TRIAL INTERACTIVE

9.2 Reader Guide, v. 1.0

TRANSPERFECT

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Version History

Author	Revision	Date	Change History
Polly Chakraborty	1.0	20 June 2017	Document finalized

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1. About This Guide

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

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

2. About Trial Interactive

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

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

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

3. Getting Started

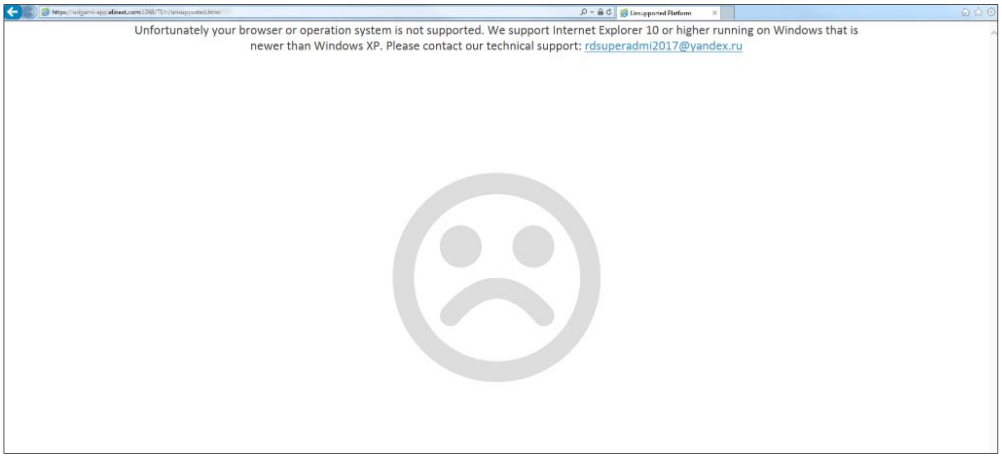
This section includes basic information that will help you get started with Trial Interactive.

3.1. Browser and Operating System Support

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

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

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



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

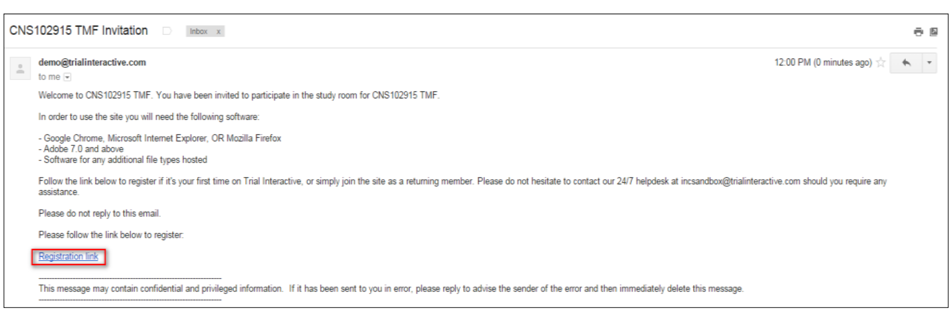
3.2. Confidentiality Agreement

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

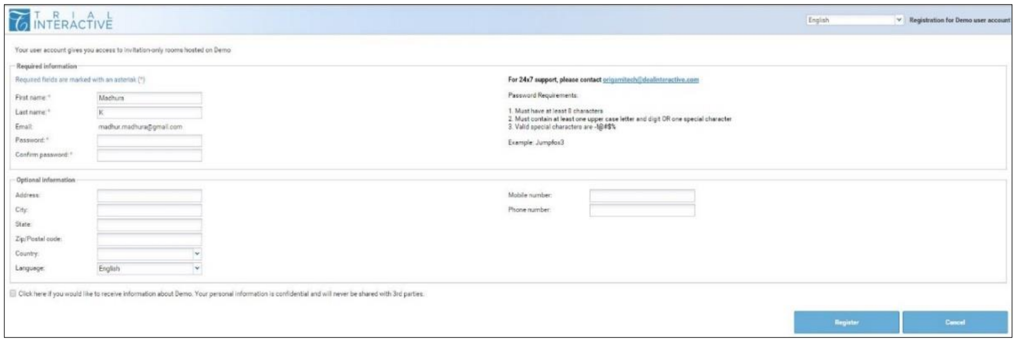
- When the user logs in the first time and visits the room or accesses the room, or
- When the user visits the room each time or refreshes the page, or
- When the user uploads a document from the Home page, or
- When entering a room through multiple sessions.

3.3. Receiving and Responding to a Room Invitation

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



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

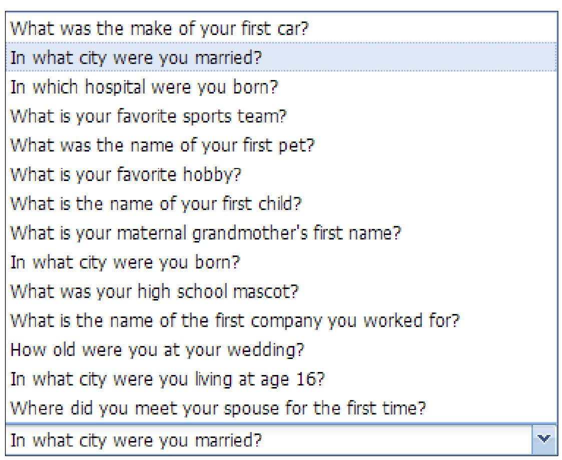


2. Type in your first name, your last name, and your email address as requested on the page in the appropriate fields.
3. Create your secure password, and confirm the password by re-typing it in the **Confirm password** field.

Password requirements:

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

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



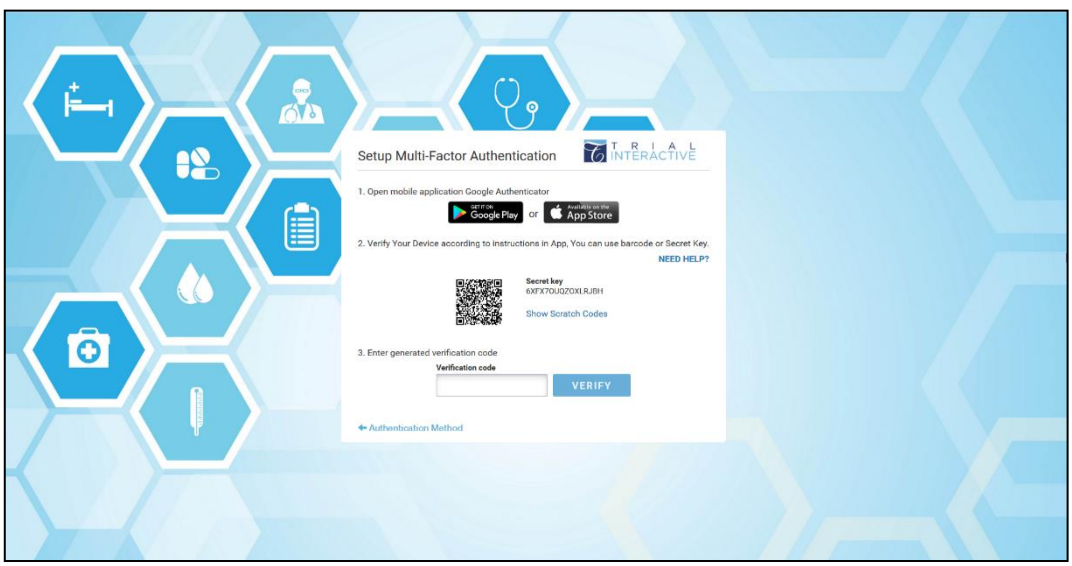
5. Type your answer in the appropriate field. Based on client preference, some rooms have only one password recovery question.
6. Select your second password recovery question.

7. Type the answer to that question.
8. Complete the other fields at the bottom of the registration page as directed by the study sponsor.
9. Click **Register**. You will be directed to a confirmation page.

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

3.4. Logging in using Multi-Factor Authenticator

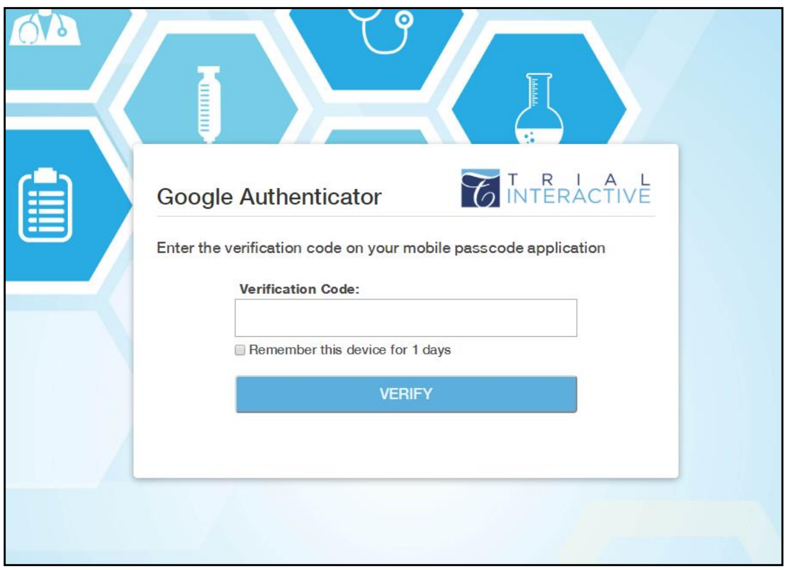
If your system is enabled for Multi-Factor authentication using Google Authenticator, you will be lead to the **Setup Multi-Factor Authentication** page on logging in with your login credentials. Refer to the screenshot below:



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

1. From Google Play Store or App Store on your mobile device, install **Google Authenticator**.

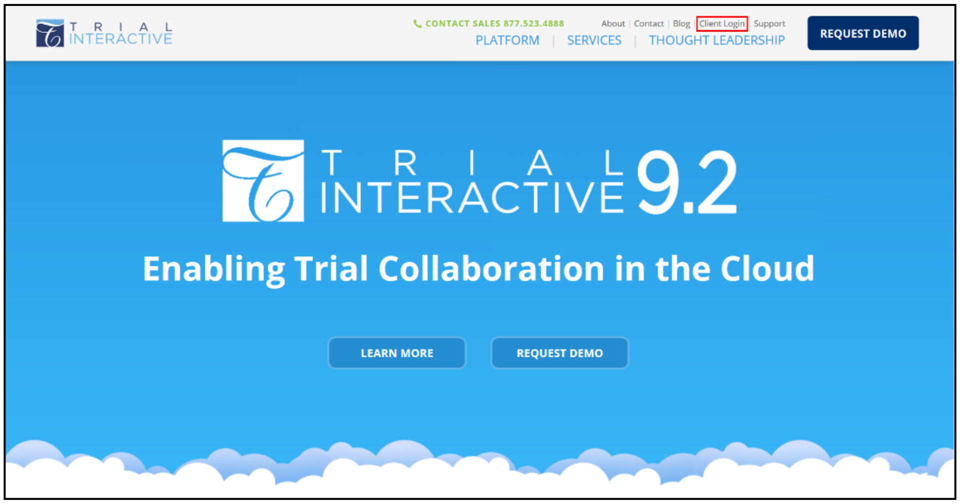
2. Add your Trial Interactive account by **scanning the bar code** on your computer's Login screen from your mobile device, or enter the **Secret key** in the field provided by your Authenticator on your mobile device . Refer to the screenshot above.
3. The above step will generate a **verification code**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



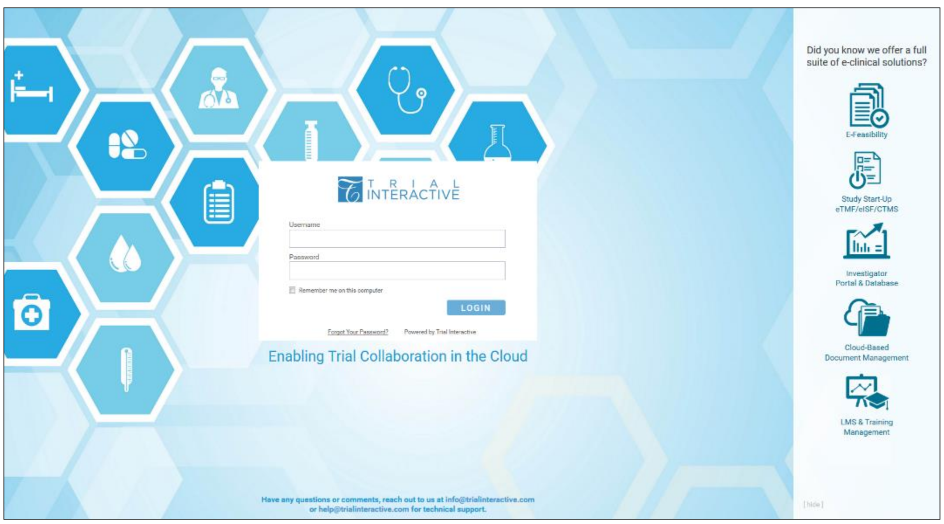
3.5. Logging In on Subsequent Visits

To log in to Trial Interactive:

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



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



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

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

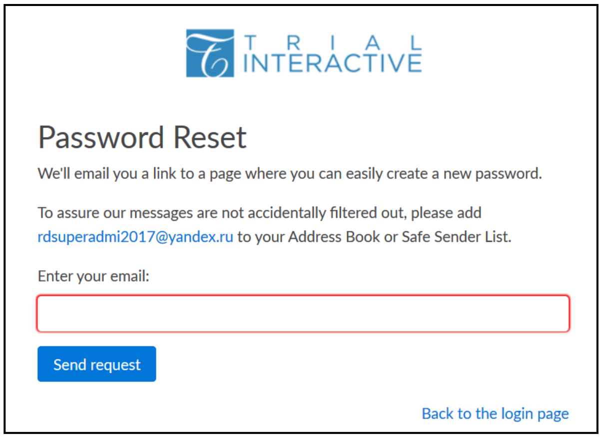
   If you are logging in the first time, the Trial Interactive Homepage for the account associated with the login username appears, else you are redirected to the same location in the application that you were in upon a subsequent login.

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

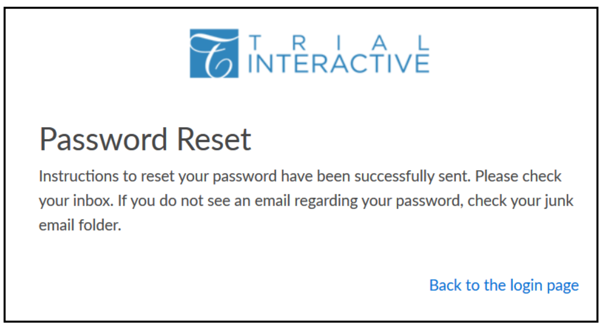
3.6. Requesting a password reset

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

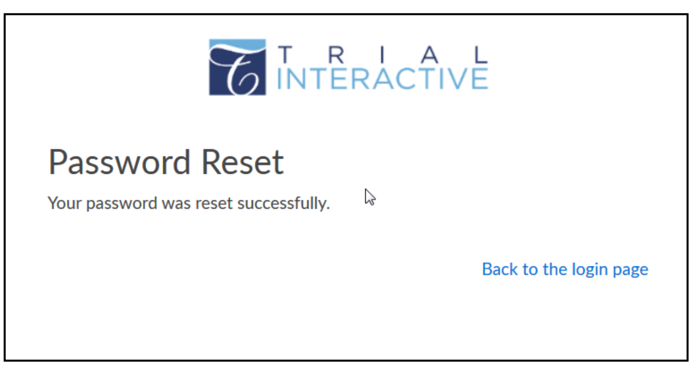
Users do not need to contact the Help Desk. In most cases, the user can perform the Password Reset operations without any outside help.



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

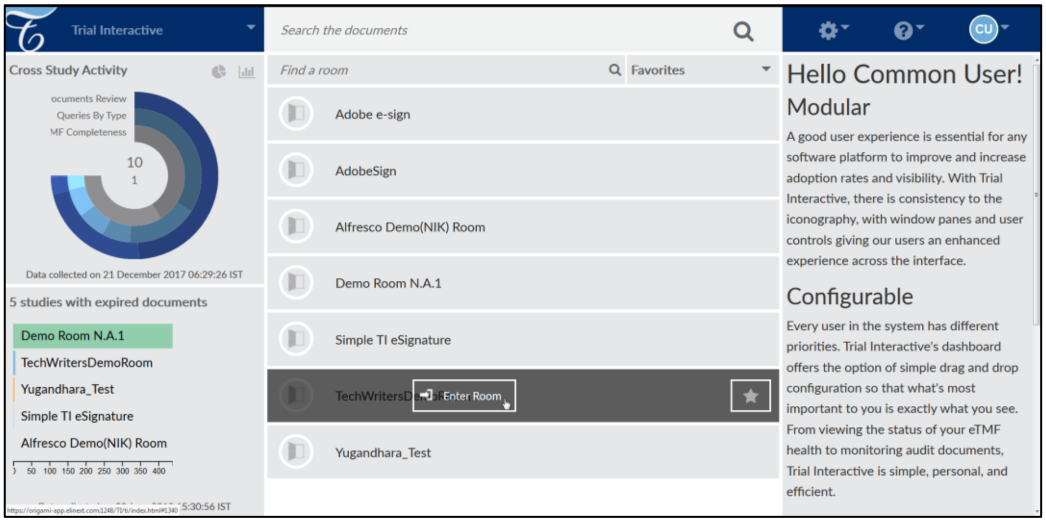


3. You will receive an email with the **Reset Password** link.
4. Click the link to lead you to the **Password Reset** page.
5. Respond to the security questions and click **Next**.
6. You are taken to the **Change Password** page. Enter the new password and confirm again.
7. Click **Set new password**.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

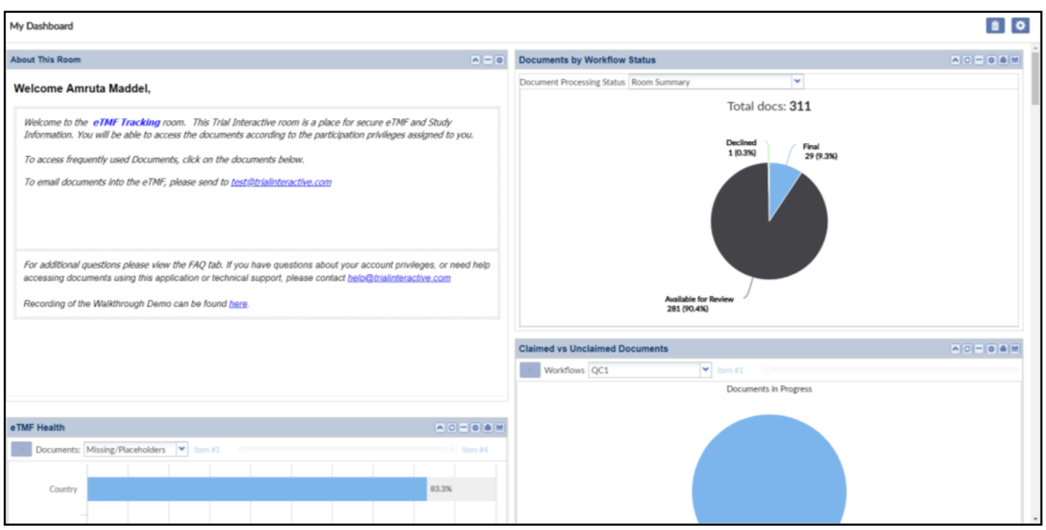


3.7. Accessing a Trial Interactive Room

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



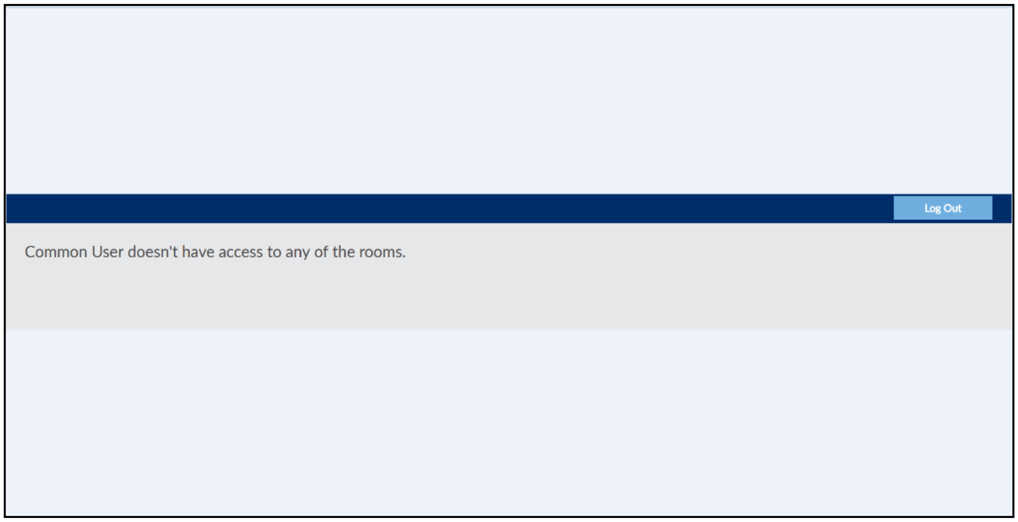
Your screen opens to the Dashboard view of the selected room. You can find more information in the [Main Module View](#) section of this guide.



3.8. Logging In without access to rooms

If a user who does not have access to rooms in the system tries to log in, such a user is automatically logged off and redirected to a separate advisory page. A user might not have access to rooms if the user's access to the rooms have expired or revoked.

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



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

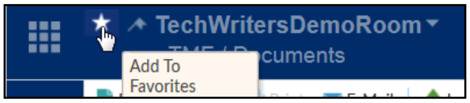
You can contact the helpdesk if you want to configure a different message to be displayed in the advisory page.

3.9. Marking Favorite Rooms

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

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

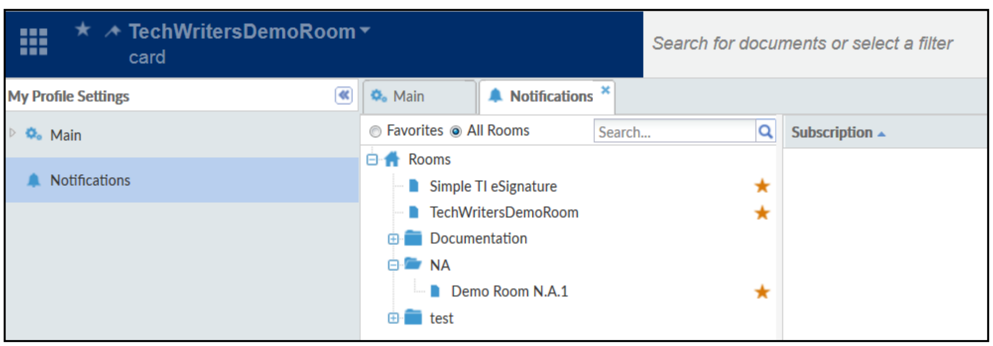
B. On entering a study room, you can add it to Favorites by clicking the star at the top left corner of the page where the room name is displayed. The room can easily be removed from the list by clicking the star again.



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

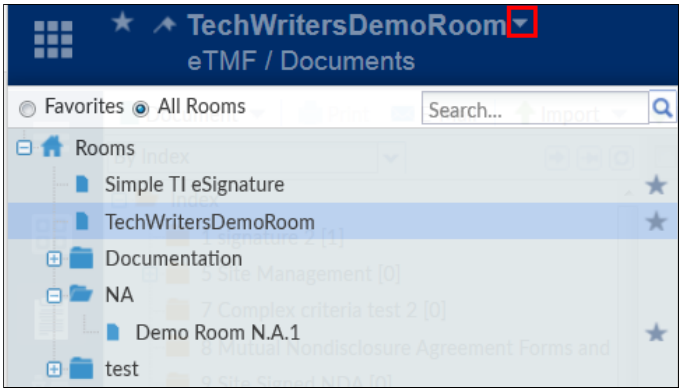
D. The list of all rooms to which you are assigned is also available through the user profile.

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



3.10. Navigating between Rooms

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

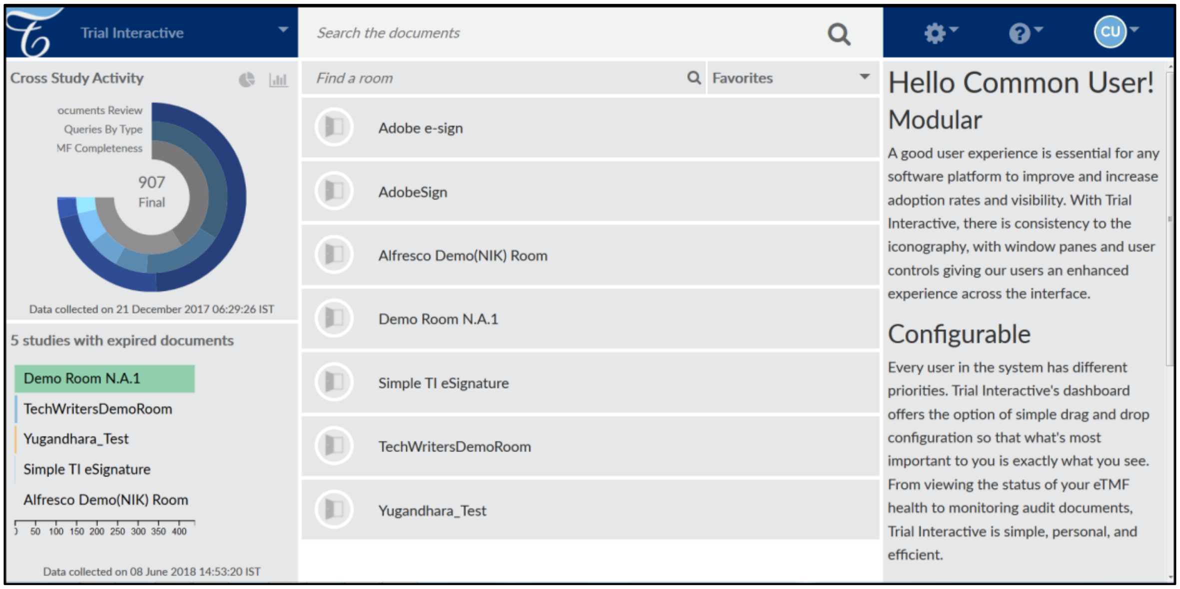


Click a room name from the list and the system will navigate you to the selected room.

4. The Trial Interactive Home Page

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

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



The Trial Interactive Home Page is divided into:

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

4.1. The Dashlets

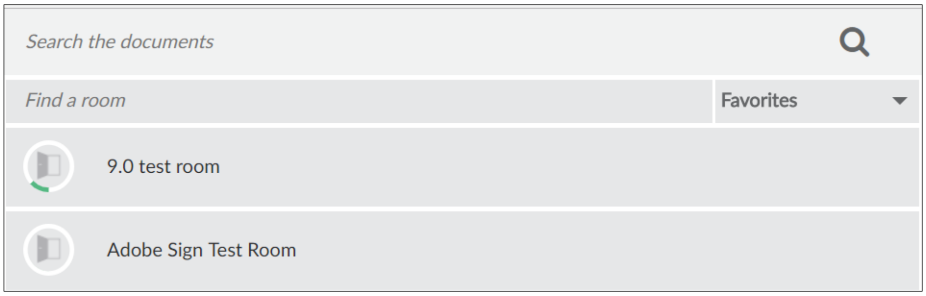
From the Home Page, a reader can view the following dashlets:

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

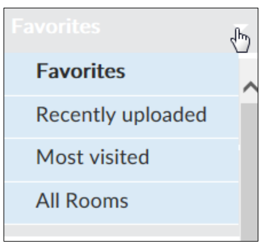
Each dashlet and dashboard is discussed in detail in subsequent sections.

4.2. The Room Pane

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

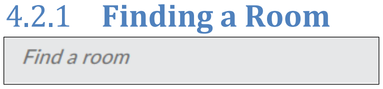


The user can choose which rooms to view through the filters selected from the dropdown at the top of the room pane. The filters are broadly classified into the following types:



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

4.2.1 Finding a Room



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

4.2.2 Searching for Documents

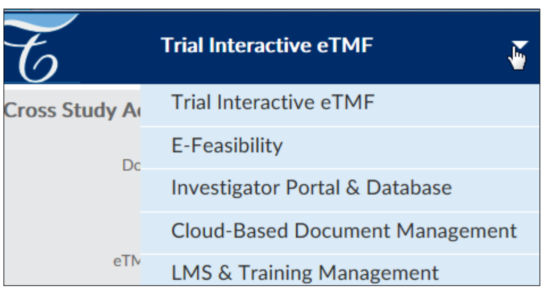
This is discussed in detail in section [Searching Documents].

4.3. The toolbars

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

4.3.1. The Trial Interactive eTMF dropdown

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



4.3.1 The Help and Language dropdown

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

4.4. The Username dropdown

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

- The **Classic Home Page** which is the home page of Trial Interactive 9.0
- The Profile settings of your login through My Profile. You can also access this from within a room and is discussed in section 5.2.5, and
- Logout

5. Main Module Views

5.1. About the Main Module Views

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

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

5.2. The Title Bar

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

5.2.1. The Navigation Grid

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

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

1. Home
2. Tasks

3. eTMF
4. Quality Review/Audit
5. Q&A
6. FAQ
7. Reports
8. Start-Up
9. SWS

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

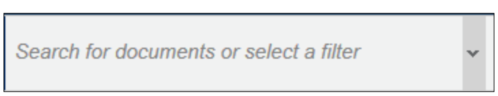
The Start-Up module is available to users who have the Study Start-Up action selected in user profile, who are members of the data room's Study Start-Up Team group, and who are Start-Up Specialists in the data room. A detailed description of this module is out of the scope of this guide, hence the Start-Up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

5.2.2. The Room Change Dropdown

This is discussed in detail in Navigating between Rooms.

5.2.3. The Search Box

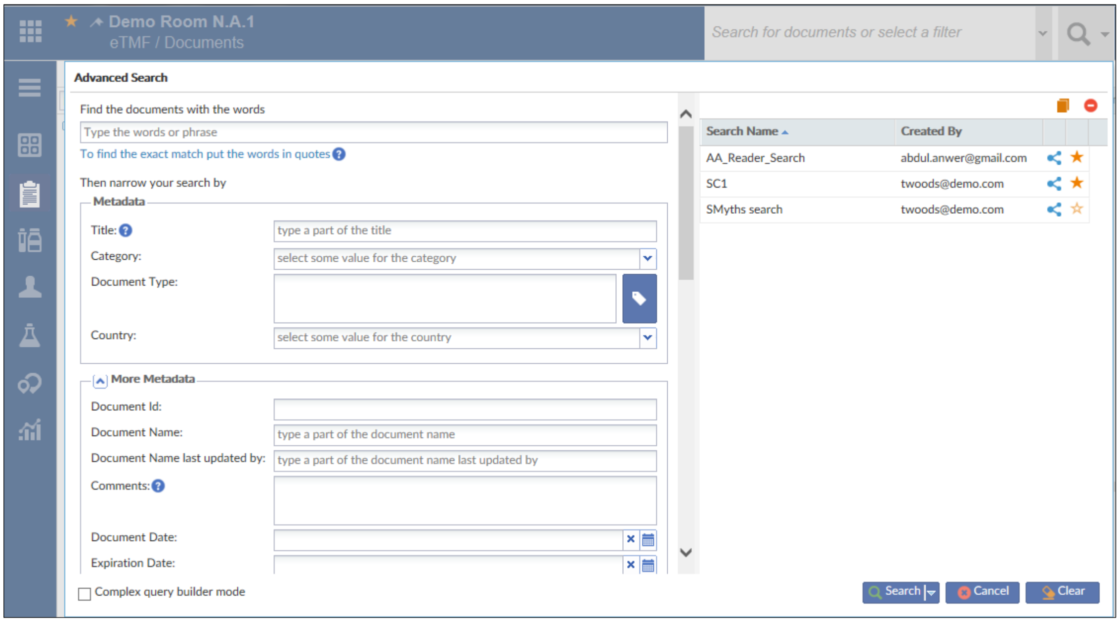
You can search for documents across their studies in Trial Interactive through the **Search Box**. By default the Search Box has the view as shown in the screenshot below:



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

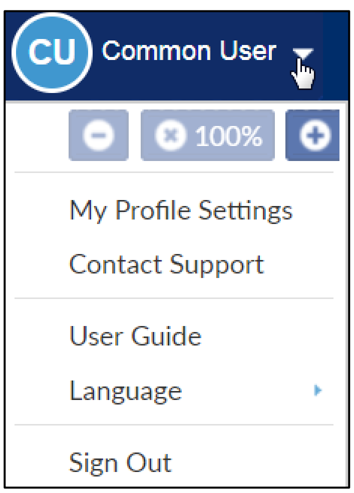
5.2.4. The Advanced Search

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



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

5.2.5. Username Dropdown



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

My Profile Settings

This discussed in detail in section My Profile.

Contact Support

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

User Guide

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

Language

To set the language for your account, navigate to **Language** under your profile name. Select the language of your choice from the drop-down.

Sign Out

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

5.2.6. Study Contact

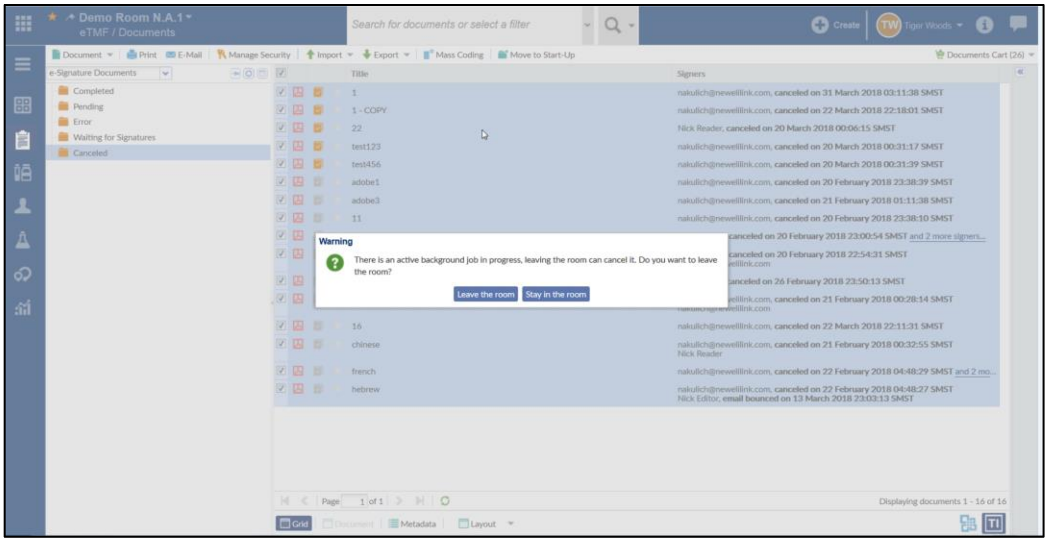
This opens the Study Contact popup with the contact phone number for any study related queries and email addresses for the documents submissions via Inbox.

5.2.7. Notifications

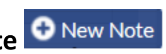
Through **Notifications**, which is located at the extreme top right corner of the dashboard, you can view messages and results of various jobs that you perform in Trial Interactive. This will be discussed through various sections as the need arises.

Background Jobs

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



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

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

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

5.3. Main Module Area

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

5.3.1. The Toggling Menu Bar

The modules like the **eTMF**, and **Audit** host the toggling menu bar which allows the user to access several other major functionalities. The functionalities that may be allowed for access from the toggling menu bar depends upon the activities the user might be required to perform from within a module. For example, the **Audit Module** allows access to the **Audit**, and **Documents** functionality from the toggling menu; whereas the eTMF module allows to access many more functionalities like the **Dashboard**, **Documents**, and **Milestones**.

The toggling menu bar can be expanded or collapsed by clicking the three white lines on it. Two most common functionalities available to the above mentioned modules are the **Dashboard**, and the **Documents.** The other functionalities which are specific to the particular module would be discussed in respective sections.

