TRIAL INTERACTIVE

TRIAL INTERACTIVE 10.0 – ADMIN GUIDE

Version 1

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Yogesh Inamdar	1.0	07-Jan-2020	Initial Creation

Contents

Page Mapping with Topics

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

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

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

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

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

Getting Started

Read this Online Help Roadmap before use.

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

About this Online Help

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

On the Help Home Page

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

OR

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

Inside the Chapter

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

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

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

Job Aids and Video Tutorials

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

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

Job Aids

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

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

- How to Run TMF Reconciliation Report
- Topics Mapping to Pages in Help

Video Tutorials

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

Click anyone of the links below to play the Videos:

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

Signing into Trial Interactive

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

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

System Requirements

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

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

To access Trial Interactive you need to have the following:

Get access to Trial Inteactive on:	
General	Make sure you have: • Broadband Internet Access • A browser that supports encryption • Cookies enabled

Standard Supporting Browsers	Trial Interactive works on the following browsers: • Internet Explorer 10 and higher • Edge: Version 20 or later(officially supported by Microsoft only) • Chrome for Windows users • Firefox and ESR Releases for Windows users • OS X Safari for Mac Users
Required Operating Systems	**Windows® operating system:** • Windows 7 and higher **Macintosh® operating system** • Mac OSX releases
Client Software	Client Softwares required for Trial Interactive are: • For **Edit Online**: Microsoft Office 2010 SP1 or higher • Optional: Adobe Acrobat, Adobe Standard, or Professional Version 8 or higher along with the PDF Viewer • For SAS Datasets: SAS Viewer or compatible. The free version is available on: https://support.sas.com/downloads/browse.htm?fil=&cat=74
Optional Add-Ons (Separate License)	Besides the above softwares, make sure you also have: • DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Version) • Adobe Sign (Latest Document Cloud Version)

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

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

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

Receiving and Responding to Room Invitation

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

Figure 1: Room Invitation Email

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

User Registration

Important:

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

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

Step 1: Registration - Required Information

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

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

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

Step 2: Registration - Optional Information

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

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

Step 3: Registration - Custom Information

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

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

Requesting a Password Reset

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

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

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

Signing in without access to rooms

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

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

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

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

The Trial Interactive Home Page

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

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

Click the required Room Name to enter a room.

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

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

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

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

Room View

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

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

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

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

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

Viewing Room Details

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

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

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

Room Search and Accessing a Trial Interactive Room

Room Search

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

To perform a room search:

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

Accessing a Trial Interactive Room

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

Cross Study Document Search

Documents Search

We can perform two types of searches on documents:

1. **Cross Study Search:** When you search for documents across all studies that you have access to, you are performing a cross study search. You can execute this search from the **Home Page Search** functionality. Refer to the screenshot below:

2. **Documents Search:** When you search for documents from within a room or study, you are performing a Document Search. Refer to the screenshot below:

The process to execute both the types of searches is the same except for the location of executing the search:

1. Navigate to the Home Page or a Trial Interactive room as required.
2. Click the Search icon from the blue bar located on the top of the dashboard.
3. The Search popup appears.
4. From the Documents dropdown, click **Documents**. Refer to the screenshot below:

5. Enter the search criteria in the **Search box** next to the Documents dropdown.
6. Click **Go** or press **Enter** to search for the document. Refer to the screenshot below:

7. Documents matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:

8. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
9. Hover the mouse over **Document icon** to get a preview of the documents.
10. Click the document icon. The document **Metadata** panel opens to the extreme right of the **Document Grid**.

11. The top ribbon bar provides you the functionalities like **Reset password**, **Unlock and Deactivate** the user. Each of these links are discussed in the respective topics.
12. Click the checkbox next to the **User** icon. The following are displayed to the extreme right of the grid:
    a. User Details
    b. The Rooms to which the user has access to.

TI Home Page Filters

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

The filters consists of the following main filters:

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

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

Summarized (Overview) View of Rooms

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

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

Refer to the screenshot below:

Countries

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

Active Sites

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

Study Start-Up Sites

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

Total Documents

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

Detailed View of Rooms

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

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

Refer to the screenshot below:

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

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

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

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

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

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

Add Users to a Room

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

1. Click 

dropdown at the extreme right of the **Room Name** on the home page.
2. Click the **Add Users** option from the dropdown list that appears. The **Add Existing Users** window opens. Refer to the screenshot below:

3. You can choose to select multiple rooms to add users to by clicking **Add** button next to the Room textbox.
4. Enter the **Email Address** of the user, assign **Role** to the user, select **Actions** to assign to users.
5. Select the **Groups** to add users to the group. You can select multiple groups.
6. Click **Create**. The users get added to the room.

Upload Documents to a Room

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

1. Click 

dropdown at the extreme right of the Room Name on the home page to revel the options.
2. Click the **Add Document** option from the dropdown list that appear.
3. Fill in the required details.

Marking Favorite Rooms

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

1. From the home page by clicking the star which changes its colour to golden on selection to the left of the room name. Refer to the screen shot below:

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

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

a. Navigate to **My Profile Settings** from the User menu.
b. Select **Notifications** from the menu on the left.
c. Click the golden star to the right of the room names to mark the selected rooms as **Favorites**.

Adding Tasks to a Room

To add documents to a room:

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

2. The **Create Task** window opens.
3. Fill in the details as instructed on the screen.
4. Click **Save** when all the information is filled.

Main Navigation and Inter-Room Navigation

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

From here find more details on the following:

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

Main Navigation from Home Page

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

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

Main Navigation from within a Room

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

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

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

1. Home
2. Tasks
3. Trial Interactive eTMF and the Documents Module on page 163
4. Quality Control
5. Start-Up
6. Audit/Quality Review
7. Communication
8. Q&A

9. FAQ
10. Reports
11. Collaborative Workspace

Navigating between Rooms

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

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

User Menu

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

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

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

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

About This Room

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

The standard Welcome message offers the following links.

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

You can click the **Edit** icon at the top right corner of the dashlet to type in new information or edit existing information on the dashlet. After editing the dashlet contents, click **Save** to save the contents and exit, or **Cancel** to exit from the Edit screen.

User Menu - Help

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

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

My Profile Settings

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

To access **My Profile Settings**:

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

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

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

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

My Profile Main Section

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

From here you can access the following:

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

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

General Information - Time Zone

To set the time zone applicable to you:

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

General Information - Language

To set your preferred language:

1. Click the **Language dropdown.**
2. Scroll down to locate your preferred language.

3. Click the language to select it.
4. The selected language displays in the box.
5. A popup confirming the same appears. Click '**x**' on the popup to dismiss it.
6. Click **Save**.

General Information - Enable Custom Date Input

With the Trial Interactive 10.0 release, while coding a document, in addition to selecting the date from the **Calendar Date Picker**, you can **directly type in dates** in the format preferred by you. The system interprets the date entered by you manually and saves it based on your geo location that it is capable of detecting.

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

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

Change Password

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

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

To set the password:

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

Password Recovery - Secret Questions

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

To set the secret questions and their answers:

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

User Avatar

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

Sites Filtering Options

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

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

Change Email Address

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

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

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

Default Context Configuration

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

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

My Profile Notifications Section

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

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

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

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

Once you make your Notifications selections, click **Save** in the lower right corner.

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

Important:

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

Language Settings

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

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

Notifications

Through **Notifications** panel, located below the **About This Room** dashlet, you can view messages and results of various jobs that you perform in Trial Interactive. This will be discussed through various sections as the need arises.

The right panel of this section displays the following tabs:

- **Tasks:** Click this tab to get a list of all the tasks that are ongoing, pending, or are overdue. This is a shortcut that provides you an overview of all the tasks in your current room. You no longer need to visit the Tasks module for the details and can access them directly here.
- **Queries:** Click this tab to get a list of all the queries pending for action. You can click any individual query link to lead you to the Queries sub-module for you to initiate your actions on it.
- **Background Jobs:** Through this tab you are notified about a background job that is executing or are completed.
- **Actions:** Click this tab to view messages and results of various jobs that you perform in your Trial Interactive room. Some messages like downloading/mass coding documents provide the **Get Job Result** button that you click to get further details on the action like a message or a downloadable zip.

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

Guide

You can access the online help of the version of the Trail Interactive from here. Clicking **Guide** opens the help in the browser.

Signout

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

My Profile Settings

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

To access **My Profile Settings**:

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

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

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

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

My Profile Main Section

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

From here you can access the following:

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

Sub-sections with the My Profile Main Section	Purpose
Default Context Configuration	From this section, you can set the default landing page when you enter a room.

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

General Information - Time Zone

To set the time zone applicable to you:

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

General Information - Language

To set your preferred language:

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

General Information - Enable Custom Date Input

With the Trial Interactive 10.0 release, while coding a document, in addition to selecting the date from the **Calendar Date Picker**, you can **directly type in dates** in the format preferred by you. The system interprets the date entered by you manually and saves it based on your geo location that it is capable of detecting.

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

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

Change Password

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

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

To set the password:

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

Password Recovery - Secret Questions

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

To set the secret questions and their answers:

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

User Avatar

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

Sites Filtering Options

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

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

Change Email Address

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

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

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

Default Context Configuration

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

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

My Profile Notifications Section

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

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

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

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

Once you make your Notifications selections, click **Save** in the lower right corner.

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

Important:

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

User Management

Administrators can manage Groups and Users and Contacts through User Management

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

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

You can reach this page from the following locations:

a. **Main Navigation** by clicking the **Users Management** application. Refer to the screenshot below:

b. **Room Settings → Security**

From the User Management page:

1. Click  for the **Users** page to create/edit/delete groups in a room. This is also the default page that you land in when you open the *User Management* application.
2. Click  for the **Groups** page to add/edit/delete users in a room
3. Click  for the **Contacts** page to add/edit/delete contacts in a site

User Management - Users

From this page you can do the following:

1. Invite users through Regular Invite or Quick Invite.

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

Viewing Users

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

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

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

   shows the users by Admin role.

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

User Views	Description
By Organization	By Organization view lists the organizations for which there are users in the room. The organization to which the user belongs are specified during user creation.
By Role	By Role view lists the users belonging to the categories of Admins, Editors and Readers.
By Status	By Status view lists the users under categories as **Pending** for invitation, **Invited** to the room, **Registered** to the room, users who **Visited** the room, and users with **No Access** to the room.
By Group	By Group views lists the groups to which the users belong to in the room. The groups are specified during user creation.

Regular Invite

Note: *Users can also be invited from the **Room Settings → Security → Users.***

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

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

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

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

Edit User

1. Complete the User Profile as required.
2. The fields of importance are discussed below:
   a. **User Email**: This is used by the user as an unique identity to login to Trial Interactive. This can be typed in or searched by clicking the magnifying lens icon at the end of the field. If you type in an email address that does not adhere to an email id format, you will receive a validation error message asking you to enter the correct one.
   b. **Role**: Choose the role from the dropdown to be assigned to the user. The roles can be either of an **Admin**, **Editor** or **Reader** in a particular room.
   c. **Actions** : These are tasks that the user would be allowed to perform under the specific role can be assigned by selecting the Action name from the Actions dropdown.
   d. **Expiration Date** : Enter this date if you want the user access to be revoked after the lapse of a particular period.
   e. **Organization**: Choose from the dropdown the organization to which the user belongs to. The Administrator can also create an organization, if not available from the list, by clicking the '+' sign at the end of the textbox.
   f. **Allow Multiple Sessions**: Click the toggle bar to **Yes** if you want to allow the user to login through different browsers at the same time.
   g. **Invite Later**: Click the toggle bar to **Yes** if you want to prepare a user for the room but not want to send the real invitation. So users will be prepared for invitation sending and when time comes, they can be invited later. For example, a user is in training and would be allowed access to the room later.
   h. **Silent Invite**: Click this toggle bar to **Yes** if you want to invite the user without sending the invitation email. In such case, you will need to provide a temporary password in the **Password** field that appears on activating this option.

   Remember: *You can select either Invite Later or Silent Invite only at a particular point of time.*
3. Click **Next** to proceed to the **Groups memberships** page to add the user to the required group. Refer to the screenshot below:

Groups Memberships

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

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

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

Quick Invite

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

Follow the steps as below to quick invite users:

1. From the **Users Management → Users**, click the **Invite** dropdown from the top menu bar and then select **Quick** from the list of options that appear.
2. The **Quick Invite** page opens.
3. Enter the email addresses of all the users you want to send invitation to.
4. Complete the required fields, adding email addresses and selecting the role the invitees will be assigned to. ***You can Invite single or multiple Readers or Editors or Administrators at one time.***
5. Select **Invite Later**, **Silent Invite** and **Invite Later** toggle buttons when appropriate.
6. Click the **Groups** textbox to assign the user to the appropriate group(s).
7. Click **Add**. Refer to the screenshot below:

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

Editing and Deleting Users

Editing Users

Follow the steps as below to edit a user access:

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

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

   Refer to the screenshot below:

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

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

Deleting Users

Follow the steps below to delete users from a room:

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

Changing User Access

Follow the steps as below to edit a user access:

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

icon.
5. The **Change Access** popup opens.
6. Complete the details as required.
7. Click **Apply**.Refer to the screenshot below:

The fields of importance are discussed below:

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

Resending Invitation

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

To re-invite users:

1. From the left pane, select the preferred category to view the users .
2. From the list of users displayed in the right pane under the selected category, tick the checkbox for users to whom you want to resend the invitations.
3. From the top ribobn bar, click the **Resend Invitation** 

icon. A popup appears asking you to confirm.Refer to the screenshot below:
4. Click **Yes**.
5. Invitations are resent to the selected users and a confirmation notification appears for the same.

Exporting Users

You can either export all the users available in the room, or export only selected users as required.

Each of processes are discussed in separate sections below:

Exporting Selected Users

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

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

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

Exporting All Users

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

User Management - Contacts

From this page you can do the following:

1. View contacts by Investigative Sites
2. View contacts by Investigative Site Main Contacts

Viewing Contacts

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

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

1. From the **User Management**, click **Contacts** from the left menu.
2. Click the **three dots** next to the **View by** on the Index Pane at the left of the dashboard.
3. This opens the **View Users By** popup window with the list of categories for user viewing.
4. Select the category under which you want to view the users.
5. Click **Select** located at the bottom of the popup window.
6. The category and the list of users grouped under the categories are displayed in the Index Pane. The screenshot below

   shows the users added to the **investigative sites** ‘Annabot IND’.

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

User Views	Description
By Investigative Site	By Investigative Site view lists all the Study Start-Up Sites and their contacts who are also users in the room.
By Investigative Site Main Contcts Only	By Investigative Site Main Contacts only lists all the Study Start-Up Sites and their main contacts in the room.

User Management - Groups

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

Administrators can manage groups in the following manner:

1. The names of groups

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

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

You can perform the following activities from Groups:

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

Each of these are discussed in the seperate topics. Navigate to the topics from the left menu to access them.

Adding New Group

New Groups can be defined and added by clicking **Add Group** 

button from the left of the **Groups**panel.

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

3. Enter the new group's name.
4. Add the description of the new group. 5

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

5. Assign **Actions** or tasks that the group of users can perform under the specific role by ticking the checkbox next to the Action name in the dropdown.
6. The Administrator can also view the actions available in a room along with their purpose from the **Main Navigation -> Settings -> General -> Actions**. This is discussed in Section **Actions**.
7. Click **Create**. The new security group appears in the Groups list with no users assigned to it.

Adding Child Group

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

Follow the steps as below to create child groups:

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

3. Click **Add Child Group** from the top menu.
4. The **Select Groups** popup opens.
5. Select the required group from the list to for which you want to create child group.
6. Click **Select**. Refer to the screenshot below:

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

Editing a Group

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

Follow the steps as below to edit a new group:

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

Deleting a Group

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

Follow the steps below to delete a group:

1. Select the required group from the left pane you wish to delete.
2. Click Delete from the top menu.
3. A confirmation window opens.

4. Click **Yes**.

Adding Users to a Group

Follow the steps below to add users to group:

1. Navigate to **Main Navigation → Users Management → Groups**.
2. Select the required group from the Index pane. The list of users appear in the right pane.
3. Click **Add User to Group** Add Users to Group from the top menu in the right pane to add the user to the group.
4. The **Select Users** window opens up.
5. Select the users you wish to add to a group and click **Select**. The users get added to the group. Refer to the screenshot below:

Editing and Deleting Users from a group

Editing User in a Group

User in a group can be edited by selecting the user from a group and clicking **Edit** from the top menu. Follow the on-screen instructions to edit the user details. Refer to the screeshot below:

Deleting User from a group

Select the user from the required group and click **Delete** ✖ Delete from the top menu to delete it from the group. Click **Yes** on the confirmation window that opens if you wish to delete the user.

Room Settings

Access the **Room Settings** from the **Main Navigation** by clicking the **Settings** application.

Refer to the screenshot below:

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

Refer to the screenshot below:

General Settings

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

About

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

About This Room

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

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

Instructions

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

Dashboard Setup

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

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

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

   The field becomes active with a dropdown arrow at the right end of the field.
3. Click the dropdown arrow. A set of selections becomes available to the Administrator.

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

From the Dashboard Settings, the following activities are available:

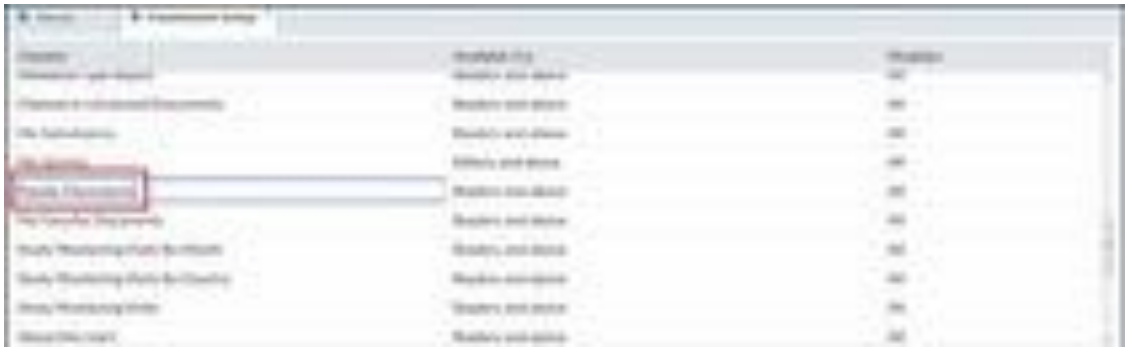
1. Renaming a dashlet
2. Default Dashboard Setup

Above activities are discussed in details in the sections below.

Renaming a dashlet

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

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



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

Default Dashboard Setup

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

Milestones Settings

Follow the steps below to configure milestones:

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

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

5. Choose from the **Existing list** of milestones to enable that milestone for your room **or** enter the milestone name to create New milestone. Refer to the screenshot above.
    a. Select the **Milestones Category** as **Study, Site, or Country**.
    b. Select the **Milestone Type** from the dropdown and click **Ok**.
    c. To select **Milestone Type** of your choice, you will need to add milestone types.
        1. You can create **Milestones Type** on the fly by clicking the '+' icon in the **Milestone Type** field.
        2. Once a milestone type is created, it will not automatically populate in the textbox. Select the milestone type from the dropdown.
6. The milestone thus created is enabled by default.
7. Double-click a milestone, or select an existing milestone and click **Edit** to edit a milestone.
8. Select a milestone and click **Delete** to delete it.

Inbox Settings

From this page Admin can enable the Inbox feature.

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

Inbox

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

   Note: *The Administrator has the ability to disable the inbox feature or to allow non-participants in the room to send documents to the room's inbox.*
2. Ticking the checkbox of **Convert Email Body** option, will automatically convert the emails that enter the Inbox into PDFs.
3. Choose **Unpack Zip-Archives** to extract files from an attached zip folder.
4. To prevent duplicate publishing of email converted documents to the room activate the **Check duplicates by hash value**.

Communication

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

Start-Up Inbox

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

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

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

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

Forms Settings

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

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

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

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

Adding a Custom Field

Editing a Metadata Field

Deleting a Field

Setting Advanced Validation Fields

Adding a Custom Field

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

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

   Note: *If this option is activated, users can't save the form unless this field is filled out when they have made modifications to a document's Document Profile metadata.*
8. The **Validation type** field is dependent on **Field Type**. For instance, if the Text Field Type is selected, you might restrict the entries made there to alphabetical characters or alphanumeric characters.
9. Click **Add to Grid**. The view returns to the full **Document Profile Form** display.

Editing a Metadata Field

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

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

Deleting a Field

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

   Note: *If the field is already in use, you will see a warning message, asking if you really want to delete the field.*
3. If you delete by mistake, you can click the **Undo** button to undo the changes.

Setting Advanced Validation Fields

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

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

1. Click **Advanced Validation** in the menu ribbon. The **Edit Advanced Fields validation** window opens.

   Refer to the screenshot below:

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

   Note: *For fields for which the field data must be selected from a particular set of options, you need to choose from the dropdown menu of selections. For date-related metadata fields, the Equals field converts to a calendar selection. For some metadata fields, the Equals field is a textbox.*
5. Click the **Actions** button. Select the appropriate radio button to define what action will be implemented in the field or fields that will be selected in the next step of the process.
6. Click the checkbox or checkboxes for the field or fields that you want to be affected in this field validation.
7. Click **Save**. The selected Action will apply to the selected Fields when the Validation Criteria you have set are met in a particular document's metadata.

Integrations

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

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

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

Documents, on uploading, would then move directly to the related folder assigned to their document types and acquire the status as final. Refer to the screenshot below:

General Integrations

1. Navigate to the **Main Navigation->Settings-> Integrations-> General Integration**. Refer to the screenshot below:

2. Tick the checkbox to upload documents as **Final**

Documents, on uploading, would then move directly to the related folder assigned to their document types and acquire the status as final.

CTMS Integration

1. Navigate to the **Settings-> Integrations-> CTMS Integration**. Refer to the screenshot below:

2. Tick the checkbox to **Upload CTMS documents as Final**.

IRB Integration

IRB Integration Settings

From the room **Settings -> Integrations -> IRB Integration** you can decide the location and the status of the IRB documents in the eTMF.

Trial Interactive introduces a new **IRB Uploads folder** the name of which can be configured from the **Settings -> Documents -> Index Outline**.

Potential Sites Module and Settings

There can be cases where multiple sites are found during IRB Integration, or a site could not be identified, or sites are incorrectly imported.

Under the circumstances, the system creates a list of **Potential Investigative Sites** and notifies appropriate groups about the potential sites.

1. To configure the Potential sites email recipients navigate to **Settings->Integrations->IRB Integrations**. Refer to the screenshot below:

2. Click **Select** next to the Potential sites email recipient and select the email recipients as instructed. The email template for the emails to be received by potential sites email recipients can be setup from the **Email Templates** in the room **Settings -> Email section**. A screenshot of the system provided email template is shown below:

3. With Trial Interactive, you can manage potential investigative sites from the Potential Sites module if IRB Integration is enabled for you.
4. The module is accessible by clicking the Potential Sites icon  from the toggling menu in the eTMF module. Refer to the screenshot below showing the **eTMF/Potential Sites** module.

Note: *As an Administrator, you can create sites from potential sites or delete the ones that cannot be converted into sites.*

Documents

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

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

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

Documents Module

Auto Purge Settings

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

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

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

Document Expiration Settings

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

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

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

Automatic Document Name Generation

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

1. Tick the checkbox to enable **Use auto generated document name as output name** option.

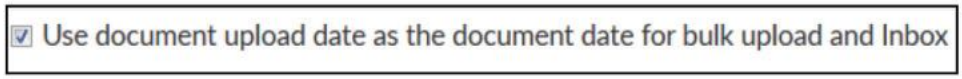
2. Click **Regenerate Document Names** button to regenerate document names of selected document types.
3. The **Select Document Types to Regenerate Documents Names** window. Select the **document types** and their **categories** for which you want to regenerate document names. Refer to the screenshot below:

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

Document Upload Date as Document Date

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

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



Edit Online

Tick this option to **enable edit of a document by multiple users**. Refer to the screenshot below:

For every chanage made in the settings, remember to click **Save** at the bottom of the window to update the settings.

Document Replacement Reasons

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

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

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

eTMF Health Settings

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

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

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

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

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

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

Index Outline

Administrator can decide on number of functions and appearances related to the Trial Interactive room's index.

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

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

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

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

Auto Prefix

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

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

Documents Count

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

- Click a folder to open the documents contained in it in the Documents Grid.

- Tick the **Show documents count** checkbox in the settings.
- Users in the room will see a number in brackets that indicates how many documents are in each index folder.

Changing the Index Name

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

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

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

Empty Folders Options

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

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

Hide index on add new document

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

It this option is enabled:

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

Auto Indexing

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

1. Click the magnifying glass. Full index list appears.

2. Select the folder indicated by the client. In this example, the folder is named **19 nick folder 1**.
3. Click **OK**. The window closes.
4. Click **Save** at the bottom of the **Index Outline** panel.

Non-PDF to PDF Document Conversion Settings

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

3. Select the appropriate radio button to make the conversion, **Manual or Automatic**.
4. Edit the list of file types that can be converted.
5. Click **Save** if you have made acceptable changes.

Document Types and Management

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

In the conduct of a clinical trial, scores if not hundreds of different kinds of documents need to be collected, categorized, and filed – some general documents, some documents that are specific to the countries in which studies are being conducted, and some documents that are specific to the investigative sites involved in the study.

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

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

Refer to the screenshot below:

The Documents under the Document Types created from here can be viewed under the By Document Type view.

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

1. Document Types Management
2. Common Configuration
3. Adding Document types to Metadata Panel and By Document Type View

Document Types Management

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

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

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

From this page you can perform various actions as below. All of these are discussed in separate child-topics.

Expand this topic from the left pane of this help to reveal the following child-topics:

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

Modify Documents Types

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

Figure 2: Modify Document Types' Tree

   a. To add a new document type, click the main category into which the new document type is to be assigned. If the folder already contains document types, click the + sign next to the category's folder icon to see the

document types already contained in the category. The categories are marked by the yellow folder icons and the actual document types by the blue document icon.

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

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

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

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

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

Building the Document Type Profile

1. Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.
2. In the **Profile** tab, type in the **Short Name** for the document type. This can be the same as the **Document Type** name that you created in the previous steps, or it can be abbreviated if the original name is long.
3. The **IRB Document Type ID** is one of the fields besides Site ID and IRB Number that is required by the system for IRB Integration. This field will be available only if IRB Integration is enabled in the room.

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

4. The **Category** has already been assigned by your first steps of creating the new document type, so this field is not enabled.
5. Click the wrench icon next to the **Auto Name Rules** field. When the metadata gets filled out for documents of this type, the auto naming rules you set up here will be applied to these documents. The client typically supplies a file with prescribed document types and the auto naming rules that they want assigned to the document types. An **Auto Name Rules** window opens. Refer to the screenshot below:

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

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

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

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

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

d. Back in the **Auto Name Rules** window, click the white arrows icon to the right of the **Preview** box. The box populates with a generic preview of the selected Auto Naming pattern. Refer to the screenshot below.

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

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

Specifying the Related Folder

1. In the **Profile** tab in the panel on the right, click the magnifying glass icon next to the **Related Folder** box.

A window opens, displaying the folders available for assigning the new document type.

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

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

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

Include Phases/Milestones

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

From the list of milestones that appear:

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

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

Milestone Related Fields Auto Enabling

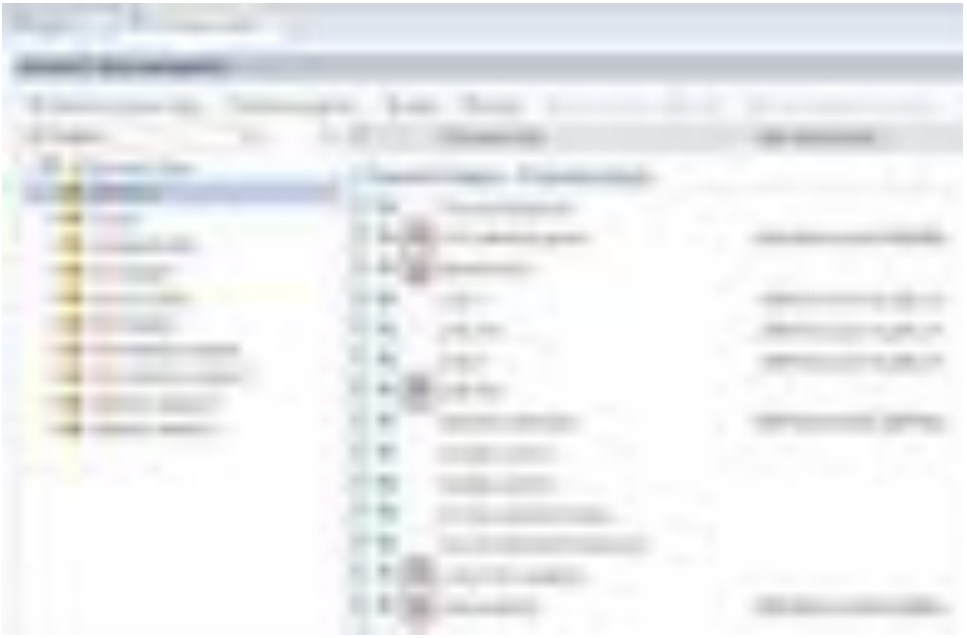
When a user selects one or more items in the Study Milestones, Investigative Site Milestones, or Country Milestones files in the Document Type Profile, **the system will automatically mark the 'Milestone' and 'Milestone Date' document fields as visible and required**. This will be reflected in the custom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

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

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

Adding Document Types to Required Documents

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



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

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

Include in Document Tracker Report

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

Auto Document Type Prediction Keyword(s)

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

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

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

Modifying Document Type Fields

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

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

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

   The pane becomes active, no longer grey in appearance.
3. Click the boxes in the columns marked **Visible** and **Required** as dictated by the client request.

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

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

   Then select another document type whose metadata fields are the same.
4. When you have finished making the requested changes, click **Save** at the bottom of the pane.

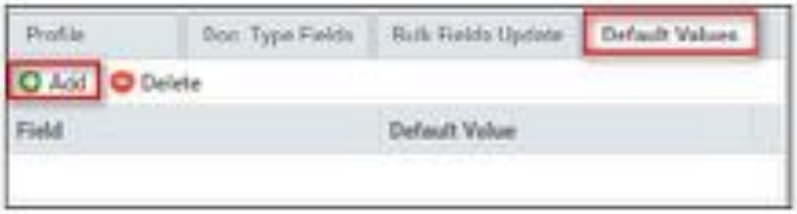
   Note: *The Search box allows you to type in simple search criteria to help you find particular metadata fields in the list.*

Default Values

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

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

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



11. Click **Save**.

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

Common Configuration

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

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

Adding Document Types to Metadata Panel and By Document Type View

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

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

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

Required Documents Settings

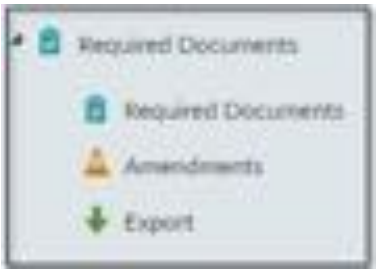
With the help of **Required Documents Settings**, Administrators establish and edit the Required Documents for a study. Different document types may be required for all Investigative Sites involved in a study, or there may be documents that are required of investigative sites that are located in particular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

Once Document Types are set up for a room from Document Types Management, you can set up the Required Documents.

Note: *It is recommended that administrators contact the Trial Interactive Project Management Team if any changes or additions are needed here. Once Document Types are set up for a room from* ***Document Types Management****, you can set up the Required Documents.*

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

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



Required Documents can be defined for the following:

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

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

Required Documents

1. From the left section of the panel you can select the category (**Sites, Country, IRB/EC, and General**) of the Required documents. By default, **All Sites** category is chosen.
2. From the right section of the panel, named as Document Types, you can:
   a. **Add** Add or **Delete** Delete a Required Document to the category selected from the left pane.
   b. **Assign Milestones** Assign Milestone to selected Required Document Types.
   c. View the activity log of the selected category from the **Change Log** Change Log.
   d. Once a Required Document is added, it appears in the Document Types Grid.

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

All Sites

Country Specific

IRB/EC Specific

General

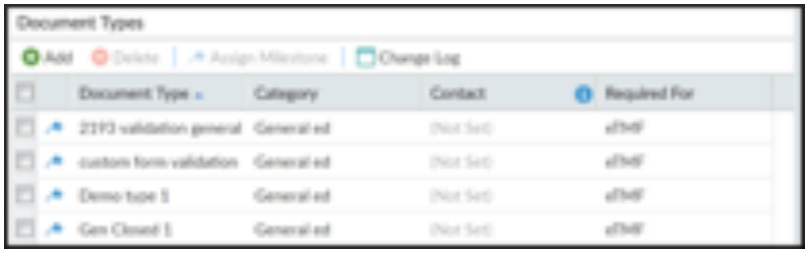
Assigning Milestones to Required Documents

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

1. Select the category from the left pane.

2. Except for All Sites and General categories, select the Country or IRB/EC from the left pane.
3. Select the Required Documents from the right pane.
4. Click **Assign Milestone** Assign Milestone from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:

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



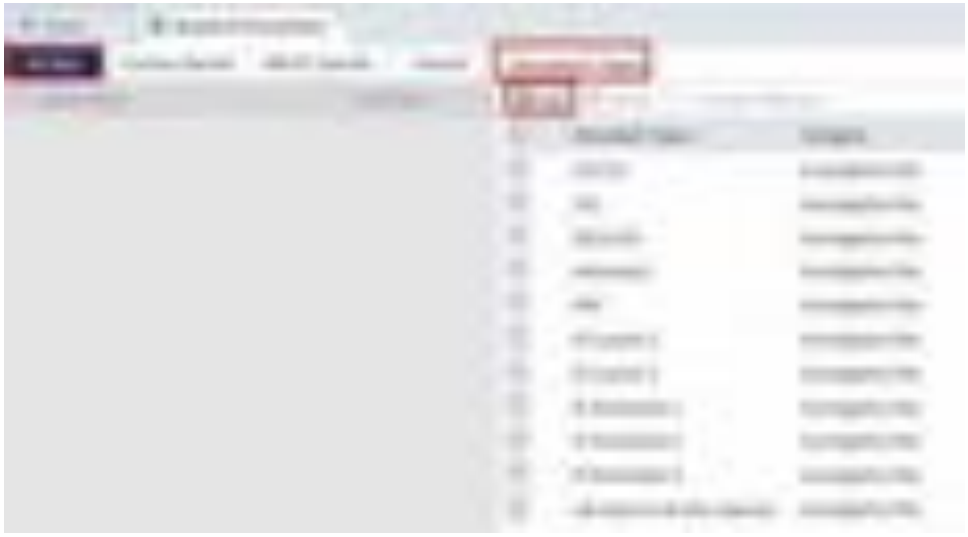
All Sites

All Sites

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

Adding All Sites Required Documents

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



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

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

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

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

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

Deleting All Sites Required Documents

To delete a Required Document Type for All Sites:

1. Click **All Sites** tab from the left panel of the **Required Documents Panel**.
2. From the list of Required Document Types in the grid, tick the checkboxes to select the Required Document Types to be deleted.
3. Click **Delete** from the top ribbon bar of the **Document Types** window on the right. Refer to the screenshot below:

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

Country Specific

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

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

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

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

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

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

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

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

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

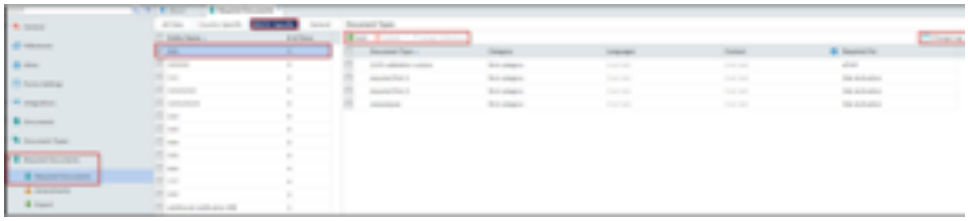
IRB/EC Specific

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

Adding IRB/EC Specific Required Documents

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

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



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

   The **Required Documents** window opens, providing you the opportunity to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).
5. Selection of the **Investigative Site** radio button activates the list of document types included under **Site Management**.
6. Selection of the **Study** radio button activates the document types included under the **General document category**.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction, if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.

   a. **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
   b. **Languages**- Select the language from the list to be applicable to the Required Document.

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

10. Click **Save**.
11. Begin again at the top of the Required Documents window to continue adding for different contacts under Investigative Site..

12. Select the **Study** documents to be required.
13. Click **Save & Close**.
14. Select the next **IRB/EC** in the list to which you need to add required documents, and follow the process steps above.

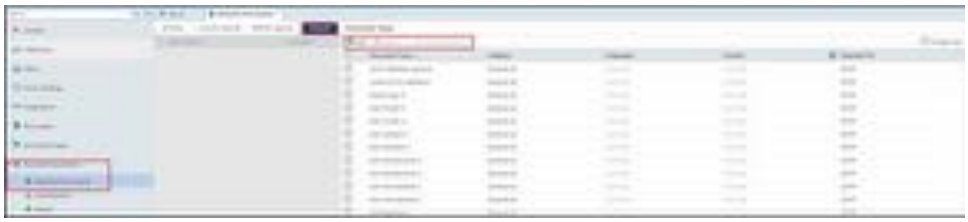
Deleting IRB/EC Specific Required Documents

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

General View

Adding General Required Documents

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



6. Click the category folder from which you need to select the Required Document that you want to add to the list for all sites. The list of the available document types in that category folder appears.
7. Click the checkbox next to one or all of the documents to be required.
8. Click **Save & Close** if you have documents from only one category folder to add, or click **Save** if you need to add more required documents.

Deleting Required Documents

To delete a Required Document Type for All Sites:

1. Click **General** tab from the left panel of the **Required Documents Panel**.
2. From the list of Required Document Types in the grid, tick the checkboxes to select the Required Document Types to be deleted.
3. Click **Delete** from the top ribbon bar of the **Document Types** window on the right. Refer to the screenshot below:
4. You will receive a warning asking you to confirm the action.
5. Click **Yes** to confirm and delete.
6. The Required Document Types are removed from the list.

Required Documents Milestones Linking

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

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

from the top ribbon bar.

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

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

Amendments

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

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

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

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

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

   Refer to the screenshot below:

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

Export Required Documents

In this panel, Administrator users can export either **All required documents** or **Selected documents**.

Refer to the screenshot below:

Required Documents can be exported in two ways:

1. Select **All required Document** Option to export documents from all document source categories
2. Select **Selected documents** option.

a. Export window opens for you to choose from **Amendments or/ and eTMF or/ and Site Activation** sources of documents.

Refer to the screenshot below:

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

c. New Export window opens for you to select required **Entity Types and Categories** to export documents.

Refer to the screenshot below:

d. Click **Next.** Final Export window opens to review criteria chosen by you.

Click **Previous** to make changes in the selection or click **Next** to export Required Documents.

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

f. An excel file is generated with a list of required documents and you can save the file for your records.

Refer to the screenshot below:

Countries

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

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

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

Countries Settings

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

Follow the steps below to perform the country settings:

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

   Refer to the screenshot below:

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

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

Add Countries

Follow the steps below to add countries:

1. Click **Add**  from the ribbon above the country listing. The **Create Country** window opens.

   Refer to the screenshot below:

2. Click the dropdown arrow at the right end of the **Country** field. An alphabetized list of countries is populated to select from.
3. Select the name of the country to be added. The name of the selected country populates the **Country** field.

   Note: *You can ease the process of finding the country name in the list by typing the first few characters in the country name. The dropdown list will shorten to include only the countries whose names begin with the characters you have typed.*
4. If the client has supplied country-specific **Study Contact #**, include the associated number in the field.
5. Click **Create**. The name of the newly added country appears in the alphabetized list.
6. Repeat these steps until you have added all of the countries associated with the study.

Edit Countries

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

Follow the steps below to edit countries:

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

3. It might be that after you've added the country to the list you are supplied with the study contact number later.
4. Click **Study Contact#** field to change the information.
5. Click **Select** next to **Read Only Members** or **Full Access Members** or **Regulatory Approvers** to add or delete users or groups of users from the access settings.

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

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

Delete Countries

Follow the steps below to delete the countries:

1. Select the country or countries that you need to delete from the list by clicking the checkbox next to the country's name(s).
2. Click **Delete**  at the top of the **Countries** window. The country name(s) will delete automatically, without giving you a warning.

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

Template Folders

In this window, you can **Add, Edit, or Delete** template folders and subfolders in the root folder for managing country-specific documents.

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

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

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

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

Editing Names of Folders and Subfolders

Follow the steps below to edit the names of folders and subfolders:

1. Select the folder to be edited.
2. Click **Edit** from the menu at the top of the window or right-click the folder name and select Edit from the available options.
3. Make the necessary changes to the folder name.
4. Press **Enter**.

Deleting Folders

Follow the steps below to delete folders and subfolders:

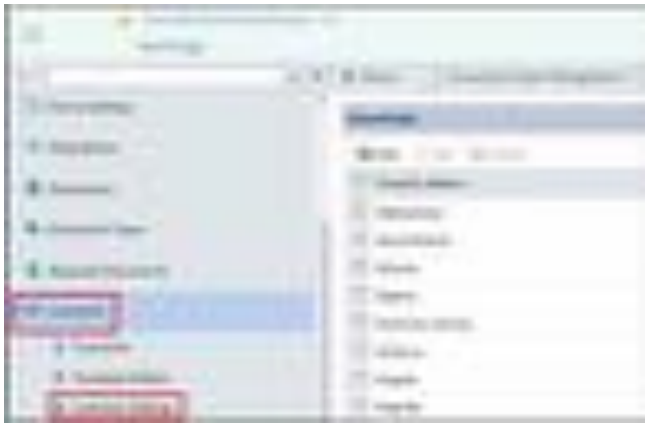
1. Select the folder to be deleted.
2. Click **Delete** from the menu at the top of the window or right-click the folder name and select **Delete** from the available options. The folder disappears from the index structure.

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

Common Settings

In the Common Settings window you can:

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



Investigative Sites

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

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

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

General Settings

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

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

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

    b. Click in the **Rule Editor** box.
    c. Double-click the insertions in the **Available Templates** box in the order in which you want them to appear in the naming pattern.
    d. Once you have made the selections, click the blue box to the right of the **Preview** box to see how the folder names will appear in the room's index.

e. Once the naming pattern is set up correctly, click **OK** at the bottom of the window.

You return to the **General settings** panel.

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

a. Click in the field.

b. Type the root folder.

c. Hit the **Enter** key on the keyboard.

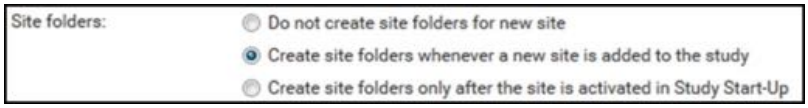
3. Selection of the **Sort Order** for the Site Management folder is made in the next field. This dictates where the folder appears in the room's folder index.

a. Click in the field.

b. Type the number of the client's preference.

c. Hit **Enter** on the keyboard.

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



5. Like the previously described settings, the rest of the settings in this panel are dictated by client preferences. Closely follow any and all instructions from the client in controlling these settings.

6. Hover the mouse over the question marks in blue circles for more information about specific options on the screen.

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

Study Start-Up Settings

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

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

Contact Types

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

1. Click **Add**. The **Contact Type** field becomes active.
2. Type the contact name provided by the client.
3. Hit **Tab** or **Enter**.
4. Click the field in the **Group** column to make it active.
5. Click the far-end right edge of the field to activate the dropdown menu.

6. Select the group title from the list that best corresponds to the client-requested Contact Type name.

   Additions and changes made here are saved automatically.

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

Submission Profile Status

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

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

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

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

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

Template Folders

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

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

2. Type the name of the first folder in the available field.
3. To add another folder at the same index level, click the **Index Root** folder and click **Add**.
4. To add a sub folder inside a folder you have already created, click the name of the new folder and click **Add**.

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

Investigative Site Status

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

CRA Visit Types

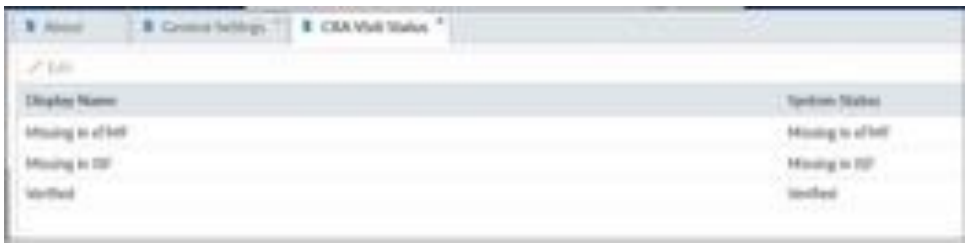
A CRA might need to create **CRA TMF Reconciliation Report** to reconcile documents during site visits. While creating the report, the visit type must be chosen so that reports generated during two or more site visits can be differentiated with ease. Refer to the screenshot below:

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

1. To add a new visit type, click the **Add** button at the top of the portlet window.
2. Type in the desired term and press **Enter**. Changes made here are saved automatically. These visit types automatically appear in the dropdown while creating the **CRA TMF Reconciliation Report**.
3. To edit a visit type, double-click the visit type, or select it and click the **Edit** button from the toolbar above.
4. To delete a visit type, select the visit type and click **Delete** from the toolbar above.

CRA Visit Status

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



Regulatory Approval Status List

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

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

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

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

Communication Types

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

1. To add a new Communications Type label, click the **Add** button. An empty test field opens.
2. Type in the label. By default, the new communication type is not Enabled. Refer to the screenshot below:

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

Issues

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

1. Click **Add**. A text field opens.
2. 

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

Regulatory Packet Options

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

Email Settings

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

From here you can configure email functionality as follows:

Email Templates

Room Legal Hold Notifications

Notification Preferences

Notification Columns

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

Email Templates Settings

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

Refer to the screenshot below:

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

Notification columns

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

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

Refer to the screenshot below:

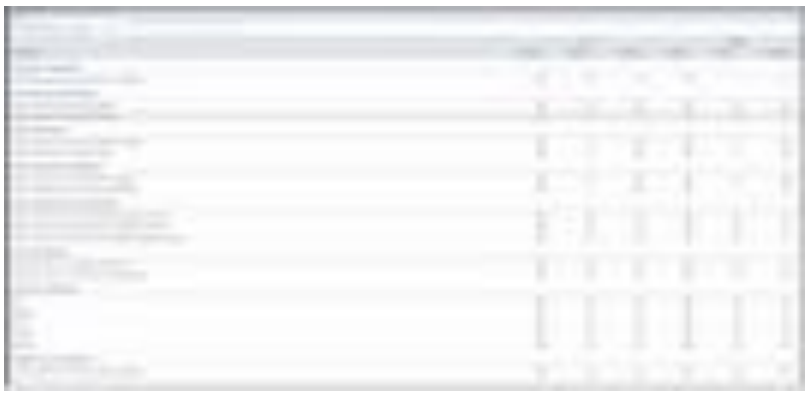
To filter the columns that would appear in the **notification emails**:

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

Notification Preferences Settings

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

1. Enter the **Mini newsletter frequency** with which the Mini newsletters will be sent to subscribers. Refer to the screenshot below:



2. In the **Subscription** panel, enable the appropriate notifications that will be available to the room's users.
   - Using the options grid on the right of the Subscriptions window, you can select which notifications you would like to receive. Below are the definitions of each notifications type and their use:
     - **Enabled**: This enables the possibility to subscribe on related notifications.
     - **Default**: This enables the user to subscribe by default on the related notification but with the possibility ti unsubscribe.
     - **Mandatory**: The user gets automatically subscribed without the possibility to unsubscribe.
   - Administrators can choose alert systems, depending on which notification systems have been enabled by the room's Administrator.
     - A new audit query response is submitted
     - A Document is updated in the eTMF, and/or Start-Up
     - A New Document is added to the eTMF, and/or Start-Up
     - A user visits a room for the first time
     - A user registers within a room
     - A New Question is added
     - A New Answer is added to a question
     - Workflows
     - Workflow Query response submissions

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

   Tip: *You can elect to receive either a mini summary of notifications or nightly newsletters recapping all of the new events in the past 24 hours for each of the five notification categories.*
3. Once you have made your Notifications selections, click **Save**.

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

Room Legal Hold Notifications Settings

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

1. Click **Select** to set up the **users** wo will be notified when a room is put on legal hold. Refer to the screenshot above.
2. The **Notification recipients** window opens for you to select from the list of **Users**.
3. Select the number from the **Notification offset (days)** dropdown. It will decide the number of days before the legal hold end date when the notifications should be sent to those users.
4. Click **Save** from the bottom of the grid.

