



TRIAL INTERACTIVE V10.6 - USER GUIDES V1.0

**TRANS**PERFECT  
LIFE SCIENCES

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## VERSION HISTORY

Author	Revision	Date	Change History
Samuel Pawar	1.0	19-Nov-2024	Initial Document Creation

## HARDWARE AND SOFTWARE REQUIREMENTS

The following describes the hardware and software requirements to use the Trial Interactive v10.6 platform.

System Requirements	
<b>Operating System</b>	<ul style="list-style-type: none"> <li>Windows Version 7 or higher</li> <li>All currently supported Mac OSX releases</li> <li>iOS and Android for my mobile app (see myTI release notes)</li> </ul>
<b>Browser</b>	<ul style="list-style-type: none"> <li>Microsoft Edge: Version 88 and later</li> <li>Google Chrome: Current release and earlier</li> <li>Mozilla Firefox: Current and ESR releases</li> <li>Apple Safari: Current release and earlier</li> <li>NOTE: TI Sign requires that pop-up blockers be disabled for the Trial Interactive domain.</li> </ul>
<b>Client Software</b>	<ul style="list-style-type: none"> <li>For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally.</li> <li>For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred).</li> <li>Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer.</li> <li>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®.</li> </ul>
<b>Optional Add-Ons</b>	<ul style="list-style-type: none"> <li>DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions)</li> <li>Adobe Sign (Latest Adobe Document Cloud Version)</li> <li>Optional: SAS Viewer or compatible software must be installed for SAS Datasets. The free version is available here: <a href="https://support.sas.com/downloads/browse.htm?fil=&amp;cat=74">https://support.sas.com/downloads/browse.htm?fil=&amp;cat=74</a></li> </ul>

## WHAT'S NEW IN TRIAL INTERACTIVE V10.6?

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### 1. ORGANIZATIONS

#### 3<sup>rd</sup> Party Vendor Support

**ETMF-214** - When handling 3<sup>rd</sup> Party Vendors in the eTMF, additional folder structures with document type classifications must be managed easily within the index. There should be a way to enter 3<sup>rd</sup> Party Vendors as Organizations within a client domain, and a way to select from these Organizations to populate folder structure and required documents for each Vendor within rooms.

This feature will implement third-party Vendors within the eTMF, creating folder structures and required documents, along with metadata about these Organizations, including type, subtype, service provided, address, and contact information. For customers using a CTMS, these Organizations may be shared and managed there and populated to the client domain.

This feature will implement Organizations within other room types including QMS and Site Collaborate rooms, allowing for supplier and vendor management and required documentation.

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### 2. USER INTERFACE

#### New Look and Feel

**TTI-2528** - For all solution offerings, this enhancement brings a new level of convenience and efficiency to the user experience with a new look and feel to the metadata quick view panel, showing all key information for each document including the Document ID, Submitted Name, and the Generated Name. Shortcuts such as claim, release, check-in, check-out, and workflow actions are now supported at the panel's top, providing the most common actions available to the user.

A new navigation panel is available as well, providing quick access to all modules, products, and solutions as well as a clear breadcrumb showing where you are in the platform and providing additional information such as the protocol number of the trial.

For Collaborate and QMS, this feature improves collaborative reviews by enabling the display of the document metadata panel during active sessions. This feature allows participants to view essential metadata alongside the collaborative session, providing immediate context that can significantly inform and guide the review process. With key information such as metadata, info, version history, review history, queries, instructions, submitted name, document ID, generated name, and collaborate status readily accessible, collaborators can make more precise and informed contributions, leading to a more streamlined and effective review cycle. This integration represents a critical step towards a more transparent and connected review experience, ensuring all participants are aligned and fully informed throughout the collaboration.

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### 3. GRID VIEWS

#### Advanced Metadata Filters

**TTI-2379** - Enhance your oversight of the room and grid view with advanced document filters. This feature provides a robust set of dropdown filters to each grid view for users to efficiently view, sort, and filter document data, optimizing the management and oversight of the eTMF, QMS, and other room types. When combined with the 'Expand' feature, documents may be quickly filtered down to just what you need to review.

For the eTMF, key filters such as zone, section, artifact, sub-artifact, index number, document type, and various dates are now available from any grid view. These filters may be saved to a private view of data or a public view that is set as the default by the administrator.

Additionally, for the QDMS a new 'Training Required' checkbox has been integrated into the metadata options to support compliance and training protocols. Streamline your reporting by exporting a comprehensive list of documents under review directly from the grid into Excel, simplifying reporting, data analysis, and tracking. This multi-faceted tool is engineered to elevate the precision and productivity of your document review processes.

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### 4. TI AUTOMATE

#### Save time by automatically coding documents as they get uploaded

**TTI-3613** - With the introduction of a new Artificial Intelligence service to TI Automate, documents may be automatically classified with their metadata extracted once uploaded to a room. This exciting new feature has the following key capabilities:

- TI Automate is pre-trained on the eTMF reference model, so no additional training is necessary. Your users are up and running with the press of a button.
- In addition to metadata, new investigative sites and new site contacts that are detected in certain documents, such as Form 1572, are automatically added with verification.
- TI Automate has a high accuracy rate that is well above 90% for structured documentation.
- Documents that come in as images are automatically OCR' so that the required metadata may be extracted.
- For non-eTMF rooms, the metadata may be modified and mapped to meet your specific business needs. Site Collaborate and QDMS service offerings are supported for auto-classification, and new document types are easily supported.
- Over 20+ languages are supported out of the box, allowing TI Automate to translate metadata from documentation as needed.
- Just like past TI Automate capabilities, a Confidence Score is assigned to each document and compared against a configurable Confidence Threshold. If the score is high enough, the document may be promoted in the workflow to allow for 'human in the loop' verification.
- TI Automate is a self-training system. Documents that fail to meet the Confidence Threshold are sent for analysis and improvement.

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## 5. TI ANALYTICS

### View eTMF, CTMS, LMS, and QMS KPI Dashboards, Reports, and Tabular Reports

**TTI-3285** - In 10.6, we are adding a new BI and Reporting Solution called TI Analytics.

Standard Analytics Dashboards: Current KPI dashboards will be augmented by standard KPI dashlets for CTMS, eTMF, SSU, LMS, and QMS. These dashlets will be made available using the Reporting Data Warehouse. Cross-study and cross-product dashlets are also possible to create.

Create and Customize Interactive Visualizations and Dashboards: TI Reporting domains are made available to provide sophisticated 'live' dashboard customization capabilities in TI. This will allow us to easily create for clients custom and scheduled dashboards tabular reports and data exports from a single fully managed cloud-based BI service.

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## 6. IDENTITY AND ACCESS MANAGEMENT

An updated Identity and Access Management component is rolling out, 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 will only need to register once on the TI Platform to access all TI products, studies, and environments.
- Each dedicated environment keeps its own preferences regarding password requirements, timeouts, and expirations.
- Supports configuration of multiple SSO systems for a single application and set of users.
- Easily activate multiple options for Sign On, including Single Sign On, Multi-Factor (MFA) using text message or app, One-Time Password (OTP), and familiar SSO options such as MS Teams and Okta.

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## 7. CENTRAL HELP PORTAL

### A Single Portal to Access All Documentation, Help, Training, and Support

**ETMF-1053** - A central portal that all customers can access, providing them with the latest help, videos, job aids, ideas, tickets, and requests. This portal will have the following features:

- The portal will be completely secure, only accessible to TI customers, and available from every product and every dedicated instance.

- All online help will be made available centrally for all TI modules and customer solutions
- Customers will have access to the Manage Engine service desk ticketing system for their tickets and the creation of new tickets
- All Service Requests will be made available, with 'self-serve' custom forms for Archive requests, Site Updates, User Updates, and all other formal requests.
- The latest product release notes will be made available, as well as PDF documentation.
- For Focus Group members, access to the Idea portal will be provided.

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## 8. CONTACT START and END DATES

### **Track contacts accurately for more precise expired document reporting.**

**TTI-3305** - During a clinical trial, site personnel change often at the site, and investigators may participate in a trial for a brief period, and then hand the responsibility to another investigator. This makes tracking required documents somewhat challenging at times, and the expiration of medical licenses and similar documents should be aware of when an investigator joined or left the site staff to ensure documents are not marked as required when they are not needed.

For these reasons, a Contact in the eTMF will now support start and end dates to improve both required and expired document tracking. These start and end dates may be inherited from the CTMS, or they may be set on individual contacts within the eTMF. Once set, these dates are compared against document expirations, ensuring that expiring documents are not tracked for a Contact that has already left the trial (or has not yet joined).

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## 9. QUALITY REVIEW FAILURE REASONS

**TTI-3597** - When a particular document fails during a Quality Review Audit, the system currently prompts for a free text reason for failure. While this free text allows for description, it does not provide for a simple, configurable list of failure reasons like the one supplied during normal QC. This enhancement will add this list, prompting the auditor for a specific reason for failure that may be more easily tracked, managed, and reported.

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## 10. COLLABORATE: CTMS LETTER WORKFLOWS

### **Simplified Visit Report and Letter Workflows, Back-to-Back Comparison of Regenerated Reports with Accept/Reject Capability**

**TTI-3731** - Monitoring Trip Reports and Letters requires a clear, concise workflow. At times, the report must be regenerated from the original data. In these cases, it must be simple to compare the differences and comments between the new and previous versions, and easily accept or reject the changes and comments. This is now also possible with letters, and letter workflows support a clear signature and allow the option for the letter to be quickly reviewed and sent.

After a visit report has been regenerated from the original data, this enhancement provides the capability to compare, accept, reject changes, and view comments between the new and previous versions of the visit report.

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## 11. COLLABORATE: View Active DOCUMENT REVIEWS From One Place

### **Introducing a Consolidated View of Currently Active Workflows and Documents You Are Editing**

**TTI-3344** - This feature removes the "Collaborative Workspace" submodule for Collaborate/QMS/EDMS Room Types and enhances the "Documents" module with new views. The Index view shows all documents in various workflow stages, allowing review workflows to be created from drafts. The Currently Editing view replaces Collaborative Workspace views, showing all documents a user is engaged with, including offline and collaborative tasks. A new Recents view shows documents that were recently edited by the current user, and a Planned view provides all required documents needed completion for that user based on their Responsible Party. Other updates include reorganized views and metadata quick view panel enhancements, focusing on QDMS and Site Collaborate solutions.

## 12. COLLABORATE: TEAM EDIT INSTRUCTIONS and REVIEW UPDATES

**TTI-3727** - This new enhancement introduces the ability to set the name of the collaborate review and provide specific instructions, along with a notification, when initiating a collaborative review session. This is especially beneficial for subsequent review rounds, allowing the review initiator to guide participants' focus—such as directing attention to a particular section—which streamlines the process and eliminates redundant efforts.

An additional enhancement elevates collaboration by empowering all review participants, not just owners and admins, to provide their review comments back, with a notification, when they've completed their reviews.

Finally, if an incorrect effective date is set, the Document Owner may now resend the original document through the approval workflow after changing key pieces of metadata, such as the effective date.

## 13. COLLABORATE: Workflow Options Based on Business Needs

### Automated Processing Room Workflow with Workflows Configured by Document Type

**TTI-3816** - In this Collaborate/QDMS enhancement, documents introduced into the system are instantly engaged in an automated processing workflow, optimizing the initial handling and processing stages. This automatic workflow ensures that no document coming into the room is left unmanaged or untracked. However, recognizing the need for flexibility, the system allows for manual reassignment to alternative workflows, accommodating unique document requirements or changes in project direction.

With this enhancement, workflows and their templates may now be associated with specific Document Types. This provides a greater degree of control over what workflows each specific document type may be engaged in. Additional controls are added to clarify what CTMS workflows and templates may be associated with Visit Reports and Letters.

Finally, in Collaborate / QMS rooms, Document Owners and Proxy Owners may now exclude a document from a workflow, and they are immediately prompted for the new desired workflow based on the Document Type.

## 14. COLLABORATE: Send Safety Letter Acknowledgements

### Safety Letters and Other Critical Site Documents in the TI Safety Solution

**TTI-2975** - This enhancement, focused on the Safety Letter tracking solution, introduces a streamlined 'Read and Understand' acknowledgment feature, which significantly simplifies the process of confirming the review of critical documents at a Site. With this capability, users can electronically acknowledge new documents such as CIOMS, DSURs, Investigator Brochures and other critical documents, ensuring the timely confirmation of safety issues and avoiding manual follow-ups. With just a click, notifications are sent to all relevant parties, who can then acknowledge and confirm its receipt. Each acknowledgment is logged as a separate record, maintaining a transparent and traceable record of who has reviewed and understood the document. This system additionally supports the cancellation and replacement of the acknowledgment.

## 15. SSU: Sponsor Oversight

**TTI-3539** - For CROs using TI Study Start-Up, Sponsors are required to review and approve the first few sites before all Sites can be activated. This is required as the Sponsors want to oversee the process.

- The system shall support an additional level of QC check for documents called 'Sponsor Review'
- The system shall allow the Start-up Specialist (SUS) to push any documents for Sponsor Review.
- The system shall provide a new view for the Sponsor (just like the regulatory Reviewer) to access the documents available for review
- The Sponsor shall have the ability to approve or reject the documents submitted for review.

## 16. SSU IRB APPROVAL: Submission Packages

**TTI-2988** - SSU supports creating, tracking and managing Submission Packages for Health Agencies. However, submissions are required to be made to IRBs and Ethics Committees throughout the lifecycle of the Study.

With this enhancement, SSU will expand the concept of Submission Packages to IRBs/ECs.



- The system shall allow creating of Submission Packages for IRBs associating them with Sites.
- The Submission Packages shall have different status.
- When approving the Submission Package, the system shall prompt the User to identify the Sites for which the approval has been received.
- The system shall allow approving all or some Sites associated with the Submission Package
- Approval for submission packages shall trickle down to sites IMPROVEMENTS SUBMISSION PACKAGES

In the European Union, a single submission package is created that is used for multiple countries. This new feature provides a way to assign a submission package to multiple countries.

- When creating a submission package, or when editing it, the User has the ability to assign multiple countries in the submission package profile tab.
  - When multiple countries are chosen, this submission package automatically shows in each of those countries.
- When the status of the submission package is changed, it automatically shows the status for all the countries associated with that submission package.

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## 17. REPORT UPDATES

The following reporting improvements have been made:

### Updated Feature:

- **Audit Summary Report:** Includes the percentage quality of the quality review
- **Document Submission Inventory Workflow Report:** Includes the Organization name to provide the name of the company the user belongs to
- **Placeholder Report:** Now includes information about the assignee for each placeholder, and a listing of all documents linked.
- **Document Review Report:** Many new fields have been added.
- **Queries Report:** Editor users can now view all queries.
- **UPDATED All Reports:** Manager role may now configure the reports dashboard.
- **UPDATED All Reports:** Now contain a description of the report.

### New Feature:

- **Index/Filing Structure Report:** Provides a validated snapshot of a TI Room's current configuration for both the index and document types
- **Controlled Documents Report:** Provides comprehensive details of controlled documents
- **Acknowledgments Report:** Provides details on the current set of acknowledgments.

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## 18. TECHNICAL UPDATES

The following technical improvements are made to Trial Interactive:

- TI now supports a new content store, supporting much larger file sizes and improved performance.
- TI now supports an upgraded database service, improving performance and scalability.
- TI now supports a Universal Document ID for all Document Types and all rooms, allowing for a simpler association and management of document classification.
- TI Viewer: A new version of the TI Viewer is now included, supporting bulk page rotations and an improved user interface
- TI Editor: A new version of the TI Editor is now included, supporting back-to-back document comparison and many other capabilities
- TI now supports the detection and reporting of problematic files, including encrypted files, Portfolio PDFs, password-protected documents, and digitally signed PDFs.



## CHAPTER 1: GETTING STARTED

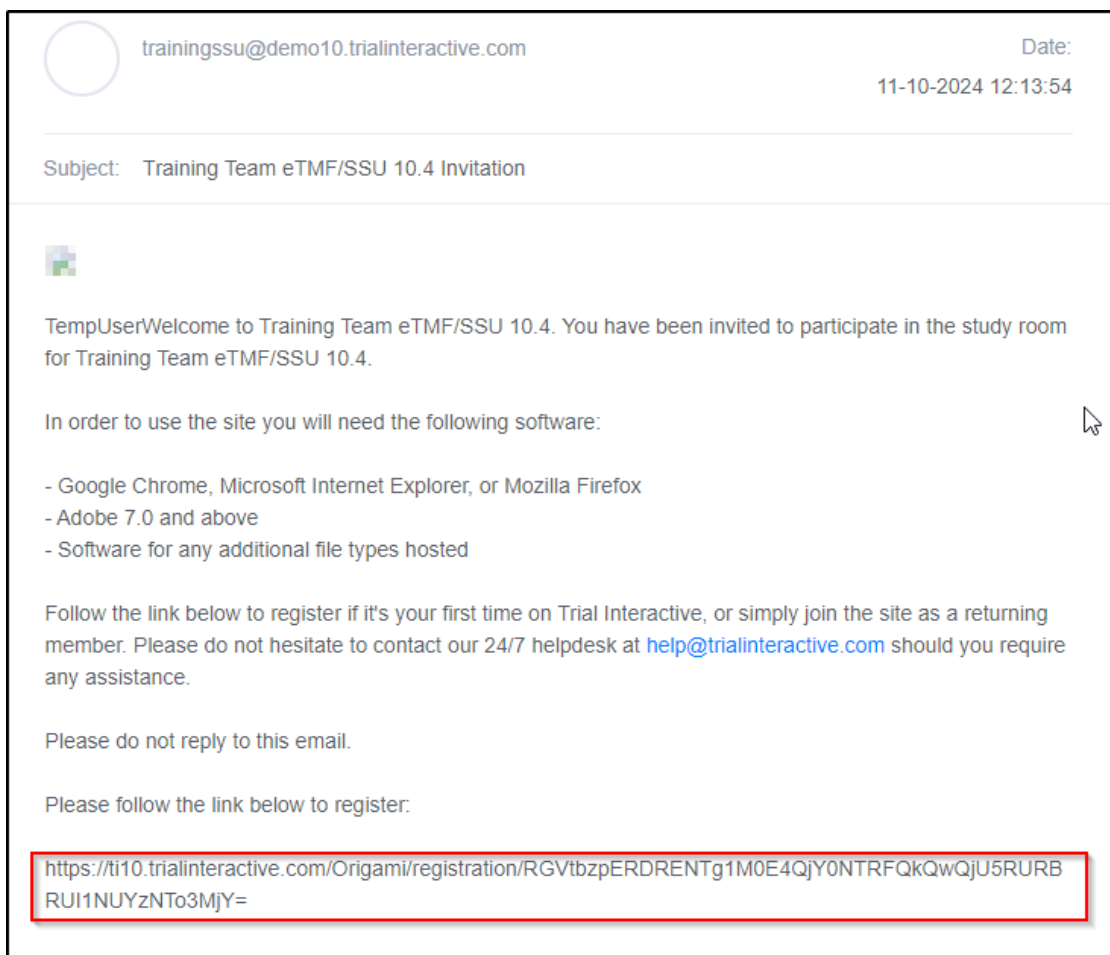
This section describes the signing-in, room invitations, and user registration in Trial Interactive v10.6

Trial Interactive helps clinical teams build an eTMF for clinical trials and 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 priorities 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

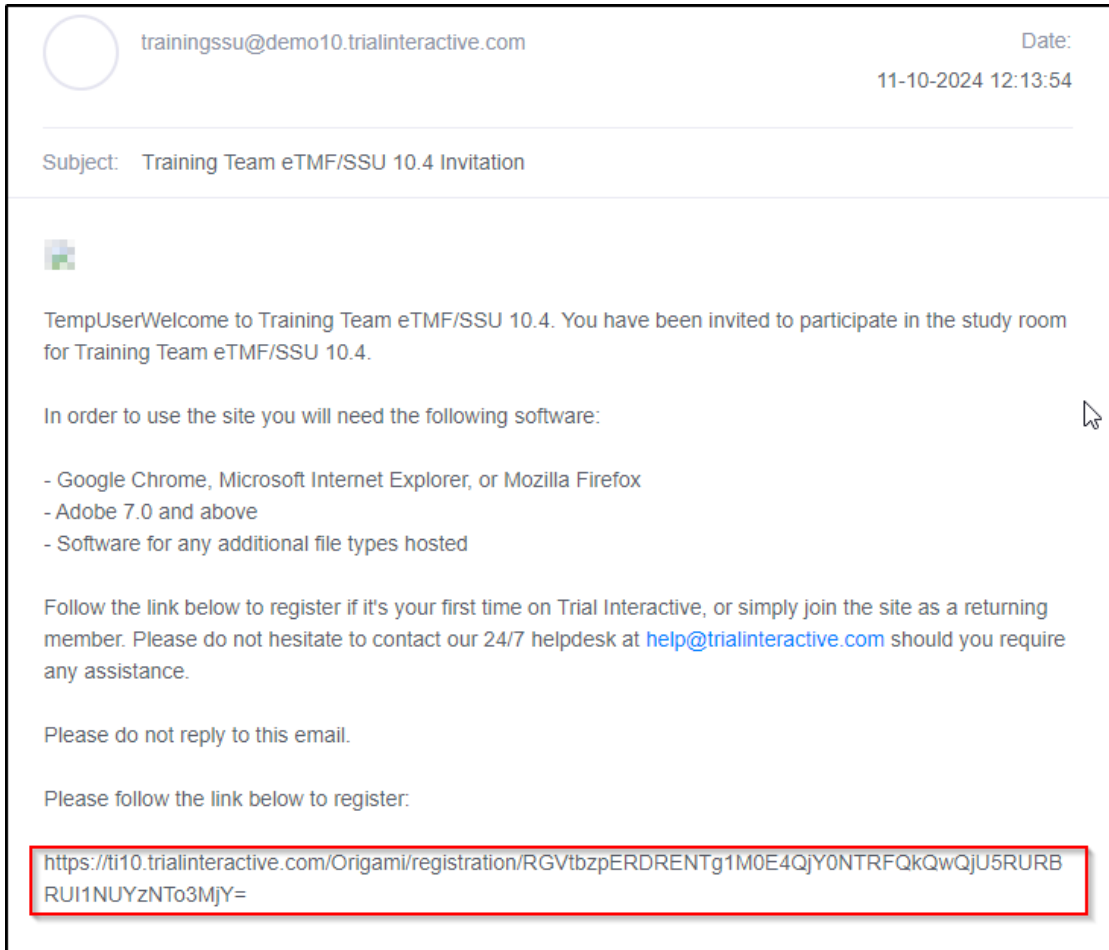
1. Once a Trial Interactive room Administrator has sent you an invitation, you will receive an email message with a registration link. Refer to the screenshot below.

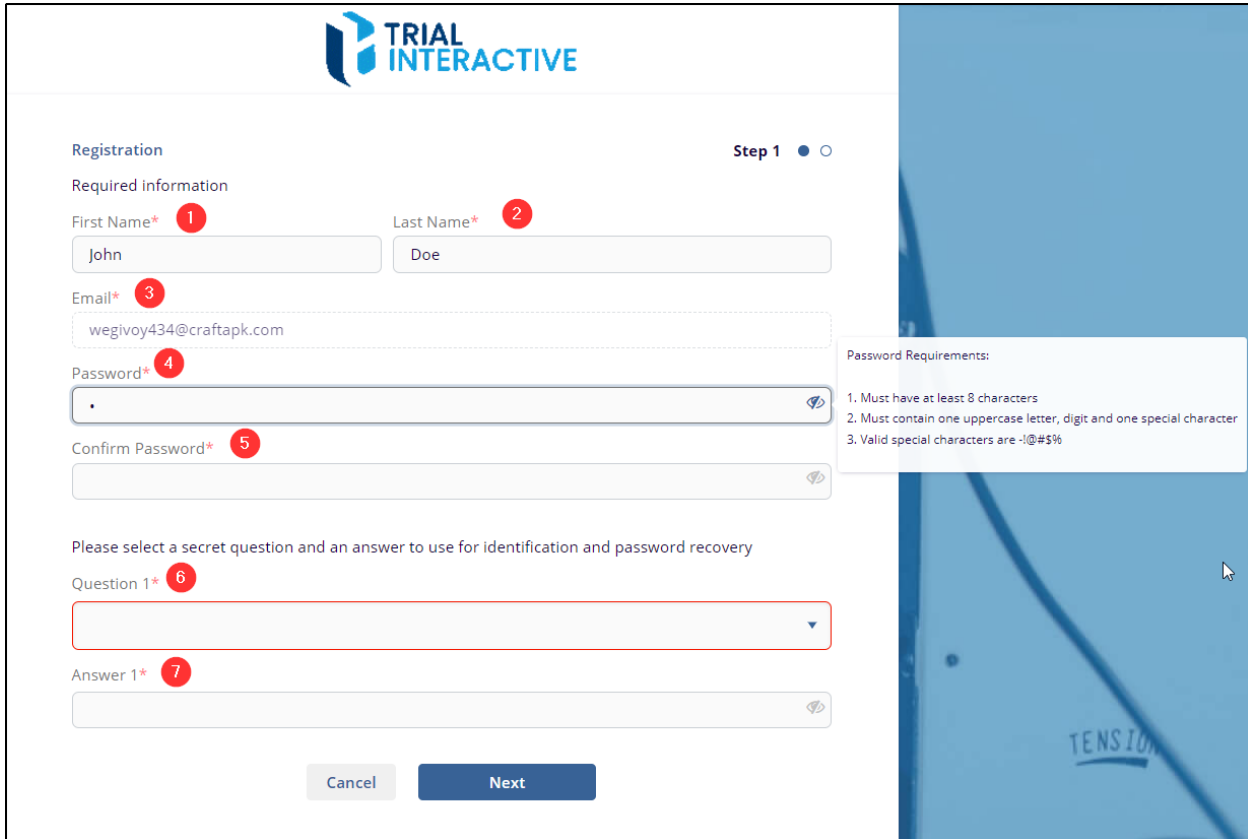


**Note:** Complete a one-time registration when you receive your first email notification for room access. Once registered, you can sign into your room directly. If you're invited to additional rooms, no further registration is required. New rooms will automatically appear on your Home page under your list of accessible rooms. You will continue to receive email notifications for any future room invitations.

19. Steps for Registration:

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





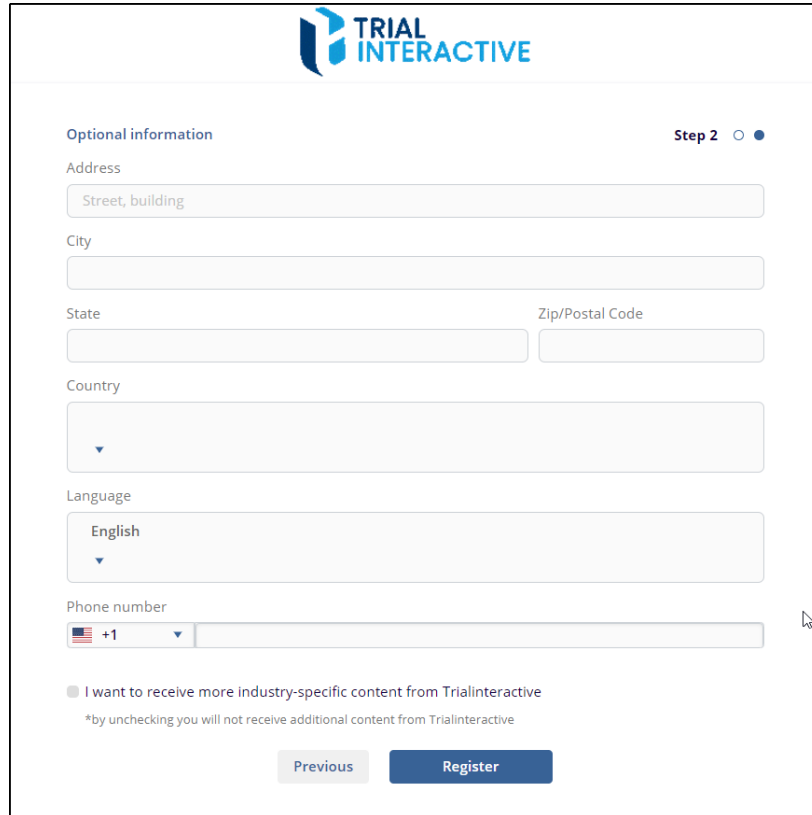
2. Enter your **first name** and **last name** in the provided field.
3. Email address will be automatically filled by the system.
4. Create a secure password, then re-enter it in the Confirm Password field to verify.

**Note:** Hover over the Password field to view the tooltip with specific password requirements.

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

## 20. Step 2: Registration - Optional Information

1. On this page, enter your contact address, phone number, and any other relevant details. Click on **Register** to proceed.



**Optional information** Step 2

Address

City

State  Zip/Postal Code

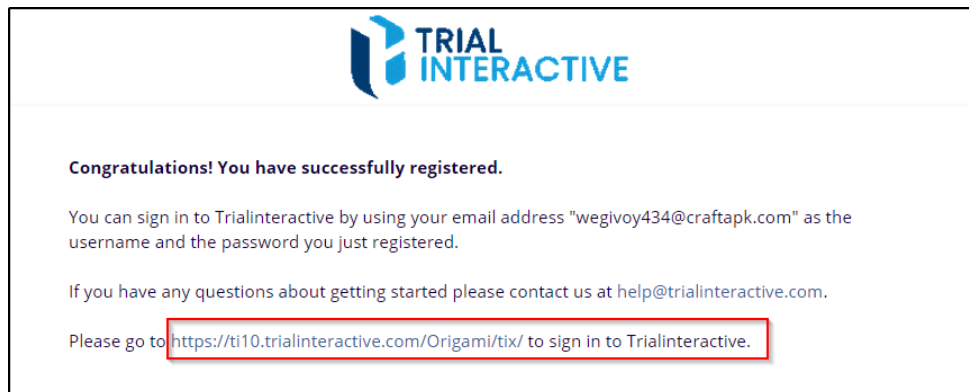
Country

Language

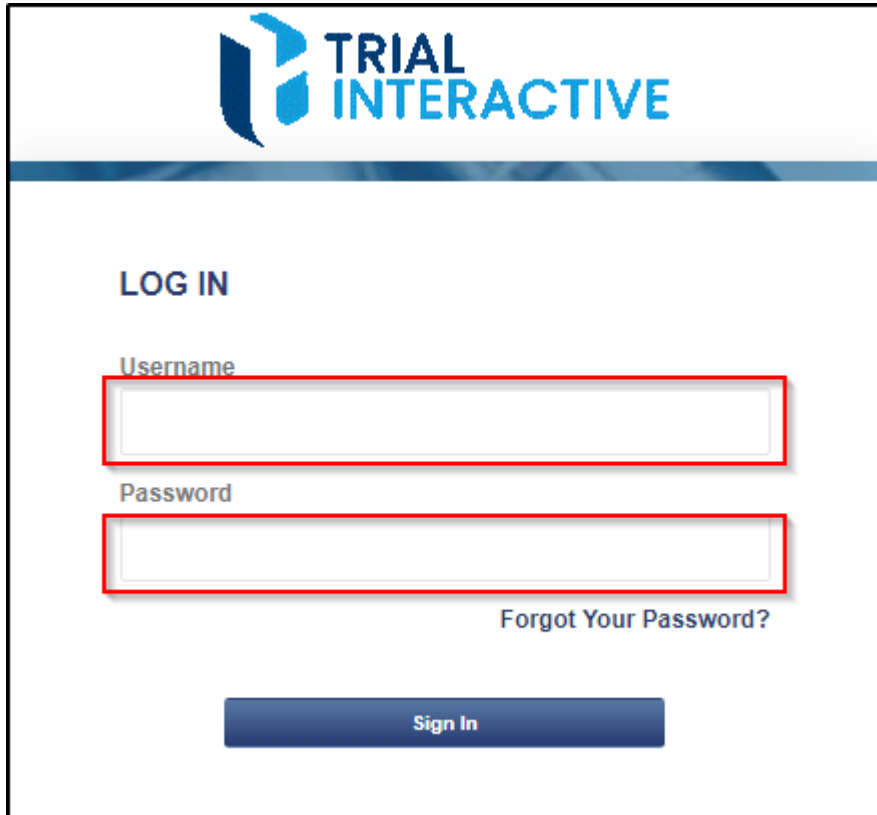
Phone number

I want to receive more industry-specific content from Trialinteractive  
\*by unchecking you will not receive additional content from Trialinteractive

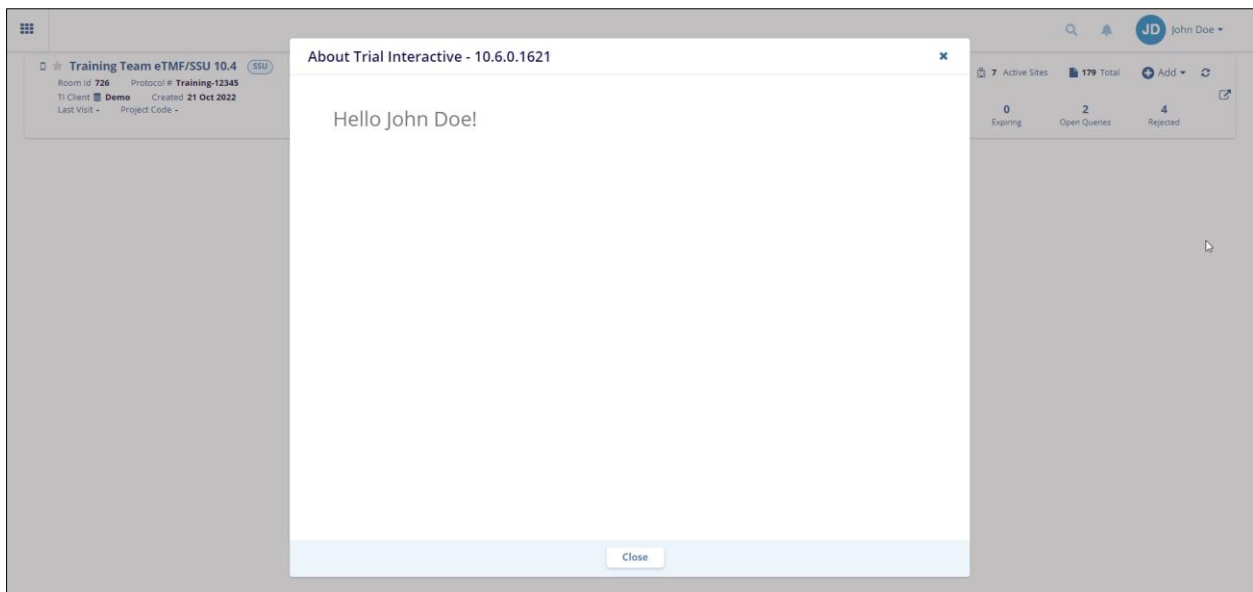
2. After clicking the registration button, a confirmation pop-up will appear, indicating that you have successfully registered. The pop-up will also include a link to the room that has been assigned to you.
3. Click on the bottom link to access the room. Refer to the screenshot below.



4. It will be redirected to the Trial Interactive login page. Enter the username and password you provided during the registration process, then click the **Sign In** button to log in.



5. it will be redirected to the Trial Interactive Home Page. Refer to the below screen.

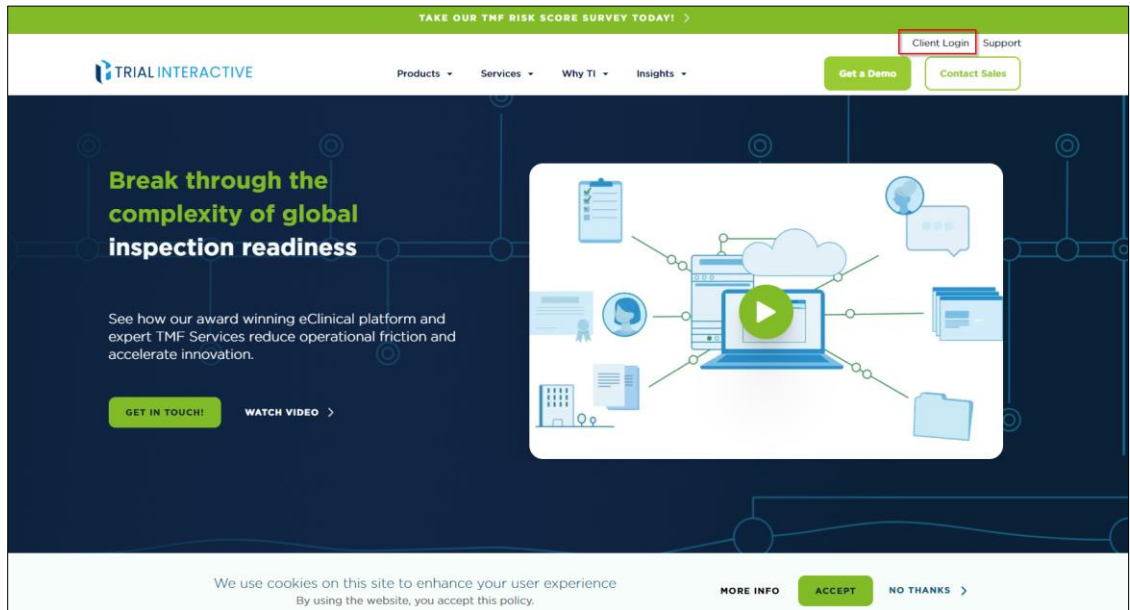


6. To learn more about Trial Interactive Home Page [Click here.](#)

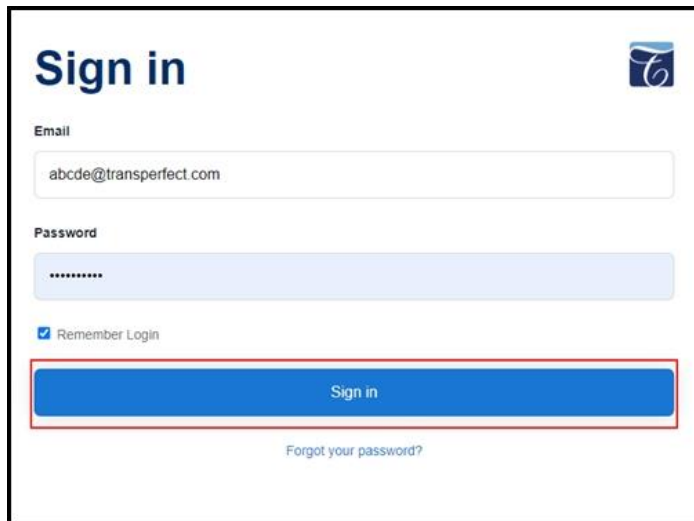
## Signing in on Subsequent Visits

### 21. How to login 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.



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 the **Trial Interactive Home page**.



The screenshot shows the Trial Interactive Sign in page. It features a 'Sign in' heading, an 'Email' input field with the text 'abcde@transperfect.com', a 'Password' input field with masked characters, a 'Remember Login' checkbox, and a 'Sign in' button. The 'Sign in' button is highlighted with a red box. Below the button is a link for 'Forgot your password?'.

### Requesting a Password Reset

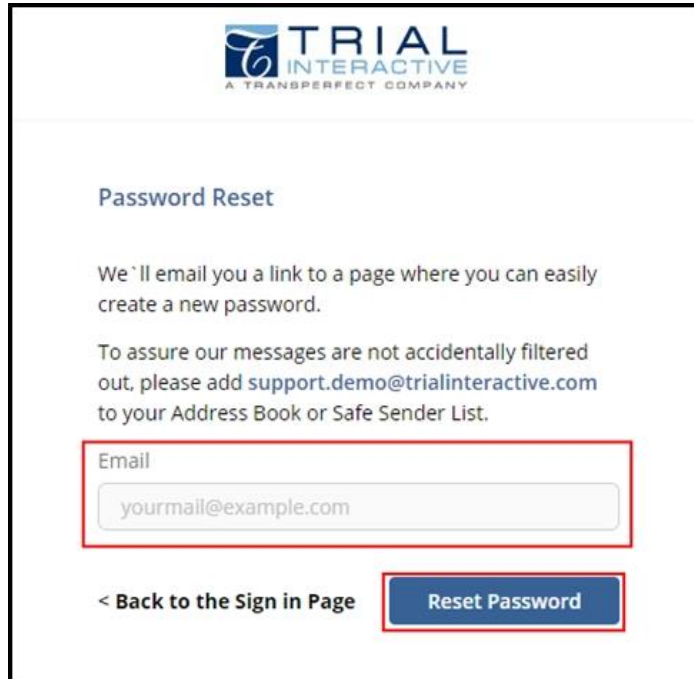
In the event that you have forgotten your password, click 'Forgot Your Password?' at the bottom of the login window to initiate an account password reset.



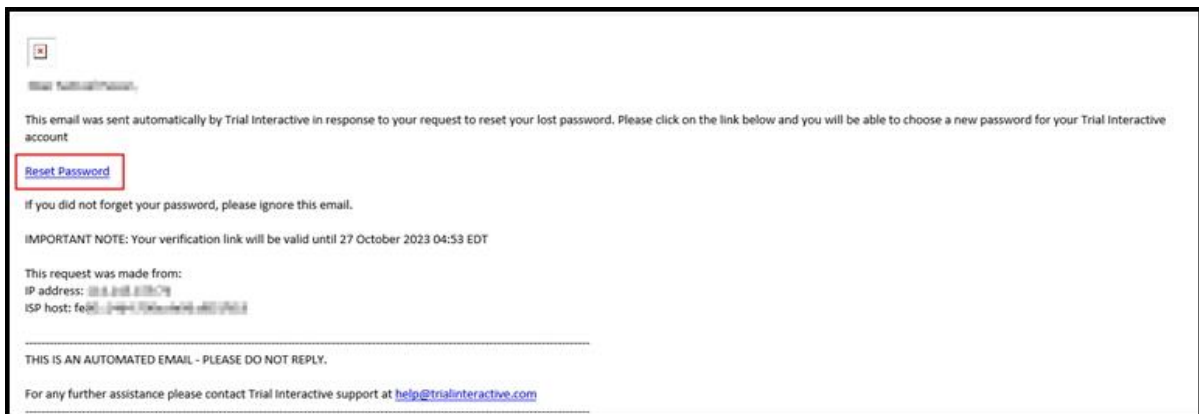
Users do not need to contact the Service Desk. In most cases, the user can perform the Password Reset operations without any outside help. When you click the 'Forgot your Password?' link, a password reset email will be sent to the email address associated with your user account.

**Follow these steps to reset your password:**

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



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



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.



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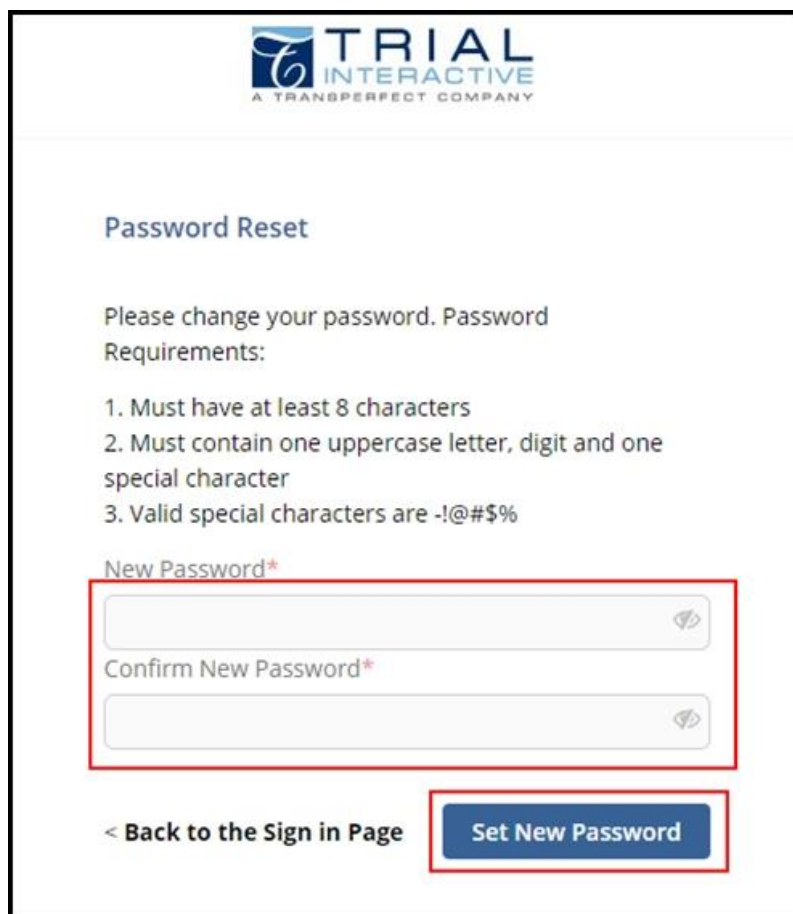
**Password Reset**

Please answer secret questions

What was the name of your first pet?

< **Back to the Sign in Page** **Next**

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



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**Password Reset**

Please change your password. Password Requirements:

1. Must have at least 8 characters
2. Must contain one uppercase letter, digit and one special character
3. Valid special characters are -!@#\$\$%

New Password\*

Confirm New Password\*

< **Back to the Sign in Page** **Set New Password**

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

## CHAPTER 2: TRIAL INTERACTIVE HOME PAGE

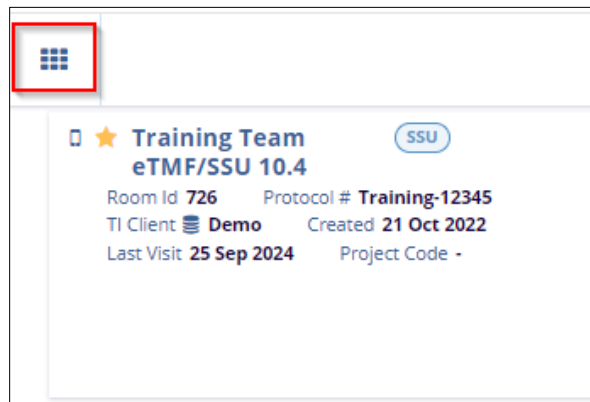
This section provides all the functionalities of the homepage and an overview of all the rooms assigned to the user.

Once signed in to Trial Interactive, users are automatically directed to the **Trial Interactive Home Screen**, as shown in the screenshot below.

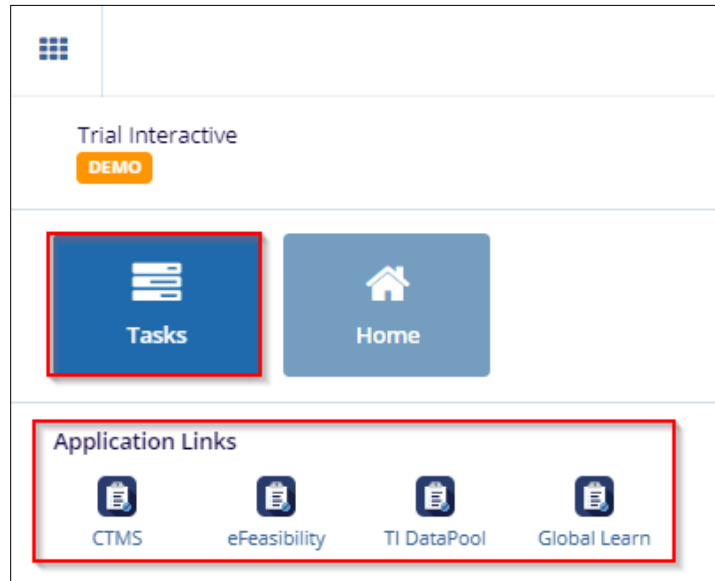


### Home Page Grid View.

1. Click on the **Grid** icon at the top left corner.

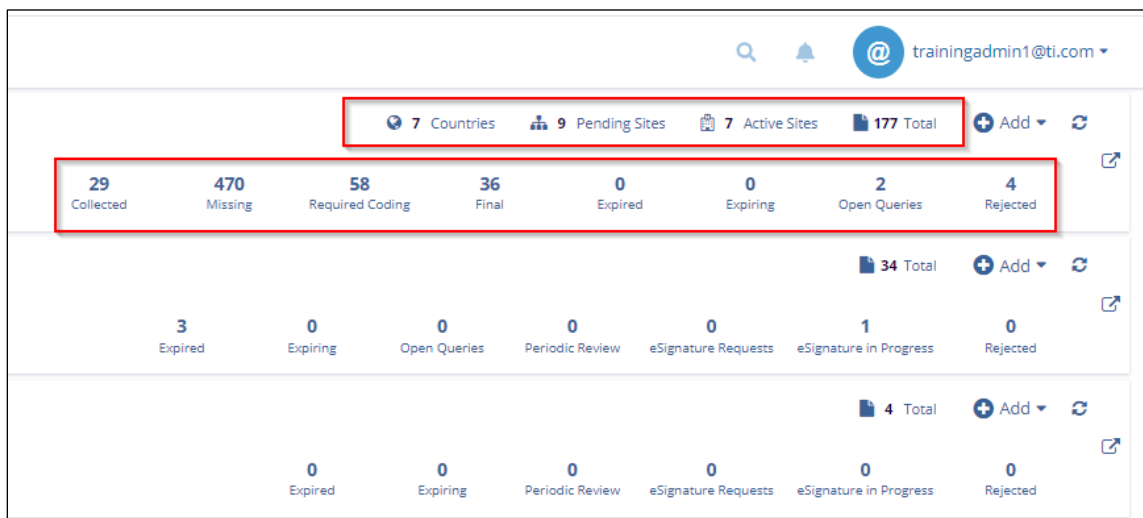


2. It displays the Tasks and Application Links.
3. To check the assigned task, click on the **Task**. It will redirect the user to the Task grid view.
4. Additionally, the user can access the application by clicking on the **Application Name**. Refer to the screenshot below.



### Rooms Documents view on Homepage

1. On the right side of the Home Page, users can view the total number of Countries, Pending Sites, Active Sites, and the total number of documents available in the room.
2. The Home Page provides an overview of document statuses, including the number of **Collected**, **Missing**, **Required Coding Final**, **Expired**, **Expiring**, **Open Queries**, and **Rejected** documents.

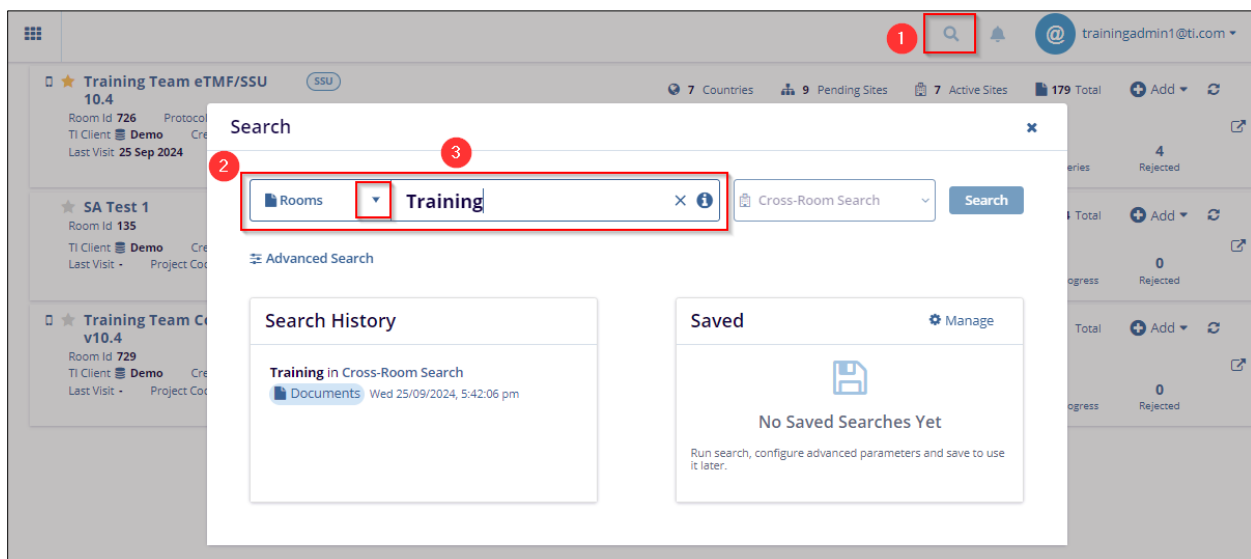


3. Below all the entities have been explained.
  - **Countries:** This is the number of countries in the room. It is available for eTMF or Collaborate rooms.
  - **Pending sites:** This is the number of non-active investigative sites. It is available for eTMF or Study Start-Up rooms.
  - **Active sites:** The number of active investigative sites. It is available for eTMF or Study Start-Up rooms.
  - **Expired documents:** 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
  - **Total documents:** 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.
  - **Collected documents:** 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.

- Missing documents:** 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.  
 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.
- 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
- 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.
- Open queries:** This is the number of "Pending" and "In Progress" queries in the room. It is available for all rooms with queries.
- 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.
- 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.
- Periodic review:** This is the number of documents that 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.
- 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 Trial Interactive Room

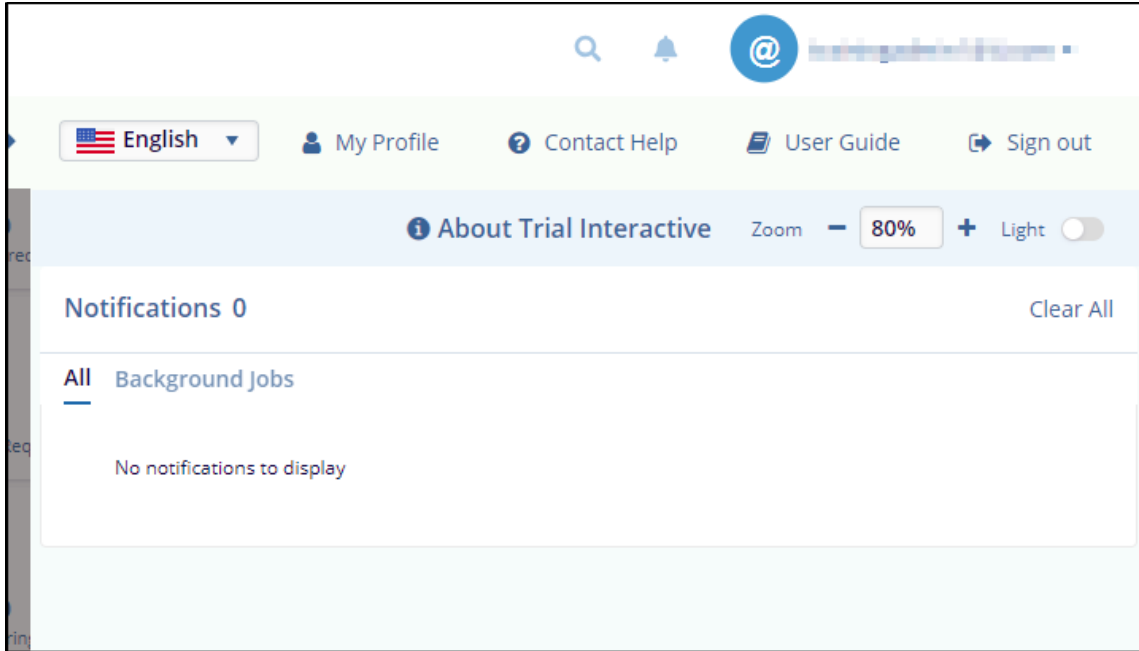
- At the top right of the application, you'll find a magnifying glass icon for searching assigned rooms.
- Click the magnifying glass icon to open the search screen.
- From there, select a room entity from the drop-down menu and type the room name to search.
- Click on the room name in the panel to enter the room. Refer to the below screenshot



- To learn how to perform advanced search in TI, click [Advanced Search](#).

## Homepage username menu

1. Click on **the Bell Icon, @Symbol or Username** on the top left corner. These three options will display a side window user can check Profile, Contact Help, User Guide, About Trial Interactive and Notifications.



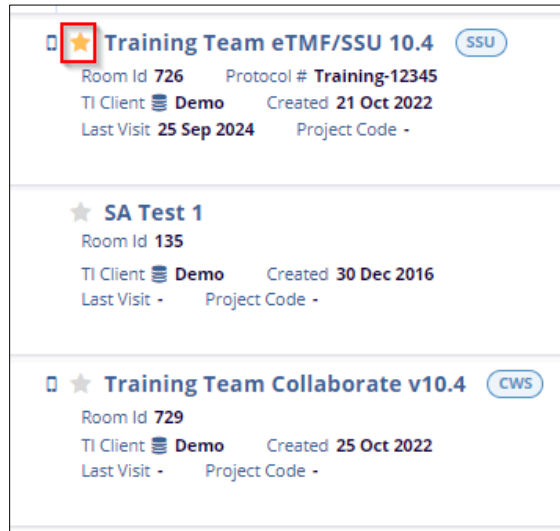
## myTI Enabled Rooms

To make it easier to keep track of the rooms you have access to through both the standard online application and myTI, an icon will now appear next to any room accessible via myTI. This icon will also be visible within the room itself and will be added to your Username Menu dot for quick identification.



### Mark Room as Favorite

1. On the left side of the Home Page, users can view a list of all assigned rooms, along with detailed room-specific information. Key details, including Room ID, Creation Date, Last Visit, Protocol, TI Client, and Project Code, are displayed for convenient reference. Users can also mark a room as a favorite by clicking the Star Icon.



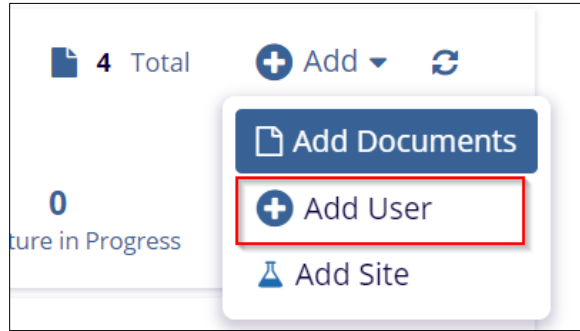
### Add Users to a Room from the Home page

#### Steps to Add Users to a Room from the Home Page:

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



2. From the dropdown list, select 'Add Users'. This will open the User Invitation window.



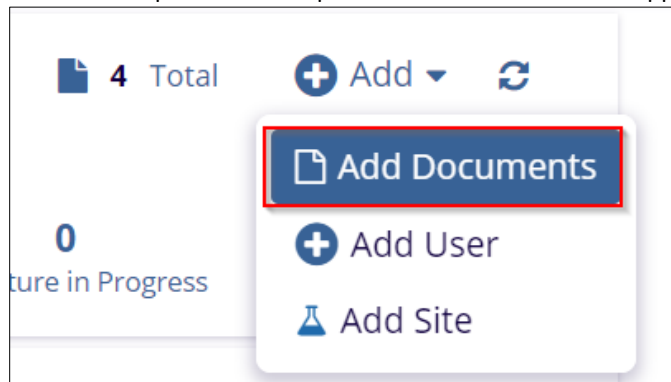
3. Insert all Mandatory fields. We have three sections **User details**, **Invitation Details**, and **Contact Details**.
4. Select any Groups if you want to add the user to a group.
5. From the **Organization** dropdown, choose the relevant organization. You can also create a new organization by clicking the (+) sign.
6. In the **Invitation** Details section, we can select the appropriate **Expiration Date** and **Time**. It is used to remove user access from a particular room after a specific period.

### Import Documents to a Room from Home Page

1. Click the Add dropdown button located on the right side of the room on the home page.

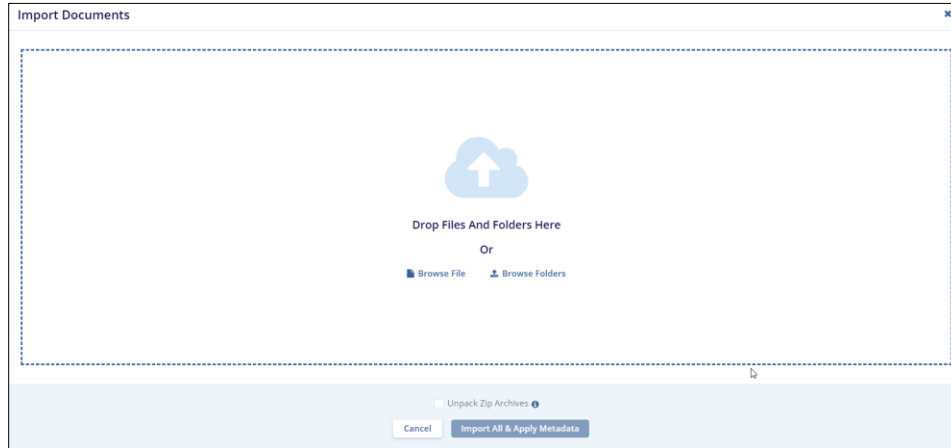


2. Select 'Add Documents' from the dropdown. The Import Documents window will appear.



3. **Drag and drop** the files into the window, or click '**Browse**' at the bottom of the page to locate and upload the required document.





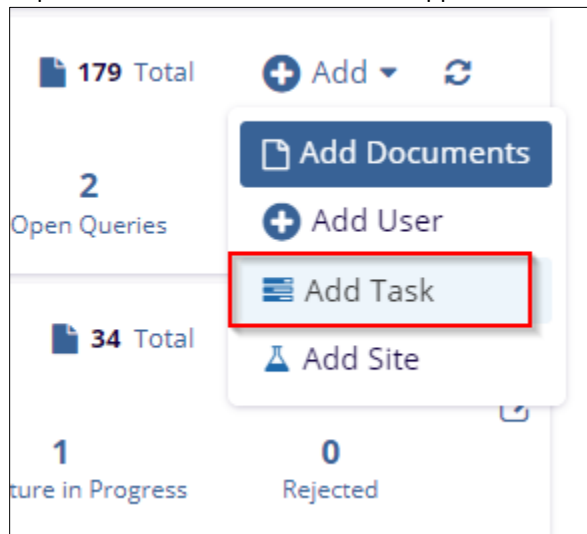
4. After uploading the document user can apply Metadata.

### Add Task to a Room from the Home Page

1. Click the Add dropdown button located on the right side of the room on the home page.




2. Select 'Add Task' from the dropdown. The Add Task window will appear.




3. The **Create Task** window will open.
4. Enter the required details as prompted on the screen.

**Create Task**
✕

Subject

Start Date  

Due Date  

Priority  ▼

Status  ▼ ✕

Complete %  ▲▼

Description

Assign To \*  ✕

Reminder

Category  ▼ ✕

Trial

Attachments

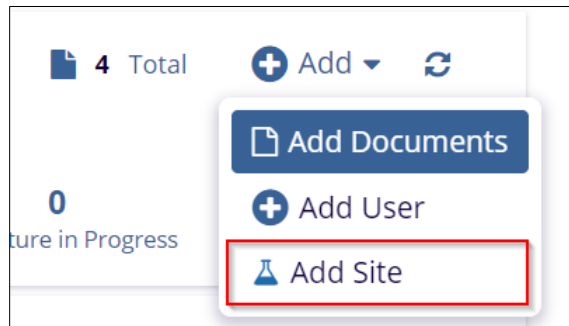
5. Once all the information is entered, click **Save** to complete the task creation.

## Add Sites to a Room from the Home Page

1. Click the **Add** dropdown button on the home page's right side of the room.



2. Select **'Add Sites'** from the dropdown. The **New Site** window will appear.



## CHAPTER 3: USERNAME MENU

This section describes the functions and features under the Username Menu.

To Navigate the user menu, click on the user’s name or the drop-down arrow displayed in the top right corner of the homepage

Through the **Username Menu**, you can access the following:

- Language Settings
- My Profile
- Contact Help (Contact Support)
- User Guide
- Sign Out
- About Trial Interactive
- Zoom
- Dark Mode/Light Mode
- Notifications



### Language Setting

To set your preferred language:

1. Click on the **Language dropdown**.
2. Scroll down to locate your preferred language.
3. Click on the **language** to select it.
4. The room menu and field labels will change to the selected language.

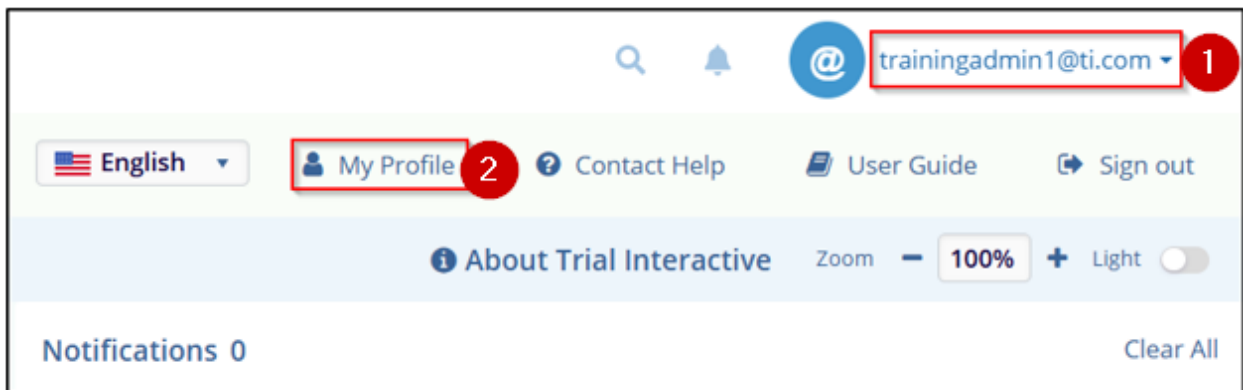


## My Profile

By clicking on the **'My Profile'** option. The User can manage the 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.

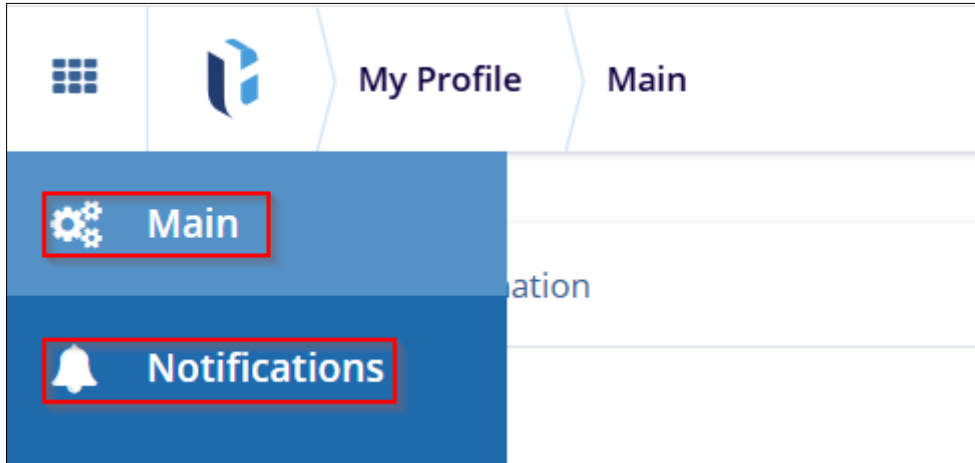
### To access My Profile:

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



My Profile area is divided into two sections:

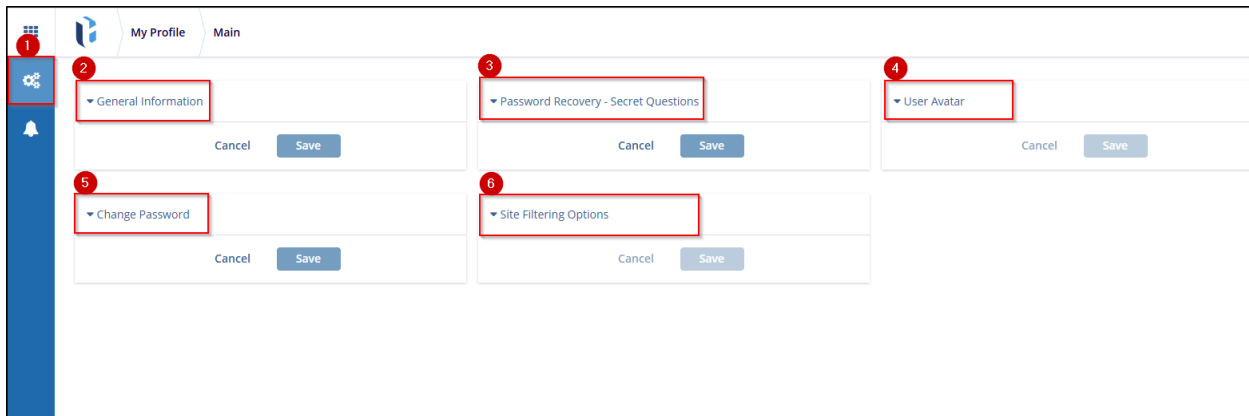
- **Main (My Profile Settings)**
- Notifications



Navigate to the vertical menu at the left to choose sections. Click on the Main section from the left panel.

In this Section, you will find the following **User Profile Dashlet**.

- **General Information**
- **Password Recovery - Secret Questions**
- **User Avatar**
- **Change Password**
- **Site Filtering Options**



## 22. General Information

To set the preferred language and date applicable:

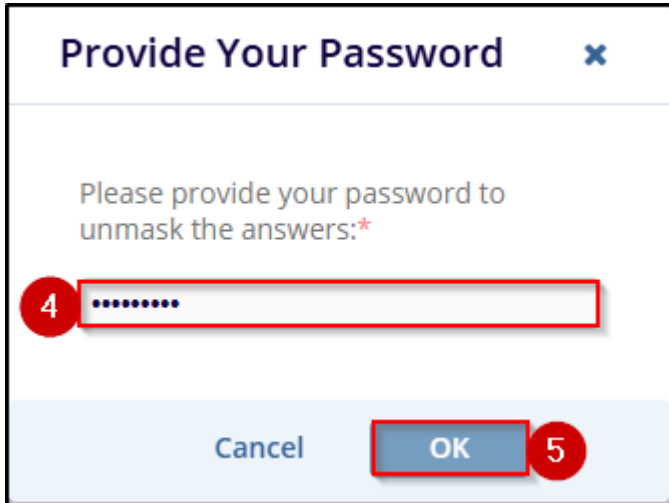
1. Click on the **Language dropdown**.
2. Scroll down to locate your preferred language.
3. Click on the **language** to select it.
4. The user profile dashlet and field labels will change to the selected language.
5. Click on the checkbox to enable custom date input.
6. Enter the date format preferred by user. **Date format should contain day ("D", "DD"), month ("M", "MM", "MMM", "MMMM"), year ("YY", "YYYY") and separator ("/", "-", ".")**
7. Once done, Save the changes. By clicking on the **Save** button.

### 23. Password Recovery – Secret Question

You are required to set the answers to secret questions to help recover passwords in case they forget their Password.

To set the secret questions and their answers:

1. Click the down arrow in the "**Question 1**" field. Scroll through the list of questions in the popup and select your preferred question.
2. Click on the question of your choice to select it.
3. Enter your answer in the "**Answer**" field.
4. To confirm your password click on the "**Unmask answer**" icon.
5. A pop-up will appear "**Please provide your password to unmask the answer**". Provide your answer and click on the "**Ok**" button.
6. Click the "**Save**" button.



## 24. Change password

In this section, you can change the existing password to set a new one.

To set the password:

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

Note: Password Requirements:

- Must have at least 8 characters.
- Must contain one uppercase letter, digit, and one special character.
- Valid special characters are -!@#\$\$%



▲ Change Password

---

Please change your password

Password Requirements:

1. Must have at least 8 characters
2. Must contain one uppercase letter, digit and one special character
3. Valid special characters are -!@#\$\$%

Current Password\*

 1
 

New Password\*

 2
 

Confirm New Password\*

 3
 

Cancel  4

## 25. 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.

▲ Site Filtering Options

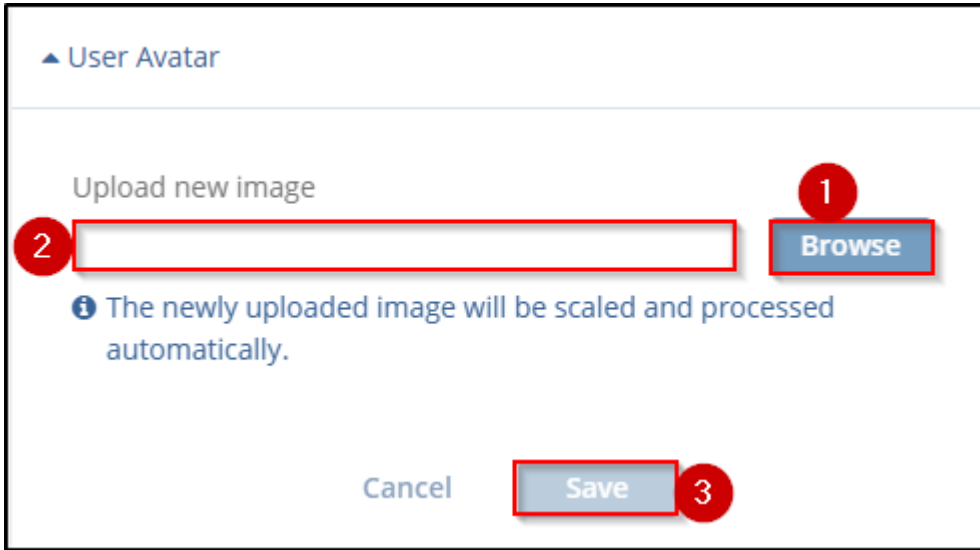
---

1  Show only my sites (my favorite sites, and the sites where I am CRA / Start Up Specialist)

Cancel  2

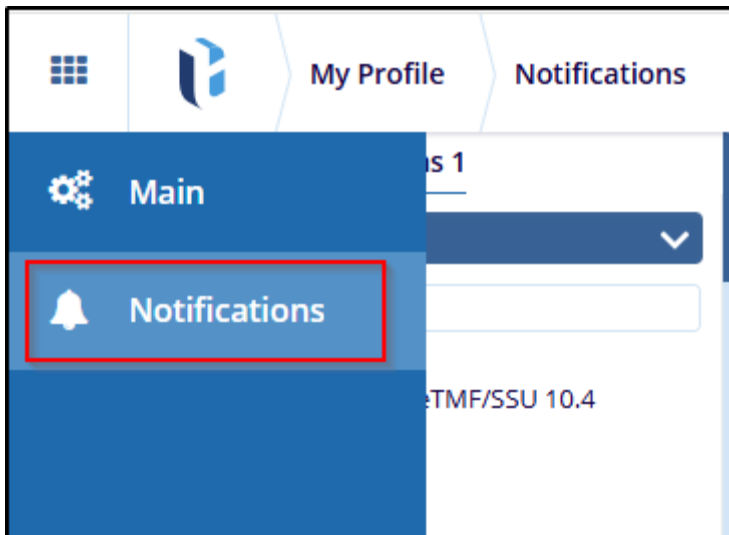
## 26. User Avatar

Click on the “Browse” button to upload a new image for your login, and click the “Save” button.



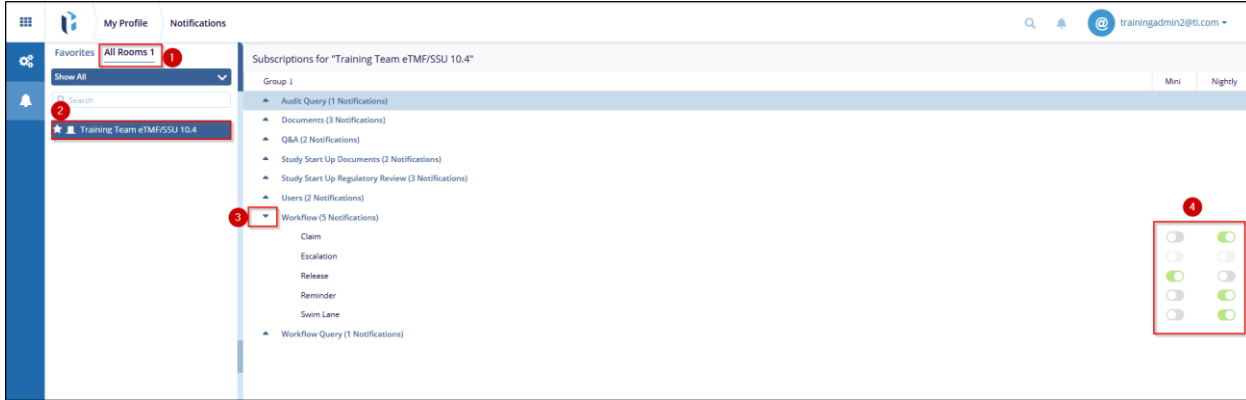
## 27. My Profile Notifications

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.



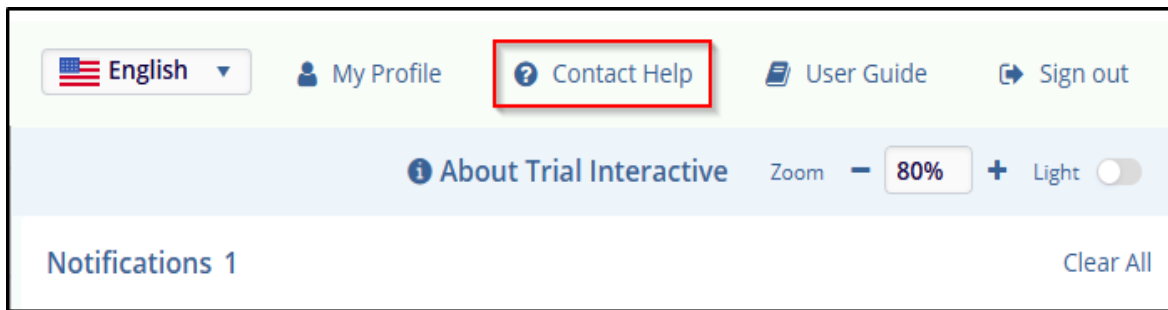
Select the desired room from the list of studies in the left pane of the Notifications panel. Using the options grid on the right of the Subscriptions window, you can select which notifications you would like to receive. Administrators can choose which notifications are available for you, and they can 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 room administrator selects the frequency of mini-notifications in the Settings module.



## Contact Help

In this section, where you need any help related to Trial Interactive, you can contact the **Service Desk** by clicking on **“Contact Help”** from the Username Menu.



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

**Contact Support** ✕

Hello User, please use this form to contact the Service Desk

Room Name\*

Email Address\*

Open Sans ▾ 12 ▾ 🔥 **B I U S** 🔗 ☰ ▾ ☰ ▾ ☰ ▾

➤ Send

### User Guide

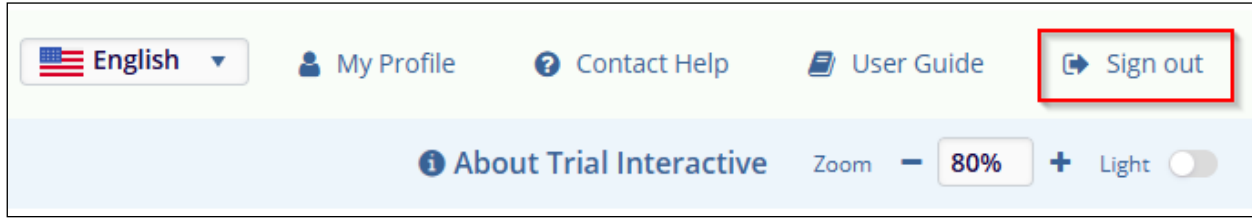
This section takes you to the “**Online User Guide**” which contains the full contents of this document, in addition to job aids and videos designed to help you perform many of the most common tasks in Trial Interactive.

My Profile
 Contact Help
 User Guide
 Sign out

About Trial Interactive
Zoom - 80% + Light

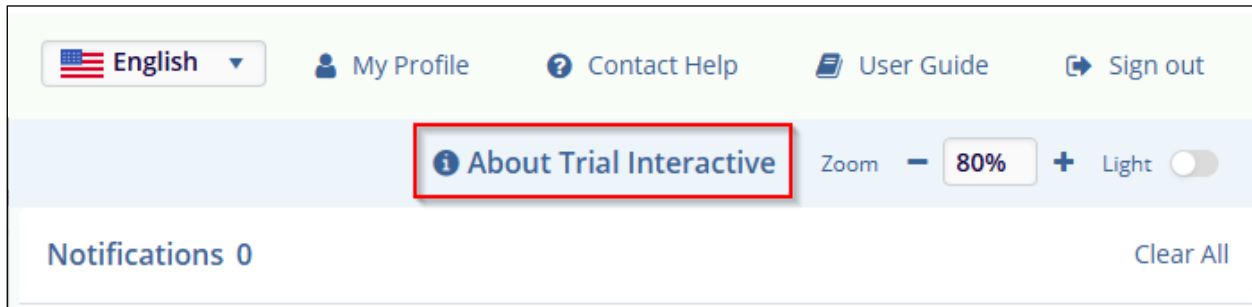
### Sign Out

Click on the **Sign-out** button at the top right corner, as shown in the below screenshot and you will be logged out of your account.

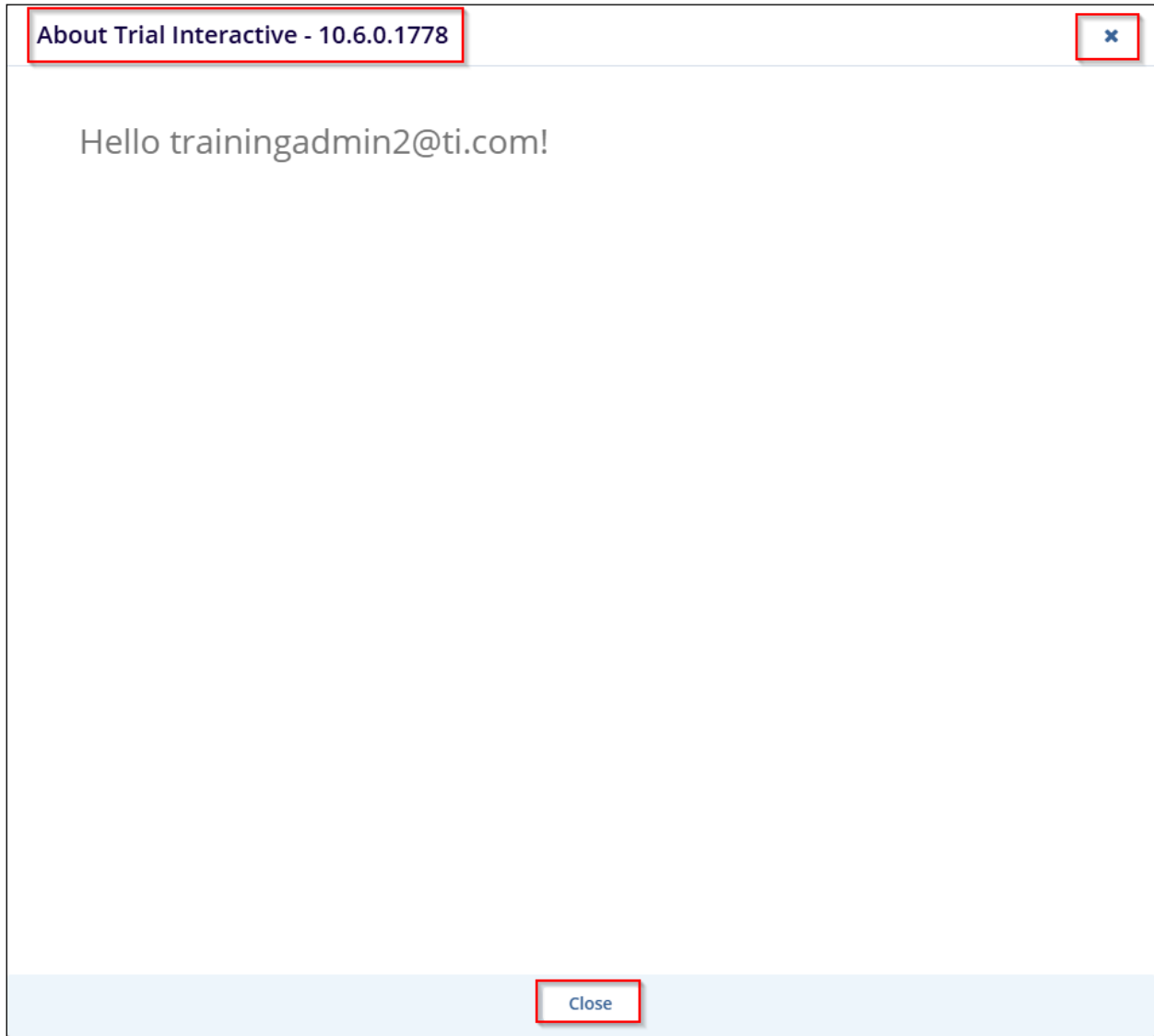


### About Trial Interactive

Click on the " **About Trial Interactive**" link to reveal the **About Trial Interactive**. Administrator-level users typically configure this to welcome new users and provide them with information about the **Trial Interactive version**.

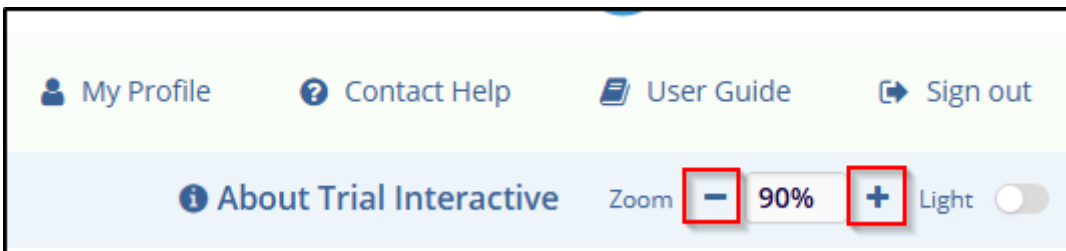


Click on "close button" at the bottom, to close the pop-up window of Trial Interactive



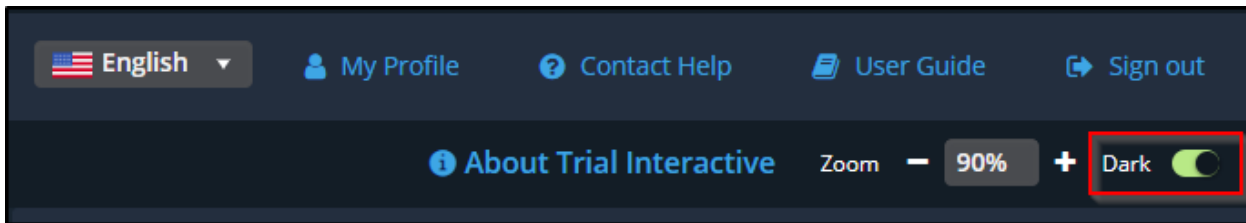
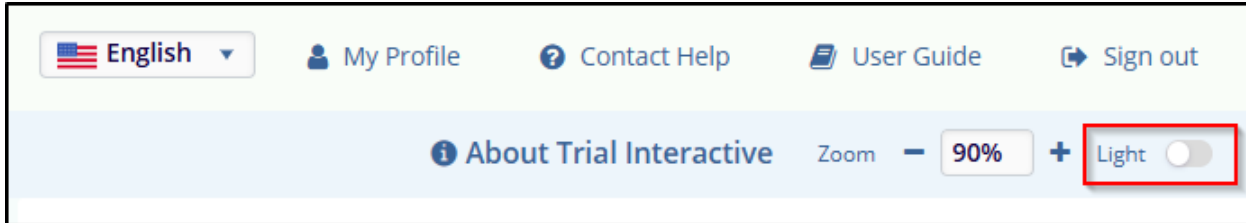
## Zoom

To zoom in on a room, press on “+ sign” to enlarge the content size. To zoom out, press on “– sign” to decrease the content size, as shown in the below screenshot.



## Dark mode/light mode

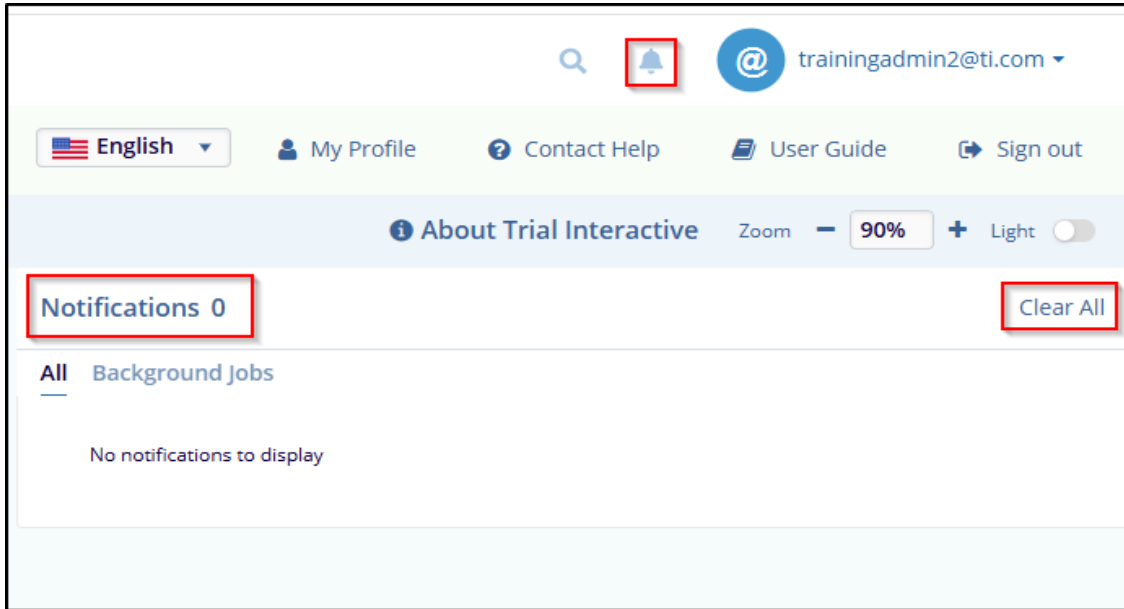
To switch between Dark Mode and Light Mode. Choose **Dark Mode** for a low-light-friendly interface or **Light Mode** for a brighter look, switch based on your system preferences. As shown in the below screenshot.



## Notifications

When the Username Menu slides out from the side of the screen, the lower portion is dedicated 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 screenshot below:



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.
- **Background Jobs:** Through this tab, you are notified about a background job that is executed or 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.
- **Clear All:** Click on this tab to immediately clear all notifications.

## CHAPTER 4: TRIAL INTERACTIVE USER MANAGEMENT

The User Management Module allows room administrators to manage Contacts, Groups, and Users.

Administrators can do the following from within this application:

- **Invite new users to a room/study**
- **Create groups of users**
- **View lists of room users under different categories**
- **Edit user profiles**
- **Change the access level of users in a room and groups to which they are assigned**
- **Resend invitations to room users**
- **Filter and Export users**
- **Revoke a user's access**

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



The screenshot displays the Trial Interactive dashboard interface. At the top, there is a navigation bar with the Trial Interactive logo, a user profile for 'Training Team eT...', and a 'Module eTMF' dropdown. Below the navigation bar, the dashboard content is organized into a grid of blue buttons, each with an icon and a label. The buttons are arranged as follows:

- Row 1: Start-Up (flask icon), eTMF (cubes icon), QC Review (document icon), Communication (envelope icon).
- Row 2: CRA Reconciliation (line graph icon), Periodic Quality Review (document icon), Tasks (list icon), Reports (bar chart icon).
- Row 3: **Users Management** (group of people icon, highlighted with a red border), Q & A (speech bubble icon), FAQ (speech bubble icon), Queries (two speech bubbles icon).
- Row 4: Event Manager (calendar icon), Settings (gears icon), Home (house icon).

On the right side of the dashboard, there is a vertical sidebar with a 'ew M' label and a blue button.

## User Management - User

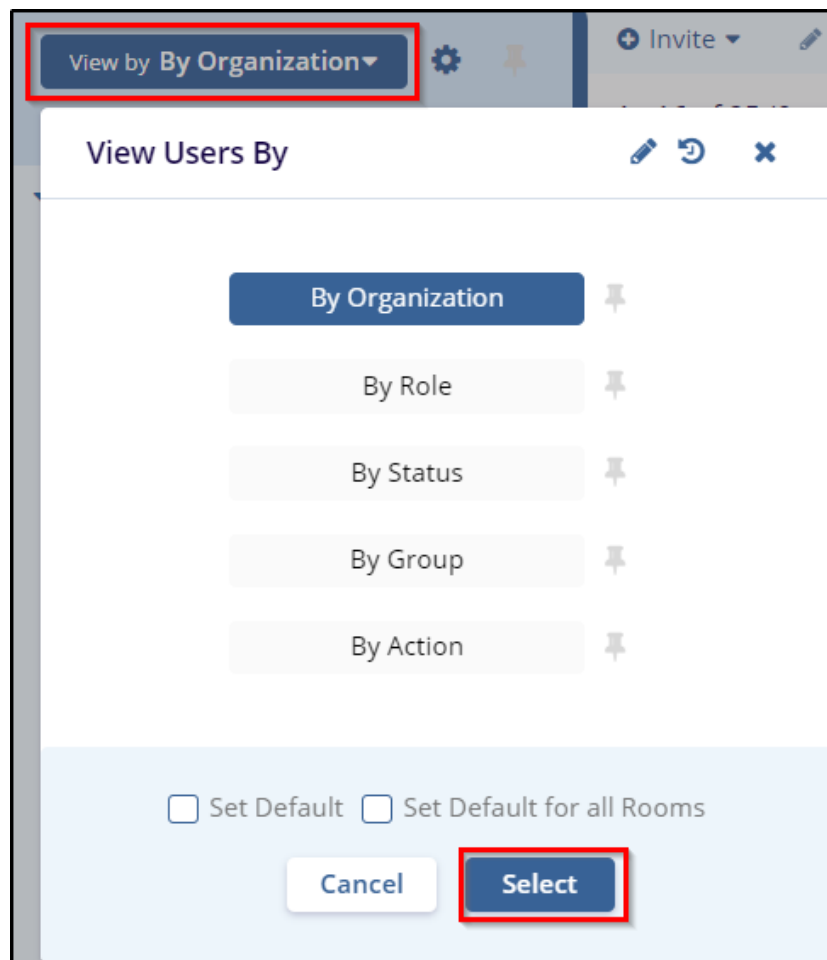
From this page, you can do the following:

- Invite users
- Edit user profiles
- View user access to the room
- Export user data

### 28. How to view users

In Trial Interactive, users are categorized for easier access and viewing. You can filter users by different categories using the following steps:

1. Click the **View By** dropdown in the left panel.
2. A list of available categories will appear.
3. Select the category you'd like to use to filter the users in the room.
4. Click **Select** at the bottom of the popup window.
5. Additionally, you have two options for setting the default view:
6. **Set Default:** By checking the **Set Default** box, you can set the selected category as the default view for the current room.



## 29. User Profile Fields

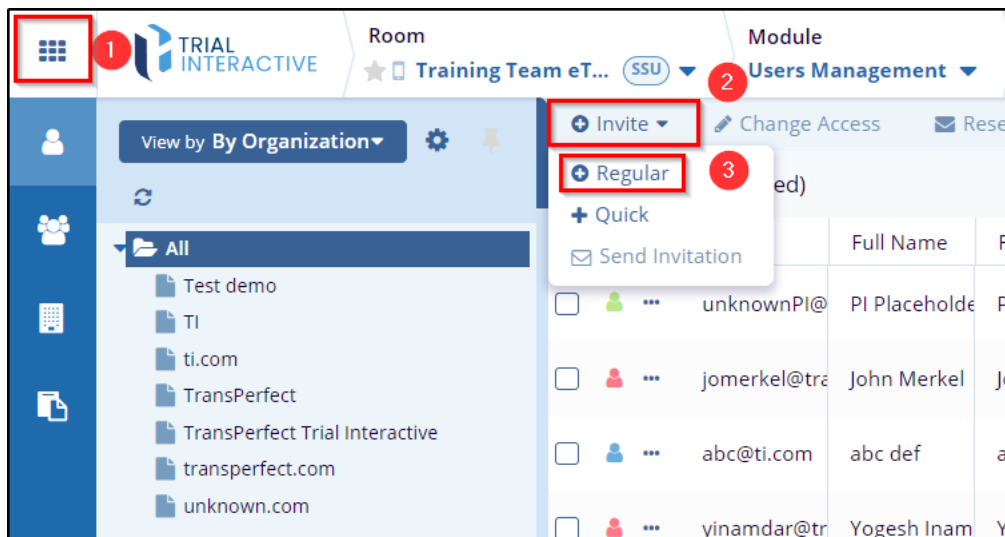
The fields of importance are discussed below:

1. **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.
2. 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.
3. **Role:** Choose the role from the dropdown.
4. **Actions:** These are tasks that the user would be allowed to perform in addition to the basic rights associated with their user access role.
5. **Expiration Date:** Enter this date if you want the user's access to be revoked on a certain date.
6. **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.
7. **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.
8. **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.

## 30. How to Invite New Users via the Regular Invitation

Here's a streamlined process for inviting new users using the Regular Invitation method:

1. Navigate to Users Management: Go to the Navigation Grid → Users Management → Users.



2. Click the Invite dropdown in the top menu bar, then select 'Regular' from the list.
3. Fill in the required details on the form that appears. To Understand All mandatory fields, Click [Here](#).

The screenshot shows the 'User Invitation' form with two tabs: 'User' and 'Groups'. The 'User' tab is active, displaying 'User Details' and 'Invitation Details' sections. The 'User Details' section includes fields for Email, First Name, Middle Name, Last Name, Title, Prefix, Suffix, Role, and Organization. The 'Invitation Details' section includes an Expiration Date field with a calendar icon and an 'Invite Later' checkbox. At the bottom of the form, there are 'Cancel' and 'Save' buttons, with the 'Save' button highlighted by a red box.

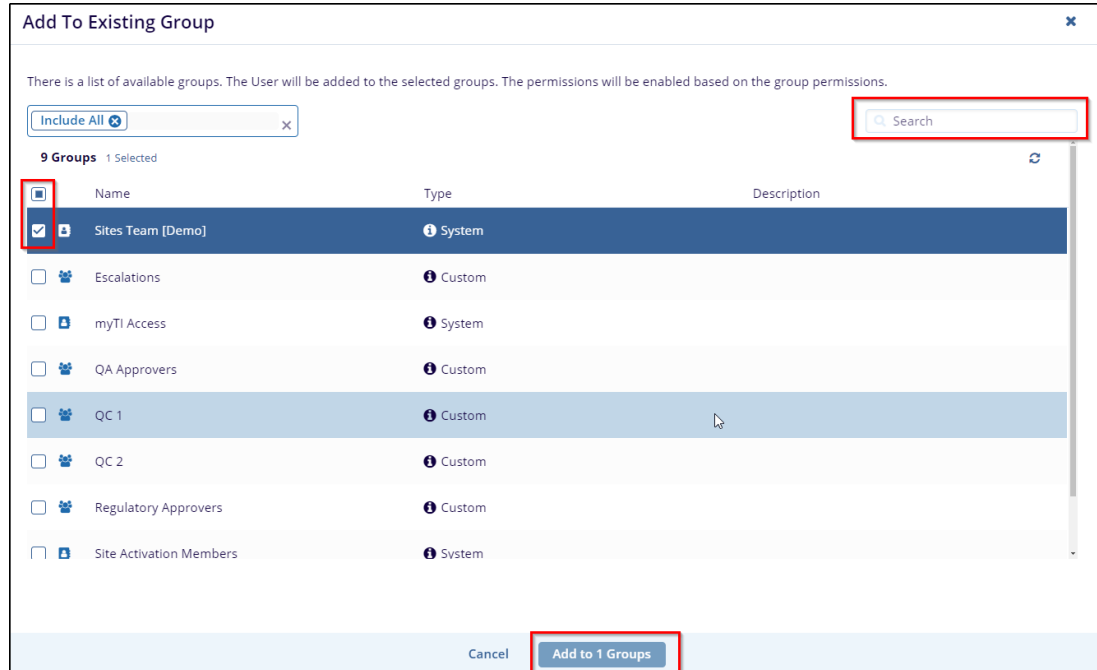
4. Assign Groups (Optional): To assign the user to a group, click on the Groups tab at the top.

This screenshot shows the 'User Invitation' form with the 'Groups' tab selected. The 'User' tab is underlined, and the 'Groups' tab is highlighted with a red box. Below the tabs, the 'User Details' section is visible, starting with an 'Email' field.

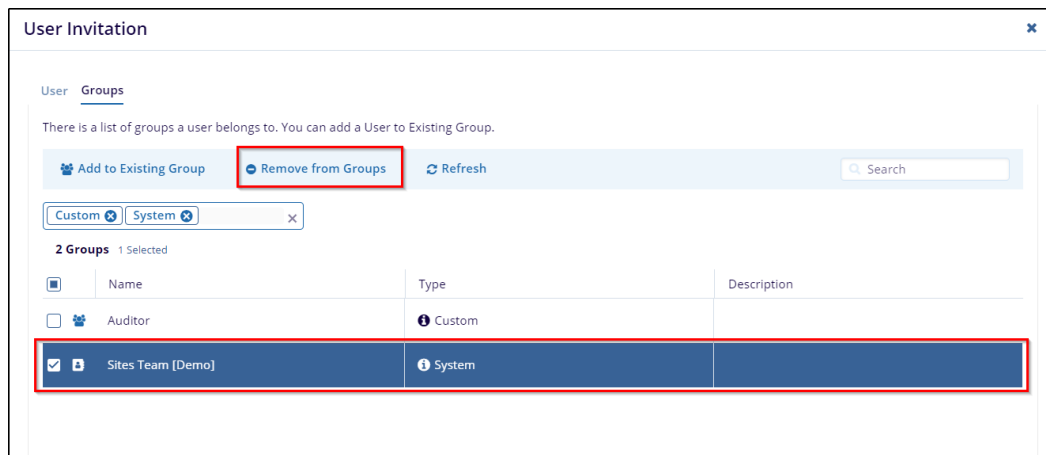
5. Select "Add to Existing Group" from the top.

This screenshot shows the 'User Invitation' form with the 'Groups' tab selected. Below the tabs, there is a message: "There is a list of groups a user belongs to. You can add a User to Existing Group." Below this message are three buttons: "Add to Existing Group" (highlighted with a red box), "Remove from Groups", and "Refresh". At the bottom, there is a list of groups: "Custom" and "System", each with a close button (X).

6. The **Add to Existing Group** window will appear. Select the group(s) by checking the corresponding checkboxes. You can also search for a group from the left side of the screen.



- Once selected the required groups, click on the **“Add to Group”** button at the bottom.
- To remove the user from a group, check the group’s checkbox and click on the **“Remove from Group”** button at the top.



- After assigning the user to the group(s), return to the User Invitation screen and click Save to complete the process.
- Add to Existing Group Window will appear select the group by clicking on the checkbox and Click on the **“Add to Group”** button from the bottom. From the left side of the screen, the user can search the group as well.
- To remove the user from the group, click on the checkbox of the group and click the **“Remove from Groups”** button from the top.

### User Invitation ✕

User Groups

There is a list of groups a user belongs to. You can add a User to Existing Group.

➤ Add to Existing Group
➤ Remove from Groups
↻ Refresh

Custom ✕
System ✕
✕

**2 Groups** 1 Selected

	Name	Type	Description
<input type="checkbox"/>	Auditor	Custom	
<input checked="" type="checkbox"/>	Sites Team [Demo]	System	

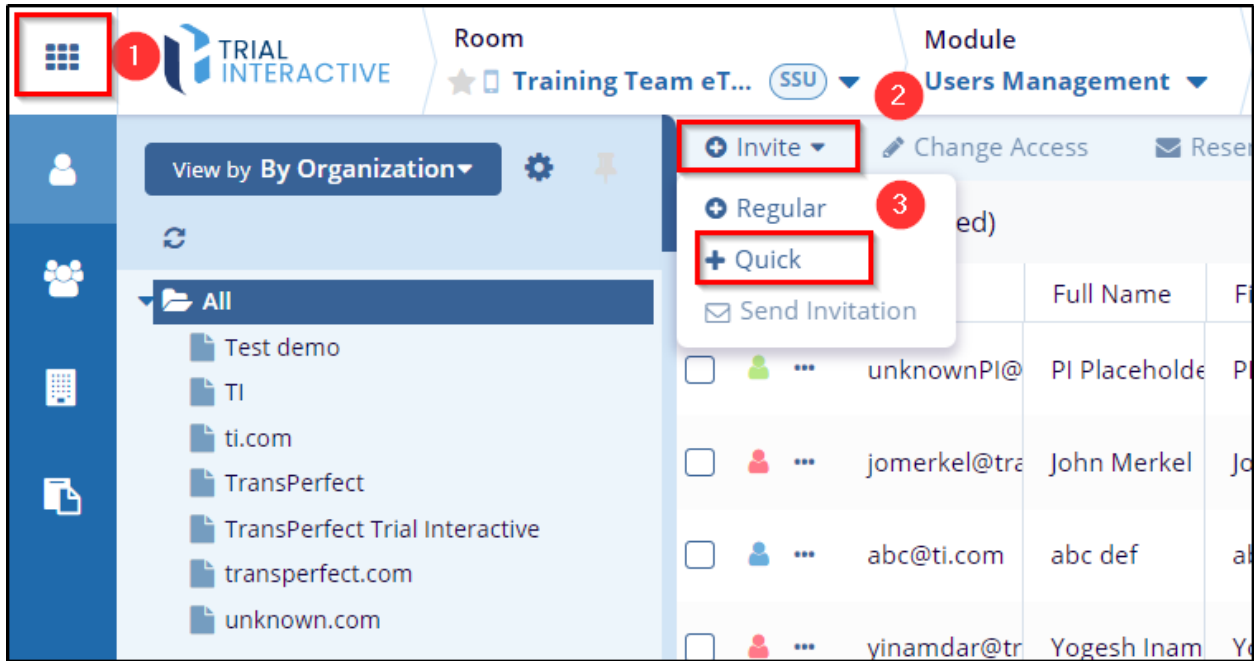
12. After adding to the group come by to user screen and click the save button. Completed the user invitation process using a regular invite.

## 31. Inviting New Users via the Quick Invitation

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

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 the **Invite Later** if appropriate.
6. Click the **Groups** text box to assign the users to any appropriate groups.
7. Click **Add**.

Refer to the screenshot below:

### Quick Invite ✕

Email List\*

This field is required

Role\*

This field is required

Expiration Date

Actions

Invite Later

Groups

## 32. Editing a User's Profile

User access can be adjusted at any time from the **User's Management** module. Follow these steps to edit a user's profile:

1. Click on the username or checkbox from the list of displayed users. This will open the **User Details** window from right side.

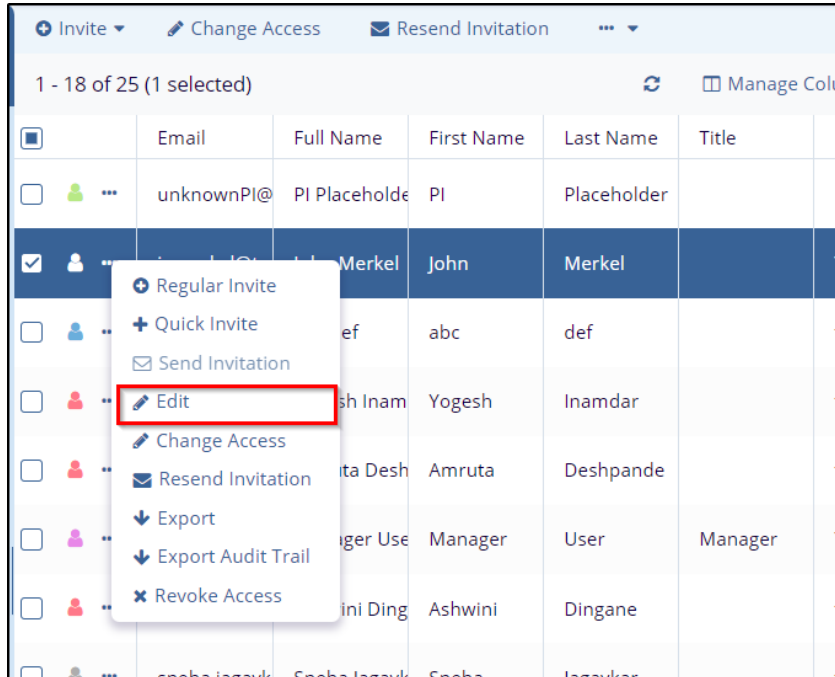
The screenshot shows the 'Users Management' module in the application. A table lists 25 users, with the first user 'unknownPI@...' selected. The 'User Details' panel on the right is open, showing fields for Email, First Name, Middle Name, Last Name, Title, Prefix, Suffix, and Role. The 'Role' dropdown is set to 'Editor'. The 'User Details' panel is highlighted with a red border.

Checkbox	Email	Full Name	First Name	Last Name	Title	Organiza...	Address
<input checked="" type="checkbox"/>	unknownPI@...	PI Placeholder	PI	Placeholder		unknown.com	
<input type="checkbox"/>	jomerkel@tr...	John Merkel	John	Merkel		TransPerfect	
<input type="checkbox"/>	abc@ti.com	abc def	abc	def		ti.com	
<input type="checkbox"/>	yogesh@ti.com	Yogesh Inam	Yogesh	Inamdar		ti.com	
<input type="checkbox"/>	amdeshpand	Amruta Desh	Amruta	Deshpande		ti.com	
<input type="checkbox"/>	ManagerUser	Manager Use	Manager	User	Manager	TI	
<input type="checkbox"/>	adingane@tr...	Ashwini Ding	Ashwini	Dingane		ti.com	
<input type="checkbox"/>	snehajagavk	Sneha Jagavk	Sneha	Jagavkar		ti.com	
<input type="checkbox"/>	lorenzoadmir	Demo Admin	Demo	Admin		ti.com	
<input type="checkbox"/>	manskandh	Mansi Kandh	Mansi	Kandhare		ti.com	Aundh
<input type="checkbox"/>	reader111	Reader 111	Reader	111		Test demo	
<input type="checkbox"/>	ssuinbox@tic	ssuinbox@tic				ti.com	

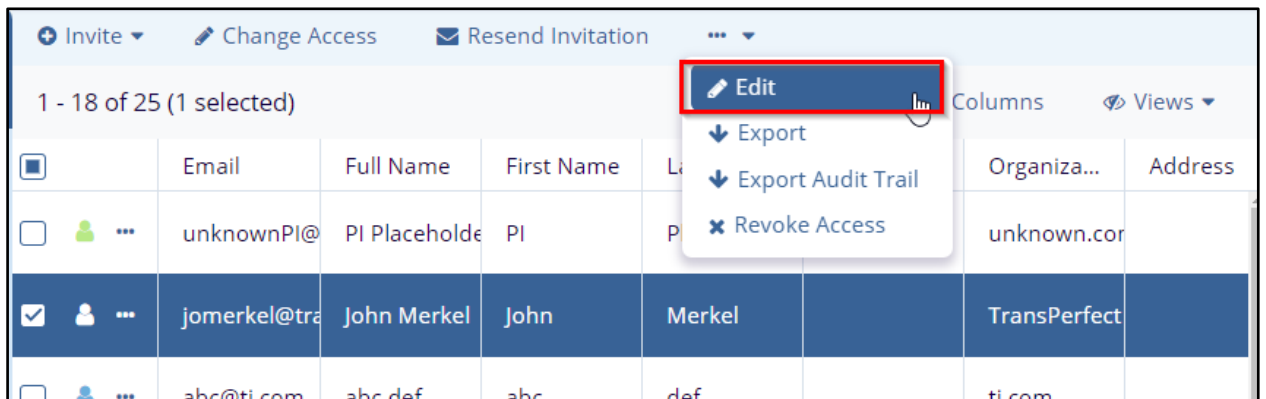
2. If the panel on the right side of the screen does not open automatically, you may need to expand it manually by clicking on Open.



3. Select the user from the displayed list and use the right panel to edit the necessary details, such as name, role, or other profile information.
4. Alternatively, you can use the three dots located on the user's grid entry to open the menu of actions associated with user accounts. From here, select **Edit** to modify the User, Groups, Sites, and Activity Log.



5. There is one more option to reach the **User Details** window. Click on the three dots from the menu ribbon above the grid.



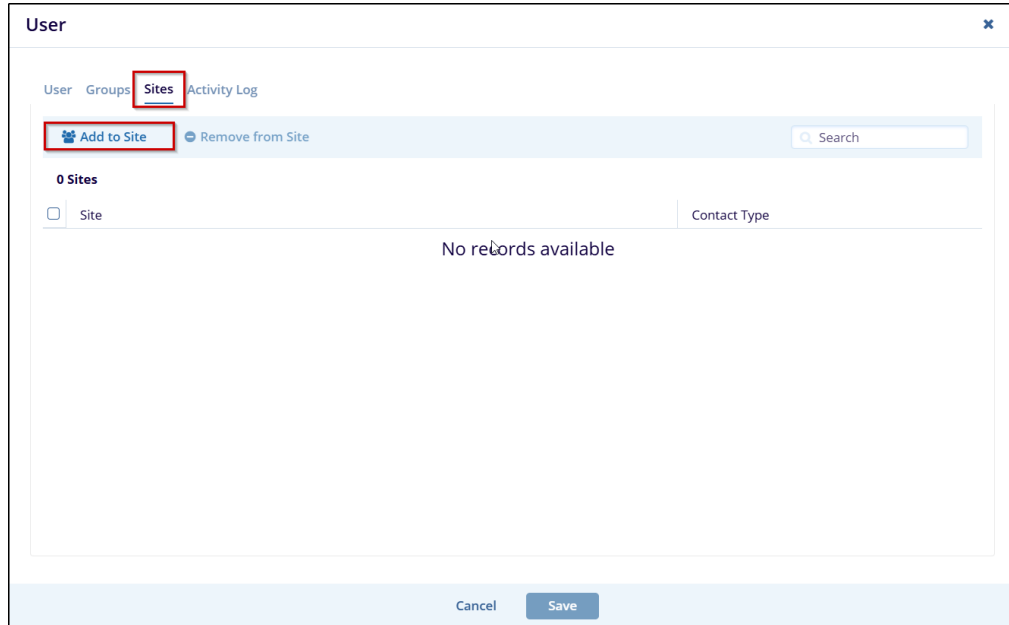
6. The **User details** window will open, allowing you to modify the user's information. Follow the on-screen instructions to edit the user details as needed.

7. Click **Save** to apply the changes. For further changes move to the **Group** section.
8. In the **Groups** tab, you can manage the groups a user belongs to. You have the option to:
  - Add the user to an existing group by selecting the desired group(s) and clicking **Add to Existing Group**.
  - Remove the user from selected groups by marking the checkbox next to the group and clicking **Remove from Groups**.

Refer to the below screenshot

	Name	Type	Description
<input type="checkbox"/>	Auditor	Custom	
<input type="checkbox"/>	CRAs	Custom	These users will all gain access to the CRA Re...
<input type="checkbox"/>	QC 1	Custom	
<input type="checkbox"/>	QC 2	Custom	
<input type="checkbox"/>	Site Activation Members	System	

9. Once you've made the desired changes, click **Save** to confirm. If further modifications are needed, such as **How to Assign a User to Sites**, you can navigate to the Sites tab.
10. Click on the Add to Sites button to add the site to the user.



11. In the **Add to Site** window, you can assign the user to multiple sites:

- Use the **Search** bar to find specific sites if needed.
- Select the checkboxes next to the sites you want to add the user to. You can select multiple sites, and the count of selected sites will be displayed.
- Once you've made your selections, click **Add to [Number] Site(s)** to confirm.

Refer to the below screenshot

### Add To Site ✕

There is a list of available Sites. The User will be added to the selected Sites.

**49 Sites** 2 Selected

<input type="checkbox"/> Site	Principal Investi...	Status	<span style="border: 1px solid red; border-radius: 50%; padding: 2px;">1</span> Country
<input type="checkbox"/> Borrís J		PENDING	United Kingdom
<input checked="" type="checkbox"/> D John	John Keats	ACTIVE	
<input checked="" type="checkbox"/> John d	Ashwini Dingane	PENDING	
<input type="checkbox"/> Site - 100 Editor	Editor 100	PENDING	United States
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	United States
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	India

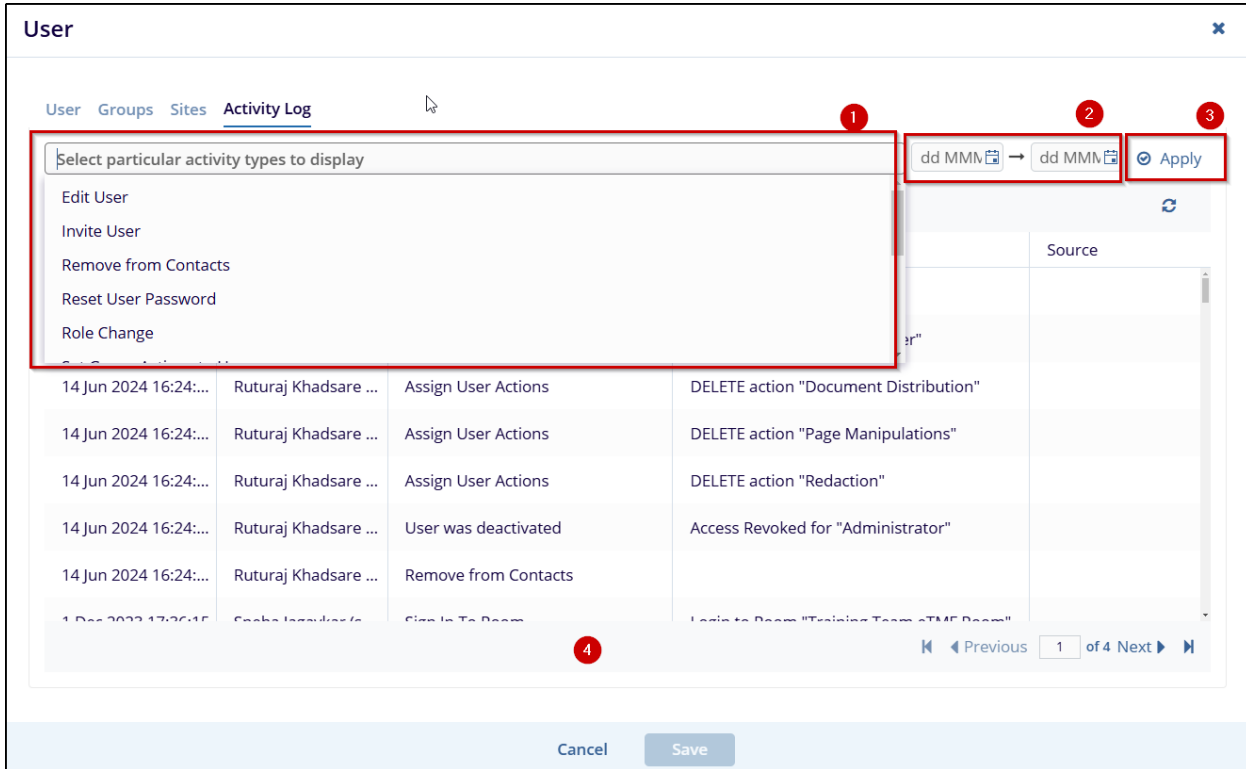
⏪ Previous 1 of 5 Next ⏩

Cancel
**Add to 2 Site**
3

12. To make more modifications move to the next section Activity Logs

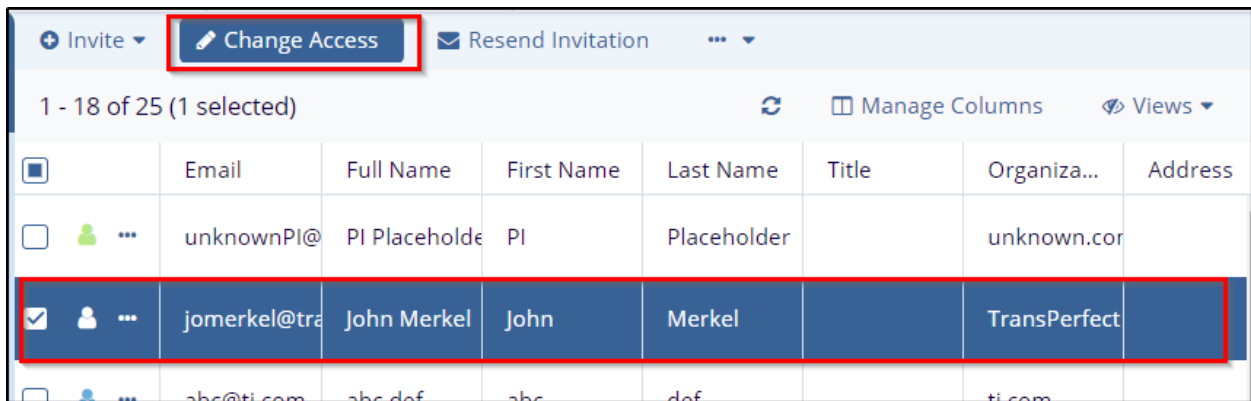
13. To filter and view specific user activity logs, follow these steps:

- Click on the Select particular activity types to display a dropdown to see a list of activity types. Choose the relevant activity types you wish to view.
- Select the date range by clicking on the date fields.
- Click Apply to display the filtered activities.
- Review the displayed activities, and if you wish to save any changes or selections, click Save.



### 33. Change User Access

1. Select the user from the list of users displayed and click **Change Access** from the menu ribbon above the grid.
2. 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.



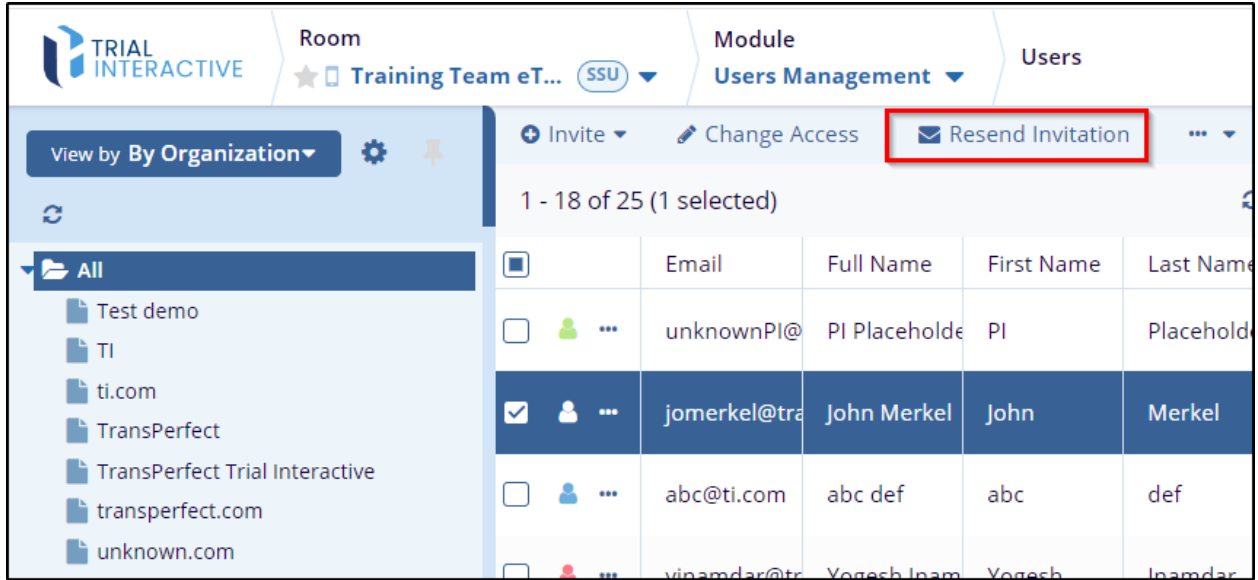
### 34. Resending an Invitation

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

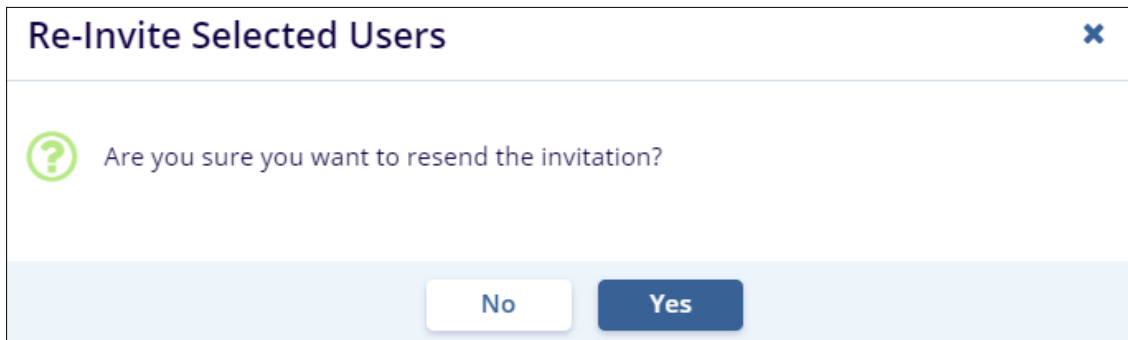
To resend an invitation:

1. From the left pane, select the preferred category to view the users.

- 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.
- From the top ribbon bar, click the **Resend Invitation** icon. A popup window will appear, asking you to confirm.



- Click the **Yes** button.



