TRIAL INTERACTIVE 10.0 – EDITOR GUIDE

Version 1

Approvals

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Version History

Author	Revision	Date	Comment
Yogesh Inamdar	1.0	07-Jan-2020	Initial Creation

Contents

Page Mapping with Topics

This section gives you an overview of the TI 10.0 topics that are mapped to pages in this help.

Keyword	**Topics in help**	**Recommended Page Title in help**	**Job Aids**	**Videos**
Login	Login using MultiFactor Authentication Login using Google Autheticator Logging in on Subsequent Visits	Getting Started		
Password	Request a passoword Reset	Getting Started		
Home Page	Summarized View of rooms Detailed View of rooms	Trial Interactive Home Page		
Uploading and Importing Documents	Uploading documents to room Importing documents to a room	Trial Interactive Home Page Importing Documents and Metadata		
Documents	Deleted and Expired Documents	Deleted and Expired Documents		
Navigation	Main Navigation Changing Rooms from within a room	Main Navigation and Inter-Room Navigation		
Users	Creating, editing and deleting users Inviting Users - Qucik Invite Regular Invite Resending Invitations	Users Management Room Settings → Security → Users		
Groups	Creating , editing, and deleting groups Adding, editing and deleting users from groups	Users Management Room Settings → Security → Groups		
My Profile	My Profile Settings My Profile Notifications	My Profile Settings User Menu		
Dashlets	Dashlets	Dashboard and Dashlets		

Room Index	Index Views	Trial Interactive eTMF and Documets Module → Documents View → The Room Index		
Document Grid	Previewing Documents and Metadata Copying or Moving Documents Documents Context Menu (right-click on a document)	Trial Interactive eTMF and Documets Module → Documents View → The Documents Grid		
Documents Cart	Documents Cart	Trial Interactive eTMF and Documets Module → Documents View → The Documents Grid → Top Ribbon Bar		
Searches	Documents Search, Searching Users, Advanced Search, Room Search	Searches		
Quality Control	Editing an Existing Workflow Auto-Claiming a Document, Reassigning a Reviewer, Resolving a Query	Quality Control Settings Quality Control Process		
Quality Review	Creating an Audit Profile Performing Audits Exporing Audits Performing Audit Response Resolving Queries Adding document back to Audit Profile	Quality Review		
Tasks	Adding, Editing and Deleting Tasks Exporting Tasks Assigning Tasks	Tasks		
eSignature	TI eSignature	eSignature → Signing documents in TI eSignature.		

	Adobe eSignature	eSignature → Signing documents in Adobe eSignature.		
	DocuSign eSignature	eSignature → Signing documents in DocuSign eSignature.		
CRA Reconciliation	Documents Reconciliation	CRA Reconciliation → Documents Reconciliation		
	CRA TMF Reconciliation Report	CRA Reconciliation → Creating and Viewing the CRA TMF Reconciliation Report		
Contacts	View Contacts Contact Data Convert to User(s)	Sites, Required Documents, Countries and Contacts → Contacts		
Sites	Site Views Adding, Editing and Deleting Sites Site Security Importing Sites Exporting Sites	Sites, Required Documents, Countries and Contacts → Sites		
Communications	Communication Inbox Communication Outbox	Communications		
Q and A	Creating Questions and Answers Exporting Q&A Deleting Q&A	Q&A → Q&A Module		
FAQ	Creating, editing and deleting FAQ Emailing FAQ Exporting FAQ FAQ's Cart	FAQ → FAQ Module		

Milestones	Configuring Milestones Adding Milestones to Document Types, Studies, Countries Editing and Deleting Milestones	Milestones and eTMF Completeness → Milestones		
eTMF Completeness	CRA Visit Types	Milestones and eTMF Completeness → eTMF Completeness		

Getting Started

Read this Online Help Roadmap before use.

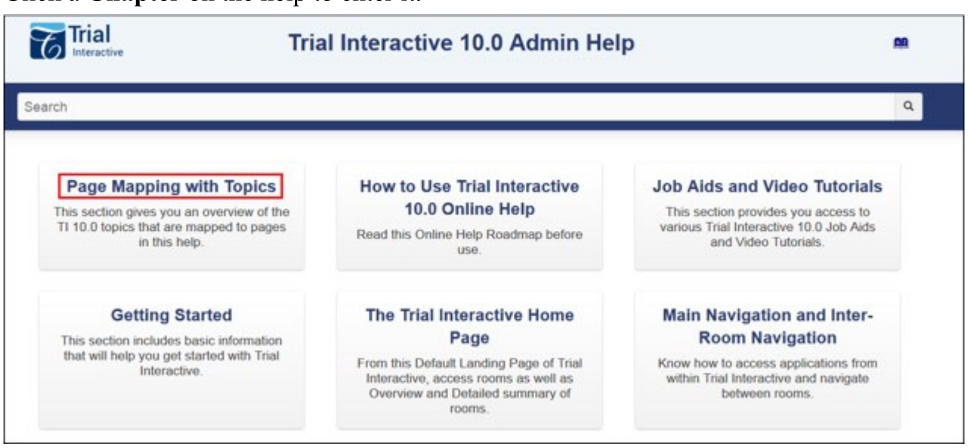
This Online Help is to assist users to understand and use the TransPerfect Trial Interactive 10.0 platform, which is used by Life Science Companies to conduct eTMF, Study Start-Up, licensing, due diligence, and clinical trial collaboration activities in a secure online environment. This help contains a descriptive overview of the Trial Interactive tool and step-by-step procedures of Trial Interactive functions.

About this Online Help

This online help works the same way as other online helps work. To find the content you are looking for, click the **Chapter** in the help or enter the search text in the **Search** field of the help.

On the Help Home Page

1. The **Home Page** displays the chapter name in large cards.
2. Click a **Chapter** on the help to enter it.



OR

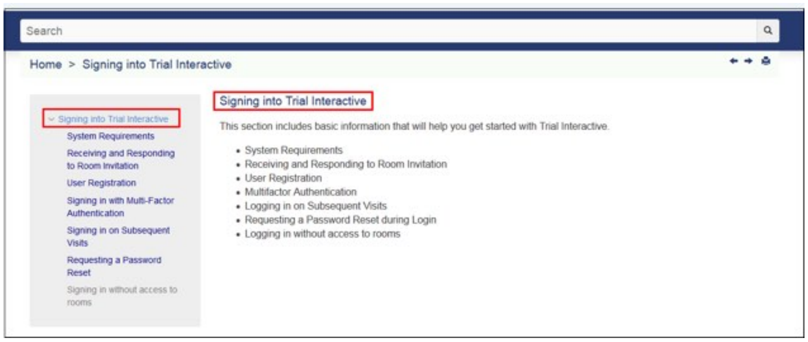
3. Enter a **keyword** in the **Search** textbox to find the topic.

Inside the Chapter

1. Choose a topic from the left panel.
2. To open a topic:

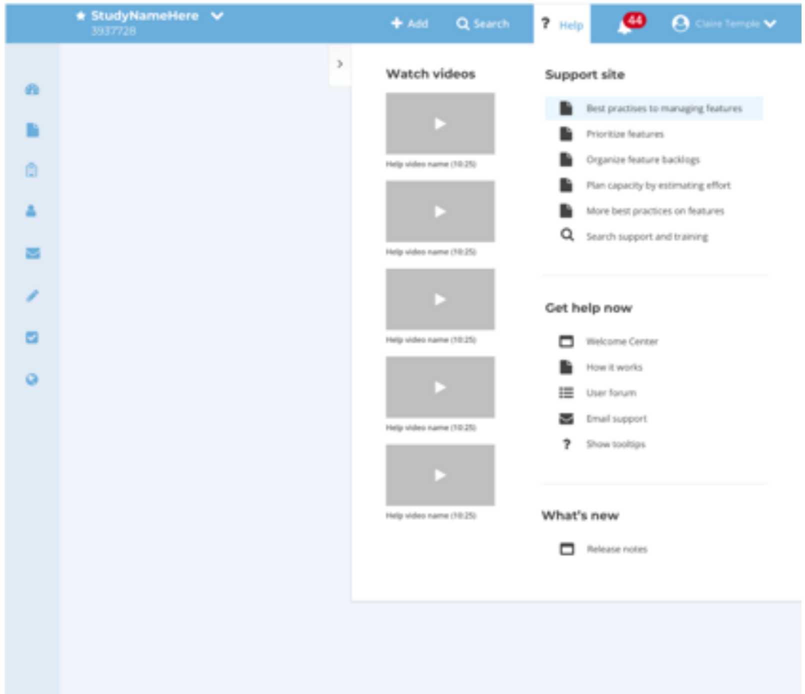
- Click next to the required topic or sub-topic to expand the hidden content or,
- Click the topic name to open the topic in the right pane.

3. Click the arrows on the menu bar to navigate to previous and next topic.
4. Click the **Home** link on the menu bar to navigate to the Home Page from the current page.
5. If the topic contains sections in it, they are displayed as links in the **On this page** panel located to the right of the page. Click a link to navigate to a section directly from the **On this page** panel.
6. Click on the menu bar to expand/collapse sections of the topic.
7. Click to print the current page of the help.
8. Click a screenshot to open the **full size view**.
9. Click the **Trial Interactive Logo** or the **Title** of the help to navigate to the Home page.
10. Click the on the top right corner of the help to navigate to the **Index** entries.
11. Inside the topic, the **Selected** topic appears in **Blue** on the left of the help as shown in the screenshot below:



Help

Through the Help link expect to get access to Training Videos, Online Help, Support Site, Latest releases besides many more.



Job Aids and Video Tutorials

This section provides you access to various Trial Interactive 10.0 Job Aids and Video Tutorials.

Click the respective links to access the **Job Aids** or **Video Tutorials** from the left panel of this help.

Job Aids

Click anyone of the links below to open a job aid in a separate tab:

- How to Manipulate Document Pages
- How To Do Page Manipulation
- How to Merge Documents
- How to Redact
- How to Remove Expired Documents on Dashboard
- How to Create Amendments
- How to Upload a Document
- How to Enable Document Publishing to eTMF
- How to respond to an Audit Finding
- How to Restore a Deleted Document
- How to Create an Ad hoc report
- How to use CRA TMF Reconciliation
- How to Run TMF Reconciliation Report
- Topics Mapping to Pages in Help

Video Tutorials

Important: *Right click on any of the links and click **Open Link in New Tab** to open the video in a new tab.*

Click anyone of the links below to play the Videos:

1. How to Audit as Regulatory Inspector
2. How to Modify the Index
3. How to View Reports

Signing into Trial Interactive

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

- System Requirements
- Receiving and Responding to Room Invitation
- User Registration
- Multifactor Authentication
- Logging in on Subsequent Visits
- Requesting a Password Reset during Login
- Logging in without access to rooms

System Requirements

Know the required browsers and operating systems to access Trial Interactive.

To get the best experience on Trial Interactive, make sure your web browser and operating system meet the recommendations mentioned below. You can upgrade to the latest browser version by using these links:

To access Trial Interactive you need to have the following:

Get access to Trial Inteactive on:	
General	Make sure you have: • Broadband Internet Access • A browser that supports encryption • Cookies enabled
Standard Supporting Browsers	Trial Interactive works on the following browsers: • Internet Explorer 10 and higher • Edge: Version 20 or later(officially supported by Microsoft only) • Chrome for Windows users • Firefox and ESR Releases for Windows users • OS X Safari for Mac Users

Required Operating Systems	**Windows® operating system:** • Windows 7 and higher **Macintosh® operating system** • Mac OSX releases
Client Software	Client Softwares required for Trial Interactive are: • For **Edit Online**: Microsoft Office 2010 SP1 or higher • Optional: Adobe Acrobat, Adobe Standard, or Professional Version 8 or higher along with the PDF Viewer • For SAS Datasets: SAS Viewer or compatible. The free version is available on: https://support.sas.com/downloads/browse.htm?fil=&cat=74
Optional Add-Ons (Separate License)	Besides the above softwares, make sure you also have: • DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Version) • Adobe Sign (Latest Document Cloud Version)

If Trial Interactive 10.0 is accessed through any of the unsupported browsers, or operating systems mentioned above, a message is shown.

With Trial Interactive 10.0, a user will be logged out if the user is logged on multiple sessions in different browsers at the same time.

Note: *To enable multiple sessions at the same time, the administrator needs to enable it for you while inviting a user to room.*

Receiving and Responding to 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.

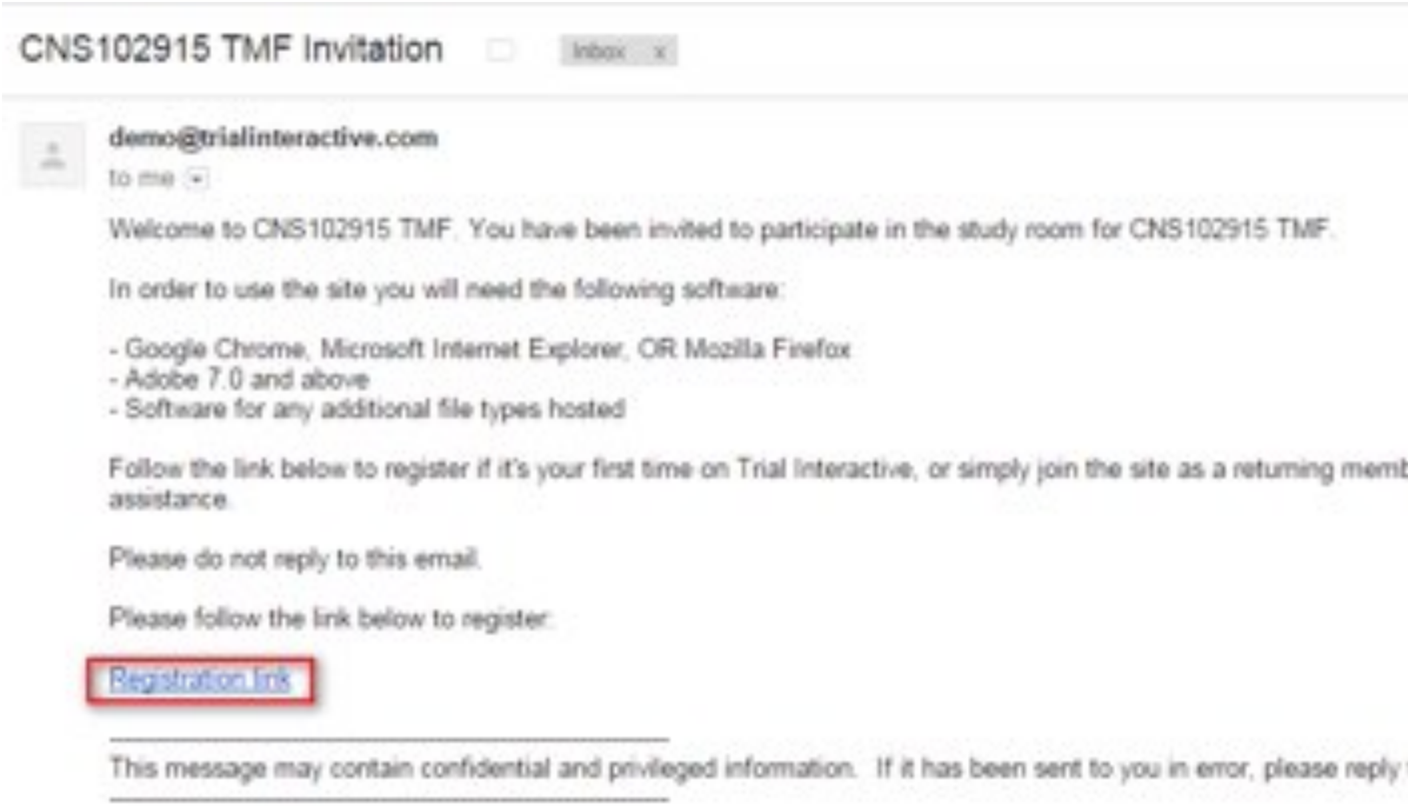


Figure 1: Room Invitation Email

Click **Registration link** near the bottom of the message, and you are directed to the Trial Interactive user account registration page. Follow on to User Registration page for the complete process.

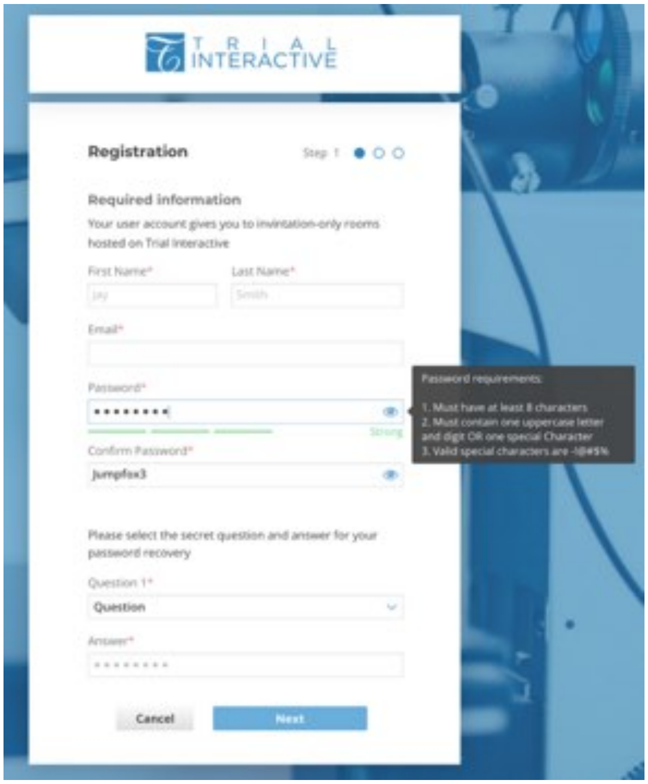
User Registration

Important:

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

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

Step 1: Registration - Required Information



1. Click the Registration link near the bottom of the message, and you are directed to the Trial Interactive user account registration page.
2. Type in your first name, your last name, and your email address as requested on the page in the appropriate fields.
3. Create your secure password, and confirm the password by re-typing it in the **Confirm password** field.

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

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

Step 2: Registration - Optional Information

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

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

Step 3: Registration - Custom Information

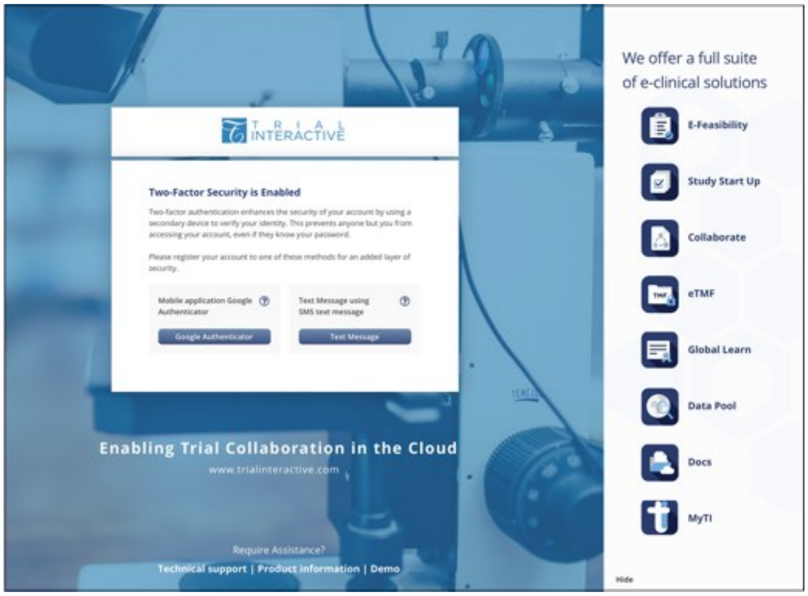
Enter your contact email ids. You may want to click **Previous** to go back and verify the information entered or click **Register** to be taken to a confirmation page.

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

Signing in with Multi-Factor Authentication

Note: *Users are prompted to authenticate the login credentials using the Multi Factor Authentication only if it is enabled for them in a room.*

After you have registered to TI and proceeded to login the first time, you will be lead to the **Setup Multi-Factor Authentication** page if your system is enabled for Multi-Factor authentication using **Google Authenticator** and **Text Message (SMS)**.

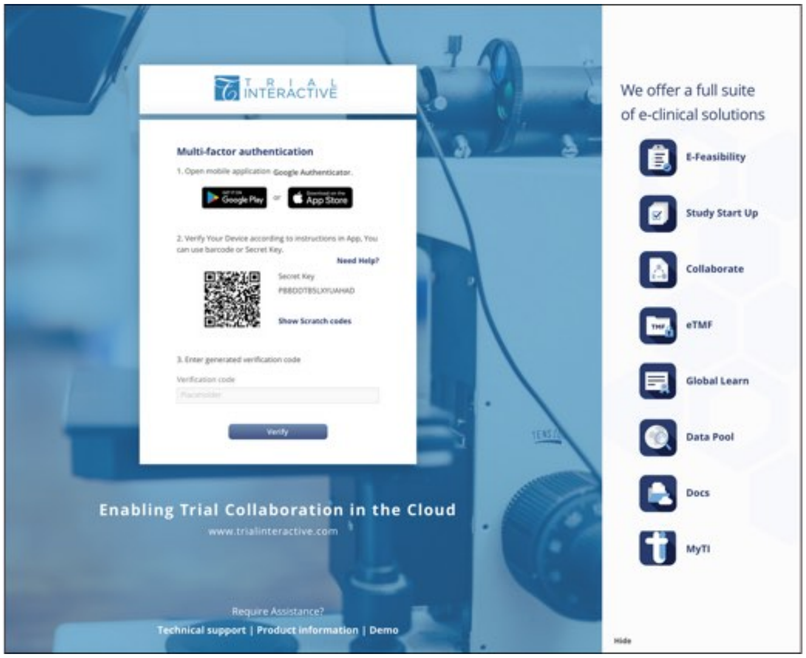


The user can choose to either login using **Google Authenticator** by scanning the bar code on the computer or use **Text Message (SMS)** functionality for login in. Each of these functionalities are discussed in detail in the sections below:

Signing in using Google Authenticator

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. Select the method **Google Authenticator** from the **Two Factor Security**.
2. The **Multifactor Authentication using the Google Authenticator** page opens.
3. From Google Play Store or App Store on your mobile device, install **Google Authenticator**.
4. 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 below:

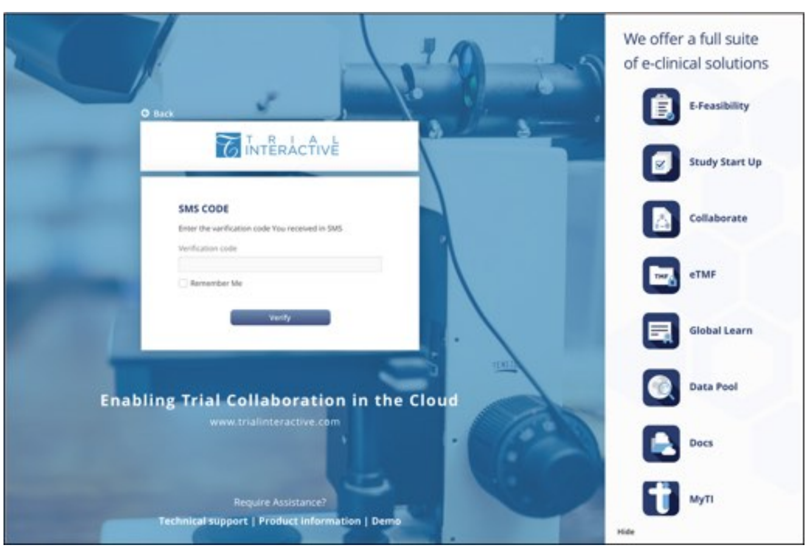


5. The above step will generate a **verification code** on your mobile device.
6. Enter the verification code on the **Setup Multi-Factor Authentication** page on your computer. Click **Verify**.
7. You will now be logged in.
8. When you log in for a Subsequent Visit, you will only be asked for the verification code generated by Google Authenticator after you have entered your login credentials.

Signing in using Text Message (SMS)

Follow the steps below to login using text message:

1. On selecting the **Text Message** method from the Two Factor Security page, you will be asked to enter your **phone number** .
2. Enter the phone number and click **Save**.
3. The **SMS Code** is then sent to your registered mobile number.
4. Enter the **SMS Code** received in your mobile device on the computer screen. Click **Verify**. Refer to the screenshot below:



5. You will now be logged in.

6. When you log in for a Subsequent Visit, you will only be asked for the **SMS Code** which is received in your mobile device after you have entered your login credentials.

Signing in on Subsequent Visits

To log in to Trial Interactive

1. Using your preferred internet browser, navigate to http://www.trialinteractive.com
2. Click the **Client Login** button located at the top right corner of the page
3. The Trial Interactive Login page with links to a suite of e-clinical solutions offered by TransPerfect Life Sciences appears.

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

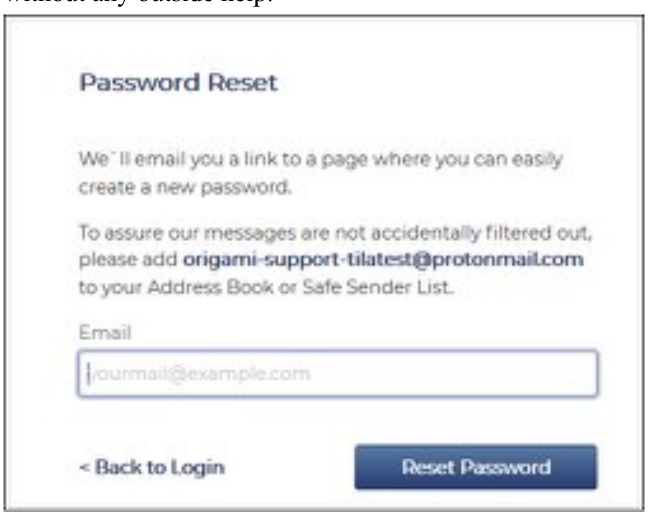
   If you are logging in the first time, the Trial Interactive Homepage for the account associated with the login username appears, else you are redirected to the same location in the application that you were in upon a subsequent login.

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

Requesting a Password Reset

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.

Signing 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.

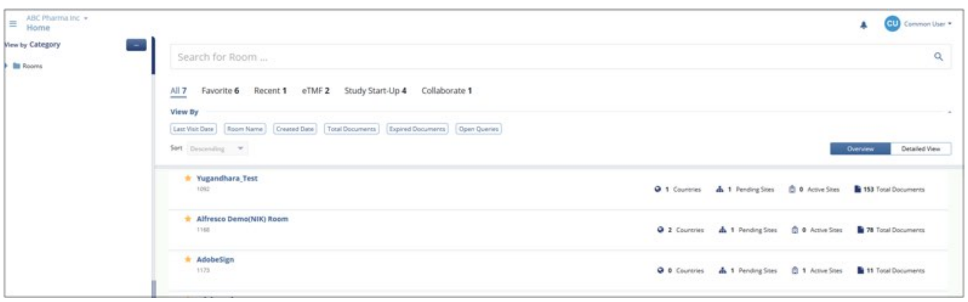
Click the **Logout** button to redirect to the standard login page.

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

The Trial Interactive Home Page

From this Default Landing Page of Trial Interactive, access rooms as well as Overview and Detailed summary of rooms.

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



Click the required Room Name to enter a room.

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

You can do the following from the Trial Interactive 10.0 Home Page:

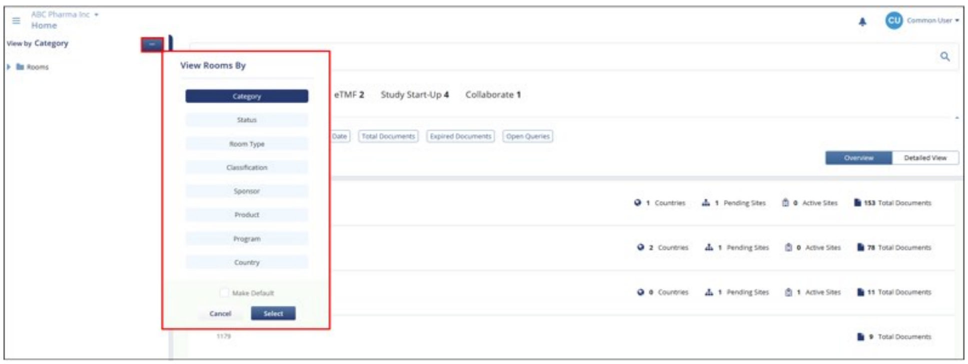
1. View Rooms
2. Search for Studies, Sponsors, and Sites across all rooms
3. Cross Study Document Search
4. Get a Summarized Overview of rooms
5. Get a Detailed View of rooms
6. Filter and Sort Rooms
7. View and Mark favorite rooms

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

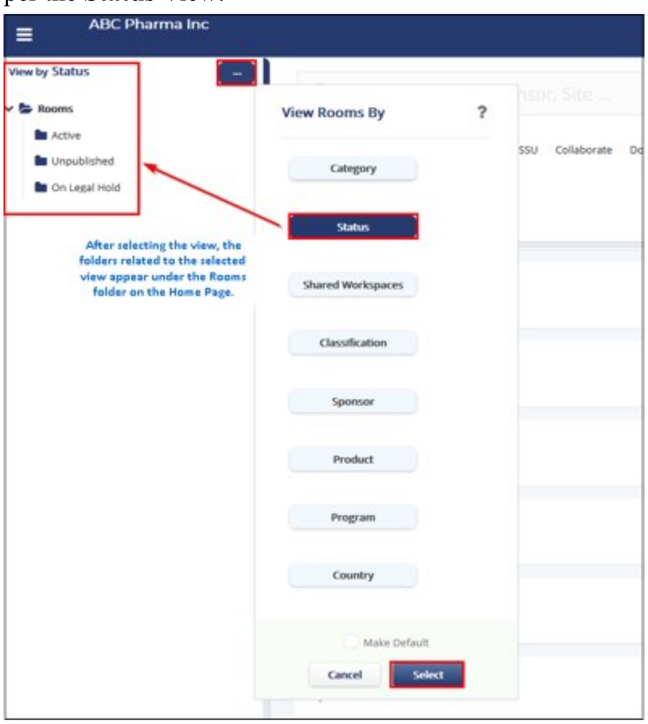
Room Views

TI Home page provides you with the different views through which you can filter rooms.

Click the  icon next to the **View By** from the left of the page as shown in the screenshot below:



Click the required view from the **View Rooms By** popup and then click **Select** to filter and view the rooms on the home page. When you select the **view** form the **View Rooms By** popup, the folders related to the selected view display under the **Rooms** folder in the **View Selector** pane. The screenshot below show an example for the rooms as per the **Status** View:

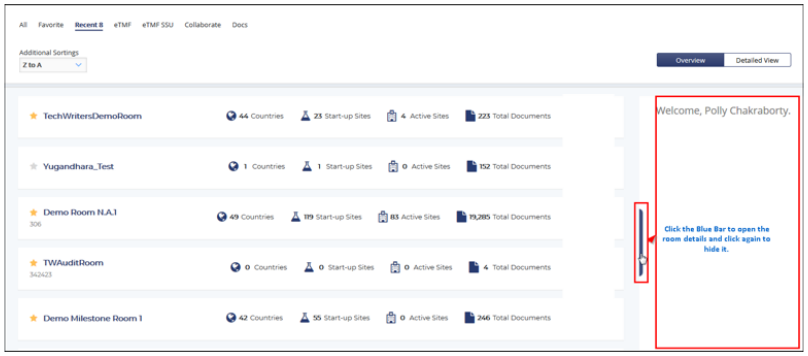


Click the required folder in the Index to view the list of rooms in the **right pane** below the filters. If there is a huge list of rooms in the right pane, you can further apply TI Home Page Filters and Sortings to view and access the required room.

Alternatively, you can also search rooms by entering a room name in the Search text box located at the top of the TI Home Page. The results displays below if the search criteria is met.

Viewing Room Details

You can also view the details of the room and the related information by clicking the **Blue Bar** to the extreme right of the home page. Refer to the screenshot below:



Besides TI Home Page, the Room Details can be also viewed from the User Menu after entering a room.

Note: *This panel of Room Details is static and can be viewed irrespective of the view selected of the rooms.*

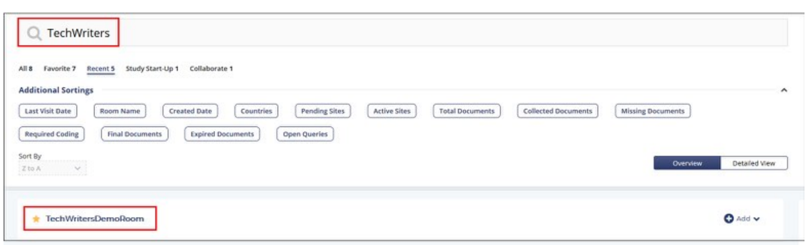
Room Search and Accessing a Trial Interactive Room

Room Search

Trial Interactive allows you to search for rooms easily in cases you have access to hundreds of rooms.

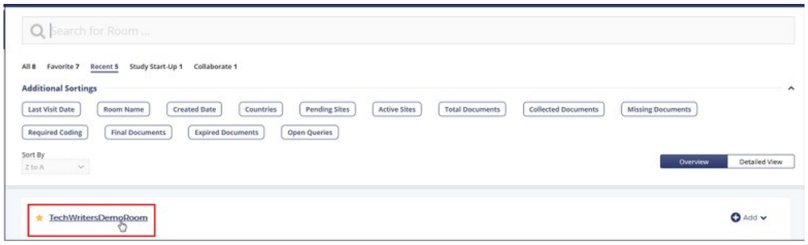
To perform a room search:

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



Accessing a Trial Interactive Room

Click on the required room name in the panel below the blue line to enter the room. Refer to the screenshot below:



Cross Study Document Search

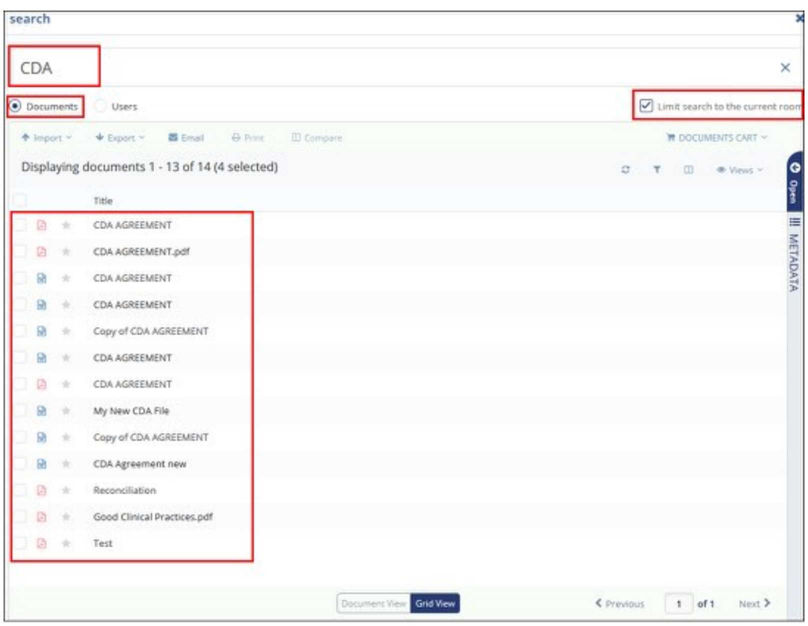
Documents Search

To search for users, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
2. The **Search** window appears which consists of the following sections:
    a. The **Search** textbox.
    b. The **Documents** and **Users** radio buttons.
    c. The **Limit search to the current room** checkbox.
3. Select the **Documents** radio button. The documents grid appears below.

    Note: *If you select the **Limit search to the current room** checkbox, the search results display corresponding to the current room*

4. Enter the **Document Name** in the **Search** field and the corresponding results display in the grid below. Refer to the screenshot below:

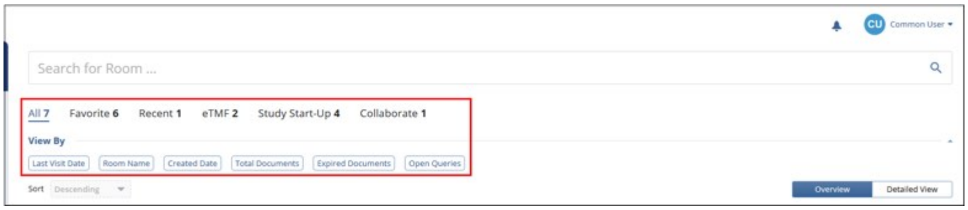


You can perform the following action from the Search Window:

1. Code the document
2. Import and Export the document
3. Email document
4. Compare documents

TI Home Page Filters

TI Home Page provides variety of filters through which you can filter the rooms. Refer to the screenshot below:



The filters consists of the following main filters:

1. **All:** This link displays all rooms that you have access to.
2. **Favorite:**This link displays the list of all rooms that you have marked favorite.
3. **Recent**: This link displays the list of room that have been visited recently with the latest visited room at the top.
4. **Study Start-Up**: This link displays all Study Start-Up rooms.
5. **Collaborate**: This link displays the list of all TI Collaborate rooms.

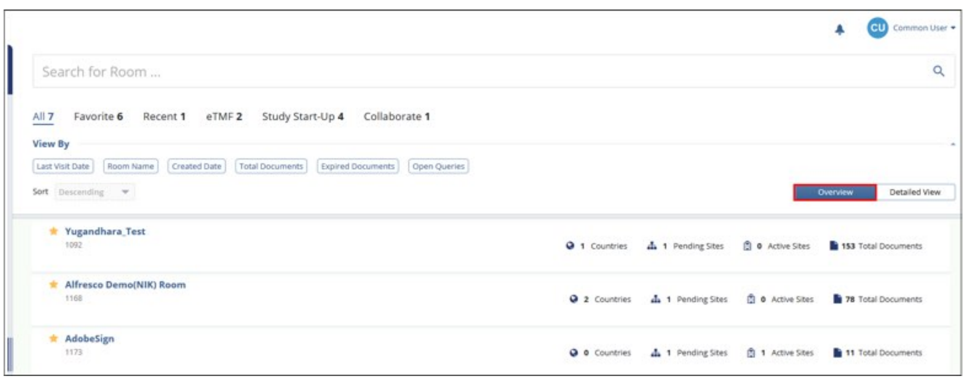
Below these main filters, TI Home Page provides **Additional Sortings** which allows you to sort the room as per the options in the sortings. *These Additional Sortings varies with every main filter.*

Summarized (Overview) View of Rooms

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

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

Refer to the screenshot below:



Countries

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

Active Sites

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

Study Start-Up Sites

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

Total Documents

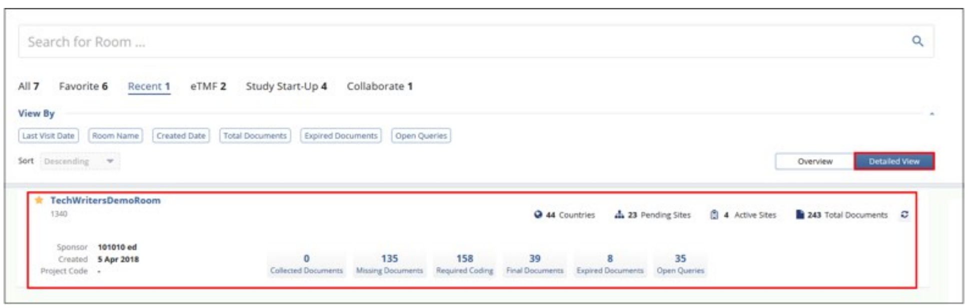
The number next to **Total Documents** link shows the **total count** of documents pertaining to a room.

Detailed View of Rooms

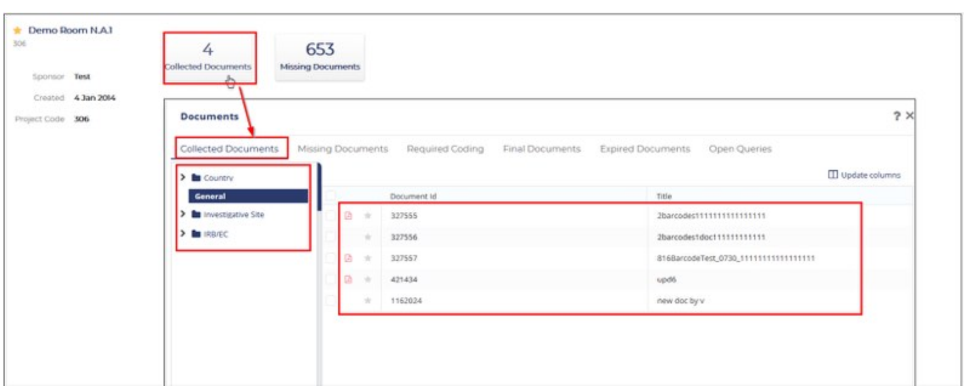
From the Home Page, click the **Detailed** button located at the top right corner of the page to view rooms and studies as large cards with the following information:

1. Open Queries
2. Collected Documents
3. Missing Documents
4. Expired or Expiring Documents
5. Require Coding
6. Quality Control 1
7. Quality Control 2
8. Final Documents
9. Rejected Documents

Refer to the screenshot below:

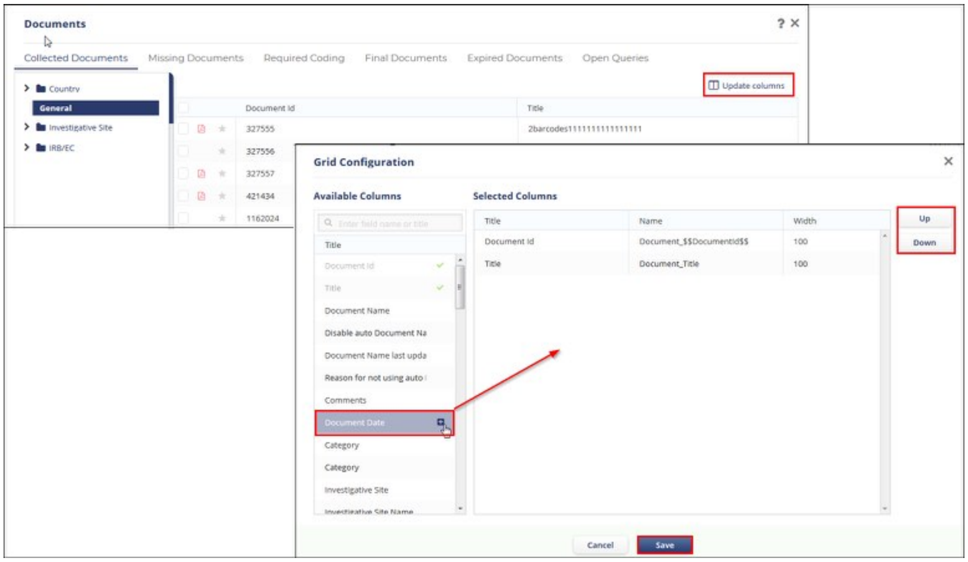


Click the required tab next to the room name. The **Document** window opens which display the list of documents. The screenshot below show an example for the expanded view of the **Collected Documents** tab which displays the list of documents:



You can drill down the folders in the Index on the left to locate the required document.

Besides, you can also configure the columns in the **Document** window as required by clicking the **Update Columns** link at the top right corner of the window. Refer to the screenshot below:



Clicking the **Update Columns** link opens the **Grid Configuration** window which allows you to configure the columns in the document grid. You can add and delete the columns to display for a document in the **Document Grid** as required.

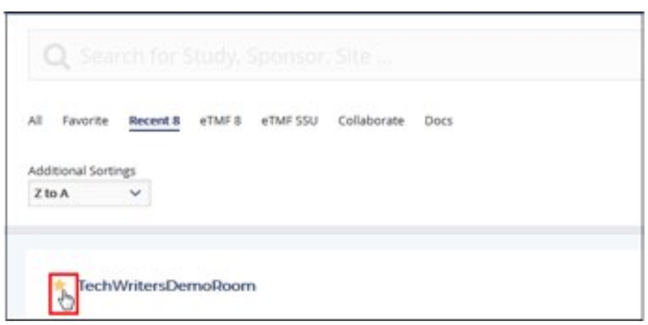
You can also **change the order** of the columns in the Selected Columns section by clicking the **Up** and **Down** buttons located to the right of the Selected Columns.

Similarly, you can view the list of documents for **Missing Documents**, **documents that require coding**, **Final Documents**, **Expired Documents** and **Open Queries**.

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.

1. From the Home Page by clicking the star which changes its colour to **golden** on selection to the left of the room name. Refer to the screenshot below:

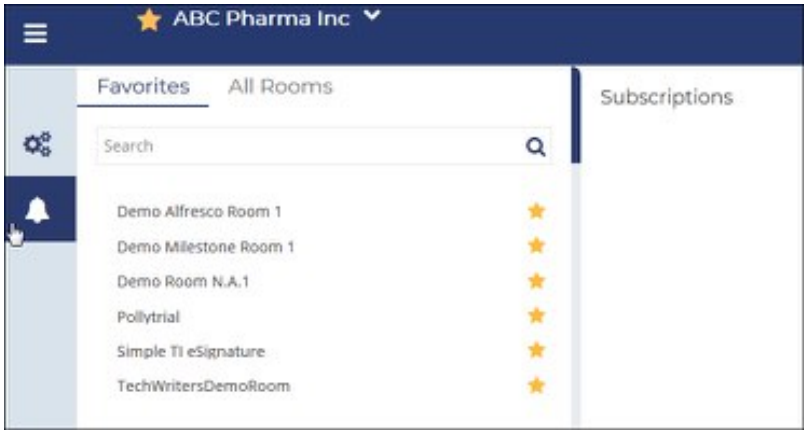


2. On entering a study room, you can add it to **Favorites** by clicking the star at the top left corner of the page where the room name is displayed. The room can easily be removed from the list by clicking the star again. Refer to the screenshot below:

The list of all rooms to which you are assigned is also available through the User Profile.

a. Navigate to **My Profile Settings** from the User menu.
b. Select **Notifications** from the menu on the left.

c. Click the golden star to the right of the room names to mark the selected rooms as **Favorites**.



