TRIAL INTERACTIVE

Trial Interactive v10.5 User Guide 0.1

TRANSPERFECT LIFE SCIENCES

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VERSION HISTORY

Author	Revision	Date	Change History
Samuel Pawar, Sneha Jagavkar	1.0	10-Nov-2023	Initial Document Creation

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Chapter 1. Trial Interactive v10.5 Overview and Features

Hardware and Software Requirements

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

System Requirements	
Operating System	• Windows Version 7 or higher • All currently supported Mac OSX releases • iOS and Android for myTI mobile app (see myTI release notes)
Browser	• Microsoft Edge: Version 88 and later • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • NOTE: TI Digital Sign requires that pop-up blockers are turned off for the Trial Interactive domain. • NOTE: Microsoft® concluded support of Internet Explorer™ 11 in January 2022. Internet Explorer™ 11 is no longer supported in 10.4 and above.
Client Software	• For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally. • For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred). • Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. • Optional: Drag and Drop from Outlook to Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available to support this feature on Internet Explorer® and Firefox®.
Optional Add-Ons	• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) • Optional: SAS Viewer or compatible software must be installed for SAS Datasets. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74

What's New in TI v10.5?

Platform interoperability

Propagating visits data from CTMS to Trial Interactive eTMF and Collaborate Rooms

Events such as site visits often generate a need to track associated documentation. In Trial Interactive v10.5, we introduce an efficient and compliant approach for sharing status information and triggering Events and their related document requirements between CTMS and eTMF.

<u>This feature improvement adds these abilities:</u>

- Automated communication between the eTMF and CTMS regarding events and related document requirements, helping to ensure eTMF health and accuracy. The status of Studies, Countries, Sites, and Visits are shared across all platform systems, and Events may now be triggered in the eTMF when a status changes.
- Once an event is triggered, essential event information, such as Study ID/Protocol Number or Room ID, Room Offering, Event Name, Event Category, Site ID, Site Number, Country Code, Event Status, and Event Status Date, will be set automatically without any user intervention required. Any placeholders required by the Event will immediately be available for assignment.

Our users often have multiple TI rooms dedicated to the same study and do not yet have the CTMS module at their disposal for easy tracking and sharing of information. TI has now improved our ability to share site profile data directly from CTMS to multiple study-related rooms and data from room to room.

This improved system synchronization of site profile data and contacts between CTMS and rooms associated with a study makes a cohesive user experience regardless of allowing the user to utilize the CTMS with an eTMF or eTMF-only with multiple rooms associated with a study.

TI Automate

Confidence level for documents processed using TI Automate

Automation of document processing and indexing is critical to modern clinical studies, given the sheer volume of documentation associated with even a single trial. However, it can be difficult to be certain that an automated process can easily handle discrepancies and judgment calls that a human document reviewer would handle.

With TI v10.5, the Trial Interactive machine learning capability will award a confidence score for those documents processed using TI Automate, the machine learning and metadata extraction service. The confidence score is calculated using an algorithm that assigns weight to (a) the success of document classification and (b) the success in the extraction of metadata fields.

Suppose the indexing and extraction of a particular document exceeds a configurable confidence threshold. In that case, the document will move automatically to the next workflow stage, skipping the indexing stage completely and moving on to the review stage.

With TI v10.5, users of TI Automate can easily select which documents need to be reviewed personally and for which documents the system was able to correctly and confidently perform indexing.

Related Documents

In the eTMF, it is essential to be concerned with what is present and what is missing. It is important to audit the eTMF for essential documents that may or may not be present, and it is helpful if the system can tell you which missing documents may be related to a collected one. In 10.5, enhancements to the Related Document feature will allow the creation of named document relationships of specific types, for example, Translations and Notes to File. Additionally, document relationships may now be created automatically based on configuration. This will allow a full set of related documents to show for a variety of completeness scenarios:

- 1572s forms can show all the related or missing CVs, Medical Licenses, and Financial Disclosure Forms.
- Protocol Amendments can show all the related or missing signature pages and signoffs.
- Translations of documents can show, indicating their language.
- Related Notes to Files can show for certain documents.
- Other useful relationships may be easily configured.

Related Documents - Manual and Automatic Relationship

When performing indexing, related documents need to be related to each other in the eTMF for easy filing and to make it easier to find the related documents as needed. Trial Interactive v10.5 allows for document storage rooms to be set up with expected document relationships in advance. Since the relationship is already established, navigating to a related document or placeholder is simplified even further by adding the 'Related' tab of the metadata panel.
The 'Related' tab, available in the document and audit modules, shows placeholders for required documents and each required document's relationship type and metadata. Users can also add a new manual relationship, compare documents, link, and unlink documents, and open a document in a new window.
Similarly, it is important during a completeness audit for auditors to be able to view not just related documents but placeholders for required documents as well.

Support Related Documents as Relationships in Required Document

Frequently, audits are set up in TI rooms for specific document types. It is also the case that documents related to those specific document types should be reviewed as well for the sake of completeness. TI v10.5 enables users to easily review a designated document as well as those documents to which it is related.

Event Manager

Event Profile Improvements

With the launch of the Event Manager, Trial Interactive allowed the creation of events to track a specific list of document types that must be collected in association with an event. This resulted in active rooms seeing many events and related data. TI v10.5 gives the user a host of UI improvements, including improved filters, metadata, and an improved user workflow, making it even easier to associate a document with a placeholder generated as a part of an event. Configuring the required document trigger criteria has been simplified to enhance how the required documents list and the Event Manager work together, merging identical placeholders in the completeness views to simplify things

Contact Management

TI v10.5 makes managing contacts easier than ever with new filters and the ability to edit additional fields from within the Contacts view. Contacts are also now exportable directly from the complete list in the Contacts module.

Update Contact information

Those who run clinical studies are not always notified on time when a site contact is removed from the site team. As a result, dates in the eTMF may not accurately reflect the date of the personnel change, causing potential issues with expired documents, etc. TI v10.5 adds the ability to manually enter the correct date when activating and deactivating a site contact to avoid these issues in the future and ensure that all data collected is accurate. Any documents set to expire are added or removed from the expired documents list based on the contact start and end dates.

Filter addition and Views on the Contact list and Export.

When mass communications must be sent out to site personnel, it is always easier to get contact information directly from the system with exactly what information is needed on the first try. To aid with that, v10.5 adds the ability to filter the contacts list and export it directly from the contact list.

eTMF Reconciliation

Raise general query using CRA Reconciliation module

The ability to raise a general query from anywhere in the eTMF Documents module has proven invaluable for users who come across something that causes questions or needs to be reviewed. In TI v10.5 expands that ability to the CRA Reconciliation module so that a user who encounters a questionable document no longer needs to navigate back to the Documents module and re-locate the document to open the query and can do it directly from the query module.

Export Metadata about Reconciliation

The addition of the Export option to the Query module allows the export of the grid field with all applicable metadata columns about reconciliation.

Query Module

Addition of bulk assignee to many Queries at once

In TI v10.5, during a team personnel change, our partners often need to reassign queries from users who recently left the team. With TI v10.5, users will have the ability to make this change in bulk rather than one at a time, saving them quite a bit of time and energy while managing queries.

Export option addition to the Query module

Our users rely on TI to help them get the right information as easily as possible whenever they need it. TI 10.5 adds the Export option to the Query module, the ability to update columns and save filters, and configurable columns for query sender and recipient.

eTMF General Usability

General Improvements

Our goal is always to make Trial Interactive an intuitive and user-friendly solution. To that end, TI v10.5 will make some changes to our user interface and configuration options, including the following:

New Feature 'Expand Button'

You often need to view all the documents under a site at once. That is useful when looking for documents from a specific related date without knowing exactly where they are filed, allowing you to see them in one list without opening many folders.

Through a new 'Expand' button, TI v10.5 provides a simple way to show all the documents in the room or under a subfolder so that users can easily see all of the documents in a simple list without requiring many subfolder clicks. This also allows users to more easily filter documents by index number, section, zone, artifact, and many other metadata options. This switch does not persist forever; it only shows when selected, just like a grid filter.New feature 'Rejected Documents'

TI v10.5 adds the number of rejected documents as a standard KPI metric on the dashboard and home page for easy analysis.

eTMF Studies, Countries, Sites, Visits

Country Information Page and Status in TI

Keeping track of country statuses can be confusing in multinational studies. The new Countries page in TI v10.5 gives users an easy way to keep track of the progress of all countries included in a study. Changes to the Country status can now automatically trigger Events.

Also added is a Visit log, showing all current and past Site Visits in one central place under the Site with the Visit Completion Date

Search Improvements

The following improvements have been made to the global search:

- Users may now search against Deleted Documents.
- Users may now search by Username in the Cross-Study Room Search.
- Users will now see a Go To Query selection in the search results when they search for Queries.
- When filtering a Cross-Study Room Search by Room, the Room Names will now be shown when filtering.
- User Search will now be available for administrators in Cross-Study Room Search.

Identity and Access Management

With TI v10.5, a new Identity and Access Management component is available, providing global authentication and authorization for the TI platform, all TI users, and all applications and modules. This component will support the following new capabilities:

- New Users must only register once on the TI Platform to access all TI products, instances, and environments.
- This will allow customers to sign on once to access all applicable TI products and Instances and Environments.
- It will allow each dedicated customer to continue to have their preferences regarding password requirements, timeouts, and expirations.
- It will support the configuration of multiple SSO systems for a single application and set of users.
- It will provide better flexibility around which application users should have SSO, which should have MFA, and which should have both. MFA will be able to be enabled or disabled for each user.
- It will have the capability to be deployed with no customer or end-user impacts and will not require any password changes.

Collaborate Enhancements

Trial Interactive collaborate module allows the users to work together on editing/reviewing documents. The all-improved TI Collaborate now offers many solutions, such as auto-routing improvements, team edit improvements, offline checkout improvements, and signature improvements.

TI v10.5 makes several key updates to the TI Collaborate functionality to make it easier for users to collaborate on documents and share them with the necessary rooms. TI has improved the auto-routing functionality between rooms when sharing or publishing documents between TI rooms. Additionally, TI v10.5 now allows adding groups of users to a collaborative editing session rather than having to assign one user at a time while simultaneously updating the UI to make it even easier to create these sessions.

Auto-routing of documents

Understanding the challenge of efficient document organization and routing, this enhancement allows the auto-routing of documents to specific folders upon their import into a room.

- Document Sharing: Documents shared within a room are routed to specific folders based on their Document Type metadata.
- Bulk Uploads: Uploaded documents are auto-organized according to their associated Document Type metadata.
- API Integrations: Documents sent to the room via API are sorted into designated folders based on their metadata.
- Drag and Drop: Manually moving documents between rooms or browser tabs triggers auto-routing based on Document Type metadata.

Improve Team Edits Window to 'Add Groups' as Collaborators

The improved TI v10.5 Collaborate module allows adding groups to the team edit sessions. Moreover, the users also can extract the users from a specific group and add them as collaborators.

eSignature Notifications

When a document is sent through eSignature, instead of notifying all signers at once that they must sign the document at the start of the serial signature process, each signer is notified in turn, receiving a notification when it is their turn to sign the document.

Approve and Rejected Notification

Addition of an optional email notification to the document submitter when a Document's status changes, indicating if the document has been approved or rejected.

Disabling offline check-out option for Collaborate/Team Edit

A room option to, if desired, prevent off-line checkout and require track changes to the document

Major Study Start-Up Refresh

In TI v10.5, we have upgraded the SSU module's user interface to align it with the friendly, intuitive experience that users expect.

TI v10.5's upgrades to the SSU user interface aim to provide the same features and functions that our customers love but to give it a 'face lift' that simplifies the user experience.

Some of the changes that you can expect to see are:

- New UX Design: A complete overhaul to benefit all system users.
- Contracts and Budgets: The ability to upload and track contracts and budgets in SSU.
- Activate Countries/IRBs: SSU Specialists can ensure that all country and IRB requirements are met before activating sites.
- Improved Agency Submissions: Users now can arrange the order of the documents, rename documents, etc., that are required for agency submissions.
- Improved Amendments: Introducing an easier way to create, complete, and track amendments for all categories.
- Improved IRB Profile: Significant improvements allow users to associate multiple IRBs to a site. Additionally, users now have the flexibility to assign an IRB as Central or Local.
- A new dashlet for tracking cycle time for different stages of the site activation process.

General Improvements

TI SSU enforces all essential documents to be reviewed as a part of a two-step workflow, i.e., by a Study Start-up Specialist and Regulatory Reviewer.

Automatic Submission for Second Step Approval

The Study Start-up Specialist will no longer be required to submit documents to the Regulatory Reviewer for approval. The system would automatically push these documents for second-step approval and notify the Start-Up Specialist.

TI SSU supports communication with Sites through Regulatory Packages and Emails linking documents. Additionally, the system supports maintaining communication logs and setting up the next Contact date.

Activation of Countries and IRB's

Activation Countries and Approving IRB's

Study Start-Up has long been known for streamlining the process of gathering the necessary information and documentation required for site activation. However, it is equally vital that we draw attention to the need to collect essential documents for those countries where a trial is to be run and the associated IRB/ECs. TI v10.5 introduces the ability to review country and IRB/EC documents and 'activate' these entities as a required step before activating any related sites, giving additional confidence that everything is completely ready for those activating sites in SSU.

Global IRBs and ECs

Multiple IRBs assigned to Sites and Flexibility to assign IRB as Central/Local

There are complexities in working with IRBs and ECs when working with sites that are spread globally. Wi 10.5, the system allows more flexibility in managing these intricacies.
In the EU, it is common for sites to work with multiple IRB/ECs. With TI v10.5, the system allows multiple agencies to be mapped to a site.
Similarly, an IRB may be assigned as a Central IRB for one site, but another site uses the same IRB as a local IRB. With TI v10.5, the system now allows the flexibility to use the IRB/EC as Central or Local, based on the requirement

Dashlet for Cycle Time

New feature Cycle Time Dashlet

Tracking cycle time for activating sites in clinical trials is paramount. This metric enables researchers and stakeholders to identify potential bottlenecks and streamline the process, ultimately accelerating the timeline for bringing life-saving treatments to patients. In v10.5 introduces a new dashlet for effectively monitoring the time taken to accomplish each step in activating sites.

Improvements to Submission Profile

Submission Profiles Improvement and Documents Management in Submission Packages

It's important that submissions are flexible and organized in each country, with the ability to order documents and be submitted multiple times.

In TI 10.5, the existing functionality around Submission Profiles will be improved, organized under each country, with the ability to re-order documents and submit them many times

Budgets and Contracts

Budgets and contracts are essential for activating sites in many countries. Budgets and contracts must be finalized in many countries before submitting to a health agency. TI SSU v10.5 has improvements to support this requirement.

New tab for Budgets and Contracts

A new tab has been added to the site profile for capturing budgets and contracts for each site. Documents can be uploaded as an optional feature.

TI v10.5 also includes the ability to add multiple budgets 'on the go' at the site level by adding another set of required metadata fields.

New Report: CRA Reconciliation

With TI v10.5, a new report shows Visit Status, Reconcile Date, Reconciled By and Submitted On across multiple sites simultaneously.
The report lists all the documents by these statuses:

- Missing in eTMF
- Missing in ISF
- Verified
- Null (if haven't checked by CRA yet)
- Blank status (not verified during the visit)

New Report: Documents for Completed Events

Documents status on Completed Events Report

With TI v10.5, a new report is available that lists the status of the documents for the completed events. This report provides a more robust picture as the users can now monitor the collection of documents for completed events. The report includes both placeholders and already-filed documents.

New Report: Document Timeliness

Calculate the time from Submission to Finalization.

CROs and Sponsors need to strictly monitor the cycle time for processing documents. It becomes important to identify the time to submit the document to the eTMF and then from submission to finalization.

Currently, this is supported through KPI dashboards. With TI v10.5, the system has a new report for providing details of every document submitted in the system with the cycle times for each step.

New Report: Document Timeliness

Calculate time from Query Generation → Response → Resolution

All document queries must be addressed/resolved within the designated SLA, as any delay has an impact on the Queries. With TI v10.5, a new report is available to help CROs and Sponsors track the time taken from:

- Query Generation to Query Response
- Query Response to Query Resolution

This report allows users to identify blockers and mitigate them.

New Report: Consolidated Completeness Report

Consolidated Completeness Report for all categories

Until now, the system provided three separate reports for document completeness for Site, Trial, and Country categories.

TI 10.5 introduces a new report that provides a consolidated completeness view for all three categories of documents. The report also provides a summary of the documents for the three categories.

Improvements – Queries Report

Adding Query Response to the Queries Report

Previously, the query report showed if a response was received and the respondent's details but not the actual response. With this improvement, the report also displays the actual response in the query history.

Queries Re-assigned shown on the Queries Report

When queries are re-assigned because the document submitter is no longer available, it is extremely helpful that the person to whom the queries are re-assigned is also shown on the query reports. This helps with follow-up if the queries remain outstanding.
Keeping this use case in account with v10.5, the Queries report has a new column to display the details of the new assignee. In cases of multiple reassignments, the field will display the latest reassignment.

Adding Issues to the Queries Report

The Queries Report now has a new column to display any issues about the query to help the TMF manager utilize this report more effectively.

Allow Query Managers to run the Queries Report

Previously, only Admins or Editors/Managers with the Document Manager action could run query reports. With v10.5, Query managers can run query reports to quickly and easily get an overview of all queries within a study room.

Report Improvements

Last Document Approved to SSU Cycle Time Reports

The SSU Cycle Time Reports now display an additional column to indicate the date of the last document approved for the Site. This date would be based on the percentage progress bar for Site-level documents.

Adding Comments to Document Placeholder Report

When creating a placeholder, the 'Comment' field is available and is utilized to add details. However, until now, each placeholder needed to be viewed to see this content as unavailable when the report was created. TI v10.5 includes Comments field data, allowing more robust content to be readily downloaded, viewed/shared without manually checking and updating reports.

Adding Audit Response Comments and Audit Recheck Response Information to Quality Review Report

The Quality Review Report now includes two additional columns for Audit Response Comments and Audit Recheck Response information to make the report more robust by providing relevant information.

Chapter 1. Getting Started

Trial Interactive helps clinical teams build an eTMF for clinical trials and to manage content from author to archive. It all starts with workflow, metadata, and content strategy — define your essential documents, determine your required metadata, configure your index structure, and manage eTMF health in quality reviews, reports, and dashlets. Along the way, Trial Interactive helps you prioritize the eTMF and content workflows, collect the documents required to activate your investigative sites, collaborate with the study teams at the sponsor, CRO, and site, as well as integrate with other Clinical platforms so that you can sync with other teams and other types of data. This online help contains a descriptive overview of the Trial Interactive tool and step-by-step procedures of Trial Interactive functions.

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

Signing in to Trial Interactive for the First Time

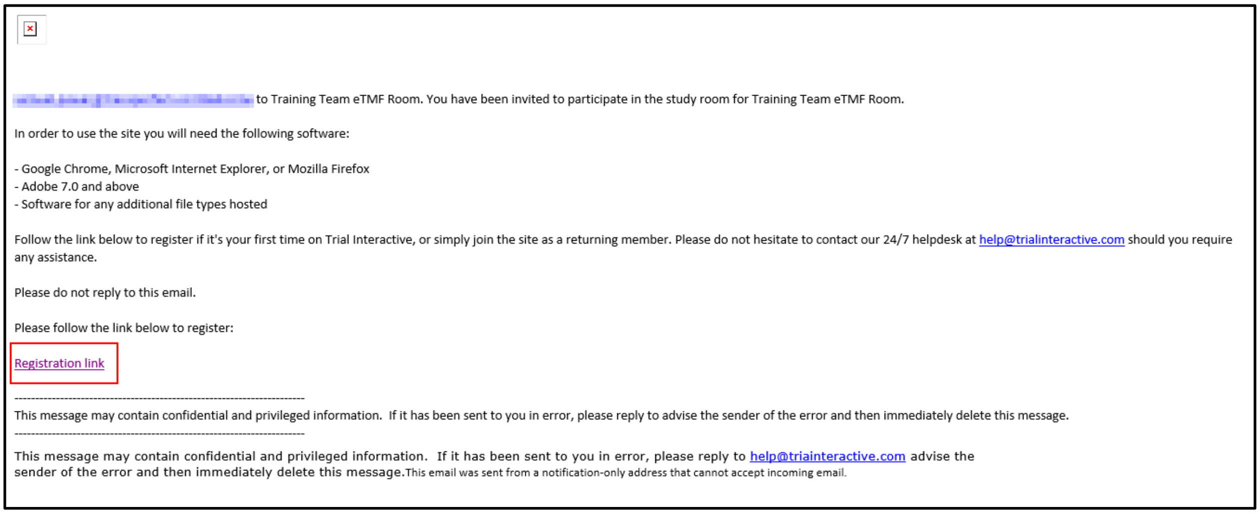
This section includes basic information that will help you get started with Trial Interactive v10.5.

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

With Trial Interactive v10.5, a user will be logged out if the user is logged on multiple sessions in different browsers at the same time. It is not possible for users to log into Trial Interactive on multiple devices simultaneously.

Receiving and Responding to a Room Invitation

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



[redacted] to Training Team eTMF Room. You have been invited to participate in the study room for Training Team eTMF Room.

In order to use the site you will need the following software:

- Google Chrome, Microsoft Internet Explorer, or Mozilla Firefox
- Adobe 7.0 and above
- Software for any additional file types hosted

Follow the link below to register if it's your first time on Trial Interactive, or simply join the site as a returning member. Please do not hesitate to contact our 24/7 helpdesk at help@trialinteractive.com should you require any assistance.

Please do not reply to this email.

Please follow the link below to register:

Registration link

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete this message.

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to help@triainteractive.com advise the sender of the error and then immediately delete this message. This email was sent from a notification-only address that cannot accept incoming email.

Figure 1: Registration link

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

User Registration

1. Register to the application only once as a first-time user upon receiving an email notification from a room.
2. You can sign into your room after registration.

3. If you are invited to other rooms hereafter, you need not register again. The new room will appear on your Home page on the list of all rooms to which you have been granted access.
4. Emails will be sent to you for any further room invitations.

After you have received your invitation email with a **Welcome** message and **Registration** link, you should follow the steps below to register:

Step 1: Registration - Required Information

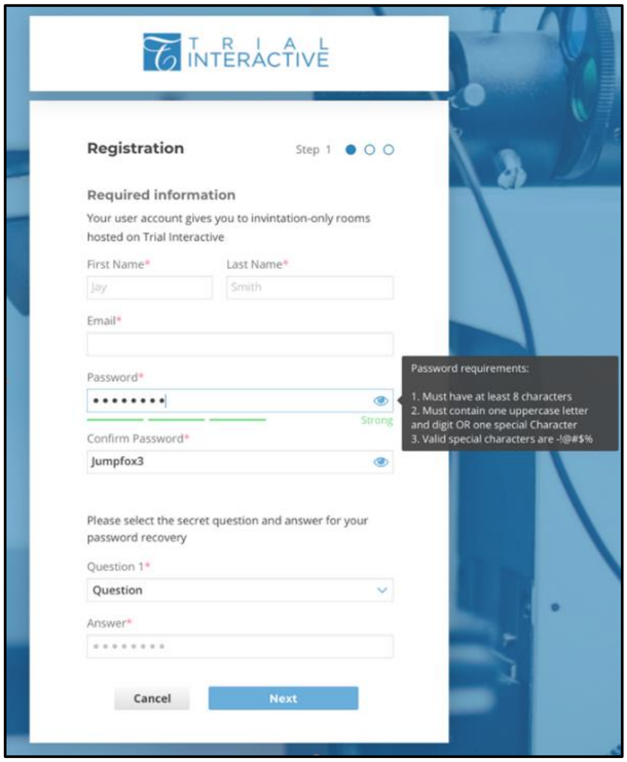


Figure 2: Registration page

1. Click the Registration link near the bottom of the message, and you will be 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

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

Step 3: Registration - Custom Information

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

Signing in on Subsequent Visits

To log in to Trial Interactive

1. Using your preferred internet browser, navigate to https://www.trialinteractive.com/
2. Click the **Client Login** button located at the top-right corner of the page.

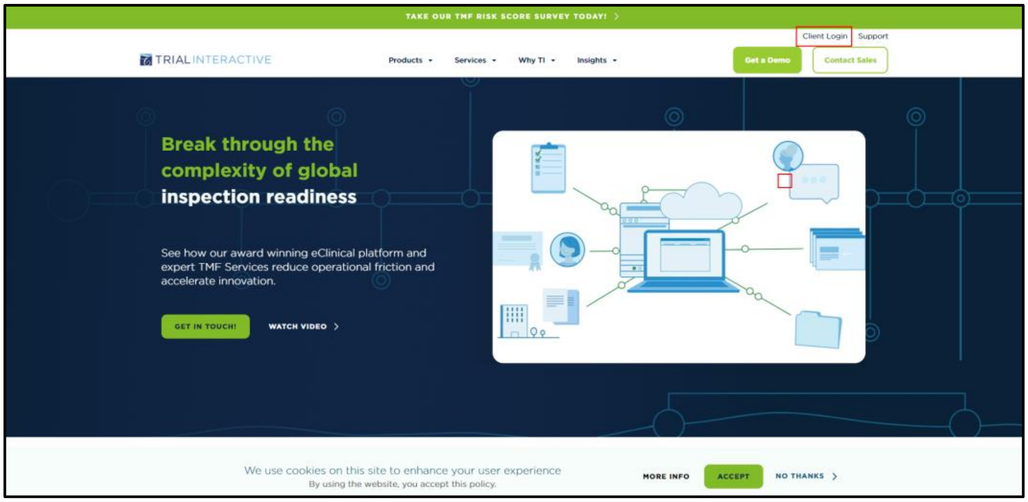


Figure 3: Trial Interactive browser page

3. The Trial Interactive Login page appears.
4. Enter your Username and Password. Your Username is the full email address that was submitted by the client-appointed Administrator and is likely the one to which the initial invitation was sent.
5. Once you click on the **Sign in** button, it will redirect you to Trial Interactive Home page.

Figure 4: Trial Interactive Sign-in page

Requesting a Password Reset

In the event that you have forgotten your password, click 'Forgot Your Password?' at the bottom of the login window to initiate an account password reset.
Users do not need to contact the Service Desk. In most cases, the user can perform the Password Reset operations without any outside help. When you click the 'Forgot your Password?' link, a password reset email will be sent to the email address associated with your user account

Follow these steps to reset your password:

1. Enter your **Email address** in the field provided and click the **Reset Password** button.

Figure 5: Password Reset page

2. You will receive an email with the **Reset Password** link.

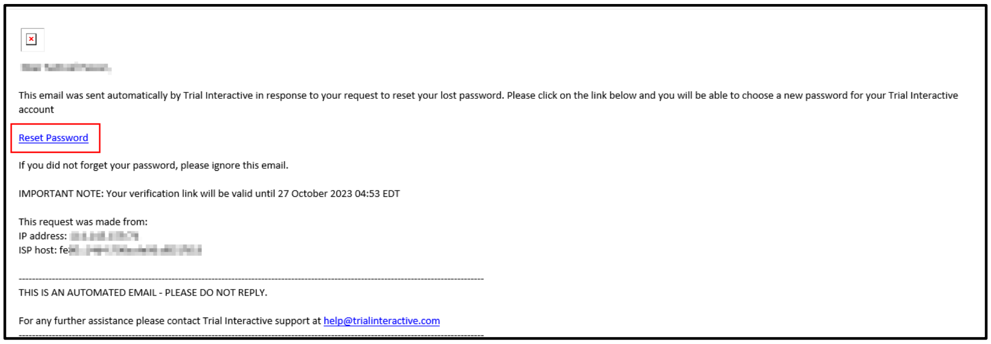


Figure 6: Reset Password email page

3. Once you click the Reset Password link. It will redirect you to the Trial Interactive Password Reset page. Respond to the security questions and click the **Next** button.

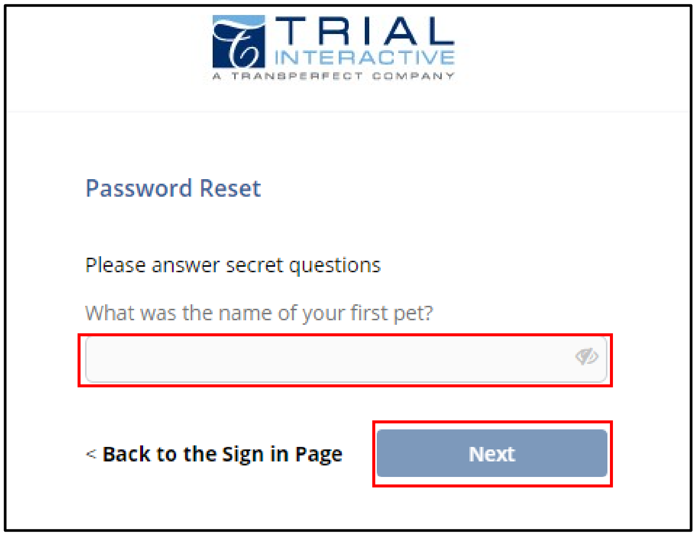


Figure 7: Password Reset page

4. Enter your **New Password** and **Confirm New Password**, follow the Password Requirements mentioned in the below screenshot and Click on the **Set New Password** button.

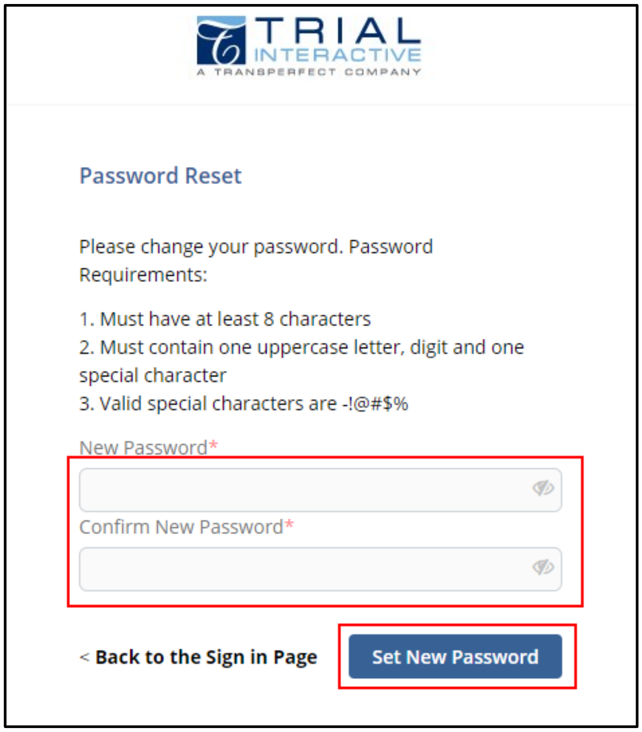


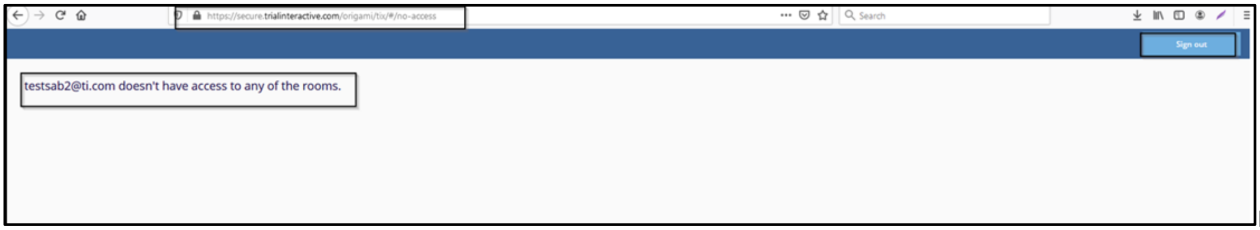
Figure 8: Password Reset page

5. The system confirms that the password was successfully reset. Click Back to the login page to log in with your new password.

Signing in without access to rooms

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

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



Figure

9: No Access page

Chapter 2. The Trial Interactive Home Page

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

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

screenshot.

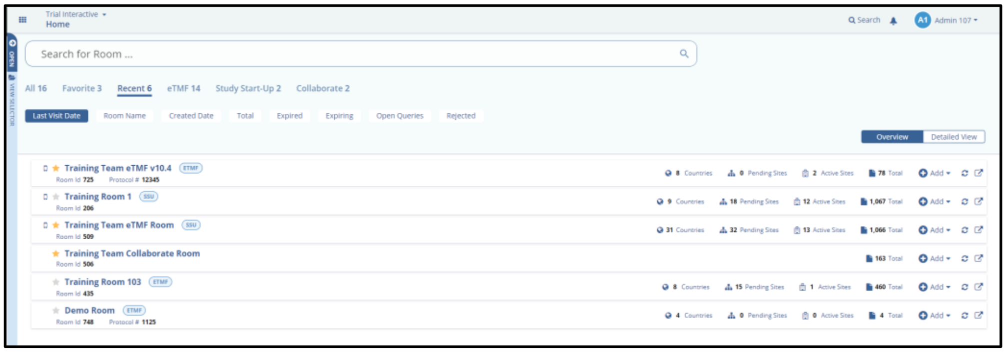


Figure 1: Home page

A new tab **Rejected** is added to the Trail Interactive Homepage.

When we click on the **Rejected** Tab on the Homepage, it shows Rejected document numbers from each room. This helps the user to understand how many documents are Rejected from each room.

Refer to the screenshot below.

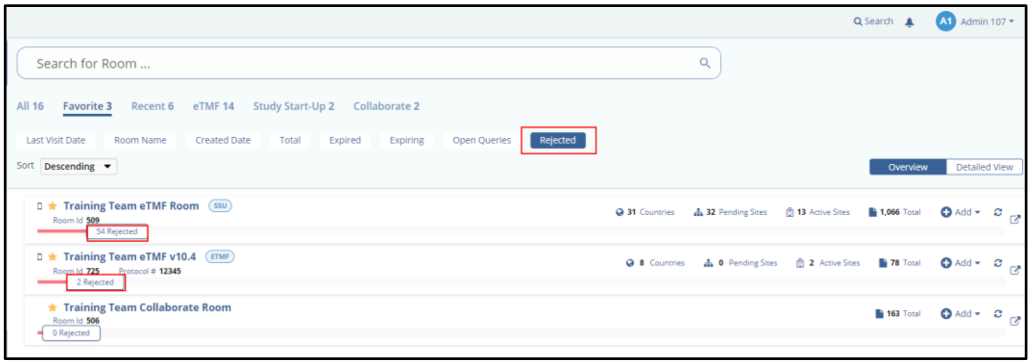


Figure 2: Home page (Rejected tab)

Click the required room name to enter a room.

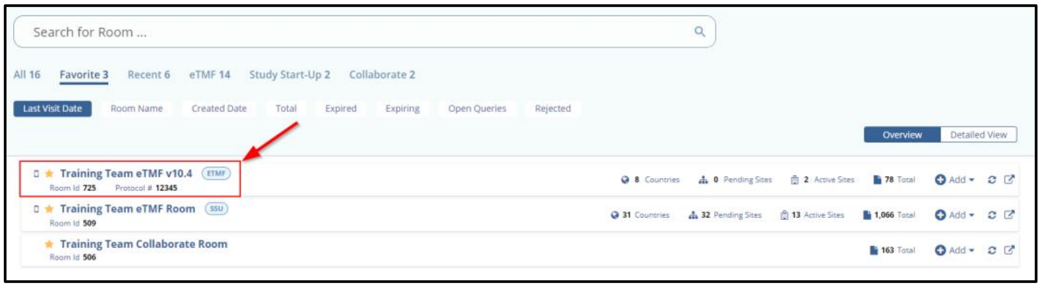


Figure 3: Entering room

Room Views

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

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

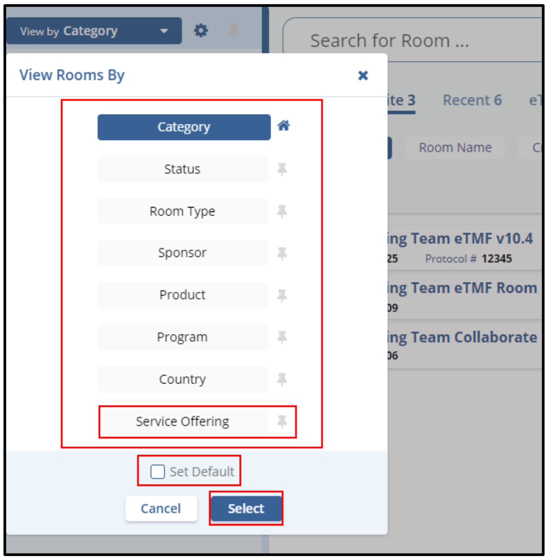


Figure 4: Filter Categories

A new "**Service Offering**" pin view has been added in this version.

Viewing Room Details

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

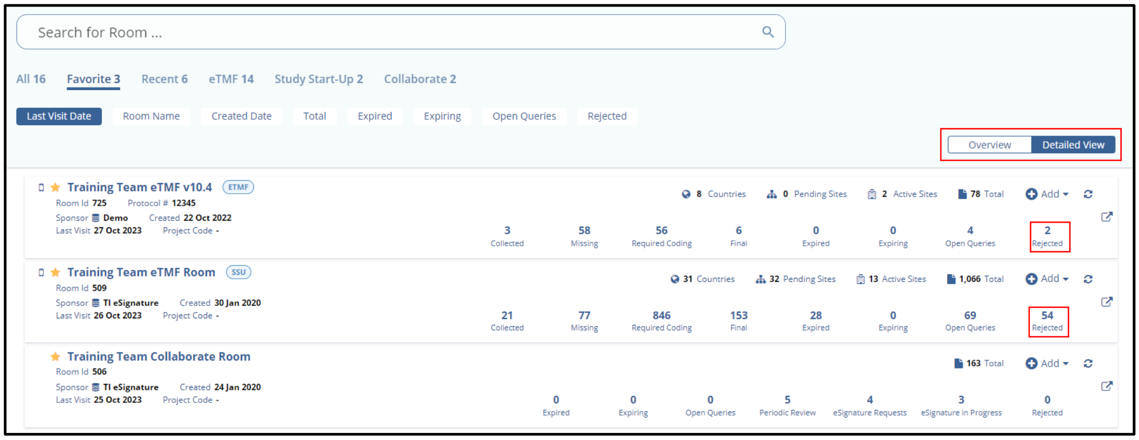


Figure 5: Room view

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

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

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

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

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

<u>Collected documents</u>
The number of collected documents. This number includes all documents marked as required for the eTMF which we consider to be collected. It is available for eTMF or Study Start-Up rooms. This item is clickable. Available only in Detailed View mode.

<u>Missing documents</u>
The number of missing documents. This number includes all eTMF placeholders that have no document that can be considered as collected. This number represents the difference between the number of all required

documents in a room and the number of required documents that we have already collected. It is available for eTMF or Study Start-Up rooms and is clickable. Available only in Detailed View mode.

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

Required coding

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

Final documents

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

Expiring documents

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

Open queries

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

eSignature requests

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

eSignature in progress

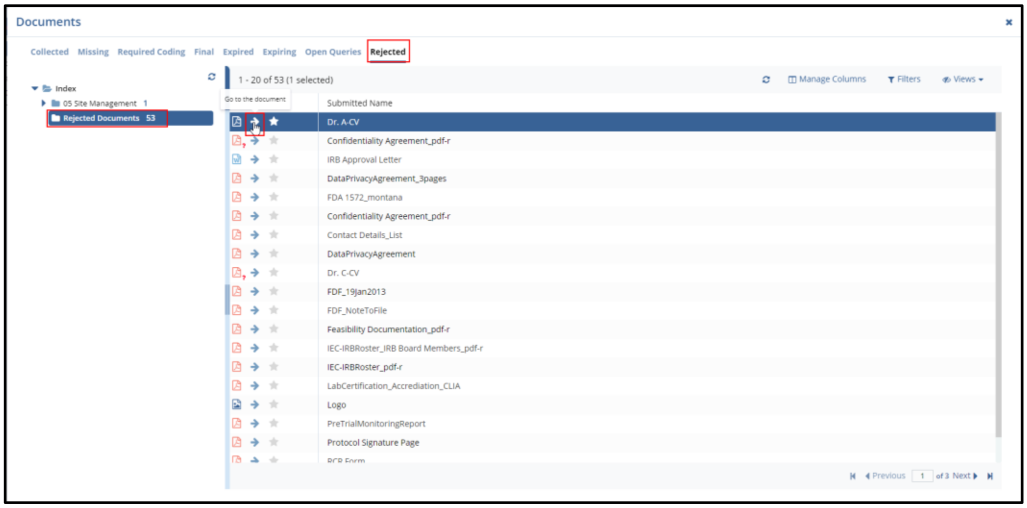
This is the number of documents that were sent to the eSignature workflow stage and signing is in progress. It is available for Collaborate and TI Docs rooms with eSignature enabled. It is clickable. Available only in Detailed View mode.

Periodic review

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

Rejected Documents

This is the number of **Rejected documents** in the room. When we click on the **Rejected** Symbol. The Rejected Documents window appears with the list of rejected documents presented in the room. Users can go to the document by clicking on the **left-pointing arrow** symbol.



Room Search and Accessing a Trial Interactive Room

Room Search

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

To perform a room search:

1. Enter the required room name in the **Search** Bar at the top of the page and hit the enter button.

2. Rooms matching the search criteria are displayed in the panel below the filters, else a message 'No Rooms Found' is displayed.

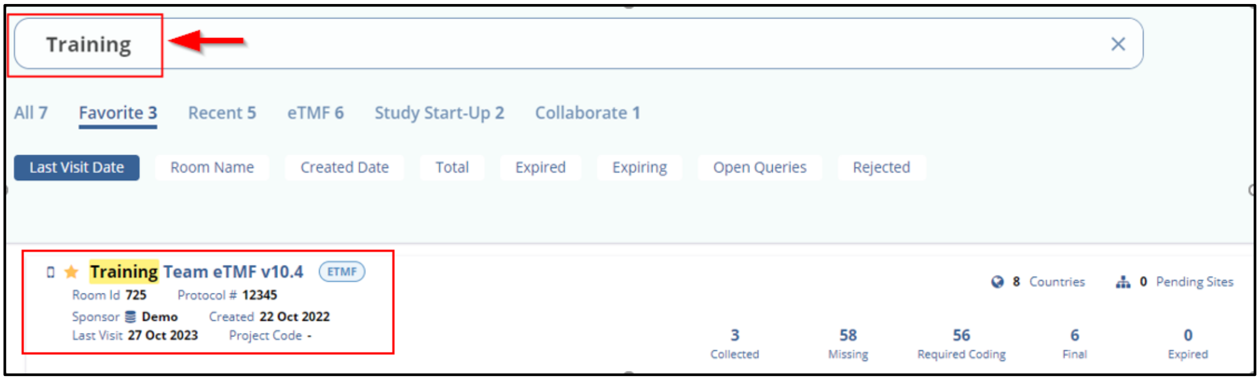


Figure 6: Room Search

Accessing a Trail Interactive Room

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

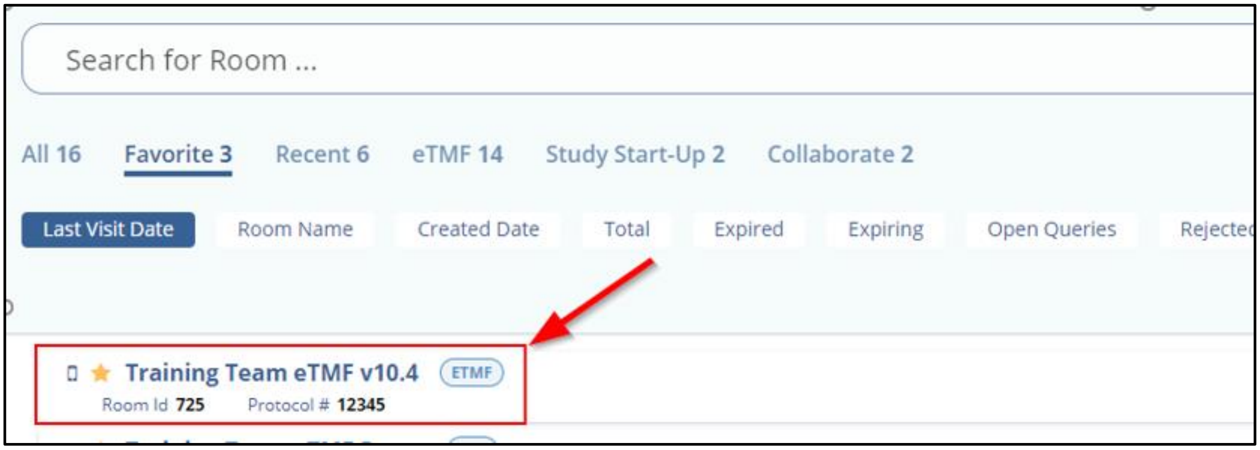


Figure 7: Room Access

Cross Study Document Search

Documents Search

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

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

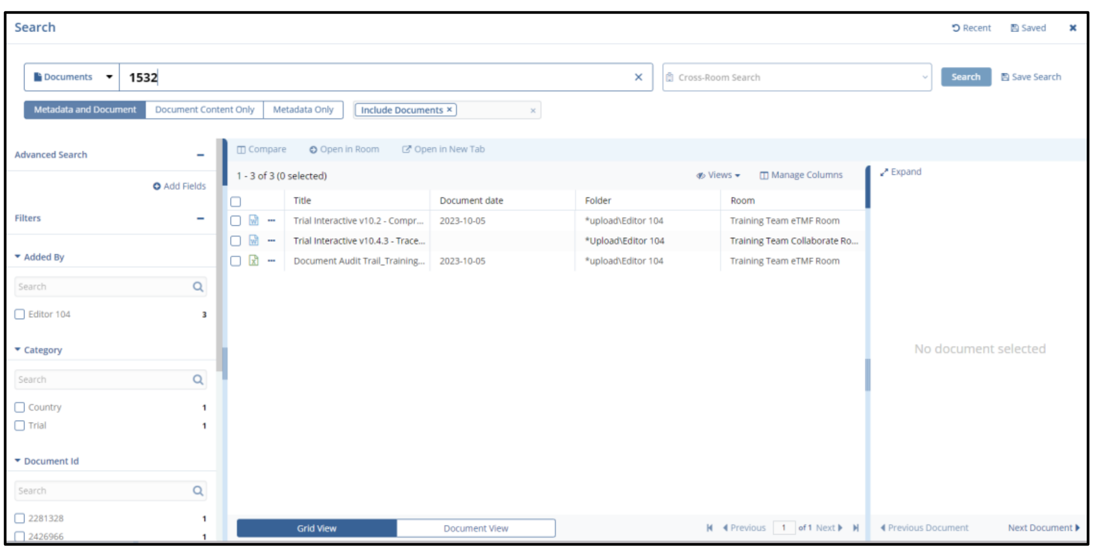


Figure 8: Document Search

Advanced search

Added an **"Apply Filter"** button to the advanced search panel. Users who perform an advanced search can now add a search field and update their search results immediately using an 'Apply Filters' button directly in the Advanced Search panel rather than relying only on the primary search button.

TI Home Page Filters

The **TI Home Page** provides a variety of filters through which you can filter the rooms displayed.

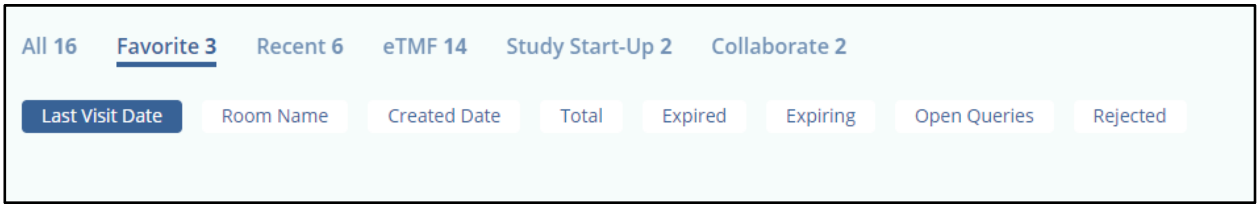


Figure 9: Home page filters

<u>The filters consist of the following:</u>

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

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

Summarized (Overview) View of Rooms

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

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

Figure 10: Room Overview

Countries

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

Active Sites

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

Pending Sites

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

Total Documents

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

Detailed View of Rooms

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

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

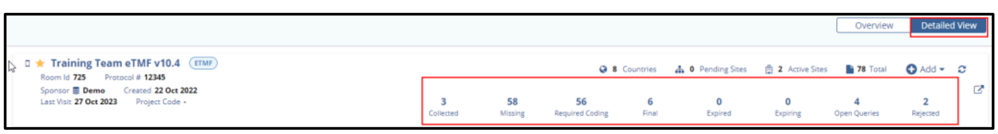


Figure 11: Detailed View

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

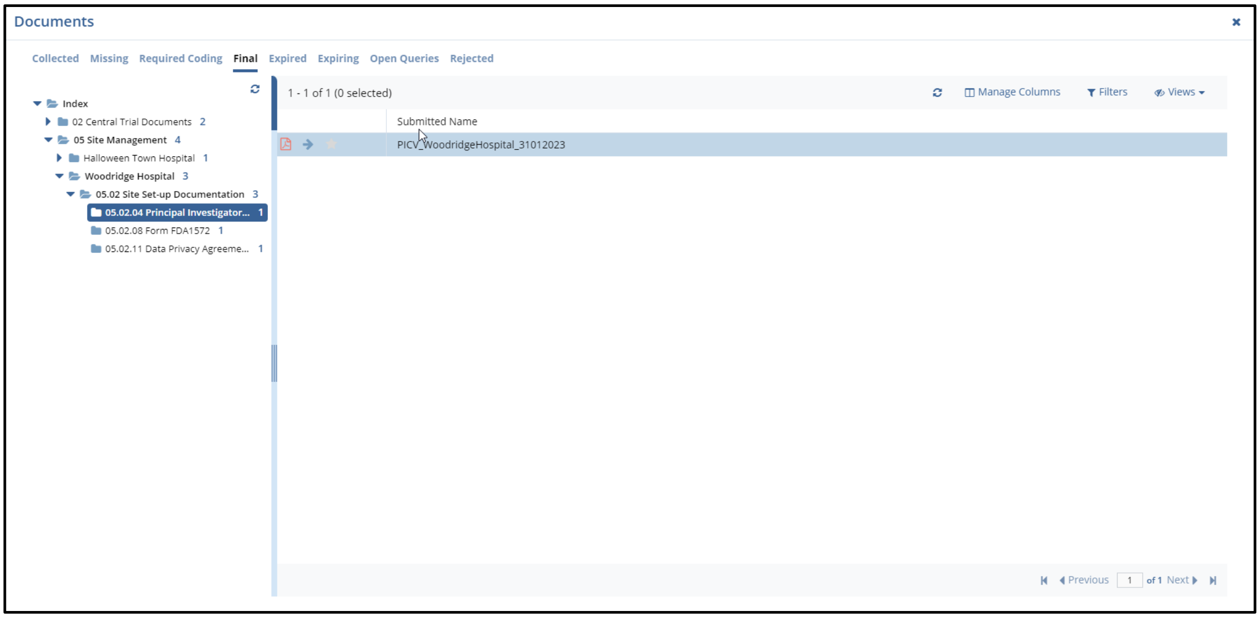


Figure 12: Detailed view

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

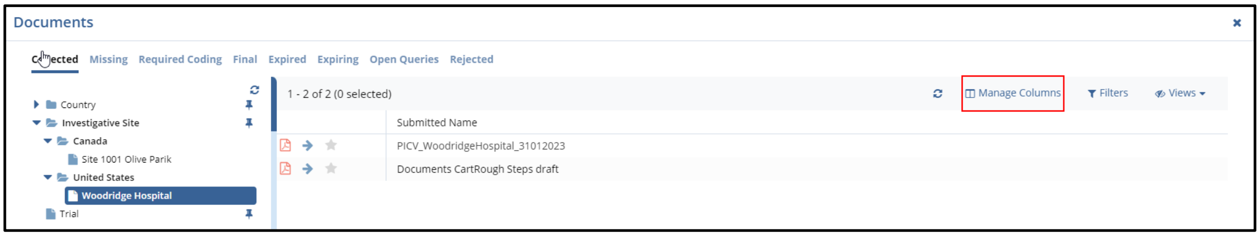


Figure 13: Manage Column

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

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

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

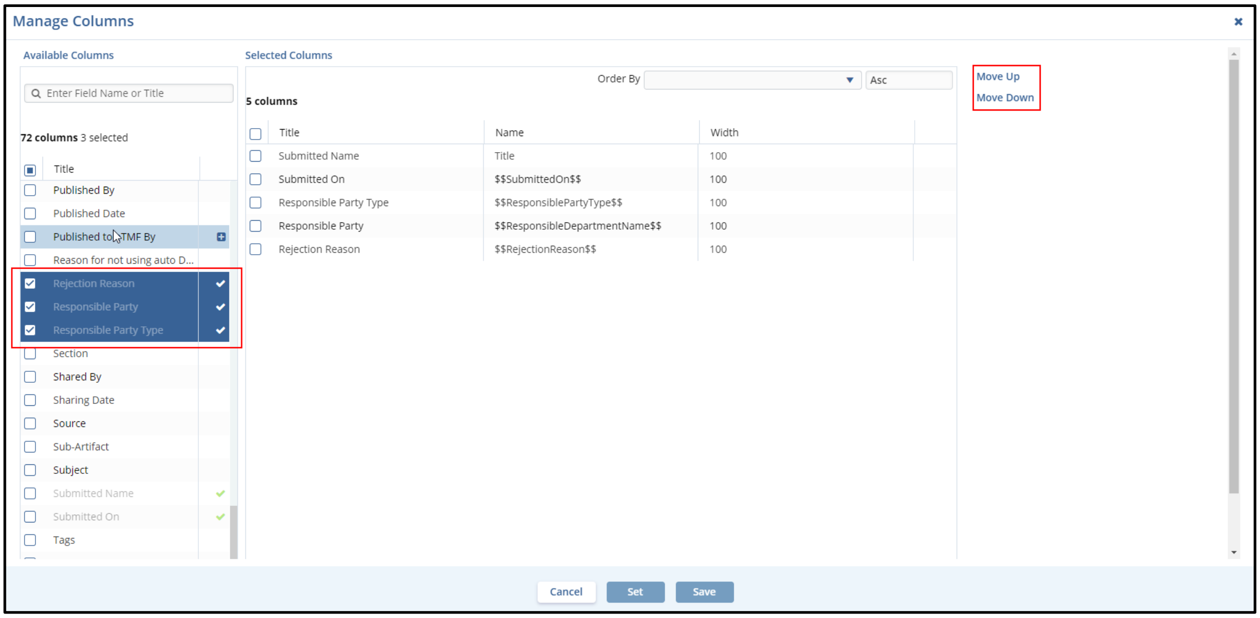


Figure 14: Manage Column

myTI Enabled Rooms

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

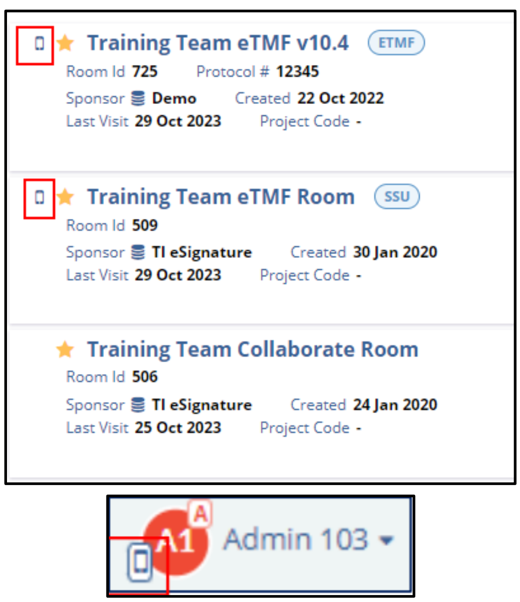


Figure 15: myTI Enable Rooms

Add Users to a Room

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

1. Click the '**Add'** dropdown at the right side of the room line on the home page.

2. Click the '**Add Users'** option from the dropdown list that appears. The User Invitation window will open.

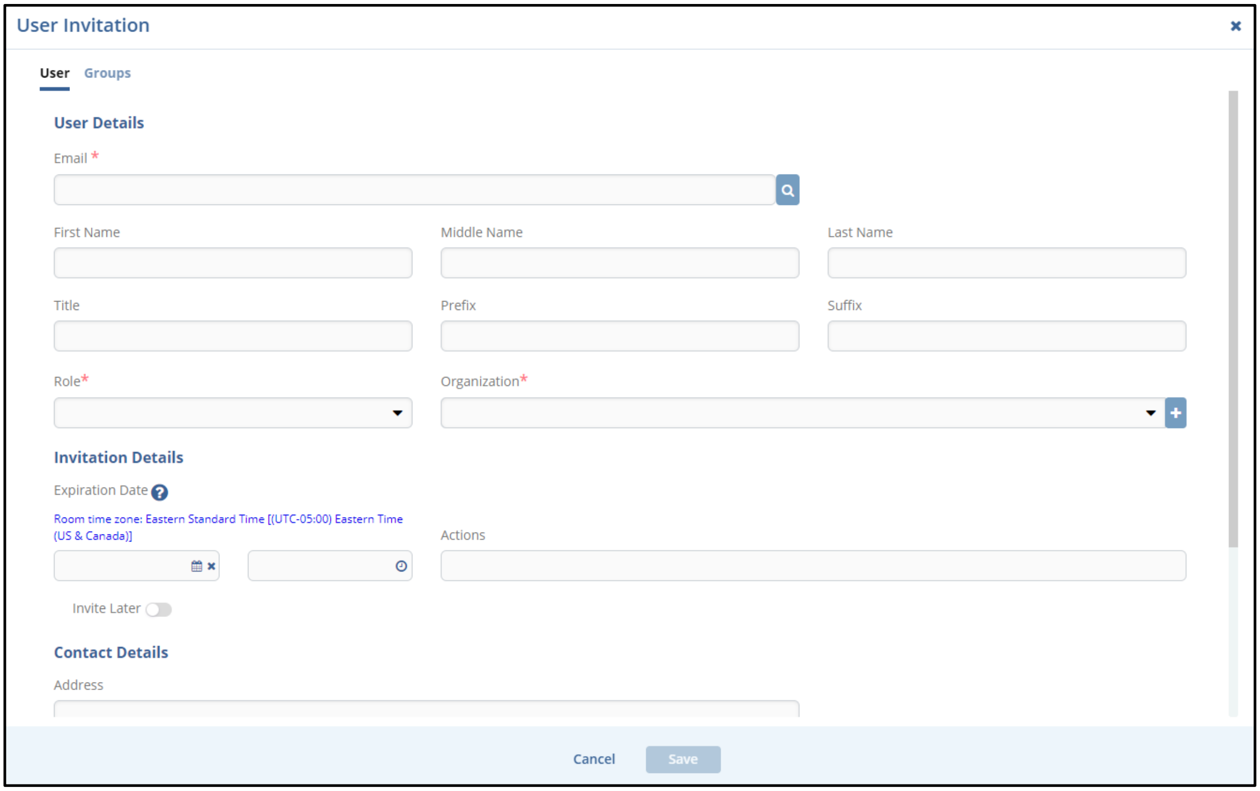


Figure 16: User Invitation

3. Enter the **Email address** of the user, assign a role to the user, and select **Actions** as appropriate.

4. Select any Groups to add users to that group

4. Select **Organization** from the drop-down list of Organization. You can also create a new **Organization** by clicking on the (**+**) sign.

5. Click Save to add the user to the room and send the invitation.

a. If the 'Invite Later' option was chosen, you will need to locate the user's account in the room to send the invitation.

In this version, a new section is added '**Invitation Details'** wherein we can select the appropriate **Expiration Date** and **Time**. It is used to remove user access from a particular room after a specific period.

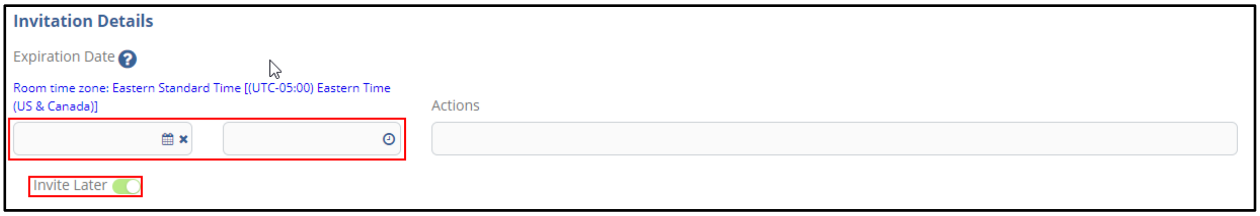
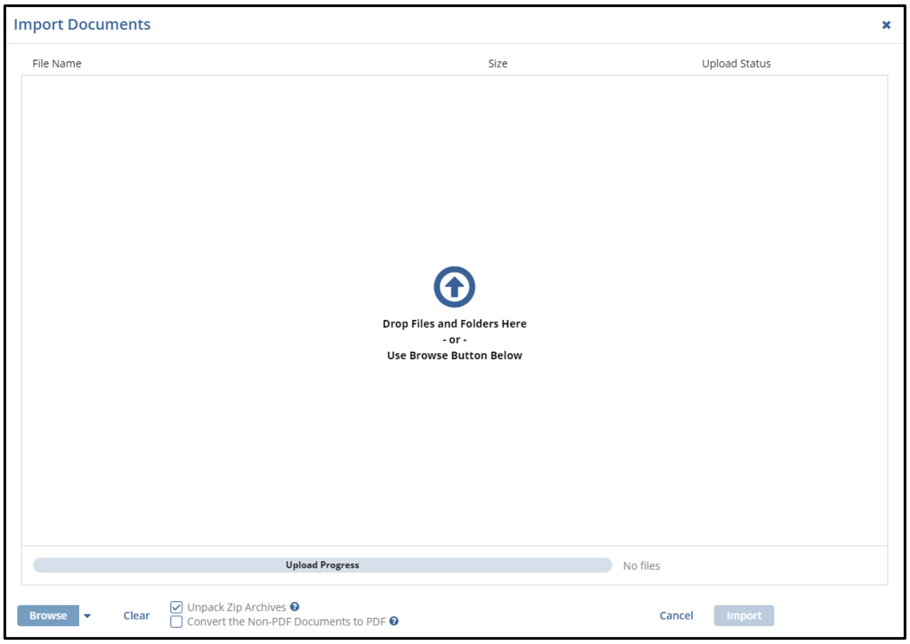


Figure 17: Invitation Details

Upload Documents to a Room

1. To add the document from the **home page**, click the **Add** drop-down button available on the right side of the room.
2. Select **Add Documents,** Import Documents window will appear.
3. Drag and drop the files or click '**Browse'** at the bottom of the page to navigate to the required document to be uploaded.



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 rooms as favourites.

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

Figure 18: Favorites

Adding Tasks to a Room

To add tasks to a room:

1. Click the **Add** dropdown to the right of the required room name and select the **Add Task** option.

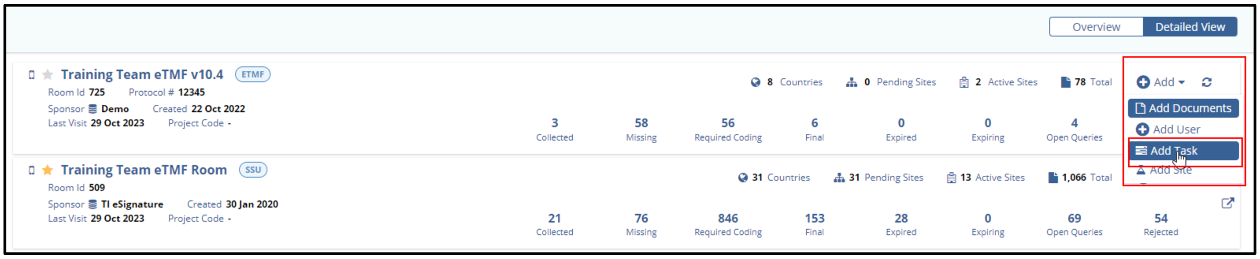


Figure 19: Task

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

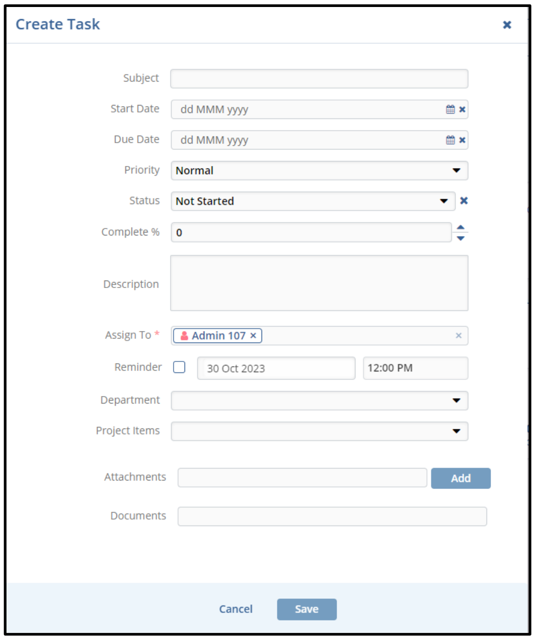


Figure 20: Create Task

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

Chapter 3. Main Navigation and Inter-Room Navigation

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

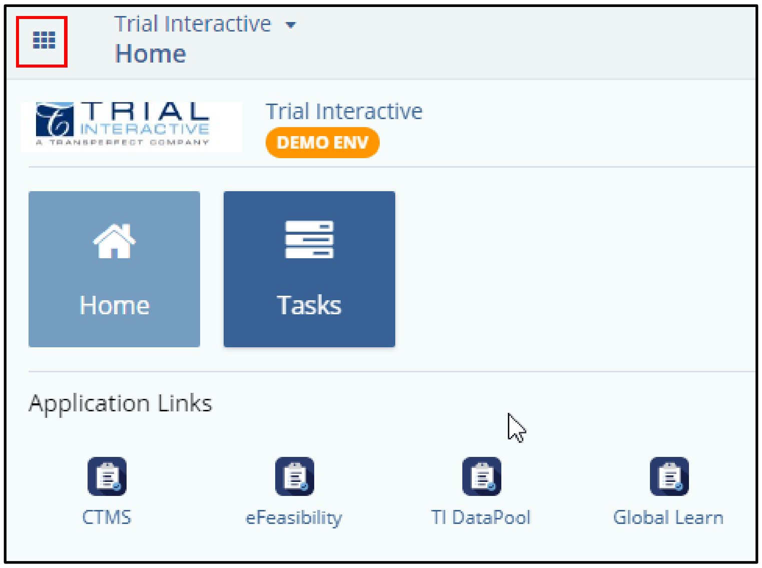


Figure 1: Navigation Grid

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

Main Navigation from Within a Room

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

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

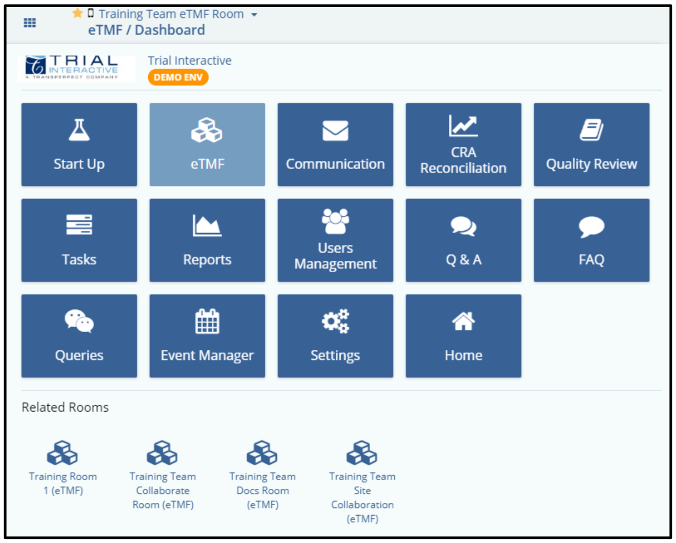


Figure 2: List of Module

Navigating between Rooms

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

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

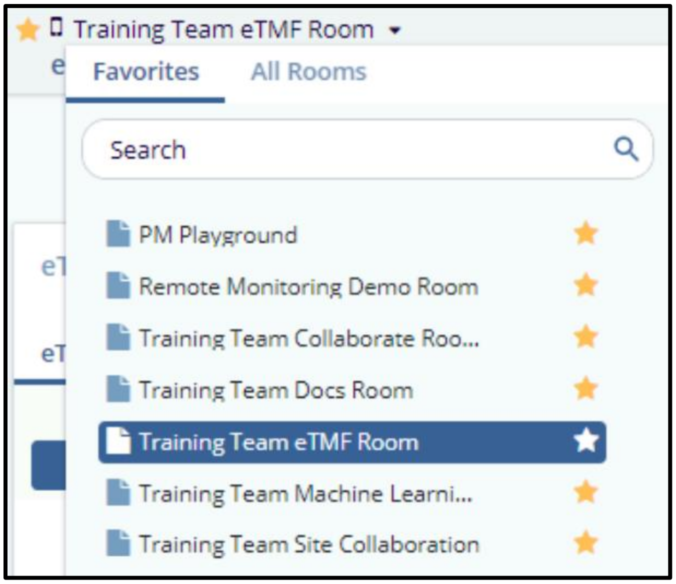


Figure 3: Room Search option

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

Chapter 4. Username Menu

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

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

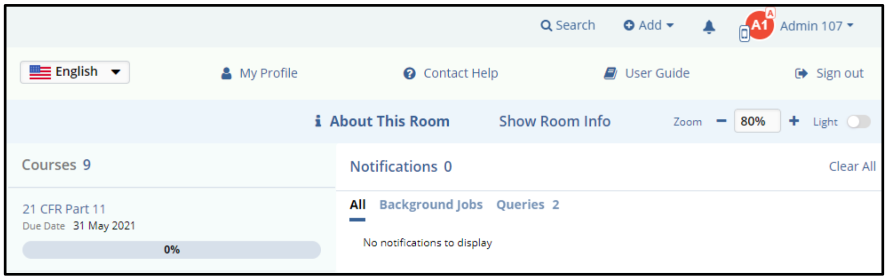


Figure 4: Username Menu

Through the Username Menu, you can access the following:

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

About This Room

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

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

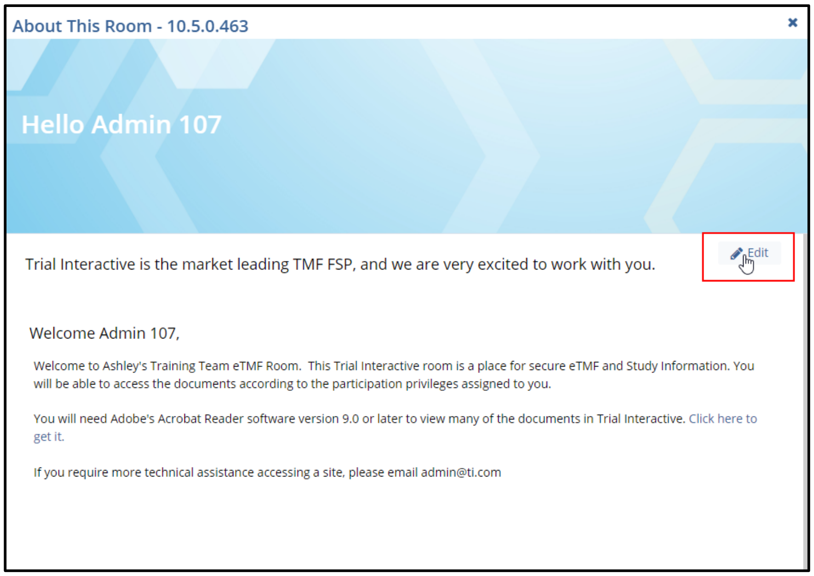


Figure 5: About This Room page

Contact Help

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

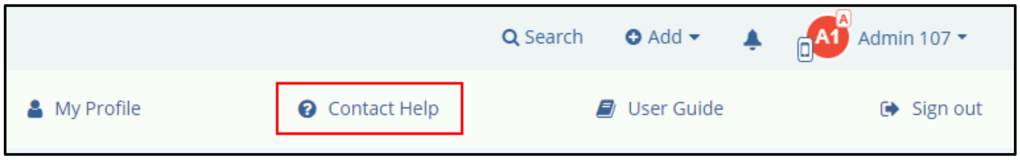


Figure 6: Contact Help

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

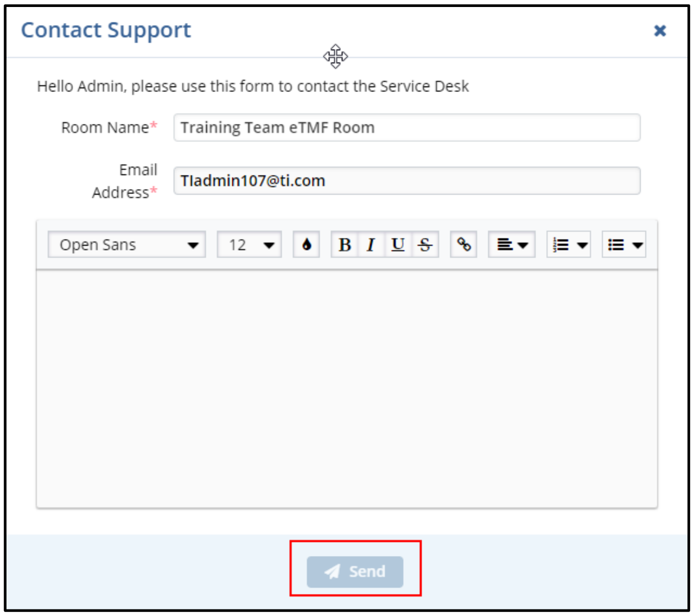


Figure 7: Contact Support.

General Information - Language

<u>To set your preferred language:</u>

1. Click the **Language** dropdown.
2. Scroll down to locate your preferred language.
3. Click the **language** to select it.
4. The room menu and field labels will change to be displayed in the language of your choosing.

Figure 8; Language

My Profile

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

To access My Profile:

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

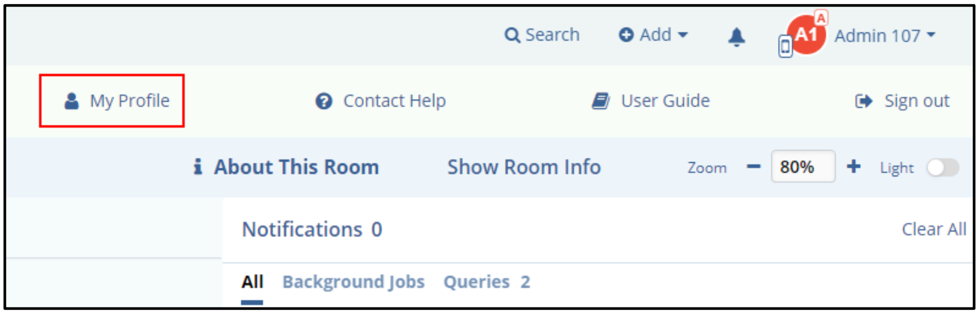


Figure 9: My Profile

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

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

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

My Profile-Main Section

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

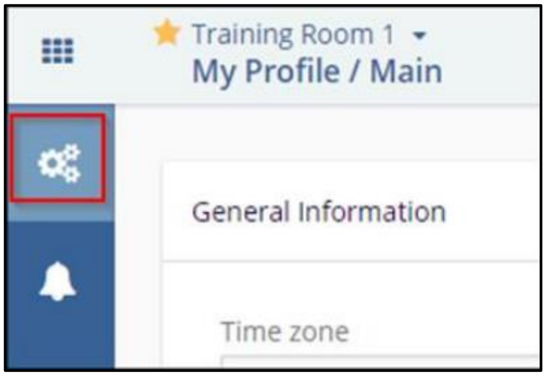


Figure 10: Main Section

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

- **General Information**
- **Password Recovery – Secret Questions**
- **User Avatar**
- **Change Password**
- **Site Filtering Options**
- **Default Context Configuration**

General Information – Time Zone

To set the time zone applicable to you:

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

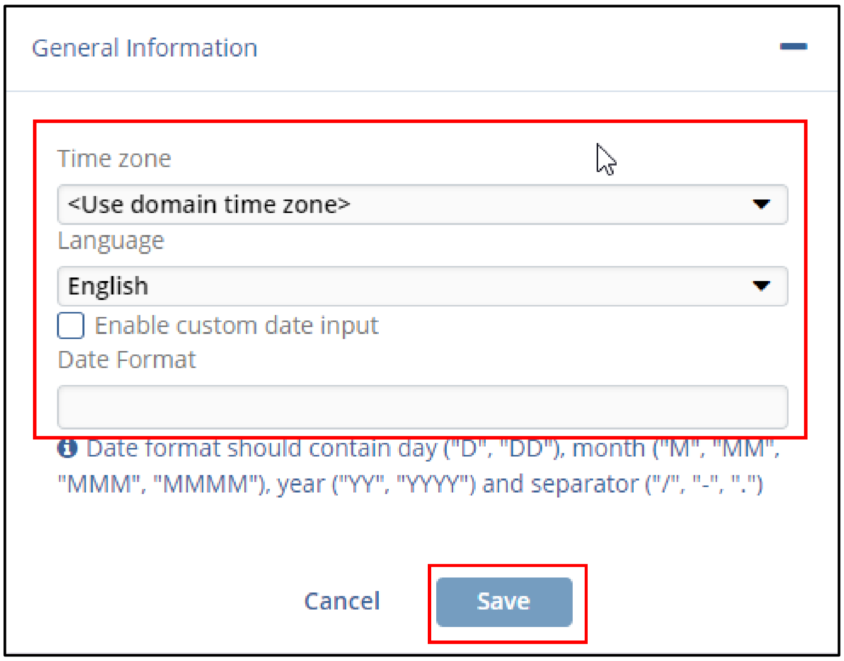


Figure 11: General Information

General Information – Enable Custom Date Input

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

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

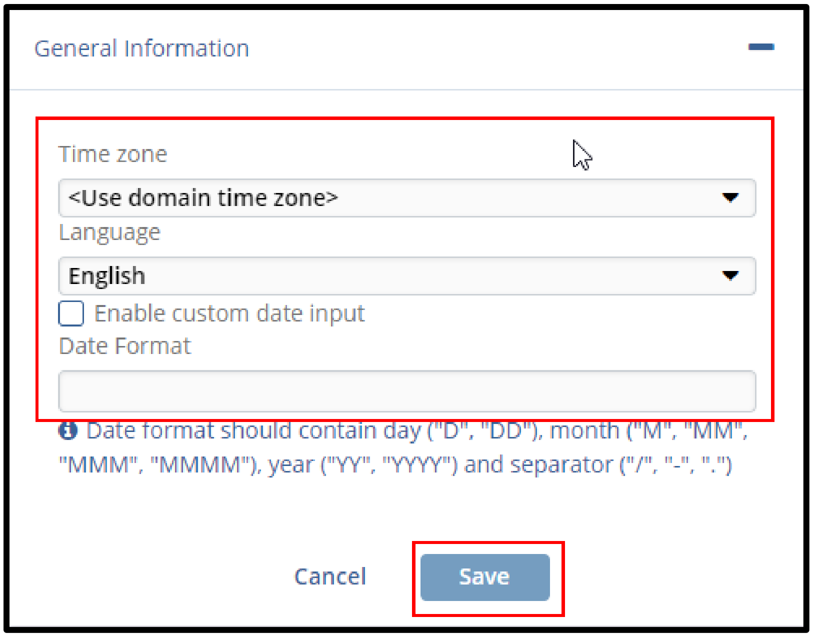


Figure 12: General Information

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

Change Password

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

To set the password:

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

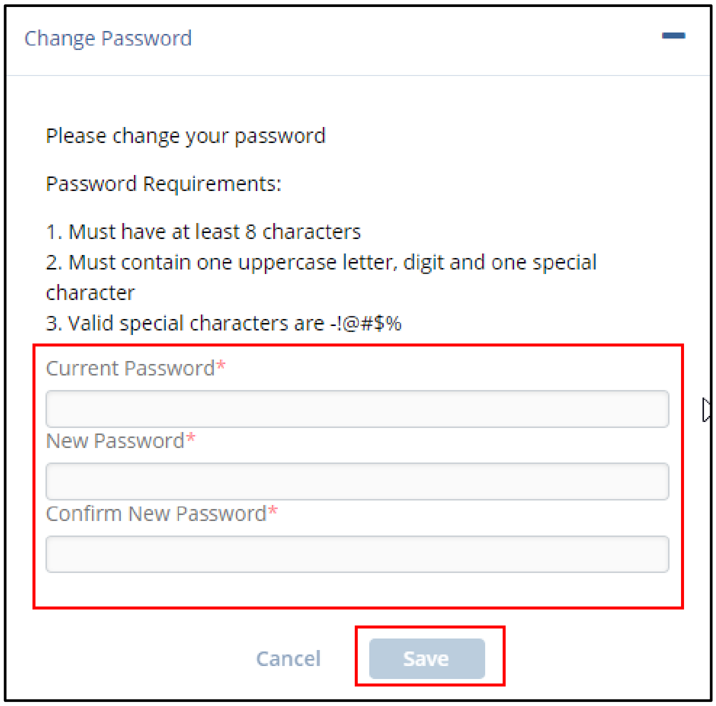


Figure 13: Change Password

Password Recovery -Secret Question

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

To set the secret questions and their answers:

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

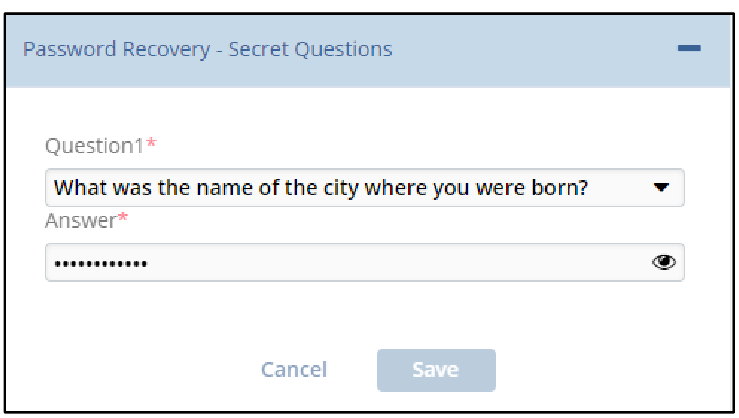


Figure 14: Password Recovery

User Avatar

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

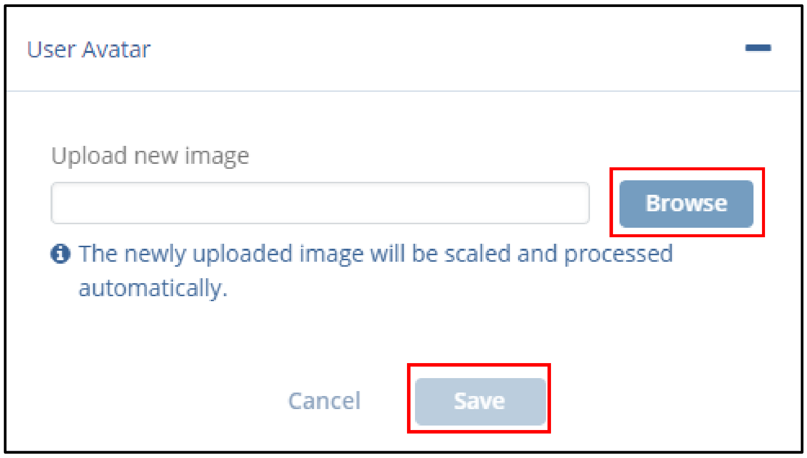


Figure 15: User Avatar

Sites Filtering Options

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

Refer to the screenshot below:

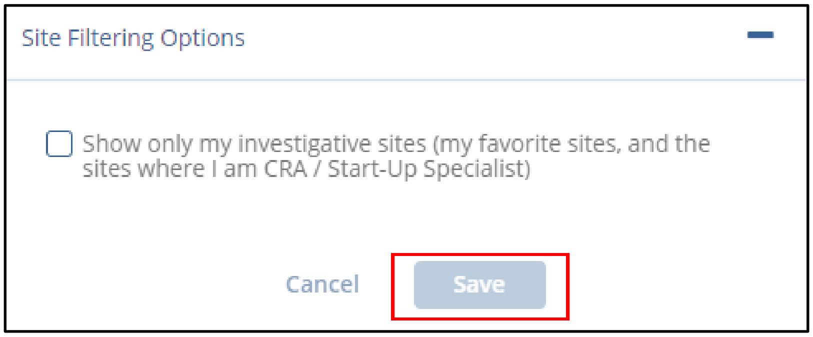


Figure 16: Sites Filtering options

On selecting this option, the filter icon in the **Sites** module appears in red.

Figure 17: Sites Filter Icon

Default Context Configuration

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

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

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

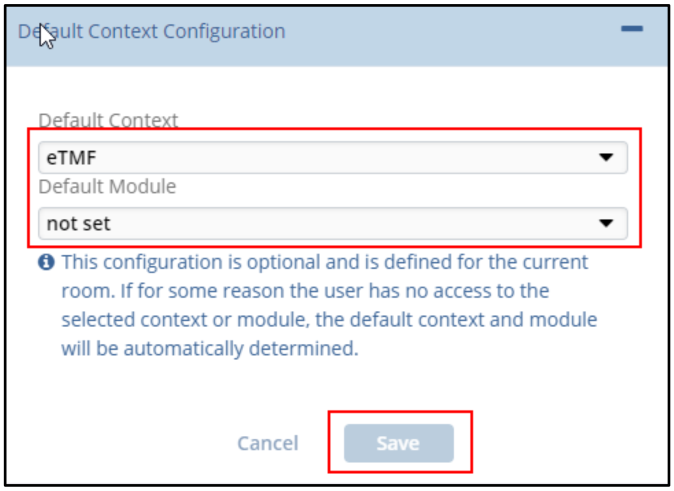


Figure 18: Default Context Configuration

My Profile Notifications Section

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

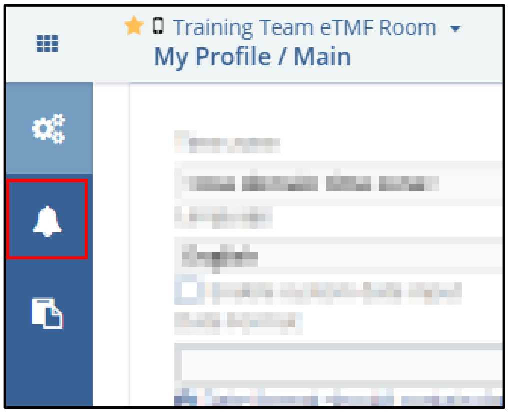


Figure 19: Notification Section

Select the desired room from the list of studies in the left pane of the Notifications panel. Using the options grid on the right of the Subscriptions window, you can select which notifications you would like to receive. Administrators can choose which notifications are available for you and they can make some choices default or mandatory:

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

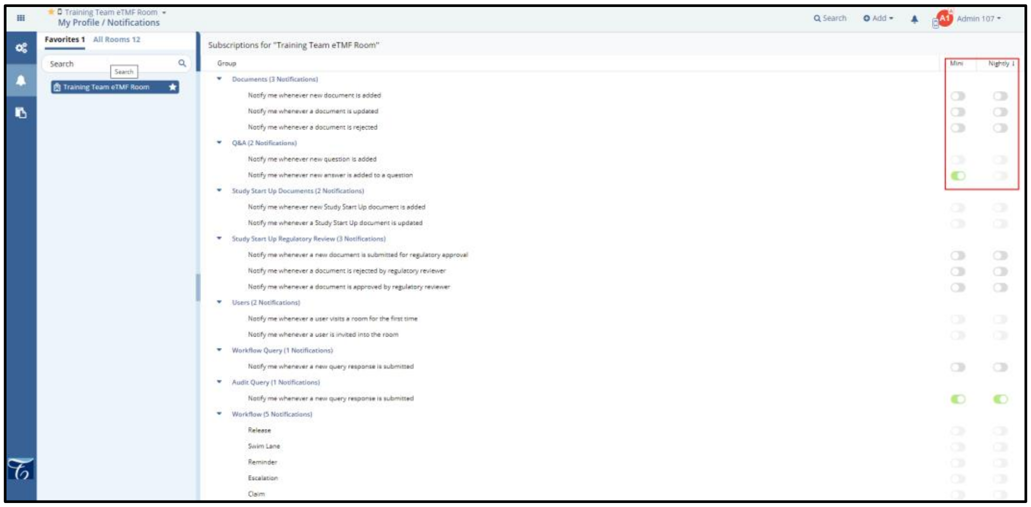


Figure 20: Notification Settings window

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

Job Processing Notifications

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

Refer to the screenshots below:

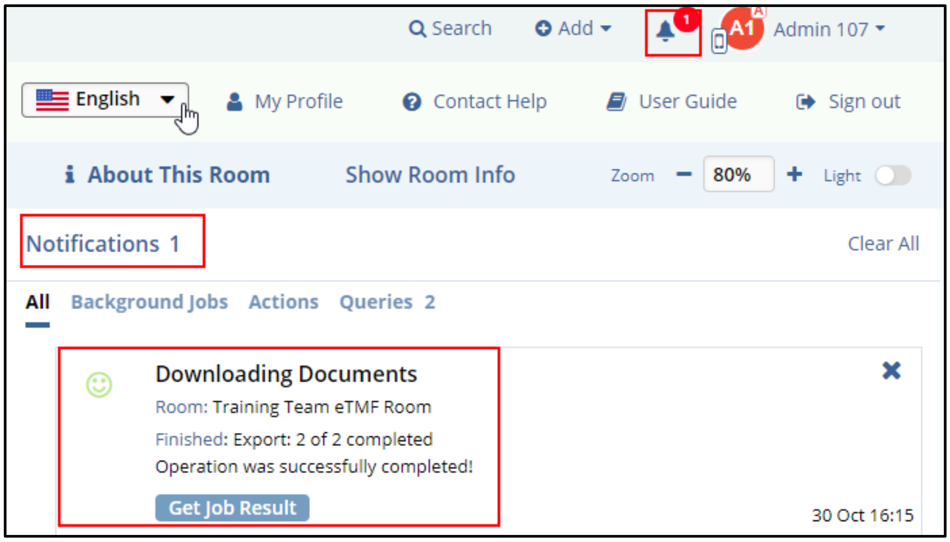


Figure 21: Notification pop-up

This section displays the following tabs:

- **All:** Click this tab to get a list of all the tasks that are ongoing, pending, or overdue. This is a shortcut that provides you with an overview of all the tasks in your current room.
- **Queries:** Click this tab to get a list of all the queries pending action. You can click any individual query link to lead you to the Queries sub-module for you to initiate your actions on it.
- **Actions:** Need Definition
- **Background Jobs**: Through this tab, you are notified about a background job that is executing or is completed.
    - Some messages like downloading/mass coding documents provide the Get Job Result button that you click to get further details on the action like a message or a downloadable file.

User Guide

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

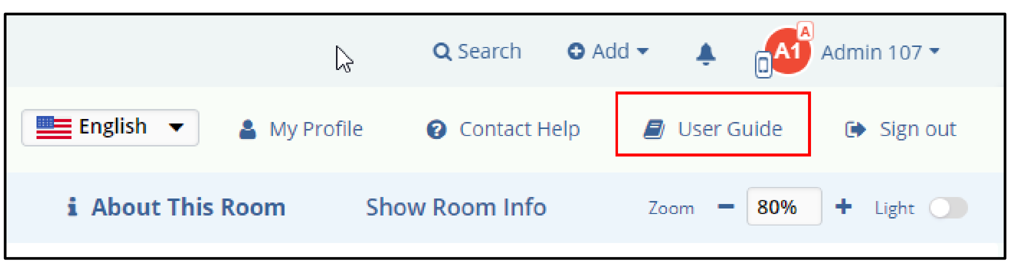


Figure 22: User Guide

Sign Out

Click the **Sign-out** button to end your current session as shown in the below screenshot.

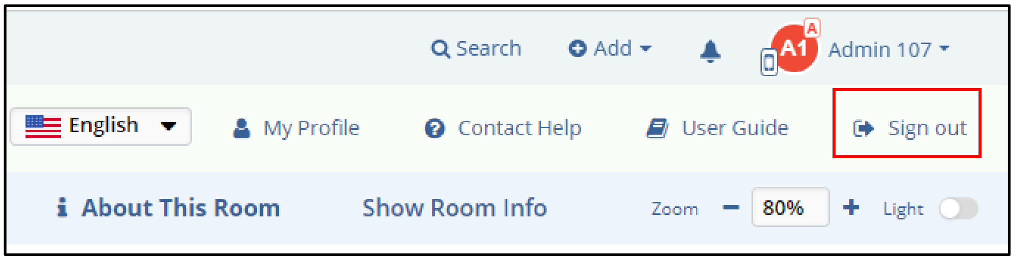


Figure 23: Sign out

Chapter 5. User Management

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

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

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

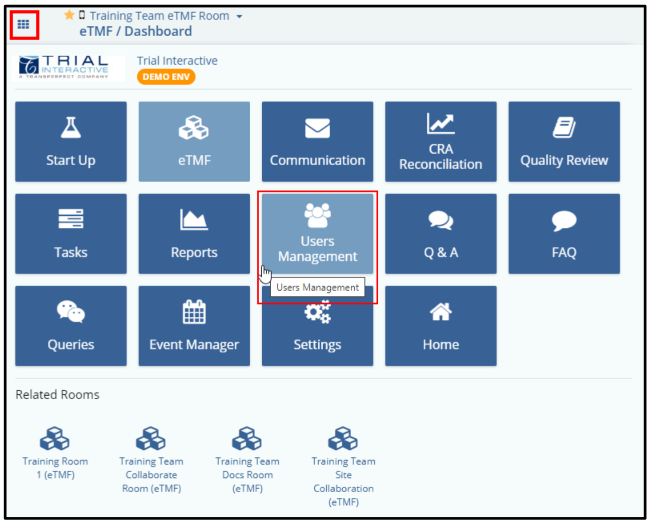


Figure 1: Navigation Grid

Users Management – User

From this page, you can do the following:

1. Invite users
2. Edit user profiles
3. View user access to the room
4. Export user data

Viewing Users

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

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

1. Click the **View By** dropdown menu in the left panel.
2. This opens the menu with the list of categories available.
3. Select the category you want to use while viewing the room's users.
4. Click **Select** located at the bottom of the popup window.
5. There are two options to set the view by default.
    - **Set Default**: Clicking the **Set Default** checkbox user can set the default view for the same room.
    - **Set Default for All Rooms**: Clicking the **Set Default for All Rooms** checkbox user can set the default view for all rooms.

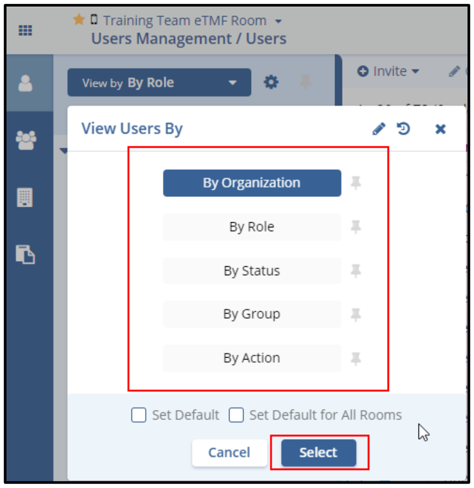


Figure 2: View By

6. The category and the list of users grouped under the categories are displayed in the Index Pane. The screenshot below shows the room administrator-level users with a 'By Role" view applied.

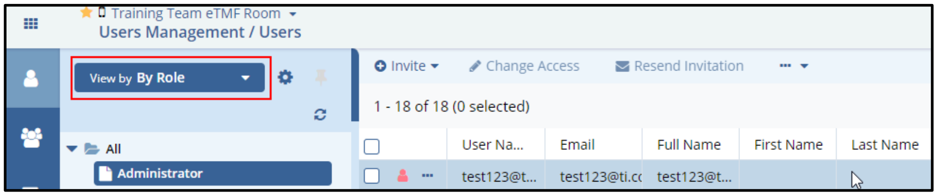


Figure 3: View by Role

User can **'pin'** existing views using a pinned icon is added to the 'view by' menu. This allows users to select which views they prefer rather than always having to choose from all of the available views. Once pinned, when clicking on the '**View by'** dropdown menu, users are presented with only those views they have pinned, providing a faster way to switch to their preferred views Documents module. This can be modified at any time.

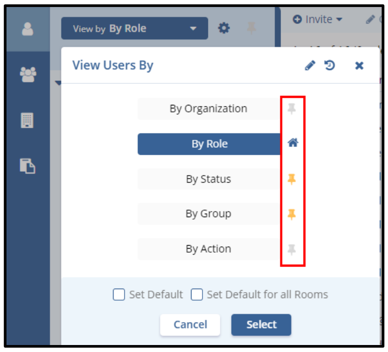


Figure 4: Pinned View

Inviting New Users via the Regular Invitation

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

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

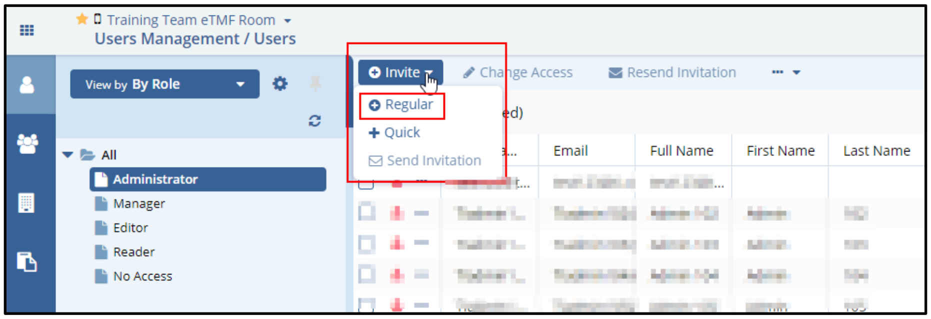


Figure 4: Regular Invitation

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

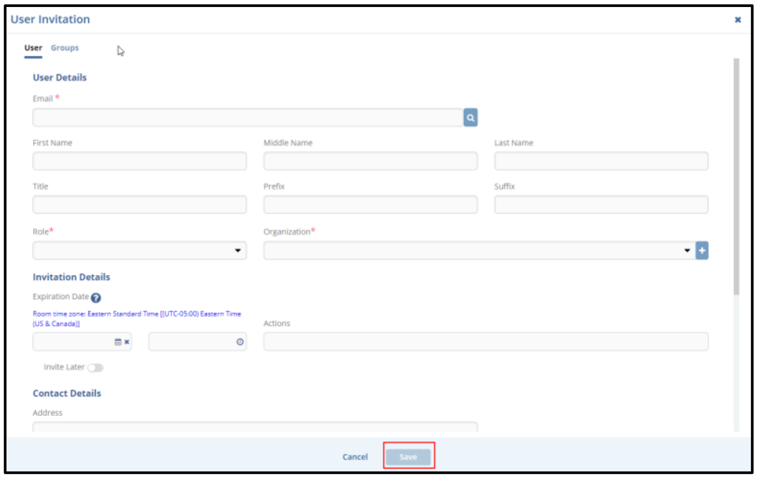


Figure 5: User Invitation Page

User Profile Fields

<u>The fields of importance are discussed below:</u>

- User Email: This is used as a unique identifier to log in to Trial Interactive. This can be typed in or, in the case of users who are already in the system, searched by clicking the magnifying lens icon at the end of the field.
    - If you type in an email address that does not adhere to an email ID format, you will receive a validation error message asking you to enter the correct one.
- Role: Choose the role from the dropdown.
- Actions: These are tasks that the user would be allowed to perform in addition to the basic rights associated with their user access role.
- Expiration Date: Enter this date if you want the user's access to be revoked on a certain date.
- Organization: Choose from the dropdown the organization to which the user belongs. The Administrator can also create an organization, if not available from the list, by clicking the '+' sign at the end of the textbox.
- Invite Later: Click the toggle bar if you want to create a user for the room but do not want to send the invitation yet.
- Regulatory Agency Inspector: Users who are invited as Regulatory Agency Inspectors will have reduced access to the multiplicity of dashboards and modules that regular TI users need to be trained on prior to granting system access. These users will only have access to the Quality Review module and the FAQ module and will, therefore, require significantly less initial training than a standard room user.

Inviting New Users via the Quick Invitation

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

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

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

Refer to the screenshot below:

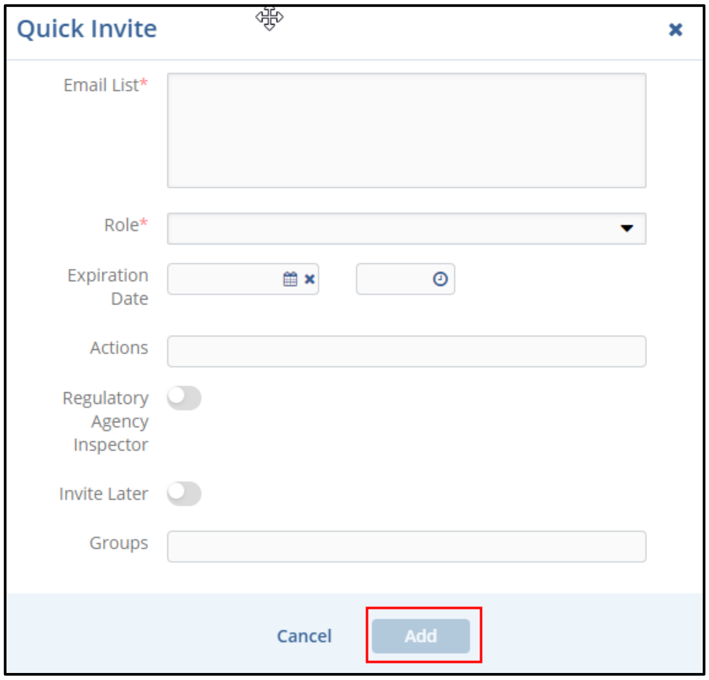


Figure 6: Quick Invitation Page

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

Editing a User's Profile

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

- Double-click on the user in the list of users displayed.
  - This will open the user's profile in a new window.
- Select the user from the list of users displayed and use the right panel.
  - You may need to open the panel on the right side of the screen if it does not open automatically.

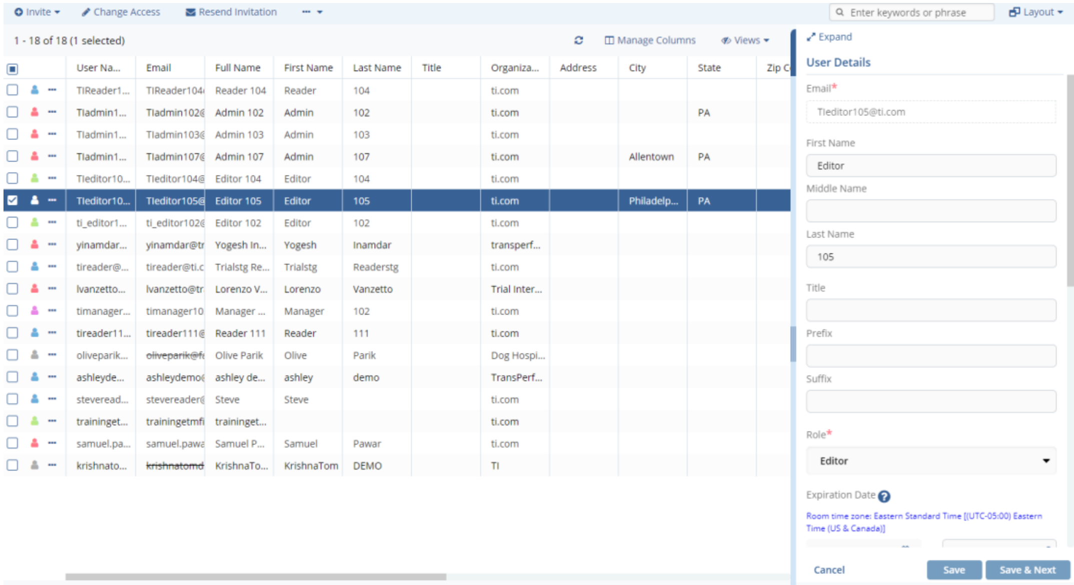


Figure 7: User edit option 2

- Use the three dots on the user's grid entry to open the menu of actions associated with user accounts.

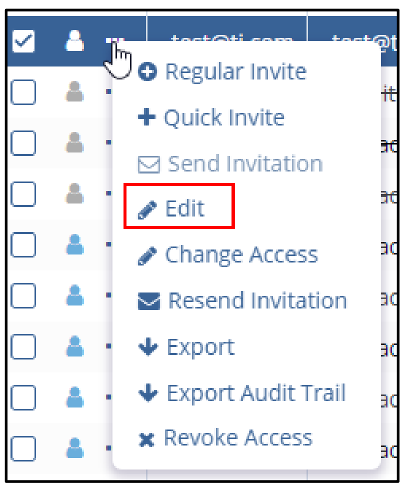


Figure 8: User Edit option 3

- Select the user from the list of users displayed and click the three-dot menu above the grid to expand the list of menu items.
    - Once the menu opens, select "Edit"

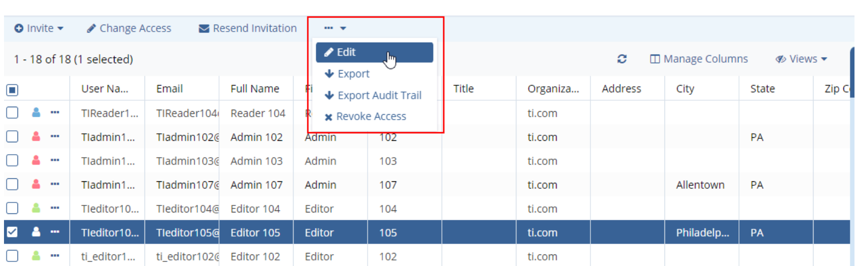


Figure 7: User Edit option 4

- Select the user from the list of users displayed and click “Change Access” from the menu ribbon above the grid.
    - This does not open the user profile but does provide an opportunity to adjust the user’s general access privileges and can be used to edit multiple users at once.

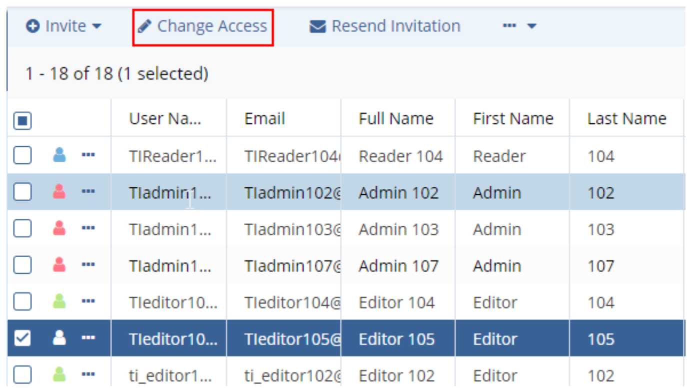


Figure 8: User Change Acess

Make whatever changes are required and press the **Save** button to finalize them.

Resending an Invitation

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

<u>To resend an invitation:</u>

1. From the left pane, select the preferred category to view the users.
2. From the list of users displayed in the right pane under the selected category, tick the checkbox for users to whom you want to resend the invitations.
3. From the top ribbon bar, click the Resend Invitation icon. A popup window will appear asking you to confirm.

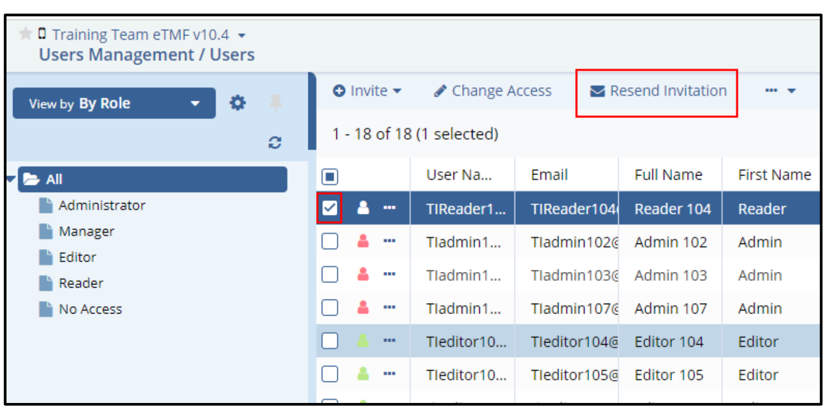


Figure 9: Resend Invitation

4. Click the **Yes** button.

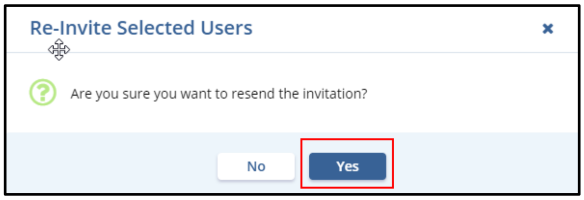


Figure 10: Re-invite Confirmation

5. The invitations will be resent to the selected users and a confirmation notification will appear.

Figure 11: Notification Message

Exporting User Information

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

Exporting Selected User Profile Information

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

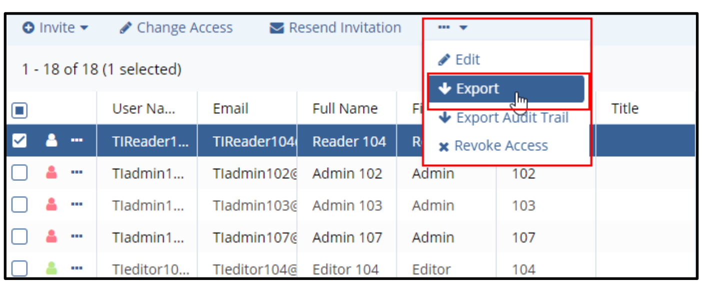


Figure 12: Export

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

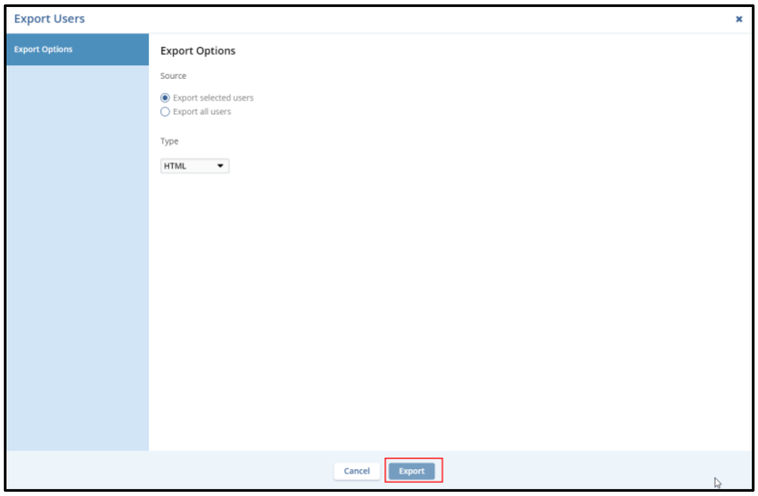


Figure 13: Export Option

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

Figure 14: Notification Message

Exporting user Audit Data

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

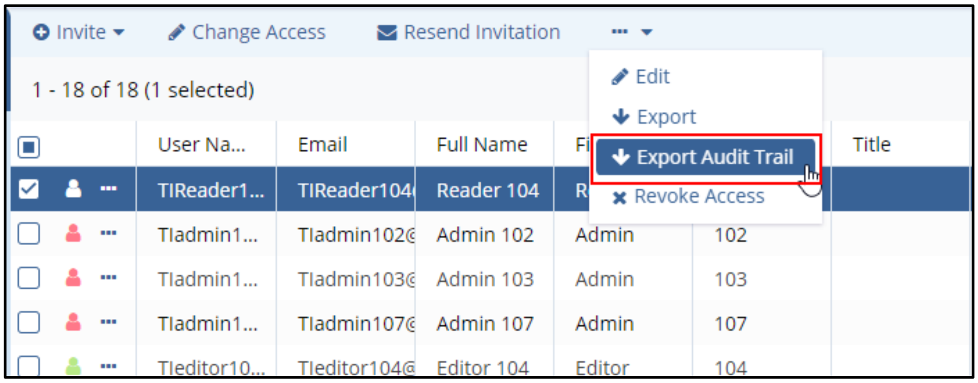


Figure 15: Export Audit Trail

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

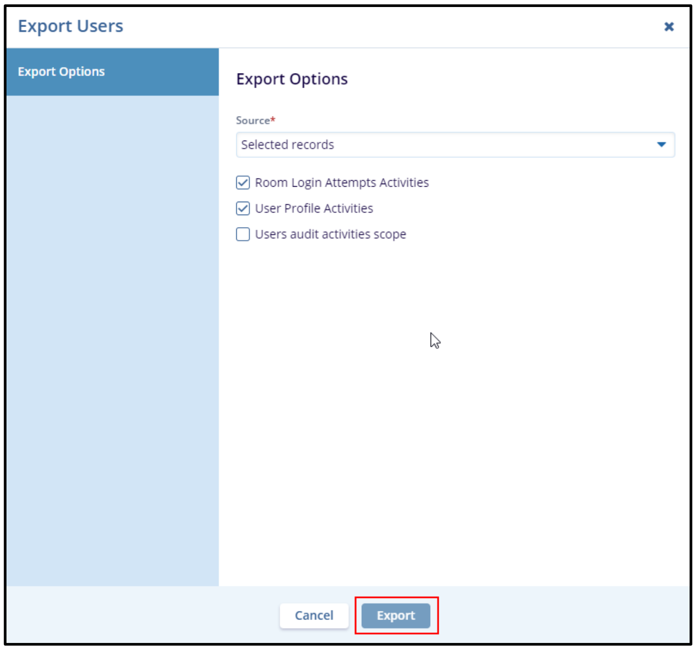


Figure 16: Export Options

User Management - Groups

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

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

Groups are used to grant users access to particular folders, files, and actions. From the Groups area, room administrators can do the following:

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

Adding a New Group

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

1. From Users Management, click the Groups icon from the left menu.
2. To add a new group, click the **Add Group** button from the left pane.

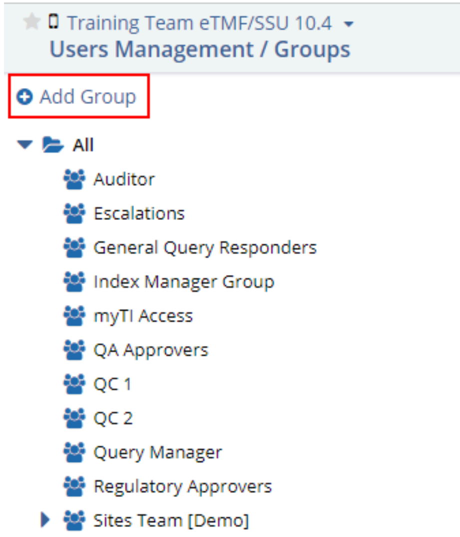


Figure 17: Add Group

3. The Create new group window opens. Refer to the screenshot below:

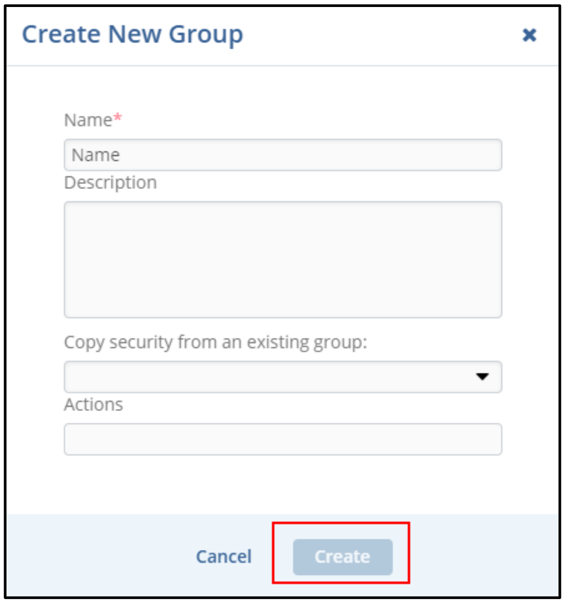


Figure 18: Create New Group

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

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** that members of the group can perform by selecting from the list of actions in the dropdown menu.
6. Click **Create**. The new group appears in the Groups list with no users assigned to it.

Adding a Child Group

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

Follow the steps below to create child groups:

1. Click the arrow to the left of All Groups to expand groups and select the parent group from the list to which you want to add the 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.

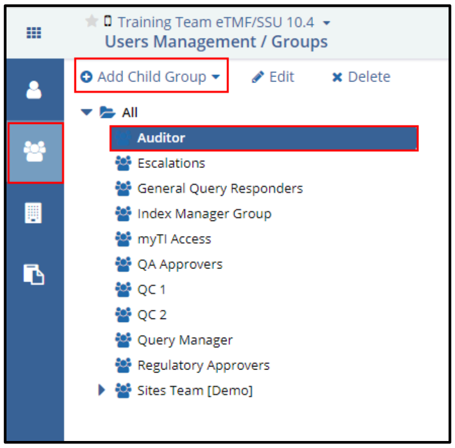


Figure 19: Add Child Group

3. Click the **Add Child Group** Drop-down from the top menu. There are two options for groups.
   a. Add New Child Group
   b. Add Existing Child Group

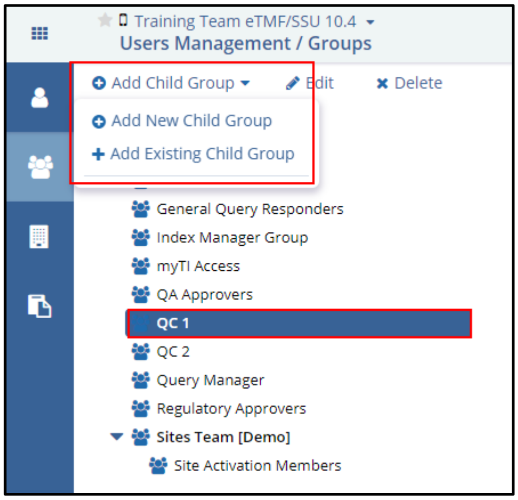


Figure 20: Add New Child Group

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

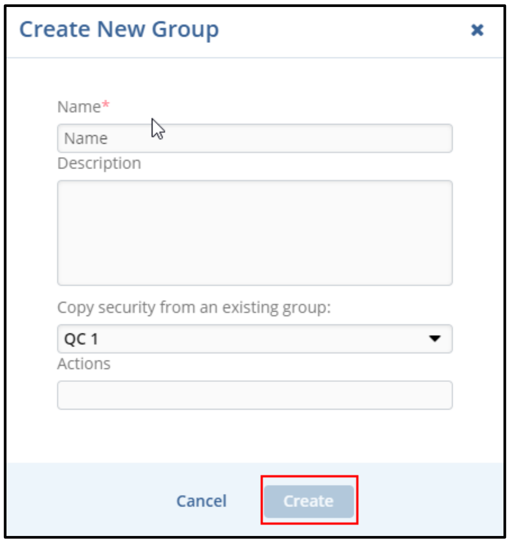


Figure 21: Create New Group

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

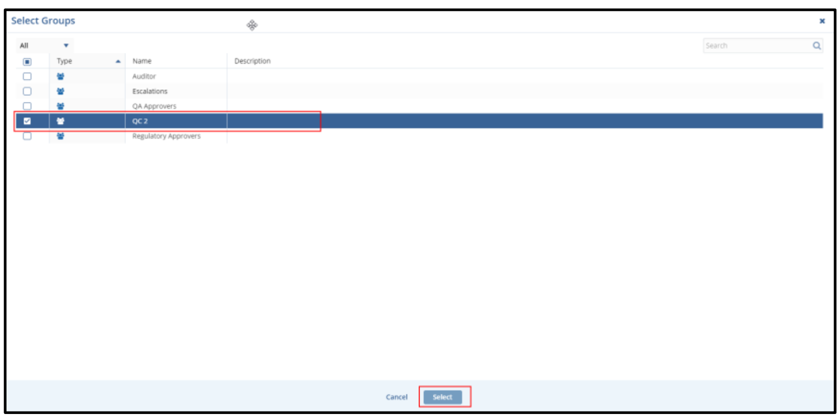


Figure 22: Select Group

Editing a Group

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

Follow the steps below to edit a group:

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

5. Click Save.

Refer to the screenshot below:

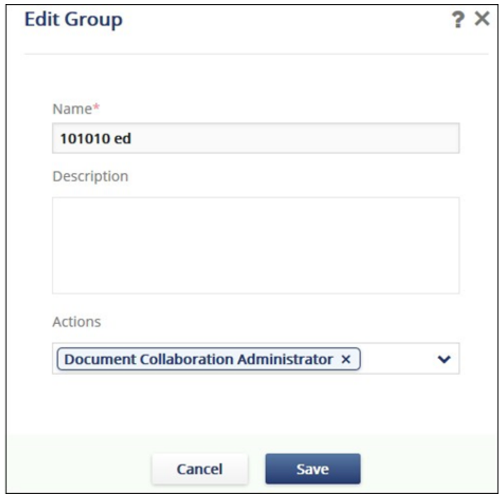


Figure 23: Edit Group

Deleting a Group

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

<u>Follow the steps below to delete a group:</u>

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

Click the **Yes** Button to confirm.

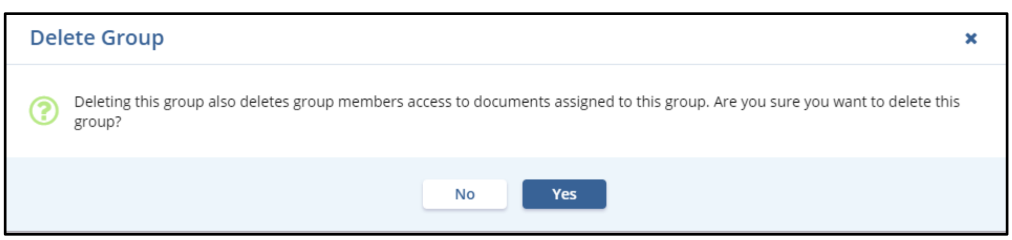


Figure 24: Delete Group

Adding Users to a Group

Follow the steps below to add users to a group:

1. Navigate to the **Users Management** > **Groups** icon from the left pane.
2. Select the required group from the Index pane. The list of users appears in the right pane.

3. Click **Add User to Group** option from the top menu bar to add the user to the group.
4. The Select Users window opens up.
5. Select the users you wish to add to a group and click '**Select**.' The users will be added to the group.

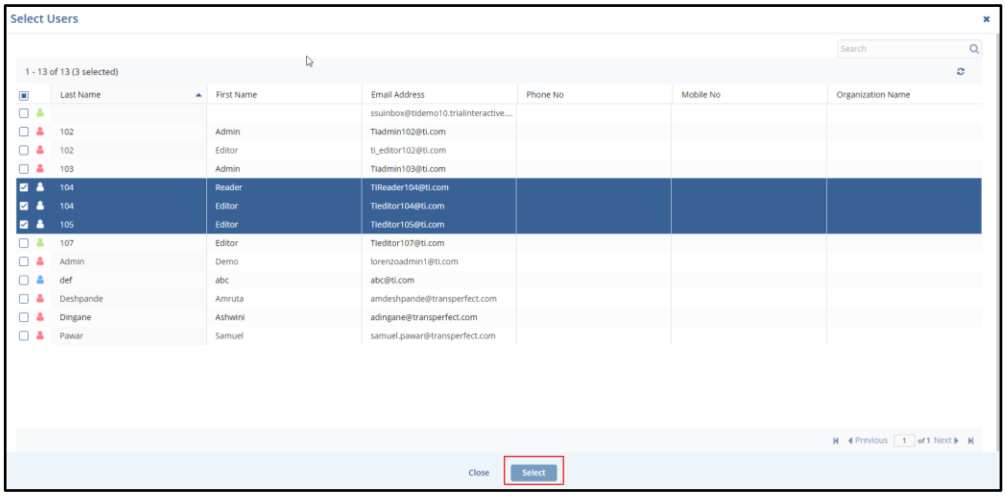


Figure 25: Select Users

Editing and Deleting Users from a Group

Editing User in a Group

Users in a group can be edited by selecting the user from the list of group members and clicking Edit from the top menu. Follow the on-screen instructions to edit the user details.

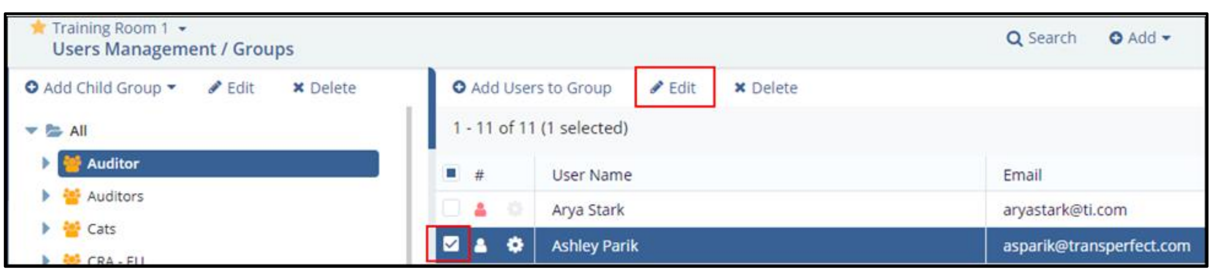


Figure 26: Edit User

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

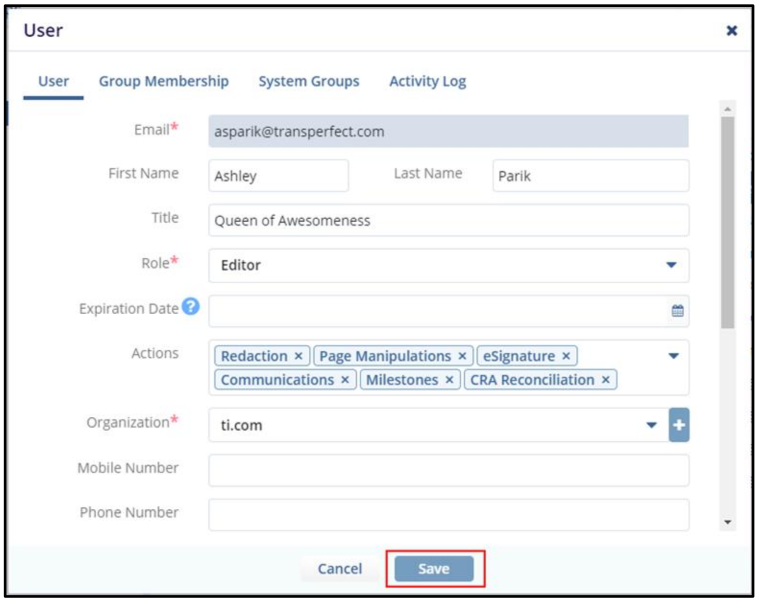


Figure 27: User Edit Page

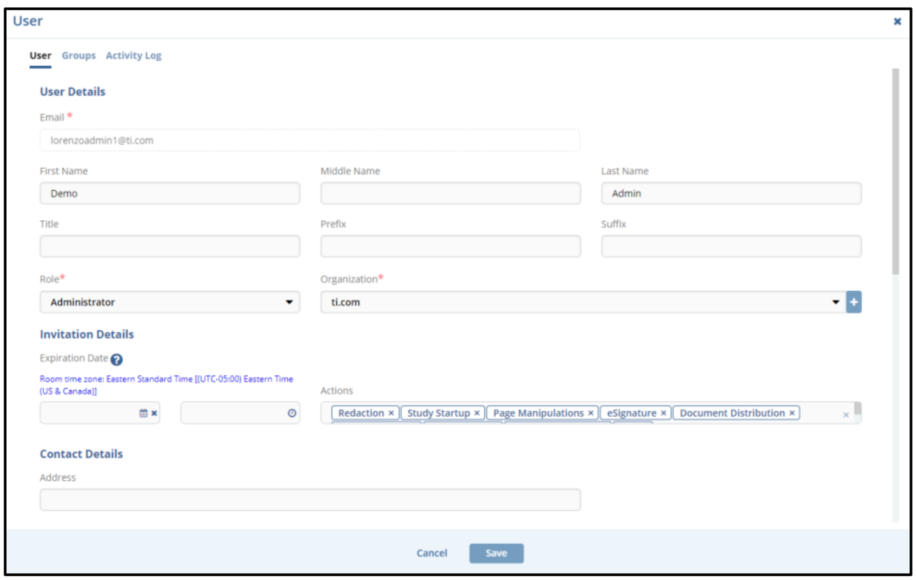


Figure 27: User Edit Page

Deleting a User from a Group

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

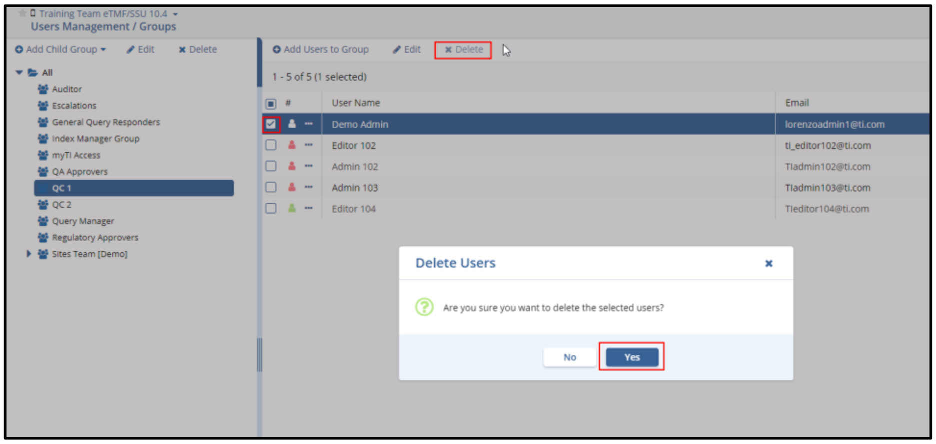


Figure 28: Delete Users

Adding a User to the General Query Responders Group

There is a system-generated group called **General Query Responders** available in the Groups area of the Users Management module. Administrator-level users will be able to add any Editor or Administrator-level user to this group. Readers are not eligible for inclusion in this group. Members of this group will be responsible for responding to general queries created by other room users.

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

The Query Manager Group

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

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

Chapter 6. Room Settings

Access the Room Settings from the Navigation Grid by clicking the Settings tile.

Refer to the screenshot below:

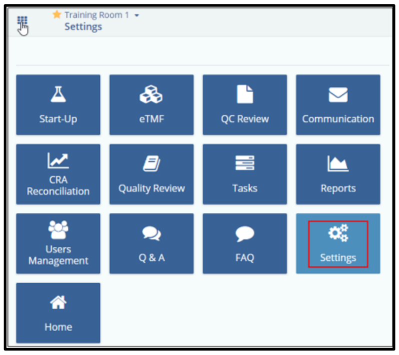


Figure 1: Setting Module

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

Refer to the screenshot below:

Figure 2: General Tab

General Setting

About

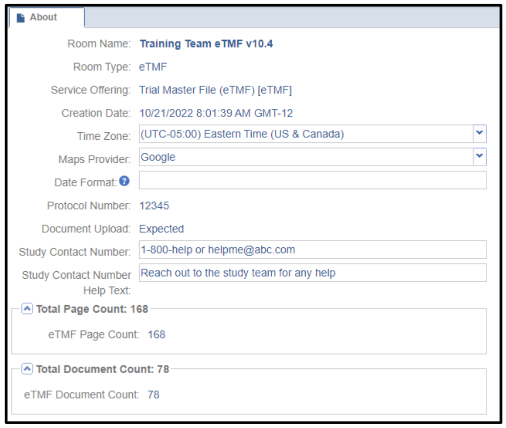


Figure 3: About

This window displays the room's **name, room type**, and **creation date** among other details. Here, you can add a phone number for the Study contact person. You can click on the expand icon to view details. Be sure to save any changes you wish to keep.

In TI v10.5 new fields are added **Service Offering, Map Providers, and Total Page Count.**

About This Room

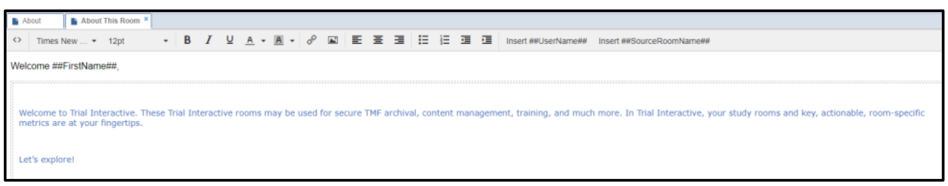


Figure 4: About this Room

In this window, the user can see and change the information contained in the room's welcome message, which is the message that all users see when they first access the room. This space can also be used to share important information about the study once the study is in full swing. Once you have made the desired changes, click Save in the lower-left corner of the box.

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

Instructions

Instructions under general settings can be filled out by administrator-level users. By doing so, this portlet will give 'instructions' to users on their first entry to the room.

Organizations List

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

Organisations that currently have users assigned to them cannot be deleted. To delete an organization, you may have to go to Users Management and reassign any users to another organization before proceeding.

Data Grid Navigation

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

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

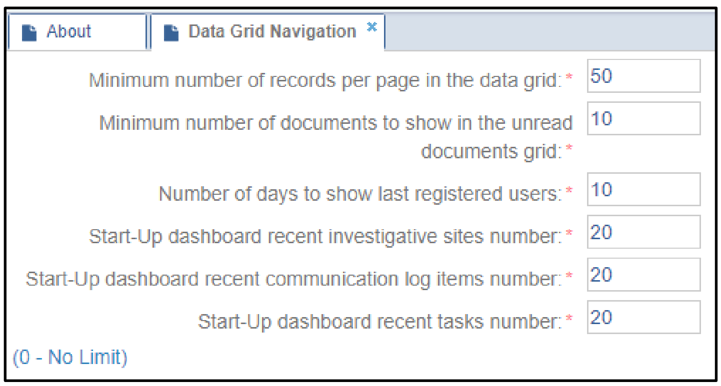


Figure 5: Data Grid Navigation

Machine Translation

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

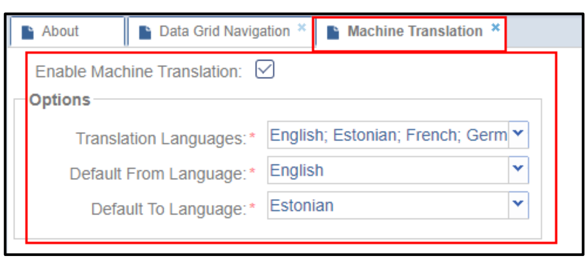


Figure 6: Machine Translation

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

Event Manager Settings

Event Types

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

Common Event Configuration

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

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

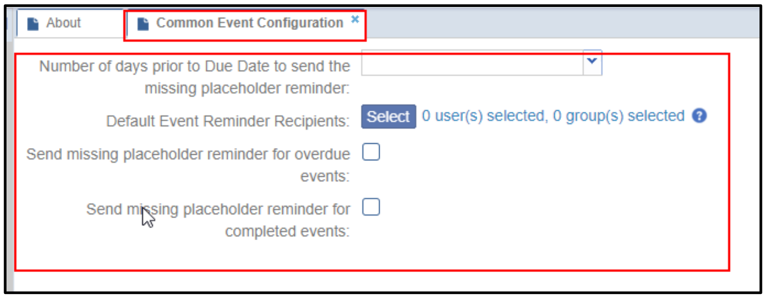


Figure 7: Common Event Configuration

TransPort Integration

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

Inbox Settings

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

Navigate to Navigation Grid->Settings->Inbox.

Refer to the screenshot below:

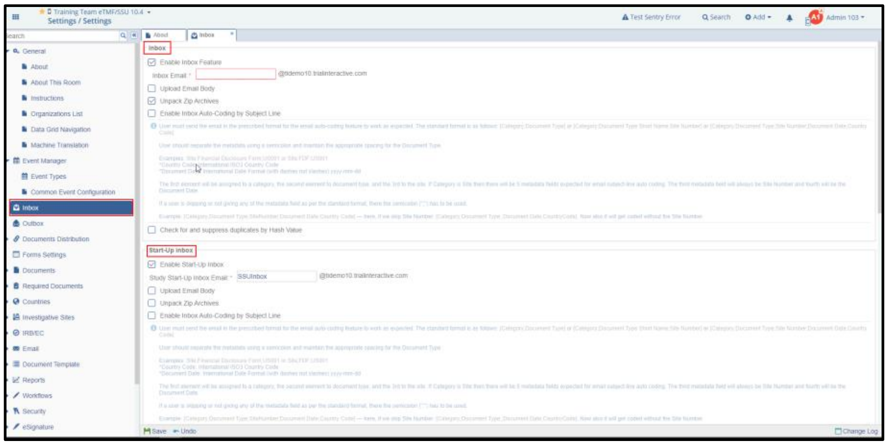


Figure 8: Inbox

Figure 8: Inbox

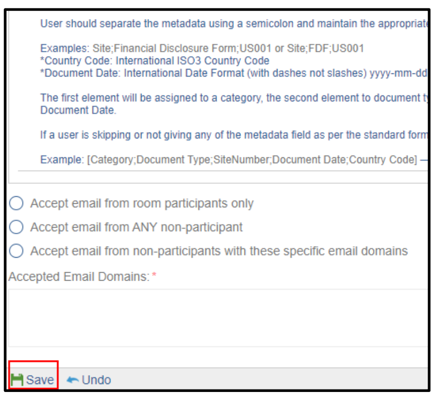


Figure 8: Inbox

Inbox and Start-Up Inbox Options

- Room administrators can enable the Inbox by ticking the checkbox to make it possible for room participants to send trial documents directly to the room's inbox.
- Ticking the checkbox of the 'Convert Email Body' option will automatically convert the emails that enter the Inbox into PDFs.
- Choose 'Unpack Zip-Archives' to extract files from an attached zip folder.

- The ‘Enable Inbox Auto Coding’ option allows users to send emails into the room with subject lines formatted along certain guidelines so that the document is received with certain metadata already applied to it.
  - Hover over the blue circle “Tool Tip” to see specific requirements.
- To prevent duplicate publishing of email-converted documents to the room, activate the ‘Check for and Suppress Duplicates by Hash Value’ option

Communication Inbox Options

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

Email Sender Options

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

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

Outbox Settings

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

Documents Distribution Settings

Users can be allowed to share documents from one room to another. This function will create a copy of the document in a target room which is still functionally linked to the source document. This is most commonly utilized when publishing documents from a TI Content Management room. Any versioning of the shared document would be shown in the target room once the new version became effective in the source room.

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

Common Configuration

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

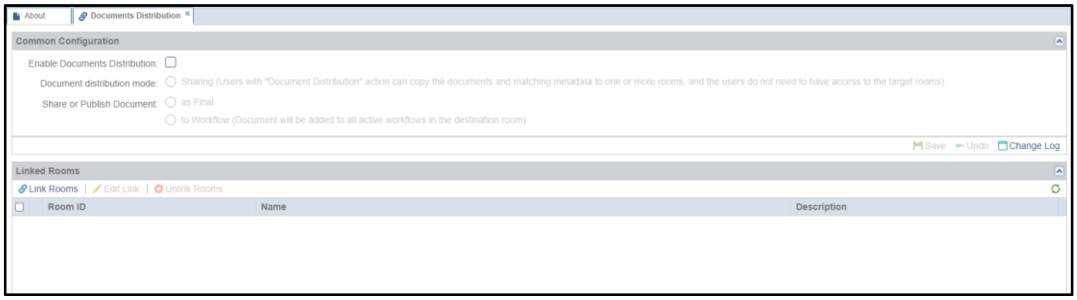


Figure 9: Document Distribution

Forms Settings

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

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

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

Figure 10: Forms Settings

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

- Adding a Custom Field
- Editing a Metadata Field
- Deleting a Field
- Setting Advanced Validation Fields
- Order Filters Fields
- Show TMF from Fields

Adding a Custom Field

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

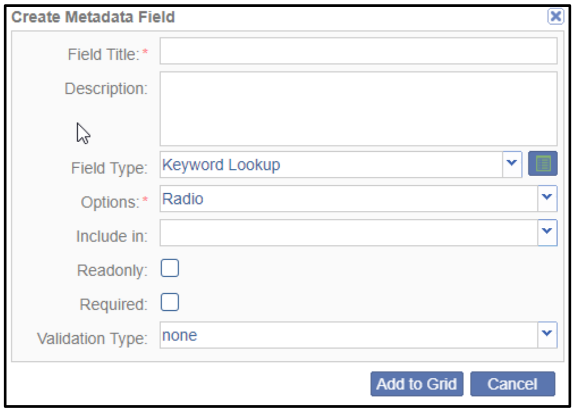


Figure 11: Create Metadata Field

3. Select the most appropriate option:
    a. **Checkbox** – the values entered display as a list and users can choose one or more
    b. **Radio** – The user must choose only one value from the list
    c. **Combo** – users can choose only one value from a dropdown list
4. Click the '**Include in'** dropdown arrow and select the appropriate option.
    - The options in this menu correspond to the options on the Forms Settings grid.
5. Click the **Read-only** checkbox if required.
6. Click the **Required** checkbox if necessary.
7. The **Validation type** field is dependent on the Field Type. For instance, if the Text Field Type is selected, you might restrict the entries made there to alphabetical characters or alphanumeric characters.
8. Click '**Add to Grid'**. The view returns to the full Document Profile Form display.
9. Press '**Save**' if you wish to keep the new field.

Editing a Metadata Field

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

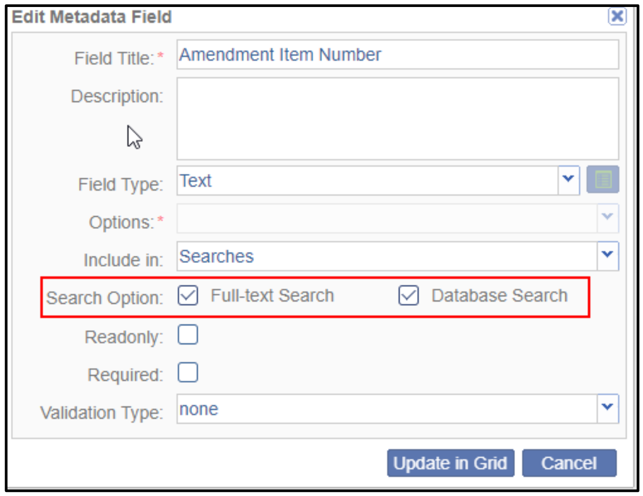


Figure 12: Edit Metadata Field

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

In this version, a new feature is added Search Option: Full text Search Database Search.

Deleting a Field

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

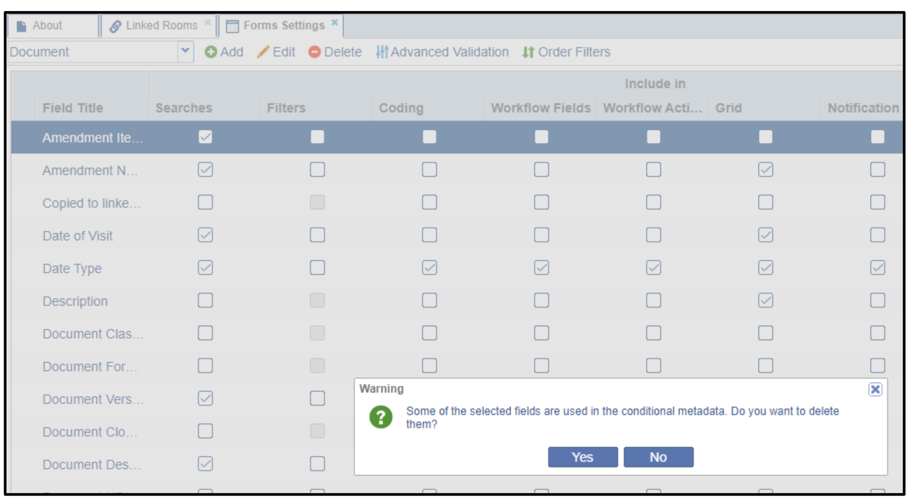


Figure 13: Deleting Field

Setting Advanced Validation Fields

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

1. Click Advanced Validation in the menu ribbon. The Edit Advanced Fields validation window opens. Refer to the screenshot below:

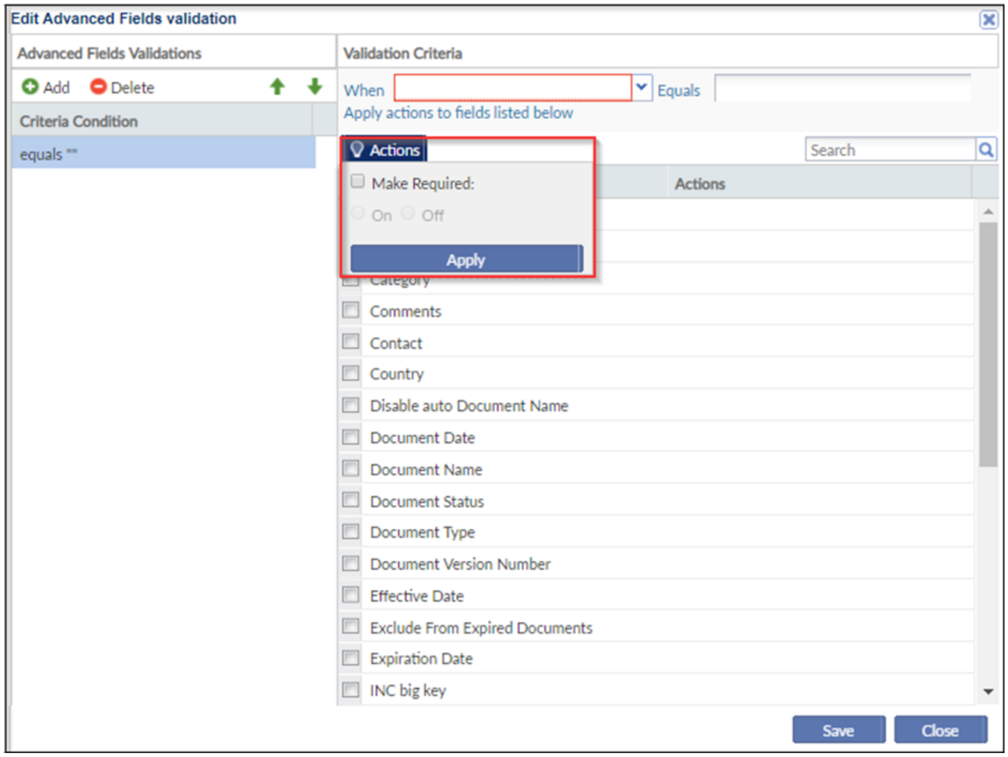


Figure 14: Edit Advance Fields Validation

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 field.
4. Complete the 'Equals' field.

   Note: For fields for which the field data must be selected from a particular set of options, you need to choose from the dropdown menu of selections. For date-related metadata fields, the 'Equals' field converts to a calendar selection. For some metadata fields, the 'Equals' field is a textbox.

5. Click the 'Actions' button. Select the appropriate radio button to define what action will be implemented in the field or fields that will be selected in the next step of the process.
6. Click the checkbox or checkboxes for the field or fields that you want to be affected in this field validation.
7. Click Save. The selected Action will apply to the selected Fields when the Validation Criteria you have set are met in a particular document's metadata.

Type-Ahead Fields

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

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

General Integration

By default, all documents uploaded into the system will take their 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, upon being uploaded, would then move directly to the related folder assigned to their document types and acquire the status as final. Refer to the screenshot below:
3. Navigate to the Navigation Grid->Settings--> General Integration.
4. Tick the checkbox to upload documents as Final
5. Tick the checkbox to skip validation of the duplicated document name.
6. Tick the checkbox to **Accept documents without the required Metadata.**

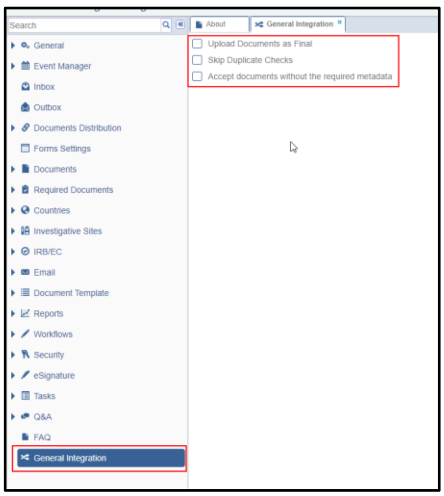


Figure 15: General Integration

Documents

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

Documents Module

Auto Purge Settings

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

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

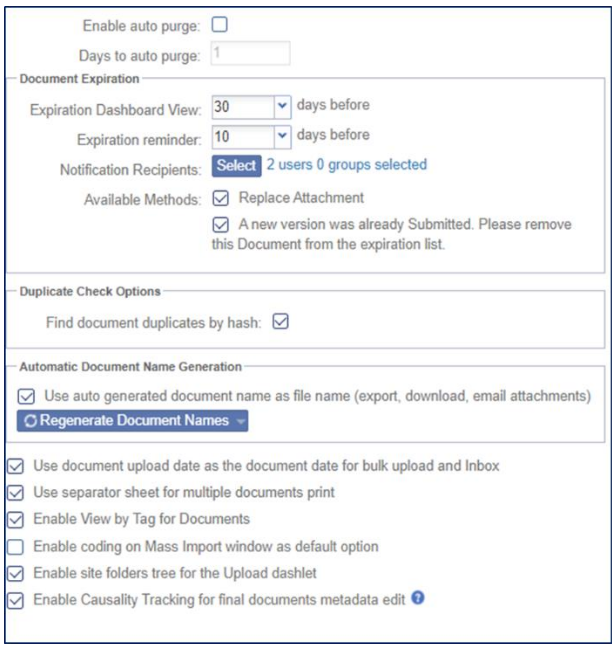


Figure 16: Documents Module

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

Document Expiration Settings

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

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

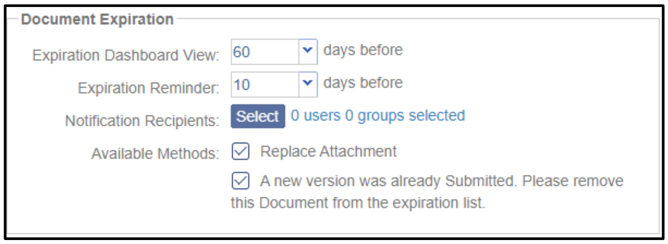


Figure 1: Document Expiration

- The **Expiration dashboard view** field controls how much lead time users will have to see and act upon an expiring document before its actual expiration date.
- The **Expiration reminder** field controls when reminder emails should be sent regarding documents that will be expiring soon.
- Click Select from the **Notification Recipients** field to select users/groups who should receive a notification email.
- The **Available Methods** area allows room administrators to choose which options are available to their users in the Expiring Documents dashlet.
  - Replace Attachment will allow users to replace the file attached to the existing metadata. All versions of the document will be visible in the 'Versions' tab of the metadata panel.
  - The 'A new version was already Submitted. Please remove this Document from the expiration list' option indicates that another version of this document has been submitted to the room as a separate document and that the expiring document should be removed from the list of expired/expiring documents.

Duplicate Check Options

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

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

Figure 17: Duplicate Check Options

Automatic Document Name Generation

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

Document Upload Date as Document Date

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

- Enable the Use document upload date as the document date for bulk upload and Inbox option by ticking the checkbox.
  - Now, the upload date will automatically be assigned as the document date in the document profile.

Use Separator Sheet for Multiple Documents Print

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

Enable View by Tag for Documents

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

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

Enable coding on Mass Import Window as Default Option

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

Enable Site Folders Tree for the Upload Dashlet

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

Enable Causality Tracking for Final Documents Metadata Edit

Administrators and Document Manager users can alter metadata for final documents in a study room. Enabling this option has two effects:

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

Document Replacement Reasons

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

Navigate to Navigation Grid->Settings -> Document -> Document Replacement Reasons.

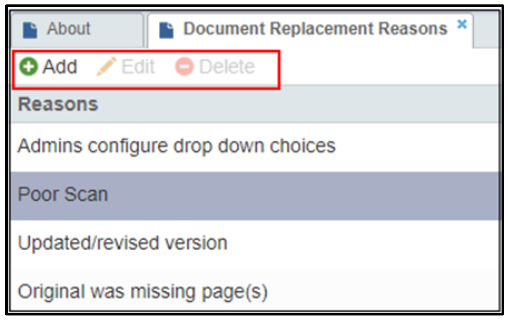


Figure 18: Document Replacement Reasons

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

Query Manager Options

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

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

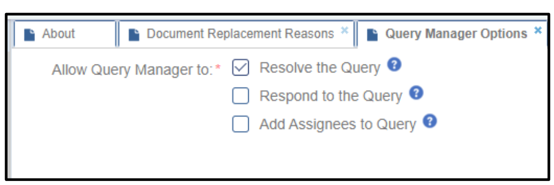


Figure 19: Query Manager Options

eTMF Health Settings

- The 'Check study site status for the eTMF completeness' option can be enabled or disabled here. When enabled, it allows the room to either include or ignore site document requirements based on the specific site status as configured in the document-type profile.

- The user can also choose when the system would consider a requirement as having been considered to be collected using the radio buttons on the screen.
    - ‘As soon as the document is submitted to the room’ would cause the room to indicate that a placeholder was fulfilled successfully as soon as a document was uploaded with the corresponding metadata.
    - ‘When the document’s QC review is completed’ would indicate that missing document placeholders could only be fulfilled by documents marked as ‘Final’ by the room’s QC Workflow.
- The option to ‘Exclude the sites with the following status from the eTMF completeness tracking’ would indicate that document requirements for sites in the chosen status would not be considered during the calculation of the room’s eTMF health.
- Administrators can also choose whether or not to include recommended (non-required) documents when calculating the room’s eTMF health.
- Finally, the user can set the refresh rate for completeness data, indicating how often the room calculates eTMF health.

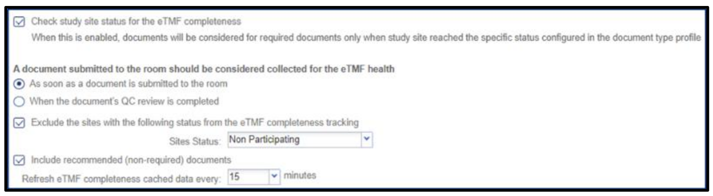


Figure 20: eTMF Health Setting

Index Outline

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

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

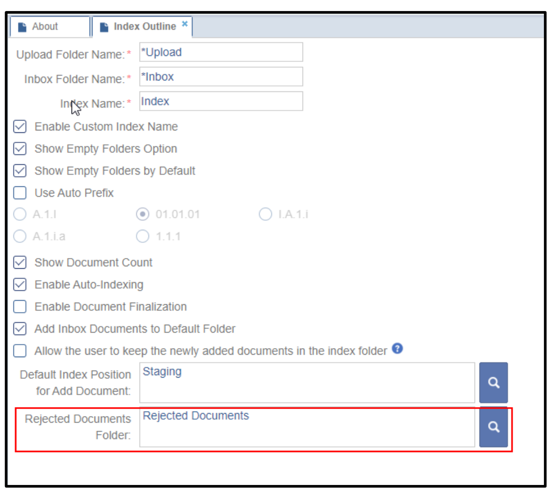


Figure 21: Index Outline

- All documents imported are populated in the Upload folder unless they have been assigned metadata during upload.

- The folders in a room index are numbered, and the subfolders follow a standard numbering system.
    1. These folder numbers are called as Folder Prefixes, whose settings can be decided from the Auto Prefix option.
    2. Activate or inactivate Auto Prefixing of folders in the room's index by ticking the Use auto prefix checkbox. Refer to the screenshot above.
    3. If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index.
    4. Auto prefixing inserts the desired prefix of numbers or letters to identify the levels of the folders in the index.
- Numbers after the folder names indicate how many documents are available to you in each folder. Check the 'Show Documents Count" option to enable these numbers on the room's documents module.
- Enable Auto Indexing to determine whether or not documents can be routed automatically to the correct index location as indicated in the related document-type profile.
- The default location for documents that have been uploaded with metadata assigned is indicated in the 'Default index position for Add document" field.
- A new feature, the Rejected Documents Folder with Search icon, has been added in this version.
    1. To add a Rejected documents folder click on the search Icon.

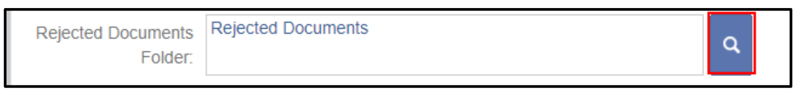


Figure 22: Rejected Documents

2. Select the folder that you want to add to in rejected documents folder. Click the **OK** button.

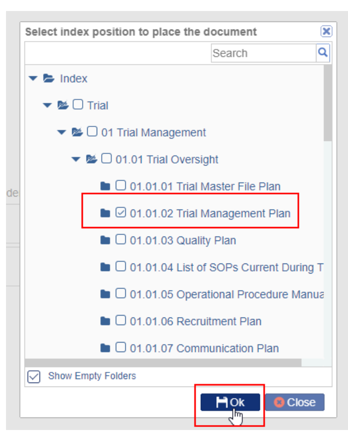


Figure 23: Index position

3. The file will be added to the **Reject folder** box.

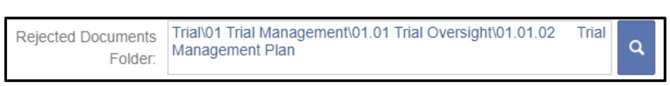


Figure 23: Rejected Folder

- Documents that are emailed into the room's inbox are typically stored in each user's Inbox folder, but this can be altered by choosing to enable the 'Add inbox documents to default folder' option which would then route all documents emailed to the room inbox directly to the default folder (Staging, in the screenshot above).
- Users can click and drag documents directly to any folder of their choosing depending upon access rights. Whether or not those documents stay in the index folder is determined by the final setting: 'Allow the user to keep the newly added documents in the index folder"

Non-PDF to PDF Document Conversion Settings

1. Navigate to Navigation Grid -> Settings -> Documents-> Document Conversion.
2. Tick the checkbox to Enable Non PDF to PDF conversion. Refer to the screenshot below:
3. Select the appropriate radio button to make the conversion, Manual or Automatic.
4. Edit the list of file types that can be converted.

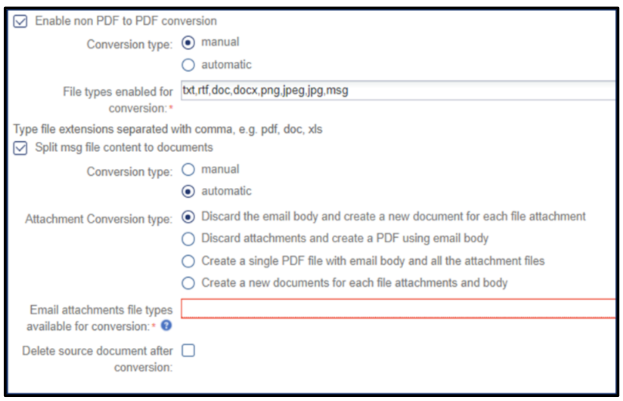


Figure 24: Non-PDF to PDF document

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

Document Certification

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

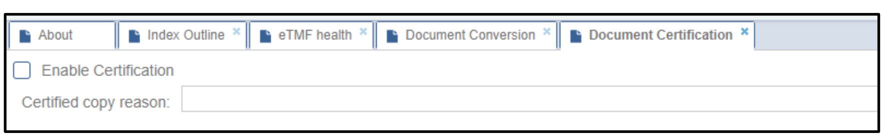


Figure 25: Document Certification

Document Types and Management

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

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

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

1. Navigate to Navigation Grid -> Settings.
2. Select Document Types from the menu on the left.
3. The Document Types option expands to reveal two sub-options:

    a. Document Types Management and
    b. Common Configuration.

4. Click and view each panel separately.

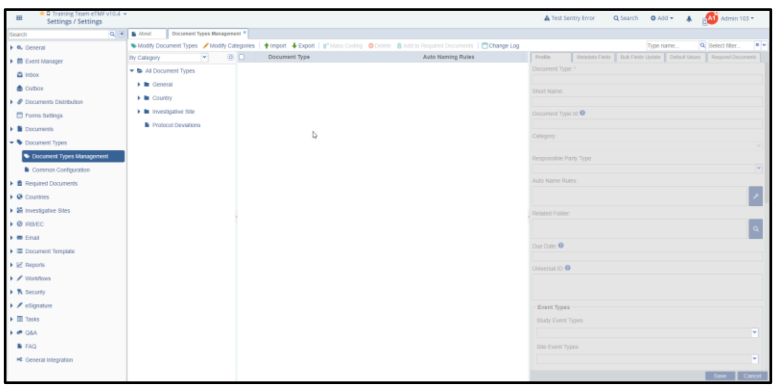


Figure 26: Document Type Management

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

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

- Modify Document Types
- Building the Document Type Profile
- Specifying the Related Folder
- Include Phases/Milestones
- Adding Document Types to Required Documents
- Include in Document Tracker Report
- Auto Document Type Prediction Keyword(s)
- Modifying Document Types Fields
- Default Values

Modifying Document Types

1. Click the 'Modify Document Types' option from the ribbon above the dashboard.
2. A new 'Modify Document Types' Tree' window opens, displaying the folder structure of Document Types in a tree view.

    a. Document Types can be added to the category folders, edited in their current positions, and deleted through this view. In the figure below, the Investigative Site folder is open, displaying the document types that are added in that category.

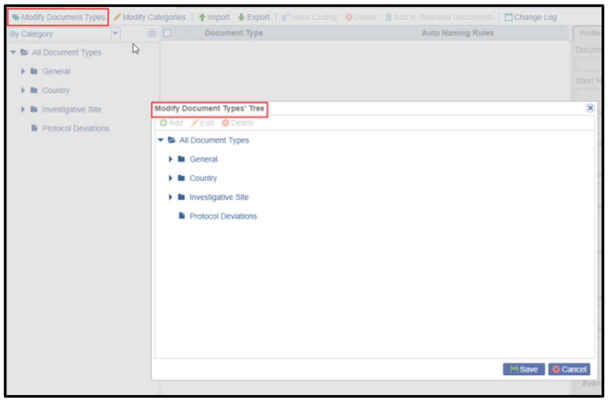


Figure 27: Modify Document Types

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

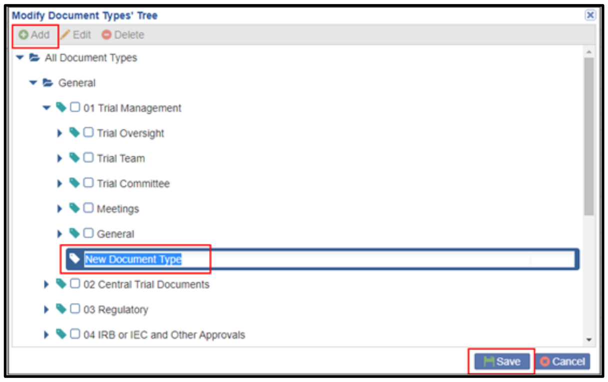


Figure 28: Add Document

3. Type the name of the new document type to be added to the category folder.
4. Press the Enter key. If you have more document types to add to this or other categories, you can repeat this process.

5. When you have added all of the necessary new document types, click ‘Save’ at the bottom of the window. That window closes, and you return to the primary Document Types view. The document type that you have just created has now been routed to a proper index position. Refer to the screenshot below:

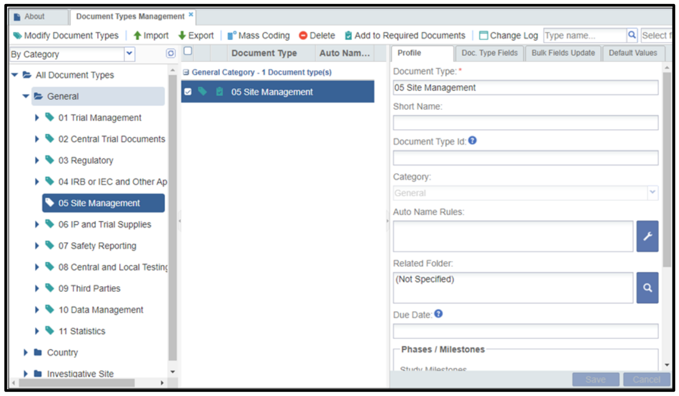


Figure 29: Site Management

Building the Document Type Profile

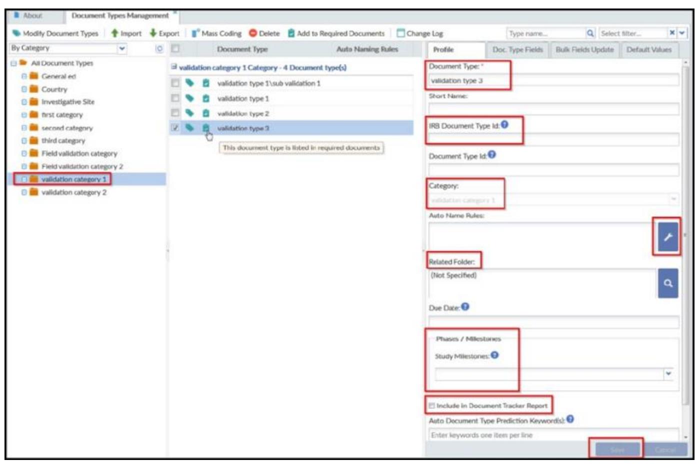


Figure 30: Document Type

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 the Site ID and IRB Number that is required by the system for IRB Integration. This field will be available only if IRB Integration is enabled in the room. This field can accept multiple values separated by semi-colon and should be unique within the document type category.
4. The Category has already been assigned by your first steps of creating the new document type.
5. Click the wrench icon next to the Auto Name Rules field. When the metadata gets filled out for documents of this type, the auto-naming rules you set up here will be applied to these documents. All initial document types and auto-naming rules are determined by the configuration manual. An Auto Name Rules window opens. Refer to the screenshot below:

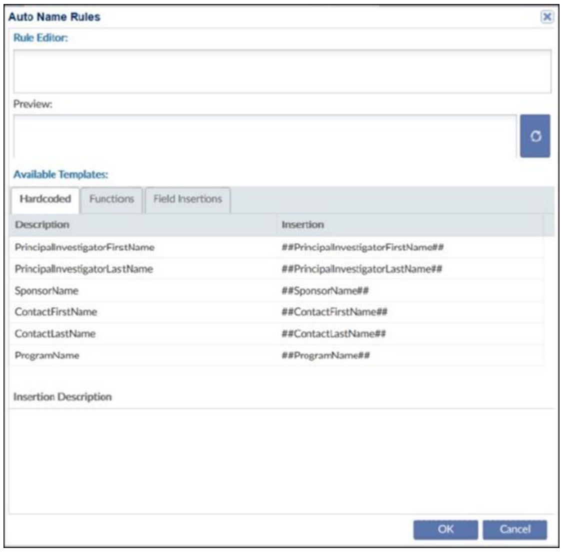


Figure 31: Auto Name Rules

The following set of instructions describes the insertion of a standard set of fields for the 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 the Sponsor's Name.

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

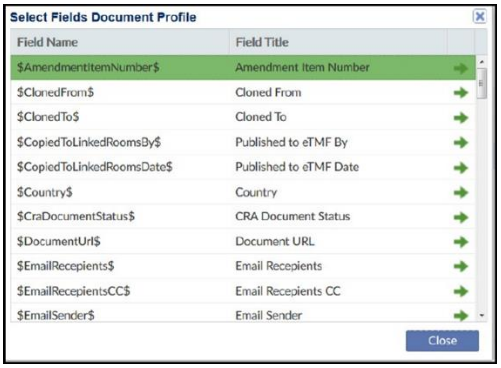


Figure 32: Select Fields Document Profile

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

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

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

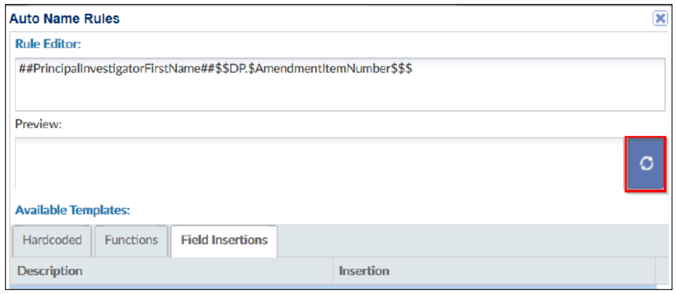


Figure 33: Auto name Rules

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

Specifying the Related Folder

1. In the Profile tab in the panel on the right, click the magnifying glass icon next to the Related Folder box. A window opens, displaying the folders available for assigning the new document type.

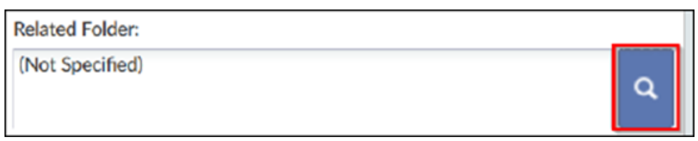


Figure 34: Related Folder

2. Select the proper folder or subfolder for the document type. In this example, we have chosen the Relevant Communications folder.

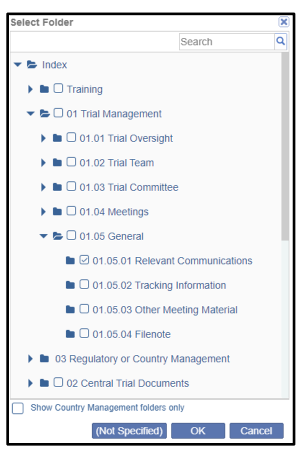


Figure 35: Select Folder

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

Doc Type Fields

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

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

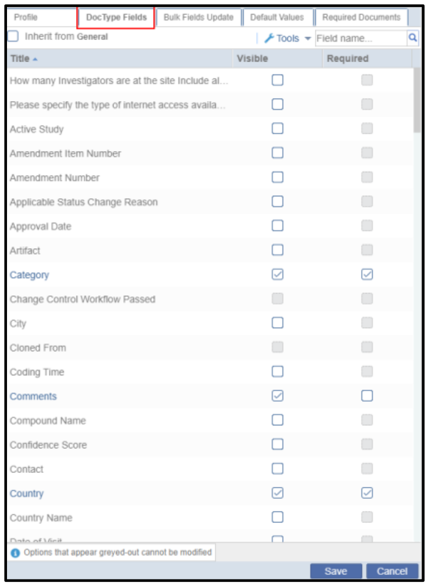


Figure 36: DocType Fields

Adding Document Types to Required Documents

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

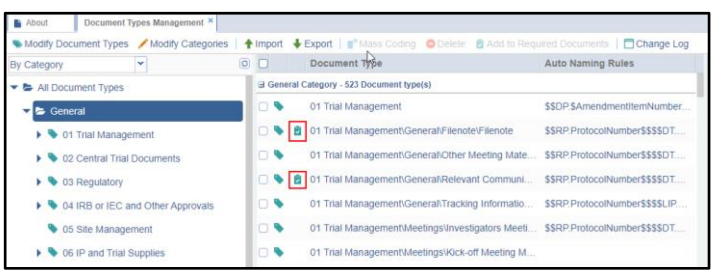


Figure 37: General

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

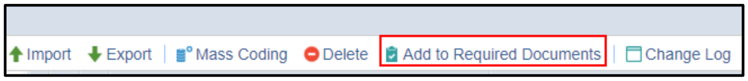


Figure 38: Add to Required Documents

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

Include in Document Tracker Report

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

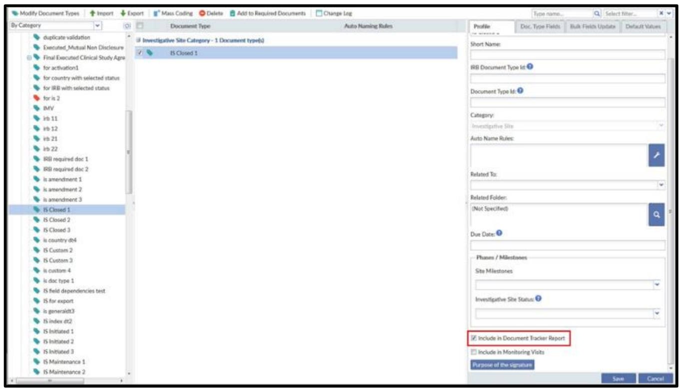


Figure 39: Document Tracker Report

Reference Metadata

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

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

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

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

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

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

Default Values

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

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

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

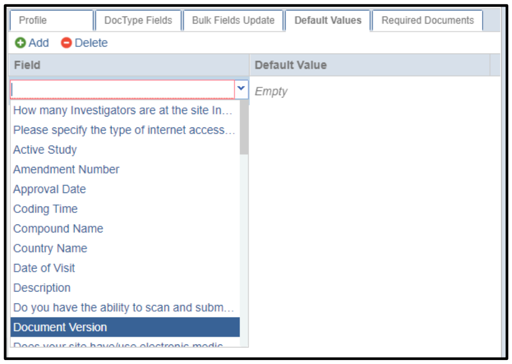


Figure 40: Default Values

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:

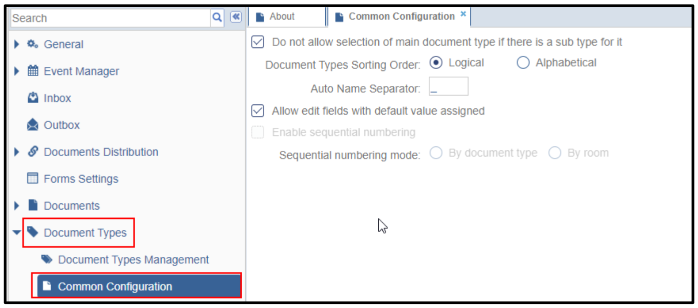


Figure 41: Common Configuration

- 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.
- In this version new checkbox is added to **Enable sequential numbering.** It allows sequential numbering with two options.
  - By Document type
  - By Room
- If you make any changes in this panel, click Save at the bottom of the panel.

Required Documents

With the help of Required Documents Settings, Administrators establish and edit the Required Documents for a study. Different document types may be required for all Investigative Sites involved in a study, or there may be documents that are required for 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 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.

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

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

Figure 42: Required Documents

Required Documents can be defined for the following:

- All Sites
- Country-Specific
- IRB/EC

Required Documents

1. From the left section of the panel, you can select the category (Sites, Country, IRB/EC, and General) of the Required Documents. By default, the All Sites category is chosen.
2. From the right section of the panel, named as Document Types, you can:
    a. Add or Delete a Required Document to the category selected from the left pane.
    b. Assign Milestones to selected Required Document Types.
    c. Assign Event types will help to enable Event Types.

Figure 43: Assign Event Types

    d. Document Type Profile display All fields shown in the screenshot below.

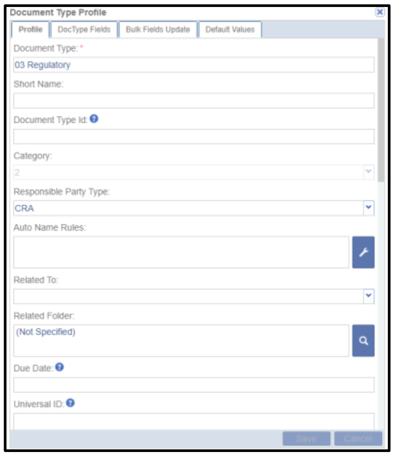


Figure 44: Document Type

    e. View the activity log of the selected category from the Change Log
    f. Once a Required Document is added, it appears in the Document Types Grid.

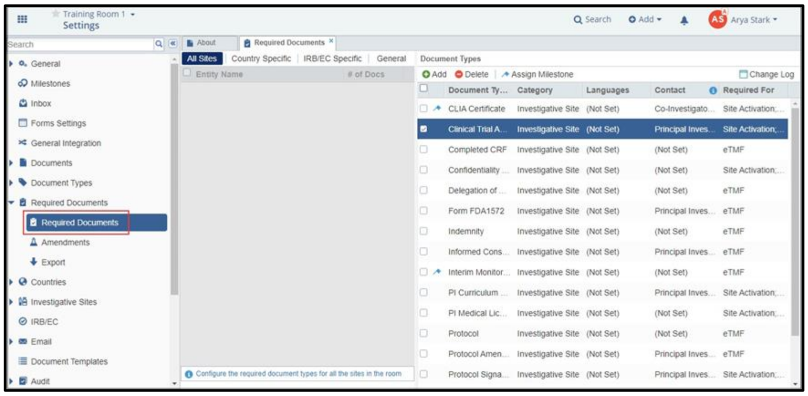


Figure 45: Required Document

Adding Documents to the List of Documents

1. Click the **relevant** tab from the left panel of the **Required Documents** menu.
    a. For Country and IRB/EC documents, pick the relevant country or IRB/EC.
2. Click **'Add'** from the top ribbon bar of the Document Types window on the right. Here, Refer to the screenshot below:

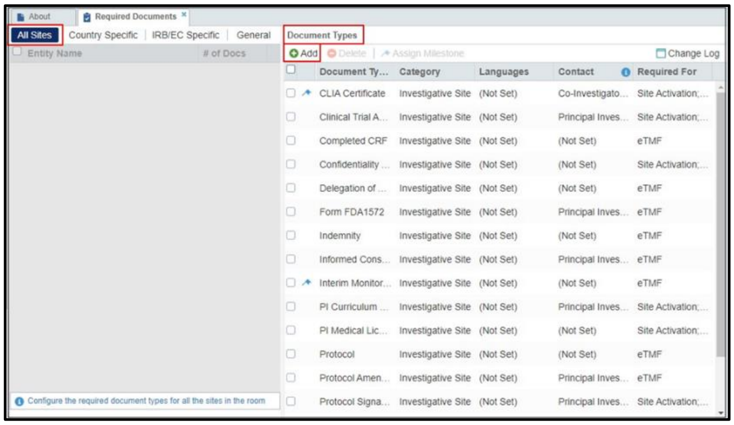


Figure 46: Adding Documents

3. The **Required Documents** window opens for you to add Required Documents for your sites under specific categories.

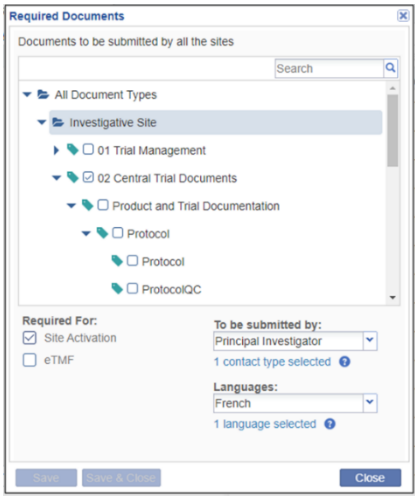


Figure 47: Required Documents

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

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

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

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

Deleting Documents from the List of Required Documents

To delete a Required Document:

1. Click All Sites tab from the left panel of the Required Documents Panel.
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:

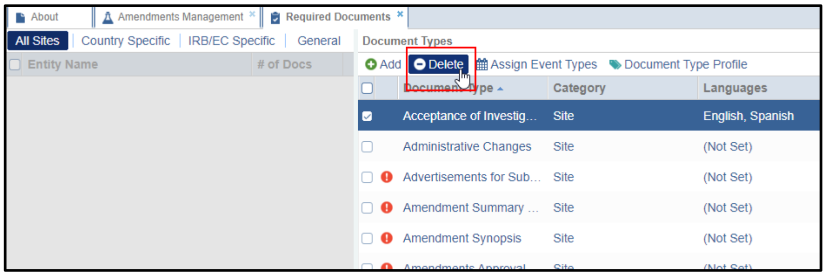


Figure 48: Deleting Documents

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

Amendments (SSU Rooms Only)

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

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

Follow the steps below to add a new amendment:

1. Click the ‘Add’ button from the top ribbon bar. The Create Amendment window will open. Refer to the screenshot below:

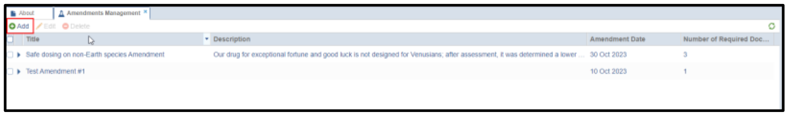


Figure 49: Add Amendment

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

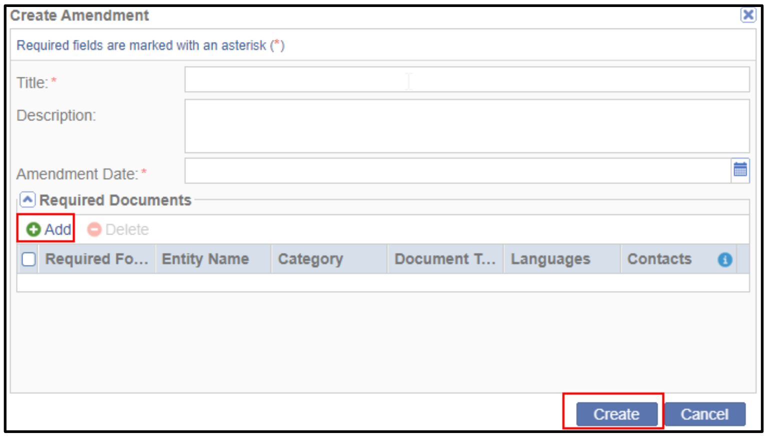


Figure 50: Create Amendment

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

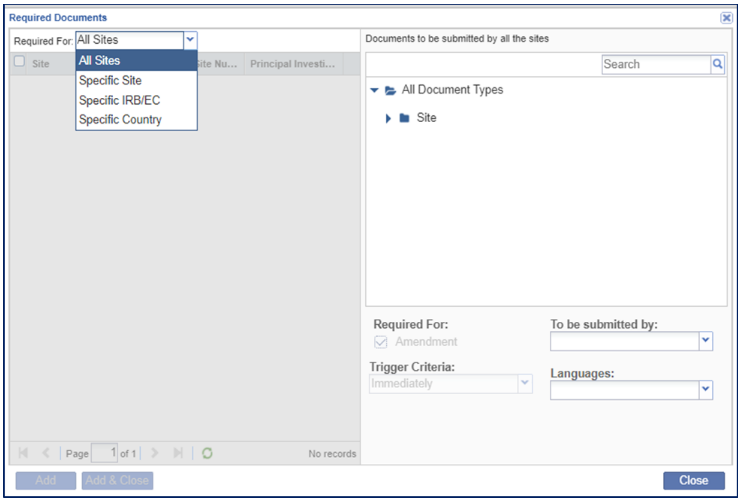


Figure 51: Required Group

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

Export Required Documents

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

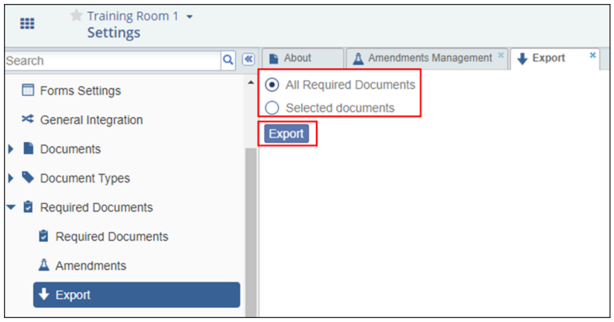


Figure 52: Export Documents

Required Documents can be exported in two ways:

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

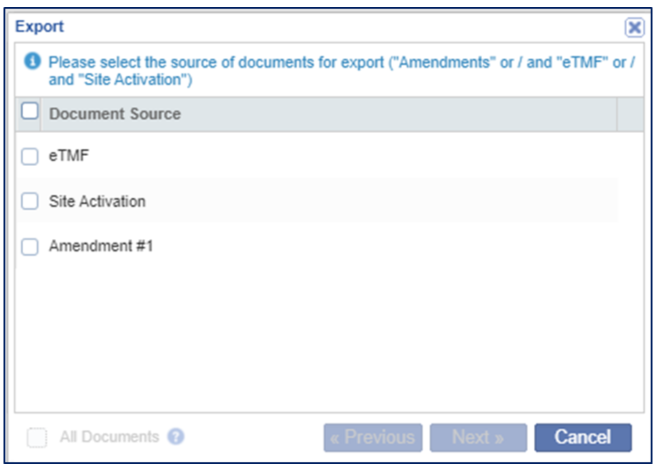


Figure 53: Source Document list

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

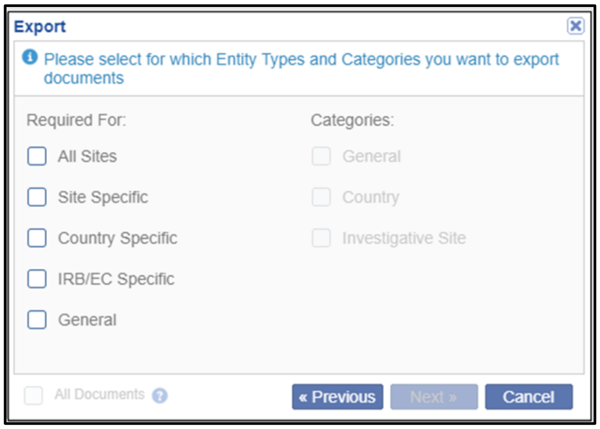
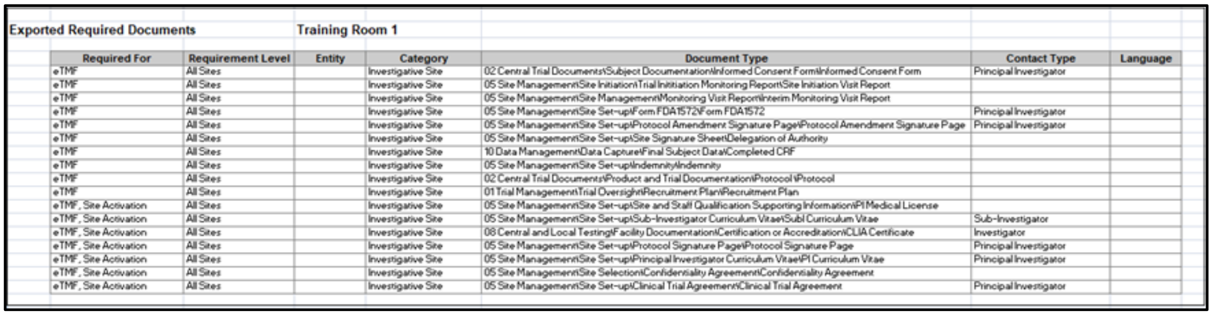


Figure 57: Entity Type and Categories

3. Click Next.
    - The final Export window will open for you to review the chosen criteria.
4. Click ‘Previous’ to make changes in the selections or click ‘Next’ to continue.
5. Press the ‘Export’ button to export the list of documents selected.
6. A notification will display indicating that the job was completed successfully.
7. An excel file is generated with a list of required documents and you can save the file for your records.