Document Template Settings

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

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

Quality Control Settings

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

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

To access the Quality Control Settings:

1. Navigate to the **Main Navigation-> Settings → Workflows**.

   From **Workflows Settings**, we discuss about:

   a. Common Workflow Settings
   b. Creating, Editing, and Deleting Quality Control Review Statuses
   c. Creating, Editing, and Deleting Quality Control Document Statuses
   d. Creating, Editing, and Deleting Quality Control Profiles

      Each of these are discussed in the separate topics in this help.

Common Settings

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

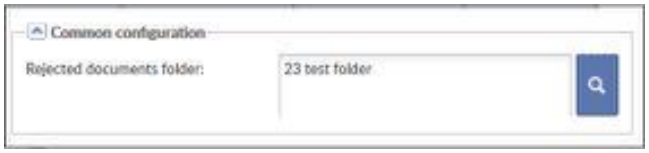
Admin can perform the following Common Settings in a Workflow:

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

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

Workflow Common Configuration

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



Default ranges configuration

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

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

  Refer to the screenshot below:

Each field above is editable, you can simply enter the values separated by semicolon. Each option is discussed in separate sections below:

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

Timeline configuration

Refer to the screenshots below:

- If you specify values in the timeline, the values will be automatically set for you at the time of workflow creation.
- If you happen to change your mind at the time of creation, you may select values as required as opposed to that set in the timeline configuration.
- The configurations are optional here except for the Clarification auto release, which means a document that is pending for clarification will be automatically released if it was not released back to the workflow by the reviewer within the defined time period.
- Users can delete timeline values from a Workflow profile as well as for existing workflows by clicking the cross icon next to the fields in the **Timeline Configuration pane**l or from the **Timeline** tab in a **Workflow Profile Editor**. Refer to the screenshots above.

Issue email

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

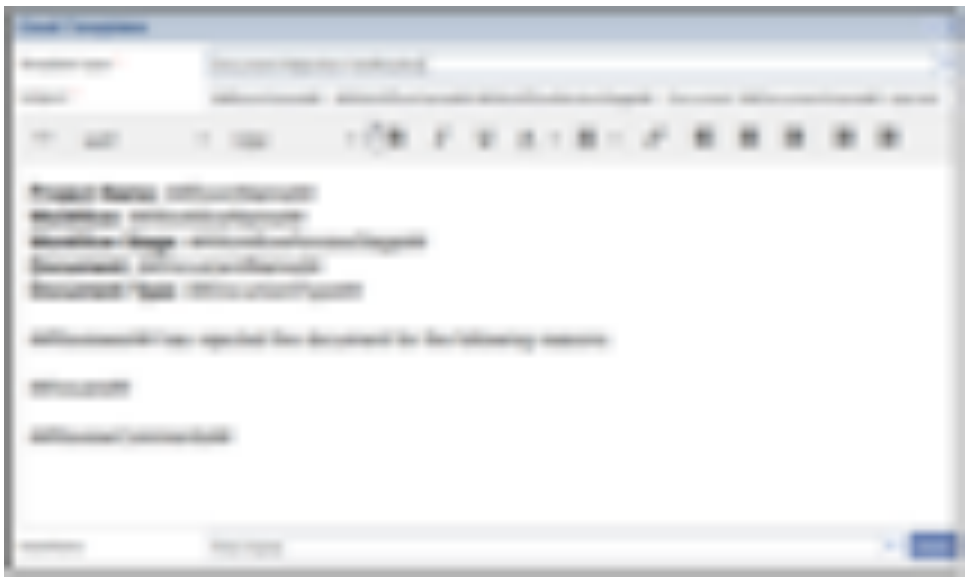
2. Click the dropdown arrow to choose the attachment mode to be either **Files as links or Files as attachments**. Refer to the screenshot above.
3. Click **Save** from the bottom of the grid.

Rejection Email Configuration

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

1. Click **Select** from the **Rejection Email** settings.
2. **Workflow rejection notification email recipients** window opens. Refer to the screenshot below:

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

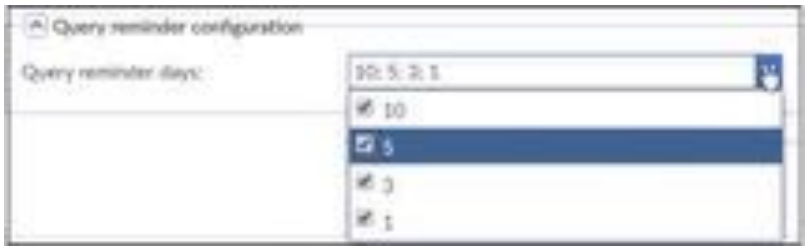


You can change the Rejection Email Template from **Settings-> Email ->Email Template**

Query reminder configuration

From **Query Reminder configuration** Admin can configure reminder emails' schedule.

Refer to the screenshot below:



1. As per the above configuration, reminders will be sent on the 10th day, 5th day, and the 3rd day, if the user does not respond to a query with a document.
2. You can change the number of days from Query reminder date range (days) in Default ranges configuration.

Auto claim configuration

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

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

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

Creating the Quality Control Workflow

To creare a Quality Control workflow follow the procedure below:

1. From the **Settings → Workflows → Workflows**,click the **Add** button from the grid. The **Workflow Editor** window opens.

   Refer to the screenshot below:

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

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

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

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

11. Change the **Stage Name**, if desired. Click the **Approvers** tab. Refer to the screenshot above.
12. This allows you to **add users/groups** as reviewers of the documents for the particular stage in the workflow.

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

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

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

14. Click the **Issues** section to assign the reasons in case the reviewer rejects a document/asks for clarification.Some of the standard issues could be **Missing Pages, Missing Signature, Blank Pages, Incorrect Study, Poor Scan, Duplicate, and Expired Documents**.
15. To make metadata **fields**, as required, available for a workflow configuration, proceed to **Forms Settings** and select the **Workflow Fields**, as required.

- These fields will appear in the **Fields** panel at the bottom of the **Customs** tab. Tick the fields as required for the review. Refer to the screenshot below:

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

16. Click the **Notifications** tab.
    - Here, you can allow for email notifications to be enabled for the event names listed.
    - For users who want to be notified only in case of **Claim**, **Release**, or **Escalation**, groups can be added accordingly.
17. In case you have fed in values in **Timeline Configuration**, the values would be populated by default in the **Timeline** tab. You may choose to override the previously set configurations, if desired.
18. **Actions** is an optional tab allowing for complex workflow building.
    - It enables a workflow to have a jump. A specific document can jump to a certain stage.
    - For example, a Form FDA 1572 after QC1 review, can jump to a stage 3 review, where Regulatory Affairs perform a 2nd review on the document.
    - While efficient for complex workflows, it is not required for regular workflows creation.
19. Click **Next** when all tabs have been reviewed.
    - Repeat the similar steps for each stage of approval.
    - Settings may change per approval stage, like **approvers, notifications, and timelines**.
20. When finished, click **Next**.
21. The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If no errors, click **Finish** when done.

Editing An Existing Workflow

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

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

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

   If one needs to be disabled, uncheck the associated box. Remember to click **Save**.

Deleting An Existing Workflow

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

Security

From here Admin can perform various functions of security configuration.

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

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

General Security Settings

Users Security Settings

Groups Security Settings

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

General Security Settings

From here you can perform the following functions:

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

All above topics are discussed in separate sections

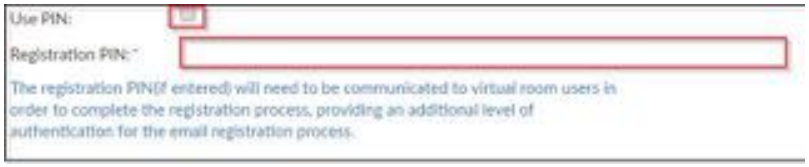
Logout Timer Configuration

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

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

Invite Participant Settings

As an Administrator, you can add a layer of security to the user registration process. Refer to the screenshot below:



To use this extra layer of security:

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

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

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

Redaction Settings

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

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

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

Actions Security Settings

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

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

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

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

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

PDF Watermark Options Settings

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

- Watermarks are only displayed when a document is not in **final** workflow status.
- Therefore, once the document becomes final, the watermark will no longer be available on the document; this is an automatic process.
- In this panel, Administrators can select which metadata fields will comprise the watermark, and they can select the appearance and position of the watermark. Refer to the screenshot below:

1. Activate or inactivate the **Add Watermark on documents** option by clicking the check box.
   - Activation of this option also activates the option of allowing non-PDF documents to be printed or downloaded without watermarks.
2. Tick the checkbox to **Display watermark for Administrator users**.
3. Type in the **Text** of the message to be displayed as the watermark using the text strings from the list provided.
4. Tick the checkbox to **Rotate watermark if page is rotated**.
5. Select the **Font name** from the dropdown.
   - The dropdown list can be extended to include all fonts by clicking the Show all fonts checkbox.
6. Select whether the watermark text will be rendered as **Bold** and/or **Italic** text.
7. Select or confirm the **Font Size** from the dropdown menu.
8. Select the **Font color** from the dropdown menu.
9. Select whether or not to **Embed the font to the PDF**.
10. Select the **Position** of the watermark.
11. Select whether the watermark will appear in the **Foreground** or the **Background** of the document text.
12. Click **Save**.

Document Viewers Settings

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

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

Document Encryption Options

The system provides **Digital Rights Management (DRM)** functionality. This feature provides additional security options to the users.Refer to the screenshot below:

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

Confidentiality Agreement Settings

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

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

Following are the steps to enable the Confidentiality Agreement:

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

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

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

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

User Management - Users

From this page you can do the following:

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

10. Update preferences

Regular Invite

Note: *Users can also be invited from the **Room Settings → Security → Users.***

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

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

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

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

Edit User

1. Complete the User Profile as required.
2. The fields of importance are discussed below:
   a. **User Email**: This is used by the user as an unique identity to login to Trial Interactive. This can be typed in or searched by clicking the magnifying lens icon at the end of the field. If you type in an email address that does not adhere to an email id format, you will receive a validation error message asking you to enter the correct one.
   b. **Role**: Choose the role from the dropdown to be assigned to the user. The roles can be either of an **Admin**, **Editor** or **Reader** in a particular room.
   c. **Actions** : These are tasks that the user would be allowed to perform under the specific role can be assigned by selecting the Action name from the Actions dropdown.
   d. **Expiration Date** : Enter this date if you want the user access to be revoked after the lapse of a particular period.
   e. **Organization**: Choose from the dropdown the organization to which the user belongs to. The Administrator can also create an organization, if not available from the list, by clicking the '+' sign at the end of the textbox.
   f. **Allow Multiple Sessions**: Click the toggle bar to **Yes** if you want to allow the user to login through different browsers at the same time.
   g. **Invite Later**: Click the toggle bar to **Yes** if you want to prepare a user for the room but not want to send the real invitation. So users will be prepared for invitation sending and when time comes, they can be invited later. For example, a user is in training and would be allowed access to the room later.
   h. **Silent Invite**: Click this toggle bar to **Yes** if you want to invite the user without sending the invitation email. In such case, you will need to provide a temporary password in the **Password** field that appears on activating this option.

   Remember: *You can select either Invite Later or Silent Invite only at a particular point of time.*

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

Groups Memberships

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

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

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

Quick Invite

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

Follow the steps as below to quick invite users:

1. From the **Users Management → Users**, click the **Invite** dropdown from the top menu bar and then select **Quick** from the list of options that appear.
2. The **Quick Invite** page opens.
3. Enter the email addresses of all the users you want to send invitation to.
4. Complete the required fields, adding email addresses and selecting the role the invitees will be assigned to. ***You can Invite single or multiple Readers or Editors or Administrators at one time.***
5. Select **Invite Later**, **Silent Invite** and **Invite Later** toggle buttons when appropriate.
6. Click the **Groups** textbox to assign the user to the appropriate group(s).
7. Click **Add**. Refer to the screenshot below:

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

Viewing Users

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

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

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

   shows the users by Admin role.

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

User Views	Description
By Organization	By Organization view lists the organizations for which there are users in the room. The organization to which the user belongs are specified during user creation.
By Role	By Role view lists the users belonging to the categories of Admins, Editors and Readers.

User Views	Description
By Status	By Status view lists the users under categories as **Pending** for invitation, **Invited** to the room, **Registered** to the room, users who **Visited** the room, and users with **No Access** to the room.
By Group	By Group views lists the groups to which the users belong to in the room. The groups are specified during user creation.

Resending Invitation

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

To re-invite users:

1. From the left pane, select the preferred category to view the users .
2. From the list of users displayed in the right pane under the selected category, tick the checkbox for users to whom you want to resend the invitations.
3. From the top ribobn bar, click the **Resend Invitation** 

icon. A popup appears asking you to confirm.Refer to the screenshot below:
4. Click **Yes**.
5. Invitations are resent to the selected users and a confirmation notification appears for the same.

Editing and Deleting Users

Editing Users

Follow the steps as below to edit a user access:

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

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

   Refer to the screenshot below:

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

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

Deleting Users

Follow the steps below to delete users from a room:

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

Changing User Access

Follow the steps as below to edit a user access:

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

icon.
5. The **Change Access** popup opens.
6. Complete the details as required.
7. Click **Apply**.Refer to the screenshot below:

The fields of importance are discussed below:

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

Exporting Users

You can either export all the users available in the room, or export only selected users as required.

Each of processes are discussed in separate sections below:

Exporting Selected Users

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

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

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

Exporting All Users

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

User Management - Groups

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

Administrators can manage groups in the following manner:

1. The names of groups

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

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

You can perform the following activities from Groups:

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

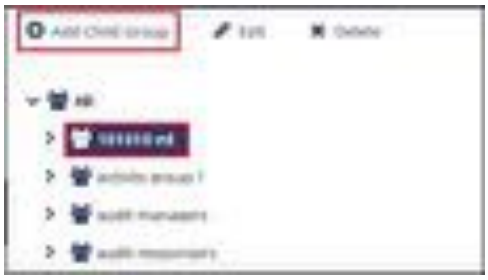
Each of these are discussed in the seperate topics. Navigate to the topics from the left menu to access them.

Adding Child Group

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

Follow the steps as below to create child groups:

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



3. Click **Add Child Group** from the top menu.
4. The **Select Groups** popup opens.
5. Select the required group from the list to for which you want to create child group.
6. Click **Select**. Refer to the screenshot below:

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

Editing a Group

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

Follow the steps as below to edit a new group:

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

E-Signature Settings

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

Selecting e-signature vendors

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

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

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

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

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

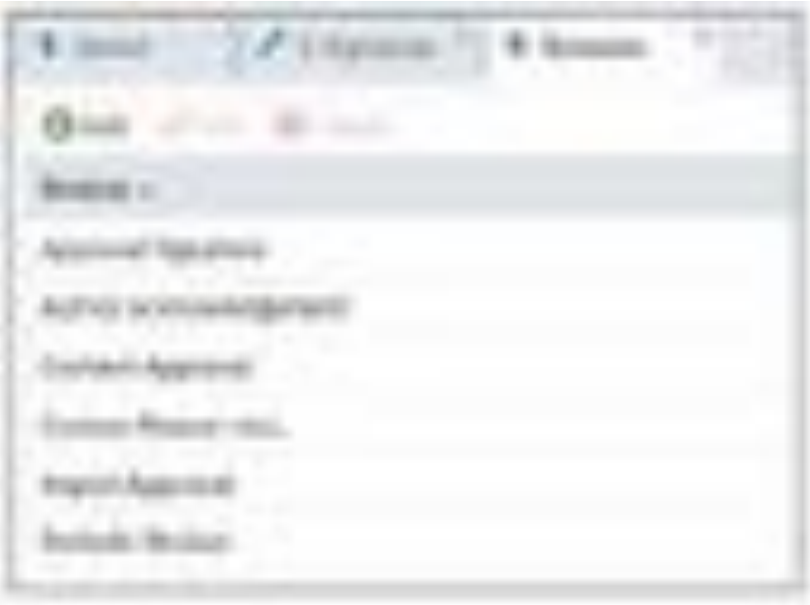
3. An Administrator can choose to enable or disable the use of an e-signature for users in a room by choosing the **None** option from the dropdown.
4. Click **Save** if you make any changes here.

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

Configuring reasons for e-signature

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

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



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

Setting the Purpose of the e-signature

Purpose of the e-Signature is an additional text to display on the top of the send to e-signature form. Refer to the screenshot below:

1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Purpose of the signature**.
2. In the Right Panel you can write the Purpose of the e-signature.
3. Click **Save**.

Tasks Settings

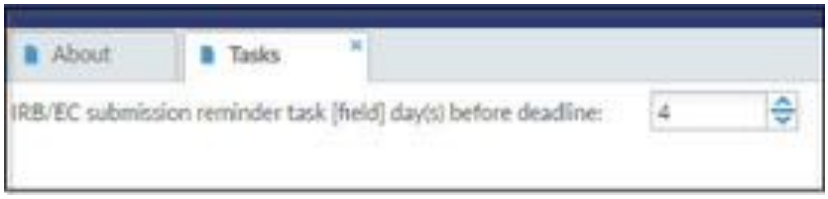
The Administrator wouuld need to set up certain configurations for tasks in a room from **Main Navigation → Room Settings → Tasks.** These configurations are listed below:

1. Tasks
2. Tasks Category

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

Tasks

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

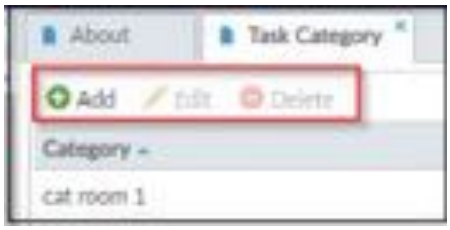


3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.

Task Category

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

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



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

Q&A Settings

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

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

To access the Q&A Settings:

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

From this section we discuss about:

1. Configurations for questions and answers
2. Setting up Subject Matters for the categorization of the questions and answers
3. Adding Editing and Deleting Question Levels

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

Q&A Configuration

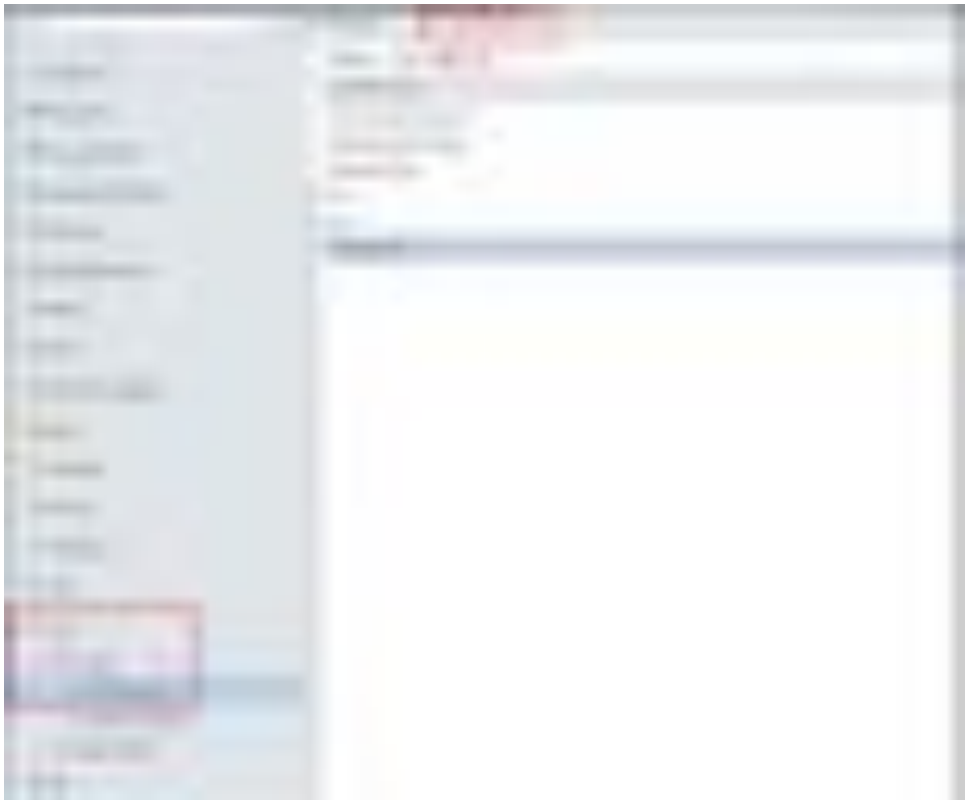
From here you can enable and disable the following three options:

1. The ability to delete questions and answers.
2. The activation of Subject Matter categories.
3. The activation of question issue levels.

   Refer to the screenshot below:

Q&A Question Level

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



From here, you can perform the following:

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

Each of these are discussed in the sections below:

Adding New Question Level

To add new question level:

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

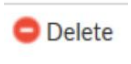
Editing a Question Level

To edit a question level:

1. Select the level and click **Edit** from the top ribbon . You can also double-click the question level to edit.
2. The field becomes editable.
3. Edit the details as required. Refer to the screenshot below:

Deleting a Question Level

To delete a question level:

1. Select the level and click **Delete** 

from the top ribbon to delete it.

Question Subject Matter

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

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

This window consists of two panels:

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

All of the above are discussed in subsequent sections below:

Adding Subject Matters

To create Subject Matters:

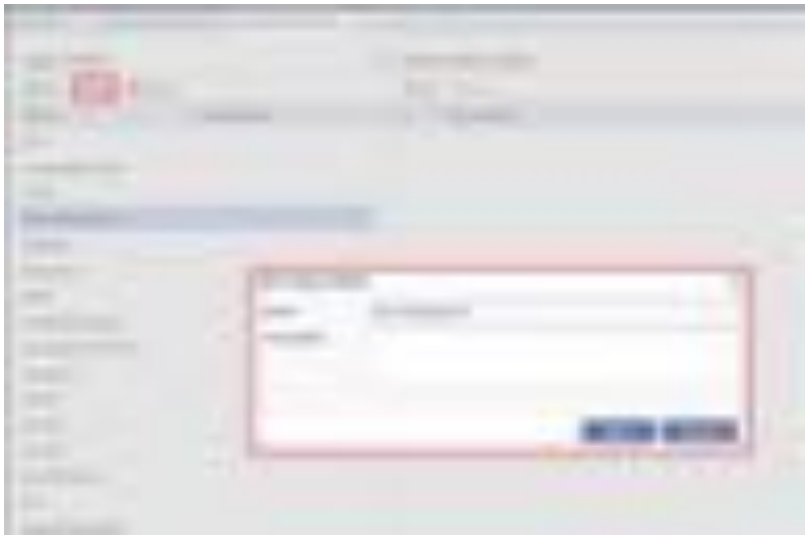
1. From the **Subject Matters panel** toolbar, click **Add**.
2. The **Create Subject Matter window** opens. Refer to the screenshot below:

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

Editing Subject Matters

To edit Subject Matters:

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



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

Deleting Subject Matters

To delete a Subject Matter category:

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

Assigning Subject Matter Experts to Subject Matters

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

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

   A **Select users** window opens, displaying the full list of the room's registered users who are eligible to be assigned the role of Subject Matter Expert – users with Administrator or Editor access to the room.
3. Click the checkbox next to the name of the user you want to assign to the expert role.
4. Click **Select** at the bottom of the window. The changes are automatically saved. Refer to the screenshot below:

Now, when a user asks a question and assigns it to the Q&A category and the Subject Matter while creating the question, the assigned expert will be notified of the question that needs their attention. The expert can then view the question in the Q&A module.

Removing Subject Matter Experts from Subject Matters

To remove a Subject Matter Expert from Subject Matters:

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

FAQ Settings

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

Adding FAQ Categories

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

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

Editing FAQ Categories

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

Deleting FAQ Categories

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

Document Types and Management

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

In the conduct of a clinical trial, scores if not hundreds of different kinds of documents need to be collected, categorized, and filed – some general documents, some documents that are specific to the countries in which studies are being conducted, and some documents that are specific to the investigative sites involved in the study.

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

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

Refer to the screenshot below:

The Documents under the Document Types created from here can be viewed under the By Document Type view.

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

1. Document Types Management
2. Common Configuration
3. Adding Document types to Metadata Panel and By Document Type View

Document Types Management

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

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

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

From this page you can perform various actions as below. All of these are discussed in separate child-topics.

Expand this topic from the left pane of this help to reveal the following child-topics:

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

8. Modifying Document Types Fields
9. Default Values

Modify Documents Types

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

Figure 3: Modify Document Types' Tree

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

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

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

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

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

Building the Document Type Profile

1. Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.
2. In the **Profile** tab, type in the **Short Name** for the document type. This can be the same as the **Document Type** name that you created in the previous steps, or it can be abbreviated if the original name is long.
3. The **IRB Document Type ID** is one of the fields besides Site ID and IRB Number that is required by the system for IRB Integration. This field will be available only if IRB Integration is enabled in the room.

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

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

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

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

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

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

d. Back in the **Auto Name Rules** window, click the white arrows icon to the right of the **Preview** box. The box populates with a generic preview of the selected Auto Naming pattern. Refer to the screenshot below.

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

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

Specifying the Related Folder

1. In the **Profile** tab in the panel on the right, click the magnifying glass icon next to the **Related Folder** box.

A window opens, displaying the folders available for assigning the new document type.

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

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

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

Include Phases/Milestones

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

From the list of milestones that appear:

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

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

Milestone Related Fields Auto Enabling

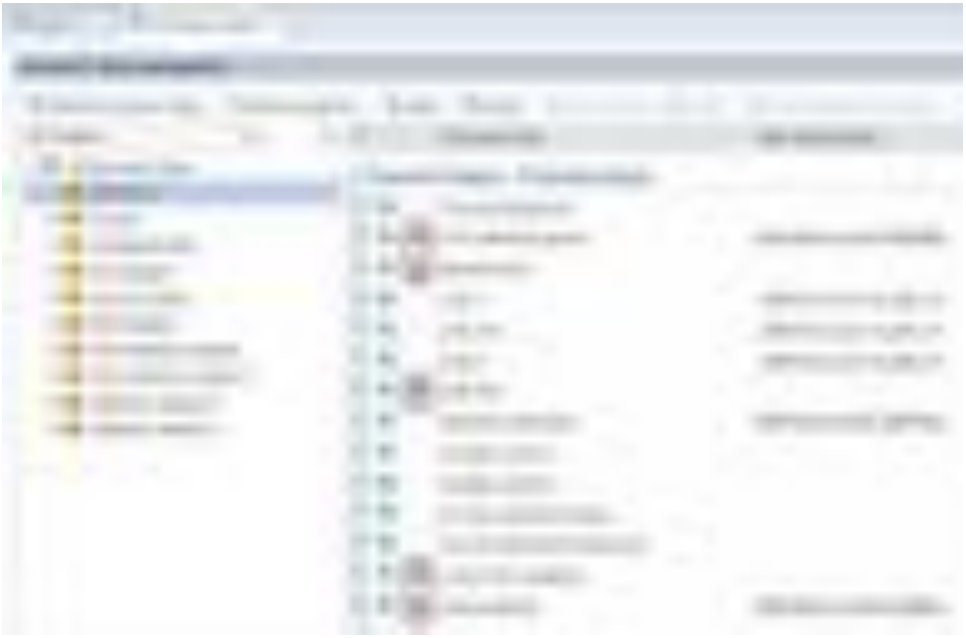
When a user selects one or more items in the Study Milestones, Investigative Site Milestones, or Country Milestones files in the Document Type Profile, **the system will automatically mark the 'Milestone' and 'Milestone Date' document fields as visible and required**. This will be reflected in the custom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

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

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

Adding Document Types to Required Documents

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



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

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

Include in Document Tracker Report

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

Auto Document Type Prediction Keyword(s)

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

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

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

Modifying Document Type Fields

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

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

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

   The pane becomes active, no longer grey in appearance.
3. Click the boxes in the columns marked **Visible** and **Required** as dictated by the client request.

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

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

   Then select another document type whose metadata fields are the same.
4. When you have finished making the requested changes, click **Save** at the bottom of the pane.

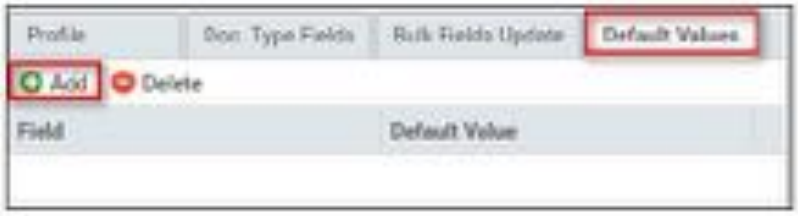
   Note: *The Search box allows you to type in simple search criteria to help you find particular metadata fields in the list.*

Default Values

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

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

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



11. Click **Save**.

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

Common Configuration

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

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

Adding Document Types to Metadata Panel and By Document Type View

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

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

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

Trial Interactive eTMF and the Documents Module

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

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

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

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

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

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

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

Dashboard Dashlets

Know how to configure dashboard and dashlets in a room.

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

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

Arranging your dashboard views include deciding:

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

Dashlets

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

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

Dashboard Settings

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

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

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

   The field becomes active with a dropdown arrow at the right end of the field.
3. Click the dropdown arrow. A set of selections becomes available to the Administrator.

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

From the Dashboard Settings, the following activities are available:

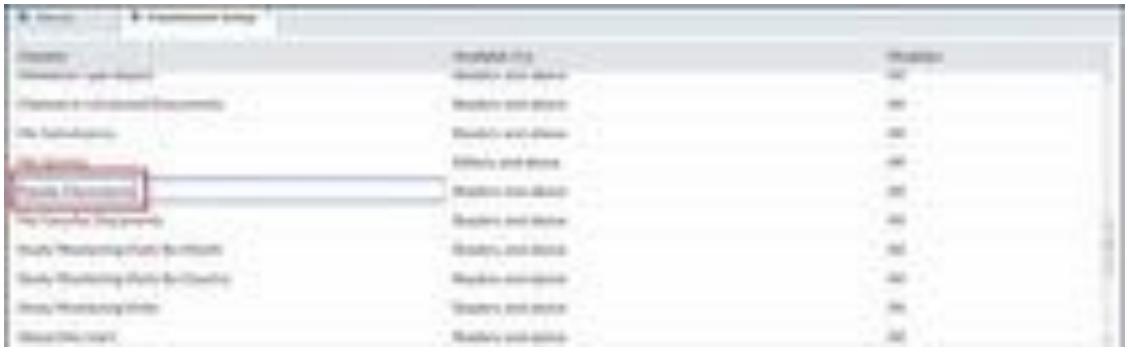
1. Renaming a dashlet
2. Default Dashboard Setup

Above activities are discussed in details in the sections below.

Renaming a dashlet

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

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



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

Default Dashboard Setup

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

Configure Dashboard

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

Refer to the screenshot below:

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

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

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

Laying Dashlets in your dashboard

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

Dashlet - Common

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

The following tabs are available in the dashlets:

1. About The Room
2. Updates
3. Project Links
4. My Courses

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

About This Room

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

The standard Welcome message offers the following links.

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

You can click the **Edit** icon at the top right corner of the dashlet to type in new information or edit existing information on the dashlet. After editing the dashlet contents, click **Save** to save the contents and exit, or **Cancel** to exit from the Edit screen.

Dashlet Common - Bulletin Board

Dashlet Common - Project Links

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

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

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

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

Each of these activities are discussed in the sections below:

Adding a new link

To add a new link:

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

Editing a link

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

Deleting a link

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

Dashlet Common - My courses

Dashlet - Documents

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

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

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

The Documents Dashlet contains the following tabs related to documents:

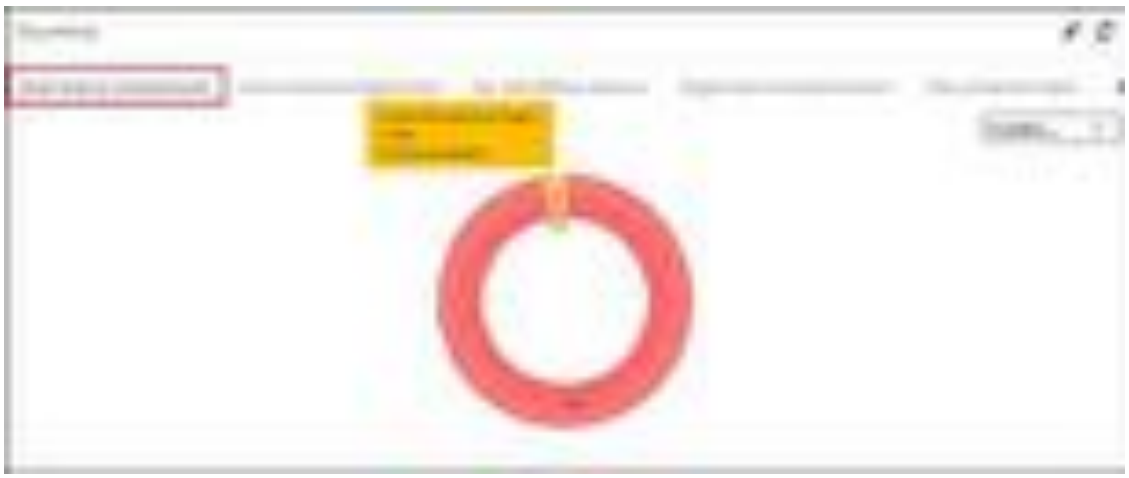
1. Claimed & Unclaimed
2. Documents Expiration
3. By Workflow Status
4. Rejection and Clarification
5. Documents View
6. eTMF Health
7. My Queries
8. Documents Submissions
9. Open Queries by Age
10. Popular Documents
11. Pending Documents Review
12. Unread
13. My Favorite Documents
14. Milestones Timeline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

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

Dashlet - Claimed & Unclaimed

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

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



Dashlet - Documents Expiration

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

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

This opens the **Add New Version window** which provides the available methods to replace an attachment, or add a new document and retain it alongside the older version, or remove the older version if a new version is already submitted. Refer to the screenshot below:

Dashlet - Documents by Workflow Status

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

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

Refer to the screenshots below:

Dashlet - Documents Clarification and Rejection

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

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

Dashlet - eTMF Health

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

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

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

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

Dashlet - My Queries

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

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

Dashlet - Open Queries by Age

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

Dashlet - Popular

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

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

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

Dashlet - Pending Documents Review

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

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

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

Dashlet - Unread

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

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

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

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

Dashlet - Documents to be Signed

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

Dashlet - Milestone Type Report

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

Dashlet - Tasks

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

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

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

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

Dashlet - Recent Communications Log

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

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

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

Dashlet - Users

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

Dashlet - Investigative Sites

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

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

Dashlet - Expiring Sites

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

Dashlet - Recently Updated Sites

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

Dashlet - Site Activation Status

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

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

Dashlet - Study Monitoring Visits

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

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

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

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

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

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

Dashlet - Collaborative Review

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

The followind dashlets are available in the Collaborative Dashlet:

1. Documents to Approve

2. Documents to Sign
3. Pending Documents Review
4. Collaborative Documents

Dashlet - Documents to Approve

This dashlet displays the list of all documents that are pending for approval in TI Collaborative.

Click the document to open the document for appoval.

Dashlet - Pending Documents Review

The **Pending Documents Review** dashlet gives a list of all documents that are pending for review. Click the document to open the document in the TI Collaborate view and complete the review.

Dashlet - Collaborative Documents

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

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

Documents View

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

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

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

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

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

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

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

Table 1: The Documents View

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

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

Documents Module Settings

Important:

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

The settings that need to enabled for a document are discussed in detail in the Settings → Documents → Documents Module.

The Room Index

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

From the Index Pane:

- View the room's folder structure
- Search and navigate to sub-folders
- Modify Index Structure
- Export Index
- Refresh Index
- View Security on an Index Folder
- Export documents from an Index Folder
- Add documents to an Index Folder
- Index Outline Settings and By Index View

Choose View - Viewing the Room's Index Structure

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

To toggle between the various views of the Index Structure:

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

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

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

By Index and Index Outline Settings

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

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

The following settings are configured from the Index Outline:

- By Index View
- Changing the Index Name
- Empty Folders Options
- Hide Index on add new docum
- Auto Indexing

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

By Index View

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

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

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

Auto Prefix

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

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

Documents Count

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

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

Changing the Index Name

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

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

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

Empty Folders Options

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

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

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

Hide Index on add new documents

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

If this setting is enabled:

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

Auto Indexing

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

1. Click the magnifying glass. Full index list appears.

2. Select the folder indicated by the client. In this example, the folder is named **19 nick folder 1**.
3. Click **OK**. The window closes.
4. Click **Save** at the bottom of the **Index Outline** panel.

By Country

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

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

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

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

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

By Site

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

All sites belonging to a particular country are listed under its specific country. Click a site name to list the documents belonging to the site in the Document Grid. Refer to the screenshot below:

The configurations for an Investigative Site can be setup from **Settings -> Investigative Sites**.

The dashlets related to Investigative Sites are:

1. Expiring Sites
2. Recently updated sites
3. Site Activation Status
4. Site Activation Progress
5. Sites Activation by Country
6. Study Monitoring Visits By Country

By Reviewer

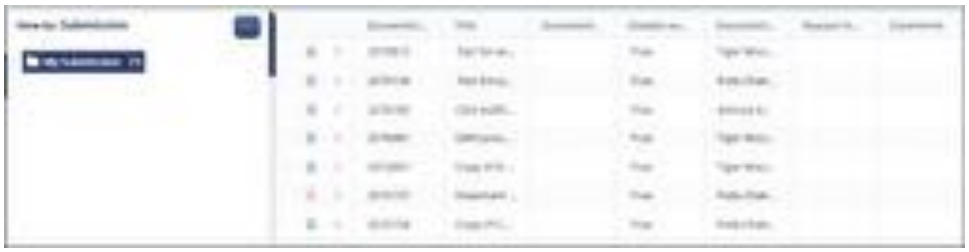
Administrators can reassign documents claimed in the workflow to other reviewers.

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

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

My Submissions

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



My Reviews

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

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

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

By Workflow

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

Non Final Documents By Stage

TO BE ADDED LATER.

By Status

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

By Document Type

This view groups all documents by its Category as the parent folder. Each **Category** folder further holds documents grouped by document types as sub folders.

These Document Types are created from Document Types Management in Room Settings.

Clicking each document type displays the documents of that type in the **Document** view. Refer to the screenshot below:

eSignature

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

Click the folder to view the required documents.

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

By Sender

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

From here the user can:

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

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

By Recipient

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

From here the user can:

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

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

eTMF Completeness

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

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

The system:

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

By Posted Date

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

By Security

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

Processed Documents

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

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

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

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

Deleted Documents

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

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

By Group

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

Missing Documents

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

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

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

Collected Documents

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

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

Modify Index

Configuring the Index Structure

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

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

Adding Parent Folders / Child Folders

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

1. Click the ⋮ icon next to the **View By Index** search box. A popup appears.

   Refer to the screenshot below:

2. Click the **Modify Index** 

icon .
3. The **Modify Index** popup window opens. Refer to the screenshot below:

4. Select the root folder of **Index** from the popup to add a parent folder, else click a parent folder (or subfolder) into which you want to add a subfolder.
5. Click the '+' icon and type in the folder name in the textbox that appears. Press **Enter**.
6. The new folder appears under the root/parent folder.
7. Repeat the above steps to create another parent / child folder.
8. Click **Save**.

Editing Folder Names

1. You can change the name of an existing folder.
2. Click the **Modify index** icon from the popup.
3. The **Modify Index** popup window opens.
4. Click the folder you want to rename.
5. Select the **pencil** icon.
6. The selected folder and its name appear in a highlighted box.
7. Make your changes, then press **Enter**.
8. Click **Save**.

Deleting Folder Names

1. To delete a folder, click the folder in the **Modify Index window**.
2. Click **Delete** folder.
3. Click **Save**.

Note: *Deleting a folder will delete all of its contents including documents and subfolders.*

Important: *If you have already clicked Delete folder in error, you can still click Cancel at the bottom of the Modify Index window. The change will not be saved.*

Exporting and Refreshing Index

Exporting Index

Export index allows you to export the index structure of the room. You can choose to export the index for the chosen folder, or only the index outline. The index can be exported in either HTML, or Microsoft Excel, or Microsoft Word formats. Besides these, you may also choose to export empty, or system folder as also documents unpublished to the eTMF.

To export index:

1. Click the **Export Index** 

from the popup and export the index as per the actions required. Refer to the screenshot below:

Index Search

In the Search box below the **View By Index** pane, enter the name of the folder you want to search.

Press **Enter**, or click the magnifying lens icon to reveal matching contents.

Click the Cross next to the right of the search box to delete the search criteria.

The Documents Grid

You can perform the following from the Documents Grid.

- Preview and Viewing a document and its metadata
- Access the Document Context menu on a document by the mouse right-click
- Configure the Documents Grid
- Copy or move documents

Configuring the Document Grid

Through this option you can decide which columns to display or hide from the Document, Workflow, or Audits Grid. Thus, you can decide exactly what information you want to see and configure the grids accordingly to suit your view .

1. Navigate to **eTMF/Documents** module.
2. Click the **Update Columns** icon from the top right corner of the documents grid. Refer to the screenshot below:

3. The **Grid Configuration** window opens which displays the following panels:
   a. **Available Columns Panel**: This panel display the list of all available columns in a room.
   b. **Selected Columns Panel** : This panel displays the list of all columns that are selected and added from the Available Columns.
4. To add a column to the **Selected Columns** pane from the **Available Columns** pane, hover the mouse over the column name in the Available Coulmns. The + sign appears next to the column name.
5. Click the + sign to add the column to the **Selected Columns.** The column gets added to the list of Selected Columns. Refer to the screenshot below:

6. Alternatively, you can also **double-click** the coulmns in the Available Columns to add to the Selected Columns.
7. After adding the columns to the Selected list, they are **greyed out** in the Available Columns list and a **small green tick** appears to the next of the column name as shown in the screenshot below:

8. Similarly, you can remove the columns from the Selected Columns list by clicking the **-** icon that apppears next to the column name on hovering the mouse over the column OR double-click the column to remove it from the list.
9. Besides adding and deleting columns, you can also change the sequence of the columns by clicking the **Up** or **Down** 

buttons located at the extreme right of the window.
10. Click **Save** to save to changes.

Previewing and Viewing a Document and its Metadata

This allows you to view the document metadata and the document in the seperate panels in the eTMF / Documents module. These are discussed in the sections below:

Viewing Document Metadata

To access the Document Metadata, follow the steps as below:

1. From the **Documents** module, select the document from the grid.
2. Hover the mouse over the bar to the right of the grid. The **Metadata Viewer** 

display with the **Open** text on it.
3. Click the viewer to open the **Metadata Panel**. *Notice that when you open the metadata panel, the Metadata Viewer bar changes the **Open** text to **Hide** clicking which you can hide the metadata panel*

4. The **Document Data Panel** opens which displays the **Document Metadata** by default. Refer to the screenshot below:

As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The icons at the bottom of the panel provide access to several essential functions, such as saving changes and updates in the metadata panel as shown in the screenshot above.

Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings -> General Information section. Refer to the screenshot below:

Previewing a document

To preview the selected document:

1. Select the checkbox next to the document.
2. Click the **Document View** button at the bottom of the grid.
3. The document opens in the Arender view. Refer to the screenshot below with the sequence of steps in number denoted:

Copying or Moving Documents

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Follow the steps below to copy documents:

1. Select the document(s) to be copied or moved in the grid.
2. To **move** the document(s) to another folder, drag the document from the grid and drop it to the destination folder in the Index Pane.
3. To **copy** the document/s to another folder, hold the *Ctrl or Shift key*, and drag and drop the document to the destination folder in the Index Pane.

While copying or moving a document you will be asked to re-code the document profile and will open the **Edit Document Profile** window to enter the details. Follow the instructions to complete the form. You may choose to replace the attachment at this time if required. If you replace the attachment you can view the version history in the document's metadata panel.

Note: *Viewing of version history on replacing attachments is available only in Alfresco rooms. For more details follow on to section Replace Documents.*

If the **Hide Index on add new document** option is on, editors will not be able to copy or move a document and will receive the warning as below.

Documents Grid Views

While in a specific folder, user may want to filter the columns and view only the columns that are required. This can be done by customizing the grid view. You can create your own view and set that particular view as a default view so that you can view only that information which is required in the grid.

Besides, you can also apply filters to the grid and save the view for the future use.

To set and customize a view:

1. Navigate to the **eTMF/ Documents** view.

2. Select the reqiured folder and update the columns as needed. The documents grid gets updated as required.
3. Click the **Views** dropdown at the top right corner of the grid.
4. The list of options appear. Refer to the screenshot below:

5. You can perform the following actions:

   a. Save View
   b. Set Default View
   c. Show all views
   d. Share the Views

Each of this is discussed in the sections below:

Save Views

After updating the columns in the grid, click **Views → Save View**. The **Save View** window opens. Refer to the screenshot below:

Enter the name of the view and enable the options by clicking the toggling buttons below for the default view. You can either make the view default for you or for all the user who access the folder to which the view has been set. Click **Save** to save the changes.

On saving, you can see the name of the view and columns also gets updated. Everytime you visit the folder, you can select the view for the grid. Refer to the screenshot below:

Show All views

If the room has multiple views created in a room, and aif they are visible to all users, you can view all the views in a room.

To display all views:

1. Click **Show All Views** from the from the Views dropdown. Refer to the screenshot below:

2. The **Views** window opens which contains the following tabs:
   a. **All** : This displays the list of all the views in a room.
   b. **Created by me** : This displays the list of all views that are created by you.
   c. **Shared by me**: This displays the list of all the views that are shared by you to the other users.
   d. **Shared with me**: This displays the list of all the views that are shared to you by the other users.
   e. **Default Views**: This displays the list of all default views.

The screenshot below show an example of the **All** views:

Note: *The **Delete** and **Select** buttons are enabled only when you select a view from the list.*

To delete a view, select a view from the list and click the **Delete** button at the top right corner of the window.

Share Views

Note: *This option is enabled in the Views dropdown only when a you select a view created from the list.*

To share view:

1. Select a view you want to share from the list of views. The selected name of the view displays.
2. Now, click the **Views** dropdown. The list of options appear.
3. Click **Share View.** Refer to the screenshot below:

4. The **Share window** opens.

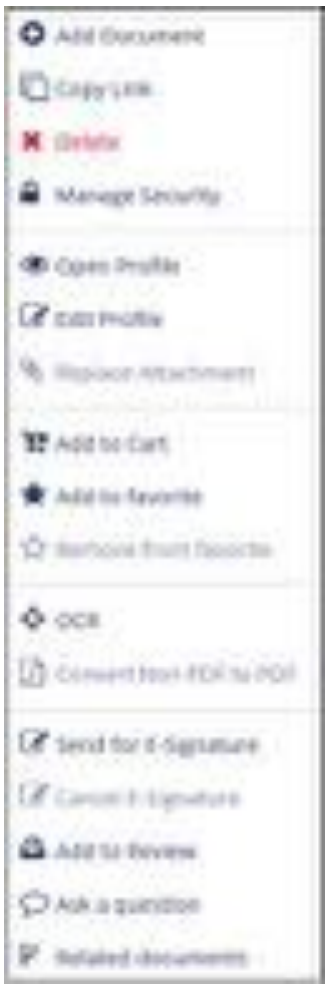
5. Select the **Groups** or **Users** to whom you want to share the view. Double click the user from the left pane to add them to the Selected mambers pane.
6. After selecting Gorpus/Users, click **Share**. Refer to the screenshot below:

7. This shared view now displays under the list of Shared by me in the Show All Views.

Documents Context Menu

You can perform the horde of activities on a document from the Document Actions as well as by right-clicking on a document in the Document Grid.

Refer to the screenshot below to get a list of actions possible from the **Documents Context Menu**. Each of the functionalities are discussed in separate topics available from the left panel of this topic help.



Adding a Document

1. From the **Documents** Module, right-click on a document in the Document Grid.
2. Select the **Add Document** option and the **New Document** window opens. Enter the details as required to create a new Document profile. Refer to the screenshot below:

3. Select the appropriate **Category** from the dropdown list: **General**, **Country**, or **Investigative Site.**
4. Depending upon the category selected, the document's Submitted Name field would appear or disappear. Enter the Submitted Name as required.
5. Select the **Document Type**, and **Document Date**. Type in the date if that is configured for you.
6. Add pertinent Comments, if necessary. The Index position will populate automatically, based on the folder you selected from the index.
7. Click the **Add** button at the right end of the Attachment field to attach a document.
8. Click **Save**.

Deleting Documents

Deleting Documents

To delete a document:

1. Navigate to the **Documents** module.
2. Select the document(s) from the documents grid.
3. From the right-click menu, select **Delete**. Refer to the screenshot below:

Deleted Documents View

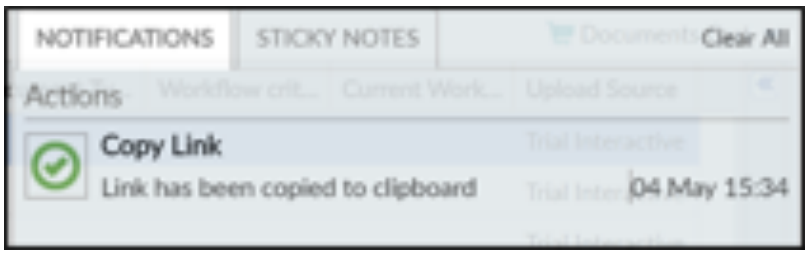
All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.