Main Navigation and Inter-Room Navigation

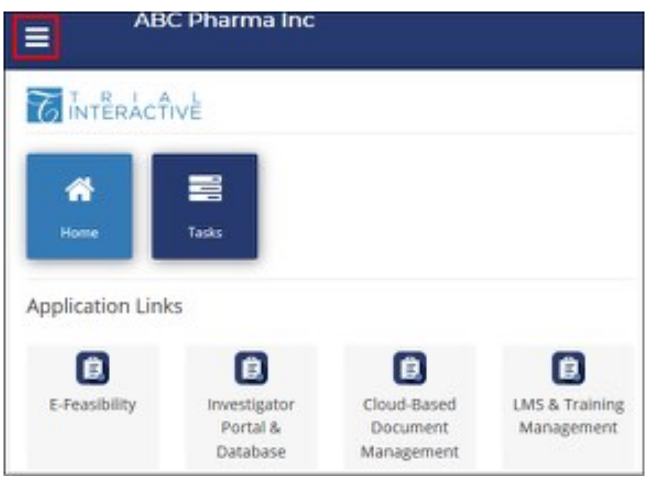
Know how to access applications from within Trial Interactive and navigate between rooms.

From here find more details on the following:

1. Main Navigation from Home Page
2. Main Navigation from Within a Room
3. Navigating between Rooms

Main Navigation from Home Page

Main Navigation from the Home Page can be accessed by clicking the **three lines** located at the top left corner of the page. Refer to the screenshot below:

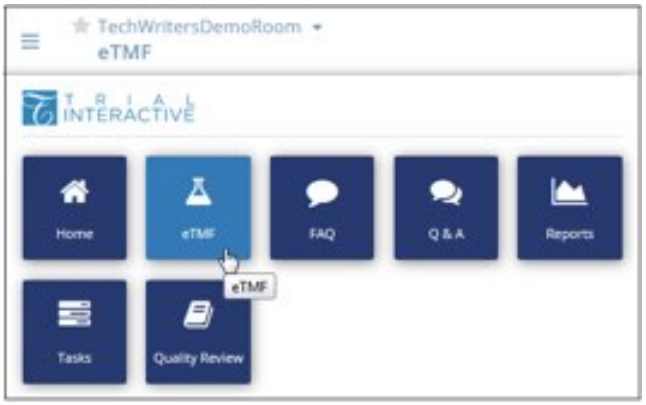


You can access the **Home Page** and **Tasks** application from the Main Navigation. Besides applications, you can also access other **Application Links** from the Main Navigation of the Home Page. These application links takes you to the website of the respective links.

Main Navigation from within a Room

On **entering a room** from the Home Page, you are landed on the **eTMF/Documents** Module.

In a room, as a user of Trial Interactive, you can choose which application to view in a dashboard by clicking the **three lines** located at the extreme top left corner of the page. Refer to the screenshot below:



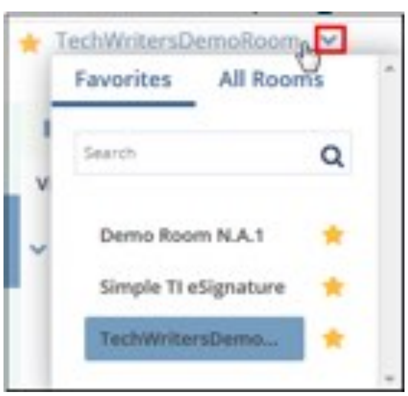
The different modules that can be viewed from a particular Main Module depend on the functionality that can be allowed from the particular Main module. Within Trial Interactive, you can view the following Main Modules:

1. Home
2. Tasks
3. Trial Interactive eTMF and Documents Module
4. Quality Control
5. Start-Up
6. Audit/Quality Review
7. Communications
8. Q&A
9. FAQ
10. Reports
11. TI Collaborate

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



User Menu

This is the popup you access on clicking the User Avatar.

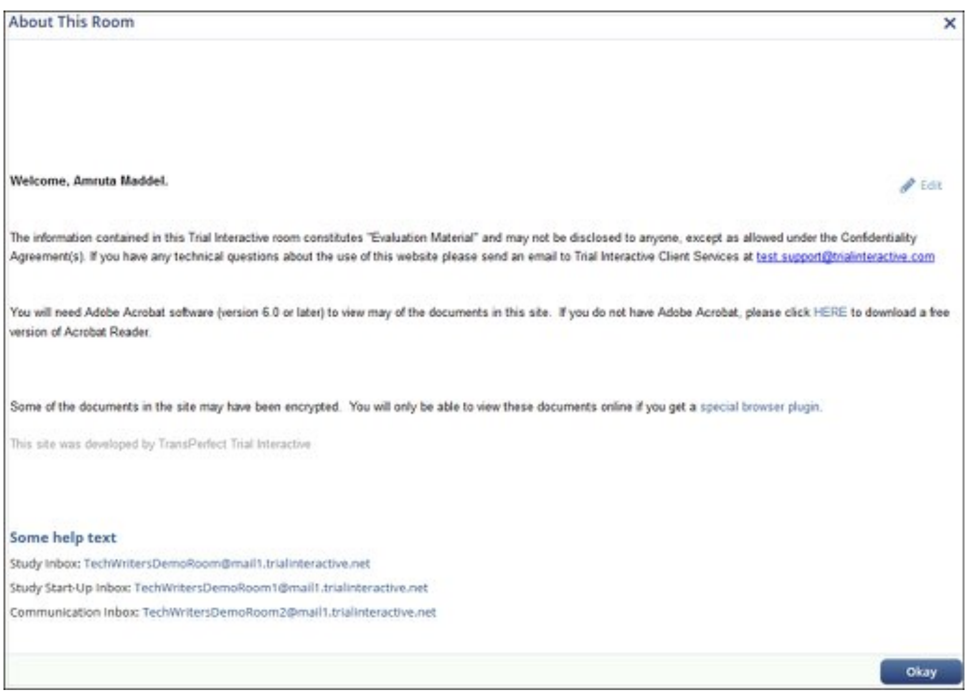
Through the User Menu located at the top right corner you can access the following:

1. My Profile Settings
2. About This Room
3. Language Settings
4. Help (Contact Support)
5. Guide
6. Notifications
7. Logout

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

About This Room

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



The standard Welcome message offers the following links.

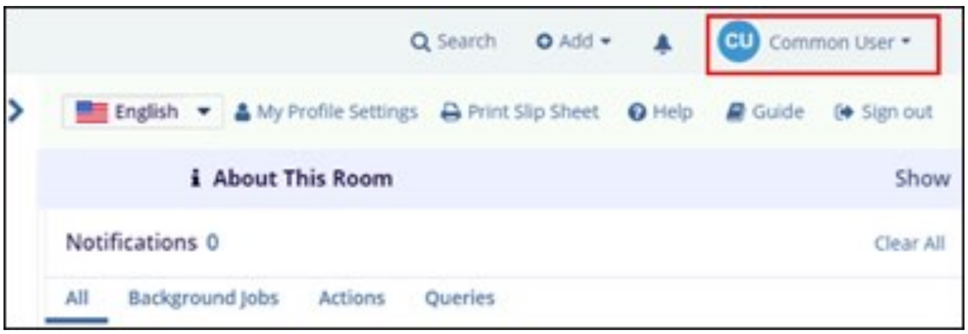
- Link to help desk email. Use this email address when you have technical issues with the Trial Interactive tool.
- Link to Adobe Acrobat download site. You need an up-to-date document viewer to view documents.
- Link to special browser plug-ins so that you can view encrypted documents.
- Click the ‘x’ to dismiss the popup.

You can click the **Edit** icon at the top right corner 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.

User Menu - Help

In a scenario where you need any help related to Trial Interactive, you can contact the help desk by clciking the **Help** from the User Menu.

Clicking **Help** opens the **Contact Support** email window to allow you to enter the details for the request needed and send it to the help desk. Refer to the screenshot below:

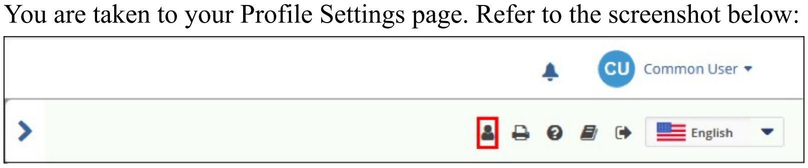


My Profile Settings

From here you can manage your profile and other profile activities.

To access **My Profile Settings**:

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



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

a. My Profile Main Section
b. My Profile Notifications Section.

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

My Profile Main Section

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

From here you can access the following:

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

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

General Information - Time Zone

To set the time zone applicable to you:

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

General Information - Language

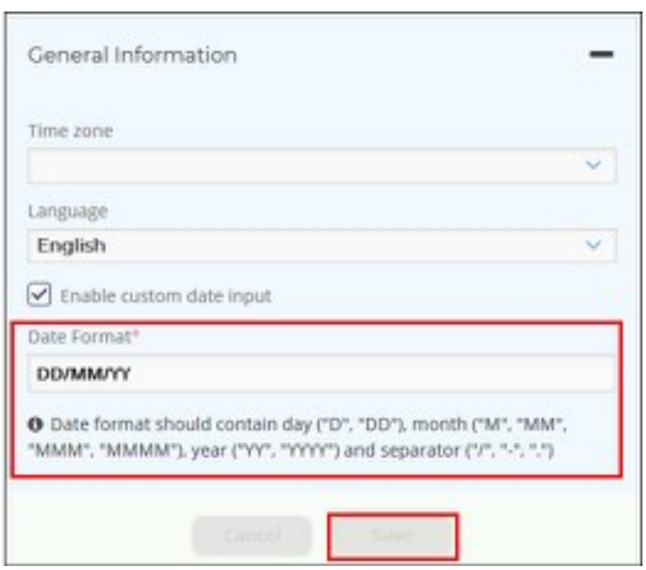
To set your preferred language:

1. Click the **Language dropdown.**
2. Scroll down to locate your preferred language.
3. Click the language to select it.
4. The selected language displays in the box.
5. A popup confirming the same appears. Click '**x**' on the popup to dismiss it.
6. Click **Save**.

General Information - Enable Custom Date Input

With the Trial Interactive 10.0 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.

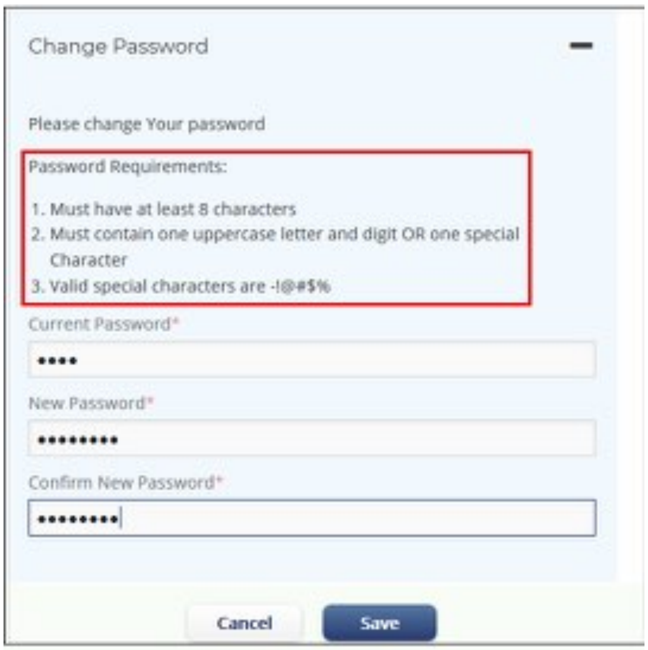
Change Password

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

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

To set the password:

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



Password Recovery - Secret Questions

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

To set the secret questions and their answers:

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

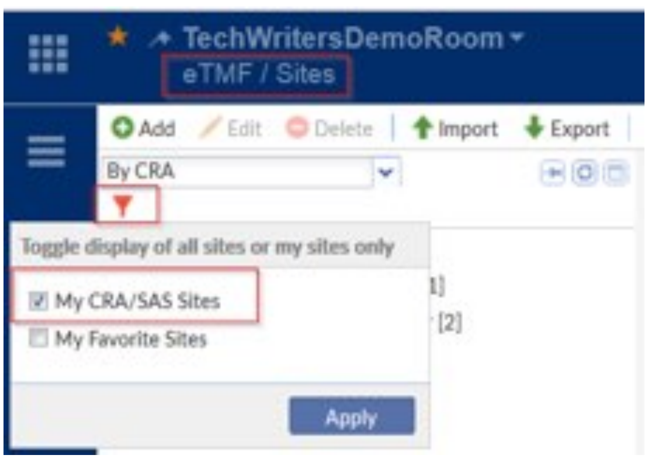
User Avatar

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

Sites Filtering Options

You can choose to view only those sites where you are the CRA or only SAS Sites from the Sites sub-module or in the SSU application in Trial Interactive by **ticking this checkbox** and **Saving** the changes. Refer to the screenshot below:

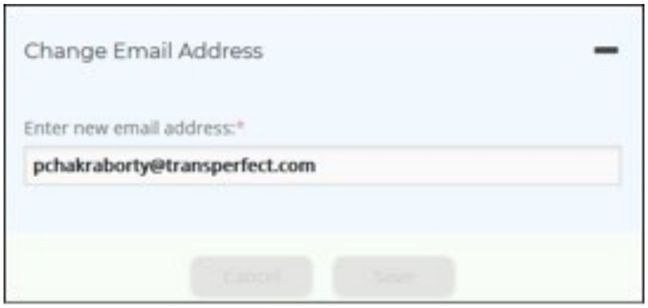
On selecting this option, the toggle in the Sites sub-module appears in red color and the option 'My CRA/SAS Sites' are ticked by default. Refer to the screenshot below:



Change Email Address

This will change the email address of the user. Enter your new email address and click **Save**.

You will now be able to send and receive emails to and receive from the newly inserted email id. Refer to the screenshot below:



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

Default Context Configuration

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

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

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. Refer to the screenshot below:

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

Besides, you can also mark rooms **favorite** from here.

Important:

*The availability of the notification option is determined by the client-appointed Administrator in each room. Some notifications may not be enabled and appear greyed out to the user. For example, workflow notifications may not be available to users with Editor access.*2019

Language Settings

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

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

Notifications

Through **Notifications** panel, located below the **About This Room** dashlet, 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.

The right panel of this section displays the following tabs:

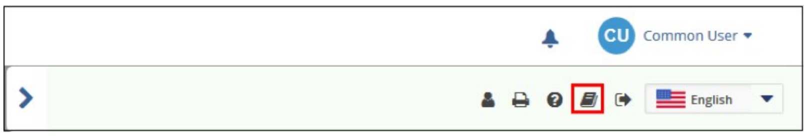
- **Tasks:** Click this tab to get a list of all the tasks that are ongoing, pending, or are overdue. This is a shortcut that provides you an overview of all the tasks in your current room. You no longer need to visit the Tasks module for the details and can access them directly here.

- **Queries:** Click this tab to get a list of all the queries pending for action. You can click any individual query link to lead you to the Queries sub-module for you to initiate your actions on it.
- **Background Jobs:** Through this tab you are notified about a background job that is executing or are completed.
- **Actions:** Click this tab to view messages and results of various jobs that you perform in your Trial Interactive room. Some messages like downloading/mass coding documents provide the **Get Job Result** button that you click to get further details on the action like a message or a downloadable zip.

The left panel of this section displays the **Courses** that you are required to complete and those that you have completed and certified for.

Guide

Click the **Book** icon from the User Menu to open the help. The Reader Help opens in the new tab of the browser. Refer to the screenshot below:



Signout

Click **Sign out** to end your current session to come out of the application.

Trial Interactive eTMF and the Documents Module

Know more about the Trial Interactive eTMF Application and eTMF Documents from here.

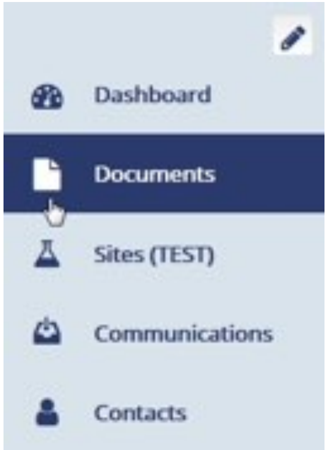
The Trial Interactive eTMF Application acts as a central access point to not only Clinical Trial Documents but also to eTMF Sites, Contacts, eTMF Completeness and CRA Reconciliation Reports, reports in the form of **Dashlets** for all clinical trial activities, and also to IRB Integration and Potential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

You can access this module from the Main Navigation. Refer to the screenshot below.

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

1. Dashboard Dashlet View
2. Documents View
3. Sites View etc.

from the menu bar on the left. Refer to the screenshot below:



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

Dashboard Dashlets

Know how to configure dashboard and dashlets in a room.

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

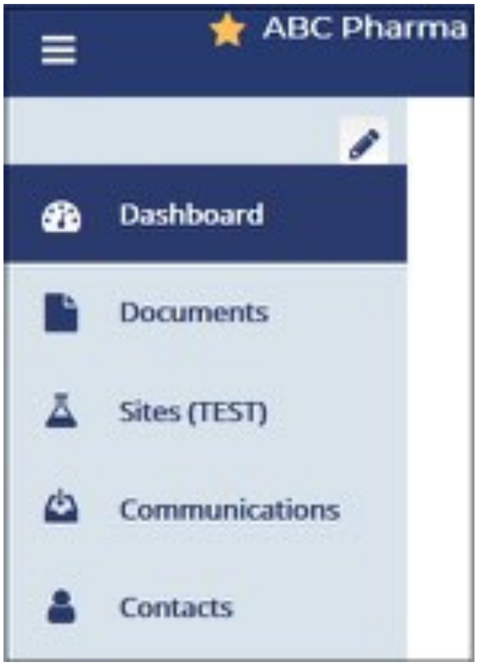
Individual users in Trial Interactive have the option to arraneg their own Dashboard views.

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.

Dashlets

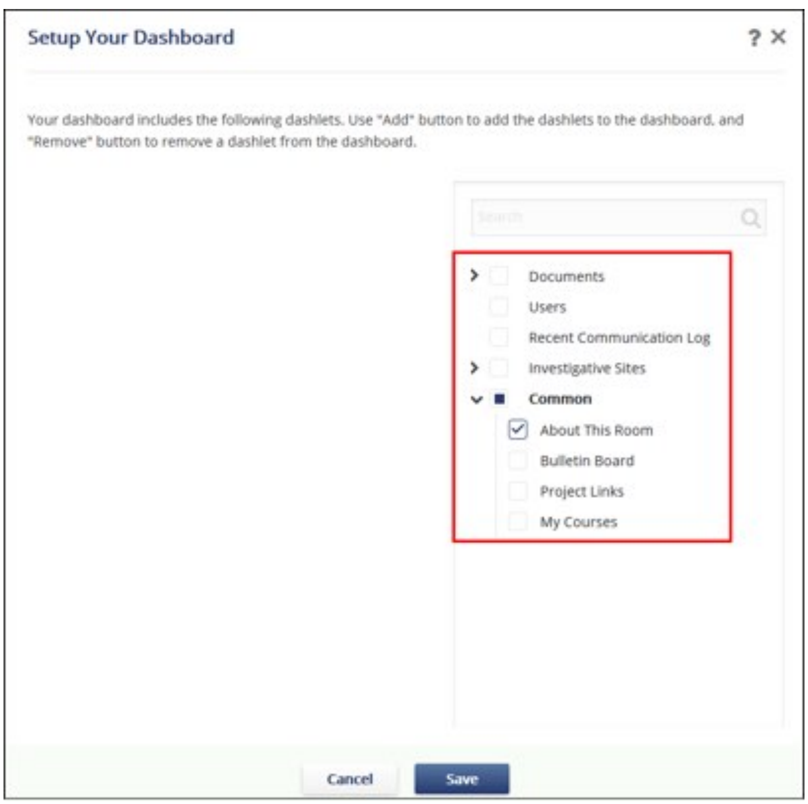
A dashlet is a component in a dashboard with functionalities of its own. A dashlet may provide information on a particular feature in the form of a report, a graph or a description on a particular topic. Dashlets are independent of each other and are contained in a dashboard. In a way of its own, they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

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

Configure Dashboard

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

Refer to the screenshot below:



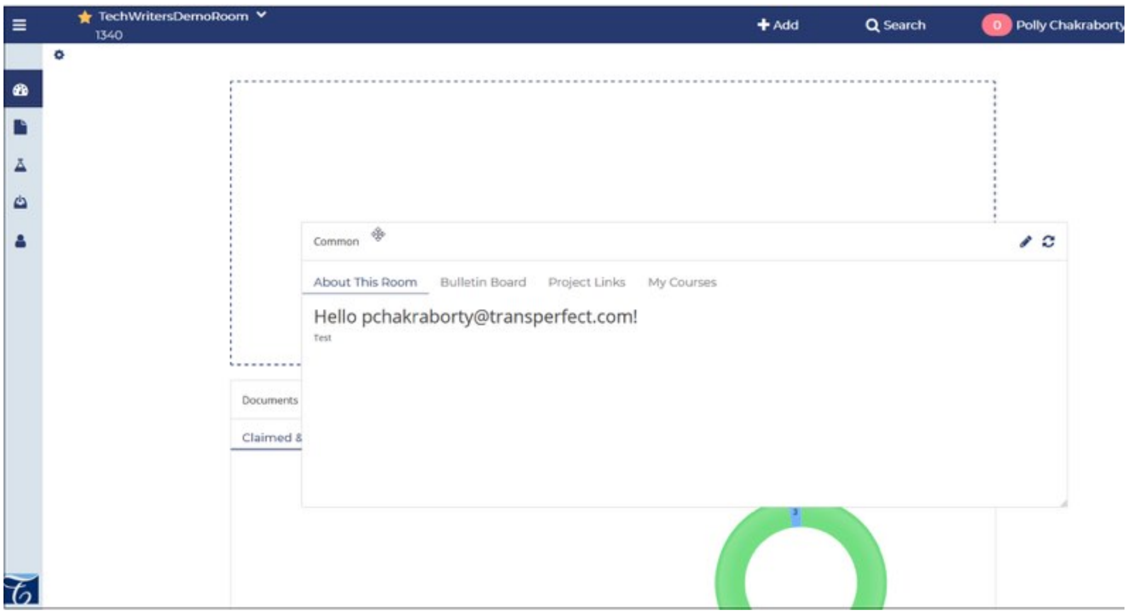
The dashboard is divided into the following parent dashlets which have child dashlets associated with each of them:

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

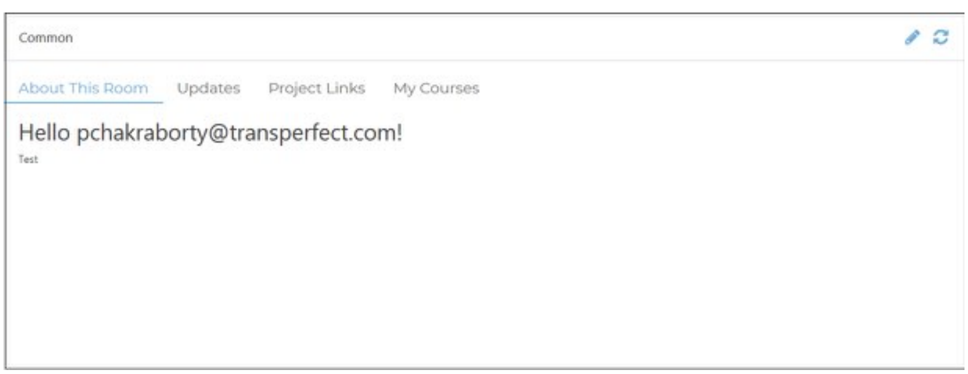
   Click the arrow next to the required parent dashlets to revel the child dashlets to add them the dashboard as shown in the screenshot above. On selecting the dashlets, click **Save** and the dashlets appear on the dashboard.

Laying Dashlets in your dashboard

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



Dashlet - Common



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

The following tabs are available in the dashlets:

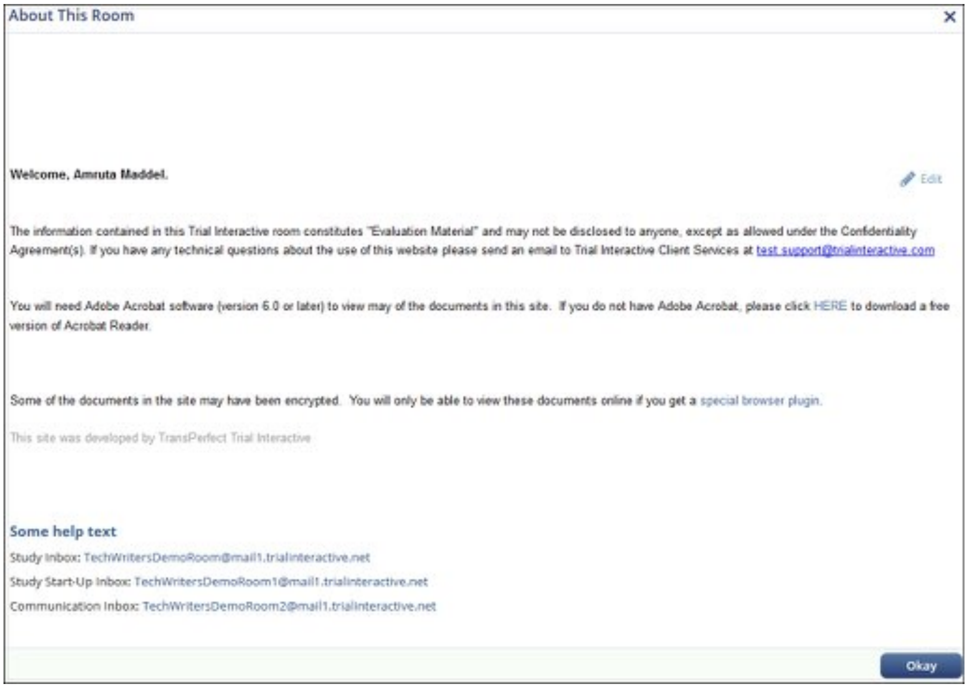
1. About The Room
2. Updates

3. Project Links
4. My Courses

Each of these are discussed in the seperate topics. Click the topics on the left to open the topic.

About This Room

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



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.
- Click the 'x' to dismiss the popup.

You can click the **Edit** icon at the top right corner 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.

Dashlet Common - Bulletin Board

Dashlet Common - Project Links

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

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

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

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

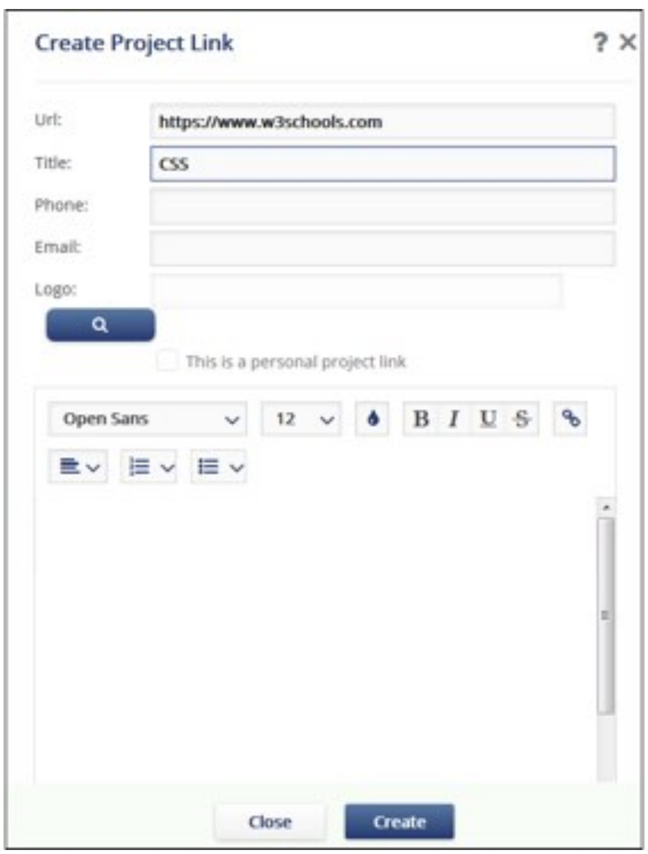
Each of these activities are discussed in the sections below:

Adding a new link

To add a new link:

1. Click the **Create** 

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



Editing a link

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

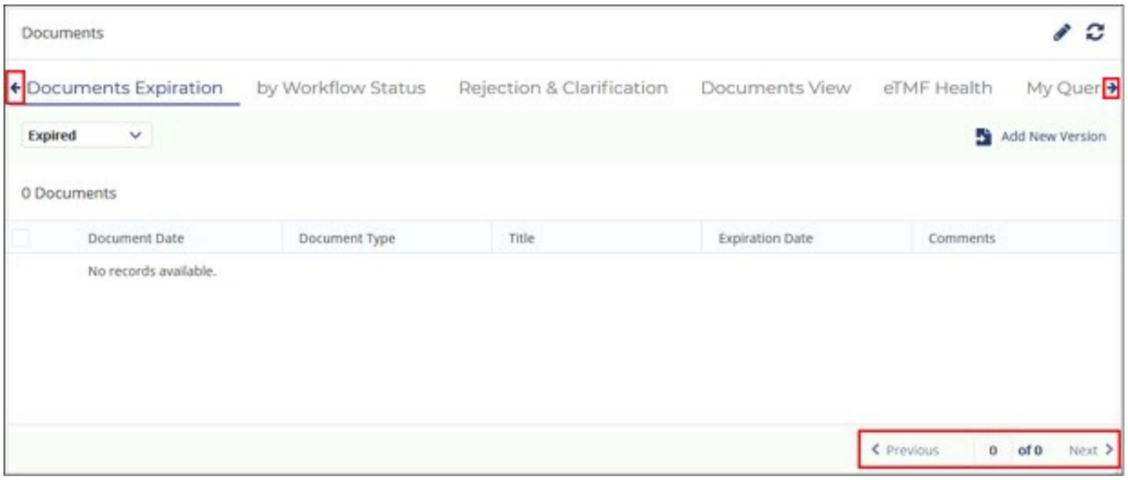
Deleting a link

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

Dashlet Common - My courses

Dashlet - Documents

The Documents Dashlet gives an overview of the all documents and their related activites in a room. Refer to the screenshot below:



The dashlet provides the **Right** and **Left** arrows to the extremes of the dashlet to allow you to navigate to the sub-dashlets dashlets contained in the Document Dashlet.

Besides, for every dashlet of the Doucments Dashlets, you can also use the **Previous** and **Next** arrows to move among the documents in the dashlet as shown in the screenshot above.

The Documents Dashlet contains the following tabs related to documents:

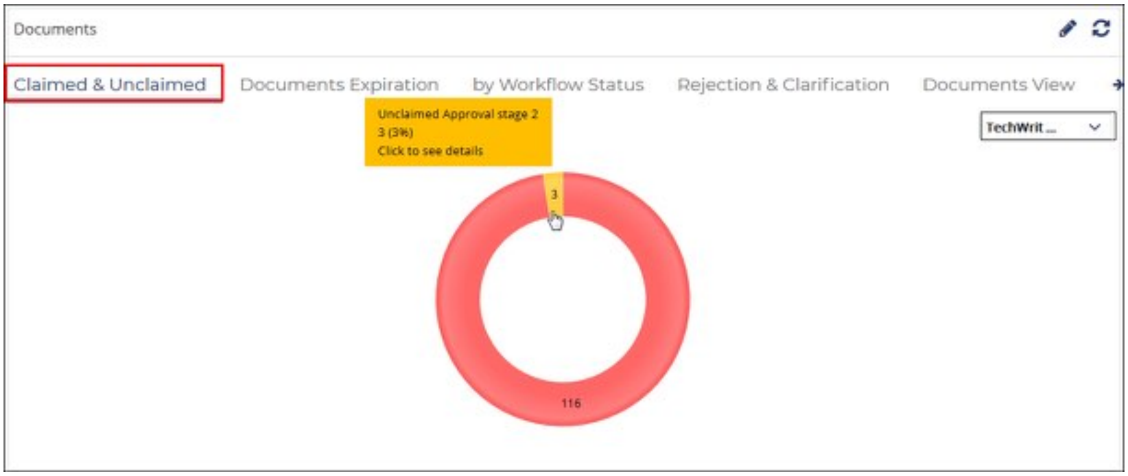
1. Claimed & Unclaimed
2. Documents Expiration
3. By Workflow Status
4. Rejection and Clarification
5. Documents View
6. eTMF Health
7. My Queries
8. Documents Submissions
9. Open Queries by Age
10. Popular Documents
11. Pending Documents Review
12. Unread
13. My Favorite Documents
14. Milestones Timeline
15. Milestone Type Report
16. Tasks

Each of these are discussed in the seperate topics. Select the topic from the left pane to open it.

Dashlet - Claimed & Unclaimed

The **Claimed vs. Unclaimed Documents** dashlet provides a count of all documents that are in a workflow and are either **claimed**, **unclaimed**, or **in progress**. You can further click on each slice of the interactive donut chart to obtain further detailed information.

The dashlet also provides the dropdown to select the workflow as required and dispay the Donut Chart as per the selected workflow. Refer to the screenshot below:

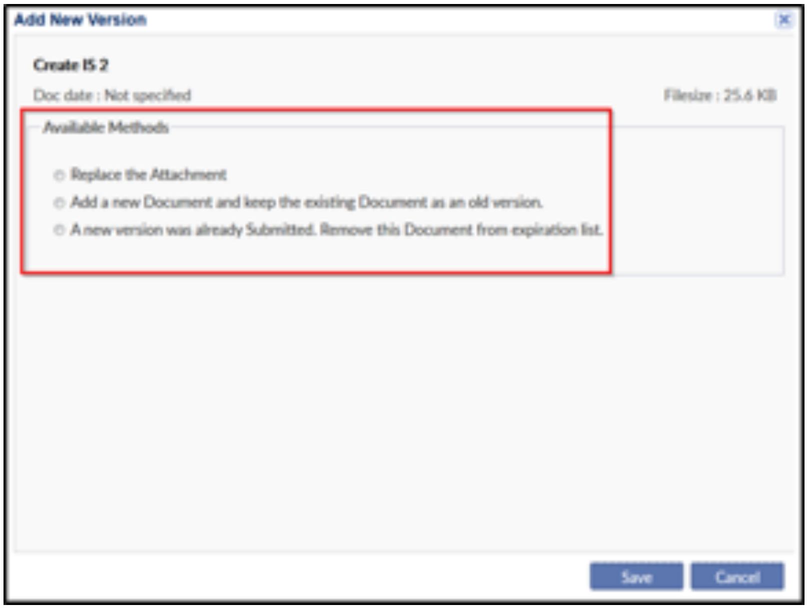


Dashlet - Documents Expiration

The **Documents Expiration** dashlet lists the **expiring** and **expired** documents as specified in the expiration period (N). The dashlet has two views that can be selected through an **Expired** dropdown. To set the views click the **Expired** dropdown located on the top left corner. Refer to the screenshot below:

Click the **Add New Version** button from the top right corner of the dashlet to replace a document.

This opens the **Add New Version window** which provides the available methods to replace an attachment, or 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:

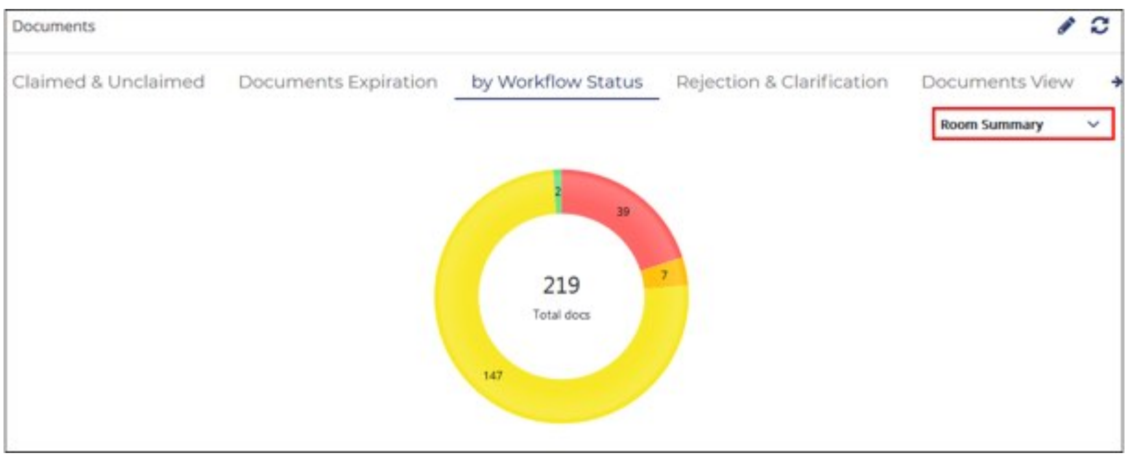


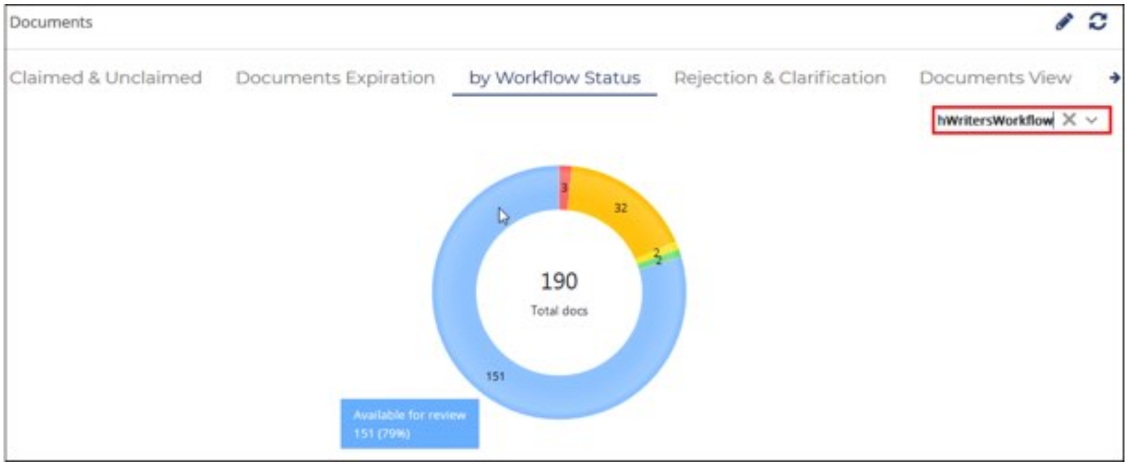
Dashlet - Documents by Workflow Status

The **Documents by Workflow Status** dashlet displays the document processing status in the document review workflow through donut chart. By changing the dropdwon menu, you can view the document processing status:

1. As a complete Room Summary, or
2. As workflow stages defined.

Refer to the screenshots below:

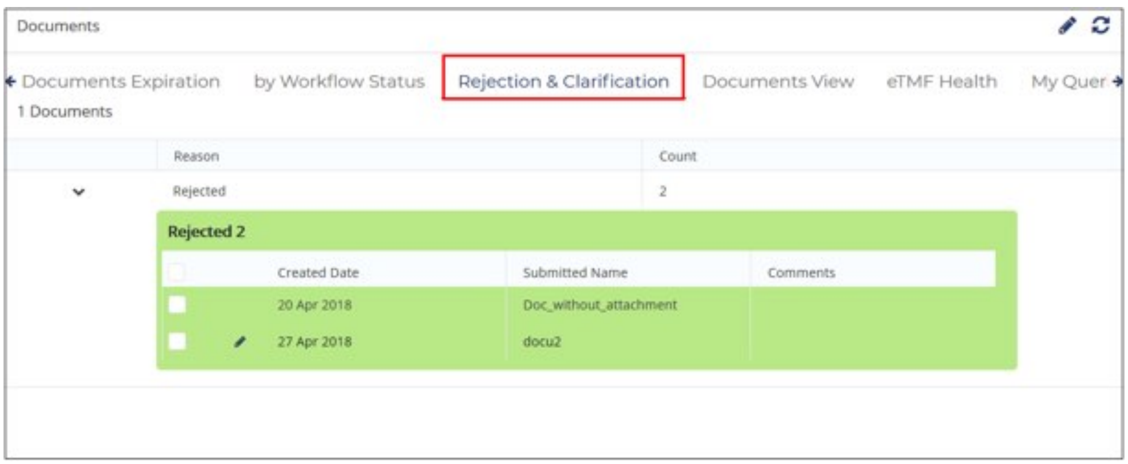




Dashlet - Documents Clarification and Rejection

The **Documents Rejection and Clarification** dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.

You can further double-click on the count to view the list of documents associated with a particular rejection or clarification reason. Refer to the screenshot below:



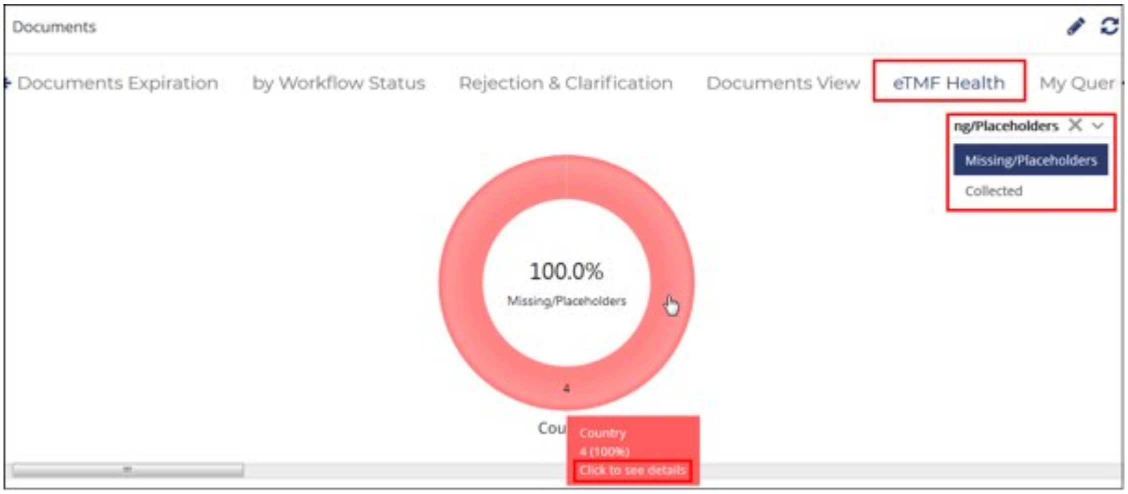
Dashlet - eTMF Health

The **eTMF Health** dashlet displays a donut chart that indicate what percentage of required eTMF documents are either collected or currently missing. From the top right corner of the donut chart, Administrator users can manually set the chart type to be displayed.

Hovering the mouse over the donut chart shows a popup with more detailed progress percentage for the category of the documents.

Click a donut to drill down to the lowest level to list the missing/placeholder documents. Additionally, you can use the **Add Placeholder** button 

to conveniently upload a missing document/placeholder, or to edit a placeholder right off the dashlet. To view any changes, refresh the chart to update the missing documents list. Refer to the screenshot below:



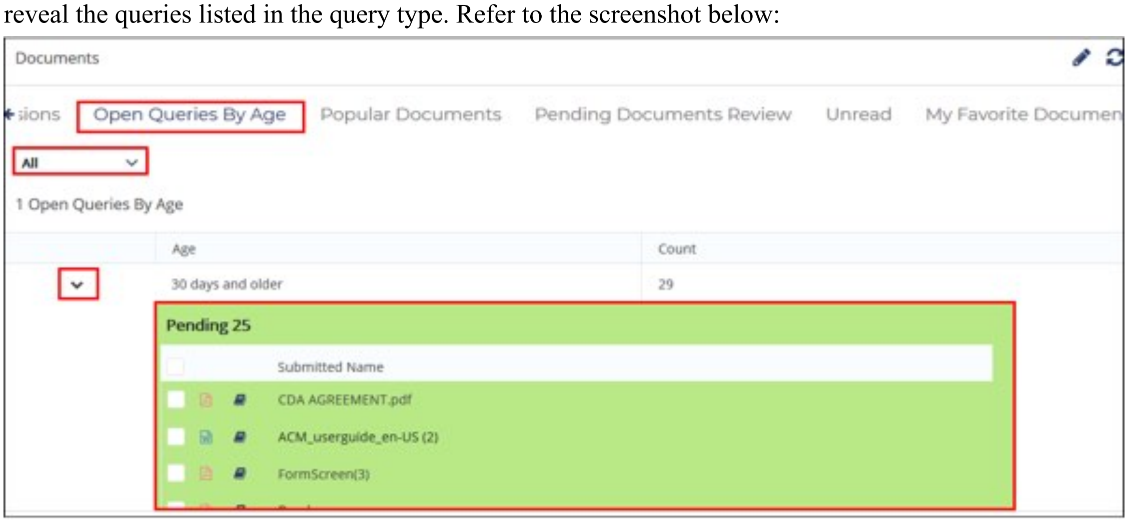
Dashlet - My Queries

The **My Queries** dashlet gives a list of documents based on their queiry types. The query types could be All, Workflow, or Audit. Refer to the screenshot below:

Click the **All dropdown** to toggle between different views to view the queries.

Dashlet - Open Queries by Age

The Queries by Age dashlet conveniently displays those documents that are 30 days and older in age and also provides a documents count. The query types could be **All**, **Workflow**, or **Audit**. Click the arrow next to the age to reveal the queries listed in the query type. Refer to the screenshot below:

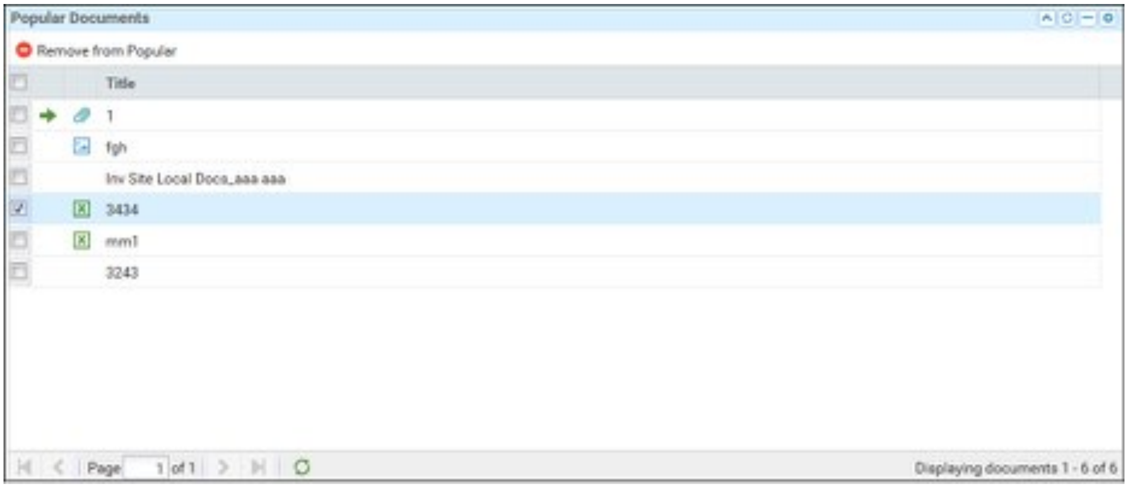


Dashlet - Popular

The **IP Release Documents** dashlet displays the list of documents that have been **marked as popular** by an Admin or Editor through the Document Cart and which are used frequently.