Refer to the screenshot below:



Exported Required Documents — **Training Room 1**

Required For	Requirement Level	Entity	Category	Document Type	Contact Type	Language
eTMF	All Sites		Investigative Site	02 Central Trial Documents\Subject Documentation\Informed Consent Form\Informed Consent Form	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Initiation\Trial Inititiation Monitoring Report\Site Initiation Visit Report		
eTMF	All Sites		Investigative Site	05 Site Management\Site Management\Monitoring Visit Report\Interim Monitoring Visit Report		
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Form FDA1572\Form FDA1572	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Protocol Amendment Signature Page\Protocol Amendment Signature Page	Principal Investigator	
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Site Signature Sheet\Delegation of Authority		
eTMF	All Sites		Investigative Site	10 Data Management\Data Capture\Final Subject Data\Completed CRF		
eTMF	All Sites		Investigative Site	05 Site Management\Site Set-up\Indemnity\Indemnity		
eTMF	All Sites		Investigative Site	02 Central Trial Documents\Product and Trial Documentation\Protocol \Protocol		
eTMF	All Sites		Investigative Site	01 Trial Management\Trial Oversight\Recruitment Plan\Recruitment Plan		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Site and Staff Qualification Supporting Information\PI Medical License		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Sub-Investigator Curriculum Vitae\SubI Curriculum Vitae	Sub-Investigator	
eTMF, Site Activation	All Sites		Investigative Site	08 Central and Local Testing\Facility Documentation\Certification or Accreditation\CLIA Certificate	Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Protocol Signature Page\Protocol Signature Page	Principal Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Principal Investigator Curriculum Vitae\PI Curriculum Vitae	Principal Investigator	
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Selection\Confidentiality Agreement\Confidentiality Agreement		
eTMF, Site Activation	All Sites		Investigative Site	05 Site Management\Site Set-up\Clinical Trial Agreement\Clinical Trial Agreement	Principal Investigator	

Figure 59: Exported Data

Countries

When a study includes investigative sites located in different countries, those countries need to be added to the room. As a result of this, country-specific folders will be set up in the room’s folder structure to accept and store country-specific documents and users will be able to choose the appropriate country when setting up new investigative sites in that country.

Countries Settings

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

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

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

Refer to the screenshot below:

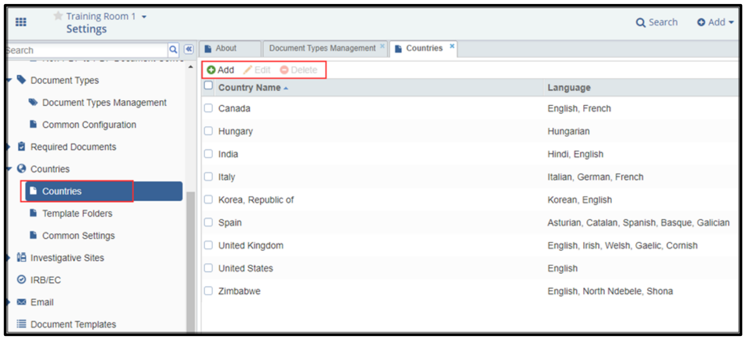


Figure 60: Countries Settings

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

Add Countries

Follow the steps below to add countries:

1. Click **Add** from the ribbon above the country listing.
    - The Create Country window will open. Refer to the screenshot below:

Figure 61: Create Country

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

Edit Countries

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

Follow the steps below to edit countries:

1. Select the required country from the grid to be edited. Click '**Edit'** at the top of the Countries window.

2. The Edit Country window will open. Refer to the screenshot below:

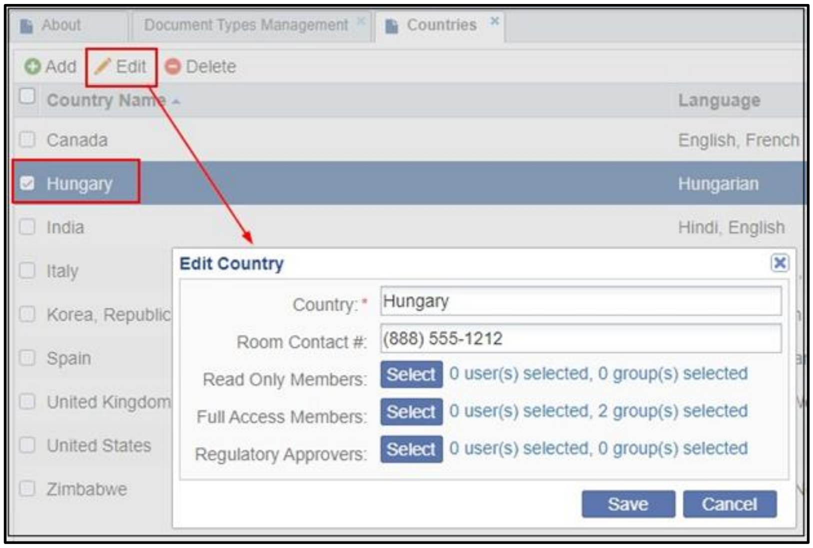


Figure 62: Edit Country

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

Delete Countries

Follow the steps below to delete the countries:

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

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

Template Folders

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

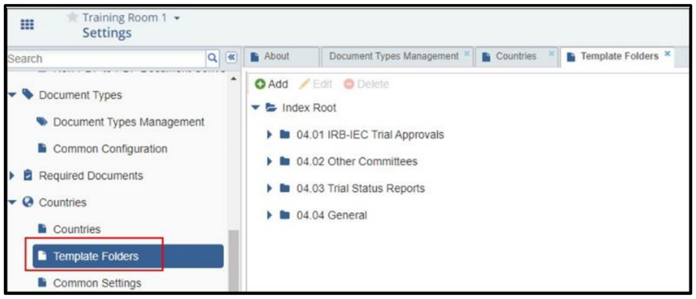


Figure 63: Template Folders

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

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

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

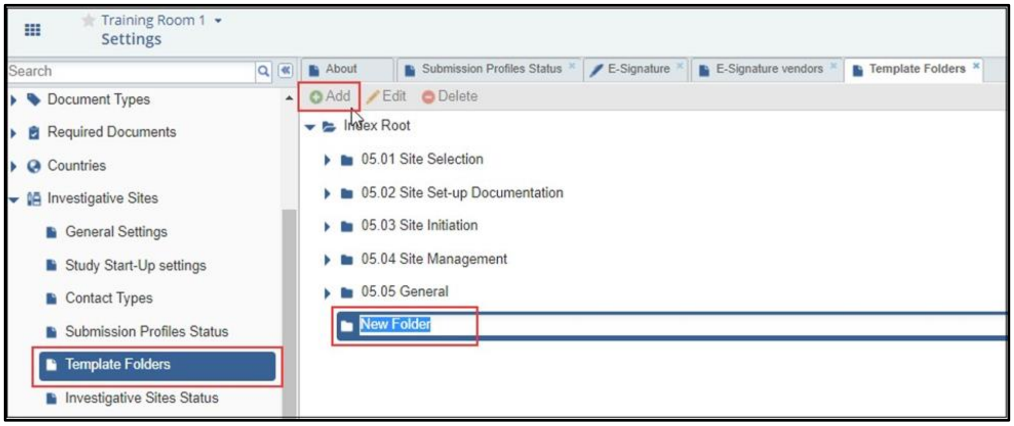


Figure 64: Adding Folders and Subfolders

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**.

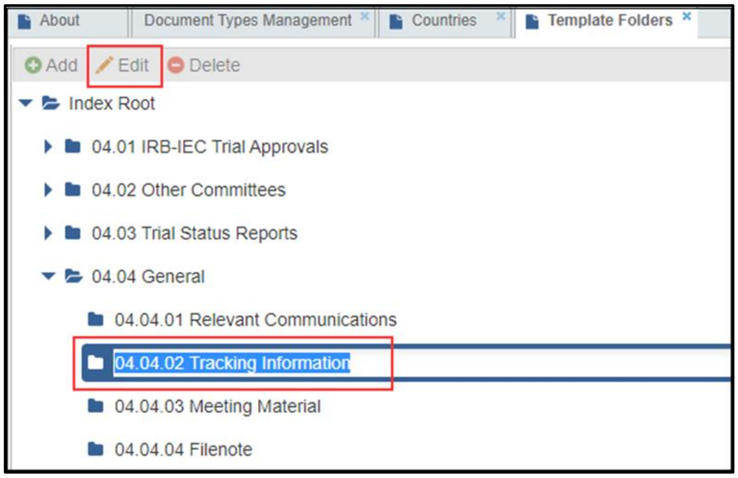


Figure 65: Editing folders

Deleting Folders

Follow the steps below to delete folders and subfolders:

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

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

Common Settings

In the Common Settings window, you can:

1. Enable or disable the Template Folders.
2. Edit the Root folder name.
3. Change the Sort Order, the place in the room's index structure where the Country Management folder appears.
4. You can adjust the Read-Only and Full Access security settings. Select the users or groups to set access. If you make any changes in this window, click Save.

Refer to the screenshot below:

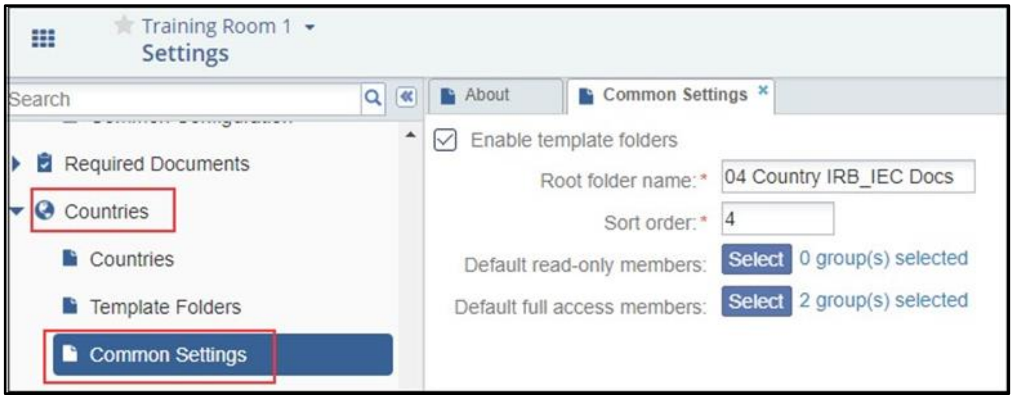


Figure 67: Common Settings

Countries Status

Investigative Sites

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

General Settings

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

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

Figure 68: Investigative Site Setting

1. Click the **wrench** icon to the right of the Investigative Site Naming Pattern box.
    a. An **Auto Name Rules** window opens.
    b. The naming pattern is built and displayed in the **Rule Editor** box. The information that populates in the box is selected from the list of Available Templates. You can also type text into the Rule

Editor. In the example below, '**Site'** and '[Site Management]' has been typed into the naming pattern.

Refer to the screenshot below:

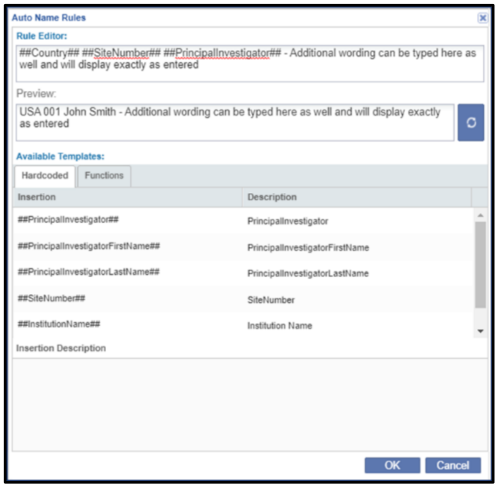


Figure 67: Auto Name Rules

2. Click in the **Rule Editor** box.
3. Double-click the insertions in the Available Templates box in the order in which you want them to appear in the naming pattern.
4. Once you have made the selections, click the blue box to the right of the Preview box to see how the folder names will appear in the room's index.
5. Once the naming pattern is set up correctly, click OK at the bottom of the window.
6. In the next available field, set the Root folder name. This is the title that is given to the main folder in the room's index that will hold the subfolders for each investigative site involved in the study.
7. Click in the field.
8. Type the root folder.
9. 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.
10. Click in the field.
11. Type the number order where it should appear in the index.
12. The next area contains three radio buttons for Site folder creation in the eTMF. Click the option that fits your needs.

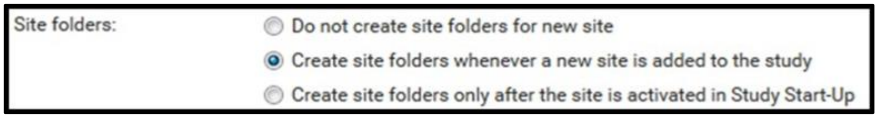


Figure 68: Site Folders

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

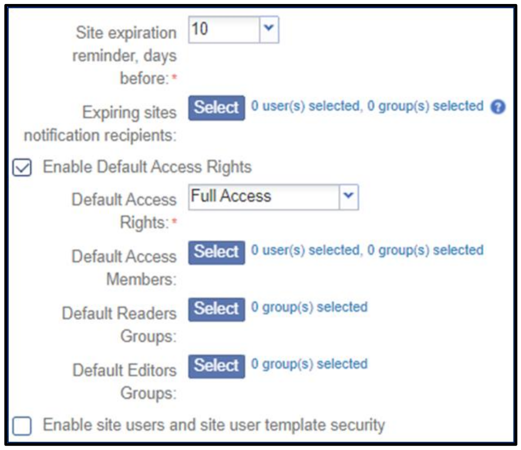


Figure 69: Template Security

14. The ‘Enable site users and site user template security’ option is most typically enabled in eISF rooms where strict site security must be maintained. For additional information on these settings, please see the section on Investigative Site Template Folders.
15. Click ‘**Save’** after making any additions, selections, or changes in the General Settings panel.

Study-Start Up Settings

In this panel, Administrator users can manage the study start-up settings for investigative sites. If your study room does not include Study Start Up, this menu will not appear.

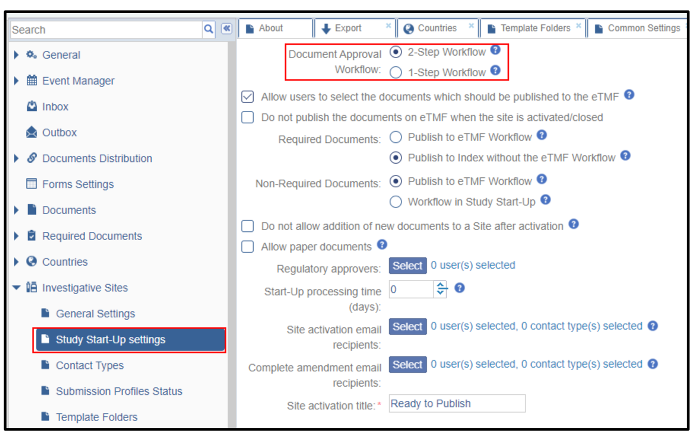


Figure 70: Study Start-up settings

- Allow users to select the documents which should be published to the eTMF
    - When this is disabled, SSU will automatically move all documents over to the eTMF upon site activation.
    - When this is enabled, the user who activates a site will be able to choose which documents move to the eTMF upon site activation.
- Do not publish the documents to eTMF when the site is activated

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

Contact Types

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

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

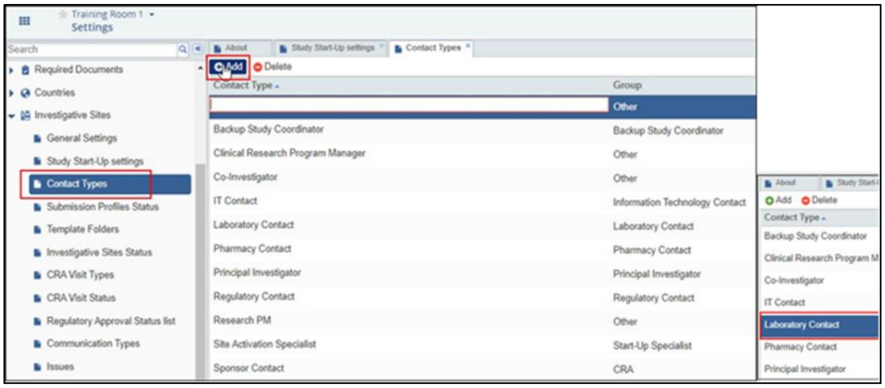


Figure 72: Contact Types

Additions and changes made here are saved automatically.

Submission Profile Status

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

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

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

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

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

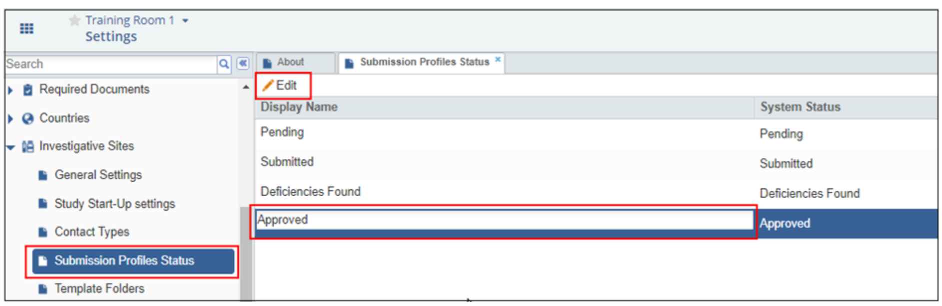


Figure 73: Submission Profile Status

Template Folders

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

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

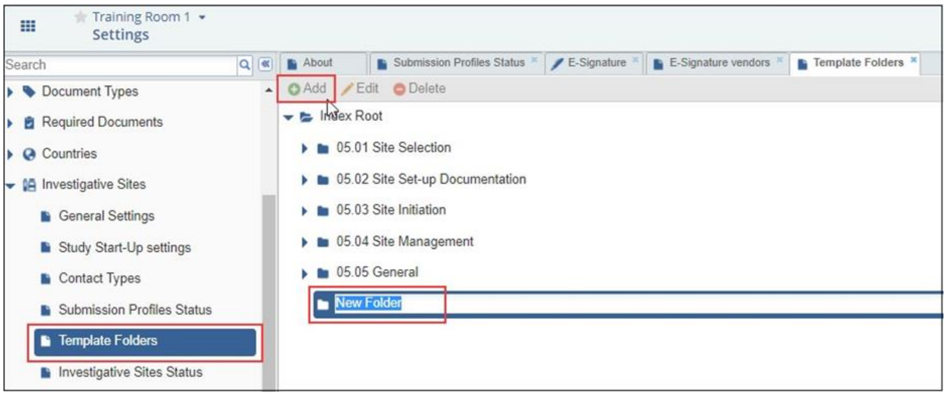


Figure 74: Template Folder

2. Type the name of the first folder in the available field
3. To add another folder at the same index level, click the Index Root folder and click Add.
4. To add a subfolder inside a folder, you have already created, click the **name** of the new folder and click **Add**.
5. Continue adding folders and subfolders until the full Investigative Site Folder Index is complete and in compliance with the client's request.
6. Similarly, **Edit** or **Delete** the folders by selecting them as required.

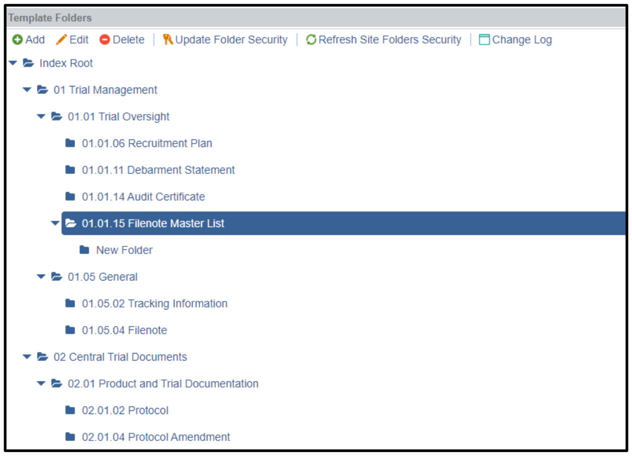


Figure 75: Template Folder Page

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

Investigative Site Status

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

- Click the 'Edit' button on the top or double click on the specific display name to edit.

- Site statuses can be enabled or disabled as well. click on the Drop-down menu from top- right corner and Select **Yes** or **No** entry to change the value.

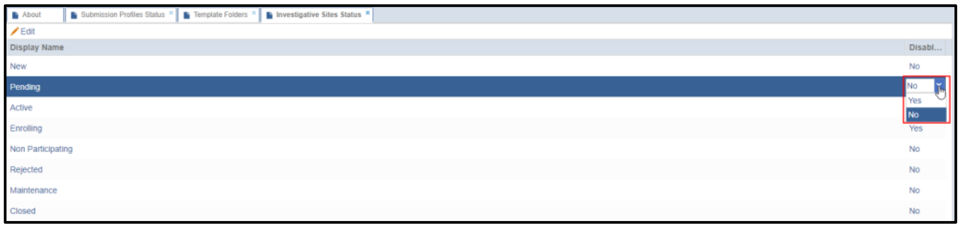


Figure 76: Investigative Site Status

CRA Visit Types

The visit types maintained in this area are available to CRA users in the CRA Reconciliation module. A CRA might need to create a CRA TMF Reconciliation Report to reconcile documents during site visits. While creating the report, the visit type must be chosen so that reports generated during two or more site visits can be differentiated with ease. Refer to the screenshot below:

Figure 77: Create CRA

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

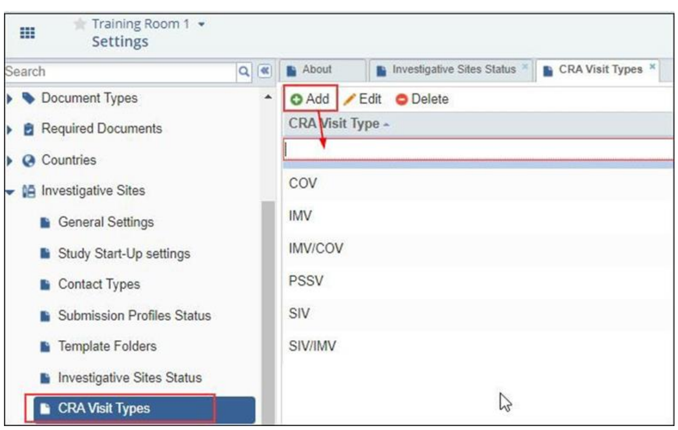


Figure 78: CRA Visit Type

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

CRA Visit Status

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

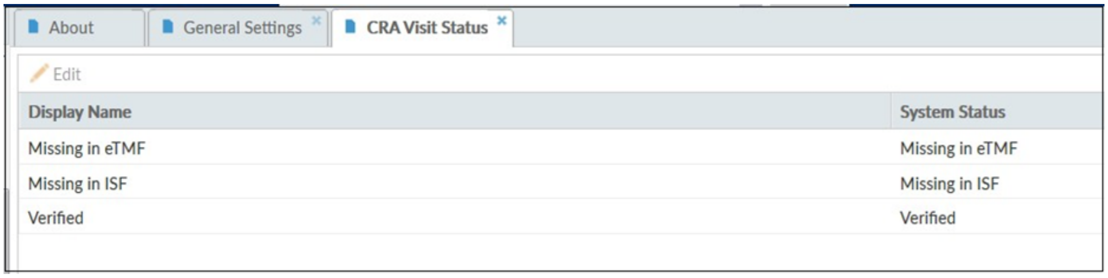


Figure 79: CRA Visit Status page

Communication Types

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

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

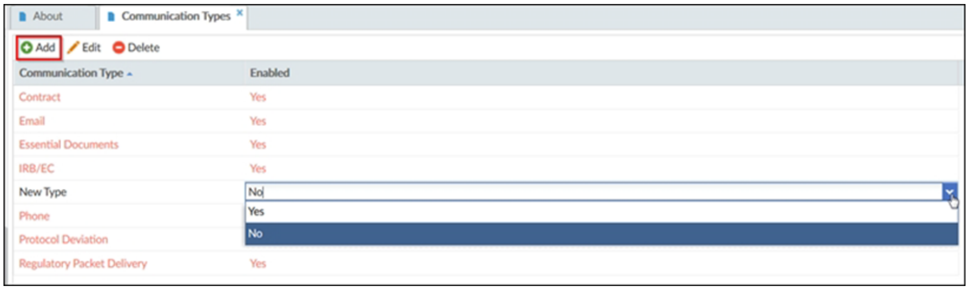


Figure 80: Communication Type Page

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

Issues

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

1. Click **Add**. A text field opens.
2. Type the description of the issue in the field.

3. Press Enter. The changes are saved automatically.

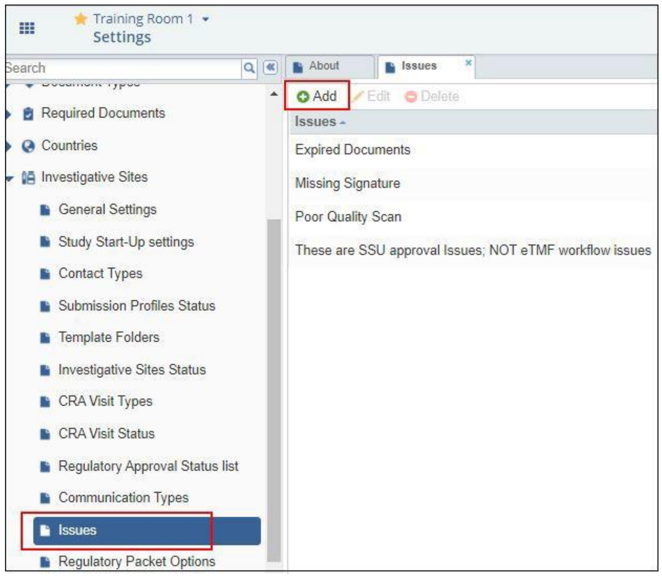


Figure 81: Issues

Regulatory Packet Options

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

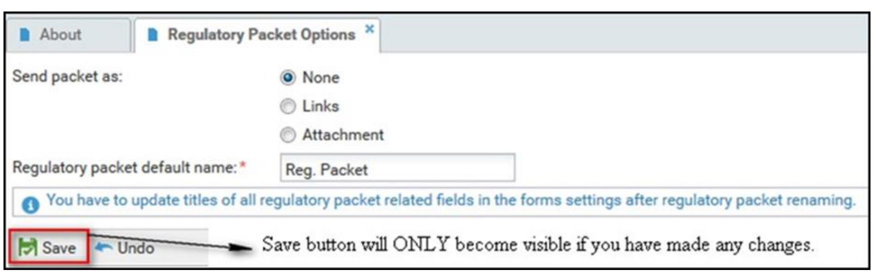


Figure 82: Regulatory Packet Options

IRB/EC Settings

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

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

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

Email Settings

Email Templates

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

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

Refer to the screenshot below:

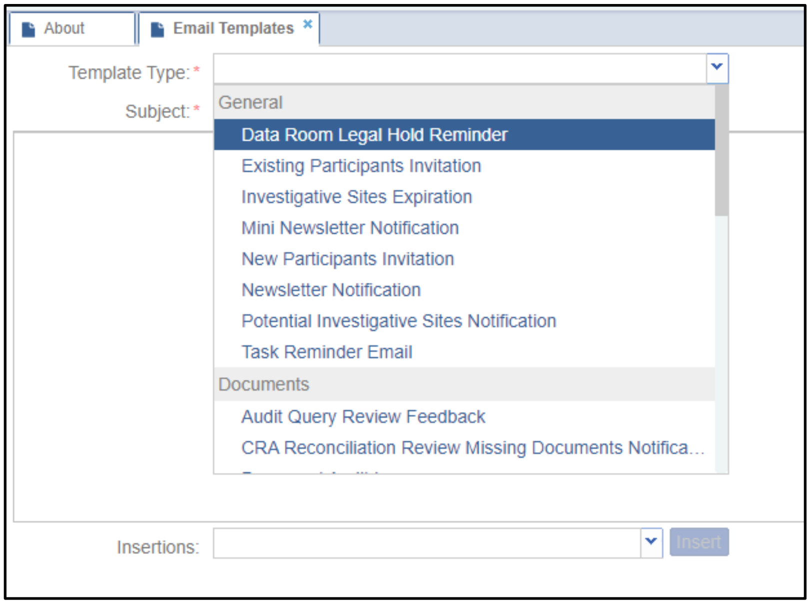


Figure 83: Email Setting

Room Legal Hold Notification Settings

Note: Super Administrator users from the TI Service Desk can put a Legal Hold on Rooms when required.

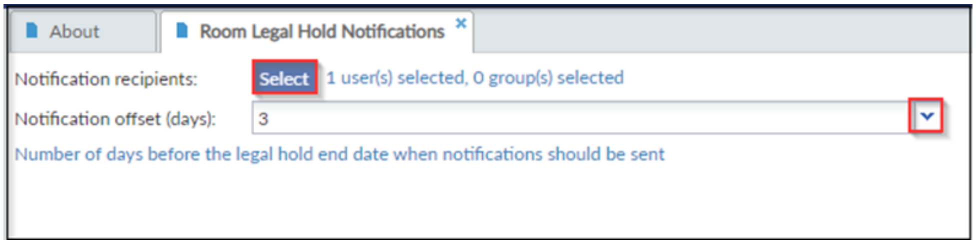


Figure 84: Room Legal Hold Notifications

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

Notifications Preferences Settings

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

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

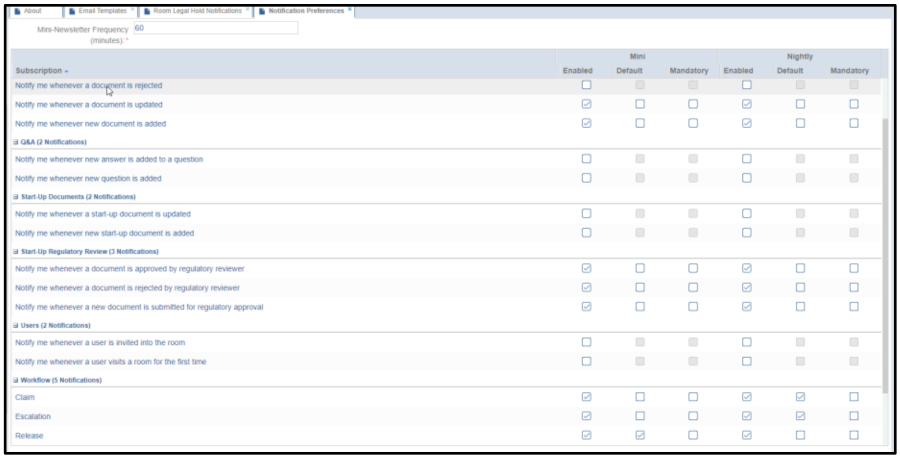


Figure 85: Notifications Preferences Settings

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 users to subscribe to related notification.
  - Default: This subscribes all users to the related notification by default but with the possibility to unsubscribe.
  - Mandatory: All users get automatically subscribed without the possibility to unsubscribe.

Notification Columns

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

The Notification Columns are available for the following categories:

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

Refer to the screenshot below:

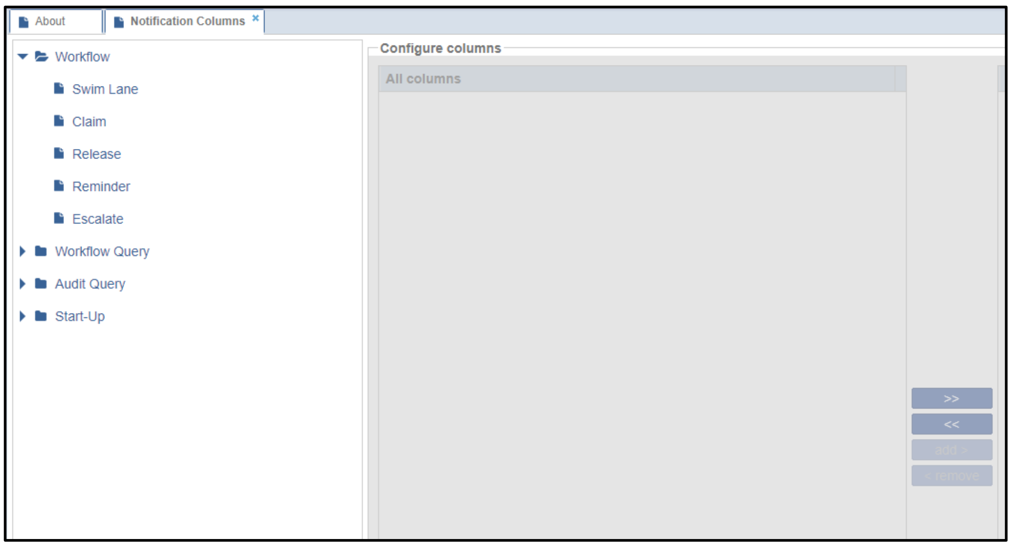


Figure 86: Notification Columns

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

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

Document Template Settings

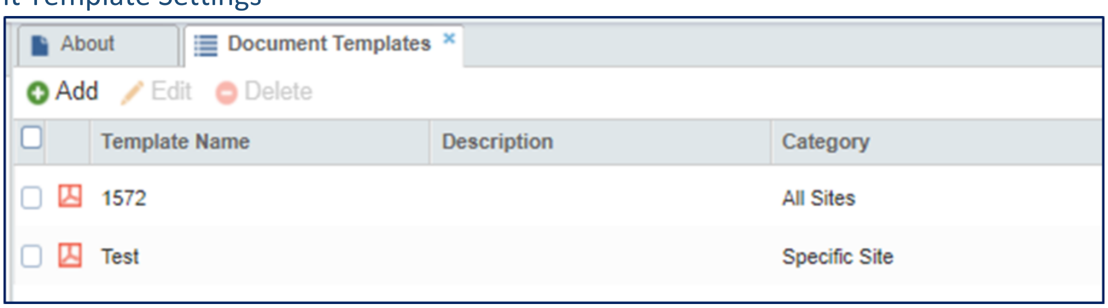


Figure 87: Document Template Settings

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

Follow the instructions below to add a new template document:

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

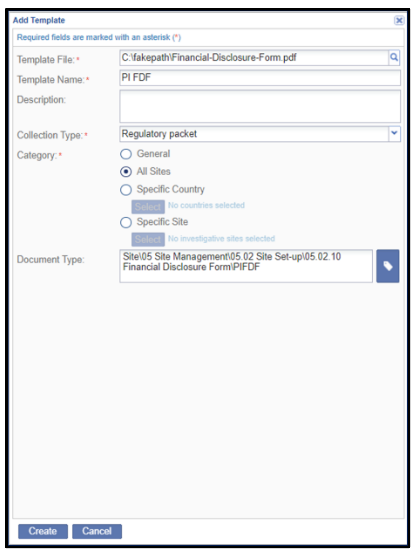


Figure 88: Adding Template

Reports Settings

Heatmap Settings

Trial Interactive has the ability to display cross-room metrics in the KPI Dashboard, accessible from the Home screen. The KPI heatmap is color coded so that metrics which are out of the acceptable range are highlighted. The values associated with those metrics are controlled here. Double click on any setting to edit the value.

Target Period (in days):* 10

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

Figure 89: Heatmap Settings

Workflow Settings

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

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

To access the Quality Control Settings:

Navigate to the Navigation Grid -> Settings -> Workflows.

Common Settings

Admin can adjust the following in the Common Settings area:

- **Common Configuration**
- **Default Ranges Configuration**
- **Timeline Configuration**
- **Issue Email**
- **Rejection Email Configuration**
- **Query Reminder Configuration**
- **Auto-Claim Configuration**

<u>Workflow Common Configuration</u>

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

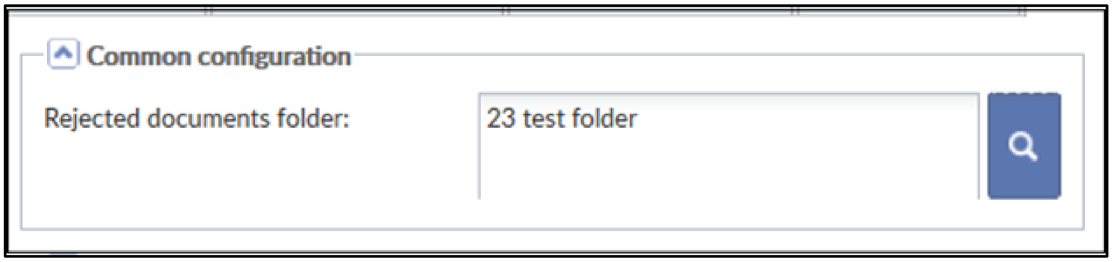


Figure 90: Common Configuration

Default Ranges Configuration

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

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

Refer to the screenshot below:

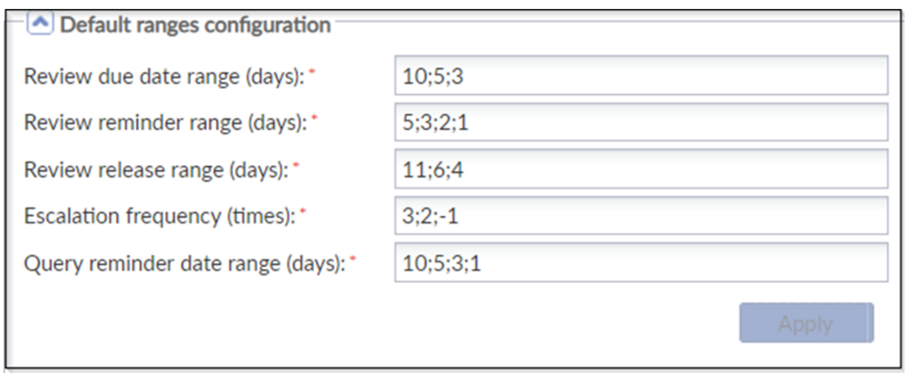


Figure 91: Default Ranges Configuration

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

1. **Review due date range (days).**
    a. Here you specify the days when the review would be due after claiming the documents for review.
    b. You may specify multiple values, all of which will be populated in the dropdown while creating the workflow to enable you to select a value as appropriate.

2. **Review reminder range**
    a. Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.

   b. If multiple values are specified, all of them would be populated in the dropdown during workflow creation, and you may select multiple values as required.
   c. In the screenshot above, the Reminder schedule is 5;3;2 which means:
      i. the reviewer will receive reminders 5 days before the due date,
      ii. then 3 days before the due date,
      iii. and then 2 days before the due date if the reviews are pending.

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

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

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

<u>Timeline Configuration</u>

Refer to the screenshot below:

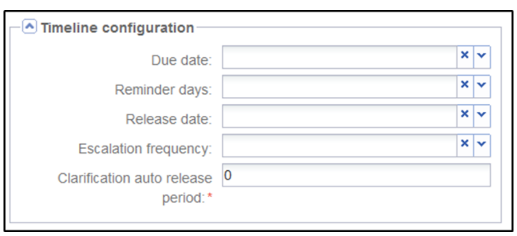


Figure 92: Timeline Configuration

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

- The configurations are optional here except for the Clarification auto release, which means a document that is pending for clarification will be automatically released if it was not released back to the workflow by the reviewer within the defined time period.
- Users can delete timeline values from a Workflow profile as well as for existing workflows by clicking the cross icon next to the fields in the Timeline Configuration panel or from the Timeline tab in a Workflow Profile Editor.

Issue Email

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:

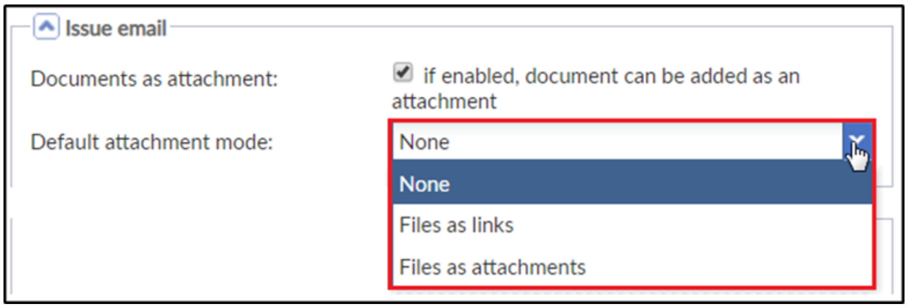


Figure 93: Email Issues

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

Query Reminder Configuration

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

Figure 94: Query Reminder 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 the auto-claiming of a document, the Administrator will need to enable the configuration from this panel. Refer to the screenshot below:

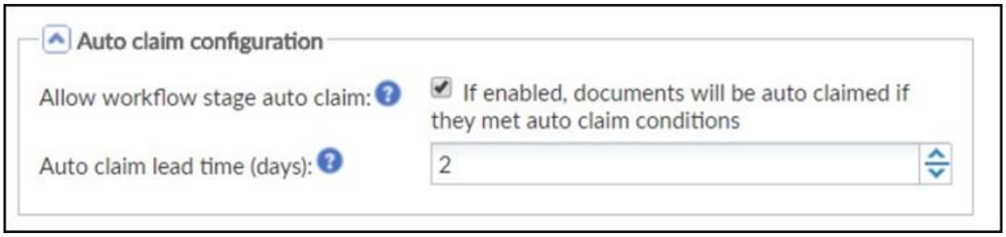


Figure 95: Auto claim Configuration

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 Quality Control Workflow

To create a Quality Control workflow follow the procedure below:

1. Click the Add button from the grid.
    - The Workflow Editor window will open. Refer to the screenshot below:

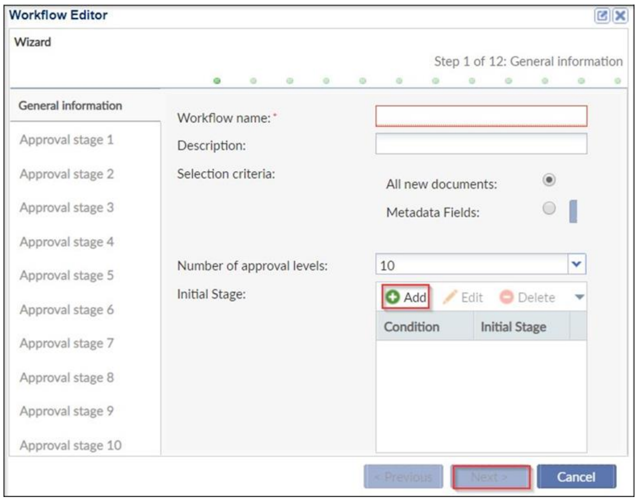


Figure 96: Workflow Editor

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, and so on.
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:

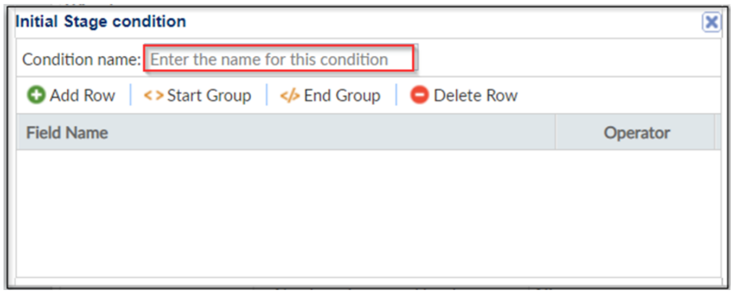


Figure 97: Initial Stage Condition

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

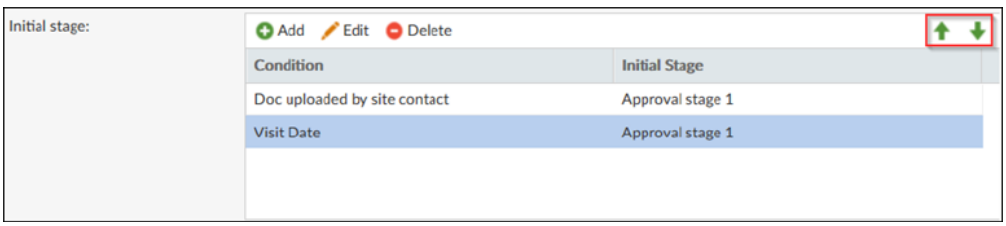


Figure 98: Initail Stage

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

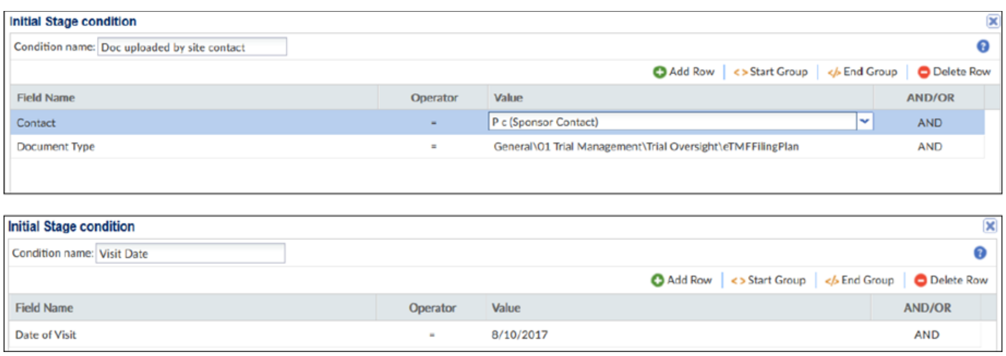


Figure 99: Initial Stage Condition

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

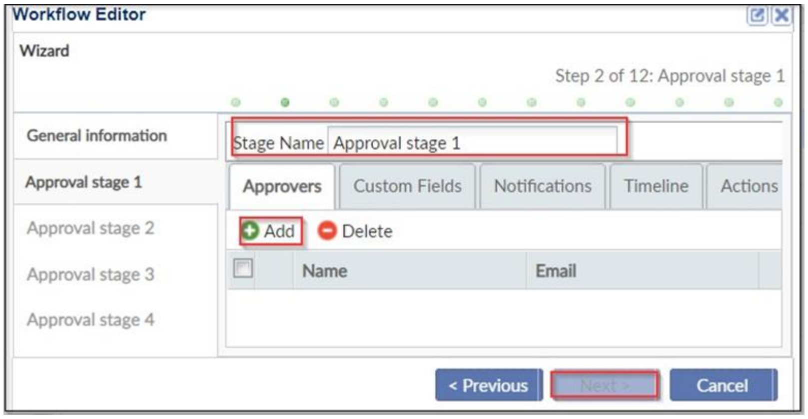


Figure 100: Workflow Editor

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

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

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

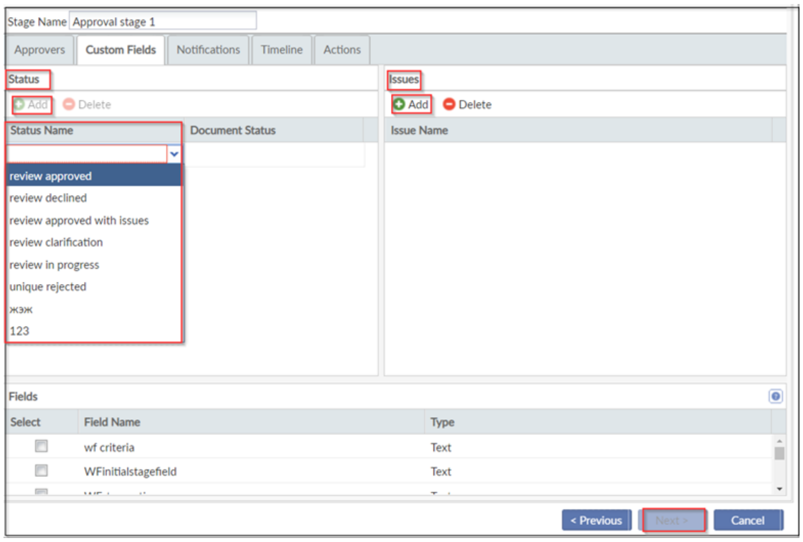


Figure 101: Approval Stage One

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

8. Click the Issues section to assign the reasons in case the reviewer rejects a document/asks for clarification. Some of the standard issues could be Missing Pages, Missing Signature, Blank Pages, Incorrect Study, Poor Scan, Duplicate, and Expired Documents.
9. To make metadata fields, as required, available for a workflow configuration, proceed to Forms Settings and select the Workflow Fields, as required.
    a. These fields will appear in the Fields panel at the bottom of the Customs tab. Tick the fields as required for the review. Refer to the screenshot below:

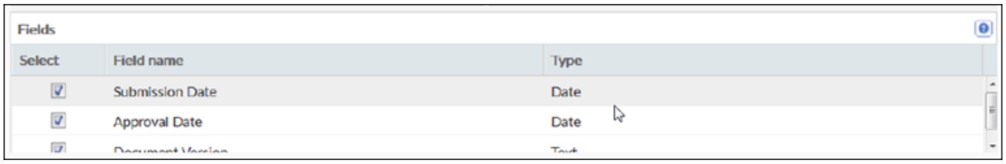


Figure 102: Fields

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

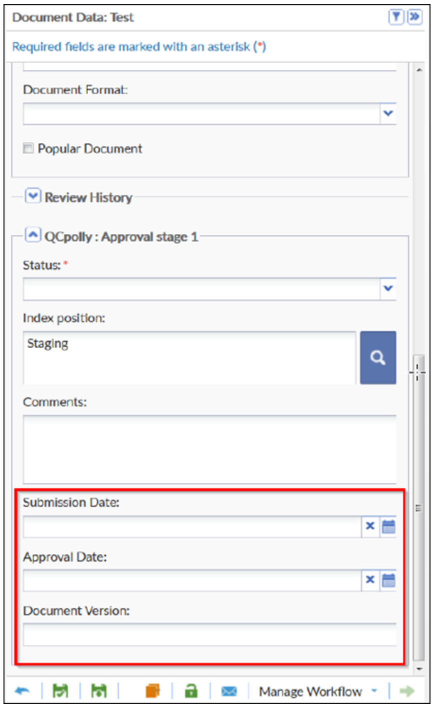


Figure 103: Document Data Test

10. Click the Notifications tab.
    a. Here, you can allow for email notifications to be enabled for the event names listed.
    b. For users who want to be notified only in case of Claim, Release, or Escalation, groups can be added accordingly.

11. In case you have fed in values in Timeline Configuration, the values would be populated by default in the Timeline tab. You may choose to override the previously set configurations if desired.
12. Actions is an optional tab allowing for complex workflow building.
    a. It enables a workflow to have a jump. A specific document can jump to a certain stage.
    b. 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.
    c. While efficient for complex workflows, it is not required for regular workflows creation.
13. Click Next when all tabs have been reviewed.
    a. Repeat similar steps for each stage of approval.
    b. Settings may change per approval stage, like approvers, notifications, and timelines.
14. When finished, click Next.
15. The Workflow finish is the last step. Any errors in the workflow will appear here that need to be addressed. If there are no errors, click Finish when done.

Editing an Existing Workflow

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

Deleting an Existing Workflow

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

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

Quality Control Review Status

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

- The Display Name' is the name of the status that would be visible on the user interface, whereas the System Status is pre-defined values that you assign to review status.
- Regardless of what the Display Name is, the documents will be routed to one of the workflow folders in QC Review/My Reviews based on the system status.

1. Click Add.
2. Enter the Display Name
3. Double click the System Status field, click the dropdown arrow, and select the System Status from the list.

Editing Review Status

1. Select the required Review Status to be edited and click Edit.

2. The Review Status field becomes editable.
3. Make the required changes.
4. Double click the System Status field, click the dropdown arrow, and select the System Status from the list.

Deleting Review Status

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

Security

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

General Security Settings

From here you can perform the following functions:

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

Logout Timer Configuration

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

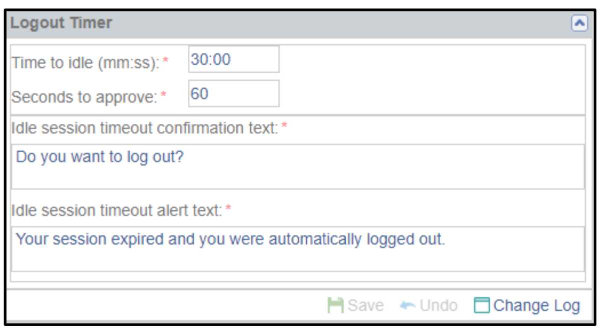


Figure 104: logout Timer Configuration

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

Invite Participant Settings

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

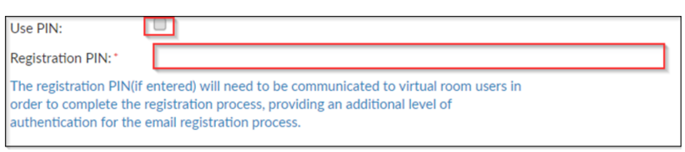


Figure 105: Invite Participants Settings

To use this extra layer of security:

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

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

Redaction Settings

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

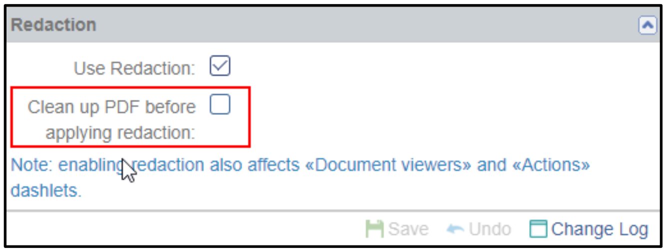


Figure 106: Redaction Settings

In this version , a new checkbox is added "Clean up PDF Before applying redaction.

2. Click Save from the bottom of the grid.

Actions

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

Figure 107: Actions

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

PDF Watermark Options Settings

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

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

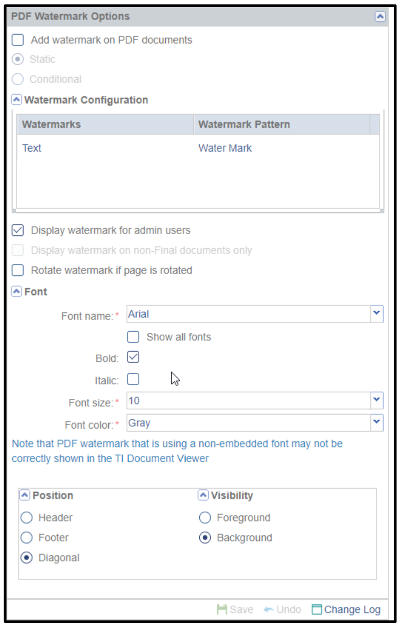


Figure 108: PDF Watermark Options

1. Activate or inactivate the Add Watermark on documents option by clicking the checkbox.
    - Activation of this option also activates the option of allowing non-PDF documents to be printed or downloaded without watermarks.
2. Tick the checkbox to Display the watermark for Administrator users.
3. Double-click on the Watermark Pattern to enable editing.
4. Click on the wrench icon to open the Watermark Pattern window.
5. Select from the available insertions in the "Available Templates" portion of the window.
    - To use one of these insertions, select the point in the Rule Editor where the text should appear and then double-click on the desired insertion.
6. Users can also free-type text into the Rule Editor
7. When you are satisfied with the pattern, press OK.
8. Tick the checkbox to Rotate watermark if page is rotated.
9. Select the Font name from the dropdown.
    - The dropdown list can be extended to include all fonts by clicking the Show all fonts checkbox.
10. Select whether the watermark text will be rendered as Bold and/or Italic text.
11. Select or confirm the Font Size from the dropdown menu.
12. Select the Font color from the dropdown menu.
13. Select whether or not to Embed the font to the PDF.
14. Select the Position of the watermark.

15. Select whether the watermark will appear in the Foreground or the Background of the document text.
16. Click Save.

Document Viewers

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

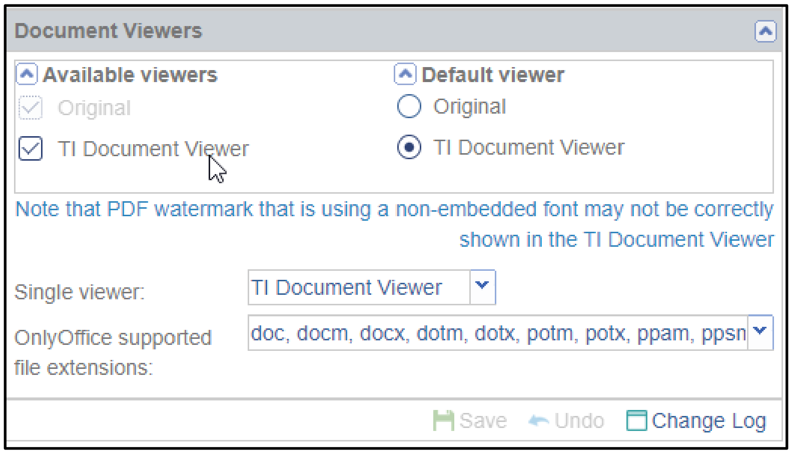


Figure 109: Document Viewers

1. Select the viewers that will be available to users in the data room.
2. Select whether the Default viewer for users in the room will be the Original viewer or the TI Document Viewer.
    - It is our recommendation that the TI Document Viewer be the default viewer. Some document functionality depends upon the use of this viewer.
3. Select a Single viewer from the dropdown list if you want to restrict the availability for users.
4. In this version, a new drop-down menu is added as **OnlyOffice supported file extension.**
5. 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:

Figure 110: Document Encryption Options

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

Follow these steps to enable the Confidentiality Agreement:

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

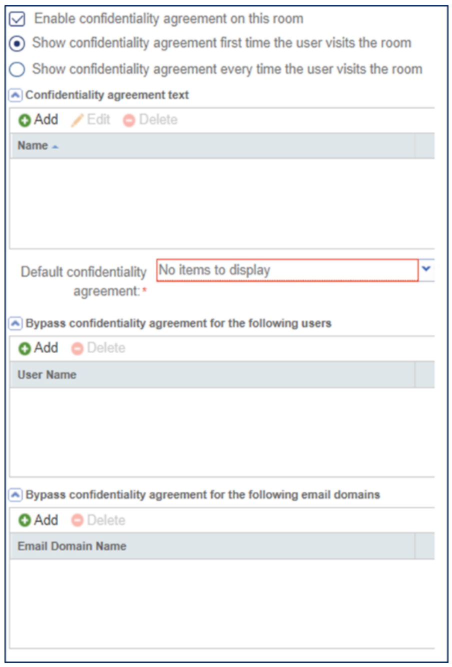


Figure 111: Confidentaility Agreement

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:

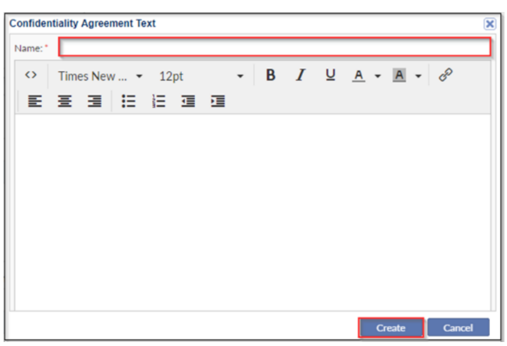


Figure 112: Confidentiality Agreement Text

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

Manager Access

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

e-Signature

Vendors

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

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

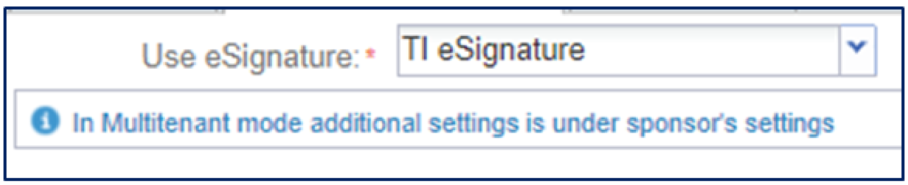


Figure 113: e-Signature

Reasons

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

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

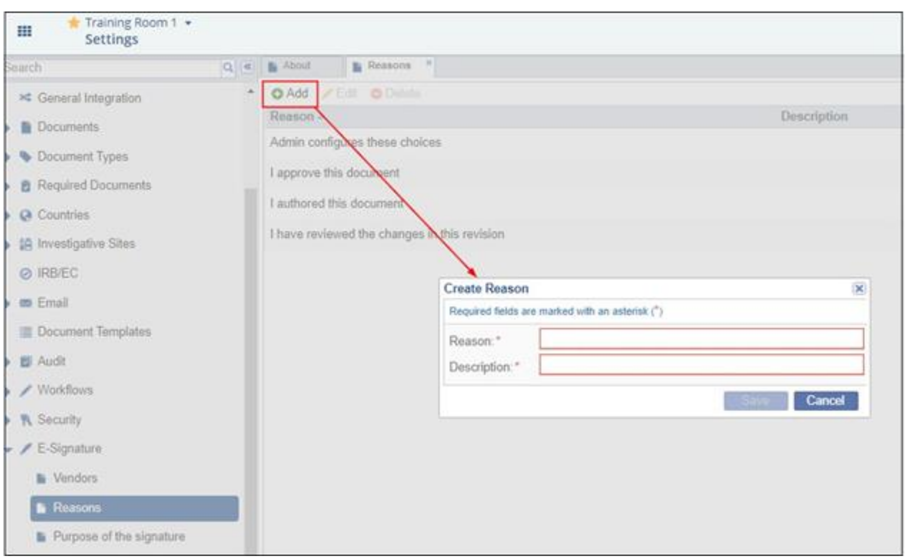


Figure 114: Create Reason

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

Purpose of The 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:

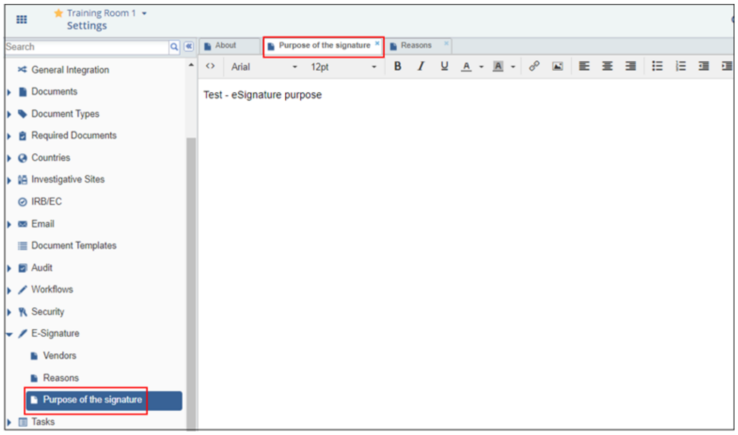


Figure 115: Purpose of the Signature

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

Tasks

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

Tasks

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

Figure 116: Tasks

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

Task Category

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

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

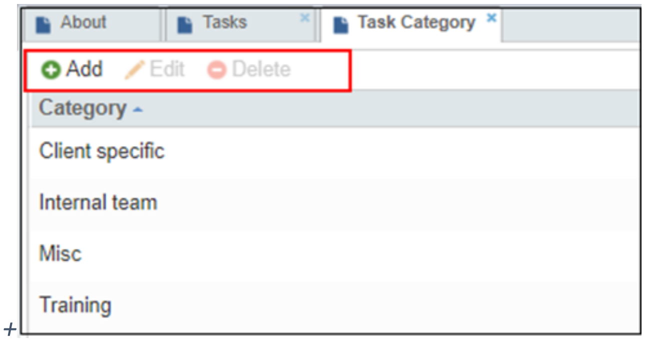


Figure 117: Tasks Category

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

Q&A

General

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

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

Q&A Configuration

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

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

Refer to the screenshot below:

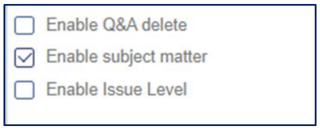


Figure 118: Q&A configuration

Q&A Question Level

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

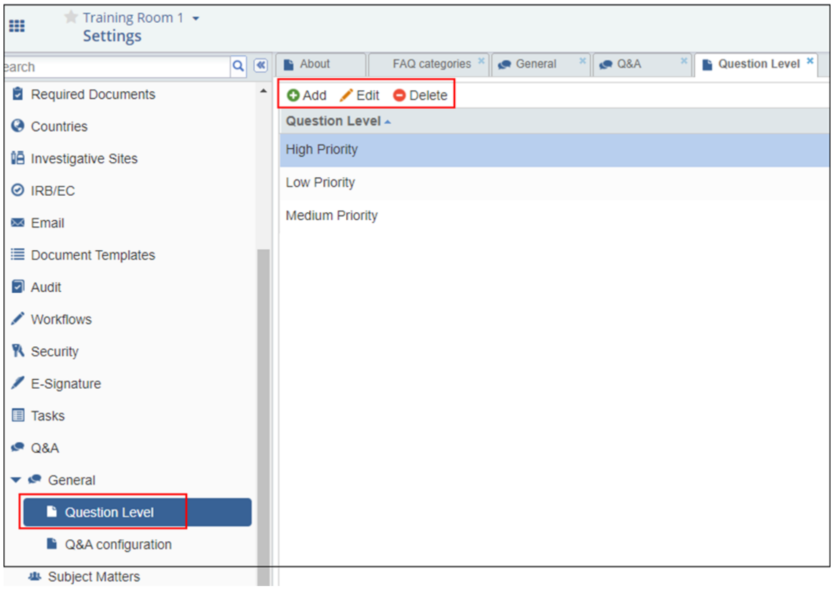


Figure 119: Q&A Question level

Adding New Question Level

To add a new question-level:

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

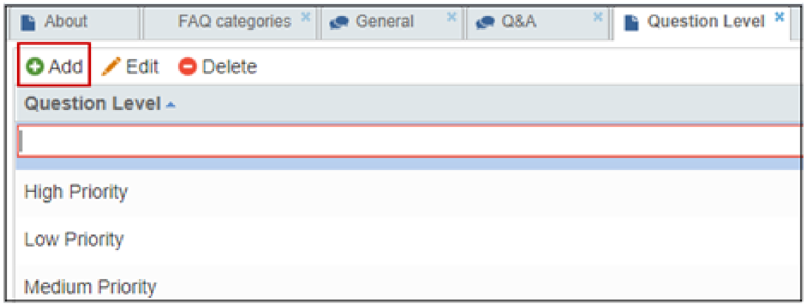


Figure 120: Adding New Question level

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.
   - The field becomes editable.
2. Edit the details as required. Refer to the screenshot below:

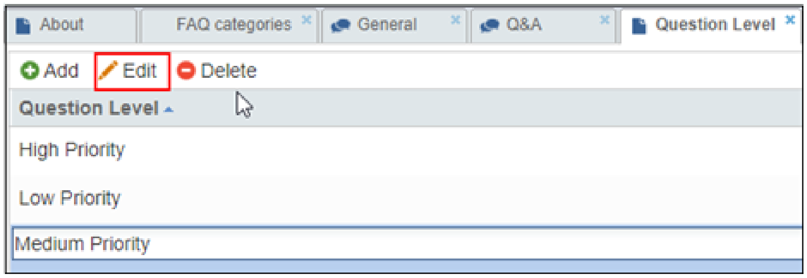


Figure 121: Editing a Question Level

Deleting a Question Level

To delete a question-level:

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

Question Subject Matter

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

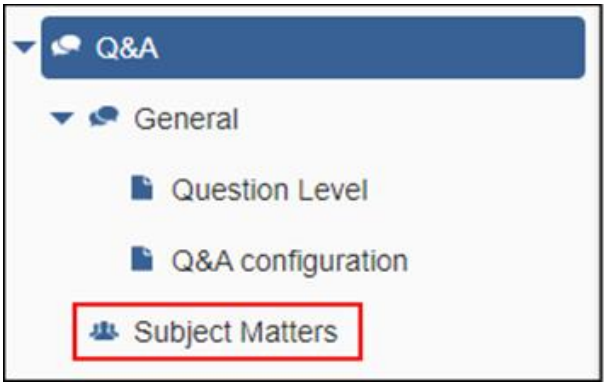


Figure 122: Subject Matters

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

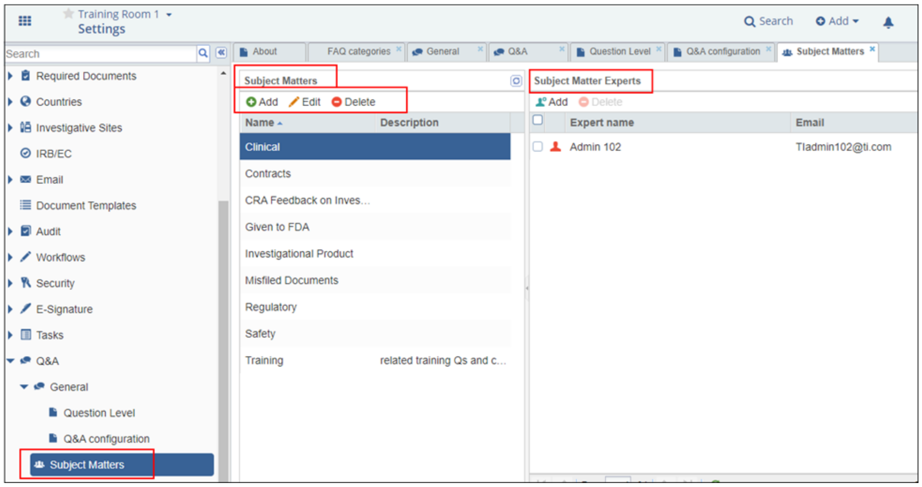


Figure 123: Subject Matter Experts

This window consists of two panels:

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

Creating Subject Matters

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

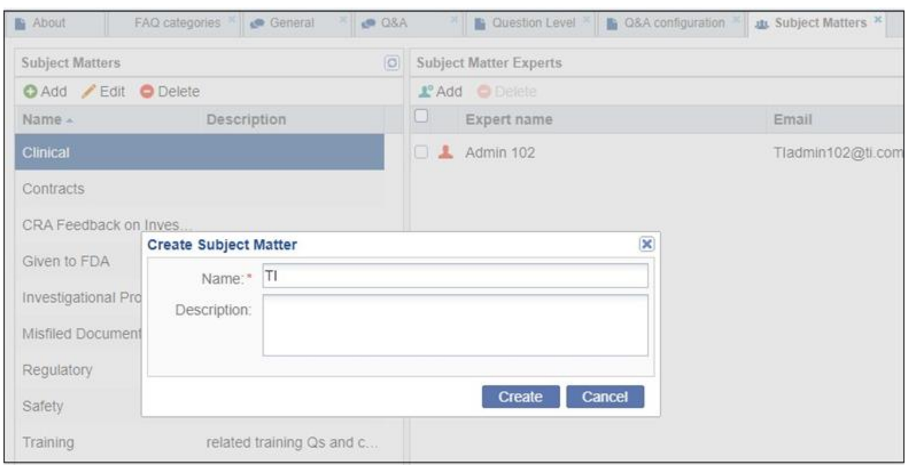


Figure 124: Create Subject Matter

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:

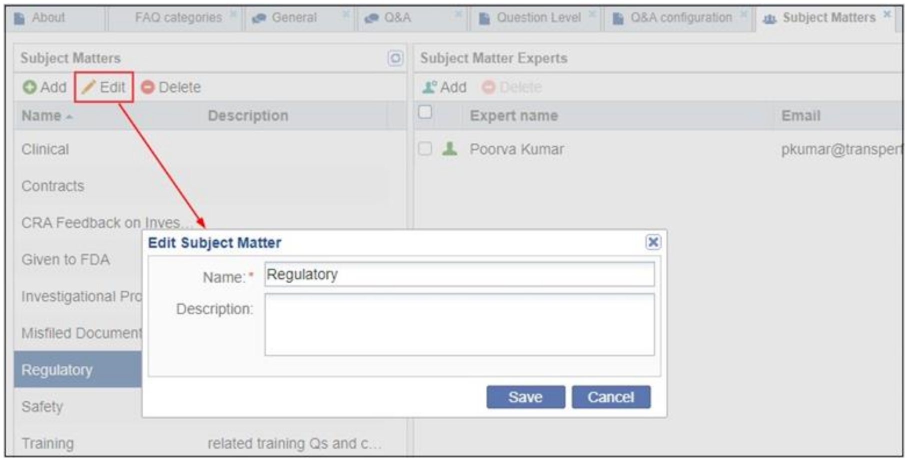


Figure 125: Edit Subject Matter

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

<u>Deleting Subject Matters</u>

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.

<u>Assigning Subject Matter Experts to Subject Matters</u>

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

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

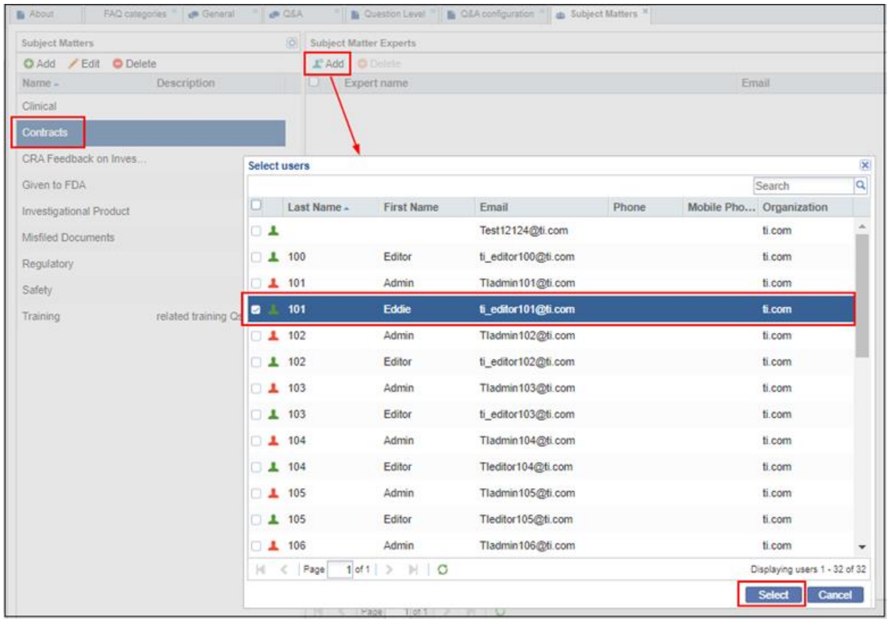


Figure 126: Assigning Subject Matter Expert

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

Removing Subject Matter Experts from Subject Matters

To remove a Subject Matter Expert from Subject Matters:

1. Click the Name of the Subject Matter.
2. The list of Subject Matter Experts appears in the Subject Matter Expert Panel.

Select the checkbox next to **the** name(s) of the Subject Matter Expert you want to delete.

3. Click Delete from the toolbar.
4. The names of the Subject Matter Experts is deleted from the list.

FAQ Module

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

During a Clinical Trial, so many questions come up from the team. These questions can range from document naming conventions, instructions on how to classify certain metadata and content, who to contact for specific study information, all the way to entries for each Investigative Site providing contact information and other critical information. If your CRAs, CTAs, and Clinical Document Specialists have access to the right answers your project can run much more efficiently. Simply click on the FAQ Module and take a look.

How it Works

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

Adding FAQ Categories

1. Navigate to Navigation Grid à Settings à FAQ
2. Click Add. Refer to the screenshot below:

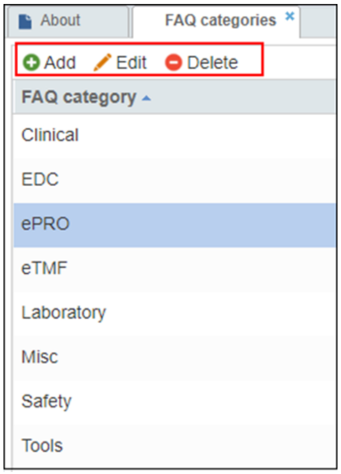


Figure 127: Add FAQ

3. Click Save after making any changes.

Editing FAQ Categories

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

Deleting FAQ Categories

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

Chapter 7. Trial Interactive eTMF and the Documents Module

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 **Navigation Grid** in the upper-left corner of the screen. Refer to the screenshot below.

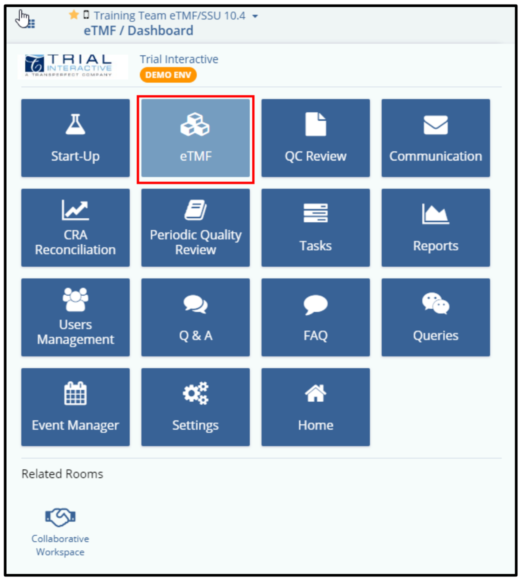


Figure 2: ETMF Module

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

- Dashboard
- Documents
- Translations
- Sites
- Contacts
- Countries
- Audit Trial
- Related Documents Settings.

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

Refer to the screenshot below:

Figure 2: Menu Bar

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

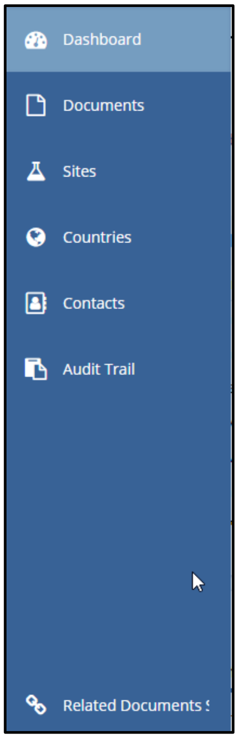


Figure 3: Expanded Menu Bar

Documents Module

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

Here, you can configure and store 'essential documents' about clinical trials, view and edit document attachments, manage security privileges on them, import and export documents and their metadata, and mail them to other users in addition to many other functions.

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

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

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

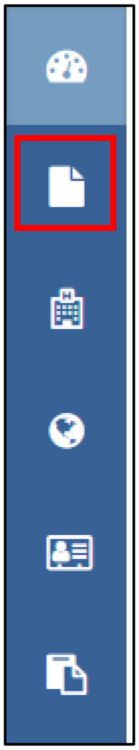


Figure 4: Document Module

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

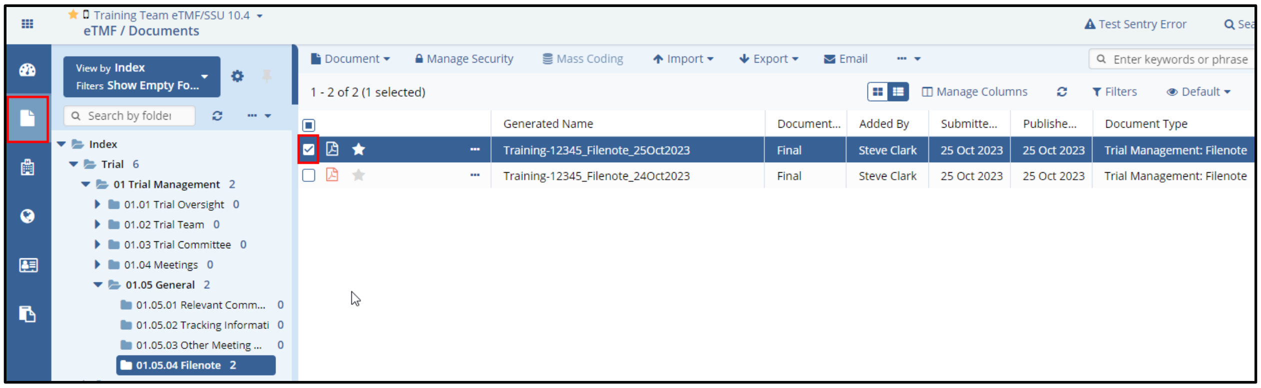


Figure 5: Document Module View

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

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

- **Index:** This view displays all of the room's documents by their index location.
- **Document Type:** This view displays all documents based on their assigned document types.
- **Site:** This view shows all room documents based on their site association.
- **Country:** This view shows all room documents based on their country association.
- Tag: Tag is a metadata field by which documents can be linked or associated. This view displays all documents organized by the tags assigned to them. One document may be associated with multiple tags.

- **Query by Sender:** This view shows all queries organized by the query sender.
  - Users will see different queries depending on their user access level.
    - Administrator-level users will see all queries in the room.
      - Administrator users can choose to view only their queries.
    - Other users, unless granted additional privileges, will see only their queries.

- **Query by Recipient:** This view shows all queries organized by the query recipient.
  - Users will see different queries depending on their user access level.
    - Administrator-level users will see all queries in the room.
      - Administrator users can choose to view only their own queries.
    - Other users, unless granted additional privileges, will see only their own queries.

- **Submissions:** This view will display every document ever submitted to the room by the user regardless of status or index location.
  - Deleted documents will not display.

- **My QC/Reviews:** This view is only available to users who are a part of the room's QC workflow. From this view, users who are a part of the workflow will be able to perform all associated functions.
  - Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the My Reviews view or the Quality Control module in the folder with unclaimed documents under the workflow configured by you.

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

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

- **eSignature:** From this view, users can view documents that require eSignature and perform eSignature-related functions.
- **By Status:** This view allows users to view all room documents grouped by their QC Workflow status (ex. QC 1 Approved, Final, etc.)

- **By Reviewer:** This view allows users to view all documents currently claimed by QC workflow personnel.
  - Administrators can reassign documents claimed in the workflow to other reviewers.

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

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

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

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

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

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

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

- **Security:** This view shows documents organized by their affiliated security access group.
- **Group:** This view shows documents organized by their affiliated group.
- **Posted Date:** This view shows documents organized by the date that they were added to the study room.
- **Deleted Documents:** This view shows all documents that have been deleted. From here, documents can be restored or purged from the system.
- **Processed Documents:** This shows documents that have undergone some form of process in the room. The most common of these would be conversion to PDF or application of OCR.
- **Documents Security:** This view displays all documents that have specific document-level security applied.

Configuring the Index Structure

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

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

Adding New Folders

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

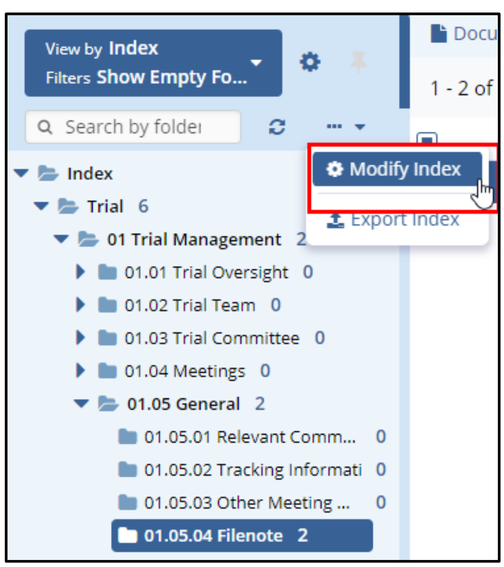


Figure 6: Modify Index

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

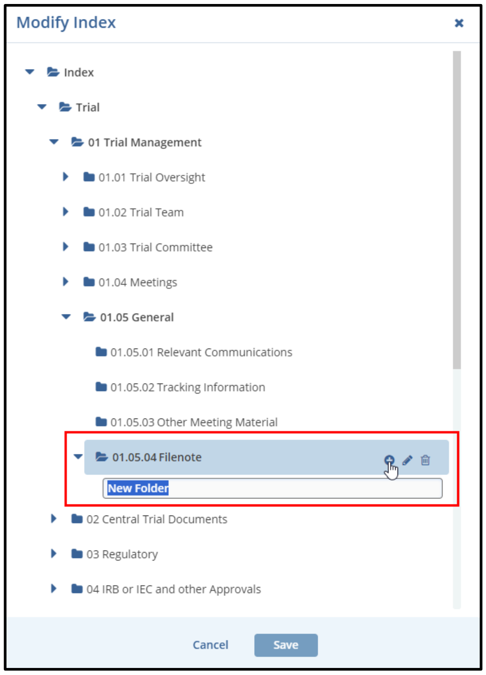


Figure 7: Modify Index Page

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

Editing or Deleting an Existing Index Folder

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

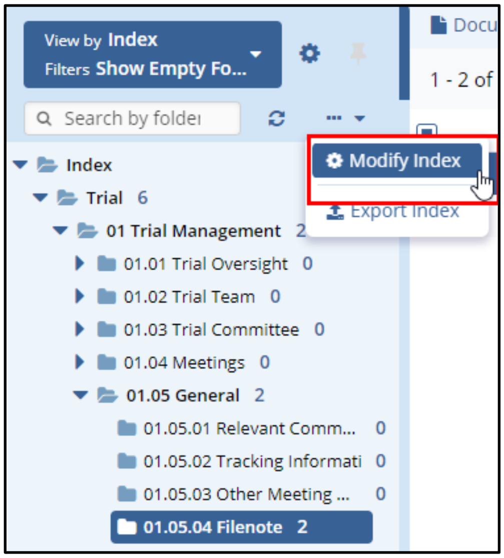


Figure 8: Modify Index

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

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

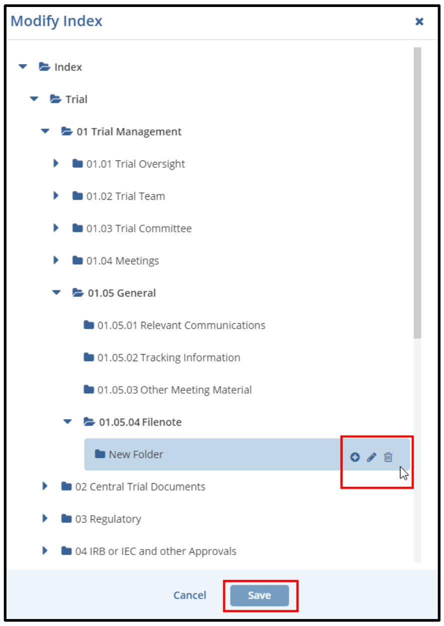


Figure 9: Edit and Delete Folder

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

Editing Country and Site Level Folders

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

Exporting the Index Structure

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

To export the index:

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

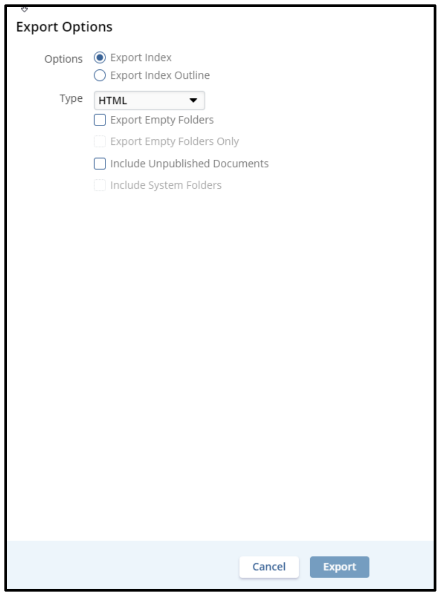


Figure 10: Export Index Structure

The Documents Grid

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

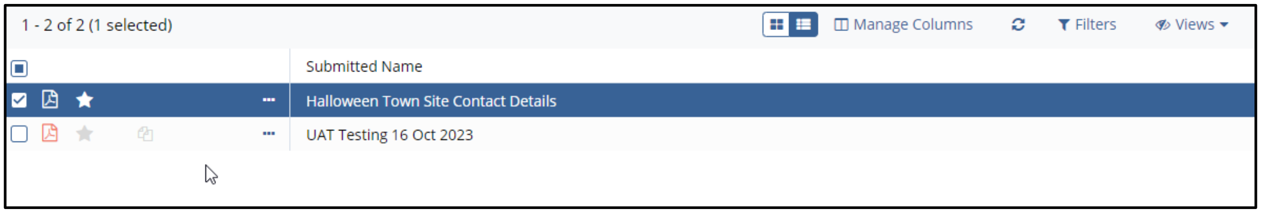


Figure 11: Document Grid

Choosing between the Grid View and the Card View

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

Grid View

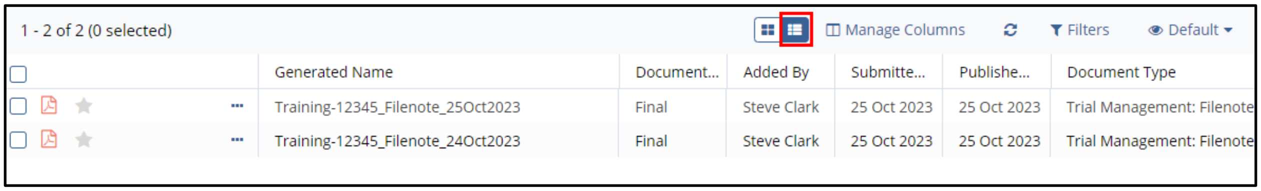


Figure 12: Grid View

Card View

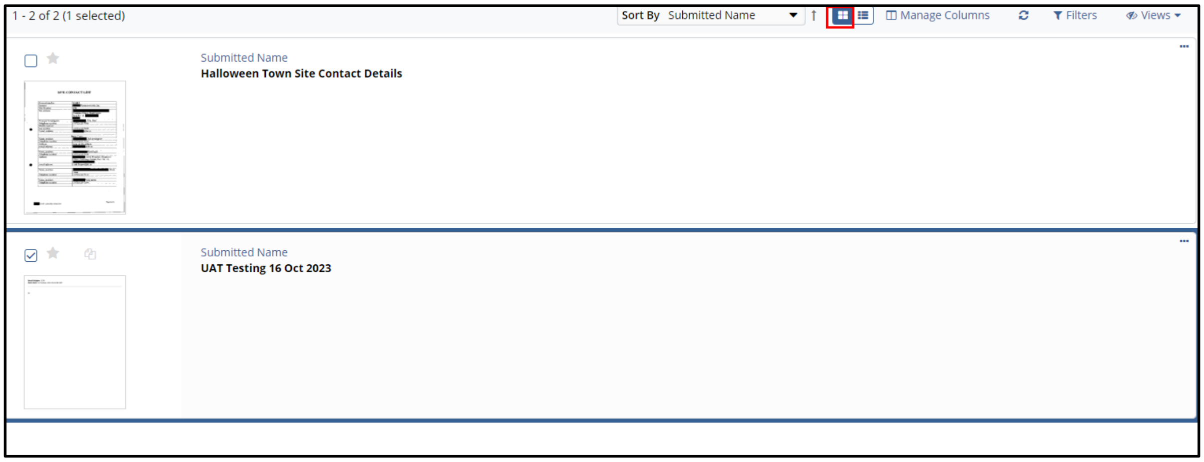


Figure 13: Card View

Configuring the Document Grid

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

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

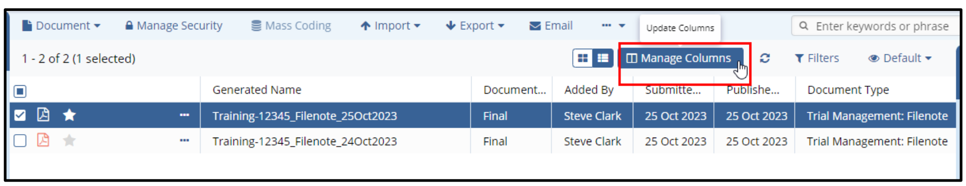


Figure 14: Manage Columns

2. The Manage Columns window will open which displays the following panels:
    a. **Available Columns Panel**: This panel displays the list of all available columns in a room.
    b. **Selected Columns Panel**: This panel displays the list of all columns that are selected and added from the Available Columns.
3. To add a column to the Selected Columns pane from the Available Columns pane, hover the mouse over the column name in the Available Columns.
    - A '+' sign appears next to the column name.
4. Click the '+' sign to add the column to the Selected Columns. The column gets added to the list of Selected Columns.

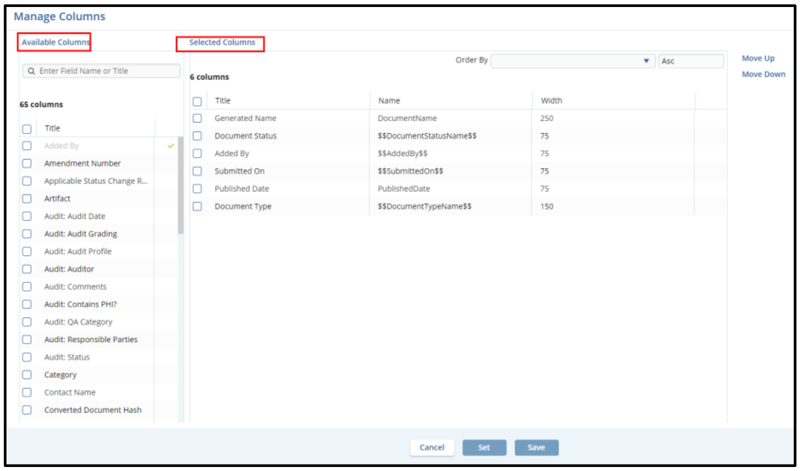


Figure 15: Manage Columns Page

5. Alternatively, you can also double-click the columns in the Available Columns to add to the Selected Columns.
6. After adding the columns to the Selected list, they are greyed out in the Available Columns list.
7. Similarly, you can remove the columns from the Selected Columns list by clicking the - icon that appears next to the column name on hovering the mouse over the column OR double-click the column to remove it from the list.
8. Besides adding and deleting columns, you can also change the sequence of the columns by
9. clicking the **Up or Down** buttons located at the extreme right of the window.
10. Click **Save** to save to changes.

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

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

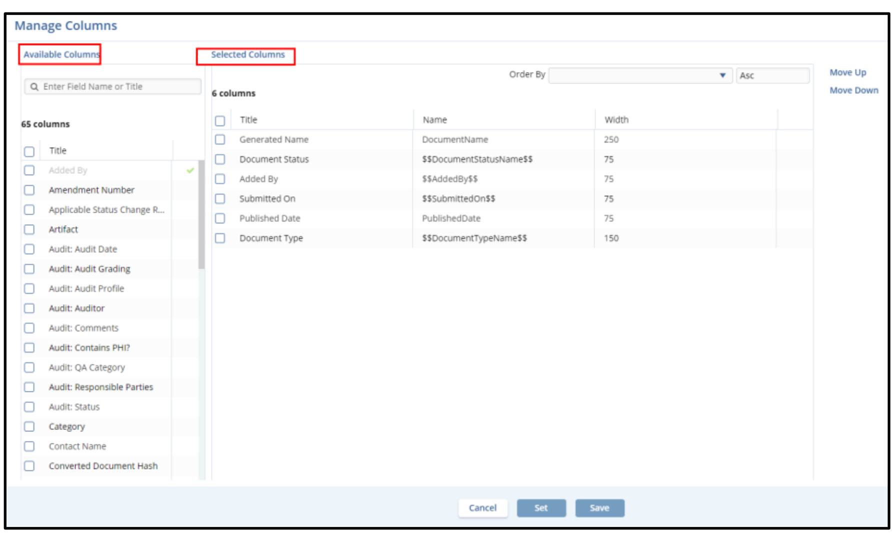


Figure 16: View Types

Saving your View

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

From the Manage Columns window:

1. Press ‘**Save’**
   - This opens the Save View window (see the screenshot below)

Figure 17: Save View

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

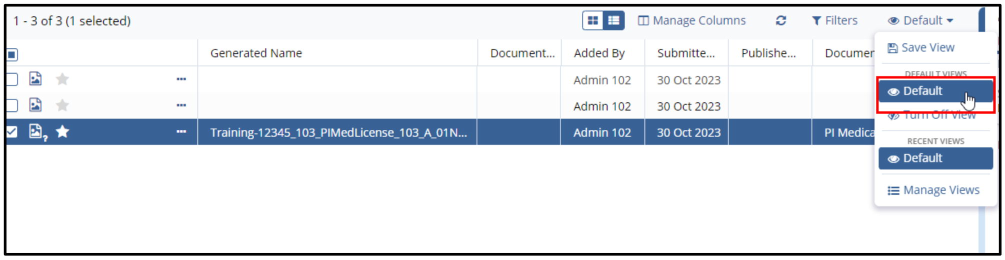


Figure 18: Default

Sharing Your View of the Grid

Once you have saved your view, you will be able to share it with any other room user. This is particularly useful when bringing on a new team member who may not be familiar enough with Trial Interactive to easily find necessary information via the Grid. To share your view, follow the steps below:

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

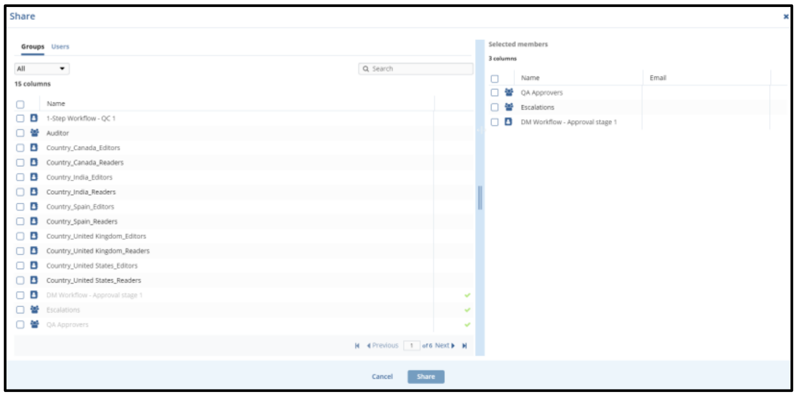


Figure 19: Sharing View

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

Show All views

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

To display all views:

1. Click Manage Views from the from the Views dropdown. Refer to the screenshot below:

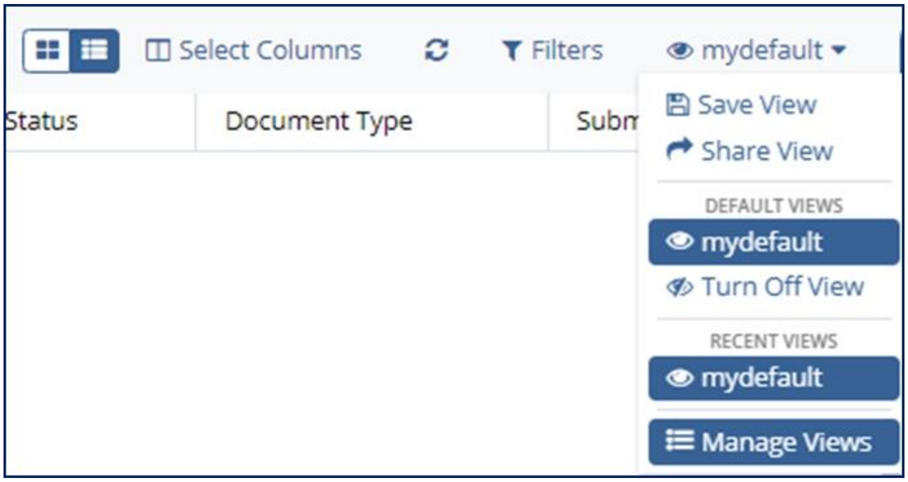


Figure 20: Manage View

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

The screenshot below shows an example of the All views:

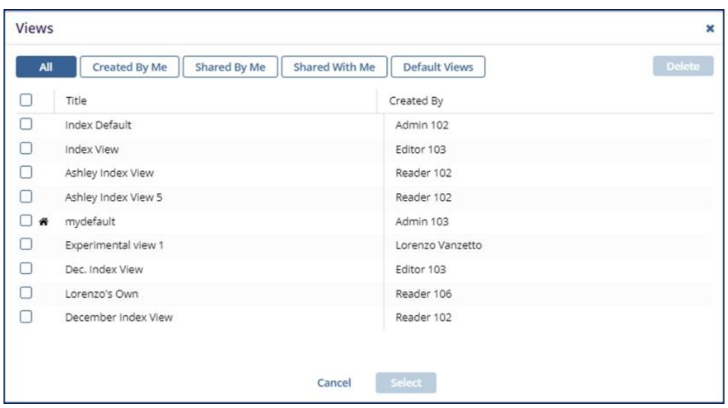


Figure 21: All Views

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

Previewing and Viewing a Document and its Metadata

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

Viewing Document Metadata

To access the Document Metadata, follow the steps 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.

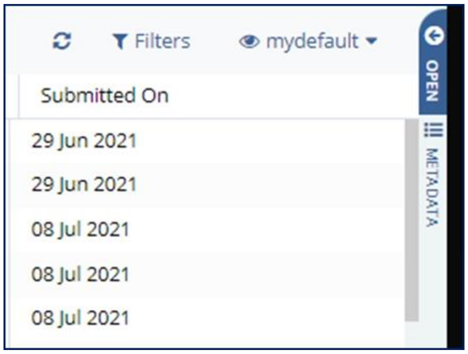


Figure 22: Open Metadata

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

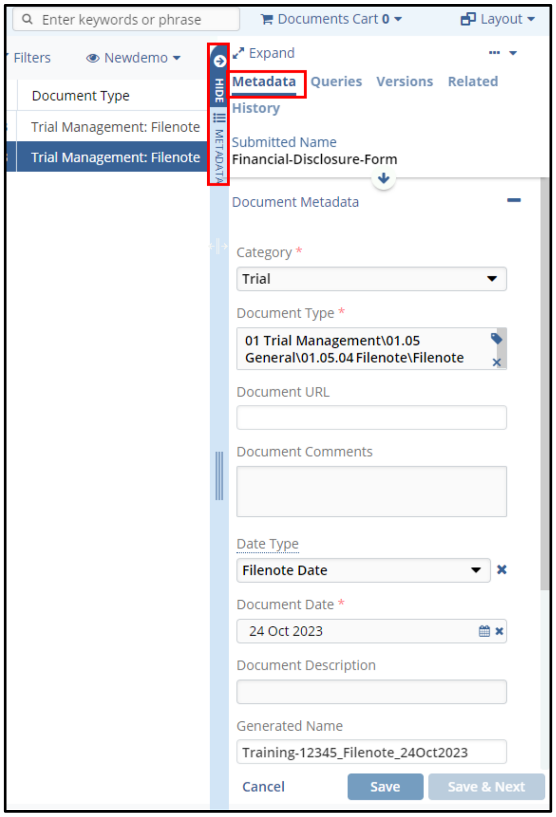


Figure 23: Metadata Fields

Editing Document Metadata

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

- Administrator-level users can edit metadata for any document.
- Editor-level users and Manager users with Document Manager permission can edit metadata for any document.
- Editor and Manager users can edit metadata for non-final documents.
- Reader-level users cannot alter metadata for any document.

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

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

Viewing Documents

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

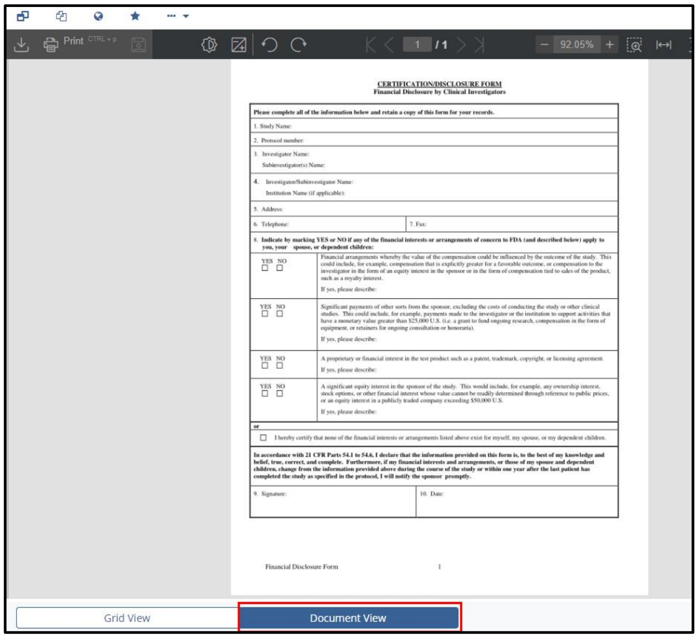


Figure 24: Detailed View

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

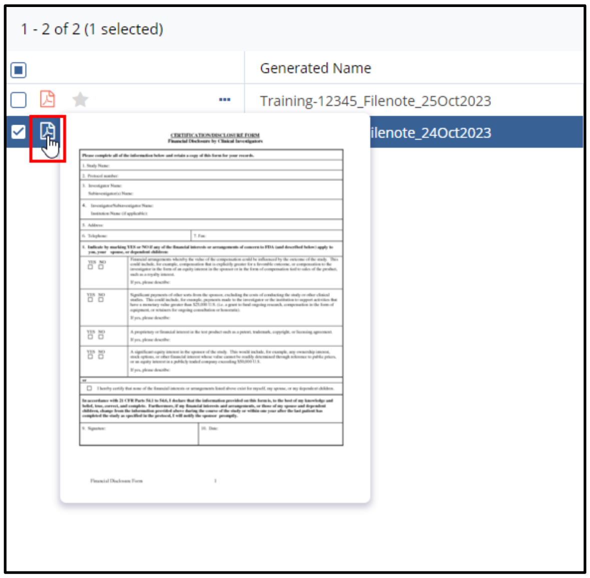


Figure 25: Detailed View Icon

Copying or Moving Documents

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

Follow the steps below to copy documents:

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

Grid Filters

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

1. Click the Filter icon above the document grid.
2. The Filter options are enabled at the top left corner of the documents grid.
3. From the enabled options, you can perform the following:
    a. Create a New Filter
    b. Manage Filter

Each of these is discussed in the separate sections.

Creating a New Filter

1. Click the '+ Create New Filter' button above the documents grid.
2. The Create Filter window opens. The window displays the following:
    a. A textbox that displays the Title for the filter selected.
    b. Notice that there are two plus signs to the right of the window which allow you to create a single filter or a group of filters.

c. The options for matching the filter records. Refer to the screenshot below:

Figure 25: Create Filter

Adding Single Filter

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

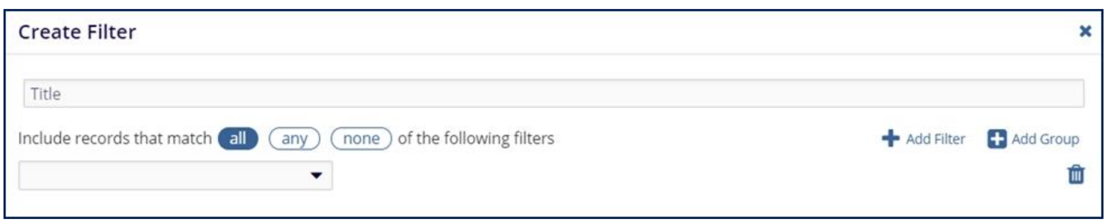


Figure 26: Single Filter

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

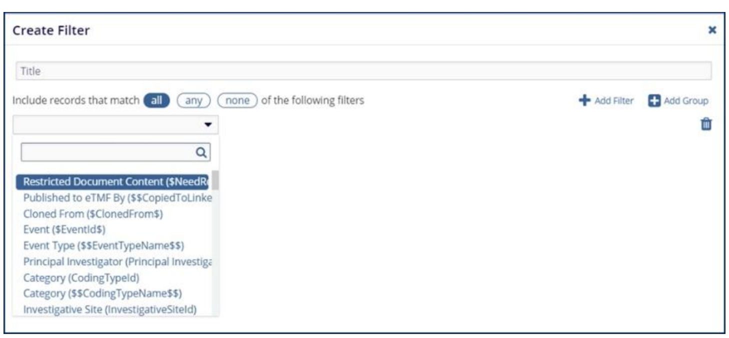


Figure 27: Operator options

4. When you have applied all of the applicable filters, press the ‘Create’ button.

5. The filter will appear above the grid, select the filter to apply it to the grid contents. The screenshot below shows an example of the filter result applied for the Title = Test.

Figure 28: Applied Filter

Add Existing Filters / Manage Filters

Manage filters allow 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:

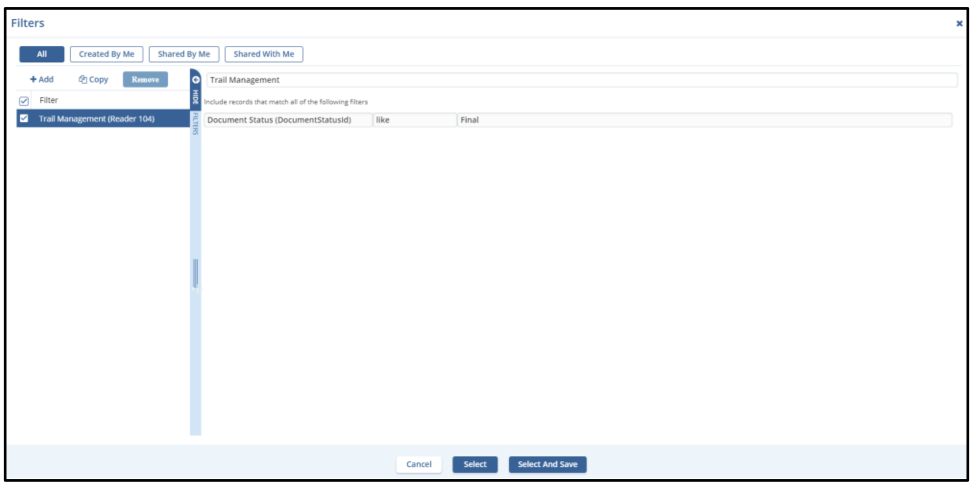


Figure 29: Manager Filters

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

- Share Filters
- Clone Filters
- Remove Filters

Sharing Filters

To share a filter:

1. Select the filters from the list of filters in the Filter window.

2. The selected filter appears in the right pane of the window and the buttons Clone, Delete, Share, Cancel, and Save are enabled. Refer to the screenshot below:

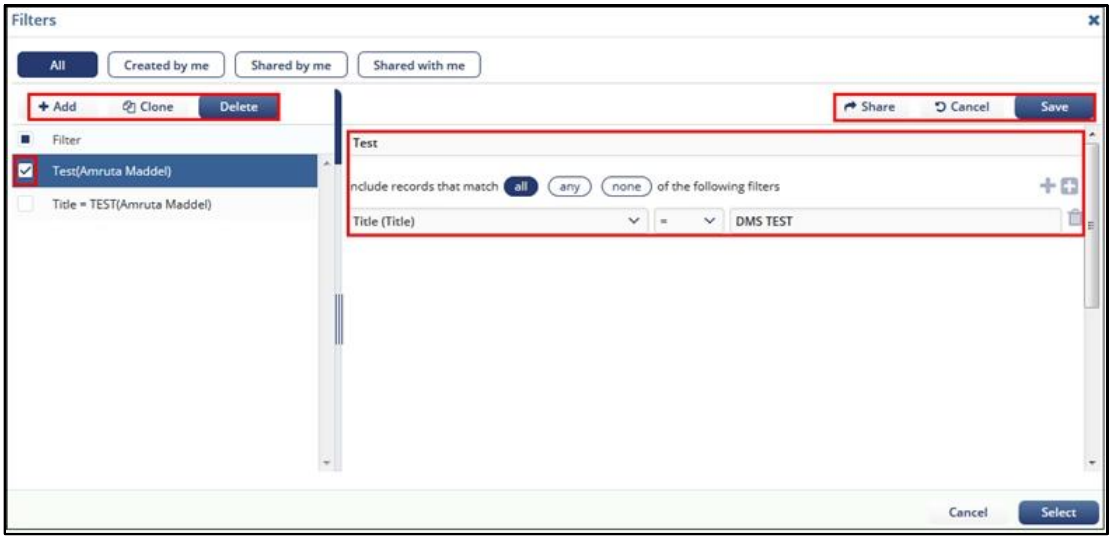


Figure 30: Sharing Filters

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.

Removing Filters

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

Viewing Shared Filters

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

The Document Activities Menu

Depending upon your user access rights, there are a great many activities that can be performed from the Document Activities Menu. To open this menu, select a document or a placeholder from the Grid and either right-click or use the three-dot menu. (See the screenshot below)

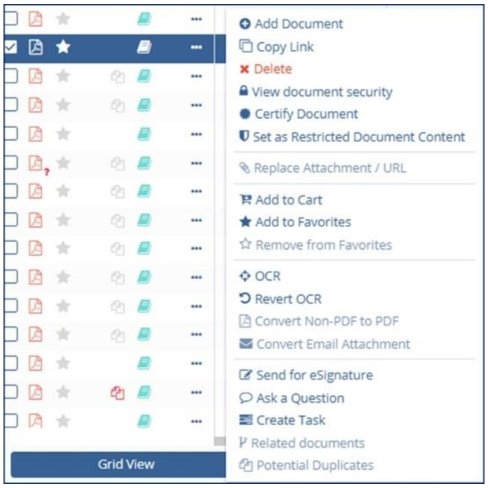


Figure 31: Document Activities Menu

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

Adding a Document via the Document Activities Menu

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

Deleting a Document via the Document Activities Menu

Administrator-level users will be able to select 'Delete' from the Document Activities menu for any document in the room except those currently claimed for review in either an Audit Response or the QC Workflow. Editor and Manager-level users can delete documents so long as the user is the one who uploaded the document and that document has not been claimed by the QC workflow. Once a document is final, Editor and Manager level users will not be able to delete the document without additional permissions applied to their account.

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

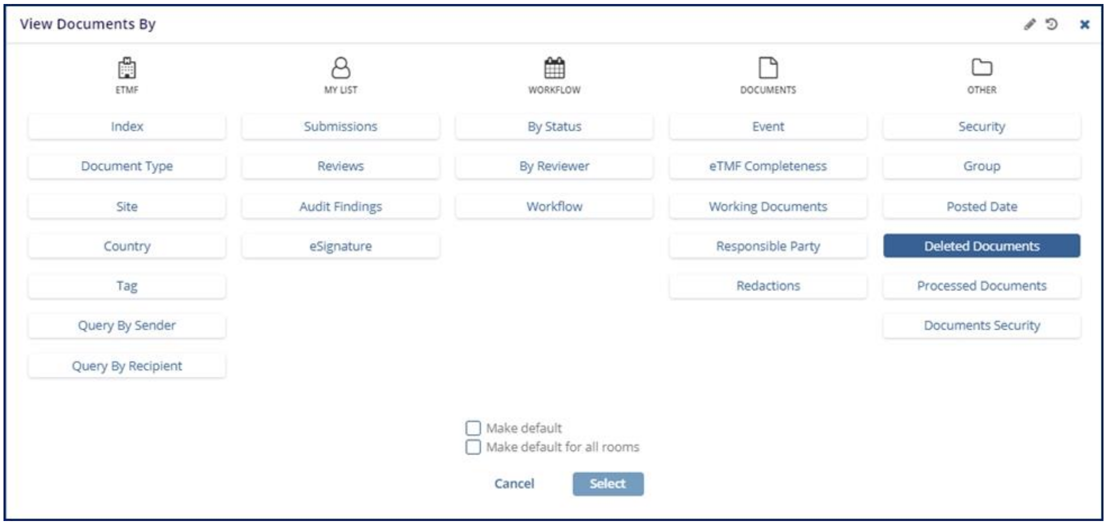


Figure 32: Deleted Document View

Purging a Deleted Document

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

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

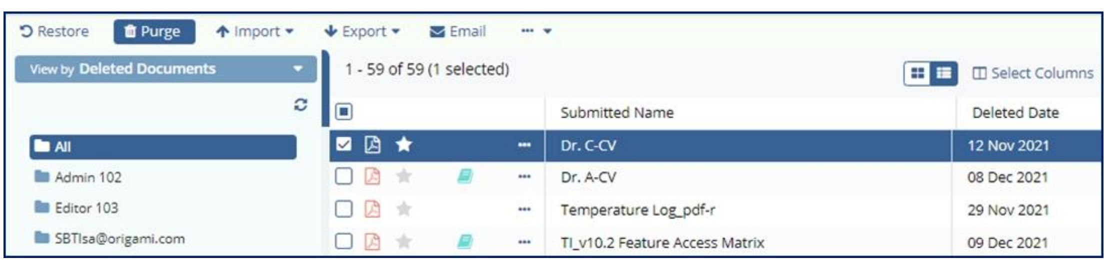


Figure 33: Purge option

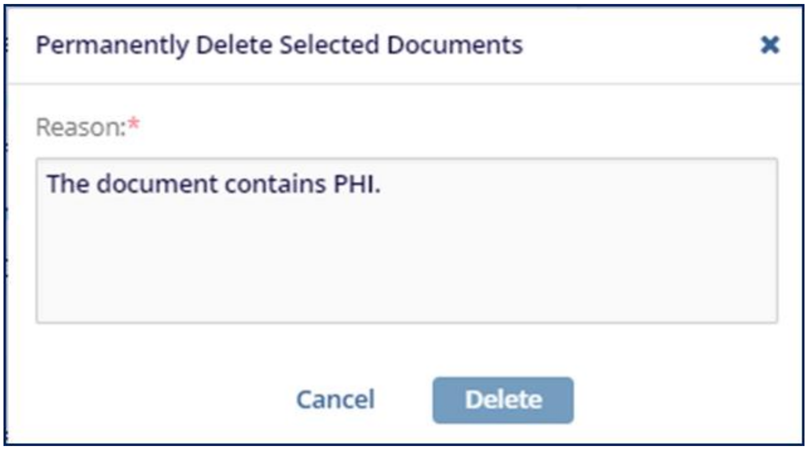


Figure 34: Permanently Delete Documents page

Rejected Folder

A new setting is added to support a Rejected folder within the eTMF for Room Administrators, and a new Document Rejection function is now available to Admins, Document Managers, and Room Managers. Any documents in Upload, Inbox, Staging, and Rejected Folders are not considered to be Final. A **'Reason for Rejection**' dropdown is now available for workflow documents and documents in the rejected folder/status are now excluded from eTMF health calculations.

Note: Users will not be able to drag and drop documents into this folder to prevent awarding an erroneous status should a non-rejected document be placed in this folder.

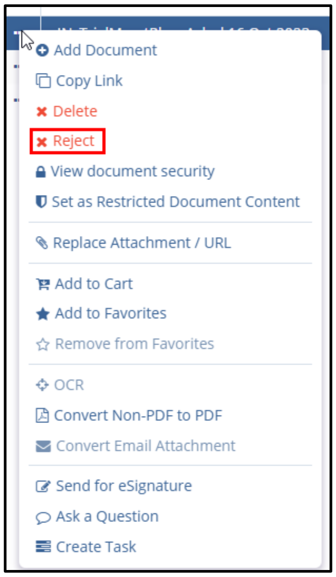


Figure 35: Reject Field

Figure 36: Rejected Document Page (Reason for Rejection)

To reject a document outside of the standard workflow steps, the user must either be an administrator or they must have the **Document Manager** action enabled on their user account. For users who meet these requirements, rejecting a document can be accomplished by right-clicking on the document or by clicking on the three-dot menu in the grid and selecting the '**Reject'** option from the document actions menu.

Copying a Link to a Document

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

Adding a Document to the Documents Cart

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

Marking a Document as a Favorite

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

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

View Document Security

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

Certify Document

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

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

OCR/Revert OCR

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

Ask a Question

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

Convert Non-PDF to PDF

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

The Document Metadata Panel

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

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

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

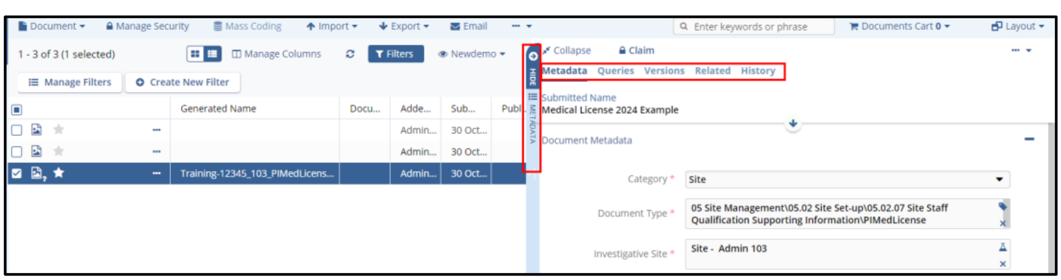


Figure 37: All panel

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

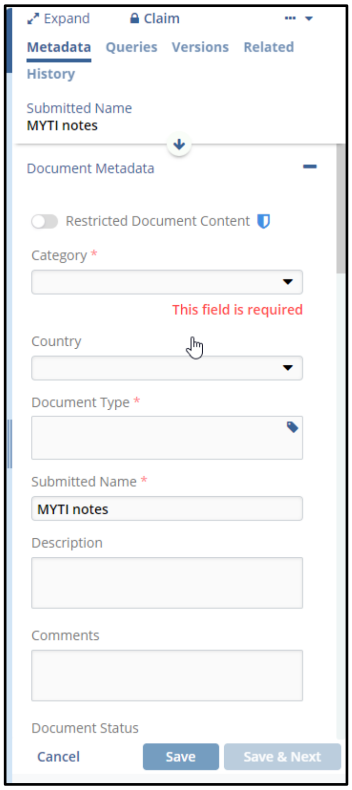


Figure 38: Metadata Panel

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

The Metadata Panel also provides the Claim button and the three-dot menu icons at the top of the panel to allow you to claim documents in workflow and perform various actions on the document.

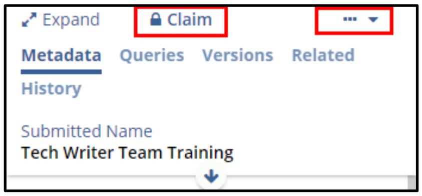


Figure 39: Claim and Three Dot feature

Workflow Functions in the Metadata Panel

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

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

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

Workflow History

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

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

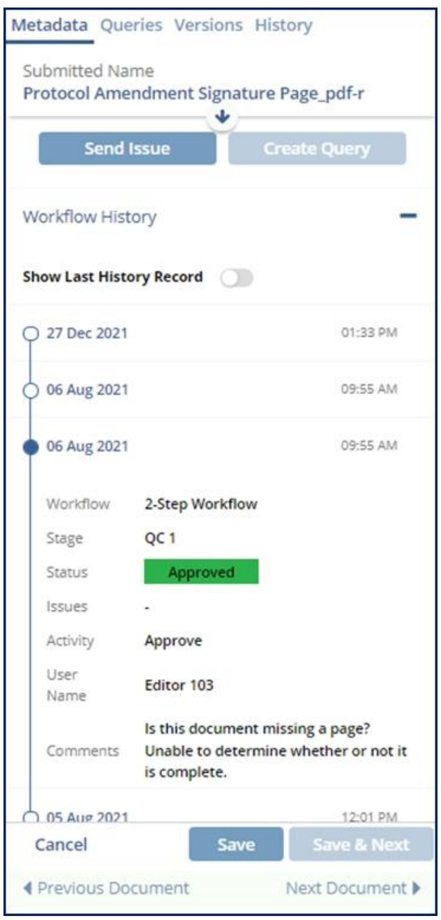


Figure 40: Workflow History

Viewing and Working Queries from the Metadata Panel

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

Versions Tab

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

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

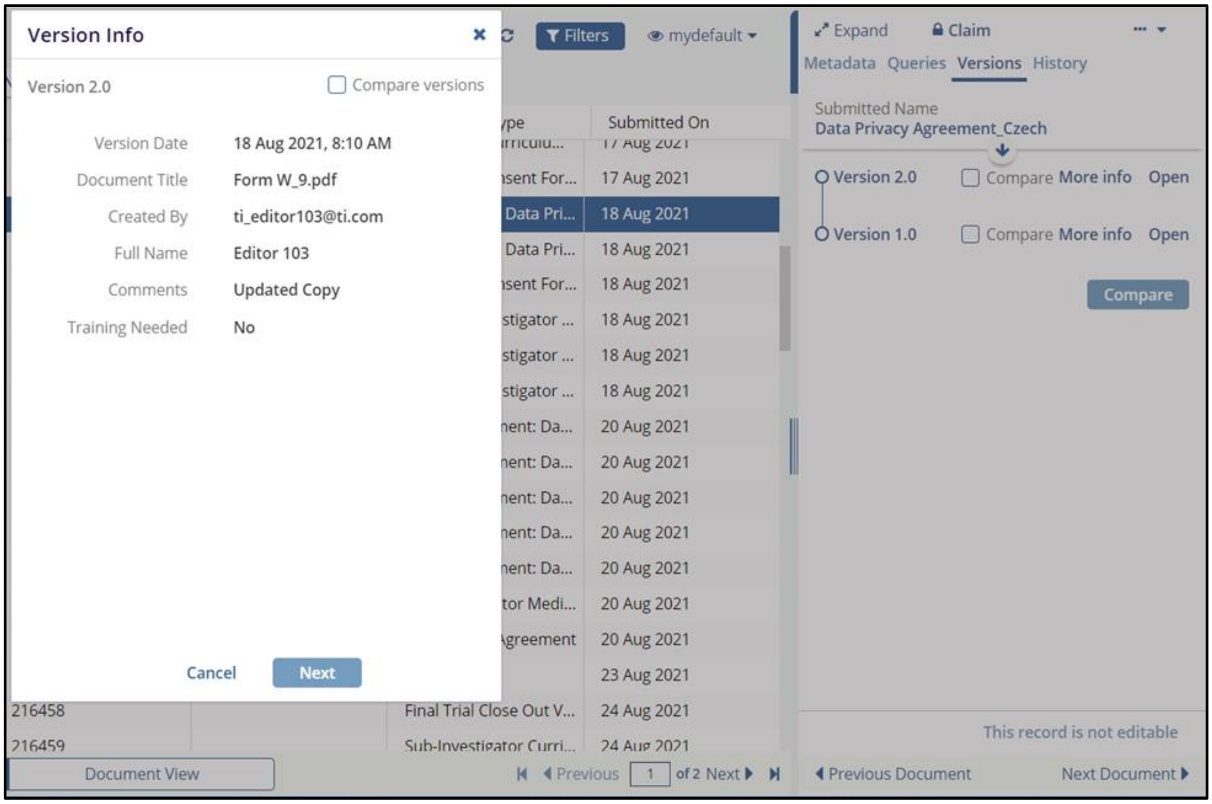


Figure 41: Version Information Page

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

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

History Tab

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

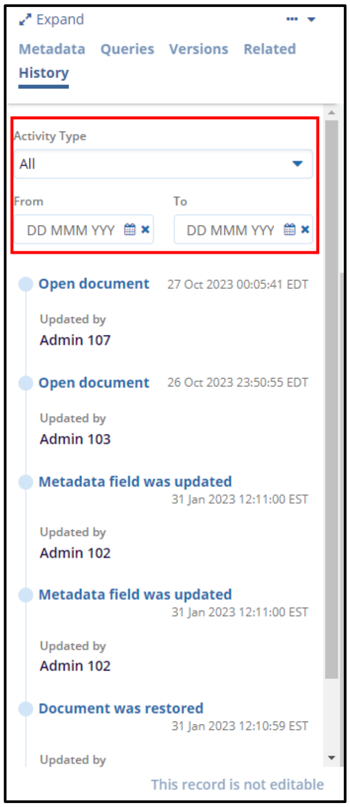


Figure 42: History Tab

Document History Filters

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

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

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.

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:

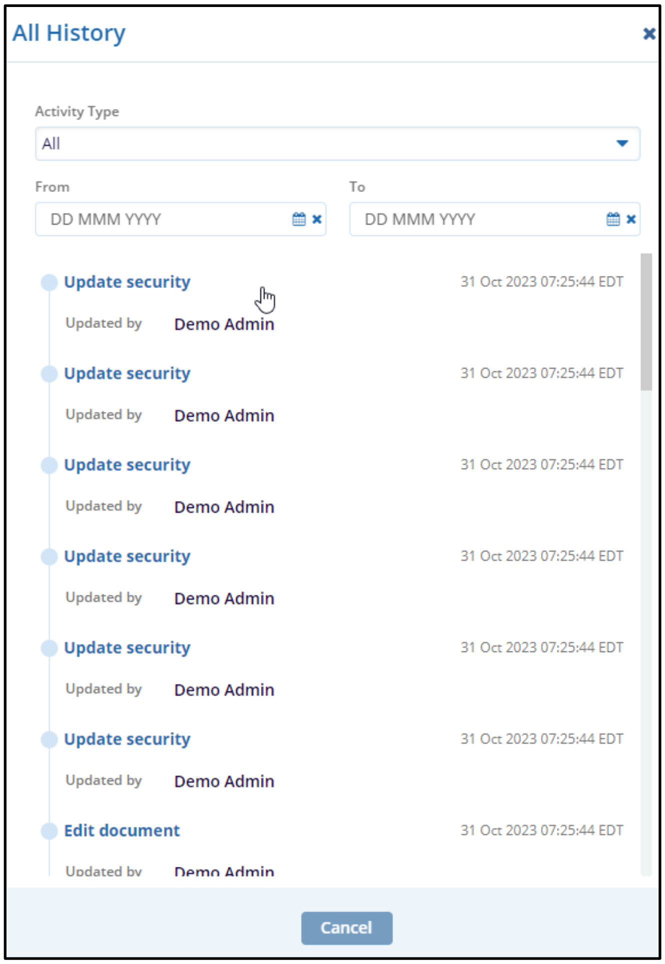


Figure 43: All History Page

Documents Module- Top Menu Ribbon

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

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

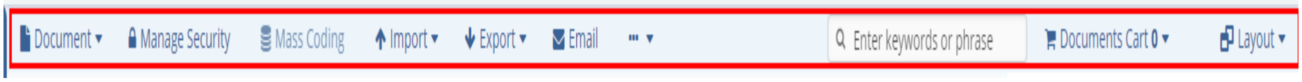


Figure 44: Documents Module – Top Menu Ribbon

Document Activities

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

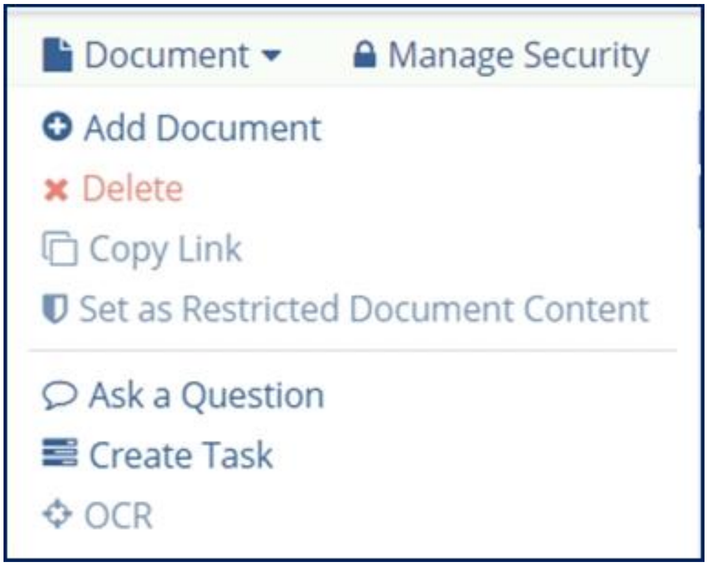


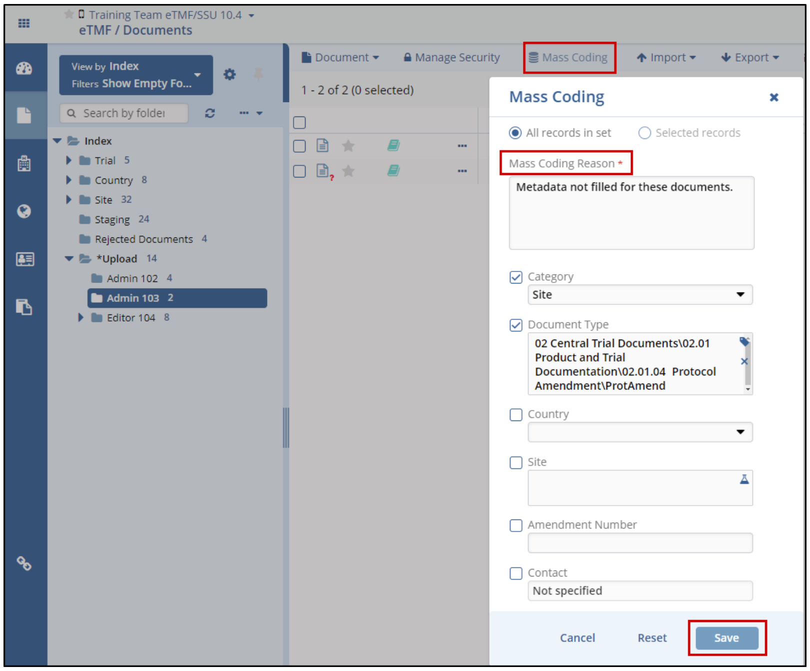
Figure 45: Document Activities.

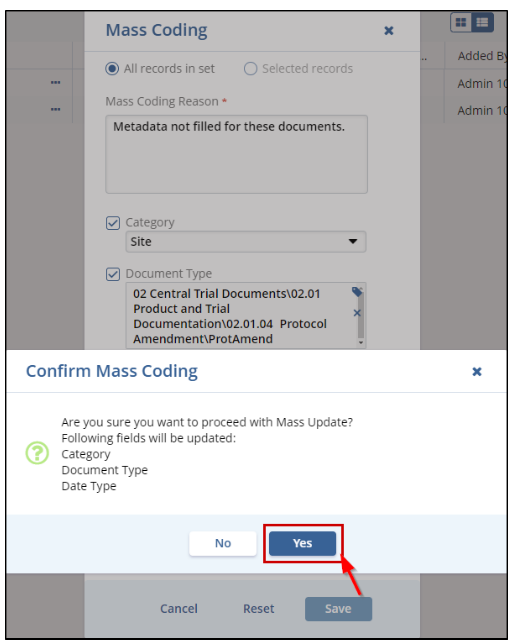
Manage Security

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

Mass Coding

The Mass Coding function, allows the user to apply metadata to multiple documents at the same time. **A room can be configured to allow both Causality Tracking and Mass Coding.** Click the **Mass Coding** button displayed in the top menu bar to open the popup window. Enter the reason in the field (mandatory) and if required, mention the details in the other fields. Click the **Save** button displayed at the bottom of the popup window. Refer to the screenshots below.





Alternatively, the user can also drag-drop the documents in document cart and select the **Mass Coding** option from the **Actions** dropdown menu.

Email

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

1. If applicable, select the documents related to your email.
2. Press the Email button above the grid.
    - This will open the Email window.
3. You can either type the email recipients into the appropriate line or use the 'To' and 'CC' buttons to select recipients from the list of users.
4. Type your message.
5. If applicable, indicate whether or not the documents should be attached to the email using the radio buttons at the lower-left corner of the window.
6. Press 'Send' when done.

Move to Study Start-Up

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

Print

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

Compare

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

Local Search

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

Importing Documents and Metadata

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

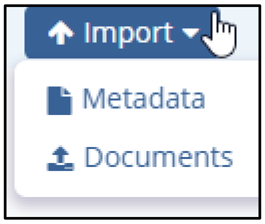


Figure 46: Import Option

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

1. Click on the **Import** button above the documents grid.
    - This will open the **Import Documents** window.
2. Add documents to the area at the left either by dragging them from your desktop or by searching for them on your computer. To open the browsing window either click on the Browse button or the arrow at the center of the documents area.
    - When adding .zip files to the room, review the options at the bottom of the window to indicate whether or not these files should be unpacked during upload. Password-protected files cannot be unpacked by the system during upload.
3. Indicate whether or not any non-PDF documents should be converted to PDF files during the upload process. The types of files that can be converted are specified in the room's settings.
4. Indicate, via the checkbox at the top of the right side, whether or not any metadata should be applied to the documents.
    - Metadata can be applied to all documents at once or to a subset of documents. To apply metadata to only some of the documents, check the box next to the documents to which the metadata should be added.
5. Press '**Import'** or, if you have applied metadata, Press 'Import and Apply Metadata.'
    - If you have chosen to apply metadata to only a few of the documents, only those documents will be uploaded to the room. Repeat steps 4 and 5 until all documents have been uploaded.

Exporting Documents and Metadata

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

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

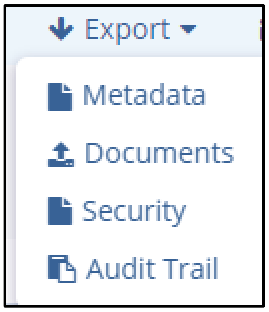


Figure 47: Export Metadata

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

To Export metadata, follow these steps:

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

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

To Export Documents, follow these steps:

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

To Export security information, follow these steps:

1. Locate the documents whose information should be exported.
2. Check the box next to each document to be exported.
3. Click the Export button and choose ‘Security’
   - The Export Security window will open.
4. Choose from the Source options:
   a. Selected records
   b. All documents in the current grid
   c. All documents in the room
5. Press ‘Next’
6. Choose which metadata fields should be included in the export
7. Press ‘Export’

Exporting Instant Audit Trials

Auditors often ask for immediate access to the audit Trial of a specific document or set of documents. It is critical to be able to provide this information immediately and respond to the audit request.

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

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

To export an audit Trial, follow the steps below:

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

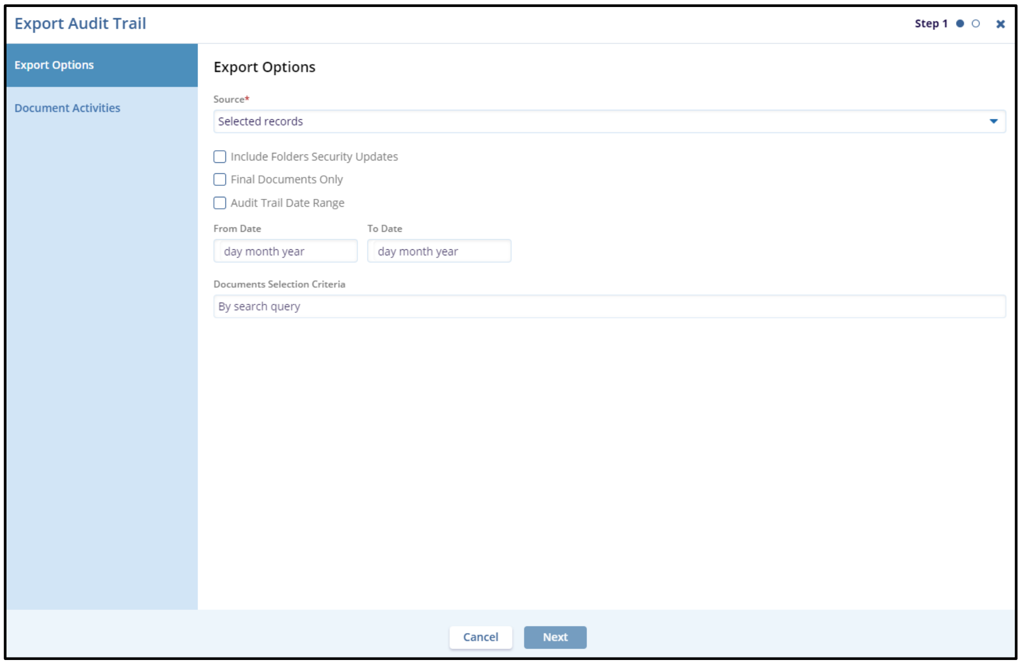


Figure 48: Export Audit Trial

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

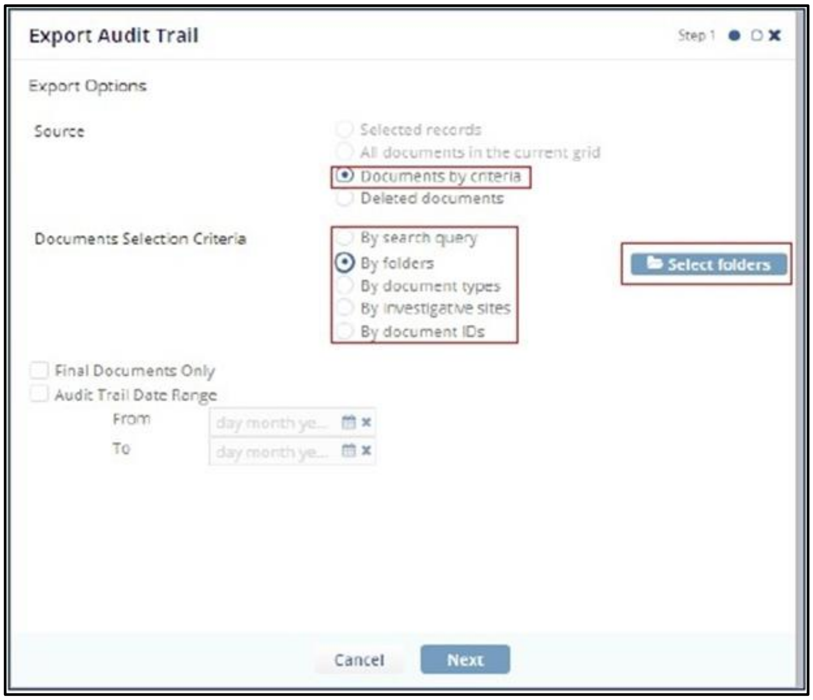


Figure 49: Audit Trial

8. Choose the appropriate criteria and press the Select button.
9. When you have indicated all necessary criteria, press Next to continue.
    - A confirmation window will open showing you the selected criteria.
10. Review the selected criteria and, if they are correct, press Export.
11. A message will be displayed when the export is ready for download.
12. Press Get Job Results to download the file.

The Documents Cart

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

Adding documents to the Documents Cart

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

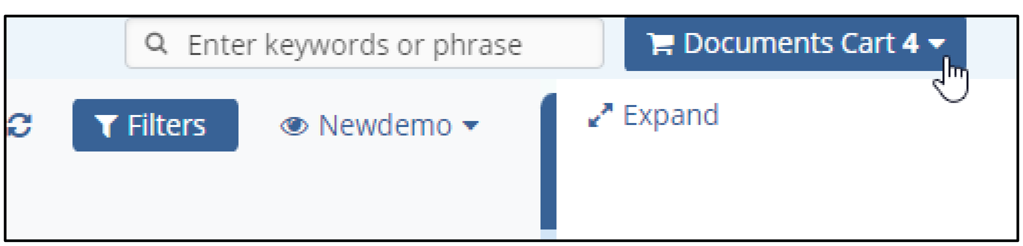


Figure 50: Document Cart

Copying documents to Other Rooms

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

1. Add the required documents to the Documents Cart.
2. Click the arrow next to the Documents Cart to open the cart window.
3. Select the documents which you wish to copy to other rooms.
4. Click Copy and select 'To other Rooms.' Refer to the screenshot below.

Figure 51: Copying Documents to Other Rooms

5. The Clone Document window will open up and prompt you to specify to which study rooms documents the documents should 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 index as final documents without going through the workflow, select the checkbox next to publish documents to the index as final documents.
8. Click **Copy**. The document type of the destination room will determine the auto-naming rule for the document. Refer to the screenshot below:

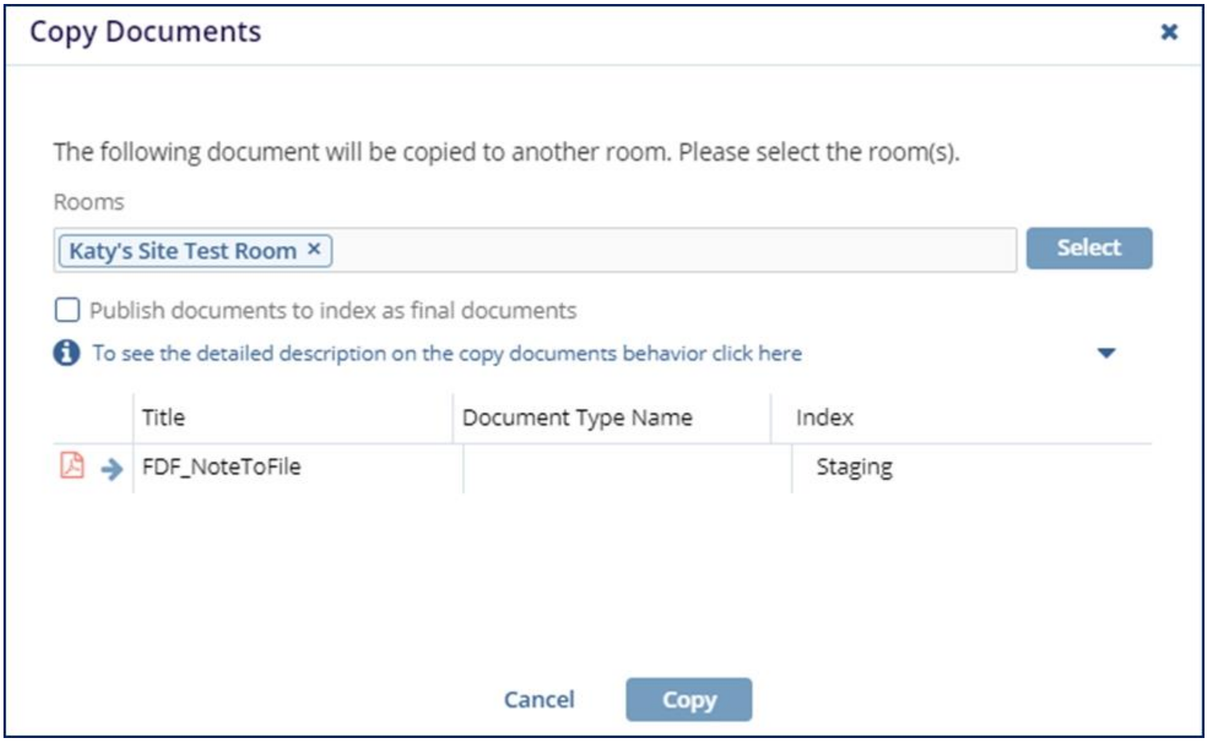


Figure 52: Copying Documents

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 the 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 that you wish to clone for other Investigative Sites.
4. Click Copy and select Investigative Sites. Refer to the screenshot below.

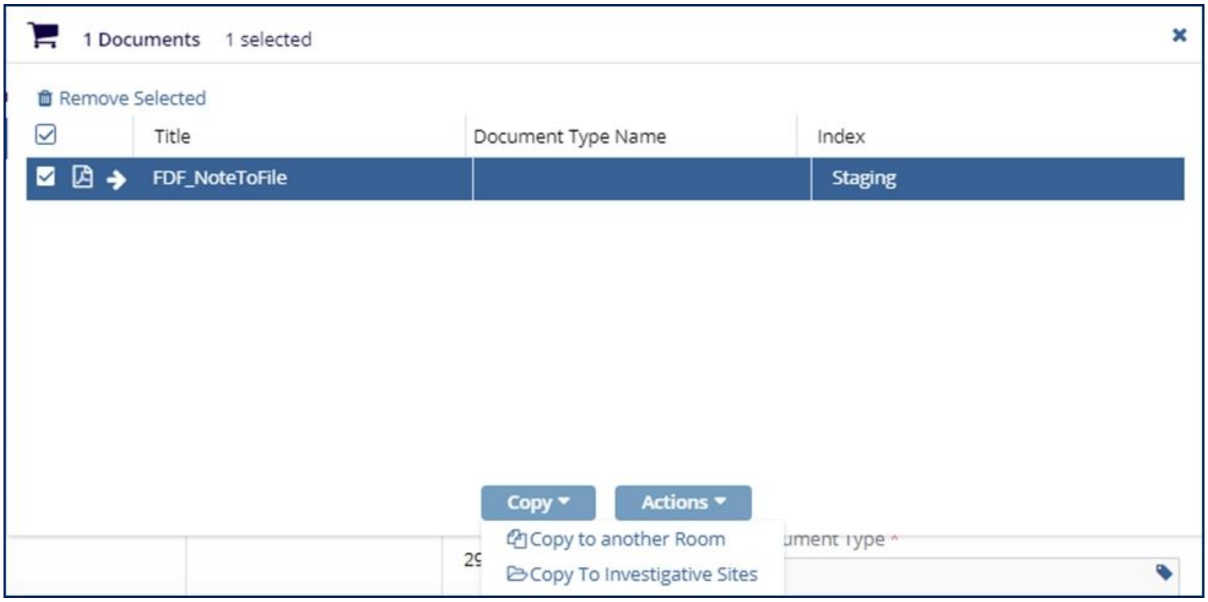


Figure 53: Copying Documents to Investigative Sites

5. The Clone Documents to Investigative Sites window opens up and asks you to select investigative sites. Click the 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 in the next section.
    c. If you choose By Country, a dropdown with the list of countries gets activated for you to choose from.

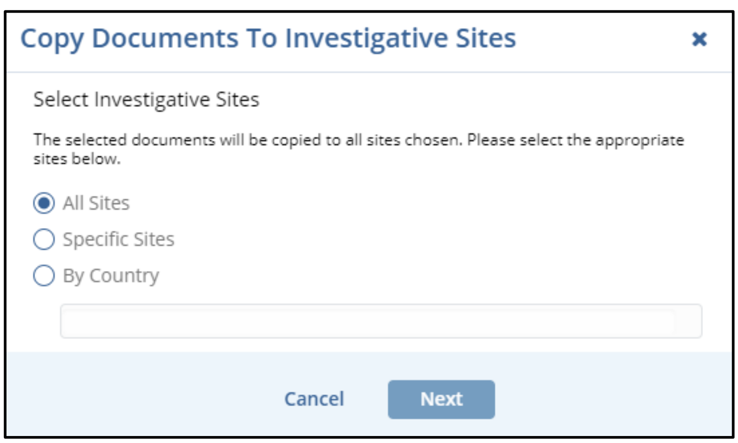


Figure 54: Copying Document Options

6. Click Next folder selection.
7. Once the folder is selected, click Copy. The documents are copied to the Investigative Site folder. Refer to the screenshot below:

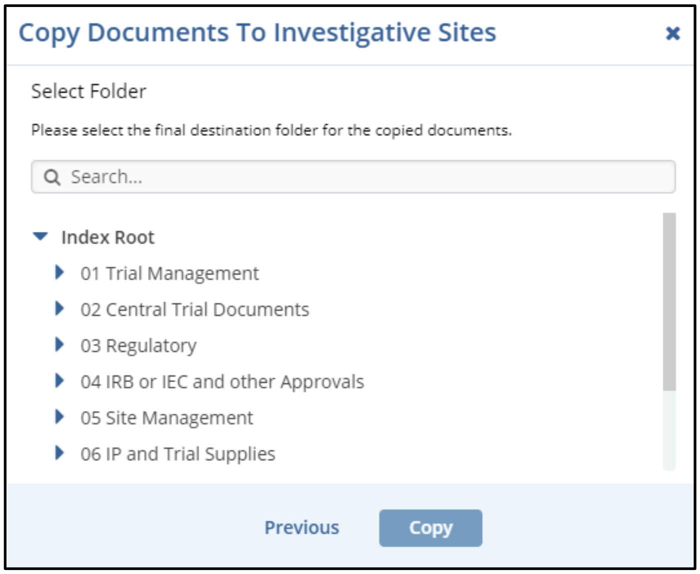


Figure 55: Folder to copy documents

Merging documents

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

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

Figure 56: Merge Documents

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

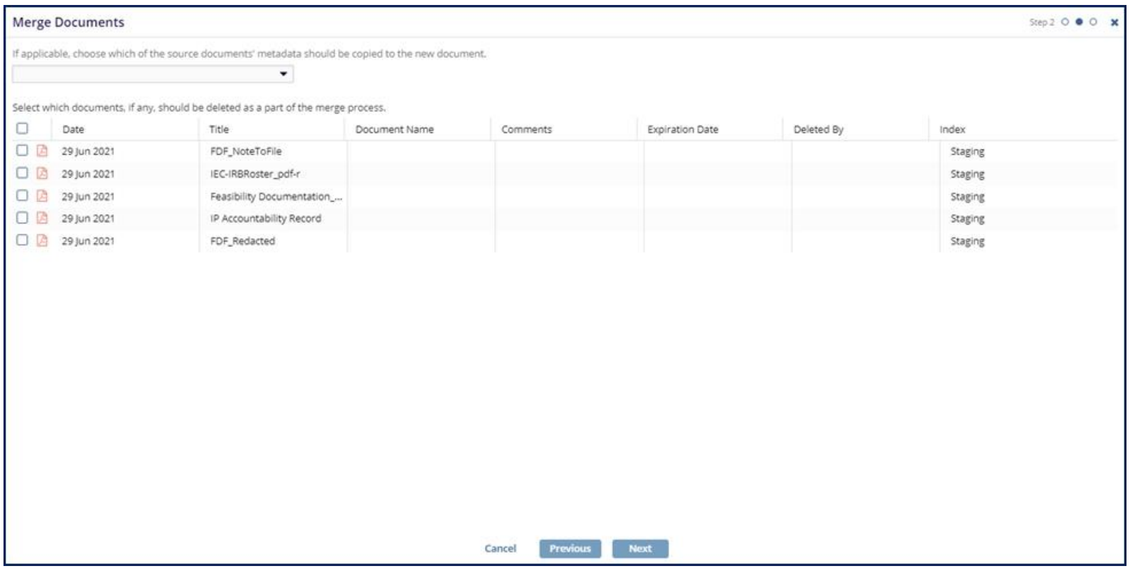


Figure 57: Merge Documents Page

7. The dropdown menu at the top of the screen allows you to clone the metadata from any of the source documents.
8. The lower area, listing the source documents, is there in case the user wishes to delete any of the source documents as a part of the merge process.
    . The source documents will only appear here if the user has the appropriate access rights to the documents to delete them.
    a. Any document selected will be deleted as a part of the merge process.
9. Press 'Next'
10. Confirm the metadata for the merged document and press 'Finish'

Linking documents

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

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

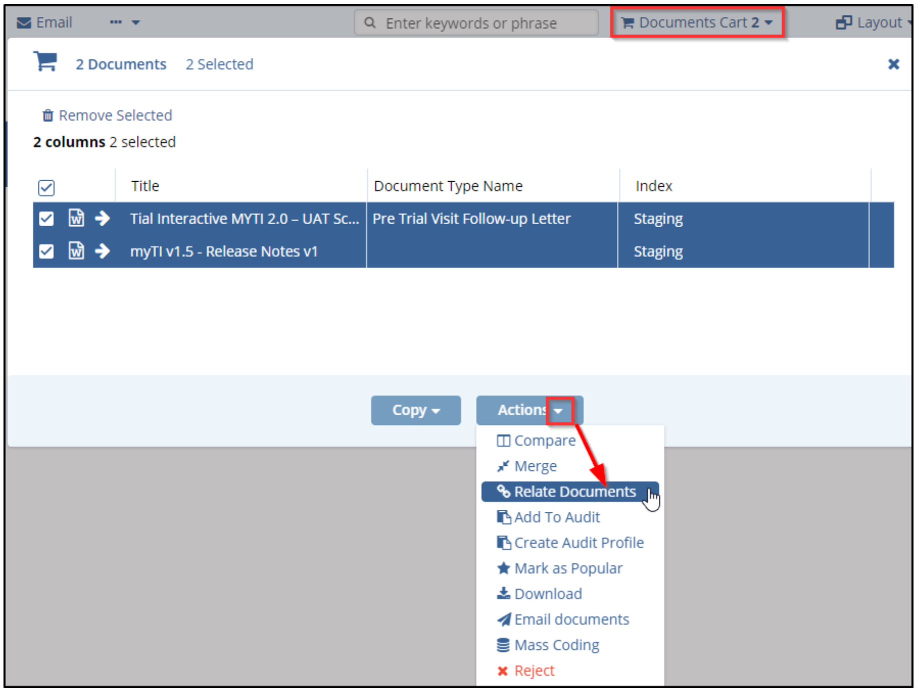


Figure 58: Linking Documents

4. The Relate Documents window will open. Select the appropriate option from the dropdown menu. See the screenshot below:

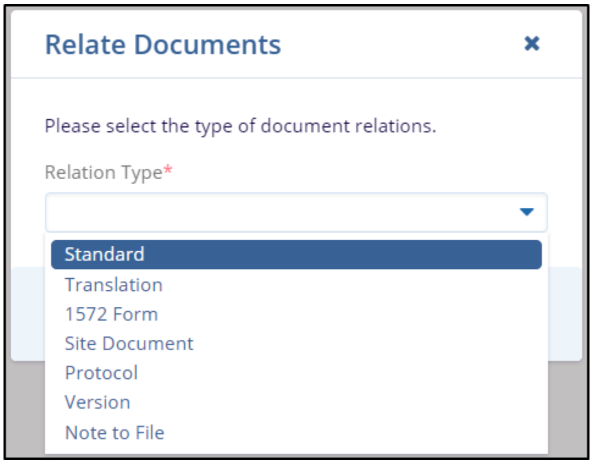


Figure 59: Linking Document Page

5. Press Save to complete the relating documents process. A notification 'Documents related' is displayed in the top right corner of the screen.

Adding documents to an Audit

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

1. Add required documents to the **Documents Cart**.
2. From the Documents Cart, select the appropriate documents.
3. Click Actions and then select **Add to Audit**.

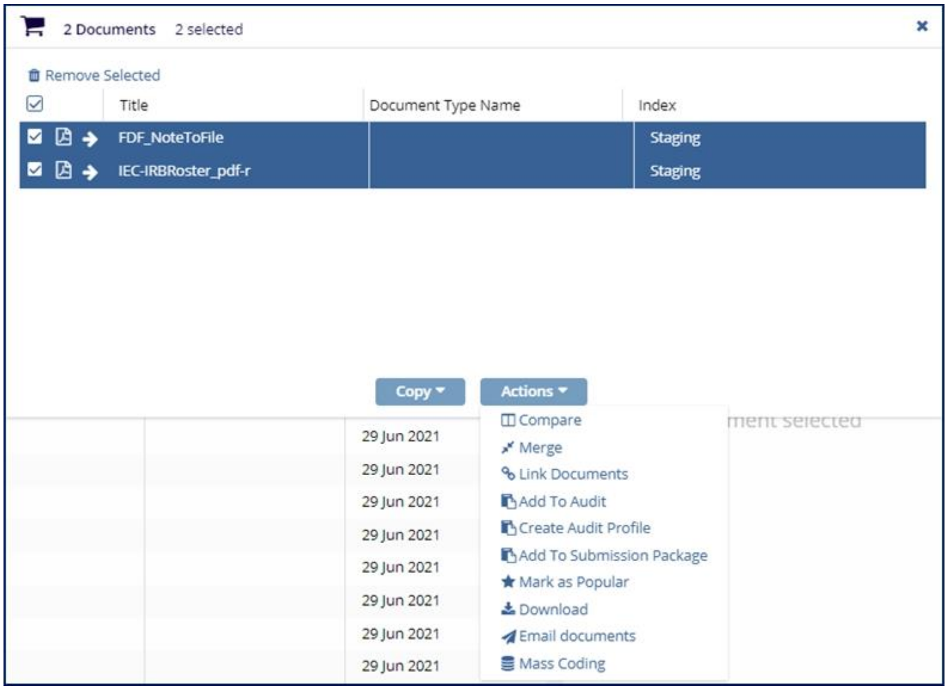


Figure 60: Adding Documents to Audit

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

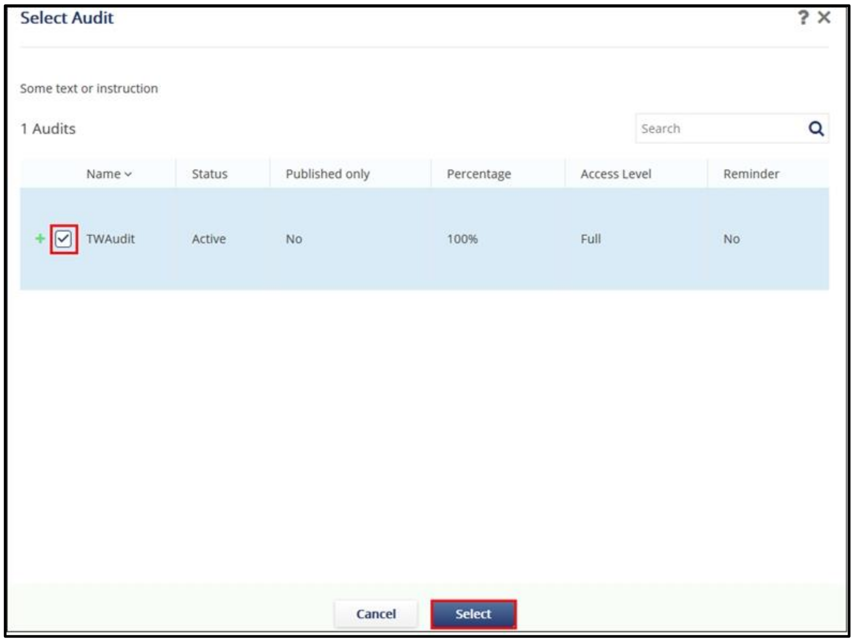


Figure 62: Select Audit

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

Create an Audit Profile

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

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

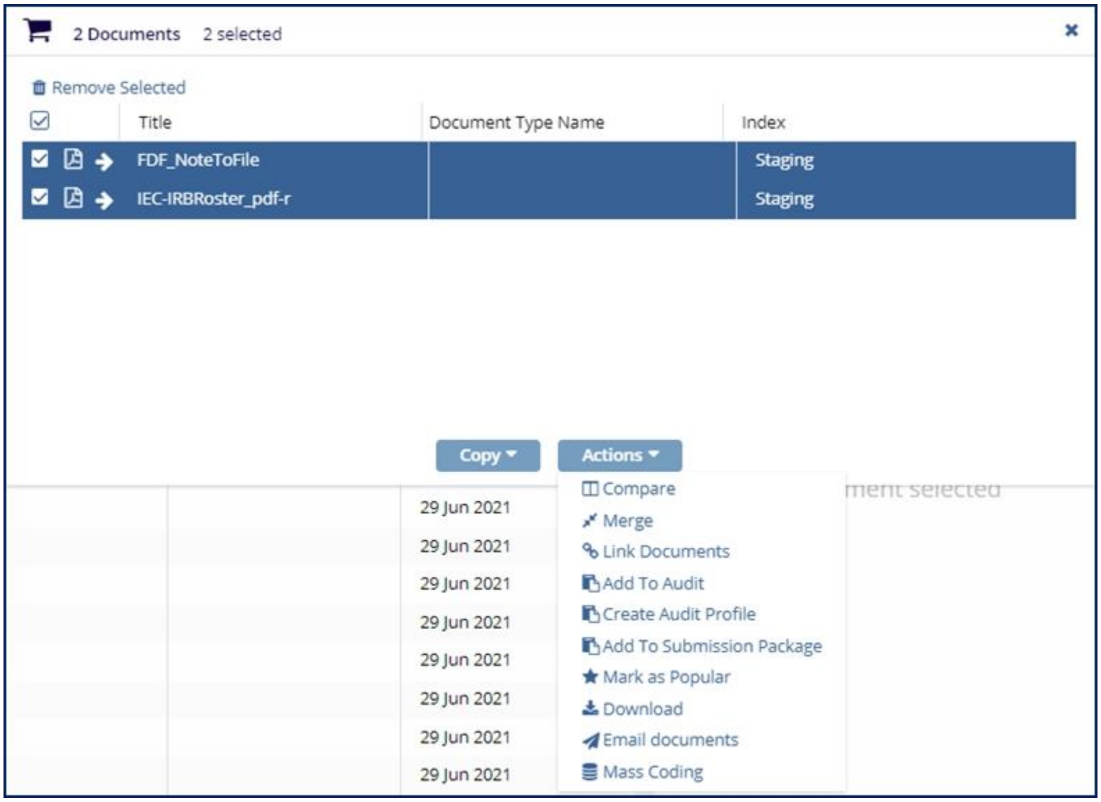


Figure 63: Create Audit Profile

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 is discussed under the Quality Review section in detail.

Adding Documents to a Submission Package

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

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

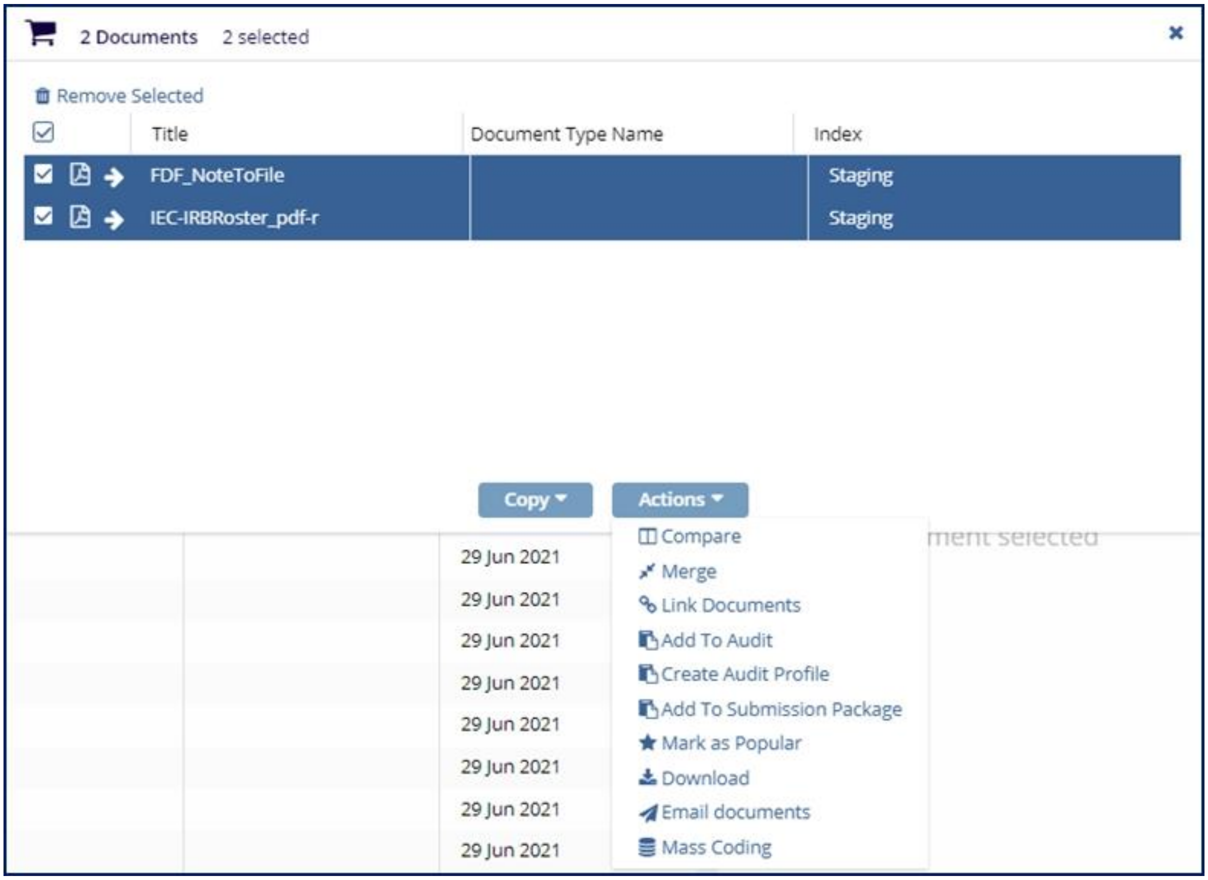


Figure 64: Adding Document to a Submission Package

4. The Select a Submission window opens.
5. Choose the Submission Package and press 'Select'

Downloading documents

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

Mass Coding

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

Email

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

1. If applicable, select the documents related to your email.
2. Press the Email button above the grid.
   - This will open the Email window.

3. You can either type the email recipients into the appropriate line or use the 'To' and 'CC' buttons to select recipients from the list of users.
4. Type your message.
5. If applicable, indicate whether or not the documents should be attached to the email using the radio buttons at the lower-left corner of the window.
6. Press 'Send' when done.

Marking documents as Popular

- Administrator, Manager, and Editor users can mark certain documents as popular using this option.
- Add required documents to the Documents Cart.
- Click Actions and then select Mark as Popular. Refer to the screenshot below.
- A pop-up message- Documents successfully marked as popular appear.
- The selected documents now appear on the dashboard- Popular Documents dashlet

Layout

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

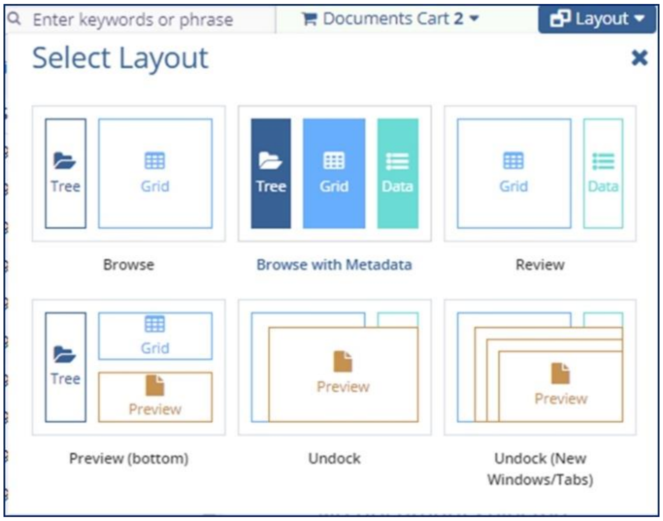


Figure 65: layout panel

Managing Folder Security

Administrator users can manage folder security. This section discusses the major interface for doing so but the user can also right-click on index folders to view and edit that specific folder's security. As the same can be done via this interface, the folder-specific method will not be discussed in depth here. Some rooms, such as eISF rooms have separate security controls for site folders. Those are controlled from the Settings menu. Please see Site Template Folder Security for more information.

To assign Folder Level Security:

1. Click Manage Security from the top ribbon bar. The Manage Security window opens.

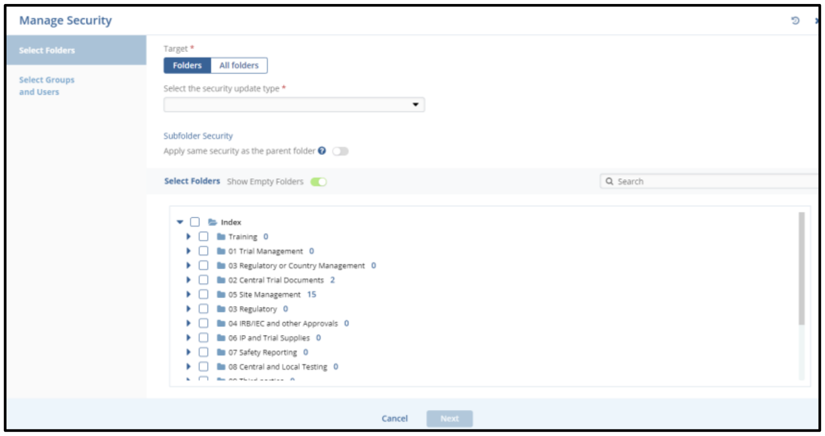


Figure 66: Manage Security Page

2. Select the Folders button from the ‘Select the Target’ section. The panel that displays the Index structure becomes active allowing you to select exactly to which folders you would like to apply security. You must select at least one folder from this list.
    - If you select the ‘All Folders’ option, the changes will automatically be applied to all folders whose security can be managed from this interface.
3. Select whether or not the changes should apply to all subfolders or only to the folders specifically chosen.
4. Click the toggle button next to the folders whose security should be changed or, if you chose to include all subfolders then choose only the relevant parent folders.
5. Choose the type of security update
    a. **Update existing security:** This option leaves all current security definitions in place and adds on any new definitions set in step two of the manage security process.
    b. **Overwrite existing security:** This option erases all current security definitions and replaces them entirely with the definitions set in step two of the manage security process.
    c. **Remove from existing security:** This option leaves intact any security definitions already assigned but removes access for any group(s) or user(s) specified in step two of the manage security process.
    d. **Restrict access to administrators only:** This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.

f. Click ‘**Next’**

g. Using the Groups and Users tabs on the left side of the control window, select the Groups and/ or Users to update security rights.

h. Enter the username to add the group or users to the Security Grid and select the checkbox. Refer to the screenshot below:

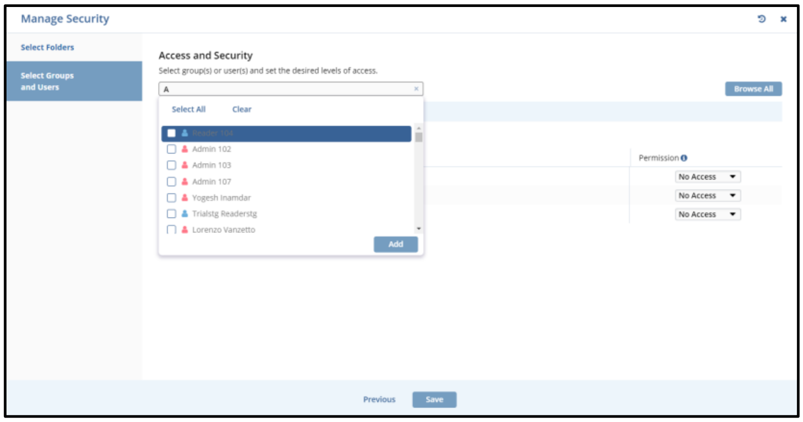


Figure 67: Access and Security

Once the users or groups are selected. you will need to define their security access rights.

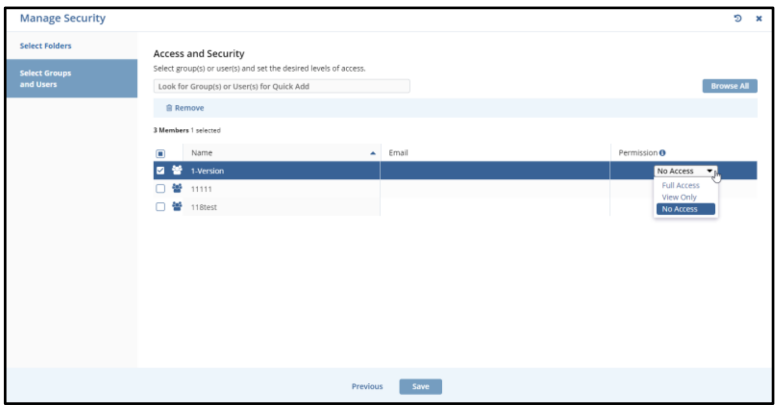


Figure 68: Access Permissions

a. Full Access – Users have unhindered access-level-appropriate access to the documents.
b. Read-Only Access – Users can only view the documents.
c. No Access – These users will not even see this folder on their room index and cannot access any associated files.
d. No Watermark – This option will only appear for rooms in which the watermark option is enabled. It allows the selected user to view the documents in the chosen folders without the watermark.
e. (Collaborate rooms only) Proxy Document Owner – This allows the specified user to act as a document owner for any documents contained in the selected folders.

i. Click **Save**

Managing Document Level Security

This allows for security definitions to be set at the individual document level, allowing for the greatest control and flexibility on the security definitions as documents within a single folder can have different security/access rights. If document-level security is used, each document will maintain its unique security settings, even as it is moved from one folder to another in the index outline, until its security definitions are changed.

1. Open a folder that contains documents from the Index outline.
2. Select one or more documents from the Document Grid whose security setting you want to modify.
3. Click the Manage Security button located in the upper toolbar. The Manage Security tool opens.
4. Click the button for Selected documents.

5. Select the security update type by clicking one of the four options, as described in the previous section of this guide.
6. Click Next. The second stage of the Manage Security tool populates the window.
7. Using the Groups and Users tabs on the left side of the control window, select the Groups and/ or Users to update security rights 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.

Unblinded Solutions

Background
An unblinded document is a document that that discloses information about the intervention assignment in a clinical trial. In a double-blind randomized trial, it is required that neither the patient nor the clinician is aware if the patient is recieving treatment or placebo. If that blind is broken, the patient's trial data is invalidated and cannot be used to prove efficacy. Documents or data that disclose information about this intervention assignment are known as Unblinded information, and must be protected from clinicians and clinical staff. The key challenge inherent in the storage and management of electronic Trial Master File (eTMF) documents for studies that contain blinded documents is maintaining the integrity of the blinding while ensuring proper document accessibility and regulatory compliance. This involves several critical aspects:

- **Segregation of Data:** Blinded documents need to be stored separately, ideally in a separate repository, from unblinded documents to prevent accidental unblinding. This requires a robust system for categorizing and segregating documents.
- **Access Control:** Strict access controls must be implemented to ensure that only authorized personnel can view blinded documents. This includes setting permissions and audit trails to monitor who accesses what information and when.
- **Regulatory Compliance:** Ensuring compliance with regulatory requirements such as Good Clinical Practice (GCP), GDPR, and other relevant guidelines is essential. This includes maintaining secure, traceable, and auditable records.
- **Document Integrity:** Maintaining the integrity and confidentiality of blinded documents while enabling necessary updates and collaboration can be challenging, especially in a digital environment where data breaches and unauthorized access are risks.

What is an Unblinded Solution?
Trial Interactive's Unblinded eTMF solution provides a validated, dedicated repository to electronically store these documents for a trial where the blind has not yet been lifted keeps these documents separate from other trial documents. Separating unblinded trial documents from blinded trial documents allows for the ability to align document work streams with regulatory compliance practices. It also enables an unblinded study team to follow critical processes for metadata and document approval without revealing restricted trial information.

What does the solution do?

- Leverages configuration to support TMF completeness and contemporaneousness
- Allows for segregation of blinded and unblinded documents when used in conjunction with a blinded eTMF solution.

- Eliminates the need for complex folder- and document-level security. These complex configurations can introduce blinding risk.
- Provides a quick and easy ability to combine both blinded and unblinded documents into a single space once the blind has been lifted.
- Contains a streamlined index developed from the CDISC Reference Model highlighting the documents that typically contain unblinded content.
- Eliminate complex security assignments that introduces the risk of unblinding data and documents.
- Meet regulatory guidance (insert guidance here) that requires unblinded documents to be stored in an independent, separate repository.
- Facilitate the ability of a user to identify restricted document content prior to filing.

System/Technical Requirements

- The Unblinded eTMF solution is assumed to have a limited number of users with approved access to unblinded documents.
- This solution has a streamlined index targeting unblinded document types.
- This solution has the ability to set Required Documents to provide accurate TMF completeness.
- This solution has an Event Manager with Trigger Criteria enabled to meticulously track study documentation.
- This solution has the ability to perform Quality Review for oversight.

High-level technical capabilities:

- Users can view, modify metadata on documents within a workflow
- Users can Copy/move documents between rooms/Sites
- Users can perform Quality Review
- Users can add Event Triggers/Event Manager to rooms to manage placeholders
- Users can run reports on Inventory, KPIs, User Access
- Ability to access Audit Trail
- Ability to add or remove user access

Solutions available for interoperability:

- Global Learn
- CTMS
- TI Connector
- TransPort Translations

Chapter 8. Events

Event Manager

The Event Manager was created as a new way to manage amendments, milestones, visits, and other events that occur during a Clinical Trial. It is important to have a simple way to recognize clinical events as they happen in order to get the most accurate picture of eTMF Health. That way, as amendments, visits, and other activities occur, the eTMF 'knows' what documents are needed in association with those events and can even plan them, including the responsible party and due date.

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

Before Creating Events

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

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

Creating an Event Type

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

1. Select the Event Types area of the Event Manager. This is indicated by a gearwheel icon on the far left of the screen.
2. Click on the "Add" button in the menu bar above the list of events already in the room.

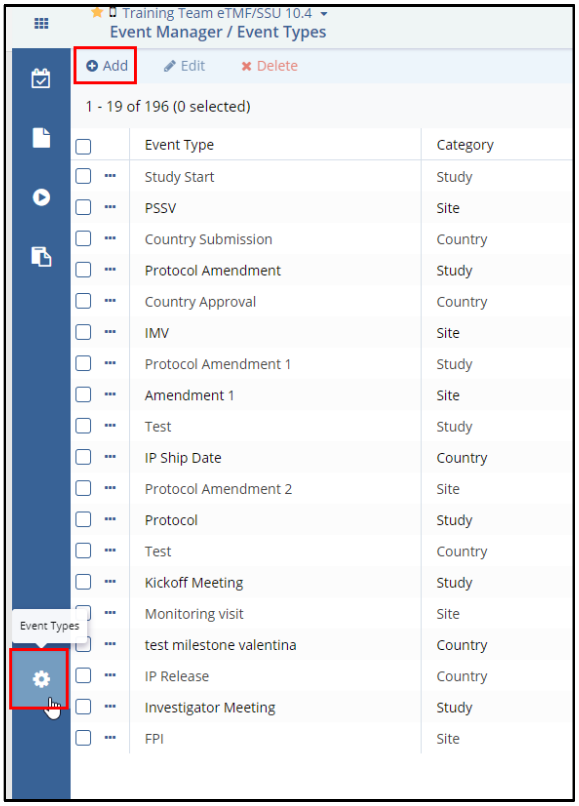


Figure 1: Event Manager Module

3. The “Create New Event Type” window will open.
4. Fill out the required fields.
    - The Event Type field allows you to name the new event.
    - Category indicates whether this is related to a Study, Country, or Site level event.
    - The Due Date Period field allows you to indicate how much time users have to submit the documents after the event has taken place. Also, we have a description textbox to enter the related information.

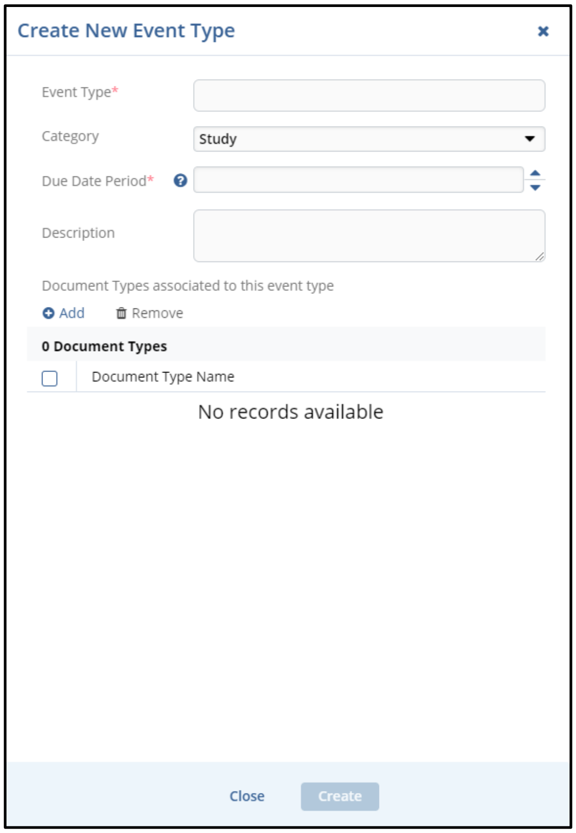


Figure 2: Create a New Event Type

5. Use the “Add” button above the Document Type Name field to open the Select Document Type window.

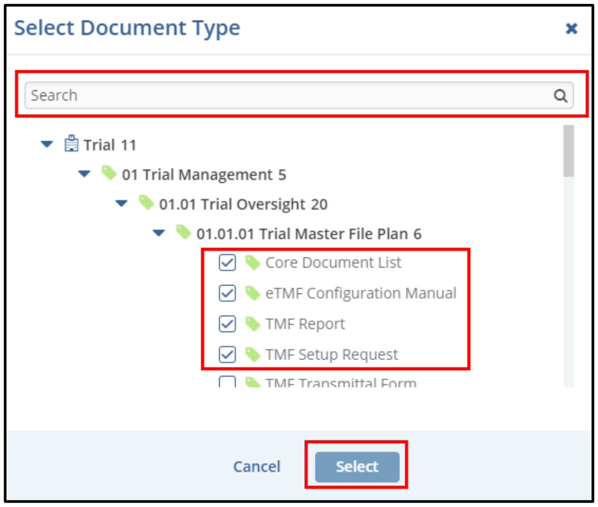


Figure 3: Document type Page

6. You can search for the document type via the search bar at the top of the window or by drilling down in the index structure until the correct document type entry is shown.
7. Check the box next to the correct document type(s) and click Select to add the selected document type(s) to the event being created.
8. You can remove the added document type. Click the checkbox to remove the document type and Click on the remove button.