5.3.2. Dashboard

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

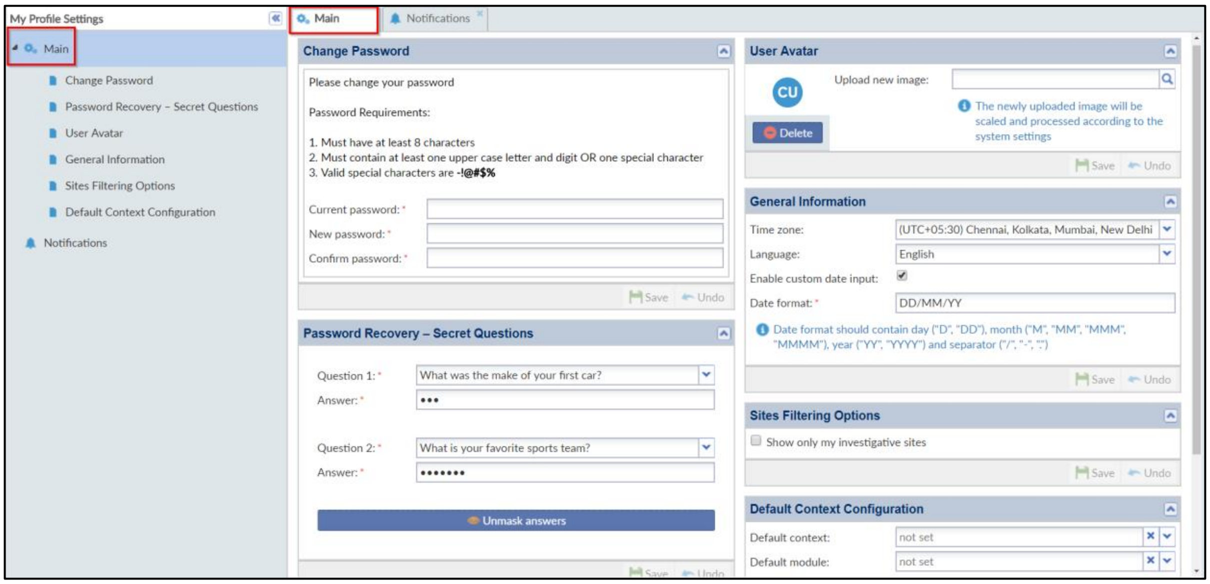
This section is discussed in detail in Chapter Dashboard Dashlet View.

6. My Profile

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

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

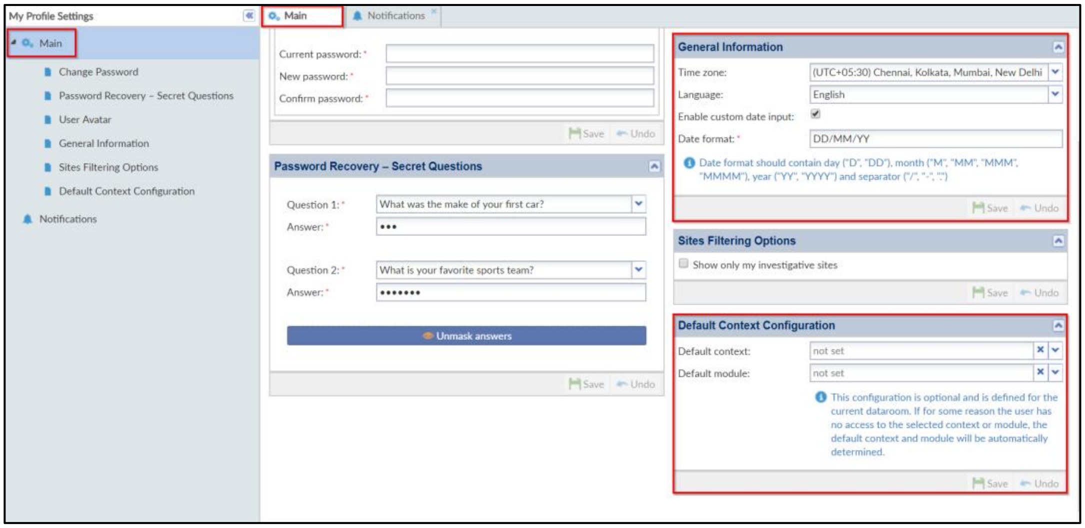
From both the locations you will get the view as shown in the screenshot below:



6.1. The My Profile Main Section

Through **My Profile Settings** you can change password or set up password recovery questions, upload or delete your avatar image, set up your time zone or language, set filtering options for the sites you want to access, and the default context configuration.

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



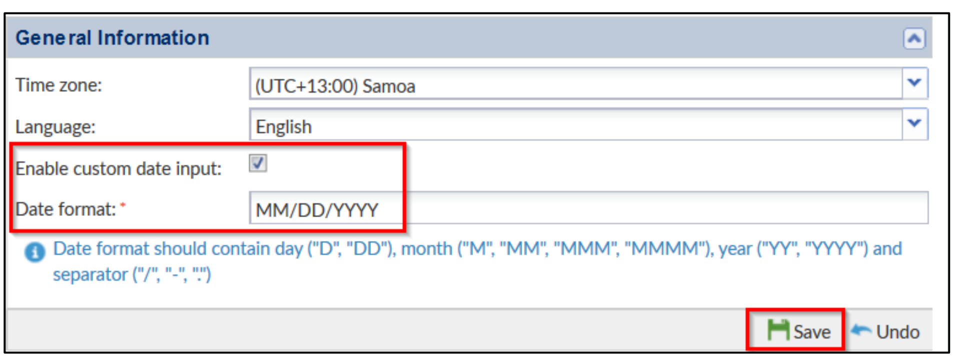
Follow the instructions on the dashboard to configure your profile settings as required.

6.1.1. General Information

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

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

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



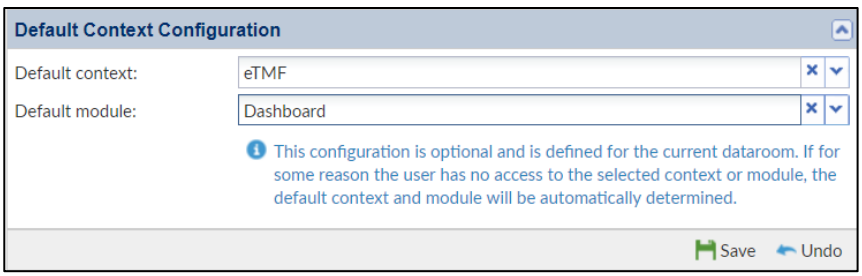
1. Tick the checkbox **Enable custom date input**.

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

6.1.2. Default Context Configuration

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

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



6.2. The My Profile Notifications Section

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

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

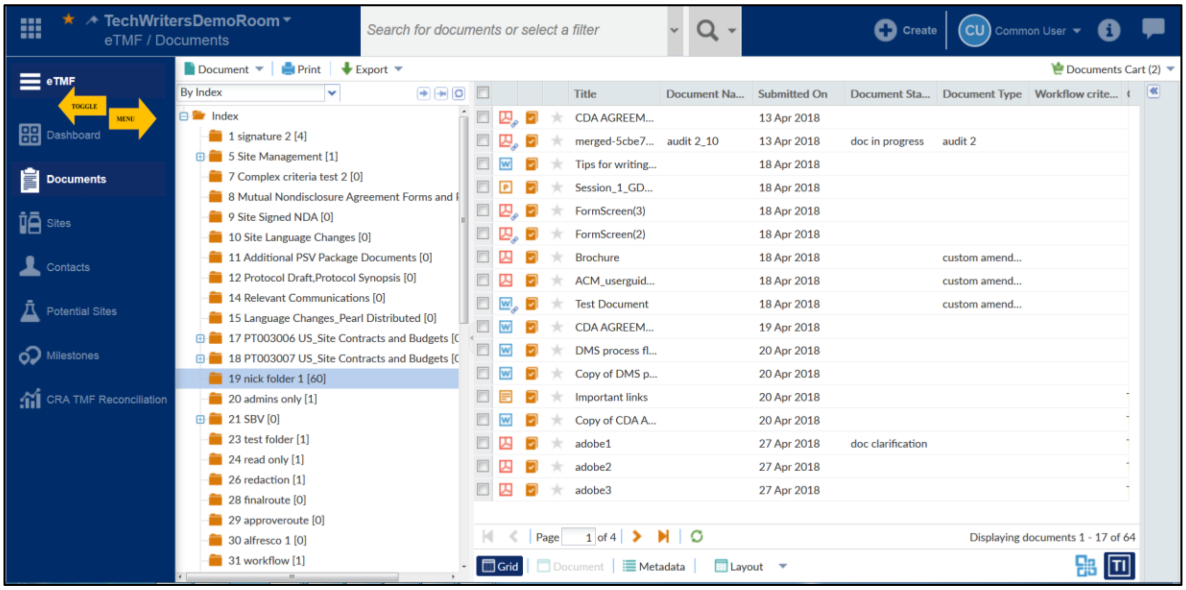
- A new audit query response is submitted
- A New Document is added or updated in eTMF, or Start-Up
- A New Question or Answer is added
- Workflows

- A new Workflow Query Response is submitted
- A New Document is submitted, approved, or rejected by the Regulatory Reviewer

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

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

7. The eTMF Module

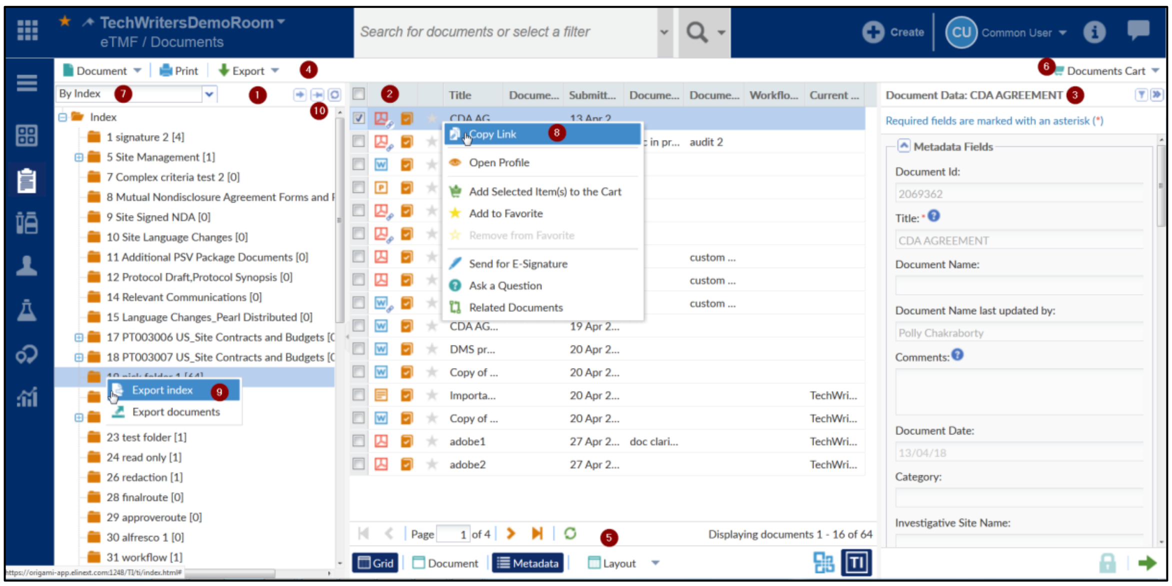


Through the eTMF Module, you can perform a host of activities like reviewing the status of the studies through the dashlets, and accessing the documents available in the room. The menu bar on the left allows you to toggle between the Dashboard Dashlet view, Documents view, the Sites view, the Contacts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

All these views can be enabled for you by the administrator and are discussed in subsequent sections below.

8. Documents View - Introduction

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



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

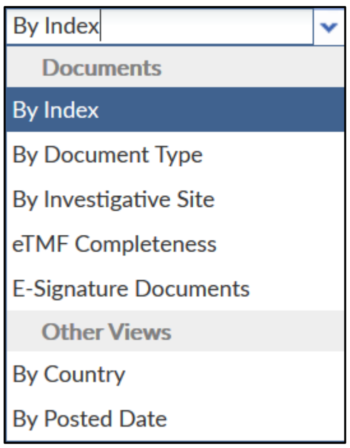
Number	Part
1	The Room’s Index Pane
2	The Document Grid/Viewer Pane
3	The Document Data Pane (that is typically hidden behind the double caret button)
4	The top menu ribbon
5	The lower tool bar, at the bottom of the Document

	Grid/Viewer Pane
6	Document Cart
7	Current View
8	Right-click popup on Document
9	Right-click popup in Index Pane
10	Buttons on Index pane

9. Documents view – Room's Index Pane

9.1. Current Views

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



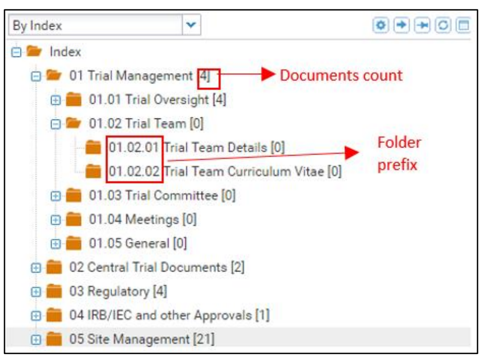
Each of the **Current View** options are discussed in the table below:

Current View option	Feature details
By Index	This is the Index Pane view which
By Document Type	This view groups all the documents by its Category as the parent folder. Each Category folder further holds documents grouped by Document types as sub-folders. Clicking each Document Type displays the documents of that type in the **Document** view.
By Investigative Site	This lists the document type as per the Investigative Sites available in the room.

eTMF Completeness	This lists collected, missing documents and acts as placeholder for missing documents that do not fall under the required documents section.
e-Signature Documents	This allows users to view all e-Signature documents with their signers.
By Country	This displays the documents in each country where the study is being conducted.
By Posted Date	This displays the documents by their posted dates.

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

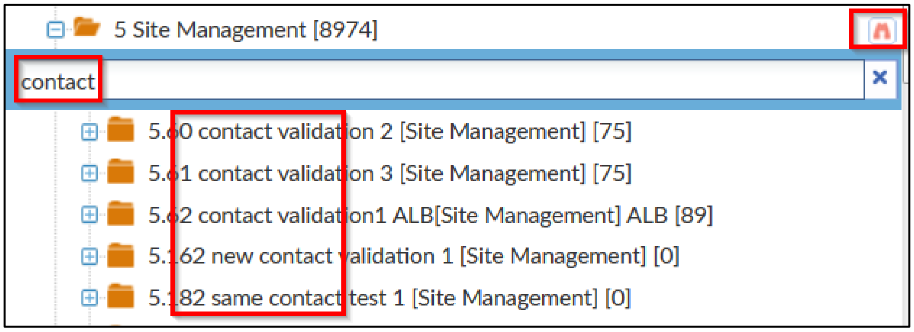
9.2. By Index view



The **By Index View** shows the full folder index of the room with child pages. If a folder contains sub-folders, it can be expanded to list its content by clicking the expand icon. These folders are numbered, and the subfolders follow a standard numbering system. Numbers in parentheses after the folder names indicate how many documents are available to you in each folder. Click a folder to open the documents contained in it in the Documents Grid. Refer to the screenshot below.

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

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



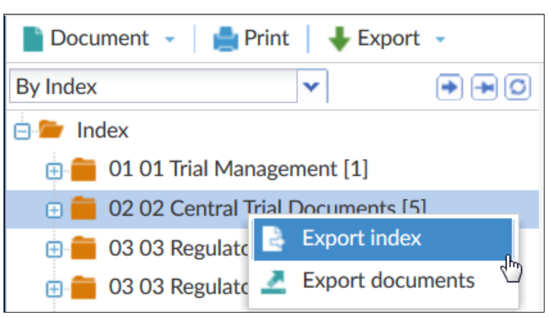
Click the cross to delete the search criteria and then the Red Search icon dismiss the textbox.

9.3. Buttons on Index Pane

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

Available Icon	Purpose
	To refresh the dashlet
	To export index.
	To set default view of index.

9.4. Right-click popup on Index

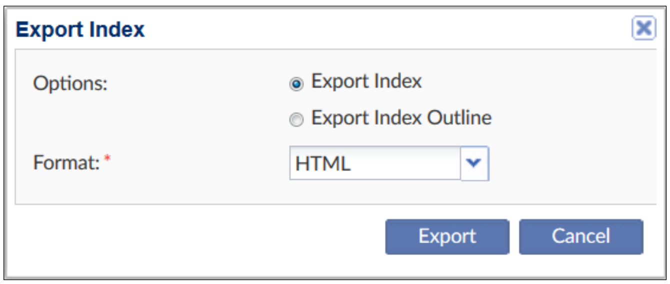


As shown in the screenshot above, through the right-click popup in the Index pane, a reader can:

1. Export index
2. Export documents

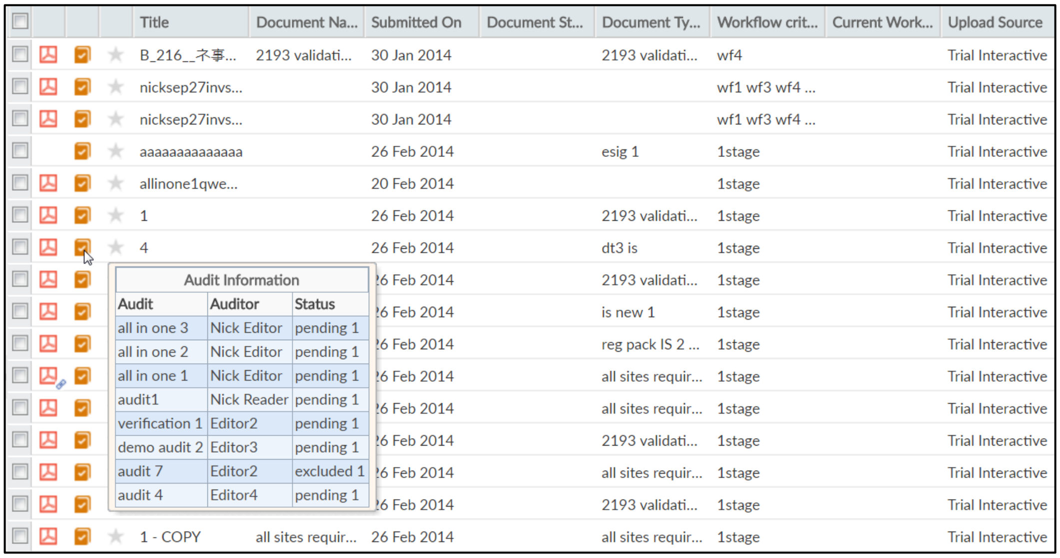
Export documents allows you download documents of the chosen folder after a confirmation. This is the same as downloading documents from the Documents Cart.

Export index allows you to export the document structure index of the room. You can choose to export the index for the chosen folder, or only the index outline. The index can be exported in either HTML, or Microsoft Excel, or Microsoft Word formats.



10. Documents view – Document Grid

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



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

Audit Information

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

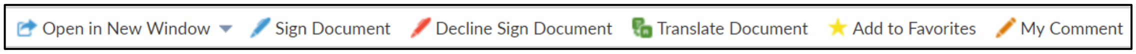
The procedure to view a document is:

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

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

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

10.1. Document Grid View Tool Bar

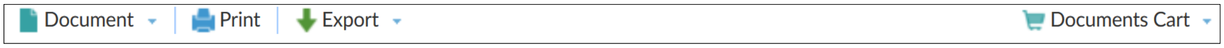


This toolbar is available once you open a document for viewing. The options available here allow you to change what displays on your screen and the arrangement of the material. You can toggle back and forth between viewing a document and seeing the list of the documents in a selected folder by clicking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

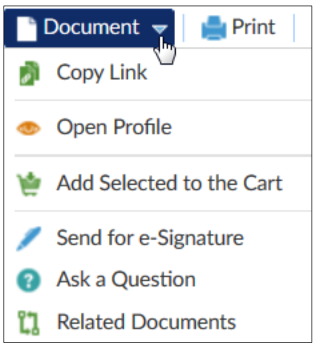
- You can opt to **open** the document in a **new window**. If you click this option, the selected document pops up in a new reader window. This function is available to all users with Administrator level access.
- You can **Sign** a **Document** or **Decline** to **Sign Document** if it is sent for e-Signature.
- If the **Machine Translation** option has been activated for your room, the **Translate Document** button is available to you.
- Similarly, you can **Add** a document **to favorites** Add to favorites from here. If a document is added to favorites, you will see the **Remove from favorites** icon Remove from favorites instead.
- Also, you can add comments to a document through **My comment,** which will open an **Edit Comment** window for adding comments.

11. Document view – Top menu ribbon

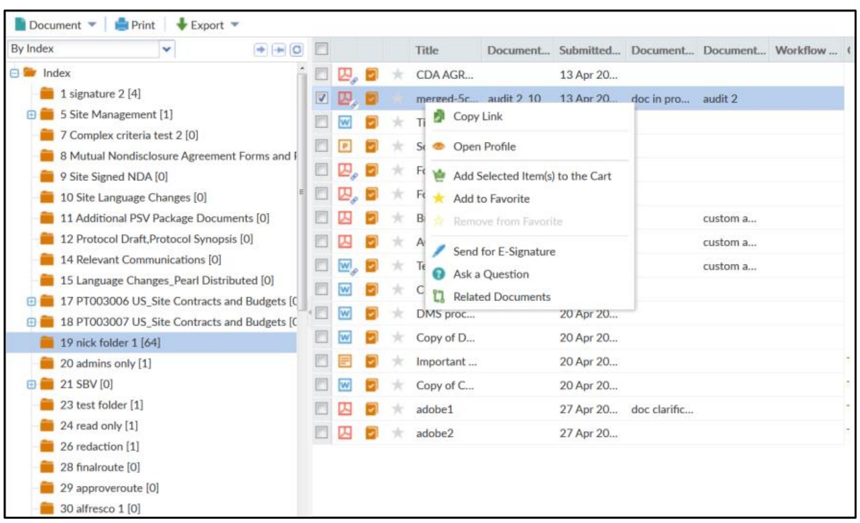
The Top menu ribbon in the **Document** view offers Administrators access to many important Trial Interactive functionalities.



11.1. Document dropdown/Right-click on a document



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



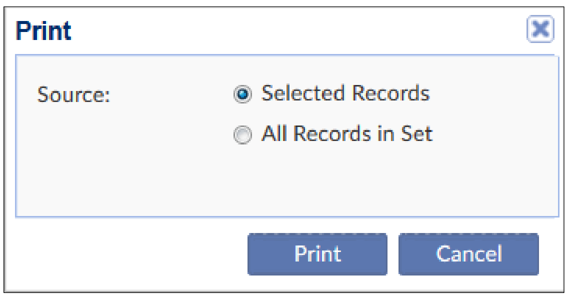
As shown in the screenshots above, a horde of activities can be performed on a Document by right-clicking it or from the Document Dropdown such as Copy Link, Open Profile, Add Selected to the Cart, Send for e-Signature, Ask a Question, and Related Documents.

Each of the functionalities are discussed in separate chapters.

11.2. Print

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

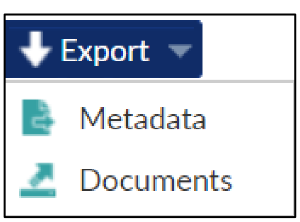
1. To activate the **Print** function, first click a folder in the index so that documents populate on the document grid.
2. Select one or more documents from the grid that you want to print.
3. Click the **Print** icon in the menu ribbon. The **Print** window opens.
4. Click the appropriate radio button,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



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

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

11.3. Export



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

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

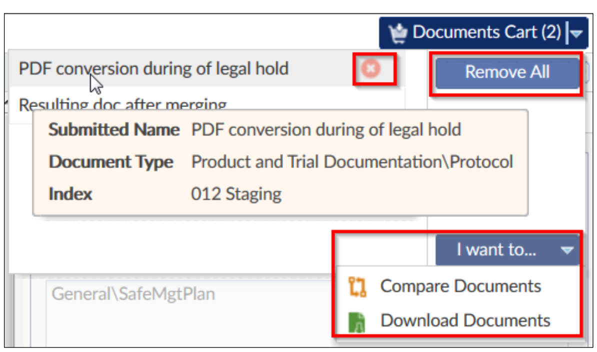
11.4. Document Cart

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

The Document Cart icon 

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

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

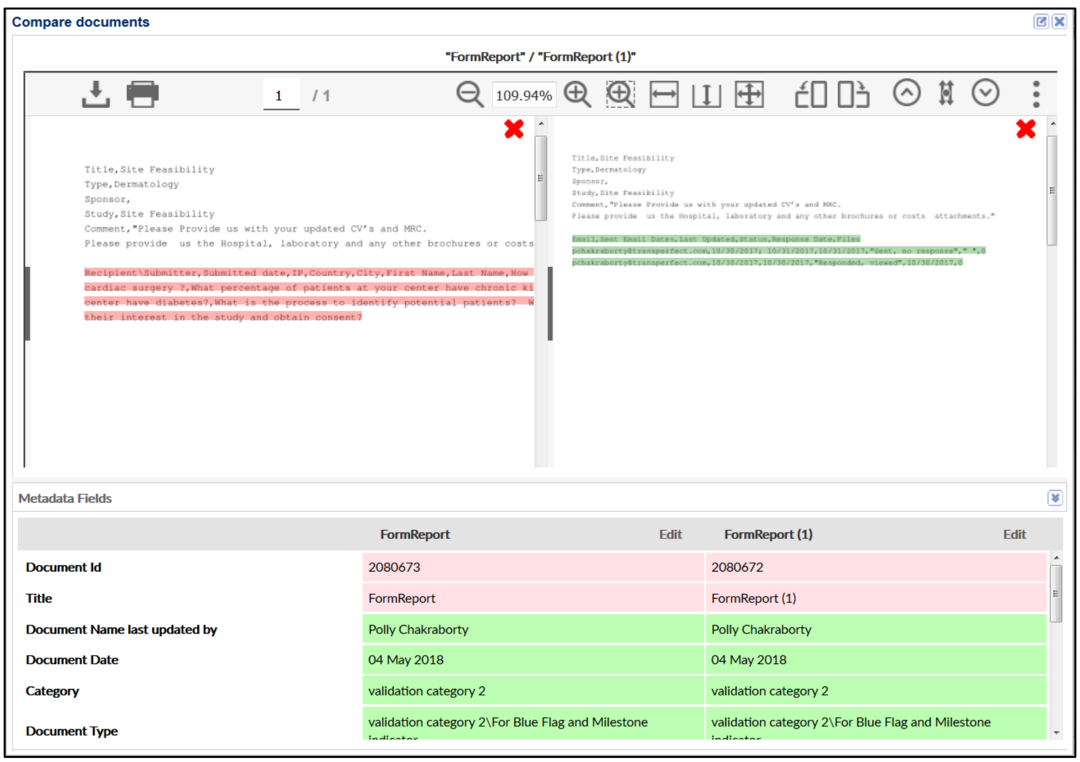


11.4.1. Document Cart – I want to…Compare Documents

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

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

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

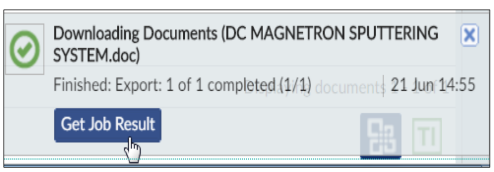


To facilitate easy and seamless comparison of documents:

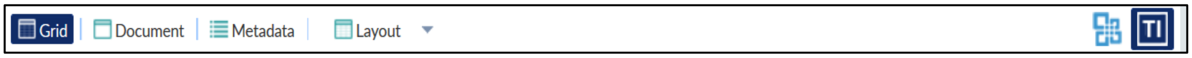
1. The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
2. The **documents scroll at once in sync** with each other when you drag the scroll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

11.4.2. Document Cart – Download Documents

Add documents to the cart and select the option **I want to…Download Documents**. The documents get downloaded in a .zip format and a notification regarding the same is received. Documents added without attachments cannot be downloaded and the archived zip of downloaded documents will not contain documents without attachments.



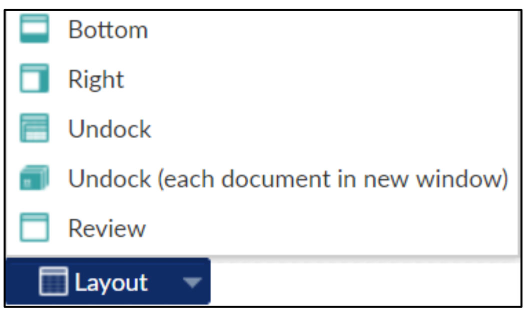
12. Documents view – Lower toolbar



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

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

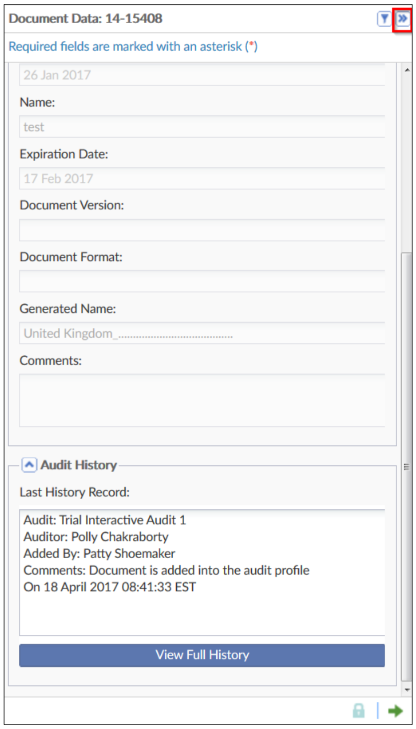
2. The document appears in a new pop-up window. The layout of this window can be selected from **Layout** as show in the screenshot above. Hover the mouse over the Layout button to know your current layout in a popup. The window can be laid out at the **Bottom** of the grid, or at the **Right** of the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



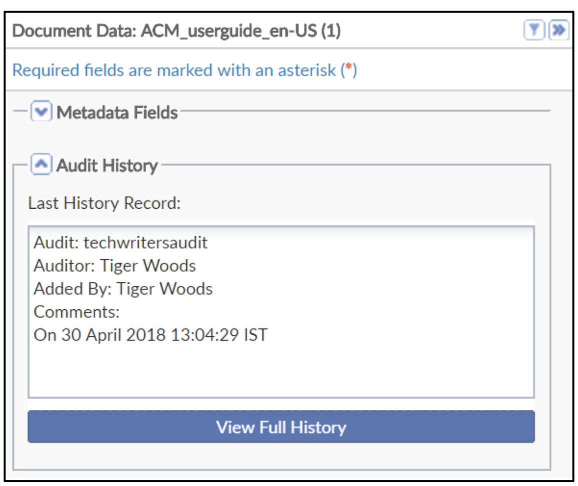
3. To return to the document grid, click **Grid** at the bottom of the viewing panel.

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

13. Documents view – Document Data/Metadata Pane



You access this pane by clicking the double-caret on the right side of the screen or by clicking **Metadata** button at the bottom of the **Document Grid**. As a Reader, you can view a document's metadata but cannot edit the fields. You can also view the **Audit History** from here.



Click the **View Full History** button to view the complete **audit history**. Here you can view the timestamp of the audit history of the document under various audit profiles respectively.

14. Document viewers

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

1. Original Document Viewer
2. TI Document Viewer

14.1. TI Viewer

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

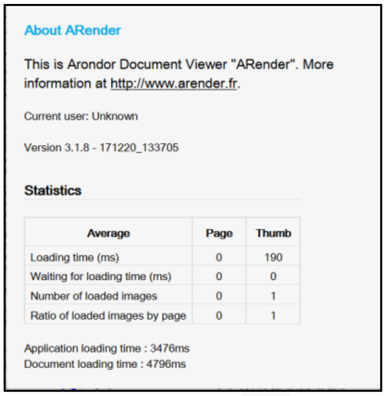
1. Viewing 300 + document and major document formats
2. Displaying Zip content
3. Displaying Email Messages
4. Full-text search documents
5. Automatic conversion and downloading of non PDF files to PDF in TI Viewer and retaining the original format in the grid.

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

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

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

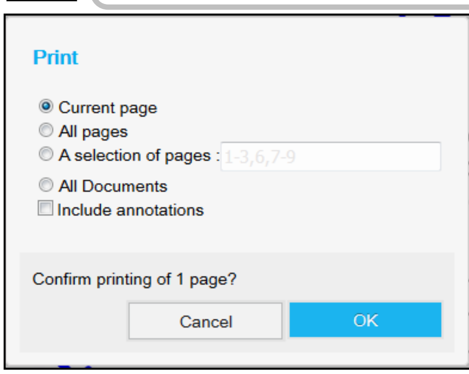
- Click the **About** option to view the information of the TI Viewer.



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

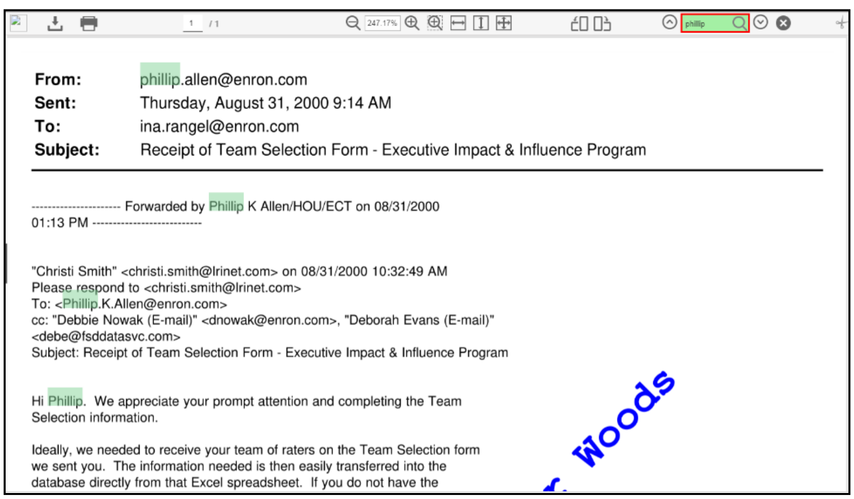
  To download the original version of the document, you will need to switch to the Original Viewer.
- Click the **Print** icon to print all the pages, or only the current page that is open in the viewer, or range of pages.