Copy Link

Clients might need to copy a document link through the Document dropdown in the eTMF module. They can choose the type of document link to copy through **Copy Link Settings** option.

Once the Copy Links settings are made, follow the steps as below to copy a link:

1. Navigate to the **Documents** Module.
2. Select the required document from the grid and right click on it.
3. Click **Copy Link** to **copy the link to a documen**t, or to **copy the link to a document with metadata** and a notification about the same is received. Refer to the figure below:



Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings, the document will either open up in the browser for you to read, or the link will take you to the eTMF room and open the document and its metadata for you to view. **Copying and pasting the link of an empty document shall display the message 'This document profile does not have an associated document'.**

Purging and Restoring Documents

Deleted documents can be restored or purged by clicking the required icon located on the top ribbon from the **Document dropdown** or from the **right-click menu** on the document . Restored documents take the same place in the index they were located in before deletion. Refer to the screenshot below:

Documents can also be **auto purged** if so required by client. For such documents, the admin can enable the Auto Purge form the Room Settings.

Opening Document Profile

In the **Documents** module, select the document and click **Open Profile** from the right-click menu on the document. Refer to the screeshot below:

On clicking Open Profile, you will see the Document Profile for the selected document. In this view, the fields are static. Refer to the screenshot below:

Editing Document Profile

In the Documents module, select the document and click **Edit Profile** from the right-click menu on the document and the fields are no longer static. Refer to the screenshot below:

By this route, an Administrator can edit the document profile. Editing profie is also possible from the Metadata Panel.

Add Selected to Cart

Add Selected Document to Cart

Proceed to section Adding Selected Documents to Cart for the detailed information.

Adding and Removing Favorites

Adding Favorites

Click **Add to favorite** from the Documents Context Menu menu to mark document as favorite. Similary, click **Remove from favorite** from the right-click menu to unmark document as favorite.

Besides, you can aslo click a **Star** to the left of a document to mark/unmark it as a favorite.

Ask a Question

Ask a Question

This allows you to create a question related to a particular subject. Click the link Ask a Question to lead you to the topic

Note: You can also perform this action from the **Documents Actions** dropdown on the top menu bar.

Convert Non PDF to PDF

Convert Non PDF to PDF and PDF fix

This allows you convert the Non PDF documents to PDF. You can view these converted PDF documents under the **Processed view** of the documents.

e-Signature

In this section we discuss about the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

OCR

OCR

This allows you to choose the language for OCR.

OCR can also be performed from the **Documents Actions dropdown** on the top ribbon bar.

To specify languages for OCR:

1. Right-click on the required document from the grid. The **Document Context Menu** popup appears.
2. From the Context Menu, select **OCR**.
3. The **Select OCR languages** popup appears.
4. Click the textbox and select the languages as applicable from the dropdown.

5. Click **Ok.**

Document Process Options

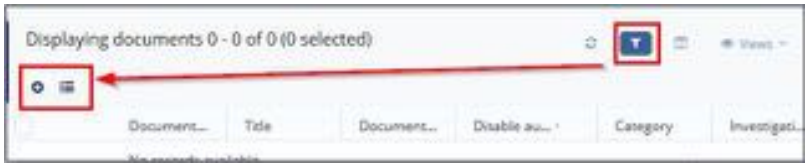
PDF Fix

Grid Filters

For a document grid, you can apply and save filters to make the search for the documents easier.

To apply filters:

1. Click the **Filter** icon above the document grid.
2. The Filter options are enabled at the top left corner of the documents grid. Refer to the screenshot below:



3. From the enabled options, you can perform the following:
   a. Create New Filter
   b. Add Existing Filter/Manage Filter

   Each of these is discussed in the separate sections below:

Creating New Filter

1. Click the + sign above the documents grid.
2. The **Create Filtter** window opens. The window displays the following:
   a. A textbox which displays the **Title** for the filter selected.
   b. The options for matching the filter records. Refer to the screenshot below:

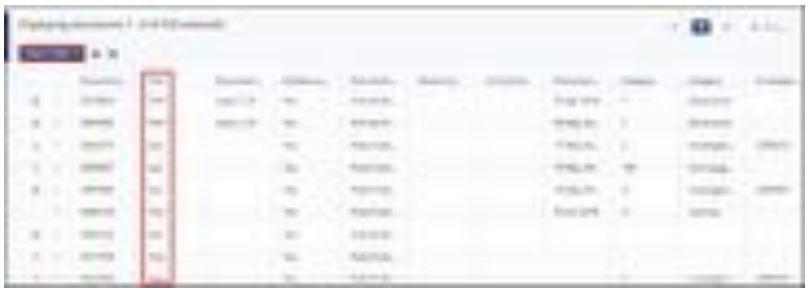
3. Notice that there are two + plus signs to the right of the window wich allows you to create a **single filter** and **group of filters.**

Adding Single Filter

4. To add a single filter, click the **first** + sign. Refer to the screenshot below:

5. A dropdown appears. Click the dropdown and select the fields to which you want to apply filters.
6. Select the operator and enter the value for the selected field. Refer to the screenshot below:

7. Click **Add** if you wish to display the filter in the current view or click **Create** if you want to save the filter and use it later.
8. After creating a filter, when you select the filter and apply it for the document grid, the search results display accordingly. The screenshot below shows an example for the filter result applied for the **Title = Test**.



9. Similarly, you can add group filters to apply for document grid and search for the results by clicking the second + sign 

. Proceed further as discussed above to add group filters.

Add Existing Filters / Manage Filters

Manage filters allows you to view and share the created filters by you and by others. When you click the Manage Filters  icon above the documents grid, the **Filters** window opens. Refer to the screenshot below:

You can perform the following activities on the filters in Manage Filers window:

1. Share Filters
2. Clone Filters
3. Delete Filters

Sharing Filters

To share a filter:

1. Select the filters from the list of filters in the **Filter** window.
2. The selected filter appears in right pane of the window and the buttons **Clone**, **Delete**, **Share**, **Cancel** and **Save** are enabled. Refer to the screenshot below:

3. After selecting a filter, click the **Share** button. The **Share** window opens.
4. Select the **Users / Groups** to whom you want to share the filter and click **Share**.

Deleting Filters

Similarly, select the filter from the list of filters and click **Delete** to delete the filter.

Viewing Shared Filters

You can view the filters that are **created by you**, **shared by you** and that are **shared with you** by clicking the required tabs in the Filters window.

The Working Area and Grid

When you open the **eTMF/Documents** module, the following appears:

1. The Room Index on page 184
2. The Documents Grid
3. The Working Area and Grid

In Trial Interactive 10, the eTMF index is separated from the working folders which include Working Documents, Rejected Documents, Uploaded and Emailed documents . User can perform various actions like **document coding**, **document replacing and attaching** , **adding documents to workflow or audit** etc. from this Working Area. The folders in the working area are hard coded and any documents coming in the room, either by uploading or emailing are available for further process or actions from this Working Area. Refer to the screenshot below:

Besides working on documents, you can also drag and drop the documents from the Working Area to the required eTMF folders above like for the **Country** and **Site** views, the user can easily drag and drop documents from the working folders into **missing documents** and **placeholders** in the eTMF.

Note: *Documents can be dragged only out of Working Area but not into the Working Area.*

Hiding or Unhiding the Working Area/Staging panel

To hide or unhide the Working Area, hover the mouse over the bar above the Working Area. The **Hide - Working Area**bar appears. Refer to the screenshot below:

Hiding the Working Area

You can also drag the Working Area/Staging to the extreme left to hide the Work Area. Refer to the screenshot below:

Similarly, you can also drag the Working Area/Staging Area **up** to increase the size of the window and the number of documents count in the grid.

The Document Data Panel

The Right Panel opens by default in the **eTMF Documents Module** when you click **Documents** from the left pane.

From the **Right Panel** located at the right of the documents grid, you can view the following panels after you select a document from the grid:

1. Metadata panel
2. Workflow panel
3. Queries panel
4. Versions panel
5. History panel
6. eSignature panel

Each of the functionalities above are discussed in separate topics available from the left panel of this help.

You can **hide** this panel by hovering the mouse to the the right of the grid and clicking the **Hide** arrow. Refer to the screenshot below:

Besides, you can also hold the panel and drag it to the extreme left of the page. Refer to the screenshot below:

Metadata Panel

Metadata Panel is activated by default when you select a document.

As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The buttons at the bottom of the panel provide access to several essential functions, such as saving changes and moving to next document in the metadata panel. Refer to the screenshot below:

Notice that you can manual enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings → General Information section.

You can also shuffle back and forth between documents in the grid by clicking the **Previous Document** and **Next Document** links at the bottom of the Metadata panel.

The Metadata Panel also provides the **Claim** button and the **More (Settings)** icons at the top of the panel to allow you to claim docuemnts in a workflow and perform various actions on the document.

Workflow Panel

You can do the follwing from the Workflow Panel:

1. Claim Documents in a workflow
2. View the Workflow History
3. Initiate a Query
4. Release a document from a workflow'
5. Reassign Reviewer
6. Exclude document from a workflow

The Workflow panel dispalys all the details of the document workflow.

Click the **Date** to view from the **Workflow History** section to view the full history of the dcocument in a workflow as shown in the screenshot below:

Queries Panel

From the Queries tab, you can not only view the queries received, but also can resolve them.

You can view queries in TI by various methods:

1. **Query Email :** By the Query Responder from the query email received in his/her inbox
2. **By Recipient View** : The Query Responder can view the queries received under the By Recipient view if the said query responder has access to such a TI room and documents related to the query.
3. **By Sender View**: The Reviewer can view the queries from the By Sender view if such a reviewer is the creator and sender of the query.
4. **By Reviewer**: This view is available only for admins and such a user can view the queries sent and responded by all the reviewers. (add to profiling for admins)
5. **By Reviews**: The reviewer can view all the queries from the By Reviews view which he/she has initiated.

Viewing a Query

To view a query, follow the steps as below:

1. From the **eTMF/documents** application, click **Choose View** next to the Index View.
2. The **View Documents By** popup appears.
3. Select the **By Sender** view and click **Select** at the bottom of the page.
4. The folders with the name of reviewers appear.
5. Click the required folder. The following folders are available for the query:
    a. **Pending**: This folder contains all the queries sent and are awaiting the response.
    b. **In Progress**: This folder contains all the queries which are responded.
    c. **Resolved**: This folder contains all the queries which are resolved.
6. Select the required document from the grid and click **Query** tab from the metadata panel.
7. The queries display in the **Queries** panel.
8. Click the query to view the full query history.
9. The query displays the following:
    a. The email body of the query that was initiated.

b. The responses and attachments to the query displayed by green sections. Refer to the screenshot below:

c. Expand the required section to view the details for the sections.

Viewing Query History

To view the query history, open the required query and click the **Query History** button at the bottom of the Queries panel. This opens the history of the query in the **Query History** window. Refer to the screenshot below:

From the Query History window, select the required query activity from the left pane and the details of the history displays in the right pane.

Versions Panel

Versions Panel allows you to view and compare the different version of a document.

Select a document from the grid and click **Versions** tab from the **Right panel**. The different versions of the document are displayed in the versions tab, if applicable. Refer to the screenshot below:

Clicking **More info** next to the version number opens the **Version History** which gives the detailed view of the document version history. Refer to the screenshot above.

History Panel

The History panel gives an overview of a document history. This panel displays the top four entries of the activities performed on the document. Here, you can apply filters to view the history of a document. Refer to the screenshot below:

Document History Filters

The History Panel provides the following filters to allow you to view a document history:

1. **By Organization**: Use this filter if you want to view the document history based on the organization.
2. **Activity Type**: Use this filter if you want to view the document history by the activity performed on it.
3. **Date Filter**: Use this filter if you want to view the document history within the set date range.
4. **View All History**: Click this button to view the full history of a document. The full document history opens in a popup. You can also apply the filters from the **All History** popup.

Viewing Document Activity

Every activity in the History panel is denoted by a node. Click the node to view the **description**, **date**, **time**, and **name of the person** who performed the activity on the document. Refer to the screenshot below:

Viewing All History

Clicking the **View All History** button 

opens the **All History** popup which displays the complete history of a document and also allows you to filter the document history based on the **Organization**, **Activity Type** and **Duration**. Refer to the screenshot below:

eSignature panel

The eSignature Panel:

1. Allows send the document for eSignature if it is not initiated for eSignature yet.
2. Display the status of the document eSignature if it is initaited for eSignature.

Besides eSignature Panel, you can aslo send the documents for eSignature from the **Document Context Menu** by right clicking on a document.

Cancel eSignature

If the document is waiting for eSiganture, the eSignature Panel displays the status of the document as shown in the screenshot below:

Select the eSignature and click the **Cancel E-Signature** button at the bottom of the eSignature Panel if you wish to cancel the eSignature of any document. Click **Yes** on the pop-up that appears to confirm the cancellation.

The Top Ribbon Bar

This bar is located at the top of the Documents Dashboard and allows access to various functionalities on documents:

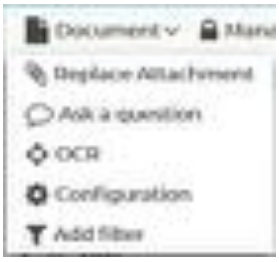
- The Document Actions
- Manage Security on documents
- Print
- Email
- Move to Startup
- Import
- Export
- Comparing Documents
- Documents Cart
- Dashboard Layout

Refer to the screenshot below:

Each of the above functionalities is discussed in separate topics available from the left panel of this help.

Document Actions

You can perform the horde of activities on a document by from the Document Dropdown located on the top ribbon bar of the eTMF Documents Dashboard.



Each of the functionalities are discussed in sections below:

Replace Attachment

To replace a document attachment or URL:

1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.
2. The dropdown appears.
3. Select **Replace Attachment / Add URL**.
4. The **Replace Attachment / Add URL** popup window opens.
5. Select the **File** radio button to replace an attachment, or select the **URL** radio button to replace the URL
6. To attach a document click **Browse** and select the required document from the Explorer, whereas to replace a URL ????
7. Enter the reason for replacement.
8. Click **Apply**

Ask a Question

Click the link Ask a Question to lead you to the topic.

OCR

To select languages for OCR:

1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.
2. The dropdown appears.
3. Select **OCR**.
4. The **Select OCR languages** popup appears.
5. Click the textbox and select the languages as applicable from the dropdown.

6. Click **Ok.**

Manage Security

The Trial Interactive platform allows for two different approaches for defining security rights in the Trial Interactive site. Security can be set on a **folder level** or on a **document level**.

Note: *You can also Manage Security for Sites which is different from managing security for documents and is discussed in topic **Manage Security for Sites**.*

Folder Level Security

This allows to assign security for the individual folders in the Index of the room. This automatically applies the security to the documents when they are uploaded in the assigned security folders.

To assign Folder Level Security:

1. Click **Mange Security** 

from the top ribbon bar. The **Manage Security** window opens. Refer to the screenshot below:

2. Select the **Folders** button from the **Select a Target section** in the left panel of the window. The panel on the right that displays the Index structure becomes active allowing you to select exactly to which folders you would like to apply the security change. You must select at least one folder from this list.

   By leaving the **Apply same security as the parent folder** checkbox unchecked, you can select specific subfolders on which to modify the security settings. If you check the box, you need only to select the main folders whose security settings you want to modify.

3. Select the checkbox next to the folders to which the security is to be applied.
4. Select the Security Update Type for the folder from the following options.

Security Type	Description
Update existing security	This option leaves all current security definitions in place and adds on any new definitions set in step two of the manage security process.
Over write security	This option erases all current security definitions and replaces entirely with the definitions set in step two of the manage security process.
Remove from existing security	This option leaves intact any security definitions already assigned, but removes access for any group(s) or user(s) specified in step two of the manage security process.
Restrict access to Administrators only	This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.

5. Click **Next**. The **Access and Security** step of the Manage Security opens.
6. Using the **Groups** and **Users** tabs on the left side of the control window, select the Groups and/or Users to update security rights.Refer to the screenshot below:

7. Hover the mouse over the group/user name in the left pane. The **Plus icon** appears to the right.
8. Click the **Plus icon** to add the group and /or users to the Security Grid to the right pane. *Notice that the group and /or user is grayed out when you add them to the Security Grid and a small green tick appears to the right of the selected group/user.* This moves the Groups and/or Users into the **Security grid** on the right. Refer to the screenshot below:

9. Select the required security definitions that you want to update for the selected group/user.

Security Option	Description
Full Access	Non Encrypted access allowing for full printing and saving rights
View Only	Allows users to only view the PDF while restricting printing and saving
No Watermark	If the watermark is in use in the site, this access will provide the users access to a non-watermarked version of the PDF file
Redacted	Gives the users access to the redacted version of the file while preventing access to the original (non-redacted) version

10. Click **Save**. This applies the security permissions on the folders for the selected groups and/or users.

> **Note:** *By selecting the target as All documents in the top left panel of the Manage Security tool, you need only to Select the security update type before clicking Next and selecting which groups or users to include in the security modification.*

Document Level Security

> **Note:** *To set the document level security, the option for document security needs to be enabled in the room by your Administrator.*

This allows for security definitions to be set at the individual document level, allowing for the greatest control and flexibility on the security definitions as documents within a single folder can have different security/access rights. If document level security is used, each document will maintain its unique security settings, even as it is moved from one folder to another in the index outline, until its security definitions are changed.

1. Open a folder that contains documents from the Index outline.
2. Select one or more documents from the Document Grid whose security setting you want to modify.
3. Click the **Manage Security** button located in the upper toolbar. The Manage Security tool opens.
4. Click the button for **Selected documents**.
5. Select the security update type by clicking one of the four options, as described in the previous section of this guide.

6. Click **Next**. The second stage of the Manage Security tool populates the window.
7. Using the **Groups** and **Users** tabs on the left side of the control window, select the Groups and/or Users to update security rights for by double clicking on the listings. This moves the Groups and/or Users into the **Security grid** on the right.
8. Select which security definitions you want to update for the selected group/user, as described in the previous section of this guide.
9. Click **Save**, and the security definitions are in place.

By Security View

The By Security view shows the list of all the documents based on the security provided to the folders. To view the folders by security:

1. Click the **three dots**  next to **View by Index**. The **View Documents By** pop-up opens.
2. Select the **By Security** view**.**
3. Click **Select**. The Index displays the documents and folders based on the security level.

By group

The By Group view shows the list of all the documents and folders belonging to a particular group. To view the folders by group:

1. Click the **three dots**  next to **View by Index**. The **View Documents By** pop-up opens.
2. Select the **By Group** view.
3. Click **Select**. The Index displays the documents and folders based on the security level.

Email

To email a specific document as attachment or as a link, click the **Email** option from the top robbon and follow the on-screen instructions. You can save an outgoing email as a PDF documnent. On clicking **Send**, the **Save Converstion** dialog box opens up. Refer to the screenshot below:

If required, you may also opt to save the document as PDF and publish it to investigative sites. Upon selecting your option, the **Document Profile** dialog box pops up. Enter the details and click **Finish**. The email communication is now saved as a PDF document in the folder as mentioned in the **Default index position for Add document** in the **Settings -> Documents -> Index Outline**. The email PDF has only Subject, date sent, and body of the email as its contents. You can view this email sent from the **Communications Outbox** module.

Print

The **Print** function is self-explanatory. You can order a printed hard copy of a document through this menu option.

1. To activate the **Print** function, first click a folder in the index so that documents populate on the document grid.
2. Select one or more documents from the grid that you want to print.
3. Click the **Print** 

icon from the top ribbon. The **Print** window opens.
4. Click the appropriate radio button, **Selected Records** or **All Records in Set**.
5. Click **Print**.
6. Follow the usual steps of creating a printout from your computer.

If the user has opened a folder with documents and has not selected a document or particular set of documents from that view, the **Print** option is still available. When the user clicks the option without having selected a document, the default is to print all of the documents in the set. Follow the on-screen instructions to complete this operation.

Move to Start-Up

Note: *The Move to Start-Up option is available only in rooms in which the Start-Up Module is active.*

Move to Start-Up option can be used to **move documents from the eTMF back to the appropriate Start-Up folder** in the case that documents have been delivered and deposited in the eTMF prematurely.

1. Navigate to **Main Navigation-> eTMF module**.
2. Select the required document/s from the grid and click the **Move to Start-Up** button 

from the top ribbon bar.

Import

You can import multiple **documents** and **metadata** using just their metadata to a room. Click the **Import** 

dropdown to reveal the import options - **Documents** and **Metadata**.

Each of these are discussed in the seperate topics and can be accessed from the left of this menu.

Export

Documents can be exported from:

1. The **Export** dropdown from the top ribbon bar
2. The **Documents Cart**
3. The **Download documents** when opening a document in the **Original Viewer**

Three options are available for Administrators from the **Export Dropdown** on the top ribbon bar - **Metadata**, **Documents**, and **Security**. Refer to the screenshot below:

All of these options are discussed in seperate topics accessible from the left panel of this help.

Exporting Metadata

This function gives you a compressed file with the information you requested in XLSX spreadsheet file

To export metadata,

1. Click the **Metadata** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:

2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
   a. **Select All**: Tick this checkbox if you wish to select all metadata fields.
   b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.
4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:

5. Click **Export**.

Exporting Documents

Exporting documents is same as downloading documents from the **Documents Cart**.

You can **track an export**, **exclude previously exported documents**, or **include metadata during export**. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.

The documents or selected documents get exported in a .zip file. The .zip will include the following:

1. A **folder with the exported documents** in it.
2. An **excel worksheet** with the metadata, if you happen to export metadata.
3. A **.log** file which opens in Notepad to give the list of previously exported documents that were excluded during export. Here again, you have to select the option to exclude previously exported documents to enable this.
4. An **ErrorsLog.xml** file that includes details of documents that fail to export.

To view the exported file, navigate to the **Notifications .**

Exporting Security

This allows you to export all the security accesses for selected records for all documents in the grid, all documents in the room. The output of the export job is an .xlsx file that can be accessed from the **Notifications.** Follow the steps below to export documents security:

1. Click the **Security** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:

2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:

a. **Select All**: Tick this checkbox if you wish to select all metadata fields.
b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.

4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:

5. Click **Export**.

Layout

You can change the layout view of the grid by clicking the Layout option from the top ribbon bar. Follow the steps below to change the layout of the gird.

1. Navigate to **eTMF Documents module.**
2. Select the **Layout** 

option from the top ribbon bar. The **Select Layout** popup opens.

   Refer to the screenshot below:

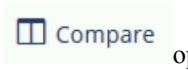
3. Select the required layout and the document grid sets it layout as selected.

Compare

Documents can be compared from in the following ways:

1. From the top ribbon in the eTMF Documents module.
2. From the Documents Cart.

To compare docments,

1. From the **eTMF Documents** module, select the folder from the Index to open the documents in the grid.
2. Select the required documents to compare and click the **Compare** 

option from the top ribbon bar.
3. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the viewer chosen by you. You can also expand the metadata fields on the bottom using the double-caret bar to compare documents metadata conveniently at once.

Bulk Uploading

Besides Importing documents, you can also upload documents in a bulk to the room. Follow the steps below to bulk upload documents in a room.

1. Navigate to **eTMF Documents** module.
2. Click the **Bulk Upload** 

option from the top ribbon bar. The **Import Documents** window opens.
3. Following the on-screen instructions, either drag-and-drop files from your own computer into the upload panel or use the **Browse** button on the window to select documents to upload. Refer to the screenshot below:

4. Choose **Unpack Zip-archives** if you wish to extract files from an attached zip folder.
5. Tick the checkboxes for documents to be uploaded and click **Import.** These documents are uploaded to the upload folder. You can later edit the metadata of these documents from the **Metadata Panel** as required.

Documents Cart

Perform various functions from here like **copying documents to rooms or sites, comparing, merging or linking** documents besides many more.

Users select documents to add to the Document Cart either from the Documents Context Menu, or by selecting documents from the grid and then clicking the **Add to Cart** button from the top ribbon menu.

The **Documents Cart** 

icon is located on the upper right hand corner of the document grid and works just like a shopping cart.

Adding documents to the Documents Cart

1. Locate the document which is to be added to the Document Cart and select the checkbox next to it. Now process of addition can be done in two ways.
   a. Click **Add to Cart** from the upper right hand corner.
   b. Right click and select **Add Selected to the Cart** option.
2. Once a document is added, it will automatically update to reflect the number of documents available in the cart. Refer to the screenshot below:

Removing documents from the Documents Cart

Follow the steps below to remove documents from the Documents Cart:

1. Click the arrow next to the **Documents Cart**. A popup window opens.
2. Select the checkboxes next to the documents and click Delete button to the right of the selected documents.
3. If you wish to remove all the documents, click the **Remove All** button. Refer to the screenshot below:

Copying documents to Other Rooms

Trial Interactive allows Cross-Study **Copy** of Documents through this functionality. When users select the **Copy to Other Rooms** option from the Documents Cart, selectred documents as well as their metadata will be copied to other rooms.

1. Add required documents to the Documents Cart.
2. Click the arrow next to the Documents Cart. A pop-up opens.
3. Select the documents wich you wish to copt to other Rooms.
4. Click **Copy** and select **to other Rooms.** Refer to the screenshot below.

5. The **Clone Document** window will open up and prompts you to specify to which study rooms documents shall be copied.
6. Click the **Select** button which opens the **Rooms** window to allow you to select the rooms to copy the documents to.
7. If you wish to publish documents to the insdex as final documents without going through the workflow, select the checkbox next **to publish documents to the index as final documents**.
8. Click **Clone**. The document type of the destination room will determine the auto-naming rule for the document. Refer to the screenshot below:

Copying documents to Investigative Sites

This option is helpful when Administrator users wish to distribute the same document, such as training documents, across different investigative sites. To avoid copying these documents one-by-one, you can simply use this option in Documents Cart.

1. Add required documents to the Documents Cart.
2. Click the arrow next to the Documents Cart. A pop-up opens.
3. Select the documents which you wish to clone to other Investigative Sites.
4. Click **Copy** and select **to Investigative Sites**. Refer to the screenshot below.

5. The **Clone Documents to Investigative Sites** window opens up and asks you to select investigative sites. Click radio button next to your choices.
   a. If you choose **All Sites**, just click **Next**, to select the folder to which the documents will be cloned.
   b. If you choose **Specific Sites**, just click **Next**, and it will give you site choices on the next section.
   c. If you choose **By Country**, a dropdown with the list of countries gets activated for you to choose from.
6. Click **Next** folder selection.
7. Once the folder is selected, click **Clone**. The documents are copied to the Investigative Site folder. Refer to the screenshot below:

Compare Documents

The **Compare Documents** tool in Documents Cart lets you view and compare two or three documents at the same time by placing those side by side. You can use the **ABBYY Optical Character Recognition** (if that is enabled for you) to support the comparison of documents from document scans and images.

1. Add required documents to the Documents Cart.. A pop-up window opens.
2. Select the documents from the list you wish to compare.
3. Click **Actions** at the bottom of the window and then select **Compare**. Refer to the screenshot below.

4. The documents open in the **Compare Documents** window with each document side in a seperate window of their own using the **Arender** view. Refer to the screenshot below:
5. To facilitate easy and seamless comparison of documents:
   a. The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
   b. The **documents scroll at once in sync** with each other when you drag the scroll bar to facilitate easier viewing and comparison if you have activated the 'Synchronize document scrolling' from the toolbar.
   c. The system displays appropriate messages when two documents are identical.

d. The print and download options for comparison are available to you only if you have **Full Access** to the documents.

Merging documents

An Administrator user can merge two or more documents into one document.

1. Add required documents to the Documents Cart..
2. Select the documents form the cart you want to merge into one, either to use as a single document in the room or to download and print as a single document..
3. Click **Actions** and then select **Merge**. Refer to the screenshot below.

Linking documents

Administrator users can link documents together with this option.

1. Add required documents to the Documents Cart.
2. Select the documents from the cart.
3. Click **Actions** and then select **Link.** Refer to the screenshot below:

4. The **Link Documents** window opens. Select 2 or more than 2 documents to link and click **Yes**. Refer to the screenshot below:

5. A pop-up message appears to confirm the documents are successfully linked.
6. Afterward, whenever you right-click on one of the linked documents and click **Related Documents**, interrelated documents will all be displayed on the screen.

Adding documents to Audit

Admin can add documents to the cart from the grid and include them in an existing audit by using the **Add to Audit** option.

1. Add required documents to the Documents Cart.
2. From the Documents Cart, select a document.
3. Click **Actions** and then select **Add to Audit**. Refer to the screenshot below:

4. The **Select Audit** window opens.
5. Select the Audit to which you wish to add documents to.
6. Click **Select**. Refer to the screenshot below:

Note: *The Audits in the Select Window are displayed only when you select Add Documents to pool on Demand Basis option while creating an Audit profile.*

Create Audit Profile

Admins can add documents to the cart from the grid and create audit profiles using the **Create Audit Profile** option.

1. Add required documents to the Documents Cart.
2. From the Documents Cart, select a document.
3. Click **Actions** and then select **Create Audit Profile**. Refer to the screenshot below:

4. The **Create Audit Profile** popup opens.
5. Follow the instructions on the form to create the audit profile as required.

Note: Creating Audit Profiles are discussed under the Quality Review section in detail.

Adding documents to Submission Package

Admin can add documents to the cart from the grid to include them in a start-up submission package by using this option.

1. Add required documents to the Documents Cart..
2. Select the documents from from the cart.
3. Click **Actions** and then select **Add to Submission Package**. Refer to the screenshot below:
4. The **Select a Submission** window opens.

Marking documents as Popular

Administrator users can mark certain documents as popular using this option.

1. Add required documents to the Documents Cart.
2. Click **Actions** and then select **Mark as Popular.** Refer to the screenshot below.
3. A pop-up message- **Documents successfully marked as popular** appears.
4. The selected documents now appear on the dashboard- **Popular Documents** dashlet

Downloading documents

1. Add required documents to the Documents Cart.
2. Click **Actions** and then select **Download**. Refer to the screenshot below.

Adding documents to existing review

Admin can add documents to the cart from the grid and include them in an existing review workflow by using the **Add to existing review** option.

1. Add required documents to the Documents Cart.
2. Click **Actions** and then select **Add to existing review**. Refer to the screenshot below.
3. The **Select a Review** window opens. Select a review from the list of reviews and click **Select.** Refer to the screenshot below:

4. **Confirmation** pop-upopens. Select **Yes**.
5. **The review were added successfully** message appears. The review can be accessed from the**Collaborative Authoring** module.

Creating a new review

Admin can also add documents to the cart from the grid to include them in a new review workflow by using the **Create new Review** option**.**

1. Add required documents to the Documents Cart.
2. Click **Actions** and then select **Create new review**. Refer to the screenshot below:

3. The **Create review** window opens. Fill in the details under **New Review Info, Participants,** and **Documents**.
4. Click **Save**. **New review was successfully created** message appears.

Potential Sites and IRB Integration

This allows you to locate the Unique Sites using the combination of Study Name and Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

Note: *If the system finds matching conditions like site, IRB number and IRB document type in the Study Start-up Site Profile, the documents for the imported site will be uploaded into the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which is discussed below.*

This section includes the following sections:

1. IRB Integration and Settings
2. Potential Sites and Modules

Dashboard Dashlets

Know how to configure dashboard and dashlets in a room.

All Trial Interactive dashboards are primarily composed of dashlets. As a user you can configure your dahsboards to suit your preferences, views and convenience for efficient performance.

Individual users in Trial Interactive have the option to arraneg their own Dashboard views.

Arranging your dashboard views include deciding:

1. The layout of the dashlets on your dashboard by moving them around,
2. The dashlets to view along with their distribution on the dashboard, and
3. The configuration of each dashlet.

Dashlets

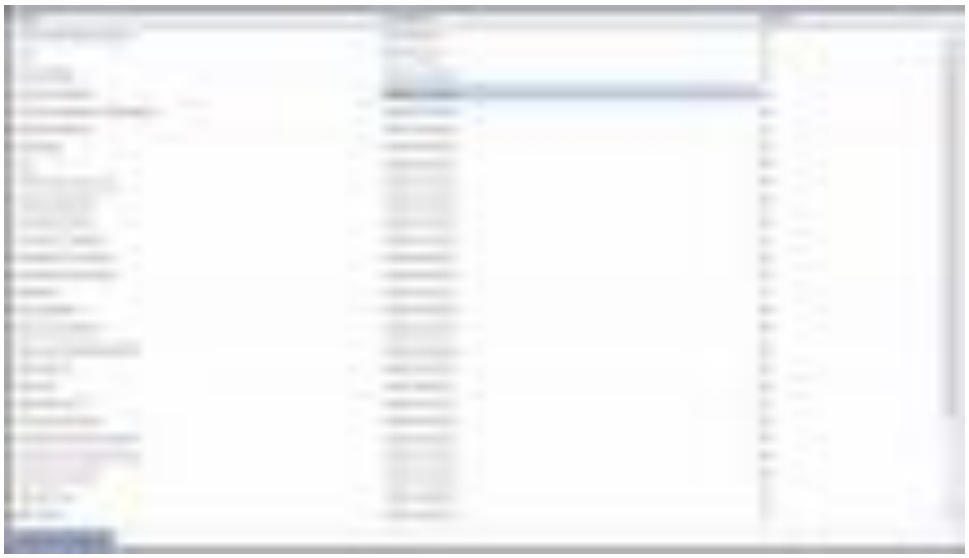
A dashlet is a component in a dashboard with functionalities of its own. A dashlet may provide information on a particular feature in the form of a report, a graph or a description on a particular topic. Dashlets are independent of each other and are contained in a dashboard. In a way of its own, they play a significant role in the look and feel of a dashboard.

To visit a Room Dashboard, click **Dashboard** from the left menu from the eTMF module. Refer to the screenshot below:

Dashboard Settings

As one of the sub-section of **General** room setting tabs, the Administrator will see the **Dashboard Setup** box. An Administrator can change the information that will be available to users in the room when they access their **Dashboard**.

To **modify the availability of dashlets** to users, here are the steps to follow.



1. Navigate to **Main Navigation-> Settings -> General -> Dashboard Setup.**
2. Double-click any of the dashlet lines in the **Available for** column.

   The field becomes active with a dropdown arrow at the right end of the field.
3. Click the dropdown arrow. A set of selections becomes available to the Administrator.

4. Select which users in the room will see any particular dashlet in their **Dashboard** views.
5. Click **Save** if you have made acceptable changes.

From the Dashboard Settings, the following activities are available:

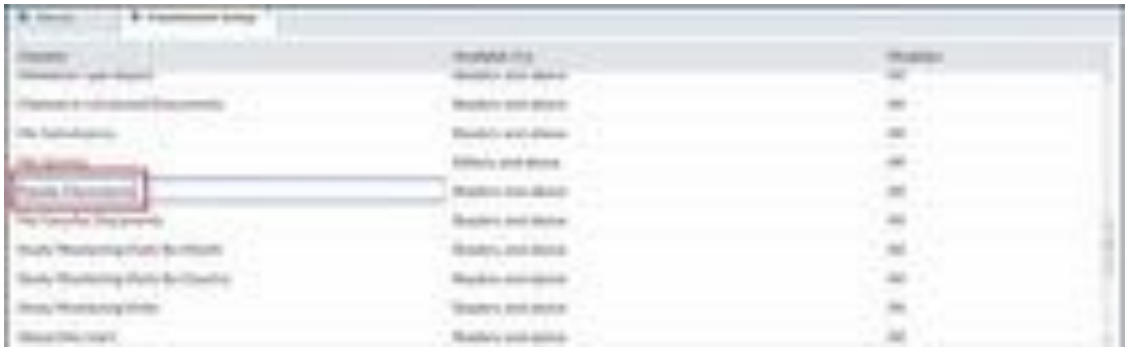
1. Renaming a dashlet
2. Default Dashboard Setup

Above activities are discussed in details in the sections below.

Renaming a dashlet

To **rename a dashlet** follow the steps as below:

1. Double-click the name of a dashlet that you want to rename from the Dashlet column of the Dashboard Setup window.



2. Type in the new name into the activated field.
3. Click **Save**.

Default Dashboard Setup

You can set the default dashboard for the minimum level role by clicking the button at the bottom of the Dashboard Setup panel. The **Default Dashboard Setup** window opens. Make the appropriate choices as required and click OK.

Configure Dashboard

The ***Configure Dashboard*** icon at the extreme top left corner of the Dashboard page opens the **Setup Your Dashboard** window which lists out the dashlets available for a particular dashboard.

Refer to the screenshot below:

The dashboard is divided into the following parent dashlets which have child dashlets associated with each of them:

1. Documents
2. Users
3. Recent Communication Log
4. Common

   Click the arrow next to the required parent dashlets to revel the child dashlets to add them the dashboard as shown in the screenshot above. On selecting the dashlets, click **Save** and the dashlets appear on the dashboard.

Laying Dashlets in your dashboard

To arrange the dashlets, simply drag-and-drop them to a location of your choice on your dashboard. This is demonstrated below:

Dashlet - Common

The Common Dashlet gives the overview of the room and the related information to the room. Administrators can rename thedashlet by clicking the **Pencil** icon from the top the right corner of the dashlet and refresh the dashlet by clicking the **Refresh** icon .

The following tabs are available in the dashlets:

1. About The Room
2. Updates
3. Project Links
4. My Courses

Each of these are discussed in the seperate topics. Click the topics on the left to open the topic.

About This Room

Click the **Show** button to reveal the **About This Room** dashlet. This is typically configured by Administrator level users to Welcome new users and provide them with information pertaining to the room. An administrator can also upload any information through the room's Settings that is pertinent to the study that they would like to share with users.

The standard Welcome message offers the following links.

- Link to help desk email. Use this email address when you have technical issues with the Trial Interactive tool.
- Link to Adobe Acrobat download site. You need an up-to-date document viewer to view documents.
- Link to special browser plug-ins so that you can view encrypted documents.
- Click the ‘x’ to dismiss the popup.

You can click the **Edit** icon at the top right corner of the dashlet to type in new information or edit existing information on the dashlet. After editing the dashlet contents, click **Save** to save the contents and exit, or **Cancel** to exit from the Edit screen.

Dashlet Common - Bulletin Board

Dashlet Common - Project Links

The Project Links tab displasy the links to different systems that are used for the study and their contact information.

Note: *The project links are displayd in the tab only when you select the Shared button located at the right of the tab.*

Following activities are available for the administrators in the Project Links tab:

1. Adding a new link
2. Editing a link
3. Deleting a link

Each of these activities are discussed in the sections below:

Adding a new link

To add a new link:

1. Click the **Create**  button from the top left corner of the tab.
2. The **Create Project Link** window appears.
3. Enter the URL, Title, Contact details, Email, Logo and any description.
4. Click **Create** at the bottom of the window. The link is added to the Project List. Refer to the screenshot below:

Editing a link

Click the **Edit** icon  next to the link. Follow the on-screen instructions and edit the required details.

Deleting a link

Click the **Deletet** icon  next to the link. Follow the on-screen instructions to delete the link.

Dashlet Common - My courses

Dashlet - Documents

The Documents Dashlet gives an overview of the all documents and their related activites in a room. Refer to the screenshot below:

The dashlet provides the **Right** and **Left** arrows to the extremes of the dashlet to allow you to navigate to the sub-dashlets dashlets contained in the Document Dashlet.

Besides, for every dashlet of the Doucments Dashlets, you can also use the **Previous** and **Next** arrows to move among the documents in the dashlet as shown in the screenshot above.

The Documents Dashlet contains the following tabs related to documents:

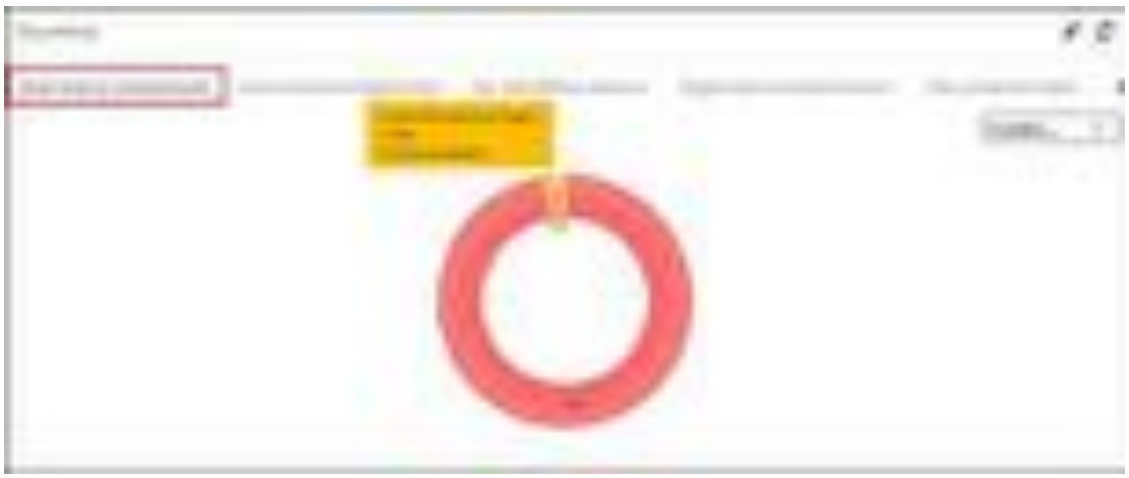
1. Claimed & Unclaimed
2. Documents Expiration
3. By Workflow Status
4. Rejection and Clarification
5. Documents View
6. eTMF Health
7. My Queries
8. Documents Submissions
9. Open Queries by Age
10. Popular Documents
11. Pending Documents Review
12. Unread
13. My Favorite Documents
14. Milestones Timeline
15. Milestone Type Report
16. Tasks

Each of these are discussed in the seperate topics. Select the topic from the left pane to open it.

Dashlet - Claimed & Unclaimed

The **Claimed vs. Unclaimed Documents** dashlet provides a count of all documents that are in a workflow and are either **claimed**, **unclaimed**, or **in progress**. You can further click on each slice of the interactive donut chart to obtain further detailed information.

The dashlet also provides the dropdown to select the workflow as required and dispay the Donut Chart as per the selected workflow. Refer to the screenshot below:



Dashlet - Documents Expiration

The **Documents Expiration** dashlet lists the **expiring** and **expired** documents as specified in the expiration period (N). The dashlet has two views that can be selected through an **Expired** dropdown. To set the views click the **Expired** dropdown located on the top left corner. Refer to the screenshot below:

Click the **Add New Version** button from the top right corner of the dashlet to replace a document.

This opens the **Add New Version window** which provides the available methods to replace an attachment, or add a new document and retain it alongside the older version, or remove the older version if a new version is already submitted. Refer to the screenshot below:

Dashlet - Documents by Workflow Status

The **Documents by Workflow Status** dashlet displays the document processing status in the document review workflow through donut chart. By changing the dropdwon menu, you can view the document processing status:

1. As a complete Room Summary, or
2. As workflow stages defined.

Refer to the screenshots below:

Dashlet - Documents Clarification and Rejection

The **Documents Rejection and Clarification** dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.

You can further double-click on the count to view the list of documents associated with a particular rejection or clarification reason. Refer to the screenshot below:

Dashlet - eTMF Health

The **eTMF Health** dashlet displays a donut chart that indicate what percentage of required eTMF documents are either collected or currently missing. From the top right corner of the donut chart, Administrator users can manually set the chart type to be displayed.

Hovering the mouse over the donut chart shows a popup with more detailed progress percentage for the category of the documents.

Click a donut to drill down to the lowest level to list the missing/placeholder documents. Additionally, you can use the **Add Placeholder** button 

to conveniently upload a missing document/placeholder, or to edit a placeholder right off the dashlet. To view any changes, refresh the chart to update the missing documents list. Refer to the screenshot below:

Dashlet - My Queries

The **My Queries** dashlet gives a list of documents based on their queiry types. The query types could be All, Workflow, or Audit. Refer to the screenshot below:

Click the **All dropdown** to toggle between different views to view the queries.

Dashlet - Open Queries by Age

The Queries by Age dashlet conveniently displays those documents that are 30 days and older in age and also provides a documents count. The query types could be **All**, **Workflow**, or **Audit**. Click the arrow next to the age to reveal the queries listed in the query type. Refer to the screenshot below:

Dashlet - Popular

The **IP Release Documents** dashlet displays the list of documents that have been **marked as popular** by an Admin or Editor through the Document Cart and which are used frequently.

To remove a document from the Popular list, click **Remove from Popular** button on the dashlet.

To view the document, click the icon. Refer to the screenshot below:

Dashlet - Pending Documents Review

The **Pending Documents Review** dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for **All** users, or only for yourself through **My Review**. Refer to the screenshot below:

Click the **All Pending Documents dropdown** from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

1. **My Pending Documents**: This display the list of all pending documents that are assigned to you for review.
2. **All Pending Documents**: This display the list of all pending documents that are pending for review in a room.

Dashlet - Unread

The **Unread** dashlet shows the three different views of documents in eTMF module - **Unread** , **Pending** and **Unclaimed**. Refer to the screenshot below:

Click the **Unread** button to list any of the documents posted in the Trial Interactive site that have not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of.

Click the **Unclaimed** button to get a list of documents that have not been claimed for review.

Click the **Pending** button to get a list of documents that are yet to be reviewed.

Dashlet - Documents to be Signed

The **Documents to be Signed** dashlet gives a list of document pending for signature. Refer to the screenshot below:

Dashlet - Milestone Type Report

The **Milestone Type Report** dashlet gives the percentage of missing/placeholder documents, or collected documents for a particular milestone type associated with a site in the form of a bar graph.

Dashlet - Tasks

The **Tasks** dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the **Status** and the **Assignee**from their respective drop-downs to get the task details.

All Tasks lists all the tasks belonging to the selected assignee.

My Tasks lists all the tasks pending recently, today, or are overdue.

You can also export selected tasks or all tasks in the current grid by clicking the **Tasks Export** icon located on the top right corner of the dashlet. After the export job is over, you can retrieve the job result from the **Notifications** by clicking **Get Job Result** which then downloads the export job as an .xlsx file on your hard disk.

Dashlet - Recent Communications Log

The **Recent Communication Logs** dashlet gives a list of all communications made during the site start-up and activation stage.

Clicking the **View All Communication log** link from the top right corner of the dashlet to view the list iof all communication log.Refer to the screenshot below:

You can also rename the dashlet by clicking the **Pencil** icon to the right of the dashlet and refresh the dashlet by cliking the **Refresh** icon .

Dashlet - Users

The **Users** dashlet provides a helpful option that lists new users or all users in a study with filters to sort users by organization and by their organization and access level (role). You can also invite a new user here by clicking the **Invite**button placed in the upper right corner. **Double-clicking** the icon next to the Last name opens the **Edit User** popup to allow editing of the user profile. Refer to the screenshot below:

Dashlet - Investigative Sites

The Investigative Sites dashlet display the overview of Sites in the form of Pie Chart. The dashlet contains the following tabs for the related to the sites:

1. **Expiring** : Display the details and count of expired sites in the form of Pie Chart.
2. **E-Feasibility by Country**: Display the count and details of sites based on E-Feasibility by Countries.
3. **Study Monitoring Visits**: Display the count of sites based on the Study Monitoring Visits.
4. **Recently Updated**: Display the count of all recently updated sites.

Dashlet - Expiring Sites

The **Expiring Sites** dashlet gives a list of all sites that are expiring in a future date. Refer to the screenshot below:

Dashlet - Recently Updated Sites

The Recently Updated Sites gives the activation progress of all sites in a room. Hover the mouse over the Progress% column to view the list of documents that are missing to complete the site activation. Refer to the screenshot below:

Dashlet - Site Activation Status

This dashlet offers three views – Sites By Country, e-Feasibility By Country, and Sites Activation Progress.

Select the **Site By Country** view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshot below:

Dashlet - Study Monitoring Visits

The dashlet **Study Monitoring Visits** provides two different views study monitoring visits – **Monitoring Visits By Month,** and **Monitoring Visits By Country**, in the form of a donut chart. This dashlet can be configured to display the **Visit Date** instead of the **Created Date** through the **Configure Dashlet** feature as discussed above. Refer to the screenshots below:

The dahslet provides the **Date Ranges** to filter the sites. Besides selecting dates in the date columns, you can aslo scroll the bar between the ranges to filter the sites.

When you select the '**By Country**' option from the dropdown at the top right corner, you will be finally be able to view the documents for the particular country. Click the section on the donut chart to delve further for the country documents.

The **Study Monitoring Visits** dashlet is connected to the **Document Type Settings**. Therefore, Administrator users can go to **SettingsàDocumentTypesàDocumentTypesManagement**, and assign or modify document types. Through the configuration box, users can manually specify whether to include the document in the Monitoring Visits or not.

If you choose to include a new document type, the **Study Monitoring Visits** dashlet will be updated to reflect the change.