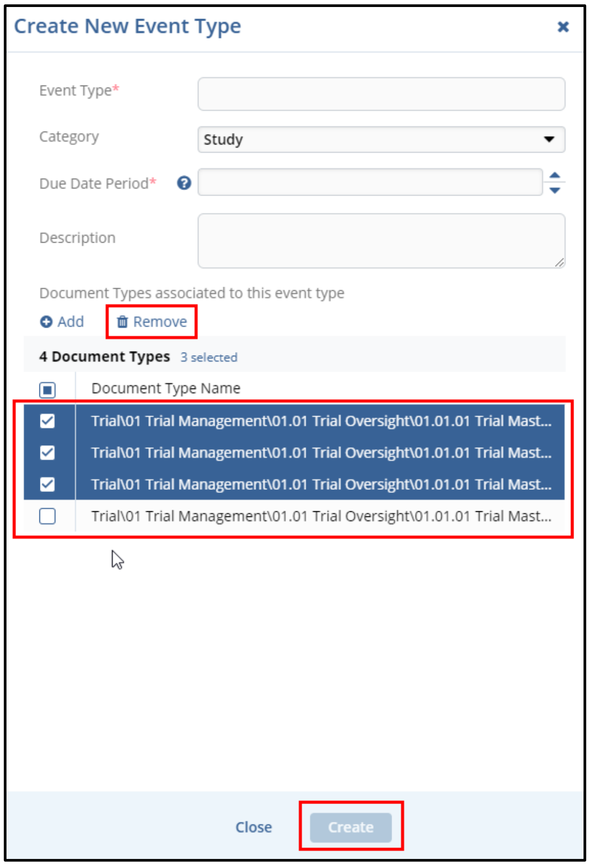


Figure 4: Remove Added Document Type

9. Once all document types have been added, press the Create button to create the event type.

Creating an Event

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

Events can be created using the following steps:

1. Access the Events module. Any previously created events should be displayed in the window.

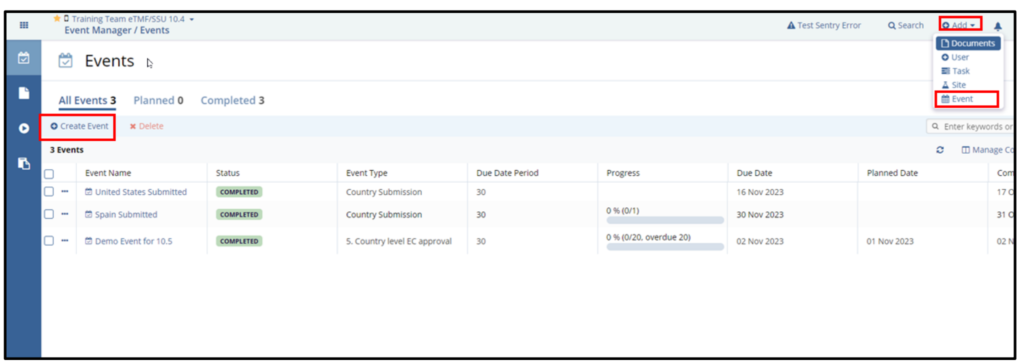


Figure 5: Create Event options

2. Click on the **Add** button in the menu bar above the list of events or you can click on **Create Event** Button. The “Create Event” window will open.
3. Using the Category field, indicate whether the event being planned is a Study, Country, or Site level event.

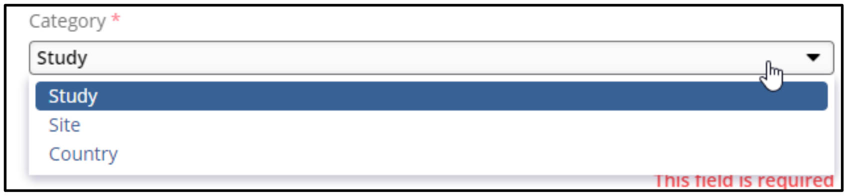


Figure 6: Category

4. Choose the Event Type from the dropdown menu.
5. Give the event a name and fill out any other fields as desired.
    a. The planned date field will be critical to tracking the timeliness of event document submissions.
    b. The Due Date Period should be automatically populated based on the value entered during the creation of the Event Type.
    c. The Status field can be used to indicate whether an event is being planned or has already been completed. Most events will be created with the status of “**Planned**.”

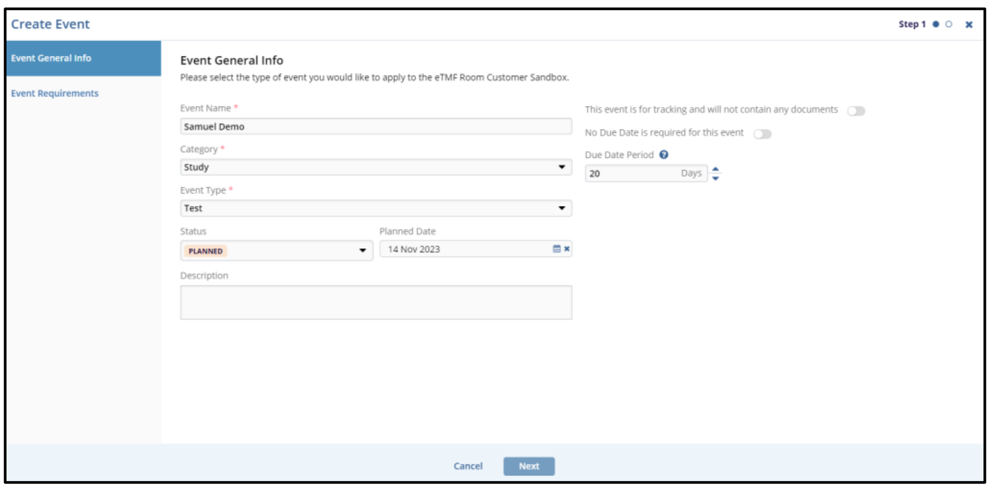
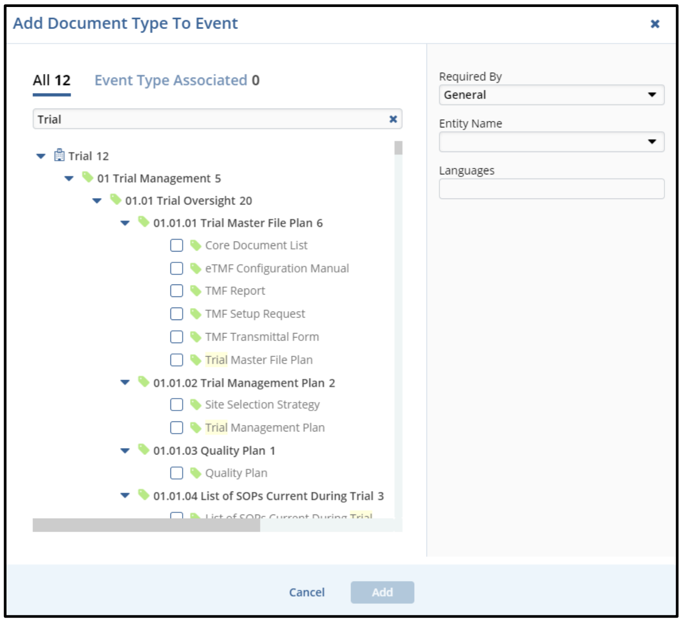


Figure 7; Create Event Type

6. Press “**Next**”
7. The next screen allows the user to confirm whether all required document types for this event are displayed. The list will be populated based on the values chosen during the creation of the Event Type.
    - If another document type is required, the user can press the “**Add**” button in the menu bar above the right panel. This will open the “**Add Required Document Types**” window.
        - Use the Search bar or manually drill down in the folder structure to locate the required document type and press “**Add**”.

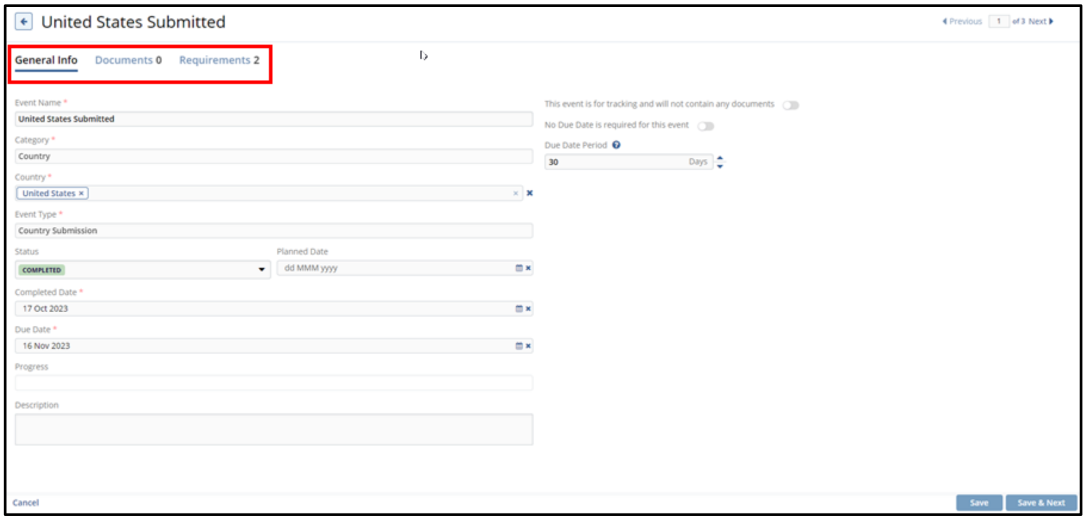


8. You can remove the added document type. Click the **checkbox** to remove the document type and Click on the **Remove** button.
9. Once all required document types have been added to the event, press **Finish** to complete the event creation process. The event will be displayed in the list of created events.

Modifying an Event

Follow these steps to modify an existing event:

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

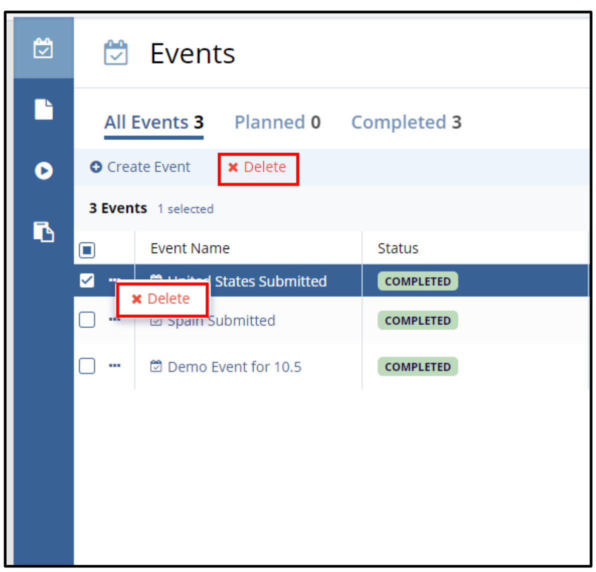


Deleting the Event

<u>Follow these steps to modify an existing event:</u>

1. Access the Events module. Any previously created events should be displayed in the window.
2. Select the event to Delete.
3. There are two options to delete the event.

    - Click the **Delete** button from the top right corner.
    - Click on three dots and select **Delete**.



Assigning Documents to Event Placeholders

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

1. Select the Documents area of the Event Manager. This is indicated by a page icon.
2. The user can change their view of the Documents area using the “View by” dropdown menu. The available completeness views are the same as those available in the eTMF Documents module except for “View by Event.” We will be addressing the “View by Event” view in these instructions.
3. Using the index pane at the left side of the screen, drill down to the Event in question and click on it to show the missing and collected documents in the central “Grid” pane.
4. If it is not already expanded, click on the “Open Staging Area” button at the bottom of the screen to access those documents currently housed in the Staging, Inbox, and Upload folders.
5. Click on the document location and locate the document that applies to the placeholder displayed in the upper portion of the screen.
6. Click and drag the appropriate document from the lower panel onto the document placeholder in the upper panel.
7. The document will be coded based on the placeholder metadata.
8. Press the Refresh button above the Grid or in the Index pane to see the selected document in place of the Placeholder that was filled.

Chapter 9. Dashboard

Study Room Dashlet Settings

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

Configure Dashboard Setup

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

Edit Dashboard

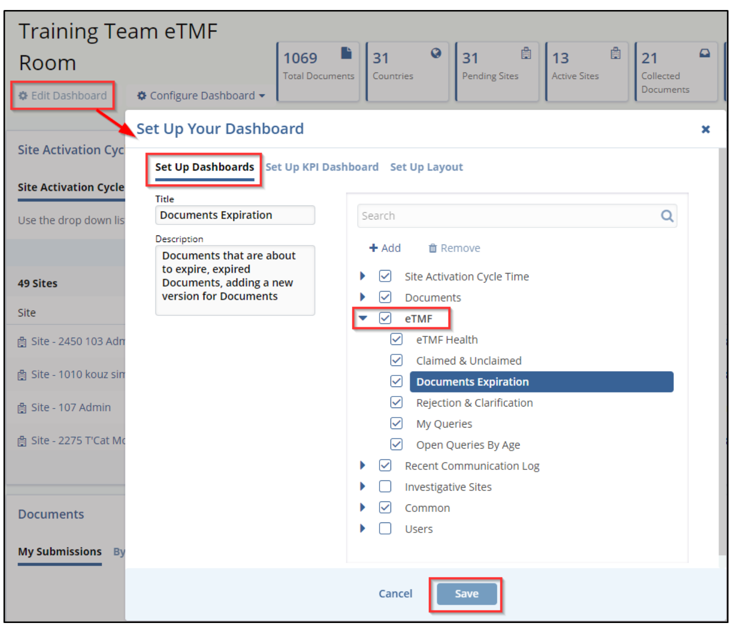
This button is displayed in the top left corner. By clicking this button, the user can do the following:

- **Set Up Dashboards**
- **Set Up KPI Dashboards**
- **Set Up Layout**

Set Up Dashboards

Here, the user can set up their dashboard as required. Follow the steps below to setup the dashboard.

1. Click the **Edit Dashboard** button displayed in the top left corner to open the Set Up Your Dashboard popup window.
2. By default, the Set Up Dashboard option is displayed. Expand the fields using the arrow. Select the required checkbox(s).
3. Click the **Save** button displayed at the bottom of the popup window. By performing these steps, the required options are reflected in the dashlets.
4. **(Optional)** The user can add a new dashlet and also remove an existing one by clicking the **Add** and **Remove** button displayed in the popup window below the Search field. **Note:** While adding a new dashlet the user has to mention the Title and Description in the left side fields. Also, the user can only remove the newly added fields and not the pre-defined fields.

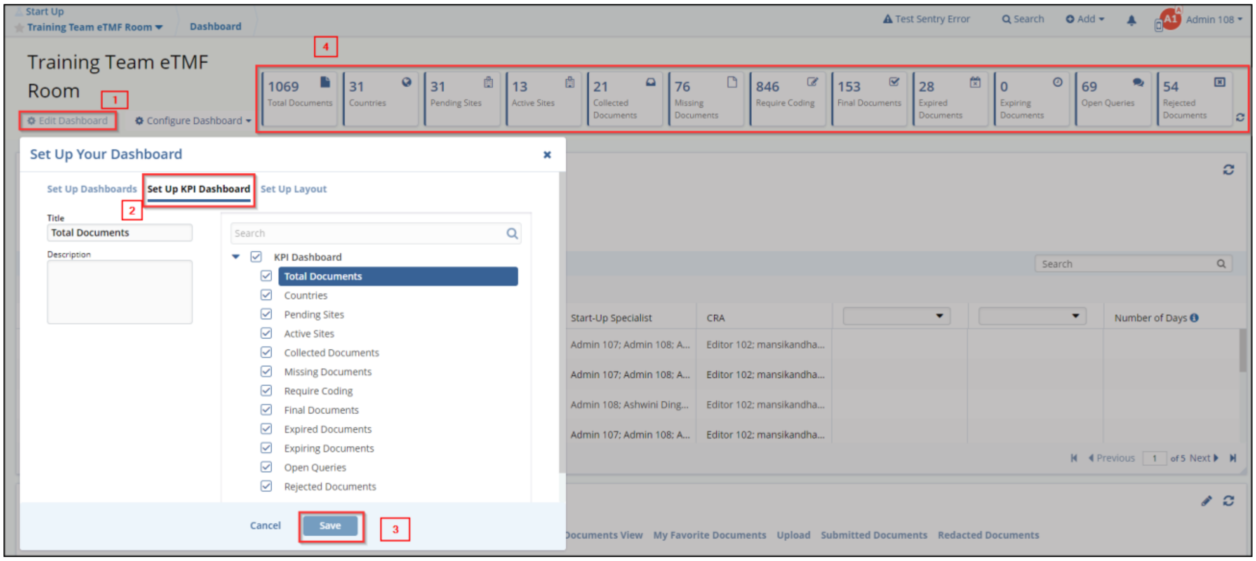


Note: The checkbox(s) selected for each dashlet from the set up dashboard window, only those tabs will be displayed in the dashlets.

Set Up KPI Dashboard

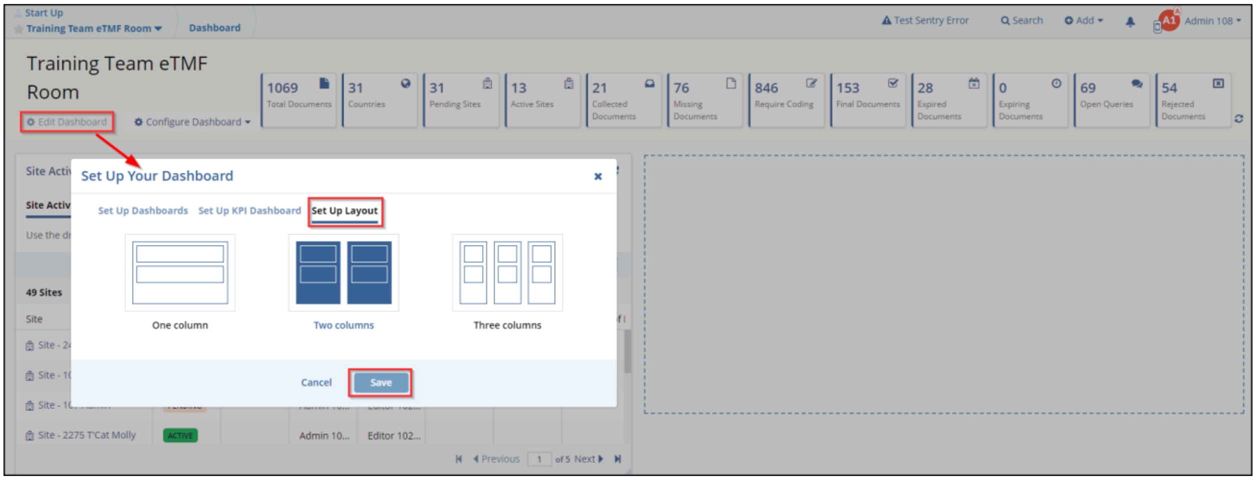
Here, the user can setup the dashlets displayed on the top center to right corner of the screen. The selected tabs are displayed as tiles on the screen. Follow the steps below to set up the KPI dashboard.

1. Click the **Edit Dashboard** button displayed in the top left corner to open the Set Up Your Dashboard popup window.
2. Click the **Set Up KPI Dashboard** tab. Expand the fields by clicking the KPI Dashboard arrow.
3. Select the required checkbox(s) from the available list.
4. Click the **Save** button displayed at the bottom of the popup window.
5. The selected tabs are displayed as tiles on the top of the screen. Refer to the screenshot below.



Set Up Layout

This tab helps the user to select and setup a layout for the entire Dashboard. The user has the options to select from – One, Two or Three Columns. Click the **Save** button displayed at the bottom of the popup window to reflect the changes. Selecting the appropriate option sets the dashboard with a different look. Refer to the screenshot below.



Configure Dashboard

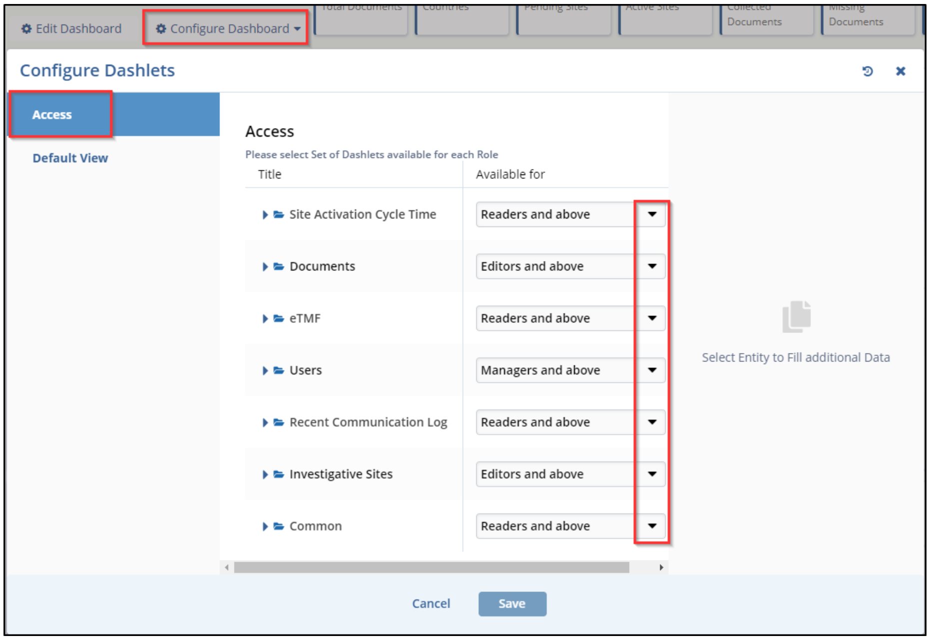
The Configure Dashboard helps the user to arrange the dashboard as required. The user has two options for configuring the dashboard –

- **Configure Dashlets**
- **Configure KPIs**

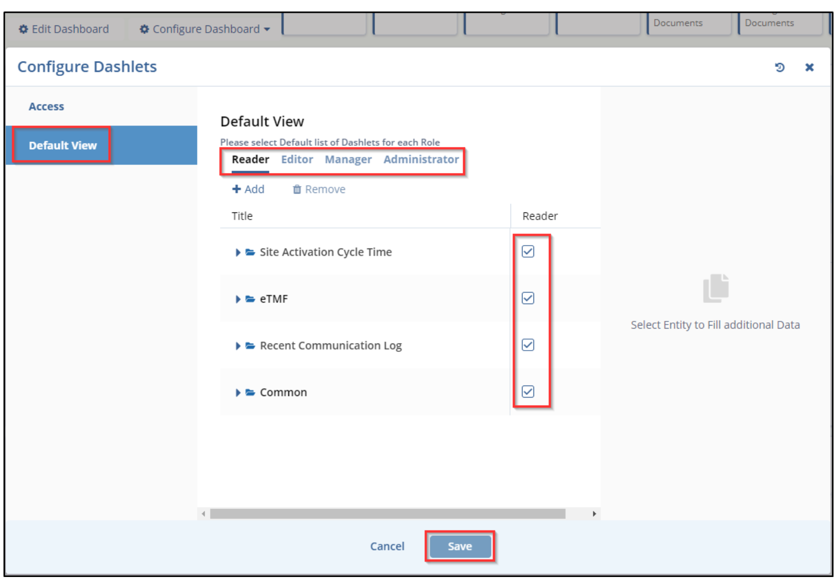
Configure Dashlets and KPIs

Follow the steps below to configure the dashlets.

1. Click the **Configure Dashboard** button displayed next to Edit Dashboard button. This opens the Configure Dashlets popup window.
2. In the Access tab, select the roles from the dropdown menu for each tab keeping in consideration the Titles mentioned in the left side pane.



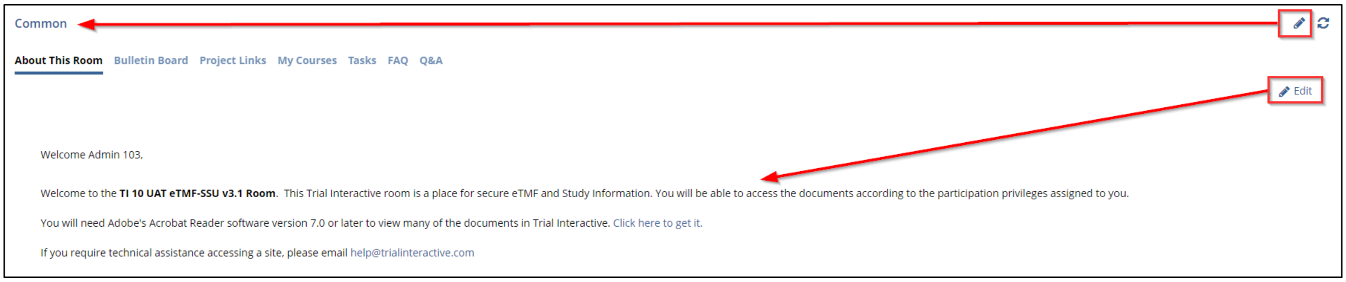
3. The Default View tab, select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager and Administrator.
4. Click the **Save** button displayed at the bottom of the popup window.



Dashlet Descriptions – Common Grouping

About This Room

In this window, the user can see and change the information contained in the room's Welcome message, which is the message that all users see when they access the room. This space can be used to share important information about the study. Administrator and Manager level users can make changes to this dashlet by pressing the 'Edit' button. Once you have made the desired changes, click Save. Any changes made will be immediately visible to all room users.

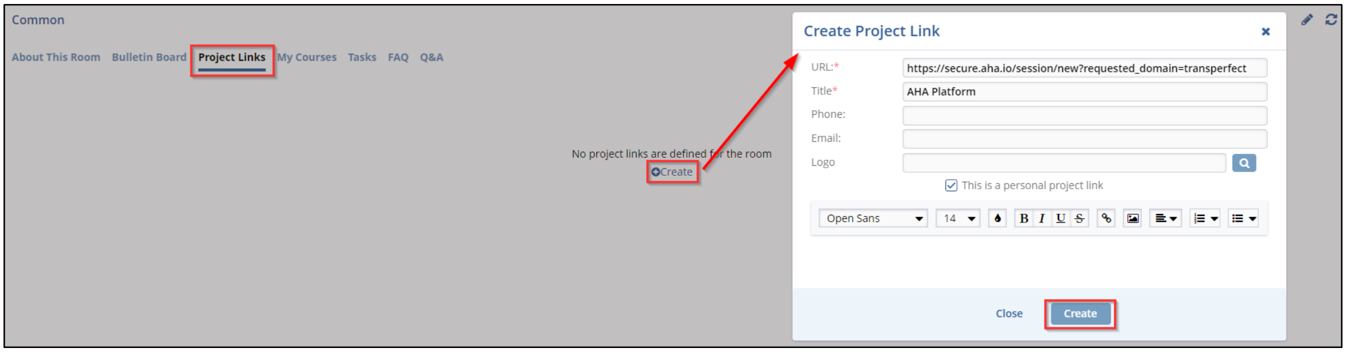


Bulletin Board

This is set up by the administrators to provide messages to the team which can be information regarding a room or problems within a study. It can be edited by administrators and managers.

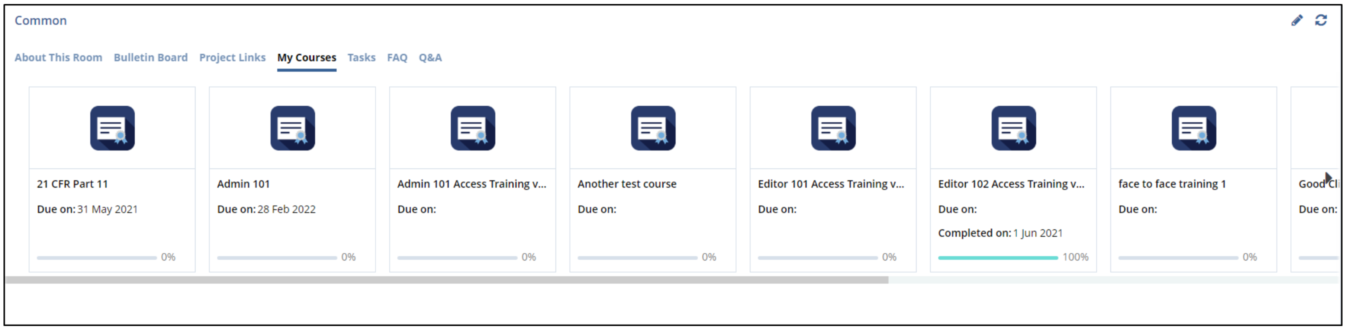
Project Links

The Project Links dashlet displays the links to different websites that are used for the study. Editor level users and above may create links by pressing the 'Create' button. Selecting the checkbox allows the to keep the project link as personal.



My courses

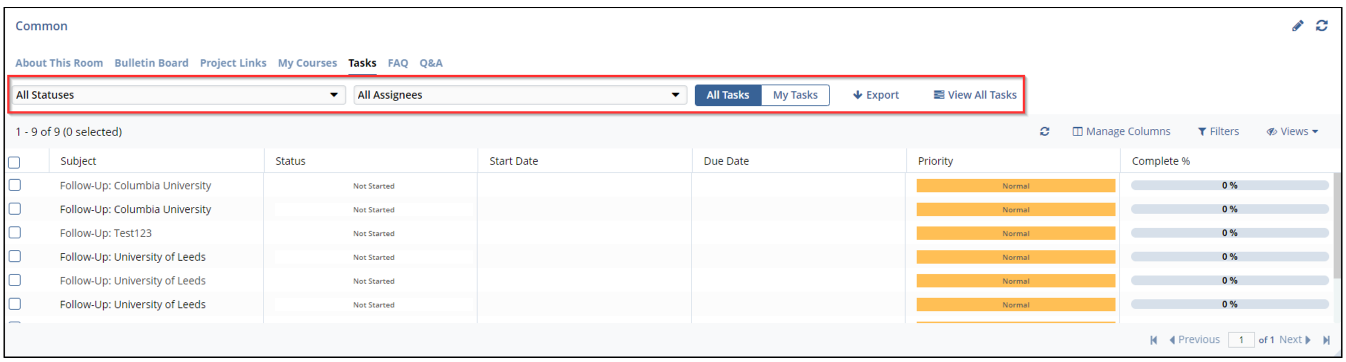
Some study rooms are integrated with Global Learn in order to conduct appropriate study-related training. This displays your courses. Each course displayed serves as a link which, when clicked, will take the user to that course in Global Learn.



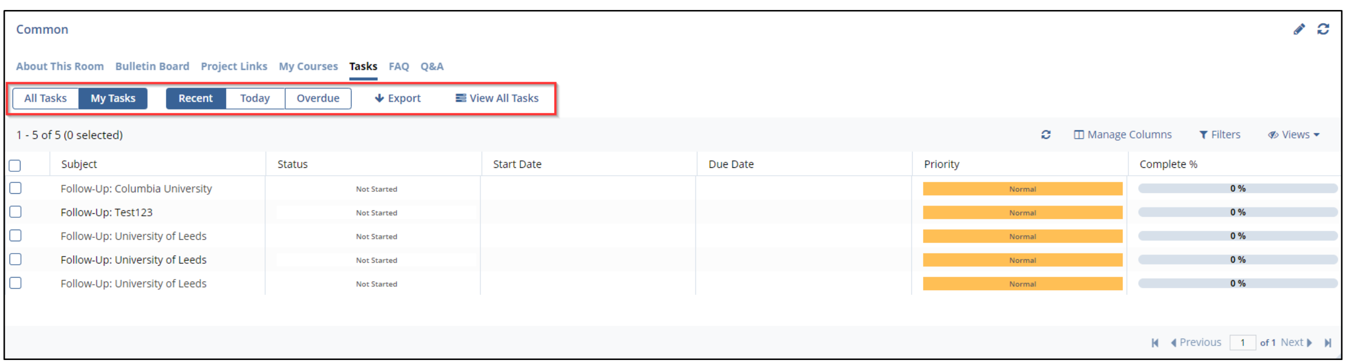
Tasks

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

All Tasks lists all the tasks belonging to the selected assignee. By default, the All Tasks tab is selected. The user can select the required status from the All Statues dropdown and Assignees from the All Assignees dropdown.

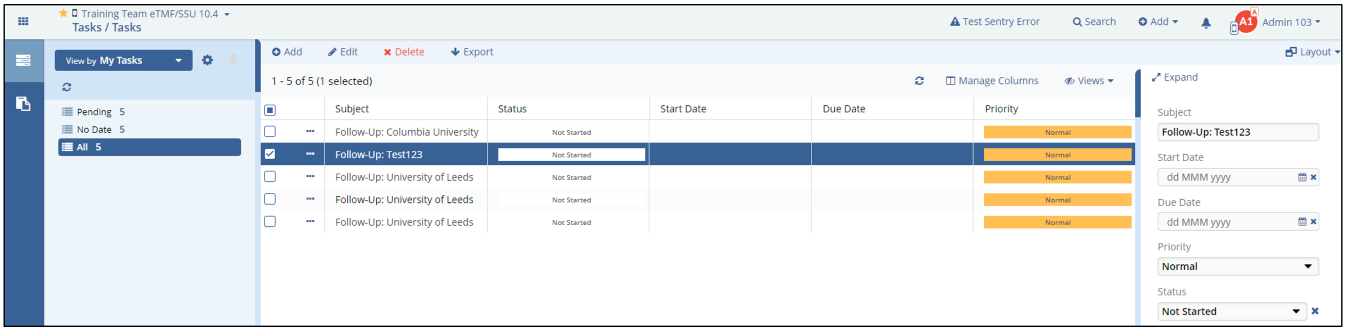


My Tasks lists all the tasks pending recently, today, or are overdue.



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

Clicking the **View All Tasks** button the user is redirected to the Tasks page of eTMF module.



The FAQ Dashlet

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

The Q&A Dashlet

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

Dashlet Descriptions – eTMF Grouping

eTMF Health

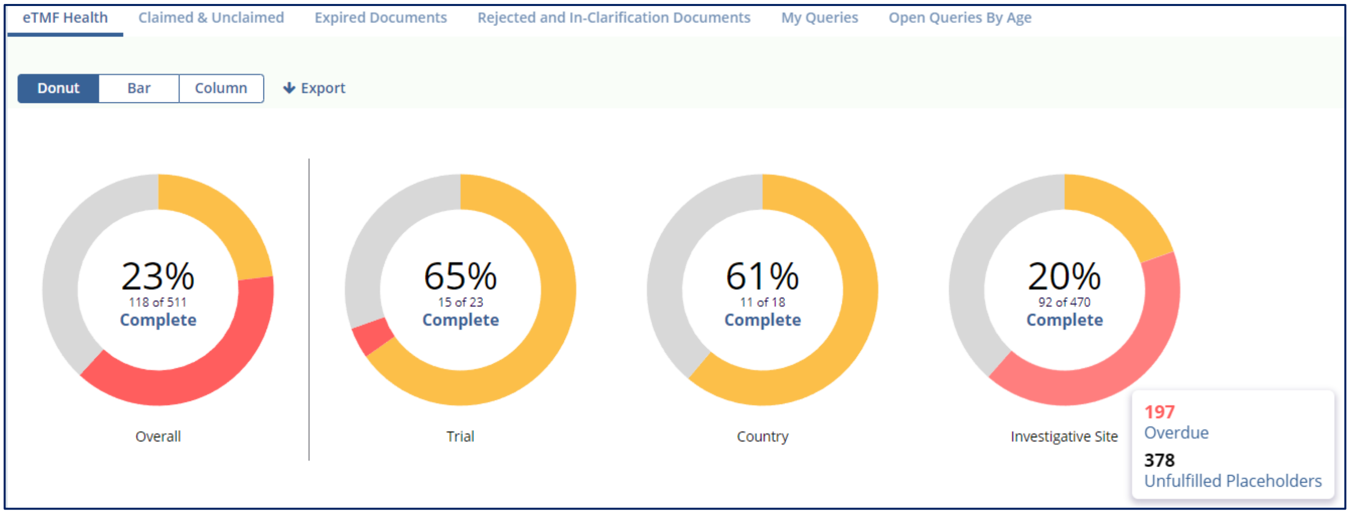
This dashlet shows a summary of the percentage of missing and collected documents as defined by the room's configuration. Each category of documents is listed and has its own chart. To view the missing documents at each category level, click on the appropriate 'donut' chart to drill down if required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

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

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

This dashlet follows the following definitions:

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



Claimed & Unclaimed

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

The dashlet also provides the dropdown to select the workflow as required and displays the Donut Chart as per the selected workflow.

Expired Documents

The Expired Documents dashlet lists the expiring and expired documents as specified in the expiration period. The dashlet has two views that can be selected through an Expired dropdown. To set the views, click the Expired dropdown located on the top left corner.

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

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

- Locate the document in the dashlet.
- Check the box next to the document.
- Click the '+Add New Version' button at the top-right of the dashlet.
  - This opens the 'Add New Version' window.
- Select the appropriate replacement option.
  - The options available are configurable by the room administrator in the Settings area.
- If 'Replace the Attachment' is chosen,
  - Press the 'Browse' button and locate the new version of the file.
  - Set the new expiration date
  - Indicate the reason for the replacement
- If the 'A new version was already submitted. Remove this document from the list' option is chosen nothing else

needs to be done. The document will be removed from the list of expiring documents.

- Press 'Save'

Rejected and In-Clarification Documents

This dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.
You can double-click on the count to view the list of documents associated with a particular rejection or clarification reason.

My Queries

The My Queries dashlet gives a list of documents based on their query types. The user can use the dropdown menus to narrow down the queries displayed.
Responding to queries is covered more in-depth in the Queries chapter of this guide but this dashlet can also serve as a portal for responding to queries. To respond to a query via the My Queries dashlet, locate the Pending query and press the 'Respond to query' button.

Open Queries by Age

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

Dashlet Descriptions – Documents Grouping

My Submissions

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

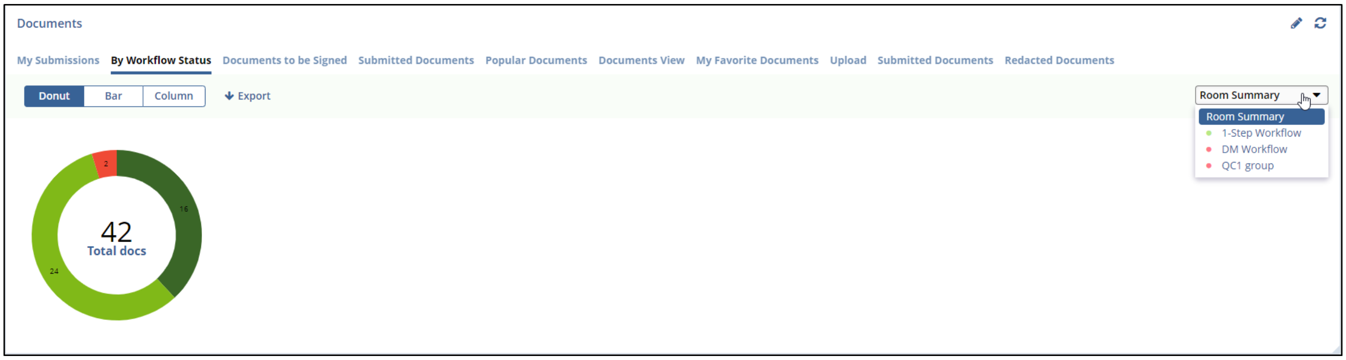
This operates very much like the already familiar Favorite Documents and Popular Documents dashlets. Users can click on the document type icon (PDF, Word, etc.) in order to launch a preview of the document in a separate window or click on the blue arrow to be taken directly to the document within the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

By Workflow Status

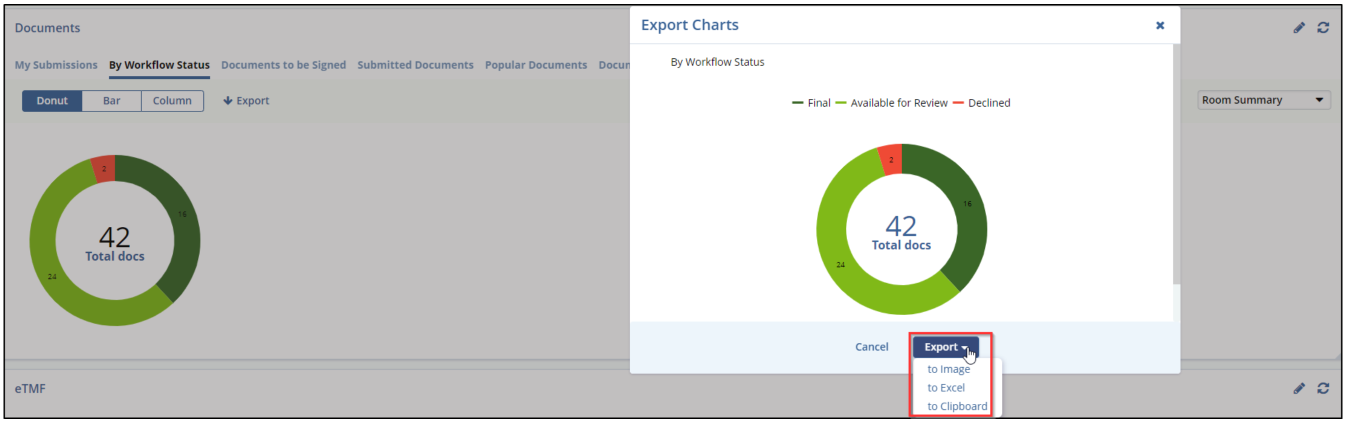
The Documents by Workflow Status dashlet displays the document processing status in the document review workflow through a donut chart. By changing the dropdown menu, you can view the document processing status:

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

This tab displays the total number of documents by the workflow status. Select the appropriate option from the dropdown menu to view the summary of the documents in Donut/Bar/Column format. By default, the Room Summary option is selected in the dropdown menu.

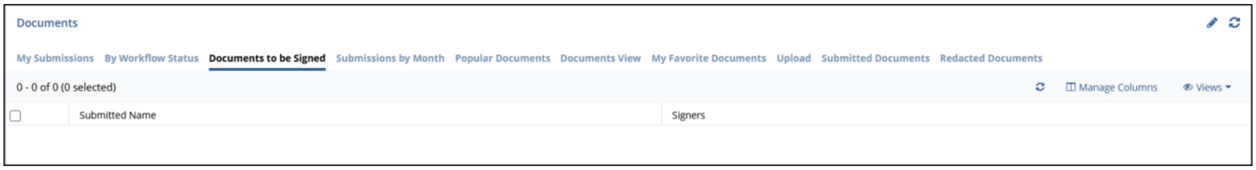


The user can also export this data by clicking the **Export** button. The user can export the data in – **Image, Excel or Clipboard**.



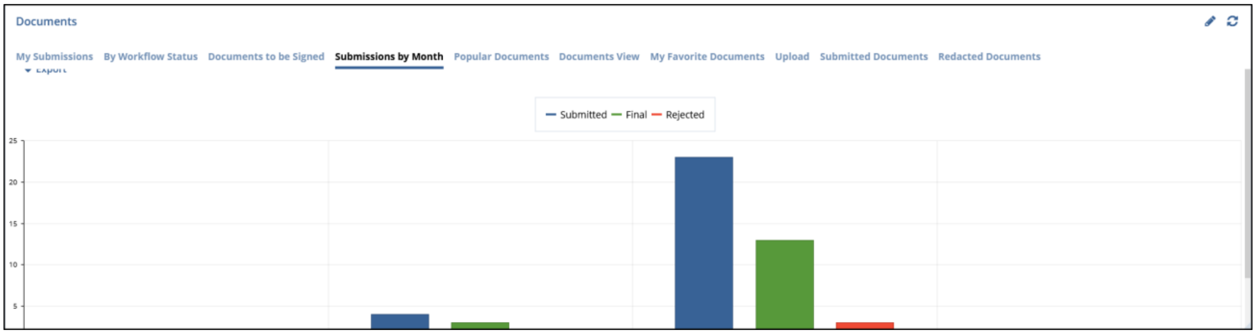
Documents to be Signed

This tab displays the documents in a grid pane that are waiting for signature by that specific user.



Submissions by Month

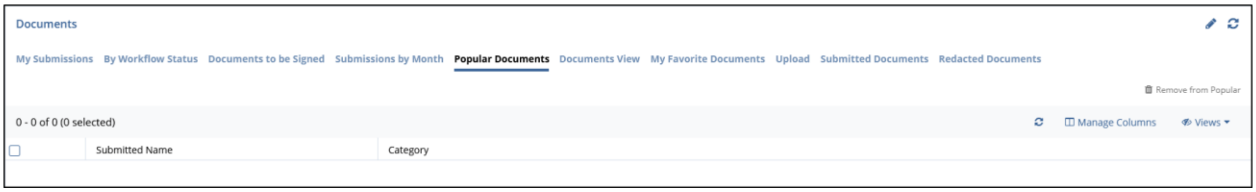
This tab displays a graph bar for the submissions done in the last six months.



Popular Documents

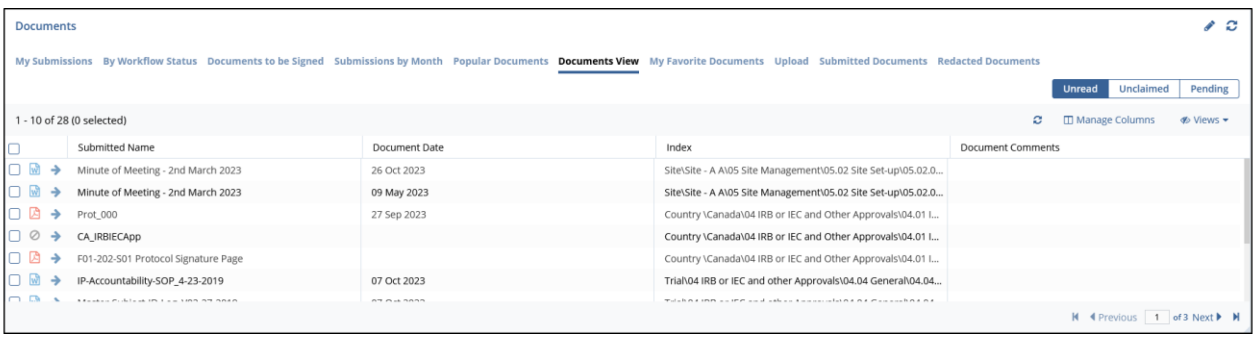
The IP Release Documents dashlet displays the list of documents that have been marked as popular by an Administrator, Manager, or Editor through the Documents Cart and which are used frequently.

To remove a document from the Popular list, click Remove from Popular button on the dashlet. To view the document, click the icon or click on the blue arrow to be taken to the document in the Documents module.



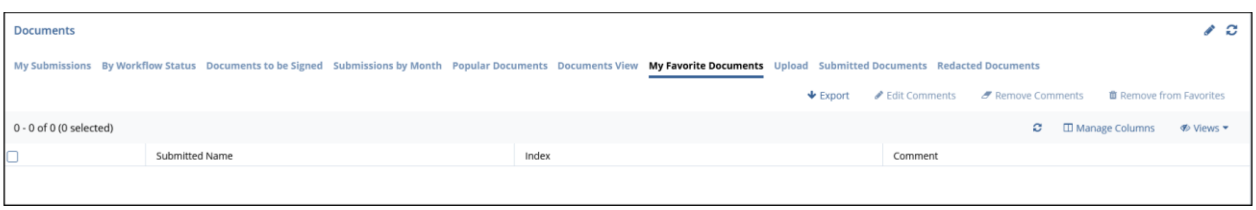
Documents View

This tab displays the documents in a grid pane with a selection tab for – Unread, Unclaimed, and Pending.



My Favorite Documents

This tab displays the documents that are marked as favorite by the user.

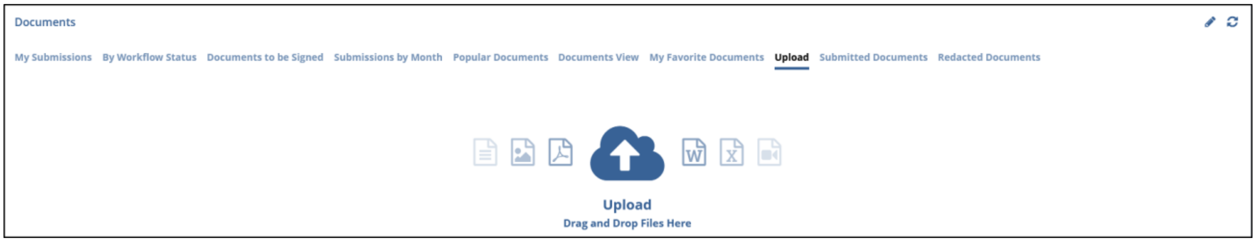


Upload

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

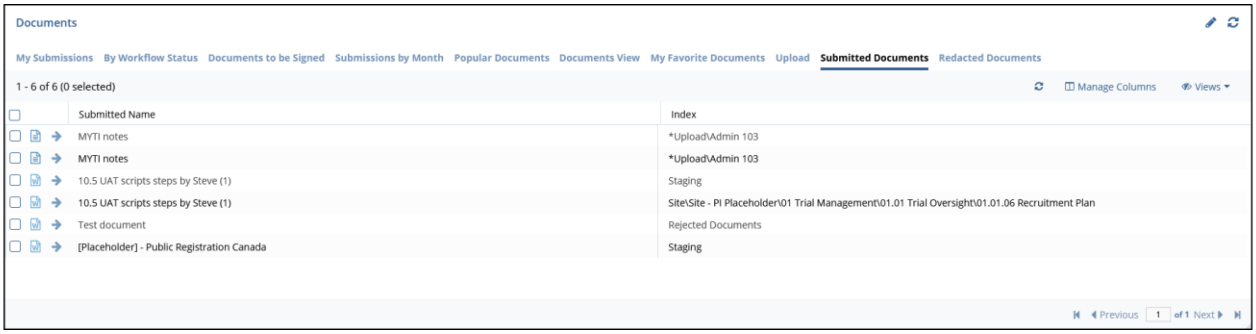
In order to use the Upload dashlet, simply drag a file from your computer desktop into the dashlet and press Import. In rooms where it has been enabled, users will be able to see the index folders associated with sites and can upload documents directly to a specific folder.

This tab helps the user in uploading the document(s) by the drag-drop method.



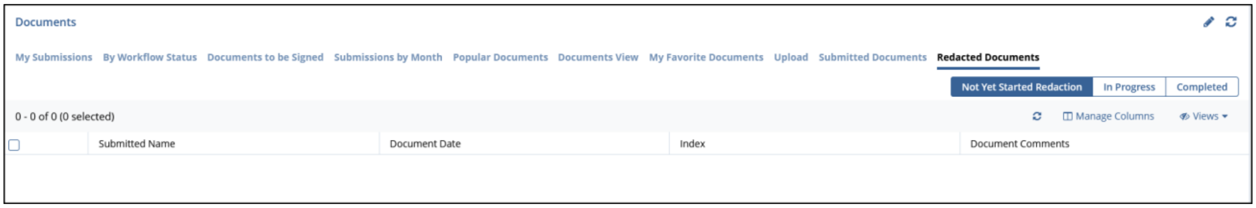
Submitted Documents

This tab displays the documents that are submitted by the user.



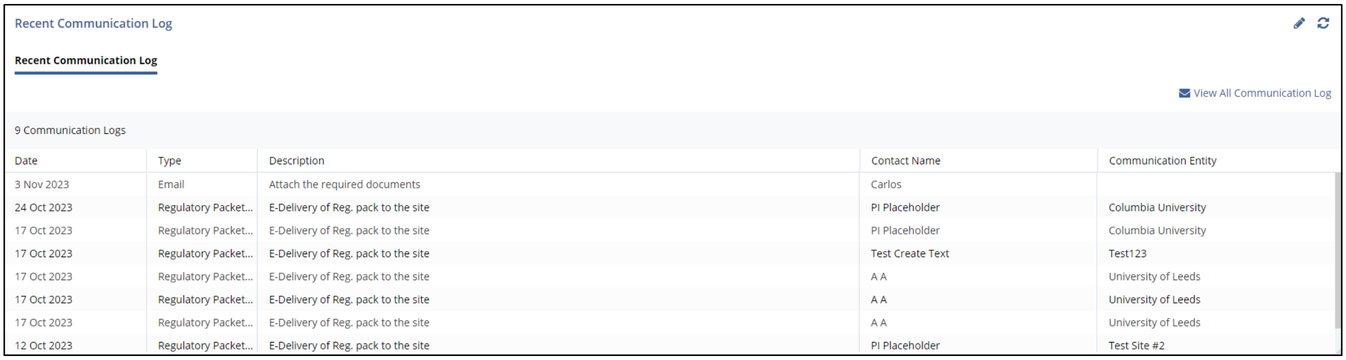
Redacted Documents

This tab displays the documents that are redacted by the user.



Dashlet Descriptions – Recent Communication Log

The Recent Communication Logs dashlet gives a list of all communications made during the site start-up and activation stage. Click the View All Communication Log to go the Communications module of Start-Up dashboard.



Date	Type	Description	Contact Name	Communication Entity
3 Nov 2023	Email	Attach the required documents	Carlos	
24 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	PI Placeholder	Columbia University
17 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	PI Placeholder	Columbia University
17 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	Test Create Text	Test123
17 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	A A	University of Leeds
17 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	A A	University of Leeds
17 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	A A	University of Leeds
12 Oct 2023	Regulatory Packet...	E-Delivery of Reg. pack to the site	PI Placeholder	Test Site #2

Dashlet Descriptions- Users (Administrators Only)

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

Name	Email	Phone	Organization
test123demo@ti.com	test123demo@ti.com		Test demo

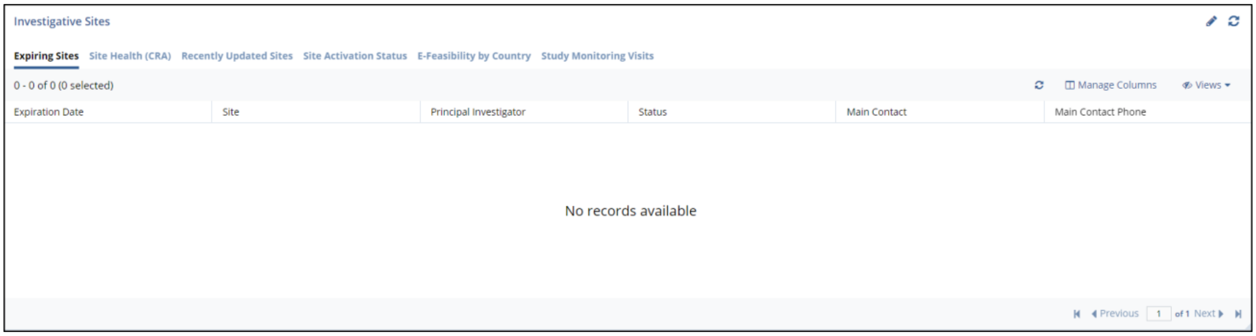
Dashlet Descriptions – Investigative Sites

This dashlet displays details for the Expiring Sites, Site Health (CRA), Recently Updated Sites, Site Activation Status, E-Feasibility by Country, and Study Monitoring Visits. In this dashlet the user can only edit the name of the dashlet.

Note: Only those tabs are displayed in this dashlet that were selected after clicking the Edit Dashboard button.

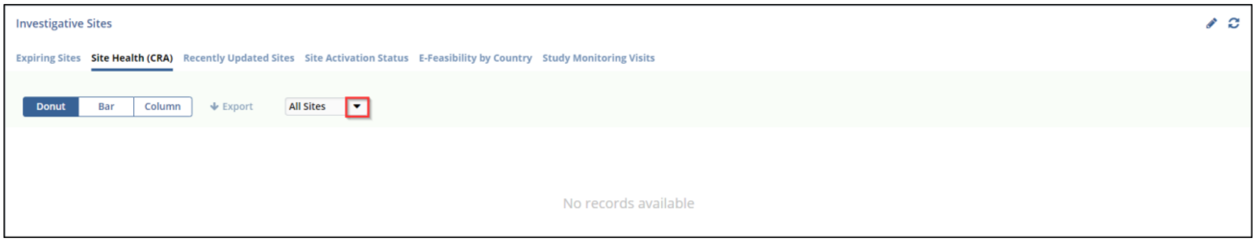
Expiring Sites

This tab gives a list of all sites that are expiring in a future date.



Site Health (CRA)

This tab displays the health of a site in a Donut, Bar, Column format. the user can Export the data in an Image, Excel or Clipboard format. the user can also filter the sites with either – All Sites or My Sites.

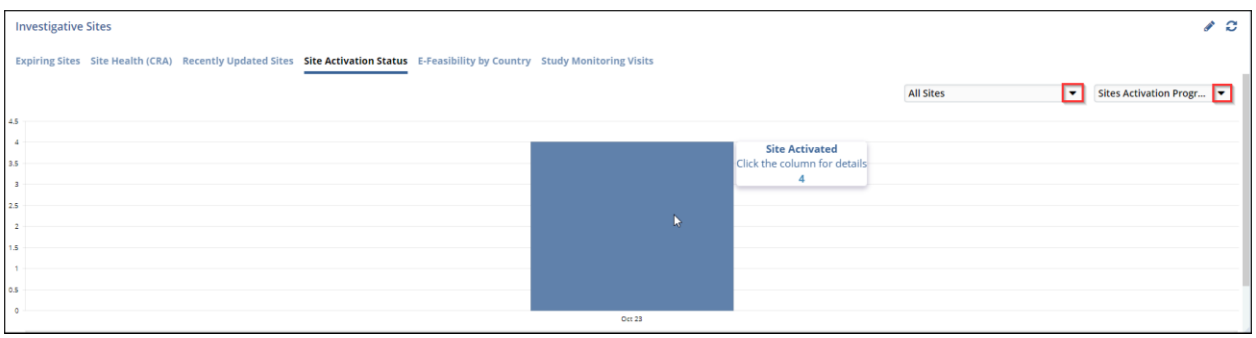


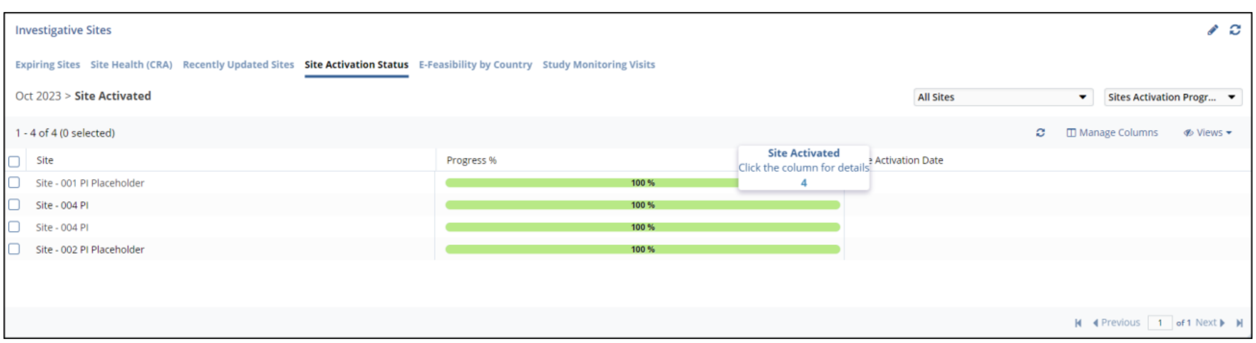
Recently Updated Sites

This tab gives the activation progress of all sites in a room. This tab displays the sites that are recently updated by the user. The sites are displayed in the grid with the Site Name, Principal Investigator, Status, and Progress columns. The user can Edit the dashlet's name, Refresh, Manage Columns, and save Views for this tab. By clicking the **View All Sites** button displayed in the right corner redirects the user to the Sites page of SSU module.

Site Activation Status

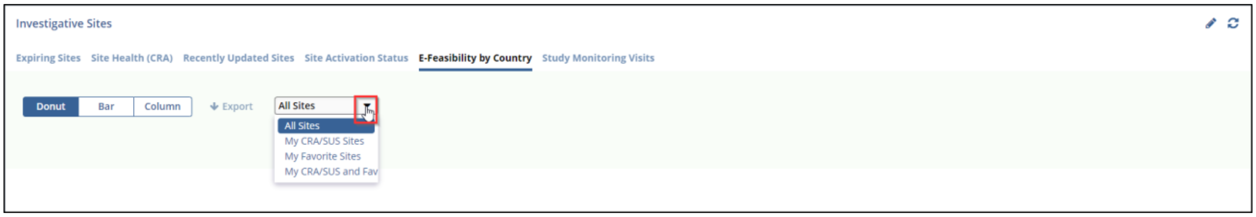
This tab offers two views – Sites By Country, and Sites Activation Progress. Select the Sites By Country option from the Dropdown menu to reveal the total number of Active Sites, Sites Pending for Activation, and Sites Rejected from activation in each country in the form of Donut, Bar or Column. This tab displays the status of an activated site in a bar format. Click the bar to view the detailed progress of the sites activated. The user has the option to select and filter the site activation status for Sites and Progress from the dropdown menus displayed in the right corner.





E-Feasibility by Country

This tab displays the E-Feasibility by Country.



Study Monitoring Visits

This tab displays an overview for past six months of the monitoring visits. The tab displays the data in a Donut, Bar, Column format. The user can select the date and month by clicking the Calendar icon to view the data. The user can also Export the data as required in an Image, Excel or Clipboard format. the user can apply the filters By Month and By Country to view the data.

Chapter 10. Document Queries

Document queries have several different uses in Trial Interactive but, generally speaking they provide users with a method of asking questions about documents. The specific use of queries in a study room may be guided by internal SOPs specific to the study.

Workflow Queries

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

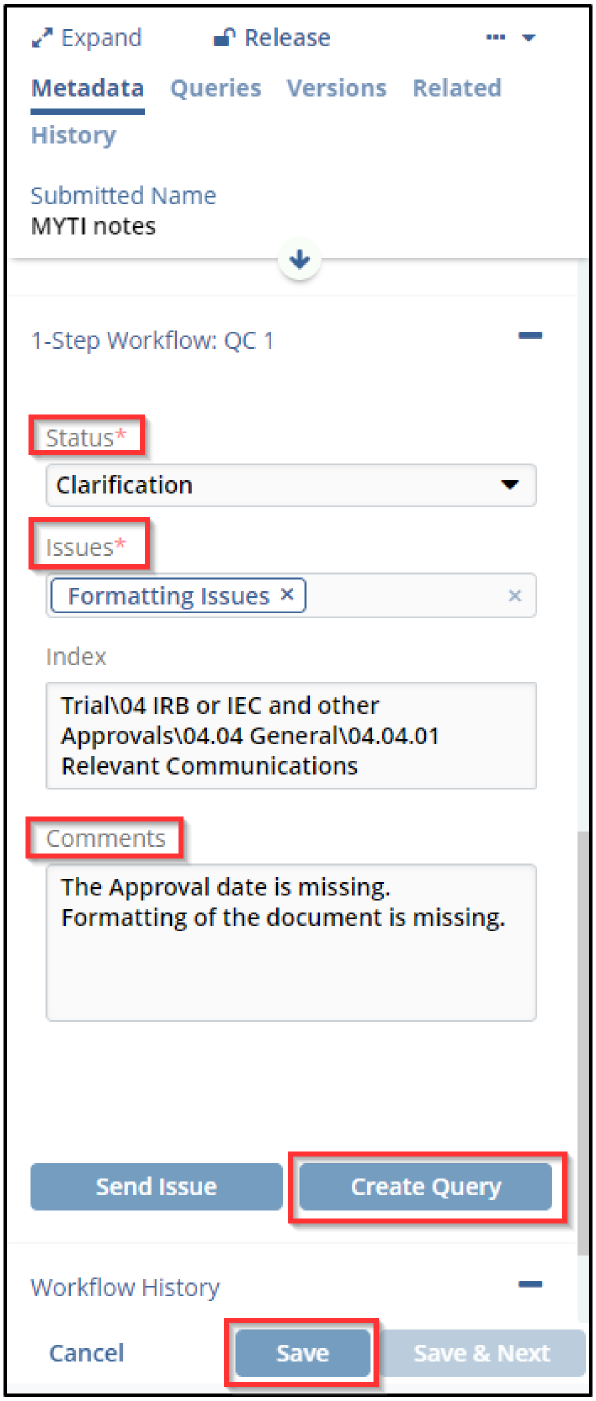
Note: The eTMF and Queries Modules both display distinctive data, whereas the eTMF modules displays only documents and the Queries module display all the queries present in the room. Additionally, if a single document contains multiple queries, the eTMF module indicates only one count, whereas, the Queries Module reflects the accurate count, showing each individual queries.

Opening a workflow query

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

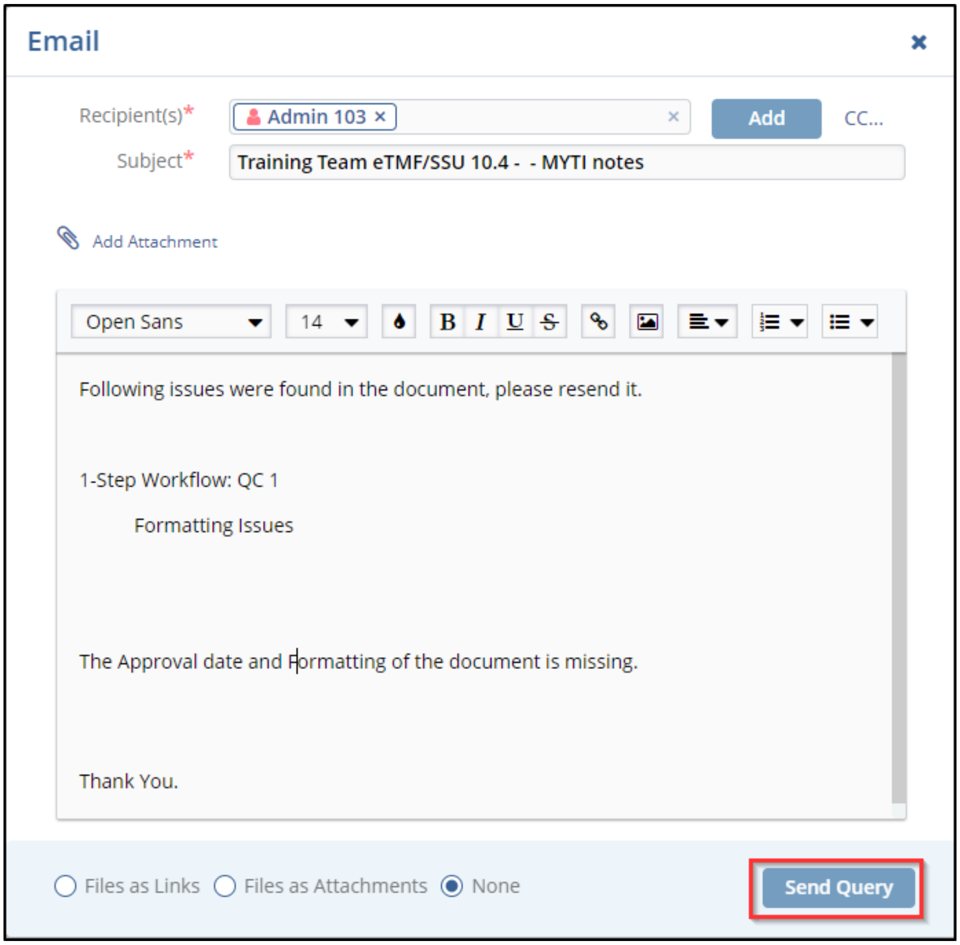
To open a workflow query, follow these steps:

1. Apply metadata to the document as accurately as possible.
    a. Some fields will be required even if the point of the query is to clarify the required value. Fill in the field to the best of your ability.
2. Select the status of "**Clarification**" from the dropdown menu to the document and indicate the issue.
    a. It is not required to add comments to a document when applying a status of 'Clarification' but it is highly recommended that you be as specific as possible in order to give the query recipient enough detail to correctly and quickly answer your question.
3. Enter the details in the **Comments** field to enable the 'Create Query' button.
4. Click the '**Create Query**' button displayed below the Comments field in the metadata panel.



5. This opens the Email popup window.
6. The email window will automatically populate with the submitter as the recipient, the template email, the issues chosen, and any comments that you provided. Customize the email and add any additional recipients as necessary.

7. Select the appropriate option from the following radio buttons available at the bottom of the email popup window –
    - Files as Links
    - File as Attachments
    - None.
8. Click the ‘**Send Query**’ button displayed at the bottom of the popup window next to the radio buttons.



9. Click the ‘**Save**’ button displayed at the bottom of the metadata panel.
    a. If you inadvertently press the ‘Save & Next’ button, you will need to go get your document from the ‘Clarification’ folder at the left side of the screen before continuing.

Responding to a Workflow Query

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

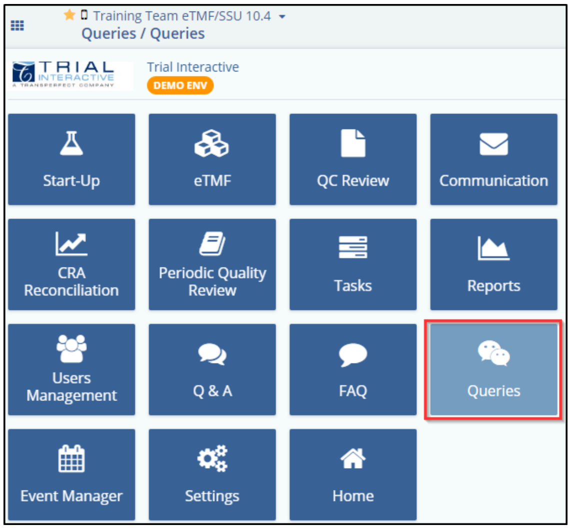
Responding to a query can happen from multiple locations in the system:

1. **Email**
    a. Replying to the query email will add a response to the query in the system.
2. **The Documents Module**
    a. Query by Sender view
    b. Query by Recipient view
    c. Any other view where the document can be chosen and the metadata panel can be accessed
3. **The Queries Module**
4. **The My Queries Dashlet**

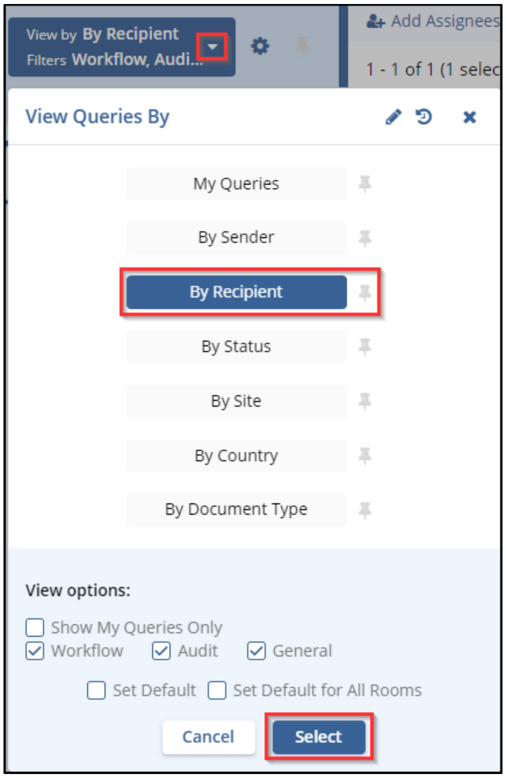
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To respond to a query from inside the system:

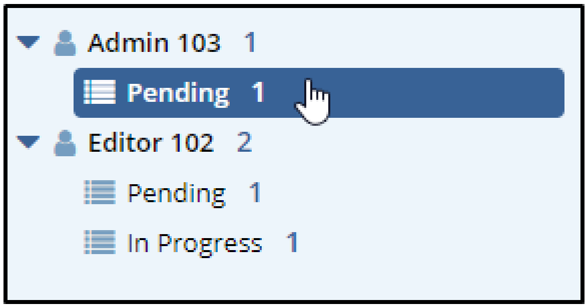
1. Navigate to the Queries Module via the Navigation Grid at the top-left corner of the screen.
    a. This will open a view that defaults to ‘My Queries’ which are queries in which you are listed as either the sender or the recipient.



2. Choose the 'By Recipient' view from the dropdown menu at the top-left.

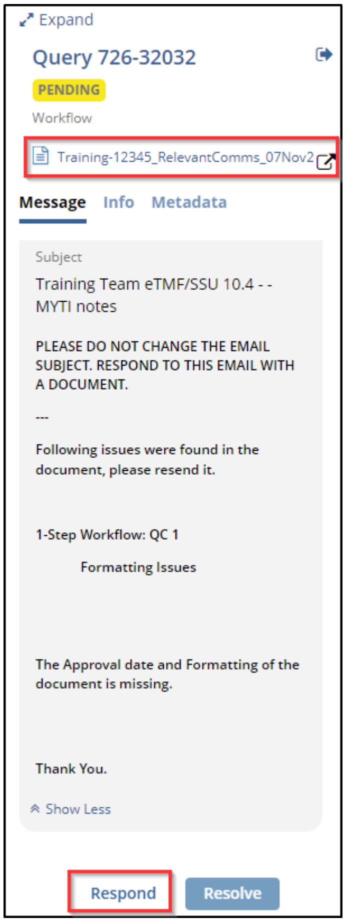


a. Users who have access to view queries for multiple users will need to expand their own list by clicking on the arrow next to their username.

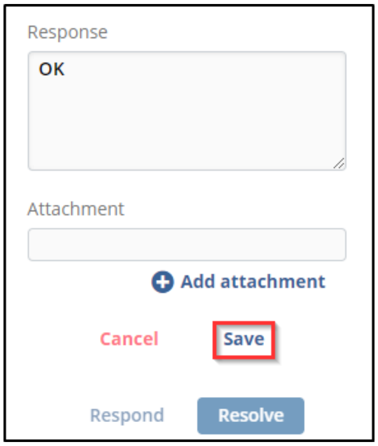


3. Select your Pending queries.
    a. This will cause the documents grid to populate.
4. Select the document whose query you wish to review and respond to.
    a. The metadata panel will populate with the query information.
    b. For other areas of the system, choosing the document will also cause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

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



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



Resolving a workflow query

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

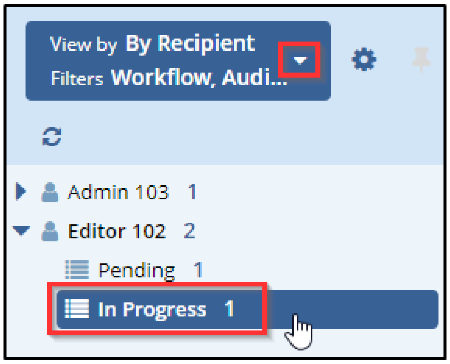
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

5. The Documents Module
    a. The Reviews view
    b. Query by Sender view
    c. Query by Recipient view
    d. Any other view where the document can be chosen and the metadata panel can be accessed
6. The Queries Module
7. The My Queries Dashlet
8. The QC Workflow module

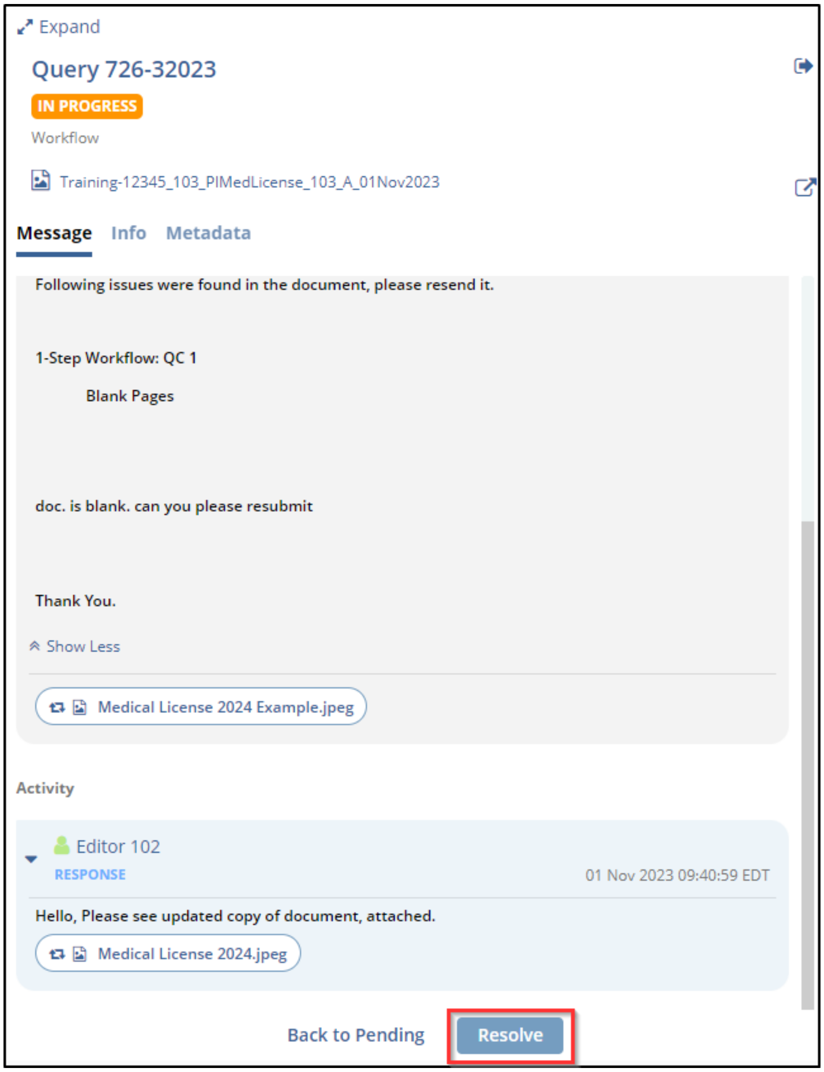
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To resolve a query, follow these steps:

- Locate the 'In Progress' query
    a. Pending queries can be resolved too but the status indicates that no response has been received.



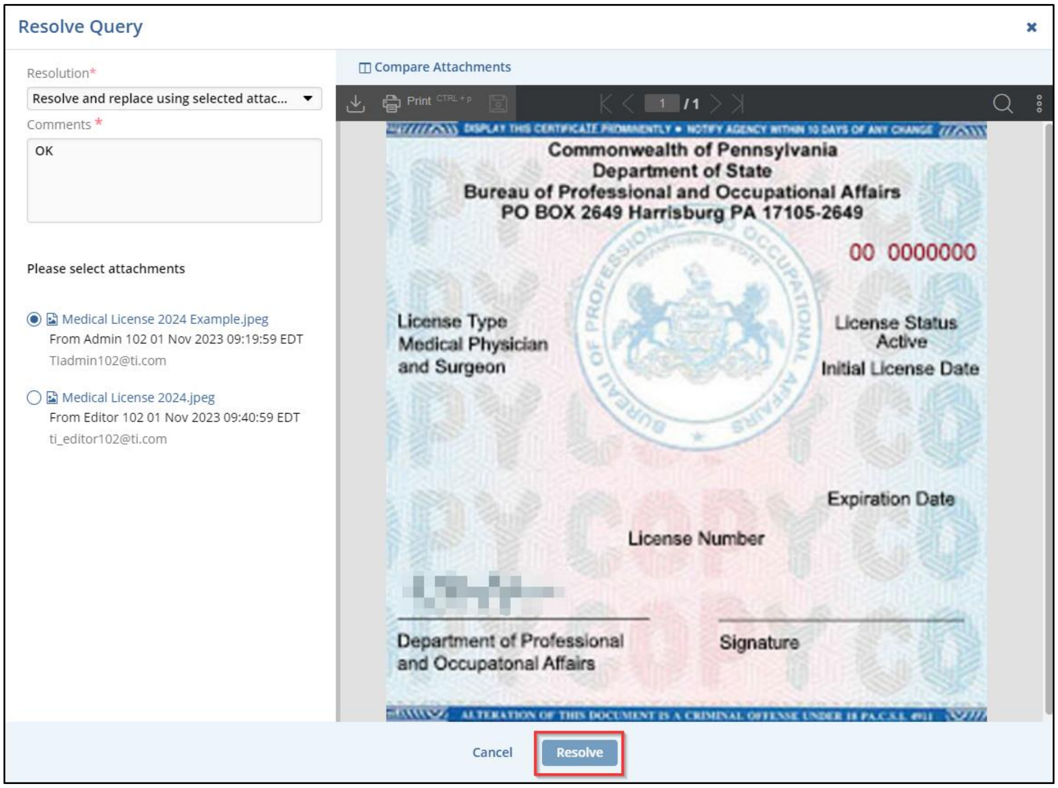
- Click on the query in the grid.
    a. The metadata panel loads in the metadata panel.
    b. For users who opt to perform these steps from other locations in the system, you may have to select the Query tab of the metadata panel.
    c. The query response will appear lower down in the panel and is usually colored green or blue depending upon your system settings.



- Read the response and, if it answers your question, click the ‘Resolve’ button.
    a. The ‘Resolve Query’ popup window is displayed.
- Choose your Resolution type using the dropdown menu.
    a. **Resolve** – This option would be used if no replacement document was received during the query process.
    b. **Resolve and Replace using selected attachment** – This option would be used if the user wants to replace the attached file.

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

- Add a comment indicating why the query is being resolved.



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

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

- If appropriate, choose the file to move forward with.
- Click the 'Resolve' button displayed at the bottom of the popup window.
    a. If you have chosen either the 'Resolve' or 'Resolve and replace using selected attachment' option then this is the last step.
    b. If you have chosen to reject the existing document and use a replacement attachment, press 'Next'
- Apply the correct metadata to the new document.
- Click the 'Resolve' button.

Audit Queries

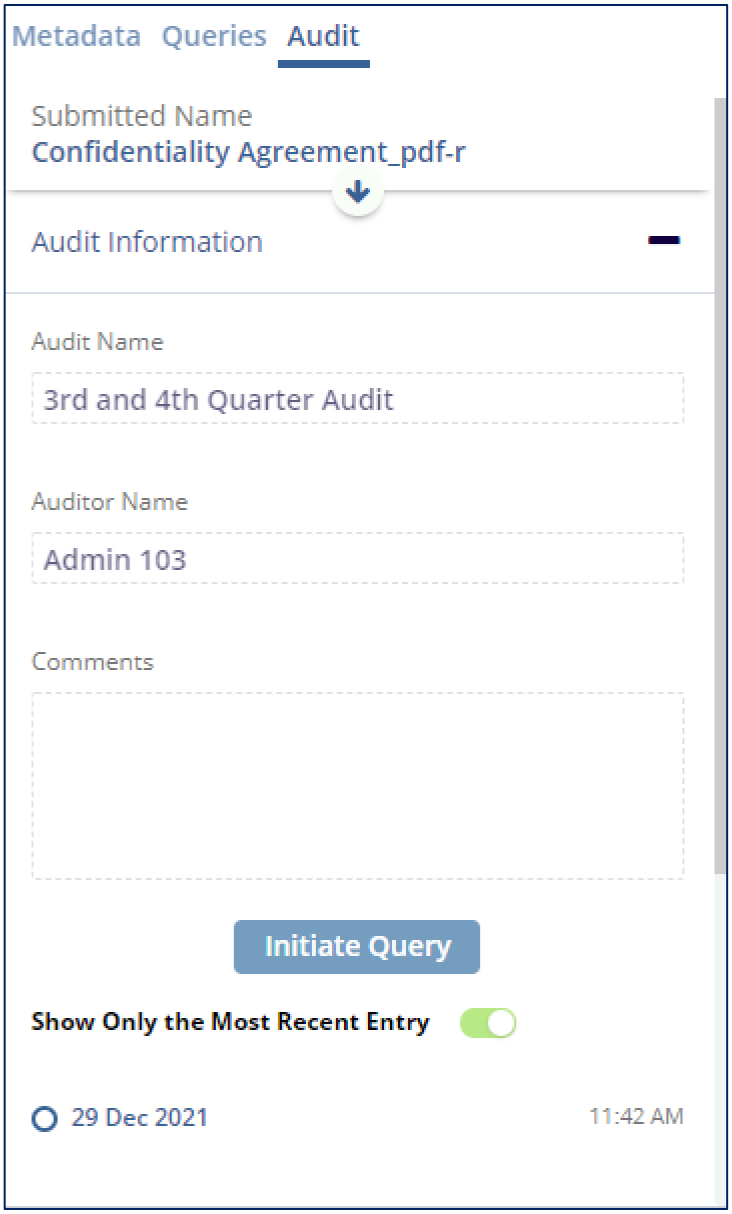
Audit queries can be opened at two different points during the quality review process. In the first case, the Auditor can open a query against a document if they need assistance determining if the document should be passed or failed. The second, and likely more common usage, would be when the document has been failed and the Audit Responder needs to correct any audit findings.

Opening an audit query

It is assumed that the user is already a part of the audit and has already either been assigned the document for review or claimed the audit finding for review. For these instructions, we are focusing on the Audit Responder role but the general instructions are the same.

To open an audit query, follow these steps:

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



- This will open the email window.

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

Responding to an audit query

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

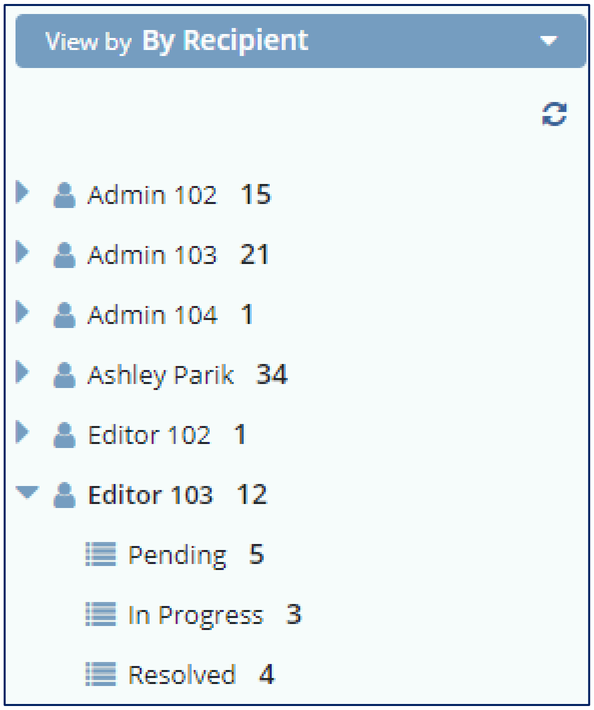
Responding to a query can happen from multiple locations in the system:

9. Email
    a. Replying to the query email will add a response to the query in the system.
10. The Documents Module
    a. Query by Sender view
    b. Query by Recipient view
    c. Any other view where the document can be chosen and the metadata panel can be accessed
11. The Queries Module
12. The My Queries Dashlet

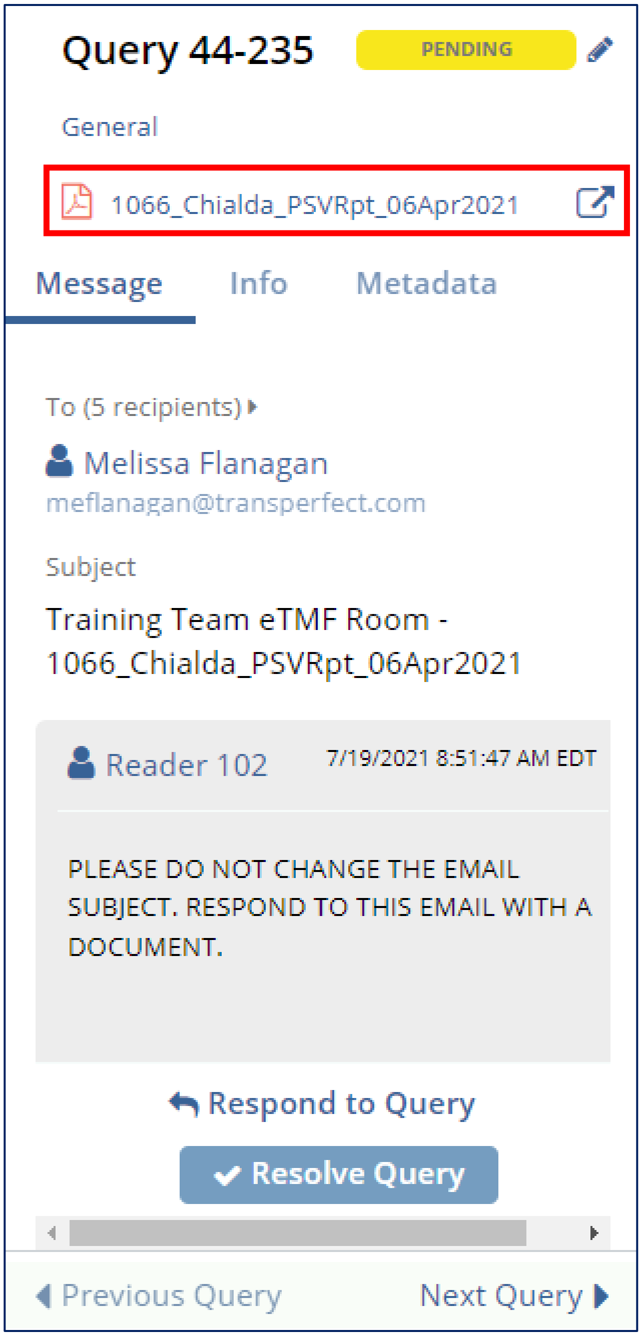
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To respond to a query from inside the system:

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



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



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

Resolving an audit query

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

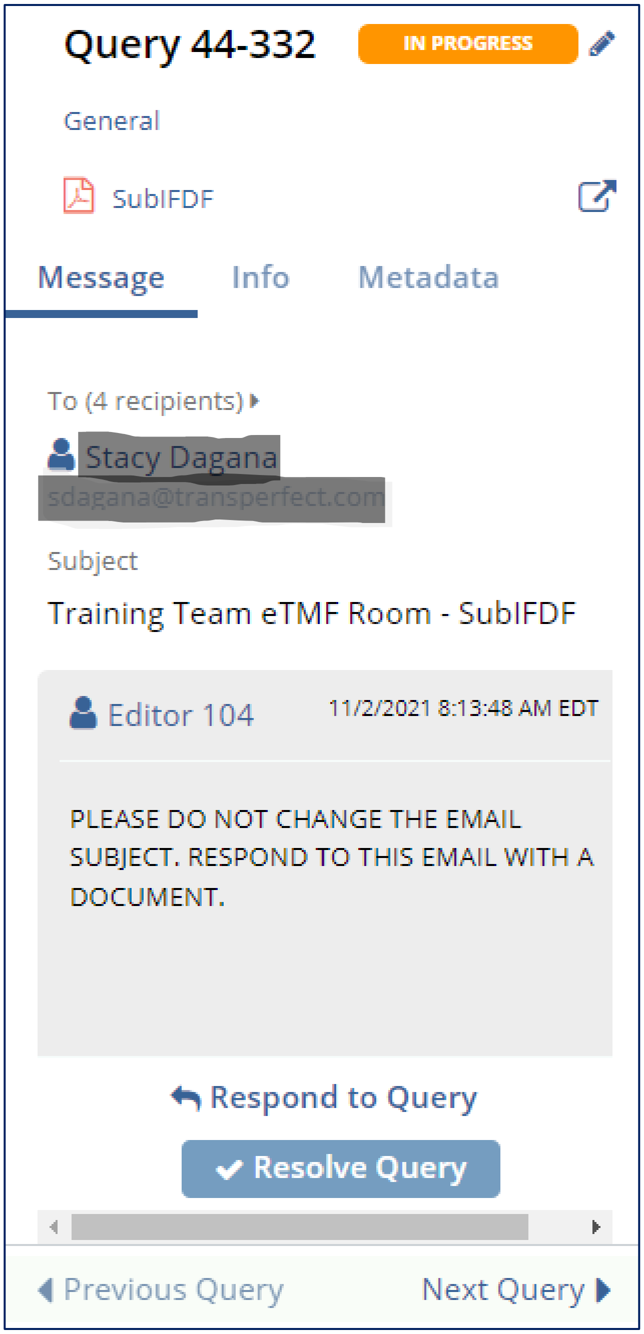
‘Working’ a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

13. The Documents Module
    a. Query by Sender view
    b. Query by Recipient view
    c. Any other view where the document can be chosen and the metadata panel can be accessed
14. The Queries Module
15. The My Queries Dashlet

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

To resolve a query, follow these steps:

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



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

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

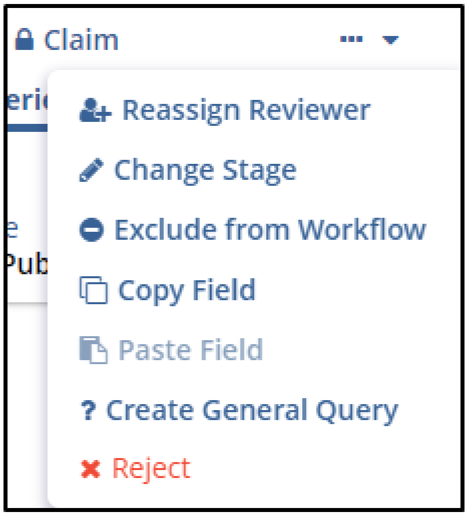
General Queries

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

Opening a general query

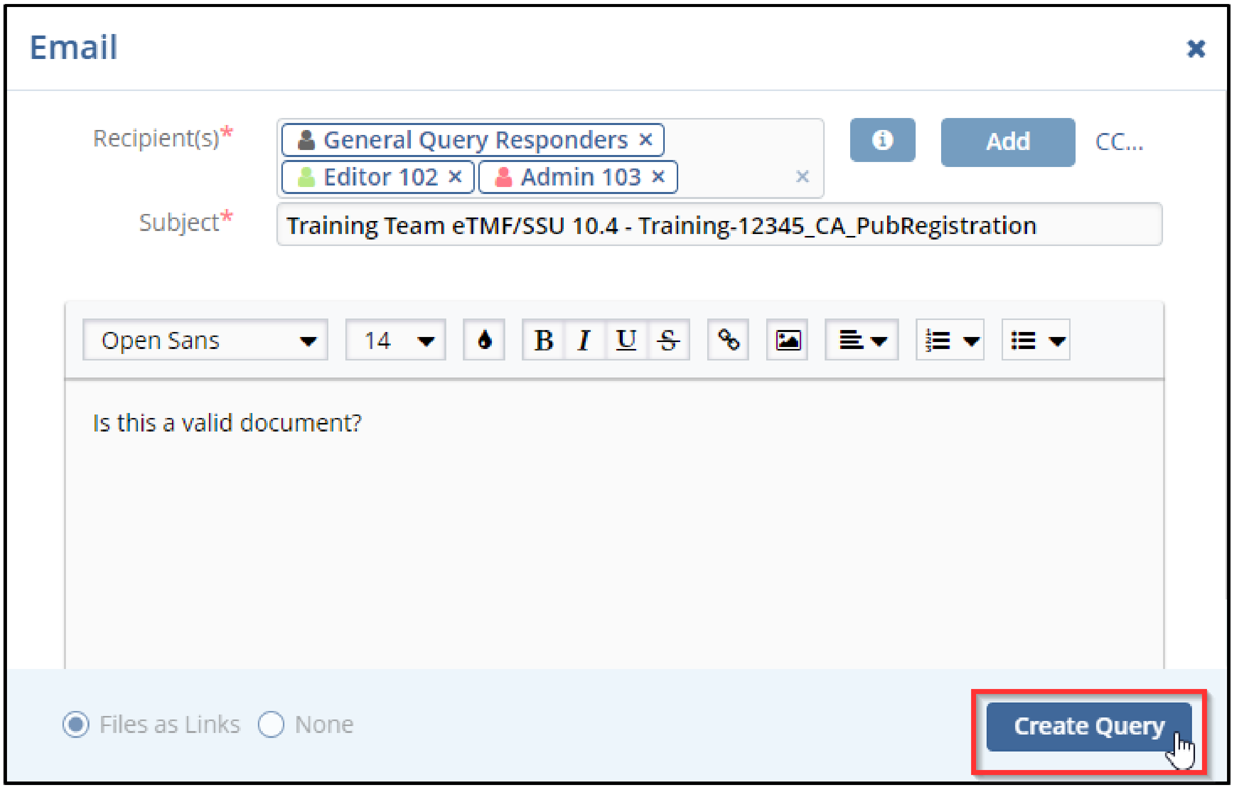
All Trial Interactive users can issue general queries against any document or document placeholder in the eTMF. In order to open a general query on a document, follow the steps below:

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



5. Select the "**Create General Query**" option. This will open the Email window.
6. Readers and Editors will not be able to select an individual recipient of their query. Instead, the General Query Responder group will be the dedicated recipients of these queries. At this point, Administrators will be able to select a recipient.

7. Compose the email and, when done, press “Create Query” to send the message to the selected recipients.



a. These queries can be tracked using the Queries Module, the Query by Sender or Query by Recipient views, or via the My Queries dashlet on the dashboard.

Responding to a General Query

The recipient of a query will receive an email as shown in the steps for sending a general query. If the sender was a Reader or Editor, they will not have been able to designate a specific responder. In cases like these, the members of the General Query Responders group would be able to respond to the query from within the system.

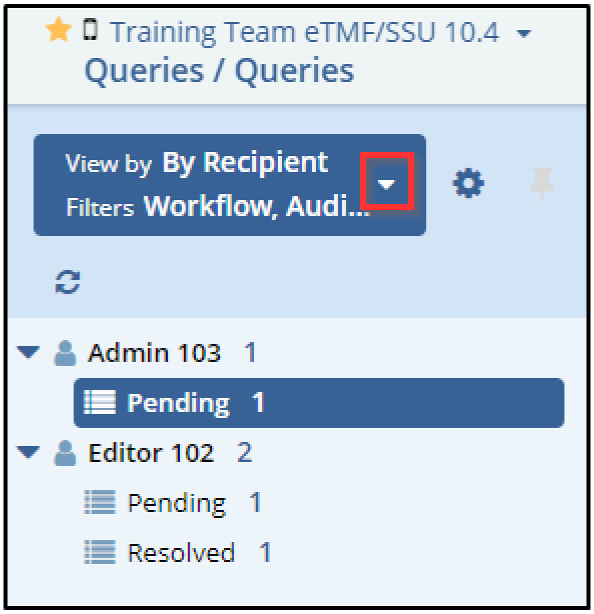
Responding to a query can happen from multiple locations in the system:

1. The Documents Module
    a. Query by Sender view
    b. Query by Recipient view
    c. Any other view where the document can be chosen and the metadata panel can be accessed
2. The Queries Module
3. The My Queries Dashlet

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

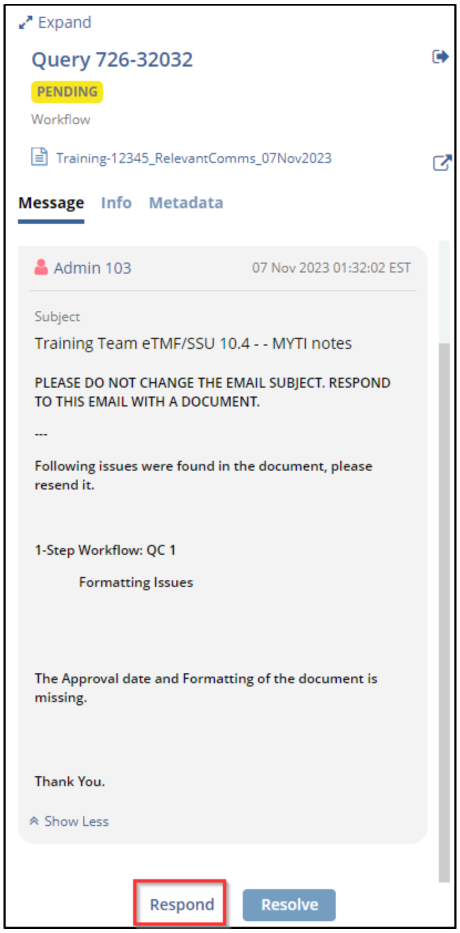
To respond to a query from inside the system:

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

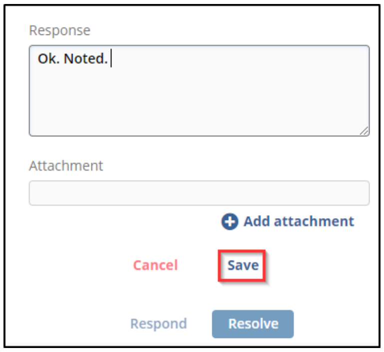


3. Select your Pending queries.
    a. This will cause the documents grid to populate.
4. Select the document whose query you wish to review and respond to.
    a. The metadata panel will populate with the query information.
    b. For other areas of the system, choosing the document will also cause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

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



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



Resolving a general query

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

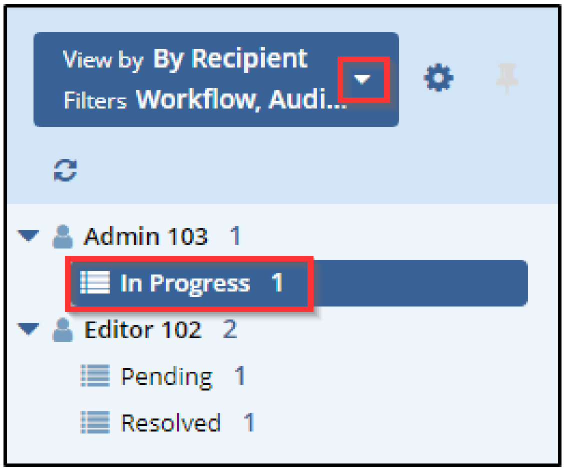
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

1. The Documents Module
    a. Query by Sender view
    b. Query by Recipient view
    c. Any other view where the document can be chosen and the metadata panel can be accessed
2. The Queries Module
3. The My Queries Dashlet

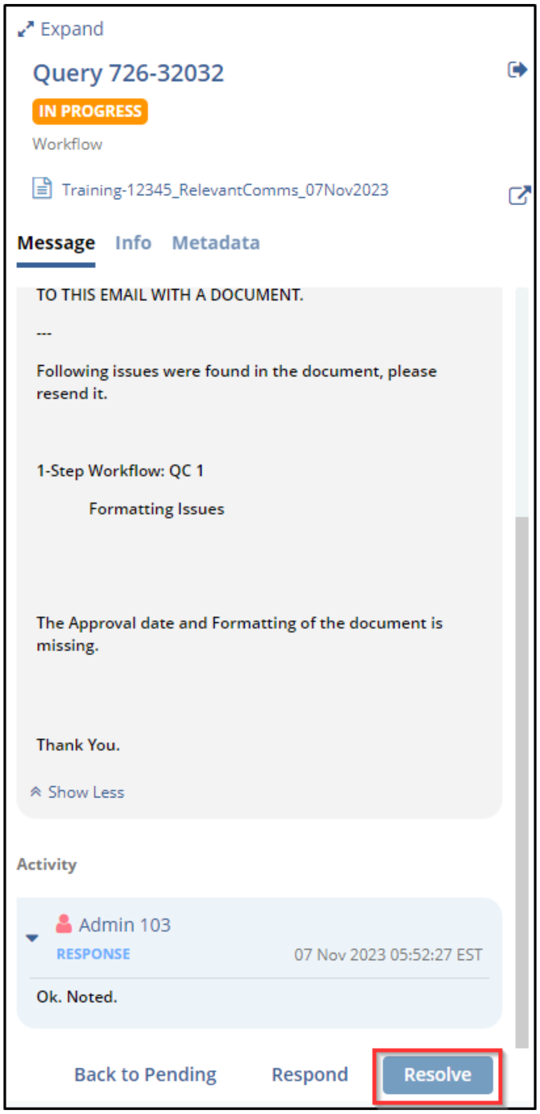
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

To resolve a query, follow these steps:

1. Locate the 'In Progress' query
    a. Pending queries can be resolved too but the status indicates that no response has been received.

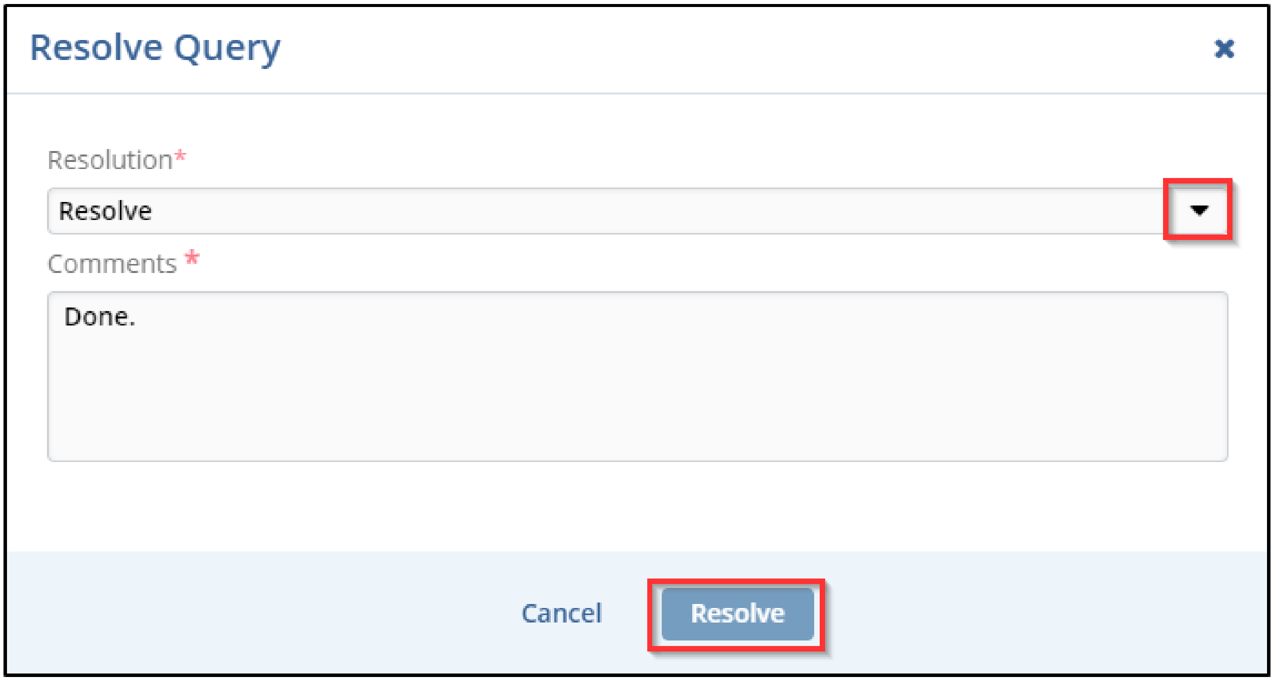


2. Click on the query in the grid.
    a. The metadata panel will load
    b. For users who opt to perform these steps from other locations in the system, you may have to select the Query tab of the metadata panel.



    c. The query response will appear lower down in the panel and is usually colored green or blue depending upon your system settings.
3. Read the response and, if it answers your question, click the '**Resolve**' button displayed at the bottom of the metadata panel.
    a. The 'Resolve Query' window will open.

4. Add a comment indicating why the query is being resolved.
5. Click the '**Resolve**' button displayed at the bottom of the popup window.

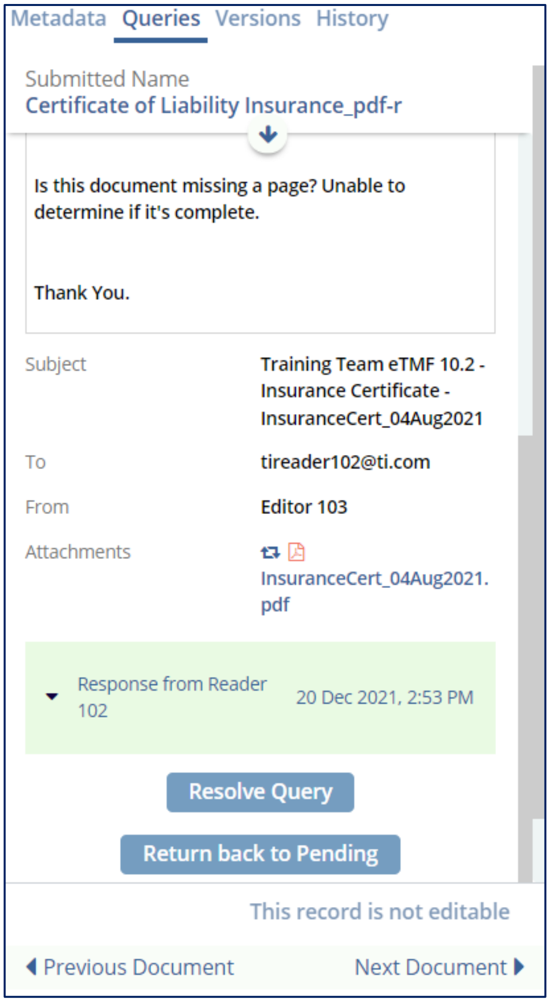


The Queries Module

Viewing a Query

To view a query, follow the steps as below:

- In the Queries module, click Choose View next to the Index View.
- The View Documents By popup appears.
- Select the By Sender view and click Select at the bottom of the page.
- The folders with the name of reviewers appear.
- Click the required folder. The following folders are available for the query:
    - **Pending:** This folder contains all the queries sent and are awaiting the response.
    - **In Progress:** This folder contains all the queries which are responded.
    - **Resolved:** This folder contains all the queries which are resolved.
- Select the required document from the grid and click Query tab from the metadata panel.
- The queries display in the Queries panel.
- Click the query to view the full query history.
- The query displays the following:
    - The email body of the query that was initiated.
    - The responses and attachments to the query displayed by green sections. Refer to the screenshot below:

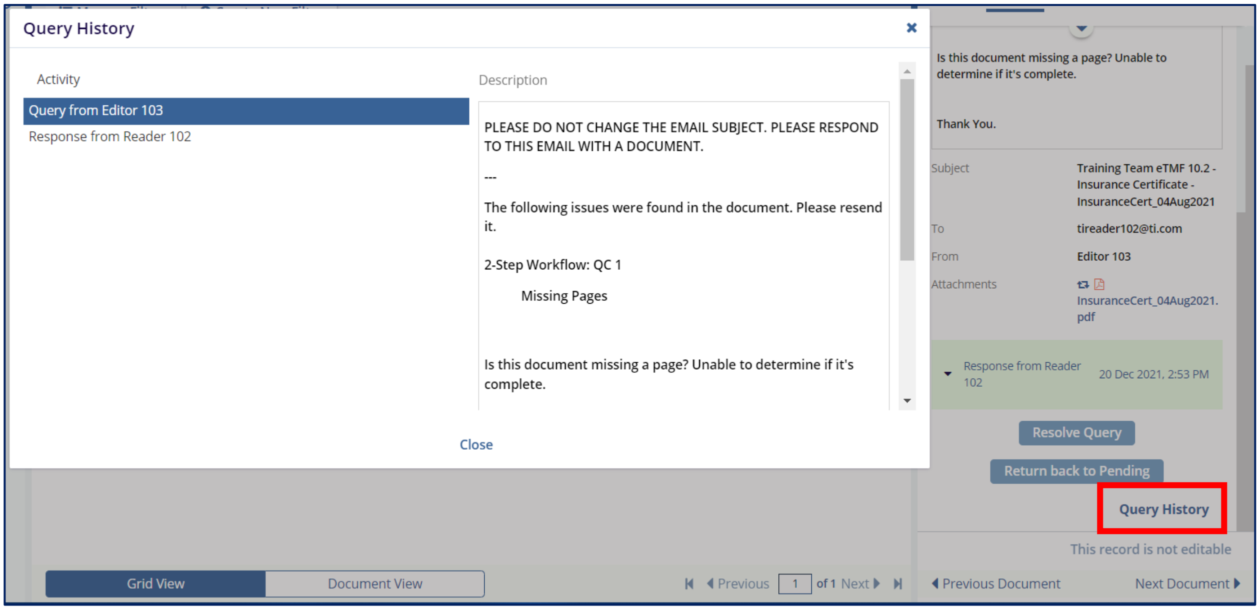


- Expand the required section to view the details for the sections.

Viewing Query History

To view the query history, open the required query and click the Query History button at the bottom of the Queries panel.

This opens the history of the query in the Query History window. Refer to the screenshot below:

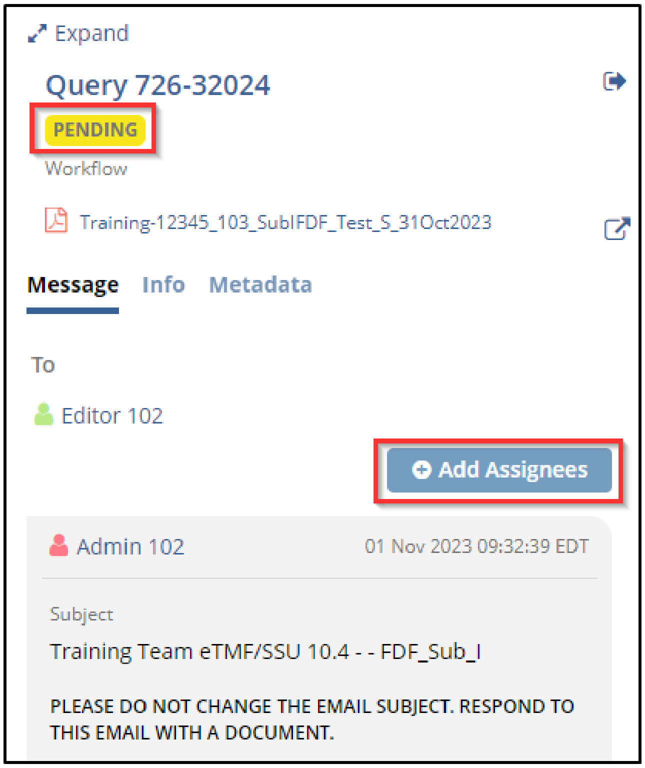


From the Query History window, select the required query activity from the left pane and the details of the history displays in the right pane.

Reassigning a query to a new recipient

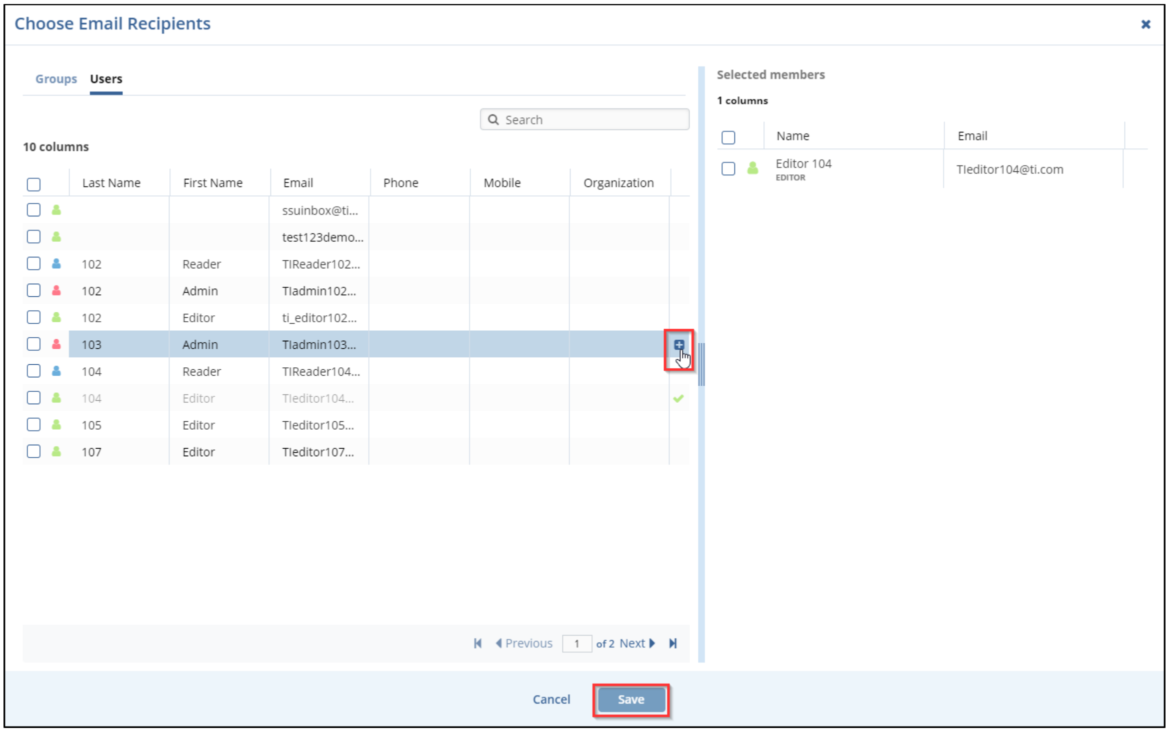
Administrator users and those users who are added to the Query Managers group can add an additional recipient to a query. Users can perform this action by locating the query in the Queries module. follow the steps below to reassign a query to a new recipient.

1. Click the **Add Assignees** button in the metadata panel on the right.

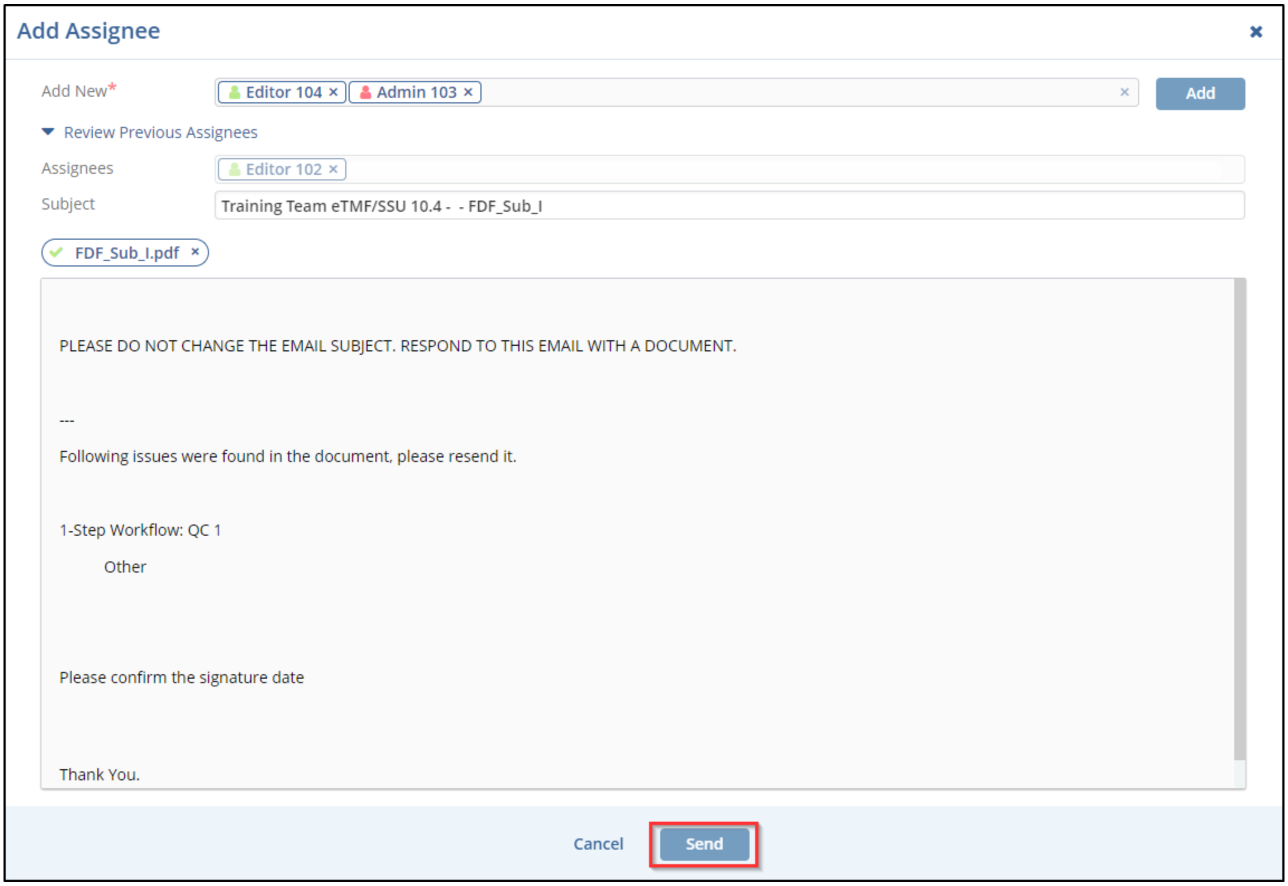


2. This opens the Add Assignee popup window.
3. Click the **Add** button displayed in the top right corner of the popup window.

4. This opens the Choose Email Recipients popup window. Select the required recipients to reassign the query. Click the Plus icon OR drag drop the name to the right panel.
5. The selected assignees are reflected in the right-side panel.
6. Click the **Save** button displayed at the bottom of the popup window.



7. The selected names are reflected in the Add New field of the Add Assignee popup window.
8. (Optional) Click the down arrow to view the previous assignees.
9. Click the **Send** button displayed at the bottom of the popup window.



Chapter 11. Searching

This section helps to understand the documents search, user search, and room search in the application.

Trial interactive now supports a cross-room, full-text indexed, segmented, and filtered search capability, with support for all record types and facets, including document types and metadata fields.

This new search interface has the following powerful capabilities:

- Record-type search based on topic and record type, allowing for searching of documents, users, queries, and other segments.
- Filters based on any document metadata, implemented as facets to allow simplified fast filtering of search results.
- A new full-text index based on automatic text extraction and OCR.
- Support for full metadata searching within a room and across multiple rooms.
- Integrated selection of saved and recent searches, with rapid re-searching.
- Continued support of the custom grid view for search results with integrated exports, compare, document cart, and other actions.
- Continued support of instant document review with metadata panel from the search screen.
- Actionable result set based on record type, with easy navigation to the document.
- Continued support of flexible search terms and wildcards.

Documents Search

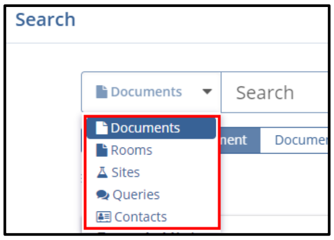
We can perform two types of searches for documents:

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

- **Documents Search:** When you search for documents from within a room or study, check the box Limit search to the current room. Refer to the screenshot below:

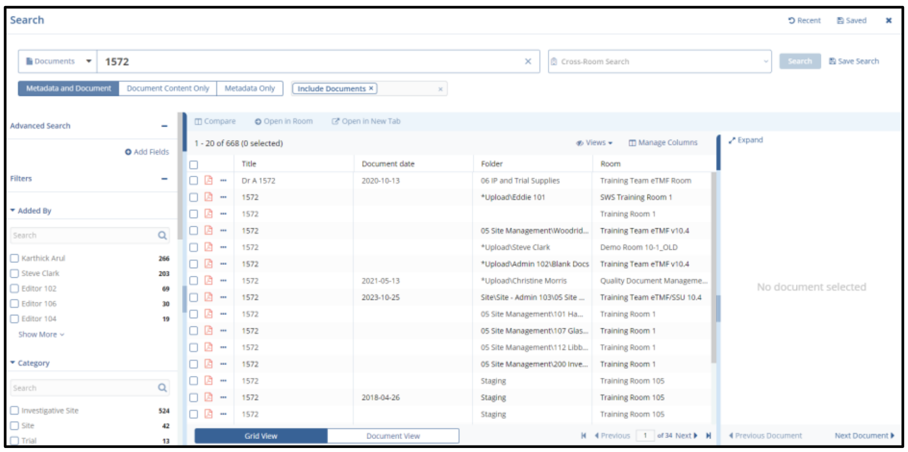
The process to execute both types of searches is the same except for the location of executing the search:

1. Navigate to the Home Page or a Trial Interactive room as required.
2. Click the Search icon next to the username menu.
3. The Search popup appears.
4. Select Documents from the dropdown of the following options:
    a. **Documents**
    b. **Rooms**
    c. **Sites**
    d. **Queries**
    e. **Contacts**

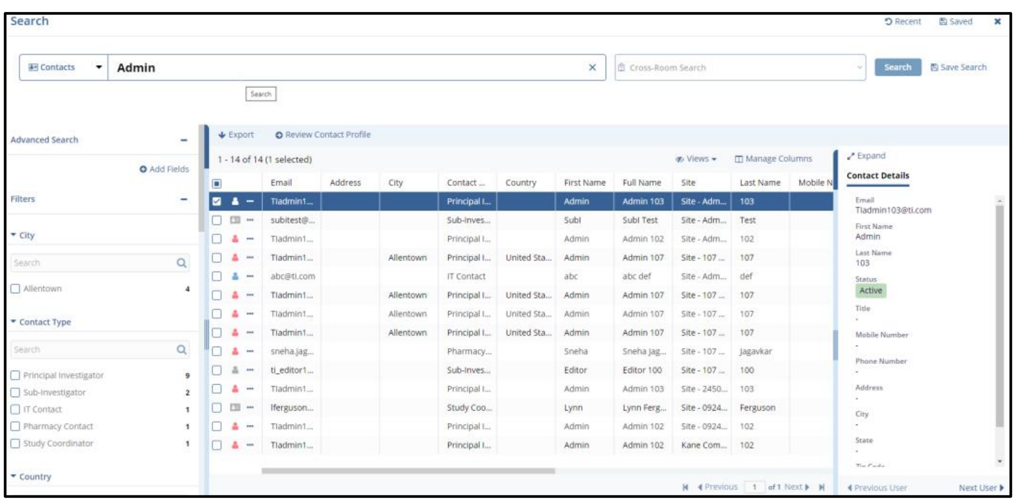


Note: Only Administrator users will be able to view all of these options.

5. Enter the search criteria in the Search box.
6. As soon as the text is entered in the Search box, the search process starts.
7. Items matching the search criteria are displayed in the Grid below the Search box or else a message No records available is displayed. Refer to the screenshot below:



4. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
5. Hover the mouse over the Document icon to get a preview of the documents.
6. Click the document icon. The document Metadata panel opens in the right pane.
7. Similarly, select the **Contact** option to perform the contact search. When the results are displayed and the user selects any record, **Contact** Details are displayed in the right pane.

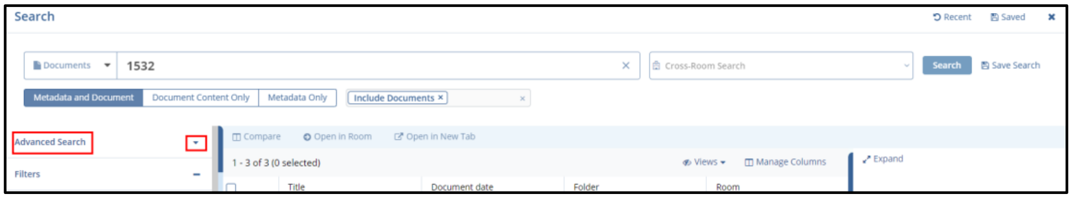


Advanced search

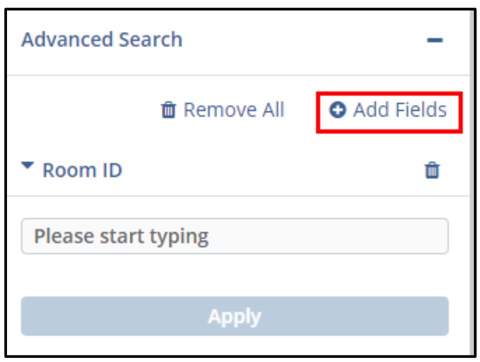
Added an **"Apply Filter "** button to the advanced search panel. Users who perform an advanced search can now add a search field and update their search results immediately using an 'Apply Filters' button directly in the Advanced Search panel rather than relying only on the primary search button.

To perform Advanced Search, follow the below Steps:

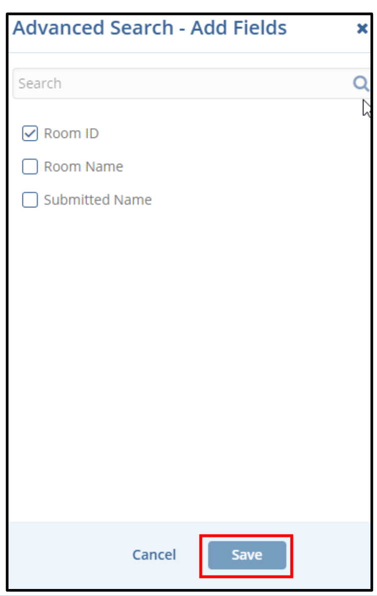
1. From the Search page Click on the **Advanced Search** drop-down icon available on the left panel. Refer to the screenshot below.



2. To add fields, click on the Add Fields (+) icon. The **Advanced Search – Add Fields** window will appear.

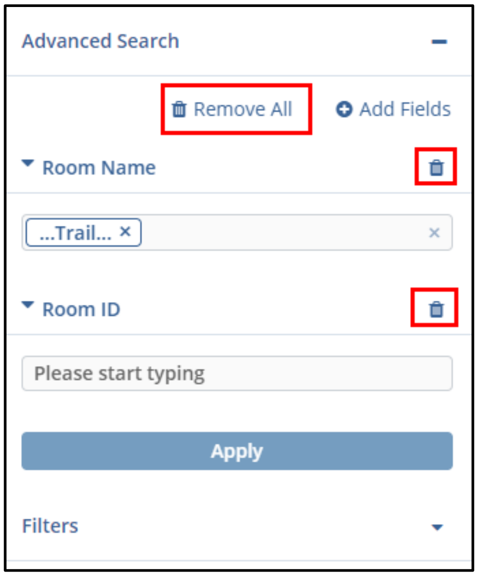


3. You can search the field and click the checkbox added with the field name. Once you click the Save button. The fields will be visible on the left panel of the Search Page.



4. Add the condition and Click on the Apply button.
5. You can also delete the Added Field. There are two options.

   - To delete a single field, click on the Delete icon presented in a field.
   - To Delete all fields, click on the **Remove All** tab.

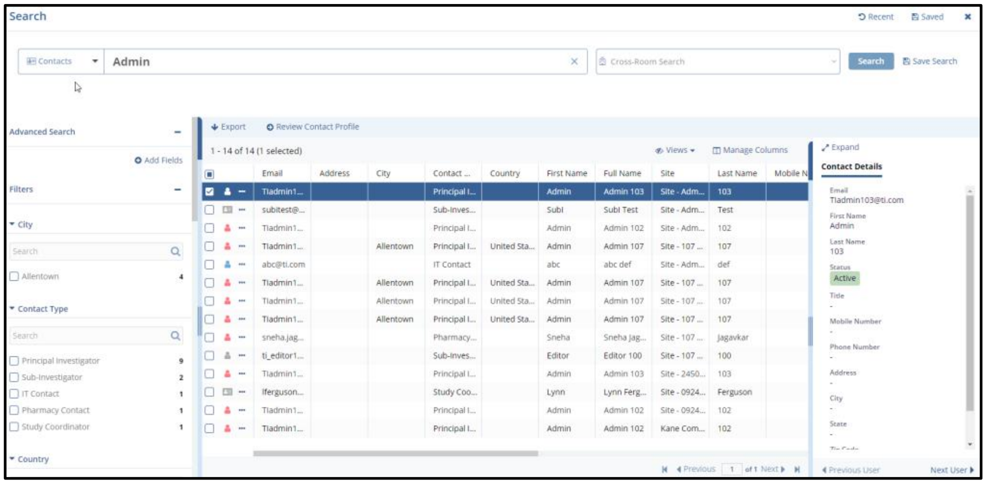


Searching Contacts

To search for users, follow the steps below:

1. From the Home Page, or from within a room as appropriate, click the Search icon located at the top right corner of the screen.
2. The Search window appears. Select **Contacts** from the options given.
3. Enter the user name in the Search textbox at the top of the window. This displays the contacts in the Records section if available.

   Refer to the screenshot below:

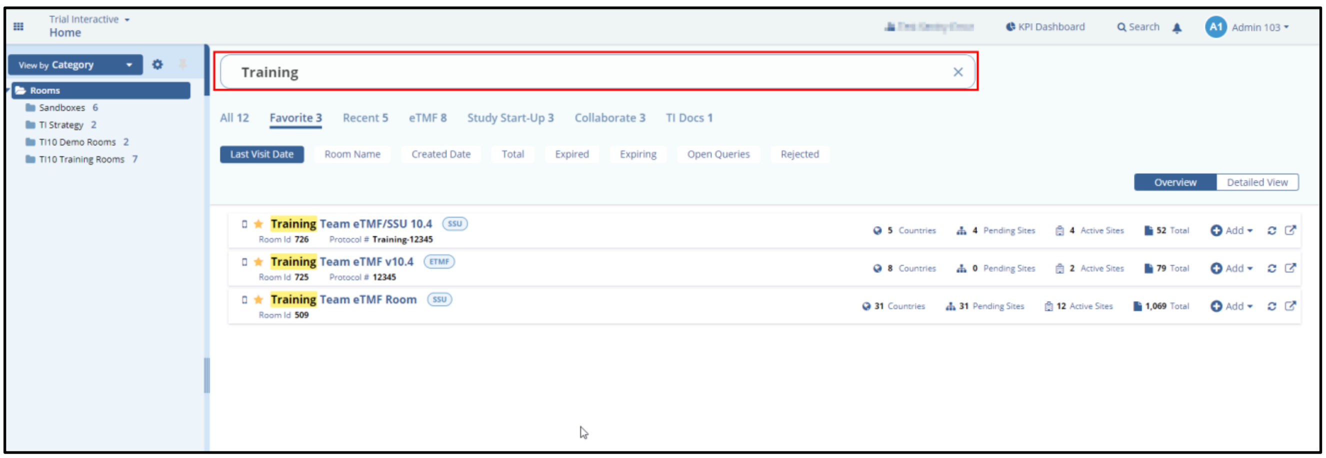


4. Upon selecting a required from the results grid, details of that user will be displayed in the **Contact Details** section in the right pane.

Room Search

To search for a room, follow the steps below:

1. The Search textbox is located on the home page to perform the room search.
2. On the home page of the application, all the rooms are displayed and the user can use this search functionality to easily search for the desired room.
3. Enter the room name in the search textbox and a search starts automatically as and when the text gets entered. Refer to the screenshot below:



Chapter 12. Importing Documents and Metadata

There are a large number of ways that Documents can be added to a room. This chapter will not be an exhaustive discussion of every possible method.

Other methods are mentioned in relevant chapters of the user guide

Adding Documents Directly to an Index Folder

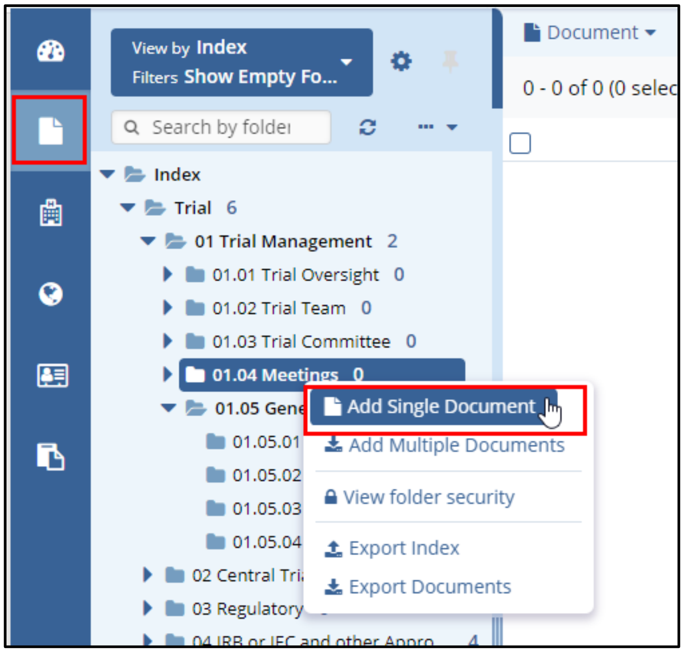
You can add Single or Multiple documents to an index folder. Each of these is discussed in the sections in the subsequent topics.

Adding a Single Document to an 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.

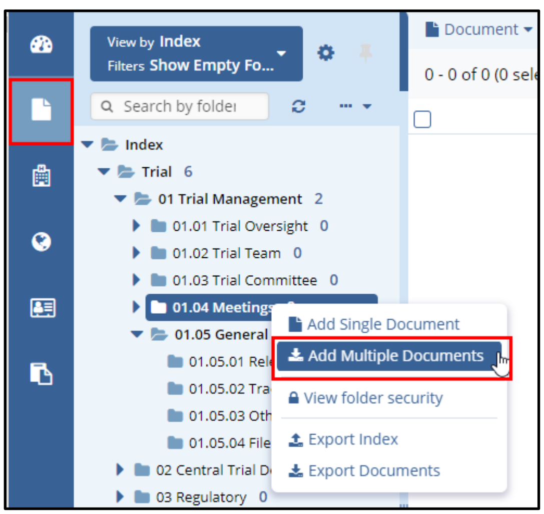
   Refer to the screenshot below:



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

Adding Multiple Documents to an Index Folder

1. From the Documents Module, select a folder in the index.
2. From the right-click popup, select Add Multiple Documents.



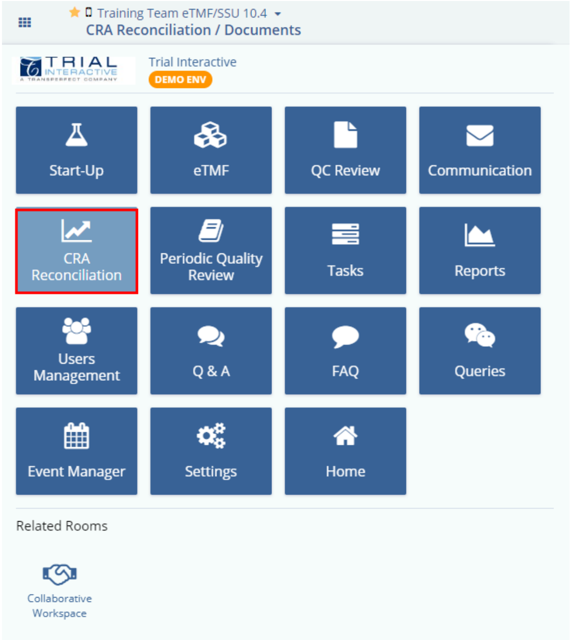
3. This opens the Import Documents window. Add documents to the window and press ‘Import.’ A more in-depth discussion of this import window can be found in the section on importing documents and metadata.

Chapter 13. CRA Reconciliation

CRA Reconciliation

This section helps you find the details about the CRA Reconciliation Reports that allow CRA to make decisions regarding further site visits.

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



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 the reconciliation process.
2. Reports: This module allows the CRA to create a CRA Report which will include all the documents reviewed by the CRA since the last report created by him/her.
3. Audit Trail:

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

Note: Any user can be granted access to the CRA Reconciliation module but the reconciliation and reporting functions will only be available to users who have been designated as a CRA for a site. This designation is not available to room administrators.

- In rooms with Study Start-Up enabled, this module can also be used to track sites to which the user has been assigned as a Site Activation Specialist.

Documents Reconciliation

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

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

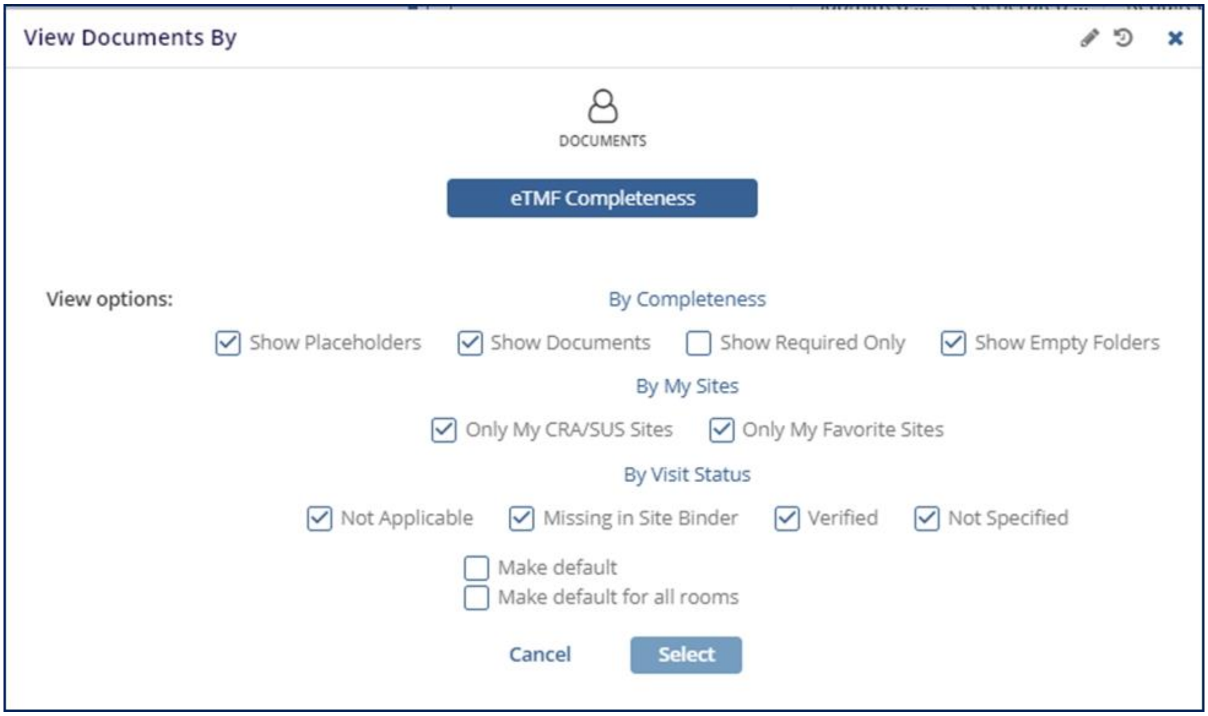
CRAs can avail of this information from the Site Report so that they can verify the outstanding documents during their next site visit.

Follow the steps below to reconcile documents:

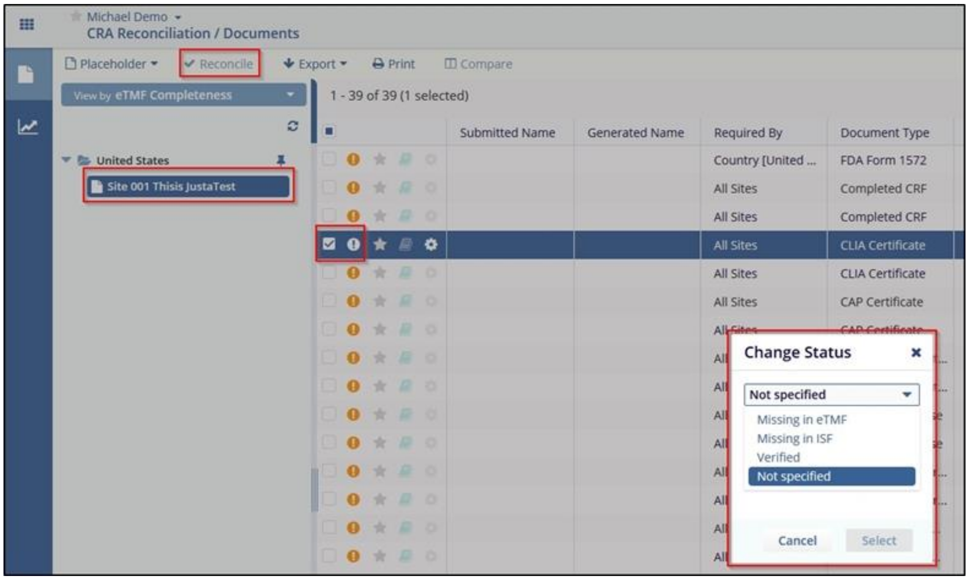
1. Navigate to the CRA Reconciliation Module.

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

2. If the warning is displayed, click the Filter icon below the view and uncheck My CRA/SAS Sites or My Favorite Sites from the filter. Refer to the screenshot below:



3. Click Apply.
4. The list of folders appears in the view.
5. Click the appropriate folder to display the list of sites.
6. Select the appropriate site from the selected folder to get the list of missing, collected, and placeholder documents in the grid.
7. Click the document and then click the **Reconcile** button.
8. Select the appropriate status from the dropdown menu.
9. Press 'Select'

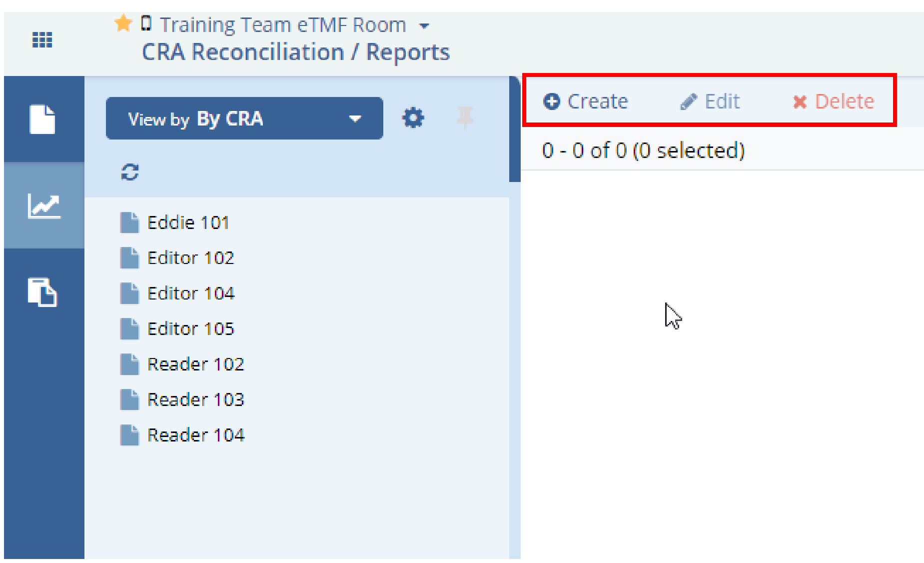


Creating and Viewing CRA TMF Reconciliation Reports

The CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. You can access this page from the Navigation Grid. On entering the reports area via the link on the left side of the screen, you can find the list of reports displayed in the grid.

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

You also have the option to Create edit, or delete a CRA Reconciliation TMF Report from the Create, Edit, or Delete icons located on the top ribbon. Refer to the screenshot below:



Creating a CRA TMF Reconciliation Report

1. Once the Reconciliation process is complete, you can create the CRA TMF Reconciliation report from the Reconciliation Report area.

2. Select the appropriate filter from the Current View. Any Previous reports will populate the grid.
3. Select the appropriate site and click Create from the top ribbon bar to run a new report.
   - If this is the first report being created for the site, simply click the ‘Create’ button and then manually enter the site information in the form that opens.
4. The Create CRA TMF Reconciliation window populates with documents from the latest reconciliation. Complete the required fields.
5. Fill in the appropriate details and click ‘Create.’
6. You will receive a notification that the Site Report is created successfully. The report will then be displayed in the grid.

Editing a CRA TMF Reconciliation Report

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

Deleting CRA TMF Reconciliation Report

1. Select the required site from the Current View and click the Delete button on the top menu bar.
   - You will only be able to delete reports which you generated.
2. Click Yes on the confirmation popup that appears if you wish to delete the report from the list.

Chapter 14. Quality Review

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

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

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

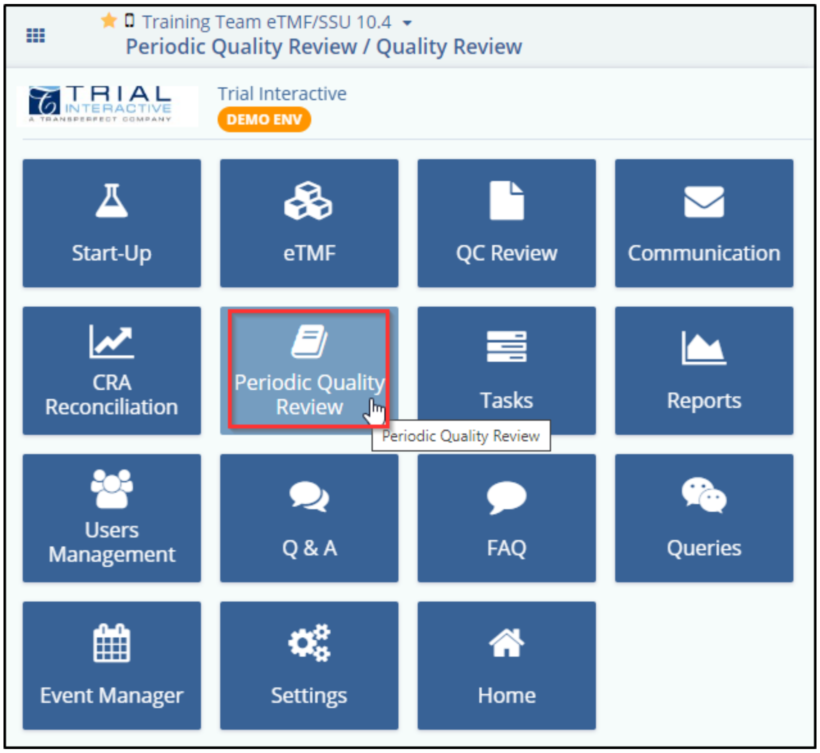


Figure 1: Quality Review Icon

Quality Review Settings

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

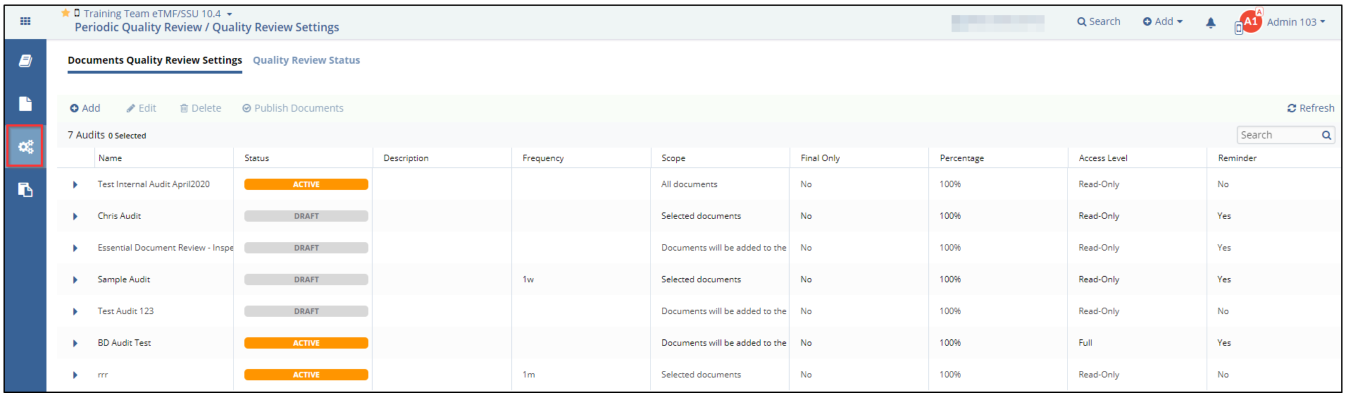


Figure 2: Quality Review Settings

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

Managing Quality Review Statuses

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

The 5 basic system statuses are:

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

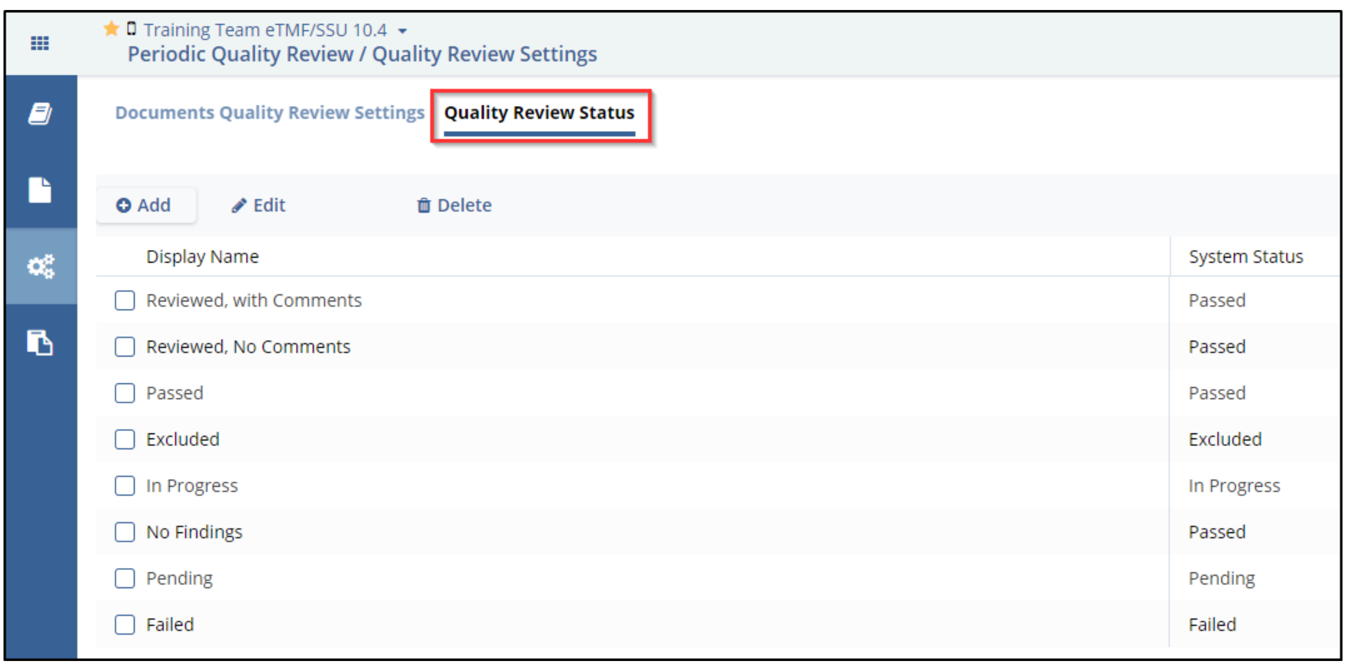


Figure 3: Quality Review Status

Add an Audit Status

Follow the steps below to add audit statuses:

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

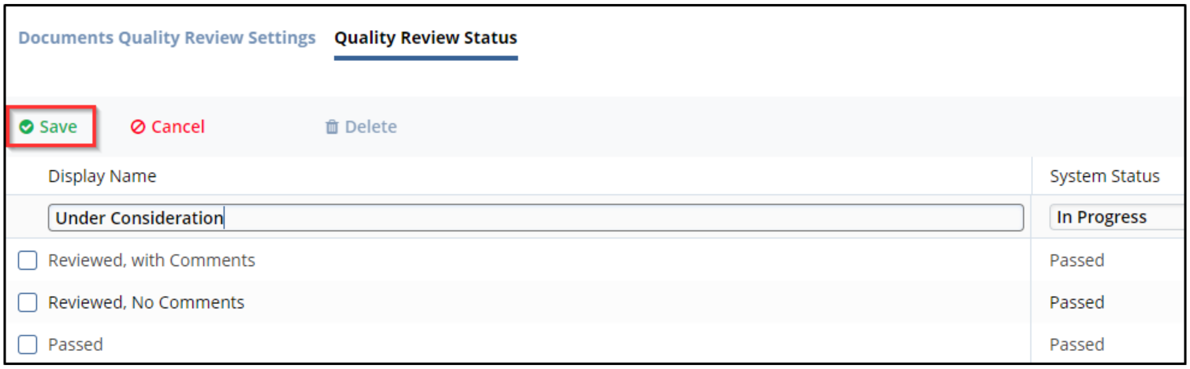


Figure 4: Quality Review Status-Add

Edit an 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. Pressing the '**Edit**' button from the top ribbon bar or,
    b. Clicking the Edit button that appears while hovering the mouse over the status.

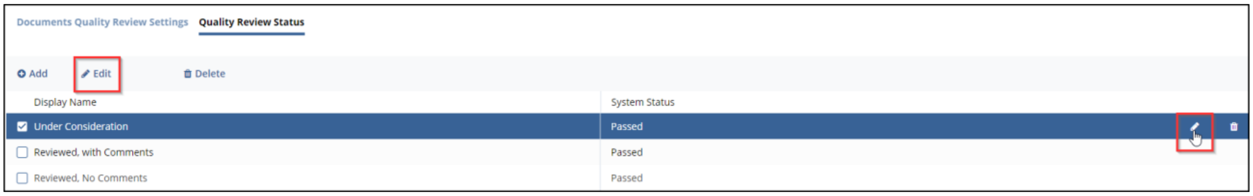


Figure 5: Quality Review Status-Edit Icon

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:

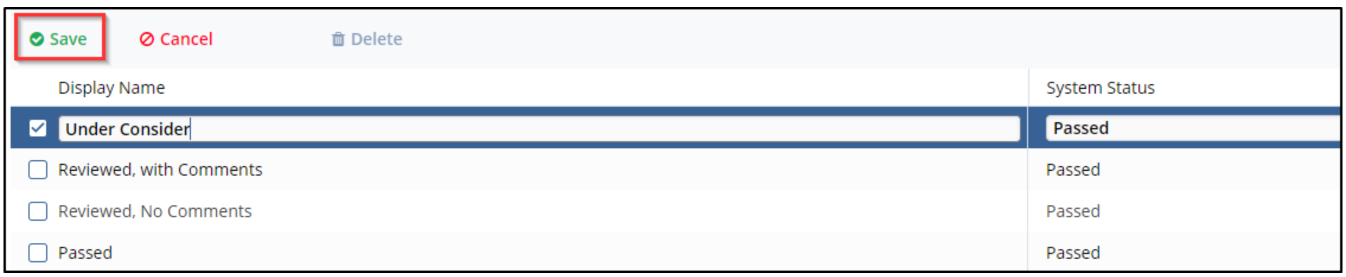


Figure 6: Quality Review Status-Edit

4. Make the required changes and click **Save**.

Deleting an Audit Status

Follow the steps below to delete an audit status:

1. Select the status from the list in the Quality Review Status window.
2. Either click ‘Delete’ from the top ribbon bar or click the trash can icon that appears on hovering the mouse over the status.

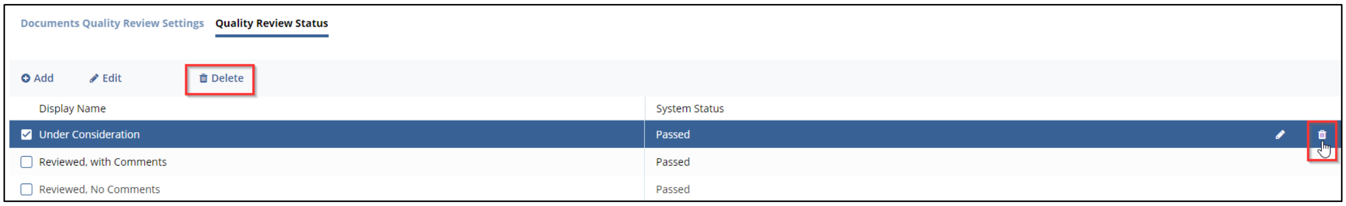


Figure 7: Quality Review Status-Delete

Duplicate an Existing Audit

Users of Trial Interactive often need to run the same quality review audit multiple times, changing a few details such as the participating auditors. You may also need to change the audit scope after an audit has started, but do not wish to impact the current audit.

There are now two options:

1. Duplicate an Existing Audit: Use this option when you wish to duplicate an existing audit, running the same scope again but with different users involved. You may update the scope in the new audit if you need, but once it is published, no further scope changes can be made.
    a. To duplicate an existing audit, select the audit from the list of existing audits and press the 'Duplicate' button in the menu bar above the list.

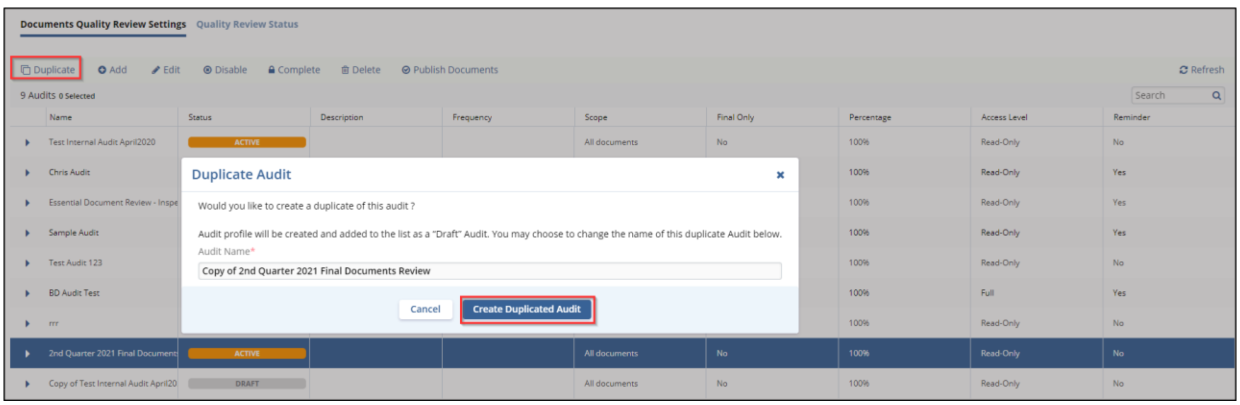


Figure 8: Quality Review Status-Duplicate

2. Documents from Selected Audits: Use this option when you want to create a new audit that contains the documents from prior audits. This allows you to choose from the existing users involved in those audits, and merge and include all the same sets of documents from those prior audits.

Additionally, this improvement:

- Simplifies the duplication of existing audits, providing an option to easily do this so that audits may be managed through a regular maintenance cycle.
- Corrects the audit scope for audits using the 'Do not include already audited documents' feature, limiting this scope to only Active and Completed audits, and ignoring Disabled audits.
- Adds ‘Disabled’ and ‘Completed’ statuses for audits, allowing an improved tracking of audit statuses.
- Restricts updates to the Audit Scope for existing active audits, requiring duplication of the current audit instead.
- Improves the descriptions and tooltips on the Audit Scope page.

Add a New Audit

In Trial Interactive, before creating an Audit Profile, it may be helpful to understand the various roles that are assigned to users as a part of creating the audit:

1. Auditor: Users assigned to this role are responsible for reviewing documents and assigning them a status of passed or failed. Any level of user can be assigned to this role.
2. Audit Manager: Users assigned to this role can see audit results, create an audit export, reassign documents to other auditors, release audit findings from review, and make changes to the audit profile. Only editors and higher-level users may be assigned to this role.
3. Audit Responder: Users assigned to this role are responsible for taking action to rectify audit findings generated by the auditors during their review of the documents. Only editors and higher-level users can be assigned to this role.

The process for creating a new audit profile is discussed below:

Note: Prior to beginning this process, it is crucial that you ensure that all applicable Quality Review Statuses should have already been created.

1. Navigate to the Quality Review Settings area of the Quality Review module.
2. Click the ‘**Add**’ button displayed in the top menu bar above the grid.
   a. This will open the Create Audit Profile window.

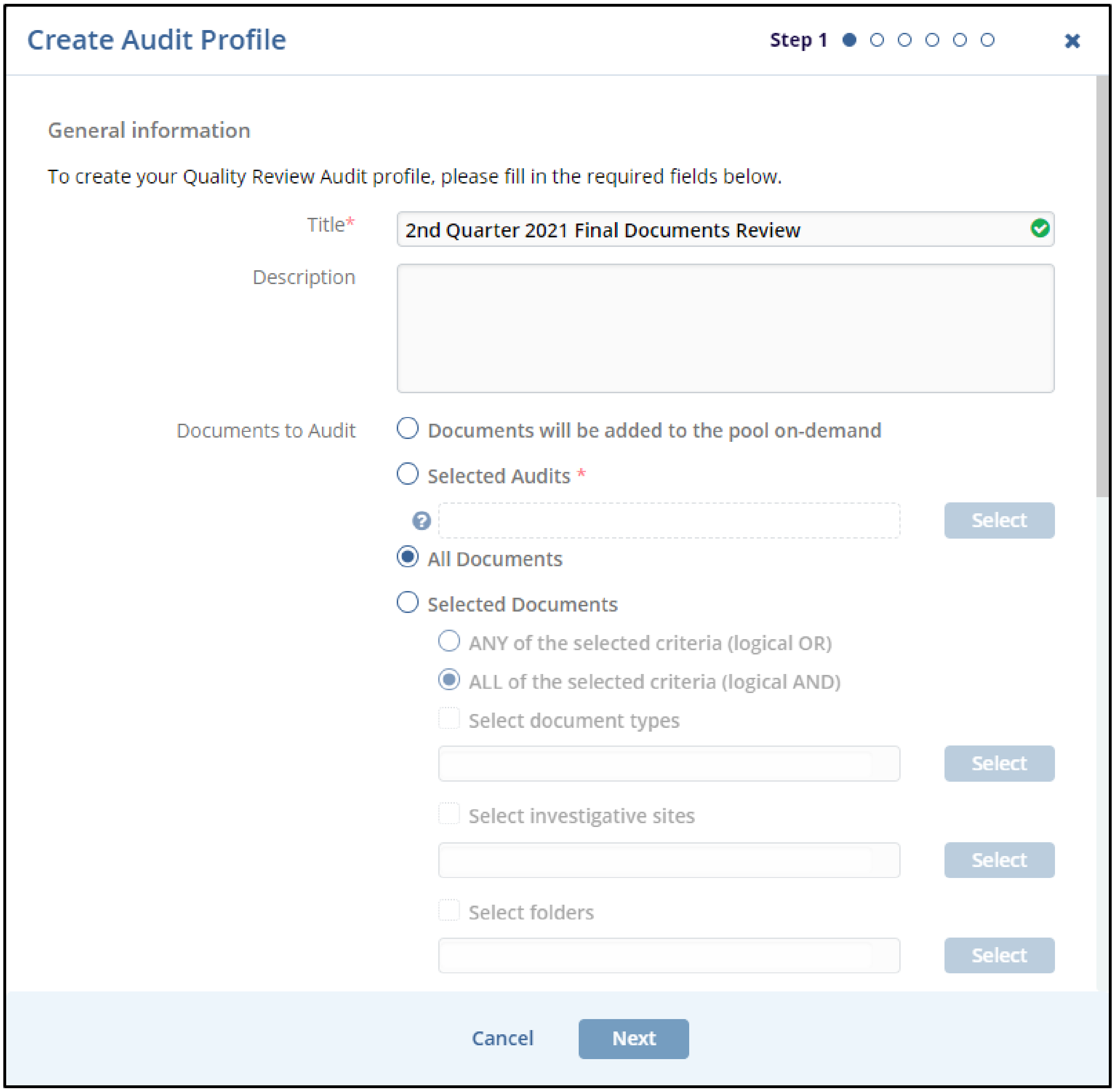
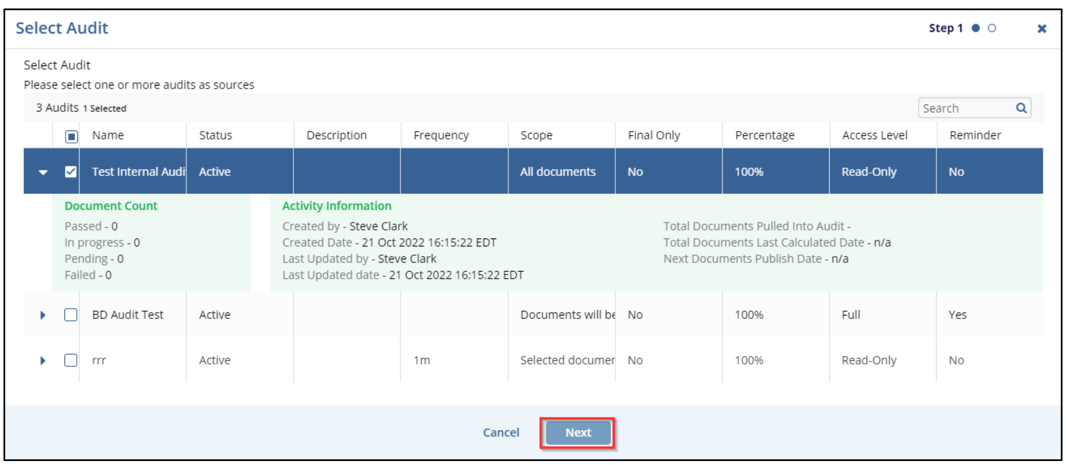
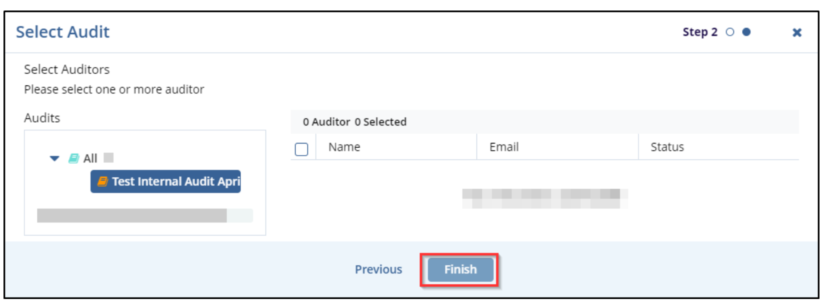


Figure 9: Create Audit Profile

3. Enter a **Title** for the audit profile.
    a. It is generally best to be as specific as possible here. For example: 2nd Quarter 2021 Final Documents Review.
4. The **Description** field is not required but it is highly recommended as it serves as a mission statement of sorts for the audit and will assist in choosing the correct audit settings in the remainder of the fields.
    a. For example: "This audit will review a random 20% of all documents that were published to the eTMF during the 2nd quarter of 2021."
5. The '**Documents to Audit**' area has several options to choose from:
    a. Documents will be added to the pool on-demand: This option will create a blank audit with no documents in it. Editor, manager, and administrator users can then add documents to the audit manually via the Documents Cart.
    b. Selected Audits: This option indicates that the audit will be reviewing the work done in a prior audit or set of audits. If you select this option, you will be asked to specify which audit and which auditor(s) you wish to review.
    c. Click the **Select** button to open the 'Select Audit' popup window.



    d. Click the **Next** button to select the auditors in the next step.



e. <u>All Documents:</u> This option will cause the system to gather all documents which meet the criteria chosen below.

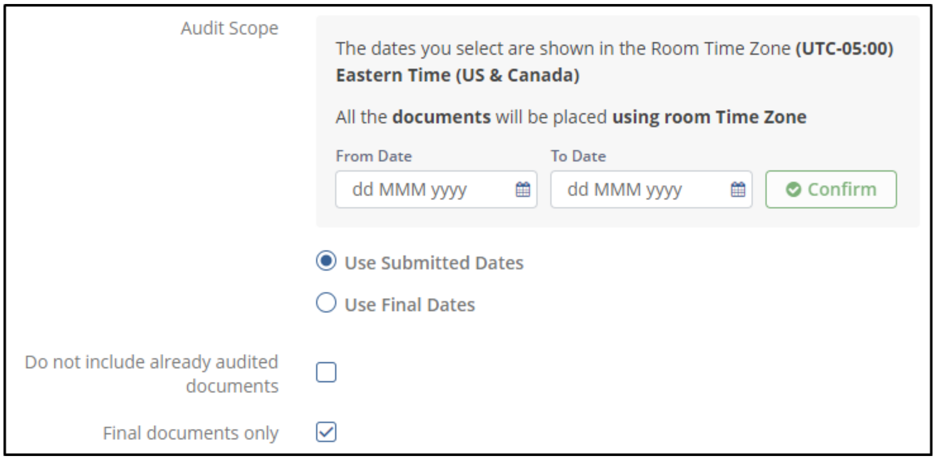
f. <u>Selected Documents:</u> This option allows the user to specify the criteria which the room will use in gathering documents for review.

i. The user will first need to specify whether the room should take in to account ANY or ALL of the criteria specified.

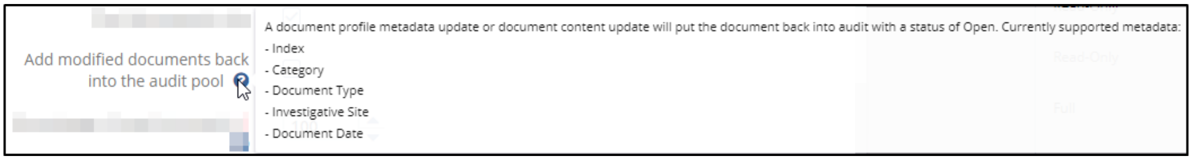
ii. Select any one OR all the checkboxes for – Select Document Types, Investigative Sites, or Folders.

iii. Click the '**Select**' button to choose the appropriate and required document type, investigative site and folder.

6. The **Audit Scope** is only applicable to audits which are reviewing documents from a specific timeframe.
   a. In the example from above (2nd Quarter 2021 Final Documents Review), the user would specify the beginning and end dates for the 2nd Quarter of 2021.
7. The '**Use Submitted Dates**' and '**Final**' radio buttons are asking the user to specify which date should be used when determining whether or not the document falls into the Audit Scope designated in step 6.
   a. **Use Submitted Dates:** The date that the document was submitted to the room.
   b. **Final:** The date that the document was made 'Final' and published to the index.
8. Indicate whether or not the system should include documents which were already included as a part of another audit.
9. Indicate whether the system should include only documents which are in a 'Final' status.
   a. If this option is not checked, it is possible that a document may go through the QC Workflow and the Quality Review Audit at the same time. This may cause some confusion and is not recommended.



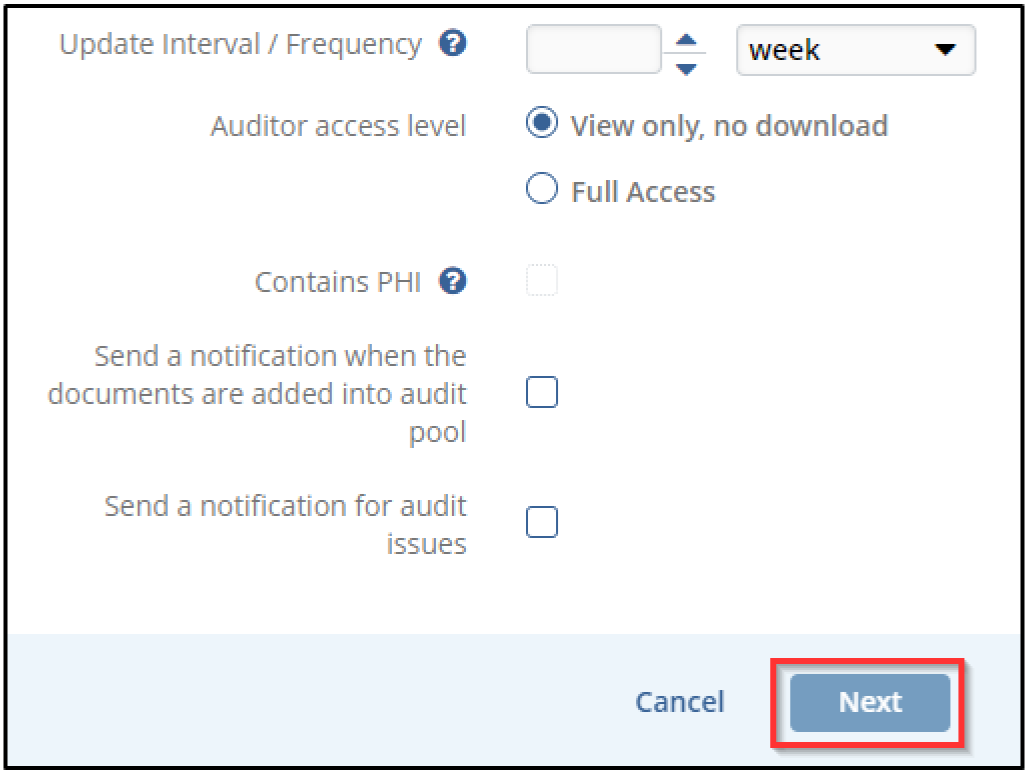
10. Sometimes, when the Audit Responder is addressing an Audit Finding, a document's metadata may be updated. The 'Add modified documents back into the audit pool' option tells the system that, if any of the following metadata fields were updated as a part of the correction, the document should be re-added to the audit for another review.
    a. Index
    b. Category
    c. Document Type
    d. Investigative Site
    e. Document Date



11. The 'Percentage of new documents' tells the system that, whenever it gathers documents matching the criteria above, it needs to take a random sampling matching the designated percentage.

12. The 'Update Interval/Frequency' field is for use in ongoing audits which will need to be updated at regular intervals. The system will go out and gather new documents matching the specified criteria at the indicated interval.
13. Indicate the auditor access level.
    a. **View Only, no download:** This restricts the auditor to viewing documents.
    b. **Full Access:** This allows the auditor to download or modify documents based on their user access level rights. This is most commonly applied to internal audits.
14. Indicate whether the auditors should have access to the 'Contains PHI' function.
    a. This function allows an auditor who discovers PHI in the room to immediately delete the attached file. This will move the file record (metadata only) to the Audit Responder so that they can upload a redacted version of the document.
15. There are two types of audit notification that can be sent. Indicate whether or not the room should send audit notifications.

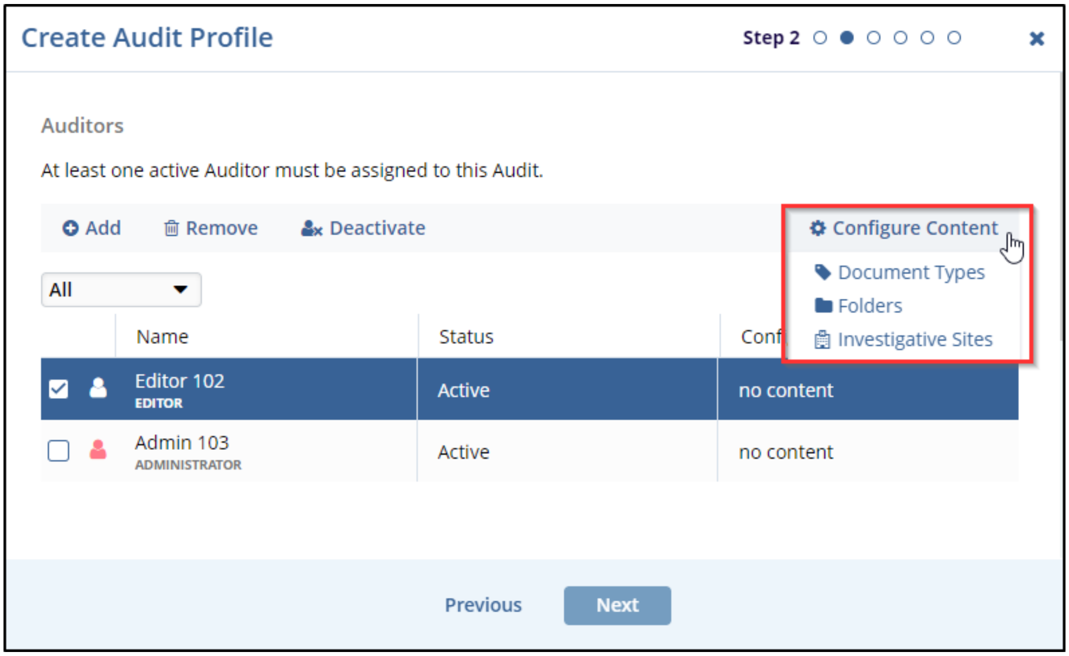
16. Click the ‘Next’ button displayed at the bottom of the popup window.



17. The next step is to assign the users who will be Auditors in the audit.
18. Click the ‘**Add**’ button.
    a. This opens the ‘Add Users and Groups’ window.
19. Move any applicable users and/or groups to the right panel by clicking and dragging, double clicking, or by pressing the **+** sign that appears at the right side of the user’s line.
20. Click the **Add** button displayed at the bottom of the popup window.
21. If multiple auditors have been added, the ‘Configure Content’ option may be used. It is optional.
    a. This option is most useful when you have chosen specific criteria such as document types or investigative sites and you would like a specific auditor to review a specific document type or all documents associated with a specific site.
    b. Select the auditor and click the ‘Configure Content’ button displayed in the top right corner.

    c. Choose which criteria will be used in assigning documents to this auditor:
        i. Document Types
        ii. Investigative Sites

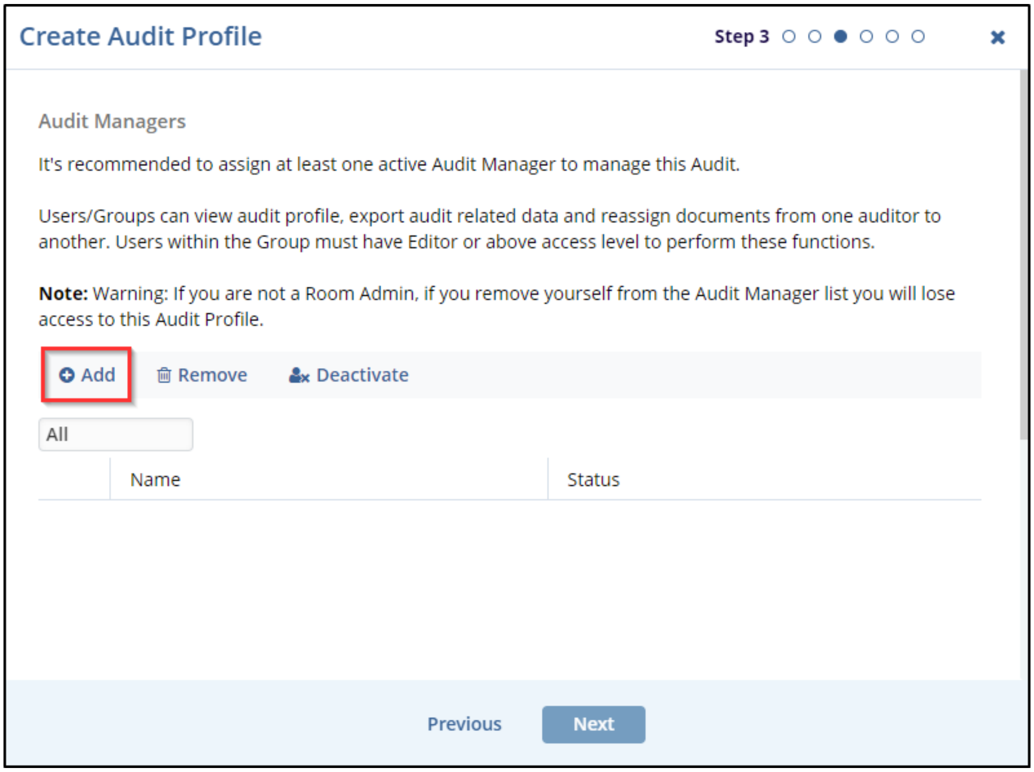
iii. Folders



d. Once selected, another window will open in which you will be able to specify which document types, sites, or folders apply to the specified user.

22. When you are done adding auditors and, if necessary, configuring content, click the '**Next**' button.
23. The next step is to assign the users who will be Audit Managers in the audit.

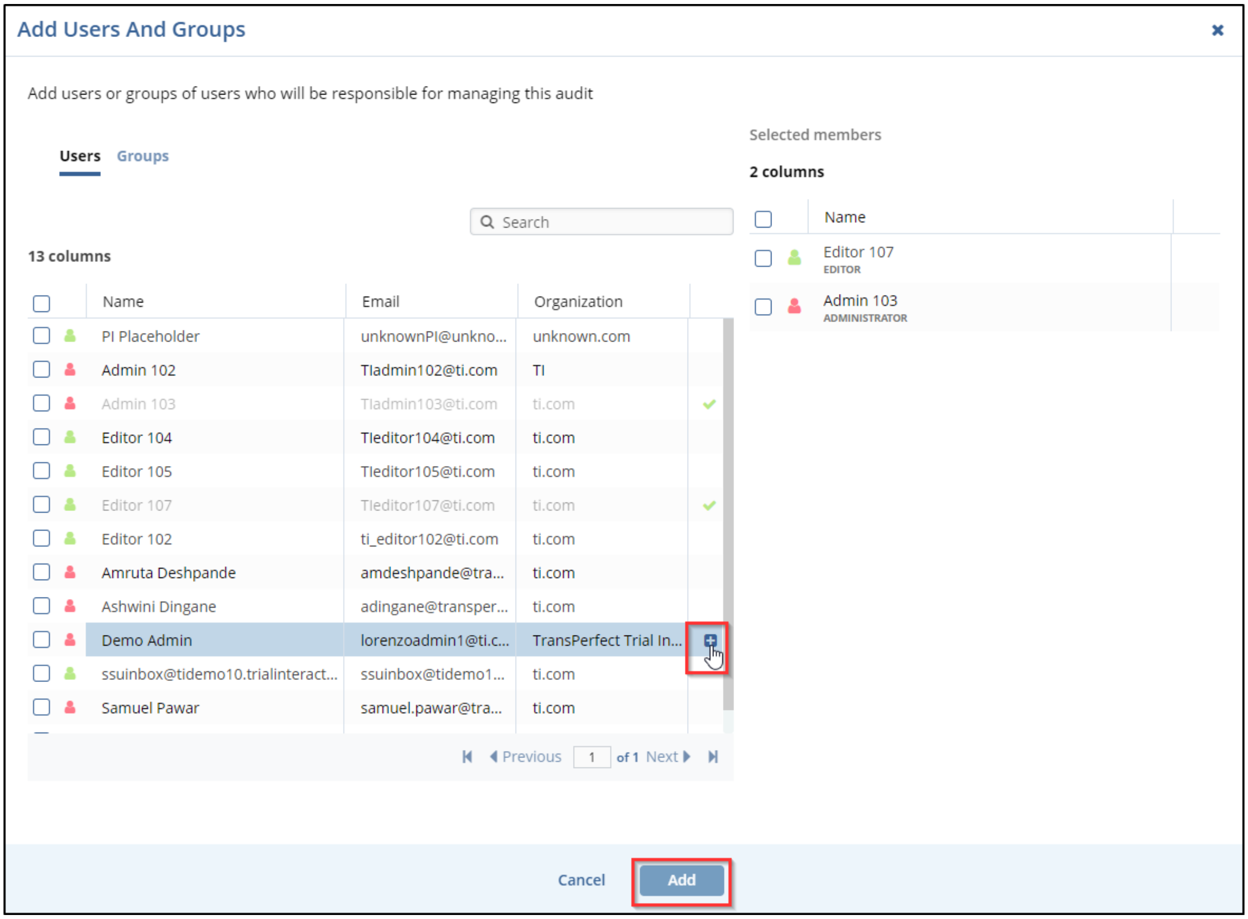
24. Click the '**Add**' button displayed at the top left corner of the popup window.



   a. This will open the 'Add Users and Groups' window.