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

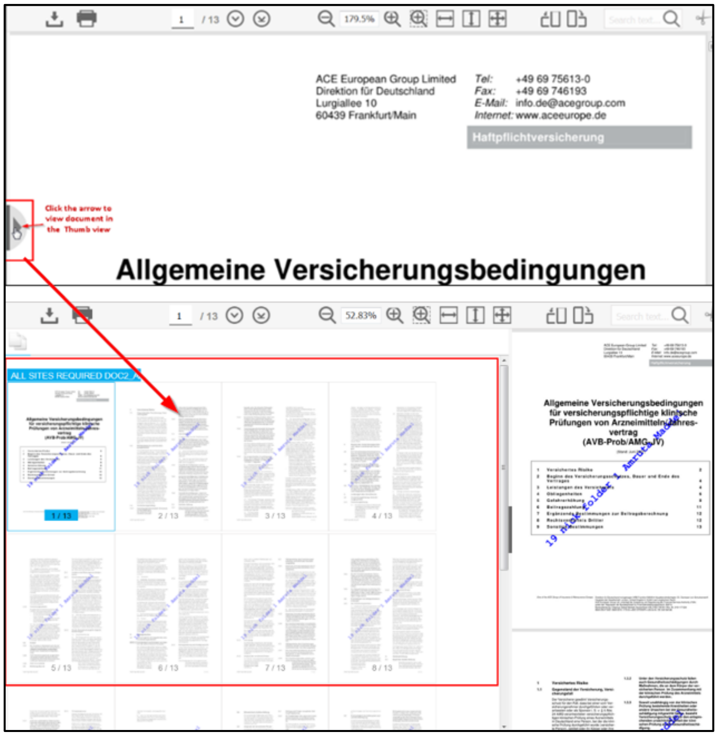


- You can also move to the desired page by entering the page number in the **Current Page** 1 box or scroll to the **Previous Page** or **First Page** and **Next** or **Last Page**. **Note that the Previous Page and First Page options appears when you are on the second and further pages of the document.**

- The **Minus** option and the **Plus** option allows you to Zoom Out and Zoom In the document respectively as per your requirement by clicking the button. Contrary, you can also type in the zoom percent in the box 90% next to the **Minus** option.
- The Zoom in zone option allows you to zoom In the selected area/zone of the page.
- The **Full Width** option allows you to zoom out the document enough to span the entire window.
- The **Full Height** and **Full Page** options allows view the multiple pages of the document at a time in the window.
- The **Turn Page Left** option allows you to rotate the document to the left.
- The **Turn Page Right** option allows you to rotate the document to the right.
- You can search for a text in the document by entering the search criteria in the **Search box** Search text... and clicking the magnifying lens icon next to it. This will highlight the matching the search criteria across all pages.
- You can delete the search criteria by clicking the **Cross** next to the **Search box.**



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


ACE European Group Limited
Direktion für Deutschland
Lurgiallee 10
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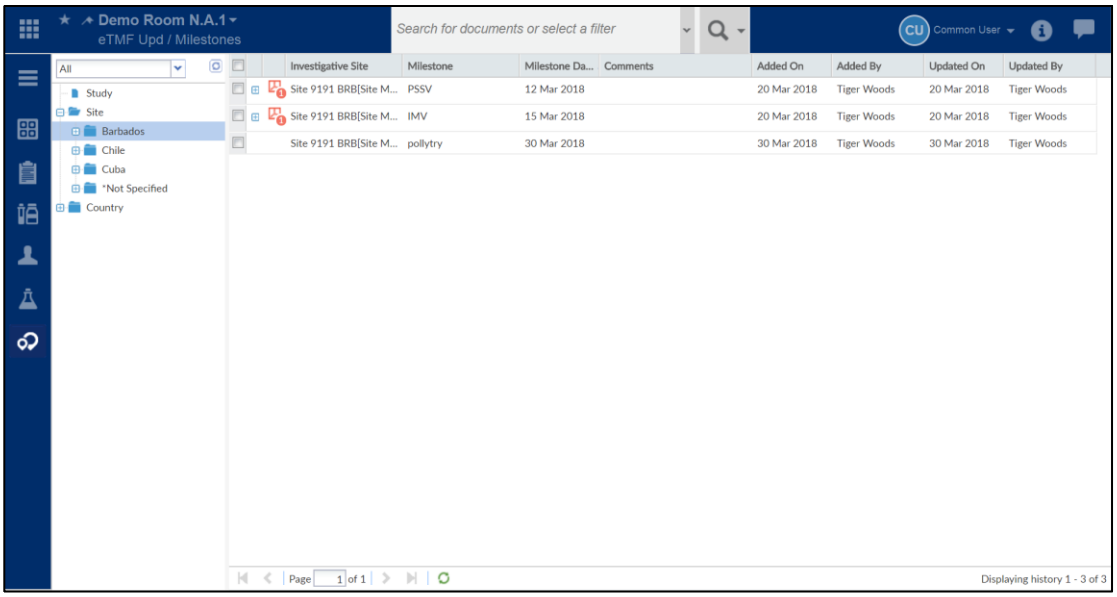
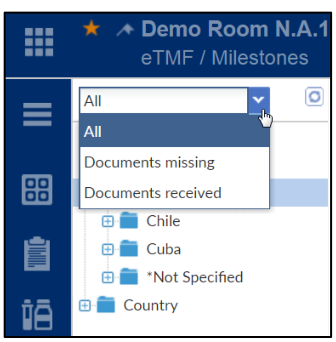
Tel: +49 69 75613-0
Fax: +49 69 746193
E-Mail: info.de@acegroup.com
Internet: www.aceeurope.de
Haftpflichtversicherung
Click the arrow to view document in the Thumb view
Allgemeine Versicherungsbedingungen
ALL SITES REQUIRED DOC2
Allgemeine Versicherungsbedingungen für versicherungspflichtige klinische Prüfungen von Arzneimitteln Jahresvertrag (AVB-Prob/AMG_IV)

15. Milestones

Study Milestone is the 'objective-to-reach' for a particular study room, and this function displays the list of milestones that will be used for the current study room. The reader can view a milestone histories from the **Milestone module**  that can be selected from the toggling menu bar. On entering the dashboard, the reader can see the list of milestone histories, if they were created. The milestones in the Milestone modules are categorized by study, site and country. The number in color red next in the grid indicates the number of documents associated with a milestone in the chosen category.



Besides categorizing milestones the milestone module also allows you to filter milestone events by **Documents Received** vs. **Documents Missing**.



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

16. eTMF Completeness and CRA TMF Reconciliation Report

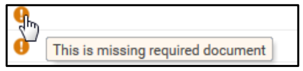
eTMF Completeness is a milestone indicator of a clinical study process based on the status of the documents required for the study. The eTMF Completeness view lists the collected, missed, and placeholder documents required to complete a study along with the milestones linked with each document and its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

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

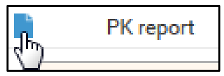
16.1. eTMF Completeness

In the Documents module, select eTMF Completeness as the current view in the index pane. From within the Document Grid or from the **Add Placeholder** dropdown_ Add Placeholder on the top ribbon, placeholders can be created, edited, deleted for a document. Refer to the screenshot below:

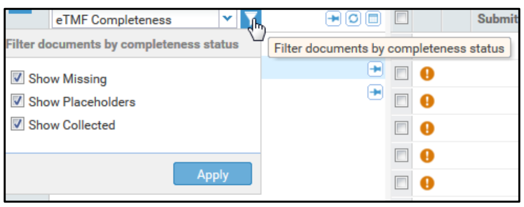
Read the components in the screenshot as below:

1. **Missing Documents:** 

2. **Collected Documents:** 

3. **Placeholder Documents:** 

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



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

16.2. Creating the CRA TM Reconciliation Report

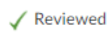
Trial Interactive 9.2 helps the CRA to reconcile documents during their site visits through the Site Report. CRAs needs to take some important decisions regarding documents for sites:

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

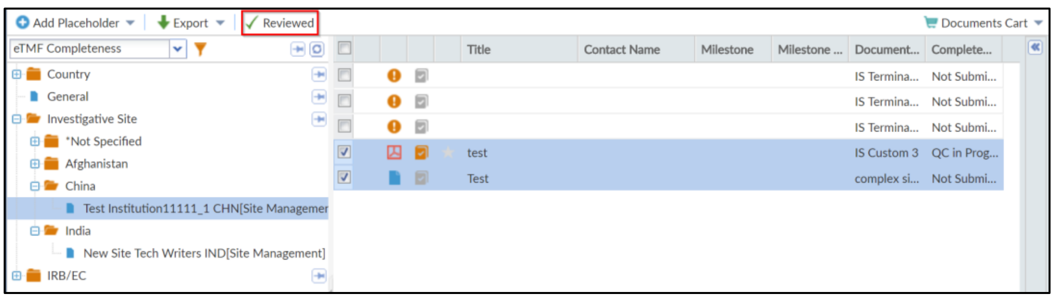
CRAs can avail this information from the **Site Report** so that they can verify the outstanding documents during their next site visit.

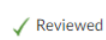
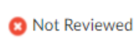
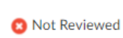
The procedure to create a **Site Report** is detailed below:

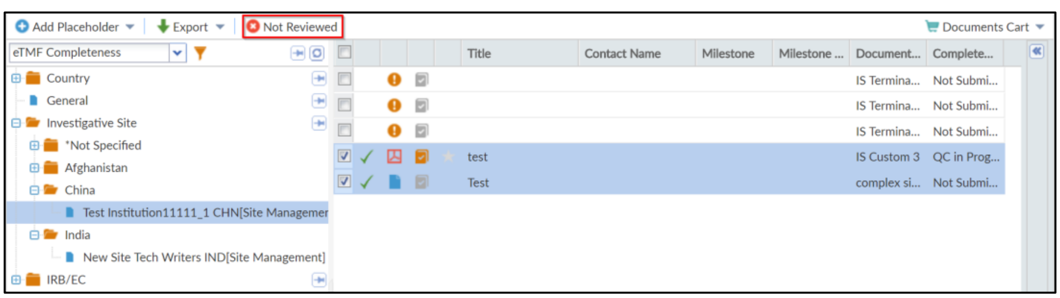
1. Select **eTMF Completeness** from the **Current View**.
2. Set the **filter** for eTMF Completeness for all the three options as shown above, and click **Apply**.

3. Select a **site** from the **Current View** so that it shows the list of **missing, collected, and placeholder documents** in the grid.
4. You can **mark the documents as reviewed** for the document types which have documents attached to them.
5. To mark the documents as present, select a document from the grid and click the icon **Reviewed**  from the top ribbon bar.

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

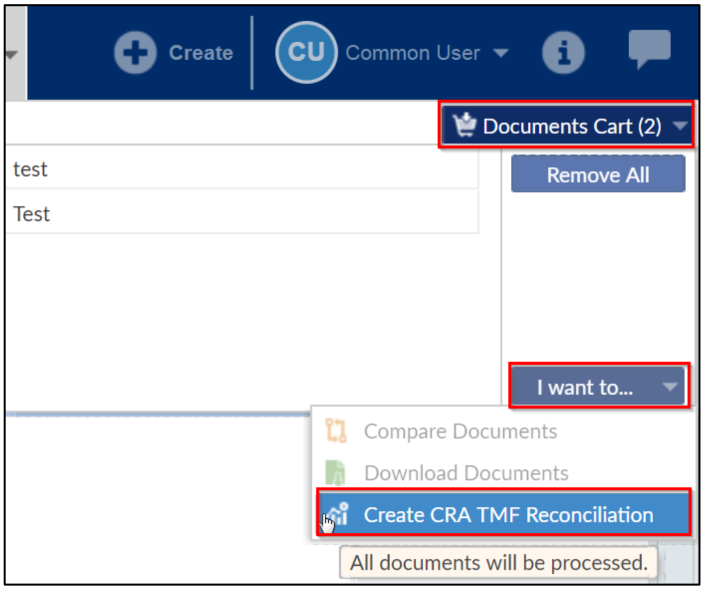


6. The documents now acquires a green tick next to it.
7. Similarly mark all the documents which need to be included in the **Site Report**.
8. Once the documents are marked as reviewed, the **Reviewed**  icon changes to **Not Reviewed** .
9. You can click the **Not Reviewed**  icon to **unmark** the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

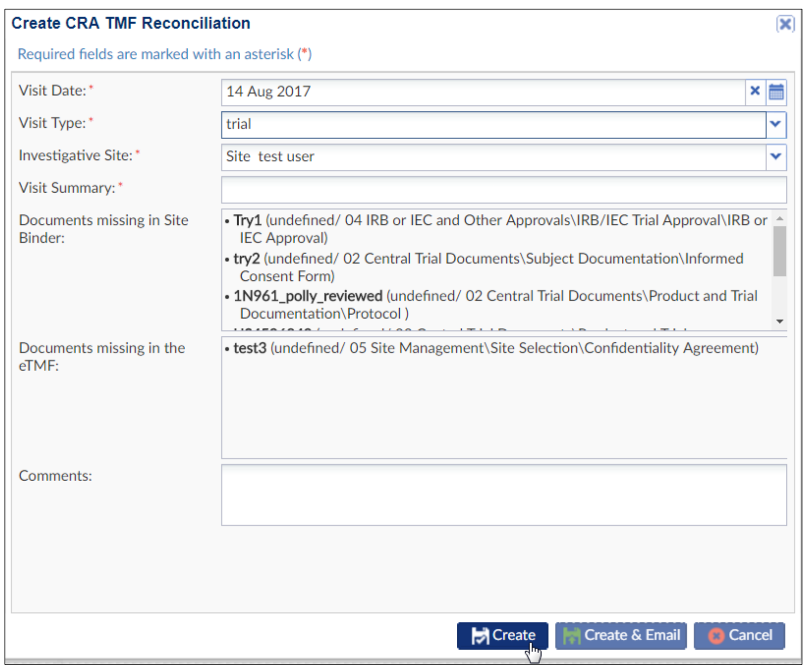


10. Once the documents are marked as reviewed, select them from the grid and **add them to the cart.**
11. Now click the **Documents Cart dropdown** and select **I want to -> Create CRA TM Reconciliation,** or

Click the **+Create** button and click **Add CRA TMF Reconciliation** from the dropdown.



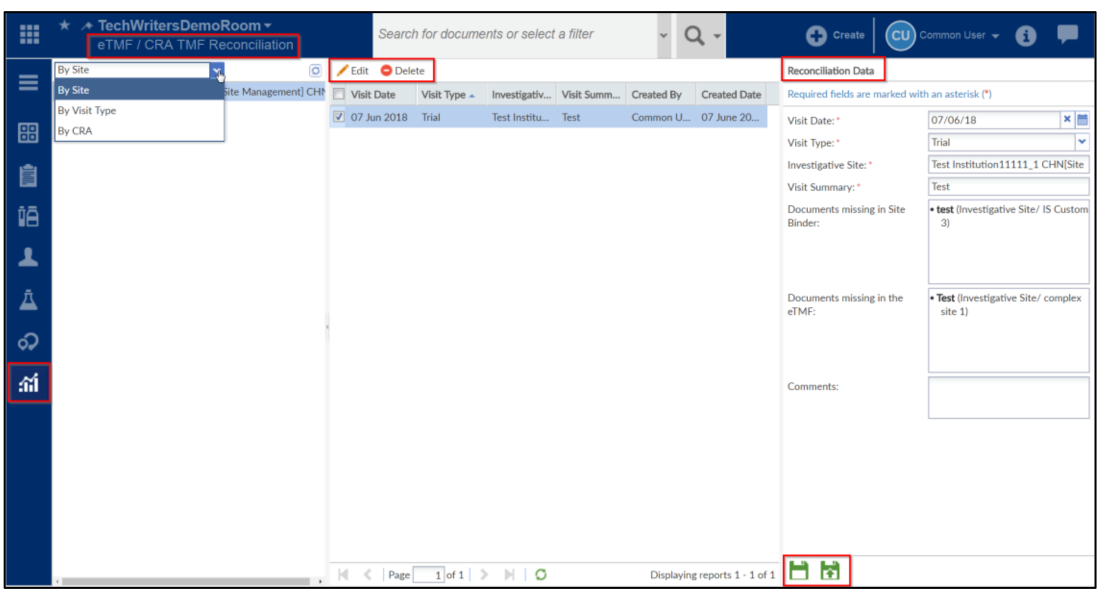
12. The **Create CRA TMF Reconciliation** window opens.
13. Fill in the details and click **Create**.



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

16.3. Viewing the CRA TMF Reconciliation Report

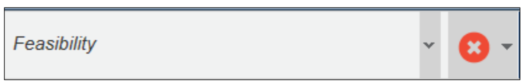
CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. If as a reader, you are also a CRA in a site, you can access this module from the toggling menu bar by clicking the **CRA TMF Reconciliation** icon. On entering the dashboard, you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



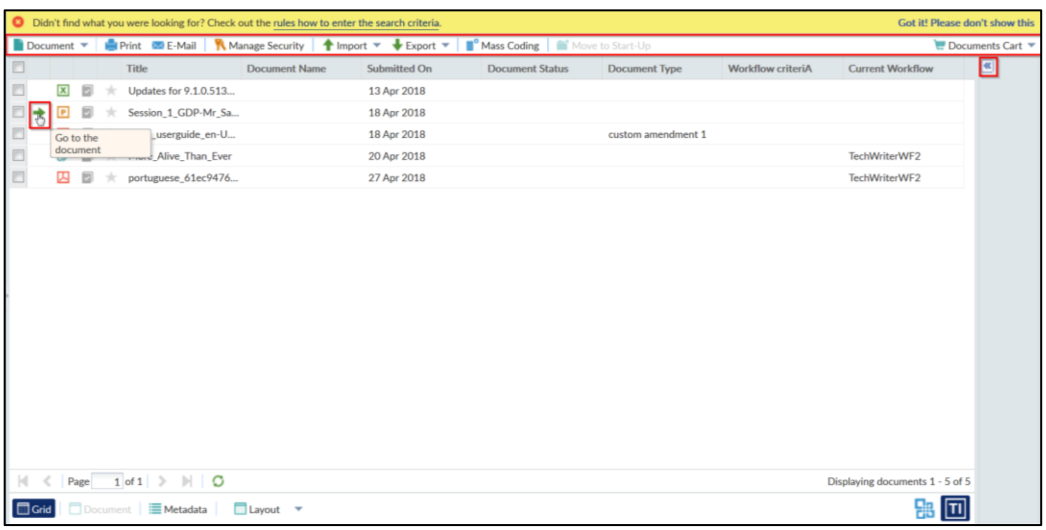
17. Searching Documents

To start a search:

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



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



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

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

7) The **Top Menu Ribbon** is still accessible from the **Search Results** window and you may use the functionalities for the searched documents as required.

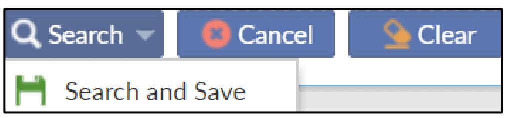
8) Besides the above, the system also displays a **Help Text link** in the Search Results window to take you to a page in a separate tab with detailed information on syntaxes to create complex search queries to streamline your search further. Refer to the screenshot below:

18. Advanced Search

18.1. Defining and Saving Searches

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

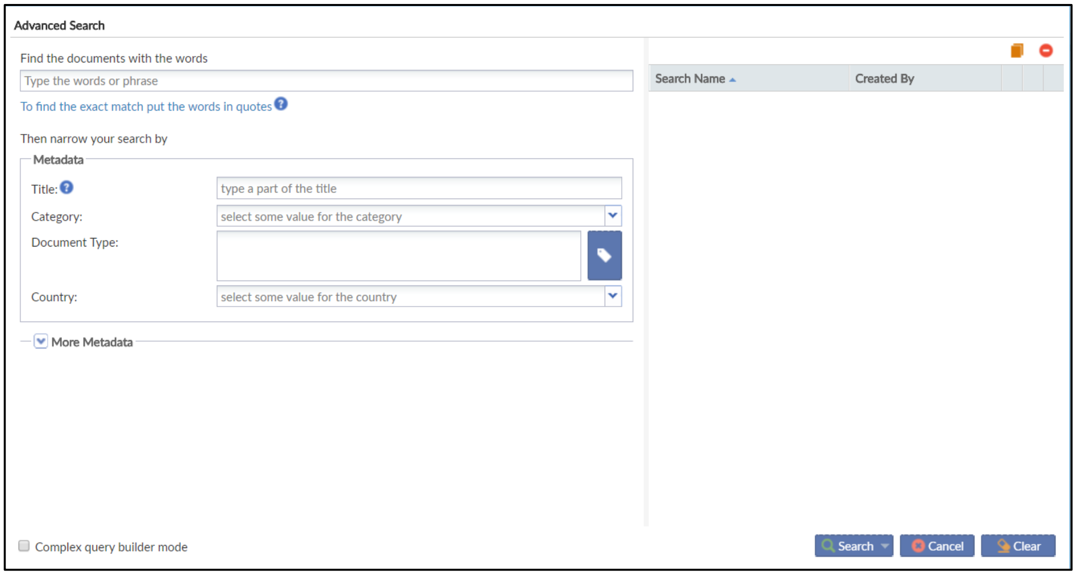
1. Navigate to Advanced Search popup window as mentioned above.
2. Enter your search criteria in the textbox under ***Find the documents with the words***.
3. Click the down-arrow in **Search** button at the right hand bottom of the **Advanced Search** popup window.
4. Click **Search and Save.** Refer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



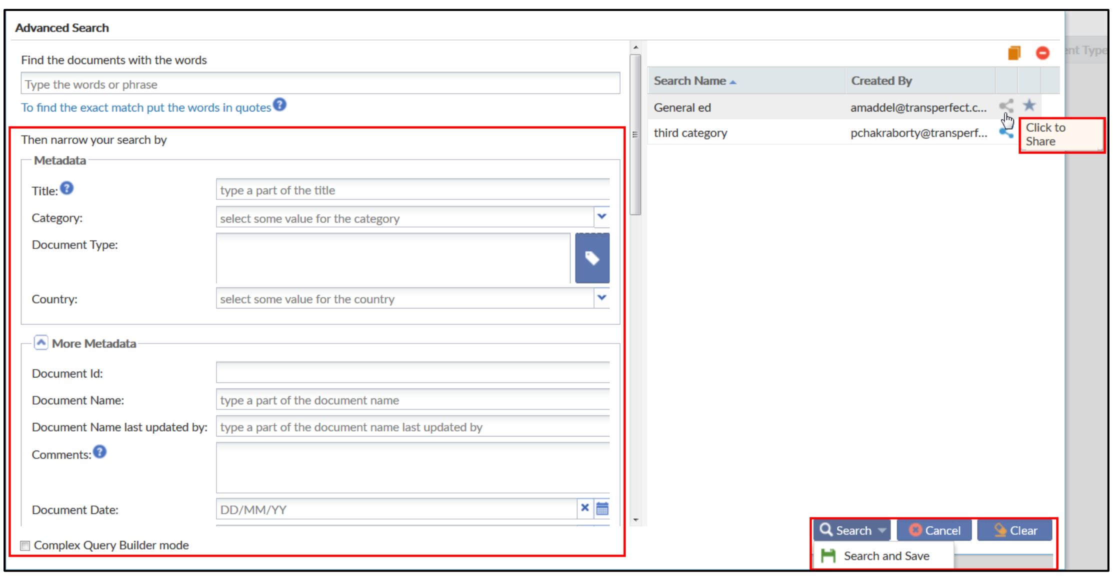
5. This will open the **Search Name** dialog box. Enter the name of the search in the box and click **Ok**.
6. This will initiate the search and will also save it.
7. The search thus created can now be re-used by clicking the down arrow in the **Search Box.**
8. You can share a search by clicking the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

18.2. Advanced Functionalities of Advanced Search

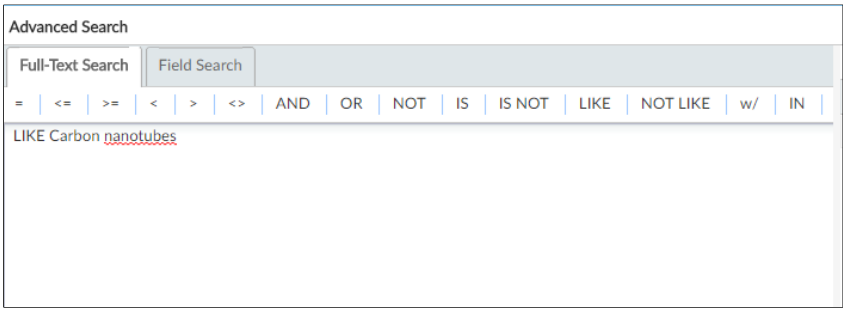
By initiating an **Advanced search**, you can search the full-text of the room's documents or you can choose to search the metadata fields for the room's documents through the **Field Search** tab. Click the arrow to bring up a window to build your advanced search.



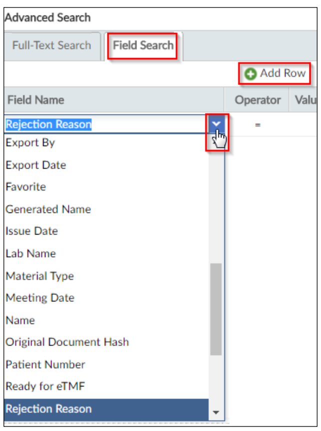
You can further narrow down search results by utilizing the Advanced Search function. In addition to entering general search terms, users can enter metadata information such as the Investigative Site Name, or the Category to which the desirable document might belong. Click **Search** when you are done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



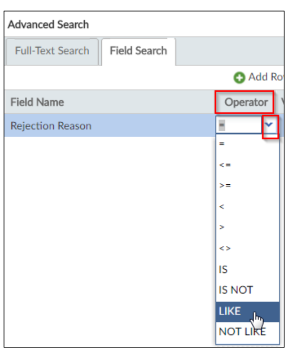
You can also use the **Complex query builder** to refine the search further to match exact text from documents or to match metadata fields. Tick the **Complex query builder mode checkbox**. This will open the **Full-Text Search** and **Field Search** tabs in Advanced Search. Enter your search criteria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



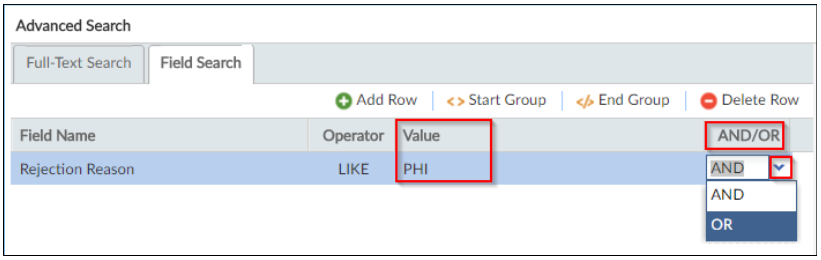
For a field search, click the **Field Search** tab. Click **Add Row** to add fields. Click the added field to select the **Field Name** from the dropdown.



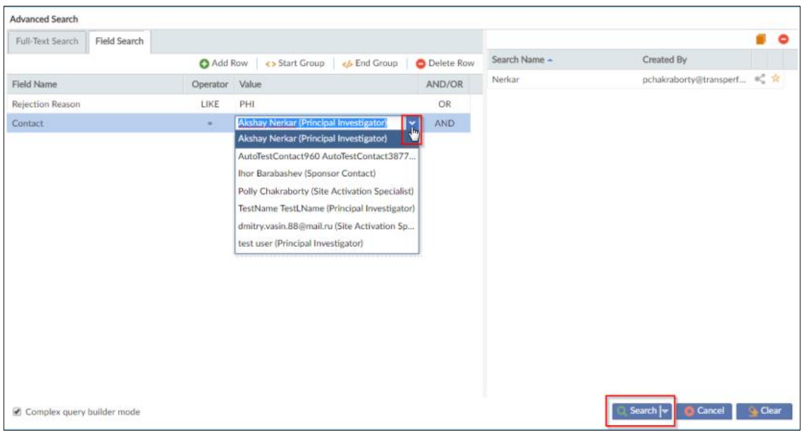
Click the **Operator** field and select the operator as required from the dropdown.



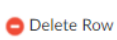
Click the **Value** field and enter the value, or select from the dropdown as required. Now click the **AND/OR** field and select the logical operator as required.



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



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

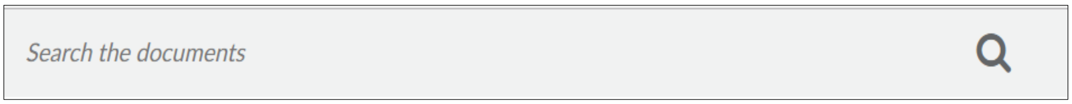


ribbon bar.

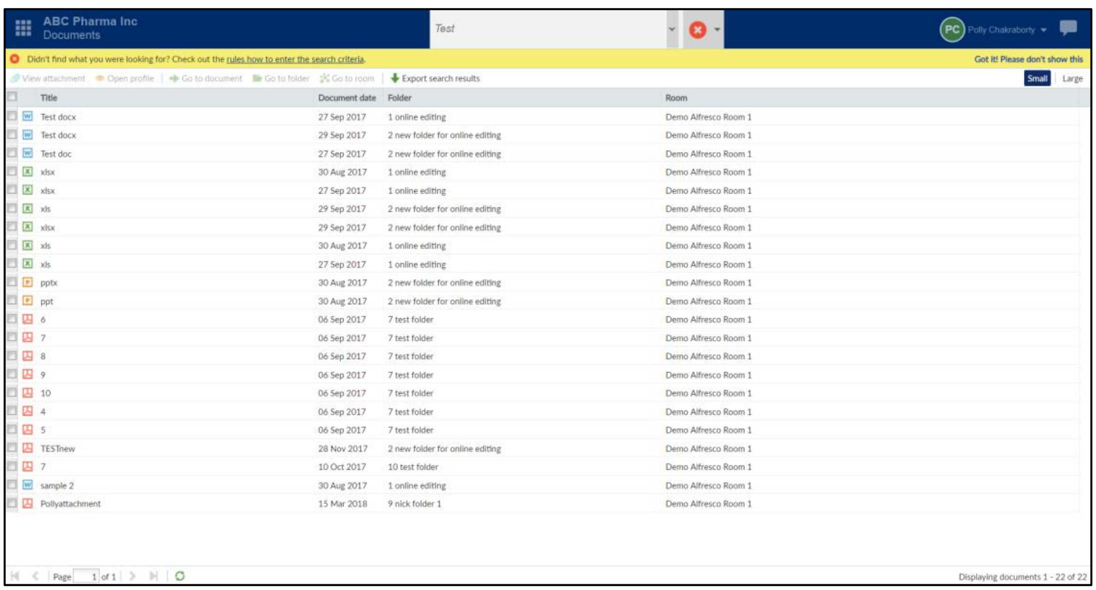
19. Cross Study Search

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

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



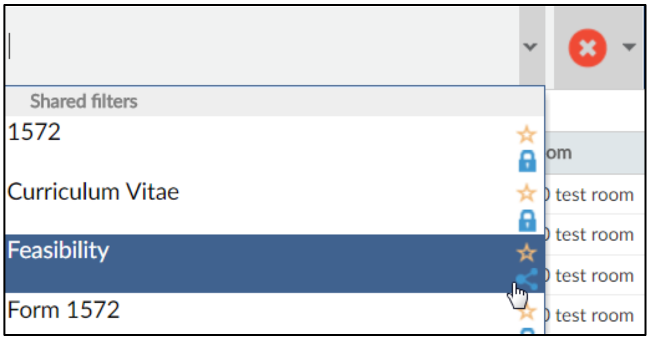
2. Click the magnifying icon next to the search box or hit Enter.
3. The search system then returns a list of all files in the rooms that have that search term in the document title, along with the document date and the room and folder where it is located.



Title	Document date	Folder	Room
Test docx	27 Sep 2017	1 online editing	Demo Alfresco Room 1
Test docx	29 Sep 2017	2 new folder for online editing	Demo Alfresco Room 1
Test doc	27 Sep 2017	2 new folder for online editing	Demo Alfresco Room 1
xlsx	30 Aug 2017	1 online editing	Demo Alfresco Room 1
xlsx	27 Sep 2017	1 online editing	Demo Alfresco Room 1
xls	29 Sep 2017	2 new folder for online editing	Demo Alfresco Room 1
xlsx	29 Sep 2017	2 new folder for online editing	Demo Alfresco Room 1
xls	30 Aug 2017	1 online editing	Demo Alfresco Room 1
xls	27 Sep 2017	1 online editing	Demo Alfresco Room 1
pptx	30 Aug 2017	2 new folder for online editing	Demo Alfresco Room 1
ppt	30 Aug 2017	2 new folder for online editing	Demo Alfresco Room 1
6	06 Sep 2017	7 test folder	Demo Alfresco Room 1
7	06 Sep 2017	7 test folder	Demo Alfresco Room 1
8	06 Sep 2017	7 test folder	Demo Alfresco Room 1
9	06 Sep 2017	7 test folder	Demo Alfresco Room 1
10	06 Sep 2017	7 test folder	Demo Alfresco Room 1
4	06 Sep 2017	7 test folder	Demo Alfresco Room 1
5	06 Sep 2017	7 test folder	Demo Alfresco Room 1
TESTnew	28 Nov 2017	2 new folder for online editing	Demo Alfresco Room 1
7	10 Oct 2017	10 test folder	Demo Alfresco Room 1
sample 2	30 Aug 2017	1 online editing	Demo Alfresco Room 1
Pollyattachment	15 Mar 2018	9 nick folder 1	Demo Alfresco Room 1

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

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

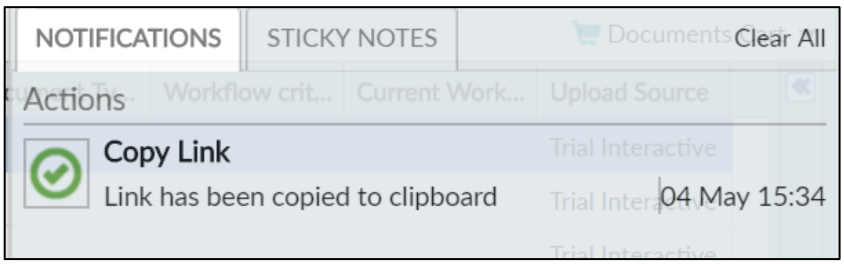


If you click on the down arrow icon of the Cross-Study search box, you can conveniently view your search terms. Therefore, if you want to re-use these search terms later, they are readily available.

20. Copy Link

Clients might need to copy a document link through the Document dropdown in the eTMF module. To copy a link navigate to the Documents module.

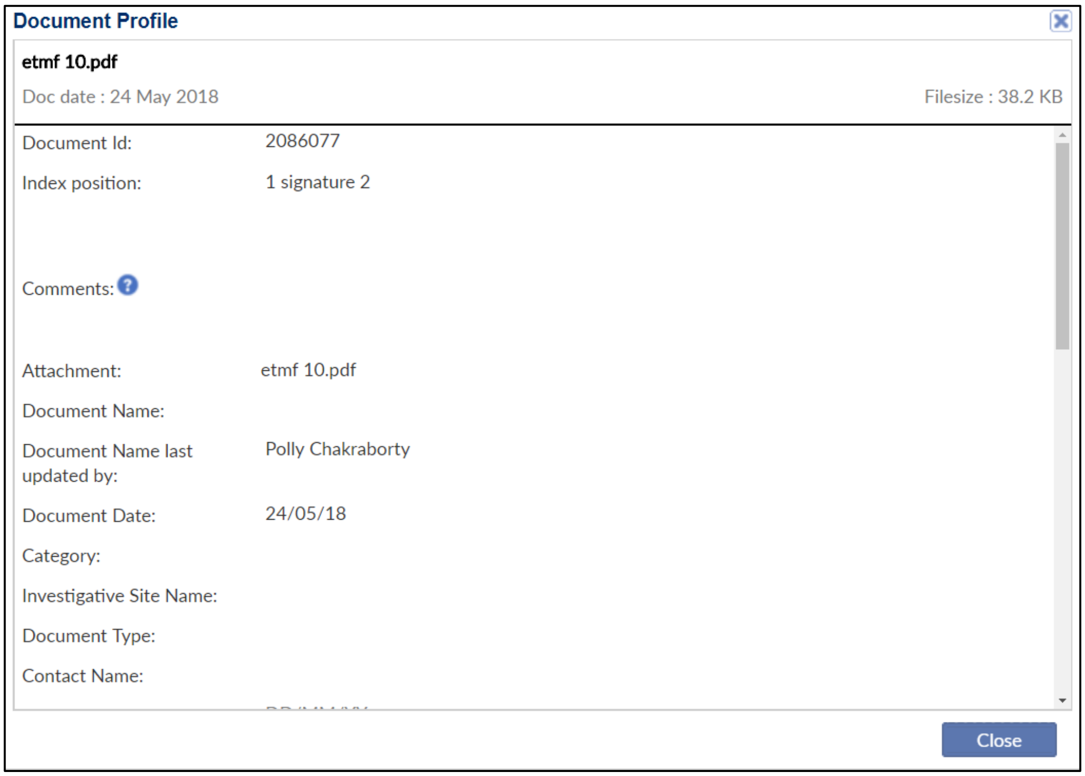
- Select a document from the grid. Click **Copy Link** to **copy the link to a document**, or to **copy the link to a document with metadata.**
- Once the Copy Link option is selected, the document URL gets copied to the clipboard and a notification about the same is received.



- Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings by your room administrator, 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'.**

21. Viewing Document Profile

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

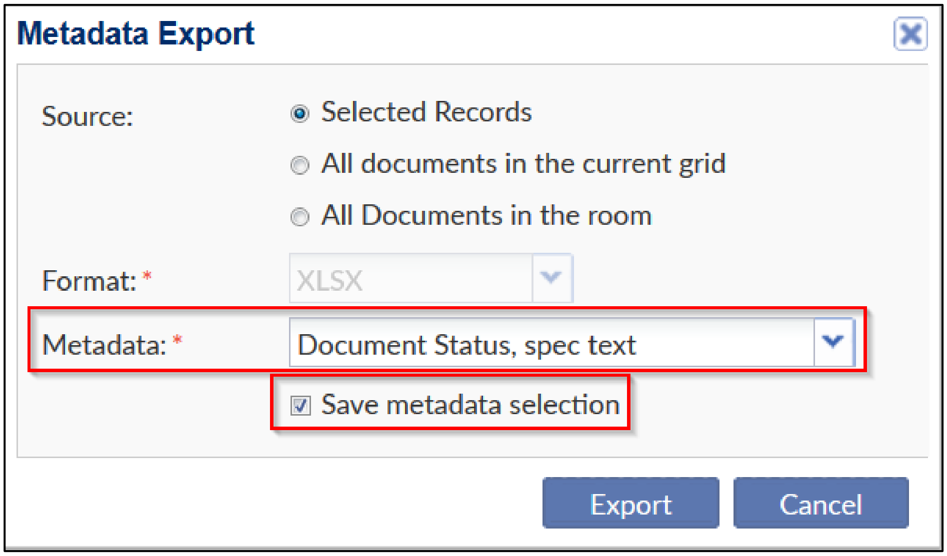


22. Export/Download Documents and Metadata

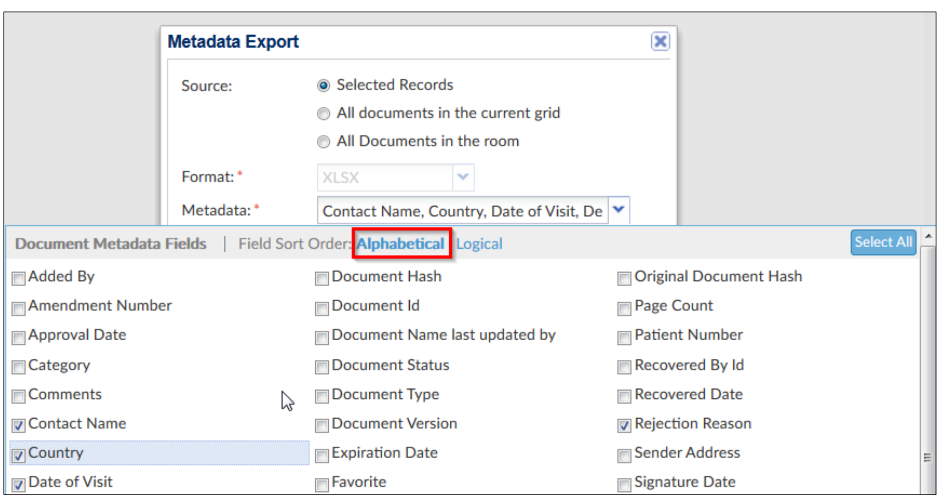
Two options are available to the Reader from the Export dropdown on the top menu ribbon – **Metadata**, and **Documents**.

22.1. Exporting Metadata

To export metadata, click the **Metadata** option from the **Export dropdown** located on the top menu ribbon. This opens the **Metadata Export** window. Refer to the screenshot below.

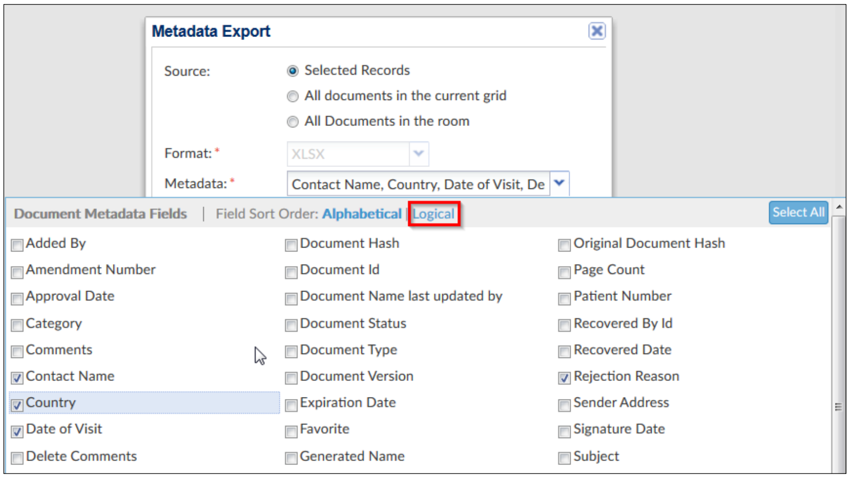


Click the down arrow at the far end of the **Metadata** field to reveal the dropdown with the document metadata. Select the metadata to export.



Click **Export.**

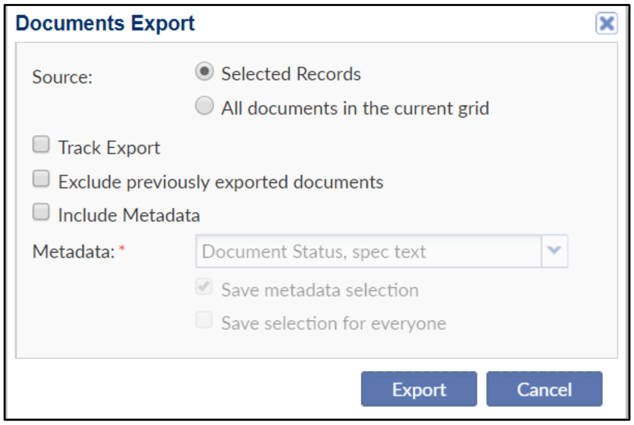
This function gives you a compressed file with the information you requested in XLSX spreadsheet file. As shown in the picture above, by default, the metadata fields are listed in **Alphabetical** order for export. But if you so wish, you may select the **Logical** order for exporting metadata. Your super admin can set the default display of the metadata fields to **Logical**, if required.



- ***If you click the radio button to export All Documents in the data room, that's exactly how the download will perform. If the room has thousands of documents, you will download thousands of documents and all of the associated metadata fields chosen from the Metadata dropdown.***
- ***If you tick the checkbox next to 'Save metadata selection', you will find the metadata automatically selected in the dropdown window during your subsequent export selection.***

22.2. Exporting Documents

Exporting documents is the same as downloading documents from the cart, but with the Export Documents option from the Export dropdown you can avail many other functionalities as discussed below:

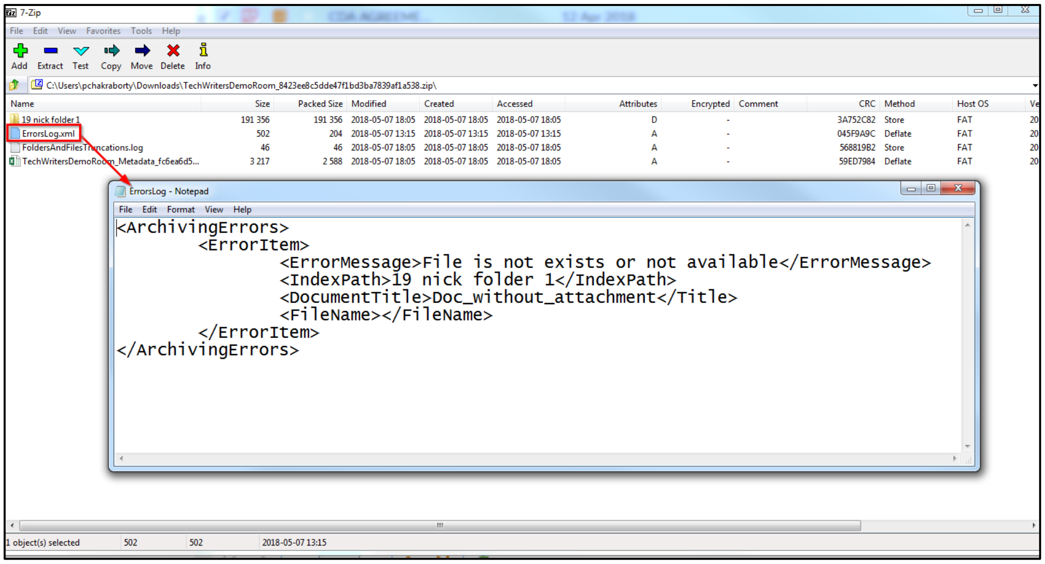


You can track an export, exclude previously exported documents, or include metadata during export. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.

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

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

Refer to the screenshot below:



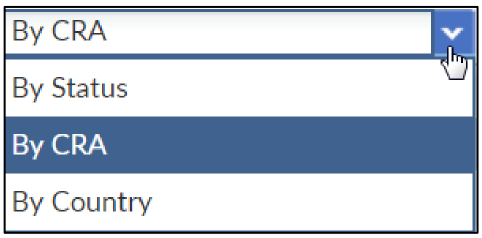
To view the exported file, navigate to the **Notifications** .

23. Sites and Contacts

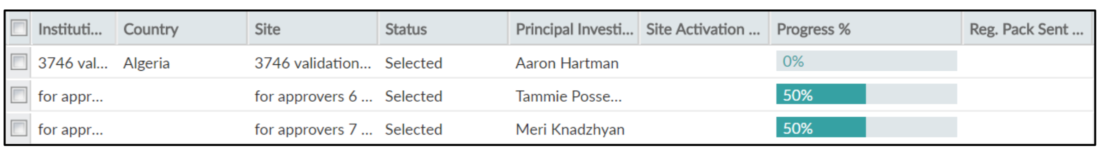
You can access the **Sites** module by clicking **Sites** icon on the menu bar at the left. The **Sites Module** is used for site management purposes and allows the administrator to track the progress of the sites. It gives detailed information on all investigative sites available in a room **By Status**, **By CRA**, and **By Country**.

23.1.1. By Status

Select **By Status** from the dropdown in the Index Pane of Sites Dashboard.



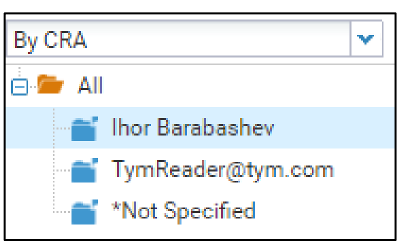
This will populate the data of all the sites available in the room based on their progress report in the right pane of the dashboard.



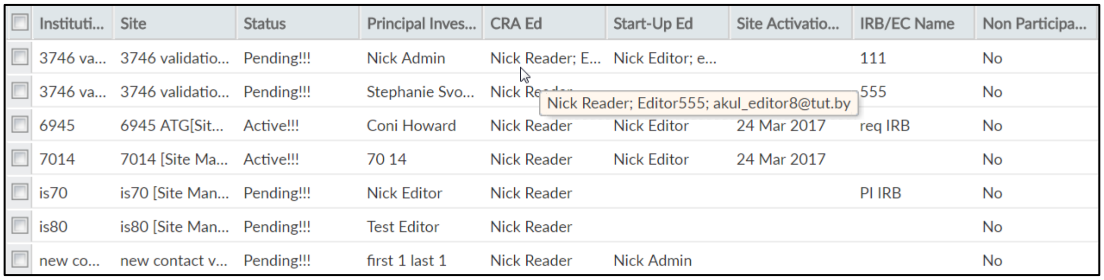
Instituti...	Country	Site	Status	Principal Investi...	Site Activation ...	Progress %	Reg. Pack Sent ...
3746 val...	Algeria	3746 validation...	Selected	Aaron Hartman		0%	
for appr...		for approvers 6 ...	Selected	Tammie Posse...		50%	
for appr...		for approvers 7 ...	Selected	Meri Knadzhyan		50%	

23.1.2. By CRA

Select **By CRA** from the dropdown in the Index Pane of Sites Dashboard.



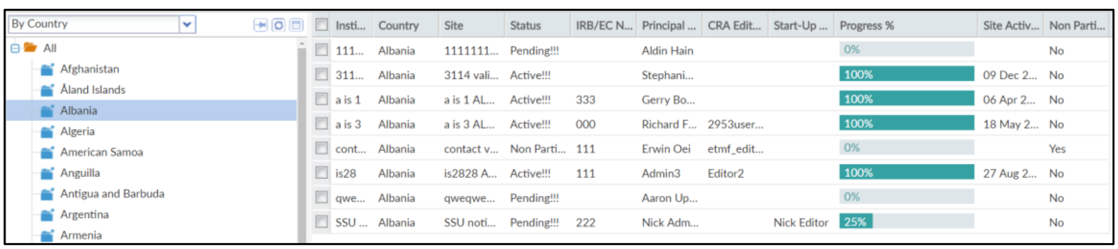
This will populate the Clinical Research Associate (CRA) for the available sites in the Index Pane on the left. Click the name of a CRA to populate the site details associated with that particular CRA in the right pane.



Instituti...	Site	Status	Principal Inves...	CRA Ed	Start-Up Ed	Site Activatio...	IRB/EC Name	Non Participa...
3746 va...	3746 validatio...	Pending!!!	Nick Admin	Nick Reader; E...	Nick Editor; e...		111	No
3746 va...	3746 validatio...	Pending!!!	Stephanie Svo...	Nick Re...			555	No
6945	6945 ATG[Sit...	Active!!!	Coni Howard	Nick Reader	Nick Editor	24 Mar 2017	req IRB	No
7014	7014 [Site Ma...	Active!!!	70 14	Nick Reader	Nick Editor	24 Mar 2017		No
is70	is70 [Site Man...	Pending!!!	Nick Editor	Nick Reader			PI IRB	No
is80	is80 [Site Man...	Pending!!!	Test Editor	Nick Reader				No
new co...	new contact v...	Pending!!!	first 1 last 1	Nick Reader	Nick Admin			No

23.1.3. By Country

Select **By Country** from the dropdown in the Index Pane of Sites Dashboard. This will populate the countries where the studies are being conducted in the Index Pane on the left. Click the name of a country to populate the site details associated with that particular country in the right pane. Refer to the screenshot below.

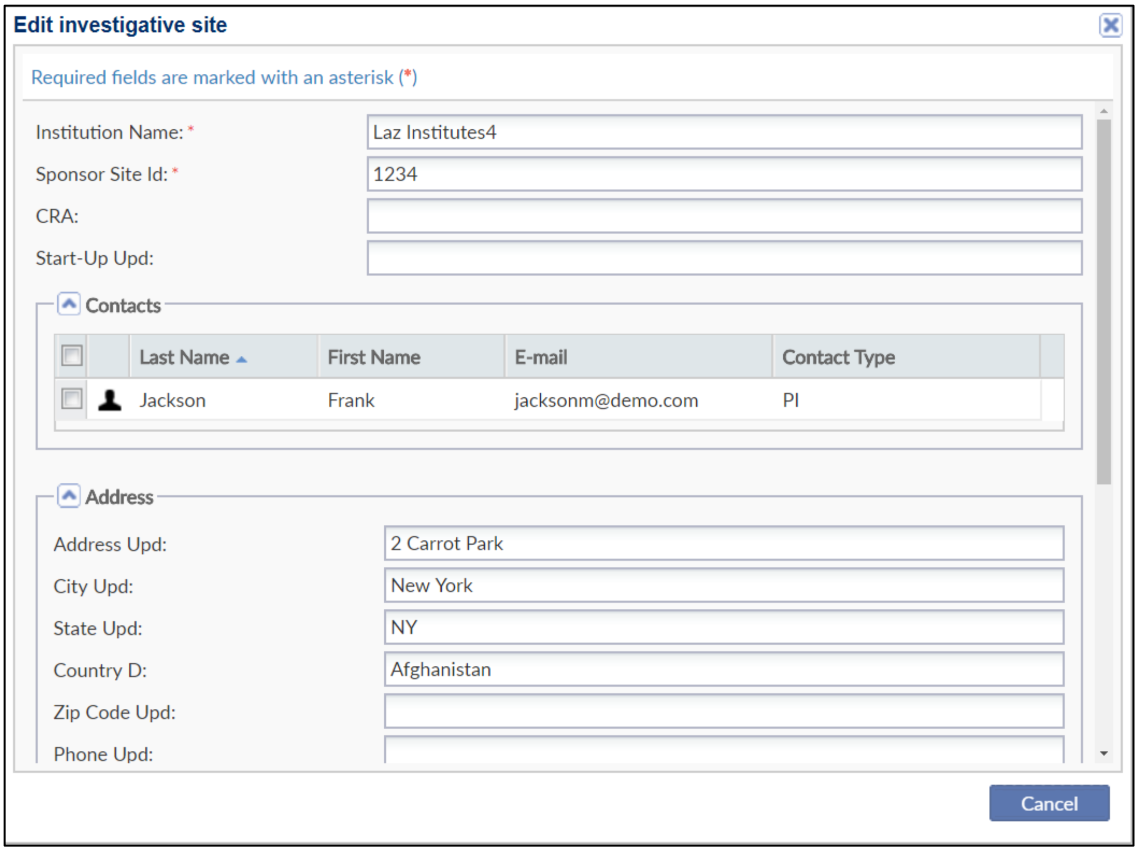


Insti...	Country	Site	Status	IRB/EC N...	Principal ...	CRA Edit...	Start-Up ...	Progress %	Site Activ...	Non Parti...
111...	Albania	1111111...	Pending!!!		Aldin Hain			0%		No
311...	Albania	3114 vali...	Active!!!		Stephani...			100%	09 Dec 2...	No
a is 1	Albania	a is 1 AL...	Active!!!	333	Gerry Bo...			100%	06 Apr 2...	No
a is 3	Albania	a is 3 AL...	Active!!!	000	Richard F...	2953user...		100%	18 May 2...	No
cont...	Albania	contact v...	Non Parti...	111	Erwin Oei	etmf_edit...		0%		Yes
is28	Albania	is2828 A...	Active!!!	111	Admin3	Editor2		100%	27 Aug 2...	No
qwe...	Albania	qweqwe...	Pending!!!		Aaron Up...			0%		No
SSU ...	Albania	SSU noti...	Pending!!!	222	Nick Adm...		Nick Editor	25%		No

Besides retrieving site details, you can perform other activities associated with a site like **viewing** a site profile and **exporting** site details. All the above activities can be performed by accessing the icons located on the top ribbon bar. Note that the other buttons are disabled for you.

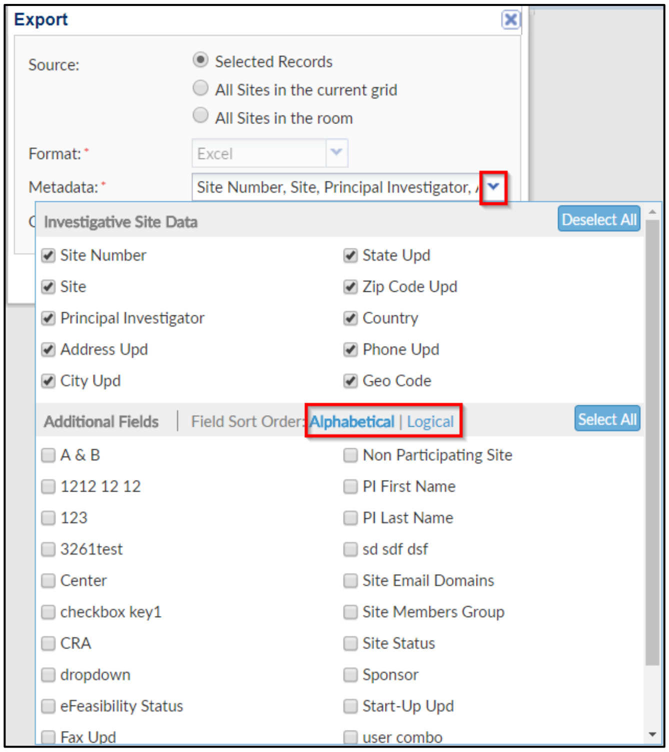
23.1.4. Viewing Site Profile

Open the **Site Profile** window by clicking the caret symbols » at the top right corner of the dashboard or by clicking the **View Profile** View profile button of the top ribbon bar. This will open the Site profile window for you to view the selected site details. You will not be able to make any changes in a site profile. Refer to the screenshot below.

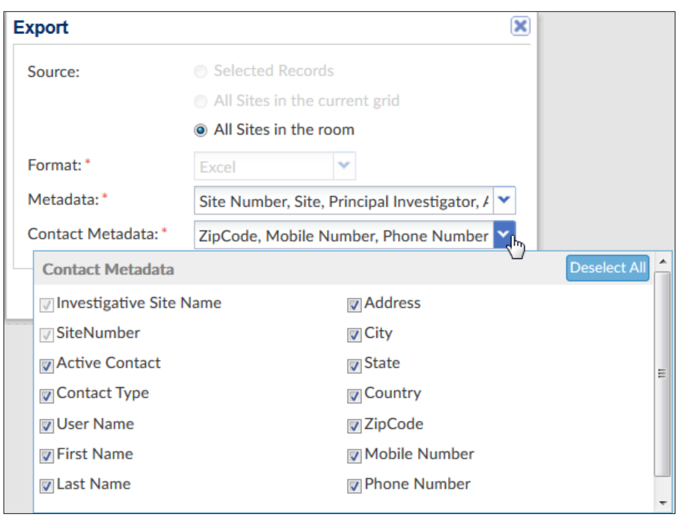


23.1.5. Exporting Sites

You can also export site metadata through the **Export** window that appears on clicking the **Export** icon Export on the ribbon. Refer to the screenshot above. You may export sites selected from the right panel, or all the sites in the current grid or room. To export site data, it is mandatory to select the **Site Metadata Fields** as shown below:

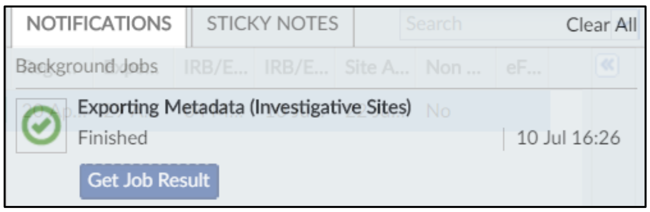


You can export the additional fields in either alphabetical or logical order of selection. Similarly, to export site contact data, you need to select **Contact Metadata** fields as shown below:



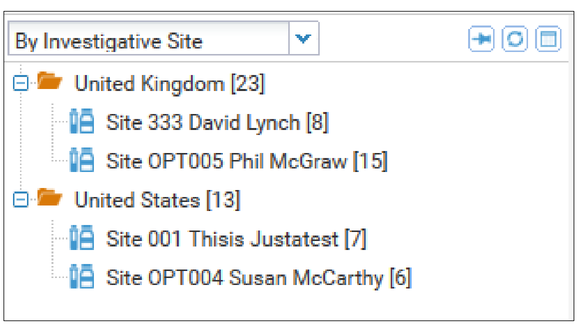
The export job result will be saved as an excel file. During export, a popup showing the status of the export job is shown. Refer to the screenshot below.

The export result are also populated in the **Notifications.** Click **Get Job Result** to view the excel file.



23.2. By Investigative Site

This lists the current view of the documents based on Investigative Sites. Investigative Sites are places where the clinical studies are conducted. This view shows the segregation of Investigative Sites as located in different countries. All sites belonging to a particular country are listed under its specific country. Click a site name to list the documents belonging to the site in the Document Grid. Refer to the screenshot below:



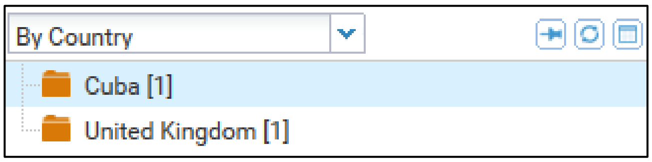
The dashlets related to Investigative Sites are:

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

23.3. By Country

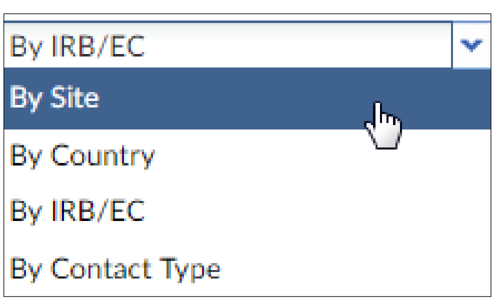
In the **By Country** view, the documents pertaining to studies in each country are listed. Folder by the names of countries are created with each folder having the documents associated with it.



23.4. Contacts

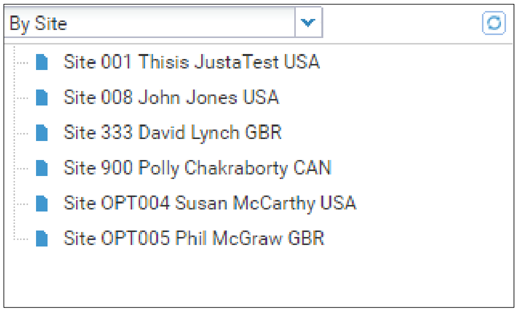
A clinical trial includes a varied range of people with different profiles, who are a part of the study. Such people are a valuable source of information and are required at various stages of the study. Trial Interactive helps to maintain the detailed profile of such people as Contacts for a study. Some examples of contacts could be the Principal Investigator, Sponsor, Co-Investigator, regulatory authorities, authorities in the IRB.

You can access the **Contacts** module by clicking **Contacts** icon on the menu bar at the left. The **Contacts Module** gives detailed information on all contacts available in a room **By Site**, **By IRB/EC**, **By Country**, and **By Contact Type**.



23.4.1. By Site

Select **By Site** from the dropdown in the Index Pane on the left of the Contacts Module. This will reveal all the sites available in the room.

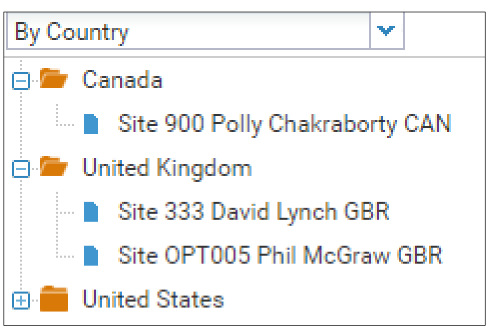


Click a site. This will populate the data of all the contacts available for the particular site in a room in the right pane of the dashboard.

Name	Contact Type	Phone	Main Contact	Provide Documents
new Contact	Pharmacy Contact		No	No
Test Yuga	Principal Investigator		No	Yes
Yugandhara Dahiphale26	Pharmacy Contact		No	No

23.4.2. By Country

Select **By Country** from the dropdown in the Index Pane of the Contacts Dashboard.

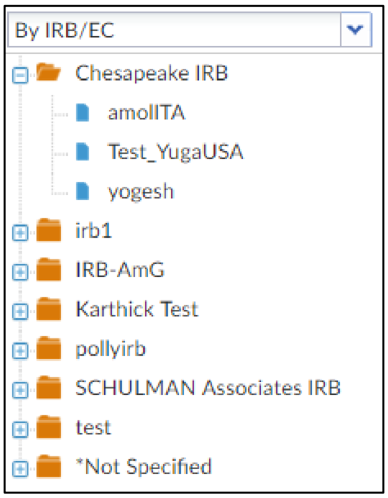


This will list all the countries with the sites where the studies are being conducted in the Index Pane on the left. Clicking a country to expand the dropdown will reveal the sites under it. Click a site to populate the contact details associated with the site in the right pane.

	Name	Contact Type	Phone	Main Contact	Provide Documents
	new Contact	Pharmacy Contact		No	No
	Test Yuga	Principal Investigator		No	Yes
	Yugandhara Dahiphale26	Pharmacy Contact		No	No

23.4.3. By IRB/EC

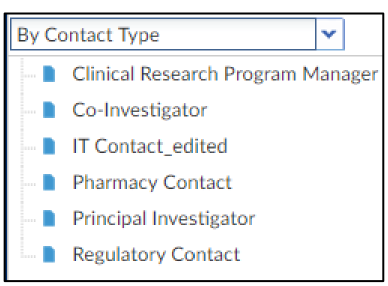
Select **By IRB/EC** from the dropdown in the Index Pane of Contacts Dashboard. This will populate the IRBs associated with the sites in the Index Pane on the left. Clicking an IRB will expand the dropdown to reveal the sites associated with it.



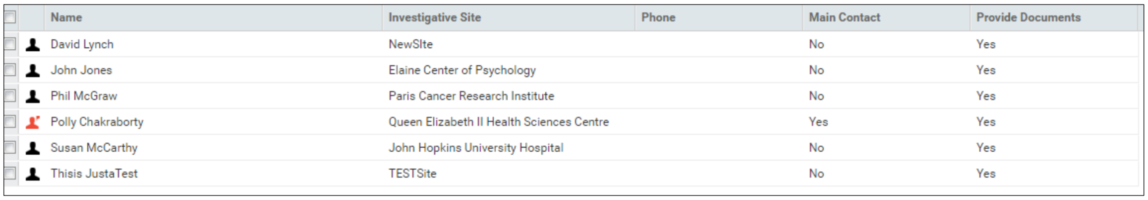
Click a site to populate the contact details associated with the site in the right pane.

23.4.4. By Contact Type

Select **By Contact Type** from the dropdown in the Index Pane of Contacts Dashboard. This will populate the contact types associated in the room in the Index Pane on the left.



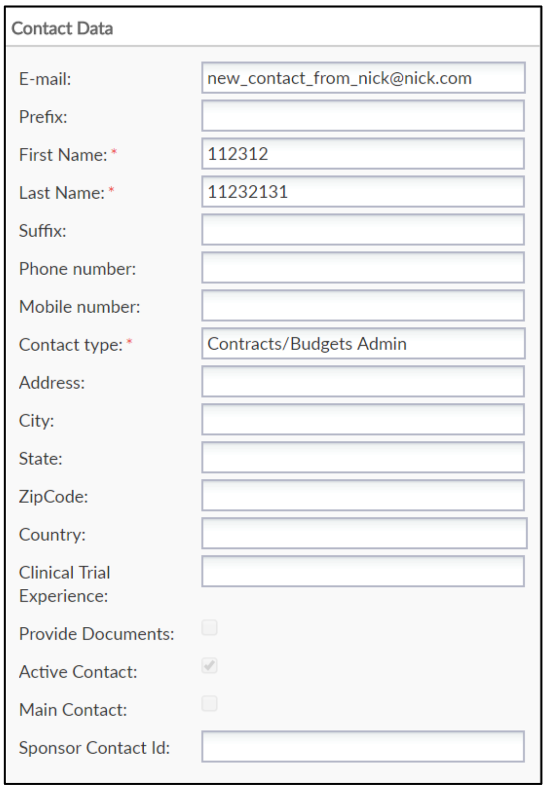
Clicking a contact will list the contact details associated with a particular site in the right pane of the dashboard.



Name	Investigative Site	Phone	Main Contact	Provide Documents
David Lynch	NewSIte		No	Yes
John Jones	Elaine Center of Psychology		No	Yes
Phil McGraw	Paris Cancer Research Institute		No	Yes
Polly Chakraborty	Queen Elizabeth II Health Sciences Centre		Yes	Yes
Susan McCarthy	John Hopkins University Hospital		No	Yes
Thisis JustaTest	TESTSite		No	Yes

23.4.5. Contact Data

Selecting a contact in the grid will highlight the **Contact Data** window at the extreme right of the grid in the right pane. You can view details of the contact here.



Contact Data

E-mail:	new_contact_from_nick@nick.com
Prefix:	
First Name: *	112312
Last Name: *	11232131
Suffix:	
Phone number:	
Mobile number:	
Contact type: *	Contracts/Budgets Admin
Address:	
City:	
State:	
ZipCode:	
Country:	
Clinical Trial Experience:	
Provide Documents:	
Active Contact:	✓
Main Contact:	
Sponsor Contact Id:	

Contacts can be added through the Sites Dashboard. This is discussed in the previous section. They can also be added from the Document Data Panel.

24. Electronic Signature

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

Discussed below are three e-signature options that are available with Trial Interactive:

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

Proceed to the respective e-signature option depending on the vendor configured for your room.

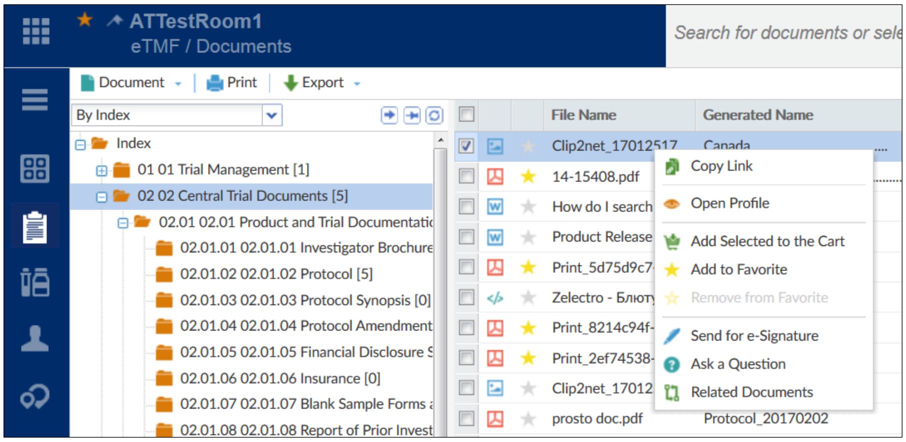
24.1. TI e-Signature

For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) which is now back with some modifications from the TI version 8.13.

24.1.1. Assigning signers to the documents

1. Visit the desired room in Trial Interactive.

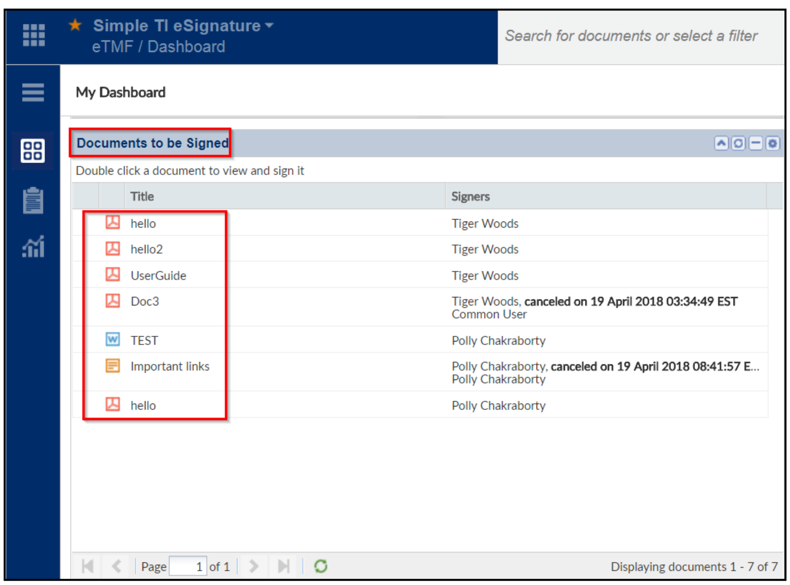
   Click the **Documents** tab. If you have recently uploaded the document, click the **Upload** tab and navigate to open the desired folder within the Upload tab. The list of documents will be displayed in the right pane.
2. Right click the desired document and click **Send for e-signature**.