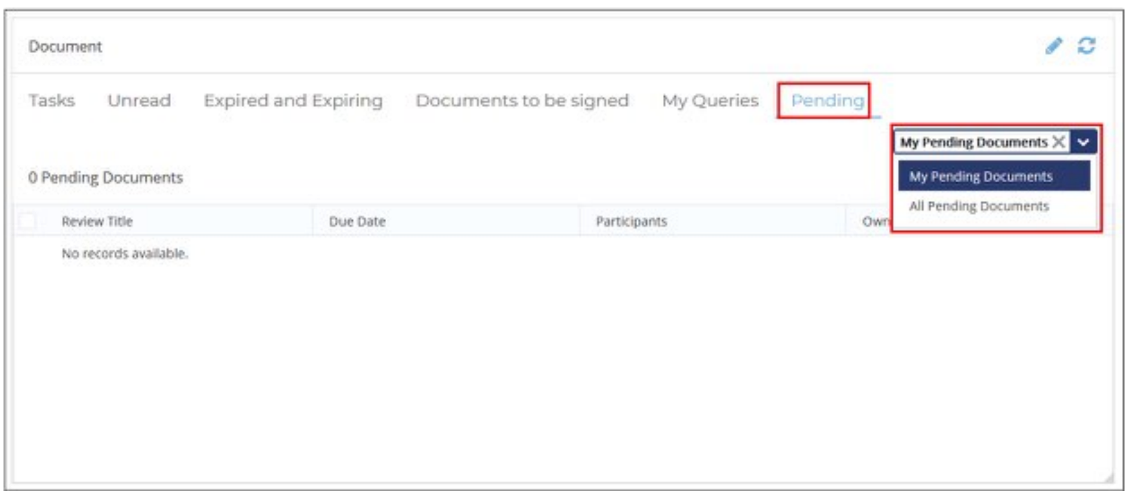
To remove a document from the Popular list, click **Remove from Popular** button on the dashlet.

To view the document, click the icon. Refer to the screenshot below:



Dashlet - Pending Documents Review

The **Pending Documents Review** dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for **All** users, or only for yourself through **My Review**. Refer to the screenshot below:

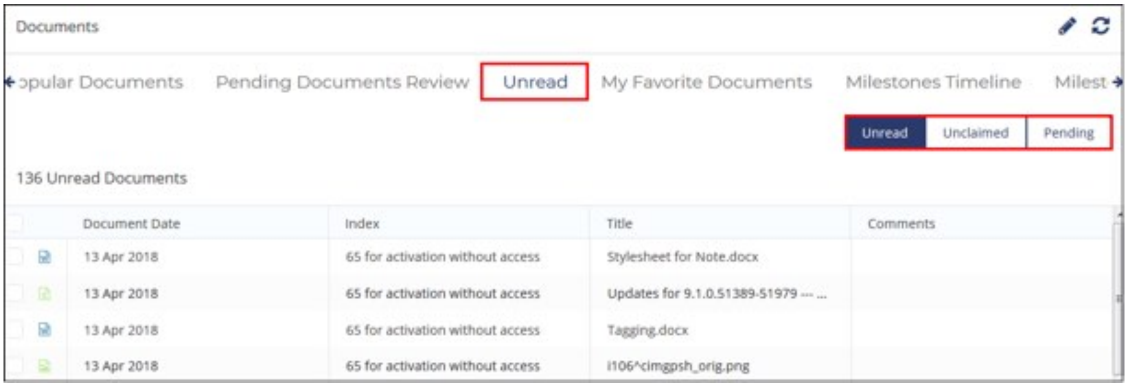


Click the **All Pending Documents dropdown** from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

1. **My Pending Documents**: This display the list of all pending documents that are assigned to you for review.
2. **All Pending Documents**: This display the list of all pending documents that are pending for review in a room.

Dashlet - Unread

The **Unread** dashlet shows the three different views of documents in eTMF module - **Unread** , **Pending** and **Unclaimed**. Refer to the screenshot below:



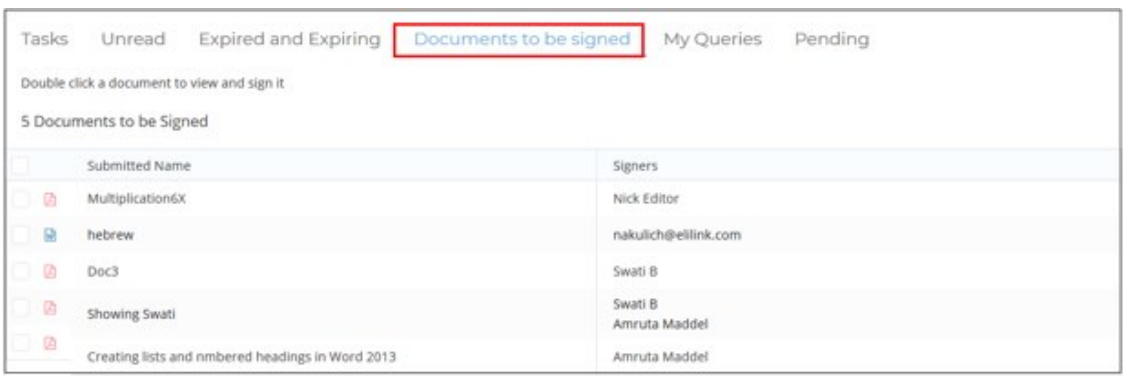
Click the **Unread** button to list any of the documents posted in the Trial Interactive site that have not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of.

Click the **Unclaimed** button to get a list of documents that have not been claimed for review.

Click the **Pending** button to get a list of documents that are yet to be reviewed.

Dashlet - Documents to be Signed

The **Documents to Sign** dashlet gives a list of document pending for signature. Refer to the screenshot below:



Dashlet - Milestone Type Report

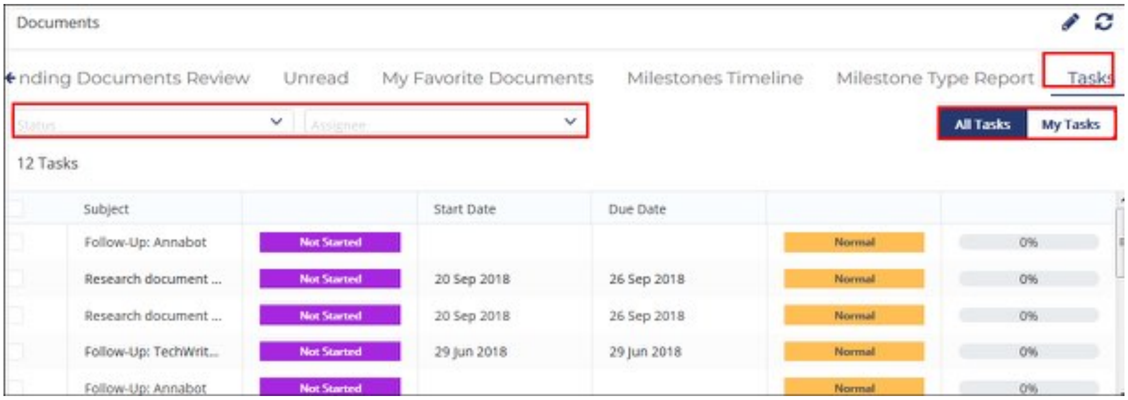
The **Milestone Type Report** dashlet gives the percentage of missing/placeholder documents, or collected documents for a particular milestone type associated with a site in the form of a bar graph.

Dashlet - Tasks

The **Tasks** dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the **Status** and the **Assignee**from their respective drop-downs to get the task details.

All Tasks lists all the tasks belonging to the selected assignee.

My Tasks lists all the tasks pending recently, today, or are overdue.

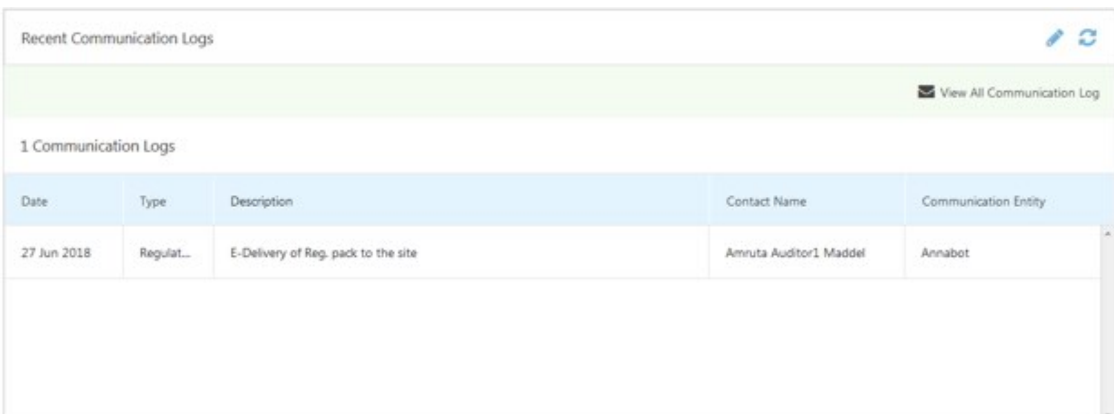


You can also export selected tasks or all tasks in the current grid by clicking the **Tasks Export** icon located on the top right corner of the dashlet. After the export job is over, you can retrieve the job result from the **Notifications** by clicking **Get Job Result** which then downloads the export job as an .xlsx file on your hard disk.

Dashlet - Recent Communications Log

The **Recent Communication Logs** dashlet gives a list of all communications made during the site start-up and activation stage.

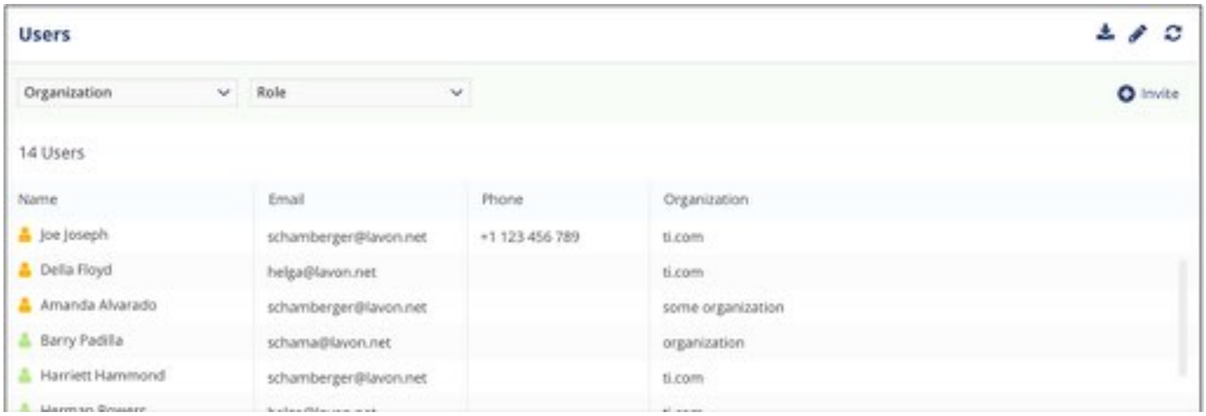
Clicking the V**iew All Communication log** link from the top right corner of the dashlet to view the list iof all communication log.Refer to the screenshot below:



You can also rename the dashlet by clicking the **Pencil** icon to the right of the dashlet and refresh the dashlet by cliking the **Refresh** icon .

Dashlet - Users

The **Users** dashlet provides a helpful option that lists new users or all users in a study with filters to sort users by organization and by their organization and access level (role). You can also invite a new user here by clicking the **Invite**button placed in the upper right corner. **Double-clicking** the icon next to the Last name opens the **Edit User** popup to allow editing of the user profile. Refer to the screenshot below:



Dashlet - Investigative Sites

The Investigative Sites dashlet display the overview of Sites in the form of Pie Chart. The dashlet contains the following tabs for the related to the sites:

1. **Expiring** : Display the details and count of expired sites in the form of Pie Chart.
2. **E-Feasibility by Country**: Display the count and details of sites based on E-Feasibility by Countries.
3. **Study Monitoring Visits**: Display the count of sites based on the Study Monitoring Visits.
4. **Recently Updated**: Display the count of all recently updated sites.

Dashlet - Expiring Sites

The **Expiring Sites** dashlet gives a list of all sites that are expiring in a future date. Refer to the screenshot below:

Dashlet - Recently Updated Sites

The Recently Updated Sites gives the activation progress of all sites in a room. Hover the mouse over the Progress% column to view the list of documents that are missing to complete the site activation. Refer to the screenshot below:

Dashlet - Site Activation Status

This dashlet offers three views – Sites By Country, e-Feasibility By Country, and Sites Activation Progress.

Select the **Site By Country** view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshot below:

Dashlet - Study Monitoring Visits

The dashlet **Study Monitoring Visits** provides two different views study monitoring visits – **Monitoring Visits By Month,** and **Monitoring Visits By Country**, in the form of a donut chart. This dashlet can be configured to display the **Visit Date** instead of the **Created Date** through the **Configure Dashlet** feature as discussed above. Refer to the screenshots below:

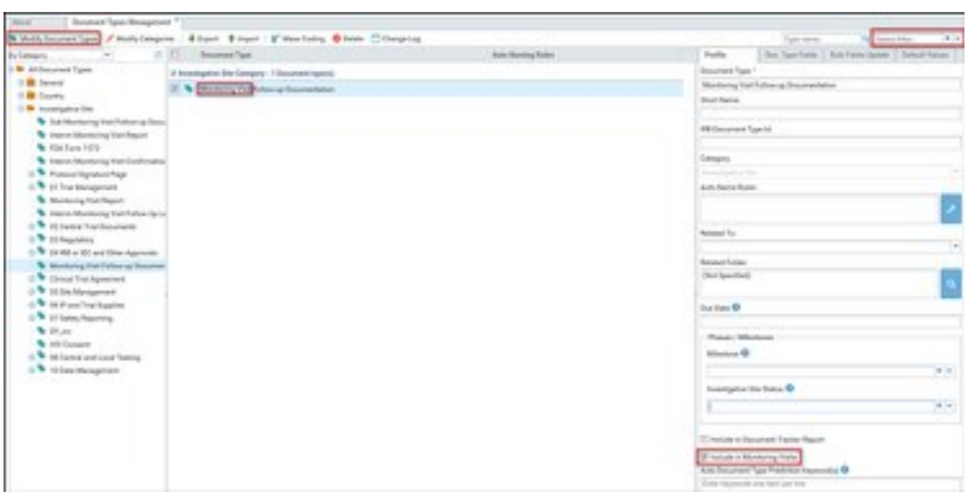
The dahslet provides the **Date Ranges** to filter the sites. Besides selecting dates in the date columns, you can aslo scroll the bar between the ranges to filter the sites.

When you select the '**By Country**' option from the dropdown at the top right corner, you will be finally be able to view the documents for the particular country. Click the section on the donut chart to delve further for the country documents.

The **Study Monitoring Visits** dashlet is connected to the **Document Type Settings**. Therefore, Administrator users can go to **SettingsàDocumentTypesàDocumentTypesManagement**, and assign or modify document types. Through the configuration box, users can manually specify whether to include the document in the Monitoring Visits or not.

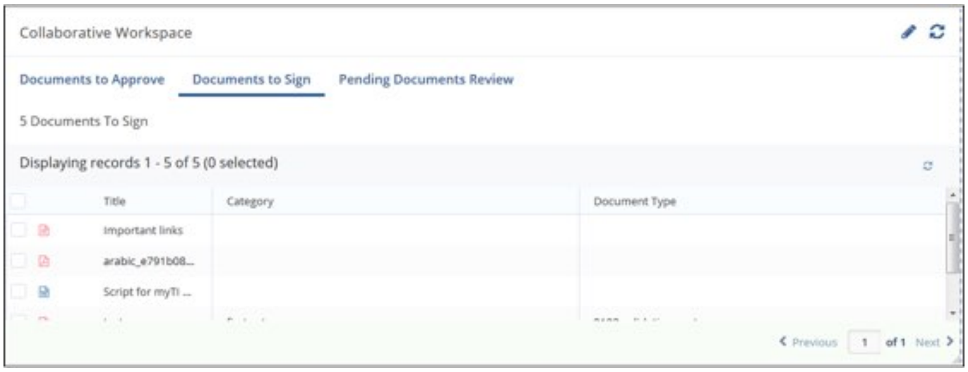
If you choose to include a new document type, the **Study Monitoring Visits** dashlet will be updated to reflect the change.

For your convenience**,** a **search box** and a **filter option** are also available in the Document Type Management section in the Settings. These features help users track which documents, and how many documents are needed to be collected for specific document types. Refer to the screenshot below:



Dashlet - Collaborative Workspace

The Collaborative Workspace dashlet gives you the overview of all the documents that are in a Collaborative Workspace. Refer to the screenshot below:

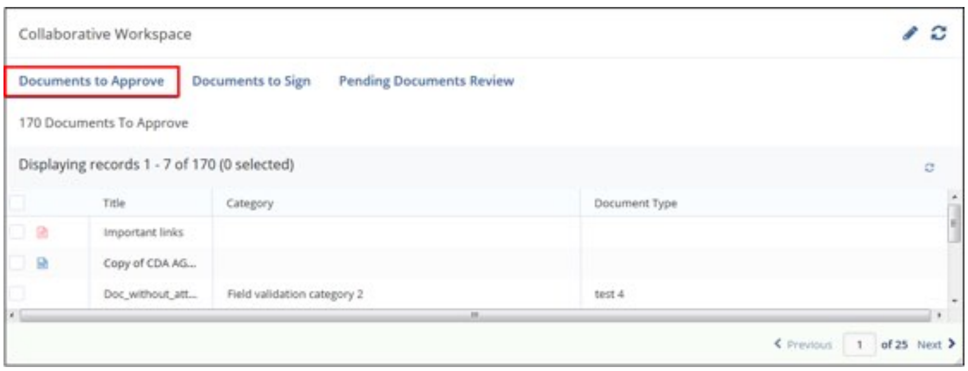


The followind dashlets are available in the Collaborative Dashlet:

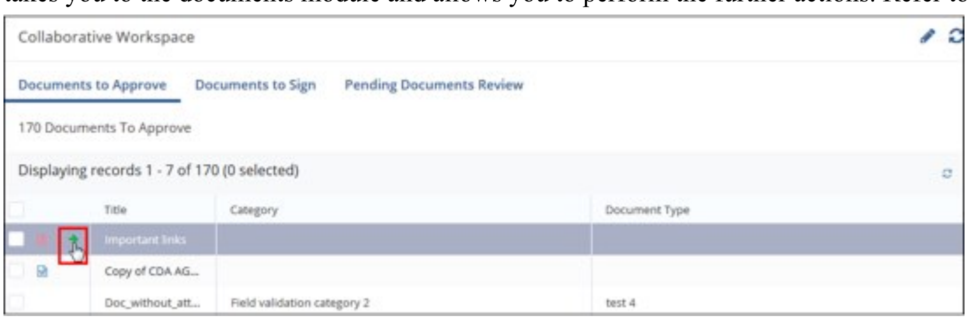
1. Documents to Approve
2. Documents to Sign
3. Pending Documents Review

   Each of these is discussed in the separate topics.

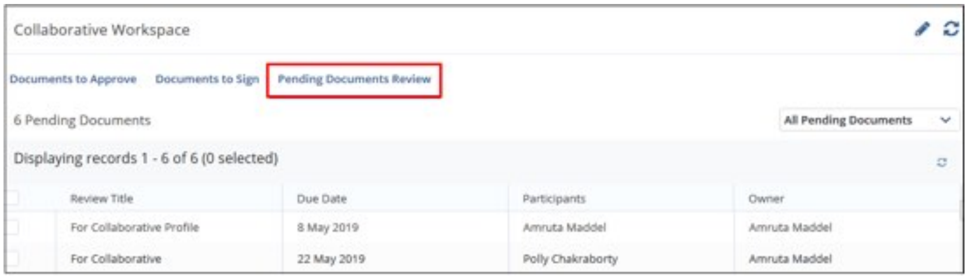
Dashlet - Documents to Approve



The Documents to Approve dashlet displays the list of documents that are pending to for approval in the Collaborative Workspace. When you hover the mouse over the document, a green arrow appears which when clicked, takes you to the documents module and allows you to perform the further actions. Refer to the screenhot below:



Dashlet - Pending Documents Review



The **Pending Documents Review** dashlet gives a list of all documents that are pending for review in the Collaborative Workspace. You can choose to view the documents pending for review for **All** users, or only for yourself through the drtopdown that is located at the top right of the corner of the dahslet. Clicking the green arrow next to the Review Title leads you to the Collaborative Workspace module to complete the review. Refer to the screenshot below:

Dashlet - Collaborative Documents

The **Collaborative Documents**dashlet displays the list of all collaborative documents.

From this dashlet, you can also create a new **Collaborative Profile** by clicking the **Create Profile** button located at the top right corner of the dashlet.

Documents View

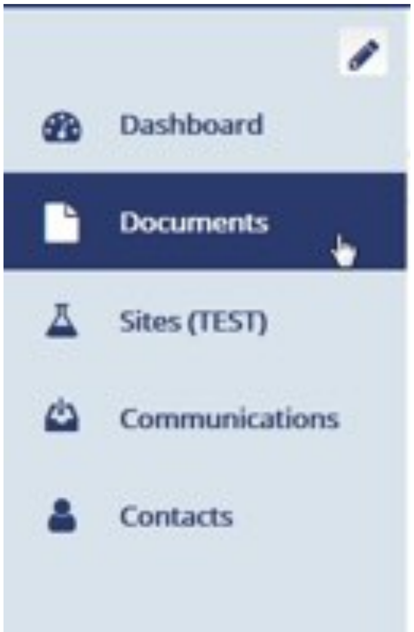
The **Trial Interactive eTMF Documents** is the central repository for all the clinical trial documents in their original digital format with Digital Signatures wherever applicable, records or documents converted from one format to another like paper documents, images converted to PDFs, besides **videos**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

Here, you can configure and store trial master file **'essential documents'** pertaining to clinical trials, view and edit documents attachments, manage security privileges on them, import and export documents and their metadata, mail them to other users besides many others.

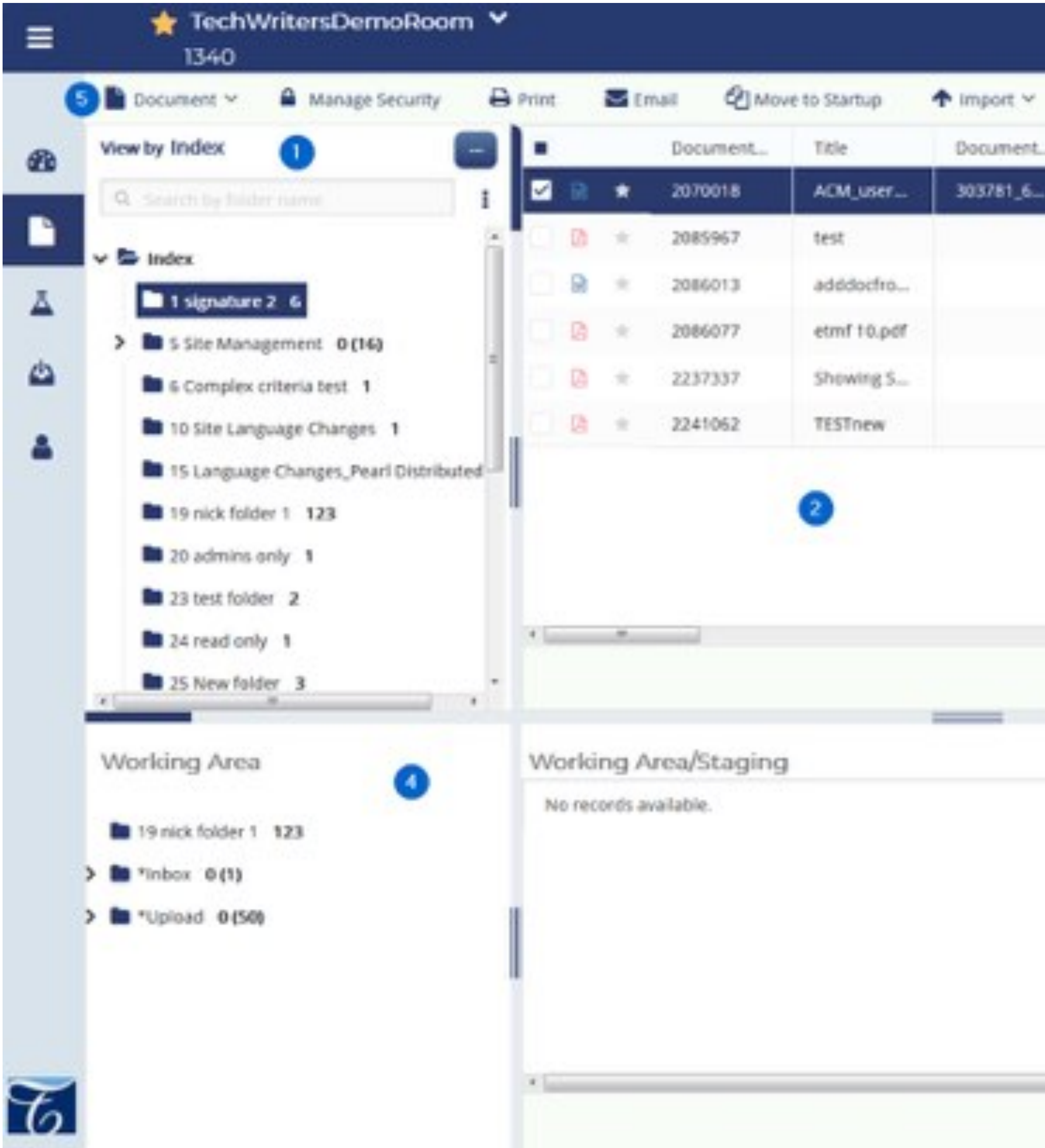
To comply to **eTMF Completeness**, you can track the progress right from documents collection to finalization of a document through **Milestones** and assignment of **Tasks** to authorized personnel. Besides, this application also provides you the facility to post **Questions and Answers** along with generation of **FAQs** for further insight.

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

You can access the **Documents View** by clicking the **Documents** icon from the menu bar at the left of the dashboard. Refer to the screenshot below:



Clicking the **Documents icon** from the menu bar at the left leads you to the **Documents dashboard**. Refer to the screenshot below:



Refer to the table below for more description on each numbered part.

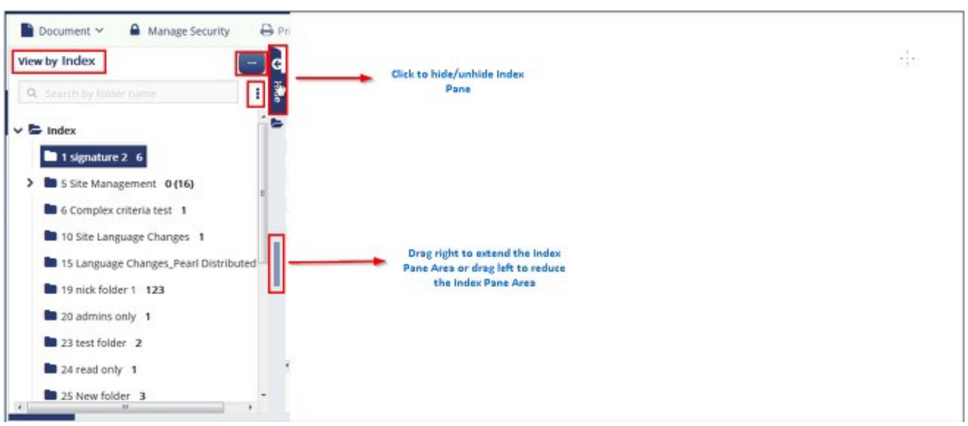
Table 1: The Documents View

No.	Part Name	Description
1.	The Room Index	The Room Index consists of folders organized into a tree like structure starting with **Index** as the root folder.
2.	The Documents Grid	Select a child folder from the Index to populate and view its documents in the Documents Grid.
3.	The Document Data Panel	Tick a checkbox next to a document in the Documents Grid to populate the Document Data Panel.
4.	The Working Area	
5.	The Top Ribbon Bar	Access various functionalities required for eTMF operations from here.

Click the links in the table below for more details on each part or section.

The Room Index

- The Room Index consists of folders organized into a tree like structure starting with **Index** as the root folder.
- The Index consists of **parent and child folders** and can either be cloned during room creation or created from the scratch.
- The Index Folders are categorized as per the **Document Types** specified from the Room Settings and consists of three main categories – **General**, **Country Management** and **Site Management**.
- **Documents emailed to a room get stored in the room's Inbox folder.**
- **Similarly, all documents imported are populated in the Upload folder.**
- If a folder contains sub-folders, you can **expand** it to list its content by clicking the expand arrow icon next to a collapsed folder.
- Similarly, you can **collapse** an Index folder by clicking the collapse arrow icon next to an expanded folder.
- To locate documents in a child folder you drill down to the last child folder and click on it.
- The documents in the child folder populate in the **Documents Grid**.
- Tick a checkbox in the Documents Grid to view its metadata in the **Metadata tab** of the **Right Panel**.
- Besides the Metadata tab, the **Right Panel** also consists of the **Workflow, Queries, Versions, History, and eSignature tabs**.



From the Index Pane:

- View the room's folder structure
- Search and navigate to sub-folders
- Modify Index Structure
- Export Index

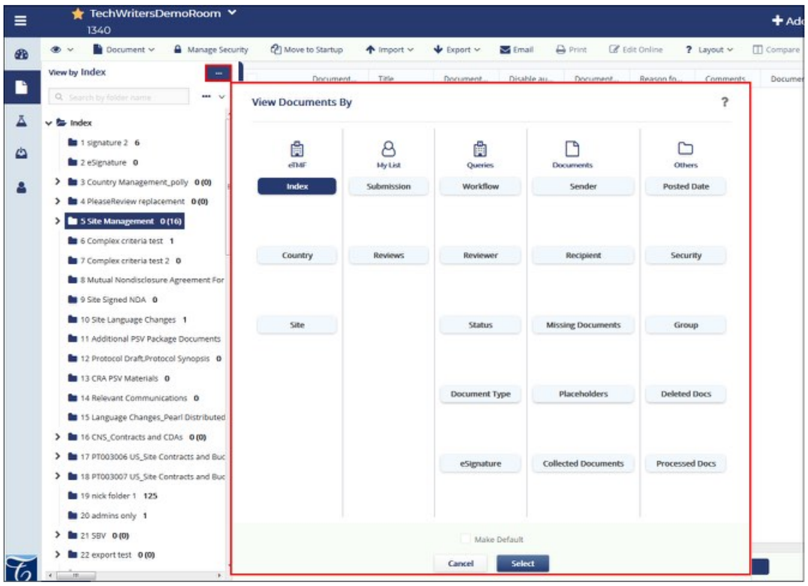
- Refresh Index
- View Security on an Index Folder
- Export documents from an Index Folder
- Add documents to an Index Folder
- Index Outline Settings and By Index View

Choose View - Viewing the Room's Index Structure

You can view a room's index and its documents from the Index Pane of the room, From the Index Pane, you have access to various kinds of views to the folder structure. The default view provided by the system is **By Index**.

To toggle between the various views of the Index Structure:

1. Click the **Choose View** button on the Index Pane.
2. This opens the **View Documents By** popup with various view options. Refer to the screenshot below:

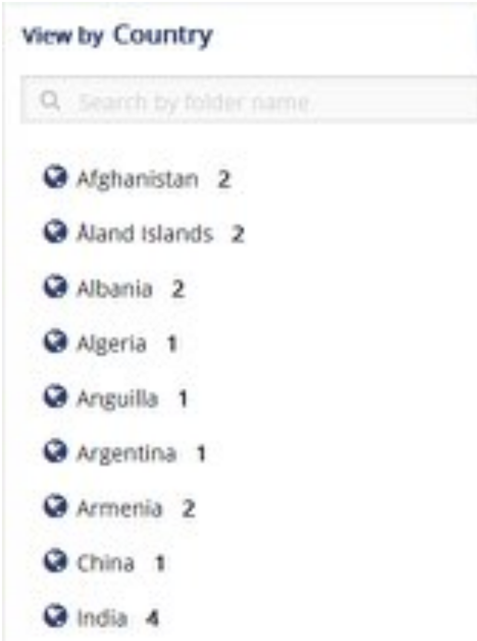


Tip: *Select a view and tick the **Make Default** checkbox to make that view the default view. You will then see the documents sorted and grouped by the view you marked as default everytime you visit the room.*

Each of the view options are discussed in separate topics available from the left pane of this help.

By Country

From this view, you can access all documents and placeholders of the **Category Country** having a country name metadata specified in its Country Field. When you access this view from within the Documents sub-module, you see all eTMF documents of the category Country. Refer to the screenshot below:



Under each country as a parent folder, the documents are further categorized by its **Document Types**.

You can also view the category country documents in the By Index view under the **Country folder** (the name that you provide to this folder depends on your room settings).

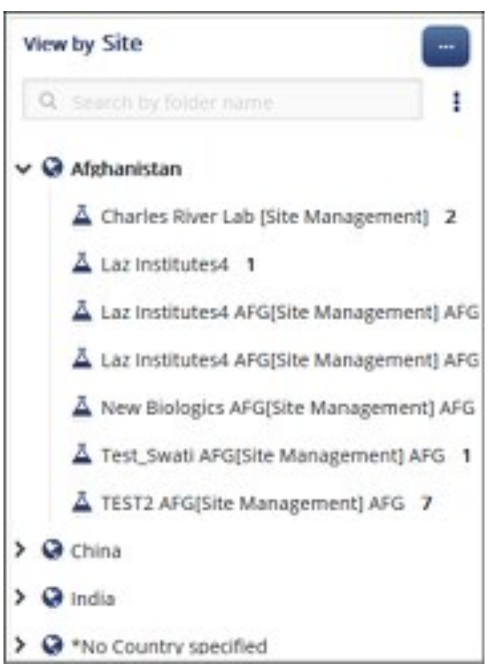
For more details on how to set up this folder and its hierarchy follow on to Chapter Countries.

To know more about Site Specific Country Category documents proceed to **Site -> By Country view**.

By Site

From this view, you can access all documents and placeholders associated with the **Investigative Sites**. Sites are places where the clinical studies are conducted. This view show the segregation of Investigative Site as located in the various 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

By Reviewer

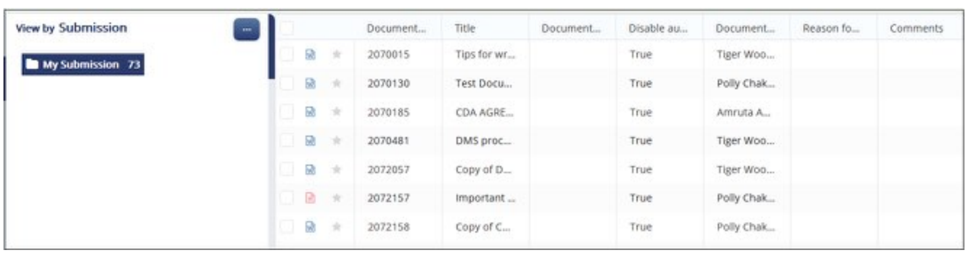
Administrators can reassign documents claimed in the workflow to other reviewers.

1. From the **Documents** view, select **By Reviewer** as the Current view for the index.
2. Open the index folder of the reviewer whose claimed documents you want to reassign.
3. Click the folder holding **claimed document** to reveal its contents. The list of that user’s claimed documents populates the document grid.
4. Select the documents from the list that you want to reassign.
5. The **Reassign reviewers** button becomes active in the menu ribbon above the document grid.
6. Click **Reassign reviewers**. A **Reassign reviewers** window opens.
7. From the **Workflow** dropdown, select the workflow you want to adjust.
8. The **Stage** field auto-populates.
9. From the **Reviewer** dropdown, select the reviewer to whom you want to reassign the documents.
10. Click **OK**.

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

My Submissions

All the documents that the user imports, emails or adds to the room are populated in the the My Submission folder. Refer to the screenshot below:



My Reviews

Note: *If you are the part of the reviwers group which you are assigned to the workflow, the My Reviews in the eTMF Documents module is automatically activated for you. You can have the same reviews as in My Reviews from the Quality Review module as well.*

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

For more details on workflow, refer to chapter **Quality Control.**

By Workflow

From this view you access the documents available to the user for review in the various stages of workflow. Refer to the screenshot below:

Non Final Documents By Stage

TO BE ADDED LATER.

By Status

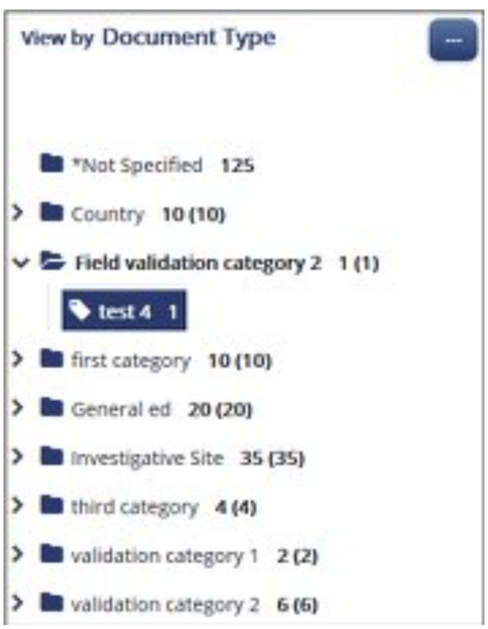
This view displays the current workflow status of documents. Refer to the screenshot below:

By Document Type

This view groups all documents by its Category as the parent folder. Each **Category** folder further holds documents grouped by document types as 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. Refer to the screenshot below:



eSignature

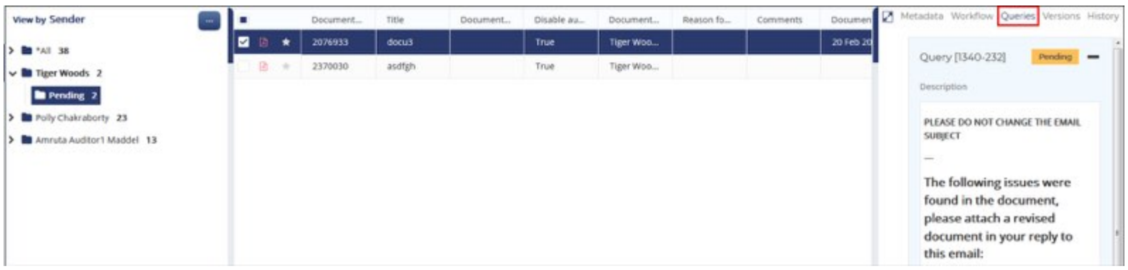
This view groups all eSignature documents under **Completed**, **Waiting**, and **Canceled** category. Refer to the screenshot below:

Click the folder to view the required documents.

You can also choose to **Cancel eSignature** by selecting a document from the **Waiting for eSignatures**.

By Sender

This view display documents grouped by reviewers who have raised queries on documents during a **Quality Review** or **Quality Control** and have sent them for clarification. Refer to the screenshot below :



From here the user can:

1. View the query.
2. Resolve a Query.
3. Respond to a Query.

Click the links above to know more in detail about each topic.

By Recipient

This view display documents grouped by the recipients of the queries received by them for clarification from the reviewers in a **Quality Review/Quality Control.**

From here the user can:

1. View a query.
2. Respond to a query.
3. Resolve a query.

Click the links above to know more in detail about each topic.

eTMF Completeness

This view lists collected, missing documents and acts as placeholder for missing documents that do not fall under the required documents section.

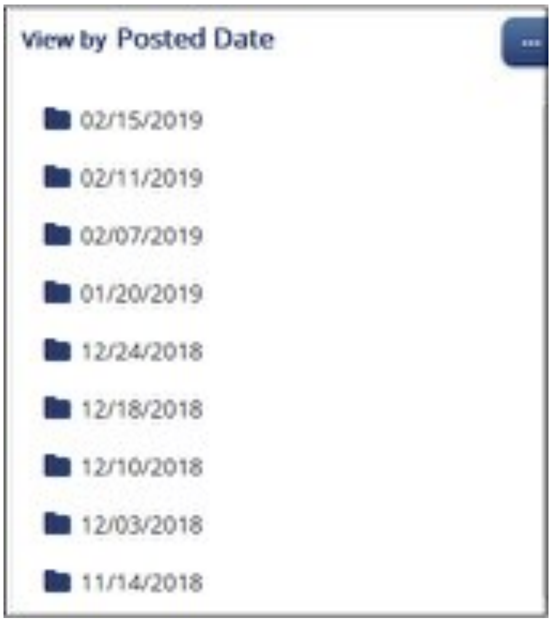
From within the Document Grid or from the **Add Placeholder** dropdown on the top ribbon, placeholders can be created, edited, deleted for a document. Documents can be attached to placeholders or missing documents from the **Add Document** located on the top ribbon bar or by dragging and dropping them from the Windows Explorer.

The system:

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

By Posted Date

In the **By Posted Date** view, the documents are grouped as per the days they were **posted/imported/added**. Folders by posted dates are created. Clicking each folder displays the documents posted on that particular day. Refer to the screenshot below:

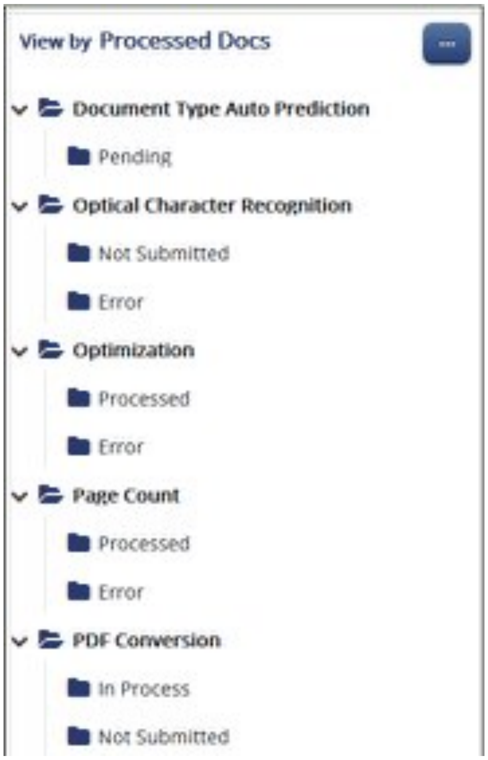


By Security

The **By Security** view shows all the documents based on the security accesses provided to users and group of users. Documents are segregated under folders by the name of users showing the level of their access. Refer to the screenshot below:

Processed Documents

All the documents that traverse through various processes in a study can be viewed from here. Refer to the screenshot below.



Some examples of processes in a study that the documents need to pass through are **OCR**, **Optimization**, **PageCount**, **PDFConversion**, **PDFFixation**, **PublishtoeTMF**, and **DocumentTypeAutoPrediction**. The documents are listed under each process in this. Under each process, the documents are further categorized into **Not Submitted**, **Pending**, **Processed**, and **Error**.

For example, as a user, you might want to submit documents for PDF Conversion. All the documents that were converted into PDF will appear under the **Processed->PDF Conversion** folder. If some documents could not be converted into PDF due to some error, they will appear under the **Error** folder. The documents that were not submitted for PDF Conversion will appear under the **Not Submitted** folder, and those that are still pending for conversion will appear under the **Pending** folder.

Similarly, all documents that are published from a Shared Workspace to its eTMF room get recorded under **Publish to eTMF** sub-folder in the **Processed** folder.

Deleted Documents

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

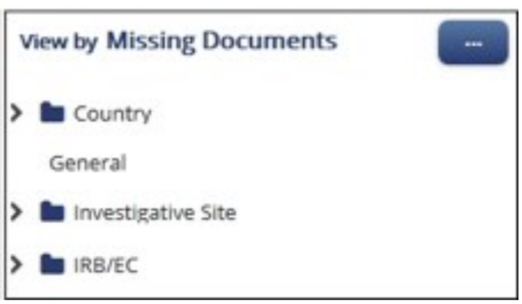
For more details on deleted documents proceed to Chapter Deleted and Expired Documents.

By Group

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

Missing Documents

This view displays the list of all missing documents in a room. Refer to the screenshot below:



Click the folder from the left to view the documents. You can also edit the metadata of the documents from the **Metadata** Panel.

To edit the metadata, select the document from the appropriate folder and edit the metadata. **Click** Save to commit the changes.

Collected Documents

This view displays the list of all **Collected Documents** in a room. Refer to the screenshot below:

Click the folder from the left to open the list of sites. Select the required site to open the documents in the grid.