25. Move any applicable users and/or groups to the right panel by clicking and dragging, double clicking, or by pressing the + sign that appears at the right side of the user's line.

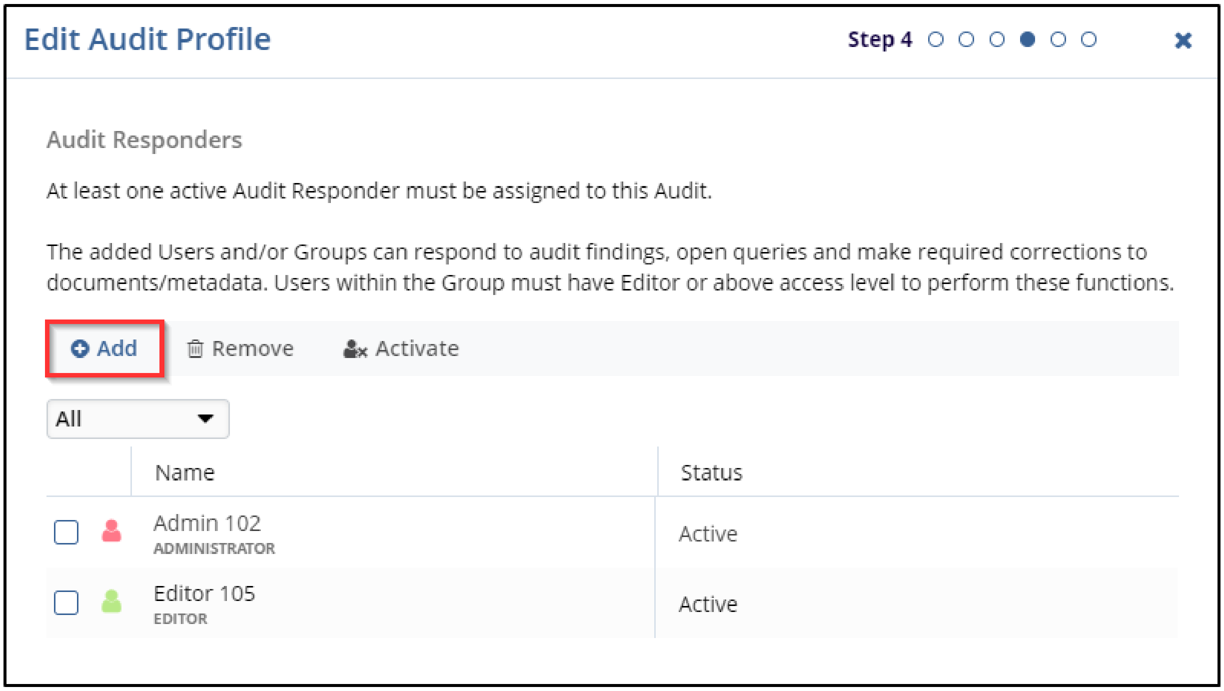
26. Click the '**Next**' button when done.



27. The selected Audit Managers are reflected in the grid.
28. The next step is to assign the users who will be **Audit Responders** in the audit.

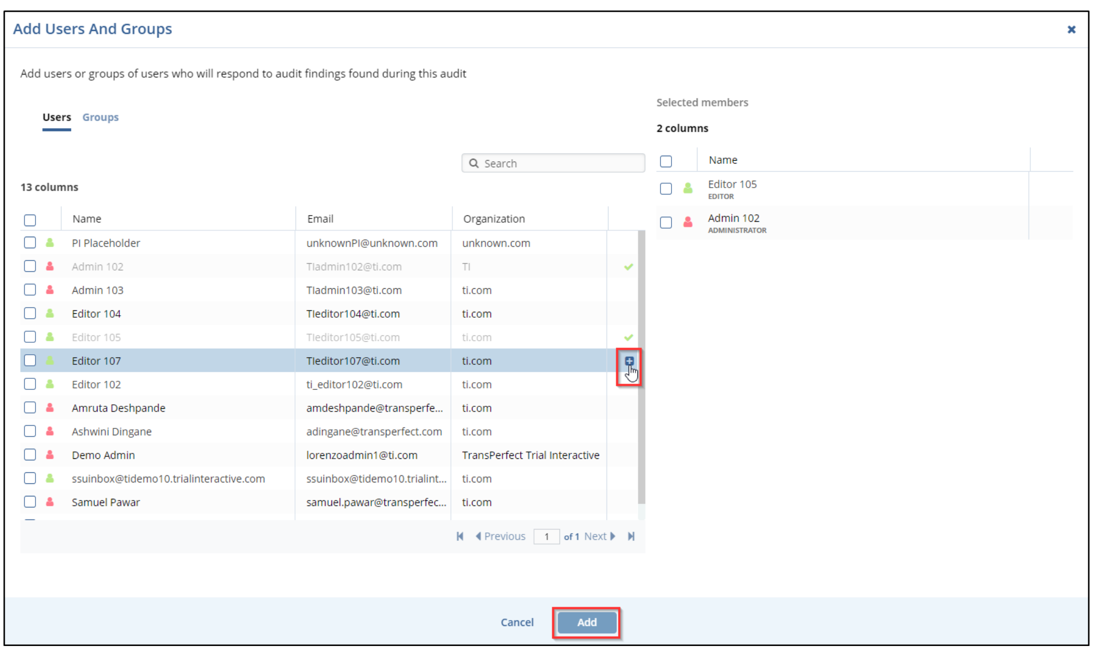
Note: The users cannot be the same for Audit Responders as those who are added as Auditor Managers.

29. Click the '**Add**' button.



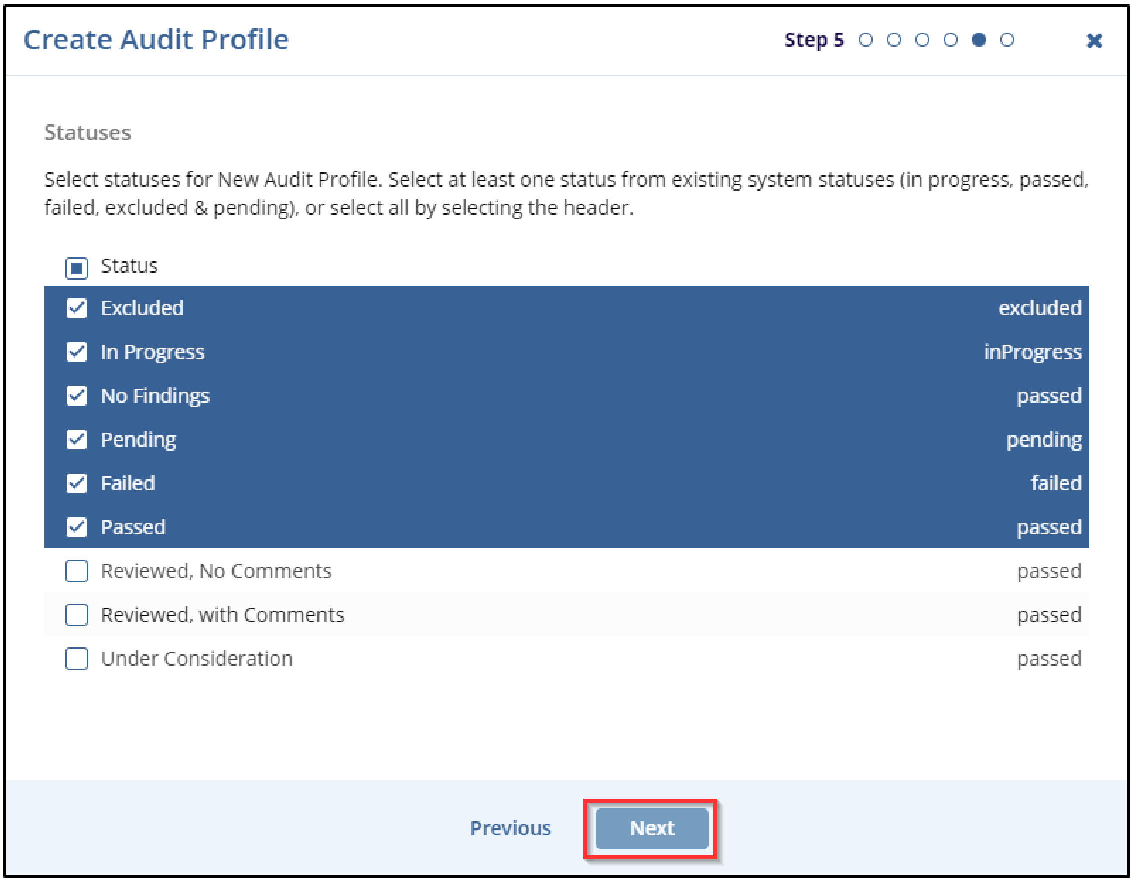
a. This will open the 'Add Users and Groups' window.

30. Move any applicable users and/or groups to the right panel by clicking and dragging, double clicking, or by pressing the **+** sign that appears at the right side of the user's line.



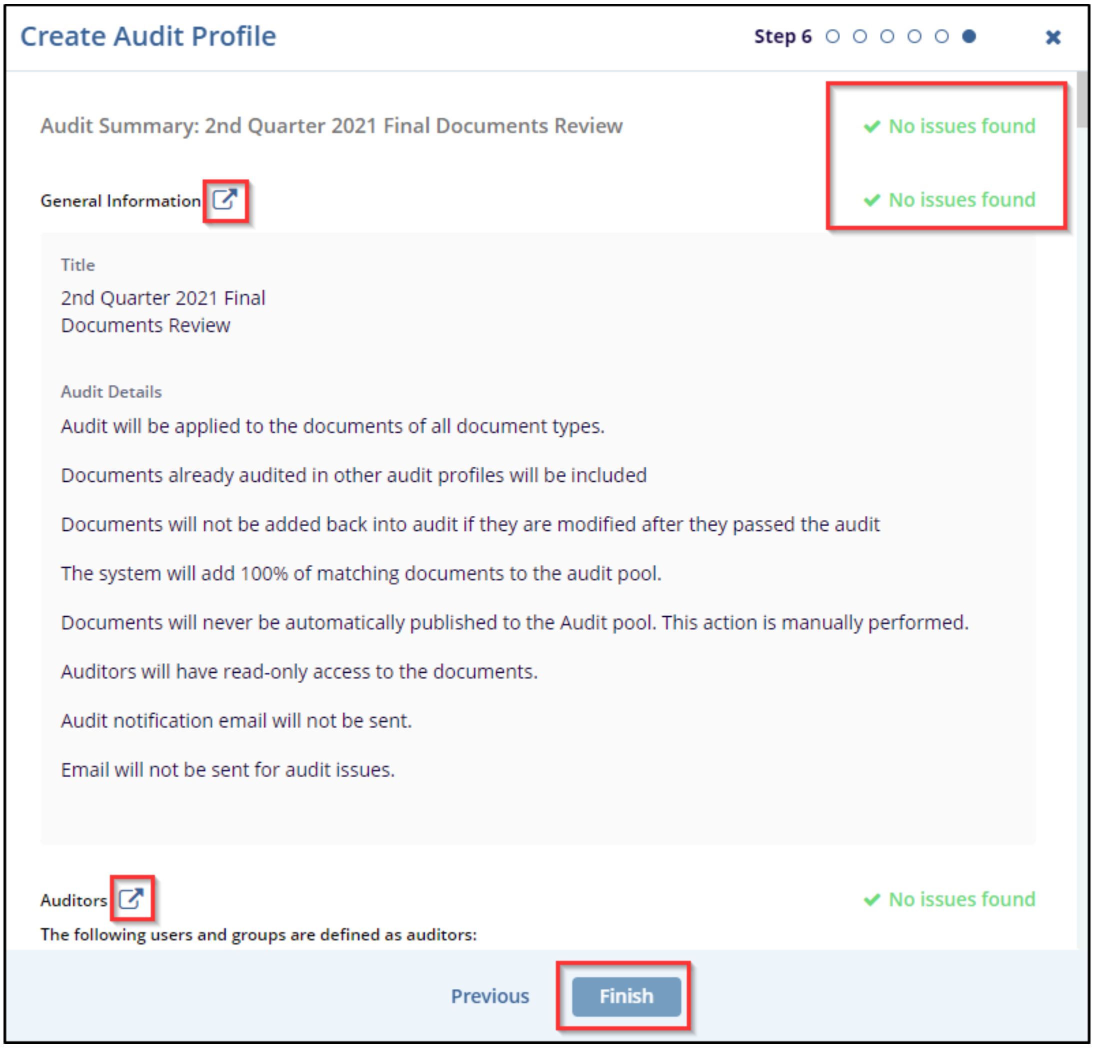
31. Click the '**Next**' button when done.

32. In the next window, you will be required to choose the document statuses for use in the audit.
    a. These must have been created prior to beginning the audit.
    b. You will be required to include at least one status for each of the basic 5 system statuses:
        i. Passed
        ii. Failed
        iii. Pending
        iv. In Progress
        v. Excluded

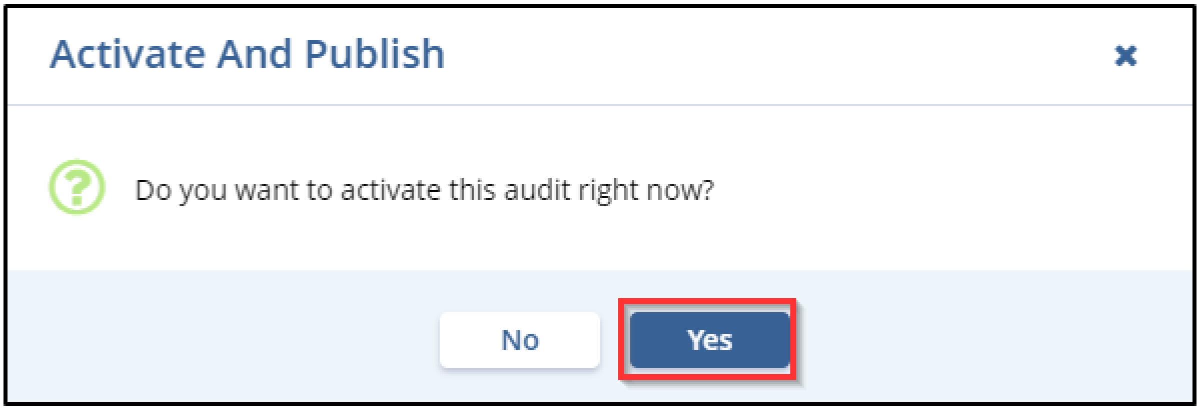


33. Click the '**Next**' button when done.

34. The final screen indicates if there are any errors detected.
    a. The most common of these would be if you had a user added as both an Audit Manager and an Audit Responder.
35. If there are any errors, use the section link to go back and correct the error.



36. When you are done, click the ‘**Finish**’ button.
37. A window will open asking you if you want to activate the audit.
    a. If you press ‘No’ the window will close and the audit will be added to the list in an ‘Inactive’ status.
    b. If you press ‘Yes’ the window will close and the audit will be added to the list in an ‘Active’ status.



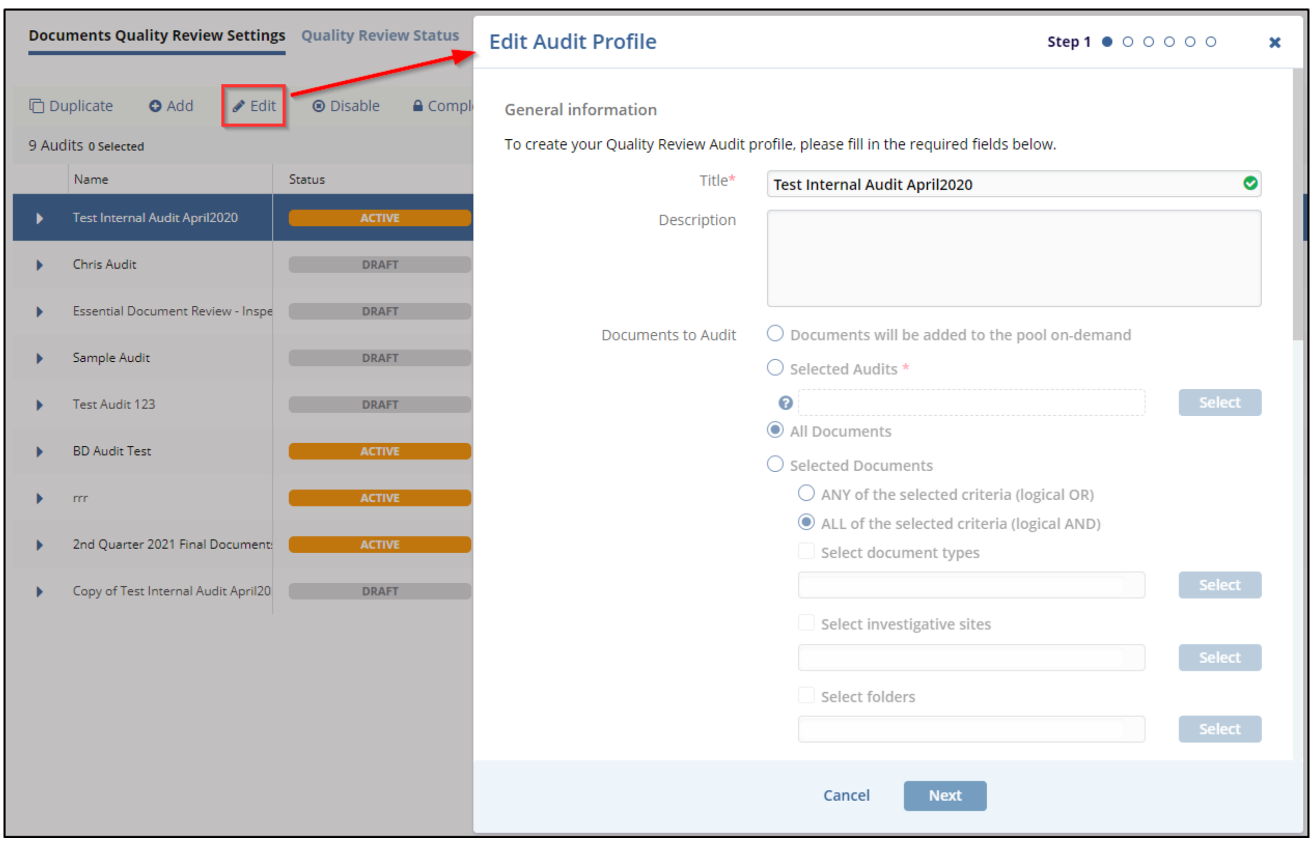
    c. The Document Quality Review Settings displays the newly added audit profile in the grid.

Edit an Audit

Existing audits can be edited by any room administrator or any user who is indicated as one of the Audit Managers for the audit in question. For example, an Editor or Manager level user who is designated as an Audit Manager for one of several quality review audits in the room will be able to navigate to the Quality Review Settings menu. The difference between their view and the Administrator view will be that the Administrator will see all audits whereas the Editor or Manager user will only see the audit in which they are indicated as the Audit Manager.

Follow the steps below to edit an existing audit:

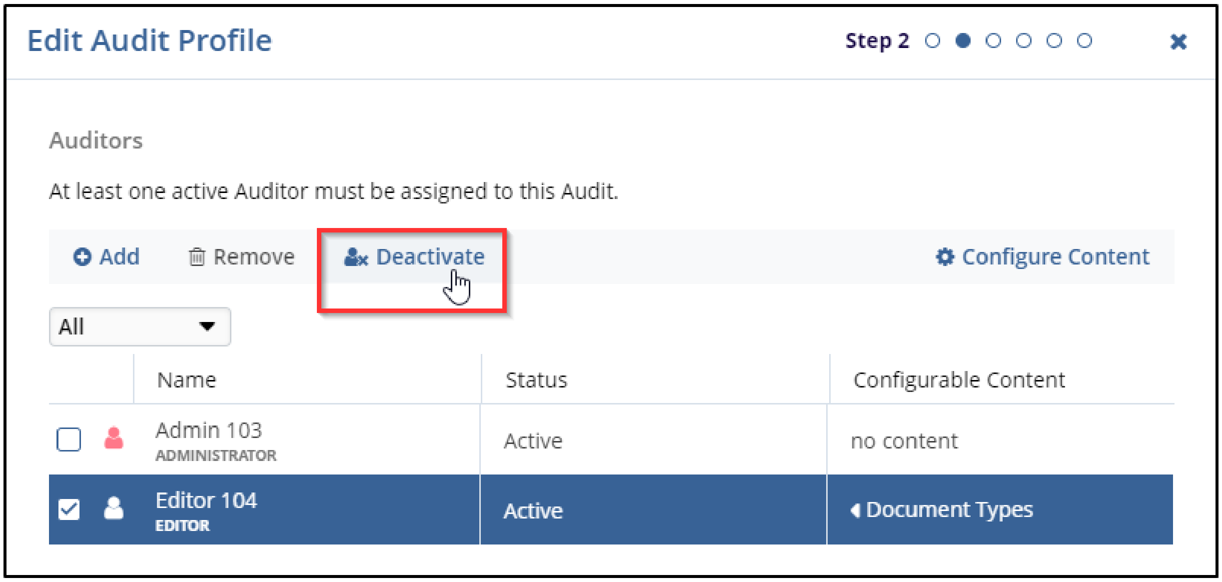
1. Select the audit from the list.
2. Click the **Edit** button from the top menu bar.
3. The Edit Audit Profile window opens.
4. Follow on to the steps and make any required changes to the audit profile.



Deactivating an Auditor

While you are editing an audit, you will have the option to remove an auditor from the audit. In order to do that, please follow the steps below:

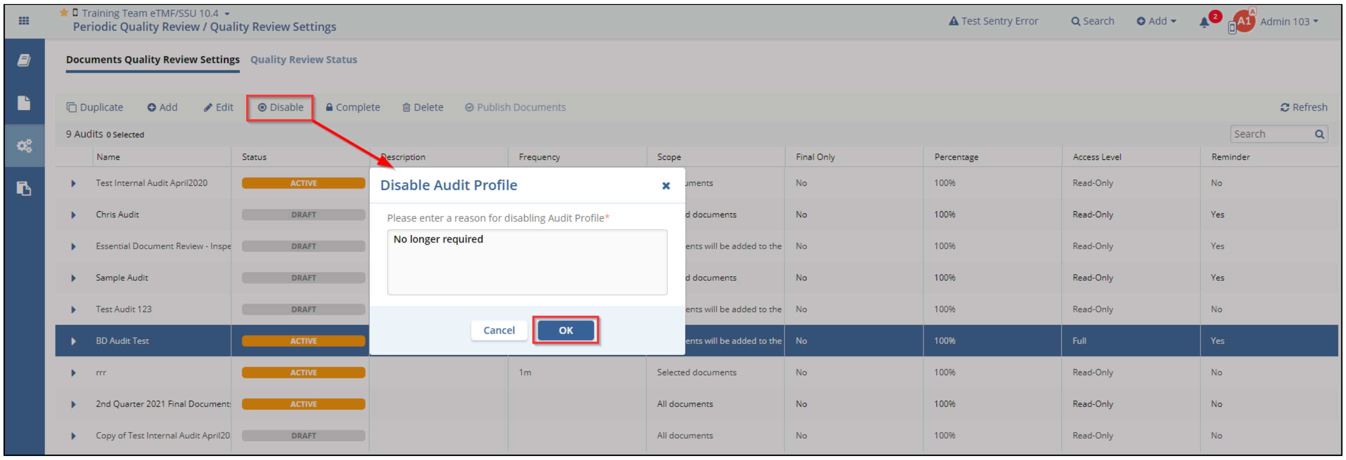
1. Open the audit profile for editing and to the auditors page.
2. Select the auditor who needs to be removed from the audit.
3. Click the ‘**Deactivate**’ button.



   a. This will open the ‘Documents Reassignments’ window.
4. Choose what to do with the user’s remaining documents.
   a. Leaving the ‘Automatically reassign all documents randomly between existing auditors’ box checked will do just that. The auditor’s remaining documents will be reassigned randomly.
   b. If the box is unchecked, you will be able to choose an auditor to reassign the documents to. Move the selected recipient from the left side of the window to the right side.
5. Press ‘Add’
6. Proceed through the remainder of the Edit Audit wizard and press ‘Finish’ to save your changes.

Disable an Audit

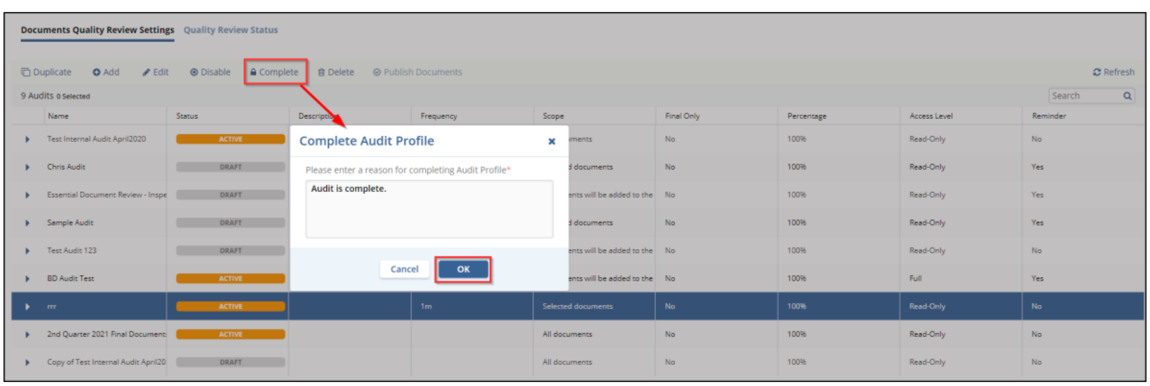
Disabling an audit can be done by the user when the audit is not required. Click the **Disable** button displayed in the top menu bar. Enter a reason in the popup window displayed and click **OK**.



Complete an Audit

The audit is complete only when the Status column displays an 'Active' status for an specific audit.

1. Select the checkbox of an audit that displays 'Complete' status.
2. Click the **Complete** button displayed in the top menu bar.
3. Enter a reason in the popup window (mandatory).
4. Click the **OK** button displayed at the bottom of the popup window.

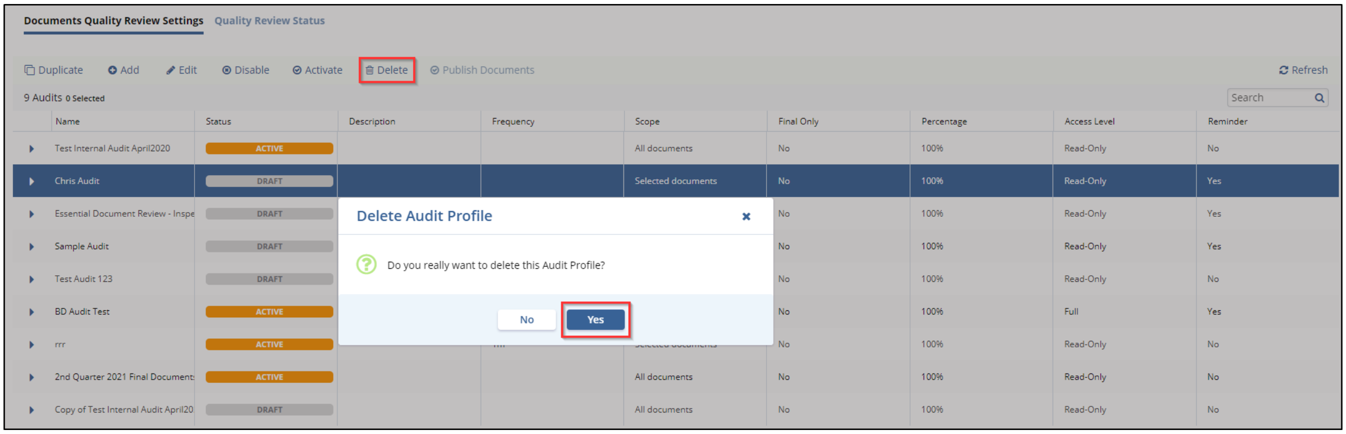


Note: Selecting an audit to complete that has a 'Draft' status, the top menu bar does not display the 'Complete' button.

Delete an Audit

Deleting an audit can only be done until a document has been reviewed. Once a document has been reviewed as a part of the audit, the audit can only be stopped.

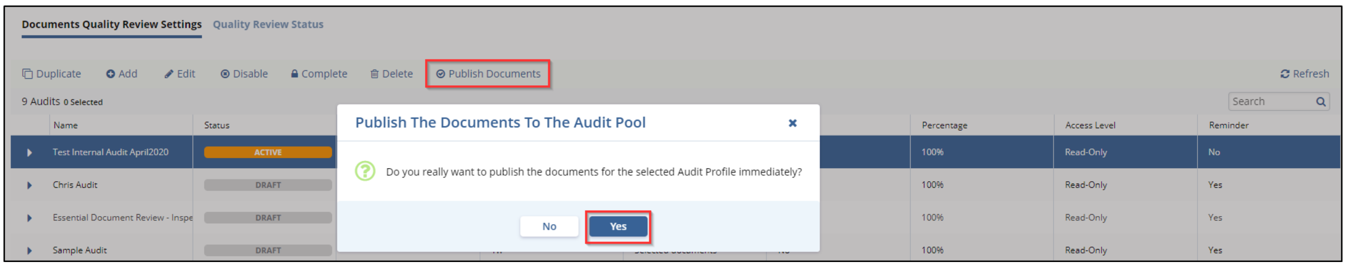
1. Select the audit.
2. Click the '**Delete**' button at the top of the grid.
3. The audit will be removed from the list.



Publishing Documents to an Audit

Sometimes, users will keep an audit profile in a study room which needs to be deactivated and reactivated. If an audit is reactivated and new documents need to be added to the audit you can select the audit and then press the ‘Publish Documents’ button.

Note: Only those audit documents can be published that display an ‘Active’ status.

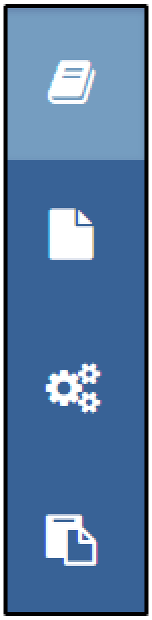


Performing Audit Functions

If you are assigned as an Auditor or Audit Manager in your trial room, the Quality Review module is available to you in the Navigation Grid at the top-left of the screen.

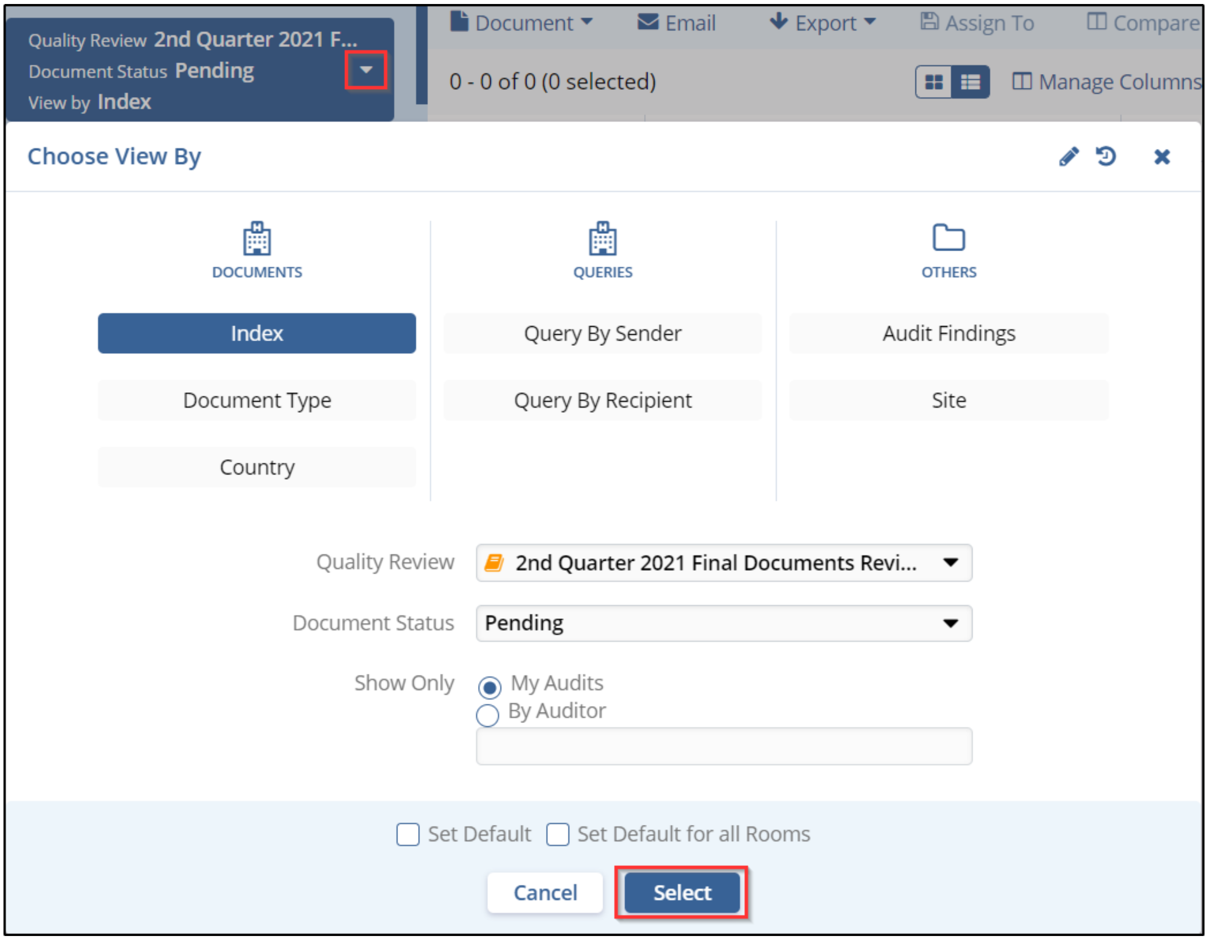
The Quality Review module has the following views available in the vertical menu at the left side of the screen:

1. Quality Review: This view allows you to select an audit and perform audit-related functions.
2. Documents: This is the standard Documents module and allows the user access to search for documents within the index.
3. Settings: This allows you to configure settings for Quality Review.
4. Audit Trail: This displays the data of the actions performed on a document.



Selecting An Audit

Much like the Documents module, the Quality Review module has a view selection dropdown menu at the top of the index pane. Use this menu to select your preferred view of the documents in the audit. See the screenshot below:



The Quality Review dropdown menu allows Reader, Editor, and Manager level users to see the audits that they are currently a part of in either the Auditor or Audit Manager role. Administrators can see all audits here.

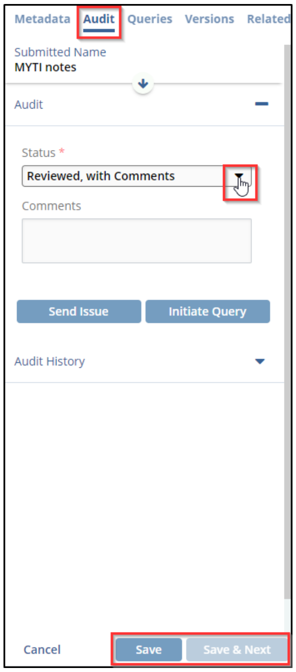
Audit Managers will also have an option to view either their own audits (if they are also acting as an auditor for the audit) or they can check up on the progress of other auditors in the selected audit.

When you have made your choice, press 'Select' to be taken to the audit.

Reviewing a Document

Follow these steps to review a document in an ongoing audit:

1. Select an audit in which to work.
2. Drill down in the index to locate a document in need of review.
3. Select the document from the grid.
4. Open and review the document per internal standards.
5. In the metadata panel, choose the Audit tab.
6. Assign a status to the document.
    a. The available statuses may vary from audit to audit.
    b. If you have assigned the document a status indicating that the document failed, it is highly recommended that you add comments in the box below in order to explain to the Audit responder why the document failed the audit.
7. The audit fields are customizable. Fill in values for any other required fields. See the screenshot below:



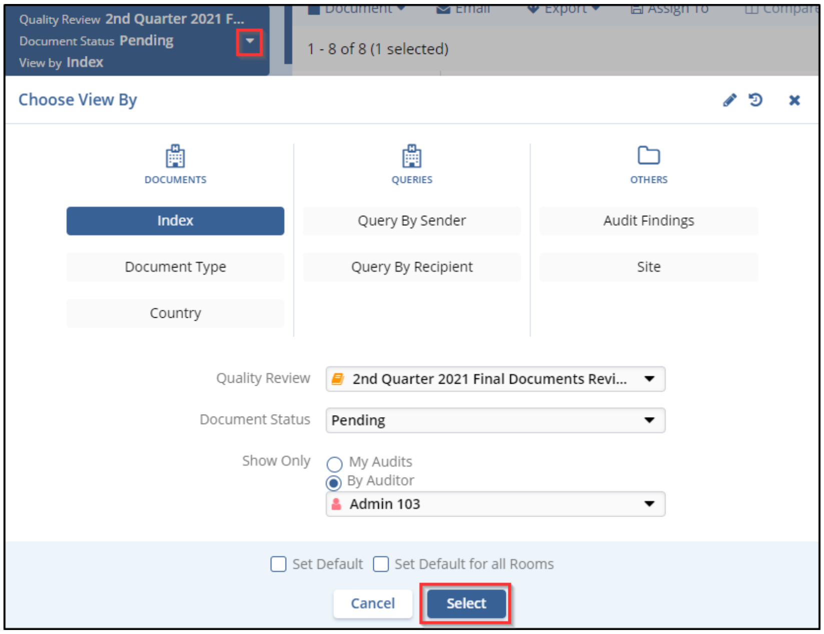
8. Press 'Save' or 'Save & Next'

Note: Auditors can also send audit queries. For more information on this, please see the chapter on Queries.

Reassigning a Document to Another Auditor

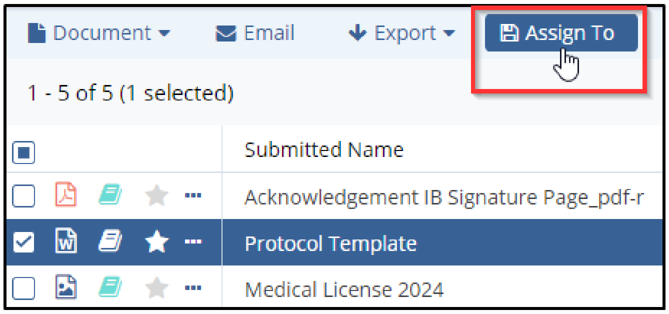
Sometimes an Audit Manager need to reassign a document to another auditor. Follow the steps below to perform this action.

1. Select the audit and choose to view Pending documents for the currently assigned auditor. See the screenshot below:



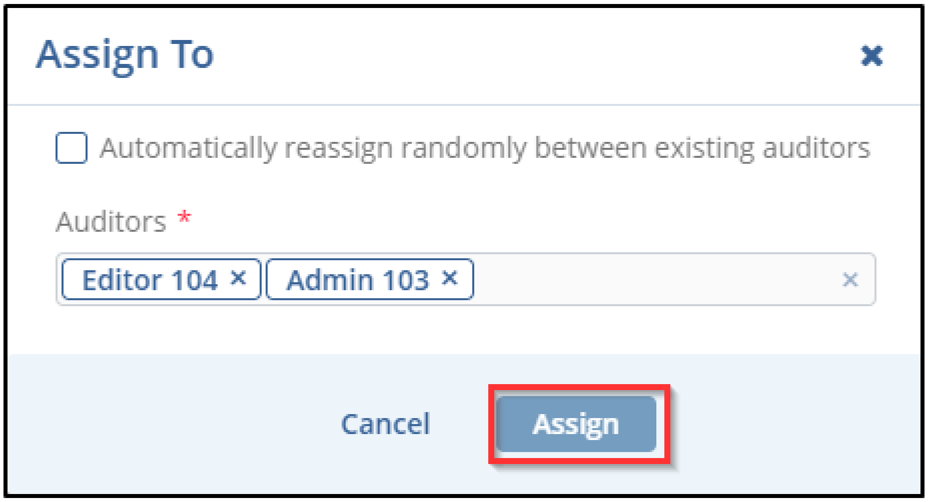
2. Click the **Select** button displayed below in the window.
3. Locate the document to be reassigned and check the box for the document on the Grid.

4. Press the ‘Assign To’ button above the Grid.



a. The ‘Assign To’ window will open.

5. You may leave the box checked to allow the system to randomly reassign the reviewer or you may uncheck the box and manually pick a new reviewer.

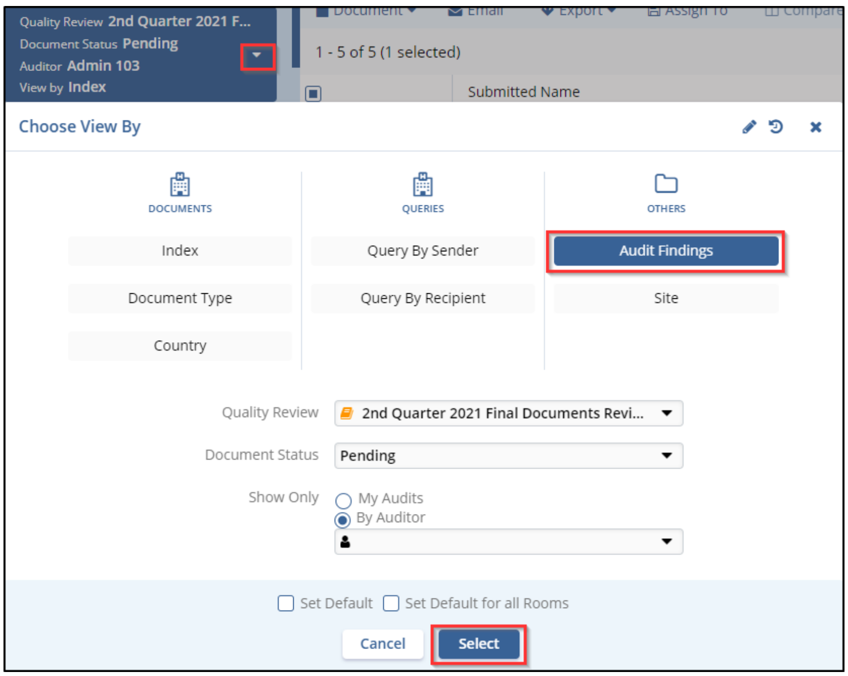


6. When you have chosen, press the ‘Assign’ button.

Releasing an Audit Finding from an Audit Responder

An Audit Manager can release a document currently claimed for correction by an Audit Responder. To do so, follow the steps below.

1. Navigate to the Quality Review module and use the dropdown menu above the index to select the correct audit and the 'Audit Findings' view. See the screenshot below:



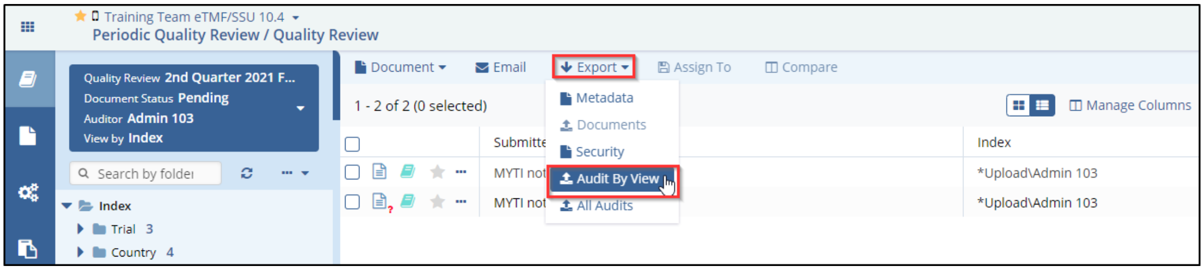
2. Click the '**Select**' button.
3. The audit findings will display in the index panel organized by who currently has them claimed.
4. Select the correct finding on the Grid.
   a. The metadata panel will populate.
5. Click the '**Release**' button at the top of the metadata panel.

Exporting Audit Data

An Audit Manager can export a report related to the documents assigned to any particular audit.

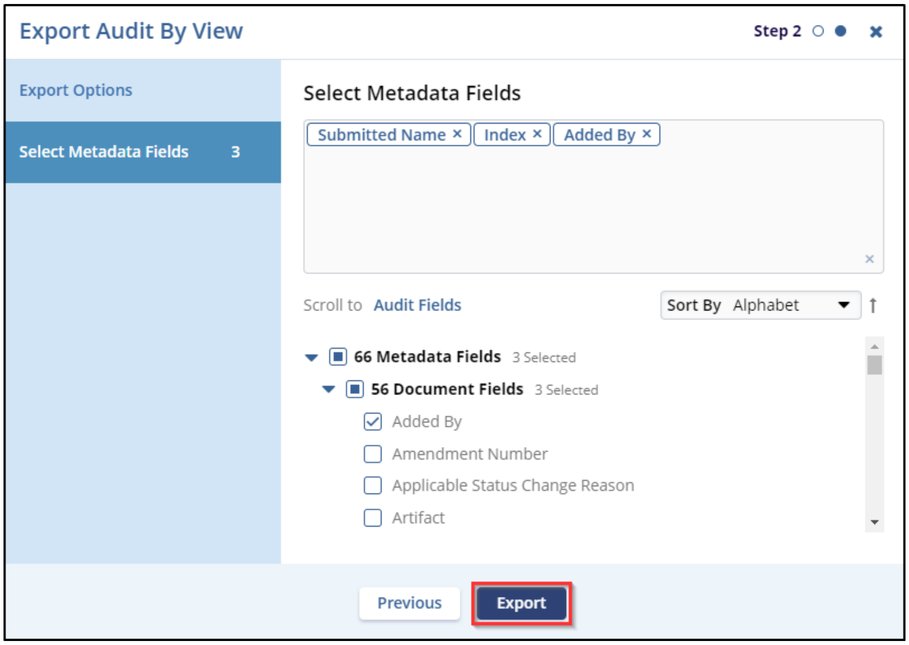
To Export Data - Audit By View:

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 the dropdown menu of **Export** button on the top menu bar.
4. Click the **Audit By View** option.



5. This opens the Export Audit By View popup window.
6. Select the required radio button from the Export Options Step-1. Click the **Next** button.

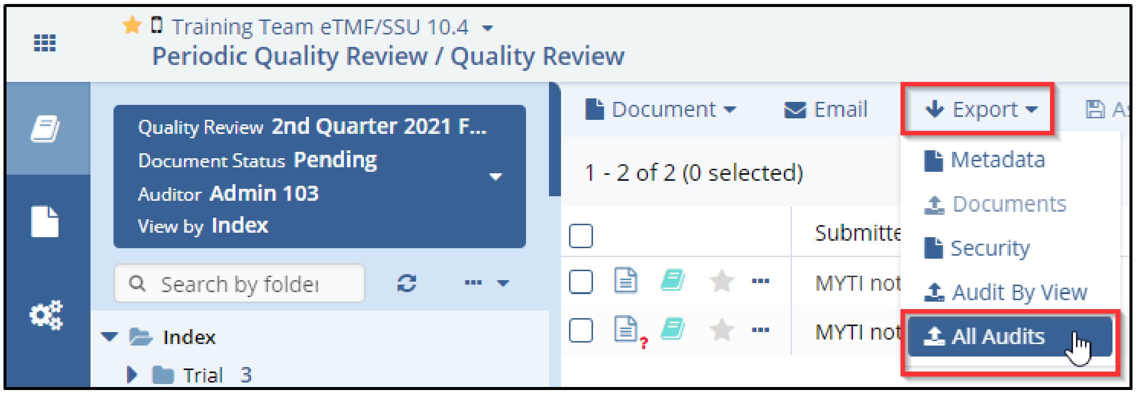
7. Select the required checkbox(s) for the metadata fields to be displayed in the 'Select Metadata Fields' box.
8. Click the **Export** button displayed at the bottom of the popup window.



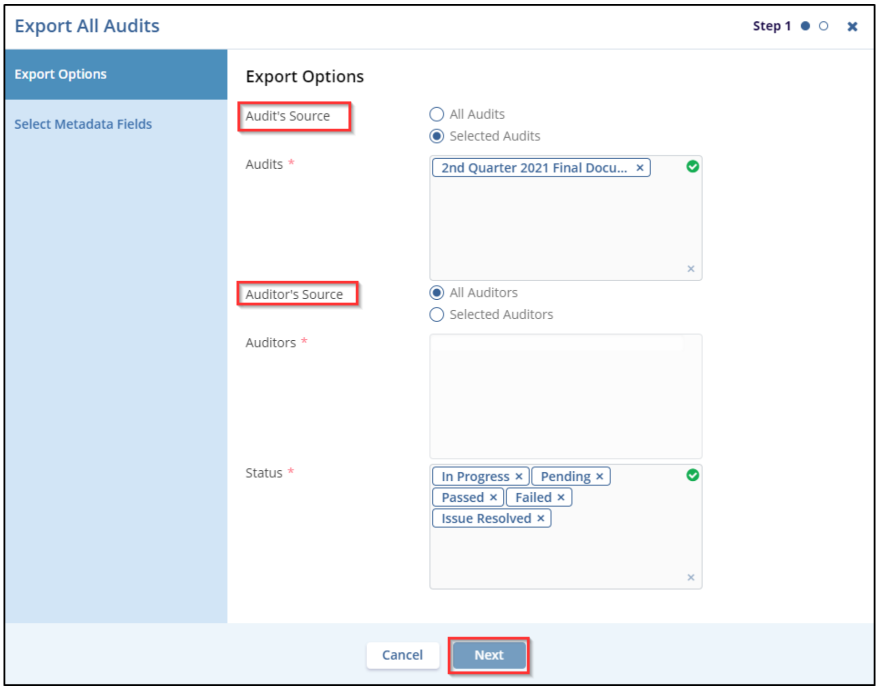
9. A notification is displayed on the top right corner of the screen. Click the **Get Job Result** button.
10. The file is downloaded in your system's 'Downloads' folder.

To Export Data – All Audits:

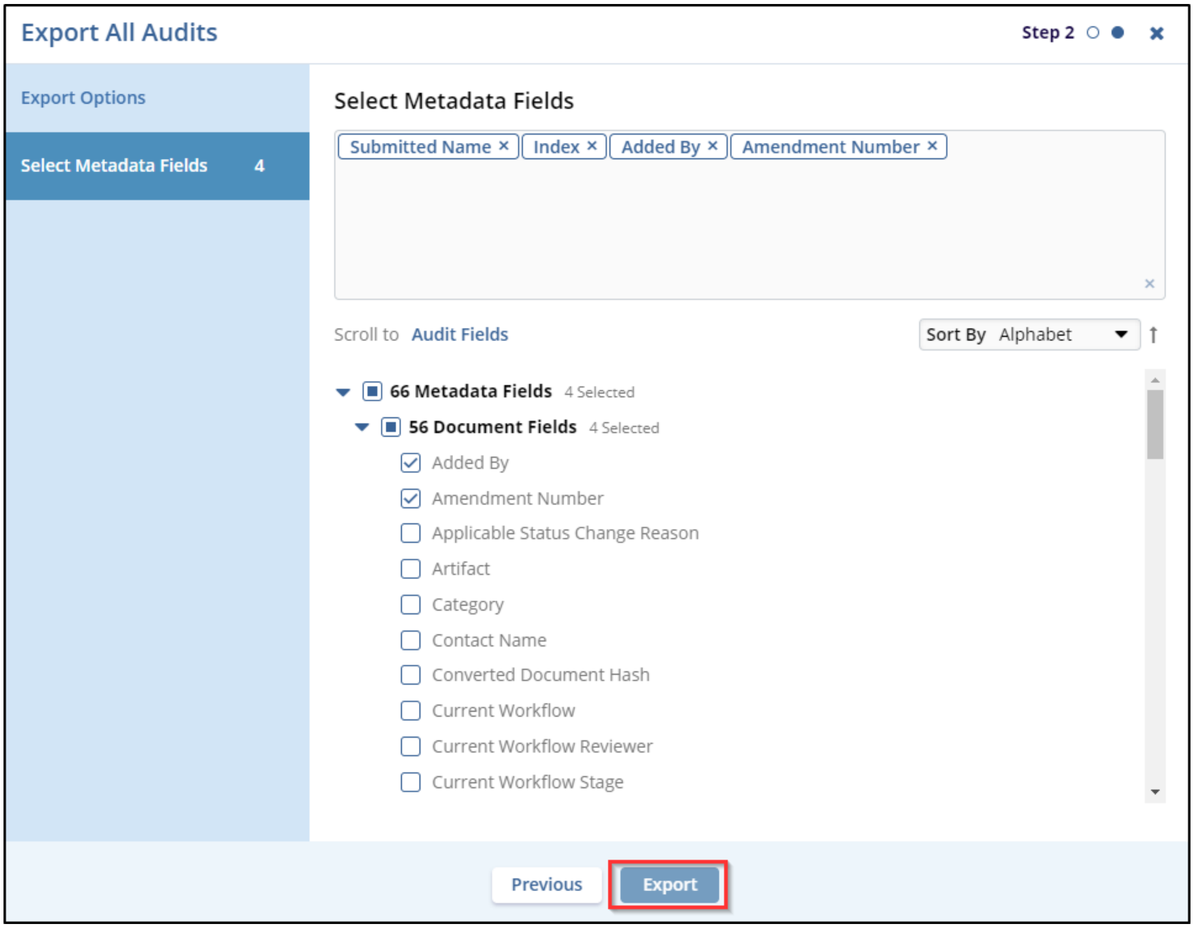
1. From the Quality Review module, click **Audit** from the left menu bar.
2. Select the audit on which you would like to run the audit report from the list of active audits.
3. Select the documents from the list and click the dropdown menu of **Export** button on the top menu bar.
4. Click the **All Audits** option. This opens the Export All Audits popup window.



5. Select the required radio buttons for – Audit's Source, and Auditor's Source in Step-1.
6. Click the **Next** button.



7. Select the required checkbox(s) for the metadata fields to be displayed in the ‘Select Metadata Fields’ box.
8. Click the **Export** button displayed at the bottom of the popup window.

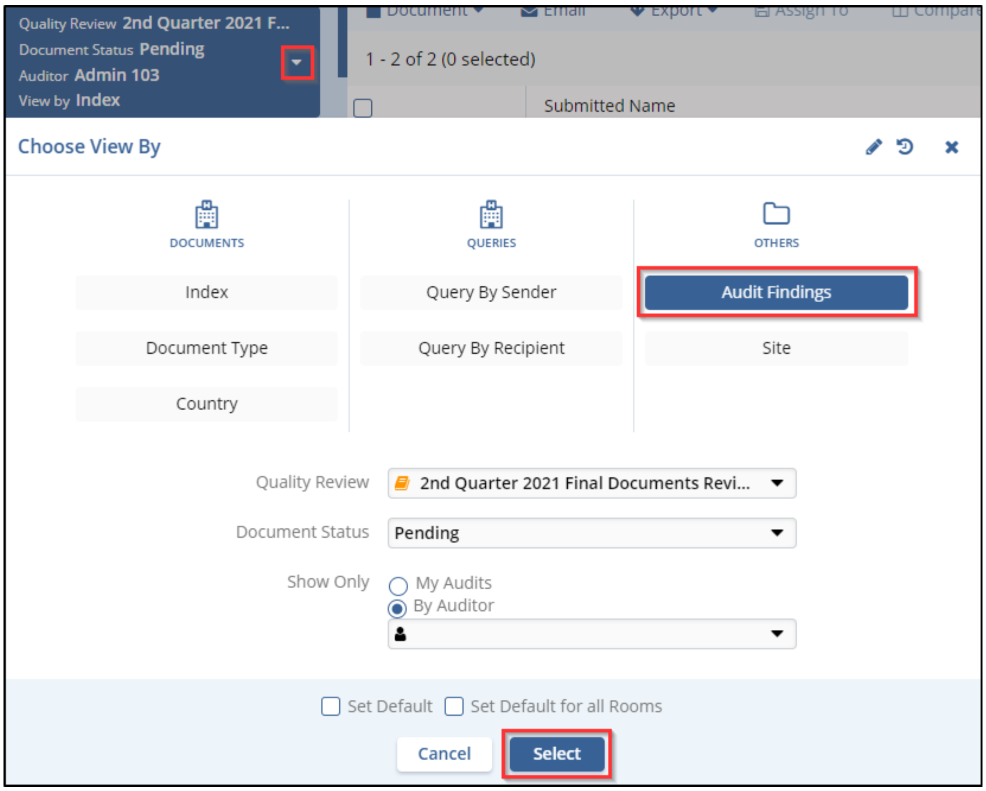


9. A notification is displayed on the top right corner of the screen. Click the **Get Job Result** button.
10. The file is downloaded in your system’s ‘Downloads’ folder.

Responding to Audit Findings

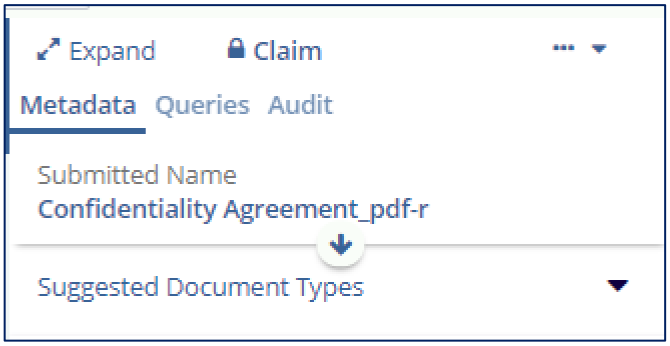
The Audit Responder is designated during the creation of the audit. There can be multiple audit responders for an audit. In order to respond to audit findings, follow the steps below:

1. Navigate to the Documents module.
2. Select the Audit Findings view from the dropdown at the top of the Index panel on the left.



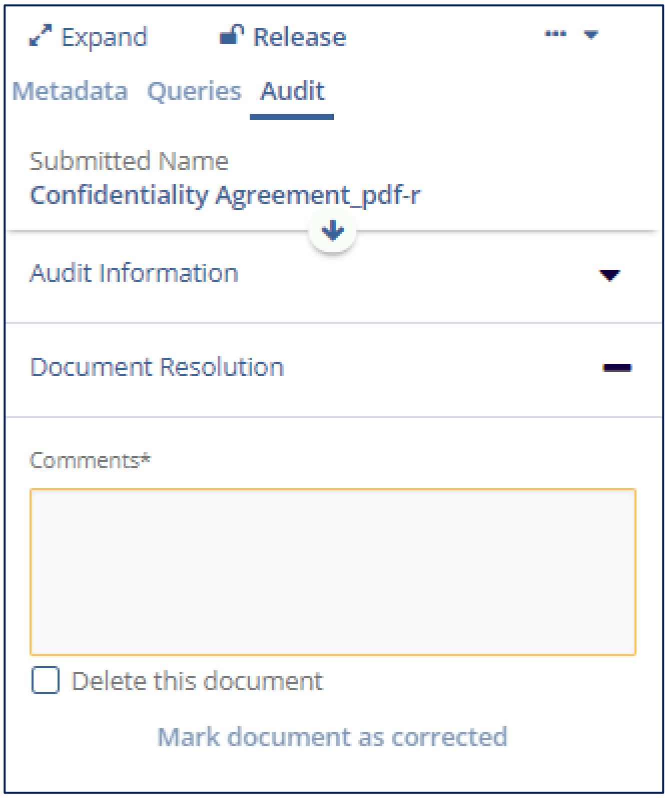
3. The index panel will populate with audit findings organized by their respective audit.
4. Drill down to locate an audit finding.
5. Select the finding in the grid.

6. Press the ‘Claim’ button at the top of the metadata panel.



7. If the audit finding has already been claimed by another user, you will not be able to claim the finding for review.
8. Select the Audit tab of the Metadata panel.
9. If necessary, expand the ‘Audit Information’ section to view the reviewer’s comments indicating why the document was failed.
    a. The Audit Comments field can also be brought into the user’s grid column layout. For more information, please see the section on customizing your grid view.
10. Make any necessary corrections based on the comments.
    a. This may require the user to initiate an audit query. For more information on this, please see the chapter on Queries.
11. Once all corrections have been made, return to the Audit tab of the metadata panel and expand the ‘Document Resolution’ section.
12. Make any comments necessary.

13. If the appropriate resolution requires that the document should be deleted, check the box under the comments field:



14. Press ‘Mark Document as Corrected’

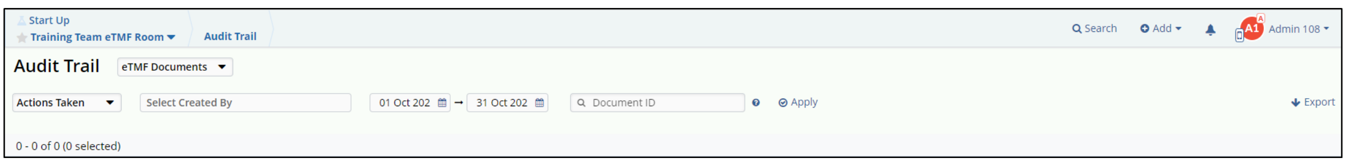
Audit Trail

Audit Trail is a security-relevant chronological set and source of records, that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed in this section. The subsequent section describes in detail the filters available for the audit trail.

Note: By default, the audit trail's grid pane is empty and the documents are displayed only after entering username in the 'Select Created By' field and clicking the **Apply** button displayed in the top right corner.

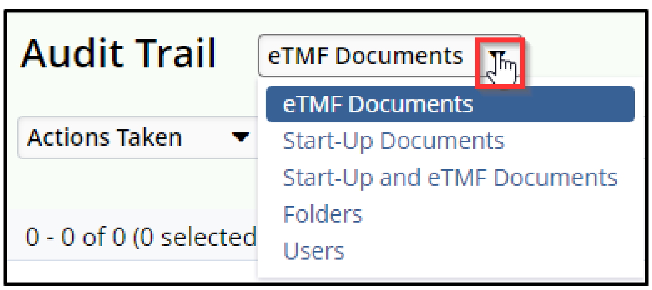
Filters for Audit Trail

To view the Audit Trail section, click on the **Audit Trail** icon from the toggling menu bar. By default, the page displays only the filters available for searching a document. Refer to the screenshot below.



Options

The user has five parameters from the dropdown to select to filter this section: eTMF Documents, Start-Up Documents, Start-Up and eTMF Documents, Folders, and Users. Refer to the screenshot below.

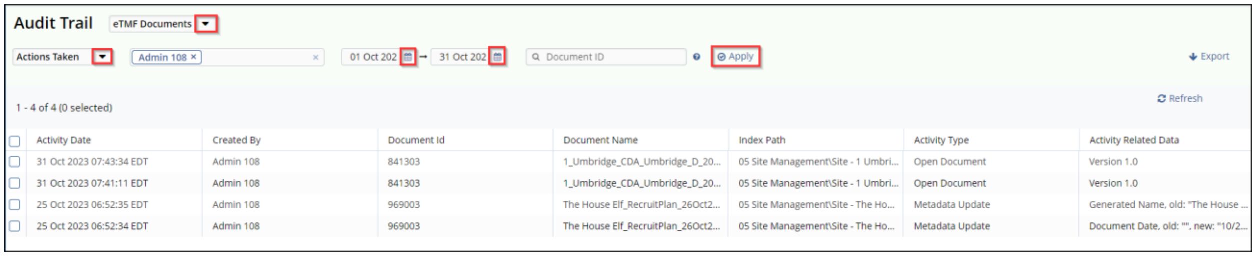


Note: The Audit Trail User Interface changes as per the option selected from this dropdown menu.

User Interface for eTMF and Start-Up Documents

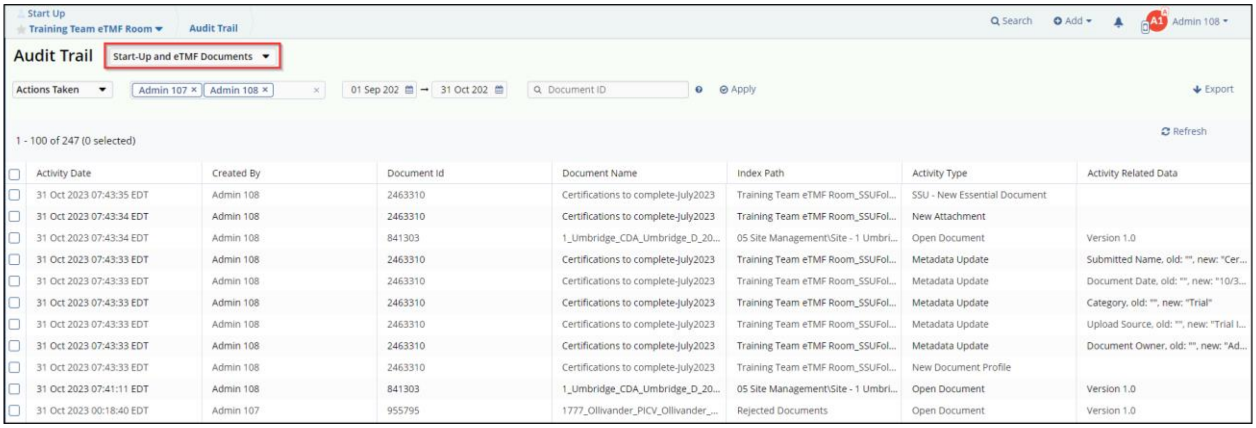
Follow the steps below to view the audit trail for eTMF Documents:

1. Click the dropdown menu displayed next to the Audit Trail page Title.
2. Select the **eTMF Documents** option to search documents –
3. Select the appropriate option from the Actions Taken dropdown menu.
4. Enter name(s) in the Created by field.
5. Click the Calendar icon to select the Start and End date for the documents.
6. (Optional) Enter the Document ID in the last field.
7. Click the **Apply** button. Refer to the screenshot below.



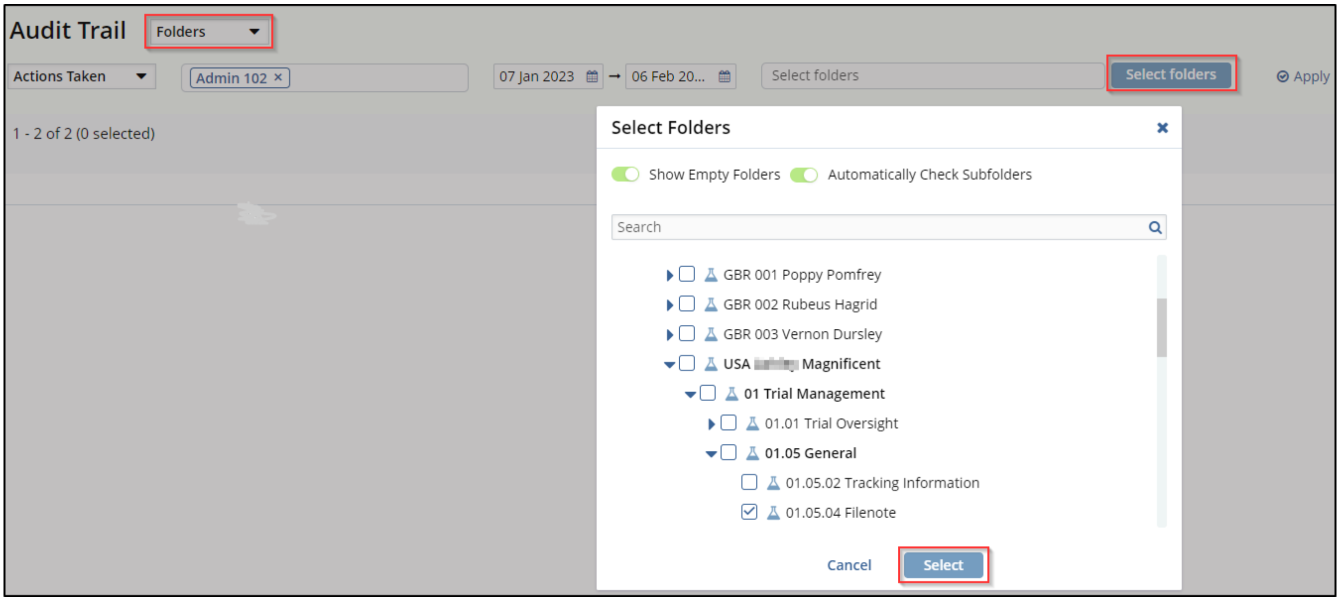
User Interface for Start-Up and eTMF Documents

This feature helps the user to search and apply filters combinedly for eTMF and Start-Up module. Refer to the **User Interface for eTMF and Start-Up Documents** page for more details.



User Interface for Folders

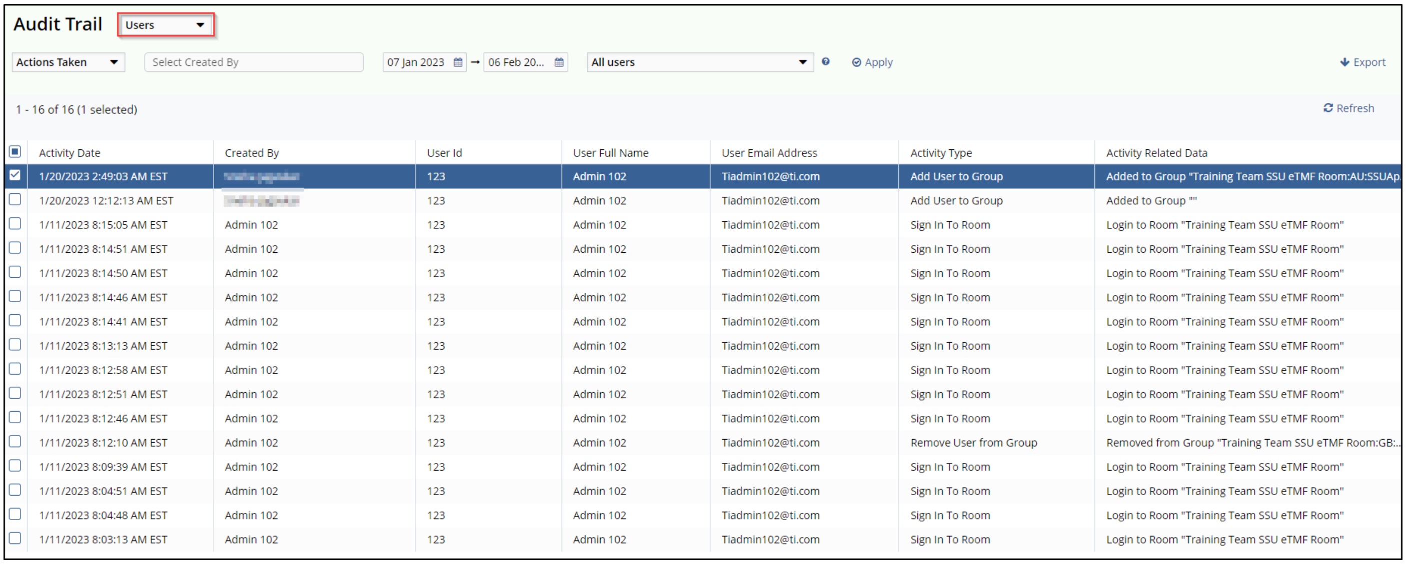
Select the Folders option to search documents – Actions Taken, Created by, Start and End date, and Document ID. Refer to the screenshot below.



The user can search for a document in the Select Folders popup window to select the correct document.

User Interface for Users

Select the Users option to search documents – Actions Taken, Created by, Start and End date, and All Users dropdown menu. Refer to the screenshots below.



Audit Trail Users

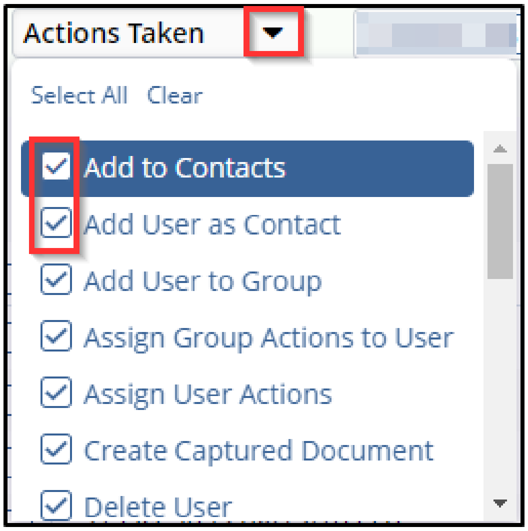
Actions Taken | Select Created By | 07 Jan 2023 → 06 Feb 20... | All users | Apply | Export

1 - 16 of 16 (1 selected) | Refresh

Activity Date	Created By	User Id	User Full Name	User Email Address	Activity Type	Activity Related Data
1/20/2023 2:49:03 AM EST	[redacted]	123	Admin 102	Tiadmin102@ti.com	Add User to Group	Added to Group "Training Team SSU eTMF Room:AU:SSUAp
1/20/2023 12:12:13 AM EST	[redacted]	123	Admin 102	Tiadmin102@ti.com	Add User to Group	Added to Group ""
1/11/2023 8:15:05 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:14:51 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:14:50 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:14:46 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:14:41 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:13:13 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:12:58 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:12:51 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:12:46 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:12:10 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Remove User from Group	Removed from Group "Training Team SSU eTMF Room:GB:..
1/11/2023 8:09:39 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:04:51 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:04:48 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
1/11/2023 8:03:13 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"

Actions Taken Dropdown

This dropdown displays a list of actions to be selected from the dropdown menu for filtering the documents. Select one, few, or all checkbox(s) to apply the required filter. By default, all checkboxes are selected. Refer to the screenshot below.



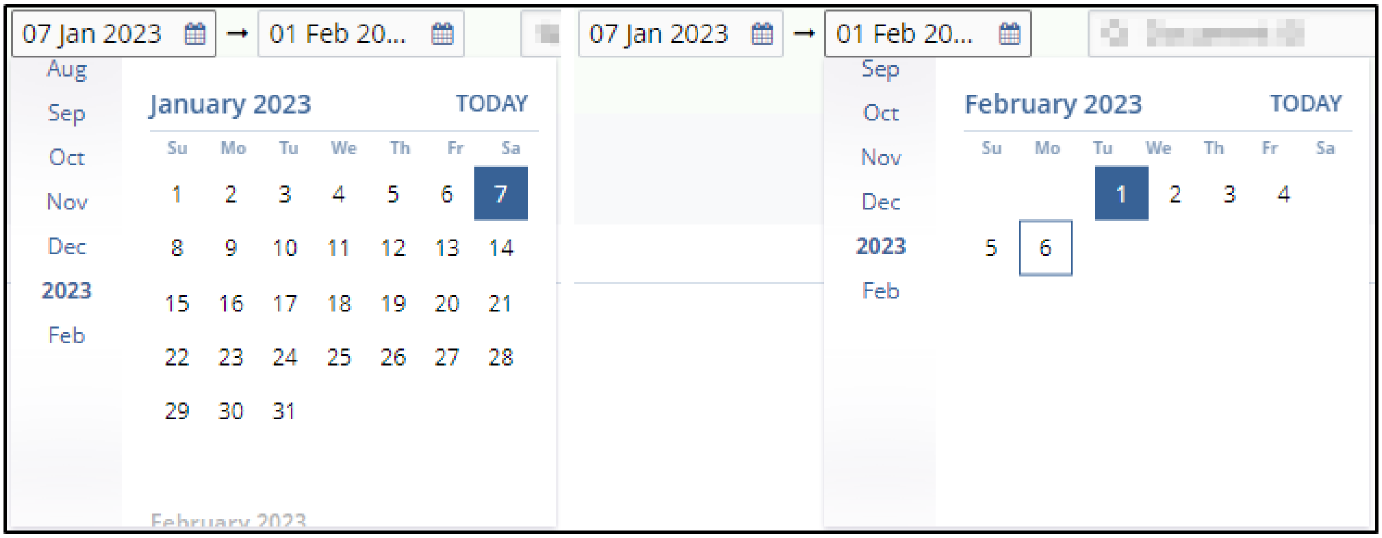
Select Created By Filter

Enter a username in this field to search for a document. Click **Apply**, displayed on the right side, to view the search results.

Refer to the screenshot below.

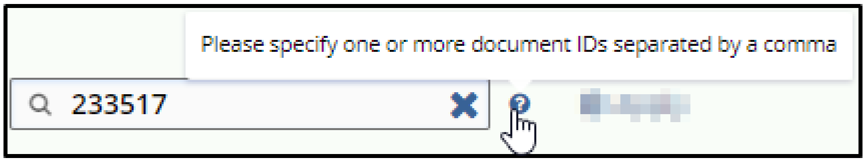
Date Filter

Select the dates in these fields to search a document. By default, the start date is set for the previous month, and the end date is set for today. Click the calendar icon 'To-From' to select dates and apply the filter. Click the **Apply** button, displayed on the right side, to view the search results. User can select dates from the previous year too by scrolling up on the Months field. Refer to the screenshot below.



Document ID Filter

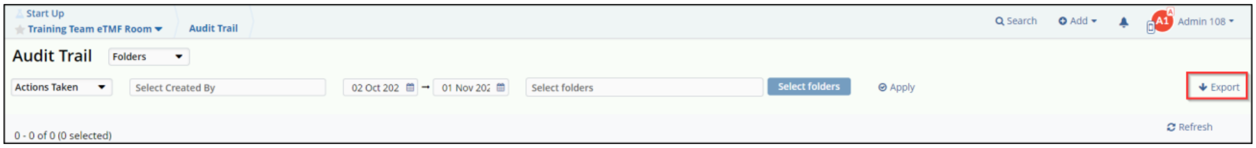
This field helps the user to find a document by the ID number. Enter the document ID and click the **Apply** button displayed on the right side, to view the search results. Refer to the screenshot below.



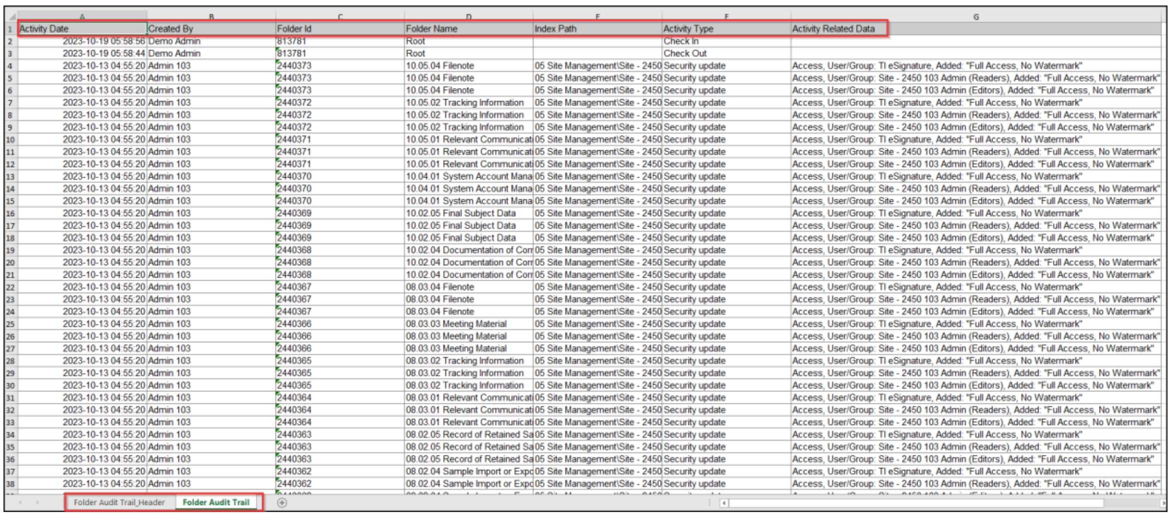
Export

The user can export the Audit Trail in an Excel sheet for reference. Follow the steps below to export.

1. Click the **Export** button displayed in the right corner, to view the details of the audit trail in an excel sheet.



2. Click on **Get Job Result** button displayed in the notification on the top right corner. The document is downloaded and is reflected in the Downloads folder of your system. The Excel sheet displays two tabs – **Folder Audit Trail Header and Folder Audit Trail**. Refer to the screenshot below for the details of the columns available in the Excel sheet.



	A	B	C	D	E	F	G
1	Activity Date	Created By	Folder Id	Folder Name	Index Path	Activity Type	Activity Related Data
2	2023-10-19 05:58:56	Demo Admin	813781	Root		Check In	
3	2023-10-19 05:58:44	Demo Admin	813781	Root		Check Out	
4	2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
5	2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
6	2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
7	2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
8	2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
9	2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
10	2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
11	2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
12	2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
13	2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
14	2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
15	2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
16	2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
17	2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
18	2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
19	2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Corr	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
20	2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Corr	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
21	2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Corr	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
22	2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
23	2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
24	2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
25	2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
26	2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
27	2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
28	2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
29	2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
30	2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
31	2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
32	2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
33	2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
34	2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
35	2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
36	2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
37	2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Expo	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
38	2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Expo	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"

Folder Audit Trail_Header | Folder Audit Trail

The **Activity Related Data** column displays the activities carried out over a document.

Refresh

Click the **Refresh** button displayed at the top right corner to update the list of searched documents.

Chapter 15. Quality Control

This quality control section will be focused primarily on workflows about eTMF rooms.

However, the same processes are utilized in many TI Content Management room types as well. eTMF rooms tend to have a more standardized 1 or 2-step QC review workflow whereas Content Management rooms can have multiple workflows depending upon site, sponsor, or other SOP requirements.

Because of the potential issues that can be encountered when designing and implementing workflows, we recommend always working with the TI Support Desk about workflows. Workflows are created and maintained in the Settings area of Trial Interactive. For additional information on this process, please see that section.

Performing eTMF Quality Control Functions

Editor, manager, and administrator-level users can all perform Quality Control functions. Reader-level users cannot perform these tasks.

To be a part of the quality control workflow, the user must be added to at least one of the QC-related groups in the Users Management area. For more information on how to add users to a group, please see the related section of this guide. In Content Management rooms, a user's group is likely related to their job function and then that department or other group would be selected for inclusion in the approval workflow.

For more information on approving a document in a collaborative room, please see the section on versioning a controlled document.

Claiming a Document for Review

Once a user has been added to a QC workflow, the first step is to claim a document for review. The user must first claim the document because all newly added documents come into the workflow in a pool of documents normally referred to as '**Available for Review.**'

To claim a document for review, please follow these steps:

1. Navigate to the **Documents module**.
2. Select the 'Reviews' view from the dropdown menu above the index pane.
    - This view will only appear in the list if you have been added to the workflow.

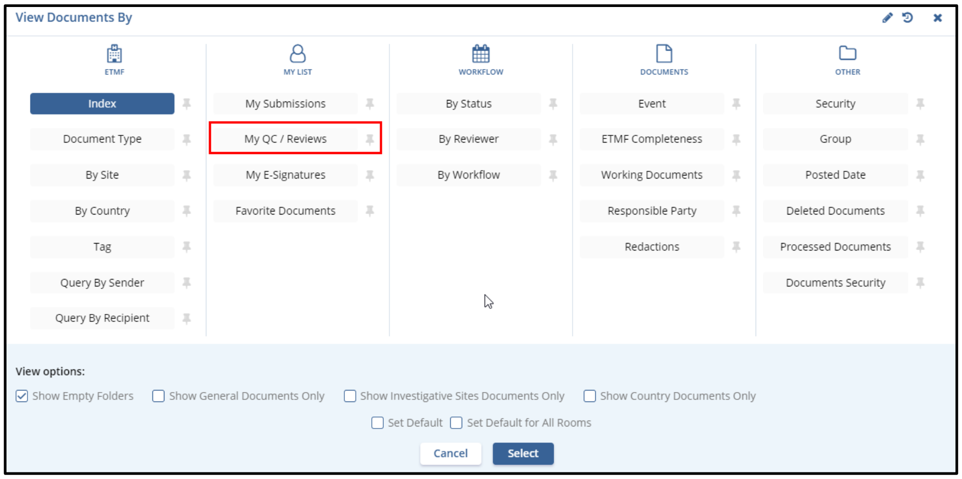


Figure 10: View by My QC/Reviews

3. When the screen loads, the index pane will load with all of the workflows in which the user is a participant. This will normally be just one workflow. Expand the workflow to see the status folders.

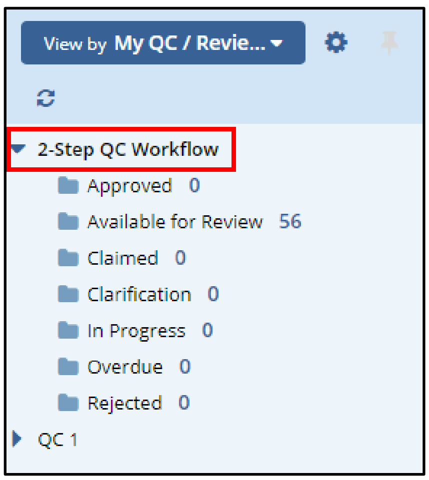


Figure 2: QC Workflow folders

4. Select the '**Available for Review**' folder.
   - The documents grid will populate with a list of documents that could potentially be claimed by the user. The list of documents may not be the same for any two users depending upon what step of the workflow they are assigned to and whether or not they have already reviewed the document.
     - Users who have reviewed a document in step 1 of a multi-step QC workflow will not be able to claim the document in any later step.
5. Check the boxes in front of the documents to be claimed. The user could claim one document at a time but selecting multiple documents is far more efficient.
6. Click the '**Claim'** button above the documents grid.

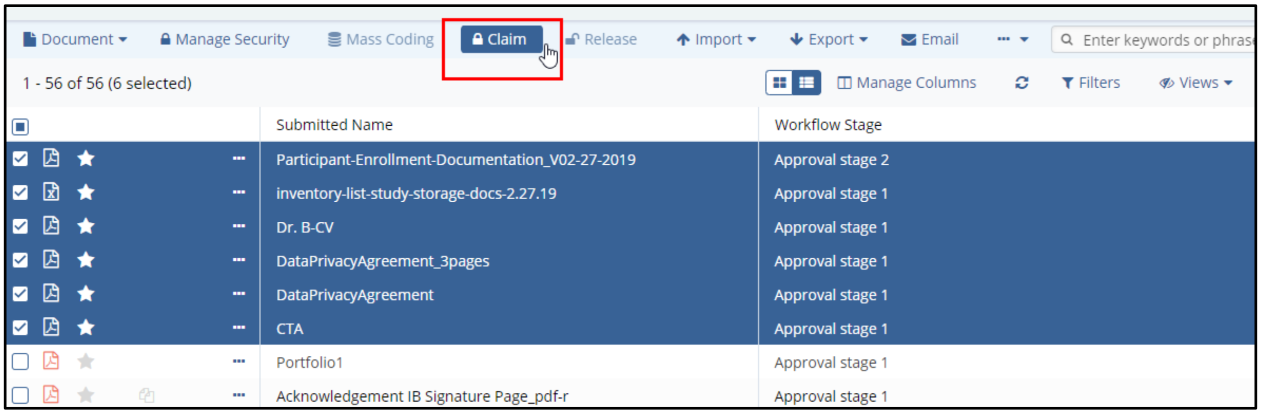


Figure 3: Claim document

7. Once the documents have been claimed, they are moved to the ‘**Claimed’** folder and are no longer visible in the ‘Available for Review’ folder.

Releasing a Claimed Document

Sometimes a user will have claimed documents that need to be returned to the pool of ‘**Available for Review’** documents so that someone else may claim them for review. Follow the steps below to release a document.

1. Click on your ‘**Claimed’** folder.
    - All of the documents you currently have claimed will populate the grid.
2. Check the box to indicate which documents should be released.
3. Press the ‘**Release’** button above the grid.

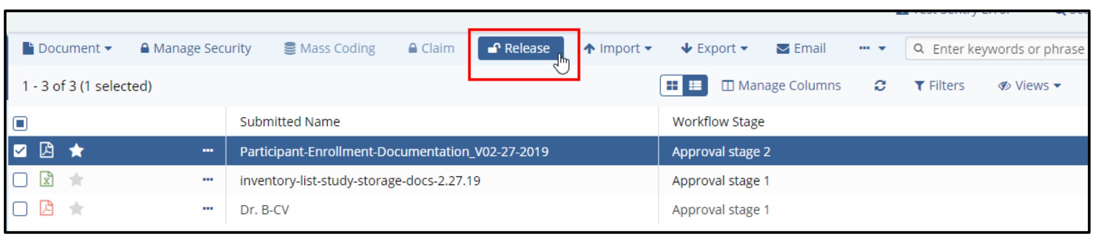


Figure 4: Release Document

4. Once released, the documents will be removed from your ‘**Claimed’** folder and returned to the ‘Available for Review’ folder.
5. Alternately, this may be done by a room administrator using the three-dot menu at the top-right of the metadata pane.

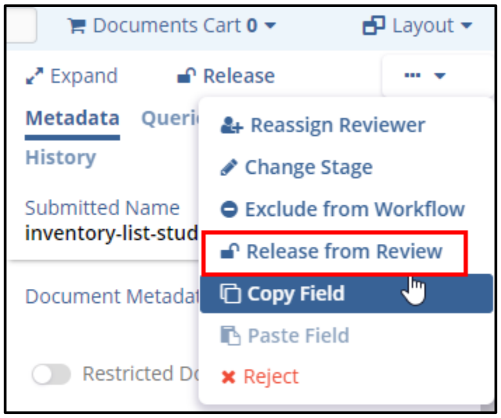


Figure 5: Release from Review Option

Reviewing a Document

Once a document has been claimed, the reviewer will need to check the document against established quality control guidelines, apply any necessary metadata, and indicate whether the document has been approved or has been rejected. QC reviewers also can launch a query to get assistance with reviewing a document. For more information regarding launching a QC Workflow Query, please see the chapter on Queries.

To review a document and assign a status to it, please follow the steps below:

1. Locate the document in your '**Claimed'** folder.
    - If the document has not been claimed, please see the section on claiming a document for review.
2. Open the document and review it according to any established guidelines for the document type.
3. If the document is in good order and can be accepted, review the metadata associated with the document and make any corrections or fill in any required fields.
4. Beneath the metadata is a workflow status area. The section is named for the workflow you are working in as well as the steps in the workflow that you are completing. Please see the screenshot below:

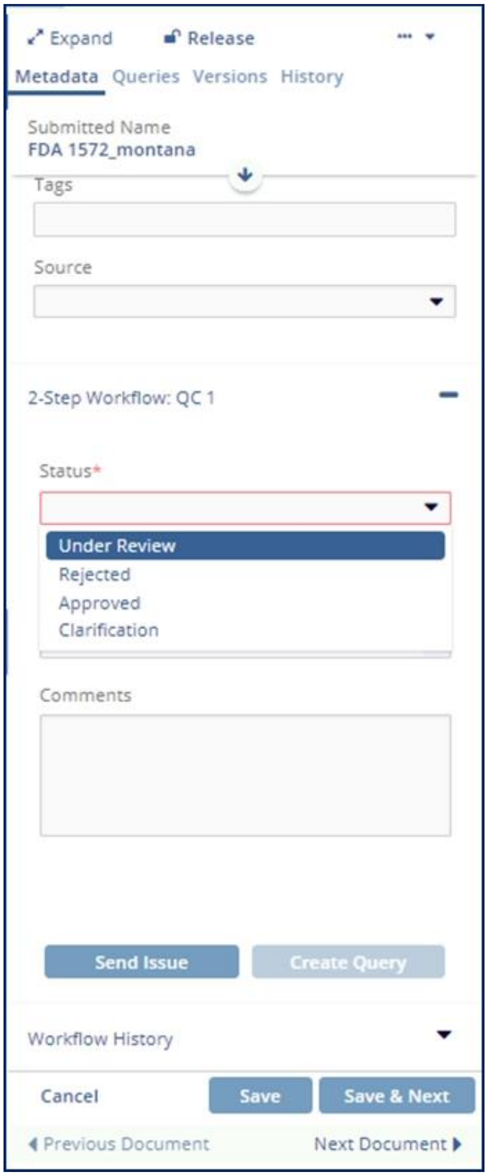


Figure 6: Status Types

5. Assign the appropriate status to the document.
    a. Note: The available statuses are assigned when the workflow is created and may vary from those shown above.
    b. **Approved:** This indicates that the document is correct and that it can either move on to the next step of the workflow or, if appropriate, be published as 'Final' to the room's index.
    c. **Rejected:** This indicates that the document has some feature that is incorrect and which will need to be rectified before the document is accepted into the room's index as '**Final**.'
        i. If this value is selected, the user does not need to fill in all of the metadata first.
        ii. Also, if this value is selected, the user will be required to indicate a reason why the document was rejected. The list of available issues is created along with the workflow and so may not contain exactly what is needed. It is strongly recommended that you also provide a comment in the box below to clarify the reason for your rejection of the document.

iii. Depending upon internal process requirements, the user may be asked to send the submitter a notification that their document has been rejected. For additional steps on how to do that, see the section below.

d. **Clarification:** This indicates that the QC Workflow reviewer (you) has a question about a document.

i. If this option is selected, the user will also need to indicate the reason for the inquiry (issue). The list of available issues is created along with the workflow and so may not contain exactly what is needed. It is strongly recommended that you also provide a comment in the box below to clarify the reason for your inquiry regarding the document.

ii. The status indicates that the reviewer intends to launch a query. For more information regarding that process, please see the chapter on Queries.

6. Once the appropriate status has been assigned, press '**Save'** or '**Save & Next**'.

Sending a Rejection Notification

Depending upon the SOP requirements for your organization, you may be required to send a notification to the document submitter that their document was rejected. To do so, follow the steps below:

1. Below the workflow comments box are two buttons '**Send Issue**' and '**Create Query**'. Once the status has been assigned and the issues have been noted in the comments, press the '**Send Issue'** button.
   - An email window will open.

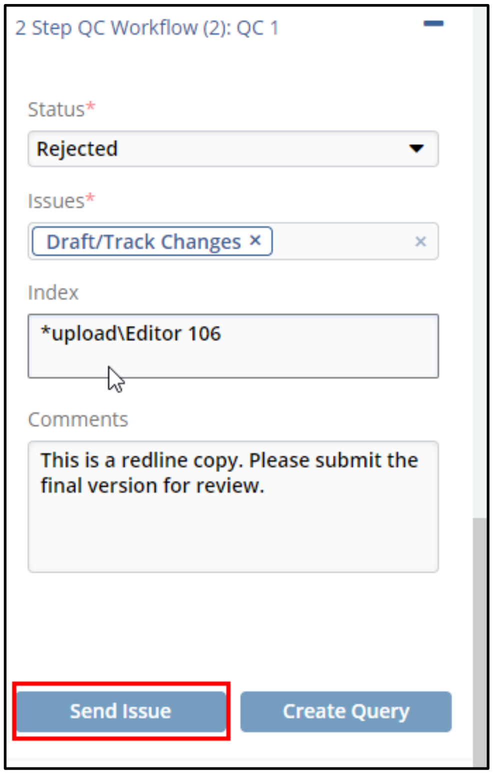


Figure 7: Send issue Option

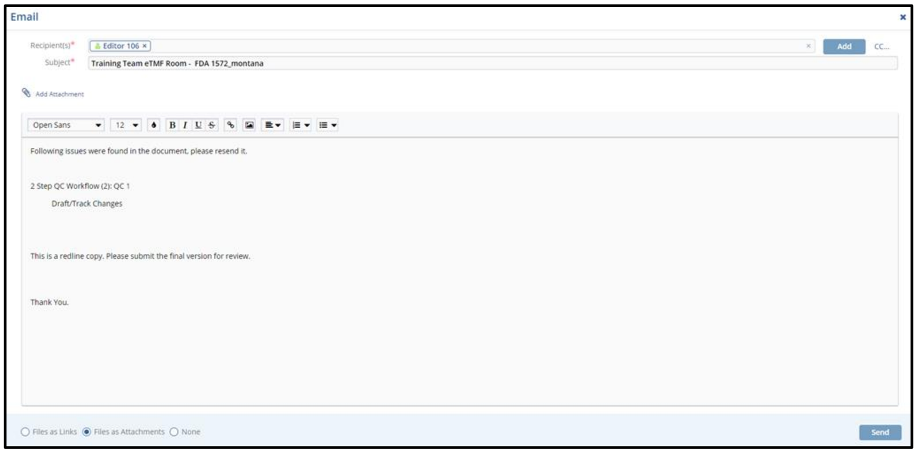


Figure 8: Send Issue Mail

2. The submitter of the document is populated by default in the Recipients area. Add any additional recipients as appropriate.
3. The text that populates comes from both a standard email template and from any comments/issues indicated. Make any necessary additions or changes to the displayed text.
4. Indicate, using the radio buttons at the lower left whether or not the document should be supplied to the recipient and, if so, in what manner.
5. Press 'Save'

Reassigning a Reviewer

Occasionally, a room administrator may need to reassign a document's reviewer. In order to do that, follow the steps below:

1. Navigate to the Documents module.
2. Select the 'By Status' view from the dropdown menu above the index pane.

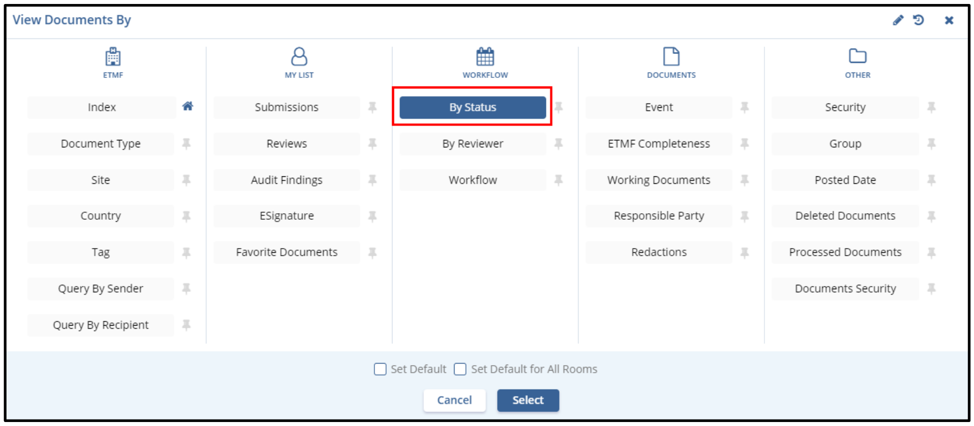


Figure 9: View by Status

3. Select the '**Claimed'** folder from the index pane.
4. Locate the document which needs to be reassigned.
   - If necessary, expand the metadata pane.

5. Click the three-dot dropdown menu at the top-right of the metadata pane.

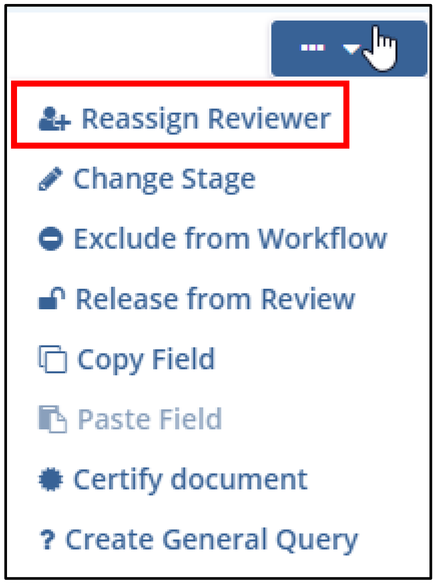


Figure 10: Reassign Reviewer

6. Click ‘Reassign Reviewer’
    - The Reassign Reviewer window will open.

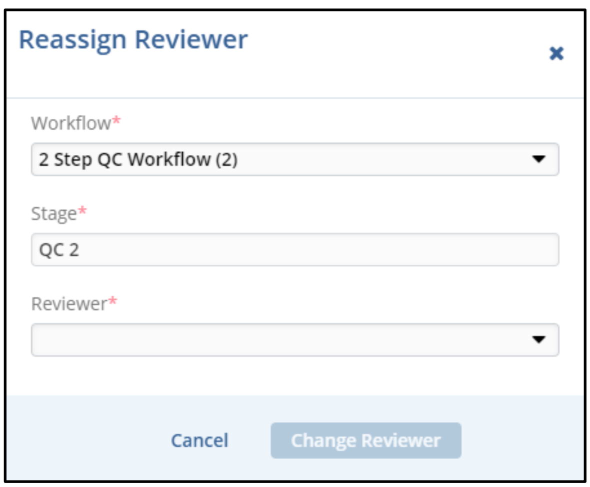


Figure 111: Reassign Reviewer Page

7. Choose the appropriate reviewer and press ‘Change Reviewer’
8. A popup will display asking if you are sure. Press ‘Yes’ if appropriate.

Excluding a Document from the Workflow

Documents can be manually excluded from the workflow if necessary. To do so, follow the steps below:

1. Locate the document.
2. Select the document in the grid.

- If necessary, expand the metadata pane.

3. Using the three-dot menu at the top of the metadata pane, choose 'Exclude from Workflow.'
   - This will cause the Exclude Document from Workflow window to open.

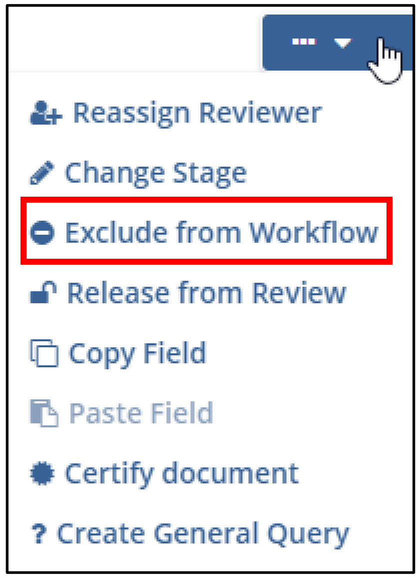


Figure 121: Exclude From Workflow

4. Indicate a reason for the exclusion.

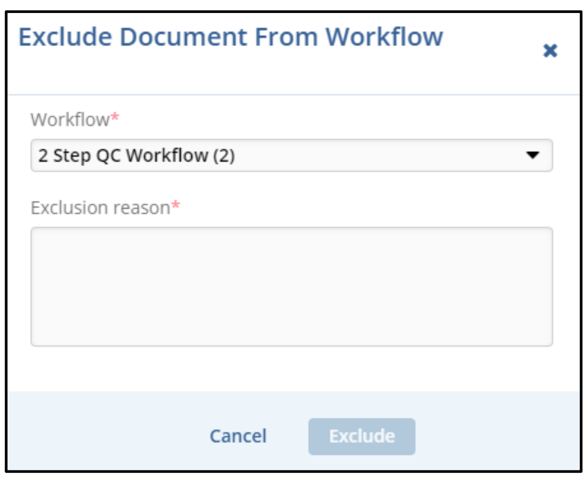


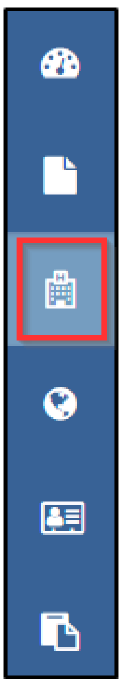
Figure 132: Exclude Document from Workflow

5. Press 'Exclude'

Chapter 16. Sites, Required Documents, Countries and Contacts

Sites

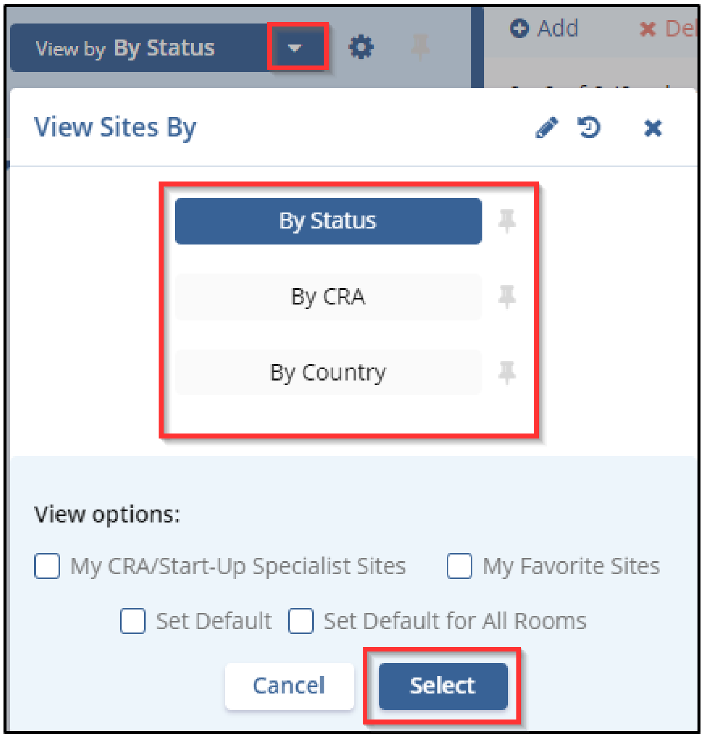
You can access the Sites module by clicking Sites icon on the left menu bar in the eTMF/ Documents module. In order for users to access the sites module, they will need to be added to the Sites Team group in Users Management. Please note that the name of this group may vary based on your instance but this is a system group.



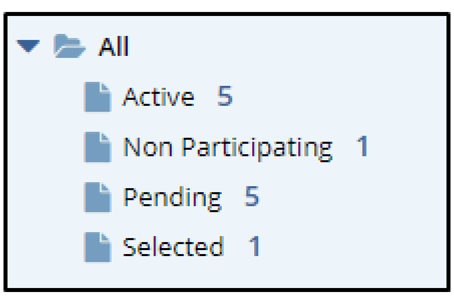
The Sites module is used for site management purposes and allows users to track the progress of the sites. It gives a detailed information on all investigation sites available in a room By Status, By CRA, By Country.

Site Views

Once you click on the Sites module, all of the sites in the room will load up and will appear organized by one of three factors: By Status, By CRS, or By Country. As with the Documents module, you can set your default options for this room or for all rooms to which you have access. You can also choose to apply filters which will display only the sites which are your favorites or to which you have been assigned as a CRA.

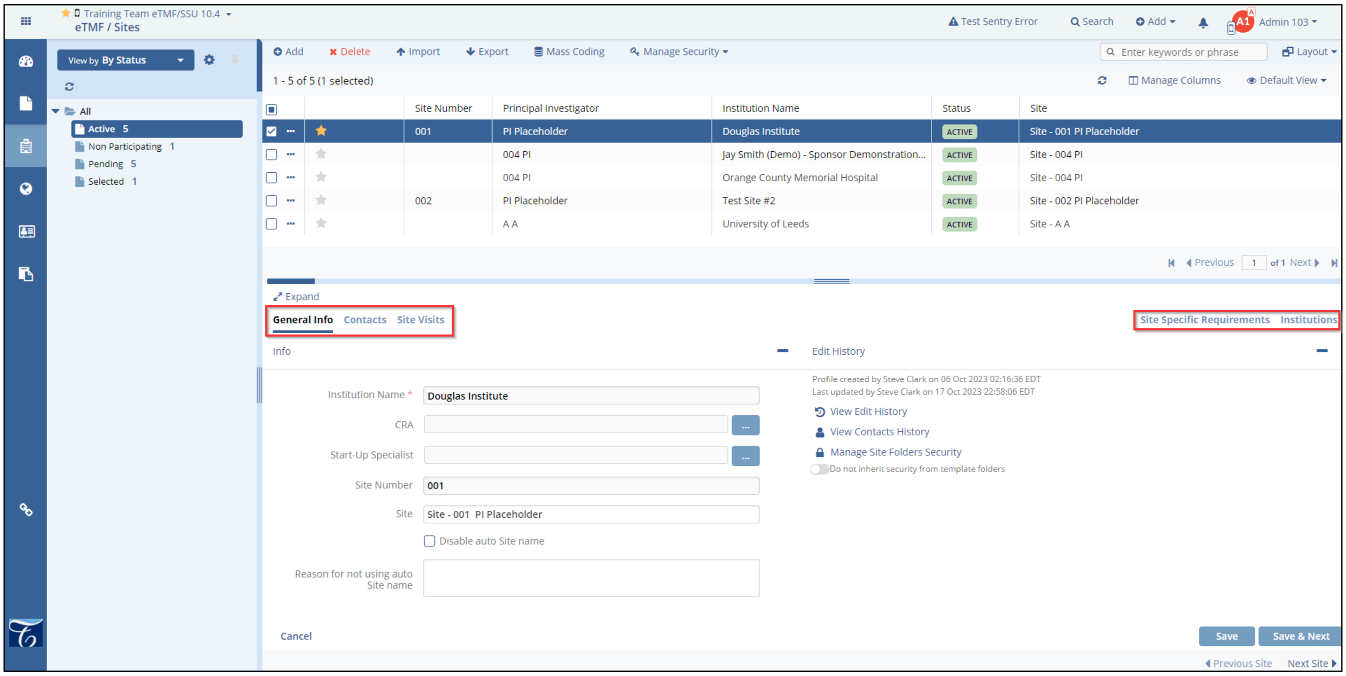


When you have chosen your view, the sites will be displayed in a related folder structure in the index pane on the left side of the screen.



Site Profile

Select a site from the grid and the Site Profile is displayed at the bottom of the grid. If the site profile area is not visible, click 'Open' at the bottom of the screen. This will allow you to view and manage all metadata related to the selected sites. Refer to the screenshot below:



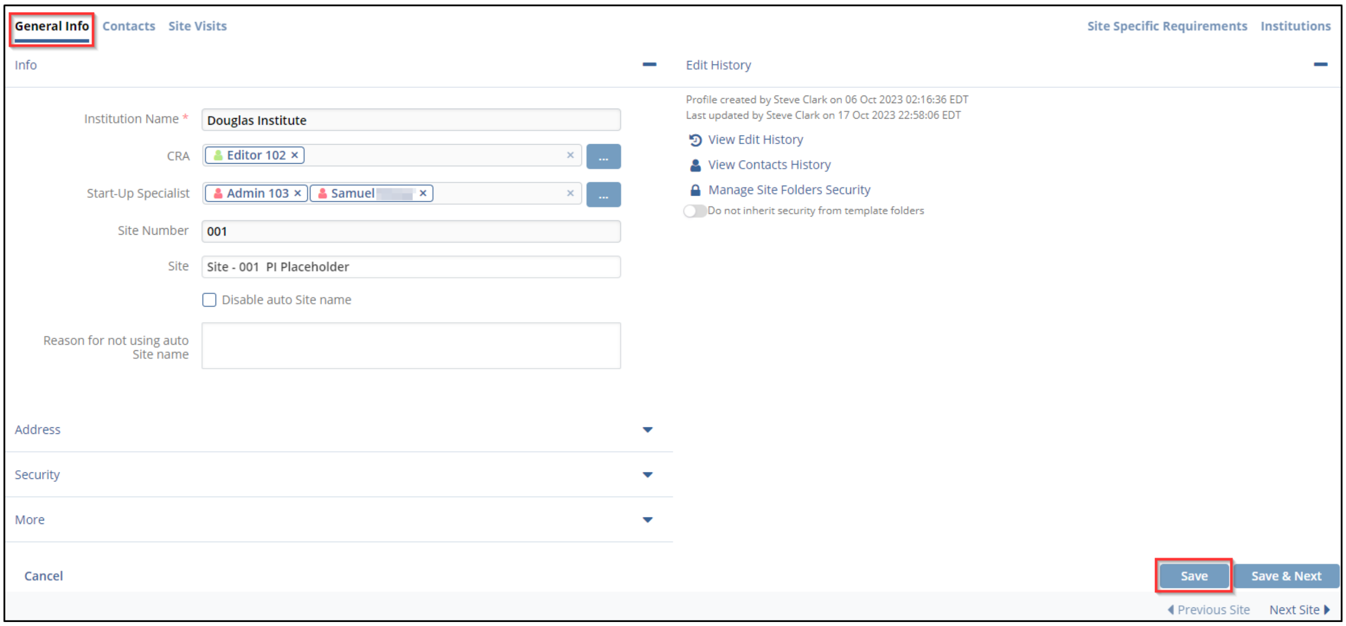
The Site Profile window provides the following:

1. General Info tab
2. Contacts tab
3. Site Visits tab
4. Specific Requirements tab
5. Institutions

Each of the tabs is discussed in the separate topics.

Site Profile - General Info

This tab displays the general information for the site. After selecting a site, click the General Info tab to edit the general details of the site. The sections (Info, Address, Security, and More) are collapsed initially. Click the down arrow to expand the section and edit related information. Refer to the screenshot below:

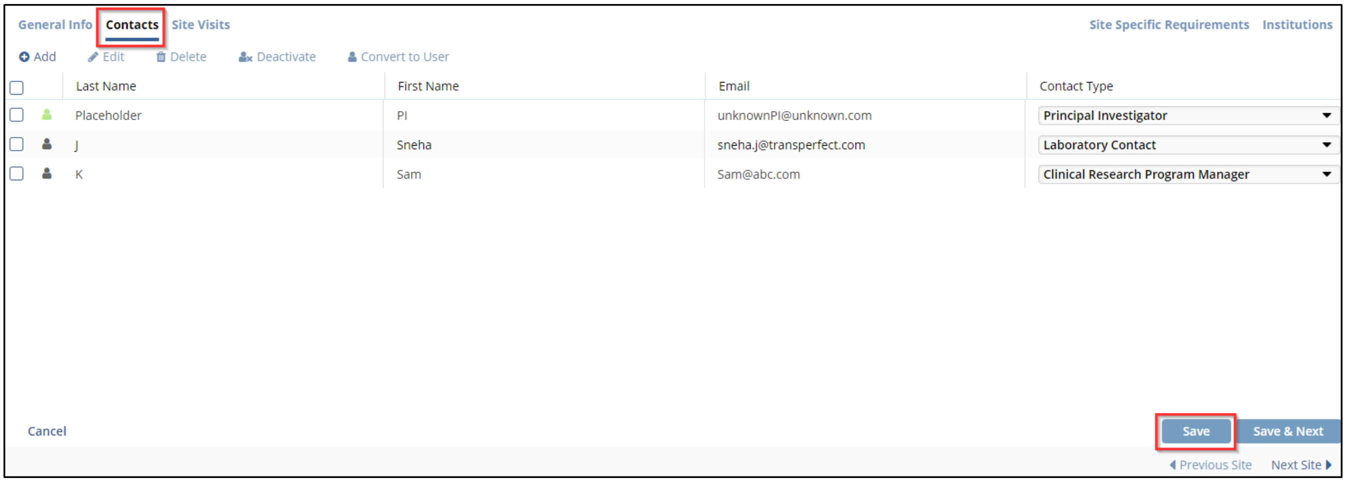


When you click the arrow, the section fields get enabled and the arrow turns to "–" sign as shown in the screenshot below. Similarly, you can update the fields in the other sections of your choice.

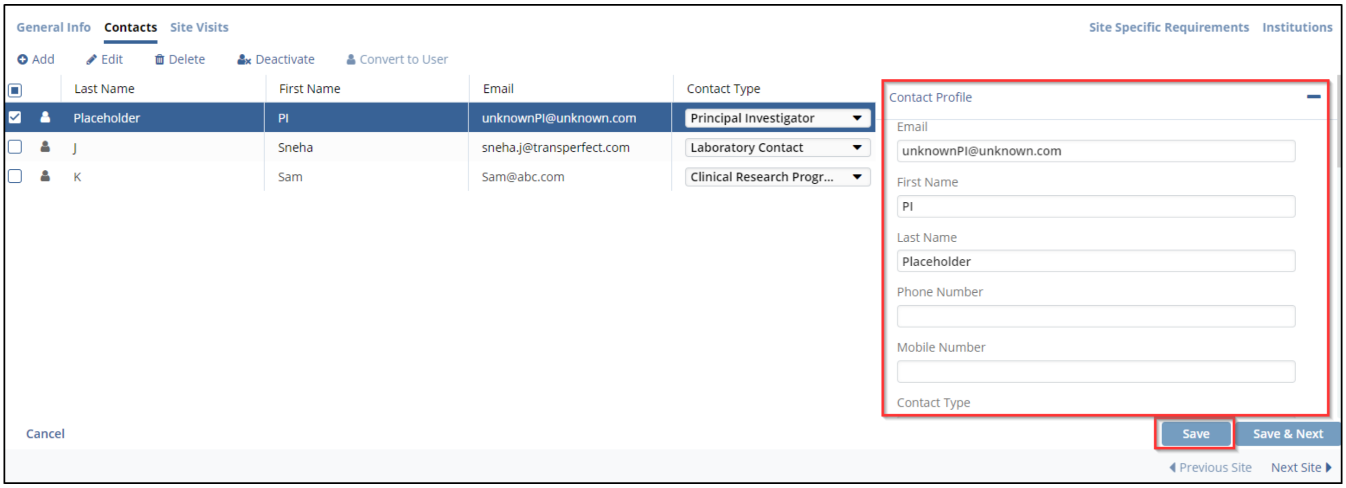
Note: Only room administrators can access the Security area of the site profile.

Site Profile – Contacts

This section displays the list of contacts that are added to a site. From here, you can add, edit, delete, deactivate contacts and also change the contact to another level. Refer to the screenshot below:

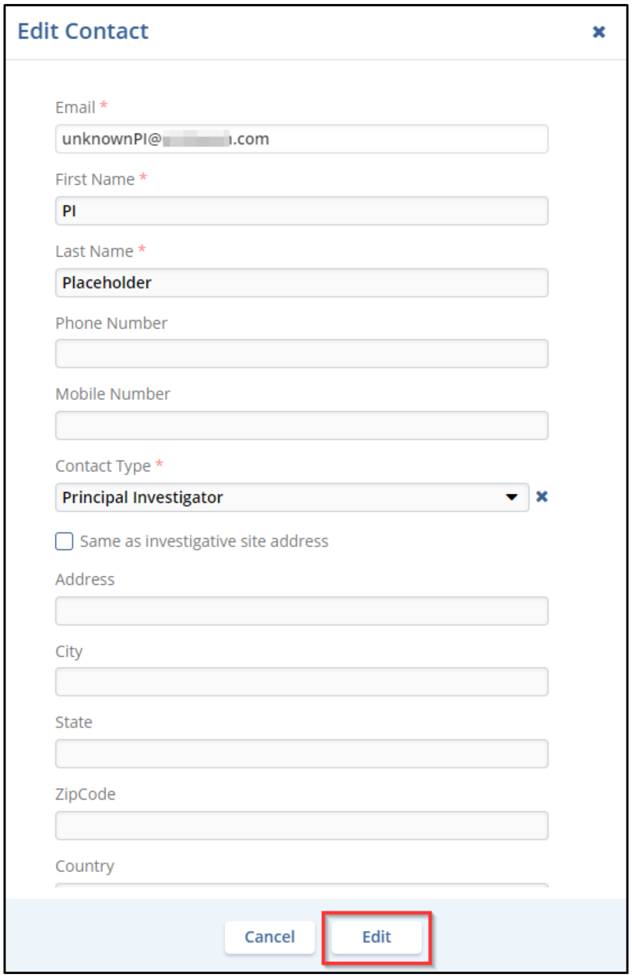


Select the checkbox of the contact profile that needs to be edited. The Contact Profile opens on the right side of the screen. Once all the details are updated, click Save to save the changes. Refer to the screenshot below:



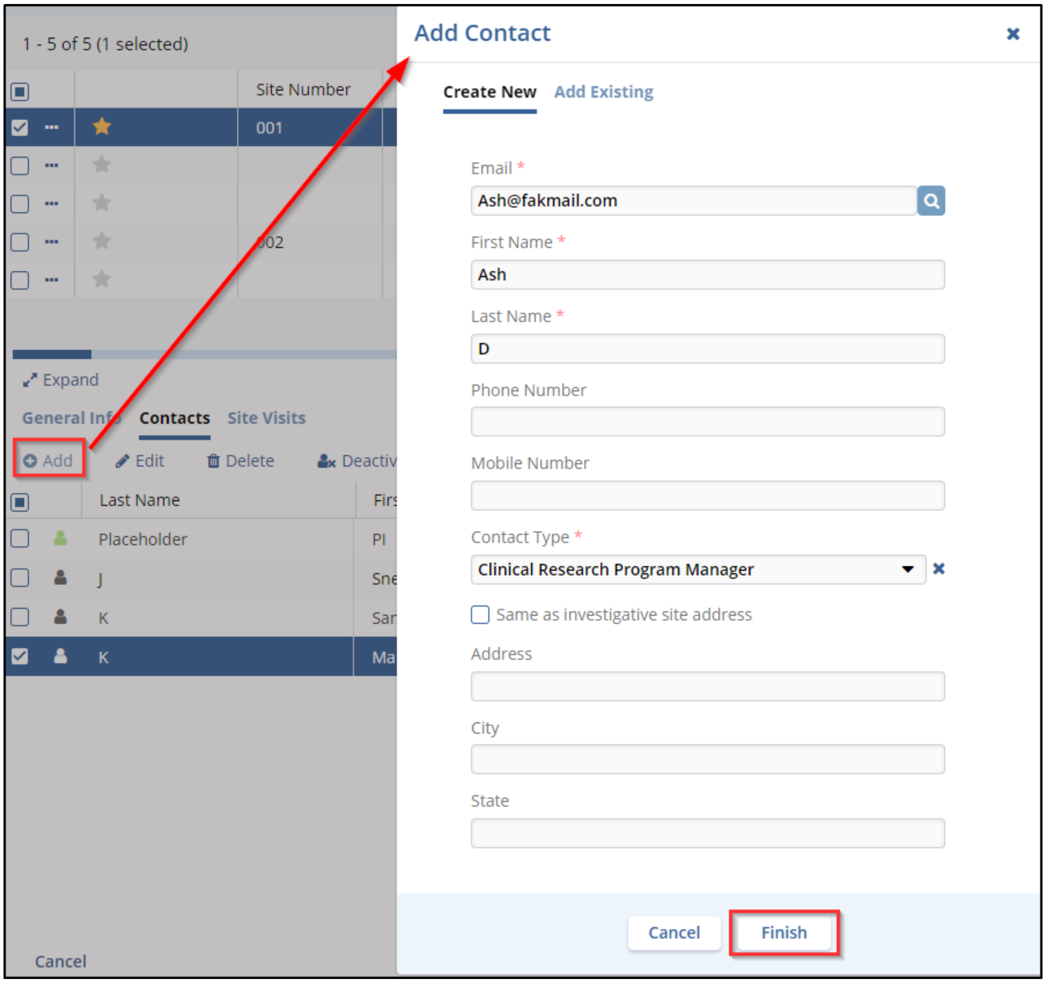
OR

Double click the user to open the Edit Contact popup window. Make the required changes and click the Edit button displayed at the bottom of the popup window. This allows you to edit the contact details of the user.



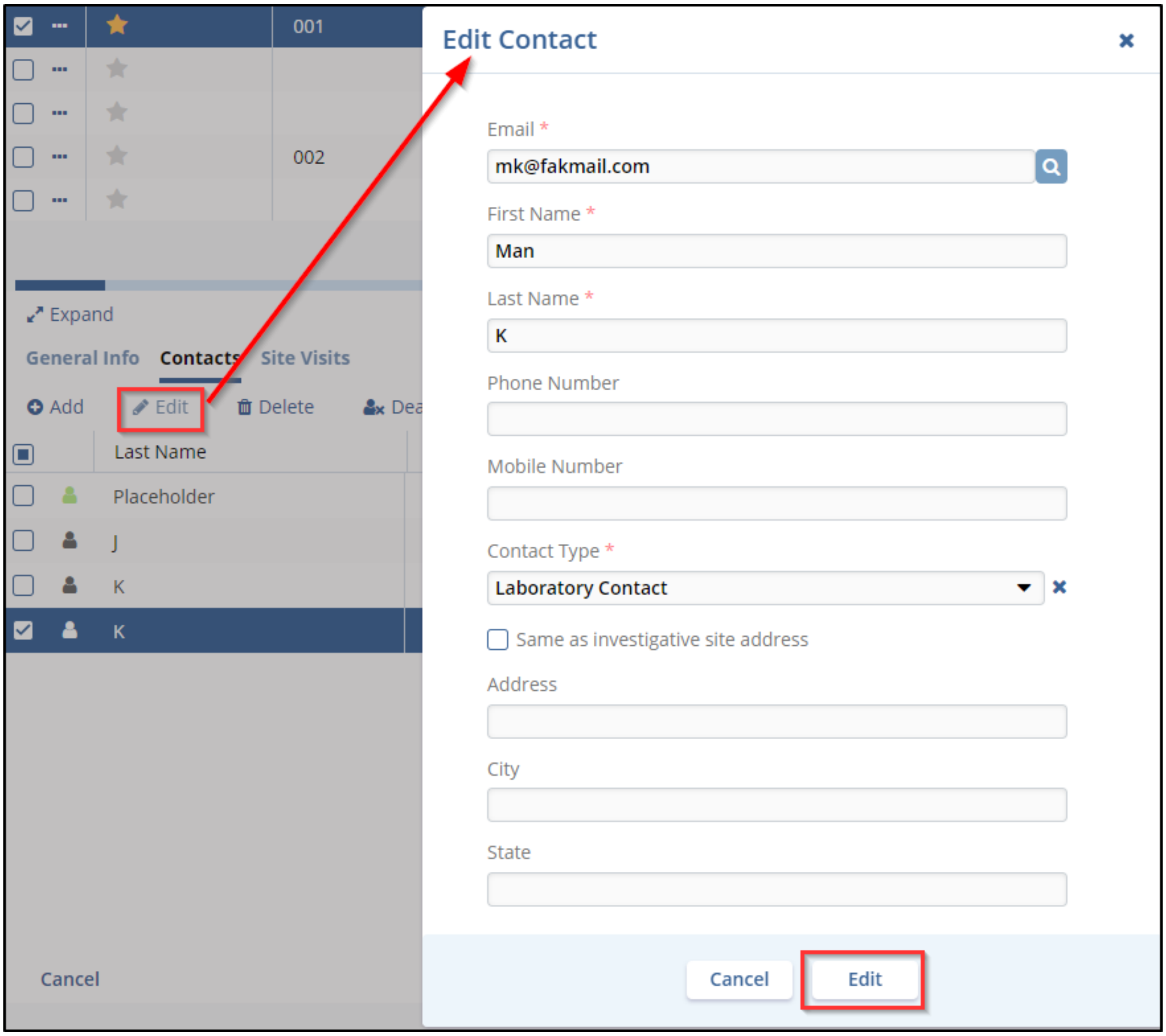
Add a Contact

- Click the **Add** button from the menu bar of the Contacts tab.
- The Add Contact window opens.
- Fill in the details for fields marked with an asterisk (*) – Email, First Name, Last Name, Contact Type. The other fields are optional to enter the details.
- Click the **Finish** button displayed at the bottom of the popup window. Refer to the screenshot below.



Edit a Contact

- Select an added contact and click the **Edit** button in the Contacts tab to edit the contact information entered as above.
- Make the required changes in the Edit Contact popup window and click the **Edit** button displayed at the bottom. The changes are reflected in the grid. Refer to the screenshot below.

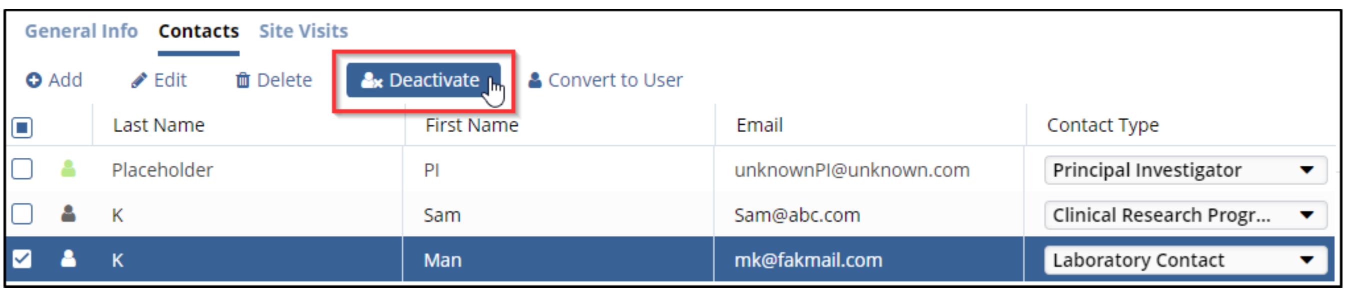


Delete a Contact

Select an added contact and click the Delete button in the Contacts tab to delete a contact's information.

Deactivate a Contact

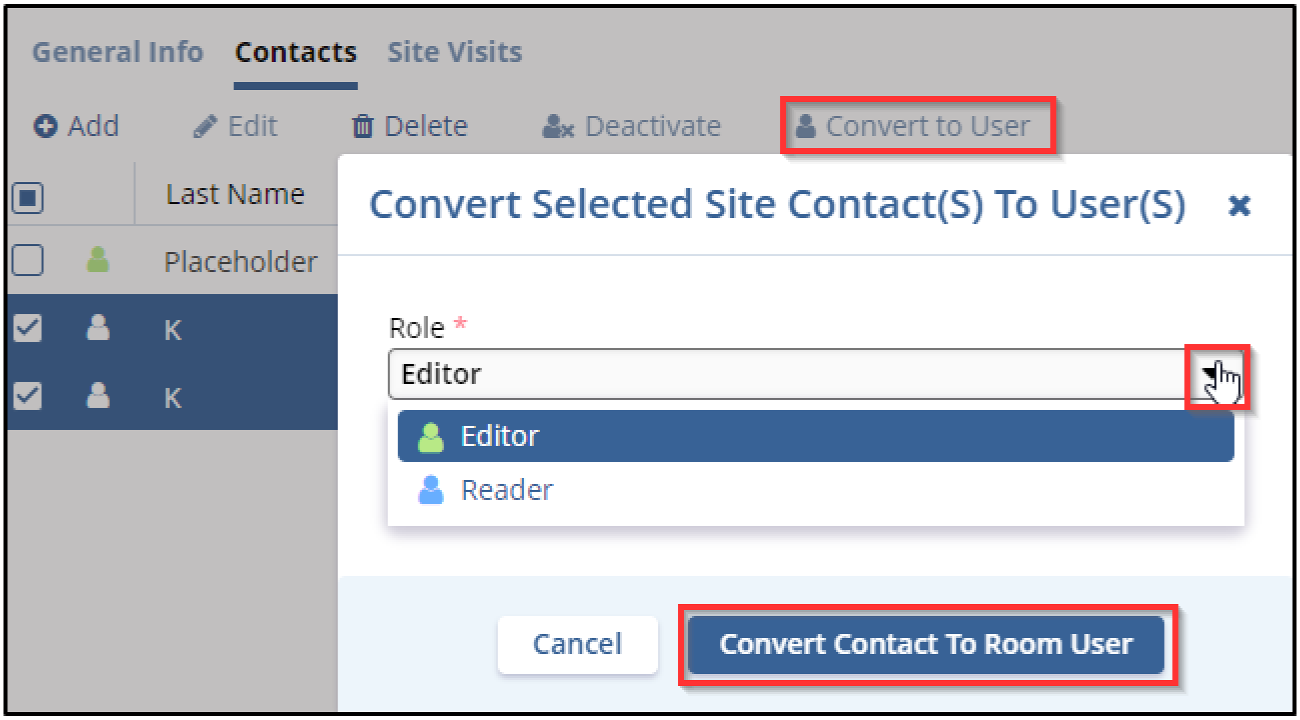
Select an added contact and click the Deactivate button in the Contacts tab to deactivate the contact.



Convert to User(s)

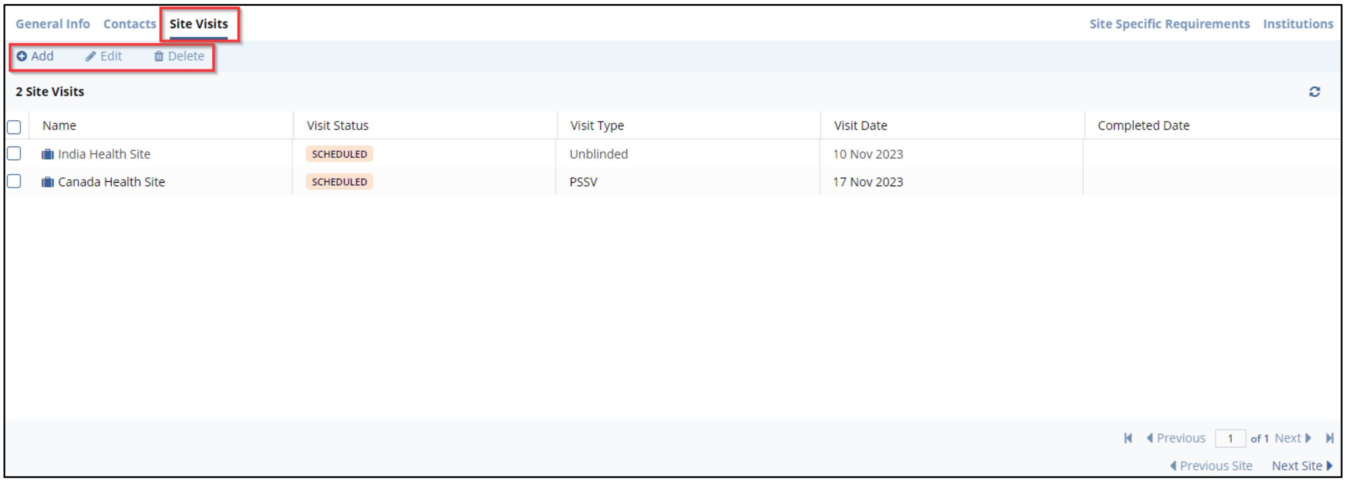
You can assign a site contact the role of editor or reader and assign actions as appropriate from the Convert to User(s) utility in the Contacts tab. Follow the steps below to convert the user(s):

- Select the checkbox(s) of the users that are to be converted.
- Click the **Convert to User** button displayed on the top menu bar. The Convert Selected Site Contact(s) to User(s) popup window is displayed.
- Select the **Role** from the dropdown menu.
- Click the **Convert Contact To Room User** button in the popup window. Refer to the screenshot below.



Site Profile – Site Visits

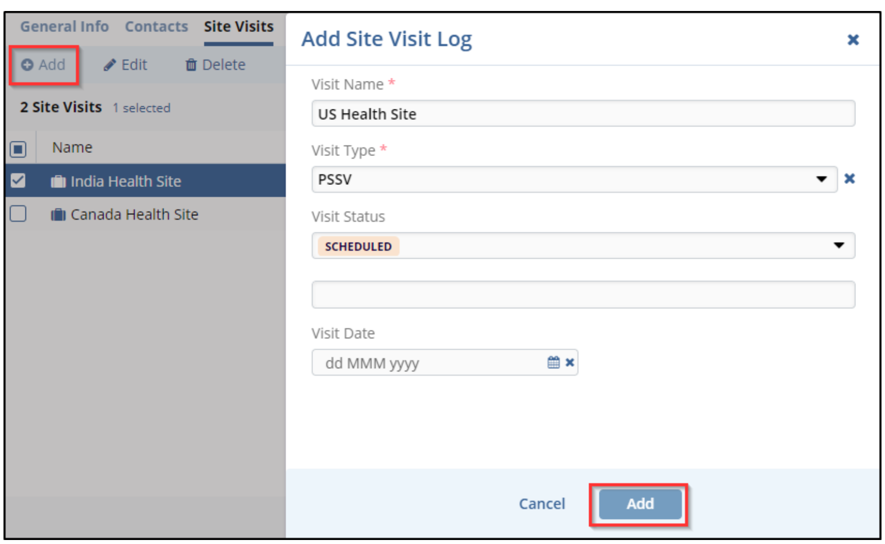
This section displays the list of site visits that are added to a site. From here, the user can add, edit, and delete site visits. Refer to the screenshot below:



Add a Site Visit Log

The user can add a site visit log by following the steps mentioned below:

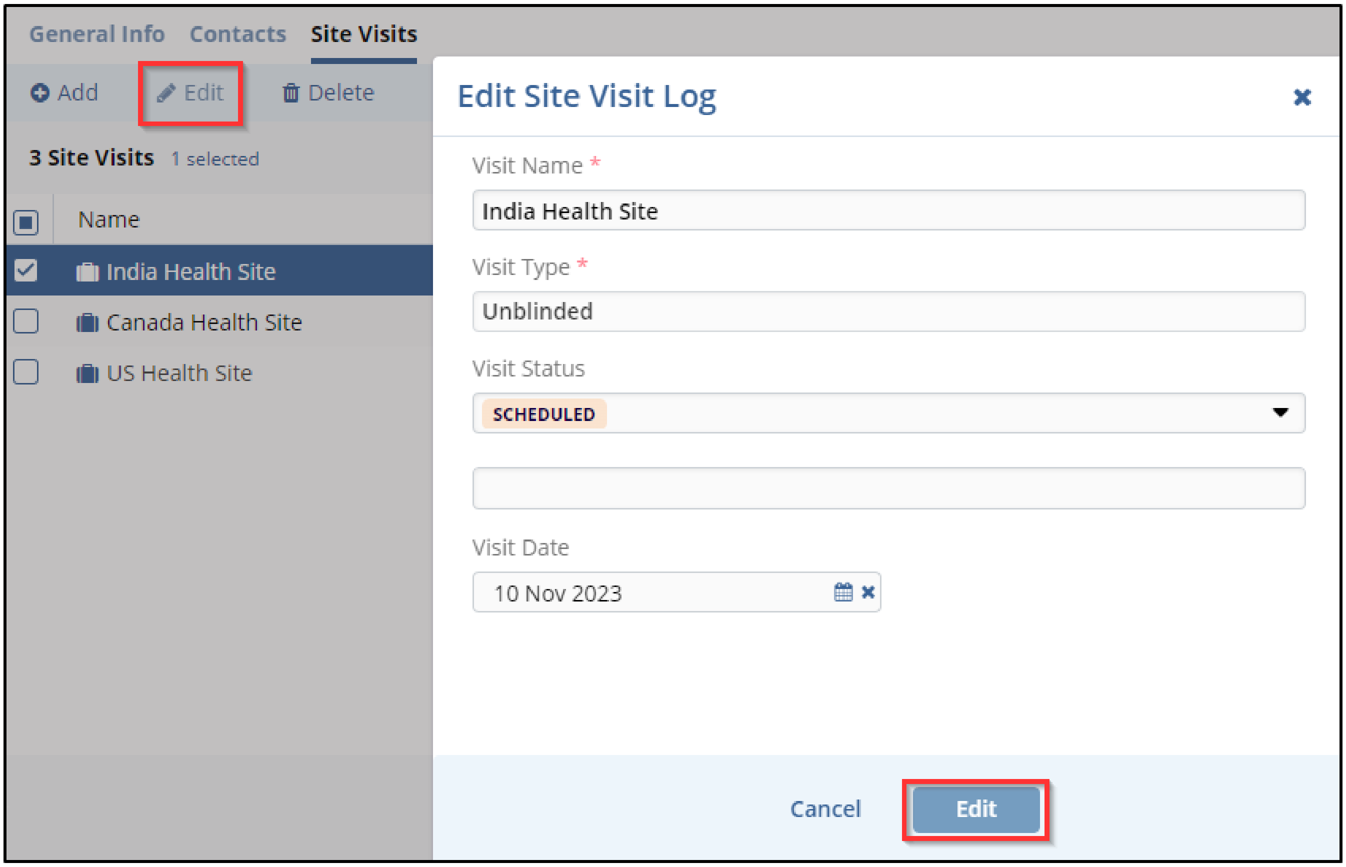
- Click the **Add** button displayed in the top menu bar of the Site Visits tab.
- Enter the details in the fields marked with an asterisk (*) – Visit Name, Visit Type.
- (Optional) The Visit status and Visit Date fields are optional.
- Click the **Add** button displayed at the bottom of the window.



Edit a Site Visit Log

The user can edit a site visit log by following the steps mentioned below:

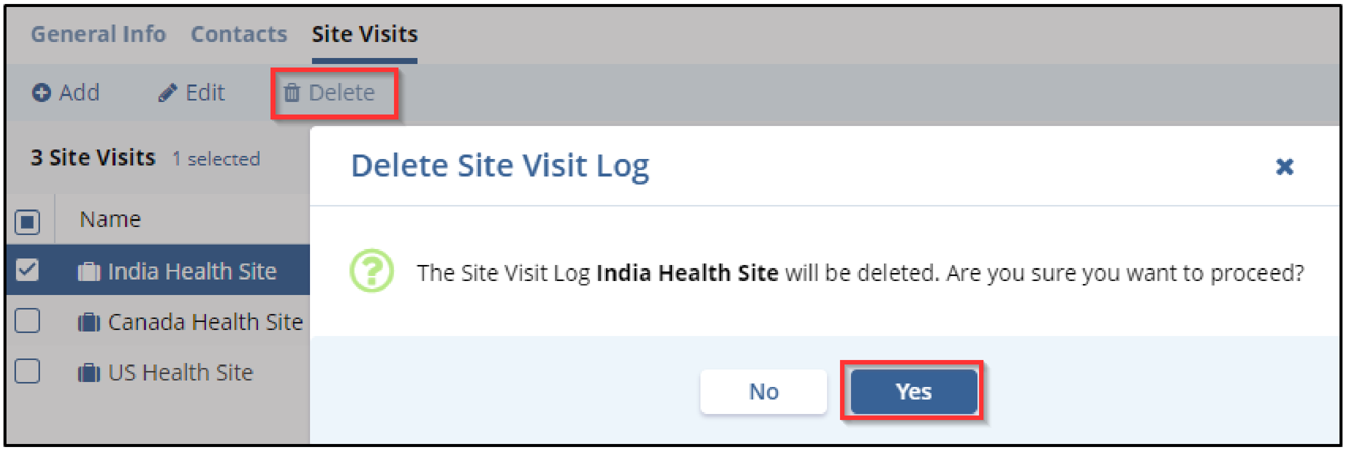
- Select the checkbox of the site that is to be edited.
- Click the **Edit** button displayed in the top menu bar of the Site Visits tab.
- Make the required changes in the Edit Site Visit Log popup window.
- Click the **Edit** button displayed at the bottom of the window.



Delete a Site Visit Log

The user can delete a site visit log by following the steps mentioned below:

- Select the checkbox of the site that is to be deleted.
- Click the **Delete** button displayed in the top menu bar of the Site Visits tab.
- Click the **Yes** button in the Delete Site Visit Log popup window.



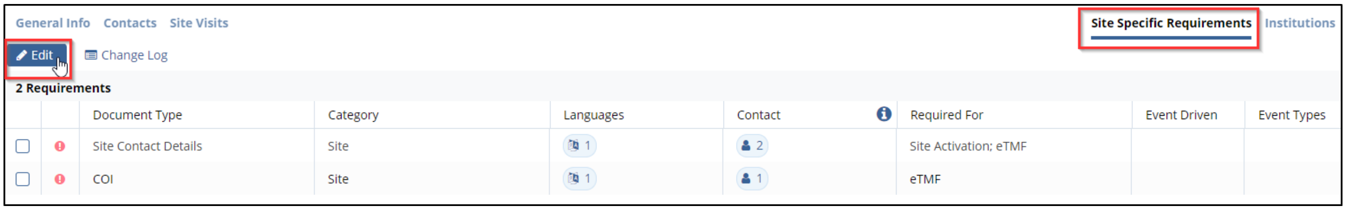
Site Profile - Site Specific Requirements

This section displays the list of all the Site-Specific Required documents. From here, the user can Add, Edit, and Remove the site visit documents, Assign Milestones to the documents, and view the Change Log History of the selected documents.

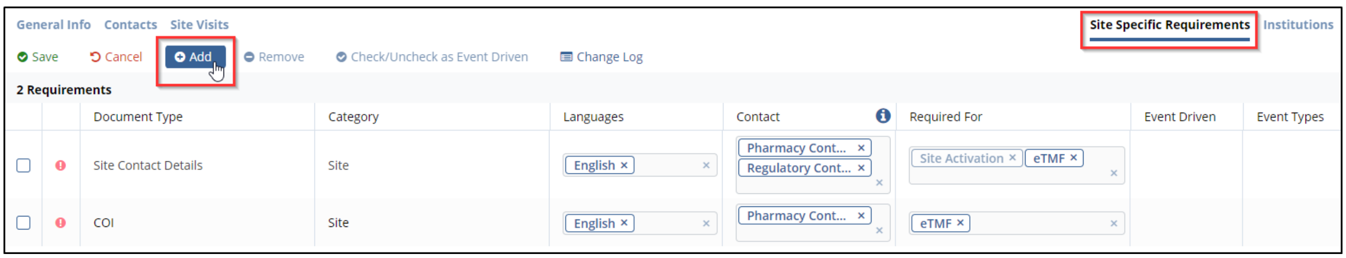
Add Site Specific Requirements

Follow the steps mentioned below to add site specific requirements:

- Select the checkbox of the site to add site specific documents.
- Click the **Edit** button displayed on the top menu bar.

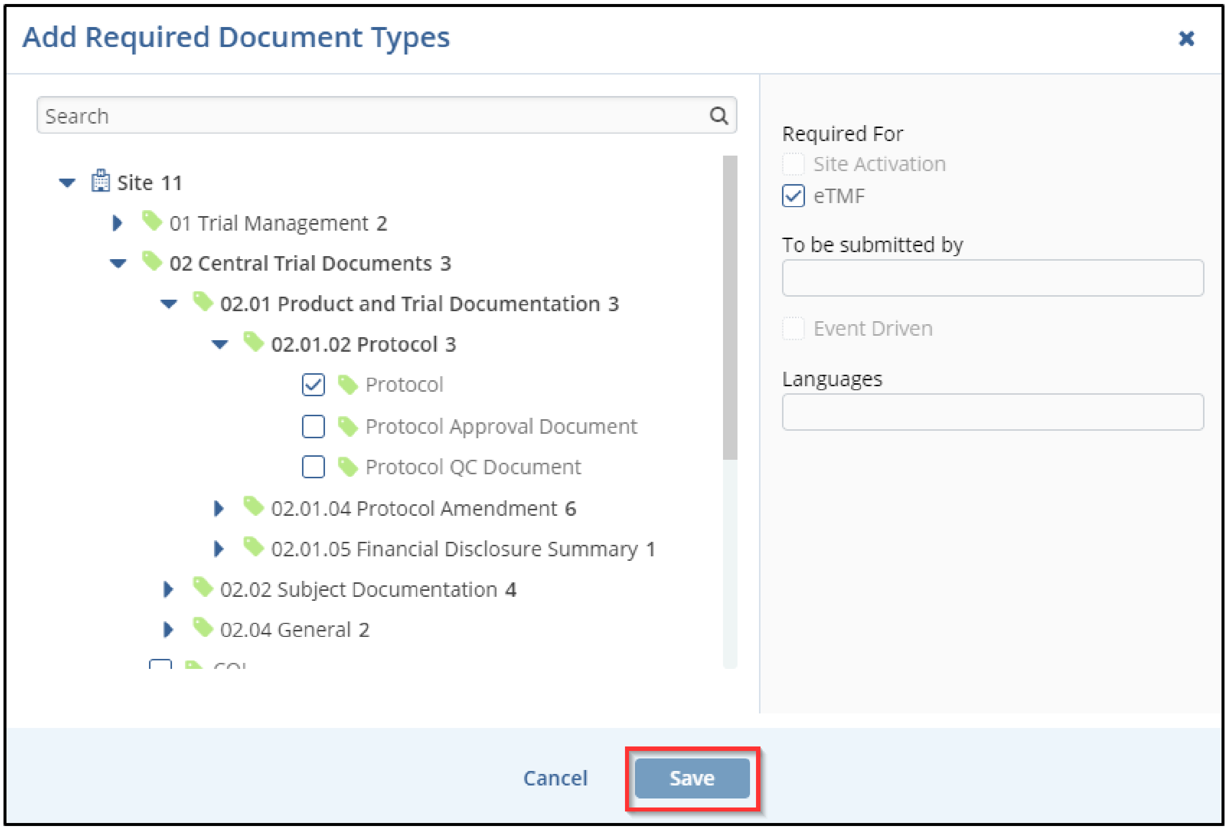


- Click the **Add** button now displayed in the menu bar.



- This opens the Add Required Document Types popup window. Expand the arrow to view the list of required document types.
- Select the checkbox of the appropriate document type.
- Select the checkbox for 'eTMF' in the right-side section of the popup window. this enables the Save button displayed at the bottom.

- Click the **Save** button displayed at the bottom of the popup window.
- The newly added site visit document type is displayed in the grid.



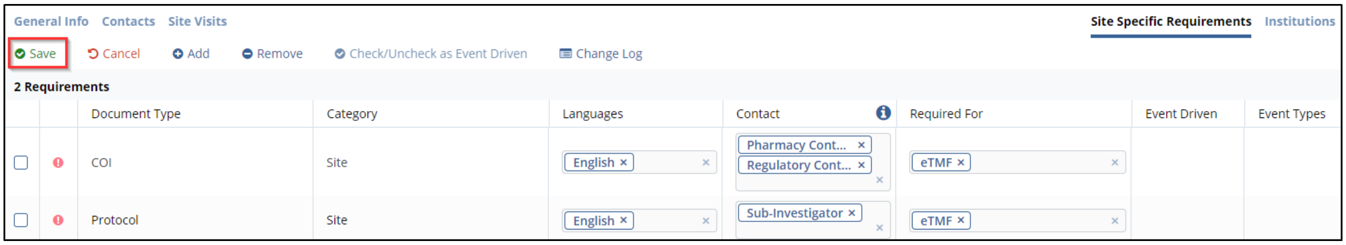
- Again, click the **Save** button displayed in the top menu bar.

Edit Site Specific Requirements

Follow the steps mentioned below to edit the site specific requirements:

- Click the **Edit** button displayed on the top menu bar.

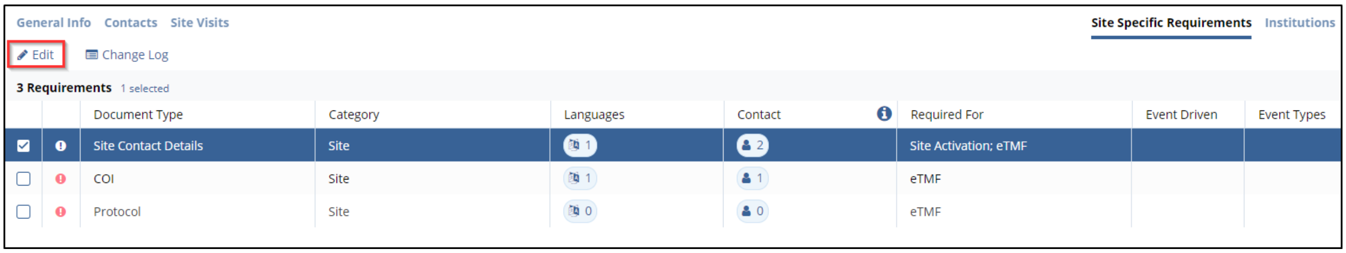
- Make the required changes in the fields.
- Click the **Save** button displayed on the top menu bar.



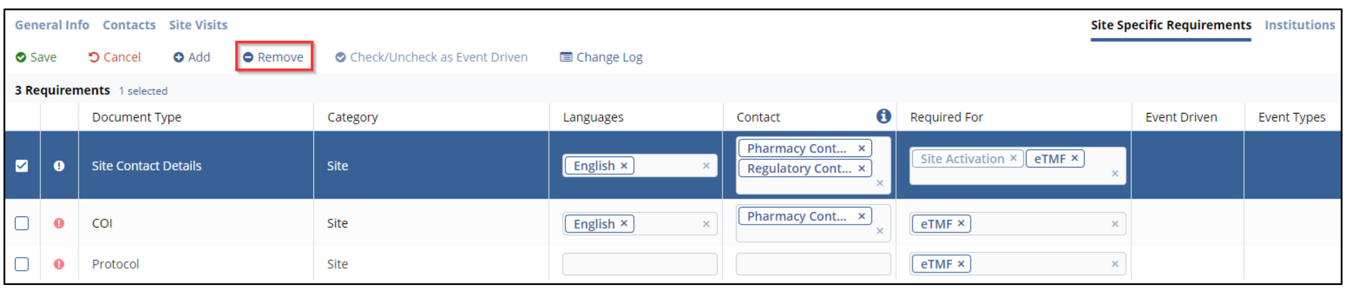
Remove Site Specific Requirements

Follow the steps mentioned below to edit the site specific requirements:

- Select the checkbox of the site visit to be removed.
- Click the **Edit** button displayed on the top menu bar.



- This changes the buttons displayed on the top menu bar.
- Click the **Remove** button.

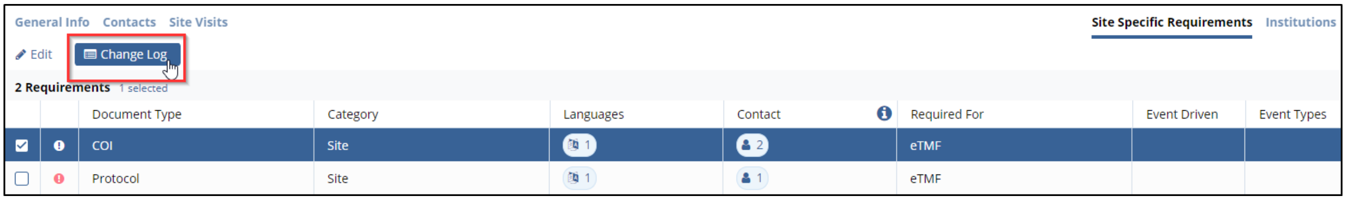


- Click the **Save** button to reflect the required changes.

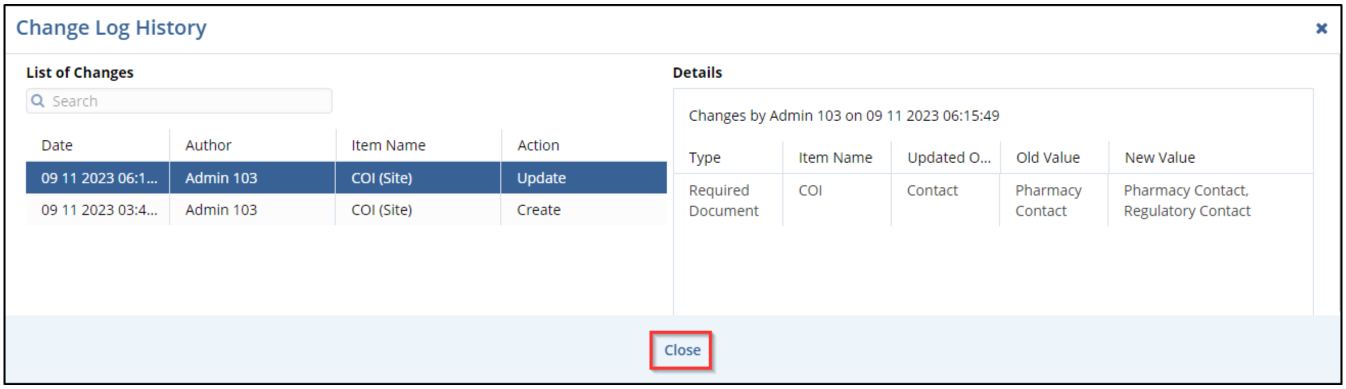
Check/Uncheck as Event Driven

Change Log

This log displays the list of changes done by a user in the documents. Click the Change Log button to view the Chang Log History popup window.



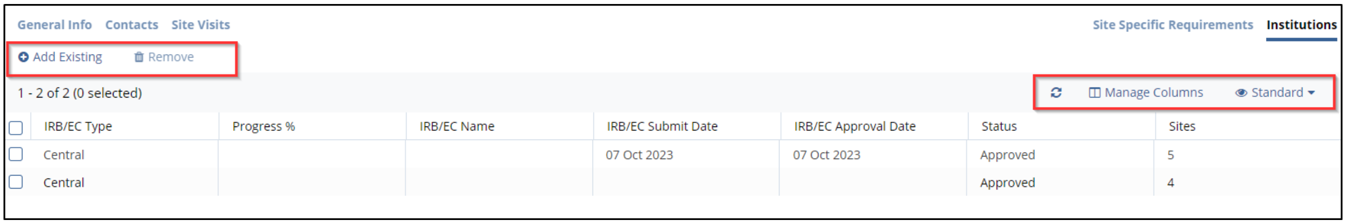
The popup window displays two sections – **List of Changes** and **Details**. Click a list to view its details in the right-side window.



Note: The user can only view the details in the Change Log History and cannot make any changes in the same.

Institutions

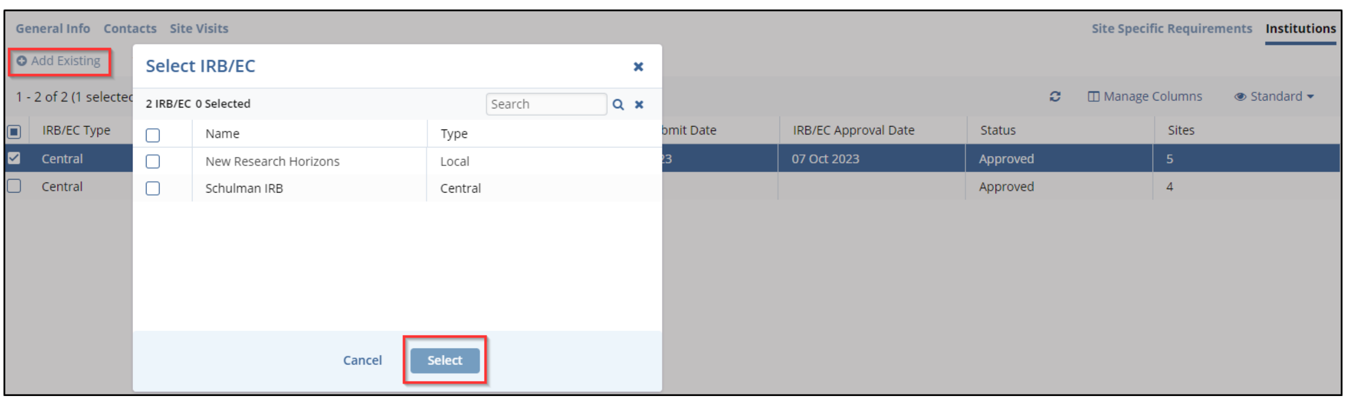
This tab helps the user to add existing IRB/EC, Remove an IRB/EC, Refresh, Manage Columns, and Save Views.



Add Existing IRB/EC

Follow the steps below to add an existing IRB/EC to the list of institutions:

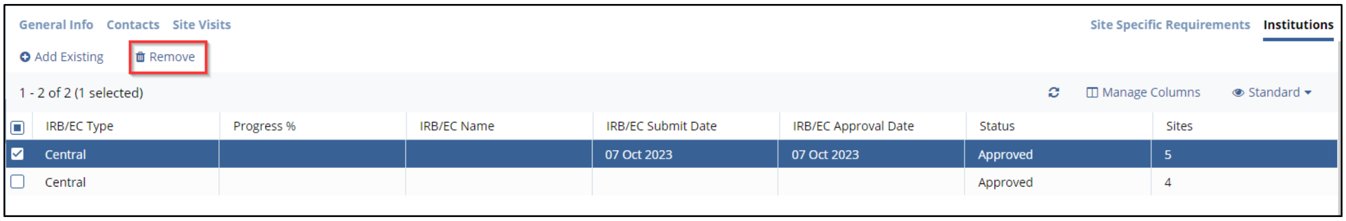
- Click the **Add Existing** button displayed on the top menu bar. This opens the Select IRB/EC popup window.
- Select the checkbox of the required IRB/EC.
- Click the Select button displayed at the bottom of the popup window.



Remove IRB/EC

Follow the steps below to add an existing IRB/EC to the list of institutions:

- Select the checkbox of the IRB/EC to be removed.
- Click the **Remove** button displayed on the top menu bar. This opens the Select IRB/EC popup window.

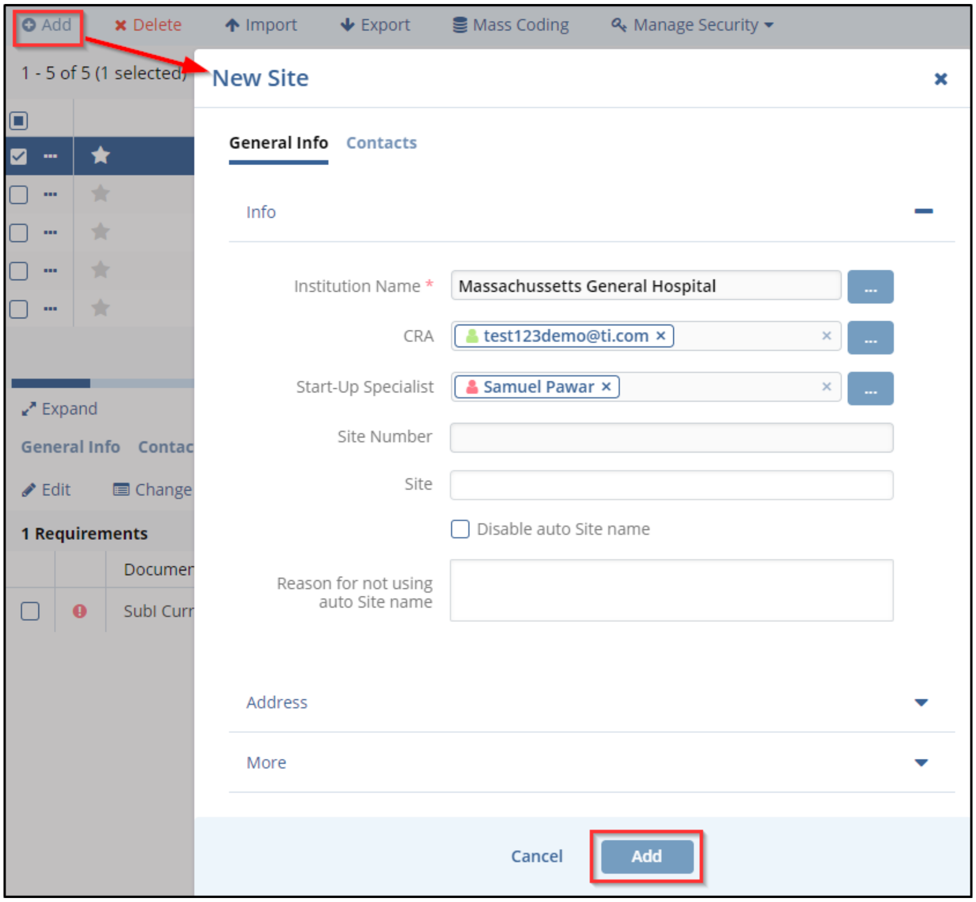


Adding, Editing and Deleting Sites

1. Important: The following description is for adding Investigative Sites in an eTMF:

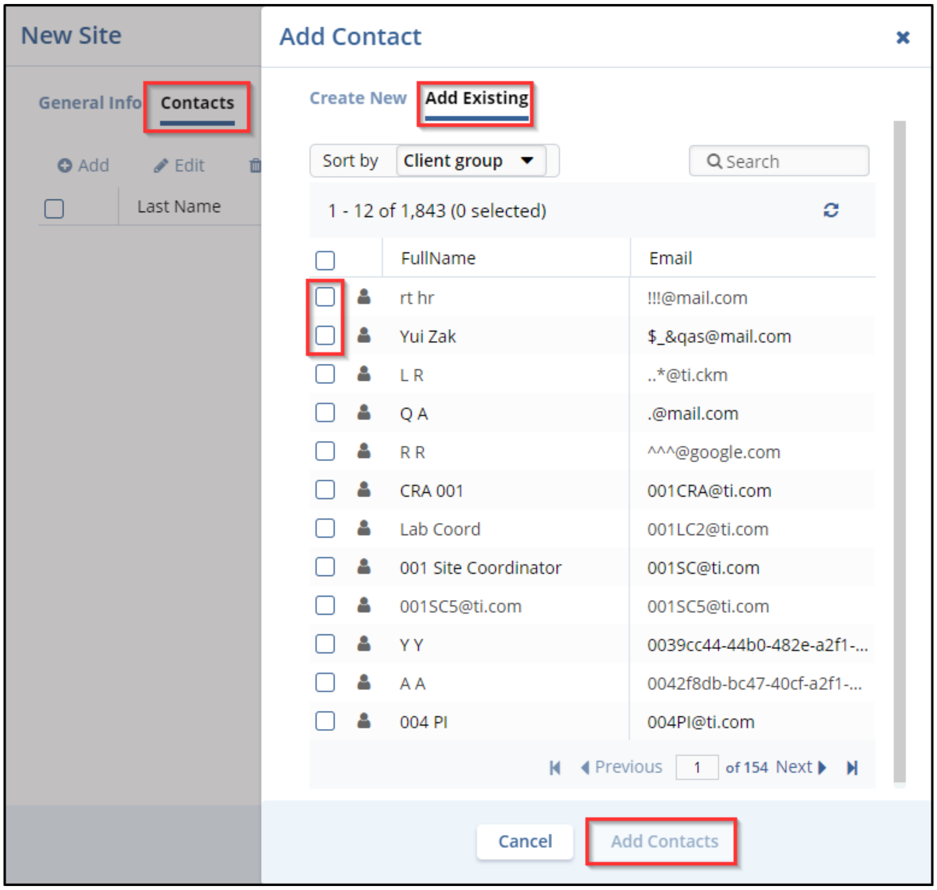
Adding a Site

1. Click the **Add** button from the top ribbon bar. The New Investigative Site window opens. Refer to the screenshot below:



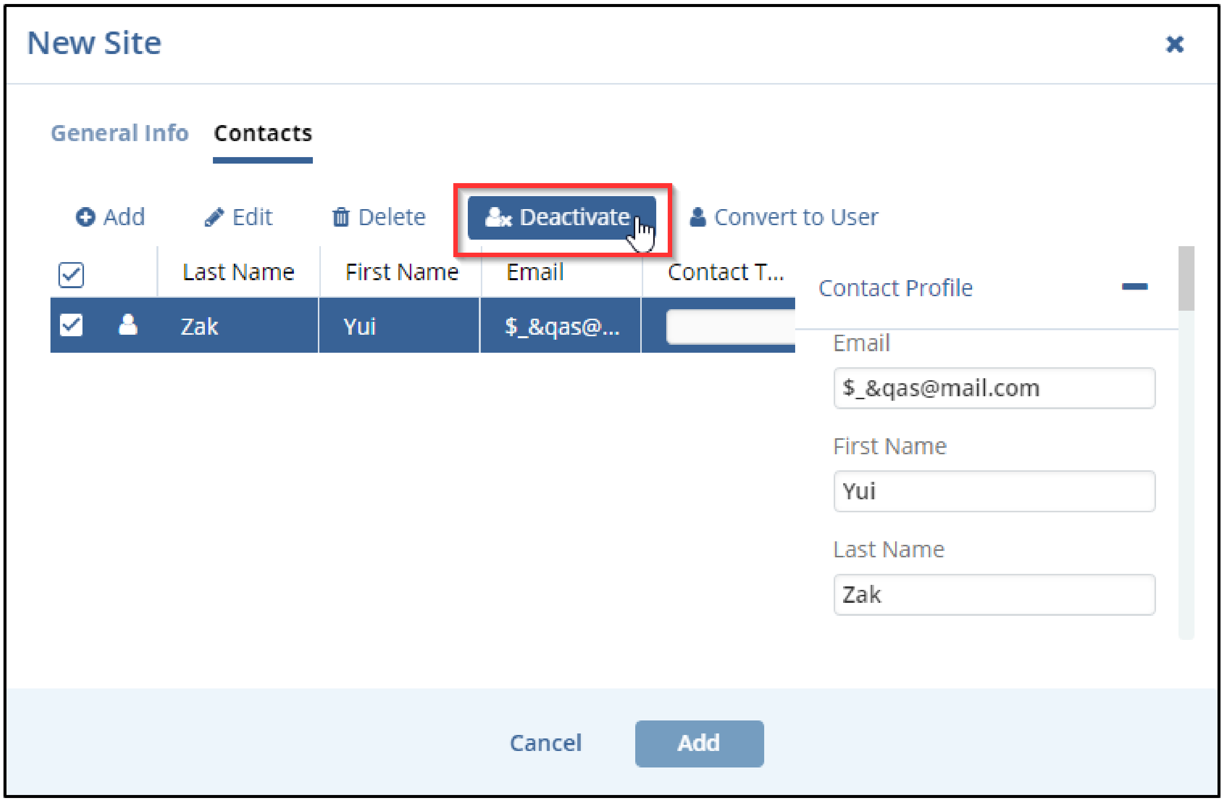
2. Either type the Institution Name in the available field or click the search icon to view the list of Available Investigative Sites. Investigative site information is stored in Trial Interactive's database.
    a. If you have used an investigative site in a previous study, the site's information will be stored and easily accessed through this option.

3. Create or Add existing contacts from the Contacts panel in the window. This information will be supplied by the client and can be created under Contact Types in Investigative Site Settings.
    a. You can also add the Contact Type by clicking the contact type field which will then reveal the dropdown list to select your choice. Refer to the screenshot below:



4. Select an added contact and click Edit in the Contacts panel to edit the contact information entered above or Delete to delete a contact information. You can also edit a contact by double- clicking the contact in the Contacts panel.

5. Click **Activate** or **Deactivate** to activate or deactivate a contact. This will either check or uncheck the Active Contact checkbox in the Edit contact window. Refer to the screenshot below.



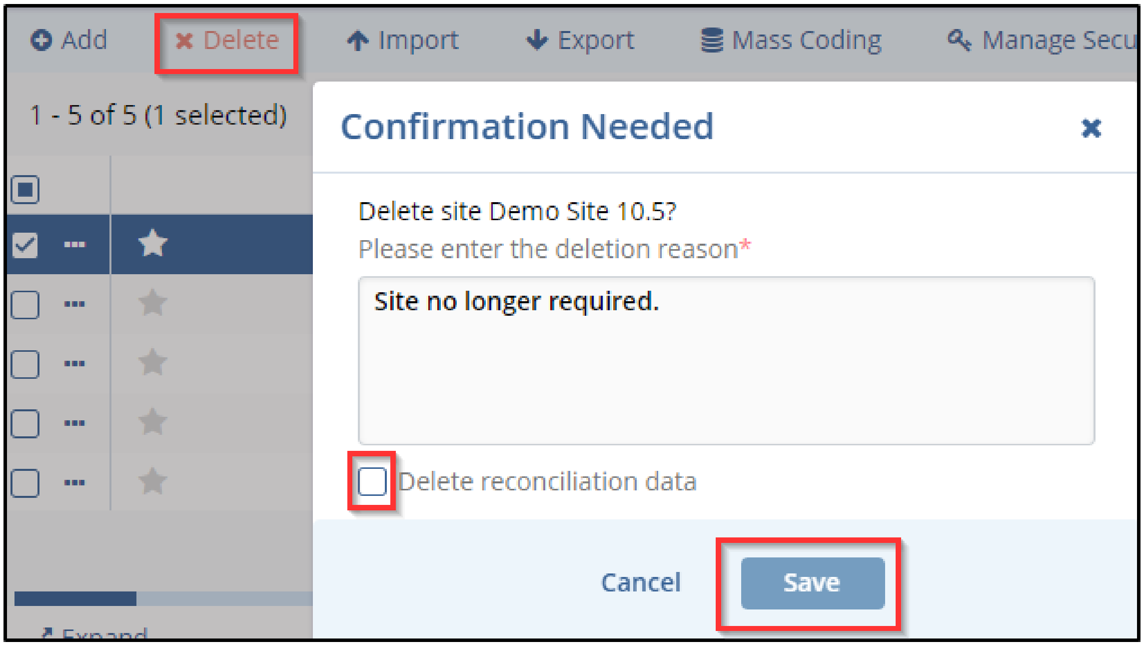
6. You can assign a site contact the role of editor or reader and assign actions as appropriate from the Contacts panel.
7. Click the dropdown arrow for '**Address**' to reveal the fields to enter the site location details.
8. Click the dropdown arrow for '**More**' to open another array of data fields. Enter the investigative site information.
9. Click the '**Add**' button displayed at the bottom of the window.

Editing a Site

Similarly, you can Edit a site by first selecting the site from the right pane and then clicking the Edit button from the top ribbon bar. You can also edit a site from the Site Profile window. This is discussed in the section regarding the Site Profile.

Deleting a Site

Select a site first and then click the **Delete** button from the top ribbon bar to delete a site. Enter a reason for deleting the site (mandatory).

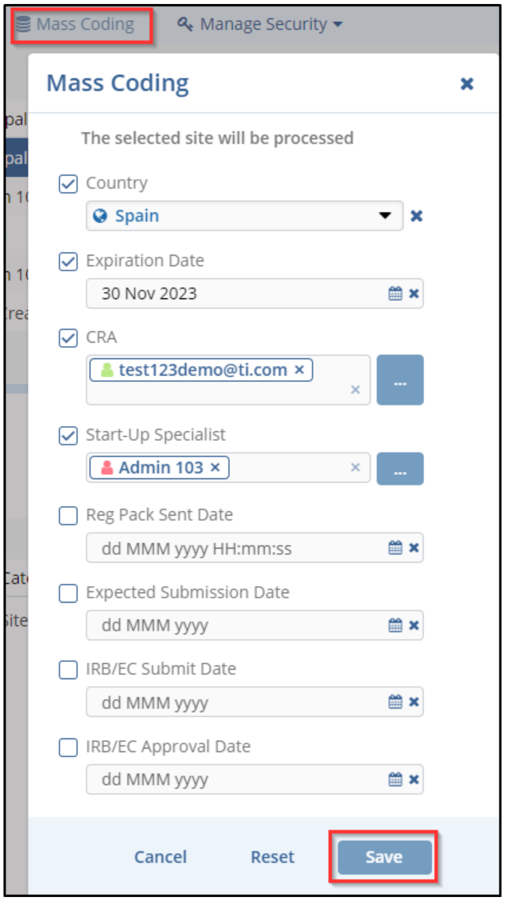


Optional- Select the checkbox for deleting the reconciliation data.

Mass Coding for Sites

Users are sometimes called upon to fill in or update information of a number of sites in a room at the same time. When these changes are consistent across a group of sites, the Mass Coding option saves a lot of time and keystrokes.

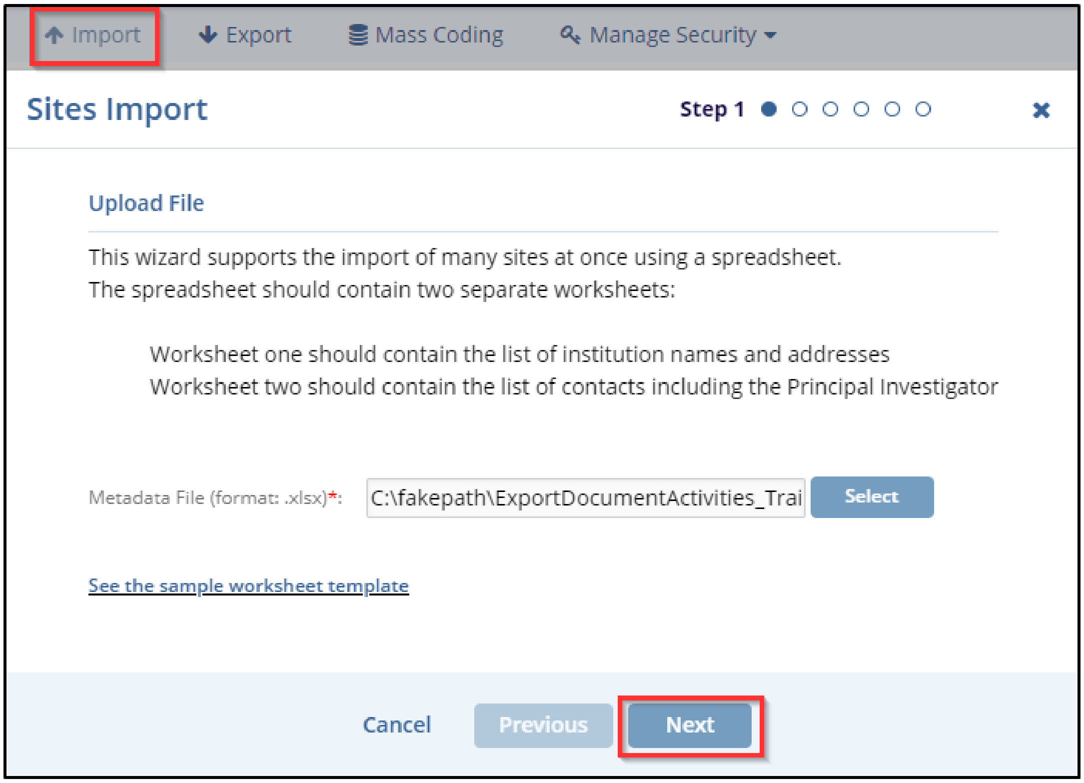
1. Select the sites to be coded in your grid.
2. Click the **Mass Coding** icon from the top menu bar. The Mass Coding window will open.
3. Fill in the details by double-clicking the fields or clicking the Calendar icon to the required fields.
4. Click **Save** to proceed with mass update of the sites' information. You can select multiple CRAs and Start-Up Specialists if required. Refer to the screenshot below.



Importing Sites

The metadata and contact information for an investigative site can be imported by using the Import icon located on the top ribbon bar. It runs the metadata import wizard where the user can upload a .xlsx spreadsheet. There is also a link to download the sample worksheet template.

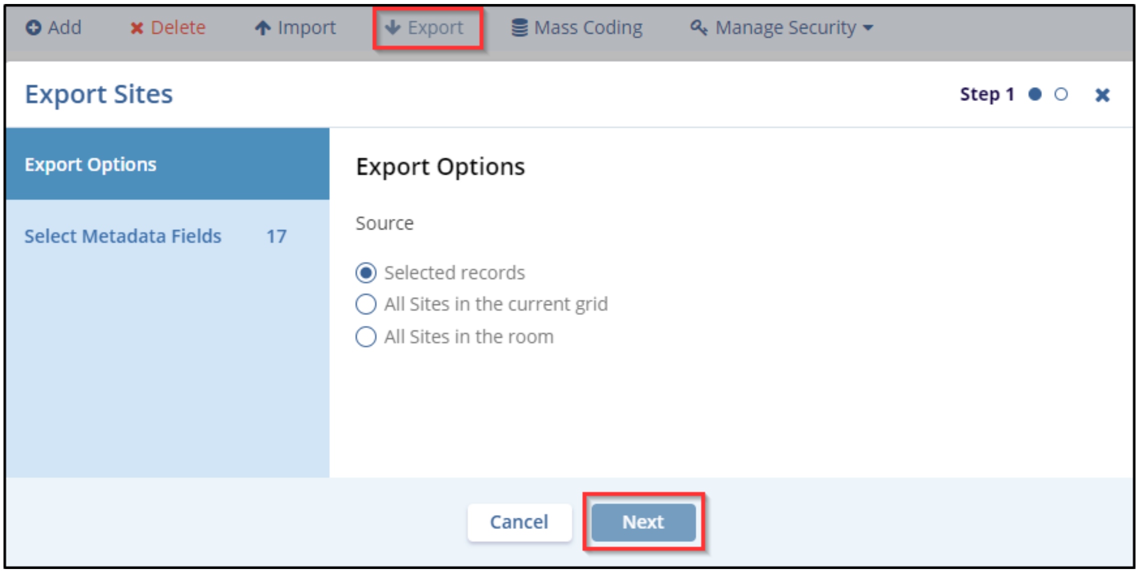
1. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import just contacts so they will be mapped to existing investigative sites. The wizard offers a link to the sample worksheet so the user can download it and fill it with actual data. Click Next. Refer to the screenshot below:

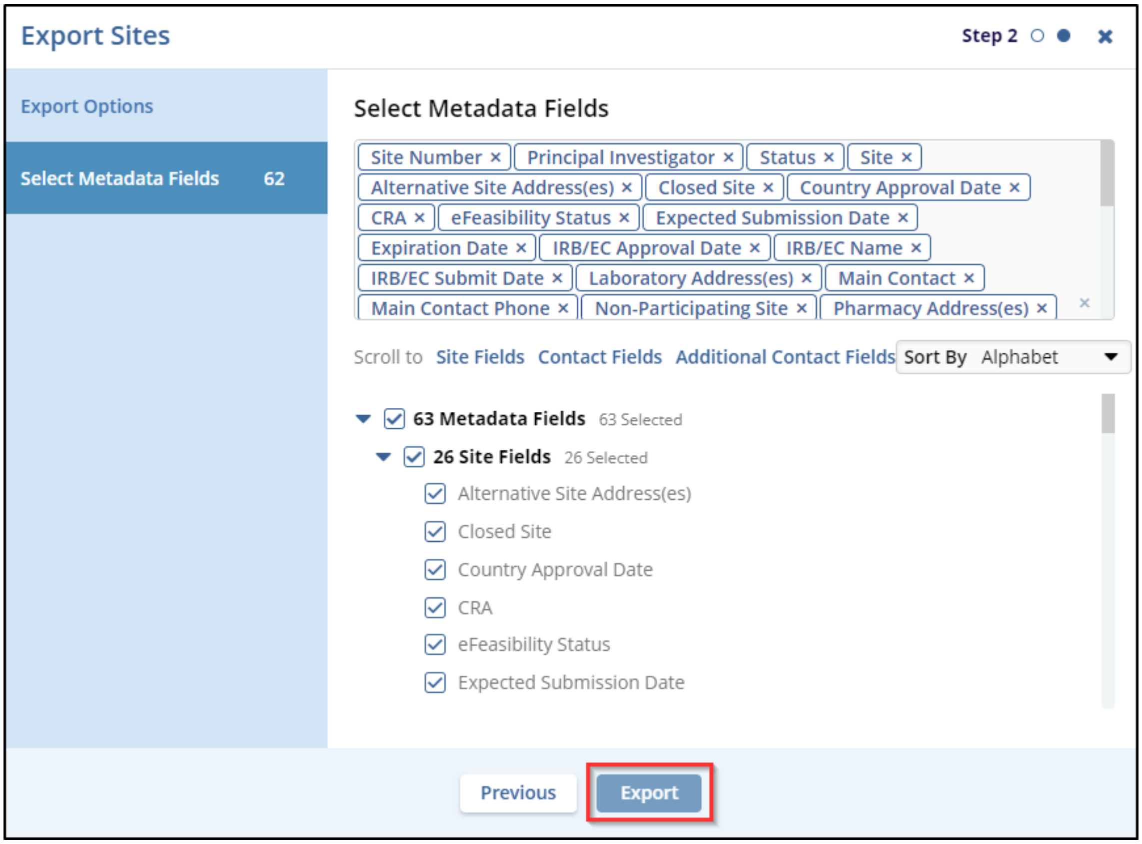


2. Setup the mapping between metadata fields and uploaded file columns for Investigative Sites.
3. Setup the Contacts related metadata. Click **Next**.
4. Review the entries made and, when ready, click Next to confirm.
5. This will begin the actual import process. Upon completion, the user will get a short report on any issues that occurred during import.
6. It is also possible to download the full report as a text file. The import operation can be aborted at any time.

Exporting Site Information

You can also export site metadata by clicking the 'Export' button on the ribbon. Select the Site Metadata Fields to be exported as shown below:

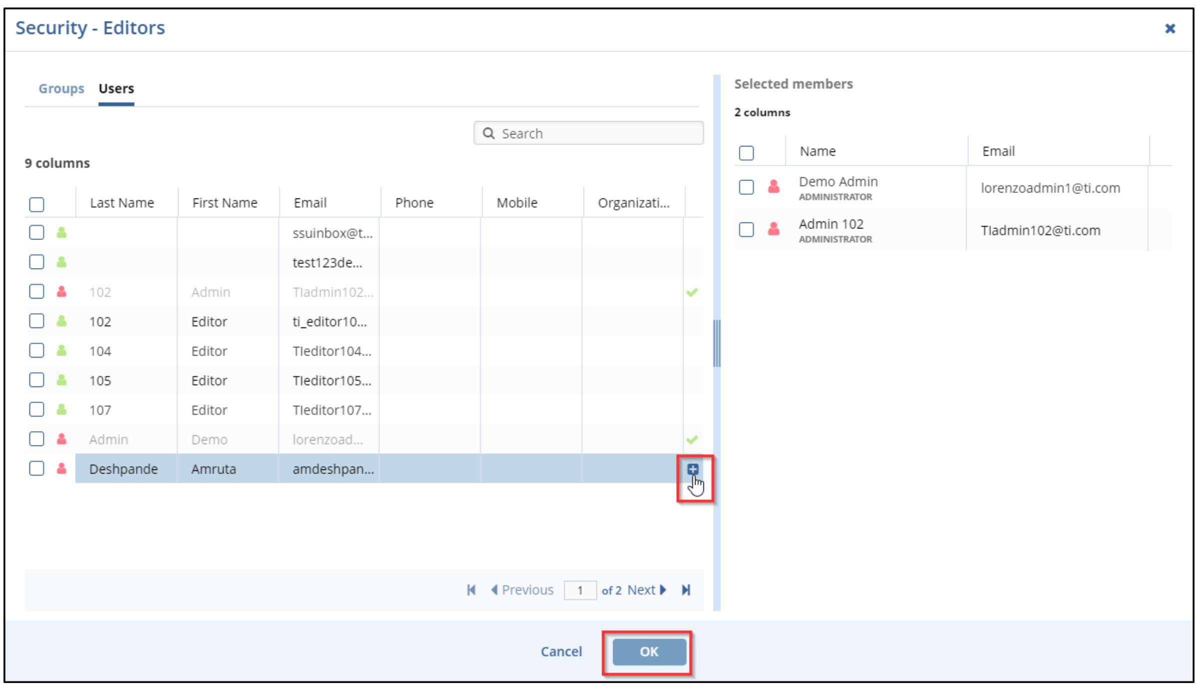




Managing Security for Sites-Editors and Readers

As mentioned in the Site Profile section, in each site profile are security groups for users. eISF rooms take especial care about who gets added to each group and, for the most part, we recommend working with the TI Service Desk to set up individual site security for those rooms. In addition to site-profile-level security, there are site-folder security setting which are discussed in the chapter on settings. These are normally set up during room configuration and specify which users or groups of users have access (and what kind of access) to each of the site folders.

