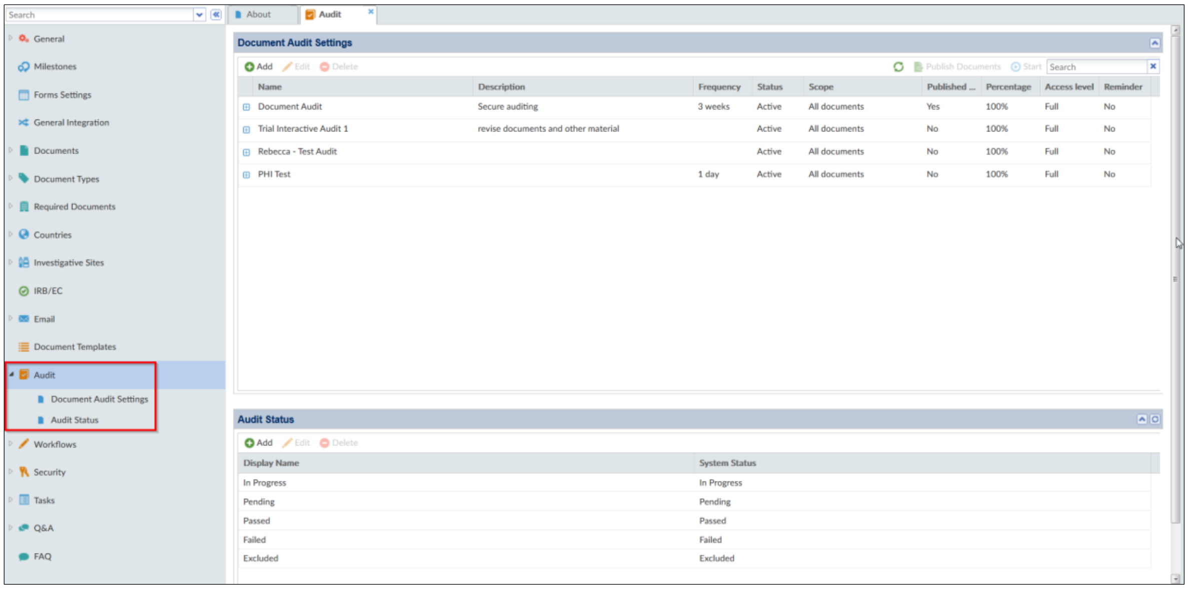
The Quality Review/Audit Module in Trial Interactive allows to record an auditor's review and comments on various documents added for audit in a trial. In Trial Interactive, you would find the following type roles for audit:

1. **Auditor**: Users under this role can see only the documents they audit.
2. **Auditor manager**: Users under this role can see audit results of all auditors and can provide their own review comments to documents. Only editors and higher level users fit this role.
3. **Audit Responder**: Users under this role are responsible to take actions on issues cited by auditors in the documents. Only editors and higher level users fit this role.

As a Trial Interactive administrator, you can access the **Audit Module** from the **Navigation Grid**:

35.1. Document Audit Settings

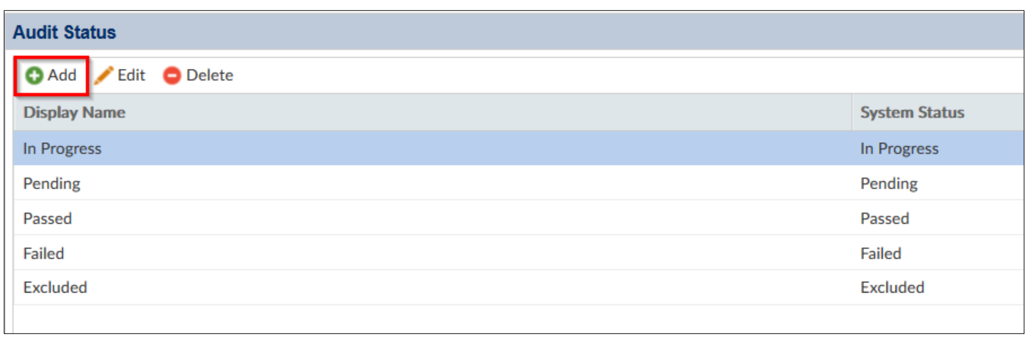
Initial Audit functionality in a trial room must be triggered by a user with Super Administrator access to the room. Once that setting has been activated, an Administrator can set up and edit audits on sets of documents in a room. The screen shot below shows a room that already has four audits set up.



35.1.1. Audit Status

Every system audit status has to be added into the **Audit Status** portlet before an audit can be built. The system statuses are Passed, Failed, Pending, In Progress, and Excluded. Each of these statuses must be mapped to a Display Name.

1. Click **Add** in the **Audit Status** portlet.



2. Type the **Display Name** into the active field that you want to map to an established **System Status**.
3. Press **Tab** on your keyboard.

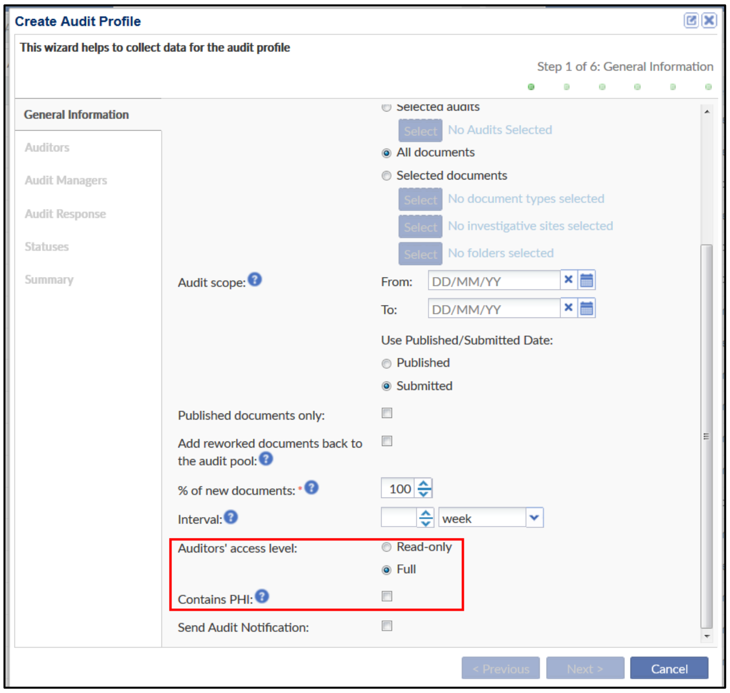
   The **System Status** field becomes active with a dropdown arrow.
4. Click the dropdown arrow and select the established **System Status** term to associate with the newly added **Display Name**.

   Changes are saved automatically.

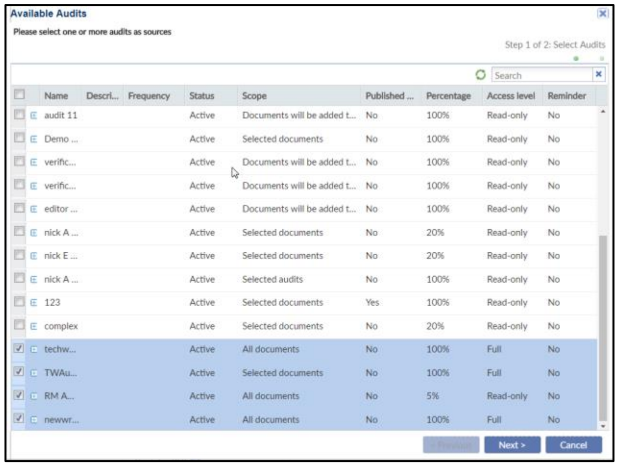
35.1.2. Creating Audit Profile

1. Click **Add** in the **Document Audit Settings** portlet.

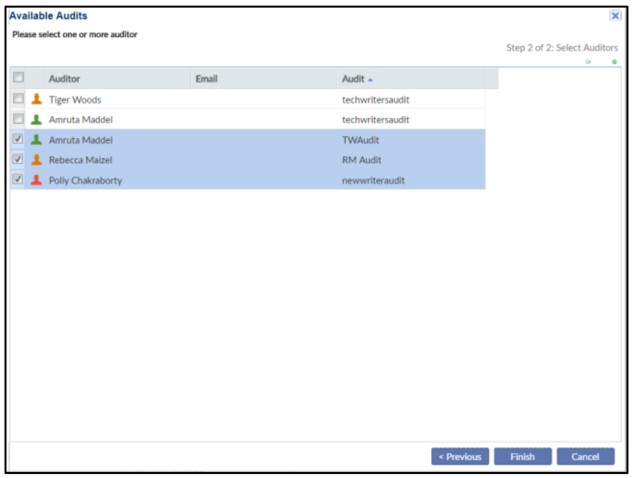
   The **Create Audit Profile** window opens.



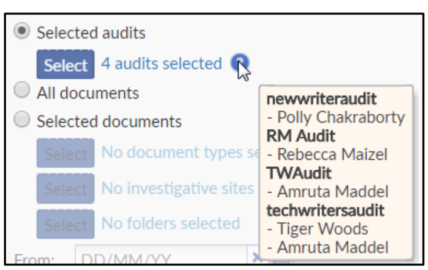
2. Enter the **Title** of the audit in the title field.
3. Enter the **Documents to audit** as required:
   a. **Selected audits**: If checked, documents passed in the selected audit profiles will be added to the current audit profile.
      i. Select audits from the list of audits. Click **Next**.



ii. Select auditors from the selected audit profiles. Click **Finish**.



The number of audits selected appears next to the option on the Create Audit Profile form. Hold the mouse over the help icon to reveal the details of the audits and auditors selected.



b. **Documents will be added to the pool on demand basis:** If checked, documents will not be added to the audit pool automatically. Instead, the user will have to add documents manually to the audit pool via Documents Cart, or by clicking the **Publish**

Documents Publish Documents button from the **Document Audit Settings** window toolbar.

c. **All documents**: If selected, the documents of all document types will be added to the audit pool for audit.

d. **Selected documents**

  i. **Selected document types**: If selected, documents for audit will be selected from the chosen document types.

  ii. **Selected investigative sites**: If selected, documents for audit will be selected from the chosen investigative sites.

  iii. **Selected folders**: If selected, documents for audit will be selected from the chosen folders.

4. **Enter the audit scope**: Documents submitted/published within the selected date range will be published to the audit pool. The Audit scope will be disabled if the documents are added to the pool on demand basis, or from selected audits.
   a. *From Date*: The day from which the audit is to start. It is not possible to select future dates as 'From Date'.
   b. *To Date*: The day till which the audit is to be completed.
5. **Select Submitted/published dates**: Audit will be applied only to submitted or published documents as per selection. Submitted documents are documents just added to the room, whereas published documents are documents added to the room as final.
6. **Published documents only**: If selected, documents added to the room as Final documents will be added to the audit pool. The user can choose to select Submitted from step 5 and check the **published documents only** checkbox. In this case, the audit pool will receive only documents that are just published to the room as final.
7. **Add reworked documents back to the audit pool**: Changing a document metadata, or replacing the document attachment will add the document back to the audit profile with open status, irrespective of the fact that the document was passed/approved during audit in the same audit profile. Currently supported metadata changes are Index, Category, Document Type, Investigative Site, and Document Date.

8. **% of new documents**: This defines the percentage of documents to be included in the audit pool as per the frequency, or audit scope. The percentage of documents are calculated from each intersection of selected investigative sites, document types and folders. Refer to the screenshots below:

In the above pictures, 80% of new documents will be added to the audit pool as below:

i. 80% of all documents having Investigative site as Laz Institutes4 AFG, document type as IRB required doc1 in folders Complex criteria and Site Signed NDA, and

ii. 80% of all documents having Investigative site as Laz Institutes4 AFG, document type as IS Maintenance1 and folders Complex criteria and Site Signed NDA

9. **Interval**: When set, the system will move the documents to the audit pool based on the period set in the interval. This will be disabled if the audit scope date range is selected.

10. **Auditors' access level**: This defines the security that the auditor receives on a document. The access level can be **Full** or **Read-only**.

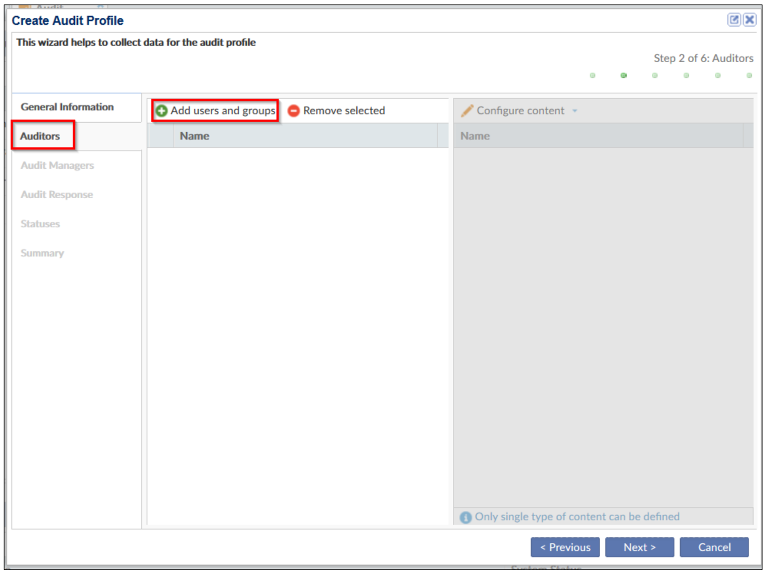
11. **Contains PHI**: The client may allow auditors to delete documents containing PHI, under which case the administrator will need to enable the **Contains PHI** functionality by ticking the checkbox next to it. To activate this checkbox, the **Auditor's access level** has to be set to **Full**.

12. **Send audit notification**: When checked, the auditor will receive an email notifying that new documents are added to the audit pool.

13. **Creation date**: The date when the audit was created.

14. **Status**: The status could be active or inactive.
15. Once you have made the selections, click **Next** at the bottom of the window.

    You will move on to the window where you will establish which users in the room will act as document Auditors.
16. Click **Add users and groups**.



***Best Practice:* Using Groups instead of individual Users when assigning Audit roles helps to make it easier to make changes to an audit once it has been established and saved. Adding a new user to a group with audit responsibilities is easier than to modify the list of users in an Audit Profile.**

17. Click the dropdown arrow next to the field that displays **Users**, and switch to **Groups**.
18. Double-click the group or groups for which you want to activate the Audit responsibility.

    The names of the groups will populate the **Selected Members** panel.
19. When all of the appropriate groups have been selected, click **Ok** at the bottom of the window.

    You return to the **Create Audit Profile** window and the name(s) of the group(s) you just designated as Auditors populates the panel.

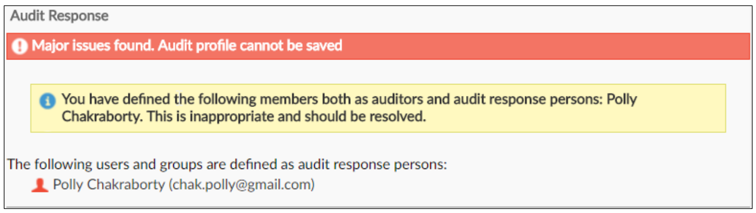
20. Click **Next** at the bottom of the window.

    The wizard move to the **Audit Managers** portion of building the Audit Profile.

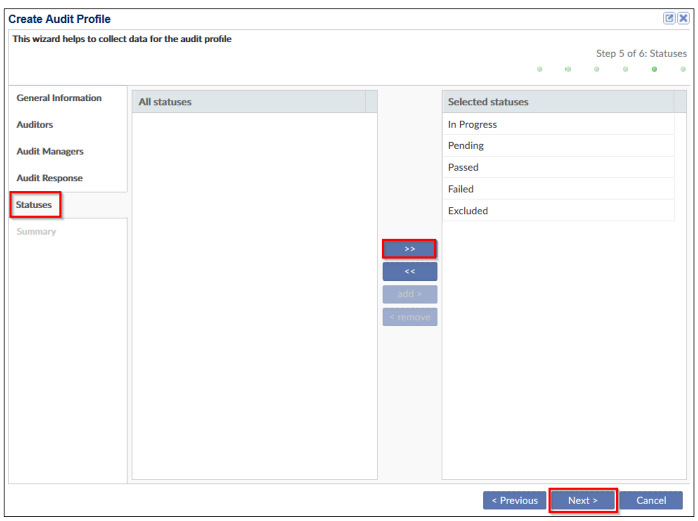
21. Make the selection of users or groups assigned to the **Audit Manager** role.

22. Move on and set up which users will be assigned to the **Audit Responder** role.

    Only editors and higher level users can be allotted the Audit Managers and Audit Responders role. **A user cannot be allotted both the Auditor and Audit Responder role for the same Audit profile.**



23. Click **Next**.



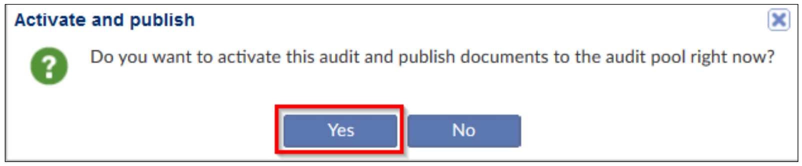
24. All of the audit statuses can be moved to the **Selected statuses** panel by clicking the double-arrow icon in the middle of the window.

25. Click **Next**.

    The **Summary** of the new audit displays in the window. If issues were found in the setup of the audit, you would be warned here.

26. If issues are cited, follow the directions in the fields showing explanations, going back to previous stages of the building of the audit profile and correct the details that have led to the issues.

27. Click **Finish.**
28. If you are sure the audit profile has been set up correctly, click **Yes** to activate the audit.

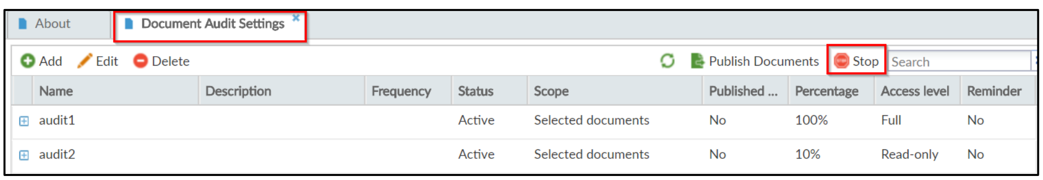


The newly activated audit appears in the display list.

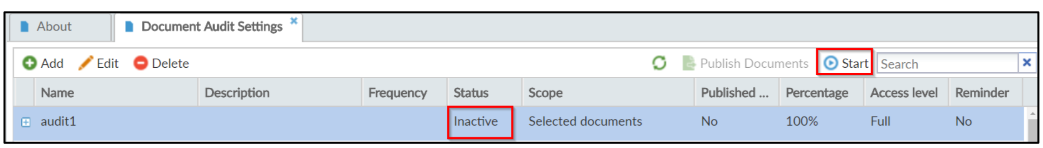
35.1.3. Inactivating and Reactivating an Audit

Room Administrators can stop and start audits that have been added to a room.

1. To inactivate an audit that is currently active:
2. Click the name of the audit in the list in the **Document Audit Settings** window.
3. Click the **Stop** button in the upper right corner of the window.



The **Status** of the audit changes from **Active** to **Inactive** in the **Status** column.



Audits can also be easily reactivated by clicking the **Start** button.

1. Click the name of an inactive audit.
2. Click **Start**.

   The **Status** changes to **Active.**

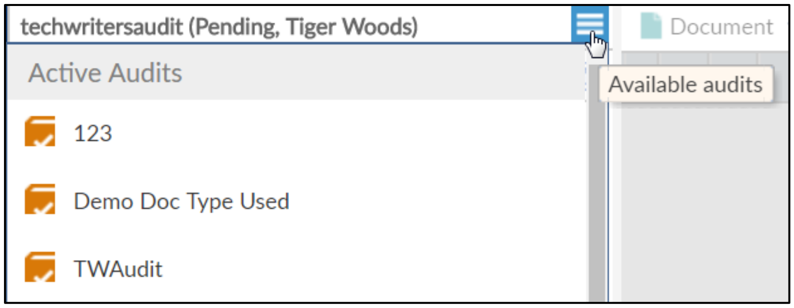
35.2. Performing Audits

If you are assigned the Auditor or Audit Manager action in your trial room, the audit feature is available to you when you click the **Quality Review** module in the toggling menu bar.

1. As a user with Auditor duties, log in to a room and click the **Audit** module icon.

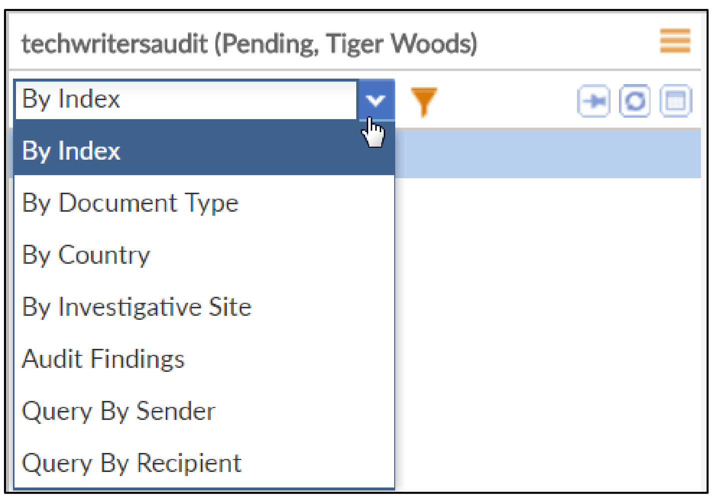
   The user can access **Audits** and **audit documents** through the panel on the left.

2. Click the three-bar icon to open the **Active Audits** menu.



3. Select an active audit. The default view is **By Index**.
4. Click the dropdown arrow to reveal the variety of available views.

   The user can also choose to view the available audit documents *By Document Type*, *By Country*, *and By Investigative Site*, *Audit Findings*, *Query By Sender, and Query By Recipient*. Select views to be displayed.



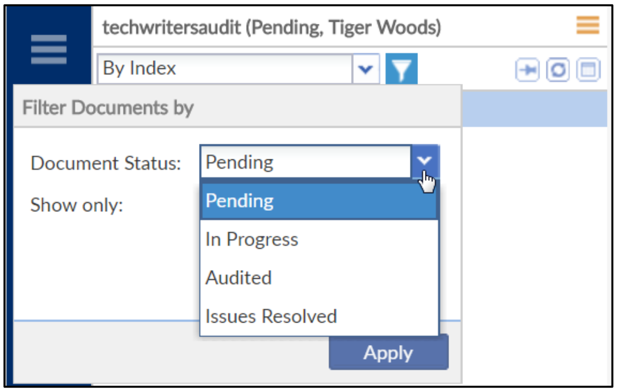
   Corresponding folders display based on the selection made by the user.

   Drill down and select the available folders. Available documents will be displayed in the grid.

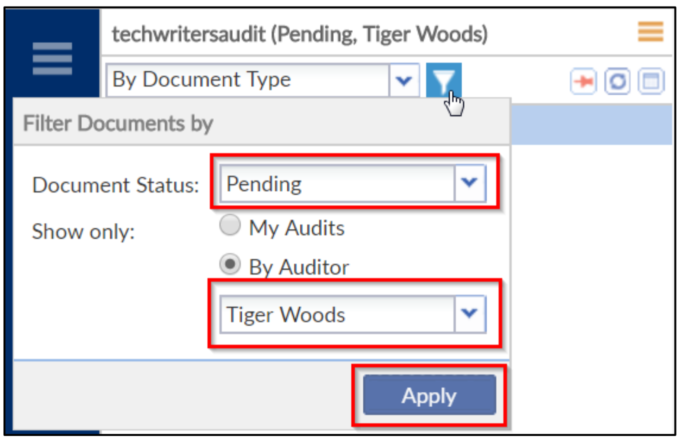
<u>The Auditor has another means by which to filter the audit documents.</u>

1. Once the Audit is chosen, click the filter icon.

2. Click the dropdown arrow at the right end of the **Document Status** field.

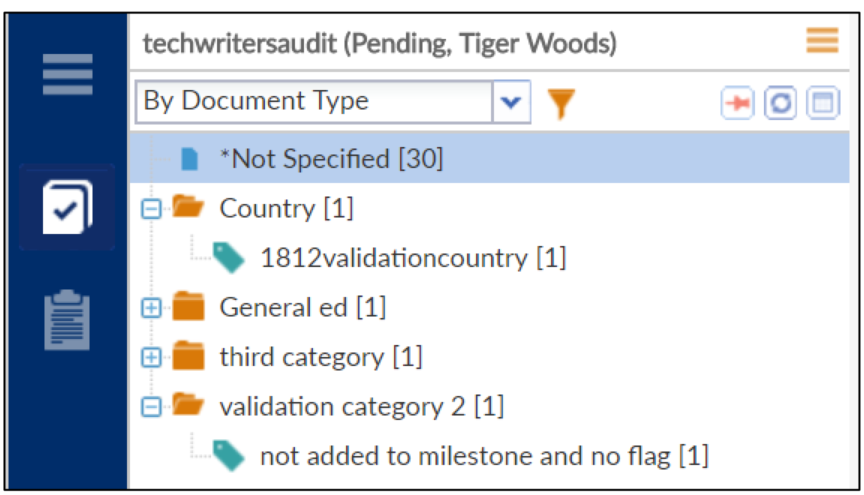


3. Select **Pending** from the list. Select the auditor as required.



4. Click the **Apply** button.

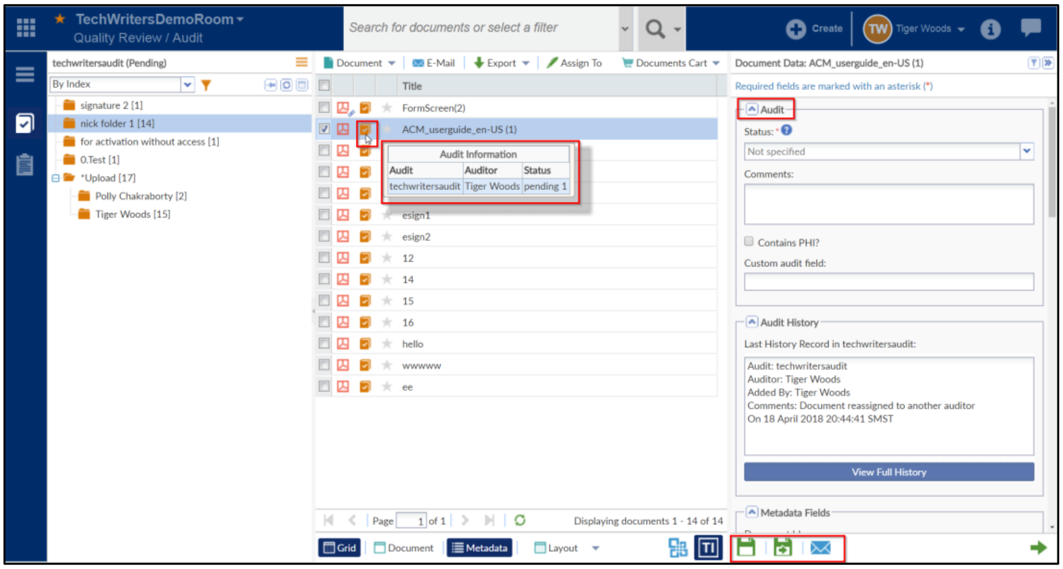
   Index folders containing documents **Pending Audit** populate the Index view panel.



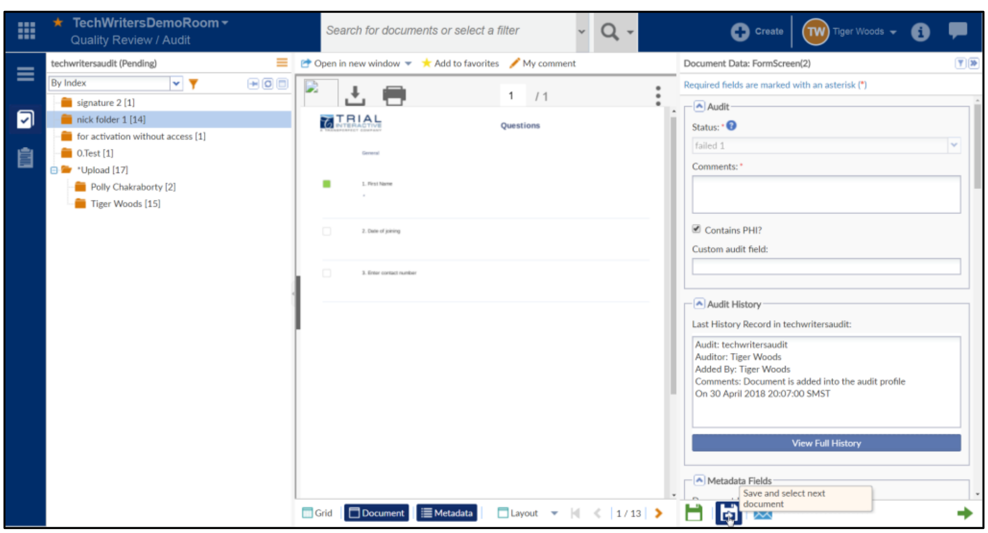
5. Open folders to locate documents published and assigned for audit.

6. Notice the **Audit Information** icon next to the document icon in the document grid.
7. Click the icon to open the Audit panel in the document metadata panel.

   Also notice the **Audit information popup** displaying the audit status of the selected document. Refer to the screenshot below:



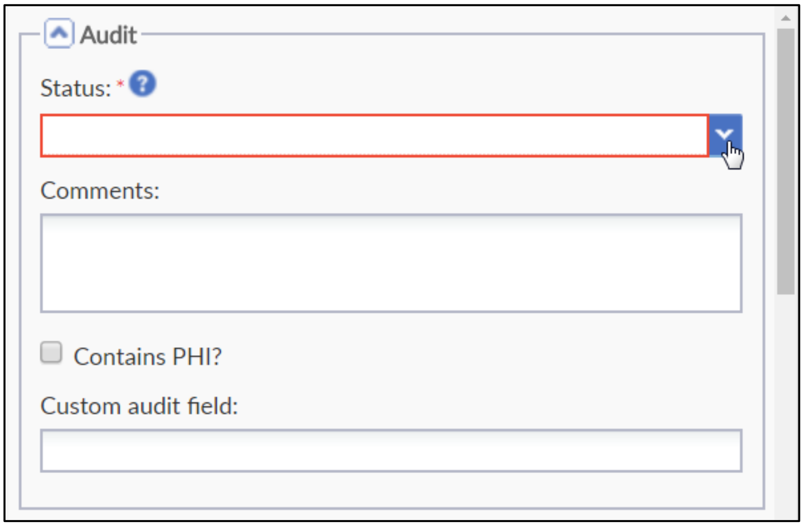
8. Open the document in the viewing panel.



9. Examine the document and its metadata to determine if it meets the established audit criteria.

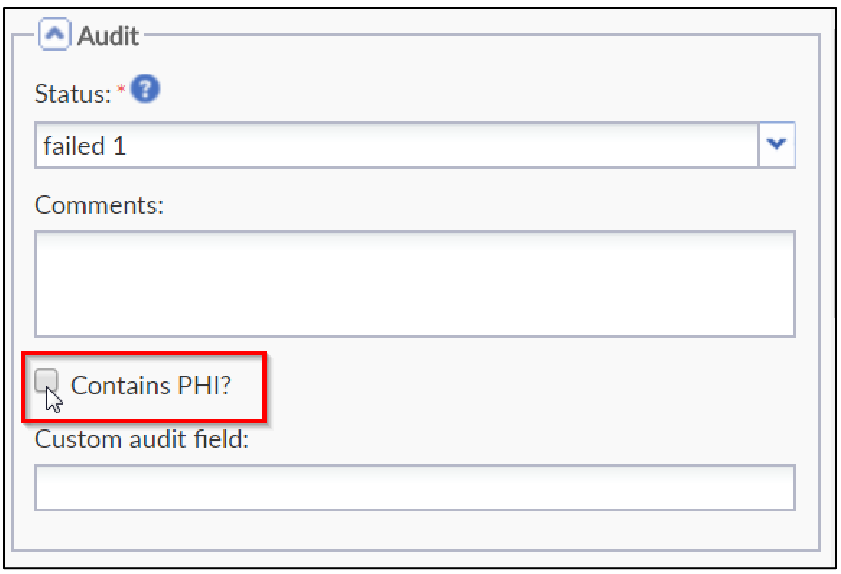
10. From the **Audit panel** in the **Metadata panel** click the dropdown arrow at the right end of the **Status** field.

    The status options appear.



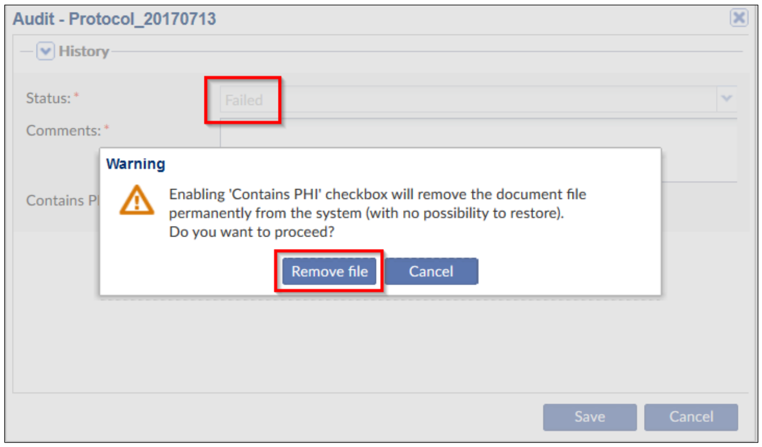
11. Click the appropriate **Status**.