Exporting and Refreshing Index

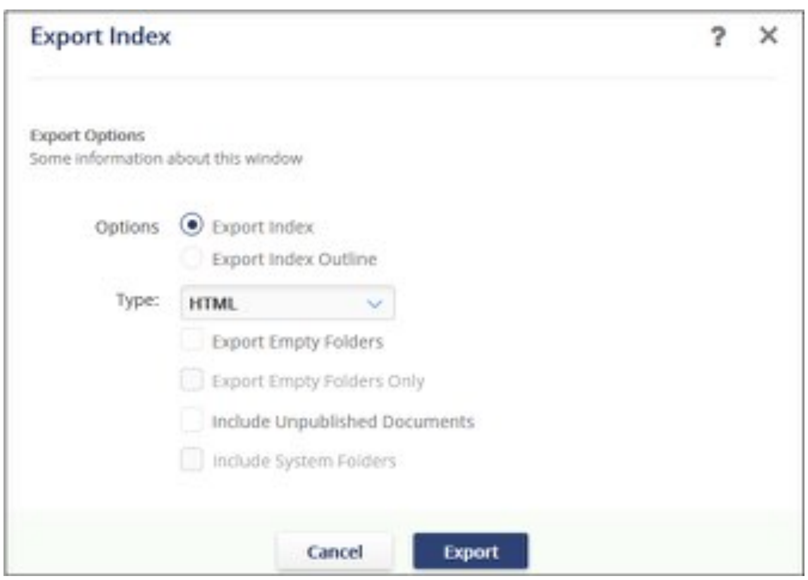
Exporting Index

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

To export index:

1. Click the **Export Index** 

from the popup and export the index as per the actions required. Refer to the screenshot below:



Index Search

In the Search box below the **View By Index** pane, enter the name of the folder you want to search.

Press **Enter**, or click the magnifying lens icon to reveal matching contents.

Click the Cross next to the right of the search box to delete the search criteria.

The Documents Grid

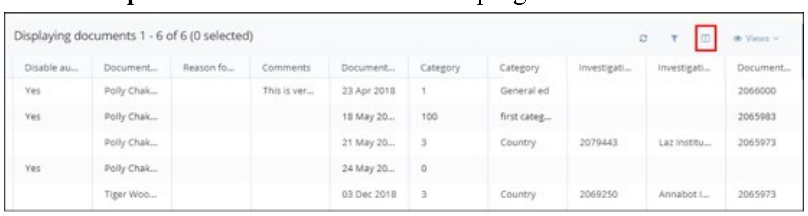
You can perform the following from the Documents Grid.

- Preview and Viewing a document and its metadata
- Access the Document Context menu on a document by the mouse right-click
- Configure the Documents Grid
- Copy or move documents

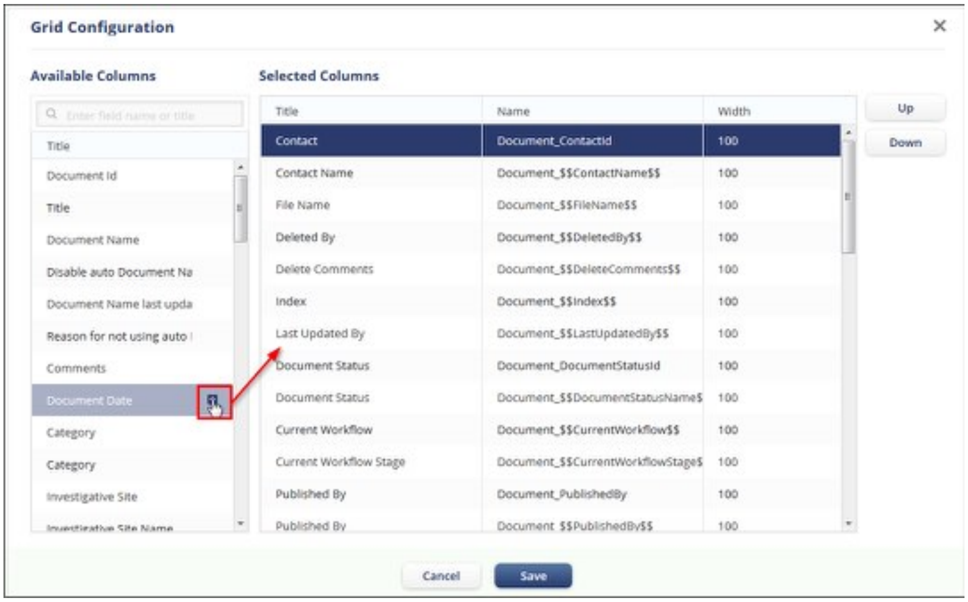
Configuring the Document Grid

Through this option you can decide which columns to display or hide from the Document, Workflow, or Audits Grid. Thus, you can decide exactly what information you want to see and configure the grids accordingly to suit your view .

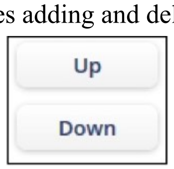
1. Navigate to **eTMF/Documents** module.
2. Click the **Update Columns** icon from the top right corner of the documents grid. Refer to the screenshot below:



3. The **Grid Configuration** window opens which displays the following panels:
   a. **Available Columns Panel**: This panel display the list of all available columns in a room.
   b. **Selected Columns Panel** : This panel displays the list of all columns that are selected and added from the Available Columns.
4. To add a column to the **Selected Columns** pane from the **Available Columns** pane, hover the mouse over the column name in the Available Coulmns. The + sign appears next to the column name.
5. Click the + sign to add the column to the **Selected Columns.** The column gets added to the list of Selected Columns. Refer to the screenshot below:



6. Alternatively, you can also **double-click** the coulmns in the Available Columns to add to the Selected Columns.
7. After adding the columns to the Selected list, they are **greyed out** in the Available Columns list and a **small green tick** appears to the next of the column name as shown in the screenshot below:

8. Similarly, you can remove the columns from the Selected Columns list by clicking the **-** icon that apppears next to the column name on hovering the mouse over the column OR double-click the column to remove it from the list.
9. Besides adding and deleting columns, you can also change the sequence of the columns by clicking the **Up** or **Down** 

buttons located at the extreme right of the window.
10. Click **Save** to save to changes.

Previewing and Viewing a Document and its Metadata

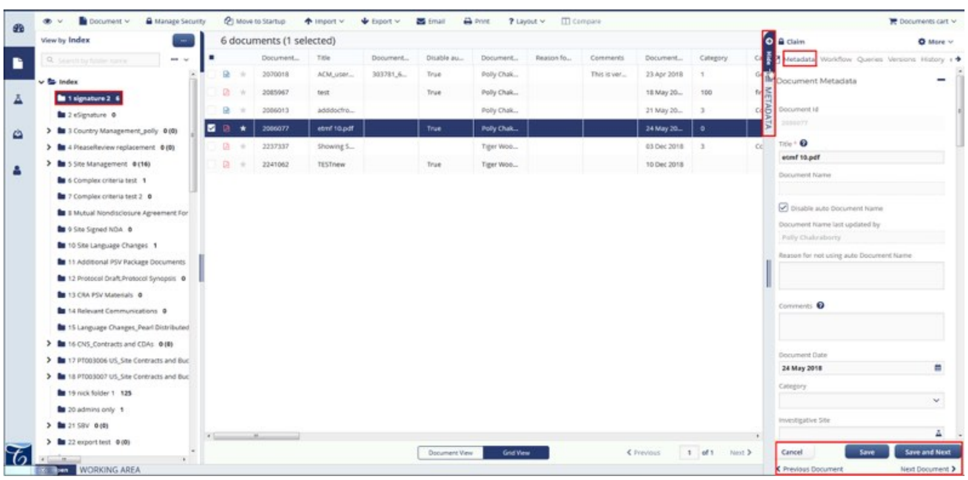
This allows you to view the document metadata and the document in the seperate panels in the eTMF / Documents module. These are discussed in the sections below:

Viewing Document Metadata

To access the Document Metadata, follow the steps as below:

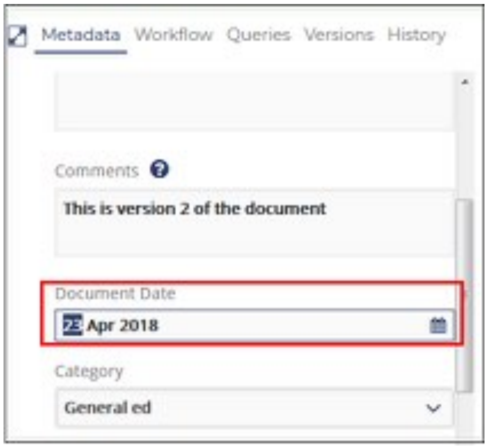
1. From the **Documents** module, select the document from the grid.
2. Hover the mouse over the bar to the right of the grid. The **Metadata Viewer** 

display with the **Open** text on it.
3. Click the viewer to open the **Metadata Panel**. *Notice that when you open the metadata panel, the Metadata Viewer bar changes the* ***Open*** *text to* ***Hide*** *clicking which you can hide the metadata panel*
4. The **Document Data Panel** opens which displays the **Document Metadata** by default. Refer to the screenshot below:



As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The icons at the bottom of the panel provide access to several essential functions, such as saving changes and updates in the metadata panel as shown in the screenshot above.

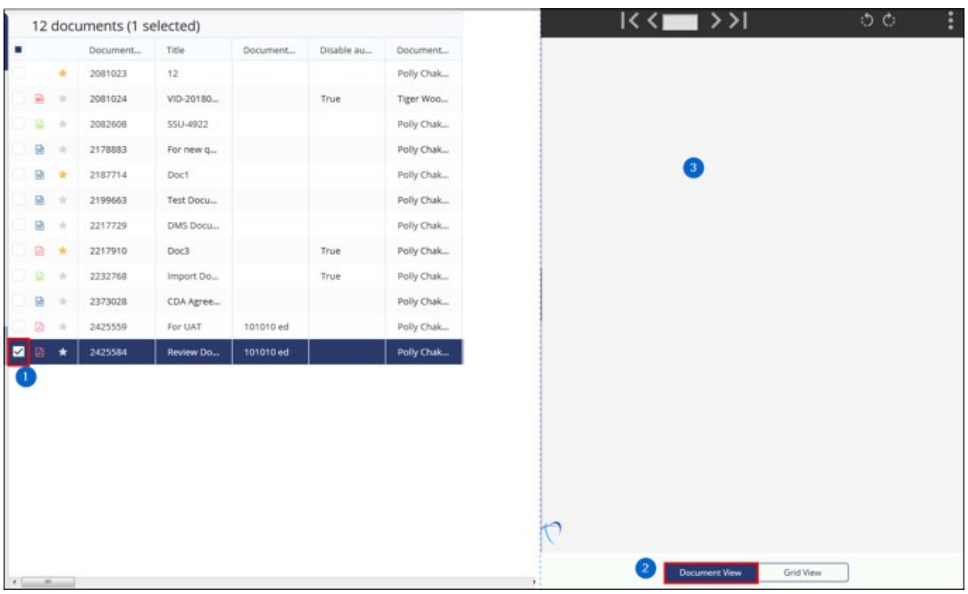
Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings -> General Information section. Refer to the screenshot below:



Previewing a document

To preview the selected document:

1. Select the checkbox next to the document.
2. Click the **Document View** button at the bottom of the grid.
3. The document opens in the Arender view. Refer to the screenshot below with the sequence of steps in number denoted:



Copying or Moving Documents

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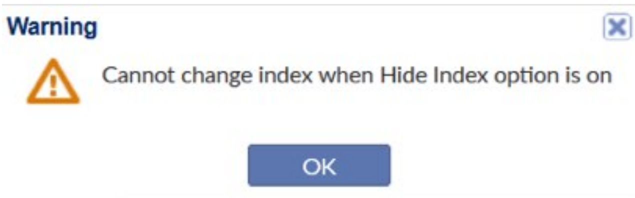
Follow the steps below to copy documents:

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

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

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

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



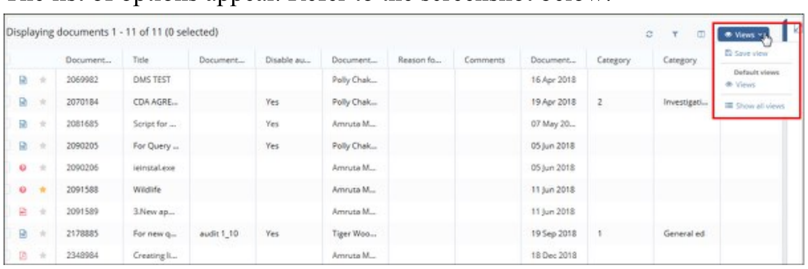
Documents Grid Views

While in a specific folder, user may want to filter the columns and view only the columns that are required. This can be done by customizing the grid view. You can create your own view and set that particular view as a default view so that you can view only that information which is required in the grid.

Besides, you can also apply filters to the grid and save the view for the future use.

To set and customize a view:

1. Navigate to the **eTMF/ Documents** view.
2. Select the required folder and update the columns as needed. The documents grid gets updated as required.
3. Click the **Views** dropdown at the top right corner of the grid.
4. The list of options appear. Refer to the screenshot below:

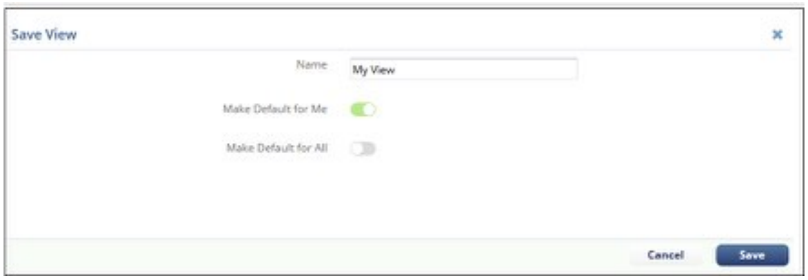


5. You can perform the following actions:
    a. Save View
    b. Set Default View
    c. Show all views
    d. Share the Views

Each of this is discussed in the sections below:

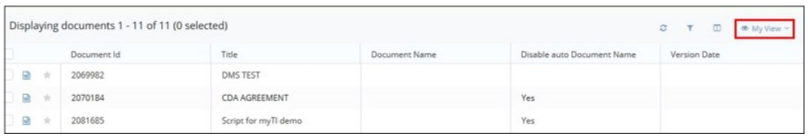
Save Views

After updating the columns in the grid, click **Views** → **Save View**. The **Save View** window opens. Refer to the screenshot below:



Enter the name of the view and enable the options by clicking the toggling buttons below for the default view. You can either make the view default for you or for all the user who access the folder to which the view has been set. Click **Save** to save the changes.

On saving, you can see the name of the view and columns also gets updated. Everytime you visit the folder, you can select the view for the grid. Refer to the screenshot below:

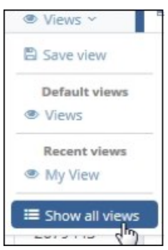


Show All views

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

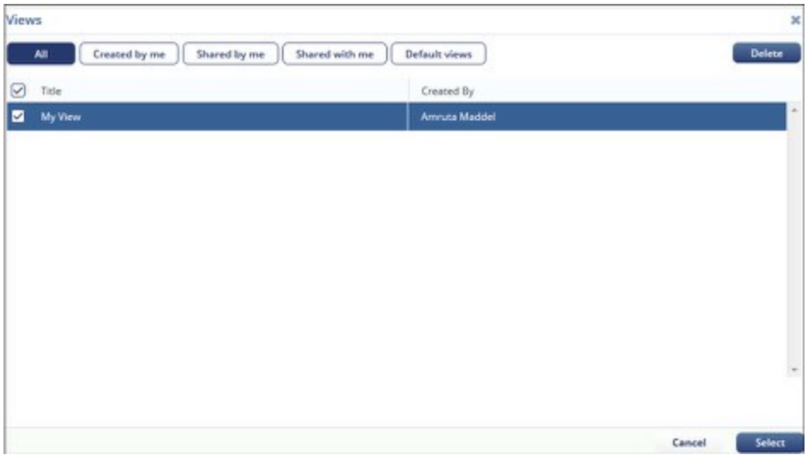
To display all views:

1. Click **Show All Views** from the from the Views dropdown. Refer to the screenshot below:



2. The **Views** window opens which contains the following tabs:
   a. **All** : This displays the list of all the views in a room.
   b. **Created by me** : This displays the list of all views that are created by you.
   c. **Shared by me**: This displays the list of all the views that are shared by you to the other users.
   d. **Shared with me**: This displays the list of all the views that are shared to you by the other users.
   e. **Default Views**: This displays the list of all default views.

The screenshot below show an example of the **All** views:



Note: *The **Delete** and **Select** buttons are enabled only when you select a view from the list.*

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

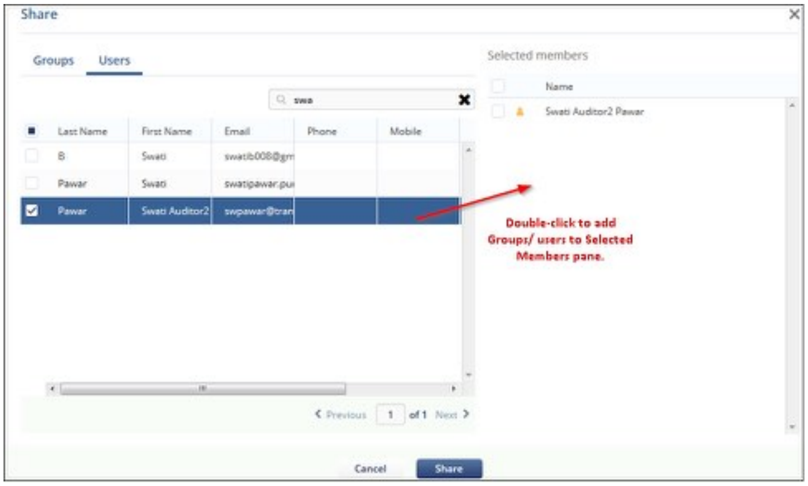
Share Views

Note: *This option is enabled in the Views dropdown only when a you select a view created from the list.*

To share view:

1. Select a view you want to share from the list of views. The selected name of the view displays.
2. Now, click the **Views** dropdown. The list of options appear.
3. Click **Share View.** Refer to the screenshot below:

4. The **Share window** opens.
5. Select the **Groups** or **Users** to whom you want to share the view. Double click the user from the left pane to add them to the Selected mambers pane.
6. After selecting Gorpus/Users, click **Share**. Refer to the screenshot below:

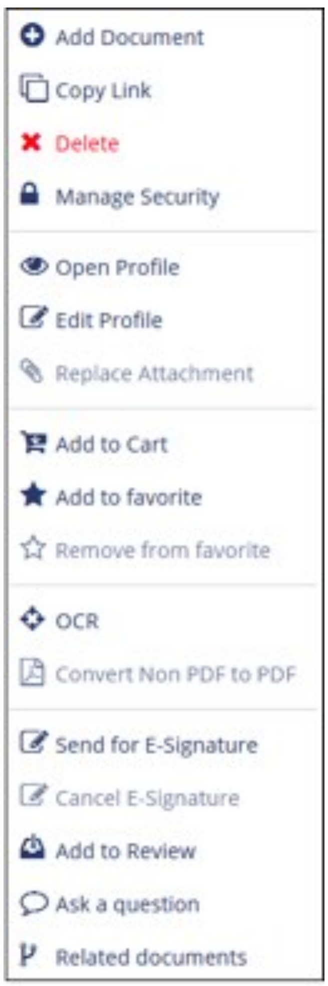


7. This shared view now displays under the list of Shared by me in the Show All Views.

Documents Context Menu

You can perform the horde of activities on a document from the Document Actions as well as by right-clicking on a document in the Document Grid.

Refer to the screenshot below to get a list of actions possible from the **Documents Context Menu**. Each of the functionalities are discussed in separate topics available from the left panel of this topic help.

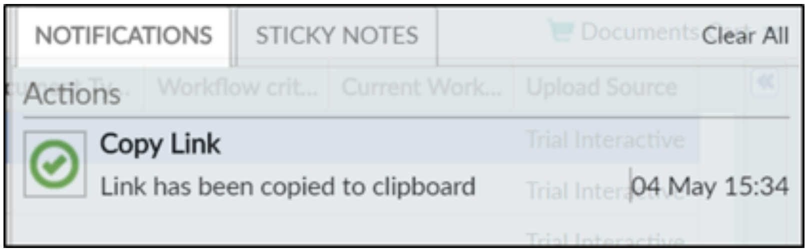


Copy Link

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

Once the Copy Links settings are made, follow the steps as below to copy a link:

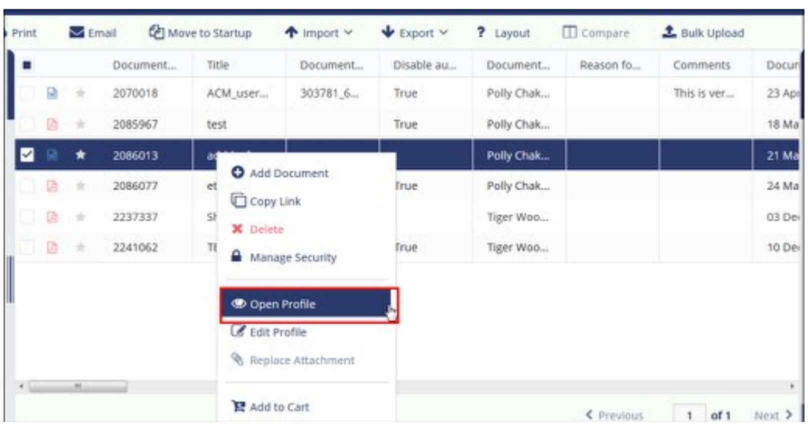
1. Navigate to the **Documents** Module.
2. Select the required document from the grid and right click on it.
3. Click **Copy Link** to **copy the link to a documen**t, or to **copy the link to a document with metadata** and a notification about the same is received. Refer to the figure below:



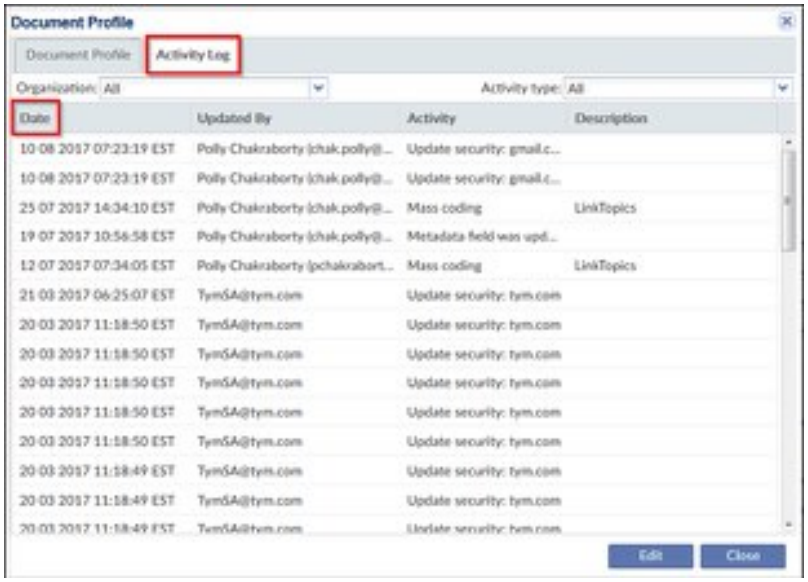
Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings, the document will either open up in the browser for you to read, or the link will take you to the eTMF room and open the document and its metadata for you to view. **Copying and pasting the link of an empty document shall display the message 'This document profile does not have an associated document'.**

Opening Document Profile

In the **Documents** module, select the document and click **Open Profile** from the right-click menu on the document. Refer to the screeshot below:



On clicking Open Profile, you will see the Document Profile for the selected document. In this view, the fields are static. Refer to the screenshot below:



Add Selected to Cart

Add Selected Document to Cart

Proceed to section Adding Selected Documents to Cart for the detailed information.

Adding and Removing Favorites

Adding Favorites

Click **Add to favorite** from the Documents Context Menu menu to mark document as favorite. Similary, click **Remove from favorite** from the right-click menu to unmark document as favorite.

Besides, you can aslo click a **Star** to the left of a document to mark/unmark it as a favorite.

Ask a Question

Ask a Question

This allows you to create a question related to a particular subject. Click the link Ask a Question to lead you to the topic

Note: You can also perform this action from the **Documents Actions** dropdown on the top menu bar.

e-Signature

In this section we discuss about the various ways of e-Signature used to sign the documents.

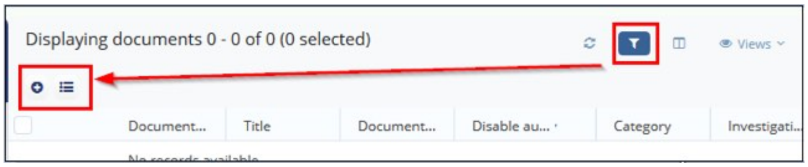
Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

Grid Filters

For a document grid, you can apply and save filters to make the search for the documents easier.

To apply filters:

1. Click the **Filter** icon above the document grid.
2. The Filter options are enabled at the top left corner of the documents grid. Refer to the screenshot below:

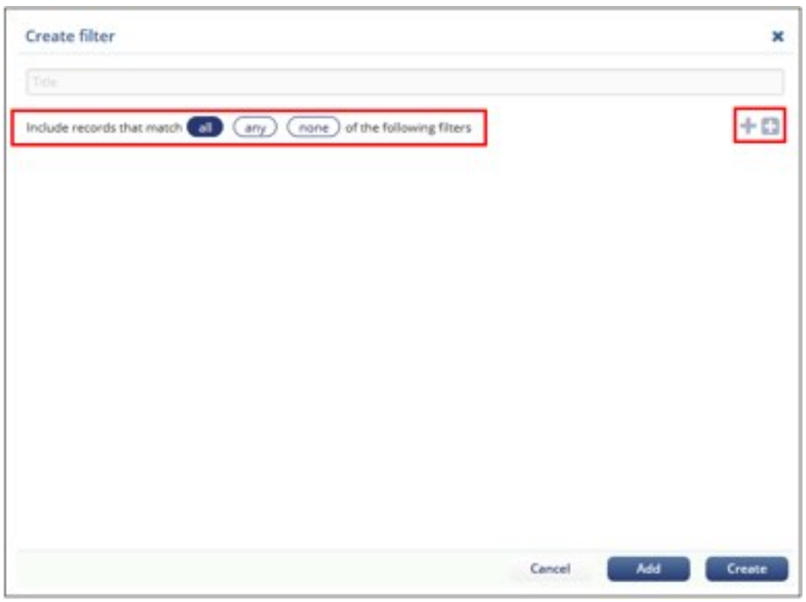


3. From the enabled options, you can perform the following:
   a. Create New Filter
   b. Manage Filters

   Each of these is discussed in the separate sections below:

Creating New Filter

1. Click the + sign above the documents grid.
2. The **Create Filtter** window opens. The window displays the following:
   a. A textbox which displays the **Title** for the filter selected.
   b. The options for matching the filter records. Refer to the screenshot below:

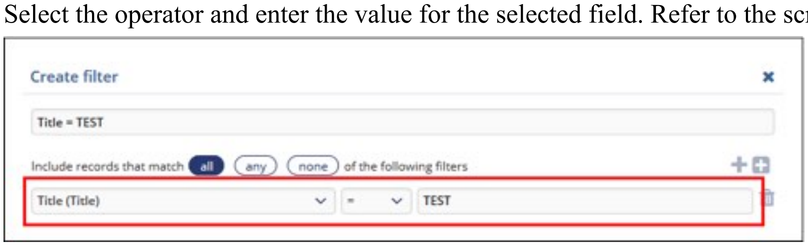


3. Notice that there are two + plus signs to the right of the window wich allows you to create a **single filter** and **group of filters.**

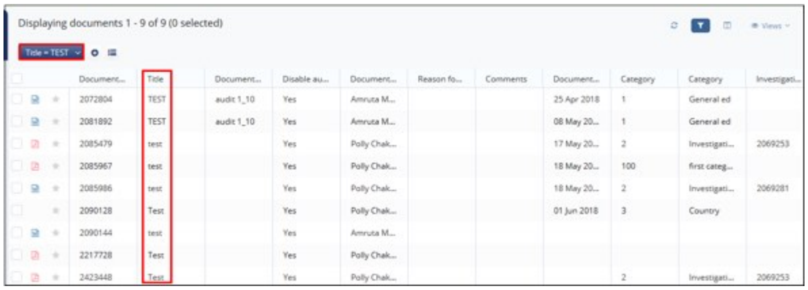
   Adding Single Filter

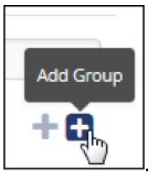
4. To add a single filter, click the **first** + sign. Refer to the screenshot below:

5. A dropdown appears. Click the dropdown and select the fields to which you want to apply filters.
6. Select the operator and enter the value for the selected field. Refer to the screenshot below:



7. Click **Add** if you wish to display the filter in the current view or click **Create** if you want to save the filter and use it later.
8. After creating a filter, when you select the filter and apply it for the document grid, the search results display accordingly. The screenshot below shows an example for the filter result applied for the **Title = Test**.

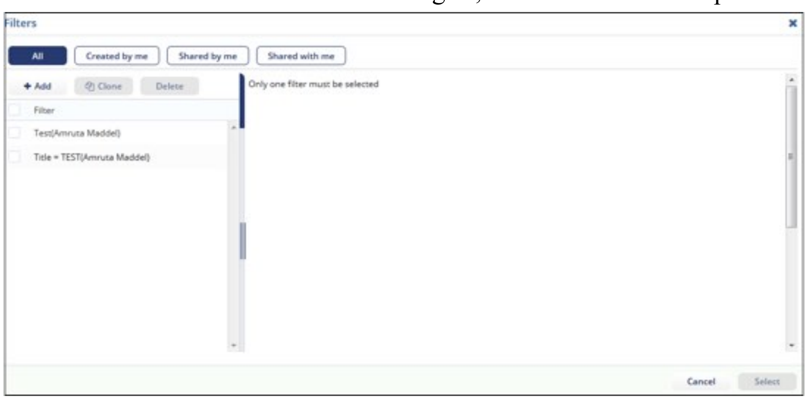


9. Similarly, you can add group filters to apply for document grid and search for the results by clicking the second + sign 

. Proceed further as discussed above to add group filters.

Manage Filters

Manage filters allows you to view and share the created filters by you and by others. When you click the Manage Filters  icon above the documents grid, the **Filters** window opens. Refer to the screenshot below:



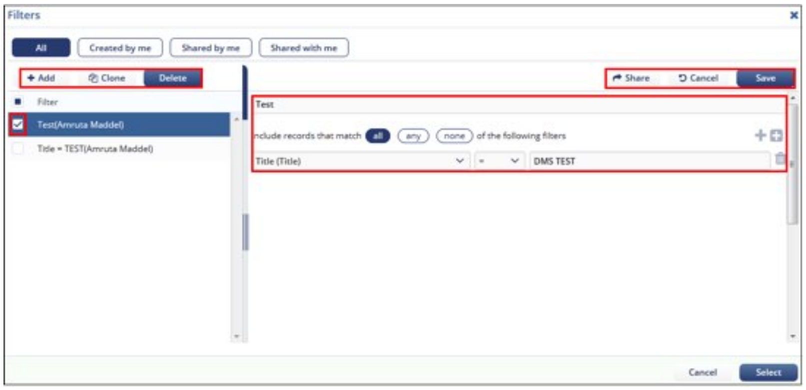
You can perform the following activities on the filters in Manage Filers window:

1. Share Filters
2. Clone Filters
3. Delete Filters

Sharing Filters

To share a filter:

1. Select the filters from the list of filters in the **Filter** window.
2. The selected filter appears in right pane of the window and the buttons **Clone**, **Delete**, **Share**, **Cancel** and **Save** are enabled. Refer to the screenshot below:



3. After selecting a filter, click the **Share** button. The **Share** window opens.
4. Select the **Users / Groups** to whom you want to share the filter and click **Share**.

Deleting Filters

Similarly, select the filter from the list of filters and click **Delete** to delete the filter.

Viewing Shared Filters

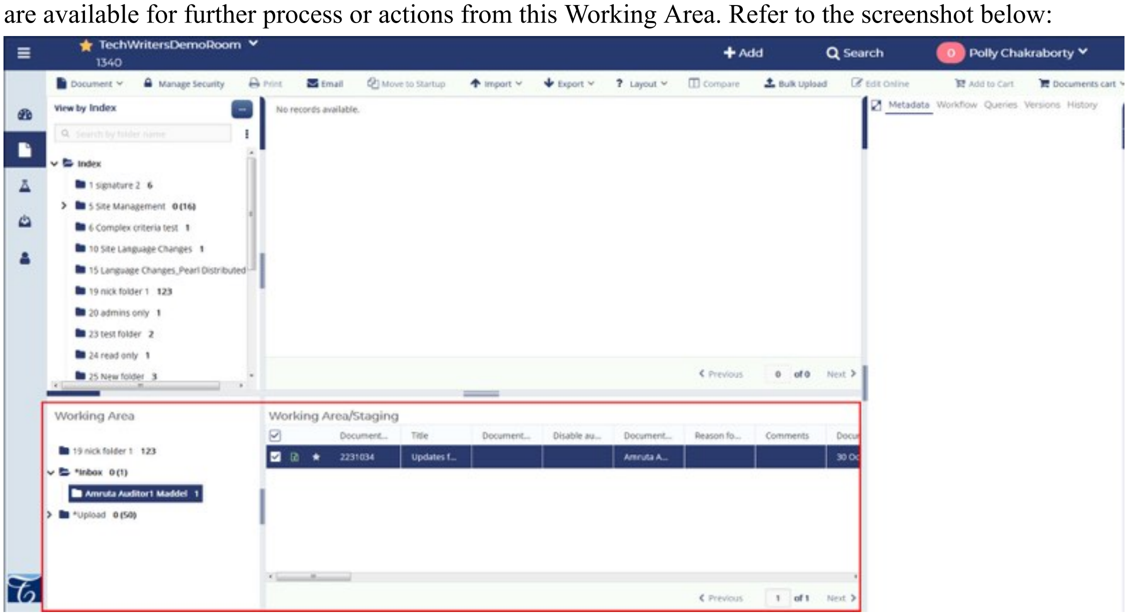
You can view the filters that are **created by you**, **shared by you** and that are **shared with you** by clicking the required tabs in the Filters window.

The Working Area and Grid

When you open the **eTMF/Documents** module, the following appears:

1. The Room Index on page 55
2. The Documents Grid
3. The Working Area and Grid

In Trial Interactive 10, the eTMF index is separated from the working folders which include Working Documents, Rejected Documents, Uploaded and Emailed documents . User can perform various actions like **document coding**, **document replacing and attaching** , **adding documents to workflow or audit** etc. from this Working Area. The folders in the working area are hard coded and any documents coming in the room, either by uploading or emailing are available for further process or actions from this Working Area. Refer to the screenshot below:

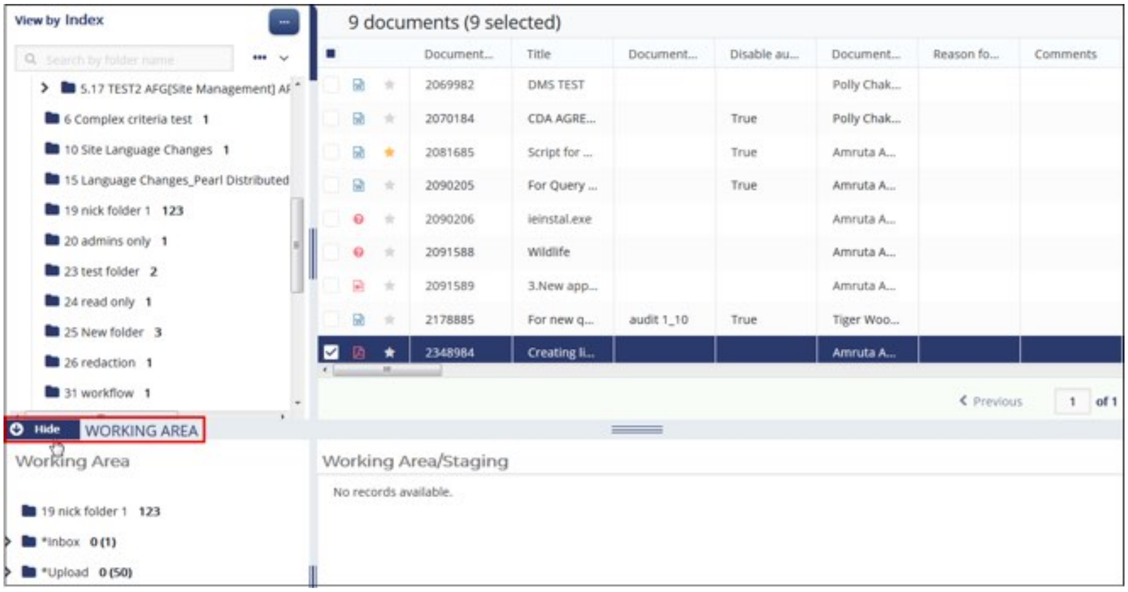


Besides working on documents, you can also drag and drop the documents from the Working Area to the required eTMF folders above like for the **Country** and **Site** views, the user can easily drag and drop documents from the working folders into **missing documents** and **placeholders** in the eTMF.

Note: *Documents can be dragged only out of Working Area but not into the Working Area.*

Hiding or Unhiding the Working Area/Staging panel

To hide or unhide the Working Area, hover the mouse over the bar above the Working Area. The **Hide - Working Area**bar appears. Refer to the screenshot below:



Hiding the Working Area

You can also drag the Working Area/Staging to the extreme left to hide the Work Area. Refer to the screenshot below:

Similarly, you can also drag the Working Area/Staging Area **up** to increase the size of the window and the number of documents count in the grid.

The Document Data Panel

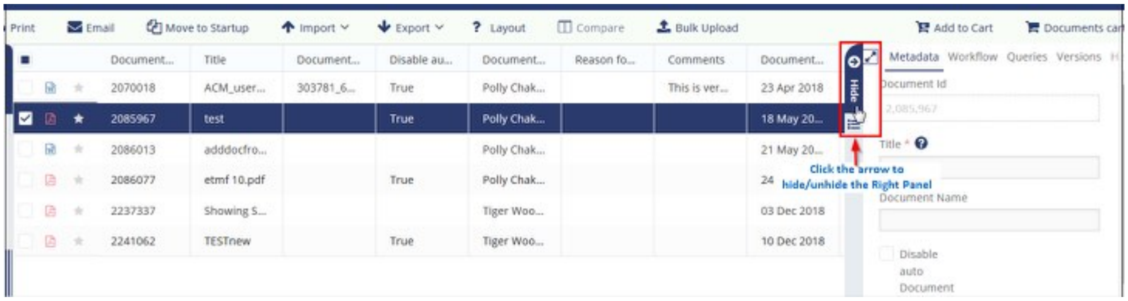
The Right Panel opens by default in the **eTMF Documents Module** when you click **Documents** from the left pane.

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

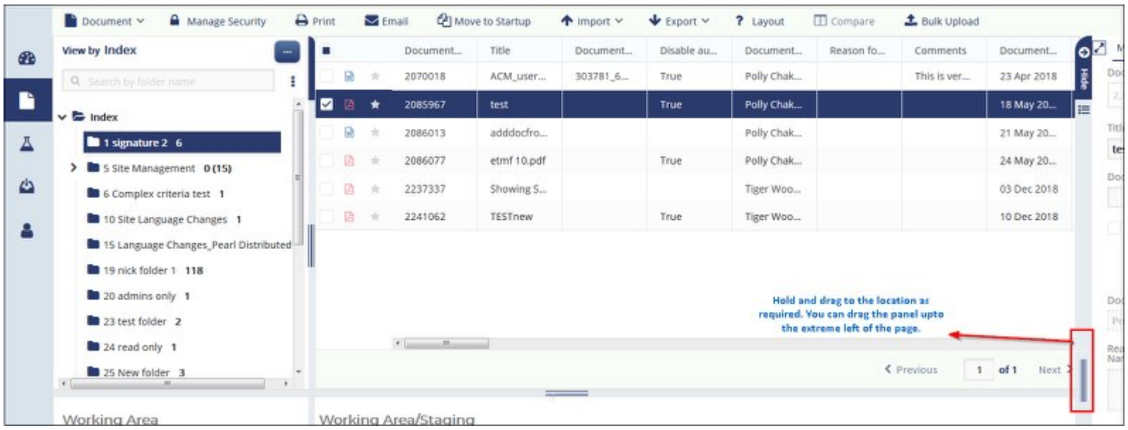
1. Metadata panel
2. Workflow panel
3. Queries panel
4. Versions panel
5. History panel
6. eSignature panel

Each of the functionalities above are discussed in separate topics available from the left panel of this help.

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



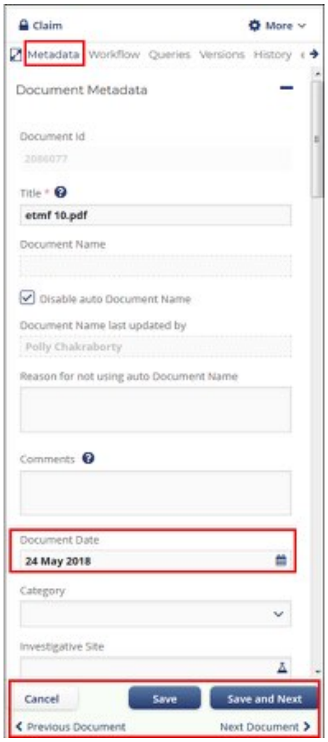
Besides, you can also hold the panel and drag it to the extreme left of the page. Refer to the screenshot below:



Metadata Panel

Metadata Panel is activated by default when you select a document.

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



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

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

The Metadata Panel also provides the **Claim** button and the **More (Settings)** icons at the top of the panel to allow you to claim docuemnts in a workflow and perform various actions on the document.

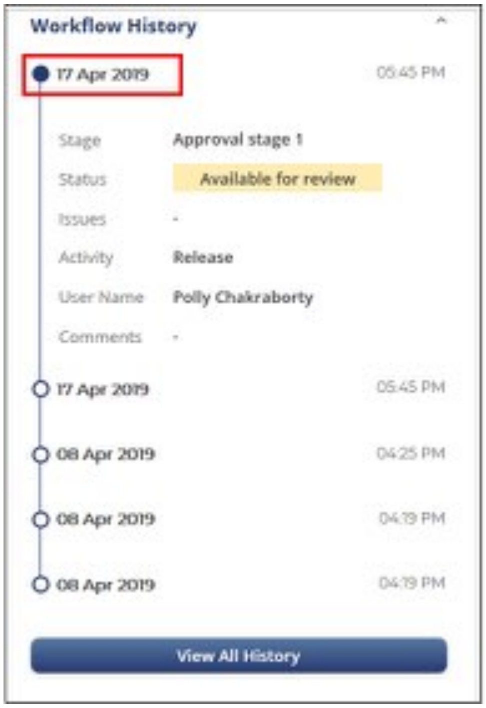
Workflow Panel

You can do the follwing from the Workflow Panel:

1. Claim Documents in a workflow
2. View the Workflow History
3. Initiate a Query
4. Release a document from a workflow'
5. Reassign Reviewer
6. Exclude document from a workflow

The Workflow panel dispalys all the details of the document workflow.

Click the **Date** to view from the **Workflow History** section to view the full history of the dcocument in a workflow as shown in the screenshot below:



Queries Panel

From the Queries tab, you can not only view the queries received, but also can resolve them.

You can view queries in TI by various methods:

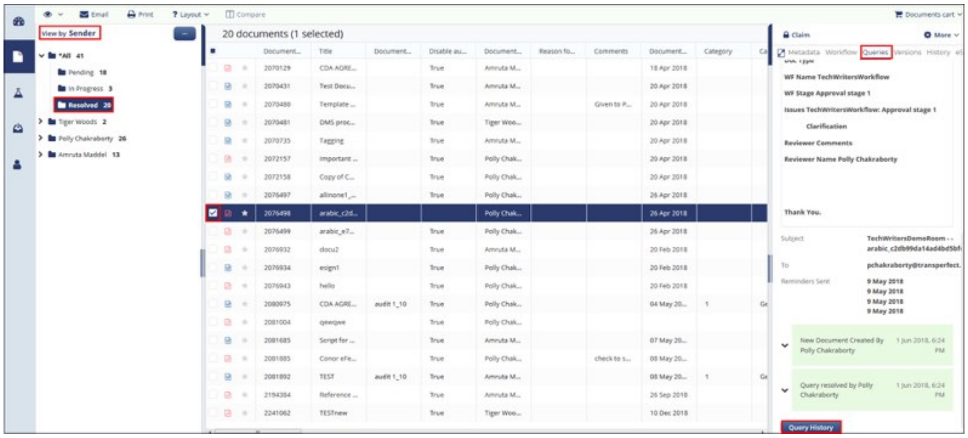
1. **Query Email :** By the Query Responder from the query email received in his/her inbox
2. **By Recipient View** : The Query Responder can view the queries received under the By Recipient view if the said query responder has access to such a TI room and documents related to the query.
3. **By Sender View**: The Reviewer can view the queries from the By Sender view if such a reviewer is the creator and sender of the query.
4. **By Reviewer**: This view is available only for admins and such a user can view the queries sent and responded by all the reviewers. (add to profiling for admins)
5. **By Reviews**: The reviewer can view all the queries from the By Reviews view which he/she has initiated.

Viewing a Query

To view a query, follow the steps as below:

1. From the **eTMF/documents** application, click **Choose View** next to the Index View.
2. The **View Documents By** popup appears.
3. Select the **By Sender** view and click **Select** at the bottom of the page.
4. The folders with the name of reviewers appear.
5. Click the required folder. The following folders are available for the query:
   a. **Pending**: This folder contains all the queries sent and are awaiting the response.
   b. **In Progress**: This folder contains all the queries which are responded.
   c. **Resolved**: This folder contains all the queries which are resolved.
6. Select the required document from the grid and click **Query** tab from the metadata panel.
7. The queries display in the **Queries** panel.
8. Click the query to view the full query history.
9. The query displays the following:
   a. The email body of the query that was initiated.