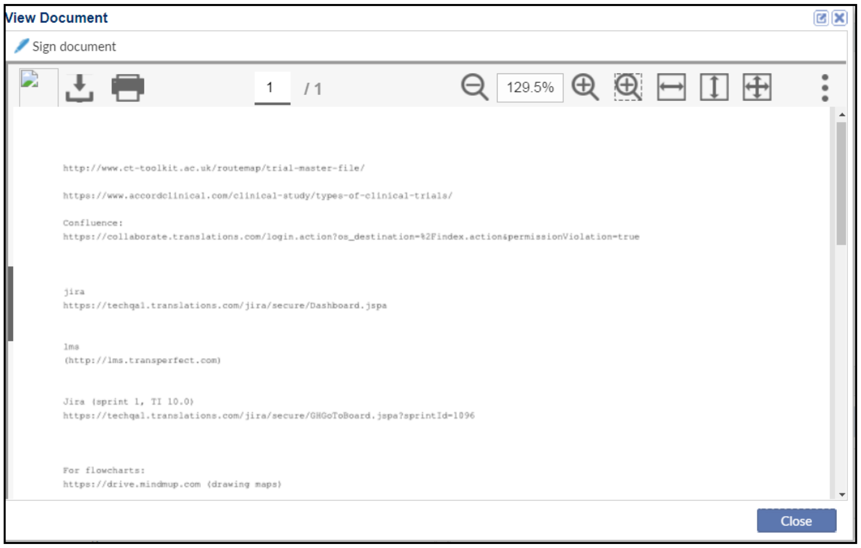
24.1.2. Signing the documents in TI – eSignature if you are a signer

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

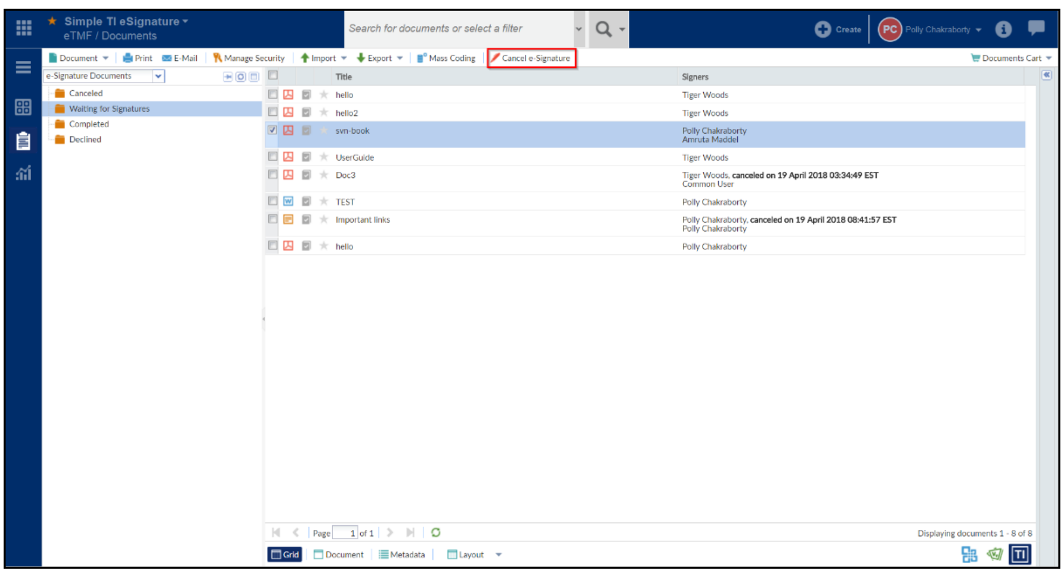
1. When you are assigned a document for eSignature, navigate to the room **Dashboard** and scroll down to find the **Documents to be signed** dashlet.



2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.



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

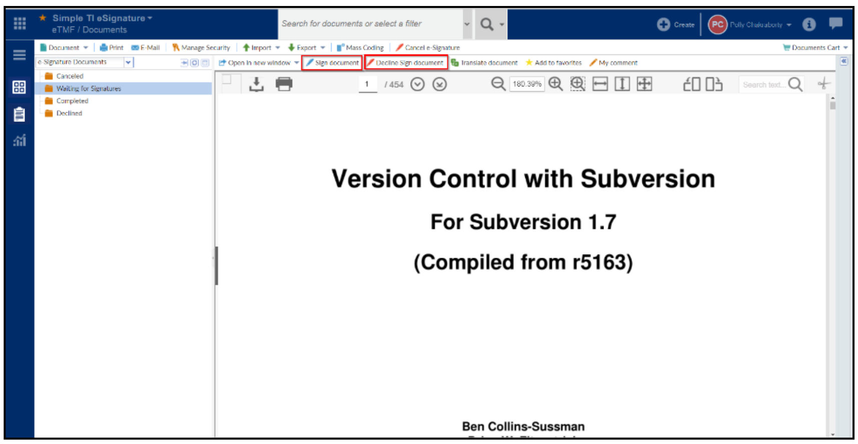


If you do not want to sign the document, directly click the **Cancel e-Signature** button from the top ribbon bar and confirm the cancellation. The document will move to the **Declined** folder under **e-Signature Documents** view.

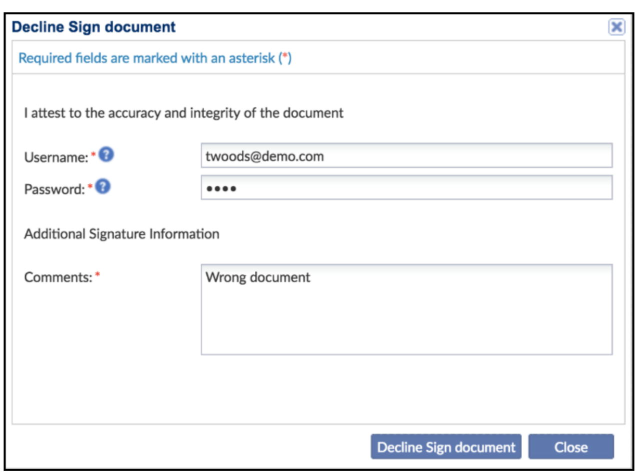
- ***Completed signatures cannot be cancelled.***
- ***Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.***
- ***Once a document is cancelled from e-signature, no one can sign the document until it is resent again.***

Either ways, to e-sign the document:

1. Open the document in the viewer and click **Sign Document** from the toolbar to begin the review and signing process. Refer to the screenshot below:



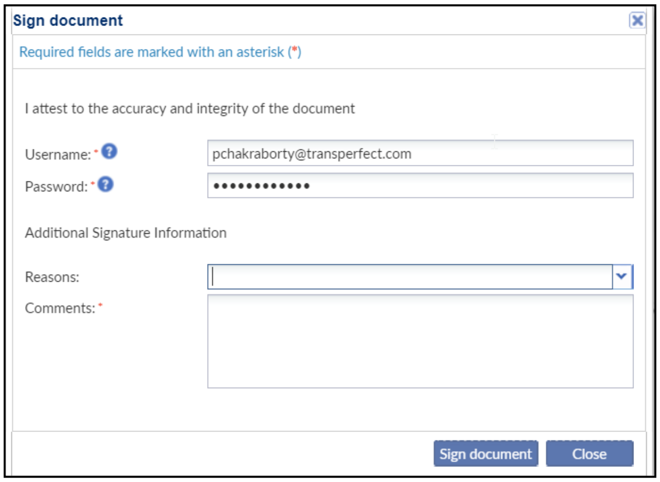
From here too, you may choose to decline to e-Sign by clicking the **Decline Sign document** button. Validate with your login credentials and enter the comments to decline. **Here too, the same rules as mentioned above apply for declining to sign a document**. Refer to the screenshot below.



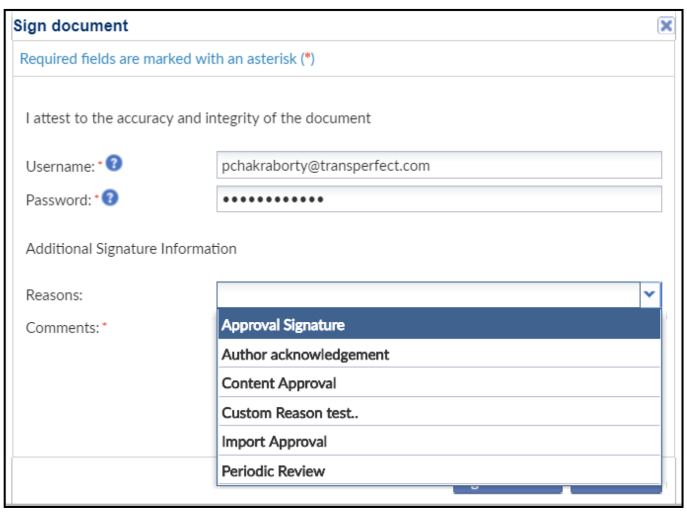
The document moves to the **Declined** folder under **e-Signature Documents** view.

3. Else click the **Sign document** button to proceed with.

   You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive.



4. Select the reasons applicable to e-sign the document and enter your comments.

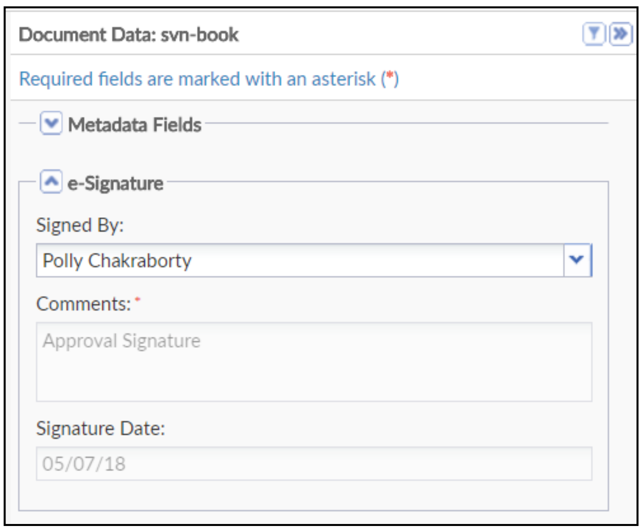


5. Click **Sign document** button.
6. You will receive a message saying that the document was successfully signed. Click **OK**.
7. If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all the signers have finished signing.

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

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

9. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under **e-Signature Documents** view.
10. Besides the **Completed** folder, you can view the e-signature history of a document in the metadata panel under the e-signature panel.



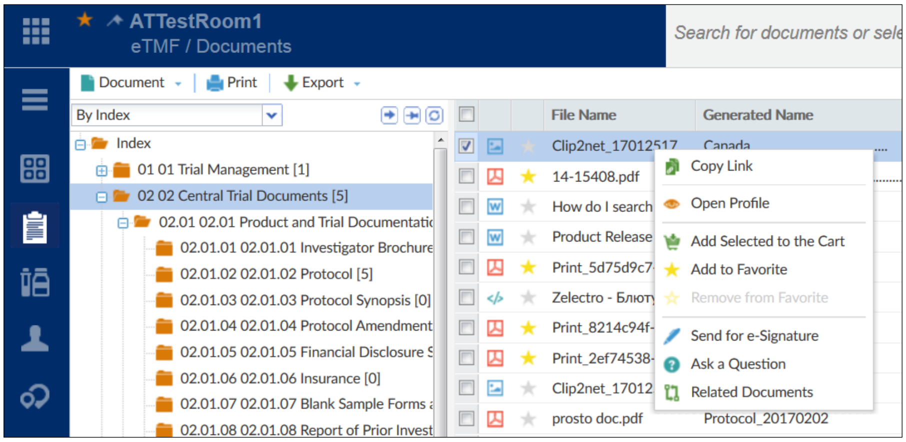
24.2. Adobe e-Sign

To use Adobe Sign to e-sign documents, the administrator must enable the feature for you.

24.2.1. How to Assign Signers to the Documents

1. Visit the desired room in Trial Interactive by clicking the room.

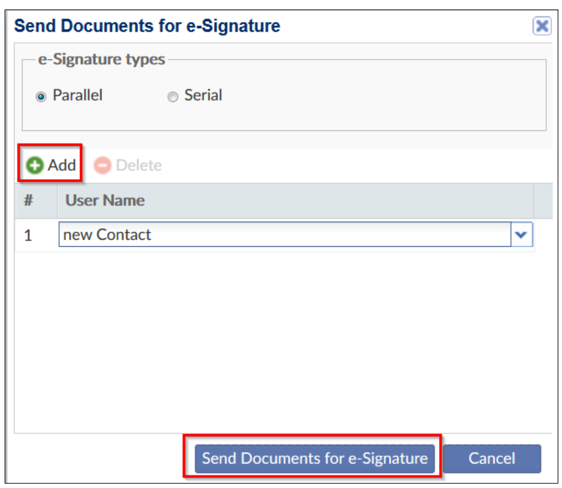
   Click the **Documents** tab. The list of documents will be displayed in the right pane.
2. Right click the desired document and click **Send for e-signature**.



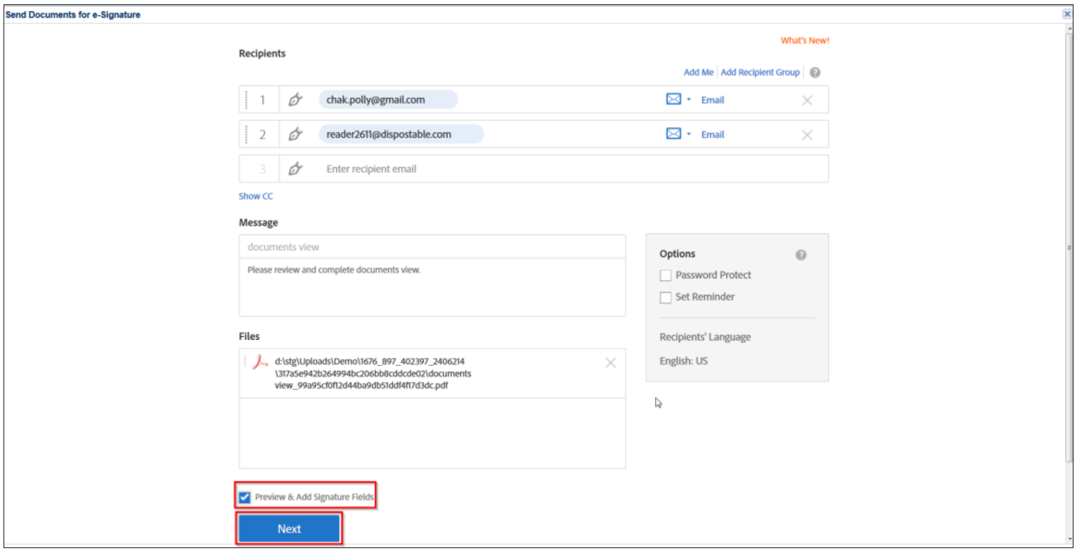
A new pop-up window to add signers for the documents will display. Add the users you wish to assign as the signers by clicking the **Add** button. You may add one or more signers to the document.

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

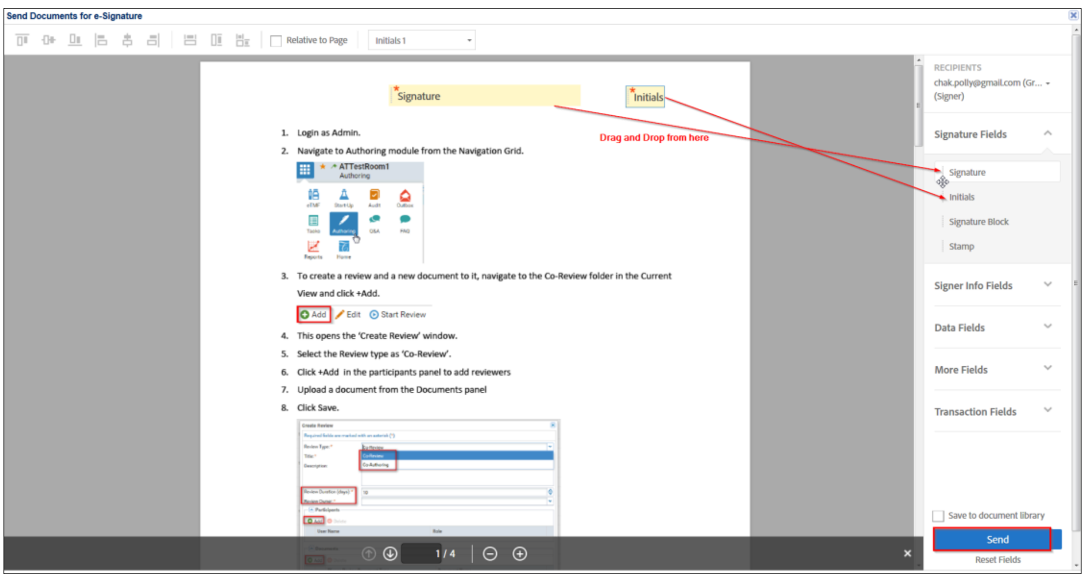
Click the **Send documents for e-signature** button after adding the desired signers.



3. A Recipients window with the list of email ids of signers enlisted opens.
4. Tick the **Preview & Add Signature Fields** checkbox to determine the placement of signatures on the document.
5. Click **Next**. Refer to the screenshot below:



6. Drag and drop the fields on your document from the right menu option that you wish to include in the signature.



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.

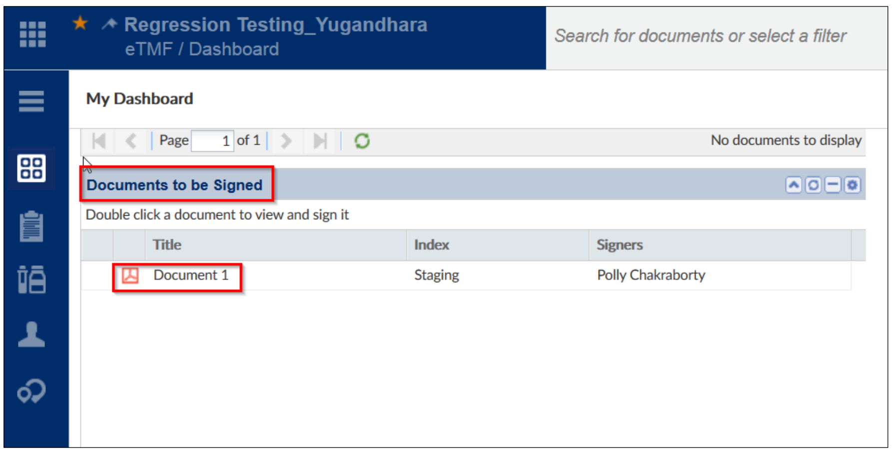
You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

24.2.2. How to Sign the Documents in Adobe Sign if you are a Signer

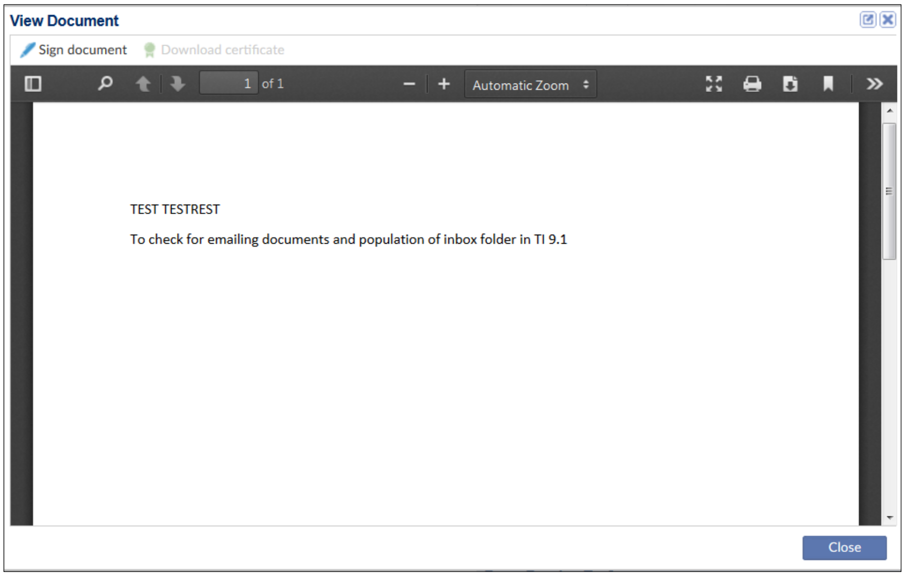
If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document.

   Alternatively, click the **Dashboard** tab and scroll down to find the **Documents to be signed** dashlet.

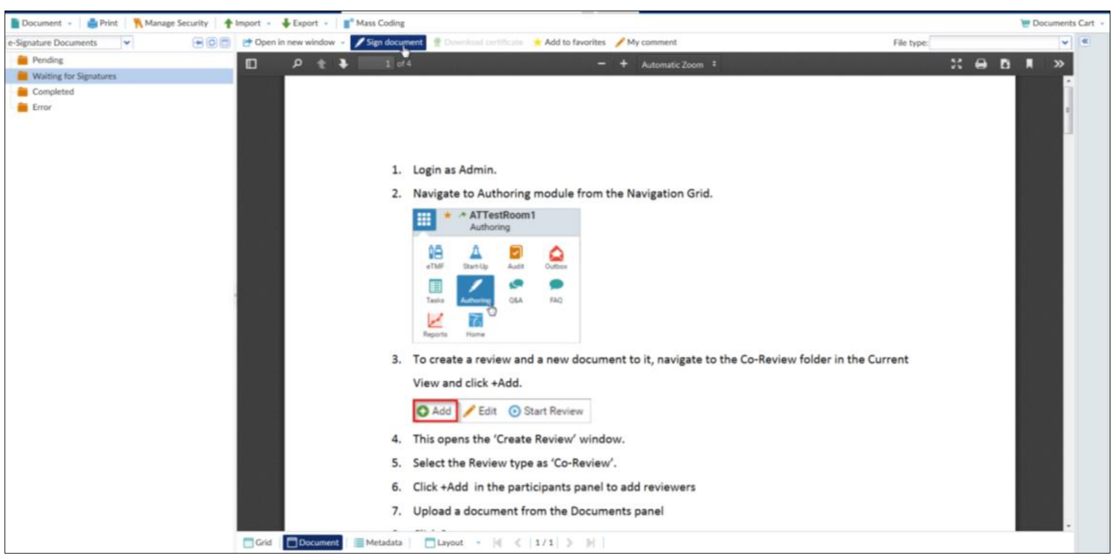


2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

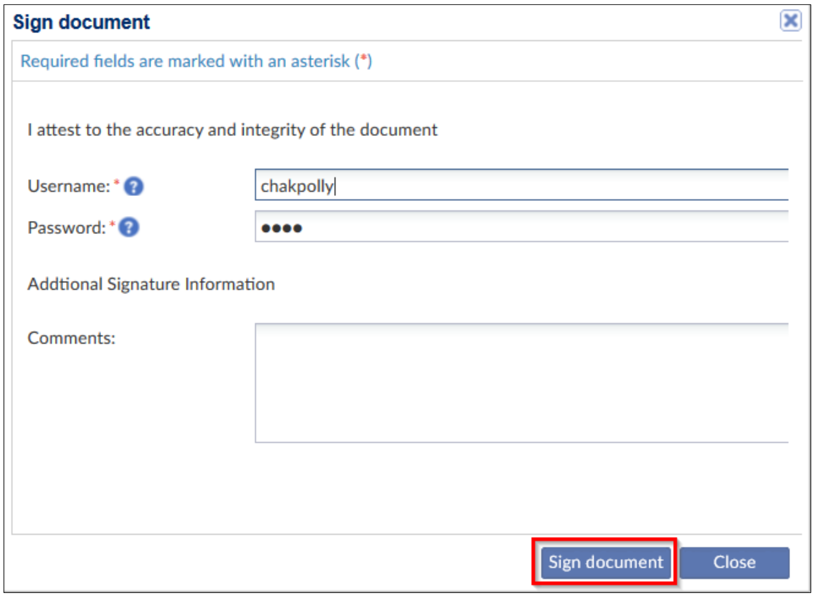


You can also proceed to the **eTMF/Documents** module and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process.

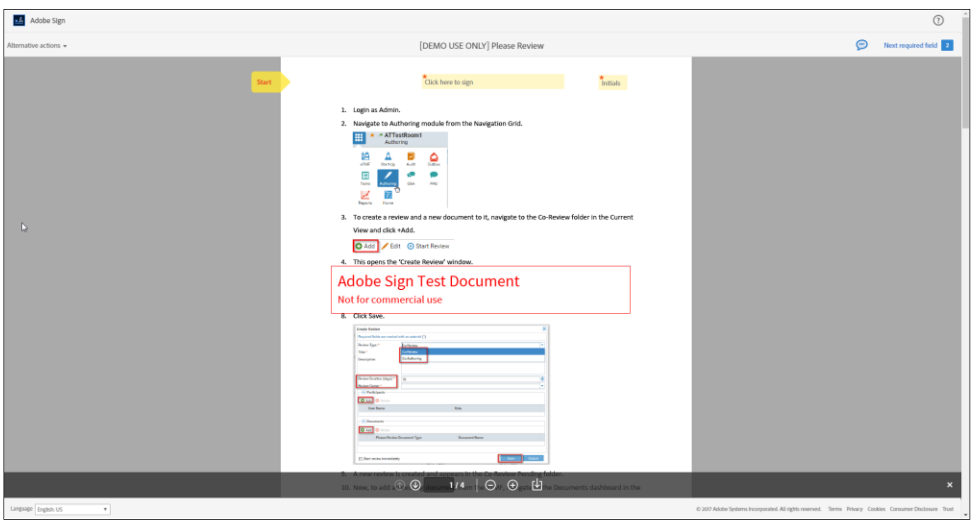
If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document.



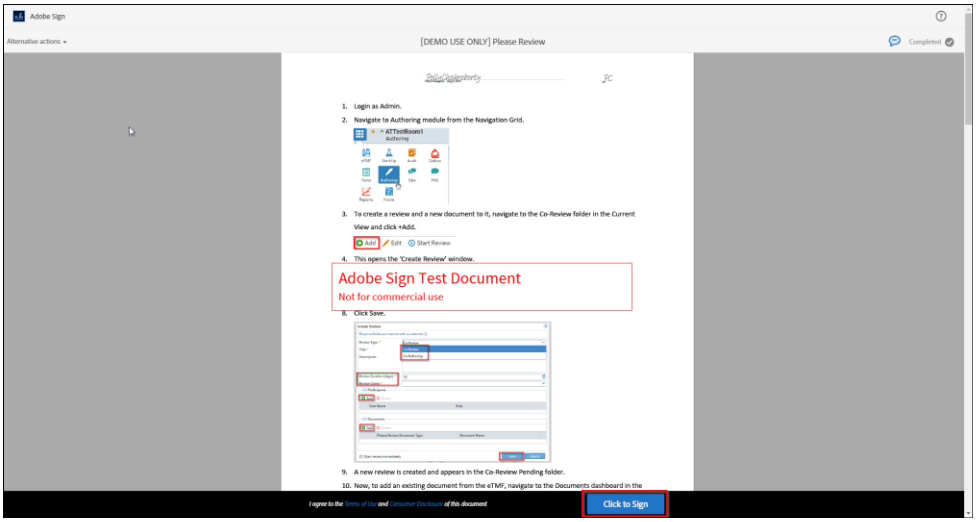
3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.



4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document.



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



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

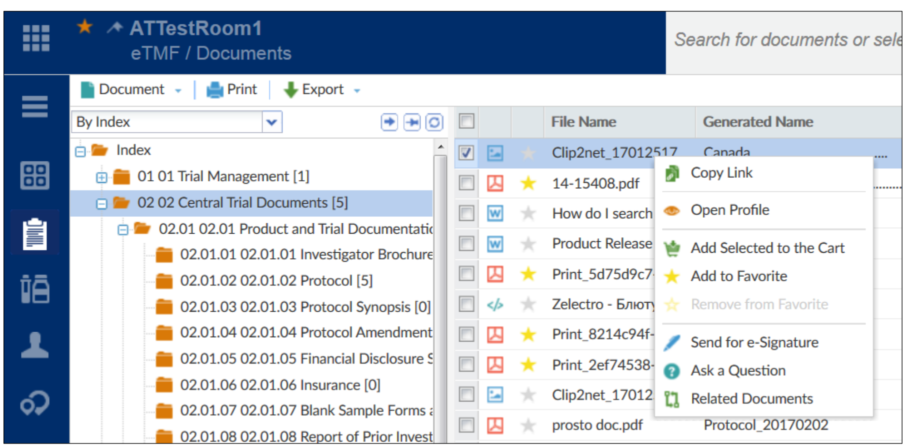
24.3. DocuSign e-Signature

24.3.1. How to Assign Signers to the Documents

Step 1: Visit the desired room in Trial Interactive by the clicking the room.

Click the **Documents** tab. If you have recently uploaded the document, click the **Upload** tab and navigate to open the desired folder within the Upload tab. The list of documents will be displayed in the right pane.

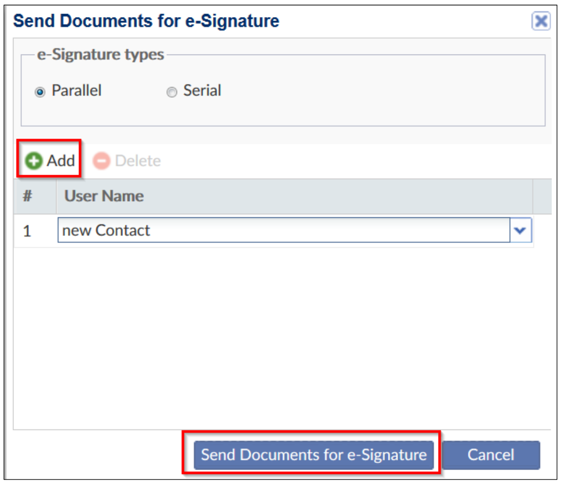
Step 2: Right click the desired document and click **Send for e-signature**.



A new pop-up window to add signers for the documents will display. Add the users you wish to assign as the signers by clicking the Add button. You may add one or more signers to the document.

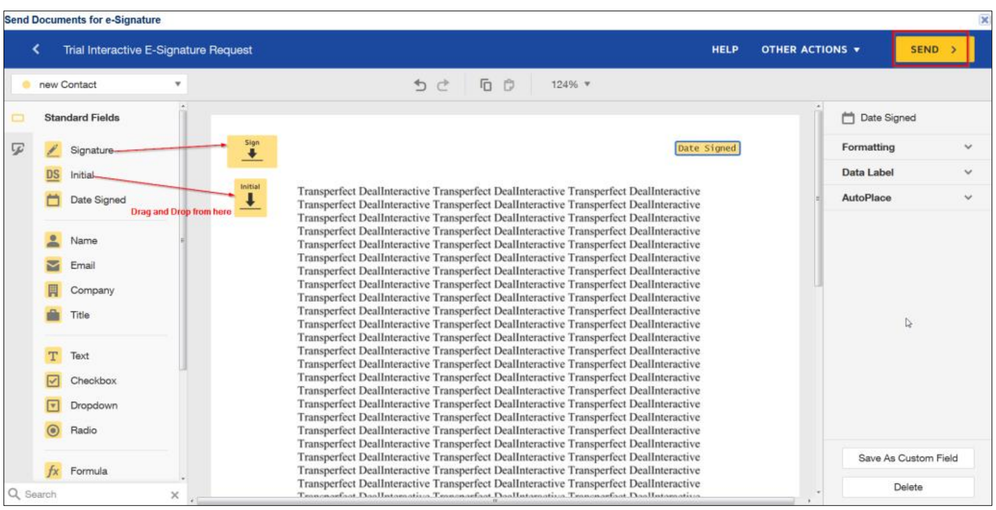
If you wish to assign a sequence in which your signers should sign the document, select the Serial option to decide the sequence.

Click the **Send documents for e-signature** button after adding the desired signers.



Step 3: 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.



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.

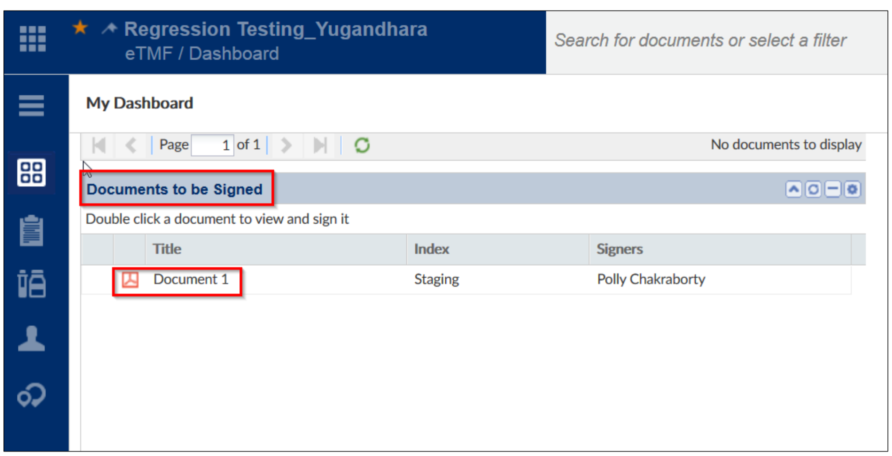
You may also review the documents to be signed, along with the signer details, in your dashboard under the Documents to be signed dashlet. Refresh the page to view the latest updates.

24.3.2. How to Sign the Documents If You Are a Signer

If you are assigned to electronically sign a document, follow the steps below for **eSignature**:

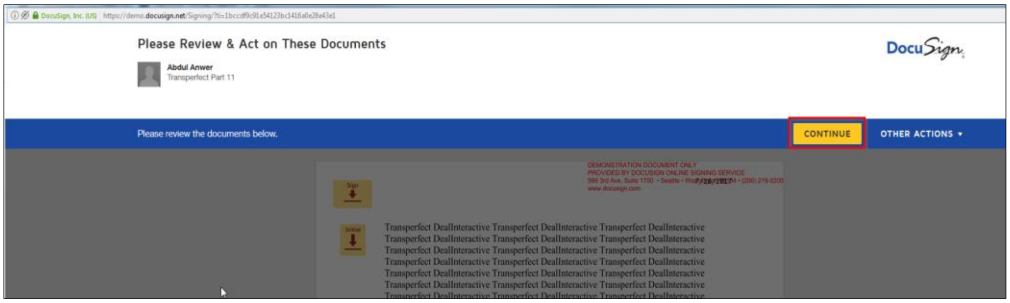
1. When you are assigned a document for eSignature, you will receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room.

2. Once in the room, click the **Dashboard** tab and navigate to the **Documents to be Signed** dashlet.

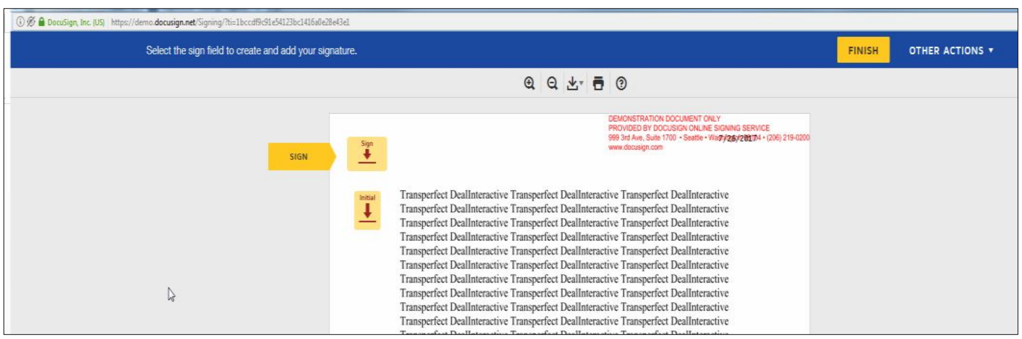


3. Click the document listed in the **Documents to be Signed** dashlet to view and sign it. Alternatively, you can navigate to the **e-Signature Documents folder** from **the Current View** in the **eTMF/Documents** module and open the documents to sign it. The rest of the procedure is the same.

4. A window will appear, allowing you to review and perform actions on the document.



5. Click **Continue.** When using the **Serial** signature feature, the location to sign will be highlighted within the document. Click the **Sign** icon to proceed; the system will prompt you to choose the font type, font size, etc. for your e-Signature. When using the **Parallel** Signature feature, all designated signature placeholders will display, allowing users to eSign irrespective of the sequence of the signature.