For your convenience**,** a **search box** and a **filter option** are also available in the Document Type Management section in the Settings. These features help users track which documents, and how many documents are needed to be collected for specific document types. Refer to the screenshot below:

Dashlet - Collaborative Review

The Collaborative Review dashlet gives you the overview of all the documents that are in a Collaborative Review. Refer to the screenshot below:

The followind dashlets are available in the Collaborative Dashlet:

1. Documents to Approve
2. Documents to Sign
3. Pending Documents Review
4. Collaborative Documents

Dashlet - Documents to Approve

This dashlet displays the list of all documents that are pending for approval in TI Collaborative.

Click the document to open the document for appoval.

Dashlet - Pending Documents Review

The **Pending Documents Review** dashlet gives a list of all documents that are pending for review. Click the document to open the document in the TI Collaborate view and complete the review.

Dashlet - Collaborative Documents

The **Collaborative Documents**dashlet displays the list of all collaborative documents.

From this dashlet, you can also create a new **Collaborative Profile** by clicking the **Create Profile** button located at the top right corner of the dashlet.

Searches

In this section we discuss about Document and Advanced Search, Cross Study Search, Search for Users, Sites, Clinical Data and Room Search

Each of the searches are discussed in separate topics available in the left panel of this help topic.

Documents Search

We can perform two types of searches on documents:

1. **Cross Study Search:** When you search for documents across all studies that you have access to, you are performing a cross study search. You can execute this search from the **Home Page Search** functionality. Refer to the screenshot below:

2. **Documents Search:** When you search for documents from within a room or study, you are performing a Document Search. Refer to the screenshot below:

The process to execute both the types of searches is the same except for the location of executing the search:

1. Navigate to the Home Page or a Trial Interactive room as required.
2. Click the Search icon from the blue bar located on the top of the dashboard.
3. The Search popup appears.
4. From the Documents dropdown, click **Documents**. Refer to the screenshot below:

5. Enter the search criteria in the **Search box** next to the Documents dropdown.
6. Click **Go** or press **Enter** to search for the document. Refer to the screenshot below:

7. Documents matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:

8. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
9. Hover the mouse over **Document icon** to get a preview of the documents.
10. Click the document icon. The document **Metadata** panel opens to the extreme right of the **Document Grid**.
11. The top ribbon bar provides you the functionalities like **Reset password**, **Unlock and Deactivate** the user. Each of these links are discussed in the respective topics.
12. Click the checkbox next to the **User** icon. The following are displayed to the extreme right of the grid:
    a. User Details
    b. The Rooms to which the user has access to.

Searching Users

To search for users, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
2. The **Search** window appears which consists of the following sections:
    a. The **Search** textbox.
    b. The **Users** radio buttons.

c. The **Records** list section to the left of the grid.
d. The **User Details** in the upper right section of the grid.
e. The **Associated Rooms** of the user in the lower right section of the grid.

3. Enter the user name in the **Search** textbox at the top of the window. This displays the user in the **Records** section if available. Refer to the screenshot below:

*Also, notice the **Limit search to the current room** checkbox next to the **Users** radio button. When this checkbox is selected, you can only perform searh only for the particular room. When it is unchecked, you can perfrom the search at the domain level.*

4. When you select the user name from the grid, the following details of the user is displayed to the right section:

a. The User Details: This sections display the details of the user.
b. The Associated Rooms: This section diplay all the rooms in a domain to which the user is associated.

Each of these is discussed in the separate sections below:

The User Details Section

This section allows you to view and udpate the user details. The following conditions can be applied in the User Details section:

Updating User Details

To update the user details:

1. Select the user from the left pane.
2. Select the **Limit search to the current room checkbox** located above the User Details section.
3. The fields of the user details are **enabled** in the User Details section to allow you to update the details.
4. Update the fields as required and click the **Save** button located at the bottom of the right panel. The changes gets saved and reflected in the user details. Refer to the screenshot below:

Viewing User Details

To view the user details:

1. Select the user from the left pane.
2. Uncheck the **Limit search to the current room checkbox** located above the User Details section.
3. The fields of the user details are available only for **viewing** in the User Details section. Refer to the screenshot below:

You can drag the **three lines** between the Associated Rooms section and User Details section to expand the sections.

The Associated Rooms Section

This sections displays all the rooms to which the user is associated along with their roles in each room. Like the User Details section, you can expand this section by dragging the section up and down.

Besides, you can also enter a room by clicking the **arrow** next to the room name. Refer to the screenshot below:

Searching Sites

To search for sites, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located on the blue bar.
2. The **Search** popup appears.
3. From the **Documents** dropdown, click **Sites**. Refer to the screenshot below:

4. Enter the site name in the **Search box** next to the dropdown and click **Go** or press **Enter**.
5. The sites matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:

6. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.

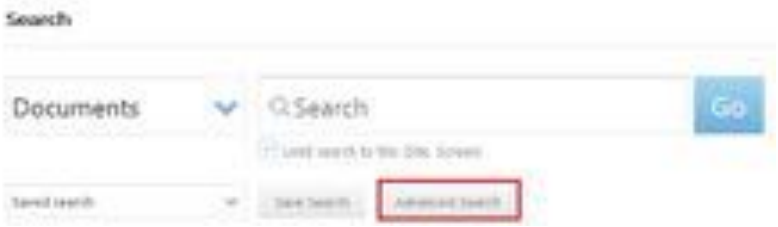
7. Notice that the top ribbon bar is also available above the Grid which provides the functionalities like **Document**, **Document Details**, **Move to Startup**, **Layout**, **Compare**, and **Add to Cart**. Each of these functionalities are discussed in the respective sections.

Advanced Search

Advance Search allows you to refine the search results by.

To perform Advanced Search:

1. From the Home Page, or from within the room, click **Search** icon from the blue bar located above your dashboard.
2. The **Search** popup appears.
3. Click **Advance Search** from the Search popup.



4. The **Advance Search section** appears below.
5. Click **Add Filter** to add the filters for the advanced search and the dropdown appears above the Add Search link.
6. Click the dropdown and select the required field that you want to include in the search.
7. Similarly, you can multiple filters to refine the search.

Room Search

Room Search and Accessing a Trial Interactive Room

Room Search

Trial Interactive allows you to search for rooms easily in cases you have access to hundreds of rooms.

To perform a room search:

1. Enter the required room name in the **Search box** at the top of the page and press **Enter** on your keyboard.
2. Rooms matching the search criteria are displayed in the panel below the filters, else a message **No rooms found** is displayed. Refer to the screenshot below:

Accessing a Trial Interactive Room

Click on the required room name in the panel below the blue line to enter the room. Refer to the screenshot below:

Importing Documents and Metadata

Here know the various ways to add documents to a study room.

Documents can be added to a room by several means such as:

1. Uploading documents from the **Home page**
2. Adding a document from the Documents module using:
   a. The **Document Action dropdown**
   b. The **Context Menu** from the document grid
3. Importing documents using:
   a. The **Import dropdown** in the Document module
4. By emailing and faxing documents to a room

Each of these are discussed in the separate topic and can be accessed from the left menu of this help.

Adding Documents to Index Folder

You can add Single or Multiple documents to an index folder. Each of these are discussed in the sections below.

Adding Single Document to Index Folder

To add a document directly to an index folder:

1. Navigate to the **Documents** module.
2. Select the folder from the index pane into which to add documents and right-click on it.
3. From the right-click popup, select **Add Single Document**. Refer to the screenshot below:

4. This will open the **Document Profile** form for you to add the details and save. This adds documents directly to the selected folder and such an added document does not appear in the default index folder or Upload folder.

Adding Multiple Documents to Index Folder

1. From the Documents Module, select a folder in the index.
2. From the right-click popup, select **Add Multiple Document**. Refer to the screenshot below:

Adding Documents from the Documents Action or Context Menu

1. From the **Documents** Module, click the **Document** dropdown or right-click on a document in the Document Grid.
2. Select **Add Document** and the **New Document** window opens. Enter the details as required to create a new Document profile. Refer to the screenshot below:
3. Select the appropriate **Category** from the dropdown list; **General**, **Country**, or **Investigative Site**.
4. Depending upon the category selected, the document's **Submitted Name** field would appear or disappear. Enter the Submitted Name as required.
5. Select the **Document Type**, and **Document Date.** Type in the date if that is configured for you.
6. Add pertinent **Comments,** if necessary. The Index position will populate automatically, based on the folder you selected from the index.
7. Click the **Browse** button next to the Attachment field to attach a document.
8. Complete other fields as necessary and click **Next** to take you to the **Document Security popup**. Here you can add group(s) and/or users(s) who would access the documents into the security grid and set the desired levels of access. A detailed description of each security access is given in *Manage Security*.

9. Click **Finish** for the new document to take its place in the default index folder or the Upload folder as set in the room settings.

Note: *You can also add/import documents by dragging and dropping them from the Windows Explorer to their relevant index folders. Upon dragging and dropping the document, the Document Profile window opens for you to code the document. The Title, Document type, and Category fields are automatically coded for you. The dragged document can be found in the Attachment/URL field of the Document Profile.*

Importing Documents

Follow the steps below to import documents metadata to a room:

1. Navigate to the **eTMF Documents** module and select **Documents** from Import dropdown.
2. The **Import Documents** window opens. Refer to the screenshot below:

3. Following the on-screen instructions, either drag-and-drop files from your own computer into the upload panel or use the **Browse** button on the window to select documents to upload.
4. After selecting documents to be uploaded, you can select the **Documents Metadata** checkbox on the right pane of the window to quickly code select metadata for these documents while the system is carrying out bulk-uploading. Therefore, if you are importing documents that are from the same investigative sites, are related to particular contact person, or belong to same document type, you can assign those at one go. This is also **Mass Coding** while importing documents.
5. While the documents are uploading, the user can monitor the **Upload Status** column in the display panel and view the progress of the upload in the progress bar at the bottom of the window. When the upload is complete, each document will display an **Upload Status** and the progress bar at the bottom of the window will read **Done**.
6. If you have specified the **Documents metadata** then click **Import and Apply coding,** and **close** button placed on the bottom right corner. A confirm Mass Coding message will pop-up. Click **Yes** to confirm.
7. If you have not specified anything on **Documents Metadata**, then after the upload is finished, simply click the **Import** for the process to begin.
8. The **Import** functionality will not allow the import of erroneous files. During import of several files, the files that were uploaded successfully will be removed from the list of files in the Import Document dialog box, but some documents will remain in the grid due to some errors while uploading. The user can try to import the left out documents again. This will not re-import the already uploaded documents but will try to import the documents remaining in the grid only. Refer to the screenshot below:
9. Once importing documents is over, click the **Close** button in the bottom right corner of the **Import Documents** window. The uploaded documents can then be found in the user's **Upload** folder in the folder index or the default index folder as specified in your room settings.

Importing Metadata

To import document metadata:

1. Select **Metadata** from the **Import** dropdwon. The **Documents Import** popup opens.
2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import multiple documents using just metadata. The wizard offers a link to the sample worksheet so user can download it and fill with actual data. Click **Next.** Refer to the screenshot below:

3. Setup the mapping between metadata fields and uploaded file columns. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.** Refer to the screenshot below:

4. You may choose **incremental data** or **data overlay** options for import of metadata. Here, you will need to mention the **Unique ID fields** for incremental import or data overlay.

   Click **Next.**
5. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.
6. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.

Uploading Videos

Trial Interactive supports the following types of video files as attachments to documents in the below mentioned browsers:

Browser Name	File Type
Internet Explorer	.mp4
Chrome	.mp4, .webm, .ogg
Firefox	.mp4, .webm, .ogg
Safari	.mp4
Opera	.mp4 (from Opera 25), .webm, .ogg

On uploading, a supported video file appears in the grid with a brown icon next to it; whereas an unsupported video file appears in the grid with a grey icon next to it. Refer to the screenshot below:

To play a video file, select the document in the grid and click the **Document** tab at the bottom of the grid, or simply double-click it. The document opens in the viewer with the **PlayVideo** button on it.

It is possible to start/pause the video, control the sound, seek through the time line, and switch to full screen mode or back. Unsupported video files open in the viewer with the message **Media format is not supported. Click here to download the file.**

Deleted and Expired Documents

Here know where the deleted and expired documents are stored.

This section includes the following:

1. Deleting and Viewing Deleted Documents
2. Expired Documents
3. Deleting Queried Documents

The above are discussed in separate topics accessible from the left panel of this help.

Deleting Documents and Viewing Deleted Documents

Deleting Documents

To delete a document:

1. Navigate to the **Documents** module.
2. Select the document(s) from the documents grid.
3. From the right-click menu, select **Delete**. Refer to the screenshot below:

Deleted Documents View

All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.

Expired Documents

As an Administrator, you might want to specify the time by which a document will expire and require a new version. You can set up the settings of expired documents from the **Main Navigation -> Settings -> Documents -> Documents Module.**

You can view the expired documents from the **Expired and Expiring Documents** dashlet.

Deleting Queried Documents

Queried documents deleted by a user can be viewed by the Administrator under the **By Sender** and **By Recipient** views also besides the **Deleted Documents view.** Such documents appear in the mentioned views with a cross colored red next to the document name in the grid. Refer to the screenshot below:

Documents which were in query and were later deleted retain their query history and are also included in query-related reports. The Query History can be viewed from the **Queries** panel in the **Right panel**.

Potential Sites and IRB Integration

This allows you to locate the Unique Sites using the combination of Study Name and Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

Note: *If the system finds matching conditions like site, IRB number and IRB document type in the Study Start-up Site Profile, the documents for the imported site will be uploaded into the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which is discussed below.*

This section includes the following sections:

1. IRB Integration and Settings
2. Potential Sites and Modules

IRB Integration and Settings

IRB Integration

IRB Integration Settings

From the room **Settings -> Integrations -> IRB Integration** you can decide the location and the status of the IRB documents in the eTMF.

Trial Interactive introduces a new **IRB Uploads folder** the name of which can be configured from the **Settings -> Documents -> Index Outline**.

Potential Sites Module and Settings

There can be cases where multiple sites are found during IRB Integration, or a site could not be identified, or sites are incorrectly imported.

Under the circumstances, the system creates a list of **Potential Investigative Sites** and notifies appropriate groups about the potential sites.

1. To configure the Potential sites email recipients navigate to **Settings->Integrations->IRB Integrations**. Refer to the screenshot below:

2. Click **Select** next to the Potential sites email recipient and select the email recipients as instructed. The email template for the emails to be received by potential sites email recipients can be setup from the **Email Templates** in the room **Settings -> Email section**. A screenshot of the system provided email template is shown below:

3. With Trial Interactive, you can manage potential investigative sites from the Potential Sites module if IRB Integration is enabled for you.
4. The module is accessible by clicking the Potential Sites icon  from the toggling menu in the eTMF module. Refer to the screenshot below showing the **eTMF/Potential Sites** module.

Note: *As an Administrator, you can create sites from potential sites or delete the ones that cannot be converted into sites.*

Potential Sites Module

With Trial Interactive, you can manage potential investigative sites from the **Potential Sites module** if IRB Integration is enabled for you. The module is accessible by clicking the Potential Sites icon from the toggling menu in the eTMF module. Refer to the screenshot below showing the **eTMF/Potential Sites module**. Refer to the screenshot below:

As an Administrator, you can create sites from potential sites or delete the ones that cannot be converted into sites.

To create a site:

1. Select a potential site from the grid as required.

2. From the Potential Site Metadata panel, click the **Create** icon to create a site. The **New Investigative Site** window opens.
3. Fill in the details to create a site from a potential one. The process to create a site is discussed in detail in section **Adding, Editing, and Deleting Sites.**

To delete a site click **Delete**from the Potential Sites Metadata panel.

Milestones and eTMF Completeness

Here, we discuss about all the aspects of Milestones and its use in eTMF Completeness.

Through various topics under this section, we discuss about:

1. Milestone Configuration
2. The Milestone Application
3. eTMF Completeness and Health
4. CRA TMF Reconciliation Report

Milestones

Milestones is the 'objective-to-reach' for a particular study room, and this function displays the list of milestones that will be used for the current study room. Administrator users can add existing or new milestones, or edit the added milestone names. You can also choose to either enable or disable the added milestones. You can inherit milestones from the domain level settings, or add a new milestone added to the room specifically. Added milestones can also be updated on the Document Types Management section of the settings. You can also use the **Milestone** section to define the current milestone, and to track which documents are needed. Besides, you can also Assign Milestones to Required Documents.

As an Administrator, you can monitor a milestone progress from the Milestone application that can be selected from ……..**Give a picture of the Milestone application.**

From the Milestones module, the administrator can add milestone histories, edit or delete them.

Note: *Before starting to monitor milestone progress, administrators need to add new or existing milestones, or edit the added milestone names from the* ***Room Settings -> Milestones****.*

From this section, we discuss under subsequent topics on:

1. Configuring Milestones
2. Adding Milestones to Document Types and Required Documents
3. Viewing Milestones
4. Adding, Editing, and Deleting Milestones
5. Milestone History Grid and Filters
6. Assigning Milestone Histories to Documents
7. Automatic association of Document Types to Milestones from the Metadata Panel

Configuring Milestones

Milestones Settings

Follow the steps below to configure milestones:

1. Navigate to **Main Navigation-> Settings->Milestones**.
2. The Milestones window opens with the list of milestones.
3. To add milestone, click **Add** from the right panel. Refer to the screenshot below:

4. The **Milestones Profile** window opens. Refer to the screenshot below:

5. Choose from the **Existing list** of milestones to enable that milestone for your room **or** enter the milestone name to create New milestone. Refer to the screenshot above.
   a. Select the **Milestones Category** as **Study, Site, or Country**.
   b. Select the **Milestone Type** from the dropdown and click **Ok**.
   c. To select **Milestone Type** of your choice, you will need to add milestone types.
      1. You can create **Milestones Type** on the fly by clicking the '+' icon in the **Milestone Type** field.
      2. Once a milestone type is created, it will not automatically populate in the textbox. Select the milestone type from the dropdown.
6. The milestone thus created is enabled by default.
7. Double-click a milestone, or select an existing milestone and click **Edit** to edit a milestone.
8. Select a milestone and click **Delete** to delete it.

Adding Milestones to Document Types

You can add a milestone thus created to Document Types to track the **eTMF Completeness** of the documents associated with such document types. This is discussed in detail in **Include Phases/Milestones** section under Document Types Management.

Milestones Module

The administrator can monitor a milestone progress from the **Milestonemodule**that can be selected from the toggling menu bar.

From the Milestones module, the administrator can add milestone histories, edit or delete them.

Note: *Before starting to monitor milestone progress, administrators need to add new or existing milestones, or edit the added milestone names from the Settings -> Milestones.*

On entering the dashboard, the administrator can see the list of milestone histories, if they were created. Refer to the screenshot below:

From here, you can perform the following:

1. Adding Milestones to Countries
2. Adding Milestones to Sites
3. Adding Milestones to Studies
4. Editing and Deleting Milestones
5. Milestone History Grid and Filters
6. Assiging Milestones Histories to Documents
7. Assigning Milestones to Document Types
8. Automatic Association of Document Types to Milestones on the Metadata Panel

Adding Milestones to Studies

Follow the steps below to add milestones to studies:

1. Click **Add** from the top menu bar in the **Milestone** module. The **Create** milestone history window opens.
2. Select the **Category** as **Study**. Refer to the screenshot below:

3. Select the **Milestone.**
4. You can either choose the date from the **Calendar Date Picker**, or enter the **date manually**.
5. Enter the **Comments** and click **Create** to create and add the milestone history in the grid.

Adding Milestones to Countries

Follow the steps below to add milestones to countries:

1. Click **Add** from the top menu bar in the **Milestone** module. The **Create** milestone history window opens.
2. Select the **Category** as **Country**. The **Country** dropdown appears.
3. Select all the countries to which the milestone event is applicable. Refer to the screenshot below:

4. Select the **Milestone.**
5. You can either choose the date from the **Calendar Date Picker**, or enter the **date manually**.
6. Enter the **Comments** and click **Create** to create and add the milestone history in the grid.

Editing and Deleting Milestones

1. To edit a milestone history, click **Edit** from the top ribbon bar.
2. To delete a milestone history, click **Delete** from the top ribbon bar.

Milestone History Grid and Filters

Besides categorizing milestones by the Study, Site, and Country, the milestone module also allows you to filter milestone events by **Documents Received** vs. **Documents Missing**. Refer to the screenshot below:

Select a filter of your choice to display the milestone history and its associated documents in the neighboring grid. Refer to the screenshot below:

Assigning Milestone Histories to Documents

Assigning Milestone to Document Types

You can assign milestones to document types from the Phases/Milestones section in the Document Type Management Profile window. To enable milestone association with a document, the **Milestone** and **Milestone Date** fields are marked as **Required** and **Visible** in the Document Type Fields in Document Types Management.

Automatic association of document types to milestones on the Metadata panel

1. If, while coding a document, there exists only one milestone history, then the milestone date and record is automatically assigned to the document and appropriate message displayed accordingly. Refer to the screenshot below:

2. If, you change happen to change the document type of a document and a new milestone data is found, the system automatically updates the values and displays a message accordingly. Refer to the screenshot below:

3. If, you change happen to change the document type of a document and no new milestone data is found, the system automatically updates the values and displays a message accordingly. Refer to the screenshot below:

4. If a document is coded with a document type that has no milestone associated with it, then the following message is displayed. Refer to the screenshot below:

eTMF Completeness

eTMF Completeness is a milestone indicator of a clinical study process based on the status of the documents required for the study. The eTMF Completeness view lists the collected, missed, and placeholder documents required to complete a study along with the milestones linked with each document and its placeholder. Therefore, through this module the Administrator can understand the quality and health of the TMF thereby enabling the Administrator to define controls to set placeholders required to collect documents to complete the clinical trial.

Controls can be set in the form of Milestones which are linked at each stage of eTMF completeness to measure the progress percent of documents collected at each stage of the eTMF completeness. For example, the Administrator can set up a milestone for a Site Visit event to include documents for a Confirmation letter sent by the CRA for a site visit, a Site Visit Report, and Follow-up Letter. Each of these documents and their types which are defined in the eTMF room can be linked to a milestone, milestone events defined for the same, and placeholders set up in the eTMF. To be able to set up the complete process and make tracking of eTMF Completeness seamless, the Administrator needs set up:

1. The eTMF Completeness metrics from the **eTMF health** in the room settings
2. The Milestones for a complete integration of documents
3. Creation of document types and their linking to milestones
4. Creation of Visit types to generate Site Reports

Important:

- *For more details on eTMF Health Settings, proceed to section **eTMF Health Setting**s*
- *For more details on CRA Visit types, proceed to section **CRA Visit Types***
- *For more details on creation of milestones proceed to section **Milestones**.*
- *For more details to link milestones with document types to track eTMF completeness proceed to section **Include Phases/Milestones.** .*
- *For more details on creating milestone events/history proceed to section **Milestones**.*

eTMF Health Settings

The eTMF Health dashlet provides information regarding the current health of the eTMF system by indicating what percentage of required eTMF documents are collected/missed so far. The document types of required documents can be linked with milestones to keep a track on their progress report.

The eTMF Health functionality under **Settings -> Documents Module -> eTMF Health**, if enabled, checks for:

1. The configurations and current status of milestones
2. The status configurations and current status of a document. This check helps to leverage the eTMF completeness reports and the eTMF Health dashlet to reflect the correct health of the eTMF system. Refer to the screenshot below:

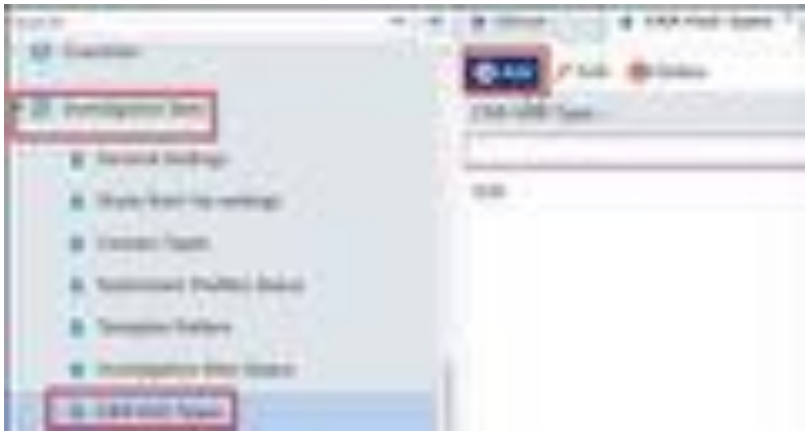
These settings will affect all dashlets and reports related to eTMF Health and completeness. Moreover, clients can also choose to reflect in the reports documents collected and submitted to **eTMF** or **QC Final** by choosing one of the **radio options** as shown above.

Click **Save** to commit the changes made.

CRA Visit Types

A CRA might need to create **CRA TMF Reconciliation Report** to reconcile documents during site visits. While creating the report, the visit type must be chosen so that reports generated during two or more site visits can be differentiated with ease. Refer to the screenshot below:

For the visit types to be populated in the dropdown as shown above, the admin will need to create visit types from this panel.



1. To add a new visit type, click the **Add** button at the top of the portlet window.
2. Type in the desired term and press **Enter**. Changes made here are saved automatically. These visit types automatically appear in the dropdown while creating the **CRA TMF Reconciliation Report**.
3. To edit a visit type, double-click the visit type, or select it and click the **Edit** button from the toolbar above.
4. To delete a visit type, select the visit type and click **Delete** from the toolbar above.

CRA Reconciliation

In this section find the details about the CRA Reconciliation Reports that helps CRA to take the decisions regarding further site visits

Trial Interactive 10.0 helps the CRA to reconcile documents during their site visits through the Site Report.

You can reach this page from **Main Navigation → CRA Reconciliation.** Refer to the screenshot below:

The module has the following sections:

1. **Documents:** This module allows the CRA to mark the documents as verified, missing in eTMF, missing in ISF or add the placeholder for an expected document as a part of reconciliation process.
2. **Reports:** This module allows the CRA to create CRA Report which will include all the documents reviewed by the CRA since the last report created by him/her.

   Each of the above modules are discussed in separate topics and can be accessed from the left pane of this help.

Documents Reconciliation

For performing Site Visits, CRAs needs to take some important decisions regarding documents for sites:

1. Which documents need to be added to both eTMF and site binder
2. Which documents need to be added to site binder from eTMF
3. Which documents need to be added from site binder to eTMF

CRAs can avail this information from the **Site Report** so that they can verify the outstanding documents during their next site visit.

Note: *Only **Pending** and **Active** sites are available for reconciliation process*

Important:

- *Missing documents cannot be marked as reviewed.*
- *Only CRAs can perform this step. Admin users will not be able to mark documents as Reviewed.*

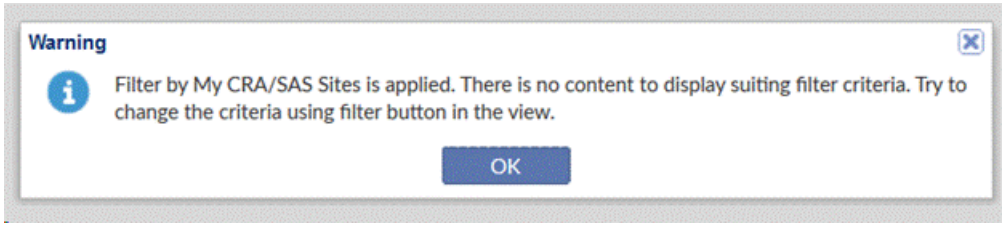
- *The CRA needs to have **CRA Reconciliation Action** enabled under the user profile.*

Follow the steps below to reconcile documents:

1. Navigate to **Main Navigation → CRA Reconciliation** Refer to the screenshot below:

2. The **Document View** opens as shown in the screenshot below:

3. Notice if you receive waring as shown in the screenshot below:



4. If the waring is displayed, click the **Filter** icon below the view and uncheck **My CRA/SAS Sites** or **My favorite sites** from the filter. Refer to the screenshot below:
5. Click **Apply**.

6. The list of folders appear in the view.
7. Click the appropriate folder to display the list of sites.

8. Select the appropriate site from the selected folder to get the list of **missing**, **collected** and **placeholder documents** in the grid.
9. while reconciliation, each document will fall into one of the three scenarios as below:
    a. ***If the document is in the ISF but not showing in the eTMF:***
        1. Click **Add Placeholder** (or if applicable, upload/email the document to the eTMF).
        2. Complete the known required fields and click **Finish** (metadata can be added / edited once the document is collected).
        3. Once all the actions are done, click the **Reconcile** button and proceed to step 11.
    b. ***If a document is in the eTMF not present in the ISF:***
        1. Click the document(s) and click the **Reconcile**button.
    c. ***When the document is in both eTMF and the ISF***
        1. Click the document and then click the **Reconcile** button.
10. Click the **Reconcile** button from the top ribbon bar to change the status of the document. The **Change Status** pop-up opens. Refer to the screenshot below:

11. Choose the required status and click **Select**.

    Note:

    - **Missing in ISF**: Select this status to indicate the document is missing in the site binder (ISF) but present in the eTMF.
    - **Verified**: Select this status to indicate the document is in both the eTMF & ISF.
    - **Not specified** Select this status to clear a previously assigned status.
12. Once the **Reconcile** process is complete, you can see the status of the document with the date. Refer to the screenshot below:
13. This site is then available for the creation of the CRA TMF Reconciliation Report in the **Report** view.

Creating and Viewing the CRA TMF Reconciliation Report

CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. You can access this page from **Main Navigation → CRA Reconciliation → Reports View**. On entering the dashboard, you can find the list of reports generated displayed in the grid. You can choose to view the reports **By Site,By Visit Type**, or **By CRA** from the current view panel on the left. Clicking a report from the grid populates the report metadata in **Reconciliation Datapanel** located at the extreme right of the dashboard. You also have the option to **Create** edit, or delete a CRA Reconciliation TMF Report from the **Create**, **Edit**, or **Delete** icons located on the top ribbon. Refer to the screenshot below:

Creating CRA TMF Reconciliation Report

1. Once the **Reconciliation** process is complete, you can create the CRA TMF Reconciliation report from the **Reconciliation Report** module. Image
2. Select the appropriate filter from the Current View. The Previous reports will populate in the grid.

3. Select the appropriate site and click **Create** from the top ribbon bar to run a new report.
4. The **Create CRA TMF Reconciliation**window populates with documents from the latest reconciliation. Complete the required fields.

   Note: *The Visit Type will be populated in the dropdown only if it is created from Settings → Investigative Sites → CRA Visit Types.* Refer to the screenshot below:
5. Fill in the appropriate details and click **Create.**
6. You will receive a **notification** that the **Site Report** is created successfully and displayed in the grid.

Editing CRA TMF Reconciliation Report

1. Select the required **site** from the **Reports** module and click the **Edit** button on the top ribbon bar.
2. The **Modify CRA TMF Reconciliation** popup opens.
3. Edit the required details and click **Save** when finished.

Deleting CRA TMF Reconciliation Report

1. Select the required **site** from the Current View and click the **Delete** button on the top menu bar.
2. Click **Yes** on the confirmation popup that appears if you wish to delete the report from the list.

Quality Control

The Quality Control / Workflow application in Trial Interactive involves the quality check of the submitted documents in a room by Quality Reviewers who are the members of the Quality Control group.

Quality Control Settings

In Workflow Settings, Admins set up important details like workflow statuses, issues in the workflow, timeline, and members of the workflow group.

All these configuration details need to be previously created by the super-admin and configured to enable the administrator to add them to the workflow. This section will take you through the various configuration details. Changes made here will be applicable to all workflows.

To access the Quality Control Settings:

1. Navigate to the **Main Navigation-> Settings → Workflows**.

   From **Workflows Settings**, we discuss about:

   a. Common Workflow Settings
   b. Creating, Editing, and Deleting Quality Control Review Statuses
   c. Creating, Editing, and Deleting Quality Control Document Statuses
   d. Creating, Editing, and Deleting Quality Control Profiles

   Each of these are discussed in the separate topics in this help.

Common Settings

The Workflow Common Settings can be accessed from **Room Settings → Workflow → Common Settings.**

Admin can perform the following Common Settings in a Workflow:

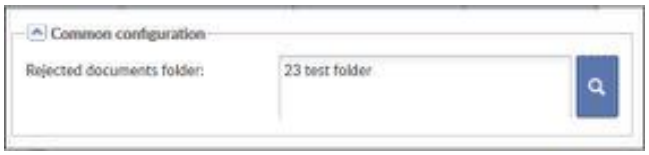
1. Common Configuration
2. Default Ranges Configuration
3. Timeline Configuratuon

4. Issue Email
5. Rejection Email Configuration
6. Query Reminder Configuration
7. Auto-Claim Configuration

Each of these are discussed in the seperate topics and can be accessed from the left of this help.

Workflow Common Configuration

Rejected Documents folder: Here you specify the folder and its index number that will hold the documents when they are rejected during the review.



Default ranges configuration

Here you can specify date ranges that would be applicable to your workflow.

- TI acknowledges the fact that various workflows would have different review and submission periods.
- Hence it allows you to specify more than one value separated by semi-colons.
- These values would be populated in the dropdown during workflow creation, and you may choose a value as appropriate.

  Refer to the screenshot below:

  Each field above is editable, you can simply enter the values separated by semicolon. Each option is discussed in separate sections below:

1. **Review due date range (days)**
   - Here you specify the days when the review would be due after claiming the documents for review.
   - You may specify multiple values, all of which will be populated in the dropdown while creating the workflow to enable you to select a value as appropriate.
   - The **Returned Back** is a new system status that can be given to a document when it is routed back to a previous workflow stage.
   - Hence, it is available from Approval Stage 2/QC2 onwards only.
2. **Review reminder range**
   - Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.
   - If multiple values are specified, all of them would be populated in the dropdown during workflow creation, and you may select multiple values as required.
   - In the screenshot above, the Reminder schedule is 5;3;2 which means:

- the reviewer will receive reminders 5 days before due date,
- then 3 days before due date,
- and then 2 days before due date if the reviews are pending.

3. **Review release range days**
   - Here you specify the days after the claim when the documents would be automatically released from the reviewer's claim list.
   - The Auto release date is always greater than the due date.
   - It will not allow you to select a value less than the due date.
4. **Escalation frequency**
   - Escalations are reminders about **not completed reviews**.
   - During workflow creation, an escalation group needs to be specified who will receive notifications about escalations.
   - Here, you specify the timeline for escalation notification frequency.
5. **Query reminder date range**
   - If the user does not respond to a query with a document, reminder emails are sent to the query recipients on the nth days as specified here.
   - So if the setting is 10; 5; 3 reminders will be sent on the 10th day, 5th day, and the 3rd day.

Timeline configuration

Refer to the screenshots below:

- If you specify values in the timeline, the values will be automatically set for you at the time of workflow creation.
- If you happen to change your mind at the time of creation, you may select values as required as opposed to that set in the timeline configuration.
- The configurations are optional here except for the Clarification auto release, which means a document that is pending for clarification will be automatically released if it was not released back to the workflow by the reviewer within the defined time period.
- Users can delete timeline values from a Workflow profile as well as for existing workflows by clicking the cross icon next to the fields in the **Timeline Configuration pane**l or from the **Timeline** tab in a **Workflow Profile Editor**. Refer to the screenshots above.

Issue email

1. From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session. Refer to the screenshot below:

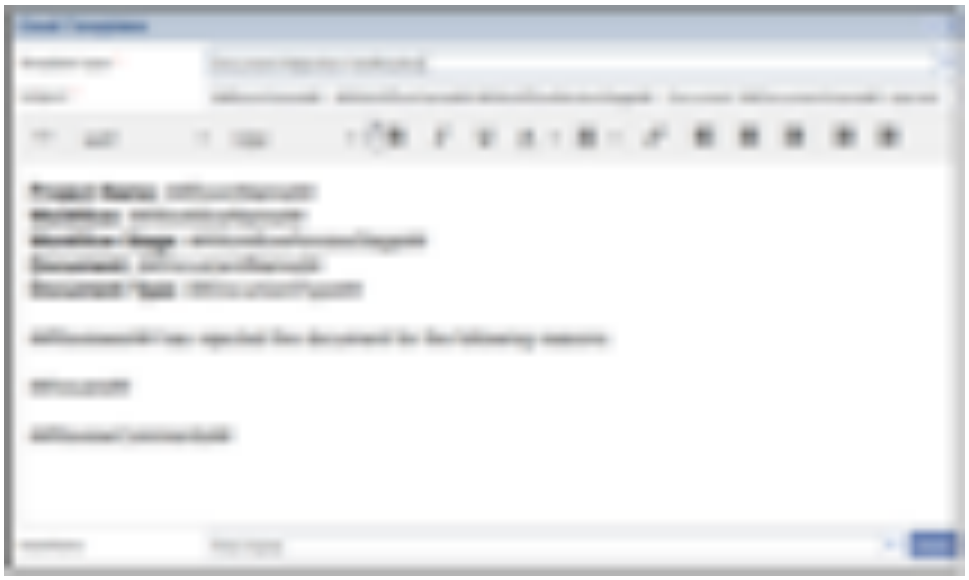
2. Click the dropdown arrow to choose the attachment mode to be either **Files as links or Files as attachments**. Refer to the screenshot above.
3. Click **Save** from the bottom of the grid.

Rejection Email Configuration

When document is rejected in the Workflow a rejection email is sent to the document owner plus the users specified in the **Rejection Email** configuration settings. Refer to the screenshot below:

1. Click **Select** from the **Rejection Email** settings.
2. **Workflow rejection notification email recipients** window opens. Refer to the screenshot below:

3. You can choose from **Users or Groups**. Select the users by **double clicking or drag** the entries to the right pane.
4. Click **OK** to save the selection of the users.

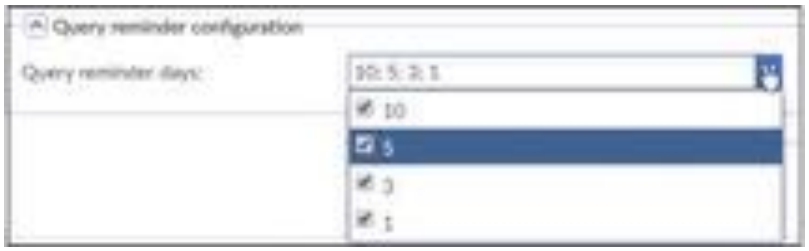


You can change the Rejection Email Template from **Settings-> Email ->Email Template**

Query reminder configuration

From **Query Reminder configuration** Admin can configure reminder emails' schedule.

Refer to the screenshot below:



1. As per the above configuration, reminders will be sent on the 10th day, 5th day, and the 3rd day, if the user does not respond to a query with a document.
2. You can change the number of days from Query reminder date range (days) in Default ranges configuration.

Auto claim configuration

Note: *If there is only one reviewer in a workflow the documents will be* ***auto-claimed by the system*** *and assigned to the lone reviewer for review.*

To enable auto-claiming of a document, the Administrator will need to enable the configuration from this panel. Refer to the screenshot below:

1. Tick the checkbox next to **Allow workflow stage auto claim**.
2. Enter the number of days after which **if the reviewer has not claimed the documents**, they will be **auto-claimed** by the system and assigned to the reviewer.

Creating the Quality Control Workflow

To creare a Quality Control workflow follow the procedure below:

1. From the **Settings → Workflows → Workflows**,click the **Add** button from the grid. The **Workflow Editor** window opens.

   Refer to the screenshot below:

2. Enter the **Quality Control Workflow** name and **Description**.
3. The Selection Criteria could be **All new documents**, or only those **Metadata fields** that need to be reviewed. Refer to the screenshot above.
4. Select the workflow levels, i.e. QC1, QC2 etc.
5. You may apply a **condition** to select documents for review as per a particular condition. Click **Add** to add a condition from the **Initial Stage** box. Refer to the screenshot above.
6. The **Initial Stage Condition** window opens. Refer to the screenshot below:

7. You may add multiple conditions and decide their sequence to filter documents with the green arrow keys. Use **And / Or** operators if you want all / either of the conditions to execute. Refer to the screenshot below:

8. As per the screenshot above, documents uploaded by the site contact on a particular site visit date would be added to the workflow. The details of each condition are as below:

9. Thus, as per the above conditions, documents of type **'General\Trial Management\Trial Oversight \eTMFFilingPlan'** uploaded by the site sponsor on the site visit date of 10th of Aug. 2017 would be added to the workflow.
10. Click **Next**. This leads you to the configuration wizard of the **first stage of the workflow**. Refer to the screenshot below:

11. Change the **Stage Name**, if desired. Click the **Approvers** tab. Refer to the screenshot above.
12. This allows you to **add users/groups** as reviewers of the documents for the particular stage in the workflow.

Note: *It is recommended to add a **Group** to save configuration time.*

13. Click the **Custom** fields tab. This is a required tab and **Statuses** and **Issues** must be added. Refer to the screenshot below:

The statuses are the ones previously created under **Review Status**. Click **Add** to add the first status and select the document status from the dropdown. Refer to the screenshot above. **Approved** and **Rejected** are the minimum statuses that need to be added to a workflow.You can include more statuses, like **Clarification** and **In Progress**, for better functionality of the workflow.

14. Click the **Issues** section to assign the reasons in case the reviewer rejects a document/asks for clarification.Some of the standard issues could be **Missing Pages, Missing Signature, Blank Pages, Incorrect Study, Poor Scan, Duplicate, and Expired Documents**.
15. To make metadata **fields**, as required, available for a workflow configuration, proceed to **Forms Settings** and select the **Workflow Fields**, as required.

- These fields will appear in the **Fields** panel at the bottom of the **Customs** tab. Tick the fields as required for the review. Refer to the screenshot below:

  - These checked fields will appear in the **Review** panel of a document in the **eTMF/Documents** module once a document is claimed for review.
  - As shown in the screenshots, the **Submission Date**, **Approval Date**, and **Document Version** fields checked in the workflow configuration appear in the **Review panel** of the **document metadata window**.

16. Click the **Notifications** tab.
    - Here, you can allow for email notifications to be enabled for the event names listed.
    - For users who want to be notified only in case of **Claim**, **Release**, or **Escalation**, groups can be added accordingly.
17. In case you have fed in values in **Timeline Configuration**, the values would be populated by default in the **Timeline** tab. You may choose to override the previously set configurations, if desired.
18. **Actions** is an optional tab allowing for complex workflow building.
    - It enables a workflow to have a jump. A specific document can jump to a certain stage.
    - For example, a Form FDA 1572 after QC1 review, can jump to a stage 3 review, where Regulatory Affairs perform a 2nd review on the document.
    - While efficient for complex workflows, it is not required for regular workflows creation.
19. Click **Next** when all tabs have been reviewed.
    - Repeat the similar steps for each stage of approval.
    - Settings may change per approval stage, like **approvers, notifications, and timelines**.
20. When finished, click **Next**.
21. The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If no errors, click **Finish** when done.

Editing An Existing Workflow

CAUTION: *Editing of existing workflow should be executed with caution because any saved changes require a new and revised workflow to be created*

While editing an existing workflow is quicker than creation, having multiple workflows enabled in the same room is not common and can cause confusion.

1. In the Workflows panel, click the **Name** of the workflow and either click **Edit**  from the top menu or double click the required workflow.
2. The **Workflow Editor** window opens. Review the steps of the workflow wizard as before, clicking **Previous** & **Next** to review the settings.
3. If no changes have been made, click **Cancel**.
4. Yet if changes were made, this has become a new and different workflow. Thus, click on **Save as**.
5. Give the revised workflow a new name. A **new workflow** is created with the new name.
6. Click **Ok** when done. A confirmation message appears confirming creation. Click **Ok**.
7. The previous workflow and the new revised workflow are both by default enabled.

   If one needs to be disabled, uncheck the associated box. Remember to click **Save**.

Deleting An Existing Workflow

Select a workflow from the list you wish to delete and then click **Delete**  from the top menu.

Quality Control Process

This section gives the complete process of the Quality Control Workflow.

Assigning a Group of Users to the Quality Control

To assign a group of users to a workflow follow the procedure below:

1. Navigate to **Main Navigation ->Settings -> Security -> Groups** or to **Main Navigation -> User Management**.
2. Create a Group.
3. **Add users** to the group. The users in this group would be the reviewers who would review the documents.
4. Now navigate to the Settings-> Quality Control-> Workflows and crete a workflow.
5. In the Workflow Editor click **Next**.
6. Click **Approvers->Groups**. The group name to select would be the one you created in step 2 above.
7. Save the changes. This would have assigned the group of reviewers to the workflow.

Activating My Reviews

If you are part of the reviewers group which you assigned to the workflow, the **Reviews** view in the eTMF Documents module is automatically activated for you. You can have the same view as in **My Reviews** from the **Quality Control Review** application as well.

Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the **Reviews** view or the Quality Control module in the **folder with unclaimed documents** under the workflow configured by you. Refer to the screenshot below:

Claiming a Document

To claim a document for review, click folder holding **unclaimeddocuments** under **Reviews** or the **By Document Status view** from within your eTMF room. This will list the documents on the right pane.

Select the document you want to claim for review and navigate to the right panel.

If Workflows have been activated in your trial room and you are a member of a **Reviewers** or **Approvers** Group, you will see a **padlock icon** at the top of the metadata panel.

1. Click the **padlock icon** to claim the document for workflow review.
2. Then click **Save**.
3. Click the **Next Document** link at the bottom of the right panel to move to the next document in the current data grid. The process can be repeated as long as there are more documents available to be claimed. You may also select documents in bulk in the Documents Grid and claim them altogether.
4. All the claimed documents move to the **folder for holding documents claimed for review** in the **Index Pane**. Click the folder to view the claimed documents in the Documents Grid.

   Note: *Once you claim a document for review, the padlock icon appears to be unlocked and changes its text to* ***Release*** *which allows you to release the claimed document.*
5. Select the document from the grid and navigate to the **Workflow** panel to the right. From the Workflow panel, you can add the appropriate workflow status to the document.

Auto-Claiming a Document

In certain business scenarios, there can be only one reviewer assigned to a Quality Control stage. Under such circumstances documents will be auto-claimed by the system and assigned to the lone reviewer for review. To enable auto-claiming of a document, the Administrator will need to enable the configuration from the Main Navigation ->Settings -> Workflows -> Common Settings -> Auto claim configuration.

Note: *If documents are present in the same stage of more than one Quality Review, and the Reviewes have only one reviewer assigned to them, the documents will not be auto-claimed.*

Assigning Quality Control Status

If you have been assigned to a Quality Review role, additional fields are available to you in the Metadata panel for documents in the Quality Control. Part of your assignment is to assign each document a Workflow Status.

1. Click **Documents** from the left menu.
2. Select **Reviews** or **Status** view from the views. Alternatively, you can also navigate to the Quality Control module from the Main Navigation.

3. Open the **folder holding document claimed**for the review by clicking the folder icon next to the folder name. A list of your claimed documents will populate the document grid.
4. Select a document.
5. View the document's contents by clicking the document's icon in the grid or by clicking the **Document View** button at the bottom of the grid.
6. Inspect the document.
7. From the **Metadata** panel, code the document as required.
8. Navigate to the **Workflow** panel. Refer to the screenshot below:

9. Click the dropdown arrow to the right of the **Status** field to reveal the available Status selections.
10. Select the appropriate status based on your review of the document's contents.
11. Select the issue from the **Issues** field and select the **Index Position** for the document.
12. Add comments to the **Comments** field if appropriate.

> **Note:** *When you select the **Review Clarification** or **Review Declined** status, the **Create Query** button appears along with the **Send Issue button** as shown in the screenshot below.*

13. Click the **Save** button at the bottom of the Workflow panel to save the workflow status you have assigned to the document, or alternatively click the **Save and Next** to continue reviewing the next document in the claimed documents queue.
14. Depending upon the status selected, the document moves to a corresponding folder under the Index Pane. For example, approved documents will move to the folder for holding documents **approved** in the workflow, rejected documents will move to the folder for holding **declined** document, documents in progress will move to the folder for holding documents **in progress** and so on.
15. You can also view the review history in the **Workflowe History** section in the Wokflow panel.

Releasing Claimed Documents Back

As a user with the Administrator role, you might find that you have claimed more documents for Quality Review than you can handle. If such a situation arises, you can release some or all of your claimed documents back into the Quality Review.

1. Click **Documents** from the left menu of the screen.
2. From the views, select **Reviews** or By **Status**, or navigate to **Quality Control** module.

All of the folders related to the Workflows in which you are an active reviewer populate the **Current view** index structure of the **eTMF/Documents Reviews view**.

3. Click the **folder holding claimed documents** from which you want to release documents.

The list of documents in that folder populates the document grid.

4. Click the checkbox above the list to select all of the items in the folder, or select individual documents by clicking the checkboxes for those individual documents.
5. Click the **Release** button from the Right Panel. Refer to the screenshot below:

6. A window opens asking for document release confirmation.
7. Click **Release** if you are sure you want to release the document or documents. .
8. Alternatively, you can also release the document by clicking **More** 

dropdown at the top right corner of the Right Panel. From the dropdown options, click the **Release from Workflow** option to release the document. Refer to the screenshot below:

That document or those documents return to the folder designated to hold **review unclaimed** documents. The documents are now available for other reviewers to claim.