    If the document contains **Protected Health Information** (PHI) and you want to delete and fail the document attachment for audit, tick the **Contains PHI?** checkbox.



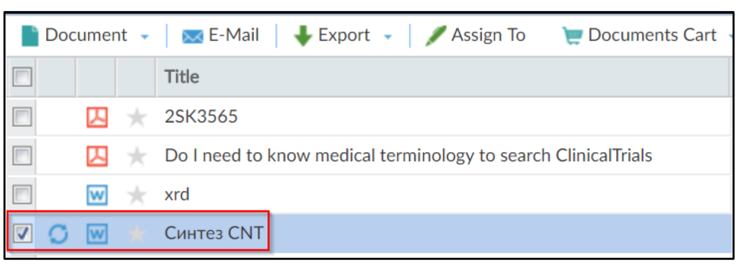
To enable the Contains PHI? field, you will need to enable the feature when setting up the Audit under Settings -> Audit -> Document Audit Settings.

On ticking this, the document automatically acquires a **failed** status and displays a warning regarding the removal of the attachment from the document.

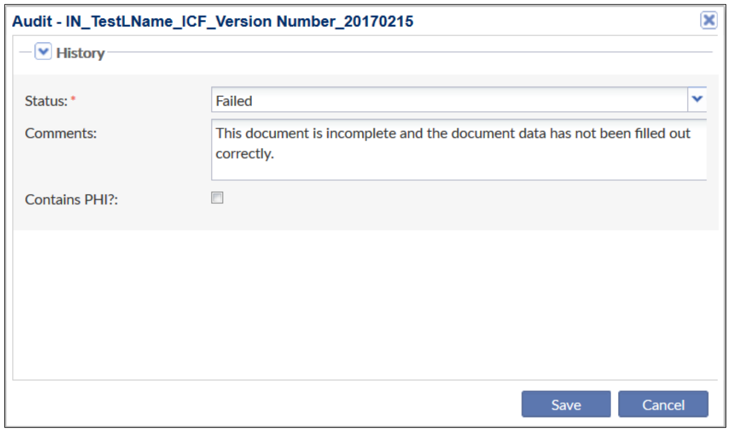


Click **Remove file** to proceed. The system deletes the attachment in the backend and displays the **Refresh** icon next to the document in the grid.

On clicking the **Refresh** icon, the document disappears from the grid and moves to the **Audited** folder.



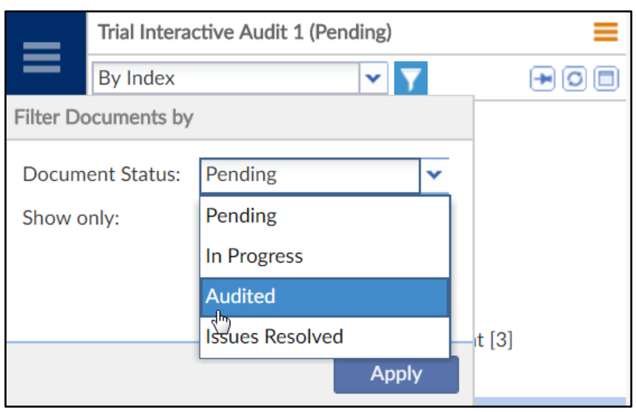
12. Insert comments as appropriate.



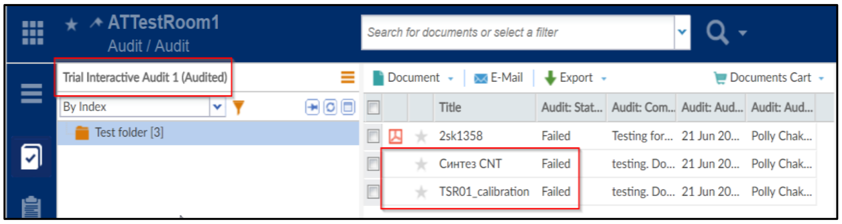
13. Click the **Save** button, or the **Save and select next button** in the lower toolbar of the window.

Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your audit criteria.

14. To view audited documents, filter the documents by Audited from the panel in the left.

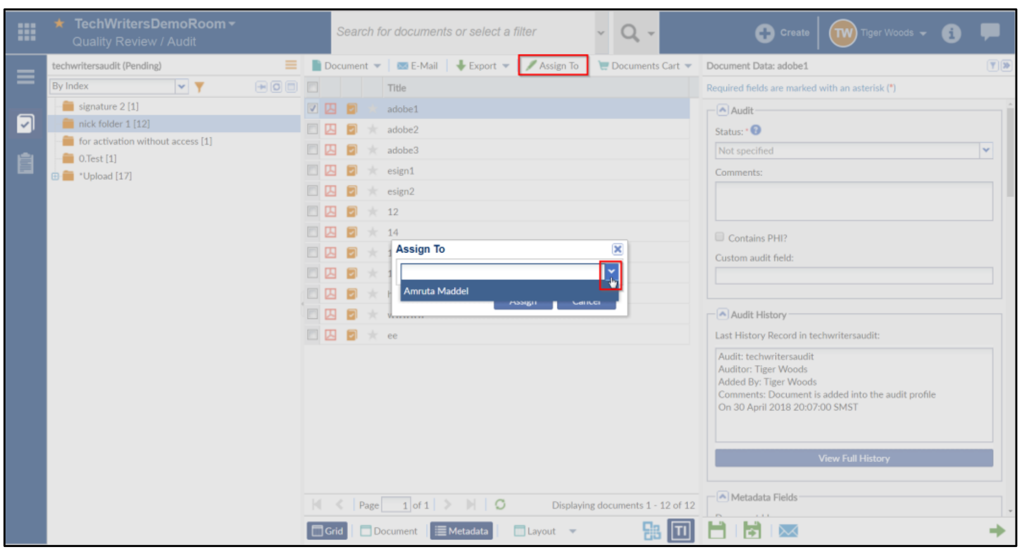


15. The audited documents appear in the grid with their respective statuses. Documents failed due to content of PHI appear in the grid without the attachment and acquire a failed status.



35.3. Reassigning documents for audit to another auditor

As an Administrator or Audit Manager, you can choose to assign a document to another auditor for audit by selecting the documents from the document grid and clicking the **Assign To** Assign To icon from the top ribbon bar. Refer to the screenshot below:



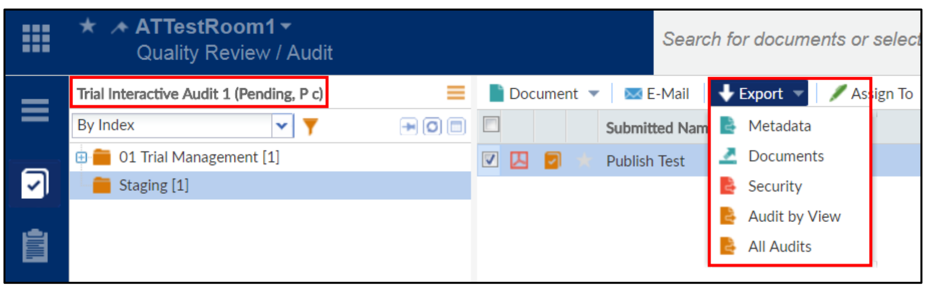
35.4. Export of Audit Reports by an Auditor or Audit Manager

An Auditor or Audit Manager can export a report of the following directly related to the documents assigned to any particular audit:

1. Metadata
2. Documents
3. Security
4. Audit By View
5. All Audits

To export an audit report:

1. Click **Audit** from the room's toggling menu bar.
2. Select the audit on which you would like to run the audit report from the list of active audits by clicking the three-bar icon.
3. Click the filter icon . From the filter documents by popup, select the required document status and the show only view (My Audits or By Auditor).
4. Click Apply.
5. Select the current view from the dropdown as required and click the folder from where you would want to export audit report.
6. A set of audit documents populate the document grid. Select them if required.
7. Click the **Export** button from the menu ribbon above the document grid.



8. From the **Export dropdown**, click the required option to generate an audit report.
9. Click the **Export** button.

   A **Background Jobs** window opens with the initial export results.
10. As instructed on the screen, click to get the export results.

    A zipped file downloads to your computer.
11. Follow the on-screen instructions to open the XLSX file.

Each option in the Export dropdown is discussed as below:

35.4.1. Metadata

This is same as discussed in Exporting Metadata section under chapter **Export Documents.**

35.4.2. Documents

This is same as discussed in Exporting Documents section under chapter **Export Documents.**

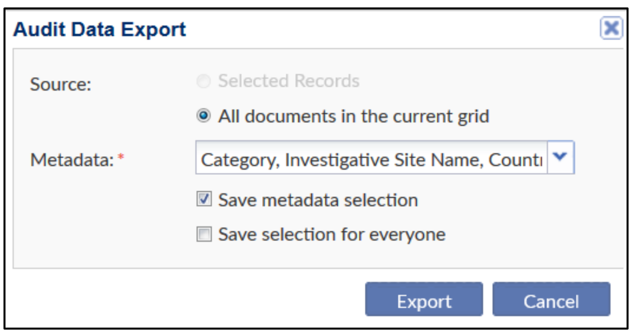
35.4.3. Security

This is same as discussed in Exporting Security section under chapter **Export Documents.**

35.4.4. Audit by View

Select **Audit by View** from the dropdown menu.

The **Audit Data Export** window opens.

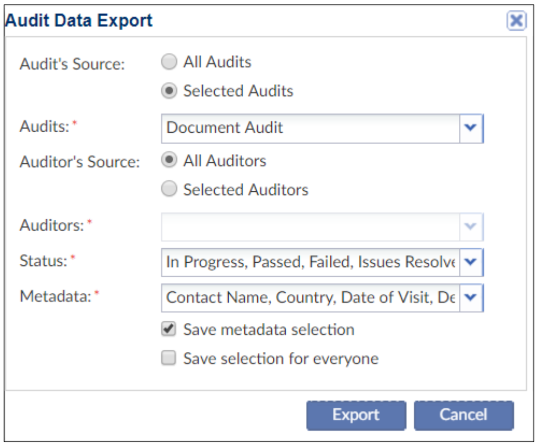


Follow the on-screen instructions to generate the audit report.

35.4.5. All Audits

Select **All Audits** from the dropdown menu.

The **Audit Data Export** window opens.



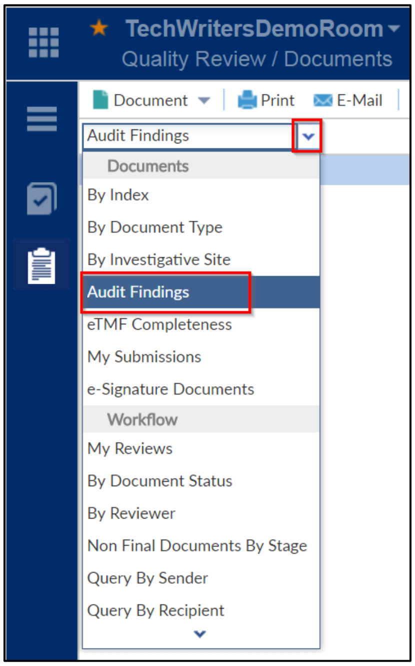
Follow the on-screen instructions to generate the audit report.

35.5. Performing the Audit Response

To perform an audit response, you must be logged in the room as an Audit Responder.

1. Navigate to the **eTMF/Documents** module or the **Quality Review/ Audit module**.
2. If you are in the eTMF Documents module, select **Documents** from the menu icons at the top of the screen.

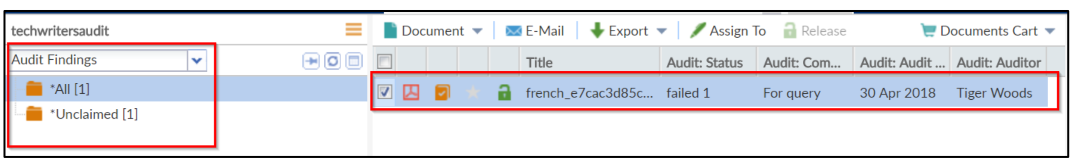
3. From either of the modules, in the Index dropdown, select **Audit Findings.**



The active audits to which you are assigned that have audits with findings populate the Index panel.

4. Click the folder for one of the audits.

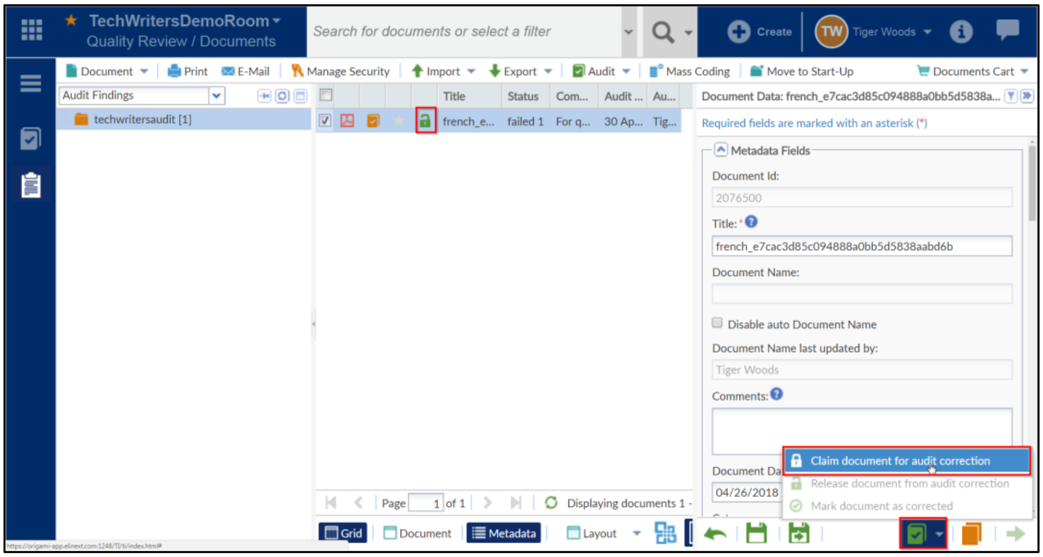
The documents with audit findings populate the document grid.



Documents in the list that are available for **Audit Response** show a padlock icon that is unlocked.

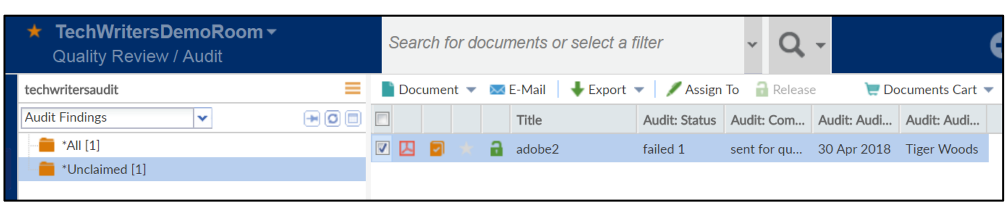
5. Select the document by clicking the checkbox.
6. Open the metadata panel for the document by clicking the **Metadata** button at the bottom of the document grid.

7. At the bottom of the metadata panel, click the **Audit** button.

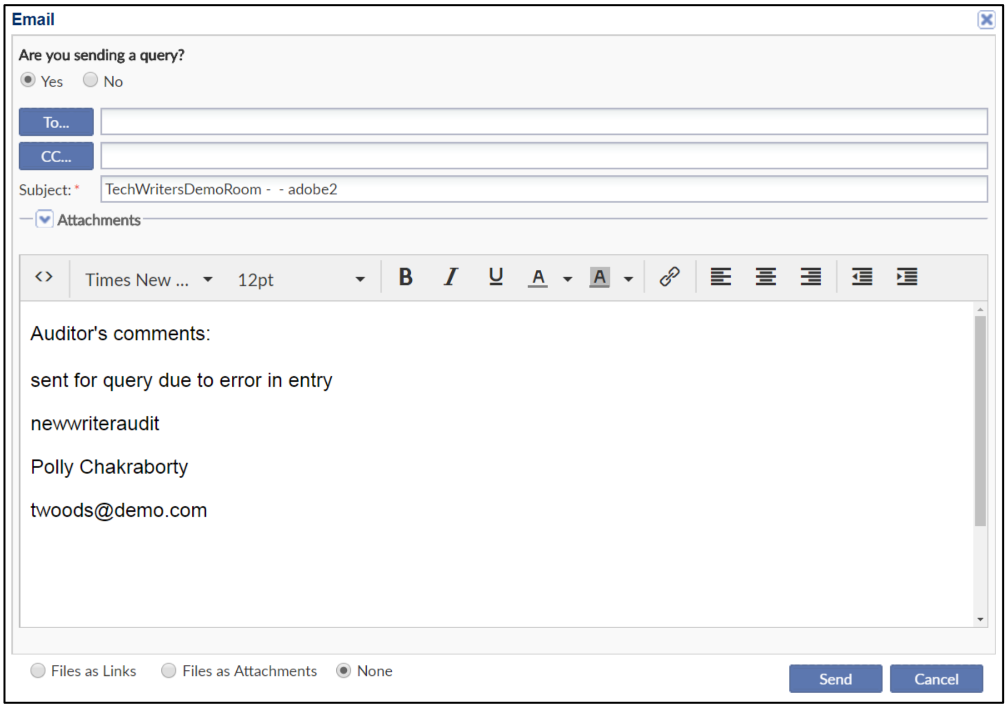


From the available options, click **Claim document for audit correction**.

8. Click **Document** at the bottom of the document grid to open the contents of the document for inspection.
9. From the Audit History panel, click **View Full History** button to view the comments included by the Auditor.
10. Appropriate actions on the part of an Audit Responder are based on the nature of the failure of the audit.
11. If the cause of the document's audit failure can be remedied by the Audit Responder, that action can be carried out.
12. In such cases, the Audit Responder then goes to the **Audit** button at the bottom of the metadata panel again and selects **Mark document as corrected**.
13. If the cause of the document's audit failure cannot be remedied by the Audit Responder, the Audit Responder clicks **Email** from the top ribbon bar or **Initiate Query** Initiate Query from the bottom of the Metadata panel.



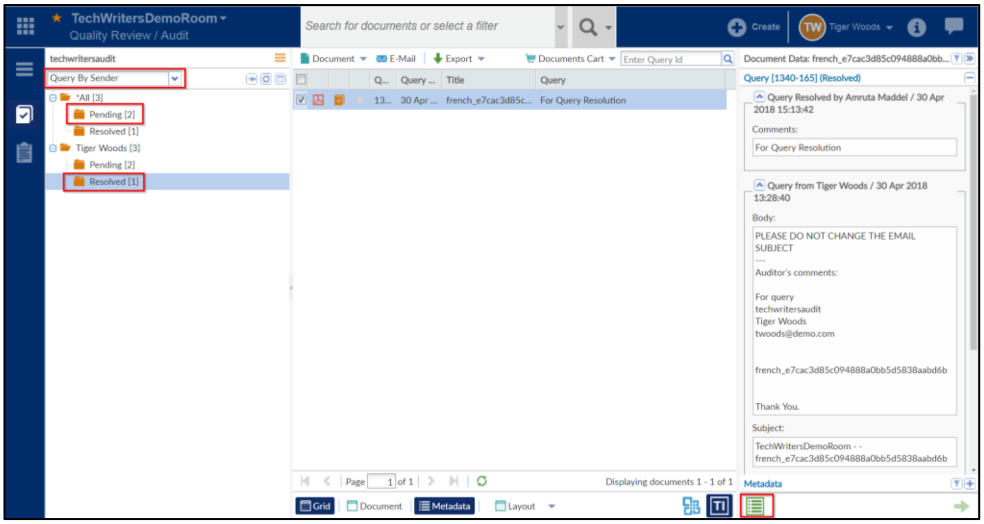
14. The **Email** popup window opens. Click **Yes** to the question **Are you sending a query?**
15. Click **To** and select the appropriate party or parties from the room's users to notify about the discrepancy discovered in the audit.



16. Include something in the Subject line and enter the text of message to alert the recipients as to what action they need to take.
17. Select **Files as Links** at the bottom of the Email window to send the document along with the email message. Documents can also be sent as attachments.

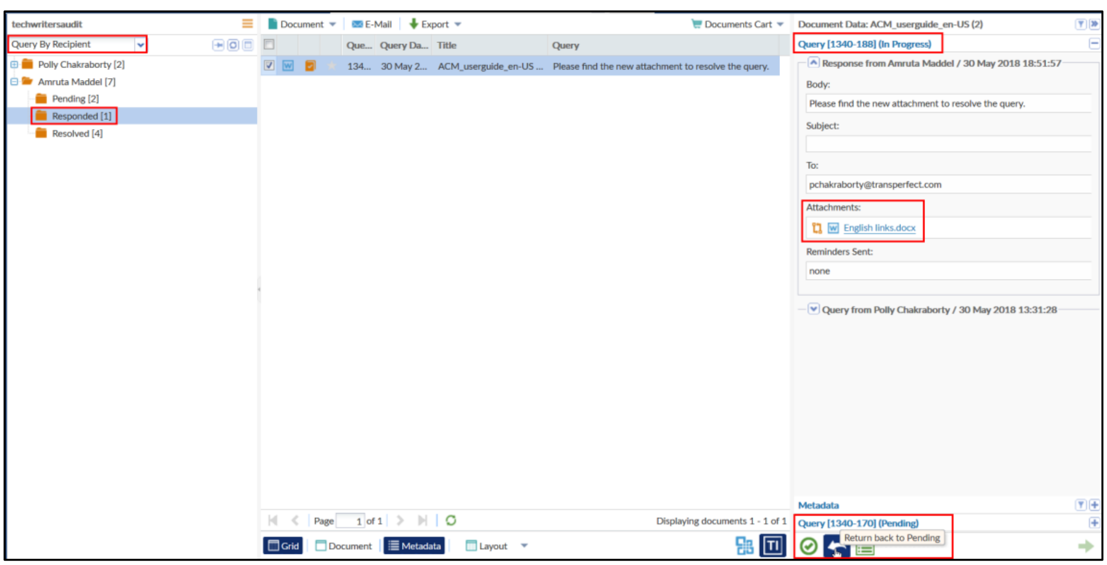
    Click **Send**.

    The selected users will receive the email message regarding the Query raised.
18. Click **Audit** sub-module from the left menu bar. The queries raised during audit can be viewed from the **Query By Sender** current view in the left index pane, if you have sent queries to be resolved during audit. Refer to the screenshot below.



35.6. Resolving Queries Raised during Audit

The user who receives the email responds back with an attachment to resolve the query. You can view the responded query in the **Responded** folder of **Query By Recipient** view under the selected audit. Refer to the screenshot below:

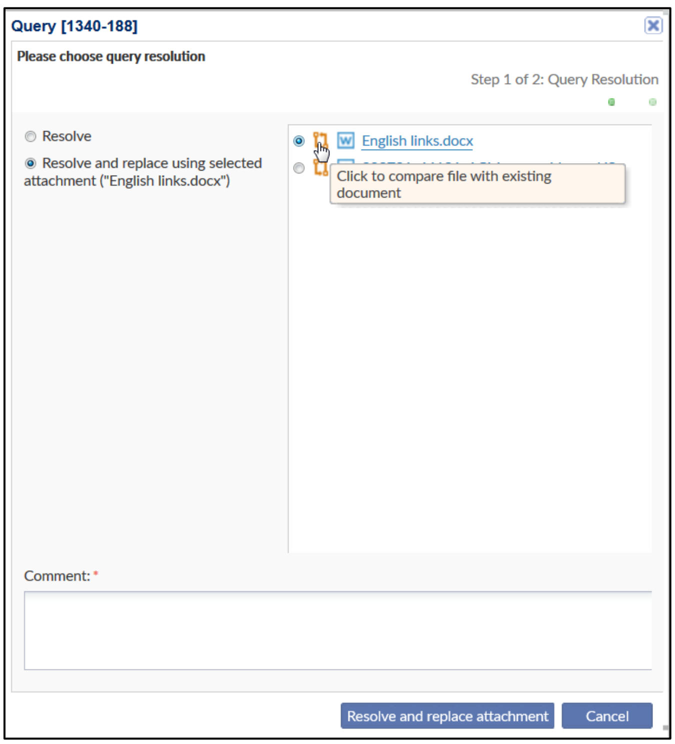


To resolve queries raised during audit:

1. Navigate to the **Query By Recipient** current view.

2. Select a query from the grid on the right.
3. Click the **Metadata** Metadata button from the bottom of the grid. This will open the Document Data Panel.
4. Click the **Resolve** button from the bottom of the **Document Data Panel**.

   If the resolution is not acceptable, you can click the **Return to Pending** button from the bottom of the metadata panel. The document returns back to the **Pending** folder and can be resent for query again.
5. This will open the **Query** window to comment and resolve the query.
6. Enter the **comments** and click the **Resolve** button or **Resolve and replace attachment** button on the window as per your selection. Refer to the screenshot below:

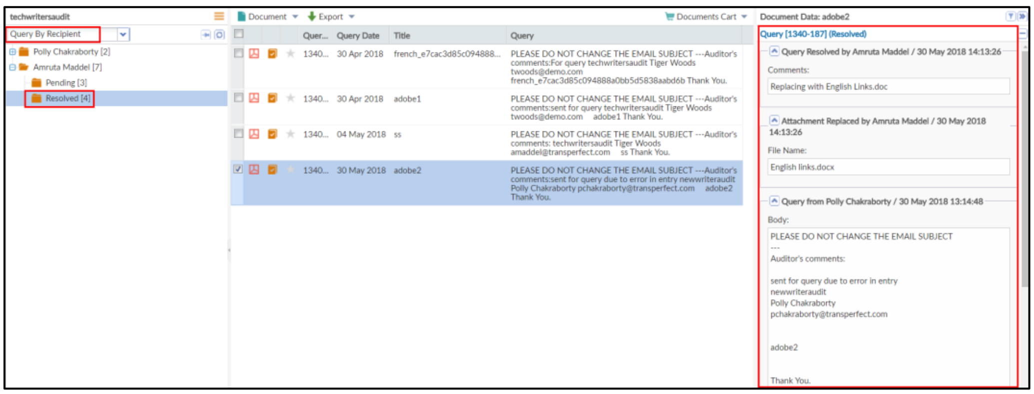


   a. **Resolve**: This option will just mark the query as resolved without any additional actions.

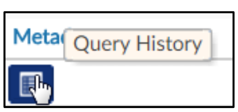
b. **Resolve and replace using selected attachment**: This option allows you to replace the existing attachment with the one which is received as a part of query response. Select the document from the right pane and click **Compare** icon to compare the attachment received with the document in audit.

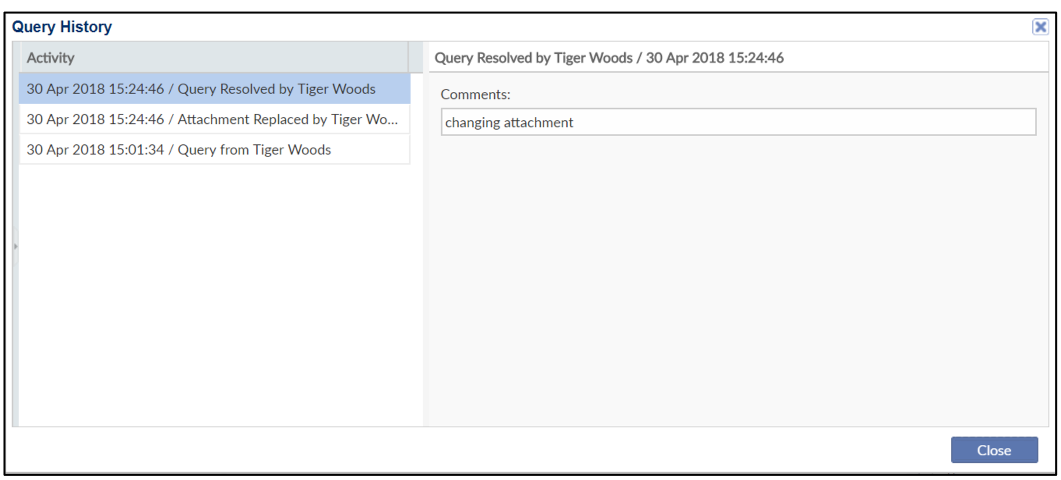
If you are satisfied with the response received, enter your comments and click Resolve and replace attachment button.

7. This will resolve the query and the query will now move automatically to the **Resolved** folder under the name of the auditor.
8. Click the **Resolved** folder from the **Index Pane** to view the resolved query. Refer to the screenshot below.



9. You can click the **Query History** icon at the bottom of the Document Data Pane for a query to view the **Query History** in a window that pops up. Refer to the screenshots below:



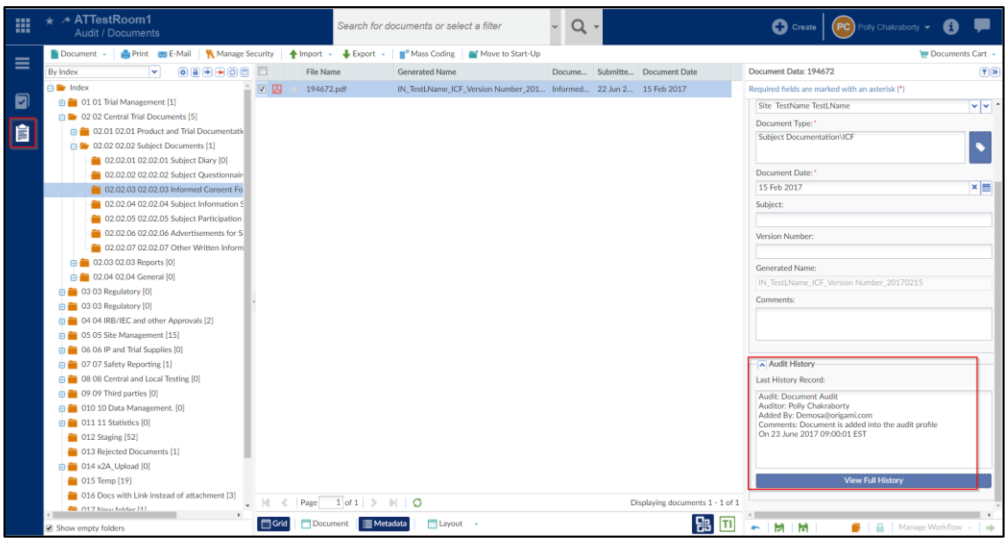


To know how to view a deleted queried document, proceed to section Deleted Queried Documents.

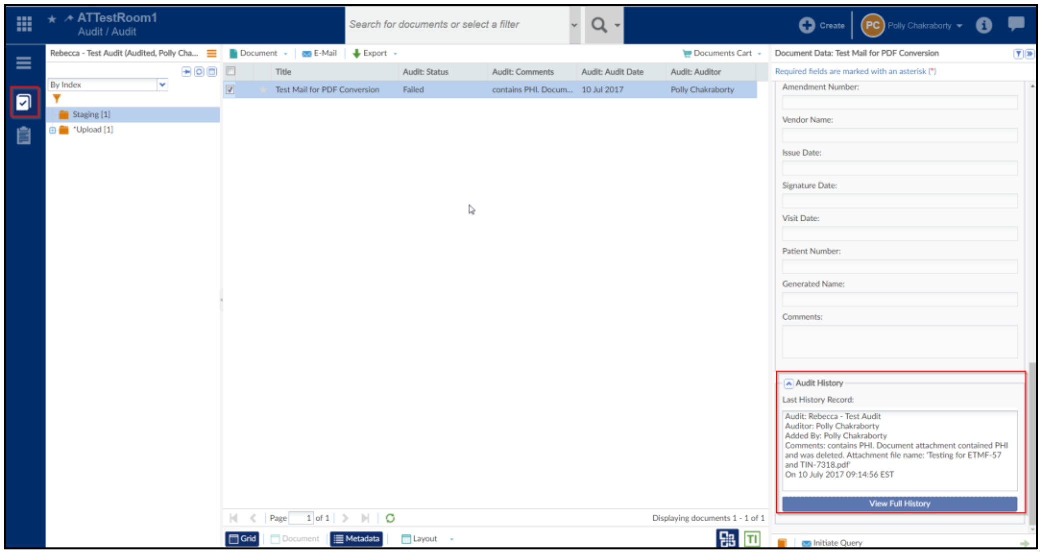
35.7. Viewing Audit History

Users can view a document's Audit history in the Metadata panel from:

1. **The Documents module**



2. **The Audit module**



Documents deleted and failed due to contents of PHI get recorded in history as **document deleted as it contained PHI information**.

35.8. Releasing documents claimed by an Audit Responder

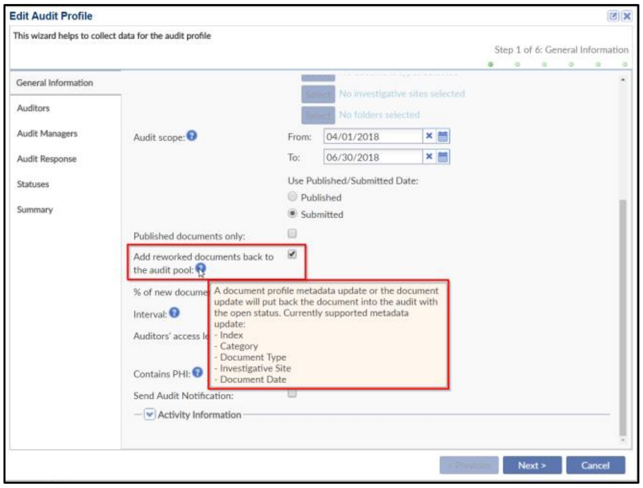
To release documents claimed for audit, select the document from the Document Grid and click the **Release** 

icon from the top ribbon bar, or from the bottom of Metadata panel of the document. This will release the document and the button will be disabled for the particular document.