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



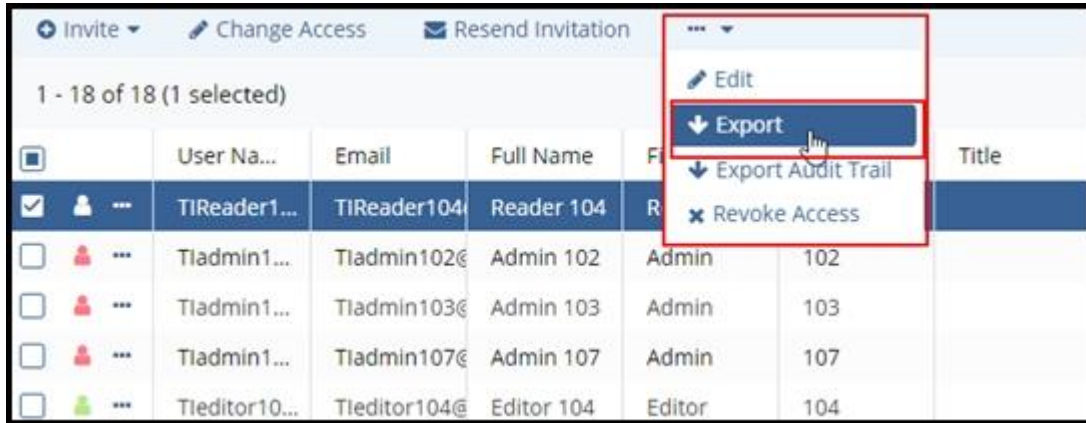
### 35. Exporting User Information

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

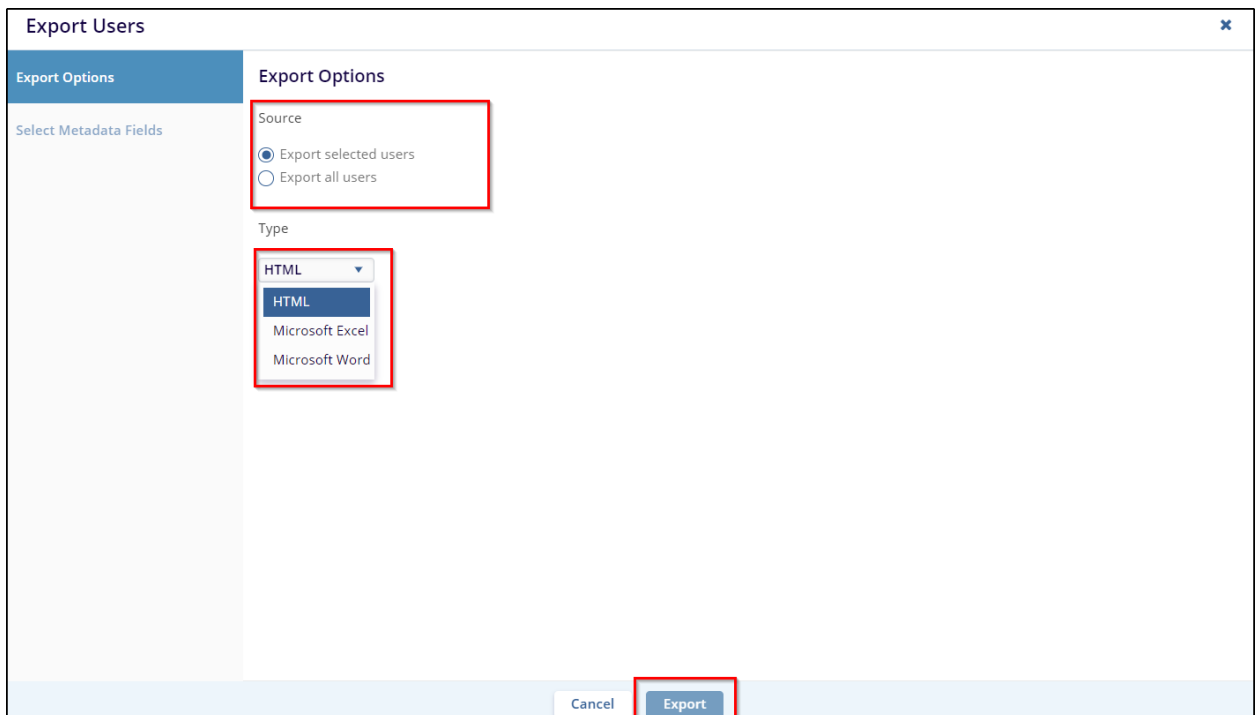
### 36. Exporting Selected User Profile Information

- Navigate to User Management → Users.

2. Locate the users whose information want 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.



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 HTML, Microsoft Excel, or Microsoft Word.

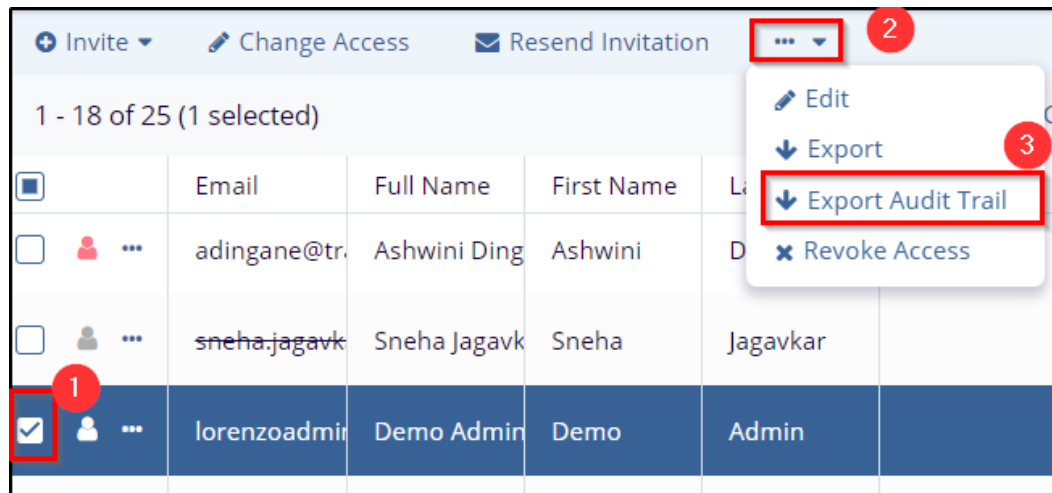


7. Click **Export**.
8. You will receive a notification about the job completion.
9. Click **Get Job Result** to download the document.



## 37. How to export User Audit Data

1. Navigate to User Management → Users.
2. Locate the users whose information needs to be exported.
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.



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



### Export Users

**Export Options**

Select Metadata Fields

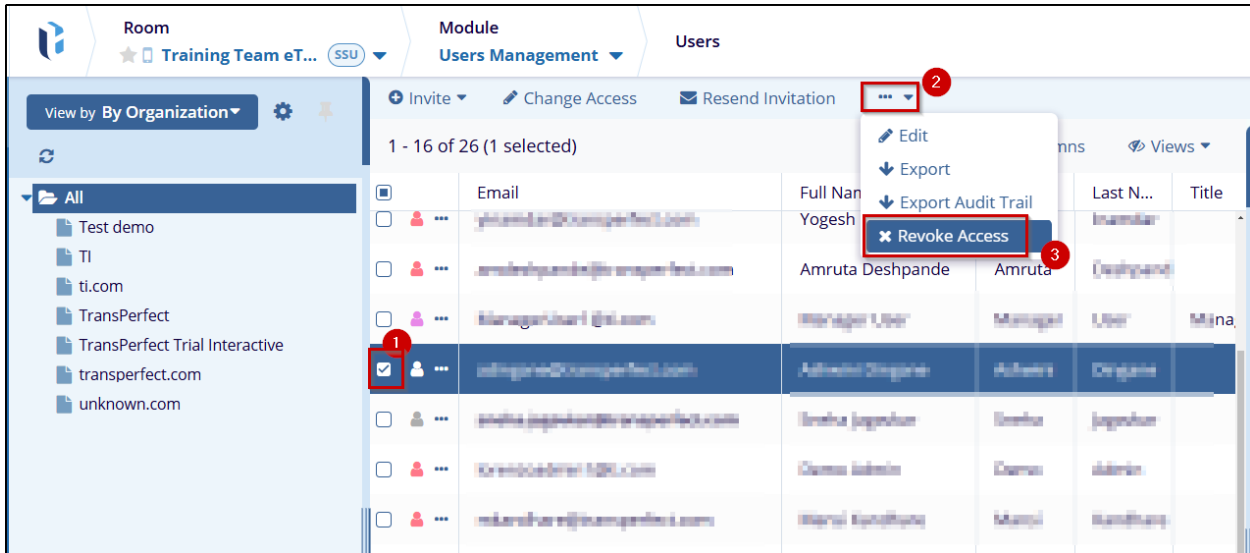
Source\*  
Selected records

- Room Login Attempts Activities
- User Profile Activities
- Users audit activities scope

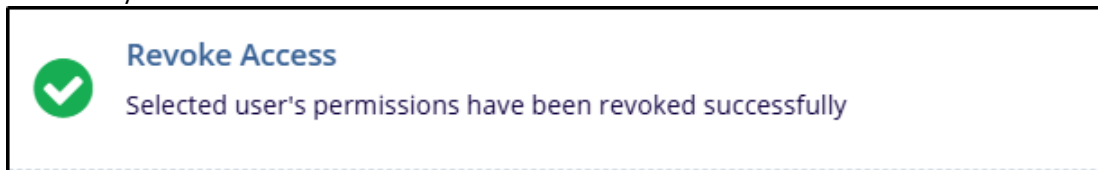
Cancel Export

### 38. How to Revoke User access

1. Navigate to User Management → Users.
2. Locate the users whose information needs to be exported.
3. Tick the checkboxes of the users.
4. From the top ribbon bar, click the three dots and then click **Revoke Access** from the options that appear.

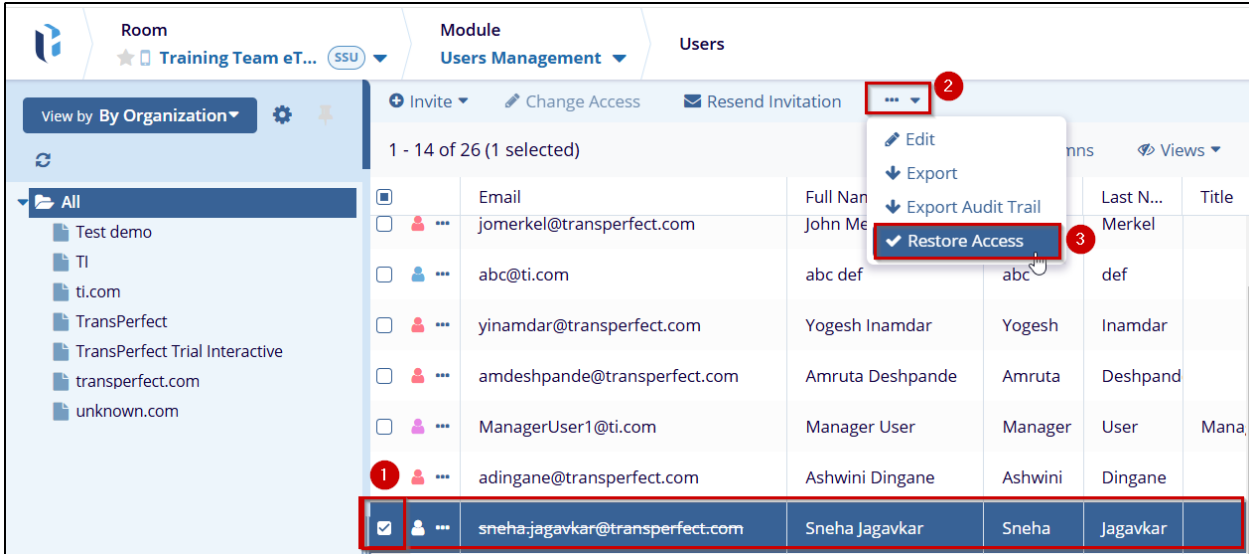


5. The **Revoke Access** confirmation window appears. Select **Yes** to proceed with the revoke access process, or choose **No** to cancel.
6. Once you click **Yes**, a notification window appears confirming that the selected user's permissions have been successfully revoked.

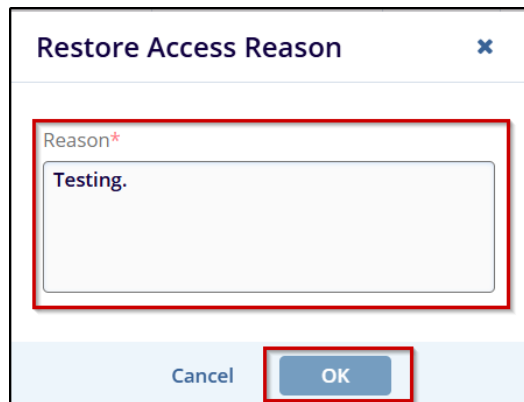


### 39. How to Restore User Access

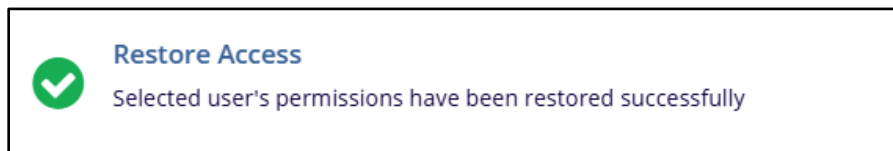
1. Navigate to **User Management** → **Users**.
2. Locate the users whose permissions you want to restore.
3. Tick the checkboxes next to the users' names.
4. In the top ribbon bar, click the **three-dot** icon and select **Restore Access** from the dropdown options.



5. The **Restore Access** confirmation window appears. Enter a mandatory reason for restoring access, then click **OK** to proceed with the process, or choose **Cancel** to exit.



6. After confirmation, a notification window will appear, confirming that the selected user's permissions have been successfully restored.



7. Ability to Assign User to Site in User Management Module

## User Management - Groups

Administrators have full control over managing user groups, including creating, deleting, and assigning users to these groups. Specifically, administrators can manage:

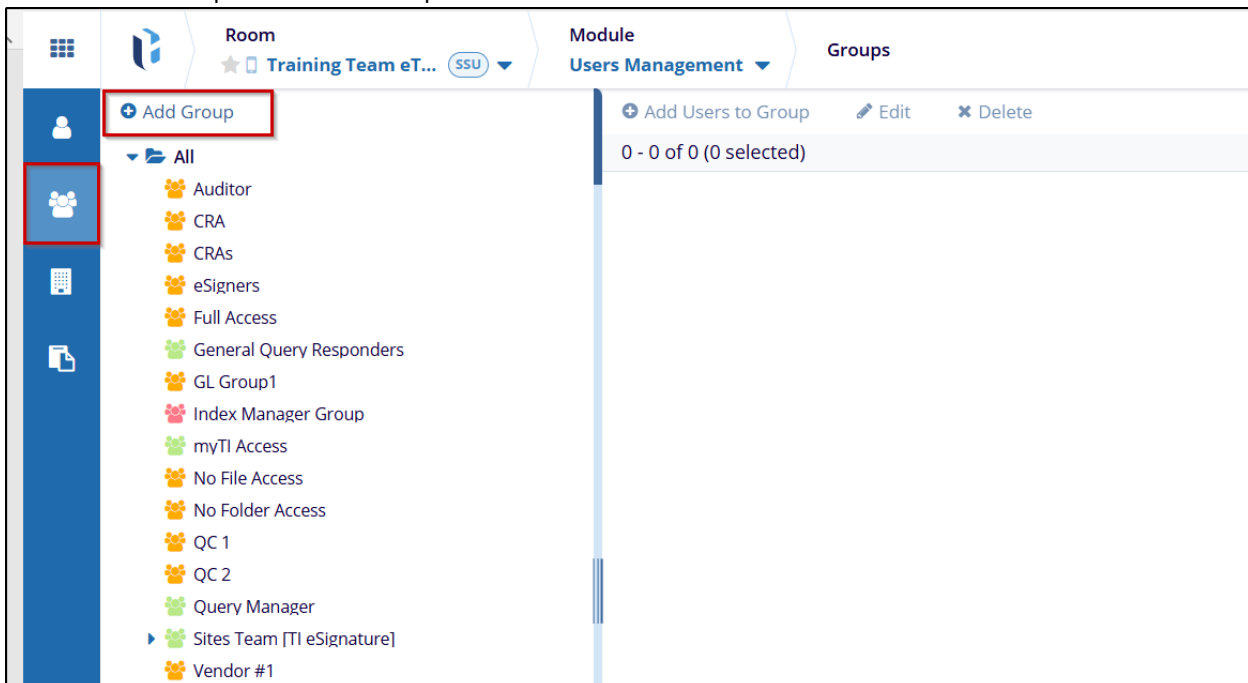
- Group names
- Group descriptions
- Group security rights
- Actions assigned to group members

Groups are essential for granting users access to specific folders, files, and actions. In the Groups area, room administrators can:

- Add a new group
- Add a child group
- Edit a group
- Delete a group

### 40. How to Add a New Group

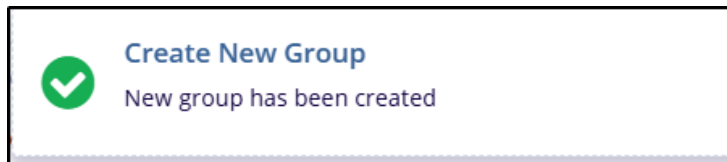
1. In User Management, click the Groups icon in the left menu.
2. Click the Add Group button in the left pane.



3. The **Create New Group** window opens. Enter a name for the new group and Add a description for the group. Refer to the below screenshot.

**Note:** You can clone security settings from an existing group. If the new group requires identical settings to an already established group, select that group from the dropdown menu.

4. Assign actions that members of the group can perform by selecting from the list of actions in the dropdown menu.
5. Click **Create**. A notification confirms that the group has been created successfully.



#### 41. How to Add New/Existing Child Group

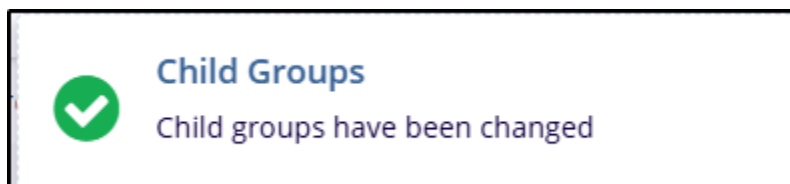
1. In **User Management**, click the **Groups** icon on the left menu to access the Groups page.
2. Click the **Add Child Group** dropdown in the top menu. You have two options Refer to the screenshot below.



- Add New Child Group:** This opens a window to create a new child group. Enter the required details and click **Create** to add the new child group.

- Add Existing Child Group:** Opens the **Select Groups** popup. Select an existing group from the list to designate it as a child group of the selected parent group, then click **Select**. Refer to the below screenshot.

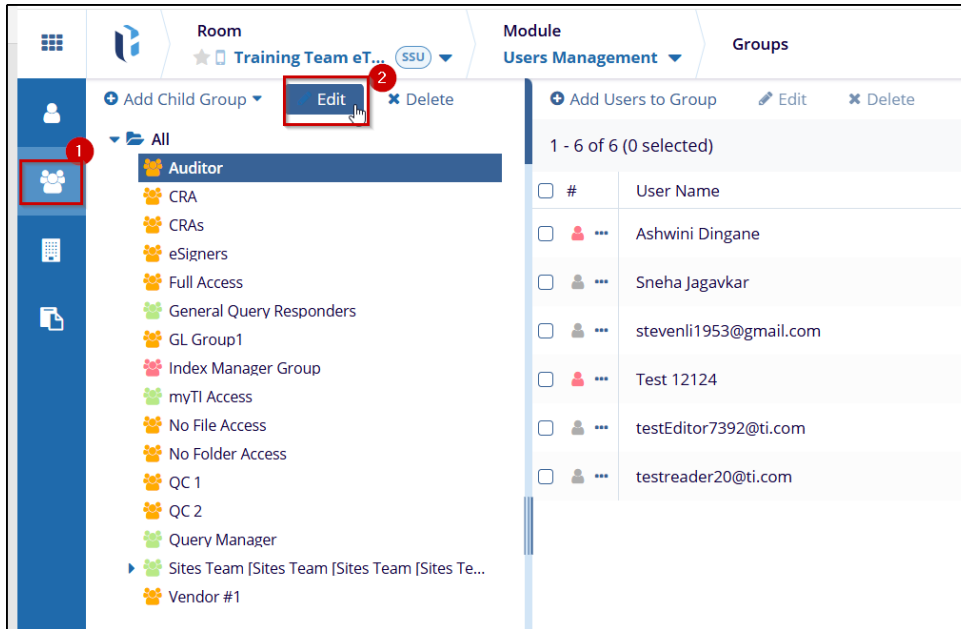
	Type	Name	Description
<input type="checkbox"/>		CRA	
<input type="checkbox"/>		CRAs	These users will all gain access to the CRA Reconciliation module.
<input type="checkbox"/>		eSigners	These users will be able to esign documents.
<input checked="" type="checkbox"/>		Full Access	
<input type="checkbox"/>		GL Group1	
<input type="checkbox"/>		No File Access	
<input type="checkbox"/>		No Folder Access	
<input type="checkbox"/>		QC 1	
<input type="checkbox"/>		QC 2	
<input type="checkbox"/>		Tech Group	
<input type="checkbox"/>		Vendor #1	



## 42. How to Edit a Group

To edit a group in the User Management module, follow these steps:

1. Click the **Groups** icon in the left menu to open the Groups page.
2. In the left pane, select the group you want to edit.
3. Click the **Edit** button in the top ribbon bar.



5. The Edit Group popup will appear.
6. Update the group details as needed.
7. Click Save to apply the changes.

### Edit Group ✕

Name\*

Description

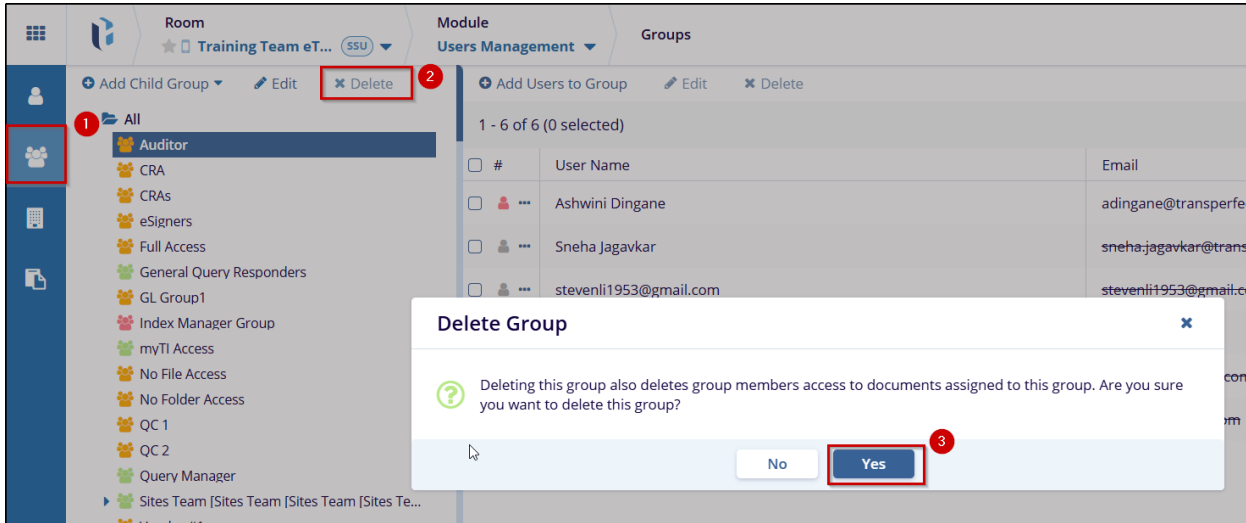
Actions

Cancel Save

### 43. How to Delete a Group

To delete a group, follow these steps:

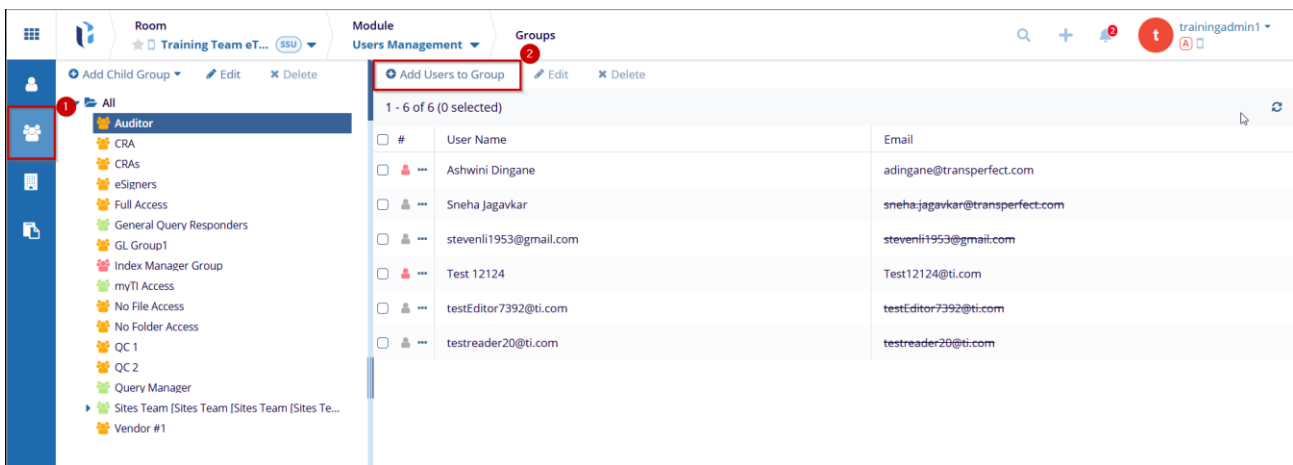
1. In the left pane, select the group you want to delete and Click Delete in the top menu.
2. A confirmation window will appear, notifying you that deleting this group will remove group members' access to the group's assigned privileges but will not delete the users themselves.
3. Click Yes to confirm the deletion. Refer to the screenshot below



### 44. How to Add Users to the Group

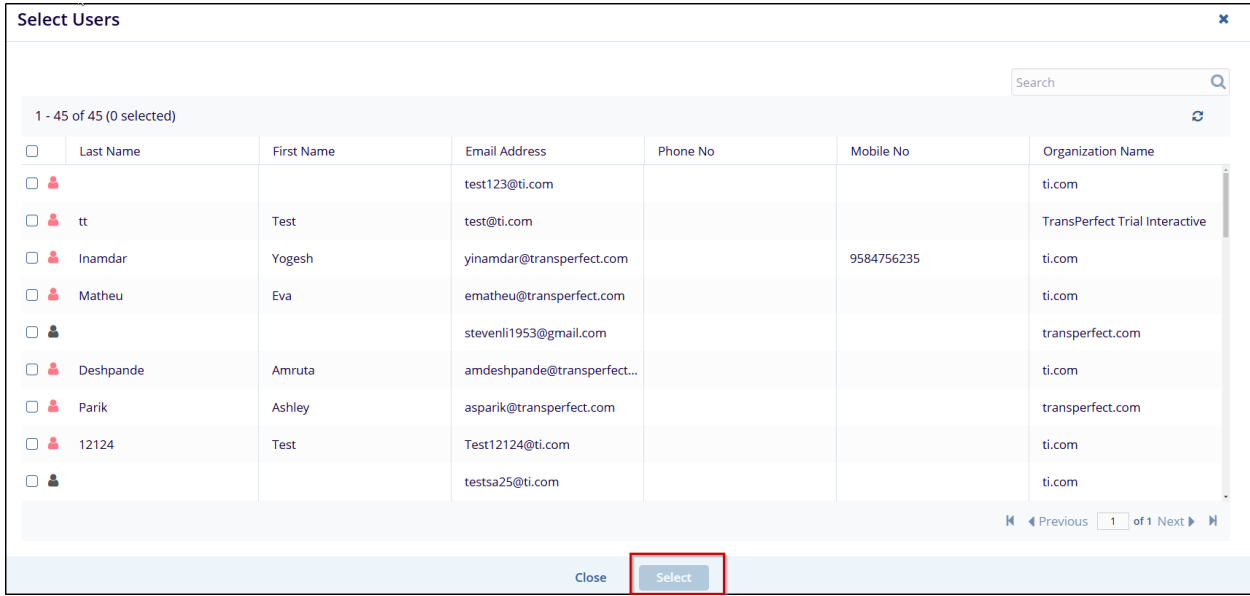
To add users to a group, follow these steps:

1. In User Management, click the **Groups** icon in the left pane.
2. Select the group you want to add users to from the list in the left pane. The group's current user list appears in the right pane.
3. Click **Add Users to Group** in the top menu bar.



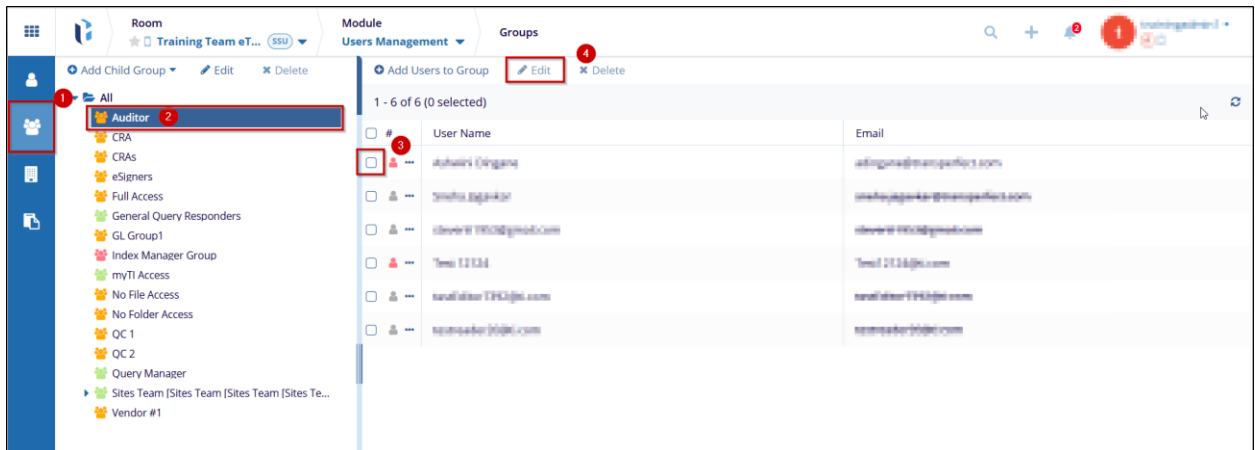
4. The Select **Users** window opens and Choose the users you want to add to the group, then click **Select**. Refer to the below screenshot.





#### 45. How to Edit Users from a Group

3. In **User Management**, click the **Groups** icon in the left menu.
4. Select the group containing the user you want to edit from the list in the left pane. The list of group members will appear on the right.
5. Select the checkbox next to the user's name and Click **Edit** in the top menu.

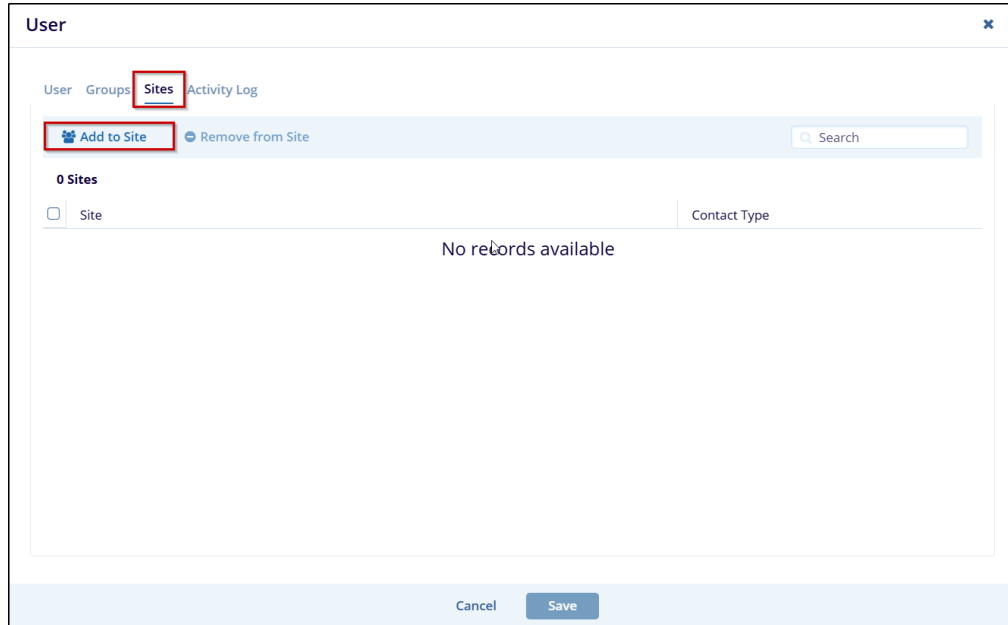


6. The **User details** window will open, allowing you to modify the user's information. Follow the on-screen instructions to edit the user details as needed.

7. Click **Save** to apply the changes. For further changes move to the **Group** section.
8. In the **Groups** tab, you can manage the groups a user belongs to. You have the option to:
  - Add the user to an existing group by selecting the desired group(s) and clicking **Add to Existing Group**.
  - Remove the user from selected groups by marking the checkbox next to the group and clicking **Remove from Groups**.

	Name	Type	Description
<input type="checkbox"/>	Auditor	Custom	
<input type="checkbox"/>	CRAs	Custom	These users will all gain access to the CRA Re...
<input type="checkbox"/>	QC 1	Custom	
<input type="checkbox"/>	QC 2	Custom	
<input type="checkbox"/>	Site Activation Members	System	

9. Once you've made the desired changes, click **Save** to confirm. If further modifications are needed, such as **How to Assign a User to Sites**, you can navigate to the **Sites** tab.
10. Click on the **Add to Sites** button to add site to the user.



11. In the **Add to Site** window, you can assign the user to multiple sites:

- Use the **Search** bar to find specific sites if needed.
- Select the checkboxes next to the sites you want to add the user to. You can select multiple sites, and the count of selected sites will be displayed.
- Once you've made your selections, click **Add to [Number] Site(s)** to confirm.

### Add To Site ✕

There is a list of available Sites. The User will be added to the selected Sites. 🔍 Search

**49 Sites** 2 Selected

<input type="checkbox"/> Site	Principal Investi...	Status	<span style="border: 1px solid red; border-radius: 50%; padding: 2px;">1</span> Country
<input type="checkbox"/> Borrís J	Borrís J	PENDING	United Kingdom
<input checked="" type="checkbox"/> D John	John Keats	ACTIVE	
<input checked="" type="checkbox"/> John d	Ashwini Dingane	PENDING	
<input type="checkbox"/> Site - 100 Editor	Editor 100	PENDING	United States
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	United States
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	
<input type="checkbox"/> Site - 107 Admin	Admin 107	PENDING	India

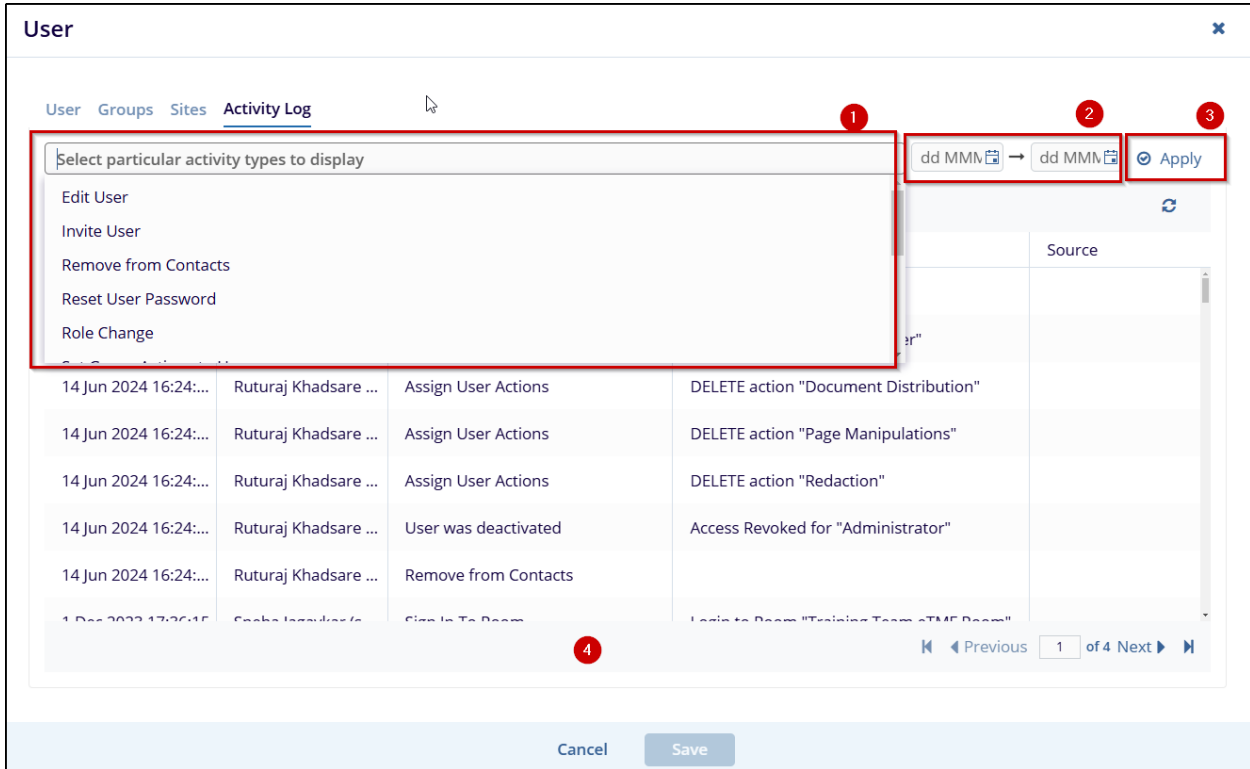
⏪ Previous 1 of 5 Next ⏩

Cancel
Add to 2 Site
3

12. To make more modifications move to the next section Activity Logs

13. To filter and view specific user activity logs, follow these steps:

- Click on the Select particular activity types to display a dropdown to see a list of activity types. Choose the relevant activity types you wish to view.
- Select the date range by clicking on the date fields.
- Click Apply to display the filtered activities.
- Review the displayed activities, and if you wish to save any changes or selections, click Save.

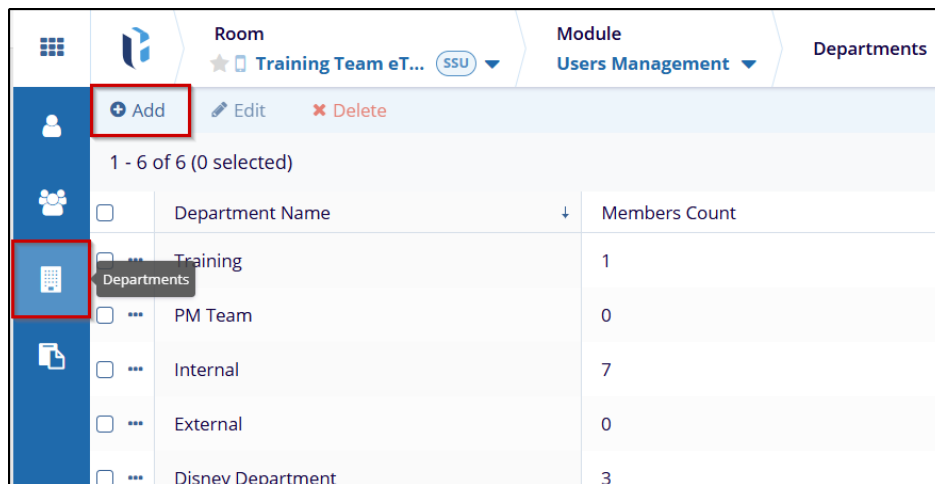


## User Management – Departments

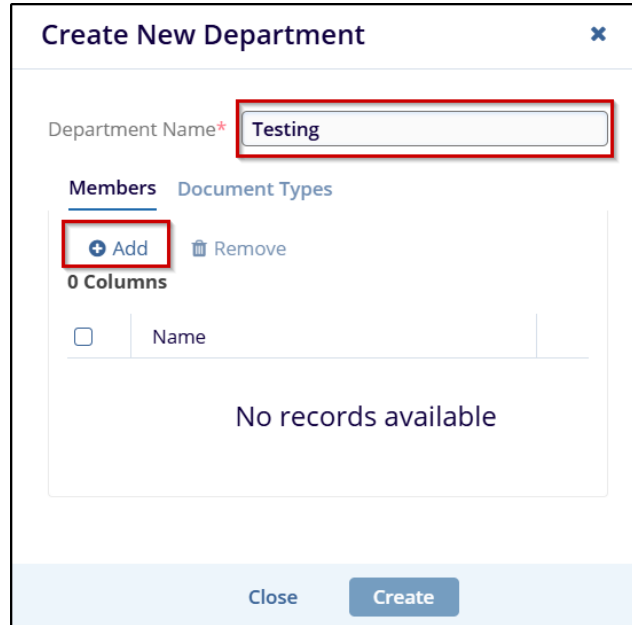
### 46. How to create a new department

#### Steps to Create New Department:

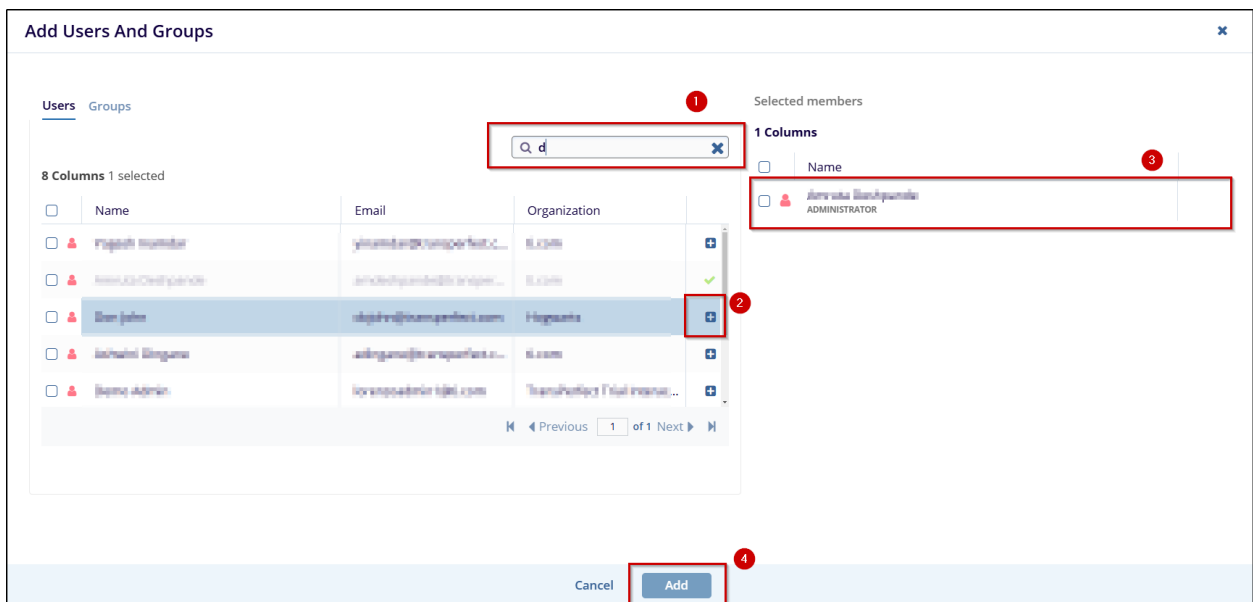
1. In **User Management**, click the Department icon in the left pane. This will open the **Department** screen. Click on the Add button at the top of the screen.



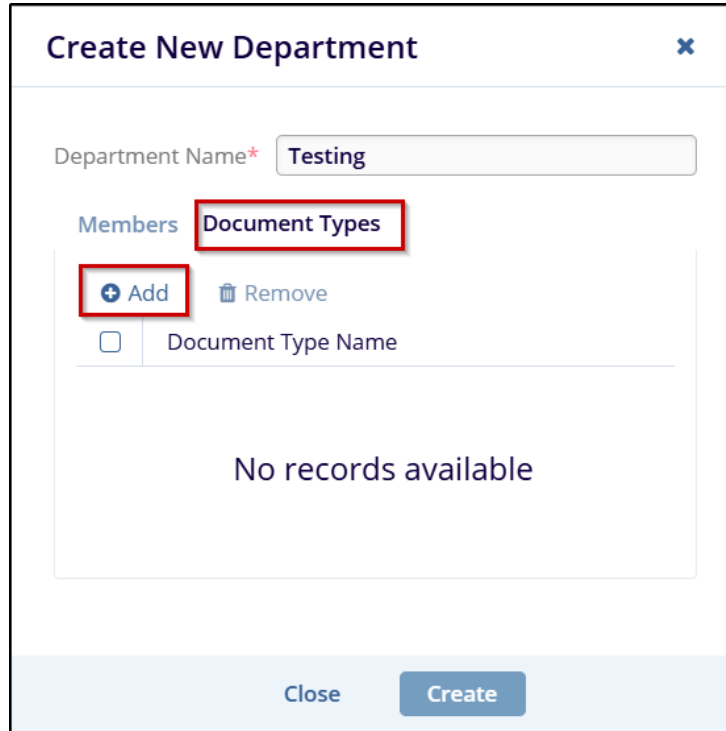
2. In the **Create New Department** window, enter the **Department Name** in the mandatory field. To add members to this new department, click on the **Add** button in the **Members** section.



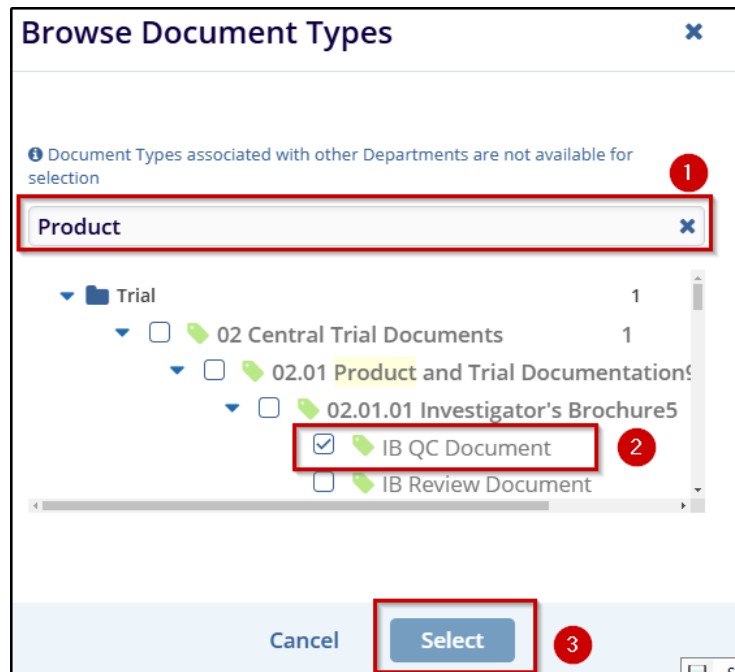
3. The **Add Users and Groups** modal will display. Use the search bar to locate users and click the + icon next to the user to select them. The selected user(s) will appear in **the Selected Members** section on the right. After confirming the selection, click **Add**.



4. To assign document types, switch to the **Document Types** tab within **the Create New Department** window. Click on the **Add** button to open the **Browse Document Types** modal.



5. In the **Browse Document Types** modal, use the search bar to locate the required document type. Select it by clicking the checkbox next to the document type, then click Select.



6. After adding members and document types, click **Create** to finalize and create the new department.

### Create New Department ✕

Department Name\*

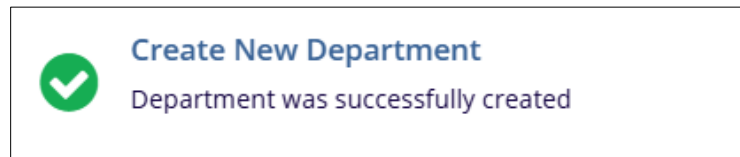
**Members** Document Types

➕ Add 🗑 Remove

<input type="checkbox"/>	Document Type Name
<input type="checkbox"/>	Trial\02 Central Trial Documents\02.01 Produc...

Close
Create

7. A notification will appear, confirming that the department was successfully created.



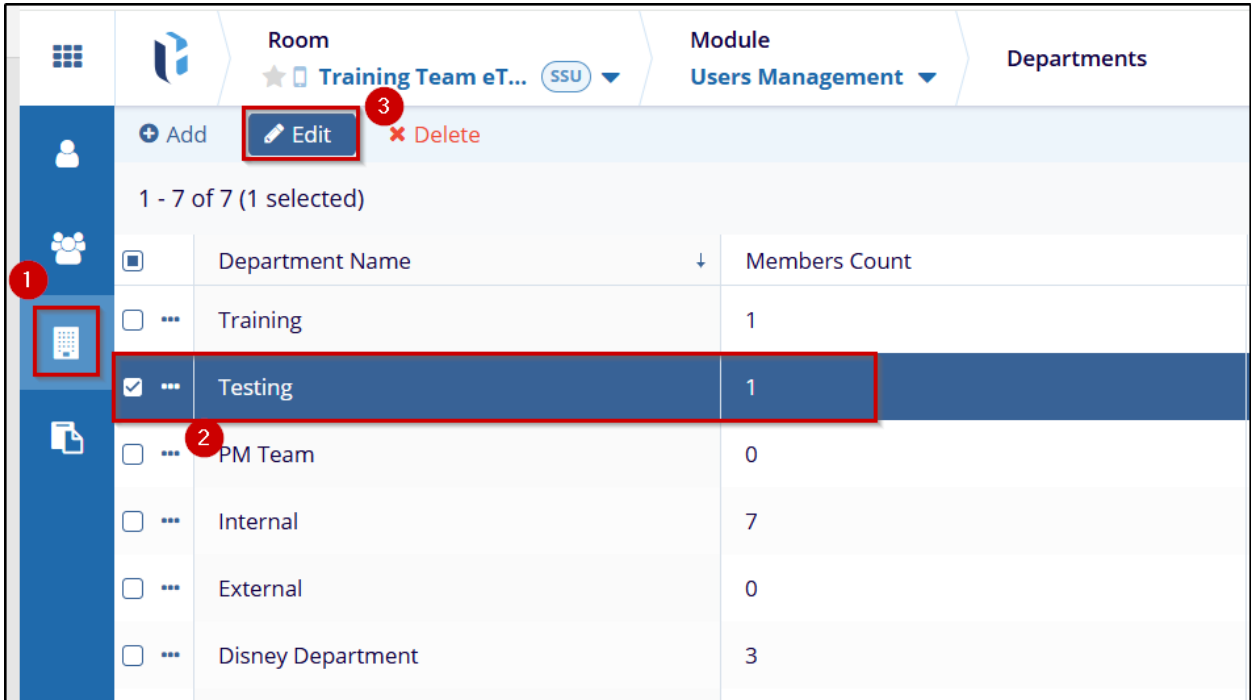

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## 47. How to Edit/Modify the Department

### Steps to Edit the Department

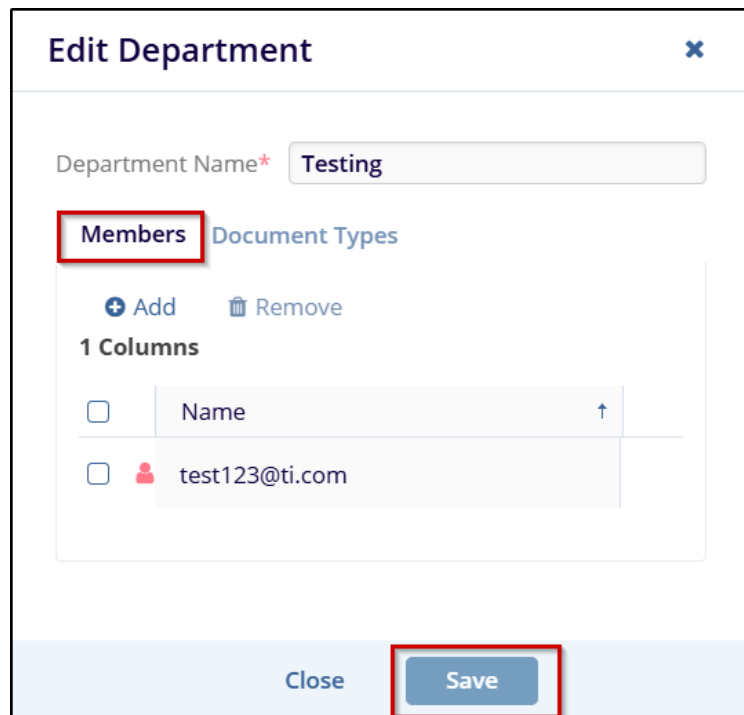
1. In **User Management**, click the **Department** icon in the left pane. This will open the **Department** screen.
2. From the list of departments, select the checkbox next to the department you want to edit (e.g., the "Testing" department in the screenshot).
3. Click the Edit button at the top of the screen.





4. In the Edit Department window, you can modify both Members and Document Types for the selected department.

- To manage members, click the Members tab. You can add or remove users by clicking the Add or Remove buttons. For adding members, a modal will display where you can search and select users. Once done, they will appear in the Members list.



- To manage document types, click the Document Types tab. You can add or remove document types by clicking the Add or Remove buttons. For adding document types, a modal will display where you can search and select the document type needed.

### Edit Department ✕

Department Name\*

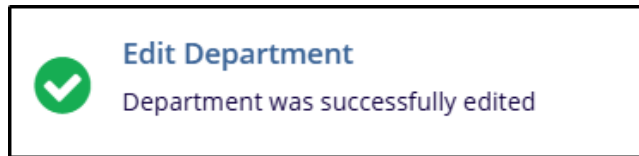
Members Document Types

+ Add    ✕ Remove

<input type="checkbox"/>	Document Type Name
<input type="checkbox"/>	Trial\02 Central Trial Documents\02.01 Prod...

Close
Save

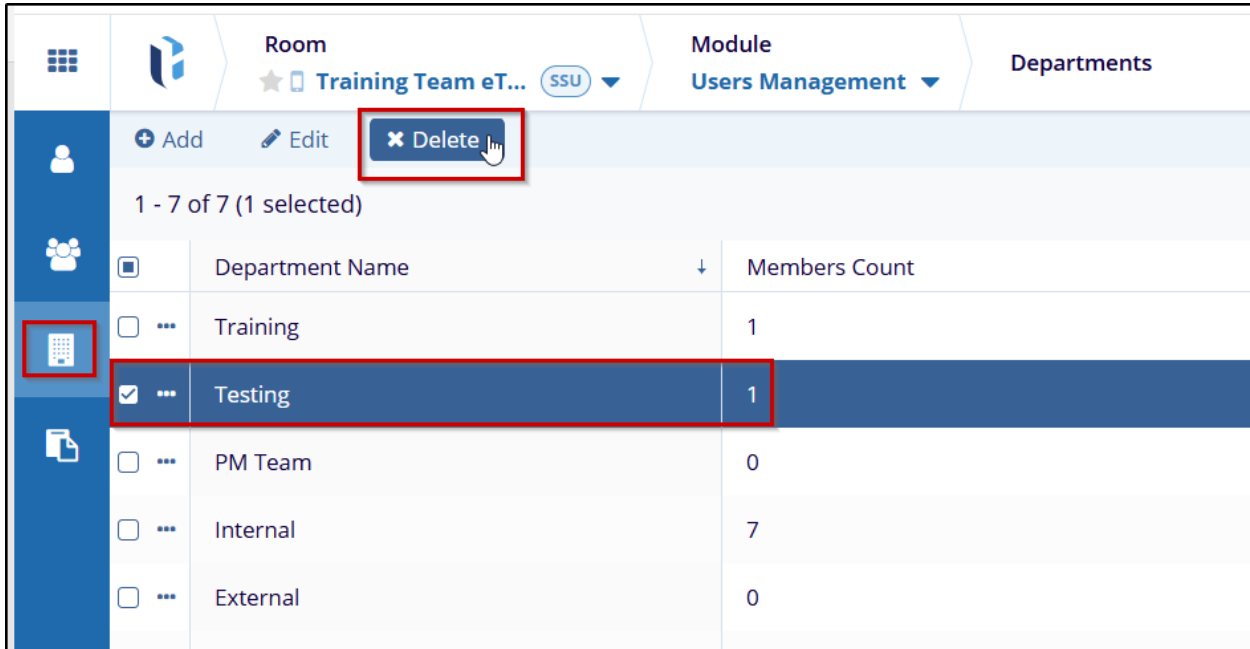
- After making the necessary changes, click Save to apply the updates to the department.



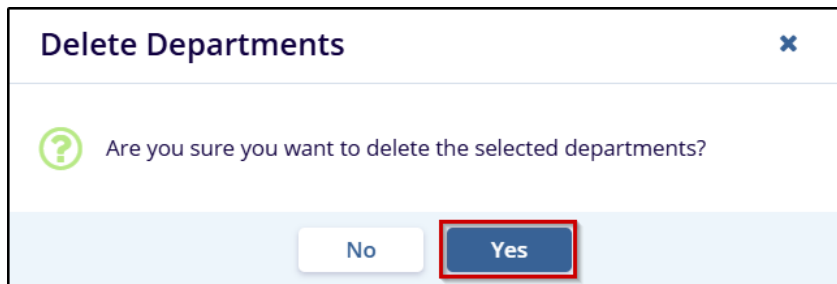
#### 48. How to Remove the Department

**Steps to Removed Department:**

- In User Management, click the Department icon in the left pane. This will open the Department screen.
- From the list of departments, select the checkbox next to the department you want to remove (e.g., the "Testing" department in the screenshot).
- Click the **Delete** button at the top of the screen.



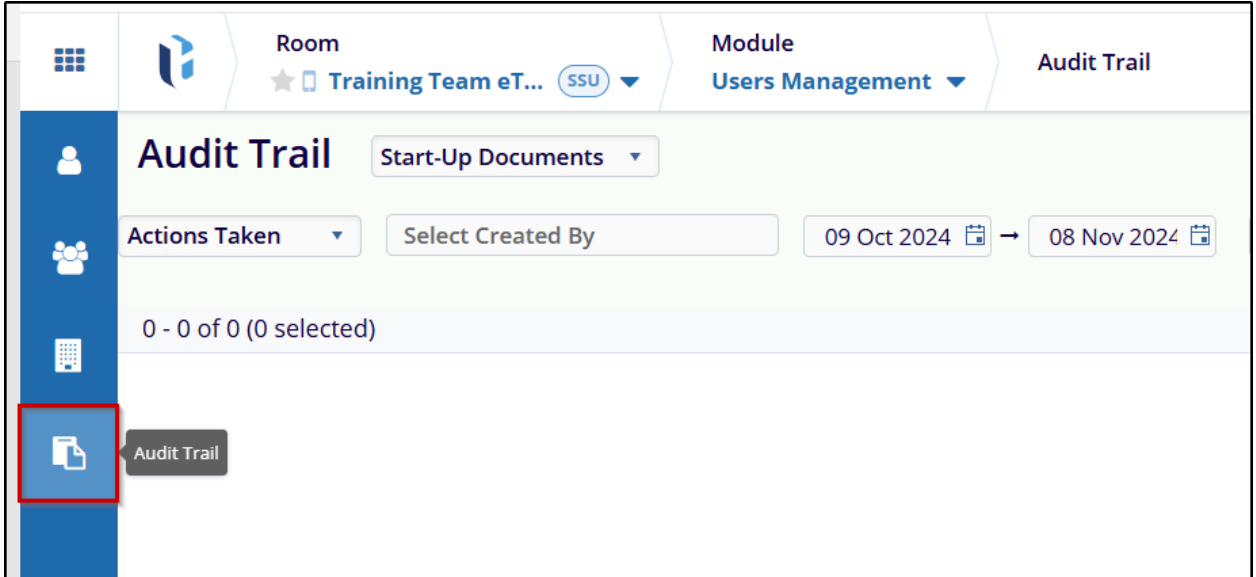
4. A confirmation dialog will appear, asking if you are sure you want to delete the selected department(s). Click Yes to confirm.
5. The department will be removed, and a notification will confirm the successful deletion.



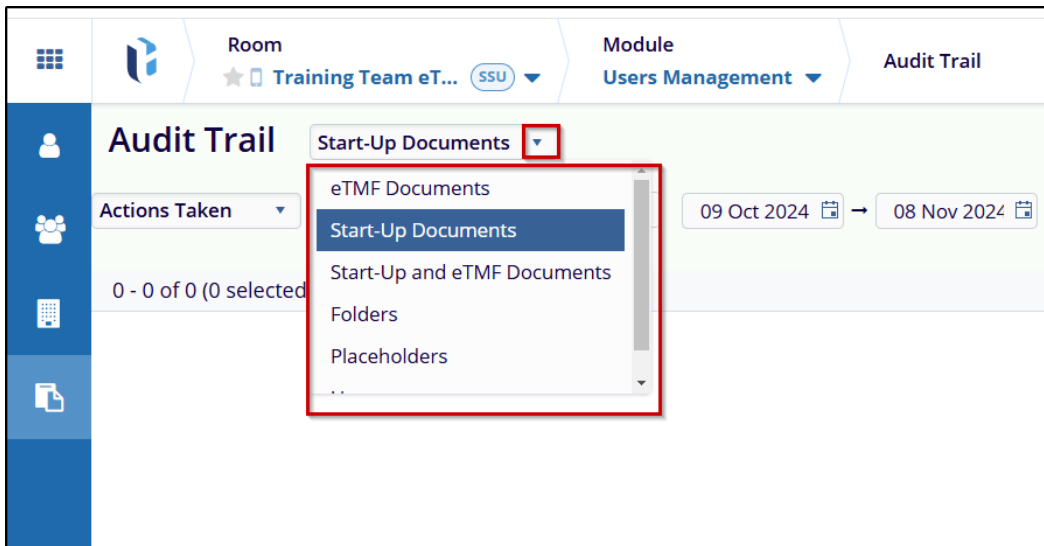
### User Management – Audit Trail

#### Steps to Search Documents in Audit Trail from User Management:

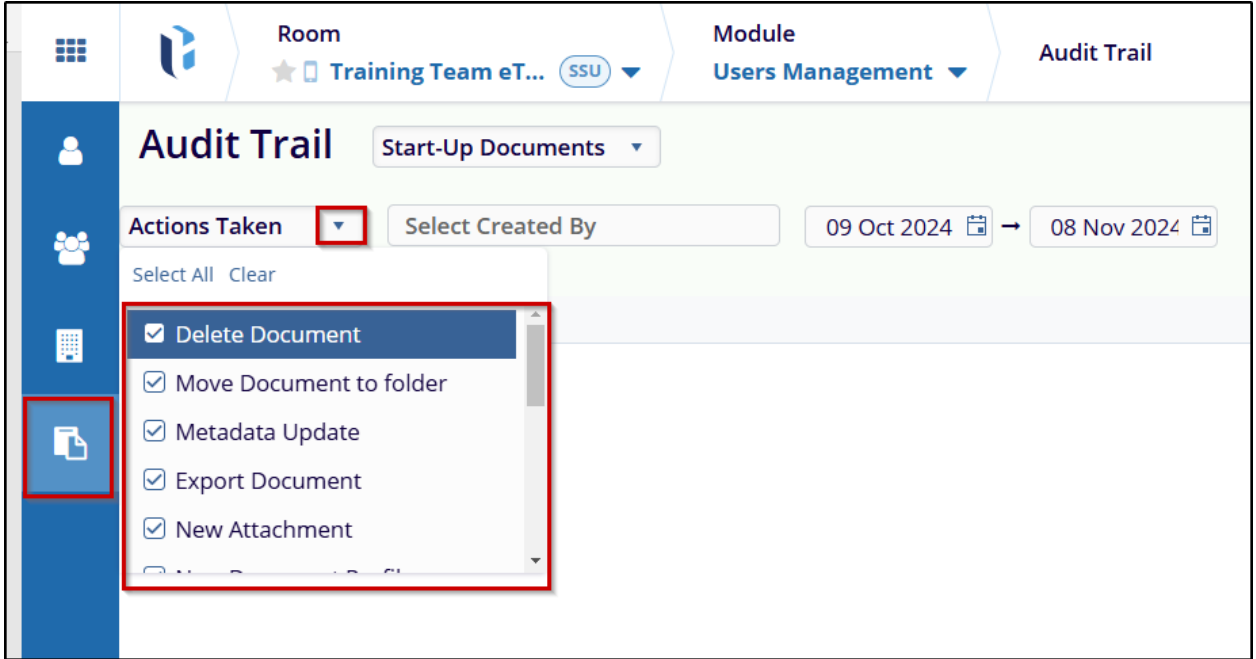
1. In **User Management**, click the **Audit Trail** icon in the left pane. This will open the Audit Trail screen.



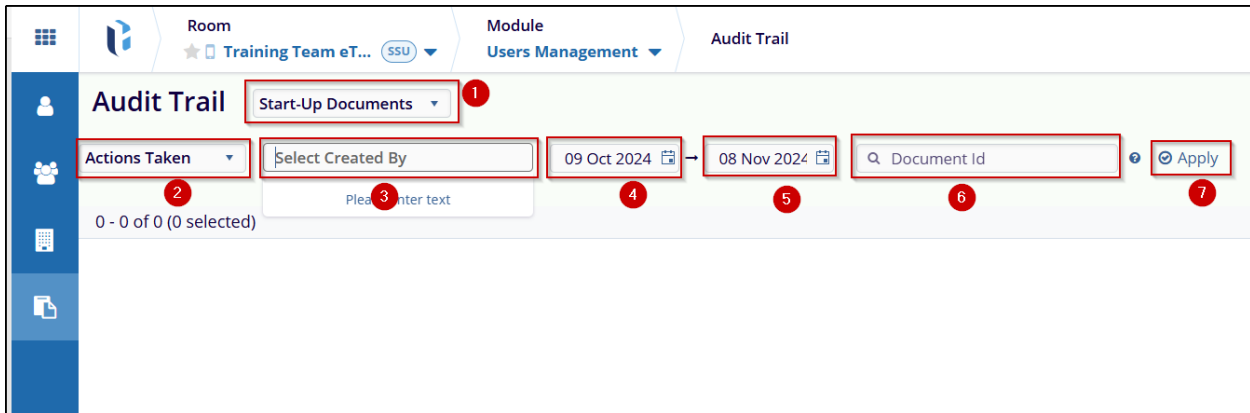
2. Click the dropdown arrow next to **Audit Trail** and select the required category (e.g., **Start-Up Documents, eTMF Documents**).



3. Click the dropdown arrow next to **Actions Taken**. Select the actions you want to filter by checking the boxes (e.g., **Delete Document, Move Document to Folder**).



4. In the **Created By** field, select the user if necessary.
5. Enter the **Start Date** and **End Date** to specify a date range.
6. If you want to search for a specific document, type its **Document ID** in the search field.
7. Click the **Apply** button to display the search results.



Activity Date	Created By	Document Id	Document Name	Index Path
07 Nov 2024 05:16:48 EST	trainingadmin1	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder
07 Nov 2024 05:16:46 EST	trainingadmin1	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder
07 Nov 2024 05:16:45 EST	trainingadmin1	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder
07 Nov 2024 05:16:39 EST	trainingadmin1	2633342	template	CA_SSUFolder
07 Nov 2024 05:16:36 EST	Demosa@origami.com	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder
07 Nov 2024 05:16:36 EST	Demosa@origami.com	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder
07 Nov 2024 05:16:36 EST	Demosa@origami.com	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder

**Exporting Audit Trail Data from User Management:**

- To export the data, select the checkbox for the documents you want to export.
- Click the **Export** button at the top right of the screen

Activity Date	Created By	Document Id	Document Name	Index Path	Activity Type	Activity Related Data
07 Nov 2024 05:16:48 EST	trainingadmin1	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder	SSU - Regulatory Review	Approved
<input checked="" type="checkbox"/> 07 Nov 2024 05:16:46 EST	trainingadmin1	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder	Open Document	Version 1.0
<input checked="" type="checkbox"/> 07 Nov 2024 05:16:45 EST	trainingadmin1	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder	Open Document Metadata	
<input checked="" type="checkbox"/> 07 Nov 2024 05:16:39 EST	trainingadmin1	2633342	template	CA_SSUFolder	SSU - Regulatory Review	Approved
<input type="checkbox"/> 07 Nov 2024 05:16:36 EST	Demosa@origami.com	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder	Metadata Update	Is Signed, old: "", new: ""
<input type="checkbox"/> 07 Nov 2024 05:16:36 EST	Demosa@origami.com	2633344	CA_SiteSelectStrat_07Nov20...	CA_SSUFolder	Metadata Update	Is Portfolio, old: "", new: ""

## CHAPTER 5: EVENTS MODULE

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.

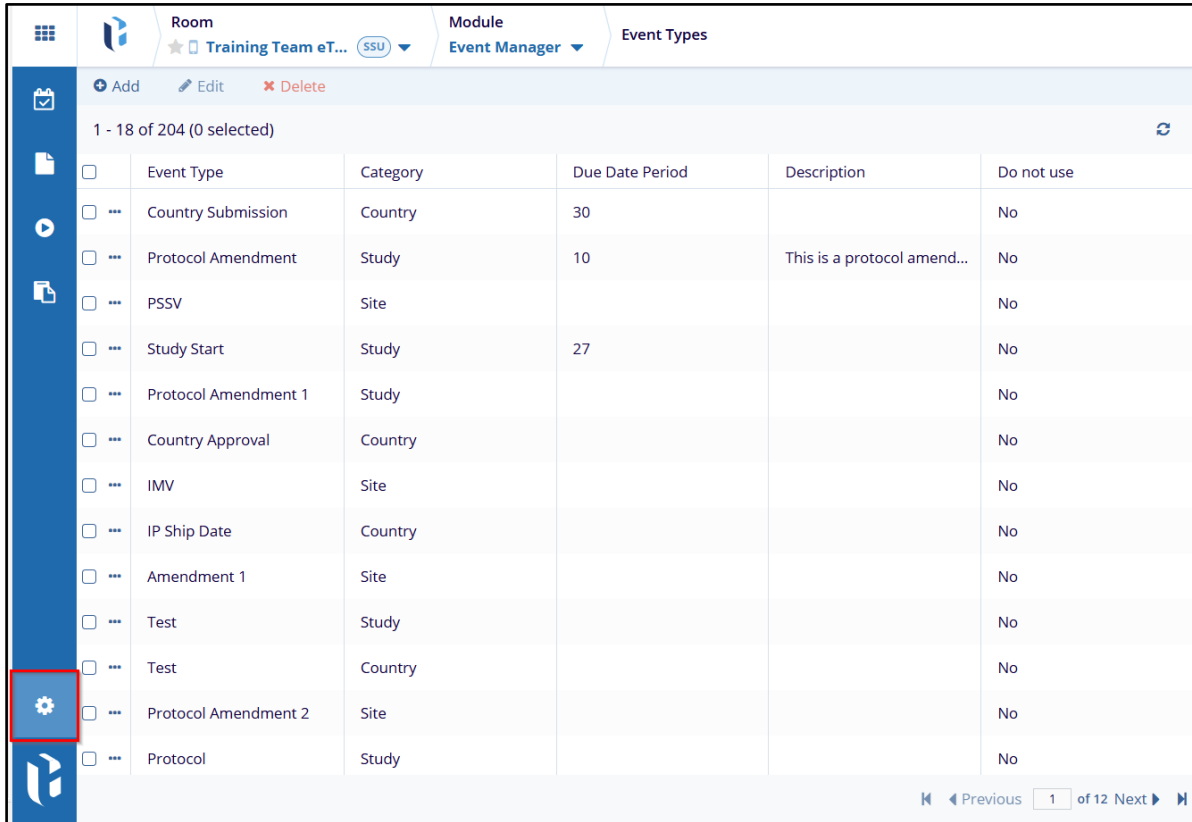
Users will have the choice to indicate whether a document type is to be required “Immediately” or upon “Event Completion.” A placeholder will be created automatically for any document which is indicated as being required immediately. Documents that are intended to be associated with events will not necessarily 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.

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 pre-populated 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.

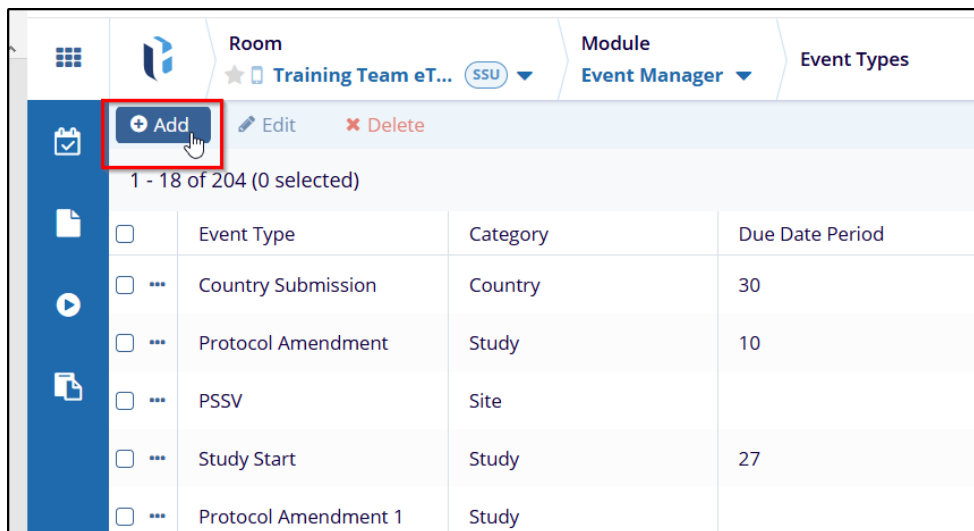
### How to Add/Create an Event Type

#### **To create an event, follow the steps below:**

1. To access the **Event Types** in the Event Manager, click on the gearwheel icon located on the far left of the screen.



2. Click the **Add** button in the menu bar located above the list of existing events in the room.

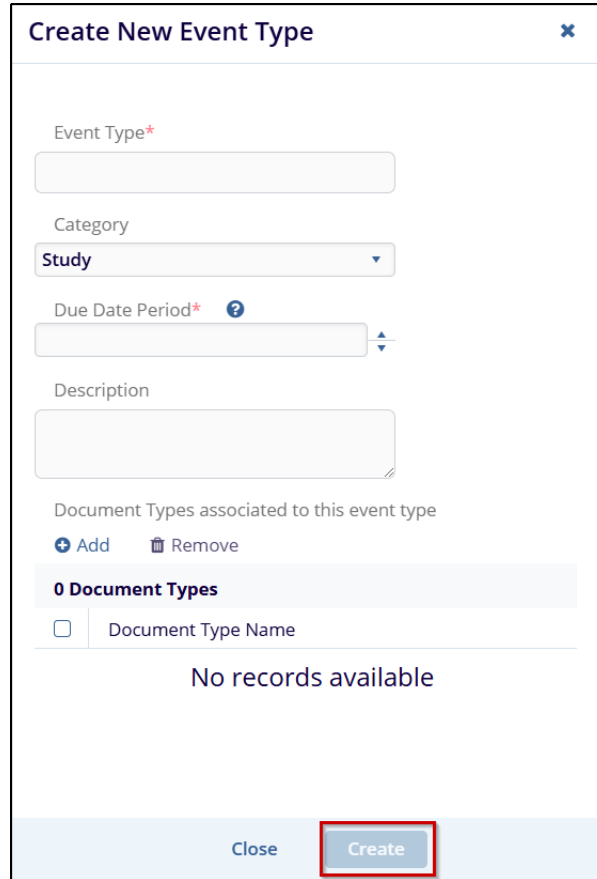


3. The **“Create New Event Type”** window will open.

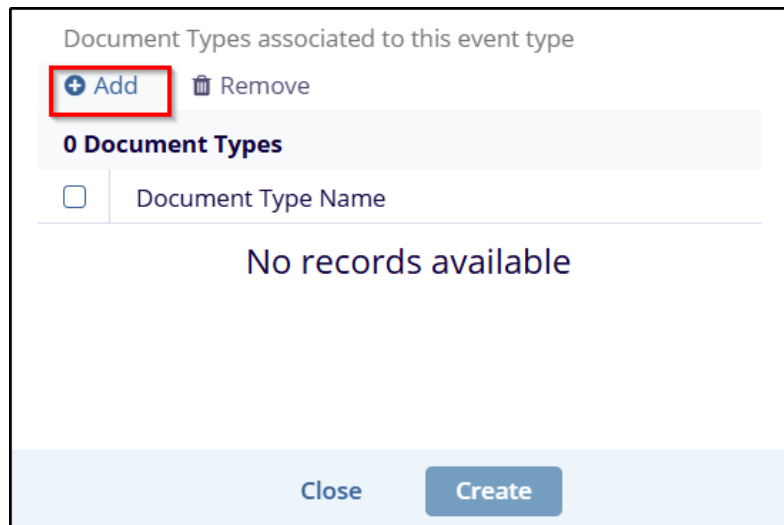
4. Fill out the required fields.

- 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 long users have to submit the documents after the event. Also, we have a description textbox to enter the related information.

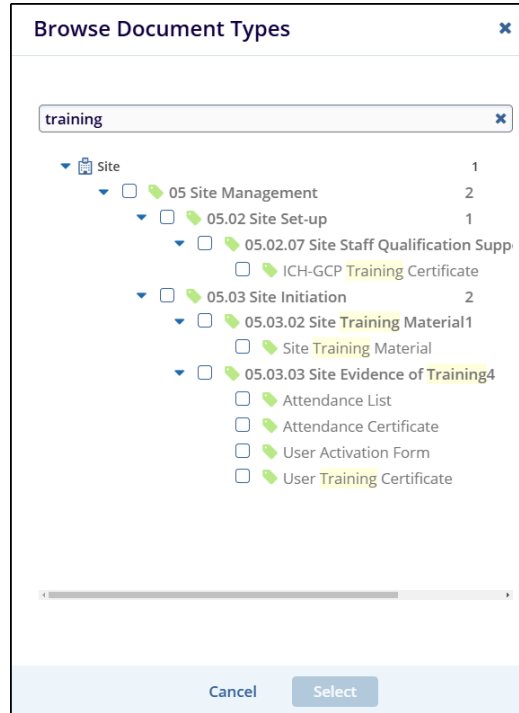




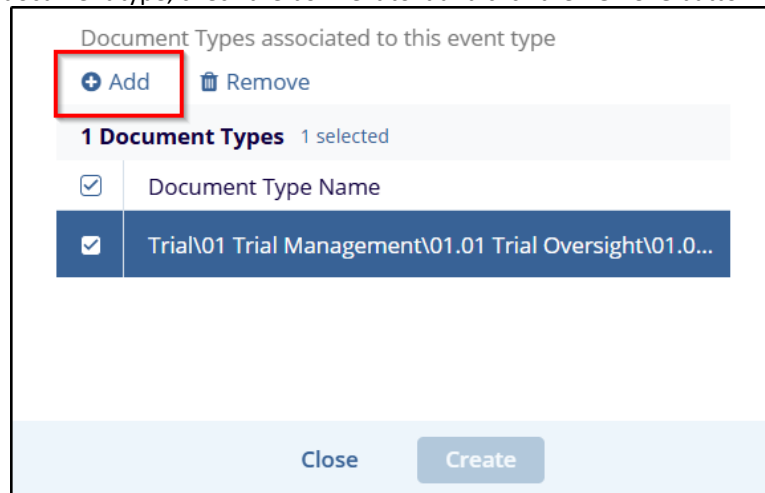
5. Use the “Add” button above the Document Type Name field to open the Select Document Type window.



6. Use the search bar at the top of the window to find the document type, or navigate through the index structure to locate the correct entry.
7. Select the desired document type(s) by checking the box next to them, then click **Select** to add the chosen document type(s) to the event.



8. To remove an added document type, check the box next to it and click the **Remove** button.

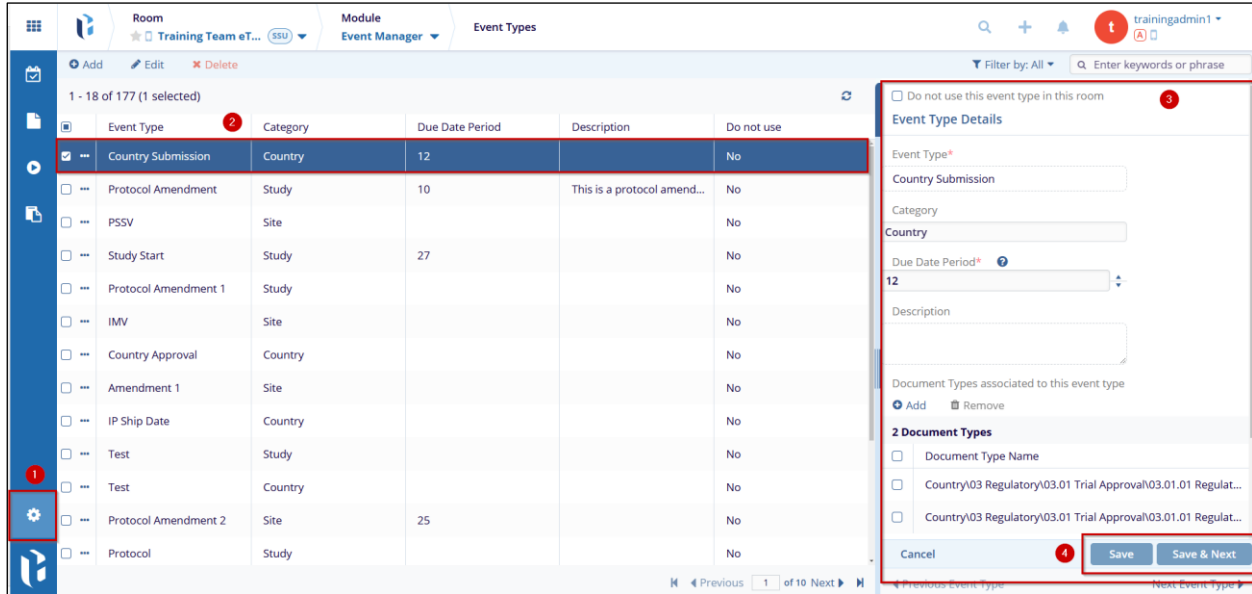


9. Once all document types have been added, press the Create button to create the event type.

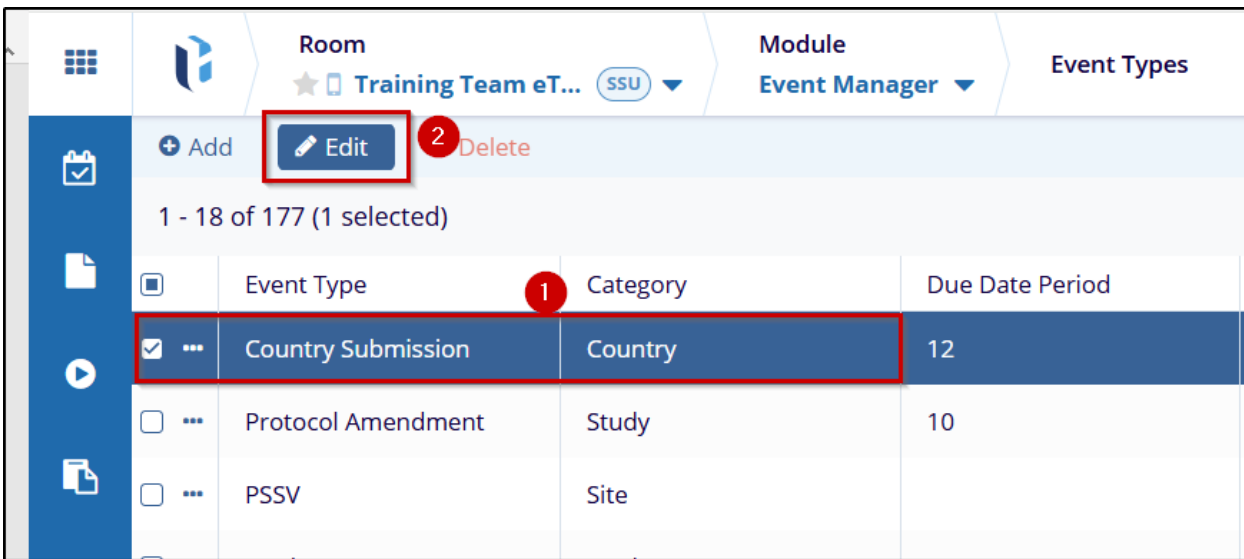
### How to Edit Event Type

#### **Step to edit the Event type**

1. In **Event Management**, click the **gear icon** in the left pane to open the Event Types screen.
2. From the list of event types, select the checkbox next to the event type you want to edit (e.g., "Country Submission").
3. From the right side of the screen event type details. Refer to the screenshot below.



4. Click the **Edit** button at the top of the screen.



1. In the **Edit Event Type** window, you can modify details like Due Date Period and associated Document Types:

- To change the **Due Date** Period, update the value in the **Due Date Period** field.
- To manage Document Types:
  - Click the **Add** or **Remove** buttons in the **Document Types** section.
  - For adding document types, a modal will display where you can search and select the required document type. Selected types will appear in the list.

### Edit Event Type ✕

Do not use this event type in this room

Event Type\*

Country Submission

Category

Country

Due Date Period\* ?

12

Description

Document Types associated to this event type

+ Add 🗑 Remove

**2 Document Types**

<input type="checkbox"/>	Document Type Name
<input type="checkbox"/>	Country\03 Regulatory\03.01 Trial Approval\03.01.0...
<input type="checkbox"/>	Country\03 Regulatory\03.01 Trial Approval\03.01.0...

Close
Save

2. After making the necessary changes, click **Save** to apply the updates to the event type.

**Edit Event Type**

Event Type was successfully edited

### How to remove Event Type from Event Manager Module

## Creating an Event

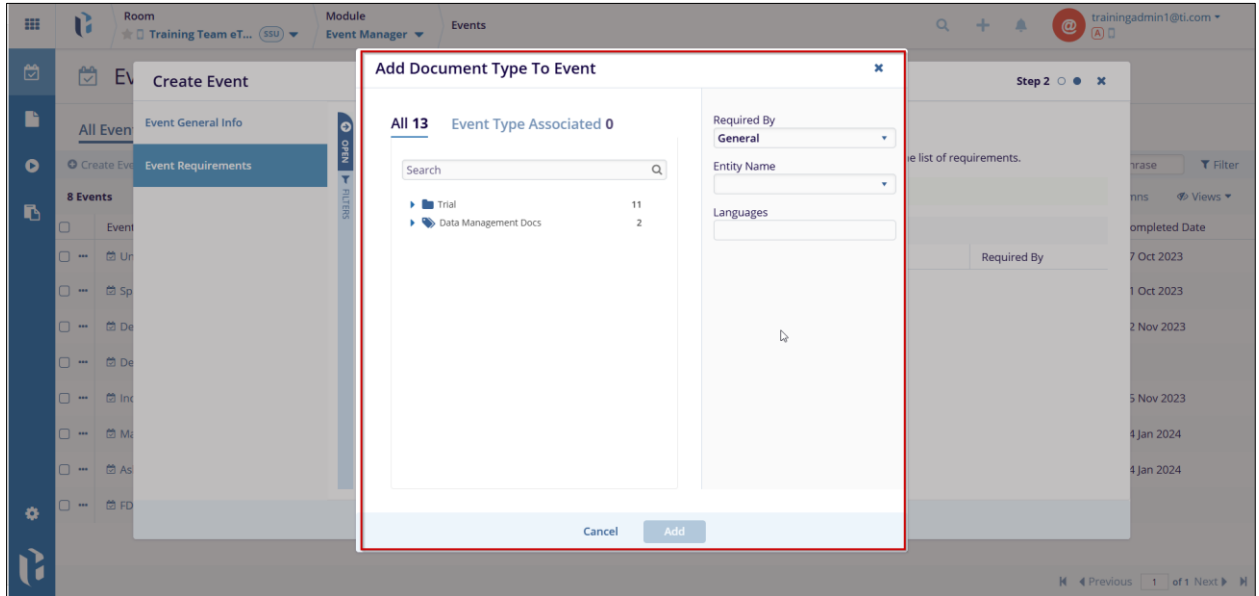
Once an appropriate event type has been created, specific events can be planned using that event type. Events that have been created can be updated at any time by the eTMF team to reflect the latest content. Each event will show its own eTMF Health measurement at the study, country, and site levels.

Events can be created using the following steps:

1. Click the **Create Event** button in the menu bar above the list of events.
2. Using the Category field, indicate whether the event being planned is a Study, Country, or Site level event.

3. Choose the Event Type from the dropdown menu.
4. Give the event a name and fill out any other fields as desired.
  - The planned date field will be critical to tracking the timeliness of event document submissions.
  - The Due Date Period should be automatically populated based on the value entered during the creation of the Event Type.
  - The Status field can indicate whether an event is being planned or has already been completed. Most events will be created with the status of **“Planned.”**

5. Press **“Next”**
6. 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 Document Type to Event”** window.
    - Use the Search bar or manually drill down in the folder structure to locate the required document type and press **“Add.”**

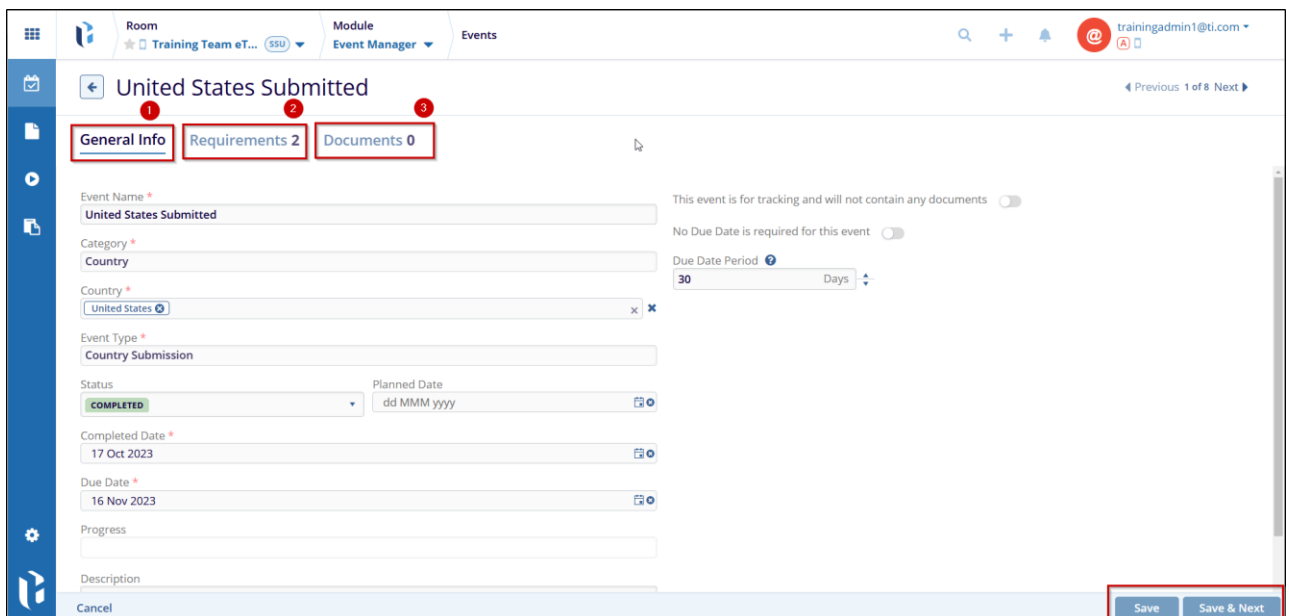


7. You can remove the added document type. Click the **checkbox** to remove the document type and Click on the **Remove** button.
8. Once all required document types have been added to the event, press **Finish** to complete the event creation process. The event will be displayed in the list of created events.

### Modifying an Event

Follow these steps to modify an existing event:

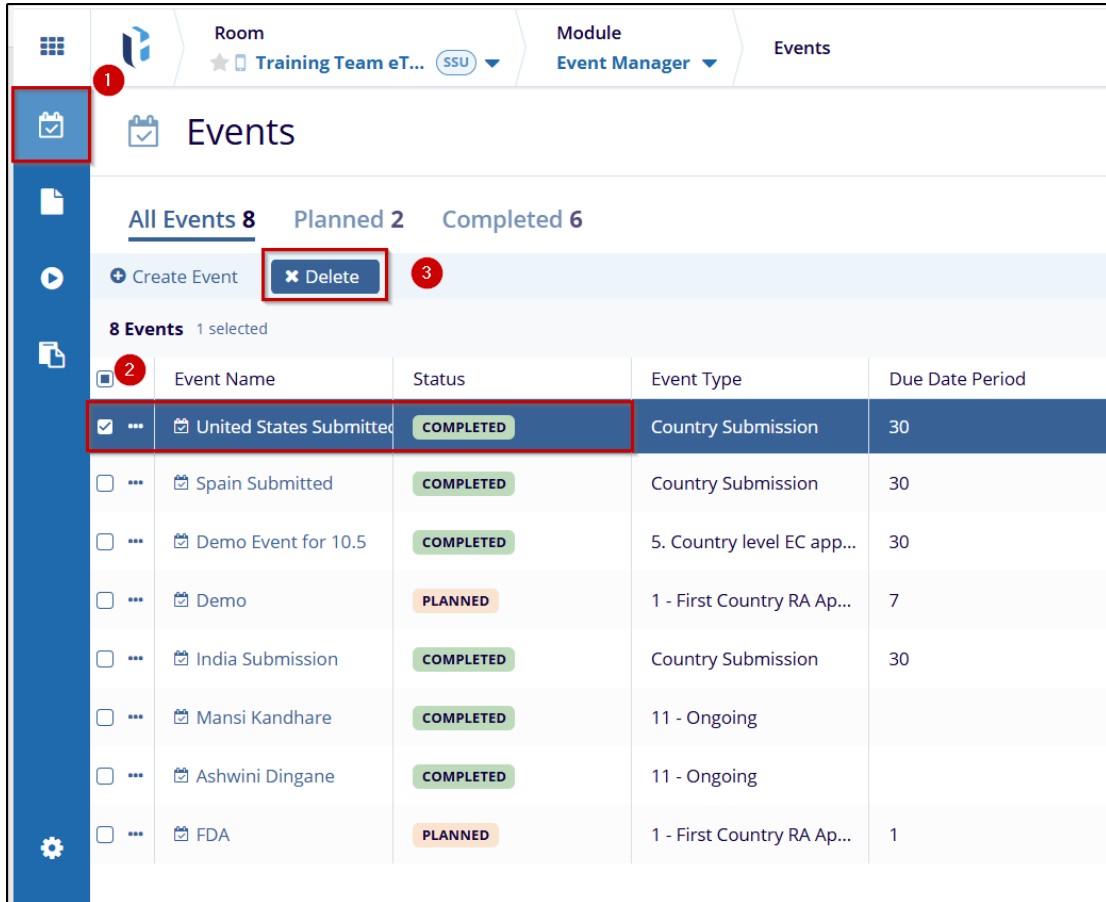
1. Access the Events module. Any previously created events should be displayed in the window.
2. Double-click on the Event to modify. The Event detail page will open. The event profile has three tabs:
  - a. **General Info:** This tab includes the name of the event, any impacted sites or countries, the 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.
3. 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.



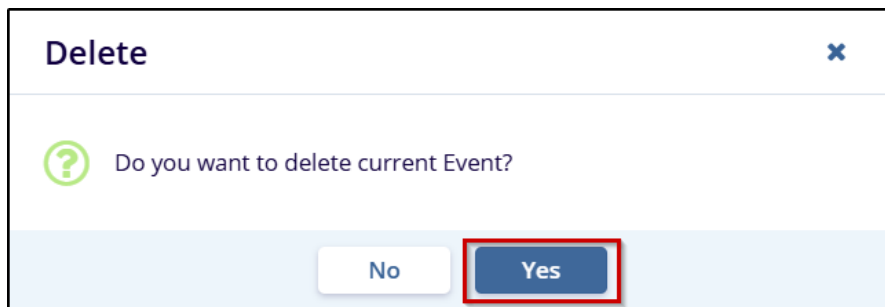
## How to Delete Events

### Steps to Delete Events.

1. In Event Manager, go to the Events section by clicking the calendar icon in the left pane.
2. From the Events grid, select the event(s) you want to delete by checking the box next to the event name.
3. Click the Delete button at the top of the screen.



4. A confirmation pop-up will appear, Click Yes to confirm the deletion or Click No to cancel the deletion.



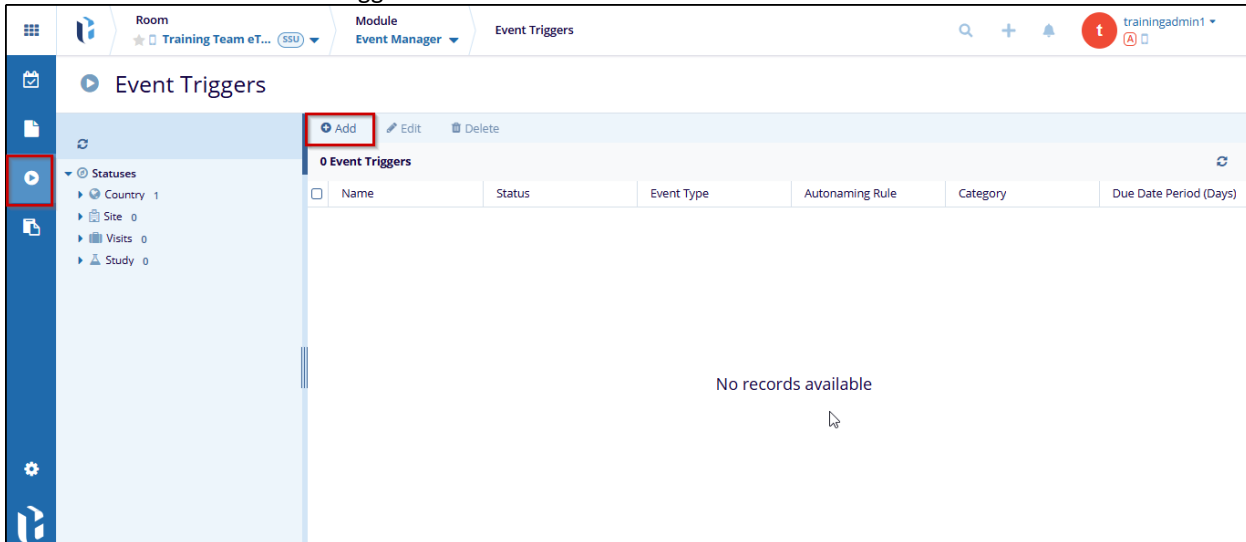
5. A success message will appear, indicating the event(s) were successfully deleted.

## Event Trigger

### 49. How to Add Event Trigger

#### Steps to Add Event Trigger

1. Open the Event Manager from the left-side menu and select Event Triggers to view existing triggers.
2. Click Add to create a new trigger.



3. In the Event Trigger General Info screen, enter the Event Trigger Name, configure Event Name autonaming if necessary, select the Category (e.g., Country), choose an Event Type, and optionally set a Due Date Period if required, choose an Event Type, set the Status to COMPLETED, select the Set Event Completed Date option (either "Same as Status Date" from the Country profile or "No Event Completed Date"), and add a Description if needed, then click Next.

4. Click **Next** to proceed, review the details, and save the event trigger.

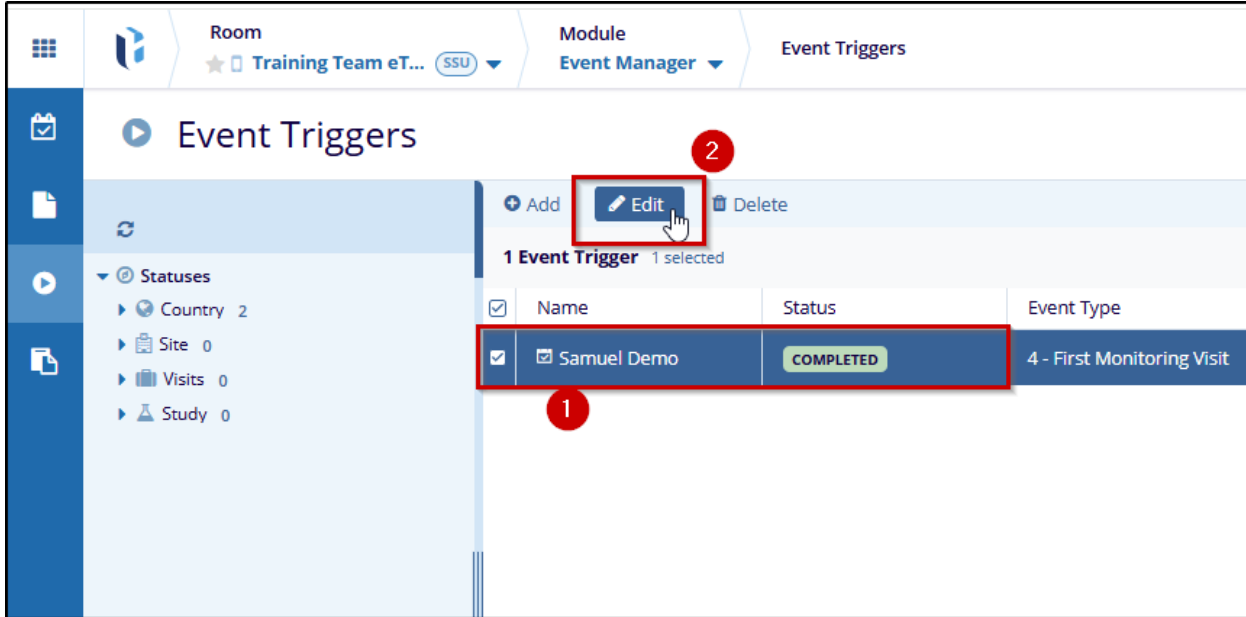


5. Added Trigger will be present in Grid.

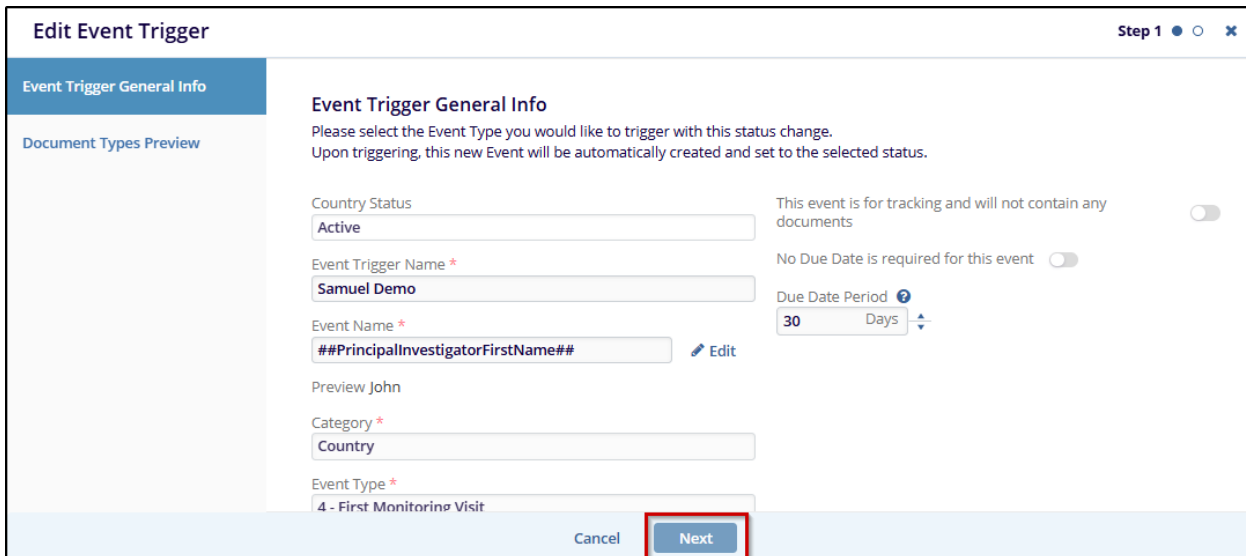
## 50. How to Edit Event Trigger

### Steps to Edit Event Trigger

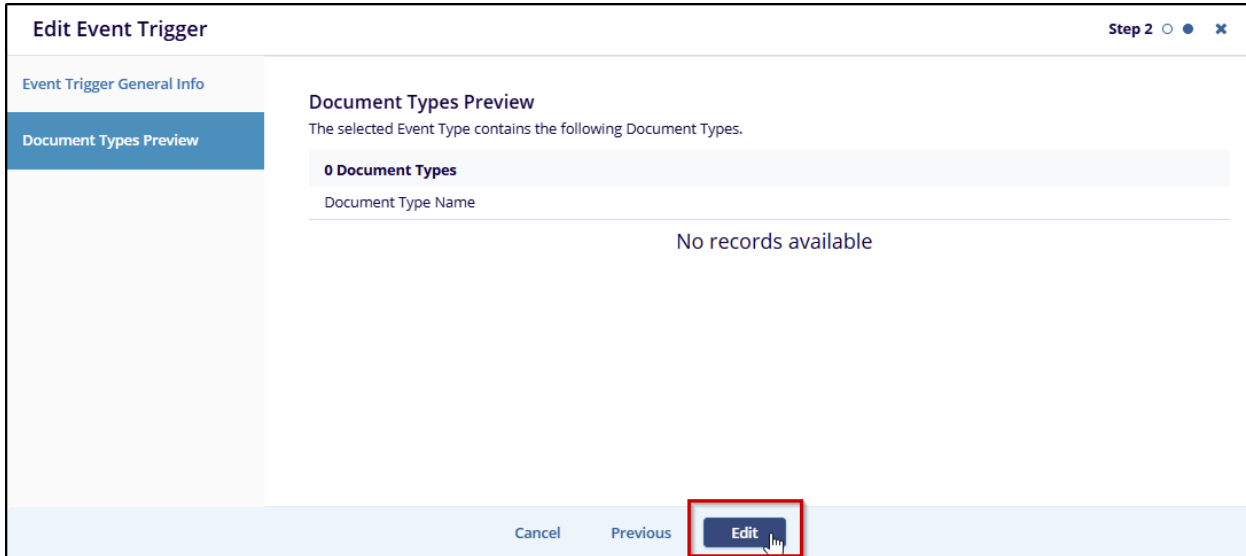
1. Select **Event Triggers** from the **Event Manager** module to view the list of triggers.
2. check the box next to the trigger you want to edit, and click **Edit**.



3. In the **Event Trigger General Info** screen, make any necessary changes to fields such as **Event Trigger Name**, **Event Name**, **Category**, **Event Type**, and **Due Date Period**, then click **Next**.



4. On the **Document Types Preview** screen, review or edit the associated document types if needed, and click **Edit** to save your changes.



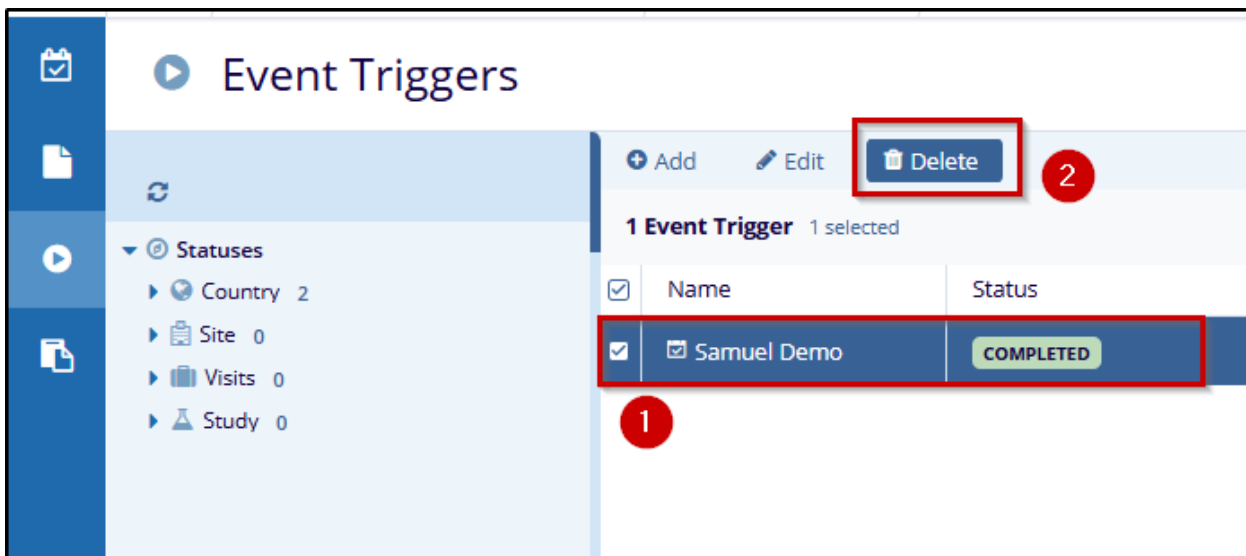
5. A confirmation message will appear, indicating the Event Trigger was successfully edited.



## 51. How to Delete Event Trigger

### Steps to Delete Event Trigger

1. In the **Event Triggers** section, select the trigger you want to delete by checking the box next to its name, then click **Delete**. A confirmation prompt will appear asking if you want to proceed; click **Yes** to confirm.



2. A message will display, indicating that the Event Trigger was successfully deleted.

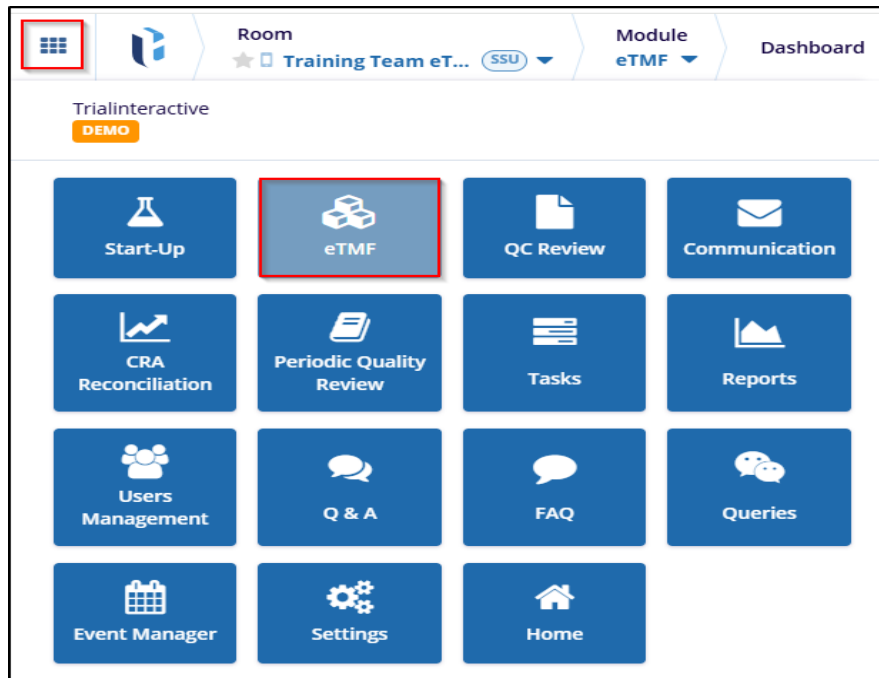


## CHAPTER 6: TRIAL INTERACTIVE ETMF MODULE

Know more about the Trial interactive eTMF Module.

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, 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.

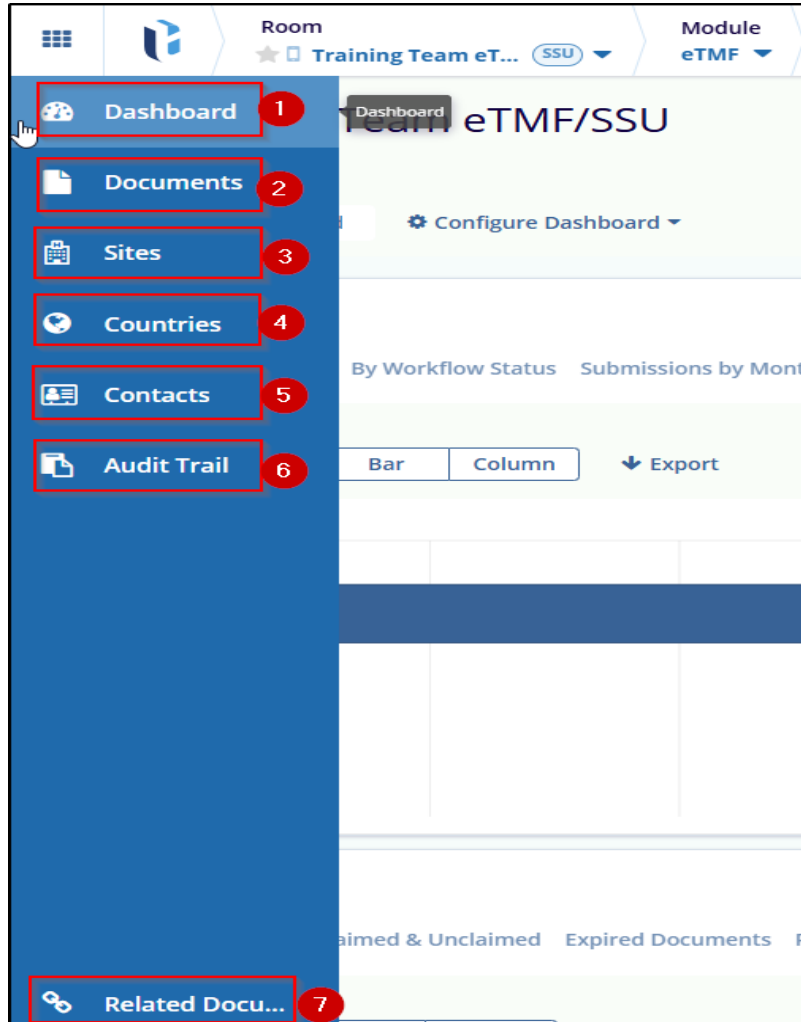


Once you enter the eTMF window, you will have access to various dashlets and can toggle between them.

In this Section, you will find the following **Dashlet**.

- Dashboard
- Documents
- Site
- Countries
- Contacts
- Audit Trial
- Related Documents settings

Refer to the screenshot below:



Navigate to the vertical menu at the left to choose sections. Click on the Dashboard section from the left panel.

### Dashboards

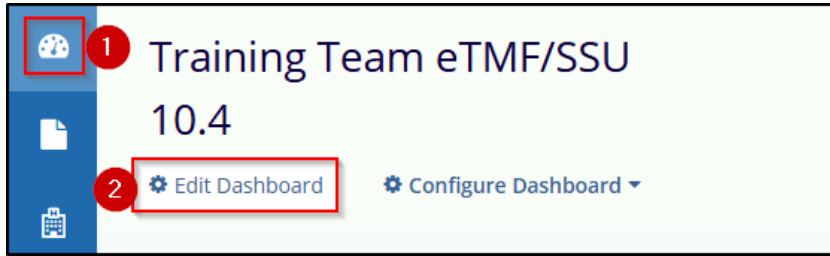
Know more about Trial Interactive Dashboard, Dashlets, and Dashlet settings.

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 dashboard.

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.

## 52. Edit Dashboard

This button is displayed in the top left corner. By clicking this button, the user can do the following:

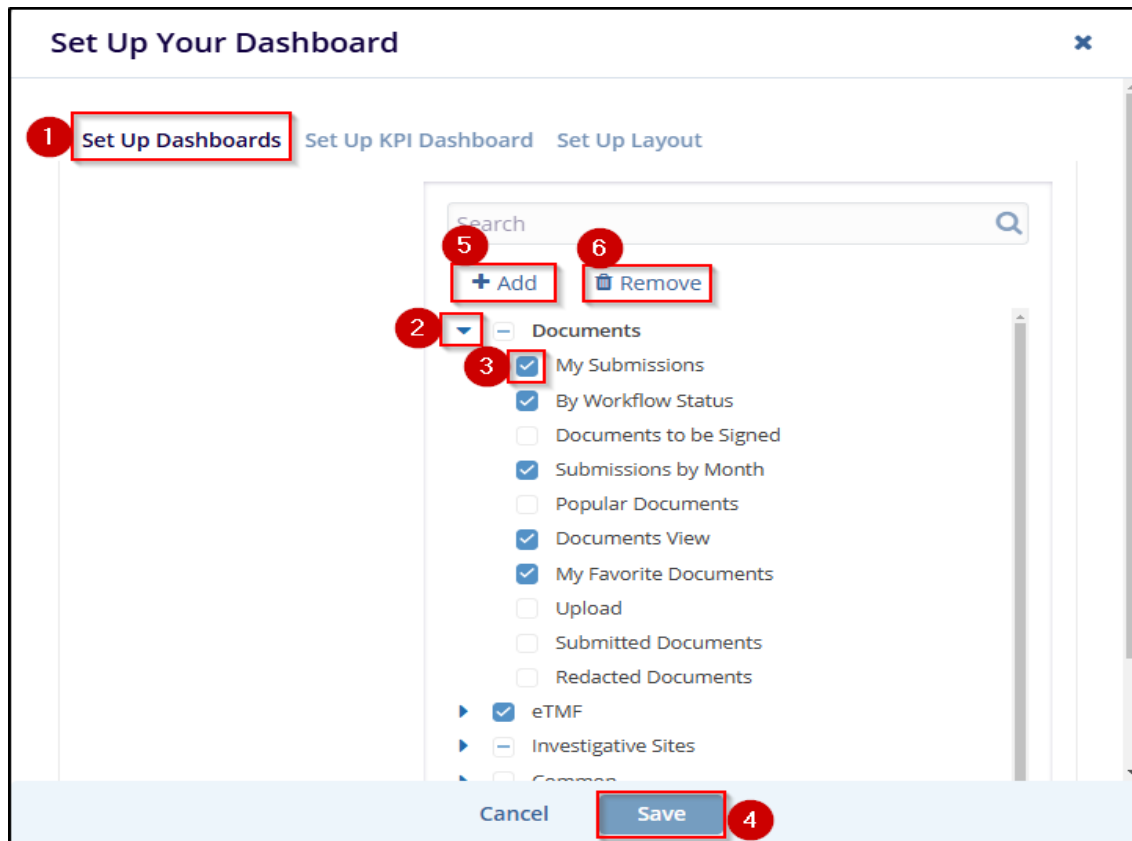


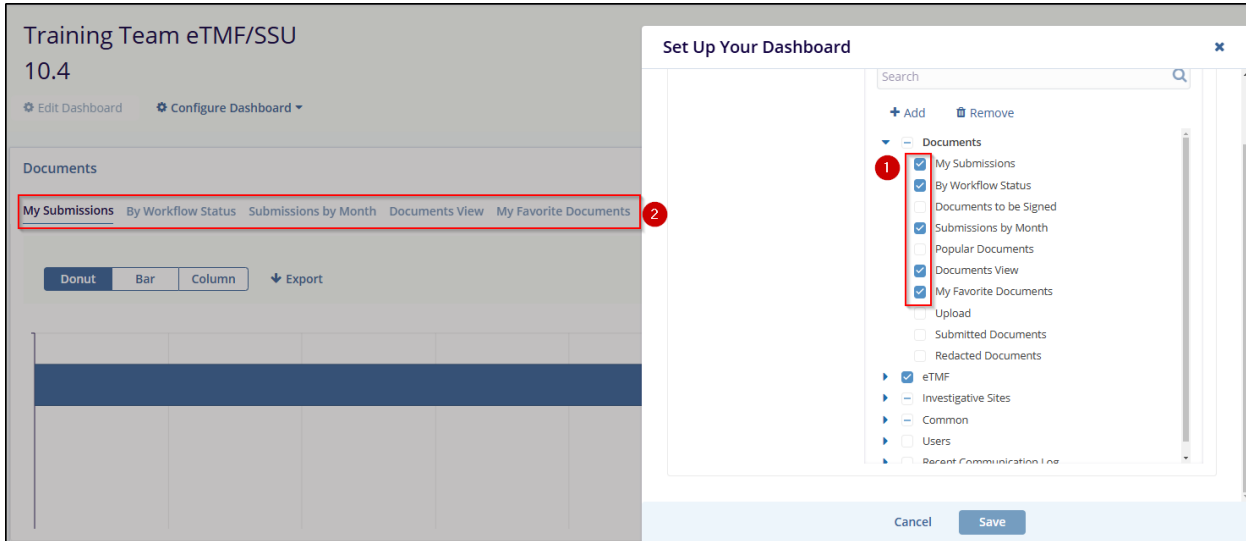
- Set Up Dashboards
- Set Up KPI Dashboards
- Set Up Layout

### Set Up Dashboards

Here, the user can set up their dashboard as required. Follow the steps below to set up the dashboard.

1. Click the **Edit Dashboard** button at 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 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.



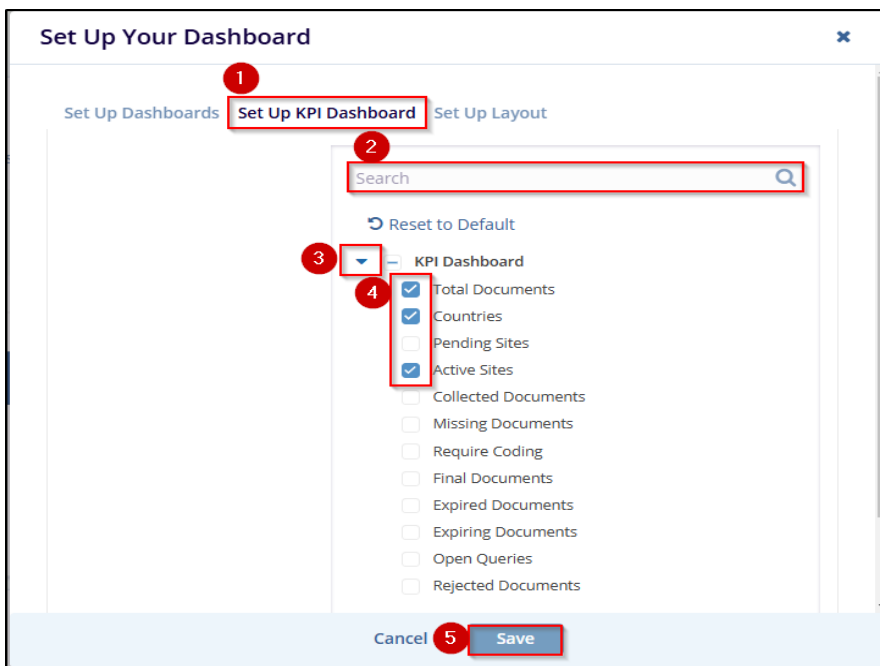


**Note:** The checkbox(s) selected for each dashlet from the setup dashboard window will only display those tabs in the dashlets. You can refer the above screenshot.

### Set Up KPI Dashboard

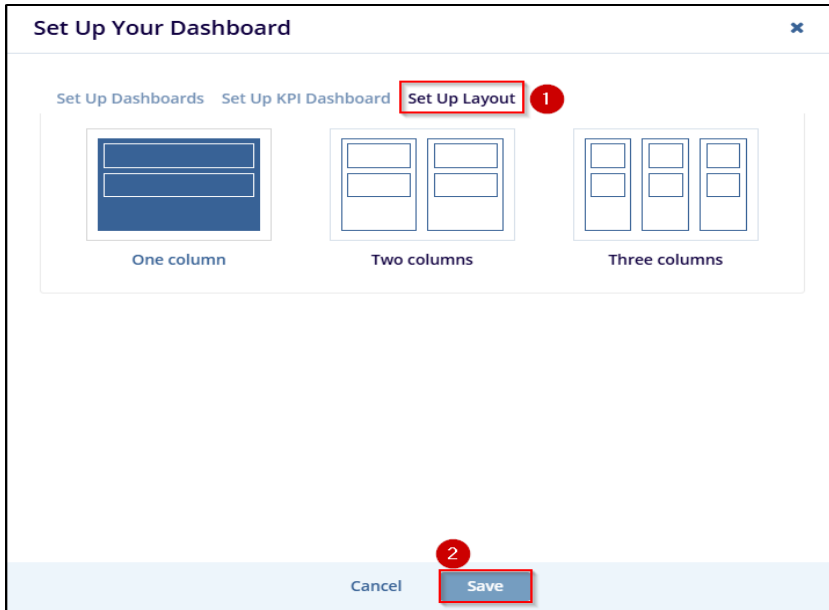
Here, the user can set up the dashlets displayed on the top center to the right corner of the screen. The selected tabs are displayed as tiles on the screen. Follow the steps below to set up the KPI dashboard.

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 select and set up a layout for the entire Dashboard. The user has the option 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.



### 53. Configure Dashboard

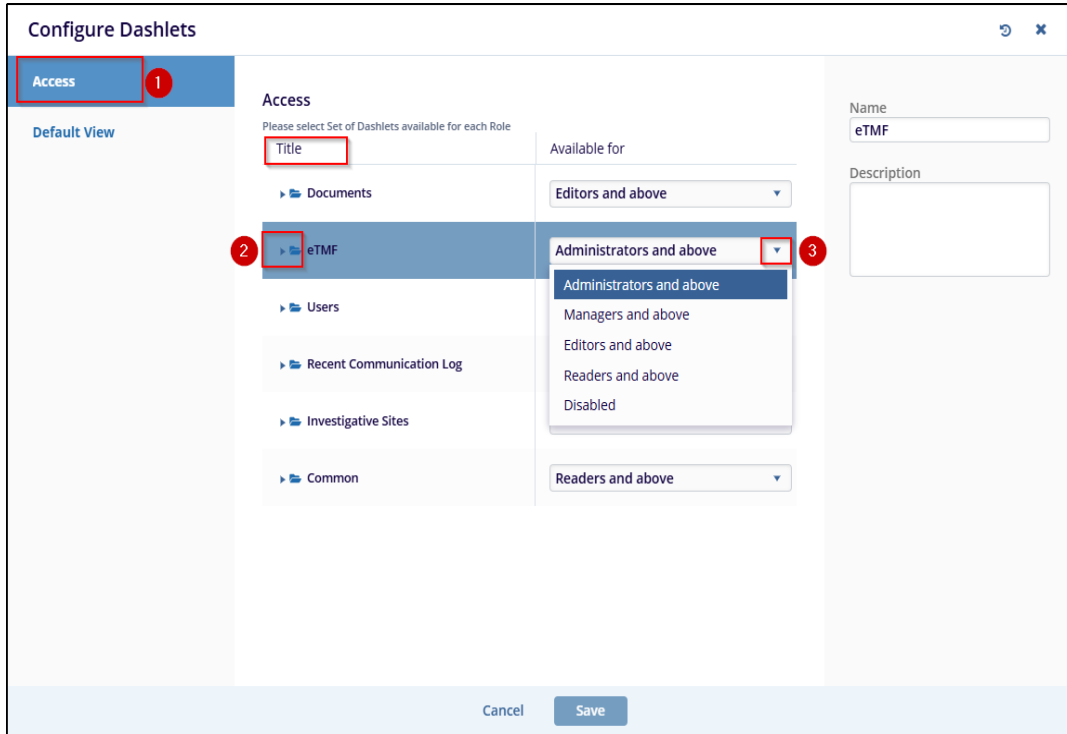
The Configure Dashboard helps the user to arrange the dashboard as required. The user has two options for configuring the dashboard –

- **Configure Dashlets**
- **Configure KPIs**

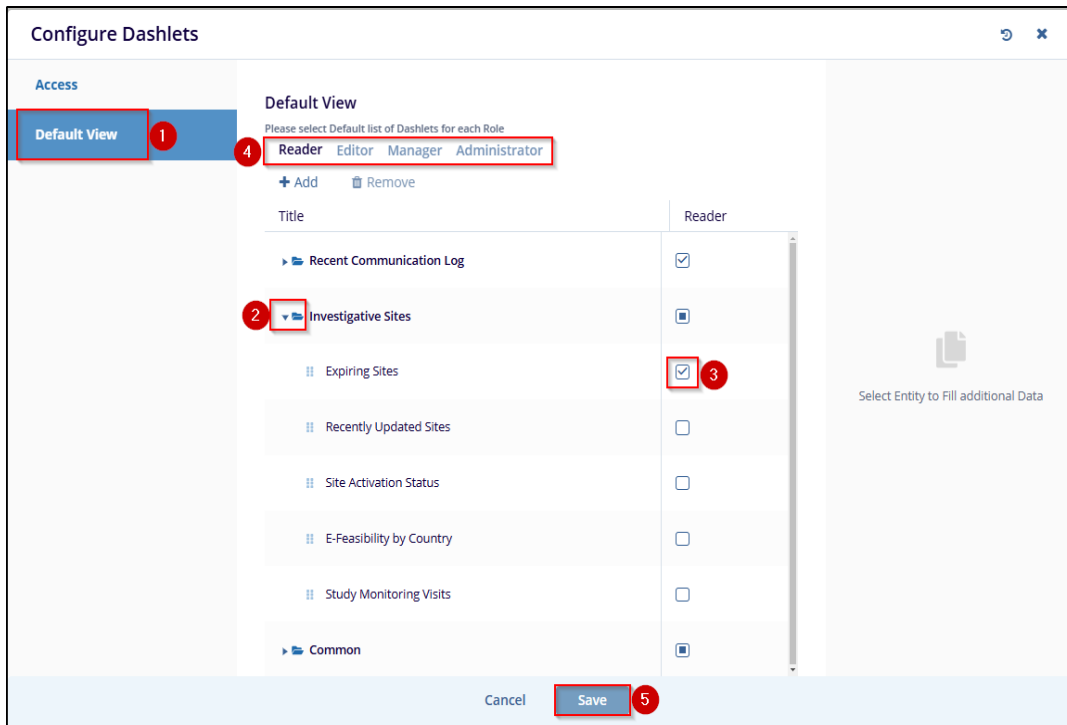
Follow the steps below to configure the dashlets.