Reassigning a Reviewer

Administrators can reassign documents claimed in the workflow to other reviewers.

1. From the **Documents** view, select the **Reviewer** view.
2. Open the index folder of the reviewer whose claimed documents you want to reassign.
3. Click the folder holding **claimed document** to reveal its contents.The list of that user's claimed documents populates the document grid.

4. Select the documents from the list that you want to reassign.
5. Click the **More** dropdown located at the top right corner of the Right Panel to reveal the options.
6. Select the **Reassign Reviewer** option from the list. Refer to the screenshot below:

7. A **Reassign reviewers** window opens.
8. From the **Workflow** dropdown, select the workflow you want to adjust. The **Stage** field auto-populates.
9. From the **Reviewer** dropdown, select the reviewer to whom you want to reassign the documents.

10. Click the **Change Reviewer** button.

    The documents are transferred to the folder for **claimed documents** of the new reviewer.

Reassigning Documents to a Different Stage in the Quality Review

> **Note:** *Documents with Final status cannot be re-assigned to workflow stages. They will not be shown on the view.*

Documents can be reassigned by Administrators and Editors with **Document Manager** action to a previous stage in a workflow from the **Non Final Documents By Stage** view in the **eTMF/Documents** module. Refer to the screenshot below:

To Change Stage of documents in bulk or individually:

1. Select the Workflow Stage of the document above the current stage.
2. Select the documents in the stage from the Documents Grid.
3. Select the **Change Stage** option from the **More**dropdown from the Right Panel as shown in the screenshot below:

4. The **Change Stage** window opens.
5. Select the Stage and click **OK**. Only stages below the current stage will be available for selection.

6. The change stage operation for bulk documents is performed in a background process and the user is notified about the same in the Notifications panel once the job is completed.
7. Once the stage is changed, the documents move to the **folder for unclaimed documents** of the selected stage.

Quality Control Query

The Workflow Query Resolution module must be enabled by a user who has Super Administrator access in Trial Interactive. When Query Resolution module is enabled, Query Reminder configuration is present in **Notification Preferences** and **Notification Columns** portlets in Email settings.

Quality Control Query involves the following processes:

1. Quality Control Query Initiation by a Reviewer
2. Quality Control Response by a Responder
3. Quality Review Query Resolution by Reviewer for Query Response without attachment
4. Quality Review Query Resolution by Reviewer for Query Response with attachment
5. Tracking Quality Control Queries
6. Excluding Documents from a Quality Review

Each of these processes are discussed in seperate topics. Click the topic from the left pane to view it.

Quality Control Query Initiation by a Reviewer

1. As a user with **Quality Control Reviewer** assignment, go to the **Documents** module.
2. Select the **Reviews** view in the index panel on the left side of the screen, or navigate to **Quality Control** module.
3. Select an active **Workflow** main folder.The related subfolders open in the index view.
4. Select a document from the folder having **unclaimed documents**.
5. Claim the document by clicking the **Claim** button located at the top of the right panel. The document moves to the **folder containing claimed documents.**
6. Navigate to the folder that contains documents claimed for workflow and select a document from the grid.
7. Navigate to the **Workflow** panel in the right.
8. Select either **Rejected** or **Clarification** as the workflow status.
9. Select one or more **Issue** from the Issue field.
10. Click the **Create Query** below the **Comments** field. Refer to the screenshot below:

An email window opens. Click **Yes** to the question **Are you sending a Query?** (add image)

11. Click the ‘To’ and/ or the ‘CC’ button at the top of the message to add recipient of the Query notification email message.

The party responsible for having sent the document to the room is an automatic recipient of the outgoing message.

Only room participants can be added to the ‘To’ and ‘CC’ fields. Other email addresses cannot be added.

The sender can include the associated workflow query document as an attachment or as a link.

12. Once all appropriate selections are made, click **Send Query**.

The email message will go out to all recipients indicated in the fields at the top.

Recipients receive an email message like this:

Each Query is assigned a unique **Query ID** number for easy tracking.

Note: *A Query ID consists of the of the Room ID where the query was generated and the Query ID separated by a dash. For example, in the above screenshot, in the Query ID 1340-175, 1340 is the Room ID and 175 is the Query ID.*

13. Click **Save**.
14. The **Reviewer** can also view the queries sent under two other views:

    a. In the folder designated to hold documents sent for clarification under **My Review** view or **Quality Control Reviews** module where the document acquires a question mark to indicate that it is in query.

    b. In the **Pending** folder under **Query By Sender** view from the eTMF/Documents module.

Quality Control Response by a Responder

The Quality Control Responder can do the following to respond to the query email received in his/her email inbox:

1. The responder can view the query email in the **By Recipient** view under the **Pending** folder.
2. The responder replies to the email query **with/without attachments** or **links** after examining the query closely.
3. Once the **Responder** replies to the query email, the query automatically moves to the **Responded** folder in the responder's room under the **By Recipient** view.
4. The *Responder may also choose to resolve the query* by clicking the **Resolve** button in the Queries panel in the **Pending** folder. Under such circumstances, the document moves to the **Resolved** folder of the **By Recipient view of the responder** and in the **By Sender view of the reviewer**.

Quality Control Query Resolution by Reviewer for Query Responses without Attachments

Once the responder replies to the query email, the reviewer can view the responded message in the room in **By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

1. From the **In Progress** folder, click the document and select the **Query Panel** from the right of the page.
2. At the bottom of the Query panel, two buttons are visible – **Respond to Query** and **Resolve Query.** Refer to the screenshot below:

3. Click the **Resolve Query** button.
4. On clicking the **Resolve Query** button from the Query panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries without attachments:

Note:

- *On clicking the Return back to Pending button, the document returns back and is available for review again. It will then need to re-start the query process from the beginning. This can be used, for example, if the responder is Out of office and an automatic reply is sent from his/her email inbox due to which the document moves to the In Progress folder.*
- *The reviewer can also click the Resolve button from the Query window in Pending folder to mark a query as resolved without any additional actions or waiting for the responder to respond to the query email. This can be used if the reviewer decides that a response is not required or the documents will be received in some other way. For example, if a query was created by mistake and the reviewer decides to cancel the query thereby resolving it.*

5. On clicking the **Resolve** button from the **Query** window, the query moves to the **Resolved** folder under the **By Sender** view for the reviewer and in the Resolved folder under the **By Recipient** view of the responder. The user can see the **Query History** in the **History** Panel to the right of the page.
6. On clicking the **Resolve and create new document button** and entering the **Comments**, the reviewer clicks the **Next** button to arrive at the **Document Profile** form. Refer to the screenshot below: (add image)
7. Enter the document metadata details and provide the attachment.
8. Click the **Resolve and create document** button.
9. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.

Quality Control Query Resolution by Reviewer for Query Responses with Attachments

Once the responder replies to the query email, the reviewer can view the responded message in the room in **By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

1. From the **In Progress** folder, click the document and select the **Query Panel** from the right of the page.
2. At the bottom of the Query panel, two buttons are visible – **Respond to Query** and **Resolve Query.** Refer to the screenshot below:

3. Click the **Resolve Query** button.
4. On clicking the **Resolve Query** button from the Query panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries with attachments:

5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the Query by Sender view for the reviewer and in the **Resolved** folder under the **Recipient** view for the responder. The user can view the Query History in the **Query** Panel from the right panel. It also moves back to the folder holding documents available for review and needs to follow the review process again. The following options are available for sending response with attachment:

Resolve and replace using selected attachment

On clicking Resolve and replace using selected attachment option:

1. The reviwer can choose from the right pane, the document as deemed fit. Two attachments are displayed at the bottom of the window – (1) that was sent as an attachment by responder to allow the reviewer to resolve the query and (2) the document that is in the review process.
2. Before taking a decision, the reviewer can click the **Compare** icon from the right pane to compare between the document under review and the attachment sent by the responder in the **Compare documents** window, or click the attachment icon to open and view the attachment in the viewer.
3. Once done, the reviewer clicks the **Close** button on the Compare documents window and clicks the **Resolve and replace attachment** button after entering the **Comments**.
4. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.
5. The original document is still seen in the grid but the attachment from the query resolution can be seen under the Query History window.

Resolve and create new document

1. Can choose whether to **Use selected attachment** below the option by ticking the checkbox next to it and also use **Copy the metadata from the original document** to create a new document, ***or***
2. Untick both the above checkboxes and proceed to ignore the attachment and create a new document by providing another attachment.
3. Either ways, the reviewer clicks the **Next** button to arrive at the **Document Profile** form.
4. If the reviewer proceeds with option **Use selected attachment** , then he/she enters the metadata and clicks **Resolve and create document** button.

1. If the reviewer proceeds **with no option selected,** then he/she enters the metadata, provides the attachment and clicks **Resolve and create document** button.
2. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.
3. The original document is still seen in the grid but the attachment from the query resolution can be seen under the **History** panel.

Tracking Quality Control Queries

Users with Administrator access in a trial room can check the status of Quality Query Queries.

1. Navigate to the **Documents** module.(add image)
2. Click the Choose View button and select **By Sender** or **By Recipient** view from the list. The Index panel populates with folders that contain the Quality Control Queries at their various stages of progress.

   Select a specific folder and the contents of the folder populates the document grid.
3. Select a specific query from the grid and open the Right panel. The history of the selected query is available by clicking the **Query** panel. The stages of the query history populate the metadata panel.
4. Click the arrows to the left of stage description to see the details of each query stage.

   If the user decides it is appropriate to create a new document in order to resolve the query, the user is required to complete the document profile, including uploading a new attached document.

Excluding Documents from a Quality Control

An administrator can exclude one or more documents from the workflow by selecting the documents and clicking the **Exclude from workflows** option from the **More** dropdown located at the top right cornerof the Right Panel. Refer to the screenshot below:

On clicking the button, the **Exclude from workflows window** pops up.

If the room has multiple workflows, the administrator can select the workflows from which to remove the document/s by clicking the dropdown arrow in the dialog box. It is mandatory to provide the reason for exclusion which gets recorded in the review history of the document. By removing a document from a workflow, the document can be found in the index where it is originally placed.

Documents moved to the Start-Up are automatically excluded from the workflow and the eTMF.

Note: *To know how to view a deleted queried document, proceed to section Deleted Queried Documents.*

Quality Review

The Quality Review/Audit application in Trial Interactive allows to record an auditor's review and comments on various documents added for audit in a trial. You can also create a Quality Review profile from here.

As a Trial Interactive Administrator, you can access the **Quality Review Application** from the **Main Navigation**:

From here we discuss the following:

1. Quality Review Settings
2. Creating a Quality Profile
3. Performing Quality Review
4. Performing Quality Review Response
5. Responding to Quality Review Queries
6. Resolving Queries Raised during Quality Review

Quality Review Settings

Initial Audit functionality in a Trial Interactive room must be triggered by a user with Super Administrator access to the room. Once that setting has been activated, an Administrator can set up and edit audits on sets of documents in a room.

Once you enter the **Quality Review Application dashboard**, you can reach the **Quality Review Settings** page from **Quality Review Application -> Audit Settings.** Refer to the screenshot below:

The screenshot above shows a room that already has audits set up.

The Audit Settings page includes the following sections:

1. **The Documents Quality Review Settings:** From here Create, Edit, or Delete Audit profiles, Refresh Audit profiles, Publish Documents to Audit Profiles, and Activate/Deactivate Audits.
2. **The Quality Review Status:** From here Create Quality Review Profiles.

The above are discussed in separate topics accessible from the left panel of this help.

The Documents Quality Review Settings

This section displays the list of all active and inactive audits that are set up in the room. Refer to the screenshot below:

From here you can do the following:

1. Adding or Creating Audits
2. Editing Audits
3. Deleting Audits
4. Refreshing Audits
5. Publishing Documents to an Audit
6. Deactivating and Reactivating Audits

Adding or Creating Audits

From the Audit Settings, click the **Add** button on the top ribbon bar and follow the procedure as discussed in the topic Creating an Audit Profile.

Editing Audits

Note: *The Edit button is enabled only when you select the audit.*

Follow the steps below to edit an existing audit:

1. Select the required audit from the list.
2. Click the **Edit**  button from the top ribbon bar.
3. The **Create an Audit Profile** window opens.
4. Follow on to the steps and complete the audit profile.
5. The created audit profile then appears in the list of audits.

Deleting Audits

Note: : *The Delete button is enabled only when you select the audit.*

Follow the steps below to delete an existing audit:

1. Select the required audit from the list in the **Documents Quality Review Settings** window.
2. Click the **Delete**  button from the menu bar.
3. You are asked for the delete confirmation.
4. Click **Yes** if you are sure to delete the audit. Refer to the screenshot below:

Refreshing Audits

Click the **Refresh** Refresh button to reset the audit list.

Publishing Documents to Audit

Documents can be either be added manually or automatically to an audit. When you select the option **Documents will be added to the pool on demand basis** while creating an audit profile, you will have to add documents manually to an audit by clicking the **Publish Documents** button.

To publish documents:

1. Select the audit from the list of audits.
2. Click the **Publish Documents** Publish Documents button in the **Documents Quality Review Settings** window.
3. Click **Yes** on the confirmation window that appears, if you are sure to publish documents. Refer to the screenshot below:

All documents are now available in the audit for review.

Deactivating and Reactivating Audits

Room Administrators can stop and start audits that have been added to a room.

Follow the steps below to inactivate an audit that is currently active:

1. Click the name of the audit in the list in **The Document Quality Review Settings** window.
2. If the audit is **Active**, click the **Stop** button from the top ribbon bar. Refer to the screenshot below:

The status of the audit changes from **Active** to **Inactive** in the Status column.

3. Similarly, you can activate the **Inactive** Audit by clicking the **Start** button on the top ribbon bar and the status changes to **Active**.

> **Note:** *The **Start** and **Stop** buttons on the top ribbon bar changes their text as per the **Audit Status** for reactivating or deactivating them*

The Quality Review Status

Every system audit status has to be added into the **Audit Status** window before an audit can be built. The system statuses are **Passed**, **Failed**, **Pending**, **In Progress**, and **Excluded**. Each of these statuses must be mapped to a Display Name.

From here you can do the following:

1. Adding Statuses
2. Editing Statuses
3. Removing Statuses Each of these are discussed in the sections below:

Adding Audit Status

Follow the steps below to add audit statuses:

1. Click the **Add**  from the **Quality Review Status** tab.
2. The field under the **Display Name** and **System Status** fields gets activated.
3. Type in the **Display Name**.
4. Click the drop down arrow from the **System Status** field and select the established **System Status** term to associate with the newly added **Display Name**.
5. Click the **Add** in the Command columns to save the changes. The status gets saved to the list. Refer to the screenshot below:

6. Notice that when you click the **Add** button and the fields get activated, the Add button changes to **Cancel**.

Editing Audit Status

Follow the steps below to edit audit statuses:

1. Select the audit status from list in the **Quality Review Statuses** window.
2. You can edit the audit in the following by:

   a. Selecting the audit from the list and then the **Edit**  button from the top ribbon bar OR,

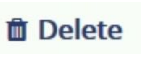
   b. Clicking the **Edit** icon that appears on hovering the mouse over the audit. Refer to the screenshot below:

3. Notice that the **Add** and **Edit** buttons changes to **Save** and **Cancel** when the audit is activated for editing. Refer to the screenshot below:

4. Make the required changes and click **Save**.

Removing Audit Status

Follow the steps below to remove audit statuses:

1. Select the audit status from the list in the **Quality Review Status** window.
2. Either click the **Delete**  from the top ribbon bar or click the **Delete** icon that appears on hovering the mouse over the audit.

Creating an Audit Profile

In Trial Interactive, before creating an Audit Profile, we would need to know the various roles that need to be assigned to users to perform audits:

1. **Auditor**: Users under this role can see only the documents they audit.
2. **Auditor manager**: Users under this role can see audit results of all auditors and can provide their own review comments to documents. Only editors and higher level users fit this role.
3. **Audit Responder**: Users under this role are responsible to take actions on issues cited by auditors in the documents. Only editors and higher level users fit this role.

> **Note:** Quality Review Profiles can be created from either the Documents Cart or from the Documents Quality Review Settings module.

Creating an Audit Profile involves the following steps in sequence:

1. Filling the General Information
2. Selecting Auditors
3. Selecting Audit Managers
4. Selecting Audit Responders
5. Selecting Statuses
6. Viewing Audit Summary

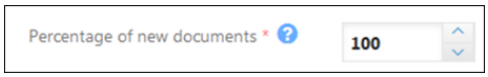
Each of the above are discussed in separate topics available from the left panel of this topic help.

Creating an Audit Profile - General Information

Follow the steps below to enter the general information for Audit Profile:

1. Navigate to **Quality Review → Documents** module.
2. Navigate to the required folder to display the documents in the grid.
3. Right click on the required documents and select the **Add to Cart** options. The documents gets added to the **Documents Cart.**
4. From the Documents Cart, select the documents and click **Actions → Create Audit Profile**.
5. The **Create Audit Profile** window opens. Refer to the screenshot below:

6. Enter the **Title** of the Audit in the title field.
7. Select the **Documents to audit** from the various radio button options available in this section. Each of the options in the Documents to Audit is discussed in detail in the topic ***Documents to Audit***.
8. Enter the **Audit Scopes**. Documents submitted/published within the selected date range will be published to the audit pool. The Audit scope will be disabled if the documents are added to the pool on demand basis, or from selected audits.
   a. ***From Date***: The day from which the audit is to start. It is not possible to select future dates as 'From Date'.
   b. ***To Date***: The day till which the audit is to be completed.
9. Select **Submitted/ published dates**. Audit will be applied only to submitted or published documents as per selection. Submitted documents are documents just added to the room, whereas published documents are documents added to the room as final.
10. Select **Published documents only**: If selected, documents added to the room as Final documents will be added to the audit pool. The user can choose to select Submitted from step c and check the **published documents only** checkbox. In this case, the audit pool will receive only documents that are just published to the room as final.
11. Select **Add reworked documents back to the audit pool**: Changing a document metadata, or replacing the document attachment will add the document back to the audit profile with open status, irrespective of the fact that the document was passed/approved during audit in the same audit profile. Currently supported metadata changes are Index, Category, Document Type, Investigative Site, and Document Date.
12. Select **% of new documents**: This defines the percentage of documents to be included in the audit pool as per the frequency, or audit scope. The percentage of documents are calculated from each intersection of selected investigative sites, document types and folders. Refer to the screenshots below:



13. Select **Frequency:** When set, the system will move the documents to the audit pool based on the period set in the interval. This will be disabled if the audit scope date range is selected.
14. Select**Auditors' access level**: This defines the security that the auditor receives on a document. The access level can be **Full** or **Read-only**.
15. Select **Contains PHI**: The client may allow auditors to delete documents containing PHI, under which case the administrator will need to enable the **Contains PHI** functionality by ticking the checkbox next to it. To activate this checkbox, the **Auditor's access level** has to be set to **Full**.
16. Select **Send audit notification**: When checked, the auditor will receive an email notifying that new documents are added to the audit pool.
17. Once you have made the selections, click **Next** at the bottom of the window. You are taken to the next step of the Audit Profile to add **Auditors**.

Documents to Audit

You can add audits and documents to the current audit profile from the various radio button options available as shown in the screenshot below:

Documents will be added to the pool on demand basis

If selected, documents will not be added to the audit pool automatically. Instead, the user have to add documents manually to the audit pool from the Documents Cart.

Selected Audits

If selected, documents passed in the selected audit profiles will be added to the current audit profile.

Follow the steps below to add audits to the current audit profile:

1. Click **Select**. The **Select Audit** window opens.
2. Select audits from the list of audits and click **Next** at the bottom of the window. Refer to the scrreenshot below:

3. Select auditors from the selected audit profiles and click **Finish** at the bottom of the window.

4. The number of audits and auditors selected appears in the **Selected audit** text box. Hold the mouse over the help icon to reveal the details of the audits and auditors selected.

5. Clicking the multiselector (textbox) opens the complete view of the audits and auditors selected. Refer to the screenshot below:

All documents

If selected, the documents of all document types will be added to the audit pool for audit.

Selected Documets - Selected document types

If selected, documents for audit will be selected from the chosen document types.

1. Click **Select** 

. The **Select Document Types** window opens.
2. Click the arrow next to the document type to navigate to the sub-types and select the checkbox next to the required document type.
3. Click **Select** at the bottom of the window. Refer to the screenshot below:

4. Besides, you can also click the textbox and select the document types from the dropdown that appears. Refer to the screenshot below:

Selected Documents - Selected Investigative Sites

If selected, documents for audit will be selected from the chosen investigative sites.

1. Click **Select**  . The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
3. Click **Select** at the bottom of the window. Refer to the screenshot below:

4. Besides, you can also click the textbox and select the investigative sites from the dropdown that appears. Refer to the screenshot below:

Selected Documents - Select Folders

If selected, documents for audit will be selected from the chosen folders.

1. Click **Select**  . The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
3. Click **Select**. Refer to the screenshot below:

Creating an Audit Profile - Adding Auditors

After adding all the general information, you are landed on the **Auditors** step. Refer to the screenshot below:

Follow the steps below to add auditors to the current audit profile:

1. Click +**Add** 

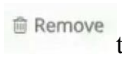
from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:

   a. Hover the mouse over the required user / group and click + icon  that appears to the right of the selected user/group or double click the user/group to add the them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to audit.
   b. You can also search for the user/group by entering the name in the Search box above the grid and then click the **Magnifying icon**  to the right. Refer to the screenshot below:

c. Click **Add** from the bottom of the **Add Users and Groups**window.

d. You are taken back to the **Auditors** window and the selected members appear in the grid.

3. Click **Next** at the bottom of the **Auditors** window.
4. You can also choose specific documents types, investigative sites and folders to be available to the auditors for audit by clicking **Configure Content** in the Auditors section.
5. During the process of creating an audit profile you may choose to remove, activate/deactivate auditors:

   a. Tick the checkboxes next to the auditor names and click **Remove** 

to remove them from the list.

   b. Tick the checkboxes next to the auditor names and click **Dectivate** 

to deactivate auditors.

   Alternatively, select a deactivated auditor and click the **Activate** 

button to activate an auditor. Refer to the screenshot below:

6. Click **Next** at the bottom of the **Auditors** window.

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Managers**.

Configure Content

Besides adding documents for current audit profile from the **General Information** step, you can also also configure the content for the auitors using Configure Content from the **Auditors** step.

Note: *This feature is enabled only if you choose **Add documents to pool on demand basis** option disabled when when you choose **Selected Audits** from the General Information step.*

Follow the steps below to configure content:

1. Select the user/group from the list of auditors.
2. Click the **Configure Content** Configure Content icon located to the extreme right of the menu bar. A popup appears displaying the options as shown in the screenshot below:

3. Click the required option to configure the content for the selected audit user/group.

   Follow the steps below to configure Document Types:

   a. Click **Select** Select. The **Select Document Types** window opens.
   b. Click the arrow next to the document type to navigate to the sub-types and select the checkbox next to the required document type.
   c. Click **Select** at the bottom of the window. Refer to the screenshot below:

   d. Besides, you can also click the textbox and select the document types from the dropdown that appears. Refer to the screenshot below:

Follow the steps below to configure Investigative Sites:

a. Click **Select** Select. The **Select Investigative Sites** window opens.
b. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
c. Click **Select**. Refer to the screenshot below:

Follow the steps below to configure folders:

Selected Documents - Select Folders

If selected, documents for audit will be selected from the chosen folders.

1. Click **Select** Select. The **Select Investigative Sites** window opens.
2. Select the checkbox next to the required investigative sites. The selected sites gets highlighted.
3. Click **Select**. Refer to the screenshot below:

Creating an Audit Profile - Adding Audit Managers

After adding Auditors, you are moved to the next step to add **Audit Managers**. Refer to the screenshot below:

Follow the steps below to add audit managers to the current audit profile:

1. Click **+Add**  from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:

3. Hover the mouse over the required user / group and click + icon that appears to the right of the selected user/group or double click the user/group to add the them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to audit.
4. You can also search for the user/group by entering the name in the Search box above the grid and then clicking the **Magnifying icon** to the right. Refer to the screenshot below:

5. Click **Add** from the bottom of the window.
6. You are taken back to the **Audit Managers** window and the selected members appear in the grid.
7. You can also **Remove** Audit Managers by clicking Remove button or **Deactivate** them by clicking Deactivate button from the menu bar. Refer to the screenshot below:

8. Select the appropriate users/groups from the grid , click **Next** at the bottom of the window.

Note:

- *The **Remove** and **Deactivate** buttons enable only when you select the auditor from the grid.*
- *The **Deactivate** button toggle to **Activate** when no auditor is selected from the grid.*

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Response**.

Creating an Audit Profile - Adding Audit Responders

After adding Audit Managers, you are moved to the next step to add **Audit Responders**. Refer to the screenshot below:

Follow the steps below to add audit responders to the current audit profile:

1. Click +**Add**  from the menu bar of the window. The **Add Users and Groups** window appears.
2. The window provides two tabs – **Users and Groups** to add users and/or groups as required. Refer to the screenshot below:

3. Hover the mouse over the required user / group and click + icon  that appears to the right of the selected user/group or double click the user/group to add the them to the auditor list. The names of the users/groups will populate the **Selected Members** panel to add to audit.
4. You can also search for the user/group by entering the name in the Search box above the grid and then clicking the **Magnifying icon**  to the right. Refer to the screenshot below:

5. Click **Add** from the bottom of the window.
6. You are taken back to the **Audit Responders** window and the selected members appear in the grid.
7. Select the appropriate users/groups from the grid , click **Next** at the bottom of the window.
8. You can also **Remove** auditors by clicking Add button or **Deactivate** them by clicking Deactivate button from the menu bar. Refer to the screenshot below:

Note:

- *The **Remove** and **Deactivate** buttons enable only when you select the auditor from the grid.*
- *The **Deactivate** button toggle to **Activate** when no auditor is selected from the grid.*
- *Only **Editors** and **higher level** users can be allotted the **Audit Manager**s and **Audit Responders** role. A user cannot be allotted both the Auditor and Audit Responder role for the same Audit profile.*

Once you have made the selections, click **Next**. You are taken to the next step of the Audit Profile to add **Audit Statuses**.

Creating an Audit Profile - Adding Statuses

After adding Audit Responders, you are moved to the next step to add **Audit Statuses**. Refer to the screenshot below:

To add the statuses:

1. Select the required audit statuses from the **Statuses** window.
2. Click **Next**. You are taken to the next step of audit profile which displays the **Audit Summary**.

Creating an Audit Profile - Viewing Summary

After adding Audit Statuses, you are moved to the next step to view **Audit Summary**. Refer to the screenshot below:

The **Audit Summary** warns for any issues found in the Audit Profile. If Issues are cited:

1. Follow the directions in the fields showing explanations , and click the arrow next to the field to navigate to page of the building of the audit profile where the issue has been cited.
2. Correct the details that have led to the issue.
3. Click **Go Back to Summary Page** and then click **Finish**.If you are sure the audit profile has been set up correctly, click **Yes** to activate the audit. Refer to the screenshot below:

4. The newly activated audit appears in the display list.

Performing Audits

If you are assigned the Auditor or Audit Manager action in your trial room, the audit feature is available to you when you click the **Quality Review** module in the toggling menu bar.

The Quality Review module has the following views:

- **Audit**: This allows you to perform audits
- **Documents**: This allows you to assign documents for audits
- **Settings**: This allows you to configure settings for Quality Review

Follow the steps below to perform audits:

1. As a user with Auditor duties, log in to a room and click the **Quality Review**icon from the Main Navigation. The user can access **Audits**, **Audit Documents** and **Audit Settings**through the panel on the left.
2. Click the **Audit** view from the left panel. The Audit view opens.
3. Click **three dots** from the left pane. The **Choose View By** popup appears as shown in the screenshot below:

4. Click the **Quality Review** dropdown to select an active audit from the list.
5. The user can also choose to view the available audit documents *By Document Type*, *By Country*, *and By Investigative Site*, *Audit Findings*, *Query By Sender, and Query By Recipient*. Select views to be displayed.
6. The corresponding folders display based on the selection made by the user. Drill down and select the available folders.

   Available documents will be displayed in the grid. .

The Auditor has another means to filter the audit documents.

1. Once the Audit is chosen, click the **Document Status** dropdown.
2. Select **Pending** from the list.
3. Select the auditor from the **By Auditor** dropdown.
4. Click the **Select** button. Index folder containing documents **Pending Audit** populate in the Index View. Refer to the screenhot below:
5. Open folders to locate documents published and assigned for audit.
6. Notice the **Quality Review Information** icon next to the document icon in the document grid.
7. Click the icon to open the Audit Panel in the Metadata Panel. Also notice that the **Quality Review Information popup** displaying the audit status of the selected document. Refer to the screenshot below:

8. Open the document in the viewing panel.
9. Examine the document and its metadata to determine if it meets the established audit criteria.
10. From the **Metadata panel** to the right, click the dropdown arrow at the right end of the **Status** field.

    The status options appear.
11. Click the appropriate **Status**.

    If the document contains **Protected Health Information** (PHI) and you want to delete and fail the document attachment for audit, tick the **Contains PHI?** checkbox.

    Note: *To enable the Contains PHI ? field, you will need to enable the feature when setting up the Audit under Document Audit Settings*

    On ticking this, the document automatically acquires a **failed** status and displays a warning regarding the removal of the attachment from the document.

    Click **Remove file** to proceed. The system deletes the attachment in the backend and displays the **Refresh** icon next to the document in the grid.

    On clicking the **Refresh** icon, the document disappears from the grid and moves to the **Audited** folder.
12. Insert comments as appropriate.
13. Click the **Save** button, or the **Save and select next button** in the lower toolbar of the window.

    Note: *Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your Audit Criteria*
14. To view audited documents, filter the documents by Audited from the panel in the left.
15. The audited documents appear in the grid with their respective statuses. Documents failed due to content of PHI appear in the grid without the attachment and acquire a failed status.

Reassigning documents for audit to another auditor

As an Administrator or Audit Manager, you can choose to assign a document to another auditor for audit by selecting the documents from the document grid and clicking the **Assign To** icon from the top ribbon bar. Refer to the screenshot below:

Here, you can resassign the auditors in either of the following ways by:

1. Clicking the **Automatically reassign randomly between existing auditors checkbox** from the **Assign to dialog** box if you wish to assign documents randomly to existing auditors, OR
2. Unchecking the **Automatically reassign randomly between existing auditors checkbox** and selecting the auditors by clicking in the textbox and then assigning auditors.

Exporting Audits

An Auditor or Audit Manager can export a report of the following directly related to the documents assigned to any particular audit:

1. Metadata
2. Documents
3. Security
4. Audit By View
5. All Audits

To export an audit report:

1. From the **Quality Review** module, click **Audit** from the left menu bar.
2. Select the audit on which you would like to run the audit report from the list of active audits.
3. Select the documents from the list and click **Export** on the top ribbon bar.

4. From the Export Dropdown, click the required option to generate an audit report.
5. Click the **Export** button. A **Background Jobs** window opens with the initial export results.
6. As instructed on the screen, click to get the export results. A zipped file downloads to your computer.
7. Follow the on-screen instructions to open the XLSX file.

Each option in the Export dropdown is discussed as below:

Metadata

This is same as discussed in **Exporting Metadata** in chapter **Exporting Metadata**.

Documents

This is same as discussed in **Exporting Documents** in chapter **Exporting Documents**.

Security

This is same as discussed in **Exporting Security** in chapter **Exporting Security**.

Audit by View

Select **Audit by View** from the Export dropdown menu. The **Audit Data Export** window opens.

Follow the on-screen instructions to generate the audit report.

All Audits

Select **All Audits** from the dropdown menu. The **Audit Data Export** window opens.

Follow the on-screen instructions to generate the audit report.

Performing Audit Response

To perform an audit response, you must be logged in the room as an Audit Responder.

1. Navigate to the **eTMF/Documents** module or the **Quality Review/ Audit module**.
2. If you are in the eTMF Documents module, select **Documents** from the menu icons at the top of the screen.
3. From either of the modules, select **Audit Findings** view.

The active audits to which you are assigned that have audits with findings populate the Index panel.

4. Click the folder for one of the audits. The documents with audit findings populate the document grid. Documents in the list that are available for **Audit Response** show a padlock icon that is unlocked.
5. Select the document by clicking the checkbox.
6. Open the metadata panel for the document by clicking the **Metadata** button at the bottom of the document grid.
7. At the bottom of the metadata panel, click the **Audit** button.

8. From the available options, click **Claim document for Audit Correction**.
9. Click **Document** at the bottom of the document grid to open the contents of the document for inspection.
10. From the Audit History panel, click **View Full History** button to view the comments included by the Auditor.
11. Appropriate actions on the part of an Audit Responder are based on the nature of the failure of the audit.
12. If the cause of the document's audit failure can be remedied by the Audit Responder, that action can be carried out.
13. In such cases, the Audit Responder then goes to the **Audit** button at the bottom of the metadata panel again and selects **Mark document as corrected**.
14. If the cause of the document's audit failure cannot be remedied by the Audit Responder, the Audit Responder clicks **Email** from the top ribbon bar or **Initiate Query** from the bottom of the Metadata panel.

15. The **Email** popup window opens. Click **Yes** to the question **Are you sending a query?**
16. Click **To** and select the appropriate party or parties from the room's users to notify about the discrepancy discovered in the audit.

17. Include something in the Subject line and enter the text of message to alert the recipients as to what action they need to take.
18. Select **Files as Links** at the bottom of the Email window to send the document along with the email message. Documents can also be sent as attachments.

    Click **Send**.

    The selected users will receive the email message regarding the Query raised.
19. Click **Audit** sub-module from the left menu bar. The queries raised during audit can be viewed from the **Query By Sender** current viewin the left index pane, if you have sent queries to be resolved during audit. Refer to the screenshot below:

Resolving Queries Raised during Audit

The user who receives the email responds back with an attachment to resolve the query. You can view the responded query in the **Responded** folder of **Query By Recipient** view under the selected audit. Refer to the screenshot below:

To resolve queries raised during audit:

1. Navigate to the **Query By Recipient** view.
2. Select a query from the grid on the right.
3. Click the **Metadata** button from the bottom of the grid. This will open the Document Data Panel.
4. Click the **Resolve** button from the bottom of the **Document Data Panel**.If the resolution is not acceptable, you can click the **Return to Pending**button from the bottom of the metadata panel. The document returns back to the **Pending** folder and can be resent for query again.
5. This will open the **Query** window to comment and resolve the query.
6. Enter the **comments** and click the **Resolve** button or **Resolve and replace attachment** button on the window as per your selection. Refer to the screenshot below:

   a. **Resolve**: This option will just mark the query as resolved without any additional actions.
   b. **Resolve and replace using selected attachment**: This option allows you to replace the existing attachment with the one which is received as a part of query response. Select the document from the right pane and click **Compare** icon to compare the attachment received with the document in audit.

      If you are satisfied with the response received, enter your comments and click Resolve and replace attachment button.

7. This will resolve the query and the query will now move automatically to the **Resolved** folder under the name of the auditor.
8. Click the **Resolved** folder from the **Index Pane** to view the resolved query. Refer to the screenshot below:

9. You can click the **Query History** icon at the bottom of the Document Data Pane for a query to view the **Query History** in a window that pops up.

Note: *To know how to view a deleted queried document, proceed to section Deleted Queried Documents.*

Adding modified document back to Audit Profile

To allow for a modified document to be added back to the Audit Profile, follow the steps as below:

1. Navigate to **Username dropdown -> Settings -> Audit -> Quality Review Settings.**
2. Select the Audit Profile as required and click **Edit** from the top ribbon bar.
3. Select the checkbox next to **Add reworked documents back to the audit pool.** Refer to the screenshot below:

4. Click **Next** and complete the remaining steps to modify the Audit Profile.

Sites, Required Documents, Countries and Contacts

In this section, we discuss about the Sites, Required Documents that are required for site activation, Country Documents and Contacts.

Sites

You can access the Sites module by clicking Sites  icon on the left manu bar in the eTMF/Documents module. The Sites module is used for site management purposes and allows the administrator to track the progress of the sites. It gives the detailed information on all investigation sites available in a room **By Status** , **By CRA** , **By Country**.

You can perform various other activities associated with a site, such as:

1. Retrieving Site Details
2. Adding, Editing, and Deleting sites
3. Importing, and Exporting Sites
4. Mass Coding metadata for sites
5. Managing Security.

Each of the above are discussed in the seperate topics and can be accessed from the left pane of this help.

Site Views

This section discuss about the various views of Sites module.

By Status

Select **By Status** from the dropdown in the Index Pane of Sites Dashboard. Refer to the screenshot below:

This will populate the data of all the sites available in the room based on their progress report in the right pane of the dashboard.

By CRA

Select **By CRA** from the dropdown in the Index Pane of Sites Dashboard. Refer to the screenshot below:

This will populate the Clinical Research Associate (CRA) for the available sites in the Index Pane on the left. Click the name of a CRA to populate the site details associated with that particular CRA in the right pane.

By Country

Select **By Country** from the dropdown in the Index Pane of Sites Dashboard. This will populate the countries where the studies are being conducted in the Index Pane on the left. Click the name of a country to populate the site details associated with that particular country in the right pane. Refer to the screenshot below.

Site Profile

Select a site from the grid and the Site Profile is displayed at the bottom of the grid. This will allow you to fill all the metadata related to the selected sites. Refer to the screenshot below:

The Site Profile window provides the following:

1. General Info tab
2. Contacts tab
3. Specific Requirements tab

Each of the tabs is discussed in the separate topics.

Site Profile - General Info

This tab displays the general information of the site.

After selecting a site, click the **General Info** tab to edit the general details of the site. Click the **arrow** next to the required section of the General Info to update. Refer to the screenshot below:

When you click the arrow, the section fields gets enabled and the arrow turns to - sign as shown in the screenshot below. Similarly, you can update the fields in the other sections of your choice.

Site Profile - Contacts

This sections displays the list of contacts that are added to a site. From here, you can **add**, **edit**, **delete**, **deactivate** contacts and also change the contact to other level. Refer to the screenshot below:

Double click the user to open the **Contact Profile** to the right of the contacts tab. This allows you to edit the contact details of the user. Once all the details are updated, click **Save** to save the changes. Refer to the screenshot below:

Adding a Contact

1. Click **Add** from the menu bar of the Contacts tab.
2. The **Add Contact** window opens.
3. Fill in the required details and click **Finish**.

Editing a Contact

Select an added contact and click **Edit** in the Contacts tab to edit the contact information entered as above.

Deleting a Contact

Select an added contact and click **Delete** in the Contacts tab to delete a contact information.

Deactivating a Contact

Select an added contact and click **Deactivate** in the Contacts tab to deactivate the contact.

Convert to User(s)

You can assign a site contact the role of editor or reader and assign actions as appropriate from the **Convert to User(s)** utility in the **Contacts** tab.

Site Profile - Site Specific Requirements

This section displays the list of all the Site Specific Required documents. From here, you can **Add** required documents to a site, **delete** the documents, **Assign Milestones** to the documents and view the **Change Log History** of the selected documents.

Adding , Editing and Deleting Sites

Important: *The following description is for adding Investigative Sites in an eTMF:*

- *Sites are added to the Study Start Up module by a slightly different method. If SSU has been enabled for the study, the user first clicks the Study Start Up icon at the top, then selects the Sites tab. The rest of the process of adding Investigative Sites is the same as the process described below.*
- *Sites added from the eTMF/Sites module also appear in the Study Start-Up, if that is enabled for you.*

Adding a Site

1. Click the **Add** 

button from the top ribbon bar. The New Investigative Site window opens. Refer to the screenshot below:
2. Either type the **Institution Name** in the available field or click the search icon to view the list of **Available Investigative Sites**. Investigative site information is stored in Trial Interactive's database. If a client has used an investigative site in a previous study, the site's information will be stored and easily accessed through this option.
3. **Create** or **Add existing** contacts from the **Contacts** panel in the window. This information will be supplied by the client and can be created under **Contact Types** in Investigative Site Settings. You can also add the Contact Type by clicking the contact type field which will then reveal the dropdown list to select your choice. Refer to the screenshot below:

   To make the Sponsor Contact ID a Required field proceed to **Settings -> Form Settings -> Investigative Site Profile**. Select the **Sponsor Site ID Field title** from the list **of System Fields** and tick the checkboxes under the **Coding** and **Required** column.

   Note: *The Sponsor Contact ID is used by the system as the unique identifier of sites used by third parties to enable their integration with Trial Interactive. Hence, the Sponsor Contact ID will need to be a Required field so that it can be passed to Trial Interactive. Similarly, to detect duplicate entries of site contacts, the email-id field is now case-insensitive.*

4. Select an added contact and click **Edit** in the Contacts panel to edit the contact information entered above, or **Delete** to delete a contact information. You can also edit a contact by double-clicking the contact in the Contacts panel.
5. Click **Activate** or **Deactivate** to activate or deactivate a contact. This will either check or uncheck the **Active Contact** checkbox in the **Edit contact** window. Refer to the screenshot below.
6. You can assign a site contact the role of editor or reader and assign actions as appropriate from the Convert to User(s) utility in the **Contacts** panel.
7. Click **Address** to reveal the fields to enter the site location details. Based on the address entered the system shall calculate the Geo Code of the site and populate it in the new field **Geo Code**. Refer to the screenshot below:

   Click **More** to open another array of data fields. Enter the investigative site information provided by the client. Refer to the screenshot below:

   Note: *The Geo Code nees to be enabled from the Settings → Form Settings → Investigative Site Profile → Geo Code. This is an important field for myTI mobile app to detect site location*
8. Click **Create** at the bottom of the window.
9. Repeat this process until all investigative sites have been created for the room.

Editing a Site

Similarly, you can **Edit** a site by first selecting the site from the right pane and then clicking **Edit** button from the top ribbon bar. You can also edit a site from the **Site Profile** window also. This is discussed under **Site Profile.**

Deleting a Site

Select a site first and then click the **Delete** button from the top ribbon bar to delete a site.

Importing Sites

The metadata and contact information for an investigative site can be imported by using the **Import** 

icon located on the top ribbon bar. It runs the metadata import wizard where the user can upload an .xlsx spreadsheet, setup columns and metadata fields mapping, perform actual import and observe the result.

1. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import just contacts so they will be mapped to existing investigative sites. The wizard offers a link to the sample worksheet so user can download it and fill with actual data. Click **Next.** Refer to the screenshot below:
2. Setup the mapping between metadata fields and uploaded file columns for Investigative Sites. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.** Refer to the screenshot below:
3. Setup the Contacts related metadata. Click **Next**.
4. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.
5. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.
6. It is also possible to download the full report as a text file. The import operation can be aborted any time.

Manage Security for Sites

There are two site level securities available for sites:

1. Editor
2. Reader

Administrators can use **Manage Security** to include users to any one of these groups:

1. Select the sites from the grid and click **Manage Security** dropdown from the top ribbon bar.
2. Select the type of users to add to the security groups. You can add either **Editors** or **Readers**. Refer to the screenshot below:
3. This will open either the **Security – Editors** or **Security – Readers** window as per your choice. .
4. Select the users in the **Users** tab to add to the security group, or/and click the **Groups** tab to select a group of users to be added to the security group. Click **OK**. An example for adding editors is shown below. The readers too would be added in a similar manner.

Mass Coding for Sites

Administrators are sometimes called upon to fill in or update the metadata of a number of sites in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Select the sites to be coded in your grid.
2. Click the **Mass Coding** tool from the top ribbon bar. The **Mass Coding** window opens.
3. Fill in the details by double-clicking the fields, and click **Save** to proceed with mass update of the sites' metadata.You can select multiple CRAs and Start-Up Specialists, if required.

Exporting Sites

You can also export site metadata through the **Export** window that appears on clicking the **Export** icon on the ribbon. Refer to the screenshot above. You may export sites selected from the right panel, or all the sites in the current grid or room. To export site data, it is mandatory to select the **Site Metadata Fields** as shown below:

You can export the additional fields in either alphabetical or logical order of selection.

Similarly, to export site contact data, you need to select **Contact Metadata** fields as shown below:

The export result are also populated in the **Notifications.** Click **GetJob Result** to view the excel file.

Required Documents

When creating a Site, it is mandatory that you submit all the essential and required documents for **Site Activation**. These Required Documents can be among the following depending upon the requirement of site activation:

1. Site Documents
2. Country Specific Documents
3. IRB/EC Specific Documents

Note: *A site cannot be activated unless all the required documents are submitted during site creation.*

Required Documents Settings

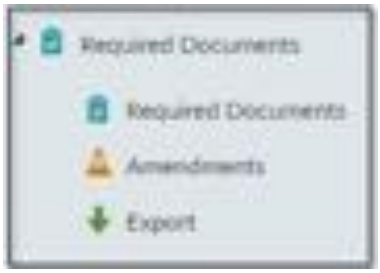
With the help of **Required Documents Settings**, Administrators establish and edit the Required Documents for a study. Different document types may be required for all Investigative Sites involved in a study, or there may be documents that are required of investigative sites that are located in particular countries. These settings are typically made at the outset of a study, but they may be modified during the course of a study under certain circumstances.

Once Document Types are set up for a room from Document Types Management, you can set up the Required Documents.

Note: *It is recommended that administrators contact the Trial Interactive Project Management Team if any changes or additions are needed here. Once Document Types are set up for a room from* ***Document Types Management****, you can set up the Required Documents.*

1. Navigate to **Main Navigation -> Settings Module**
2. Select **Required Documents** from the menus on the left.

   Refer to the screenshot below showing the various options under **Required Documents Settings**:



Required Documents can be defined for the following:

1. All Sites
2. Country Specific
3. IRB/EC

   Each of these are discussed in the separate topics and can be viewed from the left pane of this help.

Required Documents

1. From the left section of the panel you can select the category (**Sites, Country, IRB/EC, and General**) of the Required documents. By default, **All Sites** category is chosen.
2. From the right section of the panel, named as Document Types, you can:

   a. **Add** Add or **Delete** Delete a Required Document to the category selected from the left pane.

   b. **Assign Milestones** Assign Milestone to selected Required Document Types.

   c. View the activity log of the selected category from the **Change Log** Change Log.

   d. Once a Required Document is added, it appears in the Document Types Grid.

Each **View Option in the Required Documents** is discussed as below:

All Sites

Country Specific

IRB/EC Specific

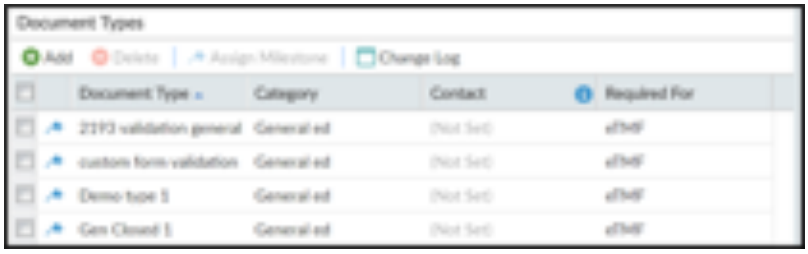
General

Assigning Milestones to Required Documents

To assign a milestone to a Required Document, follow the steps as below:

1. Select the category from the left pane.
2. Except for All Sites and General categories, select the Country or IRB/EC from the left pane.
3. Select the Required Documents from the right pane.
4. Click **Assign Milestone** Assign Milestone from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:

6. Choose the milestones from the dropdown list
7. Click **Assign Milestone** button from the popup window.
8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**. Refer to the screenshot below:



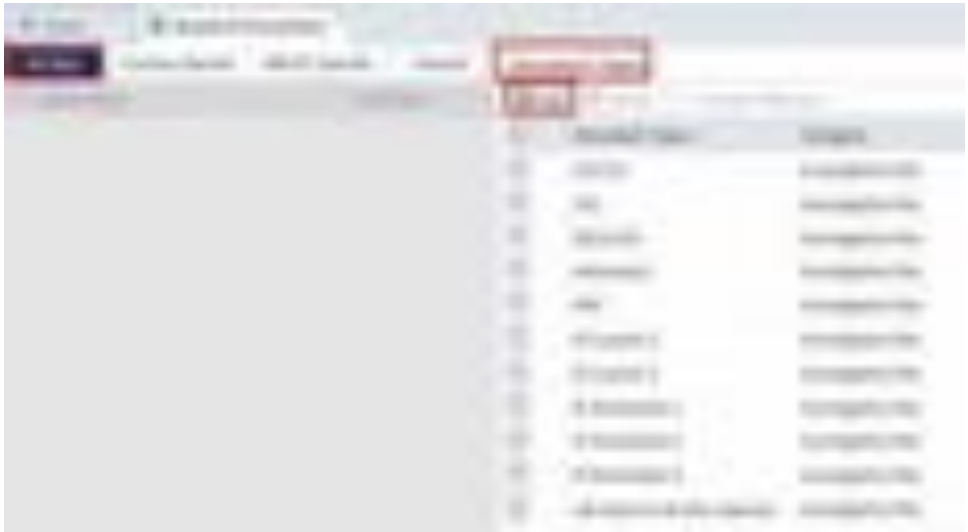
All Sites

All Sites

Note: *By default, no documents are Required Documents. Required documents must be defined in this settings view. If the room has been cloned from a previously used room, the Required Documents may already be defined.*

Adding All Sites Required Documents

1. Click the **All Sites** tab from the left panel of the **Required Documents Panel**.
2. Click **Add** from the top ribbon bar of the **Document Types** window on the right. Here, you can add document types that will be required by all sites included in the study. Refer to the screenshot below:



3. The **Required Documents** window opens for you to add Required Documents for your sites under specific categories . Refer to the screenshot below:

4. Click the **Category Folder**from which you need to select the Required Documents that you want to add to the list for all sites. The list of the available document types in that category folder appears.
5. Click the checkbox next to one or all of the documents to be required.
6. Select whether the document(s) will be required for **Site Activation** or **eTMF** by clicking the checkbox.
7. From the dropdown menus to the right, select:
   - **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
   - **Languages**- Select the language from the list to be applicable to the Required Document.