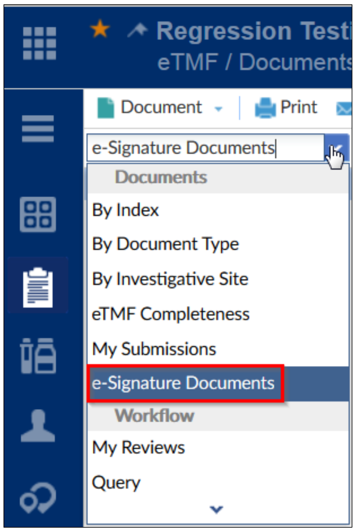


6. Upon applying your eSignature, click **Finish** to complete the eSignature process.

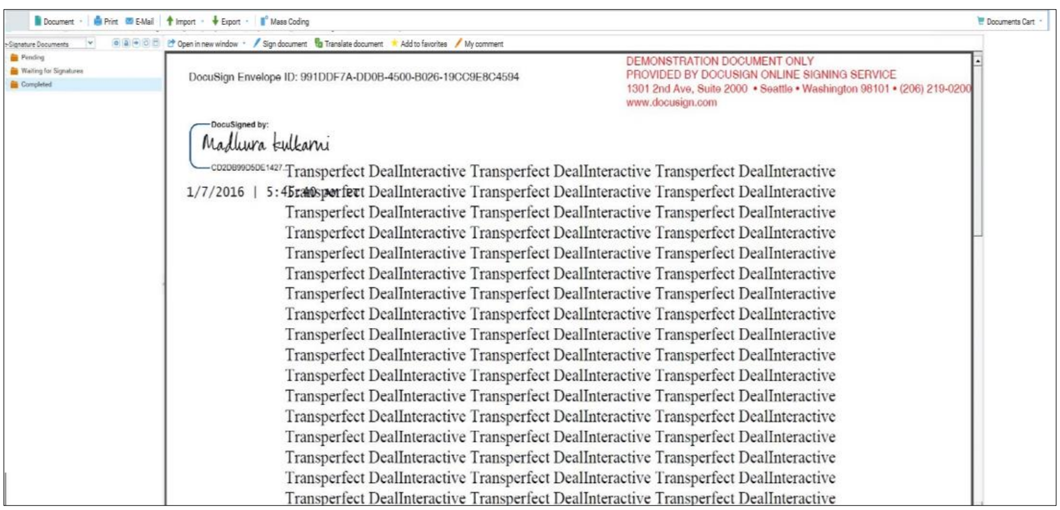
24.4. Accessing the e-Signature Documents

Users can access all **e-Signature Documents** and view their statuses within the Documents tab, following the instructions below:

1. Navigate to the room containing the eSignature documents and click the **Documents** tab.
2. Select the **e-Signature Documents** from the dropdown list located on top left panel.



3. Folders with the document status – **Pending**, **Waiting for Signatures**, and **Completed** – display in the left panel. Click on the desired folder to view documents in the right window pane. If you wish to open the document, click the document icon.
4. The eSignature document will display in the right pane.



25. Audit Module

The Audit Module in TI allows to record an auditor's review and comments on various documents added for audit in a trial. In Trial Interactive, you would find the following type roles for audit:

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

As a Trial Interactive reader, you can access the **Audit Module** from the **Navigation Grid**:

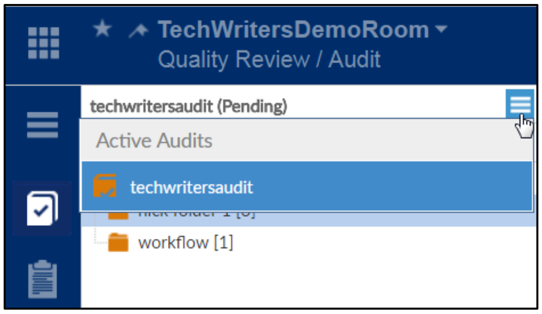
25.1.1. Performing Audits

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

1. As a user with Auditor duties, log in to a room and click the **Audit** module icon.

   The user can access Audits and audit documents through the panel on the left.

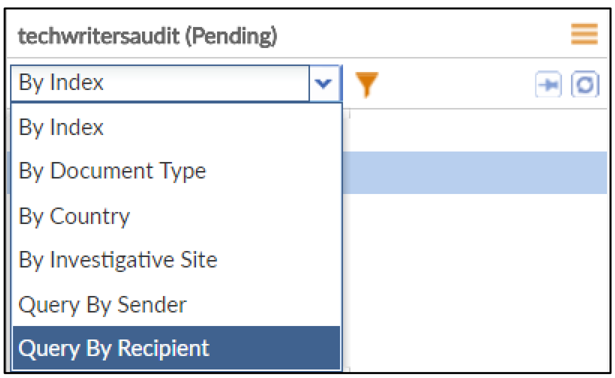
2. Click the three-bar icon to open the **Active Audits** menu.



3. Select an active audit. The default view is **By Index**.
4. Click the dropdown arrow to reveal the variety of available views.

   The user can also choose to view the available audit documents *By Document Type*, *By Country*, *By Investigative Site*, *Query By Sender, and Query By Recipient*.

   Select views to be displayed.



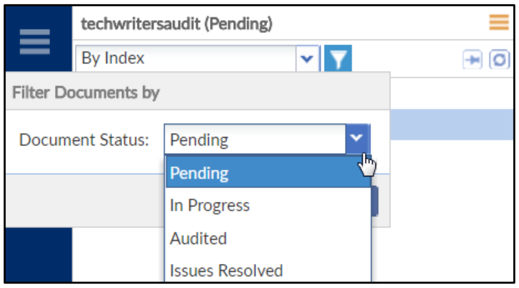
   Corresponding folders display based on the selection made by the user.

   Drill down and select the available folders. Available documents will be displayed in the grid.

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

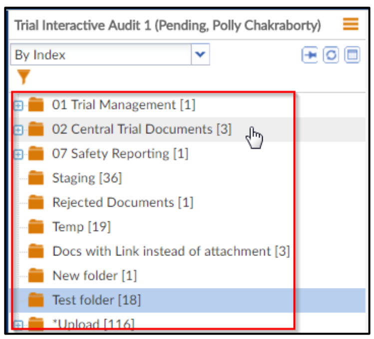
1. Once the Audit is chosen, click the filter icon.

2. Click the dropdown arrow at the right end of the **Document Status** field.

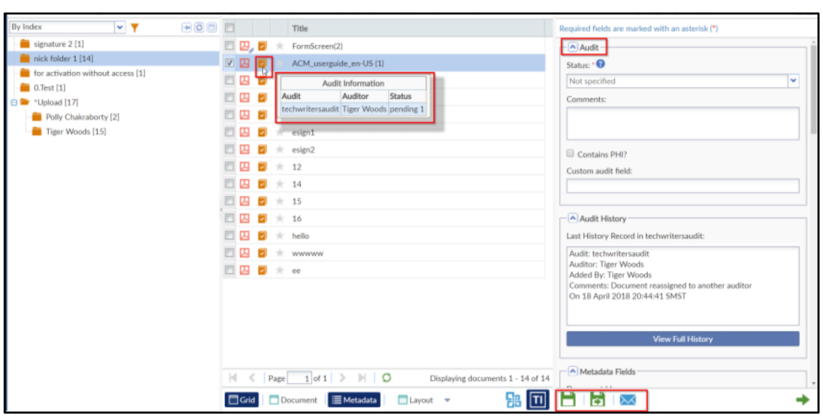


3. Select **Pending** from the list.
4. Click the **Apply** button.

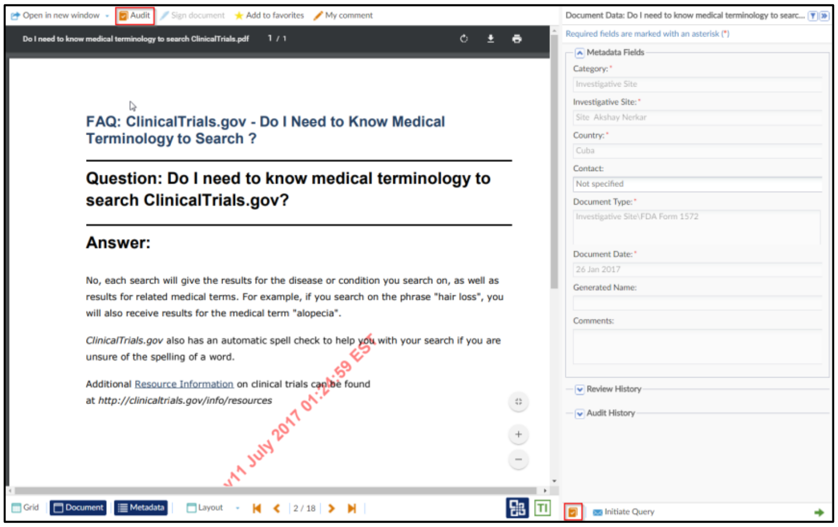
   Index folders containing documents **Pending Audit** populate the Index view panel.



5. Open folders to locate documents published and assigned for audit.
6. Select a document from the document grid.
7. Notice the **Audit Information** icon next to the document icon in the document grid.
8. Click the icon to open the Audit panel in the document metadata panel.
9. Also notice the **Audit information popup** displaying the audit status of the selected document. Refer to the screenshot below:



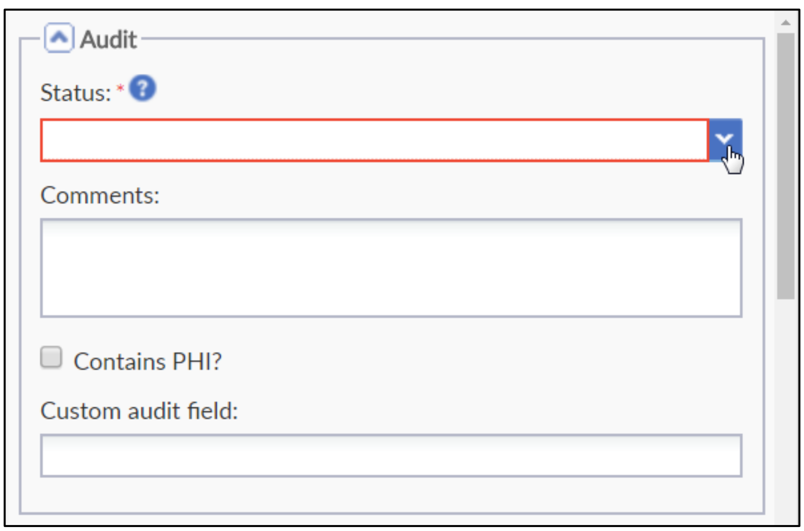
10. Open the document in the viewing panel and open the **Document Data** panel.



11. Examine the document and its metadata to determine if it meets the established audit criteria.

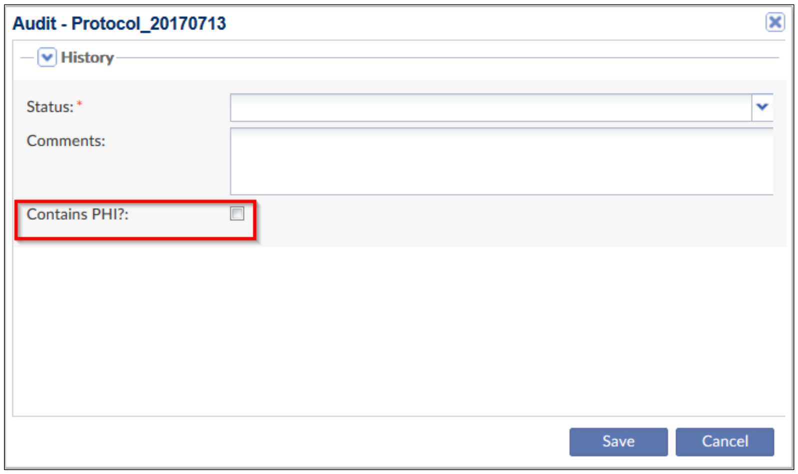
12. From the **Audit panel** in the **Metadata panel** click the dropdown arrow at the right end of the **Status** field.

    The status options appear.

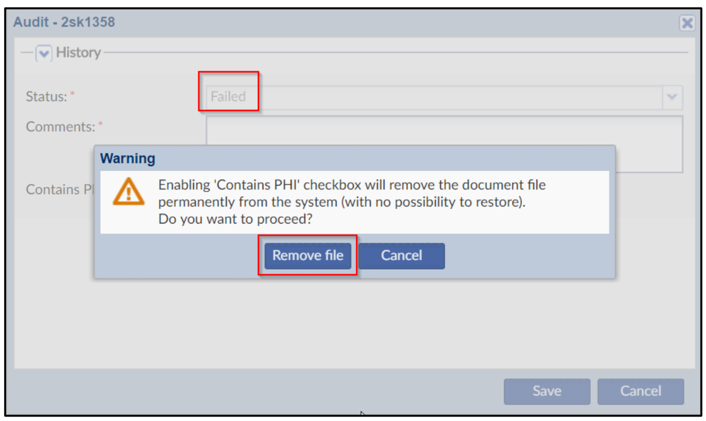


13. Click the appropriate **Status**.

    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.

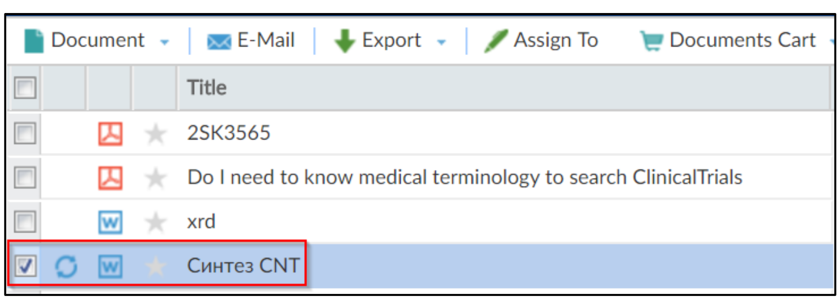


On ticking this, the document automatically acquires a **failed** status and displays a warning regarding the removal of the attachment from the document.

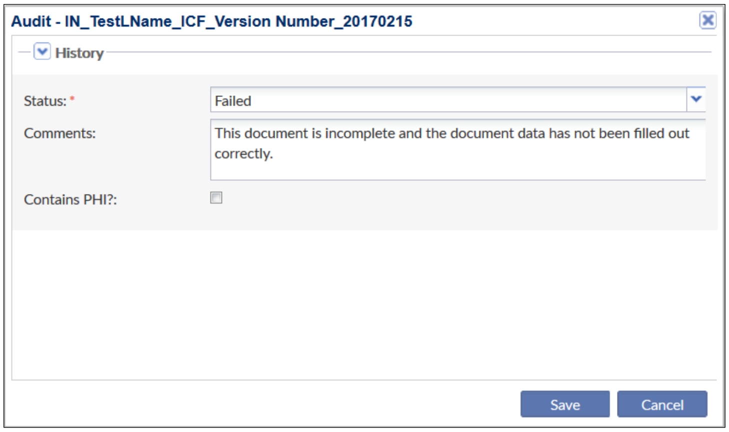


Click **Remove file** to proceed. The system deletes the attachment in the backend and displays the **Refresh** icon next to the document in the grid.

On clicking the **Refresh** icon, the document disappears from the grid and moves to the **Audited** folder.



14. Insert comments as appropriate.



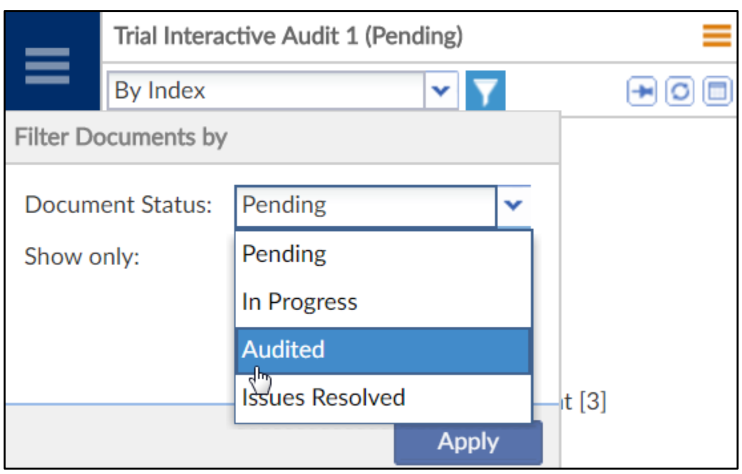
15. Click the **Save** button in the lower right corner of the window.

    The view returns to the full audit screen.

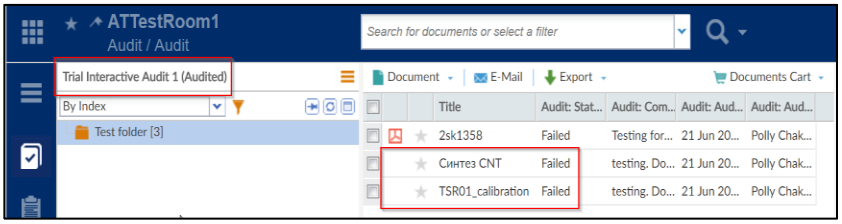
16. Select another document or another folder containing published audit documents to continue the audit.

***Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your audit criteria*.**

17. To view audited documents, filter the documents by Audited from the panel in the left.



18. 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.

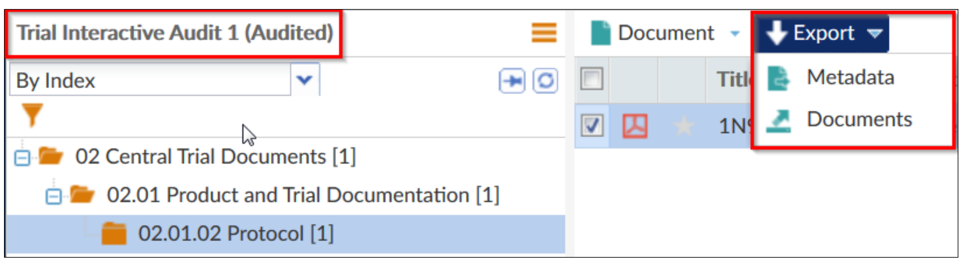


25.1.2. Export of Audit Metadata by an Auditor or Audit Manager

The reader as an auditor can export a report of metadata related directly to the documents assigned to any particular audit.

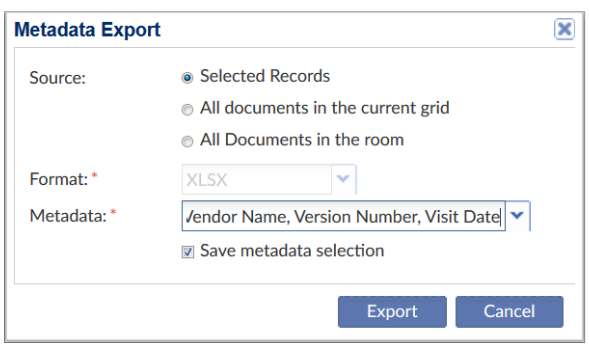
1. Click **Audit** from the room's toggling menu bar.
2. Select the audit on which you would like to run the audit report.
3. Select **Audited** from the By index view dropdown.

   A set of audit documents populates the document grid.
4. Click the **Export** button from the menu ribbon above the document grid.



5. Select **Metadata** from the dropdown menu.

   The **Metadata Export** window opens.



6. Select the criteria for the material to be downloaded from all of the available options.
7. Click the **Export** button.

   A **Background Jobs** window opens with the initial export results.

8. As instructed on the screen, click to get the export results.

   A zipped file downloads to your computer.

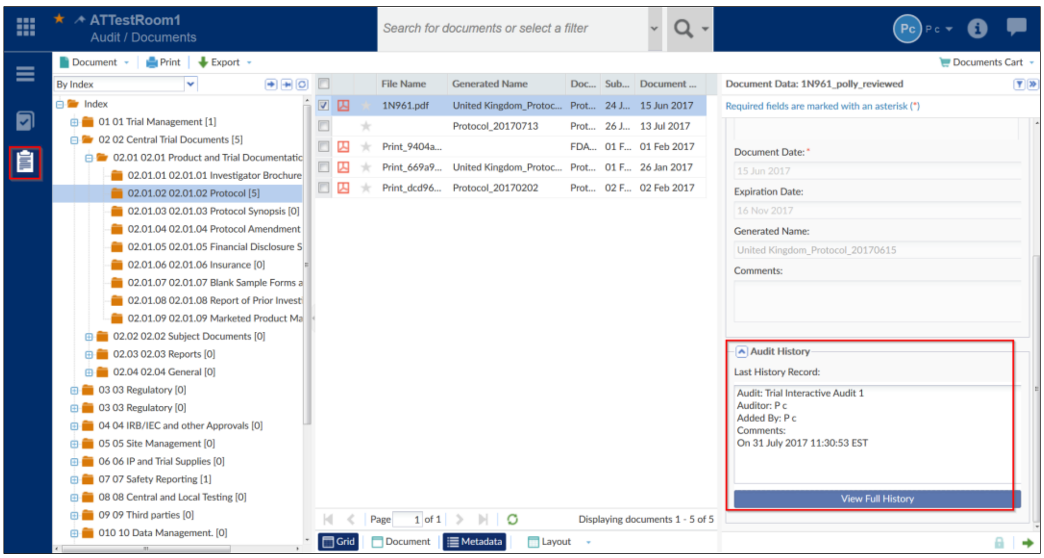
9. Follow the on-screen instructions to open the XLSX file.

10. Follow the same process as above to export Documents in the Audit module.

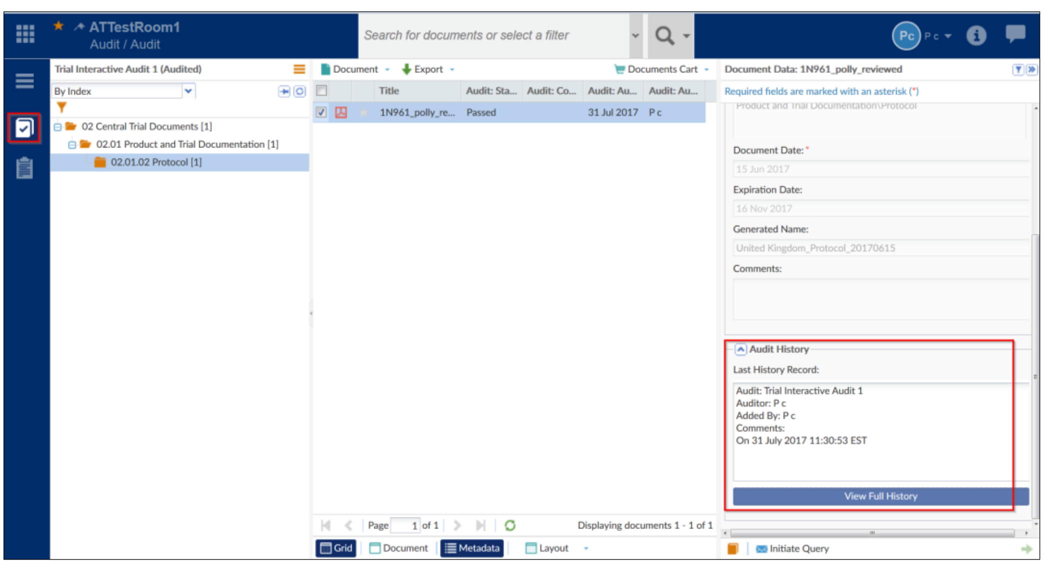
25.1.3. Viewing Audit History

Users can view a document's Audit history in the Metadata panel from:

1. **The Documents module**



2. **The Audit module**



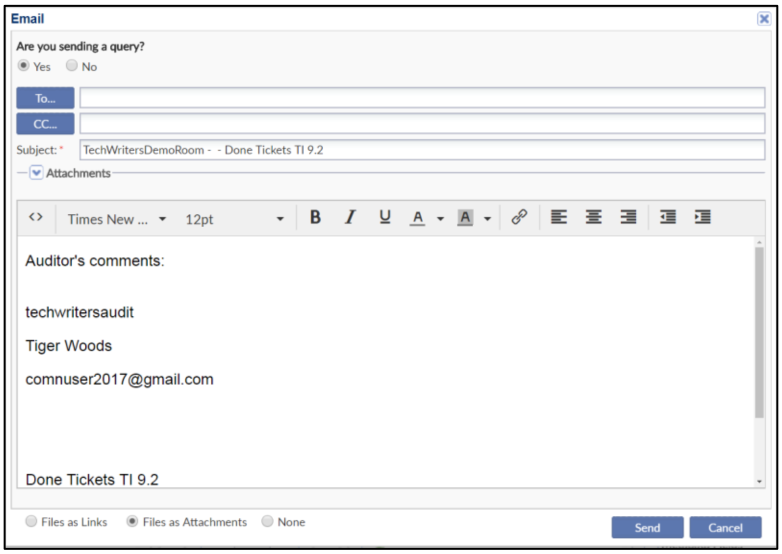
Documents deleted and failed due to contents of PHI get recorded in history as '**document deleted as it contained PHI information'**.

25.1.4. Audit Query

Audit Query Initiation by the Auditor

As an auditor, you may raise a query on a document in audit.

1. Click the envelope icon next from the bottom of the metadata panel.
2. An **Email** window opens. Click **Yes** to the question **Are you sending a query?**



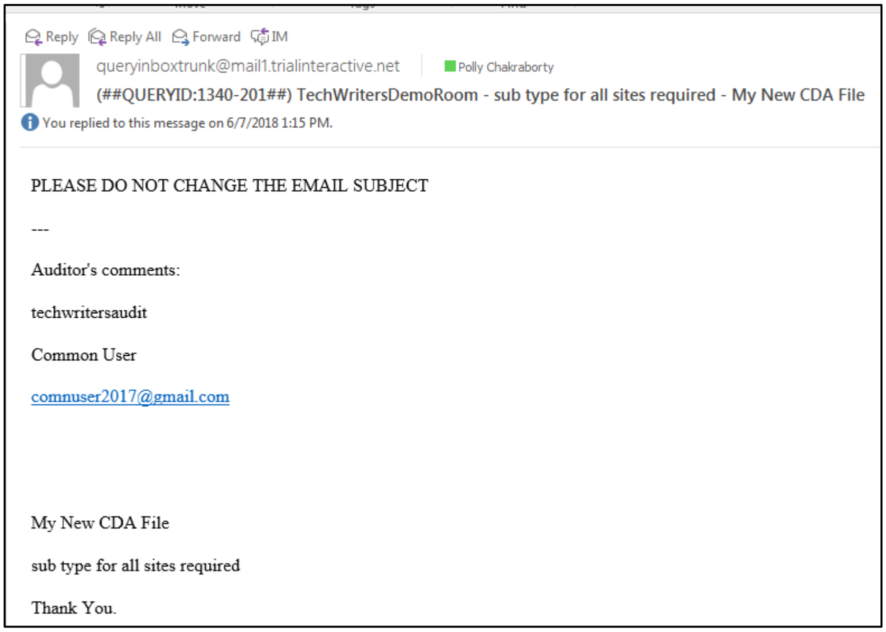
3. Click the 'To' and/ or the 'CC' button at the top of the message to add recipient of the Query notification email message.

   The party responsible for having sent the document to the room is an automatic recipient of the outgoing message.
4. Only room participants can be added to the 'To' and 'CC' fields. Other email addresses cannot be added.

   The sender can include the associated query document as an attachment or as a link.
5. Once all appropriate selections are made, click **Send**.

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

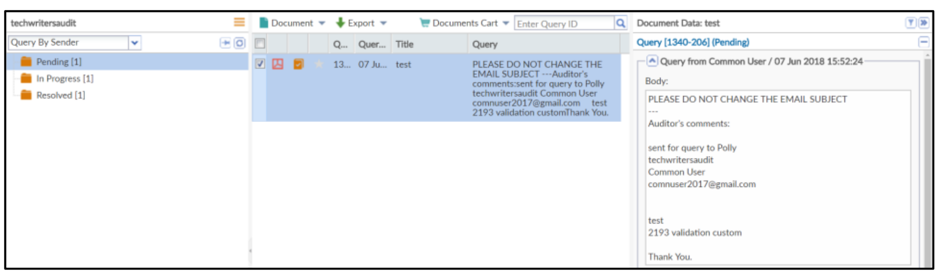
   Recipients receive an email message like this:



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

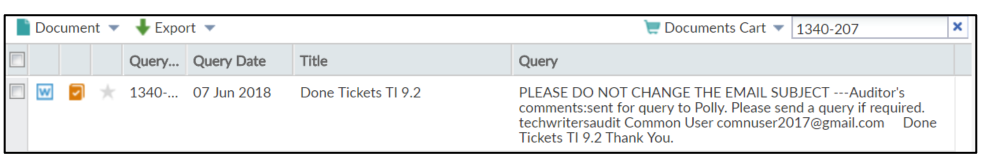
   A Query ID consists of the of the Room ID where the query was generated and the Query ID separated by a dash. For example, in the above screenshot, in the Query ID 1340-201, 1340 is the Room ID and 201 is the Query ID.

7. You can view the query sent under the **Query By Sender** view under the **Pending** folder.



Searching for Audit Queries

You can search for queries raised during audit by entering the Query id in the Search box on the top ribbon bar in the **Query By Sender** view. Refer to the screenshot below:



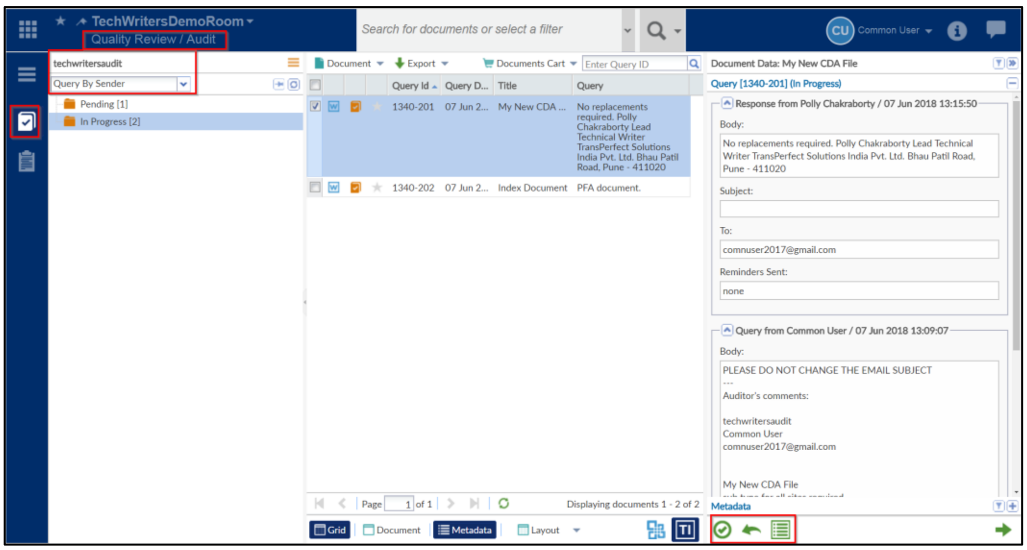
Audit Query Resolution for query responses without attachment

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

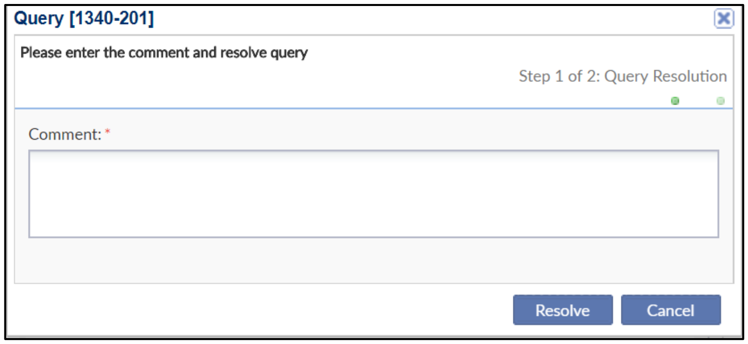
> ***If the auditor is in receipt of a query, the auditor can view it under Query by Recipient view and resolve the query from there. The procedure to resolve a query is the same for both the views and is discussed in subsequent sections.***

As the auditor you need to do the following to resolve the query:

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



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



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

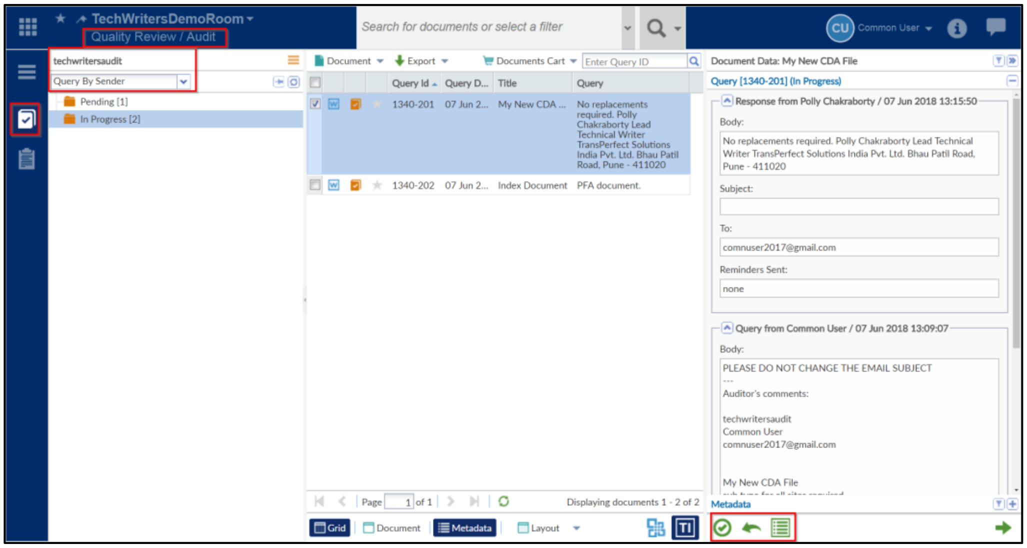
5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the **Query by Sender** view for the auditor and in the **Resolved** folder under the **Query By Recipient** view for the audit responder.

Audit Query Resolution for query responses with attachment

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

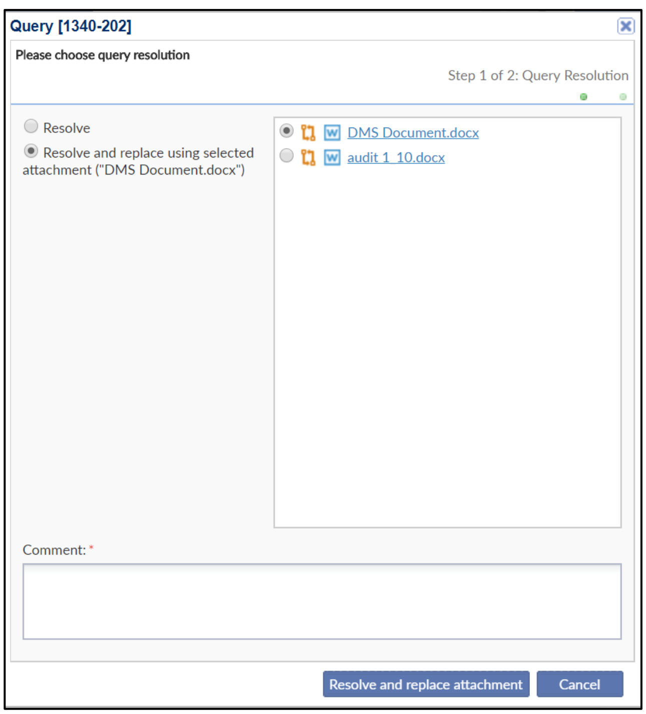
The auditor needs to do the following to resolve the query:

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



3. Click the **Resolve** button for query resolution else click the **Return back to Pending** button from the metadata panel.

4. On clicking the **Resolve** button from the metadata panel, the **Query** window opens to allow you to resolve the query. The auditor will see the following window to resolve queries with attachments:



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

5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the **Query by Sender** view for the auditor and in the **Resolved** folder under the **Query By Recipient** view for the audit responder. In this view the user can **only see the Query History button**.
6. On clicking **Resolve and replace using selected attachment**:
   a. The reviewer can choose from the right pane, the document as deemed fit. The right pane shows two attachments – (1) that was sent as an attachment by responder to allow the reviewer to resolve the query and (2) the original document that is in the audit process.
   b. Before taking a decision, the reviewer can click the **Compare** icon from the right pane to compare between the document under review and the attachment sent by the responder in the **Compare documents** window, or click the attachment icon to open and view the attachment in the viewer.
   c. Once done, the reviewer clicks the **Close** button on the **Compare documents window** and clicks the **Resolve and replace attachment** button after entering the **Comments**.

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

e. After the query is resolved with a new attachment, the original attachment will be replaced with selected one. The original attachment will be available in Document Revisions.