1. Click the **Configure Dashboard** button next to the Edit Dashboard button. You can see Configure Dashlets and Configure Dashboards.
2. Once you click on the “**Configure Dashlets**”, this popup the Configure Dashlets window.
3. In the “**Access**” tab, you can select the roles from the dropdown menu for each tab, keeping in consideration the titles are mentioned.





4. In the “**Default View**” tab, select the required and appropriate checkboxes for the roles mentioned – **Reader, Editor, Manager, and Administrator**.
5. Click on the “**Save**” button at the bottom of the popup window, to save the changes.

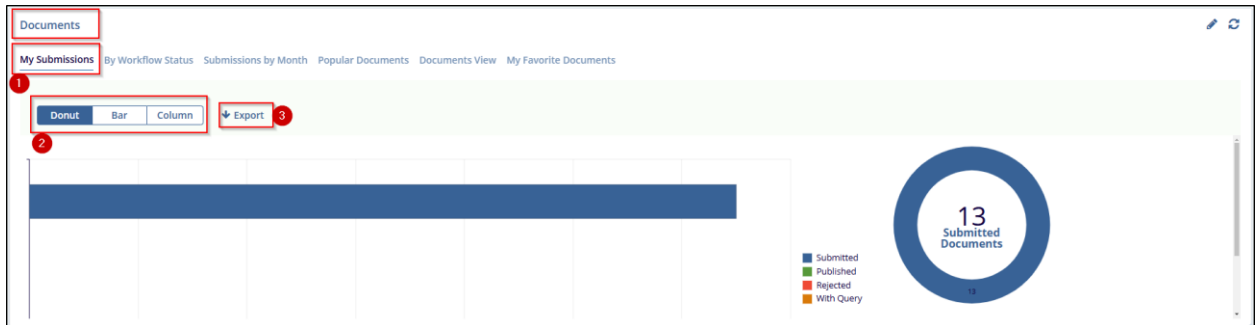


## 54. Documents

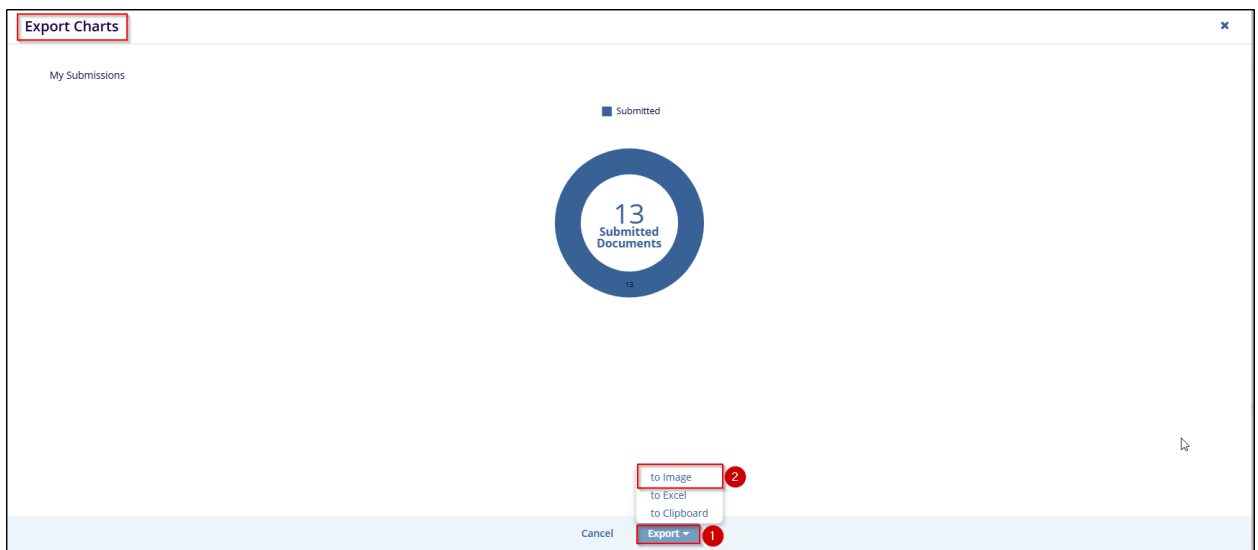
### My Submissions

The My Submission dashlet will allow users to view the files they have uploaded right from the documents.

1. This is already familiar with My Favorite Documents and Popular Documents dashlets.
2. Click on My Submissions and view the Submitted Documents Chart through the **“Donut, Bar, and Column”** view by selecting it. Next to it, you can see the blue arrow **“Export”** button.



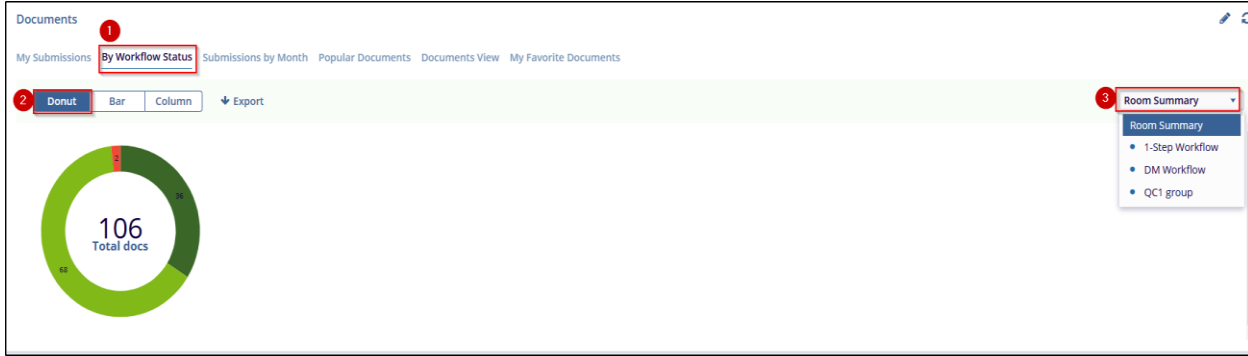
3. The user can export this data by clicking the **“Export”** button. The **“Export chart”** window will be a popup and the user can export the data in – **Image, Excel, or Clipboard format**.



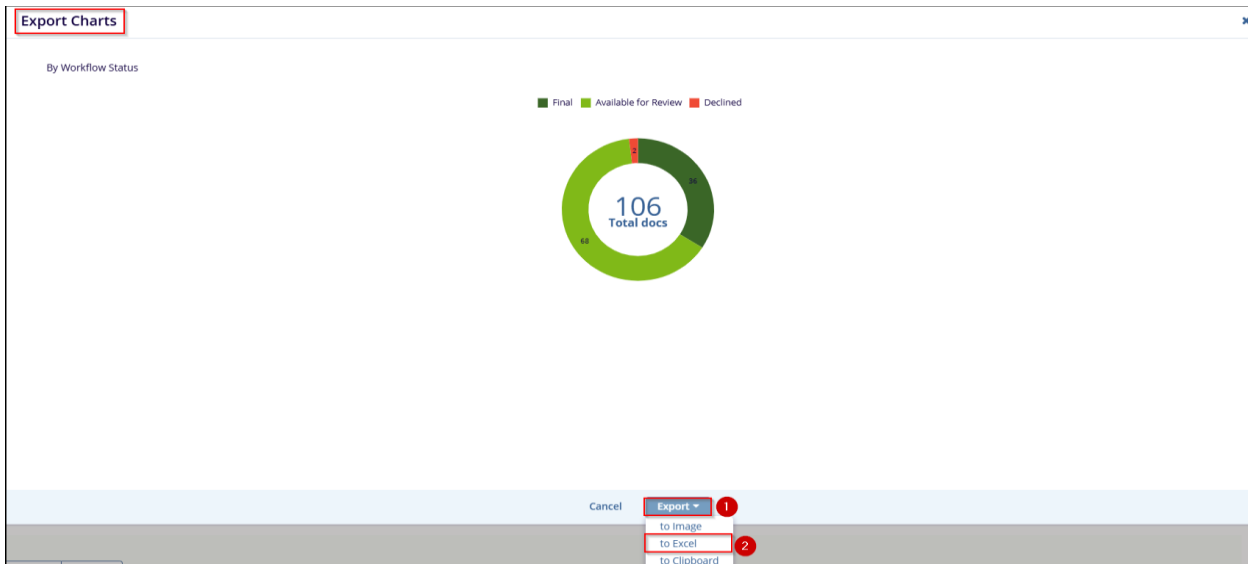
### By Workflow Status

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, the user can view the document processing status: A complete Room Summary or workflow stages are defined.

1. Click on the **“By Workflow Status”** to view the workflow chart through the **“Donut, Bar, and Column”** view by selecting it.
2. On The right side of the document window, there is a drop-down menu. By default, the Room Summary option is selected, where you can view the document processing status, and complete Room Summary, with these options
  - 1-Step workflow
  - DM workflow
  - QC1 group



3. The user can export this data by clicking the “**Export**” button. The “**Export chart**” window will be a popup and the user can export the data in – **Image, Excel, or Clipboard format.**



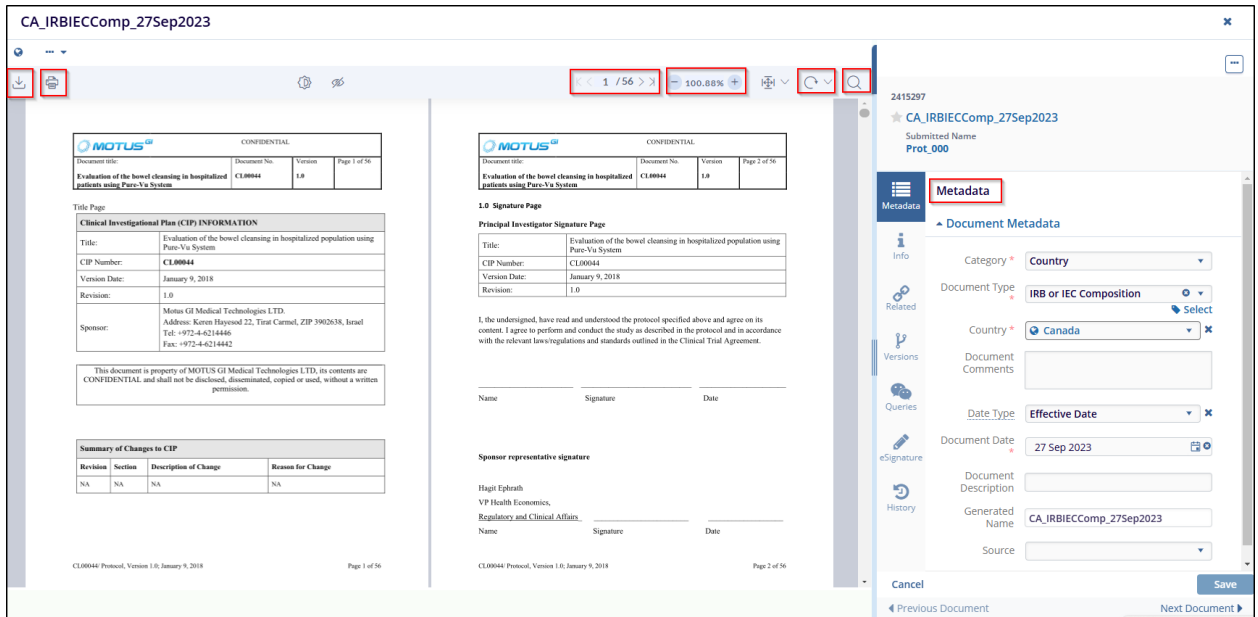
### Documents to be Signed

In the **Documents** section, select **Documents to be Signed** from the options at the top. This view will display a list of documents awaiting signatures, along with details like the document’s Submitted Name and current **signer** status.

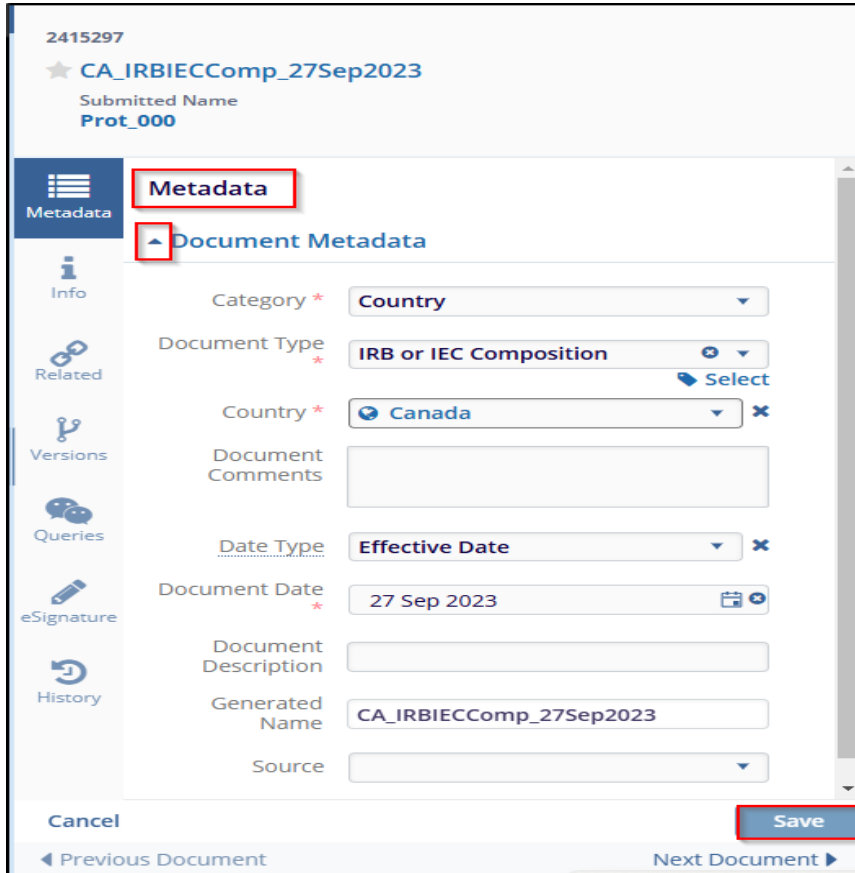
1. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, you can click on the blue arrow, which will navigate to the document index. To customize the columns displayed in the document list, click **Manage Columns** and select or deselect columns as required to personalize the view.

Submitted Name	Signers
Prot_000	Admin AP, waiting for signers
F01-202-501 Protocol Signature Page	Admin AP, waiting for signers
Dr. K 1572	trainingadmin1@ti.com, waiting for signers
Contact Details_List	Editor AP, waiting for signers

- To open a document, click the document icon next to the submitted name. This action will bring up the document in the viewer, where you can review its contents.
- In the document viewer, you can navigate between pages, zoom in/out, and adjust the view as needed. Additionally, you can access the **Metadata** panel on the right side to review or edit the document's metadata, such as **Category**, **Document Type**, and **Document Date**.



- To view or edit document metadata, click on the document's title. This action opens a detailed view of the document. In the **Metadata** tab, you can review and modify fields like Category, Document Type, Site, and other related information. After editing, click **Save** to apply any changes. Refer to the below screenshot.



2415297  
★ CA\_IRBIECComp\_27Sep2023  
Submitted Name  
Prot\_000

**Metadata**

**Document Metadata**

Category \* Country

Document Type \* IRB or IEC Composition Select

Country \* Canada x

Document Comments

Date Type Effective Date x

Document Date \* 27 Sep 2023 Calendar

Document Description

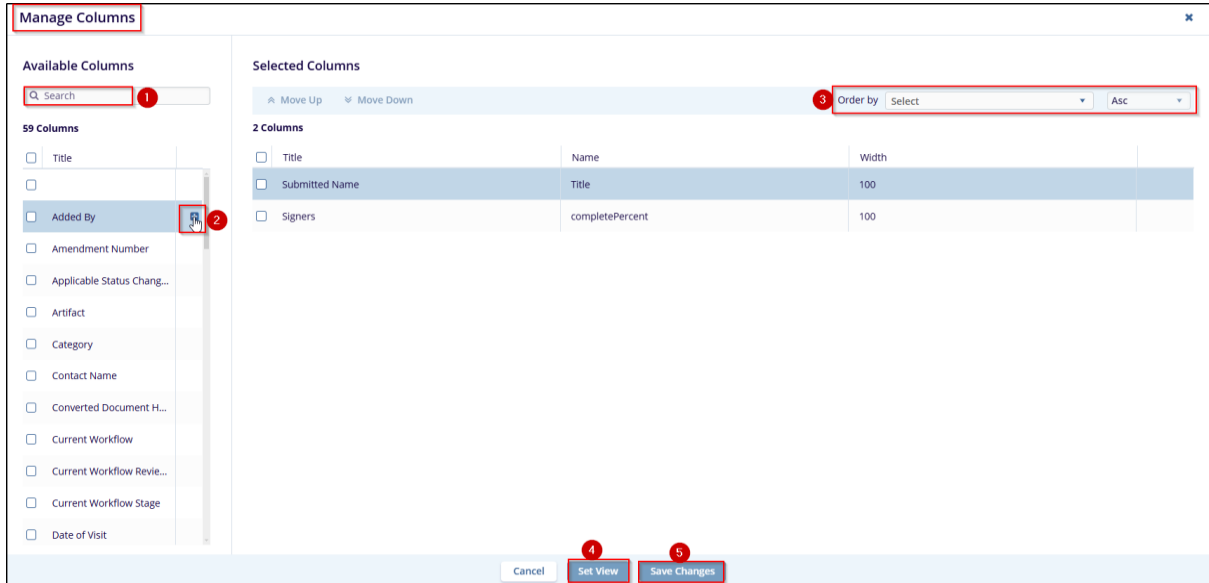
Generated Name CA\_IRBIECComp\_27Sep2023

Source

Cancel Save

◀ Previous Document Next Document ▶

5. In **Manage Columns**, use the **Search** bar to quickly find specific columns by name from the available list on the left.
6. To add a column to your view, select the checkbox next to the column name in **Available Columns**. The selected columns will appear in the **Selected Columns** list on the right. You can also deselect a checkbox to remove a column from the view. Arrange the display order of columns by using the **Order by** dropdown and choosing **Ascending** or **Descending** for ascending or descending order.
7. To set your current selections and order as the default view, click **Set View**. After finalizing your column selections and order, click **Save Changes** to apply them to the document view.

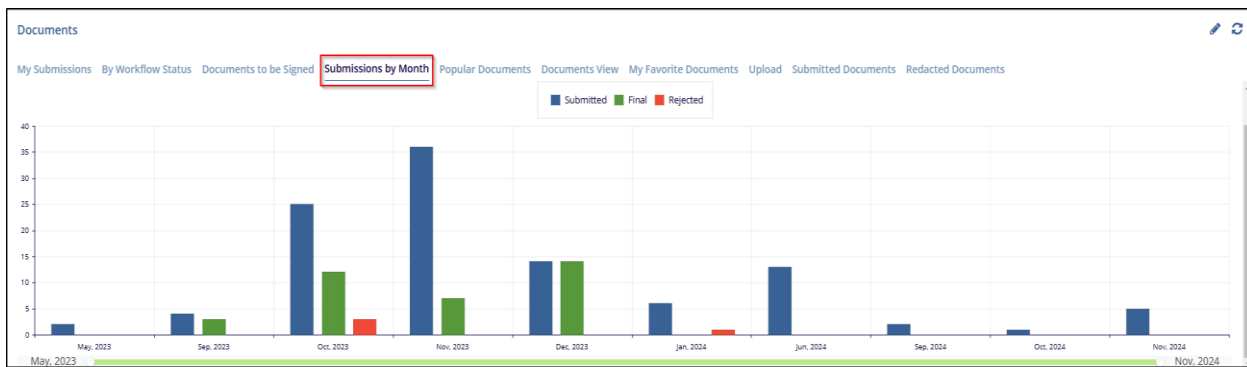


### Submissions by Month

In the **Documents** section, select **Submissions by Month** from the menu at the top. This view displays a bar chart representing the number of document submissions per month, categorized by submission status.

Each bar in the chart is color-coded to indicate the status of the documents:

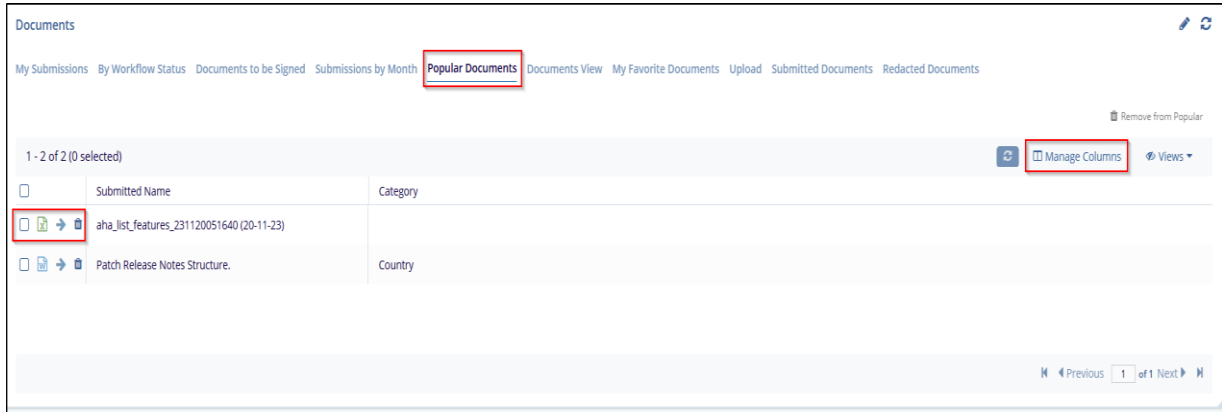
- **Blue** represents documents that have been submitted.
- **Green** represents final documents.
- **Red** represents rejected documents.



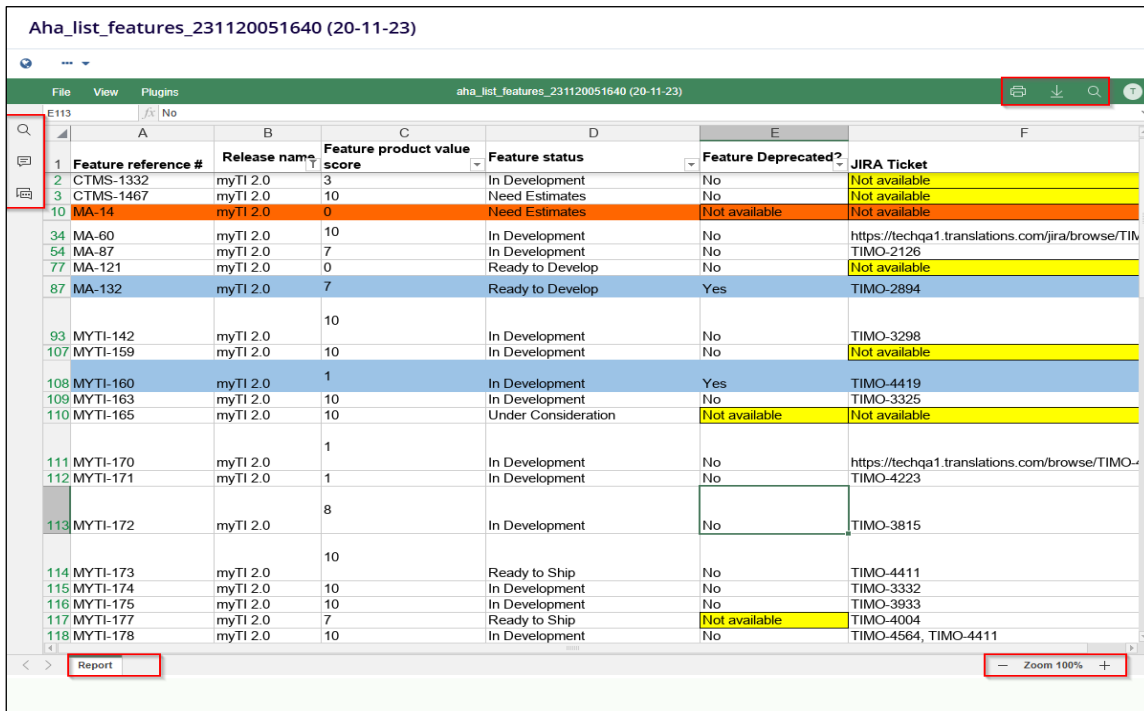
### Popular Documents

In the **Documents** section, select **Popular Documents** from the menu at the top. This view lists documents that are frequently accessed or marked as popular, along with details such as the **Submitted Name** and **Category** or **Country**.

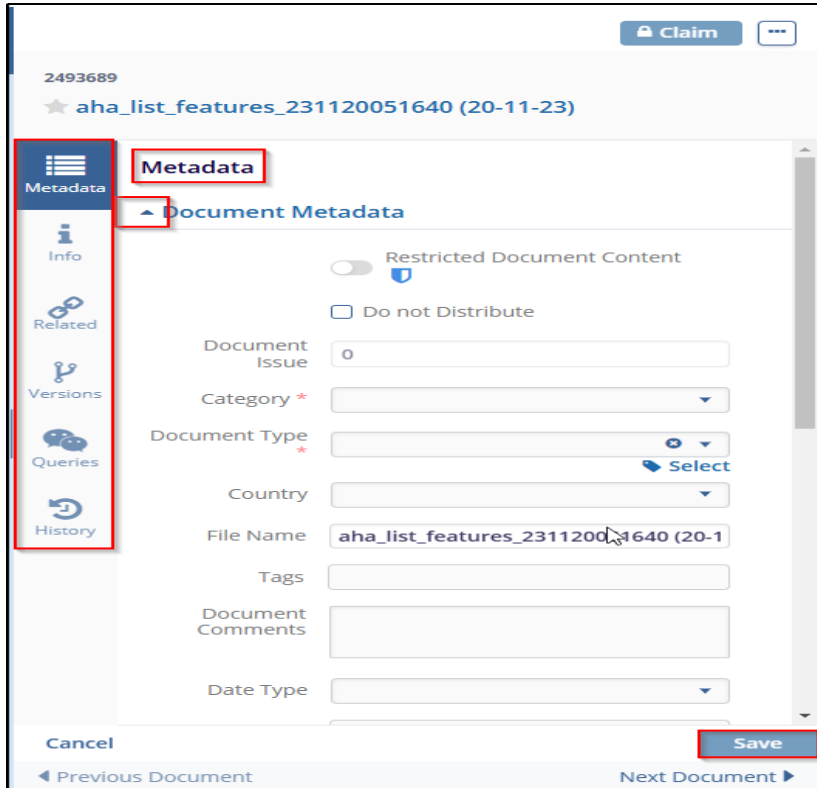
1. To remove a document from the Popular list, click on the **“Remove from Popular”** button on the dashlet. To view the document, click on the blue arrow, which will navigate the user to the document index, To customize the columns displayed in the document list, click **Manage Columns** and select or deselect columns as required to personalize the view.



2. Clicking on the Excel icon, the Excel sheet window will pop up with document metadata, where you can perform various actions, such as downloading, printing, zooming in and out, and searching.



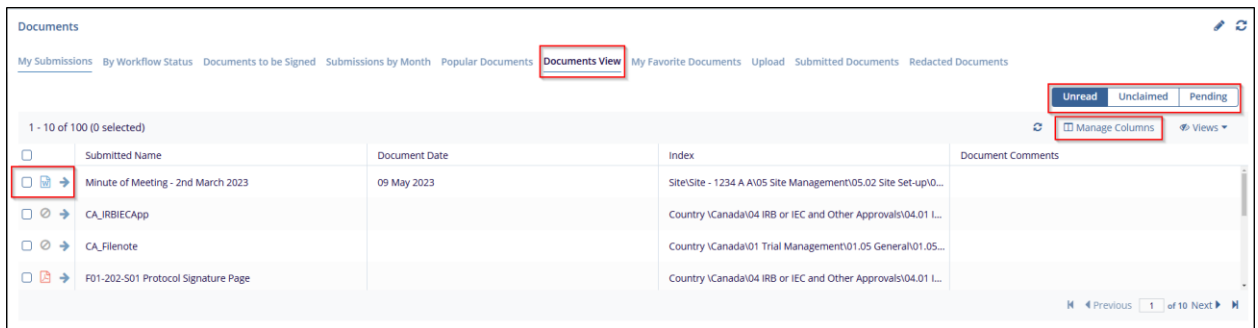
- 3.
4. On the right side of the Excel sheet, where you can find the document Metadata, Info, related, version, queries, and history section, after updating metadata or making any necessary changes, click "Save" to apply your edits. Refer to the below screenshot



### Documents View

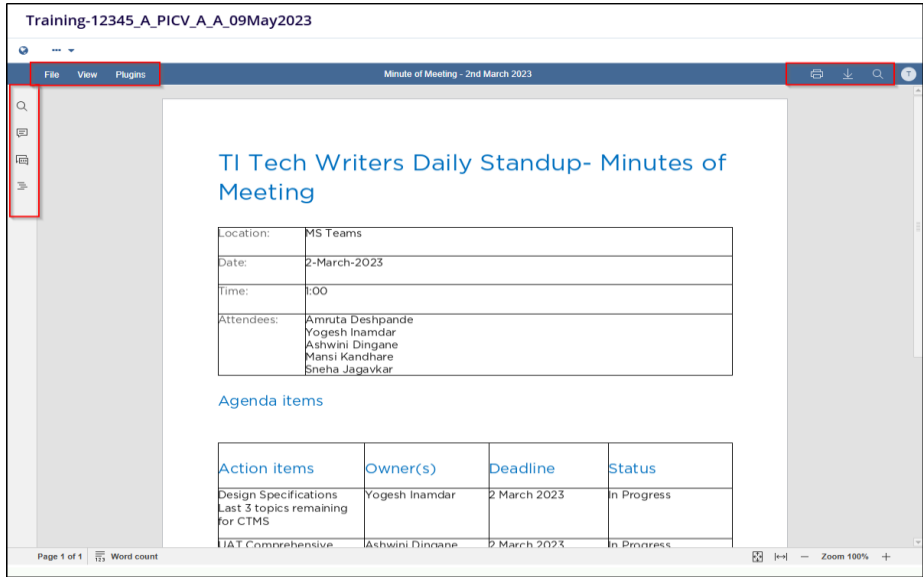
This tab displays the documents in a grid column with a selection tab for – **Unread, Unclaimed, and Pending**.

1. To view a document, click on the blue arrow, which will navigate the user to the document index. To customize the columns displayed in the document list, click **Manage Columns** and select or deselect columns as required to personalize the view.

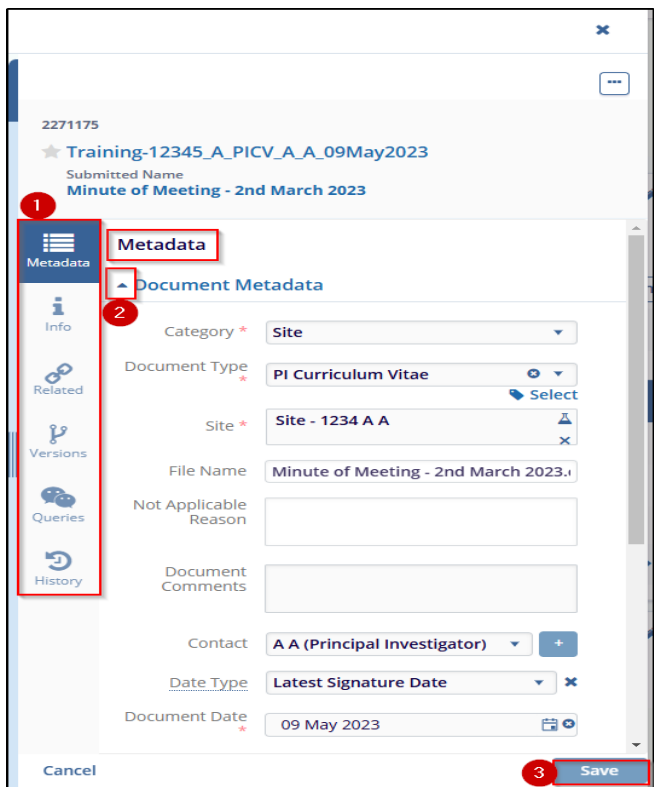


2. By clicking on the Word icon, the Word file will open with the document metadata, where you can perform various actions, **such as downloading, printing, zooming in and out, and searching**



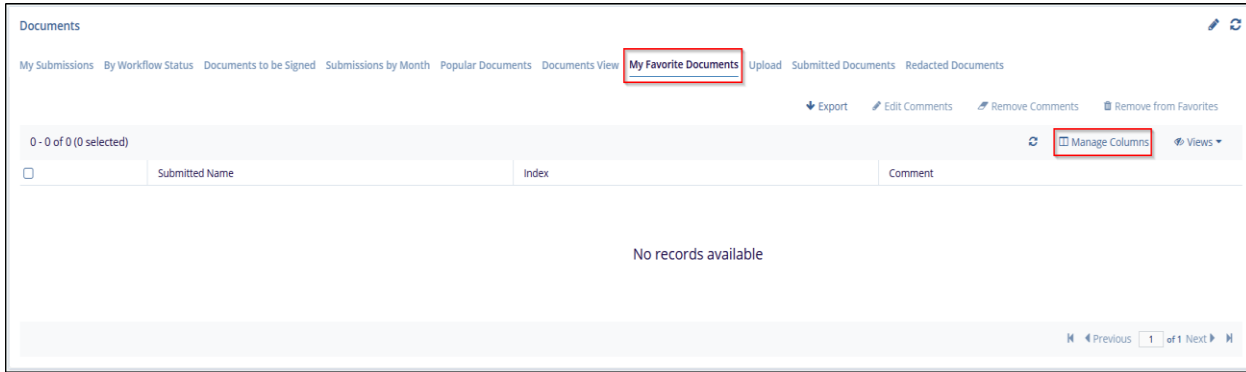


- On the right side of the Excel sheet, where you can find the document **Metadata, Info, related, version, queries, and history section**, after updating metadata or making any necessary changes, click **“Save”** to apply your edits. Refer to the below screenshot



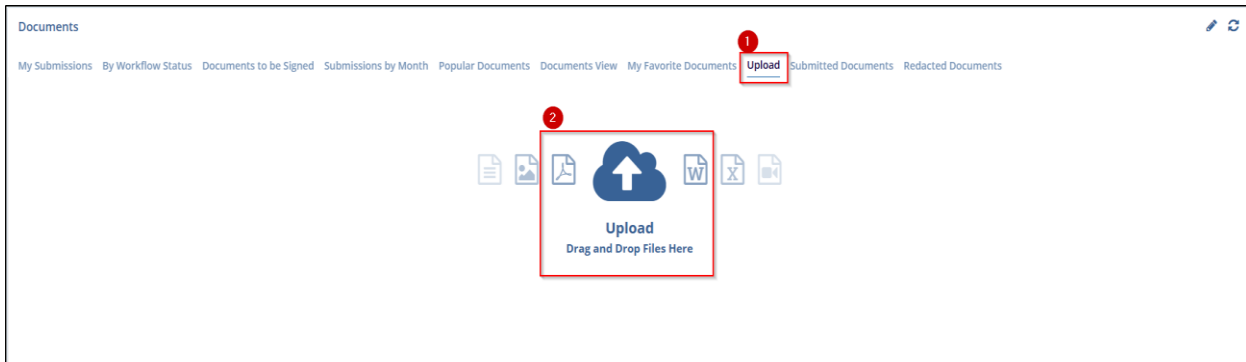
### My Favorite Documents

In this section, select **My Favorite Documents** from the menu at the top. This view displays a list of documents that you have marked as favorites, allowing you quick access to frequently used documents.

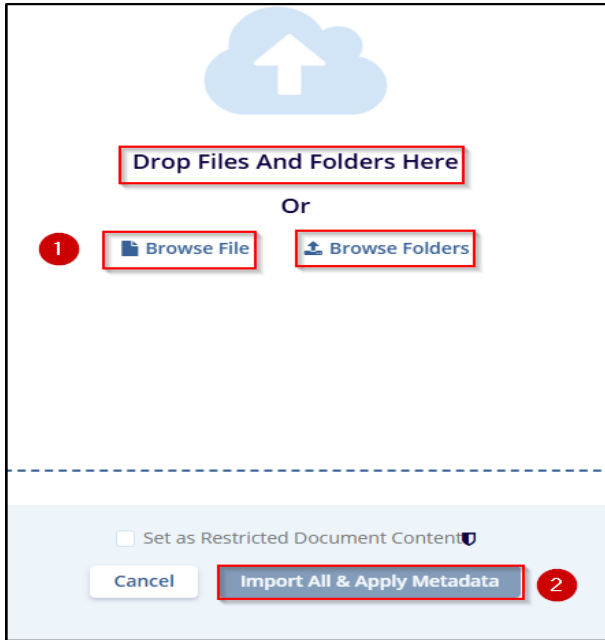


## Upload

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.



1. Navigate to the **Documents** section and select the **Upload** option from the menu at the top.
2. In the upload area, you can drag and drop files directly into the designated Upload box or click **Browse File** or **Browse Folders** to locate files from your system.
3. After selecting the files, you can set them as **Restricted Document Content** by checking the respective box if necessary.
4. Once your files are ready, click on **Import All & Apply Metadata** to complete the upload process.

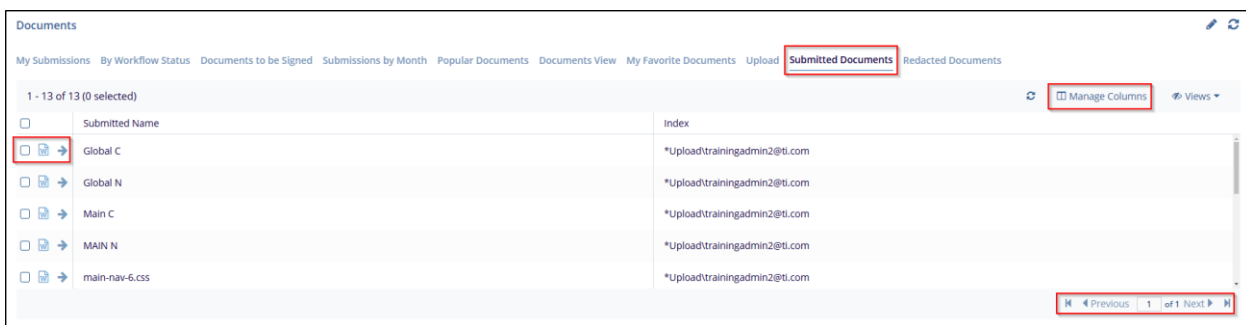


### Submitted Documents

In the **Documents** section, select **Submitted Documents** from the menu at the top. This view displays a list of documents that have been submitted, showing details such as the **Submitted Name** and **Index**.

To customize the columns displayed, click **Manage Columns** to add or remove specific columns as needed.

Navigation options at the bottom of the page, such as **Previous** and **Next**, allow you to move through pages of submitted documents.



### Redacted Documents

In this section, select **Redacted Documents** from the menu at the top. This view displays documents that are in various stages of the redaction process.

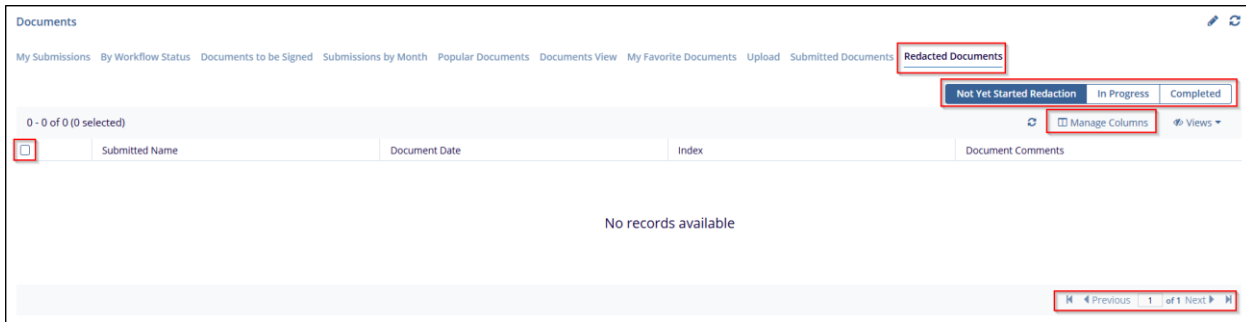
Use the status filters at the top right to sort documents by redaction stage:

- **Not Yet Started Redaction** for documents pending redaction.
- **In Progress** for documents currently being redacted.

- **Completed** for documents where redaction is finalized.

You can customize the displayed columns by clicking **Manage Columns** and selecting or deselecting columns as needed.

Navigation options, including **Previous** and **Next**, are at the bottom of the page to browse through multiple pages of redacted documents.

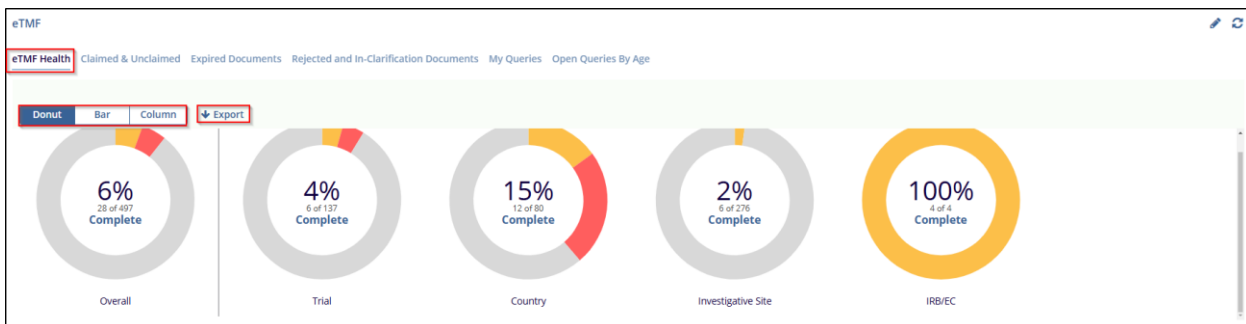


## 55. eTMF

### eTMF Health

In the **eTMF** section, select **eTMF Health** from the menu at the top. This view provides a graphical summary of the completeness status of eTMF documents across various categories, such as **Overall**, **Trial**, **Country**, **Investigative Site**, and **IRB/** and summarizes the percentage of missing and collected documents defined by the room’s configuration. Each category of documents is listed and has its chart. To view the missing documents at each category level, click on the appropriate chart to drill down if required.

To export the displayed data, click **Export**, which allows you to download the information for further analysis.

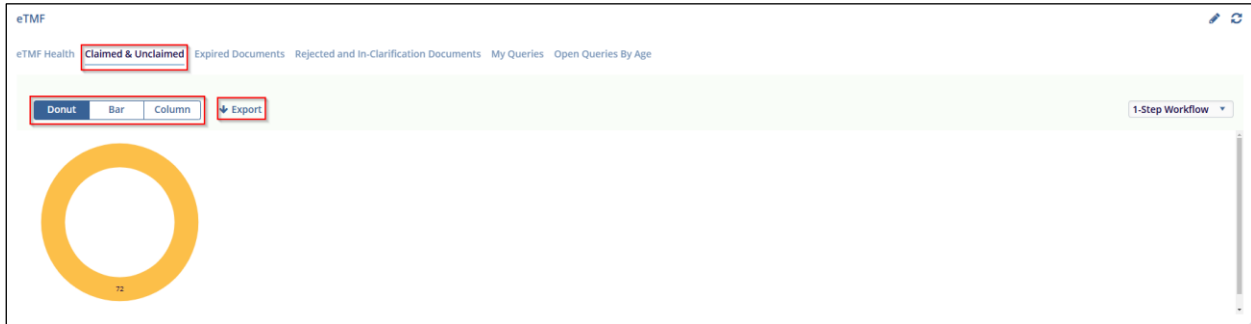


### Claimed & Unclaimed

In the **eTMF** section, select **Claimed & Unclaimed** from the menu at the top. This view provides a graphical representation of documents that have been claimed versus those that remain unclaimed within the system.

The data is displayed as a donut chart by default, showing the count of documents in each category. You can switch between chart types (Donut, Bar, Column) to view the data in your preferred format.

To export the displayed data, click **Export**, which allows you to download the information for further analysis.

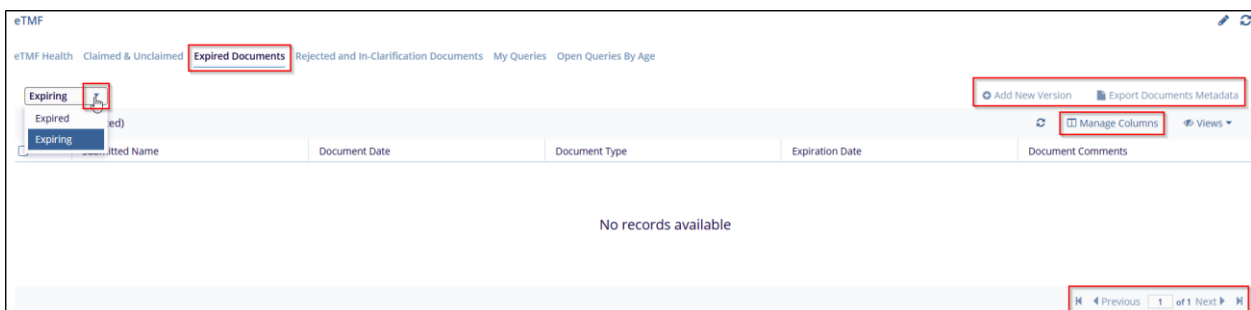


### Expired Documents

The **Expired Documents** dashlet lists documents that are either expiring or have already expired, based on the specified expiration period. This dashlet offers two views, accessible through the **Expired** dropdown at the top left corner: **Expired** and **Expiring**. To select a view, click the **Expired** dropdown and choose the desired option.

Users can also manage expired documents by replacing them with updated versions. To handle 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

The **Rejected and In-clarification Documents** dashlet displays a summary of documents that have been rejected or need clarification, the reason for each rejection, and the count of documents per rejection type. This overview helps identify common reasons for rejection and areas where clarification is frequently needed.

To view the list of documents associated with a specific rejection or clarification reason, click on the **+** sign next to the reason. This expands the section, revealing individual documents, including details such as the **Submitted Name**, **Created Date**, and **Document Comments**.

Additional options, like **Export** and **Manage Columns**, allow you to export the data or customize the column view to focus on relevant information.



Reason	Count
Blank Pages	2
Duplicate Document	2

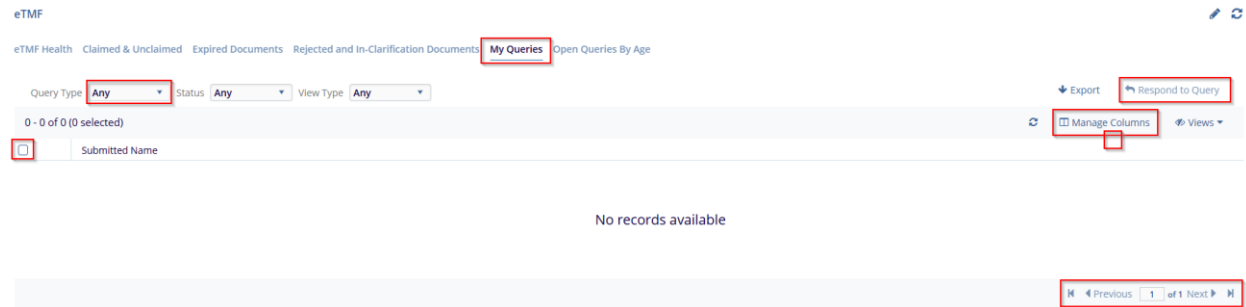
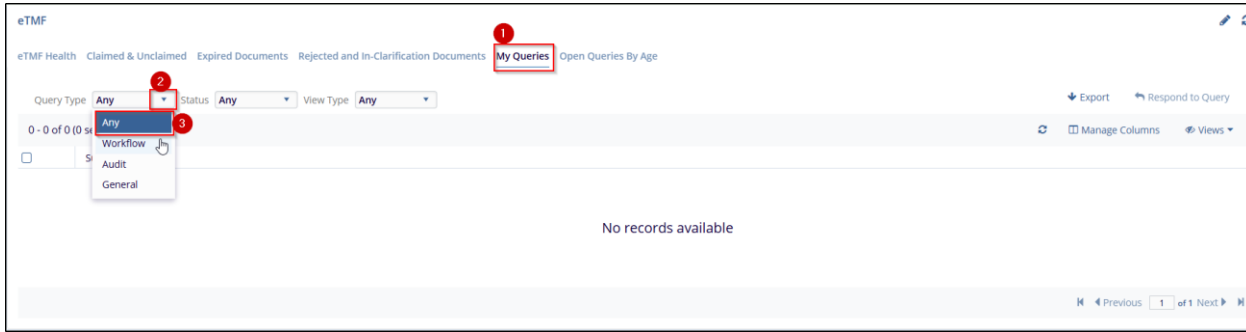
Submitted Name	Created Date	Document Comments
Test document	16 Oct 2023	

## My Queries

The **Expired Documents** dashboard lists documents that are either expiring or have already expired, based on the specified expiration period. This dashlet offers two views, accessible through the **Expired** dropdown at the top left corner: **Expiring** and **Expired**. To select a view, click the **Expired** dropdown and choose the desired option.

Users can also manage expiring or expired documents by replacing them with updated versions. To handle an expired or expiring document, follow these steps:

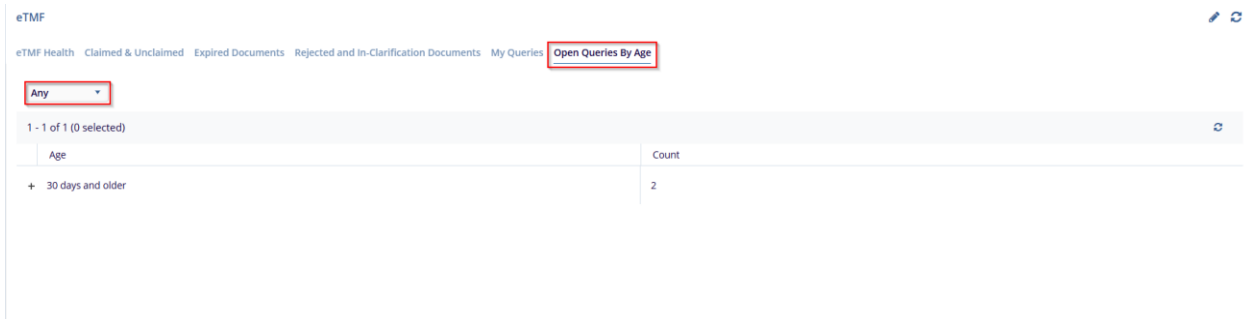
1. Locate the document in the dashlet.
2. Check the box next to the document.
3. Click the **+Add New Version** button at the top right of the dashlet. This action opens the **Add New Version** window.
4. Select the appropriate replacement option. (The available options are configured by the room administrator in the Settings area.)
  - If **Replace the Attachment** is chosen, click **Browse** to locate the new file version, set the new expiration date, and provide a reason for the replacement.
  - If **A new version was already submitted. Remove this document from the list** is chosen, no further action is needed, and the document will be removed from the expiring documents list.
5. Press **Save** to apply the changes.



### Open Queries by Age

The **Queries by Age** dashlet conveniently displays documents that are **30 days and older** and provides a **document count** for easy tracking. The **query types** available in this dashlet include **All**, **Workflow**, or **Audit**. You can select a query type from the dropdown menu located at the top left.

To view the specific queries within each age category, click the **arrow** next to the age (e.g., "30 days and older"). This will expand the list and show the detailed queries listed under the selected query type.

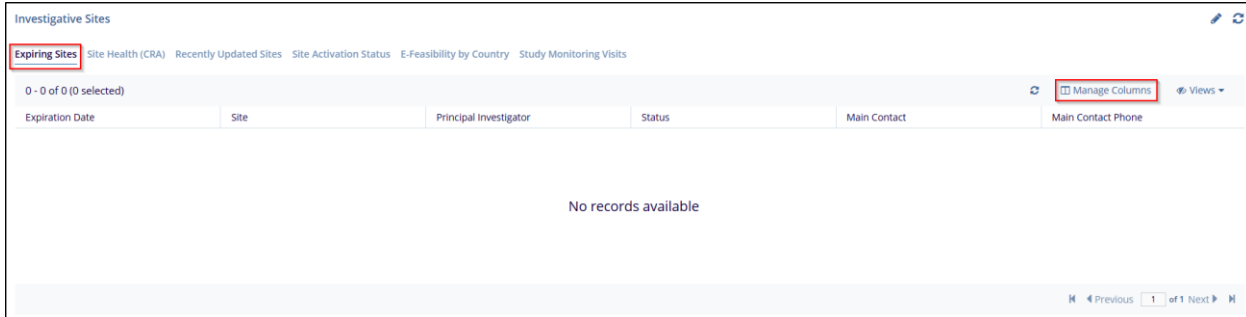


## 56. Investigative Sites

This dashlet provides an overview of key site metrics, displaying details for **Expiring Sites**, **Site Health (CRA)**, **Recently Updated Sites**, **Site Activation Status**, **E-Feasibility by Country**, and **Study Monitoring Visits**. In this dashlet, users have limited editing capabilities and can only change the dashlet's name. Note that only the tabs selected after clicking the **Edit Dashboard** button will appear in the dashlet, allowing for a customized view based on user preference.

### Expiring Sites

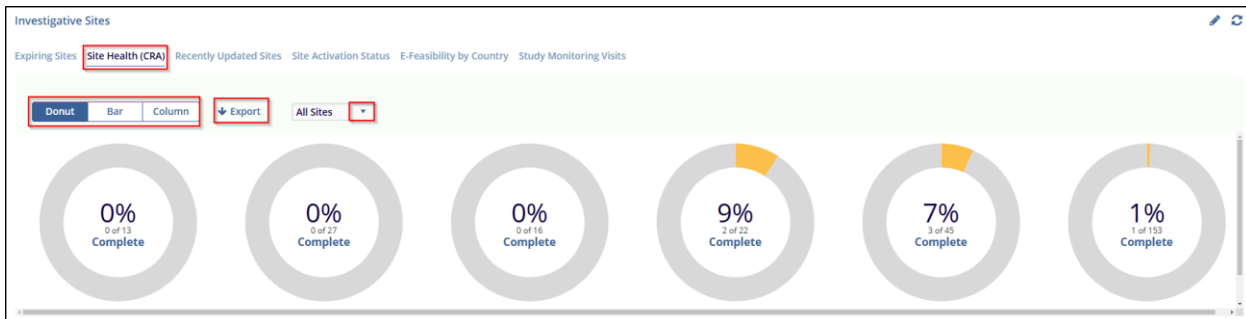
The **Expiring Sites** tab provides a list of all sites that have an upcoming expiration date. This tab includes columns displaying details such as **Expiration Date**, **Site**, **Principal Investigator**, **Status**, **Main Contact**, and **Main Contact Phone**. Users can further customize the view by clicking **Manage Columns** to add or remove specific columns as needed. This feature helps users track sites with approaching expiration dates, ensuring timely actions can be taken.



### Site Health (CRA)

The **Site Health (CRA)** tab provides a visual summary of the completion status for multiple sites, allowing users to monitor site progress effectively. This tab features three chart types—**Donut**, **Bar**, and **Column**—that display the percentage of tasks completed out of the total for each site. Users can also **Export** the data for external reporting or analysis. Additionally, the **All Sites** dropdown menu allows for filtering, enabling users to narrow down the view to specific sites or groups as needed.

1. Select a visualization type by clicking one of the **Donut**, **Bar**, or **Column** buttons. This will update the display of each site’s completion status in the chosen format.
2. Use the **All Sites** dropdown menu to filter which sites appear in the view. This is helpful if you want to focus on specific sites or subsets of data.
3. Click on the **Export** button to download the data currently displayed. This option allows you to save the information for further review or to include it in reports.



### Recently Updated Sites

The **Recently Updated Sites** tab provides a list of sites that have had recent updates, allowing users to monitor site progress and activity status. Key details displayed include **Site**, **Principal Investigator**, **Status**, and **Progress %**. Users can customize the display by managing columns, refreshing the data, and viewing all sites. This tab helps users keep track of site activity and status updates, which can be essential for ensuring that all sites meet project requirements.

- Click **View All Sites** in the top right corner if you want to see the complete list of sites without any filters applied.



- Use the **Refresh** button to update the information displayed in the list. This ensures you are viewing the most current data.
- Click **Manage Columns** to customize the information displayed. You can add or remove columns as needed to focus on specific details relevant to your review.

Investigative Sites

Expiring Sites Site Health (CRA) **Recently Updated Sites** Site Activation Status E-Feasibility by Country Study Monitoring Visits

1 - 20 of 20 (0 selected)

Refresh View All Sites Manage Columns Views

Site	Principal Investigator	Status	Progress %
USA 001 PI Placeholder	PI Placeholder	Active	100
Site - 004 PI	004 PI	Active	100
Bahama Hospital	Admin 103	Pending	0
Site - 123 test	123 test	Pending	71
USA PI Placeholder	PI Placeholder	Pending	30

### Site Activation Status

The **Site Activation Status** tab displays a bar chart showing the activation progress of sites over time. This tab allows users to filter by site groups and activation progress type, making it easier to track which sites are moving through the activation stages. The chart provides a visual representation of site activation on specific dates, helping users quickly assess activation trends and identify any sites that may require further action.

- Use the **All Sites** dropdown menu to filter the chart by specific site groups, allowing you to focus on a subset of sites relevant to your review.
- In the second dropdown menu, choose the desired **Site Activation Progress** type to adjust the chart based on specific activation criteria or milestones.
- Review the bar chart to see the number of sites activated on specific dates. Each bar represents the count of sites that reached the activation milestone on that date.



## E-Feasibility by country

The **E-Feasibility by Country** tab provides a visual overview of the feasibility assessments sent to sites in different countries. The data is presented in a chart format that can be viewed as a **Donut**, **Bar**, or **Column** chart, giving flexibility in how the information is displayed. This tab also includes an **Export** option to download the data for external analysis or reporting. The **All Sites** dropdown allows users to filter the sites by specific groups, focusing the view on particular sets of sites or regions. This feature helps users quickly see the distribution and count of feasibility assessments across countries.

1. Select your preferred chart format by clicking **Donut**, **Bar**, or **Column**. This will change how the feasibility data is displayed, allowing you to choose the visualization that best suits your analysis.
2. Use the **All Sites** dropdown to filter the data by specific site groups or regions, making it easy to focus on certain countries or subsets of sites.
3. Click on the **Export** button to download the feasibility data currently displayed in the chart. This option is useful for creating reports or conducting further analysis outside of the system.
4. The chart shows the total number of sites with feasibility assessments for each country. For example, the **Donut** chart format, indicates **1 Total site** in **India** with a feasibility status of "Sent."

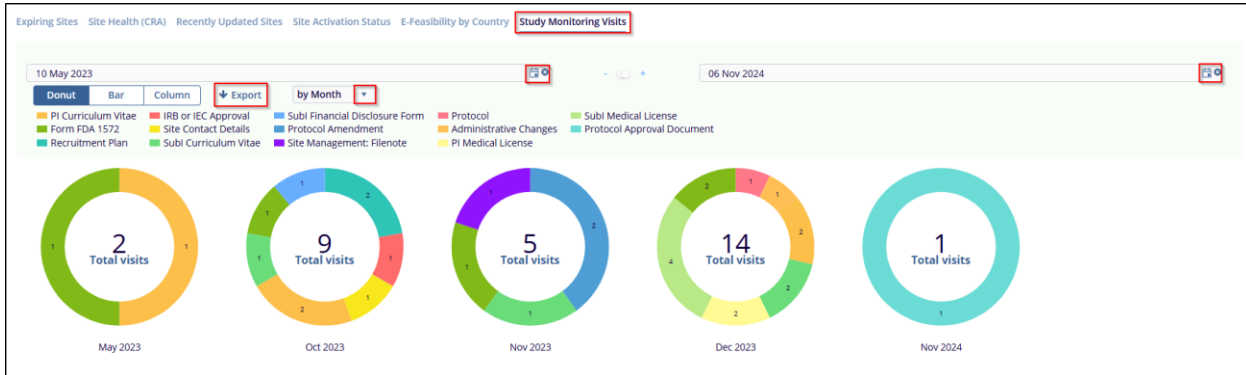


## Study Monitoring Visits

The **Study Monitoring Visits** tab provides a visual breakdown of the monitoring visits conducted over specific periods. Users can view visit data by month and year, with each circular chart displaying the total number of visits for that period and color-coded segments representing various document types (e.g., **PI Curriculum Vitae**, **Protocol Amendment**, **Administrative Changes**). The tab offers flexibility to change the chart type between **Donut**, **Bar**, and **Column** views, and an **Export** button to download the data. The date range can be adjusted using the date fields to focus on specific periods, helping users track and analyze visit trends over time.

1. Choose the date range for the data by selecting the **start date** (on the left) and **end date** (on the right). This will update the charts to show visits within the specified time frame.
2. Select **Donut**, **Bar**, or **Column** to choose your preferred chart format. This will change the display of the visit data, allowing you to view the information in a format that best suits your needs.
3. Use the **By Month** dropdown to organize the data by monthly intervals. This option can help in viewing trends over each month within the selected date range.
4. Click on the **Export** button to download the current view's data. This is useful for external analysis or reporting needs.

- Each circular chart shows the **Total visits** for a specific month or time period, with color-coded segments indicating different document types or actions completed during those visits. For example, **May 2023** shows "2 Total Visits," with each color representing different documents related to the visit.



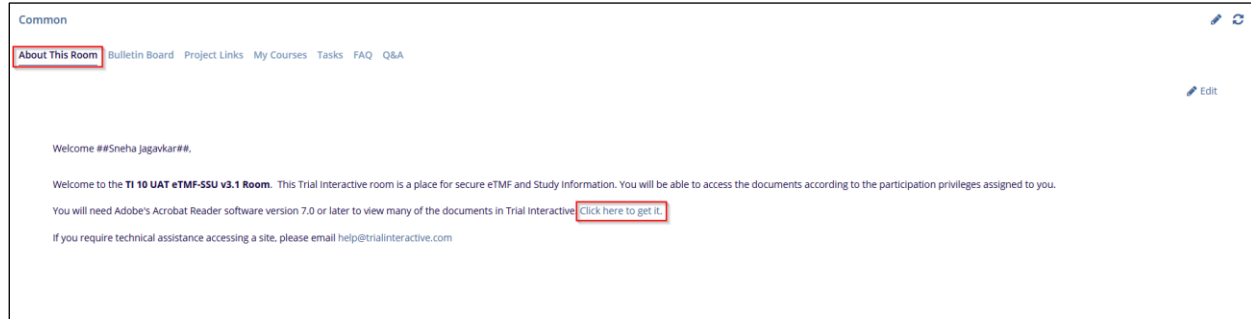
## 57. Common

The users can view and modify the room's **Welcome message**, which is displayed to all users upon accessing the room. This message area serves as a space for sharing essential information about the study, such as updates, reminders, or key details. Only users with **Administrator** or **Manager** privileges can edit this dashlet by pressing the **Edit** button. After making the desired updates, clicking **Save** will apply the changes, making them instantly visible to all users in the room, ensuring everyone has access to the latest study-related information.

### About this room

The **About This Room** section provides users with a welcome message and important information regarding the use of the room. This space can be customized to include study details, access requirements, and relevant support information. It mentions the need for **Adobe Acrobat Reader** for viewing certain documents and includes a link to download it. Users with **Administrator** or **Manager** roles can edit this content to ensure that all participants have up-to-date information and resources.

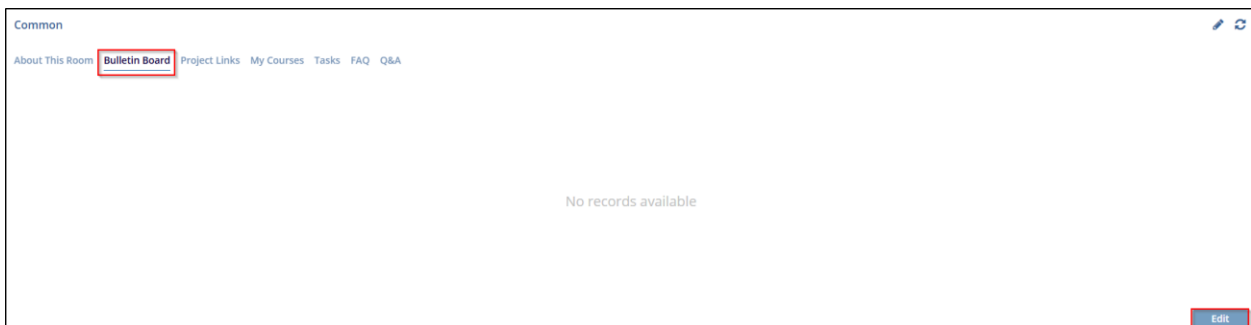
- Review the welcome message and any instructions provided. This message might contain important details about study access, document requirements, and support contacts.
- If required, click on the **Click here to get it** link to download Adobe Acrobat Reader, as it is necessary for viewing some documents in the room.
- If you are an Administrator or Manager, click the **Edit** button in the top right corner to make changes to the welcome message.
- Update the text with any new information or instructions, as needed.
- After making edits, click **Save** to apply the changes. The updated message will be immediately visible to all users in the room.



## Bulletin Board

The **Bulletin Board** section is set up by administrators to provide important messages and updates to the team. It can include information related to the room, study-related announcements, or updates about any issues or actions needed. This section serves as a central communication hub for keeping all team members informed. Both **Administrators** and **Managers** have permission to edit the content in this area, ensuring that relevant information can be updated as needed.

1. Check the **Bulletin Board** tab for any messages or updates provided by administrators. If there are no messages, it may show “No records available.”
2. If you are an Administrator or Manager and need to add or update information, click the **Edit** button located at the bottom right of the screen.
3. In edit mode, enter the message or update you wish to communicate to the team. This can include announcements, study updates, or any relevant instructions.
4. After entering the message, click **Save** to apply the changes. The updated message will then be visible to all team members on the Bulletin Board.



## Project Links

The **Project Links** dashlet displays links to various websites and resources used in the study, allowing team members quick access to important external content. Users with **Editor** level permissions and above can create new links by clicking the **Create** button. Each link can be set as **Private** (visible only to the user) or **Shared** (visible to all users). This setup allows users to organize and manage external resources effectively.

1. Click the **Create** button to add a new link to the dashlet.
2. During the link creation process, you can set the visibility of the link by selecting **Private** (for personal use) or **Shared** (for all users to see). This can be done by checking or unchecking the relevant option.

3. If you need to modify or remove an existing link, click **Edit** or **Delete** next to the respective link. Editing allows you to change details such as the title or URL, while deleting removes the link from the dashlet.
4. The list of created links will be displayed under the **Project Links** tab. Each link entry shows the title and associated details, giving users quick access to frequently used websites.



## Tasks

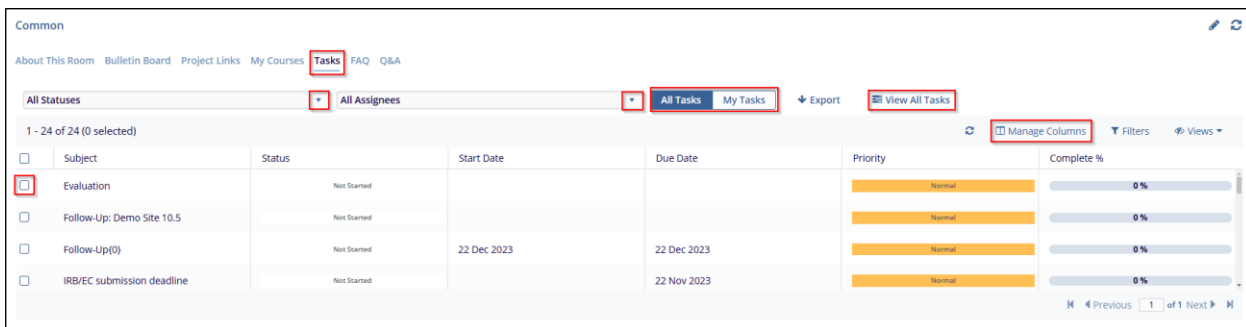
The Tasks dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the Status and the Assignee from their respective dropdown menus to get the task details.

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 Statuses dropdown and Assignees from the All Assignees dropdown.

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

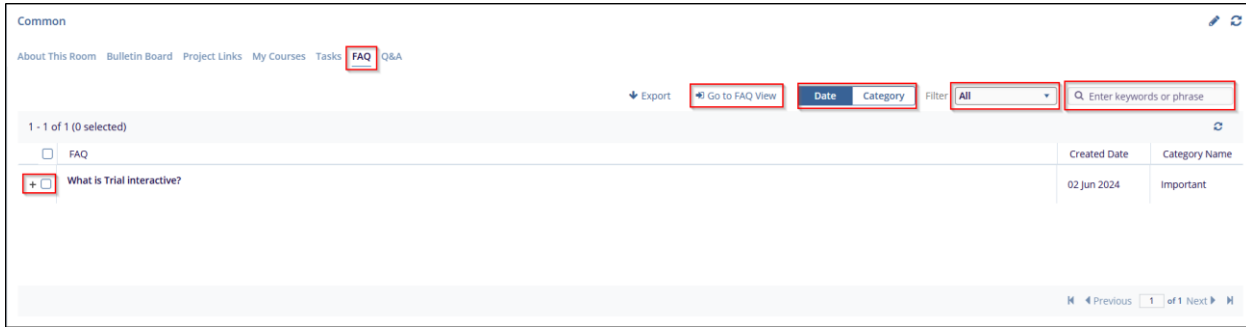
You can also export selected tasks or all tasks in the current grid by clicking the Tasks Export button located at the top center of the dashlet. After the export job is over, you can retrieve the job result from the Notifications by clicking Get Job Result, which then downloads the export job as a .xlsx file.

Clicking the View All Tasks button, the user is redirected to the Tasks page of the eTMF module.



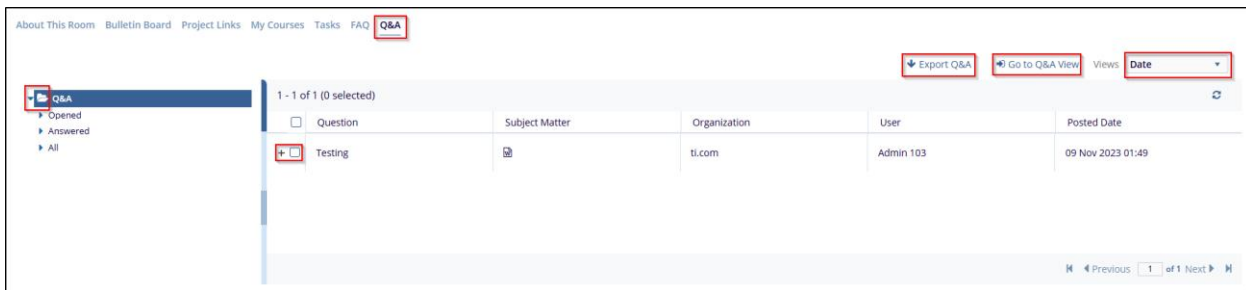
## The FAQ Dashlet

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 questions posted here. Users who have been designated as Subject Matter experts will also see questions related to their area of expertise.



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.

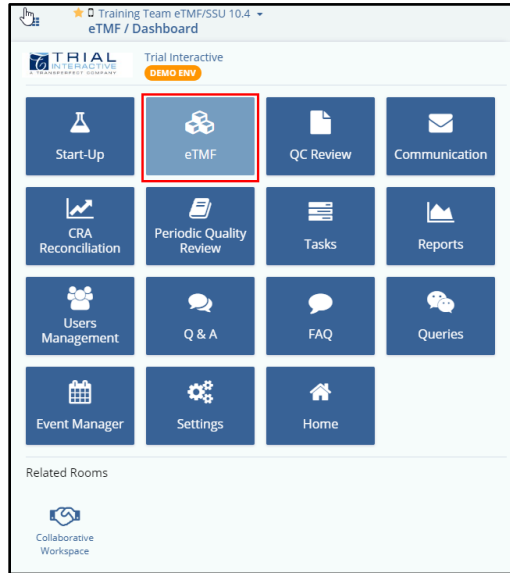


Figure 1: ETMF Module

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:



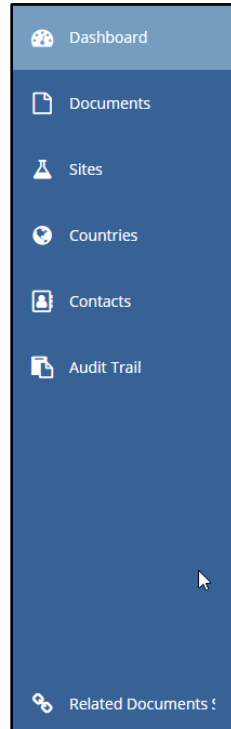


Figure 3: Expanded Menu Bar

### 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:

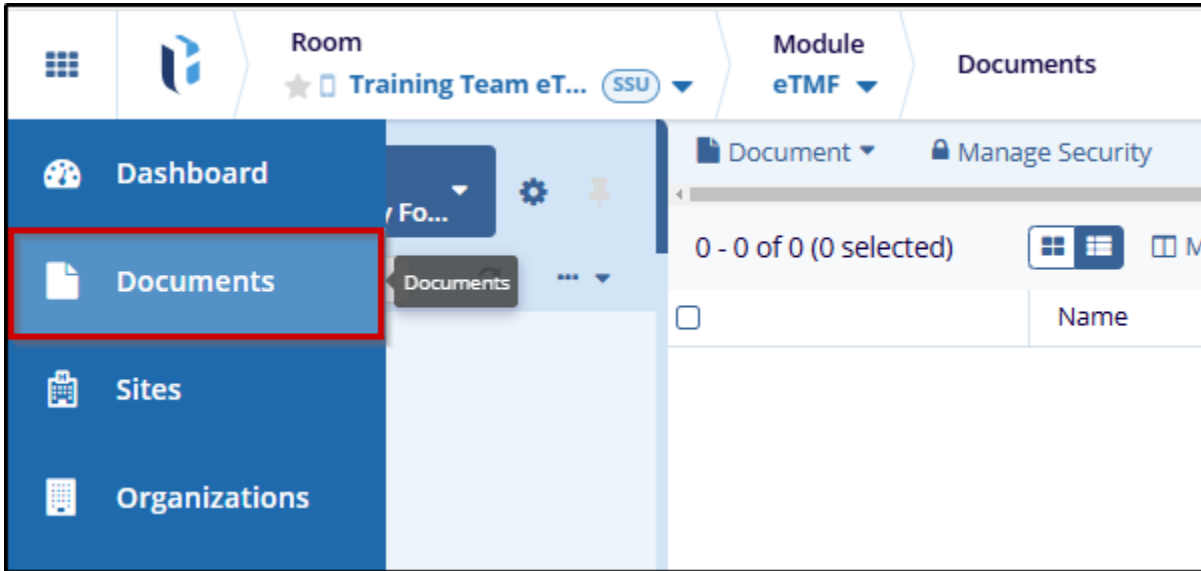


Figure 4: Document Module

## 58. 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.

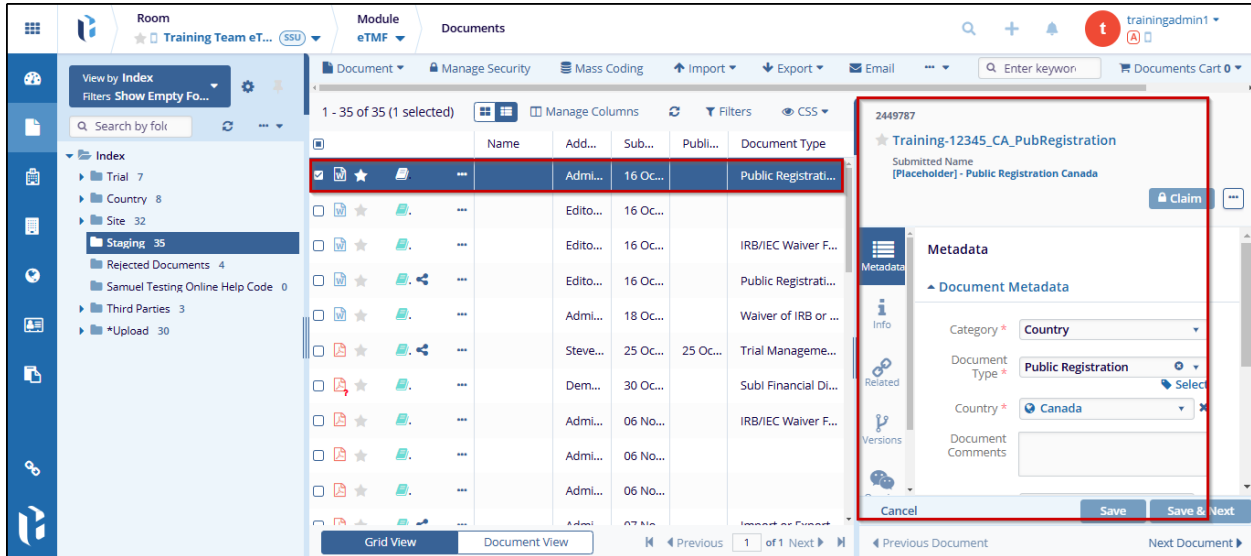
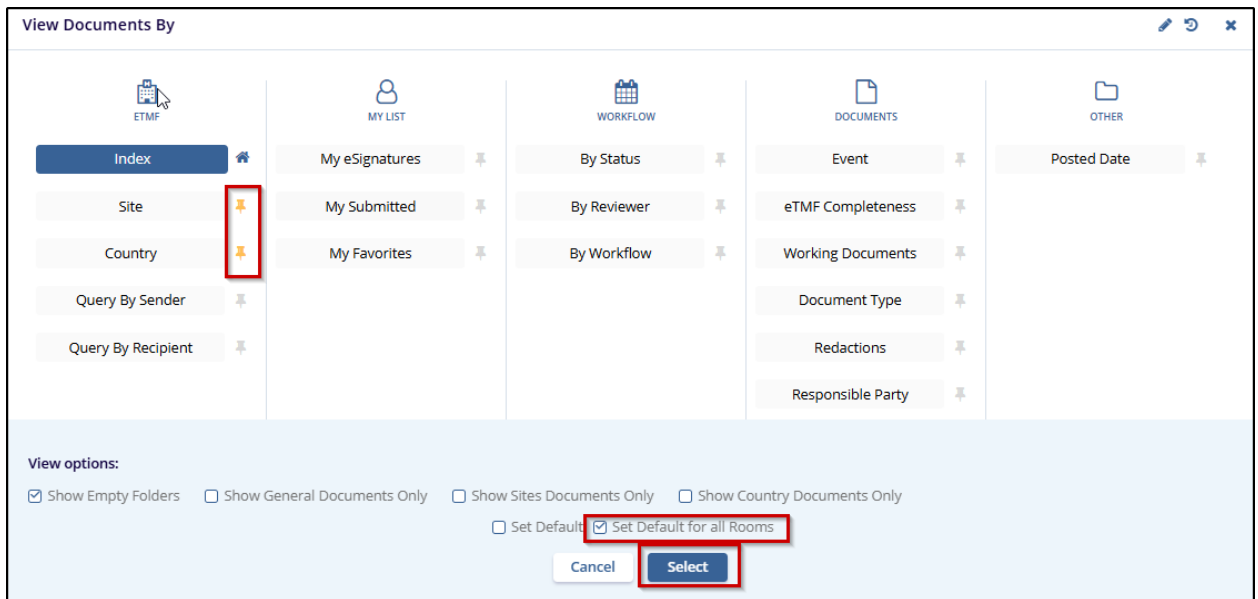
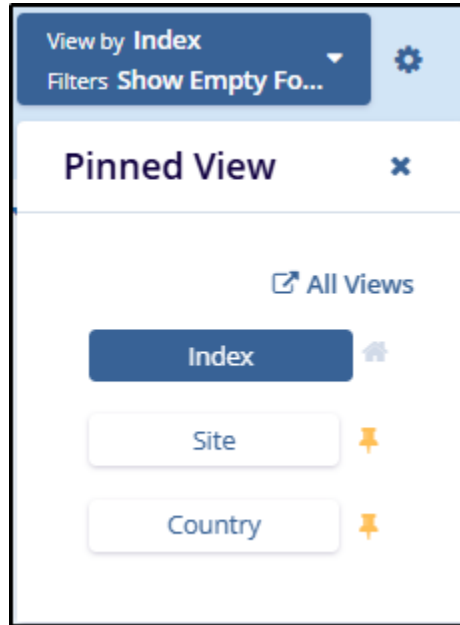


Figure 5: Document Module View

## 59. Pinned View

1. 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 Product 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.

### 60. 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:

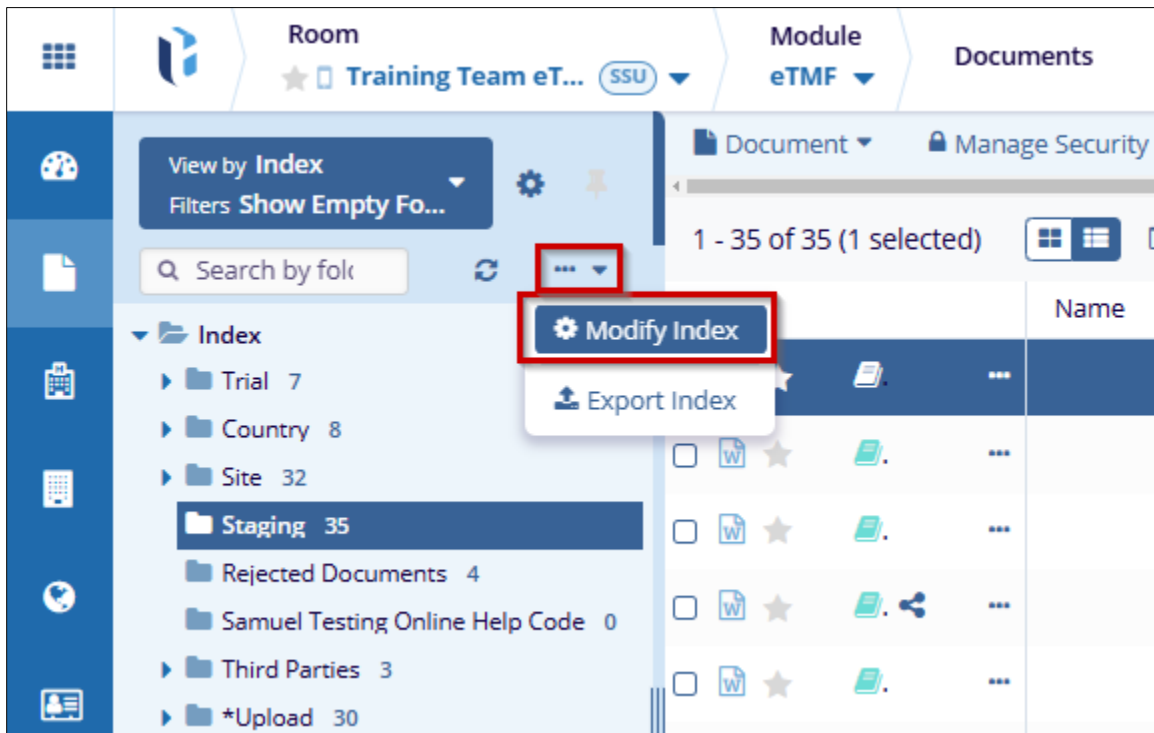


Figure 6: Modify Index

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.

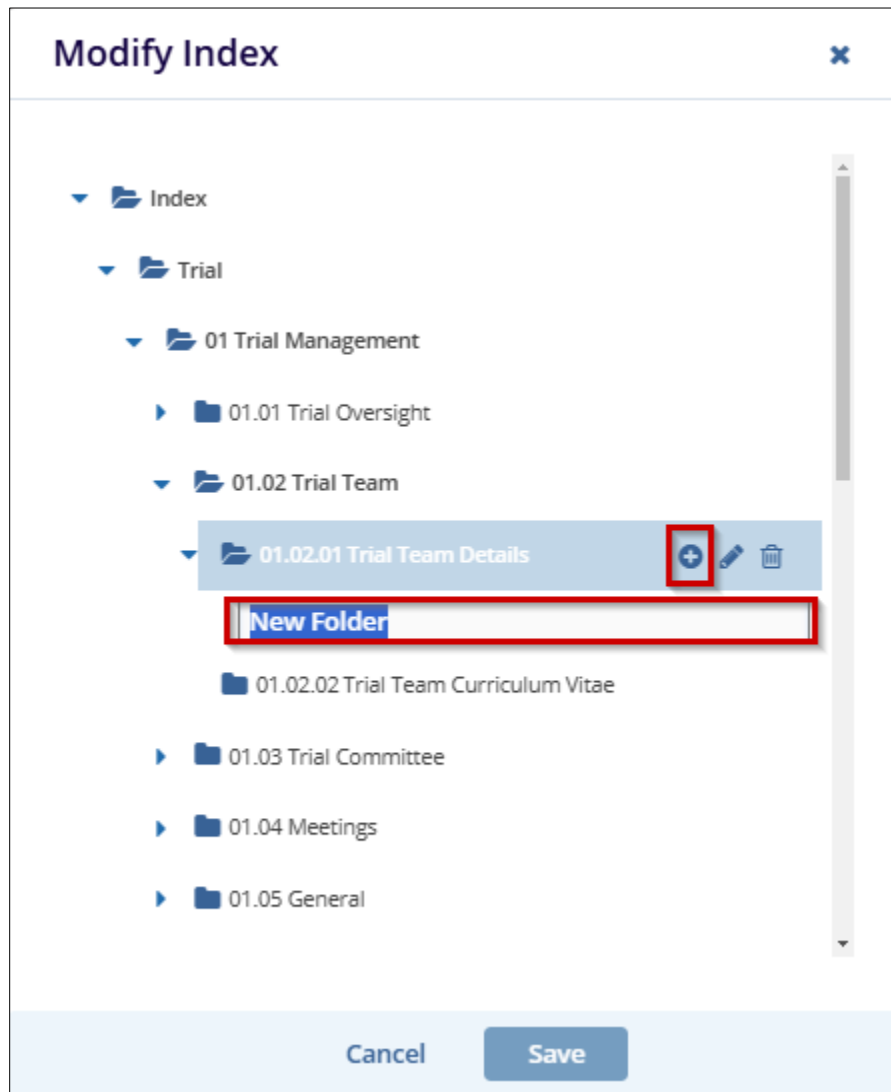


Figure 7: Modify Index Page

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**.

## 61. 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:

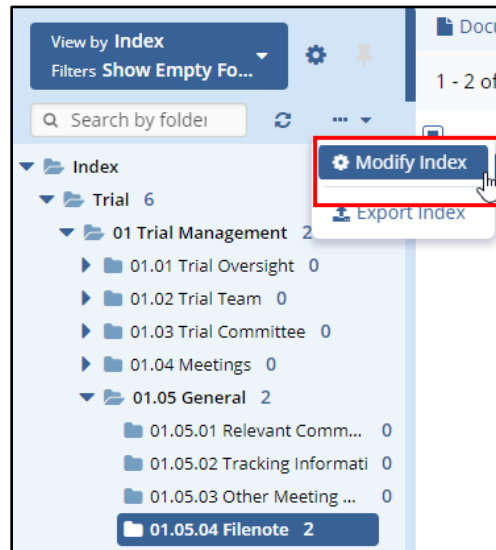


Figure 8: Modify Index

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 Product 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.



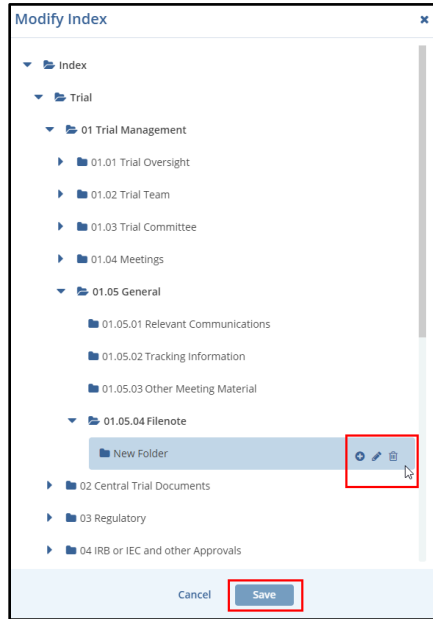


Figure 9: Edit and Delete Folder

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

## 62. 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.

## 63. 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.
  - o This will open the **Export** Index window.
2. Choose from the available options and press '**Export**' when you are ready.

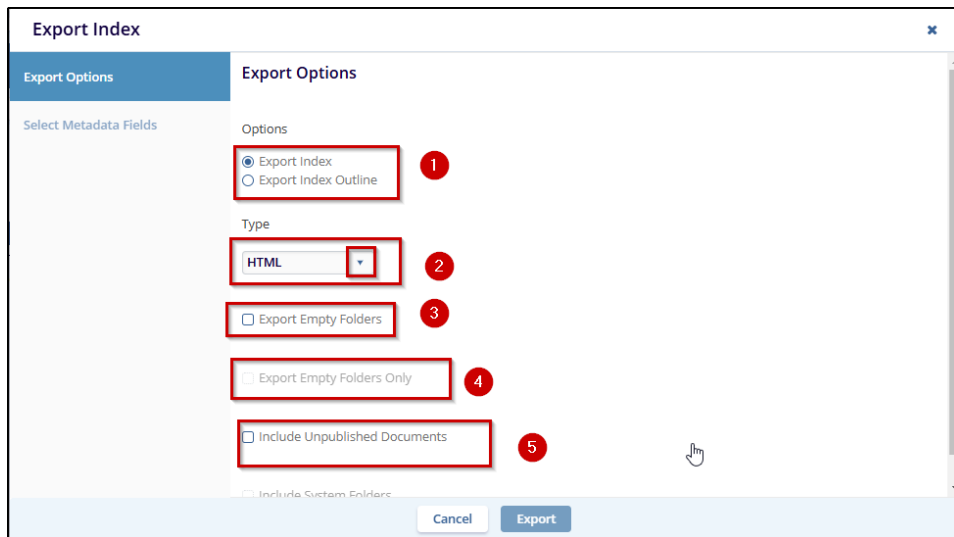
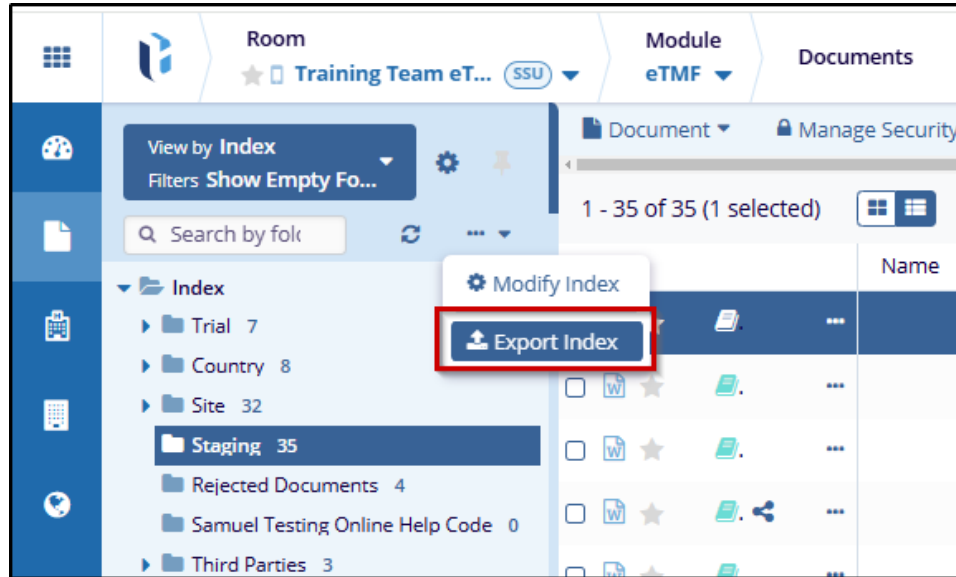


Figure 10: Export Index Structure

### The Documents Grid

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

1 - 35 of 35 (1 selected)					
	Name	Added By	Submitted On	Published Date	Document Type
<input checked="" type="checkbox"/>		Admin 103	16 Oct 2023 08:34		Public Registration
<input type="checkbox"/>		Editor 104	16 Oct 2023 08:45		
<input type="checkbox"/>		Editor 104	16 Oct 2023 08:46		IRB/IEC Waiver Form
<input type="checkbox"/>		Editor 104	16 Oct 2023 08:55		Public Registration
<input type="checkbox"/>		Admin 103	18 Oct 2023 07:50		Waiver of IRB or IEC Requirements
<input type="checkbox"/>		Steve Clark	25 Oct 2023 22:39	25 Oct 2023	Trial Management: Filenote
<input type="checkbox"/>		Demo Admin	30 Oct 2023 04:14		Subl Financial Disclosure Form
<input type="checkbox"/>		Admin 102	06 Nov 2023 14:10		IRB/IEC Waiver Form

Figure 11: Document Grid

#### 64. 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

1 - 35 of 35 (1 selected)					
	Name	Added By	Submitted On	Published Date	Document Type
<input checked="" type="checkbox"/>		Admin 103	16 Oct 2023 08:34		Public Registration
<input type="checkbox"/>		Editor 104	16 Oct 2023 08:45		
<input type="checkbox"/>		Editor 104	16 Oct 2023 08:46		IRB/IEC Waiver Form
<input type="checkbox"/>		Editor 104	16 Oct 2023 08:55		Public Registration

Figure 12: Grid View

##### Card View

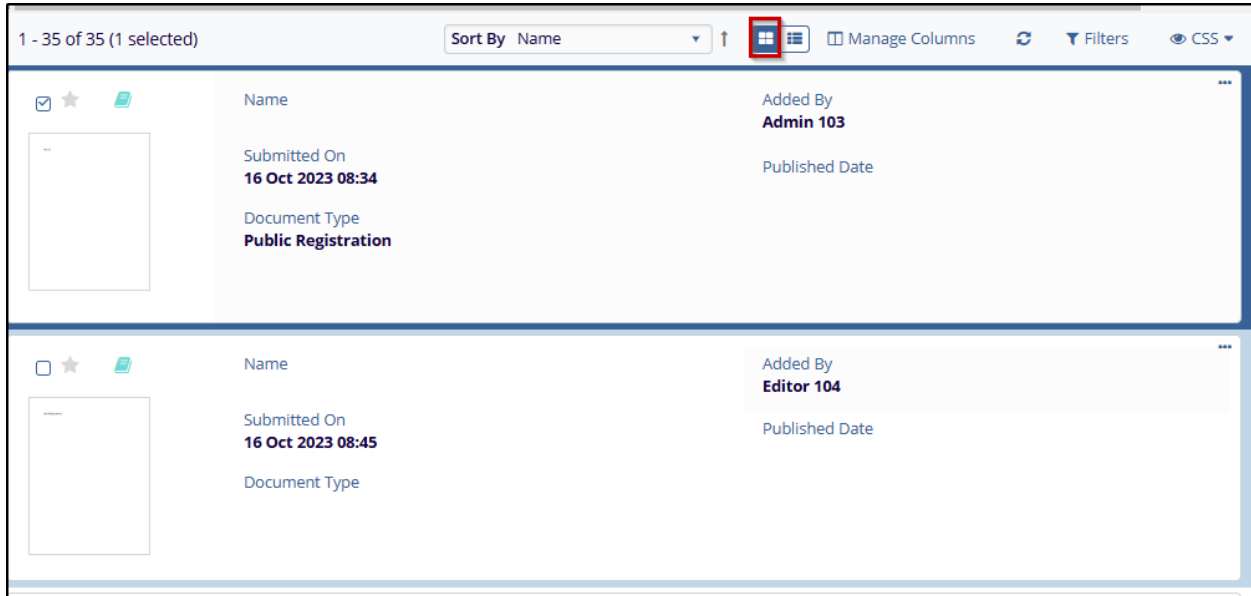


Figure 13: Card View

### 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. 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.

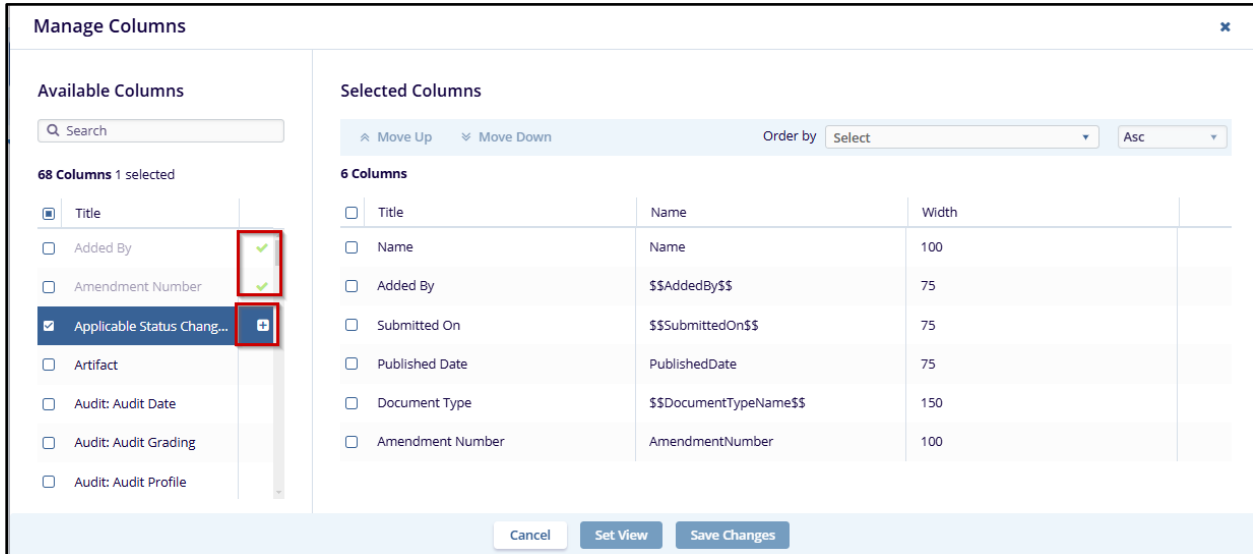


Figure 15: Manage Columns Page

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

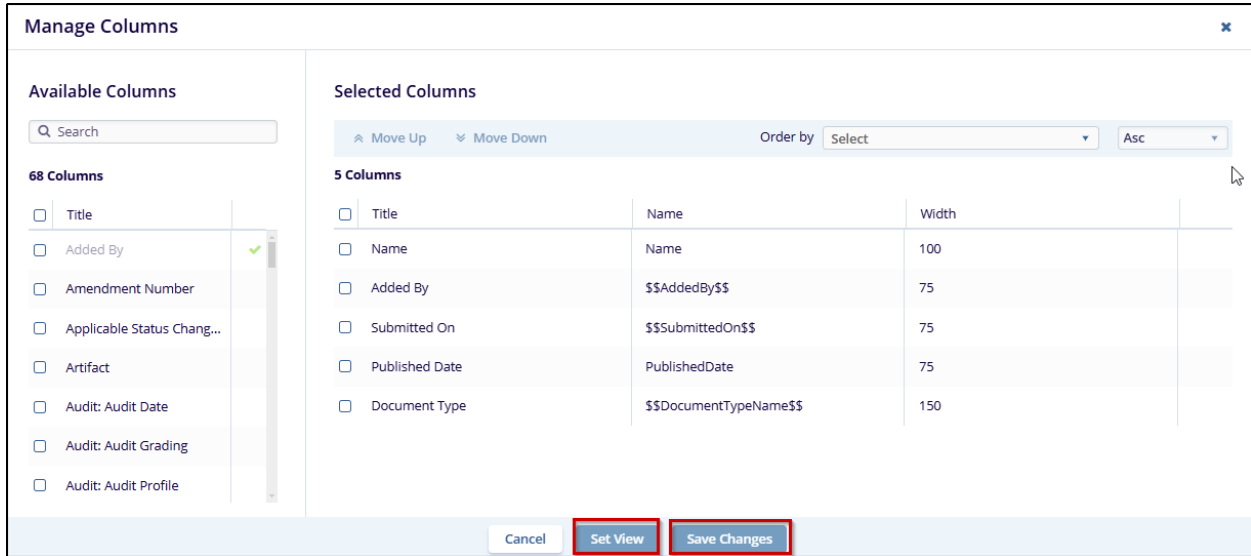


Figure 16: View Types

### 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)

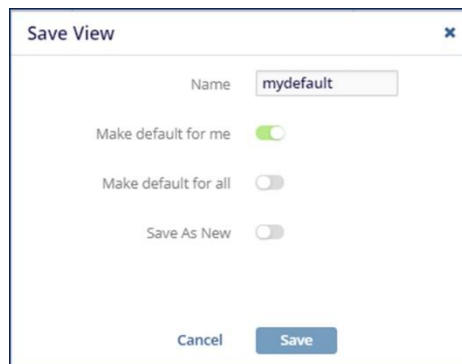


Figure 17: Save View

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.

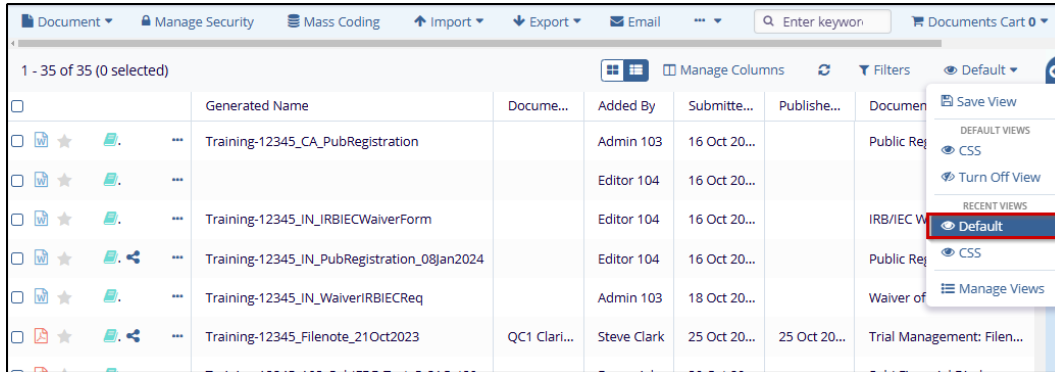
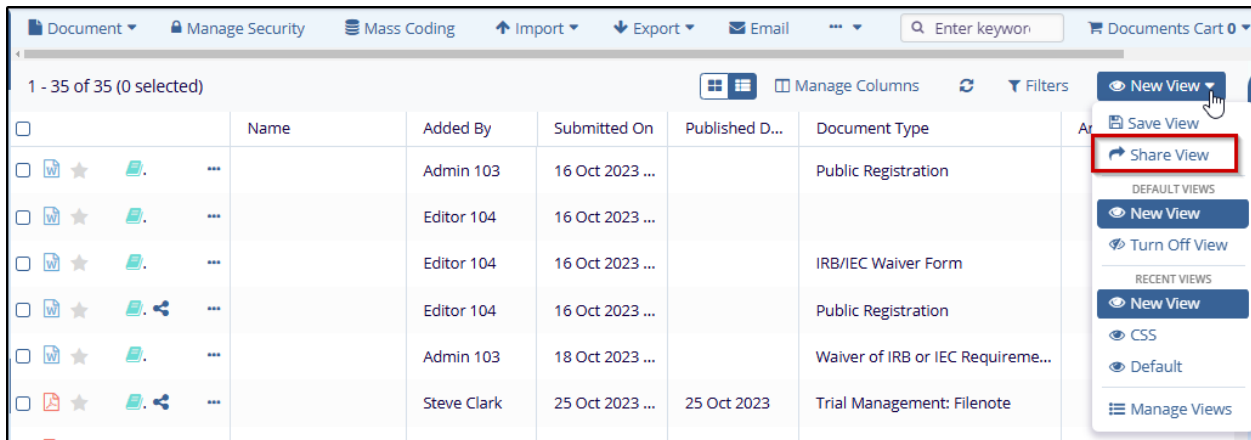


Figure 18: Default

### 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.



2. Select 'Share View'. This will open the 'Share' window. (See the screenshot below)

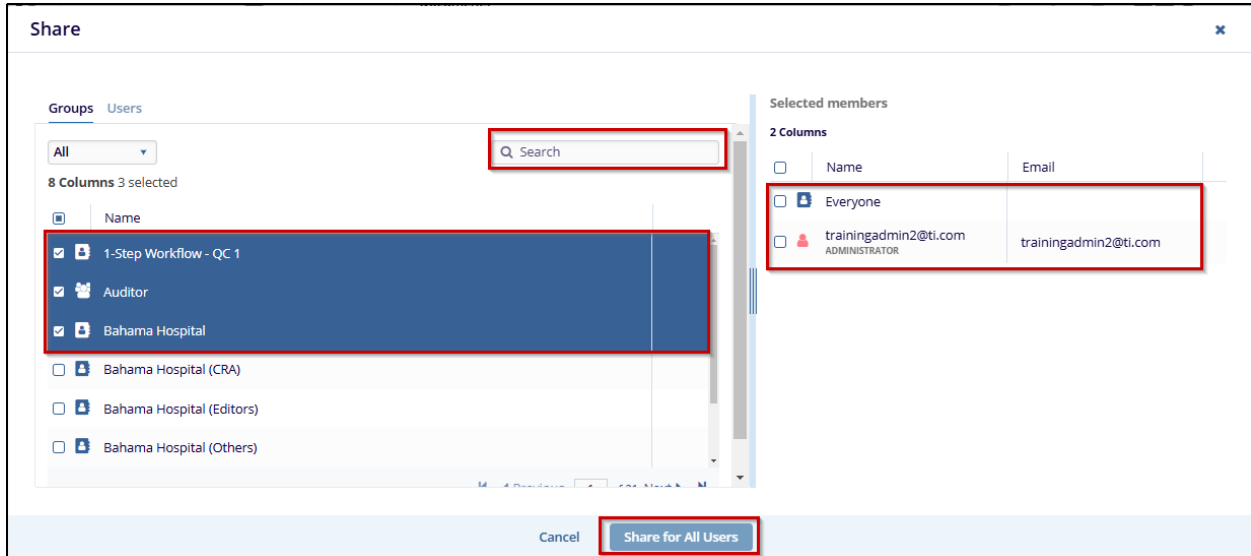


Figure 19: Sharing View

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:

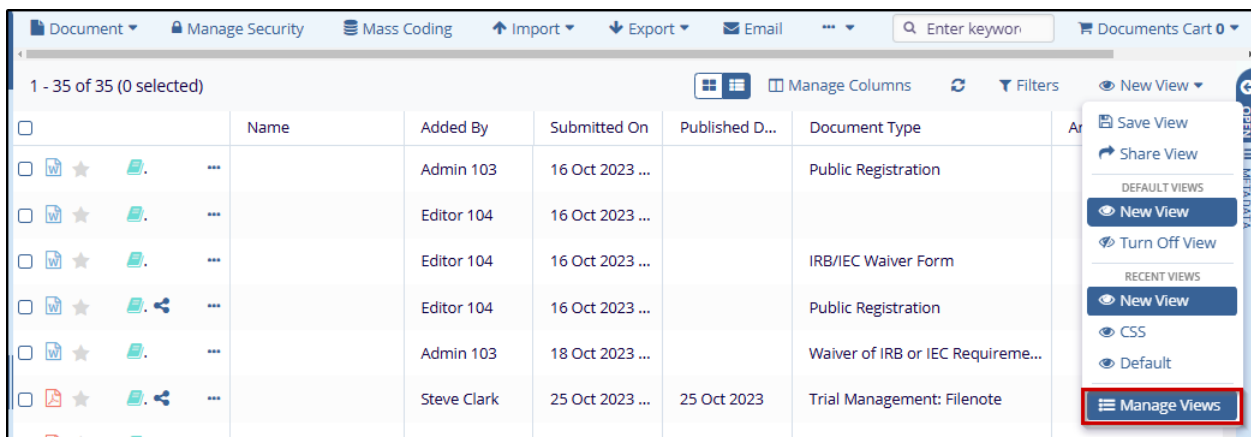


Figure 20: Manage View

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:

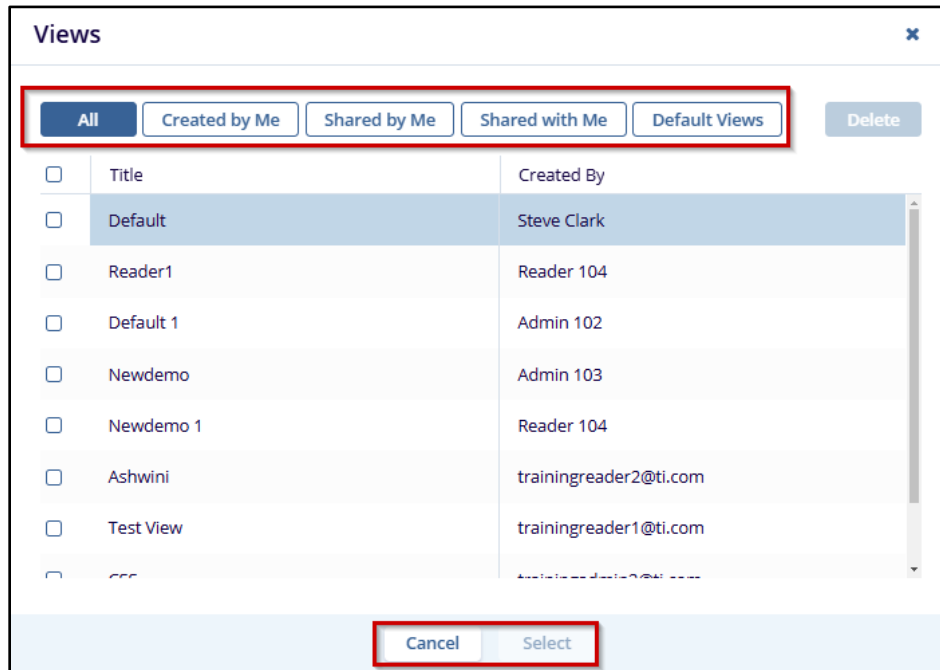


Figure 21: All Views

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

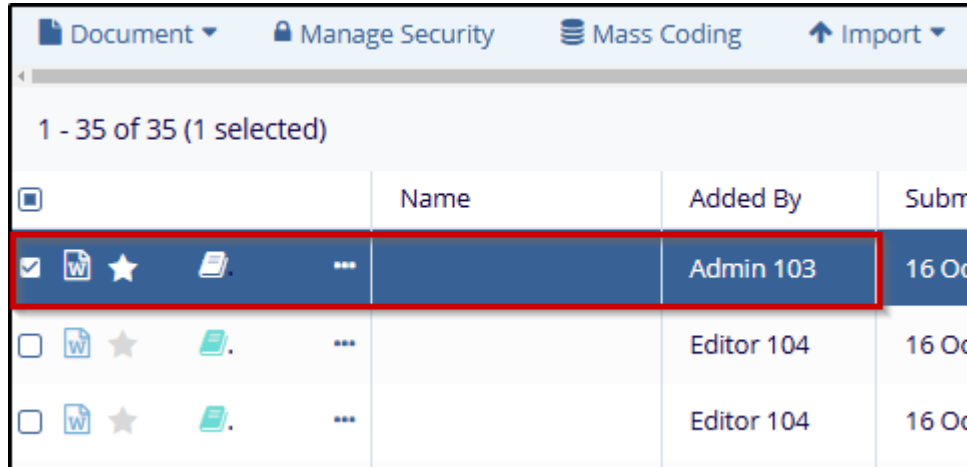
## 65. Previewing and Viewing a Document and its Metadata

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

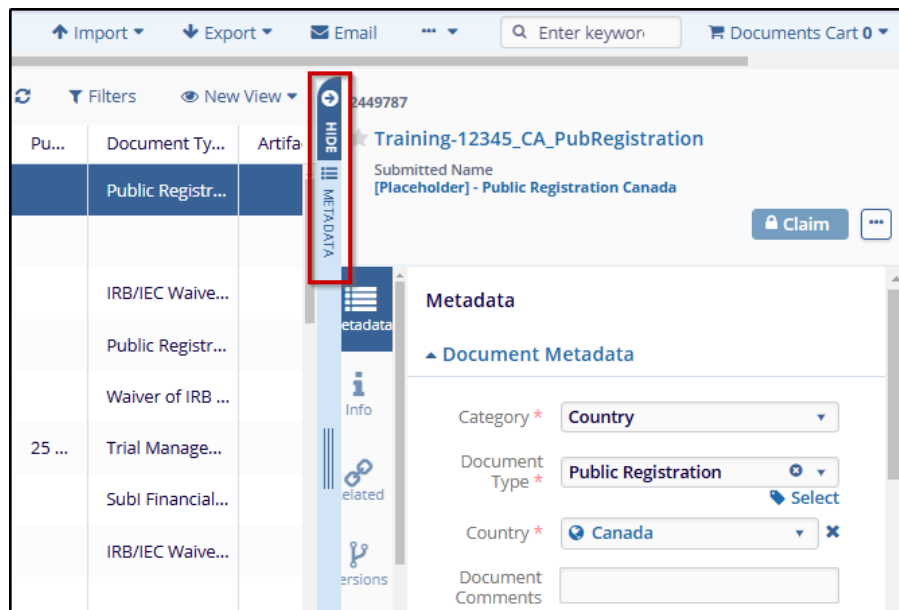


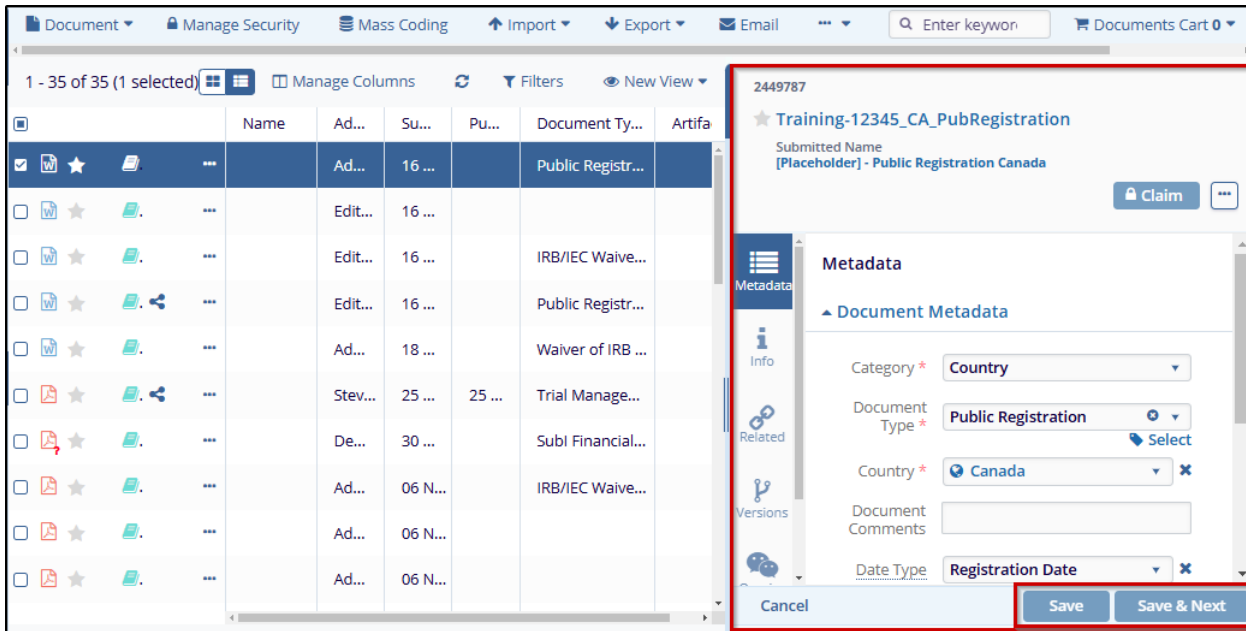
Figure 23: Metadata Fields

### 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.

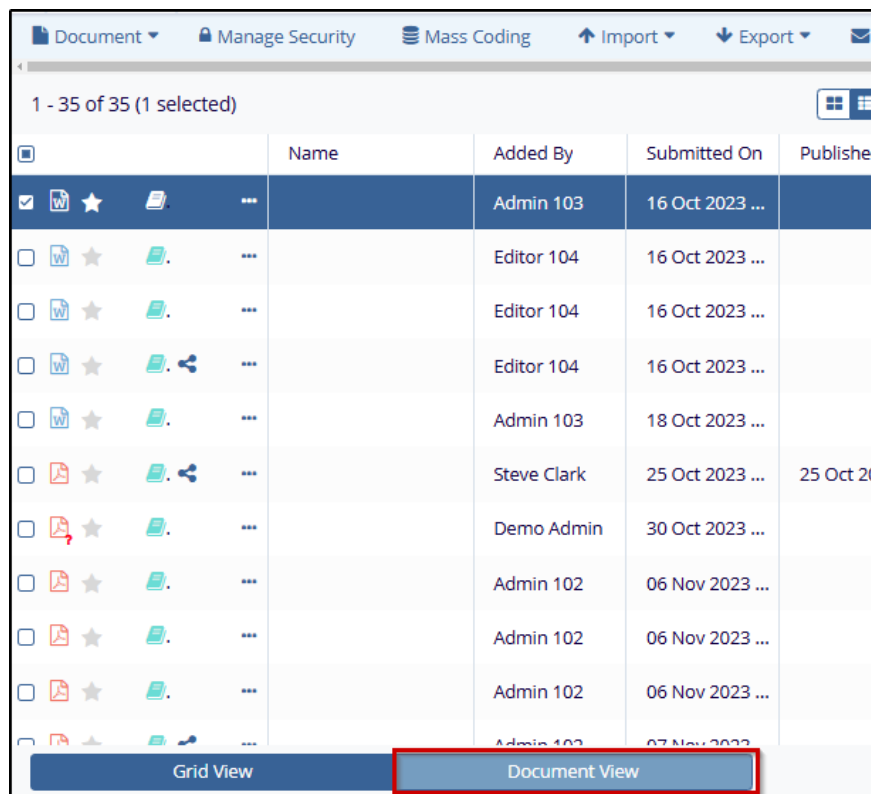
To edit document metadata, simply alter the value present in the field and press the Save or Save and Next buttons at the bottom of the metadata pane.