   Note: Document types that need to be submitted by different contact types need to be set up separately.
8. Click **Save & Close** if you have documents from only one category folder to add, or click **Save** if you need to add more required documents.

Note: *If documents are to be provided by one study contact and another document or documents are to be provided by a different contact, click **Save**; go back to the documents list; select the next set of documents, again select whether the documents are required for Site Activation or eTMF; select the contact type from the dropdown; and click **Save**. Continue this process until you have finished adding required document types for all contacts and then finally click **Save & Close**.*

Deleting All Sites Required Documents

To delete a Required Document Type for All Sites:

1. Click **All Sites** tab from the left panel of the **Required Documents Panel**.
2. From the list of Required Document Types in the grid, tick the checkboxes to select the Required Document Types to be deleted.
3. Click **Delete** from the top ribbon bar of the **Document Types** window on the right. Refer to the screenshot below:

4. You will receive a warning asking you to confirm the action.
5. Click **Yes** to confirm and delete.
6. The Required Document Types are removed from the list.

Country Specific

Sometimes, there will also be country-specific document types that will be required.

1. Select the **Country Specific** tab.

   Note: *Countries being used for a study are entered during initial Room Configuration. Instructions for **Adding Countries** can be found in another section of this guide.*

   The list of countries will activate in the left pane. Refer to the screenshot below:

2. Select the particular country for which you need to add a required document.
3. The **Document Types** window on the right becomes active.
4. Click **Add** from the top ribbon bar of the Document Types window on the right.

   The **Required Document** window opens, affording you the opportunity to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).
5. Selection of the **Investigative Site** radio button activates the list of document types included under Site Management.
6. Selection of the **Study** radio button activates the document types included under the Country document category.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction, if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.

   Note: If a specific contact type is made a requirement for document submission, all matching site users will be required to submit that document.
10. Click **Save**.
11. Begin again at the top of the **Required Documents** window.
12. Select the Study documents to be required.
13. Click **Save & Close**.
14. Select the next country in the list to which you need to add required documents, and follow the process steps above.

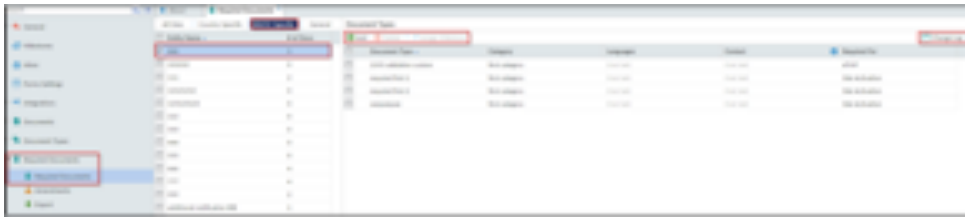
IRB/EC Specific

Sometimes, there will also be IRB/EC-specific document types that will be required.

Adding IRB/EC Specific Required Documents

1. Select the **IRB/EC Specific** tab

   The list of IRB/ECs will activate in the left pane. Refer to the screenshot below:



2. Tick the checkbox to select the particular IRB/EC for which you need to add a required document.
3. The **Document Types** window on the right becomes active.
4. Click **Add** from the top ribbon bar of the Document Types window on the right.

   The **Required Documents** window opens, providing you the opportunity to select whether the document types you are going to add will need to be provided by the investigative site or by the country (study level).
5. Selection of the **Investigative Site** radio button activates the list of document types included under **Site Management**.
6. Selection of the **Study** radio button activates the document types included under the **General document category**.
7. Select the document types that are to be marked as required.
8. Select the requirement restriction, if the document will be required for **eTMF** or **Site Activation**.
9. Select from the **To be submitted by** and **Languages** dropdown.

   a. **To be submitted by**- This is the Study Contact who is responsible for providing the selected required documents and
   b. **Languages**- Select the language from the list to be applicable to the Required Document.

   Note: If a specific contact type is made a requirement for document submission, all matching site users will be required to submit that document.
10. Click **Save**.
11. Begin again at the top of the Required Documents window to continue adding for different contacts under Investigative Site..
12. Select the **Study** documents to be required.
13. Click **Save & Close**.
14. Select the next **IRB/EC** in the list to which you need to add required documents, and follow the process steps above.

Deleting IRB/EC Specific Required Documents

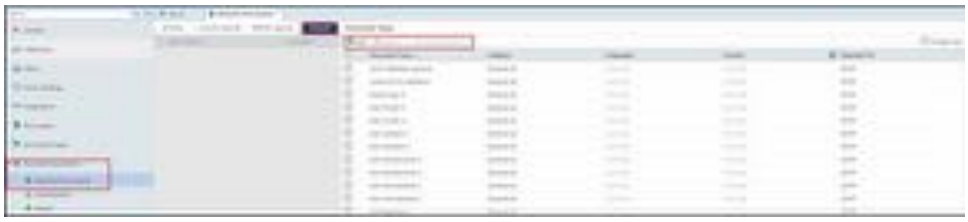
1. From the IRB/EC tab, tick the checkbox to select the particular IRB/EC.
2. The **Document Types** window on the right becomes active.
3. Select the required **Document Type** you wish to delete and click **Delete** from the top ribbon of the Documents Types window.

General View

Adding General Required Documents

1. Click the **General** tab from the left panel of the Required Documents panel.
2. The **Document Types** window on the right becomes active.
3. Click **Add** from the top ribbon bar of the **Document Types** window on the right.

4. The **Required Documents** window opens for you to add General Required Documents.
5. Select the particular **General** category for which you need to add a required document. Refer to the screenshot below:



6. Click the category folder from which you need to select the Required Document that you want to add to the list for all sites. The list of the available document types in that category folder appears.
7. Click the checkbox next to one or all of the documents to be required.
8. Click **Save & Close** if you have documents from only one category folder to add, or click **Save** if you need to add more required documents.

Deleting Required Documents

To delete a Required Document Type for All Sites:

1. Click **General** tab from the left panel of the **Required Documents Panel**.
2. From the list of Required Document Types in the grid, tick the checkboxes to select the Required Document Types to be deleted.
3. Click **Delete** from the top ribbon bar of the **Document Types** window on the right. Refer to the screenshot below:
4. You will receive a warning asking you to confirm the action.
5. Click **Yes** to confirm and delete.
6. The Required Document Types are removed from the list.

Required Documents Milestones Linking

To assign a milestone to a Required Document, follow the steps as below:

1. Select the category from the left pane.
2. Except for **All Sites** and **General** categories, select the **Country** or **IRB/EC** from the left pane.
3. Select the Required Documents from the right pane.
4. Click **Assign Milestone** 

from the top ribbon bar.
5. The **Assign Milestone** window opens. Choose the milestones from the dropdown list. Refer to the screenshot below:

6. Choose the milestones from the dropdown list
7. Click **Assign Milestone** button from the popup window.
8. Notice that the Required Documents to which you assigned milestones are now **flagged with the Milestone icon**.

Amendments

In the Amendments panel, Administrator users can add, edit, and delete amendments.

It will provide a list of documents that need to be collected after the initial set of Required Documents have been set up and rendered. Thus Administrator users can track the needed documents more conveniently.

In this dashboard, besides adding amendment required documents, you can adjust your Amendment dashboard view by sorting the columns by ascending or descending order, and also can manage which columns will be shown or hidden. Refer to the screenshot below:

1. Click the **Add** button from the top ribbon bar. **Create Amendment** window opens. Refer to the screenshot below:

2. Fill in the required details.
3. Click on the **Add** button placed under the **Required Documents** panel. **Required Documents** window opens for you to add the documents that need to be submitted for the specific amendment created.

   Refer to the screenshot below:

4. Select from the list for **To be submitted by** and **Languages**. Click **Add** to save the amendment made.
5. To edit the amendment, double-click the particular amendment or click the **Edit** button.
6. To delete, click the **Delete** button or right click on the amendment and click **Delete**.

Export Required Documents

In this panel, Administrator users can export either **All required documents** or **Selected documents**.

Refer to the screenshot below:

Required Documents can be exported in two ways:

1. Select **All required Document** Option to export documents from all document source categories
2. Select **Selected documents** option.
   a. Export window opens for you to choose from **Amendments or/ and eTMF or/ and Site Activation** sources of documents.

      Refer to the screenshot below:

b. Select required **Document Source/s** and click **Next**.

c. New Export window opens for you to select required **Entity Types and Categories** to export documents.

Refer to the screenshot below:

d. Click **Next.** Final Export window opens to review criteria chosen by you.

Click **Previous** to make changes in the selection or click **Next** to export Required Documents.

e. On successful exporting of Required Documents you will receive a notification.

f. An excel file is generated with a list of required documents and you can save the file for your records.

Refer to the screenshot below:

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**.

From this section you can do the following:

1. View Contacts
2. Mass Coding for Contacts
3. Convert to Users
4. Contact Data

Each of the above topics are discussed in seperate topics and can be accessed from the left menu of this help.

View Contacts

This section gives you the overveiw of the different types of contacts:

By Site

Select **By Site** from the dropdown in the Index Pane on the left of the Contacts Module. This will reveal all the sites available in the room.

Click a site. This will populate the data of all the contacts available for the particular site in a room in the right pane of the dashboard.

By Country

Select **By Country** from the dropdown in the Index Pane of the Contacts Dashboard.

This will list all the countries with the sites where the studies are being conducted in the Index Pane on the left. Clicking a country to expand the dropdown will reveal the sites under it. Click a site to populate the contact details associated with the site in the right pane.

By IRB/EC

Select **By IRB/EC** from the dropdown in the Index Pane of Contacts Dashboard. This will populate the IRBs associated with the sites in the Index Pane on the left. Clicking an IRB will expand the dropdown to reveal the sites associated with it.

Click a site to populate the contact details associated with the site in the right pane.

By Contact Type

Select **By Contact Type** from the dropdown in the Index Pane of Contacts Dashboard. This will populate the contact types associated in the room in the Index Pane on the left.

Clicking a contact will list the contact details associated with a particular site in the right pane of the dashboard.

Mass Coding for Contacts

Administrators are sometimes called upon to fill in or update the metadata of a number of contacts in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Click the **Mass Coding** tool from the top ribbon bar. The **Contacts Mass Coding** window opens.
2. You can choose to mass code for **all the records** in the grid, or for a **selected set of records**.
3. Either way, double-click and select yes/no from the dropdown in the **Value** field for the required metadata to be mass coded.
4. Click **Save**.
5. Confirm the message to proceed with mass coding. You will receive a confirmation about the job result which can also be retrieved from the Notifications. Refer to the screenshot below:

Convert to User(s)

As an administrator, you might want to give **Editor** or **Reader** access on some or all modules to contacts in a site. This can be achieved proceed with the following:

1. Click the **Convert to User(s)** icon on the top ribbon bar.
2. This will open the **Convert selected site contact(s) to user(s)** window.
3. Select the role as Editor or Reader as required.
4. Select the modules from the Actions as required.
5. Click **Convert to user(s)** button in the window.

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.

Note: *Contacts can be added through the Sites Dashboard. They can also be added from the Documents Panel*

Countries

When a study includes investigative sites located in different countries, the countries need to be added to the room**.** In this way, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents. To set up countries for investigative sites, navigate to:

1. The Trial Interactive room for which you want to set up countries.
2. Select the **Settings** option from **Main Navigation**.
3. Select **Countries** from the menu on the left. This option drops down to reveal the following options:
   a. Countries
   b. Template Folders
   c. Common Settings

All of the above options are discussed in separate topics accessible from the left panel of this help.

Countries Settings

Trial Interactive allows Admin to perform Countries Settings from this page.

Follow the steps below to perform the country settings:

1. Navigate to the **Main Navigation** -> **Settings Module**
2. Go to the **Countries** settings from the left menu of the settings page.

   Refer to the screenshot below:

Selecting countries will open the option in a tab in the next pane. As shown in the screenshot above, the list of countries where studies are being conducted are displayed. These countries can be **added**, **edited** or **deleted** from the buttons in the ribbon above the country listing.

Each of these are discussed in the seperate topics and can be accessed from the left menu of this help.

Add Countries

Follow the steps below to add countries:

1. Click **Add** Add from the ribbon above the country listing. The **Create Country** window opens.

   Refer to the screenshot below:

2. Click the dropdown arrow at the right end of the **Country** field. An alphabetized list of countries is populated to select from.
3. Select the name of the country to be added. The name of the selected country populates the **Country** field.

   Note: *You can ease the process of finding the country name in the list by typing the first few characters in the country name. The dropdown list will shorten to include only the countries whose names begin with the characters you have typed.*
4. If the client has supplied country-specific **Study Contact #**, include the associated number in the field.
5. Click **Create**. The name of the newly added country appears in the alphabetized list.
6. Repeat these steps until you have added all of the countries associated with the study.

Edit Countries

Once a country has been added to the list, you can add or change the study contact #, and you can adjust access to groups or to users.

Follow the steps below to edit countries:

1. Select the required country from the grid to be edited. Click **Edit** Edit at the top of the **Countries** window.
2. The **Edit Country** window opens. Refer to the screenshot below:

3. It might be that after you've added the country to the list you are supplied with the study contact number later.
4. Click **Study Contact#** field to change the information.
5. Click **Select** next to **Read Only Members** or **Full Access Members** or **Regulatory Approvers** to add or delete users or groups of users from the access settings.

These selections will probably not be available at this early stage of room configuration. Room configuration is not a strictly linear process – you will have to make additions and changes in other areas on the Trial Interactive platform in order to complete the room's configurations.

6. Click **Save**.

> **Note:** *Though you have access to these security settings here, it is not typical that you will make changes using this path.*

Delete Countries

Follow the steps below to delete the countries:

1. Select the country or countries that you need to delete from the list by clicking the checkbox next to the country's name(s).
2. Click **Delete**  at the top of the **Countries** window. The country name(s) will delete automatically, without giving you a warning.

> **Note:** *At a later stage in the study, once documents have begun to populate the room's index folders, you won't be able to delete countries that have associated documents. Adding to and editing the Countries list can go on as the study progresses.*

Template Folders

In this window, you can **Add, Edit, or Delete** template folders and subfolders in the root folder for managing country-specific documents.

> **Note:** *The details necessary for completing this stage of the room configuration come from the client – the titles and the order of the folders to be included. The folder structure is fairly consistent, but it is always study specific.*

Each of the above topics are discussed in separate topics and can be accessed from the left menu of this help.

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

1. To add a folder to the Index Root, first click **Index Root**, marked by a yellow folder icon.
2. Click **Add** near the top of the **Template Folders** window. A new folder naming field opens, temporarily named **New Folder**.
3. Type the name of the new folder name in the highlighted field.
4. Press **Enter**.
5. Repeat this process until you have entered all of the new folder names.

Editing Names of Folders and Subfolders

Follow the steps below to edit the names of folders and subfolders:

1. Select the folder to be edited.
2. Click **Edit** from the menu at the top of the window or right-click the folder name and select Edit from the available options.
3. Make the necessary changes to the folder name.
4. Press **Enter**.

Deleting Folders

Follow the steps below to delete folders and subfolders:

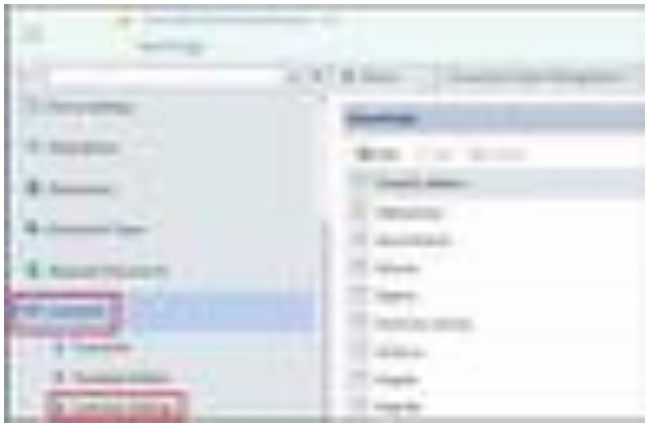
1. Select the folder to be deleted.
2. Click **Delete** from the menu at the top of the window or right-click the folder name and select **Delete** from the available options. The folder disappears from the index structure.

Note: *Folders that contain subfolders or documents cannot be deleted.*

Common Settings

In the Common Settings window you can:

1. Enable or disable the Template Folders.
2. Edit the **Root folder name**. Typically the client supplies the preference here.
3. Change the Sort Order, the place in the room's index structure where the Country Management folder (or whatever name the client has specified) appears. This setting, too, is based on client preference.
4. And, as in the **Edit** function in the **Countries** window, you can adjust the **Read Only** and **Full Access** security settings. Select the users or groups to set access. If you make any changes in this window, click **Save**. Refer to the screenshot below:



e-Signature

In this section we discuss about the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

E-Signature Settings

The client can choose the required e-Signature vendor from **Main Navigation → Settings → e-Signature → Vendors**.

Selecting e-signature vendors

The e-Signature vendor available to you depends on the vendor chosen by your organization. This section discusses the following three e-Signature options:

1. DocuSign
2. Adobe Sign
3. TI e-Signature

Follow the steps below to select the e-Signature vendor:

1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Vendors**.

2. Click the **Use E-Signature dropdown** to select the vendor. Refer to the screenshot below:

Note: *The e-Signature vendor available to you depends on the vendor chosen by your organization.*

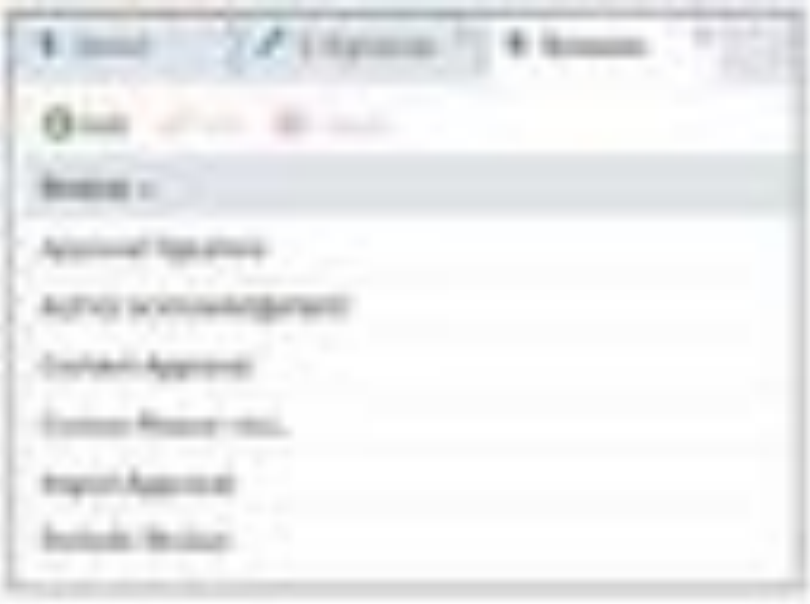
3. An Administrator can choose to enable or disable the use of an e-signature for users in a room by choosing the **None** option from the dropdown.
4. Click **Save** if you make any changes here.

Note: *If the **E-signature** is enabled, the e-Signature Action is automatically added in the **Actions** pane as discussed in Edit User. To see the addition, refresh the room in the browser.*

Configuring reasons for e-signature

While e-signing a document, the e-signers need to specify the reasons for approving or declining a document. Administrator can configure reasons for e-signature from here.

1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Reasons**. Refer to the screenshot below:



2. Click **Add** to create new reasons.
3. Select a reason from the list and click **Edit** to make changes in the existing reason.
4. Select a reason from the list and click **Delete** to delete the existing reason.

Setting the Purpose of the e-signature

Purpose of the e-Signature is an additional text to display on the top of the send to e-signature form. Refer to the screenshot below:

1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Purpose of the signature**.
2. In the Right Panel you can write the Purpose of the e-signature.
3. Click **Save**.

Assigning Users to prepare an e-Signature Envelope

1. Click the desired room in your TI session. Click **Settings** from the Main Navigation to populate the room settings.
2. Navigate to **Settings -> Security-> Users**. A panel listing all users will be displayed in the right pane. Alternatively, you may arrive to the same page from the **Main Navigation -> Users management**.
3. Click the **Invite** dropdown located on the top left corner of the user list pane. Select the invite option from the list. A **User Invitation** form will be populated.

   Fill in the fields marked with an asterisk (*), at minimum, to invite the desired user.

   From the **User Profile** tab click the **Actions** dropdown menu to select the **eSignature** option and click **Create** to assign your user to prepare the eSignature package. Refer to the screenshot below:

4. For existing users, select the user from the user list by clicking the checkbox adjacent to list populated in the right pane.
5. Click the dropdown next to the dots and click **Edit** option. An **Edit User** form will populate.Refer to the screenshot below:

6. Click the **Actions** dropdown menu and select the **eSignature** option by ticking the checkbox.
7. Click **Save** to prepare the existing user for the e Signature package.

The user added will receive an email from Trial Interactive asking them to register in order to comply with e Signature feature.

Adding Groups with the eSignature Actions

Add Groups and activate the eSignature Action for the specified groups.

1. Navigate to **Settings -> Security -> Groups**. The Groups Panel opens.
2. From the **Groups** tab, click **Add**. The **Create New Group** window opens.
3. Name the group by typing its title into the **Name** field.
4. Add a **Description**.

   The user making these additons or changes can choose to clone the security parameters already defined for another user group that has been established in the room. This cloning designation is not required.
5. Click the **Actions** dropdown. Refer to the screenshot below:

6. Click the checkbox for **eSignature** and click **Create**.

   The new user group displays in the list of **Groups** in the panel on the left.

TI eSignature

For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) to sign the documents.

This section include the following sections:

1. Assigning signers to the documents
2. Signing the documents in TI -eSignature if you are a signer

TI eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right click the desired document and click **Send for e-signature**. Refer to the screenshot below:

Alternatively, you can also send the document for eSignature from the eSignature Panel to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. Refer to the screenshot below:

Signing the documents in TI - eSignature

If you are assigned to electronically sign a document, you can sign the documents in the following ways:

- From the Documents to be signed dashlet

- From the eTMF/Documents view

Each of the ways are discussed in the sections below:

Signing Documents from the Documents to be Signed Dashlet

1. When you are assigned a document for eSignature, navigate to the room **Dashboard** and scroll to find the **Documents to be signed** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display. Refer to the sceenshot below:

   You can also proceed to the **eTMF/Documents** module or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane.

Note:

- *Completed signatures cannot be cancelled.*
- *Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.*
- *Once a document is cancelled from e-signature, no one can sign the document until it is resent again.*

Signing Documents from the eTMF/Documents view

1. Navigate to the **eSignature view** and click the **Waiting for Signature** folder to locate the document to be signed as shown in the screenshot above section.
2. Select a document and open the **eSignature Panel** to the right. The Waiting for eSignature status appear next to your name.
3. Click the username to expand the details. Refer to the screenshot below:

4. Enter all the required details and click **Sign Document** button.

5. A window opens asking you for Authenticating your credentials opens.
6. Click **OK** to authenticate your credentials. Refer to the ascreenshot below:

7. Once you are authenticated, you are directed to the confirmation dialog box asking for signing.
8. Click **OK**.
9. The **Sign Document** window opens which allows you to sign the document. Refer to the screenshot below:

10. Click the Blue button at the bottom right corner of the window to sign the document.
11. If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all the signers have finished signing. Refer to the screenshot below:

12. Open the signed document to find that a page with the signer's name and contact details, date of e-signing the document is appended as the last page to the document. In case of multiple e-signers, a page for very signer is appended.

    Note: *Signature Page will be added to PDF documents only after all signers have finished signing the document.*

13. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under **e-Signature Documents** view. You can see the status of the eSignature as **Completed** in the eSignature Panel.

Adobe eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

Adobe eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right click the desired document and click **Send for e-signature**. Refer to the screenshot below:

   Alternatively, you can also send the document for eSignature from the eSignature Panel to the right.
3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:

If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. A Recipients window with the list of email ids of signers enlisted opens.
7. Tick the **Preview & Add Signature Fields** checkbox located at the end of the page to determine the placement of signatures on the document.
8. Click **Next**. Refer to the screenshot below:

9. From the Recipients field select the signer and, drag and drop the fields on your document from the right menu option that you wish to include in the signature.
10. Repeat the above step for every e-signer.

11. Click the **Send** button located on the bottom right corner of the window to complete the signer assignment process.

    The system will trigger an email to the signers designated by you with a link to the document for eSignature.

    You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

Signing the documents in Adobe Sign

If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document. Alternatively, click the **Dashboard** tab and navigate to the **Documents to be signed** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

   You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature**view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process.

   If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Refer to the screenshot below:

3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.
4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document. Refer to the screenshot below:

5. Hit **Click here to sign** box. You will be prompted to choose your style for the signature (font, size, etc.)
6. Enter your signature and other details as required. Click **Apply.**
7. This will insert your signature. Hit **Click to Sign** . Refer to the screenshot below:

8. The document will move to the **Completed** folder under **e-Signature Documents**.

DocuSign eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

DocuSign - Assiging Signers to the Documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right click the desired document and click **Send for e-signature**. Refer to the screenshot below:

Alternatively, you can also send the document for eSignature from the eSignature Panel to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:

If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. A document preview window to determine the placement of the signatures with the designated recipient list on the left will display.

Select the desired recipient. Then drag and drop the fields on your document from the left menu option that you wish to be included in the signature. Repeat the above step for every e-signer. Refer to the screenshot below:

Click the **Send** button located on the top right corner of the window to complete the signer assignment process.

The system will trigger an email to the signers designated by you with a link to the document for eSignature.

You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

Signing the Documents in DocuSign

If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room. Alternatively, click the **Dashboard** tab in the eTMF module and scroll down to find the **Documents to be signed** dashlet.
2. Click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.
3. You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane. Either ways, click **Sign Document** to begin the review and signing process. Refer to the screenshot below:

Click **Continue.** If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Click the **sign** icon. You will be prompted to choose your style for the signature (font, size, etc.). Refer to the screenshot below:

Click **Finish** to complete the eSignature process.

Q&A

Q&A application enables you to view the list of questions asked and anwers given by users in a room besides creating them.

Remember: The Q&A functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.

From the Main Navigation select **Q&A** to reach this dashboard. Refer to the screenshot below:

From within the *Q&A* dashboard, you can:

1. Viewing Questions and Answers
2. Create questions
3. Create answers
4. Convert them to FAQ
5. Export Q&A
6. Delete questions and answers

Q&A Settings

The **Q&A** functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.

Through the **Q&A settings** view, you can add, edit, or delete **Question Levels**. In the **Q&A** configuration panel, you can enable and disable three Q&A options: the ability to delete questions and answers, the activation of Subject Matter categories, and the activation of questions issue levels.

To access the Q&A Settings:

1. Navigate to the **Main Navigation**-> **Settings Module**
2. Go to **Q&A**

From this section we discuss about:

1. Configurations for questions and answers
2. Setting up Subject Matters for the categorization of the questions and answers
3. Adding Editing and Deleting Question Levels

   All of the above are discussed in separate topics accessible from the left panel of this help.

Q&A Configuration

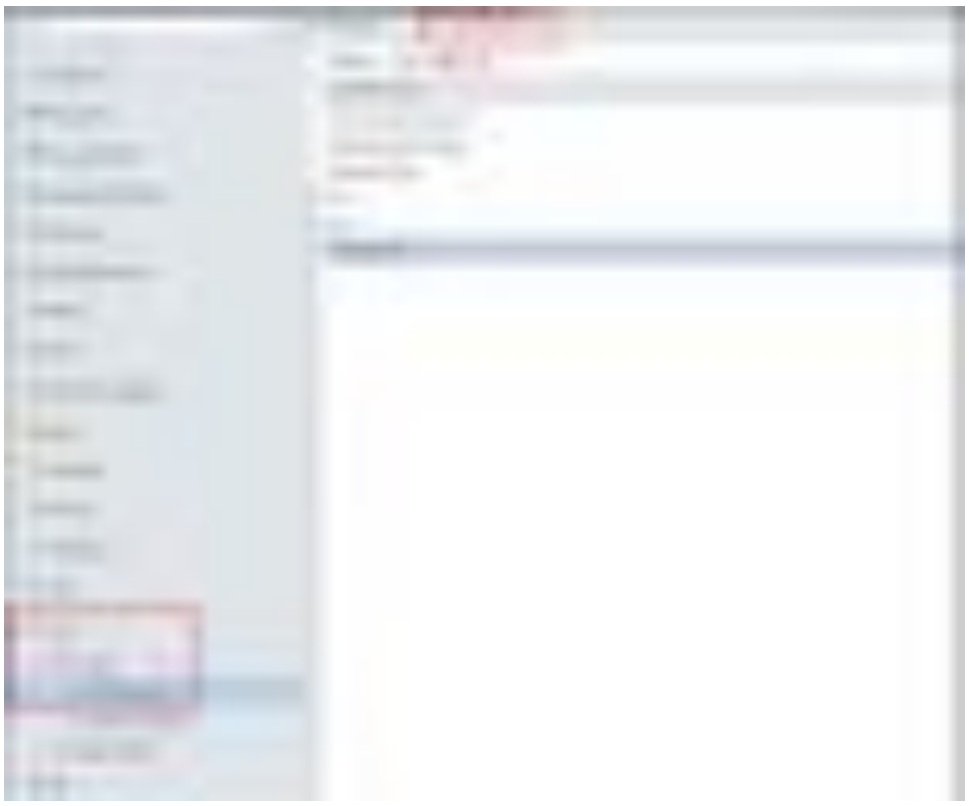
From here you can enable and disable the following three options:

1. The ability to delete questions and answers.
2. The activation of Subject Matter categories.
3. The activation of question issue levels.

   Refer to the screenshot below:

Q&A Question Level

From here, you can create the list of issues that are associated with the documents. Administrator can set these issues as per the client request. These issues are then assigned to **Subject Matter Experts** who can answer the question. Refer to the screenshot below:



From here, you can perform the following:

1. Adding New Question Level
2. Editing a Question Level
3. Deleting a Question Level

   Each of these are discussed in the sections below:

Adding New Question Level

To add new question level:

1. Click **Add** from the top ribbon.
2. A new row appears in the grid below.
3. Enter the question level. Refer to the screenshot below:

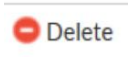
Editing a Question Level

To edit a question level:

1. Select the level and click **Edit** from the top ribbon . You can also double-click the question level to edit.
2. The field becomes editable.
3. Edit the details as required. Refer to the screenshot below:

Deleting a Question Level

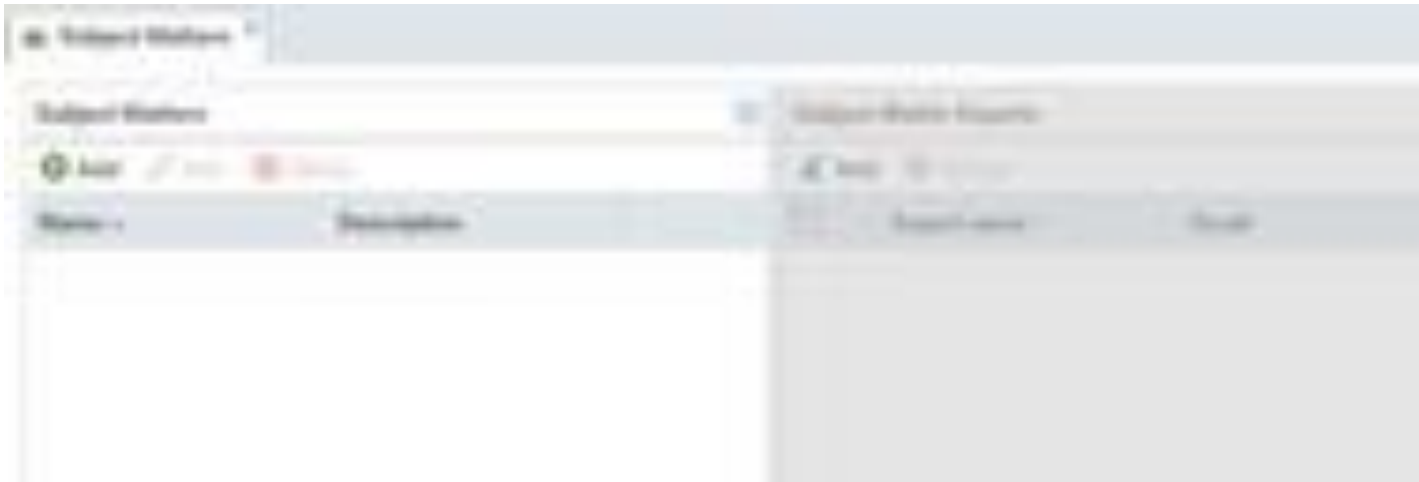
To delete a question level:

1. Select the level and click **Delete**  from the top ribbon to delete it.

Question Subject Matter

If **Subject Matter** was enabled in the Q&A Configuration, another set of options for **Subject Matters** is activated. You can access this option from the Q&A menu in the left panel of the Room Settings. Refer to the screenshot below:

Clicking **Subject Matters** from the Q&A menu opens the **Subject Matters window** in a separate tab. Refer to the screenshot below:



This window consists of two panels:

1. **Subject Matters panel** from which **Subject matter categories** can be added, edited, and deleted.
2. **Subject Matter Experts panel** from which **Subject Matter Experts** can be **assigned to** or **unassigned from** the specific Subject Matter Categories. In this way, questions from particular categories can automatically be channeled to subject matter experts when the questions are submitted in the room.

All of the above are discussed in subsequent sections below:

Adding Subject Matters

To create Subject Matters:

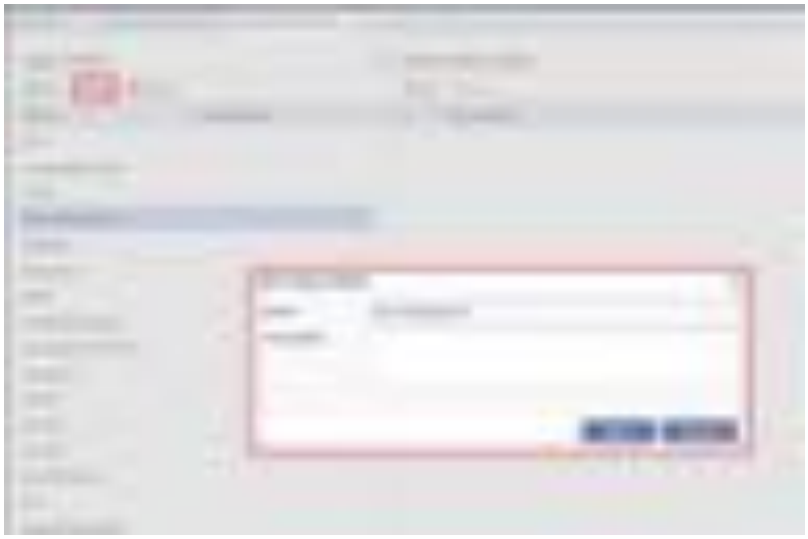
1. From the **Subject Matters panel** toolbar, click **Add**.
2. The **Create Subject Matter window** opens. Refer to the screenshot below:

3. Type the name of the Subject matter category in the **Name** field. The **Name** field is required; the **Description** field is optional.
4. Click **Create** at the bottom of the window. The new Subject Matter category is added to the list.

Editing Subject Matters

To edit Subject Matters:

1. From the **Subject Matters panel,** click on a **Subject Matter category** to select it.
2. From the **Subject Matters panel** toolbar, click **Edit**.
3. The **Edit Subject Matter window** opens. Refer to the screenshot below:



4. Edit the **Subject Matter Category name** and **Description**; click **Save**.
5. The changes are committed and visible in the list of categories.

Deleting Subject Matters

To delete a Subject Matter category:

1. From the **Subject Matters panel,** click on a **Subject Matter category** to select it.
2. From the **Subject Matters panel** toolbar, click **Delete**.
3. The **Subject Matter Category** is removed from the list of categories.

Assigning Subject Matter Experts to Subject Matters

To assign a Subject Matter Expert to a specific subject matter, select a subject matter from the list on the left.

1. Click the Name of the **Subject Matter**. The subject matter category name is highlighted in light blue.
2. Click the **Add** button from the **Subject Matter Experts** panel toolbar.

   A **Select users** window opens, displaying the full list of the room's registered users who are eligible to be assigned the role of Subject Matter Expert – users with Administrator or Editor access to the room.
3. Click the checkbox next to the name of the user you want to assign to the expert role.
4. Click **Select** at the bottom of the window. The changes are automatically saved. Refer to the screenshot below:

Now, when a user asks a question and assigns it to the Q&A category and the Subject Matter while creating the question, the assigned expert will be notified of the question that needs their attention. The expert can then view the question in the Q&A module.

Removing Subject Matter Experts from Subject Matters

To remove a Subject Matter Expert from Subject Matters:

1. Click the Name of the **Subject Matter**. The subject matter category name is highlighted in light blue.
2. The list of **Subject Matter Experts** appear in the Subject Matter Expert Panel.
3. Select the checkbox next to the name(s) of the Subject Matter Expert you want to delete.
4. Click **Delete** from the toolbar. The names of the Subject Matter Experts gets deleted from the list.

Q&A Module

You can perform the following from this page:

1. Creating Questions

2. Creating Answers
3. Convert Questions to FAQs
4. Export Q&A
5. Delete Q&A

All of the above are discussed in separate topics accessible from the left panel of this help.

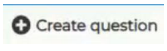
Creating Questions

You can create questions from:

1. Within the Q&A application by clicking the **Create Question** button from the top ribbon bar
2. Within the eTMF application by clicking the **Ask a Question** option in the **Document Dropdown** or from the **Document Context Menu** for a selected document

Each of the options are discussed in separate sections below:

Creating Questions from with the Q&A Application

1. Click the **Create Question** button 

from the top ribbon bar in the Q&A Application.
2. The **Create Question** popup opens.
   a. From the **Subject Matter** dropdown, select the subject matter as applicable. You may choose to ignore this action. Refer to the screenshot below:

   b. From the **Issue Level** dropdown, select the level for the issue as applicable.
   c. Enter your question in the **Question** textbox below.
   d. Click **OK**.
3. The question appears in the grid to the right of the dashboard.

Creating Questions from within the eTMF Application

From within the eTMF application, you can create questions on a particular document.

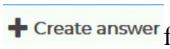
1. From the **Index pane** in the **eTMF**, navigate to the child folder and click it.
2. The documents in the child folder display in the **Documents Grid.**
3. Tick the checkbox next to the document in the grid to select it.
4. Click the **Document Actions Dropdown** from the top ribbon bar and select the option **Ask a question**. Refer to the screenshot below:

5. The **Create Question** popup opens. Refer to the screenshot in the preceding section.
   a. Select the **Subject Matter** from the dropdown. You may choose to ignore this if the subject matter is not applicable.
   b. Enter the question in the **Question** textbox.
   c. Click **OK**.
6. Navigate to the **Q&A Application** from Main Navigation.
7. Select the appropriate view and the categories in it.
8. The question appears in the grid to the right of the dashboard.

Creating Answers

When a room's users ask questions, Administrators can see them. The list will appear on your dashboard if enabled. You can enable email notifications of newly lodged questions.

To create an answer to a question:

1. Select the appropriate view and the categories in it.
2. The questions appear in the grid to the right of the dashboard.
3. Tick the checkbox next to the question for which you want to create an answer.
4. Click **Create Answer** 

from the top ribbon bar.
5. The **Create Answer** popup opens. Refer to the screenshot below:

Figure 4: Create Answer

6. Enter the answer to the question in the **Answer** textbox.
7. Click **Create**.
8. In the grid, click the arrow next to the question to open it.
9. The answer you just created appears in a green background under the selected question.
10. You can create multiple answers to a question by following all the steps above.

Creating a Hierarchy of Questions and Answers

You can also create questions to answers. That means a question may have answers to it, and any answer may again have questions and answers to it. This creates a hierarchy in the form of a question and answer inverted tree.

To create questions to answers:

1. Click on an answer to select it.
2. Click **Create Question** from the top menu bar
3. Enter the subject matter and question, and click **OK**.
4. The question appears indented below the selected answer as a child question.
5. You can enter an answer to this child question by following the steps as above.

Note: *Thus, a main question may have multiple answers and any or all answers may have questions and answers to them.*

Converting to FAQ

Once you convert a question and its answers to FAQ, they will appear in the FAQ application. The user will need to navaigate to the FAQ application from the Main Navigation to view the frequently asked questions.

To convert questions and their answers to FAQ follow the steps as below:

1. Select the appropriate view and the categories in it.
2. The questions appear in the grid to the right of the dashboard.
3. Tick the checkbox next to the question which you want to convert to FAQ.
4. Click **Convert to FAQ** 

from the top ribbon bar.
5. The Convert to FAQ window opens.
6. Format the details and select the category.
7. Click **Create** at the bottom of the window.

Exporting Q&A

As an administrator, you can Export questions and answers. To export the questions and answers follow the steps as below:

1. Select the appropriate view and the categories in it.
2. The questions appear in the grid to the right of the dashboard.
3. Tick the checkbox next to the questions which you want to export.
4. Click **Export Q&A** from the top ribbon to open the **Export Q&A** window.
5. Click **Export** to export the **selected questions**, or **all Q&A in the current grid**, or all **Q&A in the room**. Refer to the screenshot below:

Deleting Q&A

1. Select the appropriate view and the categories in it.
2. The questions appear in the grid to the right of the dashboard.
3. Tick the checkbox next to the question which you want to delete.
4. Click **Delete** from the top ribbon. The **Delete** confirmation popup opens.
5. Enter the reason for deleting the question.
6. Click **OK**. Refer to the screenshot below:

FAQs

The FAQ icon in the Main Navigation allows you to view the list of FAQs.

You can reach this page by clicking the FAQ icon from the Main Navigation.

Remember: The FAQ functions have to be activated in the room's settings. The icons will appear only if the functions are enabled when the room is created.

From within FAQ dashboard, you can:

1. Create FAQs
2. Edit FAQs
3. Delete FAQs
4. Export FAQs

All of the above are discussed in separate topics accessible from the left panel of this help.

FAQ Settings

Note: *The FAQ functions have to be activated in the room's Settings. These icons will appear only if the functions are enabled when the room is created.*

Adding FAQ Categories

1. Navigate to **Main Navigation->Settings->FAQ**
2. Click **Add**. Refer to the screenshot below:

3. Click **Save** after making any changes.

Editing FAQ Categories

1. Double-click FAQ category, or select a existing FAQ category and click **Edit**. Press **Enter** after editing.
2. Click **Save** to save the changes.

Deleting FAQ Categories

1. Select a FAQ and click **Delete**.
2. Click **Save** to save the changes made.

FAQ Module

You can perform the following from this page:

1. Create FAQs
2. View FAQs
3. Edit FAQs
4. Delete FAQs
5. Email FAQs
6. Export FAQs
7. FAQs Cart

All of the above are discussed in separate topics accessible from the left panel of this help.

Creating FAQ

Follow the steps below to create FAQs:

1. Click + **Create** 

from the top ribbon bar. The **Create FAQ** window opens.
2. Choose the required category from the **Category** dropdown.
3. Type in the question in the **Question textbox** and answer to the question in the **Answer textbox** .Notice that the Answer textbox provides you with the tool bar with the various options for managing answer to the question.
4. If you wish to add any attachment for the question, click **Add Attachment**at the bottom of the page to add the attachment/s.
5. Click **Create** and the question appears in the grid. Refer to the screenshot below:

View FAQs

To view FAQ, follow the steps as below:

1. Click the **three dots** ... at the top right corner of the Index Pane.
2. The **View FAQ by** popup opens. Refer to the screenshot below:

3. Choose the required view and click **Select**. The FAQ folder will display according to the choosen view. Refer to the screenshot below:

Editing and Deleting FAQs

Edit FAQs

Follow the steps below to edit FAQs:

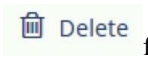
1. Select the required FAQ from the grid and click **Edit** 

form the top ribbon bar.
2. The **Edit FAQ** window opens. Refer to the screenshot below:

3. Make the required changes and click **Edit**.
4. A **Confirmation** popup box opens. Click **OK** to confirm the changes and the changes are reflected in the FAQ.

Delete FAQs

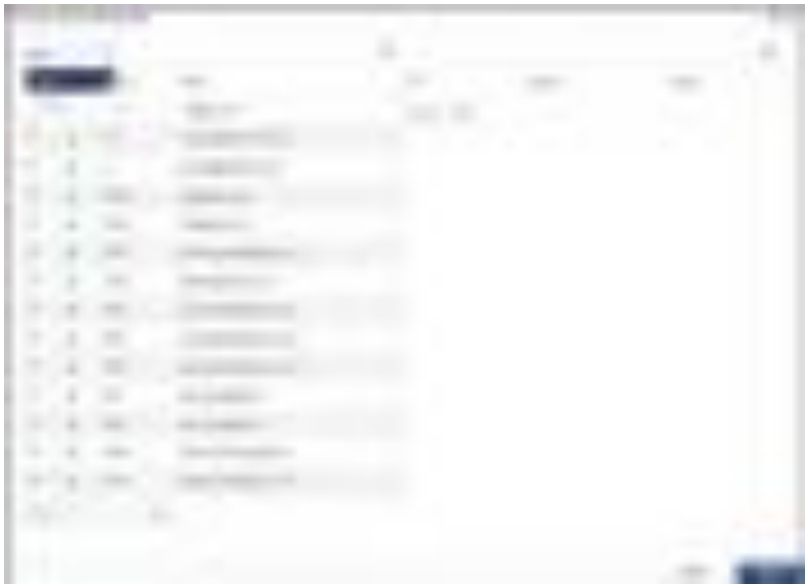
Follow the steps below to delete FAQs:

1. Select the required FAQ from the grid.
2. Click **Delete**  from the top ribbon bar. Click **Yes** on the delete confirmation box to delete the FAQ.

Emailing FAQs

The FAQs can also be sent to room users as email messages. Follow the steps below to email FAQs:

1. Select one or more FAQs from the display grid by clicking the appropriate checkbox or boxes.
2. Click Email  in the menu ribbon. A new **Email** window opens.
3. Click in the **Recipient(s)** textbox and the Choose Email Recipients window opens to allow you to add the recipients.
4. Make the appropriate selection. Either double-click on the name to be added to the **Email recipients** list or drag-and-drop the names to the panel on the right.Refer to the screenshot below:



5. Click **Save**. The view returns to the Email message window.
6. The user has the opportunity to add more users from the room to the **CC…** filed. The user can also alter the text of the message or add attachments to the message.
7. Enter the Subject for the email in the **Subject** field.
8. Click the **Send** button when the message is completely assembled.
9. The **Email** window closes, and the message is sent to the selected recipients.

Email messages sent from the **FAQ** module are tracked in the room's **Outbox** module.

Exporting FAQs

To export FAQs:

1. Select the FAQs from the grid you wish to export.
2. Click **Export** from the top menu bar.The Export FAQ window opens.
3. The following **Source** options are available for export:
   a. **Selected Records:** Use this option if you want to export only selected FAQs.
   b. **All FAQs in the Grid:** Use this option if you want to export all FAQs.
   c. **All FAQs in the room:** Use this option if you want to export all FAQs in the room.
4. Select the required source option for export. Refer to the screenshot below:

5. Click **Export**.

FAQs Cart

FAQs Cart allows you to perform various actions on the FAQs.

To add FAQs to the cart:

1. Select the required view for the FAQs.
2. Tick the checkbox next to the required FAQs and click **Add to Cart** 

at the top right corner from the top ribbon bar.
3. The selected FAQs get added to the cart. Notice that the cart displays the **count of documents** in the cart next to the dropdown.
4. Click the **FAQs Cart** dropdown. The FAQs popup opens.
5. Select the required FAQs and click Action at the bottom of the popup. The lsit of actions appear. Refer to the screenshot below:

6. Select the required option from the list. You can view the results in the Background Jobs from the Notification Panel.