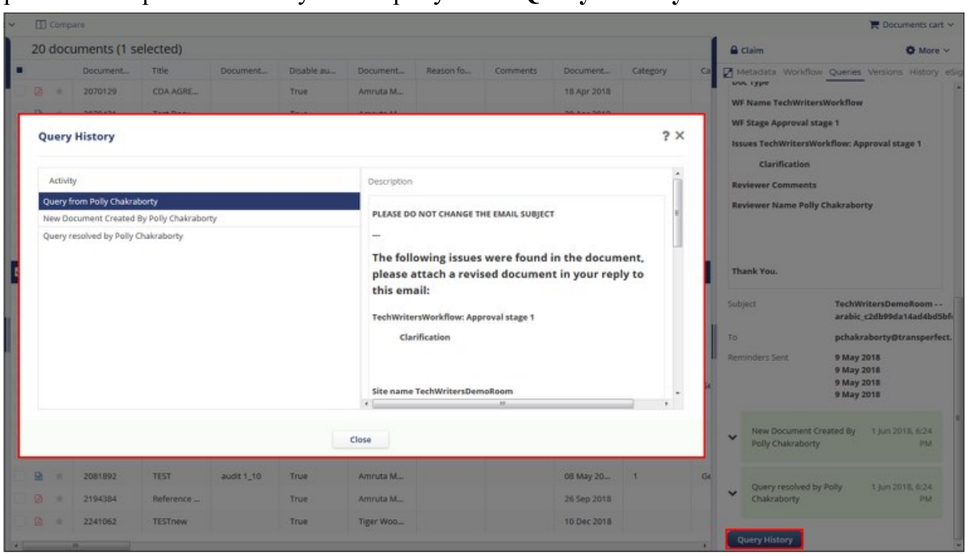
b. The responses and attachments to the query displayed by green sections. Refer to the screenshot below:



c. Expand the required section to view the details for the sections.

Viewing Query History

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



From the Query History window, select the required query activity from the left pane and the details of the history displays in the right pane.

Versions Panel

Versions Panel allows you to view and compare the different version of a document.

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

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

History Panel

The History panel gives an overview of a document history. This panel displays the top four entries of the activities performed on the document. Here, you can apply filters to view the history of a document. Refer to the screenshot below:

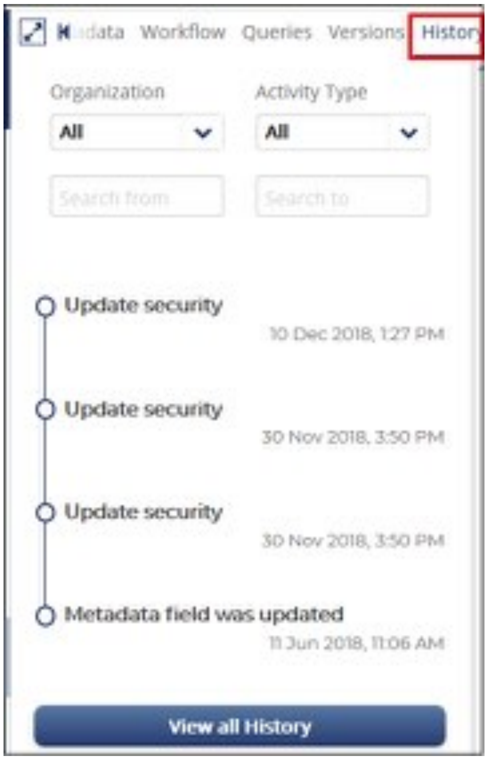
Document History Filters

The History Panel provides the following filters to allow you to view a document history:

1. **By Organization**: Use this filter if you want to view the document history based on the organization.
2. **Activity Type**: Use this filter if you want to view the document history by the activity performed on it.
3. **Date Filter**: Use this filter if you want to view the document history within the set date range.
4. **View All History**: Click this button to view the full history of a document. The full document history opens in a popup. You can also apply the filters from the **All History** popup.

Viewing Document Activity

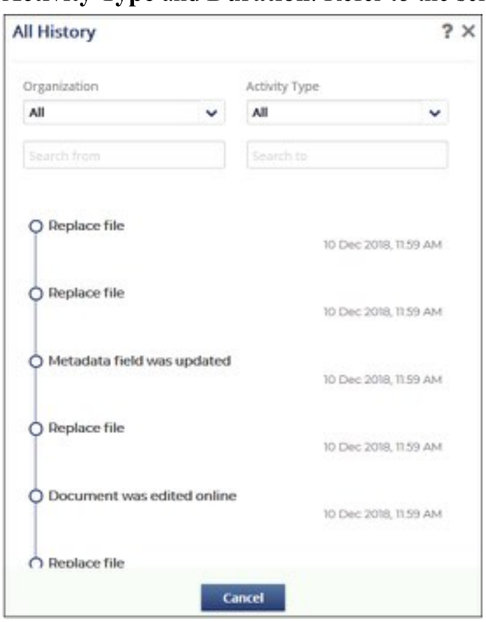
Every activity in the History panel is denoted by a node. Click the node to view the **description**, **date**, **time**, and **name of the person** who performed the activity on the document. Refer to the screenshot below:



Viewing All History

Clicking the **View All History** button 

opens the **All History** popup which displays the complete history of a document and also allows you to filter the document history based on the **Organization**, **Activity Type** and **Duration**. Refer to the screenshot below:



eSignature panel

The eSignature Panel:

1. Allows send the document for eSignature if it is not initiated for eSignature yet.
2. Display the status of the document eSignature if it is initaited for eSignature.

Besides eSignature Panel, you can aslo send the documents for eSignature from the **Document Context Menu** by right clicking on a document.

Cancel eSignature

If the document is waiting for eSiganture, the eSignature Panel displays the status of the document as shown in the screenshot below:

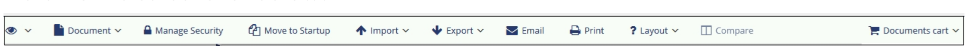
Select the eSignature and click the **Cancel E-Signature** button at the bottom of the eSignature Panel if you wish to cancel the eSignature of any document. Click **Yes** on the pop-up that appears to confirm the cancellation.

The Top Ribbon Bar

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

- The Document Actions
- Print
- Email
- Export
- Comparing Documents
- Documents Cart
- Dashboard Layout

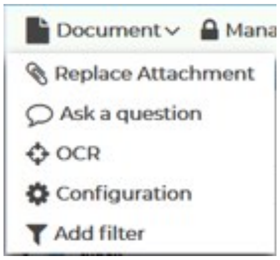
Refer to the screenshot below:



Each of the above functionalities is discussed in separate topics available from the left panel of this help.

Document Actions

You can perform the horde of activities on a document by from the Document Dropdown located on the top ribbon bar of the eTMF Documents Dashboard.



Each of the functionalities are discussed in sections below:

Replace Attachment

To replace a document attachment or URL:

1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.
2. The dropdown appears.
3. Select **Replace Attachment / Add URL**.
4. The **Replace Attachment / Add URL** popup window opens.
5. Select the **File** radio button to replace an attachment, or select the **URL** radio button to replace the URL
6. To attach a document click **Browse** and select the required document from the Explorer, whereas to replace a URL ????
7. Enter the reason for replacement.
8. Click **Apply**

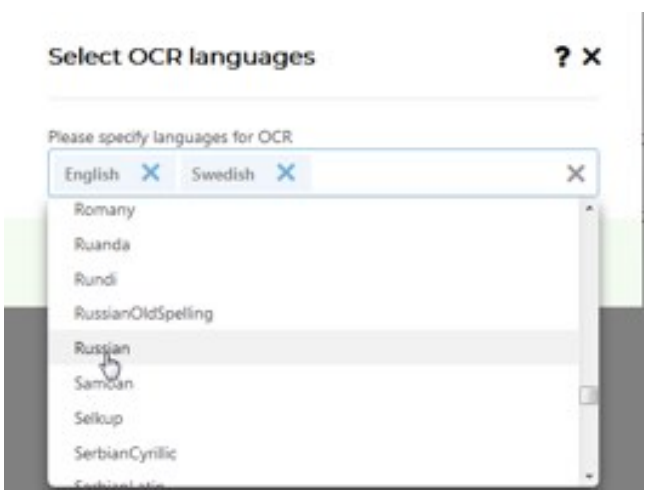
Ask a Question

Click the link Ask a Question to lead you to the topic.

OCR

To select languages for OCR:

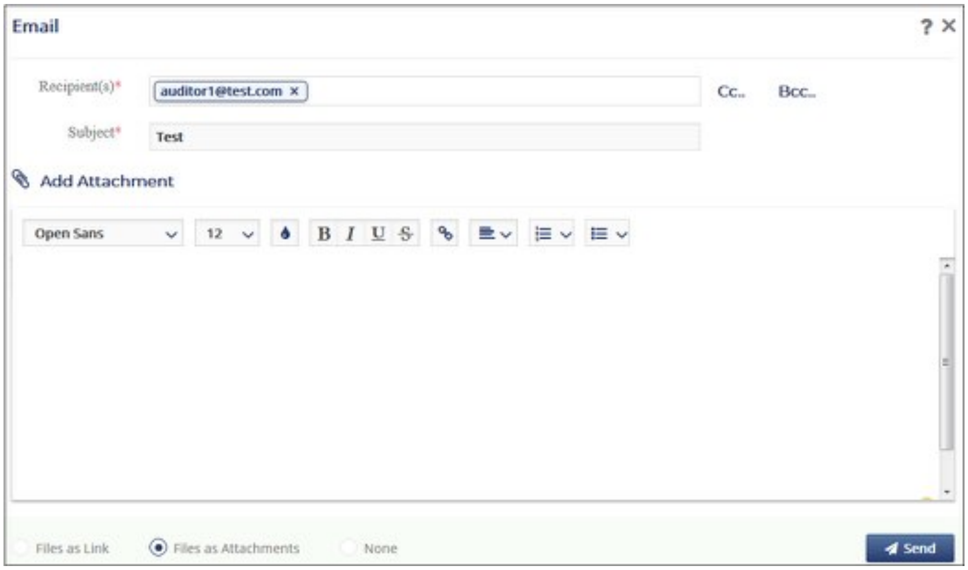
1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.
2. The dropdown appears.
3. Select **OCR**.
4. The **Select OCR languages** popup appears.
5. Click the textbox and select the languages as applicable from the dropdown.



6. Click **Ok.**

Email

To email a specific document as attachment or as a link, click the **Email** option from the top robbon and follow the on-screen instructions. You can save an outgoing email as a PDF documnent. On clicking **Send**, the **Save Converstion** dialog box opens up. Refer to the screenshot below:



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

Print

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

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

icon from the top ribbon. The **Print** window opens.
4. Click the appropriate radio button, **Selected Records** or **All Records in Set**.
5. Click **Print**.
6. Follow the usual steps of creating a printout from your computer.

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

Export

Documents can be exported from:

1. The **Export** dropdown from the top ribbon bar
2. The **Documents Cart**
3. The **Download documents** when opening a document in the **Original Viewer**

   Three options are available for Administrators from the **Export Dropdown** on the top ribbon bar - **Metadata**, **Documents**, and **Security**. Refer to the screenshot below:

   All of these options are discussed in seperate topics accessible from the left panel of this help.

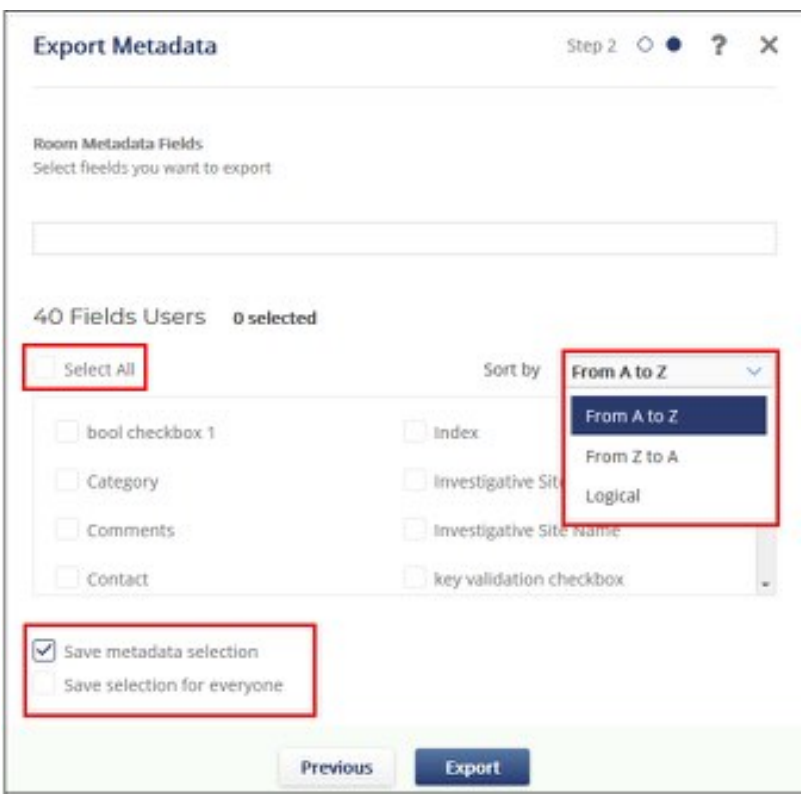
Exporting Metadata

This function gives you a compressed file with the information you requested in XLSX spreadsheet file

To export metadata,

1. Click the **Metadata** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:

2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
   a. **Select All**: Tick this checkbox if you wish to select all metadata fields.
   b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.
4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:

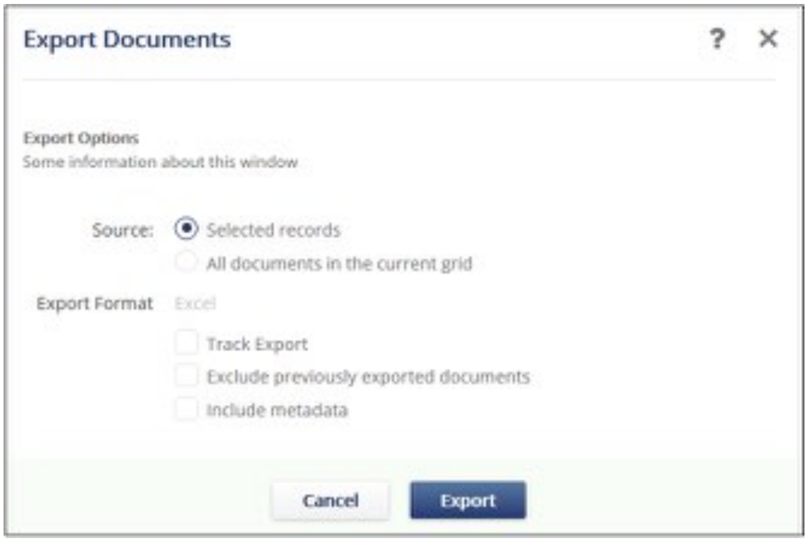


5. Click **Export**.

Exporting Documents

Exporting documents is same as downloading documents from the **Documents Cart**.

You can **track an export**, **exclude previously exported documents**, or **include metadata during export**. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.



The documents or selected documents get exported in a .zip file. The .zip will include the following:

1. A **folder with the exported documents** in it.
2. An **excel worksheet** with the metadata, if you happen to export metadata.
3. A **.log** file which opens in Notepad to give the list of previously exported documents that were excluded during export. Here again, you have to select the option to exclude previously exported documents to enable this.
4. An **ErrorsLog.xml** file that includes details of documents that fail to export.

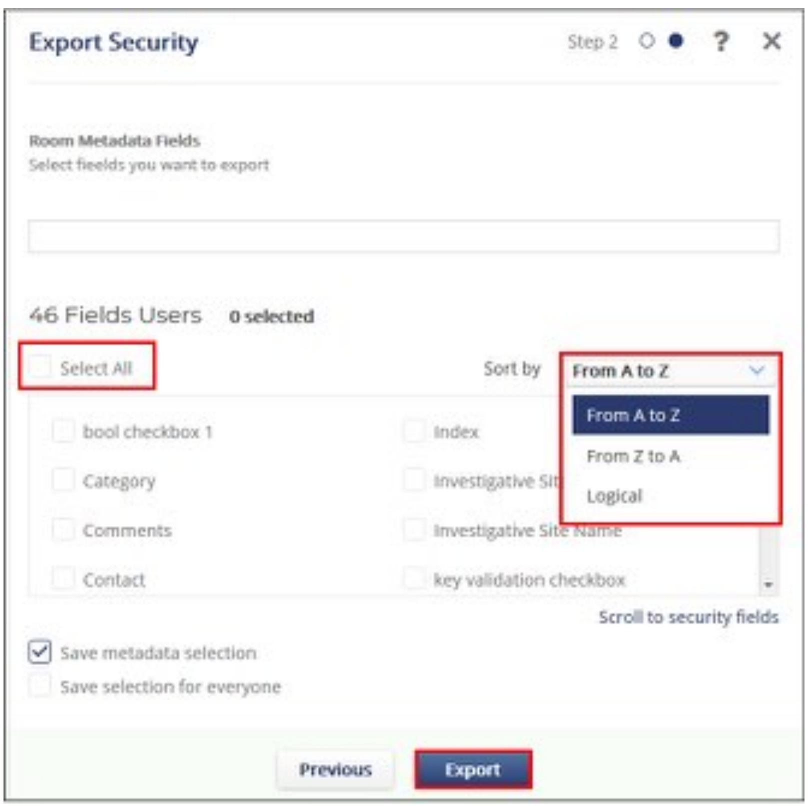
To view the exported file, navigate to the **Notifications .**

Exporting Security

This allows you to export all the security accesses for selected records for all documents in the grid, all documents in the room. The output of the export job is an .xlsx file that can be accessed from the **Notifications.** Follow the steps below to export documents security:

1. Click the **Security** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:

2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
   a. **Select All**: Tick this checkbox if you wish to select all metadata fields.
   b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.
4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:



5. Click **Export**.

Layout

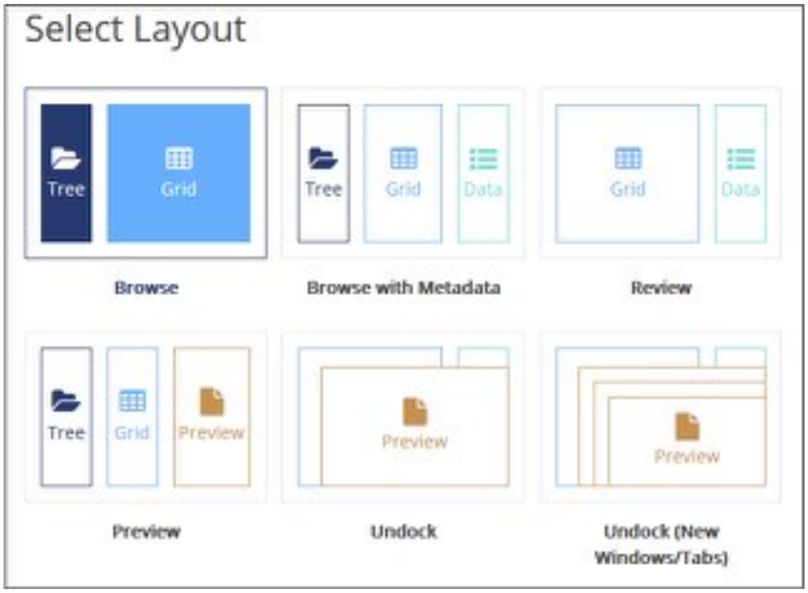
You can change the layout view of the grid by clicking the Layout option from the top ribbon bar. Follow the steps below to change the layout of the gird.

1. Navigate to **eTMF Documents module.**

2. Select the **Layout** 

option from the top ribbon bar. The **Select Layout** popup opens.

   Refer to the screenshot below:



3. Select the required layout and the document grid sets it layout as selected.

Compare

Documents can be compared from in the following ways:

1. From the top ribbon in the eTMF Documents module.
2. From the Documents Cart.

To compare docments,

1. From the **eTMF Documents** module, select the folder from the Index to open the documents in the grid.
2. Select the required documents to compare and click the **Compare** 

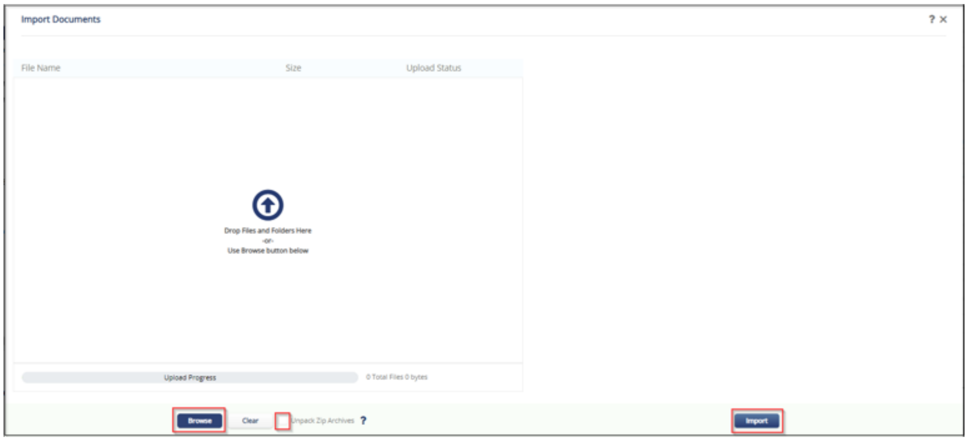
option from the top ribbon bar.
3. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the viewer chosen by you. You can also expand the metadata fields on the bottom using the double-caret bar to compare documents metadata conveniently at once.

Bulk Uploading

Besides Importing documents, you can also upload documents in a bulk to the room. Follow the steps below to bulk upload documents in a room.

1. Navigate to **eTMF Documents** module.
2. Click the **Bulk Upload** 

option from the top ribbon bar. The **Import Documents** window opens.
3. Following the on-screen instructions, either drag-and-drop files from your own computer into the upload panel or use the **Browse** button on the window to select documents to upload. Refer to the screenshot below:



4. Choose **Unpack Zip-archives** if you wish to extract files from an attached zip folder.
5. Tick the checkboxes for documents to be uploaded and click **Import.** These documents are uploaded to the upload folder. You can later edit the metadata of these documents from the **Metadata Panel** as required.

Documents Cart

Perform various functions from here like **copying documents to rooms or sites, comparing, merging or linking** documents besides many more.

Users select documents to add to the Document Cart either from the Documents Context Menu, or by selecting documents from the grid and then clicking the **Add to Cart** button from the top ribbon menu.

The **Documents Cart**  icon is located on the upper right hand corner of the document grid and works just like a shopping cart.

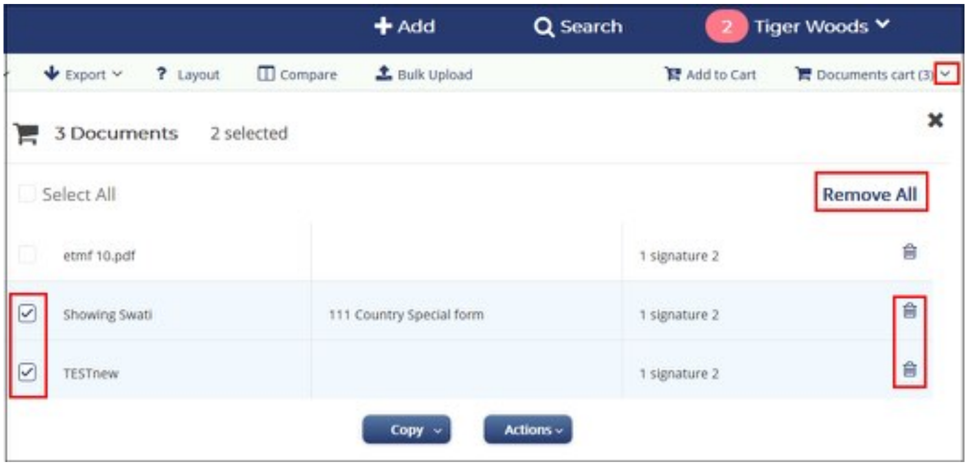
Adding documents to the Documents Cart

1. Locate the document which is to be added to the Document Cart and select the checkbox next to it. Now process of addition can be done in two ways.
   a. Click **Add to Cart** from the upper right hand corner.
   b. Right click and select **Add Selected to the Cart** option.
2. Once a document is added, it will automatically update to reflect the number of documents available in the cart. Refer to the screenshot below:

Removing documents from the Documents Cart

Follow the steps below to remove documents from the Documents Cart:

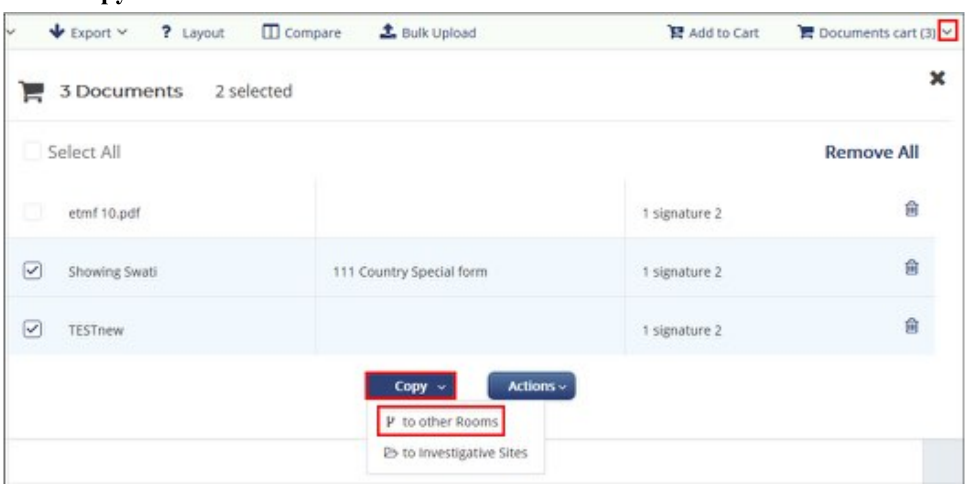
1. Click the arrow next to the **Documents Cart**. A popup window opens.
2. Select the checkboxes next to the documents and click Delete  button to the right of the selected documents.
3. If you wish to remove all the documents, click the **Remove All** button. Refer to the screenshot below:



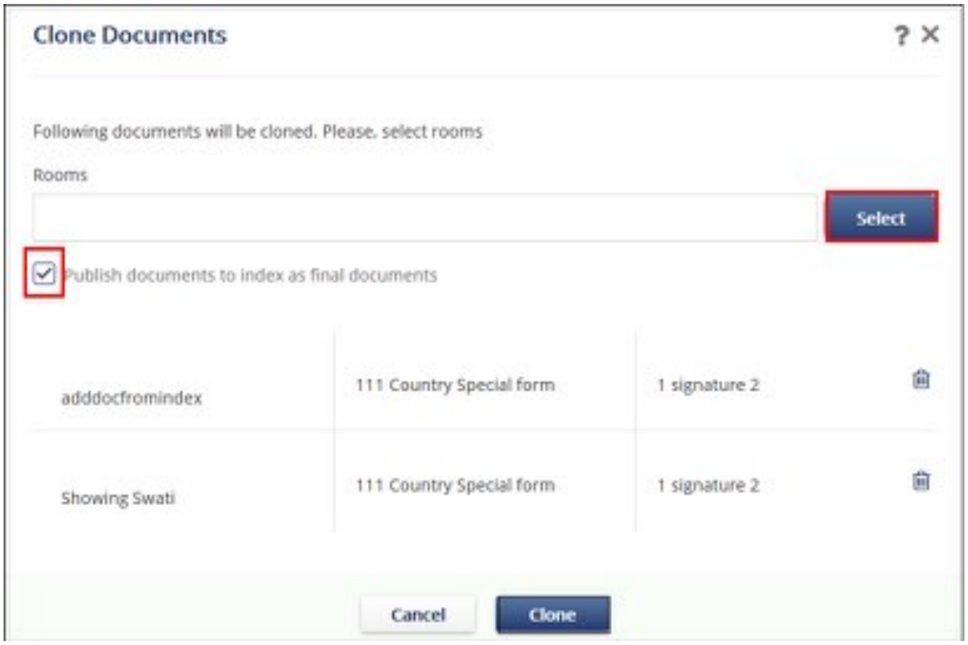
Copying documents to Other Rooms

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

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



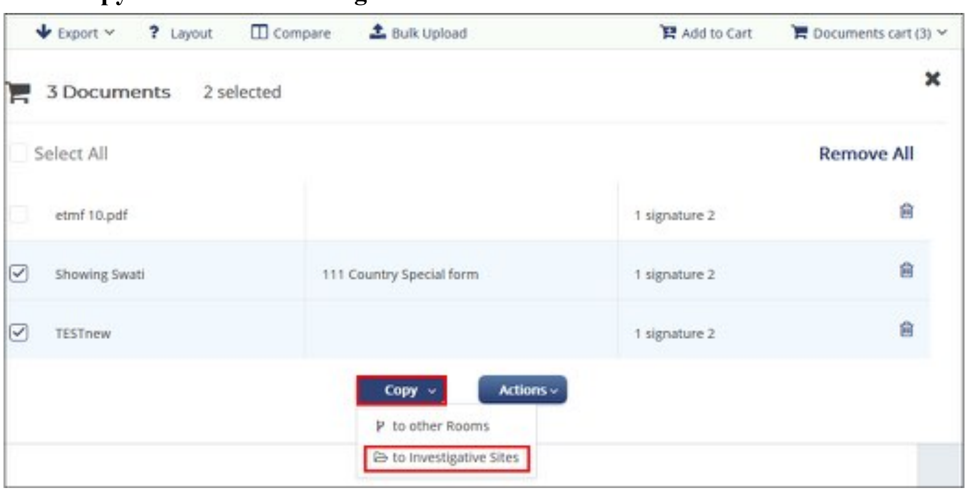
5. The **Clone Document** window will open up and prompts you to specify to which study rooms documents shall be copied.
6. Click the **Select** button which opens the **Rooms** window to allow you to select the rooms to copy the documents to.
7. If you wish to publish documents to the insdex as final documents without going through the workflow, select the checkbox next **to publish documents to the index as final documents**.
8. Click **Clone**. The document type of the destination room will determine the auto-naming rule for the document. Refer to the screenshot below:



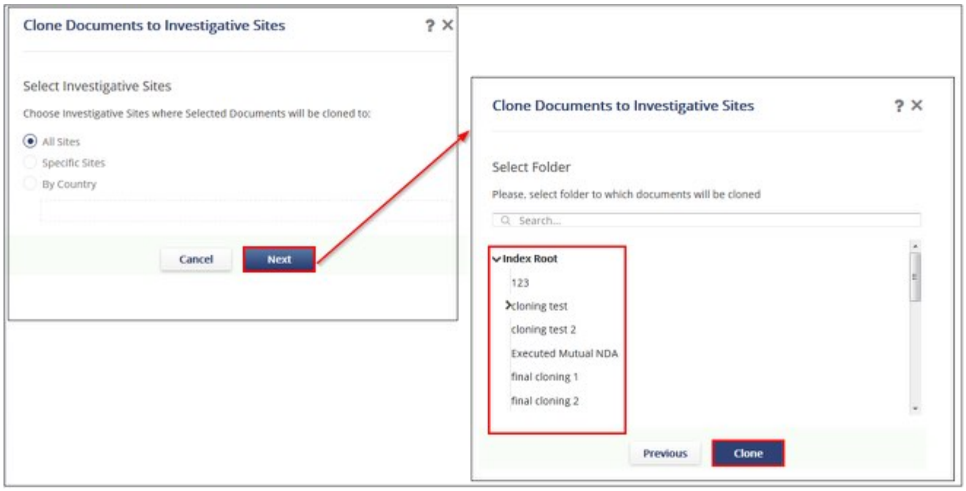
Copying documents to Investigative Sites

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

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



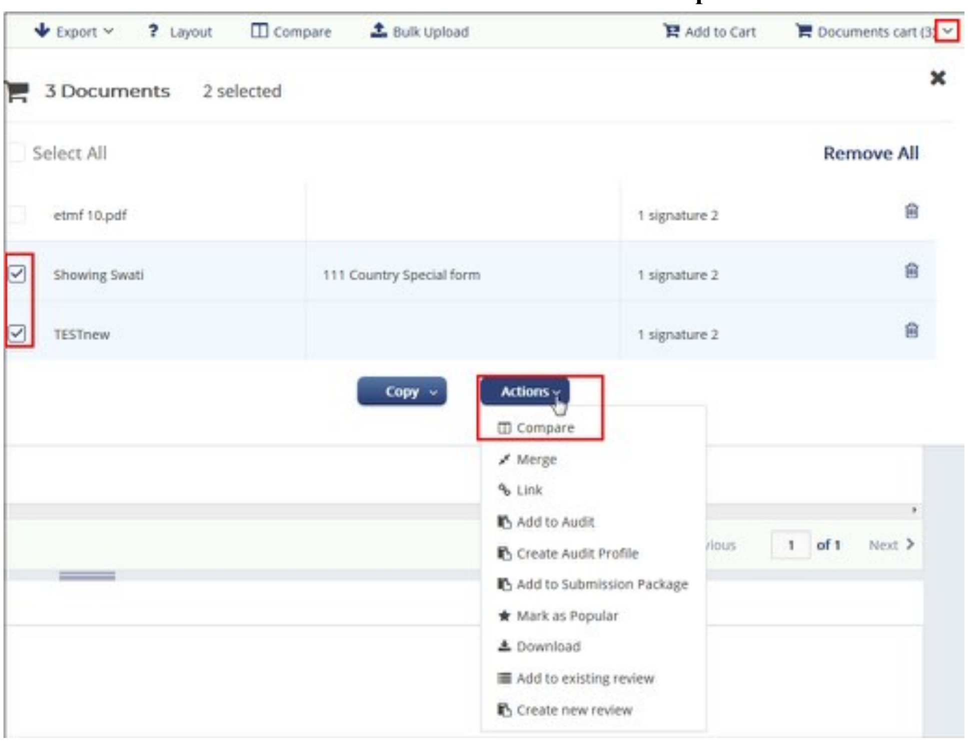
5. The **Clone Documents to Investigative Sites** window opens up and asks you to select investigative sites. Click radio button next to your choices.
   a. If you choose **All Sites**, just click **Next**, to select the folder to which the documents will be cloned.
   b. If you choose **Specific Sites**, just click **Next**, and it will give you site choices on the next section.
   c. If you choose **By Country**, a dropdown with the list of countries gets activated for you to choose from.
6. Click **Next** folder selection.
7. Once the folder is selected, click **Clone**. The documents are copied to the Investigative Site folder. Refer to the screenshot below:



Compare Documents

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

1. Add required documents to the Documents Cart.. A pop-up window opens.
2. Select the documents from the list you wish to compare.
3. Click **Actions** at the bottom of the window and then select **Compare**. Refer to the screenshot below.



4. The documents open in the **Compare Documents** window with each document side in a seperate window of their own using the **Arender** view. Refer to the screenshot below:
5. To facilitate easy and seamless comparison of documents:
   a. The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
   b. The **documents scroll at once in sync** with each other when you drag the scroll bar to facilitate easier viewing and comparison if you have activated the 'Synchronize document scrolling' from the toolbar.
   c. The system displays appropriate messages when two documents are identical.

d. The print and download options for comparison are available to you only if you have **Full Access** to the documents.

Merging documents

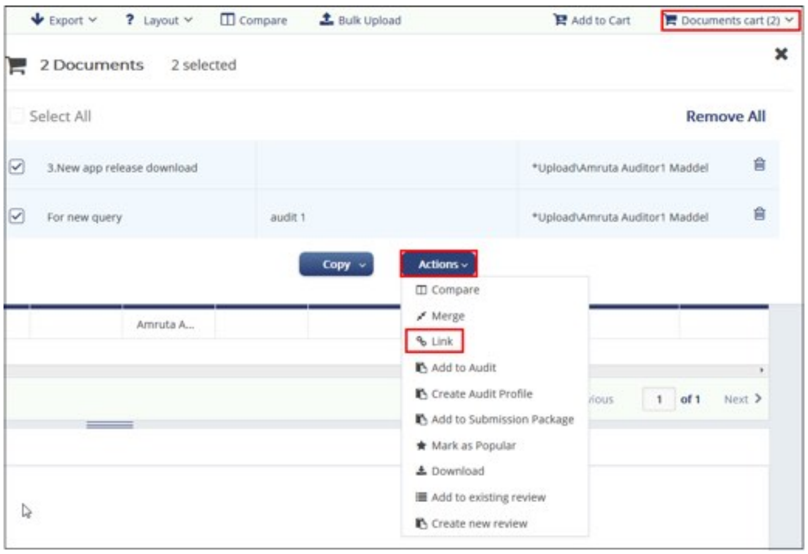
An Administrator user can merge two or more documents into one document.

1. Add required documents to the Documents Cart..
2. Select the documents form the cart you want to merge into one, either to use as a single document in the room or to download and print as a single document..
3. Click **Actions** and then select **Merge**. Refer to the screenshot below.

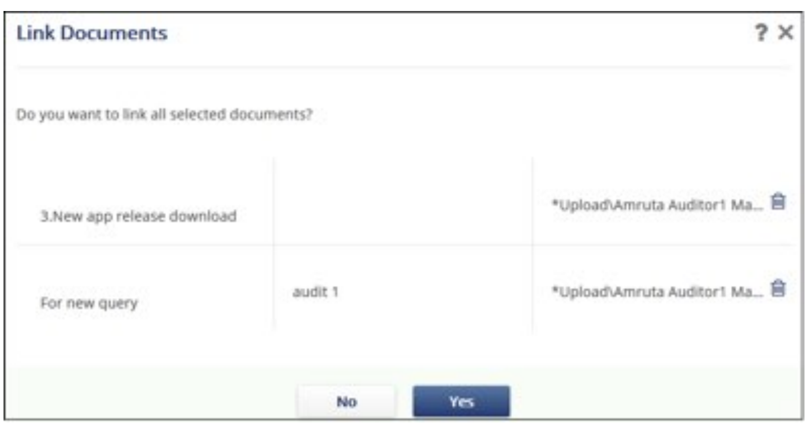
Linking documents

Administrator users can link documents together with this option.

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



4. The **Link Documents** window opens. Select 2 or more than 2 documents to link and click **Yes**. Refer to the screenshot below:

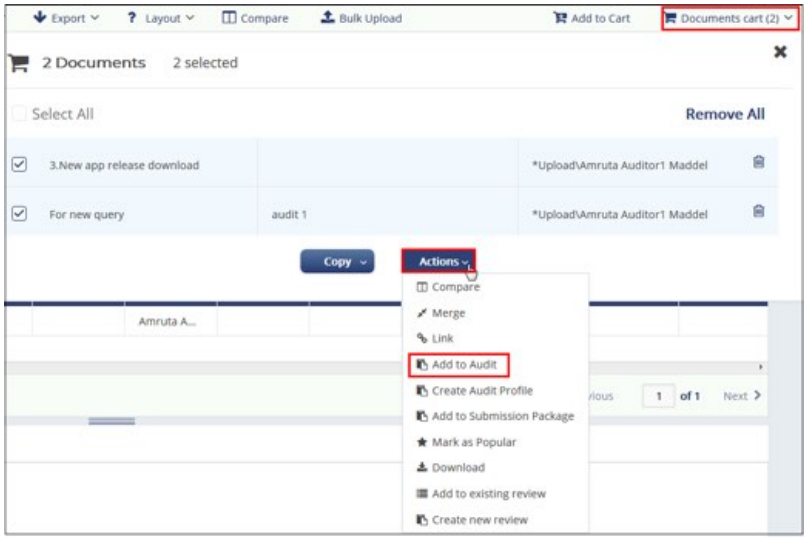


5. A pop-up message appears to confirm the documents are successfully linked.
6. Afterward, whenever you right-click on one of the linked documents and click **Related Documents**, interrelated documents will all be displayed on the screen.

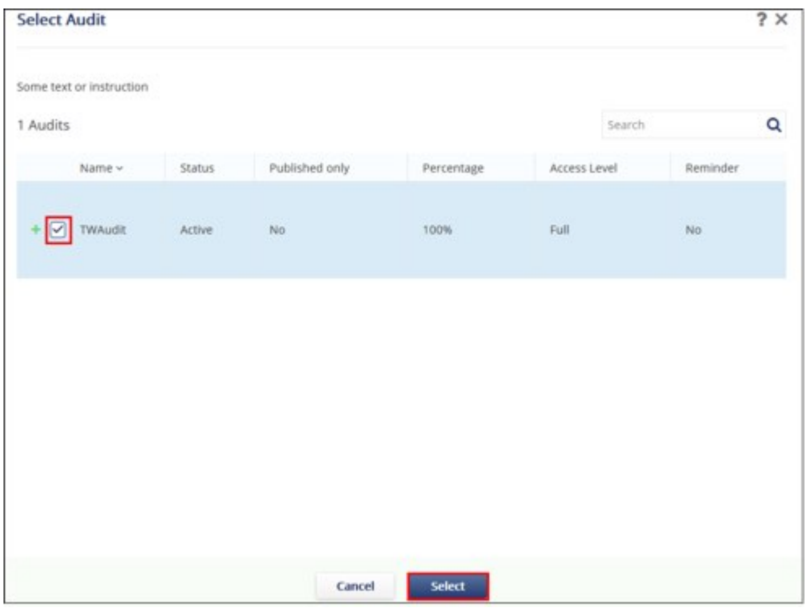
Adding documents to Audit

Admin can add documents to the cart from the grid and include them in an existing audit by using the **Add to Audit** option.

1. Add required documents to the Documents Cart.
2. From the Documents Cart, select a document.
3. Click **Actions** and then select **Add to Audit**. Refer to the screenshot below:



4. The **Select Audit** window opens.
5. Select the Audit to which you wish to add documents to.
6. Click **Select**. Refer to the screenshot below:

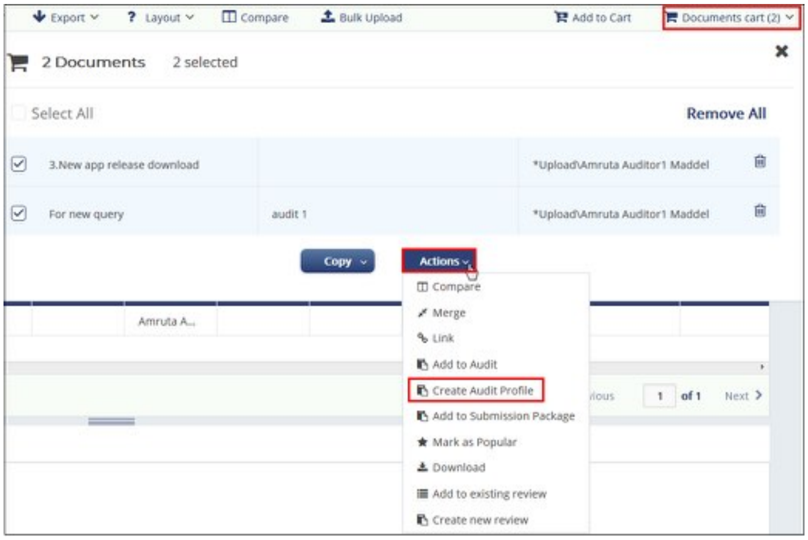


Note: *The Audits in the Select Window are displayed only when you select Add Documents to pool on Demand Basis option while creating an Audit profile.*

Create Audit Profile

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

1. Add required documents to the Documents Cart.
2. From the Documents Cart, select a document.
3. Click **Actions** and then select **Create Audit Profile**. Refer to the screenshot below:



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

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

Adding documents to Submission Package

Admin can add documents to the cart from the grid to include them in a start-up submission package by using this option.

1. Add required documents to the Documents Cart..
2. Select the documents from from the cart.
3. Click **Actions** and then select **Add to Submission Package**. Refer to the screenshot below:
4. The **Select a Submission** window opens.

Marking documents as Popular

Administrator users can mark certain documents as popular using this option.

1. Add required documents to the Documents Cart.
2. Click **Actions** and then select **Mark as Popular.** Refer to the screenshot below.
3. A pop-up message- **Documents successfully marked as popular** appears.
4. The selected documents now appear on the dashboard- **Popular Documents** dashlet

Downloading documents

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

Potential Sites and IRB Integration

This allows you to locate the Unique Sites using the combination of Study Name and Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

Note: *If the system finds matching conditions like 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.*

This section includes the following sections:

1. IRB Integration and Settings
2. Potential Sites and Modules

FAQs

The FAQ icon in the Main Navigation allows you to view the list of FAQs.

You can reach this page by clicking the FAQ icon from the Main Navigation.

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

Readers have the option to search the FAQ by typing keywords in the search box located on the top right corner of the screen. Although readers can access FAQ, they are not able to set-up FAQ.

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. Refer to the screenshot below.

Q&A

Q&A application enables you to view the list of questions asked and anwers given by users in a room besides creating them.

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

From the Main Navigation select **Q&A** to reach this dashboard. Refer to the screenshot below:

From within the *Q&A* dashboard, you can:

1. Viewing Questions and Answers
2. Create questions

Q&A Module

You can perform the following from this page:

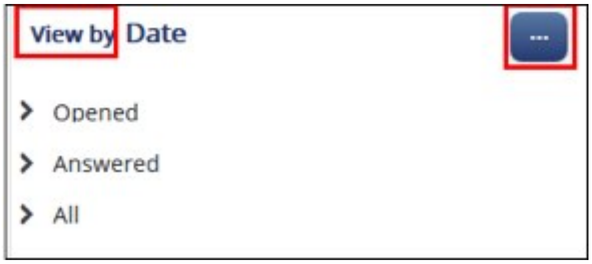
1. Creating Questions
2. Creating Answers
3. Convert Questions to FAQs
4. Export Q&A
5. Delete Q&A

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

View Q&A

To view the questions and their answers, follow the steps as below:

1. Click the **three dots** at the top right corner of the **View By**pane. Refer to the screenshot below:



2. The **View Q&A By** popup opens. Refer to the screenshot below:

The table below provides more details on each view in the popup:

Table 2: View Q&A By

View Name	Description
By Date	This view groups the questions and their answers by Today, This Week, This Month and Older.
By Subject Matter	This view groups the questions and answers as per the Subject Matter for the questions. To know how to create Subject Matter proceed to the Q&A Settings → Question Subject Matter.
By Issue Level	This view groups the questions and answers as per the Question Level created from the Q&A Settings. To know how to create Subject Matter proceed to the Q&A Settings → Question Level.
By Organization	This view groups the questions and answers as per the various organizations available in the room. You can create the organizations from **Settings** → **General** → **Organizations List**.
By Index	This view groups the questions and their answers under the categories of Opened (Questions not yet answered), Answered, and All.
Make Default	Tick this checkbox to make the selected view the default one. You will be able to see the questions and answers grouped under the default view everytime you visit the Q&A dashboard.

3. Click the desired view and click **Select**. The selected view displays in the Index Pane.
4. Click the arrow next to the parent category in the view. Refer to the screenshot below which show the **By Subject Matter** view.