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:



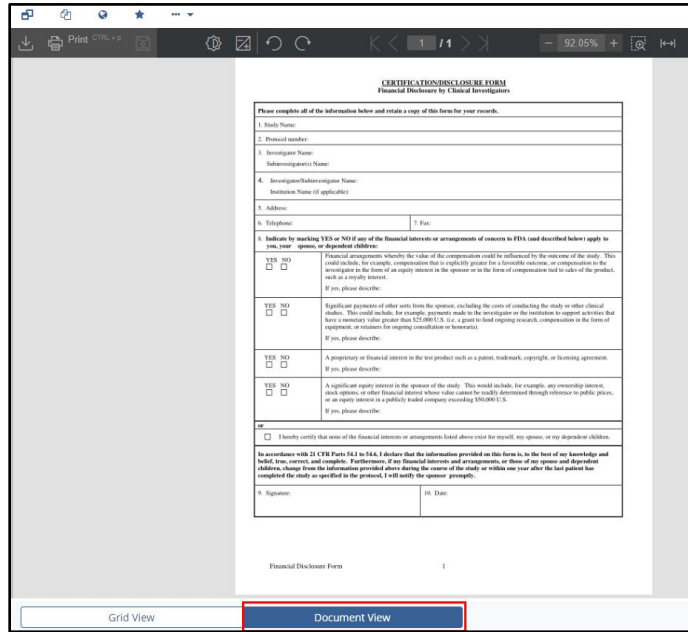


Figure 24: Detailed View

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

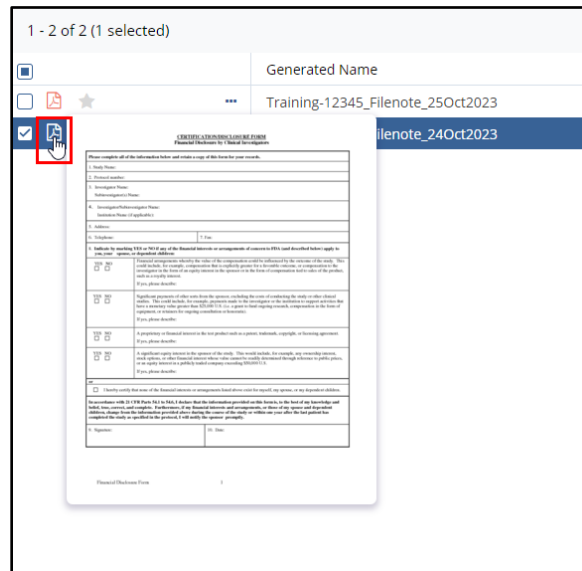


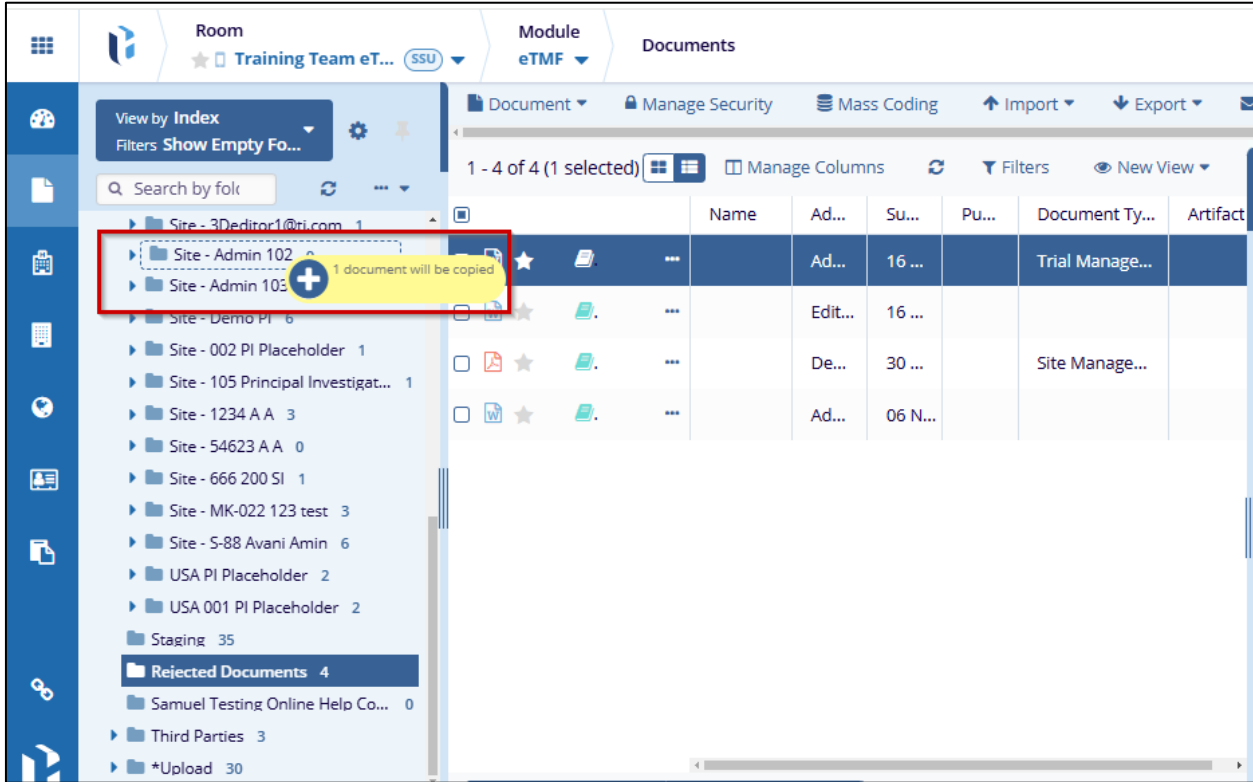
Figure 25: Detailed View Icon

### 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.

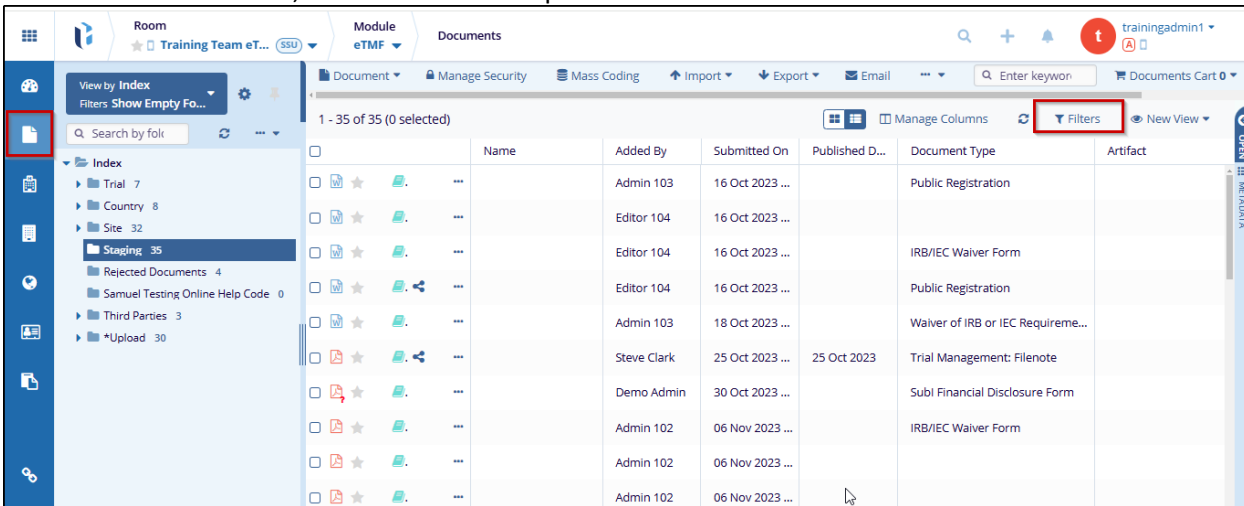


66. Grid Filters

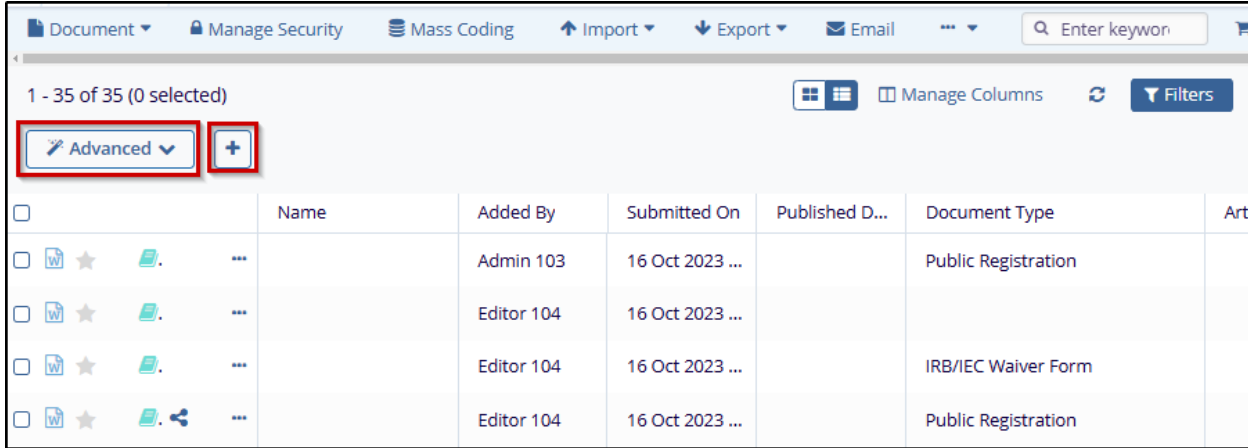
67. How to Filter Grid in ETMF module

**Step-by-step guide for filtering the grid in the eTMF module:**

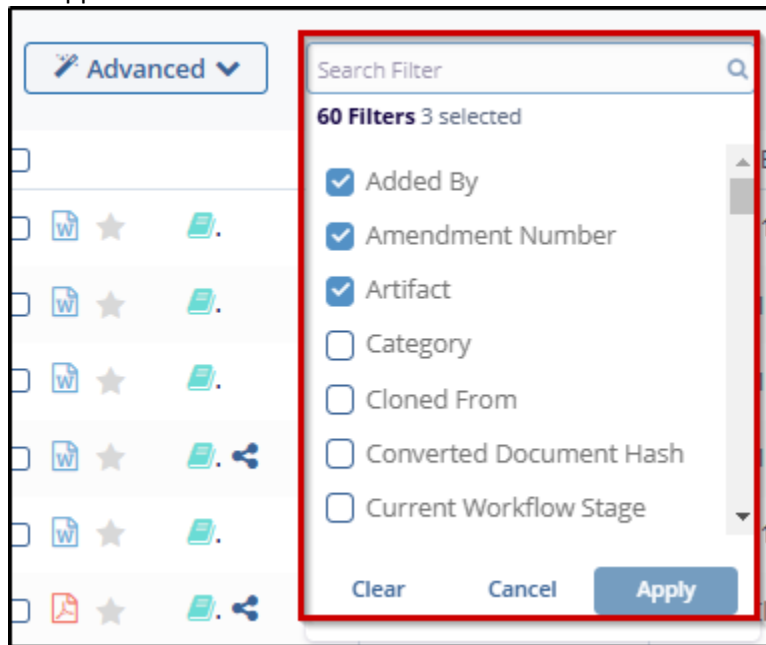
1. In the eTMF module, click on the Filters option.



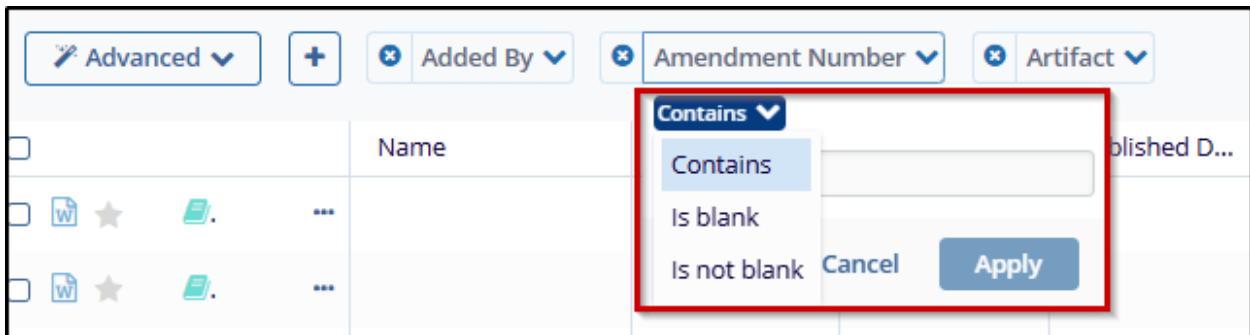
2. Two options will appear: Advanced and +. Click the + icon to add a filter.



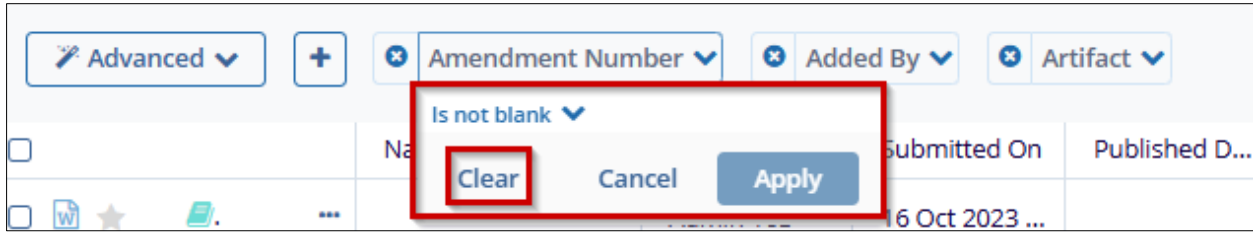
3. A dropdown menu will appear with various field names. Select the desired filter fields and click Apply.



4. The selected filters will display above the grid. Use the dropdown arrow next to each filter to apply specific conditions as needed.



5. To remove a filter, click Clear on the filter dropdown.



### 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:

**Create Filter** ✕

Title

Include records that match **all** any none of the following filters + Add Filter + Add Group

Cancel **Create**

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:



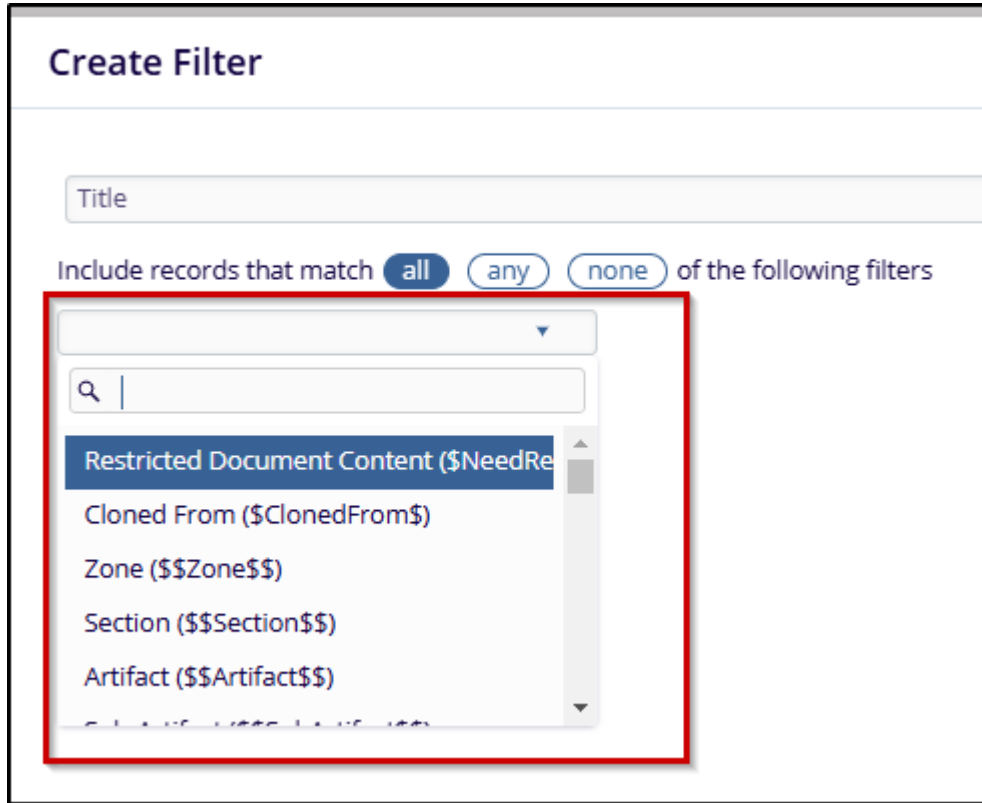


Figure 27: Operator options

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.

Displaying documents 1 - 9 of 9 (0 selected)

Title = TEST

	Document...	Title	Document...	Disable au...	Document...	Reason fo...	Comments	Document...	Category	Category	Investigati...
<input type="checkbox"/>	2072804	TEST	audit 1_10	Yes	Amruta M...			25 Apr 2018	1	General ed	
<input type="checkbox"/>	2081892	TEST	audit 1_10	Yes	Amruta M...			08 May 20...	1	General ed	
<input type="checkbox"/>	2085479	test		Yes	Polly Chak...			17 May 20...	2	Investigati...	2069253
<input type="checkbox"/>	2085967	test		Yes	Polly Chak...			18 May 20...	100	first categ...	
<input type="checkbox"/>	2085986	test		Yes	Polly Chak...			18 May 20...	2	Investigati...	2069281
<input type="checkbox"/>	2090128	Test		Yes	Polly Chak...			01 Jun 2018	3	Country	
<input type="checkbox"/>	2090144	test		Yes	Amruta M...						
<input type="checkbox"/>	2217728	Test		Yes	Polly Chak...						
<input type="checkbox"/>	2423448	Test		Yes	Polly Chak...				2	Investigati...	2069253

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:

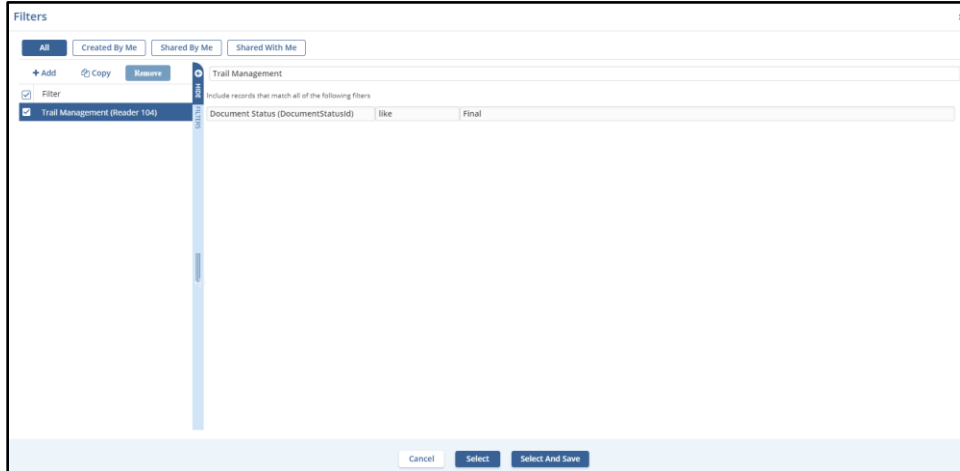


Figure 29: Manager Filters

You can perform the following activities on the filters in the Manage Filters 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:

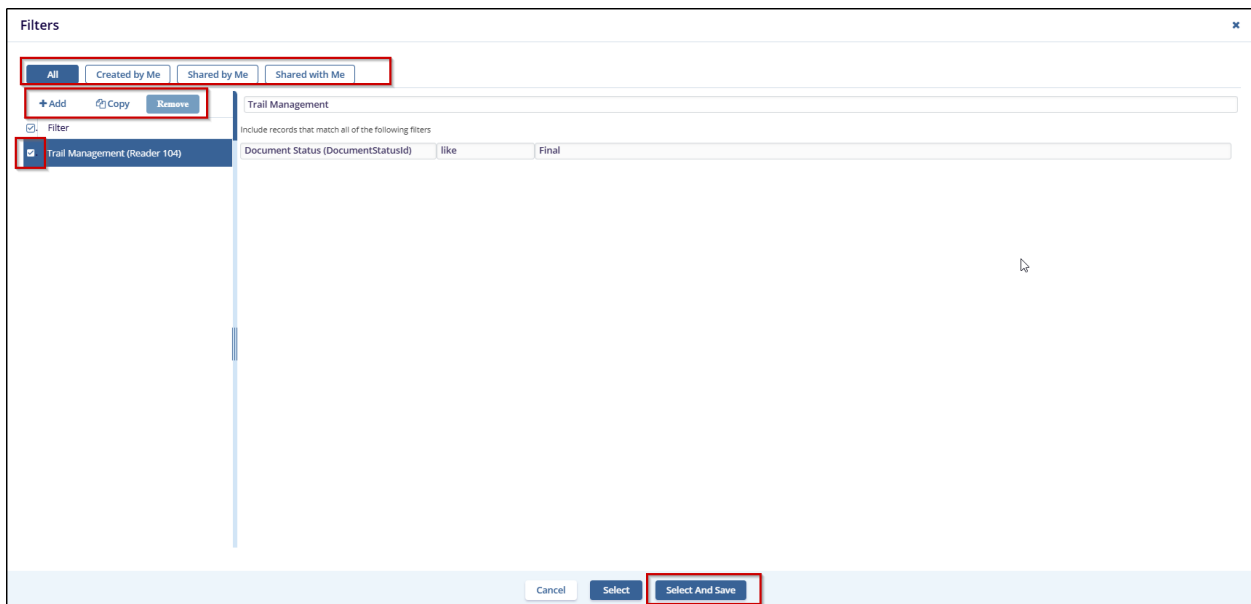


Figure 30: Sharing Filters

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.

## 68. 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)

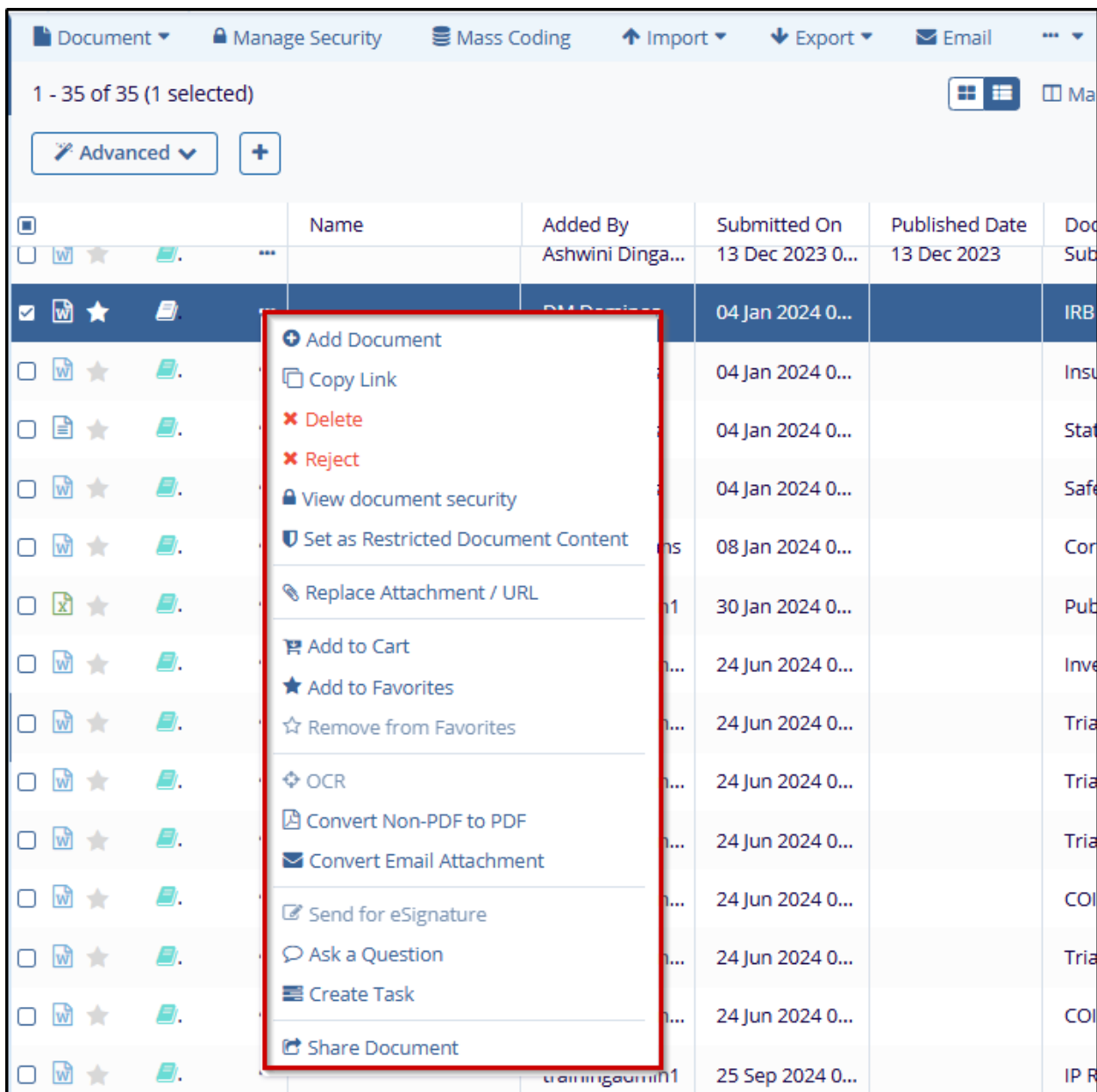


Figure 31: Document Activities Menu

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)

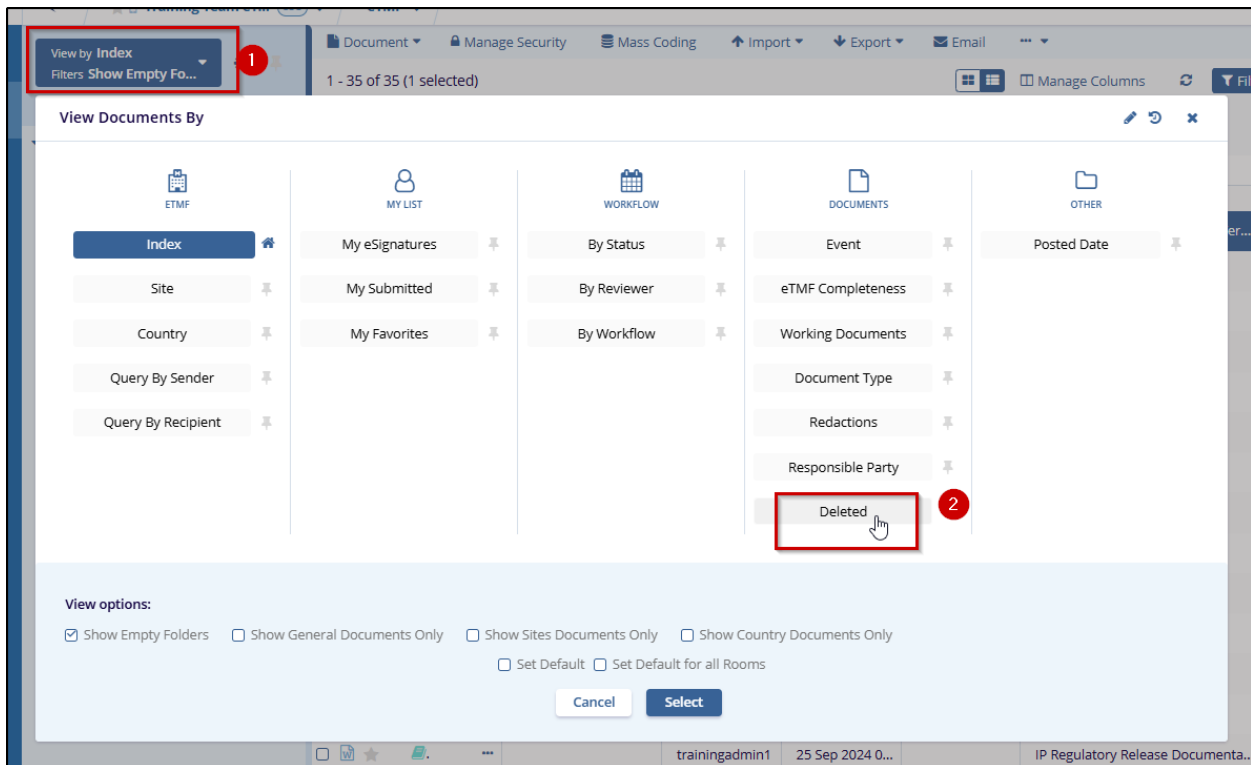


Figure 32: Deleted Document View

*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.
  - o 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)

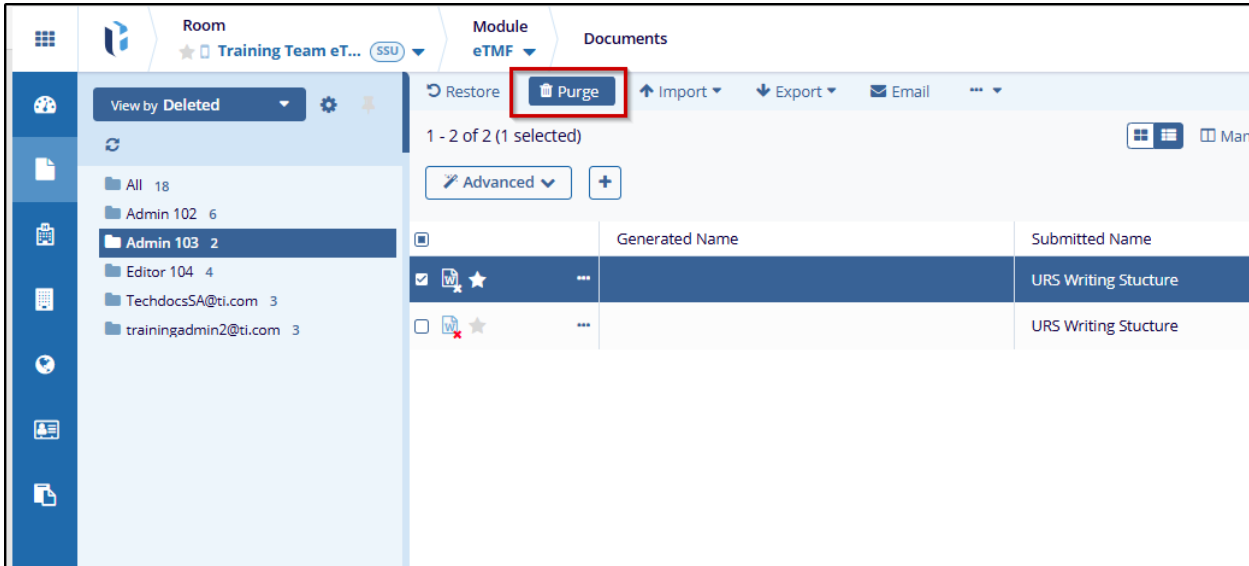


Figure 33: Purge option

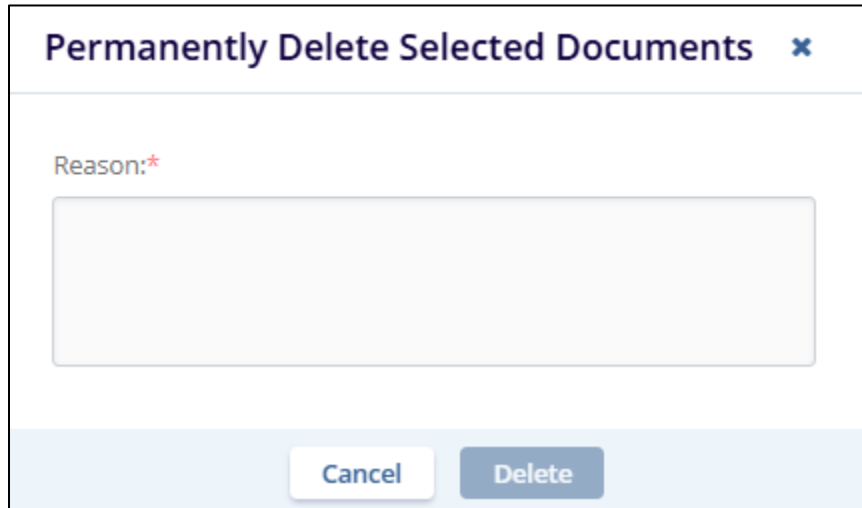


Figure 34: Permanently Delete Documents page

### 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. , n

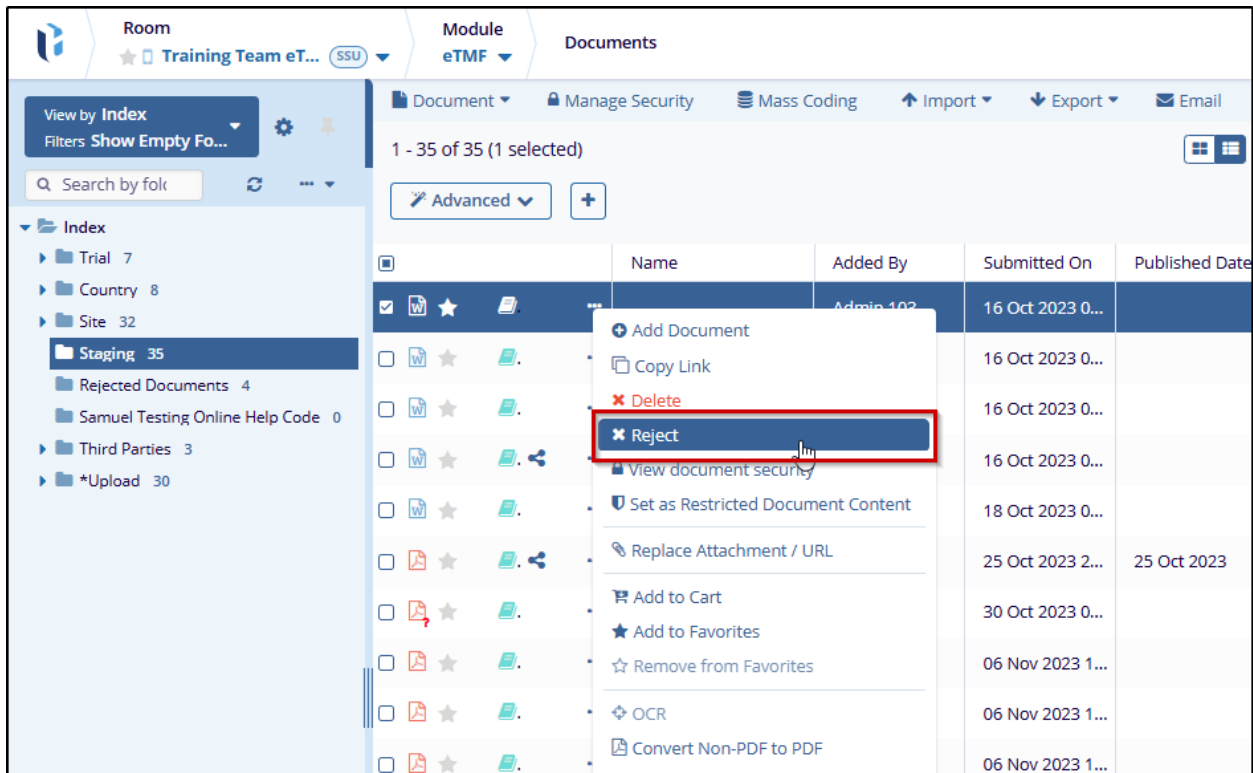


Figure 35: Reject Field

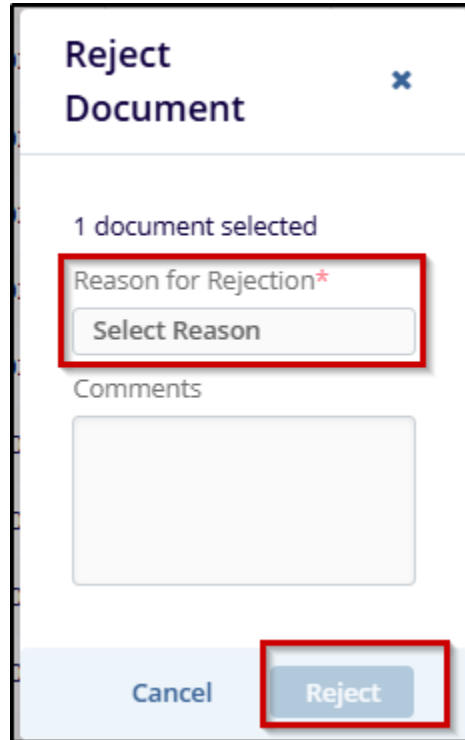


Figure 36: Rejected Document Page (Reason for Rejection)

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 favorite 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 favorite 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 favorites 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.

---

## 69. 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:



2449787

★ Training-12345\_CA\_PubRegistration  
Submitted Name  
[Placeholder] - Public Registration Canada

Claim
⋮

☰  
**Metadata**

i  
 Info

🔗  
 Related

🔗  
 Versions

💬  
 Queries

🕒  
 History

### Metadata

#### Document Metadata

Category \* Country

Document Type \* Public Registration ✖

Country \* 🌐 Canada ✖ Select

Document Comments

Date Type Registration Date ✖

Document Date \* dd MMM yyyy 📅 ✖

Document Description

Generated Name Training-12345\_CA\_PubRegistration

Source

#### Workflow History

Cancel
Save
Save & Next

◀ Previous Document
Next Document ▶

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:

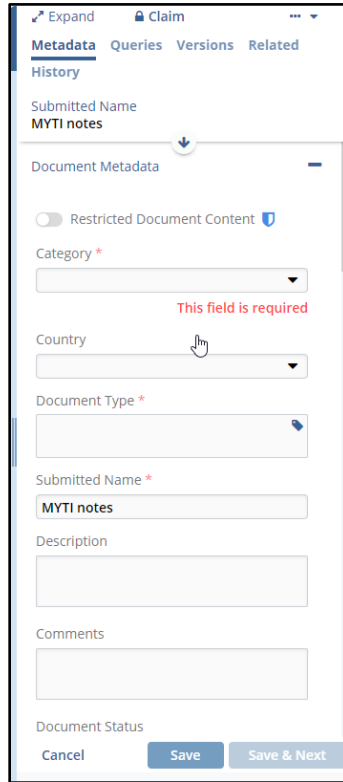


Figure 38: Metadata Panel

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.

2449787

★ **Training-12345\_CA\_PubRegistration**

Submitted Name  
[Placeholder] - Public Registration Canada

🔒 Claim
⋮

---

☰

**Metadata**

▲ Document Metadata

Category \*

Document Type \*  ⊕ ▼

Select

Country \*  ✕

Document Comments

Date Type  ✕

Document Date \*  📅 ⊕

Document Description

Generated Name

Source

▼ Workflow History

Cancel
Save
Save & Next

◀ Previous Document
Next 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:

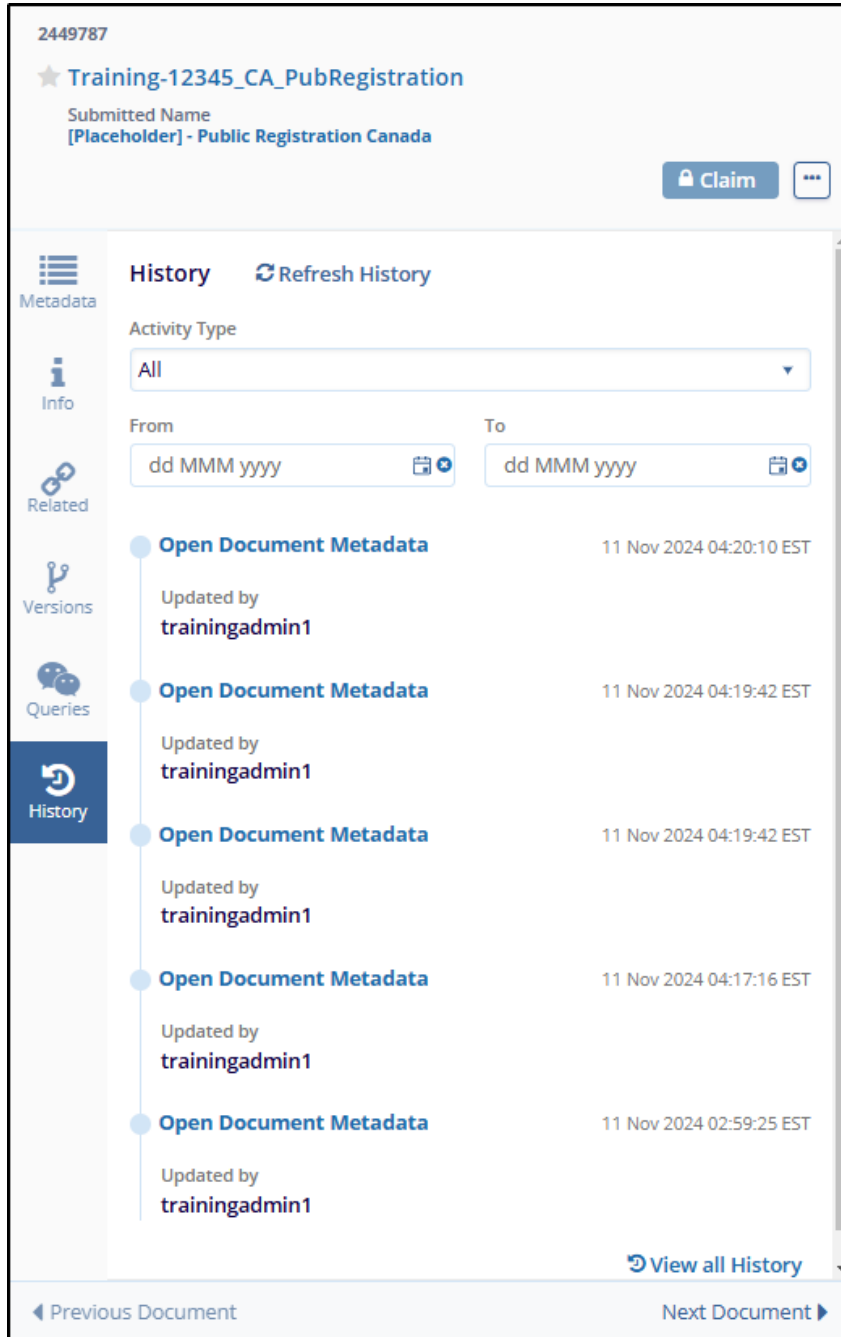


Figure 40: Workflow History

*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:

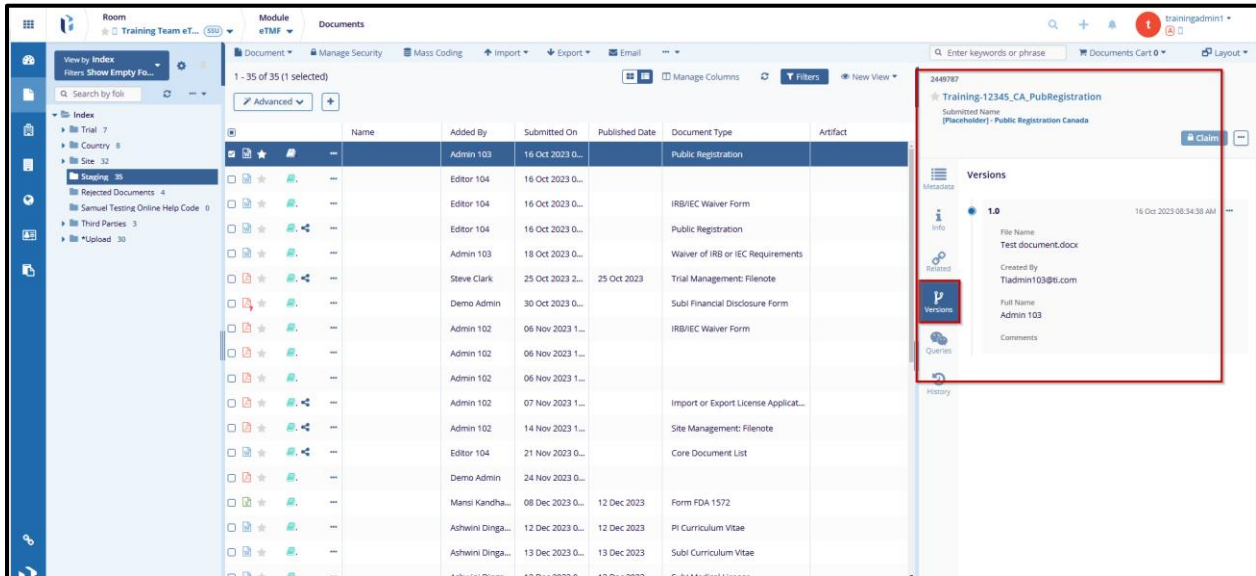


Figure 41: Version Information Page

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:

2449787

★ **Training-12345\_CA\_PubRegistration**

Submitted Name  
[Placeholder] - Public Registration Canada

[Claim](#) ⋮

**History** ↻ Refresh History

Activity Type

All

From

dd MMM yyyy

To

dd MMM yyyy

- Open Document Metadata**

Updated by  
**trainingadmin1**

11 Nov 2024 04:20:10 EST
- Open Document Metadata**

Updated by  
**trainingadmin1**

11 Nov 2024 04:19:42 EST
- Open Document Metadata**

Updated by  
**trainingadmin1**

11 Nov 2024 04:19:42 EST
- Open Document Metadata**

Updated by  
**trainingadmin1**

11 Nov 2024 04:17:16 EST
- Open Document Metadata**

Updated by  
**trainingadmin1**

11 Nov 2024 02:59:25 EST

[View all History](#)

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:



2449787

★ Training-12345\_CA\_PubRegistration  
 Submitted Name  
**[Placeholder] - Public Registration Canada**

Claim
⋮

- ☰ Metadata
- i Info
- 🔗 Related
- 📄 Versions
- 💬 Queries
- 🕒  
History

**History**
🔄 Refresh History

Activity Type

All
▼

From To

dd MMM yyyy
📅 ✖

dd MMM yyyy
📅 ✖

- Open Document Metadata
11 Nov 2024 04:20:10 EST

Updated by  
**trainingadmin1**
- Open Document Metadata
11 Nov 2024 04:19:42 EST

Updated by  
**trainingadmin1**
- Open Document Metadata
11 Nov 2024 04:19:42 EST

Updated by  
**trainingadmin1**
- Open Document Metadata
11 Nov 2024 04:17:16 EST

Updated by  
**trainingadmin1**
- Open Document Metadata
11 Nov 2024 02:59:25 EST

Updated by  
**trainingadmin1**

🕒 View all History
▼

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

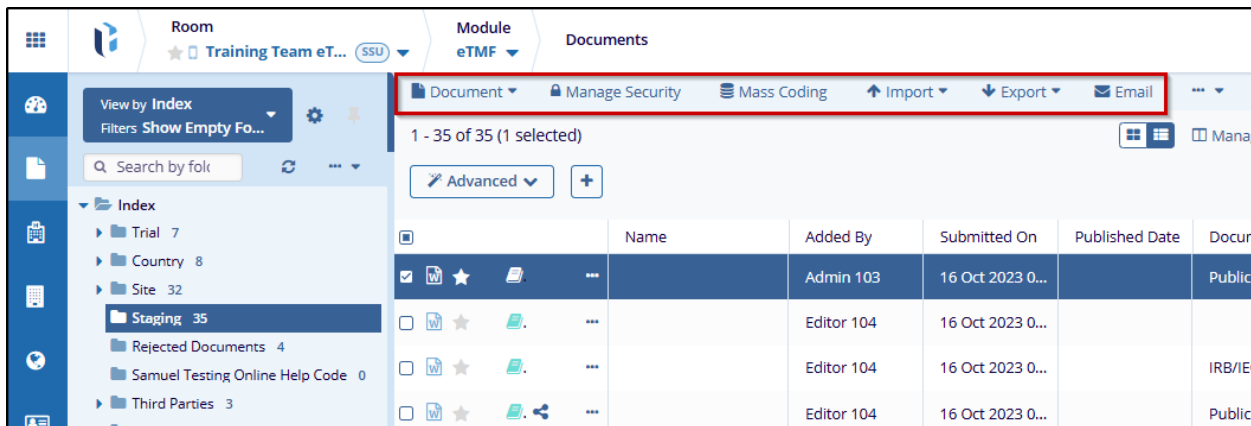


Figure 44: Documents Module – Top Menu Ribbon

## 70. 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:

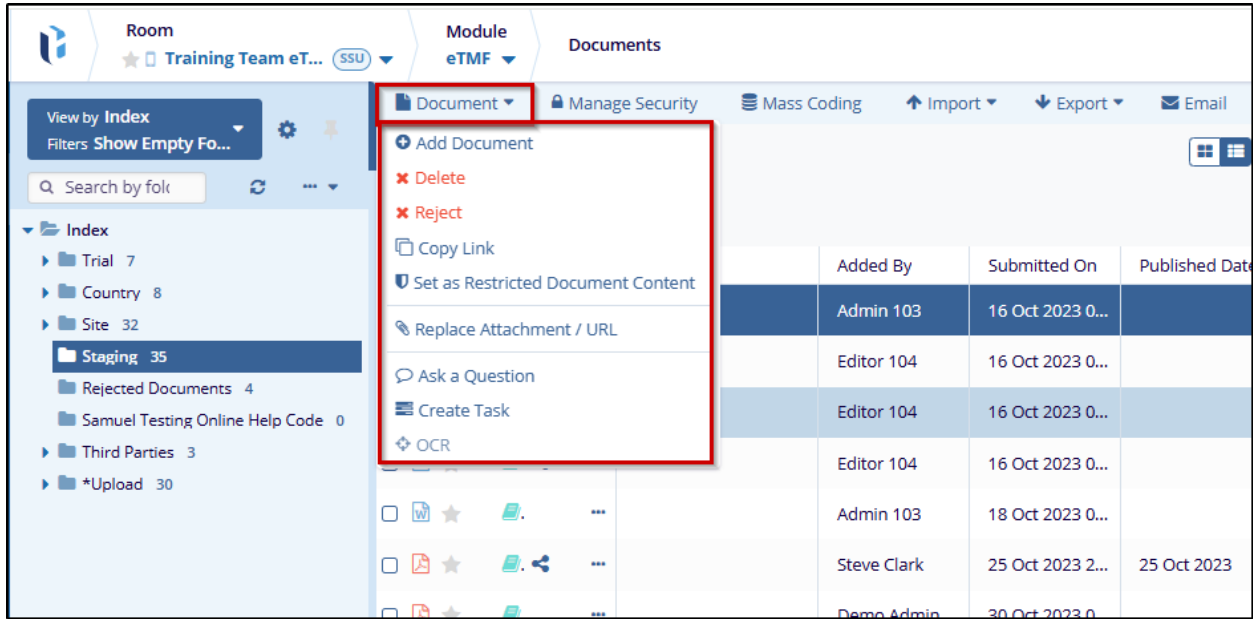
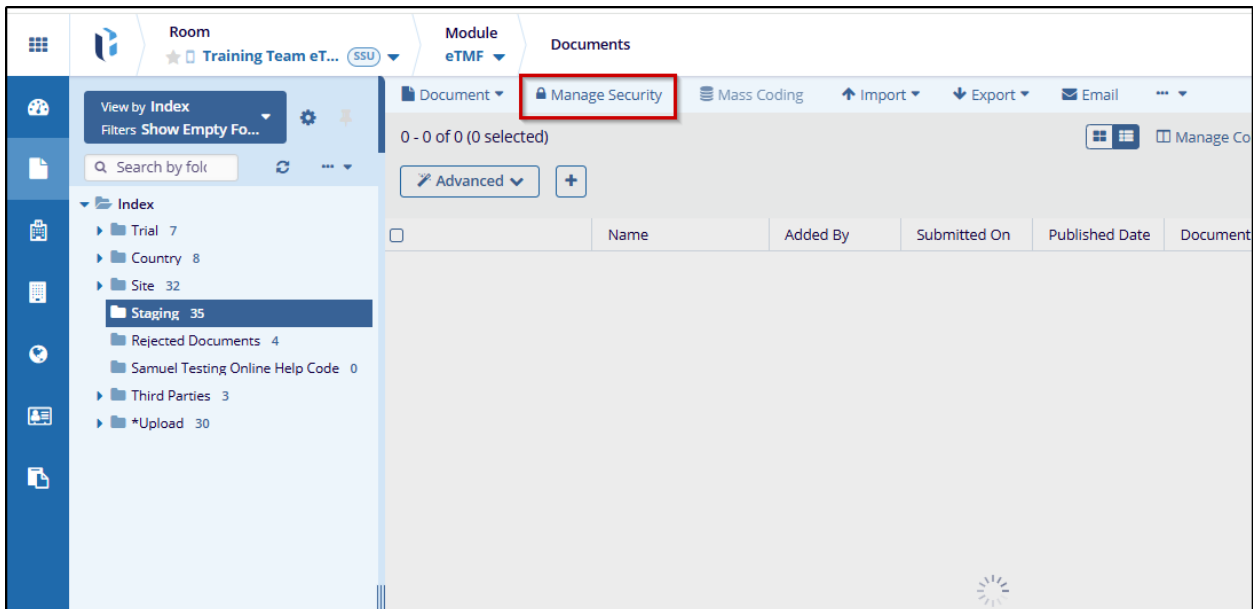


Figure 45: Document Activities.

## 71. 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.



### Manage Security

Select Folders

Select Groups and Users

Target \*

Folders All folders

Select the security update type \*

Subfolder Security

Apply same security as the parent folder

Select Folders Show Empty Folders

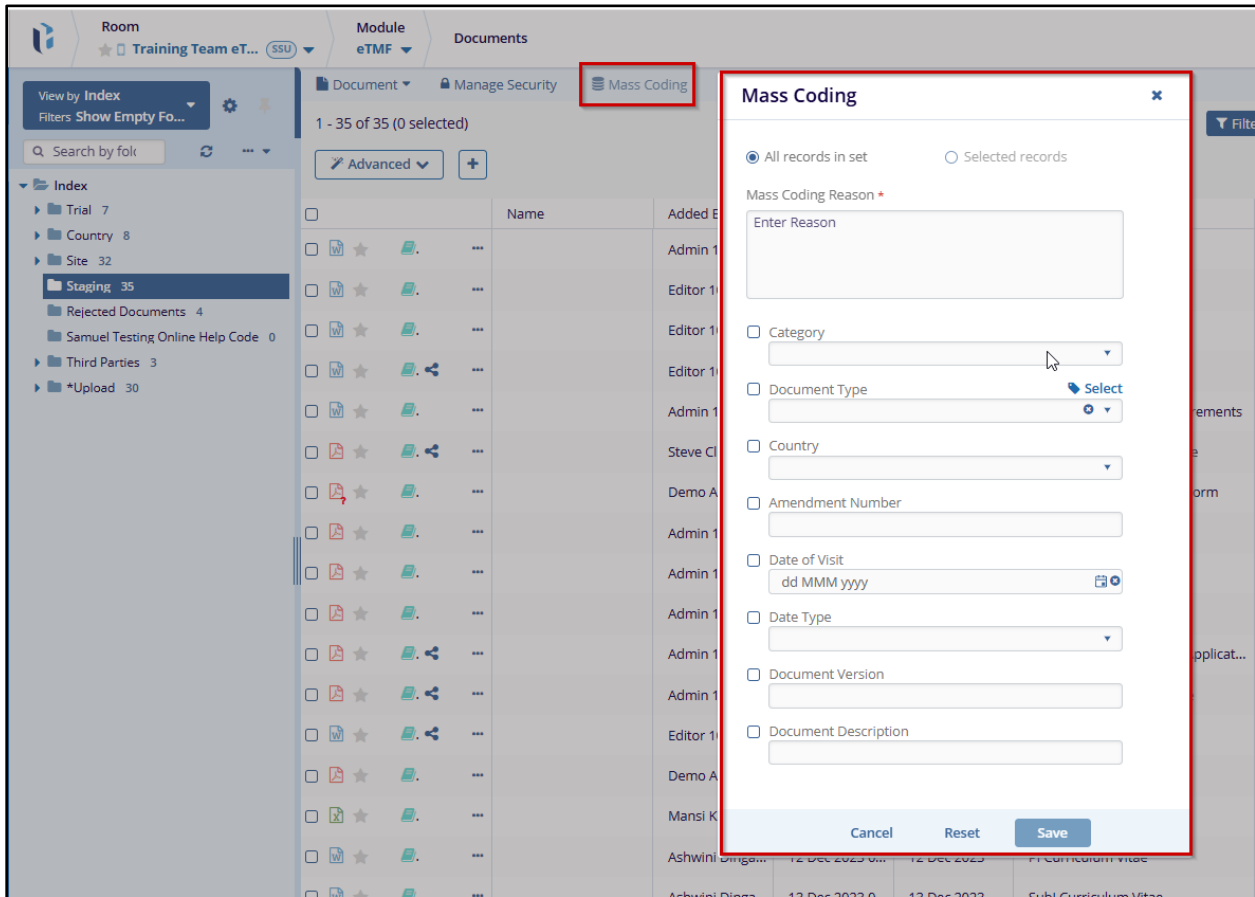
Q Search

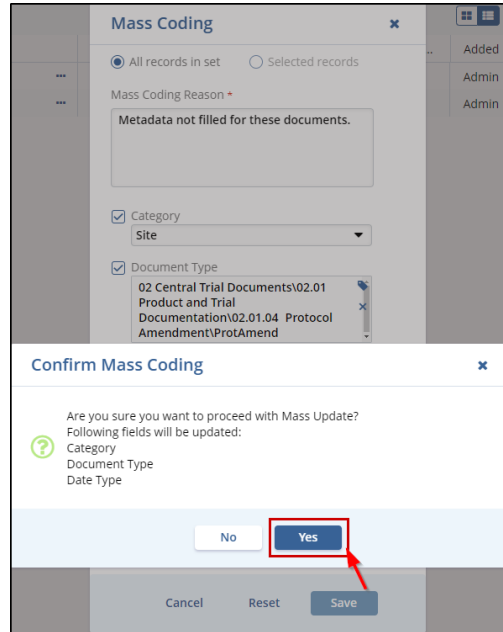
- Index
  - Trial 7
  - Country 8
  - Site 32
    - Staging 35
    - Rejected Documents 4
    - Samuel Testing Online Help Code 0
  - Third Parties 3

Cancel Next

## 72. 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.



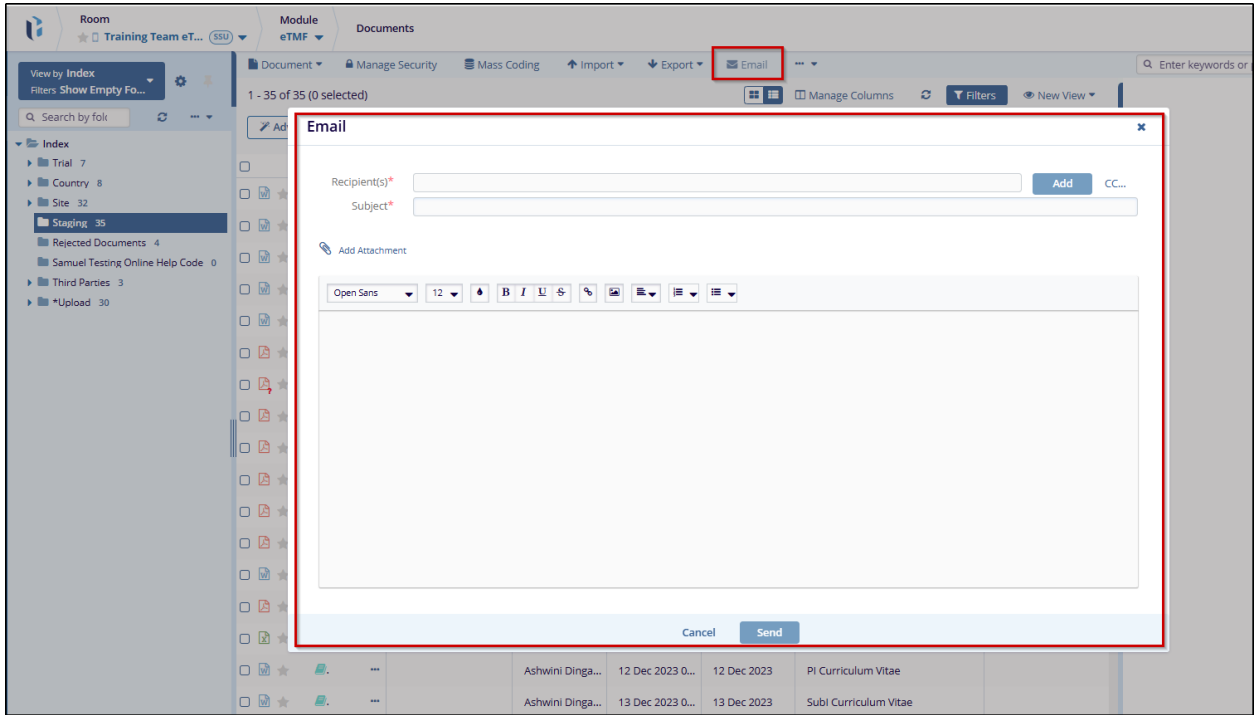


Alternatively, the user can also drag-drop the documents in document cart and select the **Mass Coding** option from the **Actions** dropdown menu.

### 73. Email

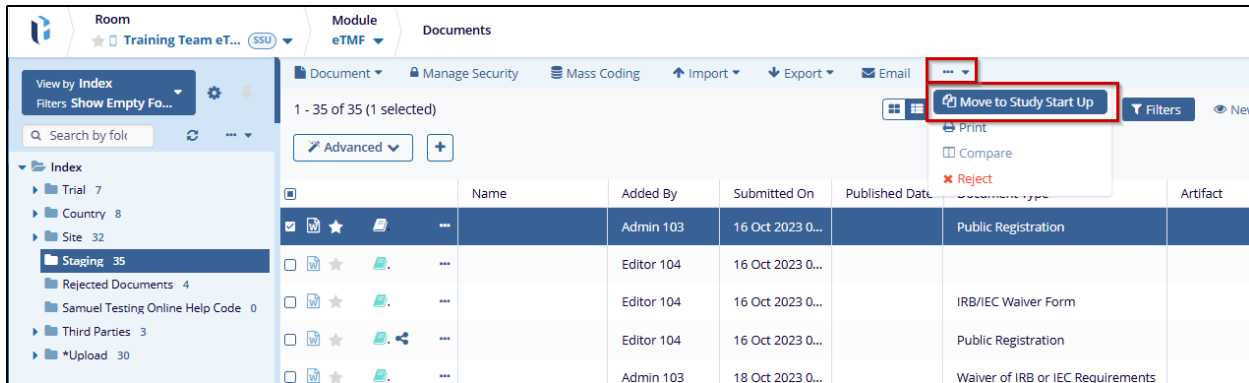
The email function allows users to send an email to another room user or contact. This could be a document-related email or not. In order to send an email, follow these steps:

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.



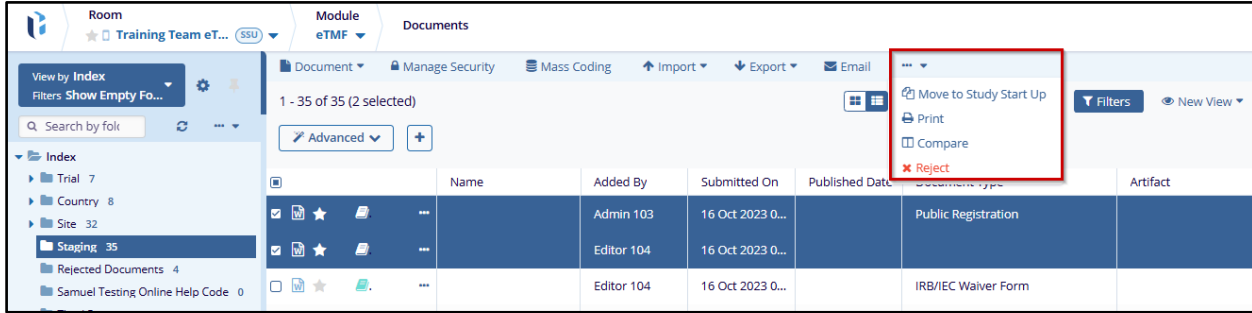
#### 74. Move to Study Start-Up

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.



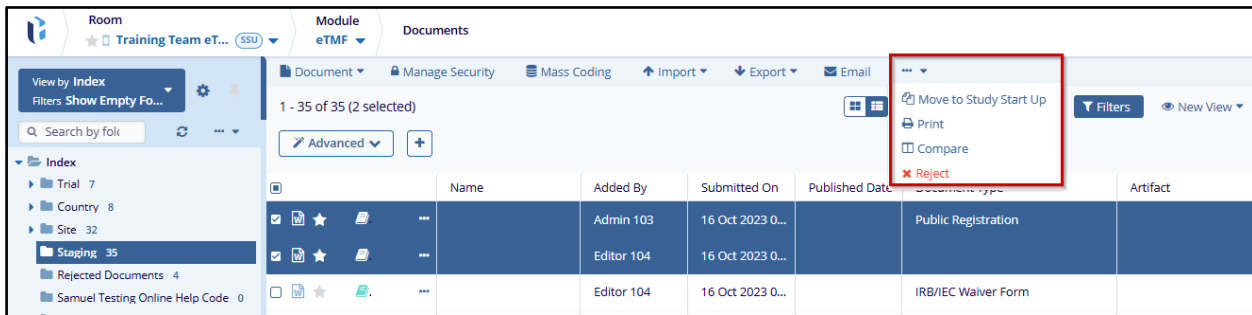
#### 75. Print

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.



## 76. 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.



## 77. 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.

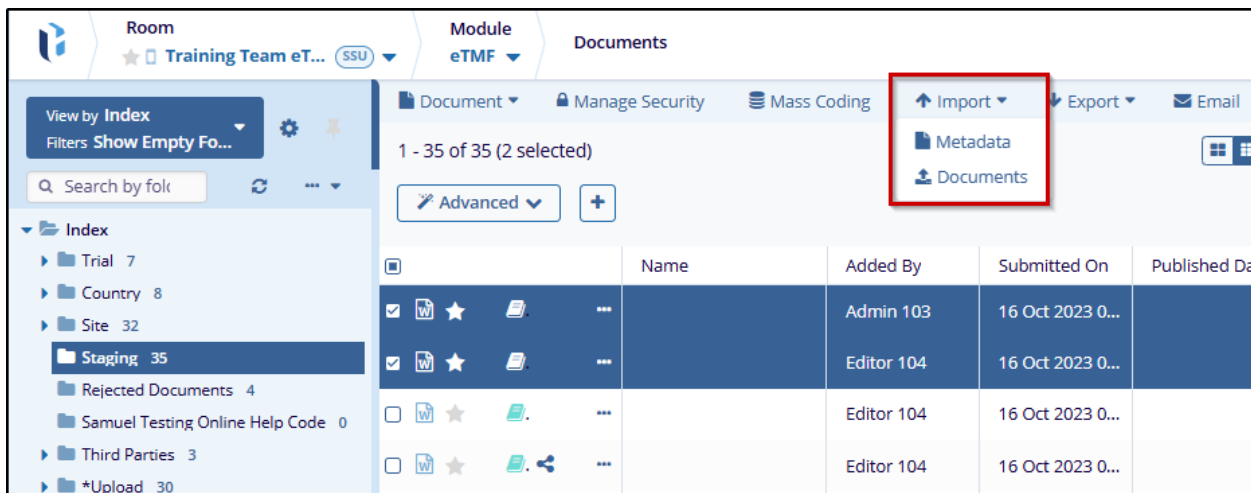


Figure 46: Import Option



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.

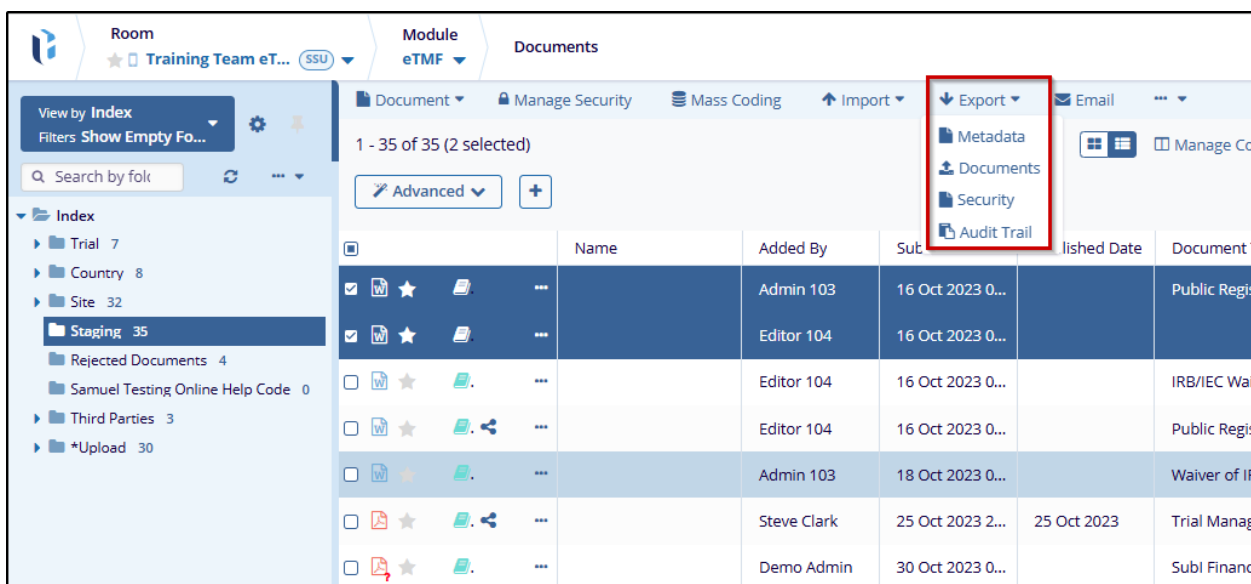
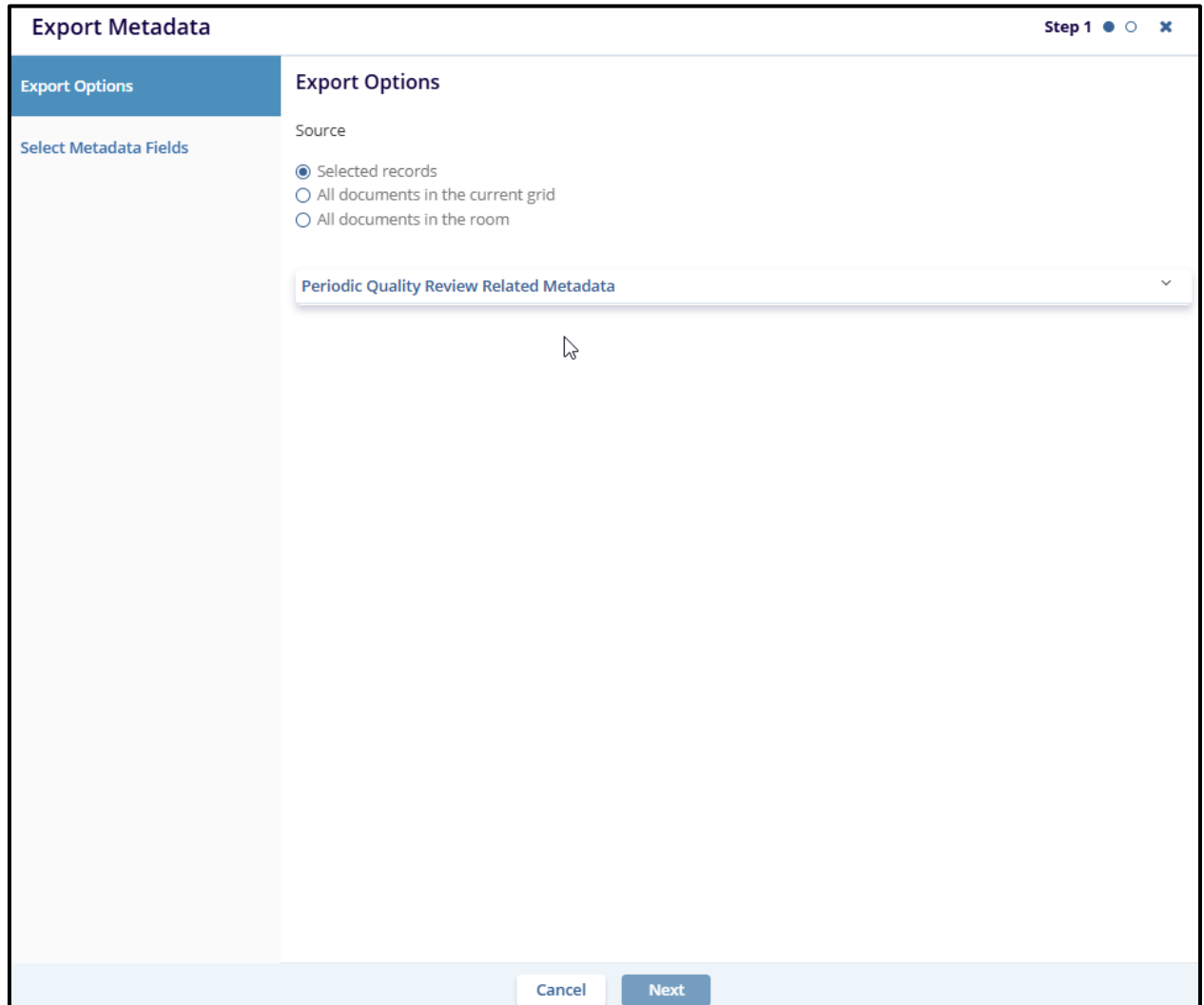


Figure 47: Export Metadata

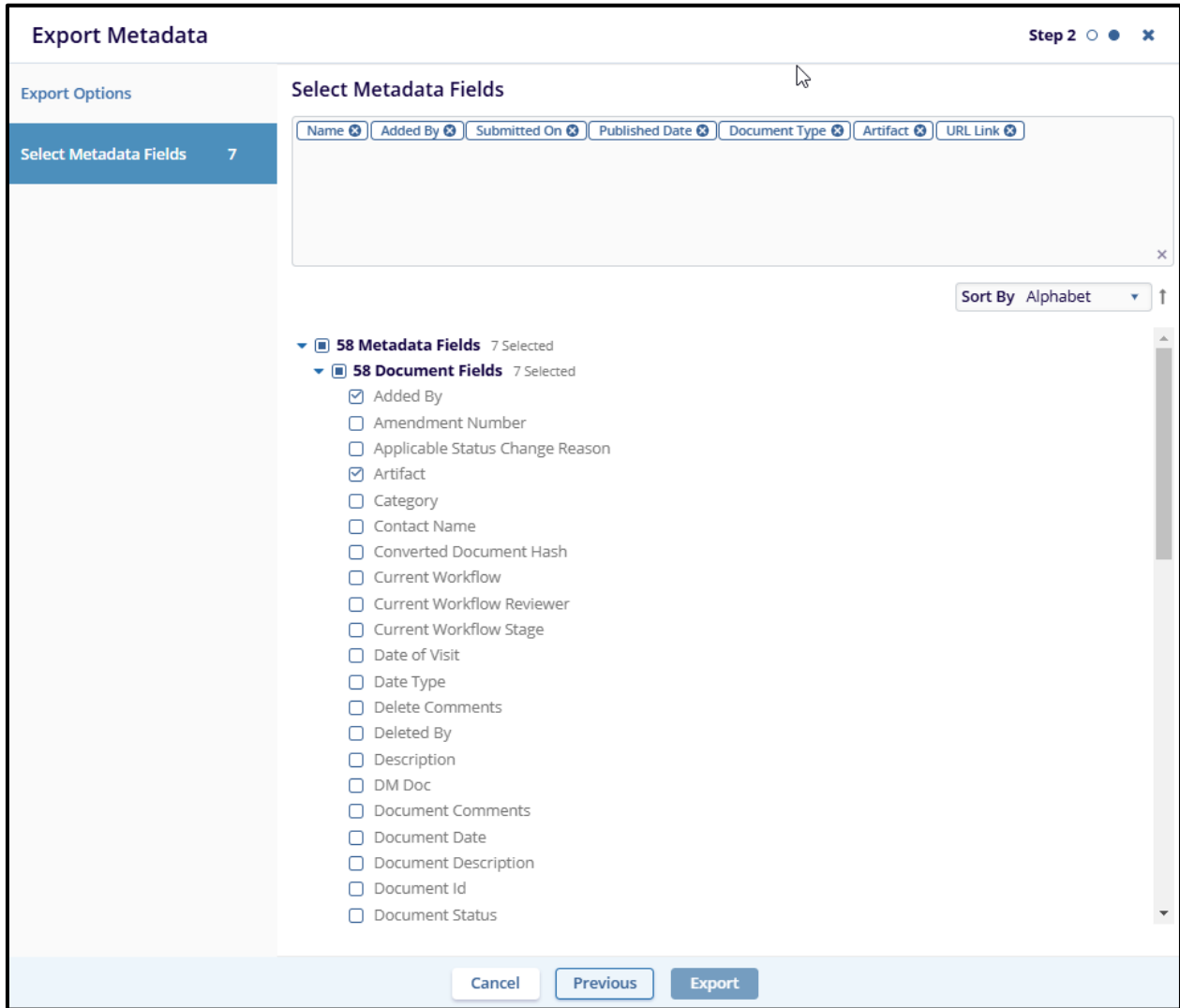
A metadata-only export is often a faster and more efficient way of gathering information regarding a subset of documents in the study room than running a related report.

**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'**
  - o The Export Metadata window will open.



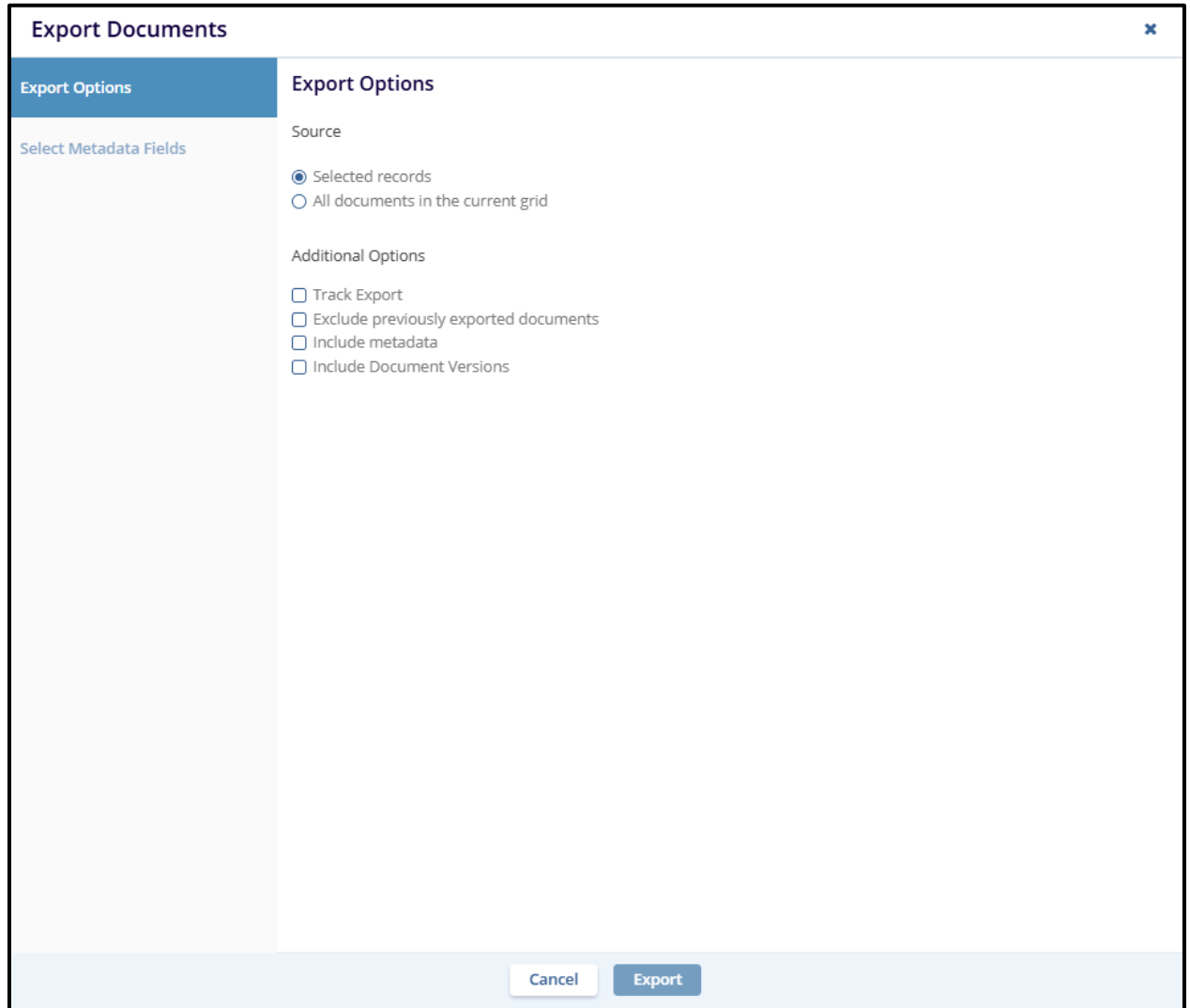
4. Choose from the Source options:
  - o Selected records
  - o All documents in the current grid
  - o All documents in the room
5. Choose whether or not the export should include Quality Review (audit) related Metadata.
  - o If you choose to export Quality Review metadata, indicate whether all information 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



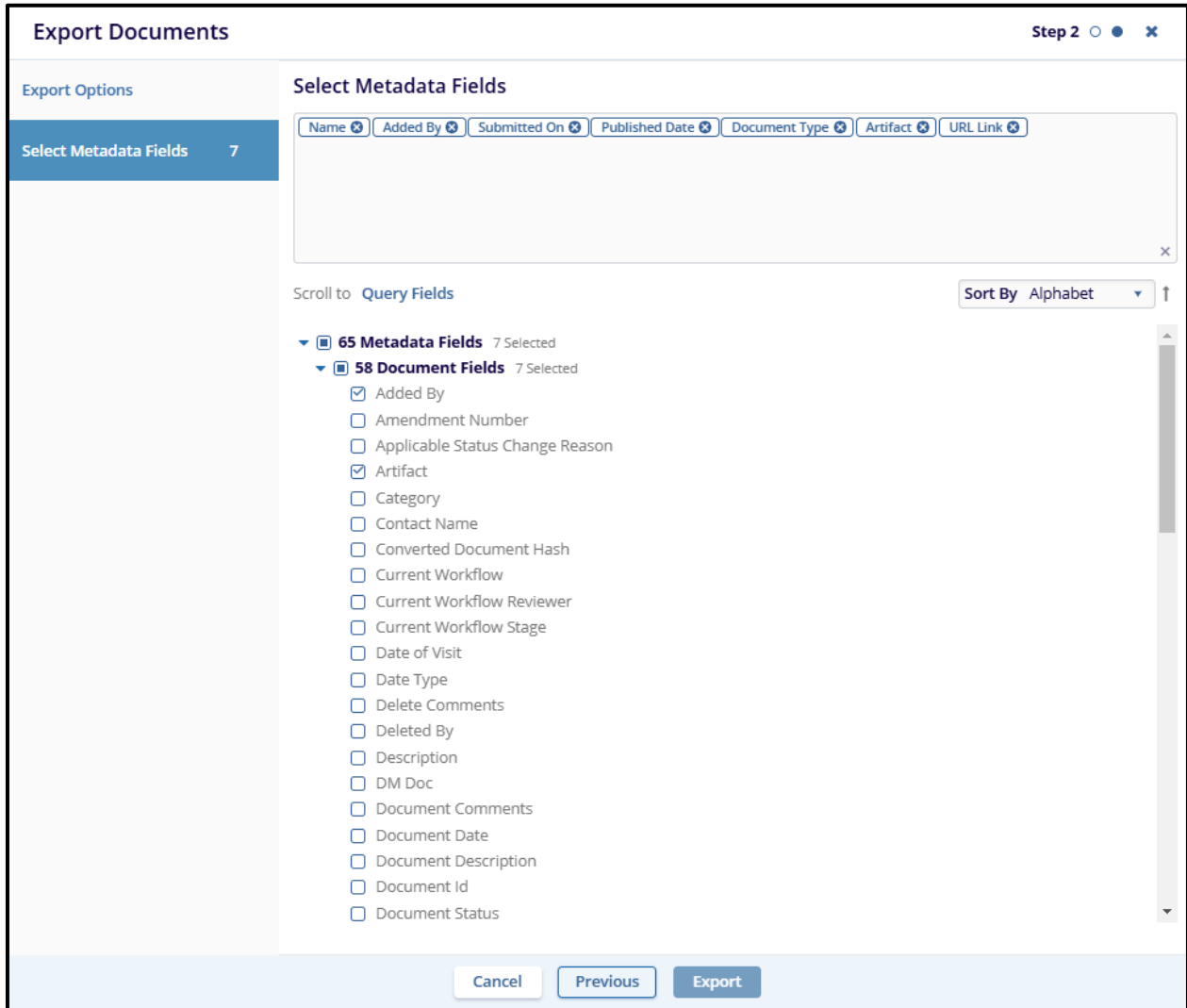
8. Press 'Export'

**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'
  - o The Export Documents window will open.



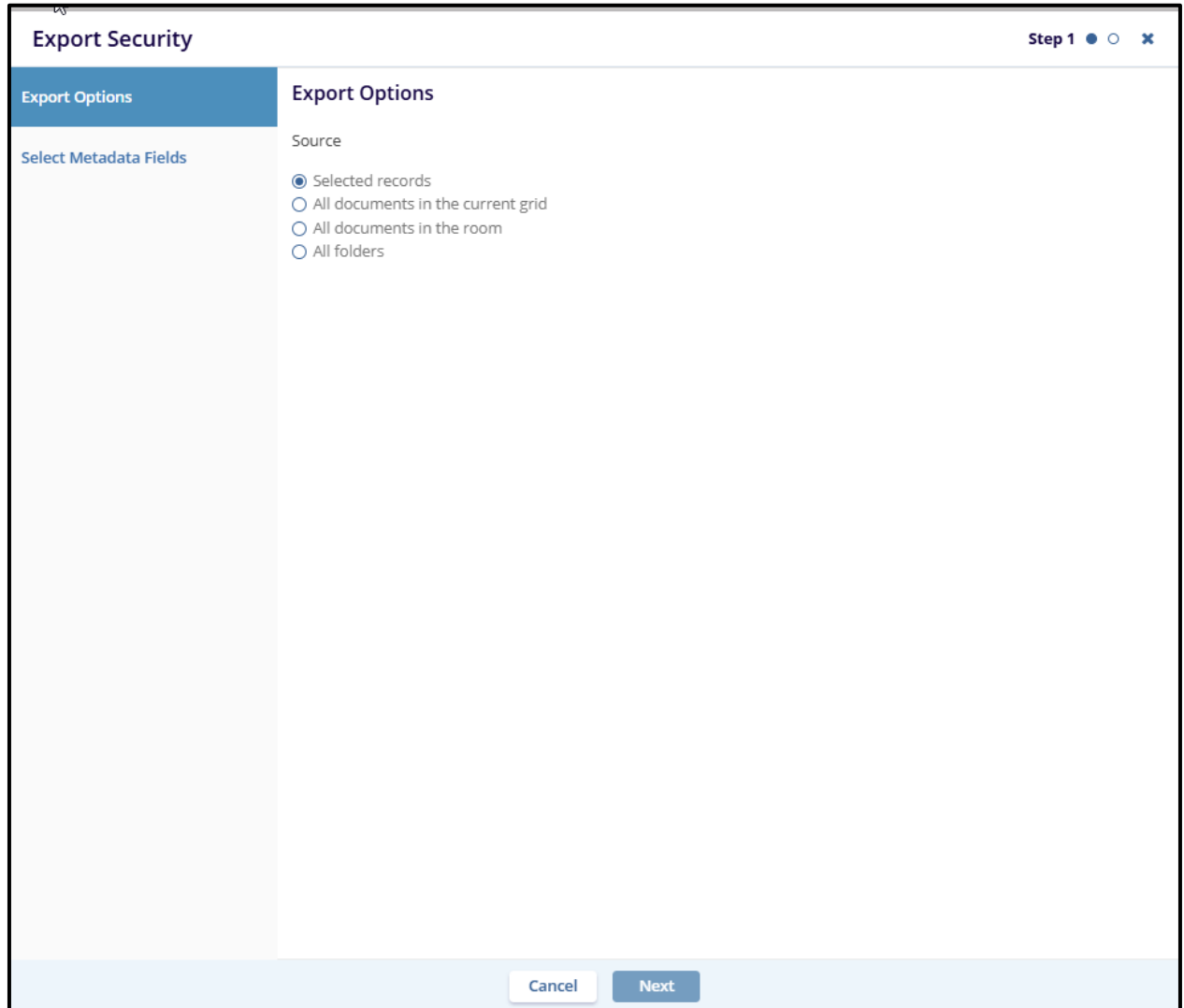
4. Choose from the Source options:
  - Selected records
  - All documents in the current grid
5. Choose from the available options (these options will vary depending upon user access rights)
  - Track Export
  - Exclude previously exported documents
  - Include Metadata
  - Include Document Versions – 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'
  - o The Export Security window will open.



4. Choose from the Source options:
  - Selected records
  - All documents in the current grid
  - 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.

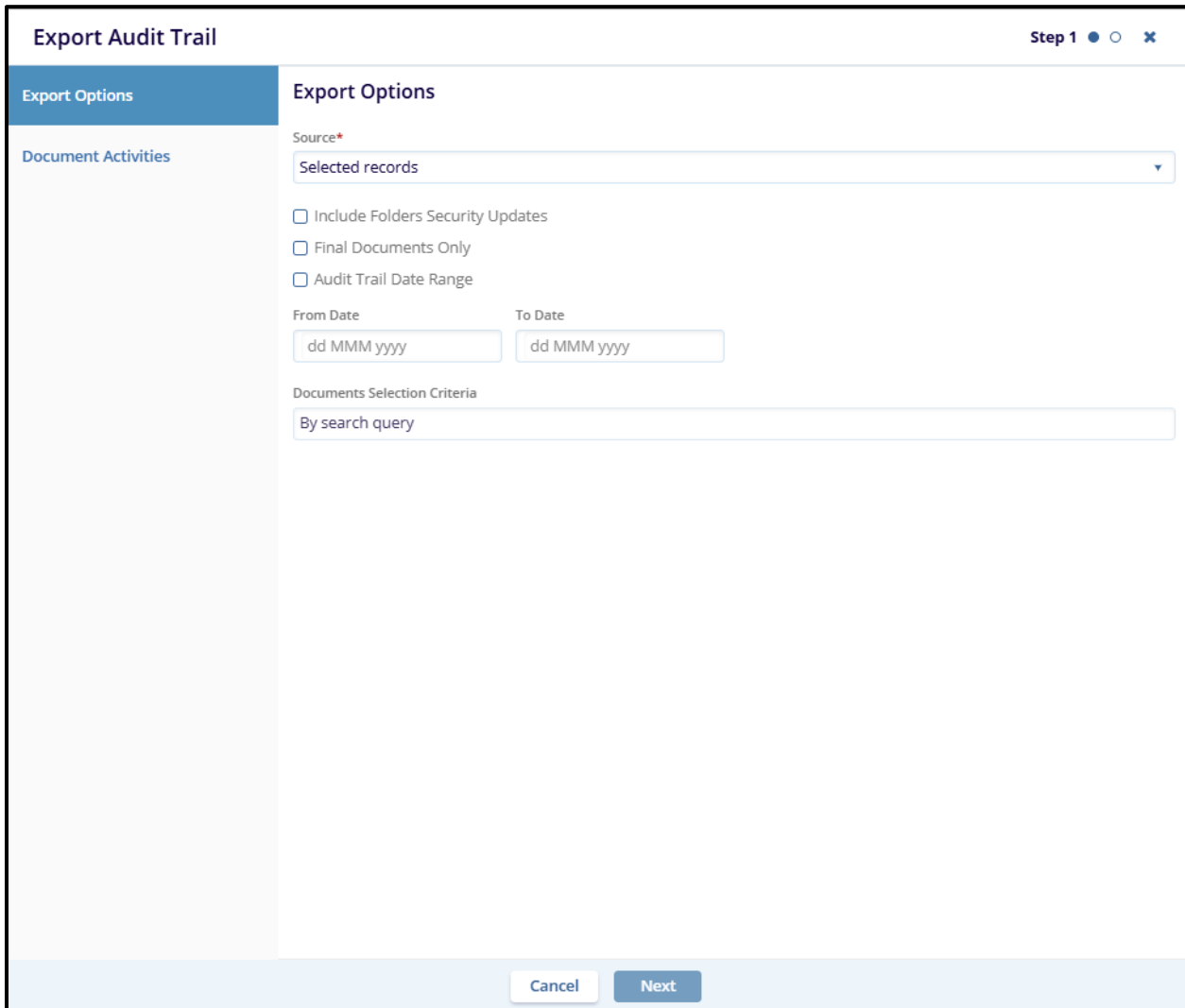


Figure 48: Export Audit Trial

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.

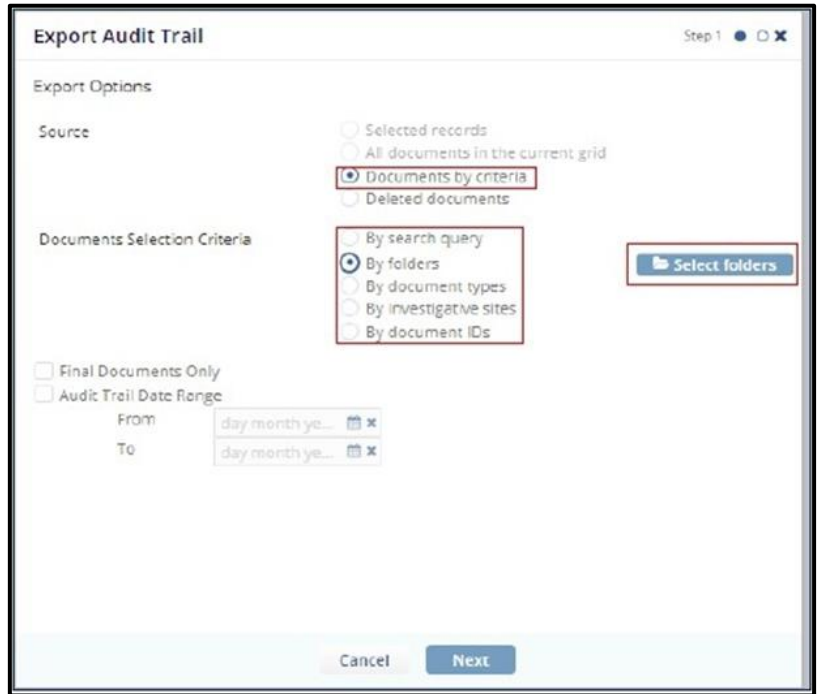


Figure 49: Audit Trail

8. Choose the appropriate criteria and press the Select button.
9. When you have indicated all necessary criteria, press Next to continue.
  - o 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.

### 78. 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:



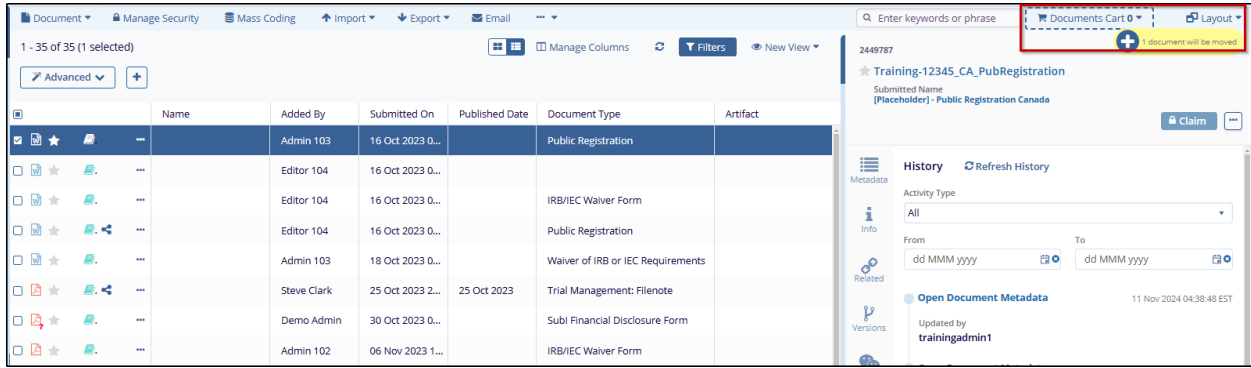


Figure 50: Document Cart

### 79. Copying documents to another 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.

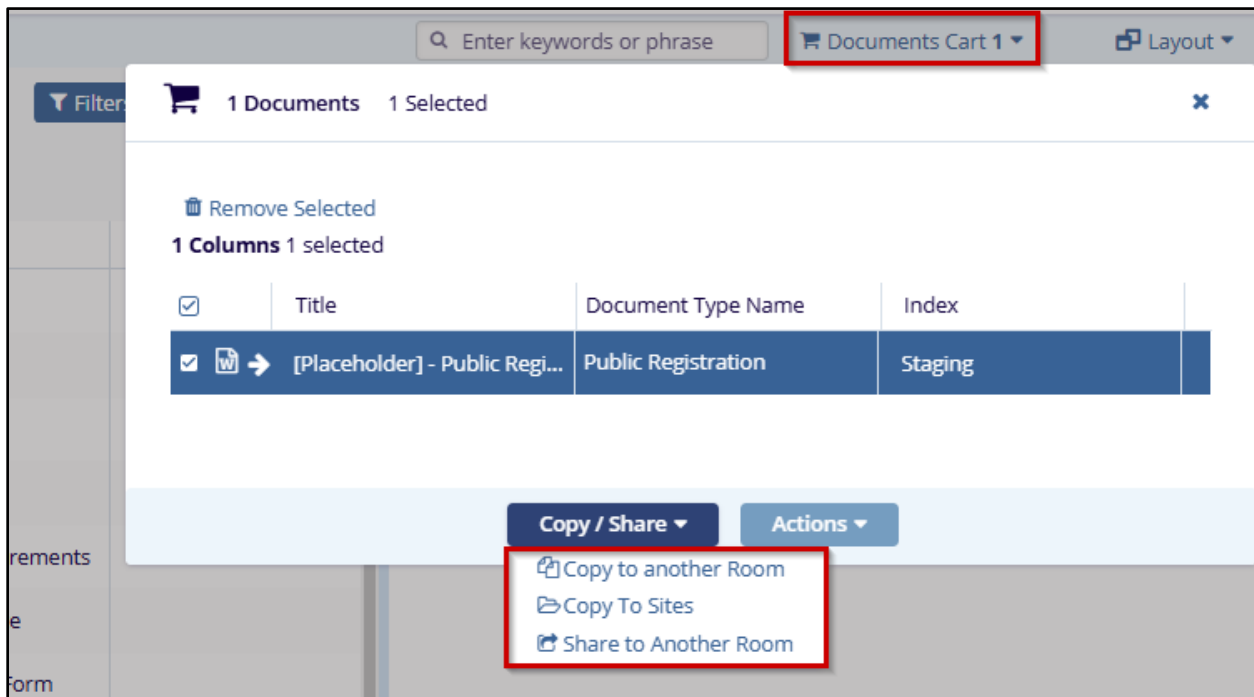


Figure 51: Copying Documents to Other Rooms

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:

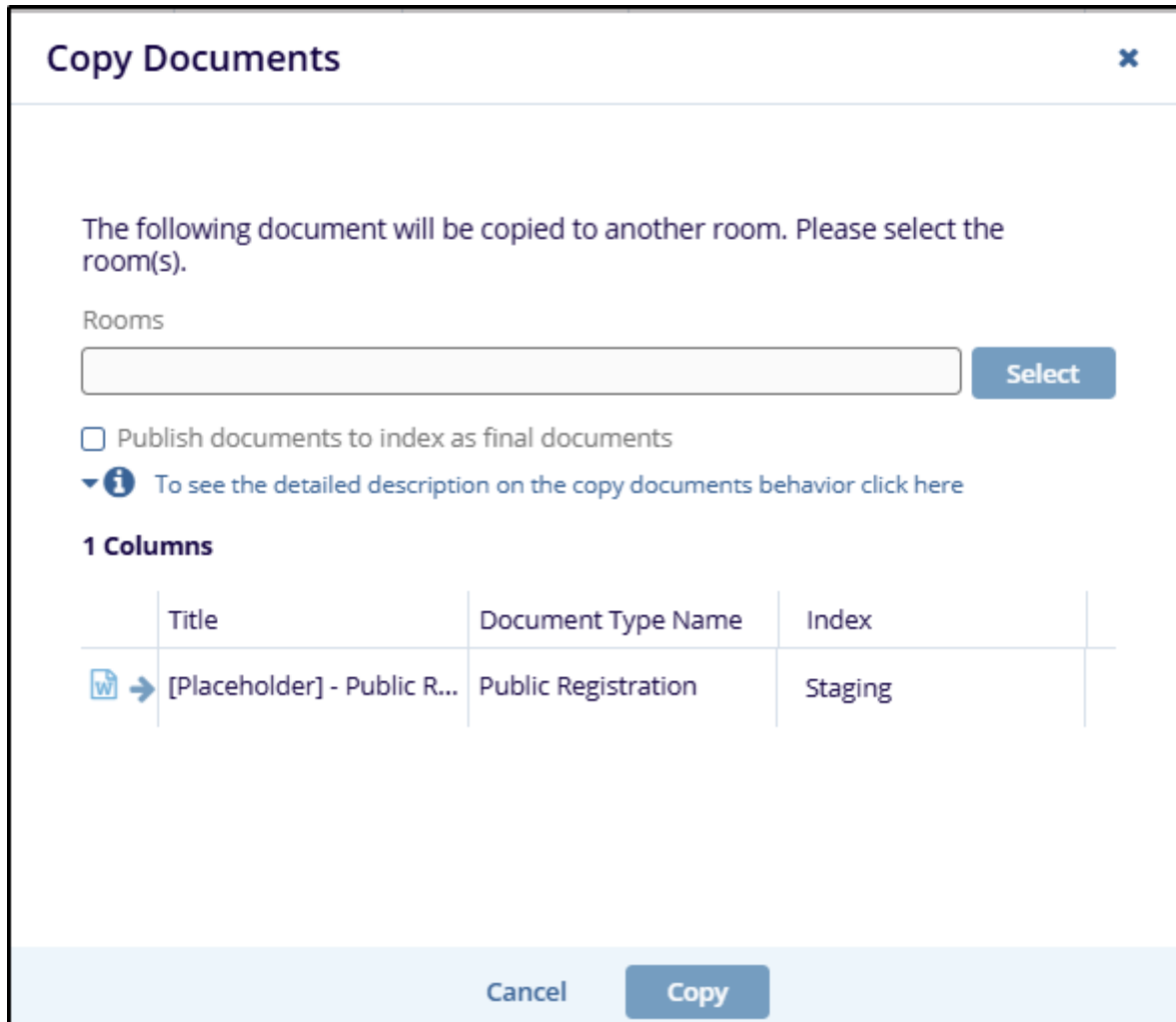


Figure 52: Copying Documents

## 80. 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.

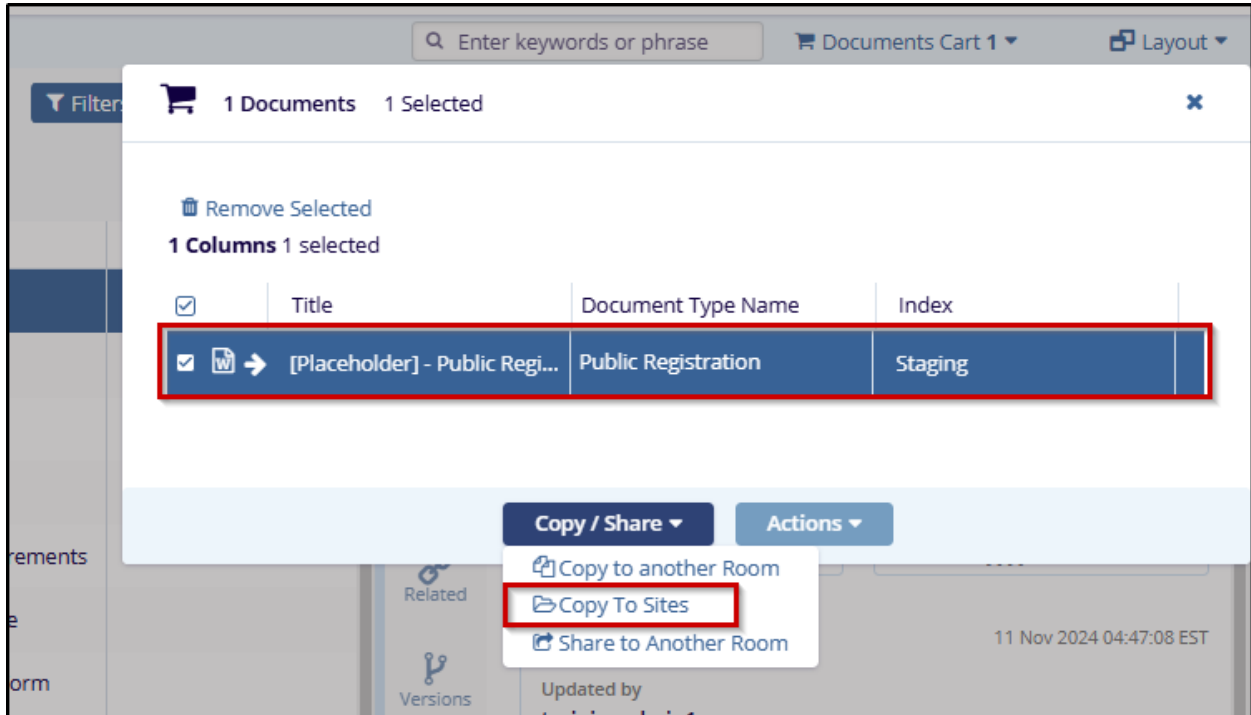


Figure 53: Copying Documents to Investigative Sites

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.

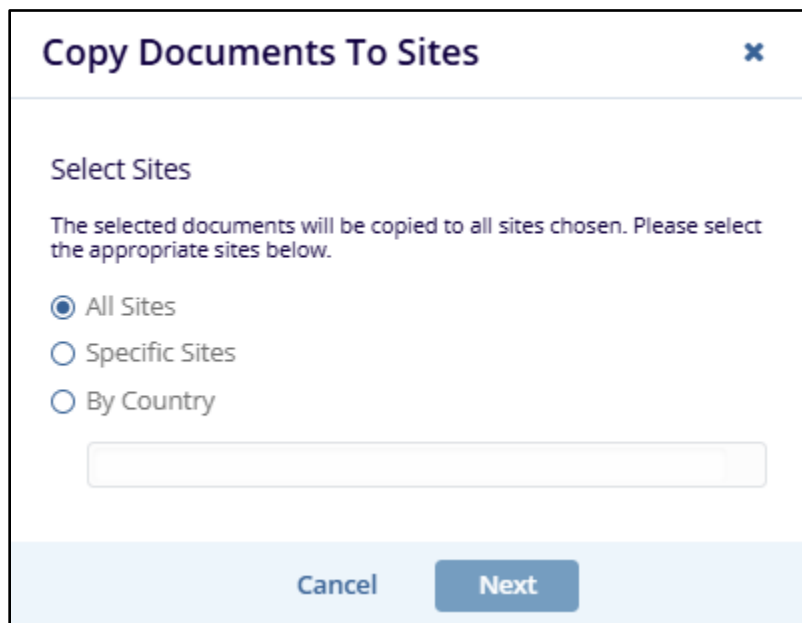


Figure 54: Copying Document Options

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:

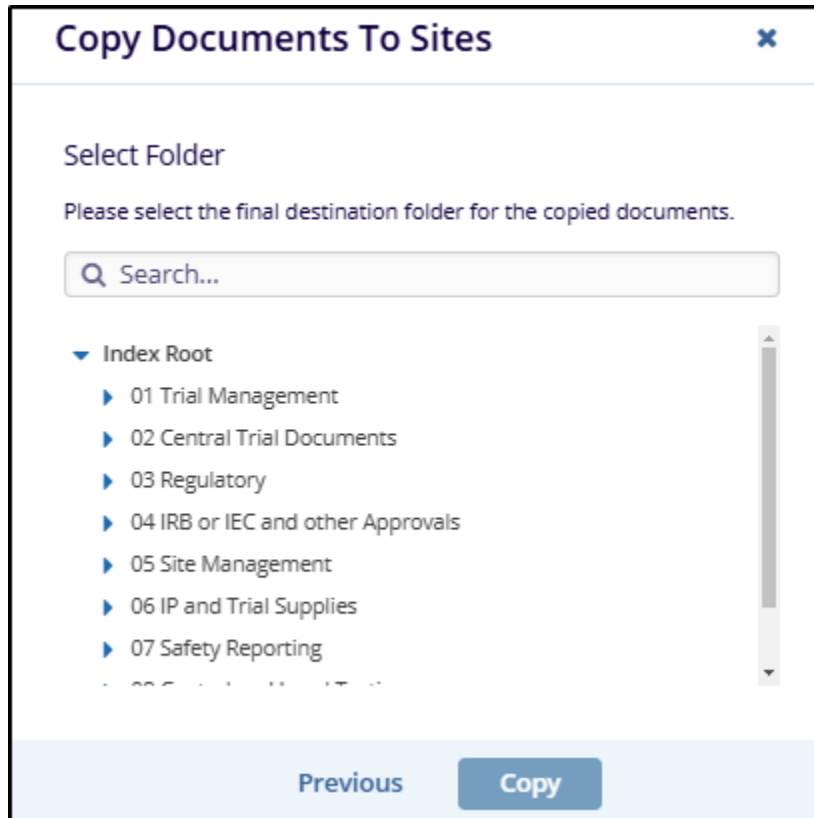


Figure 55: Folder to copy documents

## 81. 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.
  - o The Merge Documents window will open.

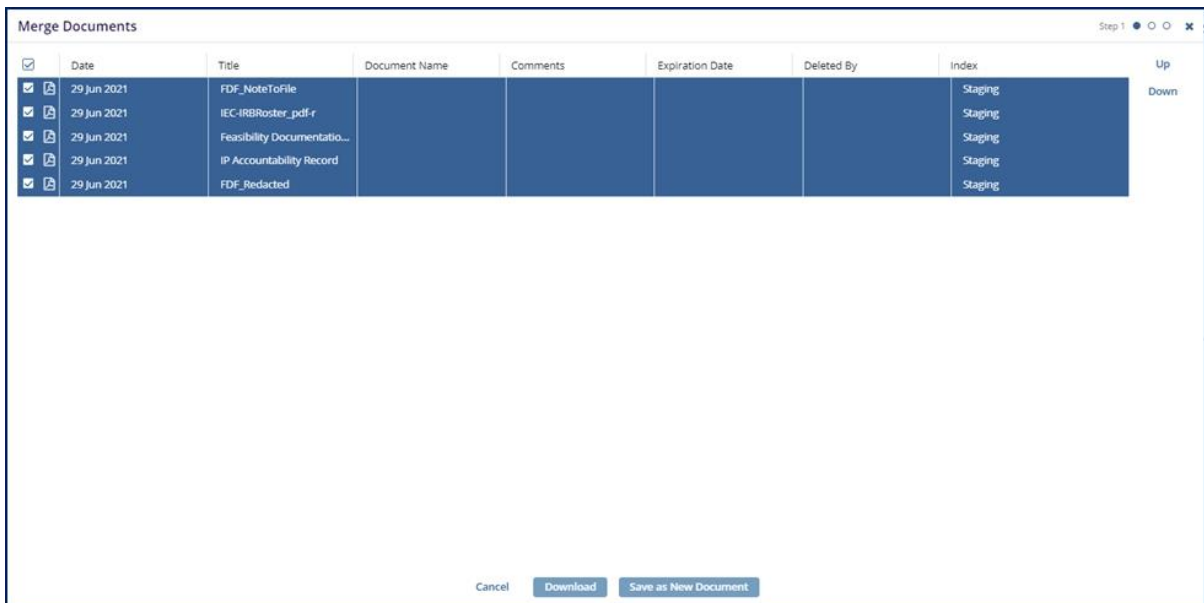
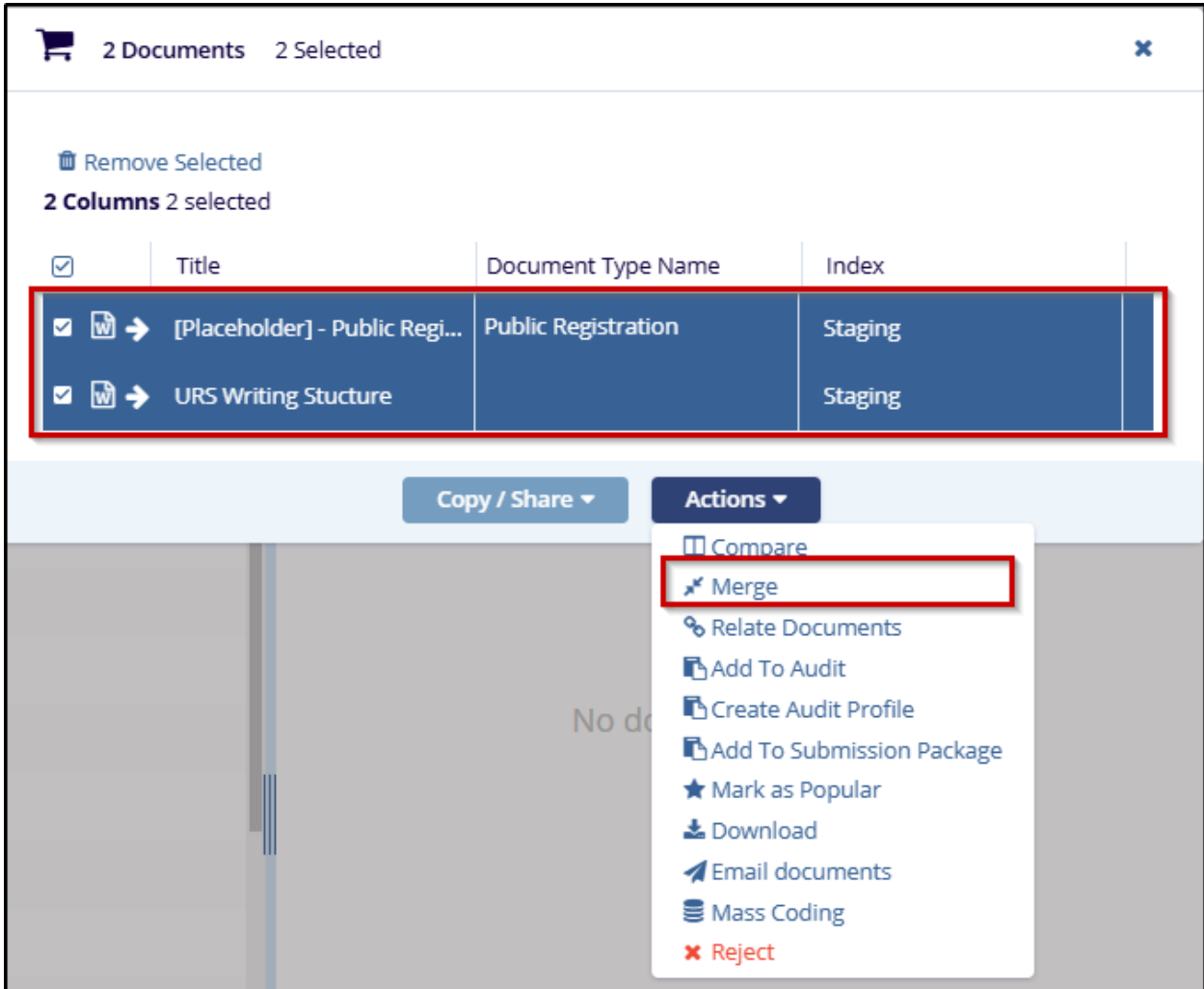


Figure 56: Merge Documents

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.
  - o Save as New Document will create the merged file as a new document in the study room. All additional steps refer to this process.
  - o The screenshot below shows the next screen that appears after pressing 'Save as New Document.'

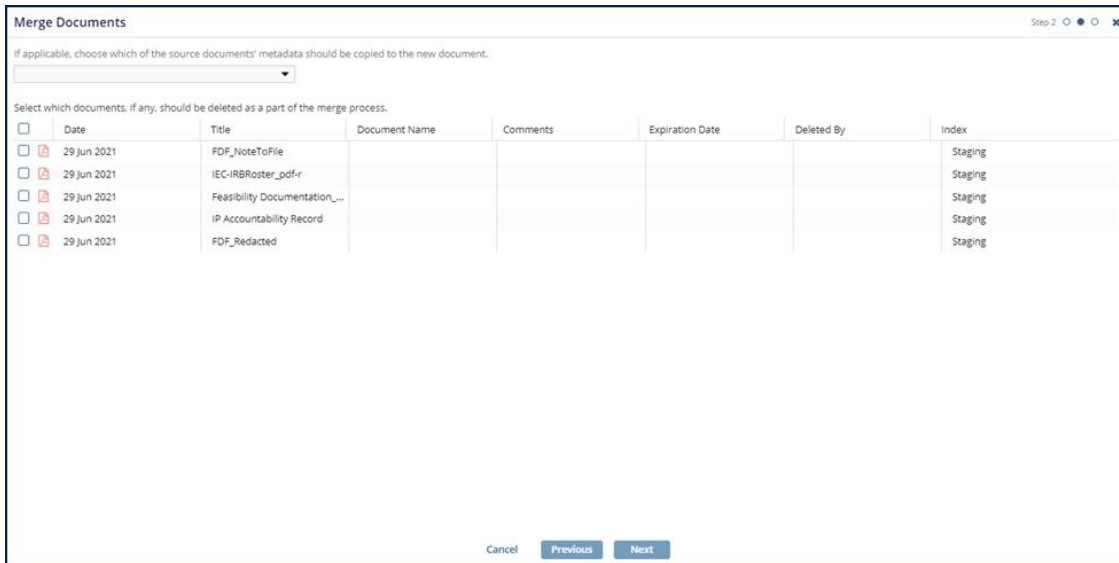


Figure 57: Merge Documents Page

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.
  - o The source documents will only appear here if the user has the appropriate access rights to the documents to delete them.
  - o 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'

## 82. 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:

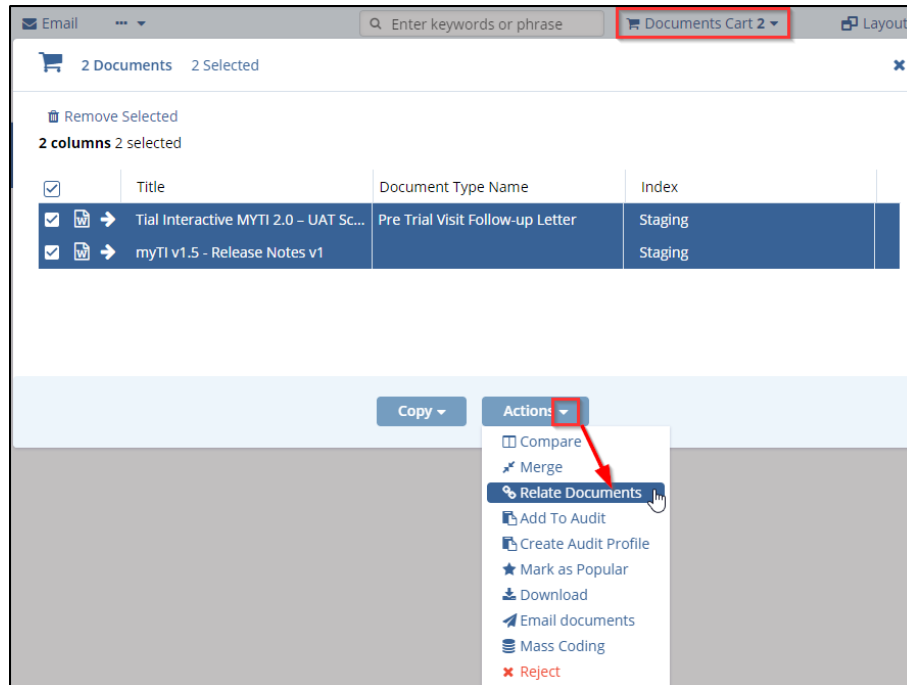


Figure 58: Linking Documents

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

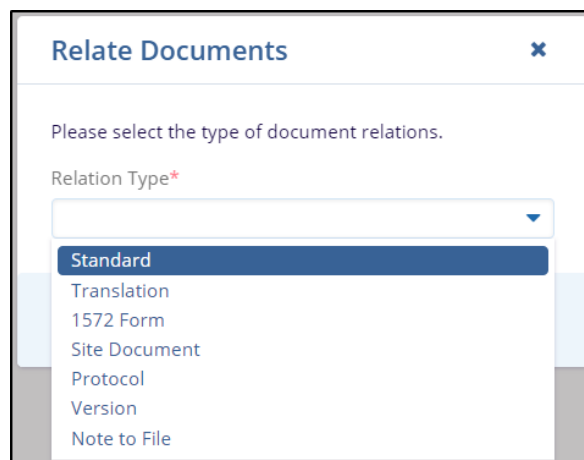


Figure 59: Linking Document Page

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

### 83. 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**.

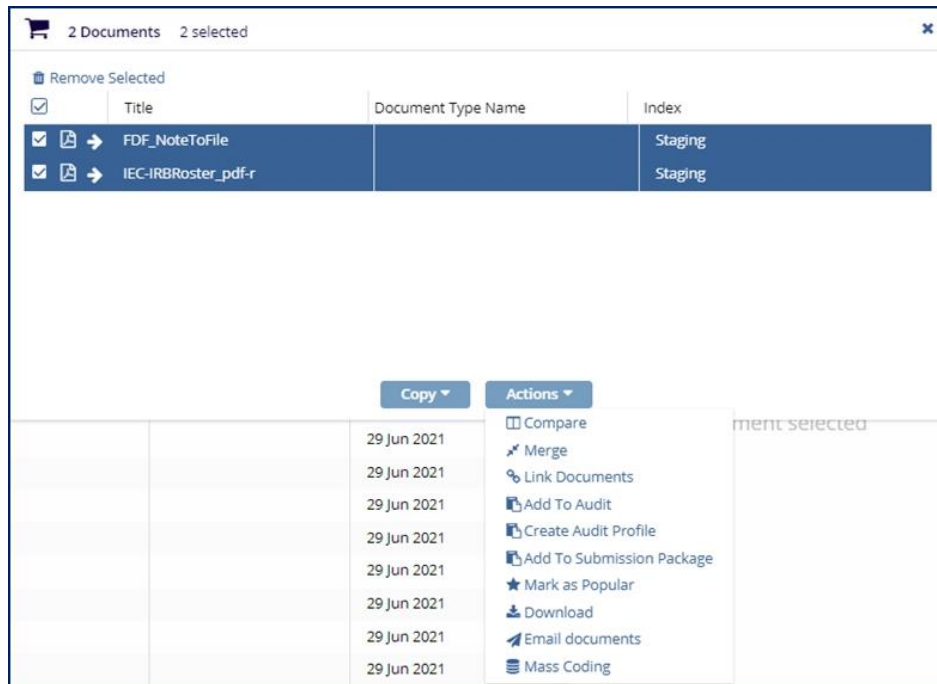


Figure 60: Adding Documents to Audit

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



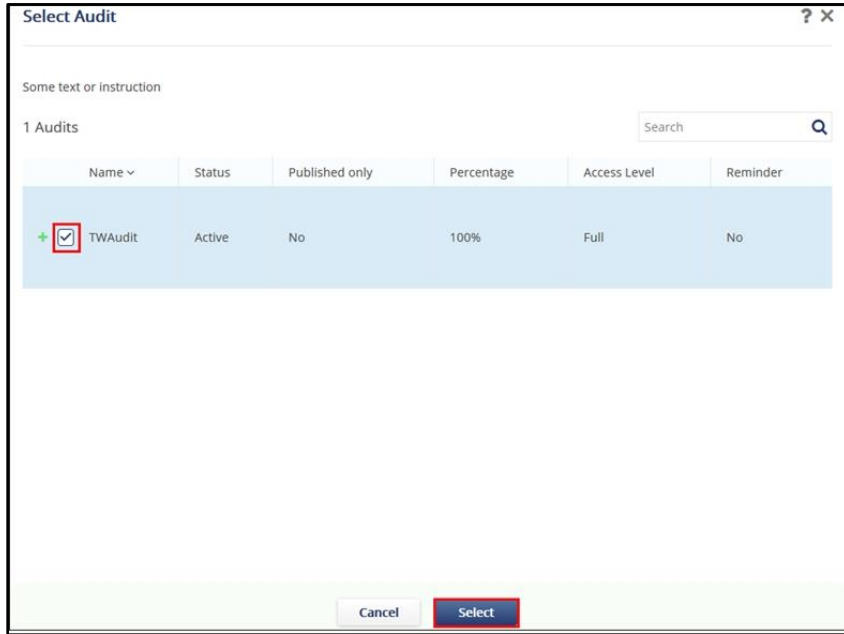


Figure 62: Select Audit

**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.

#### 84. 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:

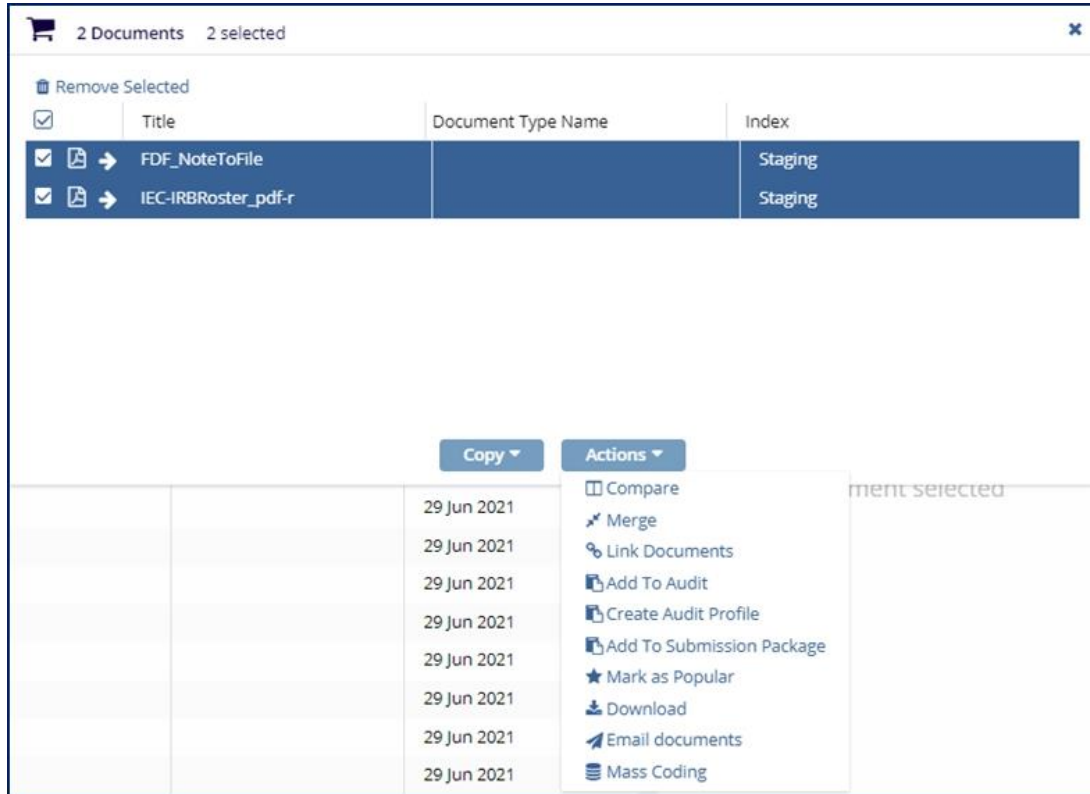


Figure 63: Create Audit Profile

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.