35.9. Adding modified document back to Audit Profile

To allow for a modified document to be added back to the Audit Profile, follow the steps as below:

1. Navigate to **Username dropdown -> Settings -> Audit -> Document Audit Settings.**
2. Select the Audit Profile as required and click **Edit** from the top ribbon bar.
3. Select the checkbox next to **Add reworked documents back to the audit pool.** Refer to the screenshot below:



4. Click **Next** and complete the remaining steps to modify the Audit Profile.

36. Shared Workspace (TI Collaborate)

A **shared workspace** (SWS) is an intermediate room where the Sponsors and Study Management Team of a clinical study can collaborate to store documents until they are sure about the contents and metadata of the documents. When the user of a Shared Workspace are clear how the TMF study will be like in terms of the metadata such as document type, they review the documents and decide on whether to publish such documents to the eTMF. Some documents may reside in the shared workspace while the others are published to eTMF by the user. When a document is published, it is auto-routed to corresponding folder as mentioned in the **Room Settings -> Documents -> Index Outline** or published as a final document based on the workspace configuration.

36.1. Shared Workspace Improvements

In Trial Interactive 9.2, many improvements as follows, are made to eliminate/reduce the errors that arise while publishing documents from the SWS to the eTMF:

1. It is no longer required to maintain the same Document Types, Site, Contacts and other details as in the eTMF room in the SWS. This reduces replication of information.
2. The user will need to first decide whether a document can be published to the eTMF by selecting the option ‘Is this a TMF Document – Yes or No’ before publishing a document.
3. If a document is TMF Applicable, the system allows the documents to be coded based on the metadata applicable from the eTMF room and allows publishing of such documents. The following fields will be fetched from the eTMF to the SWS document for its coding:
    a. Categories
    b. Document Types
    c. Investigative Sites
    d. Contacts
    e. IRB/EC
    f. Document Field Forms
4. The above greatly reduces errors that arise due to mismatch of Investigative Sites, Document Types and Contacts.

5. After a document is published to the eTMF, its metadata is no longer editable from the SWS room and the document is locked from further publication to the eTMF. Thus, it is no longer possible to publish a document that already exists in the eTMF.

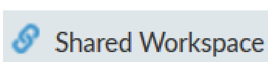
- ***A Shared Workspace room should be linked to only one eTMF room as the system is not be able to recognize the synchronization between multiple eTMF rooms thus leading to documents not being published.***
- ***Once a document is published to the eTMF, or a SWS has at least one document with 'TMF Applicable – Yes', it can no longer be unlinked from its eTMF room.***

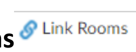
36.2. How to Enable Shared Workspace

To enable a Shared Workspace room, contact the helpdesk.

36.3. How to Link Rooms to Shared Workspace Enabled Room

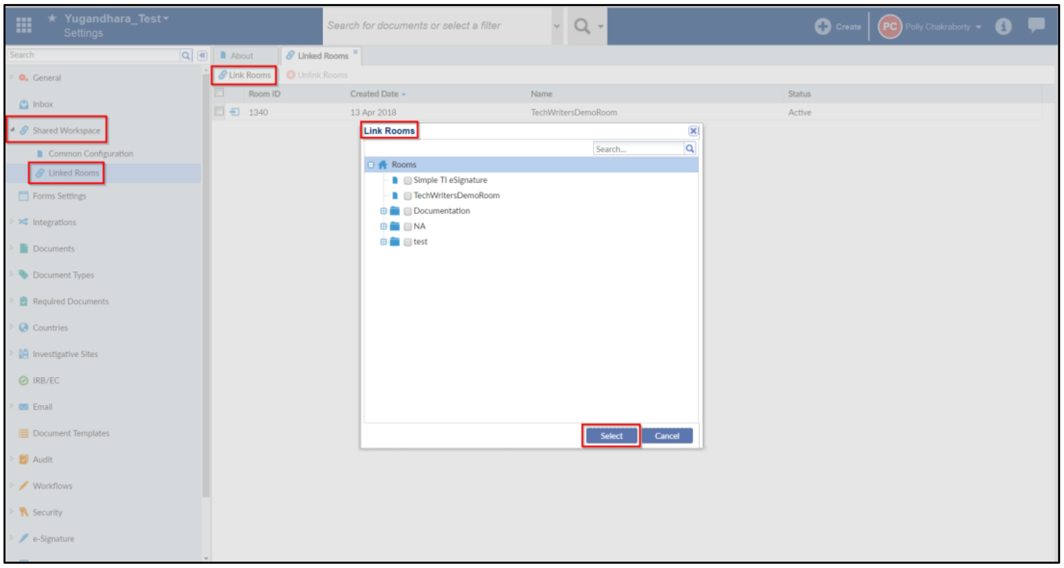
1. Enter the shared workspace and click the room **Settings.**
2. Click the **Shared Workspace -> Linked Rooms** option located on left menu bar.



3. Click the **Link Rooms** 

button in the **Linked Rooms** section. This opens the **Link Rooms** popup. Select the desired room from the Room menu list. Click **Select** 

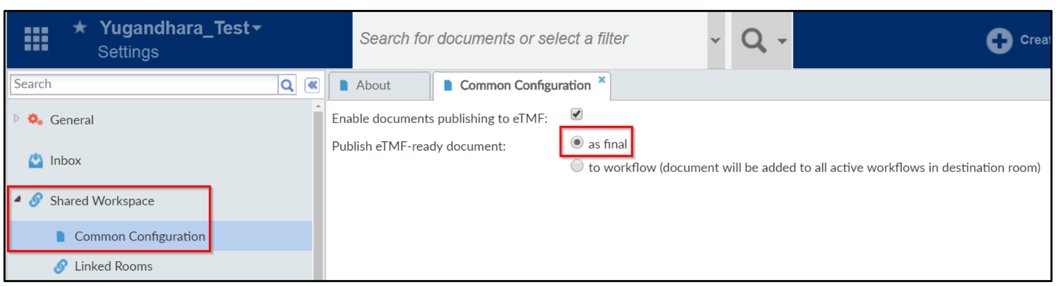
.



The rooms are now linked to your Shared Workspace source room.

4. The user has an option to publish the documents **as final** in eTMF.

   Access the **Shared Workspace** -> **Common Configuration** setting as demonstrated earlier. Click the suitable option to **Publish eTMF-ready document as final** to publish the documents to eTMF or select the **Workflow** option in order to add the documents to all active workflows in the destination room.

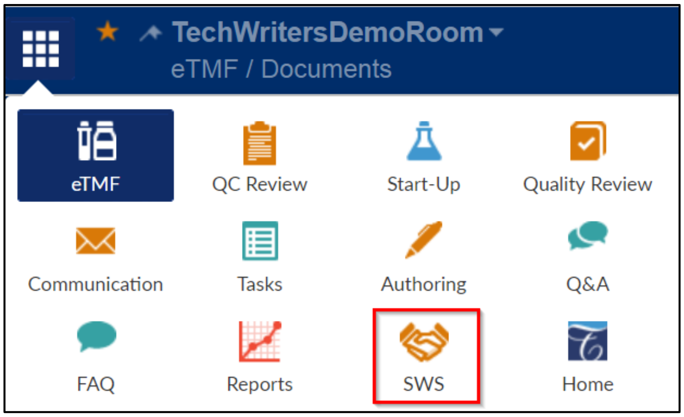


5. Click **Save** after you have made the desired changes.

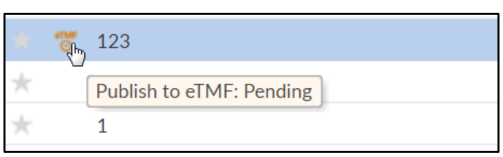
36.4. How to Publish eTMF Documents from a Shared Workspace

To publish a document to eTMF, follow the steps below:

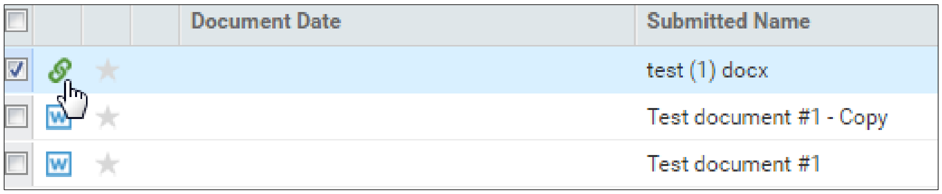
1. Navigate to the Shared Workspace room. You can navigate to the SWS from the eTMF room also by clicking the SWS icon from the Navigation Grid. Refer to the screenshot below:



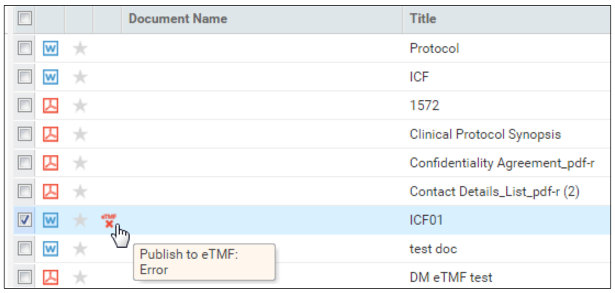
2. Navigate to Documents sub-module.
3. Find and select the document you want to publish from the Document Grid and navigate to its Metadata panel.
4. By default the Metadata panel is greyed out with only the **'Is this a TMF Document?'** radio buttons activated.
5. Select **Yes** if the document needs to be published to the eTMF. This will activate the Metadata panel and the **Save and Publish to eTMF** button located on the tool bar at the bottom of the Panel.
6. Complete the metadata coding. Notice that you will be allowed to select and apply the metadata as fetched from the eTMF room only.
7. Click the **Save and Publish to eTMF** button after you have finished coding the document.
8. Accept the warning that you are about to publish this document to the eTMF.
9. While the publishing process is going on, you will get a view showing the status of the publishing process as below:



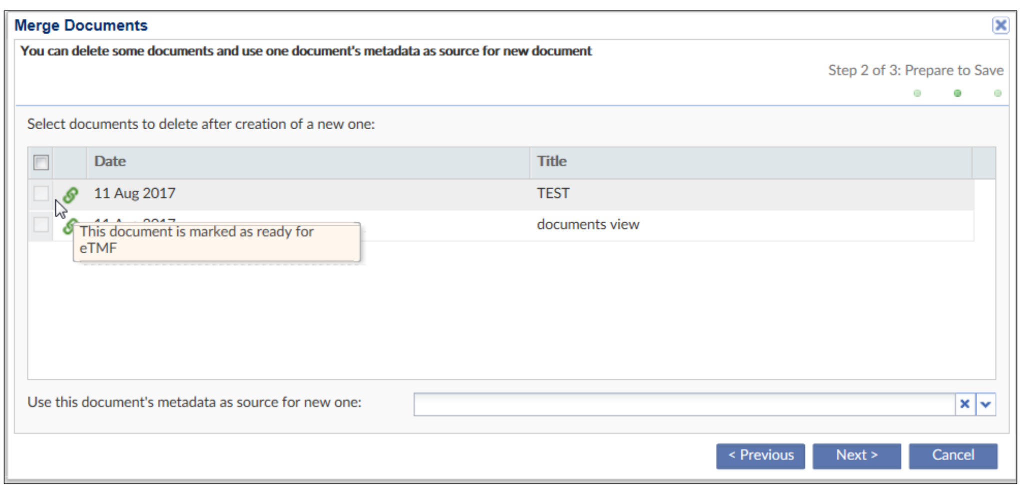
10. You can refresh the view to update the list of published document.
11. Once the document is published, it will show in the Document Grid with a hyperlink next to it. The author of the document is now the user who has published it.



12. If there is an error and the document is not published, you will be able to see it in the Document Grid.



13. You can also proceed to the **Processed Documents** folder from the Current View to see the status of the published documents.
14. A published eTMF document can be merged with other documents by adding it to the Document Cart. Follow on to section [Document Cart](#) for more details on this. **Original documents in a Shared Workspace on merging cannot be deleted if they are already published to the eTMF, even if the documents were not published due to errors.**

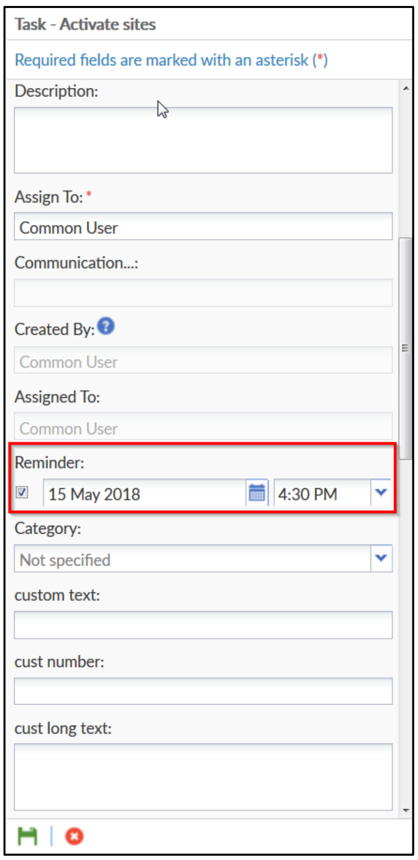


36.5. Deleting Documents from a Shared Workspace

Deleting a document that was published to the eTMF from the shared workspace will also delete the document from the eTMF. To delete the document, select the document and **right click** to select the **Delete** Delete option from the dropdown, or click the **Document Dropdown** on the top ribbon bar and click **Delete** Delete . Read the message that comes while deleting. If you still decide to go ahead, click **Yes**.

37. Tasks

Administrators can manage and track their Trial Interactive tasks for their rooms using this feature. They are given an option to add, edit, delete, and export tasks. Additionally, administrators can adjust the number of days before a task's deadline for a user to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task. Refer to the screenshot below:

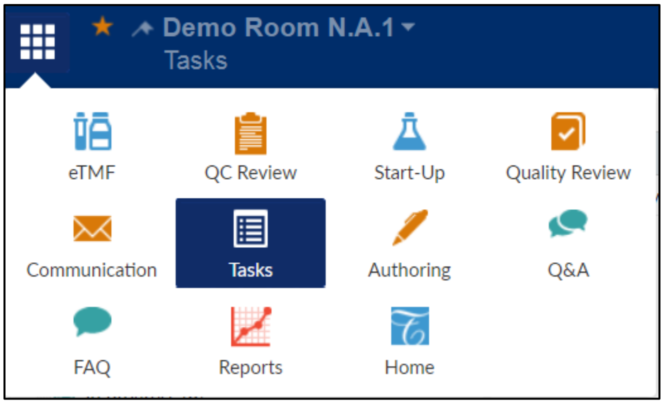


As a Trial Interactive administrator, you can access Tasks as mentioned below:

a. **Enter the room** for which you want to create tasks from the **Home** page.

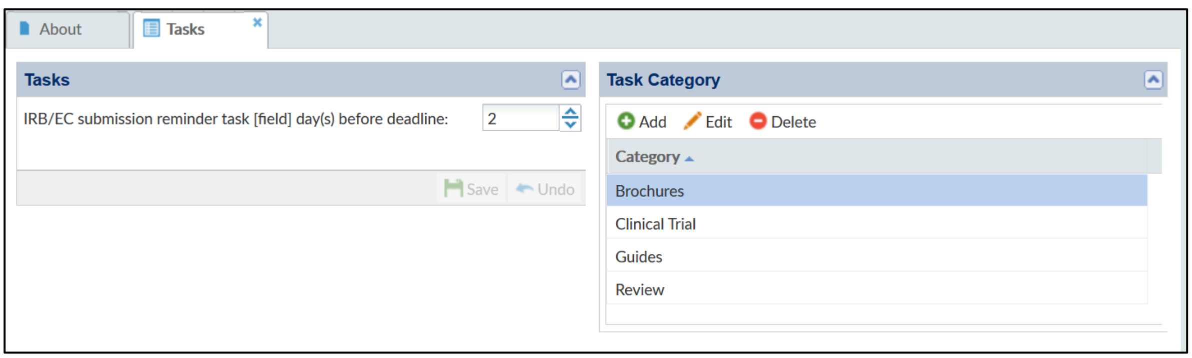
b. Click the **Navigation Grid** on the title bar from within the room.

c. Click **Tasks** icon.



37.1. Tasks Settings

An administrator would need to set up certain configurations for tasks in a room from **Username dropdown -> Settings -> Tasks**.



These configurations can be listed as follows:

1. **IRB/EC submission reminder task [field] day(s) before deadline**: 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.

2. **Task Category**: Task categories need to be specified while creating a task. These task categories need to be created so that the user may select the appropriate category from the dropdown of the **Task Creation** window. Tasks can be created, edited, or deleted through the buttons on the **Task Category** dashlet.

   a. Click +**Add** to add a task and press Enter.

b. Double-click a task, or select an existing task and hit the **Edit** button to edit a task. Press Enter after editing.

c. Select a task and hit the **Delete** button to delete it.

37.2. Tasks Module

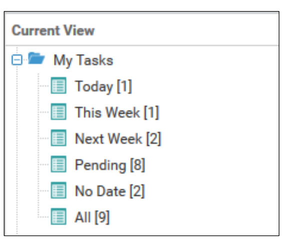
From within a room, the administrator can maintain and track tasks related to the TI room. They can add, edit, delete, and adjust their tasks.

Once inside the Tasks dashboard, you can adjust the **Current View** in the left pane by:

1. **My Tasks**
2. **By Status**
3. **By Owner**, and
4. **By Category.**

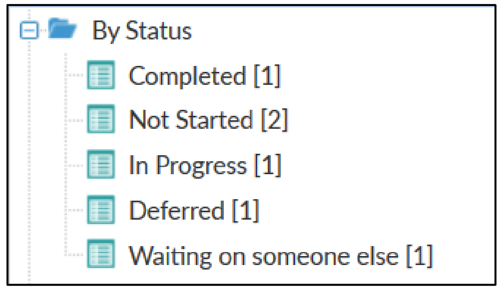
37.2.1. My Tasks

This view gives the list of tasks belonging to the user based on today, this week, next week, pending, overdue, tasks that have no starting date (No date), or all the tasks together in the document panel. The task count is also displayed next to each time frame.



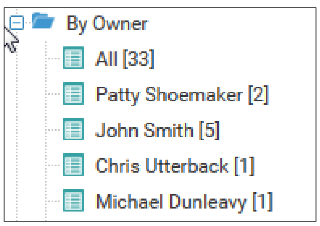
37.2.2. By Status

There are five task-statuses available. The system color-codes the status according to the specified work completion percentage. This view lists all the tasks in the document panel as per the status selected. The count of task per status is also displayed next to each status in the left pane.



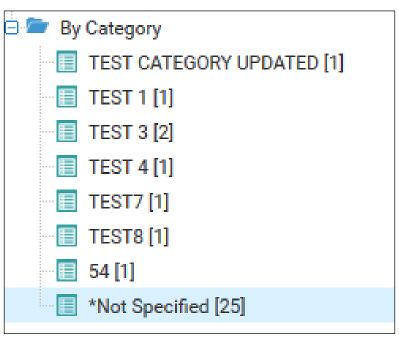
37.2.3. By Owner

This view lists the tasks belonging to a particular user or all users on the right pane. It also gives the count of tasks belonging to each user.



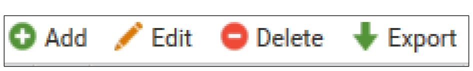
37.2.4. By Category

This lists all the tasks under each category along with their counts.



37.2.5. Adding, Editing, or Deleting Tasks

Tasks can be added, edited, or deleted from the icons in the ribbon above the dashboard.



Mention the task name in the subject text box while adding tasks from the **Task Profile** window. Tasks can be edited from the **Task Profile** window or from the **metadata panel** located on the right of the dashboard. When adding or editing a task, you are also given an option to attach files.

Simply click **Attach a file** from the **metadata panel** or in the **Task Profile** window. When you are finished attaching files, click **Save** and a clip icon with a number will appear next to the subject line on the document panel. The number next to the clip icon reflects the number of attachments for a particular task.

Other metadata fields that Administrator users can fill out include the following:

1. **Start Date:** The date when the task should be started.
2. **Due Date:** The date by which the task should be completed and submitted.
3. **Priority:** The priority of a task could be Low, Normal, or High.
4. **Status:** Depending upon the progress of the task, the status could be set as Completed, Not Started, In Progress, Deferred, or Waiting on someone else.
5. **Complete %:** The percentage of the task that is completed. Depending upon the figure entered here, the Status field automatically acquires the status of Not Started, In Progress, or Completed.
6. **Description:** Any comments on the task, one of which could be its purpose.
7. **Assign To:** Users to whom the task is to be assigned. This is covered in detail in the following section.
8. **Reminder (Date, Time):** The date and time when the assignees of the task should receive a reminder.
9. **Category**: The task categories, as created through Task Settings, are populated in the dropdown. This helps to categorize tasks.
10. **Edit history:** This is also tracked and recorded on the bottom of metadata form or Task Profile window. If any changes are made, click **Save**.

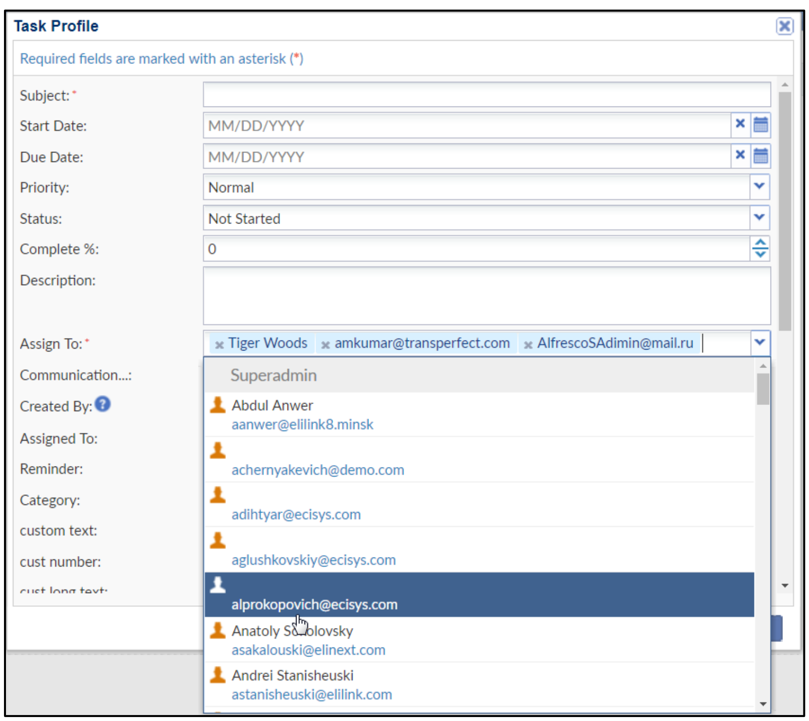
37.2.6. Assigning tasks to multiple users

Administrators and Editors can assign tasks to multiple users only while creating a task. In such case, the system creates corresponding number of separate task records, one task per user, and adds user full name to the subject line of the task. **Hence, after the task is created and saved, the administrator, if required, can edit each individual task to re-assign it to only one other user.** On re-assigning a task to another user will not only move the task to the folder by the new assignee's name under 'By Owner' view, it shall also display the name of the previous assignee in the task subject line.

To be able to assign tasks to multiple room users, the administrator must have the required privileges set up for his/her account. The administrator can also enable an editor to assign tasks to multiple room users. To know more about this, proceed to **Settings -> Security -> General -> Actions**, and then to **Security -> Users -> Invite Users** or **Security -> Users -> Edit**.

To assign a task to users:

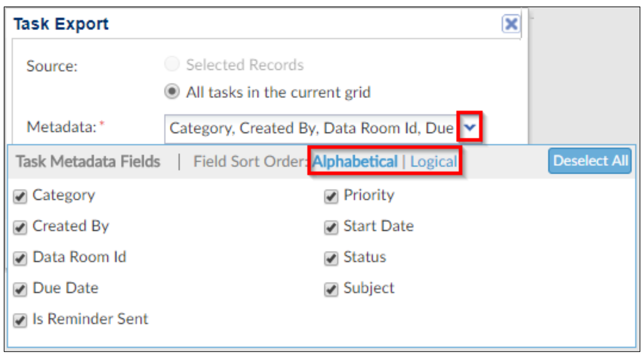
1. Click **+Add** to open the **Task Profile** window.
2. Enter the task details as required.
3. Activate the **Assign To** dropdown to reveal a list of users
4. Select the users to whom you want to assign the task from the list.
5. Click **Save**.
6. This will assign the task to multiple users as selected in the list. Refer to the screenshot below:



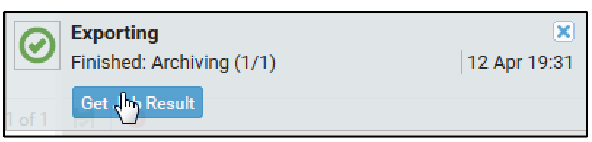
Editors can also assign tasks to administrators.

37.2.7. Exporting Tasks

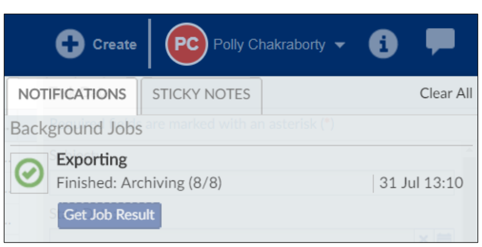
You can also export tasks through the **Task Export** window invoked by clicking the **Export** icon Export on the ribbon. You may export tasks selected from the document panel, or all the tasks in the current grid. To export tasks, it is mandatory to select the **Task Metadata Fields** which will be saved in the export job result as an excel file.



During export of tasks, a popup showing the status of the export job is shown. Refer to the screenshot below.



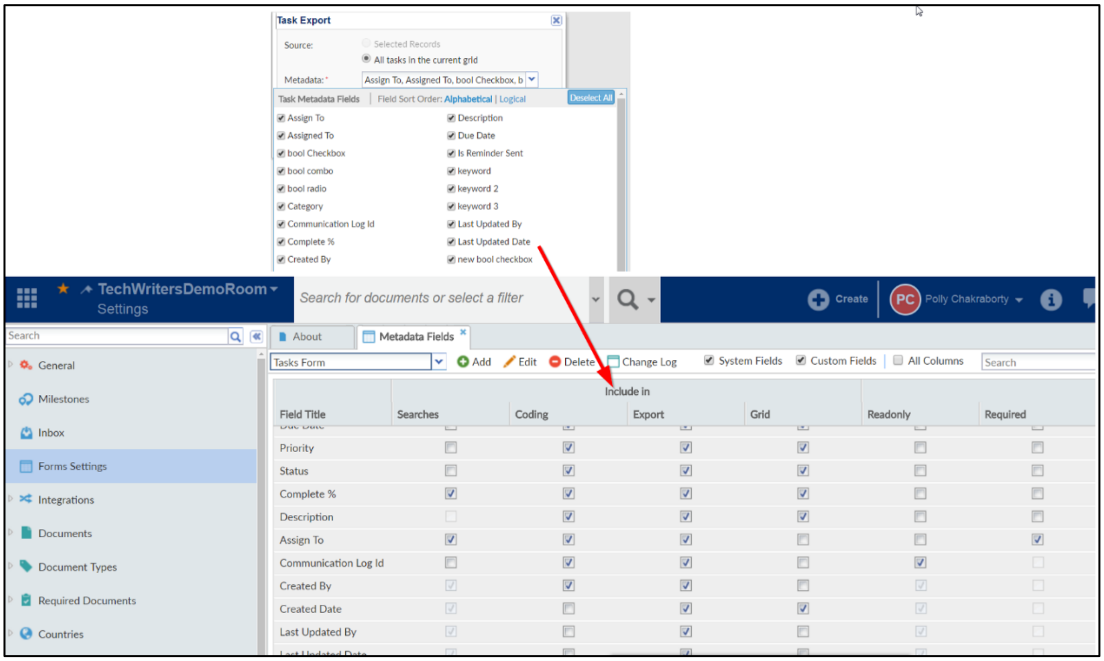
The export results are also populated in the **Notifications.** Click **Get Job Result** to view the excel file.



To enable export of tasks metadata:

1. Navigate to **Settings -> Forms Settings -> Metadata Fields**
2. Select **Tasks Form** from the drop-down.

3. Check the boxes as required under the **Export** column. These are the Metadata Fields you would want to export. Only selected fields will be available for **Task Export**. Refer to the screenshot below.



You can also view task statuses from Tasks dashlet.

38. Authoring

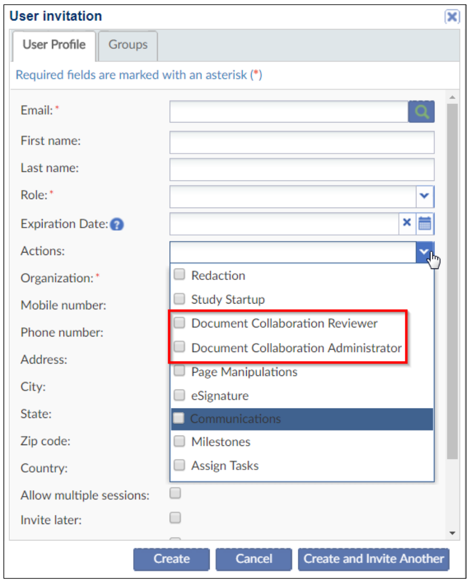
The **Document Authoring** feature which can be accessed from the **Navigation Grid** icon, includes two main features: **Document Co-Review** and **Document Co-Authoring**. These features are only available to Enterprise clients.

Document Co-Review provides functionalities to configure review processes for TI documents, or upload files and allow multiple users to perform online documents review. This feature enables users to review documents concurrently, allowing for greater flexibility as users no longer need to wait for others finish their review. The online review feature is provided by an external application, **Please Review.**

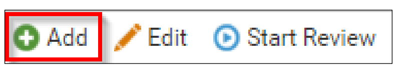
To use this feature, the Document Authoring module in the Settings needs to be enabled beforehand, and additionally, it must be communicated to Project Manager if you wish to use and activate the Document Authoring feature.

Once this feature is activated, Administrator users by default will have access to Authoring. However, for every other level users, when they are invited to participate in document review, they need to be given a specific role – either **Document Collaboration Reviewer** or **Document Collaboration Administrator** – to gain access to Authoring.

To briefly explain the given roles: **Document Collaboration Reviewer** can only ‘review’ documents that were already uploaded. On the other hand, **Document Collaboration Administrator** can publish a document to be reviewed by other reviewers and can also comment on the document.



To use the **Document Authoring** feature, the first step is to create a review. To do so, simply click on the **Add** button located on the bottom of top ribbon bar.



Next, a **Create Review** window will pop-up and you can fill out the requested information on the form.

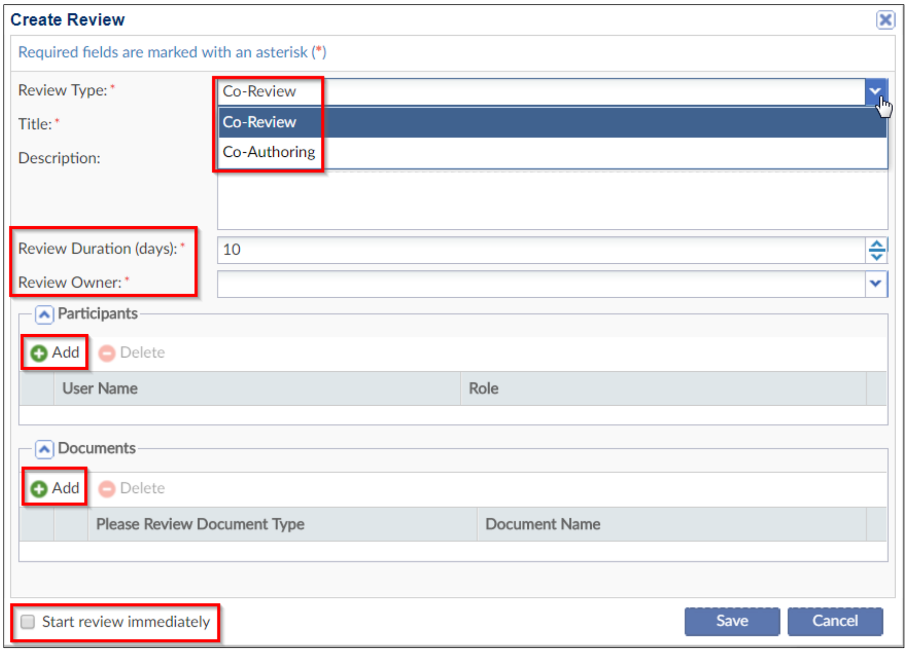
For **Review Type**, there are two options: **Co-Review** and **Co-Authoring**. In this first scenario, **Co-Review** will be chosen.

Review Duration (days) means the number of days by which the document review must be completed. Based on this parameter, the system will calculate the due date for the document review. By default, it will be set to 10 days; however, you can increase or decrease based on your preference.