If you do choose to manually add and remove users via the site profile, you will want to expand the security section as shown below (Administrators only):



Clicking in the field or on the three-dot icon will allow you to add new members or groups to the security groups listed. Reader groups are those who can only view site related information whereas Editor groups are allowed to make changes to the fields to which they have access.

Chapter 17. eSigning Document

This section describes the eSigning process in the application.

Electronic signatures may be applied in all TI room types. However, we normally would expect this to be done prior to a document being submitted to the eTMF. Trial Interactive has a native electronic signature called TI Sign but your Trial Interactive rooms can also be configured to work with other electronic signature software. Additional information on the electronic signature settings is available in the chapter on Settings.

Any user who should be able to send a document for signature or sign a document should have the eSignature action assigned to their user profile. For additional information regarding adding actions to user accounts, please see the section on User Management.

Initiating the eSignature Process

In order to send a document for signature, please follow these steps:

1. Locate the document in the **Documents module/Documents Library.**
2. Open the Document Activities menu by right-clicking on the document or by clicking on the three-dot icon on the document line in the grid.
3. Select the 'Send for eSignature' option.
    - This will open the 'Send for eSignature' window.

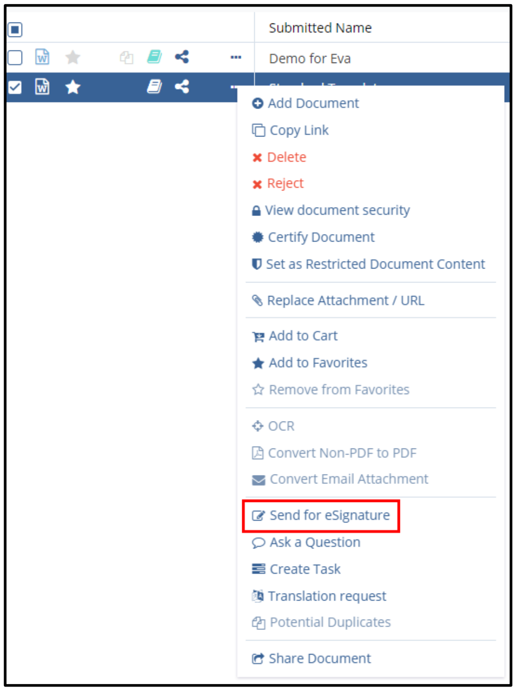


Figure 1: eSignature Sending Option

4. Choose the user or users who will need to sign the document by moving them from the left side to the right side.

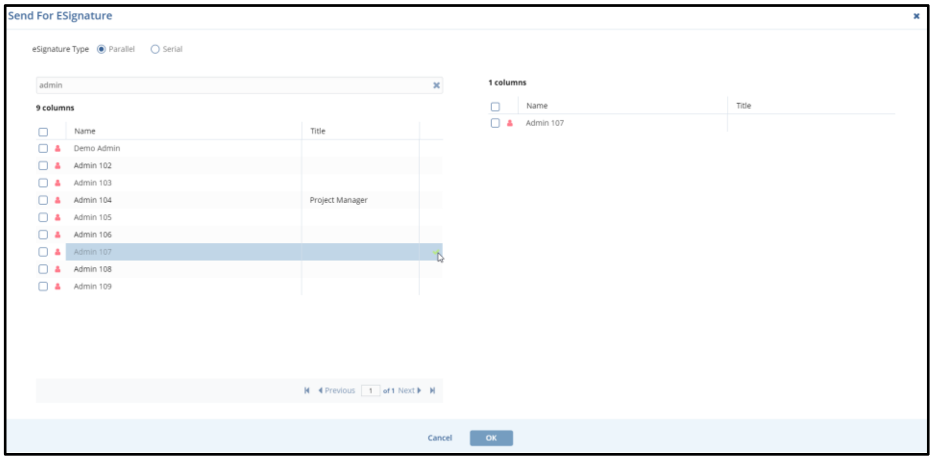


Figure 2: eSignature Page

5. Using the radio buttons at the top-left, indicate whether the signatories (assuming that there is more than one signature required) should sign in parallel or if they need to be completed one at a time.
6. Press '**OK**'
    - From this point on, the steps will vary depending on which signature vendor your study room is using. For all but TI Sign, the system interface will open and the user can complete the process using the assigned vendor.
        - See the steps below for signing documents with TI Sign.

Signing a Document with TI Sign

A user who has been assigned a document to review and sign can do so either via the related dashlet or directly from the Documents module.

Signing a document via the 'Documents to be Signed' dashlet

1. Navigate to the Dashboard and locate the 'Documents to be Signed' dashlet.

Figure 3: eSignature for Dashlet

2. Double-click on the document to be signed.
    - This will open the document and the eSignature tab of the metadata panel in a popup window.

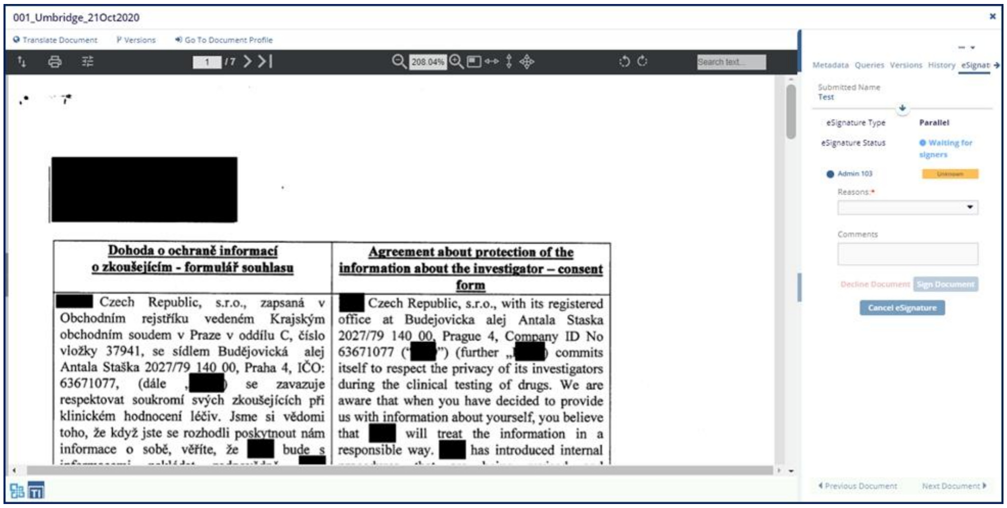


Figure 4: eSignature Tab

3. Indicate your reason (either for signing or for rejecting the document) using the dropdown menu.
    - The reasons are populated from the Settings area and are usually set up during room configuration. Please see the chapter on Settings for additional information.
4. Make any necessary comments.
5. Press the button for the appropriate action (Signing or Declining).
6. Use your Username and Password to verify your identity and complete the signature process.

Signing a document via the Documents module

1. Navigate to the document in the Documents module.
2. Select the document to be signed.
    - This will cause the document's metadata panel to populate. If necessary, expand the metadata panel.
3. Select the eSignature tab of the metadata panel.

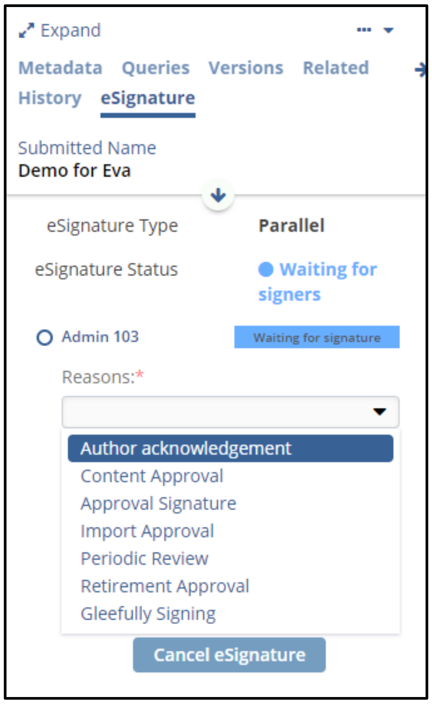


Figure 5: eSignature Reasons

4. Indicate your reason (either for signing or for rejecting the document) using the dropdown menu.
    - The reasons are populated from the Settings area and are usually set up during room configuration. Please see the chapter on Settings for additional information.
5. Make any necessary comments.
6. Press the button for the appropriate action (Signing or Declining).
7. Use your Username and Password to verify your identity and complete the signature process.

Chapter 18. Tasks

This section explains the tasks application that allows users to manage their tasks for their rooms.

Users are given an option to add, edit, delete, or export tasks. Additionally, users with appropriate actions on the user profile can adjust the number of days before a task's deadline for a user to receive an email message as a reminder of the task's due date. They can set up the reminders from the Reminder section of the metadata panel of a task.

You can access Tasks as mentioned below:

1. Enter the room for which you want to create tasks
2. Click the Navigation Grid
3. Click the **Tasks** icon.
4. You are taken to the Tasks page.
   Refer to the screenshot below:

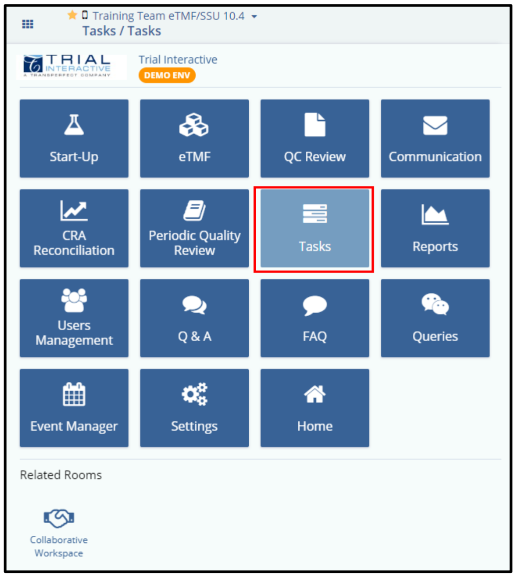


Figure 6: Tasks Module

Creating Tasks

Tasks are a way to set reminders for yourself and your team and to track the completion of study-related activities. Users who have the Assign Tasks action on their user profile can assign tasks to other users in the room.

<u>To create a task, follow these steps:</u>

1. Navigate to the Tasks module via the Navigation Grid in the top-left corner of the screen.
   - Any previously created tasks will appear in the index panel.
2. Press the 'Add' button above the index pane.
   - This will open the 'Create Task' window.

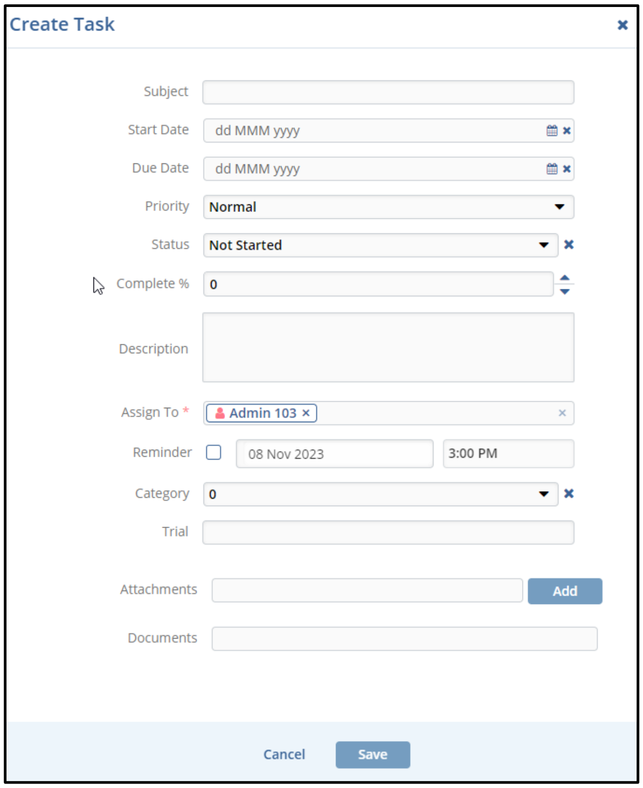


Figure 1: Create Task

Editing Tasks

<u>To edit a task, follow these steps:</u>

1. Navigate to the Tasks module via the Navigation Grid in the top-left corner of the screen.
    - Any previously created tasks will appear in the index panel.
2. If necessary, change your view of the tasks to sort them in a different way.

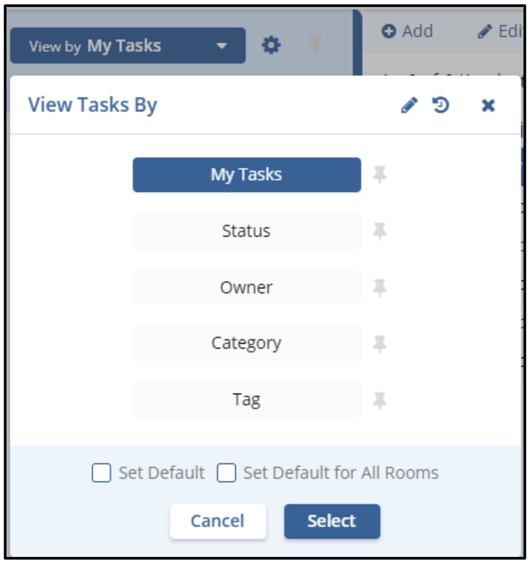


Figure 2: Task View

3. Locate the task to be edited and select it from the grid.
4. Press the 'Edit' button above the index pane.
   - This will open the 'Edit Task' window.

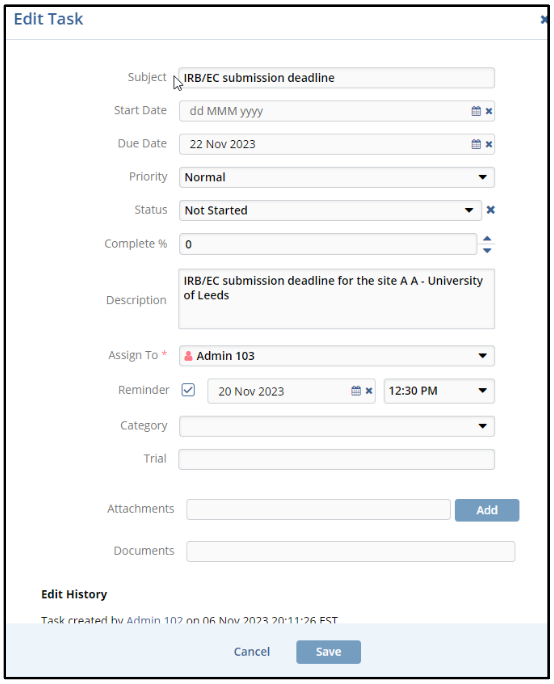


Figure 3: Edit Task

5. Make any necessary changes
6. Press '**Save'** when done.

Chapter 19. Communications

The communications module is intended to capture study-relevant communications.

Emails that are sent to the Communications Inbox are automatically converted to PDF format. Messages received in the Communications Inbox need to be reviewed by study room users to determine whether or not they are relevant to the study prior to their being added to the room's QC workflow.

The Communications module can be accessed via the Navigation Grid at the upper-left corner of the screen.

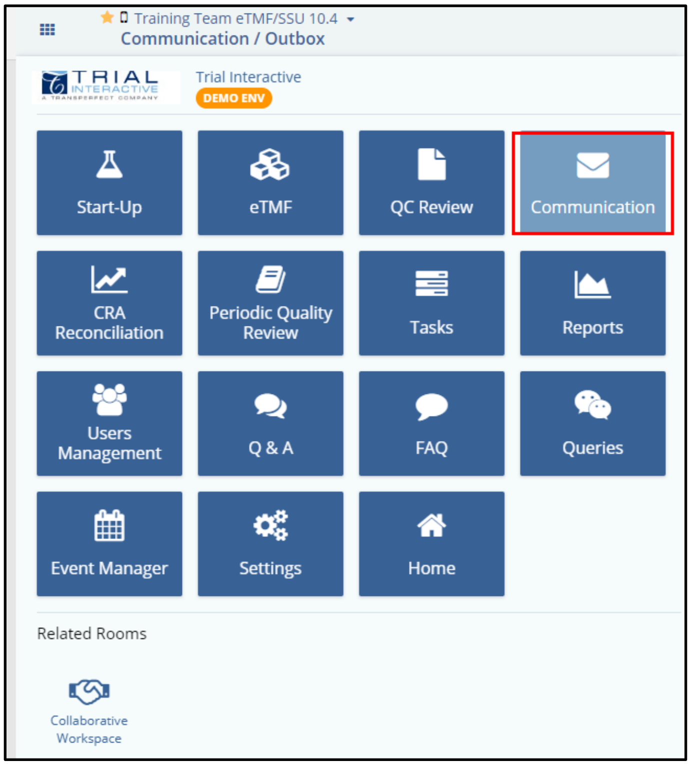


Figure 1: Communication Module

Communications Module

Once you enter the Communications Dashboard, you will have access to both the Inbox and the Outbox views from the left menu. Refer to the screenshot below:

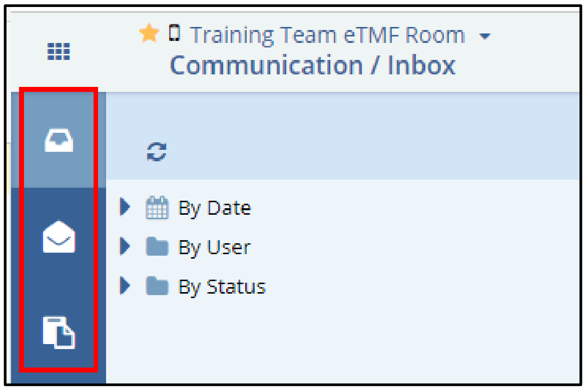


Figure 2: Inbox and Outbox module

Communication Inbox

From this area, you can perform the following functions:

- The Inbox Settings
- The Inbox Process

Reviewing Communications

Follow the steps below to review communications and mark them as relevant or non-relevant.

1. Navigate to the Communications module.
    - The communications will be displayed in the following categories:
        a. By Date
        b. By User
        c. By Status

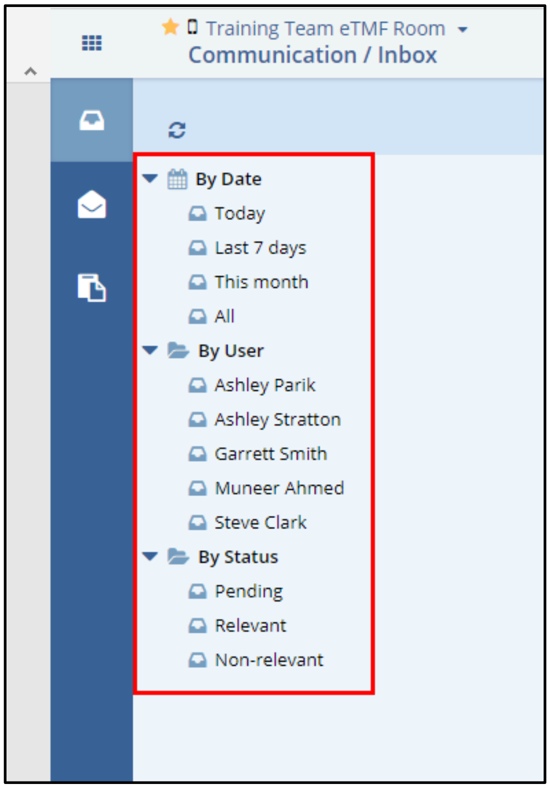


Figure 3: Inbox Folders

2. Choose whichever category you would like (By Status is recommended for this process).
    - The communications will load in the grid.
3. Select a communication in Pending status.
    - The communication's details will load in the metadata pane.

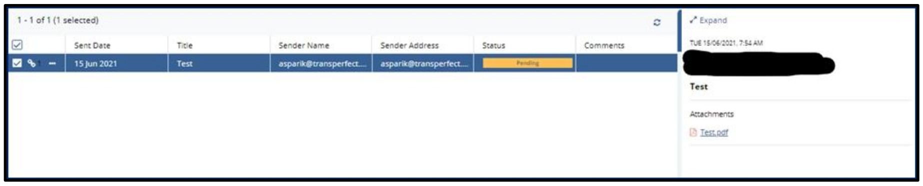


Figure 4: Communication Metadata Tab

4. Click on the pdf file shown in the metadata pane to review the communication.
5. Press either the Relevant or Non-Relevant button at the bottom of the metadata pane as appropriate. See the screenshot below.

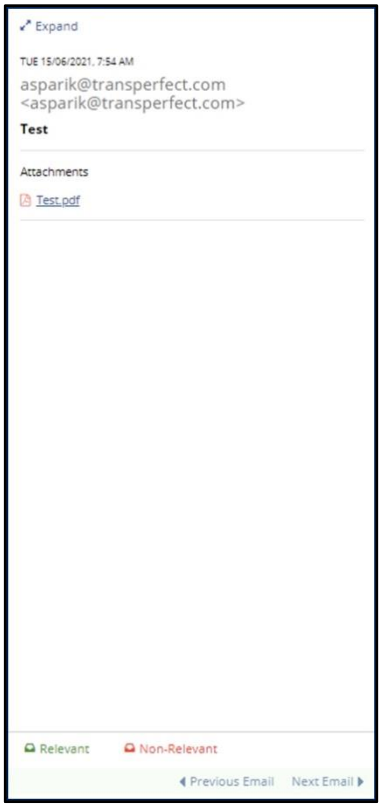


Figure 5: Relevant and Non-Relevant Options

6. If you choose 'Relevant' you are indicating that the system should generate a new document for the study room using this file. As such, you will be required to apply the required metadata in the 'New Document Profile' window.

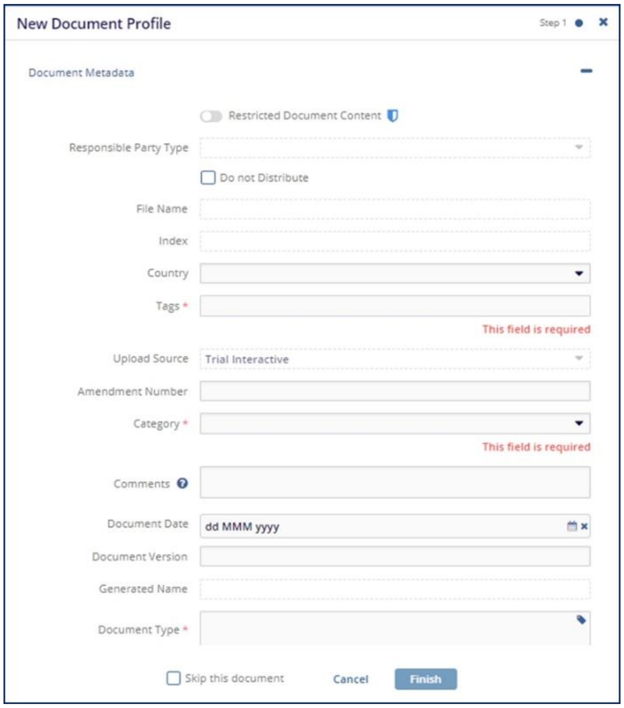


Figure 6: new Document Profile

7. When you are done applying metadata to the document, press 'Finish.'

Communication Outbox

Documents or messages emailed from a Trial Interactive room are stored in the Communication Outbox. The Communication Outbox is the holding area for messages or emails that are sent out from a Trial Interactive room. The left pane of the Outbox module gives the views of the emails By Date and By Type. You can also export communication emails.

Viewing Outbox Message Information

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

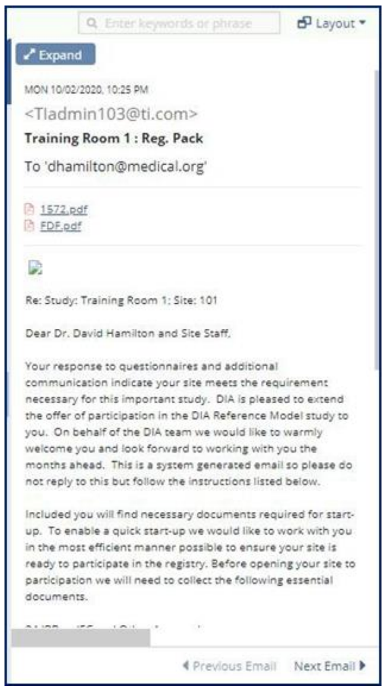


Figure 7: Communication outbox

Export Communication Emails

You can export mails by clicking the Export icon on the top ribbon bar. This will open the Export messages window. You can export all messages in the current grid, or only selected messages. Refer to the screenshots below:

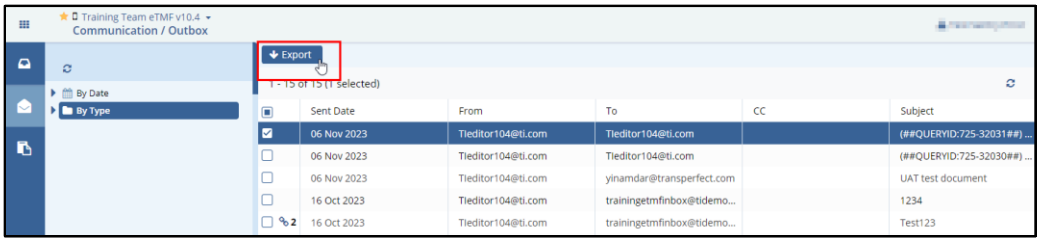


Figure 8: Communication Export

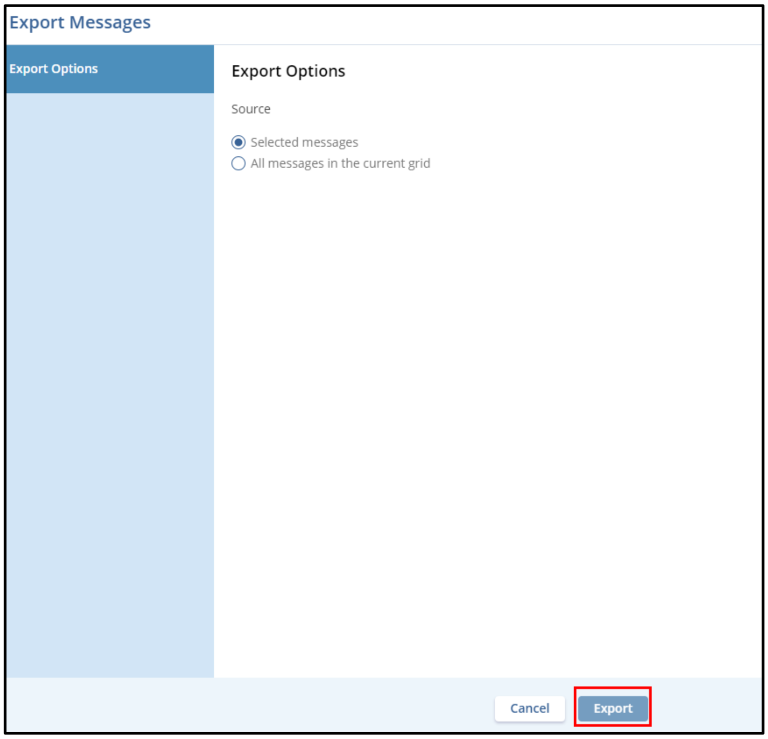


Figure 9: Export Message Page

The confirmation of the export job is displayed in a popup at the top of the grid.

You can Get Job Results from the Notifications area of the Username menu. Refer to the screenshot below.

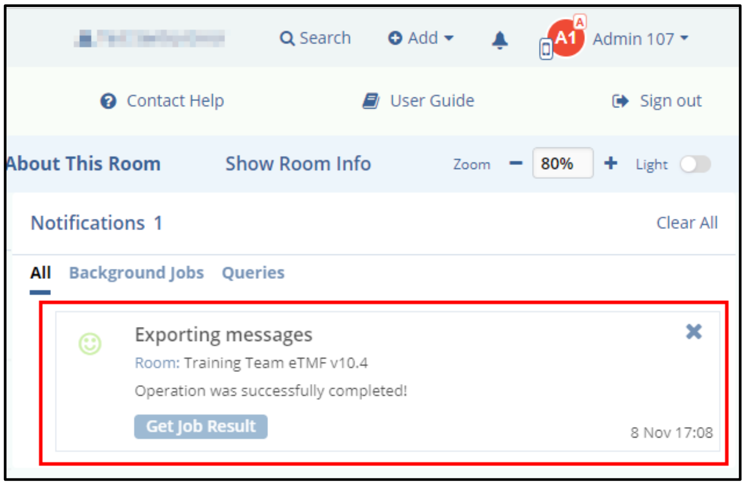


Figure 10: Exporting Notification

Chapter 20. FAQ

The Frequently Asked Questions, or FAQ Module of Trial Interactive provides a convenient and readily-available place for your study team to store all commonly-asked questions about your clinical trial.

This module may be made easily available to anyone who has access to the eTMF, Site or Study Collaborate rooms as well as a standard Content Management workspace.

During a Clinical Trial, so many questions come up from the team. These questions can range from document naming conventions, instructions on how to classify certain metadata and content, who to contact for specific study information, all the way to entries for each Investigative Site providing contact information and other critical information. If your CRAs, CTAs, and Clinical Document Specialists have access to the right answers your project can run much more efficiently. Simply click on the FAQ Module and take a look.

How it Works

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

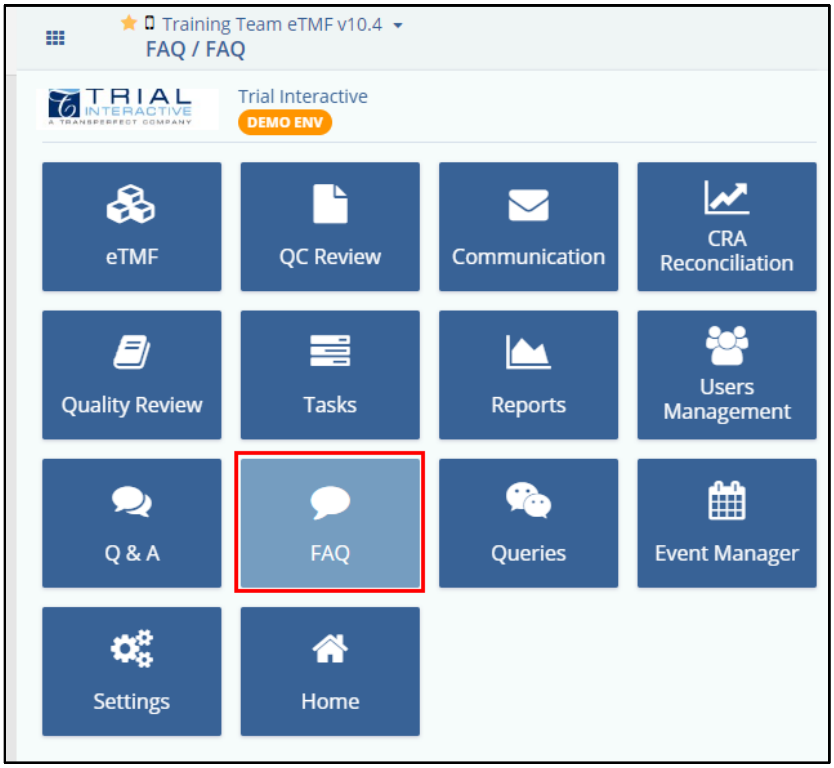


Figure 1: FAQ Module

Adding **FAQ** Categories

1. Navigate to Navigation Grid a Settings > FAQ
2. Click Add. Refer to the screenshot below:

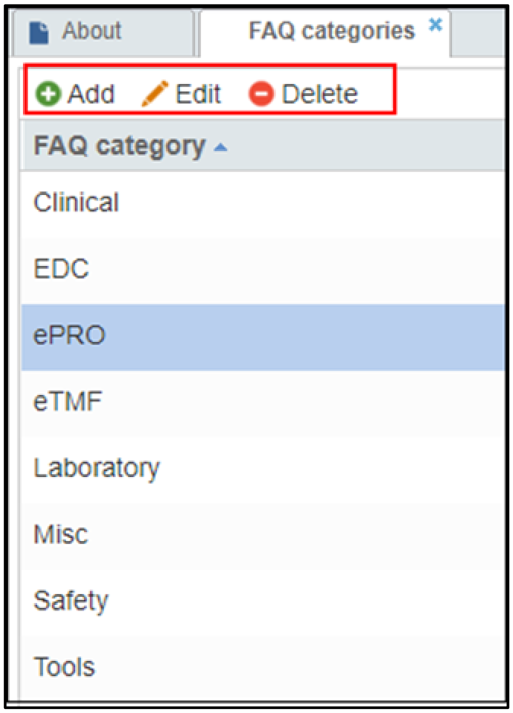


Figure 2: Setting FAQ (Add, Edit, Delete)

3. Click Save after making any changes.

Editing FAQ Categories

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

Deleting FAQ Categories

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

FAQ Module

From within the FAQ module, the users can perform the following actions

1. **View FAQs**
2. **Create FAQs**
3. **Edit FAQs**
4. **Delete FAQs**
5. **Export FAQs**

6. **Email FAQs**

Each of these actions is described in the subsequent topics

View FAQs

Once you navigate to the FAQ module from the navigation grid, you can choose the View type by choosing the options available in the View by dropdown. Refer to the screenshot below

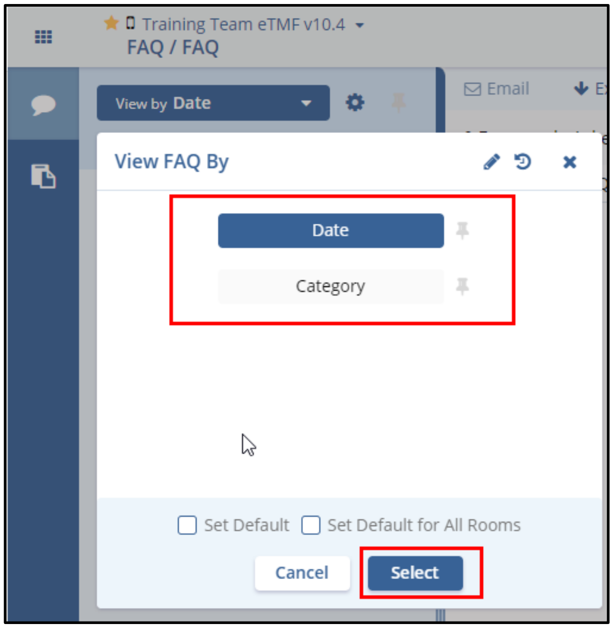


Figure 3: View FAQ by

Note: You can make a view default by checking the Make Default option

Create FAQs

To create an FAQ -

1. Click the 'Create'  button available in the top ribbon bar
2. This will open the Create New FAQ window. Refer to the screenshot below

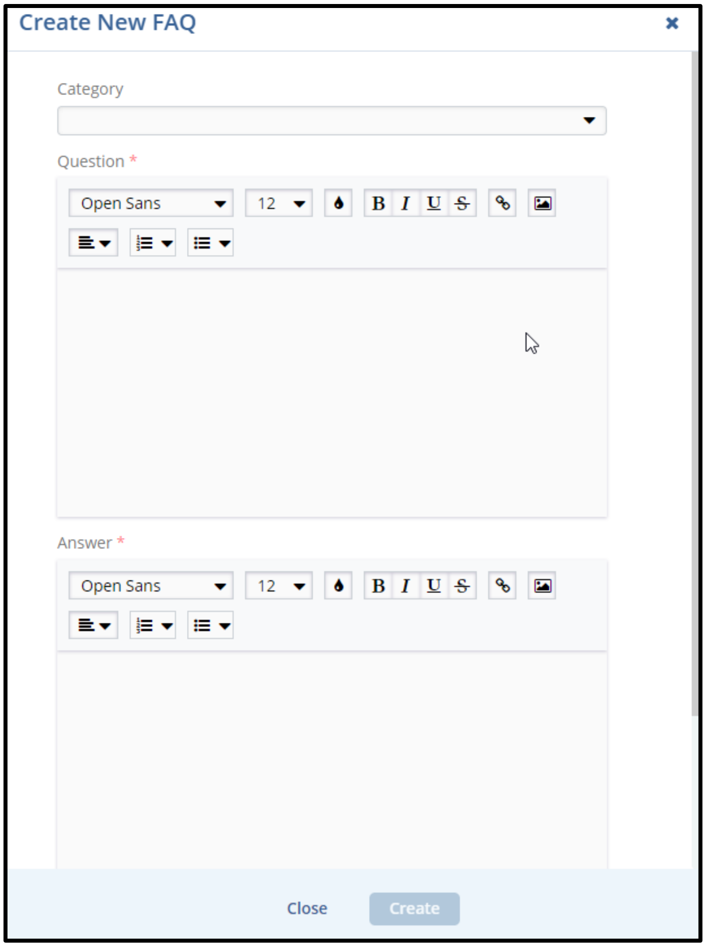


Figure 4: Create New FAQ

3. Choose the desired FAQ category from the category dropdown. Refer to the screenshot below-

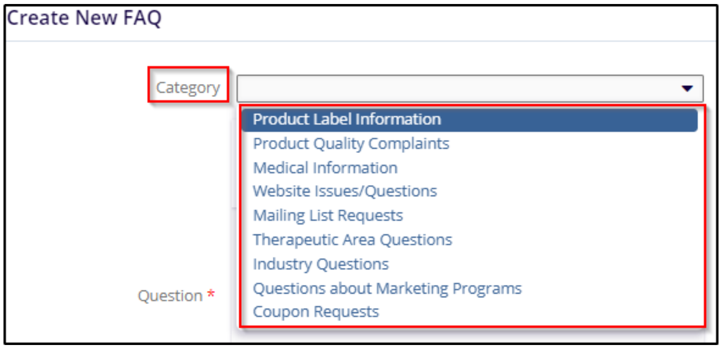


Figure 5: FAQ Categories

3. Enter the question and answer in the relevant text boxes.
4. Choose the Department Appropriately. Refer to the screenshot below.

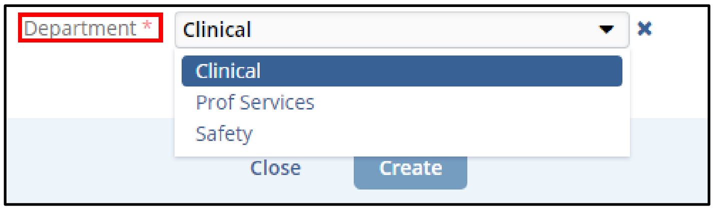


Figure 6: FAQ Department

5. Click the 'Create' button available at the bottom of the Create New FAQ window.

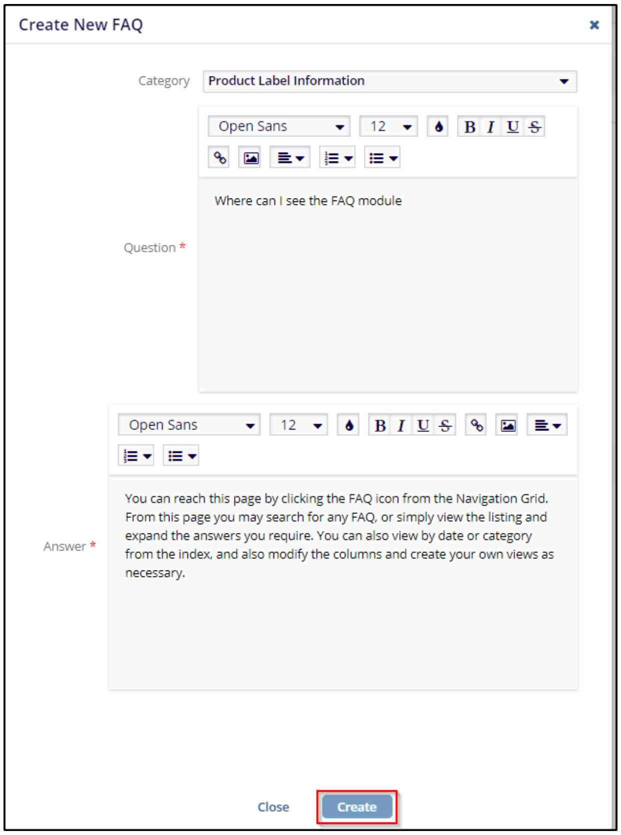


Figure 7: FAQ page

Note: While creating an FAQ you can insert a link and/or image by clicking the insert link or insert image in the create new FAQ window.

The created FAQ/s can be seen in the FAQ view as shown in the screenshot below

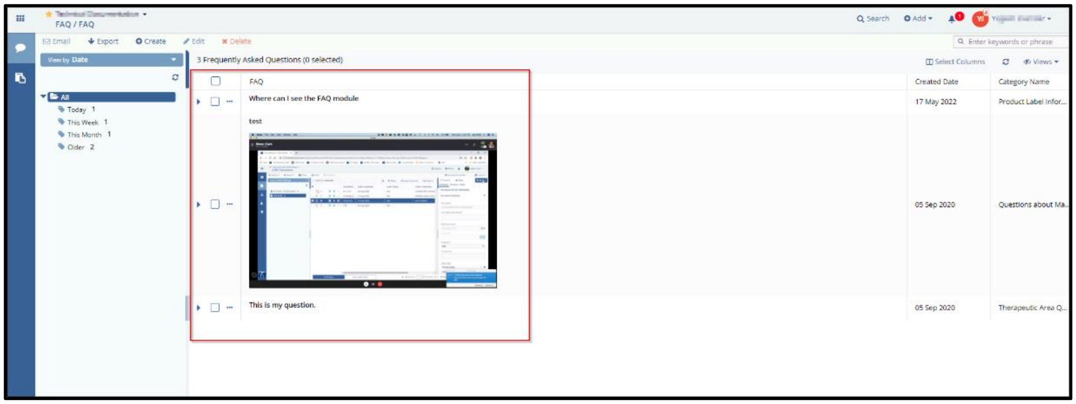


Figure 8: FAQ View

Edit FAQs

To Edit FAQ-

1. Select any of the FAQs available from the list.
2. Click the Edit  button available from the top ribbon bar

This will open an 'Edit FAQ' window as shown in the screenshot below-

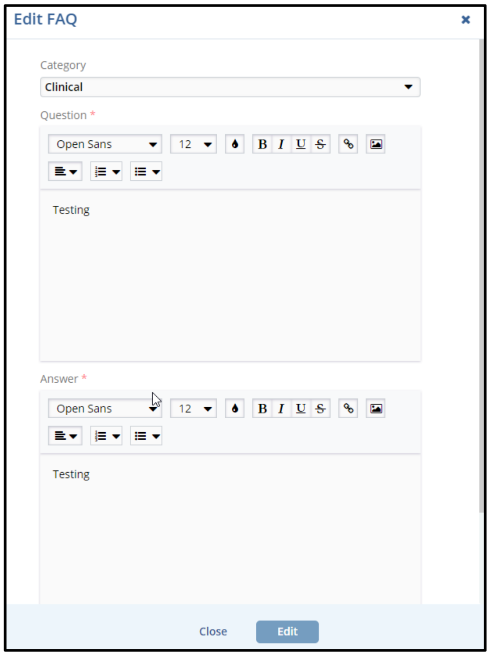
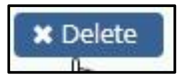


Figure 9: FAQ Edit

3. Once you make the essential changes in the FAQ click the Edit button available at the bottom.

Delete FAQs

To Delete an FAQ-

1. Select any of the FAQs from the available list and click the 

button.
2. This will open a confirmation to remove the window.

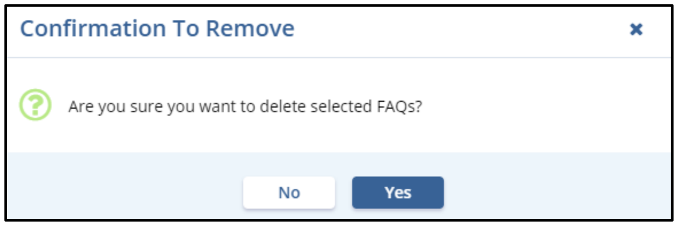


Figure 10: FAQ Delete Confirmation Message

3. Click Yes to make the deletion successful.

Note: The success of deletion can be seen as a notification message.

Export FAQs

You can export the available FAQs or selected FAQs from the FAQ module.

To Export FAQ-

1. Click the Export button from the top ribbon bar.
2. This will open the export FAQ window as shown in the screenshot below.

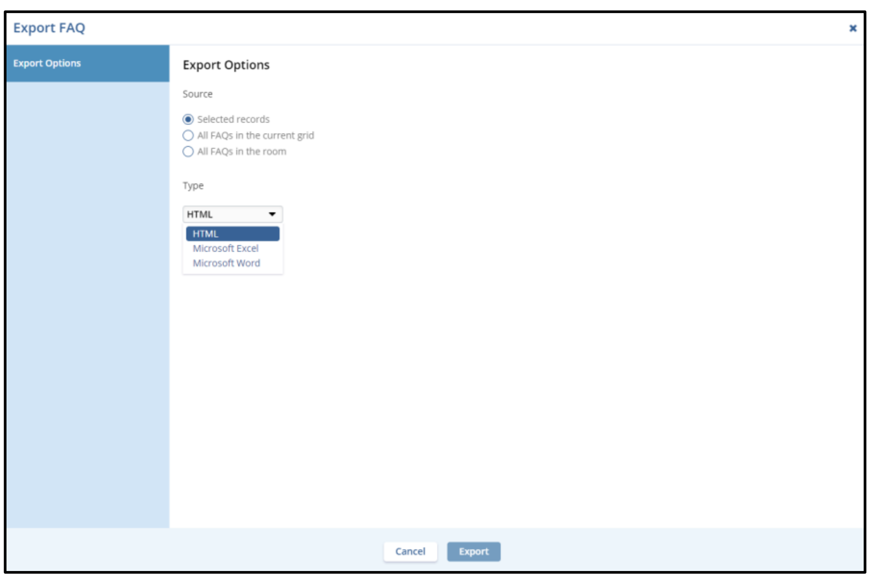


Figure 11. Export FAQ Options

3. Choose the desired source by clicking the radio button type from the dropdown and click the export button at the bottom of the window.

To Email FAQ-

1. Select any of the FAQs from the available list and click the Email button from the top ribbon bar.
2. This will open a Send Email window as shown in the screenshot below.

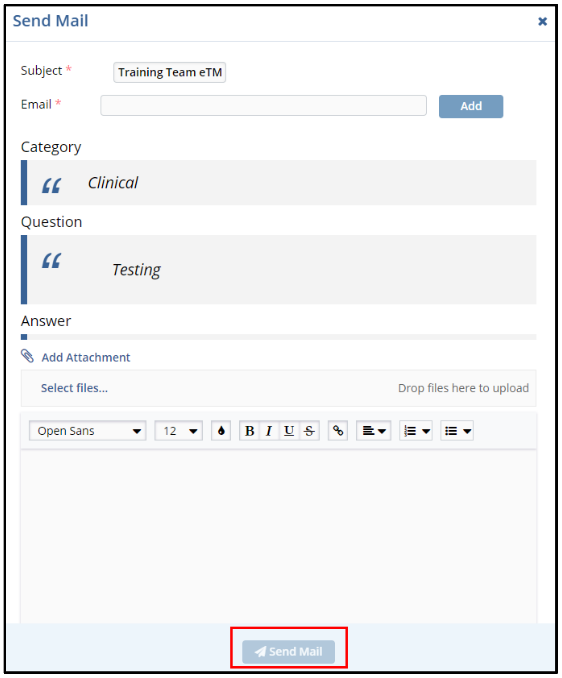


Figure 12: FAQ Email Page

3. Add an email recipient by clicking the **Add** button, enter a message and click the Send Mail button available at the bottom of the window.
4. The success message can be seen in the notification.

Chapter 21. Q&A

This section enables you to view the list of questions asked and answers given by users in a room.

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

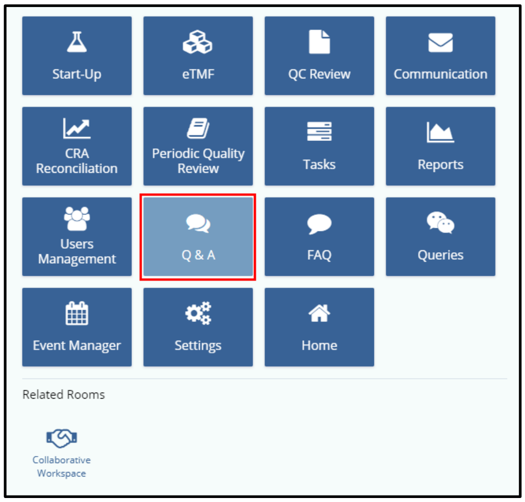


Figure 1: Q&A Module

Creating a Question

Creating a question may be done from either the Document Activities menu in the Documents module or directly from the Q&A module.

Creating a Document Specific Question

Questions that are related to a specific document should be created by the following process:

1. Navigate to the document about which you have a question.
2. Open the Document Activities menu for that specific document by either right-clicking on it or by clicking on the three-dot menu on the grid entry.

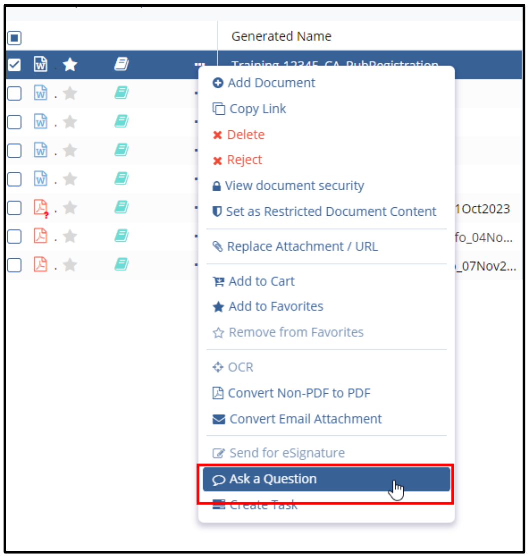


Figure 2: Ask a Question option

3. Click '**Ask a Question**.'
    a. The Ask a Question window will open.

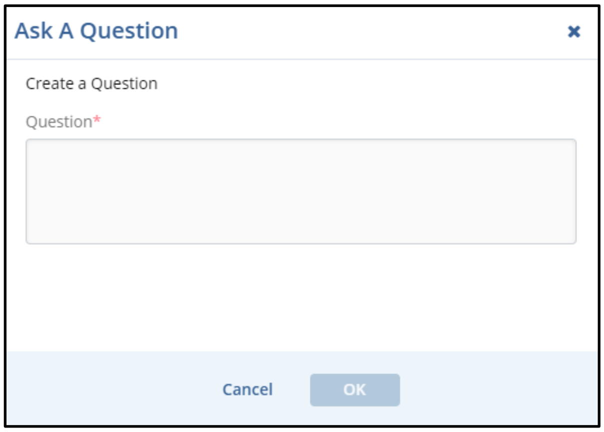


Figure 3: Ask A Question page

    b. The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.
4. If necessary, indicate the applicable subject matter and issue level.
5. Type your question into the box.
6. When you are done, press '**OK**.'
7. The question will appear in the Q&A module.

Creating a General Question

More general questions can be created from the Q&A module itself. In order to create a general question, follow the steps below:

1. Navigate to the **Q&A** module.

2. Click the '**Ask a Question**' button in the menu bar above the index panel.
    a. The Ask a Question window will open.

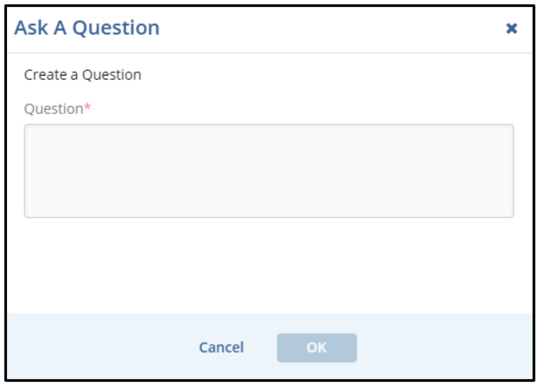


Figure 4: Ask a Question page

    b. The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.
3. If necessary, indicate the applicable subject matter and issue level.
4. Type your question into the box.
5. When you are done, press 'OK.'
6. The question will appear in the Q&A module.

Viewing the Answer to a Question

Follow the steps below to view the answer to a question:

1. Navigate to the Q&A module.
2. Locate the question in the Grid.
3. Click on the arrow next to the question to display the answer. In some cases, there may be multiple answers.

Figure 5: Answer View

Answering a Question

Administrator users and those users indicated as Subject Matter Experts may create answers to questions in the Q&A module.

Follow these steps to answer a question in the Q&A module:

1. Navigate to the **Q&A** module.

2. Locate the question to be answered.
3. Click the **Create Answer** button in the menu ribbon above the index panel.
4. This will open the **Create Answer** window.

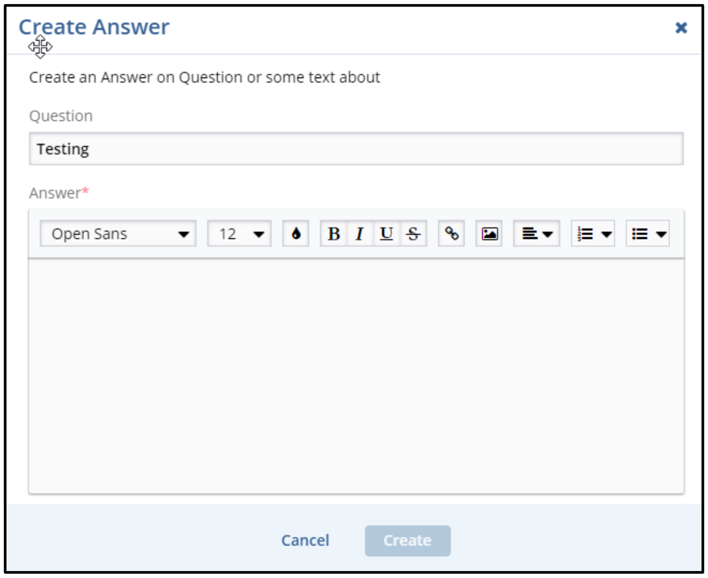


Figure 6: Create Answer

1. Type your answer in the box and press **Create** button.

Converting a Question into an FAQ Entry

1. Locate the question which needs to be converted to an FAQ entry.
2. Click on the arrow to expand the line and view the available answers.
    - Only answered questions can be converted.
3. Click on the answer to the question. If there are multiple answers, you will need to pick one – it can be edited in the next step.
4. Click the '**Convert to FAQ'** button
    - This will open

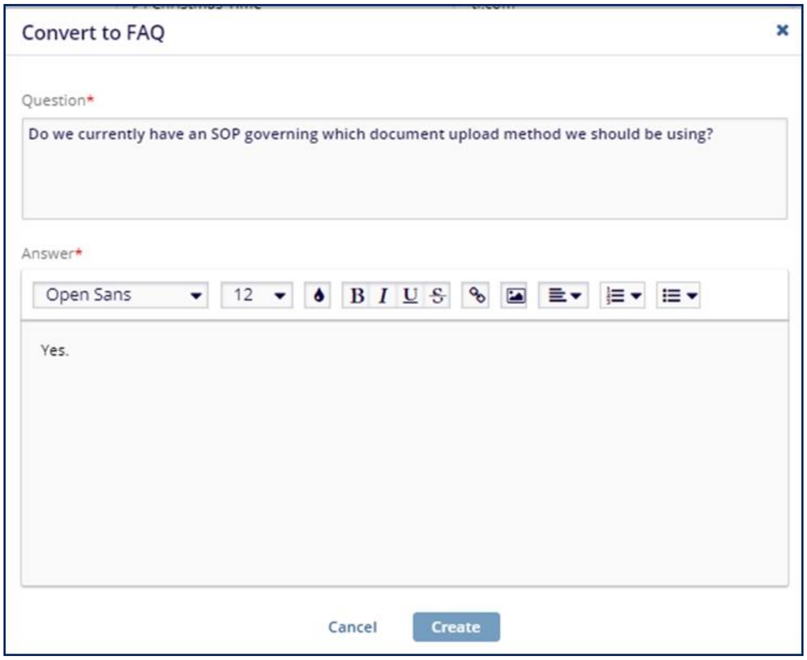


Figure 7: Convert to FAQ

5. Make any required edits to the Question and/or the Answer.
6. When you are done, press 'Create.'

Exporting Questions and Answers

Administrator level users can export questions and answers. To do so, follow the steps below:

1. Where applicable, select the question to be exported.
2. Press the **Export Q&A** button.
    - The Export Q&A window will open.

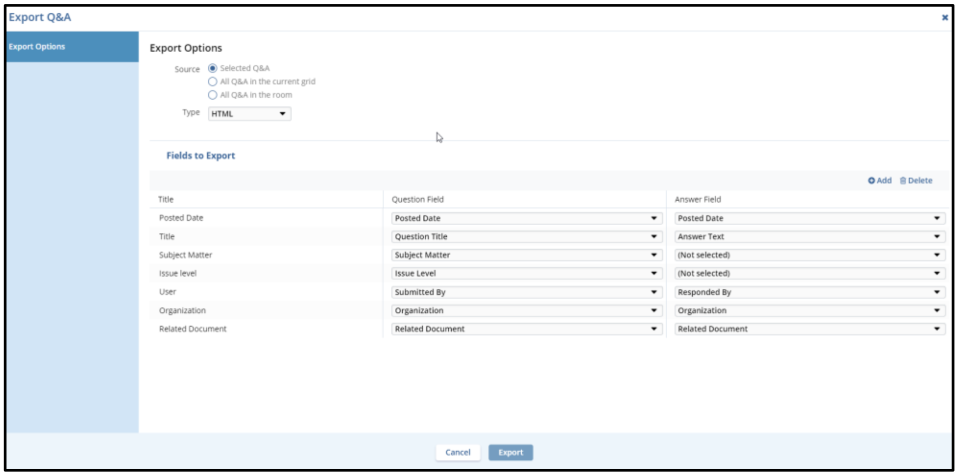
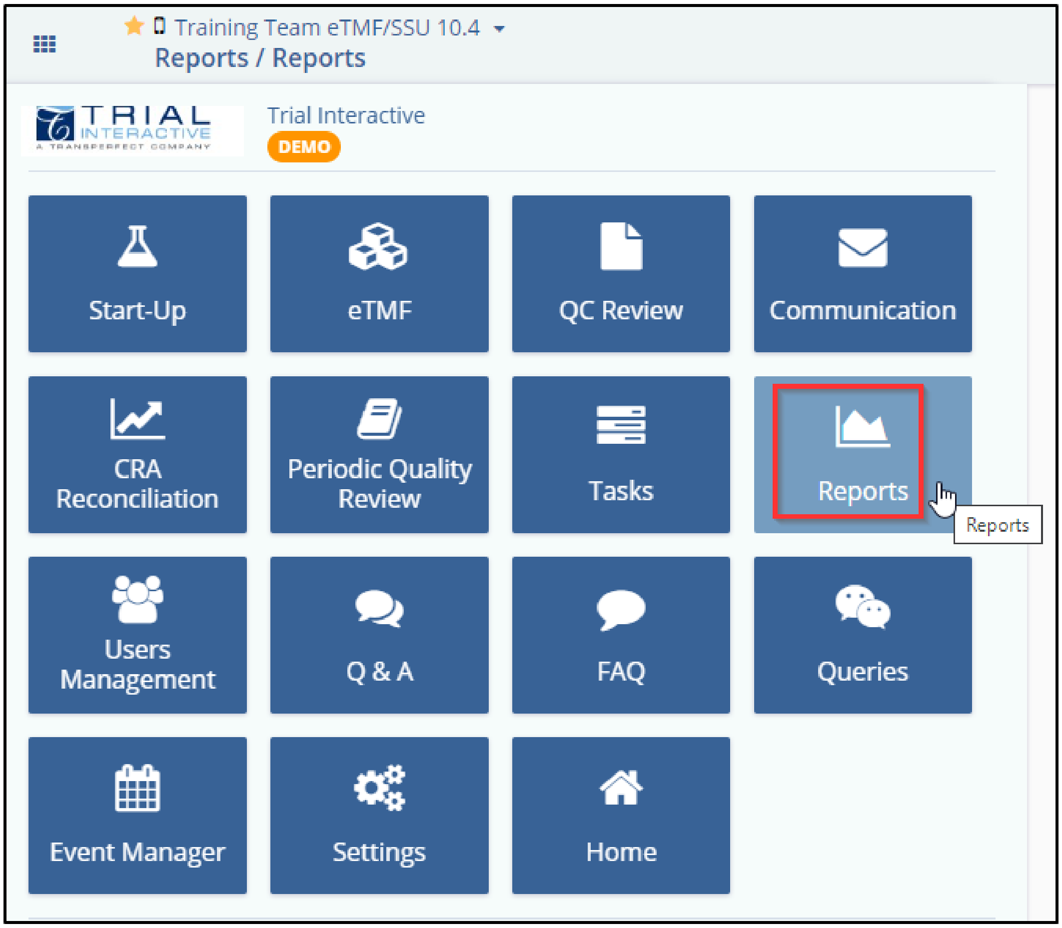


Figure 8: Export Q&A page

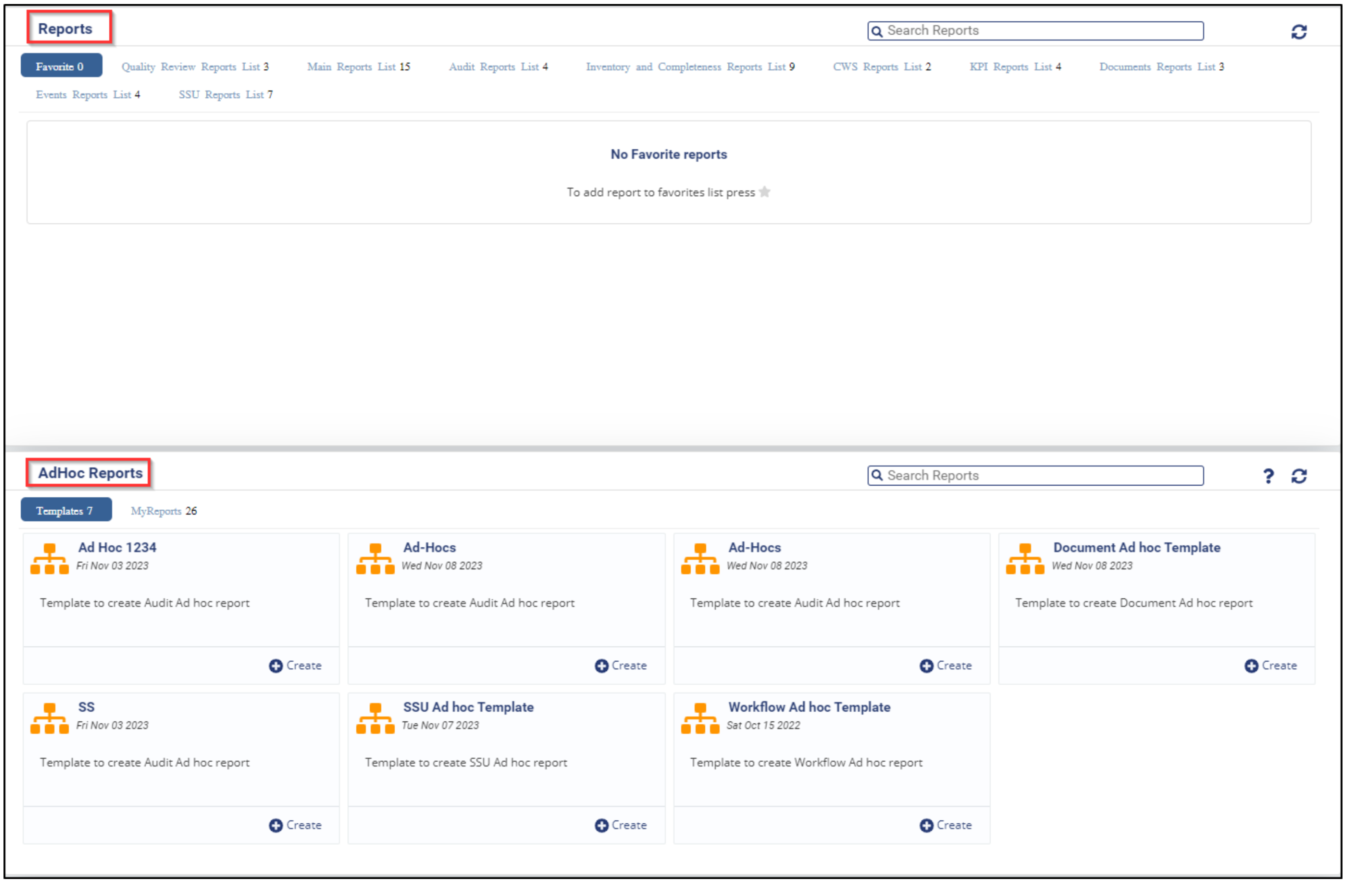
3. Select the Q&A Source and the export Type.
4. Indicate which fields should be exported.
5. Press ‘**Export’** Button.

Chapter 22. Reports

The Reports module can be accessed by clicking the Reports application from the Navigation Grid. Refer to the screenshot below:

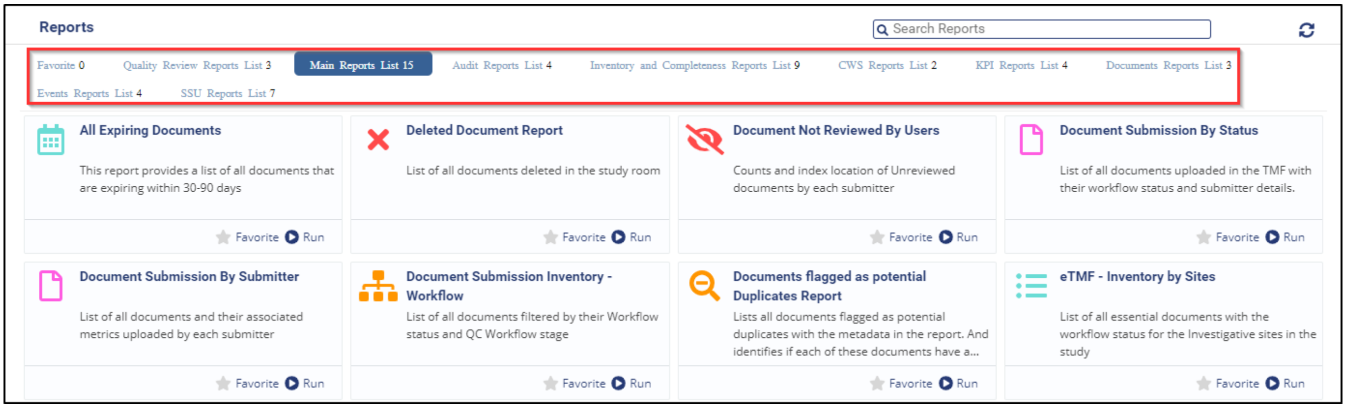


The Reports Dashboard consists of the various dashlets which gives a summary of the reports of the room. Refer to the screenshot below:

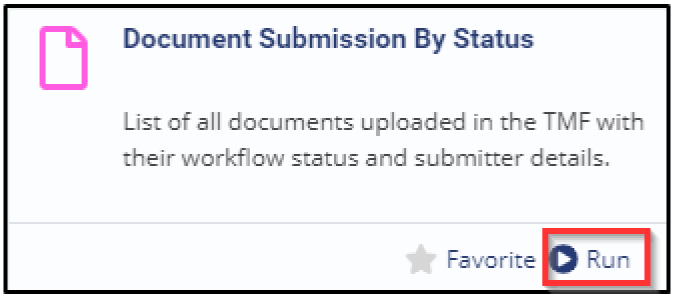


Viewing Reports from the Report List

From the Reports Dashboard, click the reports category marked in red in below screenshot. The below list of reports are from the Main Reports category.



Select any report and click on the **Run** button to view the desired report.



Chapter 23. Collaborative Workspace

Collaborative Workspace is repository for the project management related documents, some of the documents in this room will be moved to eTMF room. Collaborative workspace have a reference to astudy room.

The Trial Interactive Collaborate solution, also known as Shared Workspace, is a Clinical Collaborative Workspace Solution for clinical teams to provide Sponsors, CROs, and Sites a place toshare and author documentation to be used in the Clinical Trial and ultimately archived in the eTMF.

An integral part of TI Collaborate, TI Collaborative Authoring will provide end-users the capabilityof directly editing MS Word, Excel, and Power point documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the sametime, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

There are two types of rooms associated with Collaborative Workspace

1. TI Docs
2. TI Collaborate

TI Docs and TI Collaborate both have the ability to edit the documents online. TI Collaborate acts as Content management tool that is linked to the TMF . TI Collaborate asks 'Is this a TMF document?' while publishing the documents. With TI Collaborate the users can also publish the documents to anyother room that is not associated to Collaborative Workspace.

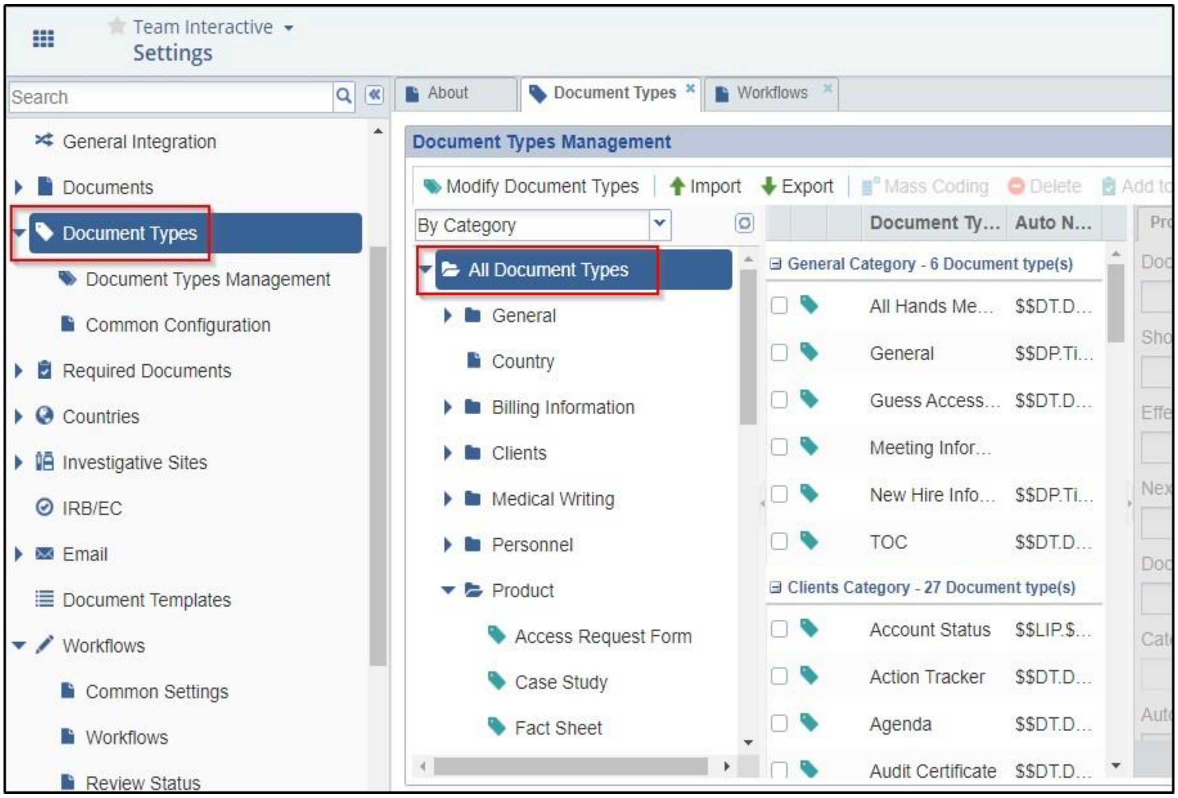
While TI Docs doesn't have any link to TMF, nor it can publish the same to any other room. However, the documents can be copied to other rooms.

Important: *To enable Collaborative Workspace room, contact the Service Desk.*

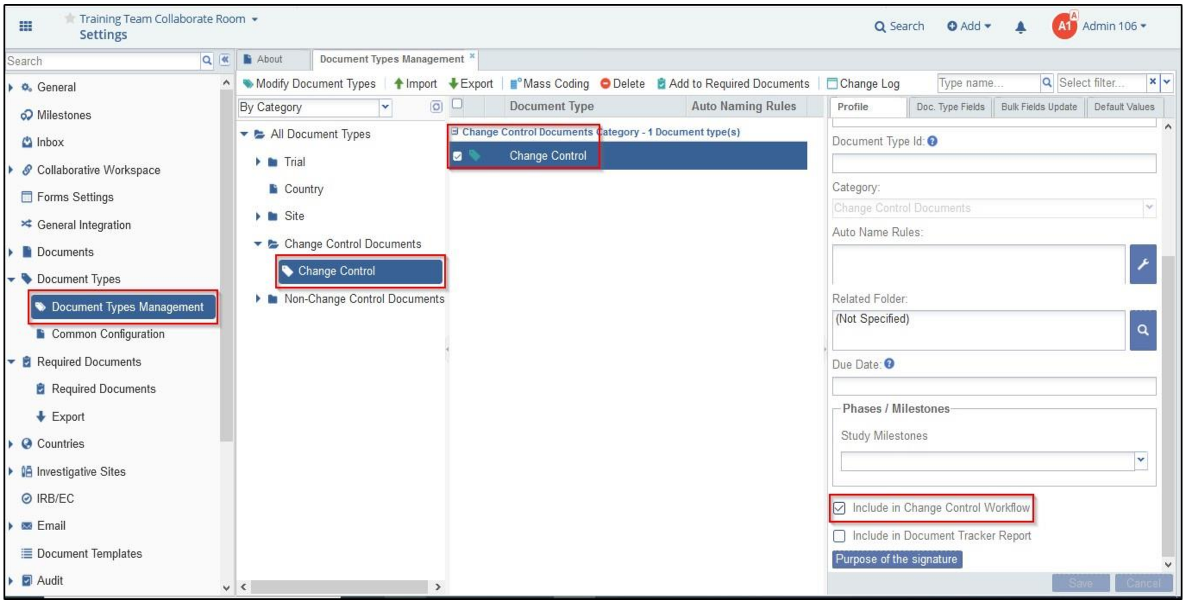
Room Configurations that impact Room Types

The room configurations that impact the room types TI Docs and TI Collaborate are described below.

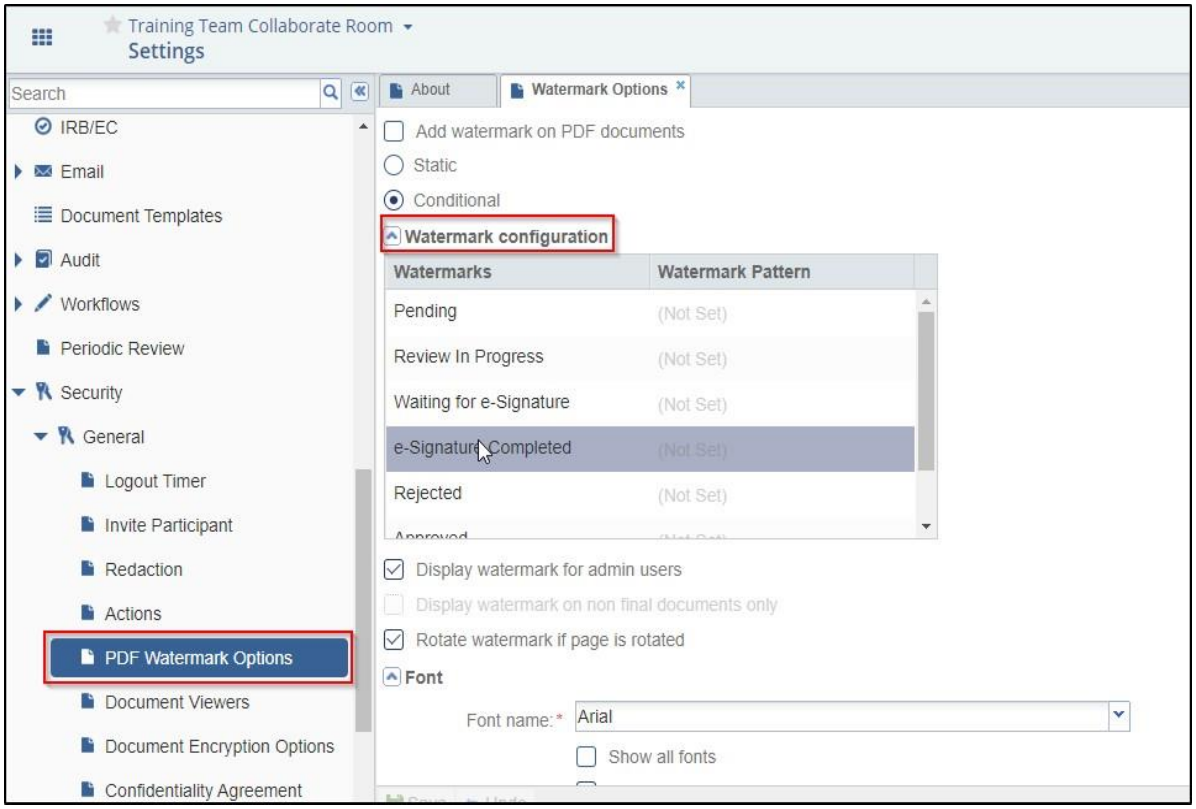
1. Document Type - The document types settings can be configured via **Settings>Document Types>All Document Types**. Refer the screenshot below.



2. **Change Control workflow** - The checkbox says this doc type can be initiated in the change control workflow. Change control workflow only allows the versions up of the documents. In the profile tab, the users can define the periodic review period and effective period. Configuring this can be seen in the screenshot below.



3. **PDF Watermark**- To insert a PDF watermark, go to **Settings> Security>General> PDF Watermark Options** and select the Watermark Configuration. Refer the screenshot below.

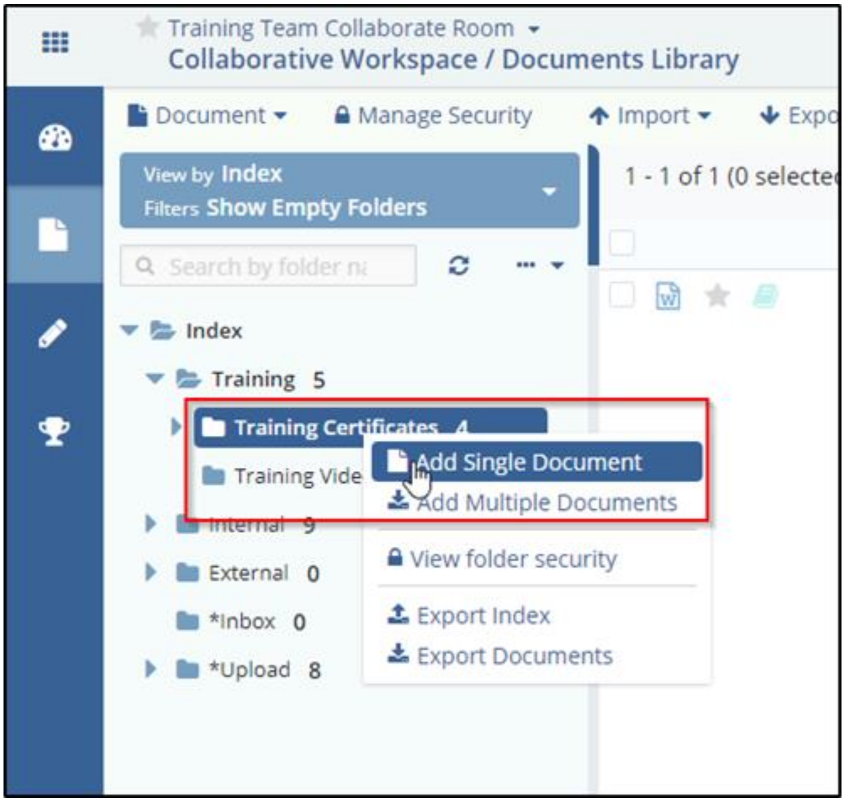


4. Converting Documents -Non PDF to PDF- To convert non PDF documents to PDF, go to **Settings>Documents>Non PDF to PDF Document Conversion** and select the conversion type.Refer the screenshot below.

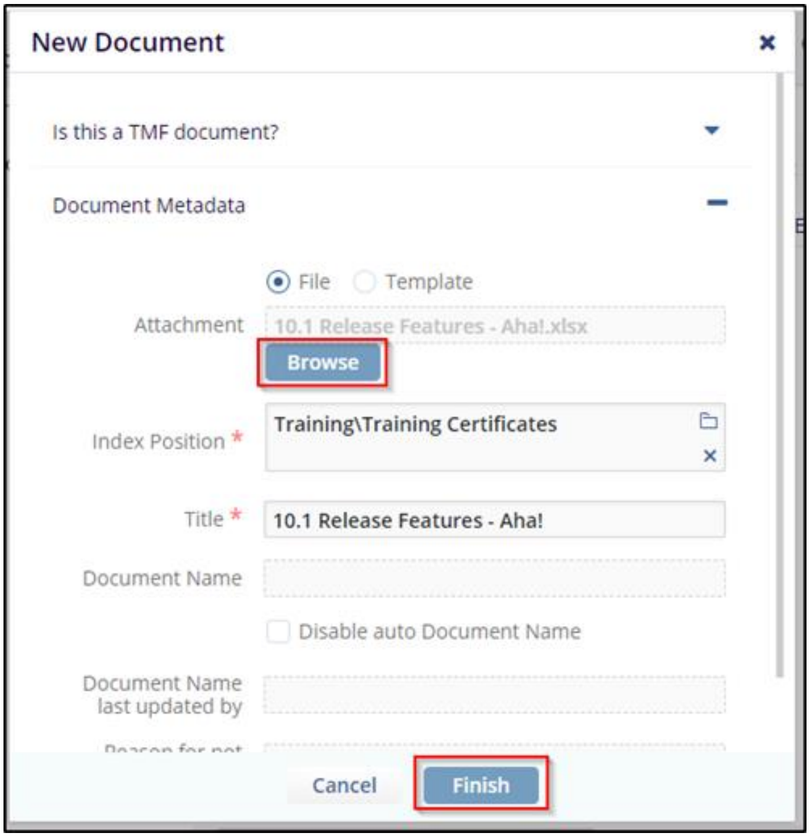
Document Upload

Documents can be added to Trial Interactive in a multitude of ways. When it comes to Collaborate/eISF rooms, we recommend using the following method:

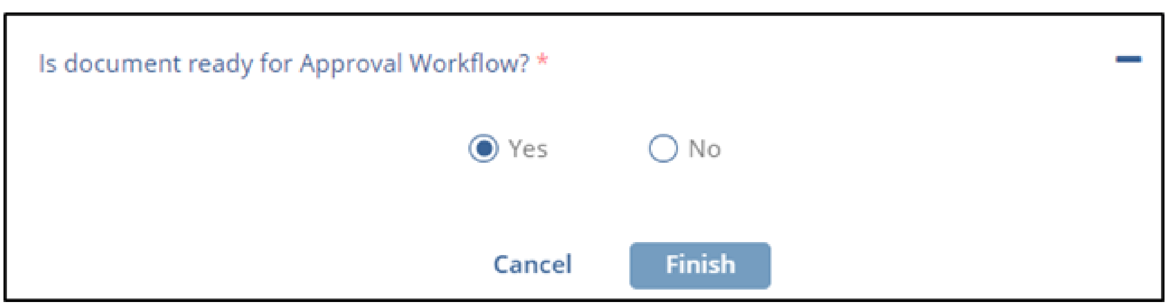
1. Start by navigating to the Document Library Index view, then select the desired upload location (folder) and right-click on it to start adding documents. Refer to the screenshot below.



2. Clicking 'Add single document' will open a 'New Document' pop-up window. If prompted, answer the question 'Is this a TMF document?' then attach a document or select an existing template, fill in the essential metadata fields, and click 'Finish' to complete the process.

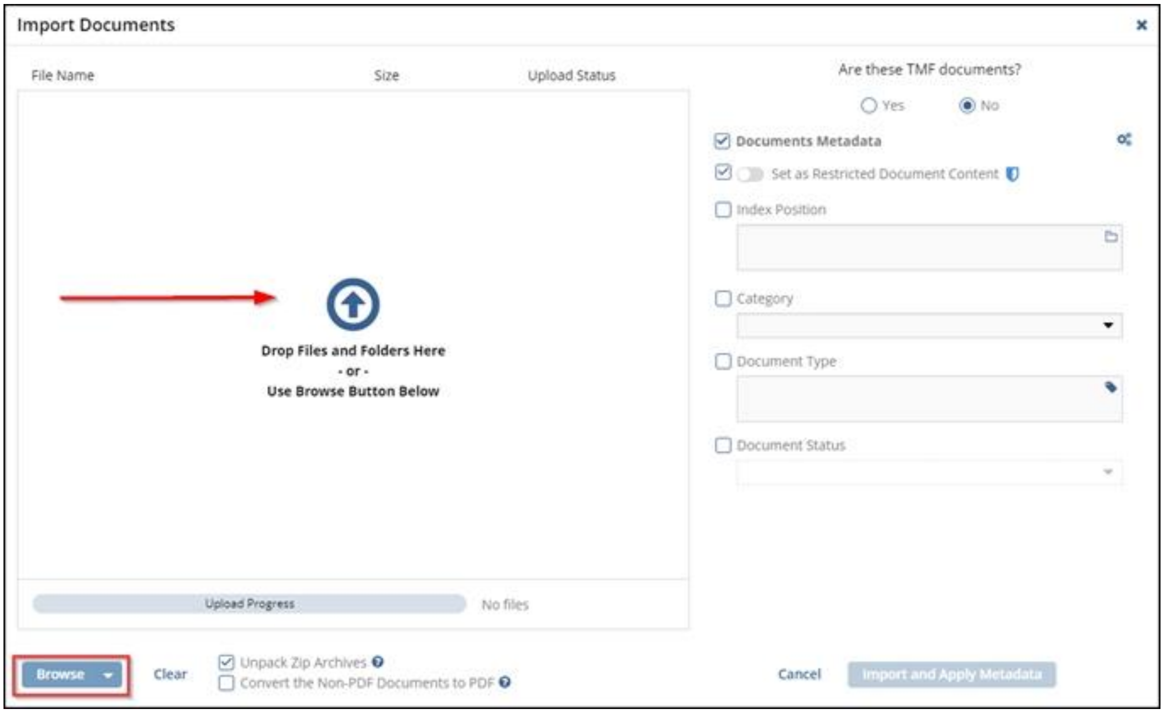


3. Additionally, when adding a single document, it is possible to define whether the document is ready for a Workflow - that is, we don't expect changes to be made to the content prior to review and approval. Selecting ‘Yes’ as shown in the screenshot below, will allow the document to be assigned to review and/or signature workflows immediately after upload.



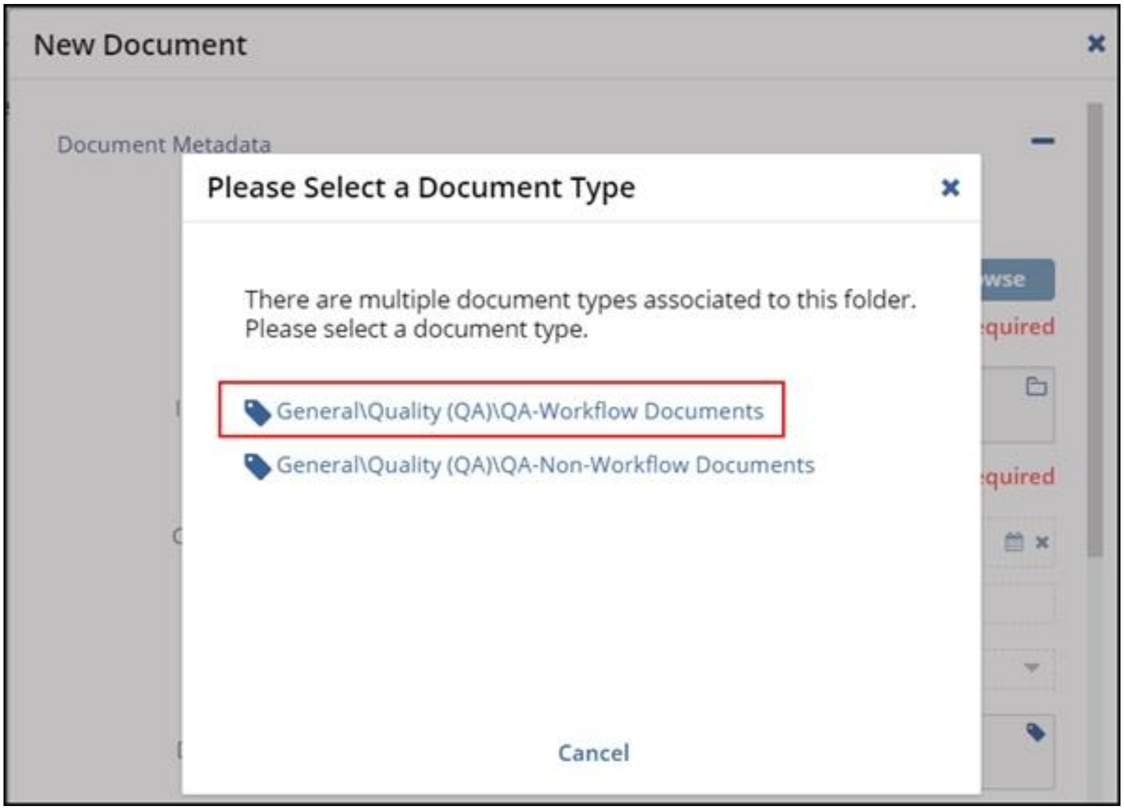
4. In case multiple documents are needed at once for upload,

   a. Choose the ‘Add Multiple Documents’ option.
   b. A different upload window opens. *(Notice the ability shown in step #3. To define documents as ready for workflow is lost using this method).*
   c. Drag documents into the white space on the left (or Browse your device contents).
   d. Use the Documents Metadata interface on the right to configure metadata for your documents if desired. Uncheck the Documents Metadata box to deactivate the fields.
   e. Click on ‘**Import**’ or ‘**Import and Apply Metadata**’ when ready to begin the file upload.



Change Control Documents

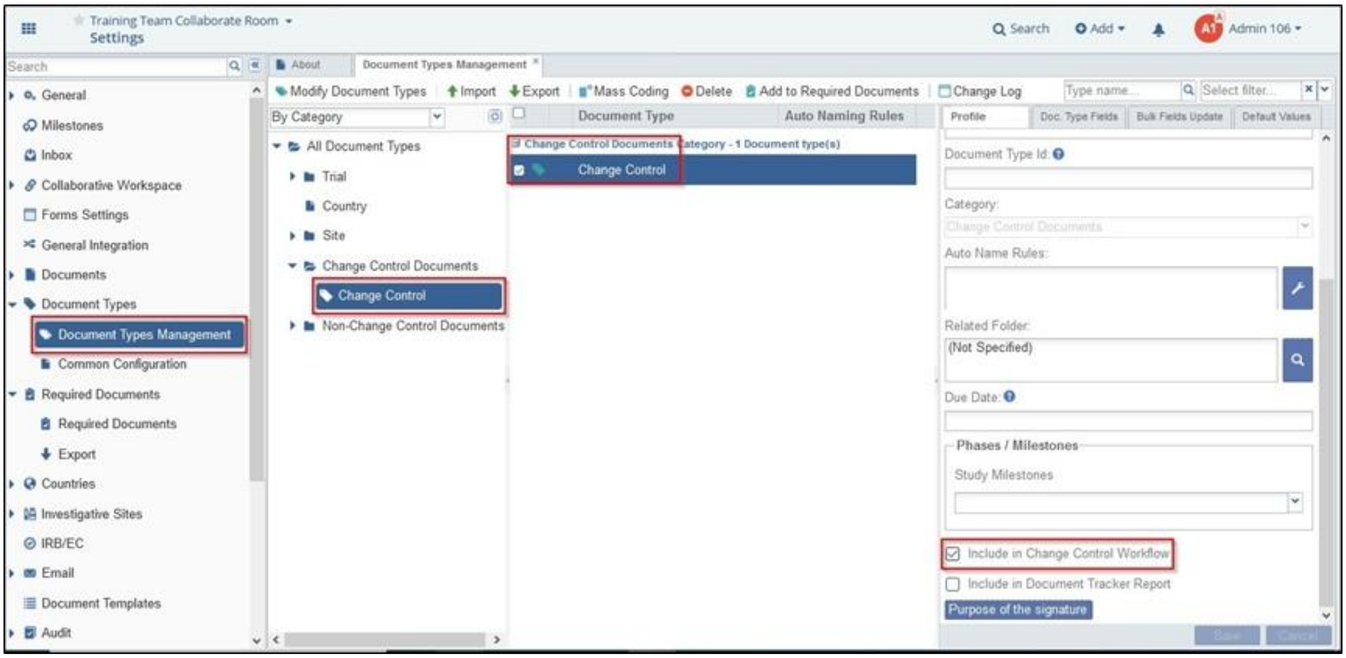
Document types requiring a Change Control workflow can be defined in room settings, with the effect that users uploading documents can select a 'Workflow' document type (either by manually applying a selection or uploading documents to a folder supporting Workflow documents only) the uploaded document will automatically be configured to require a change control workflow for versioning. See the screenshot below.



Advanced: Setting Change Control document types

In the settings menu, Document Types Management can be used to set which document types are required to go through the Change Control workflow. The screenshot below shows how to configure a document type change control. In the Profile tab on the right side, users can define the periodic review period and effective period for document review. Typically, however, this configuration is defined prior to the room being built and rarely needs changing.

Warning: For any changes in room settings, please contact your Trial Interactive liaison.



Content Editing and Versioning

Perhaps the key feature of TI Collaborate is enabling users to edit documents while tracking changes in content over multiple versions. This can be done in a variety of ways:

Individual Online Editing

Contained within TI, give users the ability to make instant changes to a document. Changes are saved manually.

Individual Offline Authoring

Using Edit Offline, users have the option to open documents within their chosen document editors and save them seamlessly back to the Collaborate Room.

Online Team Edit

With this option, a document is ‘open’ for simultaneous changes by multiple collaborators.

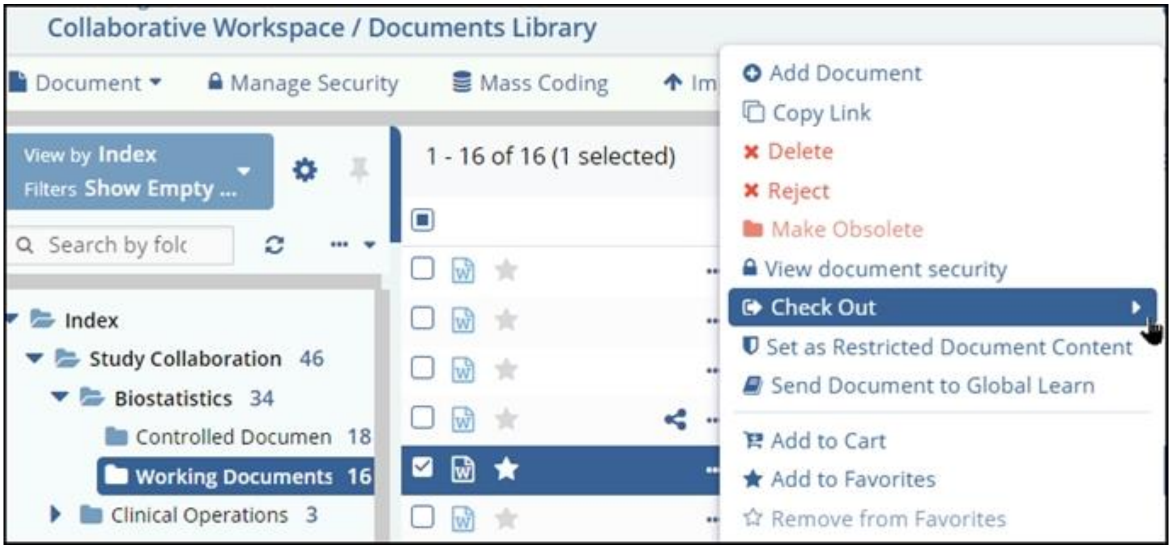
Collaborators in Team Edit can annotate a document with responses and comment threads, as well as integrated online chat. No local software installation is necessary.

Content editing in TI Collaborate is performed through a process of check-out and check-in of documents. The next section of this guide explores this process.

Checking Out and Editing

Editing of a document begins with the check-out process.

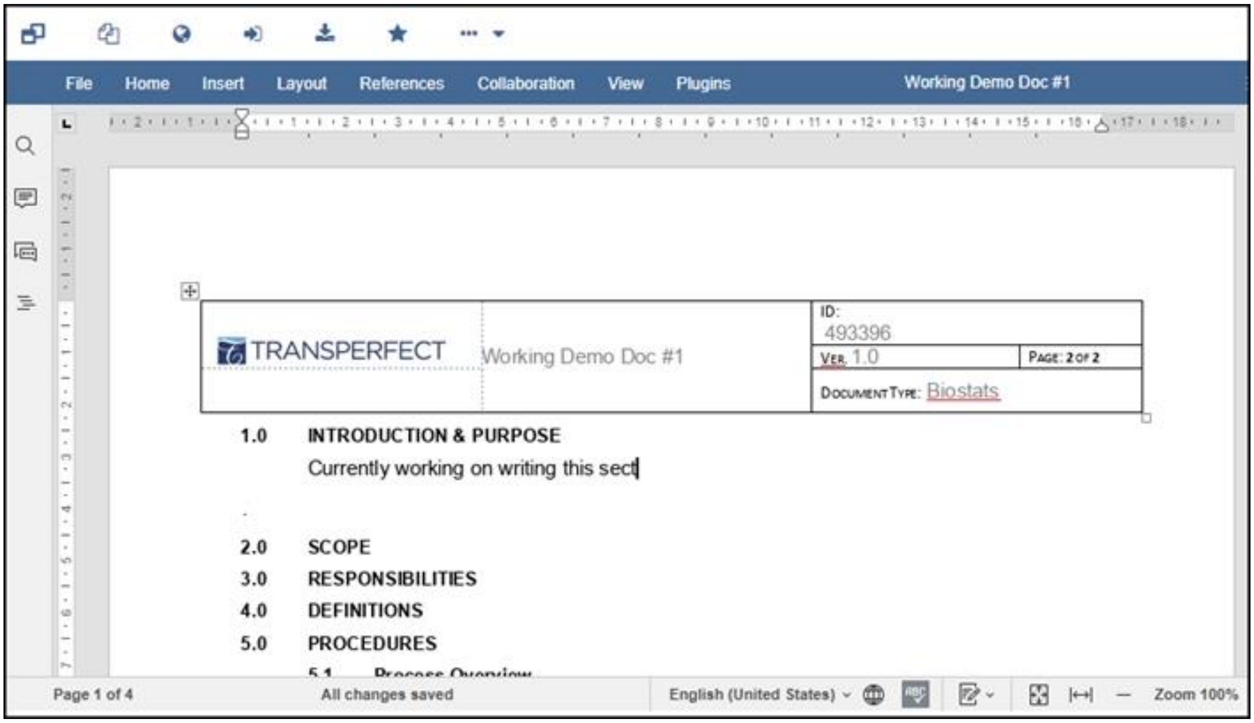
1. To check a document out, navigate to the Collaborative Workspace module and locate a document. Click on the Document Actions Menu (the three-dots icon next to a document entry) and click on Check Out, as shown in the screenshot below.



2. Select from the available check-out options according to your preference: Online (Individual Online Authoring), Offline (Individual Offline Authoring outside of TI), or Team Edit (simultaneous team collaboration).

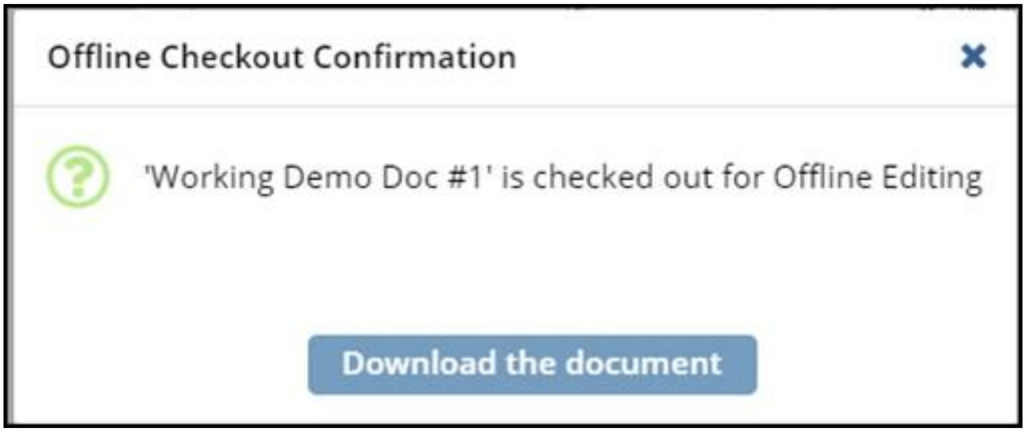
Online

This option is intended to be used by those who would like to edit the document within TI without downloading the file. Choosing this option will immediately open the Document Viewer in Edit Mode, where the user can perform any necessary changes to the document. While checked out, the document is locked for all other users preventing inadvertent overwriting or conflicting edits. Other users will be able to view and download the current effective version of the document, but they will not be able to check it out until it has been checked back in. See the screenshot below.



Offline

This option offers the user a chance to download the document to their computer. The user will then make any changes required using their preferred, locally installed software and upload an updated copy to the Collaborate room. When checking out a document offline, the document is immediately locked, and the system prompts the user to (optionally) download the document.

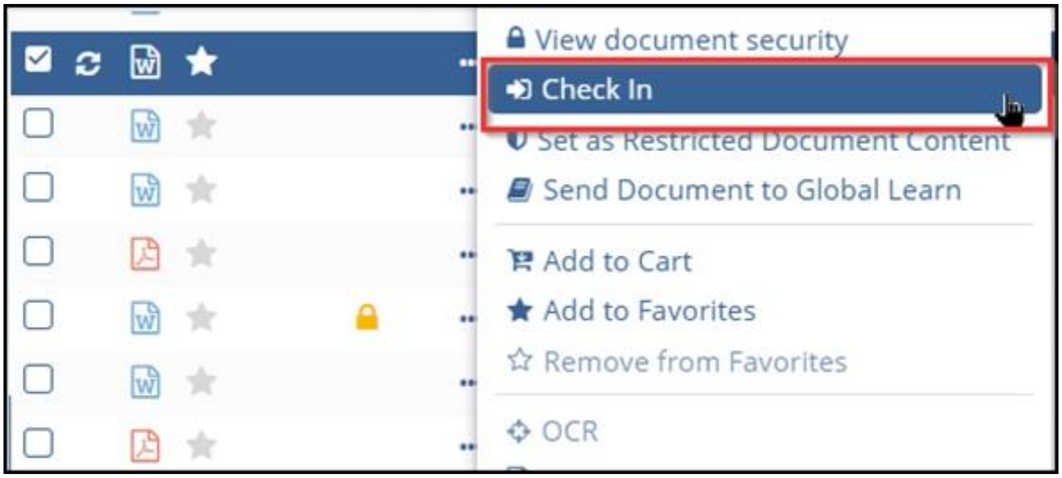


Note: *We suggest always downloading the document when using this method. This ensures you are working on the most up-to-date version of the document.*

Checking In

When a user has finished applying their changes, they will need to check the document back in.

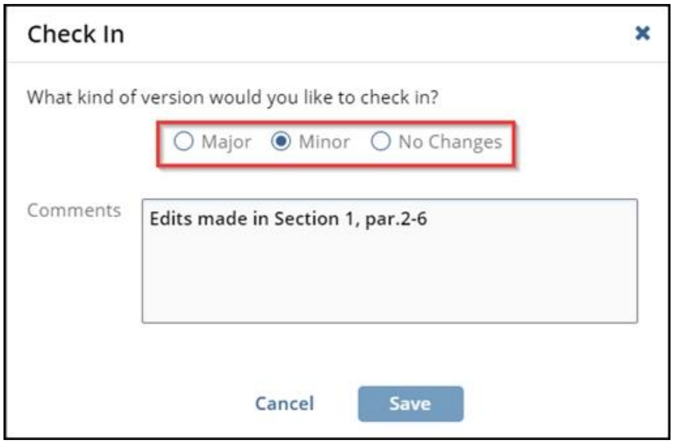
1. A Check-In button can be found in the Document Action Menu.



2. (*For Online Edits only*), users can opt to click on the Check In button above the Document Viewer instead.

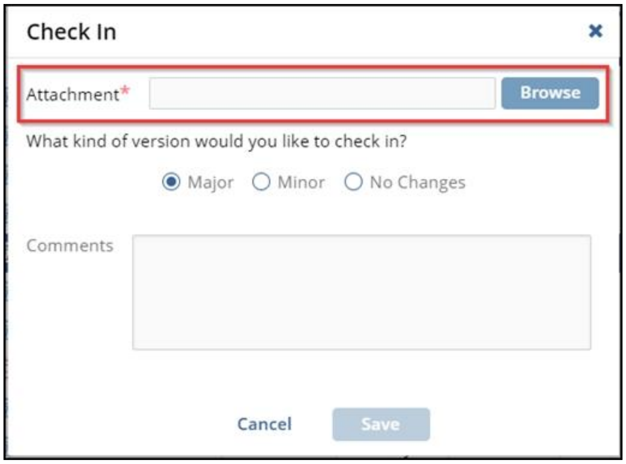
3. Users can then choose from three options:

- No Changes – any action taken during the edit session is discarded, and the document remains in its previous state and version.
- Minor Changes – this option updates the document to a new minor version (e.g., v0.1 à v0.2). Users editing documents that require a change control workflow will only be able to perform minor changes using the check-in/check-out functionality. These documents must be put through a workflow in order to have a major version change.
- Major Changes – this option updates the document to a new major version (e.g., v1.1 à v2.0). This is only available for document types that do not require a change control workflow.



Users will be able to include comments related to the actions performed before closing the window by pressing the Save button. Refer to the screenshot below for visual aid.

4. For Offline edits, the Check-In pop-up will contain a section to upload an attachment. The user will select the document they edited locally, and once it is uploaded to TI - by clicking Save - that content will serve as the new Major or Minor version of the document.



Team Edit

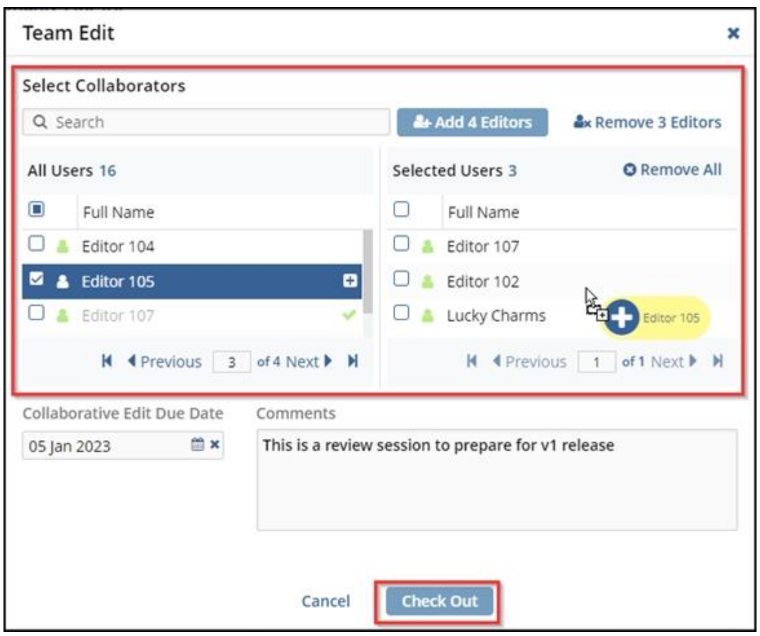
This option creates an online editing session involving multiple users, who can all work on the document simultaneously and see each other's changes in real-time.

As the changes can be performed at any time, this mode can be used by global teams with different time zones, by users in remote locations, or simply when having a meeting is not practical.

Setting Up Team Edits

The user who creates the team editing session will be identified as the Collaborative Review Owner and can set which users will take part in the collaborative effort. The owner of the session can be reassigned later, if necessary, via the metadata panel in the collaborative editing module.

1. To initiate a collaborative edit, check out the document using the **Team Edit** option.



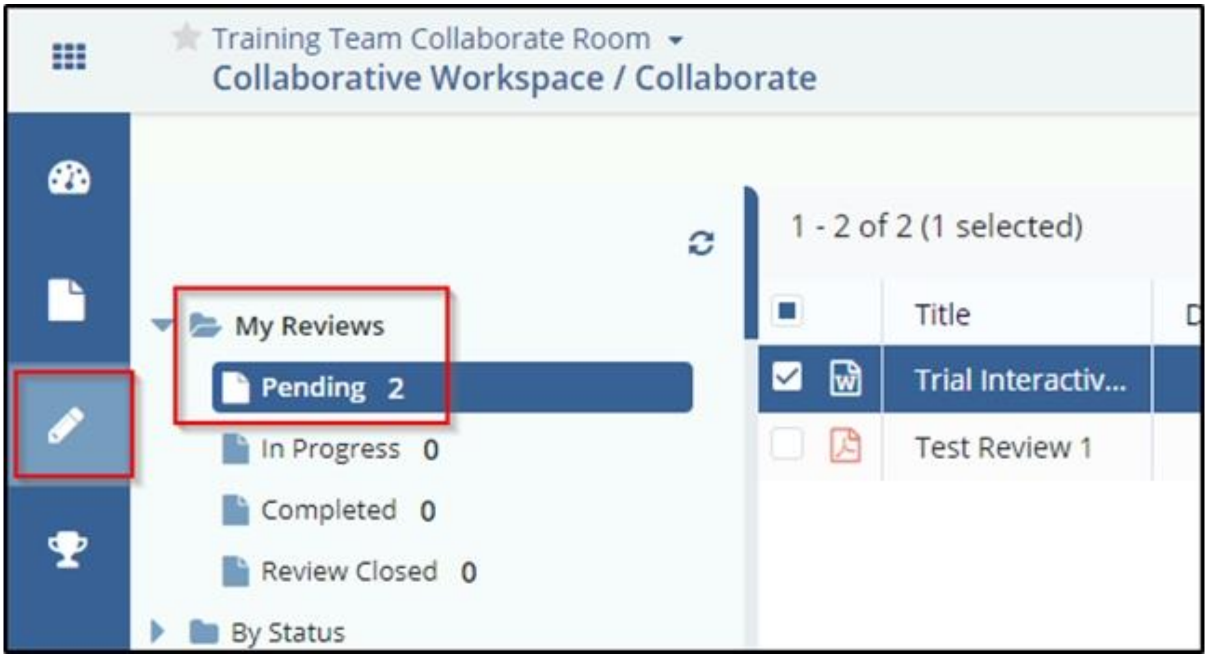
Note: The 'Add All Editors' option will automatically add to the review all editor users who have Edit rights in the folder where the document is located.

A Collaboration Due Date is also defined, which serves as an indicator for contributing users as to when the session should be completed. This date has no associated automatic function. The session will stay open until manually closed.

Comments can also be added here to help guide the collaborative effort, for example, by setting an agenda or defining roles.

2. Click the **Check-Out** option to initiate the team Edit session.
3. After setting up the Team Edit, the user is given the option to immediately begin editing the document in the collaboration window. If the user selects No, the edit view can be accessed under My Reviews à Pending in the Collaborate Module.

   All parties involved in the Team Edit also get notified by email (containing a direct link to the edit), and Pending Reviews can be accessed via the dashboard.



Participating in Team Edits

Participants in a Collaborative Review can access documents via multiple methods:

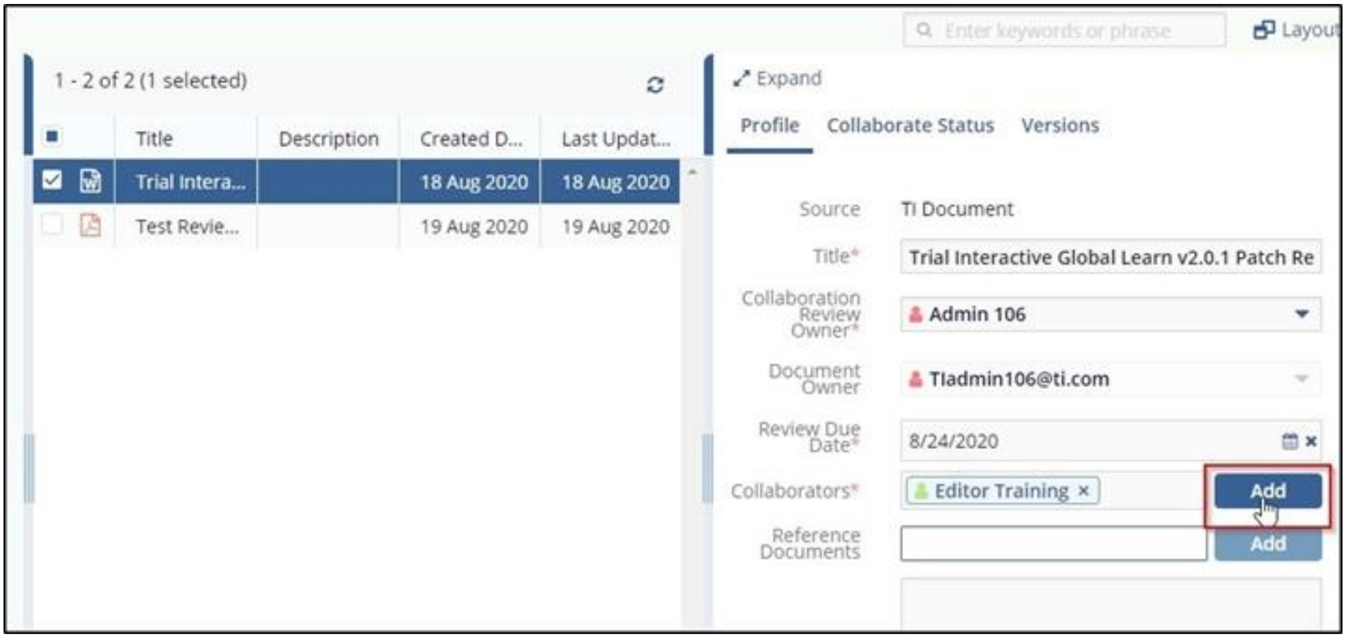
- The Collaborate module, accessed via the vertical navigation bar to the left of the screen in TI
- The Pending Collaborative Reviews dashlet, which displays all ongoing reviews assigned to the user
- The email notification received when added to the edit, which contains a direct link to the document to be edited.

Participating collaborators can edit the document in the document view. The Collaboration Review Owner is also able to make changes team editing session setup via the metadata panel.

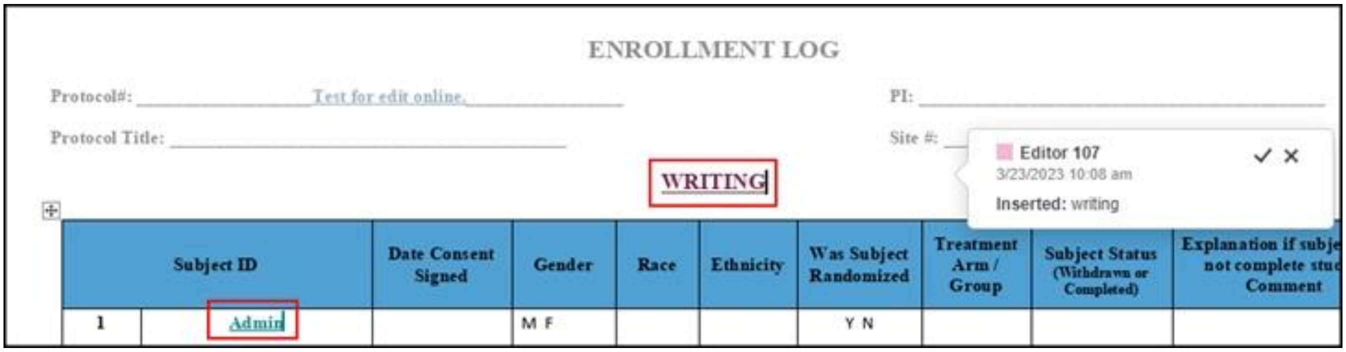
They will be able to add or remove Collaborators, update the review status, designate a new Review Owner, or close out the session and check the document in.

To add/remove collaborators, The Collaborative Review Owner can use the Profile tab in the Metadata pane:

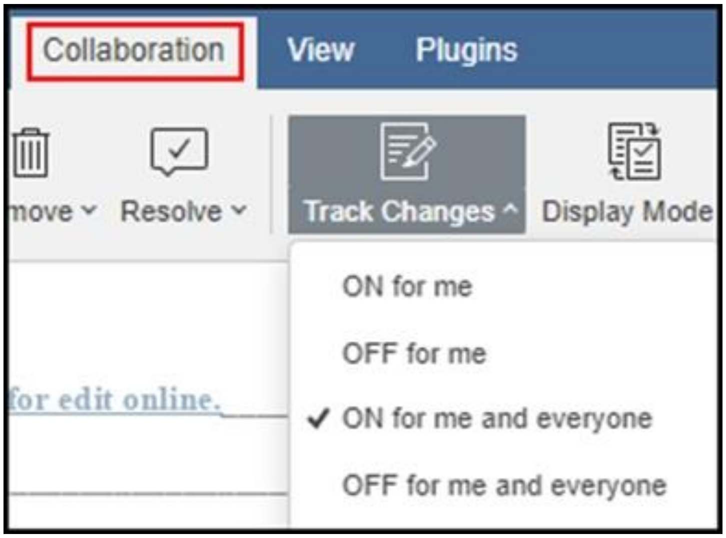
1. Clicking on the Add button next to Collaborators, a selection menu will open. Reviewers can then be added.
2. To remove a user from the ongoing collaboration, click the ‘x’ near the collaborator’s name.



Edits in a team editing session are applied the same way as for Online Check-out individual editing. Because multiple users can be making changes simultaneously, user markers will be displayed where each user is making an edit, and the users' edits will appear in a color randomly assigned to them.



Note: We recommend enabling change tracking, which can be done by clicking on the Collaboration tab and then on Track Changes, as shown below.

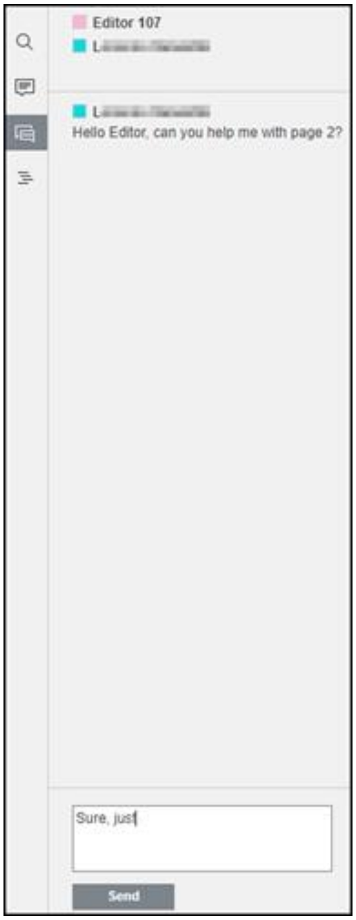


1. Click on the **Comments** button to open the related panel and review any previous comments.

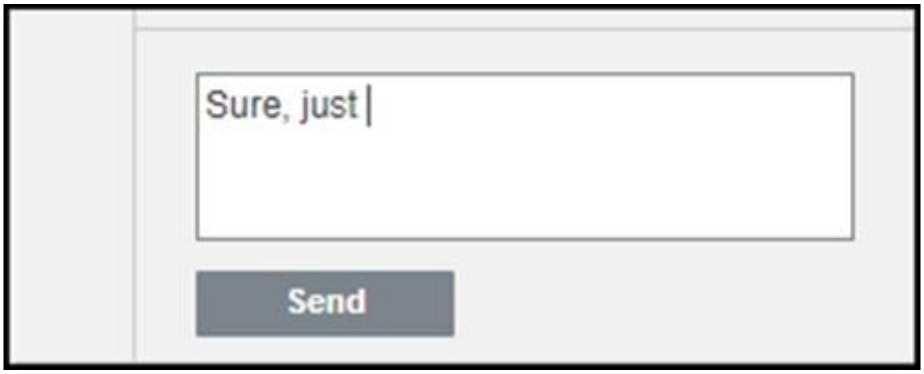
2. Comments can be Replied to, edited, removed, or resolved within this panel.
3. Click on Add Comments to Document button at the bottom of the panel to add your own comments.

Users can also chat with each other if they are working on the document at the same time.

1. A yellow icon will appear any time a new message is received.



2. Use the box at the bottom of the panel to reply.

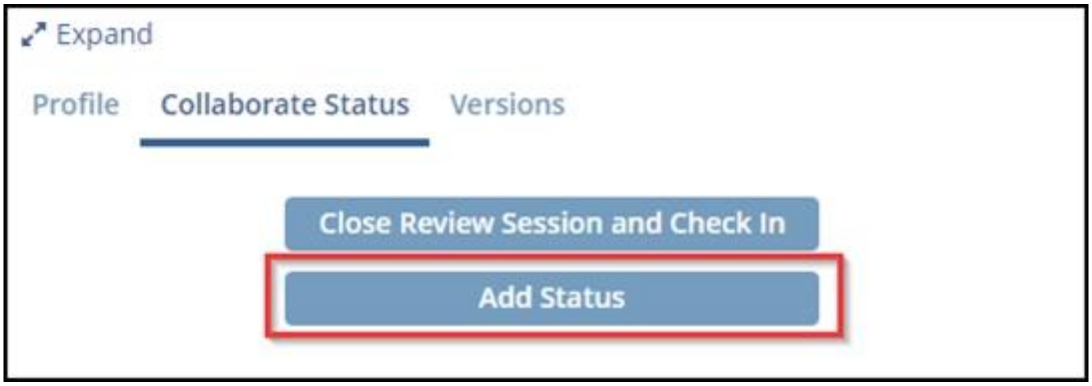


3. Chat History is discarded when the users log off.

As users complete their review of a document, they can add a status to their review. Doing this assists the session owner in assessing the progress of the review and seeing who is done and who needs additional time to review the document.

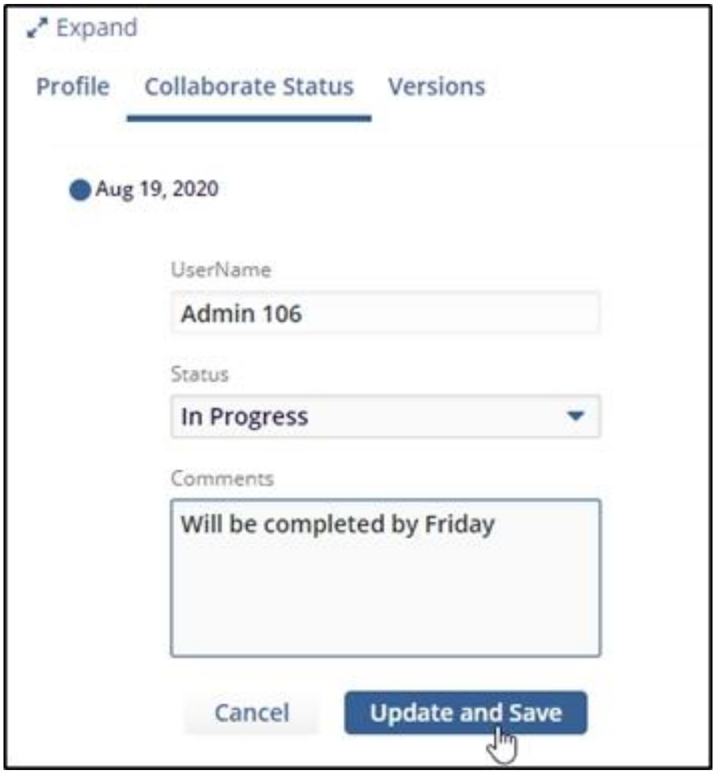
To do so, follow the steps below:

1. Expand the Metadata Panel, and click on the Collaborate Status tab.
2. Click on the **Add Status** button.

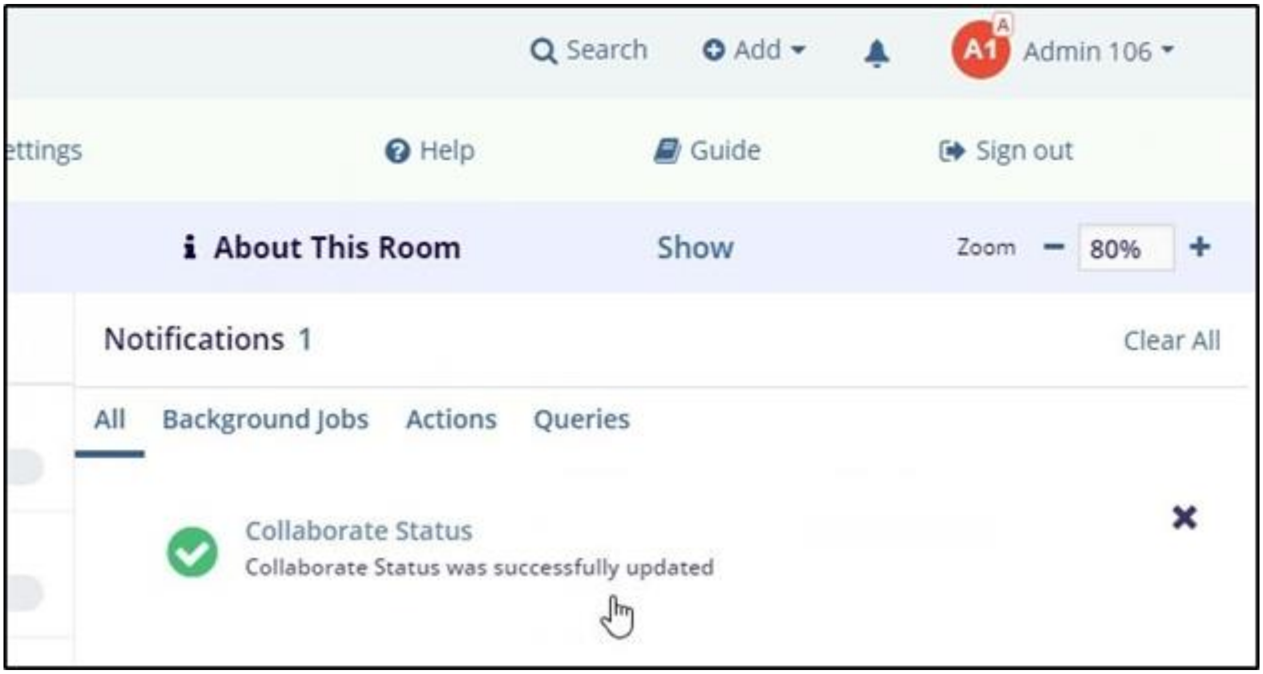


3. The status selection window opens. Choose the status from Pending, In Progress, or Completed, and (optionally) insert comments to provide updates on the work performed. Refer to the screenshots below.

4. Click on the Update and Save button to make your change effective.



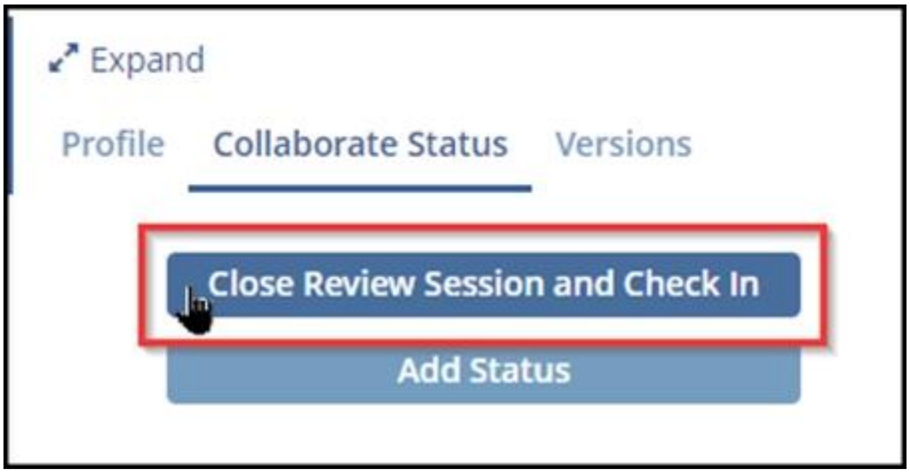
5. You will be notified by a pop-up that your status was correctly added.

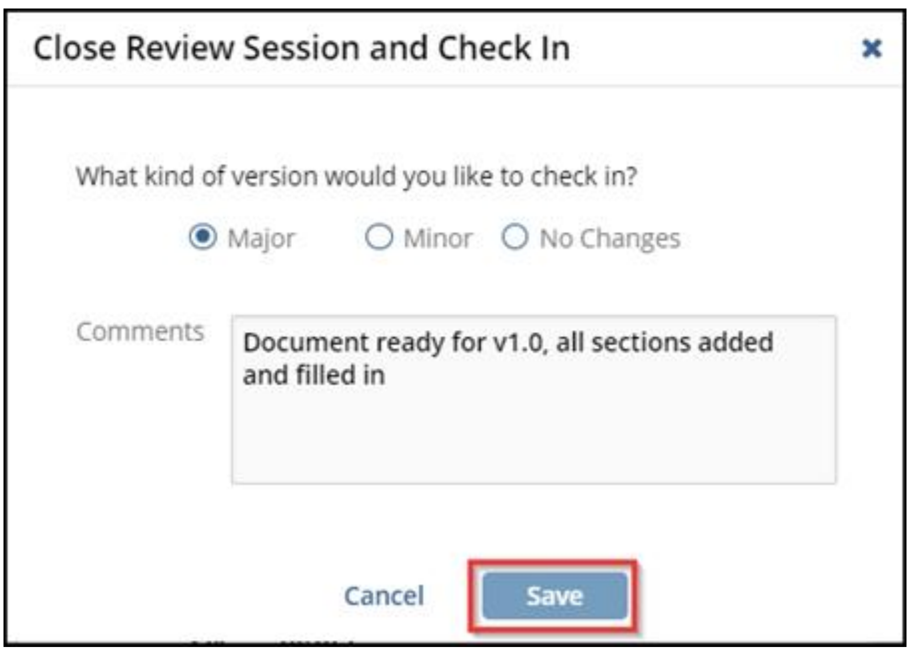


Once work on a document is complete, only the Collaboration Review Owner can close the session and check in the document.

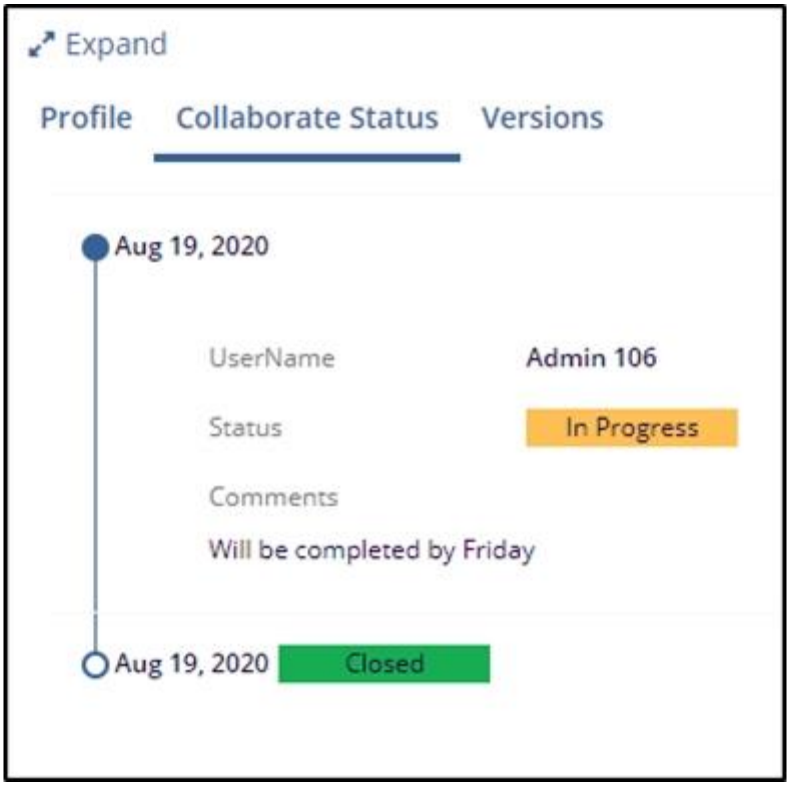
To do that, follow the steps below:

1. Click the Close Review Session and Check In button under the Collaborate Status.
2. A pop-up window appears.
3. Complete the check-in information by adding the type of revision and any comments, and then click Close Review Session and Check-In.



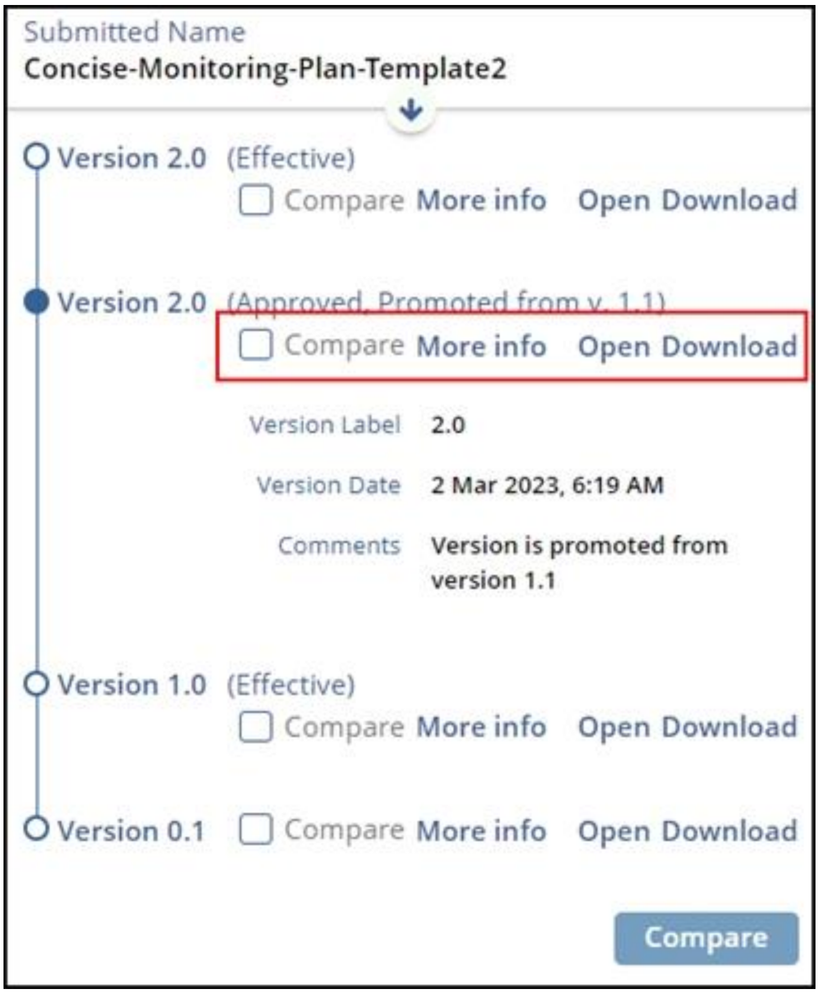


4. A Notification popup will confirm the review session is closed. the Collaborate Status will be updated to a Closed status, as shown in the screenshot below.

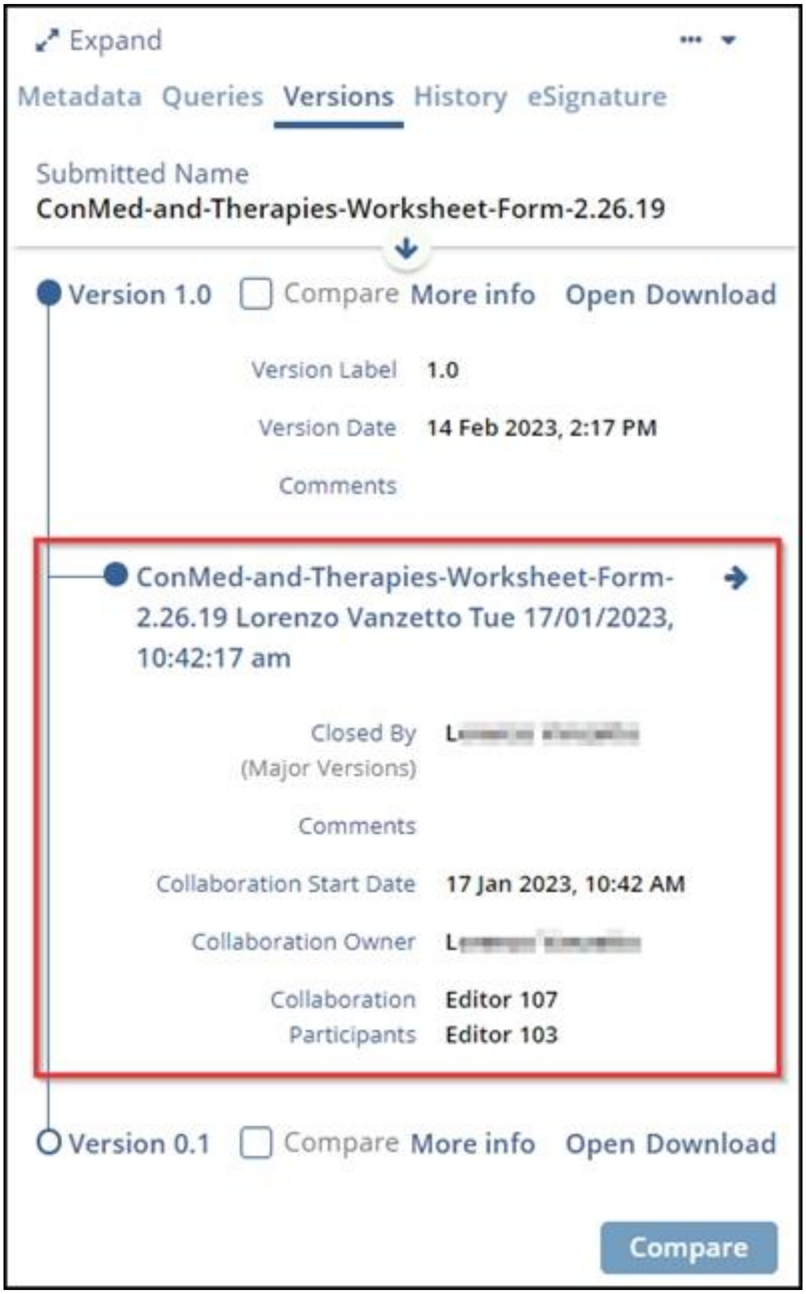


Document and Collaboration Review

All edits, regardless of method, are tracked as part of a document's history. Versions of the document can be viewed and compared in the Versions tab of the Metadata panel.



When viewing the documents library, it is important that the collaborative review history be available for any document edited in a collaborative manner. If a collaborative (Team Edit) session is ongoing or has happened in the past, details of it can be seen in the Versions tab of the Document Metadata panel.



Review and Signature Workflows

This section explains the procedure to follow to review and sing a documents.

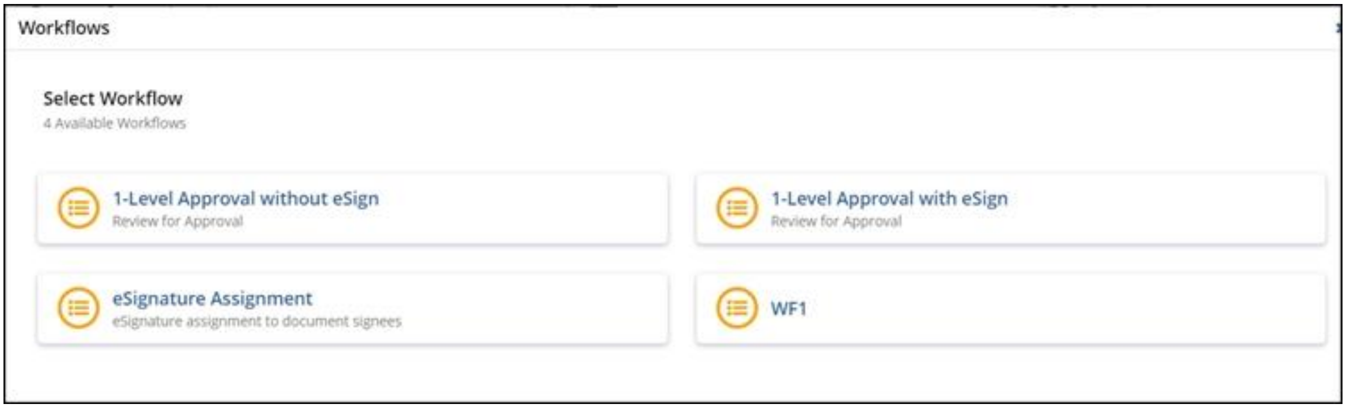
Setting Up a Workflow

Documents requiring Change Control can be submitted for review or signature workflows either upon submission to TI or after content is generated/edited in TI**.**

To initiate a Workflow, the Document Owner can open the document actions menu and select 'Initiate Workflow', or they can use the paper plane icon visible on the document line in the grid.

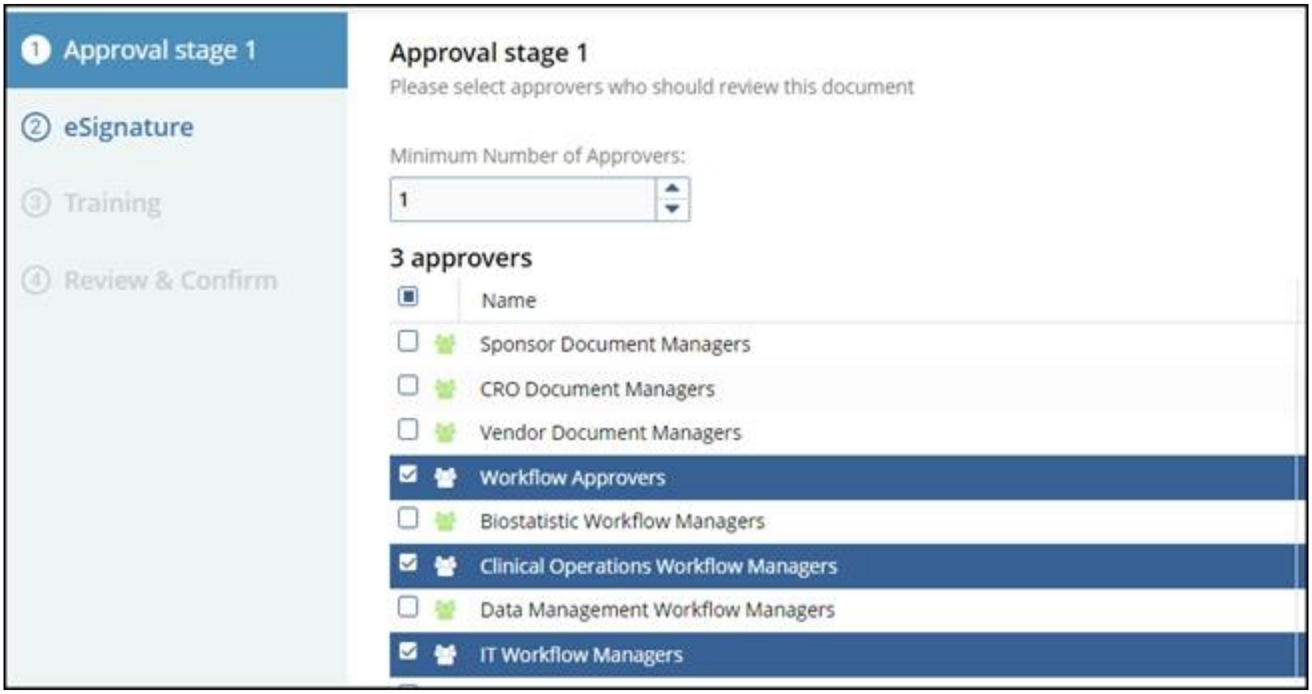
A document requiring a Workflow will be displayed in the Document Index with a paper plane icon next to it. Clicking on it will open the Workflow Setup Wizard. This step is required to initiate any Review or Signature workflow.

The Document Owner or Proxy Document Owner (as designated in the folder security settings) will select one of the workflows available in the room.



Workflows are available in the room are set in the configuration phase of the room build. If any changes or additions to the available workflows are required, contact your Trial Interactive representative.

After selecting a Workflow, the setup process will guide the user through the selection of required Reviewers and, if applicable, eSignature Managers (These are the users that will be able to create the actual eSignature request). The number of steps in the wizard may vary. The screenshot below is an example.



In the last step, the user will review and confirm the workflow settings, then activate the workflow by clicking on ‘Add Document(s) to Workflow.’

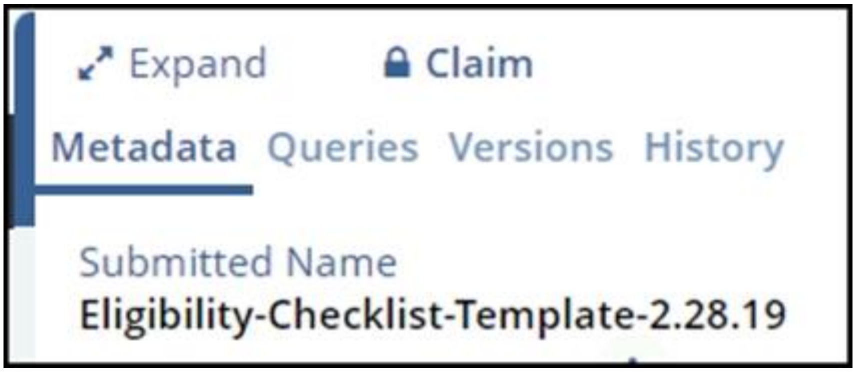
Reviewers can now locate the document to perform their review steps using the Collaborate Dashlets: Documents to Approve and Documents to Sign or by using the index views: Document Lifecycle, eSignature, and Workflow. Reviewers and signers can also access documents requiring their attention through links that are provided via email.

Important: *It is our recommendation that users should, where possible, reach out to the Trial Interactive Service Desk whenever assistance is needed in workflow creation or maintenance.*

Approving a Document

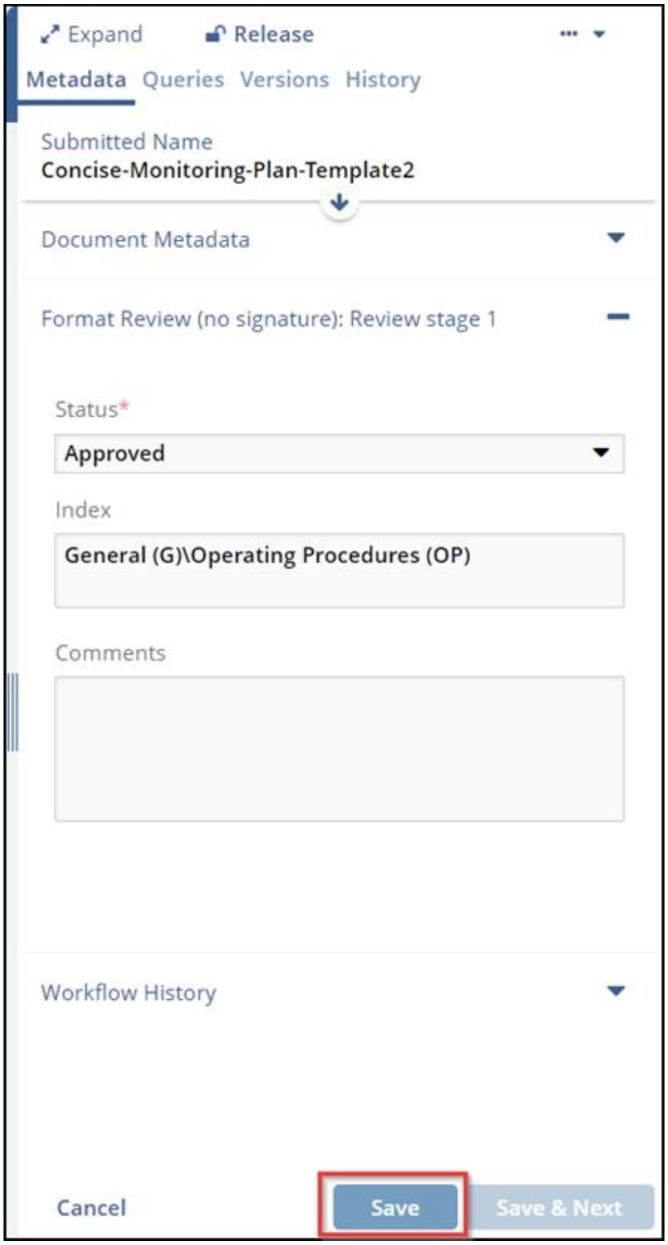
To review and approve a document, first navigate to it using one of the methods available (email link, Documents to Approve dashlet, or Document Library views).

1. Select the document and open the Metadata panel. To start the approval step, click on the Claim button at the top of the panel (shown in the screenshot below).
    - **Note:** Only designated workflow approvers will be able to perform this action.
2. Review the document content to verify it complies with your standards and requirements.



When a document is claimed, a new subsection appears at the bottom of the Metadata tab, its name based on the workflow step that currently applies (note these can be 'Review' or 'Approval' stages, but the process is the same).

3. Select the Status you want to apply to the document. For example, 'Approved' would indicate your review had a positive outcome. Add any comments, then click Save at the bottom. See the screenshot below.
4. The document is now either finalized, moved to other approvers, or moved to the eSignature stage of the workflow, as required by the workflow configuration.



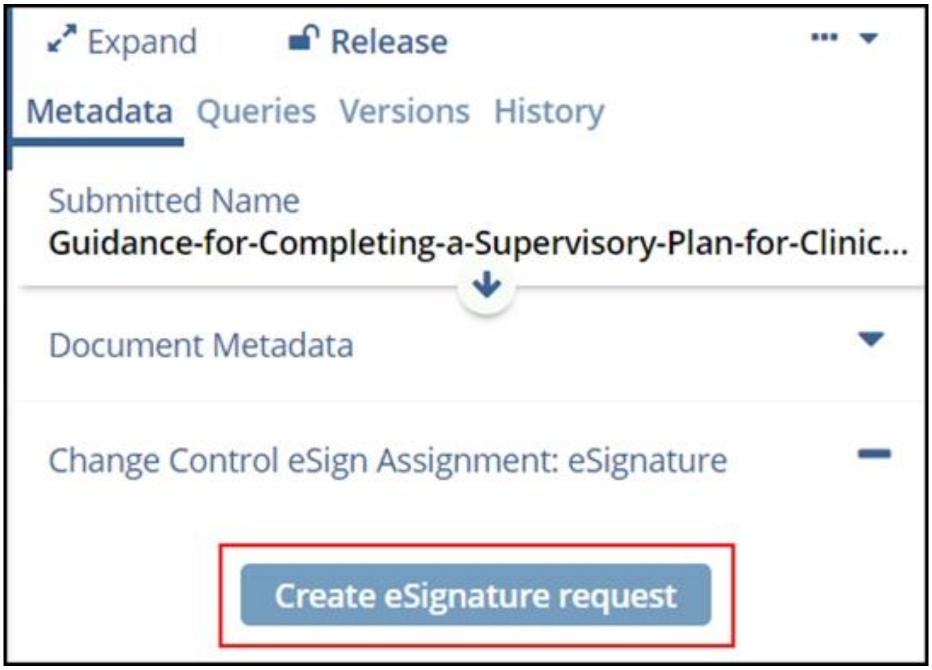
Setting Up eSignature

Documents in eSignature workflows need to be set up by an eSignature Workflow Manager.

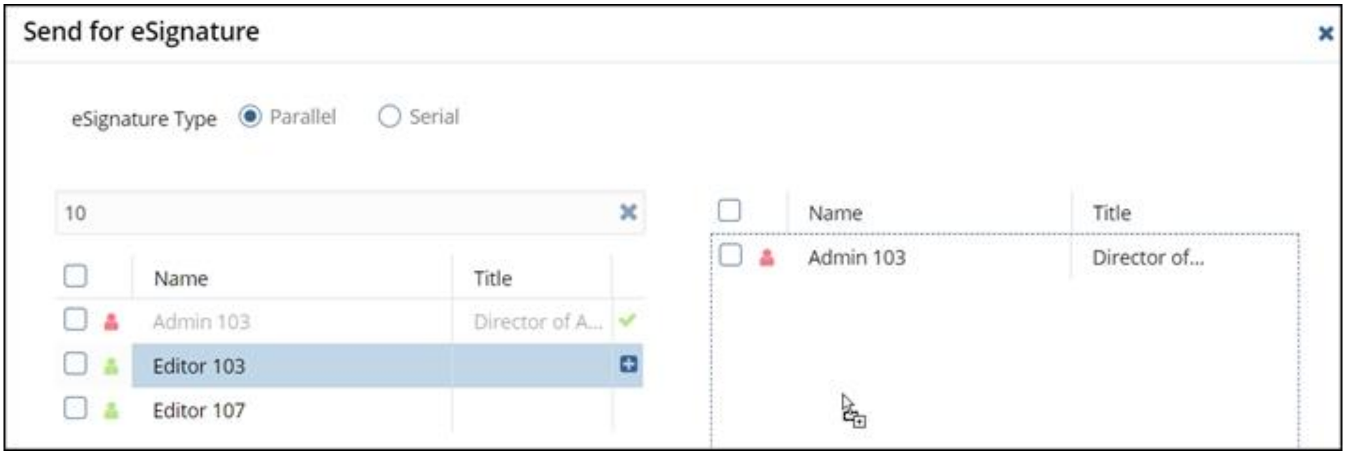
To do so, first, locate the document awaiting action using the related email notification, the Document Life Cycle dashlet or any Document Library view that displays document statuses. Documents awaiting signature setup can be found under the ‘eSignature Requests’ status in the Document Lifecycle view.

1. Select and Claim the document you wish to have signed (screenshot below).

2. Click on the **Create eSignature Request** button.



3. Move the requested signatories into the right column of the 'Send for eSignature' panel, select the type of signature, and click **OK** when ready. Details of the signature creation are covered in the dedicated section of the user guide.



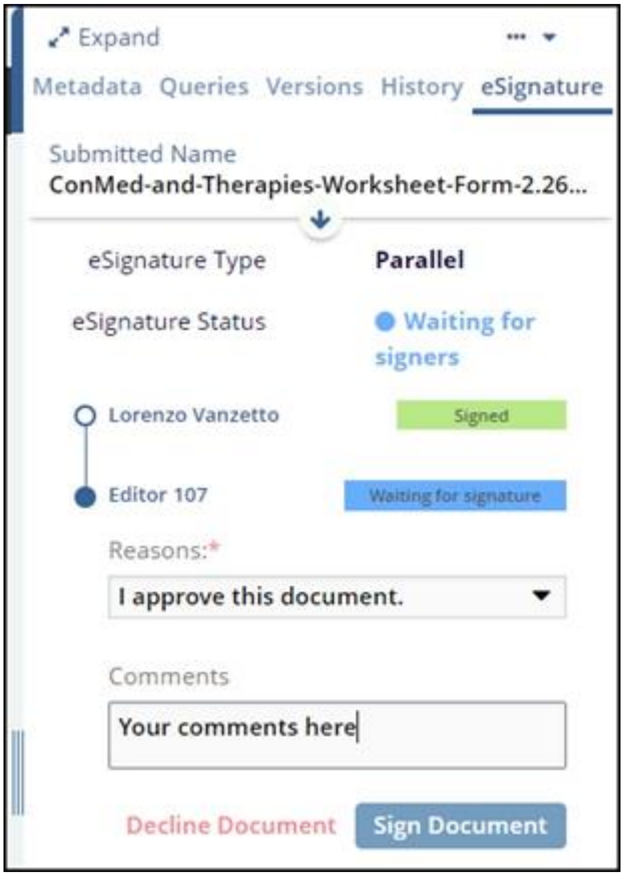
4. The selected users are required to sign and will be notified by email that their signature on the document is pending.
Note: Specific steps at this point may vary based on the eSignature vendor configured for use in the room. Please see additional materials as necessary.

Signing a Document

Please note that the specific details of how to sign a document in TI will vary depending upon the eSignature vendor configured for use in the room. The following steps outline how to sign a document using TI sign. For other vendors, please see the relevant job aids.

To sign a document, navigate to it and open its metadata panel.

1. You will find a tab called eSignature. This displays the current status of the signature workflow, including the name of the required signatories.
2. Choose a Reason from the related dropdown, add any comments you may have, then click on **Sign Document**. See the screenshot below.



3. After clicking on Sign Document, a window will open up where you will be able to apply your eSignature using your chosen eSignature provider.

Non-Approval of Documents

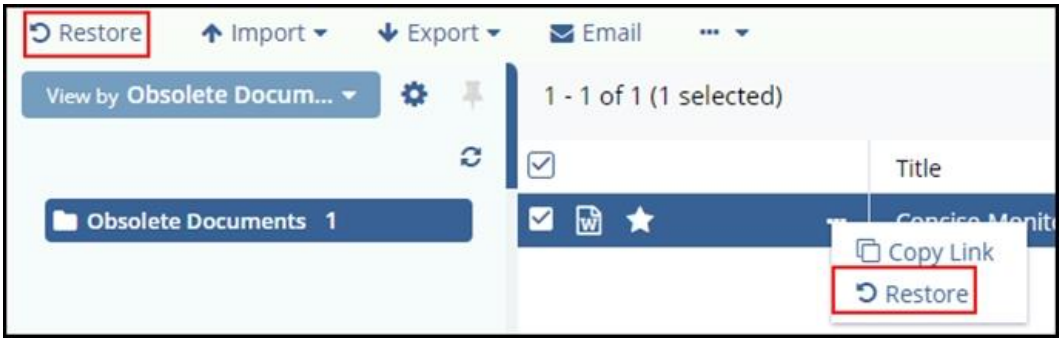
Documents can be rendered ineffective, for example, when the format is not correct, in multiple ways. Of course, an approver can refuse to move the document forward, or a signature workflow can be neutralized when someone refuses to sign.

TI Collaborate also allows for neutralization before the Workflow stage, saving precious time otherwise spent on non-satisfactory documents.

Non-controlled Documents can be Deleted using the Document Actions Menu (for more information, see the User Guide section on The Document Activities Menu).

It is also possible to render a controlled document obsolete. This can be done via the Document Action Menu, clicking the Make Obsolete button as shown in the screenshot below, and thus moving the document to a section of the library called Obsolete Documents (accessible by Admins through the View Selector). All doc history and properties will remain intact, but the document will not be eligible for editing or workflows. Documents in this area can be restored in case they were rendered obsolete in error.

Note: *Documents that are checked out or undergoing a workflow review cannot be deleted or marked as Obsolete.*



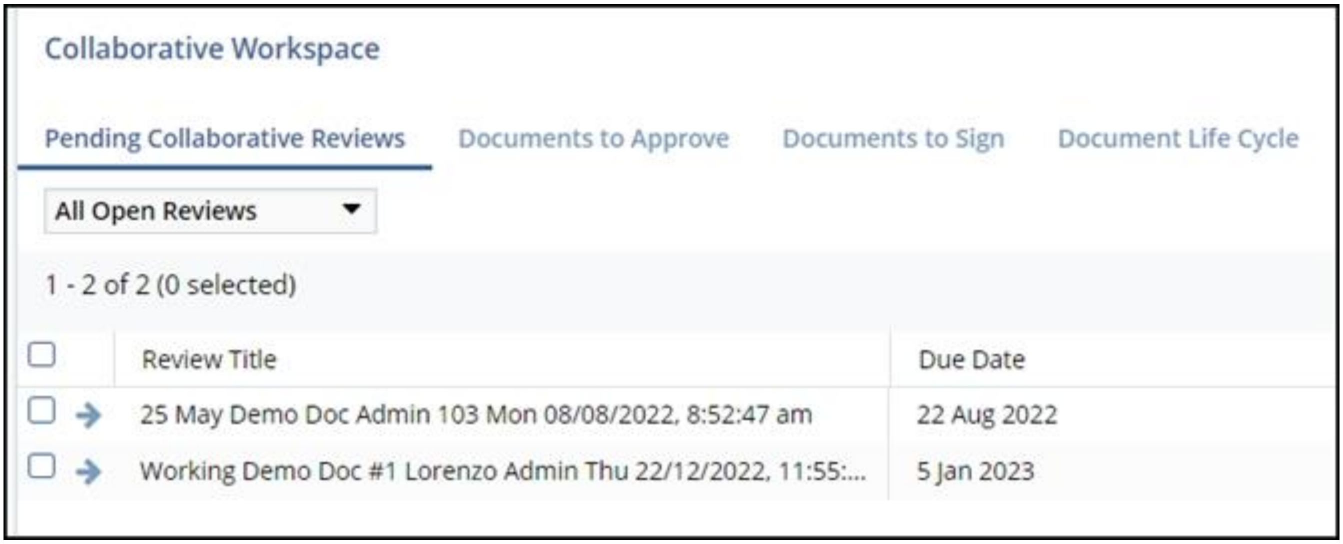
Collaborative Workspace Dashlets

The Collaborative Workspace grouping of dashlets is exclusive to TI Collaborate rooms and contains dashlets that give the user quick access to lifecycle tools and documents.

See the following subsections for a description of these dashlets and their functions.

Dashlet – Pending Collaborative Reviews

This dashlet displays all documents that are currently open in Team Edit mode for collaborative review by the current user. You can choose to view the documents pending for review for All users (default) or only for yourself by selecting My Pending Reviews. Click the dropdown located above the grid within the dashlet to toggle between these views. Refer to the screenshot below. Click on an entry to access the document's Edit interface and apply edits (see 'Team Edit' in the Content Editing section of this guide).

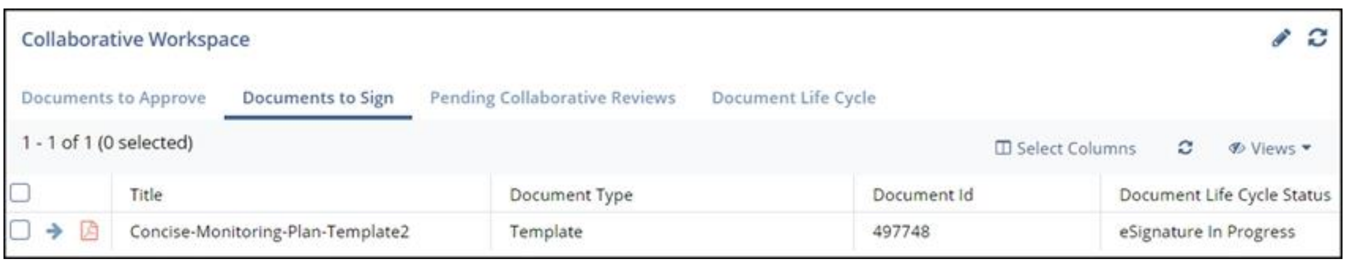


Dashlet – Documents to Approve

This dashlet displays the list of documents that are pending the user's approval in TI. Note that if the user belongs to a pool of approvers of the same level, docs may be approved without the user's intervention. Click on an entry in this list to open the document approval interface.

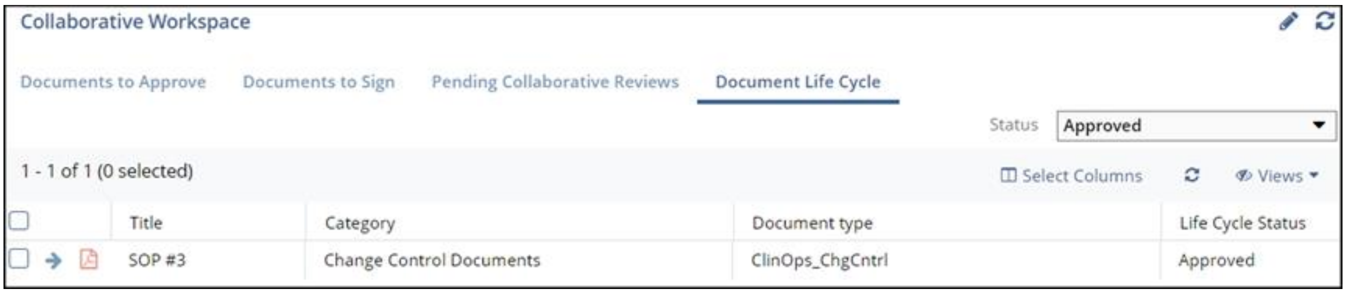
Dashlet – Documents to sign

This dashlet displays the list of workflow documents that are pending the user's signature in TI. Note that some documents may require serial signatures and may not appear here until it is the user's turn to provide their signature. Click on an entry in this list to open the document signature interface (this will use your implemented signature engine: TI Sign, Adobe Sign, etc..).



Dashlet – Document Life Cycle

This dashlet displays workflow documents based on their review status. Any status used in the room can be selected for filtering, giving the user the visibility, they need on documents. For example, documents pending review or in the process of being signed can be listed all at once here. Click on the selector on the right to choose 'Any' status or a specific one. Click on an entry in the list to view the document.



Administrative Workflows

Effective versions of controlled documents will sometimes require a minor housekeeping change after approval. These changes should not impact the effectiveness of the document. An example of this type of change would be the correction of a minor typo. It would be inconvenient to use the full versioning workflow in correcting such a trivial error, and this is why TI Collaborate includes a feature called Administrative Workflow.

The key difference between an Administrative Workflow and a standard Approval Workflow is that the Administrative workflow will appear as a minor version change, but the Effective date and Periodic Review timeframe will remain unchanged from the current effective version.

To carry out an Administrative Workflow correction, the user needs to be added to the related group in a room.

In order to start an Administrative Workflow:

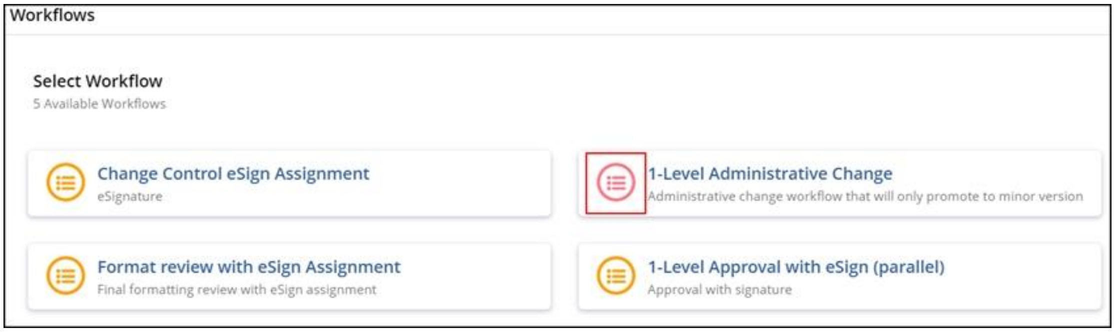
Navigate to the document requiring a change in the Document Library, and Check Out the document.

Make the necessary small change(s) and check the document in.

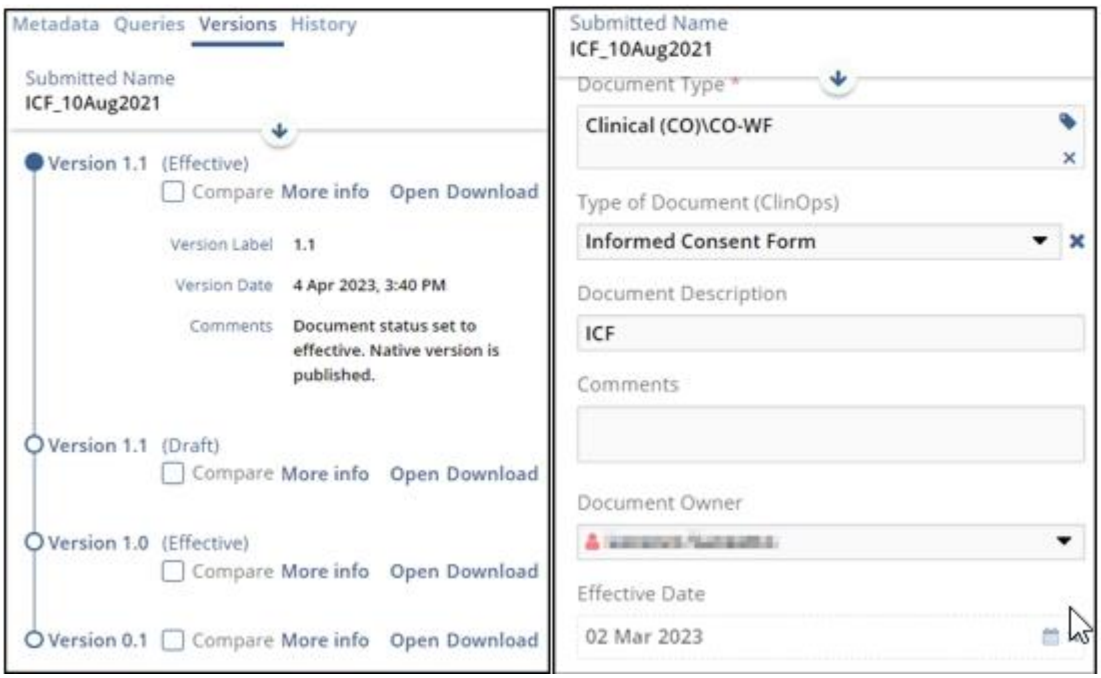
1. The document will be indicated as ready for workflow (paper plane icon).

2. Click on the paper plane icon and select your Administrative Workflow. This type of workflow can be distinguished by its red icon in the setup wizard (as per the screenshot).

3. Set up the workflow and carry out the review and approval as normal (see previous chapter on Review and Signature Workflows).



4. You can verify the document update in the document's Versions panel. The Effective Date and (where applicable) Review Period fields are unchanged.

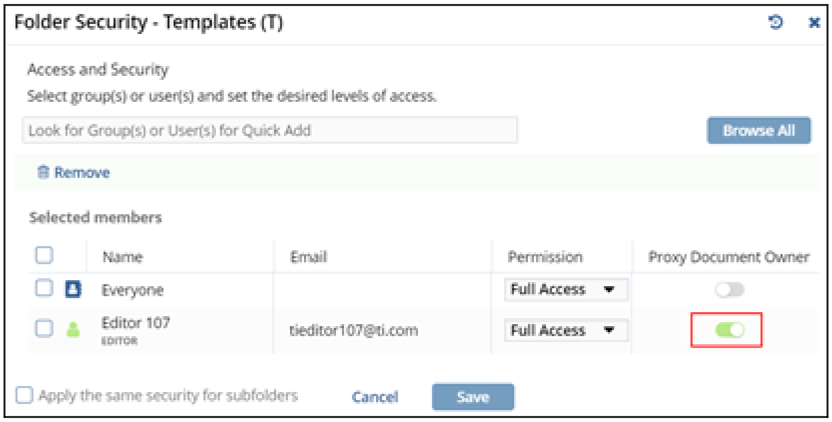


Additional Document Owner Privileges

In many cases, the user listed as the Document Owner will not be the only one who needs to have permission to send a document for review and initiate a workflow. To that end, Trial Interactive provides a security feature called Proxy Document Owner. Any user indicated as a proxy document owner via the folder security settings can then perform document owner functions for the documents in that folder.

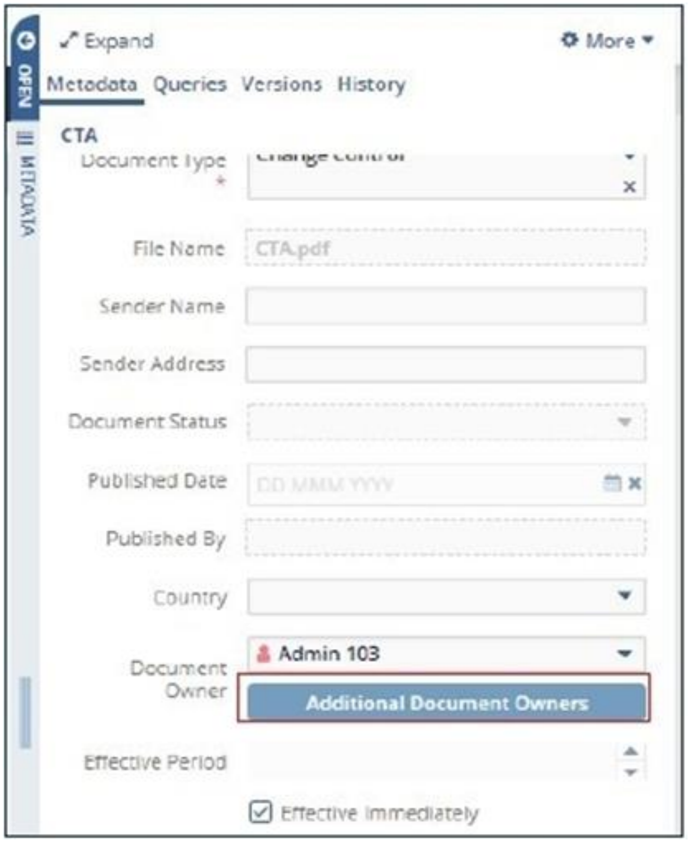
In order to assign a user as a Proxy Document Owner, follow the steps below:

1. Navigate to the Documents Library in your Content Management room.
2. Locate the folder whose security settings you wish to adjust.
3. Right-click on the folder and select View Folder Security.
4. Select the Group or User who should be added to this folder's security and move them to the right side of the window.
5. Once they are there, you will need to give the Group or User the Proxy Document Owner permission, as shown in the screenshot below.
6. Press **Save** to complete the process.



For a more detailed discussion of folder security, please see the related section in this User Guide.

Once a user has been assigned as a Proxy Document Owner, they will appear on the list of Additional Document Owners found in the Metadata Pane of any document in the folder. Please see the screenshots below:



eISF

Trial Interactive's electronic Investigative Site File (eISF) solution reduces administration loads and improves speed and compliance for site personnel, CRAs, and study teams. Digital investigative site binder processes maintain certified copies of source file documentation and essential documents required for each clinical study. A seamless, connected eTMF allows for the automatic indexing of essential documents to the TMF. The ability to conduct remote site monitoring, recommended by the FDA and EMA, helps CRAs work more efficiently in today's increasingly virtual environment while reducing travel expenses.

Background

The philosophy of Trial Interactive is that of a secure building with many floors and secure rooms, which best supports the needs of small workgroups and teams that can easily own their own content spaces and share information with other teams, promoting a truly collaborative culture. Documents may be shared between teams and rooms easily, with full source traceability, metadata structure, and enabled features. The eISF supports site and sponsor staff by providing a space for effective management of documentation used by a site in the clinical trial that is ultimately published in the eTMF. The eISF and content management rooms enable collaborative and controlled document authoring, review, and approval. Designed to include 21 CFR Part 11 compliant record control and signatures processes. The solution offers an end-to-end service platform for an organization's site content management requirements. The eISF can also work in tandem with GlobalLearn and eTMF for a complete Training Management solution to document site training.

- **Segregation of Data:** Site and participant source documents need to be stored separately, ideally in a separate repository, from sponsor documents. This requires a robust system for categorizing and segregating documents.
- **Access Control:** Strict access controls must be implemented to ensure that only authorized personnel can view site and participant sourse documents. This includes setting permissions and audit trails to monitor who accesses what information and when.
- **Regulatory Compliance:** Ensuring compliance with regulatory requirements such as Good Clinical Practice (GCP), GDPR, and other relevant guidelines is essential. This includes maintaining secure, traceable, and auditable records.
- Document Integrity: Maintaining the integrity and confidentiality of site and participant information while enabling necessary updates and collaboration can be challenging, especially in a digital environment where data breaches and unauthorized access are risks.

What is an eISF?

TI's eISF solution provides organizations with:

- A single place to share and collaborate on clinical documentation.
- The ability to align document work streams with regulatory compliance practices for document authoring, approval, access, and related training.
- The ability to co-author and collaborate on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.
- The ability to complete the end-to-end document signature process with an electronic signature.
- The ability to send documents for certified translation through TransPerfect TransPort, track their status, and receive back the translated copies and certificates.

- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.
- The ability to follow critical processes for metadata, approval, and signoffs by publishing or sharing directly with the TMF.

Target AudienceWho are the target organizations for this solution?
Clinical Operations: the eTMF Business Lead at the sponsor will understand the requirements of the protocol and know if an eISF is required for site document capture. Additionally, they will be able to advise on the approach necessary to handle site and PHI/PII data within the eISF and eTMF to determine if document redaction is required.

Who will use this solution?
An eISF is ideal for four primary user types: eISF Administrators, Site Users, Study Managers, and CRAs. Each of these primary user types have roles and responsibilities unique to the eISF solution.

The Trial Interactive eISF gives complete access to appointed administrators seeking to control the security and room settings, manage user access, and manage sites during the course of a study. Administrators of rooms are not only able to create users, assign users to specific security or activity groups, manage user access to folders and documents but also revoke access to any user within the room. Administrators can create new sites, manage existing sites, update site security, convert site contacts to users as well as update room settings and delegate certain activities to other users in the room as needed.

Site users such as site coordinators, principal and sub investigators, and any other site users who need limited access to their own documents is the second primary user type. Site users are granted access by an administrator to specific sites within the system. Most site users have the ability to access uploaded site documents, upload new documents and update metadata information. Site users also have the ability to create and sign documents within the collaborative review process and have the potential to create documents from existing document templates that have been uploaded to a room. Certain site users will have access to a restricted document folder as well as the ability to redact uploaded documents as needed.

The third type of primary user is the CRAs and monitors involved in the oversight of sites on behalf of the sponsor. CRAs and monitors are granted access by an administrator as a site user with access to their assigned sites but also to additional functions to be used in conjunction with the TMF solution. CRAs and monitors are expected to be given access to multiple sites and their restricted site folders to be able to perform source and site document verification and leverage this access to perform remote site monitoring visits.

Study managers or other sponsor staff involved in the course of a clinical trial are the fourth type of primary users of an eISF. A study manager or other sponsor user would be restricted to certain site folders, if they have access at all to site folders. Sponsor users typically have access to create new sites within the eISF room as sites are activated during the course of a study. Sponsor users also have the ability to upload new documents to share with site users. These users also typically have the ability to create a document from a document template, open collaborative reviews with site users, and send documents for signature.

Business Use Case
The eISF room provides the following business case goals:

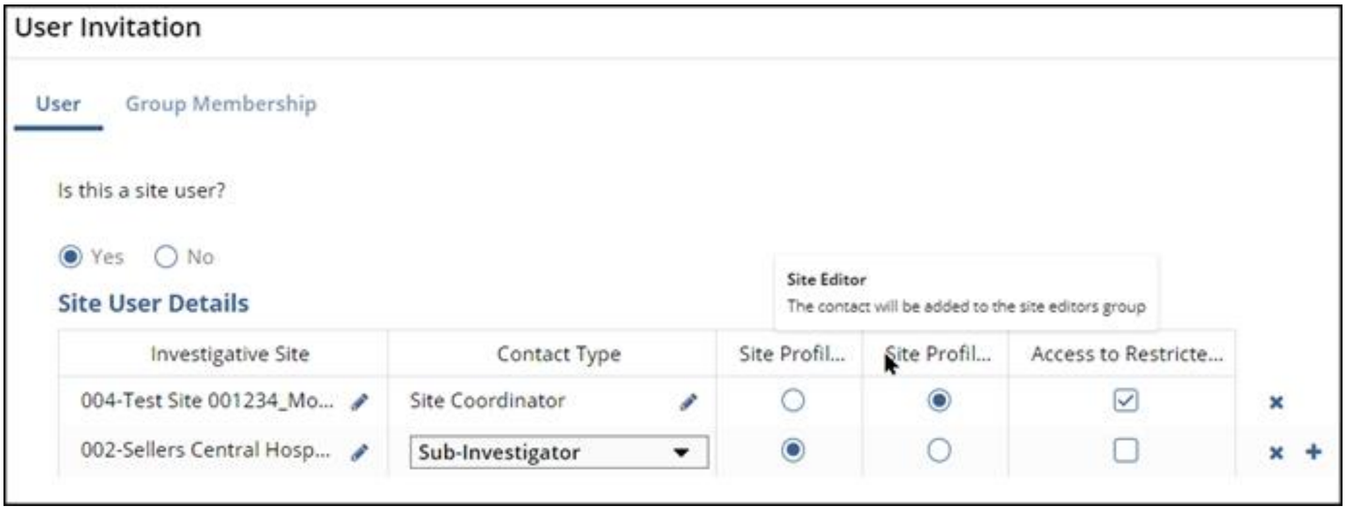
- **Simplified Storage and Accessibility for Regulatory Inspections:** An eISF repository ensures that storage of site document or Restricted Content is managed seamlessly, without the usual stress associated with the management of these sensitive documents and data. It guarantees that all necessary documents are accessible for inspectors and can be filed contemporaneously. Regulatory bodies often require immediate access to trial documents during inspections. Traditional methods of storage can lead to difficulties in locating documents quickly, especially under time constraints. By using an eISF, organizations can ensure that all documents are stored in a centralized, easily accessible location. This not only reduces the stress and time associated with preparing for inspections but also ensures compliance with regulatory requirements by maintaining up-to-date and well-organized records.

- Ensuring Compliance with Regulatory Standards and Guidelines: Using an eISF repository helps organizations stay compliant with regulatory standards and guidelines, as well as internal Standard Operating Procedures (SOPs). This includes ensuring that Monitoring Visit Reports and Letters are provided to the site in a timely manner, correlating with the effective date of the document. Compliance with regulatory standards is critical in the pharmaceutical and clinical research industries. Failure to adhere to these standards can result in significant penalties, delayed approvals, and damaged reputation. An eISF repository facilitates adherence to these standards by providing tracking mechanisms that ensure timely submission and proper documentation of site activities. This systematic approach minimizes the risk of non-compliance and enhances the integrity and credibility of the site and trial data.
- Protecting Study Integrity: Maintaining the eISF in clinical trials is essential to ensure the protection of sensitive participant information and the validity of the study. Unintentional unblinding of participant information or results can compromise the integrity of the trial, leading to inconclusive or invalid results. This not only wastes the significant financial and human resources invested in the study but can also result in reputational damage to the organization as well as the site. By using an eISF repository, organizations can securely manage and control access to sensitive information, reducing the risk of information leaks. This secure management is crucial for preserving the scientific integrity of the trial and maintaining trust with site staff, study participants, stakeholders and regulatory authorities.

Site Specific Security

When providing site users access to a study, it is important that security is automatically assigned to ensure that users can complete their tasks, such as document upload, certification, redaction, indexing, reconciliation, with the regulatory binder, and sharing to the eTMF while preventing access to material that they are not authorized to see.

Upon creation of a new user, a designation of Site User can be given to the user, along with an assignment to one or more specific sites. A user can have, therefore, a Reader-level access to one site but Editor level to another. To perform this assignment, invite a new user from the Users Management panel in an eISF room using the Regular method of an invite. See the screenshot below.



1. Select Yes under “Is this a Site User?”
2. Choose an Investigative Site, followed by the Contact Type to be assigned to the user for that Site.
3. Select whether the user should have Reader- or Editor-type access to the Site.
4. Mark the Access to Restricted Folder box if you wish the user to have access to the site Subject Documentation and other source documents.
5. You can repeat these steps for multiple Sites. Use the ‘+’ button at the right to add a new line.

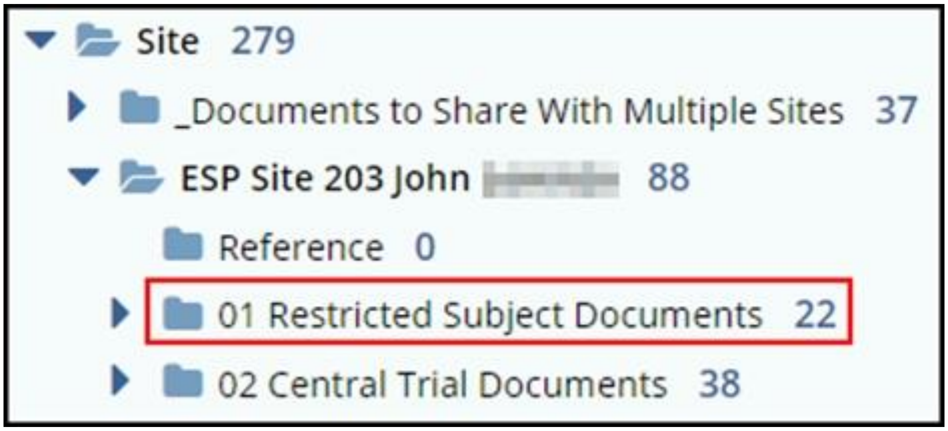
Specific permissions are assigned to users in this category based on predetermined site template-folder security configuration. This will allow users to be provided the correct security profile right away upon creation and gain immediate access to the Site Collaborate room, reducing time-to-access.