26. Shared Workspace (TI Collaborate)

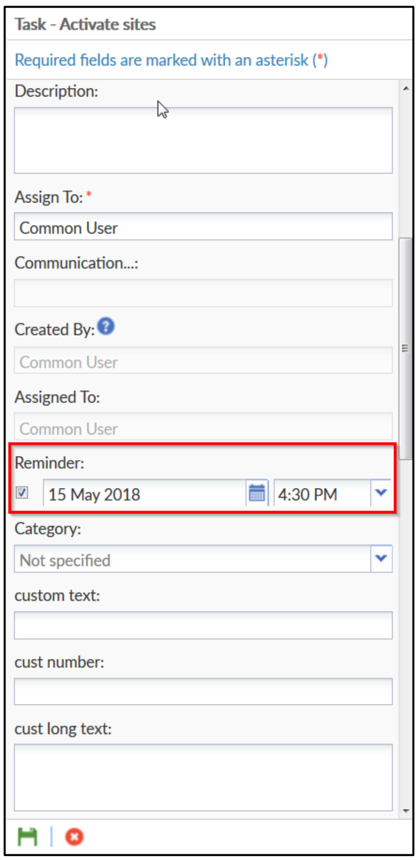
A **shared workspace** (SWS) is an intermediate room where the Sponsors and Study Management Team of a clinical study can collaborate to store documents until they are sure about the contents and metadata of the documents. When the user of a Shared Workspace are clear how the TMF study will be like in terms of the metadata such as document type, they review the documents and decide on whether to publish such documents to the eTMF. Some documents may reside in the shared workspace while the others are published to eTMF by the user. When a document is published, it is auto-routed to corresponding folder as mentioned in the room settings or published as a final document based on the workspace configuration.

You can navigate to the SWS from the eTMF room also by clicking the SWS icon from the Navigation Grid. Refer to the screenshot below:

Readers do not play a big role in a Shared Workspace room. However, they can view the draft documents, and e-sign the final version of the collaborative documents.

27. Tasks Module

Readers can manage and track their Trial Interactive tasks using this feature. They can assign tasks to themselves for a particular room. They are given an option to add, edit, delete, and export tasks. Additionally, readers can adjust the number of days before a task's deadline to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task. Refer to the screenshot below:



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

a. **Enter the room** for which you want to create tasks from the **Home** page.

b. Click the **Navigation Grid** on the title bar from within the room.

c. Click **Tasks** icon.

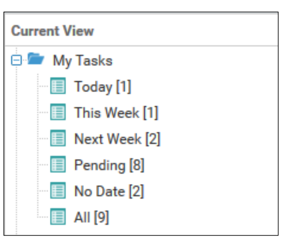
From within a room, the reader can maintain and track tasks related to the TI room. They can add, edit, delete, and adjust their tasks.

Once inside the Tasks dashboard, you can adjust the **Current View** in the left pane by:

1. **My Tasks**
2. **By Status**, and
3. **By Category**

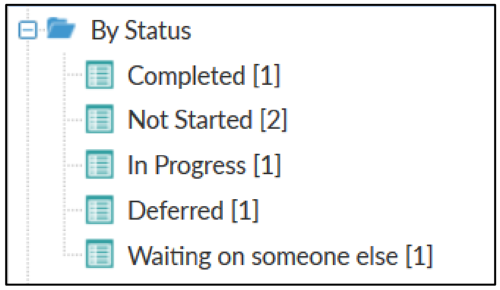
27.1. My Tasks

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



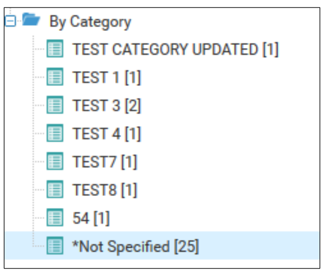
27.2. By Status

There are five task-statuses available. The system color-codes the status according to the specified work completion percentage. This view lists all the tasks in the document panel as per the status selected. The count of task per status is also displayed next to each status in the left pane.



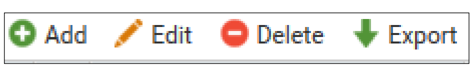
27.3. By Category

This lists all the tasks under each category along with their counts.



27.4. Adding, Editing, or Deleting Tasks

Tasks can be added, edited, or deleted from the icons in the ribbon above the dashboard.



Mention the task name in the subject text box while adding tasks from the **Task Profile** window. Tasks can be edited from the **Task Profile** window or from the **metadata panel** located on the right of the dashboard. When adding or editing a task, you are also given an option to attach files. Simply click Attach a file from the **metadata panel** or in the **Task Profile** window. When you are finished attaching files, click **Save** and a clip icon with a number will appear next to the subject line on the document panel. The number next to the clip icon reflects the number of attachments for a particular task.

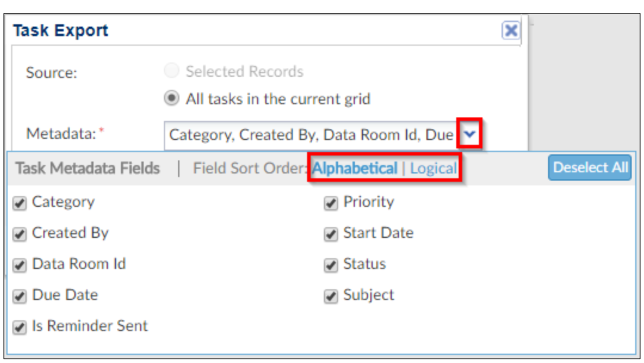
Other metadata fields that Readers can fill out include the following:

1. **Start Date:** The date when the task should be started.

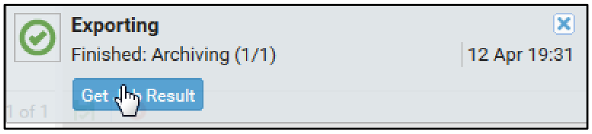
2. **Due Date:** The date by which the task should be completed and submitted.
3. **Priority:** The priority of a task could be Low, Normal, or High.
4. **Status:** Depending upon the progress of the task, the status could be set as Completed, Not Started, In Progress, Deferred, or Waiting on someone 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**.

27.5. Exporting Tasks

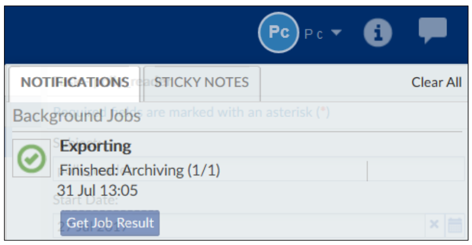
You can also export tasks through the **Task Export** window invoked by clicking the **Export** icon Export on the ribbon. Refer to the screenshot above. You may export tasks selected from the document panel, or all the tasks in the current grid. To export tasks, it is mandatory to select the **Task Metadata Fields** which will be saved in the export job result as an excel file.



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



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



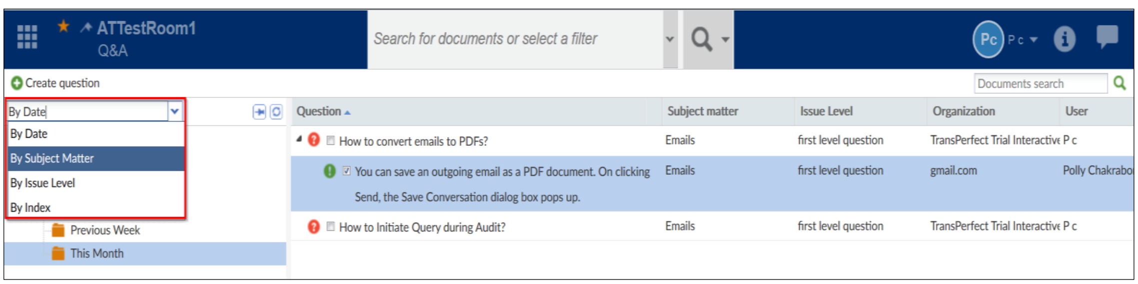
28. Q&A Module

The **Q&A** and **FAQ** functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created. Users with Reader level access are only able to view the questions that they themselves submitted to Room Administrators. Readers can view **Opened**, **Answered**, and **All** questions according to their:

- ***By Date***: The creation time of the question i.e. – Posted Today, This Week, Previous Week, This Month, and Older.
- ***By Subject Matter***: The subject matter of the questions.
- ***By Issue Level***: The issue levels could be first level, second level, and so on.
- ***By Index***: This will list out questions under categories Opened, Answered, and All

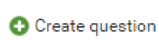
Click the **Q&A** icon in the **Navigation Grid** icon to see the list of questions asked by users in a room.

The image below displays the Opened questions that are submitted in this room by the reader.

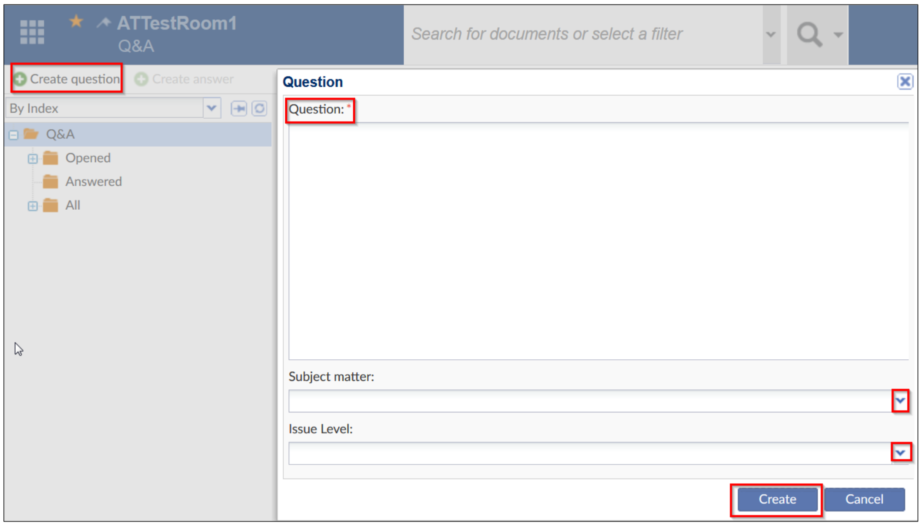


Through the top ribbon bar in the dashboard, you can create a question.

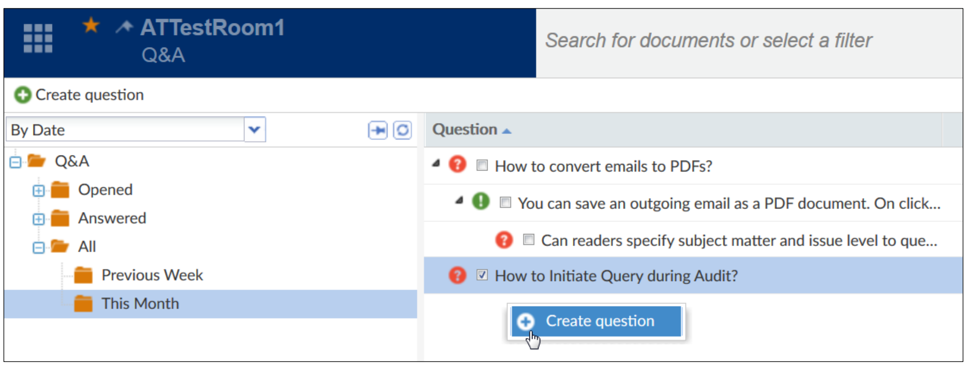
28.1. Create Questions

Click **Create question** 

in the top menu ribbon. A new window opens for you to type your question for submission. Enter the question, and select the subject matter and issue level from their dropdowns. Click **Create** to create your question.

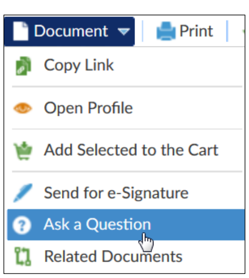


Readers can ask sub-questions by right clicking the original question in the grid, then clicking **Create Question**. Queries with sub-questions or answers are marked by an arrow symbol.



28.2. Questions about a Specific Document

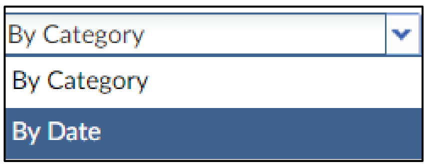
When you have selected a specific document in a data room, you can access the option to **Ask a Question** by clicking the Document dropdown in the upper left corner or by right-clicking the document icon. Select **Ask a Question** from the available menu, and a new window opens. This is discussed in the **Document Dropdown Section**.



29. FAQ Module

Reader level users are able to access **FAQ** by clicking the FAQ icon from the **Navigation Grid**. 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.

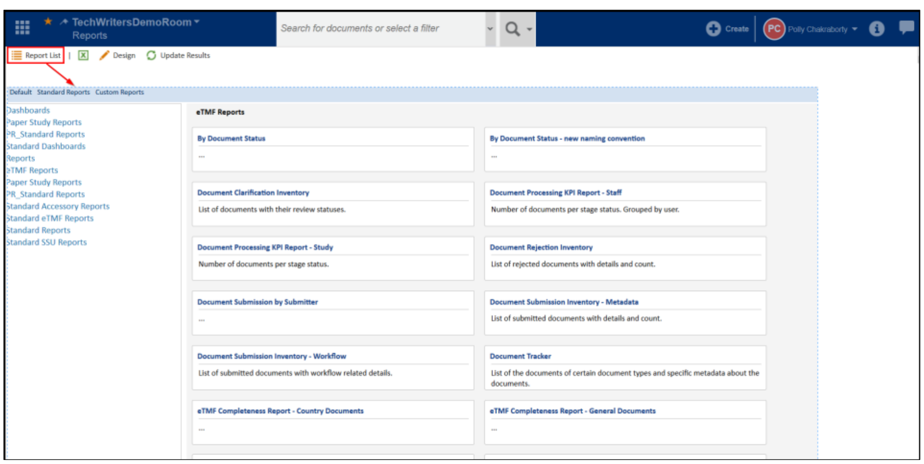


30. Reports Module

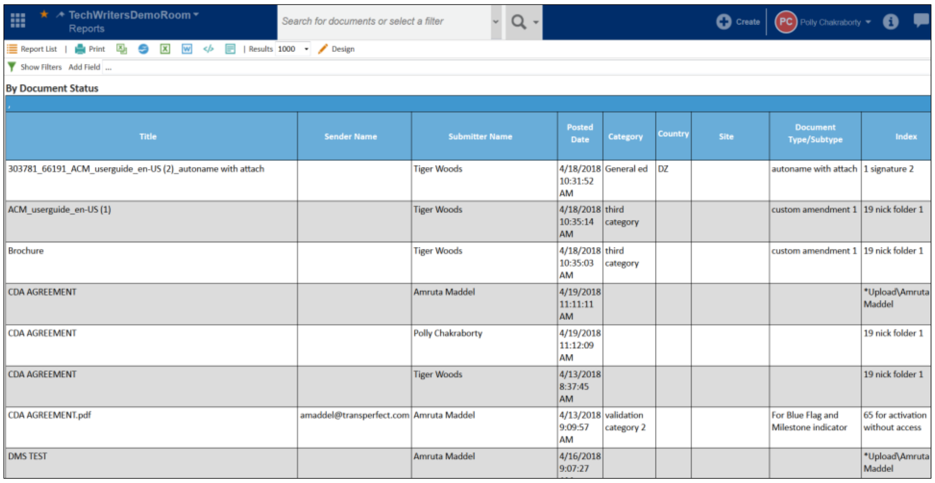
Room Administrators have the option to turn on **Reports** and make them available to other users. If Reports are activated, you can access it from the **Navigation Grid**.

30.1. Running and Viewing Reports

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



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



Title	Sender Name	Submitter Name	Posted Date	Category	Country	Site	Document Type/Subtype	Index
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
ACM_userguide_en-US (1)		Tiger Woods	4/18/2018 10:35:14 AM	third category			custom amendment 1	19 nick folder 1
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					*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					19 nick folder 1
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
DMS TEST		Amruta Maddel	4/16/2018 9:07:27					*Upload\Amruta Maddel

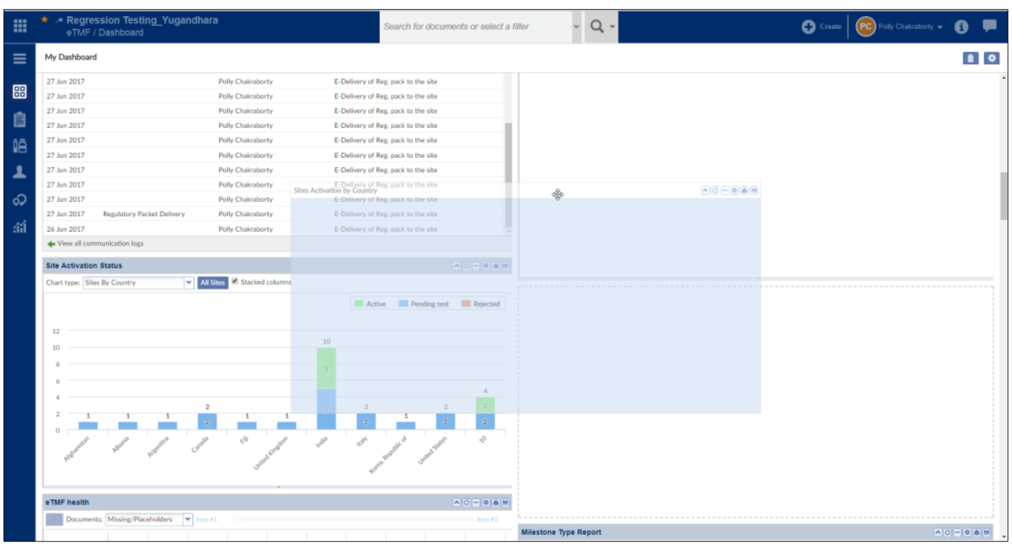
Typically, report builds are based on specific sponsor requests. For further assistance on other features of reports please get in touch with the Support team of Trial Interactive.

31. Dashboard Dashlet view

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

31.1. Laying dashlets in your dashboard

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



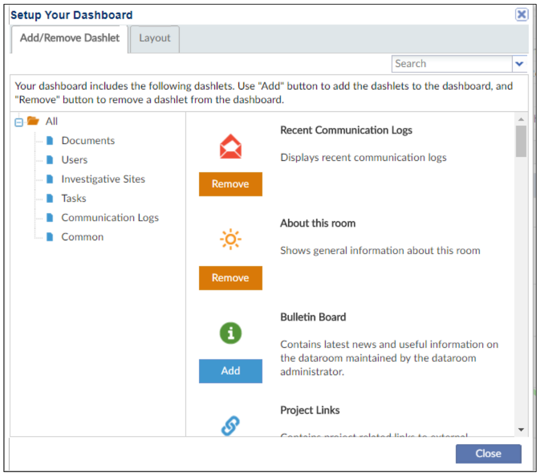
Besides moving your dashlets to make a suitable layout, you can also choose the distribution of dashlet panes on your screen, or addition/removal of dashlets through **Configure Dashboard** icon located on the top right corner of the dashboard.

31.2. Configure Dashboard

The *'Configure Dashboard'* opens the **Setup Your Dashboard** window which lists out the dashlets available for a particular dashboard and provides you with two options:

1. Add/Remove Dashlet
2. Layout

Refer to the screenshot below:

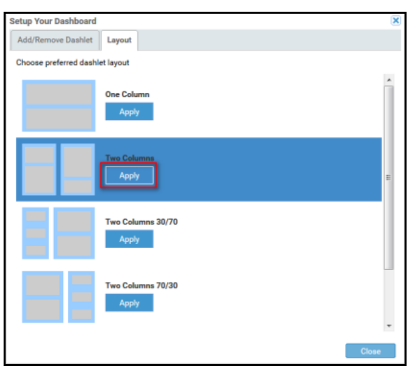


31.2.1. Add/Remove Dashlet

By clicking the **Remove** button for any particular dashlet, the user can eliminate that dashlet from the Default Dashboard view for himself or herself. These dashlets can easily be restored by clicking the **Add** icon that will replace the **Remove** icon.

31.2.2. Layout of Dashlets

By clicking the **Layout** tab at the top of the **Setup Your Dashboard** window, the user opens a new view that allows the user to choose his/her preferred dashlet layout on the viewing screen.



Simply click the **Apply** button next to the preferred arrangement and then click **Close** to enable the layout chosen by you.

31.3. Configuring each dashlet

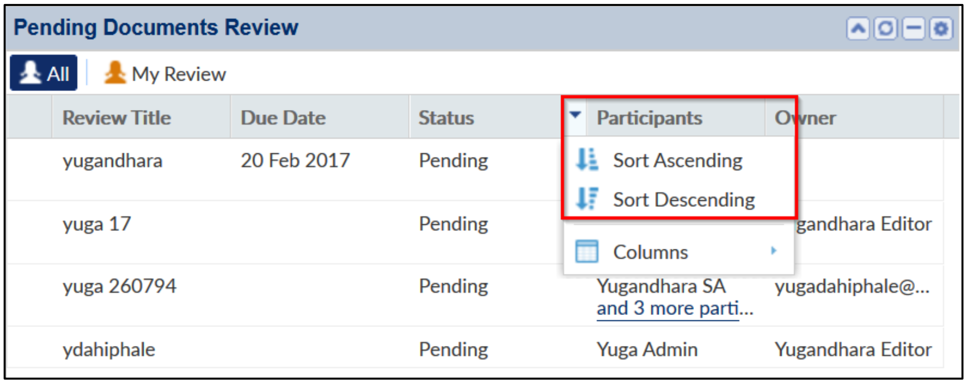
On the top right corner of each dashlet, the following features are available:

Available Icon	Purpose
	To hide the dashlet from the dashboard
	To refresh the dashlet
	To delete the dashlet from the dashboard
	To configure a dashlet column, and its height
	To print the current chart
	To save the current chart as PNG image file or to export a report or metadata fields

The Dashboard has numerous dashlets that provide users with a visual representation of categorized data in the study room.

31.4. Sorting columns in a dashlet

Some columns in a dashlet can be sorted in ascending or descending order by hovering the mouse over the column header to reveal the dropdown with sorting options. Refer to the screenshot below:



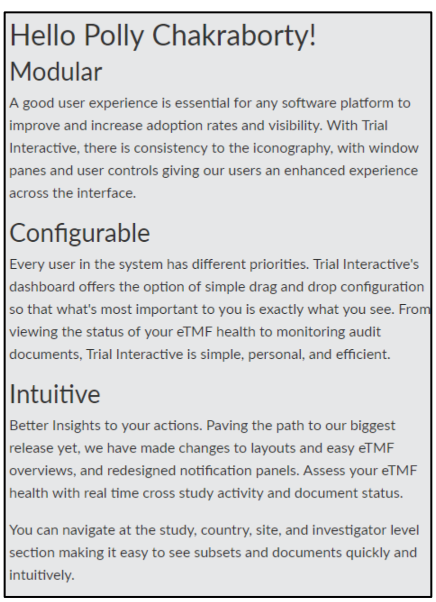
The sorting order set by one user does not affect the sorting order of the dashlet for other users.

31.5. Resizing pop-up windows or modal dialog boxes

To resize pop-up windows or modal dialog boxes:

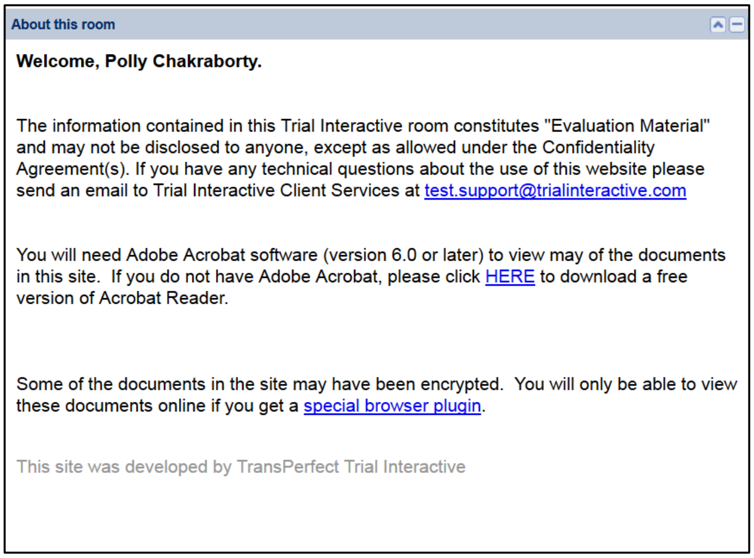
1. Place the mouse cursor at any of the edges or corner of the window/dialog box for a double arrowed control to appear.
2. Drag the side or the corner in or out to a size that fits your purpose.

31.6. Dashlet – About



The About Dashlet on the Trial Interactive Home Page provides introductory information about Trial Interactive to new users and provides the basic guidelines to get started.

31.7. Dashlet – About this room



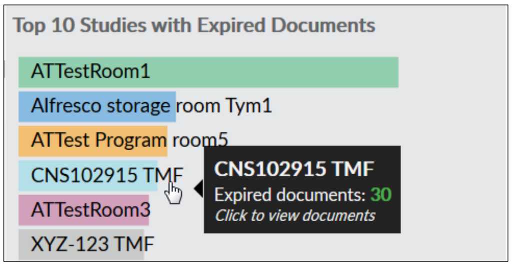
About this room is typically configured by Administrator level users to Welcome new users and provide them with information pertaining to the room. An administrator can also upload any information through the room's Settings that is pertinent to the study that they would like to share with users.

The standard Welcome message usually 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.

31.8. Dashlet – Top N Studies with Expired Documents

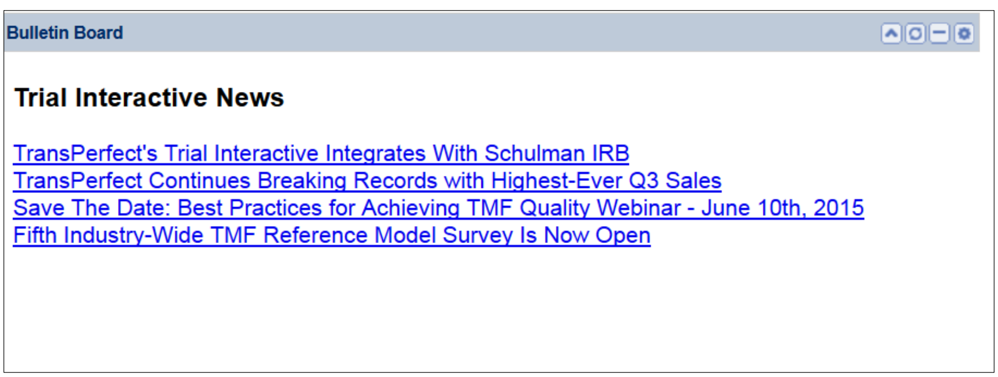
The **Studies with Expired Documents** dashlet lists the top 10 studies with expired documents and also provides a document count of expired documents on hovering the mouse pointer on each bar.



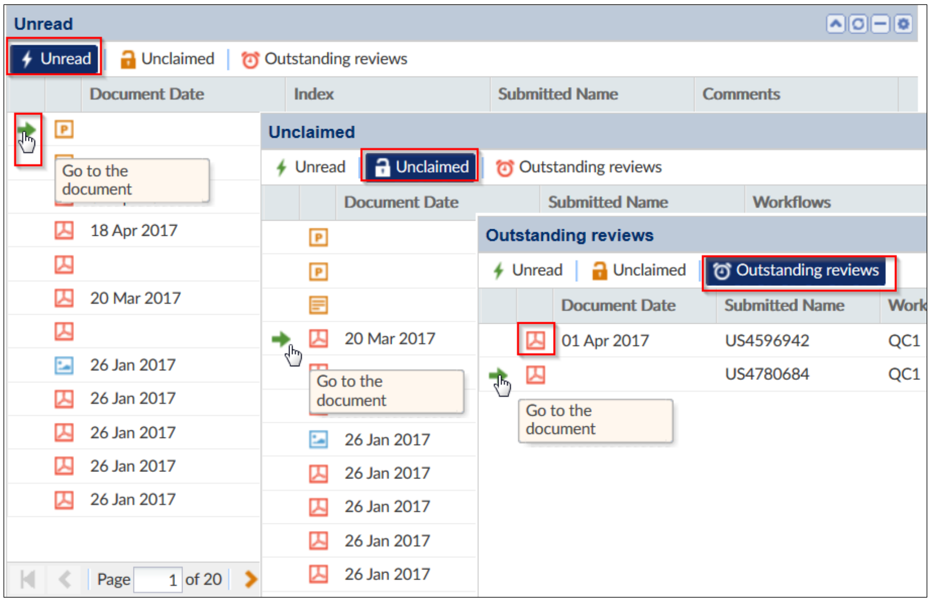
Here, you can click each bar, which represents a study, to display the list of expired documents in a popup window. Clicking a document name will take you to the room and open the document and its metadata for you to view. Click the **Expiration Date** Expiration Date button to sort the documents by expiration dates, and click the **Title** Title button to sort the documents by their titles.

31.9. Dashlet – Bulletin Board

The **Bulletin Board** dashlet contains the latest news and useful information on the data room for room participants.



31.10. Dashlet – Unread/Unclaimed/Outstanding reviews



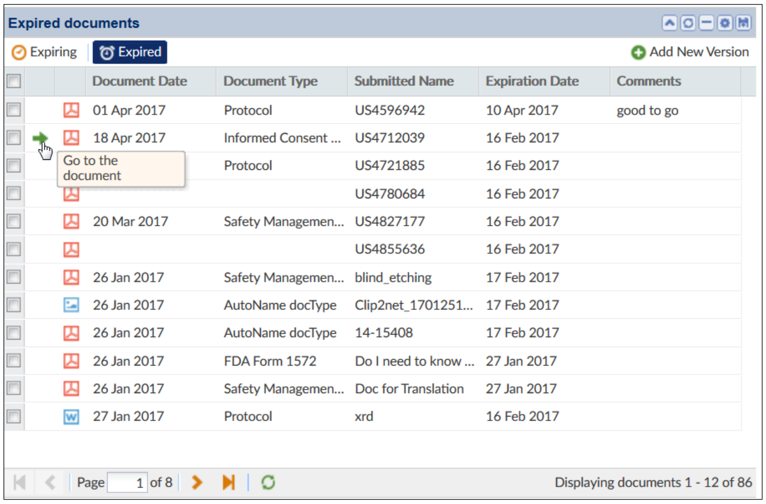
Named as **Documents View** dashlet (as seen from the Configure Dashboard/Configure Dashlet windows)**,** this dashlet provides three different views of documents in the eTMF module – **Unread**, **Unclaimed**, **Outstanding reviews**. The header of the dashlet changes as per the view selected.

Click the **Unread** tab to list any of the documents posted in the Trial Interactive site that have not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of. Click the green arrow to view the document along with its metadata, or click document icon to view the actual document. If the document is in a format other than PDF, the document downloads to your computer.

Click the **Unclaimed** Unclaimed button to get a list of documents that have not been claimed for review. Click the **Outstanding reviews** Outstanding reviews button to get a list of documents that are yet to be reviewed.

31.11. Dashlet – Documents expiring in N days/Expired Documents

The **Documents expiring in N days/expired documents** dashlet lists the expiring and expired documents as specified in the expiration period (N). To view **Expiring** or **Expired** documents, click the Expiring ` Expiring icon or Expired Expired icon on the dashlet. Refer to the screenshot below:


Expired documents

Expiring | Expired | Add New Version

	Document Date	Document Type	Submitted Name	Expiration Date	Comments
	01 Apr 2017	Protocol	US4596942	10 Apr 2017	good to go
	18 Apr 2017	Informed Consent ...	US4712039	16 Feb 2017	
Go to the document		Protocol	US4721885	16 Feb 2017	
			US4780684	16 Feb 2017	
	20 Mar 2017	Safety Managemen...	US4827177	16 Feb 2017	
			US4855636	16 Feb 2017	
	26 Jan 2017	Safety Managemen...	blind_etching	17 Feb 2017	
	26 Jan 2017	AutoName docType	Clip2net_1701251...	17 Feb 2017	
	26 Jan 2017	AutoName docType	14-15408	17 Feb 2017	
	26 Jan 2017	FDA Form 1572	Do I need to know ...	27 Jan 2017	
	26 Jan 2017	Safety Managemen...	Doc for Translation	27 Jan 2017	
	27 Jan 2017	Protocol	xrd	16 Feb 2017	

Page 1 of 8 | Displaying documents 1 - 12 of 86

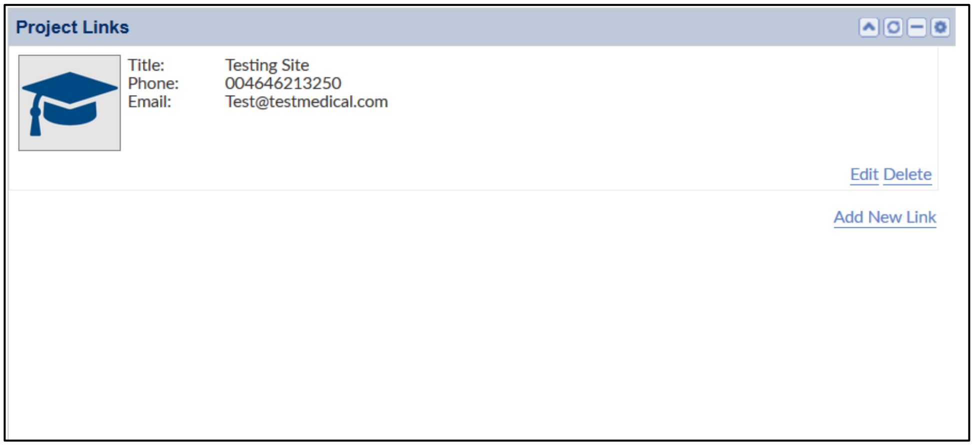
31.12. Dashlet – Study Monitoring Visits By Country and By Month

This dashlet **Study Monitoring Visits Dashlet** provides two different views study monitoring visits – **Monitoring Visits By Month,** and **Monitoring Visits By Country**, in the form of a bar graph. The following image contains the key features about the bar chart.

As you delve further, you will finally be able to view the documents for the particular country.

31.13. Dashlet – Project Links

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

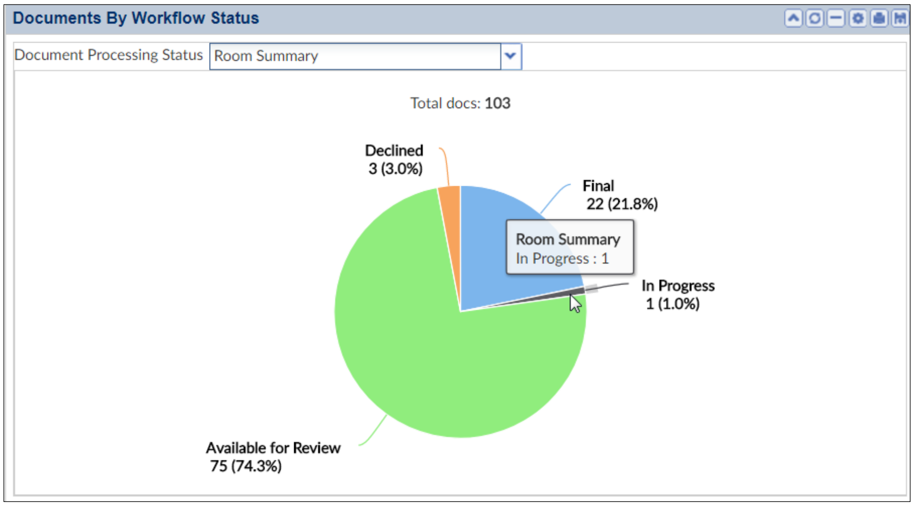


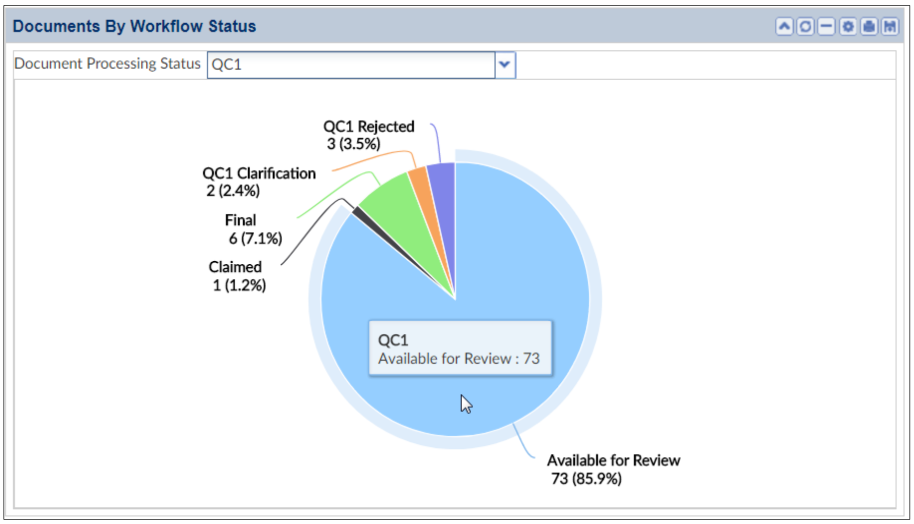
When you click an icon, a separate tab opens to display the linked page.