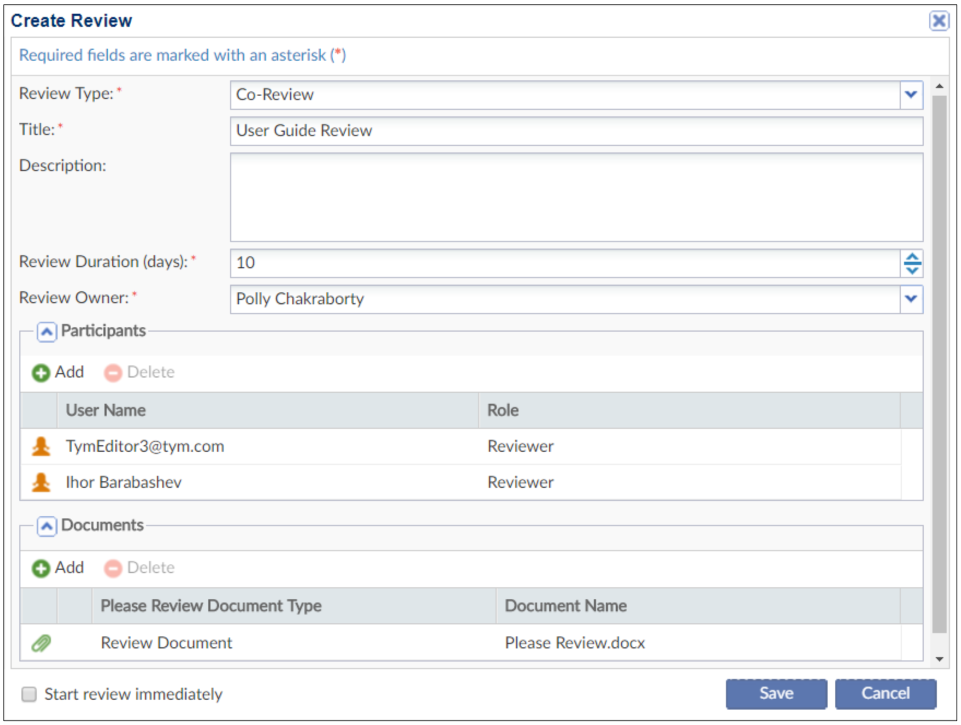
The **Review Owner** is the one who uploads the document to be reviewed by other participants. Only those with a Document Collaboration Administrator role can be the Review Owner. Add the participants or reviewers who will review or be co-authors of the document. You must add at least one document to start the process.

38.1. Only for "Co-Review" Types:

If you are certain about all of the information filled out in the "Create Review" form, there is an optional checkbox that you can click, which is located on the bottom-left corner of the form – **Start review immediately**. If this checkbox is ticked when a user has pressed the **Save** button, the server will save review definition in the Document Authoring module, and start the review.



Below is an example of information to be filled out.



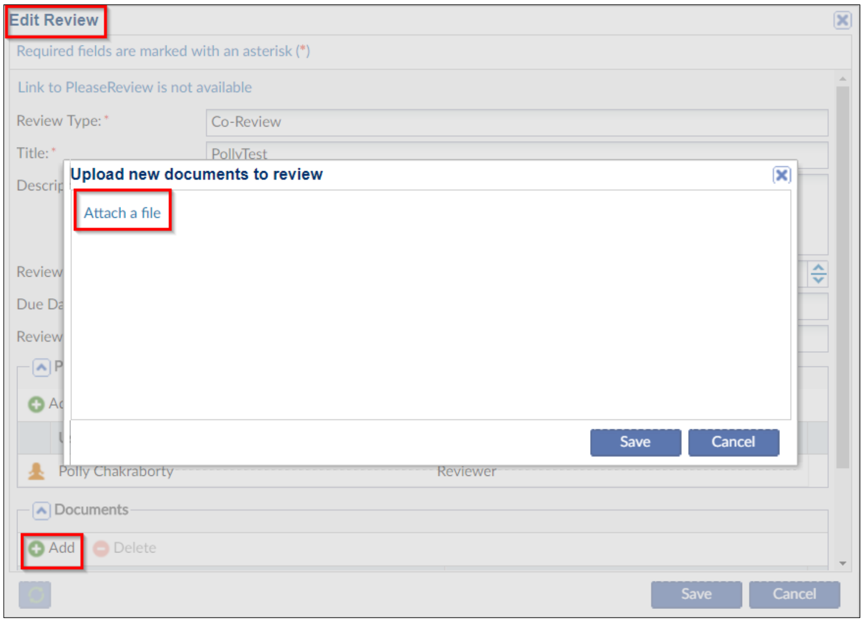
For the document section, there are two types of documents that a user can select for the review:

TI Document, which be selected from the Documents module (index)

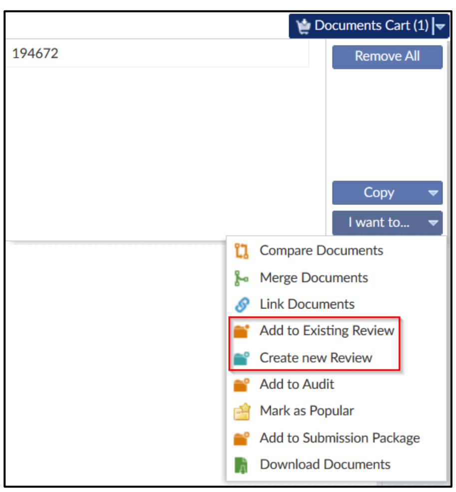
Upload a file

Within the **Edit Review** form that can be accessed from the Edit icon Edit on the top ribbon bar or from the right-hand bottom of the dashboard, users can change the title, review duration, add participants, and upload files.

In the Documents section of the Review form, there is an **Add** button that will open up a window to upload any number of files.



To select existing documents from the Index, users should navigate to the related folder or view in the eTMF Documents module, select one or more documents in the grid, and first add those document(s) to the Document Cart. Once the document(s) are added to Document Cart, two relevant options are available for Co-Review: Add to Existing Review and Create new Review.



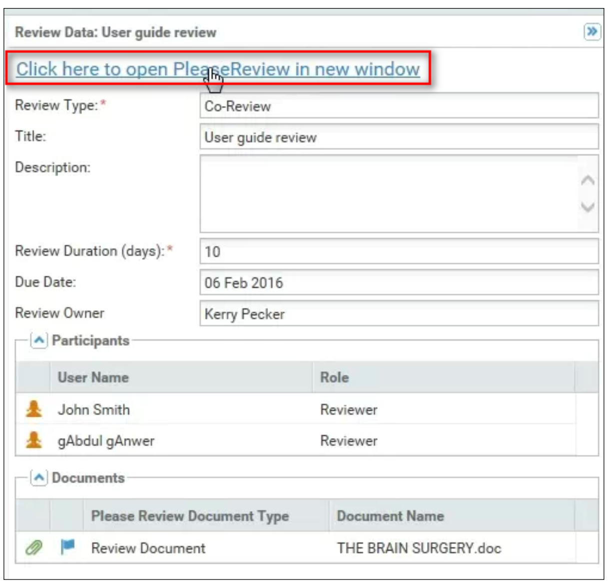
The Create new Review option follows the process previously explained. When the Add to Existing Review option is selected, a Select a Review form will pop-up. Within this form, users can select the specific review to which they want to add documents by clicking the Add document(s) to review button.

Alternatively, the documents selected from eTMF/Documents can be added to a new review, or an existing review from the Document Dropdown of by simply right-clicking documents and selecting Add to Review option from the popup menu.

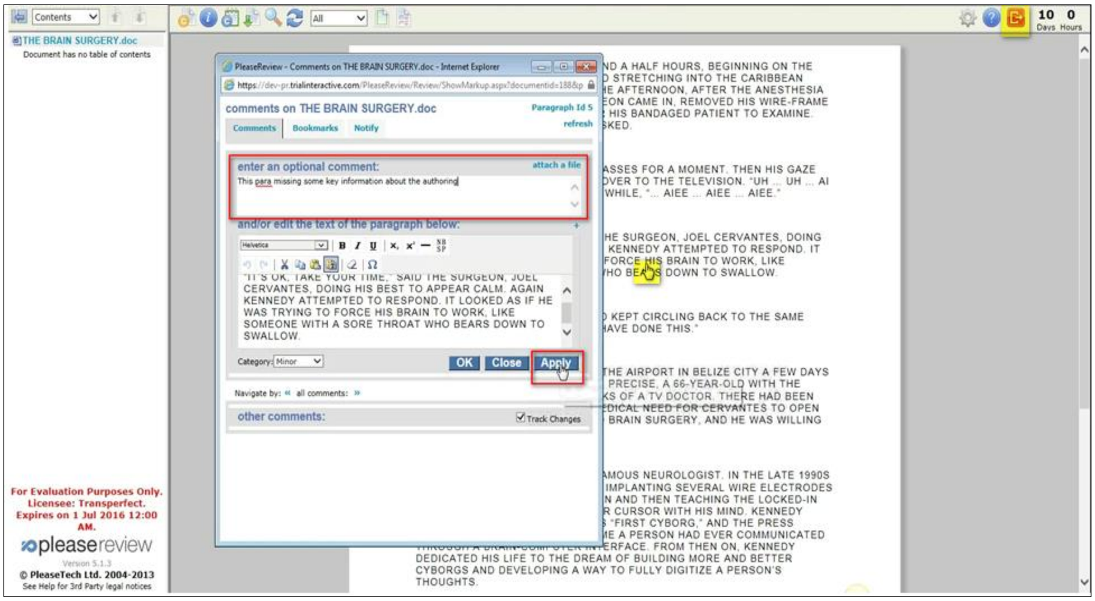
When the form is saved, the document goes into the Co-Review Pending folder. The system then sends out an email notification to all reviewers indicating that a document is available for a review. The users can simply follow the given link, and it will directly lead them to the appropriate page.

Now, users can start the document review by clicking on the Start Review icon Start Review on the top ribbon or at the right-hand bottom of the dashboard. The document then moves to the In Progress folder.

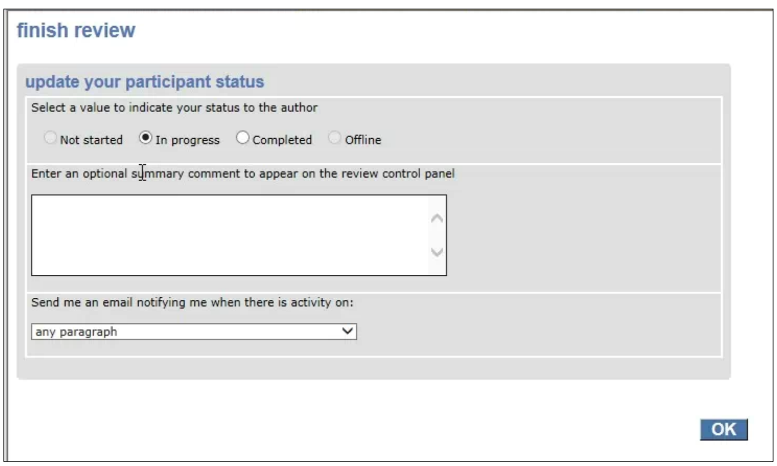
To open the document for a review, click the message where it says Click here to open PleaseReview in new window.



On the document, click the specific part where you want to add a comment or edit the text. Enter the comments and click Apply. To exit, click the red exit button on the top right corner.

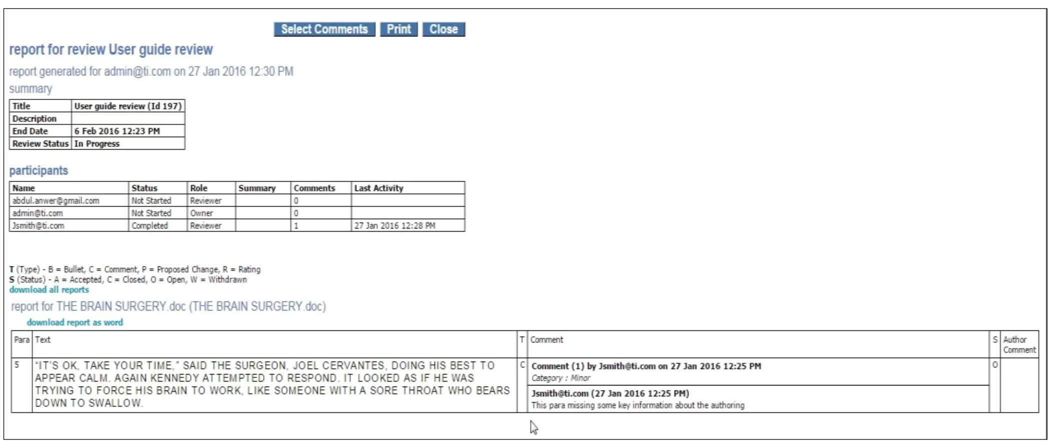


Once you exit, a Finish Review page opens up and you can update the document review status there. Provide a comment if it is necessary and click OK.

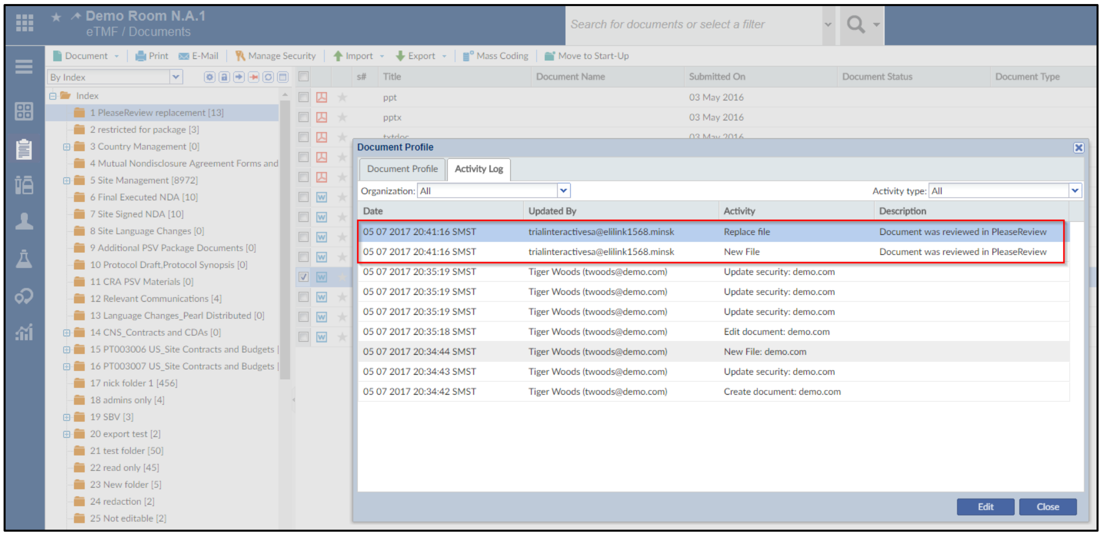


Once a review is complete, the review owner can go into PleaseReview and close out the document. The review owner can also check the status of document by clicking the message Click here to open PleaseReview in new window . This message is accessible from Authoring -> Co-Review, and by selecting the specific document.

As a review owner, you can view comments that have been added to the document. Click on View Report to display the details, as shown on the below screenshots.



After synchronization of the completed review with the server task, the review status is changed and the review moves to the Co-Review Completed/Closed folder in the Authoring module. The reviewed documents are published to eTMF in a folder designated by you as an administrator. Navigate to the eTMF Documents module. Drilldown to the folder where the published documents are filed. Right-click the reviewed document and select Open Profile. Click the Activity Log in the Document Profile popup. Here you will find that the reviewed files were uploaded as a new document and the attachments replaced. Refer to the screenshot below:



38.2. Co-Authoring

The **Co-authoring** feature allows multiple users to work on one document at the same time by assigning a particular zone to be worked on by each author.

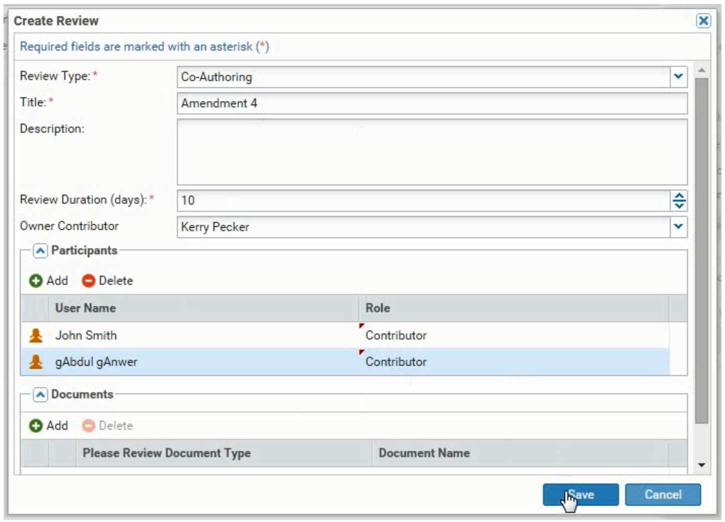
For this purpose, there are few additional roles available for Co-Authoring review:

Owner-Contributor (review owner in Co-Authoring review receives this role automatically instead of the *Review Owner* role)

Contributor (a user who can be assigned as a reviewer for a particular zone in the document)

The steps below demonstrate how to create a review for Co-Authoring.

1. Click on **Authoring** from the **Title** icon.
2. Click **Add**.
3. Fill out the form by first specifying its review type as **Co-Authoring**. Then, enter the title, review duration, and add participants and specify their roles. Lastly, add the document. Please note that only '.doc' files can be separated on Edit/Review zones for co-authoring.



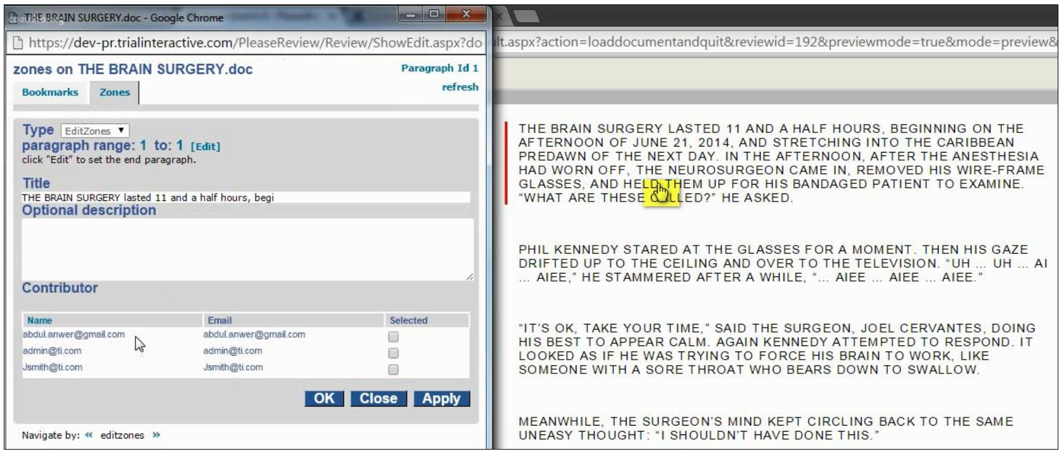
4. Click **Save.**

   When a review is created, the document is placed in the **Pending** folder under Co-Authoring.

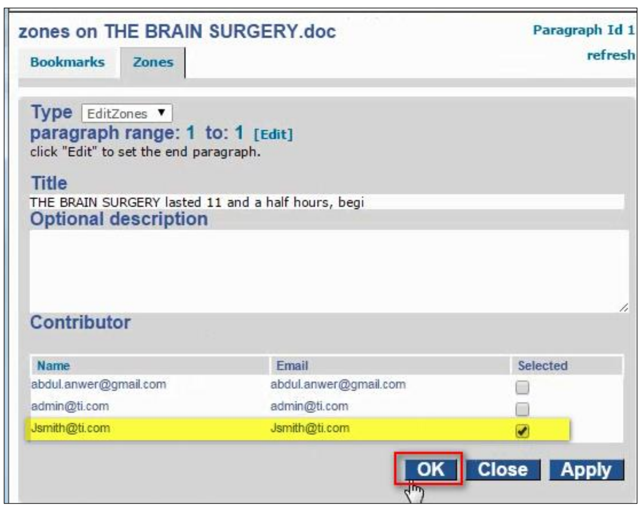
As a contributor, you cannot start the Co-Authoring review upon its creation (the related checkbox is not available for Co-Authoring review). This is because before a review can get started, the owner contributor must go to the PleaseReview and assign zones in the document to the specific contributors.

As an owner contributor, to assign zones to each contributor, locate the newly-created co-authoring document and click on the button under document section.

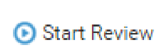
Upon opening the document, click the specific zone to be assigned to each contributor.



Under the Selected column, put a checkmark next to the name of contributor assigned for this particular zone in the document. Then click **OK**.



Repeat this process for other contributors as well to assign them to each zone. After you are finished with assigning zones, exit PleaseReview by clicking the  button located on the upper right corner.

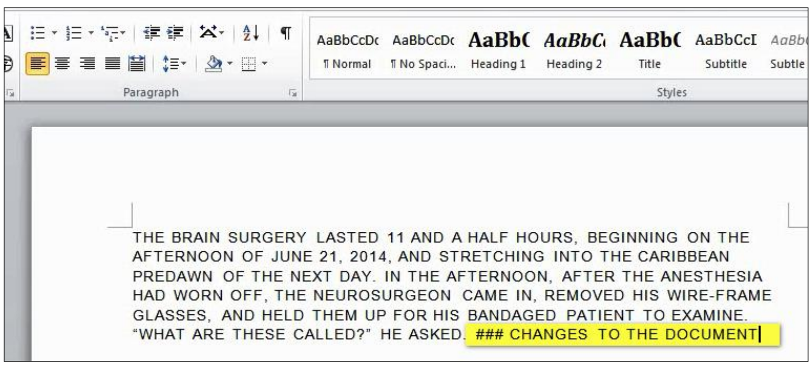
Once zones are assigned, the owner contributor must start review manually. Click on the 

button on the screen. Then, the document will be moved to the **In Progress** folder for contributors to work on their assigned zone.

If you are a contributor to a document and want to work on your assigned zone, locate the document placed under the **In Progress** folder for Co-Authoring, and click the link 

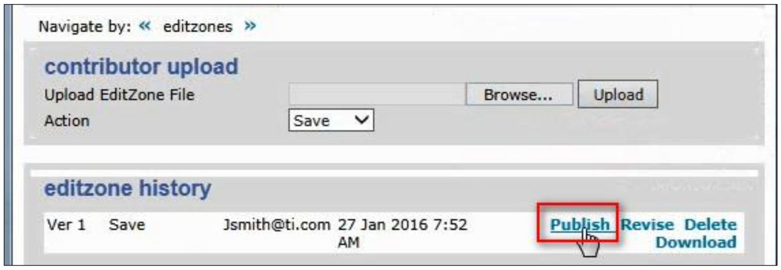
. Then, you can simply click the particular section of document that you are assigned to as a contributor, and download the document for that section only.

Make the appropriate changes and save the document.



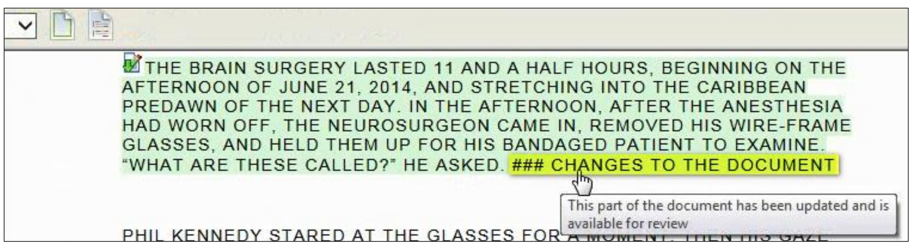
Then go back to the PleaseReview screen and browse the saved file. Click **Upload**.

If it is final and no more editing is required, click **Publish** and close the window.



Then, go back to the PleaseReview page and refresh the document.

Your new version of the particular section will appear on the document.

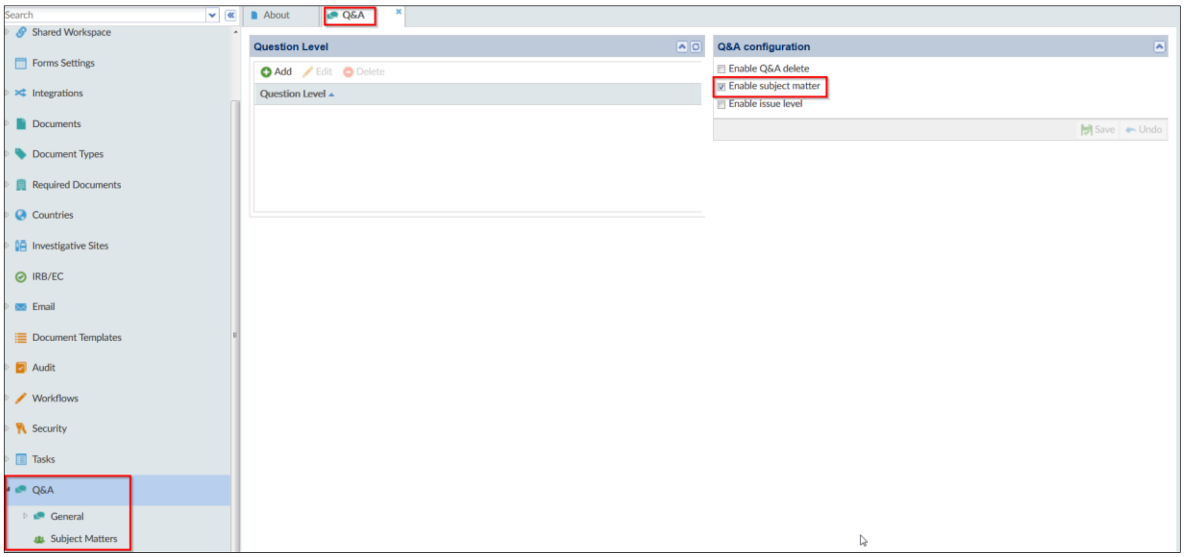


After all contributors are finished with their assigned zones, as a owner contributor, you can close out the review by following the same process as in Co-Review.On review closeout, the reviewed documents are published to eTMF as new documents as shown above in Co-Review.

39. Q&A

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.

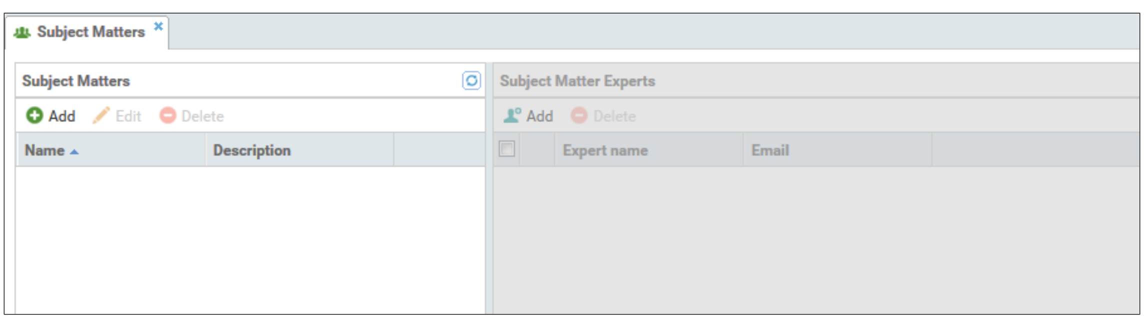
39.1. Q&A Settings



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

39.1.1. Q & A Settings -> Subject Matters

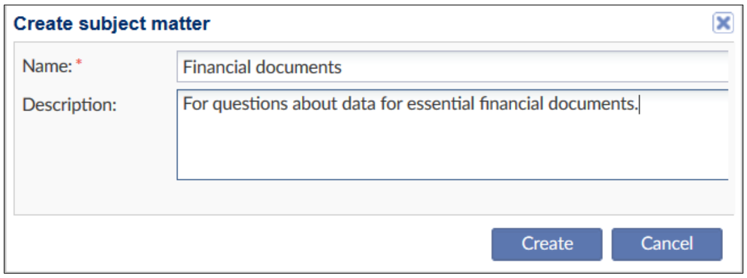
If **Subject Matter** was enabled in the previous setting, another set of options is activated.



Subject matter categories can be added, edited, and deleted. And subject matter experts can be assigned to the specific categories. In this way, questions from particular categories can automatically be channeled to subject matter experts when the questions are submitted in the room.

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

   The **Create subject matter** window opens.



2. Type the name of the Subject matter category in the **Name** field.

   The **Name** field is required; the **Description** field is optional.

3. Click **Create** at the bottom of the window.

   The new Subject Matter category is added to the list.

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

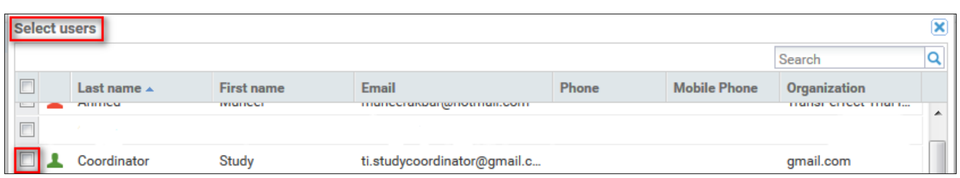
1. Click the Name of the **Subject Matter**.

   The subject matter category name is highlighted in light blue.

2. Click the **Add** button from the **Subject Matter Experts** panel toolbar.

   A **Select users** window opens, displaying the full list of the room's registered users who are eligible to be assigned the role of Subject Matter Expert – users with Administrator or Editor access to the room.

3. Click the checkbox next to the name of the user you want to assign to the expert role.



4. Click **Select** at the bottom of the window. The changes are automatically saved.

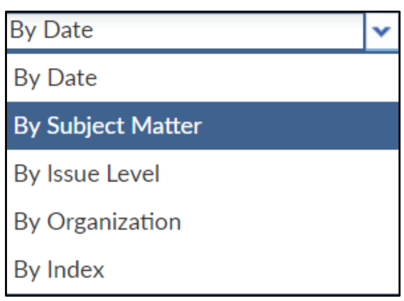
   Now, when a user asks a question and assigns it to the Q&A category and the Subject Matter while creating the question, the assigned expert will be notified of the question that needs their attention. The expert can then view the question in the Q&A module.

   Follow on to the next section for more details on the module.

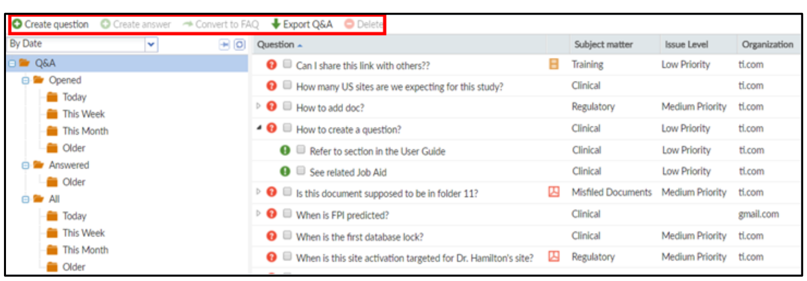
39.2. Q&A Module

Click the **Q&A** icon in the **Navigation Grid** icon to see the list of questions asked by users in a room. In the window on the left, you can see the display options available to you to view the questions:

- By Date
- By Subject Matter
- By Issue Level
- By Organization
- By Index



The image below displays the questions that have been submitted in this room.

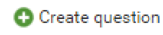


Through the top ribbon bar in the dashboard, you can:

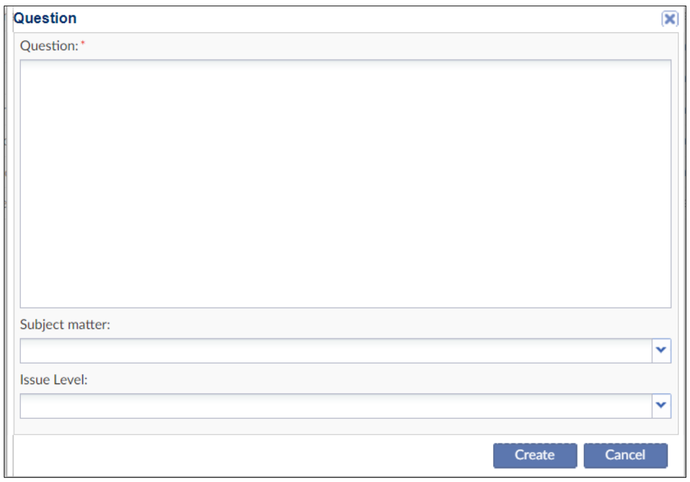
1. Create question

2. Create answer
3. Convert to FAQ
4. Export Q&A
5. Delete questions and answers.

39.2.1. Create Questions

From the Q&A module, click **Create question** 

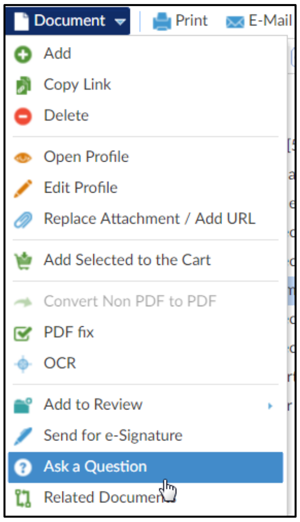
in the top menu ribbon. A new window opens for you to type your question for submission.



The Subject Matter and the Issue Level need to be previously configured from **Settings -> Q&A** as discussed in the previous section.