Given the stringent security requirements typical for a Site Collaboration (eISF) environment, we recommend the creation of new users in this type of room be handled by the Trial Interactive Service Desk in accordance with your previously defined security setup.

To have a site-specific user added to a Site Collaboration room, please reach out to your Trial Interactive representative or directly to the Trial Interactive Service Desk.

Restricted Folders

Digital Site Binders can see a wide set of contributors having access to data. To keep critical or data-sensitive documents from being unduly accessed, TI Collaborate can incorporate Restricted Folders, which will be only accessible by designated site personnel. Talk to your TI representative to include this feature in your room(s).



In a room with Restricted Folders enabled, user security can be configured so that a specific person or group of people has exclusive access to the Restricted Area for one or multiple sites, thus avoiding the peril of disclosing privileged information to non-privileged users.

Site User Identity Verification

In order to prevent unauthorized users from requesting and gaining access to a site's data, a secure PIN code can be optionally required as part of the process for granting access to a user to a site. Site administrators that are part of a 'restricted site group' can view the PIN code and make it a required part of any new user access request. Trial Interactive Service Desk personnel always verify the PIN code as part of granting access to the site.

Note: If you wish to enable these features, please contact your Trial Interactive representative.

Chapter 24. Study Start Up

The Start-up module is available to users who have the Study Start-up action selected in the user profile,who are members of the data room's Study Start-up Team group, and who are Start-up Specialists in the data room.

Study Start Up has the following changes seen in TI v10.5. The changes are explained in brief here and feature-wise in detail in the coming pages.

- **New UX Design** – The SSU design aligns with the TI v10 interface.
- **Contracts and Budgets** – SSU introduces contracts and budgets to upload/track in SSU.
- **Activate Countries/IRBs** – This allows the SSU specialist to meet all country/IRB requirements before activating any site.
- **Improved Agency Submissions** – It can arrange the order of documents and rename them required for agency submissions.
- **Improved Amendments** – SSU now has an easy way to create, complete, and track amendments for all categories.
- **Improved IRB Profile -** allows users to associate multiple IRBs to a site with an addition to assign a central or local IRB.
- **New Dashlet for tracking Cycle Time** – SSU has a new dashlet to track cycle time for different stages of site activation.

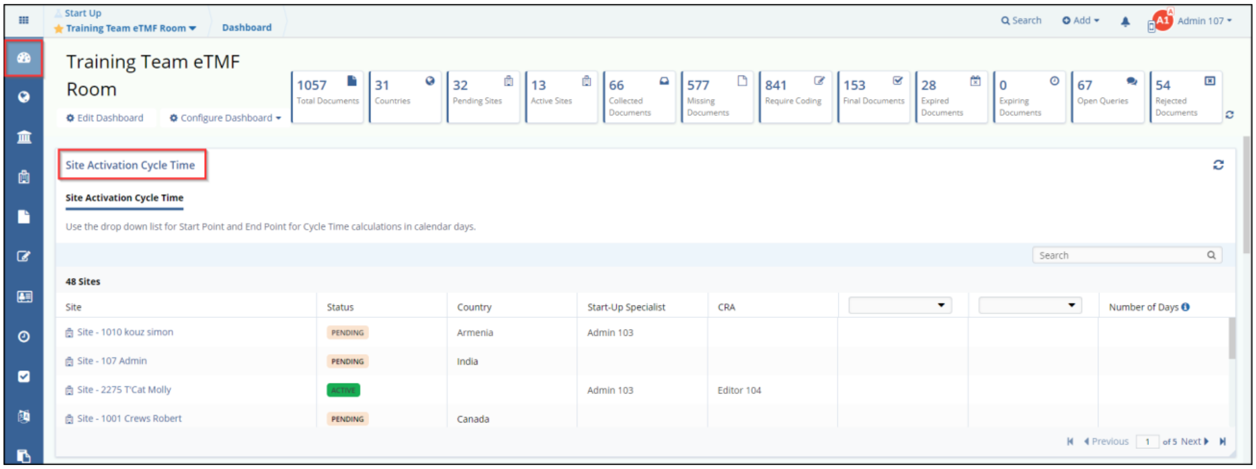


Figure 14: SSU Module

New User Experience

SSU module is updated and is in alignment with the TI v10 interface. The rules for this release are as follows:

- It refreshes the designs that are common in any modern SAAS software.
- It attempts to simplify without changing the workflow or user acceptance tests.
- SSU is optimized without taking away its usefulness for its users.

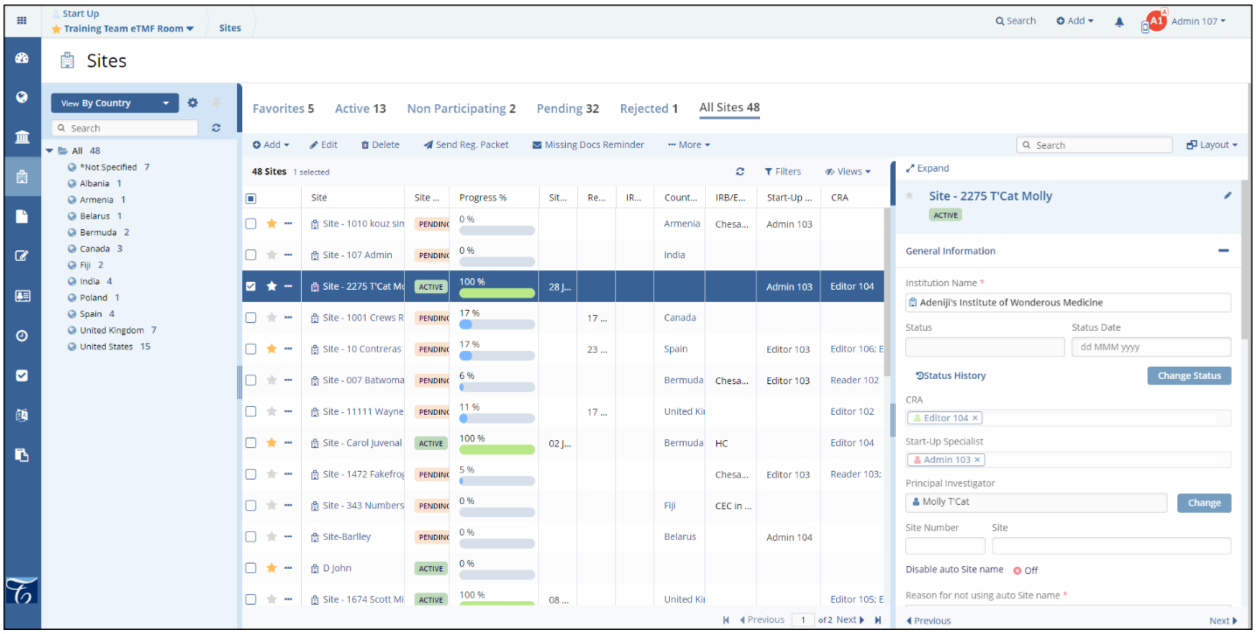


Figure 15: New User Experience

The Study Start Up Process in Trial Interactive

The sequence of steps enlisted below gives you a glimpse of the study start-up process followed within the Trial Interactive:

1. Setting up the configurations

   a. Configuring Study Start-Up Settings

   b. Adding Countries

   c. Adding IRB/ECs

   d. Setting Required/Essential Documents for Countries

   e. Setting Required/Essential Documents for IRB/ECs

   f. Setting Required/Essential Documents for all sites in a study

2. Inviting users to the study room

3. Creating/Editing/Viewing/Deleting Sites

4. Adding contacts to sites. This includes adding:

   a. Principal Investigator and other contacts

   b. Start-Up Specialists

   c. Regulatory Approvers

   d. Site Activation Specialists

5. Sending Regulatory Packets and Submission Packages submitted to IEC

6. Collecting Essential/Required documents for sites, countries, and IRB/ECs

7. Review of documents by a Start-up Specialist

   a. Translate documents to the local language if required

8. Review of documents by Regulatory Approver

9. Site Activation and publishing documents to the eTMF

10. Adding essential/required documents after site activation through amendments

Each of the processes mentioned above is discussed in detail in subsequent sections.

Basic Configurations for SSU

Setting up the basic configuration for a Study Start-up (SSU) includes specifying details like adding countries, IRB/ECs, essential/required documents, creating sites, and adding contacts to them. All these are the jobs of the data room administrator and need to be performed by an Administrator roleteam member or by your TI implementation team.
To perform these activities, the administrator needs to:

1. Login into Trial Interactive.
2. Check that the room is created; otherwise, contact the Service Desk.
3. If the room is created, enter the room and navigate to - Settings.

Study Start-Up Settings

The Study Start-Up Settings allows you to set up rules that would be critical for a site activationprocess. These settings are global and are applicable to all sites in the room.

To set up the SSU Settings, the administrator needs to:

1. Navigate to **Settings** via the navigation grid.
2. Click the arrow next to **Investigative Sites** in the left pane of the Settings window.
3. From the collapsed dropdown, click **Study Start-Up Settings.**
4. The Study Start-Up Settings window opens to the right.
5. Select the options as required.
6. Click **Save** at the bottom of the window to commit the changes. Refer to the screenshot below.

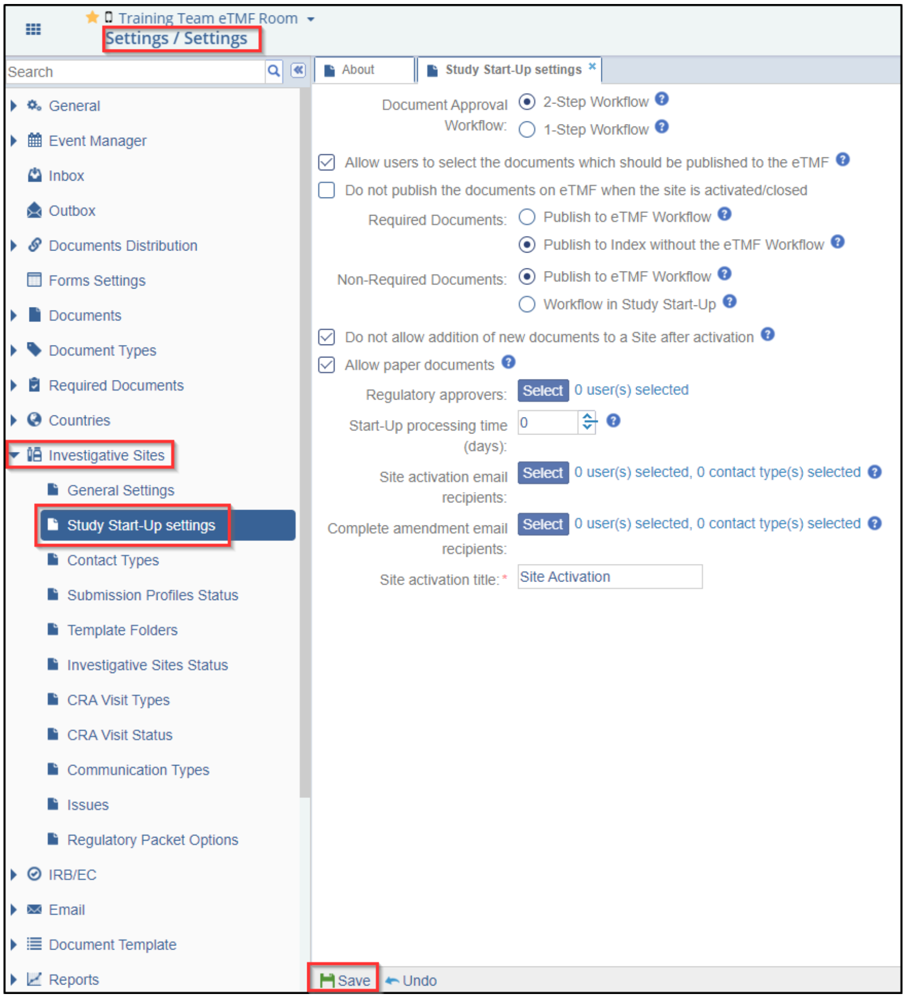


Figure 16: Settings

Referring to the screenshot above, the SSU settings window is divided into two sections:

1. Settings regarding required and non-required documents on-site activation

2. Other settings

Settings regarding required and non-required documents on-site activation

- Select a radio button for the Document Approval Workflow as per requirement – 2-Step Workflow or 1-Step Workflow.
- Select the checkbox next to the option if you do not wish to publish the documents on the eTMF when a site is activated. On selecting the checkbox, the next two options regardingEssential and Non-essential documents appear greyed out and disabled.

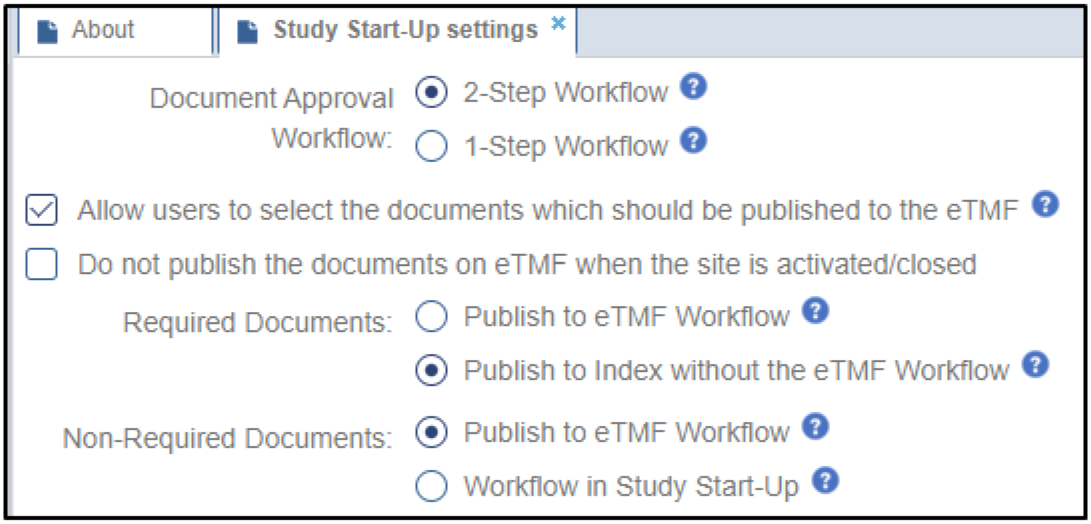


Figure 17: Settings-Required & Non- Required Documents

- Select the radio button next to the option if you wish to publish the required and non-required documents on the eTMF Workflow. These documents will be added to the workflow specified in your system on-site activation and will be taken up for QC Review as per the process. Onpublishing, the documents will be added to the default folder as specified in the Documents section under the room settings.

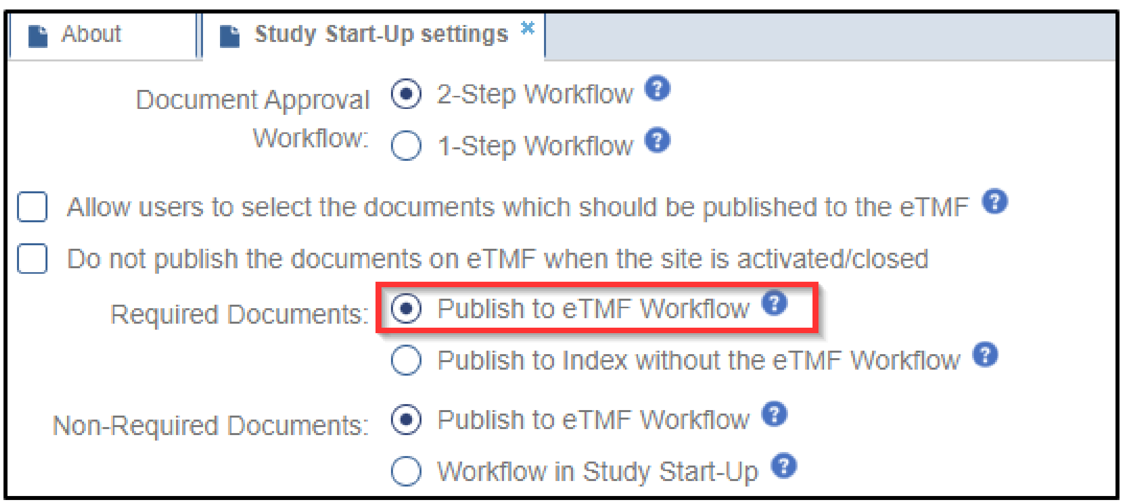


Figure 18: Publish to eTMF

Note: *To be added to the workflow, documents should match workflow conditions. If the document does not match workflow conditions, it will be placed to the default index position.*

- If you wish to publish the required documents directly to the Index without the eTMF Workflow, select the radio button next to the option. These documents will be automatically routed to the appropriate eTMF index based on the document type auto-routing configuration specified in the Related Folder panel of the Document Types section in the room settings. The screenshot below shows where a Tracking Information document will be routed to in the eTMFon-site activation.

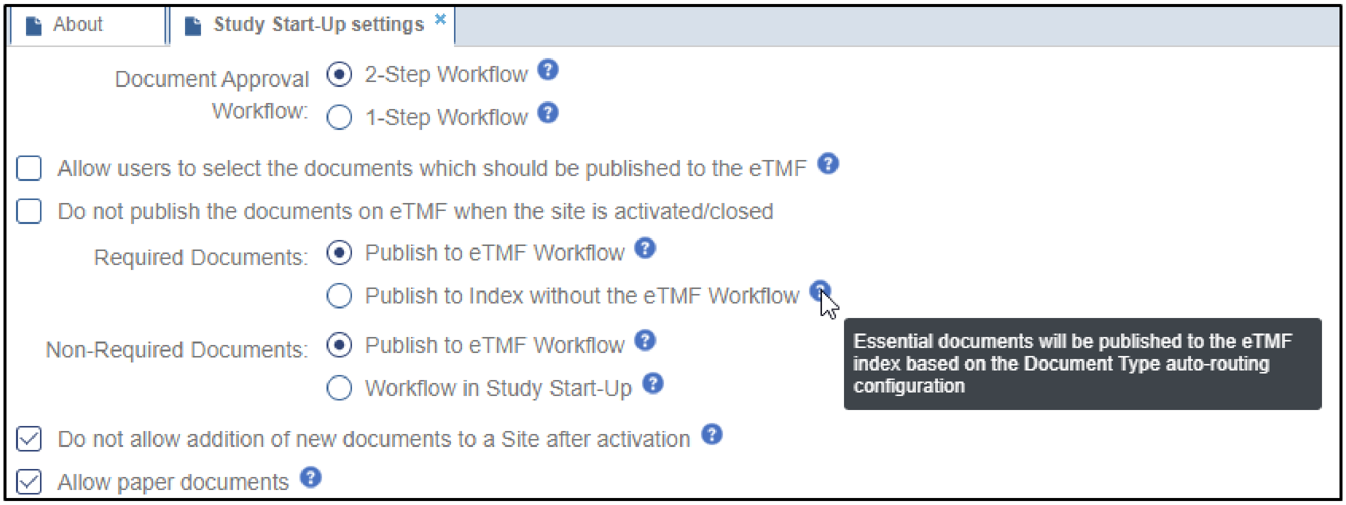


Figure 19: Required Documents

- If you wish the non-required documents to pass through the two-level approval process in SSU,select the radio button next to the option. These documents must be approved through QC Review and Regulatory Review and will be published on the eTMF with Final status on-site activation. If documents are approved after site activation, they will need to be publishedto the eTMF manually. The system will provide positions in the eTMF index for these documents as per the Auto-Indexing rules. You will need to enable auto-indexing in the Documentssection in the room settings for this to happen.

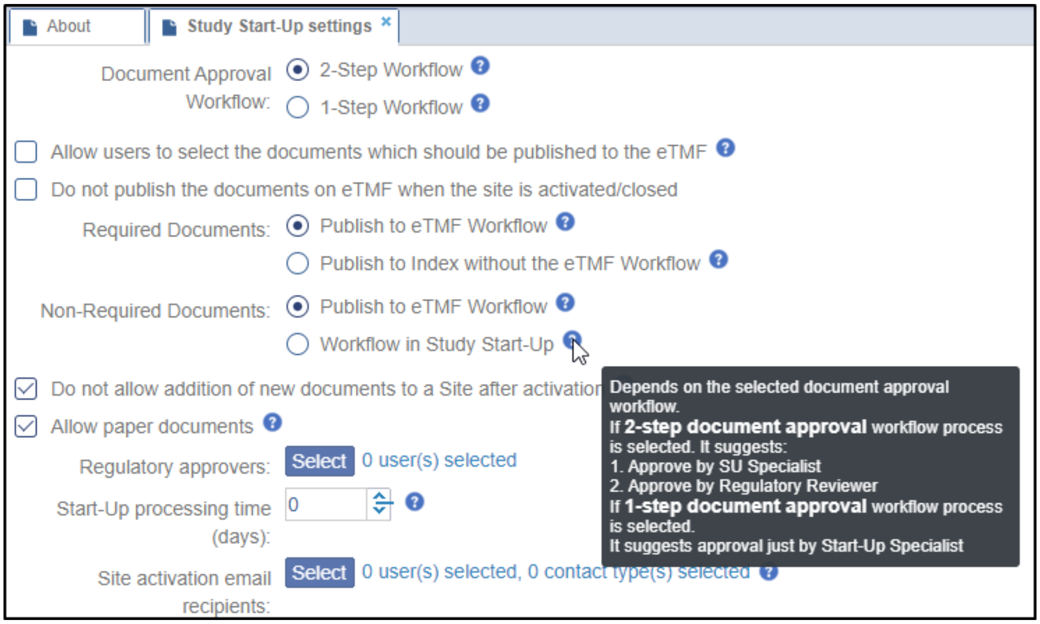


Figure 20: Workflow in SSU

- If you wish to lock down the site for any new documents after the activation, select the option as shown below:

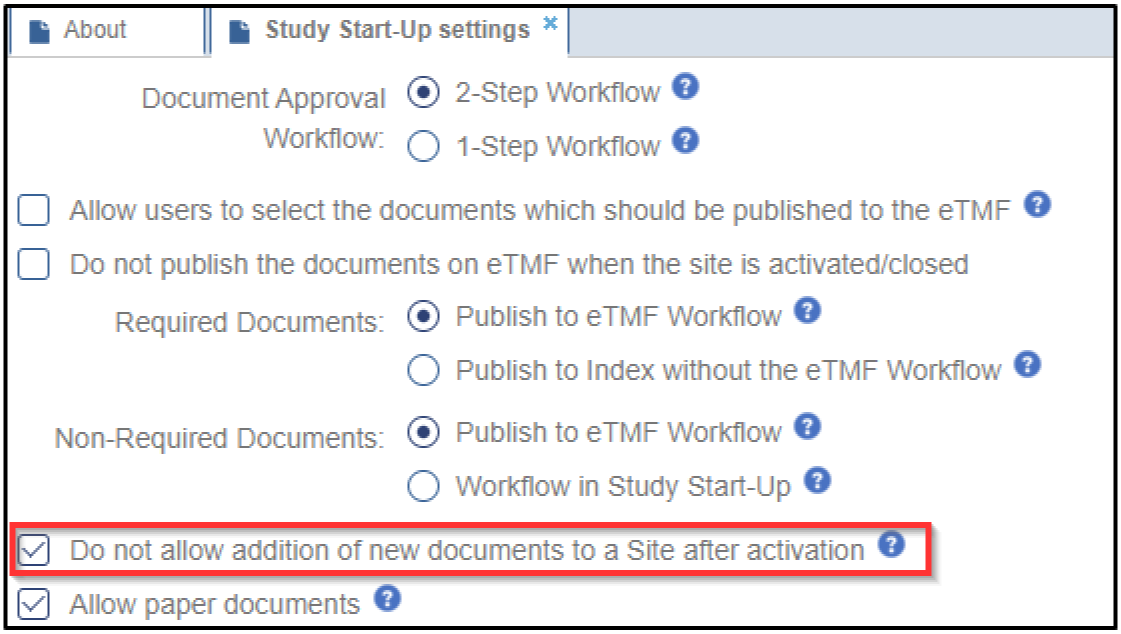


Figure 21: Site Activation

- If you need to submit paper documents instead of their soft copies, you may choose the 'Allow paper documents' option, as shown below. Such documents can be uploaded without attachments and can pass through QC Review and Regulatory Review.

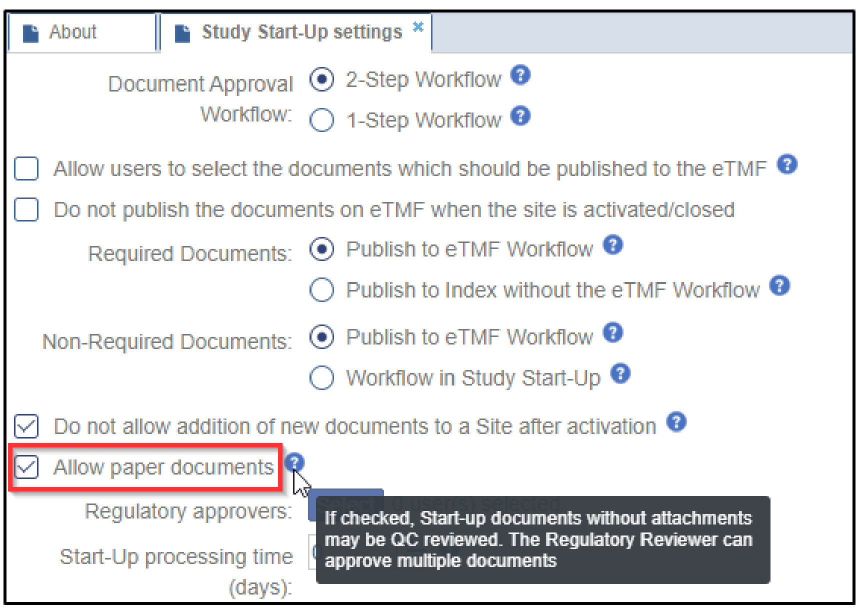


Figure 22: Paper Documents

Other settings

- You can add Regulatory Approvers globally for all sites in the room from this section. This isdiscussed in the section ‘Adding Regulatory Approvers.’

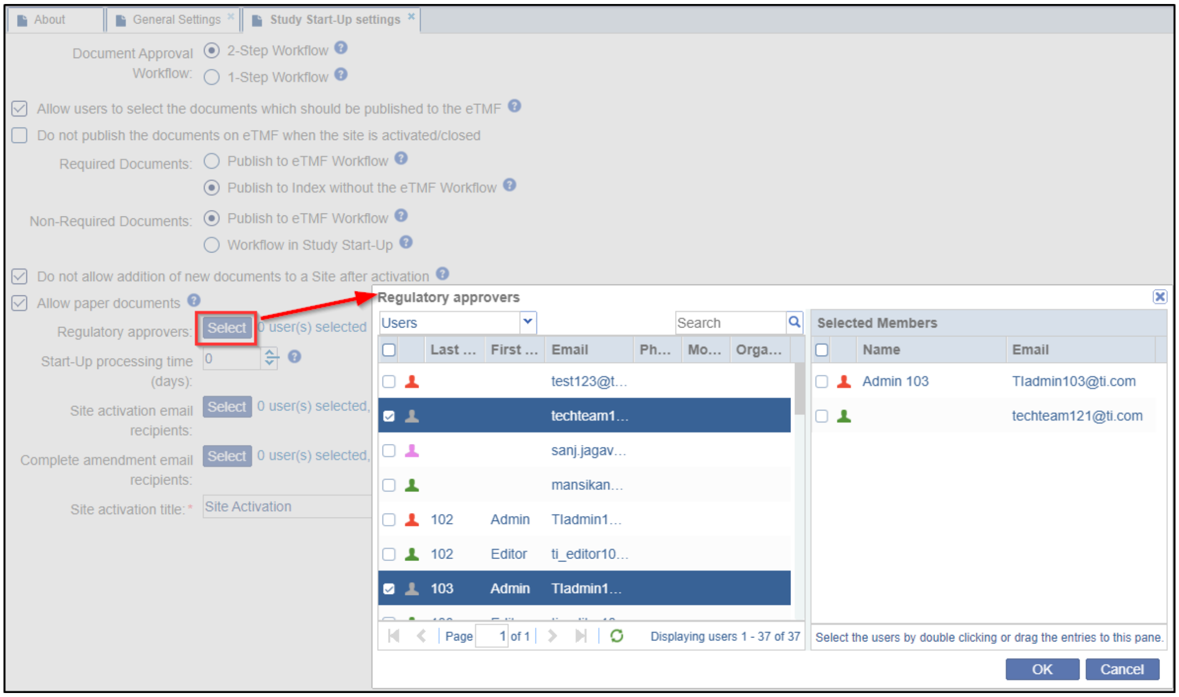


Figure 23: Add Reg Approvers

- To specify buffer time in days for site activation after IRB/EC approval, enter the number ofdays in the textbox next to the option.

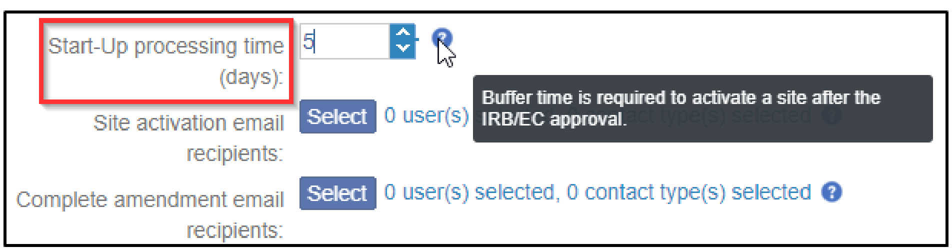


Figure 24: SSU Process Time

- Besides the above, you can also specify the contact types and users who will receive emails onsite activation, on completion of amendment documents (documents added to the site after its activation), and the title for site activation.

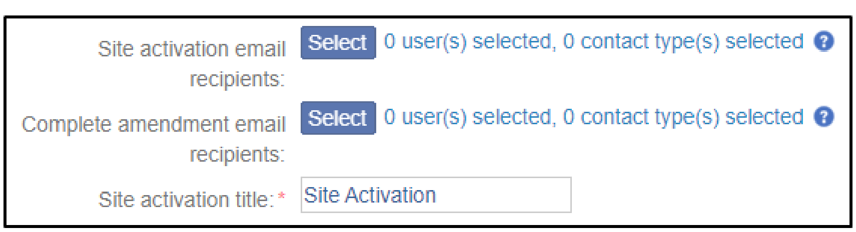


Figure 25: Site Activation

Click the **Select** button to select the users/contacts who should receive email notifications on-site activation. This will open the Site activation email recipients/Complete amendment emailrecipients window as per your selection:

a. Select Users/Contact Types from the dropdown.

b. Select the user to transfer them to the right panel by either double-clicking them ordragging and dropping them in the right pane.

c. Once the Users/Contact type is selected, they will appear greyed out in the left pane.

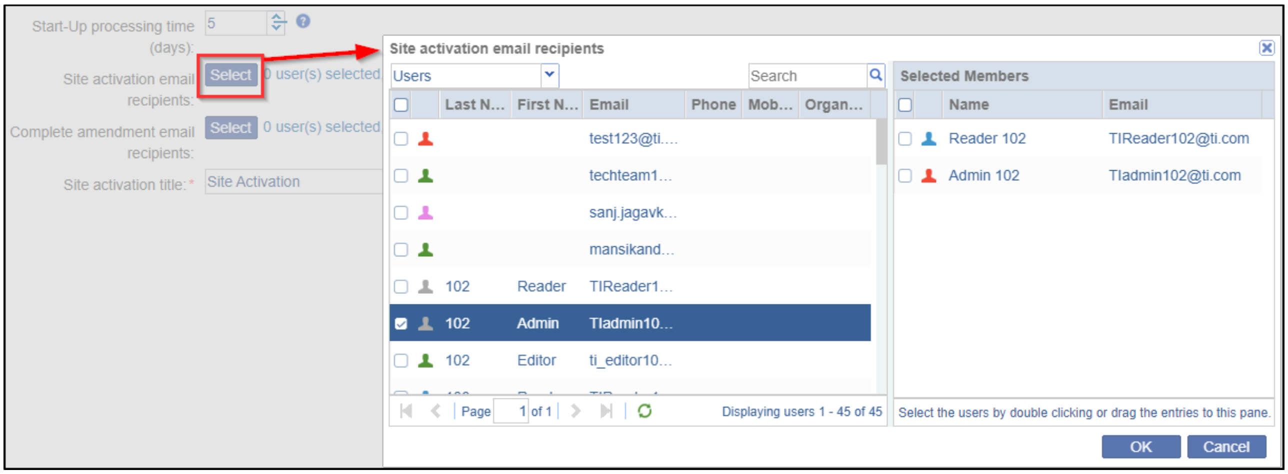


Figure 26: Site Activation Email Process

Note: Follow the same above-mentioned steps to add amendment email recipients.

General Investigative Sites Settings

The General Settings allow you to set up rules that would be critical for a site creation process. Thesesettings are global and are applicable to all sites in the room. Client preferences dictate the choices made here.

To set up the General Settings, the administrator needs to:

1. Navigate to **Settings**
2. Click the arrow next to Investigative Sites in the left pane of the Settings window.
3. From the collapsed dropdown, click **General Settings.**
4. The General Settings window opens to the right.
5. Select the options as required.
6. Click the **Save** at the bottom of the window to commit the changes.

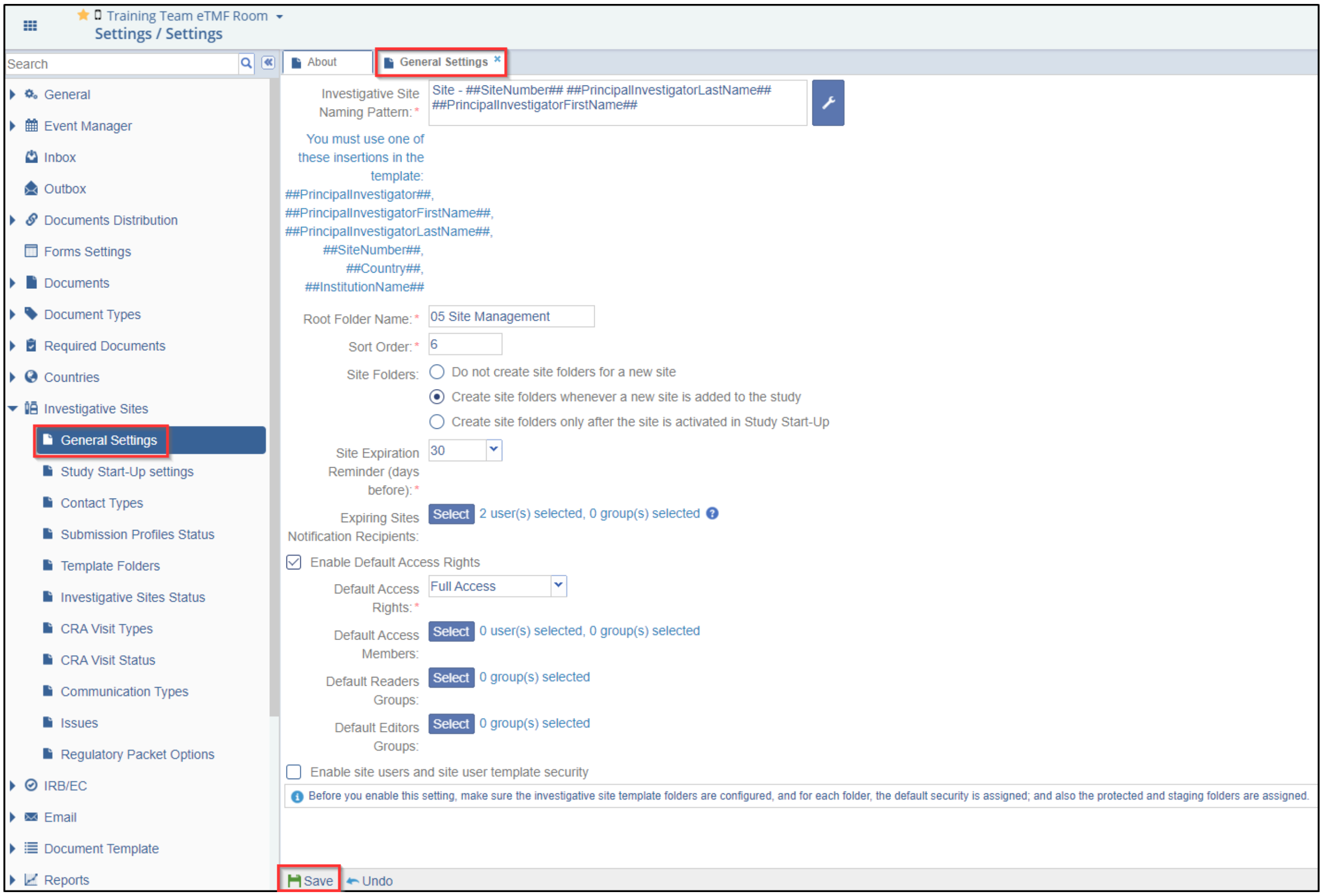


Figure 27: General Settings

Referring to the screenshot above, the General settings window allows the following to be defined:

1. Site naming pattern
2. The root folder name
3. The sort order
4. Creation of site folders
5. Site expiration reminder period
6. Site expiration notification recipients list
7. Site default access rights and members
8. Site default access editors and readers' groups

1. **Site Naming Pattern**

The investigative site naming pattern is set as per the prescribed pattern of the organization. To set the naming pattern, click the wrench icon displayed at the end of the Investigative Site NamingPattern.

Figure 28: Site Naming Pattern

This will open a new window pop-up of the Rule Editor. Here, you can define the rule for naming theinvestigative sites. Once you set the naming pattern, you can review the same by clicking the refreshicon available after the preview box. Fill in the essential details from the available templates (choose Hardcoded/Functions by toggle screen) and click the OK button at the button to save and execute the naming pattern. Refer to the screenshot below.

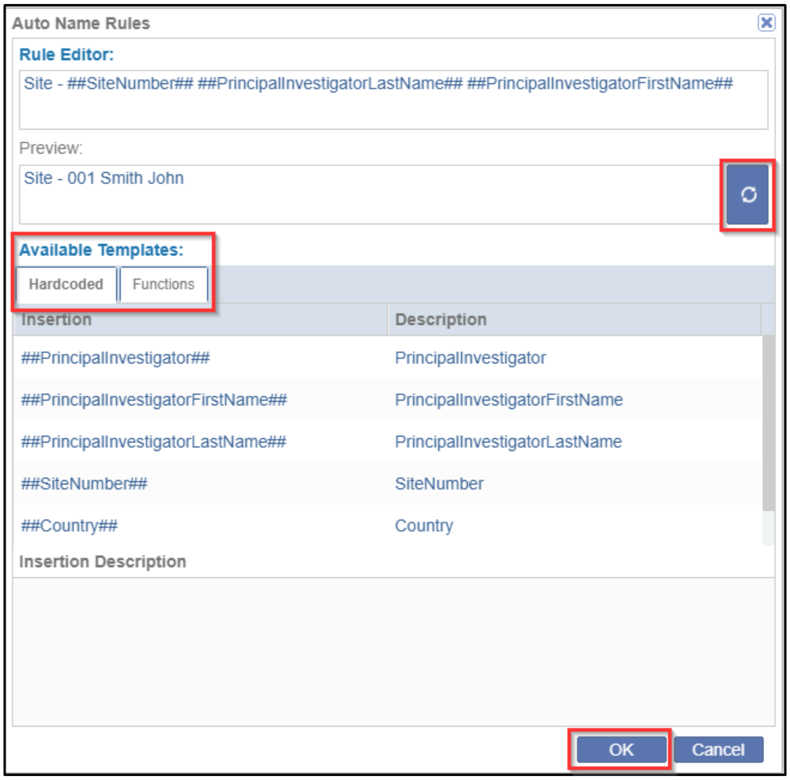


Figure 29: Available Templates

2. **Root Folder Name**

The Root folder name is set in compliance with the organization's preference. This is the title given to the main folder in the room's index that will hold the subfolders for each investigative site involved in the study**.**

Figure 30: Root Folder Name

a. Click in the field.

b. Type the root folder name.

c. Hit the Enter key on the keyboard.

3. **The Sort Order**

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

Figure 31: Sort Order

a. Click in the field.

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

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

4. **Creation of site folders**

The options listed here decide when site folders are created for a new site. The box contains three radio buttons for Site folder options. Click on the option that fits your needs**.**

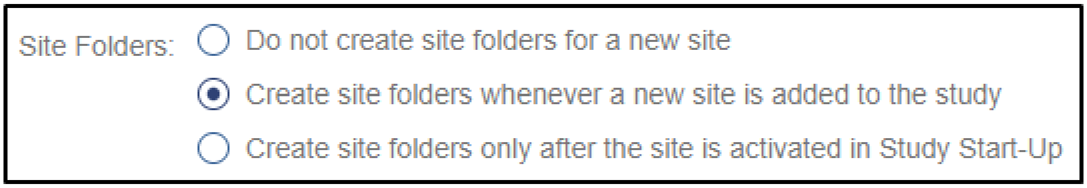


Figure 32: Site Folders Options

5. **Site expiration reminder period**

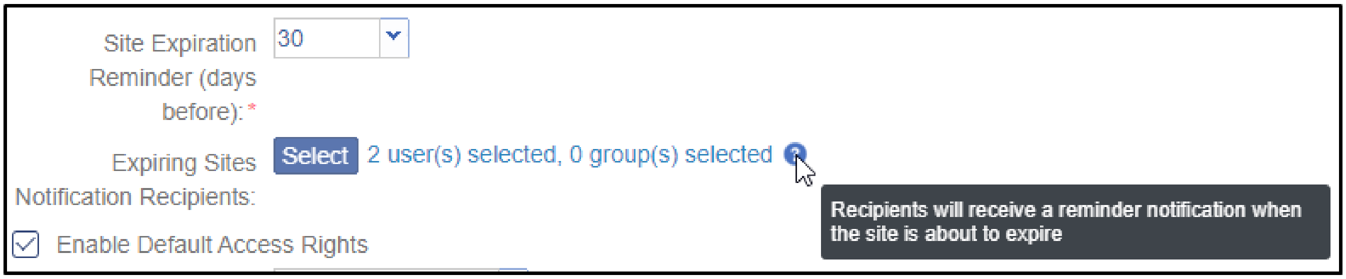


Figure 33: Site Expiration Reminder Period

The options here allow you to set the number of days before a site's expiration and when notificationswill be sent out to the users who are selected as the 'Expiring sites notification recipients'.

6. **Site expiration notification recipients list**

Click the **Select** button to select the users/groups receiving the notification reminder email. Double-click the users or drag and drop them to the right pane to add them to the recipients' list**.**

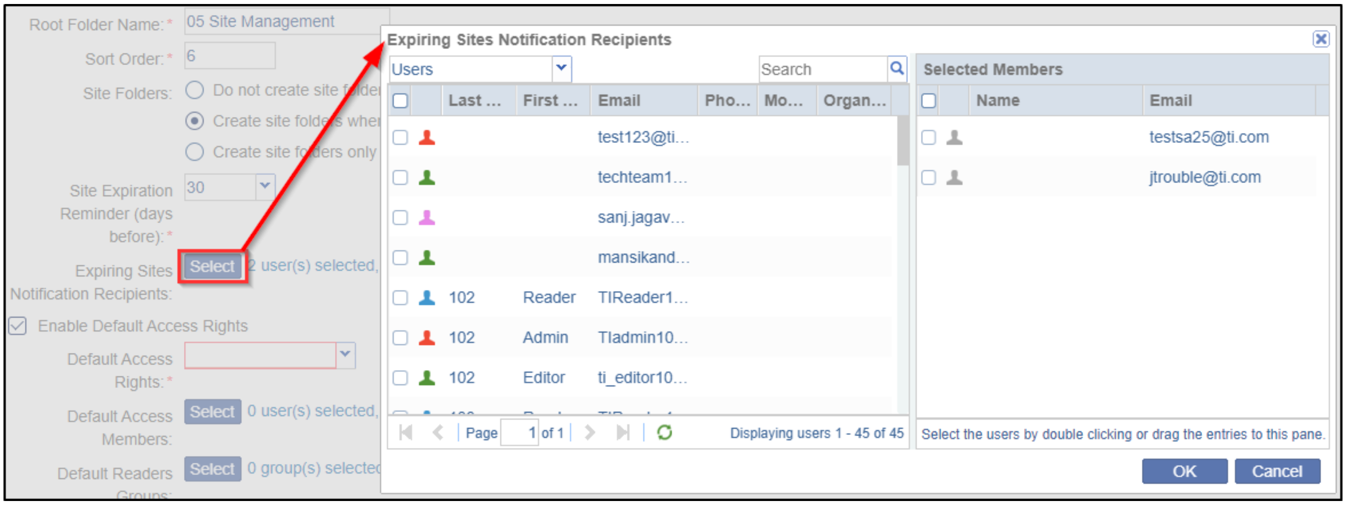


Figure 34: Site Expiration Recipient List

7. **Site default access rights and members**

This option allows you to enable default access rights and the members who possess them. To enable the default access rights, click the checkbox available before the Enable Default Right Accessoption**.**

Figure 35: Enable Default Access Rights

To define the default access rights, select any one from the dropdown available with the DefaultAccess Rights option**.**

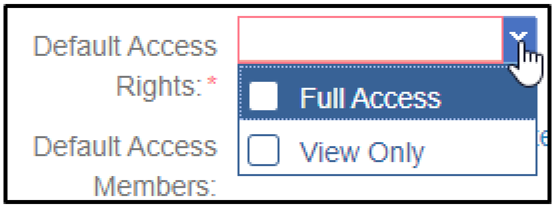


Figure 36: Default Access

To add the members with default access, click the **Select** button that opens the Default Access Members popup, where you can select the members/groups from the available list and drag them to the selected members list at the right side of the popup. Once you select all the members, click the **OK**button at the bottom of the popup to save the changes**.**

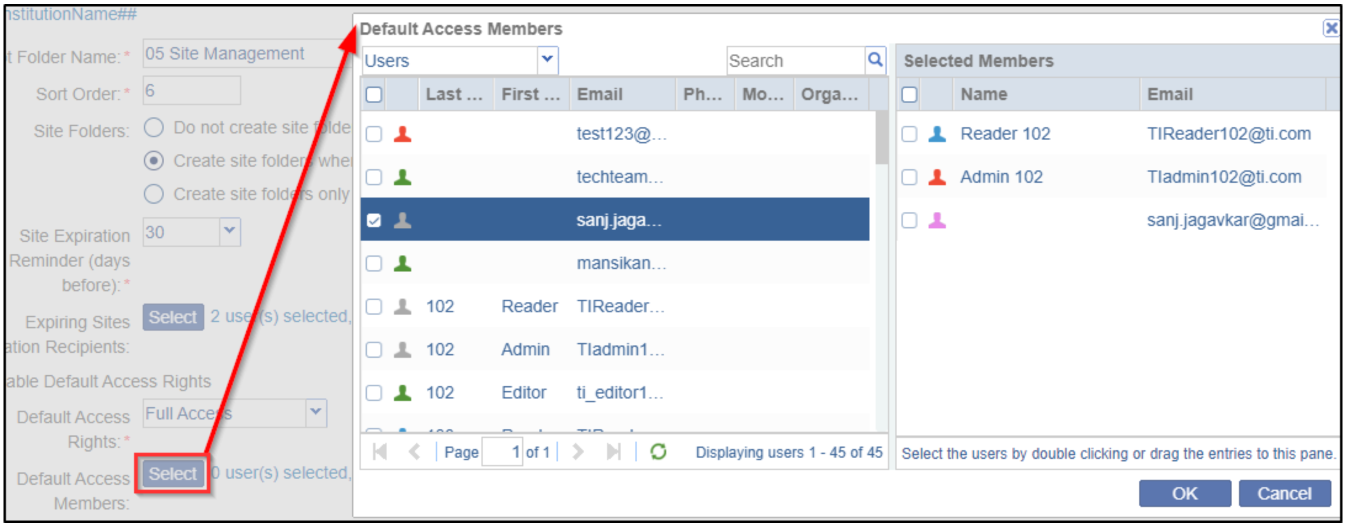


Figure 37: Default Access Members

8. **Site default access editors and readers groups**

These options allow you to set the default access to readers and editors groups. To add the default readers/editors group, click the **Select** button available after the options Default Readers/Editors Groups. This will open a popup where you can select the groups from the available list and drag themto the selected members list at the right side of the popup. Once you select all the members, click the **OK** button at the bottom of the popup to save the changes.

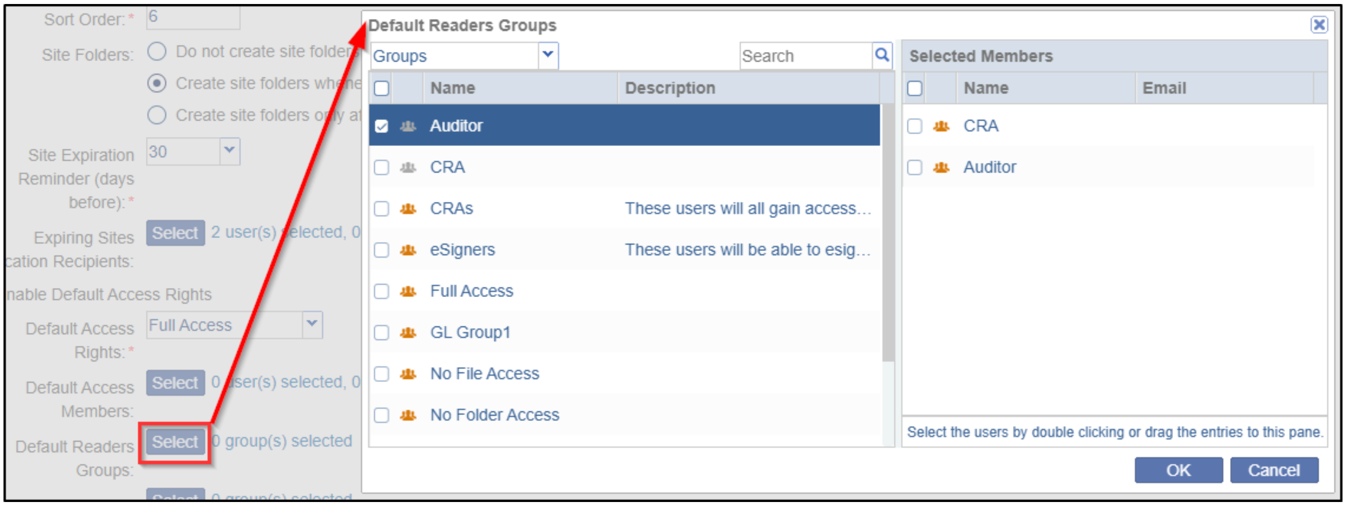


Figure 38: Default Access - Editors & Readers

Adding Countries to Data Rooms

To add countries from where the sites will be enrolling to the study, the administrator needs to do thefollowing:

1. From the Settings section, click the arrow next to Countries from the left panel to collapse itsdropdown.
2. Click the sub-option Countries from the collapsed options to reveal the Countries window on theright.
3. Click Add in the menu bar from the Countries window. This opens the Create Country popup.
4. Select the list of countries from the dropdown as required for your sites.
5. Enter the Room Contact and click Create. This will add the country to the data room.
6. Repeat the process for as many countries as required.

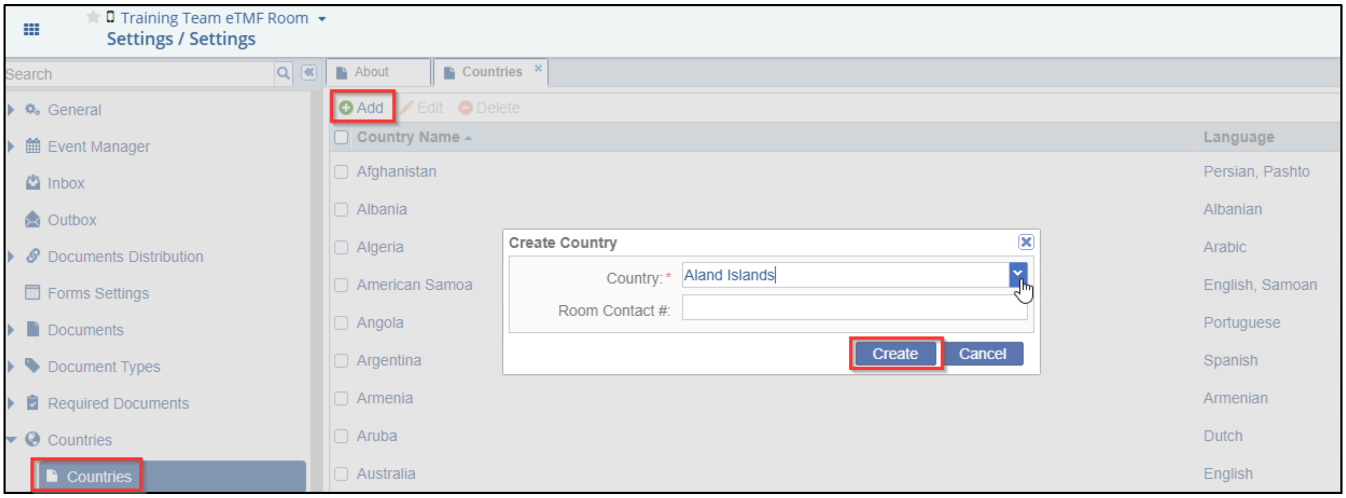


Figure 39: Add Countries

Adding or Creating New IRB/ECs

To add IRB/ECs as required by sites, the administrator needs to do the following:

1. Assuming that you are in the room Settings section, click IRB/EC from the left panel.

2. The IRB/EC Management window opens on the right.

3. Click **Add** in the menu bar from the IRB/EC Management window.

a. This opens a blank IRB/EC Profile form to fill in the data. Enter all the details as applicable (fields marked with an asterisk are mandatory to fill). Some of the important fields are discussed below:

i. **Approval Cycle**: This is the IRB/EC's processing time and can be denoted in days/weeks/months.

ii. **Buffer Time**: This is the extra time IRB/EC may need to approve the documents.

iii. **Meeting Frequency**: This denotes the meeting frequency of the IRB/EC, which could be daily/ weekly/monthly/yearly.

iv. **Submission Deadline**: This denotes the submission deadline in the day/week/month/year before theIRB Meeting Date.

b. Click the **Committee** tab in the popup. This allows you to add the details of the Ethics Committee associated with the IRB.

c. Click **Add** in the Committee tab. This will add a new row to an ethics committee named 'New Committee.'

d. Double-click each field in the row to enter the details for the committee.

e. Click **OK**.

4. This will add the IRB/EC and the centralized IRB library to the study.

5. Repeat the process for as many IRB/ECs as required. Refer to the screenshot below:

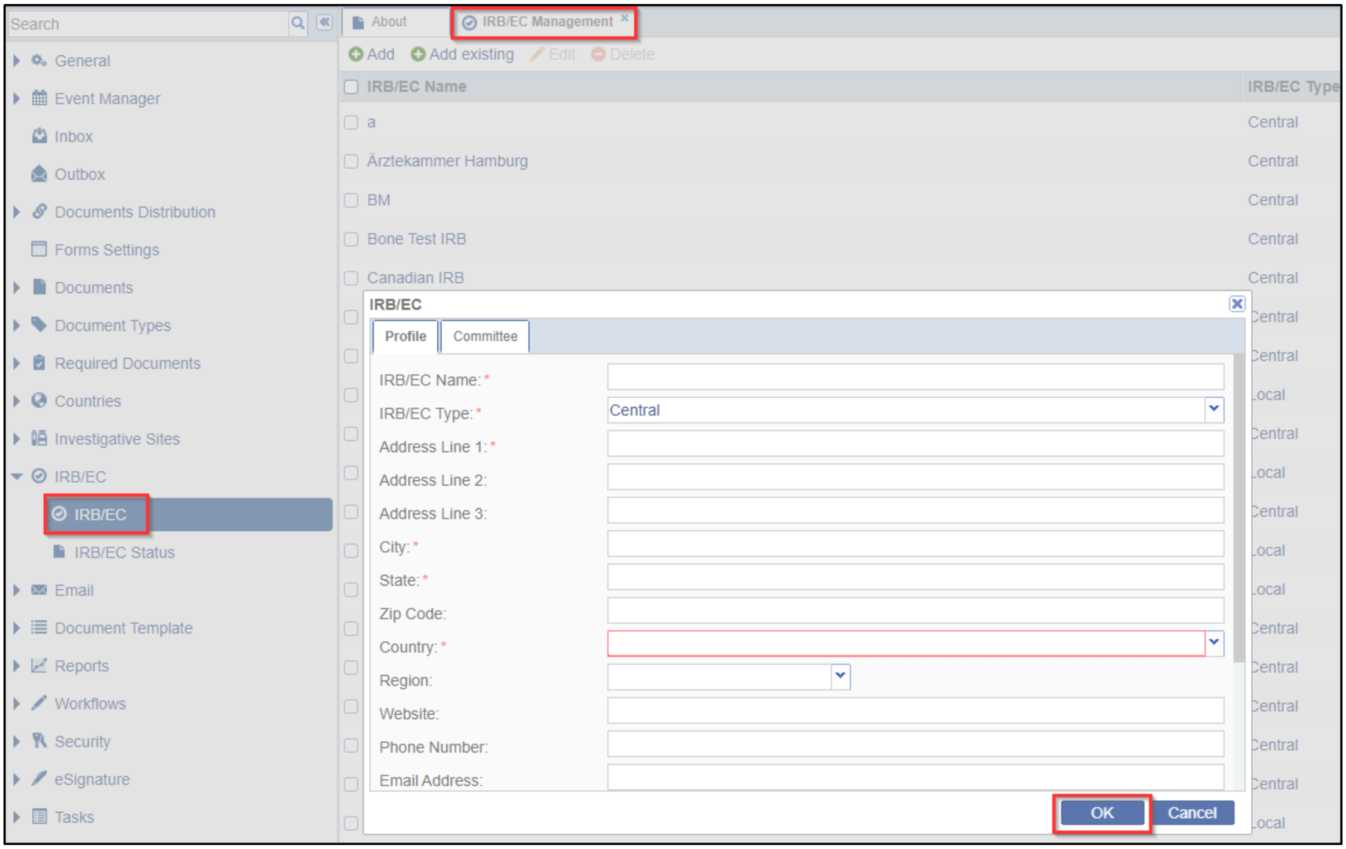


Figure 40: IRB/EC

Adding Existing IRB/ECs to Data Rooms

You can add IRB/ECs from the centralized IRB library to your data room by clicking the Add Existing option in the menu bar of the IRB/EC Management window. IRB/ECs specified in the domain level are available to all studies in the domain and can be added to your room specifically.

Clicking the Add Existing button from the menu bar will open the Select IRB/EC window listing the IRB/ECs available in the domain. You can select multiple IRB/ECs as required from the list by ticking the checkbox next to the IRB/EC names and clicking OK on completion. Refer to the screenshot below:

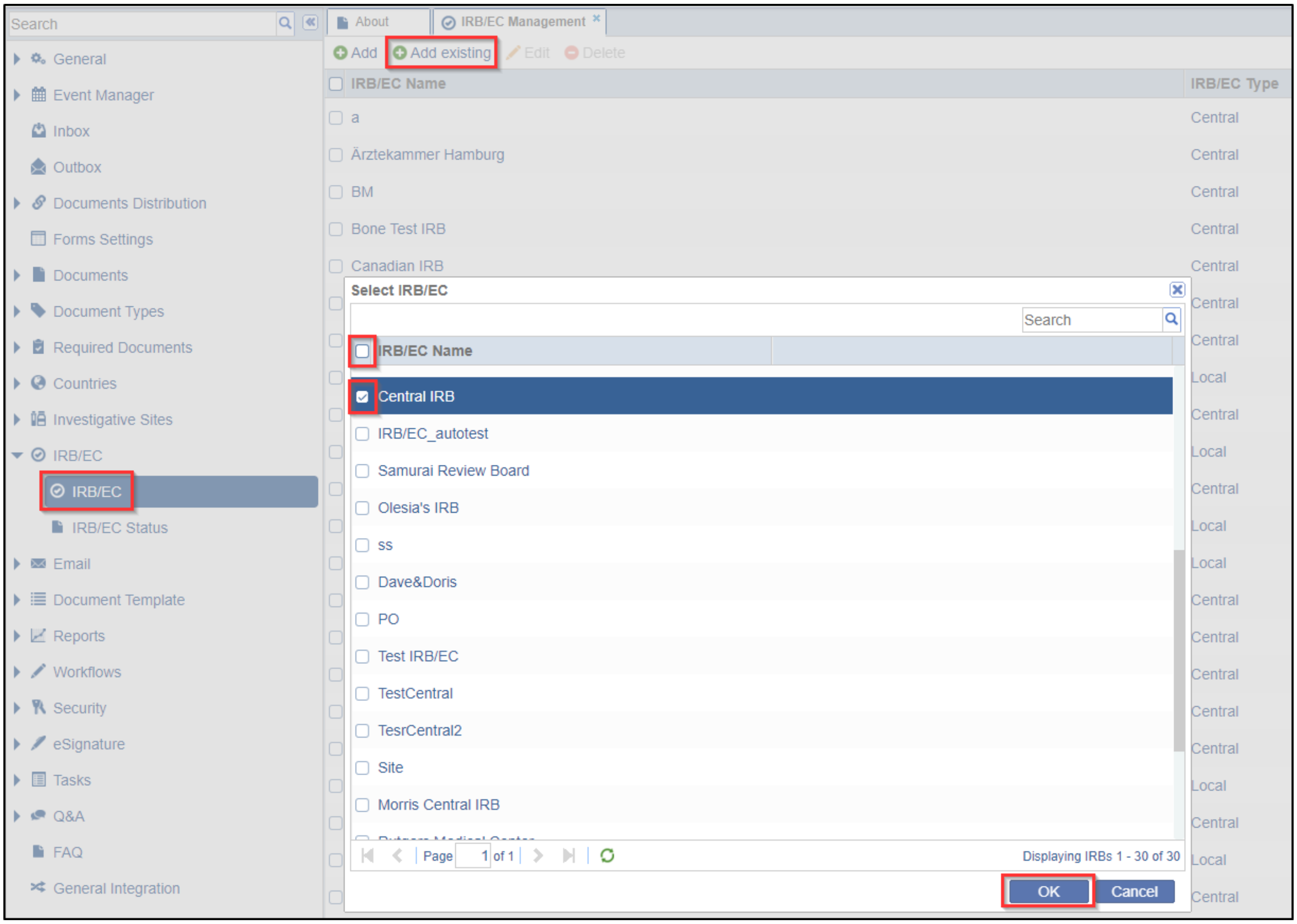


Figure 41:Add Existing IRB

Setting up Required Documents for Countries

For the user to upload collected essential documents for countries, the document types for the sameneed to be setup by the administrator. The procedure to add the Required Documents is mentioned below:

1. From the Settings section, click the arrow next to the **Required Documents** option in the left panel.

2. Click the sub-option **Required Documents** from the collapsed options to reveal the RequiredDocuments window on the right.

3. Click the **Country Specific** tab from the top menu options of the window. Refer to the screenshot below:

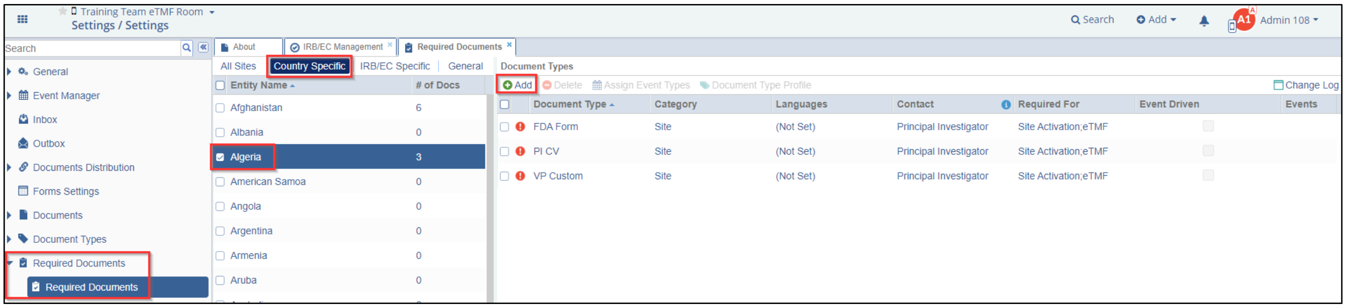


Figure 42: Set Required Documents for Countries

4. Select the checkbox next to the country for which you want to specify the Required Documents.This activates the Documents Types panel to allow you to add the required documents.

5. Click **Add** from the menu bar on top of the Document Types window.

6. This will open the Required Documents window, offering you two choices – Study andInvestigative Sites -

Choose Investigative Sites if -You wish to submit investigative site documents specific to countries.

Choose Study if- You wish to submit government-approval documents of the country.

7. Select documents as required from the collapsible tree structure listing the documents.

8. Select the Site Activation checkbox.

   Note: To select the contacts who will submit the documents from the 'To Be Submitted By' dropdown if you choose the 'Investigative Site. Option from the above.

9. Click **Save & Close**.

10. Refer to the screenshot below:

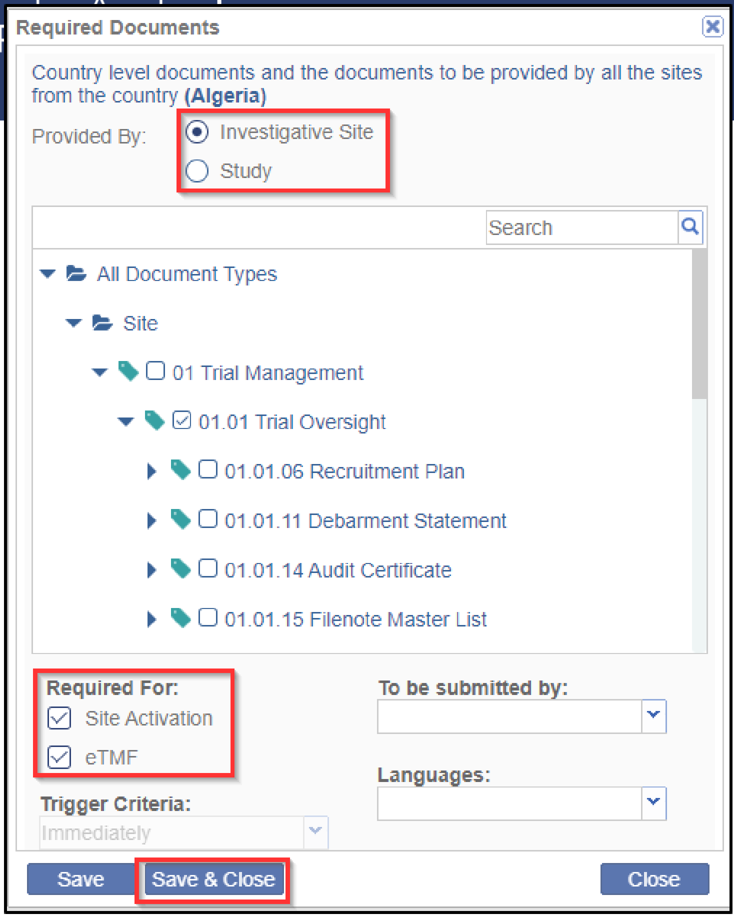


Figure 43: Set Required Docs-2

Setting up Required Documents for All Sites

For the user to add essential documents for sites, the document types for the same need to be setup bythe administrator. Required Documents for Sites can also be set up from the Settings. The procedure to add Required Documents though Settings is mentioned below:

1. Assuming that you are in the room Settings section, click the arrow next to the RequiredDocuments option in the left panel.

2. Click the sub-option Required Documents from the collapsed options to reveal the RequiredDocuments window on the right.

3. Click the **All Sites** tab. Refer to the screenshot below:

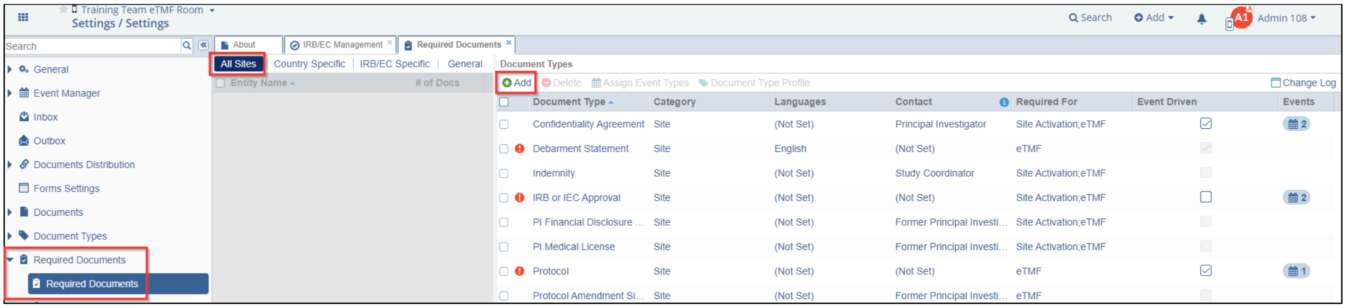


Figure 44: Set Required Documents for all Sites

4. Click **Add** from the menu bar on top of the Document Types panel.

5. This will open the Required Documents window. Select documents as required from thecollapsible tree structure listing the documents.

6. Select the Site Activation checkbox.

7. Select the contact list from the ‘To be submitted by’ dropdown as required. Multiple contacts canbe selected.

8. Click **Save & Close** to commit. Refer to the screenshot below:

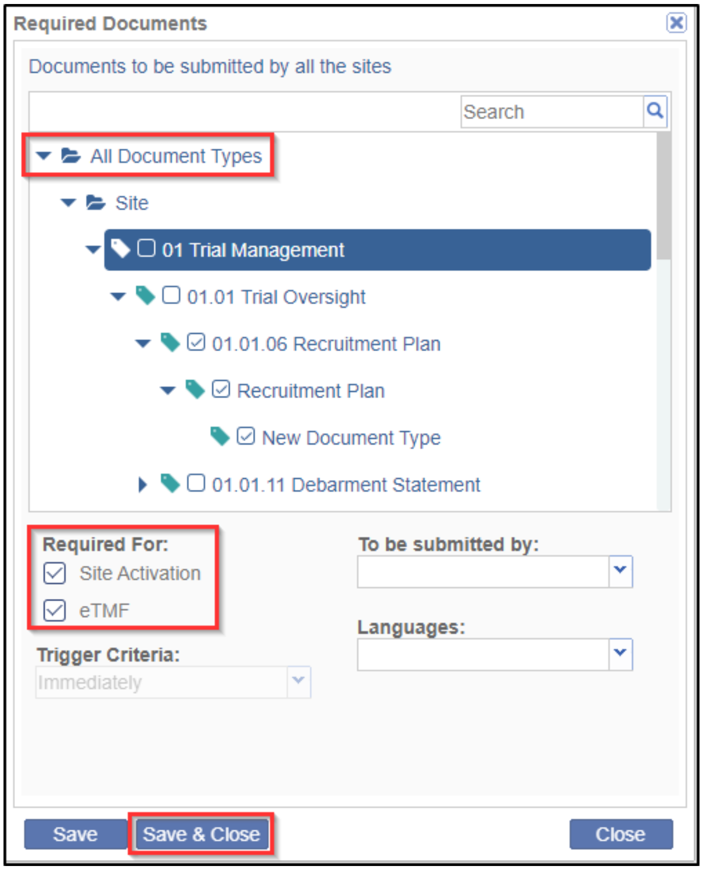


Figure 45: Save & Close

Setting up Notifications

Contacts in SSU can receive notifications via emails for the regulatory packets sent out, fordocuments collected, and approved, and for a site activation.

The administrator can set up notification preferences for Start-Up Documents and RegulatoryReview as follows:

1. Click the **Navigation pane** and select -> **Settings.**
2. Click the arrow next to **Email** in the left panel.
3. Select **Notification Preferences** from the dropdown.
4. The Notification Preferences window opens on the right.
5. Enable the options as required by your organization by selecting the appropriate checkbox(s).
6. Click the **Save** button displayed at the bottom of the window.

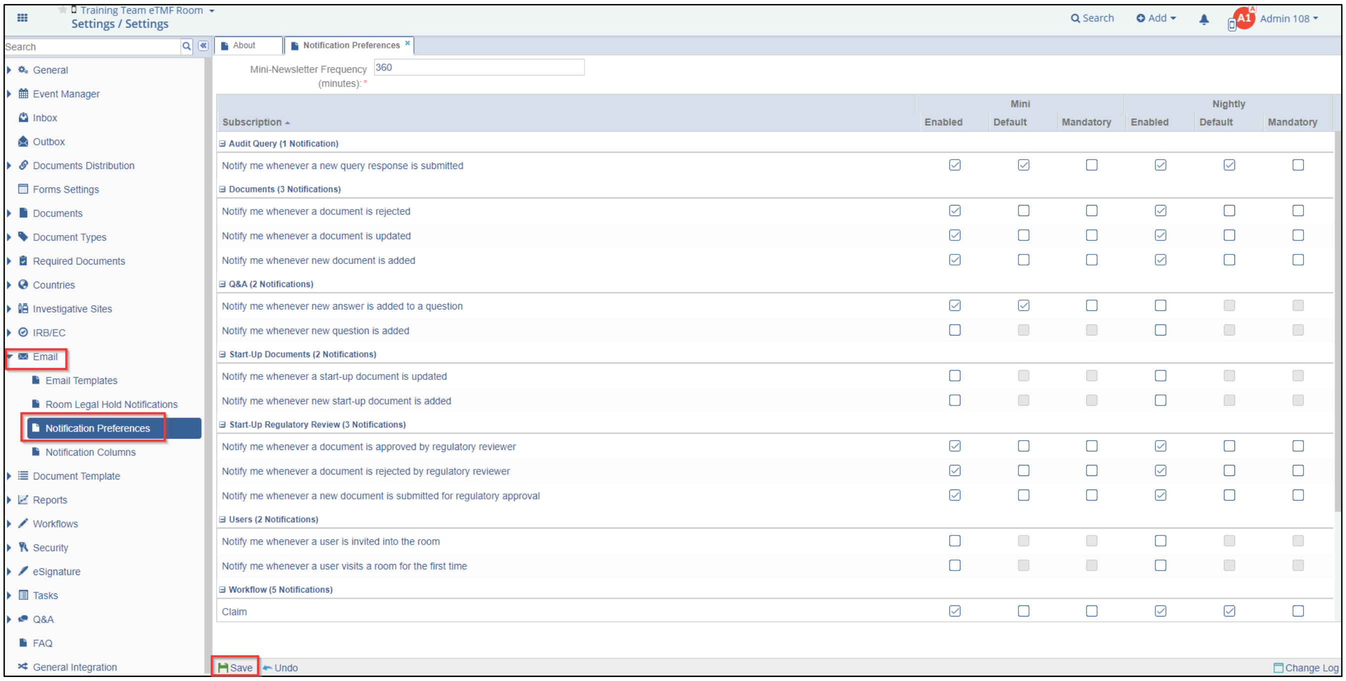


Figure 46: Set Notifications

Start Up Contacts

This section describes in detail the various user roles available in the SSU module:

- Clinical Research Associate (CRA)
- Start-Up Specialist
- Regulatory Approver
- Site Activation Member
- Other Site Contacts
- Site Activation Member

After site information is entered in TI, the regulatory packet is subsequently sent out to the site members. Suppose you are added to the Site Activation Member group. In that case, you are able to submit Essential/Required Documents to the SSU module for the Start-Up Specialist and Regulatory Reviewer to review. As a Site Activation Member, you can see and track the progress of Essential/RequiredDocuments collection and activate the site when required.

Clinical Research Associate (CRA)

A CRA is responsible for conducting a clinical trial and overseeing various important site-related functions like initiation, compliance with protocols, site visits, adherence to good clinical practices, integrity of the data collected, and protection and safety of the human subjects of the study. A CRA adds documents to a site as a part of site visits. A CRA needs to be an editor in the room to be added as aCRA in a site.

Start-Up Specialist

The Start-Up Specialist is a part of the Site Activation Member group and is the first reviewer of the SSU documents. Documents can be mailed to the specific SSU email address, imported, or attached individually in Trial Interactive. The Start-Up Specialist will review and approve or reject the document(s) and push them to the Regulatory Reviewer for final review. The Start-Up Specialistwill also activate the site after the Regulatory Reviewer approves all Essential/Required Documents at each site. A Start-Up Specialist can be an Editor or Admin in the room.

Regulatory Approver

The Regulatory Approver is the second and last reviewer of the SSU documents. (Email notificationscan be set up to notify the Regulatory Approver that documents are pending for review). The Regulatory Approver will review and approve or reject the document(s) in the Regulatory Review section in the SSU module.

Other Site Contacts

Besides the ones mentioned above, various other site contacts can be added to a site.Some of them are mentioned below:

1. Principal Investigator
2. Sub-Investigator
3. Pharmacy Contact
4. Laboratory Contact
5. Contracts Contact
6. Finance/Budget Contacts
7. Co-Investigator
8. Research Specialist

Note: A Principal Investigator is the most important contact for a site, as sites cannot be created without a Principal Investigator.

Note: An SSU specialist cannot be a site contact and an SSU Specialist at the same time. Except for the CRA, all the contacts discussed in this section can be viewed from the Contacts module. You can view sites in the **BY CRA** view from the Sites module.

Inviting contacts and Managing Security

The world of clinical trials involves many users whose responsibilities range from handling variousintricate and complex procedures to users who only review and sign documents on a site. To enablethem to carry out their duties, the users need to be given proper access and privileges to a site.

To facilitate the above, Trial Interactive (TI) implements a process that can be seamlessly aligned toa real-world scenario. It caters to various questions in a clinical trial to define the role of a user, like

---

1. What is the size of the organization?

2. Does the organization involve users who handle multiple roles or users who are assigned specificroles in a site?

3. Does the user need to oversee the complete site activities, or is it enough for the user to only be acontact point on the site?

Depending on the functionalities assigned to site users, by answering the above questions, the administrator can choose the right combination of rights and privileges.

TI implements the following process to assign a combination of rights and privileges to site membersto enable them to carry out their responsibilities:

1. It allows two security privileges to be assigned to users – Editor and Reader.

A reader is allowed read-only access, whereas an editor can perform various other advanced functionalities like adding documents and sending documents for review to activating sites.

To note, an Admin is a privileged role and is assigned to users only in specific cases discussed laterin this guide.

2. These security privileges can be assigned at two levels:

a. At room level:

If users are already registered in the room, skip the below-mentioned process.

To assign privileges to a user in a room, the Admin has to provide access to the user by inviting the user to the room. On inviting, the user receives an invitation mail in their registered email id to jointhe room. The Admin has to follow the process below:-

- Login into TI and enter the room.
- Navigate to Dashboard and click the **Users Management** module.

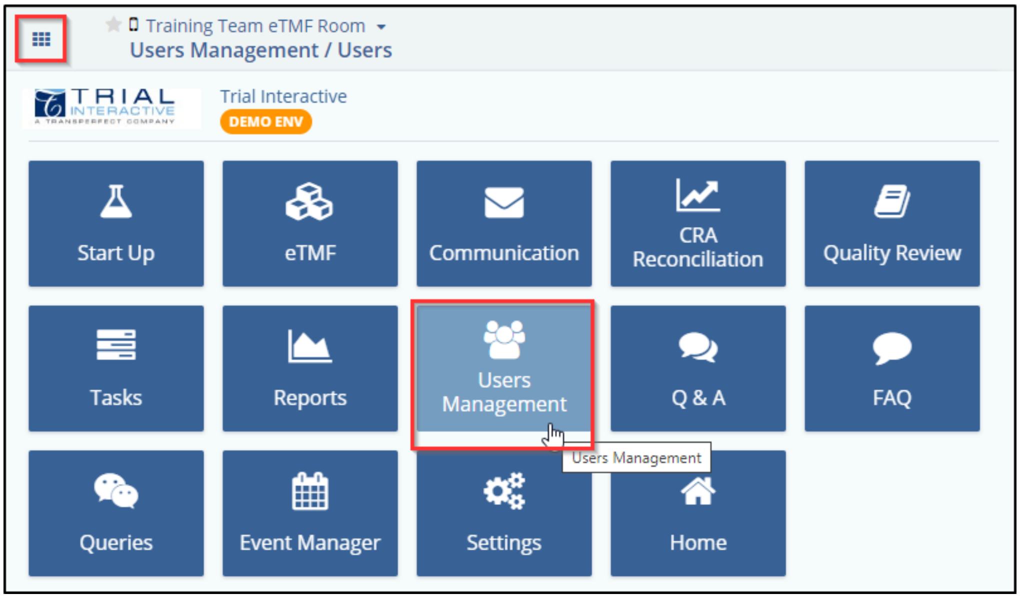


Figure 47: Users Management

- Click **Invite**, and choose **Regular**. Fill out the required information.
- Assign them appropriate roles as defined within Trial Interactive

Note: For Study Start-Up roles, the user needs to at least be an Editor in the room.

- Enable Study Start-Up as action. Click **Create**. Refer to the screenshot below:

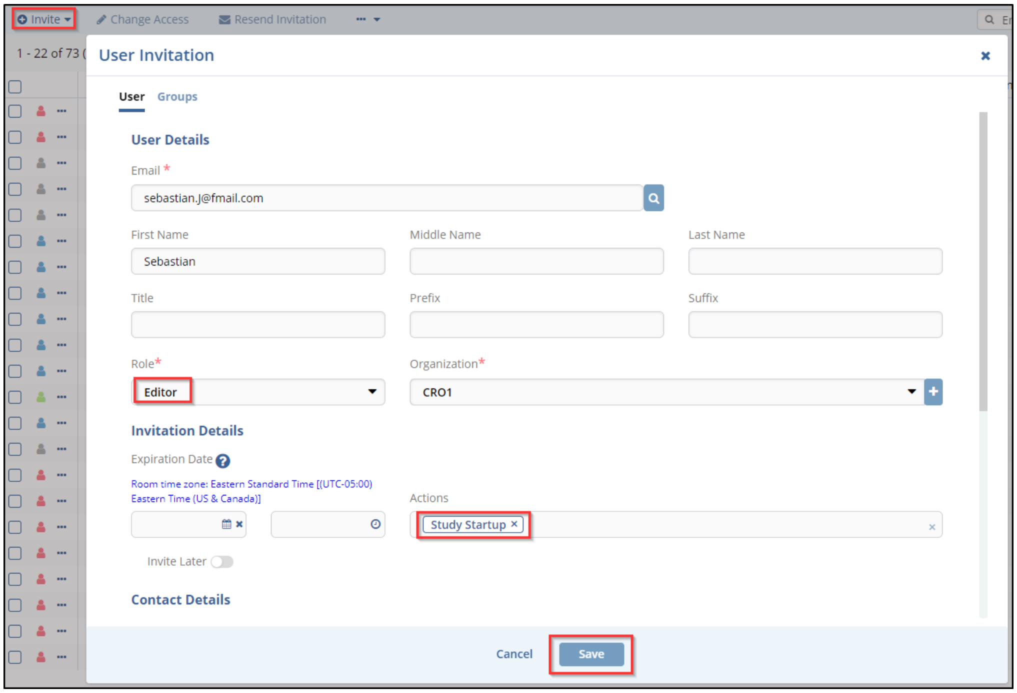


Figure 48: User Invitation

New users can also be added from within a site by the admin directly. In this case, the user socreated receives an invitation mail to join the room.

b. At site level:

Within a site, the following types of users can be added as site contacts:

1. Users belonging to a room to which the site belongs.
2. Users belonging to a room to which the site does not belong to.
3. Contacts of one site can be added as contacts to another site.

Examples of the first case could be CRAs and Start-Up Specialists. In the second case, a user could have been invited to, say, Room 1, but the user is directly added to a site of Room 2 using their email ID.In the third case, a Pharmacy Contact might not be required to access a room but needs to be in the list of contacts of the site and hence can be directly added as a site contact.

3. It provides a group named Site Activation Member that is pre-defined by the system. This is a privileged group almost equivalent to that of an Admin. Users handling multiple roles in a site can beadded to this group. This need arises from the fact that certain users might need access to all the sites, even if they are not contacts in a site. To make things easy, you can directly add theuser to this group without having to add them to each site.

Note: If a user is added to the Site Activation Members group but at the same time if for some sites the user is added as Reader, then for those specific sites, the system will restrict the user's permissions down to Reader (minimal access).

Note: *Not all contacts need to be added to this group compulsorily. To add a contact to the Site Activation Member Group, Click the Groups tab in the User Invitation window.*

The Study Start Up Module

Once you set up the basic configurations and contacts for Study Start Up, you can now move forwardto operate the module. The Study Start Up Module comprises the following topics.

1. Accessing the Study Start Up Module
2. The SSU Interface
3. Sites
4. Countries
5. IRB/EC
6. Regulatory Review
7. Collecting Required and Non-Required Documents
8. Documents
9. Regulatory Review
10. Communication Log
11. Contacts
12. Steps to Site Activation
13. Amendments
14. Overview Dashboard
15. Reports

Each of these topics with their subtopics is described in detail in the subsequent sections.

Accessing the Study Start Up Module

To access the Start-Up Module (SSU), click the Navigation Grid and then the Start-Up icon. Thiswill lead you to the Study Start-Up dashboard. Refer to the screenshot below:

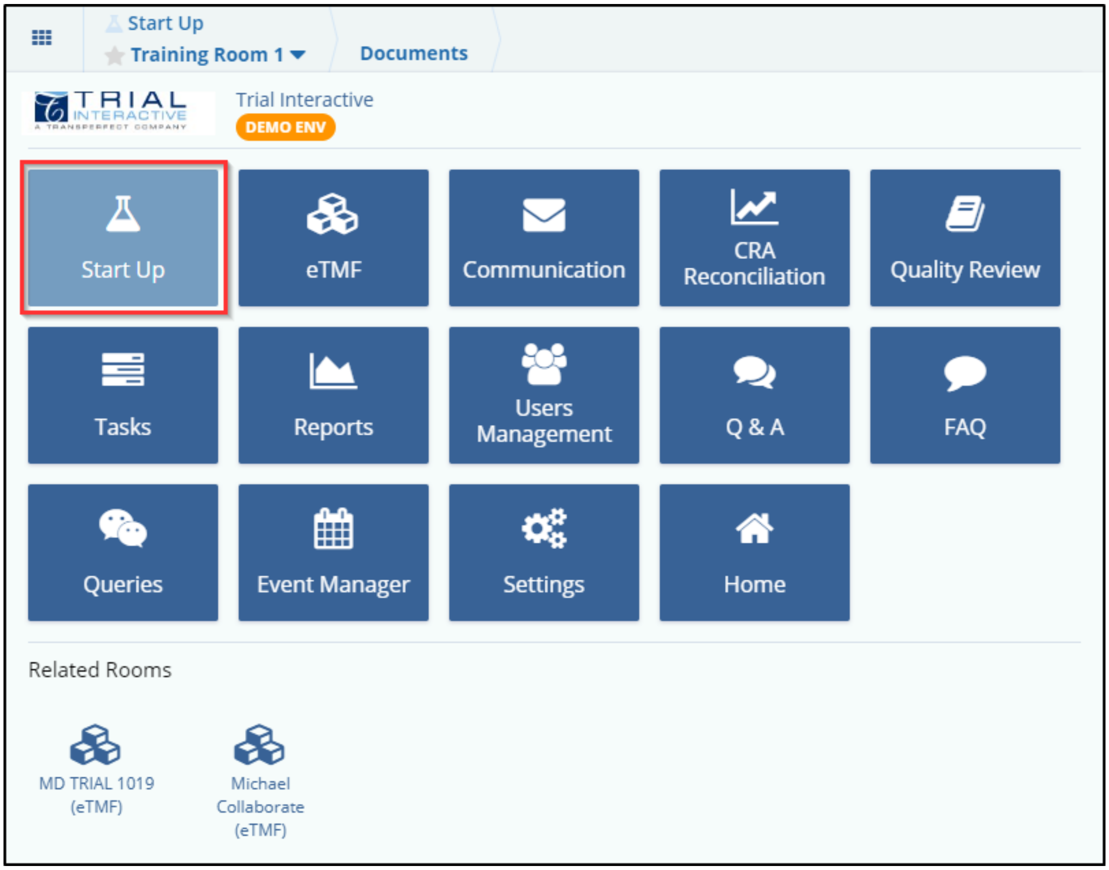


Figure 49: Start Up

The SSU User Interface

The SSU Module is a platform in Trial Interactive (TI) that allows users to Create, Monitor, and Activate sites required for Clinical Trial purposes. Through this interface, users can add, upload, and keep track of the progress of the documents collected for site activation besides reviewing them.

Log in to Trial Interactive and select the Study Startup room. You'll be taken directly to the Start-Up Overview. This room dashboard has a toggling menu bar on the left with access to various modules and the dashlets on the right. It also has a title bar on the top. Refer to the screenshot belowfor further insight into functionalities allowed from within the SSU:

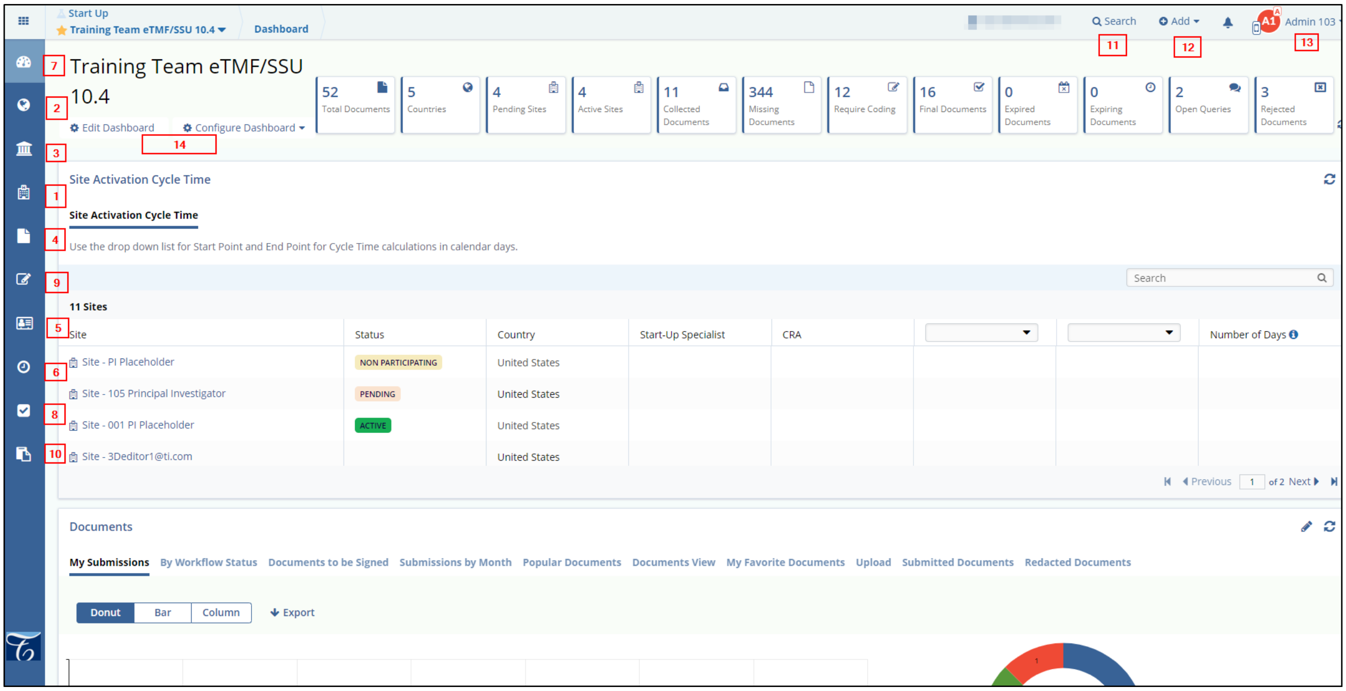


Figure 50: SSU Dashboard

The table below describes each numbered section in the screenshot:

Sr. No.	Part	Description
01	Sites	Here, the users can create sites and contacts view them based on status, country, start-upspecialist, IRB/EC, and CRA. It also allows the export, import, delete, and edit sites, Mass code metadata for sites, add documents, send regulatory packets, and manage security for the contacts in the sites.
02	Countries	Here, the users can view and edit the country profile, collecting and reviewing documents forcountries.
03	IRB/EC	Here, the users can view and edit the IRB/ECs profile, collecting and reviewing documentsfor IRB/ECs.
04	Documents	Here, the users can view, add, and keep track of all the documents collected on the SSUsite.
05	Contacts	Here, the users can view the contact details based on the User access level in the site.
06	Communication	Here, the users can view, add, delete, and edit the communication log based on the SSU User Access level on the site.
07	Dashboard	Here, the users can view various dashlets.
08	Regulatory Review	Allows the users with access as a regulatory reviewer to review the documents assignedto them.
09	Amendments	Allows the user to add, view, and apply filters to the amendments displayed in the grid.
10	Audit Trail	Allows the user to view the audit trail for all the documents that are uploaded and worked on in SSU.
11	Add	From this tab, the users can add Documents/ Users/Tasks/ Sites.
12	Username Dropdown	The users can manage user settings language, redirect to the guide, and so on.
13	Notifications	The users can view the notifications here.
14	Edit Dashboard	The users can manage and edit the dashboard by this button.

Study Start Up Dashlet for Cycle Time

The tracking of a cycle time is a must for activating sites in clinical trials as this metric enables researchers and stakeholders to identify potential bottlenecks and streamline the process, ultimately accelerating the timeline for bringing life-saving treatments to patients. TI SSU v10.5 has introduced a new dashlet for effectively monitoring the time taken to accomplish each step in activating sites.

- Input filter for start and end points for calculations.
- Heat-map to highlight performing and under-performing sites.
- Option to export the data.

This dashlet is displayed on the Dashboard of a room, as shown in the below screenshot.

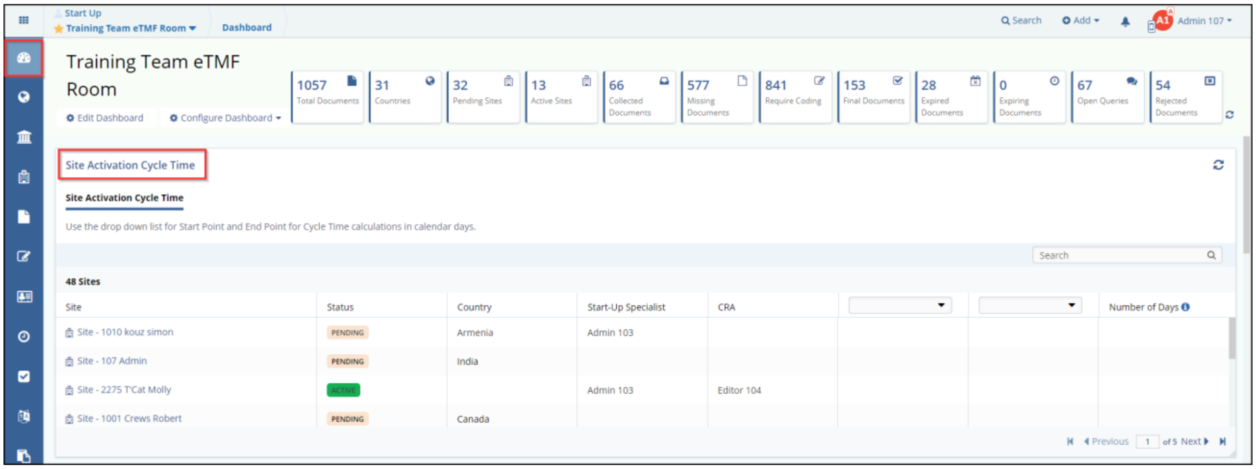


Figure 51: Site Activation Cycle Dashlet

Countries

The studies are conducted in multiple countries across the globe. Hence, the administrator needs to add the countries where the clinical trial is taking and the investigative sites locatedin the country during its initial setup and configuration. The following section discusses:

1. Viewing and editing country profiles
2. Viewing documents

Note: Adding Countries and Required Documents to Countries are discussed in sections Adding Countries to Data Rooms (page 368), and Setting up Required Documents for Countries (page 371), respectively.

The Start-Up Countries tab, accessed from the toggling menu bar on the left, allows you to setup documents for countries associated with sites. The Countries dashboard displays the countries that are marked as Favorite, Active, Canceled, Closed, On Hold, Planned, Potential, Rejected, Submitted, UAT Status, and All Countries on the top of the screen and the Grid pane in the center. Refer to the screenshot below.

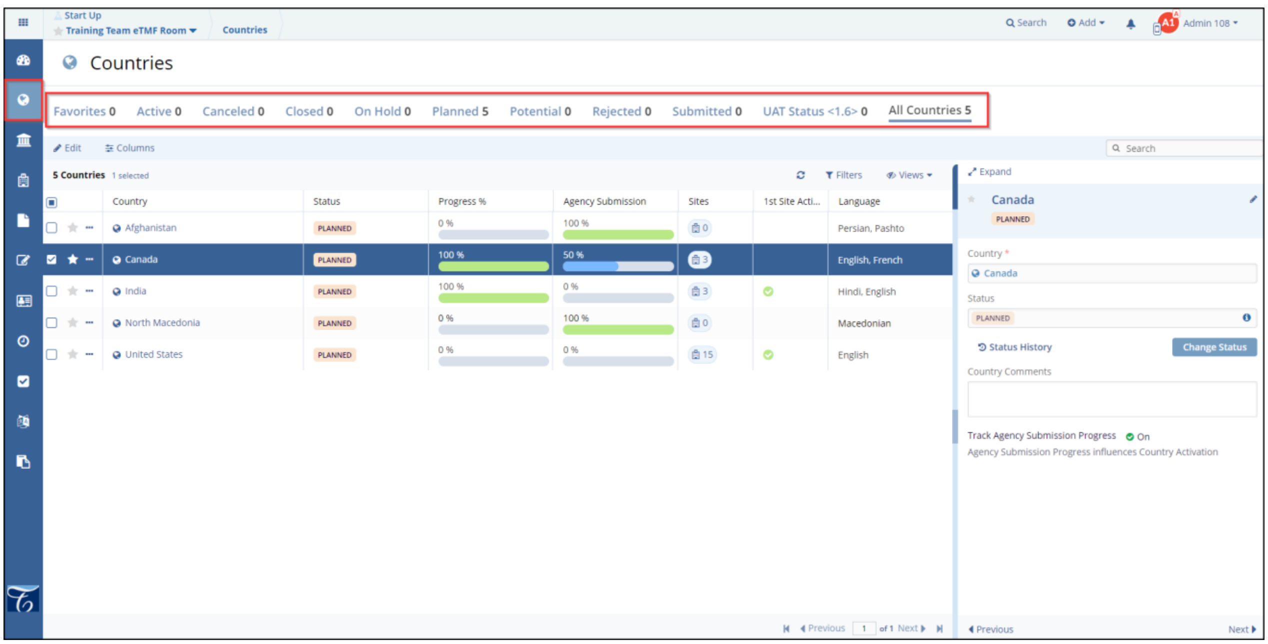


Figure 52: Countries

Viewing Countries

Countries in which the sites are located can be viewed from the list of countries appearing in the gridpane. The list of countries appearing in the grid pane is displayed without applying any filters. Follow the steps below to Manage Filters and Create New Filter for the Countries module.

Manage Filters

1. Click the **Filters** button displayed on the right side of the grid pane.
2. The ‘Manage Filters’ and ‘Create New Filter’ buttons are displayed.
3. Click the **Manage Filters** button to open a Filters popup window. By default, the All button is selected.
4. Click the **Add** button displayed below the All tab.

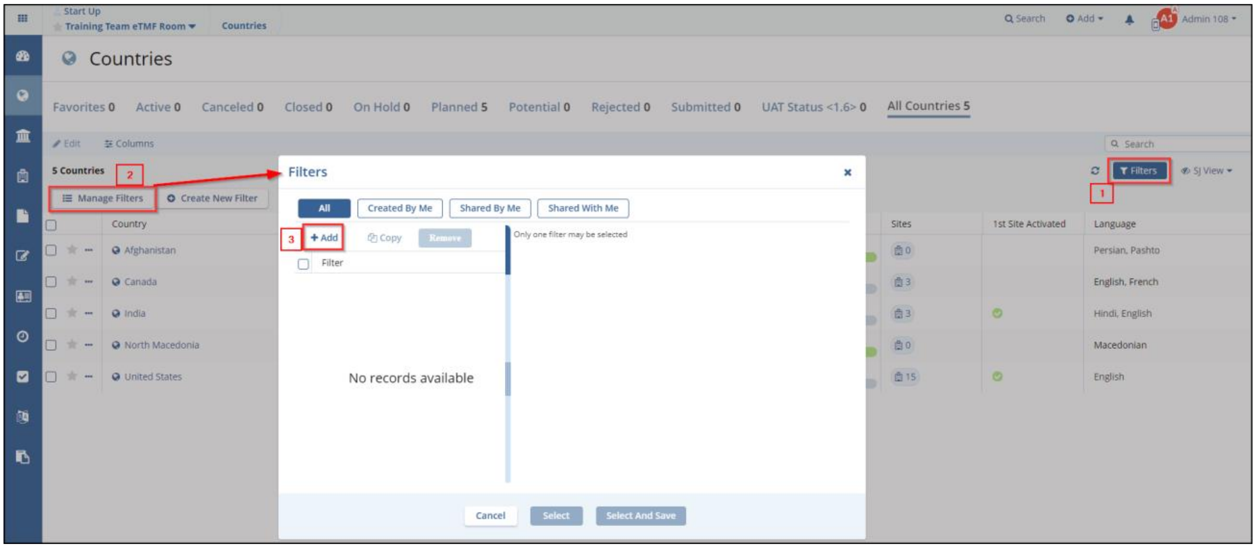


Figure 53: View Countries

5. This opens the Title, Add Filter, and Add Group tabs. Click the **Add Filter** button displayed in the right corner. A dropdown menu is displayed on the left side of the popup window.

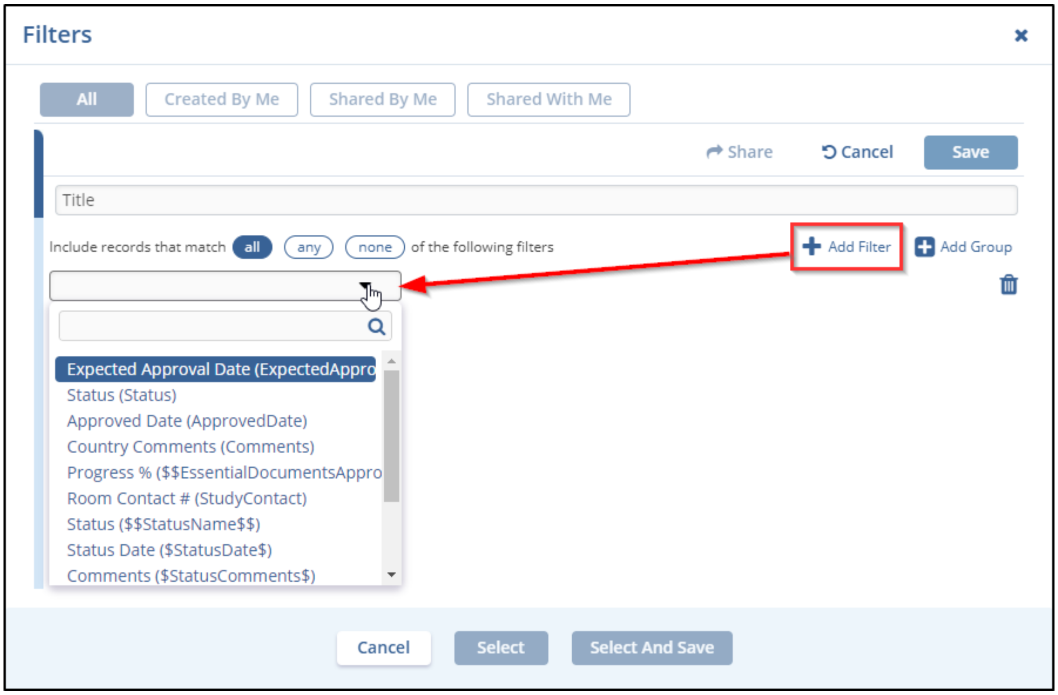


Figure 54: Countries Add Filter

6. Select a filter from the available list. This displays another two dropdown menus on the popup window.
   Note: The other two dropdown menu options change as per the option selected in the first dropdown menu. Refer to the screenshots below.

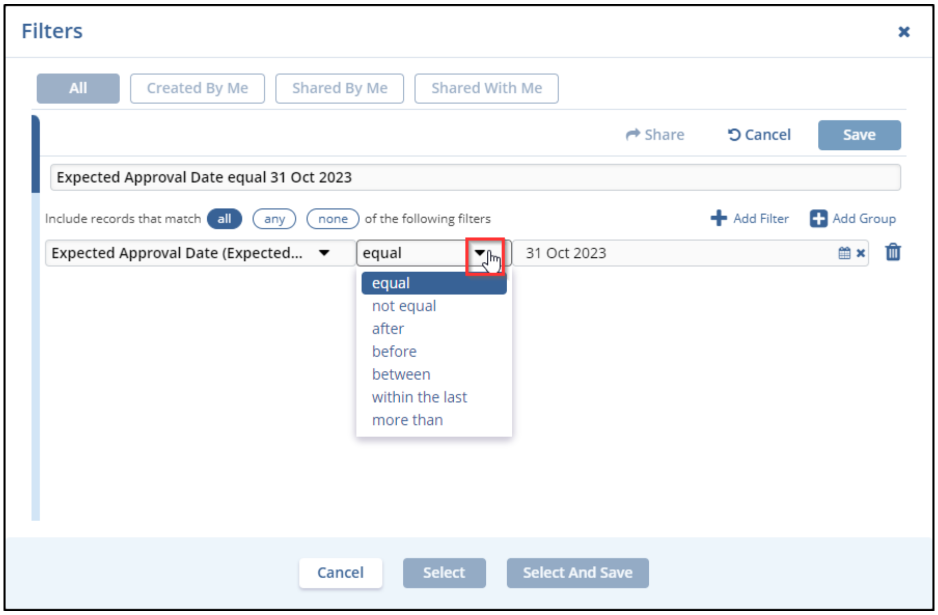


Figure 55: Countries Add Filter Dropdown

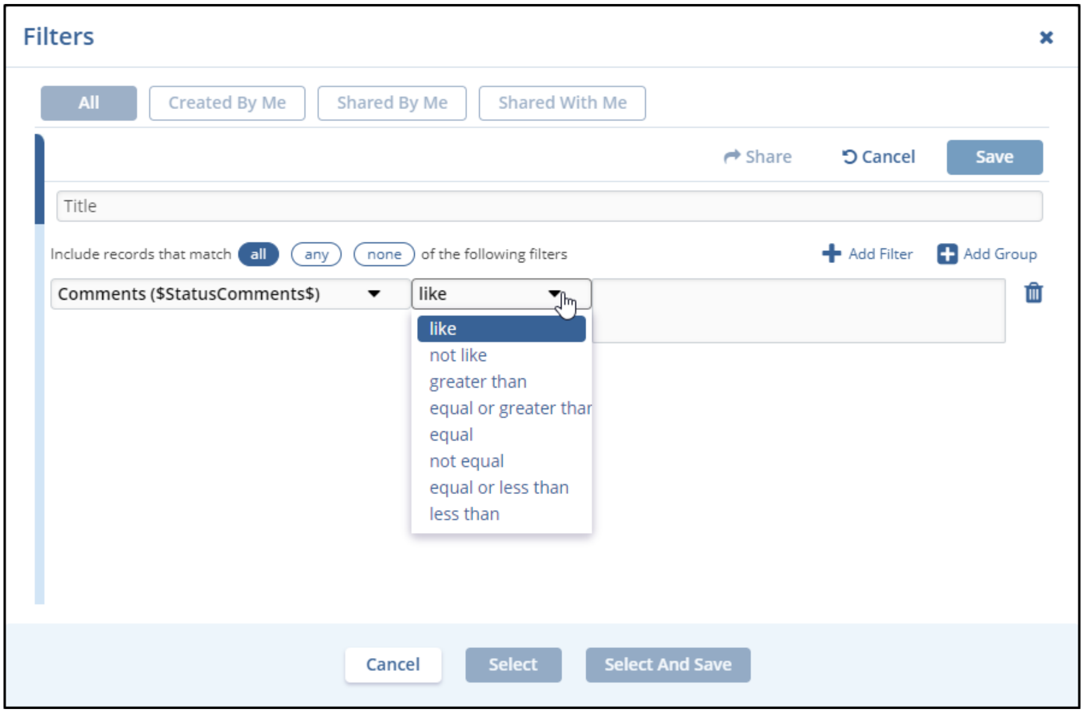


Figure 56: Countries Add Filter Dropdown

7. Click the **Save** button displayed in the top right corner of the popup window. This enables the two buttons to be displayed at the bottom of the popup window.
8. Click the **Select** or **Select And Save** buttons to apply the filters on the Countries.

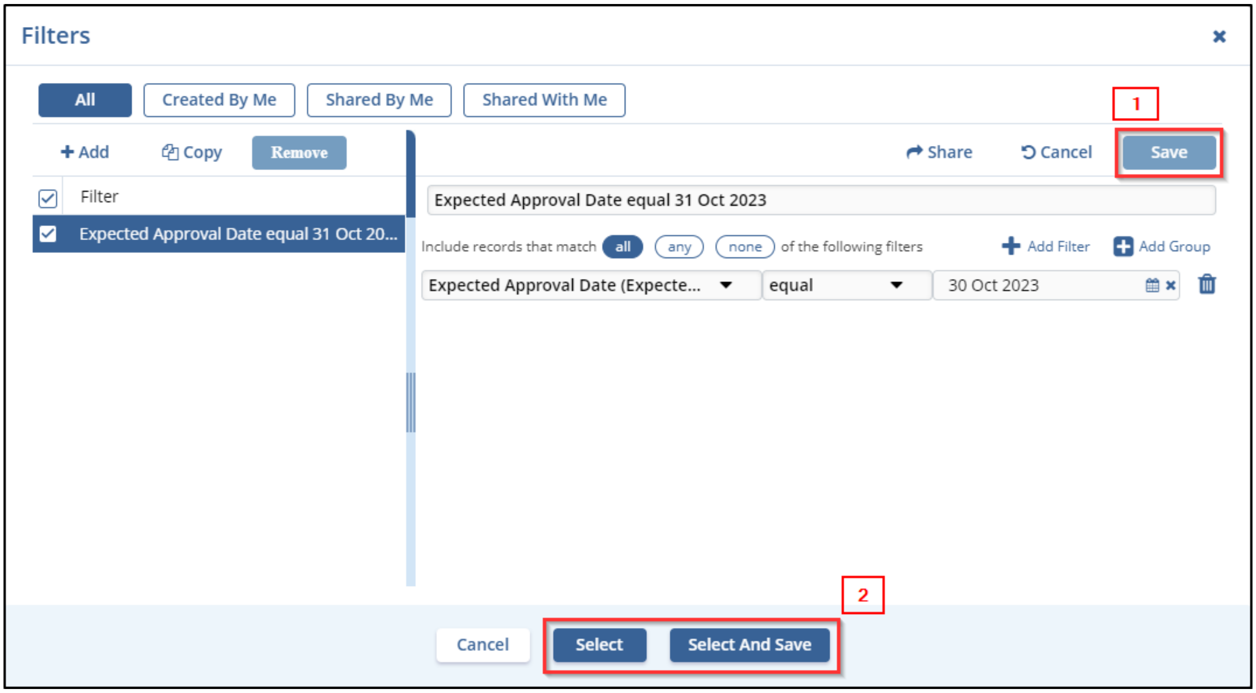


Figure 57: Countries Save

Create New Filter

1. Click the **Filters** button displayed on the right side of the grid pane.
2. The ‘Manage Filters’ and ‘Create New Filter’ buttons are displayed.
3. Click the **Create New Filter** button to open the Create Filter popup window.
4. Click the **Add Filter** button displayed in the right corner. A dropdown menu is displayed on the left side of the popup window.
5. Select a filter from the available list. This displays another two dropdown menus on the popup window. **Note:** The other two dropdown menus change as per the option selected in the first dropdown menu.
6. Click the **Create** button displayed at the bottom of the popup window.

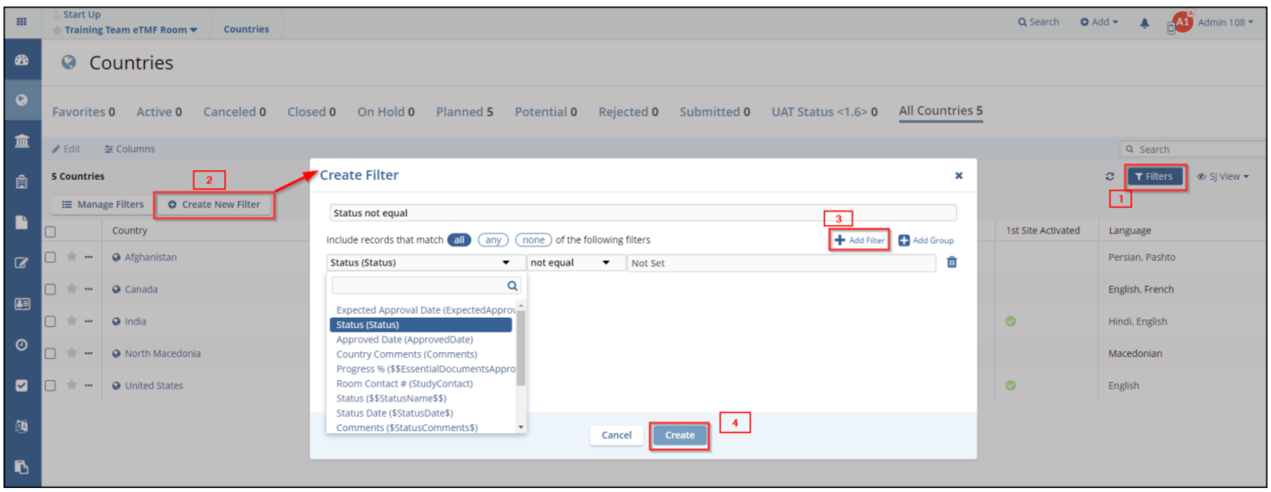


Figure 58: Countries Create New Filter

7. The created filter is displayed in the grid pane.

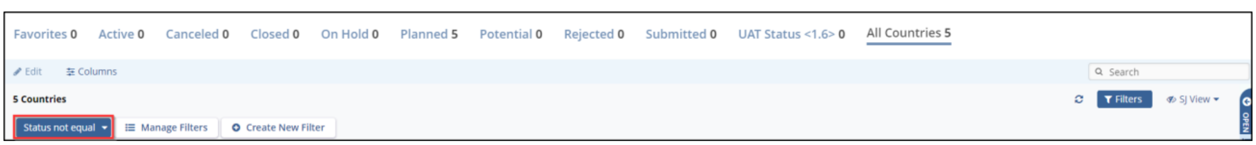


Figure 59:Countries Added Filter

8. Click the dropdown of the created filter to edit or delete the newly created filter. Refer to the screenshot below.

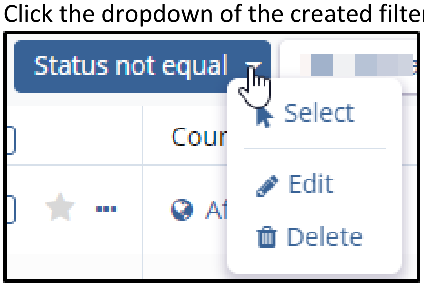


Figure 60: Countries Delete Filter

Columns

The user can manage the columns to be displayed in the grid pane by utilizing the Columns button. Follow the steps below to manage columns:

1. Click the **Columns** button displayed in the top left corner of the screen. This opens the Manage Columns popup window.
2. The Manage Columns popup window displays two sections – Available Columns and Selected Columns.
3. Select the required checkbox(s) and click the **Plus** icon in the Available Columns section.
4. The selected columns are reflected in the Selected Columns section.

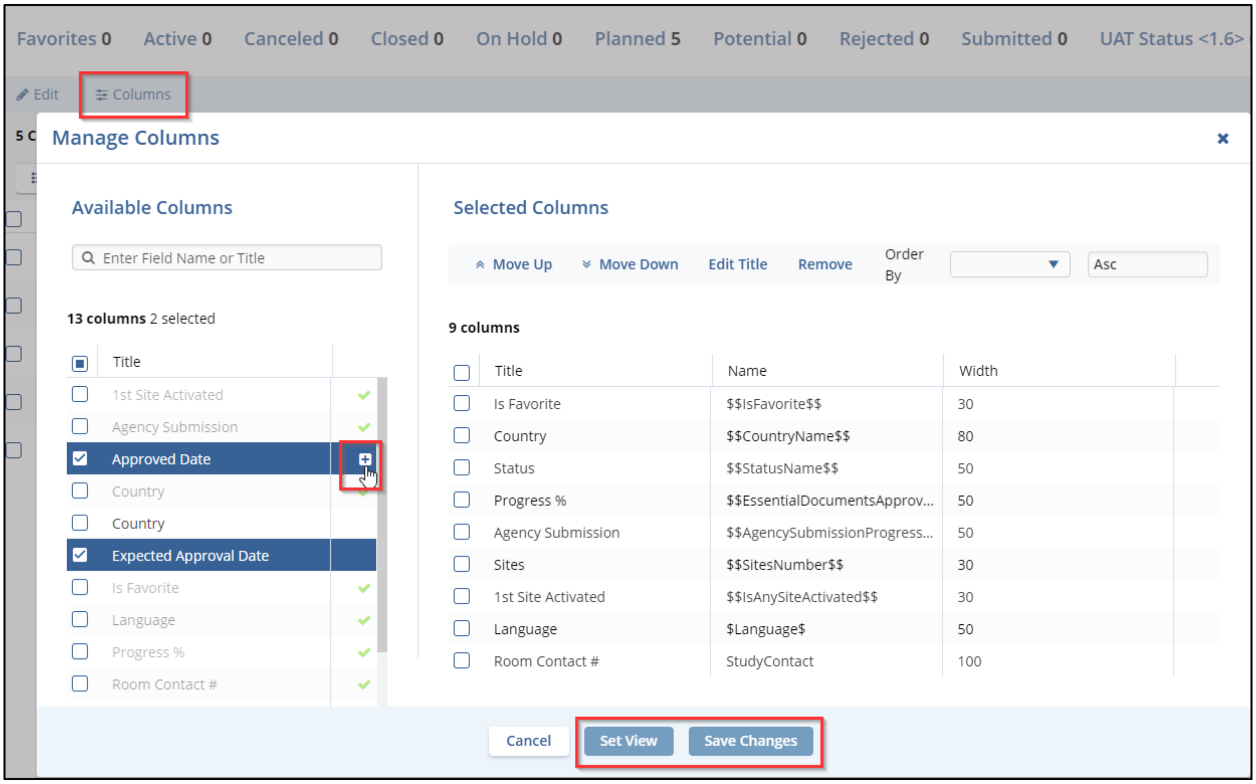


Figure 61:Countries Columns

5. Click an appropriate option from the following – **Cancel, Set View,** or **Save Changes** as required.
   Note: In the Selected Columns section, the user can move the selected columns up and down, Edit Title, Remove, and Order By as per requirement.

The Sites Current View

Click on the Country name to view the Country Details page. This page displays a progress bar for - the Documents and the Agency Submission. Below the progress bar, the page displays the tabs/links for Agency Submission, Documents, Amendments, Sites, IRB/EC, Security, and Communication log. Refer to the screenshot below.

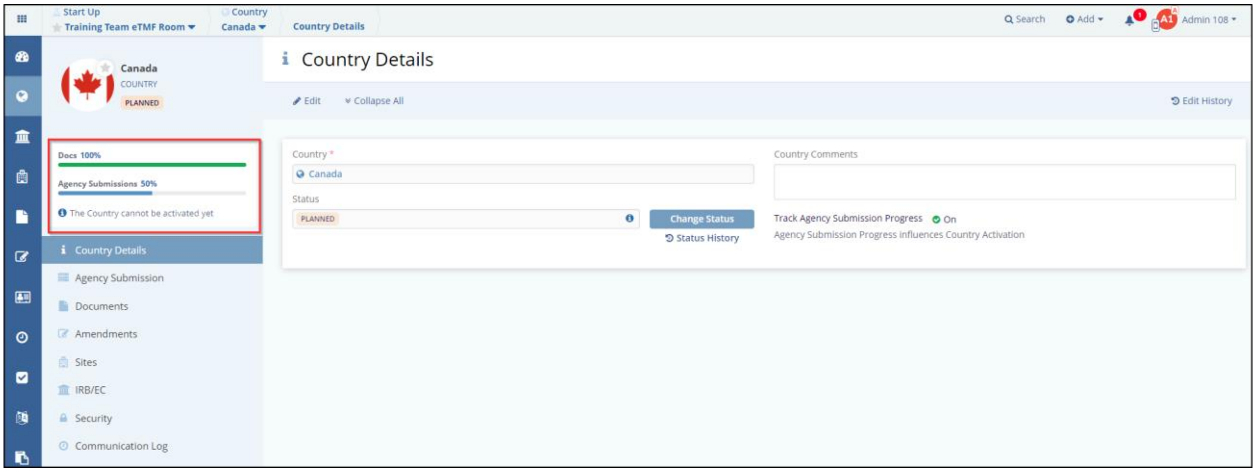


Figure 62: Countries- Sites Current View

Edit History

The user can view the history of all the edits performed by a user by clicking this button. Click the **Edit History** button to open the Status History popup window. The details are displayed in a table format. Click the **Close** button after viewing the details. Refer to the screenshot below.

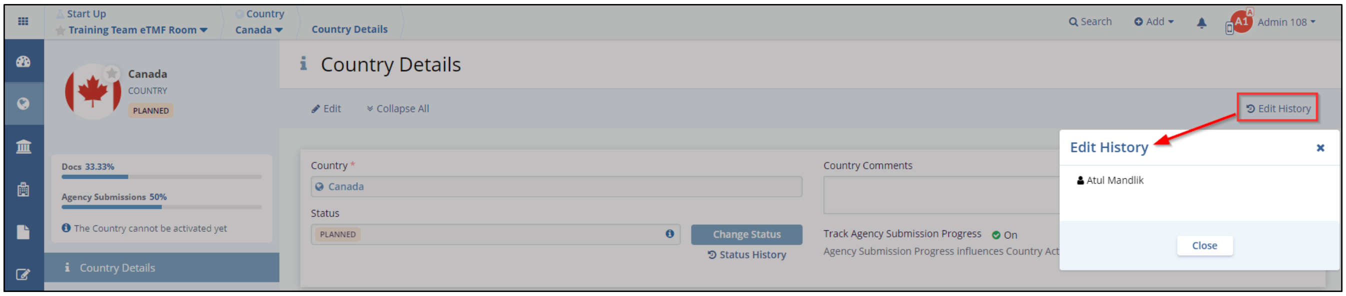


Figure 63: Countries Edit History

Note: The user can only view the details of the history and cannot make any changes.

Change Status

The user can change the status of a country by following the steps below:

1. Click the **Change Status** button displayed in the Country Details page. This opens the Change Status popup window.
2. Select the appropriate status from the dropdown menu of the Status field.
3. Select the Status Date by clicking the **Calendar** icon. Mention comments if required in the box below.
4. Click the **Save** button at the bottom of the popup window.

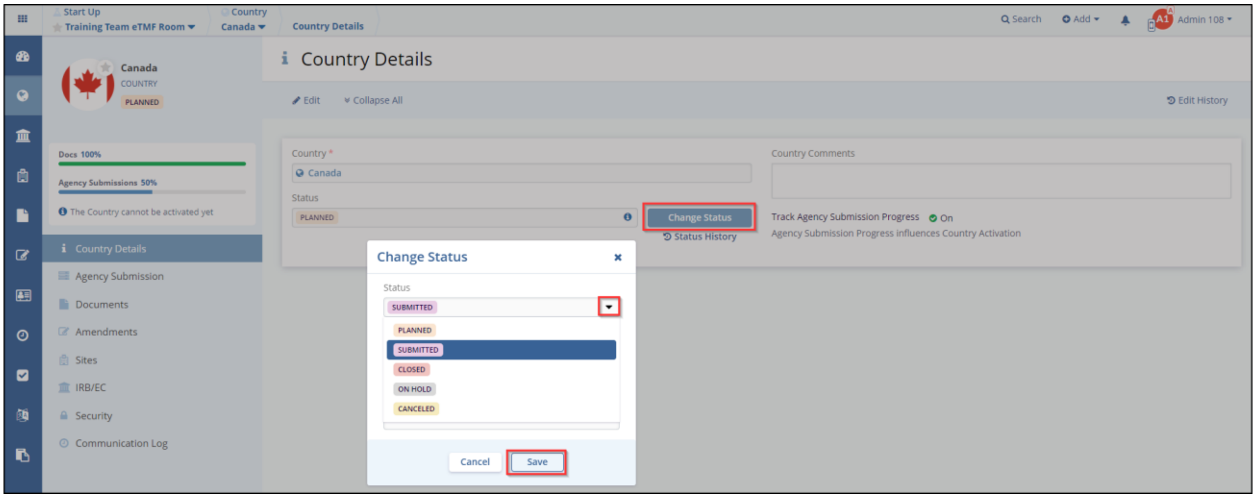


Figure 64: Countries-Change Status

Status History

A Status History button is displayed below the Change Status button. Click the button to view the name of the user who made the changes in the Country Details page. **Note:** The user can only view the history and cannot edit any information in the table displayed.

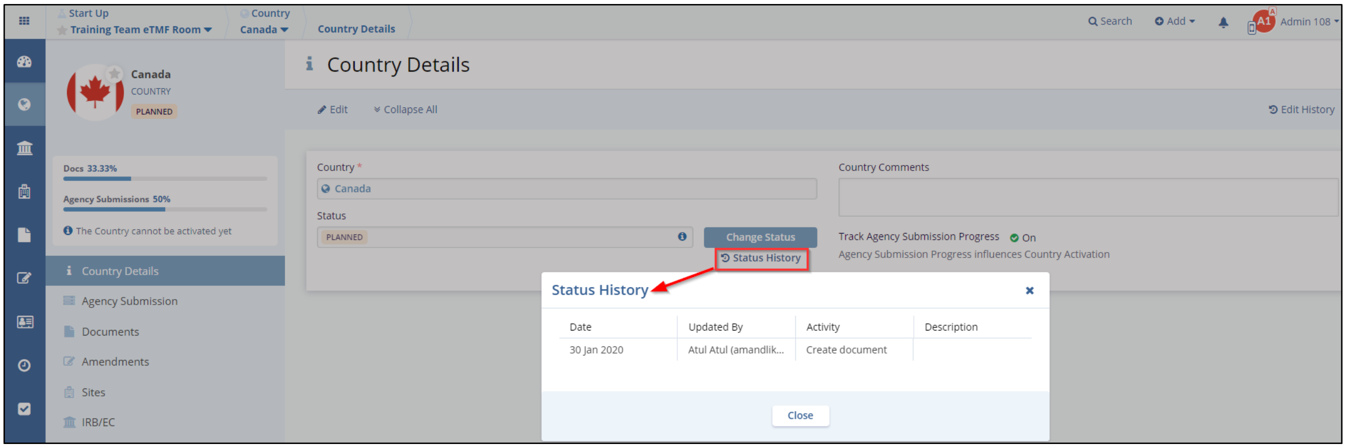


Figure 65: Countries-Status History

Agency Submission

It is common practice to associate health agencies with sites and send submission packages to them for their approval. Sites can't be activated for the clinical study unless the agency approval isreceived. A study may have multiple health agencies located in various countries. These agencies may have more comprehensive site activation submission packages involving hundreds of documentsthat need to be reviewed and approved. Since the agencies are related to countries, submission profiles and packages for them are accessed from the Countries Section.

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

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

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

Defining Health Agencies

Before adding the submission profiles and downloading packages, it is essential to define health agencies to be associated with sites. Health agencies need to be defined at the domain level.

Note: Contact the helpdesk to create Health Agencies if they are not already created.

Agency Submission

This page displays the submission packages for a country. The user can Add, Edit, Delete, Download, Manage Columns, Search, and apply Filters for an Agency Submission. Click the **Agency Submission** tab displayed in the left panel of a selected Country. Refer to the screenshot below.

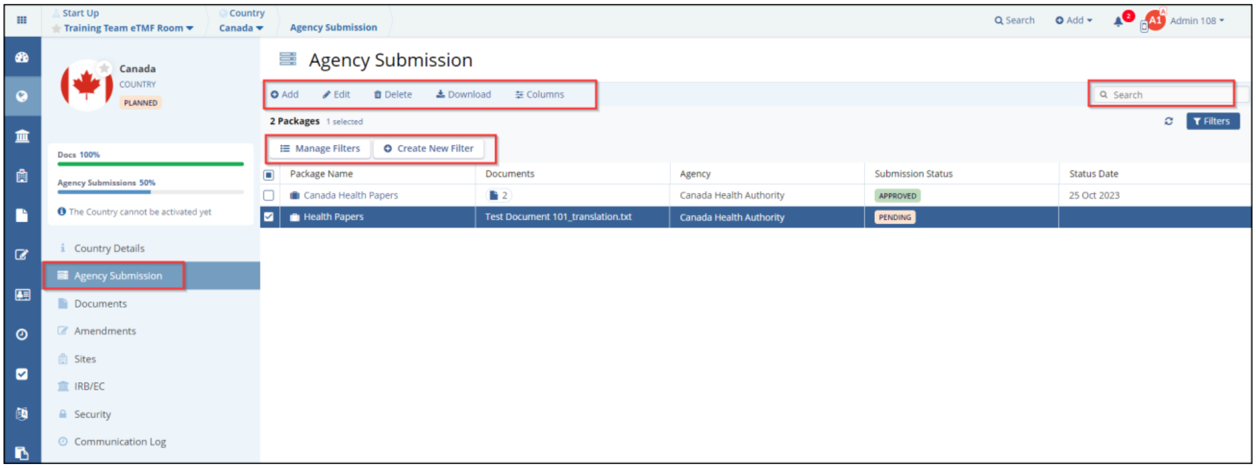


Figure 66: Countries-Agency Submission

Add Agency Submission

As mentioned above, the user can add an agency submission for a country. Follow the steps below for the same.

1. Click the Agency Submission option in the Country Details page. This opens the Agency submission Page.
2. Click the **Add** button displayed in the left corner of the top menu bar. This opens the Create Package popup window.
3. In the General Information tab, enter the details for the fields marked with an asterisk - **Package Name, Agency, and Country**.
4. Click the **Next** button displayed at the bottom of the popup window.

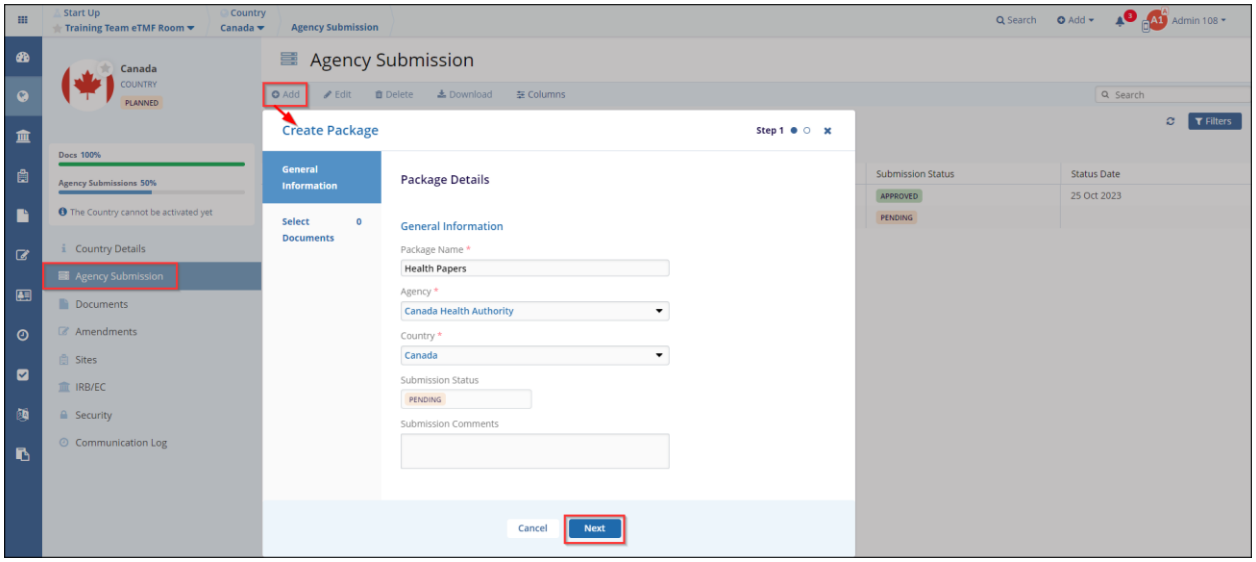


Figure 67: Countries-Add Agency Submission

5. This opens the Select Documents tab of the Create Package popup window. Select an appropriate option – Link System Documents OR Upload from Computer.
6. If you selected the **Link System Documents** option – click the **Search and Add Documents** option displayed below. This opens the Search popup window.
7. Enter a name in the Search field, and press **Enter** on your keyboard. Below the search field are three tabs displayed – Metadata and Document, Document Content Only, and Metadata Only. By default, the system has pre-selected the Metadata and Document tab. Select any of the other two tabs if you want only the document content or only the metadata.

8. Select the checkbox(s) of the documents to link and click either of the buttons displayed at the bottom of the window – **Add Documents & Continue** or **Add Documents & Close**.

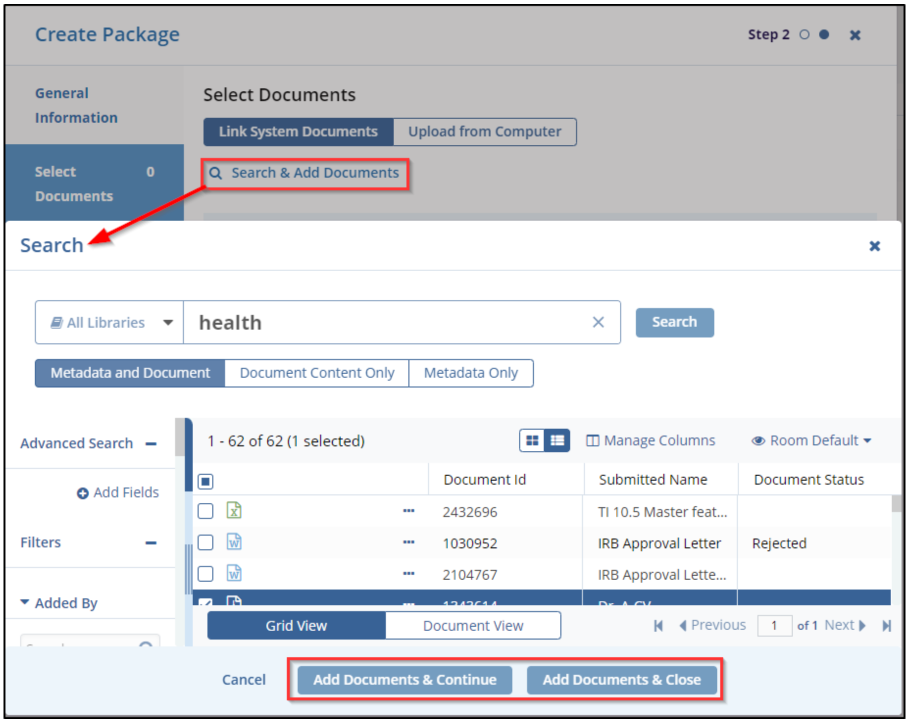


Figure 68: Countries-Search Field

9. If you selected **Upload from Computer** option – click the **Select a File** link or Drag and Drop a file.
10. Click the **Create** button displayed at the bottom of the popup window.

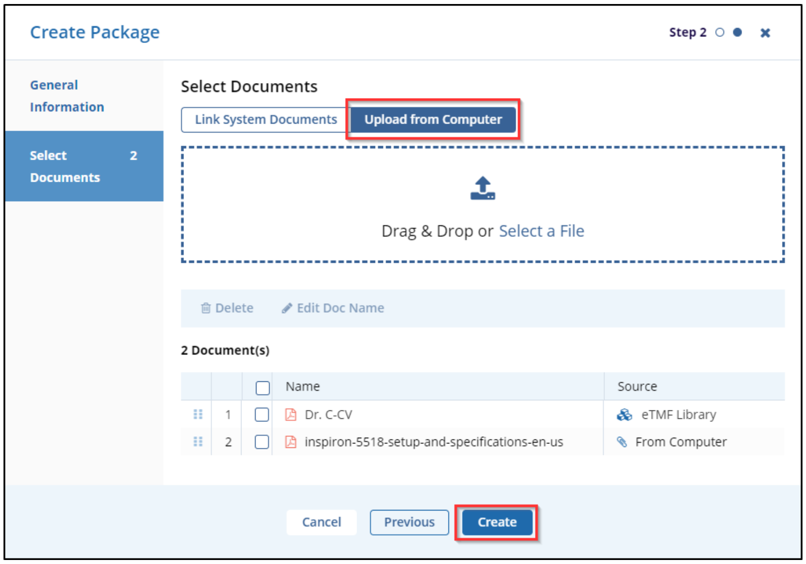


Figure 69: Countries-Upload Documents

Documents

The Documents tab in the Country page assists the user in Import, Add Required Doc, Email, Export, Manage Columns, Search, Apply, and create new Filters.

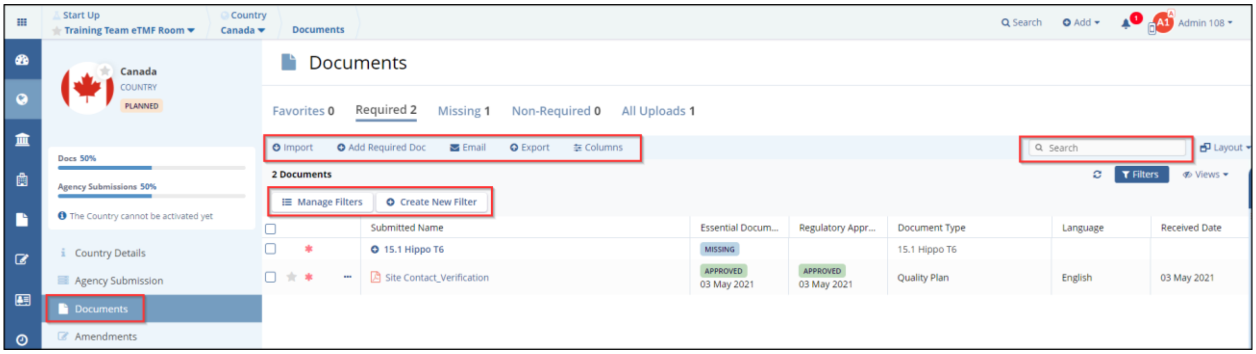


Figure 70: Countries-Documents

Import Documents

Follow the steps below to Import a document for a country.

1. Click the **Import** button displayed on the top menu bar. This opens the Import Documents popup window.
2. Drag and Drop the required files or click the **Browse File/ Browse Folders** option.

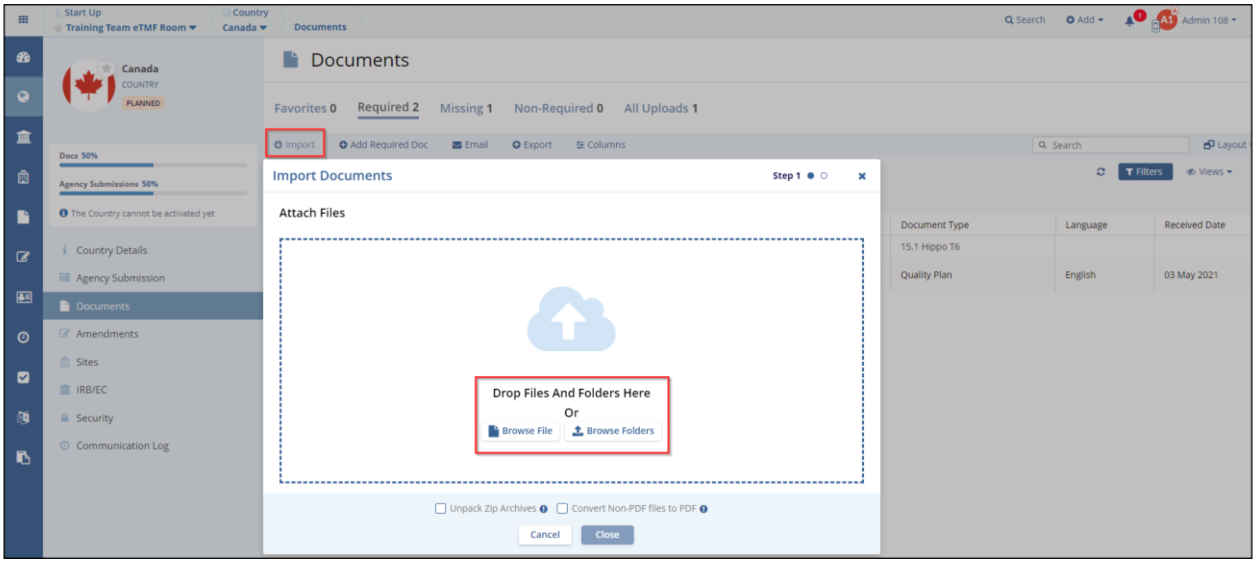


Figure 71: Countries-Import Documents

3. After the files are uploaded or dragged and dropped, the popup window displays two steps – Assign to Placeholders and Fill Metadata & Import.
4. The Assign To Placeholder – select the checkbox of the documents uploaded from the center of the popup window.
5. Select the Placeholder from the dropdown menu of the Placeholders section displayed on the right side of the popup window. Selecting the placeholders is mandatory to enable the Next button.

6. Click the **Next** button displayed at the bottom of the popup window.

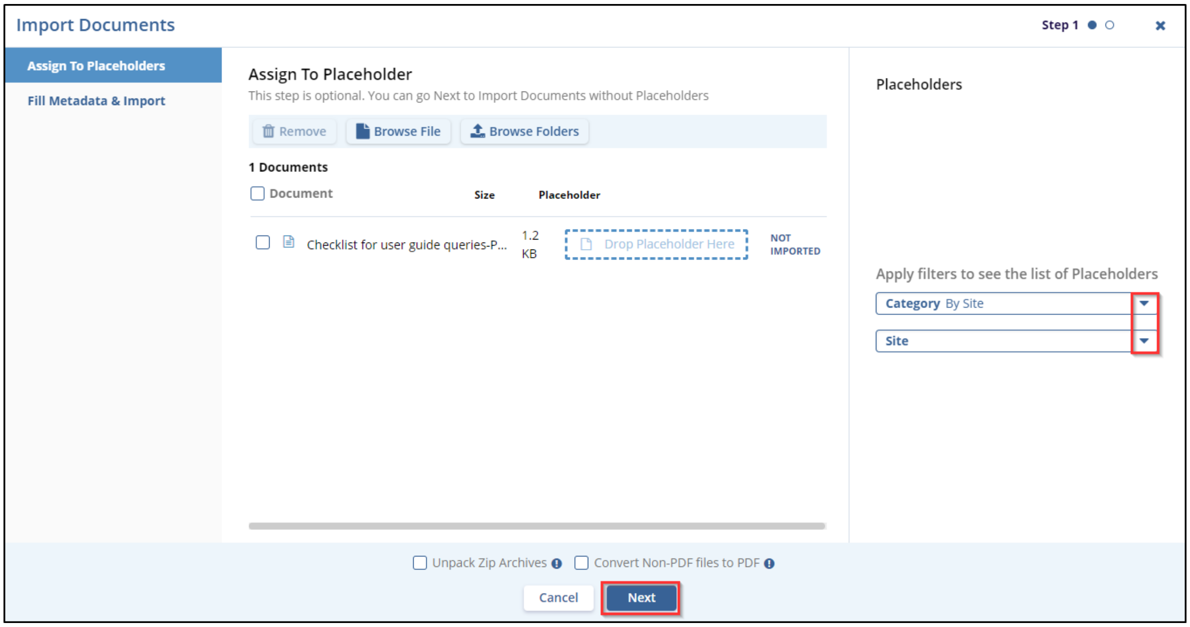


Figure 72: Countries-Assign Placeholder

7. The **Fill Metadata & Import – Step 2**, the Country and Category fields are by default selected.
8. Scroll down to view the Document Type field. Click the **Tag** icon to display a Select Document Type popup window.
9. Expand the dropdown and select the appropriate type. Click the **Select** button.

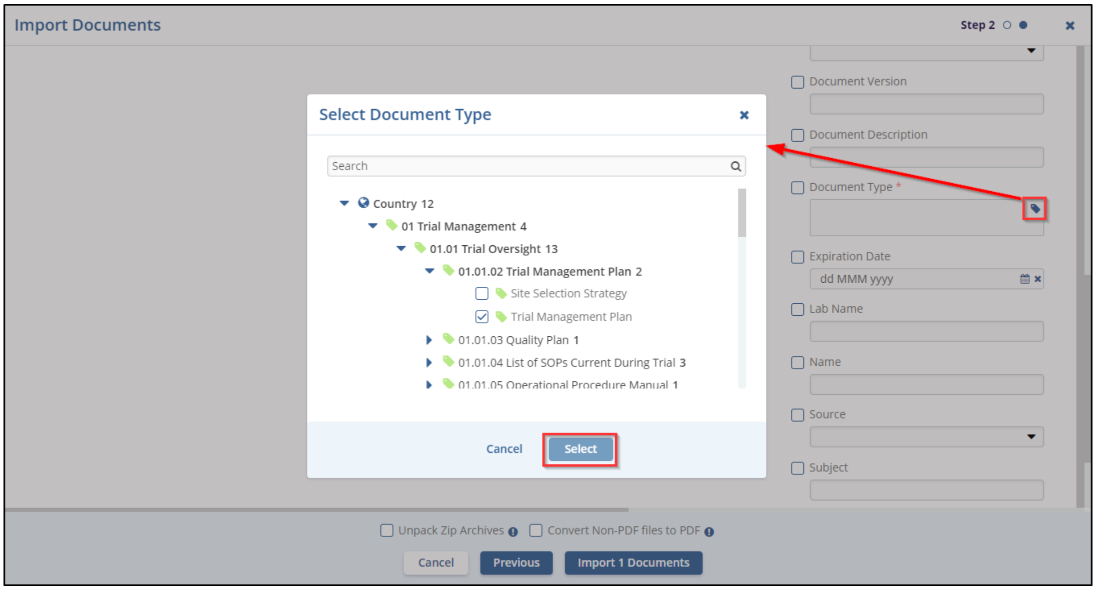


Figure 73:Countries-Select Document Type

10. The selected document type is reflected in the field.
11. Click the **Import 1 Documents** button displayed at the bottom of the popup window.

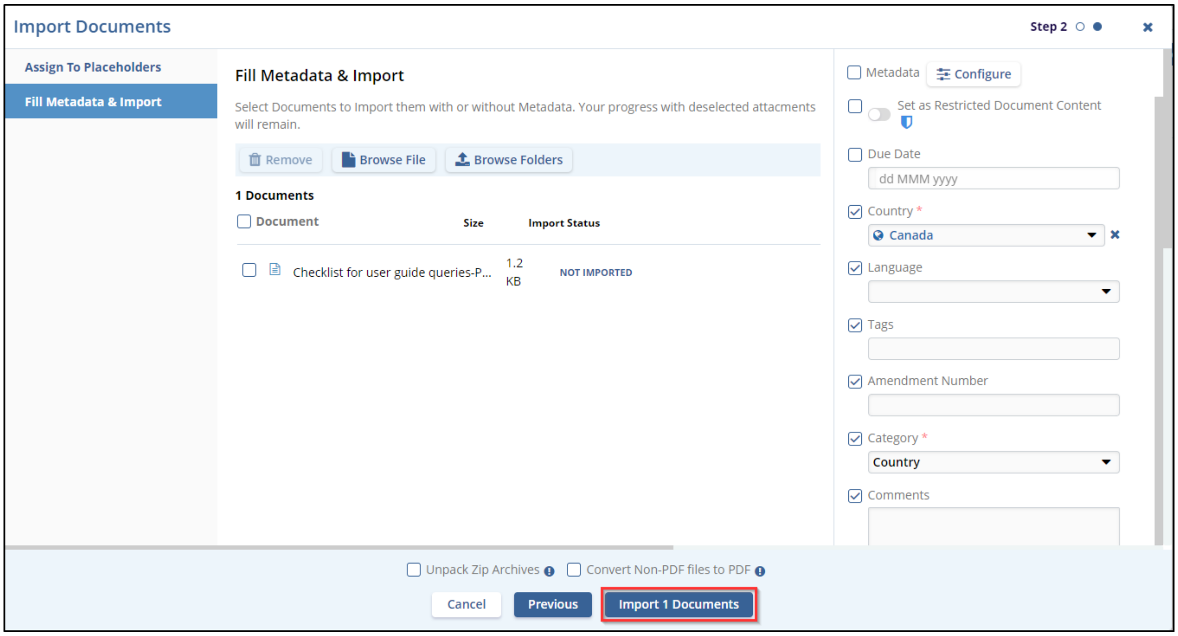


Figure 74:Countries-Import Documents

Add Required Doc

Follow the steps below to add a required document to the country.

1. Click the **Add Required Doc** button displayed in the top menu bar. This opens the Add Required Document Types popup window.
2. Expand the dropdown of the Country and select an appropriate checkbox from the available list.
3. Select at least one checkbox from the 'Required For' section on the right side. This enables the Save button at the bottom of the popup window.
4. (Optional) Select the Language(s) if required. Click the **Save** button.

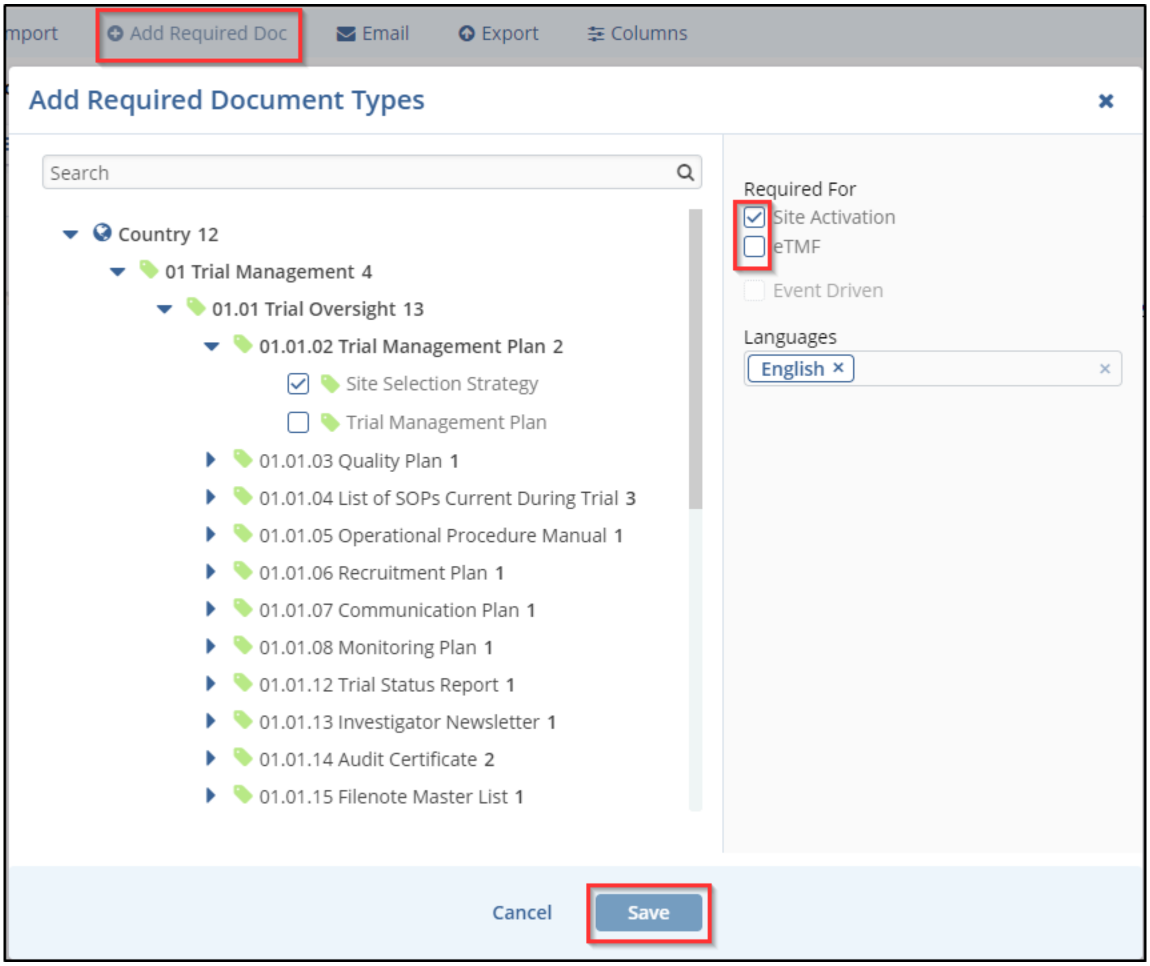


Figure 75:Countries-Add Required Document

Email

Follow the steps below to send an email to the recipient(s)

1. Click the Email button displayed in the top menu bar. This opens the Email popup window.
2. Enter the details in the mandatory fields – Recipients, Subject.
3. Write the mail in the body text box provided below.
4. Click the **Send** button displayed at the bottom of the popup window.

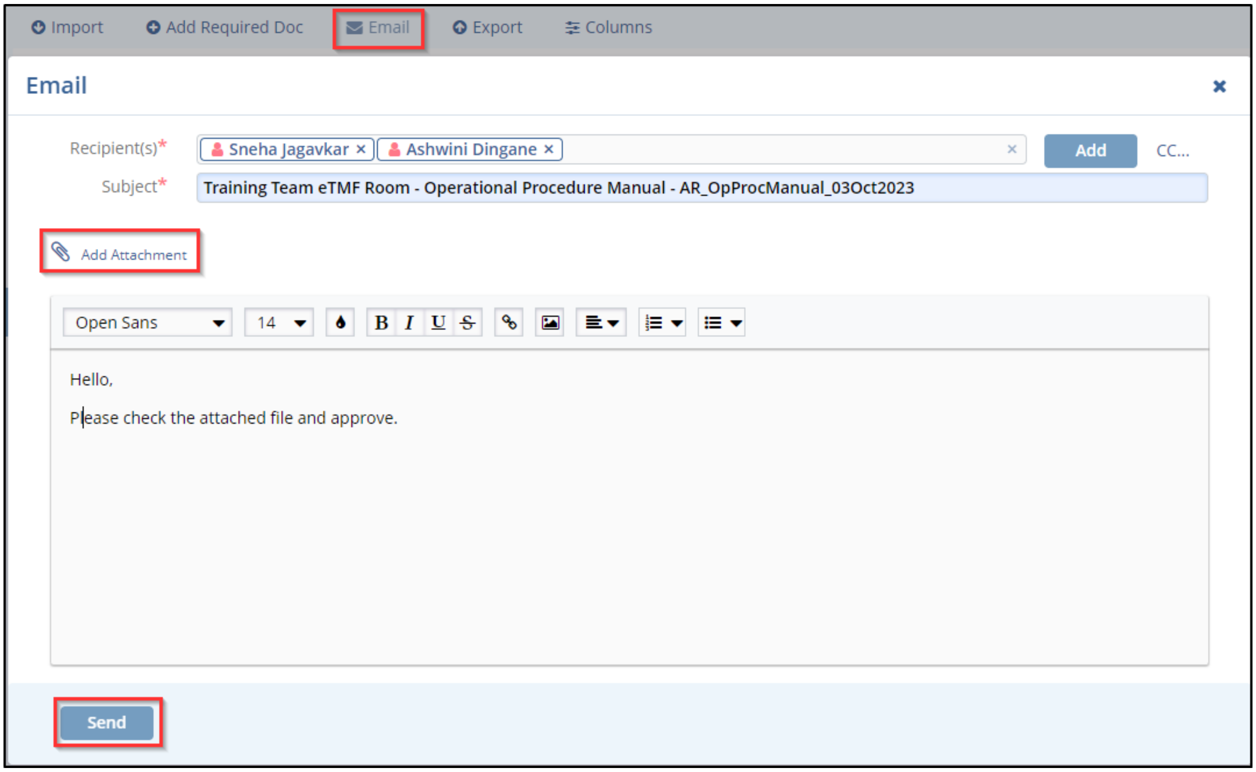


Figure 76: Countries-Email

5. Click the appropriate option – **Yes, Yes, And Publish to Investigative Sites, No** displayed in the Save Conversation popup window.

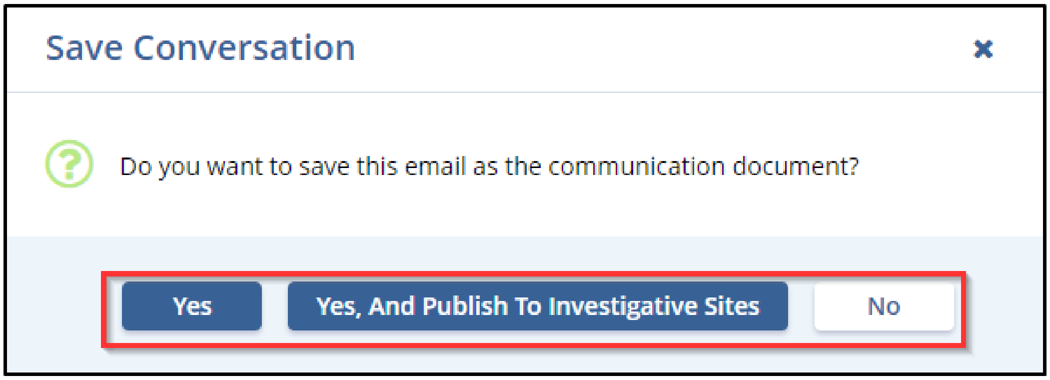


Figure 77: Countries-Save

Export

Follow the steps below to export the documents in the Country module.

1. Click the **Export** button displayed on the top menu bar. This opens the Export Audit Trail popup window.
2. Select a source from the dropdown menu for the Source field.
3. **(Optional)** select any one or all checkbox(s) as per the requirement.
4. If selected the checkbox for – Audit Trail Date Range – the From Date and To Date fields are enabled.
5. Click the **Next** button.

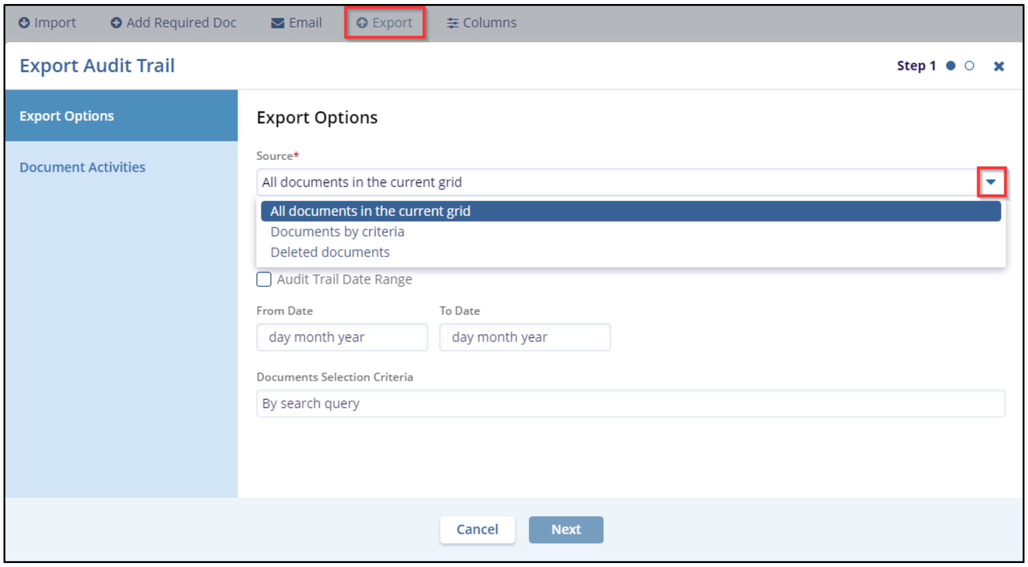


Figure 78: Countries-Export

6. Review the filled sections in Step 2 and click the **Export** button displayed at the bottom of the popup window.

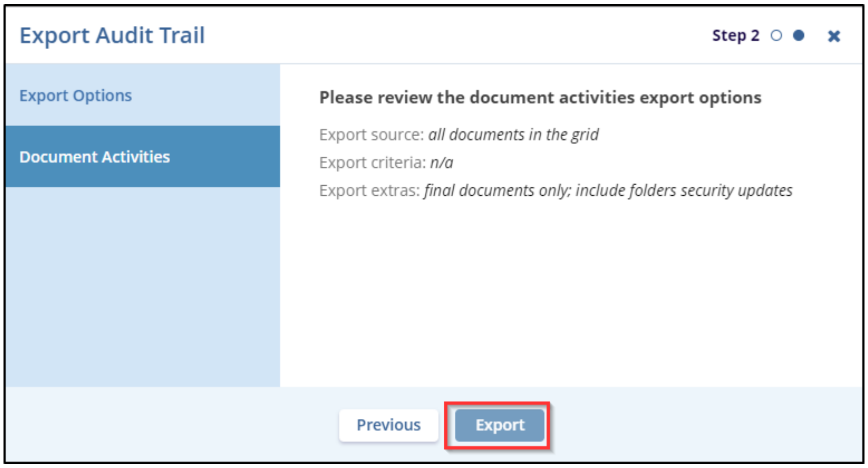


Figure 79: Countries-Export Audit Trail

Amendments

After a site is activated and the clinical trial begins, it is widespread to have amendments to the study protocol; depending on the nature of the amendments, many more essential/required documents need to be submitted by the sites. Such documents cannot be added to the site directly and can be specified only through Amendments. Amendments can be created for Investigative Sites, Country Amendments, and IRB/EC.

Sites

The Sites tab in the Country module displays the sites linked to that Country. The user can Add and Import Site List, Export Metadata, Manage Columns, Search, Manage, and Create New Filters from this page. Refer to the screenshot below.

Note: The Process for all the functions mentioned above is the same as mentioned in the Sites module. Refer to the Sites Section for [Adding](#) and [Exporting Metadata](#).

IRB/EC

The IRB/EC tab in the Country module displays the IRB/ECs linked to the particular Country. In this page, the user can Edit, Manage Columns, Search, Manage, and Create New Filters. The grid pane displays the IRB/EC Name, Status, Progress, and Address of the IRB/EC. Refer to the screenshot below.

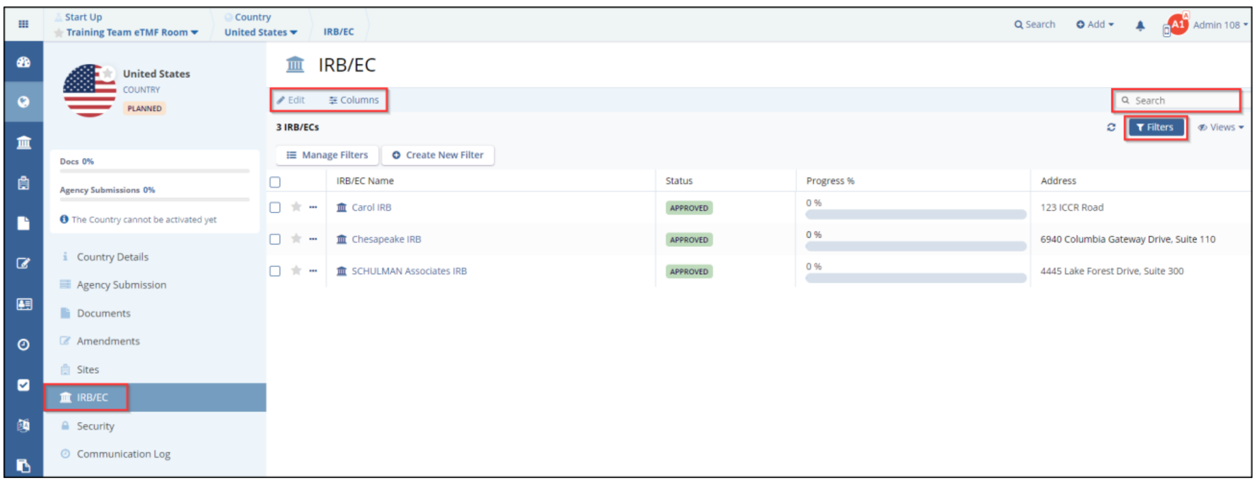


Figure 80: Countries-IRB/EC

Security

The Security page in the Country module helps the user create security to view full access and only country access to specific users and groups. The user can only edit the fields displayed on the page. Follow the steps below to set the security for the users and groups:

1. Click on the **Security** tab of the Country module. This opens the Security page in the center of the screen.
2. Click the **Edit** button displayed in the top left corner. This enables the four fields to apply security for users and groups.

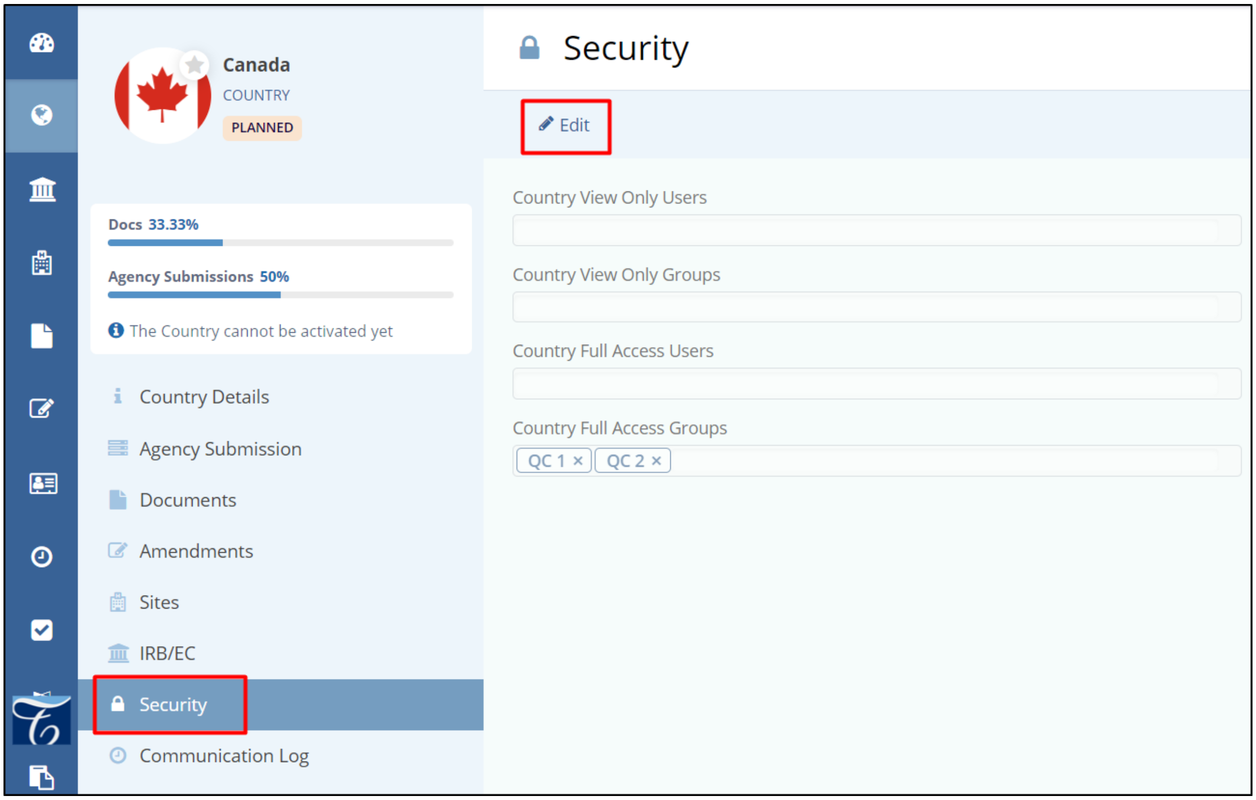


Figure 81: Countries-Security

3. Click the **three-dot** menu displayed next to the **Country View Only Users** field. This opens the Select Users popup window.
4. Select the checkbox(s) of the users whom you want to add to only view the country. Click the **Plus** sign next to the name. OR Drag and drop the name to the right-side pane.

5. The selected names are reflected in the right-side pane. Also, the selected names in the left pane are greyed out.

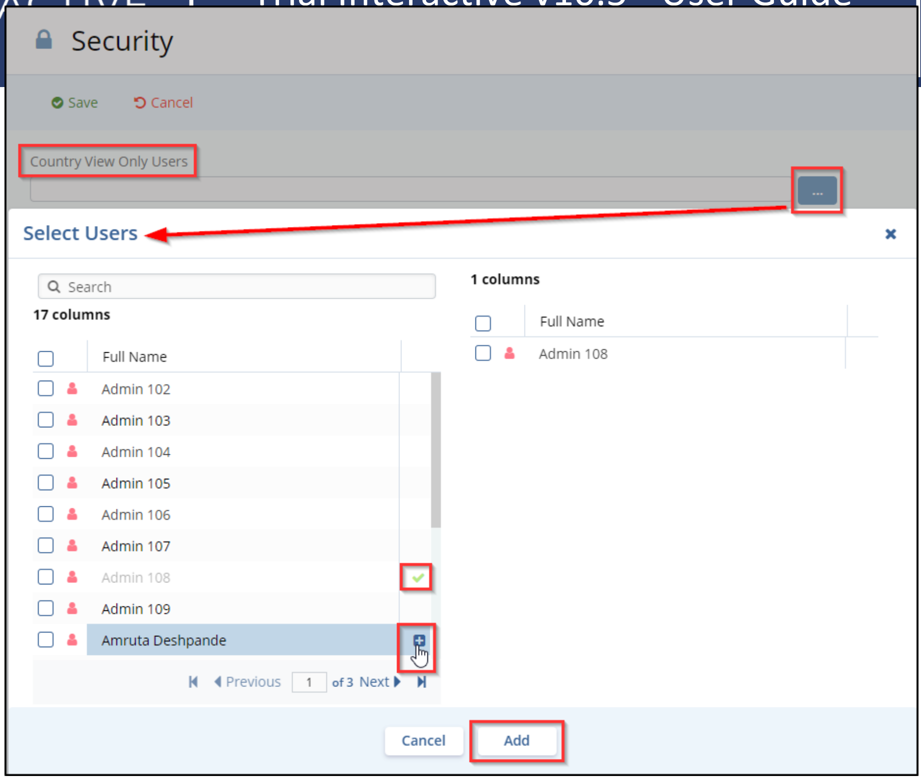


Figure 82: Countries-Security-Select Users

6. **(Optional)** to remove a selected name from the left pane, click the Minus icon displayed next to the selected name.

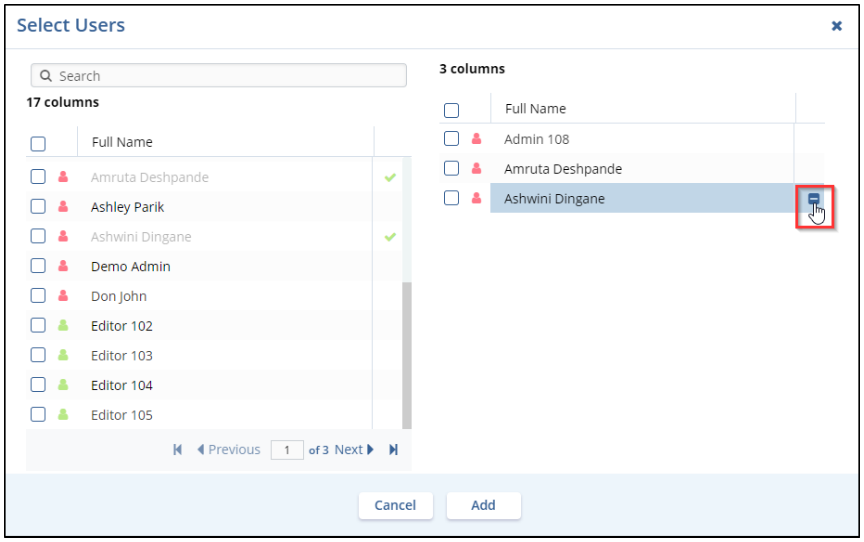


Figure 83: Countries-Security-Add Users

7. Click the **Add** button displayed at the bottom of the popup window.
8. The selected names are reflected in the Country View Only Users field.

9. Click the **three-dot** menu displayed next to the **Country View Only Groups** field. This opens the Select Groups popup window.
10. Select the checkbox(s) of the users whom you want to add to only view the country. Click the **Plus** sign next to the name. OR Drag and drop the name to the right-side pane.
11. The selected names are reflected in the right-side pane. Also, the selected names in the left pane are greyed out.
12. **(Optional)** to remove a selected name from the left pane, click the Minus icon displayed next to the selected name.
13. Click the **Add** button displayed at the bottom of the popup window.

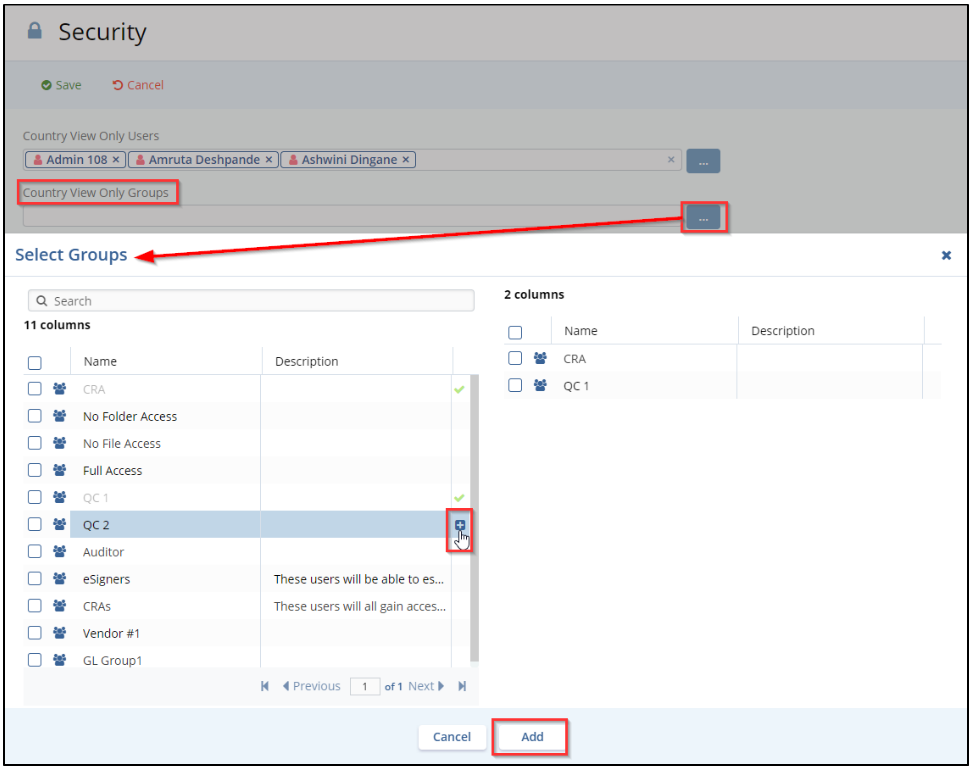


Figure 84:Countries-Security-Select Groups

14. The selected names are reflected in the Country View Only Groups field.
15. Follow steps 3-7 to add Country Full Access Users.

16. Follow steps 9-12 to add Country Full Access Groups.
17. Click the **Save** button displayed at the top left of the screen.

Figure 85: Countries-Security-Save

18. A notification is displayed on the right side of the screen mentioning changes have been made to the Country.

Communication Log

The communication log helps the user by displaying the communications that happened over some time to collect different documents from the right personnel. The user can Add, Edit, Delete, Manage Columns, Search, Manage, and Create New Filters on this page.

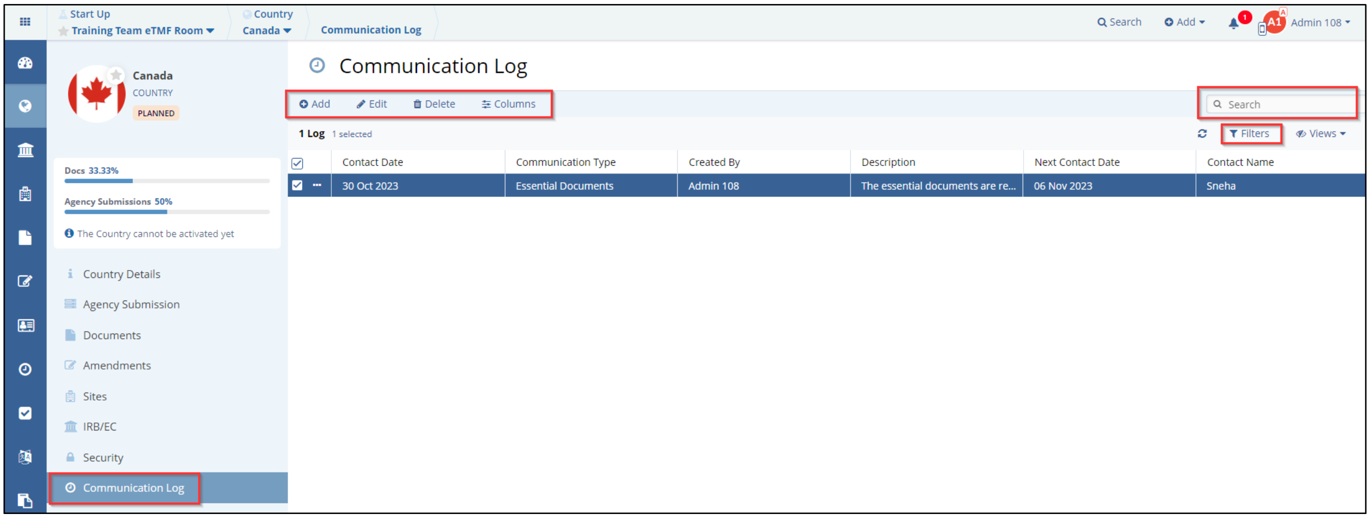


Figure 86:Countries-Communication Log

Add Log

1. Click the **Add** button displayed on the top menu bar.

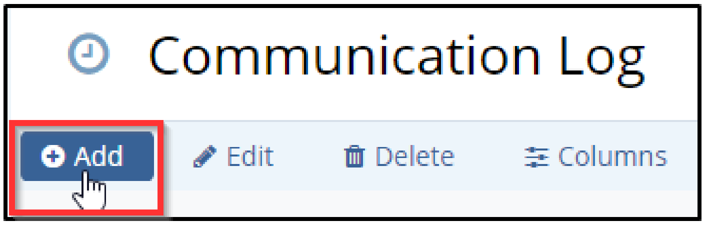


Figure 87: Countries-Add Log

2. This opens the Add Communication Log popup window. Enter the **Contact Date** by clicking the **Calendar** Icon. Select the required date from the calendar displayed. This is a mandatory field.
3. Enter the **Communication Type** by clicking its dropdown menu. This is a mandatory field.
4. Enter the details in the Description field. This is a mandatory field.
5. **(Optional)** Enter the details in the Contact Name and Next Contact Date fields.
6. Click the **Add** button displayed at the bottom of the popup window.

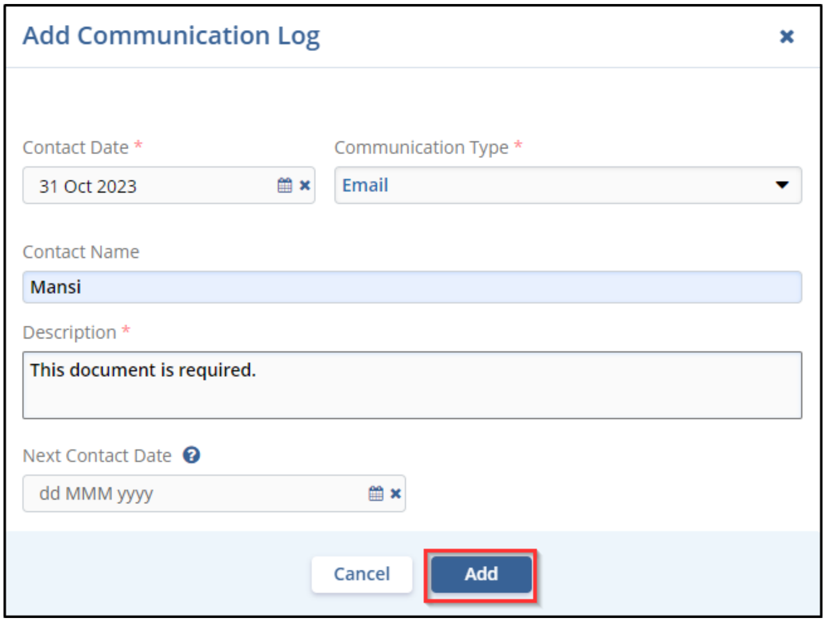


Figure 88: Countries-Add Log

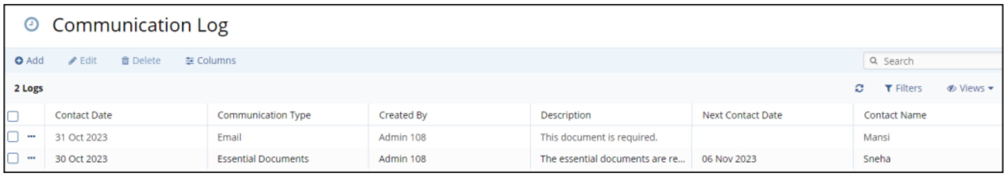


Figure 89:Countries-Add Log

Edit Log

1. Select the checkbox of the log to edit.
2. Click the **Edit** button displayed on the top menu bar. This opens a metadata panel on the right side of the screen.
3. Make the changes in the required fields and click the **Save** button at the bottom of the metadata panel.
4. The saved changes are reflected in the grid pane.

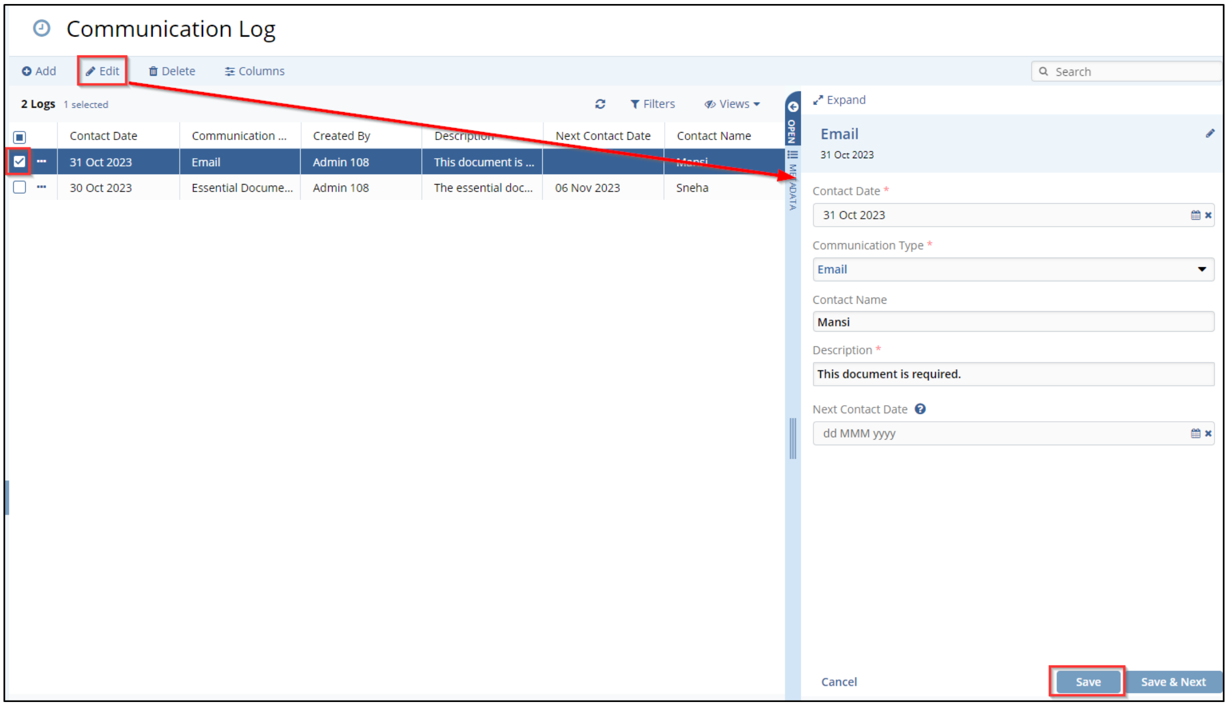


Figure 90: Countries-Edit Log

Delete Log

1. Select the checkbox of the log to delete. This enables the Delete button to be displayed on the top menu bar.
2. Click the **Delete** button.
3. Click **Delete** in the Delete Record popup window.