### 85. 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:

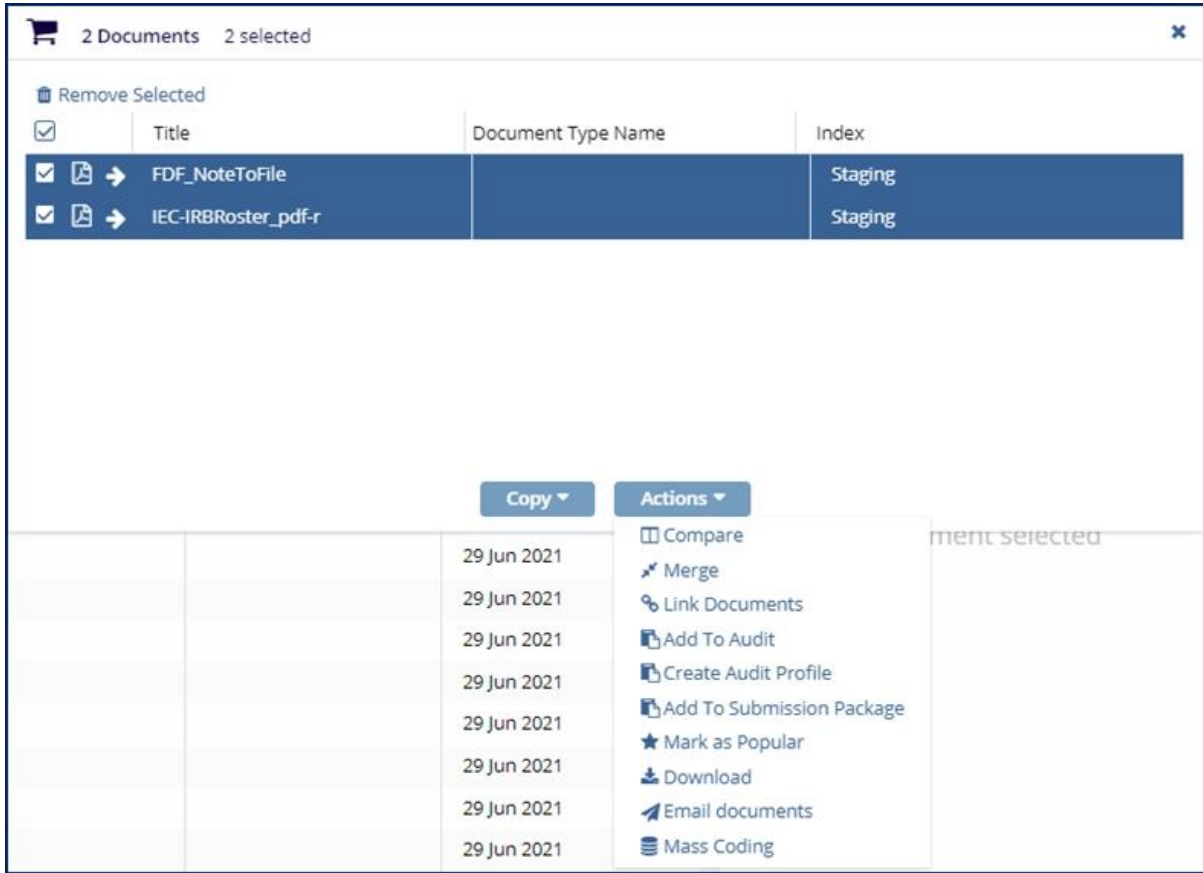
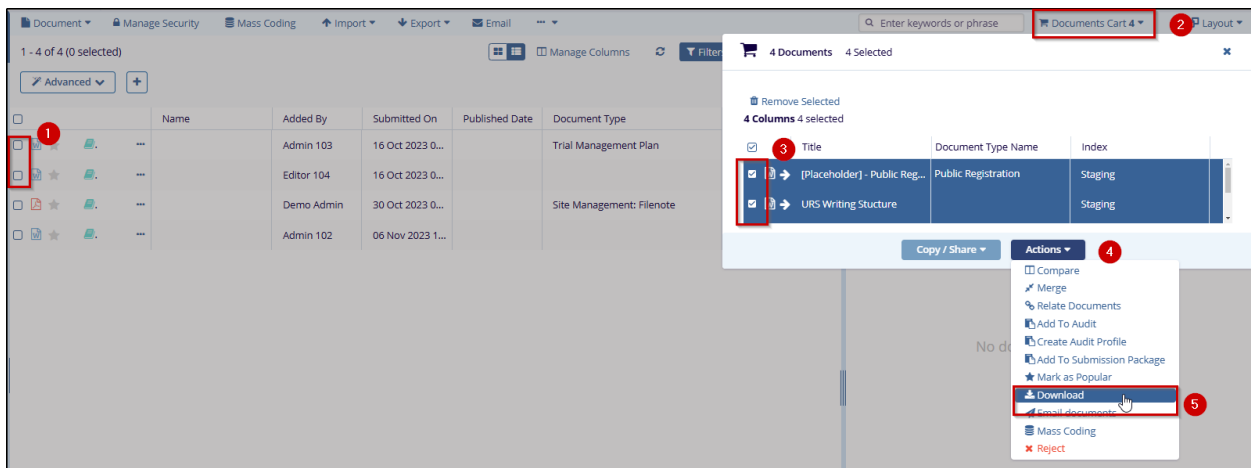


Figure 64: Adding Document to a Submission Package

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

## 86. Downloading documents

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



---

## 87. 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.

---

## 88. Email

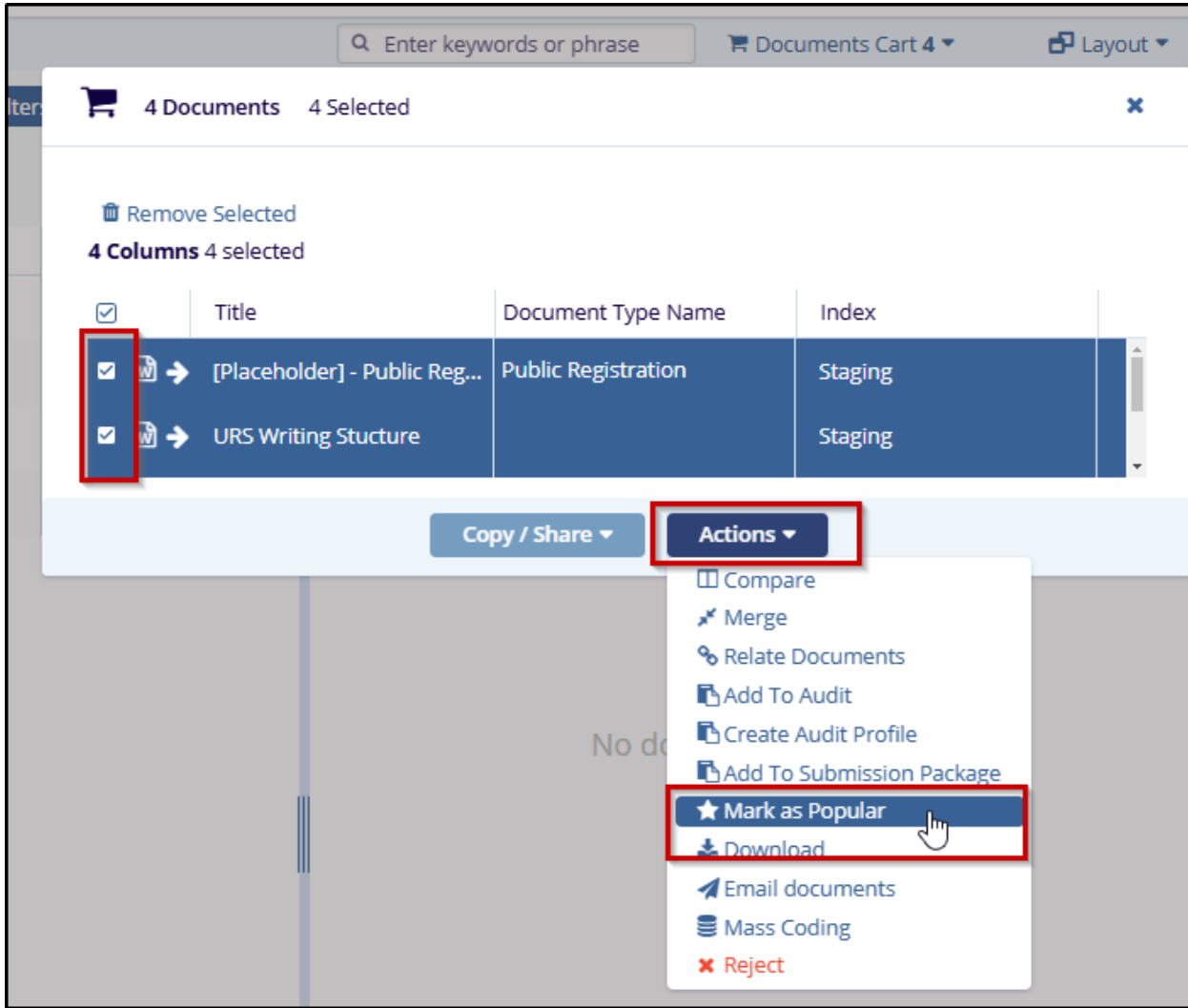
The email function allows users to send an email to another room user or contact. This could be a document-related email or not. To send an email, follow these steps:

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.

---

## 89. 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.



## 90. Layout

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

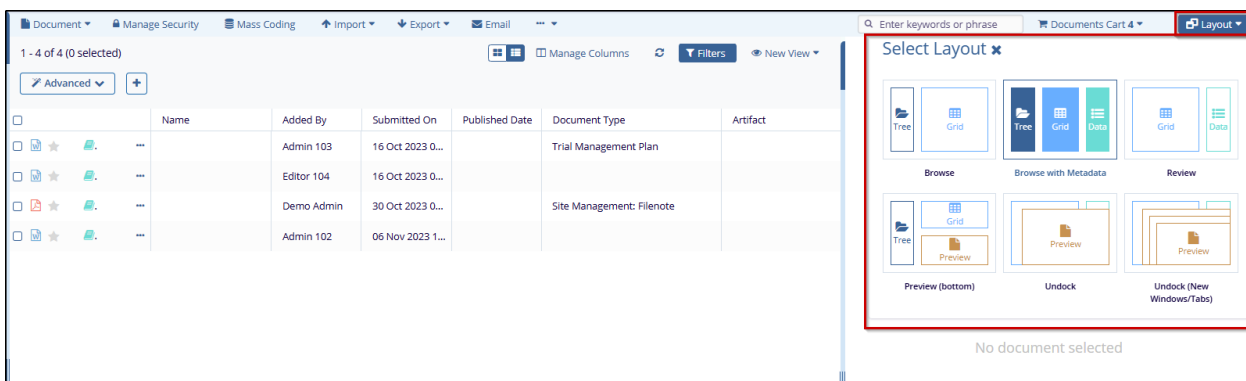


Figure 65: layout panel

## 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.

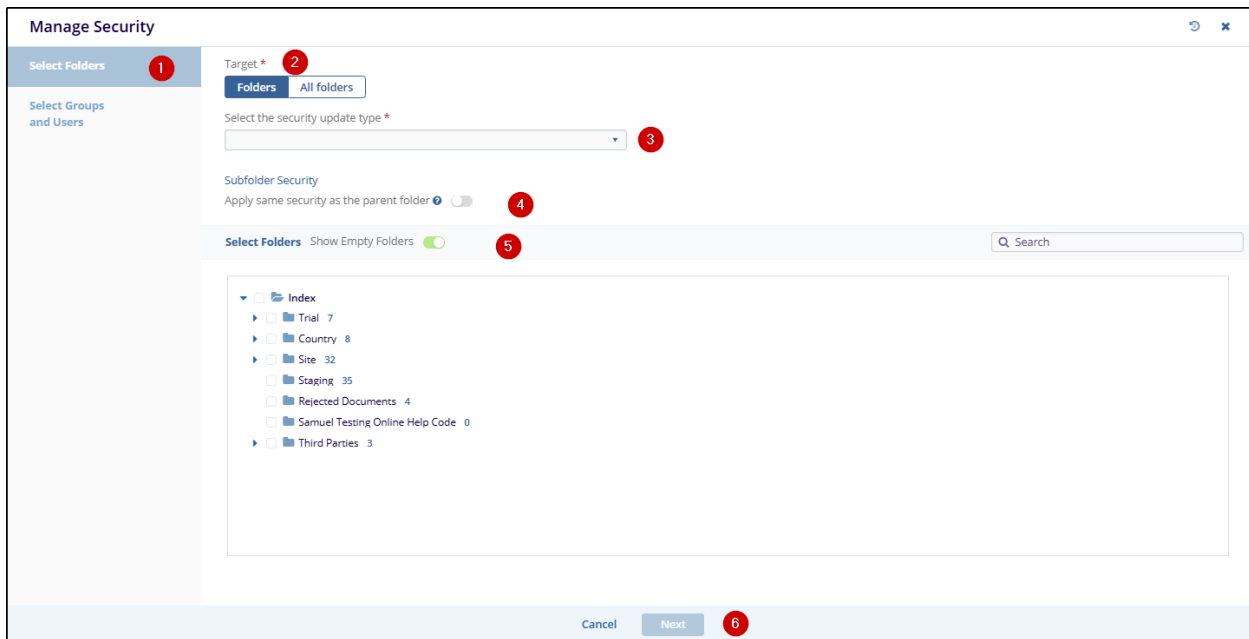


Figure 66: Manage Security Page

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.
  - o 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:

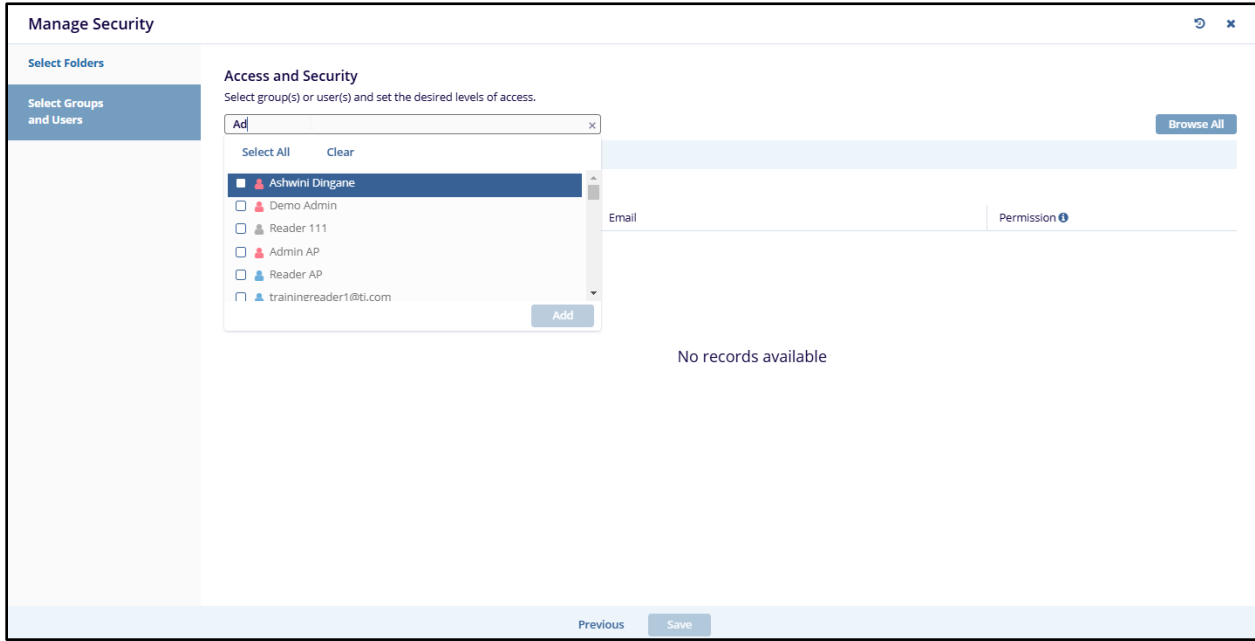


Figure 67: Access and Security

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

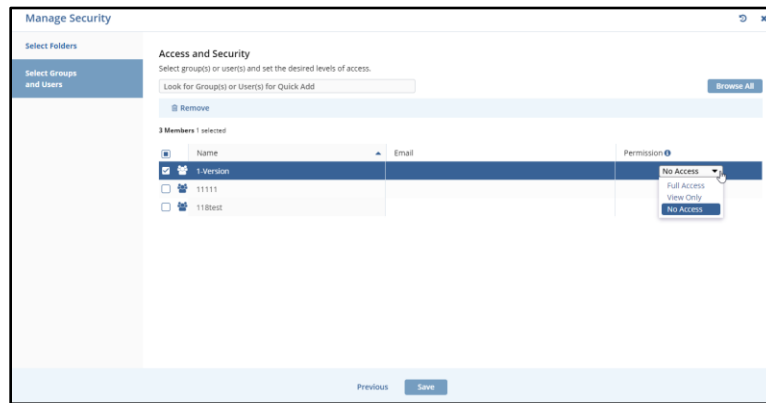


Figure 68: Access Permissions

- 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 Solution

### Background

An unblinded document is a document 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 receiving 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 that 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 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 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:

- GlobalLearn
- CTMS
- TI Connector
- TransPort Translations

### Site in eTMF Module

This section provides detailed instructions on how to:

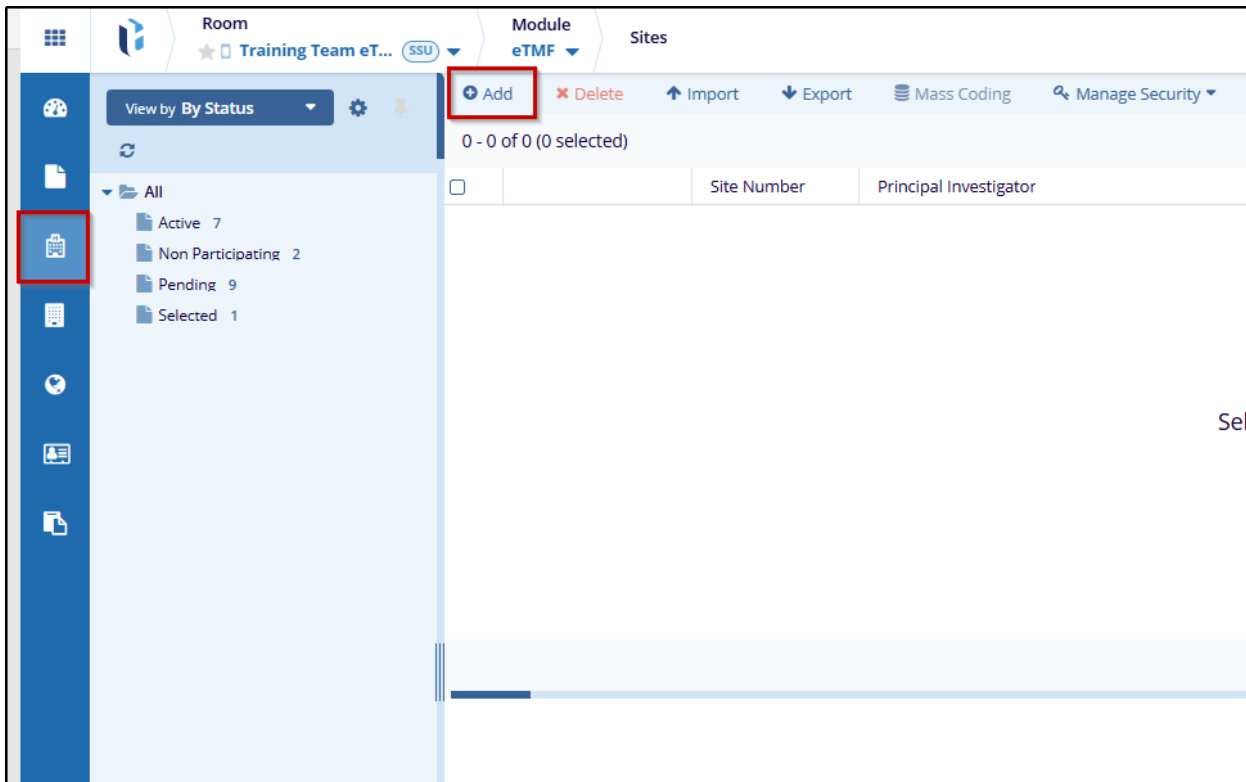
- Add, delete, import, and export data
- Perform mass coding
- Manage security settings
- Customize columns

It also covers comprehensive guidance on General Information, Contacts, and Site Visits.

## 91. How to Create New Site in ETMF module

Steps to Create Sites:

1. In the **eTMF** module sidebar, click on **Sites** to access the site management area.
2. Click the **Add** button to create a new site. This will open the **New Site** page.

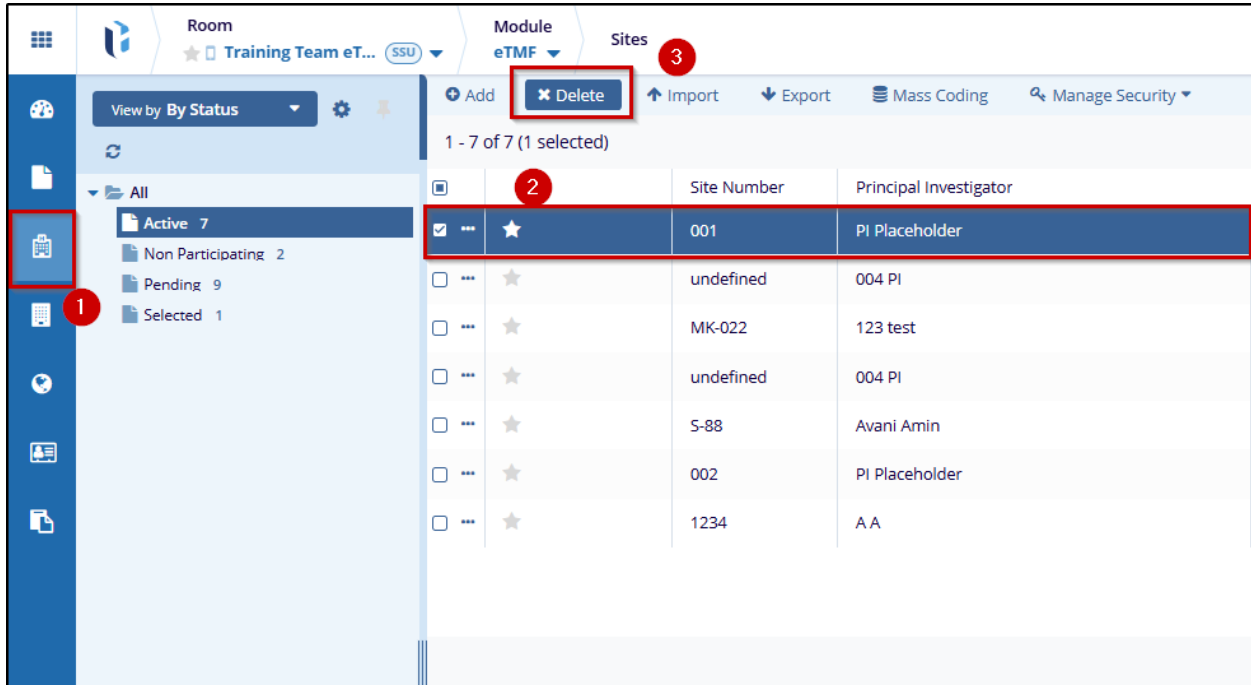


3. In the **General Info** tab, enter the required information:
  - **Institution Name** (mandatory).
  - Other fields such as **CRA**, **Start-Up Specialist**, **Site Number**, and **Site** as needed.
  - Optionally, check **Disable auto Site name** and provide a reason if not using the auto-generated name.

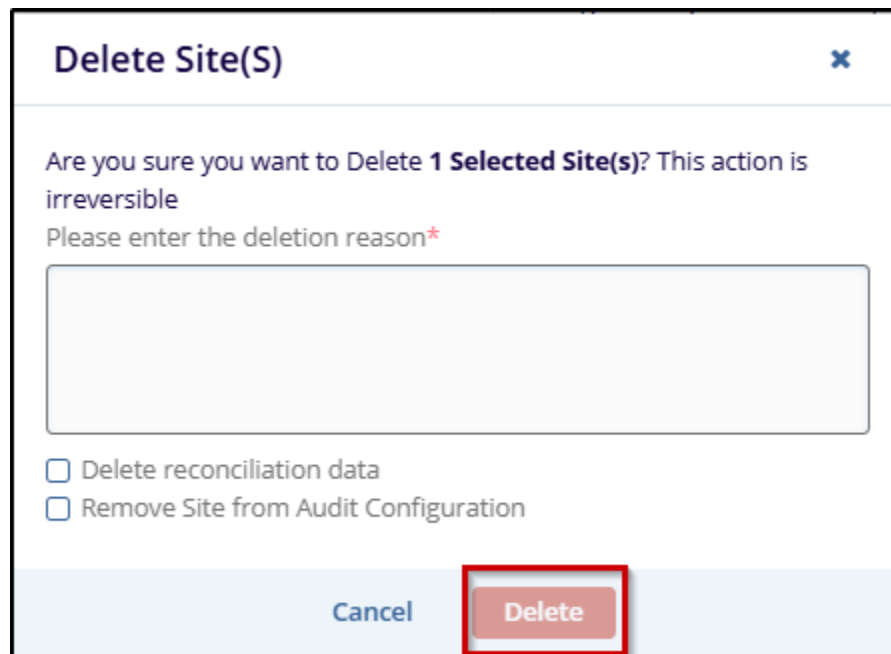
## 92. How to Delete Site in ETMF module

Steps to Delete Site in eTMF Module

1. In the **eTMF** module sidebar, go to **Sites** and select the **Active** or relevant status folder.
2. Check the box next to the site you want to delete, then click **Delete**.



- In the **Delete Site(s)** dialog, enter the reason for deletion in the provided field. Optionally, select **Delete reconciliation data** or **Remove Site from Audit Configuration** if applicable.



- Click **Delete** to confirm.
- This action is irreversible, and a confirmation message will indicate the site has been deleted.

### New Site ✕

General Info
Contacts

▲ Info

Institution Name \*  ⋮  
This field is required

CRA  ⋮

Start-Up Specialist  ⋮

Site Number

Site

Disable auto Site name

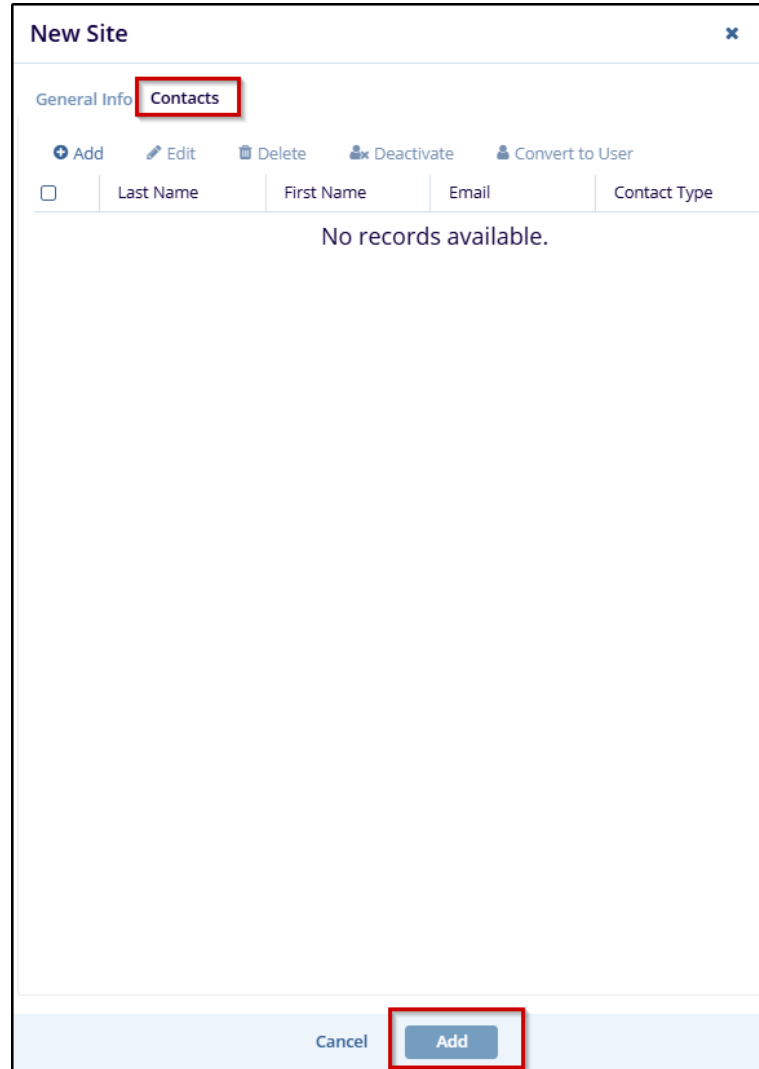
Reason for not using auto Site name

▼ Address

▼ More

Cancel
Add

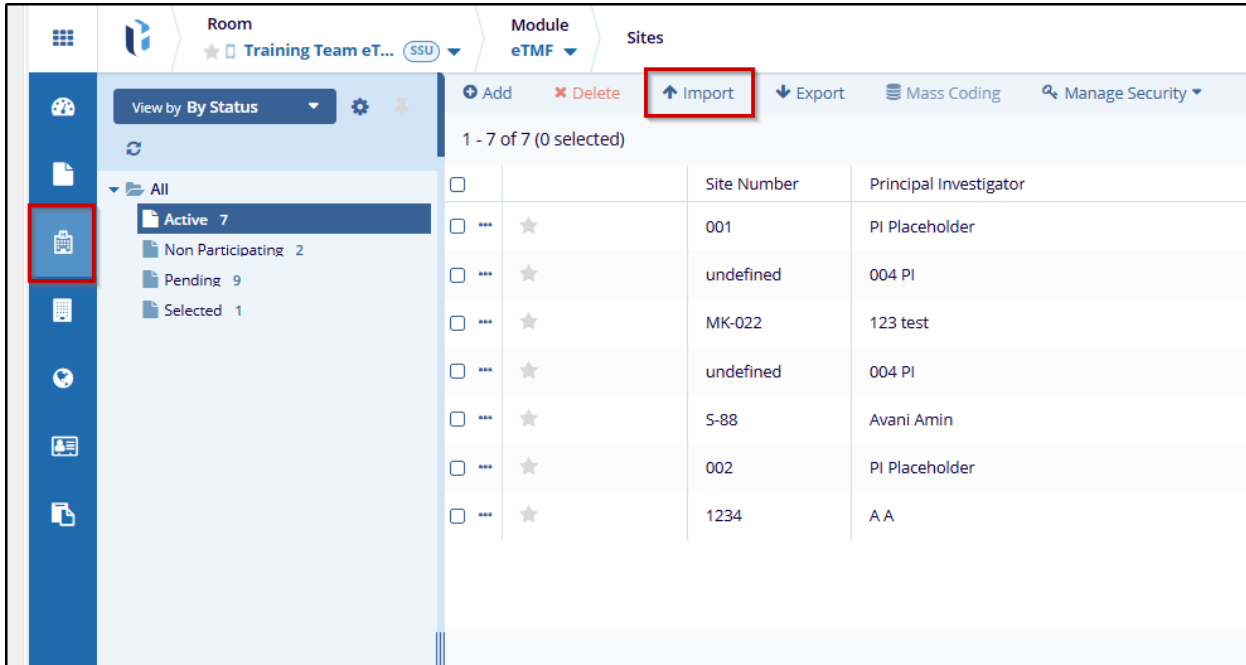
6. If you need to add contact details, go to the **Contacts** tab. Click **Add** and enter the required contact information.
7. Once all details are added, click **Save** to finalize the new site creation.



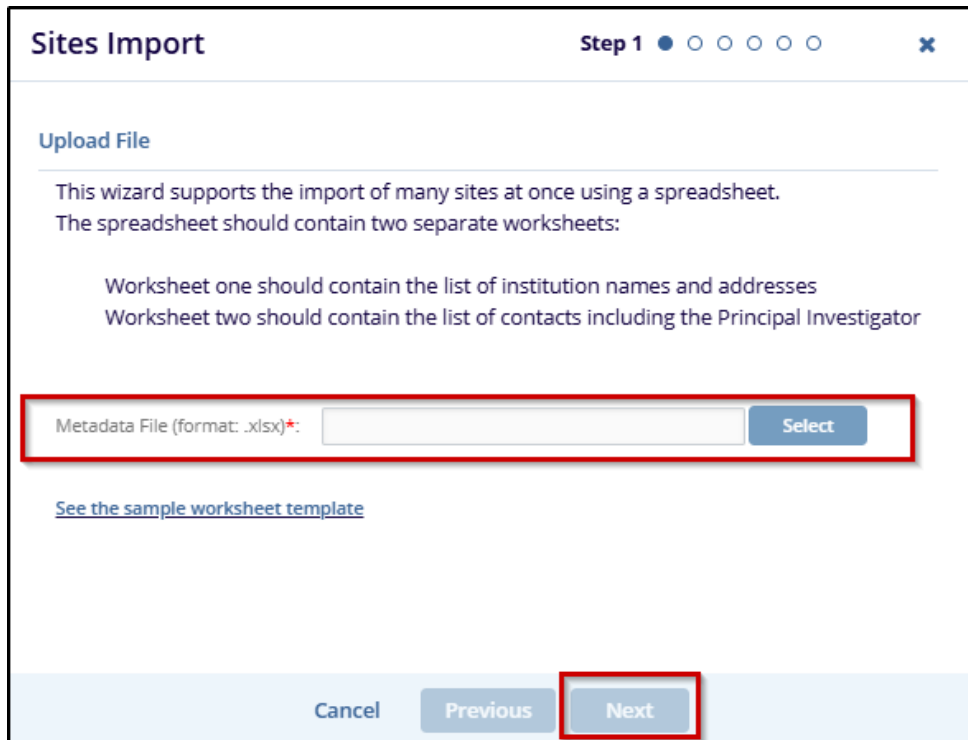
### 93. How to import Sites from eTMF Module

step-by-step guide for importing sites in the eTMF module:

1. In the **eTMF** module sidebar, click on **Sites** to access the site management area.
2. Click the **Import** button at the top of the screen.



3. In the **Sites Import** dialog, click **Select** to upload a metadata file in **.xlsx** format. Ensure that the spreadsheet contains two worksheets:
  - The first worksheet should list institution names and addresses.
  - The second worksheet should list contacts, including the Principal Investigator.

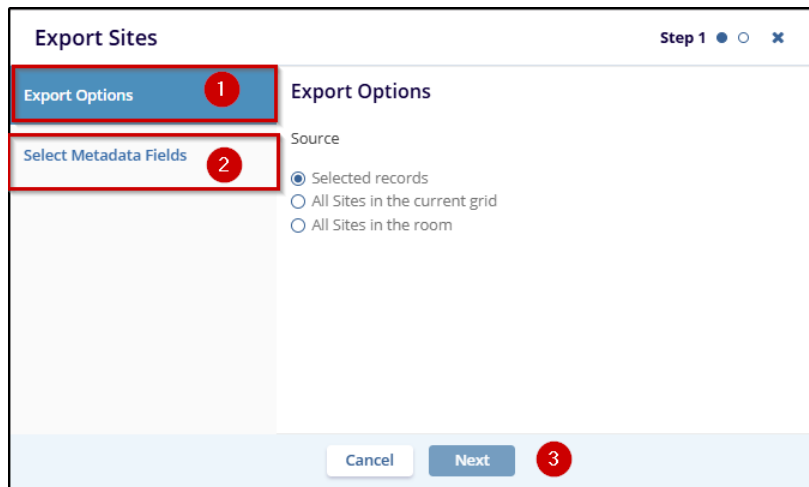
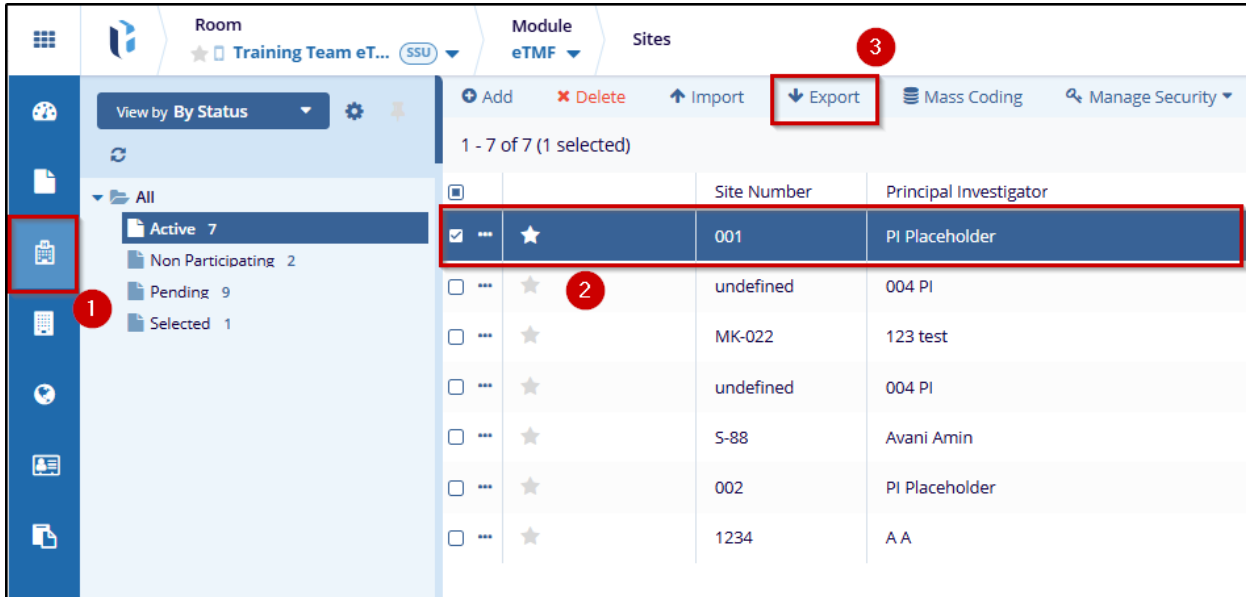


4. After selecting the file, click **Next** to proceed with the import process.

## 94. How to import Sites from eTMF Module

step-by-step guide for exporting sites in the eTMF module:

1. In the **eTMF** module sidebar, go to **Sites** and select the appropriate status folder, such as **Active**.
2. Check the box next to the site(s) you want to export.
3. Click the **Export** button at the top of the screen.



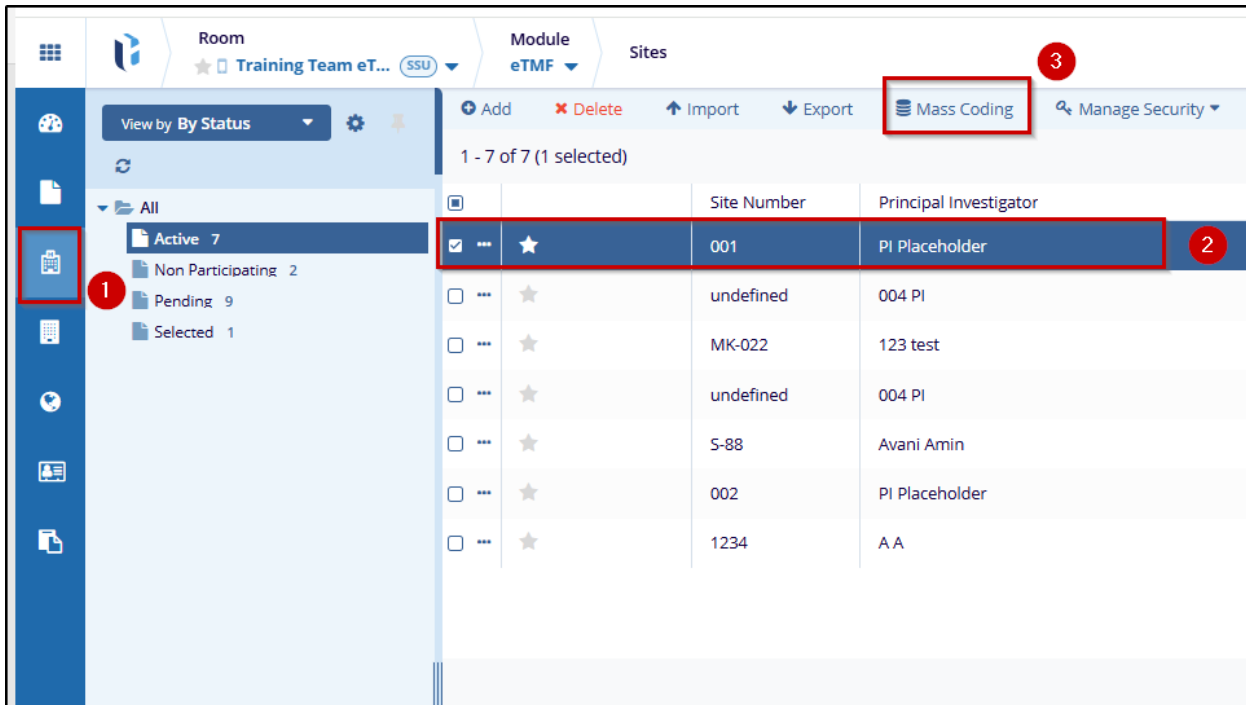
4. In the **Export Sites** dialog, under **Export Options**, choose one of the following sources:
  - **Selected records**
  - **All Sites in the current grid**
  - **All Sites in the room**
5. Click **Next** to proceed.
6. In the **Select Metadata Fields** section, choose the metadata fields you want to include in the export file.
7. Click **Next** to finalize and start the export.

## 95. How to do Mass Coding Sites from eTMF Module

the procedure for performing mass coding for sites in the eTMF module:

1. In the **eTMF** module sidebar, click on **Sites** and select the desired status folder, such as **Active**.
2. Select the site(s) you wish to apply mass coding to by checking the box next to the site name.

3. Click **Mass Coding** at the top of the screen.



4. In the **Mass Coding** dialog, enter the **Mass Coding Reason** (required).
5. Select the relevant fields you want to code, such as **Country**, **Expiration Date**, **CRA**, **Start-Up Specialist**, or any other applicable fields, and fill in the details.
6. Once all information is entered, click Save to apply the mass coding to the selected site(s).



### Mass Coding ✕

The selected site will be processed

Mass Coding Reason \*

Enter Reason

Country

Expiration Date

CRA

Start-Up Specialist

Reg Pack Sent Date

Expected Submission Date

IRB/EC Submit Date

IRB/EC Approval Date

Country Approval Date

Cancel Reset **Save**

### Mass Coding ✕

The selected site will be processed

Mass Coding Reason \*

Enter Reason

- Country  

▼
- Expiration Date  

dd MMM yyyy 📅 ✕
- CRA  

...
- Start-Up Specialist  

...
- Reg Pack Sent Date  

dd MMM yyyy HH:mm:ss 📅 ✕
- Expected Submission Date  

dd MMM yyyy 📅 ✕
- IRB/EC Submit Date  

dd MMM yyyy 📅 ✕
- IRB/EC Approval Date  

dd MMM yyyy 📅 ✕
- Country Approval Date  

dd MMM yyyy 📅 ✕

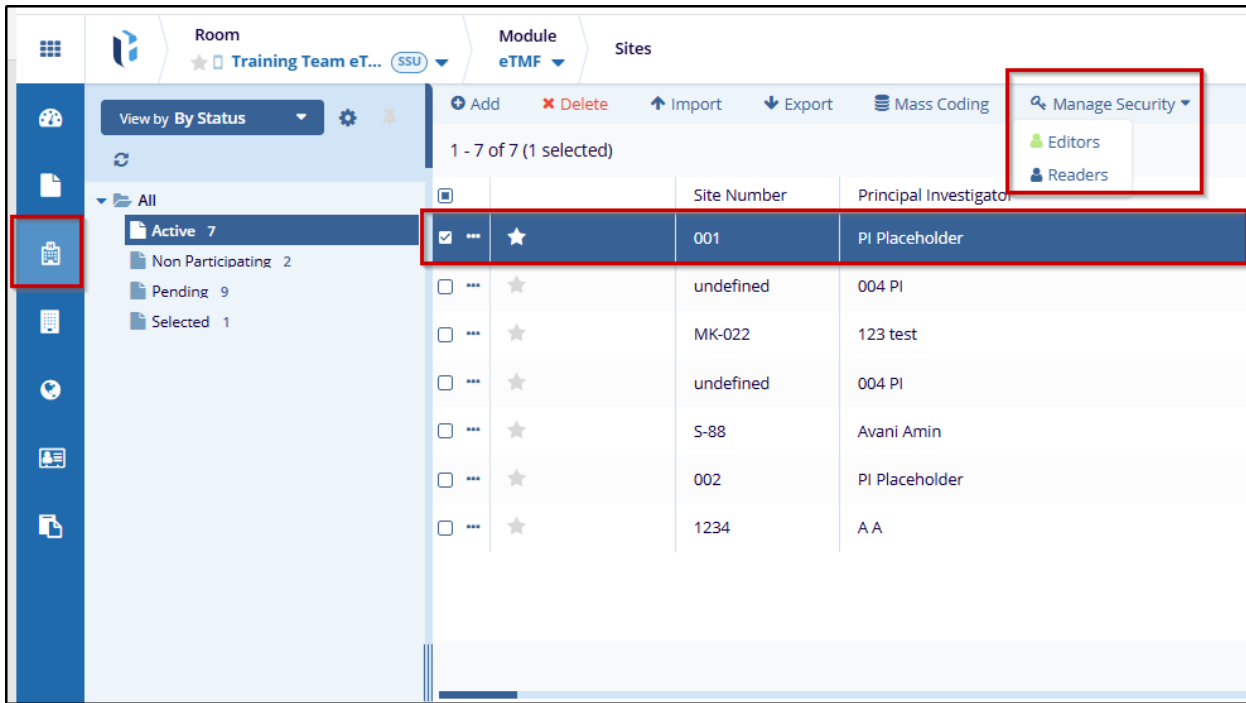
Cancel
Reset

Save

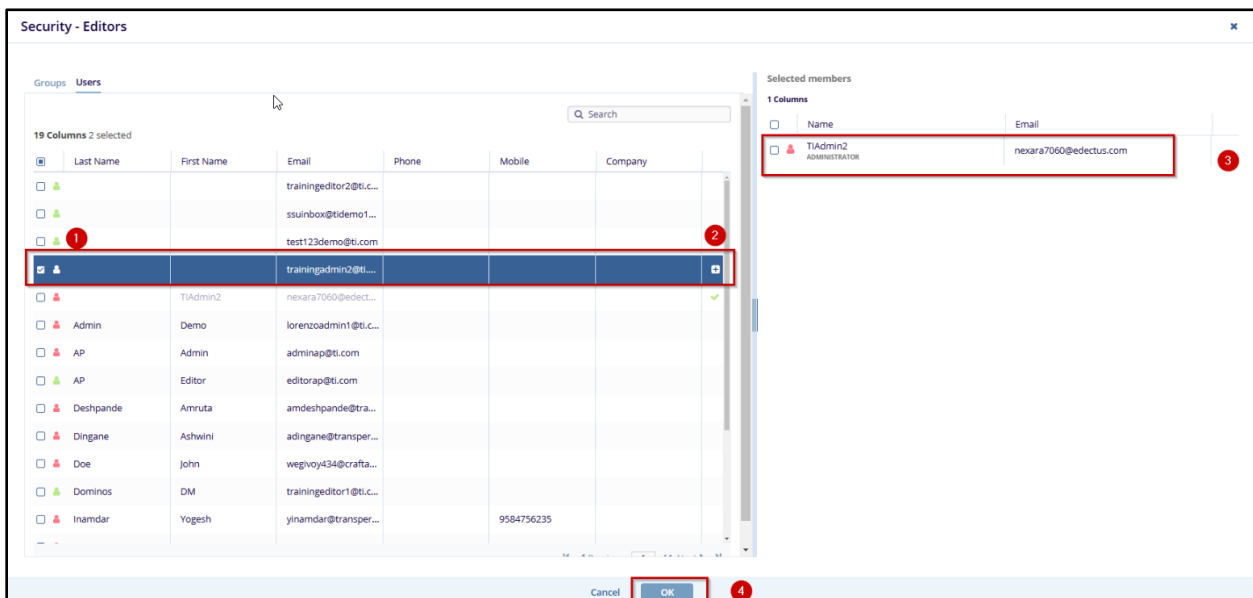
96. How to Manage Security of Sites in eTMF Module:

the procedure for managing security settings for sites in the eTMF module:

1. In the **eTMF** module sidebar, navigate to **Sites** and select the desired status folder, such as **Active**.
2. Check the box next to the site for which you want to manage security.
3. Click **Manage Security** at the top of the screen, and choose either **Editors** or **Readers** to manage permissions for those role.
- 4.



5. In the **Security - Editors** or **Security - Readers** dialog, switch to the **Users** tab.
6. Select the user(s) you want to add by checking the box next to their name in the user list.

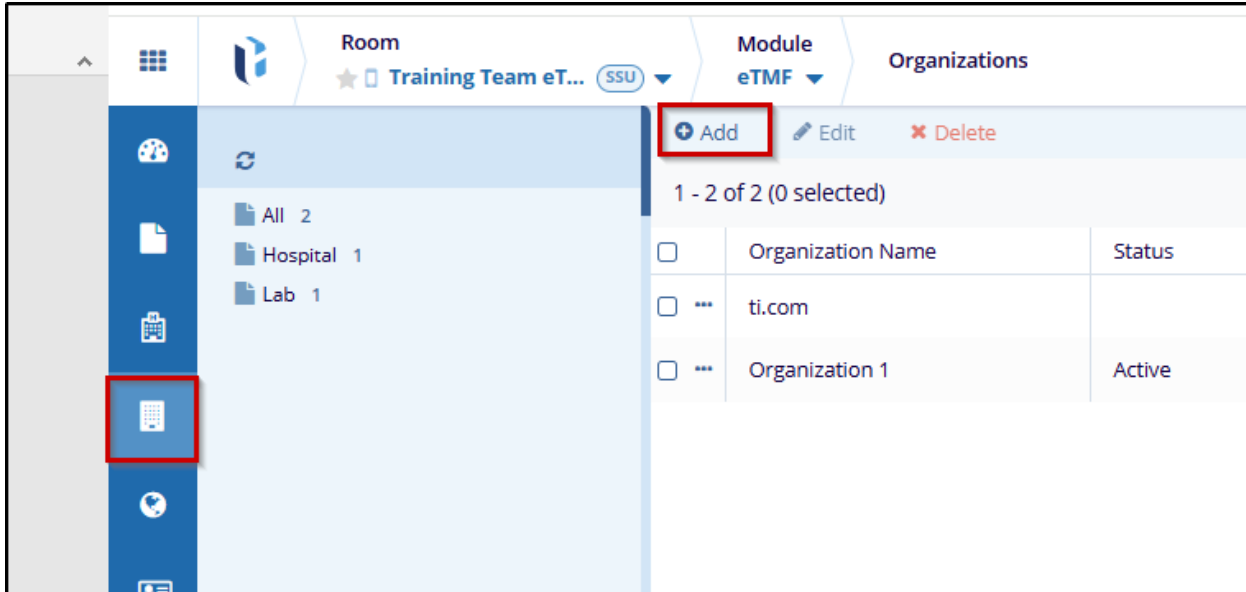


7. The selected user(s) will appear in the **Selected members** section on the right.
8. Click **OK** to save the changes.

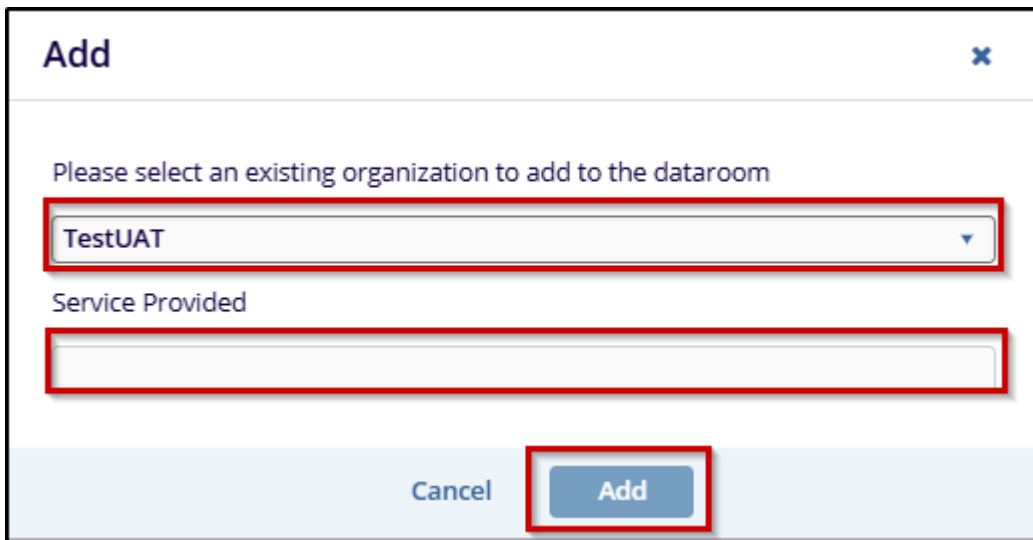
## Organization in eTMF module

### 97. How to Create an Organization in eTMF Module

1. In the eTMF module, go to the sidebar and click on the Organizations icon, represented by a grid symbol.
2. At the top of the grid, click on the Add button to open the Add Organization window.



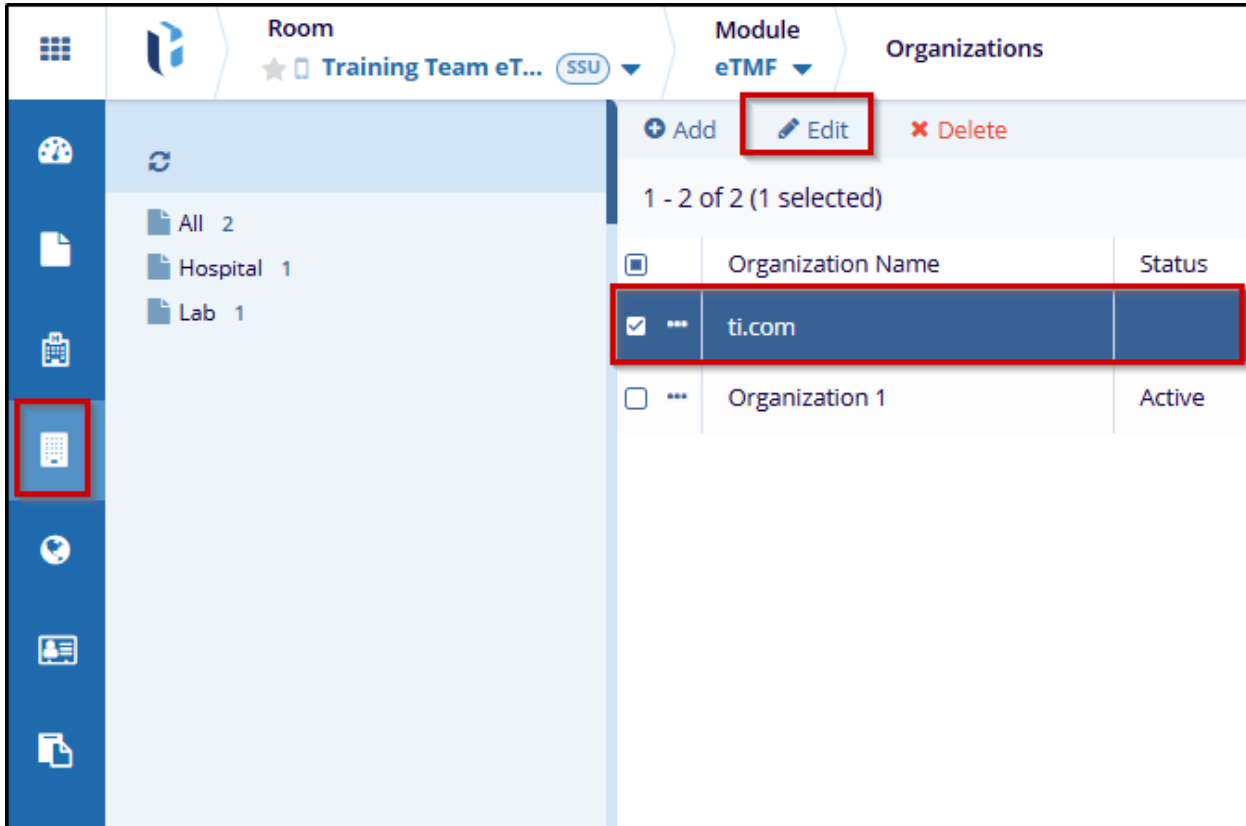
3. In the pop-up window, select an existing organization from the drop-down list labeled "Please select an existing organization to add to the dataroom."
4. "Enter the relevant information in the Service Provided field to specify the service offered by the organization."



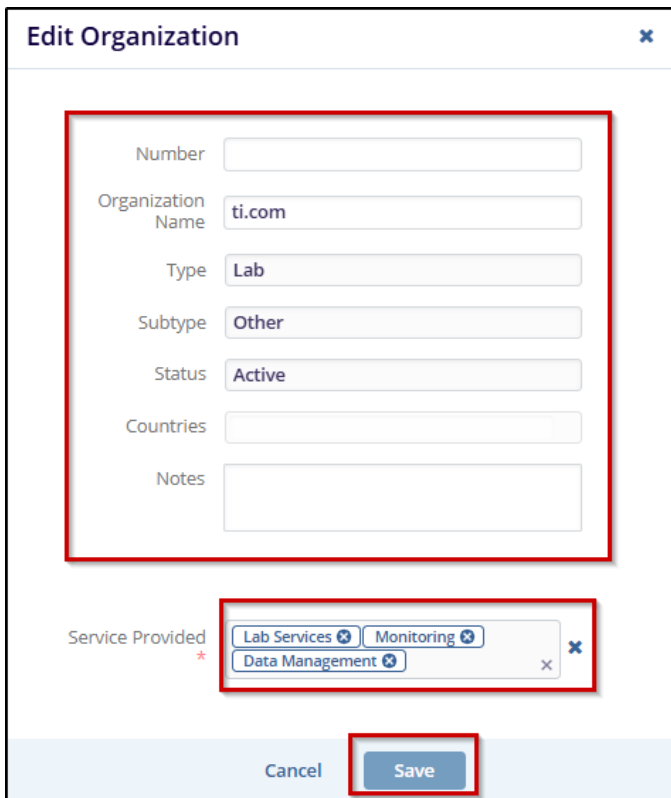
5. Click the Add button at the bottom of the window to add the selected organization to the dataroom.

### 98. How to Edit an Organization in eTMF Module

1. In the eTMF module, go to the sidebar and click on the Organizations icon, represented by a grid symbol.
2. In the organizations list, select the organization you want to edit by checking the box next to its name.
3. At the top of the grid, click on the Edit button to open the Edit Organization window.



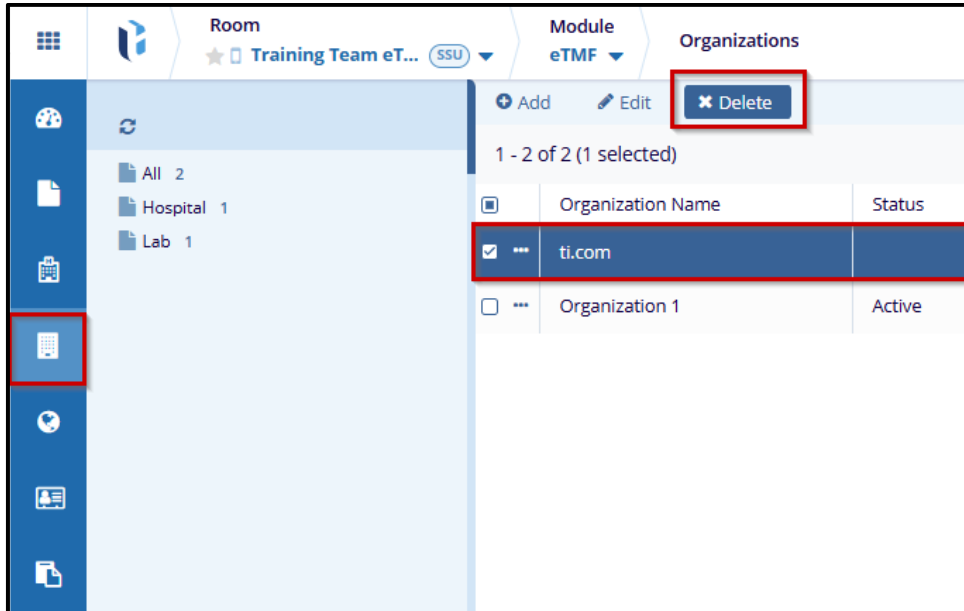
- In the Edit Organization window, make the necessary changes to the organization details, such as Number, Organization Name, Type, Subtype, Status, Countries, and Notes.
- In the Service Provided field, update the services by adding or removing options as required.



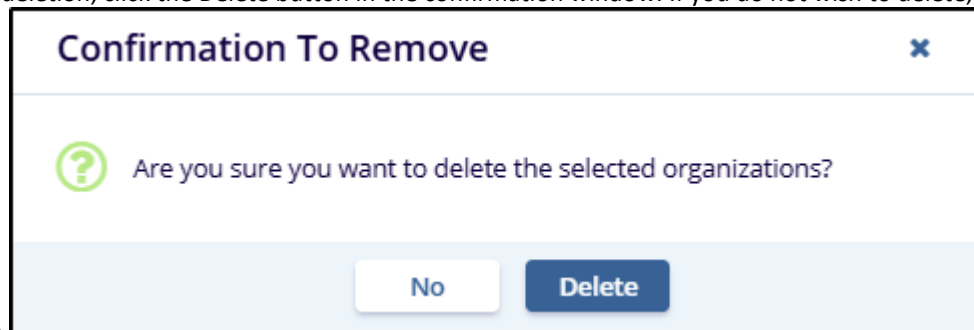
- Once all changes are made, click the Save button at the bottom of the window to apply the updates.

## 99. How to Delete Organization in eTMF Module

1. In the eTMF module, go to the sidebar and click on the Organizations icon, represented by a grid symbol.
2. In the organizations list, select the organization you want to delete by checking the box next to its name.
3. At the top of the grid, click on the Delete button.



4. A confirmation window will appear with the message, "Are you sure you want to delete the selected organizations?"
5. To proceed with deletion, click the Delete button in the confirmation window. If you do not wish to delete, click No to



cancel the action.

## Managing Countries in the eTMF Module

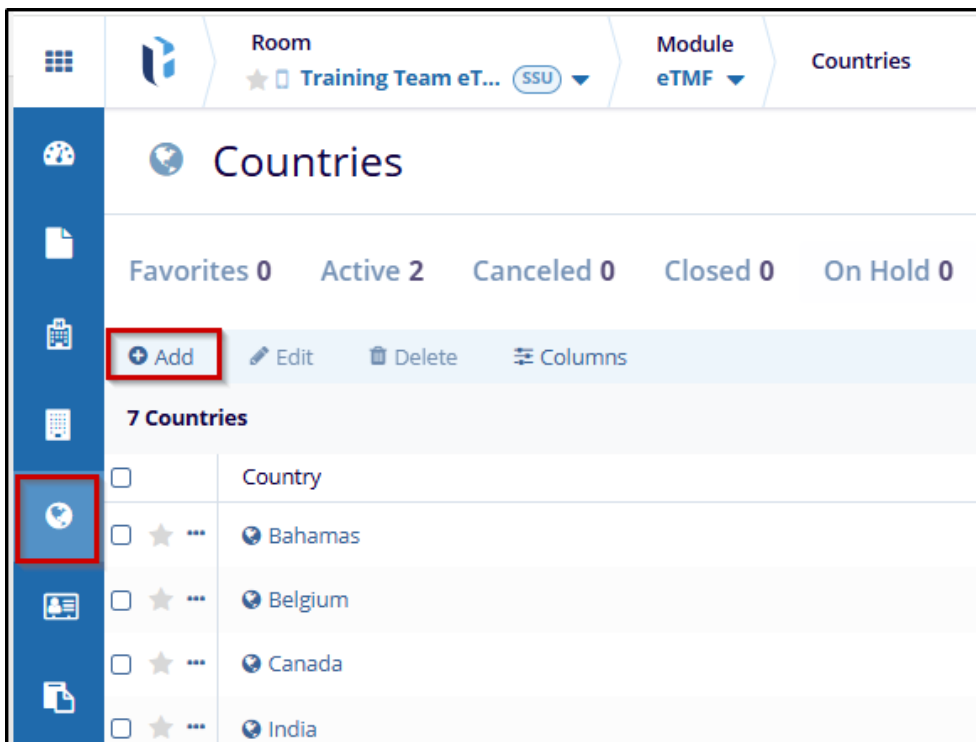
1. **Access the Countries List:** In the eTMF module, go to the sidebar and click on the **Countries** icon. This will display the list of countries with details such as **Status, Sites, Requirements, and Language**.
2. **Add a New Country:** To add a new country, click the **Add** button at the top of the countries grid. A pop-up window will appear where you can enter the country details, such as country name, status, and other relevant information. Click **Save** to add the country.
3. **Edit an Existing Country:** To edit a country, select the desired country by checking the box next to its name, then click the **Edit** button. In the **Edit Country** window, make the necessary changes and click **Save** to apply the updates.
4. **Delete a Country:** To delete a country, select it by checking the box next to its name and click the Delete button. A confirmation window will appear with the message, "Are you sure you want to delete the selected countries?" Click Delete to confirm, or No to cancel.

5. **Filter and Search:** Use the Filters and Search options at the top right to narrow down the list of countries based on specific criteria or keywords. This helps quickly locate the desired country or set of countries.
6. **View Country Details:** The grid displays columns such as Status (e.g., Active, Planned, Submitted), Sites (number of associated sites), Requirements (associated requirements), and Language (languages used in the country). Customize the view using the Columns option to display or hide specific columns as needed.
7. **Change View:** Use the Views option to switch between different saved views, allowing you to organize and display country information according to your preferences.

## 100. How to Add Countries in the eTMF Module

To add a country in the eTMF module, follow these steps:

1. In the eTMF module, go to the sidebar and click on the Countries icon, represented by a globe symbol.
2. At the top of the countries list, click on the Add button. This will open the Add Country window.



3. In the Add Country window, select a country from the Country drop-down list.
4. Optionally, fill in additional details:
  - o Expected Approval Date: Enter the expected approval date.
  - o Languages: Specify the languages relevant to the country.
  - o Country Comments: Add any comments related to the country.
  - o Room Contact #: Enter the room contact number if applicable.

5. Once all necessary information is entered, click the **Save** button to add the country to the list.

## 101. How to Edit Countries in the eTMF Module

To edit a country in the eTMF module, follow these steps:

1. In the eTMF module, go to the sidebar and click on the Countries icon, represented by a globe symbol.
2. In the list of countries, locate and select the country you wish to edit by checking the box next to its name.
3. At the top of the grid, click on the Edit button. This will open the Edit Country panel on the right side of the screen.

Country	Status	Sites	Requirements	Language
Bahamas	PLANNED	0	0	English
Belgium	ACTIVE	0	0	German, French, Dutch
Canada	ACTIVE	1	0	English, French
India	PLANNED	2	0	English, Hindi
Spain	ACTIVE	3	0	Asturian, Catalan, Spanish, Basque
United Kingdom	PLANNED	0	0	Welsh, English, Irish, Gaelic, Cornish
United States	SUBMITTED	10	0	English

4. In the Edit Country panel, make the necessary changes:
  - Under General Information, update the Country name and Status if needed.

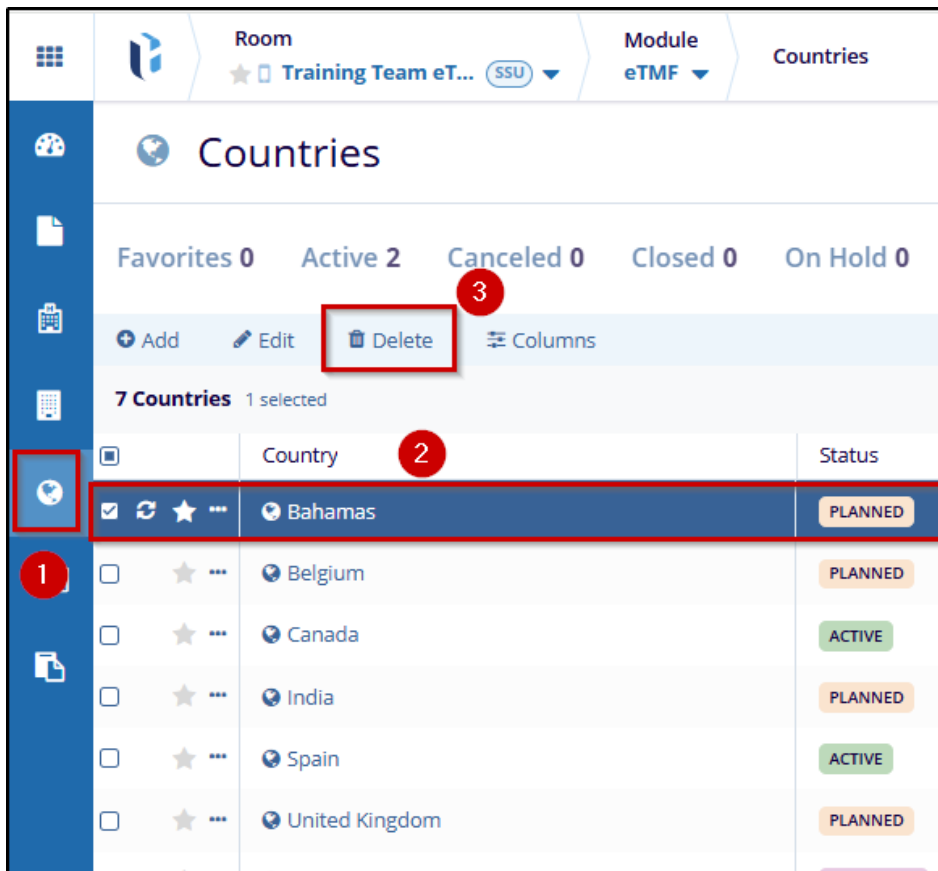


- Add or modify Country Comments as required.
  - In Additional Information, you can set or update the Expected Approval Date.
5. Once you have made the desired changes, click Save to apply the updates, or Save & Next if you want to edit the next country in the list.

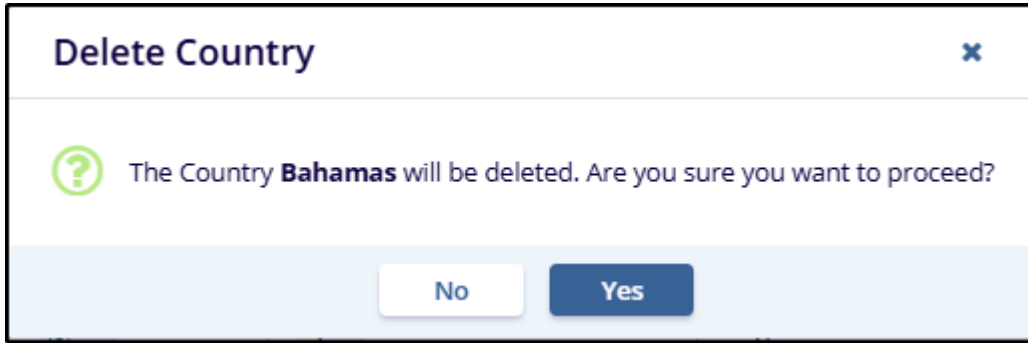
## 102. How to Delete a Countries in eTMF Module

To remove a country in the eTMF module, follow these steps:

1. In the eTMF module, go to the sidebar and click on the Countries icon, represented by a globe symbol.
2. In the list of countries, locate and select the country you wish to remove by checking the box next to its name.



3. At the top of the grid, click on the Delete button.
4. A confirmation window will appear with the message, "The Country [Country Name] will be deleted. Are you sure you want to proceed?"



### 103. How to Manage Column for Countries in eTMF Module

1. In the eTMF module, go to the relevant Countries in the sidebar.
2. Click on the Columns button in the toolbar at the top of the grid.
3. In the Manage Columns dialog, locate the Available Columns list on the left side.
4. To add a column, check the box next to the desired column name in the Available Columns list.
5. The selected column will move to the Selected Columns list on the right.
6. Use the Move Up and Move Down buttons to arrange the columns in the desired order in the Selected Columns list.
7. Adjust the width of each column as needed by entering a value in the Width field.
8. Click Save Changes to apply and save the updated column layout.
9. (Optional) If you want to save this arrangement as a custom view, click Set View before saving changes.

Room: Training Team eT... (SSU) | Module: eTMF | Countries

## Countries

Favorites 0 | Active 2 | Canceled 0 | Closed 0 | On Hold 0

+ Add | Edit | Delete | **Columns** 3

**7 Countries** 1 selected

<span style="border: 1px solid red; border-radius: 50%; padding: 2px;">1</span>	Country <span style="border: 1px solid red; border-radius: 50%; padding: 2px;">2</span>	Status
<input checked="" type="checkbox"/>	Bahamas	PLANNED
<input type="checkbox"/>	Belgium	PLANNED
<input type="checkbox"/>	Canada	ACTIVE
<input type="checkbox"/>	India	PLANNED
<input type="checkbox"/>	Spain	ACTIVE
<input type="checkbox"/>	United Kingdom	PLANNED

### Manage Columns

Available Columns

14 Columns

- Title
- 1st Site Activated 3
- Agency Submission
- Approved Date
- Country
- Country
- Expected Approval Date
- Is Favorite
- Language
- Languages
- Progress %
- Requirements
- Room Contact #
- Sites
- Status

Selected Columns

6 Columns

	Name	Width
<input type="checkbox"/>	Is Favorite	30
<input type="checkbox"/>	Country	80
<input type="checkbox"/>	Status	50
<input type="checkbox"/>	Sites	30
<input type="checkbox"/>	Requirements	50
<input type="checkbox"/>	Language	50

## CHAPTER 7: SITES, REQUIRED DOCUMENTS, COUNTRIES AND CONTACTS

### Sites

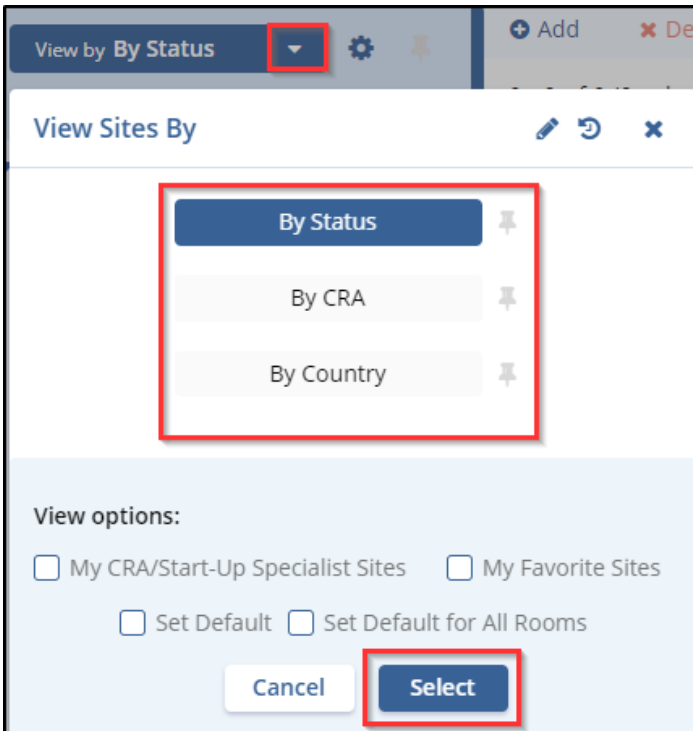
You can access the Sites module by clicking Sites icon on the left menu bar in the eTMF/ Documents module. In order for users to access the sites module, they will need to be added to the Sites Team group in Users Management. Please note that the name of this group may vary based on your instance but this is a system group.



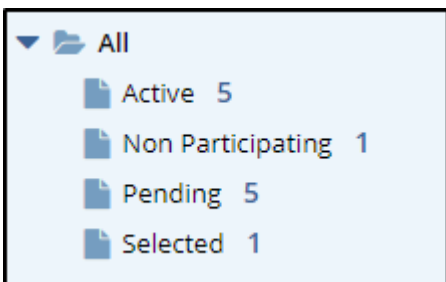
The Sites module is used for site management purposes and allows users to track the progress of the sites. It gives a detailed information on all investigation sites available in a room By Status, By CRA, By Country.

104. 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.

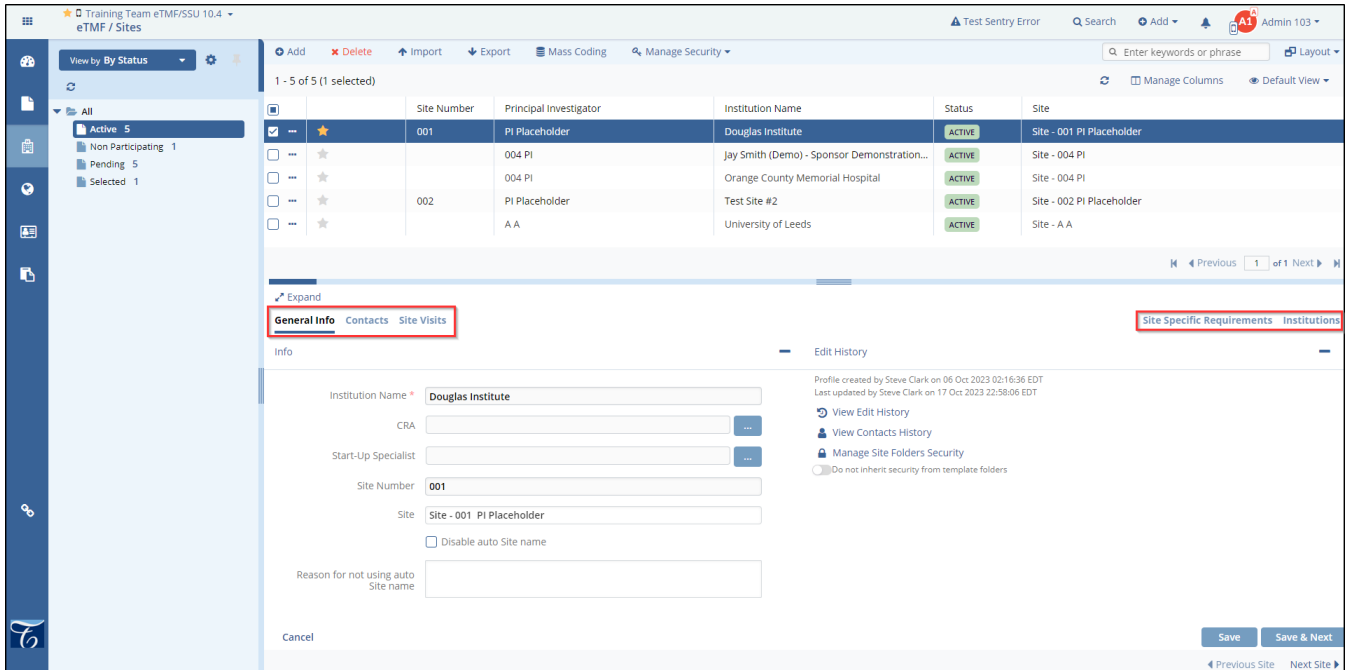


When you have chosen your view, the sites will be displayed in a related folder structure in the index pane on the left side of the screen.



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:



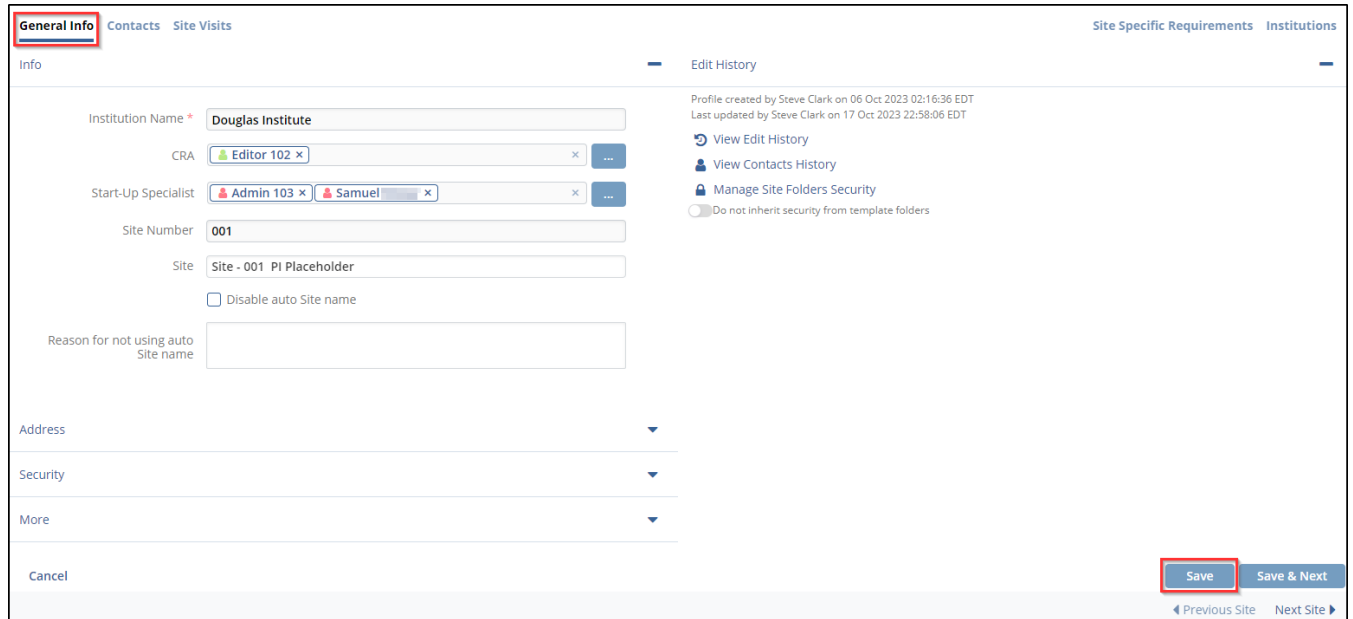
The Site Profile window provides the following:

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.

## 105. 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:



The screenshot shows the 'General Info' tab selected. The 'Info' section is expanded, displaying the following fields:

- Institution Name:
- CRA:
- Start-Up Specialist:
- Site Number:
- Site:
- Disable auto Site name
- Reason for not using auto Site name:

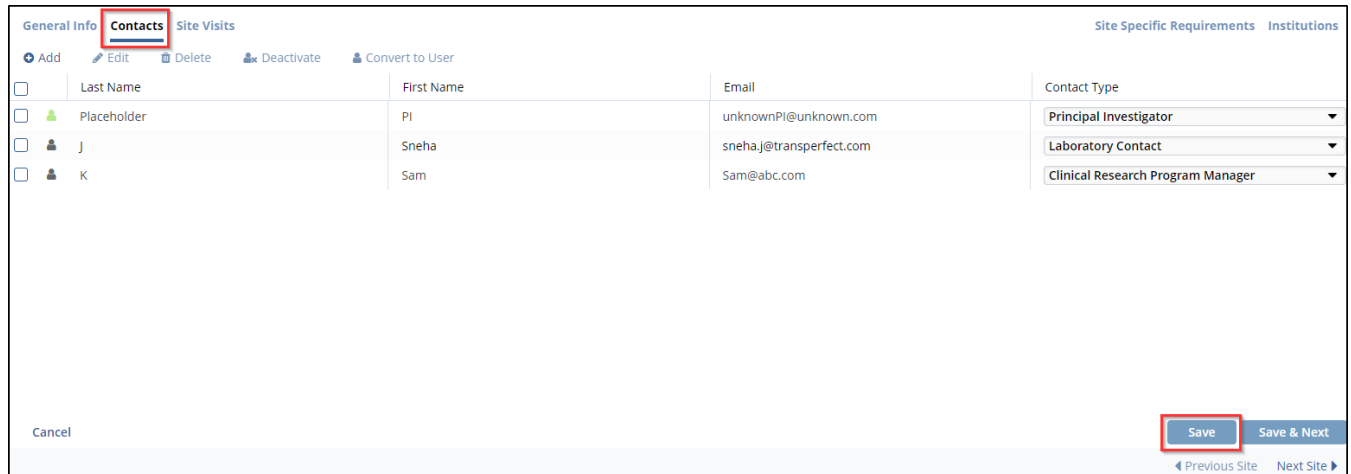
The 'Address', 'Security', and 'More' sections are collapsed. The 'Save' button is highlighted with a red box.

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.

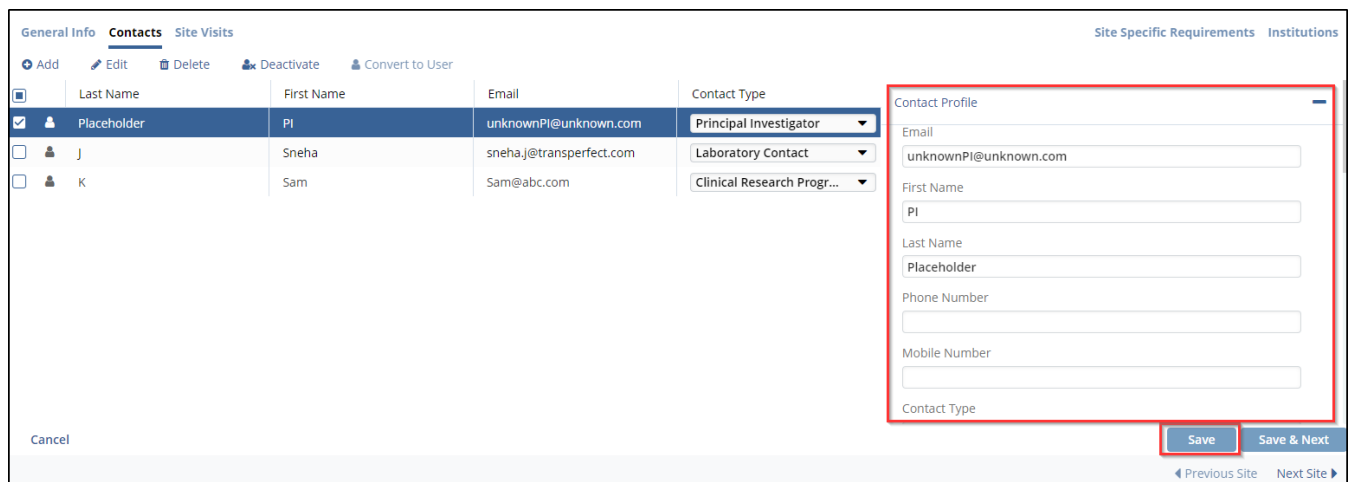
**Note:** Only room administrators can access the Security area of the site profile.

## 106. 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:



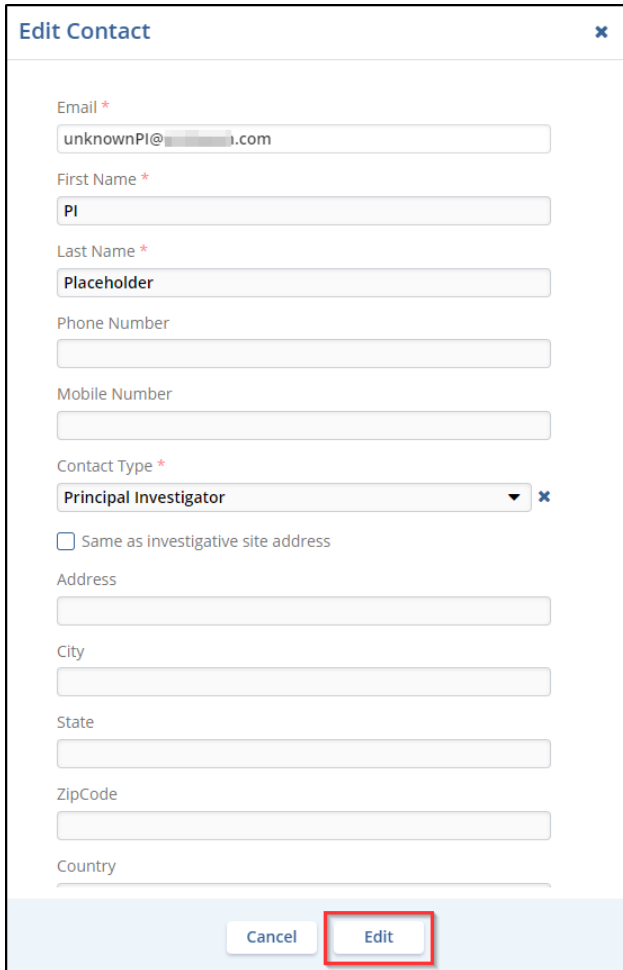
Select the checkbox of the contact profile that needs to be edited. The Contact Profile opens on the right side of the screen. Once all the details are updated, click Save to save the changes. Refer to the screenshot below:





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.



**Edit Contact** [X]

Email \*  
unknownPI@.com

First Name \*  
PI

Last Name \*  
Placeholder

Phone Number

Mobile Number

Contact Type \*  
Principal Investigator [X]

Same as investigative site address

Address

City

State

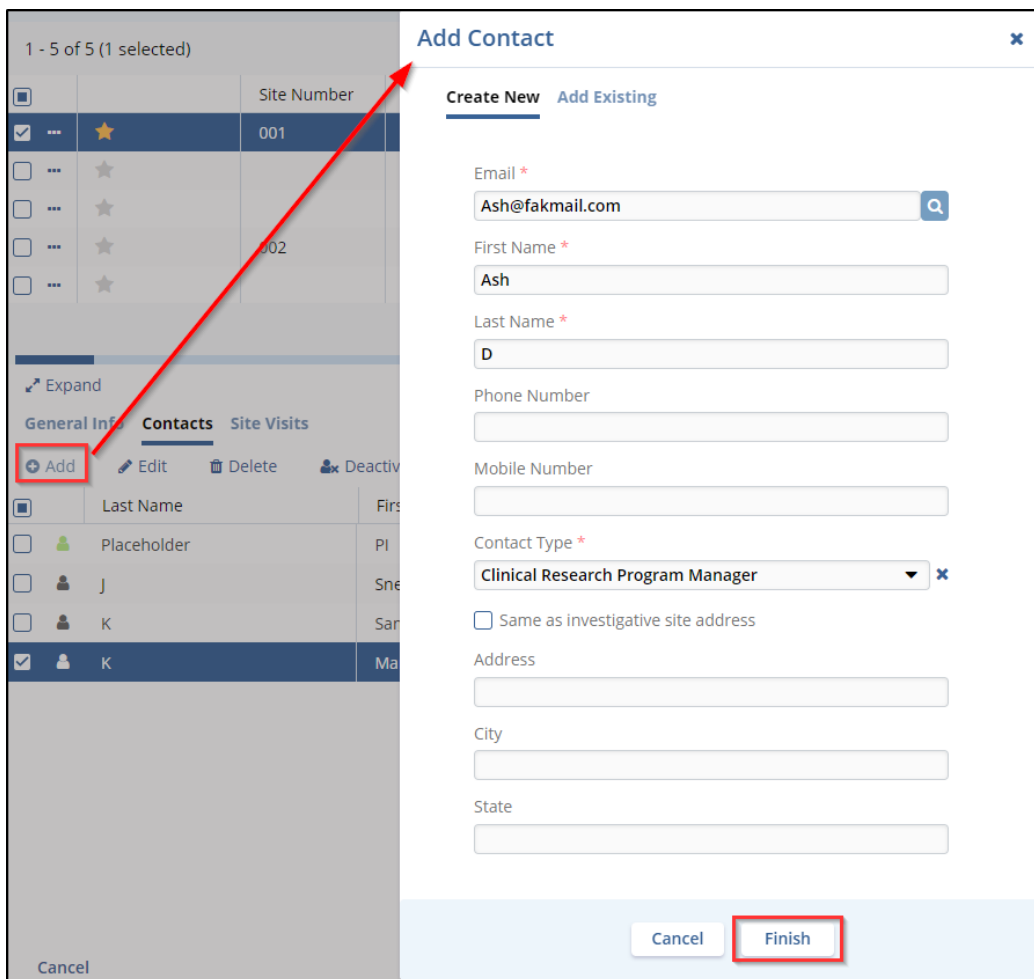
ZipCode

Country

Cancel Edit

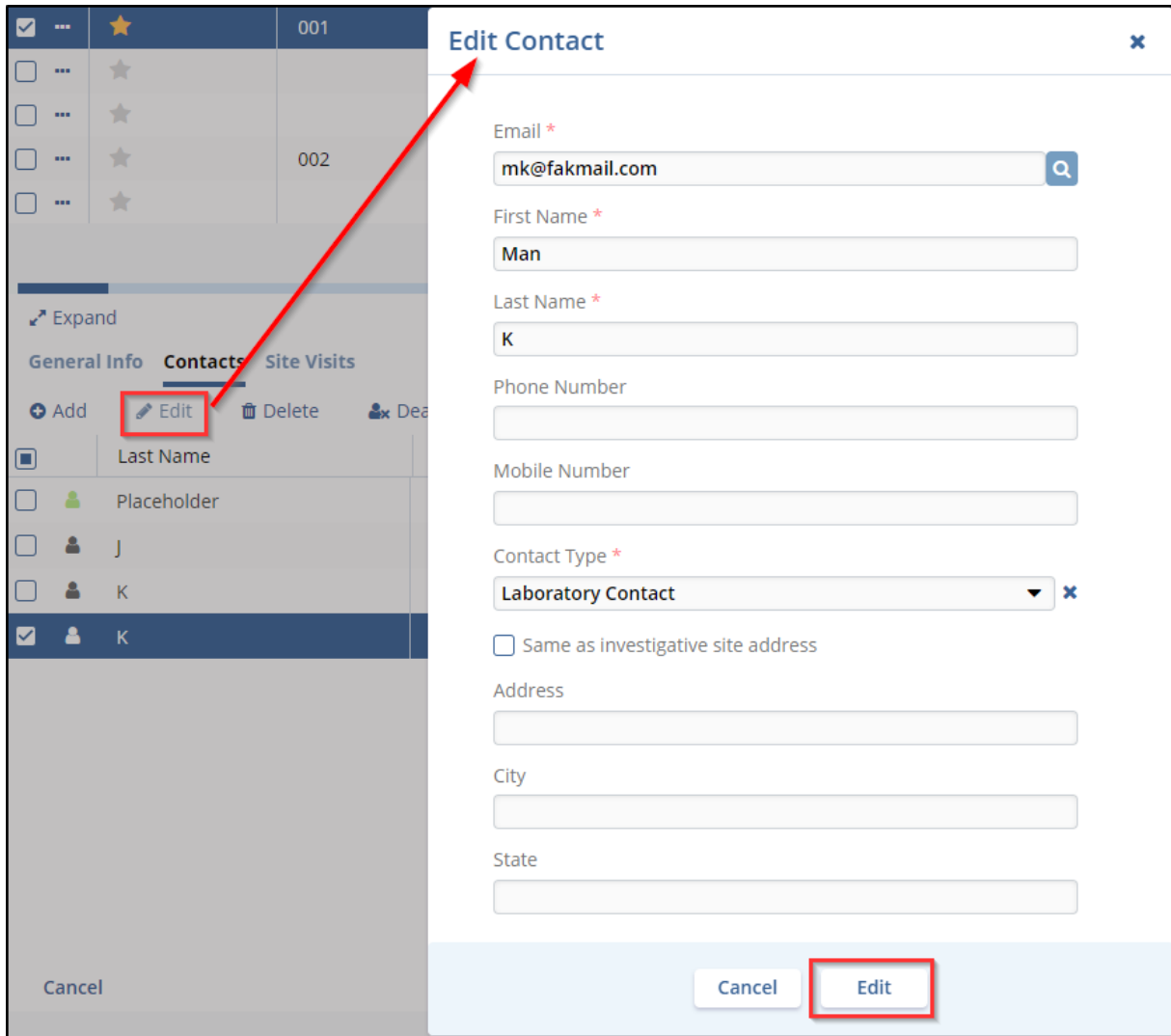
*Add a Contact*

- 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.



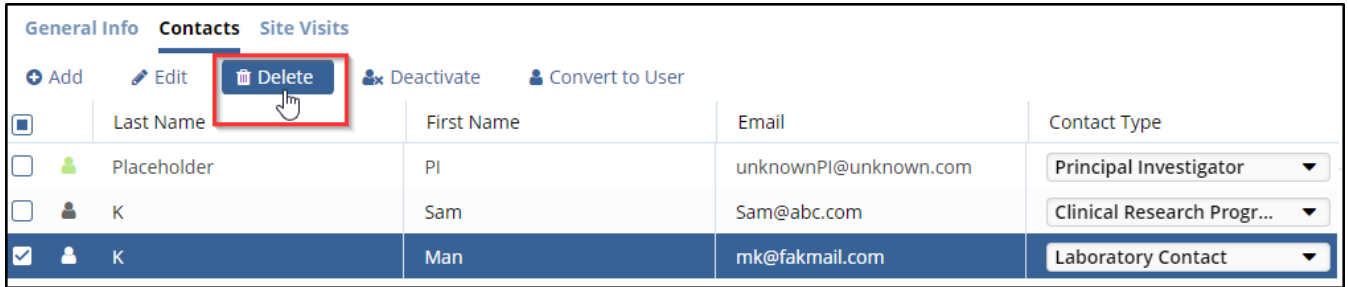
*Edit a Contact*

- 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.

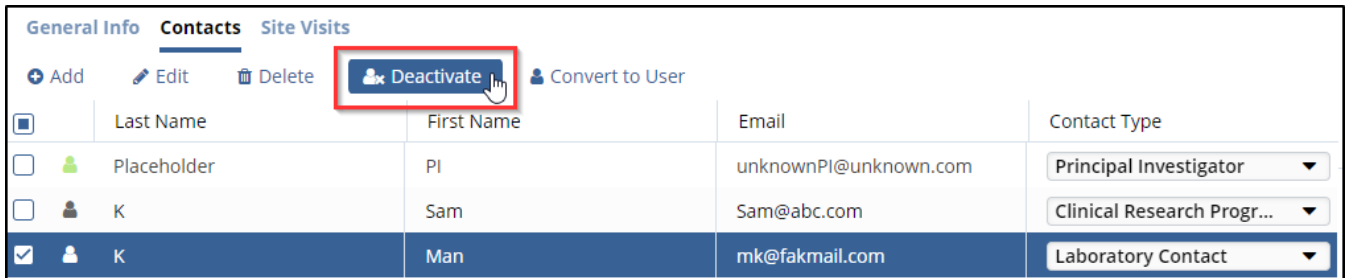


The screenshot shows the 'Contacts' tab in a software interface. At the top, there are tabs for 'General Info', 'Contacts', and 'Site Visits'. Below the tabs are action buttons: '+ Add', 'Edit', 'Delete' (highlighted with a red box and a mouse cursor), 'Deactivate', and 'Convert to User'. Below the buttons is a table with columns: 'Last Name', 'First Name', 'Email', and 'Contact Type'. The table contains three rows: a 'Placeholder' row, a row for 'K' with email 'Sam@abc.com', and a selected row for 'K' with email 'mk@fakmail.com' and 'Contact Type' 'Laboratory Contact'.

	Last Name	First Name	Email	Contact Type
<input type="checkbox"/>	Placeholder	PI	unknownPI@unknown.com	Principal Investigator
<input type="checkbox"/>	K	Sam	Sam@abc.com	Clinical Research Progr...
<input checked="" type="checkbox"/>	K	Man	mk@fakmail.com	Laboratory Contact

### Deactivate a Contact

Select an added contact and click the Deactivate button in the Contacts tab to deactivate the contact.



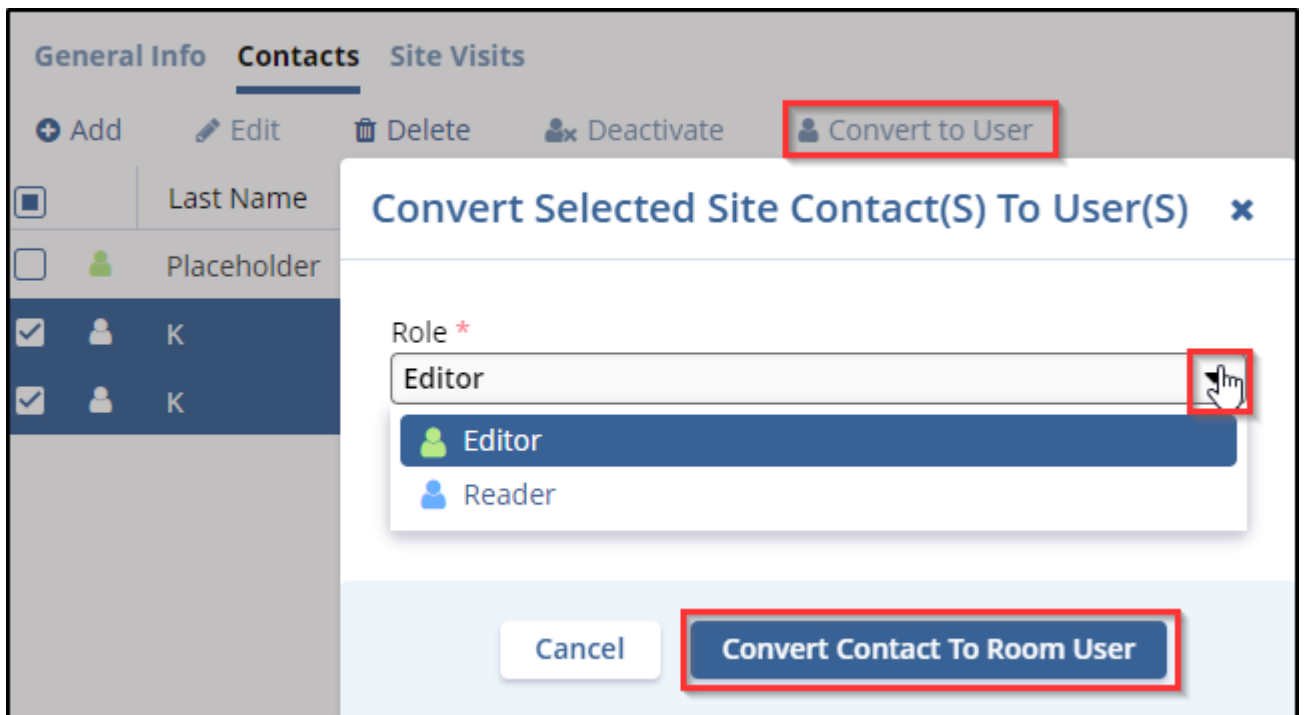
The screenshot shows the 'Contacts' tab in a software interface. At the top, there are tabs for 'General Info', 'Contacts', and 'Site Visits'. Below the tabs are action buttons: '+ Add', 'Edit', 'Delete', 'Deactivate' (highlighted with a red box and a mouse cursor), and 'Convert to User'. Below the buttons is a table with columns: 'Last Name', 'First Name', 'Email', and 'Contact Type'. The table contains three rows: a 'Placeholder' row, a row for 'K' with email 'Sam@abc.com', and a selected row for 'K' with email 'mk@fakmail.com' and 'Contact Type' 'Laboratory Contact'.

	Last Name	First Name	Email	Contact Type
<input type="checkbox"/>	Placeholder	PI	unknownPI@unknown.com	Principal Investigator
<input type="checkbox"/>	K	Sam	Sam@abc.com	Clinical Research Progr...
<input checked="" type="checkbox"/>	K	Man	mk@fakmail.com	Laboratory Contact

*Convert to User(s)*

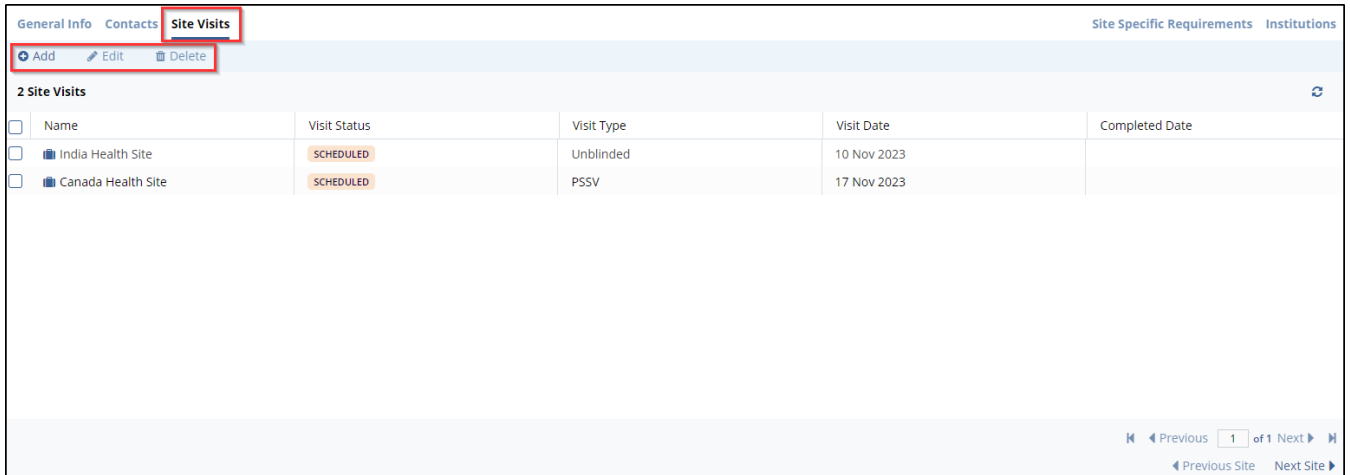
You can assign a site contact the role of editor or reader and assign actions as appropriate from the Convert to User(s) utility in the Contacts tab. Follow the steps below to convert the user(s):

- 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.



107. Site Profile – Site Visits

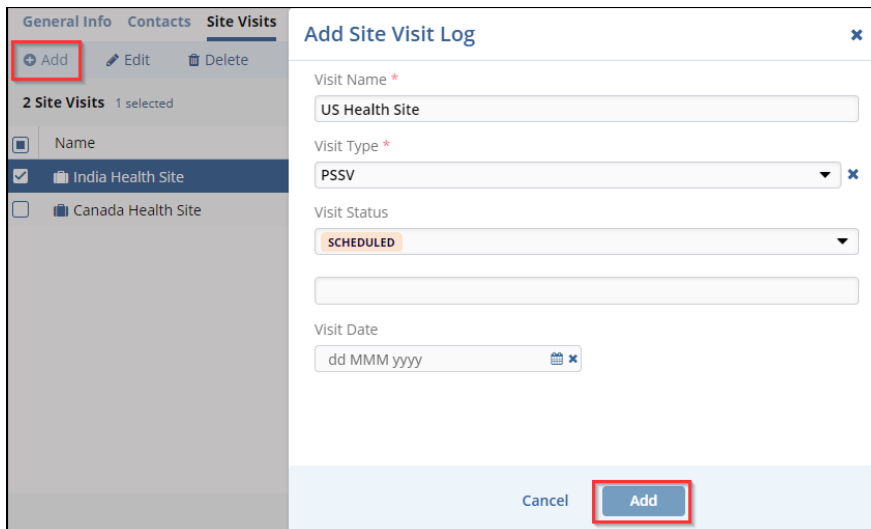
This section displays the list of site visits that are added to a site. From here, the user can add, edit, and delete site visits. Refer to the screenshot below:



*Add a Site Visit Log*

The user can add a site visit log by following the steps mentioned below:

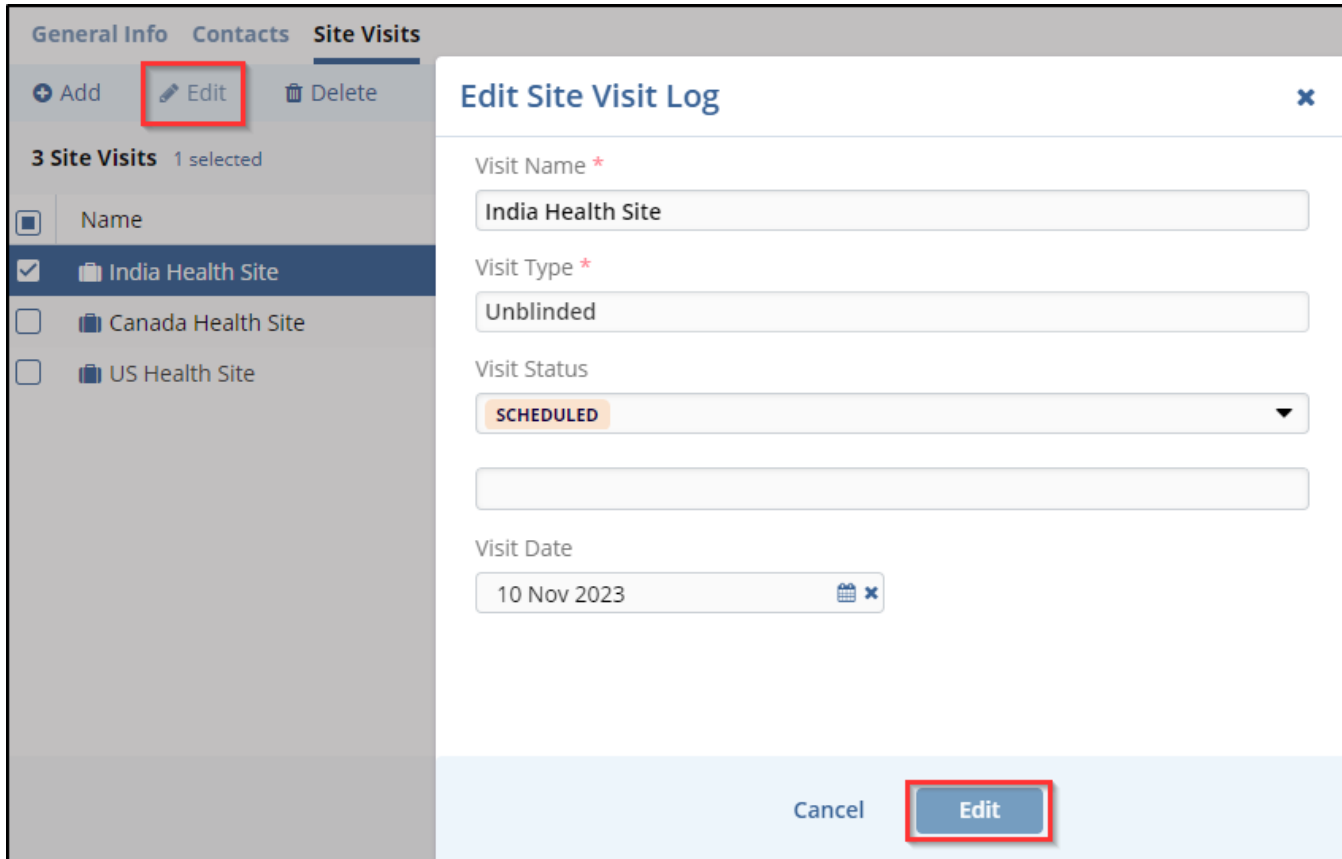
- Click the **Add** button displayed in the top menu bar of the Site Visits tab.
- Enter the details in the fields marked with an asterisk (\*) – Visit Name, Visit Type.
- (Optional) The Visit status and Visit Date fields are optional.
- Click the **Add** button displayed at the bottom of the window.



*Edit a Site Visit Log*

The user can edit a site visit log by following the steps mentioned below:

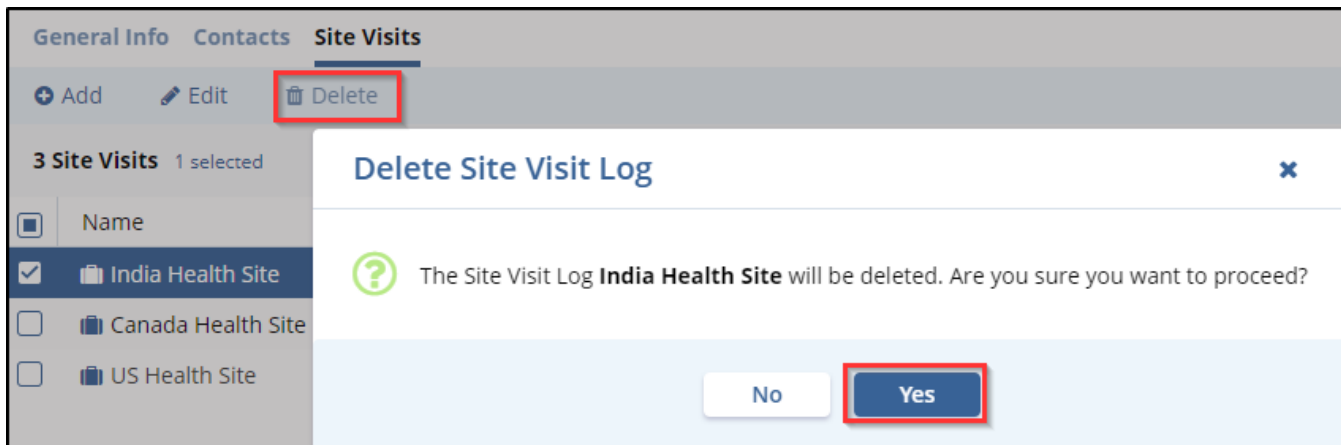
- Select the checkbox of the site that is to be edited.
- Click the **Edit** button displayed in the top menu bar of the Site Visits tab.
- Make the required changes in the Edit Site Visit Log popup window.
- Click the **Edit** button displayed at the bottom of the window.



### 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.



### 108. Site Profile - Site Specific Requirements

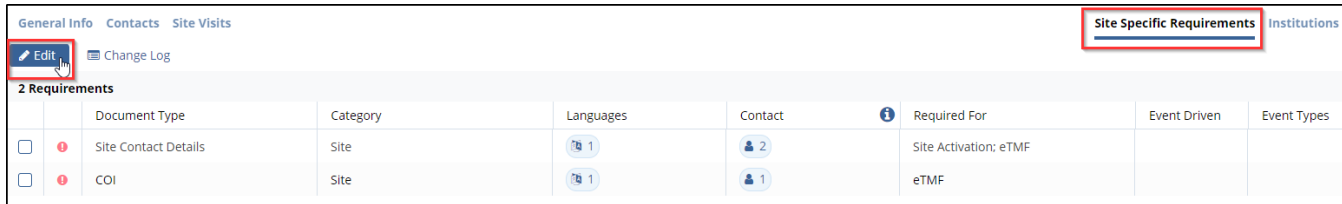
This section displays the list of all the Site-Specific Required documents. From here, the user can Add, Edit, and Remove the site visit documents, Assign Milestones to the documents, and view the Change Log History of the selected documents.



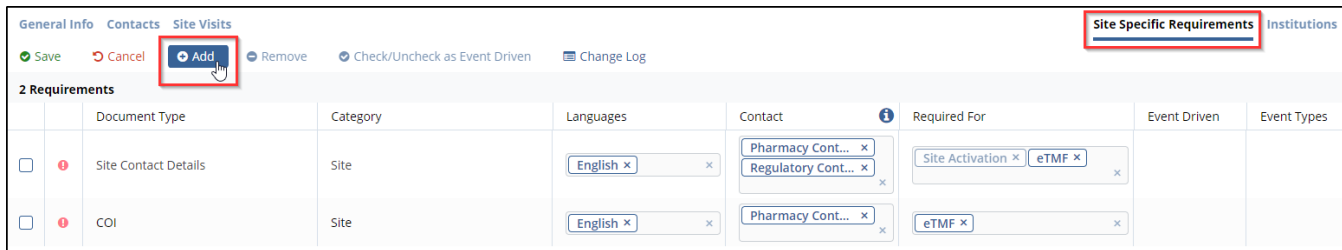
### Add Site Specific Requirements

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.

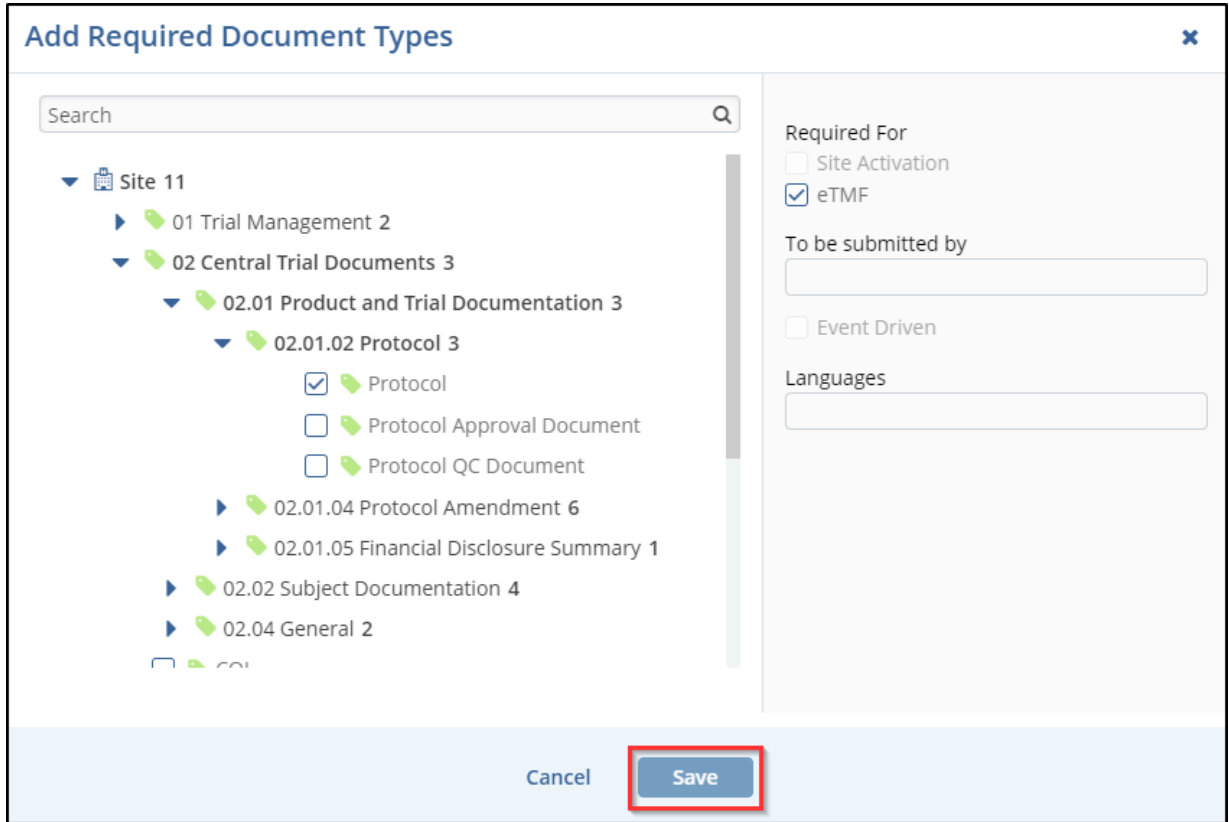


- Click the **Add** button now displayed in the menu bar.



- 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.

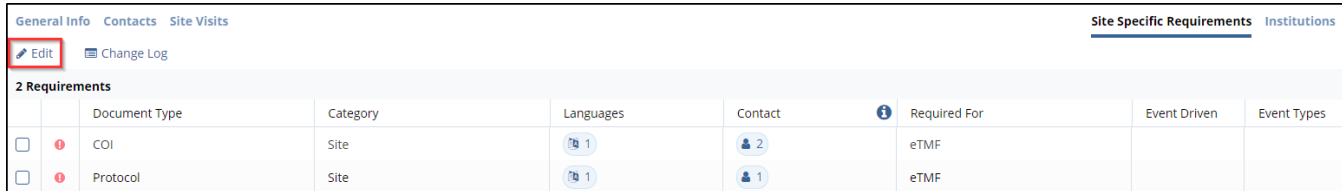


- Again, click the **Save** button displayed in the top menu bar.

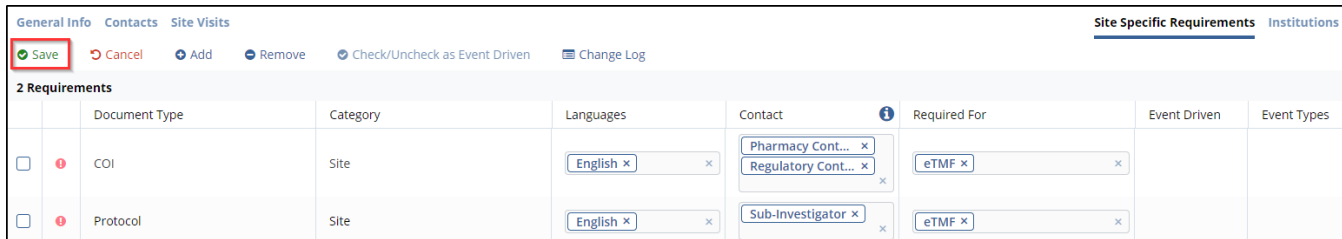
### Edit Site Specific Requirements

Follow the steps mentioned below to edit the site specific requirements:

- Click the **Edit** button displayed on the top menu bar.



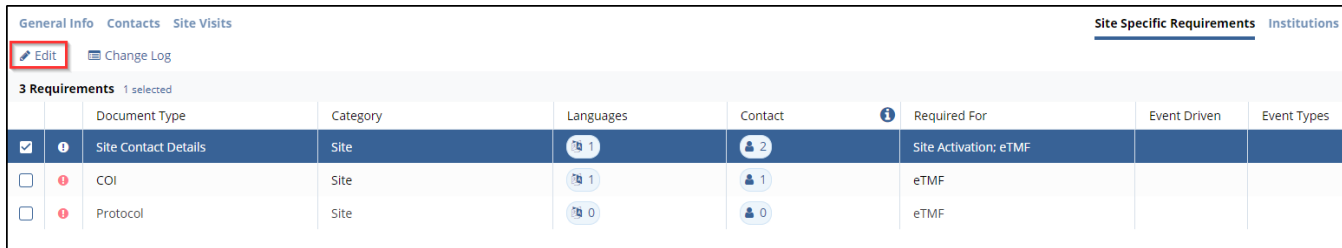
- Make the required changes in the fields.
- Click the **Save** button displayed on the top menu bar.



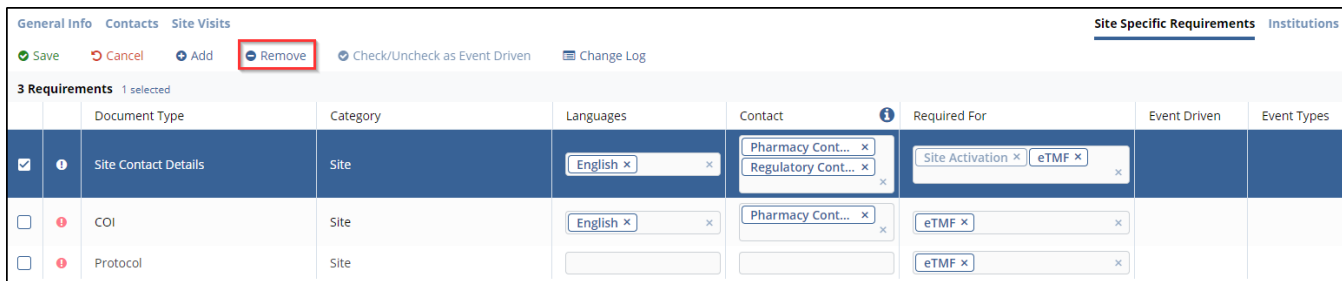
### Remove Site Specific Requirements

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.

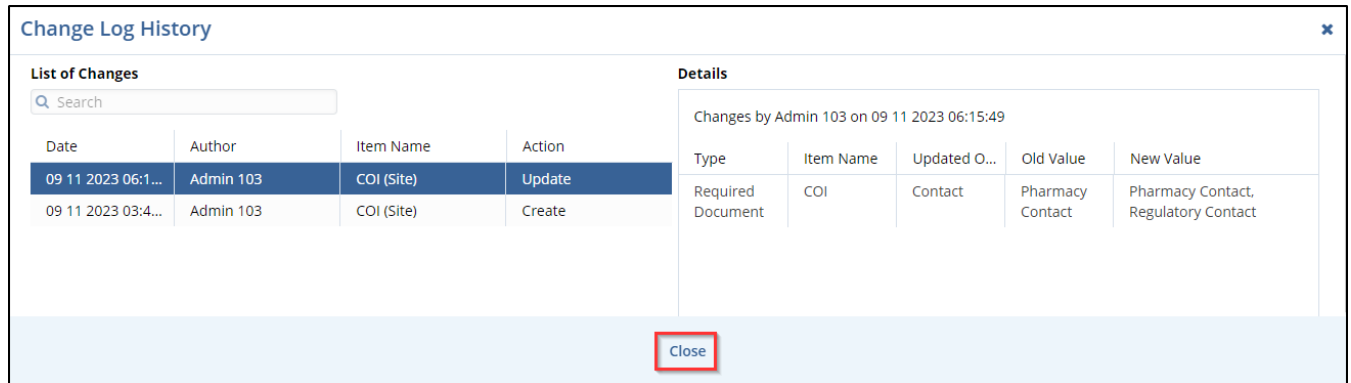
### Check/Uncheck as Event Driven

### Change Log

This log displays the list of changes done by a user in the documents. Click the Change Log button to view the Change Log History popup window.



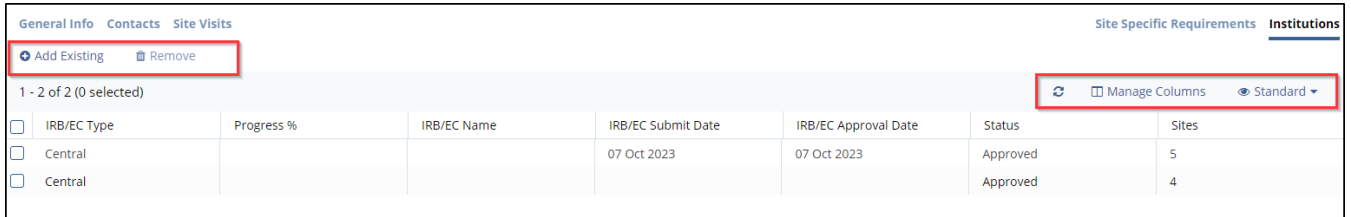
The popup window displays two sections – **List of Changes** and **Details**. Click a list to view its details in the right-side window.



**Note:** The user can only view the details in the Change Log History and cannot make any changes in the same.

## 109. Institutions

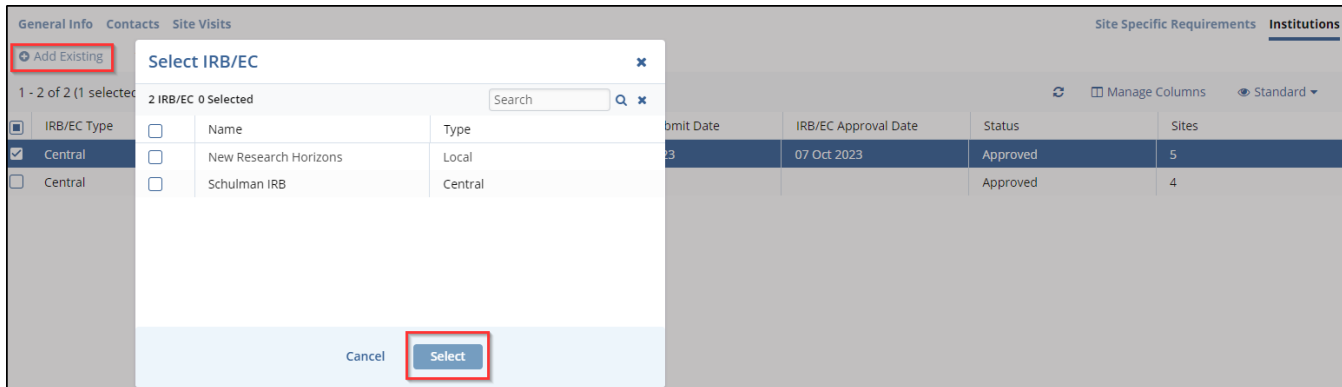
This tab helps the user to add existing IRB/EC, Remove an IRB/EC, Refresh, Manage Columns, and Save Views.