39.2.2. Questions about a Specific Document from the eTMF module

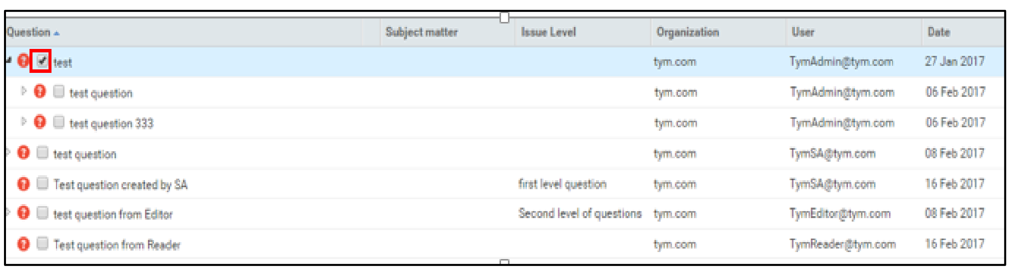
When you have selected a specific document in a data room, you can access the option to **Ask a Question** by clicking the Document dropdown in the upper left corner or by right-clicking the document icon from the eTMF module. Select **Ask a Question** from the available menu, and a new window opens.



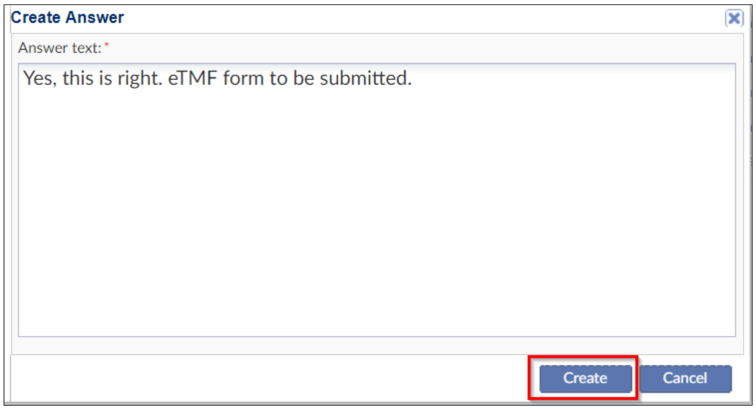
39.2.3. **Answering Questions**

When a room's users ask questions, Administrators can see them. The list will appear on your dashboard if enabled. You can enable email notifications of newly lodged questions. To answer a question:

1. Click the checkbox next to the question you want to address.



2. Click **Create Answer** Create answer in the menu ribbon, or right-click on the text of the question in the list and click **Create Answer**. A **Create Answer** box window opens.
3. Type the answer to the question.

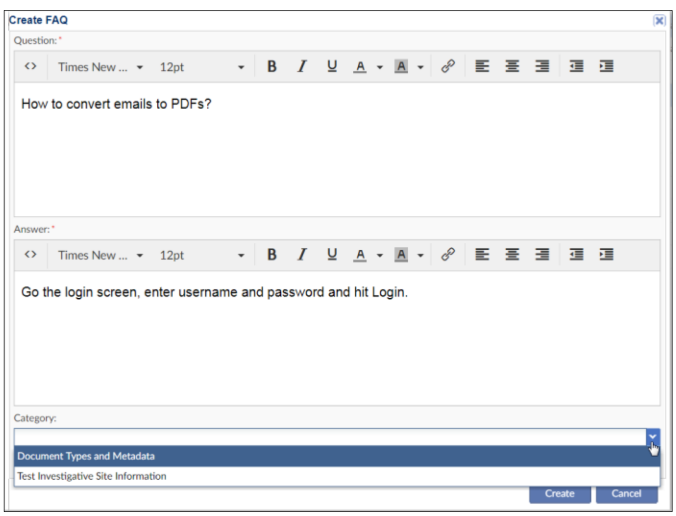


4. Click **Create**.

   The user who asked the question will get an email message leading to the answer you have created.

39.2.4. Convert to FAQ

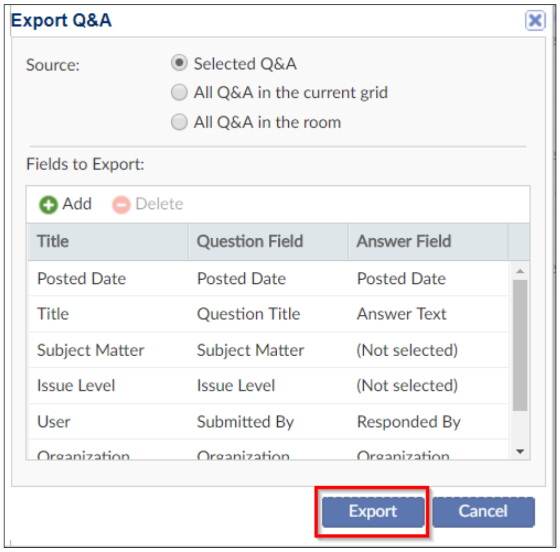
You can convert a question and its answer to FAQ. You can convert to FAQ only one question and one answer. Click **Convert to FAQ** Convert to FAQ from the top ribbon to open the **Create FAQ** window.



Format the details and select category of the question. Then click **Create** to create the FAQ.

39.2.5. Export Q&A

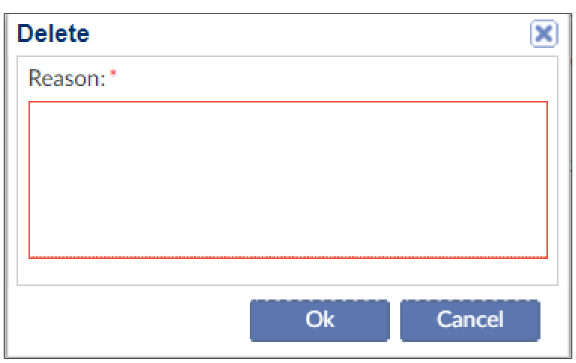
As an administrator, you can Export questions and answers. Click **Export Q&A** Export Q&A from the top ribbon to open the **Export Q&A** window. Click **Export** to export the selected questions, or all Q&A in the current grid, or all Q&A in the room.



The export job result will be saved as an excel file. During export, a popup showing the status of the export job is shown. The export result are also populated in the **Notifications.** Click **Get Job Result** to view the excel file.

39.2.6. Delete

You can delete a selected question by clicking **Delete** Delete from the top ribbon. This will open the **Delete** window. Type in the reason to delete the question. The reason will be saved in the activity log of the room.

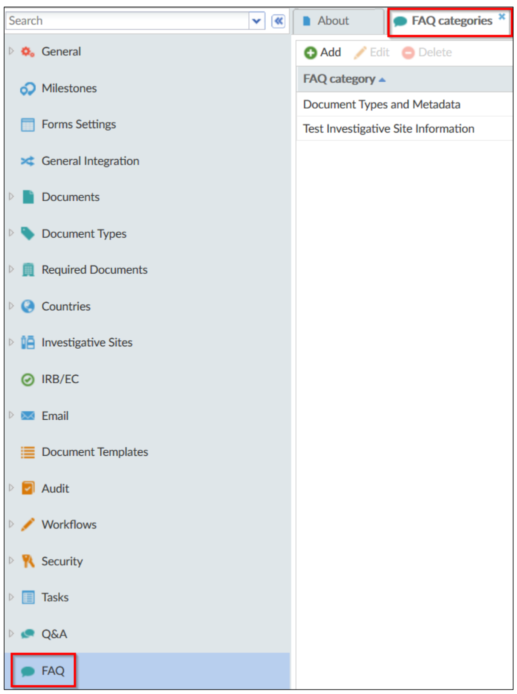


40. FAQ

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

40.1. FAQ Settings

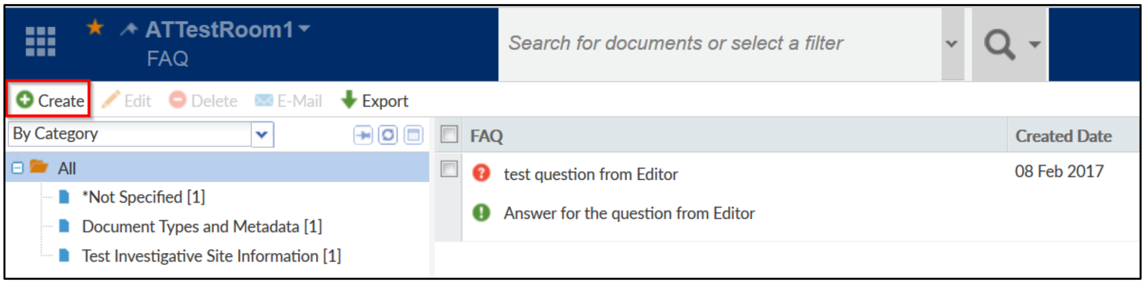
An Administrator can create FAQ categories through the **Username dropdown-> Settings ->FAQ Settings**. The **FAQ settings** tab offers the Administrator the ability to add, edit, or delete **Frequently Asked Question** categories. Changes here save automatically



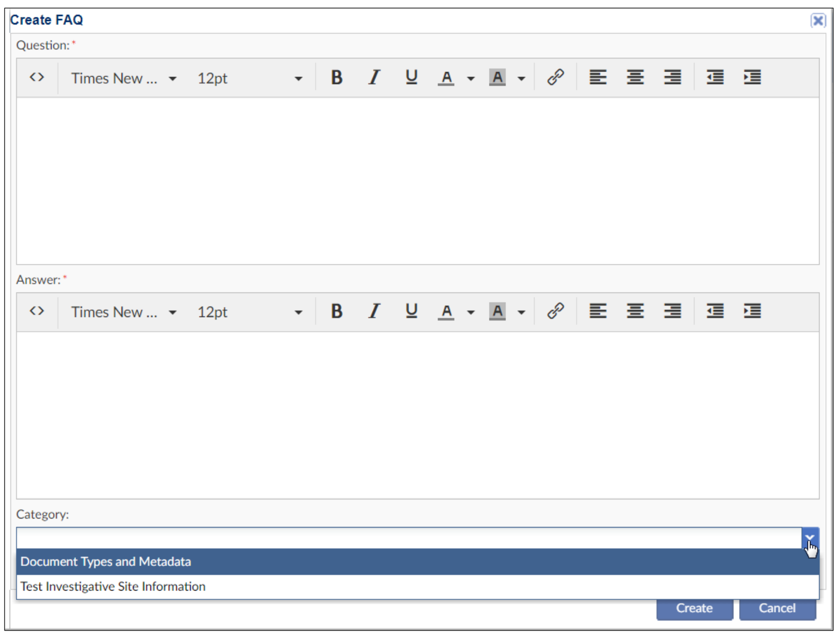
40.2. FAQ Module

FAQs, the questions and answers themselves, are added by clicking the **FAQ** icon in the top menu ribbon. The questions themselves are created by first clicking the **Create** 

icon in the top menu ribbon.

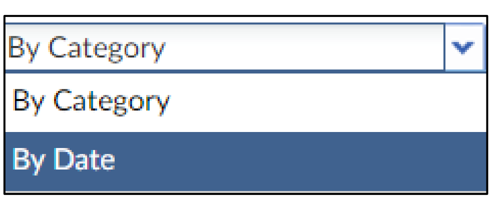


When the **Create** window opens, type in the question and its answer, then choose the category for the question from the dropdown.

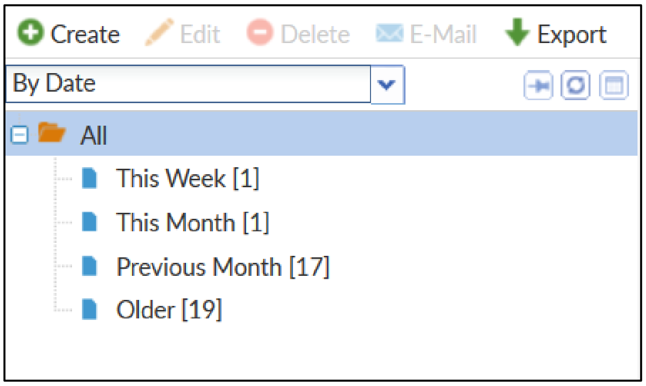


Be sure to click **Create** at the bottom of the window.

Two index views are available for FAQs: **By Category** and **By Date**. To toggle between the two views, click the dropdown arrow at the right end of the field.



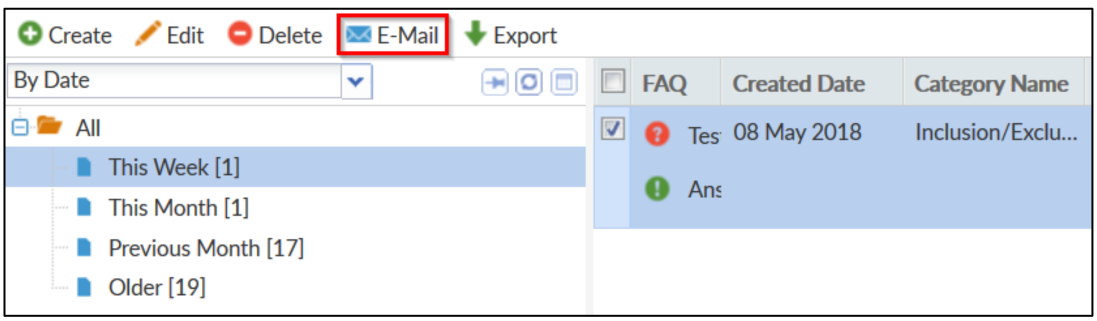
FAQ folders will display according to the chosen view.



FAQs can be edited Edit FAQ and deleted Delete FAQ through the icons on the top ribbon.

They can also be sent to room users as email messages.

1. Select one or more FAQs from the display grid by clicking the appropriate checkbox or boxes.
2. Click **Email** E-Mail in the menu ribbon.



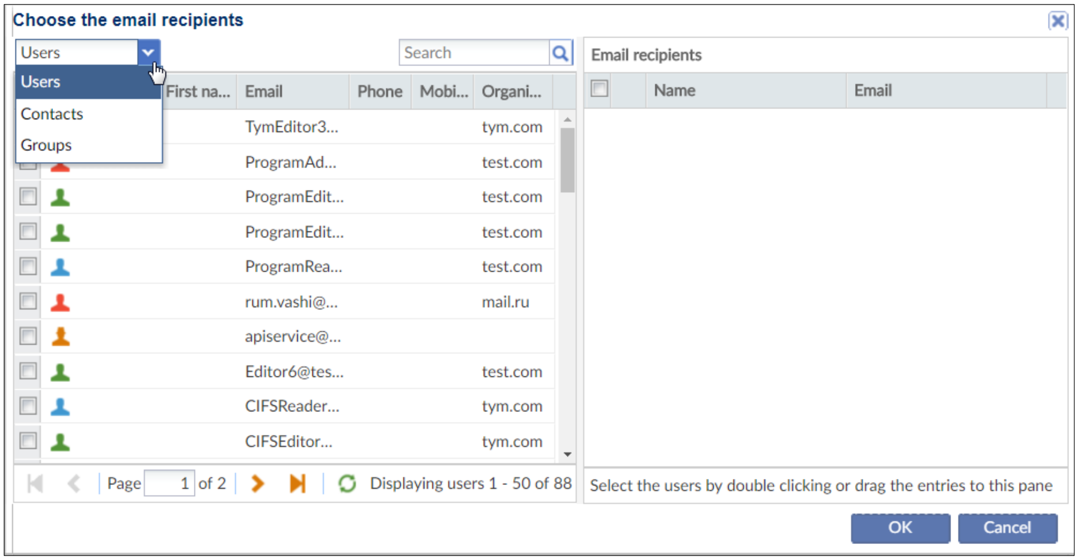
A new **Email** window opens.

3. Click the **To…** button near the top of the window.

The **Choose the email recipients** window opens.

The Administrator sending the FAQ as an email can select to send the message to individual users, to particular kinds of Contacts or to Groups defined in the room.

4. Click the dropdown arrow to activate the list



5. Make the appropriate selection. Either double-click on the name to be added to the **Email recipients** list or drag-and-drop the names to the panel on the right.
6. Click **OK**. The view returns to the **Email** message window.

   The user has the opportunity to add more users from the room to the **CC…** filed. The user can also alter the text of the message or add attachments to the message.
7. Click the **Send** button when the message is completely assembled.
8. The **Email** window closes, and the message is sent to the selected recipients.

   Email messages sent from the **FAQ** module are tracked in the room's **Outbox** module.

41. Reports

Room Administrators have the option to turn on **Reports** and make them available to other users. If Reports are activated, you will see an icon in the Navigation Grid.

41.1. Running the 'By Group' Report

1. Log in to a particular Trial Interactive Room.
2. Click **Reports** icon from the **Navigation Grid.**
3. From the **Report List** dashlet click **By Group**.

   A new browser tab opens with the report results, a bar graph and a chart showing the activity in the room broken down by groups.

You can continue to drill down into this report for more information. Click the name of a group to get a more detailed report on the group's activity. And you can drill down even further to more specific user information by clicking of individual group members' names.

41.2. Running the 'By Organization' Report

1. Log in to a particular Trial Interactive room.
2. Click **Reports** from the **Navigation Grid**.
3. Select **By Organization** in the **Report List** panel.

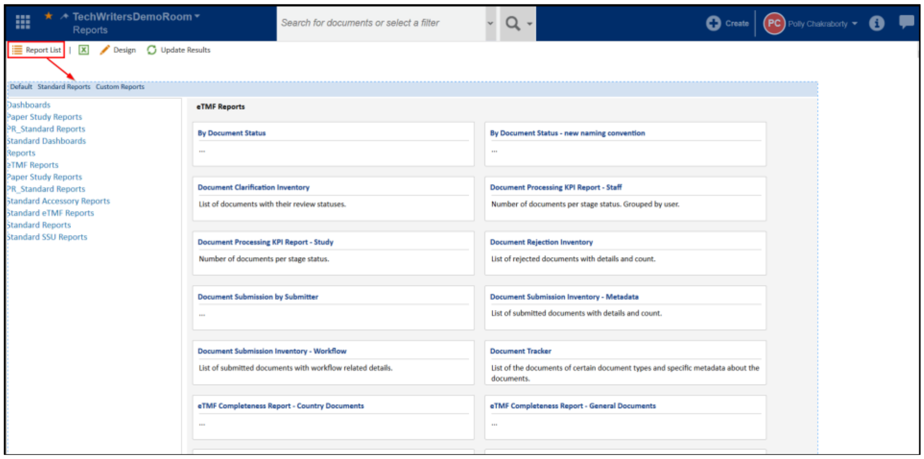
   A new browser tab opens, displaying the results of your report request, a bar graph and a chart showing the activity in the room broken down by organizations.

You can continue to drill down into this report for more information. Click the name of an organization to get a more detailed report on the group's activity. And you can drill down even further to more specific user information by clicking of individual group members' names.

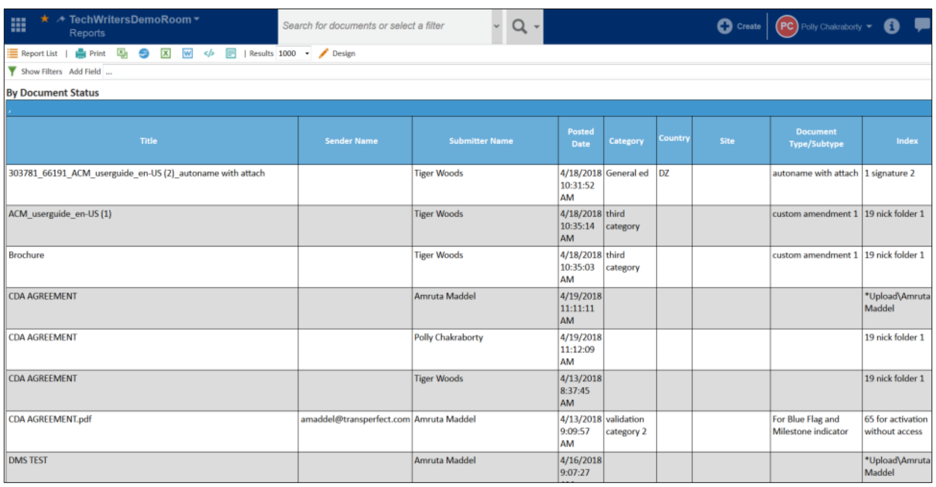
41.3. Running and Viewing Reports

As an Administrator user, you have an option to turn on Reports for other level users to access and view. Users can access pre-defined reports by clicking the **Reports** icon in the **Navigation Grid**.

This view offers links to standard activity reports and a **Report List**.



Click the name of a report and that report opens in the dashboard below. The screenshot below shows the **By Document Status** report clicked from the above screen.



Typically, report builds are based on specific sponsor requests. For further assistance on other features of reports please get in touch with the Support team of Trial Interactive.

42. Dashboard Dashlet view

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

42.1. Dashboard

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

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

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

42.2. Dashboard Settings

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

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

Dashlet	Available For	Modules
Documents By Workflow Status	Administrators	All
Users	Administrators	All
Documents View	Readers and above	All
Documents Expiration	Readers and above	All
Documents Rejection and Clarification	Readers and above	All
Open Queries By Age	Readers and above	All
Expiring Sites	Readers and above	All
Tasks	Readers and above	All
Recent Communication Logs	Readers and above	All
Recently updated Sites	Readers and above	All
Site Activation Status	Readers and above	All
Sites Activation Progress	Readers and above	All
Sites Activation by Country	Readers and above	All
eFeasibility Sites by Country	Readers and above	All
eTMF health	Readers and above	All
Sites health (CRA)	Readers and above	All
Milestone Type Report	Readers and above	All
Claimed vs Unclaimed Documents	Readers and above	All
My Submissions	Readers and above	All
My Queries	Editors and above	All
Popular Documents	Readers and above	All
My Favorite Documents	Readers and above	All
Study Monitoring Visits By Month	Readers and above	All
Study Monitoring Visits By Country	Readers and above	All
Study Monitoring Visits	Readers and above	All
About this room	Readers and above	All
Bulletin Board	Readers and above	All

Default Dashboard Setup

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

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

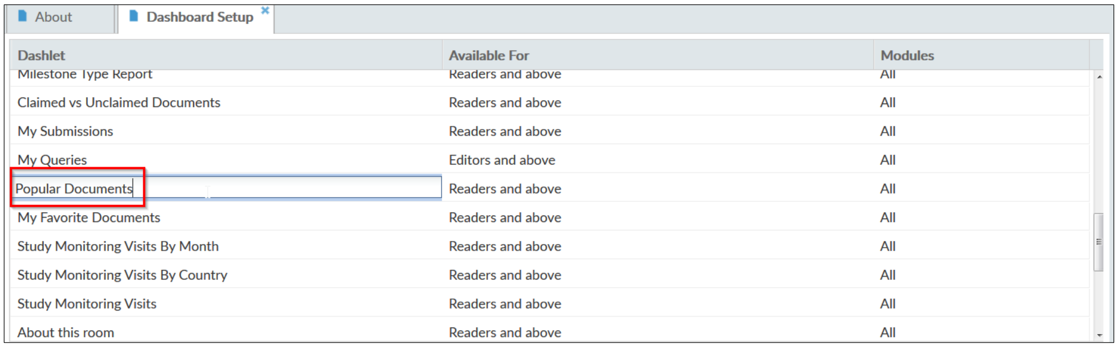
Dashlet	Available For	Modules
Documents By Workflow Status	Administrators	All
Users	Administrators	All
Documents View	Editors and above	All
Documents Expiration	Readers and above	All
Documents Rejection and Clarification	Disabled	All
Open Queries By Age	Readers and above	All

   A set of selections becomes available to the Administrator.
4. Select which users in the room will see any particular dashlet in their **Dashboard** views.
5. Click **Save** if you have made acceptable changes.

42.2.1. Renaming a dashlet

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

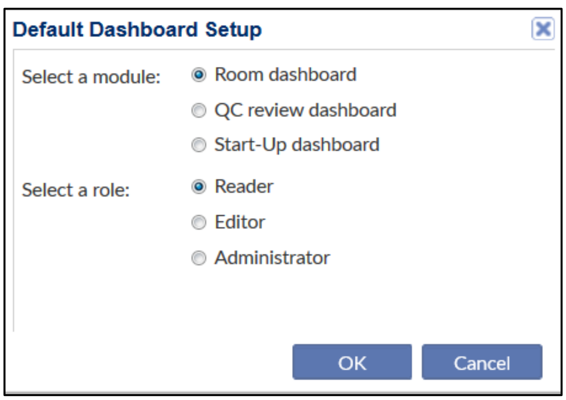
1. Double-click the name of a dashlet that you want to rename from the Dashlet column of the Dashboard Setup window.



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

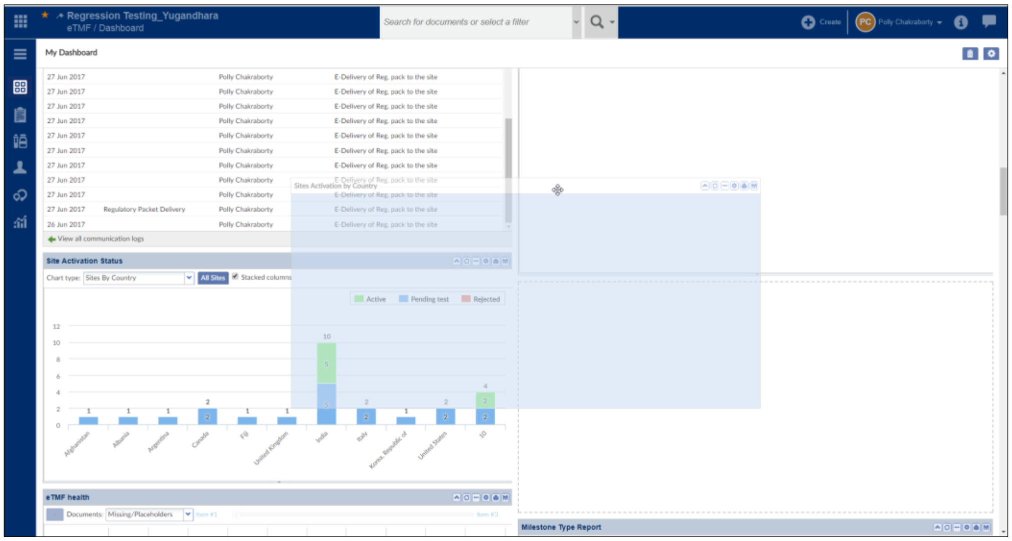
42.2.2. Default Dashboard Setup

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



42.3. Laying dashlets in your dashboard

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



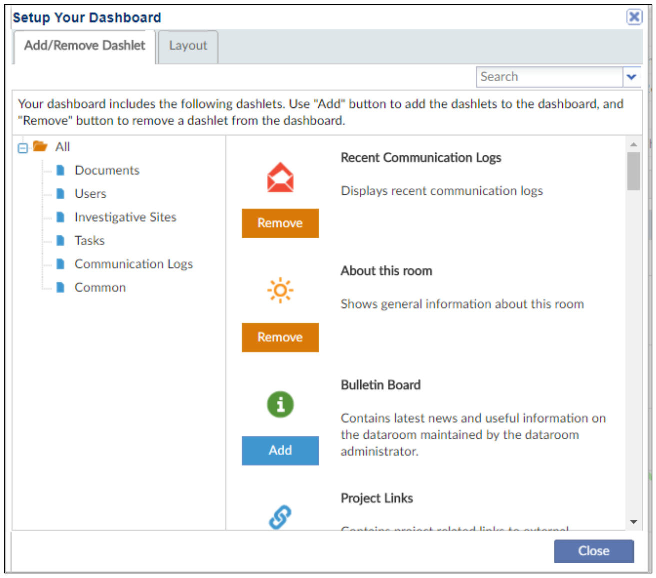
Besides moving your dashlets to make a suitable layout, you can also choose the distribution of dashlet panes on your screen, or addition/removal of dashlets through **Configure Dashboard** icon located on the top right corner of the dashboard.

42.4. Configure Dashboard

The *'Configure Dashboard'* opens the **Setup Your Dashboard** window which lists out the dashlets available for a particular dashboard and provides you with two options:

1. Add/Remove Dashlet
2. Layout

Refer to the screenshot below:

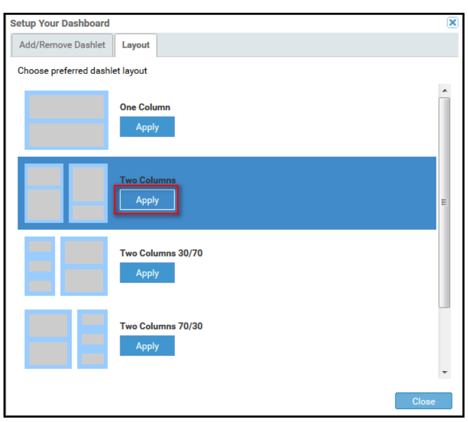


42.4.1. Add/Remove Dashlet

By clicking the **Remove** button for any particular dashlet, the user can eliminate that dashlet from the Default Dashboard view for himself or herself. These dashlets can easily be restored by clicking the **Add** icon that will replace the **Remove** icon.

42.4.2. Layout of Dashlets

By clicking the **Layout** tab at the top of the **Setup Your Dashboard** window, the user opens a new view that allows the user to choose his/her preferred dashlet layout on the viewing screen.



Simply click the **Apply** button next to the preferred arrangement and then click **Close** to enable the layout chosen by you.

42.5. Configuring each dashlet

On the top right corner of each dashlet, the following features are available:

Available Icon	Purpose
	To hide the dashlet from the dashboard
	To refresh the dashlet
	To delete the dashlet from the dashboard
	To configure a dashlet column, and its height
	To print the current chart
	To save the current chart as PNG image file or to export a report or metadata fields

The Dashboard has numerous dashlets that provide users with a visual representation of categorized data in the study room.

42.6. Renaming dashlets

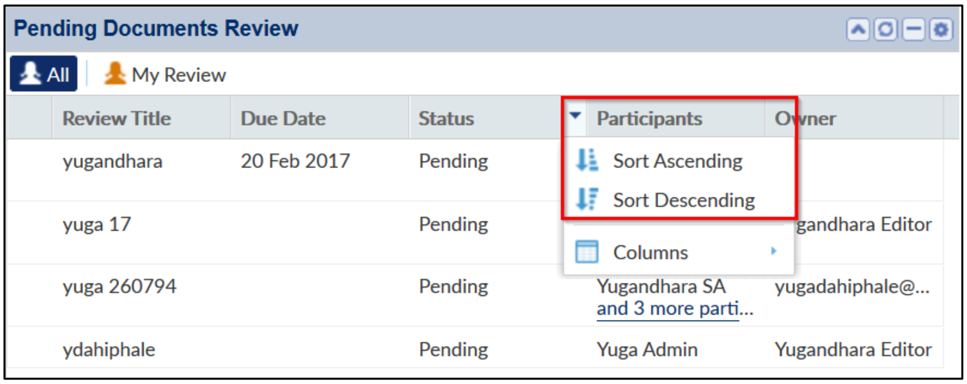
Admins can rename dashlets to suit the requirements of the organization. This is discussed in detail in section renaming a dashlet.

42.7. Adding or removing columns from dashlets

Dashlets can be configured to add or remove columns displayed on them as per the choice of the user. This feature is discussed in the Dashlets sections for dashlets that implement this feature.

42.8. Sorting columns in a dashlet

Some columns in a dashlet can be sorted in ascending or descending order by hovering the mouse over the column header to reveal the dropdown with sorting options. Refer to the screenshot below:



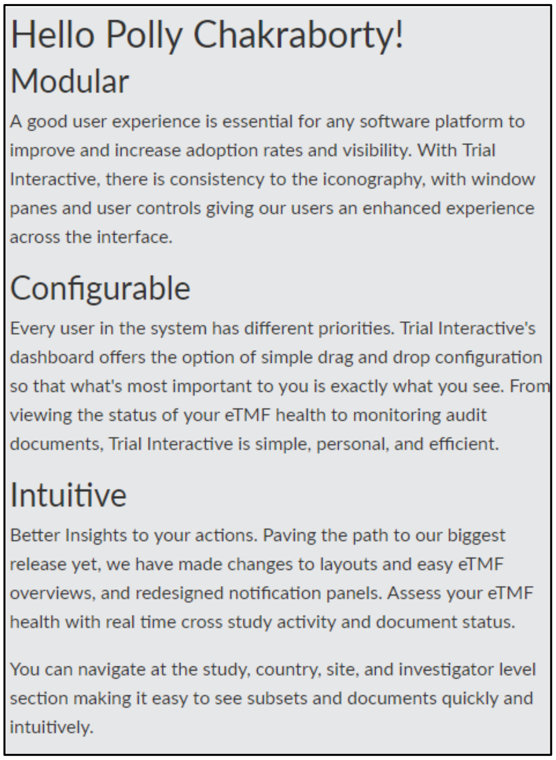
> ***The sorting order set by one user does not affect the sorting order of the dashlet for other users.***

42.9. Resizing pop-up windows or modal dialog boxes

To resize pop-up windows or modal dialog boxes:

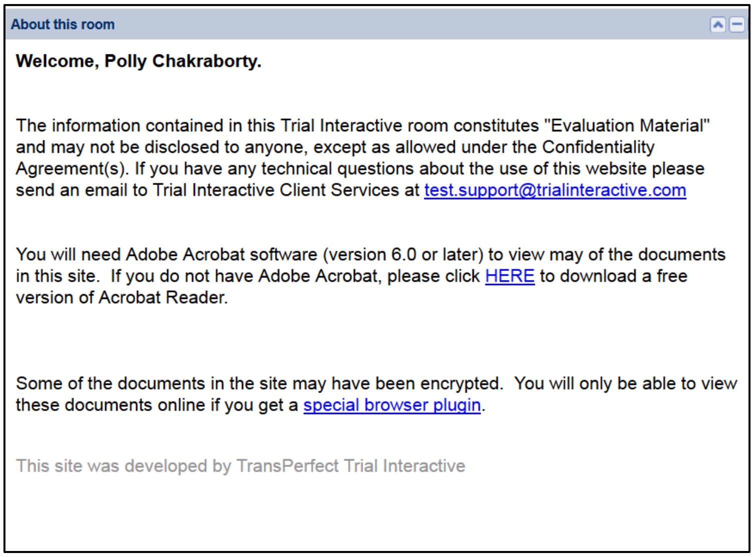
1. Place the mouse cursor at any of the edges or corner of the window/dialog box for a double arrowed control to appear.
2. Drag the side or the corner in or out to a size that fits your purpose.