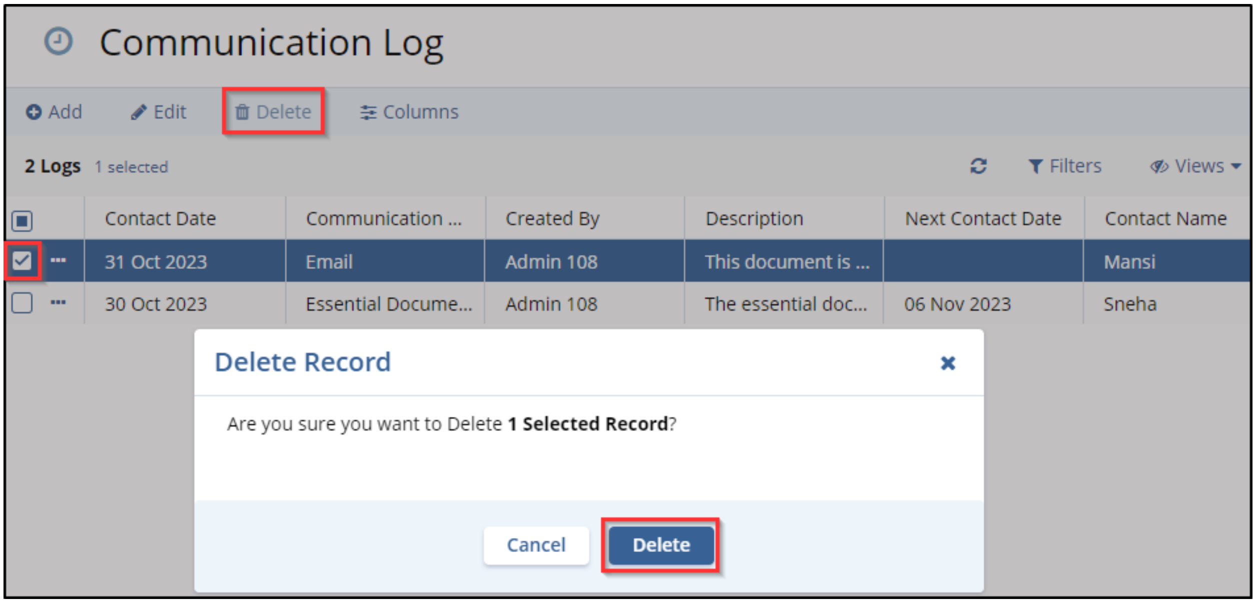


Figure 91: Countries-Delete Log

IRB/EC

Sites need to adhere to the protocols as set by the IRB/ECs for more efficient and effective performance of clinical trial operations. Today, organizations are encouraged to use central IRBs as opposed to multiple local IRBs. However, the decision to use central or local IRBs or more than one IRB of any type for a clinical trial depends upon the clinical research enterprise, especially if it intends to conduct multi-site trials.

Trial Interactive supports the use of both central and local IRBs. Although it is advisable to use a single central IRB for multi-site trials, sites may need to use more than one IRB/EC. Trial Interactive not only allows you to add IRB/ECs as required, but it also allows you to specify additional IRB/ECs. In this section, we will discuss the following:

1. Adding additional IRB/ECs to data rooms

2. Viewing IRB/ECs

3. Editing IRB/EC profile

Adding Additional IRB/EC

You can specify more than one IRB/EC for a site from within the Sites module of SSU. Proceed to the section Add Additional IRB/ECs for more details on this.

IRB/EC Grid Pane

Clicking the IRB/EC tab from the toggling menu bar on the left lists the IRB/ECs available to the room. The IRB/EC dashboard consists of the Grid pane in the center with the following columns to view and edit:

- **IRB/EC Name**
- **Status** – Displays if the IRB/EC is Approved, Submitted, Pending, or Conditional Approval.
- **IRB/EC Type** – Displays if the IRB/EC is Central or Local.
- **Progress** – Displays the percentage of required documents collected for each IRB.
- **Country** – Displays the Country name to which the IRB/EC is linked.
- **Sites** – Displays the number of sites linked to the IRB/EC.
- **Address** – Displays the address of the IRB/EC.

It has a Search textbox in the top right corner to search for IRB/ECs, a Filter button to manage and create new filters and save a view. Refer to the screenshot below.

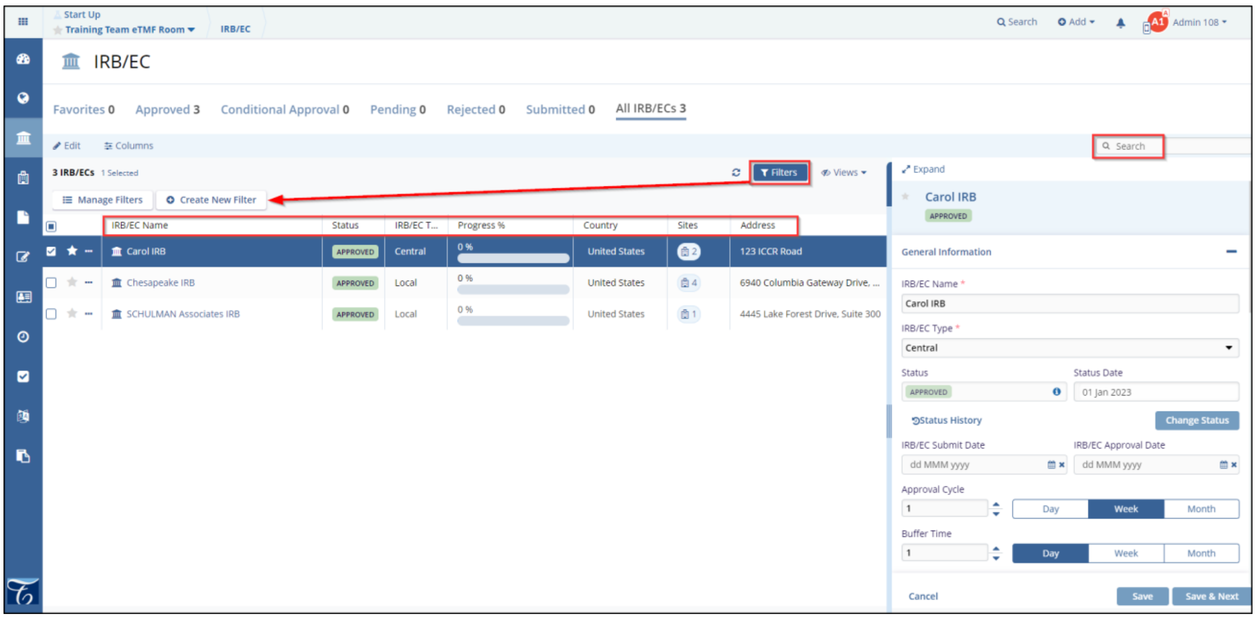


Figure 92: IRB/EC Grid Pane

View and Edit IRB/EC

1. Select a checkbox of the IRB/EC name that you want to edit.
2. Click on the **Edit** button displayed on the top menu bar.
3. A metadata panel opens to the right side of the screen.
4. Click the **Pencil** icon displayed in the right corner of the screen. This enables all four fields to be edited – General Information, IRB/EC Contact Information, Meeting Frequency, and Submission Deadline.

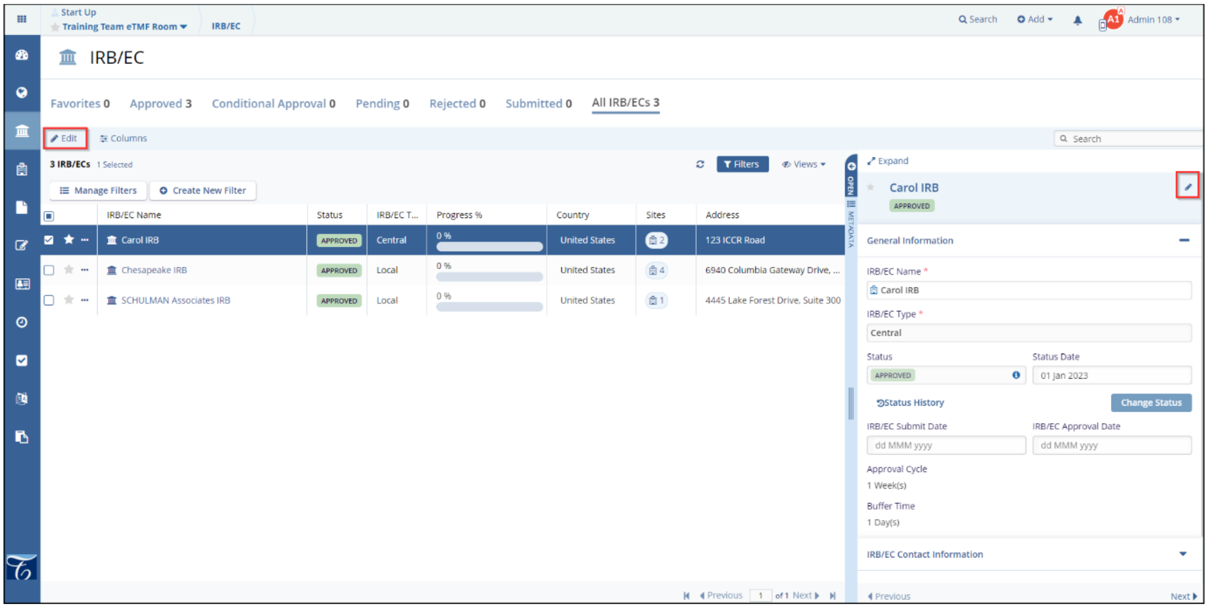


Figure 93: IRB/EC-View and Edit

5. Make the changes in the required fields and click the **Save** button displayed at the bottom of the metadata panel.

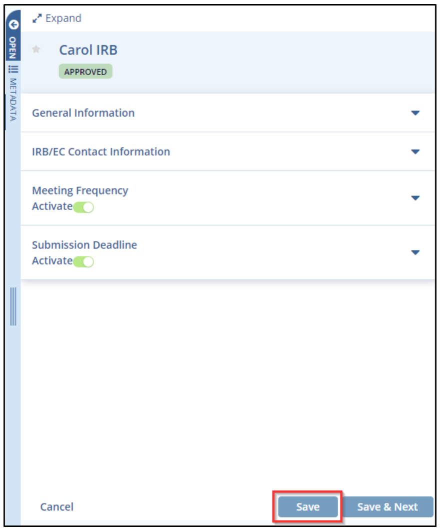


Figure 94: IRB/EC-Save Changes

Sites

The Sites tab comprises the following functionalities in Study Start Up

1. Create Sites and add contacts to them

2. Viewing sites

3. Editing site profiles and deleting sites

4. Adding additional IRB/ECs

5. Exporting Site Metadata

6. Mass Coding for sites

7. Managing Security

Clicking the Sites tab from the vertical menu bar leads you to the Sites section. This is where the Start-up Specialists will perform their functions, and the users of the sites are allowed to submit andapprove documents specific to the sites.

The Sites section consists of the Current view on the left and the Grid pane on the right. Besides these, it also allows you to perform various functionalities from the menu bar on the top of the grid pane and the buttons on the Current View window. Clicking a folder in the current view opens a listof sites in the grid pane. Refer to the screenshots below.

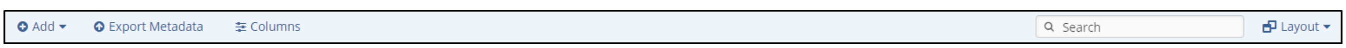


Figure 95: Sites- Top Menu Bar

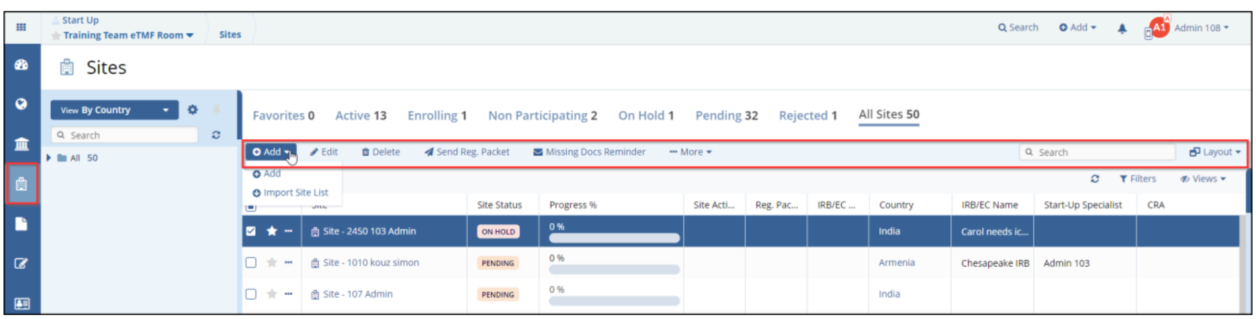


Figure 96: Sites

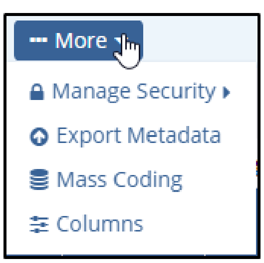


Figure 97:Sites-More

Besides the above, you can also add required documents or regulatory approvers specific only to a particular site and add room users to sites by providing them appropriate security accesses. These will be discussed in subsequent sections.

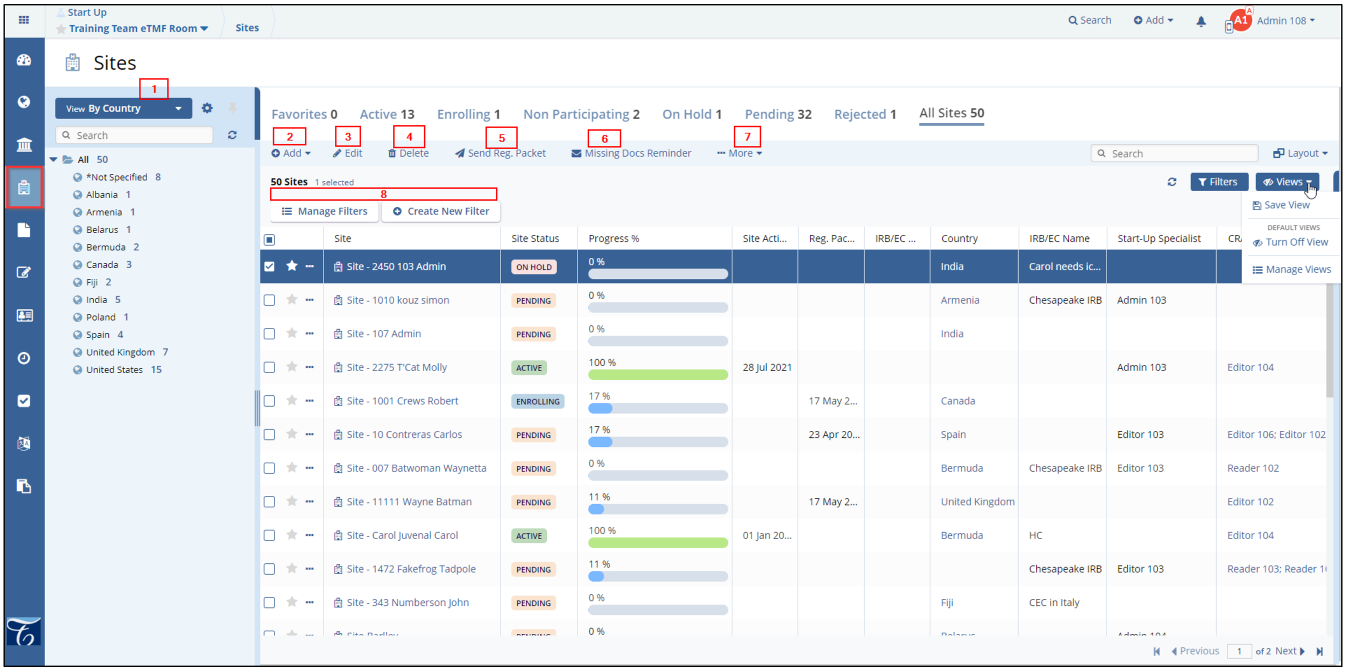


Figure 98: Sites-Dashboard

Sr No	Part	Description
01	**Site Activation**	Here, the user can choose the current view.
02	**Add**	Allows to add New Investigative Sitesand Contacts one at a time.
03	**Edit**	Allows to edit the sites.
04	**Delete**	Allows to delete the Investigative Site.
05	**Send Reg. Packet**	Allows to send the regulatory packetsto the specific sites.
06	**Missing Docs Reminder**	Allows the user to send an email regarding the missing expected documents to the recipient.
07	**More: Manage Security**	Allows to provide security roles tousers in the site.
07. a	**More: Export Metadata**	Allows to export the sites in the room.
07. b	**More: Mass Coding**	Allows to add Metadata to the multiple selected sites.
07. c	**More: Columns**	Allows the user to manage the columns to be viewed in the grid.
08	**Filters**	Allows users to manage and create new filters.

Creating Sites and Adding Contacts

You can create sites by either of the methods:

1. Adding each site and its contacts individually
2. Importing Sites and Site Contacts

1. Adding each site and its contacts individually

Sites can be created afresh or added from a list of previously created sites in other rooms related to the same sponsor in a domain. This is especially helpful if the sites are located in multiple locations.

If the user wants to create sites with the same name but different metadata like contacts, address, IRB/EC, and other details. It can also happen that a site is conducting different types of clinical trials. Hence, you might want to keep the same name, but the rest of the data can differ. Metadata such as the country and IRB/EC will be added to the new site only if the room has them configured andavailable.

To create sites, follow the procedure below:

1. Click the **Add** button from the menu bar. The Create Site window opens with six steps to complete.

Figure 99: Sites-Add

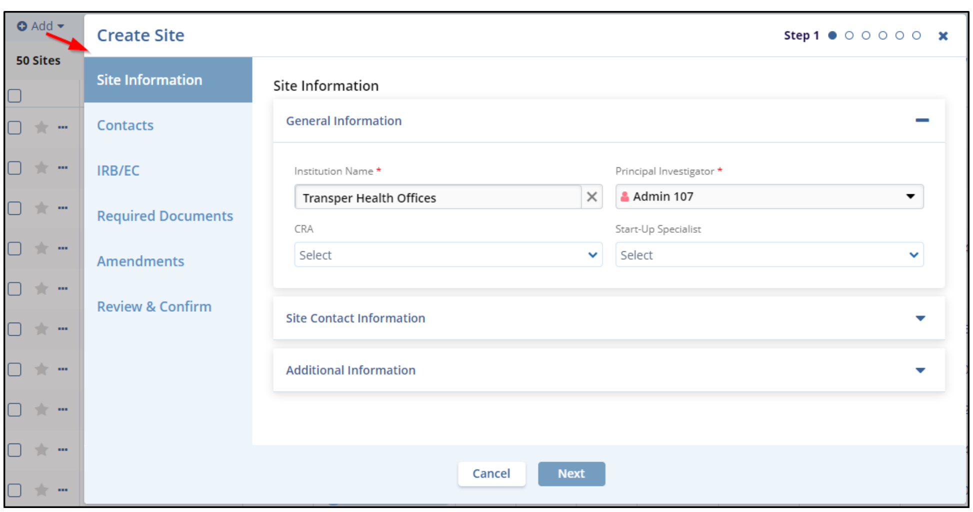


Figure 100: Sites- Create

2. In the Site Information tab, either type the Institution Name in the available field or type keywords in the field to view the list of available 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 window.

3. Select the **Principal Investigator, CRA, Start-Up Specialist** from the respective field's dropdown menu.

4. (Optional) Add required details in the **Site Contact Information** and **Additional Information** tabs. Click the **Next** button.

5. The **Contacts** tab – In step 2, the user can Create new contacts or Add Existing contacts to the site being created. In this step, the user can also Edit and Remove the contacts that are not required. Click the **Next** button.

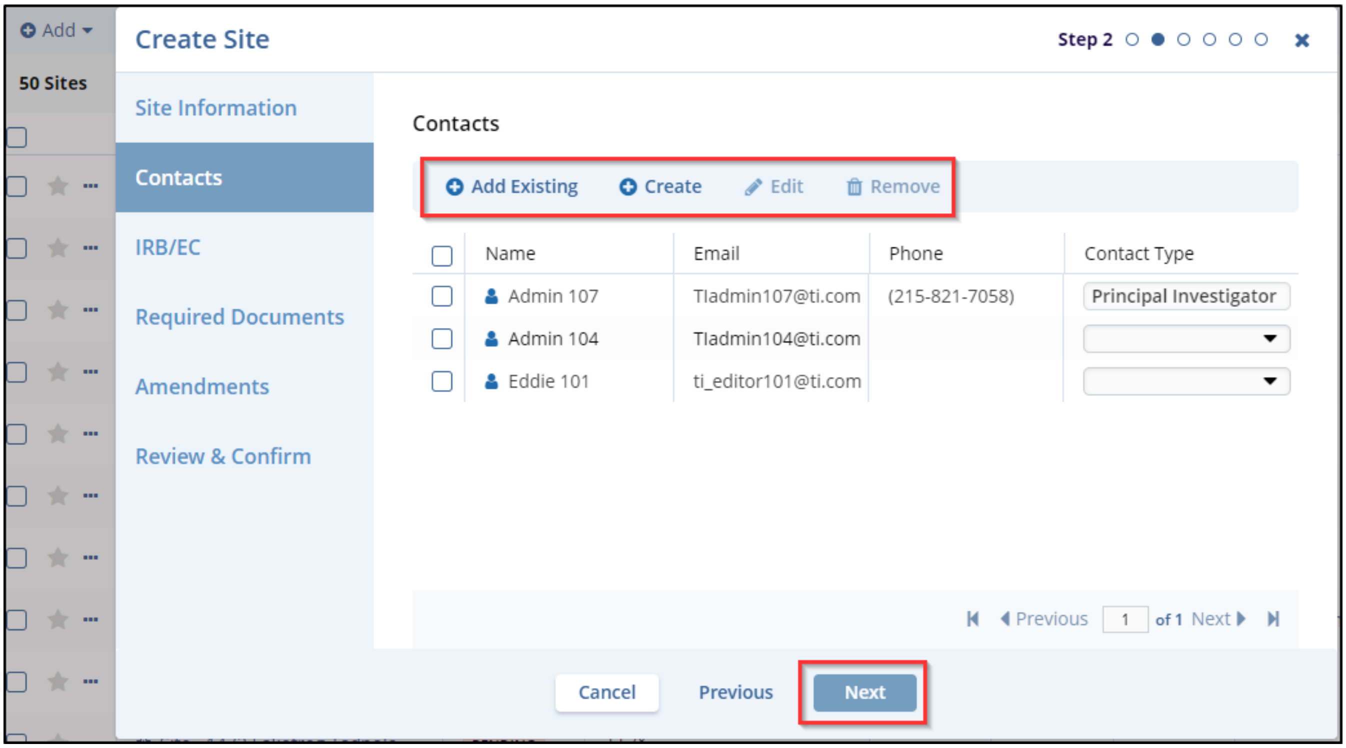


Figure 101: Sites-Create Contact

6. In the **IRB/EC** tab – Step 3, the user can Create a new contact or Add Existing IRB/ECs to the site being created. In this step, the user can also select an IRB and Set it as Local or Central, and Remove the IRB/EC that is not required. Click the **Next** button.

Note: The IRB/EC can be 'Set as Central/Local' by selecting only one checkbox at a time. Also, after setting the IRB/EC as Central, the other IRB/EC in the list's Type is changed.

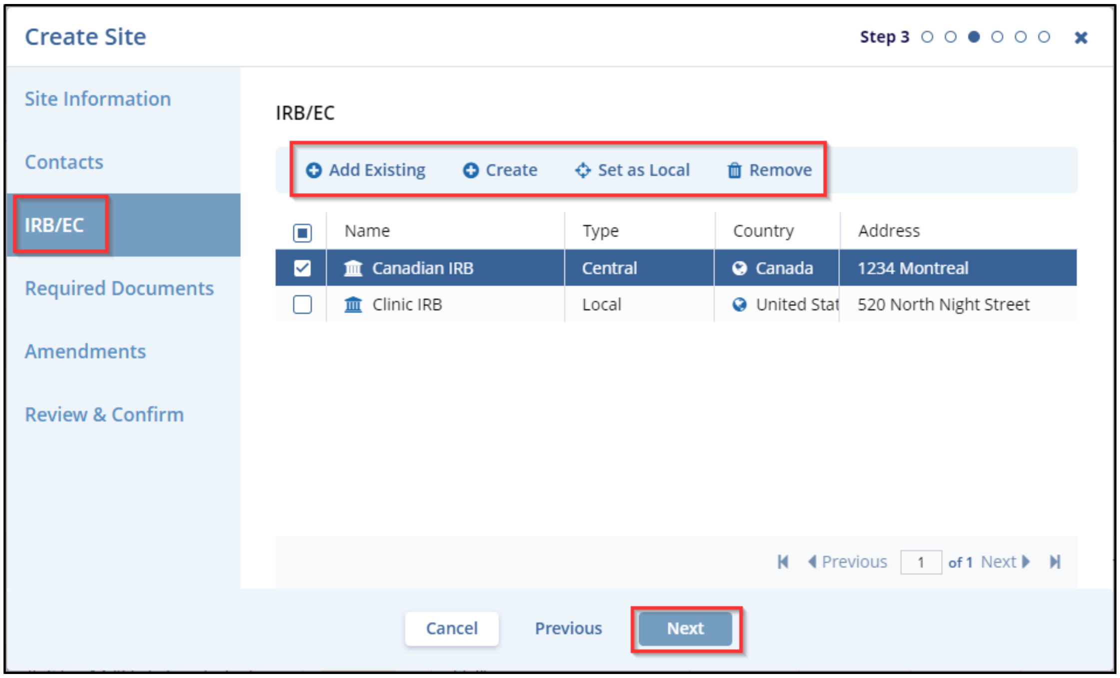


Figure 102: Sites-Create IRB/EC

7. The Required Documents tab – Step 4, click the **Add** button to open an Add Required Document Types popup window. Refer to the screenshot below.
   7. a. The Add Required Document Types window displays two sections- 'Search' on the Left side and 'Required For' on the right side.
   7. b. In the left panel, select the appropriate site and expand the arrows to select the required checkbox.
   7. c. In the right-side panel, select the required checkbox(s) to enable the Save button at the bottom of the window.
   7. d. Select the appropriate options for the 'To be submitted by' and Languages fields.

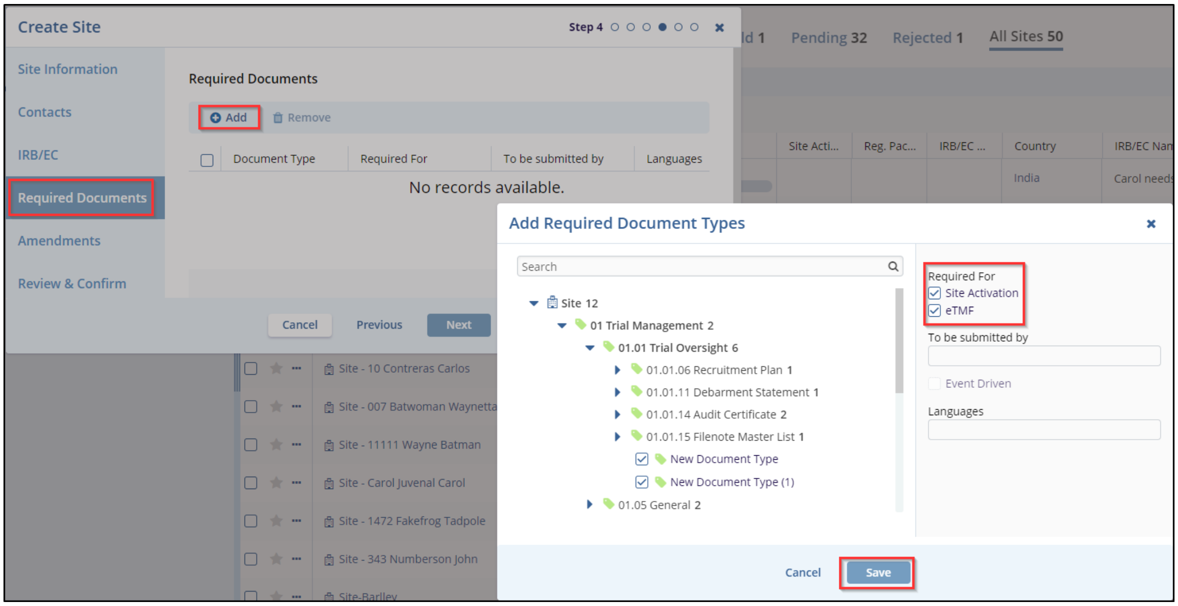


Figure 103: Sites-Add Required Documents

8. Click the **Save** button in the Add Required Document Types window.
9. The selected document types are displayed in the Required Documents tab. Click the **Next** button.

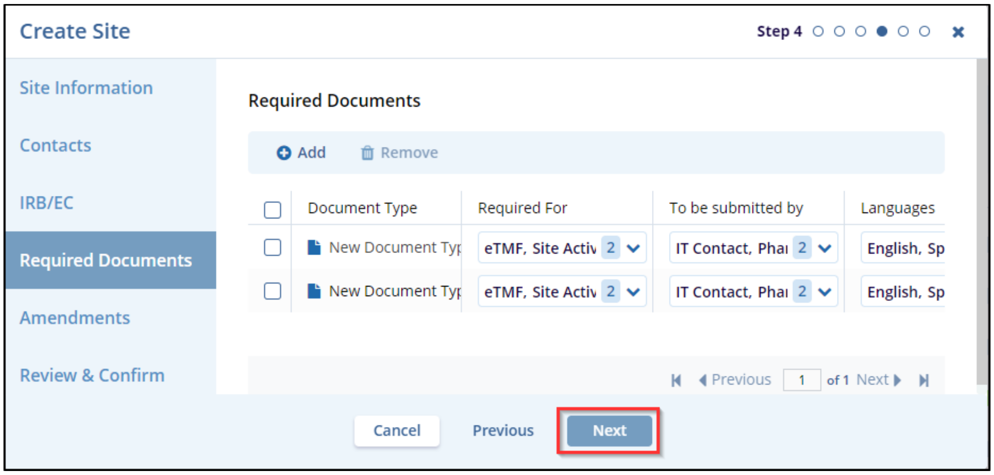


Figure 104: Sites-Add Required Documents

10. In the Amendments tab – Step 5, click on the required checkbox(s) to either set the amendments as applicable or not applicable. After selecting the required amendment, click on the **Set Applicable** button. The APPLICABLE is displayed below the selected amendment. Click the **Next** button.

Note: The 'Show only Applicable' toggle button is enabled only when an amendment is set as applicable.

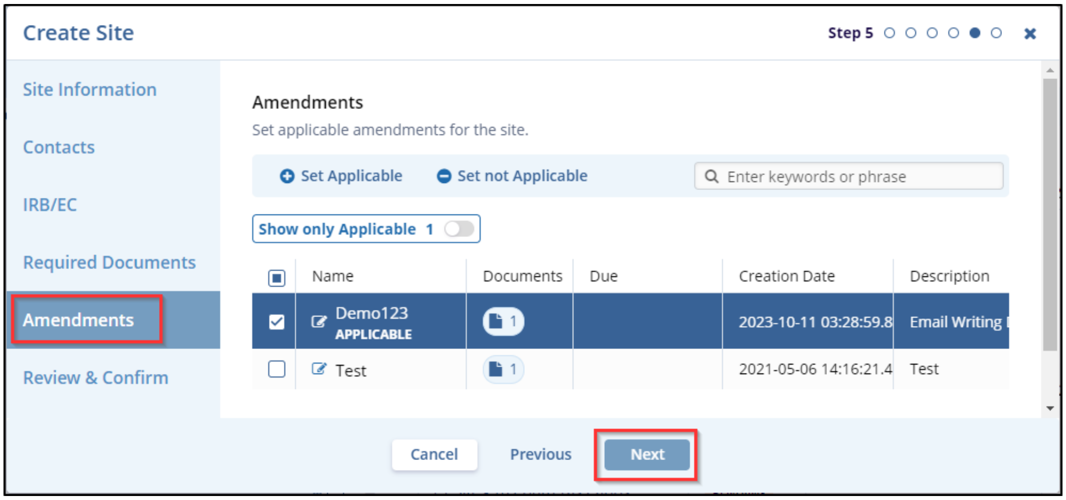


Figure 105: Sites- Amendments

11. The Review and Confirm tab – Step-6, confirm the details filled in the earlier tabs and click the **Create** button.

Note: The user can click the Previous button to edit the information filled in steps 1 to 5.

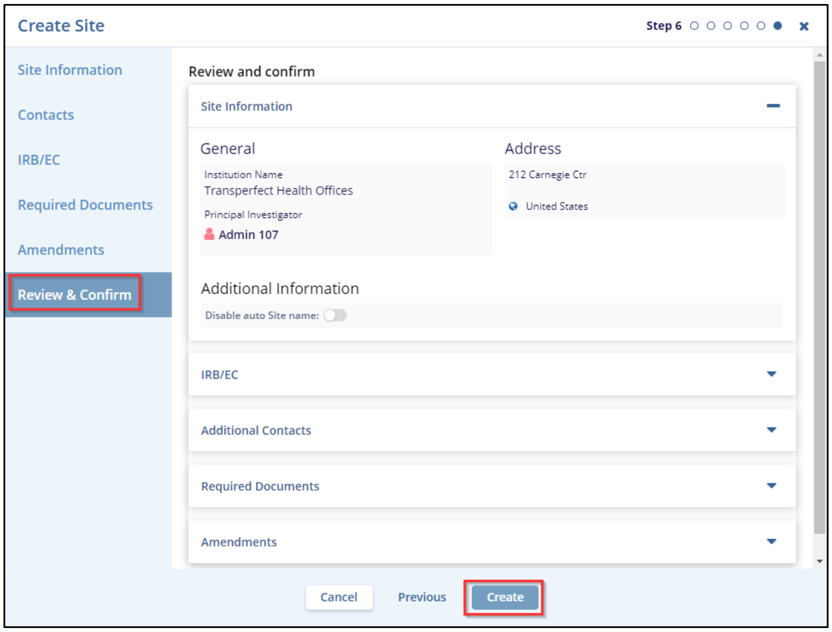


Figure 106: Sites- Review & Confirm

Importing Sites and Site Contacts

This feature is beneficial if you want to create many sites at once. This is done by entering the site details in an Excel worksheet and uploading them during the import process.

1. Click the **Import Site List** button from the Add dropdown menu.

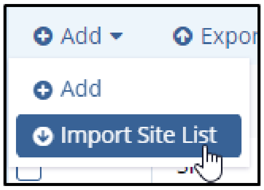


Figure 107: Sites-Import Site List

2. Click the **See the sample worksheet template** in the Investigative Sites Import popup window.

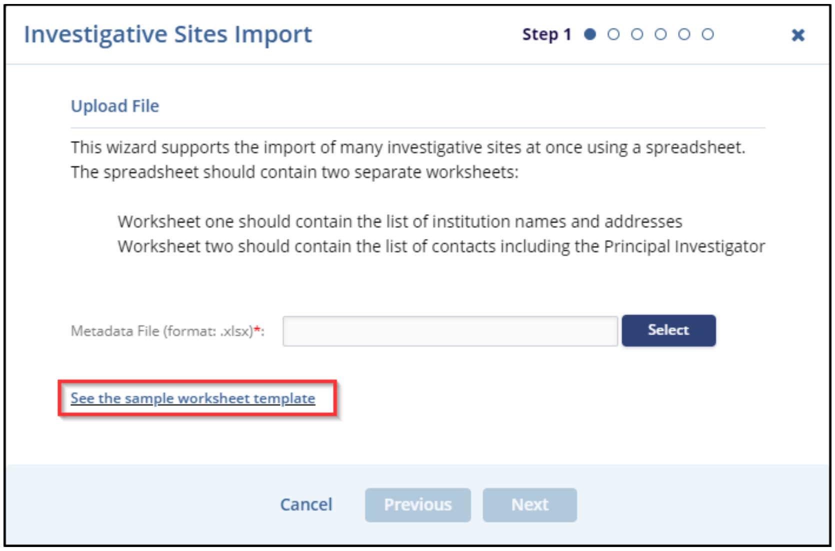


Figure 108: Sites-Sample Worksheet Template

3. The worksheet consists of threesheets – Investigative Sites, Contacts, and User Instructions. You can download the worksheet, fill it with the site metadata, and upload it. Once the worksheet is uploaded, the system will map the metadata of sitesand their contacts, and create the sites. The sites thus created appear in the grid for you to view.

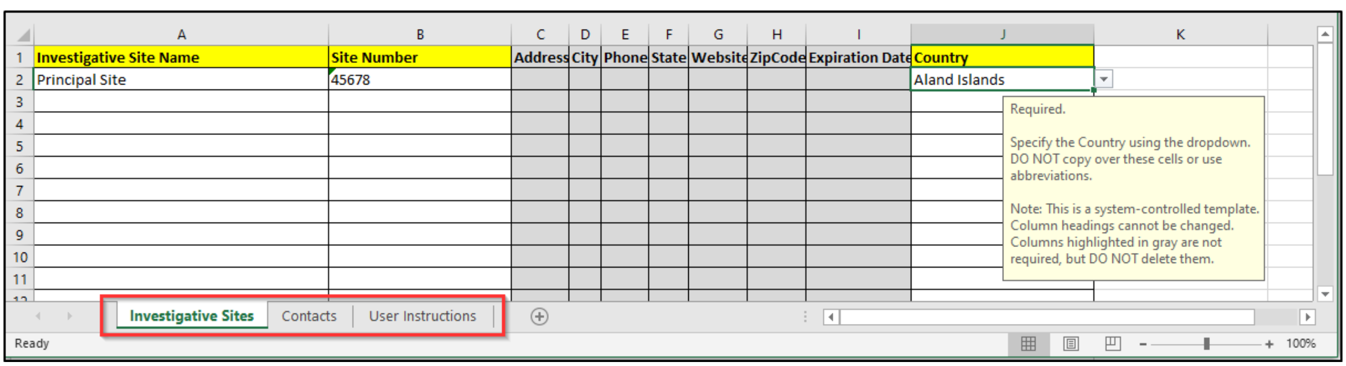


Figure 109: Sites-Excel Sheet

Note: *Read the **User Instructions** tab carefully before uploading the worksheet.*

Note: *For sites to be imported, the following rules should be adhered to:*

1. The Investigative Sites sheet cannot be left blank.

2. While importing sites, it is compulsory to specify the Principal Investigator, without which siteswill not be imported.

3. Start-Up Specialists and CRA cannot be imported. You will need to add these later and can useMass Coding for the same.

4. Sites with the same names cannot be imported.

5. Fields such as First Name and Last Name in the Contacts sheet cannot be left blank, as the systemwill verify the email ID of the user with the user's credentials from the database. If they do not match,an error will be thrown.

6. Main contact/s should be specified as they are the ones to receive the email when the regulatorypackets are sent.

7. If you want a contact to be an Active Contact, Main Contact, or Provide Documents, enter numerical '1' in the Contacts sheet for the fields. The system will automatically map the data andset the actions allowed for the user. On editing the contact from the site profile, you will find the checkboxes for these actions ticked (find more on this in the next section).

8. If the 'Active Contact' field is left blank, the contact will be deactivated by the system. You maychoose to activate the contact later if required.

9. If a site and its contacts are already imported, then more contacts can be added to the site onlymanually or through the API.

10. Data that was not imported can be mass-coded for multiple sites later (follow on to Mass Codingof Sites for further details).

Below is an example of the worksheet as guidelines for the import process:

	A	B	C	D	E	F	G	H	I	J
1	Investigative Site Name	Site Number	Address	City	Phone	State	Website	ZipCode	Expiration Date	Country
2	Principal Site	45678	Test	Kolkata				111111		Aland Islands
3	Test Site 1	1234	Test	Pune				22222		India
4	Test Site 2	1235	Test	Mumbai				333333		India
5	Test Site 3	1236	Test	Hyd				444444		India
6	Test Site 4	1237	Test	Bangalore				555555		India
7	Test Site 5	1238	Test	Delhi				666666		India
8										

Figure 110: Sites- Excel Sheet

Follow the procedure below to import the investigative sites:

1. Click the **Import Site List** button from the Add dropdown menu. The Investigative Sites Import window opens with Step 1 to perform.

2. Upload the .xlsx file containing data of sites and contacts by clicking the **Select** button.
   a. The Excel document should contain two separate worksheets – Worksheet One with the list of institution names and addresses and Worksheet Two with the list of contacts, including the Principal Investigator.
3. Click the **Next** button displayed at the bottom of the window.

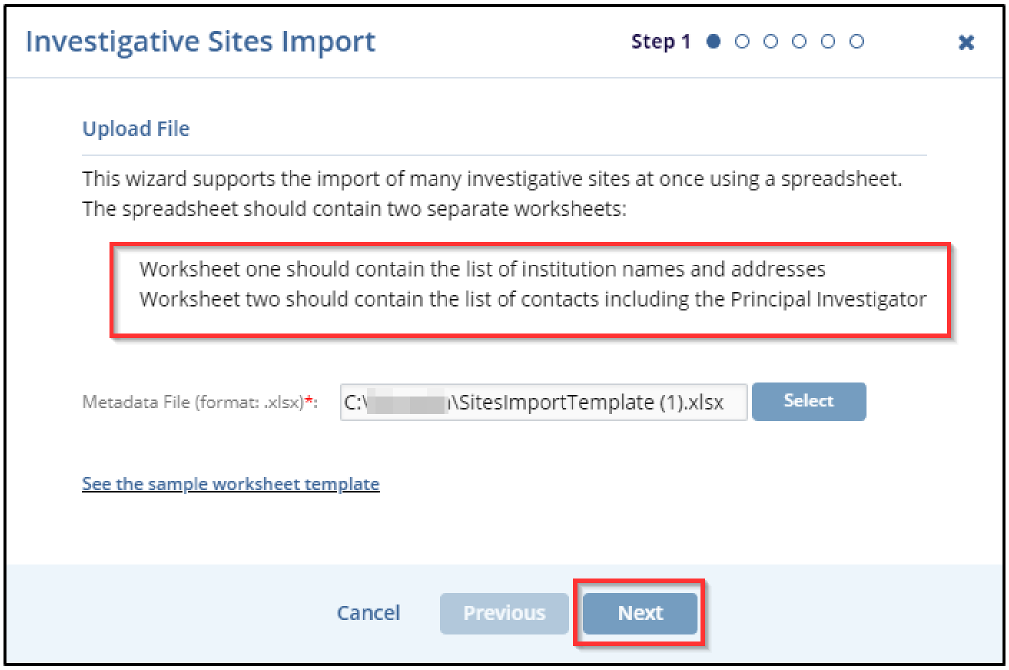


Figure 111: Sites-Investigative Sites Import

4. In the Set up metadata fields mapping – step -2, two columns are displayed – Spreadsheet Column and Metadata field. Both columns are pre-defined with different data. From the metadata field column, click the **cross** icon to ignore the specific field in the Sites to import. The fields selected with cross display as 'Ignored' in the metadata field. Select the Date Format from the dropdown menu. Click the **Next** button. Refer to the screenshot below.

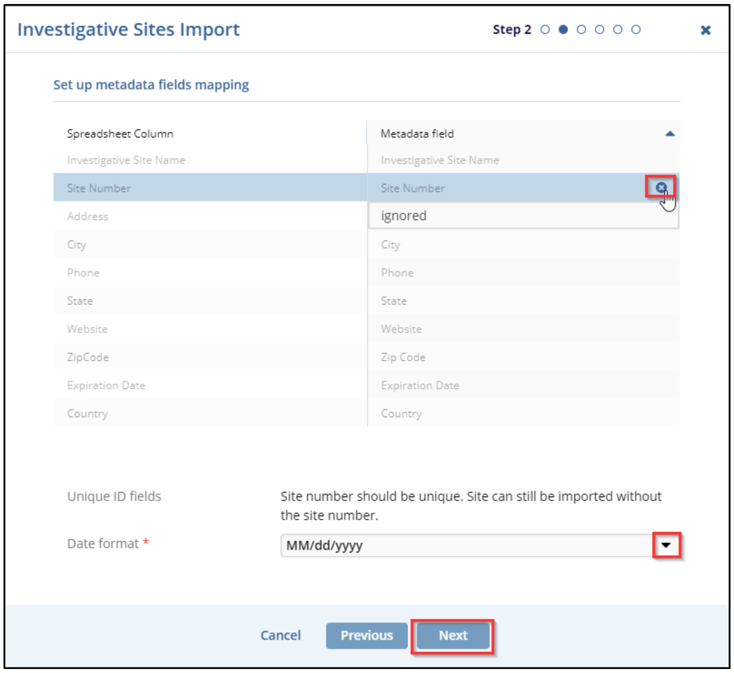


Figure 112: Sites-Next

5. Follow the procedure of the above step 4 for setting up the metadata fields for importing the contacts. Click the **Next** button.

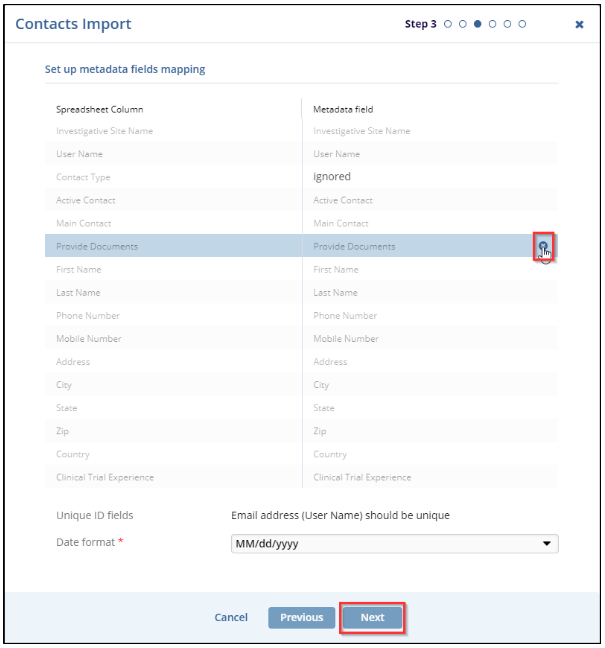


Figure 113: Sites-Contacts Import

6. Review and confirm the filled details in the Confirm site metadata fields mapping – step 4 window. Click the **Next** button. (Optional) Click the **Previous** button to edit the details.

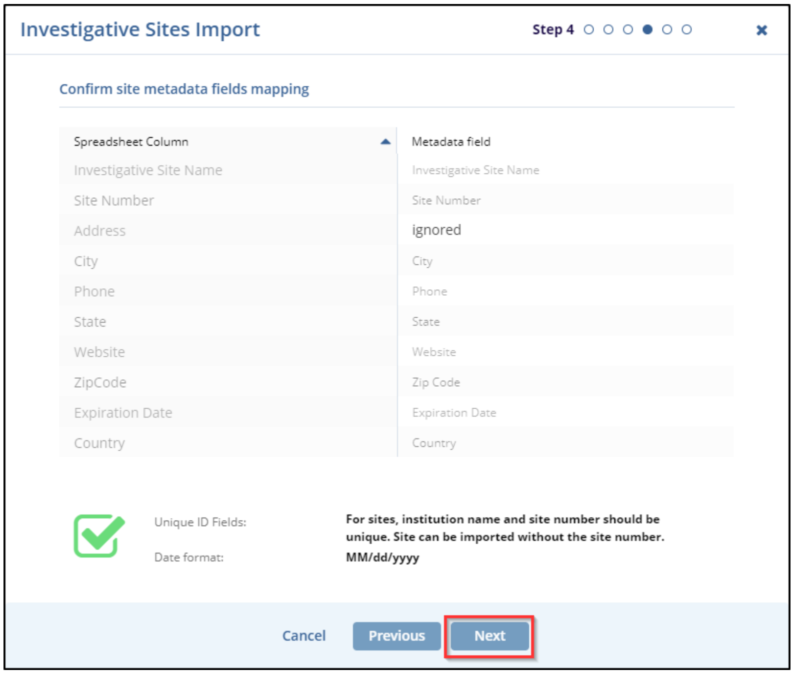


Figure 114: Sites-Next

7. Review and confirm the filled details in the Confirm Contact metadata fields mapping – step 5 window. Click the **Next** button. (Optional) Click the **Previous** button to edit the details.

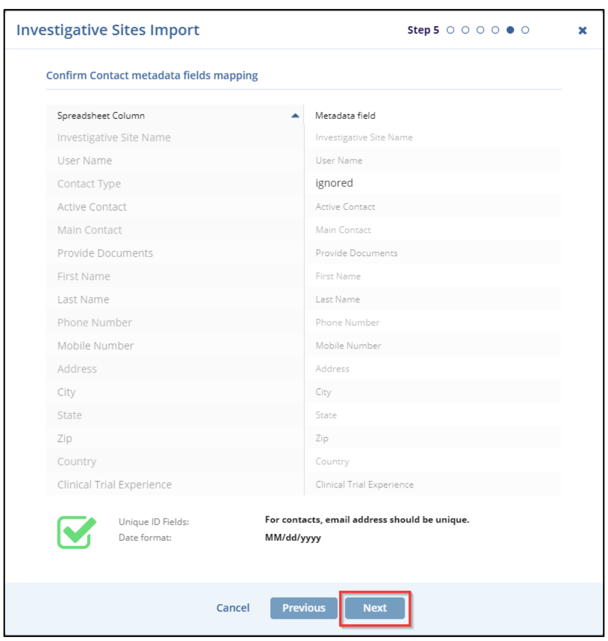


Figure 115: Sites-Next

8. An 'Information' popup window is displayed. Click the OK button.

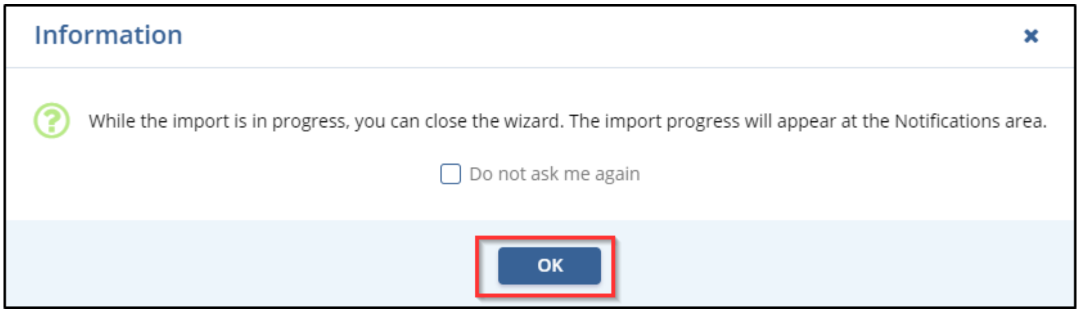


Figure 116: Sites-Information

9. Click the **Complete** button in the Review import progress and results – step 6 window.

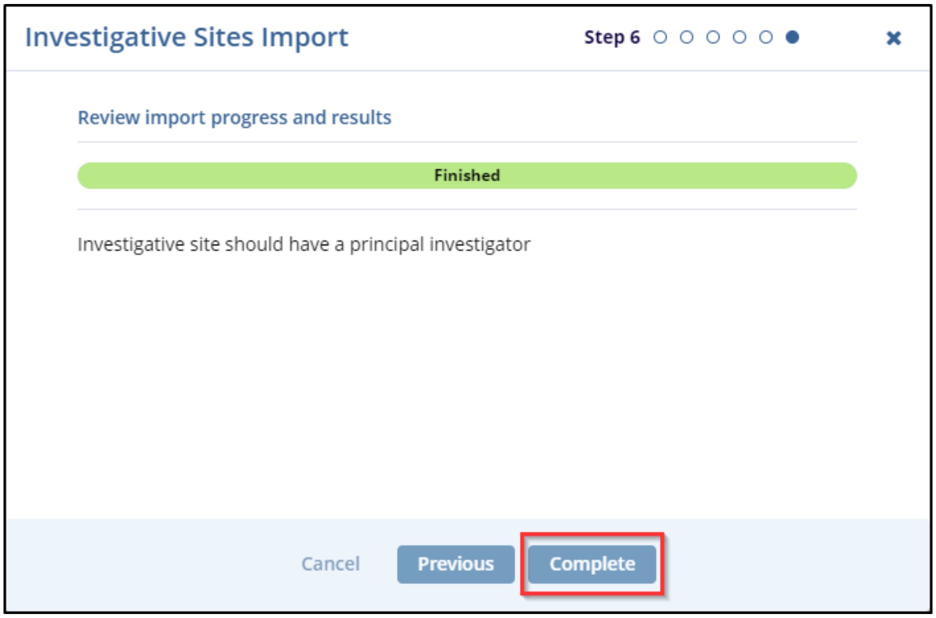


Figure 117: Sites-Complete

Viewing Sites

Sites can be viewed from the list of sites appearing in the grid pane. The user can choose to filter thesites appearing in the grid by selecting the filters from the current view dropdown, as shown below.

The Current View Dropdown offers four views:

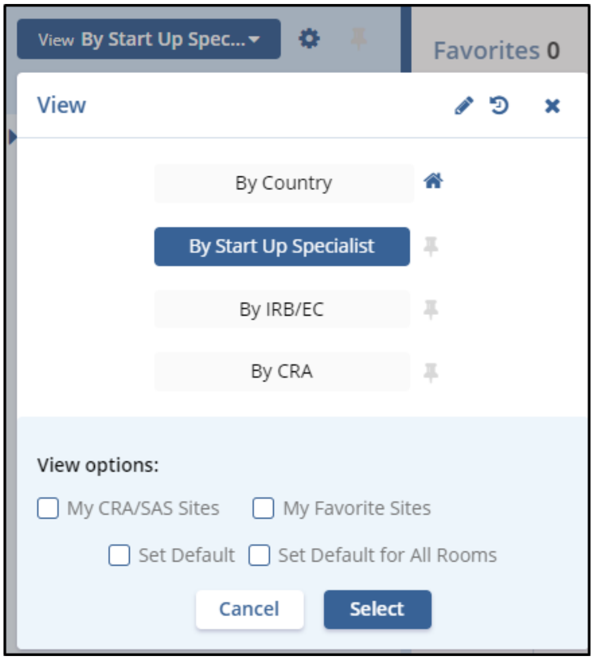


Figure 118: Sites-Current View

- **By Country**: This view reveals a list of countries, and when you select a particular country fromthe list, you see all investigative sites related to this country. Not Specified status indicates that acountry is not specified in the investigative site's profile.
- **By Start-Up Specialist**: This view displays a list of data room users with Start-Up Specialistdesignation. When you select a particular user from this list, you will see all sites where this user is set as start-up specialist. If you select Not Specified status, you will see the list of investigative sites that have no start-up specialist specified in their profiles.
- **By IRB/EC**: IRBs can be of two types: Central or Local. The central type will show you all investigative sites with a central IRB specified in their profiles. The local type will show you allinvestigative sites with local IRB specified in their profiles.
- **By CRA**: This view displays a list of data room users with CRA designation. When you selecta particular user from this list, you will see all sites where this user is set as CRA. If you select Not Specified status, you will see the list of investigative sites that have no CRA specified intheir profiles.

Buttons on the Current View

Some studies require that a data room house hundreds of sites. The user can toggle the displaybetween the sites where the user is a CRA, a Start-Up Specialist, or All Sites.

The user can refresh the current view by clicking the Refresh Current View button. Through theConfigure Grid button, the room administrator can decide the columns that team members needto display in the grid on the right or choose the default sorting column. Users can show or hide columns in the grid, but only room administrators can make additional columns available for viewing.

1. Settings Button.

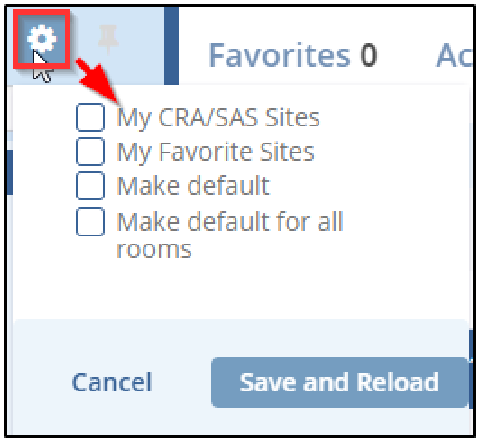


Figure 119: Sites-Buttons on Current View

2. Refresh Button.

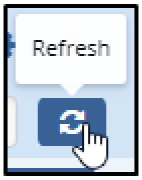


Figure 120: Refresh Button

3. Pin View Button.

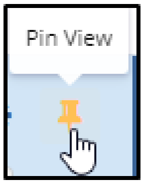


Figure 121: Pin View

Viewing or Editing Site Profiles

After selecting the required view as shown above, the user can edit a site profile as follows:

1. Select a site from the grid.
2. Click the **Edit** button in the menu ribbon to open the Site Profile in the metadata panel of the selected site. The Site Details are displayed on the right side of the screen. OR Double-click a site from the grid to open its Site Details window.

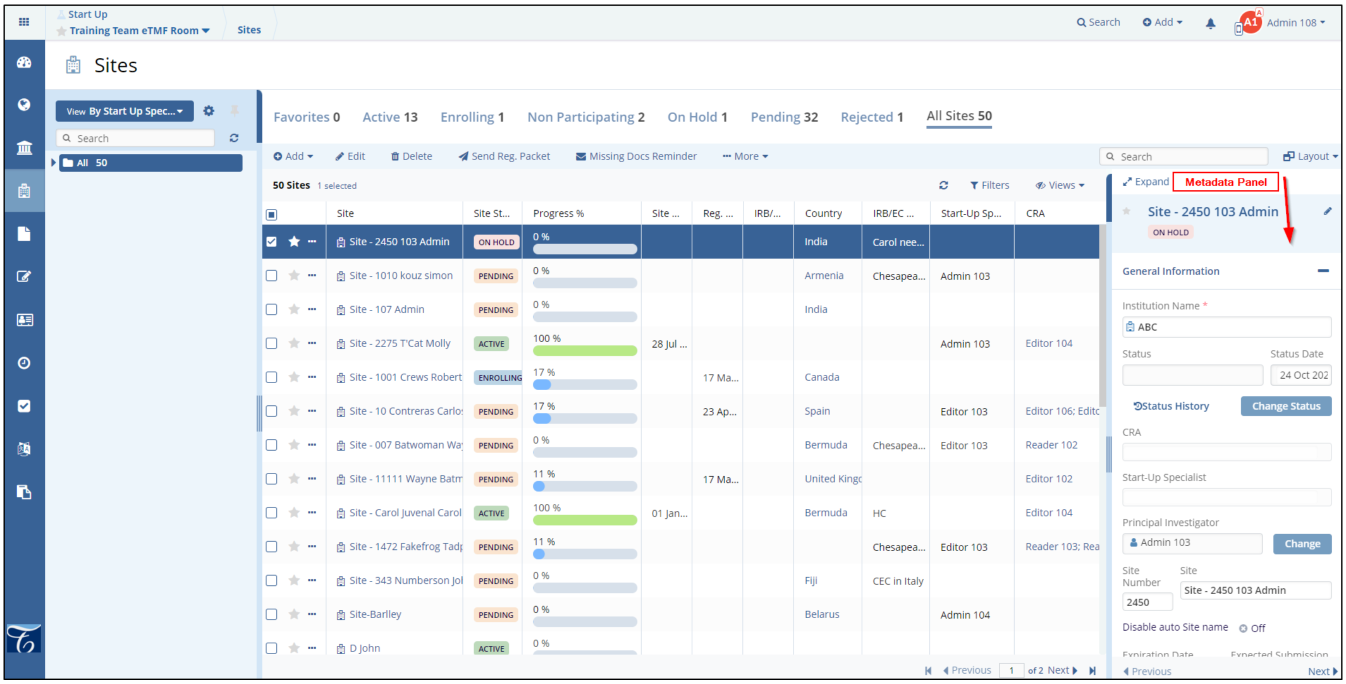


Figure 122: Sites-View/Edit site Profiles

3. The left side of the screen displays the Progress bar for the Site, Country, and IRB/EC. Below the progress bar is the notice mentioning if the site can be activated or not, depending on the percentage displayed for each field.
4. Below the progress bar, the user can navigate to:
    - Contacts,
    - Documents,
    - Requirements,
    - Amendments,
    - IRB/EC,
    - Security,
    - Communication Log and
    - Budgets and Contracts of the site.

5. Click the **Edit** button displayed on the top menu bar to make changes in the General Information, Site Contact Information, and Additional Information tabs.

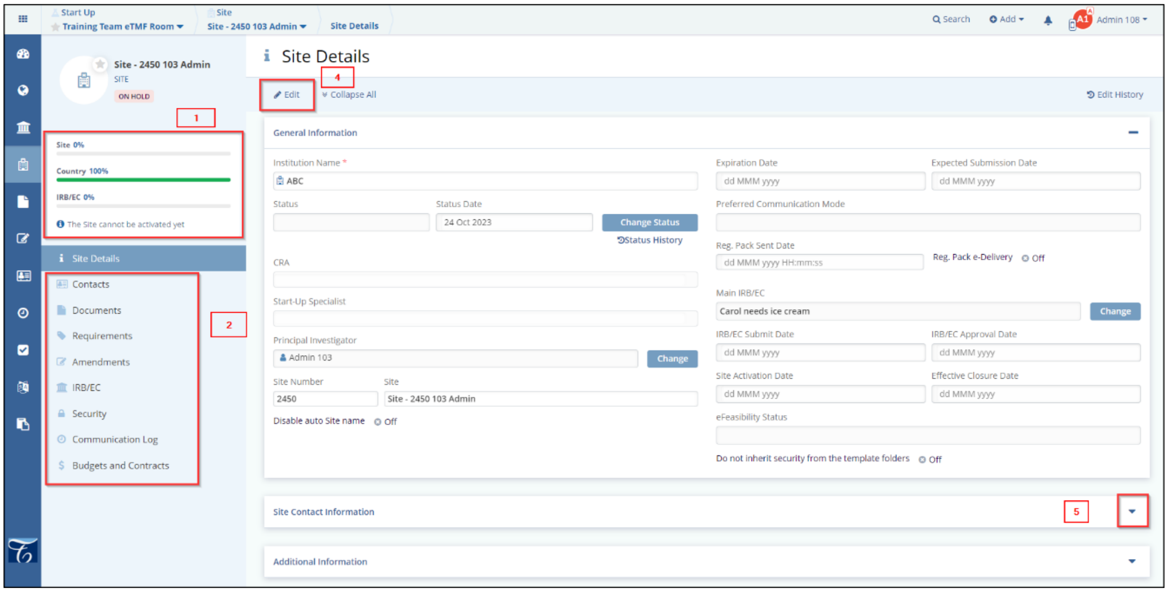


Figure 123: Sites-View/Edit site Profiles

6. Click the **Down arrow** displayed at the extreme right to expand the Site Contact Information and Additional Information sections. Refer to the above screenshot.

But if there are no IRB/EC Submit Date and Expected Submission Date specified in the site profile, the system will not display them in the right panel. Instead it will project the Next Pre-Submission Deadline Date based on the meeting schedule specified in the IRB/EC profile. To display the Projected IRB/EC Approval Date, the system will use the Next Pre-Submission Deadline Date. The process to project the Projected Site Activation Date remains the same as mentioned above. The projected Next Pre-Submission Deadline Dates can be viewed by clicking the last calendar icon nextto the Expected Submission Date field.

7. Make necessary additions or changes to the data fields in the profile. Refer to Adding sites andsites contacts in case of clarifications.

8. Click the **Save** button displayed at the top left of the panel.

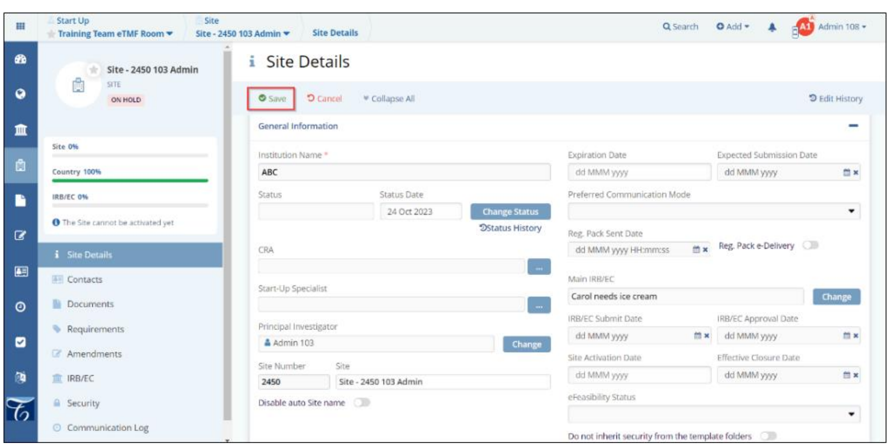


Figure 124: Sites-Save Site Profiles

Exporting Sites

Here the users can export

- Selected Records
- All Sites in the current grid
- All Sites in the data room

1. To Export a single site or a specific set of selected sites, select the site(s) by clicking the checkbox(s) at the left side of the grid.
2. Click the **Export Metadata** button in the menu ribbon above the site grid. The Export Sites window opens.
3. Choose the Source from the radio buttons.

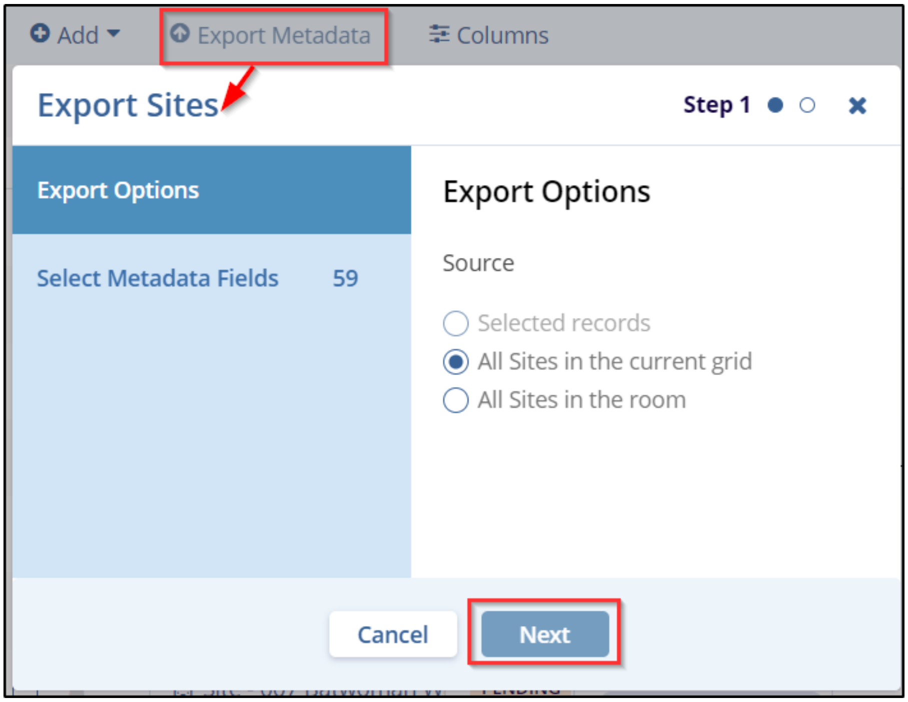


Figure 125: Sites-Export Metadata

4. Click the **Next** button at the bottom of the popup window. This opens the Select Metadata Fields – step 2 of the popup window. Activate the Metadata dropdown menu to the right of the metadata field.
5. By default, two metadata fields (Investigative Site Name and Site Number) are pre-selected for the user. Select the other required metadata fields to include in the export from the below section.

6. Expand the arrows to view the metadata fields. Select the checkbox(s) of the required metadata fields to include in the export. Refer to the screenshot below.

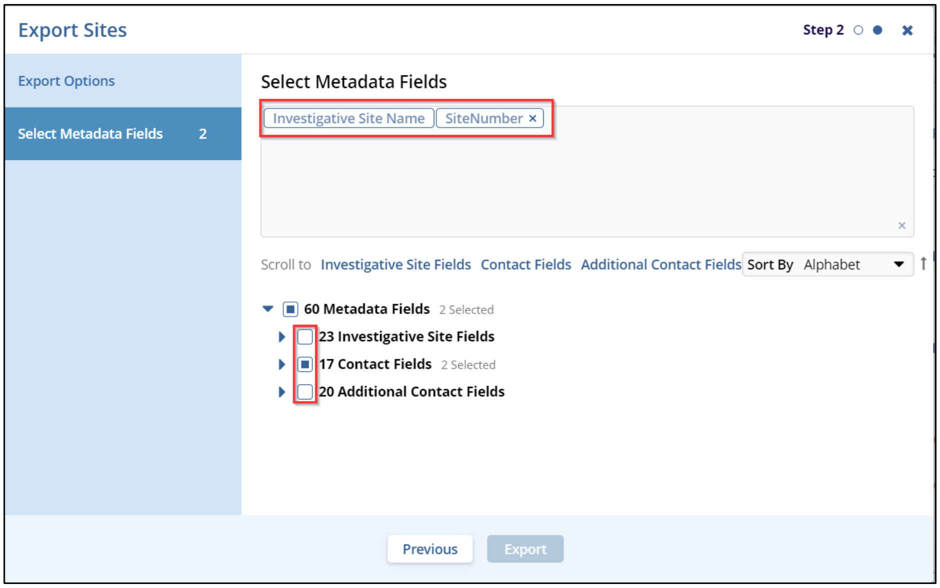


Figure 126: Sites- Select Metadata Fields

7. After selecting the required metadata fields, the Export button is enabled in the popup window. Click the **Export** button displayed at the bottom of the popup window.

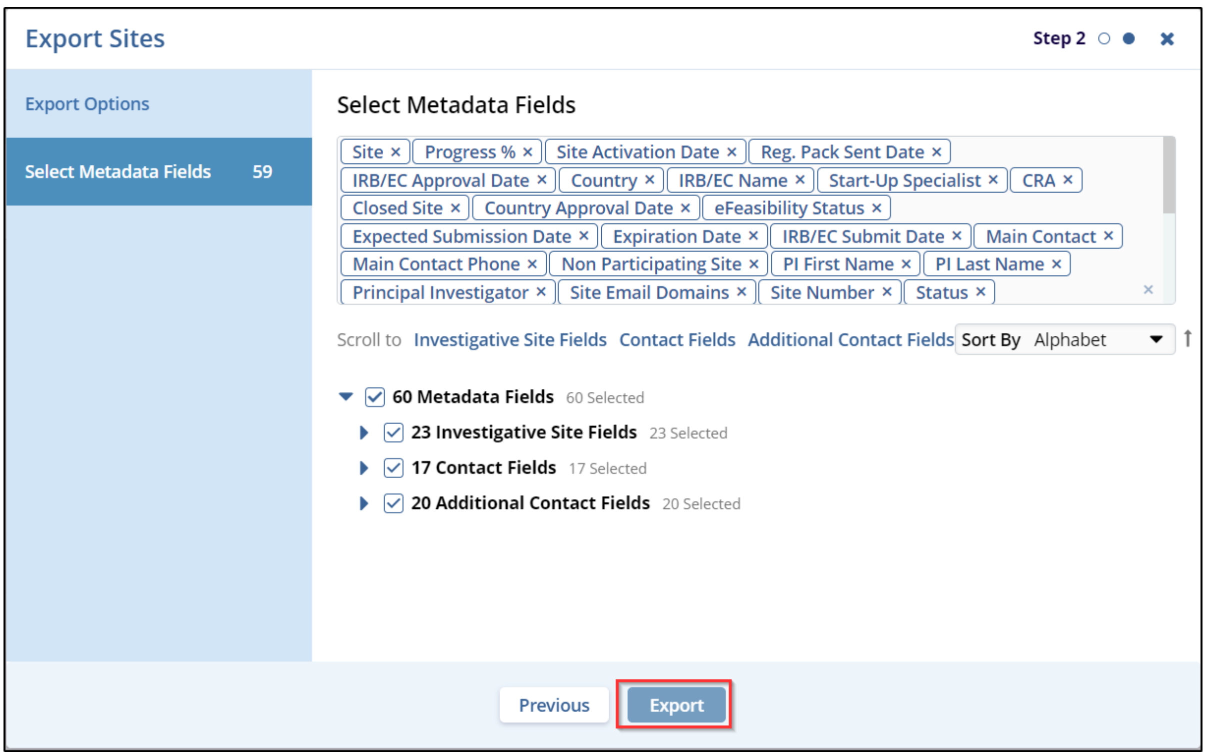


Figure 127: Sites-Select Metadata Fields

8. Once the export is complete, the user is notified about the Get Job Result in a popup on the top right side of the screen.
9. To view the exported file, click the **Bell** icon (Notifications) displayed in the top right corner of the screen.

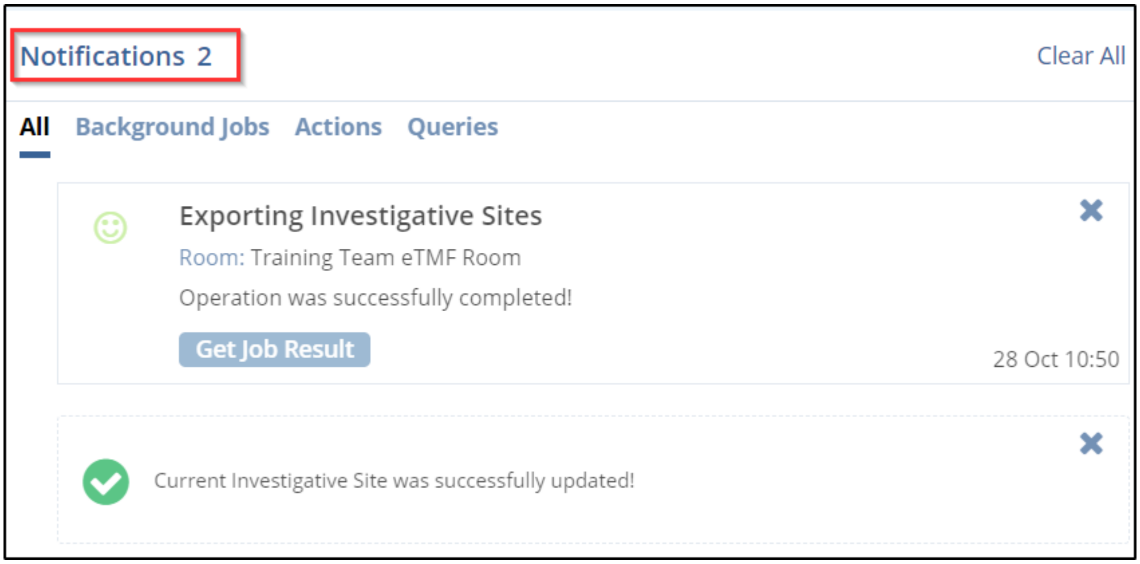


Figure 128: Sites-Notifications

Mass Coding for Sites

During the initial room configuration, the metadata fields that are available for mass coding are marked in the room's Form Settings by the room's administrators. Once that process is done, it is possible to use mass coding for metadata fields of Investigative sites.

To Mass Code sites:

1. Select the investigative sites from the list in the grid that have common metadata fields that need to be coded by clicking the checkbox(s) to the left of the Investigative Sites grid.
2. Click the **More** dropdown menu and choose the **Mass Coding** option. This opens the Mass Coding popup window.

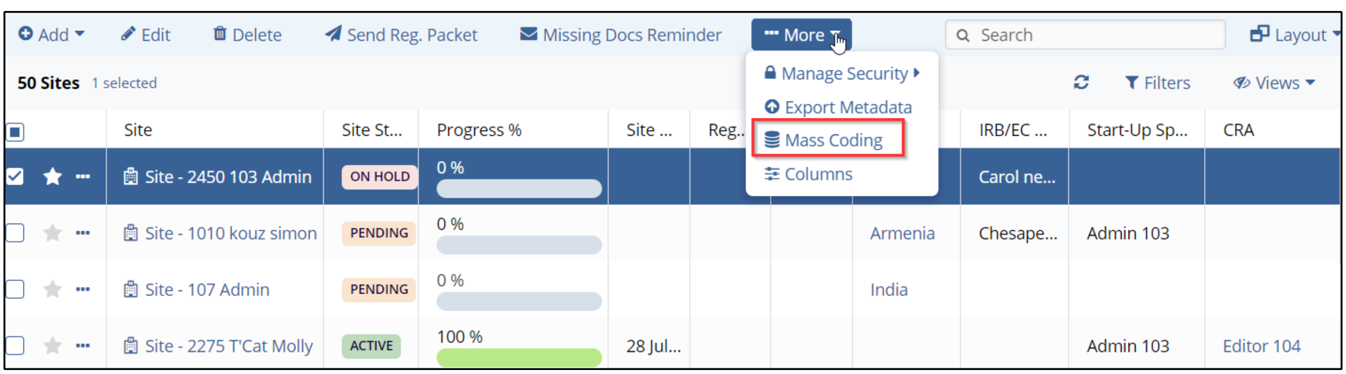


Figure 129: Sites-Mass Coding

3. The Mass Coding window displays the following fields:
   - Country,
   - Expiration Date,
   - CRA,
   - Start Up Specialist,
   - Reg Packet Sent Date,
   - Expected Submission Date,
   - IRB/EC Submit Date,
   - IRB/EC Approval Date, and
   - Country Approval Date.

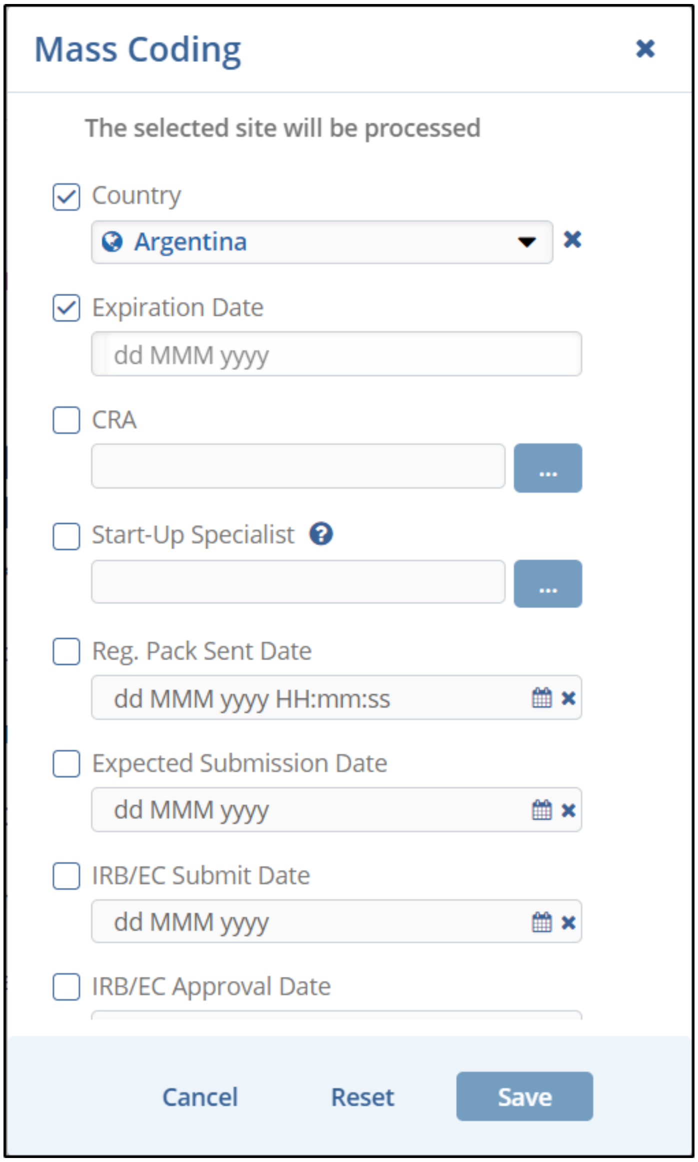


Figure 130: Site-Mass Coding Fields

a. Select the checkbox(s) of the required fields mentioned above.

Note: Step 4-9 are optional. The user can click the **Save** button without selecting all fields.

4. For the Country field select a country from the dropdown menu.
5. The Expiration Date field format is pre-defined and cannot be edited.
6. Select the **three-dot** menu for CRA and Start-Up Specialist fields. This opens the Select Users window.

a. Hover the mouse to view the user in blue color and click the **Plus** icon next to the name.
b. The selected names are reflected in the right side of the Select Users window.
c. Click the **Add** button displayed at the bottom of the Select Users window.
d. The selected users are reflected in the required fields.

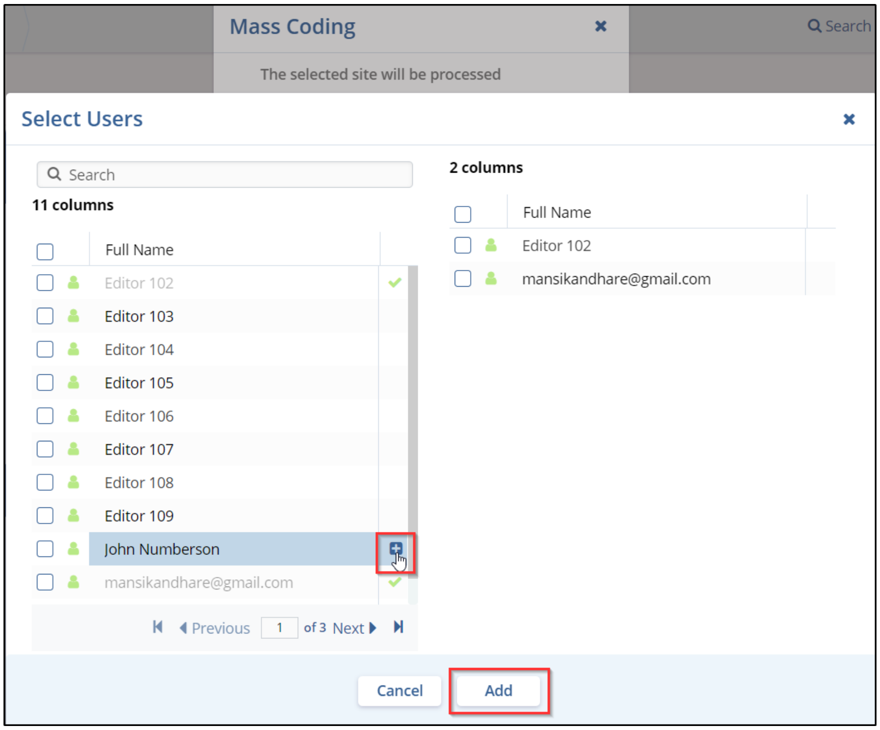


Figure 131: Sites-Select Users

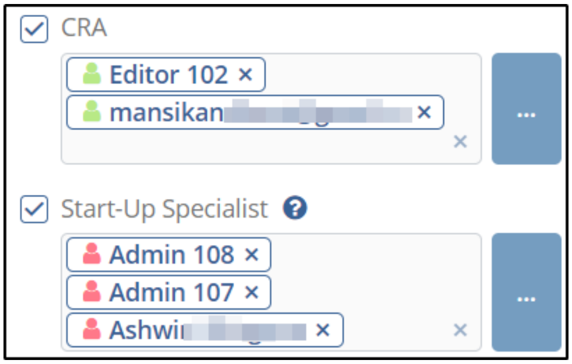


Figure 132: Sites-SSU Names

7. If selected the checkbox(s) for – Reg. Packet Sent Date, Expected Submission Date, IRB/EC Submit Date, IRB/EC Approval Date, and Country Approval Date – click the calendar icon next to these fields and select an appropriate date.

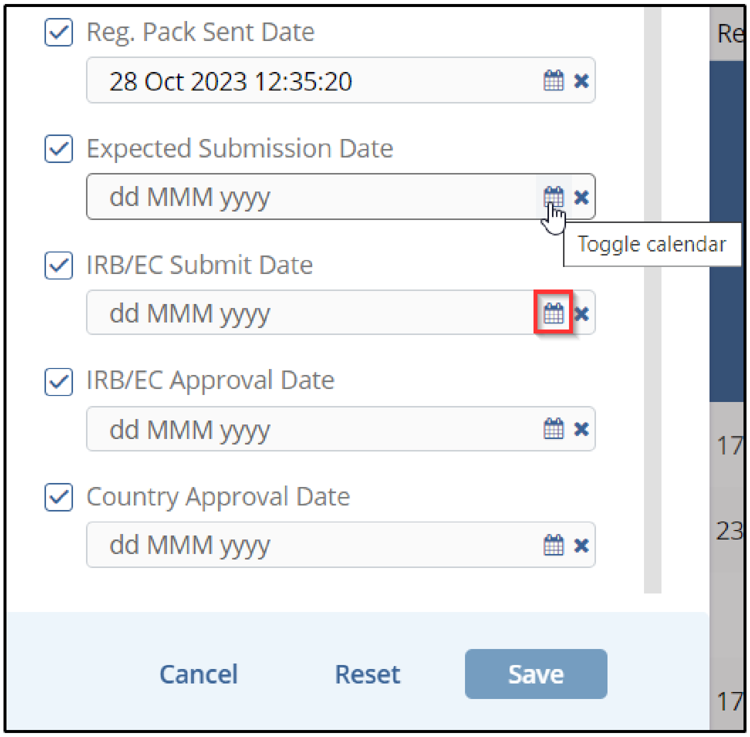


Figure 133: Sites-Calendar Icon

8. Click the **Save** button displayed at the bottom of the popup window.
9. Click **Yes** in the Confirmation window displayed on the screen.

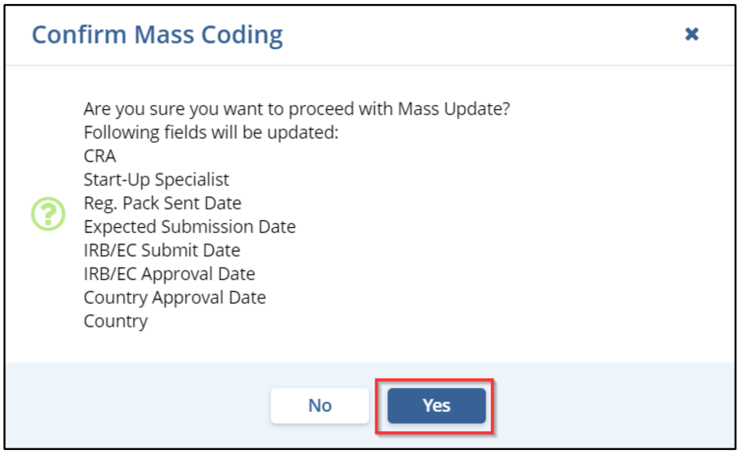


Figure 134: Sites-Mass Coding Confirmation

10. The coding changes will be added to the site profiles.

Note: If the requested coding additions or changes conflict with existing Investigative site profile data, the system displays a Warning message to the user. in such cases the coding will not be completed and the previously existing metadata will remain as a part of the site profile. To make such changes to the site profile, the user must use the Edit function mentioned earlier in this guide.

To search for sites from the grid pane, enter the search pattern in the Search textbox in the top ribbon bar and click the magnifying lens icon or hit Enter. Sites matching the search pattern will be displayed. The system will not only select sites that match the pattern from the columns in the GridPane, it will also display sites that have matching searches from the site profiles. For example, if a site has a contact that matches the search pattern, it will be displayed.

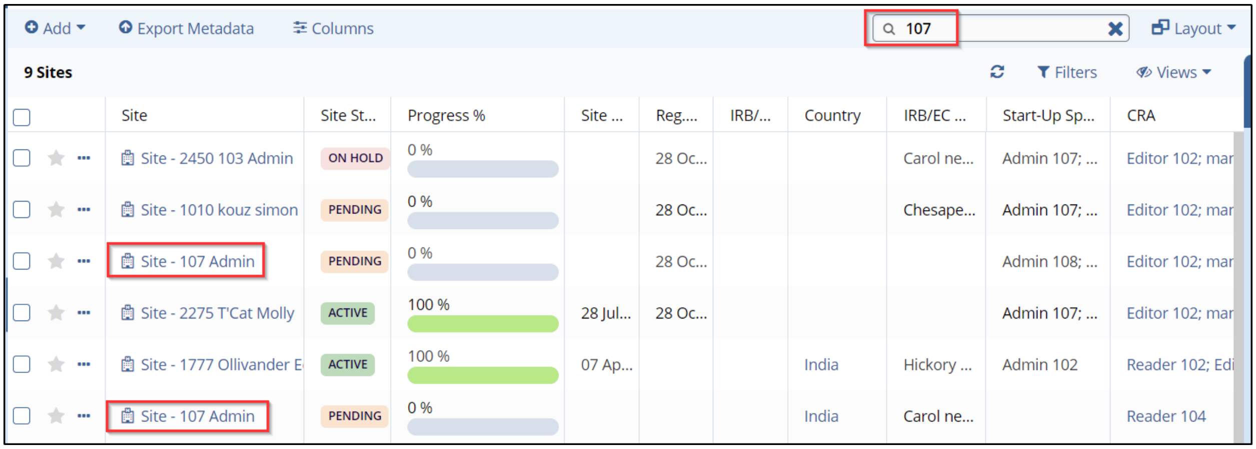


Figure 135: Sites-Search

Deleting Sites

1. Select a site from the list.
2. Click the **Delete** button from the top menu ribbon. A window pops up, asking for confirmation that you want to delete the site. It also prompts you to enter the reason for deletion.

Note: It is mandatory to enter a reason as the field is marked with an asterisk.

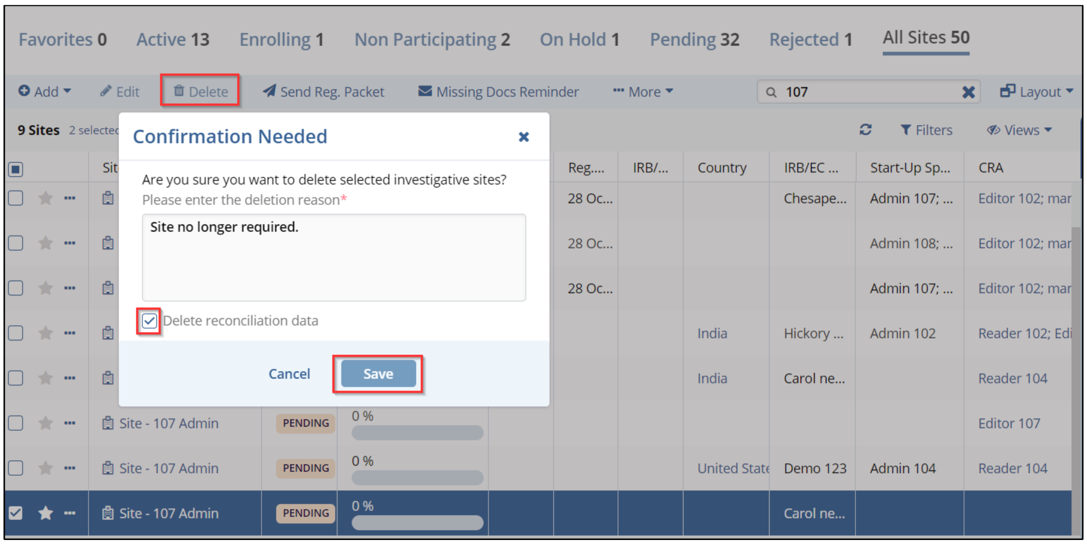


Figure 136: Sites-Delete

3. **(Optional)** Select the checkbox if you wish to delete the reconciliation data.
4. Click the **Save** button at the bottom of the popup window.
5. Sites cannot be deleted if they have already collected documents and the user receives a warning message about the same in the popup window.

Note: To delete a site, its documents must first be deleted.

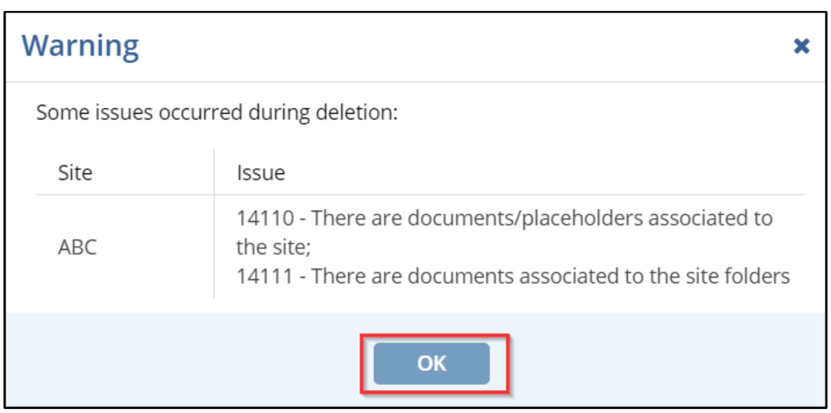


Figure 137:Sites-Delete Warning

Setting up Site Specific Required Documents

The required documents specific only for a particular site can be set up through the Requirements button located on the left pane of the Sites Profile dashboard. This is discussed as below:

1. Double-click the site from the Grid Pane to open the Sites Profile window.

2. Click the **Requirements** tab displayed on the left side of the screen of the Site Details window. This opens the Requirements window.

3. Click the **Add Required Doc** button from the top menu bar in the window.

4. Select the document types as required from the collapsible tree.

5. Select at least one of the checkboxes for 'Site Activation' and 'eTMF' to enable the Save button in the popup window.

6. (Optional) Select the contact(s) from 'To be submitted by' and 'Languages' dropdown.

7. Click the **Save** button to add the required document type.

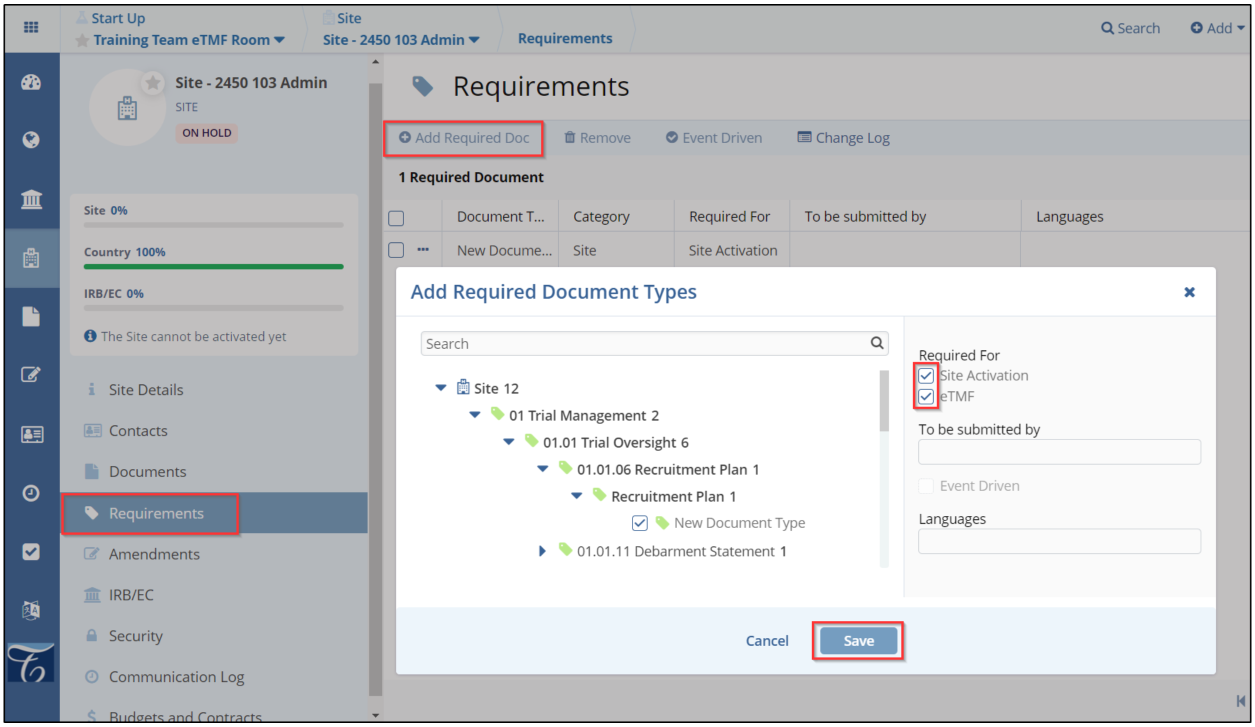


Figure 138: Site Specific Required Documents

Add Additional IRB/ECs

Although clinical trial organizations today adhere to protocols from a central IRB/EC, at times it might be required to adhere to protocols of more than one IRB/EC. For example, an organization may have one central IRB/EC, and one or more local IRB/ECs.

In the Site profile, you will be able to specify only one IRB/EC of any type. In case you need to provide additional IRB/ECs, proceed with the steps as below:

1. From the Grid Pane, double-click the site for which you want to specify additional IRB/ECs

2. The Site Details window opens.

3. Click the **IRB/EC** tab from the left pane. This opens the IRB/EC page.

4. The top menu bar displays two options – **Add Existing** and **Create**.

5. If clicked 'Add Existing' – an Add Existing IRB/EC popup window opens. Select the required checkbox(s) and click the **Add IRB/EC** button displayed at the bottom of the popup window.

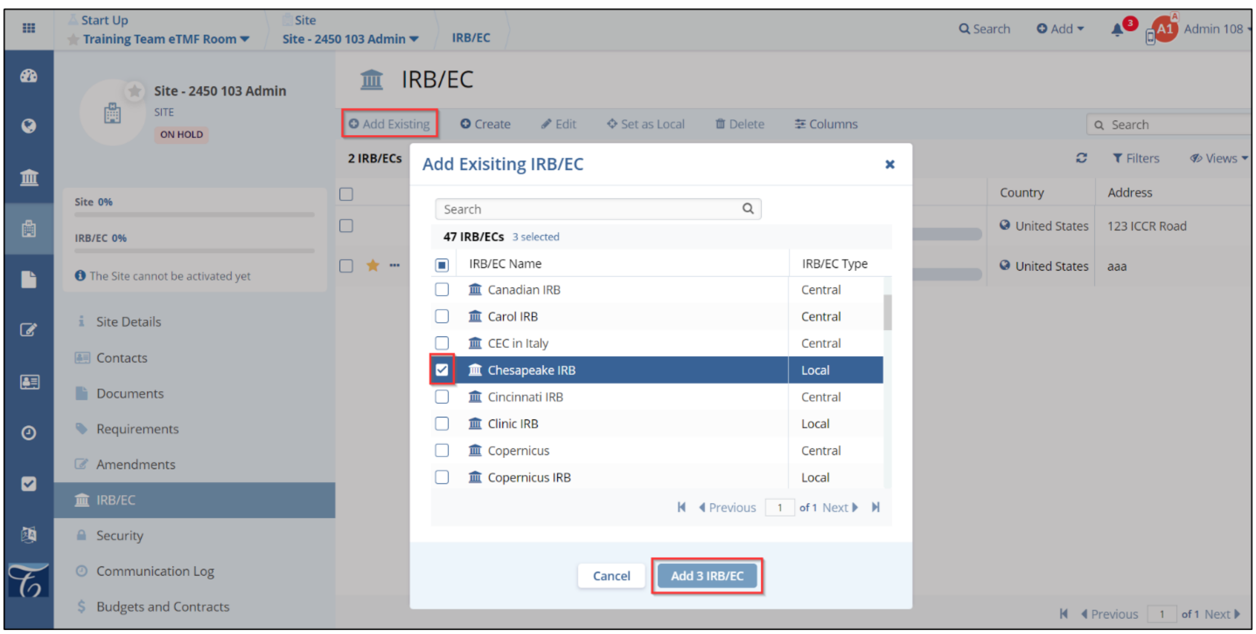


Figure 139:Sites-Additional IRB/EC

6. If clicked 'Create' – an Create IRB/EC window opens. Enter the details in all the fields marked with an asterisk and the other details if required. The fields marked with an asterisk:
    - IRB/EC Name
    - IRB/EC Type
    - Address
    - City
    - State
    - Country

7. Click **Create IRB/EC** button displayed at the bottom of the popup window.

8. If the user wants to create another IRB/EC at the same time, click **Save and Create Another button**.

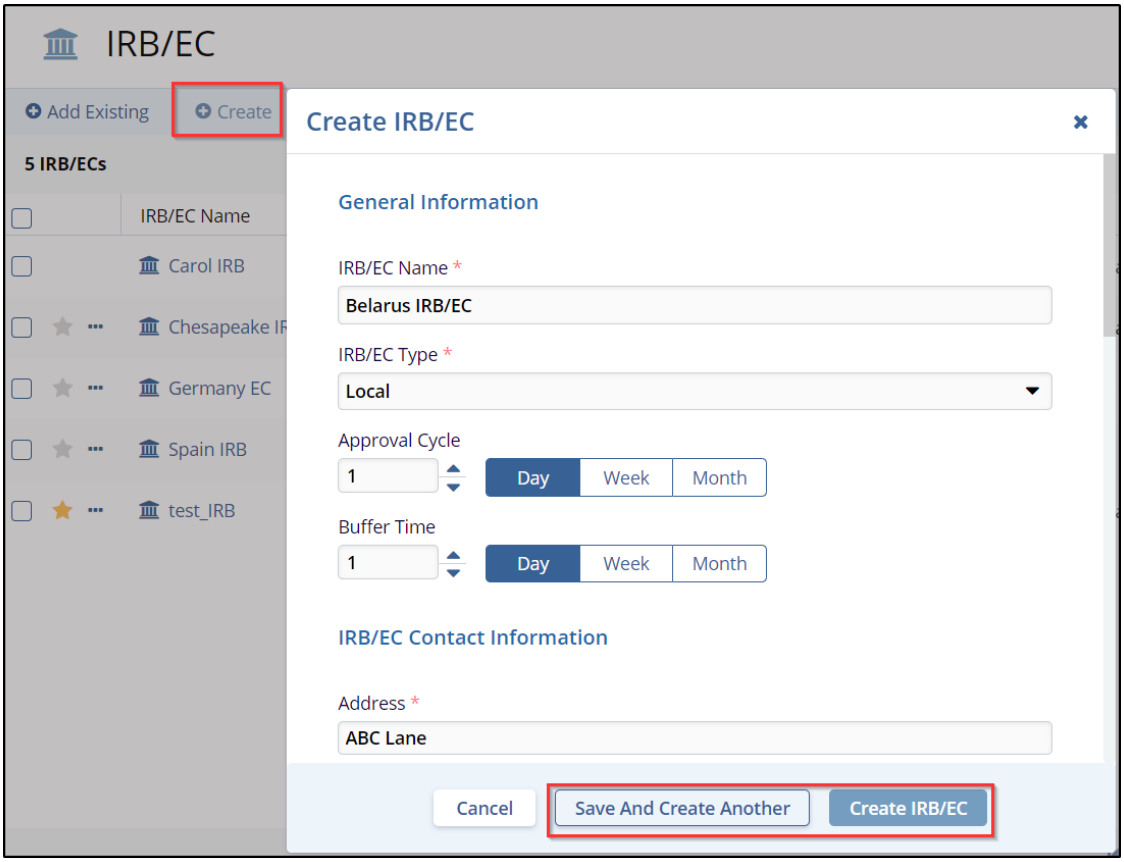


Figure 140: Sites-Create IRB/EC

9. The rest of the procedure is the same as specified in sections Adding or Creating New IRB/ECs and Adding Existing IRB/ECs to Data Rooms

10. The procedure to add from existing IRB/ECs is also the same, with the only difference that from within a site, the Add Existing functionality will only display the IRB/ECs available in the data room.

Edit History

From a site profile window, you can also view histories related to site edit, contact activities, and milestone.

Site Edit History

1. Double-click a site name from the Grid Pane to open the Site Details page.

2. Click the **Edit History** icon displayed at the top menu bar on the right side.

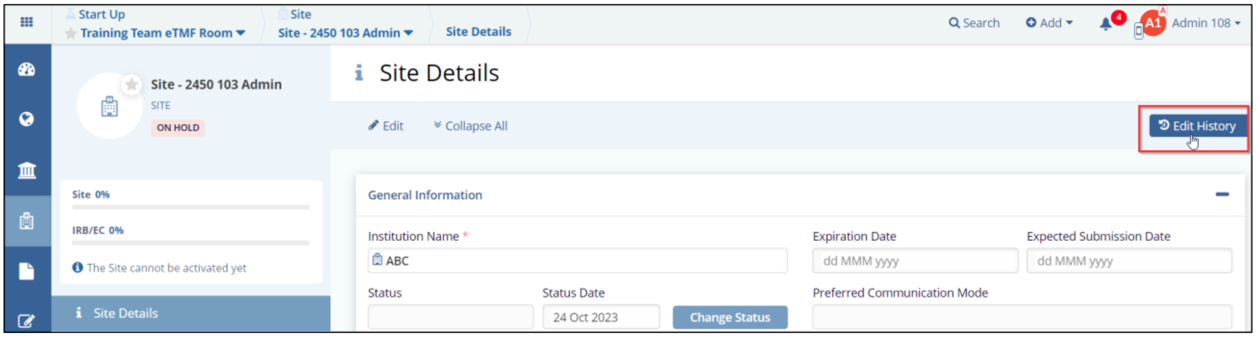


Figure 141: Sites-Edit History

3. This opens the Edit History popup window with the details of the user who worked on the site and the activity performed by the user.
4. The information here cannot be edited. Click **Close** when you are done with viewing.

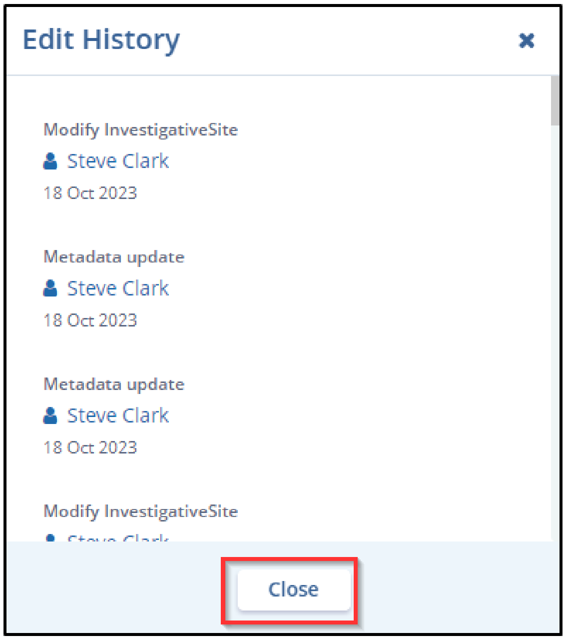


Figure 142: Sites-Edit History Window

Managing Security

We have already seen in section Accessible functionalities for SSU Users the types of security privileges provided by Trial Interactive system to the users and contacts of investigative sites. The security privileges can be provided for all sites in a data room, as well as from within theStudy Start-Up Sites section.
Access to users for all sites can be provided by adding the site users to Default editors/readers group,or by making them Default access members of sites.

From within the SSU Sites section, the administrator can view and provide security privileges tousers for site/s from two locations:

Note: The Administrator has to be site members like an SSU Specialist, or Co-Investigator, or Site Activation Member to be able to manage security of sites from within the SSU Sites section.

1. Select a checkbox of a site to change the options displayed on the top menu bar.
2. Click the **More** dropdown button and select the **Manage Security** dropdown.
3. Two options are displayed – **Editors and Readers**. From the Grid Pane the administrator can assign Editor and Reader accesses to users/group of users, thereby making them contacts of multiple sites. By selecting the checkboxes next to the site names inthe grid the administrator can make the selected users/groups member to multiple sites at one time. This is helpful if contacts will have same privileges in multiple sites.

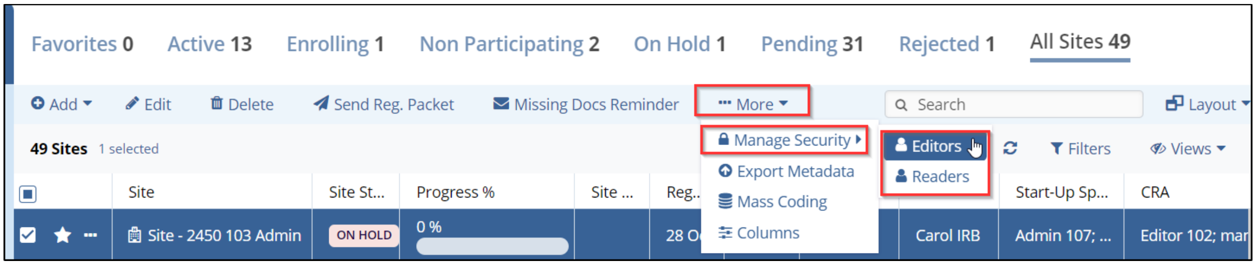


Figure 143: Sites-Managing Security

4. If **Editors** option is selected – an 'Security Editors' popup window is displayed.
5. Hover the mouse over the names to highlight in blue and view the Plus icon next to each username.
6. Click the **Plus** icon to view the name in the right side – Selected Members pane. The user can also drag drop the name if required.

7. Click the **OK** button displayed at the bottom of the popup window.

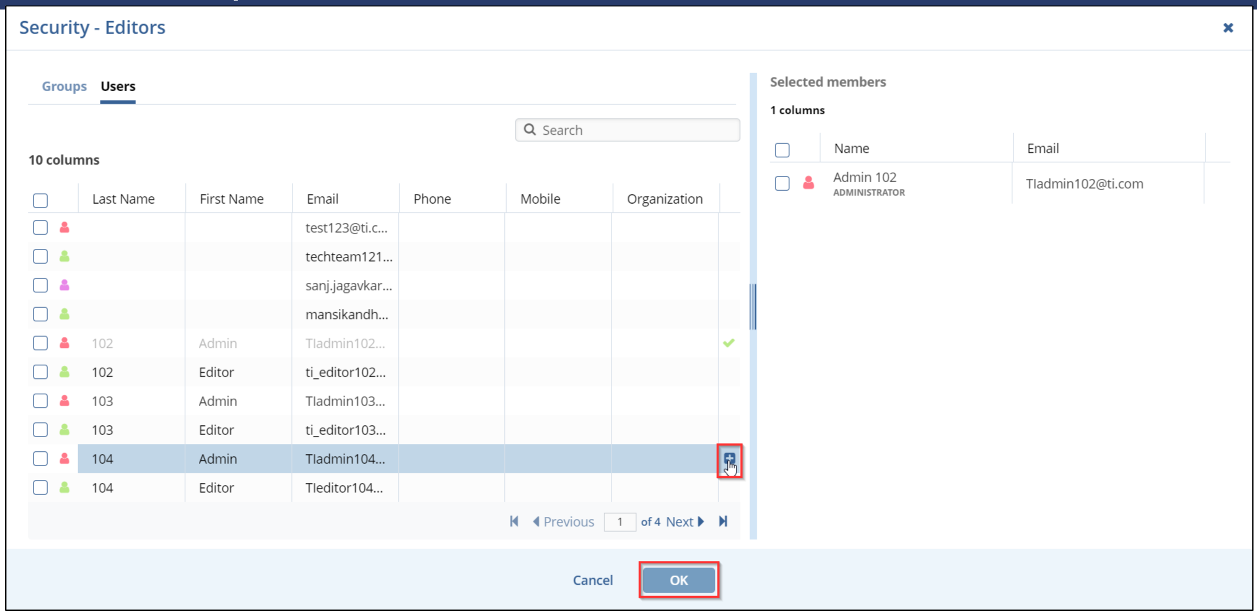


Figure 144:Sites-Security-Editors

8. A Security Update Options popup window is displayed.
9. Select the appropriate radio buttons for – Source and Options.
10. Click the **Append** button displayed at the bottom of the popup window.

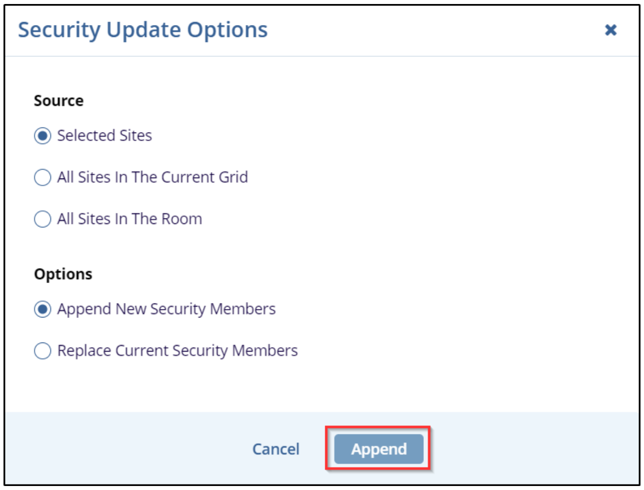


Figure 145: Sites-Security Update Options

11. If **Readers** option is selected – an 'Security Readers' popup window is displayed.
12. Follow the **steps 5-10** to manage the security for readers.

From within a Site Profile, the administrator can assign Editor, and Reader accesses to users/group ofusers for only the particular site whose profile he/she is accessing at the moment.

Besides these, the administrator can also view the contacts who are assigned Editor, and Reader privileges in the site/s, from the right pane of the Security dialog box. Refer to the screenshot above.

Note: The procedure to add users to default editors/readers groups is described in detail in the User Management section.

Steps to Site Activation

To activate a site in the Trial Interactive Study Start-Up module a series of steps must be followed.

The site information and users specific to the SSU site can be imported by TI if information is provided in a formatted excel. In addition, sites and users can be added in the site grid.

Activating a Site

Once all essential/required documents are sent by the sites to the trial room and approved by appropriate authorities, the site can be activated. Only Site Activation Members will access the site profile to activate the site. Upon site activation, documents can be auto-named, auto-routed, and auto-filed to the appropriate location within the finalized eTMF. To note, Administrator role can place preference on these automated setting features from the Study Start-Up settings.

Once all the required documents are approved by both the Start-Up Specialist and the Regulatory Reviewer, the Essential Documents Progress bar shows as 100% in the Site Profile and the Activate/Reject button at the bottom of the Site Profile dashboard appears.

To activate the site:

1. Double click on the empty space of a site to open it in the center/grid pane.

2. Click the Activate/Reject button displayed at the left bottom of the screen.

3. The Set Investigative Site Status pop up window is displayed.

3. Select the Status as Active.

4. Enter the comments.

5. Click the **Activate** button.

To reject the site:

1. Click the Activate/Reject button

2. The Set Investigative Site Status pop up window is displayed.

3. Select the Status as Rejected.

4. Select the reason for rejection from the dropdown menu.

5. Enter the comments. Click the Next button.

6. Click the **Reject** button.

The site is activated and the documents are published to the eTMF or workflow as per your settings. You receive a confirmation about the same. You can also specify the users, and contacts who will receive email confirmation on site activation from Study Start-Up settings.

The Activate/Reject button is now disappeared, and the site name appears under the Active folder in the Current window. Refer to the screenshot below:
Note: If during site activation system cannot move the documents to eTMF for some reason, such documents will not be moved and user will be warned about it. In that case site will not be activated. The reasons of why docs cannot be moved to eTMF are: duplications found, cannot determine Index position.

Documents

The Document tab from the toggling menu bar leads the user to the Documents dashboard. Typically, the Documents module is the route through which most Editors will access and view documents for a Start-Up study. This module acts as a central repository for all documents added to the various components of a study start-up.

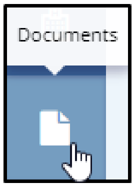


Figure 146: Documents Icon

The Documents dashboard consists of the Current view on the left and the Grid pane on the right. Besides these, it also allows you to perform various functionalities from the menu bar on the top of the grid pane, and the buttons on the Current View window. Clicking a current view opens a list of documents in the grid pane. Refer to the screenshot below.

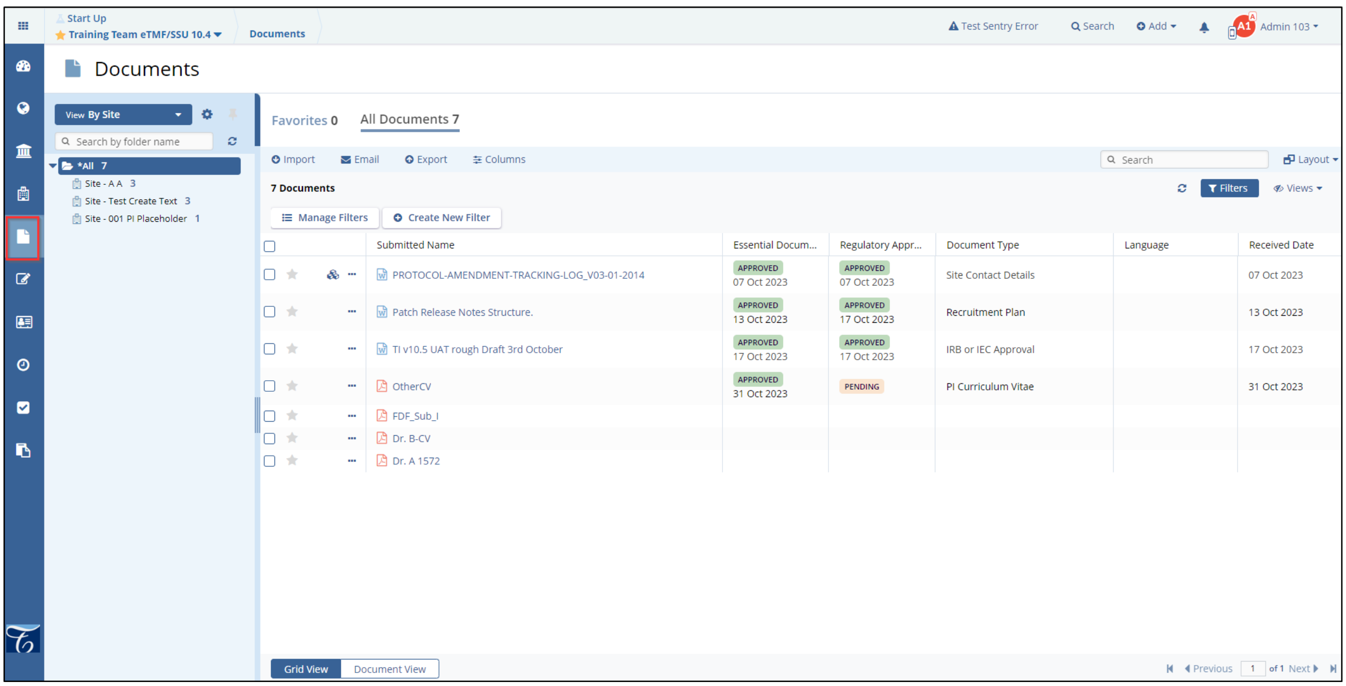


Figure 147: Documents Page

Current View

The Current View Dropdown offers seven views. Click the View By dropdown menu to view the options. Click the **Select** button displayed at the bottom of the window to view the specific documents.

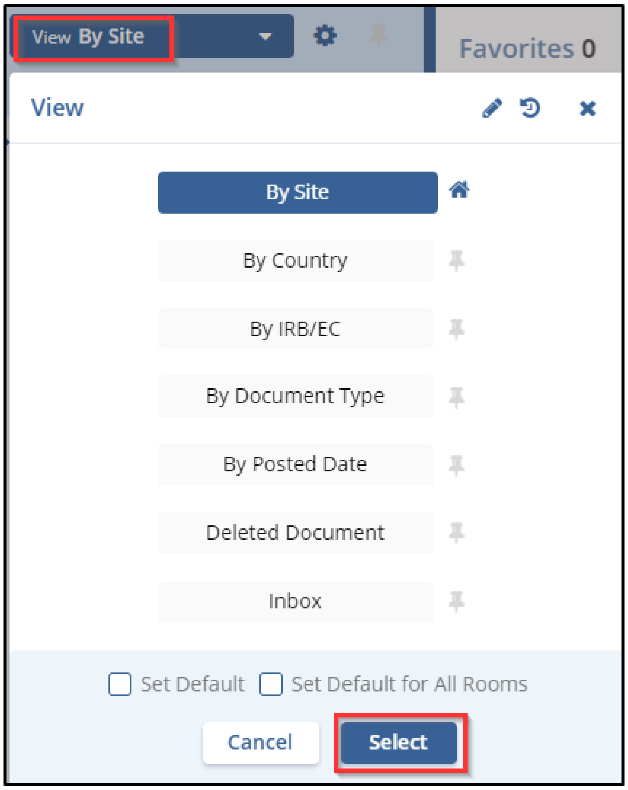


Figure 148: Documents-Current View

- **By Site**: Selecting the By Site option lists out the sites to which documents have been added. Clicking a site will display the documents submitted to the site along with their review status inthe grid pane. Refer to the screenshot below:

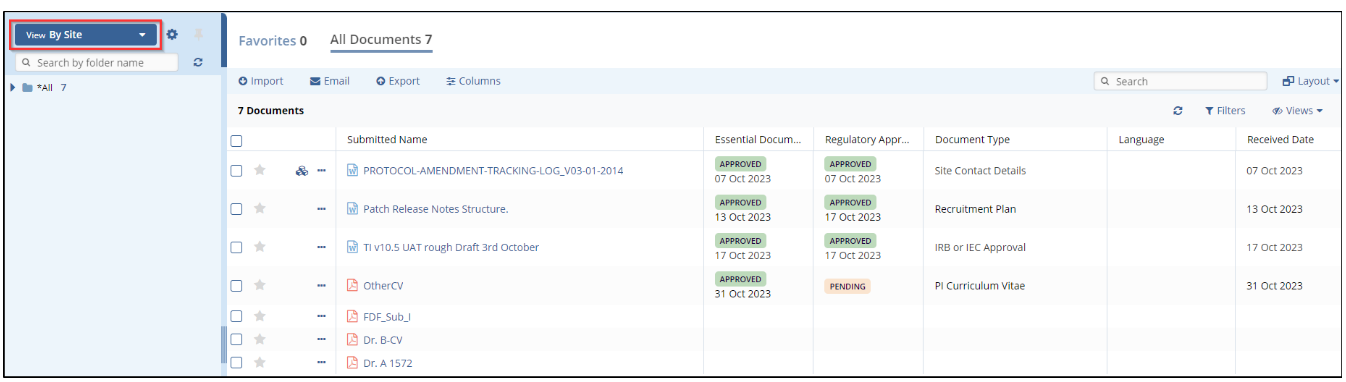


Figure 149: Documents-View By Site

- **By Country**: Selecting the By Country option lists out the countries to which documents have been added. Documents added through the Countries tab can be located here. Clicking a countrywill display the documents submitted to the country along with their review status in the grid pane. Refer to the screenshot below:

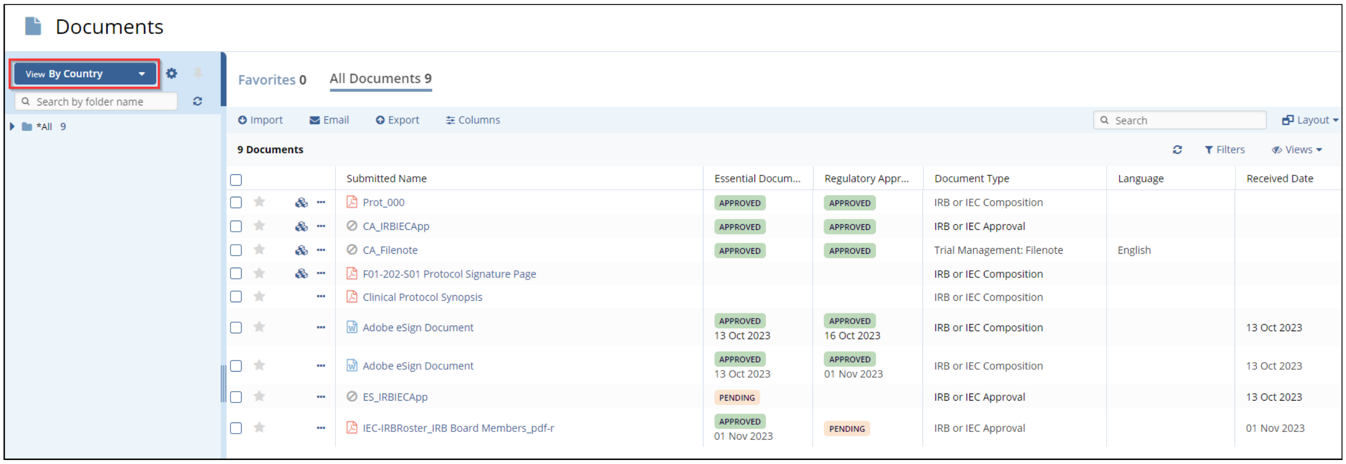


Figure 150: Documents-View By Country

- **By IRB/EC**: Selecting the By IRB/EC option lists out the IRB/ECs to which documents havebeen added. Clicking an IRB/EC will display the documents submitted to the institution alongwith their review status in the grid pane. Refer to the screenshot below:

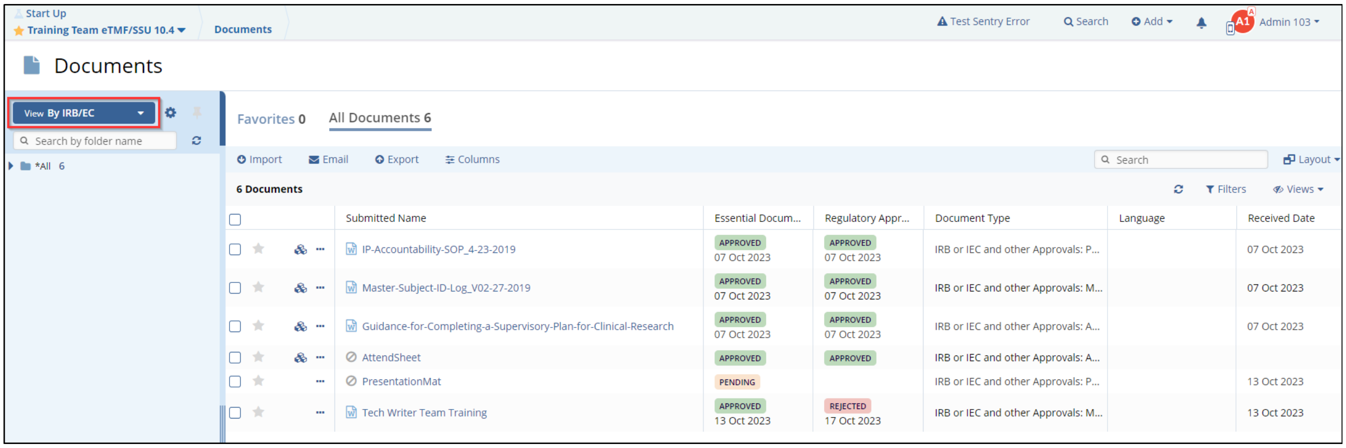


Figure 151: Documents-View By IRB/EC

- **By Document Type:** Selecting the By Document Type options lists out the various documenttypes available to the study start-up. Clicking a document type will display the documents submitted by that type along with their review status in the grid pane. Refer to the screenshot below:

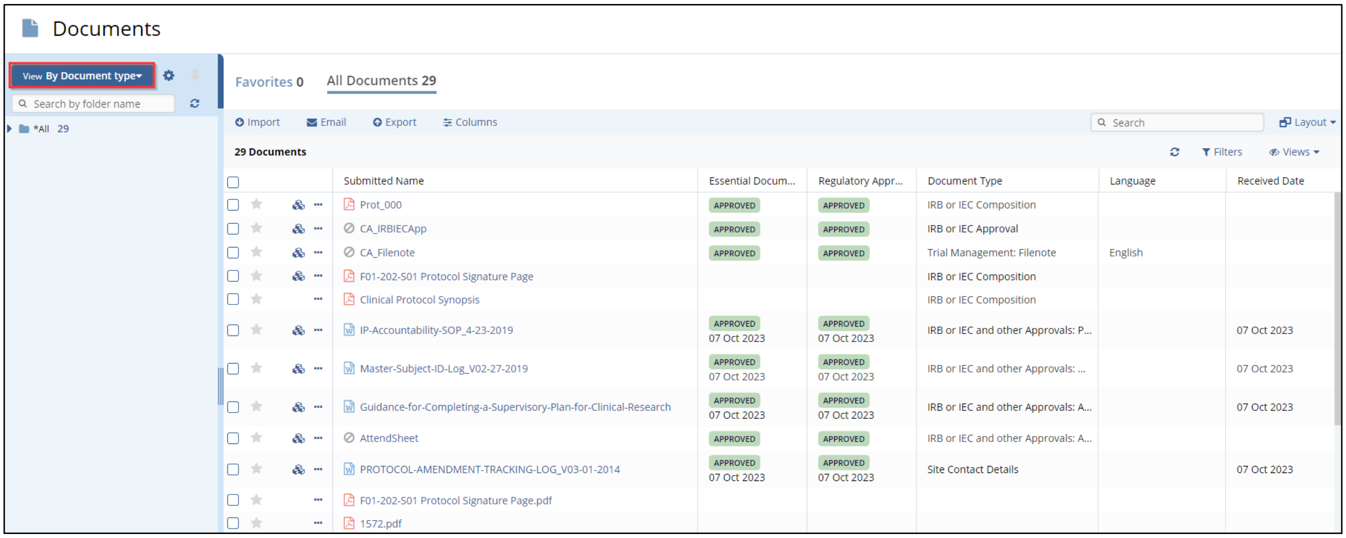


Figure 152: Documents-View By Document Type

- **By Posted Date**: Selecting the By Posted Date option lists out the dates on which documents were submitted to the sites, countries, and IRB/ECs. Clicking a date will display the documentssubmitted on that day along with their review status in the grid pane. Refer to the screenshot below.

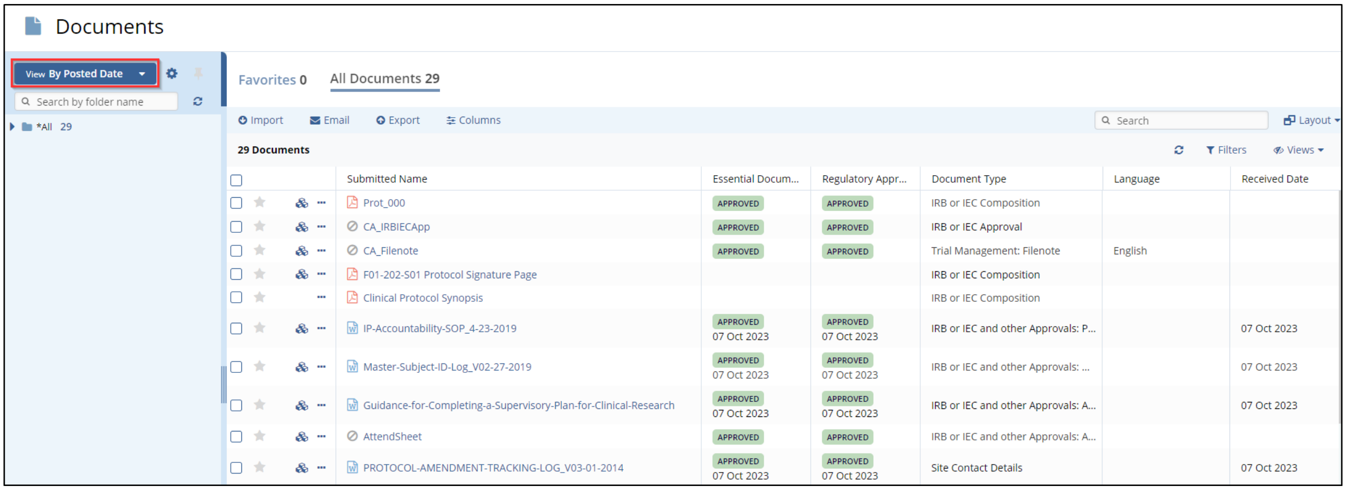


Figure 153: Documents-View By Posted Date

- **Deleted Document:** Selecting this option lists out the documents that were deleted from the sites.

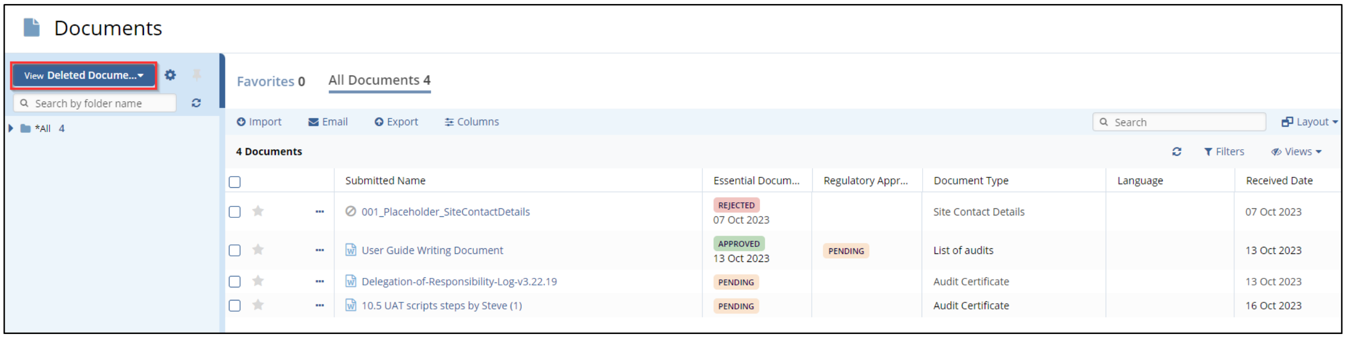


Figure 154: Documents-View By Deleted Document

- **Inbox:** Selecting this option lists out the documents that are in the Inbox folder of the user.

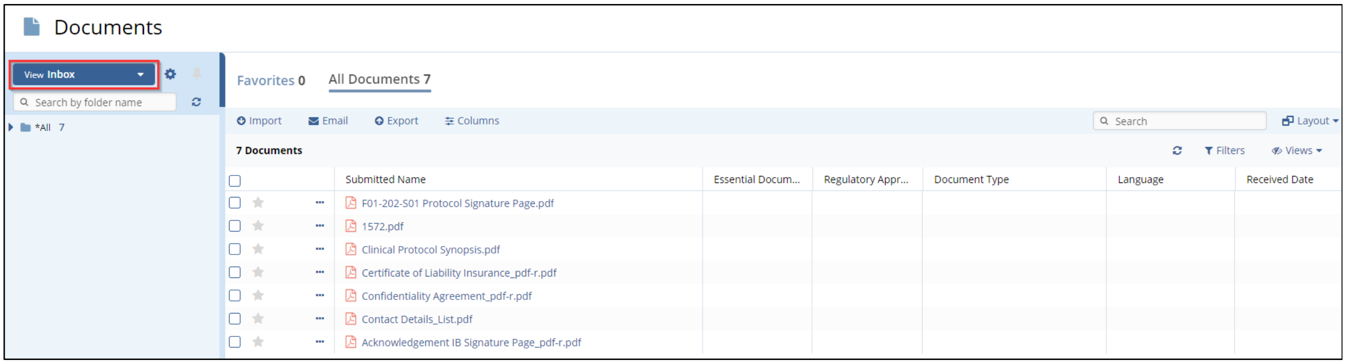


Figure 155: Documents-View By Inbox

The Documents Grid Pane

The Grid Pane displays the details of the documents and provides various other functionalities through the Menu Bar on the top, the Document Data Panel, and the Selections at the bottom of the panel.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the screenshot below:

Figure 156: Documents Top Menu Bar

The Import button helps the user to add a document to the Documents section.

1. Click the **Import** button displayed in the top menu bar.
2. This opens the Import Documents popup window.
3. Drag Drop the required files OR click the Browse File/Browse Folders option.

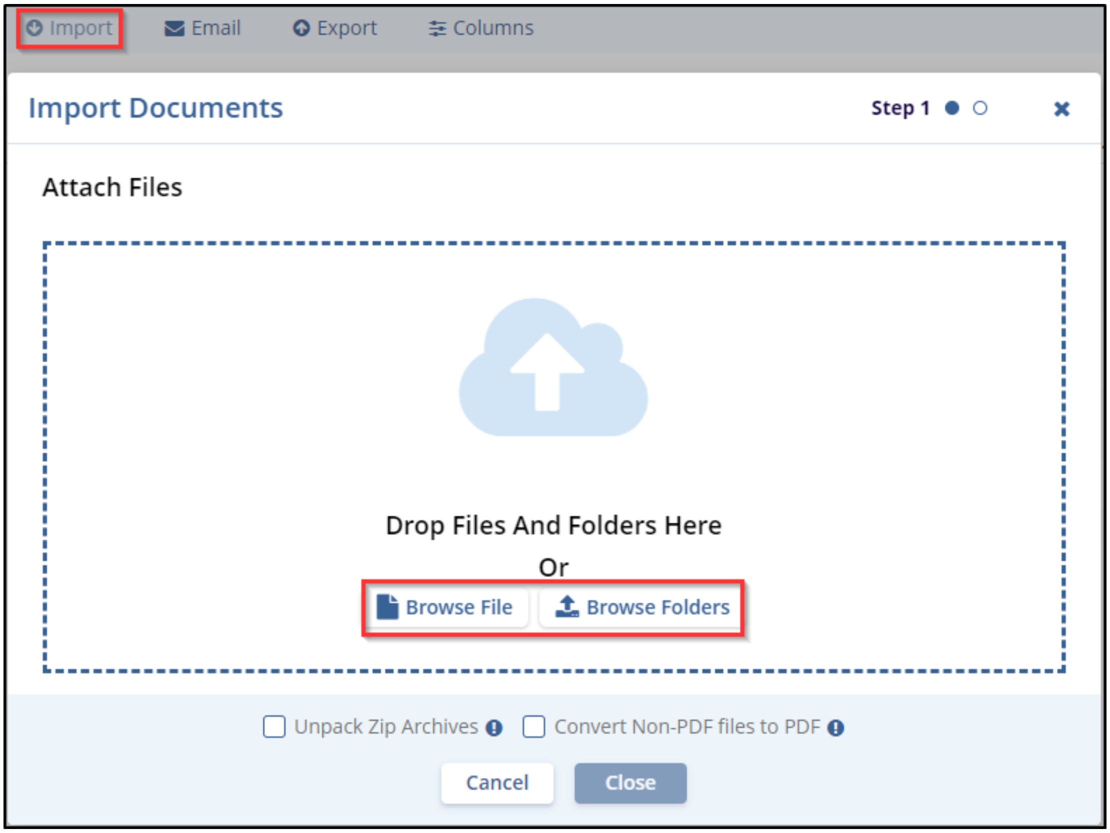


Figure 157: Documents-Import

4. Select the required file from the system.
5. The Import Documents popup window displays two options – Assign To Placeholders and Fill Metadata & Import.

6. **(Optional)** The Assign to Placeholder – select the appropriate Category from the dropdown menu.
   Note: The category selected here changes the options displayed in the next step.

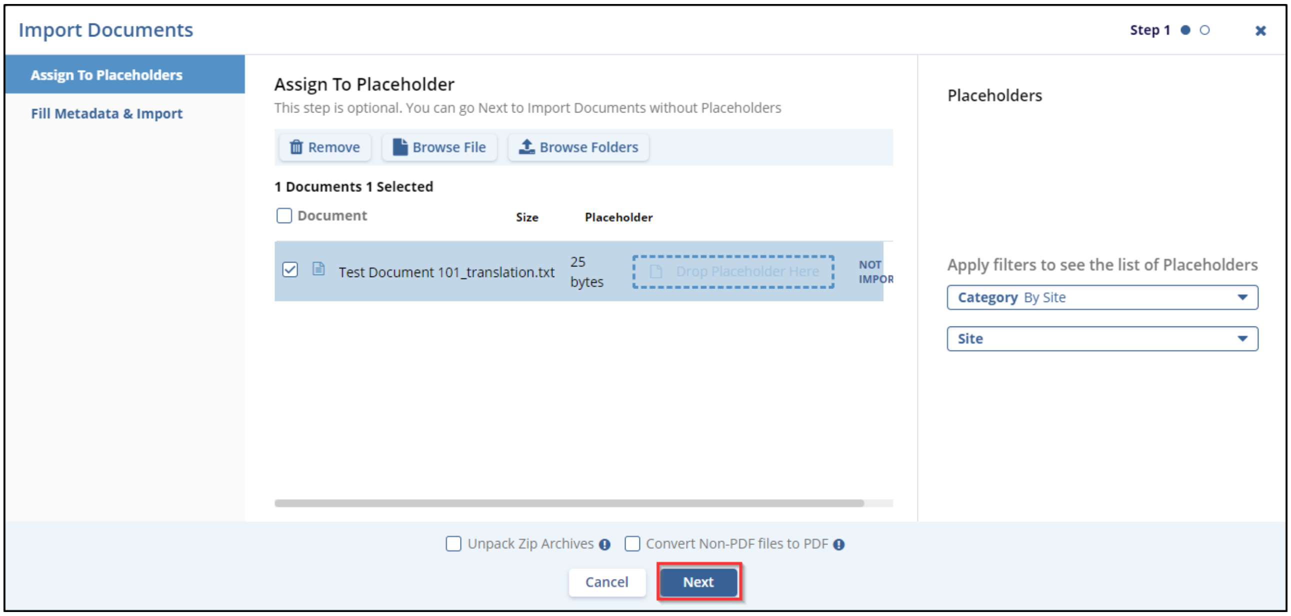


Figure 158: Documents- Assign Placeholders

7. Click **Next**.
8. The Fill Metadata & Import – enter the details in the fields marked with an asterisk (*).
9. Click the **Import Documents** button displayed at the bottom of the popup window.

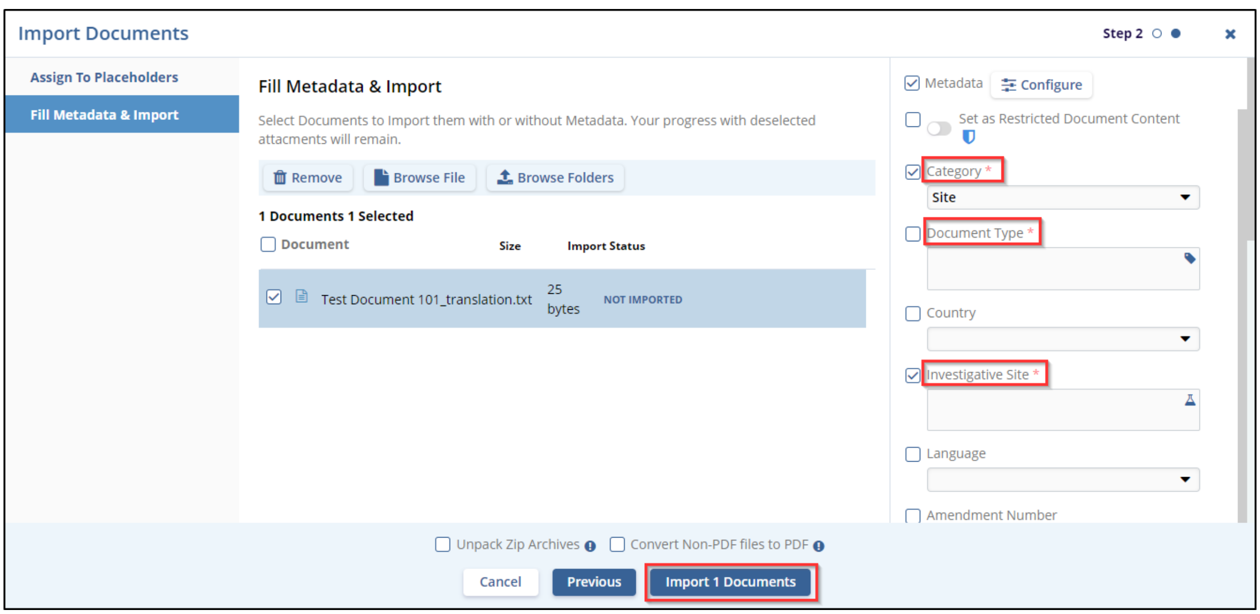


Figure 159: Documents- Fill Metadata

Email

The Email tab helps the user to send the mails to the other users.

1. Click the **Email** button displayed in the top menu bar.
2. This opens the Email popup window.
3. Enter the **Recipients** in the Recipients field (mandatory).
4. Click the **Add** button displayed at the right corner of the popup window.

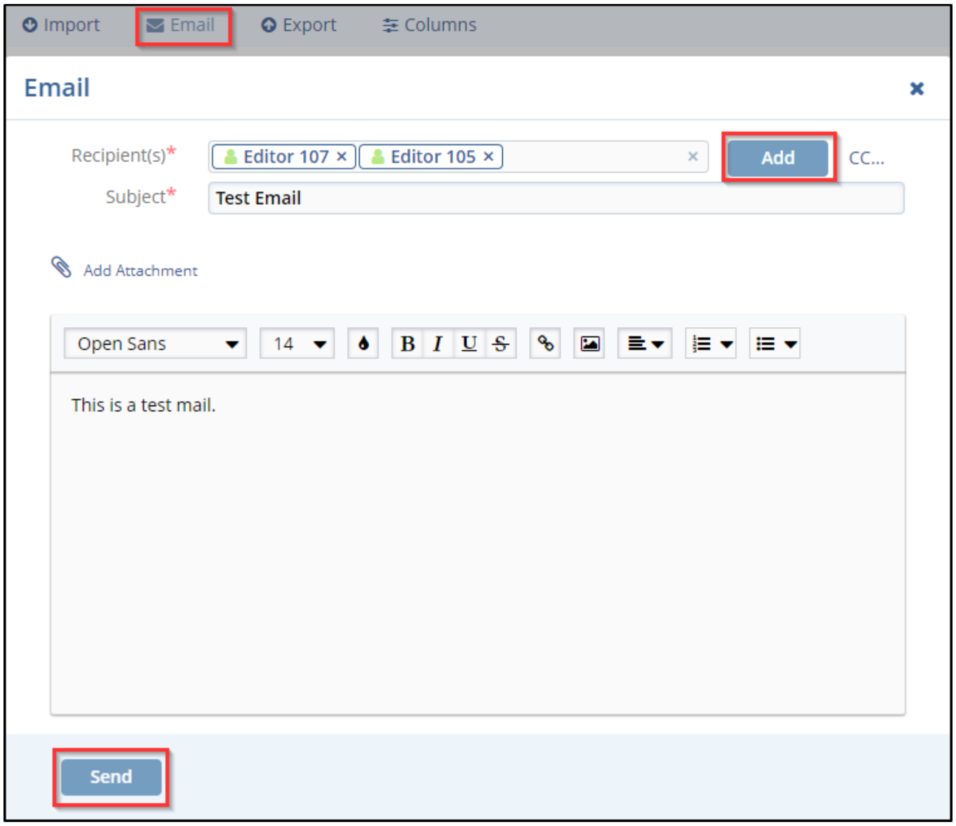


Figure 160: Documents-Email

5. The Choose Email Recipients popup window is displayed.
6. Drag drop the user(s) to the right pane.

7. Click the **Save** button displayed at the bottom of the popup window.

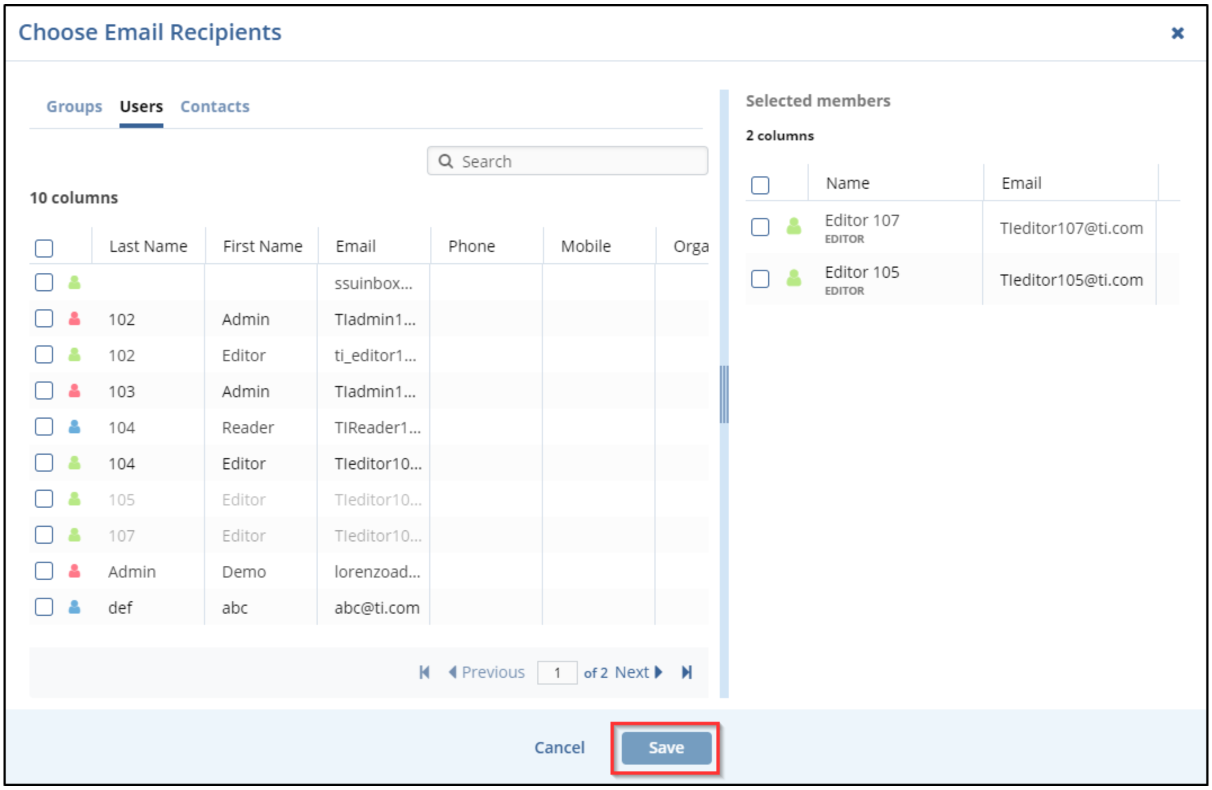


Figure 161: Documents-Choose Email Recipients

8. The selected names are displayed in the Recipients field.
9. Enter the **Subject** in the Subject field (mandatory).
10. (Optional) Click the **Add Attachment** link if required.
11. Enter the content in the body text field.
12. Click the **Send** button.

Export

The Export button helps the user to export the data in an Excel sheet.

1. Click the **Export** button displayed in the top menu bar.
2. This opens the Export Audit Trail popup window.
3. Select the appropriate option from the Source dropdown menu (mandatory).
4. Select the appropriate checkbox(s) of the options mentioned.
5. If the **Audit Trail Date Range** checkbox is selected, the From Date – To Date fields are enabled.
6. Select the required date by clicking the **Calendar** icon.
7. Click the **Next** button.

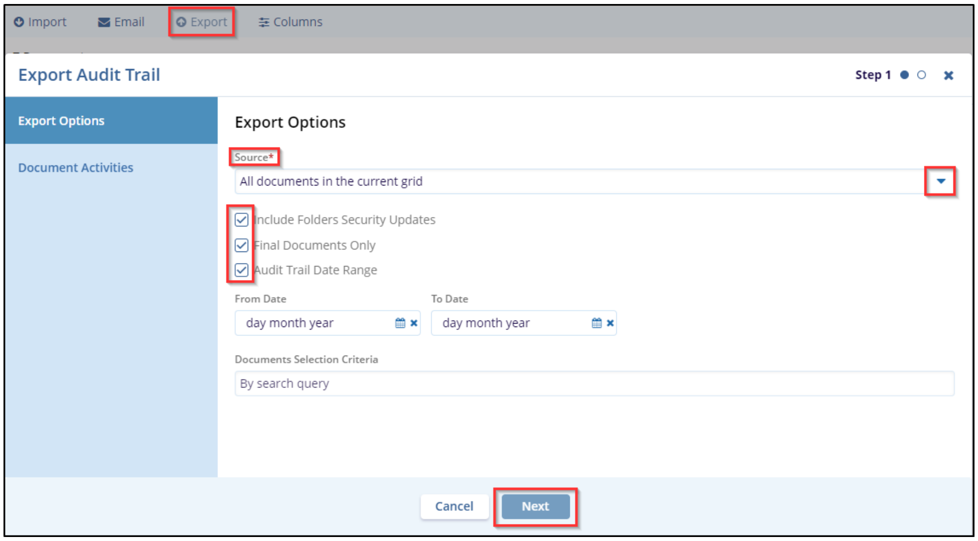


Figure 162: Documents-Export

8. Verify the details added in the previous section and click the **Export** button.

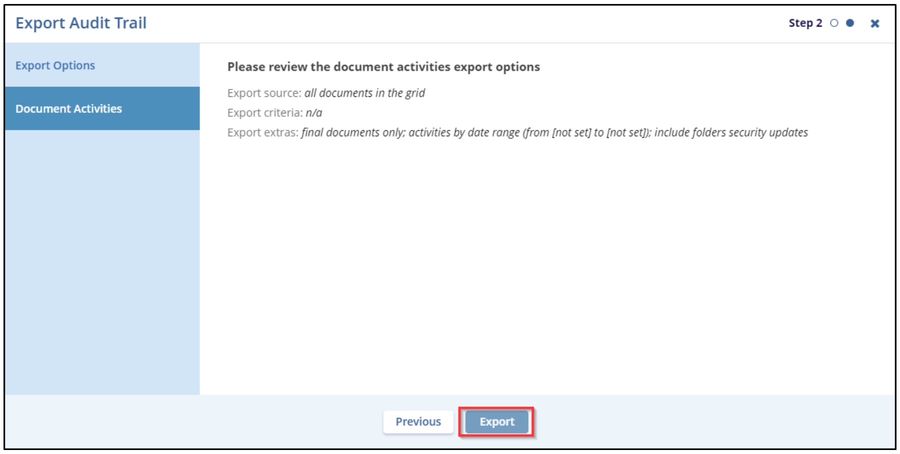


Figure 163: Documents Activities

9. A notification is displayed in the top right corner of the screen.
10. Click the **Get Job Result** button.

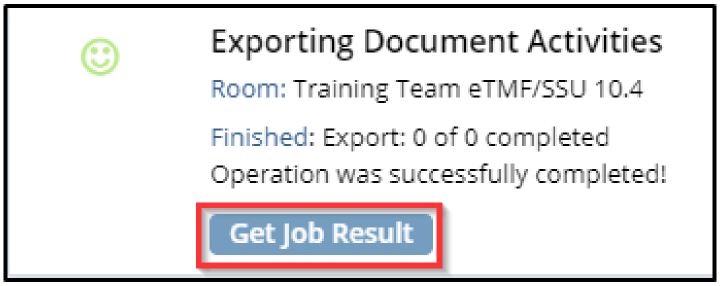


Figure 164: Documents - Get Job Result

11. The data is saved in the Downloads folder of your system.

Columns

This option helps the user to select required columns to be displayed in the grid pane of the Documents section.

1. Click the **Columns** option displayed in the top menu bar.
2. This opens the Manage Columns popup window.
3. Click the **Plus** icon of the required columns from the left pane.
4. The selected columns are reflected in the right pane.
5. Click the **Set View** or **Save Changes** option displayed at the bottom of the popup window.

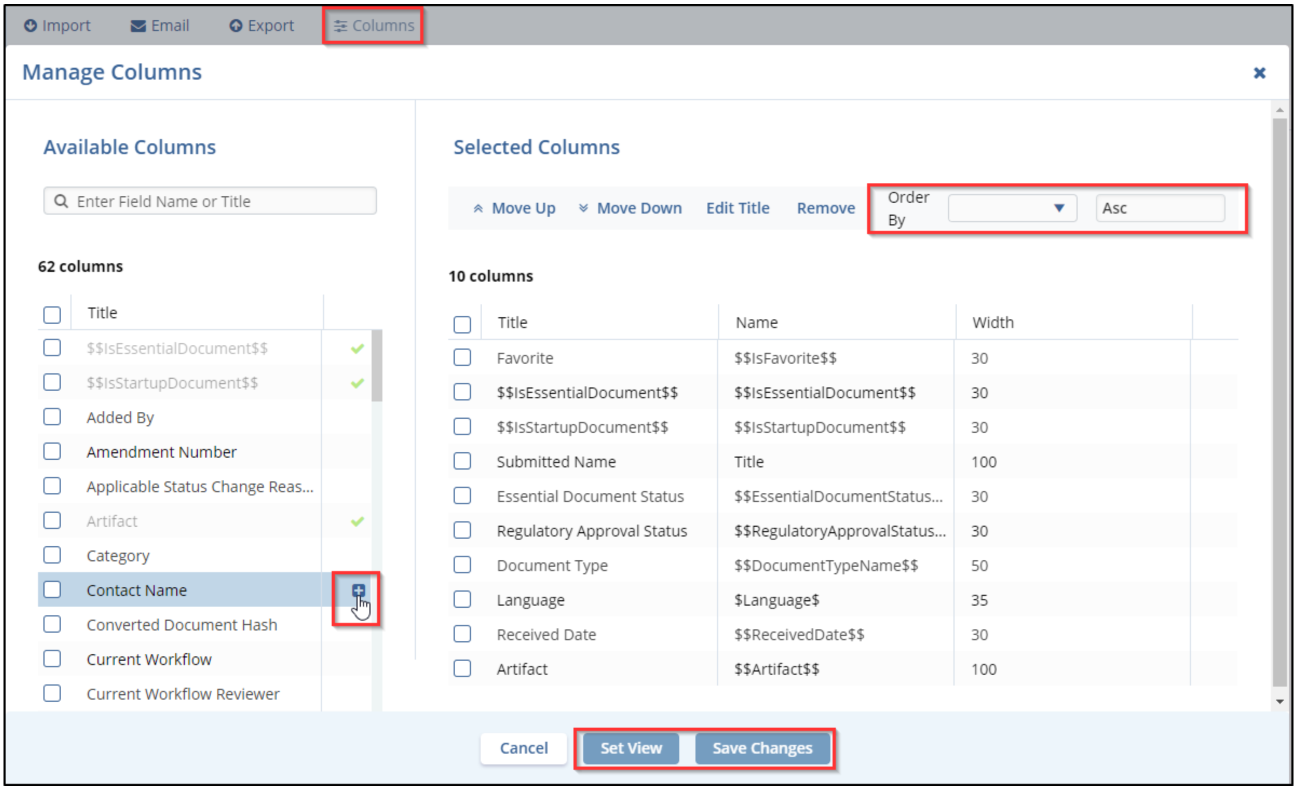


Figure 165: Documents-Manage Columns

6. The Save View popup window is displayed.
7. Enter a name in the Name field.
8. (Optional) Select the required toggle buttons.
9. Click the **Save** button displayed at the bottom of the popup window.

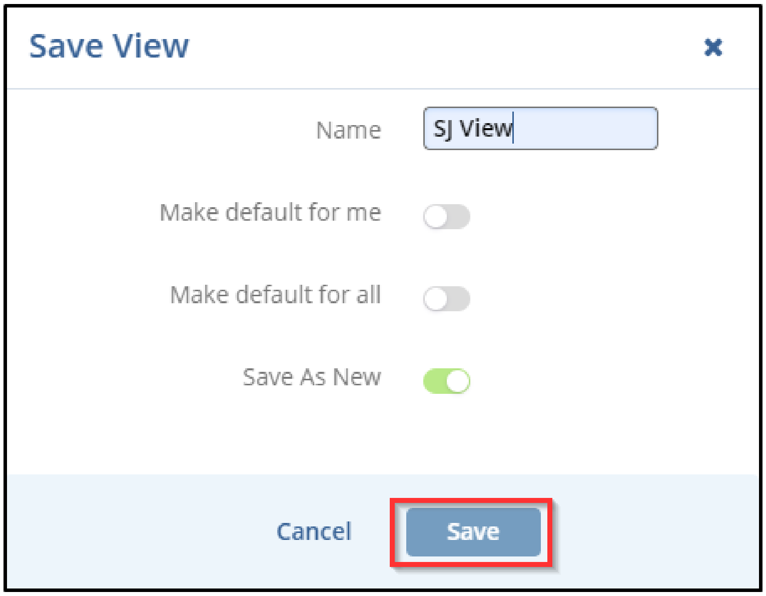


Figure 166: Documents- Save View

10. The selected options are reflected in the grid pane.

Document Dropdown

Note: The Document button and its dropdown options are displayed only when a document is selected by clicking its checkbox. Each of the available options in the dropdown are discussed in the subsequent topics.

Add to Favorites

Click the **Star** icon next to the checkbox of the document to add the document to Favorites. The Grey star becomes Yellow in color. Alternatively, the user can click the three-dot menu to view the same option.

Open Document

Select the checkbox of the document to open and click the **Word File** or **PDF icon** next to the document. OR, Select the document checkbox and click the **Document View** button displayed at the bottom of the grid.

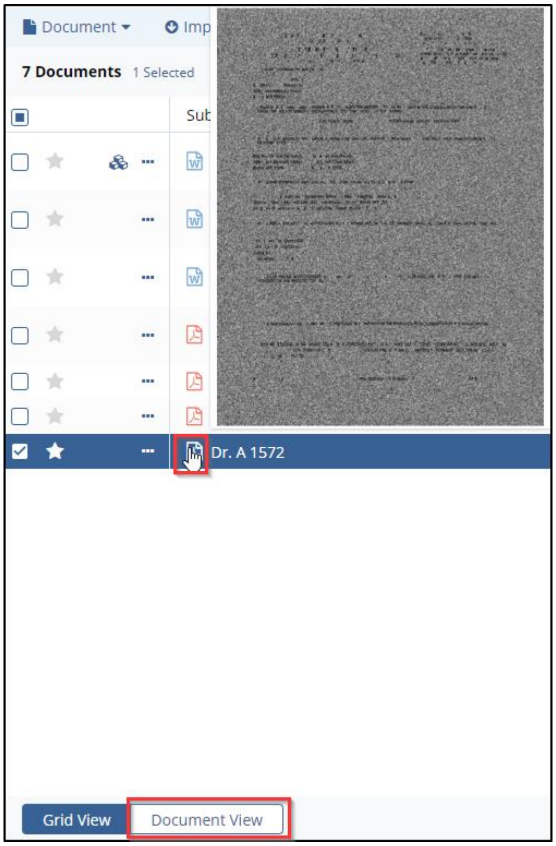


Figure 167: Document Dropdown

Set Not Applicable

This option helps the user to set a document as either applicable or not applicable.

1. Select the checkbox of the document to set as not applicable.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Set Not Applicable** option.

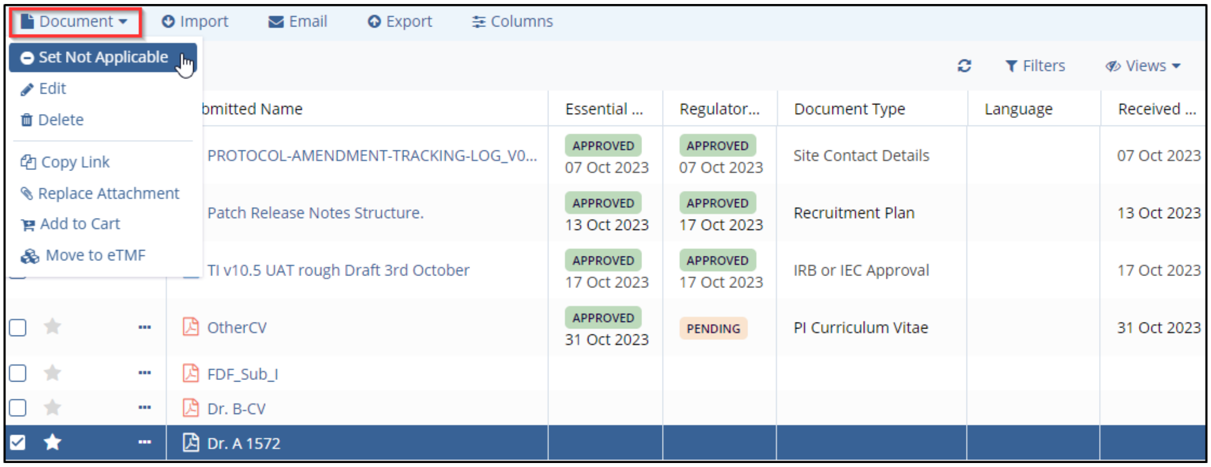


Figure 168: Document-Set Not Applicable

4. A popup window is displayed. Enter a reason in the empty field (mandatory), until then the OK button remains disabled.
5. Click the **Set Not Applicable** button in the popup window.

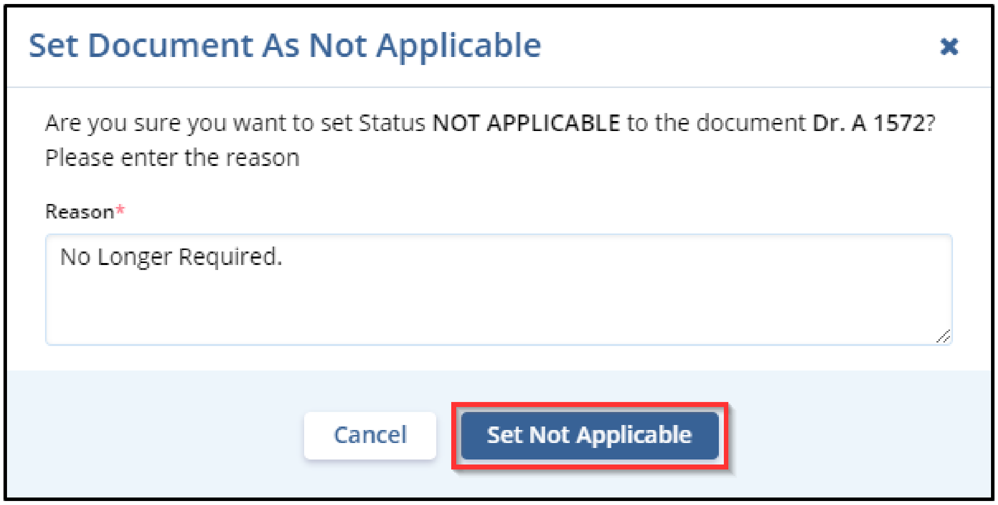


Figure 169:Document-confirm Set Not Applicable

Edit

1. Select the checkbox of the document to be edited.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Edit** option.
4. The metadata panel is opens on the right side of the screen.
5. Make the required changes in the doc and click the **Save** button displayed at the bottom of the metadata panel.

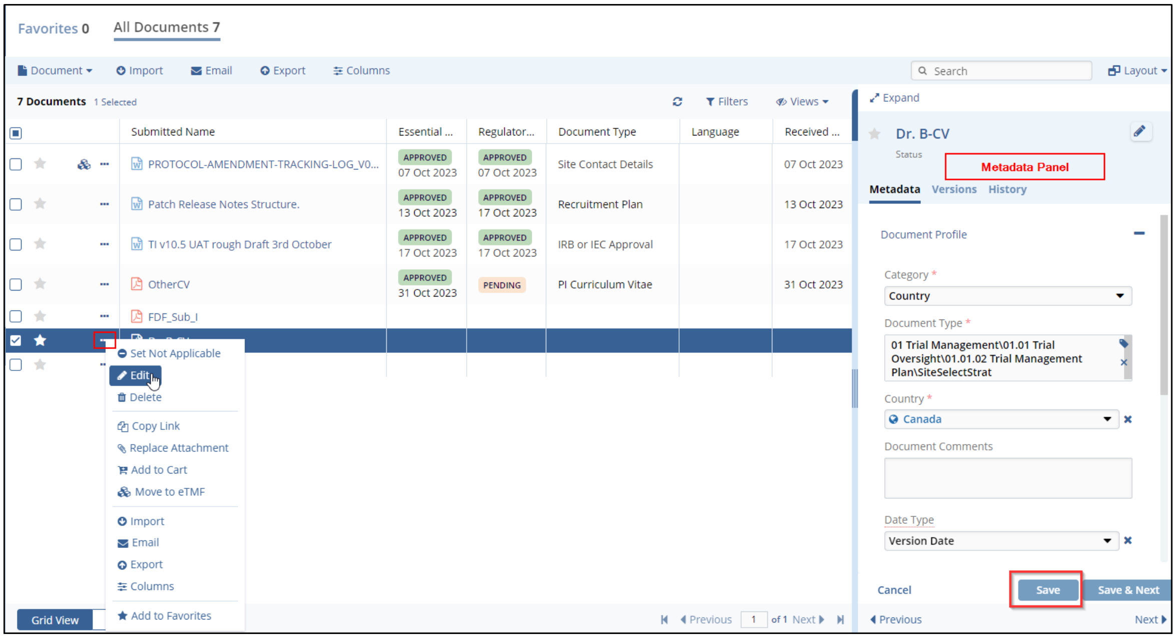


Figure 170: Document-Edit

Delete

1. Select the checkbox of the document to be deleted.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Delete** option.

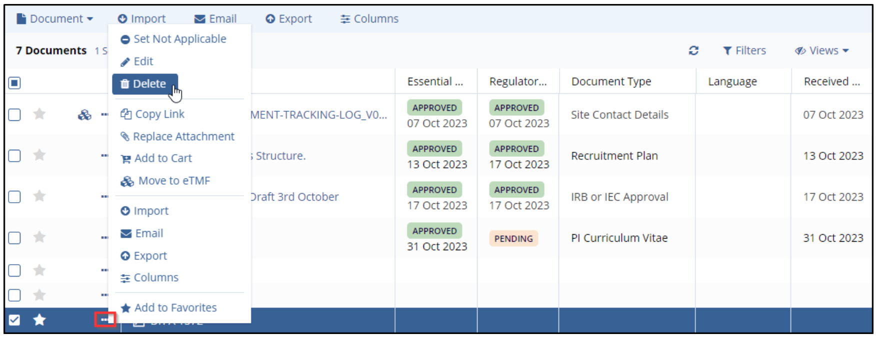


Figure 171: Document-Delete

4. A popup window is displayed. Enter a reason in the empty field (mandatory), until then the OK button remains disabled.
5. Click the **OK** button in the popup window.

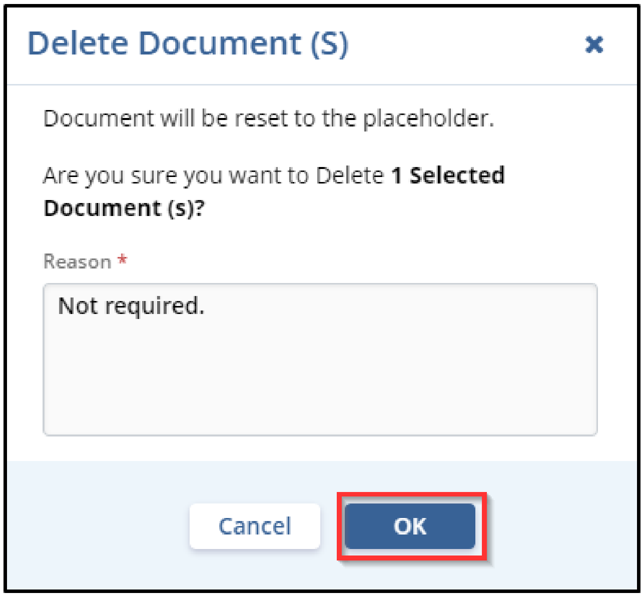


Figure 172: Documents-Confirm Delete

Copy Link

This option helps the user to copy the link of a document, or copy the link of the document with its metadata.

To copy the link of a document:

1. Select the checkbox of a document from the grid of the Documents section.
2. Click the dropdown menu of the Document button displayed in the top menu bar OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Copy Link** option**.**
4. The document URL gets copied to the clipboard.
5. A notification about the same is displayed at the bottom right corner of the screen.

Figure 173: Documents- Copy Link

6. Paste the copied URL in the browser tab.
7. The document opens in the browser for you to read.

Replace Attachment

You can replace the attachment to a document type if it is not approved by using this feature.

1. Select the checkbox of the document that needs attachment replaced.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Replace Attachment** option.

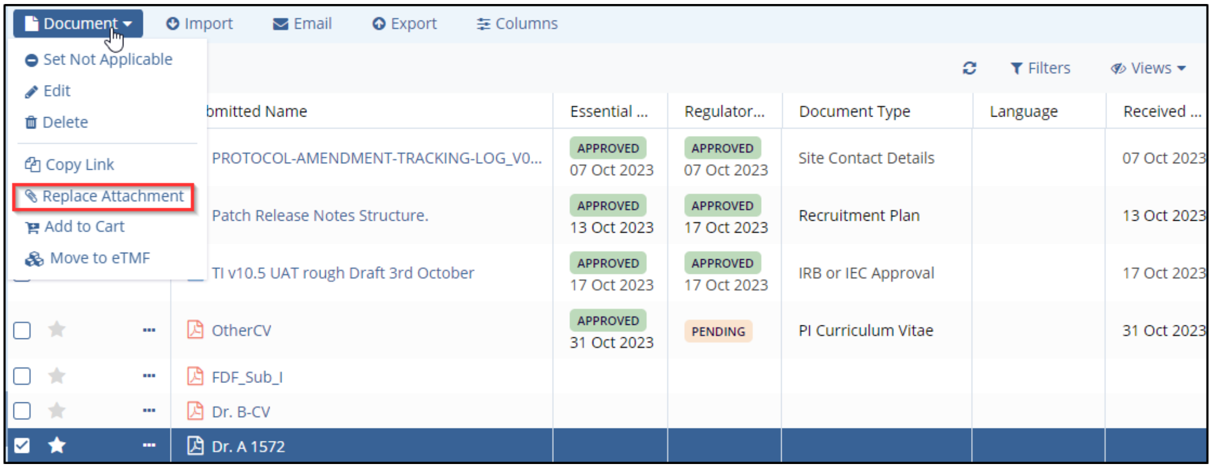


Figure 174: Document-Replace Attachment

4. The Add Document popup window is displayed. Click the **Attach URL** option.
5. Paste the link in the field – Link to External Document.
6. Click the **Add** button displayed at the bottom of the popup window.

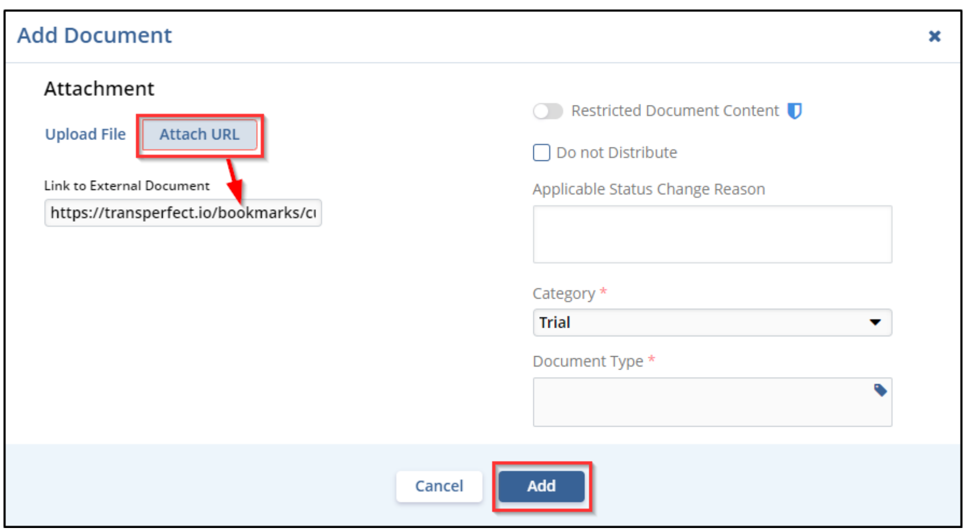
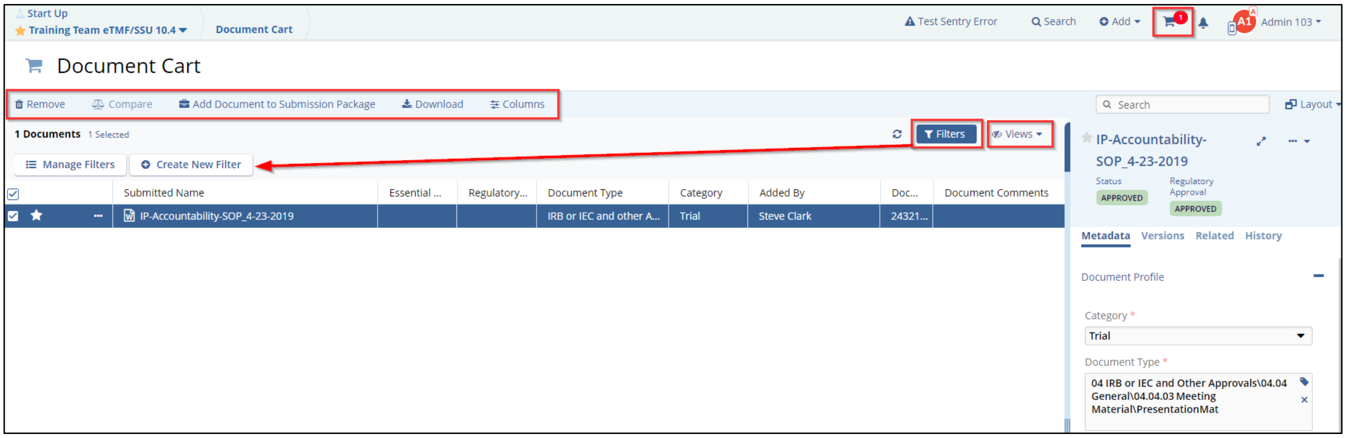


Figure 175: Documents-Attach URL

Add to Cart

You can add a document selected from the grid to the cart to compare documents, link them, add them to the submission package, or download documents.

1. Select the checkbox of the document that needs to be added to the cart.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Add to Cart** option.
4. The Document Cart icon displays a number in the top right corner.
5. Click the Document Cart icon to view the document details in the grid pane.
6. The user is able to Remove, Compare, Add Document to Submission Package, Download, Manage Columns, Manage and Create Filters, and Save Views in the grid pane.



Move to eTMF

You can move a document selected from the grid in the eTMF by clicking the **Move to eTMF** button on the top menu bar. This opens the Select index position to place the document pop up window. Refer to the screenshot below.

1. Select the checkbox of the document that needs to be moved to the eTMF.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Move to eTMF** option.

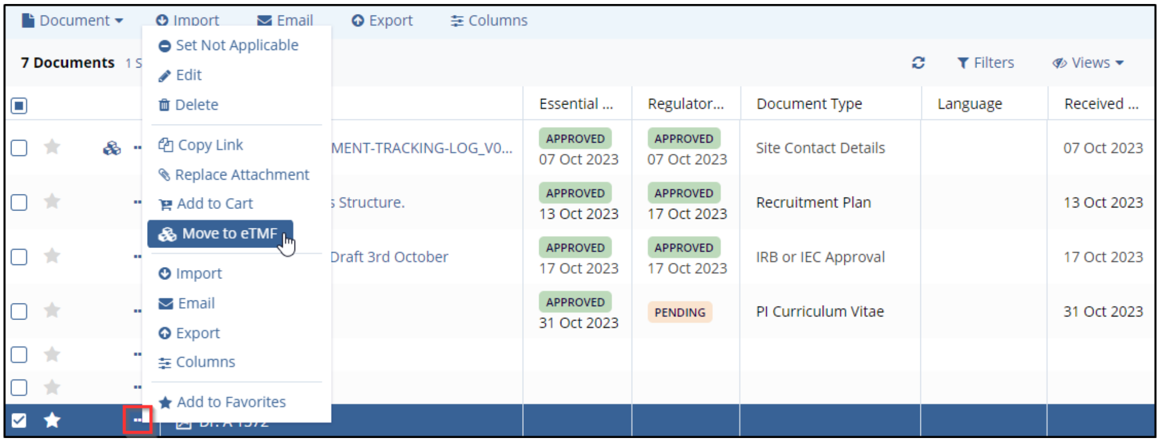


Figure 176: Documents-Move to eTMF

4. A **Move to ETMF** popup window is displayed.
5. Expand the appropriate dropdowns. Keep expanding until there is no dropdown arrow for any folder.
6. Select the checkbox of the appropriate folder. Until then the OK button is disabled.
7. Click the **OK** button displayed at the bottom of the popup window.

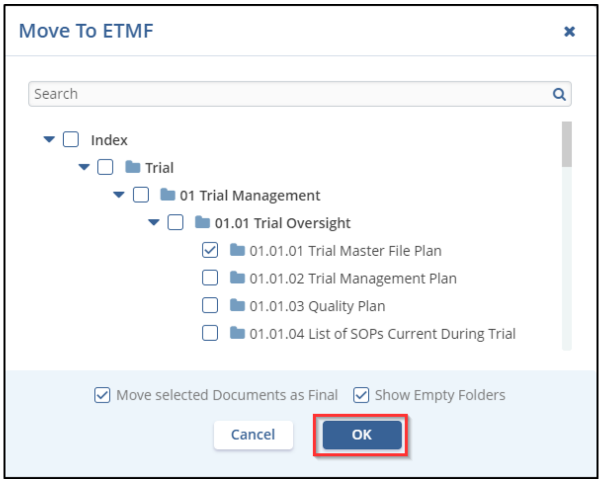


Figure 177: Documents-Move to eTMF Dropdowns

Amendments

After a site is activated and the clinical trial begins, it is very common to have amendments to the study protocol, depending on the nature of the amendments many more essential/required documents needs to be submitted by the sites. Such documents cannot be added to the site directly and can be specified only through Amendments. Amendments can be created for Investigative Sites, Country Amendments, and IRB/EC.

Creating Amendments

To create amendments, the administrator needs to do the following:

1. Navigate to **Settings**.

2. Click the arrow next to **Required Documents** in the left panel.

3. Select **Amendments** from the dropdown.

4. The Amendments Management window opens in the right panel.

Figure 178: Settings-Amendments

5. Click the **Add** button displayed at the top menu bar to open the Create Amendment window.

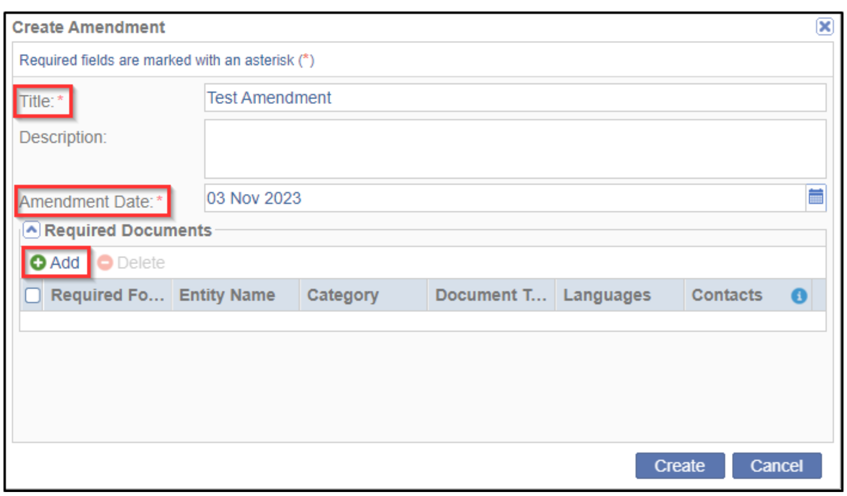


Figure 179: Settings-Create Amendment

a) Fill in the details as required.

b) Click **Add** in the Required Documents panel in this window.

c) The Required Documents window opens.

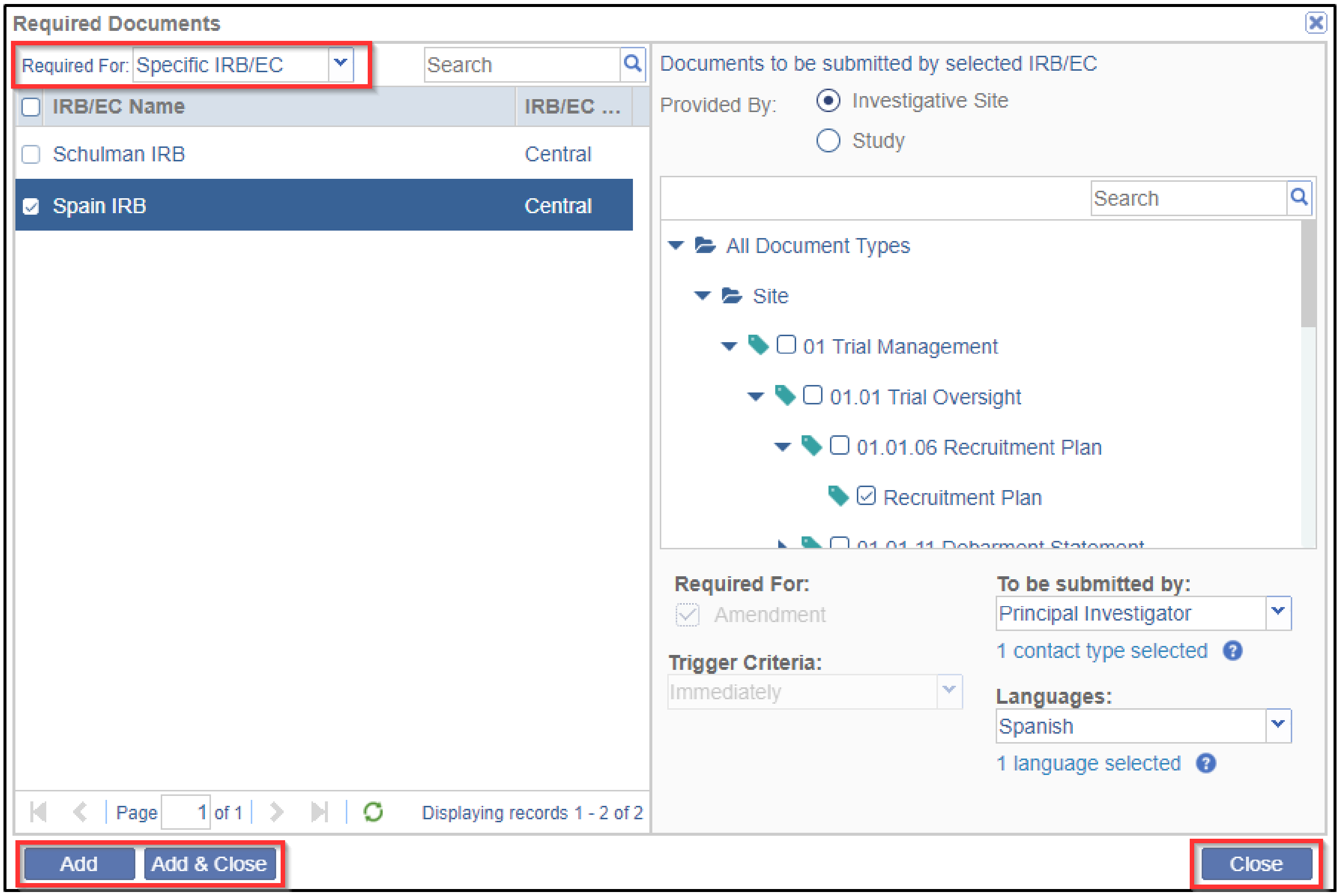


Figure 180: Settings-Amendments-Required Documents

d) From the **Required For** dropdown in the left panel select an option as required (All Sites, Specific Site, Specific IRB/EC, or Specific Country).

e) From the right panel above, in the 'Provided by' section, select a radio button.

f) Below in the right panel select the required documents that are needed after the site activation.

g) Select an appropriate option from the dropdown menu of the 'To be Submitted by' and 'Languages' fields.