5. The parent category opens to reveal the child category under it.
6. Click the required child category. The questions and their answers under it display in the grid to right of the dashboard. Refer to the screenshot below:

7. Click the **arrow** next to a question to open it and read its answers.
8. Click the **arrow** again to collapse it.

Creating Questions

You can create questions from:

1. Within the Q&A application by clicking the **Create Question** button from the top ribbon bar

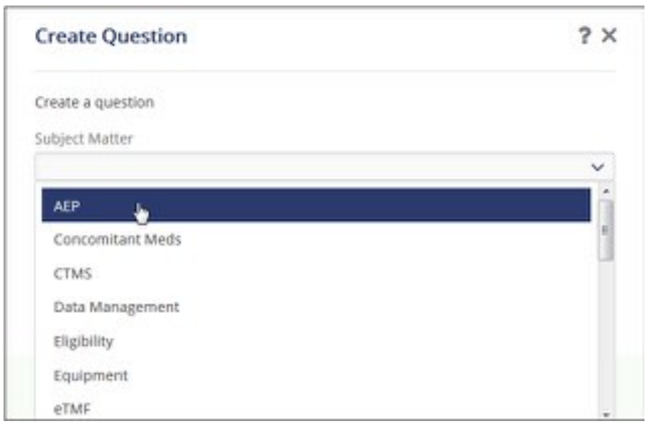
2. Within the eTMF application by clicking the **Ask a Question** option in the **Document Dropdown** or from the **Document Context Menu** for a selected document

Each of the options are discussed in separate sections below:

Creating Questions from with the Q&A Application

1. Click the **Create Question** button 

from the top ribbon bar in the Q&A Application.
2. The **Create Question** popup opens.
   a. From the **Subject Matter** dropdown, select the subject matter as applicable. You may choose to ignore this action. Refer to the screenshot below:



   b. From the **Issue Level** dropdown, select the level for the issue as applicable.
   c. Enter your question in the **Question** textbox below.
   d. Click **OK**.
3. The question appears in the grid to the right of the dashboard.

Creating Questions from within the eTMF Application

From within the eTMF application, you can create questions on a particular document.

1. From the **Index pane** in the **eTMF**, navigate to the child folder and click it.
2. The documents in the child folder display in the **Documents Grid.**
3. Tick the checkbox next to the document in the grid to select it.
4. Click the **Document Actions Dropdown** from the top ribbon bar and select the option **Ask a question**. Refer to the screenshot below:

5. The **Create Question** popup opens. Refer to the screenshot in the preceding section.
   a. Select the **Subject Matter** from the dropdown. You may choose to ignore this if the subject matter is not applicable.
   b. Enter the question in the **Question** textbox.
   c. Click **OK**.
6. Navigate to the **Q&A Application** from Main Navigation.
7. Select the appropriate view and the categories in it.
8. The question appears in the grid to the right of the dashboard.

e-Signature

In this section we discuss about the various ways of e-Signature used to sign the documents.

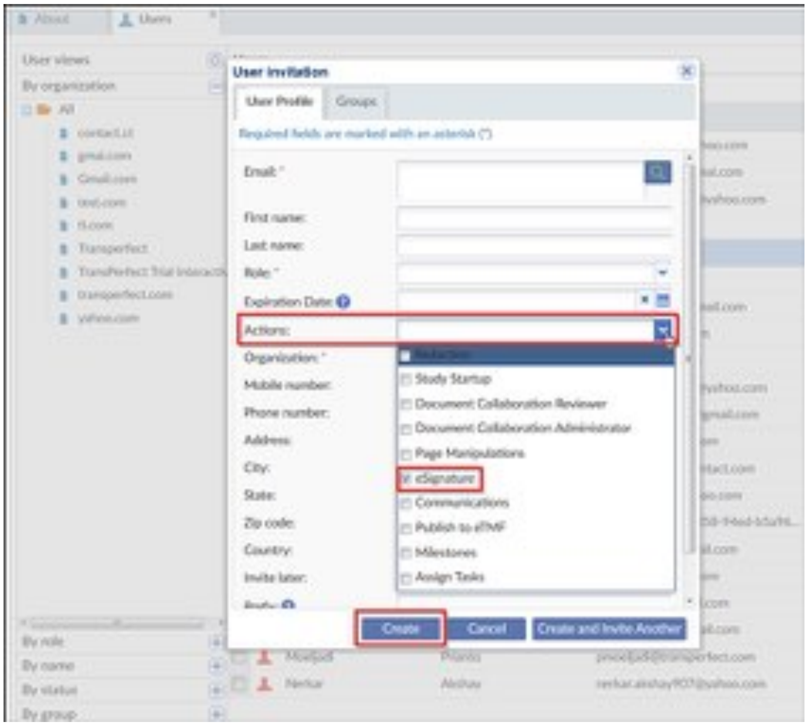
Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

Assigning Users to prepare an e-Signature Envelope

1. Click the desired room in your TI session. Click **Settings** from the Main Navigation to populate the room settings.
2. Navigate to **Settings -> Security-> Users**. A panel listing all users will be displayed in the right pane. Alternatively, you may arrive to the same page from the **Main Navigation -> Users management**.
3. Click the **Invite** dropdown located on the top left corner of the user list pane. Select the invite option from the list. A **User Invitation** form will be populated.

   Fill in the fields marked with an asterisk (*), at minimum, to invite the desired user.

   From the **User Profile** tab click the **Actions** dropdown menu to select the **eSignature** option and click **Create** to assign your user to prepare the eSignature package. Refer to the screenshot below:



4. For existing users, select the user from the user list by clicking the checkbox adjacent to list populated in the right pane.
5. Click the dropdown next to the dots and click **Edit** option. An **Edit User** form will populate.Refer to the screenshot below:

6. Click the **Actions** dropdown menu and select the **eSignature** option by ticking the checkbox.
7. Click **Save** to prepare the existing user for the e Signature package.

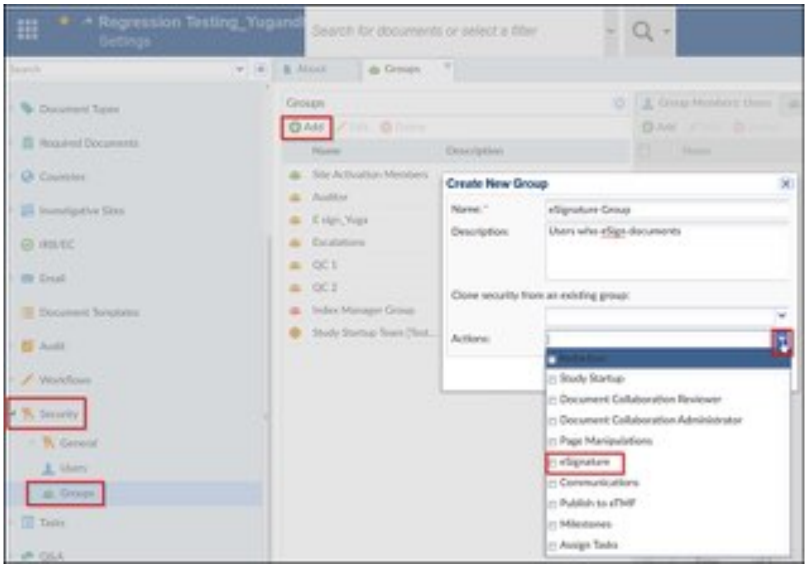
The user added will receive an email from Trial Interactive asking them to register in order to comply with e Signature feature.

Adding Groups with the eSignature Actions

Add Groups and activate the eSignature Action for the specified groups.

1. Navigate to **Settings -> Security -> Groups**. The Groups Panel opens.
2. From the **Groups** tab, click **Add**. The **Create New Group** window opens.
3. Name the group by typing its title into the **Name** field.
4. Add a **Description**.

   The user making these additons or changes can choose to clone the security parameters already defined for another user group that has been established in the room. This cloning designation is not required.
5. Click the **Actions** dropdown. Refer to the screenshot below:



6. Click the checkbox for **eSignature** and click **Create**.

   The new user group displays in the list of **Groups** in the panel on the left.

TI eSignature

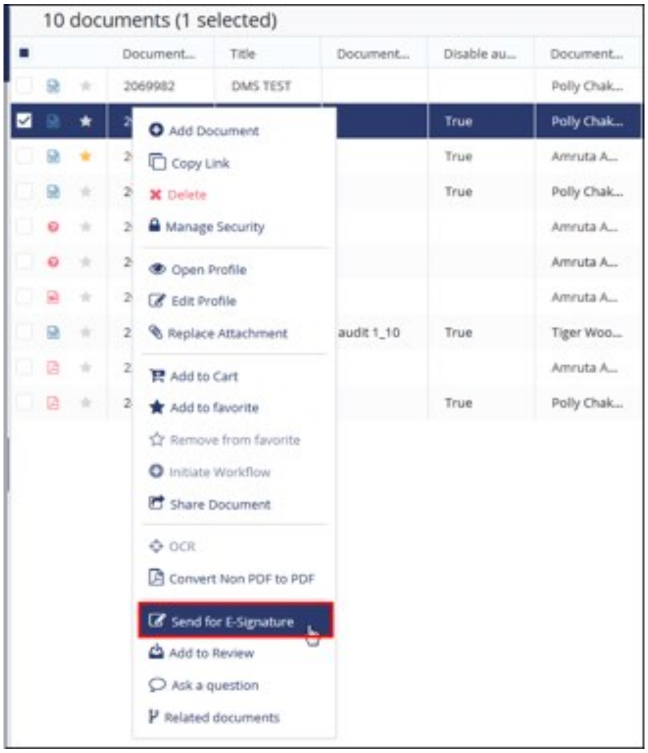
For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) to sign the documents.

This section include the following sections:

1. Assigning signers to the documents
2. Signing the documents in TI -eSignature if you are a signer

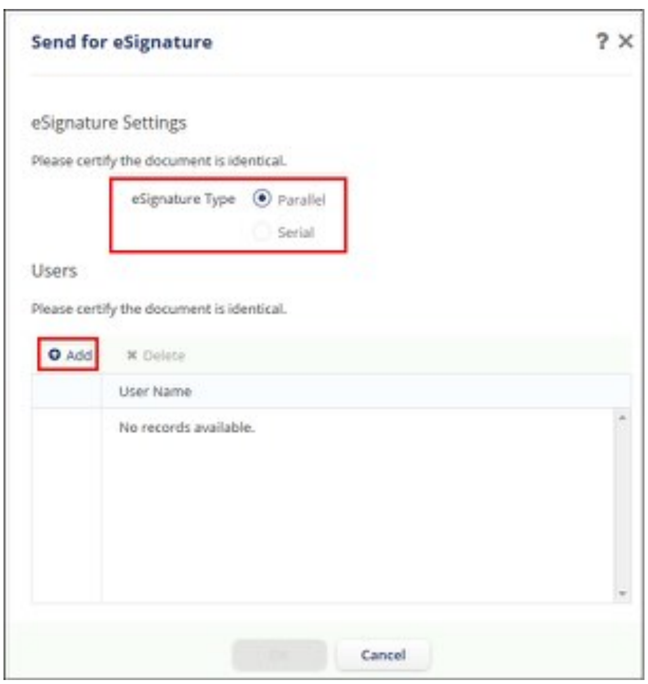
TI eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right click the desired document and click **Send for e-signature**. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. Refer to the screenshot below:



Signing the documents in TI - eSignature

If you are assigned to electronically sign a document, you can sign the documents in the following ways:

- From the Documents to be signed dashlet

- From the eTMF/Documents view

Each of the ways are discussed in the sections below:

Signing Documents from the Documents to be Signed Dashlet

1. When you are assigned a document for eSignature, navigate to the room **Dashboard** and scroll to find the **Documents to be signed** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display. Refer to the sceenshot below:

   You can also proceed to the **eTMF/Documents** module or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane.

Note:

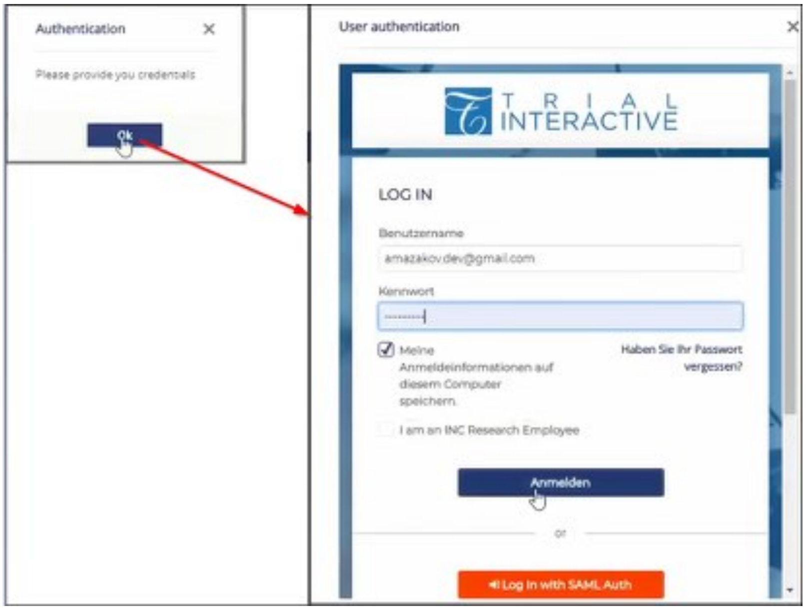
- *Completed signatures cannot be cancelled.*
- *Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.*
- *Once a document is cancelled from e-signature, no one can sign the document until it is resent again.*

Signing Documents from the eTMF/Documents view

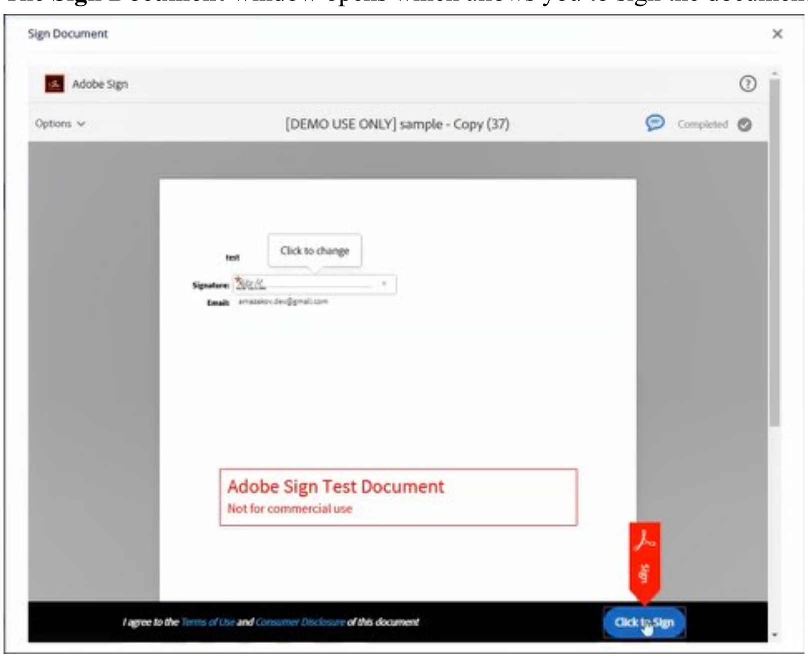
1. Navigate to the **eSignature view** and click the **Waiting for Signature** folder to locate the document to be signed as shown in the screenshot above section.
2. Select a document and open the **eSignature Panel** to the right. The Waiting for eSignature status appear next to your name.
3. Click the username to expand the details. Refer to the screenshot below:

4. Enter all the required details and click **Sign Document** button.

5. A window opens asking you for Authenticating your credentials opens.
6. Click **OK** to authenticate your credentials. Refer to the ascreenshot below:



7. Once you are authenticated, you are directed to the confirmation dialog box asking for signing.
8. Click **OK**.
9. The **Sign Document** window opens which allows you to sign the document. Refer to the screenshot below:



10. Click the Blue button at the bottom right corner of the window to sign the document.
11. If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all the signers have finished signing. Refer to the screenshot below:

12. Open the signed document to find that a page with the signer's name and contact details, date of e-signing the document is appended as the last page to the document. In case of multiple e-signers, a page for very signer is appended.

> **Note:** *Signature Page will be added to PDF documents only after all signers have finished signing the document.*

13. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under **e-Signature Documents** view. You can see the status of the eSignature as **Completed** in the eSignature Panel.

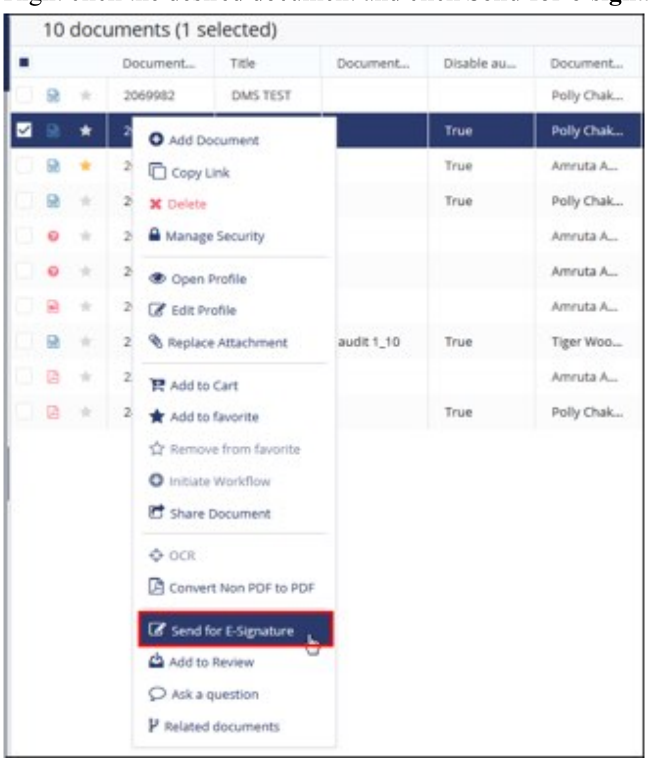
Adobe eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

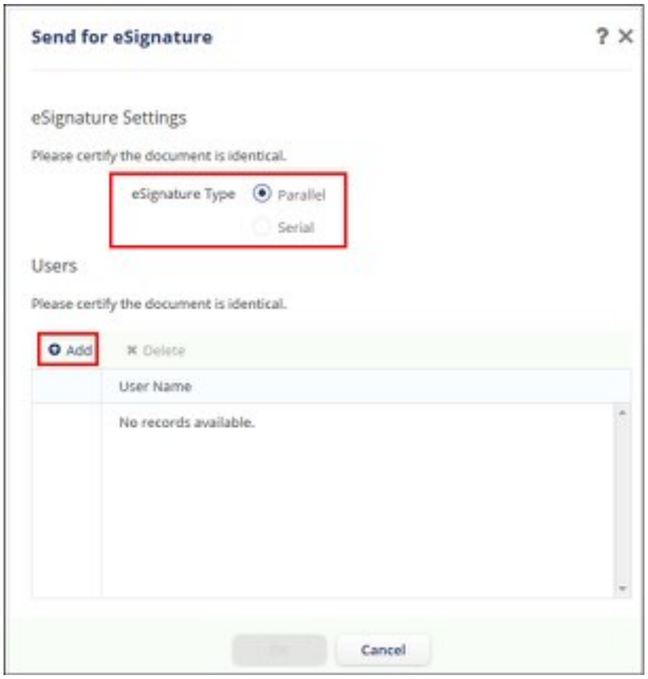
Adobe eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right click the desired document and click **Send for e-signature**. Refer to the screenshot below:



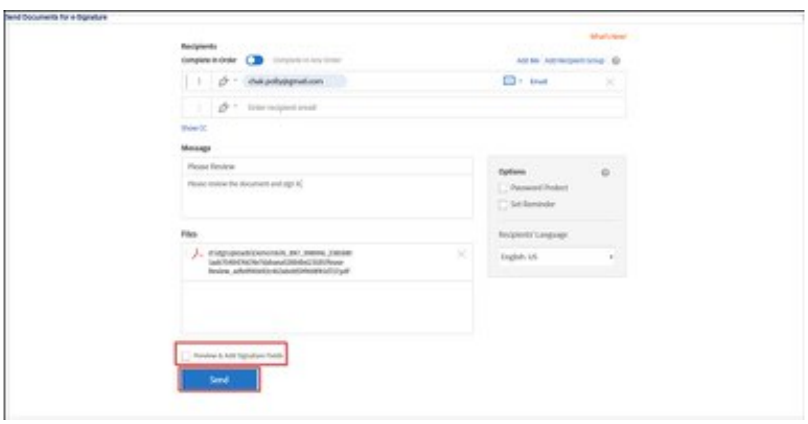
Alternatively, you can also send the document for eSignature from the eSignature Panel to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:

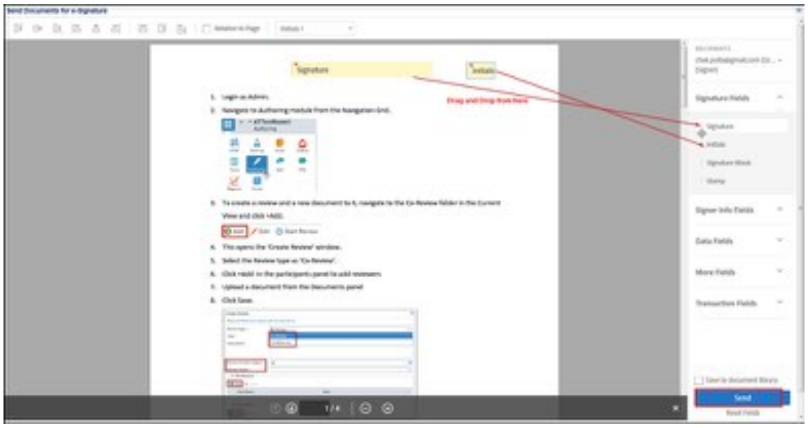


If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. A Recipients window with the list of email ids of signers enlisted opens.
7. Tick the **Preview & Add Signature Fields** checkbox located at the end of the page to determine the placement of signatures on the document.
8. Click **Next**. Refer to the screenshot below:



9. From the Recipients field select the signer and, drag and drop the fields on your document from the right menu option that you wish to include in the signature.
10. Repeat the above step for every e-signer.



11. Click the **Send** button located on the bottom right corner of the window to complete the signer assignment process.

    The system will trigger an email to the signers designated by you with a link to the document for eSignature.

    You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

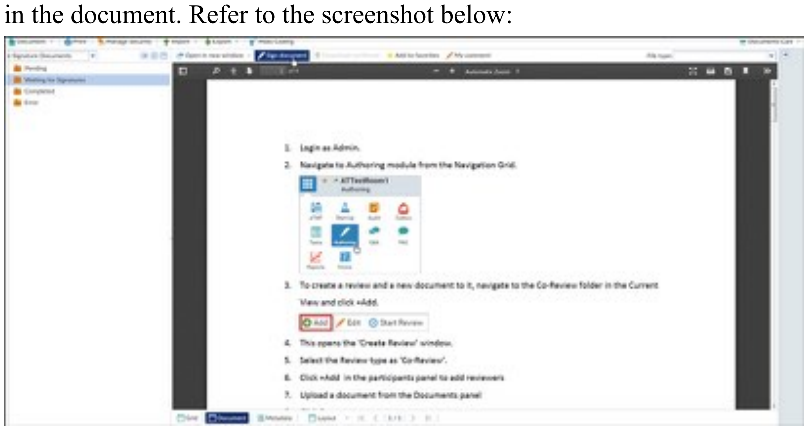
Signing the documents in Adobe Sign

If you are assigned to electronically sign a document, follow the steps mentioned here:

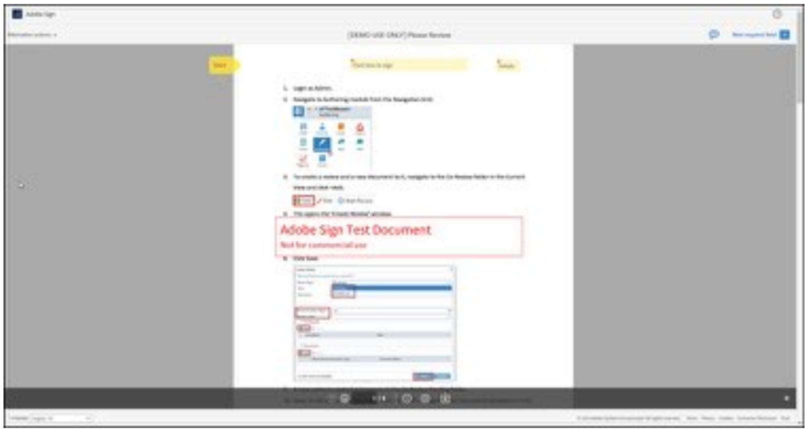
1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document. Alternatively, click the **Dashboard** tab and navigate to the **Documents to be signed** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

   You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature**view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process.

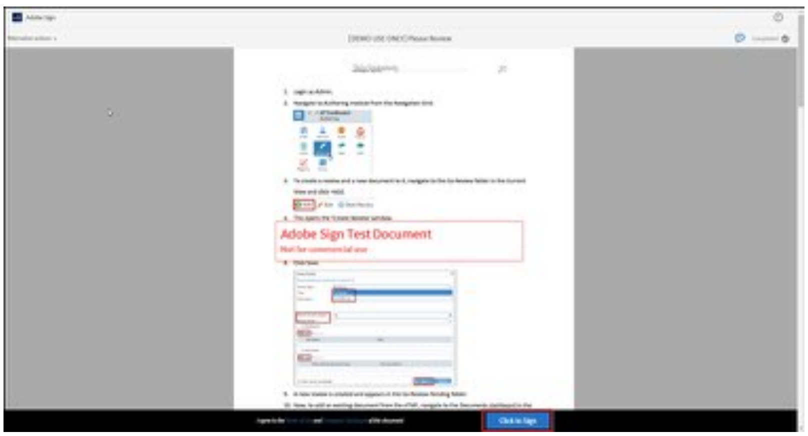
   If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Refer to the screenshot below:



3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.
4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document. Refer to the screenshot below:



5. Hit **Click here to sign** box. You will be prompted to choose your style for the signature (font, size, etc.)
6. Enter your signature and other details as required. Click **Apply.**
7. This will insert your signature. Hit **Click to Sign** . Refer to the screenshot below:



8. The document will move to the **Completed** folder under **e-Signature Documents**.

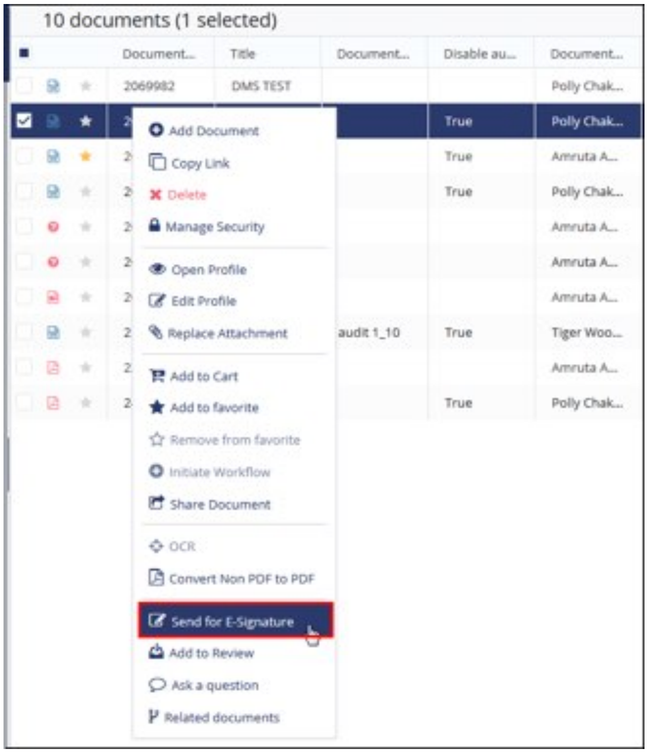
DocuSign eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

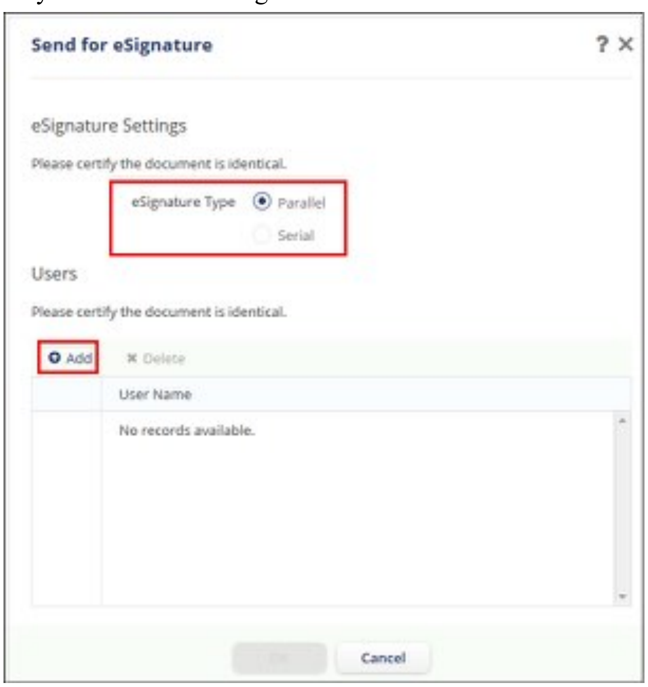
DocuSign - Assiging Signers to the Documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right click the desired document and click **Send for e-signature**. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel to the right.

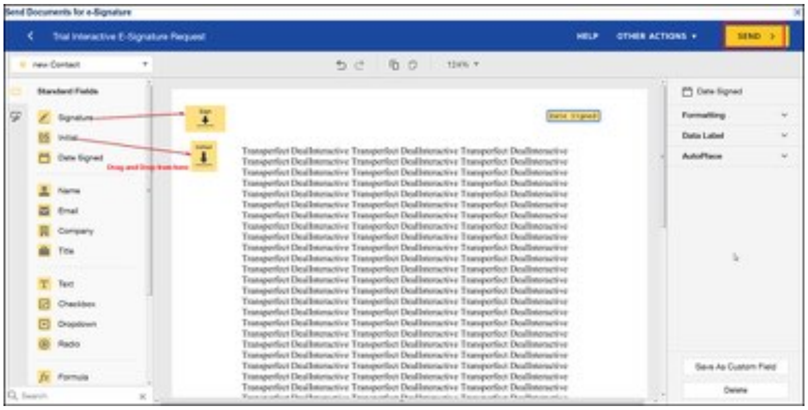
3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:



If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. A document preview window to determine the placement of the signatures with the designated recipient list on the left will display.

Select the desired recipient. Then drag and drop the fields on your document from the left menu option that you wish to be included in the signature. Repeat the above step for every e-signer. Refer to the screenshot below:



Click the **Send** button located on the top right corner of the window to complete the signer assignment process.

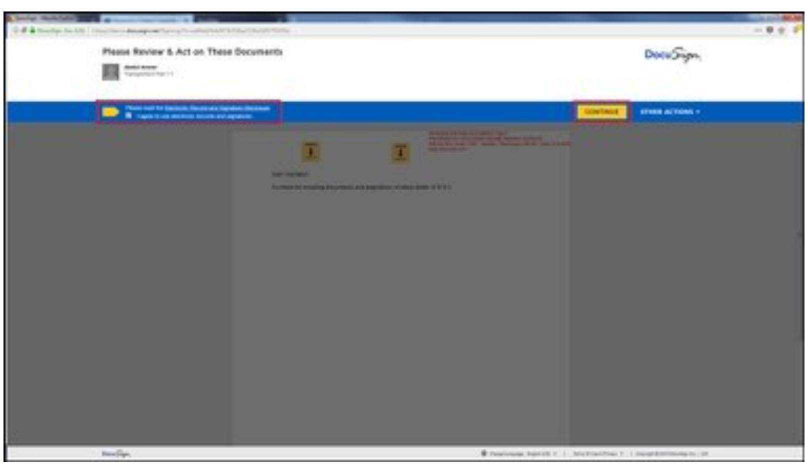
The system will trigger an email to the signers designated by you with a link to the document for eSignature.

You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

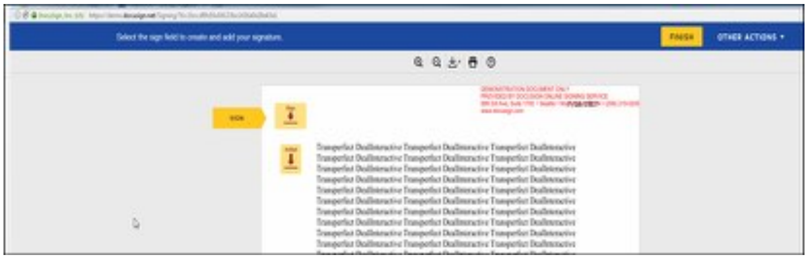
Signing the Documents in DocuSign

If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room. Alternatively, click the **Dashboard** tab in the eTMF module and scroll down to find the **Documents to be signed** dashlet.
2. Click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.
3. You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process. Refer to the screenshot below:



Click **Continue.** If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Click the **sign** icon. You will be prompted to choose your style for the signature (font, size, etc.). Refer to the screenshot below:



Click **Finish** to complete the eSignature process.

CRA Reconciliation

In this section find the details about the CRA Reconciliation Reports that helps CRA to take the decisions regarding further site visits

Trial Interactive 10.0 helps the CRA to reconcile documents during their site visits through the Site Report.

You can reach this page from **Main Navigation → CRA Reconciliation.** Refer to the screenshot below:

The module has the following sections:

1. **Documents:** This module allows the CRA to mark the documents as verified, missing in eTMF, missing in ISF or add the placeholder for an expected document as a part of reconciliation process.
2. **Reports:** This module allows the CRA to create CRA Report which will include all the documents reviewed by the CRA since the last report created by him/her.

   Each of the above modules are discussed in separate topics and can be accessed from the left pane of this help.

Documents Reconciliation

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

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

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

Note: *Only* ***Pending*** *and* ***Active*** *sites are available for reconciliation process*

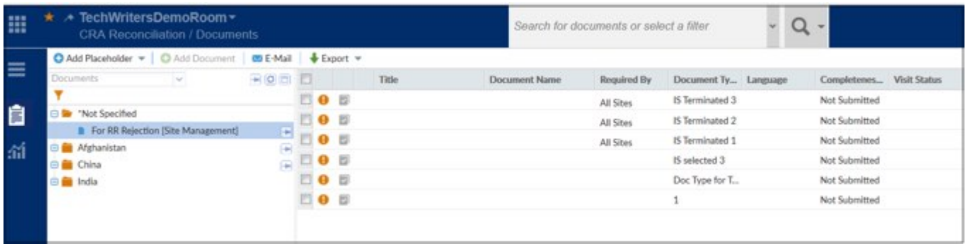
Important:

- *Missing documents cannot be marked as reviewed.*
- *Only CRAs can perform this step. Admin users will not be able to mark documents as Reviewed.*
- *The CRA needs to have* ***CRA Reconciliation Action*** *enabled under the user profile.*

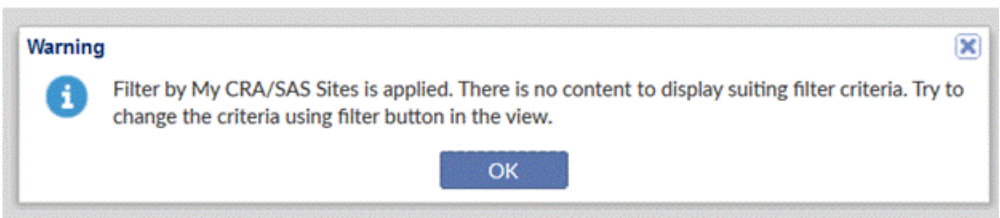
Follow the steps below to reconcile documents:

1. Navigate to **Main Navigation → CRA Reconciliation** Refer to the screenshot below:

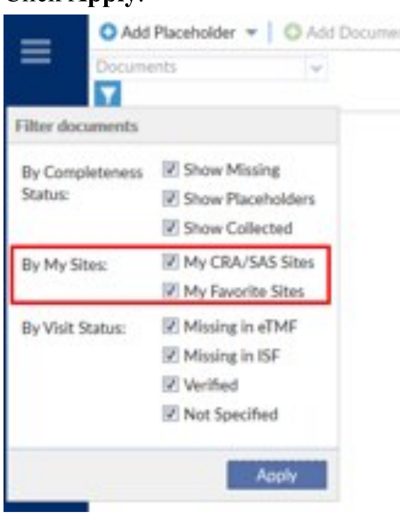
2. The **Document View** opens as shown in the screenshot below:



3. Notice if you receive waring as shown in the screenshot below:



4. If the waring is displayed, click the **Filter** icon below the view and uncheck **My CRA/SAS Sites** or **My favorite sites** from the filter. Refer to the screenshot below:
5. Click **Apply**.



6. The list of folders appear in the view.
7. Click the appropriate folder to display the list of sites.
8. Select the appropriate site from the selected folder to get the list of **missing**, **collected** and **placeholder documents** in the grid.
9. while reconciliation, each document will fall into one of the three scenarios as below:

   a. ***If the document is in the ISF but not showing in the eTMF:***

1. Click **Add Placeholder** (or if applicable, upload/email the document to the eTMF).
2. Complete the known required fields and click **Finish** (metadata can be added / edited once the document is collected).
3. Once all the actions are done, click the **Reconcile** button and proceed to step 11.

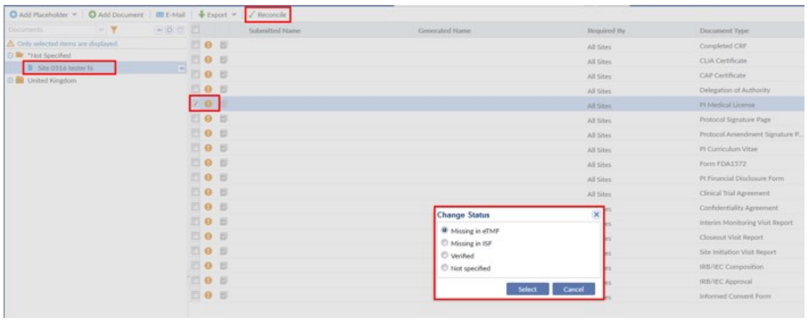
b. ***If a document is in the eTMF not present in the ISF:***

1. Click the document(s) and click the **Reconcile**button.

c. ***When the document is in both eTMF and the ISF***

1. Click the document and then click the **Reconcile** button.

10. Click the **Reconcile** button from the top ribbon bar to change the status of the document. The **Change Status** pop-up opens. Refer to the screenshot below:



11. Choose the required status and click **Select**.

Note:

- **Missing in ISF**: Select this status to indicate the document is missing in the site binder (ISF) but present in the eTMF.
- **Verified**: Select this status to indicate the document is in both the eTMF & ISF.
- **Not specified** Select this status to clear a previously assigned status.

12. Once the **Reconcile** process is complete, you can see the status of the document with the date. Refer to the screenshot below:
13. This site is then available for the creation of the CRA TMF Reconciliation Report in the **Report** view.

Creating and Viewing the CRA TMF Reconciliation Report

CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. You can access this page from **Main Navigation → CRA Reconciliation → Reports View**. On entering the dashboard, you can find the list of reports generated displayed in the grid. You can choose to view the reports **By Site,By Visit Type**, or **By CRA** from the current view panel on the left. Clicking a report from the grid populates the report metadata in **Reconciliation Datapanel** located at the extreme right of the dashboard. You also have the option to **Create** edit, or delete a CRA Reconciliation TMF Report from the **Create**, **Edit**, or **Delete** icons located on the top ribbon. Refer to the screenshot below:

Creating CRA TMF Reconciliation Report

1. Once the **Reconciliation** process is complete, you can create the CRA TMF Reconciliation report from the **Reconciliation Report** module. Image
2. Select the appropriate filter from the Current View. The Previous reports will populate in the grid.
3. Select the appropriate site and click **Create** from the top ribbon bar to run a new report.
4. The **Create CRA TMF Reconciliation**window populates with documents from the latest reconciliation. Complete the required fields.

Note: *The Visit Type will be populated in the dropdown only if it is created from Settings → Investigative Sites → CRA Visit Types.* Refer to the screenshot below:

5. Fill in the appropriate details and click **Create.**
6. You will receive a **notification** that the **Site Report** is created successfully and displayed in the grid.

Editing CRA TMF Reconciliation Report

1. Select the required **site** from the **Reports** module and click the **Edit** button on the top ribbon bar.
2. The **Modify CRA TMF Reconciliation** popup opens.
3. Edit the required details and click **Save** when finished.

Deleting CRA TMF Reconciliation Report

1. Select the required **site** from the Current View and click the **Delete** button on the top menu bar.
2. Click **Yes** on the confirmation popup that appears if you wish to delete the report from the list.

Reports

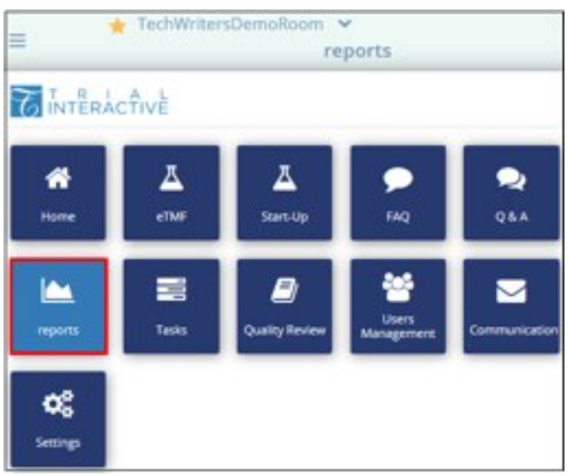
From here get the know about getting the Reports for the room activities.

Room Administrators have the option to turn on **Reports** and make them available to other users. If Reports are activated, you will see an icon in the Navigation Grid.

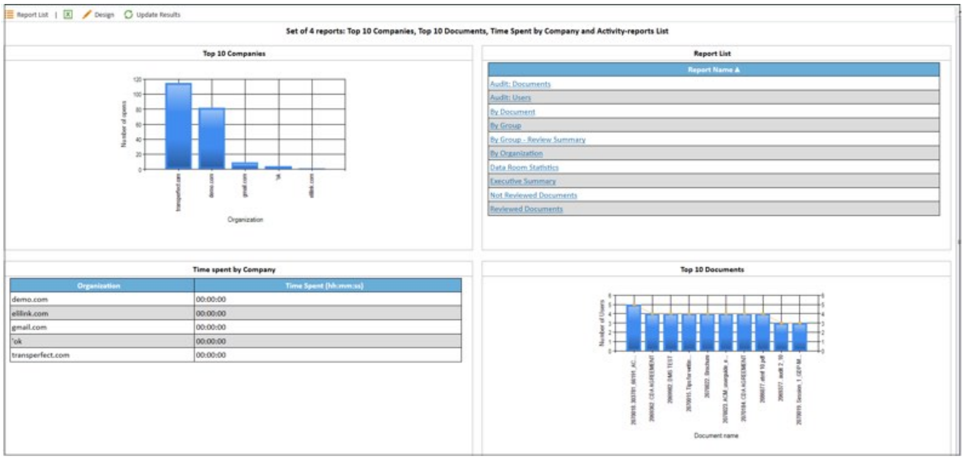
Reports Dashboard

Note: Administrator have an option to turn on Reports for other level users to access and view.

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



The Reports Dashboard consists of the various dashlets which gives the summary of the reports of the room. Refer to the screenshot below:



From the Reports Dashboard you can do the following:

1. Generate Reports from the Reports List.
2. Export the Reports.
3. Design a new dashboard
4. Update Results

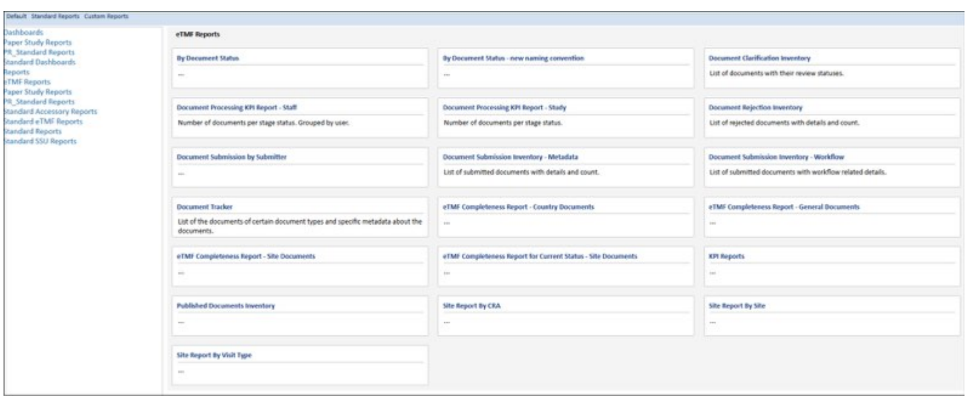
   Each of these is discussed in the seperate topics in this help.

Viewing Reports from the Report List

From the Reports Dashboard, click the **Reports List** 

option from the top menu bar.

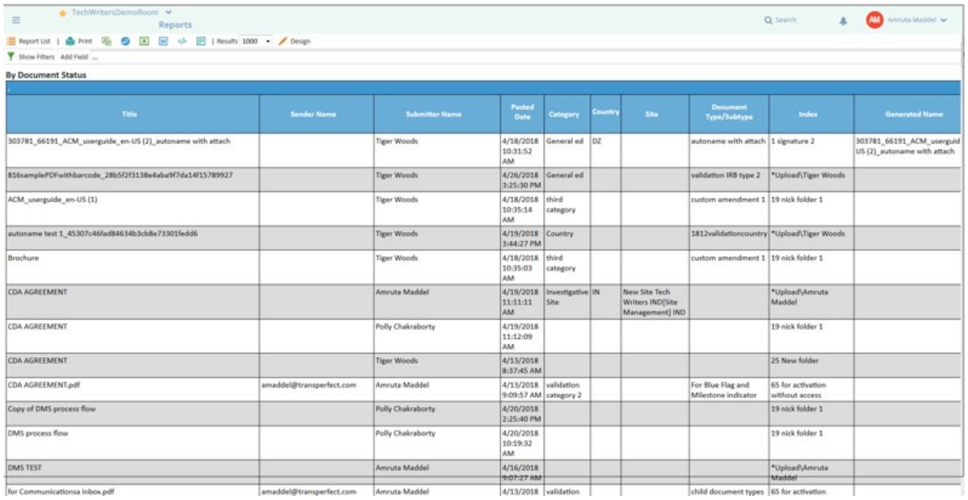
This view offers links to standard activity reports and a **Report List**.