42.10. Dashlet – About



The About Dashlet on the Trial Interactive Home Page provides introductory information about Trial Interactive to new users and provides the basic guidelines to get started.

42.11. Dashlet – About this room



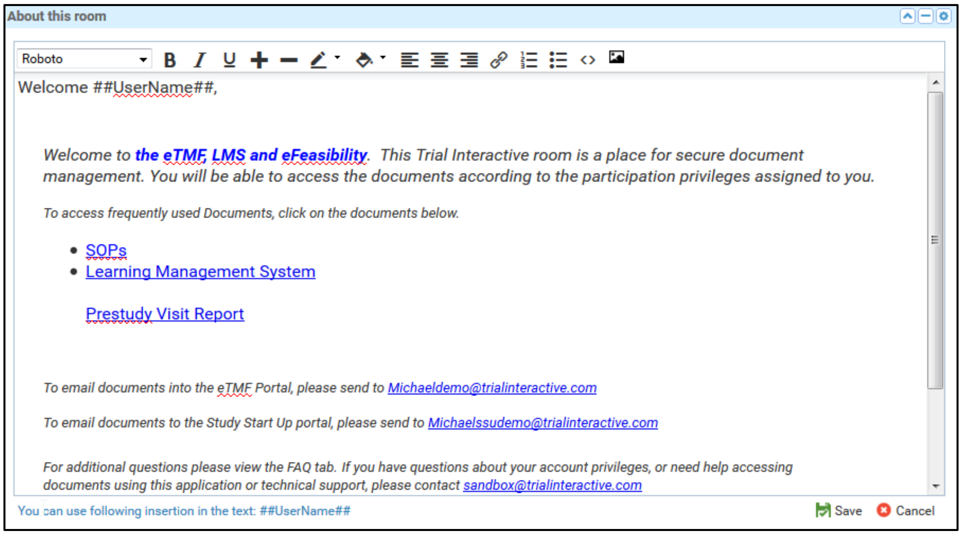
About this is room is typically configured by Administrator level users to Welcome new users and provide them with information pertaining to the room. An administrator can also upload any information through the room's Settings that is pertinent to the study that they would like to share with users.

Administrators can use this area to notify users of important information particular to the study.

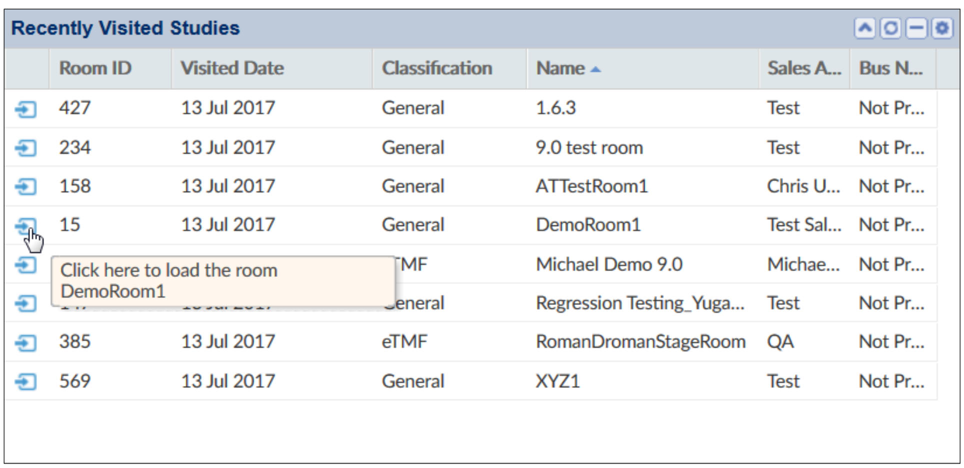
The standard Welcome message offers the following links.

- Link to help desk email. Use this email address when you have technical issues with the Trial Interactive tool.
- Link to Adobe Acrobat download site. You need an up-to-date document viewer to view documents.
- Link to special browser plug-ins so that you can view encrypted documents.

You can click the Edit icon at the bottom of the dashlet to type in new information or edit existing information on the dashlet. After editing the dashlet contents click Save to save the contents and exit, or Cancel to exit from the Edit screen.



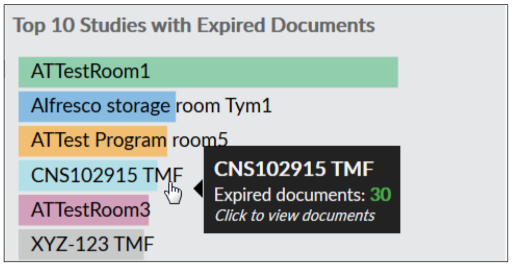
42.12. Dashlet – Recently Visited Studies



This dashlet displays the rooms recently visited by a user along with the date of the visit. Click the blue icon to visit the room.

42.13. Dashlet – Top N Studies with Expired Documents

The **Studies with Expired Documents** dashlet lists the top 10 studies with expired documents and also provides a document count of expired documents on hovering the mouse pointer on each bar.



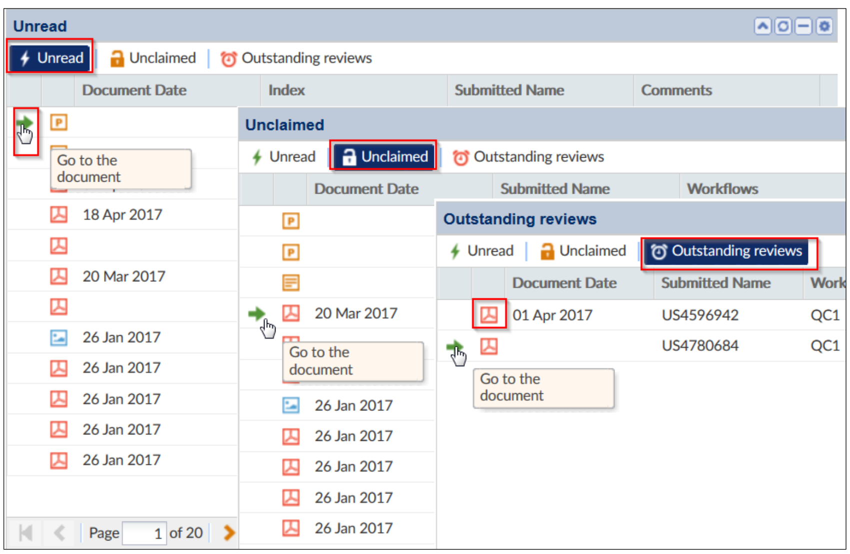
Here, you can click each bar, which represents a study, to display the list of expired documents in a popup window. Clicking a document name will take you to the room and open the document and its metadata for you to view. Click the **Expiration Date** Expiration Date button to sort the documents by expiration dates, and click the **Title** Title button to sort the documents by their titles.

To make this dashlet available to users with Reader access and above, contact the TI helpdesk.

42.14. Dashlet – Bulletin Board

The **Bulletin Board** dashlet contains the latest news and useful information on the data room for room participants. This dashlet is empty in its content by default; therefore, Administrator users should add content to this dashlet. You do so by moving the cursor to the bottom left corner and by clicking on **Edit** button. The dashlet will then display any free form text entered on the html editor. After making any changes, click **Save**.

42.15. Dashlet – Unread/Unclaimed/Outstanding reviews



Named as **Documents View** dashlet (as seen from the Configure Dashboard/Configure Dashlet windows), this dashlet provides three different views of documents in the eTMF module – **Unread**, **Unclaimed**, **Outstanding reviews**. The header of the dashlet changes as per the view selected.

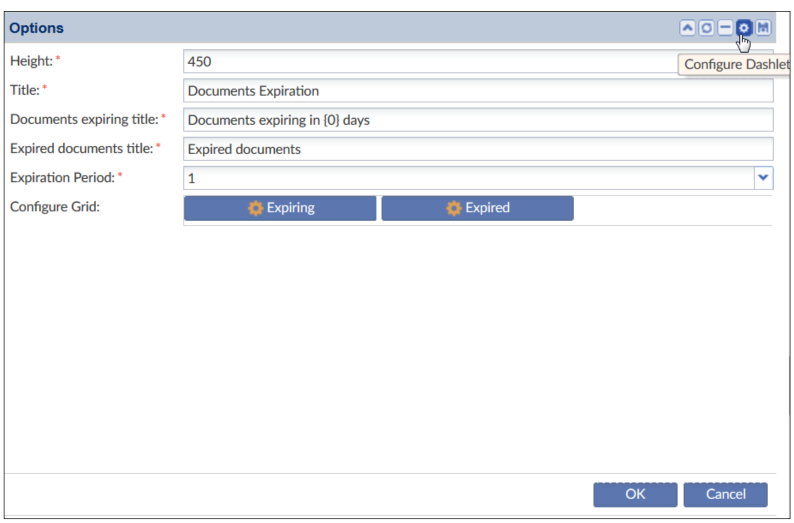
Click the **Unread** tab to list any of the documents posted in the Trial Interactive site that have not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of. Click the green arrow to view the document along with its metadata, or click document icon to view the actual document. If the document is an Excel spreadsheet, the document downloads to your computer if you are viewing it in the Original Viewer.

Click the **Unclaimed** Unclaimed button to get a list of documents that have not been claimed for review.

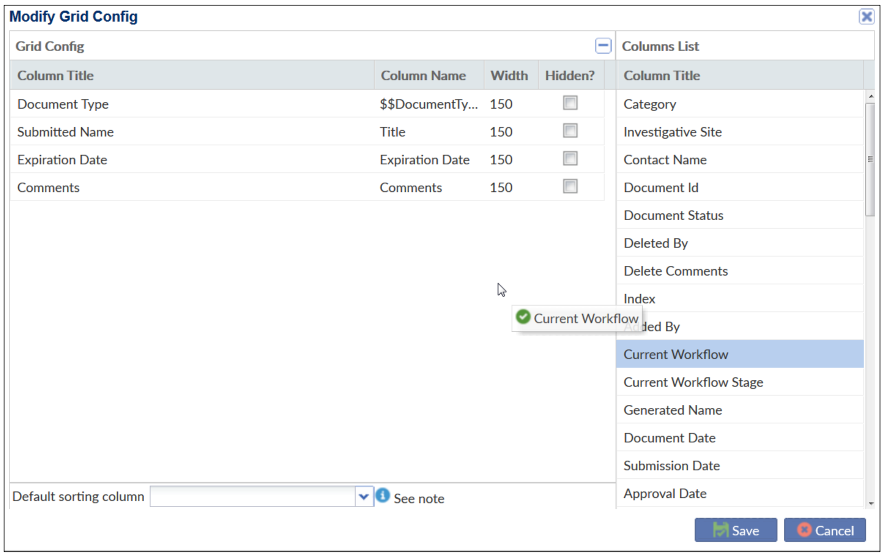
Click the **Outstanding reviews** Outstanding reviews button to get a list of documents that are yet to be reviewed.

42.16. Dashlet – Documents expiring in N days/Expired Document

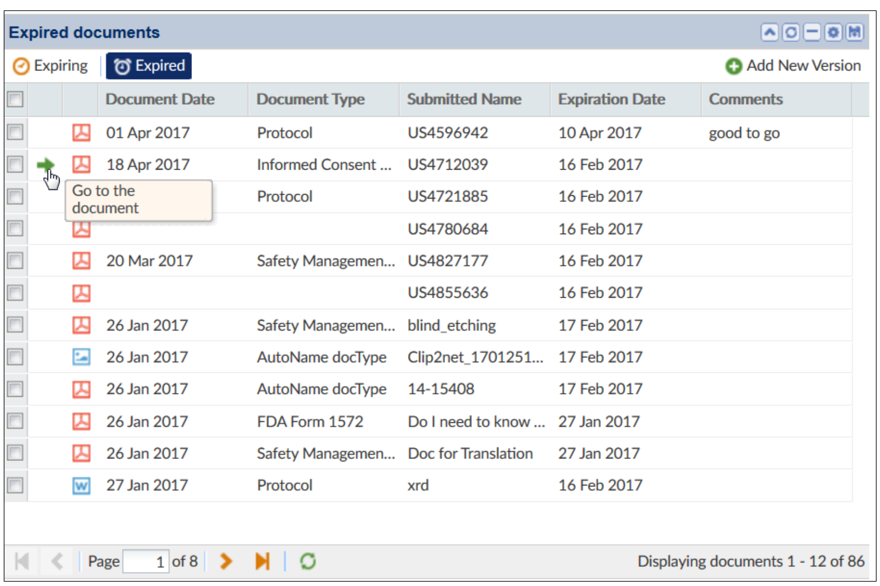
The **Documents expiring in N days/expired documents** dashlet lists the expiring and expired documents as specified in the expiration period (N). The dashlet has two views that can be selected through two buttons, **Expiring** and **Expired.** To set the views click the **Configure Dashlet** icon located on the top right corner. The header of the dashlet changes as per the view selected. To set the expiration period for the documents, click the configure icon on the top right corner of the dashlet. Refer to the screenshot below:



The columns shown on the dashlet can be selected by clicking the **Configure icon** on the **Expiring** or **Expired** button in the above screen which then opens the **Modify Grid Config** window. Drag and drop the columns from the Columns List panel to the right of the window to the **Grid Config** panel on the left. Click **Save**.

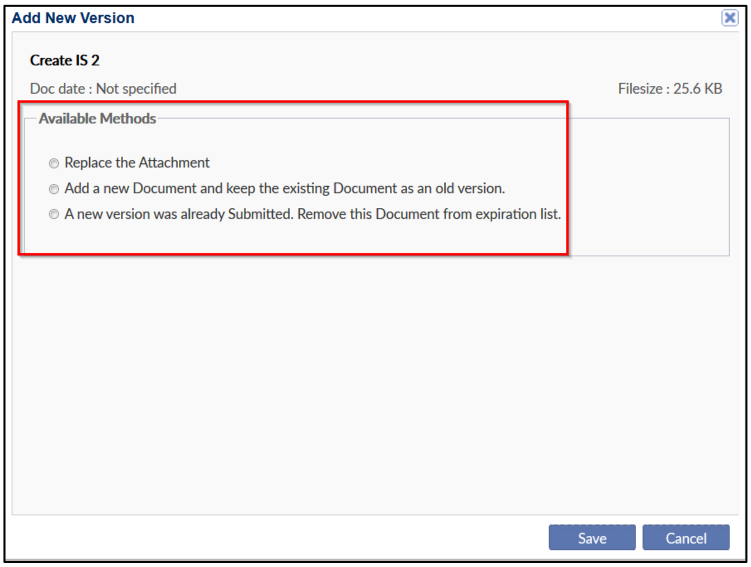


To view Expiring or Expired documents, click the Expiring ` Expiring icon or Expired Expired icon on the dashlet. Refer to the screenshot below:



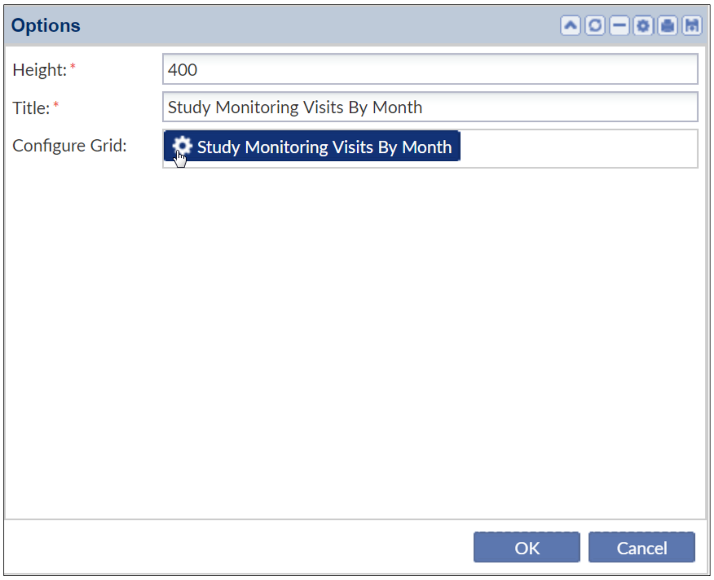
To replace a document that is expiring or expired, click the **Add New Version**

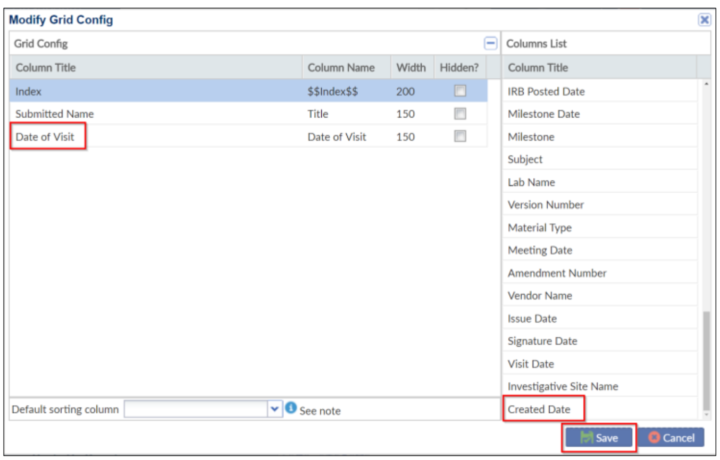
Add New Version button. This opens the **Add New Version window** which provides the available methods to replace an attachment, or add a new document and retain it alongside the older version, or remove the older version if a new version is already submitted. Refer to the screenshot below:



42.17. Dashlet – Study Monitoring Visits By Country and By Month

This dashlet **Study Monitoring Visits** provides two different views study monitoring visits – **Monitoring Visits By Month,** and **Monitoring Visits By Country**, in the form of a bar graph. This dashlet can be configured to display the **Visit Date** instead of the **Created Date** through the **Configure Dashlet** feature as discussed above. Refer to the screenshots below:





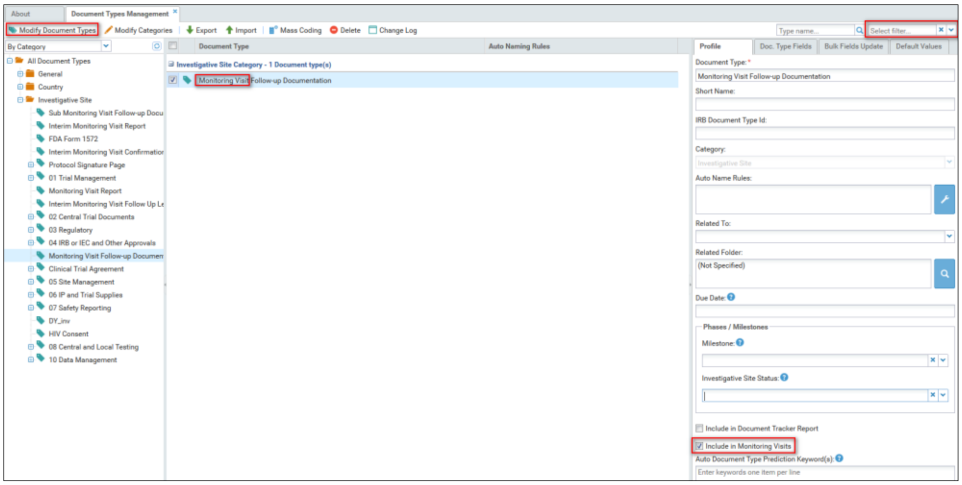
The following image contains the key features about the bar chart.

As you delve further, you will finally be able to view the documents for the particular country.

The **Study Monitoring Visits** dashlet is connected to the **Document Type Settings**. Therefore, Administrator users can go to **Settings → Document Types → Document Types Management**, and assign or modify document types. Through the configuration box, users can manually specify whether to include the document in the Monitoring Visits or not.

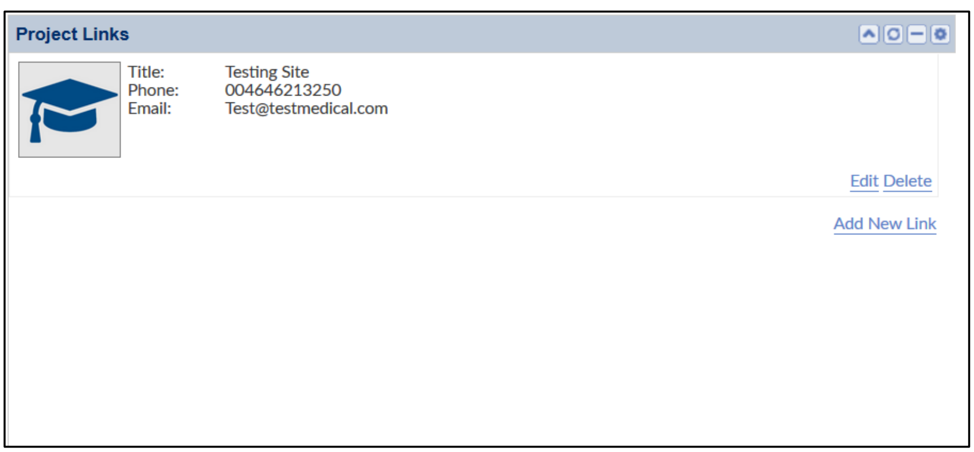
If you choose to include a new document type, the **Study Monitoring Visits** dashlet will be updated to reflect the change.

For your convenience**,** a **search box** and a **filter option** are also available in the Document Type Management section in the Settings. These features help users track which documents, and how many documents are needed to be collected for specific document types.



42.18. Dashlet – Project Links

The **Project Links** dashlet displays links to different systems that are used for the study and their contact information. Administrator users can add a new link by scrolling down to the bottom of the dashlet. There, click the **Add new link** button and give it a URL or email address, contact phone number, name (maximum of 60 characters), and description (maximum of 400 characters). Administrator users can also edit and delete links. Any user level can click the icon/image next to the link to load the link in a new tab.

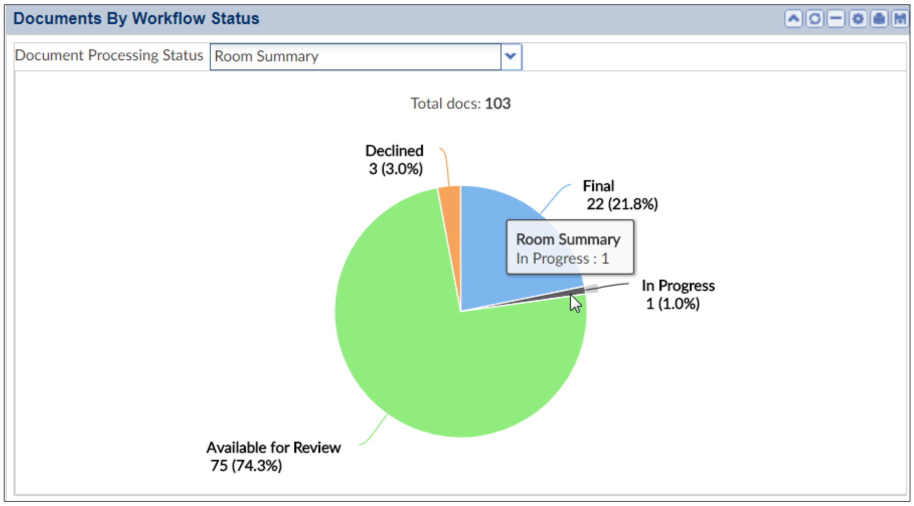


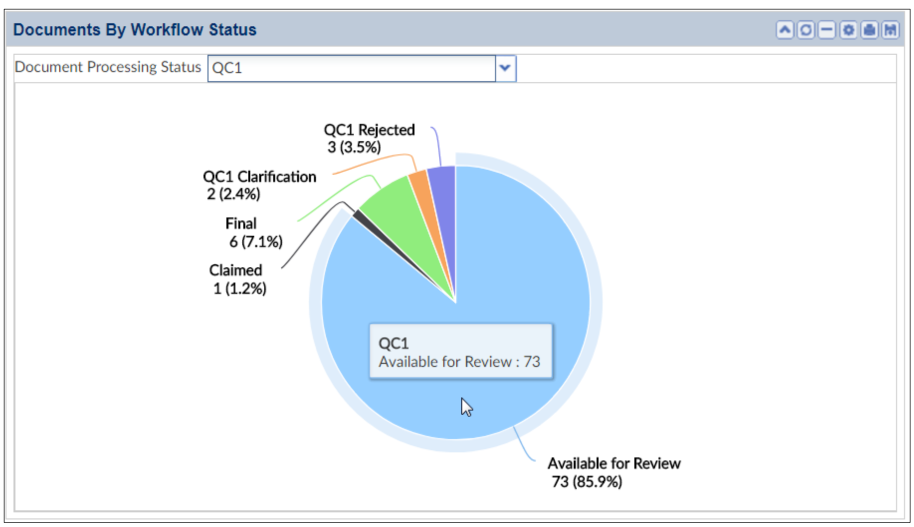
When you click on the icon, a separate tab opens to display the linked page.

42.19. Dashlet – Documents by Workflow Status

The **Documents by Workflow Status** dashlet displays the document processing status in the document review workflow through pie charts. By changing the dropdown menu, you can view the document processing status:

1. As a complete Room Summary, or
2. As workflow stages defined.

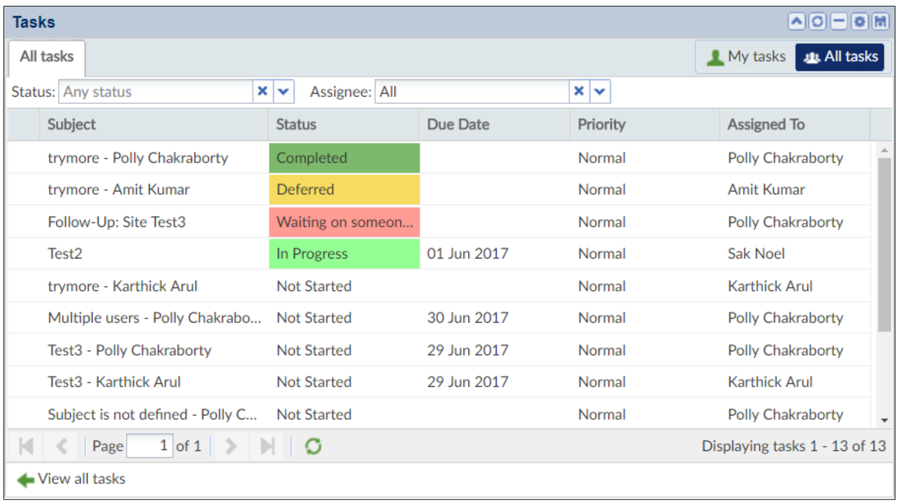




Workflows that appear in the dashlet are defined from **Settings -> Workflow**. This is discussed in Section How to Create a Workflow. The workflow status are pre-defined parameters which can be viewed in the current view **By Document Status**.

42.20. Dashlet – Tasks

The **Tasks** dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the **Status** and the **Assignee** from their respective drop-downs to get the task details. **All Tasks** All tasks lists all the tasks belonging to the selected assignee. **My Tasks** My tasks lists all the tasks pending recently, today, or are overdue. Click View all tasks View all tasks to lead you to the Tasks Dashboard in your room. Here you can view all the tasks. 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 an .xlsx file on your hard disk.

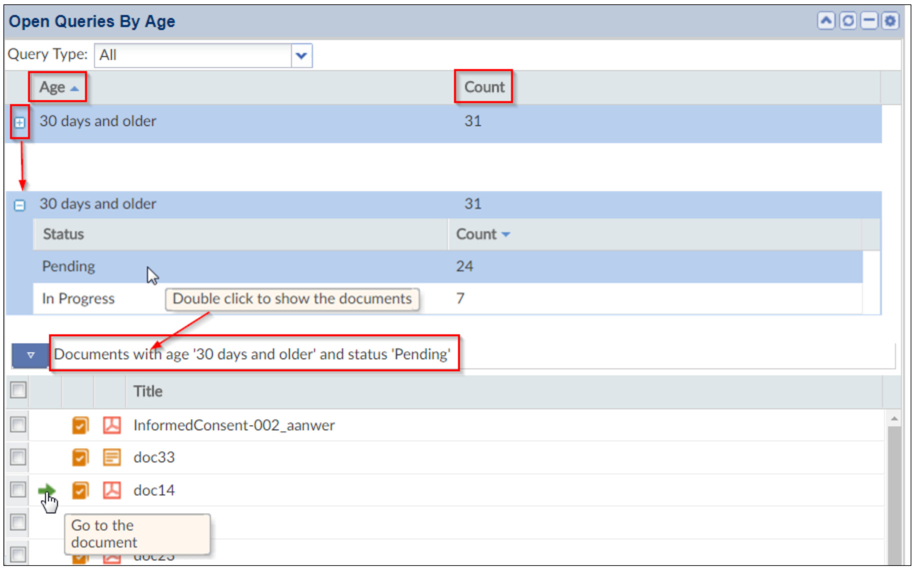


42.21. Dashlet – Open Queries By Age

The **Open Queries By Age** dashlet conveniently displays those documents that are 30 days and older in age and also provides a document count.

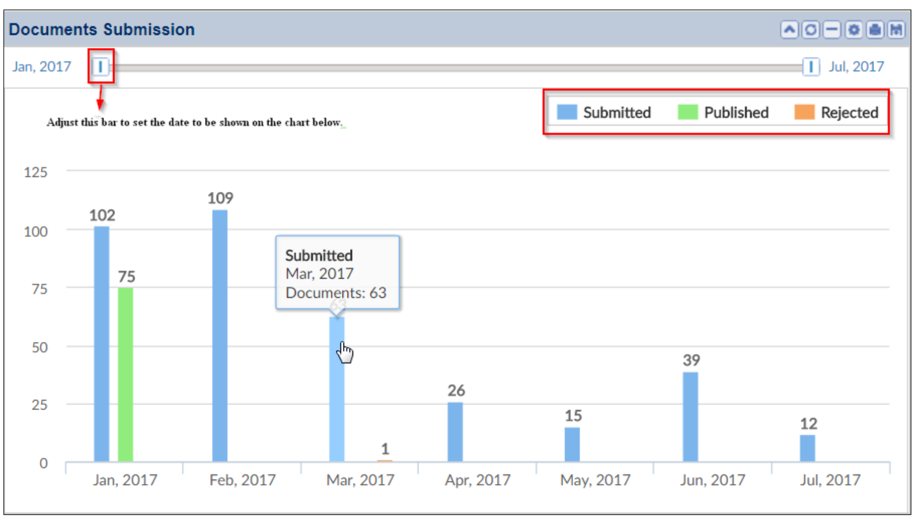
Administrator users can click on the expand icon [+] placed on the left of the age column to view its document status along with the document count.

After the drill-down, you can double-click on count to view the corresponding documents.



42.22. Dashlet – Documents Submission

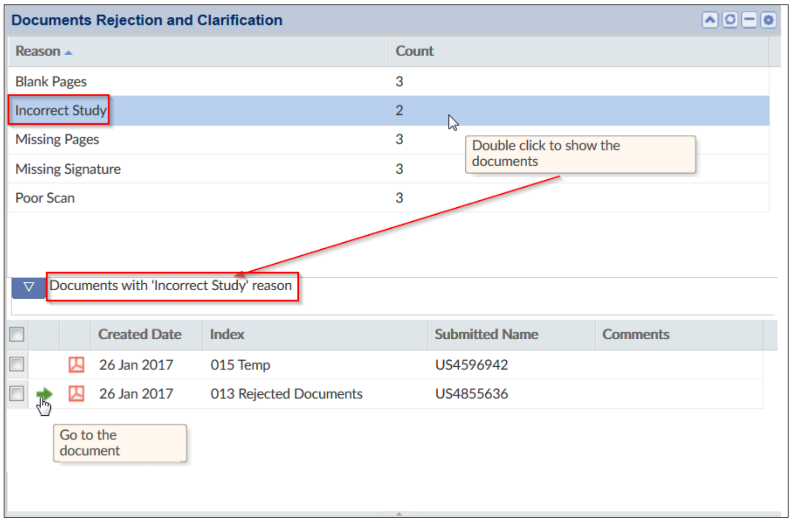
The **Documents Submission** dashlet contains a bar graph that displays the following: monthly document submissions, published documents in workflow final status, and rejected documents. This dashlet is only available if the workflow is enabled in the data room.



42.23. Dashlet – Documents Rejection and Clarification

The **Documents Rejection and Clarification** dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.

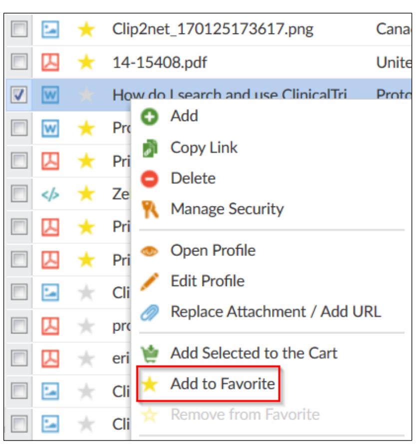
You can further double-click on the count to view the list of documents associated with a particular rejection or clarification reason.