Communications

The **Communications** module looks to automatize the manual process of managing emails and thereby reduce unnecessary workload.

The **Communications** module was introduced to cater to issues related to managing of emails in the Outlook mailbox that required teams with dedicated people to sift through the mailbox, pick out relevant mails, download them, convert them to PDF and then file them to the TMF. It incorporates the features of both the *Inbox* and the *Outbox* and comes with two views – **Outbox** and **Inbox**. You will have access to this module if it is activated for you.

You can access the Communications Dashboard from the Main Navigation by clicking the **Communications** icon. Refer to screenshot below:

Click the links below for more details on each topic:

1. The Communications Dashboard
2. The Communications Inbox
3. The Communications Outbox
4. Exporting Mails

Communications Dashboard

Once you enter the **Communications** Dashboard, you will have access to both the **Inbox** and the **Outbox** views from the left menu. Refer to the screenshot below:

Communication Inbox

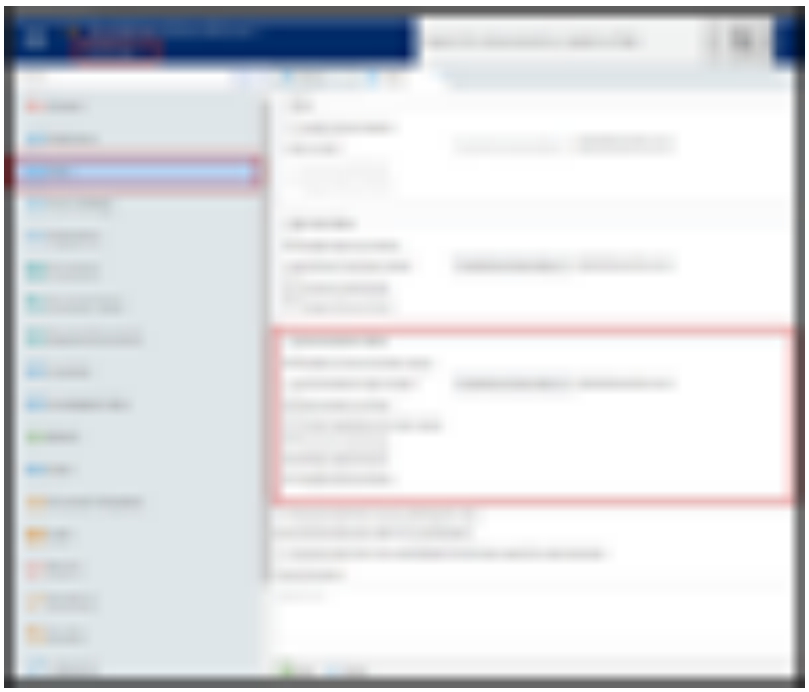
From this section, you can perform the following:

1. The Inbox Settings
2. The Inbox Process

Each of the above topics is discussed in the seperate topic and can be accessed from the left menu of this help.

Communication Inbox Settings

To enable the Communications Inbox feature, navigate to **Main Navigation → Settings → Communication Inbox**.Refer to the screenshot below:



1. To enable the **Communications Inbox**, tick the checkbox next to it. These mails can be located in the Inbox from the **Communucations Module.**
2. If you choose to file email converted documents to the eTMF as Final, tick the checkbox **Documents as Final next to it**.
3. Enable the **Merge Attachment** option to merge attachment into one document.

To commit the changes, click **Save**.

Communication Inbox Process

Below is the process for communication inbox:

1. After enabling the feature from the Inbox Settings, all the emails sent to the Communications Inbox are deposited here whereas emails sent to the eTMF inbox will be deposited to inbox.
2. Depending on the settings of the **Communications Inbox**, the email processing service converts the email into a PDF file; the Subject and date of the email are used to form the **Submitted Name** of the file.

   Note: *The settings that needs to be activated to convert an email to PDF is Convert email body*.
3. If there are any attachments to the email. They are also converted into PDF files (based on room settings) and automatically linked to the email PDF.

   Note: *The Settings that need to be activated to link attachments to the email PDF is Merge attachments*.
4. Any attachment that cannot be rendered into PDF is left in its original format.
5. The email PDF file, along with its attachment(s), if any, are stored in the **Communications Inbox** folder.
6. In the Communications Inbox, the email document is stored in **Pending** sub-folder from where the editor can mark them as **Relevant** or **Non-Relevant**. Refer to the screenshot below:

7. The documents that are marked as **Relevant** are coded by the editor in the **Document Profile** form with data such as category, document type, site and other relevant data based on the document type selection.
8. Once the editor codes the document and saves it, the document will move to the **Relevant** folder in the Inbox View. The Metadata fields are now non-editable. Refer to the screenshot below:

9. Based on the room settings, the document will be published as final or will go to the default folder and the Quality Review Workflow where the reviewers will claim the documents, approve them, and file them to the eTMF.
10. The documents that are marked as **Non-Relevant** are moved to the **Non-Relevant folder** of the Communications Inbox module and can be deleted by Administrators, if required.

Communication Outbox

Documents or messages emailed from a Trial Interactive room are stored in the **Communication Outbox.** Details on how to email is discussed in detail in section **Email**

The Communication Outbox is the holding area of messages or emails that are sent out from a Trial Interactive room. The left pane of the **Outbox** module gives the **views**of the emails **By Date** and **By Type.** .

Besides, you can also export the communication emials.

Communications Outbox Views

You can sort the emails in the following ways:

1. By Date
2. By Type

Each of these are discussed in the sections below:

By Date

This section provides the segregation of mails by the period of:

1. Today
2. Last 7 days
3. This month, and
4. All mails.

Click a period to view the communications for that period in the right pane of the dashboard. The screenshot below shows all the communication for the **current month**.

The **link** icon 1 with a number next to the **Sent Date** shows the number of attachments in the mail. Hover the mouse on the icon to view the attachment name.

By Type

This section provides the segregation of mails by their types:

1. General Communication
2. Regulatory Packet
3. QC Issues

Exporting Communication Emails

You can export mails by clicking the **Export** icon on the top ribbon bar. This will open the **Export messages** window. You can export all messages in the current grid, or only selected messages. Refer to the screenshot below:

The confirmation of the export job is displayed in a popup at the top of the grid.

You can **GetJob Result** from the **Notifications.** The export job result is saved as an .xlsx file. Refer to the screenshot below.

Communication Outbox Email Message Window

Double click a message in the grid, or check the checkbox to display the **Email Message** window at the extreme right of the dashboard. This window gives the complete metadata of a message including its body, sender, receiver, subject, sent date, and attachments. Refer to the screenshot below:

You can also change the layout of the email message window by clicking the **layout**  buttons at the top right corner of the message window.

Tasks

Tasks application allows the users to manage their Trial Interactive tasks for their rooms.

They are given an option to add, edit, delete, and export tasks. Additionally, administrators can adjust the number of days before a task's deadline for a user to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task.

As a Trial Interactive administrator, you can access Tasks as mentioned below:

1. **Enter the room** for which you want to create tasks from the **Home** page
2. Click the **Main Navigation – >App switcher**.
3. The popup with all the applications appear
4. Click **Tasks** icon.
5. You are taken to the **Tasks** page. Refer to the screenshot below:

The **Task Module** is explained in detail in separate section.

Tasks Settings

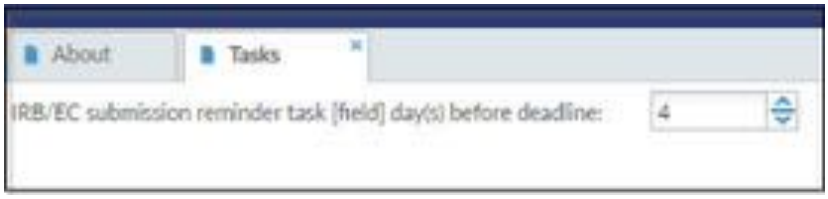
The Administrator wouuld need to set up certain configurations for tasks in a room from **Main Navigation → Room Settings → Tasks.** These configurations are listed below:

1. Tasks
2. Tasks Category

Each of the options above is discussed in separate topics which can be accessed from the left panel of this help.

Tasks

1. Navigate to **Main Navigation->Settings->Tasks->Tasks**
2. Define a number of days from **IRB/EC submission reminder task [field] day(s)** option. Refer to the screenshot below:



3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.

Task Category

Task categories need to be specified while creating a task. These task categories need to be created so that the user may select the appropriate category from the dropdown of the **Task Creation** window.

Tasks can be created, edited, or deleted through the buttons on the Task Category dashlet. Refer to the screenshot below:

1. Click **Add** to add a task and press Enter.
2. Double-click a task, or select an existing task and hit the **Edit** button to edit a task. Press Enter after editing.
3. Select a task and hit the **Delete** button to delete it.

Tasks Module

From within a room, the administrator can maintain and track tasks related to the TI room.

The Administrators can view the tasks by different views, add new tasks, edti tasks, delete tasks, and adjust their tasks. Each of these are discussed in the seperate topics and can be accessed from the left panel of this help. Additionally, administrators can adjust the number of days before a task's deadline for a user to reveive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of rthe metadata panel of the task. Refer to the screenshot below:

Tasks Views

Once inside the Tasks dashboard, you can choose to view Tasks by:

- **My Tasks**
- **By Status**
- **By Owner**, and
- **By Category**

To select the Task Views:

1. Click the **three dots** icon next to the **View by**. Refer to the screenshot below:

2. The **View Tasks By** window opens.
3. Choose the required view and click **Select**.

Note: *Click the checkbox if you wish to **Make Default** the selected view.*

4. The tasks open as per the selected view in the left pane.
5. Select the category in the left pane to open the list of Tasks in the grid.

Each of the above views are discussed in the sections below:

My Tasks

This view gives the list of tasks belonging to the user based on today, this week, next week, pending, overdue, tasks that have no starting date (No date), or all the tasks together in the document panel. The task count is also displayed next to each time frame. Refer to the screenshot below:

By Status

There are five task-statuses available. The system color-codes the status according to the specified work completion percentage. This view lists all the tasks in the document panel as per the status selected. The count of task per status is also displayed next to each status in the left pane. Refer to the screenshot below:

By Owner

This view lists the tasks belonging to a particular user or all users on the right pane. It also gives the count of tasks belonging to each user. Refer to the screenshot below:

By Category

This lists all the tasks under each category along with their counts. Refer to the screenshot below:

Adding, Editing and Deleting Tasks

Tasks can be added, edited, or deleted from the icons in the ribbon above the dashboard. Refer to the screenshot below:

Mention the task name in the subject text box while adding tasks from the **Task Profile** window. Tasks can be edited from the **Task Profile** window or from the **metadata panel** located on the right of the dashboard. When adding or editing a task, you are also given an option to attach files. Simply click **Attach a file** from the **metadata panel** or in the **Task Profile** window. When you are finished attaching files, click **Save** and a clip icon with a number will appear next to the subject line on the document panel. The number next to the clip icon reflects the number of attachments for a particular task.

Other metadata fields that Administrator users can fill out include the following:

1. **Start Date:** The date when the task should be started.
2. **Due Date:** The date by which the task should be completed and submitted.
3. **Priority:** The priority of a task could be Low, Normal, or High.
4. **Status:** Depending upon the progress of the task, the status could be set as Completed, Not Started, In Progress, Deferred, or Waiting on someone else.
5. **Complete %:** The percentage of the task that is completed. Depending upon the figure entered here, the Status field automatically acquires the status of Not Started, In Progress, or Completed.
6. **Description:** Any comments on the task, one of which could be its purpose.
7. **Assign To:** Users to whom the task is to be assigned. This is covered in detail in the following section.
8. **Reminder (Date, Time):** The date and time when the assignees of the task should receive a reminder.
9. **Category**: The task categories, as created through Task Settings, are populated in the dropdown. This helps to categorize tasks.
10. **Edit history:** This is also tracked and recorded on the bottom of metadata form or Task Profile window. If any changes are made, click **Save**.

Exporting Tasks

You can also export tasks through the **Task Export** window invoked by clicking the **Export icon** 

on the top ribbon. You may export tasks selected from the document panel, or all the tasks in the current grid. To export tasks, it is mandatory to select the **Task Metadata Fields** which will be saved in the export job result as an excel file. Refer to the screenshot below:

During export of tasks, a popup showing the status of the export job is shown. Refer to the screenshot below:

The export results are also populated in the **Notifications.** Click **GetJob Result** to view the excel file.

To enable export of tasks metadata:

1. Navigate to **Main Navigation ->Settings -> Forms Settings -> Metadata Fields**
2. Select **Tasks Form** from the drop-down.
3. Check the boxes as required under the **Export** column. These are the Metadata Fields you would want to export. Only selected fields will be available for **Task Export**. Refer to the screenshot below:

You can also view task statuses from **Tasks Dashlet.**

Assigning Tasks to Multiple Users

Administrators and Editors can assign tasks to multiple users only while creating a task. In such case, the system creates corresponding number of separate task records, one task per user, and adds user full name to the subject line of the task. **Hence, after the task is created and saved, the administrator, if required, can edit each individual task**

to re-assign it to only one other user. On re-assigning a task to another user will not only move the task to the folder by the new assignee's name under 'By Owner' view, it shall also display the name of the previous assignee in the task subject line.

To be able to assign tasks to multiple room users, the administrator must have the required privileges set up for his/her account. The administrator can also enable an editor to assign tasks to multiple room users. To know more about this, proceed to **Settings -> Security -> General -> Actions**, and then to **Security -> Users -> Invite Users**or **Security -> Users -> Edit**.

To assign a task to users:

1. Click +**Add** to open the **Task Profile** window.
2. Enter the task details as required.
3. Activate the **Assign To** dropdown to reveal a list of users
4. Select the users to whom you want to assign the task from the list.
5. Click **Save**.
6. This will assign the task to multiple users as selected in the list. Refer to the screenshot below:

Collaborative Authoring

Collababorative Authoring provides the functionality to configure review process for TI Documents and allow the review-participants to perform online documents review.

The **Collaborative Authoring** feature which can be accesses from the **Main Navigation**, includes two main features:

- Document Co-Review
- Document Co-Authoring

Note: *These features are only available to* ***Enterprise Clients****.*

Documents in Collaborative Authoring can be reviewed from the **Collaborative Authoring** module and the **eTMF/ Documents module.**

Each of these reviews are discussed in seperate topics and can be accessed from the left menu of this help.

Permissions for Collaborative Authoring Module

To access the whole Collaborative Authoring module, user should be an **Administrator** or **higher** or have the related Action: ***Document Collaboration Reviewer*** or ***Document Collaboration Administrator***.

Users with the Administrator or higher roles can perform all available actions in the Collaborative Authoring module (create new review, modify existed review, start review). All reviews are available for such users as well.

For other users who are with roles below Administrator:

1. To create new Collaboration Review, users should have a ***Document Collaboration Administrator*** action and have at least ***Editor*** role in the DataRoom.
2. To modify existing review, users should have an ***Editor*** role, ***Document Collaboration Administrator***action and should be a review creator or should be listed as a ***Review Owner*** in the review.
3. To get an access to review (retrieve list of reviews or see review details), users should be listed as a review participant (owner or reviewer) and should have the related actions: ***Document Collaboration Reviewer*** or ***Document Collaboration Administrator*** (or can be a review creator).

Co - Review

Document Co-Review feature enables users to review documents concurrently, allowing for greater flexibility as users no longer need to wait for others finish their review. The online review feature is provided by an external application, **Please Review.**

To use this feature, the **Document Authoring** module in the **Settings** needs to be enabled beforehand, and additionally, it must be communicated to Project Manager if you wish to use and activate the Document Authoring feature for the room.

Once this feature is activated, Administrator users by default will have access to Authoring. However, for every other level users, when they are invited to participate in document review, they need to be given a specific role – either **Document Collaboration Reviewer** or **Document Collaboration Administrator** – to gain access to Authoring.

To briefly explain the given roles: **Document Collaboration Reviewer** can only 'review' documents that were already uploaded. On the other hand, **Document Collaboration Administrator** can publish a document to be reviewed by other reviewers and can also comment on the document. Refer to the screenshot below:

Administrator can publish a document to be reviewed by other reviewers and can also comment on the document.

Note: *Collaborative Authoring module is accessible only for:*

- *The user with Administrator or higher role*
- *The users who have assigned actions:* ***Document Collaboration Reviewer*** *or* ***Document Collaboration Administrator***

Creating Review

Besides Collaborative Review module, the New Review for docukents can also be created from the ***Documents Cart → Creating a New Review*** *in the* ***eTMF/Documents module.***

To use the Collaborative Authoring feature, follow the steps below to create a review:

1. Click the **Add** button located at the top left corner of the ribbon bar. Refer to the screenshot below:

2. The **Create Review** window opens which has three sections - **Review Data**, **Participants**, and **Documents**.

Review Data

1. Fill in all the requiested information in the Review Data section. The information included the following:
   a. For Review Type, there are two options: **Co-Review** and **Co-Authoring**
   b. Select **Co-Review** Type.
   c. **Review Duration (days)**: This is the number of days by which the document review must be completed. Based on this parameter, the system will calculate the due date for the document review. By default, it will be set to 10 days; however, you can increase or decrease based on your preference.
   d. **Review Owner**: The Review Owner is the one who uploads the document to be reviewed by other participants. Only those with a Document Collaboration Administrator role can be the Review Owner. Add the participants or reviewers who will review or be co-authors of the document. You must add at least one document to start the process.

Participants

1. Click the down arrow from the **Participants** section to expand it.
2. Two buttons appear in the section: **Add and Remove**.
3. Click the **Add** button. The **Authoring Review Participants** window opens.
4. Select the appropriate users and click **Select**. Refer to the screenshot below:

5. The selected user(s) appear in the list of Participants as display the **Participant Role** as **Reviewer** .

Documents

1. Similarly, expand the **Documents** section which contains two buttons: **Add Documents** and **Remove**.
2. Click the **Add Document** button and select the appropriate document.

   Note: *You can add/upload multiple documents to the review* .

3. The uploaded document(s) appear in the list of Documents.

   Once all the information is filled, click **Save**. The newly created review appears in the **Pending**review list.

   Note: *Documents can be added in the following ways:*

   - TI Document from the eTMF/Documents module → Documents Cart.
   - Upload a new file(document).

   Below is an example of information to be filled out.

Alternatively, documents can be selected from eTMF/Documents can be added to review, or an existing review by simply right-clicking documents and selecting **Add to Review** option from the popup menu.

Only for Co-Review Types

If you are certain about all of the information filled out in the **Create Review** form, there is an optional checkbox that you can select, which is located on the bottom of the form – **Start Review Immediately**. If this checkbox is ticked when a user has pressed the **Save** button, the server will save review definition in the Collaborative Authoring module, and start the review.

Editing a Review Form

Select the form from the **Pending** list and open the **Metadata** to the right of the page. Notice that the fields of the Review Form are editable and you can edit the form as required. Click **Save** when all the changes are made. Here too, you can choose to **Start Review Immediately** by selecting the checkbox at the bottom of the form. Refer to the screeshot below:

When a new review is created, either from Documents module or Collaborative Authoring module, the document goes into the **Co-Review Pending** folder. The system then sends out an email notification to all reviewers indicating that a document is available for a review. The users can simply follow the given link, and it will directly lead them to the appropriate page.

Now, users can start the document review by clicking on the **Start Review** icon on the top ribbon or at the **right-hand bottom** of the dashboard. The document then moves to the **In Progress** folder.

To open the document for a review, click the message where it says *Click here to open PleaseReview in new window*. Refer to the screenshot below:

On the document. click the specific part where you want to add a comment or edit the text. Enter the comments and click **Apply**. To exit, click the red exit button on the top right corner as shown in the screenshot below:

Once you exit, a **Finish Review** page opens up and you can update the document review status there. Provide a comment if it is necessary and click **OK**. Refer to the sreenshot below:

Once a review is complete, the review owner can go into PleaseReview and close out the document. The review owner can also check the status of document by clicking the message. This message is accessible from Authoring -> Co-Review, and by selecting the specific document.

As a review owner, you can view comments that have been added to the document. Click on View Report to display the details, as shown on the below screenshots.

After synchronization of the completed review with the server task, the review status is changed and the review moves to the Co-Review Completed/Closed folder in the Authoring module. The reviewed documents are published to eTMF in a folder designated by you as an administrator.

Navigate to the eTMF Documents module. Drilldown to the folder where the published documents are filed. Right-click the reviewed document and select Open Profile. Click the Activity Log in the Document Profile popup. Here you will find that the reviewed files were uploaded as a new document and the attachments replaced. Refer to the screenshot below:

Co - Authoring

The **Co-authoring** feature allows multiple users to work on one document at the same time by assigning a particular zone to be worked on by each author.

For this purpose, there are few additional roles available for Co-Authoring review:

- ***Owner-Contributor*** (review owner in Co-Authoring review receives this role automatically instead of the *ReviewOwner* role)

- ***Contributor*** (a user who can be assigned as a reviewer for a particular zone in the document)
- ***Author-Contributor***
- ***Super-Contributtor***

The steps below demonstrate how to create a review for Co-Authoring:

1. From the Collaborative Authoring module, click the **Add** button on the top ribbon bar.
2. Select the **Review Type: Co-Authoring** , enter the title, review duration, and add participants.
3. Select the users and specify their roles from the **Participants** section.
4. Add documents from the **Documents** section.

   Note: *Only **.doc** files can be separated on Edit/Review zones for Co-Authoring*.

5. Click **Save**.

   When a review is created, the document is placed in the **Pending** folder under Co-Authoring.

   Important: *As a contributor, you cannot start the Co-Authoring review upon its creation (the related checkbox is not available for Co-Authoring review). This is because before a review can get started, the owner contributor must go to the PleaseReview and assign zones in the document to the specific contributors.*

As an owner contributor, to assign zones to each contributor, locate the newly-created co-authoring document and click the **Pin icon** on the button under document section.

Upon opening the document, click the specific zone to be assigned to each contributor. Screenshot

Under the Selected column, put a checkmark next to the name of contributor assigned for this particular zone in the document. Then click **OK**.

Repeat this process for other contributors as well to assign them to each zone. After you are finished with assigning zones, exit PleaseReview by clicking the **Exit** button located on the upper right corner.

Once zones are assigned, the owner contributor must start review manually. Click on **Start Review** button on the screen. Then, the document will be moved to the **In Progress** folder for contributors to work on their assigned zone.

If you are a contributor to a document and want to work on your assigned zone, locate the document placed under the **In Progress** folder for Co-Authoring, and click the link. Then, you can simply click the particular section of document that you are assigned to as a contributor, and download the document for that section only. Screenshot

Make the appropriate changes and save the document. Screenshot

Then go back to the PleaseReview screen and browse the saved file. Click **Upload**.

If it is final and no more editing is required, click **Publish** and close the window.

After all contributors are finished with their assigned zones, as a owner contributor, you can close out the review by following the same process as in Co-Review.On review closeout, the reviewed documents are published to eTMF as new documents as shown above in Co-Review.

Collaborative Workspace

Collaborative Workspace is repository for the project management related documents, some of the documents in this room will be moved to eTMF room. Collaborative workspace have a reference to a study room.

The Trial Interactive Collaborate solution, also known as Shared Workspace, is a Clinical Collaborative Workspace Solution for clinical teams to provide Sponsors, CROs, and Sites a place to share and author documentation to be used in the Clinical Trial and ultimately archived in the eTMF.

An integral part of TI Collaborate, TI Collaborative Authoring will provide end-users the capability of directly editing MS Word, Excel, and Powerpoint documents in the browser, and allowing multiple authors to simultaneously work

on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

Collaborative Workspace offers the following features:

1. Direct to TMF
2. Sponsor / CRO Collaboration
3. Edit Online
4. Collaborative Authoring
5. Document Templates and Required Documents (Placeholders)
6. Document Versioning
7. Site to Sponsor, Sponsor to Site, and Sponsor to CRO Workflows
8. Study Start Up Interoperability
9. Document Planning and Tracking
10. Clinical Shared Workspace Reporting

Important: *To enable Collaborative Workspace room, contact the Helpdesk.*

Linking Rooms to Collaborative Workspace Enabled Rooms

Follow the steps below to link rooms to Collaborative Workspace enabled rooms:

1. Enter the Collaborative Workspace enabled room and navigate to **Settings**from the Main Navigation.
2. Click the **Collaborative Workspace → Linked Rooms** option located on left menu bar.
3. Click the **Link Rooms** button from the Linked Room section. The opens the **Link Rooms** popup. Select the desired roomfrom the Room menu list.
4. Click **Select**. Refer to the screenshot below: The rooms are now linked to your Collaborative Workspace source room.
5. The user has an option to publish the documents **as final** in eTMF.

   Access the **Shared Workspace** -> **Common Configuration** setting as demonstrated earlier. Click the suitable option to **Publish eTMF-ready document as final** to publish the documents to eTMF or select the **Workflow** option in order to add the documents to all active workflows in the destination room. Refer to the screenshot below:
6. Click **Save** after you have made the desired changes.

Note:

- *A Collaborative Workspace room should be linked to only one eTMF room as the system is not be able to recognize the synchronization between multiple eTMF rooms thus leading to documents not being published.*
- *Once the eTMF room is linked with the Collaborative Workspace room, it cannot be linked to any other Collaborative Workspace room.*
- *Once a document is published to the eTMF, or a SWS has at least one document with 'Is this TMF Document – Yes', it can no longer be unlinked from its eTMF room.*

Creating New Collaborative Profile

Collaborative Profile can be created in the following ways:

1. From the **Collaborative Workspace** module by clicking the **Add** button, and
2. By selecting the document from the **eTMF Documents** module

Creating Review for a new document the Collaborative Workspace module

To create a new collaborative profile:

1. Navigate to the Collaboraive Workspace room.
2. From the documents module, click the **Add Document** option from the **Document Actions** menu on the top ribbon bar.
3. The New Document window opens.
4. Fill in the required details, select the **Document Types** and select the **Attachment**.

> **Note:** *If you want the document to be passed through the Change Control Workflow, select the Document Type for which the option* ***Include in Change Control Workflow*** *is enabled. This allows the system to distinguish between the documents which needs to go to change control for review and which need not.* Refer to the screenshot below:

5. Click **Finish**.
6. The new added document gets saved in the index folder that is set for the document.

Creating a Review

7. Now navigate to the document and open the document in the **Document View**.
8. Click the **Check Out** link from the Document View toolbar. The Check Out window opens. Refer to the screenshot below:

9. Select the **Collaborators** and set the **Due Date** for the review.
10. Click **Check Out.** A window opens asking you for the confirmation.
11. Click **Yes** to create a new review. This new review now appears in the **Collaborate** view of the Collaborate Workspace module for the assigned collaborators.

Creating a review from the Collaborate view

1. Navigate to the **Collaborate View** of the Collaborative Workspace module.
2. Click the **Add** button from the top ribbon bar.
3. The **Collaborate Profile** window opens.
4. Select the attachment and enter the title for the review.
5. Select the Document Owner, Review Due Date and Collaborators for the review. Refer to the screenshot below:

6. Click **Save**.
7. After this follow the steps 7-11 from the section above to review the profile.

Reviewing the Collaborative Profile

Once the document owner creates the Collaborative Profile, the created profile is visible to the document owner and to the document collaborator under the **My Reviews → Open** folder in the Collaborative Workspace.

When a new review is created, it is available for to **Review Owner** as well as to **Review Collaborator** under the **My Reviews -> Open** folder in the Collaborative Workspace module. The Collaborative Review needs to be done in the following sequence:

1. Reviewing the Collaborate Profile by collaborators.
2. Reviewing the Collaborative Profile by the Document Owner.

   Each of these processes are discussed in the section below:

Reviewing a Collaborative Profile by the Collaborator

1. As a collaborator, Navigate to the **My Reviews → Open** folder in the Collaborative Workspace module.
2. Select the required document and open it in the **Document View**.
3. Click the **Collaborate Status** tab from the Right Panel to update the document status.
4. The Collaborate Status tab provides the following actions:
   a. Close Review Session
   b. Add Status
5. Click the **Add Status** button and update the status for the review. Refer to the screenshot below:

6. Note that the review displays the **UserName** of the Collaborator.
7. Once all the updated are made, click the **Update and Save** button. The status for the review gets updated.

> **Note:** *When the collaborator set the status as Complete, the review moves from the **Open** folder to the **In Progress** folder of the **Collaborator** and the **Document Owner**.*

8. Navigate to the In Progress folder and select the document. *Notice that the status of the document still remains **In Progress** until the Document Owner completes the review process*. Refer to the screeshot below:

9. You can view the Document Status set by you in the **Collaborate Status** tab from the Right Panel.

Reviewing a Collaborative Profile by the Document Owner

1. Now as a **Document Owner**, navigate to the **Collaborative Workspace** module.
2. Select the **Collaborate** view from the left pane and open the **In Progress** folder.
3. The document review is availabe to the Document Owner in the In Progress folder.
4. Select the document and open the **Collaborate Status** tab from the right pane. Notice that the Collaborate Status also display the review status of the collaborator. Refer to the screenshot below:

5. Click the **Add Status** button to update the status of the document review and enter the comments if any.
6. Once all updates are made, click the **Update and Save button**.
7. After saving the status of the document, click the **Close Review Session** button to close the review. The Close Review Session window opens.
8. Select the significance of the changes and enter the comments if any. Refer to the screenshot below:

9. Click **Save** to save the changes.

Trial Interactive Knowledge Center

This section contains frequently asked questions, common responses to customer questions, and other information to allow for consistent and unified communication.

Access FAQ

Question: What is the inactivity time out for Trial Interactive application?

Answer: On the Multi Tenant Instance, the Trial Interactive application inactivates if left idle for 60 minutes. Customers may choose their own timeout.

Question: What is the Password Expiration duration for the Trial Interactive application?

Answer :

- Temporary password expires in 30 minutes.

- Password expires in 90 days with 1, 3 and 7 day reminders.
- If the user enters wrong username or passowrd , the application gets locked after 5 attempts.
- Dedicated customers may set these values to ones of their choosing.

DocuSign FAQ

Question - Is the Trial Interactive able to integrate with both versions of DocuSign, both normal and 21CFR Part 11 Compliant Version?

Answer: Both versions work, but each client must take responsibility to determine if they need the Part 11 compliant version. For use within the Life Sciences, choosing the 21 CFR Part 11 Compliant version of DocuSign is a must. We can support both regular and Single Sign On versions. We do not support batch signatures in an envelope, however.

Question: **If I have a stack of DocuSign user licenses, what is the process for having those users active in our system? It is necessary to understand this to determine the UAT and validation processes we need to follow?**

Answer: We request an integration key from DocuSign to marry the DocuSign system to Trial Interactive systems. TI then matches users based on identical email addresses between the two systems. If your company is not using Single Sign On, you will have two separate credentials (username/password), one for each both systems, and each is invited, removed, and managed separately.

Question – what are the eSignature workflow options in TI available for DocuSign

Answer: Currently we have an action called eSignature. You pick documents you want, prepare the envelope, send your documents for signature, choose your docusign workflow (serial or parallel), and prepare the envelope (choose users and signing order). Once sent, the users get email links or alternatively they can sign directly onto to TI and click the eSignature button.

eTMF FAQ

Question: What is the offering? Please describe Trial Interactive?

Answer: For all participants in life sciences research, who want to store electronic Trial Master File documents during the execution of a clinical trial, Trial Interactive eTMF is an electronic Trial Master file that is part of the TransPerfect eClinical Suite. The eTMF does the following:

- Streamlines the capture and management of trial content and documents throughout the study lifecycle,
- Provides a fully collaborative, closed and pre-validated environment allowing user and document workflows to execute within the context of the trial and its investigative sites, and
- Provides users with a common platform experience, unifying eTMF with other clinical trial systems.

Unlike other eTMFs that require users to send documents via email or fax, or edit documents in different places, the Trial Interactive TI Collaborate allows users to upload, draft, review, and approve documents all within the eTMF. Users access all of these documents within the same environment, providing a common audit trial of changes and a "single source of truth" for the eTMF. Together with other Trial Interactive modules such as TI Study Start Up, TI Collaborate, TI Docs, Global Learn, eFeasibility and TI Data Pool, the integrated systems speed study timelines and reduce costs while providing a comprehensive content management system throughout the study lifecycle.

Question: What are some of the features of the eTMF?

Answer: The Trial Master File contains the documents that, individually and collectively, are essential for the evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of good clinical practice (GCP) and with all applicable regulatory requirements. eTMF refers to the electronic maintenance and storage of the Trial Master File. A significant percentage of TMFs are still maintained entirely on paper. A small portion of sponsors have converted entirely to eTMF, and some sponsors use a combination of paper and eTMF. The benefits of the Trial Interactive eTMF include the following:

- Master File functionality
  - Best practice approach to eTMF with flexible configurations available
  - Accelerated study and site start-up (e.g. facilitates gathering, storage of site-level documentation)
  - Built-in Audit support and quality check processes
- Improved Compliance and Quality
  - Standard process for content submission with real-time addition of content
  - Accurate status reporting with eTMF Health Checks
  - Portfolio-wide reporting and benchmarking
  - Comprehensive services and staff augmentation available
- Enhanced collaboration
  - Single, secure place for all clinical players to share documentation in a standardized, fully reportable system
  - Collects and organizes essential clinical documentation
- Lower cost
  - Eliminates unnecessary downstream processing
  - Lower cost of ownership
  - Reduces logistical expense

Question: What are some of the differentiators of the Trial Interactive eTMF?

Answer: Key standouts of Trial Interactive eTMF:

- Part of Trial Interactive E-Clinical Platform
- Supported by Comprehensive TransPerfect Life Sciences TMF Services (Paper and Digital) with Flexible Staff Augmentation
- Fast and Flexible eTMF implementation
- Out of the Box CTMS Integration
- Both Standard and configurable TMF Reference Model Support
- Adaptable QC and Audit Process
- Simplified Coding and Auto-Naming
- CRA Mobile App Available for site document capture
- Corporate Directory Integration with Single Sign-On
- IRB Integration and Submission Support
- Built on Scalable, Proven Technology Platform
- Flexible Rules and Placeholders for Required Documents by Country, Site
- TMF Health Dashboards
- Pre-Configured Migration, Scanning, Certification, and Upload Processes
- CRA Reconciliation Support
- Ad-Hoc and Standard Reporting
- Comprehensive Audit Trail
- Standard and Controlled Document Intake
- Flexible Access Per User Across Studies
- Controlled Document Authoring
- Robust Search and Filter Capabilities

- Roll Up and Multi Study Dashboard
- Active Alerts and Notifications
- Multi-Lingual and Translation Support Locally
- Branded User Interface
- 24x7 Help Desk Email and Phone
- Email Correspondence and File Input
- 21 CFR Part 11 Compliant Digital and Electronic Signatures
- Comprehensive Validation Package
- Supports Global Studies with World-Wide Accessibility and Translation Services from the #1 Translations Company

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Question: What is the maximum number of digits for file name and document title in the eTMF?

Answer: Document title is supported up to 400 characters, but when exporting files, the system truncates path + filename longer than 256 characters.

Question: Are there file size limitations when importing documents to the eTMF?

Answer: When the documents are submitted via inbox submission, maximum size of an email with the attachments is 100 MB. When the document is uploaded via the application, the max file size is 1GB, but this depends on the internet connection and session timeout of the user - the file must import before the session times out.

Question: What browsers are supported for Trial Interactive?

Answer: Trial Interactive will be tested with all major browsers, including Chrome, Firefox, Safari, and Internet Explorer 8, 9, and up.

Question: Will Trial Interactive work on the iPad or other tablets? Will Trial Interactive work on the iPhone?

Answer: In TI version 10, Trial Interactive will support a fully responsive design. Trial Interactive is presently built upon a user interface framework that is designed to work on many screen sizes, including iPads, tablets, and mobile phone devices such as Android and iPhone. However each of these must be carefully tested to ensure it will operate correctly with that specific screen size as well as the touch interface.

In addition, the myTI product is specifically designed for the iPhone, iPad, and Android Phones and Tables for document capture and reconciliaton at the site by the CRA.

Question: Trial Interactive eTMF shows a rendition of the document instead of the original. Why?

Answer: Advantages of showing a rendition vs original document:

- Streaming : only individual pages are sent to the browser, which means the image loads immediately.
- Less Data Sent: Most produced images are smaller than the original document.
- Image Quality: Resolution quality doesn't depend on the browser and installed PC hardware.
- Since the agency (EMA) is using the exact same technology to review submissions, they are seeing the same rendition in TI.
- At any time, users can choose to view the document in the native format, which will open the file in the locally installed viewer. PDFs woll generally open in the browser, and other file types will download and attempt to open in the native viewer.

Question: In 9.2, what are the supported conversions using to create the renditions?

Answer: The following file types are supported:

- PDF - all versions
- Images: JPEG, PNG, TIFF, GIF, BMP, JNG, PBM, PSD, EPS, PS, DCM (Format DICOM) and all formats supported by ImageMagick
- Microsoft Office (97-2013): Word (.doc, .docx) , PowerPoint (.ppt, .pptx), Excel (.xls, .xlsx), WordML (.xml), Visio (.vsd)
- Composite files: ZIP, EML, MSG
- Others: TXT, OpenDocument (LibreOffice or OpenOffice)

---**Question:**

Are documents stored in Trial Interactive safe?

Answer: Extremely safe. All documents stored within the Trial Interactive system are encrypted in-place and in-transit in a private document store accessible only to the Trial Interactive application. Each encrypted document is duplicated into two separate locations, and the decryption keys are not stored with either Trial Interactive or the encrypted documents. This ensures that if any location is compromised, the documents cannot be read, and if Trial Interactive is compromised, the documents cannot be read. Only the compromising of both the hosting provider and the key storage puts any documentation at risk.

Question: Can Trial Interactive connect to more than one IdP for Single Sign On?

Answer: No. Suggestion in this case is to use a 3rd party service such as Okta, OneLogin, or PingIdentity.

Question: Does Trial Interactive support a 'deep link' directly to a specific document is a room and index?

Answer: Yes.

Question: How does Trial Interactive handle email correspondence?

Answer: What we do in 9.1:

- Customers can send email messages to an eTMF email inbox for each room.
- SSU also has an email Inbox, separate from the eTMF.
- Any documents found within the email messages will be detached and included as imported, unclassified documents within the eTMF room.
- Documents are NOT rendered to PDF.
- Email message text is not captured.
- Any file format is supported as an attachment, including .eml and .msg files.
- If customers need any content rendered to PDF, such as .eml or .msg files, TPT Legal Services can do this for them as a service.

New in 9.2 is the ability to capture email correspondence and render all email content to PDF just by copying the eTMF. What we do in 9.2:

- Existing 9.1 inbox functionality is untouched.
- We have a new email Correspondence Inbox for eTMF and SSU. This Inbox will not only detach and include the email attachments, it will also render to PDF the email messages.
- An interface exists where users can view all correspondence sent in to eTMF and SSU and decide whether or not to include it, either the email message or each attachment.
- We have a new viewing engine that supports rendering to PDF 300+ formats, including .eml and .msg files.
- If customers need any content rendered to PDF, such as .eml or .msg files, TPT Legal Services can do this for them as a service.
- At times, due to the complexity of the format, .eml and .msg files will not render properly. If customers need any content rendered to PDF, such as .eml or .msg files, TPT LEgal Services can do this for them as a service.

Again, if customers need to convert an archive of communications (.eml or .msf or .psd or .osd) to PDF we can do that as a service.

Hosting FAQ

Question: How will Trial Interactive be deployed and hosted? Is there any concern with the security of customer data?

Answer: Trial Interactive is deployed and managed as both a single-tenant and a multi-tenant SaaS application, utilizing the AWS infrastructure as a services platform, providing our customers with a highly scalable and accessible platform for eTMF. Trial Interactive itself requires no client infrastructure requiring only a browser and an Internet connection to access. Trial Interactive uses a multi-tenant architecture that allows efficient sharing of application software and hardware resources, while providing complete partitioning of each customer's data. It is managed as a single code base deployed over a distributed architecture composed of multiple components, including a web server layer, application layer, database layer, content layer and file store. Each component represents a physical set of infrastructures and provides the necessary application logic, data and security to support Trial Interactive. Hosting facilities are located in Northern Virginia and Oregon in US, and Sweden in the Europian Union.

Question: Why host on AWS? Why host on the Cloud?

Answer: The Cloud, specifically AWS, Google, Azure, and other large providers, has several advantages over on-premise and co-located hosting:

- Scalability - Infrastructure as a Service allows TI to horizontally scale based on usage. As many instances (servers) may be added to a cluster as necessary, very quickly. This allows TI to provide customers the performance they require no matter what circumstance. It also allows load balancing of processing power and memory between many users, customers, and sites.
- Standardization - Since instances can be standardized using virtual machines, all instances can be pre-configured before deployment.
- Performance - Because of scalability, performance can be provided in a consistent way. PaaS (Platform as a Service) applications available on AWS allow TI to take advantage of global caches, global temporary file space, and global database clustering, allowing the source to be local to the destination user.
- Maintenance - Powerful scripting tools like Chef and Puppet may be used to automate all server maintenance, so that all updates may be done without involving human operators, improving consistency of practice.
- Deployment - Powerful scripting tools like Chef and Puppet may be used to automate all server deployments.
- Integrations - Interoperability between systems may be accomplished using web services over TLS/SSL or VPN as needed, in addition to new technologies such as SAML for single sign on.
- More Reliable - The ability to leverage a vast infrastructure means new instances are easy to spin up and maintain. This requires a greater degree of maintenance and careful change control, but ends with a more reliable hosting platform.
- Ease of Upgrades - Upgrades may be scheduled and deployed with little customer effort outside of a standard UAT script, because TI takes on the burden of validating the software as part of the service.
- Ease of Adoption - TI has some control of the ability to engender adoption. Through User Experience testing, TI can see where adoption is dropping off, and quickly correct the software. TI can also help the customer with adoption as part of the service and rollout.
- Higher Quality - While this one is a bit tricky, it is true that TI can deploy patches faster and more safely in a Cloud environment. This comes into play with Multi-Tenant customers more clearly than Single-Tenant, however with deployment automation using Cloud tools such as Chef, Puppet, and Infrastructure deployment tools like Elastic Beanstalk, this also allows for faster patching.
- Self-Service - SaaS software is typically focused on self-service instead of centralized. This varies on the software of course, but it can often leverage tools that are not available on-premise.
- Secure - This is another tricky one, but it's true that Cloud providers take security more seriously than smaller shops. In this case larger does in fact mean better. An example is the Meltdown defect, which was patched by AWS months before it was officially announced.
- Better Features, Faster - SaaS software, because of simpler deployment, can often be delivered on a tighter, more focused release cycle.

Question: Is Trial Interactive a single point of failure? What happens if Trial Interactive goes down?

Answer: TransPerfect will have all the necessary resources in place to continue to ensure a Service Level Agreement (SLA) and uptime that is acceptable, including monitoring, on-demand scalability, hot servers and mirroring, regular backups and a host of disaster recovery and management procedures in place. Trial Interactive availability is of the utmost importance to the success of our customers. With the exception of a four-hour weekly maintenance window Trial Interactive application services are available 99.5% twenty-four hours a day seven days a week.

Question: But really, what happens if Trial Interactive goes down?

Answer: No computer system is completely immune to failure, as illustrated by multiple outages that have occurred with Amazon Web Services, Google Mail, and other single instance application providers. Should Trial Interactive go down, we will take every means to ensure it is restored within our customer's contractual SLA, and undertake a root cause analysis (RCA) or CAPA to resolve the issue permanently. When a disaster scenario occurs the Trial Interactive cloud services environment will be re-deployed into the secondary cloud services environment using the same validated processes that were used during the deployment of the primary cloud services environment. Customers will be functional within 24 hours (Recovery Time Objective) of the disaster being identified, with up to 30 minute data loss at most (Revovery Point Objective).

Question: Will TransPerfect accommodate audits by our customers to the third party being used to host Trial Interactive?

Answer: TransPerfect will ensure the appropriate level of security and privacy measures are in place at the third party through vendor audit and formal assessment procedures. As per TransPerfect audit policy, customers may visit the corporate office for formal audits of our policy and procedures. An audit of the remote hosting facility is accomplished primarily through standardized documentation such as the SSAE 16 SOC 2 and SOC 3 assessments.

Question: What is the Trial Interactive Service Level Target and AppDex Score?

Answer: The target AppDex score for Trial Interactive is Client-Side T=2.0. This means that, on average, every page turn in the Trial Interactive application returns in two seconds or less. This is a very aggressive score, as most of the time involved in a page turn concerns network speed, browser page Document Object Model (DOM) generation, and browser page rendering time. Only a small portion of the two seconds is available for the server response.

Question: What does AppDex mean, and what do we mean by an AppDex Score?

Answer: AppDex is the application index score, which is the average client side page turn based on some number of seconds T. Required is T = 2 seconds, with and expected AppDex score of 90% and higher.

Question: Who is the hosting provider for Trial Interactive?

Answer: Trial Interactive will utilize a third party infrastructure as a service (IAAS) environment at AWS. AWS operates a SSAE 16 SOC 2 (formerly SAS 70) environment that is configured per TransPerfect specification and requirements during the provisioning and deployment process as part of the product release cycle. TransPerfect quality representatives have performed a thorough analysis of the third party SAAS provider environment and concluded that they exceed the expectations required to ensure that Trial Interactive can deliver on customer service levels in a secure and efficient manner.

Question: What certifications does the hosting provider hold that are applicable to Trial Interactive?

Answer: AWS, the selected hosting provider, provides virtual servers in their own SSAE 16 SOC 2 (formerly SAS 70) data center that is configured per TransPerfect specification and requirements during the deployment

and configuration process. In addition to that, AWS holds many certifications, the details of which may be found here:https://aws.amazon.com/compliance/programs/

Question: How many application and web servers are used by Trial Interactive?

Answer: Trial Interactive require a web server, application server, a database server or service, a reporting database and server, a content server, a file and document store, an index server, and a cache server as part of its N-tier architecture. Other services will be required to manage firewall and security, load balancing, and the web services gateway and mobile gateway. TransPerfect may elect to change the configuration of the Trial Interactive service at any time in order to ensure our customers the best possible service levels.

Question: What kind of system load and performance testing has been done for Trial Interactive? What is the expected user, supplier, customer and transactional concurrency?

Answer: A full set of system load and performance tests are part of the development for Trial Interactive, with an eye to ensuring horizontal scalability in all components. This will allow Trial Interactive to scale to many users by simply adding more instances, and without requiring a major change to the application architecture to accommodate more customers.

Question: Is Trial Interactive horizontally scalable? How is this accomplished?

Answer: To be horizontally scalable means that Trial Interactive can scale up by adding additional nodes (servers) with no overall performance degradation noticed by end users. This is critically important for applications that may need to scale up to 100s of thousands of users quickly, and for applications whose user activity load varies widely based on time, day, month, and other variables. Trial Interactive has the ability to cluster web servers, application servers, and content servers, and is thus scalable in this way.

Question: Are Audit Trails for Trial Interactive preserved and archived?

Answer: Trial Interactive includes detailed audit logs showing the field changed, the old value, the new value, the data and time, and the reason for change. Electronic signatures are indicated in the audit trail as well.

Question: Define the Virus Prevention, Detection and Mitigation controls in place. How are they kept current?

Answer: Antivirus software is installed on all servers to check and isolate or remove any viruses including data, attachments, etc. Systems are configured to scan for malicious software and infected files on a regular basis. New files are automatically scanned upon save or download including email attachments. Updates to virus databases are downloaded automatically and distributed through an automated update process. For attachments, customers must maintain virus download protection in place to prevent any virus infection from that vector.

Integration FAQ

Question: Does Trial Interactive have an Application Programmer's Interface (API)?

Answer: Yes. TI has an API, currently used actively in production by several customers, that enables a close integration with a CTMS. Investigators, Sites, Contacts, Milestones, and Documents may all be passed to and from Trial Interactive.

Through integrations via the TI Integration Gateway, the Trial Interactive system can publish and receive data from other systems through a standard REST-based API. This allows Trial Interactive to receive Investigators, Sites, Study-Sites, Contacts, Milestones, Events, and Documents to and from other clinical systems such as IRB/EC, CTMS, and EDC. Trial Interactive also supports interoperability through a CMIS-compliant REST API, which is a standard for document interoperability that is supported by Documentum, OpenText, Alfresco, and many other vendors.

Trial Interactive supports single sign on, authentication, and authorization integrations through a SAML interface, supporting integration partners such as Active Directory and Okta. Finally, the Trial Interactive has available an optional TI Content Connector, which is a pub-sub integration component that can facilitate interoperability with both CMIS-compliant and non-standard REST API interfaces such as Veeva.

Question: What is the plan for Trial Interactive interoperability with other Document Management or TMF solutions?

Answer: Trial Interactive supports interoperability through CMIS, a standard format that is supported by Documentum, OpenText, Alfresco, and other vendors such as Veeva through the TI Content Connector.

Question: How is SSO supported by Trial Interactive?