31.14. Dashlet – Documents by Workflow Status

The **Documents by Workflow Status** dashlet displays the document processing status in the document review workflow through pie charts. By drilling-down on the option, you can view the document processing status:

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

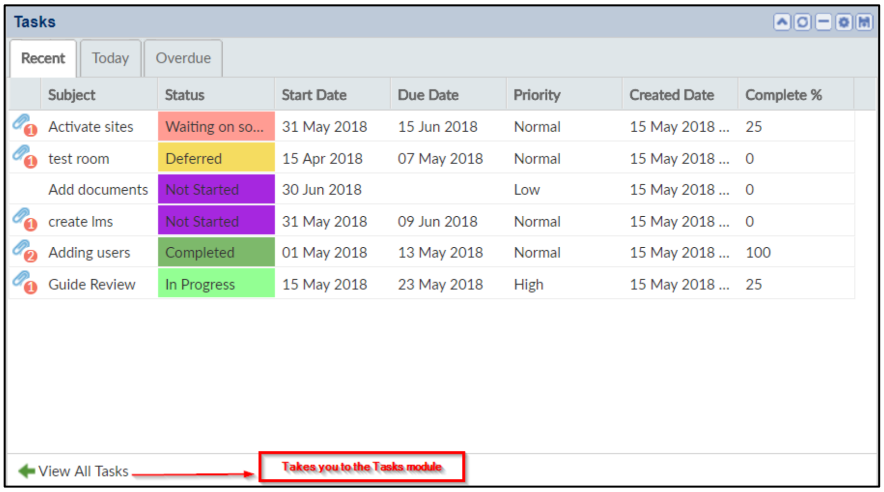




In the screenshots shown below, QC1 is the workflow is defined through Settings by the administrator.

31.15. Dashlet – Tasks

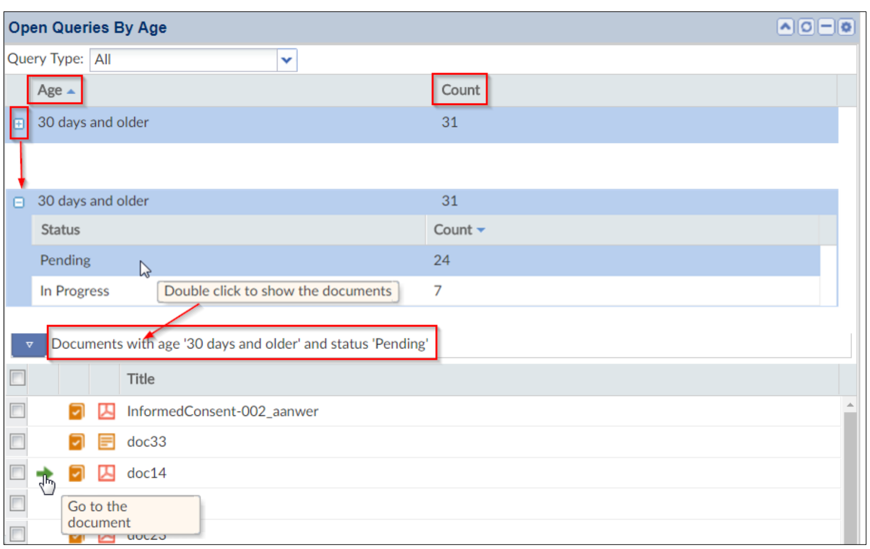
This dashlet displays tasks for the current user.



31.16. Dashlet – Open Queries By Age

The **Open Queries By Age** dashlet conveniently displays those documents that are 30 days and older in age and also provides a document count. Users can click the expand icon [+] placed on the left of the age column to view its document status along with the document count.

After the drill-down, you can double-click on count to view the corresponding documents.



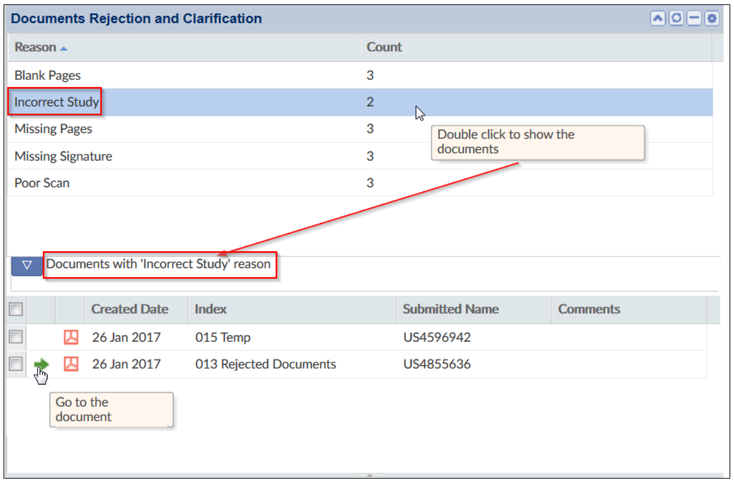
31.17. Dashlet – Documents Submission

The **Documents Submission** dashlet contains a bar graph that displays the following: monthly document submissions, published documents in workflow final status, and rejected documents. This dashlet is only available if the workflow is enabled in the data room and the reader is a member of the QC workflow group.

31.18. Dashlet – Documents Rejection and Clarification

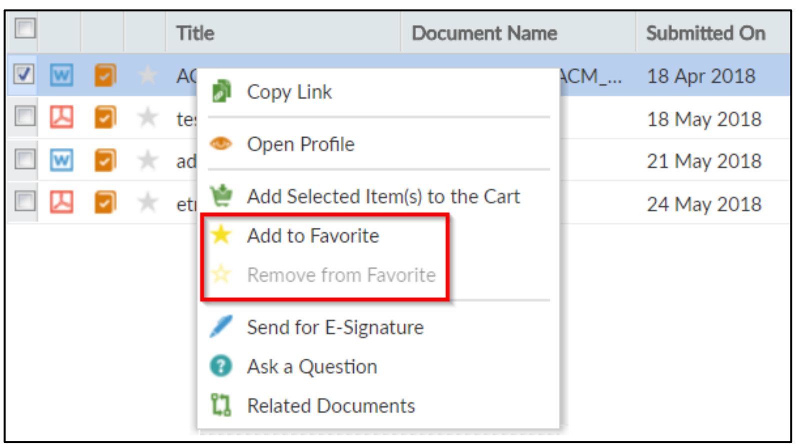
The **Documents Rejection and Clarification** dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.

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

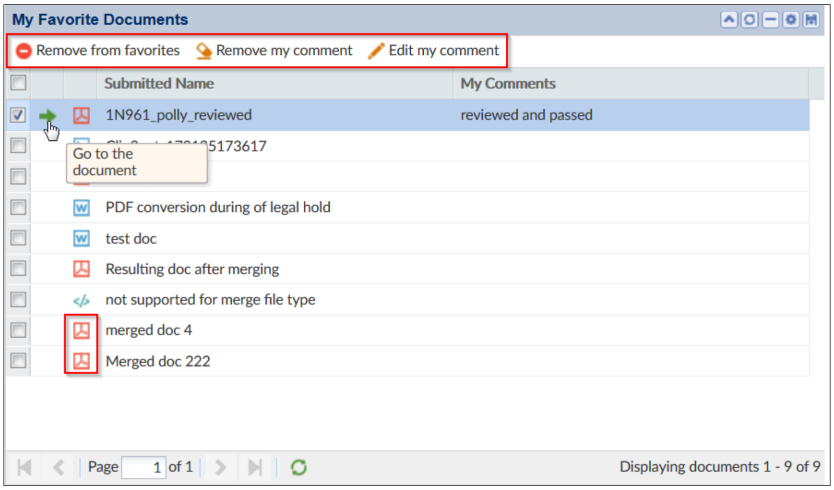


31.19. Dashlet – My Favorite Documents

Readers can add certain documents to his/her favorites, and these selected documents will appear in the dashlet, **My Favorite Documents**. To add a document to your favorites, simply right-click on the document and click **Add to Favorite**.

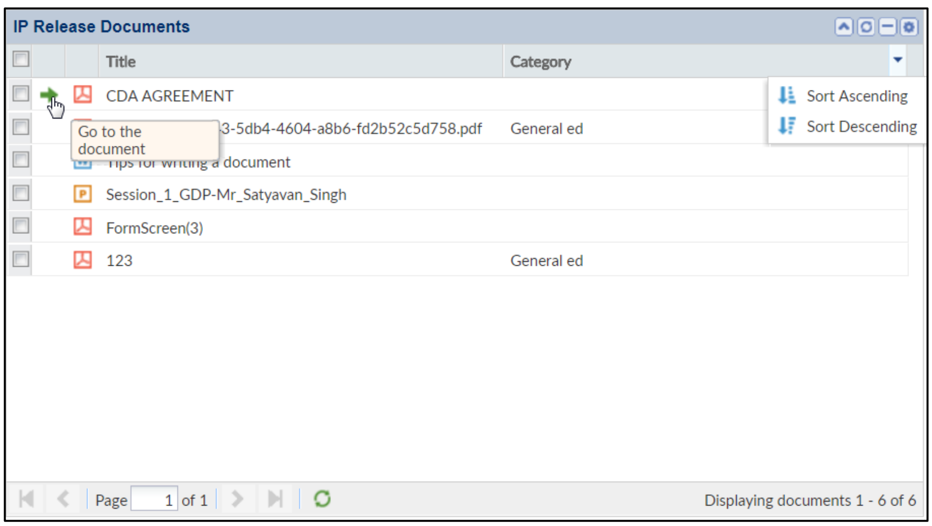


The **My Favorite Documents** dashlet displays those documents that a user has selected as his/her favorites. You can remove documents from the **Favorites** dashlet by ticking the checkmark next to the document name and selecting **Remove from Favorites**. You can also remove or edit your comments. Click on the icon to view the document right from the dashlet.



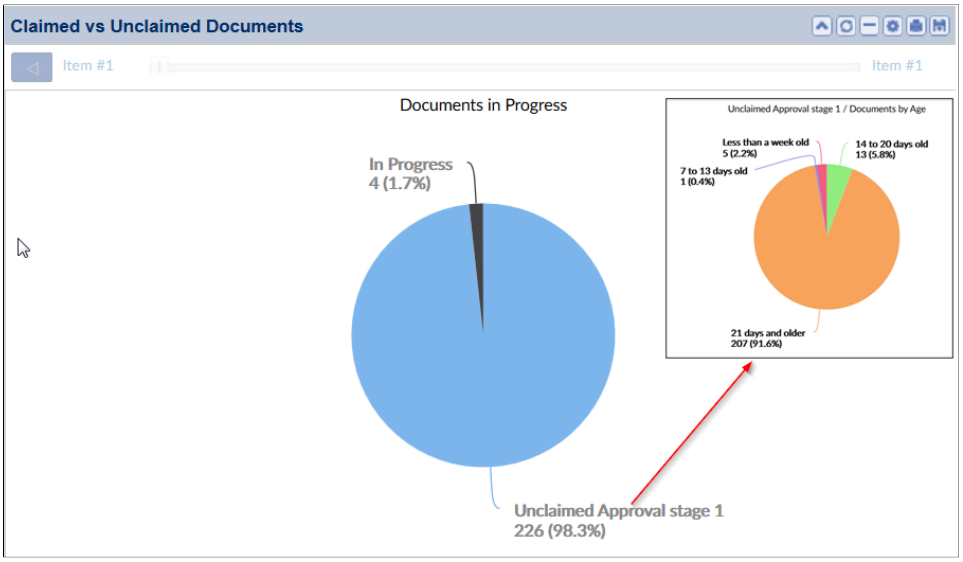
31.20. Dashlet –IP Release Documents

The **IP Release Documents** dashlet displays the list of documents that are marked as popular.



31.21. Dashlet – Claimed vs. Unclaimed Documents

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

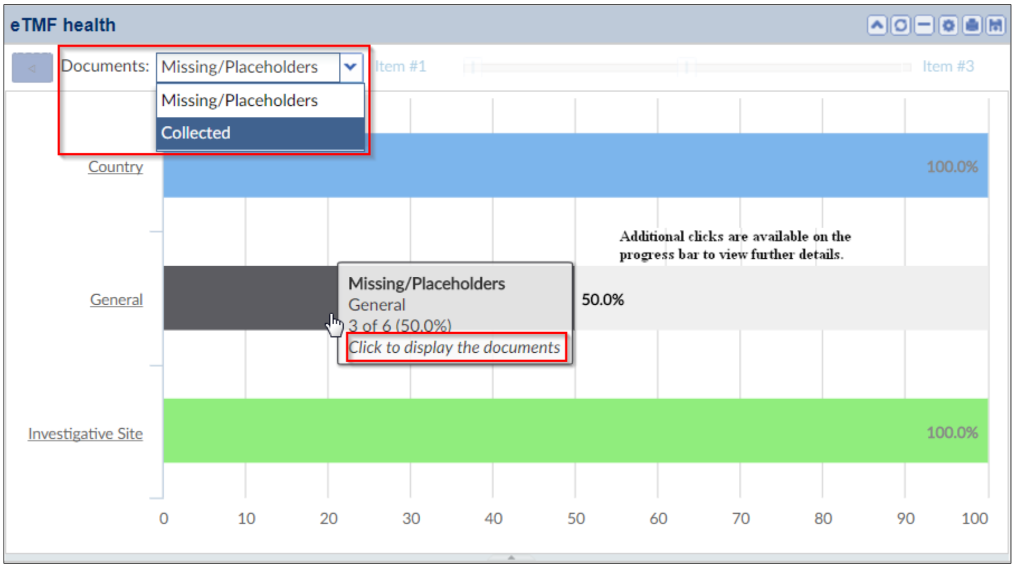


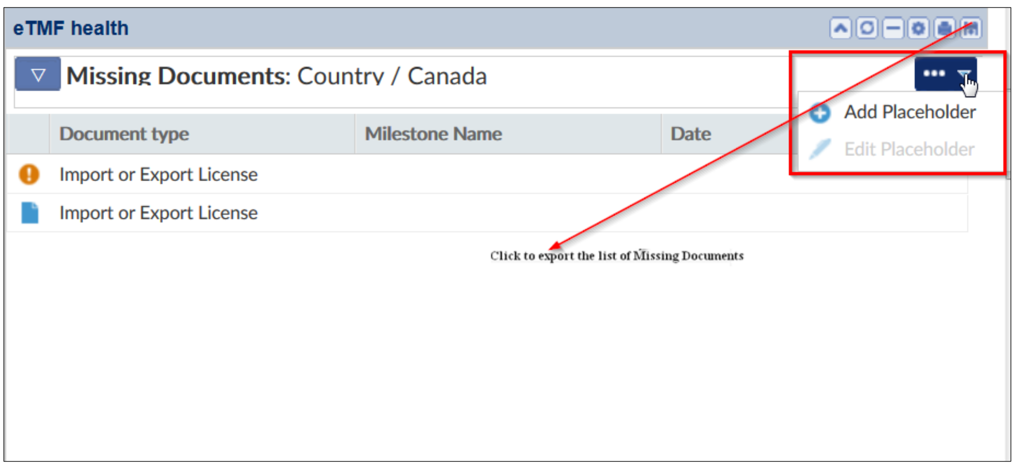
31.22. Dashlet – eTMF Health

The **eTMF Health** dashlet displays progress bar(s) that indicate what percentage of required eTMF documents are either collected or currently missing.

Hovering the mouse on each progress bar shows a popup with more detailed progress percentage for the category of the documents.

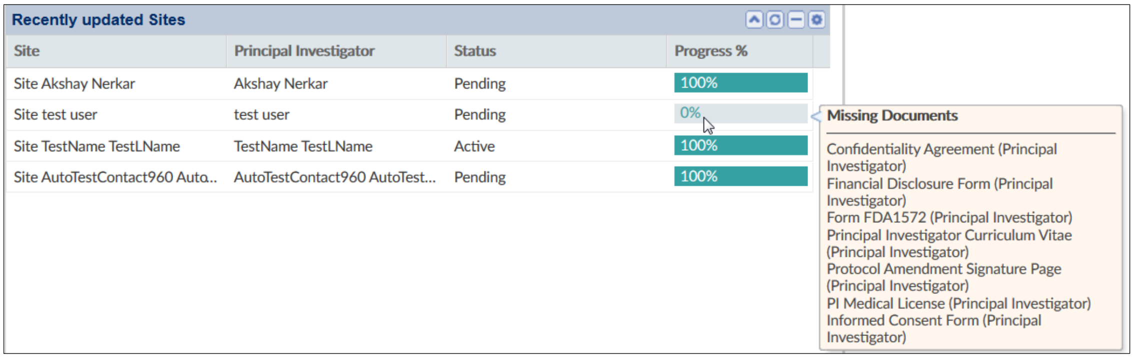
Click a bar to drill down to the lowest level to list the missing/placeholder documents. You can use the **Export current documents** button placed on the upper right corner to export the list of missing documents. Additionally, you can use the button to conveniently upload a placeholder, or to edit a placeholder right off the dashlet. To view any changes, refresh the chart to update the missing documents list.





31.23. Dashlet – Recently Updated Sites

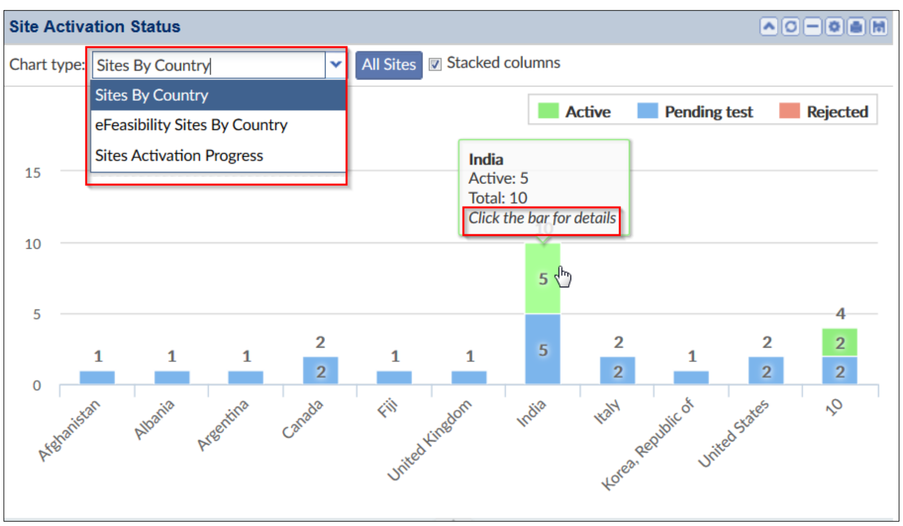
The **Recently Updated Sites** dashlet gives the activation progress report of all sites in a room. Hover the mouse over the **Progress%** column to view the list of documents that are missing to complete the site activation.



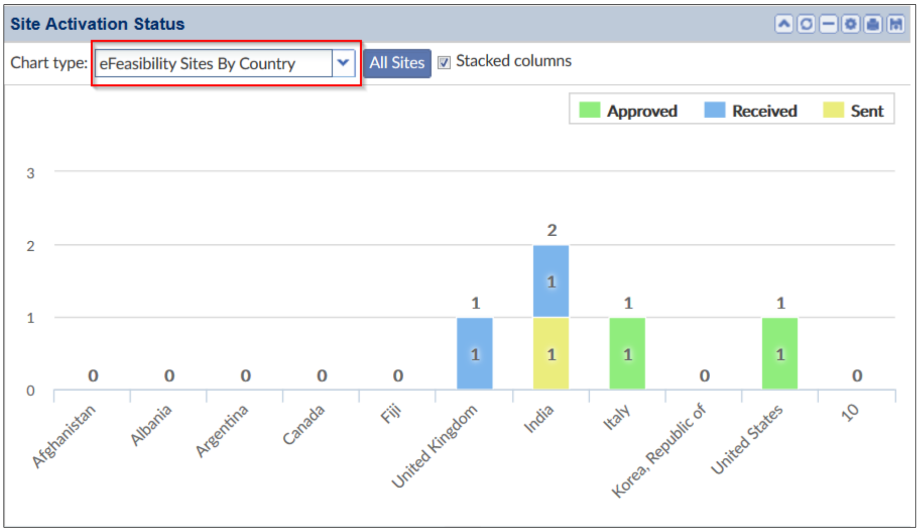
31.24. Dashlet – Site Activation Status

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

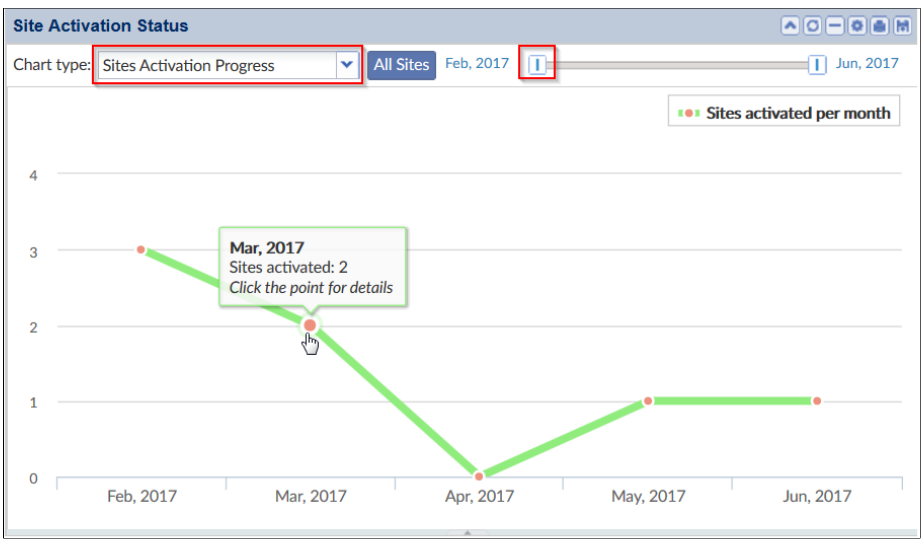
Select the **Site By Country** view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshot below.



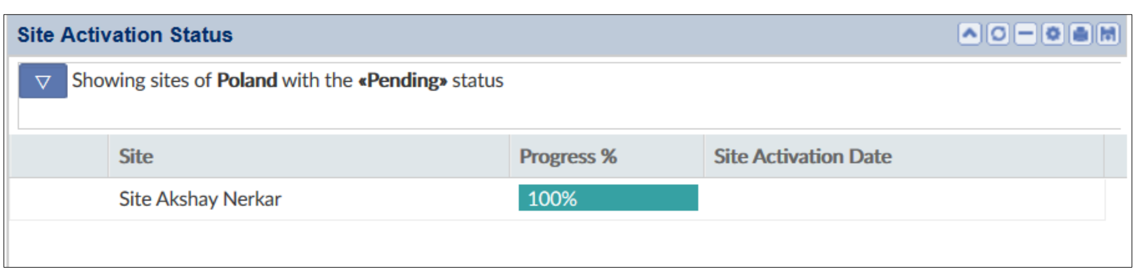
Select the **e-Feasibility By Country** view to reveal the number of documents that have been received, approved, and sent to complete the e-feasibility study for the sites.



Select the **Site Activation Status** view to reveal the number of sites activated per month. Drag the bar further to scroll down the chart.



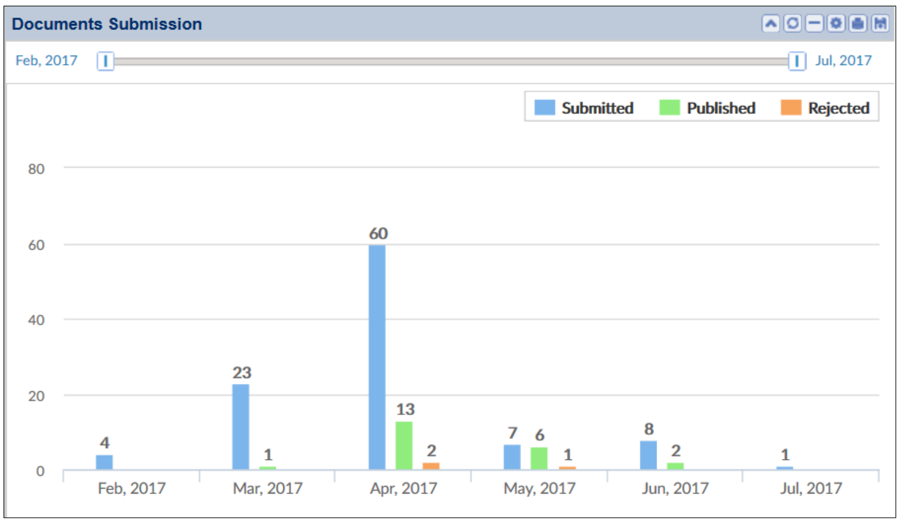
By default, the charts reflect results from all sites; however, if you wish to view only your own sites, click the **All Sites** All Sites button next to the chart type to change it to **My Sites** My Sites . Clicking a **high point** on the line graph or a **bar** in the bar graphs reveal the sites for the particular status.



Double-clicking a site name will open the **Edit investigative site** popup to allow you to edit the details of the site.

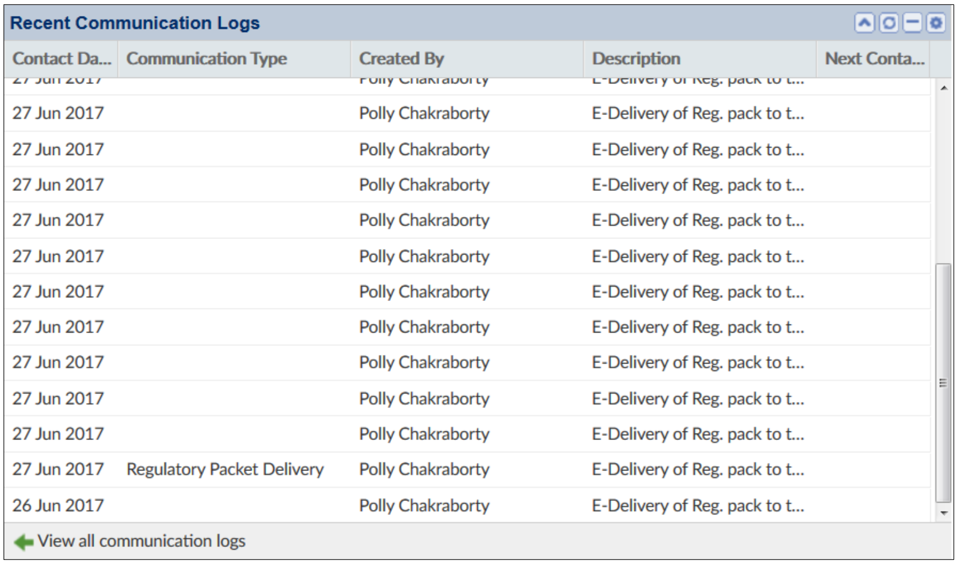
31.25. Dashlet – Documents Submission

The **Documents Submission** dashlet is visible in a room with shared workspace. It displays a bar graph showing the number of documents submitted, rejected, and published to eTMF in a particular month. Hover the mouse on a bar to view the total number of documents. Refer to the screenshot below:



31.26. Dashlet – Recent Communication Logs

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



Recent Communication Logs

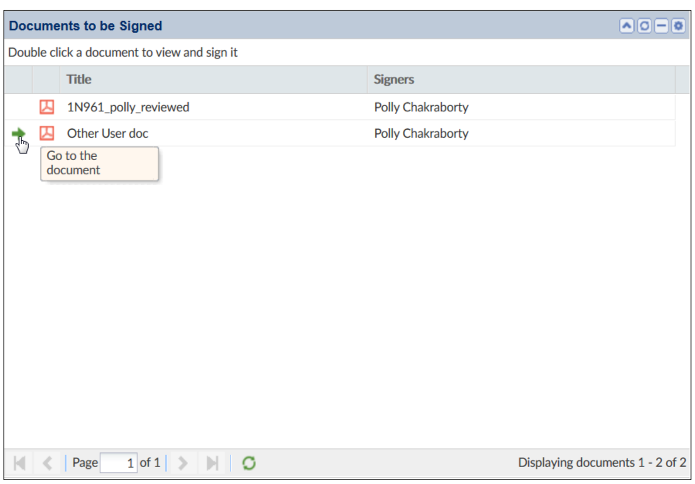
Contact Da...	Communication Type	Created By	Description	Next Conta...
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	
27 Jun 2017	Regulatory Packet Delivery	Polly Chakraborty	E-Delivery of Reg. pack to t...	
26 Jun 2017		Polly Chakraborty	E-Delivery of Reg. pack to t...	

View all communication logs

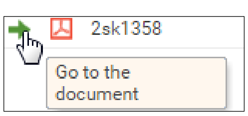
Clicking the green arrow will take you to the Start-Up/Communications module to view all the communication logs.

31.27. Dashlet – Documents to be Signed

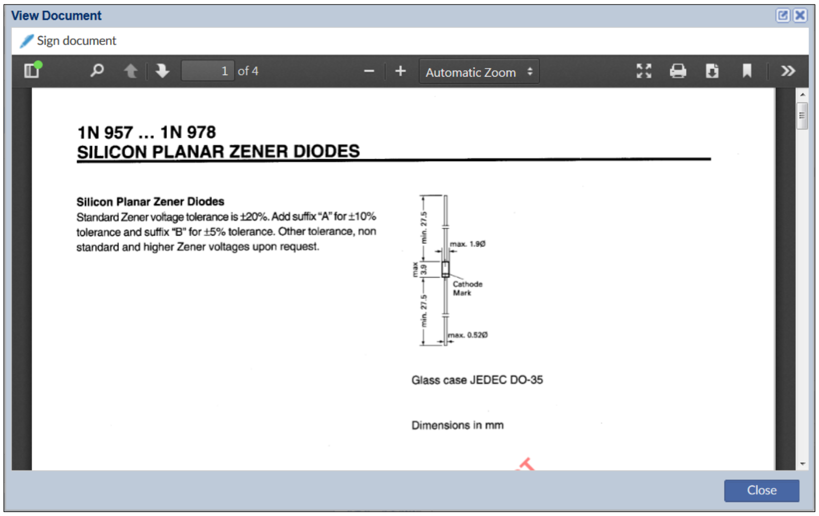
The **Documents to be Signed** dashlet gives a list of document pending for signature.



Hover the mouse over a document name for a green arrow to appear. Click the arrow to take you to the **Documents** dashboard where you can view and sign it.



You can also double click the document to view and sign it in the **View Document** popup. Refer to the screenshot below:



31.28. Dashlet – Cross Study Activity

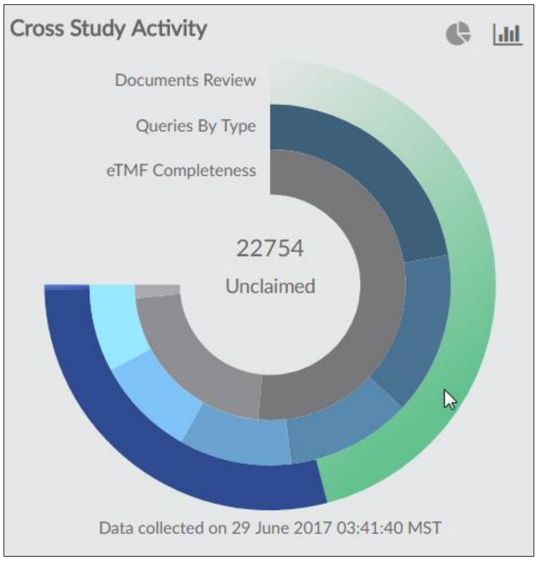
The **Cross Study Activity dashlet** gives a report in the form of a pie chart of the following activities of users across all the studies in the system:

1. Documents Review
2. Queries By Type
3. eTMF Completeness

Each activity is represented by a circle, the outermost circle representing Documents Review, the middle circle representing the Queries By Type, and the innermost circle representing eTMF Completeness. Each circle is further divided into partitions as follows:

1. The Documents Review is divided by Documents Status – Unclaimed, and Final.
2. The Queries By Type into its various types like missing pages and signature, blank pages, poor scan, incorrect study, and other types.
3. The eTMF Completeness report by Collected, Missing, and Final documents.

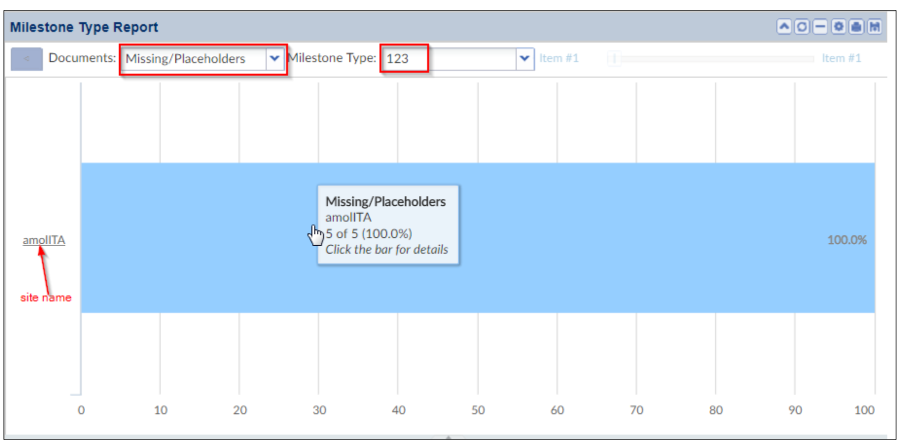
Hovering the mouse over each partition changes the color of the partition to light green and displays the number of documents in the white space in the center of the chart. Refer to the screenshot below:



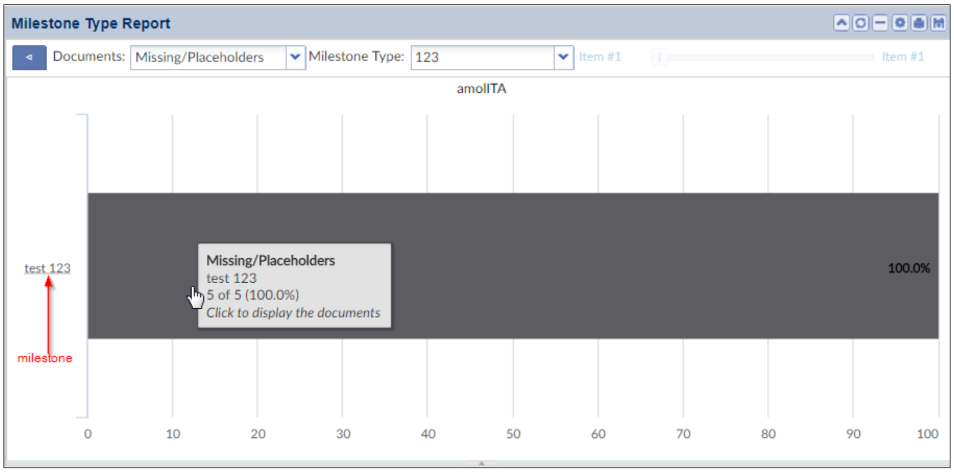
This dashlet gives a report of 22,754 documents unclaimed for review.

31.29. Dashlet – Milestone Type Report

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



Click the site name or the bar to reveal the percentage of missing/placeholder, or collected document types under each milestone for the selected milestone type.



Click the milestone bar to reveal the list of missing/placeholder required document types for the site under a particular milestone. Click the inverted arrow with dots to add/edit a placeholder directly from the dashlet for the particular selected site. Click the blue inverted arrow to return back to the original dashlet screen.