42.24. Dashlet – My Favorite Documents

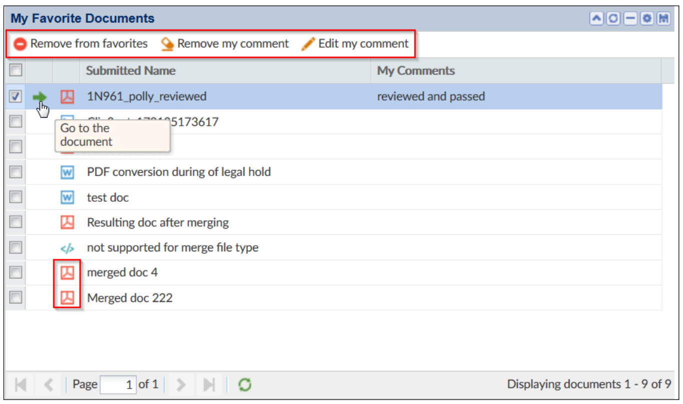
Administrator users can add certain documents to his/her favorites, and these selected documents will appear in the dashlet, **My Favorite Documents**.

To add a document to your favorites, simply right-click on the document and click **Add to Favorite**.



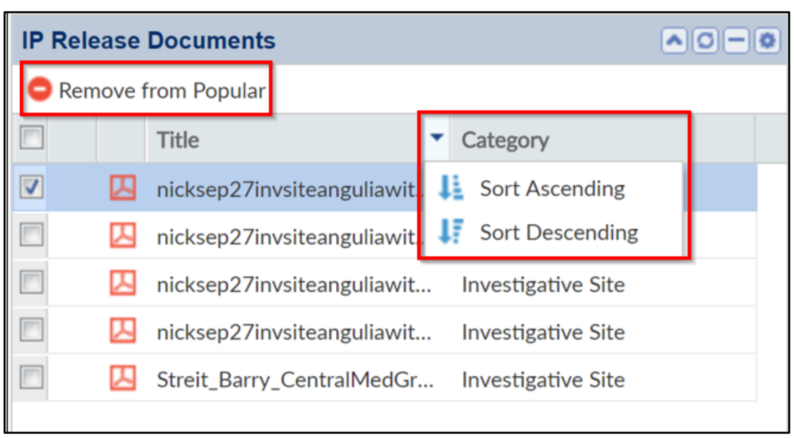
The **My Favorite Documents** dashlet displays those documents that a user has selected as his/her favorites. You can remove documents from the **Favorites** dashlet by ticking the checkmark next to the document name and selecting **Remove from Favorites**. You can also remove or edit your comments.

Click on the icon to view the document right from the dashlet.

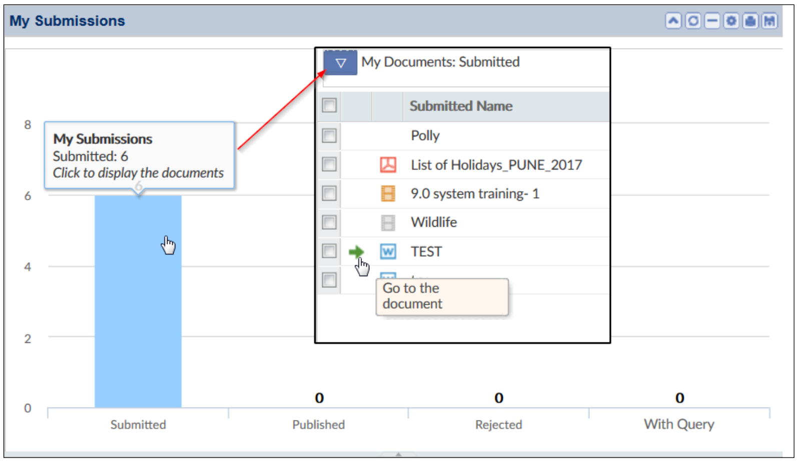


42.25. Dashlet – IP Release Documents

The **IP Release Documents** dashlet displays the list of documents that have been marked as popular by an Admin or Editor through the Document Cart. To remove a document from the Popular list, click **Remove from Popular**. To view the document, click the icon. To sort the documents listed in the dashlet in ascending or descending manner of the 'Title', hover the mouse over the column header and select an option from the dropdown.

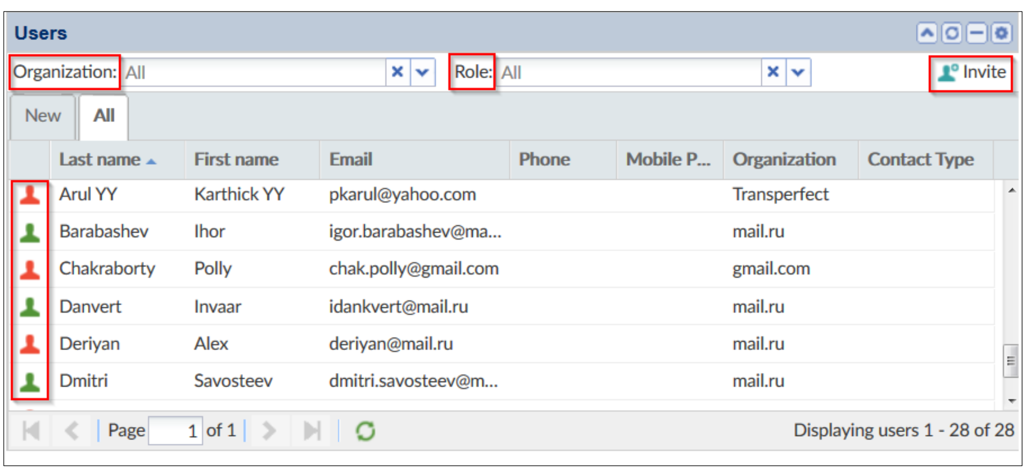


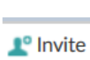
42.26. Dashlet – My Submissions



The **My Submissions** dashlet displays a bar graph of four different categories in total: Submitted, Published, Rejected, and With Query. It conveniently shows the number of documents that pertains to each category. You can further click on each bar to display the corresponding documents.

42.27. Dashlet – Users

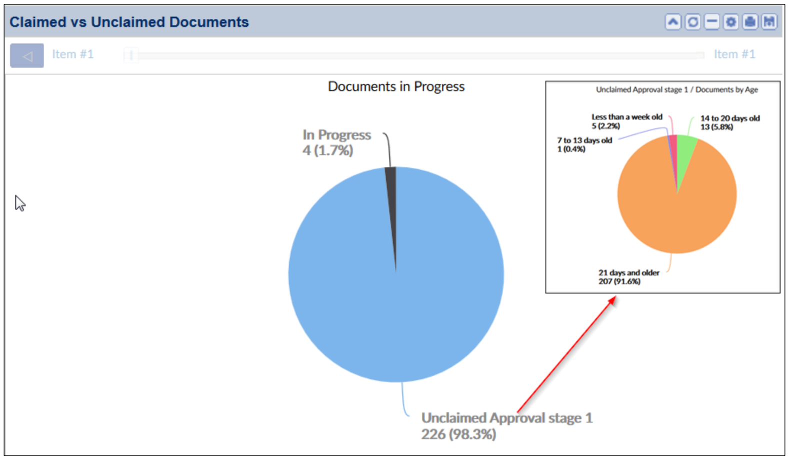


The **Users** dashlet provides a helpful option that lists new users or all users in a study with filters to sort users by organization and by their access level (role). You can also invite a new user here by clicking the **Invite** 

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.

42.28. Dashlet – Claimed vs. Unclaimed Documents

The **Claimed vs. Unclaimed Documents** dashlet provides a count of all documents that are in a workflow and are either claimed, unclaimed, or in progress. You can further click on each slice of the interactive pie chart to obtain further detailed information.

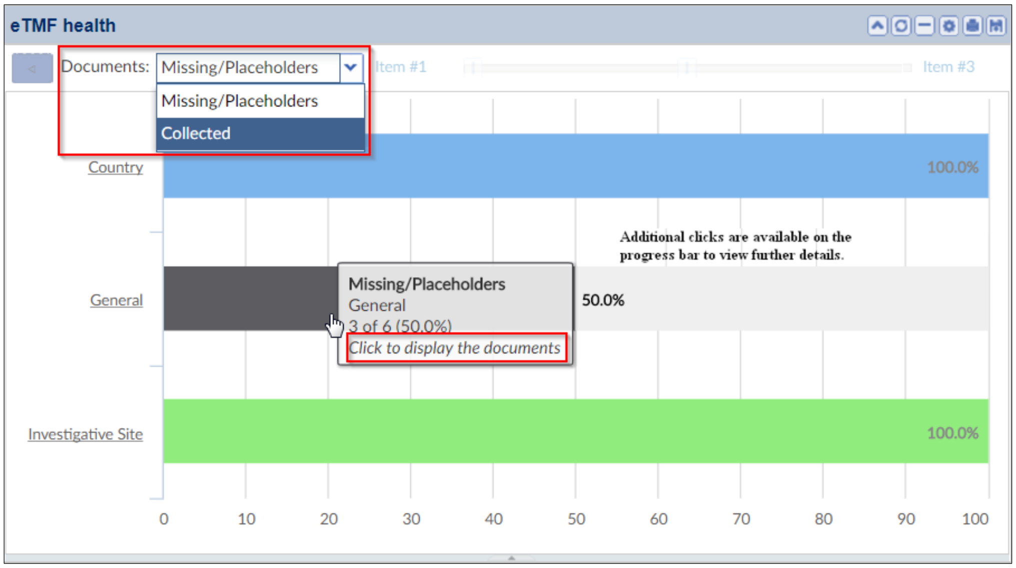


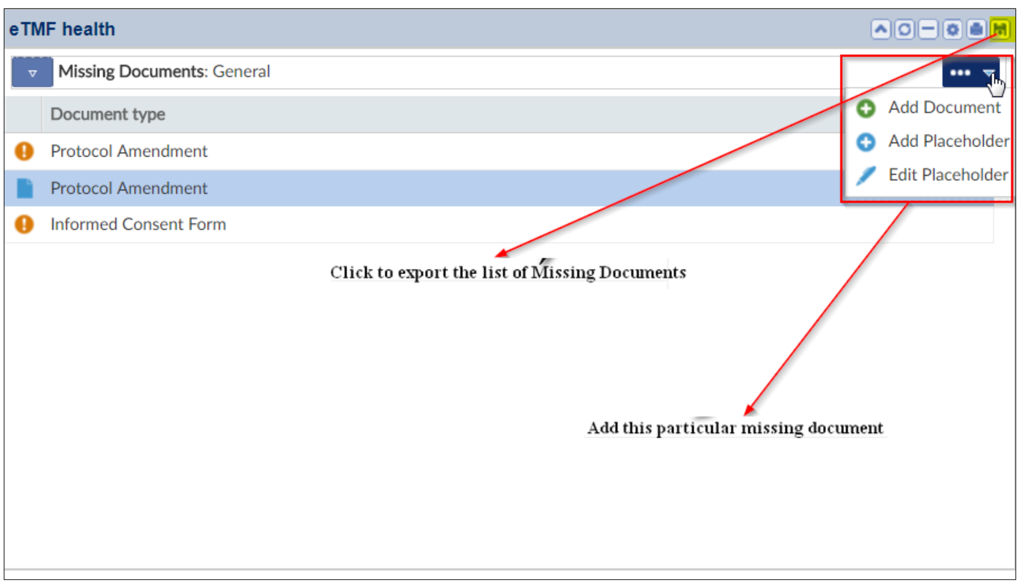
42.29. Dashlet – eTMF Health

The **eTMF Health** dashlet displays progress bar(s) that indicate what percentage of required eTMF documents are either collected or currently missing. On the top of the progress bar, Administrator users can manually set the chart type to be displayed.
Hovering the mouse on each progress bar shows a popup with more detailed progress percentage for the category of the documents.

Click a bar to drill down to the lowest level to list the missing/placeholder documents. You can use the **Save** button placed on the upper right corner to export the list of missing documents.

Additionally, you can use the button to conveniently upload a missing document/placeholder, or to edit a placeholder right off the dashlet. To view any changes, refresh the chart to update the missing documents list.

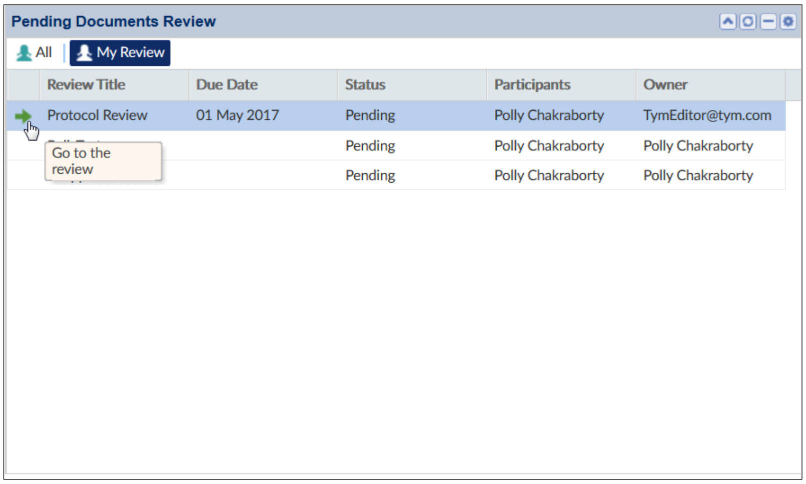




42.30. Dashlet – Pending Documents Review

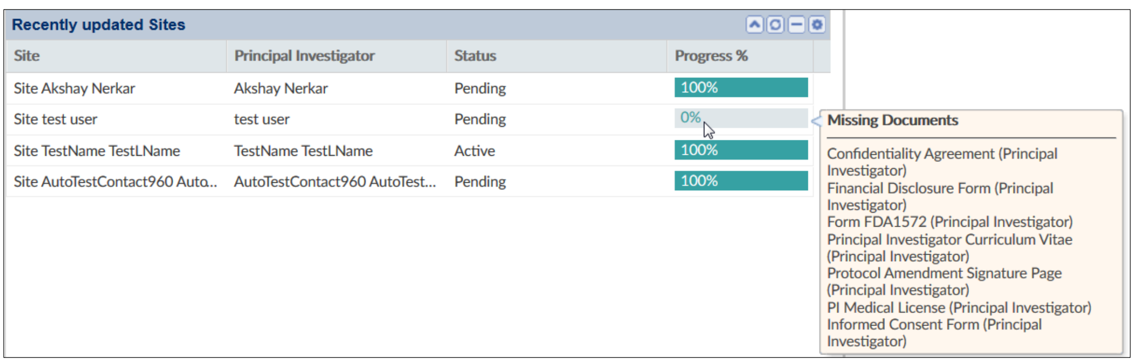
The **Pending Documents Review** dashlet gives a list of all documents that are pending for review.

You can choose to view the documents pending for review for **All** All users, or only for yourself through **My Review** My Review. Clicking the green arrow next to the **Review Title** leads you to the **Authoring** module to view further details of the review. Refer to the screenshot below:



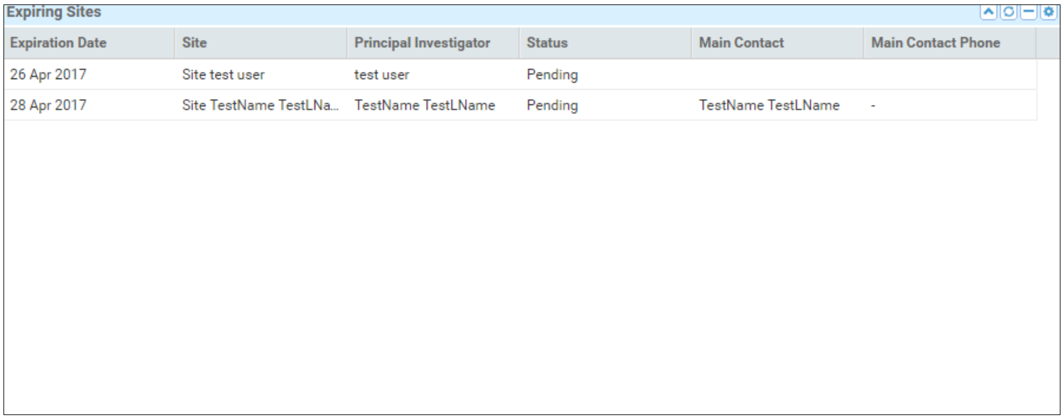
42.31. Dashlet – Recently Updated Sites

The **Recently Updated Sites** dashlet gives the activation progress report of all sites in a room. Hover the mouse over the **Progress%** column to view the list of documents that are missing to complete the site activation.



42.32. Dashlet – Expiring Sites

The **Expiring Sites** dashlet gives a list of all sites that are expiring in a future date. Refer to the screenshot below:



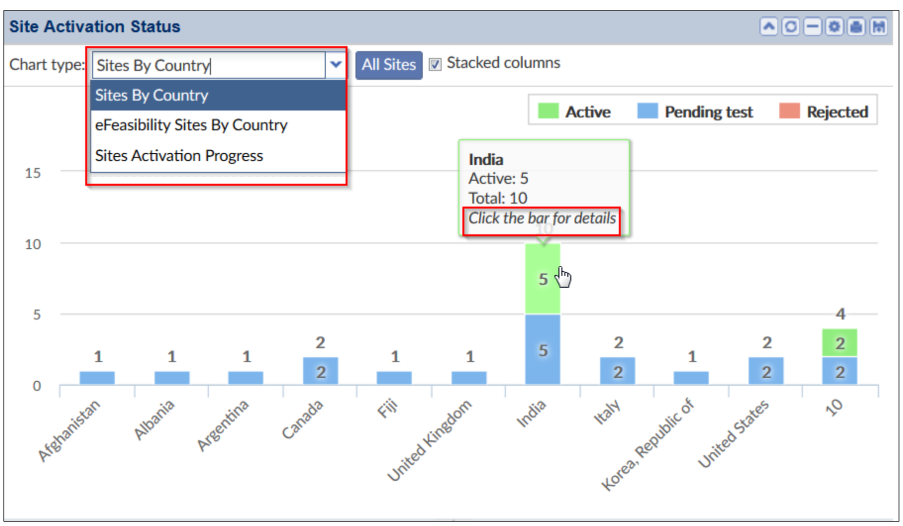
Expiring Sites

Expiration Date	Site	Principal Investigator	Status	Main Contact	Main Contact Phone
26 Apr 2017	Site test user	test user	Pending		
28 Apr 2017	Site TestName TestLNa...	TestName TestLName	Pending	TestName TestLName	-

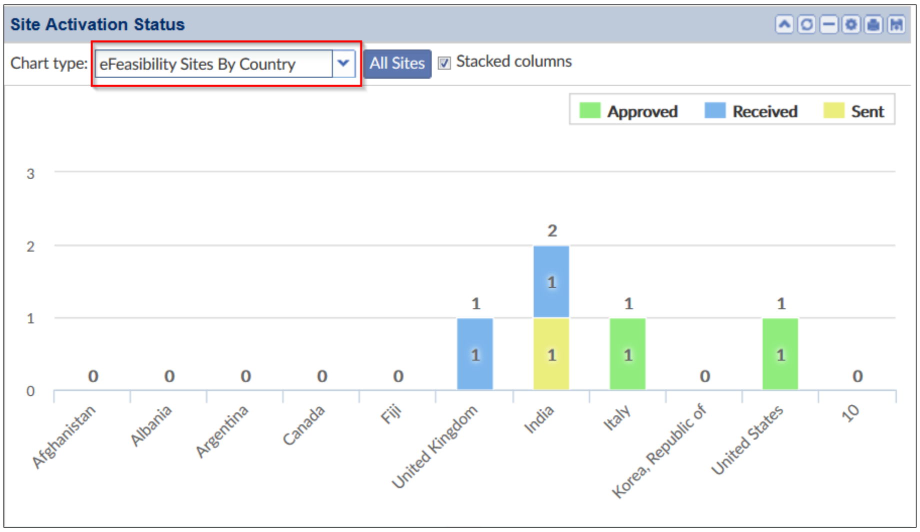
42.33. Dashlet – Site Activation Status

This dashlet offers three views – Sites By Country, e-Feasibility By Country, and Sites Activation Progress.

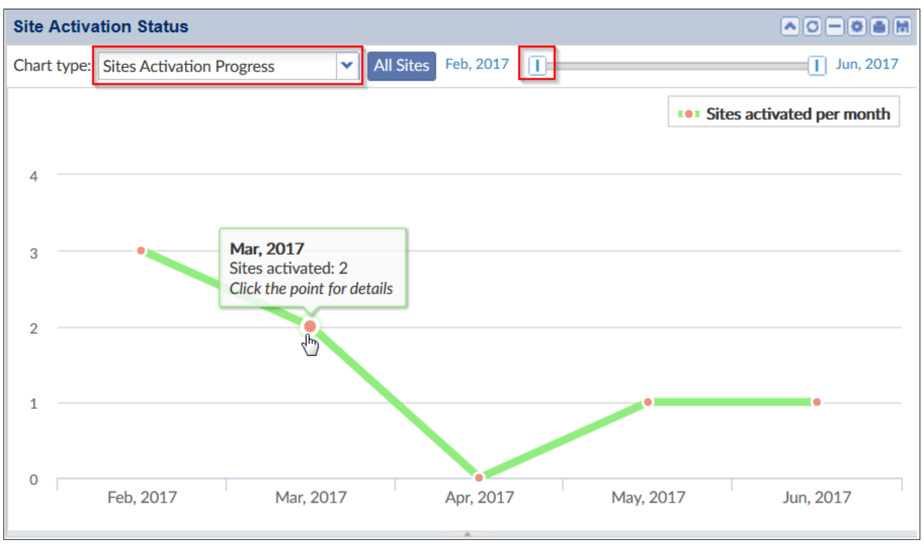
Select the **Site By Country** view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshot below.



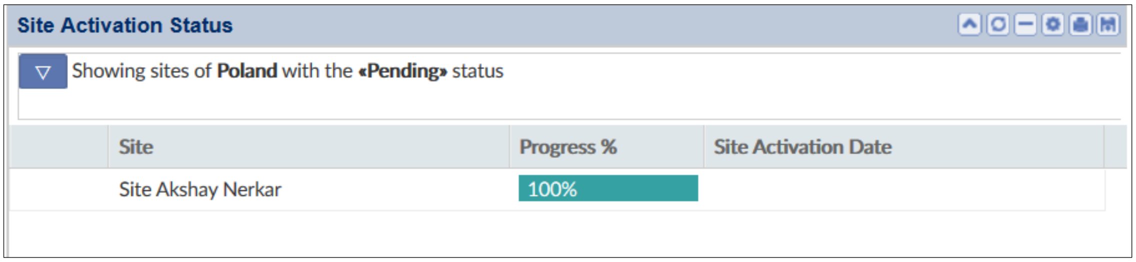
Select the **e-Feasibility By Country** view to reveal the number of documents that have been received, approved, and sent to complete the e-feasibility study for the sites.



Select the **Site Activation Status** view to reveal the number of sites activated per month. Drag the bar further to scroll down the chart.



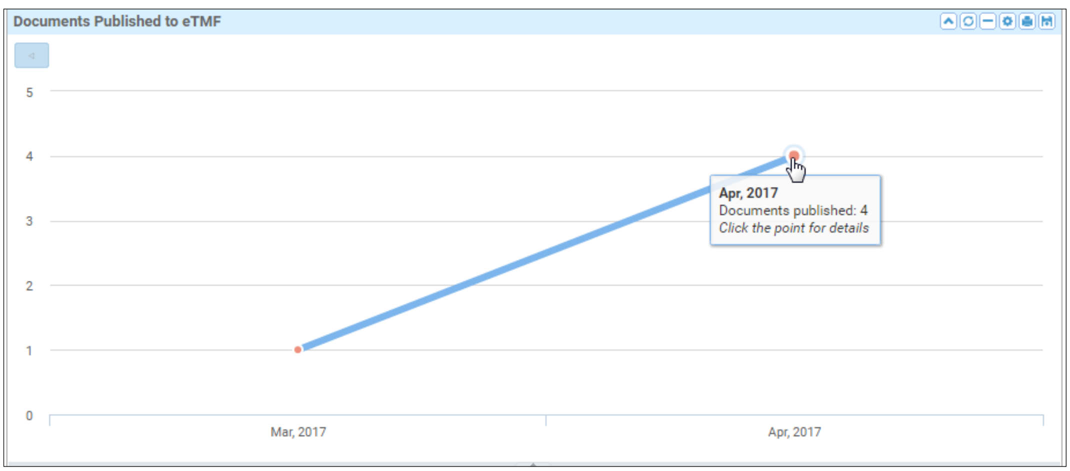
By default, the charts reflect results from all sites; however, if you wish to view sites in which you are a member, click the All Sites All Sites button next to the chart type to change it to **My Sites** My Sites . This shows the sites in which you are a member. Clicking a high point on the line graph or a bar in the bar graphs reveal the sites for the particular status.



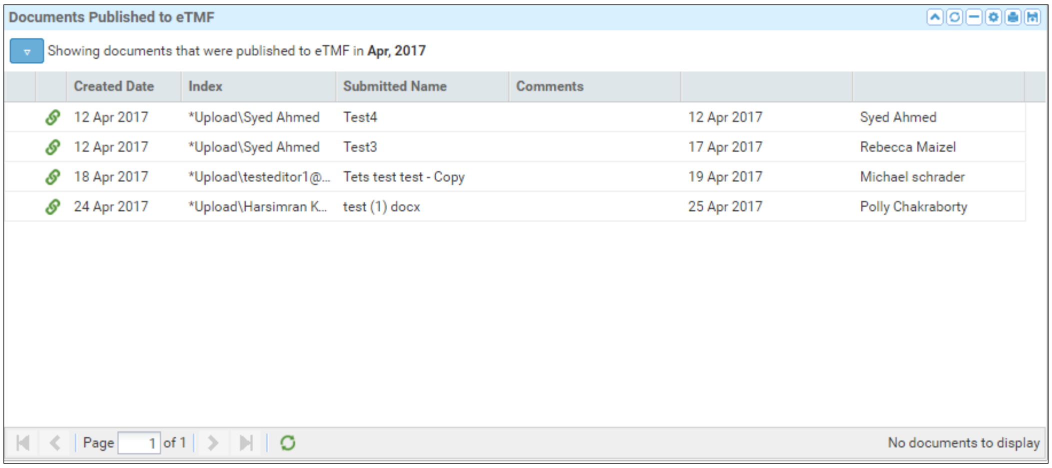
Double-clicking a site name will open the Edit investigative site popup to allow you to edit the details of the site.

42.34. Dashlet – Documents Published to eTMF

The **Documents Published to eTMF** dashlet is visible in a Shared Workspace (SWS) room. It displays a line graph showing the number of documents published to eTMF on a particular day. Refer to the screenshot below:

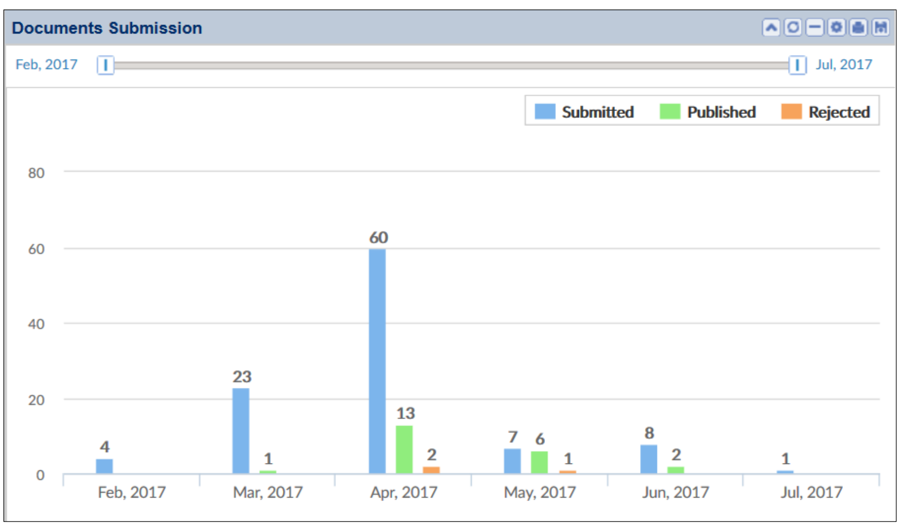


Click the point on the graph to get a list of document published.



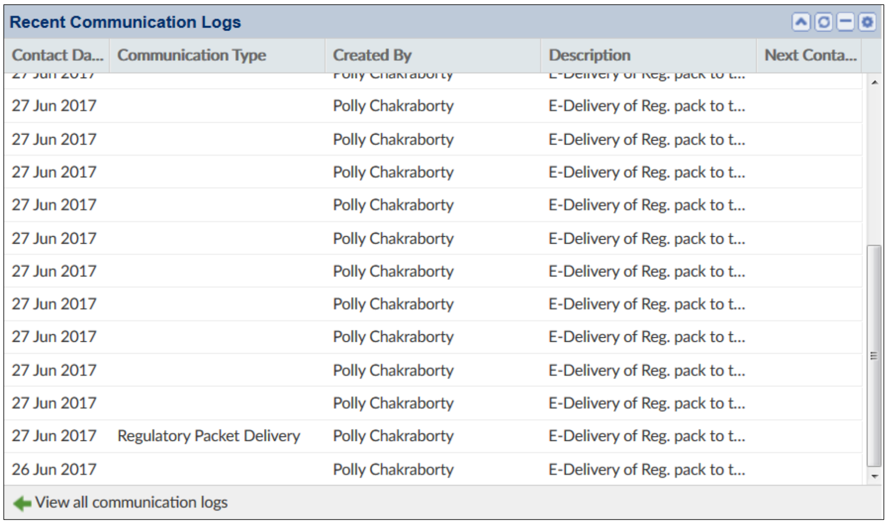
42.35. Dashlet – Documents Submission

The **Documents Submission** dashlet is visible in a Shared Workspace (SWS) room. It displays a bar graph showing the number of documents submitted, rejected, and published to eTMF in a particular month. Hover the mouse on a bar to view the total number of documents. Refer to the screenshot below:



42.36. Dashlet – Recent Communication Logs

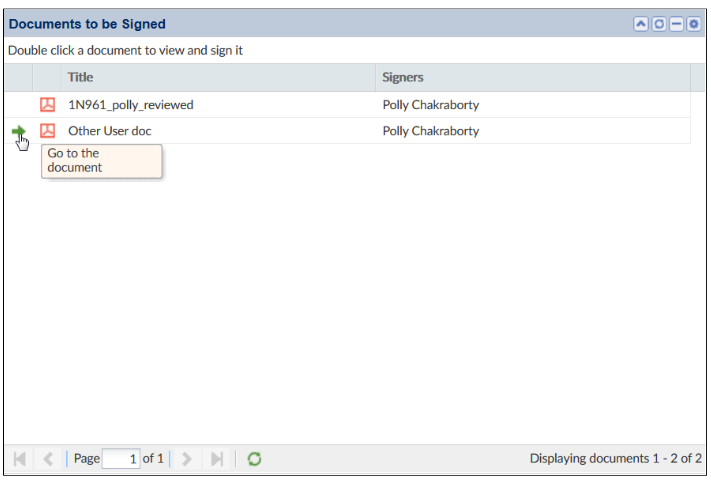
The **Recent Communication Logs** dashlet gives a list of all communications made during the site start-up and activation stage.



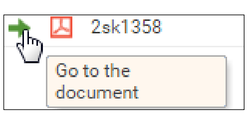
Clicking the green arrow will take you to the Start-Up/Communications module to view all the communication logs.

42.37. Dashlet – Documents to be Signed

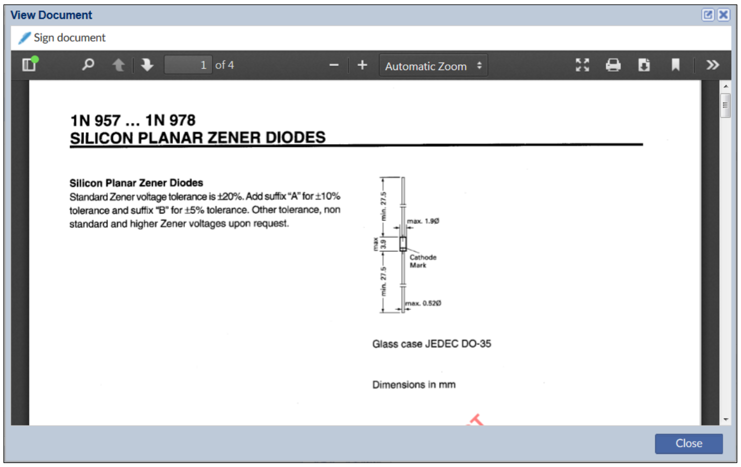
The **Documents to be Signed** dashlet gives a list of document pending for signature.



Hover the mouse over a document name for a green arrow to appear. Click the arrow to take you to the **Documents** dashboard where you can view and sign it.