### 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.

General Info							Contacts	Site Visits	Site Specific Requirements	Institutions
<input type="checkbox"/> Add Existing <input checked="" type="checkbox"/> <b>Remove</b>										
1 - 2 of 2 (1 selected)							<input type="checkbox"/> Manage Columns <input type="checkbox"/> Standard			
<input type="checkbox"/>	IRB/EC Type	Progress %	IRB/EC Name	IRB/EC Submit Date	IRB/EC Approval Date	Status	Sites			
<input checked="" type="checkbox"/>	Central			07 Oct 2023	07 Oct 2023	Approved	5			
<input type="checkbox"/>	Central					Approved	4			

## Adding, Editing and Deleting Sites

1. **Important:** The following description is for adding Investigative Sites in an eTMF:

### 110. Adding a Site

1. Click the **Add** button from the top ribbon bar. The New Investigative Site window opens. Refer to the screenshot below:

The screenshot shows the 'New Site' dialog box with the following fields and values:

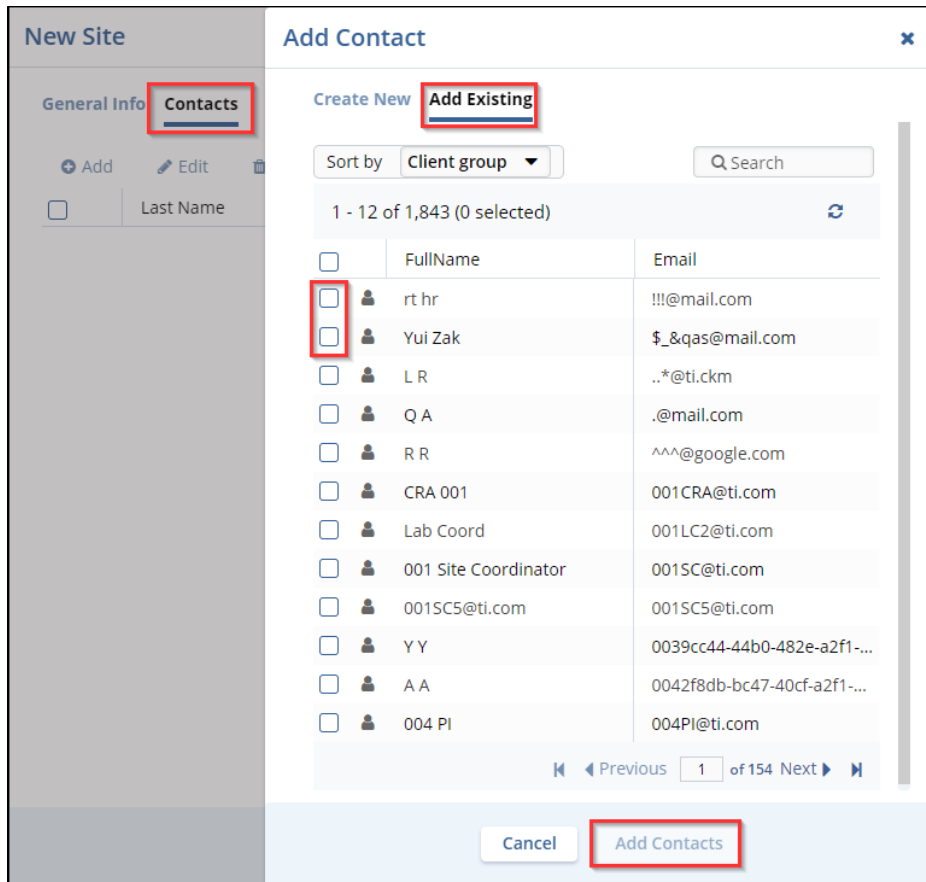
- Institution Name \***: Massachusetts General Hospital
- CRA**: test123demo@ti.com
- Start-Up Specialist**: Samuel Pawar
- Site Number**: (empty)
- Site**: (empty)
- Disable auto Site name**:
- Reason for not using auto Site name**: (empty text area)

Buttons at the bottom: Cancel, Add (highlighted).

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.

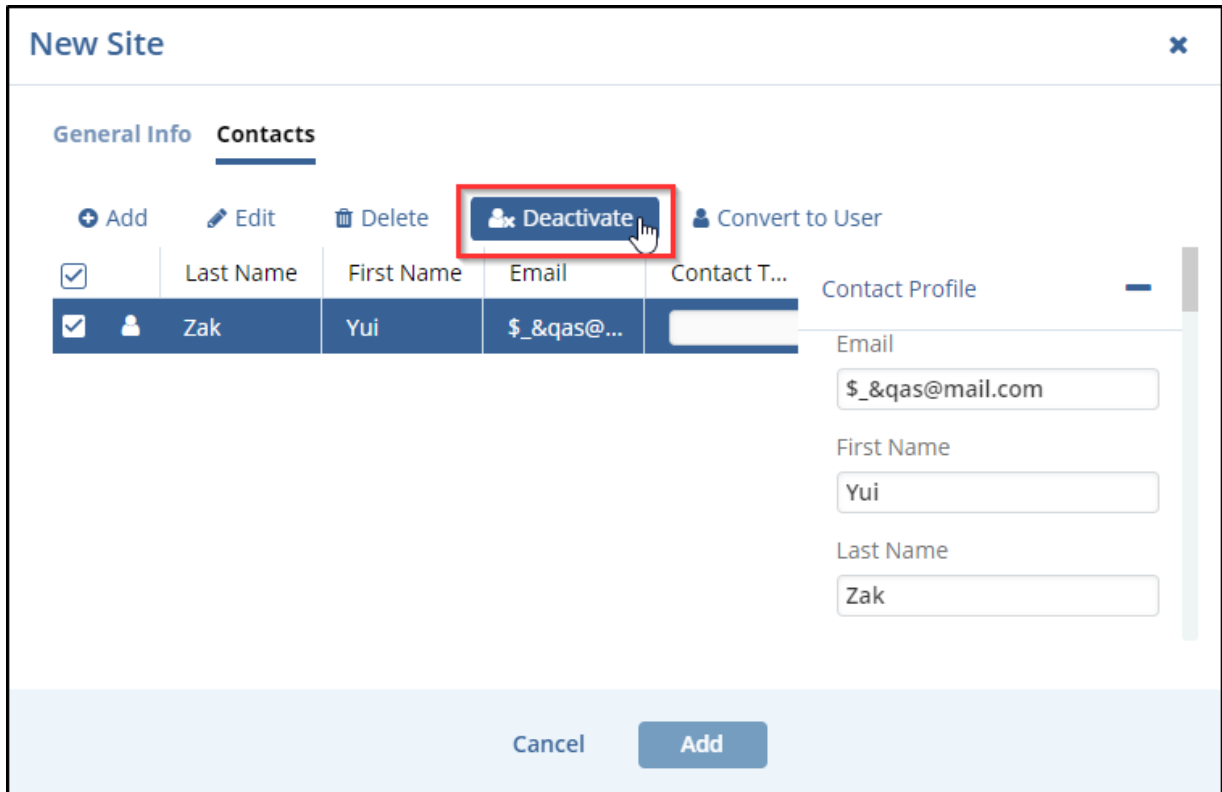


3. Create or Add existing contacts from the Contacts panel in the window. This information will be supplied by the client and can be created under Contact Types in Investigative Site Settings.
  - a. You can also add the Contact Type by clicking the contact type field which will then reveal the dropdown 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.



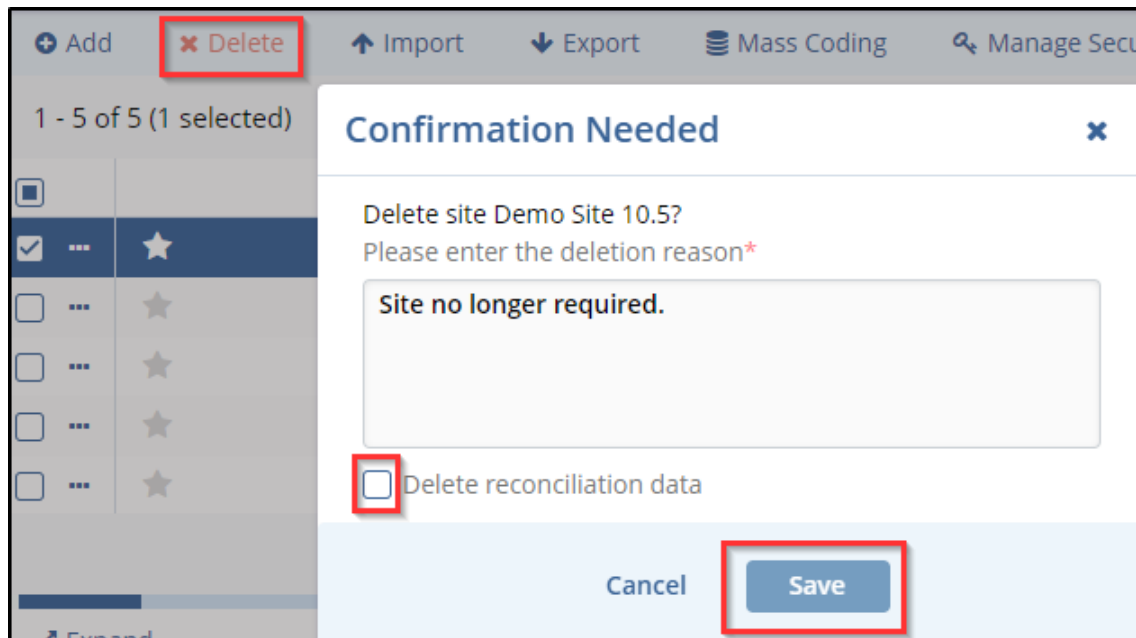
6. You can assign a site contact the role of editor or reader and assign actions as appropriate from the Contacts panel.
7. Click the dropdown arrow for **'Address'** to reveal the fields to enter the site location details.
8. Click the dropdown arrow for **'More'** to open another array of data fields. Enter the investigative site information.
9. Click the **'Add'** button displayed at the bottom of the window.

### 111. 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.

### 112. 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).

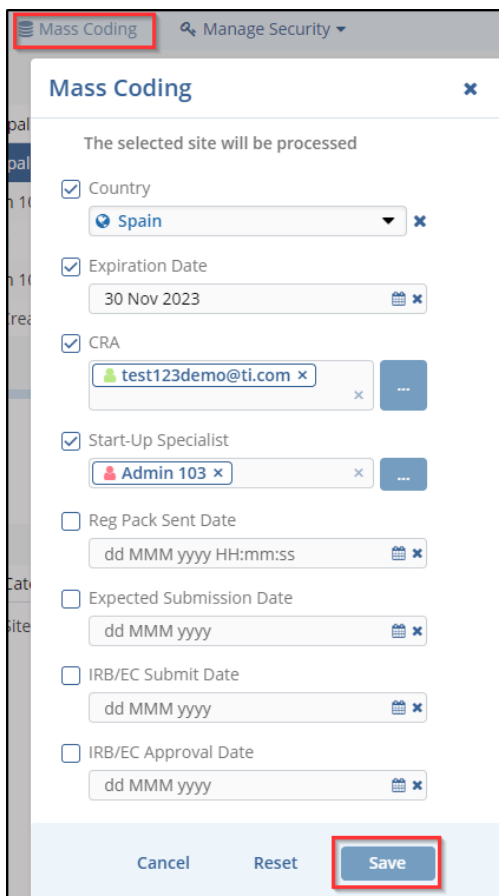


**Optional-** Select the checkbox for deleting the reconciliation data.

### 113. 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.

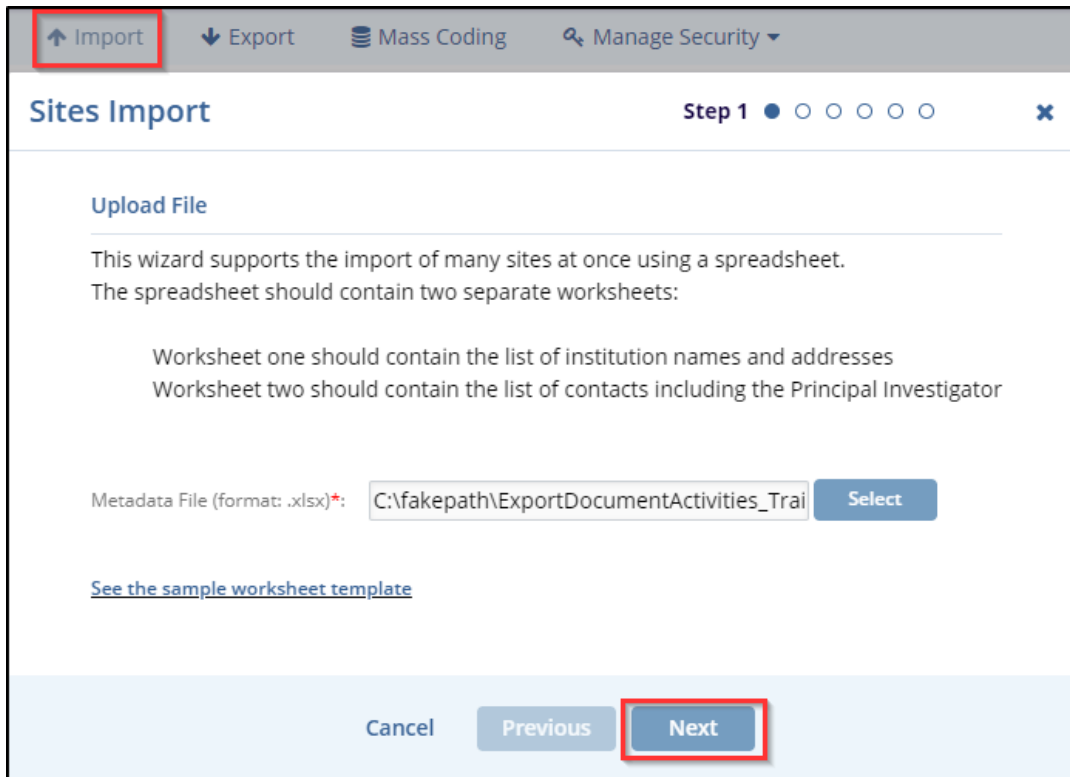


### Importing Sites

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.

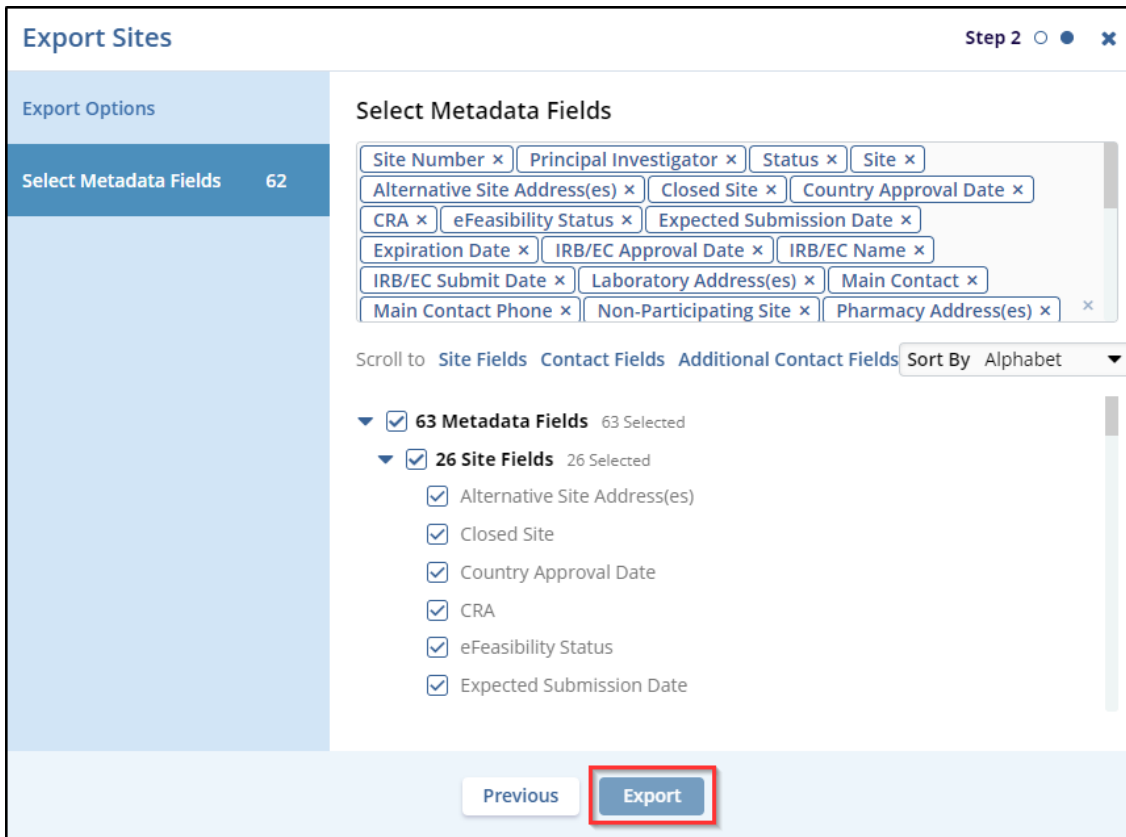
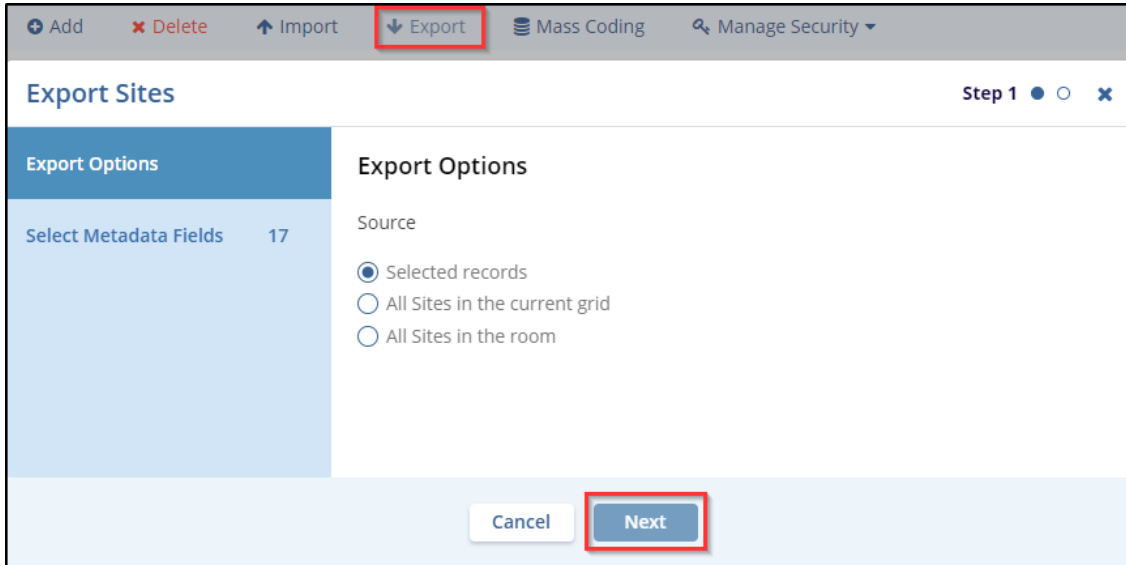
1. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import just contacts so they will be mapped to existing investigative sites. The wizard offers a link to the sample worksheet so the user can download it and fill it with actual data. Click 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:

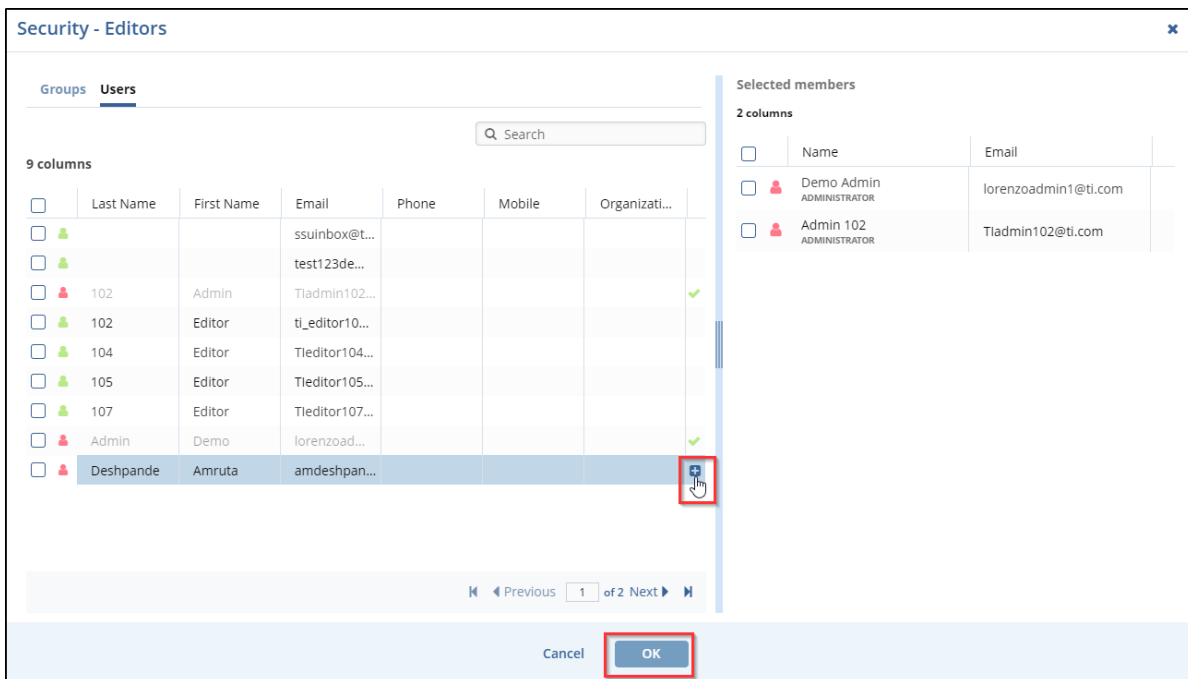


### Managing Security for Sites-Editors and Readers

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 8: 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.
  - o This will open the 'Send for eSignature' window.

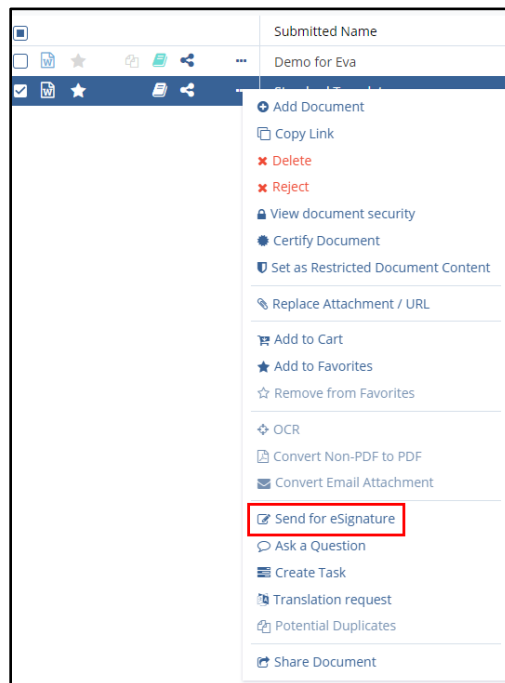


Figure 1: eSignature Sending Option

4. Choose the user or users who will need to sign the document by moving them from the left side to the right side.

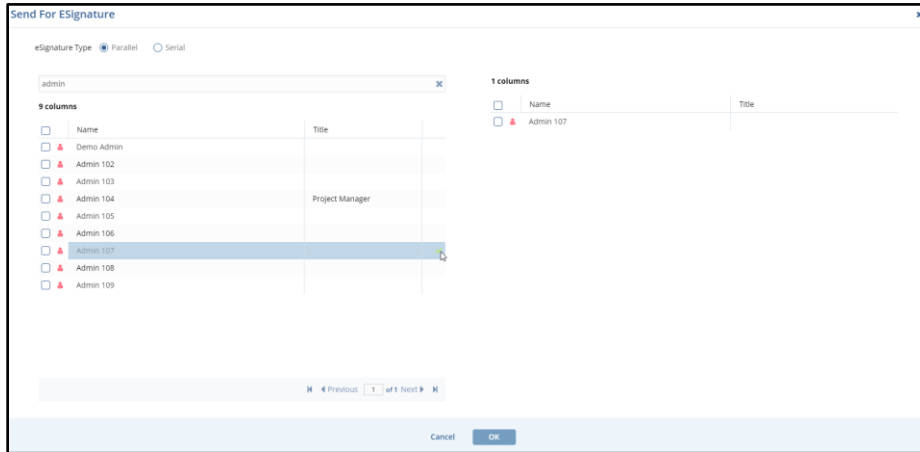


Figure 2: eSignature Page

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**
  - o 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.

#### 114. 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.
  - o This will open the document and the eSignature tab of the metadata panel in a popup window.

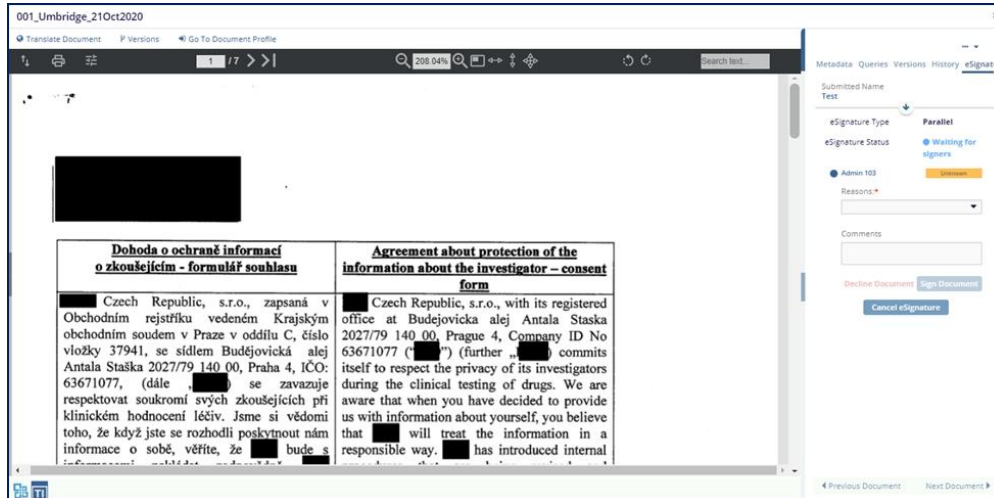


Figure 4: eSignature Tab

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.

## 115. 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.

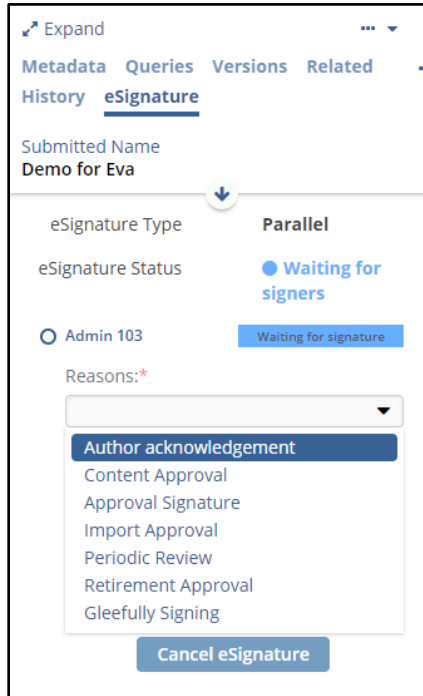


Figure 5: eSignature Reasons

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.

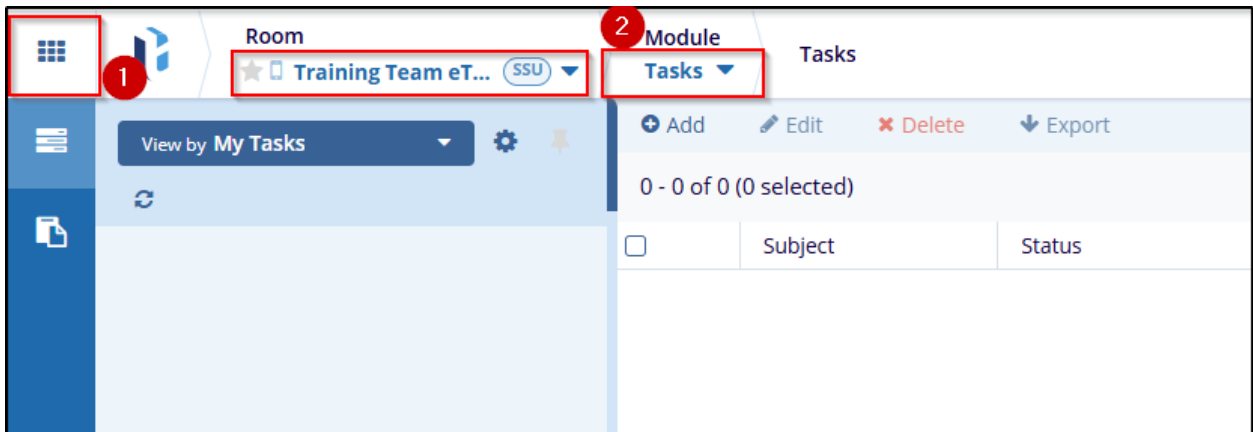
## Chapter 9: Tasks

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.

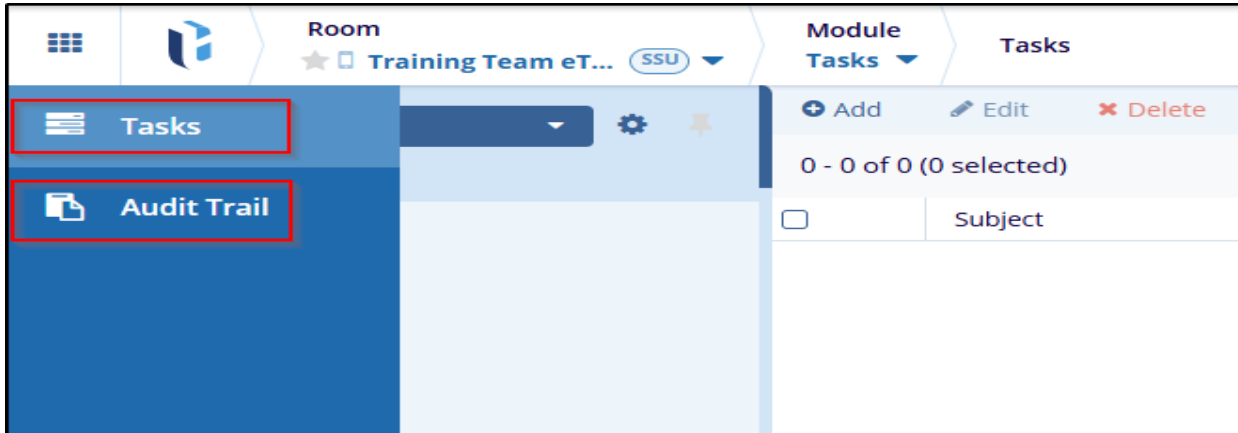
You can access Tasks Module as mentioned below:

1. Go to the room for which you want to manage tasks, as shown in the **Room** section at the top.
2. Click on the **Navigation Grid** icon (indicated by the grid icon in the screenshot) to open the menu with room options.
3. In the navigation menu, click on the **Tasks** icon to enter the tasks management area.
4. Once on the **Tasks** page, you can:
  - a. **Add** new tasks by clicking the **Add** button.
  - b. **Edit** existing tasks by selecting a task and clicking **Edit**.
  - c. **Delete** tasks by selecting them and clicking **Delete**.
  - d. **Export** tasks by clicking **Export** to download task information for reporting or record-keeping.
5. Users with the necessary permissions can set up reminders for task deadlines. To adjust the number of days before a task's due date for email reminders, navigate to the **Reminder** section within the **metadata panel** of the selected task.



The Tasks Module is divided into two sections:

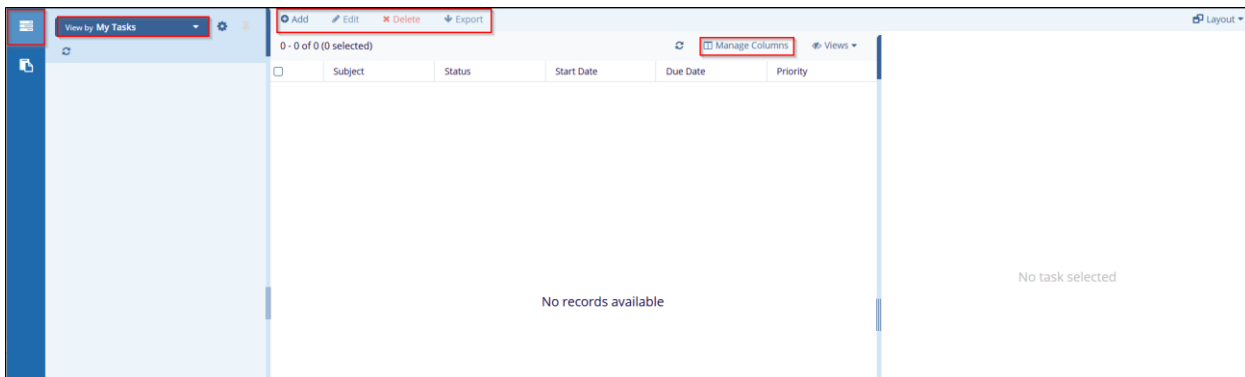
- **Tasks**
- **Audit Trail**



**Note:** Navigate to the vertical menu at the left to choose sections. Click on the tasks section from the left panel.

## CHAPTER 9: TASKS

Tasks section, which allows users to manage their tasks through different options. Users can view tasks, add new ones, edit, delete, and export task records. The interface provides an option to filter tasks by different views (e.g., "My Tasks"), and it includes a "Manage Columns" feature, which allows customization of the displayed columns.



### 116. 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.

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.

To create a task, follow these steps:

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.

**Create Task**
✕

Subject

Start Date  📅

Due Date  📅

Priority

Status  ✕

Complete %

Description

Assign To \*  ✕

Reminder

Category  ✕

Trial

Attachments  Add

Documents

Cancel
**Save**

View by My Tasks

Add
Edit
Delete
Export
Layout

Pending 1

All 1

	Subject	Status	Start Date	Due Date	Priority
1 - 1 of 1 (1 selected)	Document	In Progress	11 Nov 2024	27 Nov 2024	Normal

Subject

Start Date  📅

Due Date  📅

Priority

Status  ✕

Complete %

Description

Assign To \*

Reminder

Category

Trial

Cancel
**Save**
Save & Next

## 117. Editing Tasks

To edit a task, follow these steps:

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 differently.
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.
5. Make any necessary changes
6. Press **'Save'** when done.

Edit Task ✕

Subject

Start Date  📅

Due Date  📅

Priority  ▾

Status  ▾ ✕

Complete %  ▾

Description

Assign To \*  ▾

Reminder

Category  ▾

Trial

Attachments  ✕

Documents

## CHAPTER 10. ROOM SETTINGS

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

Refer to the screenshot below:



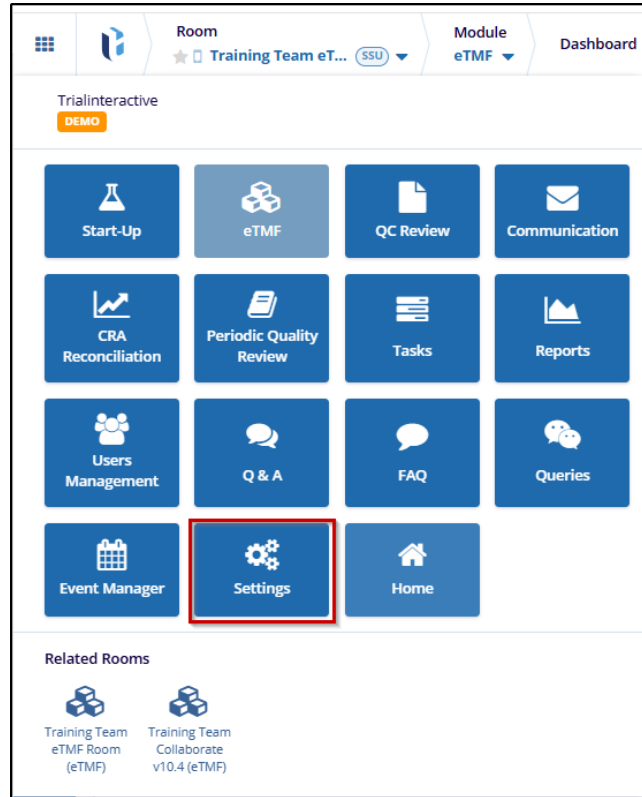


Figure 1: Setting Module

- 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:

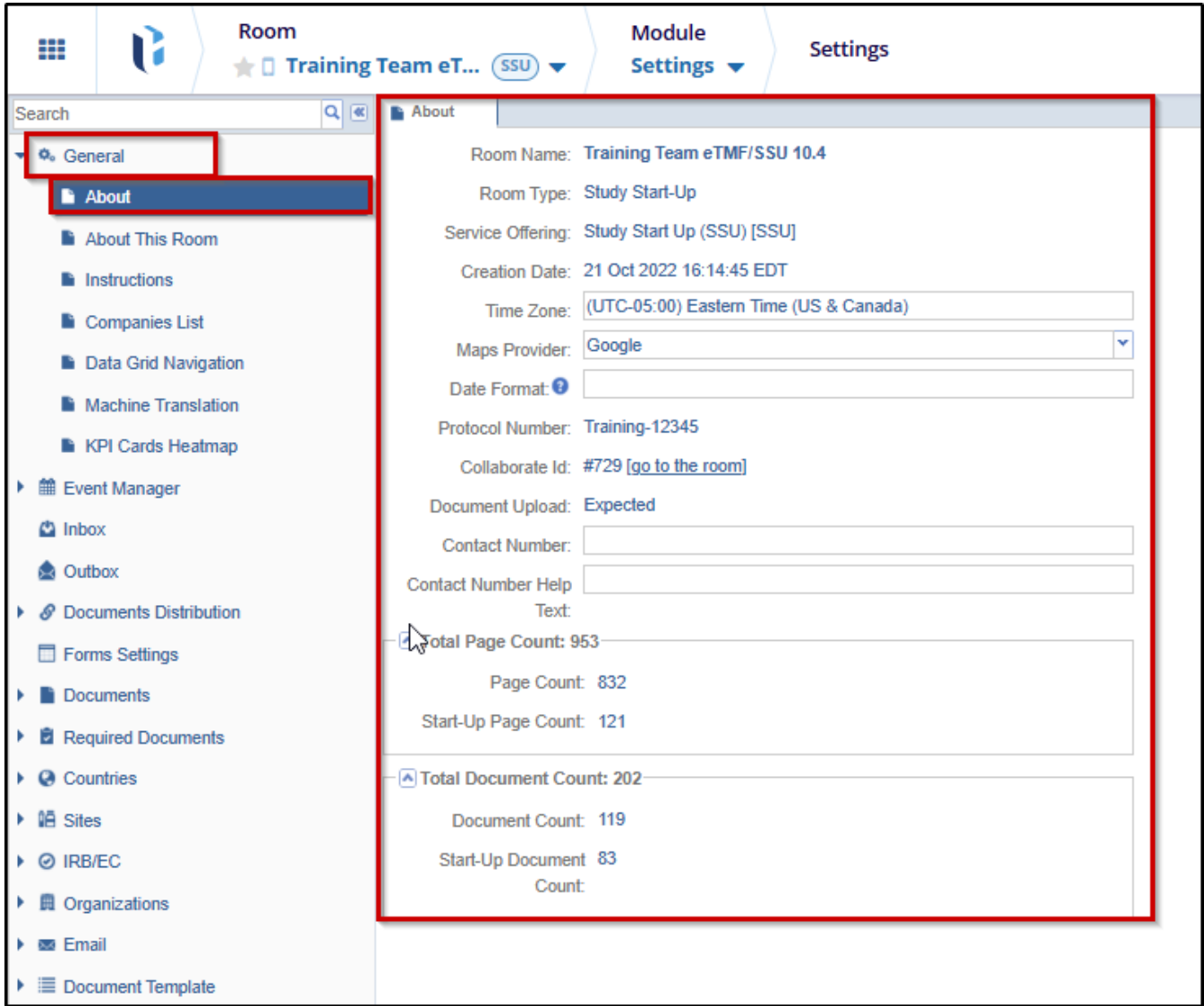


Figure 2: General Tab

General Setting

118. About

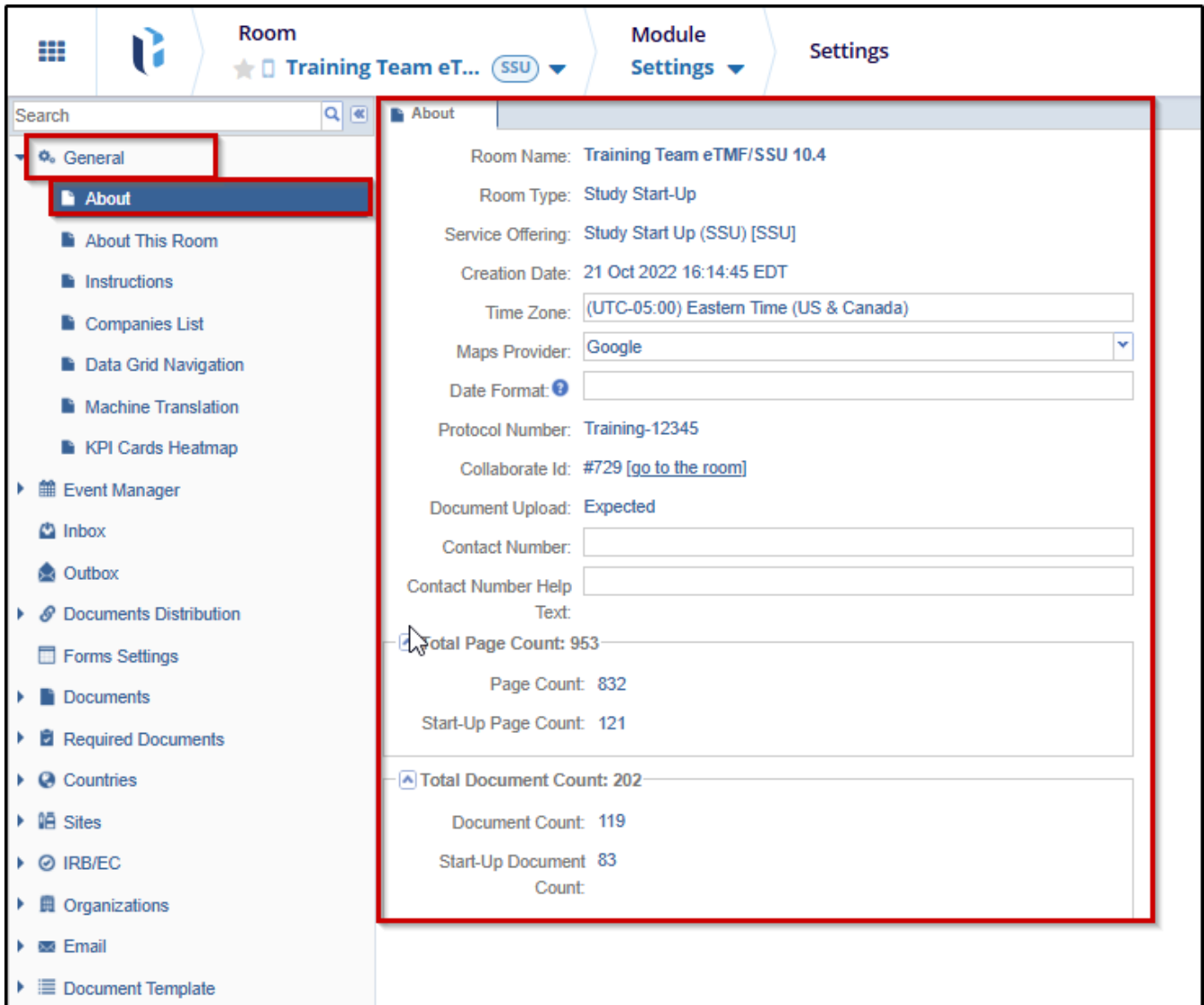


Figure 3: About

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.

## 119. About This Room

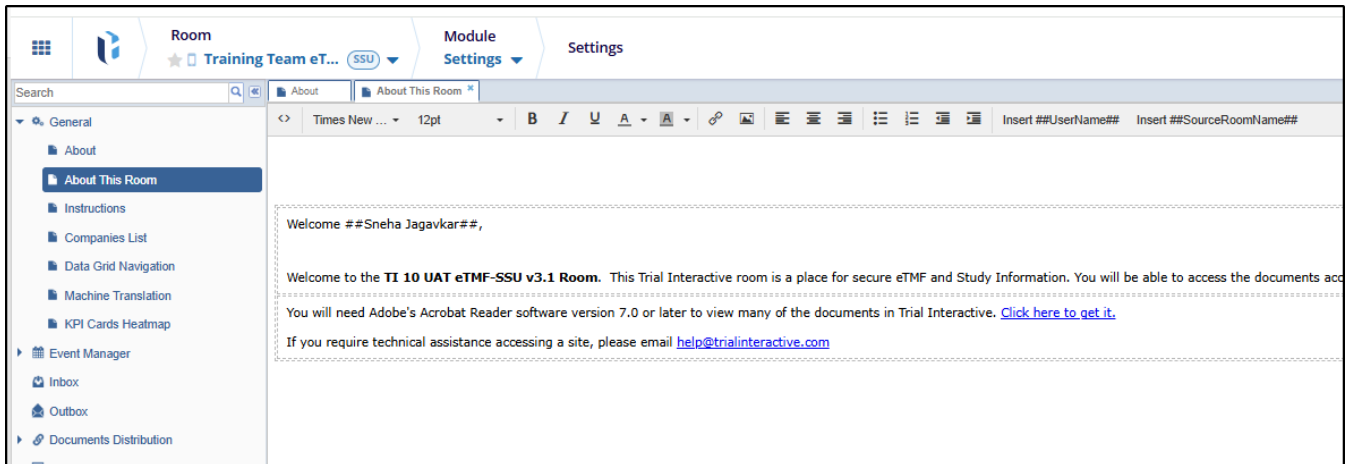


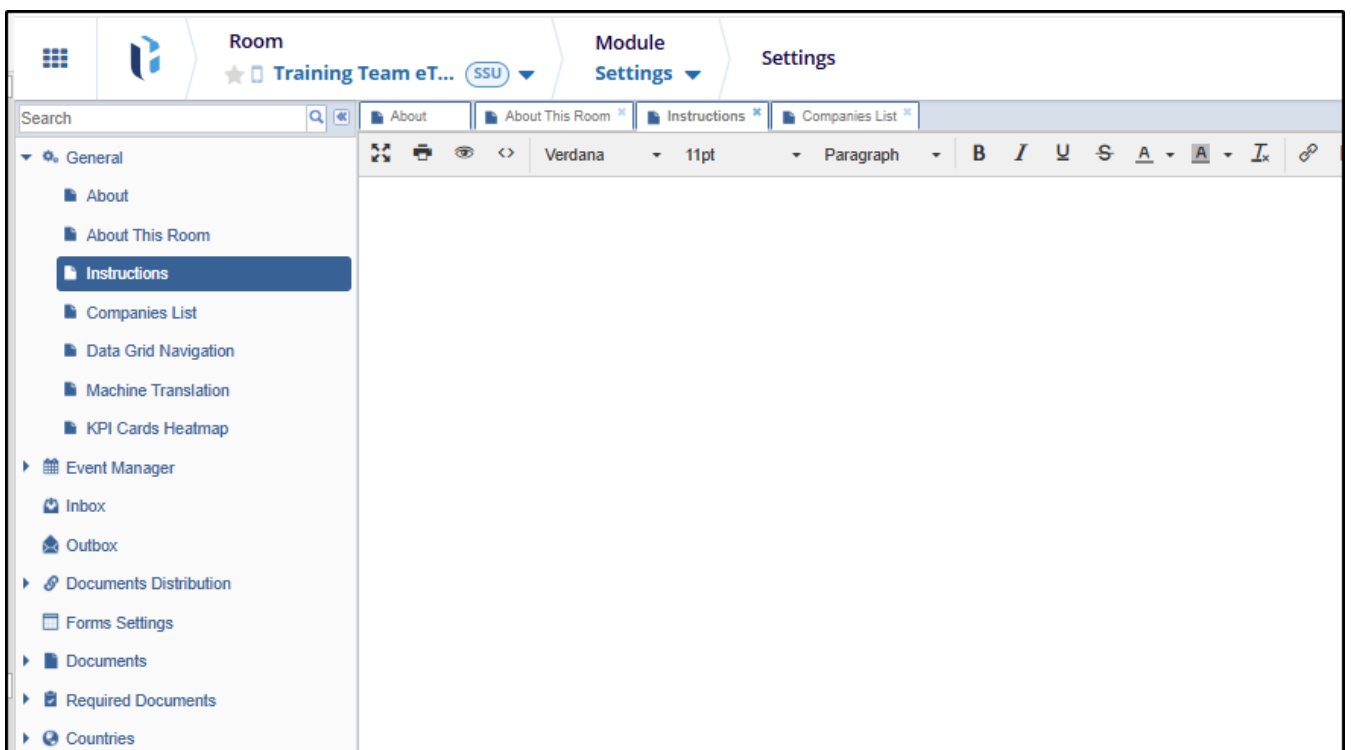
Figure 4: About this Room

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.

## 120. 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.



### 121. 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.

Organizations 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.

### 122. 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.

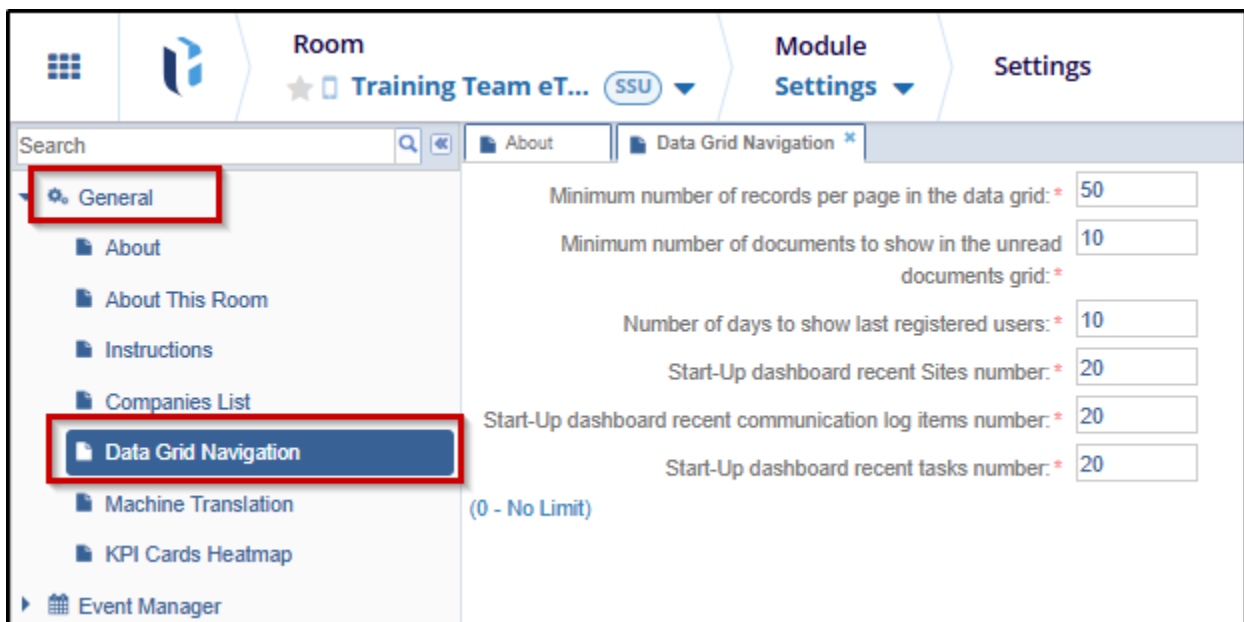


Figure 5: Data Grid Navigation

123. 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.

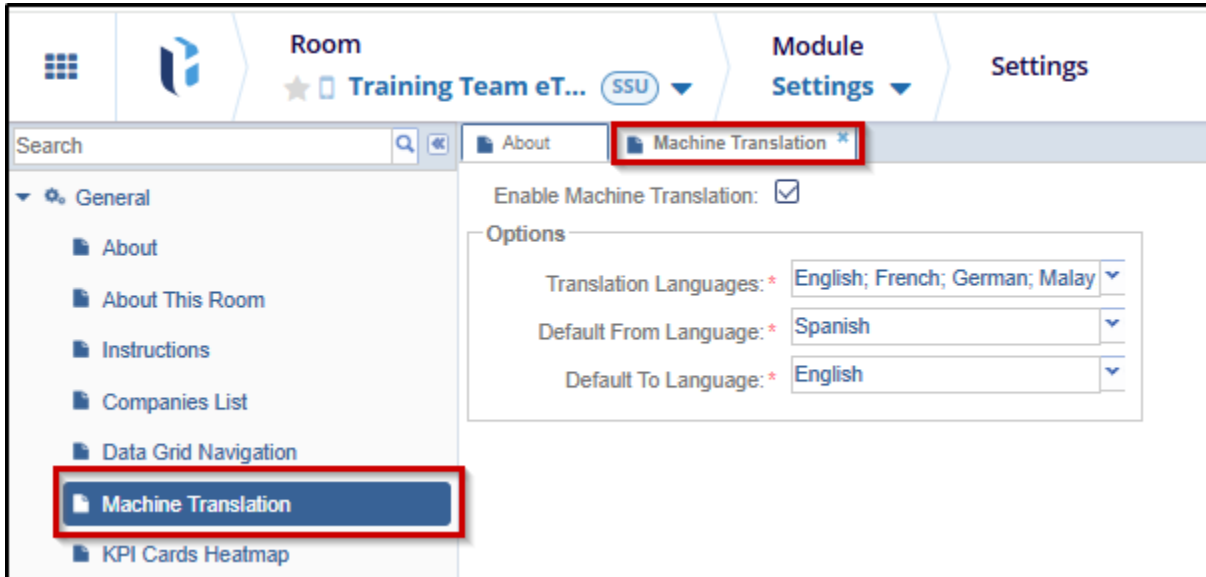
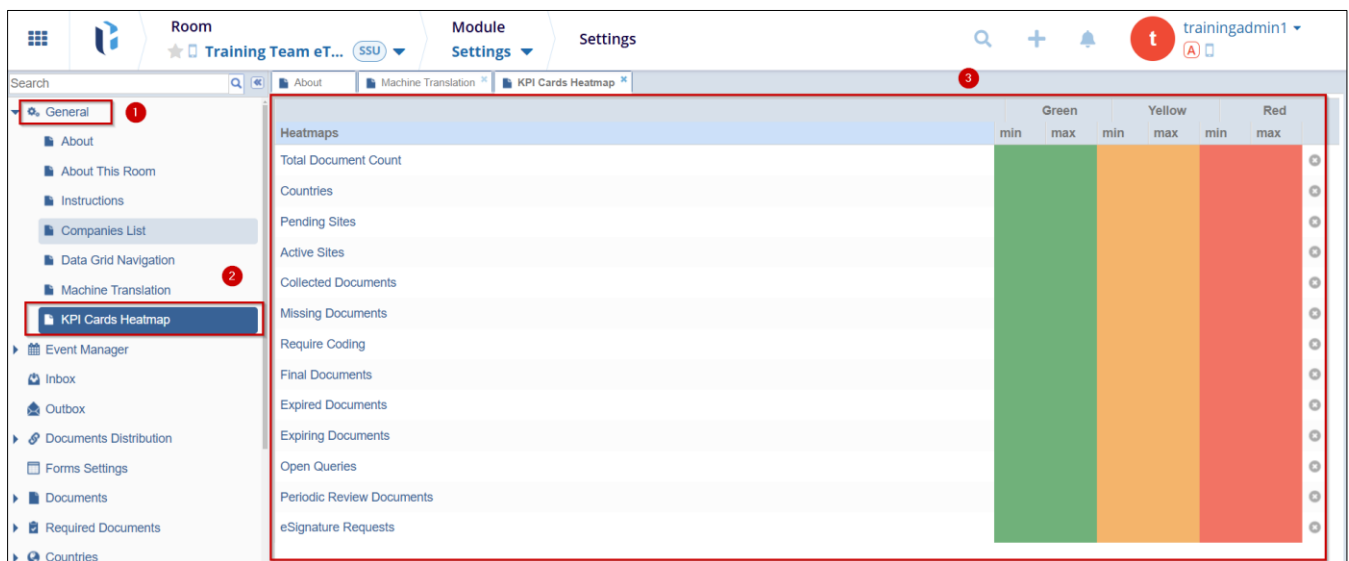


Figure 6: Machine Translation

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

*KPI Cards Heatmap in Setting*

The **KPI Cards Heatmap** in the Trial Interactive settings provides a quick visual overview of key performance indicators across various categories (e.g., Pending Sites, Active Sites, Expiring Documents, Open Queries). The heatmap uses color-coded thresholds (Green, Yellow, Red) to indicate performance levels or urgency:



## Event Manager Settings

### 124. 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.

### 125. 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.

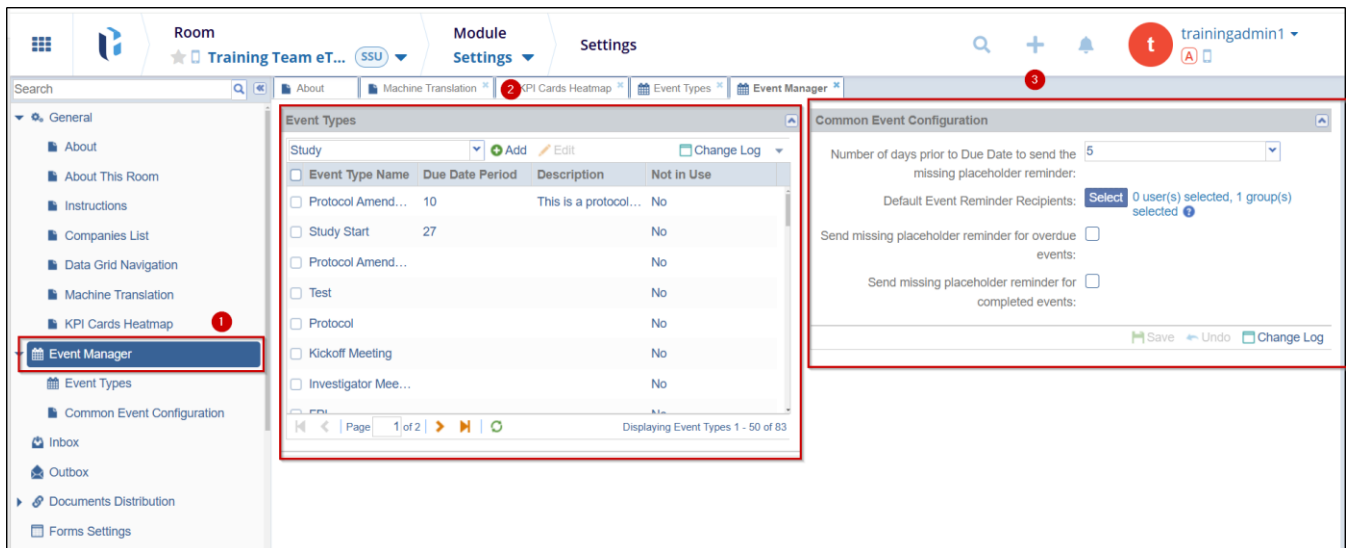


Figure 7: Common Event Configuration

## 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:

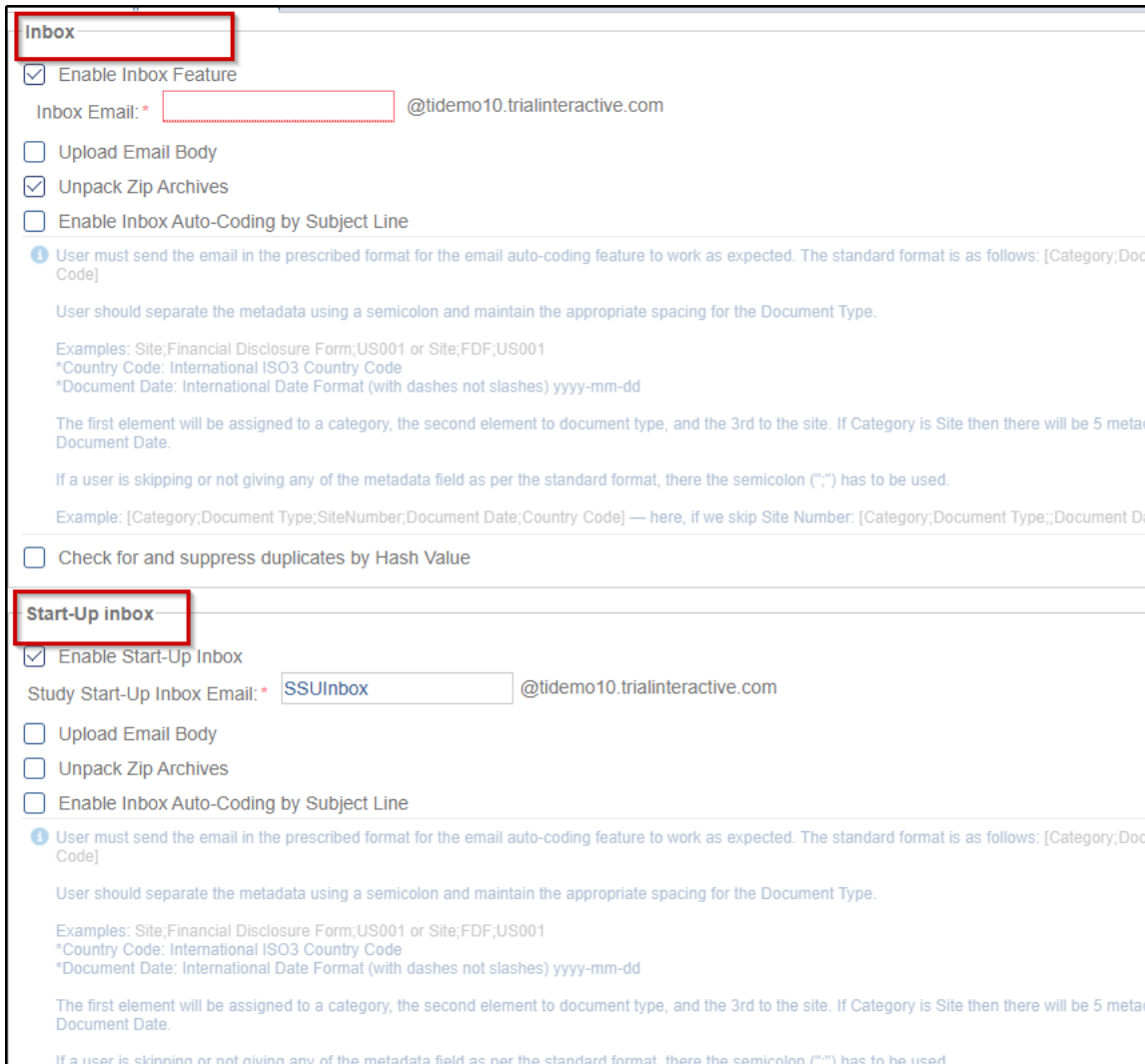
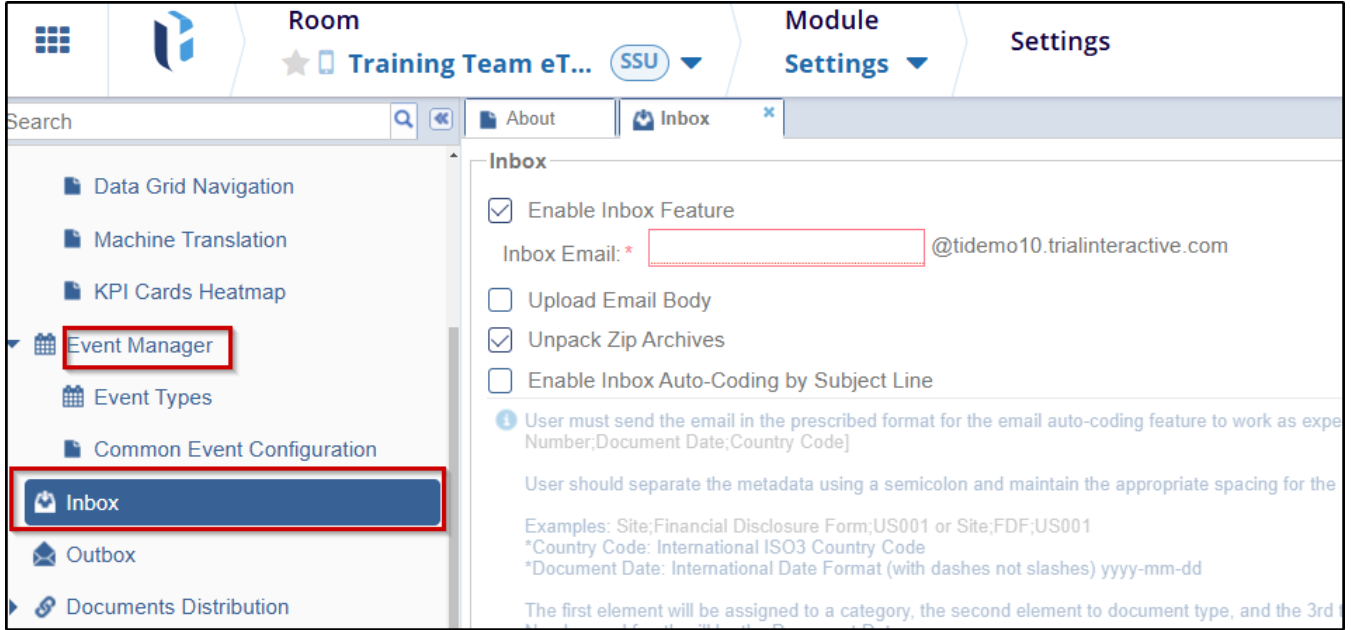


Figure 8: Inbox



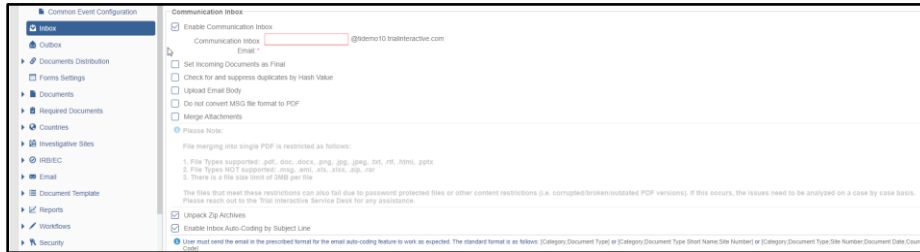


Figure 8: Inbox

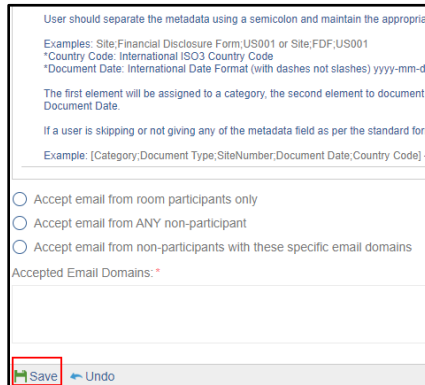


Figure 8: Inbox

## 126. 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

## 127. 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.

---

## 128. 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.

---

## 129. 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.

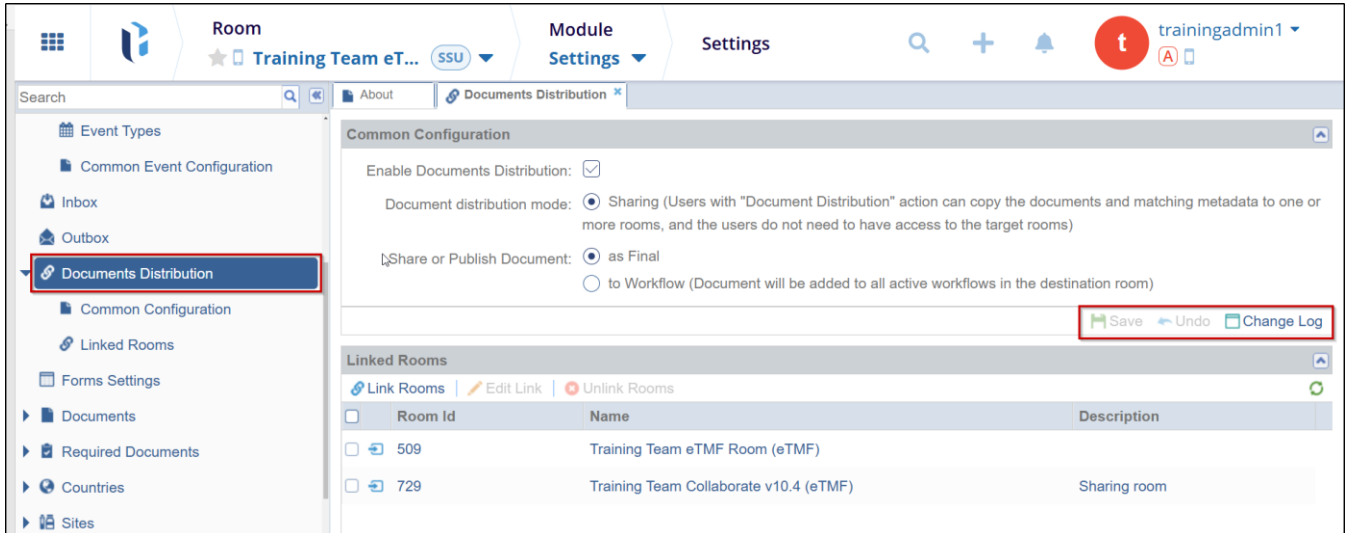


Figure 9: Document Distribution

## 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:

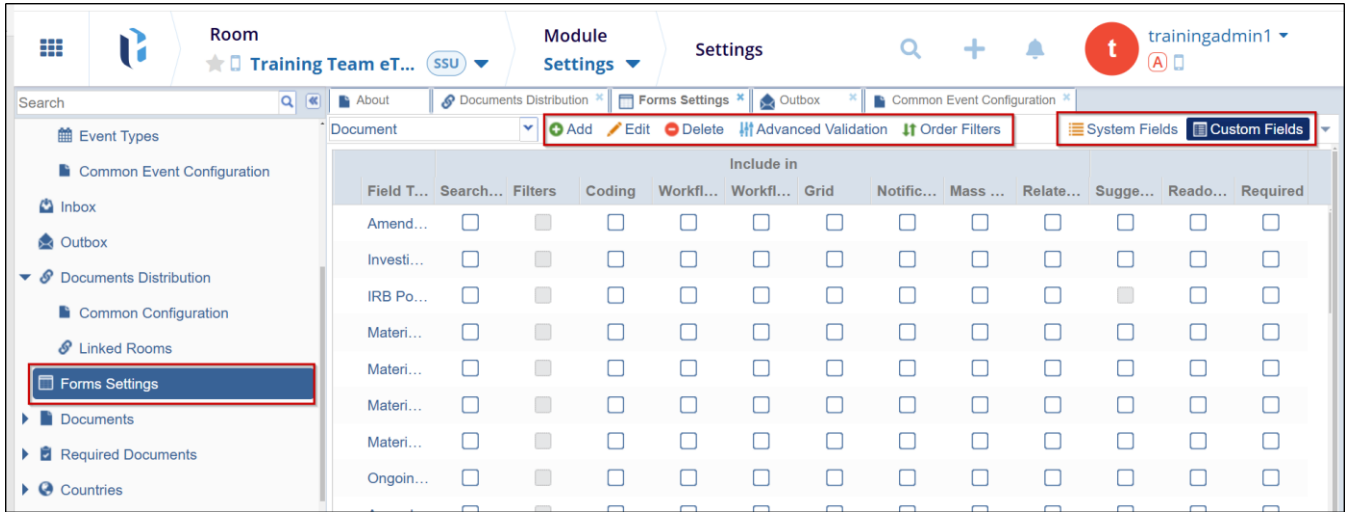


Figure 10: Forms Settings

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

130. Adding a Custom Field

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

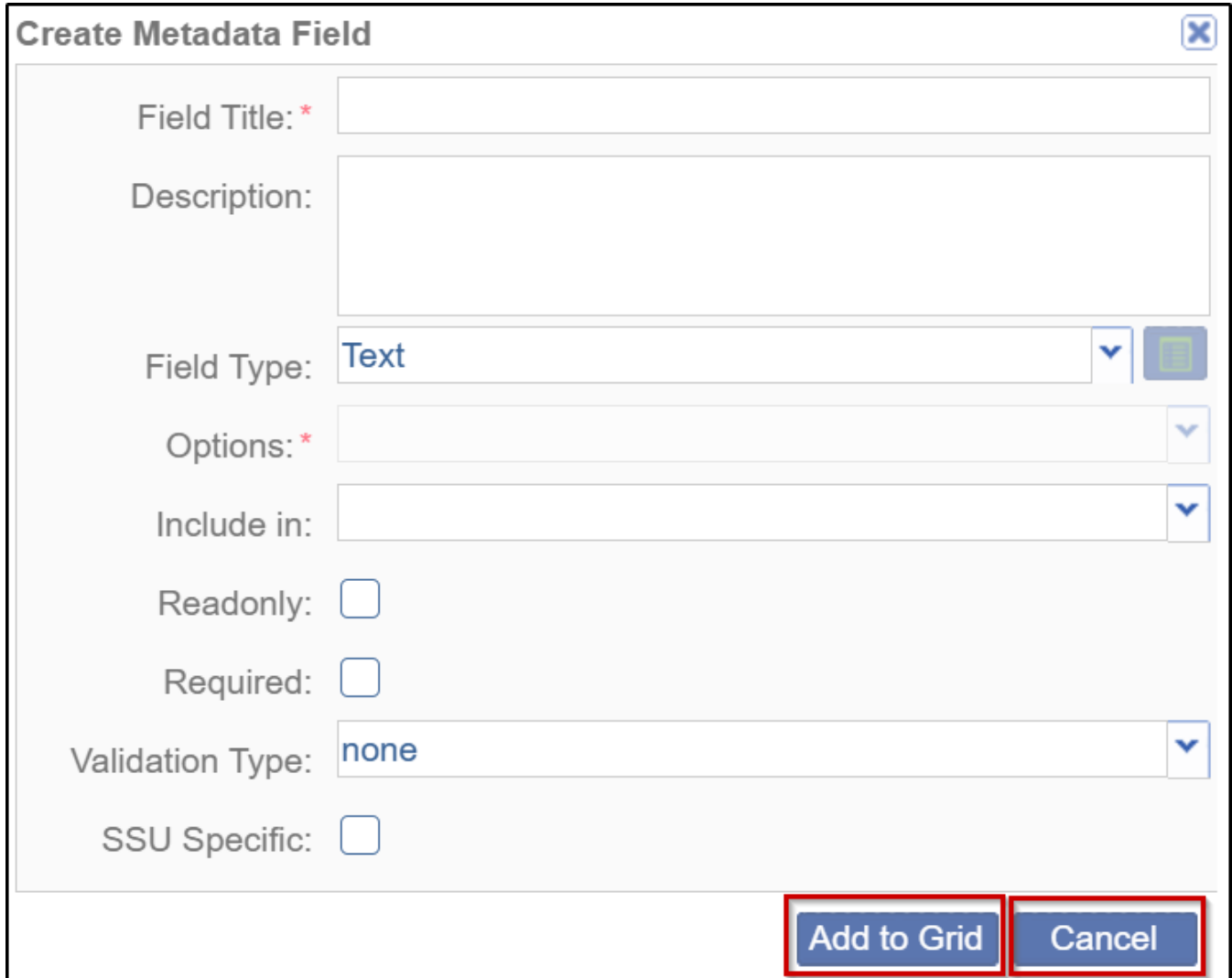


Figure 11: Create Metadata Field

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.
  - a. 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.

131. Editing a Metadata Field

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

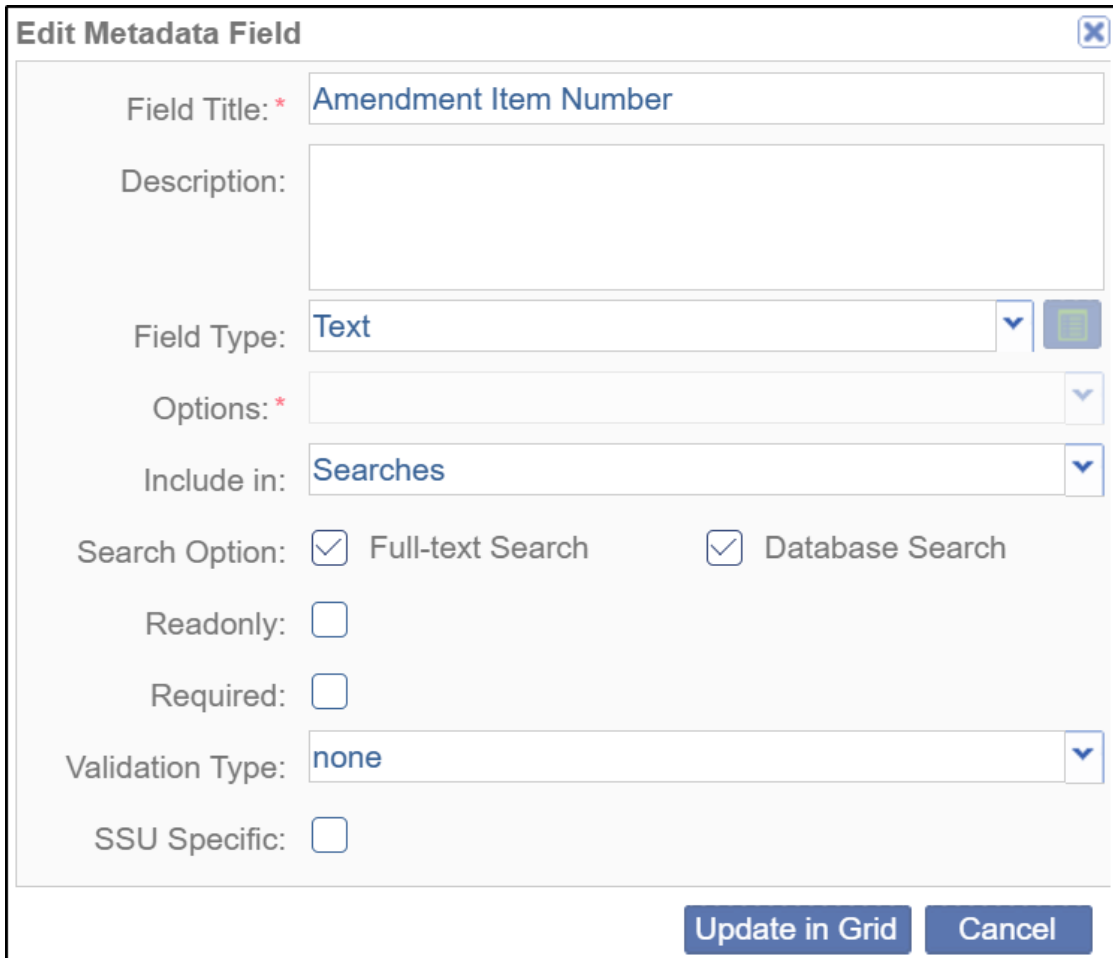


Figure 12: Edit Metadata Field

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.

132. 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.

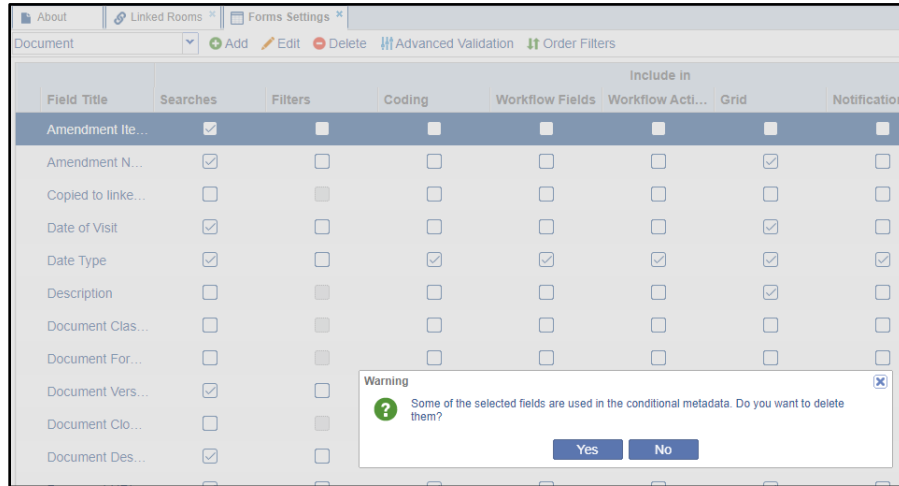


Figure 13: Deleting Field

### 133. 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:

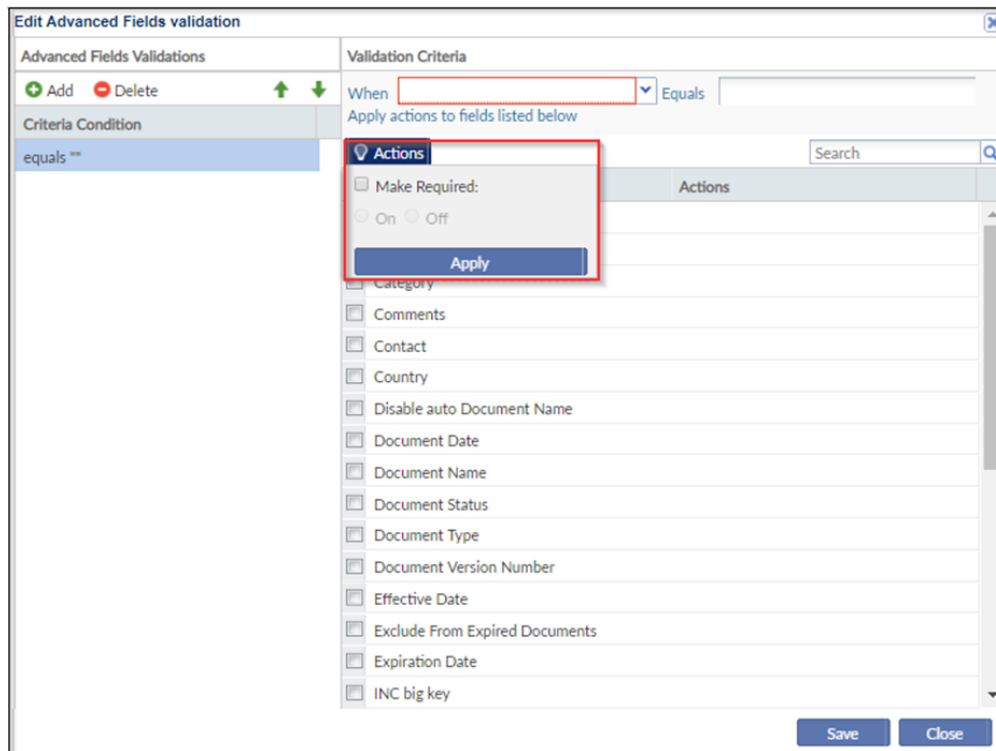


Figure 14: Edit Advance Fields Validation

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.

---

### 134. 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.
  - o 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.**



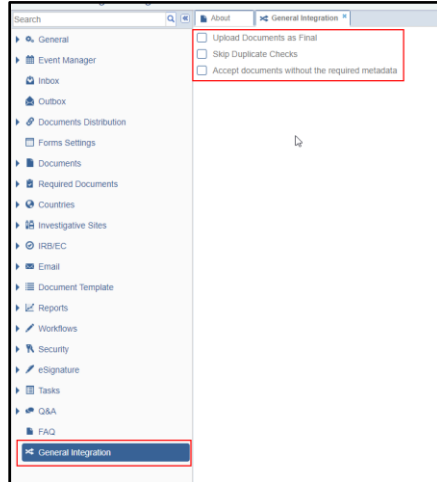


Figure 15: General Integration

135. Documents

Here, you can make all settings related to documents in a room. You can also perform the following document settings.

136. 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.**

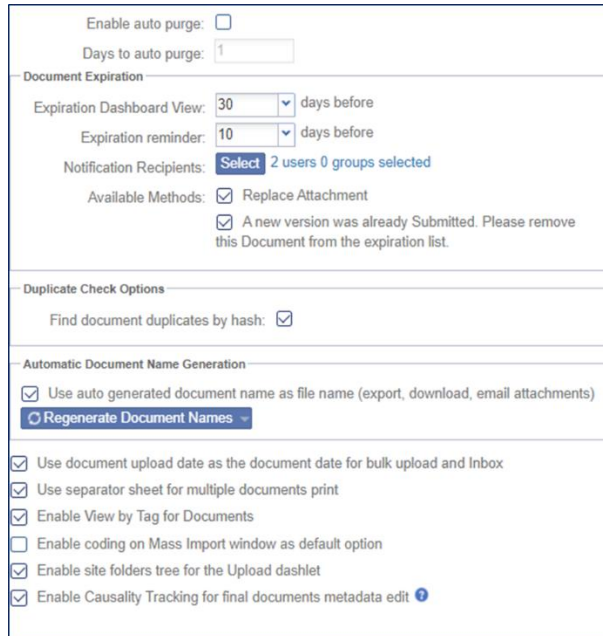


Figure 16: Documents Module

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 expiring documents. The settings for these are discussed here.

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

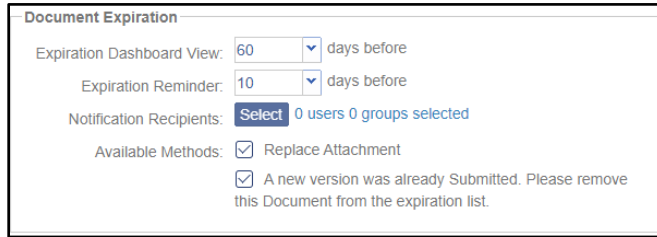


Figure 1: Document Expiration

- 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.

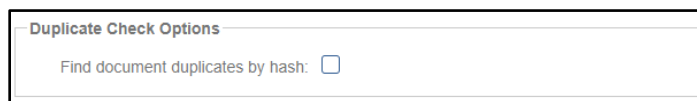


Figure 17: Duplicate Check Options

### 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.

### 137. 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.

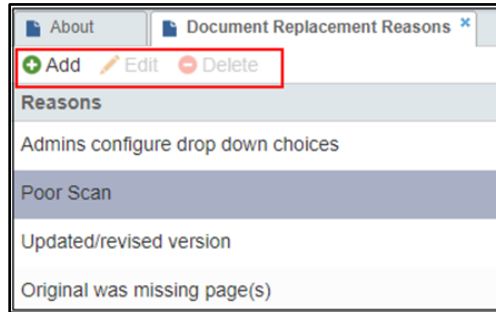


Figure 18: Document Replacement Reasons

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.

### 138. 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.

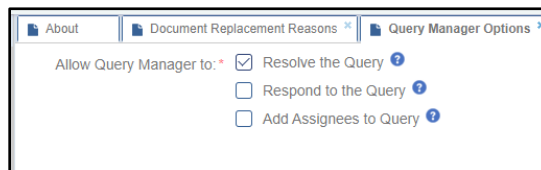


Figure 19: Query Manager Options

### 139. 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.

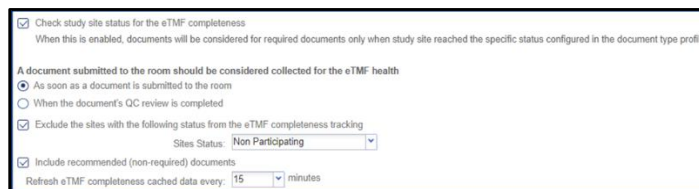


Figure 20: eTMF Health Setting

## 140. 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

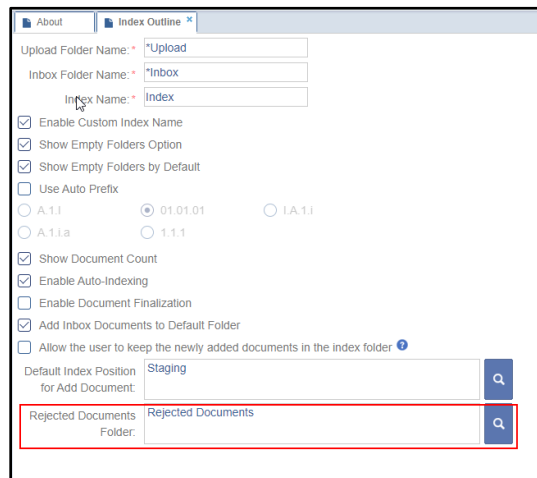


Figure 21: Index Outline

- 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.

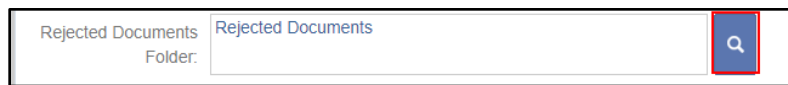


Figure 22: Rejected Documents

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

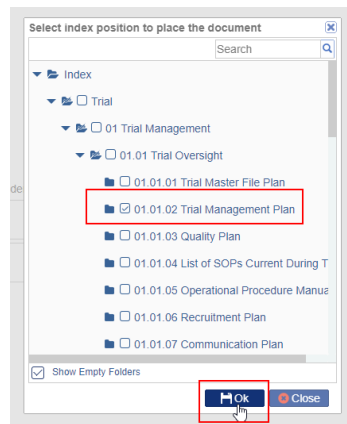


Figure 23: Index position

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

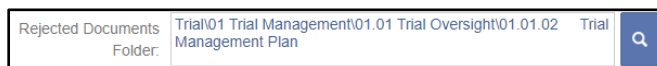


Figure 23: Rejected Folder

- 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’

#### 141. 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.

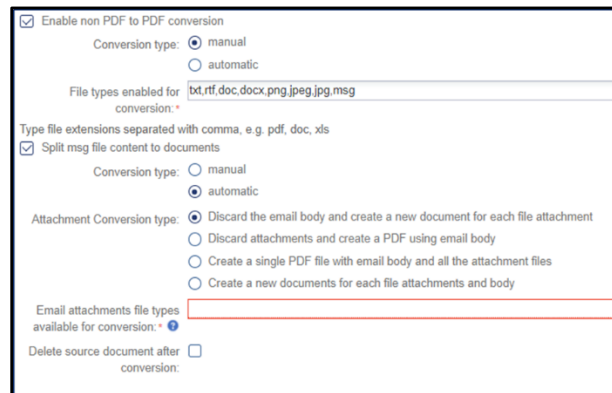


Figure 24: Non-PDF to PDF document

- 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.

#### 142. 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.

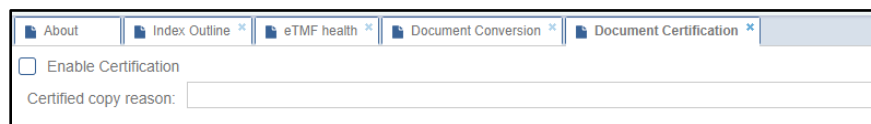


Figure 25: Document Certification

### 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.

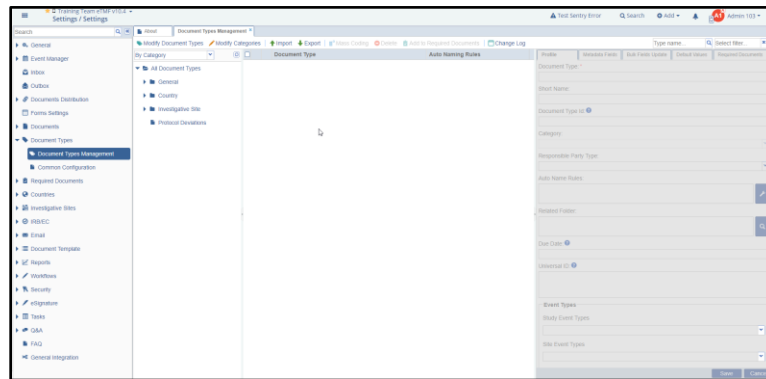


Figure 26: Document Type Management

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

#### 143. 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.

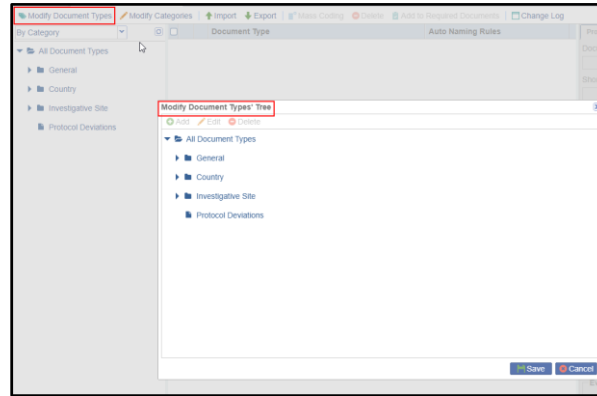


Figure 27: Modify Document Types

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:

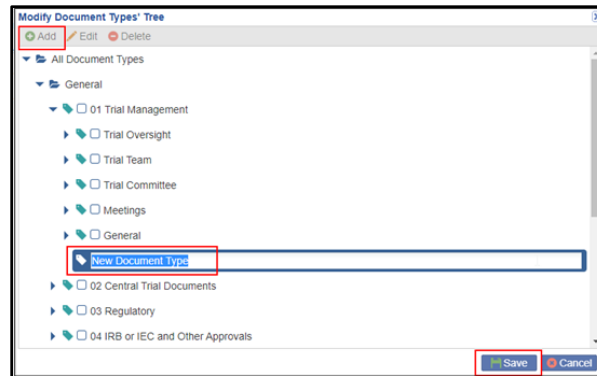


Figure 28: Add Document

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:

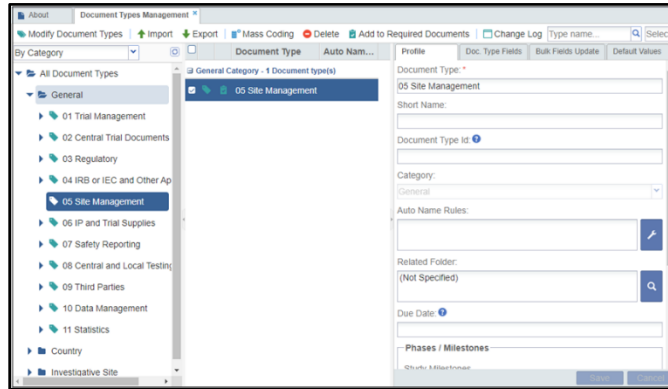


Figure 29: Site Management

## 144. Building the Document Type Profile

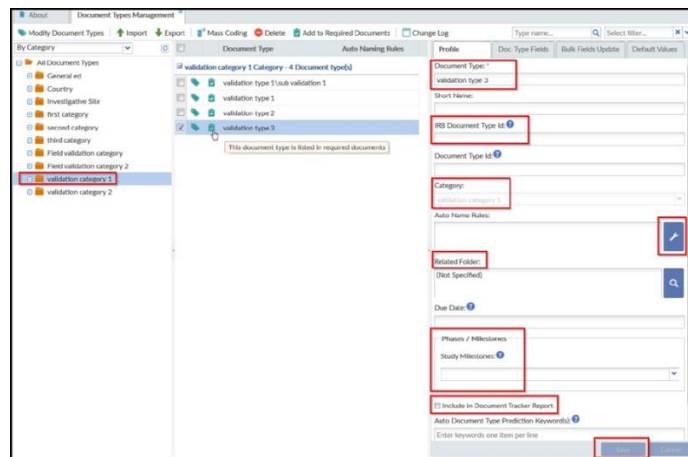


Figure 30: Document Type

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:

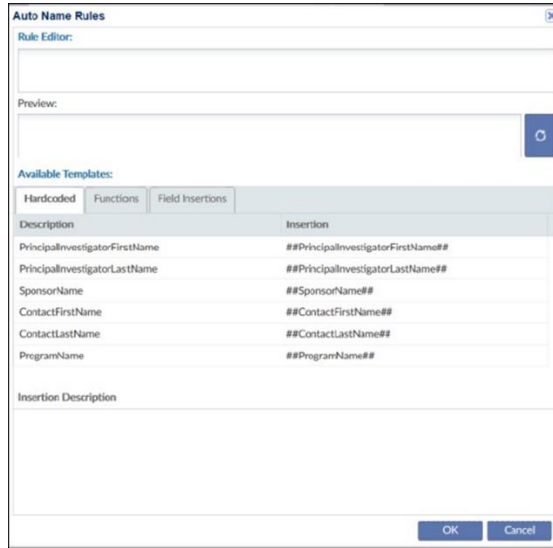


Figure 31: Auto Name Rules

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.

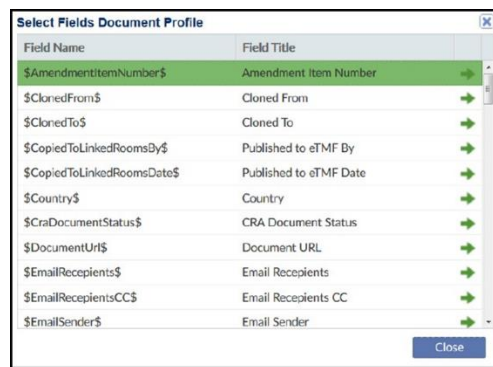


Figure 32: Select Fields Document Profile

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.

- 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.

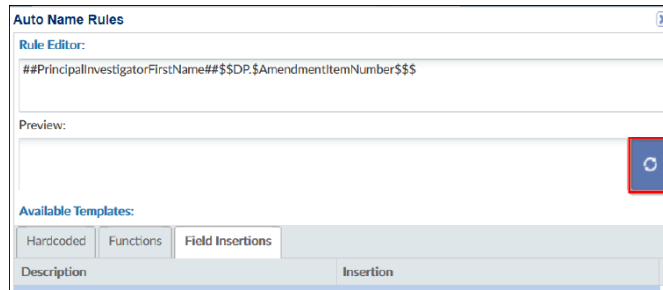


Figure 33: Auto name Rules

- Click OK at the bottom of the window to be returned to the main Document Types view.
- Click 'Save' at the bottom right of the Profile tab window.

#### 145. Specifying the Related Folder

- 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

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

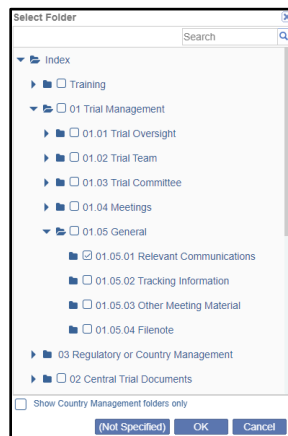


Figure 35: Select Folder

- 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.

### 146. 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.

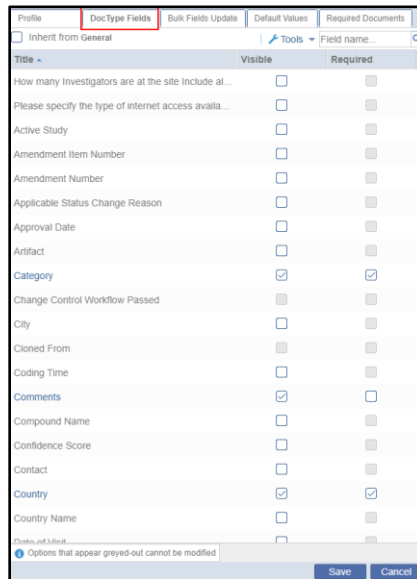


Figure 36: DocType Fields

### 147. 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:

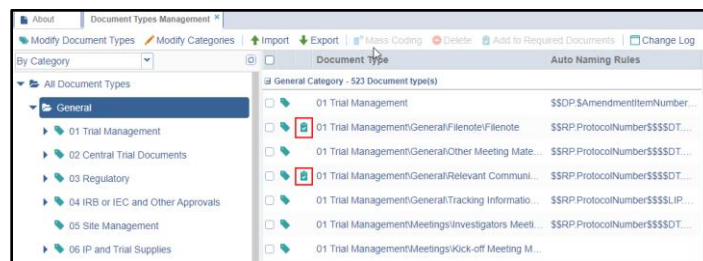


Figure 37: General

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:

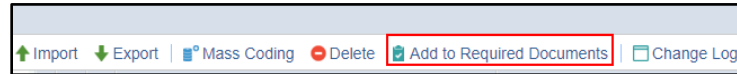


Figure 38: Add to Required Documents

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

#### 148. 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:

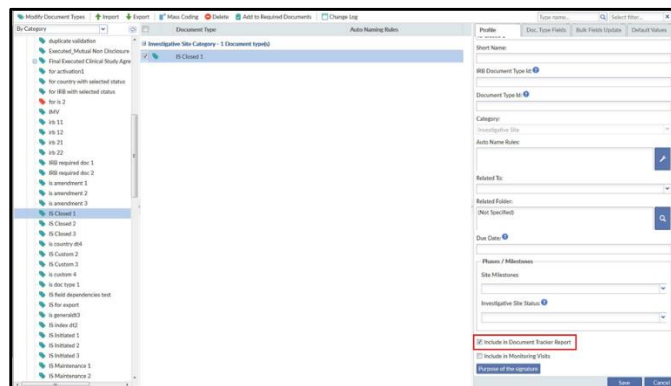


Figure 39: Document Tracker Report

#### 149. 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.

## 150. 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.

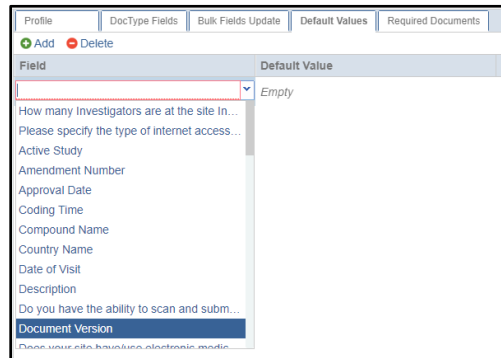


Figure 40: Default Values

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:

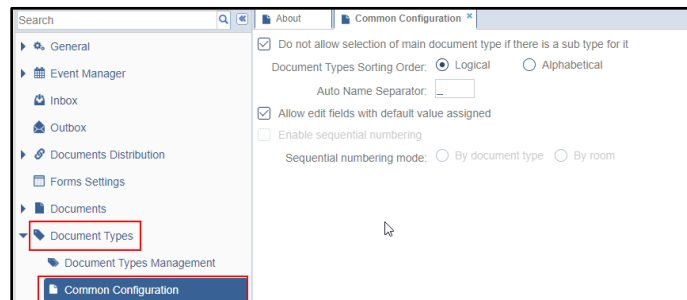


Figure 41: Common Configuration

- 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

---

## 151. 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.

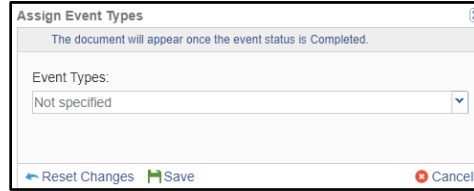


Figure 43: Assign Event Types

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

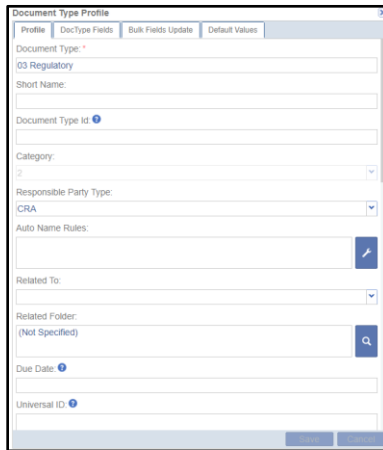


Figure 44: Document Type

- 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.

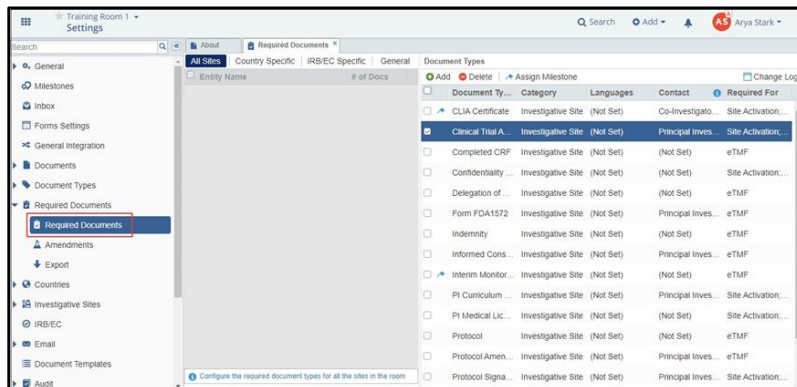


Figure 45: Required Document

## 152. 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:

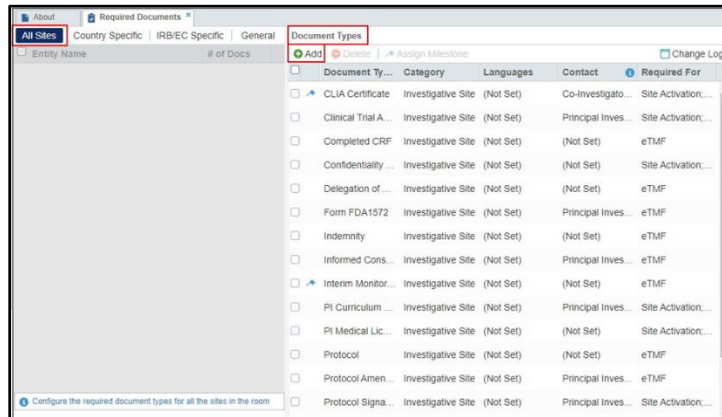


Figure 46: Adding Documents

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

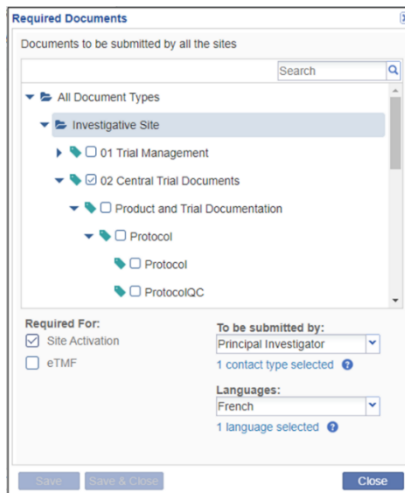


Figure 47: Required Documents

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.

- 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.

### 153. Deleting Documents from the List of Required Documents

To delete a Required Document:

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

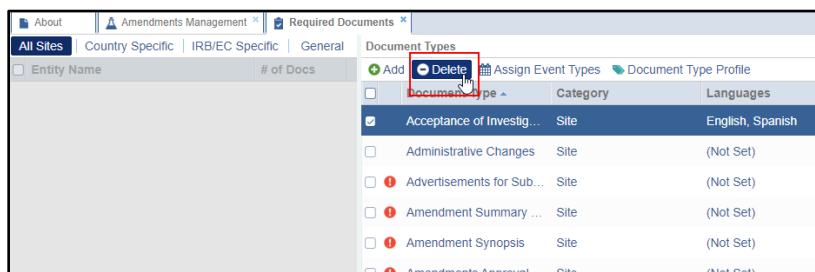


Figure 48: Deleting Documents

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

### 154. 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:

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

Title	Description	Amendment Date	Number of Required Doc...
State filing on non-Earth species Amendment	Our drug for exceptional fortune and good luck is not designed for Venusians, after assessment, it was determined a lower	30 Oct 2023	3
Test Amendment #1		10 Oct 2023	1

Figure 49: Add Amendment

2. Fill in the required details.
3. Click on the 'Add' button under the Required Documents panel.
  - o 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:
  - o All Sites
  - o Specific Sites
  - o Specific IRB/EC
  - o 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.

## 155. Export Required Documents

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

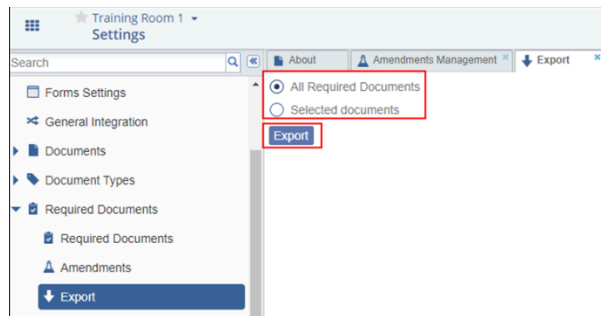


Figure 52: Export Documents

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:

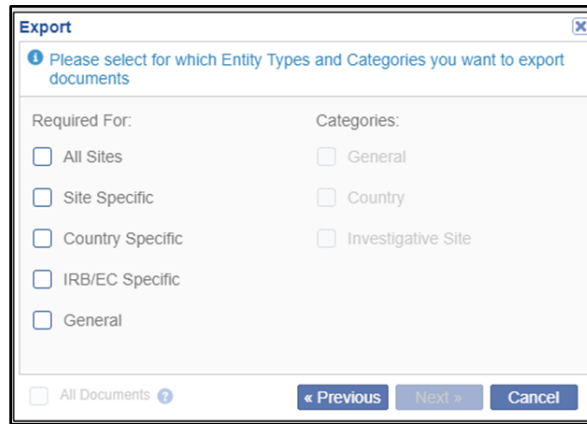


Figure 57: Entity Type and Categories

3. Click Next.
  - a. 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 Initiation 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\Fom FDA\IS72\Fom FDA\IS72	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\Sub-Investigator CV	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.

### 156. 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:

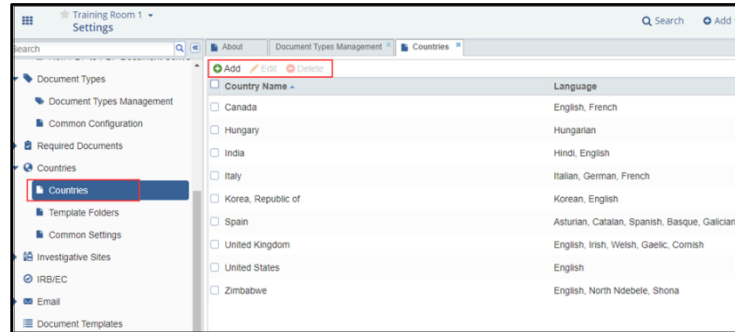


Figure 60: Countries Settings

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.
  - o The Create Country window will open. Refer to the screenshot below:

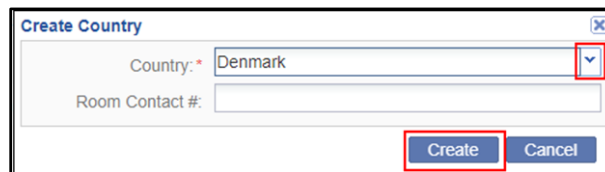


Figure 61: Create Country

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:

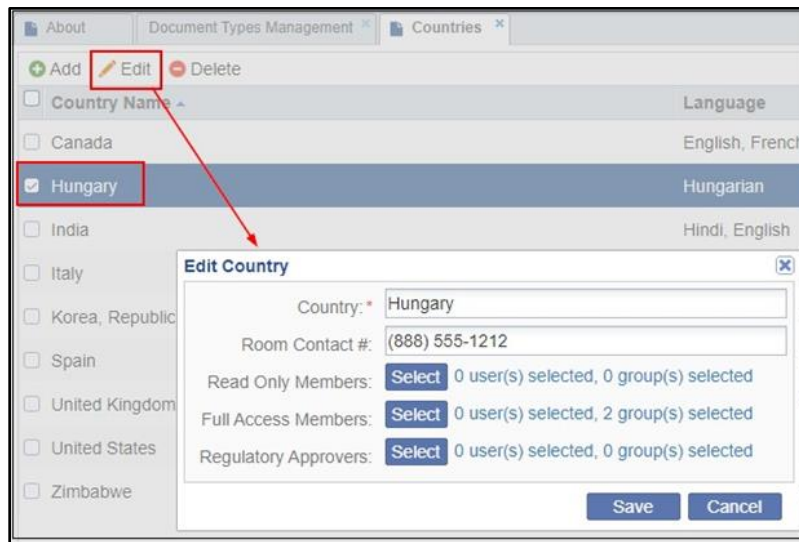


Figure 62: Edit Country

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.

---

## 157. Template Folders

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

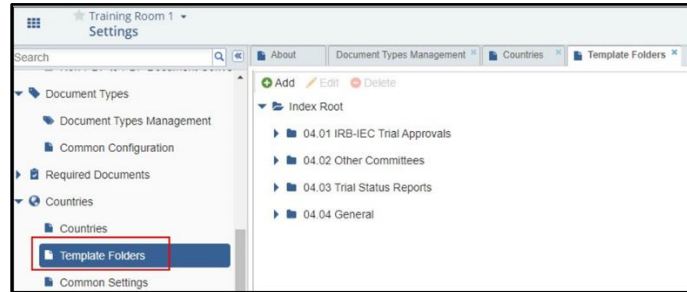


Figure 63: Template Folders

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.

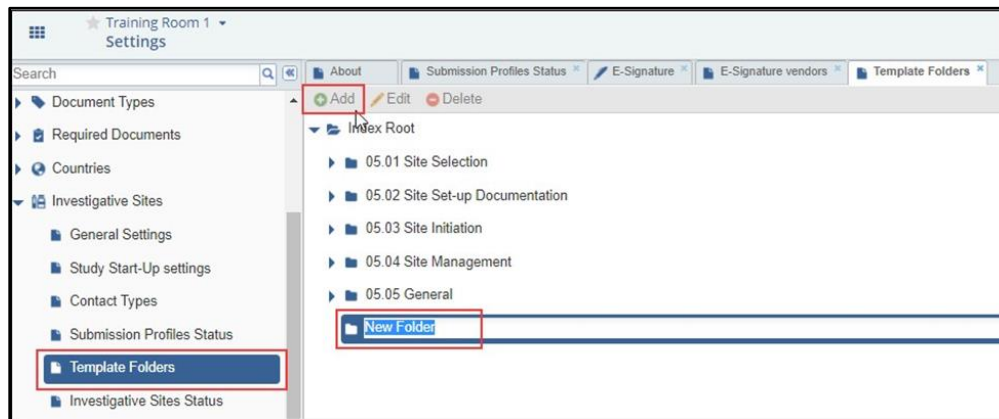


Figure 64: Adding Folders and Subfolders

### 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**.

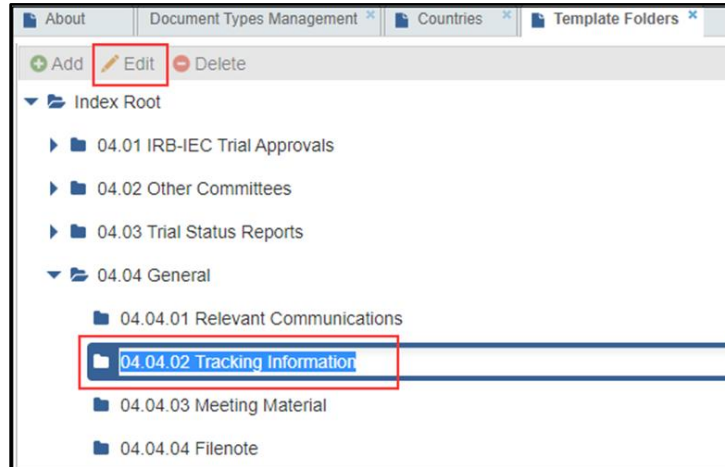


Figure 65: Editing folders

### 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.

### 158. 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:

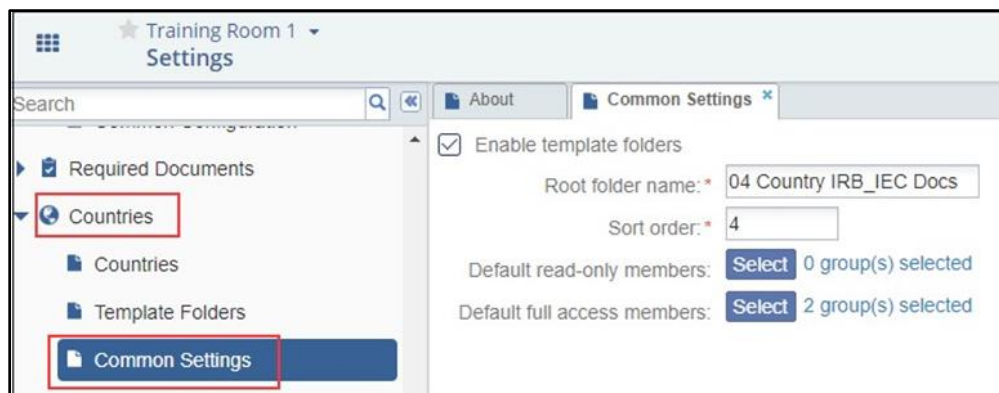


Figure 67: Common Settings

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.

159. 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:

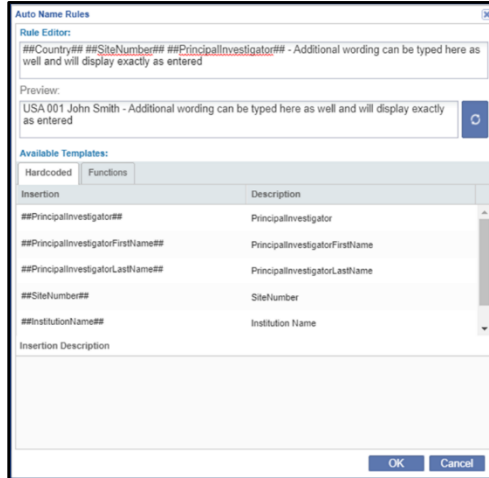


Figure 67: Auto Name Rules

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.

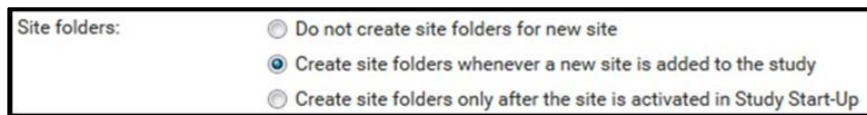


Figure 68: Site Folders

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.

## 160. 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.

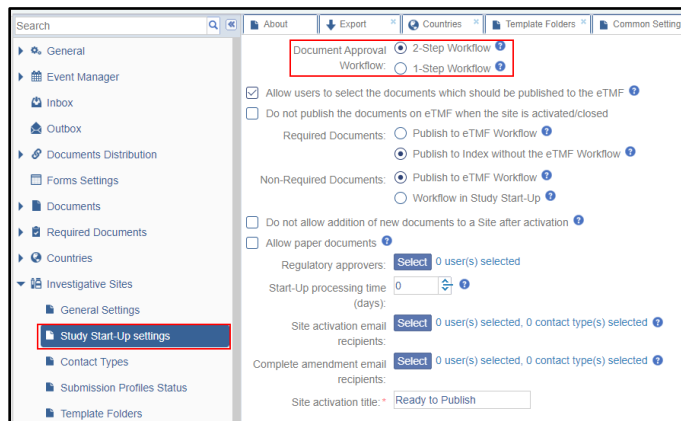


Figure 70: Study Start-up settings

- 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 an email whenever an amendment’s documentation requirements are complete.

## 161. 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.

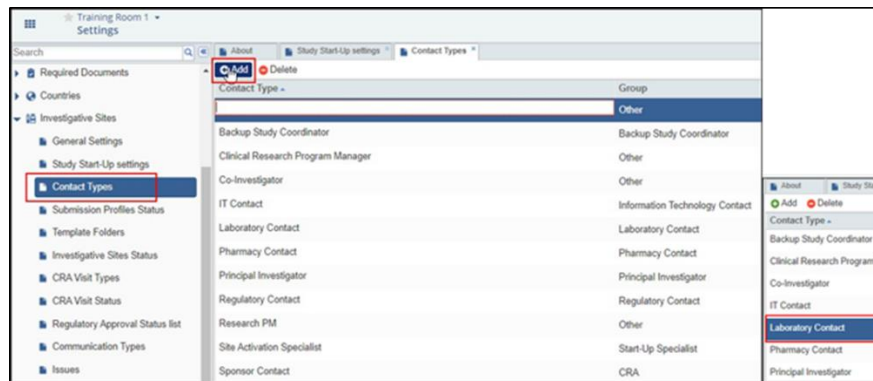


Figure 72: Contact Types

Additions and changes made here are saved automatically.

## 162. 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.

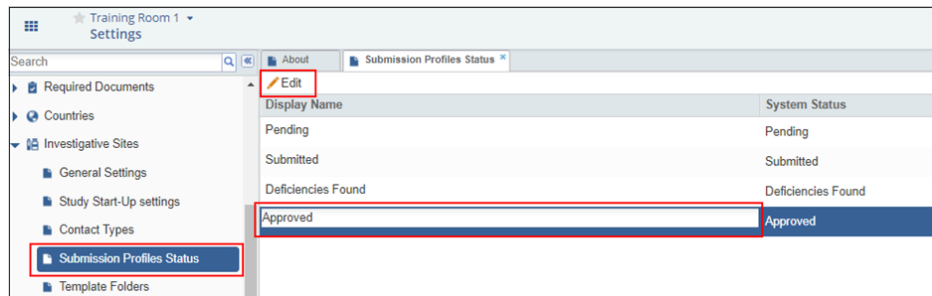


Figure 73: Submission Profile Status

### 163. 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.



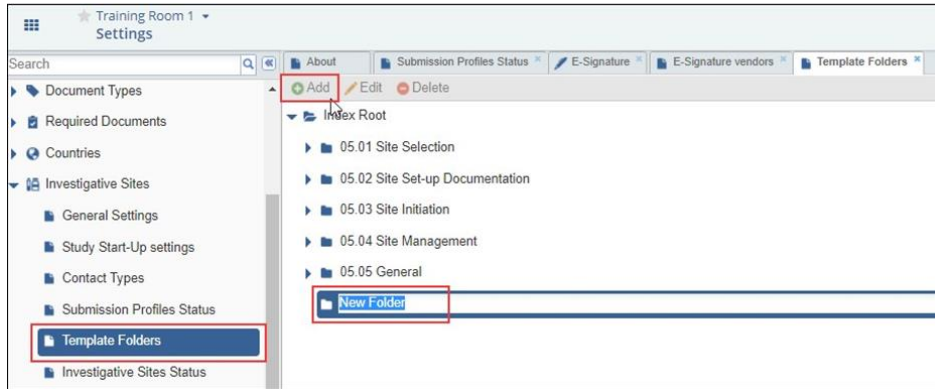


Figure 74: Template Folder

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.

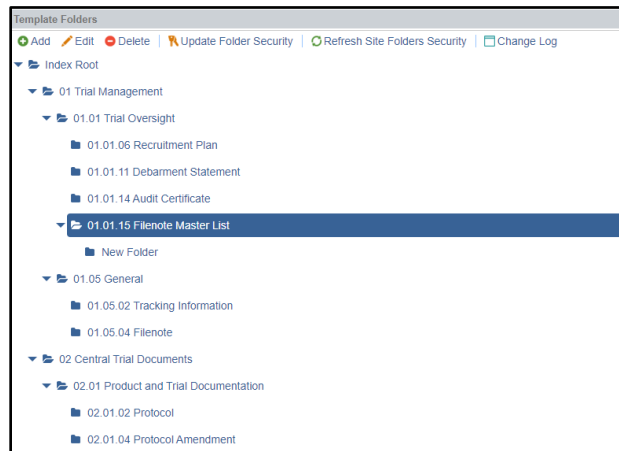


Figure 75: Template Folder Page

- 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.

## 164. 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.

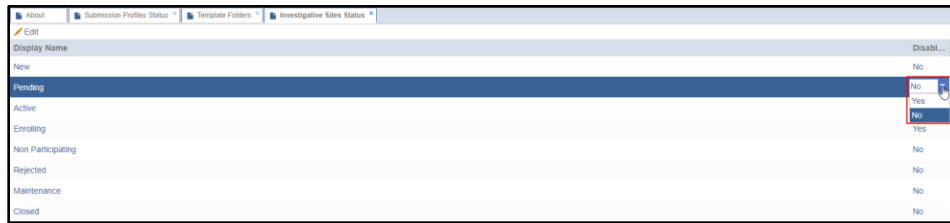


Figure 76: Investigative Site Status

## 165. 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.

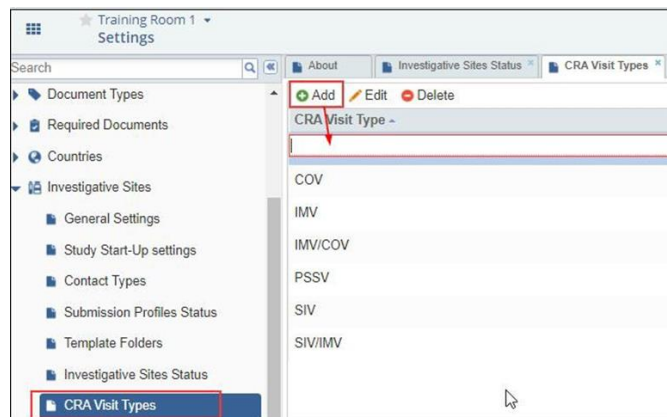


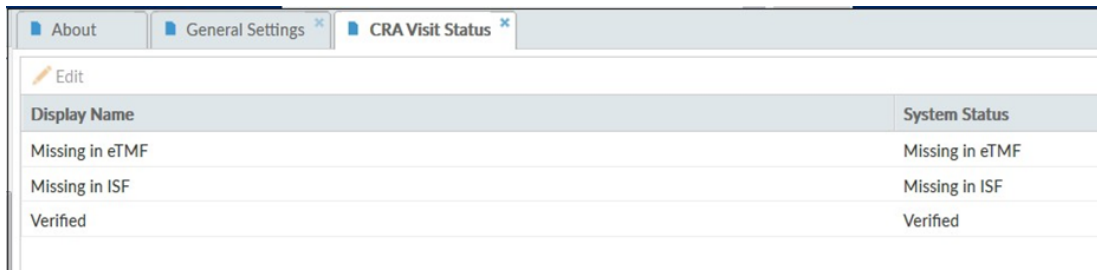
Figure 78: CRA Visit Type

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.

## 166. CRA Visit Status

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



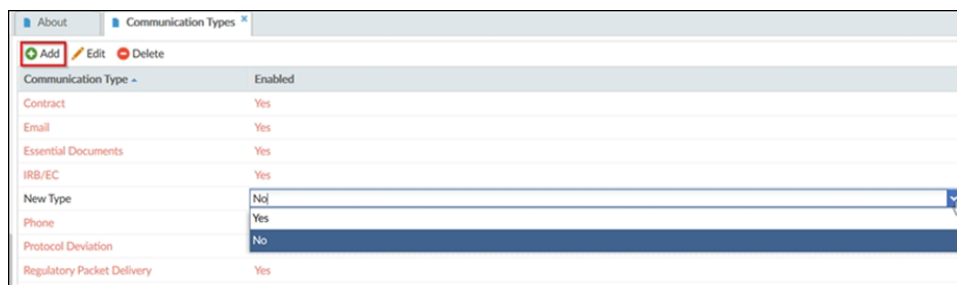
Display Name	System Status
Missing in eTMF	Missing in eTMF
Missing in ISF	Missing in ISF
Verified	Verified

Figure 79: CRA Visit Status page

## 167. 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 text field opens.
2. Type in the label. By default, the new communication type is not Enabled. Refer to the screenshot below:



Communication Type	Enabled
Contract	Yes
Email	Yes
Essential Documents	Yes
IRB/EC	Yes
New Type	No
Phone	Yes
Protocol Deviation	No
Regulatory Packet Delivery	Yes

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.

168. 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.