The Reports view consists of the following:

1. **The Left Pane**: This consists of the list of reports.
2. **The Right Pane**: This consists of the detailed view of the reports corresponding to the reports in the left pane.

   Click the name of the report and that report opens in the dashboard below. The screenshot below shows the **By Document Status** report clicked from the above screen.



By Document Status

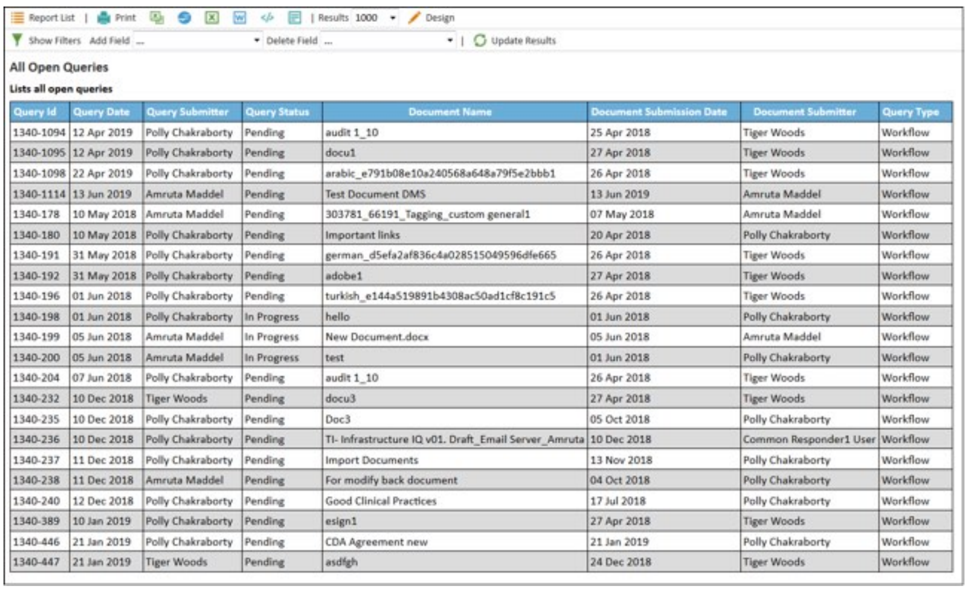
Title	Sender Name	Submitter Name	Posted Date	Category	Country	Site	Document Type/Subtype	Index	Generated Name
303781_66191_ACM_userguide_en-US (2)_autoname with attach		Tiger Woods	4/18/2018 10:31:52 AM	General ed	DZ		autoname with attach	1 signature 2	303781_66191_ACM_userguid US (2)_autoname with attach
816samplePDFwithbarcode_28b5f2f3138e4aba9f7da14f15789927		Tiger Woods	4/26/2018 3:25:30 PM	General ed			validation IRB type 2	*Upload\Tiger Woods	
ACM_userguide_en-US (1)		Tiger Woods	4/18/2018 10:35:14 AM	third category			custom amendment 1	19 nick folder 1	
autoname test 1_45307c46fad84634b3cb8e73301fedd6		Tiger Woods	4/19/2018 3:44:27 PM	Country			1812validationcountry	*Upload\Tiger Woods	
Brochure		Tiger Woods	4/18/2018 10:35:03 AM	third category			custom amendment 1	19 nick folder 1	
CDA AGREEMENT		Amruta Maddel	4/19/2018 11:11:11 AM	Investigative Site	IN	New Site Tech Writers IND[Site Management] IND		*Upload\Amruta Maddel	
CDA AGREEMENT		Polly Chakraborty	4/19/2018 11:12:09 AM					19 nick folder 1	
CDA AGREEMENT		Tiger Woods	4/13/2018 8:37:45 AM					25 New folder	
CDA AGREEMENT.pdf	amaddel@transperfect.com	Amruta Maddel	4/13/2018 9:09:57 AM	validation category 2			For Blue Flag and Milestone indicator	65 for activation without access	
Copy of DMS process flow		Polly Chakraborty	4/20/2018 2:25:40 PM					19 nick folder 1	
DMS process flow		Polly Chakraborty	4/20/2018 10:19:32 AM					19 nick folder 1	
DMS TEST		Amruta Maddel	4/16/2018 9:07:27 AM					*Upload\Amruta Maddel	
for Communicationsa inbox.pdf	amaddel@transperfect.com	Amruta Maddel	4/13/2018	validation			child document types	65 for activation	

Typically, report builds are based on specific sponsor requests.

Note: *For further assistance on other features of reports, please get in touch with the Suppor team of Trial Interactive.*

Generating Reports

From the Reports List page, click the reqiuired report to open it. Below is an example of the list of **All Open Queries**.



All Open Queries

Lists all open queries

Query Id	Query Date	Query Submitter	Query Status	Document Name	Document Submission Date	Document Submitter	Query Type
1340-1094	12 Apr 2019	Polly Chakraborty	Pending	audit 1_10	25 Apr 2018	Tiger Woods	Workflow
1340-1095	12 Apr 2019	Polly Chakraborty	Pending	docu1	27 Apr 2018	Tiger Woods	Workflow
1340-1098	22 Apr 2019	Polly Chakraborty	Pending	arabic_e791b08e10a240568a648a79f5e2bbb1	26 Apr 2018	Tiger Woods	Workflow
1340-1114	13 Jun 2019	Amruta Maddel	Pending	Test Document DMS	13 Jun 2019	Amruta Maddel	Workflow
1340-178	10 May 2018	Amruta Maddel	Pending	303781_66191_Tagging_custom general1	07 May 2018	Amruta Maddel	Workflow
1340-180	10 May 2018	Polly Chakraborty	Pending	Important links	20 Apr 2018	Polly Chakraborty	Workflow
1340-191	31 May 2018	Polly Chakraborty	Pending	german_d5efa2af836c4a028515049596dfe665	26 Apr 2018	Tiger Woods	Workflow
1340-192	31 May 2018	Polly Chakraborty	Pending	adobe1	27 Apr 2018	Tiger Woods	Workflow
1340-196	01 Jun 2018	Polly Chakraborty	Pending	turkish_e144a519891b4308ac50ad1cf8c191c5	26 Apr 2018	Tiger Woods	Workflow
1340-198	01 Jun 2018	Polly Chakraborty	In Progress	hello	01 Jun 2018	Polly Chakraborty	Workflow
1340-199	05 Jun 2018	Amruta Maddel	In Progress	New Document.docx	05 Jun 2018	Amruta Maddel	Workflow
1340-200	05 Jun 2018	Amruta Maddel	In Progress	test	01 Jun 2018	Polly Chakraborty	Workflow
1340-204	07 Jun 2018	Polly Chakraborty	Pending	audit 1_10	26 Apr 2018	Tiger Woods	Workflow
1340-232	10 Dec 2018	Tiger Woods	Pending	docu3	27 Apr 2018	Tiger Woods	Workflow
1340-235	10 Dec 2018	Polly Chakraborty	Pending	Doc3	05 Oct 2018	Polly Chakraborty	Workflow
1340-236	10 Dec 2018	Polly Chakraborty	Pending	TI- Infrastructure IQ v01. Draft_Email Server_Amruta	10 Dec 2018	Common Responder1 User	Workflow
1340-237	11 Dec 2018	Polly Chakraborty	Pending	Import Documents	13 Nov 2018	Polly Chakraborty	Workflow
1340-238	11 Dec 2018	Amruta Maddel	Pending	For modify back document	04 Oct 2018	Polly Chakraborty	Workflow
1340-240	12 Dec 2018	Polly Chakraborty	Pending	Good Clinical Practices	17 Jul 2018	Polly Chakraborty	Workflow
1340-389	10 Jan 2019	Polly Chakraborty	Pending	esign1	27 Apr 2018	Tiger Woods	Workflow
1340-446	21 Jan 2019	Polly Chakraborty	Pending	CDA Agreement new	21 Jan 2019	Polly Chakraborty	Workflow
1340-447	21 Jan 2019	Tiger Woods	Pending	asdfgh	24 Dec 2018	Tiger Woods	Workflow

For a particular report, you can do the following:

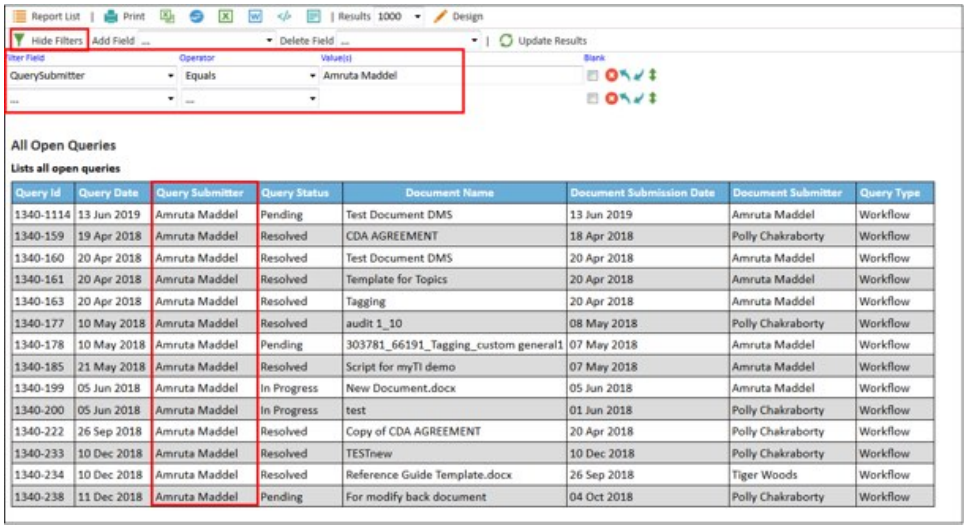
1. Apply Filters
2. Adding and deleting fields in a report
3. Print Reports
4. Download Reports

   Each if these is discussed in the sections below.

Applying Filters

You can apply filters for a report if you wish to view and generate the report with only specific information. You can apply filters for a report by clicking the **Show Filters** button in the menu bar. This enables the **Filter Field , Operator** and **Value(s), Blank** fields to allow you to select the filters for a report.

Select the Filter Field, operator and the value of the field for which you want to get the reports. An example below show a filter applied for generating a report for the open queries of a particular submitter:

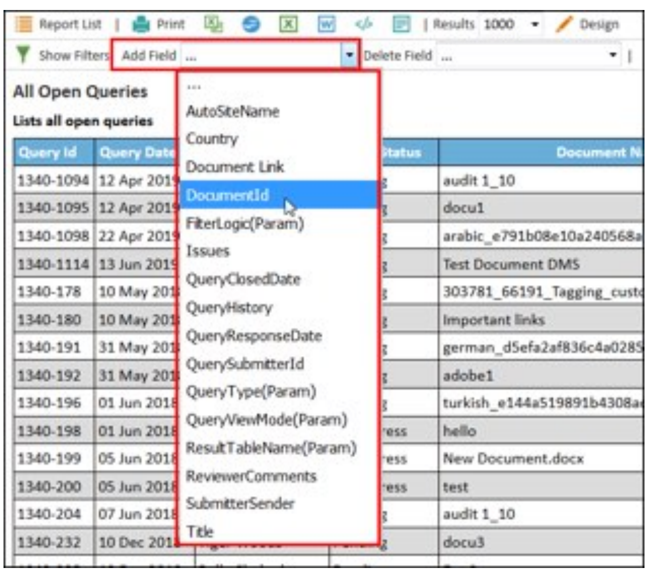


Query Id	Query Date	Query Submitter	Query Status	Document Name	Document Submission Date	Document Submitter	Query Type
1340-1114	13 Jun 2019	Amruta Maddel	Pending	Test Document DMS	13 Jun 2019	Amruta Maddel	Workflow
1340-159	19 Apr 2018	Amruta Maddel	Resolved	CDA AGREEMENT	18 Apr 2018	Polly Chakraborty	Workflow
1340-160	20 Apr 2018	Amruta Maddel	Resolved	Test Document DMS	20 Apr 2018	Amruta Maddel	Workflow
1340-161	20 Apr 2018	Amruta Maddel	Resolved	Template for Topics	20 Apr 2018	Amruta Maddel	Workflow
1340-163	20 Apr 2018	Amruta Maddel	Resolved	Tagging	20 Apr 2018	Amruta Maddel	Workflow
1340-177	10 May 2018	Amruta Maddel	Resolved	audit 1_10	08 May 2018	Polly Chakraborty	Workflow
1340-178	10 May 2018	Amruta Maddel	Pending	303781_66191_Tagging_custom general1	07 May 2018	Amruta Maddel	Workflow
1340-185	21 May 2018	Amruta Maddel	Resolved	Script for myTI demo	07 May 2018	Amruta Maddel	Workflow
1340-199	05 Jun 2018	Amruta Maddel	In Progress	New Document.docx	05 Jun 2018	Amruta Maddel	Workflow
1340-200	05 Jun 2018	Amruta Maddel	In Progress	test	01 Jun 2018	Polly Chakraborty	Workflow
1340-222	26 Sep 2018	Amruta Maddel	Resolved	Copy of CDA AGREEMENT	20 Apr 2018	Polly Chakraborty	Workflow
1340-233	10 Dec 2018	Amruta Maddel	Resolved	TESTnew	10 Dec 2018	Polly Chakraborty	Workflow
1340-234	10 Dec 2018	Amruta Maddel	Resolved	Reference Guide Template.docx	26 Sep 2018	Tiger Woods	Workflow
1340-238	11 Dec 2018	Amruta Maddel	Pending	For modify back document	04 Oct 2018	Polly Chakraborty	Workflow

You can also apply multiple filters as well by using the operator conditions to view the required results.

Adding and deleting fields in a report

Click the **Add Field** dropdown and select the required field you wish to add to the report list. The field gets added to the list. Refer to the screenshot below:



Simiarly, you can also delete a field from a report by clcking the **Delete Field** dropdown and selecting the required field from the list.

Printing Reports

Click the **Print** button in the menu bar to print the report.

Exporting Reports

You can export the reports in the following formats:

1. CSV
2. Microsoft Excel
3. Microsoft Word
4. XML
5. Open office Document
6. Rich Text Format (RTF)

Tasks

Tasks application allows the users to manage their Trial Interactive tasks for their rooms.

They are given an option to add, edit, delete, and export tasks. Additionally, administrators can adjust the number of days before a task's deadline for a user to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task.

As a Trial Interactive administrator, you can access Tasks as mentioned below:

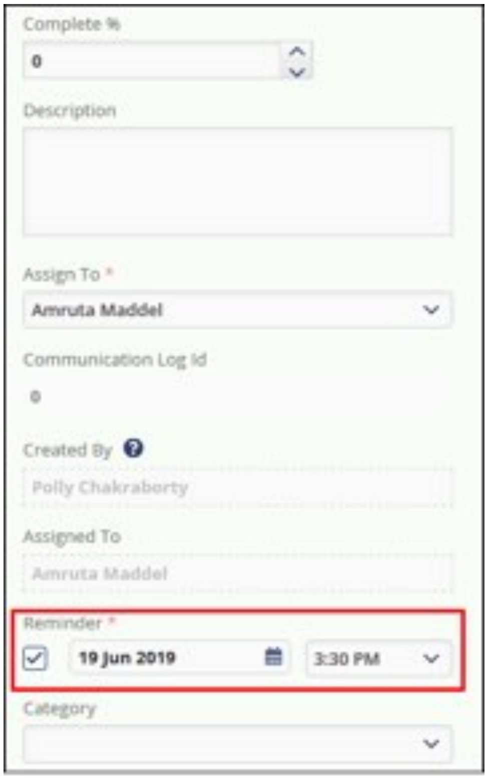
1. **Enter the room** for which you want to create tasks from the **Home** page
2. Click the **Main Navigation – >App switcher**.
3. The popup with all the applications appear
4. Click **Tasks** icon.
5. You are taken to the **Tasks** page. Refer to the screenshot below:

The **Task Module** is explained in detail in separate section.

Tasks Module

From within a room, the reader can maintain and track tasks related to the TI room.

The reader can view the tasks by different views, add new tasks, edti tasks, delete tasks, and adjust their tasks. Each of these are discussed in the seperate topics and can be accessed from the left panel of this help. Additionally, administrators can adjust the number of days before a task's deadline for a user to reveive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of rthe metadata panel of the task. Refer to the screenshot below:



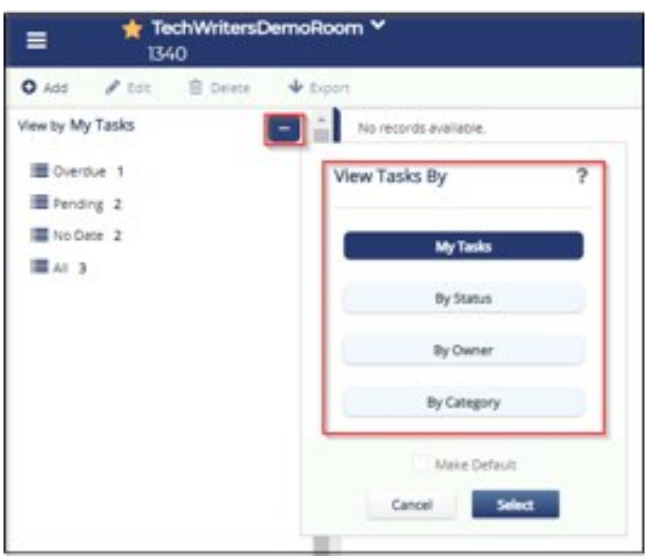
Tasks Views

Once inside the Tasks dashboard, you can choose to view Tasks by:

- **My Tasks**
- **By Status**
- **By Owner**, and
- **By Category**

To select the Task Views:

1. Click the **three dots** icon next to the **View by**. Refer to the screenshot below:



2. The **View Tasks By** window opens.
3. Choose the required view and click **Select**.

Note: *Click the checkbox if you wish to* ***Make Default*** *the selected view.*

4. The tasks open as per the selected view in the left pane.
5. Select the category in the left pane to open the list of Tasks in the grid.

Each of the above views are discussed in the sections below:

My Tasks

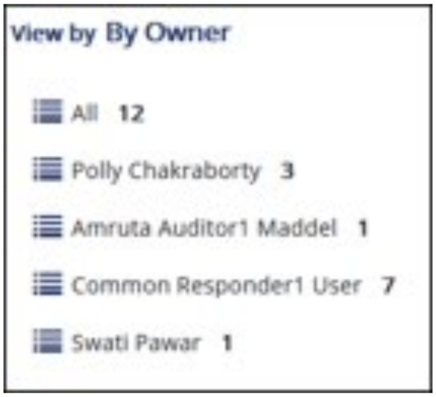
This view gives the list of tasks belonging to the user based on today, this week, next week, pending, overdue, tasks that have no starting date (No date), or all the tasks together in the document panel. The task count is also displayed next to each time frame. Refer to the screenshot below:

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. Refer to the screenshot below:

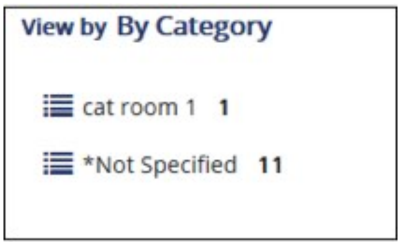
By Owner

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. Refer to the screenshot below:



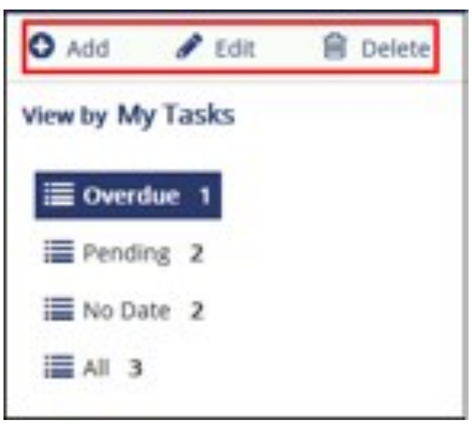
By Category

This lists all the tasks under each category along with their counts. Refer to the screenshot below:



Adding, Editing and Deleting Tasks

Tasks can be added, edited, or deleted from the icons in the ribbon above the dashboard. Refer to the screenshot below:



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:

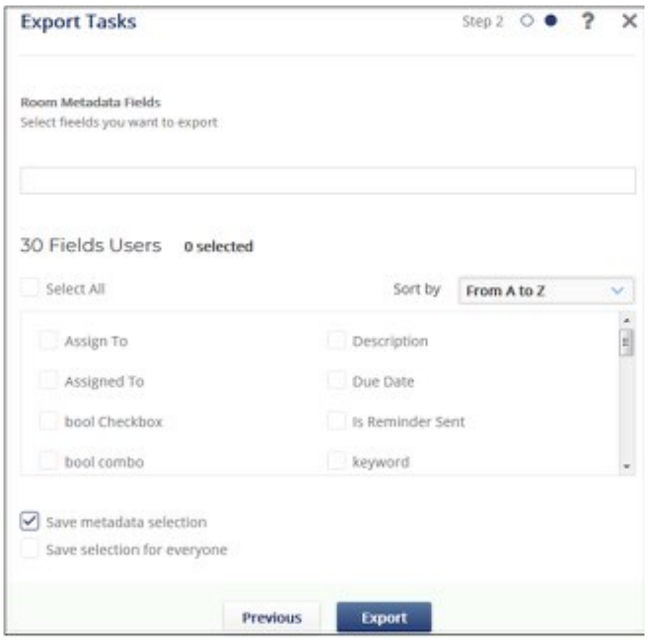
1. **Start Date:** The date when the task should be started.
2. **Due Date:** The date by which the task should be completed and submitted.
3. **Priority:** The priority of a task could be Low, Normal, or High.
4. **Status:** Depending upon the progress of the task, the status could be set as Completed, 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**.

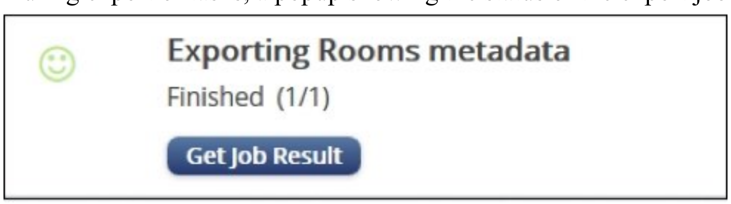
Exporting Tasks

You can also export tasks through the **Task Export** window invoked by clicking the **Export icon** 

on the top 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. Refer to the screenshot below:



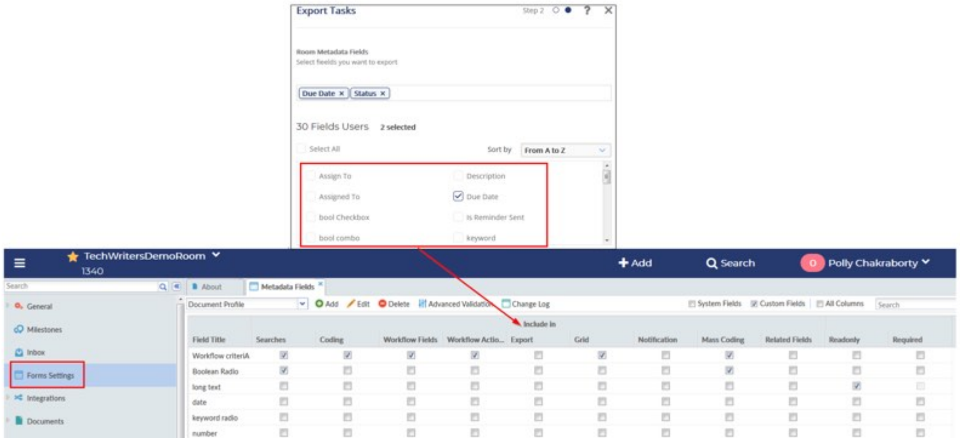
During export of tasks, a popup showing the status of the export job is shown. Refer to the screenshot below:



The export results are also populated in the **Notifications.** Click **GetJob Result** to view the excel file.

To enable export of tasks metadata:

1. Navigate to **Main Navigation ->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:

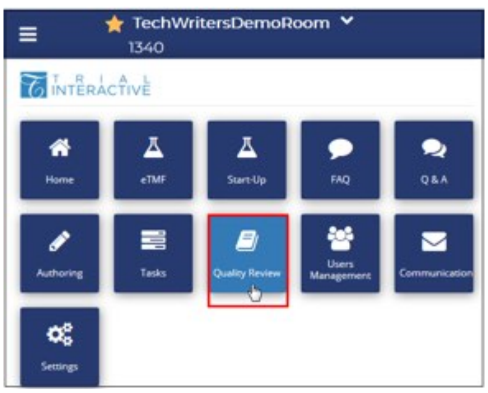


You can also view task statuses from **Tasks Dashlet.**

Quality Review

The Quality Review/Audit application in Trial Interactive allows to record an auditor's review and comments on various documents added for audit in a trial. You can also create a Quality Review profile from here.

As a Trial Interactive Administrator, you can access the **Quality Review Application** from the **Main Navigation**:



From here we discuss the following:

1. Creating a Quality Profile
2. Performing Quality Review
3. Performing Quality Review Response
4. Responding to Quality Review Queries
5. Resolving Queries Raised during Quality Review

Creating an Audit Profile

In Trial Interactive, before creating an Audit Profile, we would need to know the various roles that need to be assigned to users to perform audits:

1. **Auditor**: Users under this role can see only the documents they audit.
2. **Auditor manager**: Users under this role can see audit results of all auditors and can provide their own review comments to documents. Only editors and higher level users fit this role.
3. **Audit Responder**: Users under this role are responsible to take actions on issues cited by auditors in the documents. Only editors and higher level users fit this role.

Note: Quality Review Profiles can be created from either the Documents Cart or from the Documents Quality Review Settings module.

Creating an Audit Profile involves the following steps in sequence:

1. Filling the General Information
2. Selecting Auditors
3. Selecting Audit Managers
4. Selecting Audit Responders
5. Selecting Statuses
6. Viewing Audit Summary

Each of the above are discussed in separate topics available from the left panel of this topic help.

Creating an Audit Profile - General Information

Follow the steps below to enter the general information for Audit Profile:

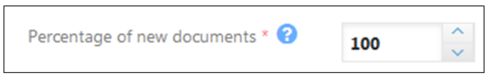
1. Navigate to **Quality Review** → **Documents** module.
2. Navigate to the required folder to display the documents in the grid.
3. Right click on the required documents and select the **Add to Cart** options. The documents gets added to the **Documents Cart.**
4. From the Documents Cart, select the documents and click **Actions** → **Create Audit Profile**.
5. The **Create Audit Profile** window opens. Refer to the screenshot below:

6. Enter the **Title** of the Audit in the title field.
7. Select the **Documents to audit** from the various radio button options available in this section. Each of the options in the Documents to Audit is discussed in detail in the topic ***Documents to Audit***.
8. Enter the **Audit Scopes**. Documents submitted/published within the selected date range will be published to the audit pool. The Audit scope will be disabled if the documents are added to the pool on demand basis, or from selected audits.

   a. ***From Date***: The day from which the audit is to start. It is not possible to select future dates as 'From Date'.

b. ***To Date***: The day till which the audit is to be completed.

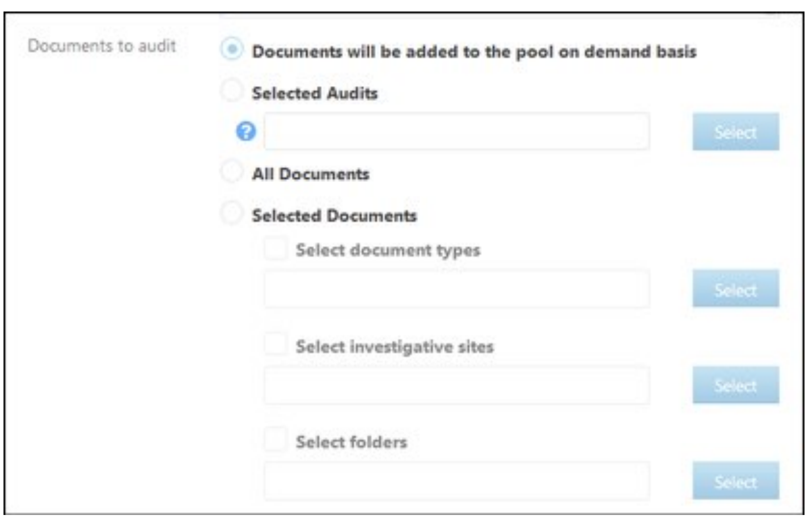
9. Select **Submitted/ published dates**. Audit will be applied only to submitted or published documents as per selection. Submitted documents are documents just added to the room, whereas published documents are documents added to the room as final.
10. Select **Published documents only**: If selected, documents added to the room as Final documents will be added to the audit pool. The user can choose to select Submitted from step c and check the **published documents only** checkbox. In this case, the audit pool will receive only documents that are just published to the room as final.
11. Select **Add reworked documents back to the audit pool**: Changing 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.
12. Select **% of new documents**: This defines the percentage of documents to be included in the audit pool as per the frequency, or audit scope. The percentage of documents are calculated from each intersection of selected investigative sites, document types and folders. Refer to the screenshots below:



13. Select **Frequency:** When set, the system will move the documents to the audit pool based on the period set in the interval. This will be disabled if the audit scope date range is selected.
14. Select**Auditors' access level**: This defines the security that the auditor receives on a document. The access level can be **Full** or **Read-only**.
15. Select **Contains PHI**: The client may allow auditors to delete documents containing PHI, under which case the administrator will need to enable the **Contains PHI** functionality by ticking the checkbox next to it. To activate this checkbox, the **Auditor's access level** has to be set to **Full**.
16. Select **Send audit notification**: When checked, the auditor will receive an email notifying that new documents are added to the audit pool.
17. Once you have made the selections, click **Next** at the bottom of the window. You are taken to the next step of the Audit Profile to add **Auditors**.

Documents to Audit

You can add audits and documents to the current audit profile from the various radio button options available as shown in the screenshot below:



Documents will be added to the pool on demand basis

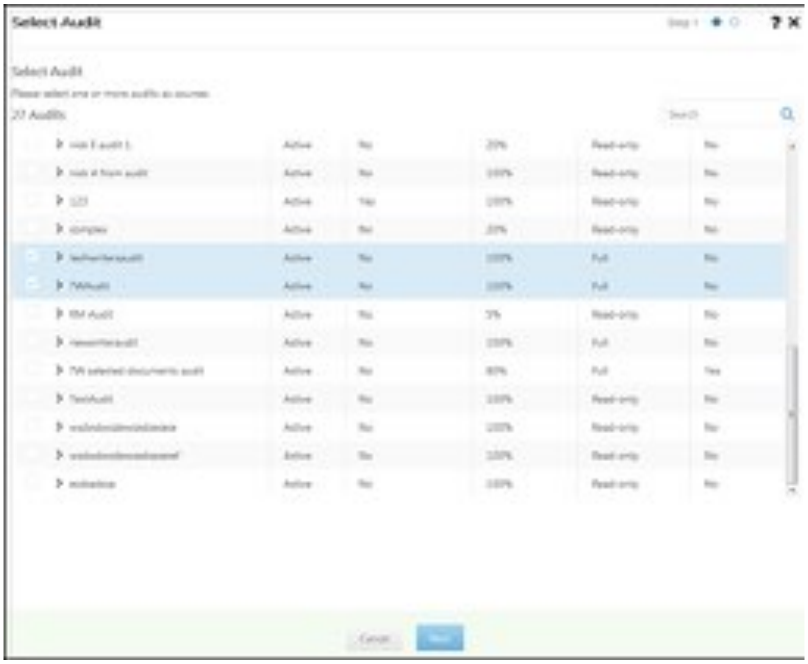
If selected, documents will not be added to the audit pool automatically. Instead, the user have to add documents manually to the audit pool from the Documents Cart.

Selected Audits

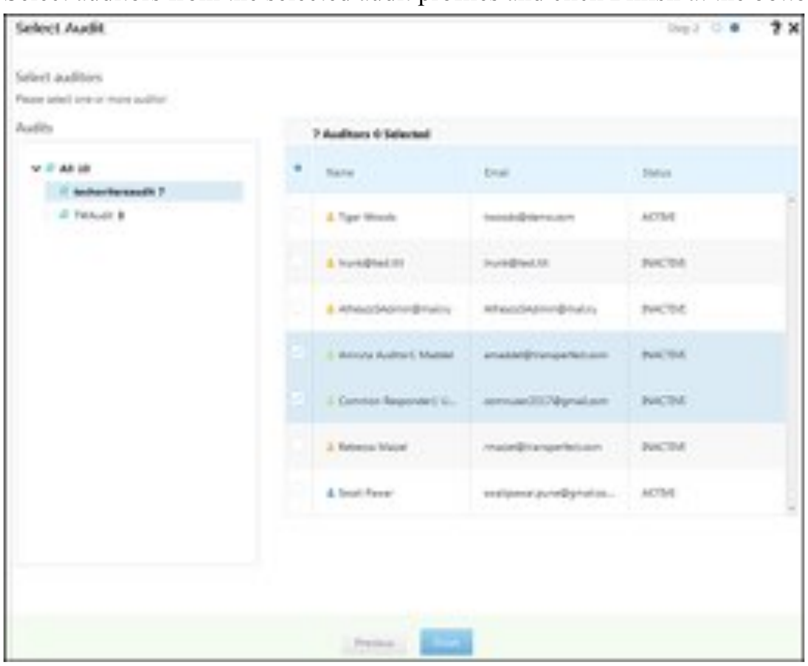
If selected, documents passed in the selected audit profiles will be added to the current audit profile.

Follow the steps below to add audits to the current audit profile:

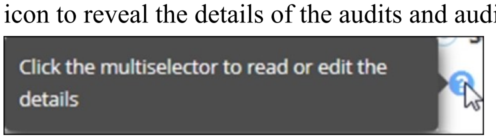
1. Click **Select**. The **Select Audit** window opens.
2. Select audits from the list of audits and click **Next** at the bottom of the window. Refer to the scrreenshot below:



3. Select auditors from the selected audit profiles and click **Finish** at the bottom of the window.



4. The number of audits and auditors selected appears in the **Selected audit** text box. Hold the mouse over the help icon to reveal the details of the audits and auditors selected.



5. Clicking the multiselector (textbox) opens the complete view of the audits and auditors selected. Refer to the screenshot below:

All documents

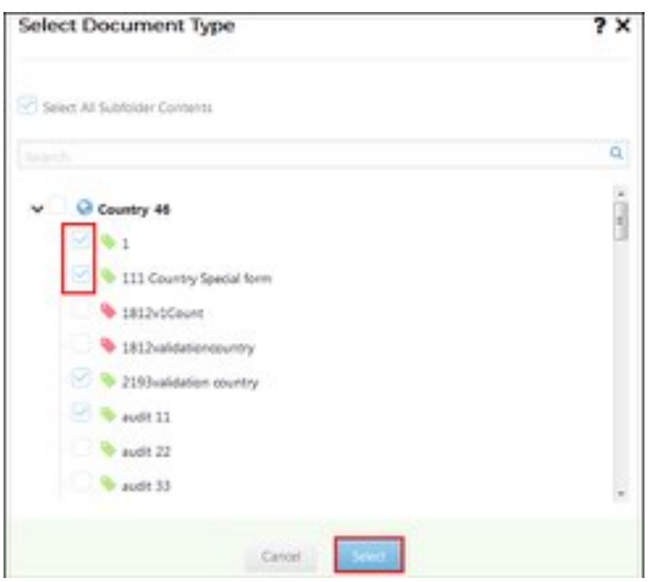
If selected, the documents of all document types will be added to the audit pool for audit.

Selected Documets - Selected document types

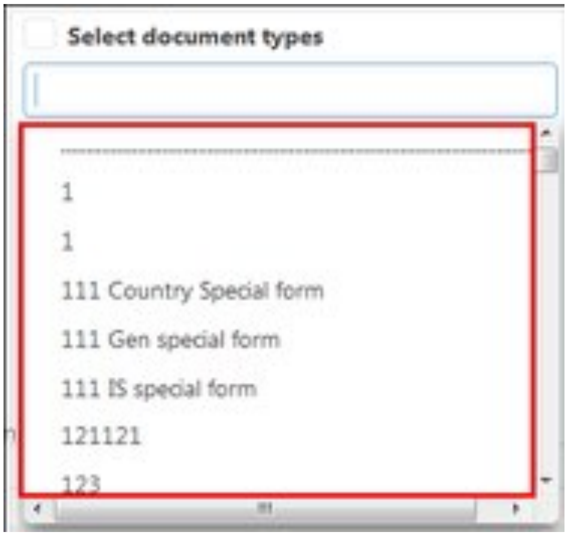
If selected, documents for audit will be selected from the chosen document types.

1. Click **Select** 

. The **Select Document Types** window opens.
2. Click the arrow next to the document type to navigate to the sub-types and select the checkbox next to the required document type.
3. Click **Select** at the bottom of the window. Refer to the screenshot below:



4. Besides, you can also click the textbox and select the document types from the dropdown that appears. Refer to the screenshot below:

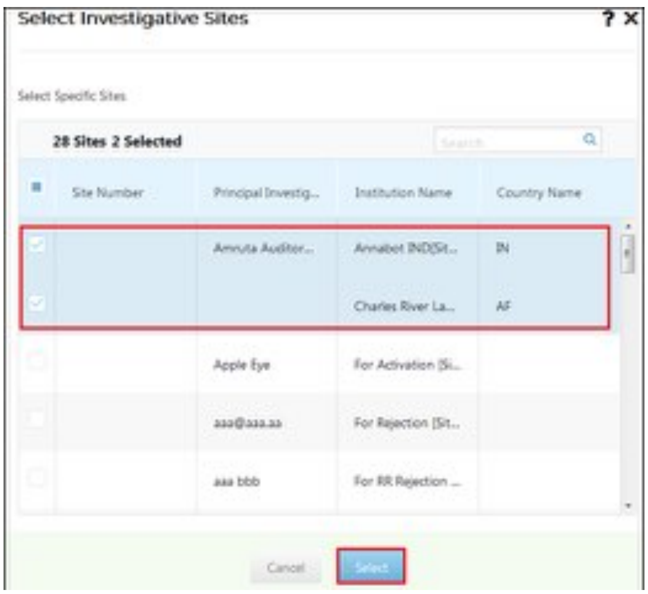


Selected Documents - Selected Investigative Sites

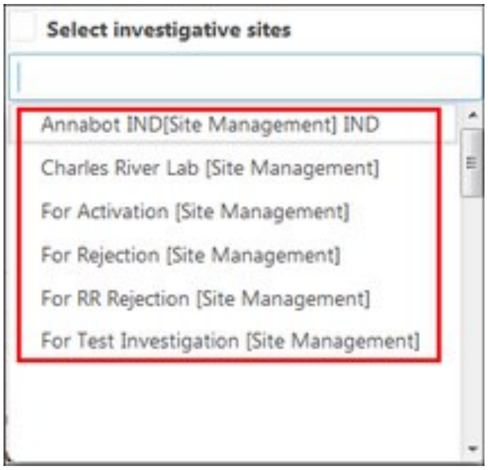
If selected, documents for audit will be selected from the chosen investigative sites.

1. Click **Select** 

. The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
3. Click **Select** at the bottom of the window. Refer to the screenshot below:



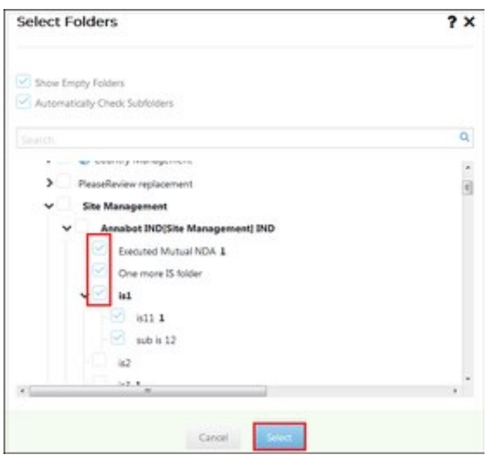
4. Besides, you can also click the textbox and select the investigative sites from the dropdown that appears. Refer to the screenshot below:



Selected Documents - Select Folders

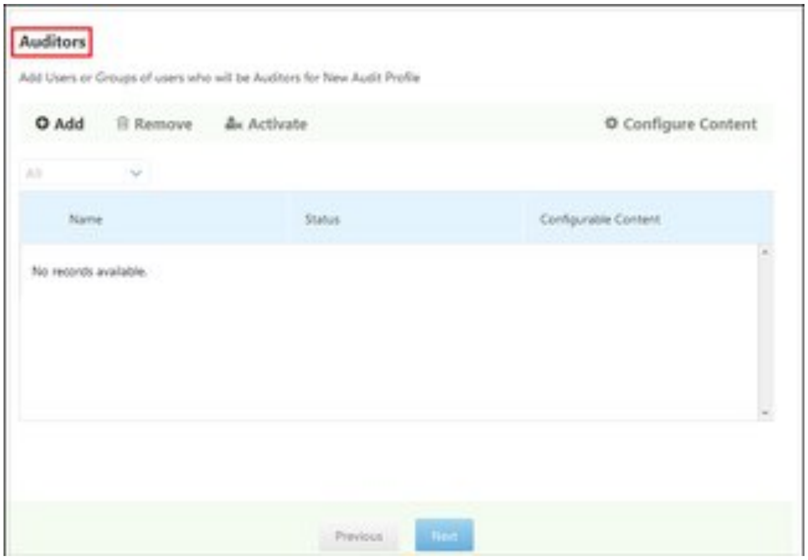
If selected, documents for audit will be selected from the chosen folders.

1. Click **Select**  . The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
3. Click **Select**. Refer to the screenshot below:



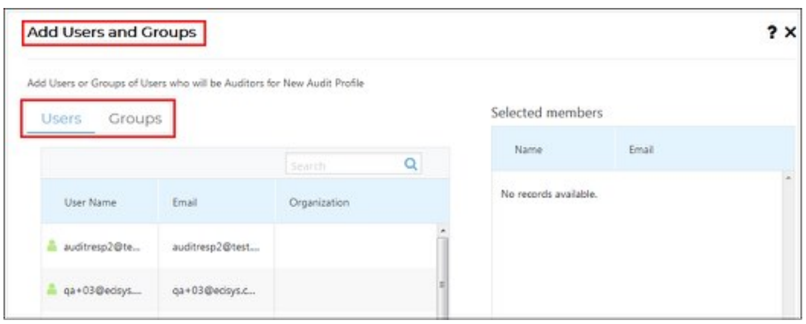
Creating an Audit Profile - Adding Auditors

After adding all the general information, you are landed on the **Auditors** step. Refer to the screenshot below:

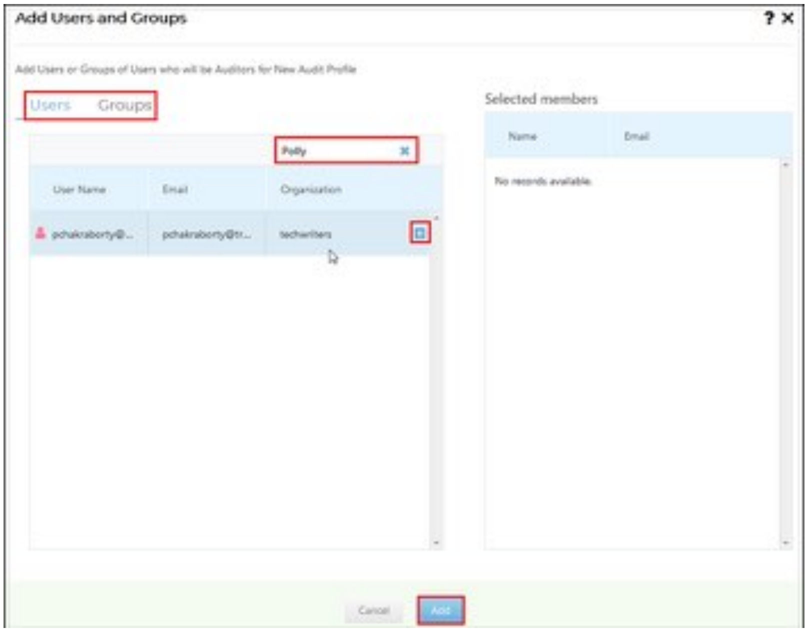


Follow the steps below to add auditors to the current audit profile:

1. Click **+Add** Add from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:



   a. Hover the mouse over the required user / group and click + icon that appears to the right of the selected user/group or double click the user/group to add the them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to audit.
   b. You can also search for the user/group by entering the name in the Search box above the grid and then click the **Magnifying icon** to the right. Refer to the screenshot below:



c. Click **Add** from the bottom of the **Add Users and Groups**window.

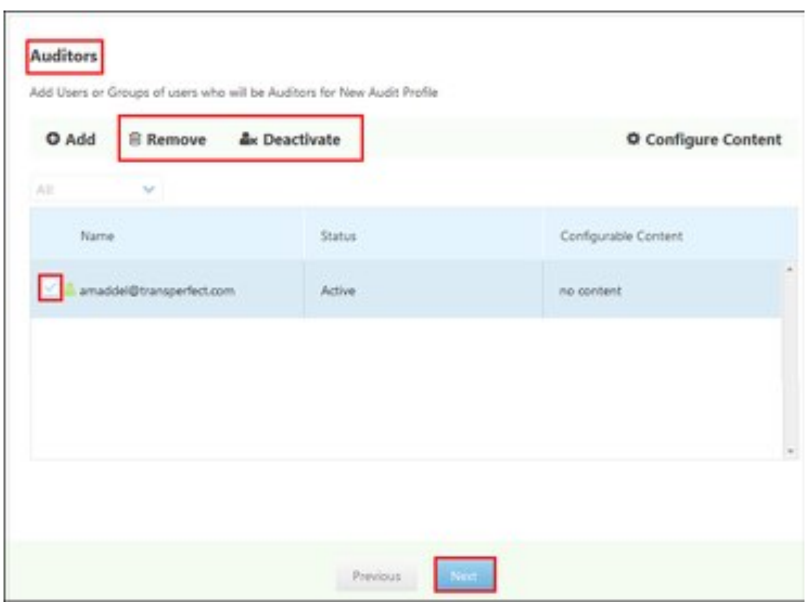
d. You are taken back to the **Auditors** window and the selected members appear in the grid.