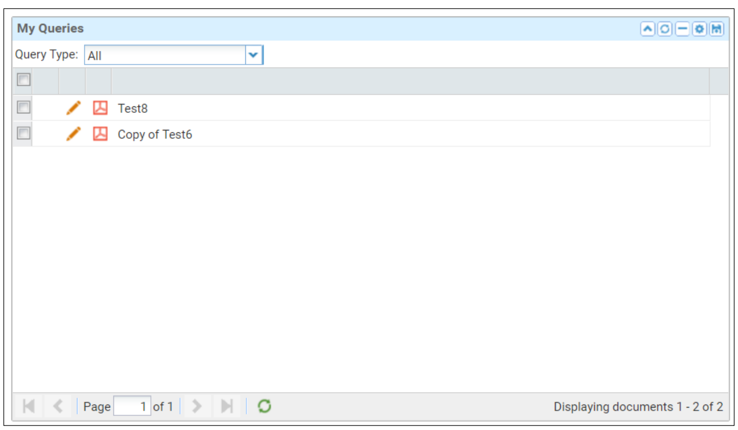


You can also double click the document to view and sign it in the **View Document** popup. Refer to the screenshot below:



42.38. Dashlet – My Queries

The **My Queries** dashlet gives a list of documents based on their query types. The query types could be All, Workflow, or Audit.



42.39. Dashlet – Cross Study Activity

To make this dashlet available to users on the Home screen with Reader access and above, contact the TI helpdesk.

The **Cross Study Activity dashlet** gives a report in the form of a pie chart of the following activities of users across all the studies to which the user has access to:

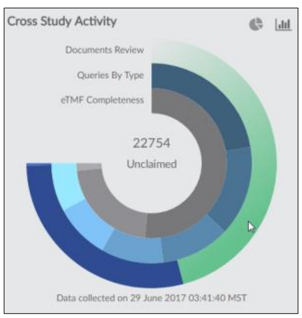
1. Documents Review
2. Queries By Type

3. eTMF Completeness

Each activity is represented by a circle, the outermost circle representing Documents Review, the middle circle representing the Queries By Type, and the innermost circle representing eTMF Completeness. Each circle is further divided into partitions as follows:

1. The Documents Review is divided by Documents Status – Unclaimed, and Final.
2. The Queries By Type into its various types like missing pages and signature, blank pages, poor scan, incorrect study, and other types.
3. The eTMF Completeness report by Collected, Missing, and Final documents.

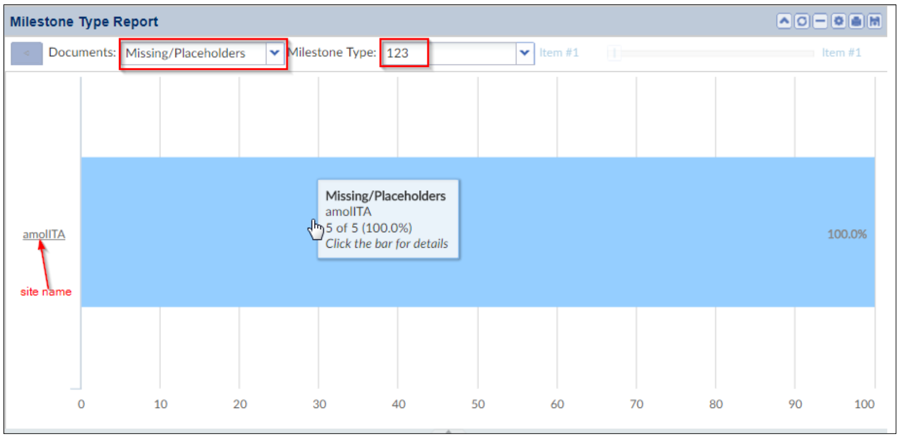
Hovering the mouse over each partition changes the color of the partition to light green and displays the number of documents in the white space in the center of the chart. Refer to the screenshot below:



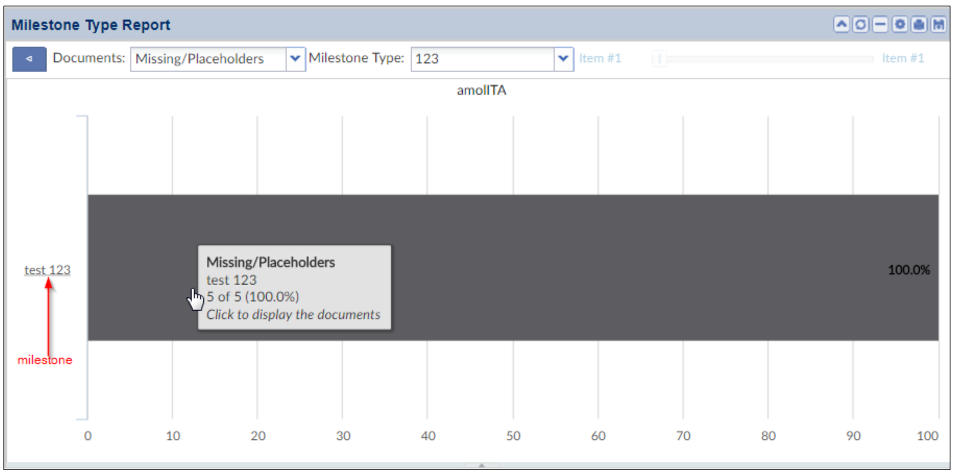
This dashlet gives a report of 22,754 documents unclaimed for review.

42.40. Dashlet – Milestone Type Report

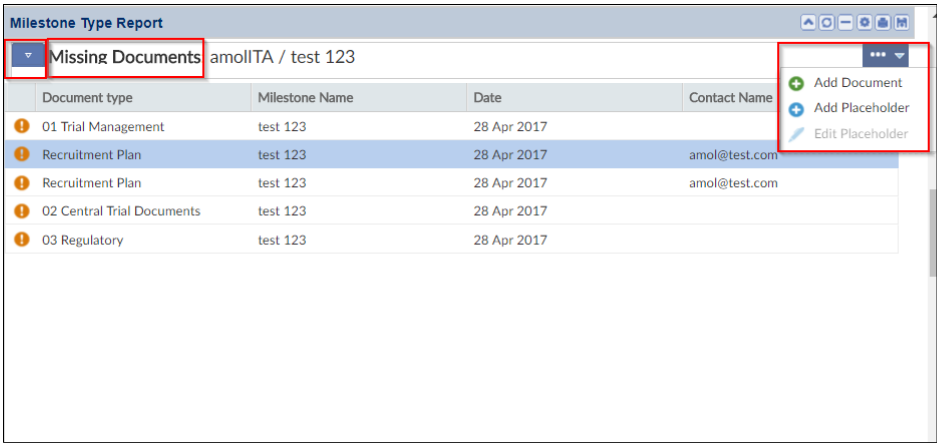
The **Milestone Type Report** dashlet gives the percentage of missing/placeholder documents, or collected documents for a particular milestone type associated with a site in the form of a bar graph.



Click the site name or the bar to reveal the percentage of missing/placeholder, or collected document types under each milestone for the selected milestone type.



Click the milestone bar to reveal the list of missing/placeholder required document types for the site under a particular milestone. Click the inverted arrow with dots  to add a document, or add/edit a placeholder directly from the dashlet for the particular selected site. Click the blue inverted arrow  to return back to the original dashlet screen.

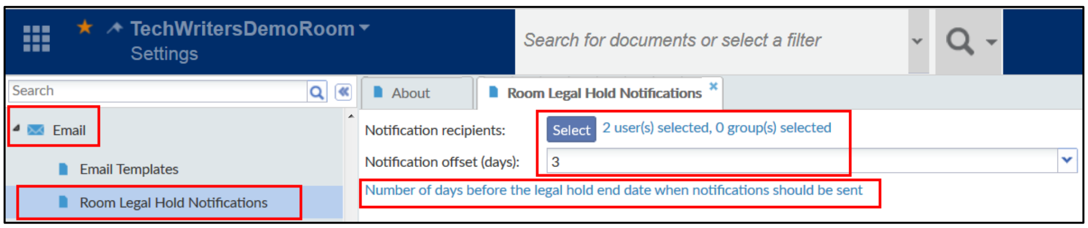


Milestone Type Report
Missing Documents
amolITA / test 123
Add Document
Add Placeholder
Edit Placeholder
Document type
Milestone Name
Date
Contact Name
01 Trial Management
test 123
28 Apr 2017
Recruitment Plan
test 123
28 Apr 2017
amol@test.com
Recruitment Plan
test 123
28 Apr 2017
amol@test.com
02 Central Trial Documents
test 123
28 Apr 2017
03 Regulatory
test 123
28 Apr 2017

43. Legal Hold

43.1. Room Legal Hold Notifications

As an administrator, you can set up the users who will be notified when a room is put on legal hold as well as decide the number of days before the legal hold end date when notifications should be sent to those users. This can be done from **Username dropdown -> Settings -> Email -> Room Legal Hold Notifications**.

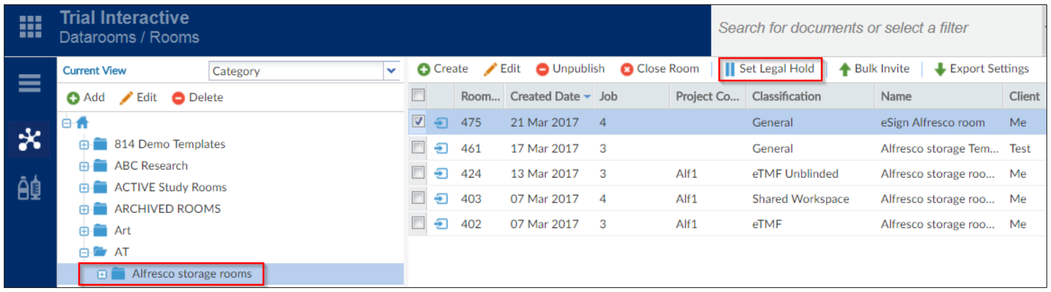


43.2. Putting Legal Hold on Rooms

All users with Administrator Level can put a Legal Hold on Rooms.

The following section provides a step-by-step guide to set a legal hold on rooms in your TI session.

1. From the **Home** page, click the **Configure dropdown** and select **Datarooms Management**. You will be taken to the **Datarooms/Rooms** module. Click the **Rooms**  tab from the toggling menu bar.
2. Click the desired room folder located on the left menu panel. A right panel listing all the rooms within the selected folder will be displayed.
3. Select the room to which you wish to set a legal hold.
4. Click the **Set Legal Hold** tab located above the room list panel. You may also right click on the selected room and select the **Set Legal Hold** option.



5. The system will prompt the user to choose a **Hold Until** date and specify the reason for legal hold. Click the calendar icon to specify the date.

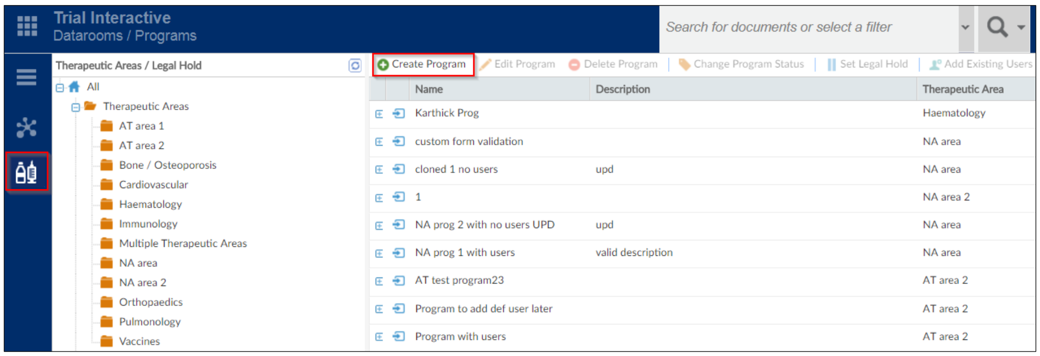
   The system also enlists the recipient/s who will receive legal hold end date notification as a reminder.

Your room is now set on **Legal Hold.**

The rooms on legal hold will be highlighted with an orange icon. Clicking the icon will load the room. An alert message will display, notifying users of the date until which the room will remain on legal hold on top banner of the room dashboard.

44. Program Management

Program Management is a centralized space where Administrator users can collect a series of documents and manage those documents that are related to a specific program. You can keep common documents which are related to all studies here. Program Management will be used to manage content before a study is launched.



To create a new program,

1. From the **Home** page, click the **Configure dropdown** and select **Datarooms Management**. You will be taken to the **Datarooms/Rooms** module.
2. Navigate to the **Programs** tab. Click the **Create Program** Create button from the top menu bar. Once clicked, a **Program Profile** wizard will pop-up, which you will have to fill out.

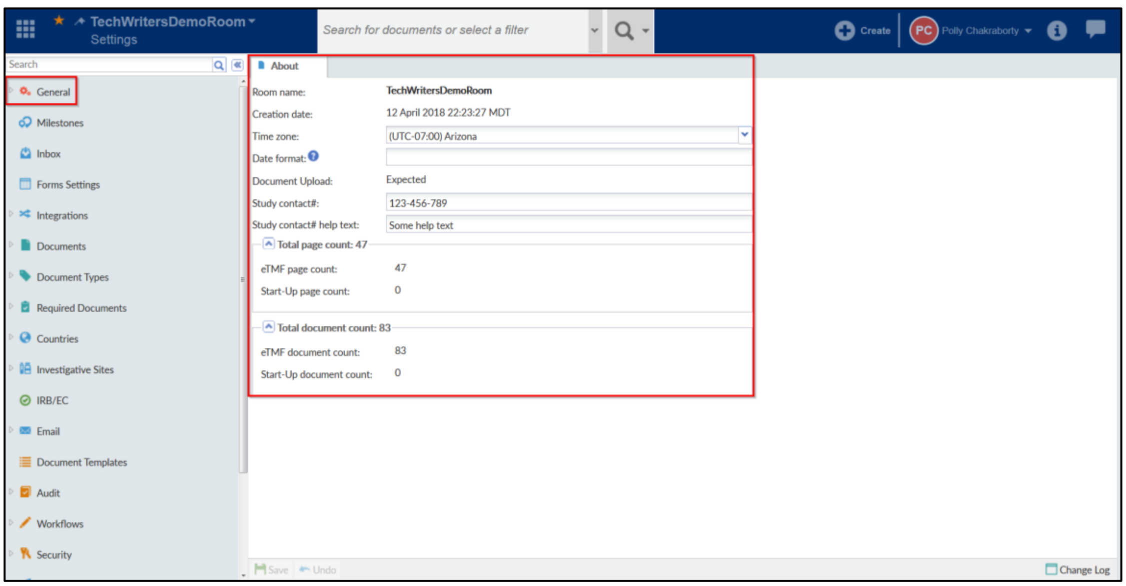
> ***You can conveniently set up the default administrators, editors, and readers that will be applied to all studies in the program.***

You can also link rooms to each program for your convenience. Additionally, you can manage the default access to studies related to your program.

45. Other Room Settings

This chapter only discusses the setting configurations that have not been discussed in earlier sections.

By default, when Administrator users click on **Settings**, it only displays the first item of the **General** settings which is the **About** page of the study room. Every room setting tab that displays on the left column is divided into sub-sections, allowing specific modifications for each defined category.



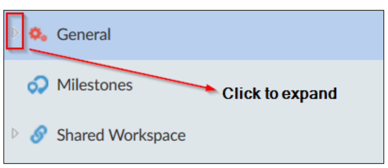
When each **sub-section** of the room setting tab is clicked, it appears as a separate tab on the right side of the screen. If users click multiple sub-sections, it will not override the previous tab, instead separate tabs will be created for each item clicked. To close the tab, simply right click on the tab and select **Close Tab**. Right-clicking a the tab will also provide an option to **Close All Tabs** and to **Close Other Tabs**. A **Search box** is also available in the Settings. If users wish to directly search for specific settings, simply type in the word without looking through the entire settings menu. The features mentioned will further be discussed in the following sections.

Administrator users can view and change most of the room settings in Trial Interactive. The client is given orientation on making the initial settings and on changing the settings in the client walkthrough. Typically, the room's settings will be decided upon during the client walkthrough, and the settings will remain unchanged, for the most part, for the duration of the study. This section of the user guide will describe the functions available through these menu selections.

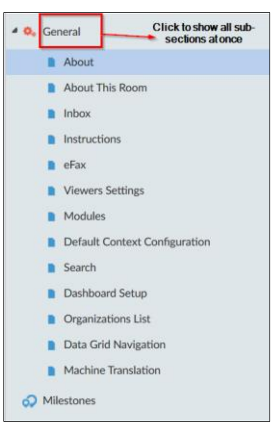
To access the room's Settings, log in to your Trial Interactive room and select **Settings** from the **Username dropdown** menu at the top right corner of the dashboard. The default opening Settings view is the **About** page of General Settings with the full array of room setting tabs listed in the menu on the left.

45.1. Accessing Sub-Section of Main Room Settings

When Administrator user wishes to directly access a specific sub-section of the left menu to modify the room settings, he/she can simply click the expand button ▷, which is located next to each main menu selection.



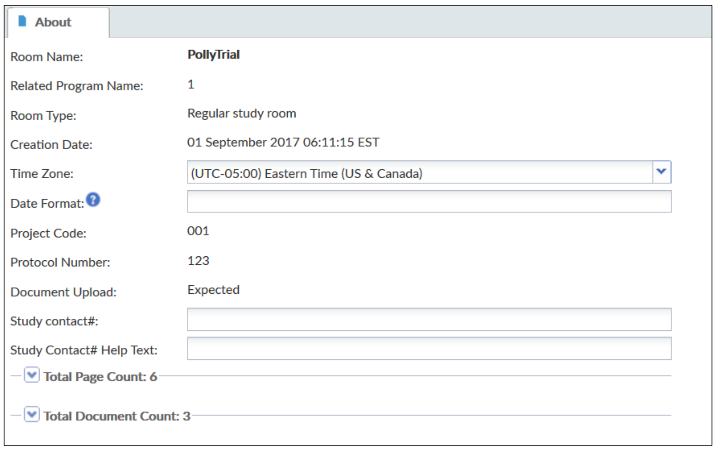
If user wants to load all sub-sections of the menu selection, simply click on the selected menu text to display all.



45.2. General Settings

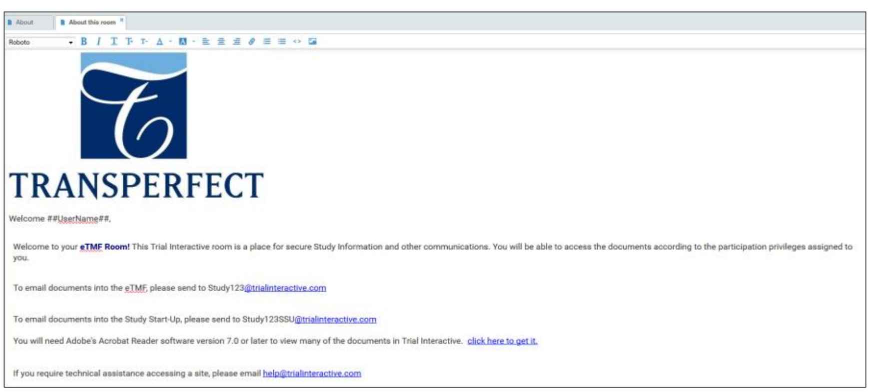
Individual settings windows are typically available to you as an Administrator under the **General settings** tab.

45.2.1. About



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

45.2.2. About this room



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

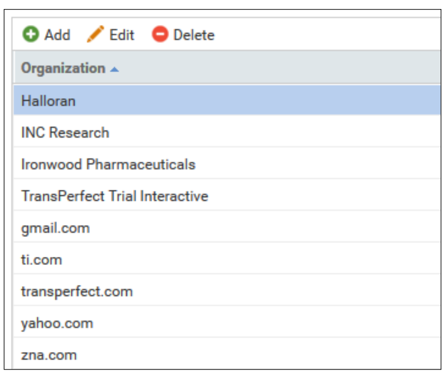
You can view the *Change Log History* by using the **Change Log** Change Log button that is directly available on the bottom right corner of the **About this Room** dashlet.

45.2.3. Instructions

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

45.2.4. Organizations List

In this box, you can view the list of organizations associated with the study. You can add organizations to the list, edit names, or delete names that are on the list but are not in use in the room. If any of the room's users are associated with an organization, that organization cannot be deleted from the list.



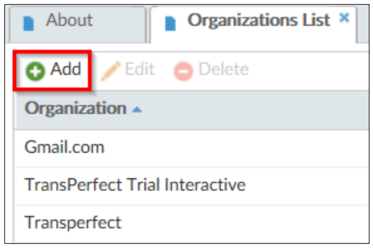
Adding Directly to the Organization List

An Administrator can add new Organizations to which to assign participants in a room by two different means.

1. Log in to a specific Trial Interactive room.
2. Click **Settings** from the top menu.

   By default, the **General settings** view opens.
3. Go to the **Organizations List** panel.

4. Click **Add**.



A blue-framed field opens inside the panel.

5. Type the name of the new organization.
6. Hit **Return**.

The new organization name appears in the list.

Adding New Organizations When Inviting New Users

1. Log in to a specific Trial Interactive room.
2. Click **Users management** from the **Username dropdown**.

The **User views** and **Users** panels populate the screen.

3. Select **Invite** from the menu ribbon in the **Users** panel.

A **User invitation** window opens.

As you enter the new User Profile, click the '+' sign at the right end of the **Organization** field.

A **New organization** window opens.

4. Type the name of the new organization to which you need to assign this new user.
5. Click **Create**.

You will be returned to the **User Profile** to complete the invitation.

Editing Names of Organizations

1. Log in to a specific data room.
2. Click **Settings** in the top menu ribbon.

By default, the **General settings** view opens.

3. Go to the **Organization list** pane.
4. Select the name of the Organization to be edited by clicking it.
5. Select **Edit** in the top menu ribbon in the window.
6. Type in the change.

7. Hit **Return**.

   The edited organization name will appear in the room's Organization list.

Deleting Organizations from the Organization List

1. Log in to a specific data room.
2. Click **Settings** in the top menu ribbon.

   By default, the **General settings** view opens.
3. Go to the **Organization list** pane.
4. Select the name of the Organization to be deleted by clicking it.
5. Select **Delete** in the top menu ribbon in the window.

   The organization name will be removed from the room's Organization list.

> ***Only Organizations with no active users can be deleted from a room. If the chosen organization has any active users in the room, you will see a Warning box indicating that the organization is already in use.***

Changes are saved automatically by the Trial Interactive platform.

45.2.5. Data Grid Navigation

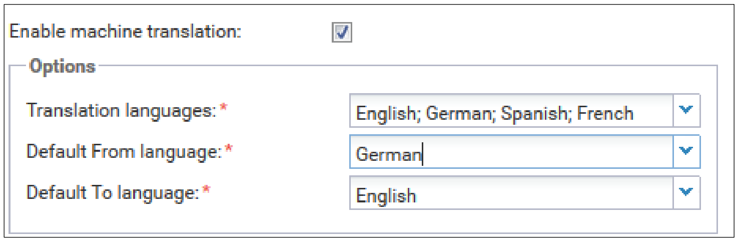
Minimum number of records per page in data grid: *	50
Minimum number of documents in the unread documents grid: *	10
Days to show last registered users: *	10
Start-Up dashboard recent investigative sites number: *	20
Start-Up dashboard recent communication log items number: *	20
Start-Up dashboard recent tasks number: *	20
(0 - No Limit)	

In the **Data grid Navigation** box, you can manipulate the number of records displayed in users' data grids, the number of records that will be listed in the **Unread Documents** grid that displays in the Dashboard view, and the duration that recently registered users to the room will be displayed on the data grid for the room. Additionally, you can set a limit on the recent investigative sites number, recent communication log items number, and recent task number on the Start-Up dashboard. Click **Save** if you have made changes.

45.2.6. Machine Translation

This feature works only with OCR.

In this box, you can choose to enable or disable the **Machine Translation** module.



Under **Options**, you can modify the list of languages available in the tool, and you can select the **Default From** and **Default To** languages. Click the dropdown menu to view available languages to be selected.

Click **Save** if you make changes here or click **Undo** to revert changes.

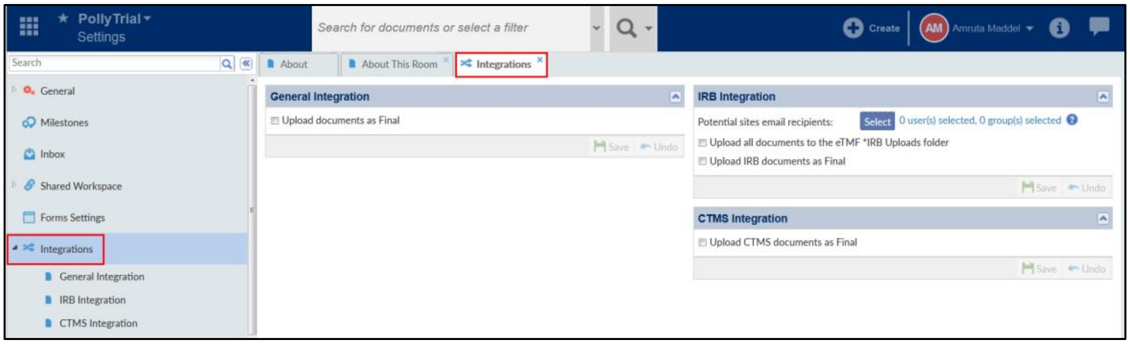
45.3. Integrations – General and CTMS

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

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

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

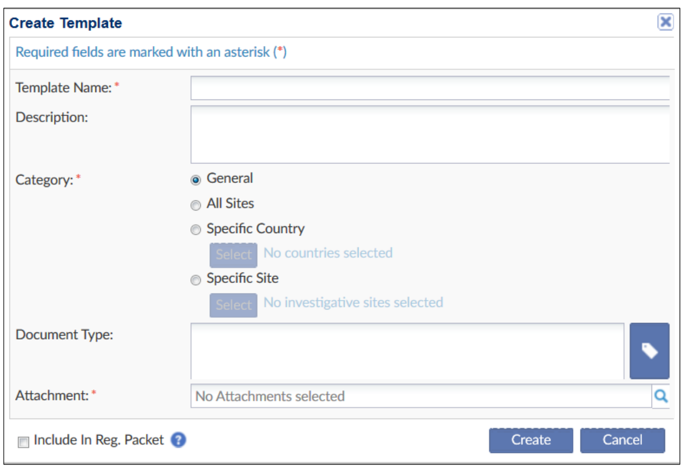
Documents, on uploading, would then move directly to the related folder assigned to their document types and acquire the status as final. Refer to the screenshot below:



As shown in the screenshot above, **Integrations** allow uploading to **eTMF** as **Final** Documents through **General Integration and CTMS Integration**.

IRB Integration is discussed in detail in section IRB Integration itself.

45.4. Document Template Settings



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

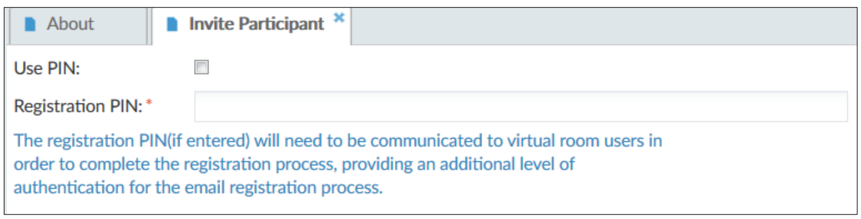
When you click on **Add**, a **Create Template**, a window will open up. Provide a template name, and choose a category to indicate where this document template will be used – General, All Sites, Specific Country, or Specific Site. Submit an attachment and lastly, you can choose to include this document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

45.5. General Security Settings

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

45.5.1. Invite Participant

As an Administrator, you can add a layer of security to the user registration process.



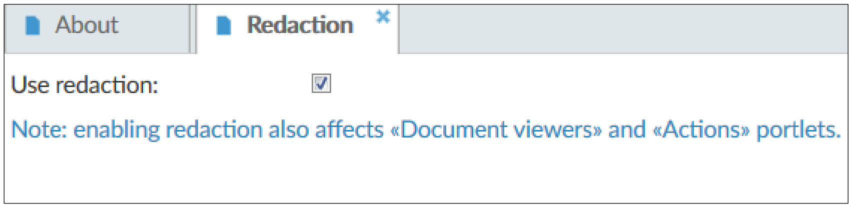
To use this extra layer of security:

1. Click the **Use PIN** checkbox.
2. Enter a **Registration PIN**.
3. Click **Save**.

   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.

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

45.5.2. Redaction

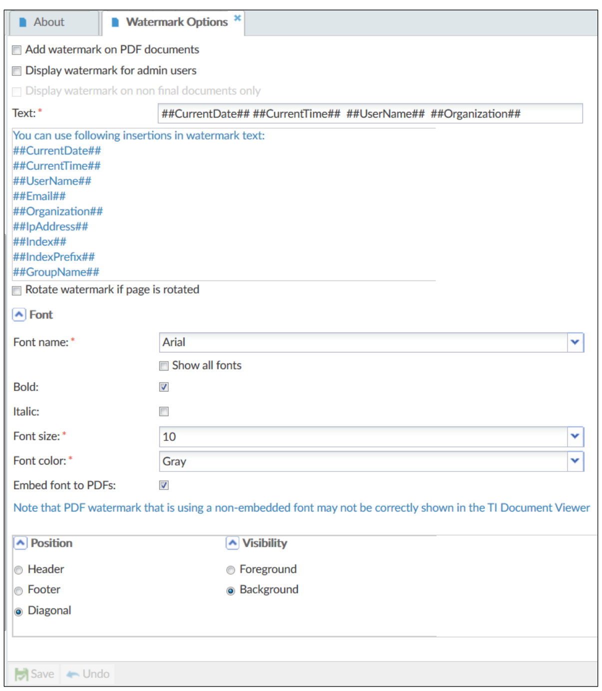


Administrators can choose to enable or disable the Redaction option in the room. Click **Save** if you make any changes here.

Enabling Redaction also affects Document viewers and Actions portlets.

45.5.3. PDF Watermark Options

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 final workflow status. Therefore, once the document becomes final, the watermark will no longer be available on the document; this is an automatic process.



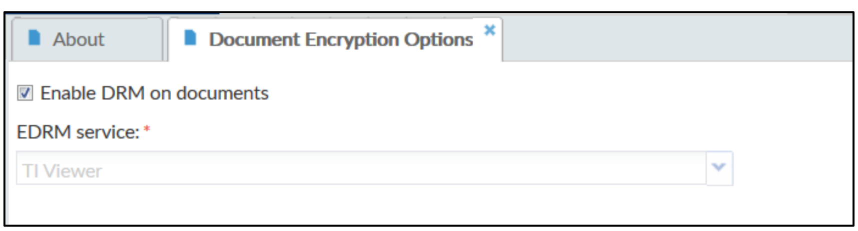
In this panel, Administrators can select which metadata fields will comprise the watermark, and they can select the appearance and position of the watermark:

1. Activate or inactivate the **Add Watermark on documents** option by clicking the check box.

   Activation of this option also activates the option of allowing non-PDF documents to be printed or downloaded without watermarks.
2. Click the checkbox to **Display watermark for Administrator users**.
3. Type in the **text of the message** to be displayed as the watermark using the text strings from the list provided.
4. Select the font name from the dropdown.

   The dropdown list can be extended to include all fonts by clicking the Show all fonts checkbox.
5. Select whether the watermark text will be rendered as Bold and/or Italic text.
6. Select or confirm the Font Size from the dropdown menu.
7. Select the Font color from the dropdown menu.
8. Select whether or not to **Embed the font to the PDF**.
9. Select the position of the watermark.
10. Select whether the watermark will appear in the foreground or the background of the document text.
11. Click **Save**.

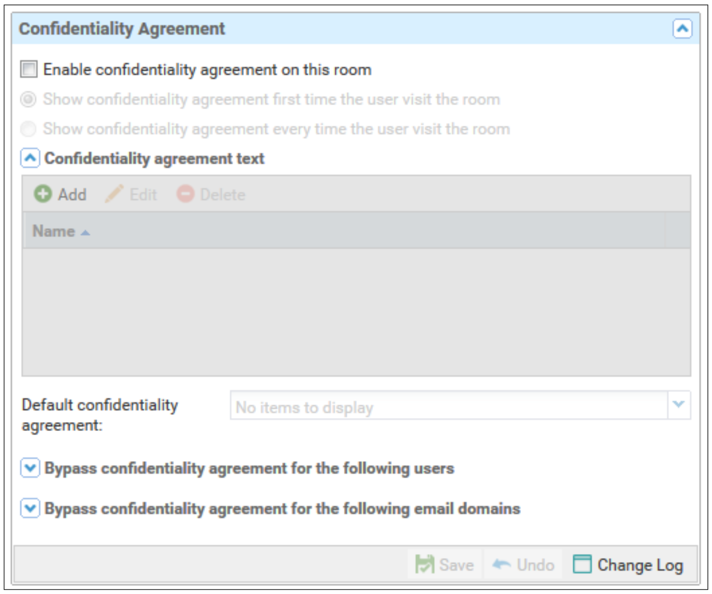
45.5.4. Document Encryption Options



The system provides Digital Rights Management (DRM) functionality to documents via integration with TI Viewer providing additional security options to users choosing to encrypt document options.

45.5.5. Confidentiality Agreement

Another layer of security that an Administrator can add to a room is a Confidentiality Agreement. This option can be enabled with a click in the box, and you can type in the text of the Confidentiality Agreement.



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

1. Click to enable/disable the Confidentiality Agreement on this room.
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.
4. Type in the name of the agreement.
5. Click **Create** at the bottom of the window.

More than one Confidentiality Agreement can be added.

You have the option to allow specific users to **Bypass the Confidentiality Agreement**.

1. Click the arrow in the box.
2. Click **Add**.
3. Add the names of users who can bypass the agreement.

   You can allow entire sets of users who have a common email domain to bypass the agreement.
4. Click the arrow box.
5. Click **Add**.
6. Type in the domain name(s) that can bypass the agreement.

   Click **Save**.