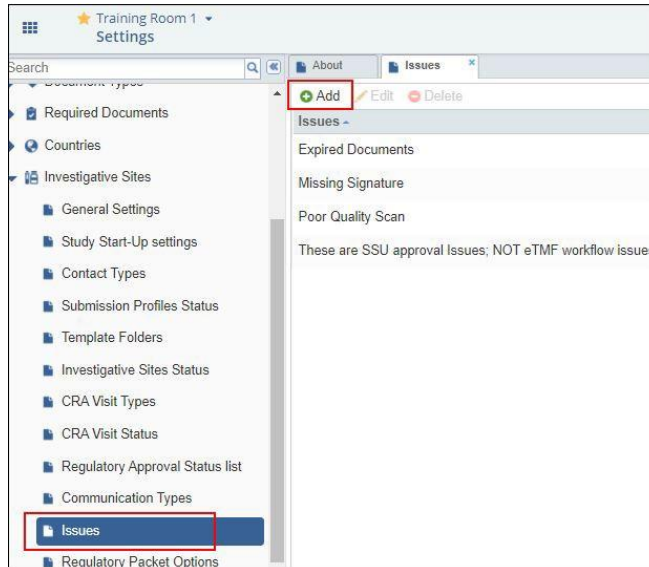


Figure 81: Issues

169. 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.

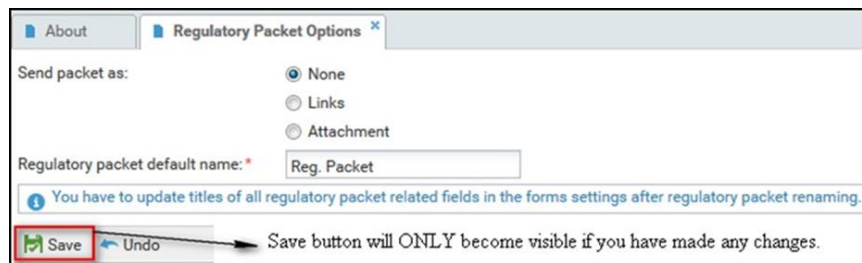


Figure 82: Regulatory Packet Options

## 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 they allow the room to predict site activation based on the approval cycle, buffer time, etc. associated with the approving organization.

## Email Settings

### 170. 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:

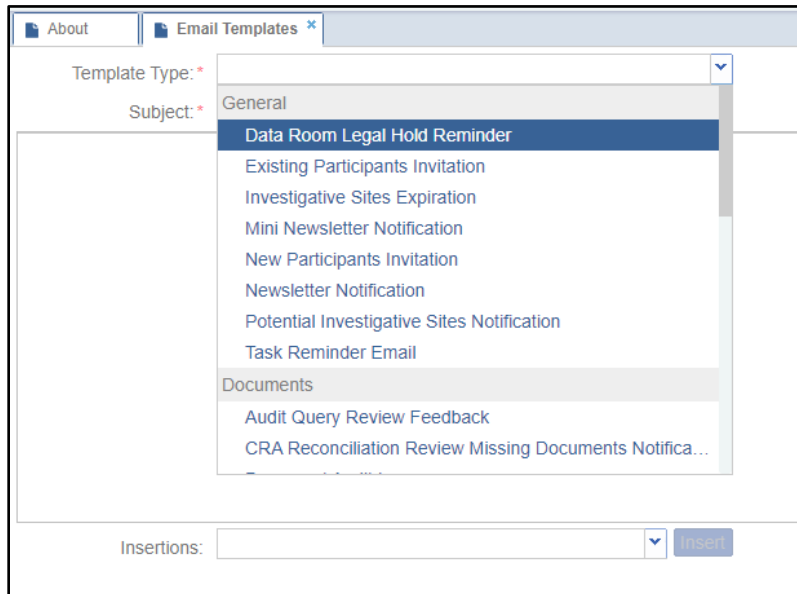


Figure 83: Email Setting

### 171. Room Legal Hold Notification Settings

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

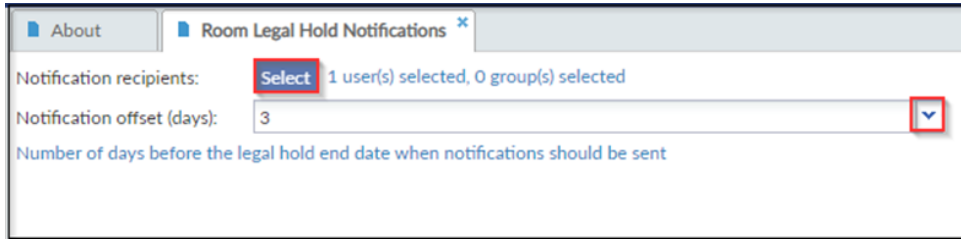


Figure 84: Room Legal Hold Notifications

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.

## 172. 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:

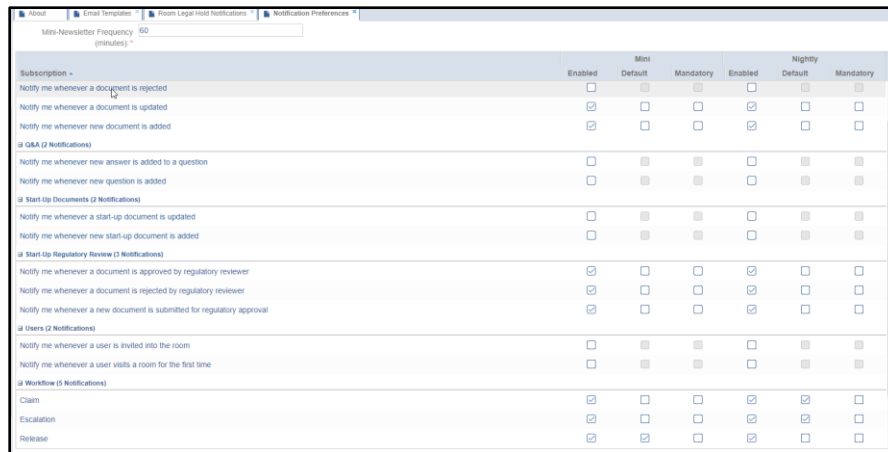


Figure 85: Notifications Preferences Settings

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.

### 173. 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:

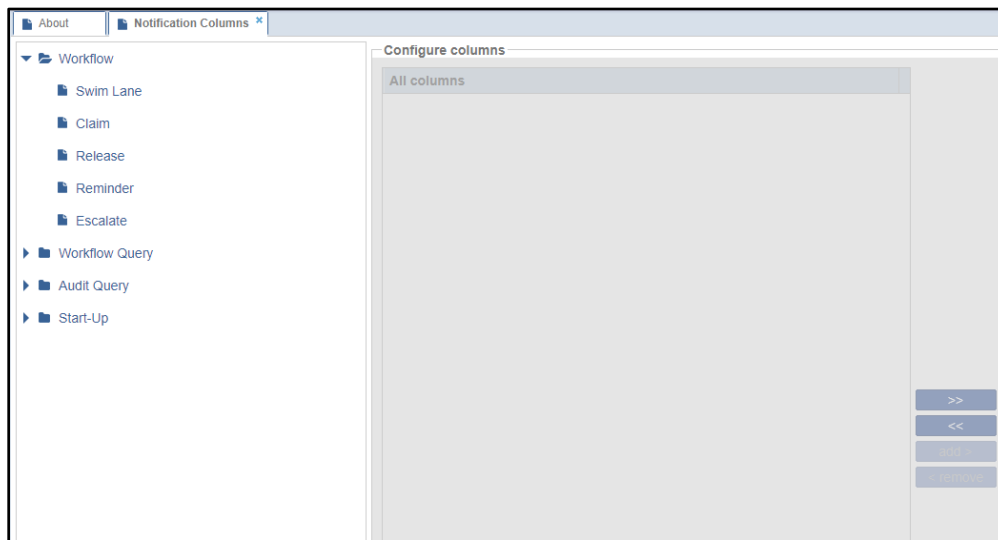


Figure 86: Notification Columns

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.

### 174. Document Template Settings

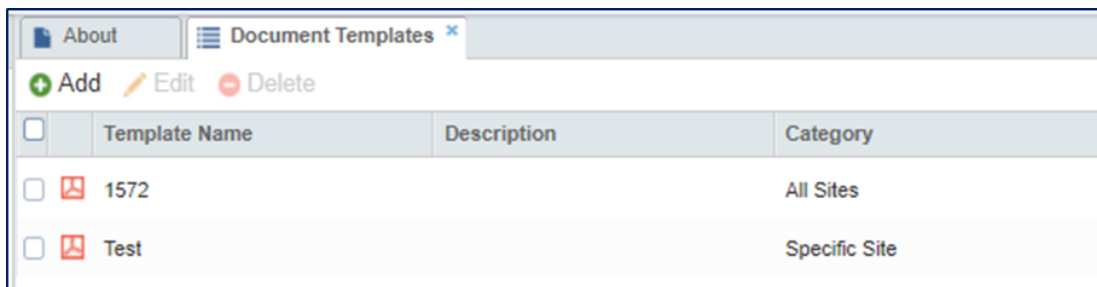


Figure 87: Document Template Settings

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.
  - General: This is more applicable to Collaborate or Docs type rooms where new SOP documents are created, reviewed, and approved.
  - 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.
  - 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.

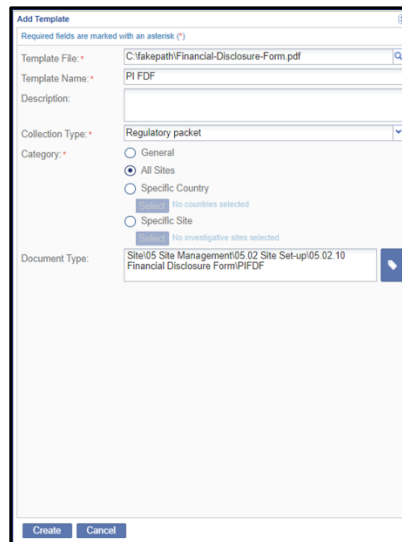


Figure 88: Adding Template

## Reports Settings

### 175. 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):

Heatmaps	Green		Yellow		Red	
	min	max	min	max	min	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.

---

## 176. 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**

### Workflow Common Configuration

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

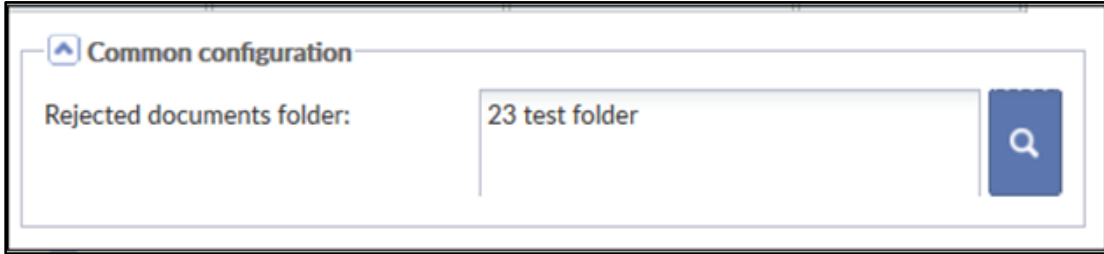


Figure 90: Common Configuration

**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:

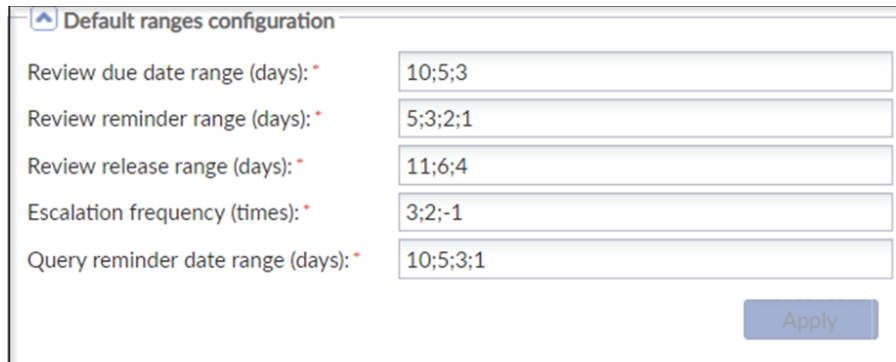


Figure 91: Default Ranges Configuration

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

**1. Review due date range (days).**

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

**2. Review reminder range**

- Here you specify the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.

- 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.

## Timeline Configuration

Refer to the screenshot below:

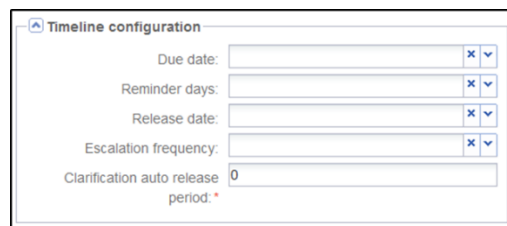


Figure 92: Timeline Configuration

- 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:

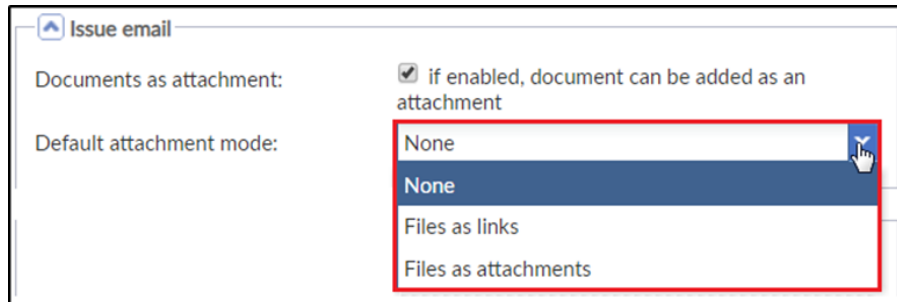


Figure 93: Email Issues

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:

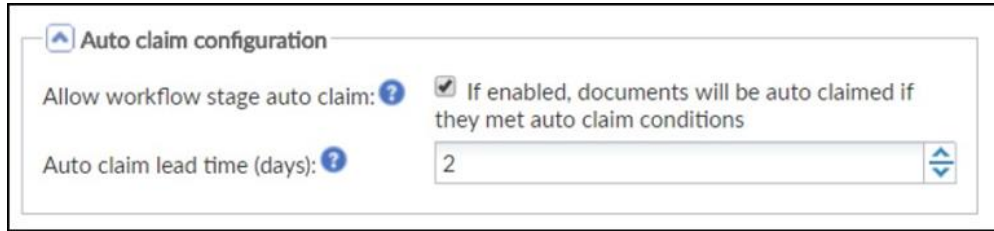


Figure 95: Auto claim Configuration

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.

### 177. Creating Quality Control Workflow

To create a Quality Control workflow follow the procedure below:

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

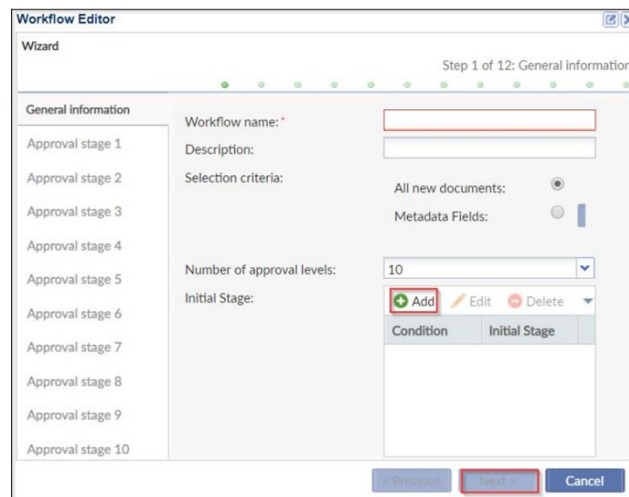


Figure 96: Workflow Editor

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:

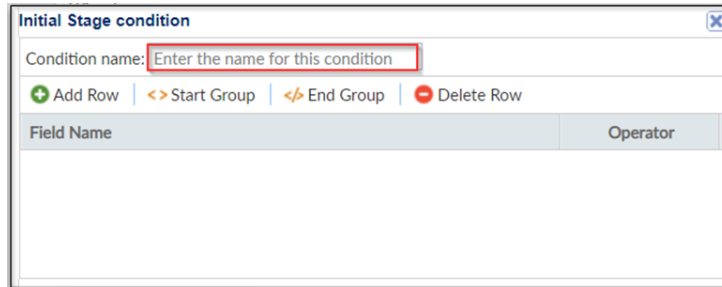


Figure 97: Initial Stage Condition

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:

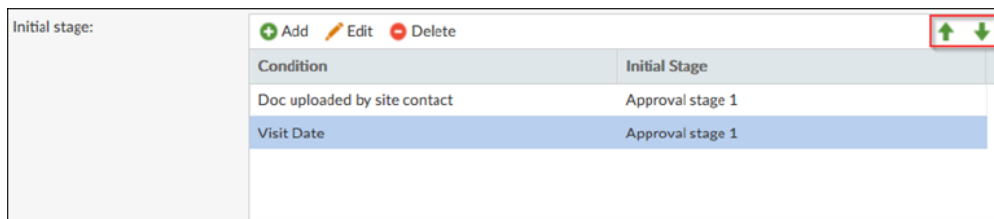


Figure 98: Initial Stage

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:

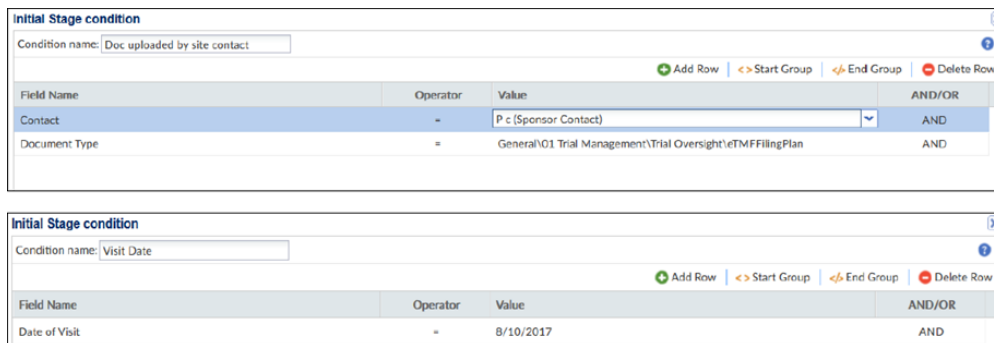


Figure 99: Initial Stage Condition

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:

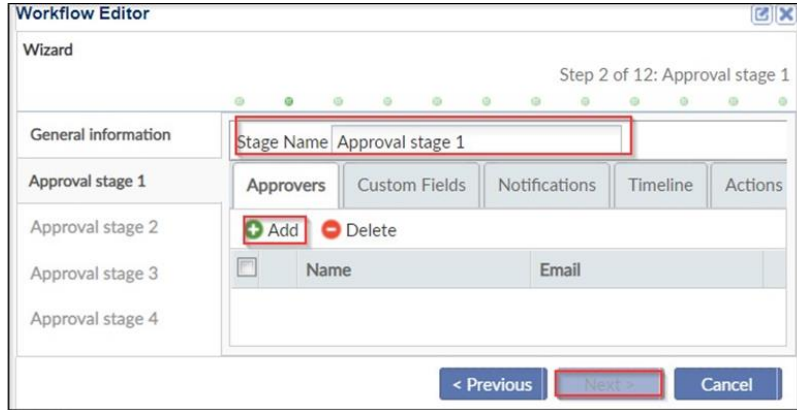


Figure 100: Workflow Editor

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:

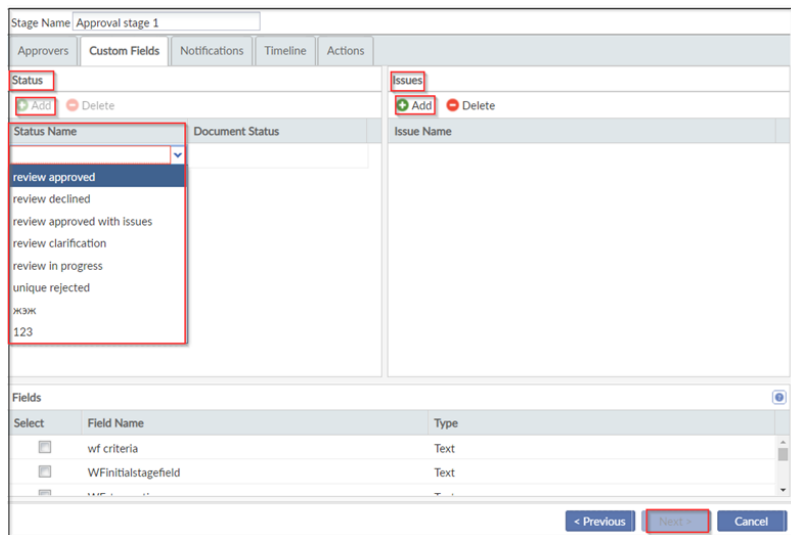
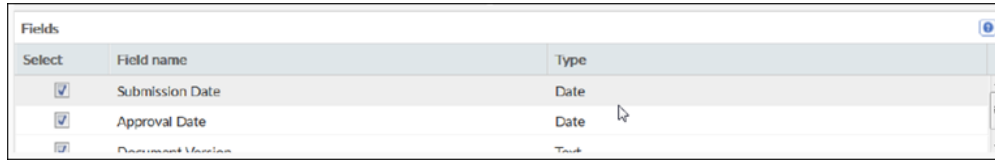


Figure 101: Approval Stage One

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:



Select	Field name	Type
<input checked="" type="checkbox"/>	Submission Date	Date
<input checked="" type="checkbox"/>	Approval Date	Date
<input checked="" type="checkbox"/>	Document Version	Text

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.

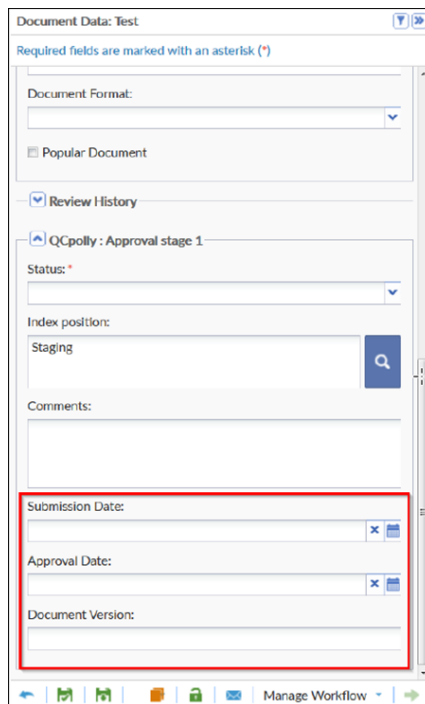


Figure 103: Document Data Test

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.

## 178. 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.

## 179. 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.

## 180. 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.

### 181. 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:

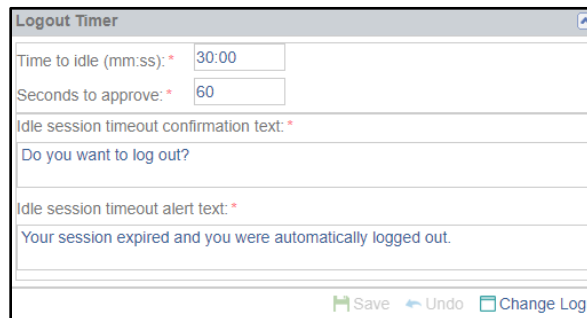


Figure 104: logout Timer Configuration

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:

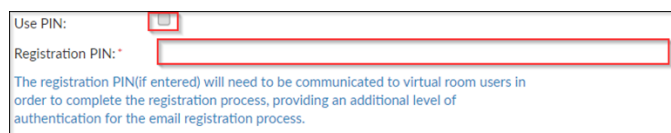


Figure 105: Invite Participants Settings

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:

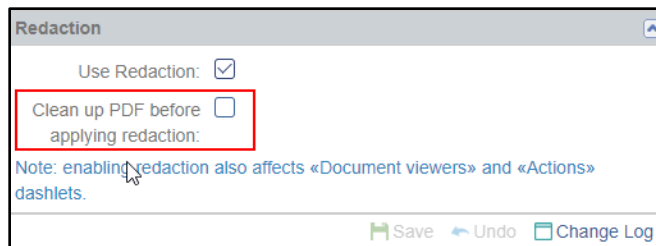


Figure 106: Redaction Settings

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:

Display name	System name
Redaction	Redaction
Study Startup	Study Startup
Page Manipulations	Page Manipulations
eSignature	eSignature
Communications	Communications
Document Distribution	Document Distribution
Event Manager	Event Manager
Assign Tasks	Assign Tasks
Document Manager	Document Manager
CRA Reconciliation	CRA Reconciliation
Enroll for GL Courses	Enroll for GL Courses
CRA	CRA

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:

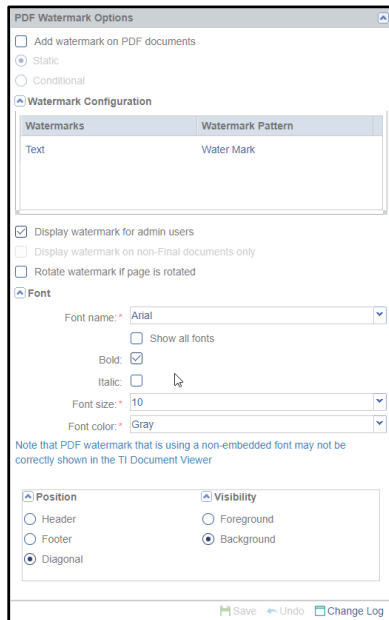


Figure 108: PDF Watermark Options

1. Activate or inactivate the Add Watermark on documents option by clicking the checkbox.
  - o 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.
  - o 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.
  - o 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:

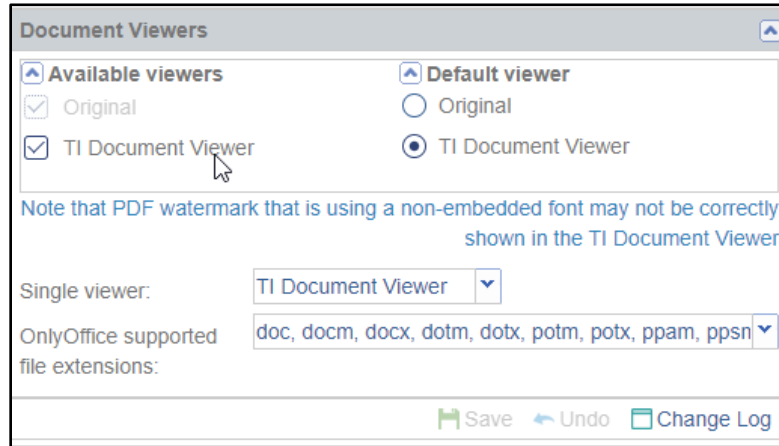


Figure 109: Document Viewers

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:

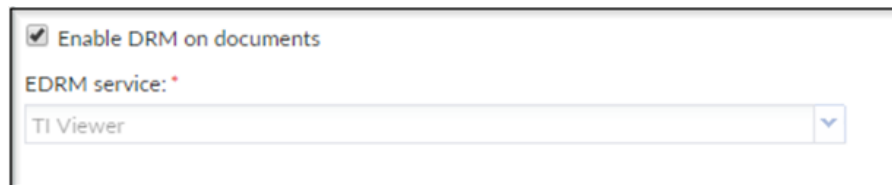


Figure 110: Document Encryption Options

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:

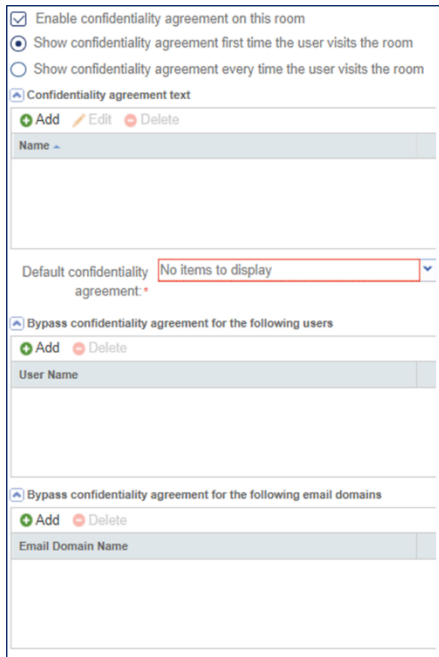


Figure 111: Confidentiality Agreement

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:

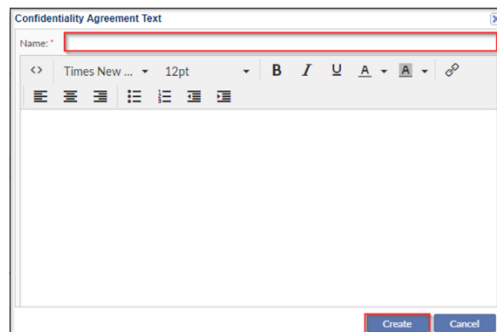


Figure 112: Confidentiality Agreement Text

4. Type in the Name of the agreement.

5. Click Create.

## 182. 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

## 183. 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

## 184. 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:

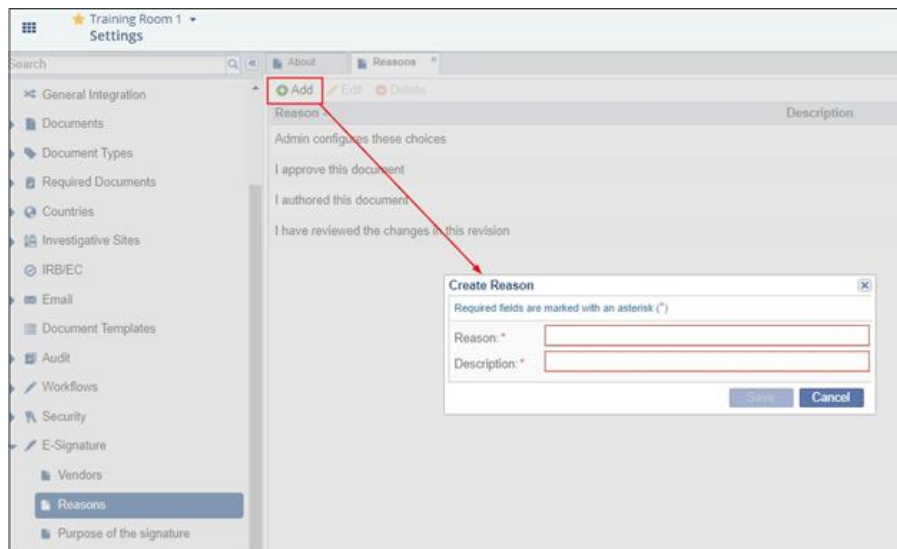


Figure 114: Create Reason

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



### 185. 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:

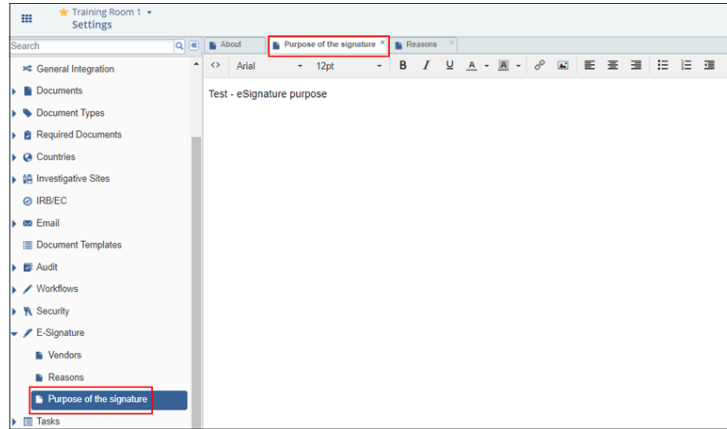


Figure 115: Purpose of the Signature

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.

### 186. 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:

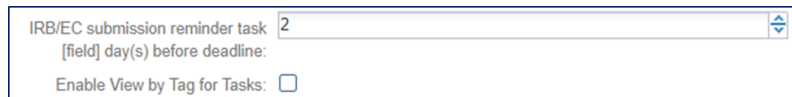


Figure 116: Tasks

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.

### 187. 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:

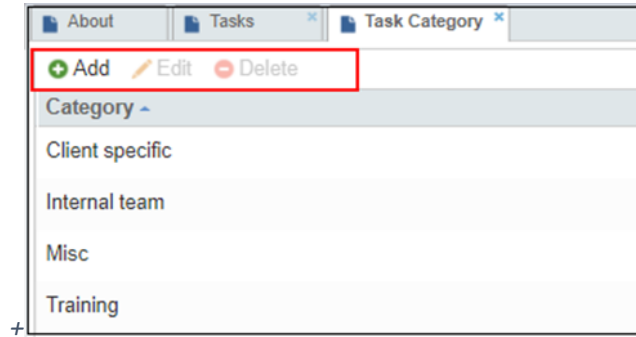


Figure 117: Tasks Category

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

### 188. 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:

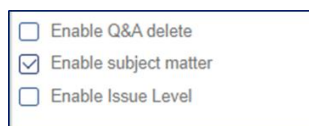


Figure 118: Q&A configuration

#### 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:

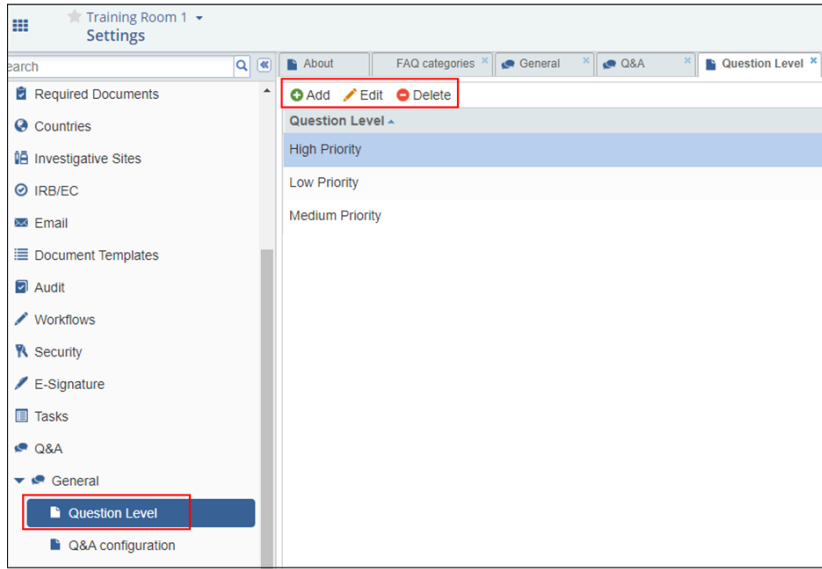


Figure 119: Q&A Question level

### **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:

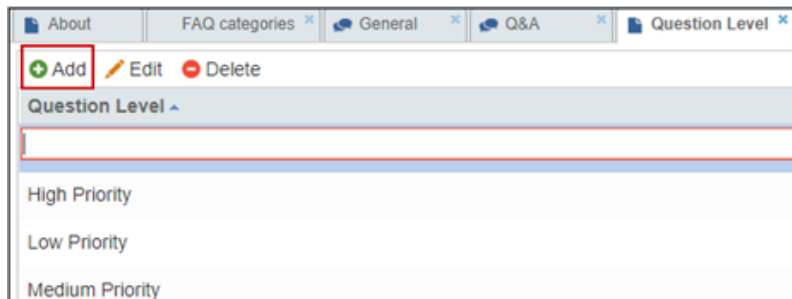


Figure 120: Adding New Question level

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

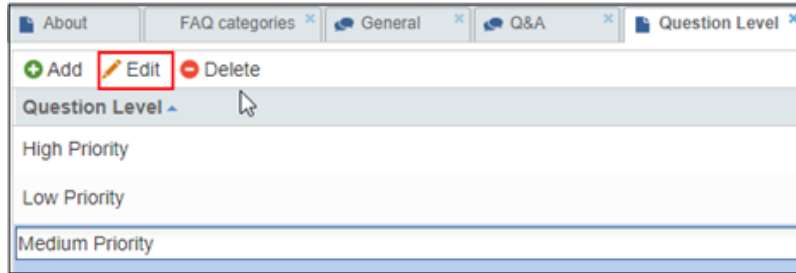


Figure 121: Editing a Question Level

### Deleting a Question Level

To delete a question-level:

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

---

### 189. 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:

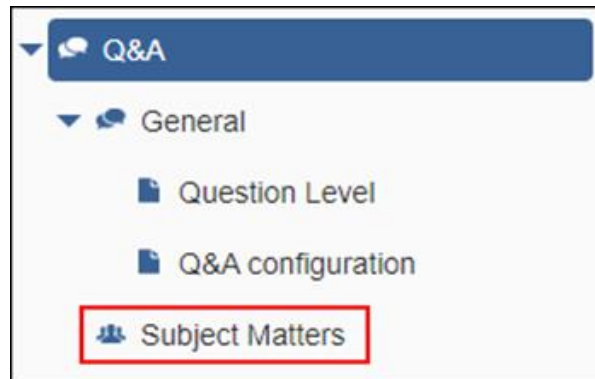


Figure 122: Subject Matters

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

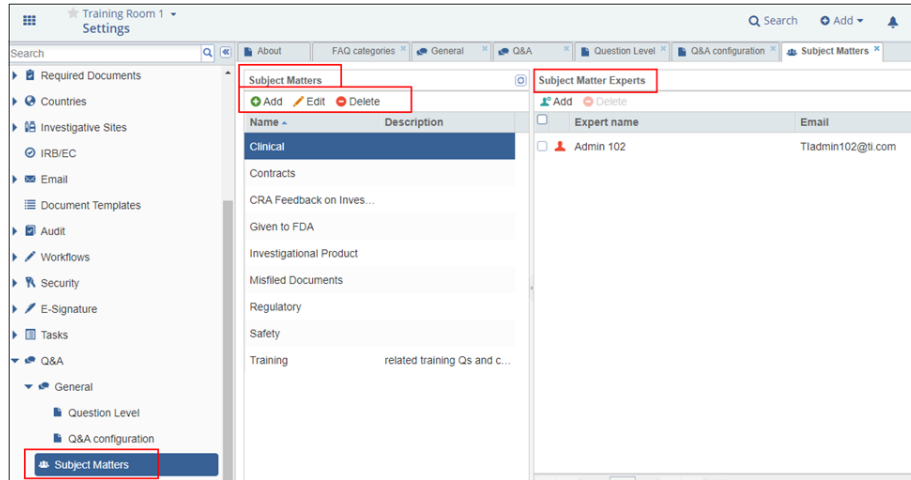


Figure 123: Subject Matter Experts

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:

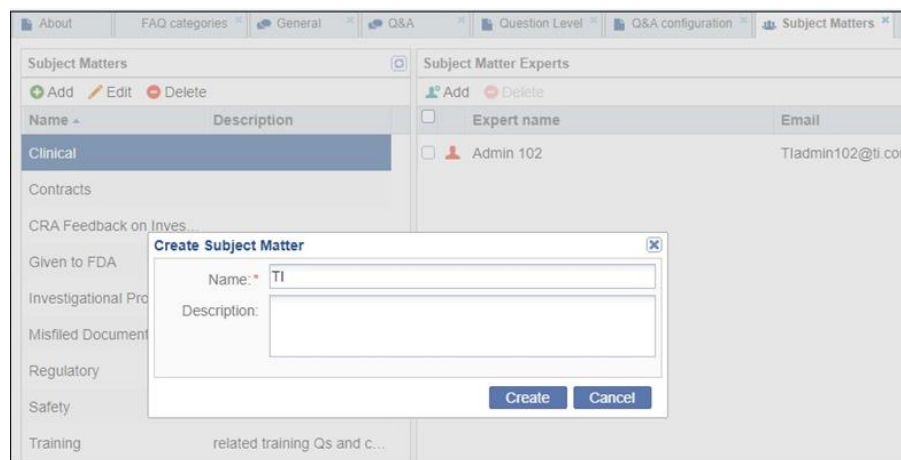


Figure 124: Create Subject Matter

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:

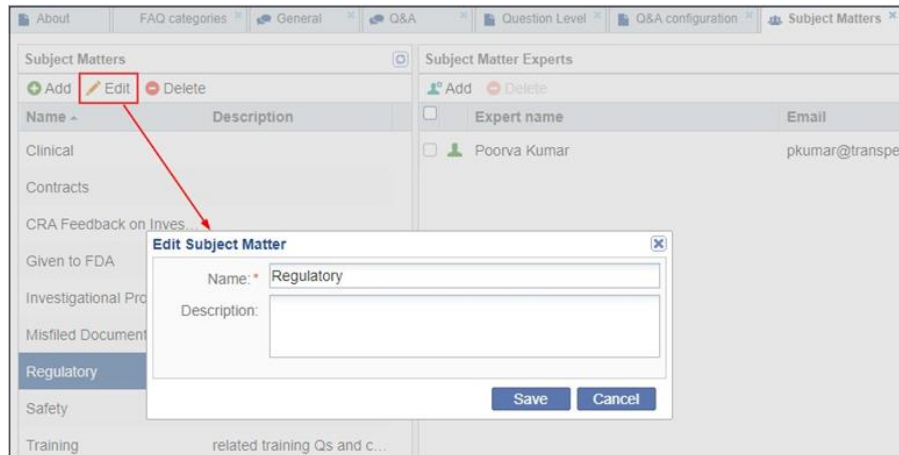


Figure 125: Edit Subject Matter

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

### **Deleting Subject Matters**

To delete a Subject Matter category:

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

### **Assigning Subject Matter Experts to Subject Matters**

To assign a Subject Matter Expert to a 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:

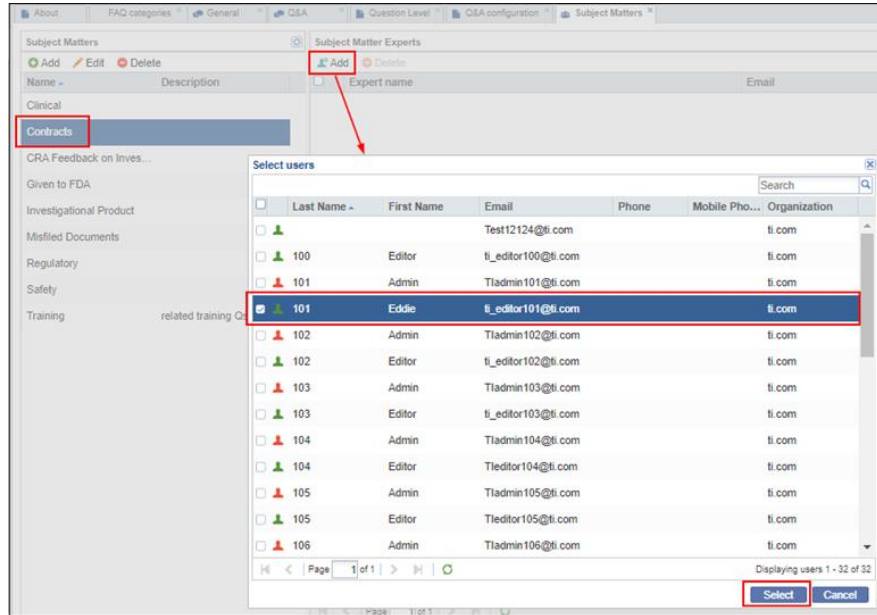


Figure 126: Assigning Subject Matter Expert

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.

---

### 190. Adding FAQ Categories

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

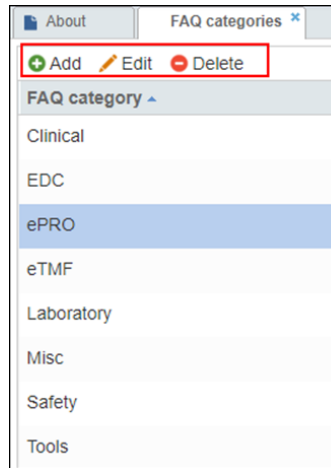


Figure 127: Add FAQ

3. Click Save after making any changes.

---

### 191. 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.

---

### 192. Deleting FAQ Categories

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



## 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.

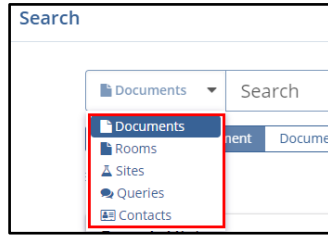
### Documents Search

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:

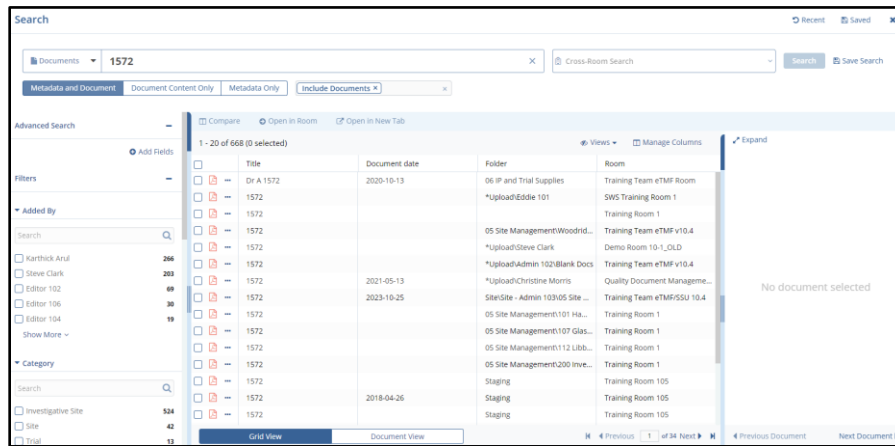
The process to execute both types of searches is the same except for the location of executing the search:

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**

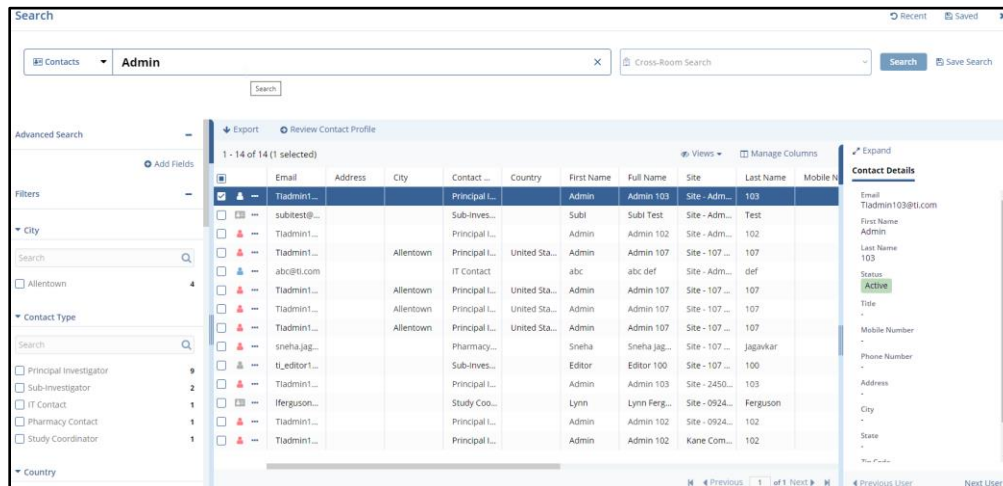


**Note:** Only Administrator users will be able to view all of these options.

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:



1. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
2. Hover the mouse over the Document icon to get a preview of the documents.
3. Click the document icon. The document Metadata panel opens in the right pane.
4. 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.

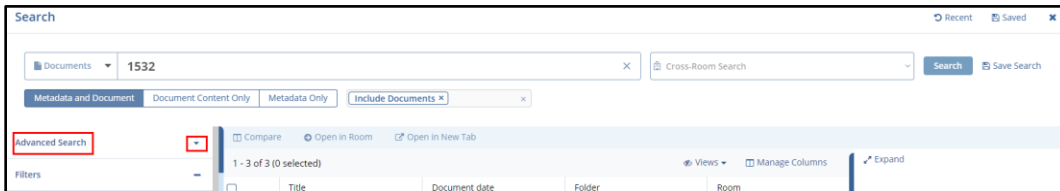


## Advanced search

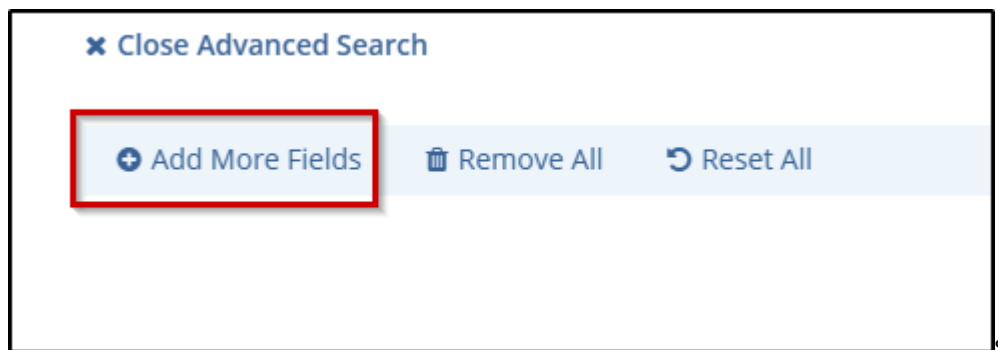
Added an **“Apply Filter”** button to the advanced search panel. Users who perform an advanced search can now add a search field and update their search results immediately using an ‘Apply Filters’ button directly in the Advanced Search panel rather than relying only on the primary search button.

To perform Advanced Search, follow the below Steps:

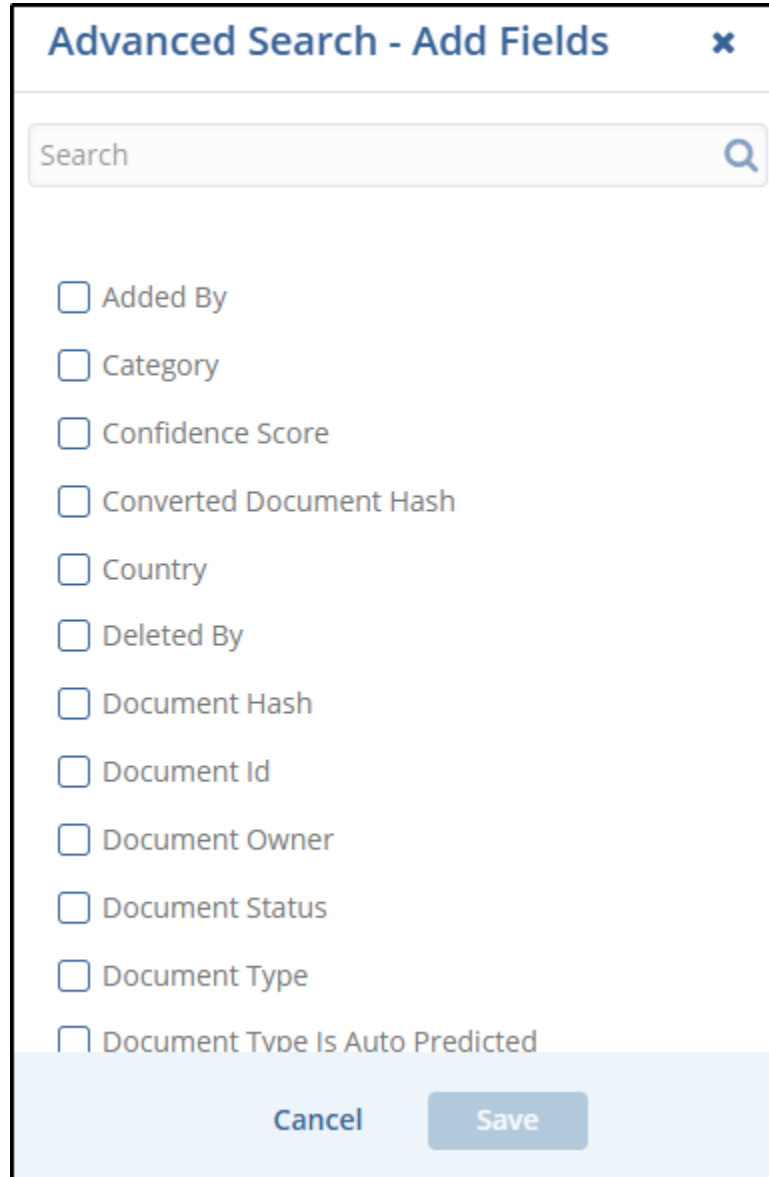
1. From the Search page Click on the **Advanced Search** drop-down icon available on the left panel. Refer to the screenshot below.



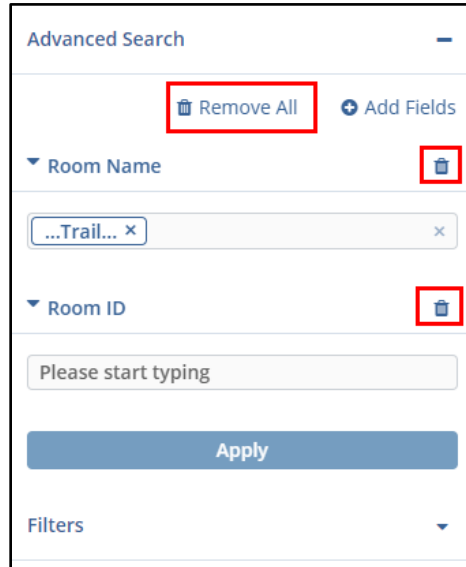
2. To add fields, click on the Add Fields (+) icon. The **Advanced Search – Add Fields** window will appear.



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.

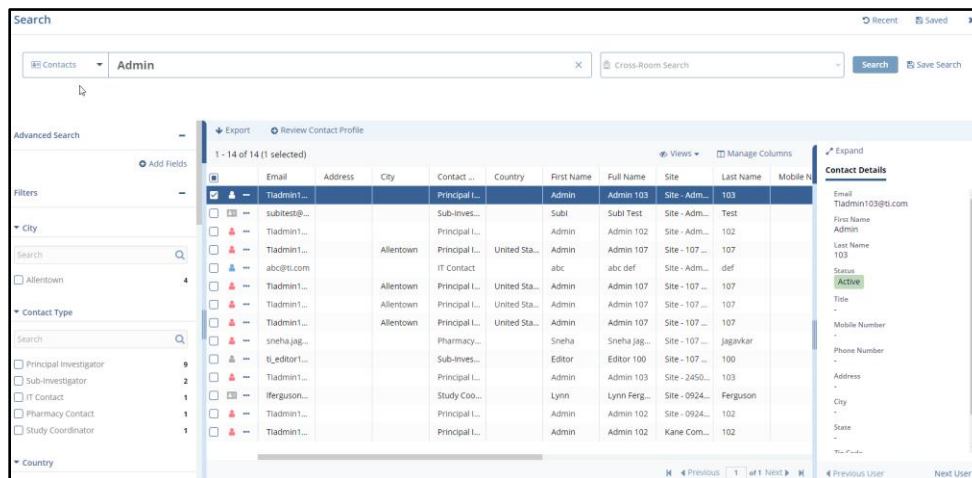


### Searching Contacts

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:



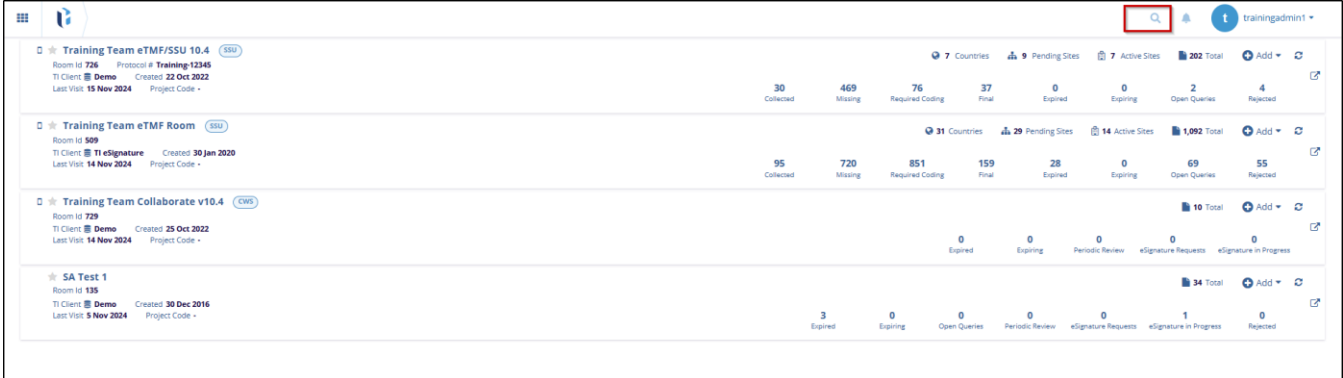
4. Upon selecting a required from the results grid, details of that user will be displayed in the **Contact Details** section in the right pane.

### 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:



Room Name	Room ID	Protocol #	Created	Last Visit	Project Code	30 Collected	469 Missing	76 Required Coding	37 Final	0 Expired	0 Expiring	2 Open Queries	4 Rejected
Training Team eTMF/SSU 10.4	726	Training-12345	22 Oct 2022	15 Nov 2024		30	469	76	37	0	0	2	4
Training Team eTMF Room	509	TI eSignature	30 Jan 2020	14 Nov 2024		95	720	851	159	28	0	69	55
Training Team Collaborate v10.4	729		25 Oct 2022	14 Nov 2024									
SA Test 1	135		30 Dec 2016	5 Nov 2024									

## 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

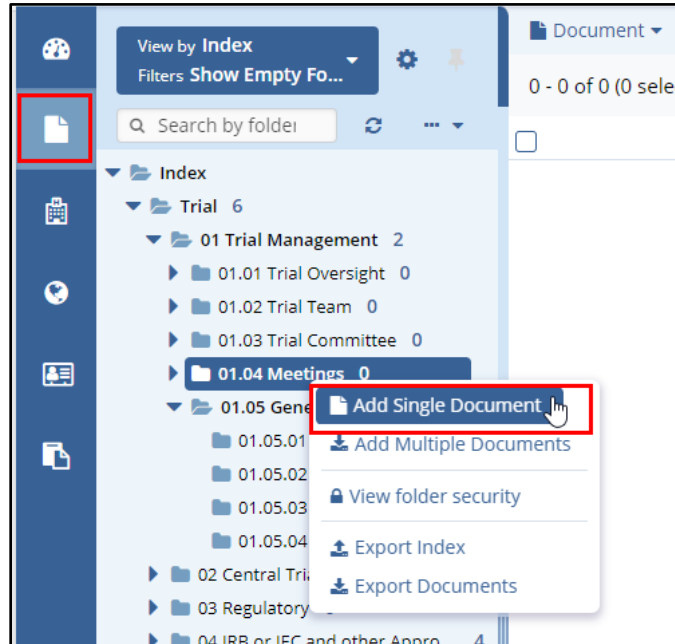
You can add Single or Multiple documents to an index folder. Each of these is discussed in the sections in the subsequent topics.

#### 193. 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.

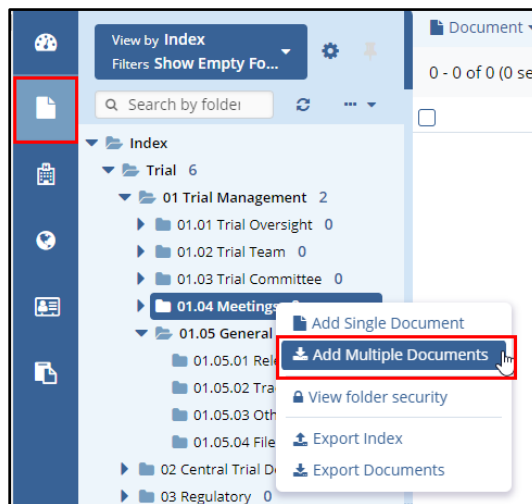
Refer to the screenshot below:



4. This will open the Document Profile form for you to add the details and save.
  - o This adds documents directly to the selected folder but, depending upon room settings, the document may be redirected to the default (staging) folder.

#### 194. 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.



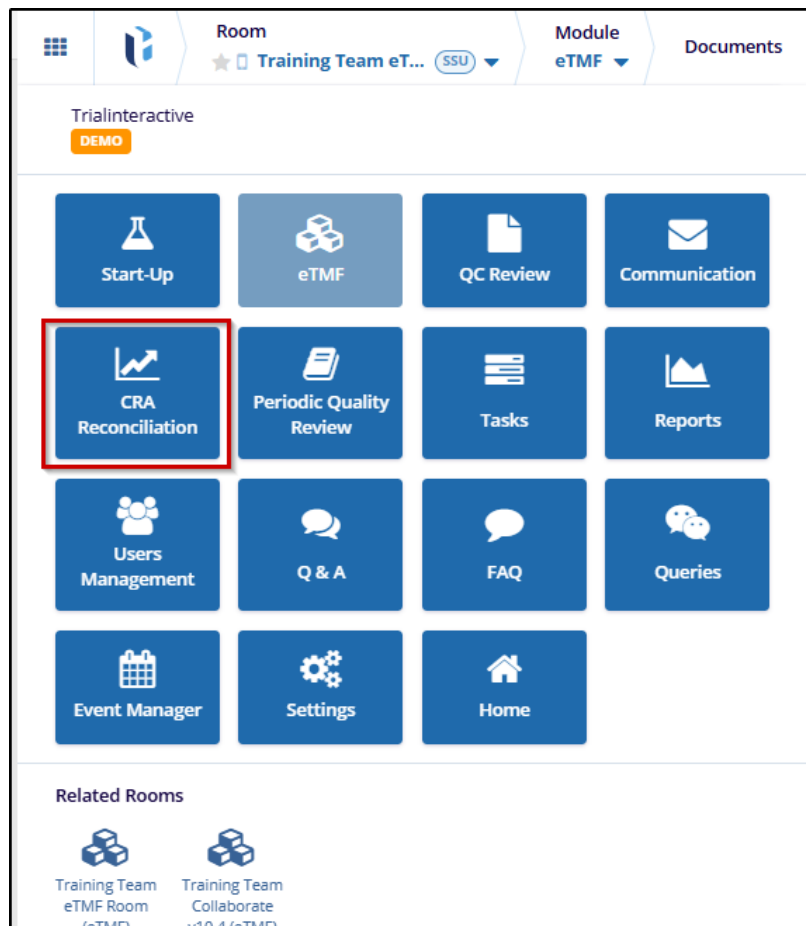
3. This opens the Import Documents window. Add documents to the window and press 'Import.' A more in-depth discussion of this import window can be found in the section on importing documents and metadata.

## 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.

## 195. 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

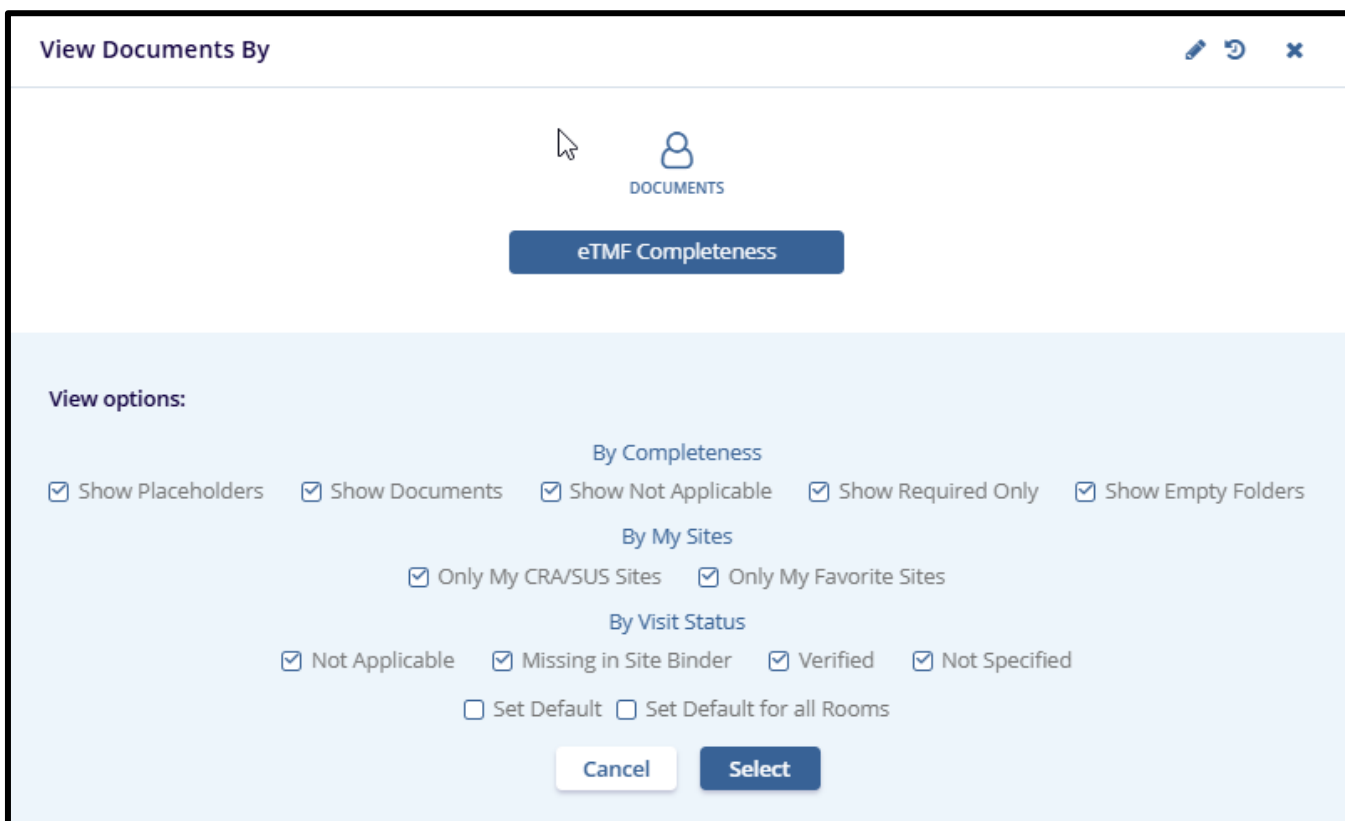
CRAs can avail of this information from the Site Report so that they can verify the outstanding documents during their next site visit.

Follow the steps below to reconcile documents:

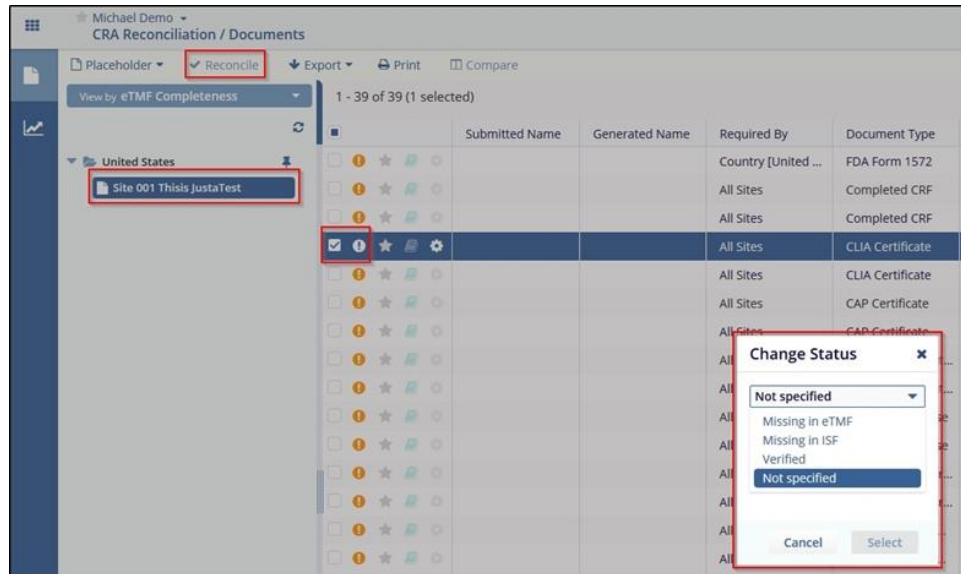
1. Navigate to the CRA Reconciliation Module.

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'

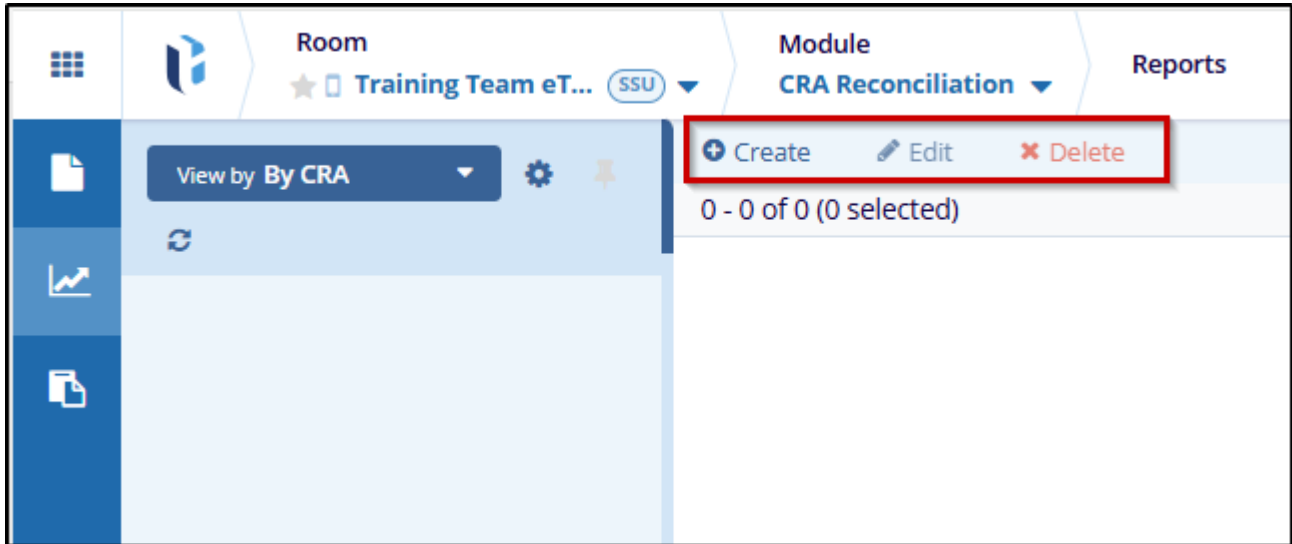


### Creating and Viewing CRA TMF Reconciliation Reports

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:



#### 196. 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.

#### 197. 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.

#### 198. 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.

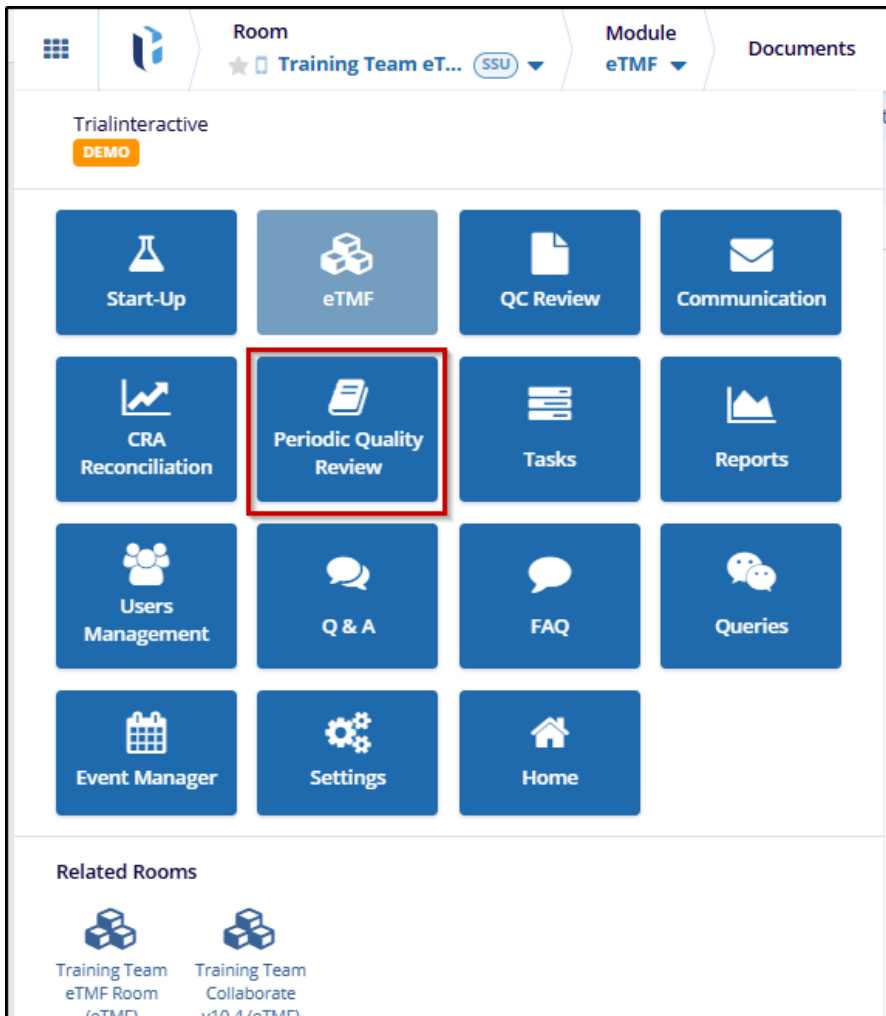


Figure 1: Quality Review Icon

199. 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.

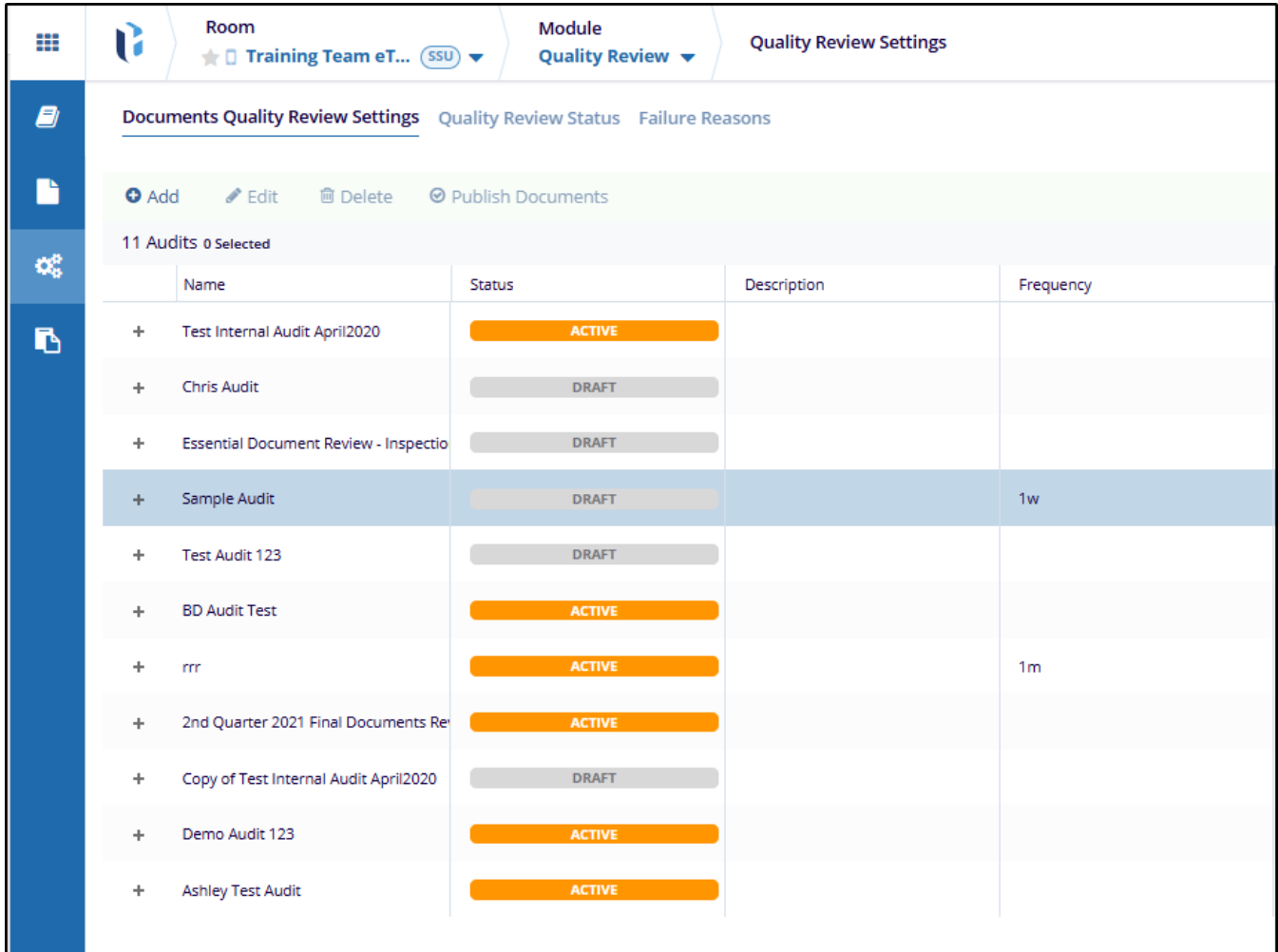


Figure 2: Quality Review Settings

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.

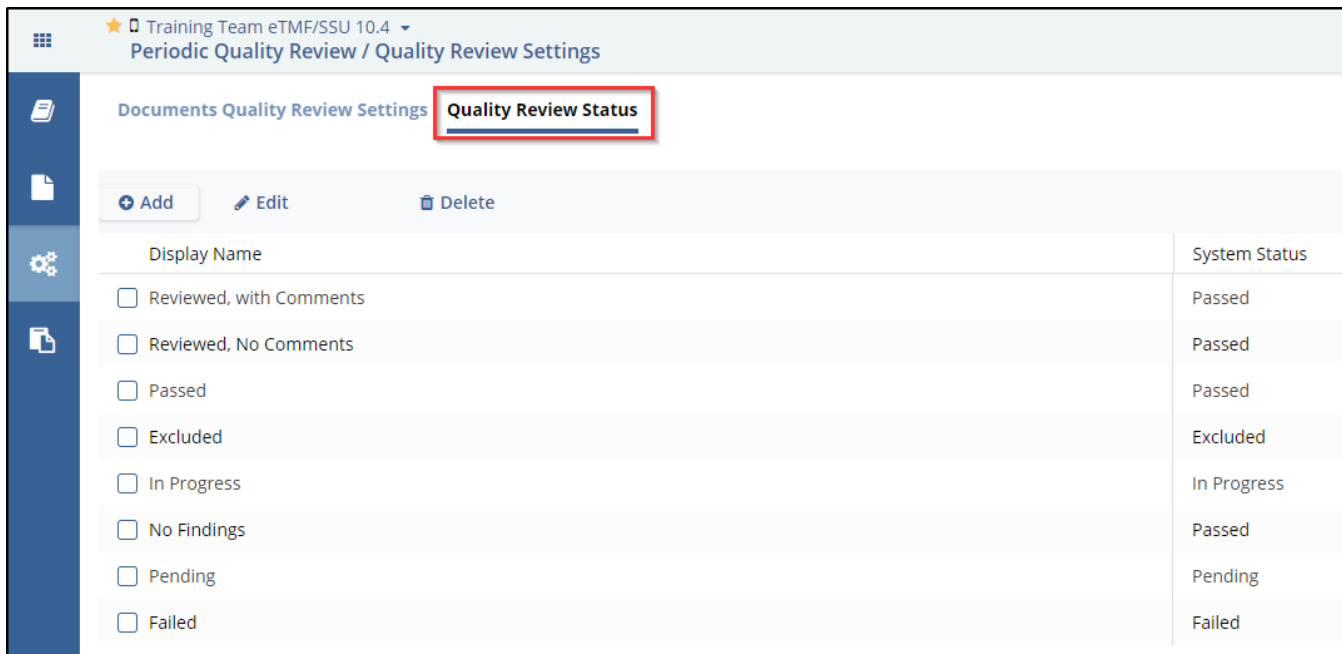


Figure 3: Quality Review Status

### 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.

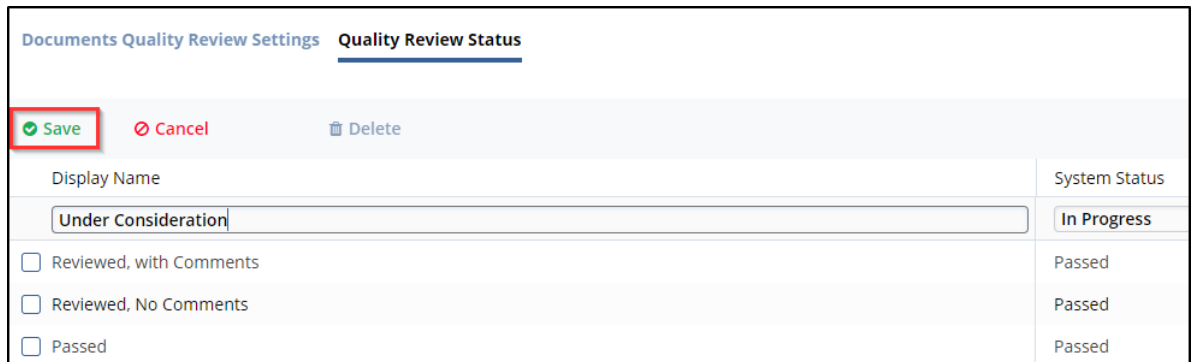


Figure 4: Quality Review Status-Add

### 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.

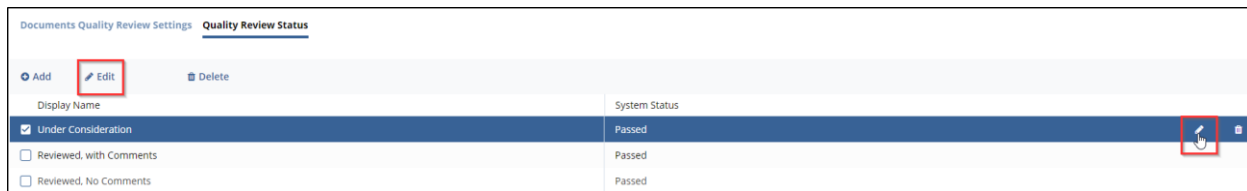


Figure 5: Quality Review Status-Edit Icon

- Notice that the Add and Edit buttons changes to Save and Cancel when the audit is activated for editing. Refer to the screenshot below:

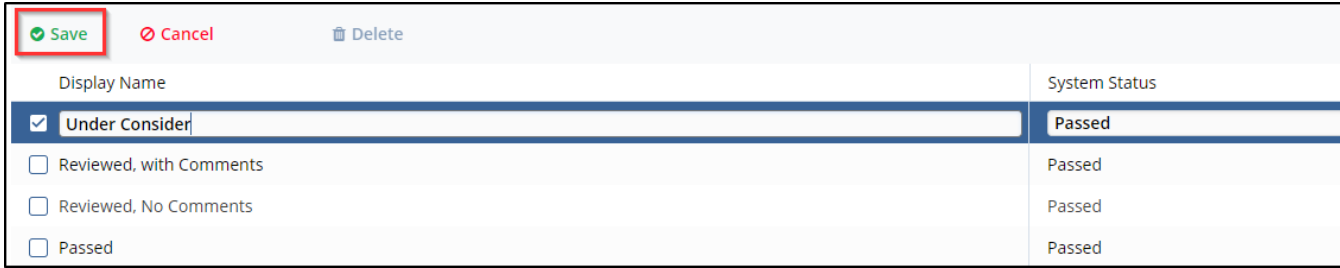


Figure 6: Quality Review Status-Edit

- Make the required changes and click **Save**.

### Deleting an Audit Status

Follow the steps below to delete an audit status:

- Select the status from the list in the Quality Review Status window.
- Either click 'Delete' from the top ribbon bar or click the trash can icon that appears on hovering the mouse over the status.

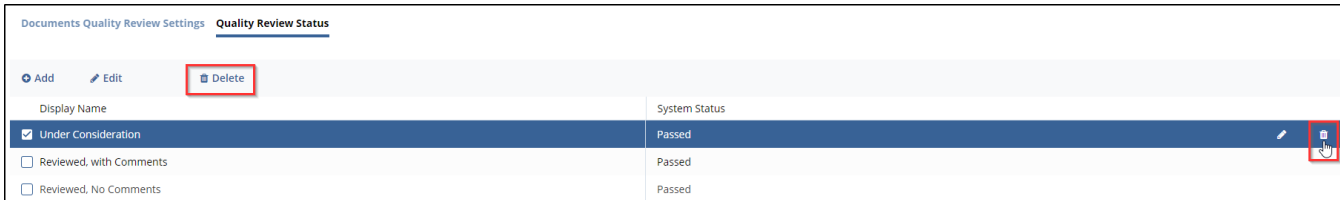


Figure 7: Quality Review Status-Delete



### 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.

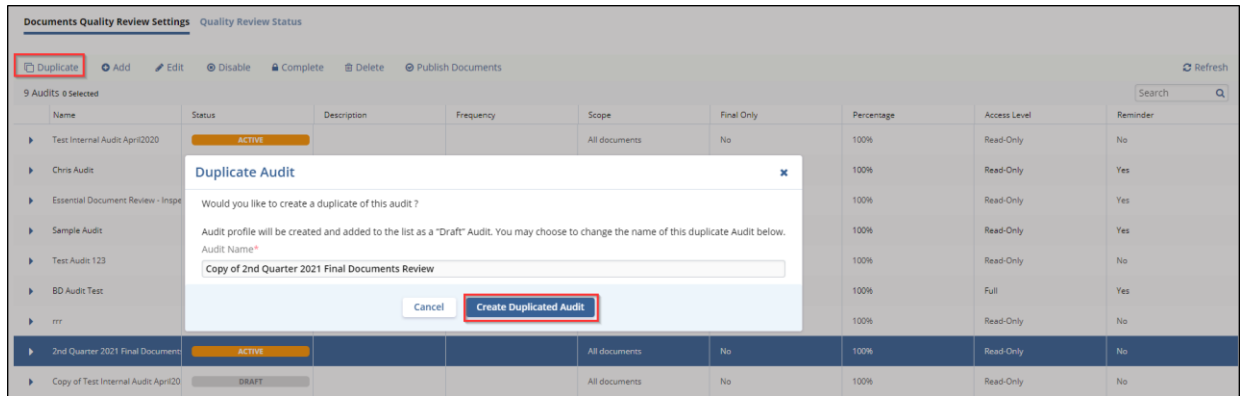


Figure 8: Quality Review Status-Duplicate

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.

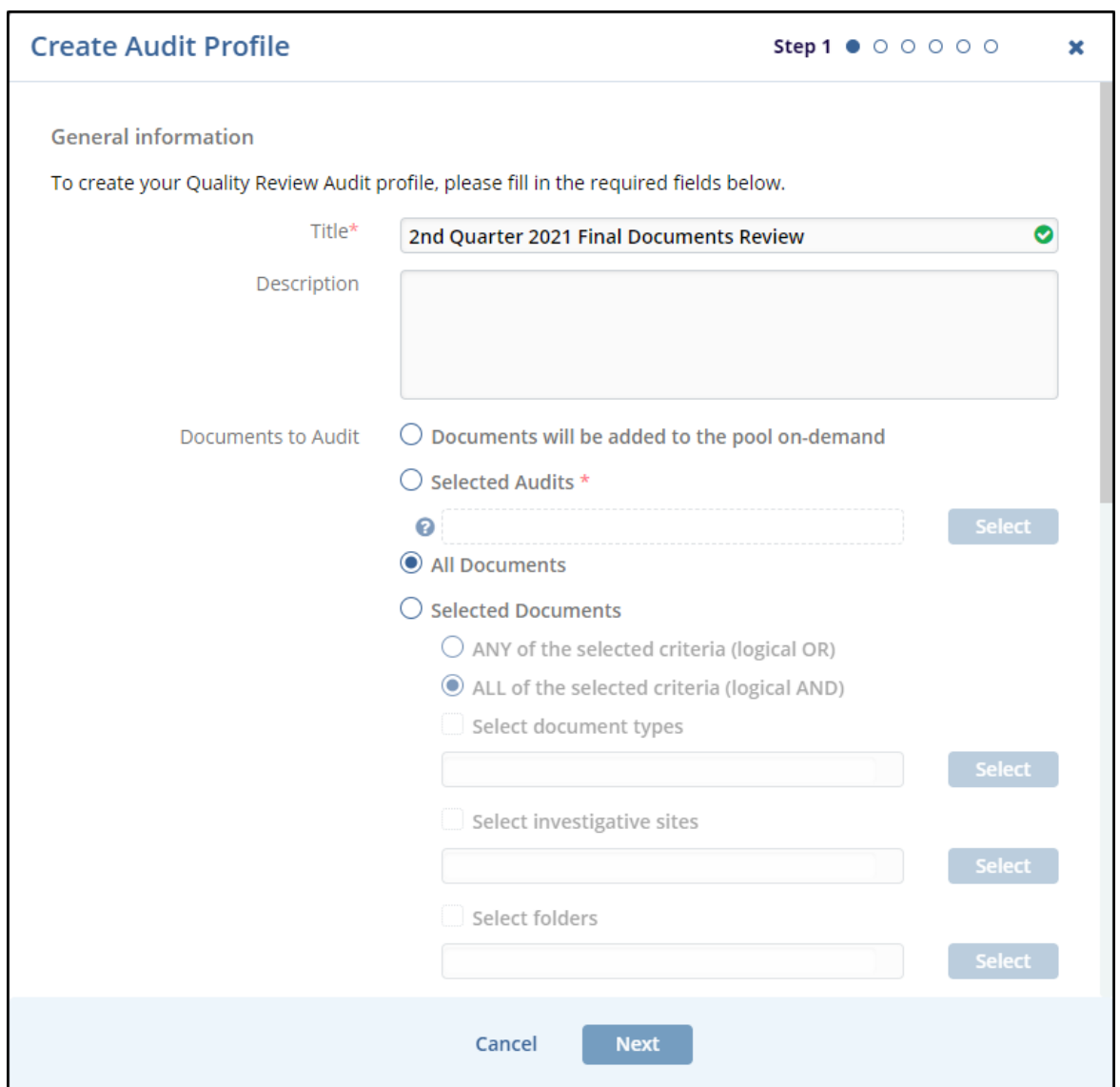
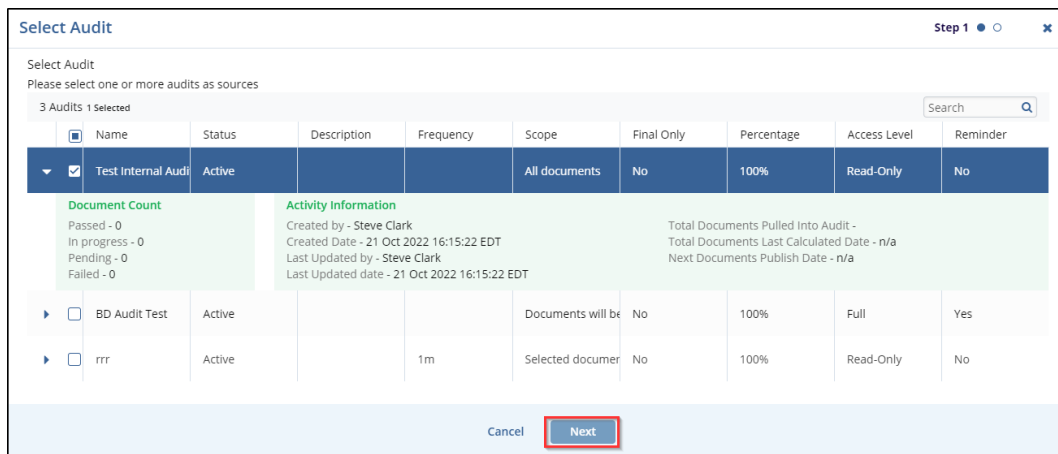
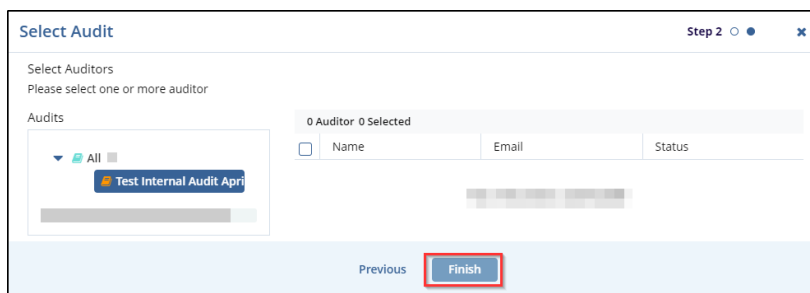


Figure 9: Create Audit Profile

3. Enter a **Title** for the audit profile.
  - a. It is generally best to be as specific as possible here. For example: 2<sup>nd</sup> 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 2<sup>nd</sup> 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. All Documents: This option will cause the system to gather all documents which meet the

criteria chosen below.

- f. **Selected Documents:** 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 (2<sup>nd</sup> Quarter 2021 Final Documents Review), the user would specify the beginning and end dates for the 2<sup>nd</sup> 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.

**Audit Scope**

The dates you select are shown in the Room Time Zone (UTC-05:00)  
**Eastern Time (US & Canada)**

All the **documents** will be placed **using room Time Zone**

From Date	To Date	
<input style="width: 100%;" type="text" value="dd MMM yyyy"/>	<input style="width: 100%;" type="text" value="dd MMM yyyy"/>	<input type="button" value="Confirm"/>

Use Submitted Dates

Use Final Dates

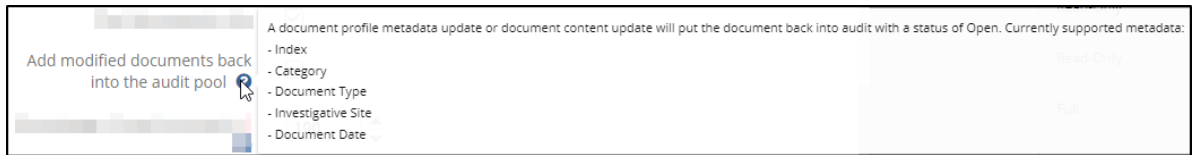
Do not include already audited documents

Final documents only

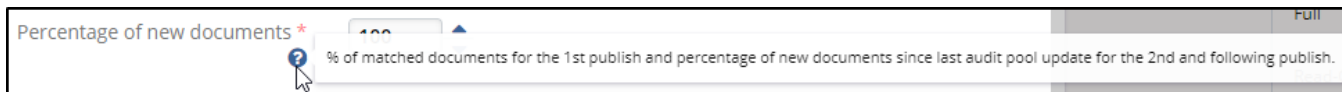
- 10. Sometimes, when the Audit Responder is addressing an Audit Finding, a document’s metadata may be updated. The ‘Add modified documents back into the audit pool’ option tells the system that, if any of

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.

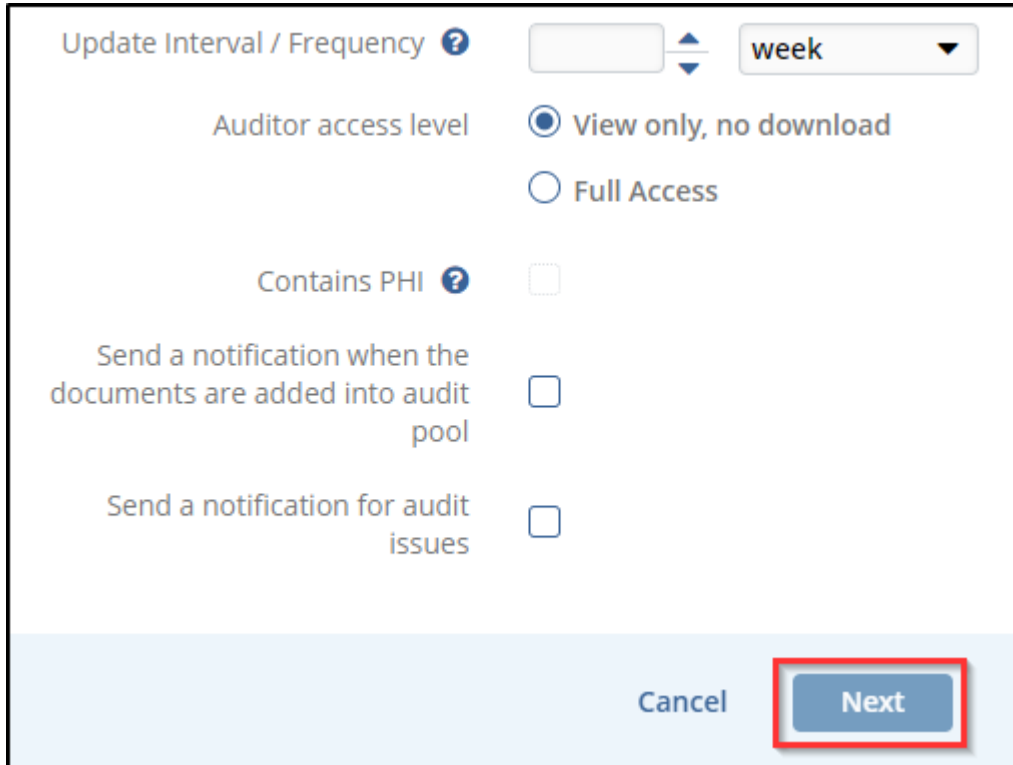
- a. **View Only, no download:** This restricts the auditor to viewing documents.
- b. **Full Access:** This allows the auditor to download or modify documents based on their user access level rights. This is most commonly applied to internal audits.

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.

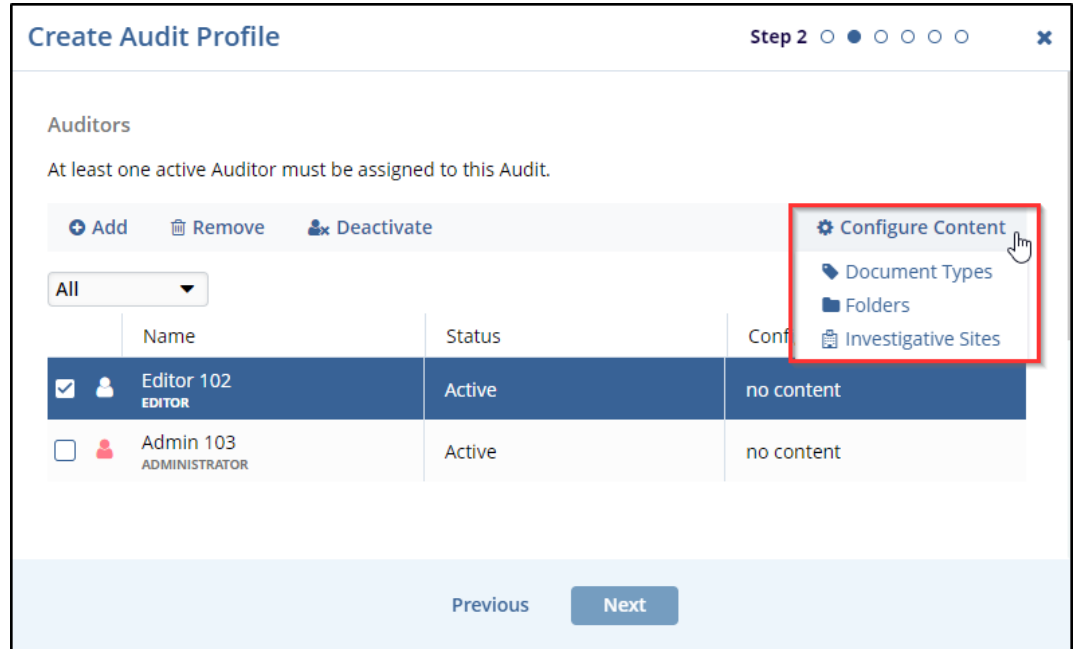
15. There are two types of audit notification that can be sent. Indicate whether or not the room should send audit notifications.

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



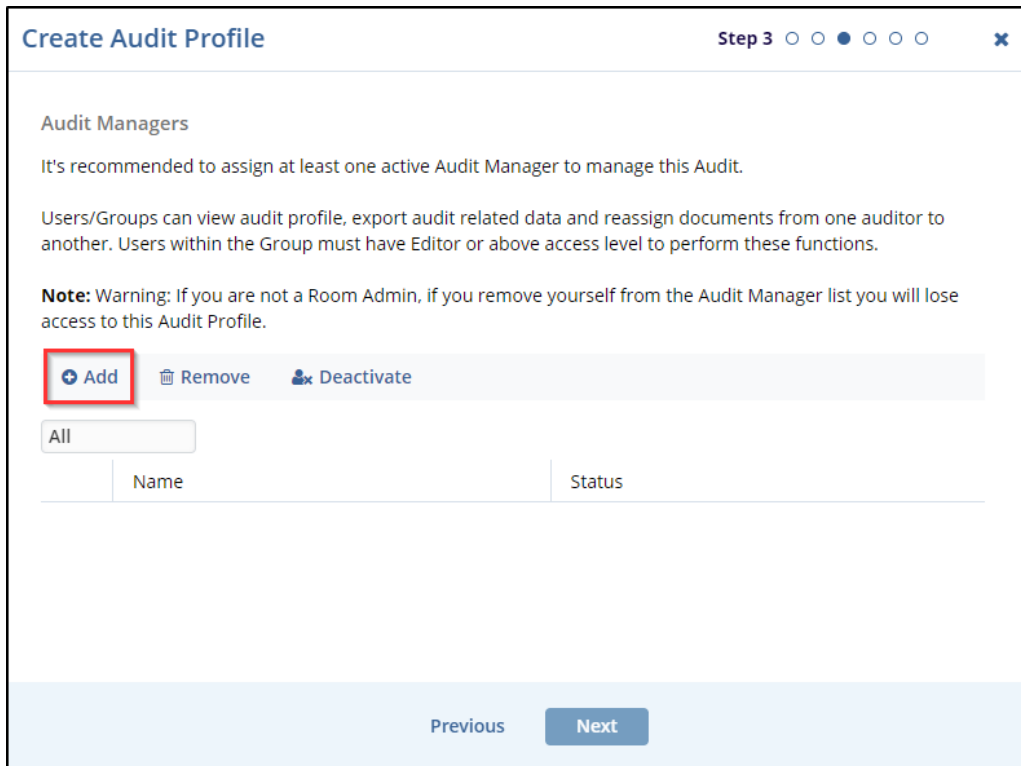


d. Once selected, another window will open in which you will be able to specify which document types, sites, or folders apply to the specified user.

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.

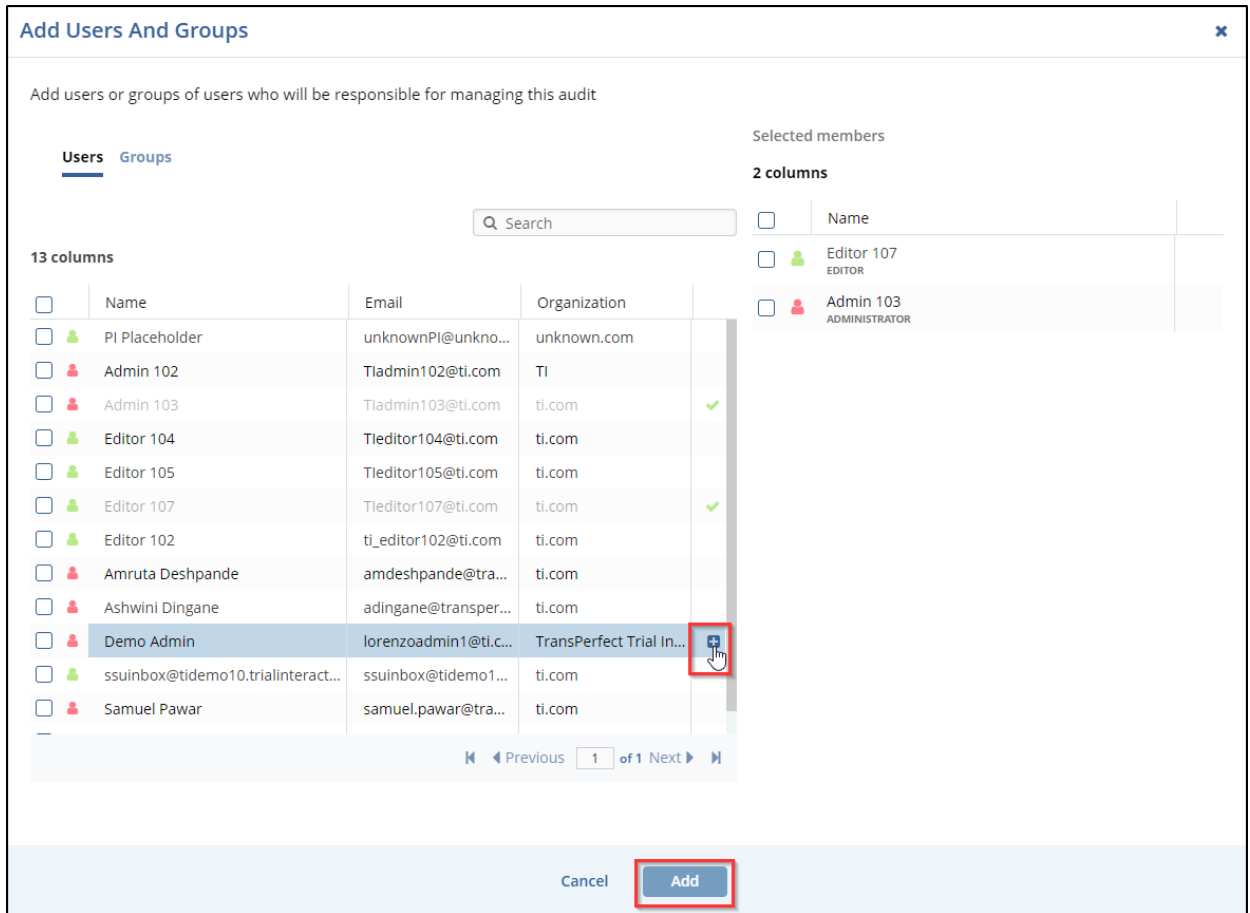
24. Click the 'Add' button displayed at the top left corner of the popup window.



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.

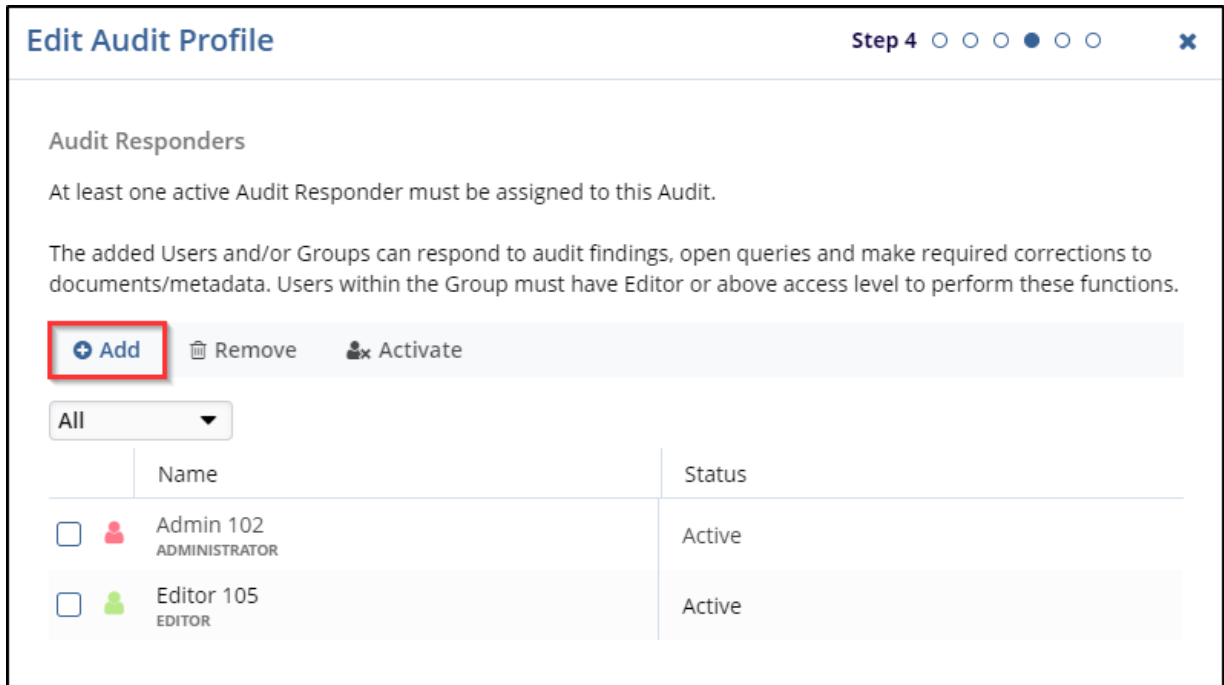


27. The selected Audit Managers are reflected in the grid.

28. The next step is to assign the users who will be **Audit Responders** in the audit.

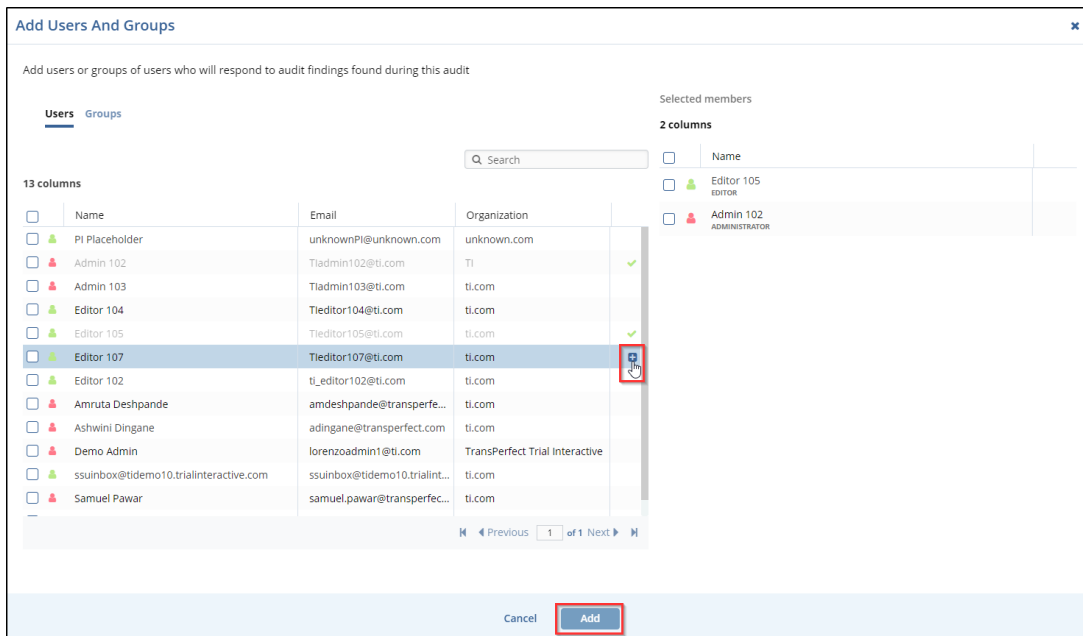
**Note:** The users cannot be the same for Audit Responders as those who are added as Auditor Managers.

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

**Create Audit Profile**
Step 5 ○ ○ ○ ○ ● ○ ✕

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**Statuses**

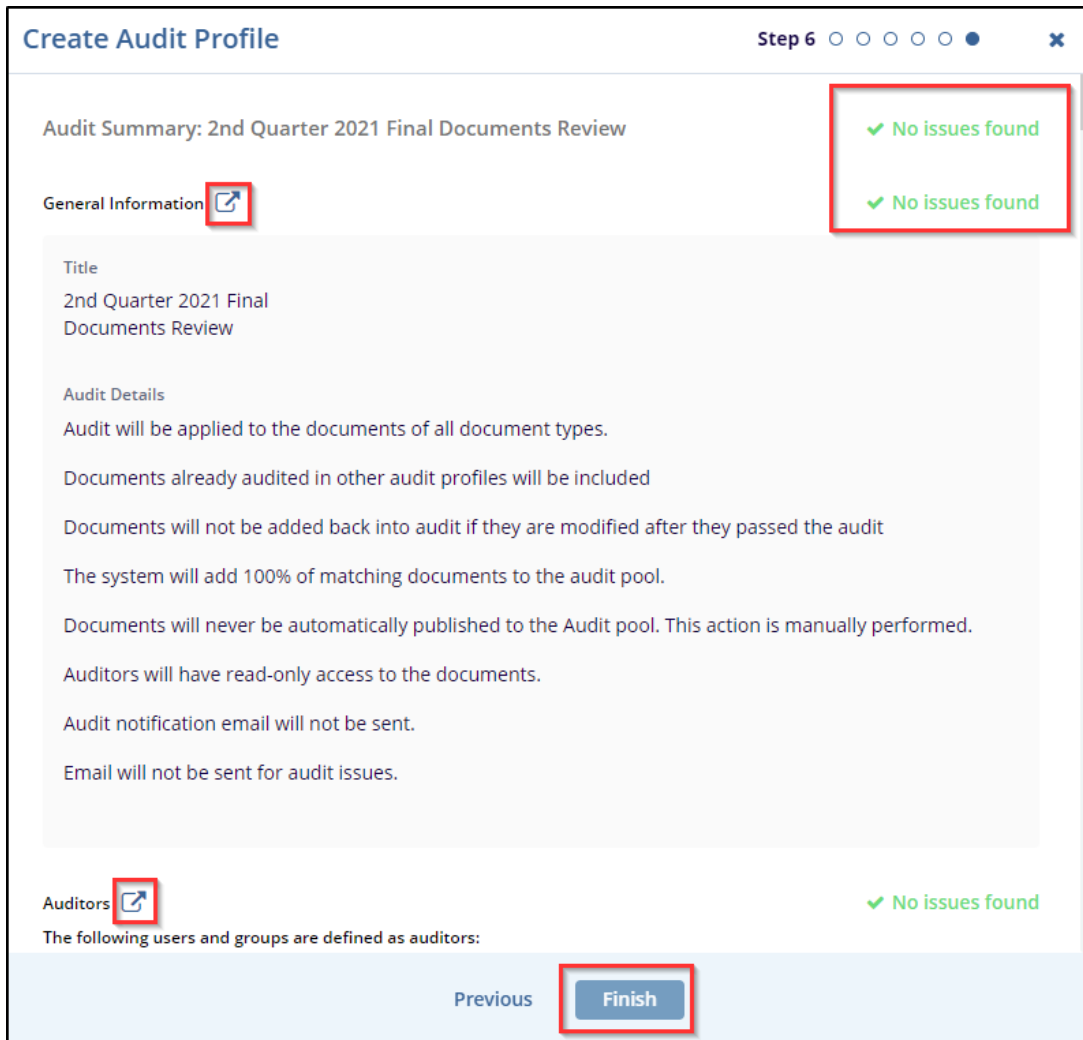
Select statuses for New Audit Profile. Select at least one status from existing system statuses (in progress, passed, failed, excluded & pending), or select all by selecting the header.

<input type="checkbox"/> Status	
<input checked="" type="checkbox"/> Excluded	excluded
<input checked="" type="checkbox"/> In Progress	inProgress
<input checked="" type="checkbox"/> No Findings	passed
<input checked="" type="checkbox"/> Pending	pending
<input checked="" type="checkbox"/> Failed	failed
<input checked="" type="checkbox"/> Passed	passed
<input type="checkbox"/> Reviewed, No Comments	passed
<input type="checkbox"/> Reviewed, with Comments	passed
<input type="checkbox"/> Under Consideration	passed

Previous
Next

33. Click the **'Next'** button when done.

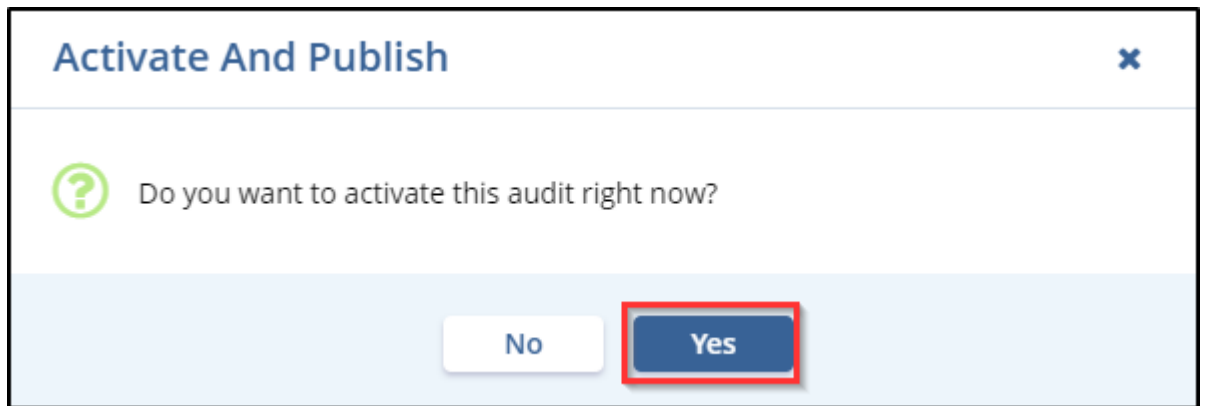
34. The final screen indicates if there are any errors detected.
  - a. The most common of these would be if you had a user added as both an Audit Manager and an Audit Responder.
35. If there are any errors, use the section link to go back and correct the error.



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.



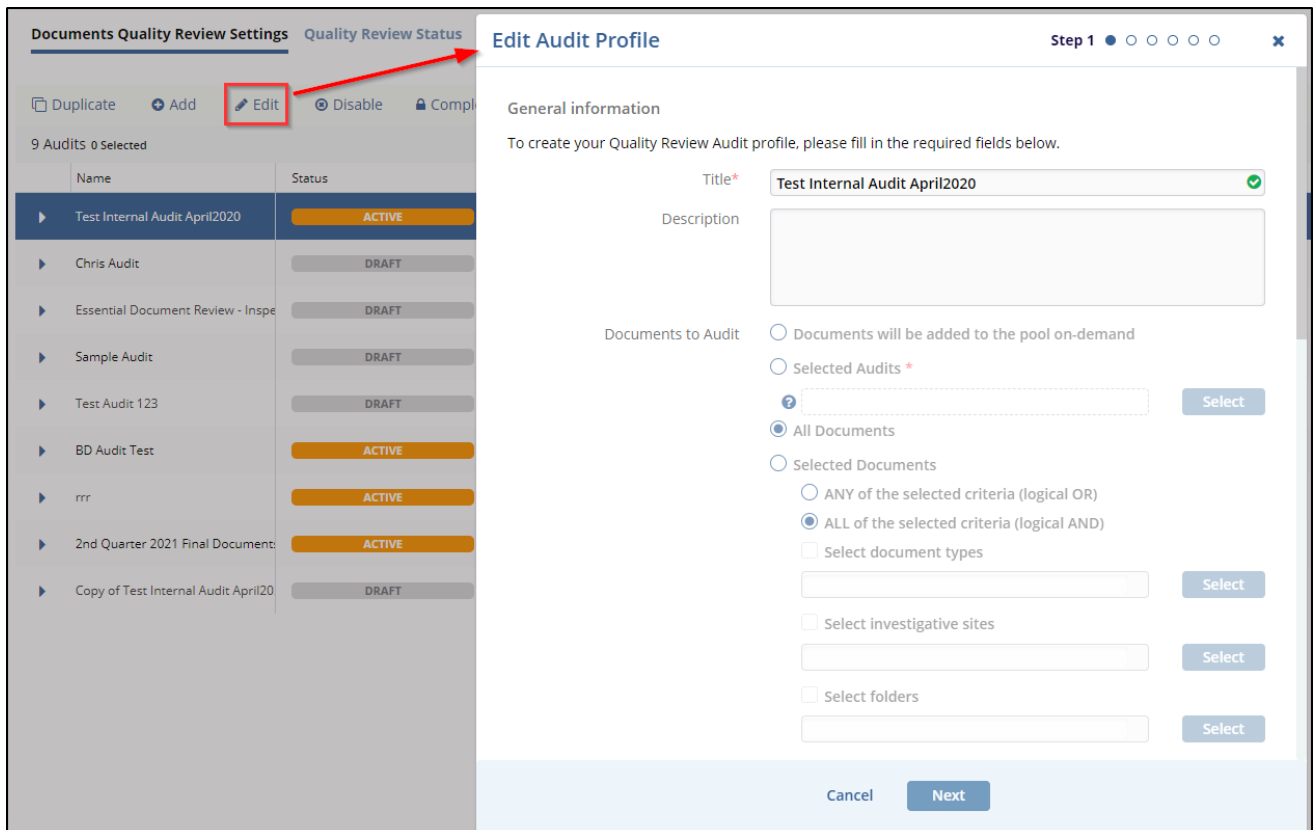
c. The Document Quality Review Settings displays the newly added audit profile in the grid.

### 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.

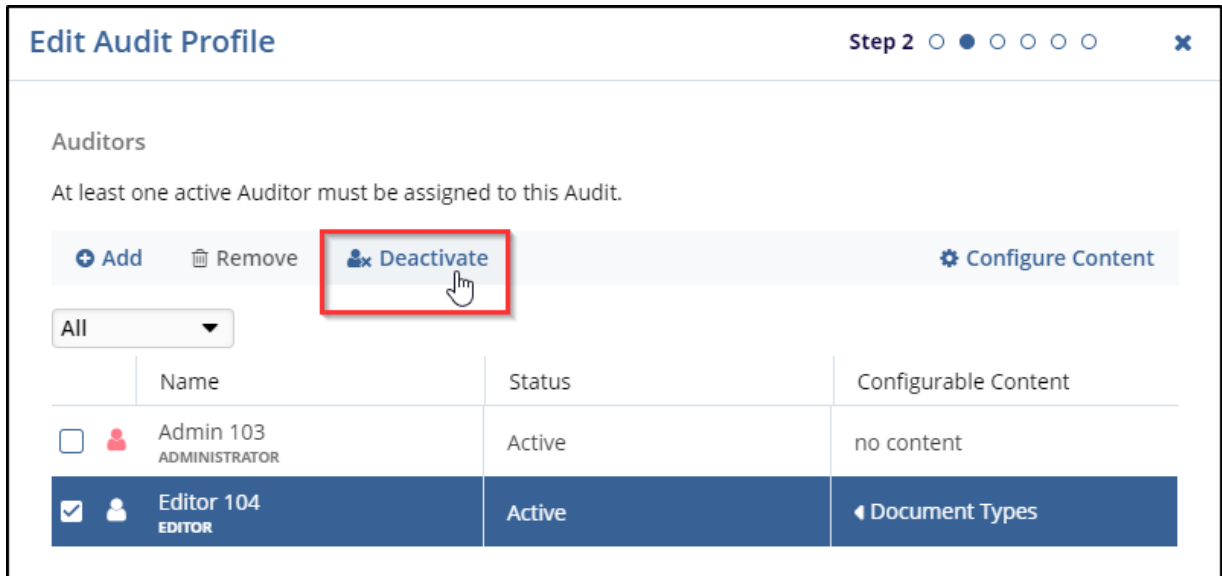


### Deactivating an Auditor



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:

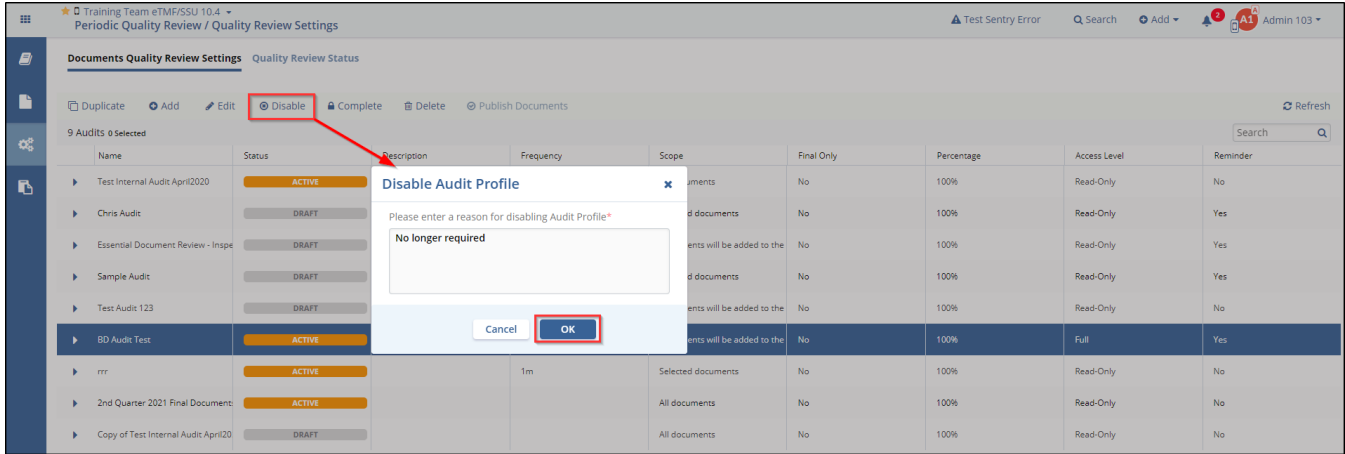
1. Open the audit profile for editing and to the auditors page.
2. Select the auditor who needs to be removed from the audit.
3. Click the '**Deactivate**' button.



- 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

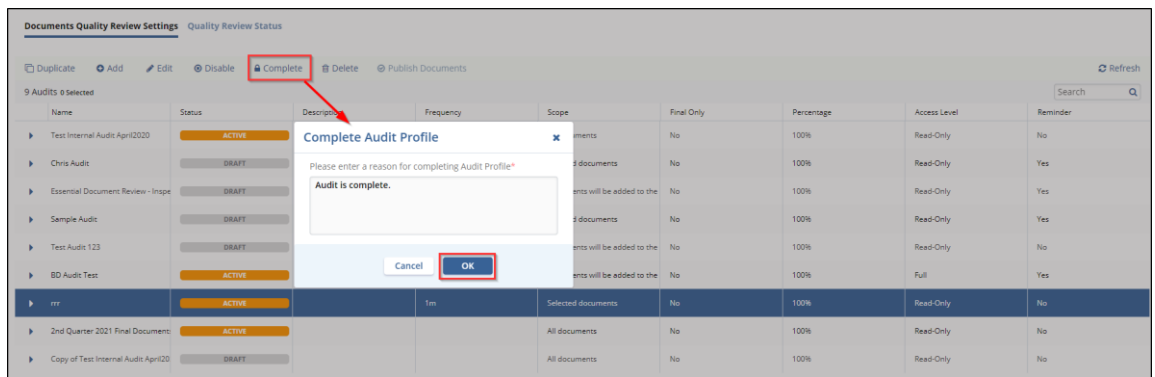
Disabling an audit can be done by the user when the audit is not required. Click the **Disable** button displayed in the top menu bar. Enter a reason in the popup window displayed and click **OK**.