3. Click **Next** at the bottom of the **Auditors** window.
4. You can also choose specific documents types, investigative sites and folders to be available to the auditors for audit by clicking **Configure Content** in the Auditors section.
5. During the process of creating an audit profile you may choose to remove, activate/deactivate auditors:

a. Tick the checkboxes next to the auditor names and click **Remove**  to remove them from the list.

b. Tick the checkboxes next to the auditor names and click **Dectivate**  to deactivate auditors.

Alternatively, select a deactivated auditor and click the **Activate**  button to activate an auditor. Refer to the screenshot below:



6. Click **Next** at the bottom of the **Auditors** window.

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Managers**.

Configure Content

Besides adding documents for current audit profile from the **General Information** step, you can also also configure the content for the auitors using Configure Content from the **Auditors** step.

> **Note:** *This feature is enabled only if you choose* ***Add documents to pool on demand basis*** *option disabled when when you choose* ***Selected Audits*** *from the General Information step.*

Follow the steps below to configure content:

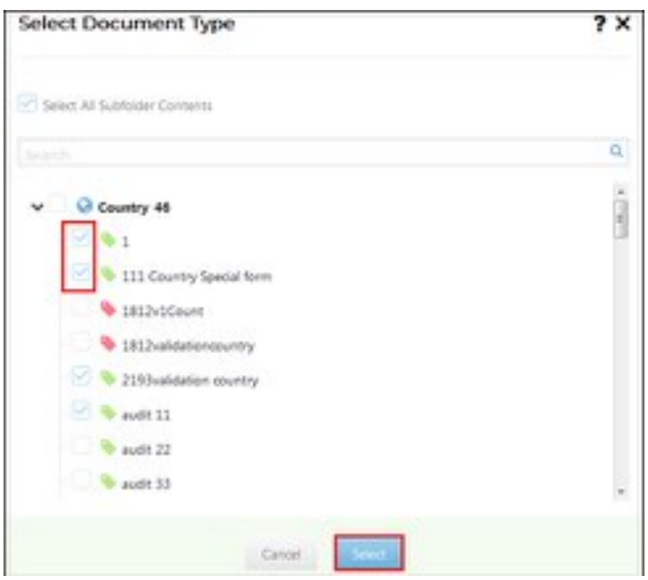
1. Select the user/group from the list of auditors.
2. Click the **Configure Content** 

icon located to the extreme right of the menu bar. A popup appears displaying the options as shown in the screenshot below:

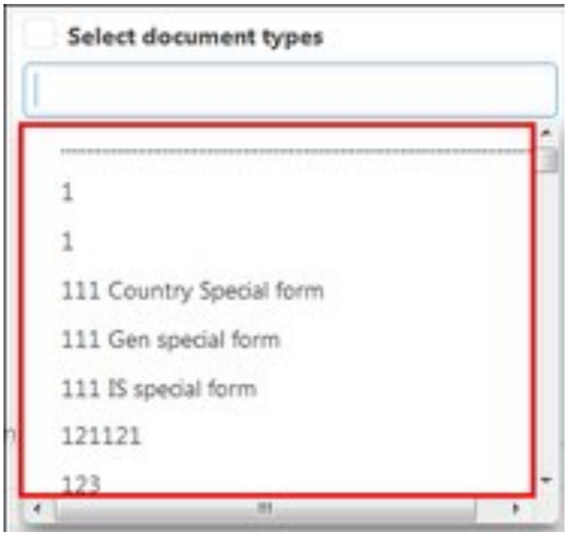

3. Click the required option to configure the content for the selected audit user/group.

   Follow the steps below to configure Document Types:

   a. Click **Select** 

. The **Select Document Types** window opens.
   b. Click the arrow next to the document type to navigate to the sub-types and select the checkbox next to the required document type.
   c. Click **Select** at the bottom of the window. Refer to the screenshot below:


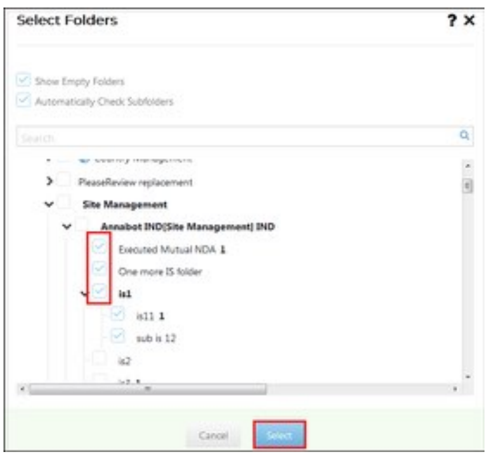
   d. Besides, you can also click the textbox and select the document types from the dropdown that appears. Refer to the screenshot below:



Follow the steps below to configure Investigative Sites:

a. Click **Select** 

. The **Select Investigative Sites** window opens.
b. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
c. Click **Select**. Refer to the screenshot below:



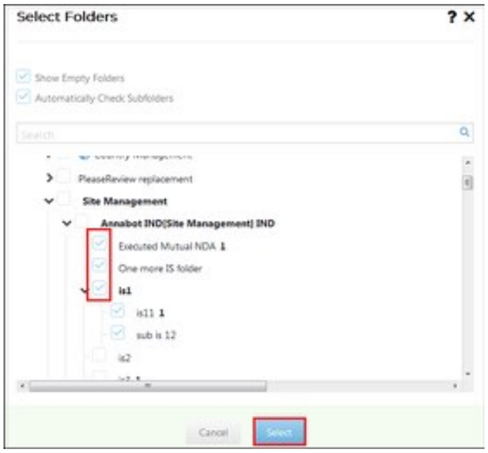
Follow the steps below to configure folders:

Selected Documents - Select Folders

If selected, documents for audit will be selected from the chosen folders.

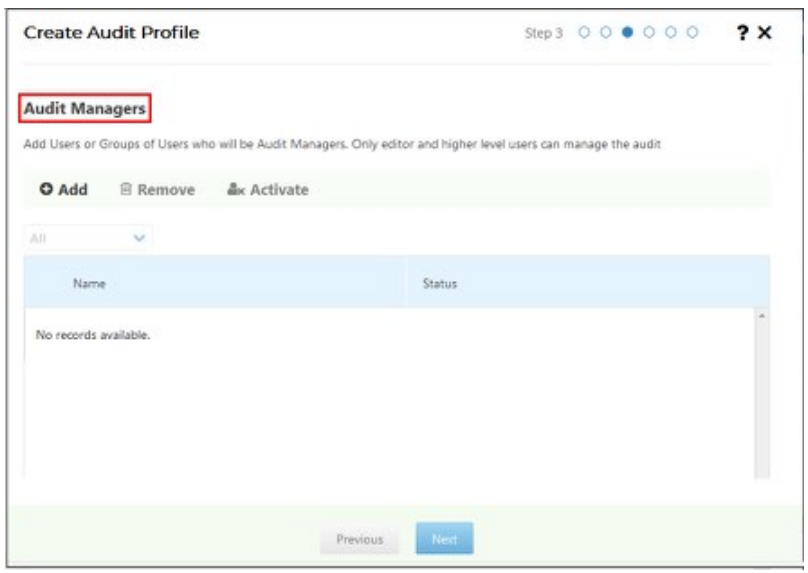
1. Click **Select** 

. The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
3. Click **Select**. Refer to the screenshot below:

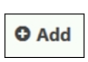


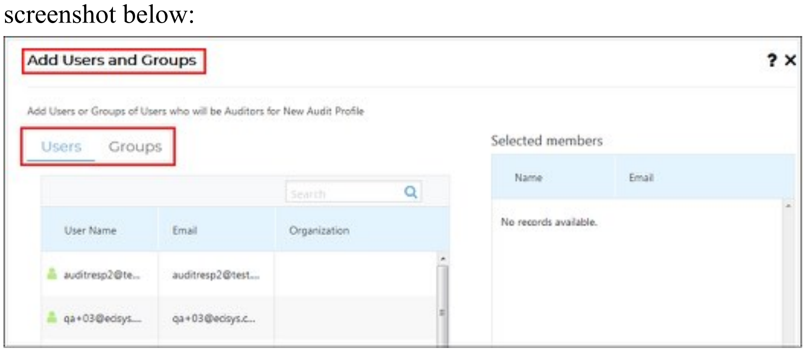
Creating an Audit Profile - Adding Audit Managers

After adding Auditors, you are moved to the next step to add **Audit Managers**. Refer to the screenshot below:

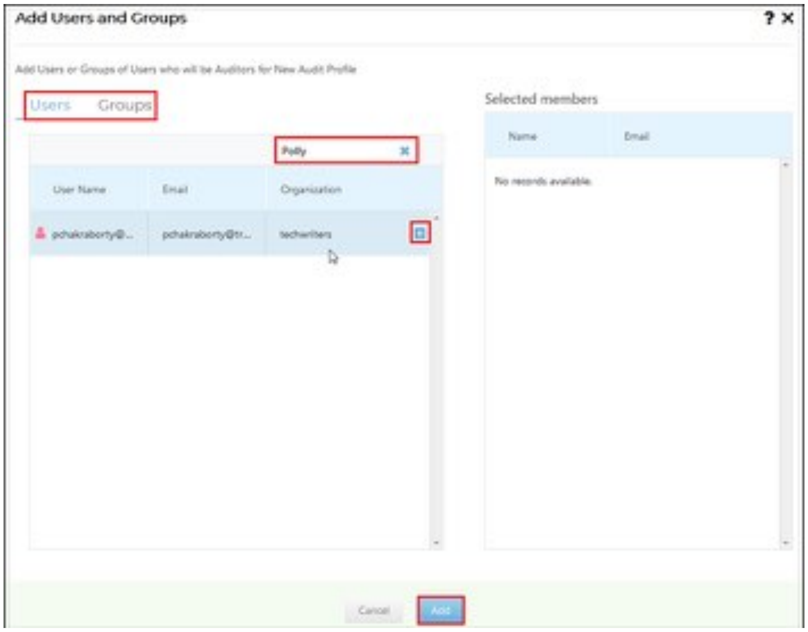


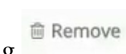
Follow the steps below to add audit managers to the current audit profile:

1. Click **+Add**  from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:



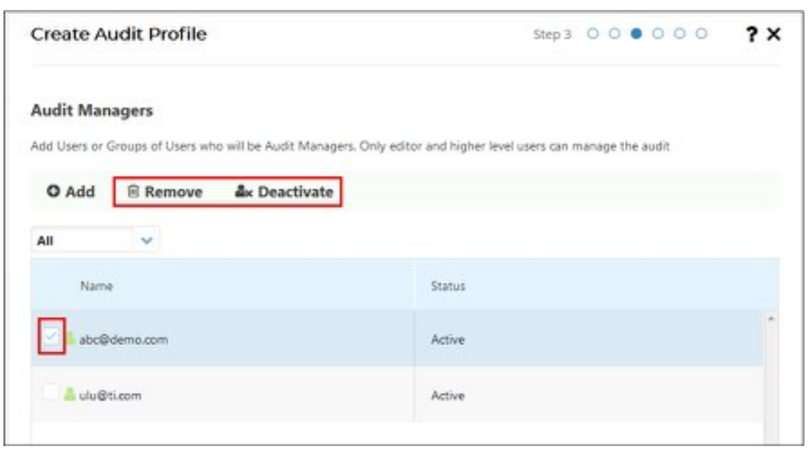
3. Hover the mouse over the required user / group and click + icon  that appears to the right of the selected user/group or double click the user/group to add the them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to audit.
4. You can also search for the user/group by entering the name in the Search box above the grid and then clicking the **Magnifying icon**  to the right. Refer to the screenshot below:



5. Click **Add** from the bottom of the window.
6. You are taken back to the **Audit Managers** window and the selected members appear in the grid.
7. You can also **Remove** Audit Managers by clicking 

button or **Deactivate** them by clicking 

button from the menu bar. Refer to the screenshot below:



8. Select the appropriate users/groups from the grid , click **Next** at the bottom of the window.

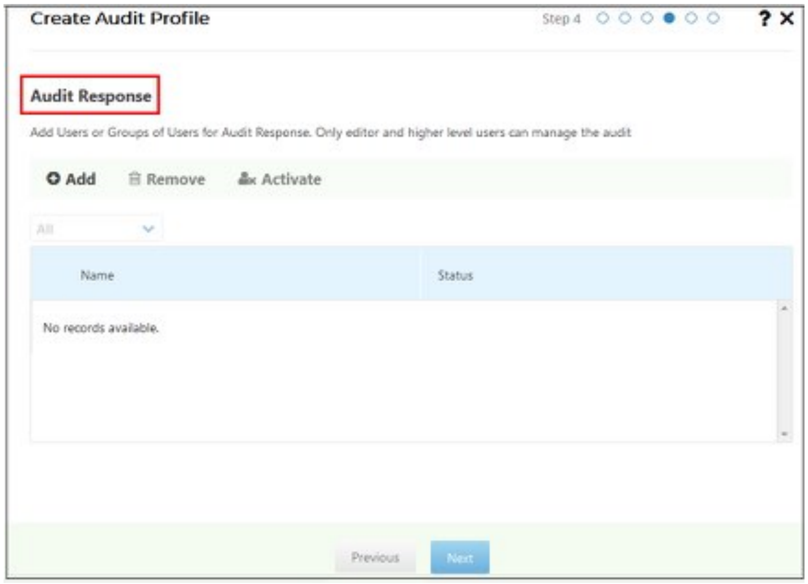
Note:

- *The **Remove** and **Deactivate** buttons enable only when you select the auditor from the grid.*
- *The **Deactivate** button toggle to **Activate** when no auditor is selected from the grid.*

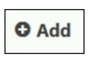
Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Response**.

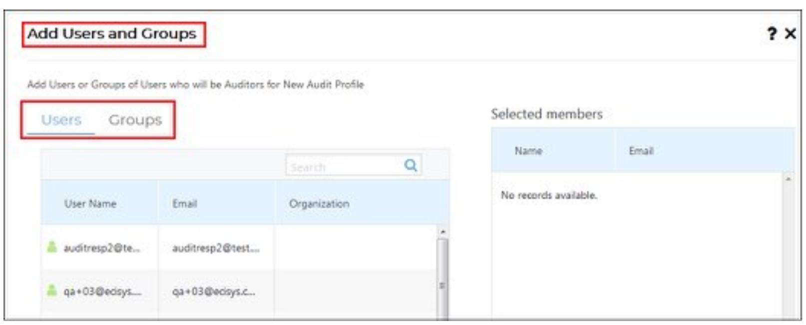
Creating an Audit Profile - Adding Audit Responders

After adding Audit Managers, you are moved to the next step to add **Audit Responders**. Refer to the screenshot below:

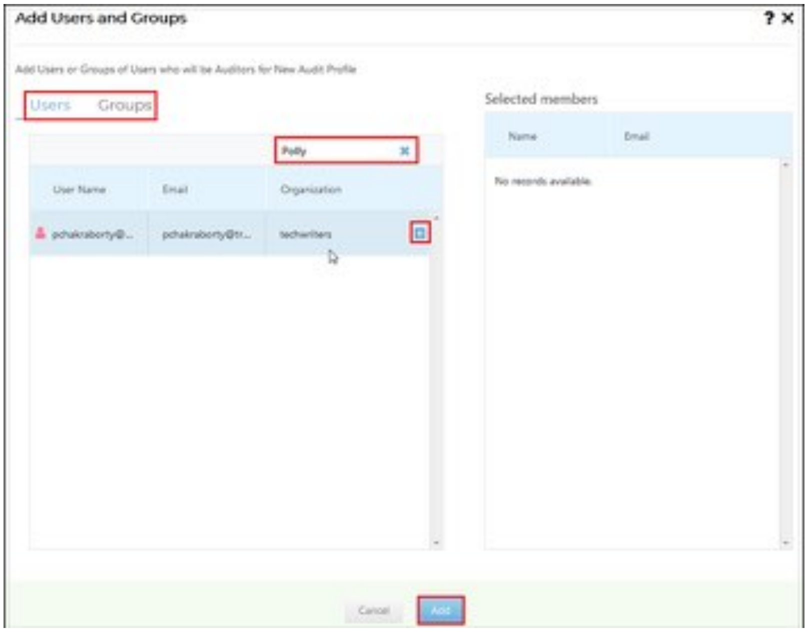


Follow the steps below to add audit responders to the current audit profile:

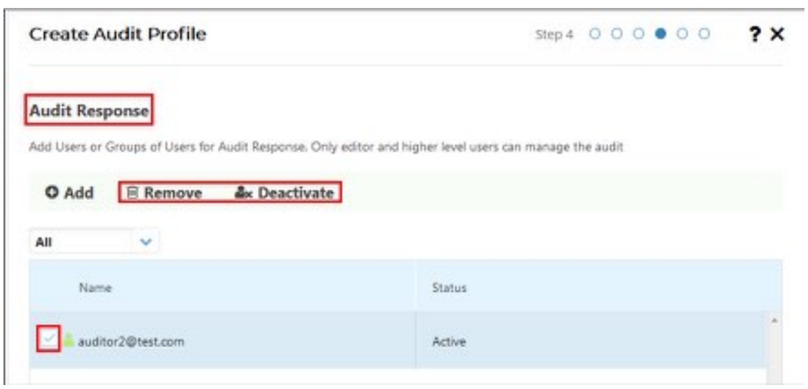
1. Click +**Add**  from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:



3. Hover the mouse over the required user / group and click + icon  that appears to the right of the selected user/group or double click the user/group to add the them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to audit.
4. You can also search for the user/group by entering the name in the Search box above the grid and then clicking the **Magnifying icon**  to the right. Refer to the screenshot below:



5. Click **Add** from the bottom of the window.
6. You are taken back to the **Audit Responders** window and the selected members appear in the grid.
7. Select the appropriate users/groups from the grid , click **Next** at the bottom of the window.
8. You can also **Remove** auditors by clicking  button or **Deactivate** them by clicking  button from the menu bar. Refer to the screenshot below:



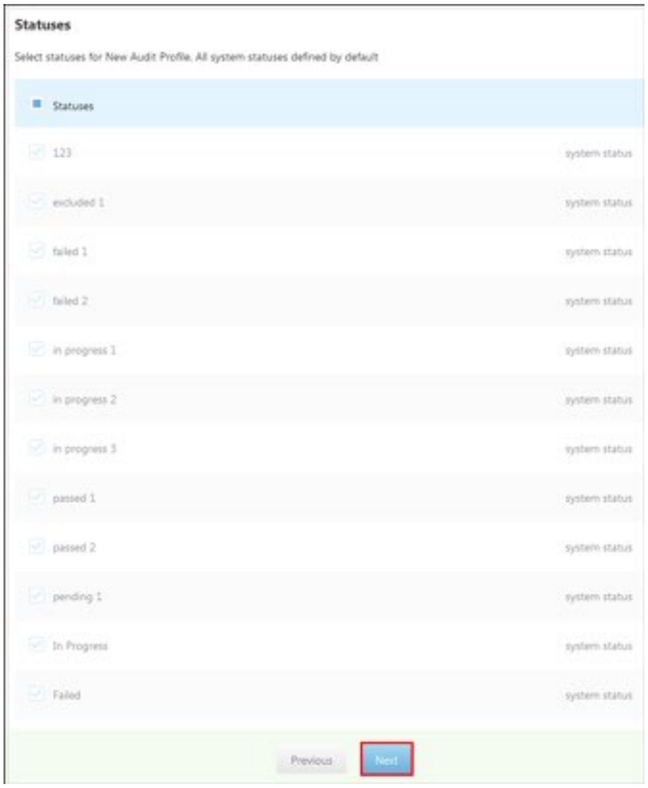
Note:

- *The **Remove** and **Deactivate** buttons enable only when you select the auditor from the grid.*
- *The **Deactivate** button toggle to **Activate** when no auditor is selected from the grid.*
- *Only **Editors** and **higher level** users can be allotted the **Audit Managers** and **Audit Responders** role. A user cannot be allotted both the Auditor and Audit Responder role for the same Audit profile.*

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Statuses**.

Creating an Audit Profile - Adding Statuses

After adding Audit Responders, you are moved to the next step to add **Audit Statuses**. Refer to the screenshot below:

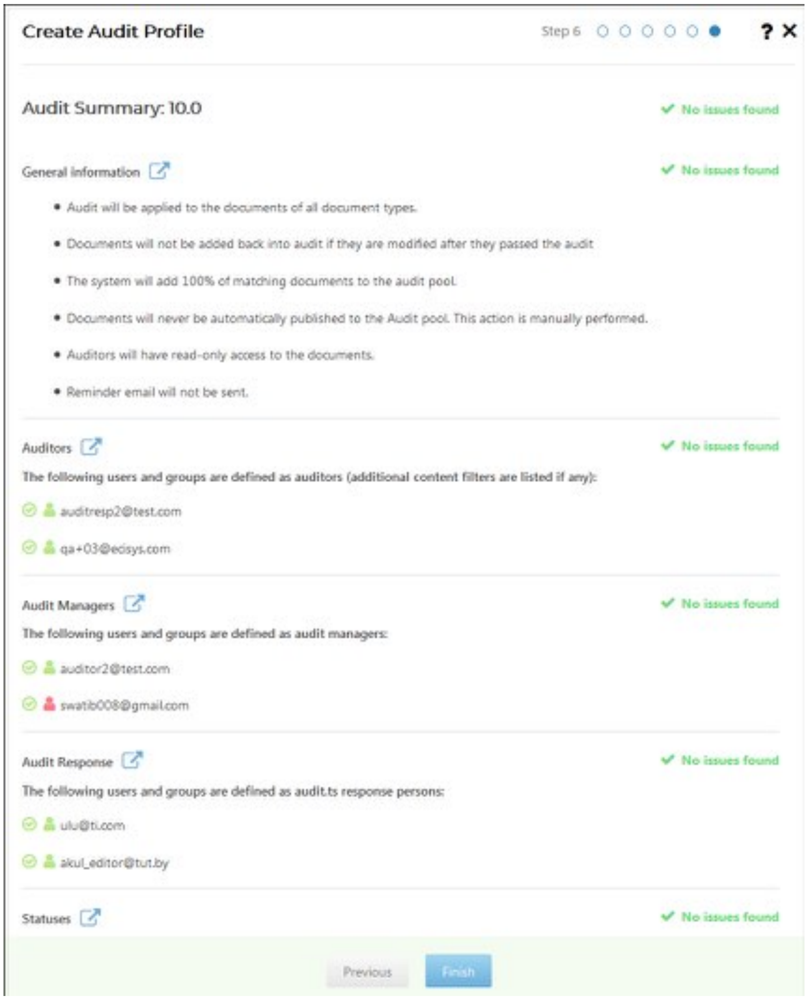


To add the statuses:

1. Select the required audit statuses from the **Statuses** window.
2. Click **Next**. You are taken to the next step of audit profile which displays the **Audit Summary**.

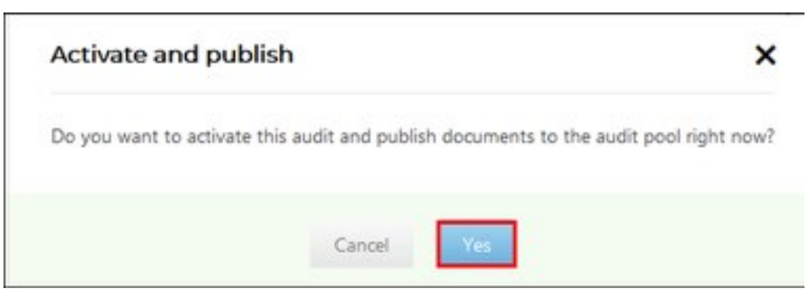
Creating an Audit Profile - Viewing Summary

After adding Audit Statuses, you are moved to the next step to view **Audit Summary**. Refer to the screenshot below:



The **Audit Summary** warns for any issues found in the Audit Profile. If Issues are cited:

1. Follow the directions in the fields showing explanations , and click the arrow next to the field to navigate to page of the building of the audit profile where the issue has been cited.
2. Correct the details that have led to the issue.
3. Click **Go Back to Summary Page** and then click **Finish**.If you are sure the audit profile has been set up correctly, click **Yes** to activate the audit. Refer to the screenshot below:



4. The newly activated audit appears in the display list.

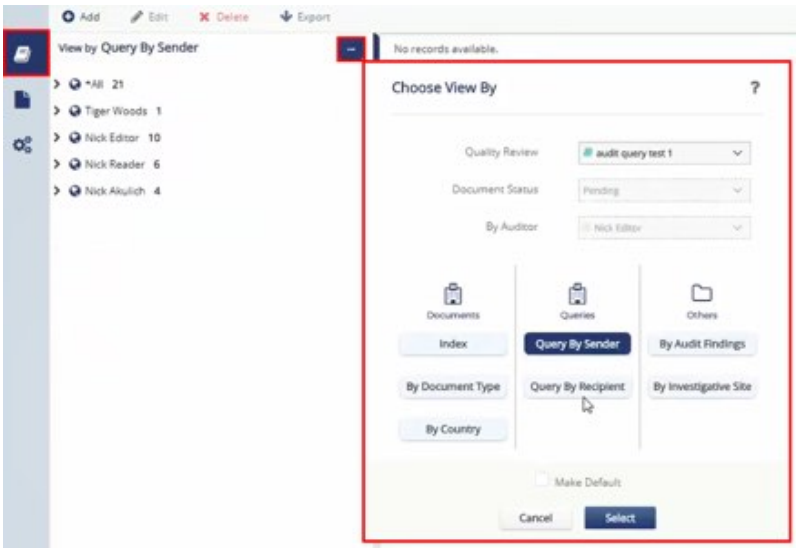
Performing Audits

If you are assigned the Auditor or Audit Manager action in your trial room, the audit feature is available to you when you click the **Quality Review** module in the toggling menu bar.

The Quality Review module has the following views:

- **Audit**: This allows you to perform audits
- **Documents**: This allows you to assign documents for audits
- Follow the steps below to perform audits:

1. As a user with Auditor duties, log in to a room and click the **Quality Review**icon from the Main Navigation. The user can access **Audits**and,**Audit Documents** through the panel on the left.
2. Click the **Audit** view from the left panel. The Audit view opens.
3. Click **View by Index** dropdown arrow from the left pane. The **Choose View By** popup appears as shown in the screenshot below:

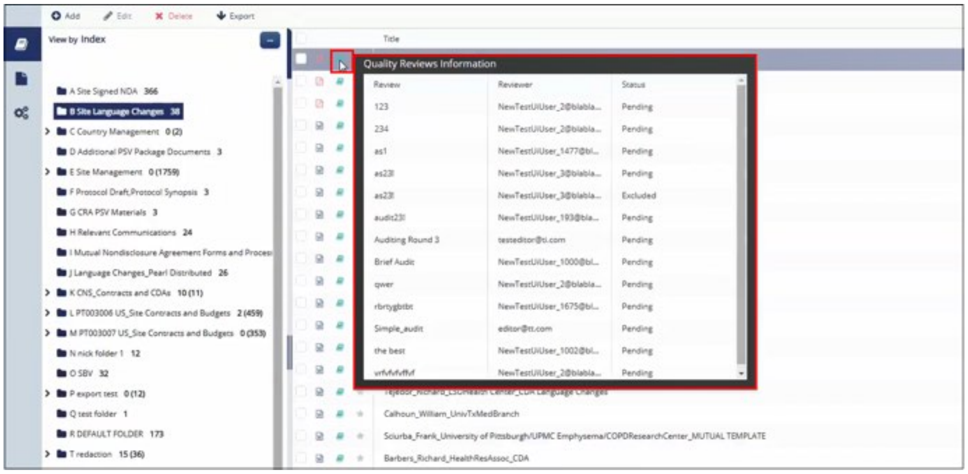


4. Click the **Quality Review** dropdown to select an active audit from the list.
5. The user can also choose to view the available audit documents *By Document Type*, *By Country*, *and By Investigative Site*, *Audit Findings*, *Query By Sender, and Query By Recipient*. Select views to be displayed.
6. The corresponding folders display based on the selection made by the user. Drill down and select the available folders.

   Available documents will be displayed in the grid. .

<u>The Auditor has another means to filter the audit documents.</u>

1. Once the Audit is chosen, click the **Document Status** dropdown.
2. Select **Pending** from the list.
3. Select the auditor from the **By Auditor** dropdown.
4. Click the **Select** button. Index folder containing documents **Pending Audit** populate in the Index View. Refer to the screenhot below:
5. Open folders to locate documents published and assigned for audit.
6. Notice the **Quality Review Information** icon next to the document icon in the document grid.
7. Click the icon to open the Audit Panel in the Metadata Panel. Also notice that the **Quality Review Information popup** displaying the audit status of the selected document. Refer to the screenshot below:



8. Open the document in the viewing panel.
9. Examine the document and its metadata to determine if it meets the established audit criteria.
10. From the **Metadata panel** to the right, click the dropdown arrow at the right end of the **Status** field.

    The status options appear.
11. Click the appropriate **Status**.

    If the document contains **Protected Health Information** (PHI) and you want to delete and fail the document attachment for audit, tick the **Contains PHI?** checkbox.

    Note: *To enable the Contains PHI ? field, you will need to enable the feature when setting up the Audit under Document Audit Settings*

    On ticking this, the document automatically acquires a **failed** status and displays a warning regarding the removal of the attachment from the document.

    Click **Remove file** to proceed. The system deletes the attachment in the backend and displays the **Refresh** icon next to the document in the grid.

    On clicking the **Refresh** icon, the document disappears from the grid and moves to the **Audited** folder.
12. Insert comments as appropriate.
13. Click the **Save** button, or the **Save and select next button** in the lower toolbar of the window.

    Note: *Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your Audit Criteria*
14. To view audited documents, filter the documents by Audited from the panel 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.

Exporting Audits

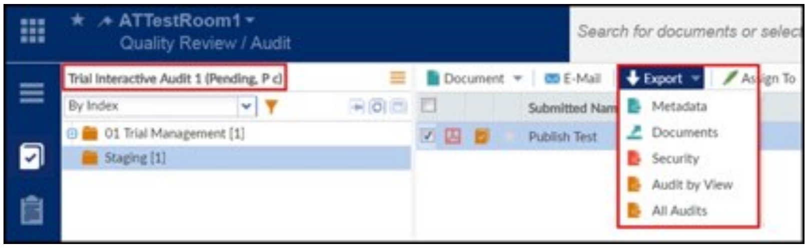
An Auditor or Audit Manager can export a report of the following directly related to the documents assigned to any particular audit:

1. Metadata
2. Documents
3. Security
4. Audit By View
5. All Audits

To export an audit report:

1. From the **Quality Review** module, click **Audit** from the left menu bar.

2. Select the audit on which you would like to run the audit report from the list of active audits.
3. Select the documents from the list and click **Export** on the top ribbon bar.



4. From the Export Dropdown, click the required option to generate an audit report.
5. Click the **Export** button. A **Background Jobs** window opens with the initial export results.
6. As instructed on the screen, click to get the export results. A zipped file downloads to your computer.
7. Follow the on-screen instructions to open the XLSX file.

Each option in the Export dropdown is discussed as below:

Metadata

This is same as discussed in **Exporting Metadata** in chapter **Exporting Metadata**.

Documents

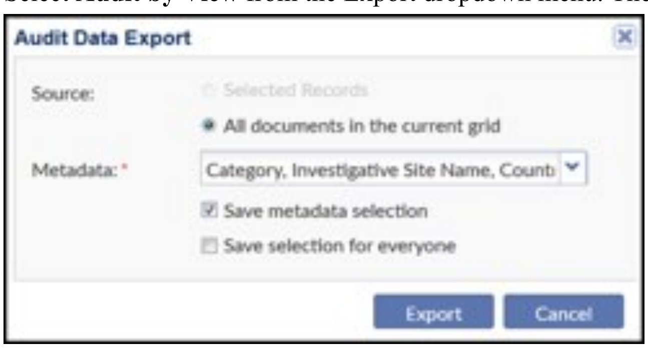
This is same as discussed in **Exporting Documents** in chapter **Exporting Documents**.

Security

This is same as discussed in **Exporting Security** in chapter **Exporting Security**.

Audit by View

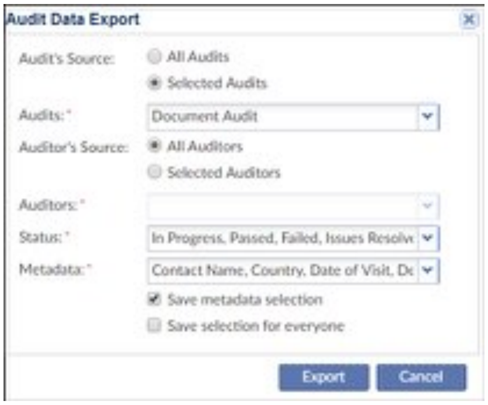
Select **Audit by View** from the Export dropdown menu. The **Audit Data Export** window opens.



Follow the on-screen instructions to generate the audit report.

All Audits

Select **All Audits** from the dropdown menu. The **Audit Data Export** window opens.



Follow the on-screen instructions to generate the audit report.

Performing Audit Response

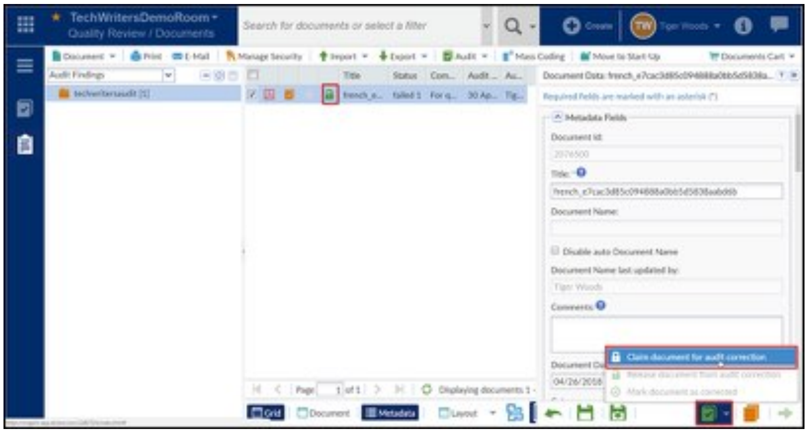
To perform an audit response, you must be logged in the room as an Audit Responder.

1. Navigate to the **eTMF/Documents** module or the **Quality Review/ Audit module**.
2. If you are in the eTMF Documents module, select **Documents** from the menu icons at the top of the screen.
3. From either of the modules, select **Audit Findings** view.

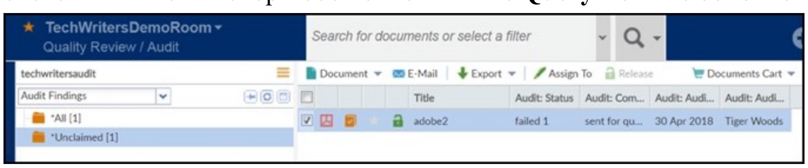
The active audits to which you are assigned that have audits with findings populate the Index panel.

4. Click the folder for one of the audits. The documents with audit findings populate the document grid. Documents in the list that are available for **Audit Response** show a padlock icon that is unlocked.
5. Select the document by clicking the checkbox.
6. Open the metadata panel for the document by clicking the **Metadata** button at the bottom of the document grid.

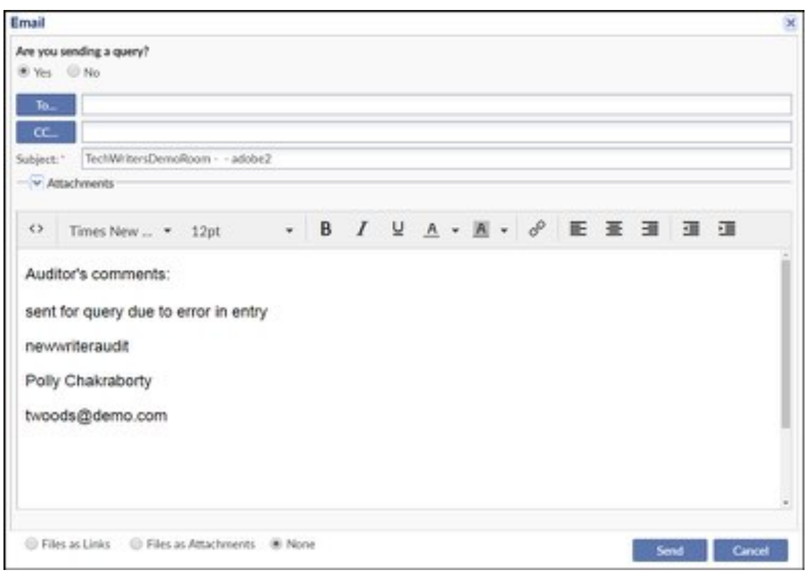
7. At the bottom of the metadata panel, click the **Audit** button.



8. From the available options, click **Claim document for Audit Correction**.
9. Click **Document** at the bottom of the document grid to open the contents of the document for inspection.
10. From the Audit History panel, click **View Full History** button to view the comments included by the Auditor.
11. Appropriate actions on the part of an Audit Responder are based on the nature of the failure of the audit.
12. If the cause of the document's audit failure can be remedied by the Audit Responder, that action can be carried out.
13. In such cases, the Audit Responder then goes to the **Audit** button at the bottom of the metadata panel again and selects **Mark document as corrected**.
14. If the cause of the document's audit failure cannot be remedied by the Audit Responder, the Audit Responder clicks **Email** from the top ribbon bar or **Initiate Query** from the bottom of the Metadata panel.



15. The **Email** popup window opens. Click **Yes** to the question **Are you sending a query?**
16. Click **To** and select the appropriate party or parties from the room's users to notify about the discrepancy discovered in the audit.

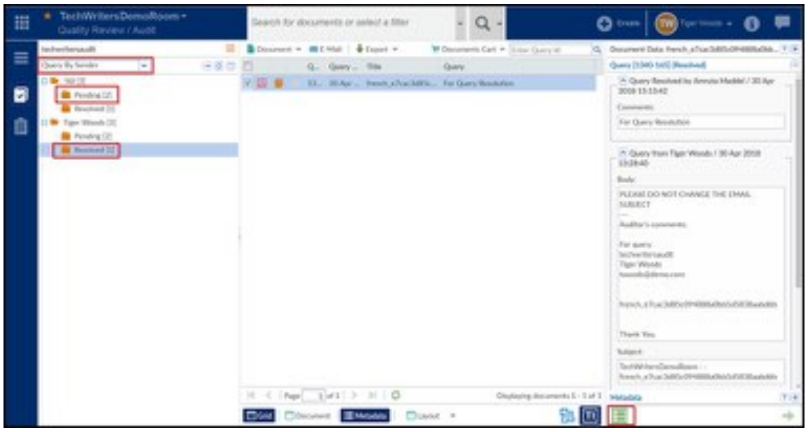


17. Include something in the Subject line and enter the text of message to alert the recipients as to what action they need to take.
18. Select **Files as Links** at the bottom of the Email window to send the document along with the email message. Documents can also be sent as attachments.

Click **Send**.

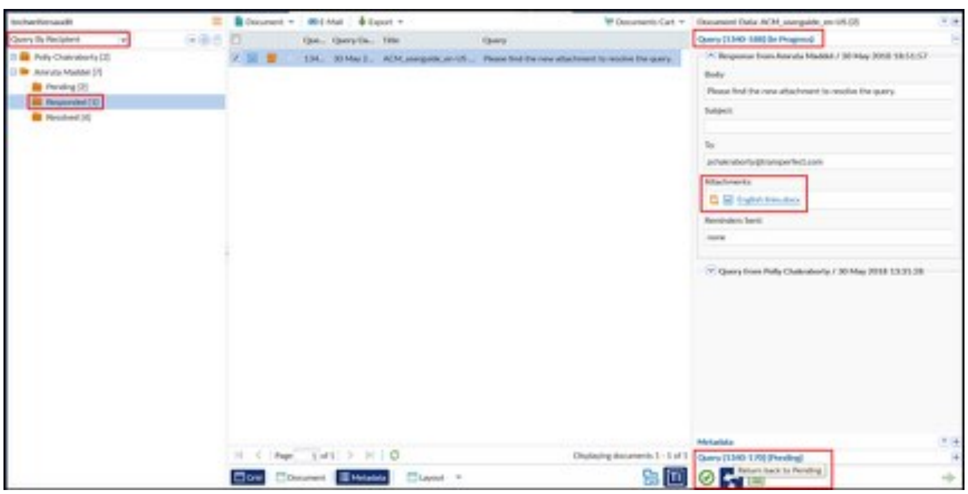
The selected users will receive the email message regarding the Query raised.

19. Click **Audit** sub-module from the left menu bar. The queries raised during audit can be viewed from the **Query By Sender** current viewin the left index pane, if you have sent queries to be resolved during audit. Refer to the screenshot below:



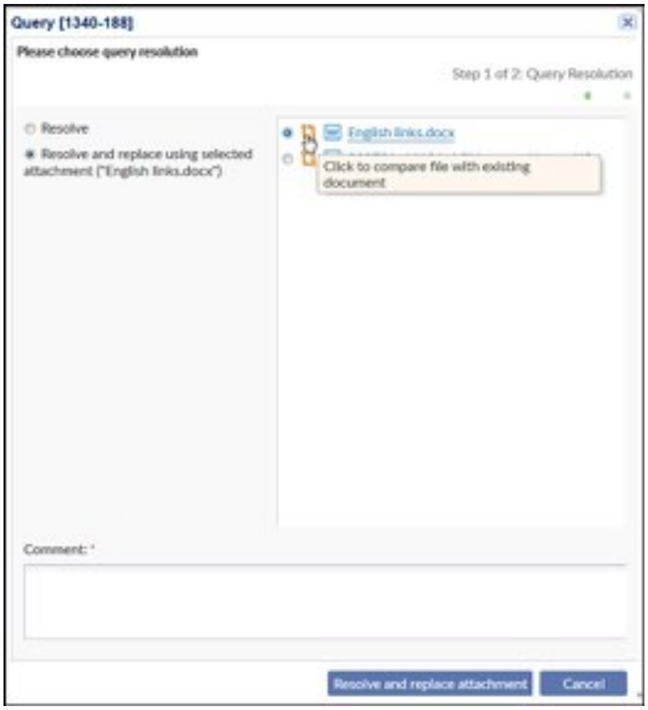
Resolving Queries Raised during Audit

The user who receives the email responds back with an attachment to resolve the query. You can view the responded query in the **Responded** folder of **Query By Recipient** view under the selected audit. Refer to the screenshot below:



To resolve queries raised during audit:

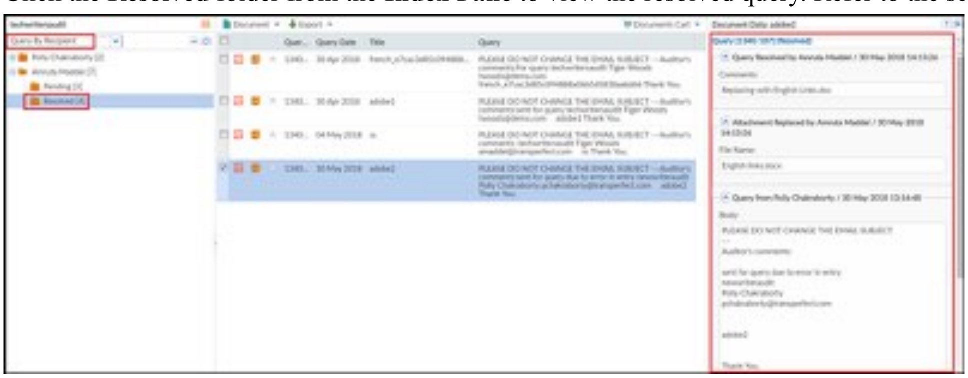
1. Navigate to the **Query By Recipient** view.
2. Select a query from the grid on the right.
3. Click the **Metadata** button from the bottom of the grid. This will open the Document Data Panel.
4. Click the **Resolve** button from the bottom of the **Document Data Panel**.If the resolution is not acceptable, you can click the **Return to Pending**button from the bottom of the metadata panel. The document returns back to the **Pending** folder and can be resent for query again.
5. This will open the **Query** window to comment and resolve the query.
6. Enter the **comments** and click the **Resolve** button or **Resolve and replace attachment** button on the window as per your selection. Refer to the screenshot below:



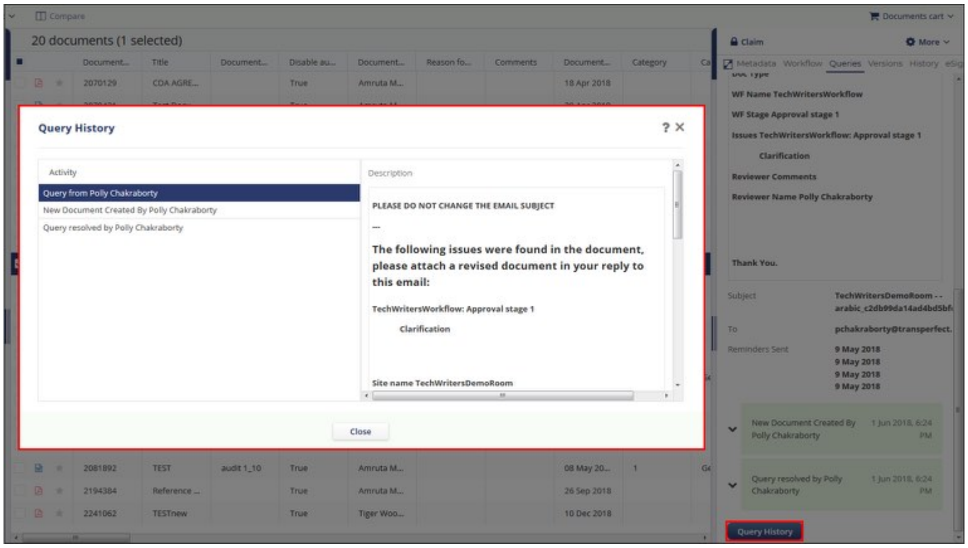
a. **Resolve**: This option will just mark the query as resolved without any additional actions.
b. **Resolve and replace using selected attachment**: This option allows you to replace the existing attachment with the one which is received as a part of query response. Select the document from the right 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.



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

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