Answer: SSO is supported through SAML 2.0, currently supported on all Dedicated client instances. A few points:

- SSO is not supported on TI eTMF Multi-Tenant until TI v10.x
- TI supports SAML 2.0 (current version of underlying protocol used to negotiate an SSO sessions between two endpoints) for dedicated clients. Will be extended to MT clients in TI v10.x
- Trial Interactive is listed as part of the Okta Integration Network (https://www.okta.com/resources/find-your-apps/?keywords=Trial%20Interactive)
    - Intention is to have the Okta Integration Network version of the TI application used only by Multi-Tenant clients.
    - Dedicated clients will be asked to create an “Internal” Okta TI Application within their Okta account (see Option2xxxx.PPT attached). Allows client to have more control of the SSO integration and provides a means for future client-specific customizations as needed. Also, this approach eliminates a single point of failure for our Okta integrations.
    - Should a dedicated client insist on implementing the Okta Certified Network version of the TI application, we can support that as well. But, should push for option ‘b’ above.
- We do not yet support policy, group or room assignments via SSO at this time (i.e. when account is created in TI via SSO, we can’t automatically, via SSO messaging, assign the user a role, group or even a study room. That all has to be done manually until we design and build the additional functionality.

Question: What integrations are supported?

Answer: See below:

myTI FAQ

Question: Does myTI have support for tablets / iPads?

Answer: Yes - the myTI product supports iOS with iPad/Tables are supported. The web interface will also resize to iPad.

Question: For mobile apps for data privacy, data security tends to be important as there is potential data being stored on the device. Is data stored/cached locally on the device? If so how is that secured?

Answer:

Yes, absolutely data security is critical and we take it very seriously. myTI was designed and built to not store anything on the device. That means no data, documents, or images are stored on the device; immediately after you have captured a document using myTI, the document is temporarily cached within myTI until the transfer to Trial Interactive eTMF is complete. The temporary cache may be disabled if needed. All operational app data is encrypted at all times. We ensure data securely only goes into TI as the documents may not be accessed in any way while the phone is powered on, and as soon as it is powered off, they disappear, encrypted in transient memory only.

This is also true if you temporarily lose your connection immediately before or during document transfer. Nothing is ever stored permanently on your device. myTI is fully secure and 21 CFR Part 11 Compliant, and the myTI Cloud hosting environment fully complies with regulatory standards for storage of encrypted eTMF documents.

Question: Does myTI have support for tablets / iPads?

Answer: Yes - the myTI product supports iOS with iPad/Tables supported through screen doubling. The web interface is not fully responsive but will resize to iPad.

Question: For mobile apps for data privacy, data security tends to be important as there is potential data being stored on the device. Is data stored/cached locally on the device? If so how is that secured?

Answer:

Yes, absolutely data security is critical and we take it very seriously. myTI was designed and built to not store anything on the device. That means no data, documents, or images are stored on the device; immediately after you have captured a document using myTI, the document is temporarily cached within myTI until the transfer to Trial Interactive eTMF is complete. The temporary cache may be disabled if needed. All operational app data is encrypted at all times. We ensure data securely only goes into TI as the documents may not be accessed in any way while the phone is powered on, and as soon as it is powered off, they disappear, encrypted in transient memory only.

This is also true if you temporarily lose your connection immediately before or during document transfer. Nothing is ever stored permanently on your device. myTI is fully secure and 21 CFR Part 11 Compliant, and the myTI Cloud hosting environment fully complies with regulatory standards for storage of encrypted eTMF documents.

Compliance FAQ

Question: What certifications does Trial Interactive and any service or hosting providers hold that are applicable to Trial Interactive?

Answer: AWS, the selected hosting provider, provides virtual servers in their own SSAE 16 SOC 2 (formerly SAS 70) data center that is configured per Trial Interactive specification and requirements during the deployment and configuration process. Once the software is deployed, the application is managed according to Trial Interactive policies and procedures, including the SDLC and Change Management processes.

Question: Are there any additional requirements that a customer will need to complete to remain compliant with the EU 95/46 data privacy directive?

Answer: No. Trial Interactive will continue to operate as a Data Processor and our customers will remain Data Controllers. Trial Interactive neither adds nor subtracts any requirements beyond those normally assigned to a data controller.

Question: Is Trial Interactive compatible with new European GDPR privacy regulations?

Answer: Yes. TransPerfect and Trial Interactive is fully compliant with GDPR, and several critical processes, such as right to be forgotten and privacy breach, are part of Trial Interactive's manual of procedures.

Question: Is the Trial Interactive implementation of Electronic Signatures compliant with Electronic Record/ Electronic Signatures regulations and guidances (e.g., US FDA 21 CFR Part 11)? If yes, describe.

Answer: Yes. Trial Interactive provides system controls necessary to meet Title 21 CFR Part 11 compliance for Electronic Records and Electronic Signatures. A separate document is avaialble that provides specific discussions around this compliance, as well as any applicable GxP regulations. In addition, Trial Interactive provides system and infrastructure controls necessary to meet Europian regulations Annex 11, as well as Japenese and global regulations commonly known as ER/ES (Electronic Records / Electronic Signatures).

Question: Besides the Trial Interactive report and acceptance of the User eSignature agreement, does Trial Interactive make it easier for customers to meet the agency requirement for eSignature agreements?

Answer: The report may be used to easily maintain these agreements with the agencies. For example, the FDA accepts one certificate from an organization (vs. requiring individual certificates from each person or User) provided the certificate makes it clear what Clinical Site Users will be covered by the certificate. The preambles to the regulation explain 21 CFR 11.100, in that the most responsible organization can submit one certificate that covers all of the external organizations where persons will use electronic signatures (http://www.fda.gov/ora/compliance_ref/part11/frs/background/11cfr-fr_03.htm) A single certification may be stated in broad terms that encompass electronic signatures of all participants, thus obviating the need for subsequent certifications submitted on a pre-established schedule. Example certification: "Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that [name of organization] intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures."

Question: What is the Trial Interactive Privacy Policy?

Answer: A privacy policy is a legal document that discloses how a party retains, processes, discloses, and purges customer's data, such as emails, personal information, credit card details, etc., and is standard fare for online websites and applications. The Trial Interactive privacy policy is same as TransPerfect's and delivered with the product via a link and states that information obtained will be only used for internal business purposes, and not shared with third parties except for relevant Users/customers for the purposes of managing a clinical process.

Question: What will Trial Interactive do with all this Trial Interactive User data?

Answer: Trial Interactive is deployed and managed as a multi-tenant SaaS application, providing our customers with a highly scalable and accessible platform for eTMF. Trial Interactive can use a multi-tenant architecture that allows efficient sharing of application software and hardware resources, while providing complete partitioning of each customer's data and local Trial Interactive connection.

Question: Are all uploaded documents stored in a secure and reliable location? Are they protected from attacks and theft?

Answer: Yes. All document attachments are carefully checked for virus and trojan attacks, and are encrypted in-place within Trial Interactive, and in-transit outside the Trial Interactive service.

Question: Please describe your documentation strategy related to company quality policies, Standard Operating Procedures (SOPs), guidelines (e.g., working practices, Work Instructions (WI), and policy. Documents that outline, in general terms and not step-by-step instructions, how specific GCP aspects (such as documentation, training, software development controls) are implemented. Are employees and contract staff trained on new or modified SOPs?

Answer: An SOP is a step-by-step sequence of instructions for how to perform operational processes or activities that were described in general terms in a policy statement.

Trial Interactive requires all employees to be trained on procedures that impact their job role. Re-training is mandatory whenever applicable SOPs are updated. Some members of the staff are trained on applicable regulations as they apply to a particular job role. Trial Interactive' staff regularly attends seminars in their area of focus, subscribe to publications, utilize the internet news feeds and blogs and attend user group meetings.

As part of Trial Interactive quality system documentation, SOPs are under the direct control of our quality assurance organization. Departmental managers responsible for given procedures are the only one with the authority to approve changes to these procedures. Internal staff that are required to utilize procedures are trained as per Trial Interactive training matrix. Customers may review procedures in an audit setting only with direct supervision of the Trial Interactive Quality Assurance organization, procedural documents are not distributed out side of the Trial Interactive environment.

Question: Does Trial Interactive accommodate customers for software audits? How will this process work?

Answer: Trial Interactive will ensure the appropriate level of security and privacy measures are in place at the third party through vendor audit and formal assessment procedures. As per Trial Interactive audit policy, customers may visit the corporate office for formal audits of our policy and procedures. An audit of the remote hosting facility is accomplished primarily through standardized documentation such as the SSAE 16 SOC 2 assessment.

: **What is the process for Certified Copy Validation?**

Answer: Each scanned record is visually inspected to ensure that the image is complete, clear, and usable. Scanned records are compared to the original paper document to ensure accuracy; as an exact copy having all the attributes and information as the original. Also, the number of original paper documents is compared to the number of scanned records to ensure that every document was scanned. The document is checked for doubled-sided pages to ensure that they are not missed.

Question: **Is Trial Interactive ICH-EC-R2 compliant?**

Answer: Yes, Trial Interactive is ICH-EC-R2 compliant. This regulation focuses are several major things with respect to the eTMF:

- **Certified Copy**: TI fully supports and meets all Certified Copy requirements, and TI keeps all the same document attributes as the original copy.

- **Minimum List of Essential Documents**: This list is reflected in the latest versions of the eTMF specification and the TI eTMF Room Configuration Standards. where this list is encoded as Required Documents in the eTMF.

- **Retention Time**: ICH-EC-R2 requires a record retention of a minimum of 15 years, to support marketing applications. Trial Interactive meets this requirement, as all data and content records in the retired instance are retained by TP for a period of five years or longer if required by applicable law or regulation.

Security FAQ

Question: Please describe the security architecture of Trial Interactive.

Answer: Trial Interactive has multiple layers of boundary protection on all externally hosted solutions. Trial Interactive has a shared application instance; however, each customer's documents are stored separately, which is logically and physically separated from the Trial Interactive database instance. There is a logical segmentation between client records, and all data is encrypted in-place and in-transit. Trial Interactive has gone through a rigorous 3rd party security break-in analysis and white box and black box testing to ensure both internal customer segments are secure as well as to ensure safety from the open Internet.

Trial Interactive uses double encryption (at-rest and in-transit) to provide optimal security. TransPerfect policies detail encryption and data protection, detection and controls, as well as systems and security. In terms of transport encryption (i.e. – data or password transmission from the client), the application uses TLS between the client browser, the application, and internal application servers. All data volumes and file content is encrypted. The application uses Hash: SHA-512 to protect shared secrets in storage. Cryptography is used in the application for data and password transmission, and data storage. SSL-2048 is used for HTTP communications and AES 256 is used for encrypted data at rest. AES 25 is used for server side encryption for RDBMS. Lastly, RSA_WITH_AES_256_CBC_SHA256 cipher suite is enabled for encryption and authentication. All communication with Trial Interactive servers goes over HTTPS/SSL. The enabled protocols are TLSv1, TLSv1.1, TLSv1.2 and the enabled ciphers are the ones recommended by the latest high security settings. This can be independently verified here: https://www.ssllabs.com/ssltest/analyze.html?d=login.trialinteractive.com.

Question: With many customers using Trial Interactive at the same time, their data will be co-mingled. Isn't that risky?

Answer: Data is actually co-mingled at many points on its journey through the Internet, in TransPerfect's internal network and eventually in Trial Interactive. Just as effective controls have been developed to segregate data in the Internet, TransPerfect has implemented identity based access controls in Trial Interactive to sustain the needed separation. Each user is identified and then authenticated to establish the session and each session is encrypted to maintain integrity and confidentiality.

Question: If a customer chooses the Trial Interactive multi-tenant product, is all the data and access still completely under a customer's control?

Answer: Yes. Even though Trial Interactive may be hosted as multi-tenant, it is still a completely closed system for each customer. This means that customers must explicitly invite each and every user to access Trial Interactive, and that all data collected in Trial Interactive is stored securely and within the customer's full control.

Question: At a technical level, please describe the security architecture and security data model of Trial Interactive.

Answer: The servers used are all hardened-kernel Linux with an externally facing hardware firewall, backed by an auto-correcting application layer firewall with intrusion detection. An important characteristic of the Trial Interactive architecture is the separation of customer data. We take data segregation very seriously and understand our customers' concern regarding data cross-population in a SaaS model. Trial Interactive leverages multiple checkpoints to verify that data bleed does not occur.

Question: Why did we choose to use a third party for Trial Interactive hosting?

Answer: Advanced web service and messaging capabilities allow us to consider distributed architectures that leverage cost effective third-party alternatives to host where it makes the most business sense (e.g. for less intricate modules of our software) without compromising quality. In short, Trial Interactive takes advantage of these newer capabilities that work better for applications that require improved scalability and reliability. Specifically, use of the Cloud allows for a greater degree of horizontal scalability, so that we can ensure our customers always achieve a high quality user experience and performance when using TI.

Question: What kind of encryption is used by Trial Interactive?

Answer: Trial Interactive uses double encryption (at-rest and in-transit). TLS is used to encrypt all data in-transit. For data at-rest identify information (passwords) uses the SHA-512 hashing algorithm.

Question: Please describe the security testing processes used for Trial Interactive.

Answer: Trial Interactive has been tested by a 3rd party security testing firm, using a standard black-box attack test, as well as a white-box internal attack test. External DOS (Denial of Service) attacks are also prevented.

Question: What are the standard password and session requirements for suppliers using Trial Interactive?

Answer: Users are identified by their email address, with verification of this email address by the customer providing access to this closed system. For Multi-Tenant customers, Passwords must be minimum 6 characters long, with uppercase, lowercase, numbers, and punctuation marks required. Passwords expire by default every 90 days, and users cannot re-use their last 3 passwords. Users failing their authentication five (5) times for either login or eSignature are locked out of the system, requiring account reset by their customer. All sessions are subject to an interactivity timeout of 5 minutes. All of these options may be modified for Single-Tenant customers.

Question: Is Federated Identity supported by Trial Interactive?

Answer: Yes. Trial Interactive serves as a Service Provider (SP) for SAML based authentication requests from an Identity Provider (IdP)

Question: Please define how general facility access is managed for Trial Interactive? What kinds of safeguards exist to prevent unauthorized access?

Answer: Trial Interactive utilizes AWS for all Trial Interactive hosting. The selected hosting provider provides virtual servers in a SSAE 16 SOC 2 (formerly SAS 70) data center that incorporates safeguards at the physical, logical, network and data access layers of their infrastructure in accordance with this certification.

Question: Does TransPerfect allow external access to the Trial Interactive network? If yes, how is it controlled and monitored?

Answer: TransPerfect designs and manages all access into the Trial Interactive cloud services environment as per the access management procedure. Third party firewall technology is deployed at our perimeter to guard against unauthorized access and access to these devices is controlled via access control lists that are maintained by select resources in our operations organization. All communication is restricted to HTTP and HTTPS (ports 80 and 443) all other access are denied. An intrusion prevention system is deployed to alert SaaS operations of unauthorized attempts to access the cloud services environment. Application tiers that support the cloud services environment are segmented and to provide further security against unrestricted access.

Access to the Trial Interactive cloud services environment by internal TransPerfect resources is strictly controlled and based upon roles. Request for access are made in the Trial Interactive access control system and require executive and operations approval. The access control system will track and record the steps in the approval process. The Trial Interactive Cloud Services environment runs on a segregated network from the corporate network and requires a separate set of credentials to be accessed. Logs are kept and reviewed for internal TransPerfect resources accessing the Trial Interactive cloud services environment.

Question: Does TransPerfect have SOPs in place to address the control and access to the Trial Interactive virtual data center and network?

Answer: Yes. The allocation and use of any privileges in a multi-user information system environment is both restricted and controlled, i.e., privileges are assigned by role; privileges are allocated on need-to-use basis; privileges are allocated only after formal authorization process per TransPerfect logical access policy. The policy addresses those systems where every user is granted access (email account, for example) and others where explicit access is required.

Question: Does TransPerfect maintain a list of current and historical users that have/had access privileges to Trial Interactive? Does TransPerfect have SOPs in place to monitor unauthorized access attempts? Are logs and reports maintained?

Answer: Yes. Operating system logs include IP addresses, attempted / unsuccessful and successful logins.

Support FAQ

Question: What is the process on how incidents are reported and how Trial Interactive supports sponsors, sites, and CROs?

Answer: Incidents are identified at TransPerfect in a number of different ways – monitoring alerts, customer calls, vendor notifications or internal observations. Once an incident is encountered it Trial Interactive's main focus is to resolve the issue and provide the customer with the expected service levels. Reported incidents are validated by TransPerfect support resources and a defined set of steps are executed to attempt to quickly resolve the issue. When an incident is severely interrupting service levels the incident is escalated. Any changes required to the production application services environment in order to resolve an incident are handled through the change management process.

Question: Will TransPerfect employees need a Trial Interactive Account? If so, how do they get one?

Answer: Services, hosting, and support employees will require test accounts for verifications and troubleshooting. These accounts must come from the customer who requires this access in order for support to troubleshoot a specific customer record.

Question: Is Trial Interactive browser independent? What browsers work best?

Answer: Trial Interactive will be tested with all major browsers, including Chrome, Firefox, Safari, and Internet Explorer 10, 11, and up.

Question: Will Trial Interactive work on the iPad or other tablets? Will Trial Interactive work on the iPhone?

Answer: In a future release. Trial Interactive is presently built upon a user interface framework that is designed to work on many screen sizes, including iPads, tablets, and mobile phone devices such as Android and iPhone. However each of these must be carefully tested to ensure it will operate correctly with that specific screen size as well as the touch interface.

Question: What documentation will be made available for customers around the support of Trial Interactive?

Answer: Training courses and documentation will be made available to customers that describes common issues and resolutions for customers.

Question: What is the overall SLA (Service Level Agreement) for Trial Interactive?

Answer: Trial Interactive provides for 24/7 email and phone Service Desk support as a backup to internal System Administration and support. The TI Service Desk is multi-lingual to handle global users. Our support staff can also accommodate the roll out of all system updates, major and minor, pending agreement on the date, time and process of implementing the updates.

Use and Access

Subject to the terms and conditions of the Agreement, Customer will have access to the Licensed Software and TransPerfect's application server for the purpose of using the Licensed Software for its intended purpose and in accordance with the specifications set forth in any User Documentation relating to the Licensed Software provided by TransPerfect.

Customer will not::

1. Transmit or share identification or password codes to persons other than authorized users.
2. Permit the identification or password codes to be cached in proxy servers and accessed by individuals who are not authorized users, or
3. Permit access to the software through a single identification or password code being made available to multiple users on a network.

Service Desk Support

TransPerfect offers global support for Trial Interactive users: 24 hours per day, 7 days per week, 365 days per year for all Trial Interactive functions. Support includes both email and phone and a range of languages if needed. TransPerfect will provide the level of support contracted by our clients. Users or subcontractors can email help@trialinteractive.com for the most prompt response or call our support. Response times for support are outlined in the table below. TransPerfect Trial interactive maintains a help system that monitors each ticket being opened through resolution for metrics tracking purposes. The help system can classify types of support needs for client to allow for review of trends and make recommendations on additional training requirements.

Maintenance Support Services

During the term of the Agreement and provided the customer has paid the applicable Service Desk Support fees set forth herein or in a statement of work, TransPerfect will provide maintenance, telephone support, correction of errors and upgrades to the Trial Interactive applications as set forth below.

- Real-time to customer’s dedicated service desk or personnel in the form of telephone support,
- Updated release notes associated with error corrections to the Trial Interactive applications,
- Error corrections to the Trial Interactive applications, and
- Customer support surveys to allow Customer to assist TransPerfect with the evaluation of their support.

Error Corrections

TransPerfect will use commercial best efforts to provide customers with error corrections within the timeframes set forth in the table below. Customers will provide TransPerfect with documentation of the error or deficiency, and customers will provide the necessary software and data required to reproduce the error or deficiency reported by the customer and all other reasonable support and assistance requested by TransPerfect as necessary to discover the cause or a cure for the reported error or deficiency in the Trial Interactive application.

Service Desk Response Times

TransPerfect's client services representative team has the following traditional Service Desk response times as part of our Support Services. All email requests will be acknowledged within 30 minutes via email notification. HIGH PRIORITY will have an email/phone response within 30 minutes and target resolution within 8 hours with updates every hour. MEDIUM PRIORITY will have an email/phone response within 4 hours and target resolution within 24 hours / 1 business day with updates every 4 hours. LOW PRIORITY will have an email/phone response within 24 hours and target resolution within 15 days. The remaining priorities pertain to service and change requests.

Facilities Security

TransPerfect’s co-located data center facilities are controlled access environments.

Network Infrastructure

The TransPerfect data center facilities will utilize a minimum of two competing fiber-optic telecommunication providers.

Question: What is the Help Desk SLA (Service Level Agreement) for Trial Interactive?

Answer: TransPerfect's client services representative team has the following traditional Service Desk response times as part of our Support Services. All email requests will be acknowledged within 30 minutes via email notification. HIGH PRIORITY will have an email/phone response within 30 minutes and target resolution within 8 hours with updates every hour. MEDIUM PRIORITY will have an email/phone response within 4 hours and target resolution

within 24 hours / 1 business day with updates every 4 hours. LOW PRIORITY will have an email/phone response within 24 hours and target resolution within 15 days. The remaining priorities pertain to service and change requests.

Priority Level	**Maximum Initial Response Time**	**Target Resolution and Updates**	**Description**
Priority 3 (LOW)	Within one (1) business day	15-day target with 5-day update	An issue that impairs the performance or functions of the software. There is no loss of data associated with the reported error or deficiency in the Trial Interactive application service and the customer's business process can continue or work around the reported issue(s) through proper business procedures with no serious impact on service levels. **Examples**: Redaction Problem, Edit Online issue, Duplicate Documents.
Priority 2 Incident (MEDIUM)	Within four (2) hours	24 hour target with 4 hour updates	An issue that substantially restricts functional operations of the software. The customer business process either cannot function or can function only temporarily with a serious impact to the customer's productivity. **Examples:** User Cannot Sign In, Audit Reporting Issues, Documents not Opening, Notification issues.
Priority 8 Change Requiest	24 Hours	45-day target	Minor Issues that require repair in a software patch and cannot easily be repaired in a hotfix, or application configuration changes. Includes requests concerning documentation, product enhancements or other administrative matters.**Examples:** Change Request, Bug Fix, Patch Release.
Priority 7 Change Request	24 Hours	15-day target with 5-day update	Non-Standard Request involving multiple members, days of manual actions taking more than usual time to fulfill, Project Work.**Examples:** Bulk Request, Manual Add/Remove/Modifications on Domain, TMF, Users, Groups, UAT Setup.
Priority 9 Change Request	10 Days	None	Requests concerning documentation, product enhancements or other administrative matters. Trial Interactive staff will evaluate whether to implement the proposed enhancement or change in the context of TransPerfect's development plans. **Examples:** Enhancement, Major and Minor Release.

Priority 1 Incident (HIGH)	Within 30 minutes of initial contact	8 hour target with 1-hour updates	Service is down or unavailable. The issue renders the software completely inoperable. The customer business process can no longer continue due to reported errors or deficiencies in the application service, and data may be lost or corrupted. This priority also concerns any issue reported during a regulatory audit or inspection. **Examples**: Application Outage, Network Outage, Natural Disaster. **Exception**: Issue reported, Query raised during a regulatory Audit or Inspection (First Response - 15 Minutes, Timely Update: 30 Minutes, Closure: 2 Hours)
Priority 5 Service Request	8 Hours	7-day target with 3-day update	Standard Service Request with 1 week completion target. **Examples:** Hybrid Room Build (7 Days), Archive Request, Doc Type Config, Custom Index Structure.
Priority 6 Service Request	8 Hours	15-day target with 5-day update	Standard Service Request with 2 week completion target. **Examples:** Fresh Room build (15 Days), Archive Request.
Priority 4 service request	8 Hours	48-hour target with 24-hour update	Standard Service Request with 48 hour completion target. **Examples:** Add/Modifying User/s Access, Room/Site Level Setting Change, Informational Queries.

Question: How are tickets escalated in support?

Answer: The TransPerfect Trial Interactive help desk application logs all tickets with a unique ticket ID number, and keeps track of the status and escalation of all tickets. All Client Service Representatives covering the TransPerfect Trial interactive help desk all fully trained and certified on all features and functions of the application. If in the event, however, a ticket comes in that the assigned client service representative is not able to complete, the ticket should immediately be escalated according to the following workflow:

- Upon receipt of a ticket, the assigned Support Analyst will analyze the requirements of the request and determines whether or not it can be completed without escalation. If it is determined that the ticket cannot be completed without escalation, the SA will immediately escalate the ticket to a member of the Solutions Engineering staff.
- If, when working on a ticket, a SA is unable to complete the ticket by the agreed upon resolution time the SA will escalate the ticket to ensure completion.
- The process for escalating a ticket consists of three parts:
    - The assigned SA will forward the ticket on to TransPerfect Trial lnteractive's internal distribution list for the SE Staff. The escalation should include the original request, a description of what work has been done on the ticket already, and the reason for the escalation.
    - The member of the SE team who will be picking up the escalation will then let all members of the SA team know that they accept the escalation.

    - The SA assigned to the ticket in the help desk application will then be updated to reflect the escalation of the ticket to the new support representative.
- Trial Interactive will use commercially reasonable efforts to resolve Support Cases as soon as reasonably practicable. A Support Case is resolved upon the earlier of the following: (i) the issue or problem is resolved; (ii) if the issue or problem is the result of an Error, the provision of a Fix or Error Correction; (iii) Trial Interactive is able to provide an alternative solution; (iv) Trial Interactive confirms that the issue or problem is not due to an Error or deficiency in the Subscribed Software; (v) Trial Interactive confirms that the issue or problem is due to a multi-vendor issue; (vi) if the Support Case is attributable to Third Party Software, Trial Interactive logs a support request with the provider of such Third Party Software; (vii) the Customer requests that Trial Interactive close the Support Case; or (viii) the Support Case has been left open for longer than the Service Level Objective. A member of the senior staff will then follow up with the SE assigned to the ticket to ensure completion.

  TransPerfect support beyond the Service Desk includes the following options that are defined in each SOW. This can include leading of workshops, oversight of other technology integrations, customizations specific to Customer, product enhancements, on-site support, other user training, validation and UAT, etc. All are billed at hourly rates defined in the SOW per the scope of work.

  - Service Desk Analyst – the Service Desk representative, completes initial troubleshooting and escalates issues to Solutions Engineer.
  - Project Manager - remains assigned to Customer: as needed at the agreed upon billable hourly rate or with a percent allocation each month to the Customer
  - Solutions Engineer - easily accessible through Service Desk and Project Manager and will be billed at the agreed upon hourly rate.
  - System Architects and Developers - often engaged for migrations, integrations, new technology upgrades, etc.
  - Quality Assurance - providing support on validation, UAT and other client requests.
  - Trainer – Training on the Trial Interactive applications as well as course and content development.

  Executive Sponsor and Corporate Governance work with TI Product Management to ensure users are optimizing the functionality of the system, gathering feedback for enhancements to the next product release, training against new product releases and functionality.

Question: What are the requirements for Disaster Recovery for Trial Interactive?

Answer: TransPerfect has implemented both business continuity and a disaster recovery plan, which addresses all elements of our technical, physical, and organizational processes in the event of a disaster. Trial Interactive's Cloud Environment has two hosting facilities to facilitate the Production and Disaster Recovery objectives of this infrastructure. Specific to our Trial Interactive and eTMF solution, our primary Cloud Environment is in Northern Virginia and our Disaster Recovery Cloud Environment is in Oregon.

TransPerfect has adopted incremental, full backup, and replication technologies for our backup and disaster recovery strategy; consequently, this also affords us the ability to adhere to any retention policy we are contractually obligated to meet. The system is backed up throughout the day, every 30 minutes via incremental backup, and every night via full backup. After we purge data from the application we can remove it from the backup set in accordance with the applied backup policy. We also have a data destruction procedure that involves physically destroying physical media as they are decommissioned.

These procedures ensure the continued delivery of services to clients in emergency situations that result in the interruption or failure of the computerized systems. Depending on the nature of the disaster, TransPerfect expects to be operational with little impact to any clients. TransPerfect has an annual verification of activities schedules, which tests the different components of our Disaster Recovery process.

Restoration Times:

- Data restore can be achieved in less than 24 hours from backup.
- Recovery Point Objective (RPO) is 1 hour or less.
- Recovery Time Objective (RTO) is 24 hours or less.

Question: What are the definitions needed for the SLA for Trial Interactive?

Answer: Definitions are below.

Off Hours means, typically 9pm – midnight in that regional time zone, EST for the Americas, GMT for Europe, and CST/JST for APAC.

Downtime means, for a server, if there is service failure or more than a five percent user error rate. User error is calculated using server monitoring software, based on results from ping tests, web server tests, TCP port tests, and website tests.

Emergency Downtime means those times where Trial Interactive becomes aware of a vulnerability or issue that, based on a risk assessment of the vulnerability or issue, TransPerfect deems to require immediate remediation and, as a result, the service is made temporarily unavailable in order for TransPerfect to address it. Emergency Downtime is not considered Downtime for purposes of Trial Interactive Uptime, and will not be counted towards any Downtime Periods.

Scheduled Downtime means those times where TransPerfect notifies you of periods of Downtime 48 hours prior to the commencement of such Downtime. Scheduled Downtime is not considered Downtime for purposes of Trial Interactive Uptime, and will not be counted towards any Downtime Periods.

Monthly Uptime Percentage means the total number of minutes in the calendar month minus the number of minutes of Downtime suffered from all Downtime Periods in the calendar month, divided by the total number of minutes in the calendar month. Uptime rate will be calculated using the following formula:

Uptime rate % = $$= 100 - \left(\frac{\text{Expected uptime minutes in month} - \text{Minutes down in month}}{\text{Expected uptime minutes in month}}\right) \times 100$$

Uptime Exclusions: The Uptime SLO does not apply to any performance issues: (i) caused by factors outside of TransPerfect's reasonable control; (ii) that resulted from any actions or inactions of Customer or any third parties; or (iii) that resulted from Customer equipment and/or third party equipment (not within the primary control of TransPerfect.)

Technical FAQ

Question: How has Trial Interactive been architected? Please describe the technologies used.

Answer: Trial Interactive is deployed and managed as both a single and multi-tenant SaaS application, providing our customers with a highly scalable and accessible platform for eClinical and eTMF. Trial Interactive itself requires no client infrastructure requiring only a browser and an Internet connection to access. Trial Interactive uses a multi-tenant architecture that allows efficient sharing of application software and hardware resources, while providing complete partitioning of each customer's data. Trial Interactive is managed as a single code base deployed over a distributed architecture composed of multiple components, including an web server layer, application layer, database layer, content layer, and file store. Each component represents a physical set of infrastructures and provides the necessary application logic, data and security to support Trial Interactive. Users will access Trial Interactive through a browser over an HTTPS connection.

Question: What types of user authentication are supported by Trial Interactive?

Answer: Trial Interactive supports a simple email and password for authentication. Trial Interactive supports a multi-factor authentication, where a code is sent to the end-user to verify identity after the username and password are entered. Trial Interactive also supports a SAML 2.0 adapter, accessible by customers as a Service Provider (SP) to allow them to leverage their own corporate directories as an IdP (Identity Provider) to Trial Interactive. Creation and support of the SAML 2.0 IdP and assertions is the responsibility of the participating organizations.

Question: We've heard that TI is moving the platform to Alfresco. What is Alfresco, and why is it important?

Answer: Alfresco is a collection of information management software products for Microsoft Windows and Unix-like operating systems developed using Java technology. Their primary software offering, branded as a Digital Business Platform is proprietary & a commercially licensed open source platform, supports open standards, and provides enterprise scale. They also have an open source, community edition available, one that we will use as the basis for future TI.

John Newton (co-founder of Documentum) and John Powell (a former COO of Business Objects) founded Alfresco Software, Inc. in 2005. The original technical staff consisted of principal engineers from Documentum and Oracle. Because of this, Alfresco can be thought of as the natural child of both Documentum and Business Objects, two award-winning platforms that still have a heavy market presence today. Alfresco was designed also as a natural improvement and iteration on those platforms, leaving behind older technology and upgrading designs. Alfresco has been benchmarked by Unisys here:

http://www.konsultex.com.br/solucoes-livres/arquivos/alfresco_benchmark_report_bl100093.pdf

This process showed the following results, on a typical, dual-core 2.6 MHz processor with 30 GB memory:

- Documents loaded and stored: 107 million
- Documents loaded per second: 140
- Read content: 0.34961 seconds
- Read property: 0.41976 seconds
- Response time for document operations:

- Processor Utilization: Average of approximately 20 percent on the application server and 15 percent on the database server.

And on AWS, the results are more impressive:

- ~1.1 Billion Documents split across 10,000 sites with a shallow, 2 level directory structure; 10 folders per level, 1000 documents per folder, 100kb documents on average
- 10 Alfresco repository nodes on AWS c3.2xlarge instances, 20 Alfresco indexing nodes hosted on AWS m3.xlarge instances, EBS file system storage and an Amazon Aurora database.
- Consistent ingestion rate of 86 million documents per day over 12 days - 100 documents per second per repository node
- Full indexing of all 1.1b documents in 5 days
- Load tested with 500 concurrent Alfresco Share users plus 200 concurrent CMIS API users using some of Alfresco's standard benchmark scenarios - average response times sub 4.5 seconds for even the longest operations

These numbers mean quite a lot. They indicate that the Alfresco platform is a powerful bedrock on which to build TI products. It can handle content better, by most measurements, than Documentum, OpenText, and many other similar systems. Building on this rock is the right choice when choosing a new platform for our eTMF, DMS, and other products.

Question: Is single-sign on supported? Can Trial Interactive integrate with providers like OKTA, Ping Identity, and One Login?

Answer: Yes, on Dedicated Clients only, SSO using SAML is supported. Providers such as OKTA, Ping Identity, and One Login are supported, as well as internal Corporate Directories such as Microsoft Active Directory.

SAML Authentication: This is supported in dedicated. This means that users can use their standard corporate directory username and password (or 3rd party) to sign in to Trial Interactive.

SAML Authorization: This is not supported. This would allow users to be assigned roles and access to Studies and Sites automatically through SAML. This is planned for a future release.

There are current plans to support SSO on MTI in 2018.

Question: What is SAML and how will customers ultimately use it for Single Sign on?

Answer: SAML (Security Assertion Markup Language) is an open source standard for trading both authentications and authorizations between two systems. It is quickly becoming an industry standard for providing a trusted handshake between two organizations for the purposes of single-sign on, used by Google and other large organizations for the purpose.

Question: Are there any data standards (either internal or external) in place for Trial Interactive?

Answer: Data in transit and at rest are encrypted to provide optimal security. Data in transit is encrypted using secure socket layer (SSL) transmissions. Data volumes are encrypted in the production cloud services environment to ensure against any unwarranted access to customer information as it passes through Trial Interactive. The Trial Interactive Cloud Services Environment will store three broad classifications of data:

- Public data: This data is available generally on the Trial Interactive web site and includes help files, eLearning videos and marketing materials.
- Private data: This data classification includes all TMF metadata and TMF documents. This data is always encrypted at-rest and in-transit within and without the Trial Interactive application.
- Confidential data: This data is restricted to authentication only, and will always be encrypted at-rest and in-transit within and without the Trial Interactive application.

Question: How is software testing and product verification handled for Trial Interactive?

Answer: Trial Interactive has a separate SQA team that reports to the Senior Director of Engineering. SQA has the responsibility to verify and approve the integrity of every build and explicitly approves each release before production. SQA engineers partner closely with our software developers to understand product requirements and create and execute comprehensive test plans.

Question: Please describe the SDLC used during the development of Trial Interactive.

Answer: Trial Interactive was created following standard TransPerfect SDLC policies and development procedures, using an agile approach to development and a continuous integration approach, with a daily build procedure generating each build and standard automated unit and regression tests executed to confirm success prior to further testing and development. To keep Trial Interactive is a fully validated state, TransPerfect runs every release of Trial Interactive through a complete validation workflow prior to GA in accordance with an SDLC policy, testing procedures, and validation plans. This validation includes standard IQ and OQ tests, as well as Performance tests, user acceptance, and a third-party security assessment. A full set installation of operational and performance qualification tests are executed according to an approved validation plan. Test results are summarized after the validation period and a full set of evidence and traceability are gathered and verified by Quality Assurance.

Once all tests have been successfully completed and reviewed, a TransPerfect-issued Validation Certification is signed and made available to customers. At that point in time, a new release will be made available to customers in a staging site, along with all formal qualification tests executed by TransPerfect. This staging environment contains the exact same services as the validation and production environments.

Question: Does TransPerfect have formally approved System Requirements?

Answer: Requirements are captured as user stories electronically and are approved by Product Management and Quality Assurance.

Question: For Trial Interactive, what programming and source code controls are used? What programming standards are in place for Trial Interactive?

Answer: A full set of programming standards with commercial source code control software is used for Trial Interactive.

Question: For Trial Interactive, does TransPerfect perform performance, robustness and stress testing? If so, describe the process.

Answer: Trial Interactive availability is of the utmost importance to the success of our customers. With the exception of a four-hour weekly maintenance window Trial Interactive cloud services are available 99.95% twenty-four hours a day seven days a week. Performance is also a key factor required to make our customer successful. In this light Trial Interactive has been designed to provide an average page turn of 2 seconds or less. This is measured by tracking the application index score (AppDex), which is defined as the average client side page turn based on some number of seconds T. This is a very aggressive score, as most of the time involved in a page turn concerns network speed, browser page Document Object Model (DOM) generation, and browser page rendering time.

Question: How are bugs tracked and retested for Trial Interactive?

Answer: Trial Interactive is being developed with a high level of quality; however, on occasion TransPerfect or a customer may find a defect. Software will not be released with any known critical or high severity defect. Low to medium severity defects will be repaired with each new release. If a high or critical defect is found, TransPerfect will assess the customer impact, and TransPerfect may deploy emergency patches to production without a software prerelease on the staging site. This will be communicated clearly to customers, and a risk assessment will be provided to customers for any defect fixed, and any patch released. Since defects will rarely impact the existing customer process, patches will be treated as any other release but with a low level of validation impacts.

Question: Does TransPerfect have formal processes in place that define Change Management and Change Control for hosted products?

Answer: TransPerfect has a validated process for change management used in all deployments and other modifications to the hosted environment.

TI Configurations FAQ

Question: What are the possible configuration decisions each new customer needs to make for a planned installation of Trial Interactive?

Answer: The following TI configurations are available:

Module/ Product Name	Description	Standard ? Extra Cost?	Available on Multi-Tenant?	Installation Considerations
AdobeSign		Separate 3rd Party License	Yes	
Custom Reports		LOE Hours, estimated by report	Yes	
DocuSign		Separate 3rd Party License	Yes	
IRB Integration		LOE Hours, estimated by separate RS and SOW	Yes	
myTI		Separate Module Pricing by Study/ Month	Yes	
OCR		Separate OEM License	Yes	
OnlyOffice		Separate OEM License	Yes	
PleaseReview		Separate 3rd Party License	No	
Single Sign On (SAML)		Standard	No	
Study Start Up		Separate Module Pricing by Study/ Month	Yes	
TI Collaborate (Shared Workspace)		Separate Module Pricing by Study/ Month	Yes	
TI eTMF		**Standard**	Yes	
Validation Package		Separate Module Pricing, flat fee with 15 days consulting	Yes	

TI Viewer FAQ

Question: **I'm seeing issues with rendering of .MSG files. What can I do?**

Answer: There are several options. .MSG (message) files are a portable email format. This format is not fully standardized, and in many cases metadata may be encoded differently in a non-standard way, depending on which email client originally created it. For this reason, rendering .MSG files is a relatively complex feature of the TI Viewer, and at times, rendering may fail and may cause a blank PDF. As TI sees rendering issues, we open defects and schedule improvements to this capability in upcoming patches.

In the interim, the following workarounds are available:

1. For a small number of files, customers can switch over to using the native viewer in TI, which will download the .MSG file to their desktop. From there they can open this file in their local Outlook/Email client and print to PDF using their local PDF print driver. This PDF can then be uploaded directly to the room in place of the original .MSG file.

2. The best solution for a large number of failures is to enable the TI communication inbox feature, released in 9.2. This email rendering works entirely differently from the .MSG file rendering. Instead of converting an .MSG file to PDF, this inbox converts the original email directly to PDF as well as any attachments, and the rendering is simpler and more dependable because the non-standard .MSG format is avoided. There is an approval cycle built into this module as well, allowing you to decide if an email is pertinent to the eTMF or not.

3. If there are large numbers of files and the communication inbox cannot be used for some reason, due to either time constraints or process limitations, TransPerfect can convert .MSG files as well as other email archive formats to PDF as a separate service.

Question: **What is the difference between Acrobat Forms (AcroForms) and XML Forms Architecture (XFA) also know as LiveCycle forms?**

Answer: AcroForms are the original PDF forms technology, first introduced in 1998. AcroForms accept input in both Forms Data Format (FDF) and XML Forms Data Format (XFDF).

The TI Viewer supports AcroForms, and only AcroForms is supported in the standard PDF/Archive format required by the FDA and other agencies. Only ADobe Reader / Acrobat currently supports XFA Life Cycle forms.

Releases FAQ

Question: How often will new releases of Trial Interactive be made available?

Answer: All new Trial Interactive releases deployed to Trial Interactive' cloud services environment will provide customers instant access to the newest features and fixes. The product is released in both dedicated and multi-tenant versions, depending on the needs of the customer. The multi-tenant versions are released in an iterative, date-bound fashion on a regular basis. The dedicated customers may choose when they wish to apply each release and patch.

- The frequency of all releases is 2 minor and one major release per year.
- The frequency of patches is monthly, unless a major or minor release occurs in the current month.
- Defects selected for specific monthly patches are determined by the 2nd week of the current month, and release notes available by the 3rd week.
- Hot fixes may be created to be applied for critical P1 or P2 incidents for both multi-tenant and dedicated customers.
- Dedicated customers are informed of each major, minor, and patch release so that they can choose when to implement each one.

Question: When a new release of Trial Interactive is ready, how will customers sign up for it?

Answer: Trial Interactive single-tenant customers may request to upgrade at any time after release by speaking to their Account or Project Manager. For multi-tenant customers, all new Trial Interactive releases will be deployed directly to our central servers, providing customers instant access to the newest fixes and features. This deployment approach will allow Trial Interactive to deliver value through the service out to our customers in a more rapid and flexible way.

Question: What kind of internal and external communication will be involved with new releases?

Answer: A regular set of internal and external messages will be sent around each iterative release. This communication will provide customer notification that a new release will be made available on the staging system on a particular date, as well as communicate to them a production release date. This communication will indicate the changes expected in each release, as well as a risk assessment of possible impacts to customers.

Question: How will customers validate new releases of Trial Interactive?

Answer: In order to keep Trial Interactive is a fully validated state, we run every release of Trial Interactive through a complete validation workflow prior to GA in accordance with an SDLC policy, testing procedures, and validation plans. This validation includes standard IQ and OQ tests, as well as Performance tests, user acceptance, and at times a third-party security assessment. A full set installation of operational and performance qualification tests are executed according to an approved validation plan against both Trial Interactive supported versions. Test results are summarized after the validation period and a full set of evidence and traceability are gathered and verified by Quality Assurance.

Once all tests have been successfully completed and reviewed, a Trial Interactive-issued Validation Certification is signed and made available to customers. At that point in time, a new release will be made available to customers in a staging site, along with all formal qualification tests executed by Trial Interactive. This staging environment contains the exact same services as the validation and production environments but will be connected to customer development, UAT, and other non-production instances.

Question: How will defects and emergency issues be repaired on Trial Interactive? How often, and in what form?

Answer: Trial Interactive is being developed with a high level of quality; however, on occasion Trial Interactive or a customer may find a defect. Software will not be released with any known critical or high severity defect. Low to medium severity defects will be repaired with each new release. If a high or critical defect is found, Trial Interactive will assess the customer impact, and Trial Interactive may deploy emergency patches to production without a software prerelease on the staging site. This will be communicated clearly to customers, and a risk assessment will be provided to customers for any defect fixed, and any patch released. Since defects will rarely impact the existing customer process, patches will be treated as any other release but with a low level of validation impacts.

Question: How will new features be made available to customers on Trial Interactive?

Answer: There are two types of new features that need description:

- New features that do not impact the existing customer processes in any way (such as minor cosmetic changes and certain new capabilities) will be made available with each new release according to the process described above.
- Big, impactful features that change the existing customer process however will need to be enabled by each customer individually on their production instance before they will ‘turn on’ for customers and their suppliers. This will allow customers to accept releases and maintain the software in its current validated state without heavy, time-intensive validation periods, and without impacting their current user flow.

Question: Can customers refuse or skip releases of Trial Interactive?

Answer: No. All releases must be ultimately accepted by customers as part of the continual improvement of the single-instance software product. Single-tenant customers may skip releases if necessary.

Question: Will a risk assessment of the impact of new releases be made available for Trial Interactive?

Answer: Yes. All features and defects fixed will come with a formal, documented risk assessment that considers cross-functional code impacts, process impacts, and any specific GxP, ERES, or other CFR compliance impacts. This will be made available in the software release notes.

Question: How will database upgrades be handled in Trial Interactive? How will migrations be handled for Trial Interactive-enabled processes?

Answer: In Trial Interactive, all database upgrades will be done automatically as part of the normal upgrade process. New migrations and processes in will not impact Trial Interactive as the two applications will run in completely separate environments.

Question: Will a product roadmap be made available for Trial Interactive?

Answer: The product roadmap will be made available for the next iterative release of Trial Interactive, to allow customers to prepare and plan for any new features they may wish to enable in their TMF process. This roadmap will be time-boxed, and so certain features may fall out of a release if they are on the ‘gray list’ and not considered to be the highest business priority. This is because Trial Interactive will be developed in an agile fashion, allowing for changes from all stakeholders to better meet the requirements of customers and to maintain an extremely high level of product quality.

Question: How do customers request system changes?

Answer: Trial Interactive engineers are focused on advancing and strengthening Trial Interactive to meet the changing TMF market and evolving customer needs. Product management will constantly monitor how Trial Interactive is being used and listen to our customers' needs to determine new business-relevant features. A percentage of development resources will be reserved to handle incoming customer requests, which will drive enhancements made to Trial Interactive.

Customers may make feature requests to their Project Managers, and upon request may recieve a report of the latest status of their feature requests, including target releases, release status, and priority.

Reports

From here get the know about getting the Reports for the room activities.

Room Administrators have the option to turn on **Reports** and make them available to other users. If Reports are activated, you will see an icon in the Navigation Grid.

Reports Dashboard

As an Administrator user, you have an option to turn on Reports for other level users to access and view.

You can reach this page by clicking the **Reports** application from the Main Navigation. Refer to the screenshot below:

The Reports Dashboard consists of the various dashlets which gives the summary of the reports of the room. Refer to the screenahot below:

From the Reports Dashboard you can do the following:

1. Generate Reports from the Reports List.
2. Export the Reports.
3. Design a new dashboard
4. Update Results

   Each of these is discussed in the seperate topics in this help.

Viewing Reports from the Report List

From the Reports Dashboard, click the **Reports List** 

option from the top menu bar.

This view offers links to standard activity reports and a **Report List**.

The Reports view consists of the following:

1. **The Left Pane**: This consists of the list of reports.
2. **The Right Pane**: This consists of the detailed view of the reports corresponding to the reports in the left pane.

   Click the name of the report and that report opens in the dashboard below. The screenshot below shows the **By Document Status** report clicked from the above screen.

Typically, report builds are based on specific sponsor requests.

Note: *For further assistance on other features of reports, please get in touch with the Suppor team of Trial Interactive.*

Generating Reports

From the Reports List page, click the reqiuired report to open it. Below is an example of the list of **All Open Queries**.

For a particular report, you can do the following:

1. Apply Filters
2. Adding and deleting fields in a report
3. Print Reports
4. Download Reports

   Each if these is discussed in the sections below.

Applying Filters

You can apply filters for a report if you wish to view and generate the report with only specific information. You can apply filters for a report by clicking the **Show Filters** button in the menu bar. This enables the **Filter Field , Operator** and **Value(s), Blank** fields to allow you to select the filters for a report.

Select the Filter Field, operator and the value of the field for which you want to get the reports. An example below show a filter applied for generating a report for the open queries of a particular submitter:

You can also apply multiple filters as well by using the operator conditions to view the required results.

Adding and deleting fields in a report

Click the **Add Field** dropdown and select the required field you wish to add to the report list. The field gets added to the list. Refer to the screenshot below:

Simiarly, you can also delete a field from a report by clcking the **Delete Field** dropdown and selecting the required field from the list.

Printing Reports

Click the **Print** button in the menu bar to print the report.

Exporting Reports

You can export the reports in the following formats:

1. CSV
2. Microsoft Excel
3. Microsoft Word
4. XML
5. Open office Document
6. Rich Text Format (RTF)

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