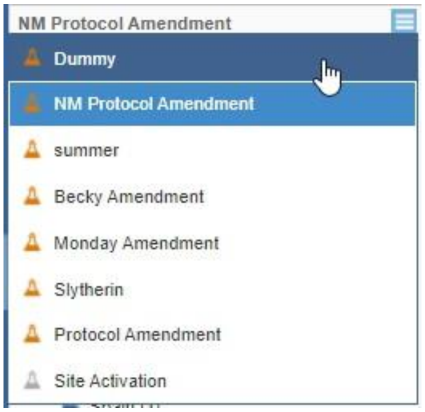
h) Click the 'Add' and 'Close' button to reflect the changes in the 'Create Amendment' window.

i) The procedure to add the documents is same as described in the earlier section of [Basic Configuration for SSU](#).

6. Click **Create** button to create the amendment.

Viewing Amendments and Adding Documents

To view amendments for a site/s and countries, navigate to the Sites section. From the Current View in the left, click the three yellow bars above the panel to activate the Filter By Amendmentdropdown. Choose the amendment as required. Refer to the screenshot below:



Double-click a site name from the Grid Pane to open the site profile window for amendments. Like the Sites, and Country section, this window also has three tabs – Essential Documents, All Documents, and Communication Log. The procedure to add documents and communications are thesame as described in section Collecting Essential and Non-Essential Documents *(page 417)*

Amendments for IRB/ECs can be viewed from the IRB/EC section. Here too, you will be able to select the required amendment from the Filter By Amendment dropdown in the Current View panel.The rest of the procedure is the same for Sites and Countries as described above.

QC Review and Regulatory Approval of Amendments

After the documents for amendment are added, essential documents will need to pass the QC Reviewand Regulatory Approval.

The non-essential documents will need to pass through the approval process only if it is specified inthe Study Start-Up settings. The settings in this section also apply to the amendments.

The process to review and approve the documents for both the processes is the same as described in earlier sections.

To Regulatory Review the documents, the Regulatory Approver will need to log in to the systemand enter the Regulatory Review section. Here too, the Regulatory Approver selects the required amendment from the Filter By Amendment dropdown in the Current View panel and selects the documents to approve/reject them from the Grid Pane.

Completing an Amendment

Once all the documents (essential and non-essential) are approved, the amendment profile window acquires the Complete Amendment button at the bottom. Click the button to complete the amendment. You will need to confirm the process by clicking Yes on the dialog box that appears onclicking the button.

On clicking 'Yes', the amendment will be completed and the documents will be published on the eTMF. Whether they will take the place in the default folder to be picked up for the workflow process, or they will be auto-routed to their respective positions in the eTMF index depends once again on your settings in the Study Start-Up section. On completing the amendment, you will receivea confirmation for the same. Click Ok to accept the confirmation.

Contacts

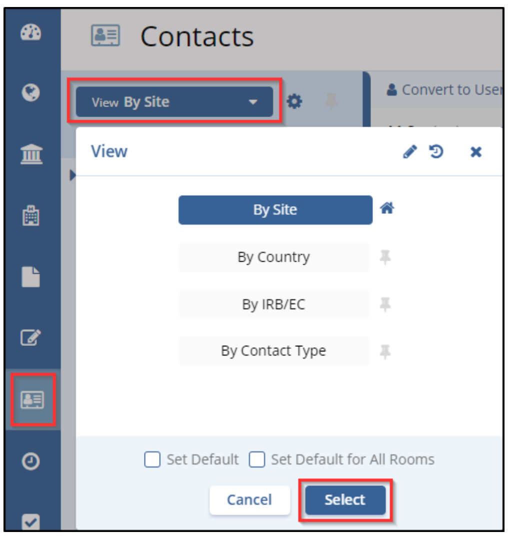
Note: The Communication Log section from Sites, Countries, and IRB/EC provides the same functionality as that available in the Communication section.

The Communication tab, accessed from the toggling menu bar on the left, holds all the messages sent and received with a study start-up for the purpose of activating a site. Opening the Communication tab, the user can see three panels: **Current View, Grid Pane,** and **Communication Data**. Refer to the screenshot below.

Current View

The Current View Dropdown offers four views:

- **By Site**: Select this option to list out the contacts added to the sites. Click a site to display the contacts of the particular site in the grid pane. If a Principal Investigator (PI) was deleted, and a new one added, the previous PI will appear greyed out. Similarly, if a contact is deactivated, it too will appear greyed out, but if a contact is deleted, it will not appear in the grid.
- **By Country**: Select this option to list out the countries which have sites added to them. Sites for which countries are not added will appear under the Not Specified category. Click the **+** next to a country to display the sites belonging to the country. Click the site to list the contacts of that site in the grid pane.
- **By IRB/EC**: Select this option to list out the sites by IRB/ECs. The sites for which IRB/ECs are not specified are listed under Not Specified category. Click a site to display the contacts of the particular site in the grid pane.
- **By Contact Type**: Select this option to list out the various contact types added to the sites in a study start-up. Click a contact type to display the names of all the people under the contact type.



The Grid Pane

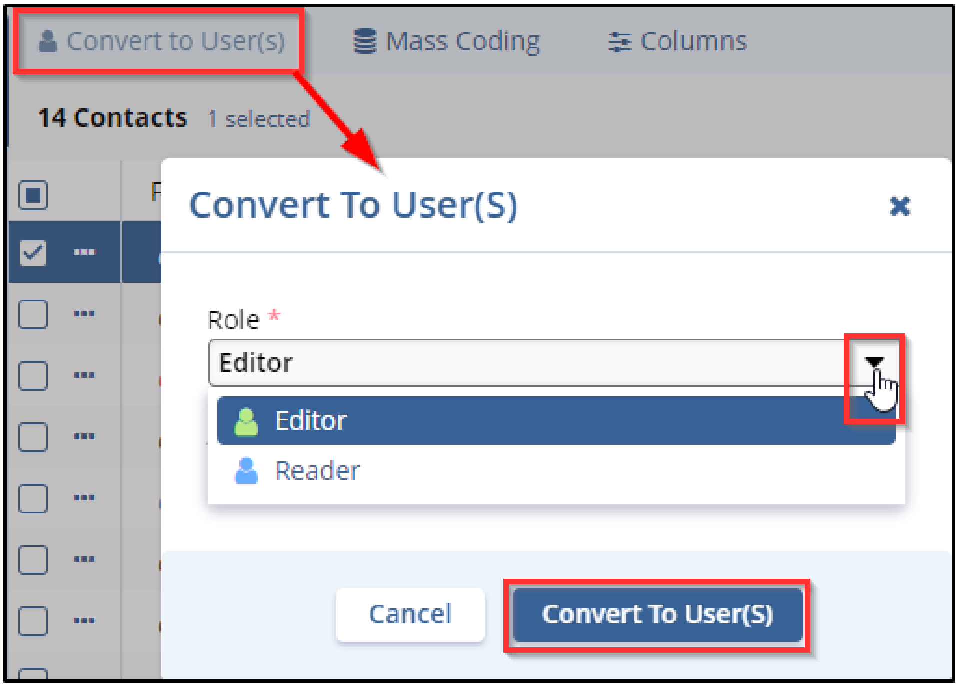
The Grid Pane displays the details of the contacts and provides various other functionalities through the Menu Bar on the top.

The Top Menu Bar

The Menu bar on the top displays buttons for various functionalities. Refer to the screenshot below.

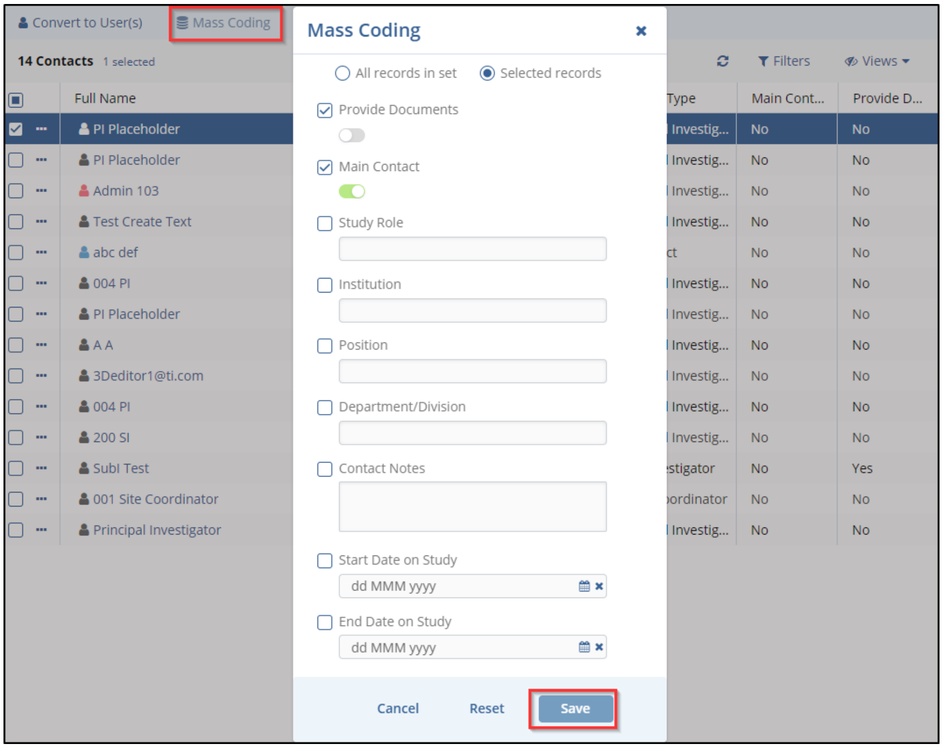
Convert to User(s)

You can choose to assign selected contacts the roles of Editors, or Readers in a site by clicking the **Convert to user(s)** button from the top menu bar. Refer to the screenshots below:



Mass Coding

1. Click the **Mass Coding** option from the top menu bar to enable you to set the all contacts in the grid pane, or only selected contacts in the grid pane as Main Contact at one go for all the sites in the study start-up. Select the appropriate radio button for the same.
2. Select the required checkbox(s) and click the **Save** button displayed at the bottom of the popup window to commit the changes. Refer to the screenshot below:

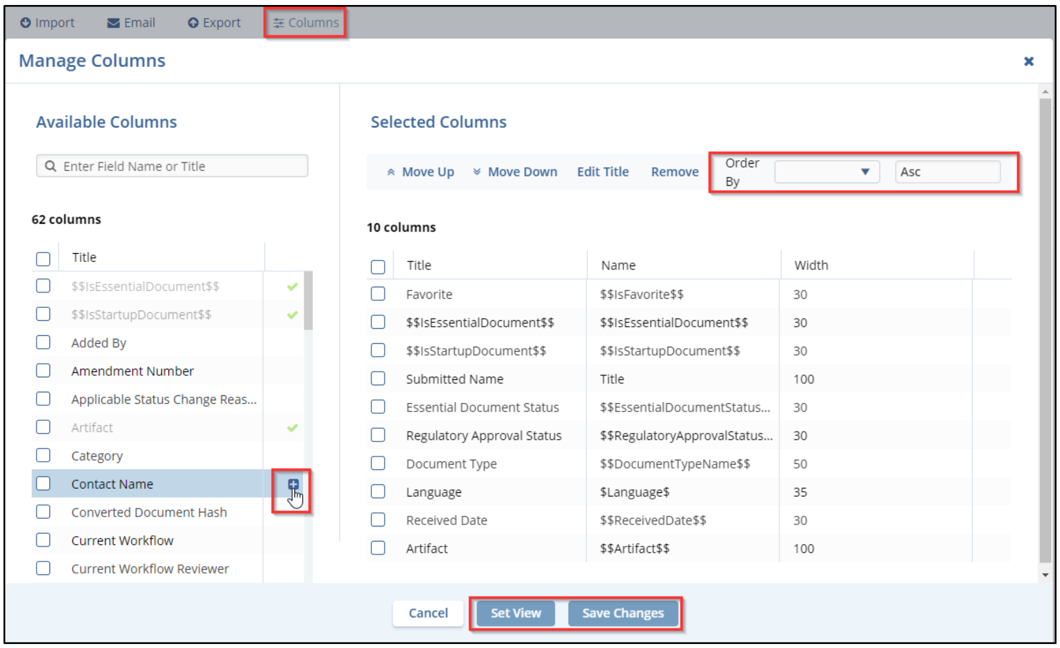


You can also decide whether the contacts can be mass coded to provide documents.

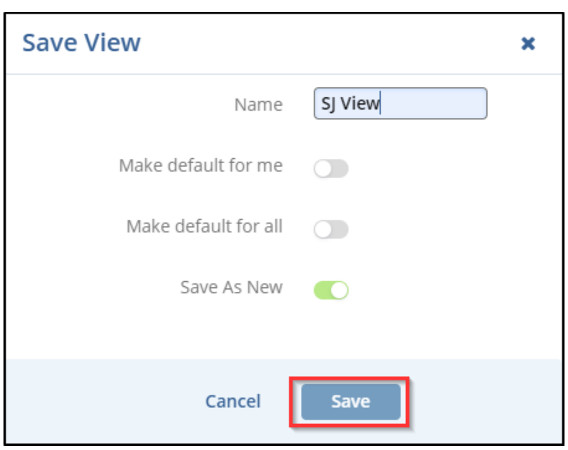
Columns

This option helps the user to select required columns to be displayed in the grid pane of the Documents section.

1. Click the **Columns** option displayed in the top menu bar.
2. This opens the Manage Columns popup window.
3. Click the **Plus** icon of the required columns from the left pane.
4. The selected columns are reflected in the right pane.
5. Click the **Set View** or **Save Changes** option displayed at the bottom of the popup window.



6. The Save View popup window is displayed.
7. Enter a name in the Name field.
8. (Optional) Select the required toggle buttons.
9. Click the **Save** button displayed at the bottom of the popup window.

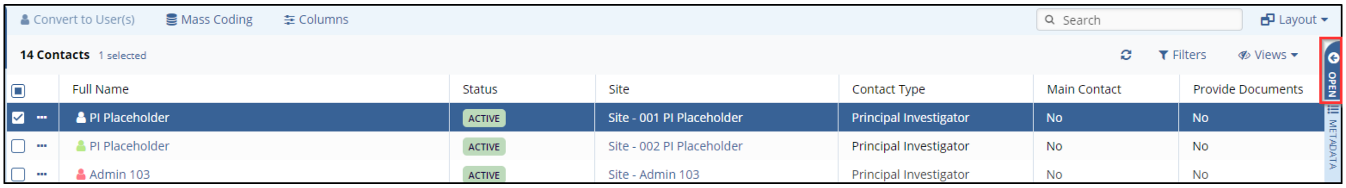


10. The selected options are reflected in the grid pane.

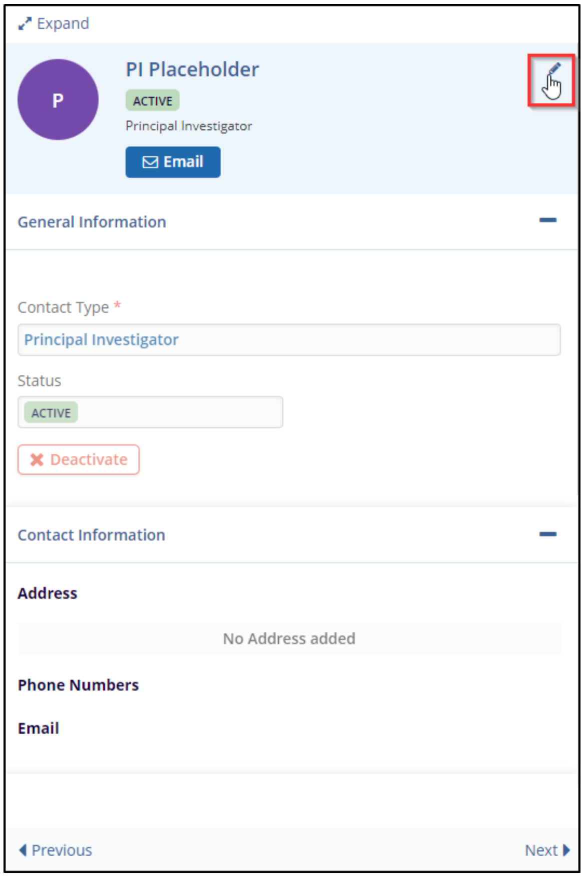
Metadata Panel

The user can make required changes to an existing contact from the metadata panel.

1. Select a checkbox of a document to edit.
2. Click the vertical **Open** button displayed on the right side of the screen.

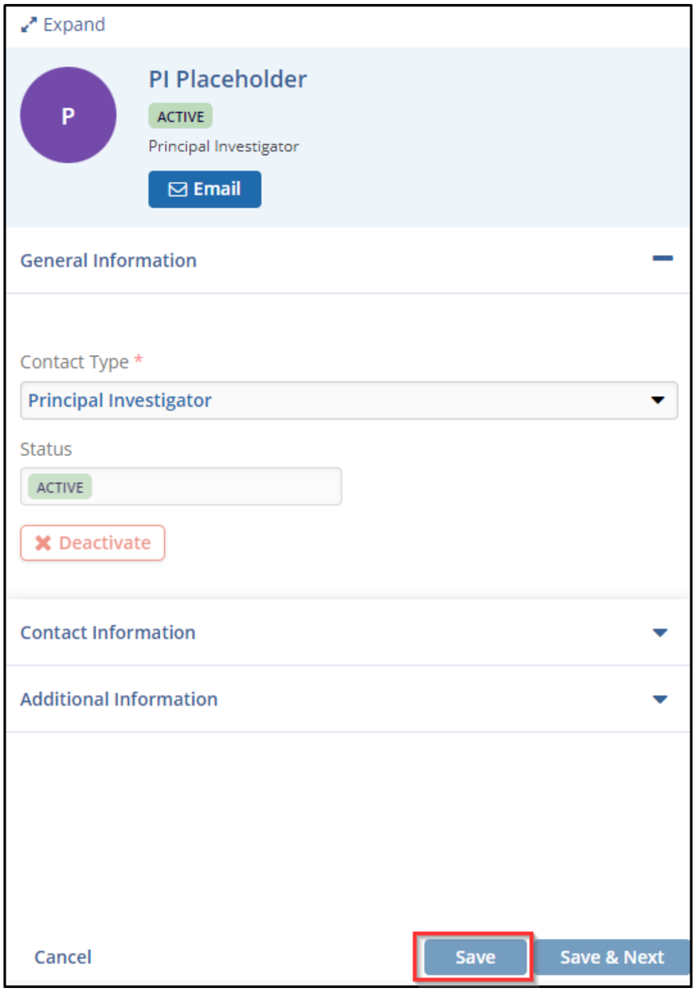


3. Click the **Pencil** icon displayed at the top right corner of the metadata panel. This enables all the fields to edit the changes.



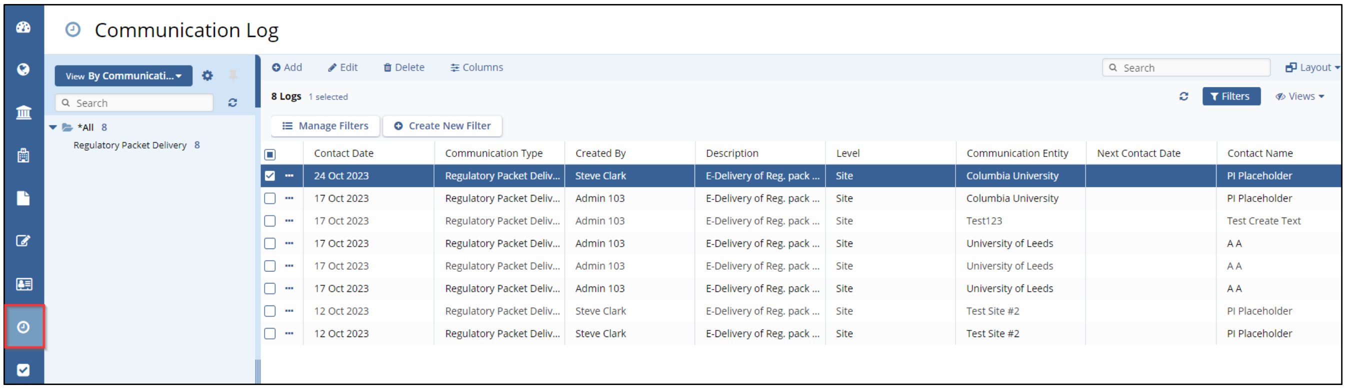
4. Make the necessary changes by manually either entering the details or selecting options from the dropdown menus.

5. Click the **Save** button displayed at the bottom of the metadata panel.



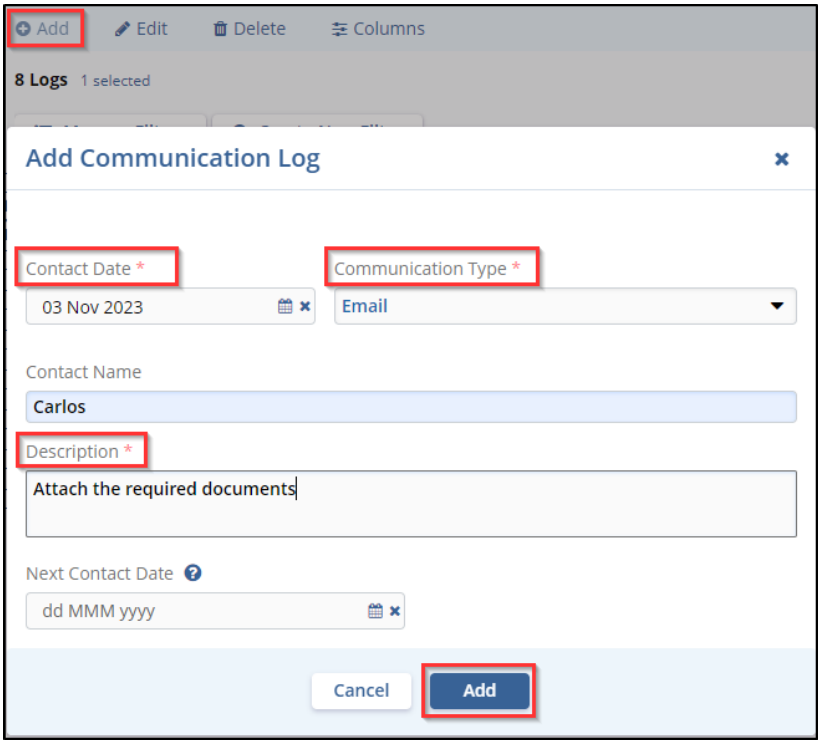
Communication Log

The communication log helps the user by displaying the communications happened over a period of time to collect different documents from the right personnel. The user can Add, Edit, Delete, Manage Columns, Search, Manage and Create New Filters in this page.



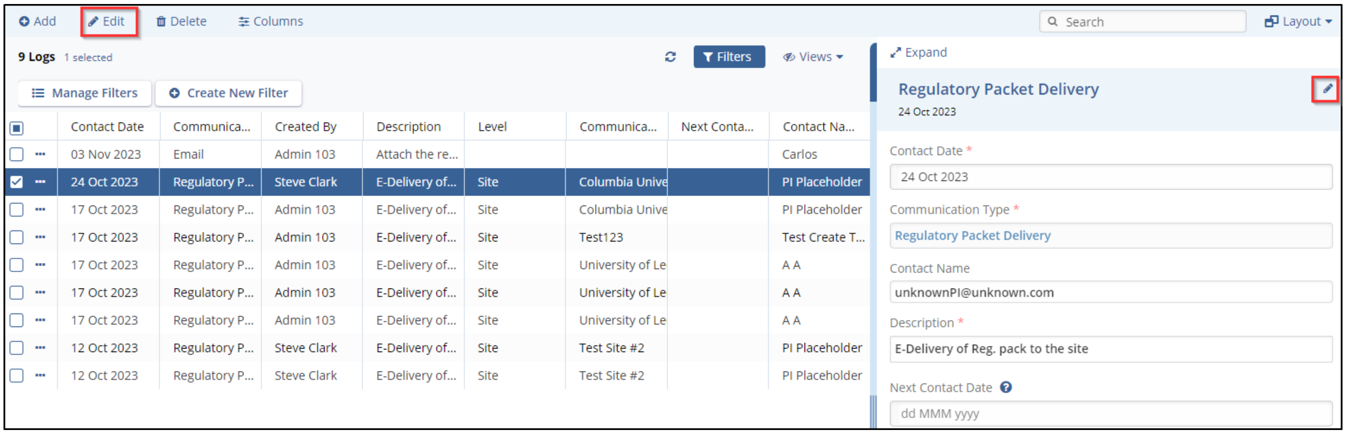
Add

1. Click the **Add** button displayed on the top menu bar. This opens the Add Communication Log popup window.
2. Enter the details in the fields – Contact Date, Communication Type, and Description. These are the mandatory fields.
3. **(Optional)** Enter the details in the Contact Name and Next Contact Date fields.
4. Click the **Add** button displayed at the bottom of the popup window.



Edit

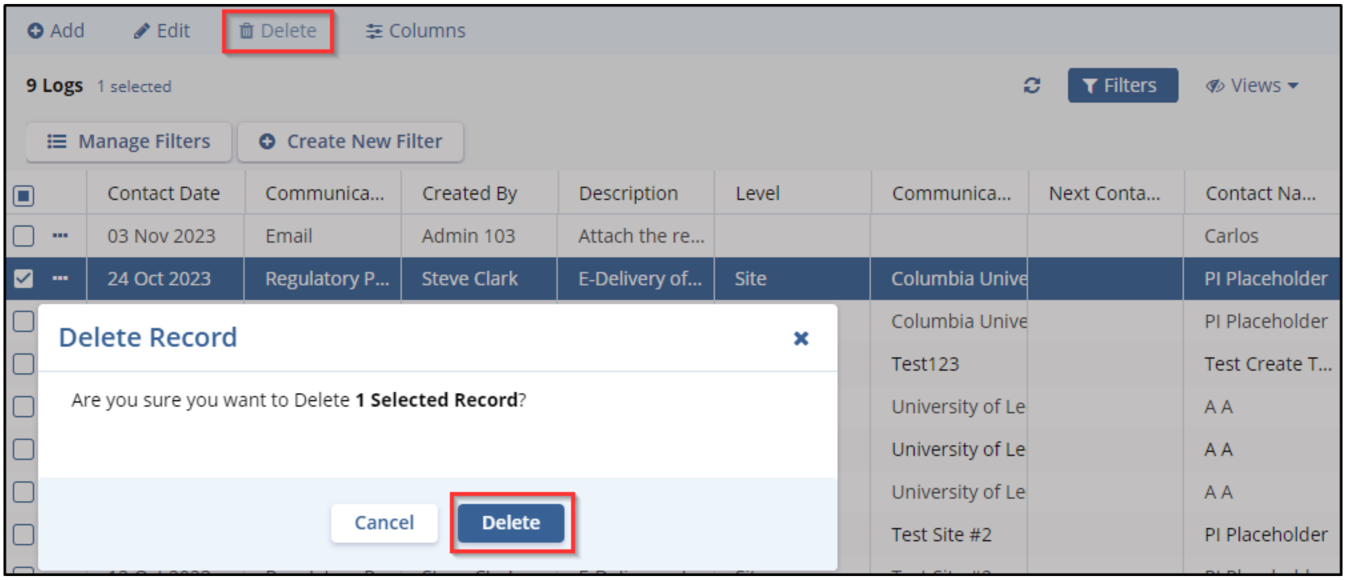
1. Select a checkbox of the log that is to be edited. This enables the Edit button on the top menu bar.
2. Click the **Edit** button from the top menu bar. Thai opens the metadata panel on the right side of the screen.
3. Click the **Pencil** icon displayed in the top right corner of the metadata panel.



4. Make the required changes and click the **Save** button displayed at the bottom of the metadata panel.

Delete

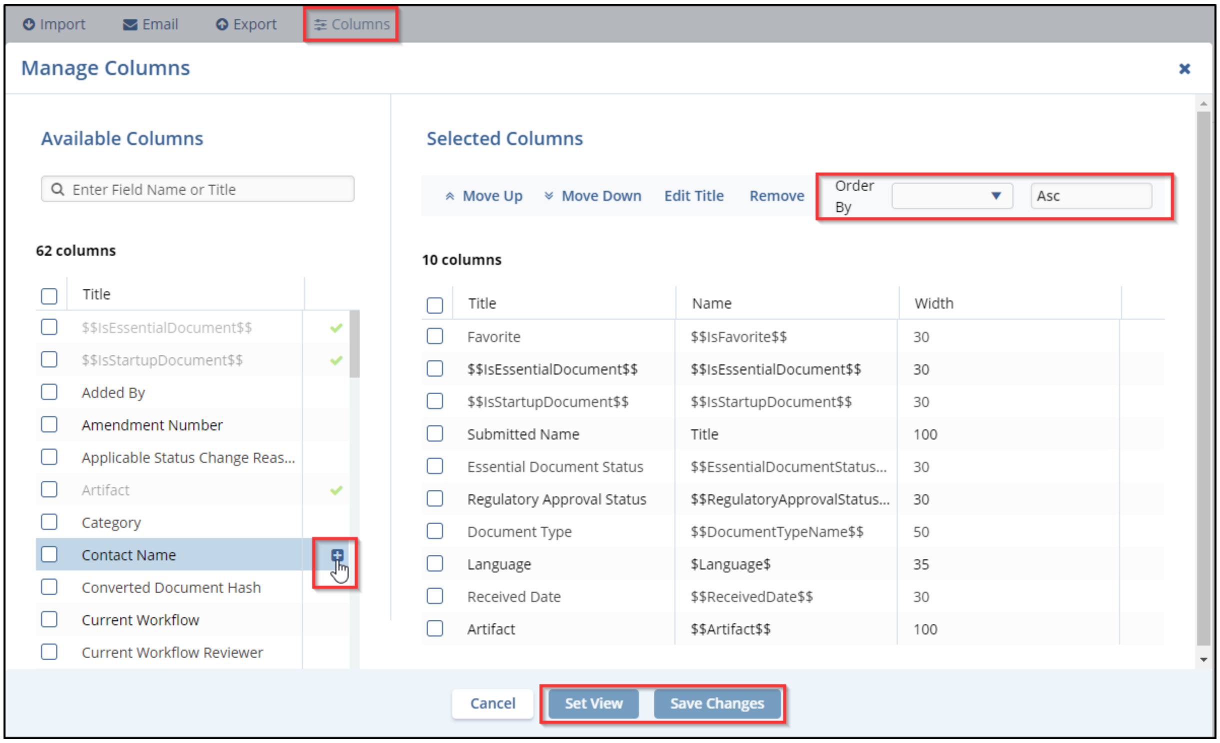
1. Select the log that is to be deleted.
2. Click the **Delete** button displayed in the top menu bar. This opens the Delete Record popup window.
3. Click the **Delete** button displayed at the bottom of the popup window.



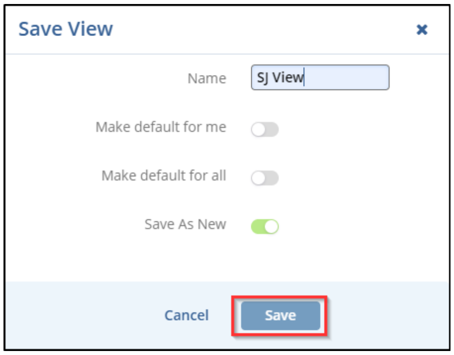
Columns

This option helps the user to select required columns to be displayed in the grid pane of the Documents section.

1. Click the **Columns** option displayed in the top menu bar.
2. This opens the Manage Columns popup window.
3. Click the **Plus** icon of the required columns from the left pane.
4. The selected columns are reflected in the right pane.
5. Click the **Set View** or **Save Changes** option displayed at the bottom of the popup window.



6. The Save View popup window is displayed.
7. Enter a name in the Name field.
8. (Optional) Select the required toggle buttons.
9. Click the **Save** button displayed at the bottom of the popup window.

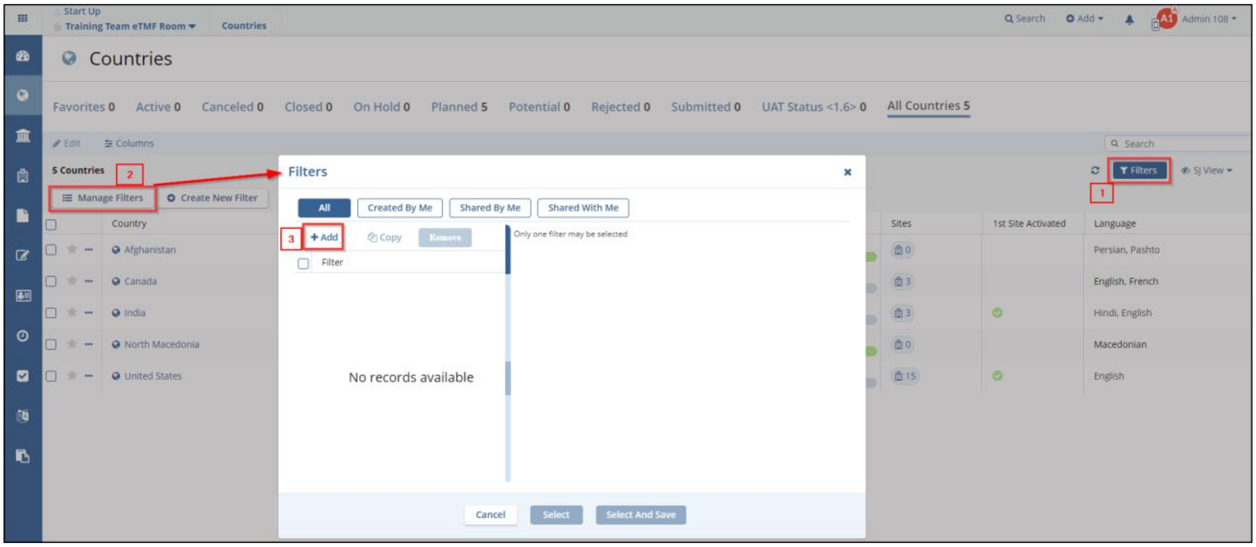


10. The selected options are reflected in the grid pane.

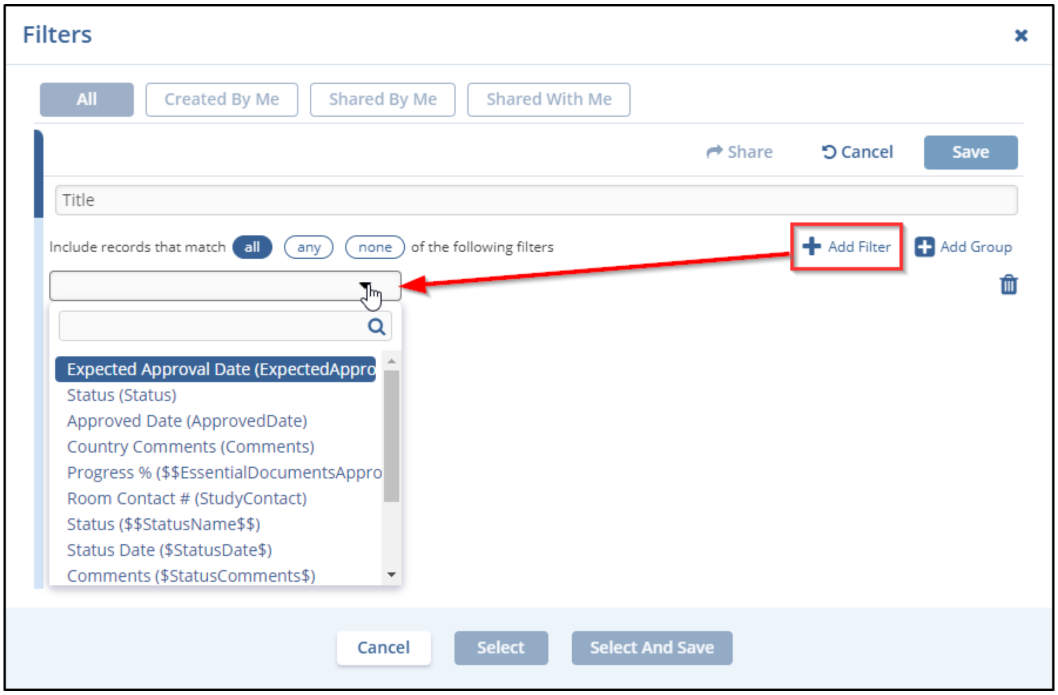
Filters

Manage Filters

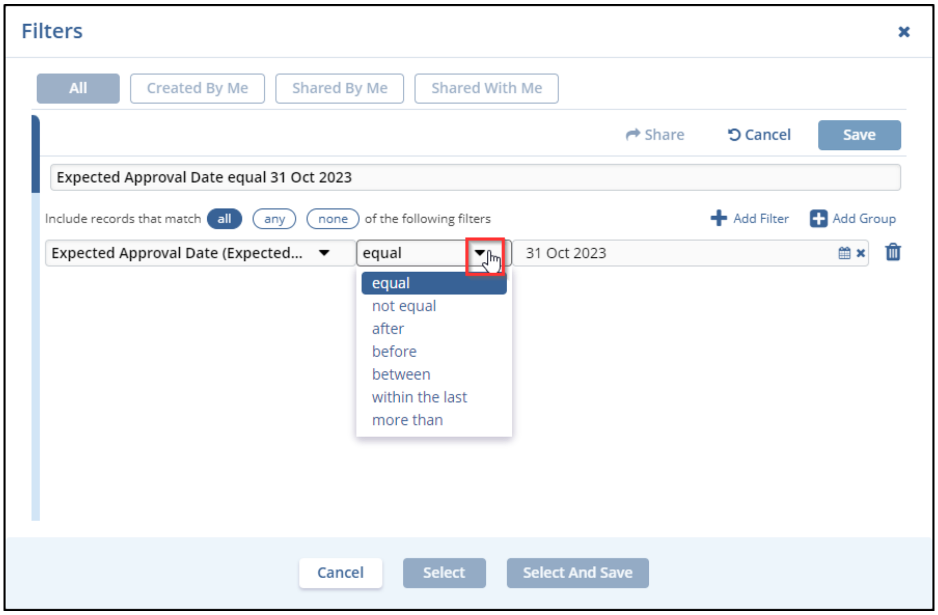
9. Click the **Filters** button displayed on the right side of the grid pane.
10. The 'Manage Filters' and 'Create New Filter' buttons are displayed.
11. Click the **Manage Filters** button to open a Filters popup window. By default, the All button is selected.
12. Click the **Add** button displayed below the All tab.

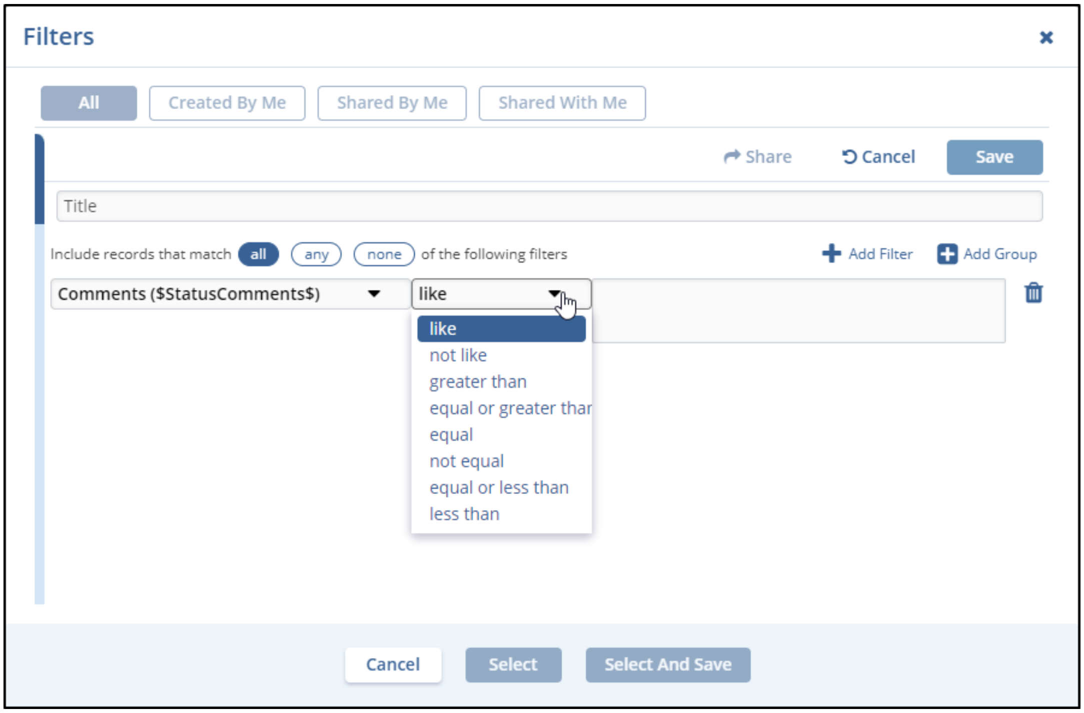


13. This opens the Title, Add Filter, Add Group tabs. Click the **Add Filter** button displayed in the right corner. A dropdown menu is displayed on the left side of the popup window.

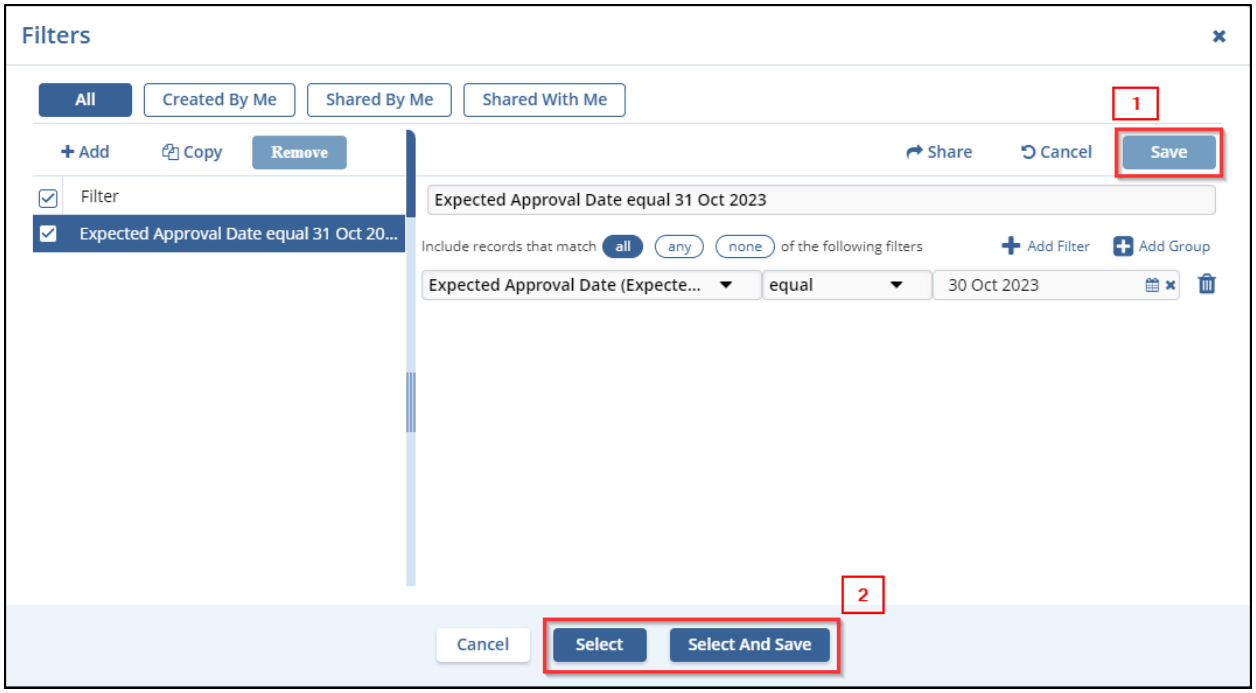


14. Select a filter from the available list. This displays another two dropdown menus on the popup window.
    Note: The other two dropdown menu options change as per the option selected in the first dropdown menu. Refer to the screenshots below.



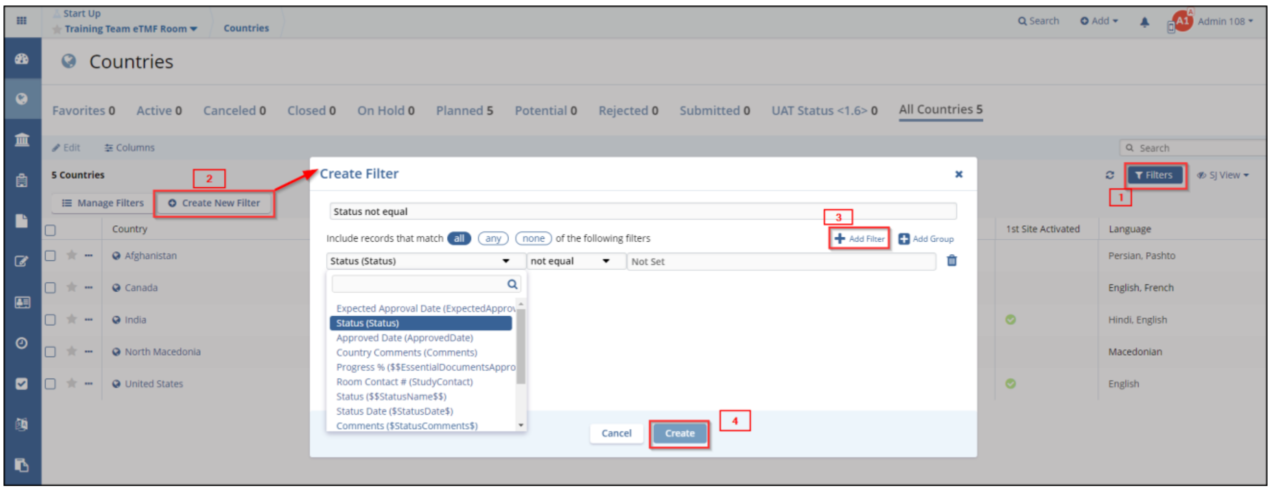


15. Click the **Save** button displayed in the top right corner of the popup window. This enables the two buttons displayed at the bottom of the popup window.
16. Click the **Select** or **Select And Save** buttons to apply the filters on the Countries.

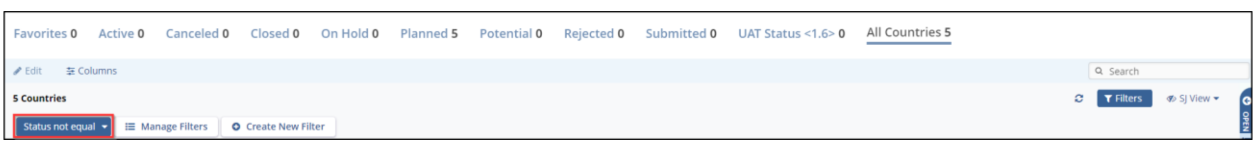


Create New Filter

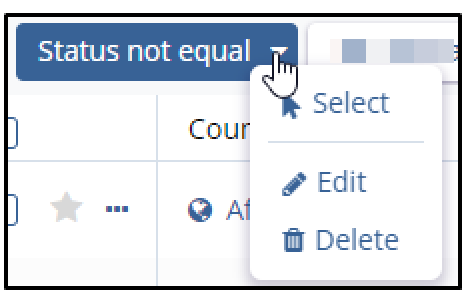
9. Click the **Filters** button displayed on the right side of the grid pane.
10. The ‘Manage Filters’ and ‘Create New Filter’ buttons are displayed.
11. Click the **Create New Filter** button to open the Create Filter popup window.
12. Click the **Add Filter** button displayed in the right corner. A dropdown menu is displayed on the left side of the popup window.
13. Select a filter from the available list. This displays another two dropdown menus on the popup window. **Note:** The other two dropdown menus change as per the option selected in the first dropdown menu.
14. Click the **Create** button displayed at the bottom of the popup window.



15. The created filter is displayed in the grid pane.



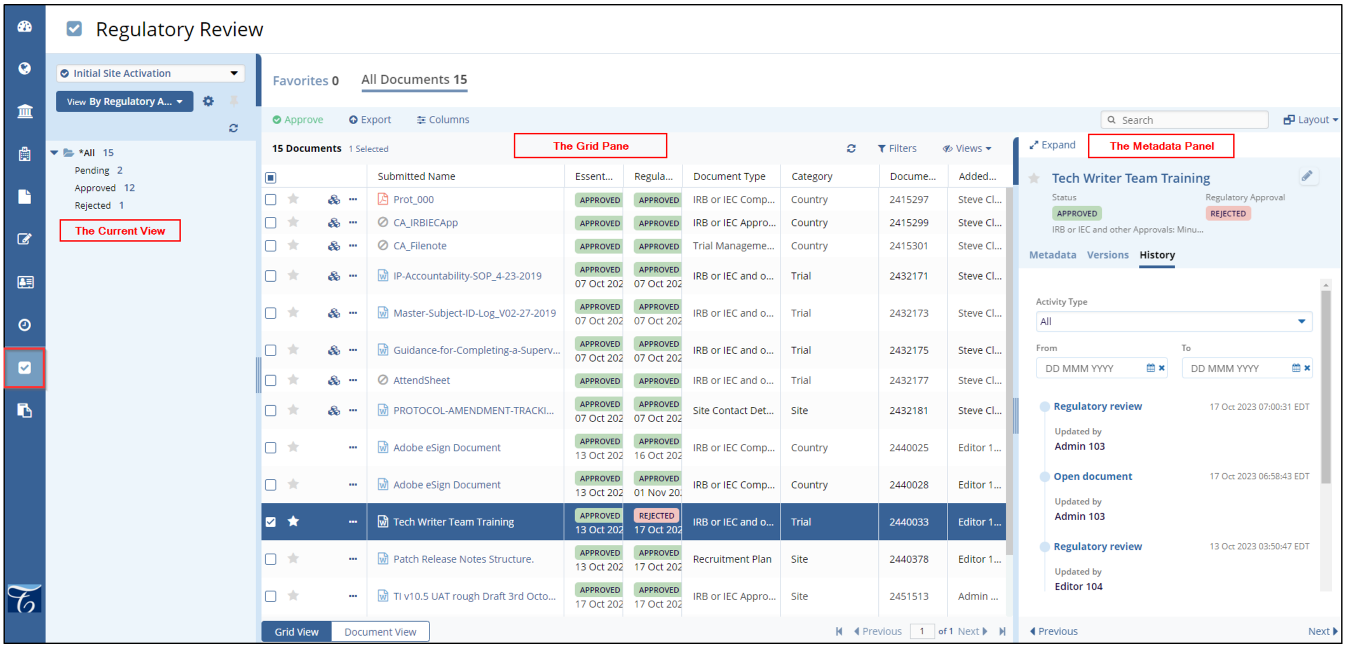
16. Click the dropdown of the created filter to edit or delete the newly created filter. Refer to the screenshot below.



Regulatory Review

From this module the regulatory reviewer can view the review statuses of the documents put up for regulatory review as well as review and approve the documents. The procedure to approve the documents by the regulatory reviewer is discussed after a brief summarization of the dashboard.

Click the **Regulatory Review** tab from the toggling menu bar to lead you to the **Regulatory Review** dashboard. The **Regulatory Review** dashboard consists of the **Current view** on the left, the Grid pane in the center, and **Document Data** panel on the right. Refer to the screenshot below.



Adding Regulatory Approvers

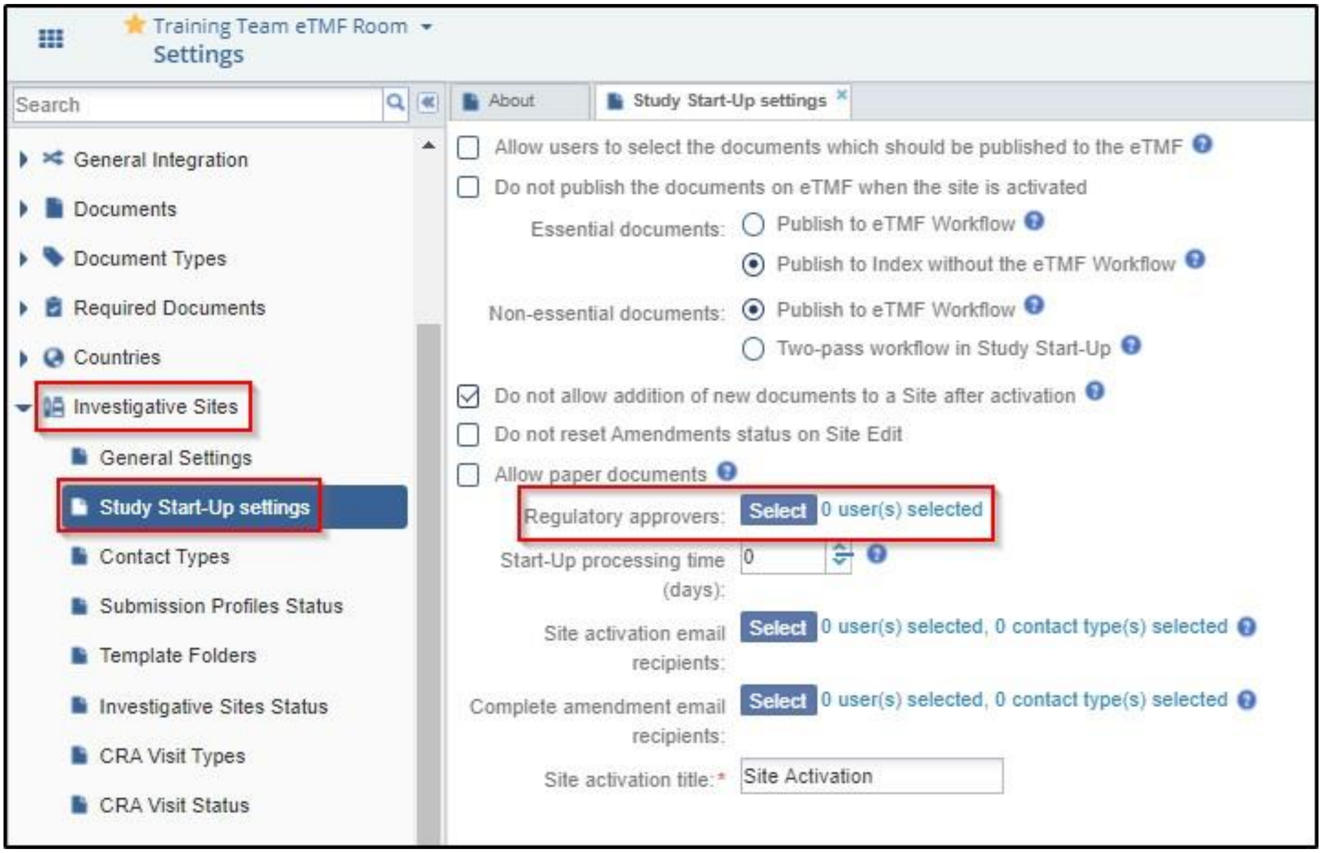
A Regulatory Approver can be a Global Regulatory Approver, Country, or Site Regulatory Approver. As a Global Regulatory Approver, you are able to perform the functions at all sites withina study room. As a Country Regulatory Approver, you are able to perform the functions at all sites in a specific country (ies). Lastly, as a Site Regulatory Approver, you are able to only perform the functions at the site(s) a room Administrator assigns.

To add Global Regulatory Approver follow the steps as below:

1. Navigate to **Settings**.

2. On the left-side panel, navigate to **Investigative Sites > Study Start-Up settings**.

3. Next to Regulatory approvers, click on Select. Add user(s) by either double clicking on the useron the left-hand side to move to the Selected Members on the right-hand side, or by dragging and dropping the user from the left-hand side to the Selected Members on the right-hand side.



Users added as Regulatory Approvers added from here will be available as Regulatory Approvers toall the sites in the room.

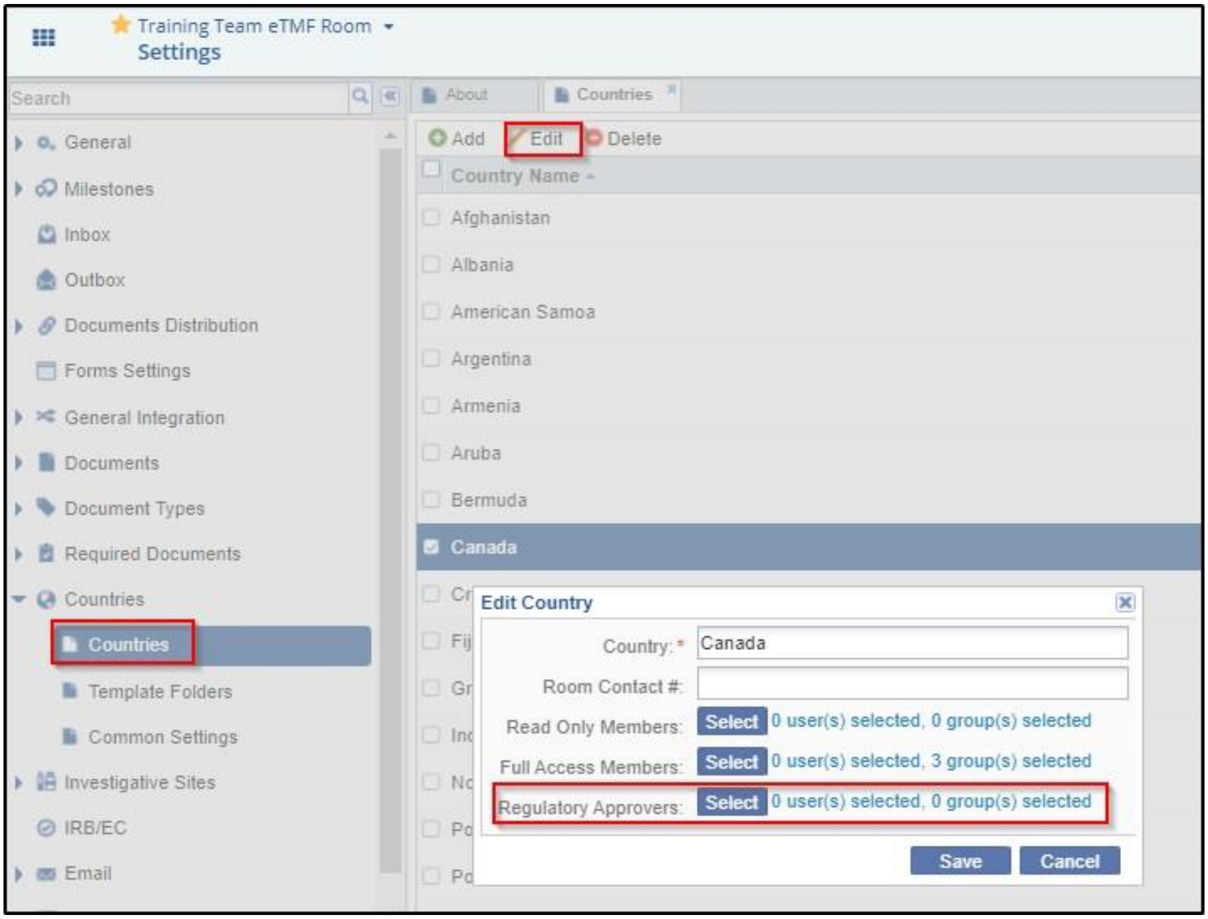
To add a Country Regulatory Approver follow the steps as below:

1. Navigate to **Settings -> Countries -> Countries**.

2. Check the box next to the country and then click **Edit**. (If the Country is not listed, click **Add** tocreate a new country).

3. Next to **Regulatory Approvers**, click **Select**. Add user(s) by either double clicking on the user onthe left-hand side to move to the **Selected Members** on the right-hand side or dragging and droppingthe user from the left-hand side to the **Selected Members** on the right-hand side.

4. Click **Save**.



5. Click **Select** to open the Regulatory Approvers windows and add the users. Click **OK**.

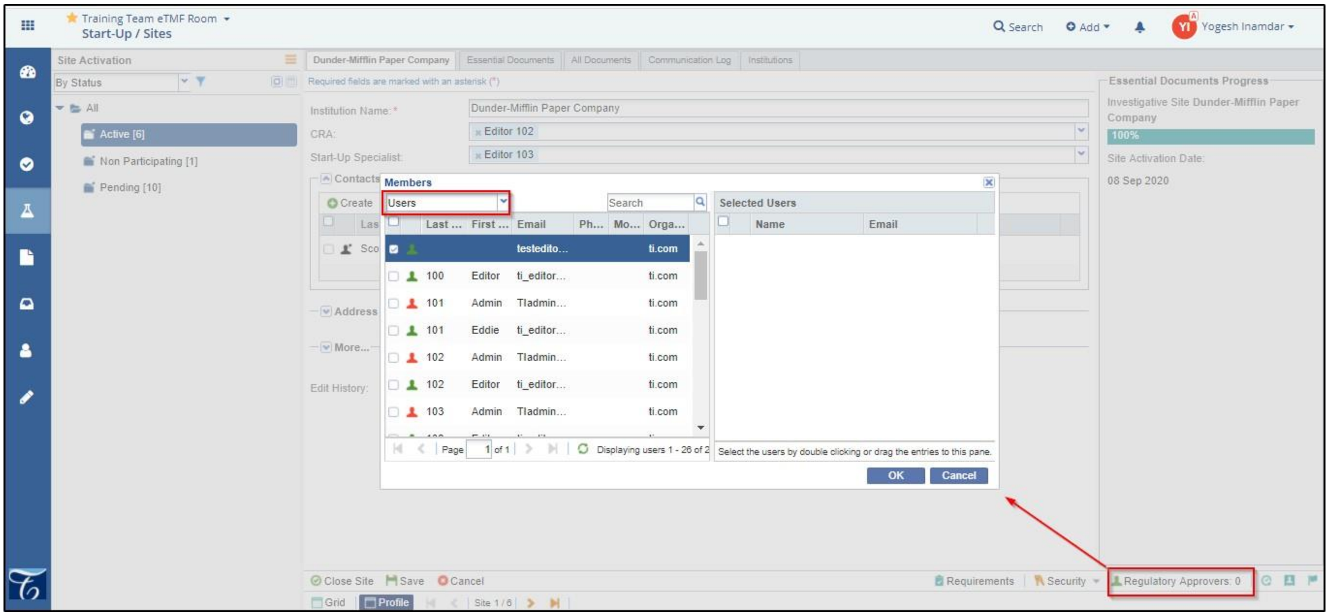
To add a Site Regulatory Approver, follow the steps as below:

1. Navigate to the **SSU module** > **Sites**.

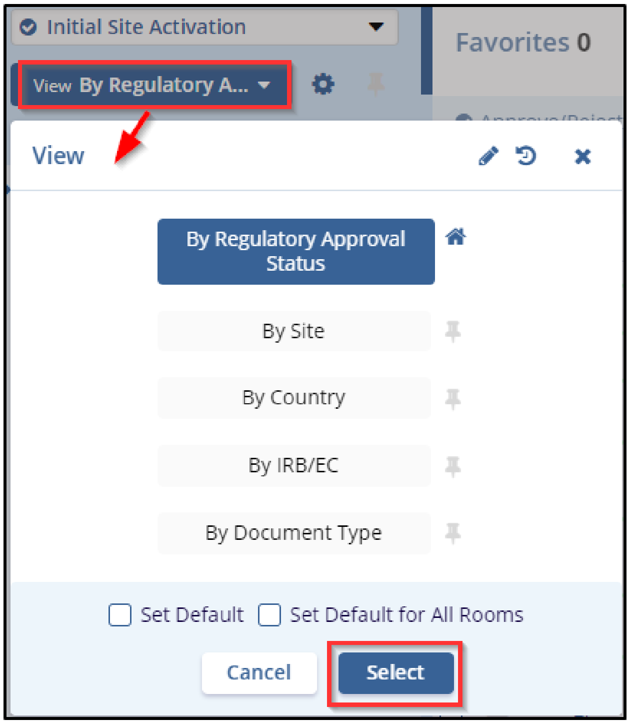
2. Double click on the site you wish to add a Site Global Regulatory Approver.

3. At the bottom right-hand corner, click on **Regulatory Approvers**. Add user(s) by either double clicking on the user on the left-hand side to move to the **Selected Members** on the right-hand side ordragging and dropping the user from the left-hand side to the **Selected Members** on the right-hand side.

4. Click **Save**.

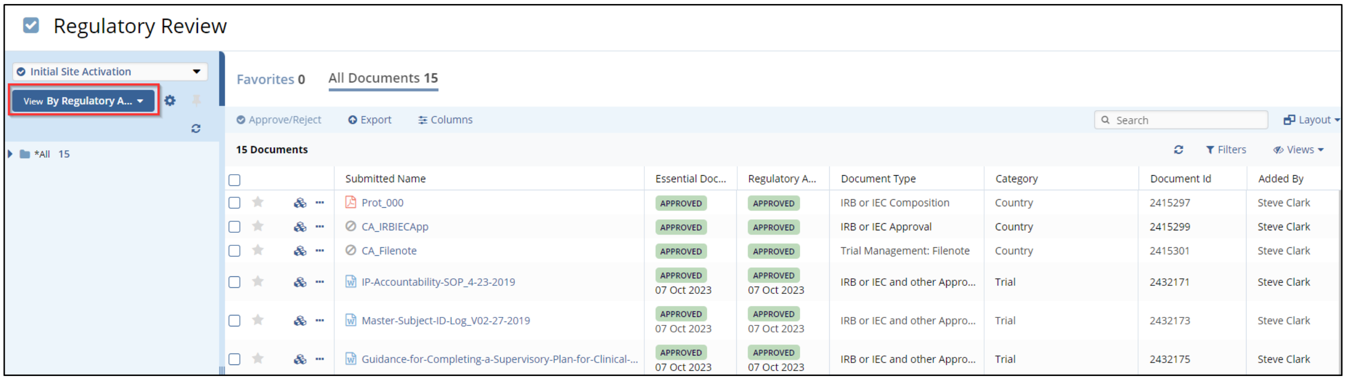


Current View

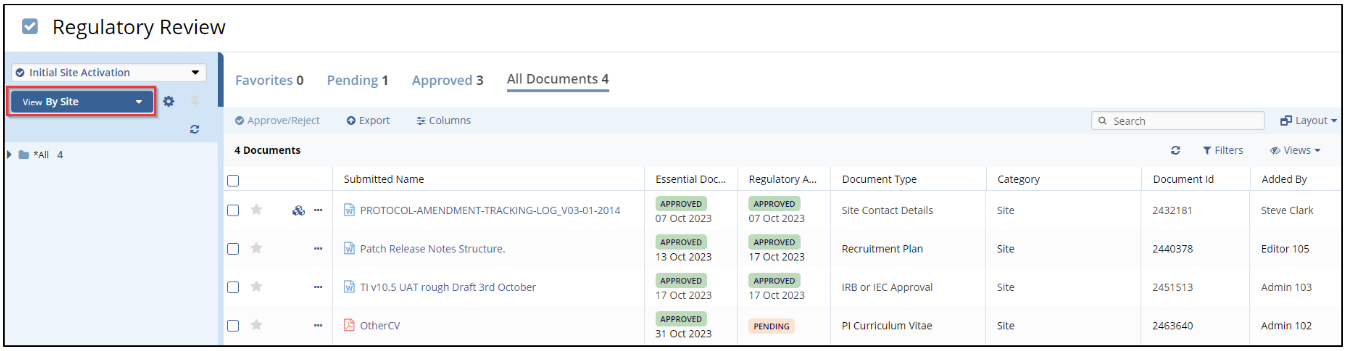


The Current View Dropdown offers five views:

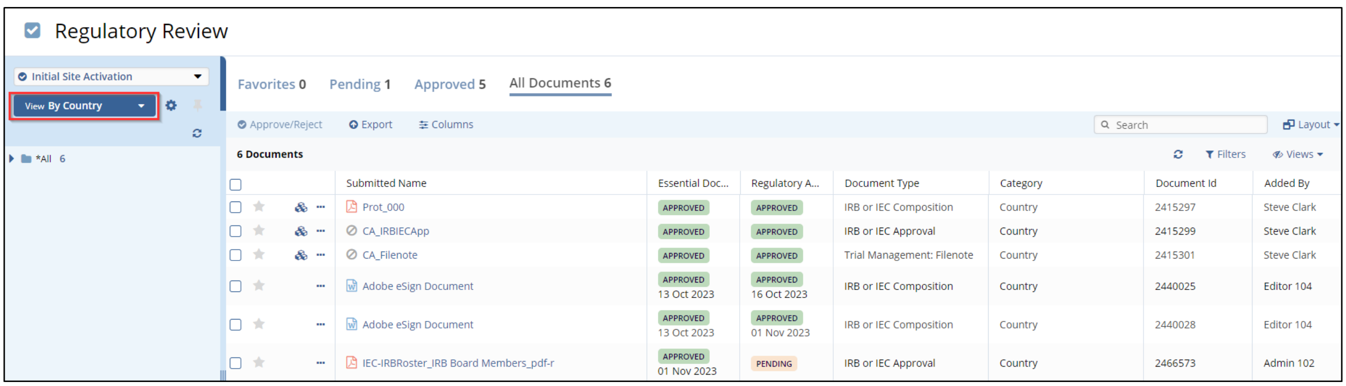
- **By Regulatory Approval Status**: The By Regulatory Approval Status groups all the documentsas per their review status i.e. Approved, Rejected and Pending. Clicking a review status group from the left panel will display the documents belonging to the particular review status group in the grid pane.



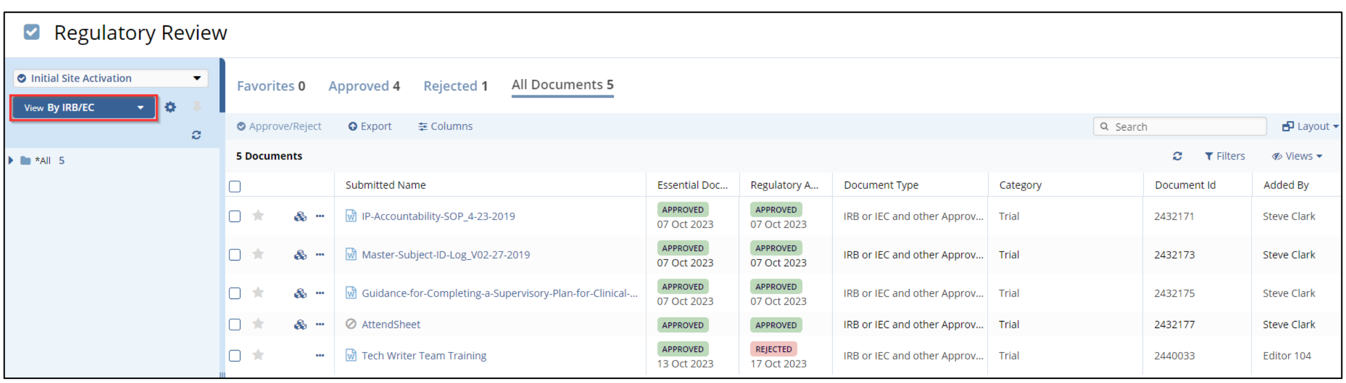
- **By Site**: The By Site option groups all the sites based on the review status of its documents. Thereview statuses of the documents could be Pending, Rejected, and Approved. Clicking a site under a particular review status will display the documents with that review status in the site in the grid pane. Refer to the screenshot below:



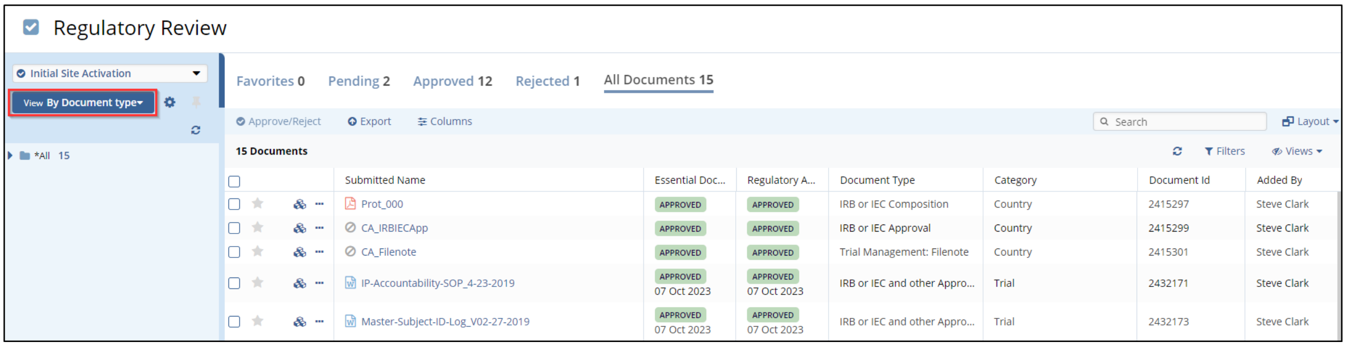
- **By Country**: The By Country option lists out the countries to which documents are added. Clicking a country from the left pane will display the documents submitted to the country alongwith their review status in the grid pane.



- **By IRB/EC:** The By IRB/EC option lists out the IRB/ECs to which documents have beenadded. Clicking an IRB/EC from the left pane will display the documents submitted to theinstitution along with their review status in the grid pane. Refer to the screenshot below:

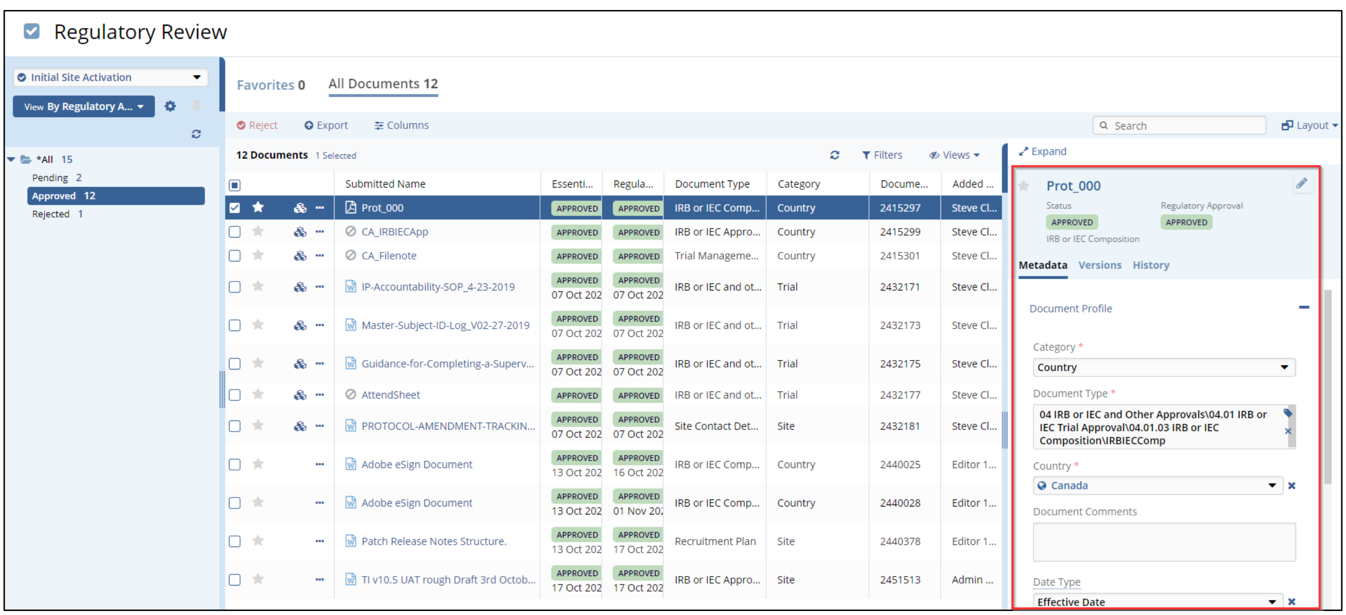


- **By Document Type**: The By Document Type options lists out the various document types available to the study start-up. Clicking a document type will display the documents submitted under that type along with their review statuses in the grid pane. Refer to the screenshot below:



Document Metadata Panel

The Document Data Panel is located on the extreme right of the dashboard and can be activated by clicking a document from the grid pane. Depending on the user's security settings and access rights and roles, this panel might be static to a user. If the user is given appropriate SSU User access rights,the data fields are editable and all changes made here must be saved.



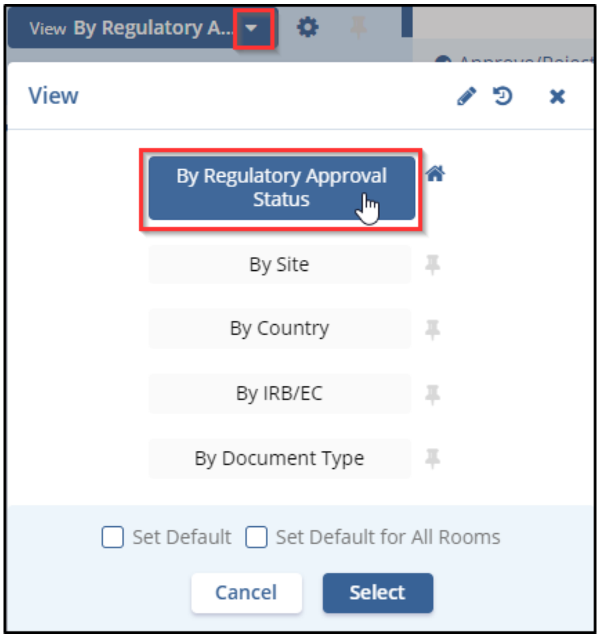
In the screenshot above, observe that the fields are non-editable. The user can switch between the Grid and the Document Data Panel by clicking any of the buttons located at the bottom of the Gridpane.

How to Regulatory Review a Document with Attachments

Once the regulatory reviewer receives an email stating about a pending review, he/she logs into TI to locate the documents waiting for review in the Regulatory Review section.

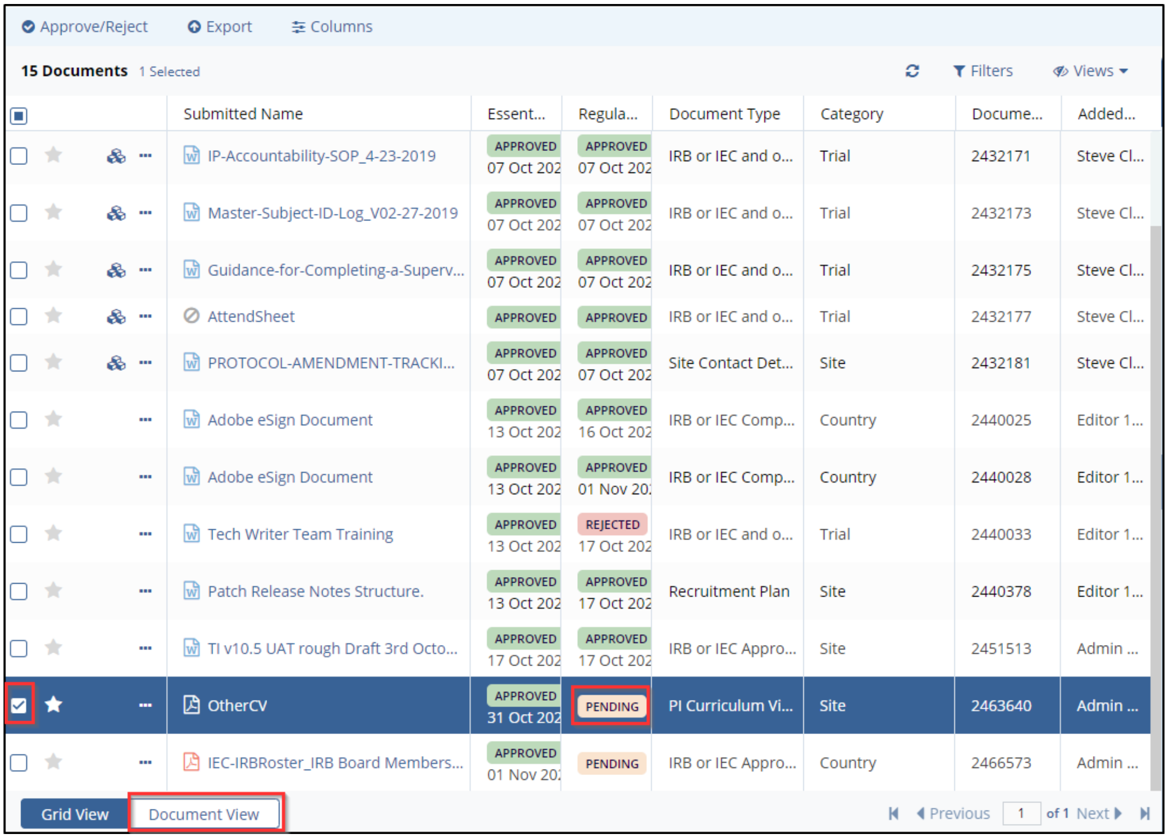
Steps to Regulatory Review a Document

1. The easiest way to find out all the documents in the Study Start-Up waiting for regulatory review is to activate the **By Regulatory Approval** Status view from the left panel which lists out all the documents in the SSU pending for approval.



2. Select the checkbox of the file that displays **Pending** status.

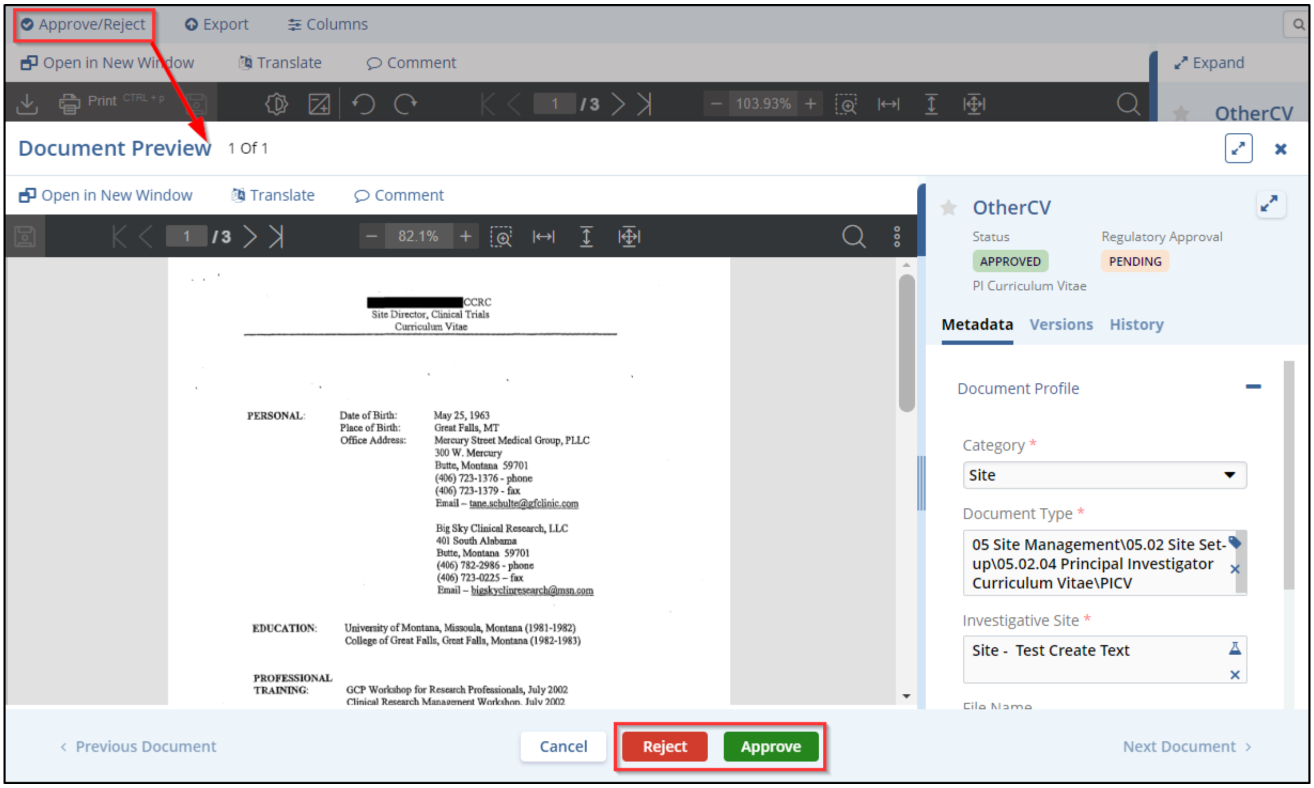
3. Click the **Document View** button displayed at the bottom if the grid pane. The document opens in the grid pane.



4. Click the **Approve/Reject** button displayed in the top menu bar. This opens the document in the ‘Document Preview’ popup window.

5. Verify if the contents in the selected document are as appropriate.

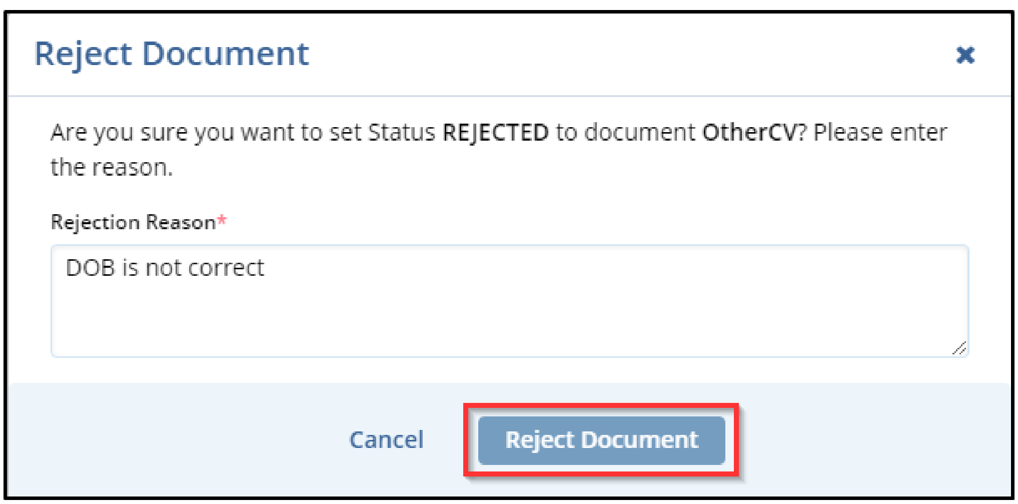
6. Click the **Reject** or **Approve** button displayed at the bottom of the popup window.



7. If the Reject button is selected, the ‘Reject Document’ popup window is displayed.

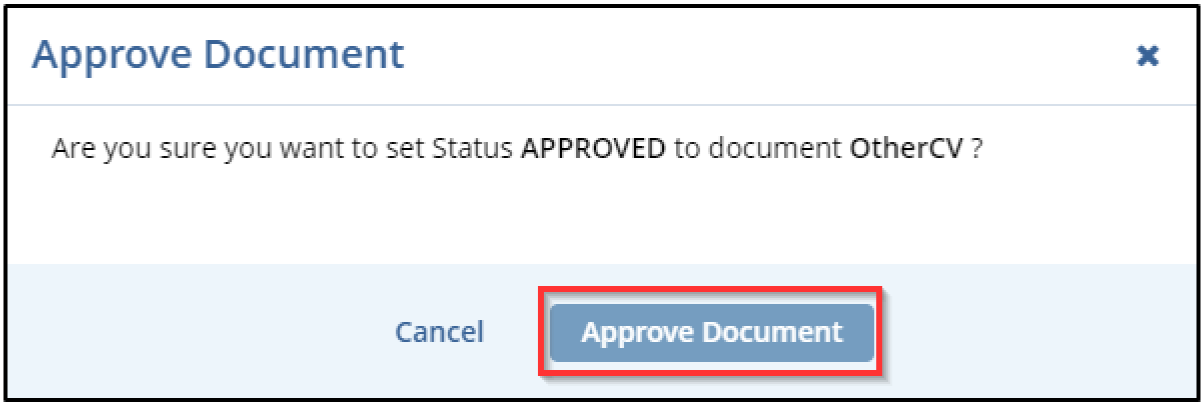
8. Enter a rejection reason in the empty field. (Mandatory).

9. Click the **Reject Document** button displayed at the bottom of the popup window.



10. If the Approve button is selected, the Approve Document popup window is displayed asking if the document is to be approved.

11. Click the **Approve Document** button displayed at the bottom of the popup window.



Depending upon the decision taken, a message will pop up indicating that the change is nowcommitted to the database. The document is now locked and cannot be opened for review again. The Regulatory Approval Status of the documents throughout the SSU will now reflect the appropriate status from Pending toApproved, or Rejected. The Document button at the bottom of the dashboard, and the Approve or Reject buttons are now disabled to prevent further changes.

Regulatory Review of Paper Documents/Documents without attachments

As discussed in earlier sections, paper documents go without attachments. In such a case, the Approve, and Reject buttons will be placed above the Regulatory Review documents grid, so it will not be required to open the document in a viewer to approve/reject it. The rest of the approval/rejection process remains the same.

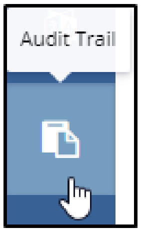
Audit Trail

Audit Trail is a security-relevant chronological set and source of records, that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed in this section. The subsequent section describes in detail the filters available for the audit trail.

Note: By default, the audit trail's grid pane is empty and the documents are displayed only after entering username in the 'Select Created By' field and clicking the **Apply** button displayed in the top right corner.

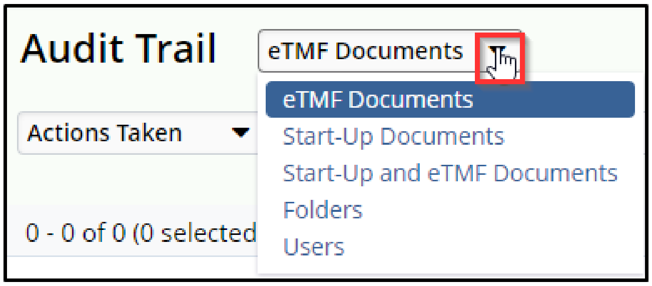
Filters for Audit Trail

To view the Audit Trail section, click on the **Audit Trail** icon from the toggling menu bar. By default, the page displays only the filters available for searching a document. Refer to the screenshot below.



Options

The user has five parameters from the dropdown to select to filter this section: eTMF Documents, Start-Up Documents, Start-Up and eTMF Documents, Folders, and Users. Refer to the screenshot below.

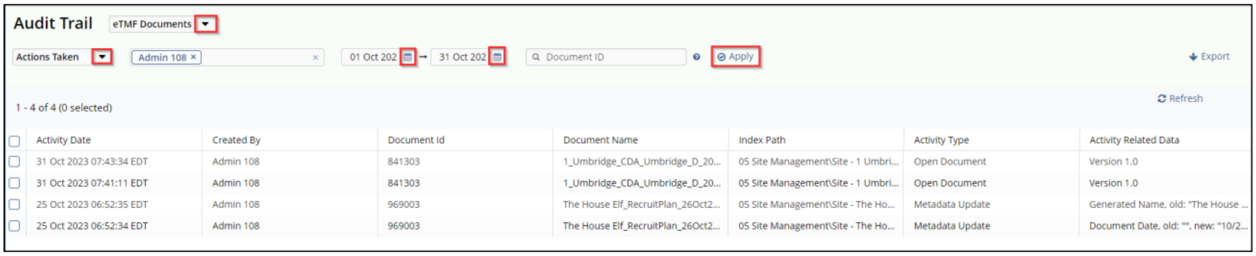


Note: The Audit Trail User Interface changes as per the option selected from this dropdown menu.

User Interface for eTMF and Start-Up Documents

Follow the steps below to view the audit trail for eTMF Documents:

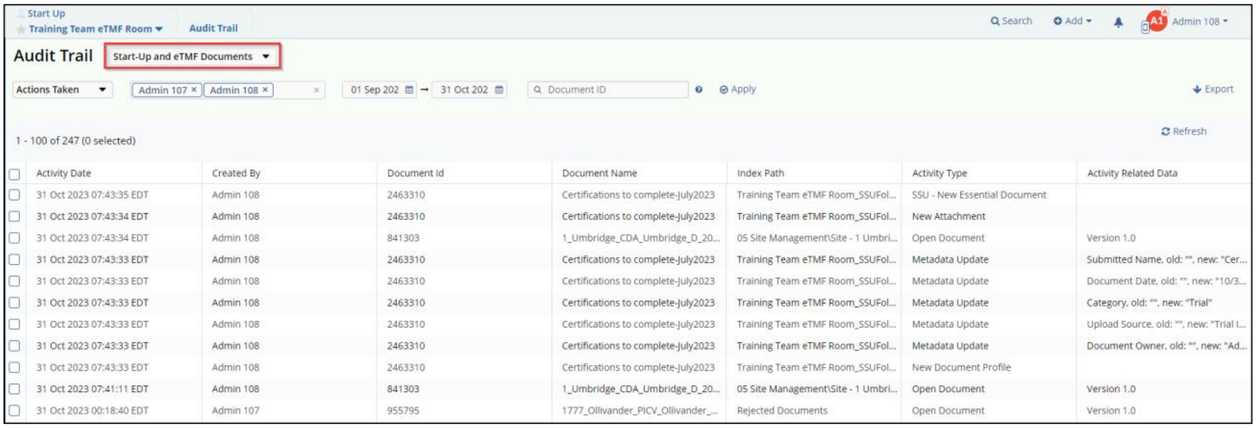
8. Click the dropdown menu displayed next to the Audit Trail page Title.
9. Select the **eTMF Documents** option to search documents –
10. Select the appropriate option from the Actions Taken dropdown menu.
11. Enter name(s) in the Created by field.
12. Click the Calendar icon to select the Start and End date for the documents.
13. (Optional) Enter the Document ID in the last field.
14. Click the **Apply** button. Refer to the screenshot below.



Activity Date	Created By	Document Id	Document Name	Index Path	Activity Type	Activity Related Data
31 Oct 2023 07:43:34 EDT	Admin 108	841303	1_Umbridge_CDA_Umbridge_D_20...	05 Site Management\Site - 1 Umbri...	Open Document	Version 1.0
31 Oct 2023 07:41:11 EDT	Admin 108	841303	1_Umbridge_CDA_Umbridge_D_20...	05 Site Management\Site - 1 Umbri...	Open Document	Version 1.0
25 Oct 2023 06:52:35 EDT	Admin 108	969003	The House Elf_RecruitPlan_26Oct2...	05 Site Management\Site - The Ho...	Metadata Update	Generated Name, old: "The House ...
25 Oct 2023 06:52:34 EDT	Admin 108	969003	The House Elf_RecruitPlan_26Oct2...	05 Site Management\Site - The Ho...	Metadata Update	Document Date, old: "", new: "10/2...

User Interface for Start-Up and eTMF Documents

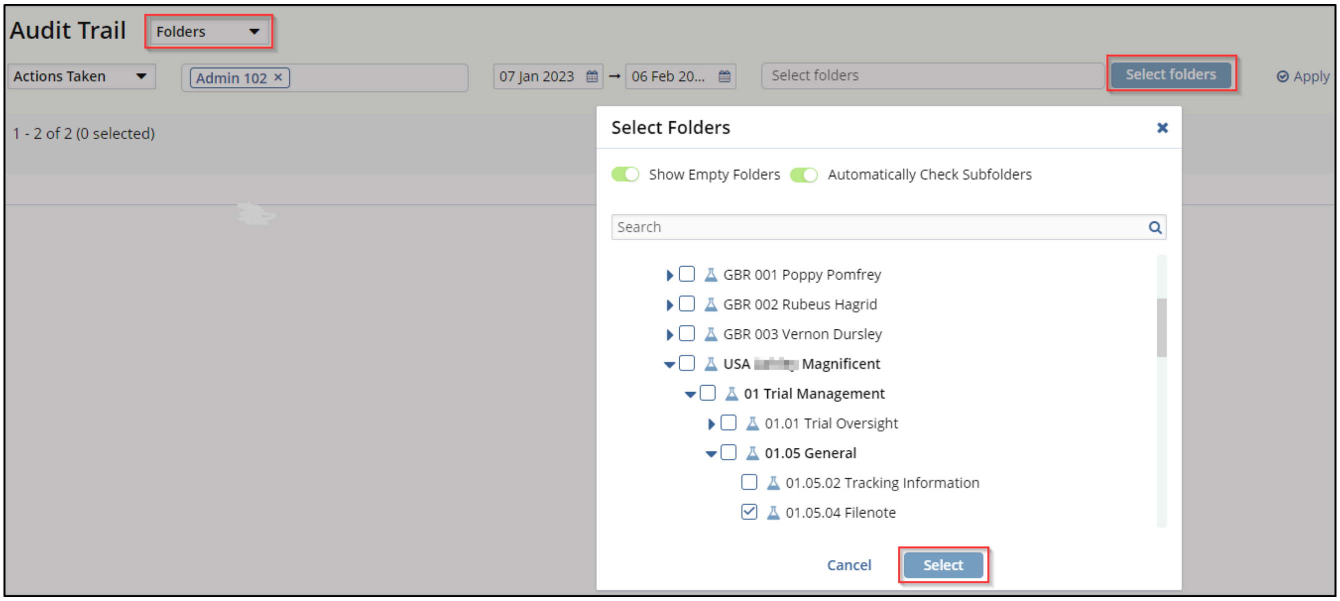
This feature helps the user to search and apply filters combinedly for eTMF and Start-Up module. Refer to the **User Interface for eTMF and Start-Up Documents** page for more details.



Activity Date	Created By	Document Id	Document Name	Index Path	Activity Type	Activity Related Data
31 Oct 2023 07:43:35 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	SSU - New Essential Document	
31 Oct 2023 07:43:34 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	New Attachment	
31 Oct 2023 07:43:34 EDT	Admin 108	841303	1_Umbridge_CDA_Umbridge_D_20...	05 Site Management\Site - 1 Umbri...	Open Document	Version 1.0
31 Oct 2023 07:43:33 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	Metadata Update	Submitted Name, old: "", new: "Cer...
31 Oct 2023 07:43:33 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	Metadata Update	Document Date, old: "", new: "10/3...
31 Oct 2023 07:43:33 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	Metadata Update	Category, old: "", new: "Trial"
31 Oct 2023 07:43:33 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	Metadata Update	Upload Source, old: "", new: "Trial I...
31 Oct 2023 07:43:33 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	Metadata Update	Document Owner, old: "", new: "Ad...
31 Oct 2023 07:43:33 EDT	Admin 108	2463310	Certifications to complete-July2023	Training Team eTMF Room_SSUFol...	New Document Profile	
31 Oct 2023 07:41:11 EDT	Admin 108	841303	1_Umbridge_CDA_Umbridge_D_20...	05 Site Management\Site - 1 Umbri...	Open Document	Version 1.0
31 Oct 2023 00:18:40 EDT	Admin 107	955795	1777_Ollivander_PICV_Ollivander_...	Rejected Documents	Open Document	Version 1.0

User Interface for Folders

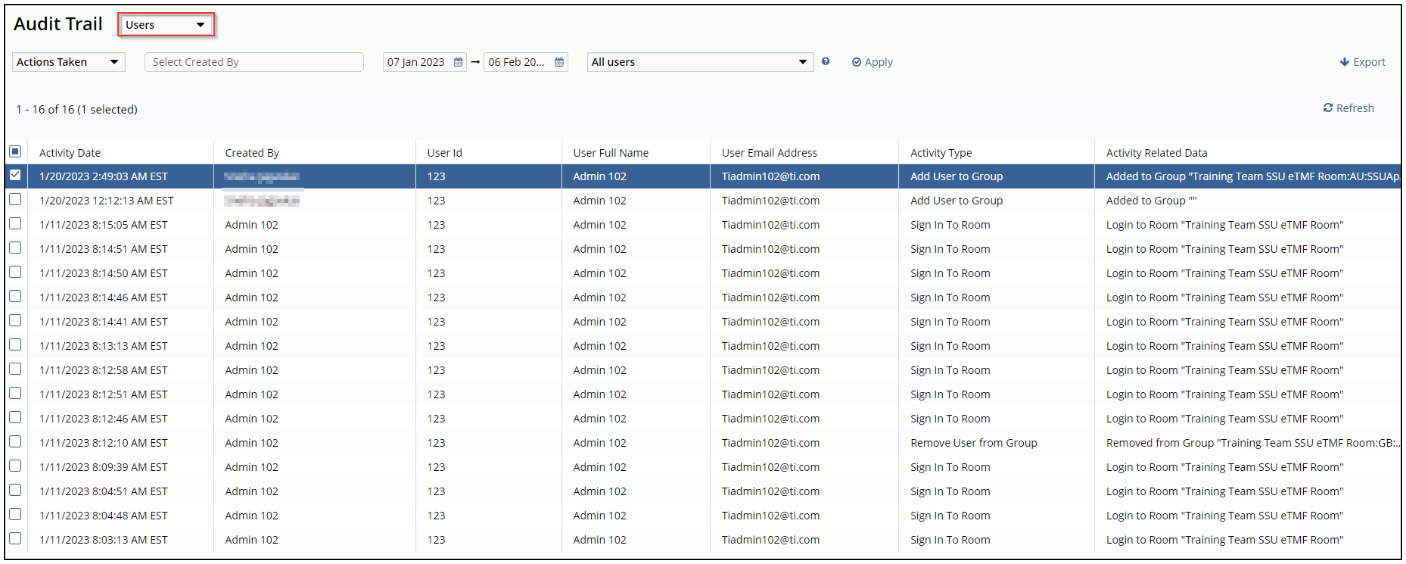
Select the Folders option to search documents – Actions Taken, Created by, Start and End date, and Document ID. Refer to the screenshot below.



The user can search for a document in the Select Folders popup window to select the correct document.

User Interface for Users

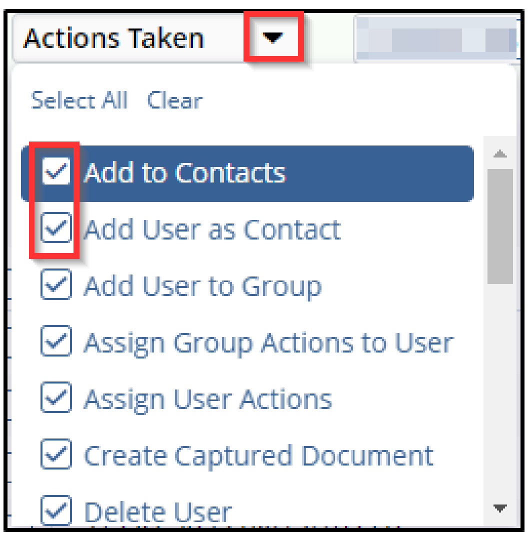
Select the Users option to search documents – Actions Taken, Created by, Start and End date, and All Users dropdown menu. Refer to the screenshots below.



	Activity Date	Created By	User Id	User Full Name	User Email Address	Activity Type	Activity Related Data
☑	1/20/2023 2:49:03 AM EST	[illegible]	123	Admin 102	Tiadmin102@ti.com	Add User to Group	Added to Group "Training Team SSU eTMF Room:AU:SSUAp
☐	1/20/2023 12:12:13 AM EST	[illegible]	123	Admin 102	Tiadmin102@ti.com	Add User to Group	Added to Group ""
☐	1/11/2023 8:15:05 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:14:51 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:14:50 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:14:46 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:14:41 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:13:13 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:12:58 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:12:51 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:12:46 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:12:10 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Remove User from Group	Removed from Group "Training Team SSU eTMF Room:GB:...
☐	1/11/2023 8:09:39 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:04:51 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:04:48 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"
☐	1/11/2023 8:03:13 AM EST	Admin 102	123	Admin 102	Tiadmin102@ti.com	Sign In To Room	Login to Room "Training Team SSU eTMF Room"

Actions Taken Dropdown

This dropdown displays a list of actions to be selected from the dropdown menu for filtering the documents. Select one, few, or all checkbox(s) to apply the required filter. By default, all checkboxes are selected. Refer to the screenshot below.

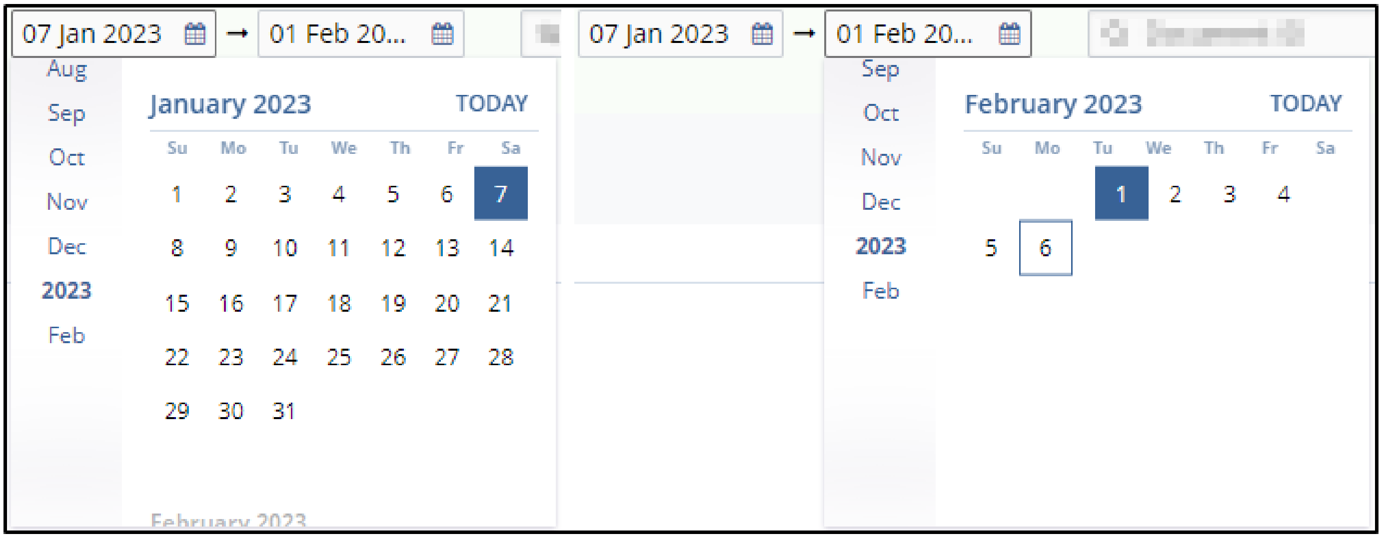


Select Created By Filter

Enter a username in this field to search for a document. Click **Apply**, displayed on the right side, to view the search results. Refer to the screenshot below.

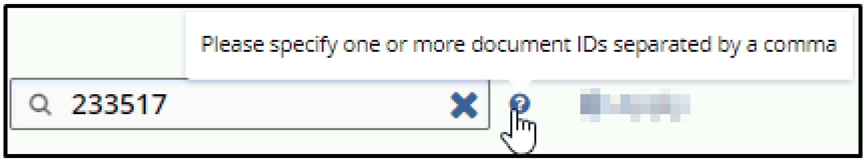
Date Filter

Select the dates in these fields to search a document. By default, the start date is set for the previous month, and the end date is set for today. Click the calendar icon 'To-From' to select dates and apply the filter. Click the **Apply** button, displayed on the right side, to view the search results. User can select dates from the previous year too by scrolling up on the Months field. Refer to the screenshot below.



Document ID Filter

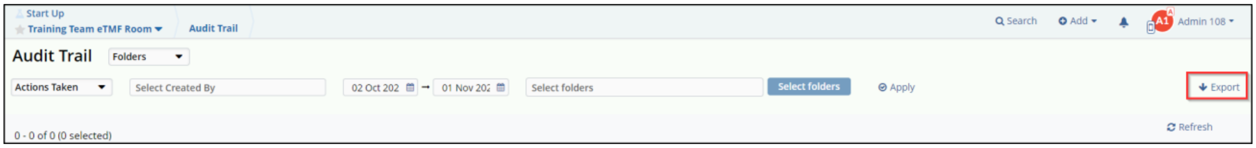
This field helps the user to find a document by the ID number. Enter the document ID and click the **Apply** button displayed on the right side, to view the search results. Refer to the screenshot below.



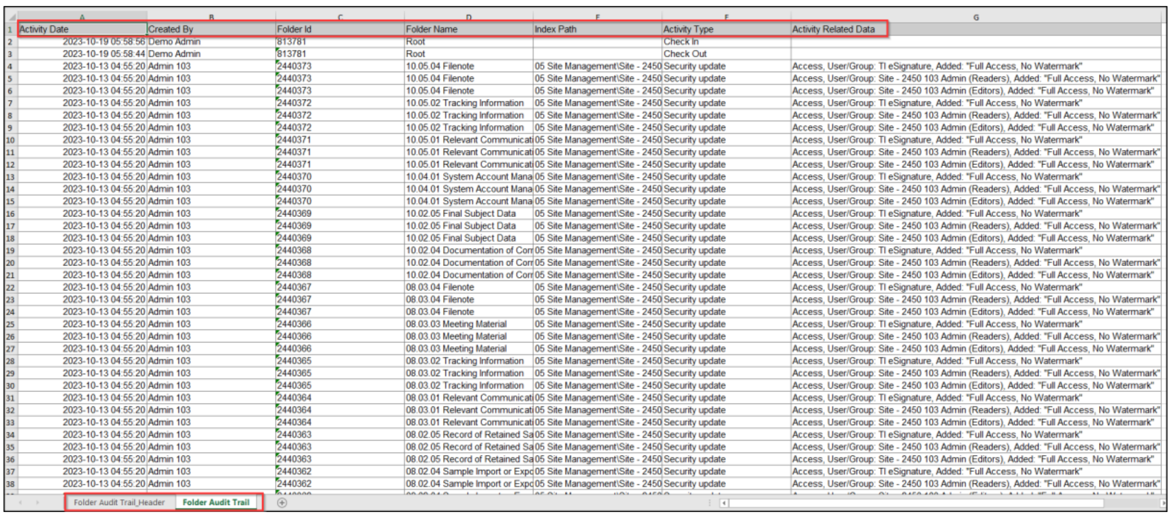
Export

The user can export the Audit Trail in an Excel sheet for reference. Follow the steps below to export.

3. Click the **Export** button displayed in the right corner, to view the details of the audit trail in an excel sheet.



4. Click on **Get Job Result** button displayed in the notification on the top right corner. The document is downloaded and is reflected in the Downloads folder of your system. The Excel sheet displays two tabs – **Folder Audit Trail Header and Folder Audit Trail**. Refer to the screenshot below for the details of the columns available in the Excel sheet.



	Activity Date	Created By	Folder Id	Folder Name	Index Path	Activity Type	Activity Related Data
2	2023-10-19 05:58:56	Demo Admin	813781	Root		Check In	
3	2023-10-19 05:58:44	Demo Admin	813781	Root		Check Out	
4	2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
5	2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
6	2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
7	2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
8	2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
9	2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
10	2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
11	2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
12	2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
13	2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
14	2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
15	2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
16	2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
17	2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
18	2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
19	2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Cor	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
20	2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Cor	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
21	2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Cor	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
22	2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
23	2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
24	2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
25	2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
26	2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
27	2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
28	2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
29	2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
30	2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
31	2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
32	2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
33	2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communicati	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
34	2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
35	2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
36	2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
37	2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Expc	05 Site Management\Site - 2450	Security update	Access, User/Group: TI eSignature, Added: "Full Access, No Watermark"
38	2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Expc	05 Site Management\Site - 2450	Security update	Access, User/Group: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"

Folder Audit Trail_Header | Folder Audit Trail

The **Activity Related Data** column displays the activities carried out over a document.

Refresh

Click the **Refresh** button displayed at the top right corner to update the list of searched documents.

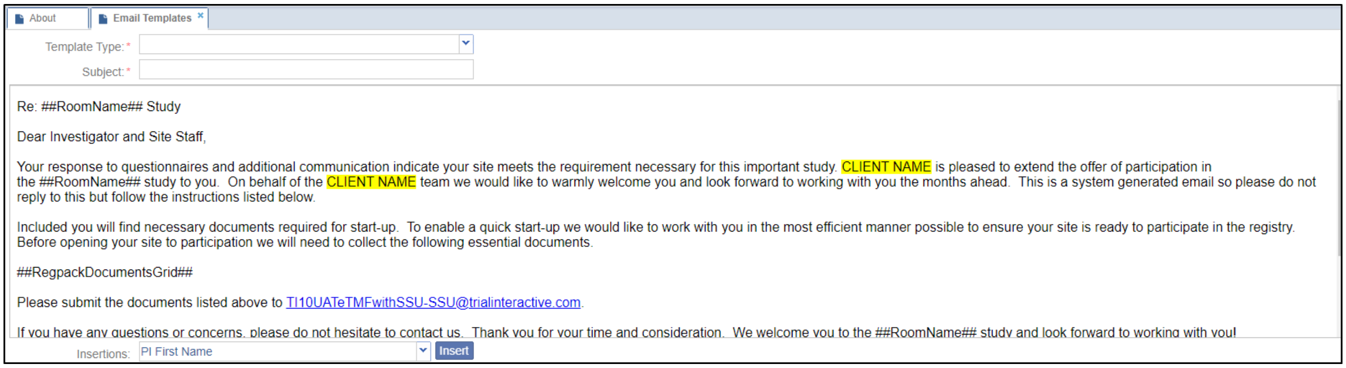
Regulatory Packets

When all required documents are collected, the Start-Up Specialists, or the sponsor, or CRO forwards an initial regulatory documents packet for collecting the documents from various contacts in the site. Main contacts receive emails with a list of regulatory documents required. If no main contacts are specified for a site, then the Principal Investigator of the site will receive the email. The administrator can set up the email template that would be sent out with regulatory packets. The email can also include document templates as attachments for specific document types if the clinical research enterprise wants to adhere to specific formats for the documents. The Main contacts, on receiving the email, go about the task of collecting the documents, getting them approved from the Principal Investigator, and submitting them to the site. They can submit documents to the site by logging into the site and adding them, or by emailing them to the room. If the documents are emailed into the room, it is the SSU Specialists' responsibility to add them to the sites.

You can choose to send regulatory packets for one or multiple sites. Before sending regulatory packets, administrator can set up email templates and document templates for specific document types as required.

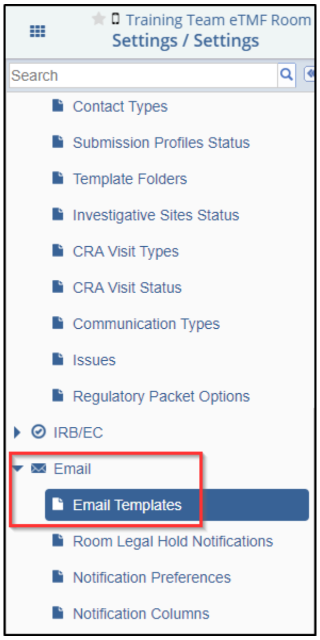
Setting Up Email Templates

The administrator can set up the body of the email template from the room's settings. By default, thesystem provides a template body with the insertions needed to tell the system to send the names of essential/required documents, and the name and contact details of the SSU Specialist**.**



All the administrator needs to do is insert the email text description. To set up the template, proceedas follows:

1. Navigate to **Settings**.
2. Select **Email** from the left panel and click the arrow next to it.
3. Select **Email Templates** from the collapsed dropdown.



4. The Email Templates window opens in the right.

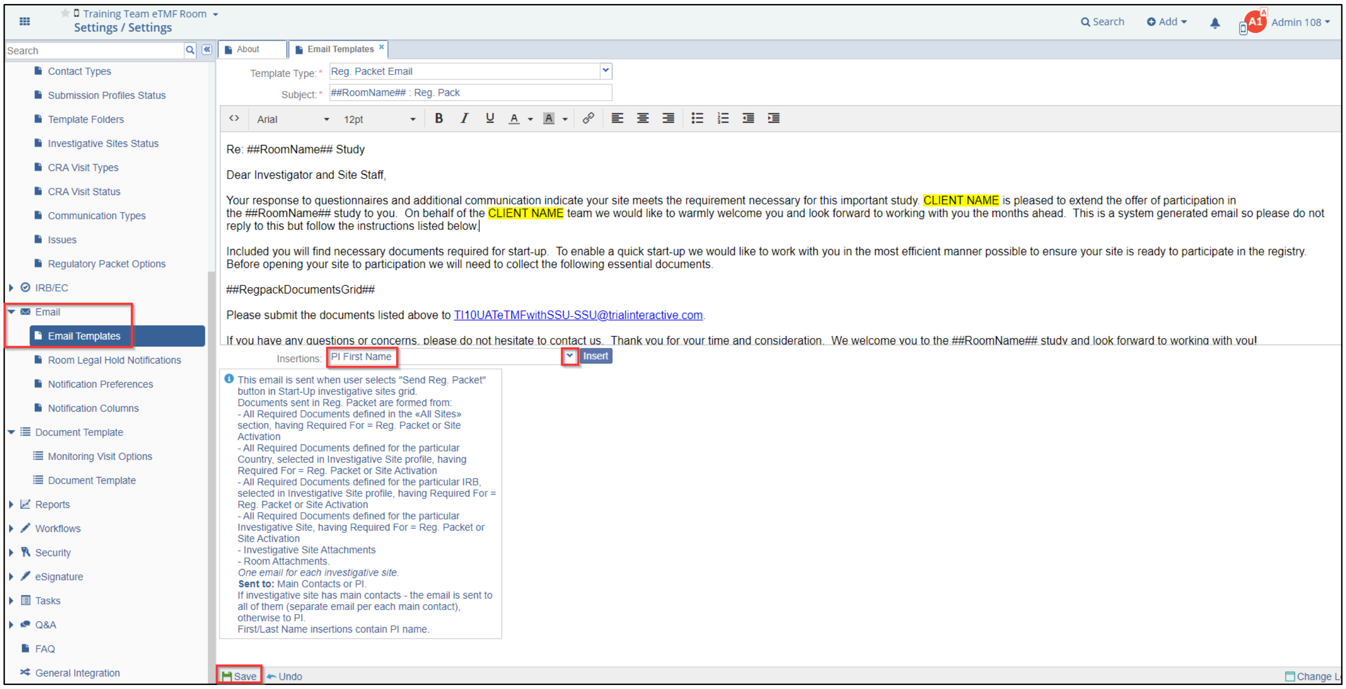
5. Select **Reg. Packet Email** from the Template type dropdown.

6. The default template populates itself.

7. Click the appropriate location in the editor and insert the email body as per the format provided by your organization.

8. Besides the insertions already provided by default, you can insert your own insertions in the email body for the PI name, Domain Name, Room Name, and Investigative Site details by choosingappropriate options from the Insertions dropdown and clicking Insert next to the dropdown.

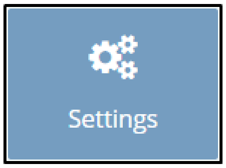
9. Click **Save** to commit the changes.



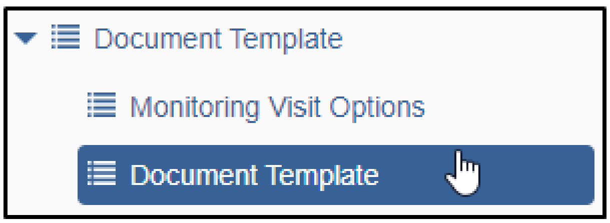
Setting Up Document Templates

To set up document templates, follow the procedure as below:

1. Navigate to the **Settings**.



2. Select the **Document Templates** from the left panel.



3. The Document Templates window opens in the right.

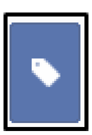
4. Click **Add** from the top menu of the window to create a template. This opens the Add Template popup window.

5. Enter the details for the mandatory fields – Template File, Template Name, Collection Type and Category.

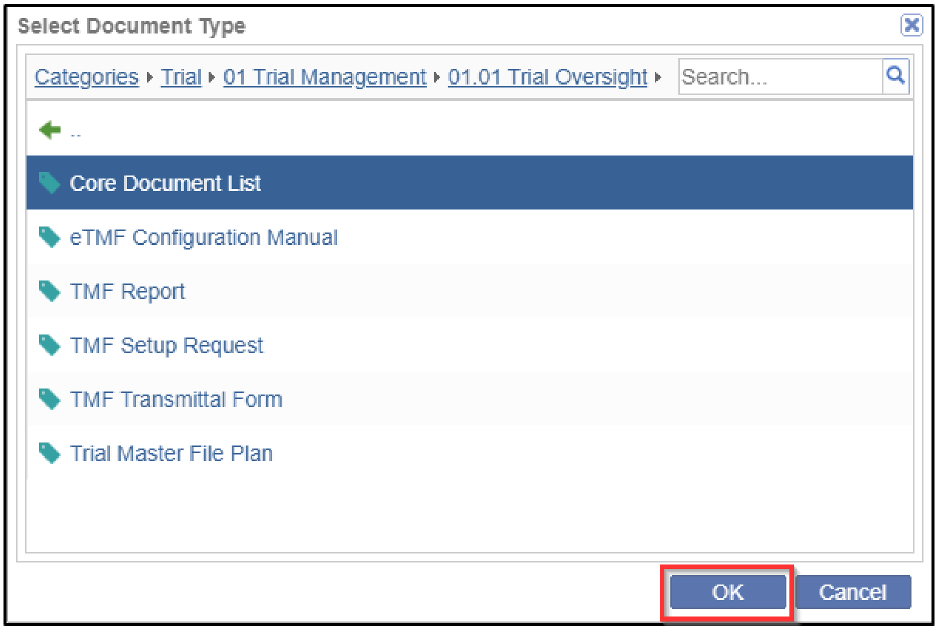
6. Select the appropriate **Collection Type** from the dropdown menu.

7. Select an appropriate radio button for the Category field. You can choose to create templates for General category documents, for All Sites, or for specific country or site from the Category section of the window. One document template can be created for any one of the categories mentioned above. Hence select a radio button as required.

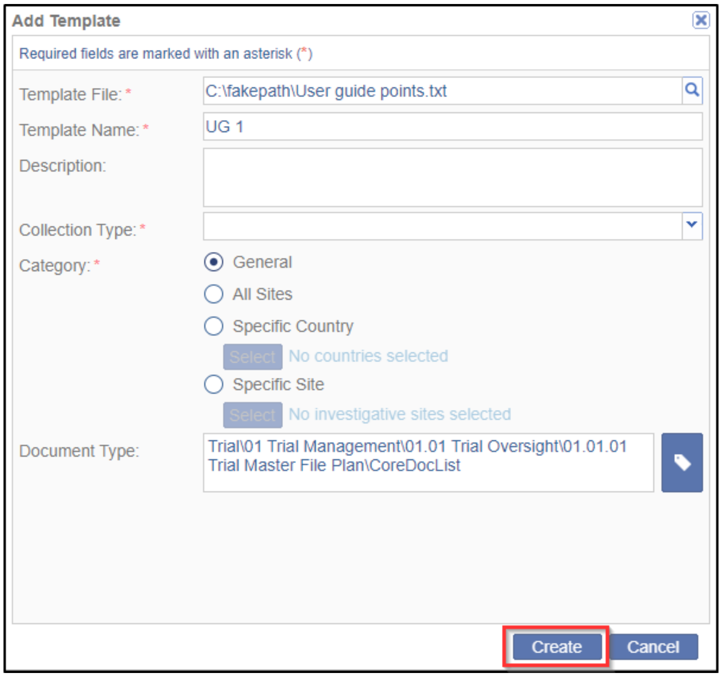
8. Click the **Tag** icon to select the Document Type. This opens the Select Document Type popup window.



9. Select the category for the document type from the list available. Keep clicking and selecting the appropriate categories until the **OK** button is enabled.



10. The selected document type is reflected in the Document Type field.
11. Click the **Create** button displayed at the bottom of the Add Template popup window.



Sending Regulatory Packets

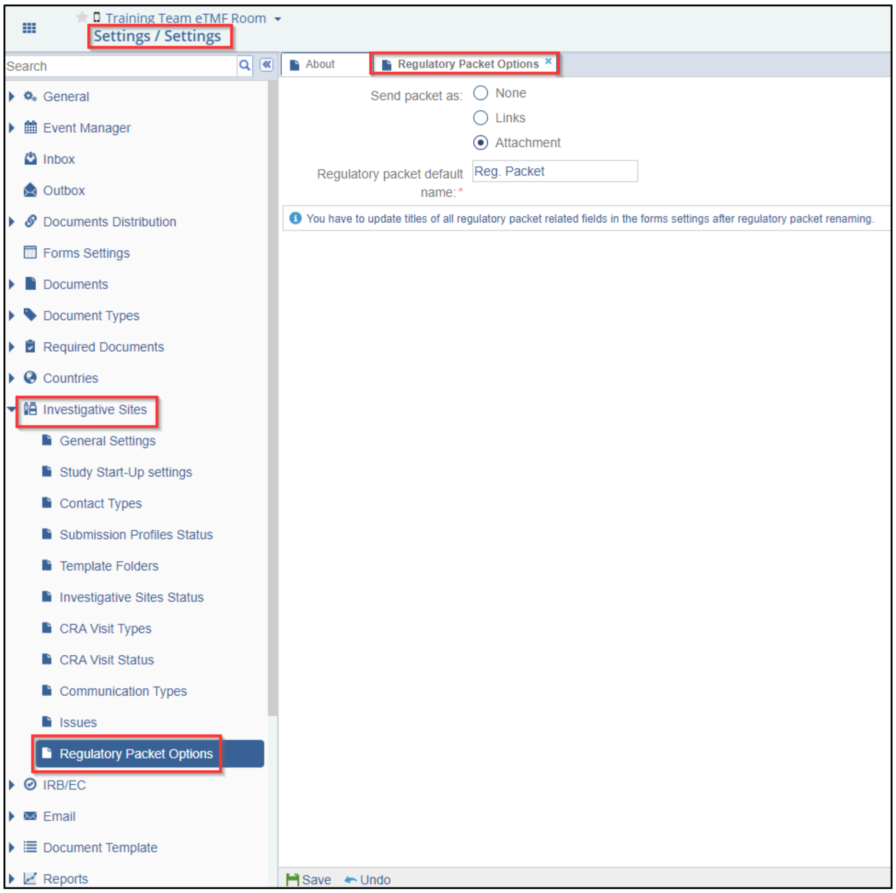
It is possible to send docs within a regulatory pack with the following options:

1. None

2. Links

3. Attachments.

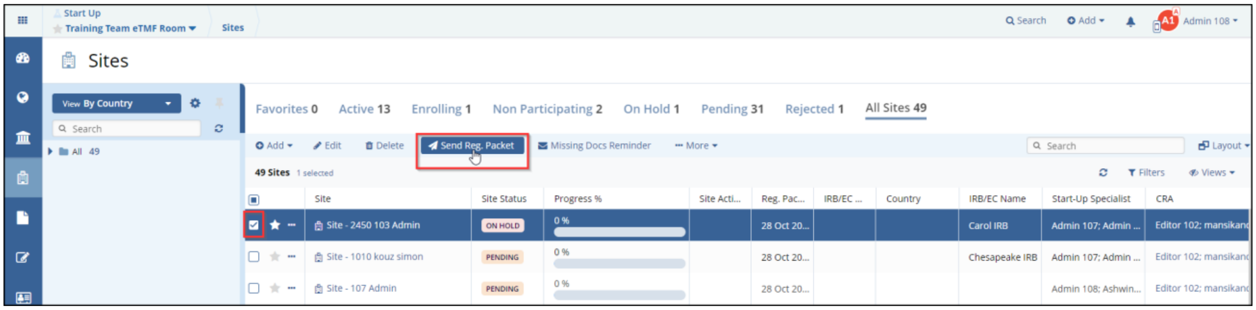
This is similar to the Email documents functionality and can be configured from **Settings ->Investigative Sites -> Regulatory packet Options**. Refer to the screenshot below:



To send regulatory packets follow as below:

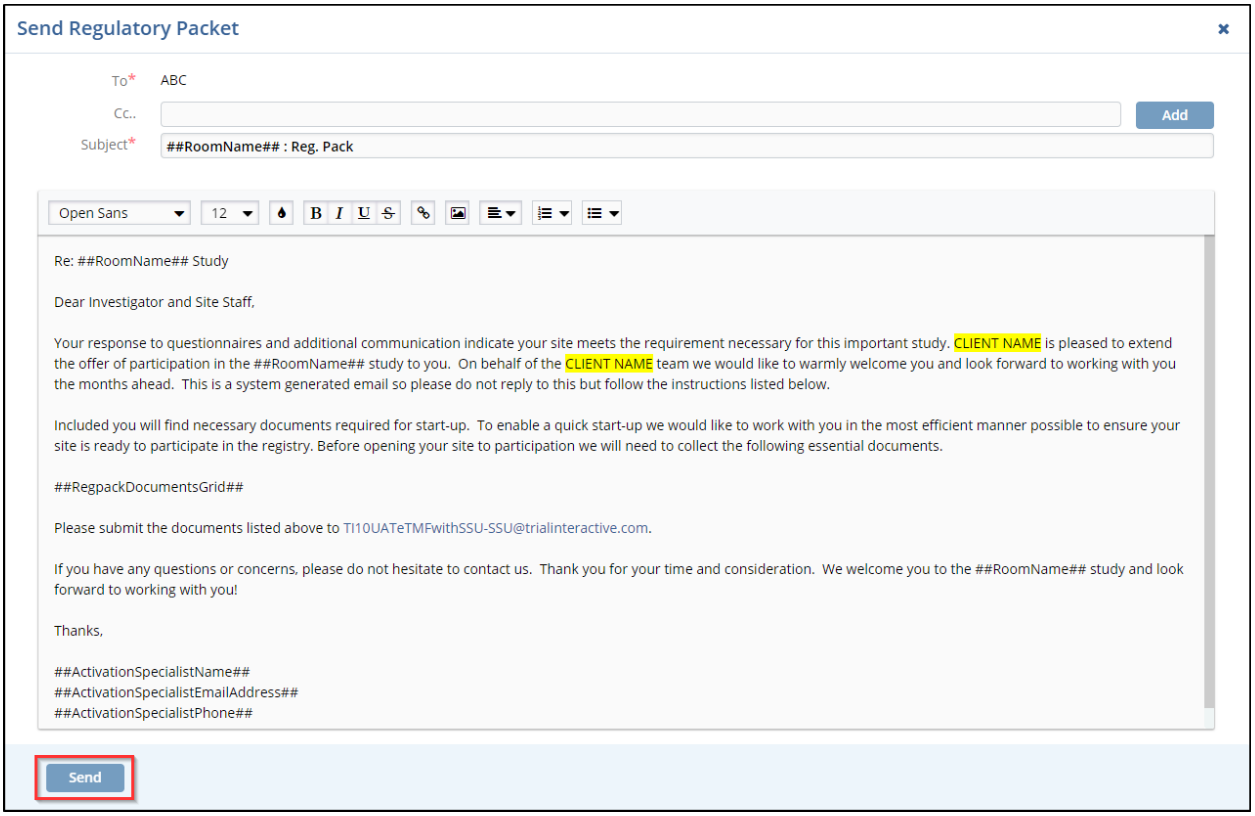
1. Navigate to **SSU>Sites**. Select the site/s for which you want to send regulatory packets from the Grid Pane.

2. Click the **Send Reg. Packet** button from the top menu bar in the Grid Pane. This opens the Send Regulatory Packet popup window.



3. **(Optional)** Enter the email address(s) in the CC field by clicking the Add button displayed in the top right corner.
4. Click the **Send** button displayed at the bottom of the popup window.
5. A notification is displayed at the top right corner as **Send Regulatory Packet- Processing** and in few minutes as – Operation was successfully completed.
6. Click the **Get Job Result** button in the notification displayed.
7. A Job Result popup window is displayed – Operation was successfully completed! Click **Close**.
8. Once the regulatory packet emails are sent to the main contacts in the site, the user receives a status message stating the issues faced by the system while sending the emails, or stating that the process was completed successfully.

9. The document templates, if created and specified for the selected sites, will be included asattachments in the emails. Below is the screenshot of a sample email:



When the regulatory packet is sent, and the site status is 'Pending', the system will automatically create a task for the SSU Specialist for the next submission deadline. The task thus created can beviewed in the Tasks module accessible from the Navigation Grid.

Collecting Required and Non-Required Documents

Once the document requirements are configured, documents can enter the room through threemethods depending on preference and access:

1. Via a unique SSU email address
2. Via Mass Import (follow to Documents section for Import of documents)
3. Via individual document attachment

As mentioned earlier, all the sites, countries, and IRB/ECs require addition of essential and non-essential documents to them.

The Grid Panes of sites, countries, and IRB/ECs allow you to add Essential Documents, non-essentialdocuments, and add/edit communication logs. The procedure to add documents is the same for sites,countries, and IRB/ECs, and is discussed in the following sections.

Overview Dashboard

The Overview Dashboard, which consists of a number of different dashlets, that can be made available to users by room Administrators, depending on the needs of the client and the particular study room. The dashlets are described here in the subsequent topics.

Edit Dashboard

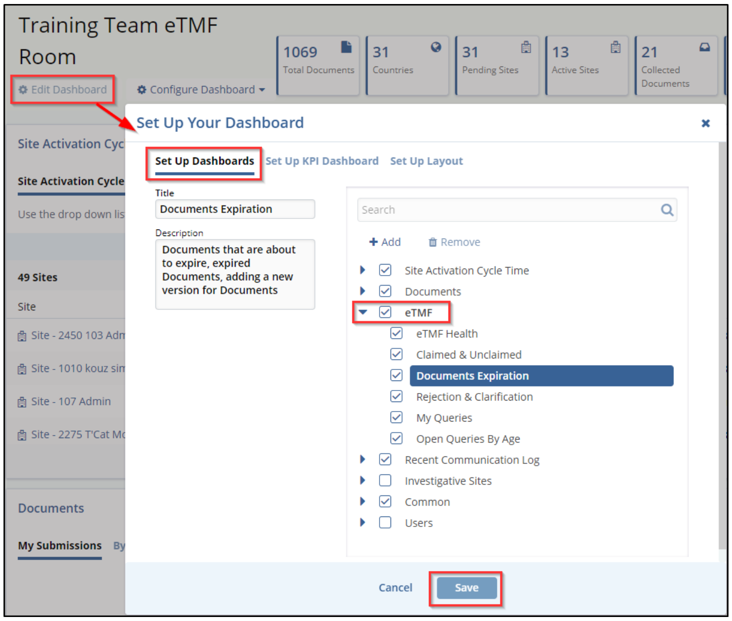
This button is displayed in the top left corner. By clicking this button, the user can do the following:

- **Set Up Dashboards**
- **Set Up KPI Dashboards**
- **Set Up Layout**

Set Up Dashboards

Here, the user can set up their dashboard as required. Follow the steps below to setup the dashboard.

5. Click the **Edit Dashboard** button displayed in the top left corner to open the Set Up Your Dashboard popup window.
6. By default, the Set Up Dashboard option is displayed. Expand the fields using the arrow. Select the required checkbox(s).
7. Click the **Save** button displayed at the bottom of the popup window. By performing these steps, the required options are reflected in the dashlets.
8. **(Optional)** The user can add a new dashlet and also remove an existing one by clicking the **Add** and **Remove** button displayed in the popup window below the Search field. **Note:** While adding a new dashlet the user has to mention the Title and Description in the left side fields. Also, the user can only remove the newly added fields and not the pre-defined fields.

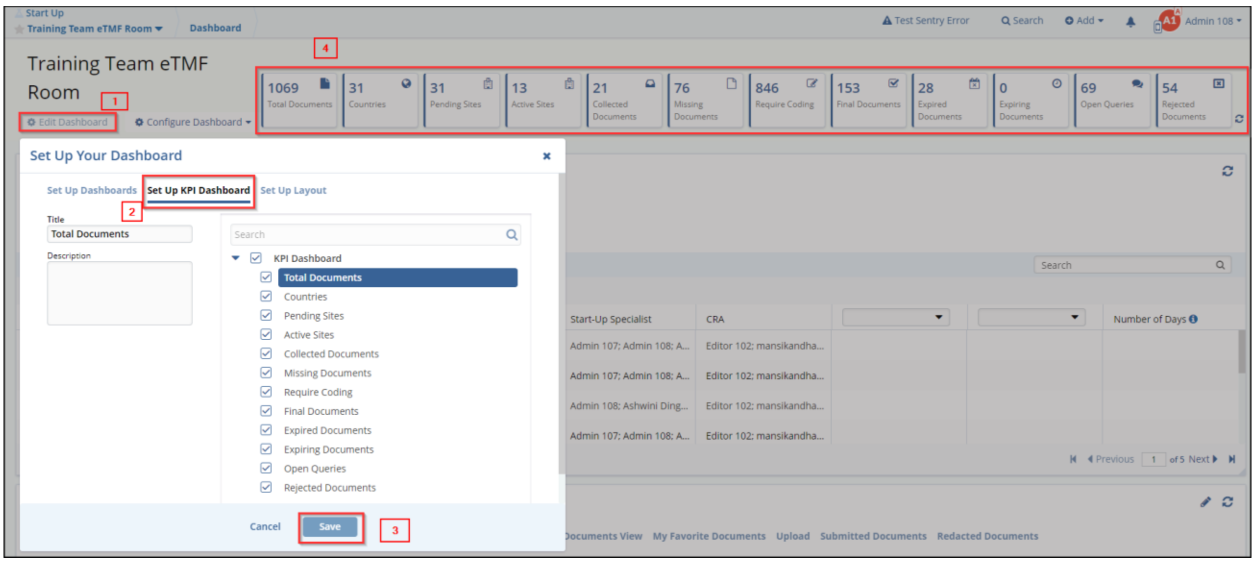


Note: The checkbox(s) selected for each dashlet from the set up dashboard window, only those tabs will be displayed in the dashlets.

Set Up KPI Dashboard

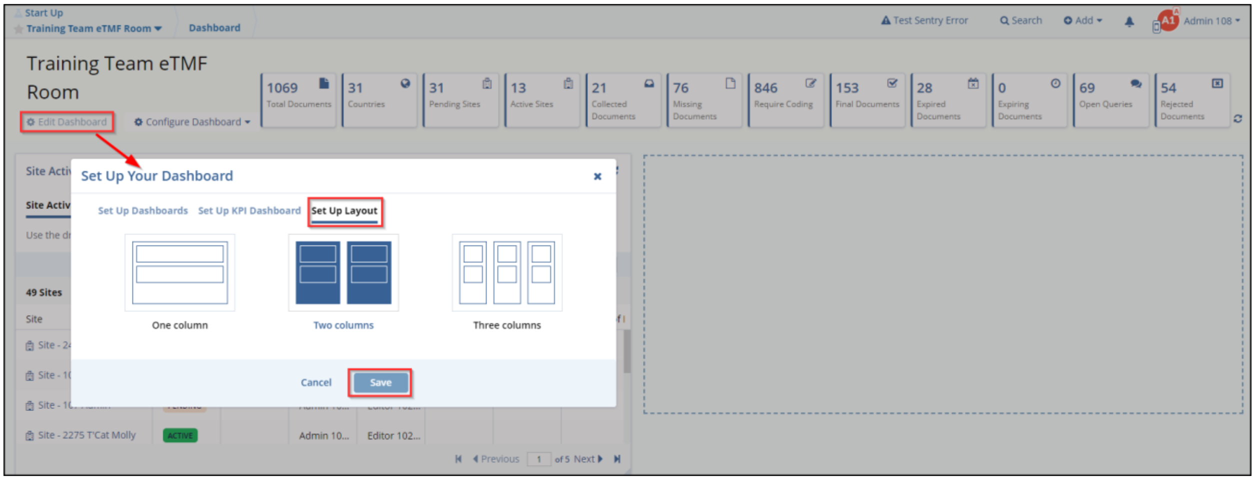
Here, the user can setup the dashlets displayed on the top center to right corner of the screen. The selected tabs are displayed as tiles on the screen. Follow the steps below to set up the KPI dashboard.

6. Click the **Edit Dashboard** button displayed in the top left corner to open the Set Up Your Dashboard popup window.
7. Click the **Set Up KPI Dashboard** tab. Expand the fields by clicking the KPI Dashboard arrow.
8. Select the required checkbox(s) from the available list.
9. Click the **Save** button displayed at the bottom of the popup window.
10. The selected tabs are displayed as tiles on the top of the screen. Refer to the screenshot below.



Set Up Layout

This tab helps the user to select and setup a layout for the entire Dashboard. The user has the options to select from – One, Two or Three Columns. Click the **Save** button displayed at the bottom of the popup window to reflect the changes. Selecting the appropriate option sets the dashboard with a different look. Refer to the screenshot below.



Configure Dashboard

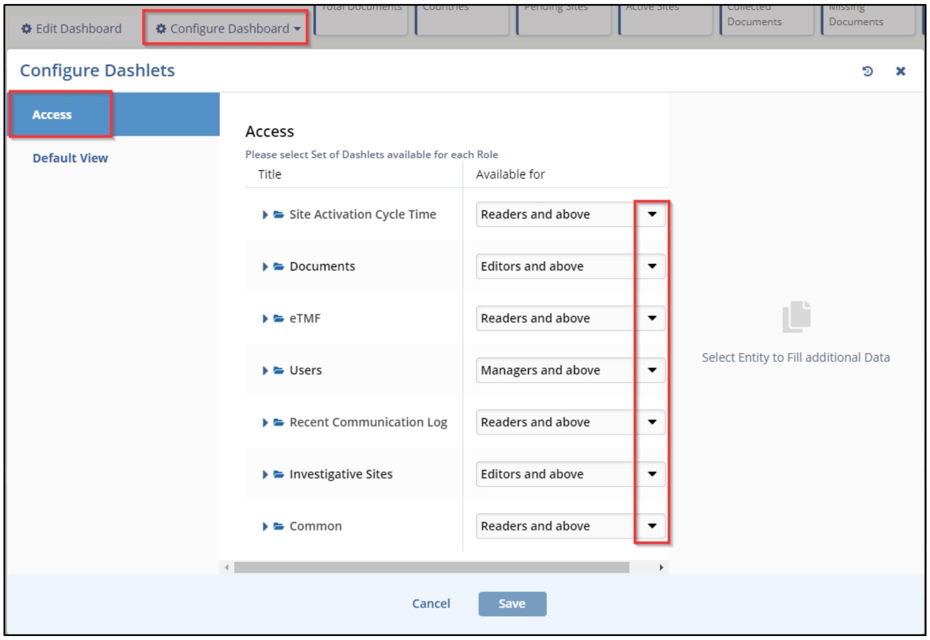
The Configure Dashboard helps the user to arrange the dashboard as required. The user has two options for configuring the dashboard –

- **Configure Dashlets**
- **Configure KPIs**

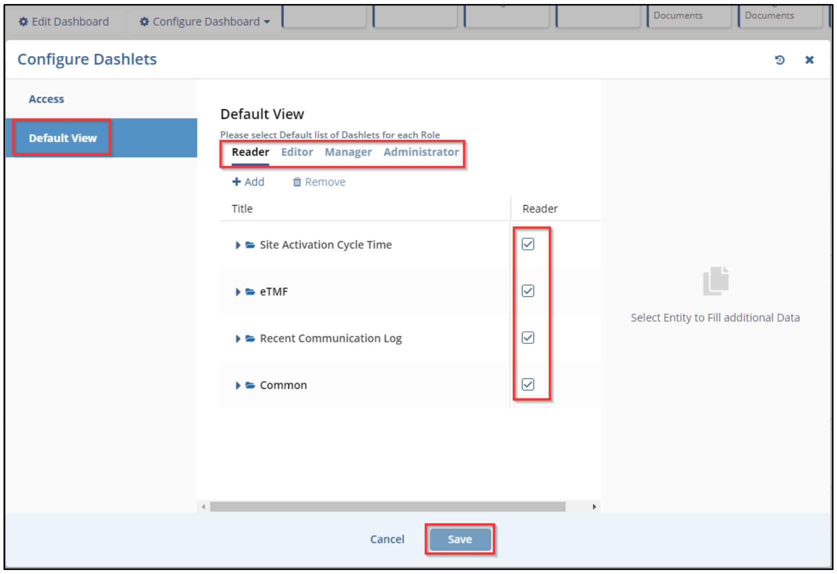
Configure Dashlets and KPIs

Follow the steps below to configure the dashlets.

5. Click the **Configure Dashboard** button displayed next to Edit Dashboard button. This opens the Configure Dashlets popup window.
6. In the Access tab, select the roles from the dropdown menu for each tab keeping in consideration the Titles mentioned in the left side pane.



7. The Default View tab, select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager and Administrator.
8. Click the **Save** button displayed at the bottom of the popup window.

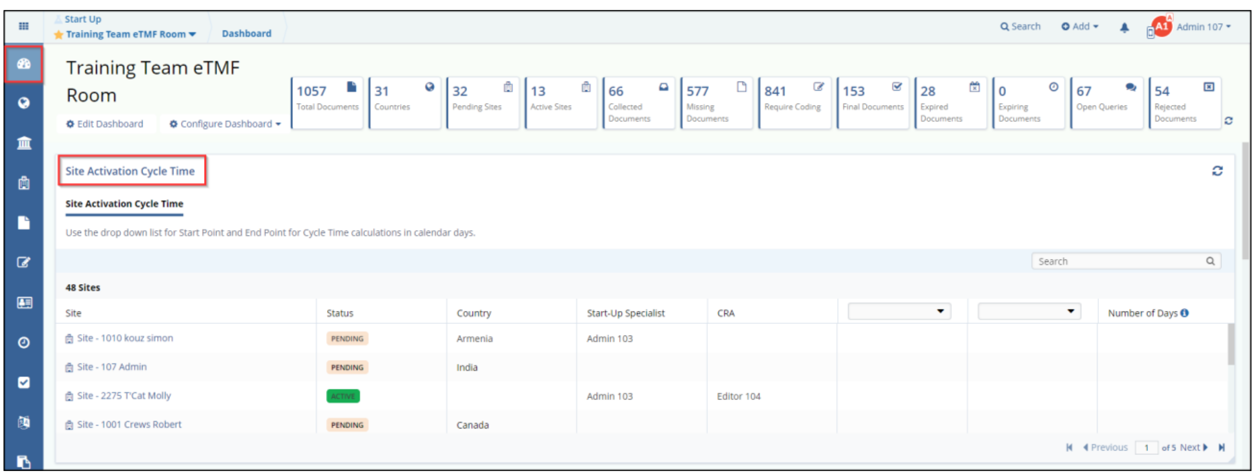


Dashlet-Site Activation Cycle Time

TI SSU has introduced a new dashlet for effectively monitoring the time taken to accomplish each step in activating sites. This dashlet provides an overview of the available sites with its status in the SSU module. The tracking of a cycle time is must for activating sites in clinical trials as this metric enables researchers and stakeholders to identify potential bottlenecks and streamline the process, ultimately accelerating the timeline for bringing life-saving treatments to patients.

- Input filter for start and end points for calculations.
- Heat-map to highlight performing and under-performing sites.
- Option to export the data.

This feature is displayed on the Dashboard of a room as shown in the below screenshot.



Dashlet-Documents

The Documents dashlet provides an overview of the documents with the following tabs –

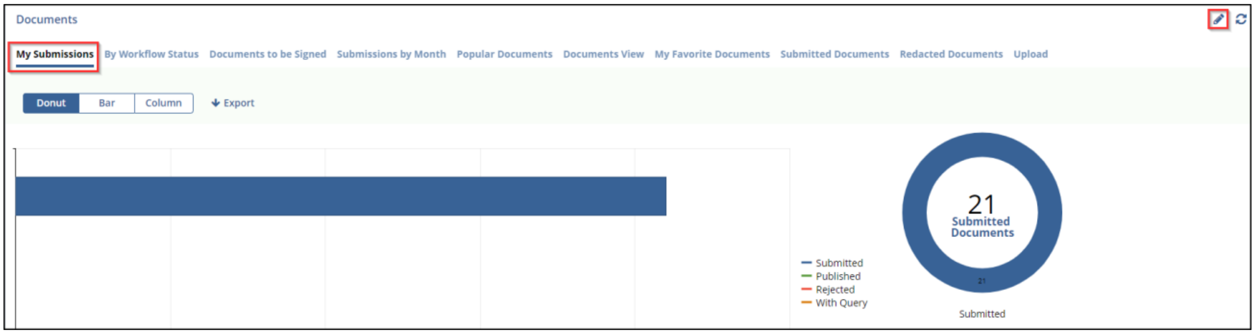
Note: Only those tabs are displayed in this dashlet that were selected after clicking the Edit Dashboard button.

- **My Submissions**
- **By Workflow Status**
- **Documents to be Signed**
- **Submissions by Month**
- **Popular Documents**
- **Documents View**
- **My Favorite Documents**
- **Upload**
- **Submitted Documents**
- **Redacted Documents**

All the tabs are explained below.

My Submissions

This tab displays the documents submitted by the user in a Donut/Bar/Column format.

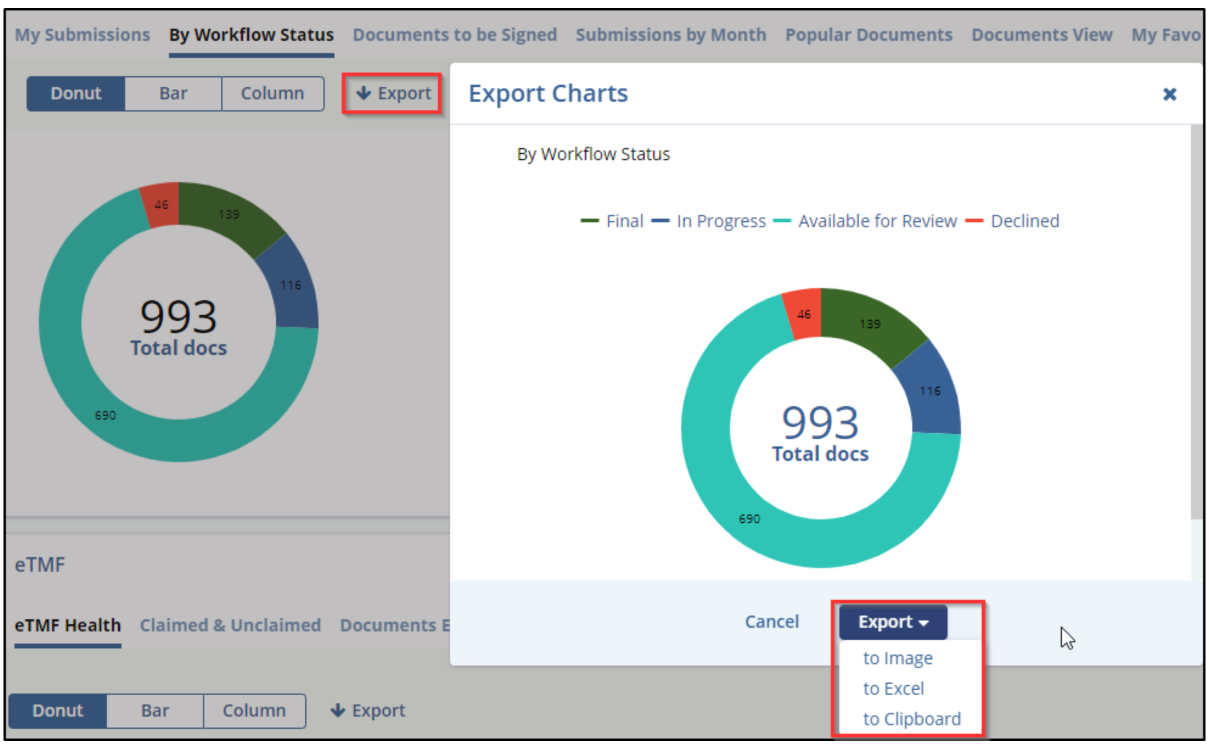


The **Pencil** icon displayed in the right corner helps the user in changing only the name of the dashlet. Click the **Confirm** button after applying the changes.

By Workflow Status

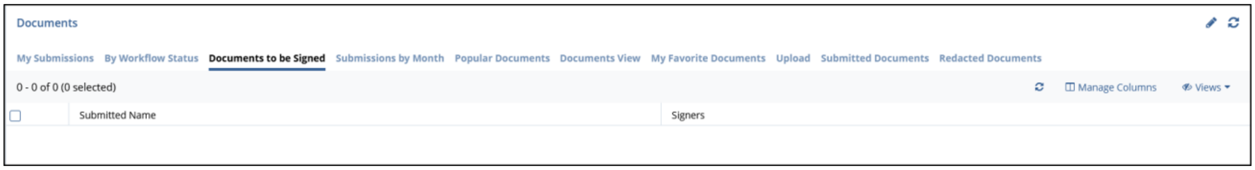
This tab displays the total number of documents by the workflow status. Select the appropriate option from the dropdown menu to view the summary of the documents in Donut/Bar/Column format. By default, the Room Summary option is selected in the dropdown menu.

The user can also export this data by clicking the **Export** button. The user can export the data in – **Image, Excel or Clipboard**.



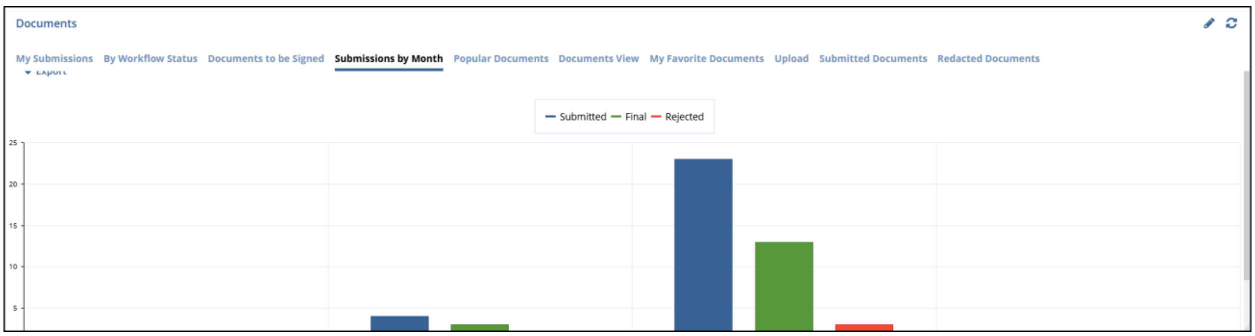
Documents to be Signed

This tab displays the documents in a grid pane that are to be signed by that specific user.



Submissions by Month

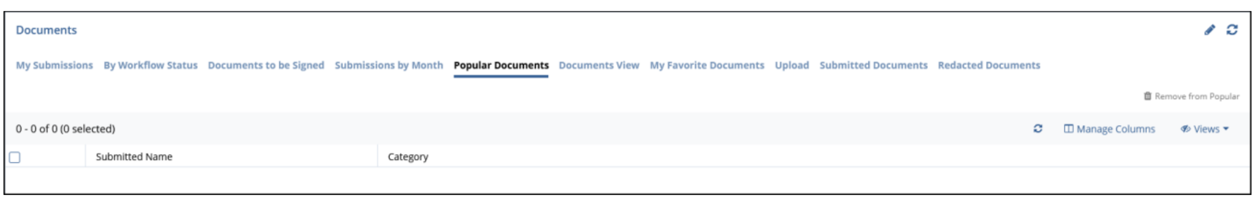
This tab displays a graph bar for the submissions done in the last six months.



Popular Documents

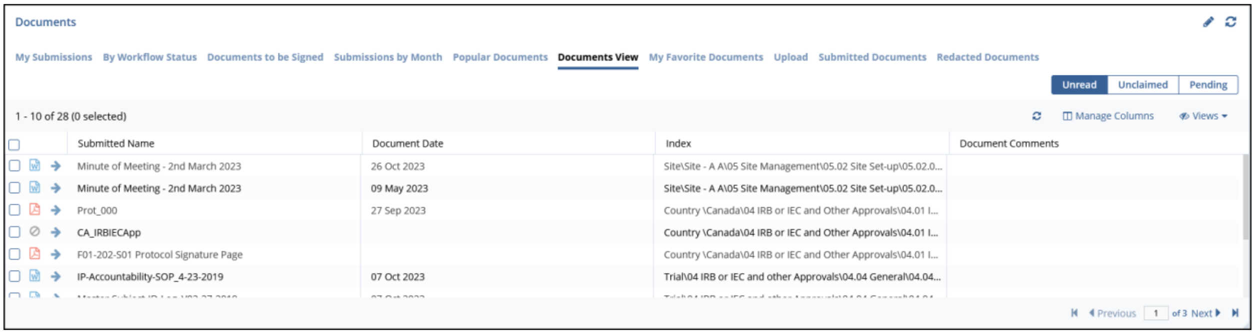
The IP Release Documents dashlet displays the list of documents that have been marked as popular by an Administrator, Manager, or Editor through the Documents Cart and which are used frequently.

To remove a document from the Popular list, click the Remove from Popular button on the dashlet. To view the document, click the icon or click on the blue arrow to be taken to the document in the Documents module.



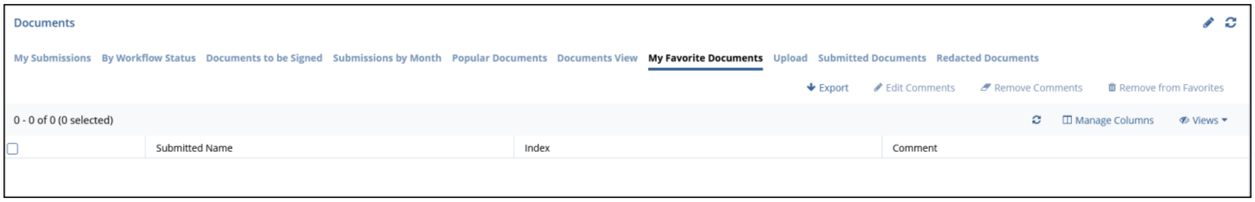
Documents View

This tab displays the documents in a grid pane with a selection tab for – Unread, Unclaimed, and Pending.



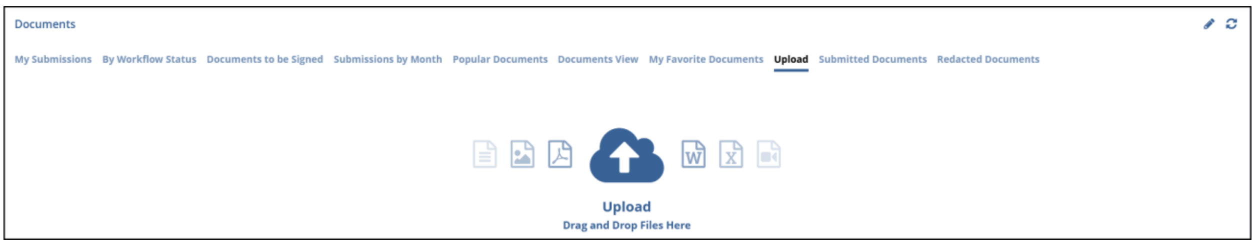
My Favorite Documents

This tab displays the documents that are marked as favorite by the user.



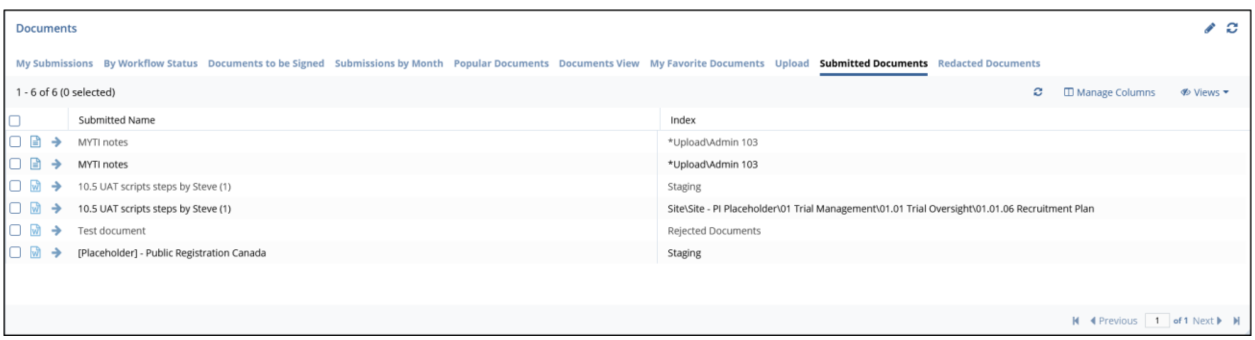
Upload

This tab helps the user in uploading the document(s) by the drag-drop method.



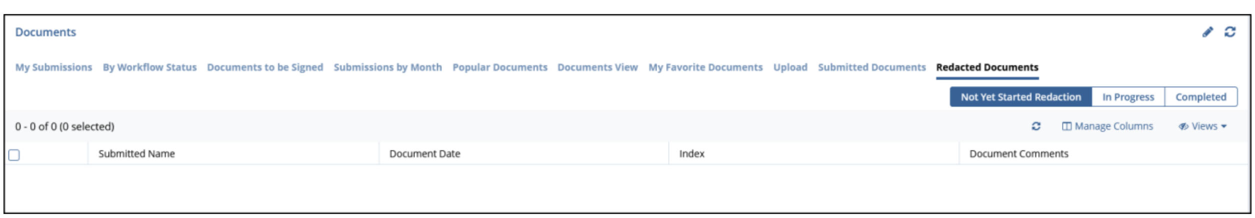
Submitted Documents

This tab displays the documents that are submitted by the user.



Redacted Documents

This tab displays the documents that are redacted by the user.



Dashlet-eTMF

eTMF Health

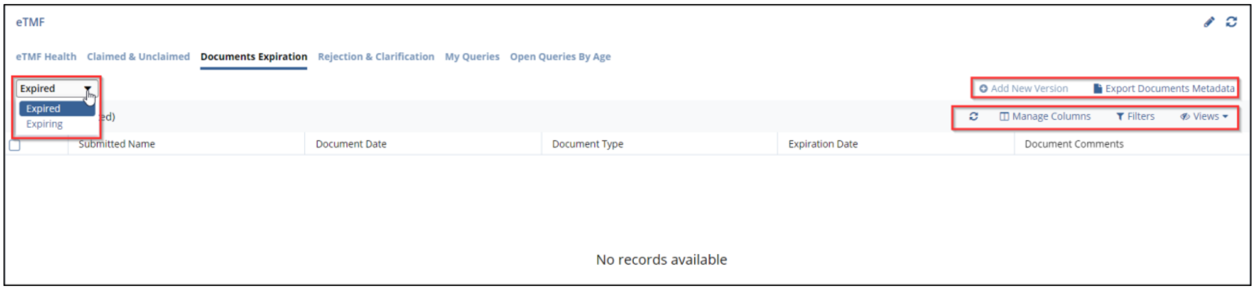
This tab displays an overview of the eTMF module in a Donut, Bar, and Column format. Any format selected displays the Overall, Trial, Country, and IRB/EC data. The user can Export the data in either an Image, Excel format and can copy to Clipboard. The user can also edit the name of the dashlet by clicking the **Pencil** icon displayed in the right corner.

Claimed and Unclaimed

This tab displays an overview of the claimed and unclaimed documents in the eTMF module in a Donut, Bar, and Column format. The user can select the workflow from the dropdown menu displayed in the right corner to view only specific workflow's data.

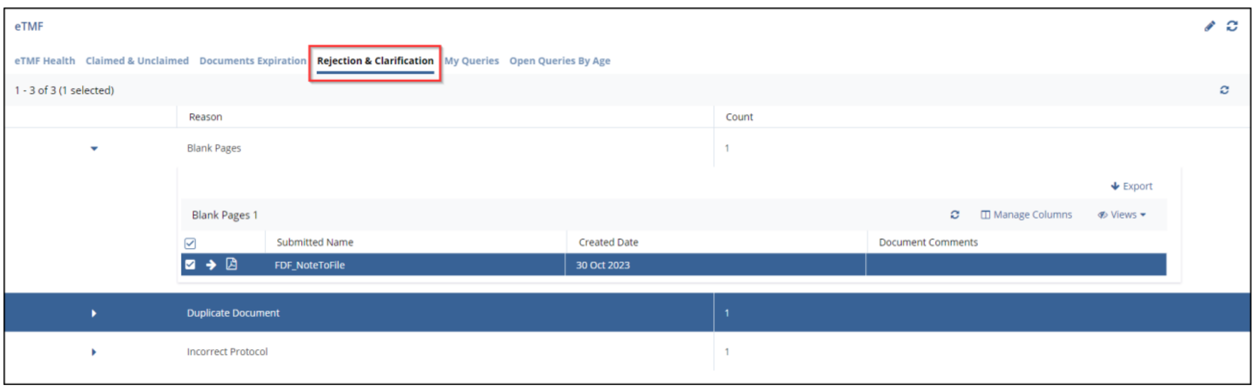
Documents Expiration

The Documents expiring in N days dashlet lists the expiring and expired documents as specified in the expiration period. the user can Add New Version to the document, Export Documents Metadata, Manage Columns, Manage and Create New Filter, Manage and Save views. The user can also choose to select the Expired and Expiring documents from the dropdown menu displayed in the left corner.



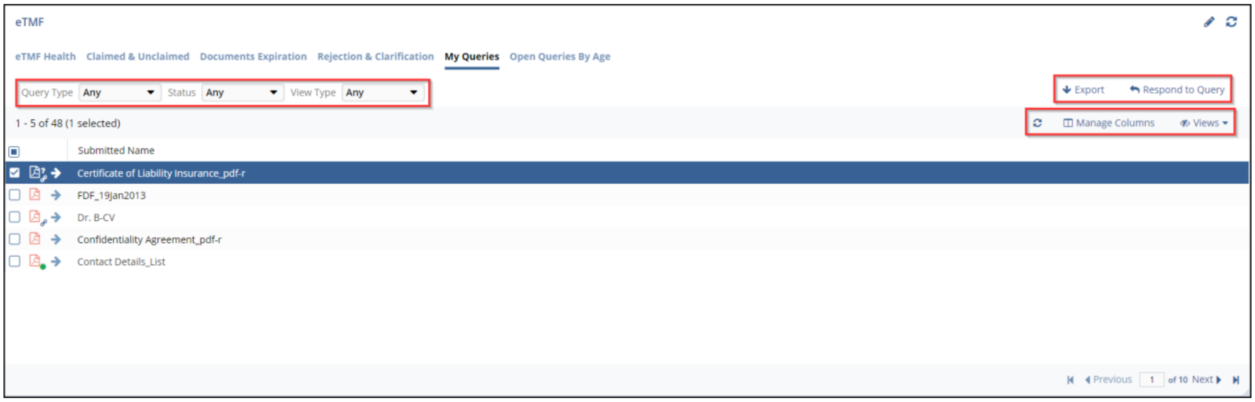
Rejection and Clarification

This tab displays the documents that are rejected and need clarification for the same. This tab displays the dropdown arrows for Blank Pages, Duplicate Documents and Incorrect Protocol. Each option displays a grid with – Submitted Name, Created Date and Document Comments. For each dropdown arrow the user can Export, Refresh, Manage Columns and Views.



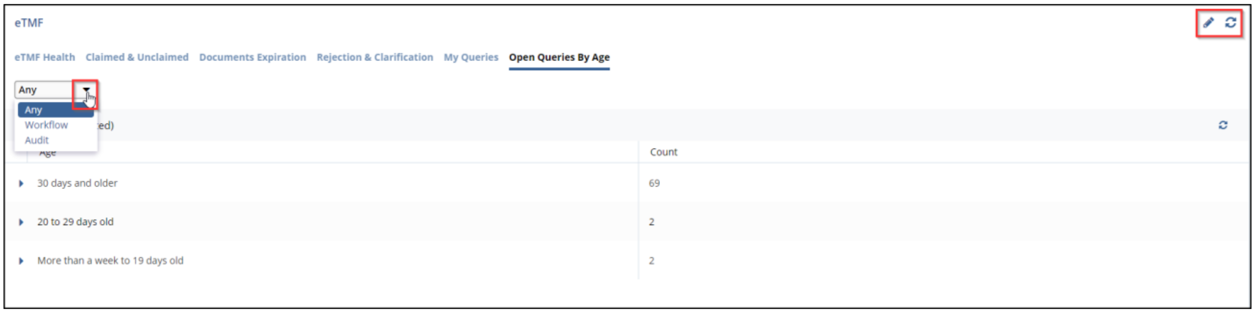
My Queries

This tab displays the documents that has queries asked by other users that have to be answered by you. The user can select the Query Type, Status and View Type of the documents from the dropdown menu provided for each field. The user can also Export the data, Respond to Query, Refresh, Manage Columns, Save View in this dashlet.

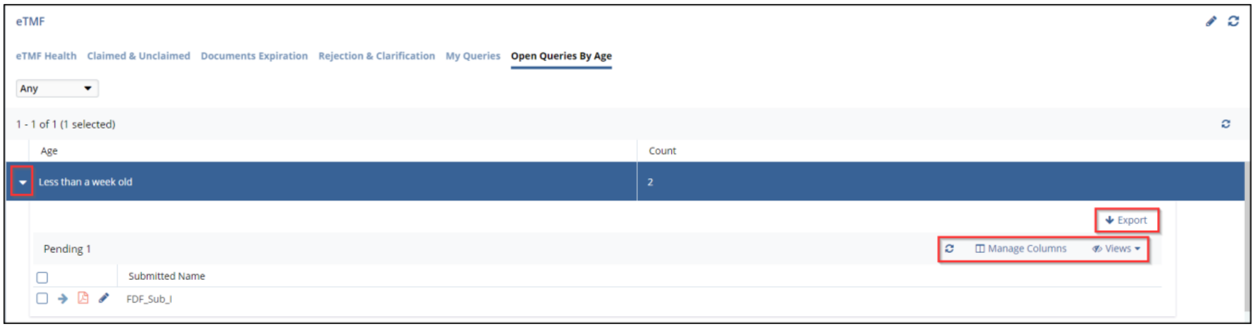


Open Queries By Age

This tab displays the queries that older than a month or more. The user can select an option from the dropdown to view the documents only for Workflow and Audit related documents.

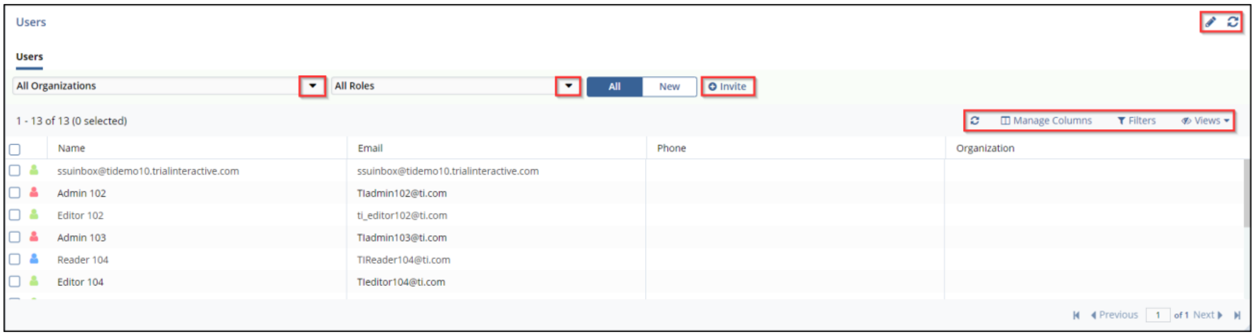


The grid displays the Age and the Count of the documents available inside the down arrows. For each dropdown arrow the user can Export, Refresh, Manage Columns, and Save Views. Refer to the screenshot below.



Dashlet-Users

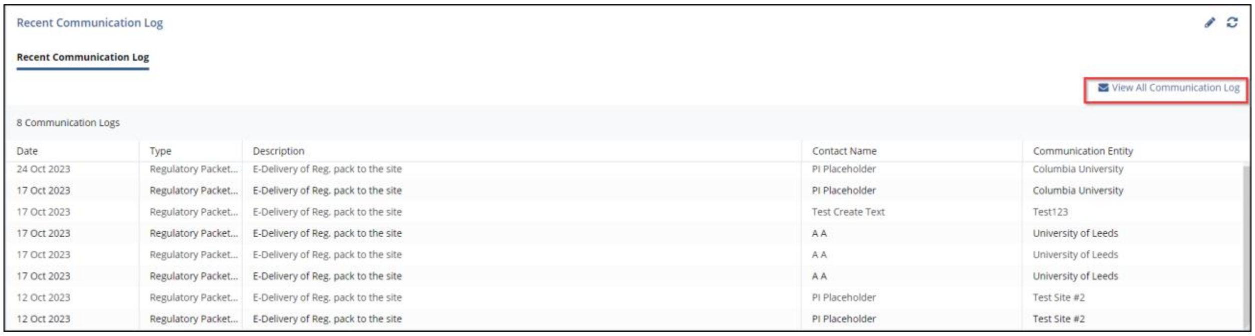
This tab displays the users available and are added in the SSU module. The user can filter the users by using the dropdown menus for Organizations and Roles. The user can also Invite a user from this dashlet and can Edit the name of the dashlet, Refresh, Manage Columns, Manage and Create New Filter, and Save Views.



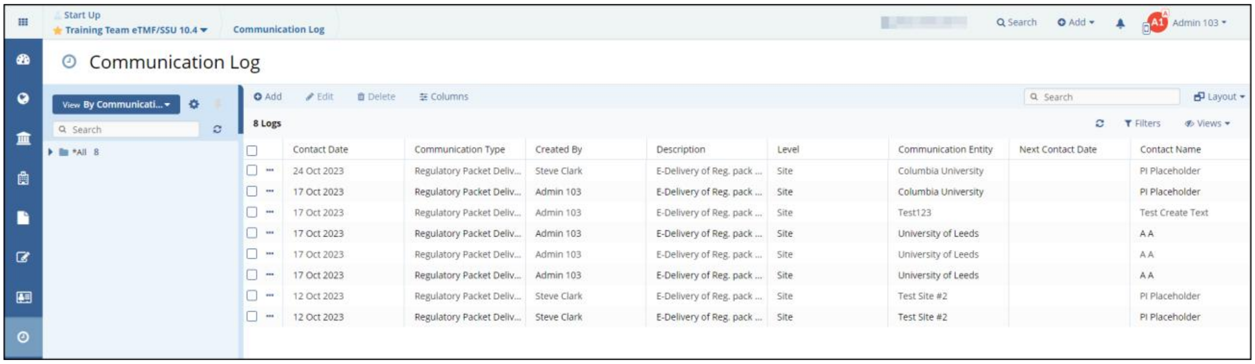
Dashlet-Recent Communication Log

This dashlet displays a list of all communications made during the site start-up and activation stage. **Note:** Only those tabs are displayed in this dashlet that were selected after clicking the Edit Dashboard button.

Click the **View All Communication Log** button displayed at the left corner of the dashlet to view a detailed log.



Clicking the **View All Communication Log** button redirects the user to the Communication Log page of the SSU module.



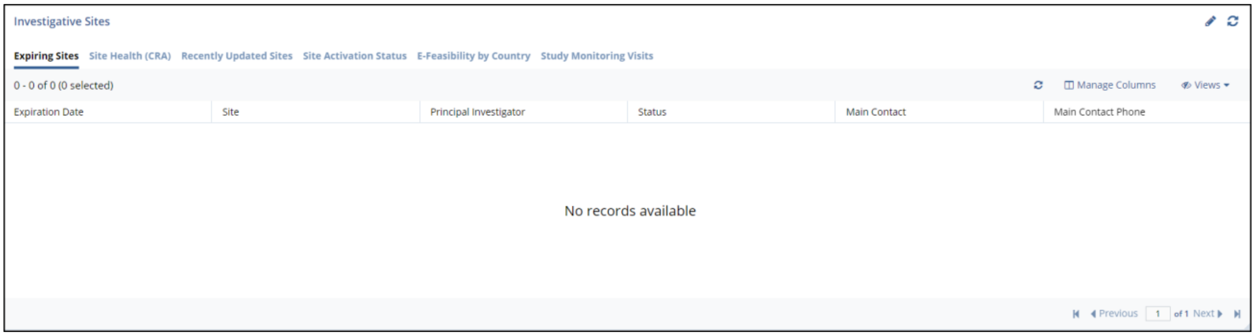
Dashlet-Investigative Sites

This dashlet displays details for the Expiring Sites, Site Health (CRA), Recently Updated Sites, Site Activation Status, E-Feasibility by Country, and Study Monitoring Visits. In this dashlet the user can only edit the name of the dashlet.

Note: Only those tabs are displayed in this dashlet that were selected after clicking the Edit Dashboard button.

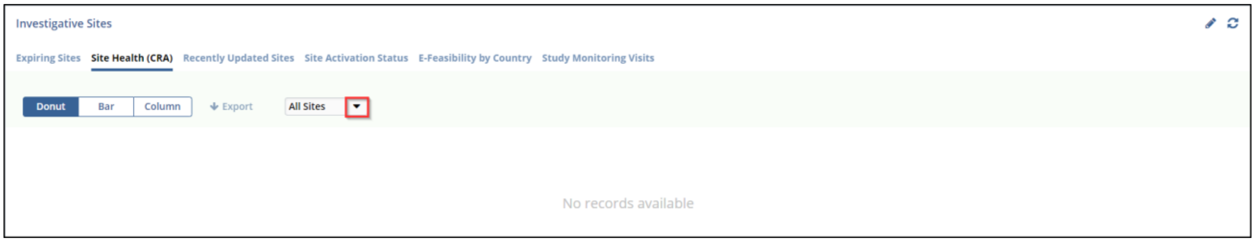
Expiring Sites

This tab displays the sites that are going to be expired.



Site Health (CRA)

This tab displays the health of a site in a Donut, Bar, Column format. the user can Export the data in an Image, Excel or Clipboard format. the user can also filter the sites with either – All Sites or My Sites.

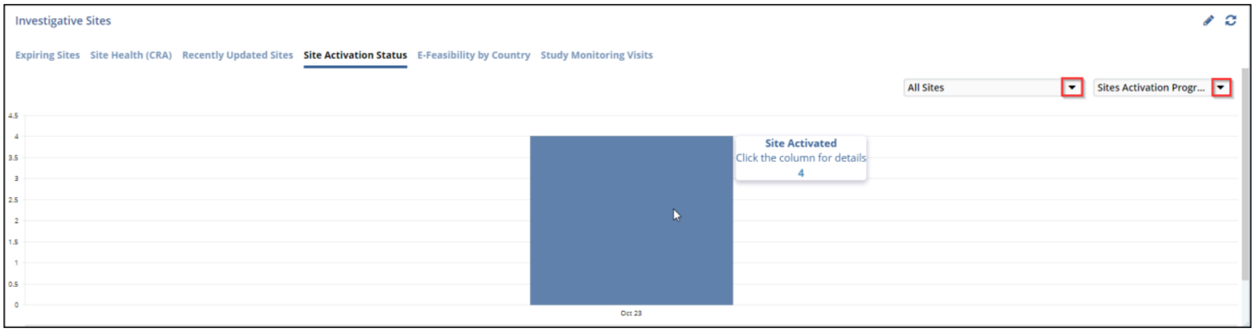


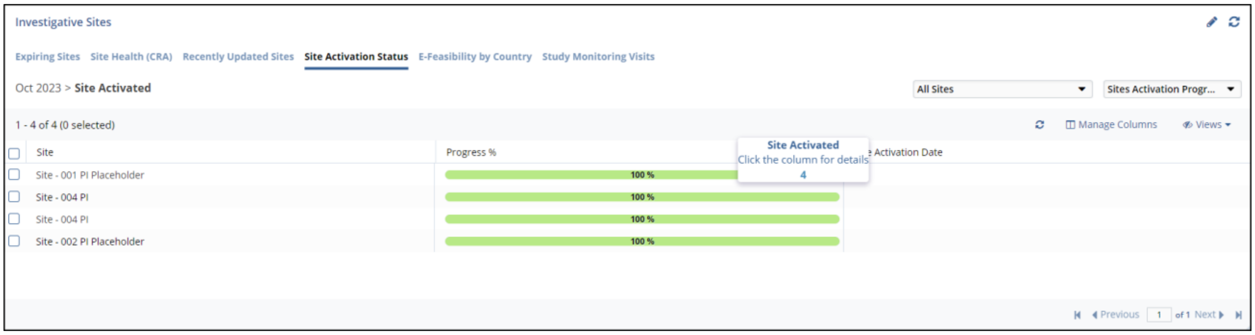
Recently Updated Sites

This tab displays the sites that are recently updated by the user. the sites are displayed in the grid with the Site Name, Principal Investigator, Status, and Progress columns. The user can Edit the dashlet's name, Refresh, Manage Columns, and save Views for this tab. By clicking the View All Sites button displayed in the right corner redirects the user to the Sites page of SSU module.

Site Activation Status

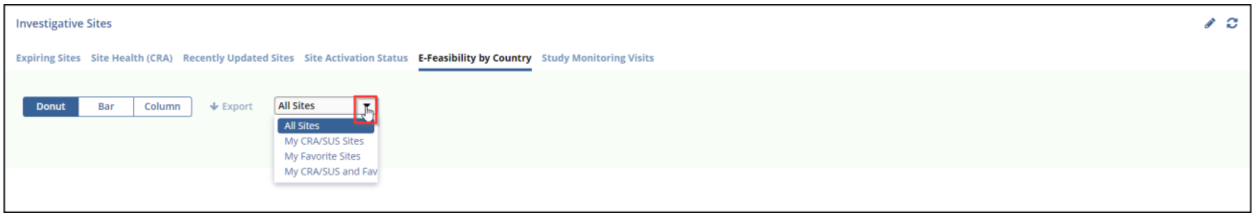
This tab displays the status of an activated site in a bar format. click the bar to view the detailed progress of the sites activated. The user has the option to select and filter the site activation status for Sites and Progress from the dropdown menus displayed in the right corner.





E-Feasibility by Country

This tab displays the E-Feasibility by Country.

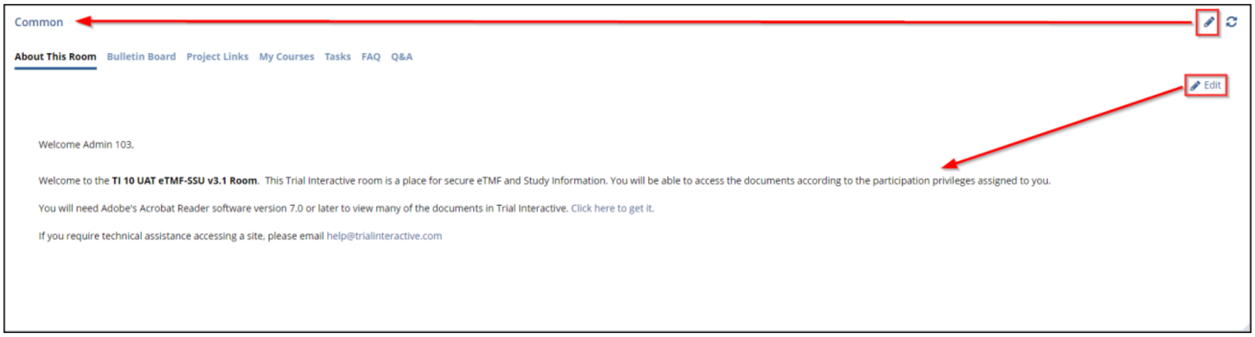


Study Monitoring Visits

This tab displays an overview for past six months of the monitoring visits. The tab displays the data in a Donut, Bar, Column format. The user can select the date and month by clicking the Calendar icon to view the data. The user can also Export the data as required in an Image, Excel or Clipboard format. the user can apply the filters By Month and By Country to view the data.

Dashlet-Common

This dashlet displays the welcome message for the user and also displays tabs – **About This Room**, **Bulletin Board, Project Links, My Courses, Tasks, FAQ and Q&A.** This dashlet displays two pencil icons. With one the user can edit the name of the dashlet while with the other the user can edit the welcome message displayed in the body text.



Bulletin Board

This is set up by the administrators to provide messages to the team which can be information regarding a room or problems within a study. It can be edited by administrators and managers.

Project Links

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

My courses

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

Tasks

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

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

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

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

FAQ

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

The Q&A

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