### 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.

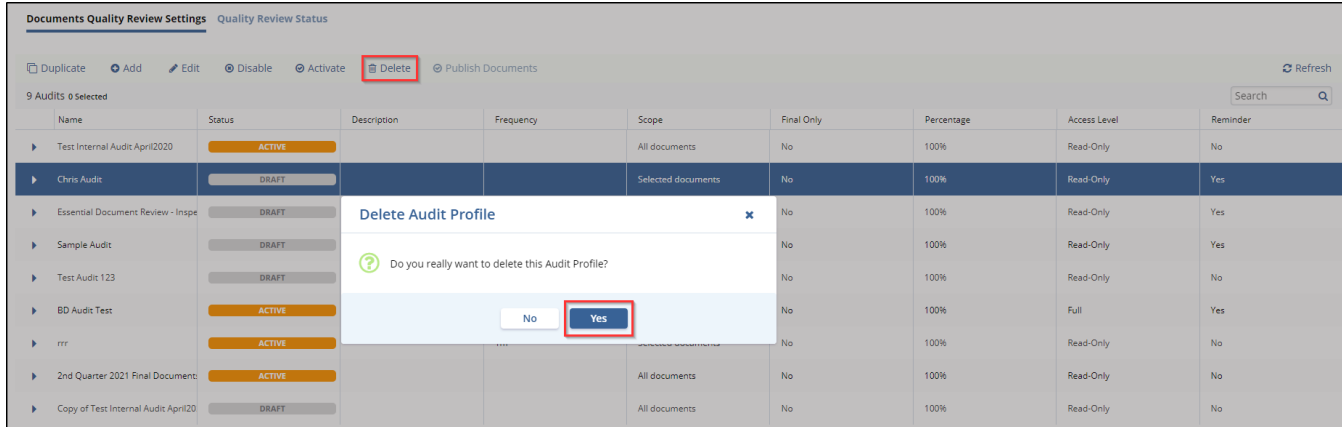


**Note:** Selecting an audit to complete that has a 'Draft' status, the top menu bar does not display the 'Complete' button.

### 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.

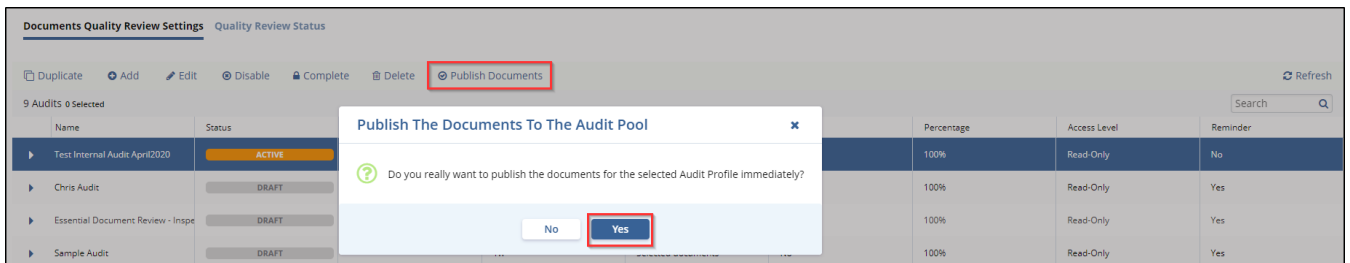
1. Select the audit.
2. Click the **'Delete'** button at the top of the grid.
3. The audit will be removed from the list.



### 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.



## 200. 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.

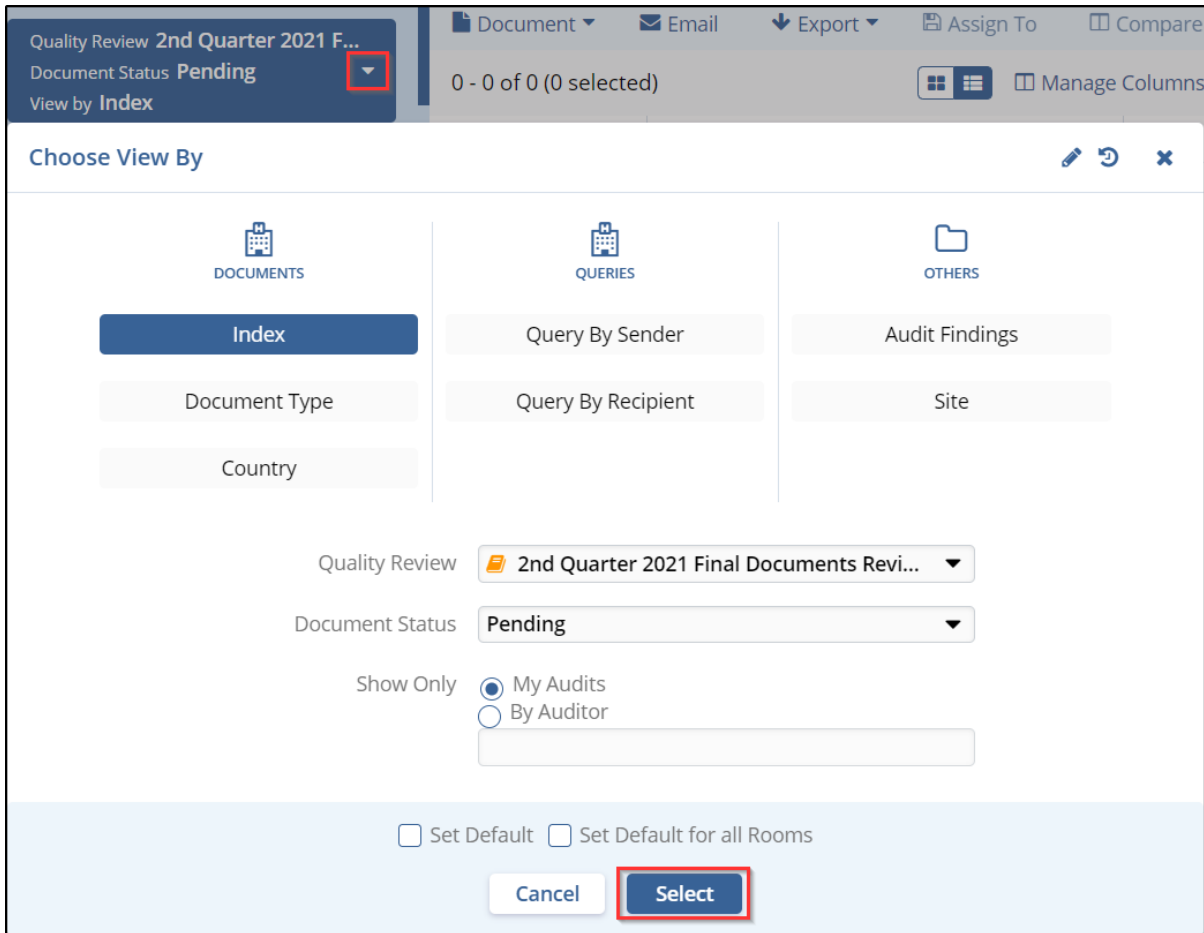
The Quality Review module has the following views available in the vertical menu at the left side of the screen:

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.

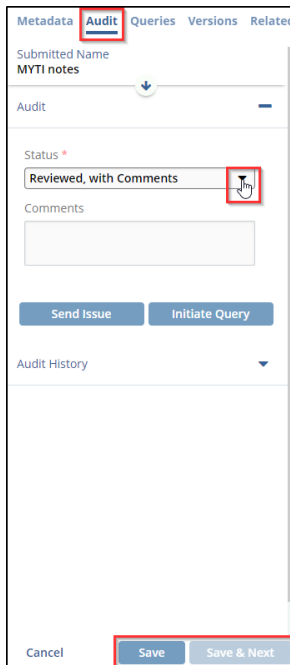
Audit Managers will also have an option to view either their own audits (if they are also acting as an auditor for the audit) or they can check up on the progress of other auditors in the selected audit.

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'

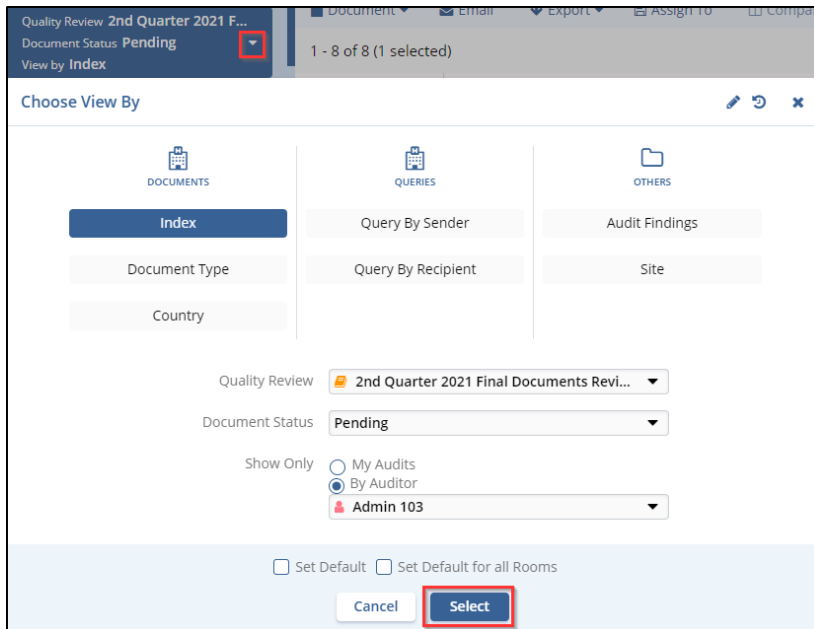
**Note:** Auditors can also send audit queries. For more information on this, please see the chapter on Queries.

### *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

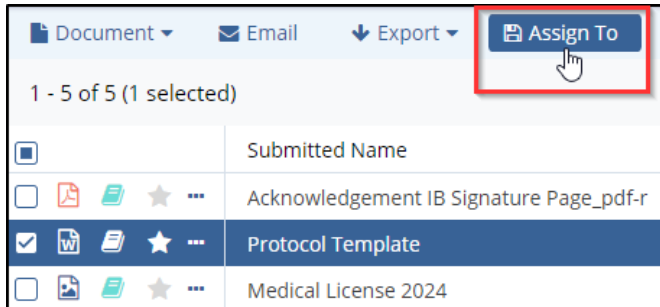
screenshot below:



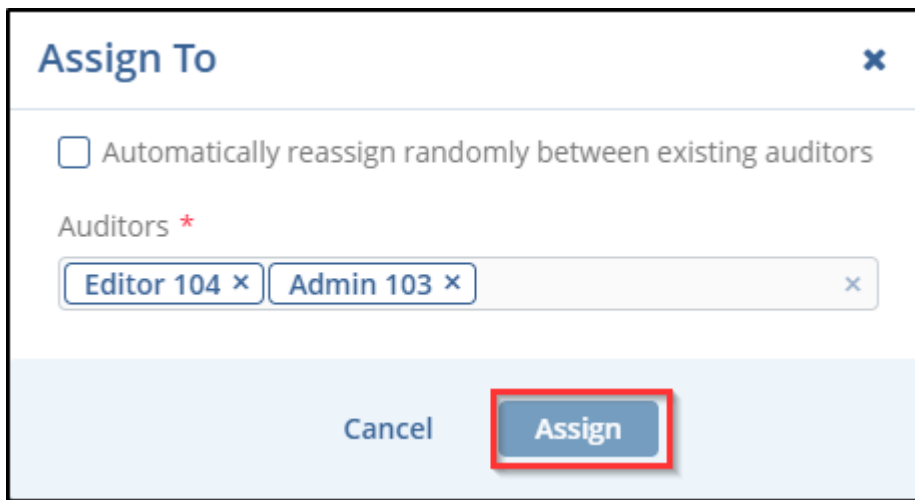
2. Click the **Select** button displayed below in the window.
3. Locate the document to be reassigned and check the box for the document on the Grid.



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.

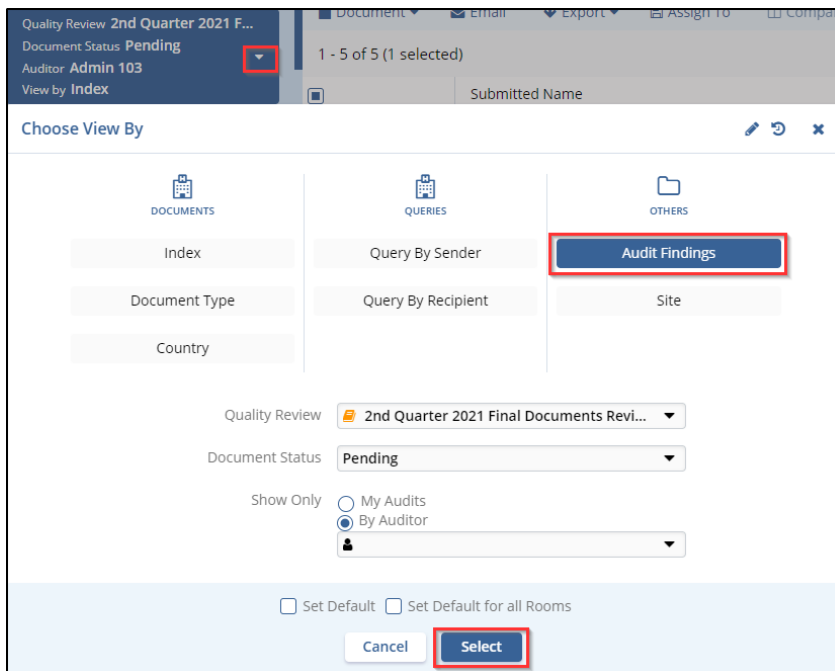


6. When you have chosen, press the 'Assign' button.

### 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.

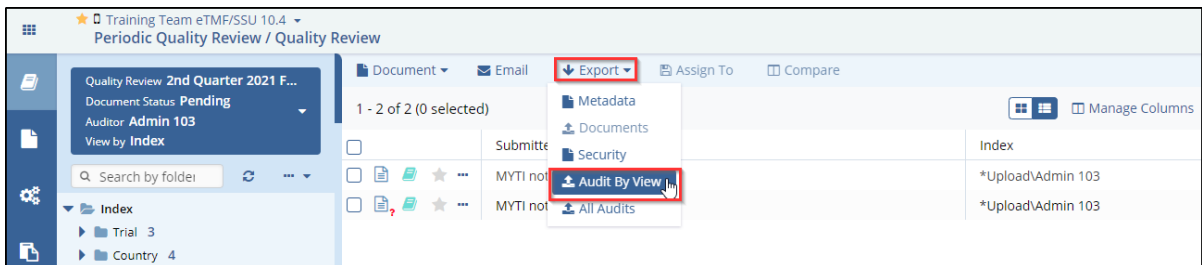


### Exporting Audit Data

An Audit Manager can export a report related to the documents assigned to any particular audit.

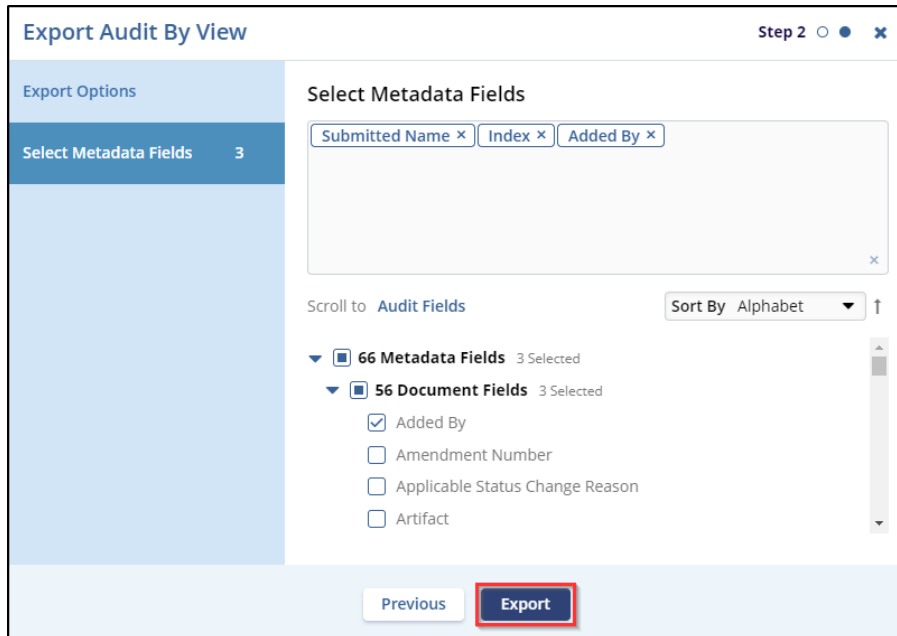
#### **To Export Data - Audit By View:**

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.

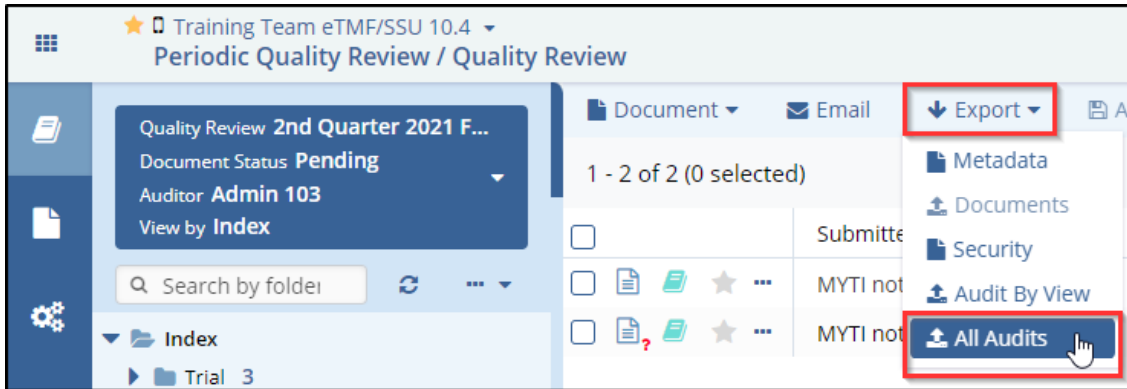
7. Select the required checkbox(s) for the metadata fields to be displayed in the 'Select Metadata Fields' box.
8. Click the **Export** button displayed at the bottom of the popup window.



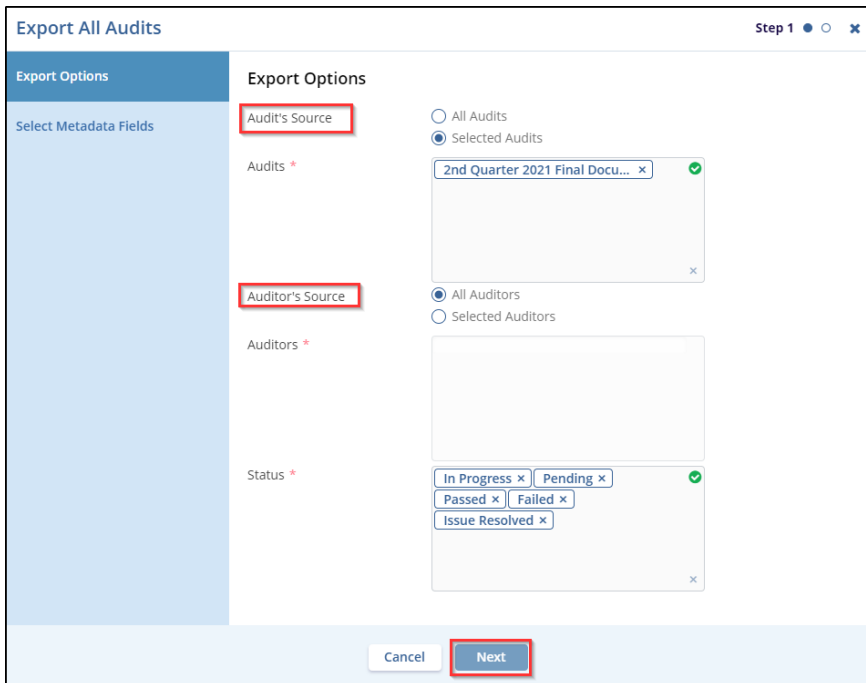
9. A notification is displayed on the top right corner of the screen. Click the **Get Job Result** button.
10. The file is downloaded in your system's 'Downloads' folder.

**To Export Data – All Audits:**

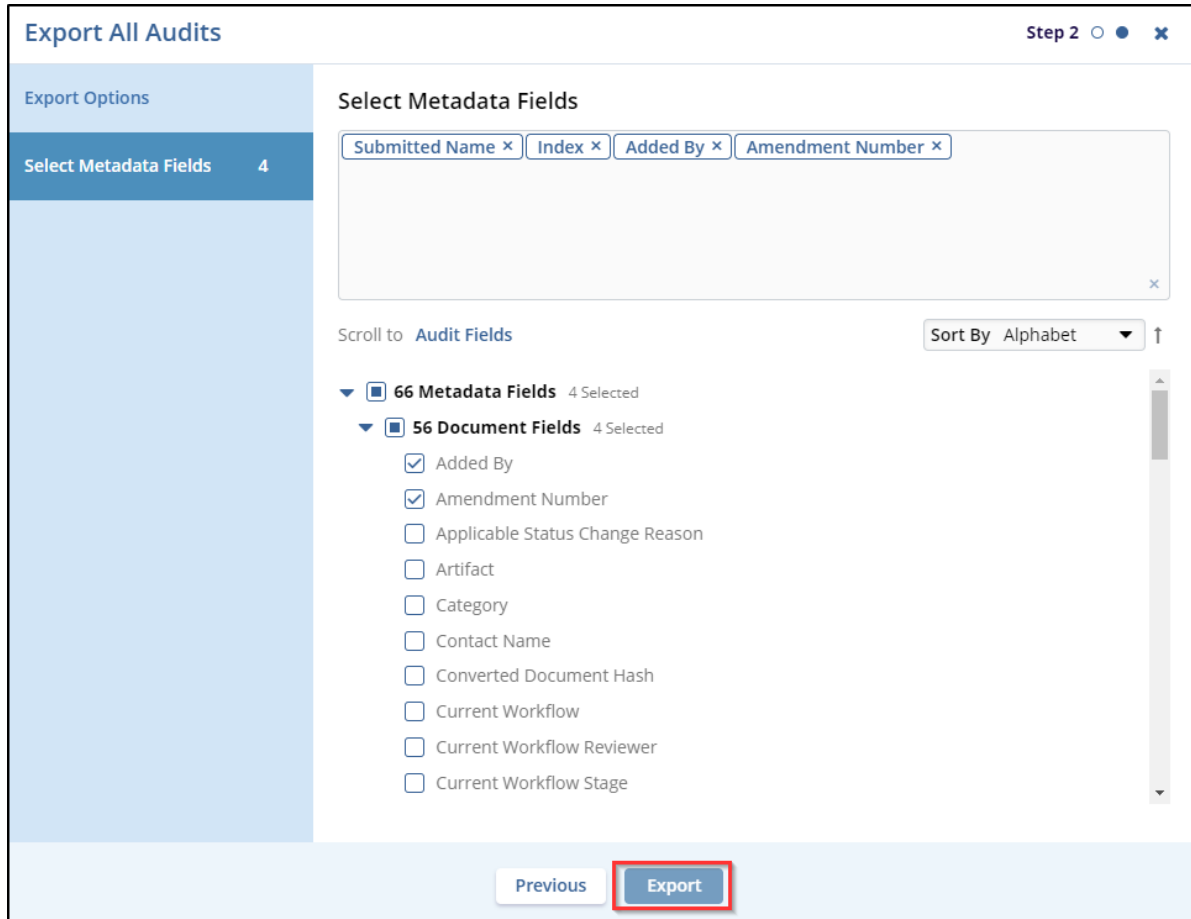
1. From the Quality Review module, click **Audit** from the left menu bar.
2. Select the audit on which you would like to run the audit report from the list of active audits.
3. Select the documents from the list and click the dropdown menu of **Export** button on the top menu bar.
4. Click the **All 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.

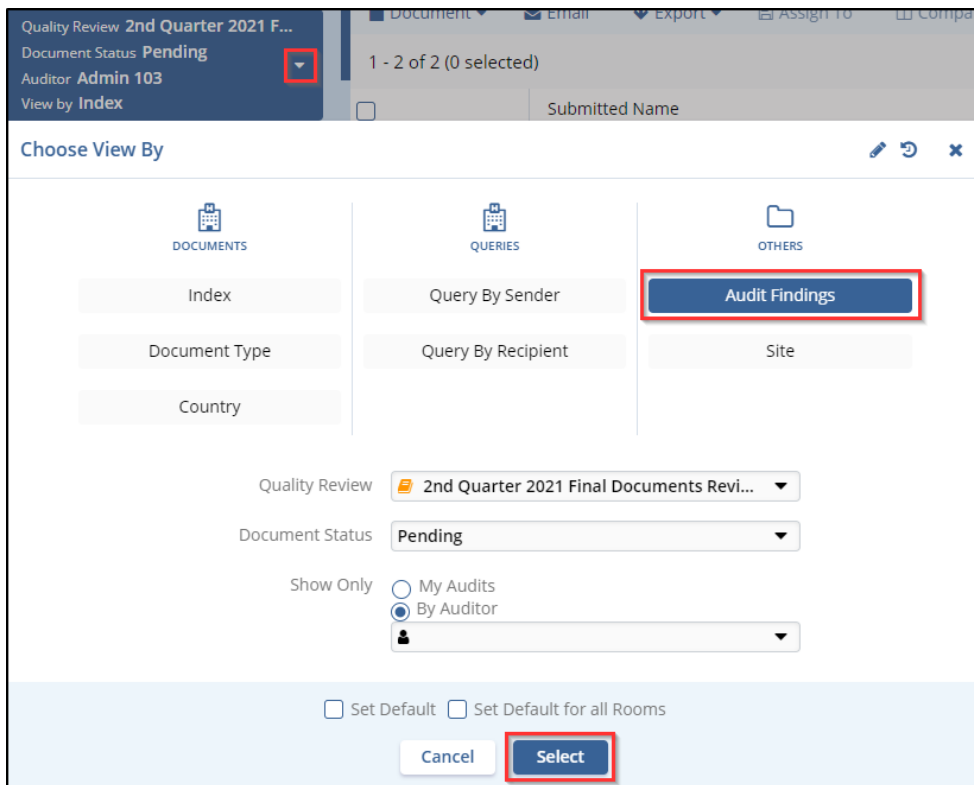


9. A notification is displayed on the top right corner of the screen. Click the **Get Job Result** button.
10. The file is downloaded in your system's 'Downloads' folder.

*Responding to Audit Findings*

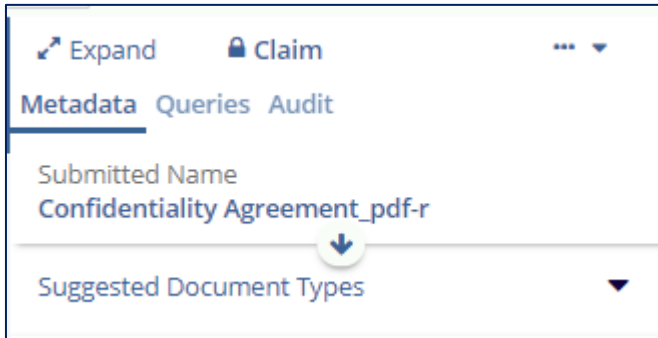
The Audit Responder is designated during the creation of the audit. There can be multiple audit responders for an audit. In order to respond to audit findings, follow the steps below:

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:

Expand Release

Metadata Queries **Audit**

Submitted Name  
Confidentiality Agreement\_pdf-r

Audit Information

Document Resolution

Comments\*

Delete this document

Mark document as corrected

14. Press 'Mark Document as Corrected'

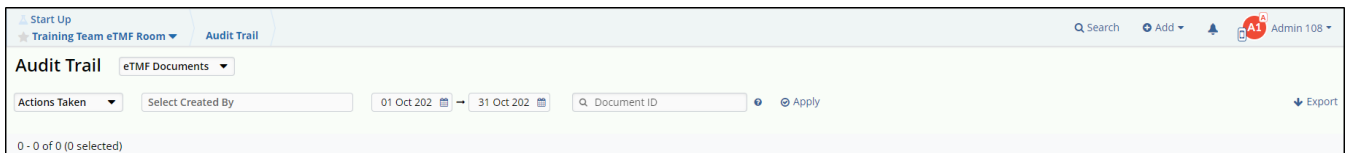
## 201. Audit Trail

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.

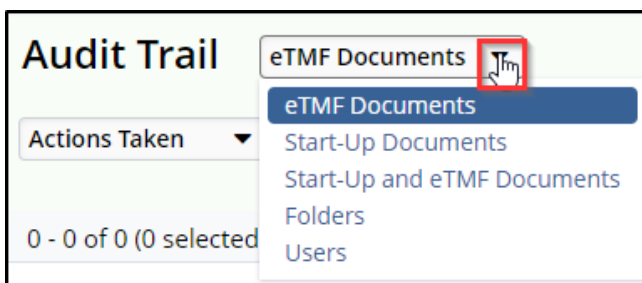
### Filters for Audit Trail

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.

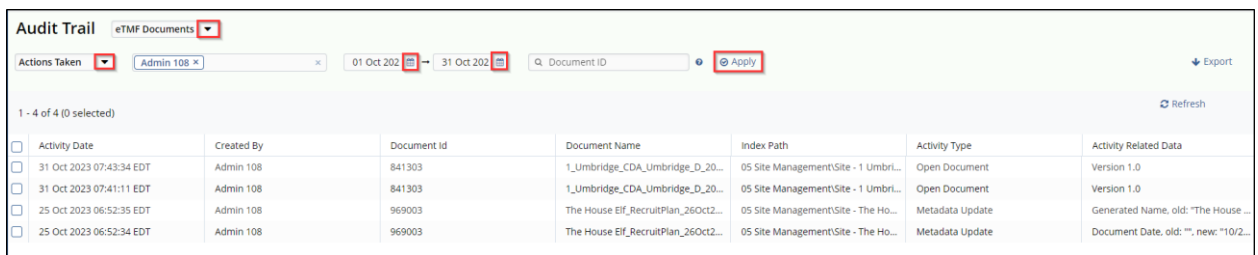


**Note:** The Audit Trail User Interface changes as per the option selected from this dropdown menu.

### User Interface for eTMF and Start-Up Documents

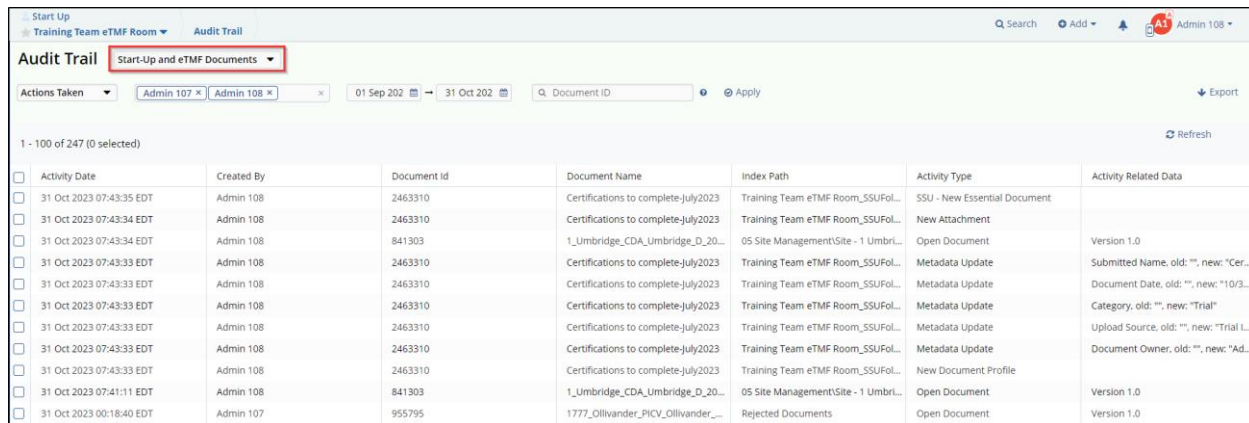
Follow the steps below to view the audit trail for eTMF Documents:

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.



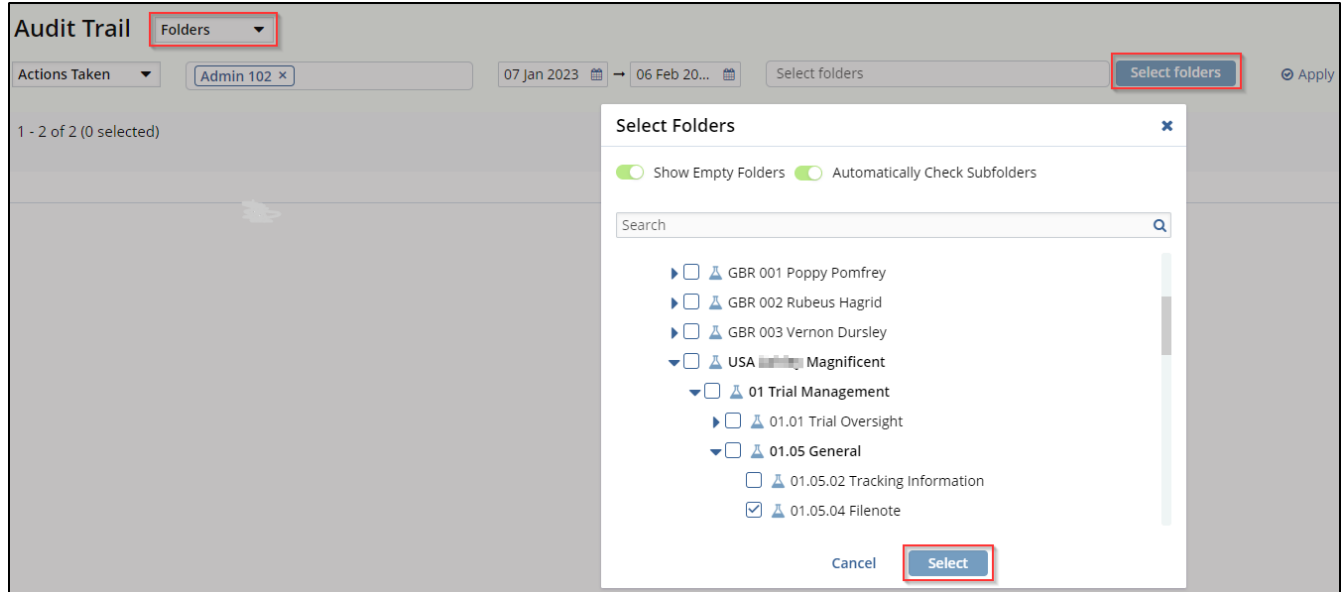
### User Interface for Start-Up and eTMF Documents

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*

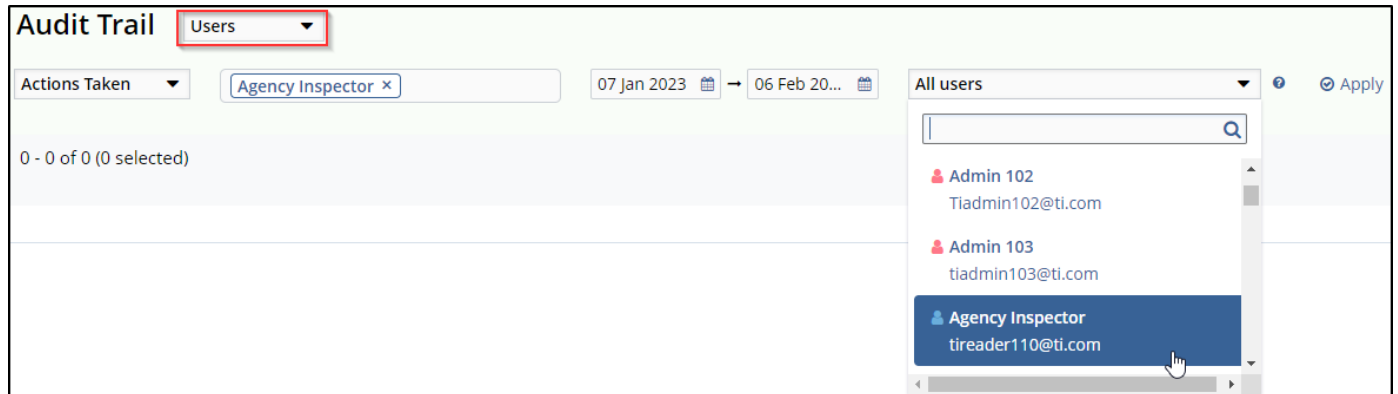
Select the Folders option to search documents – Actions Taken, Created by, Start and End date, and Document ID. Refer to the screenshot below.



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

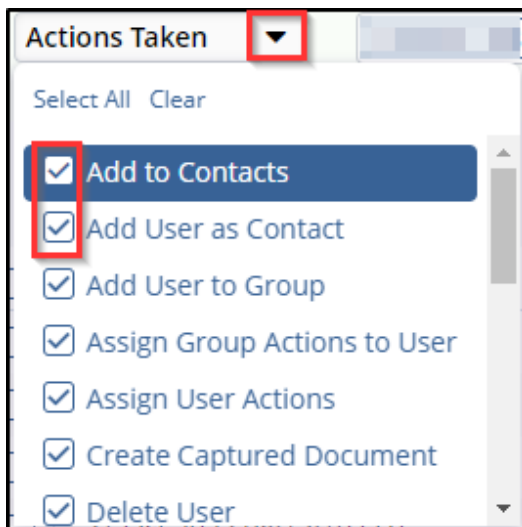
Actions Taken Select Created By 07 Jan 2023 06 Feb 20... All users Apply Export

1 - 16 of 16 (1 selected) Refresh

<input type="checkbox"/>	Activity Date	Created By	User Id	User Full Name	User Email Address	Activity Type	Activity Related Data
<input checked="" type="checkbox"/>	1/20/2023 2:49:03 AM EST	Tiadmin102@ti.com	123	Admin 102	Tiadmin102@ti.com	Add User to Group	Added to Group "Training Team SSU eTMF Room:AU-SSUAp
<input type="checkbox"/>	1/20/2023 12:12:13 AM EST	Tiadmin102@ti.com	123	Admin 102	Tiadmin102@ti.com	Add User to Group	Added to Group ""
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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...
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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"
<input type="checkbox"/>	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.

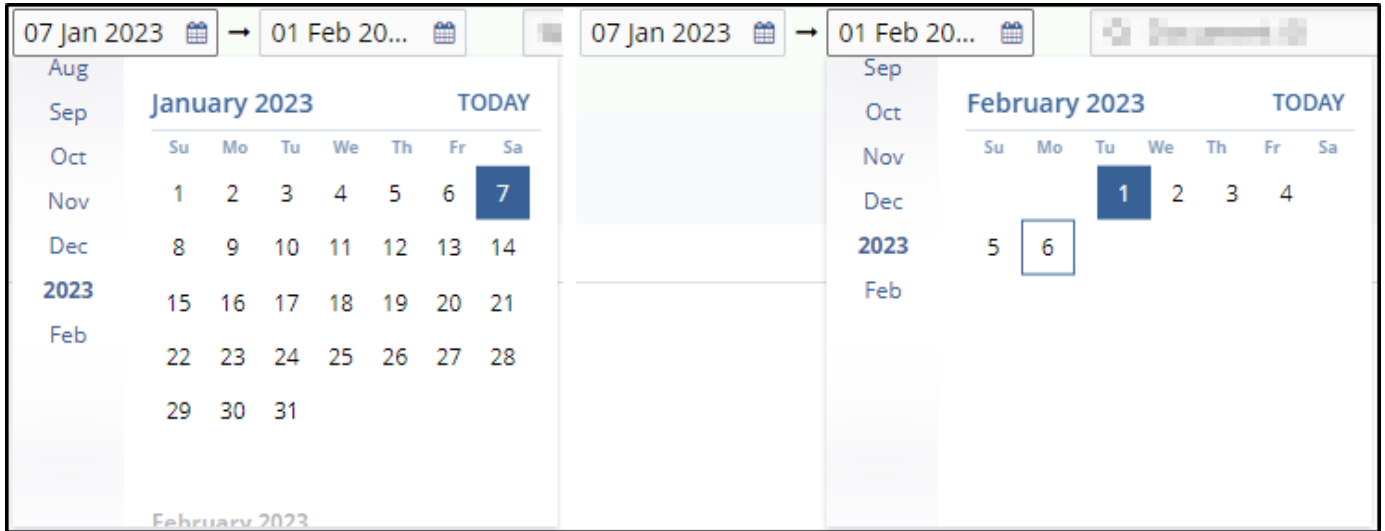
Refer to the screenshot below.



### Date Filter

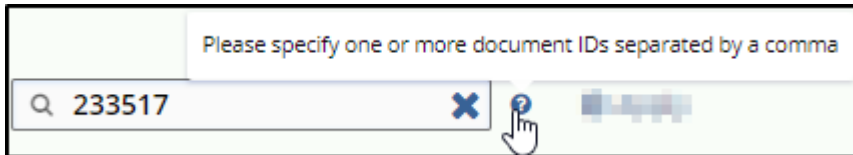
Select the dates in these fields to search a document. By default, the start date is set for the previous month, and the end

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*

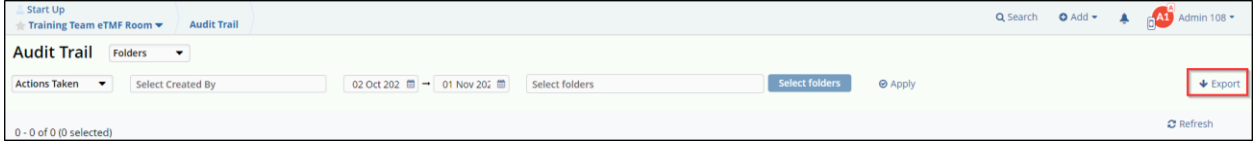
This field helps the user to find a document by the ID number. Enter the document ID and click the **Apply** button displayed on the right side, to view the search results. Refer to the screenshot below.



### 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.



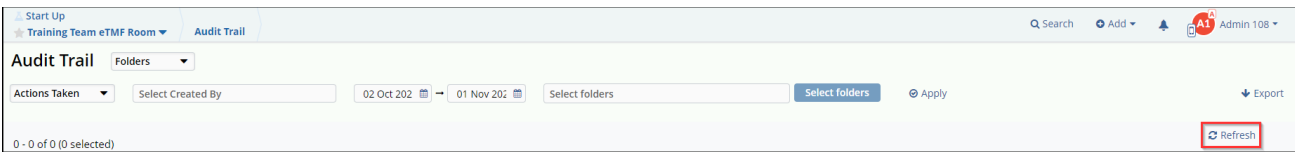
2. Click on **Get Job Result** button displayed in the notification on the top right corner. The document is downloaded and is reflected in the Downloads folder of your system. The Excel sheet displays two tabs – **Folder Audit Trail Header** and **Folder Audit Trail**. Refer to the screenshot below for the details of the columns available in the Excel sheet.

Activity Date	Created By	Folder Id	Folder Name	Index Path	Activity Type	Activity Related Data
2023-10-19 05:58:56	Demo Admin	813781	Root		Check In	
2023-10-19 05:58:44	Demo Admin	813781	Root		Check Out	
2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440373	10.05.04 Filenote	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440372	10.05.02 Tracking Information	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communication	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communication	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440371	10.05.01 Relevant Communication	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440370	10.04.01 System Account Mana	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440369	10.02.05 Final Subject Data	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Corr	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Corr	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440368	10.02.04 Documentation of Corr	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440367	08.03.04 Filenote	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440366	08.03.03 Meeting Material	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440365	08.03.02 Tracking Information	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communication	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communication	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440364	08.03.01 Relevant Communication	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440363	08.02.05 Record of Retained Sa	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Exp	05 Site Management/Site - 2450	Security update	Access, UserGroup: T1 eSignature, Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Exp	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Readers), Added: "Full Access, No Watermark"
2023-10-13 04:55:20	Admin 103	2440362	08.02.04 Sample Import or Exp	05 Site Management/Site - 2450	Security update	Access, UserGroup: Site - 2450 103 Admin (Editors), Added: "Full Access, No Watermark"

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 14. 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.

---

### 202. 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.



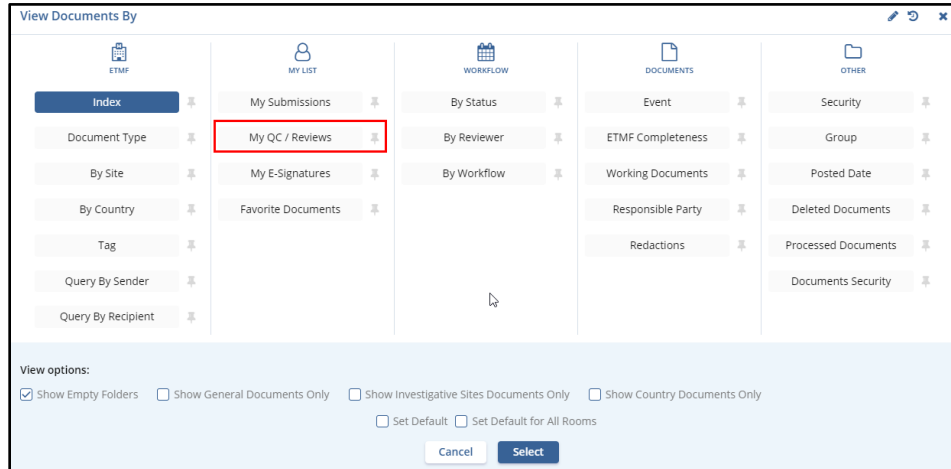


Figure 10: View by My QC/Reviews

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.

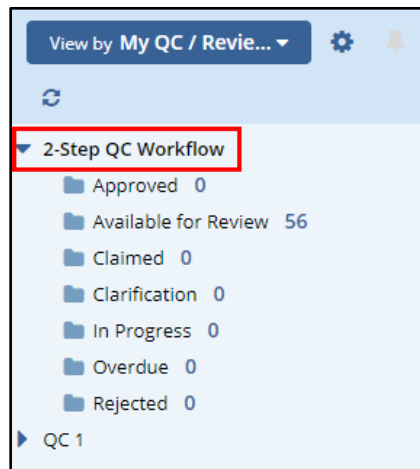


Figure 2: QC Workflow folders

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.

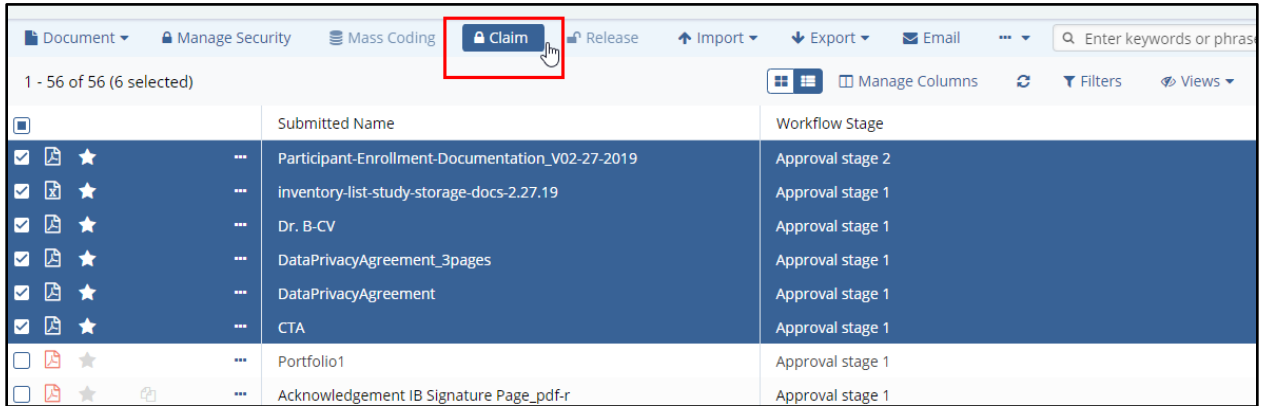


Figure 3: Claim document

- Once the documents have been claimed, they are moved to the **'Claimed'** folder and are no longer visible in the **'Available for Review'** folder.

### 203. 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.

- Click on your **'Claimed'** folder.
  - All of the documents you currently have claimed will populate the grid.
- Check the box to indicate which documents should be released.
- Press the **'Release'** button above the grid.

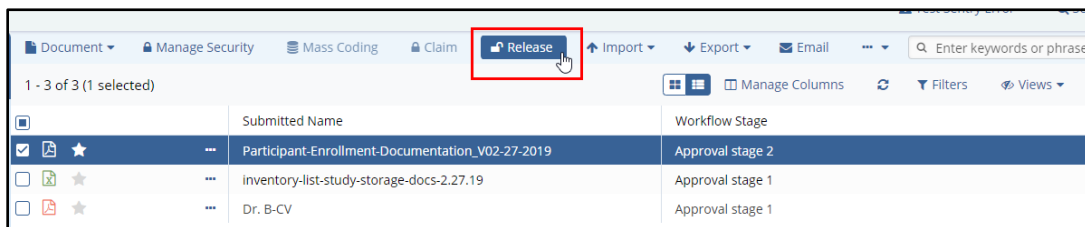


Figure 4: Release Document

- Once released, the documents will be removed from your **'Claimed'** folder and returned to the **'Available for Review'** folder.
- Alternately, this may be done by a room administrator using the three-dot menu at the top-right of the metadata pane.

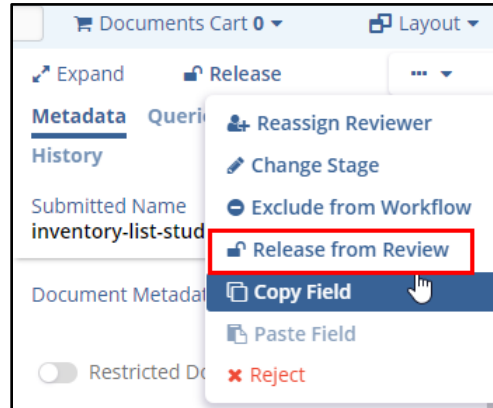


Figure 5: Release from Review Option

## 204. 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:

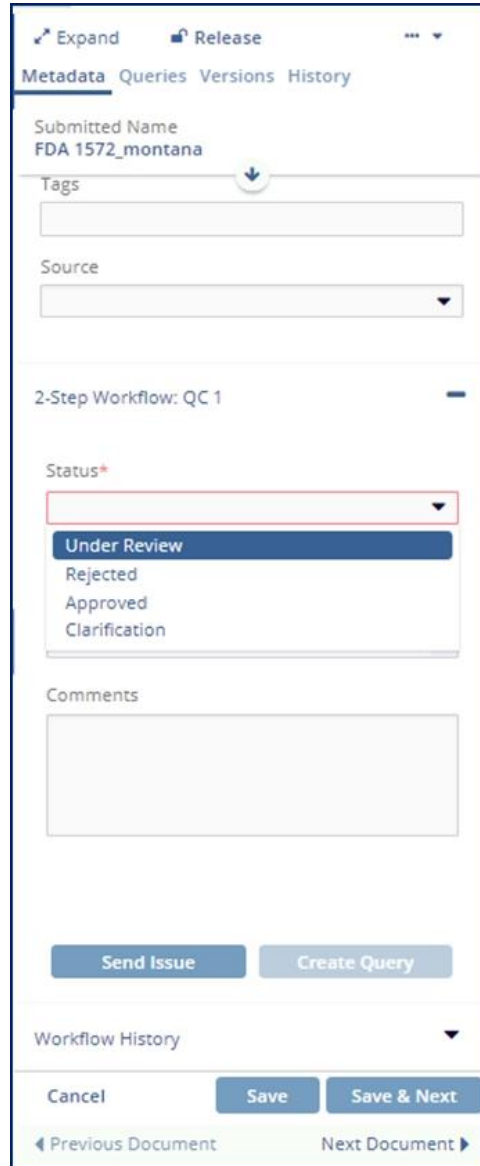


Figure 6: Status Types

5. Assign the appropriate status to the document.
  - Note: The available statuses are assigned when the workflow is created and may vary from those shown above.
  - **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.
  - **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.
  - o **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'**.

### 205. 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.
  - o An email window will open.

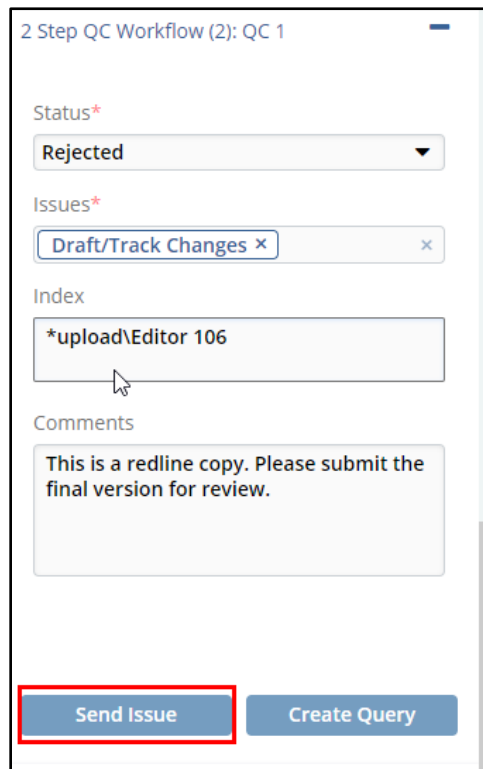


Figure 7: Send issue Option

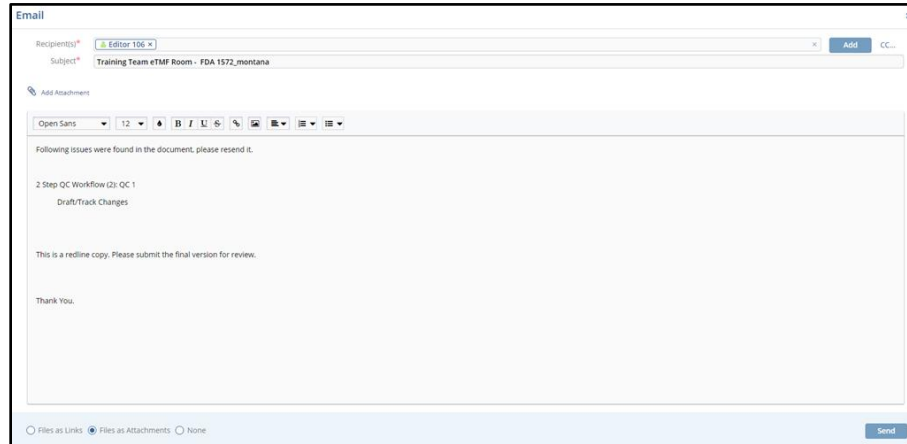


Figure 8: Send Issue Mail

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'

## 206. 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.

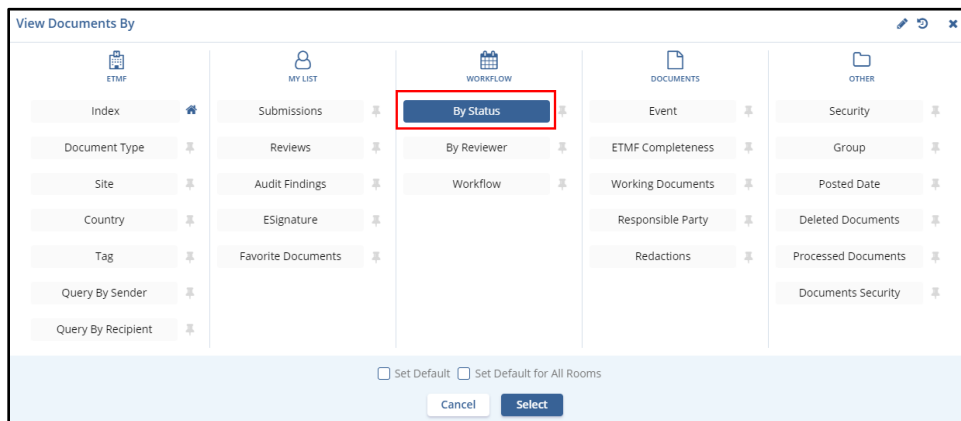


Figure 9: View by Status

3. Select the 'Claimed' folder from the index pane.
4. Locate the document which needs to be reassigned.
  - o If necessary, expand the metadata pane.
5. Click the three-dot dropdown menu at the top-right of the metadata pane.

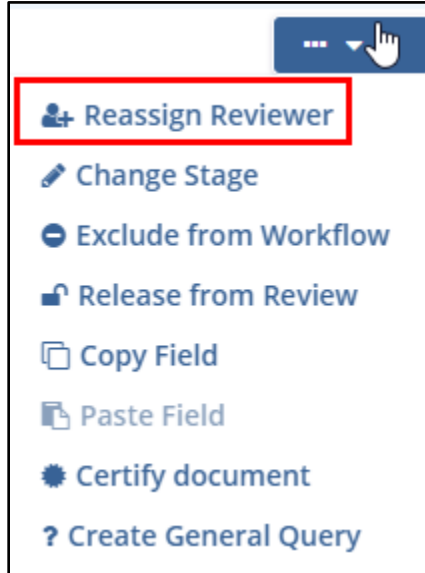


Figure 10: Reassign Reviewer

6. Click 'Reassign Reviewer'
  - o The Reassign Reviewer window will open.

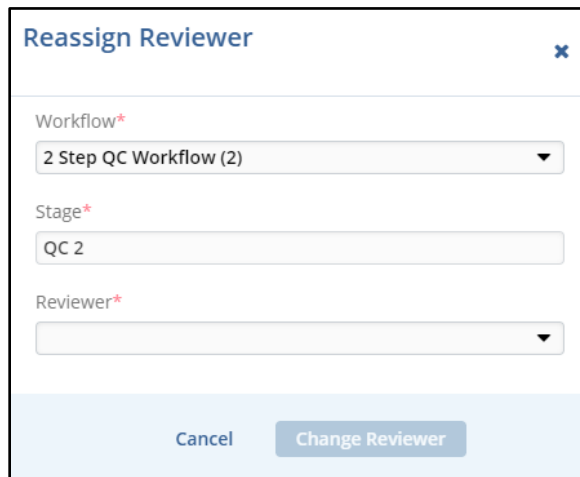


Figure 111: Reassign Reviewer Page

7. Choose the appropriate reviewer and press 'Change Reviewer'
8. A popup will display asking if you are sure. Press 'Yes' if appropriate.

## 207. 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.
  - o 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.

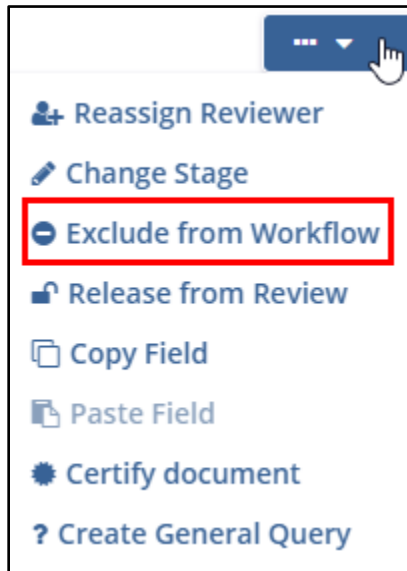


Figure 121: Exclude From Workflow

4. Indicate a reason for the exclusion.

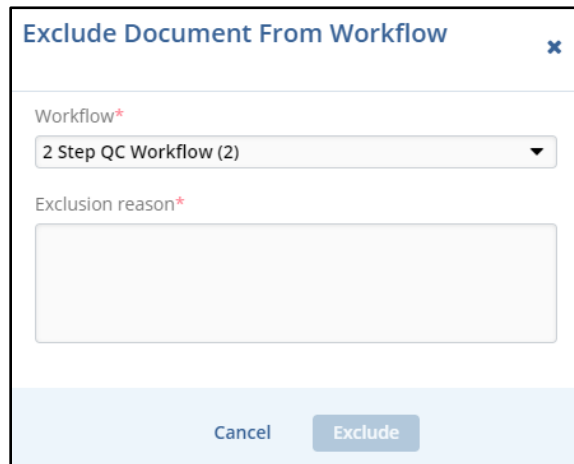


Figure 132: Exclude Document from Workflow

5. Press 'Exclude'



## CHAPTER 15. COLLABORATIVE WORKSPACE

Collaborative Workspace is repository for the project management related documents, some of the documents in this room will be moved to eTMF room. Collaborative workspace have a reference to a study room.

The Trial Interactive Collaborate solution, also known as Shared Workspace, is a Clinical Collaborative Workspace Solution for clinical teams to provide Sponsors, CROs, and Sites a place to share and author documentation to be used in the Clinical Trial and ultimately archived in the eTMF.


An integral part of TI Collaborate, TI Collaborative Authoring will provide end-users the capability of directly editing MS Word, Excel, and Power point documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

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 any other 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

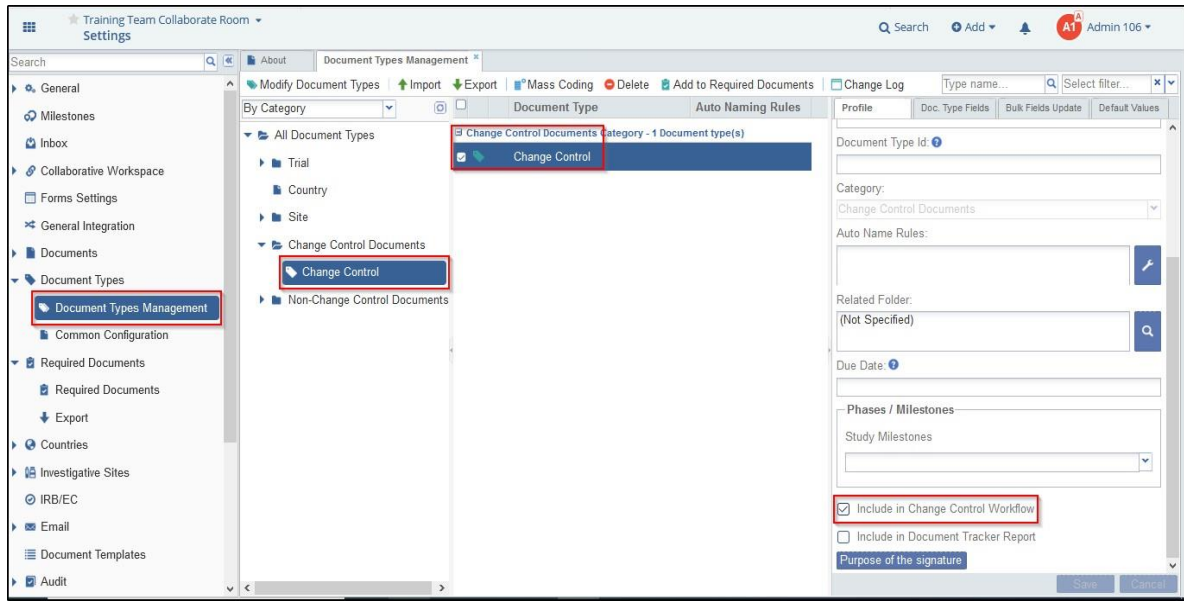
The room configurations that impact the room types TI Docs and TI Collaborate are described below.

1. Document Type - The document types settings can be configured via **Settings>DocumentTypes>All Document Types**. Refer the screenshot below.

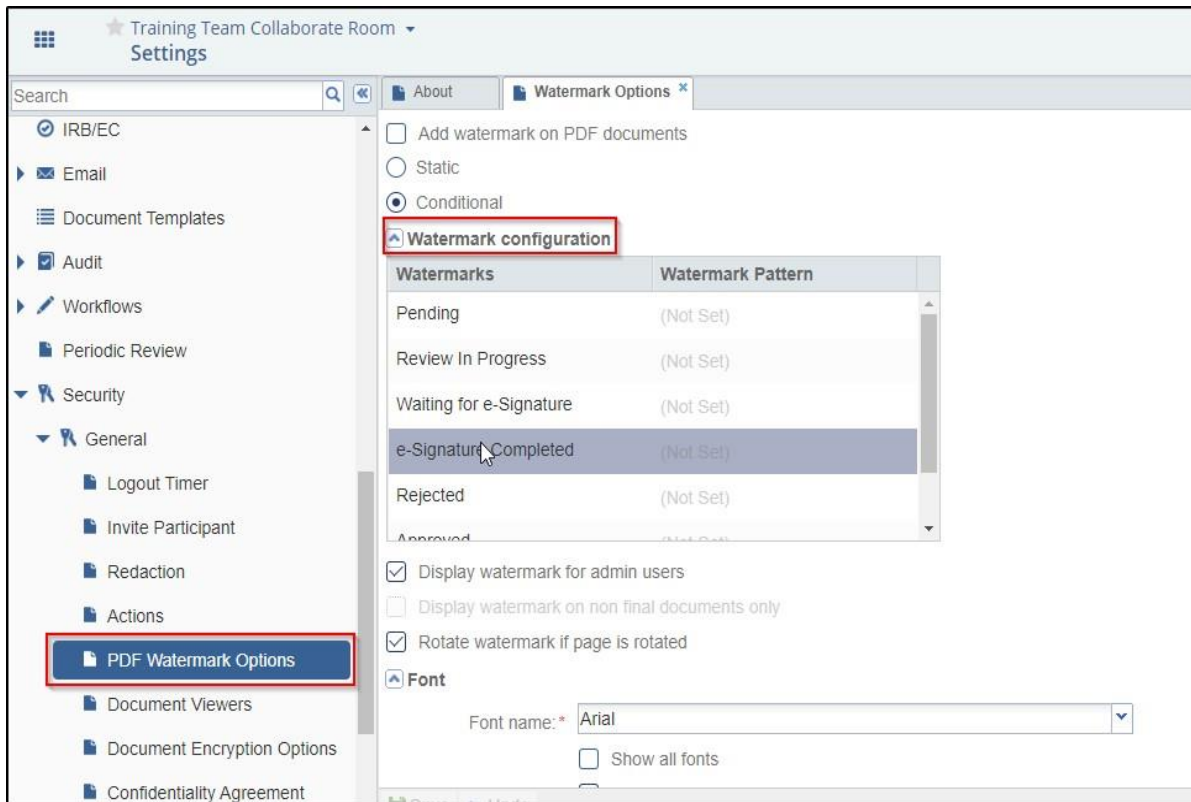
The screenshot displays the 'Document Types Management' section of the Trial Interactive software. The left sidebar contains a navigation menu with 'Document Types' highlighted. The main content area is divided into a tree view on the left and a table on the right. The tree view shows a hierarchy of categories: 'All Document Types', 'General', 'Country', 'Billing Information', 'Clients', 'Medical Writing', 'Personnel', and 'Product'. The 'Product' category is expanded, showing 'Access Request Form', 'Case Study', and 'Fact Sheet'. The table on the right lists document types under two categories: 'General Category - 6 Document type(s)' and 'Clients Category - 27 Document type(s)'. The table columns include 'Document Ty...' and 'Auto N...'. The following table represents the data visible in the screenshot:

Category	Document Type	Auto N...
General Category - 6 Document type(s)	All Hands Me...	\$\$DT.D...
	General	\$\$DP.Ti...
	Guess Access...	\$\$DT.D...
	Meeting Infor...	
	New Hire Info...	\$\$DP.Ti...
	TOC	\$\$DT.D...
Clients Category - 27 Document type(s)	Account Status	\$\$LIP.S...
	Action Tracker	\$\$DT.D...
	Agenda	\$\$DT.D...
	Audit Certificate	\$\$DT.D...

- 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.

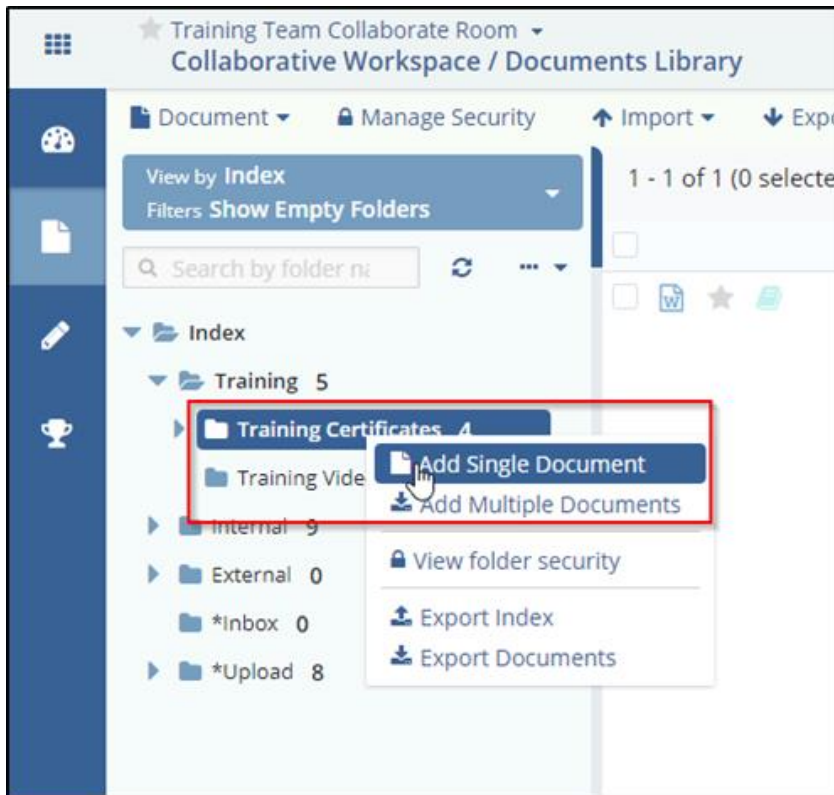


4. **Converting Documents -Non PDF to PDF-** To convert non PDF documents to PDF, go to **Settings>Documents>Non PDF to PDF Document Conversion** and select the conversion type.Refer the screenshot below.

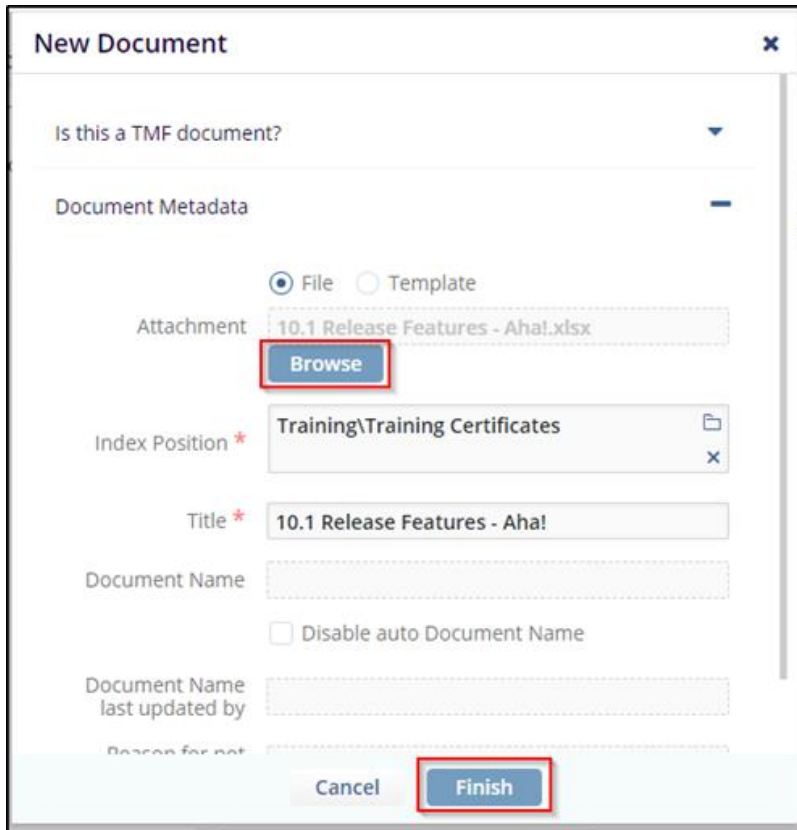
## Document Upload

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:

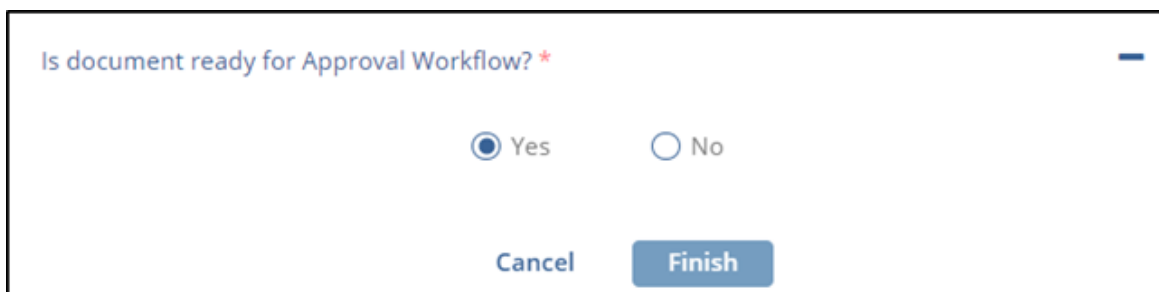
1. Start by navigating to the Document Library Index view, then select the desired upload location (folder) and right-click on it to start adding documents. Refer to the screenshot below.



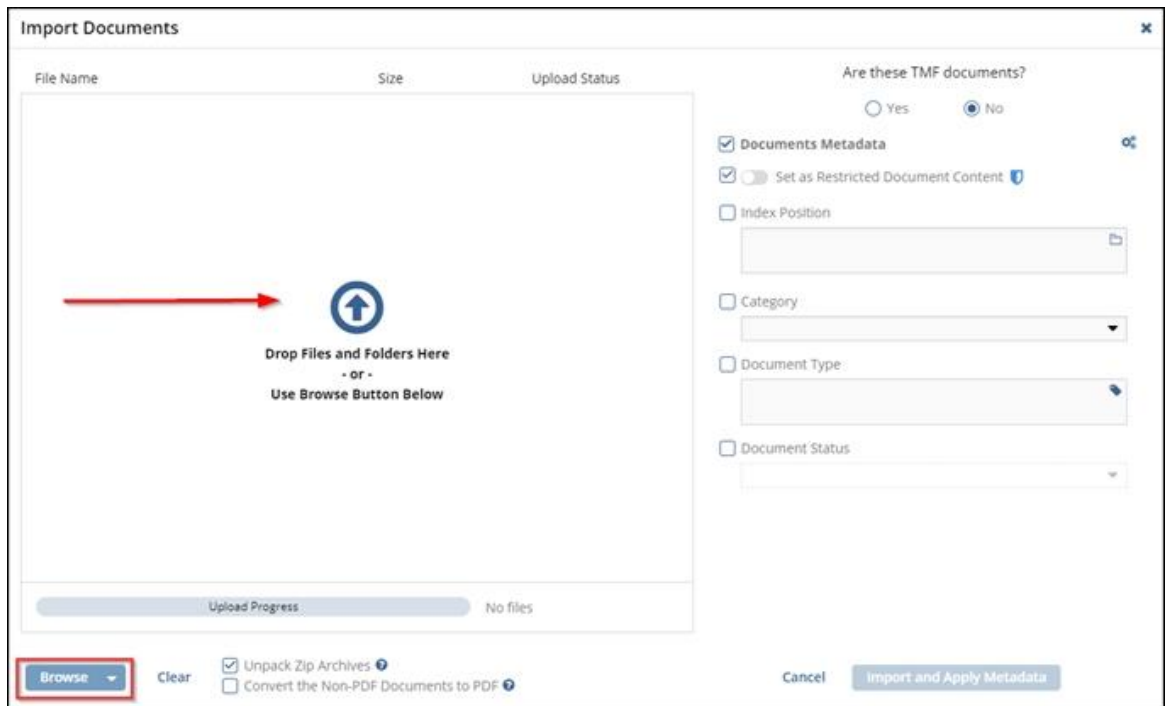
- Clicking 'Add single document' will open a 'New Document' pop-up window. If prompted, answer the question 'Is this a TMF document?' then attach a document or select an existing template, fill in the essential metadata fields, and click 'Finish' to complete the process.



- 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.

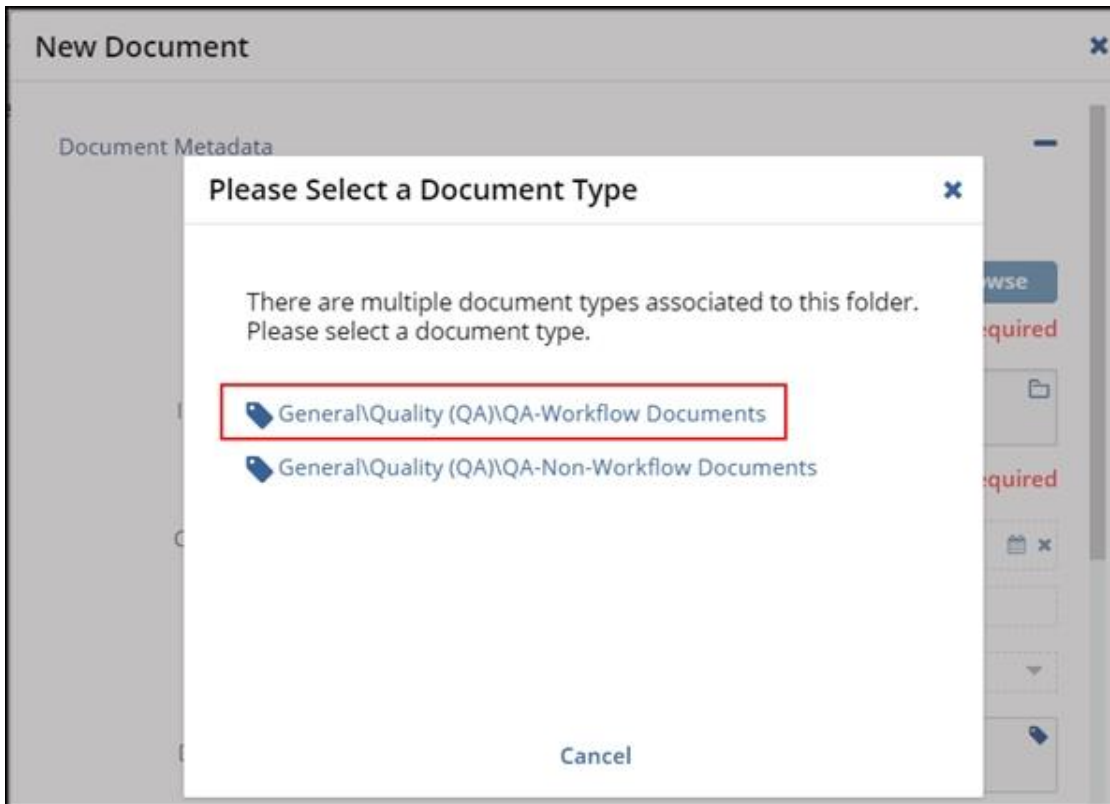


4. In case multiple documents are needed at once for upload,
  - a. Choose the 'Add Multiple Documents' option.
  - b. A different upload window opens. *(Notice the ability shown in step #3. To define documents as ready for workflow is lost using this method).*
  - c. Drag documents into the white space 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.

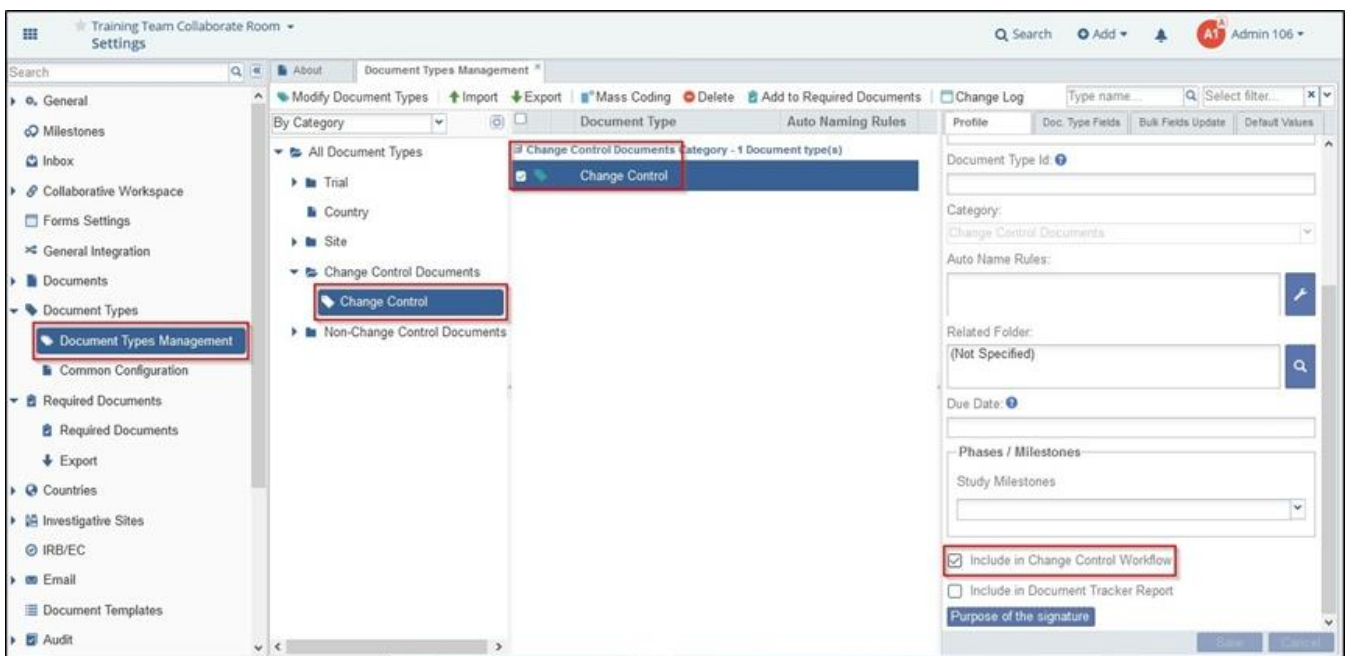




### Advanced: Setting Change Control document types

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.

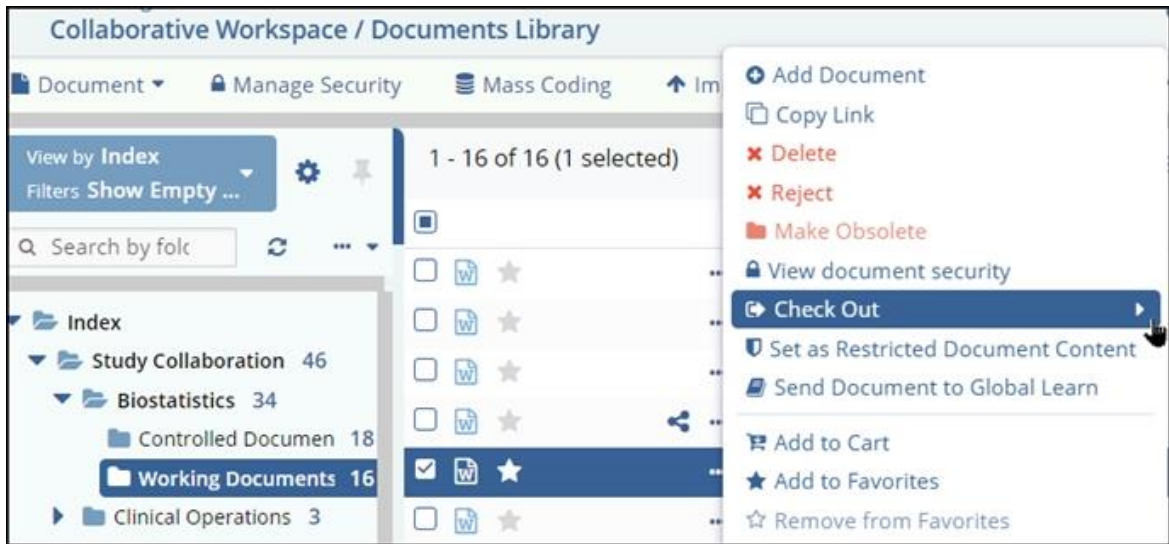
Collaborators in Team Edit can annotate a document with responses and comment threads, as well as integrated online chat. No local software installation is necessary.

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.

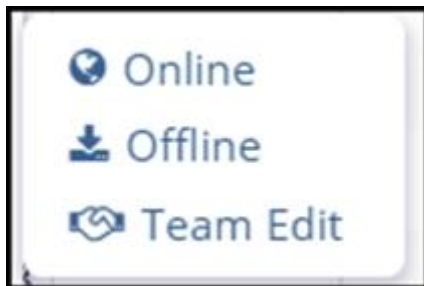
208. Checking Out and Editing

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.

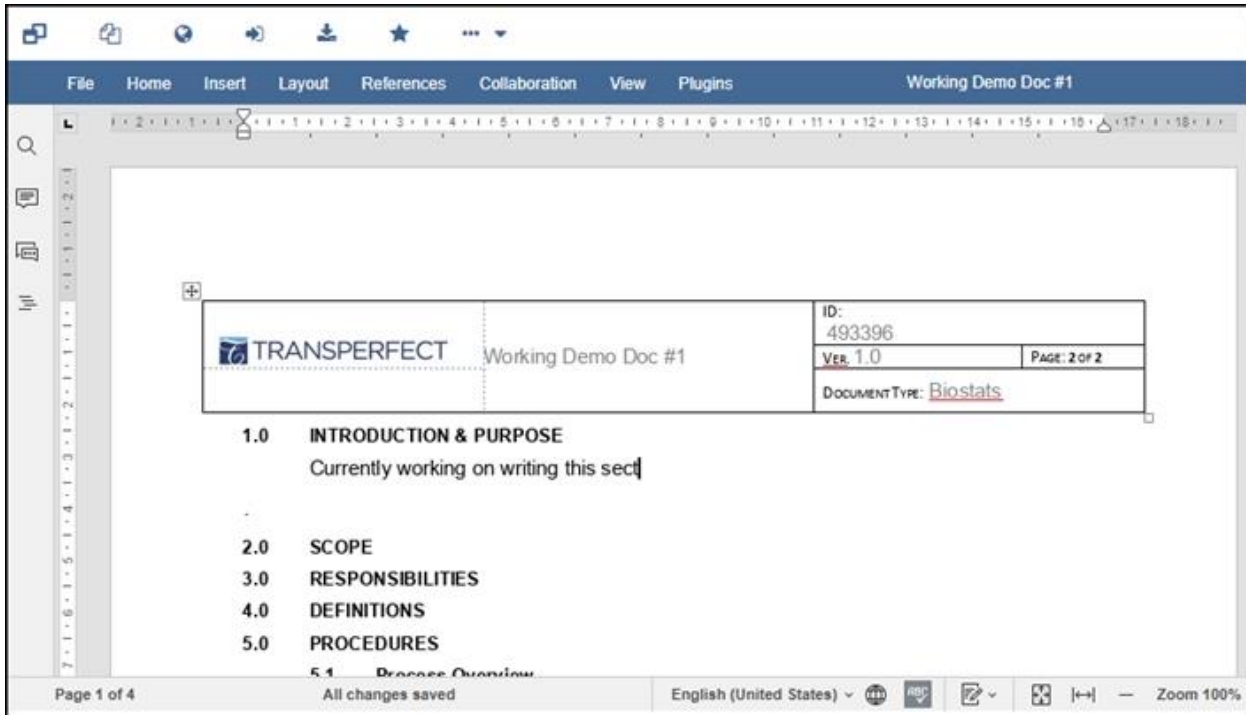


2. Select from the available check-out options according to your preference: Online (Individual Online Authoring), Offline (Individual Offline Authoring outside of TI), or Team Edit (simultaneous team collaboration).



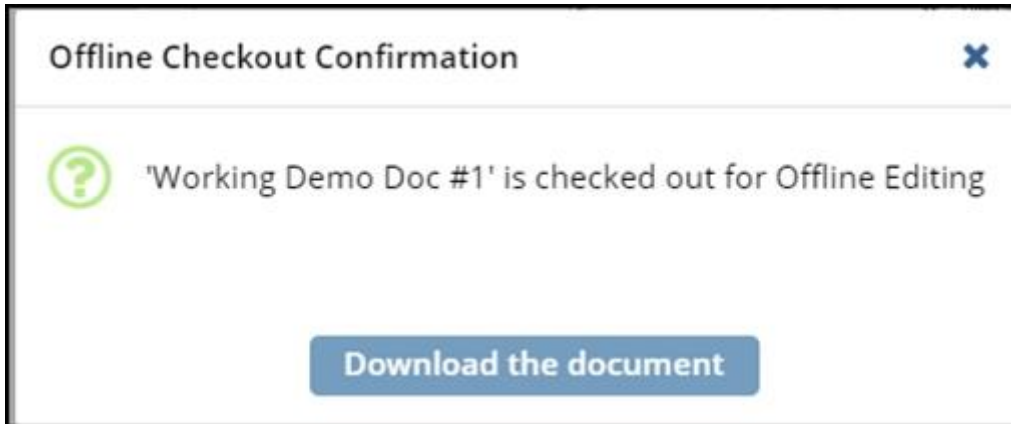
Online

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.

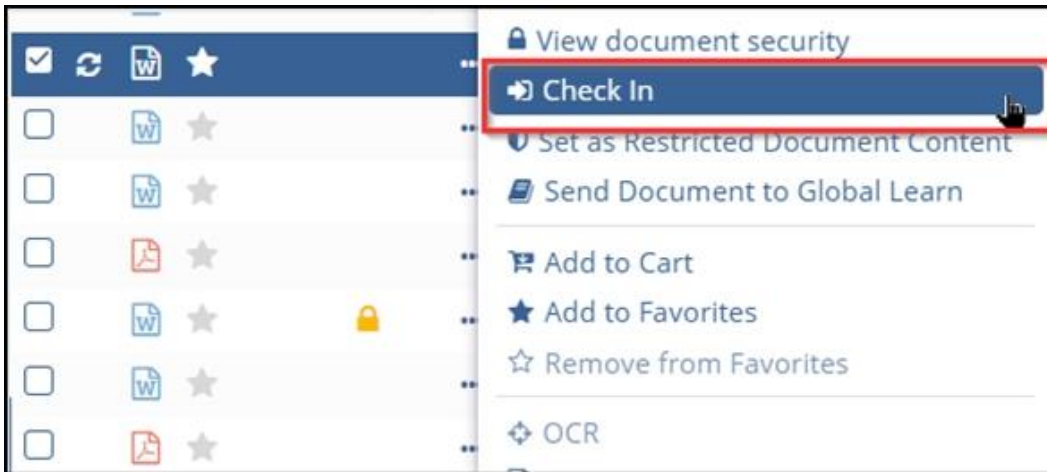


**Note:** We suggest always downloading the document when using this method. This ensures you are working on the most up-to-date version of the document.

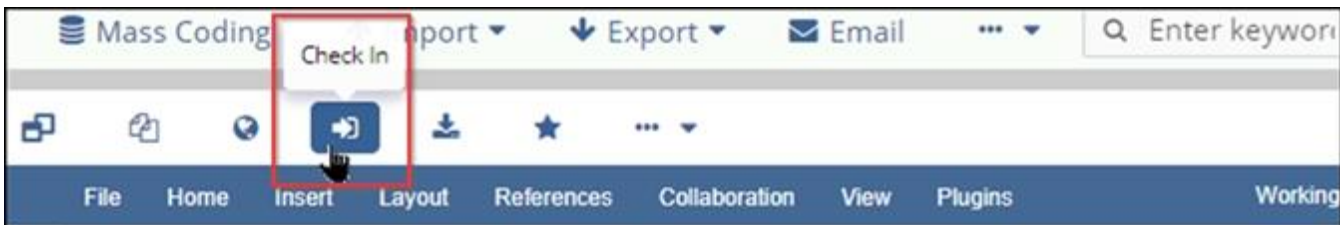
*Checking In*

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.



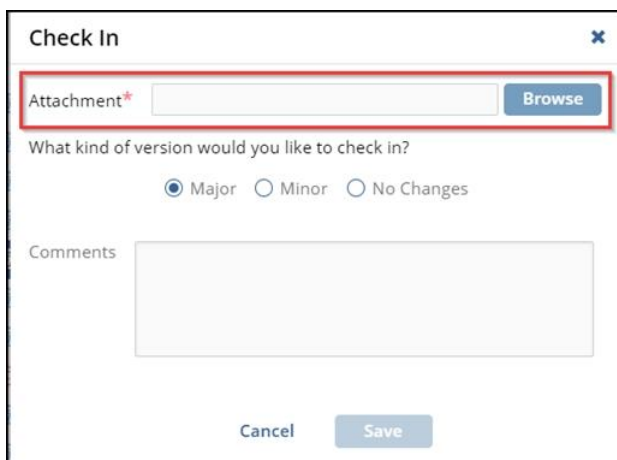
3. Users can then choose from three options:

- 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.



## 209. Team Edit

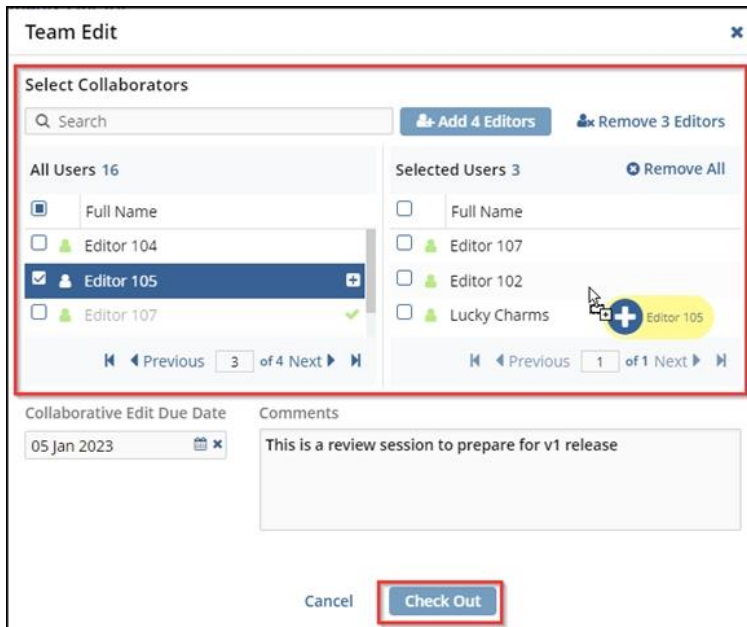
This option creates an online editing session involving multiple users, who can all work on the document simultaneously and see each other's changes in real-time.

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.

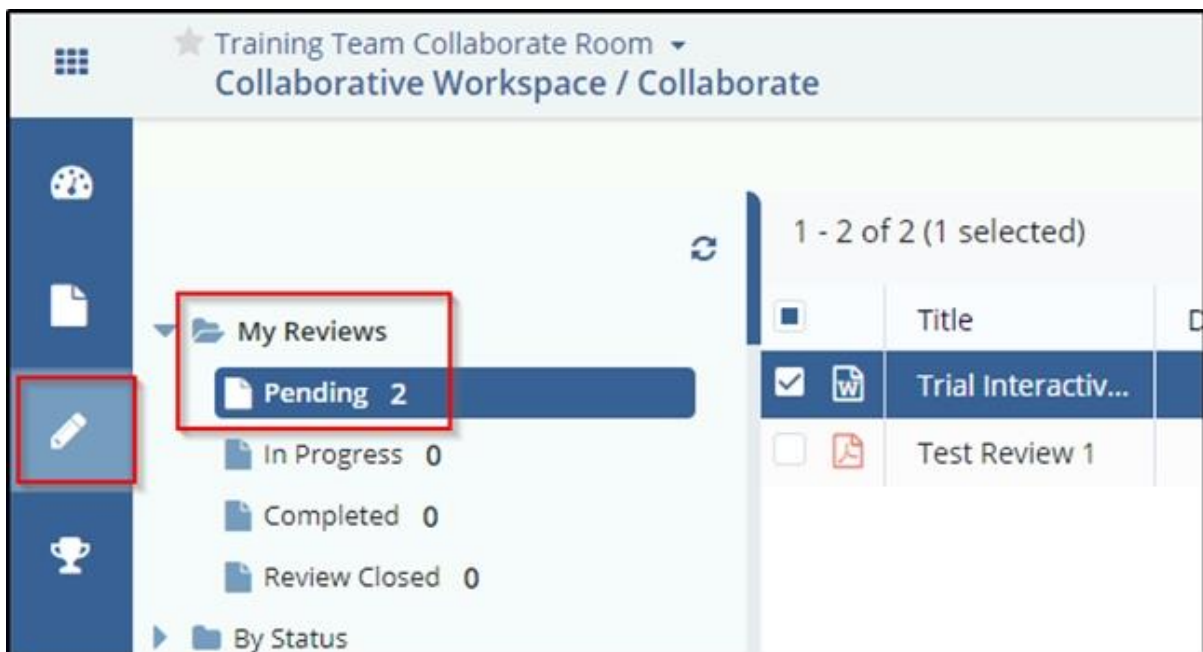


A Collaboration Due Date is also defined, which serves as an indicator for contributing users as to when the session should be completed. This date has no associated automatic function. The session will stay open until manually closed.

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:

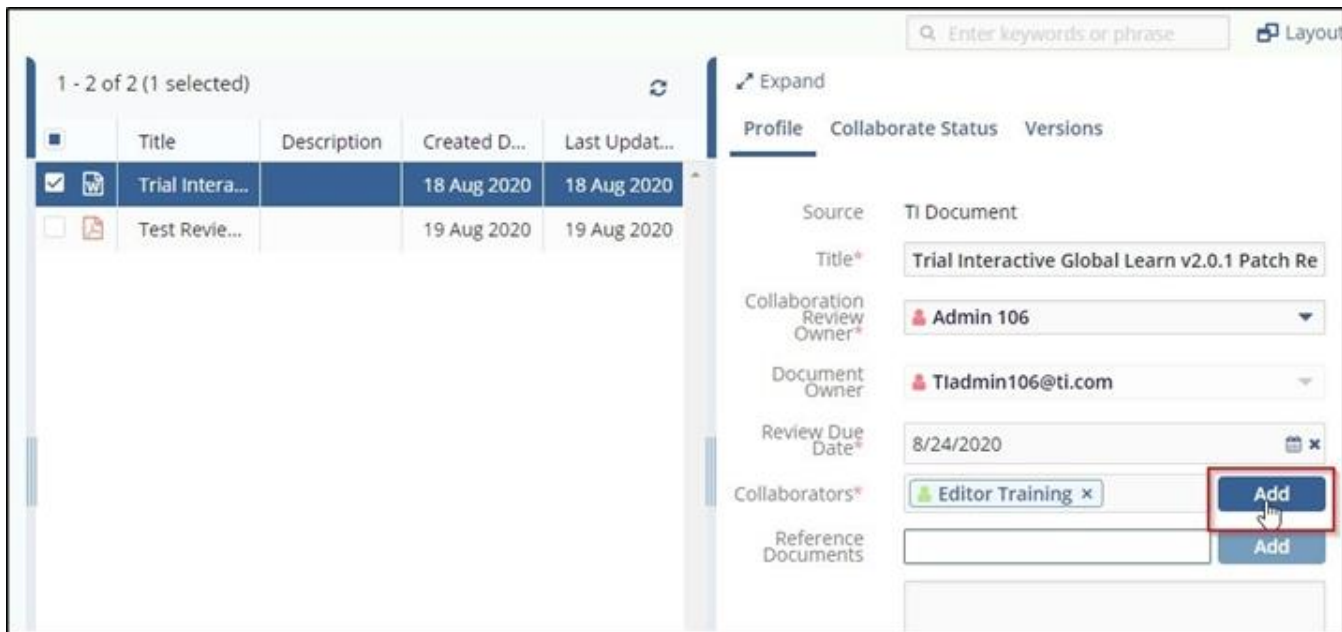
- The Collaborate module, accessed via the vertical navigation bar to the left of the screen in TI
- The Pending Collaborative Reviews dashlet, which displays all ongoing reviews assigned to the user
- The email notification received when added to the edit, which contains a direct link to the document 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.

**ENROLLMENT LOG**

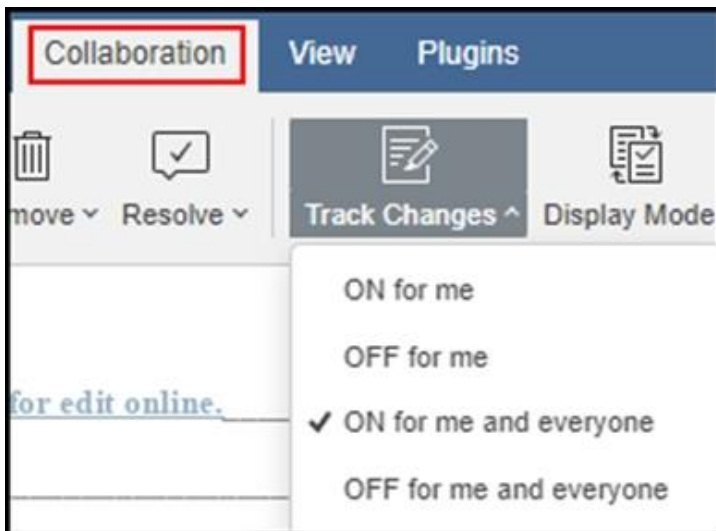
Protocol#: Test for edit online. PI: \_\_\_\_\_  
 Protocol Title: \_\_\_\_\_ Site #: \_\_\_\_\_

WRITING

Editor 107  
 3/23/2023 10:08 am  
 Inserted: writing

Subject ID	Date Consent Signed	Gender	Race	Ethnicity	Was Subject Randomized	Treatment Arm / Group	Subject Status (Withdrawn or Completed)	Explanation if subject not complete stud
1	<span style="border: 1px solid red; padding: 1px;">Admin</span>	M F			Y N			

**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.

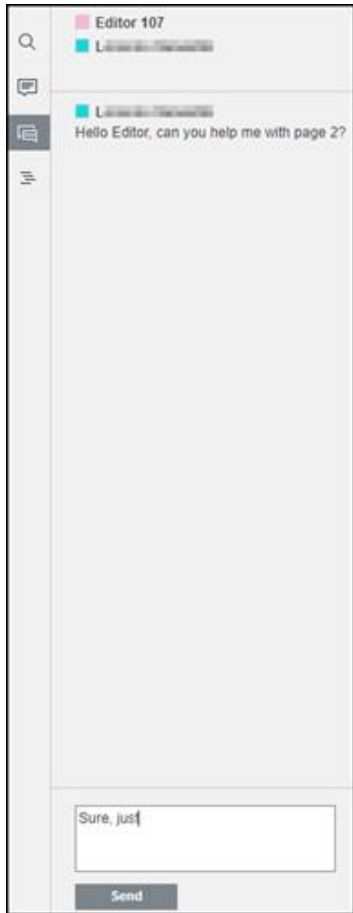


2. Comments can be Replied to, edited, removed, or resolved within this panel.
3. Click on Add Comments to Document button at the bottom of the panel to add your own comments.

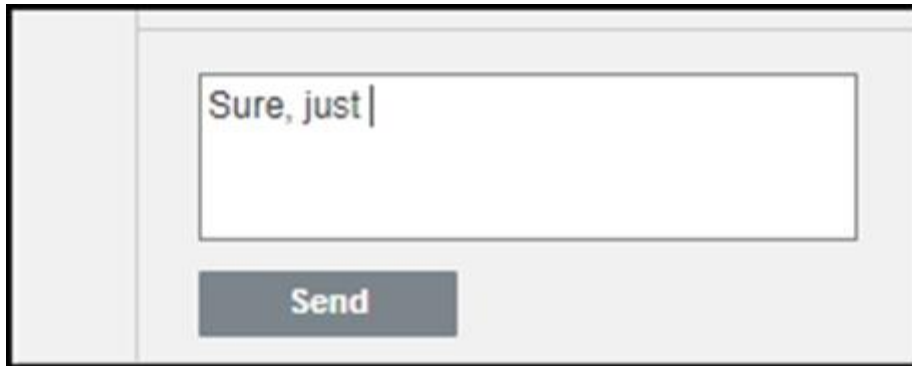


Users can also chat with each other if they are working on the document at the same time.

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.

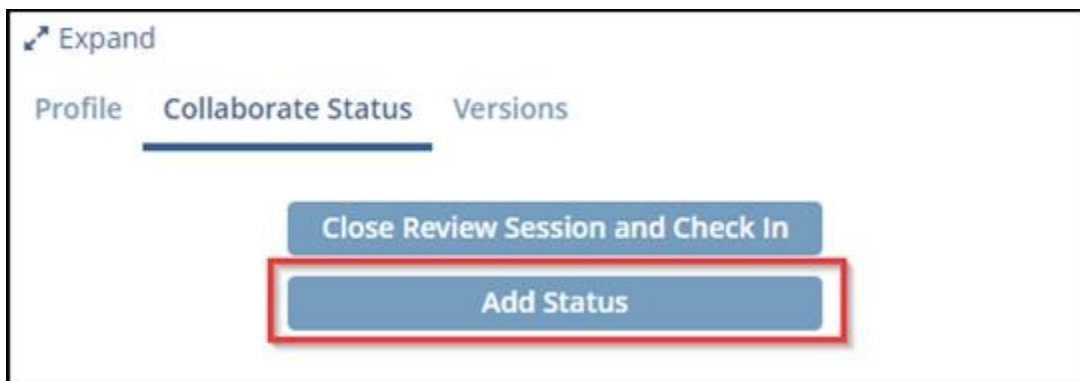


3. Chat History is discarded when the users log off.

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.

Expand

Profile Collaborate Status Versions

Aug 19, 2020

UserName  
Admin 106

Status  
In Progress

Comments  
Will be completed by Friday

Cancel Update and Save

5. You will be notified by a pop-up that your status was correctly added.

Search Add [Bell] Admin 106

Settings Help Guide Sign out

About This Room Show Zoom 80%

Notifications 1 Clear All

All Background Jobs Actions Queries

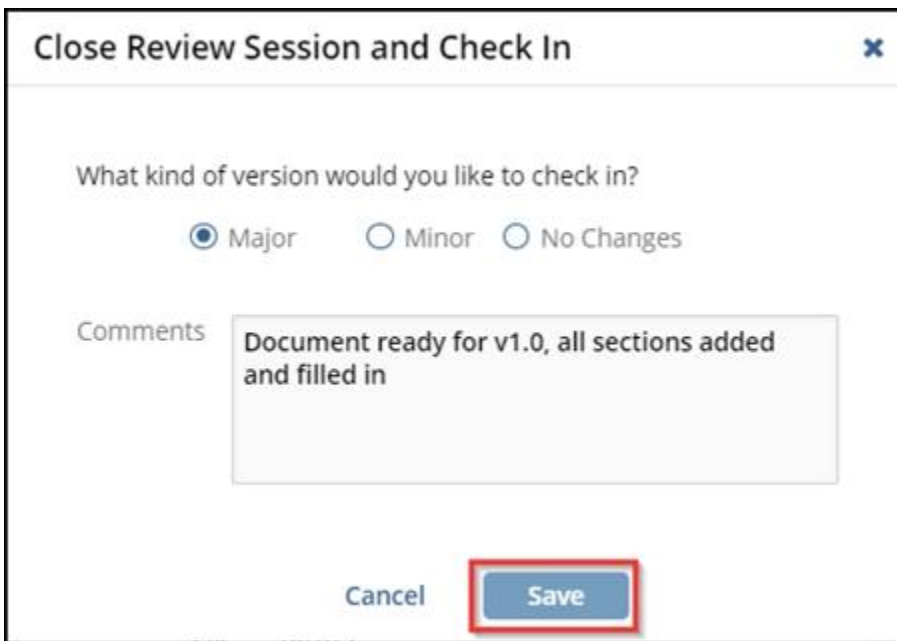
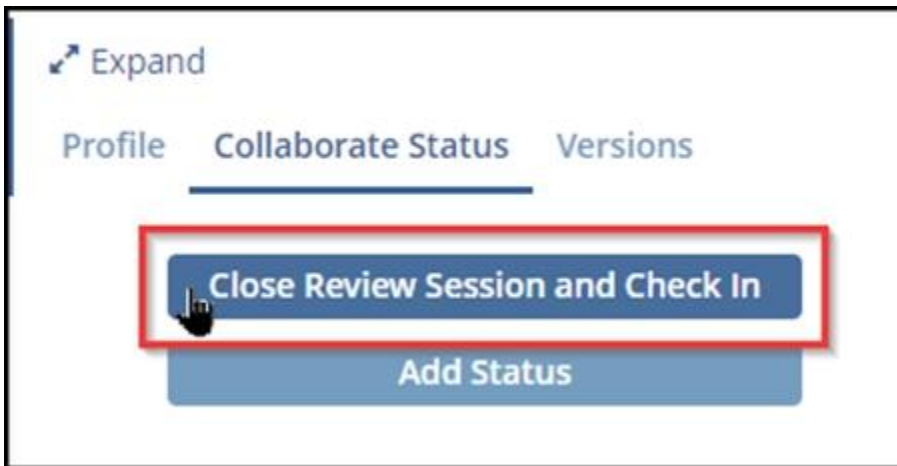
Collaborate Status  
Collaborate Status was successfully updated

*Closing a Team edit*

Once work on a document is complete, only the Collaboration Review Owner can close the session and check in the document.

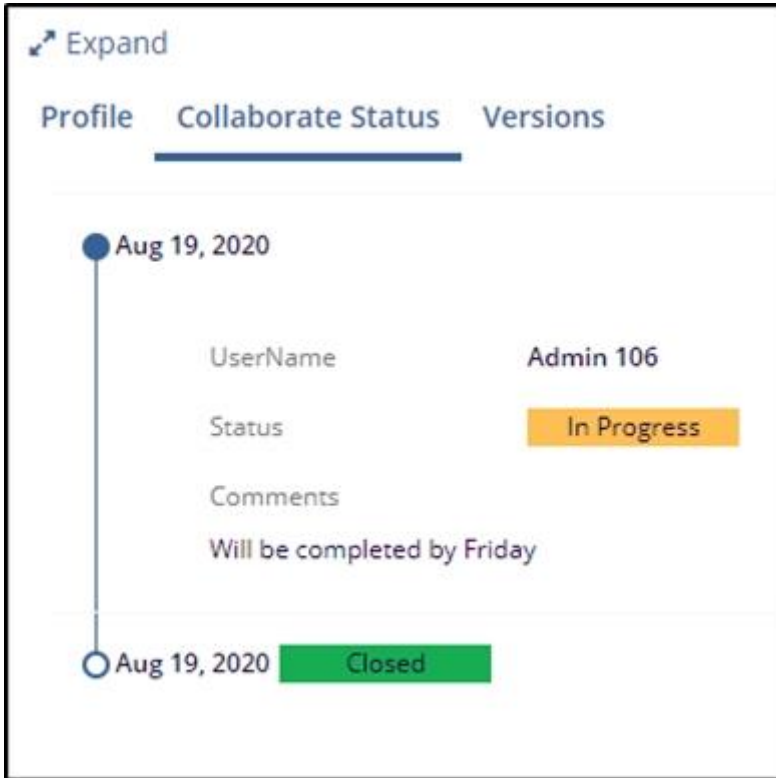
To do that, follow the steps below:

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.



Submitted Name  
**Concise-Monitoring-Plan-Template2**

Version 2.0 (Effective)  Compare More info Open Download  
 **Version 2.0 (Approved, Promoted from v. 1.1)**  Compare More info Open Download  
 Version 1.0 (Effective)  Compare More info Open Download  
 Version 0.1  Compare More info Open Download

Version Label 2.0  
 Version Date 2 Mar 2023, 6:19 AM  
 Comments Version is promoted from version 1.1

**Compare**

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.

Expand

Metadata Queries Versions History eSignature

Submitted Name  
**ConMed-and-Therapies-Worksheet-Form-2.26.19**

Version 1.0  Compare More info Open Download

Version Label 1.0  
 Version Date 14 Feb 2023, 2:17 PM  
 Comments

**ConMed-and-Therapies-Worksheet-Form-2.26.19** Lorenzo Vanzetto Tue 17/01/2023, 10:42:17 am

Closed By **Lorenzo Vanzetto**  
 (Major Versions)  
 Comments

Collaboration Start Date 17 Jan 2023, 10:42 AM  
 Collaboration Owner **Lorenzo Vanzetto**  
 Collaboration Participants Editor 107  
 Editor 103

Version 0.1  Compare More info Open Download

Compare

## Review and Signature Workflows

This section explains the procedure to follow to review and sing a documents.

### 210. Setting Up a Workflow

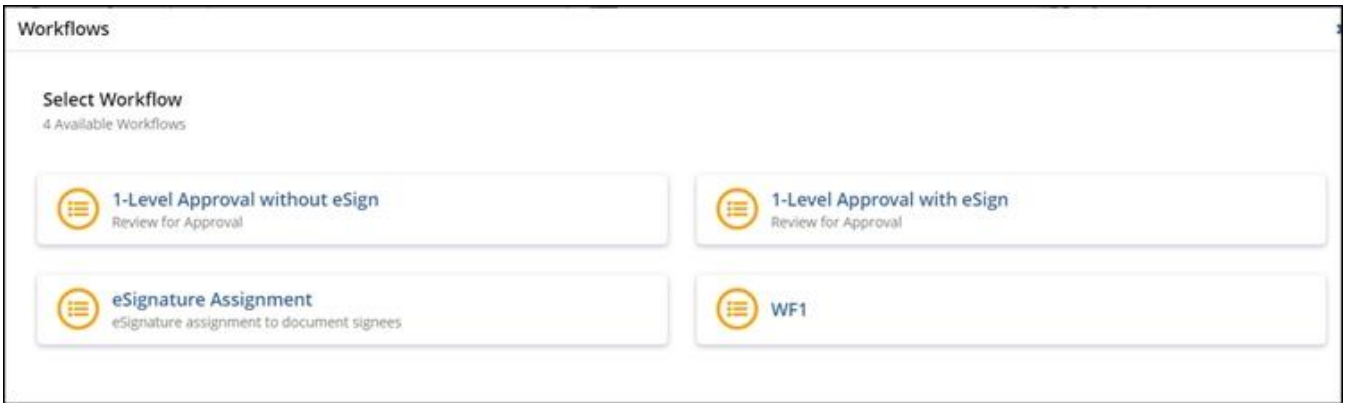
Documents requiring Change Control can be submitted for review or signature workflows either upon submission to TI or after content is generated/edited in TI.

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.

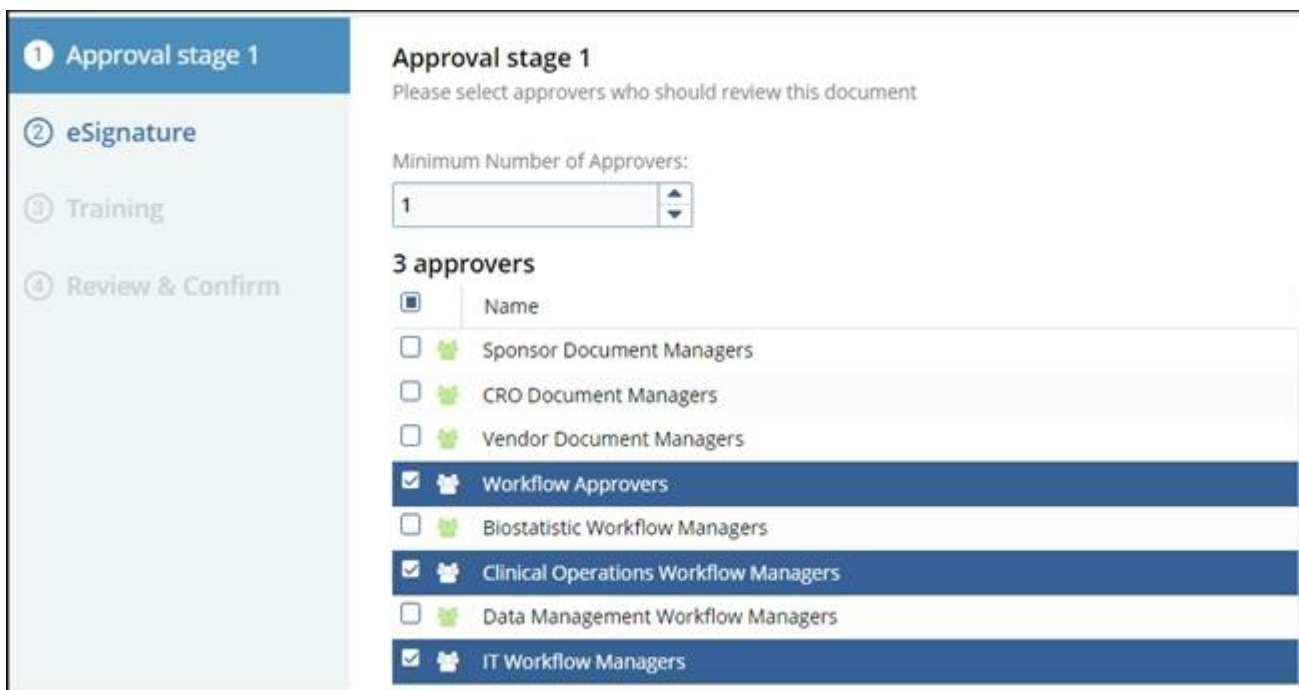


The Document Owner or Proxy Document Owner (as designated in the folder security settings) will select one of the workflows available in the room.



*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.*

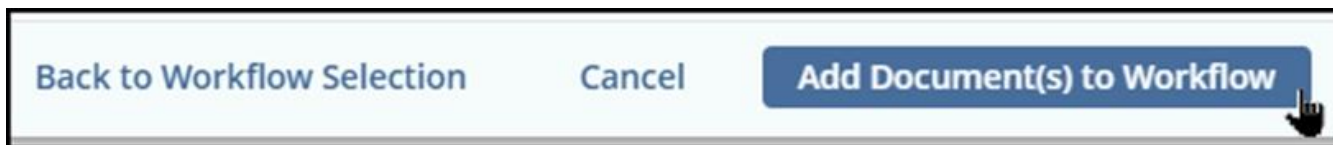
After selecting a Workflow, the setup process will guide the user through the selection of required Reviewers and, if applicable, eSignature Managers (These are the users that will be able to create the actual eSignature request). The number of steps in the wizard may vary. The screenshot below is an 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.

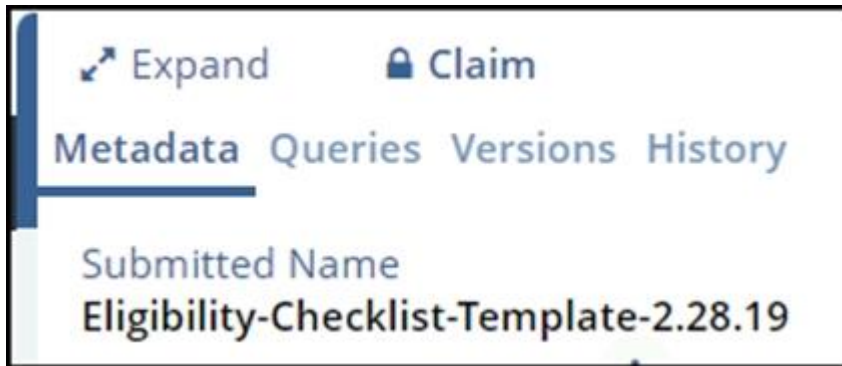
**Important:** *It is our recommendation that users should, where possible, reach out to the Trial Interactive Service Desk whenever assistance is needed in workflow creation or maintenance.*



## 211. Approving a Document

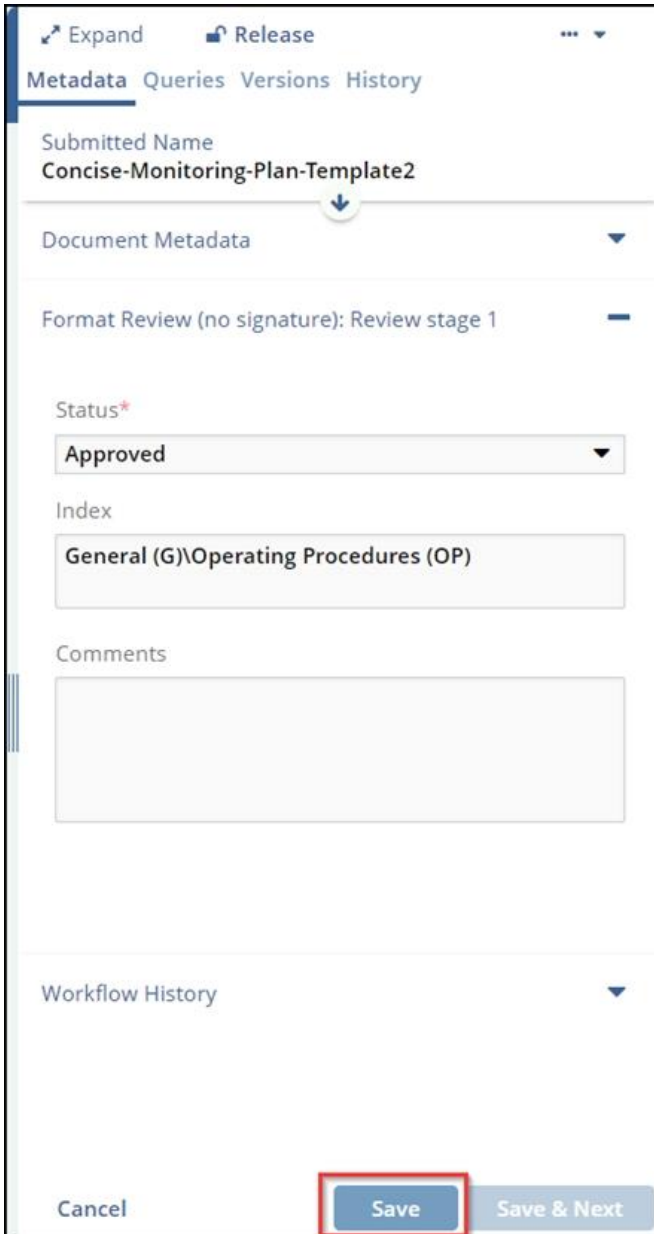
To review and approve a document, first navigate to it using one of the methods available (email link, Documents to Approve dashlet, or Document Library views).

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.



The screenshot shows a document metadata form with the following fields and controls:

- Buttons: Expand, Release, and a menu icon.
- Tabs: Metadata (selected), Queries, Versions, History.
- Submitted Name: Concise-Monitoring-Plan-Template2
- Document Metadata: A dropdown menu.
- Format Review (no signature): Review stage 1
- Status\*: A dropdown menu with 'Approved' selected.
- Index: A text input field containing 'General (G)\Operating Procedures (OP)'. A red box highlights the 'Save' button at the bottom of the form.
- Comments: A large text area.
- Workflow History: A dropdown menu.
- Buttons at the bottom: Cancel, Save (highlighted with a red box), and Save & Next.

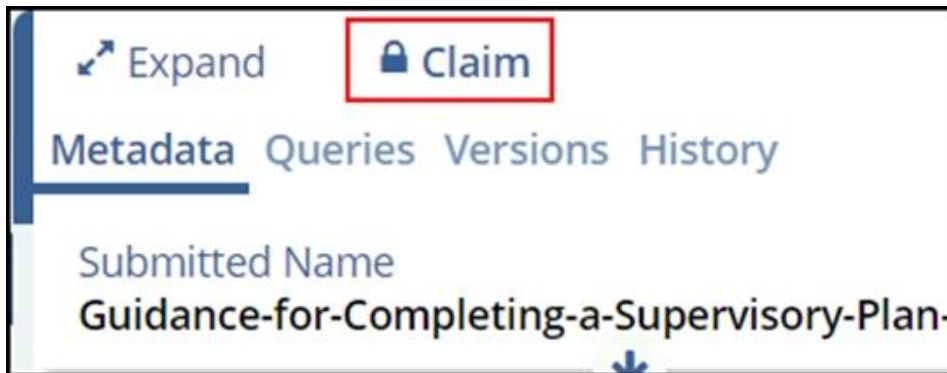
## 212. Setting Up eSignature

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.

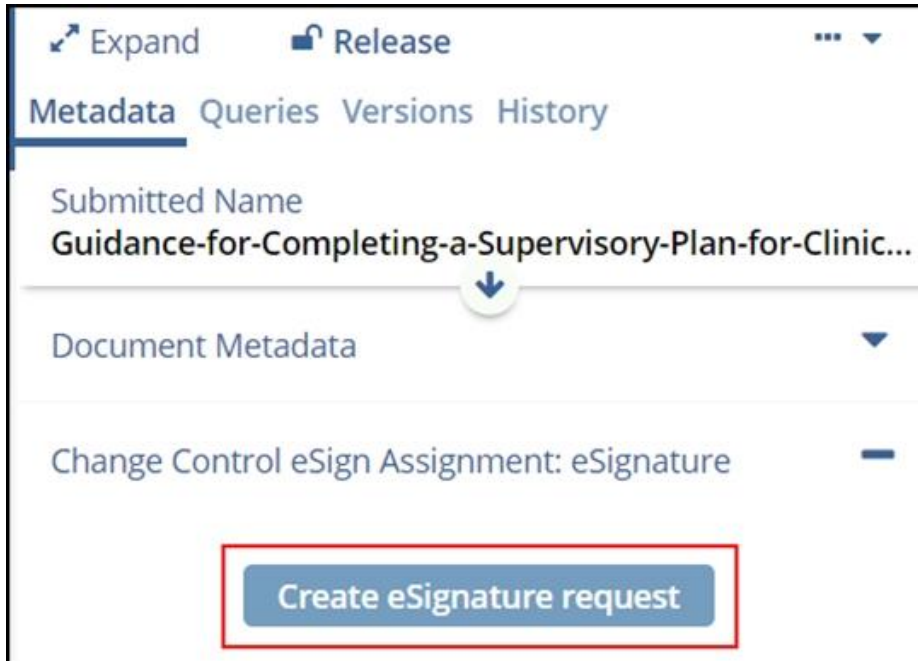


1. Select and Claim the document you wish to have signed (screenshot below).

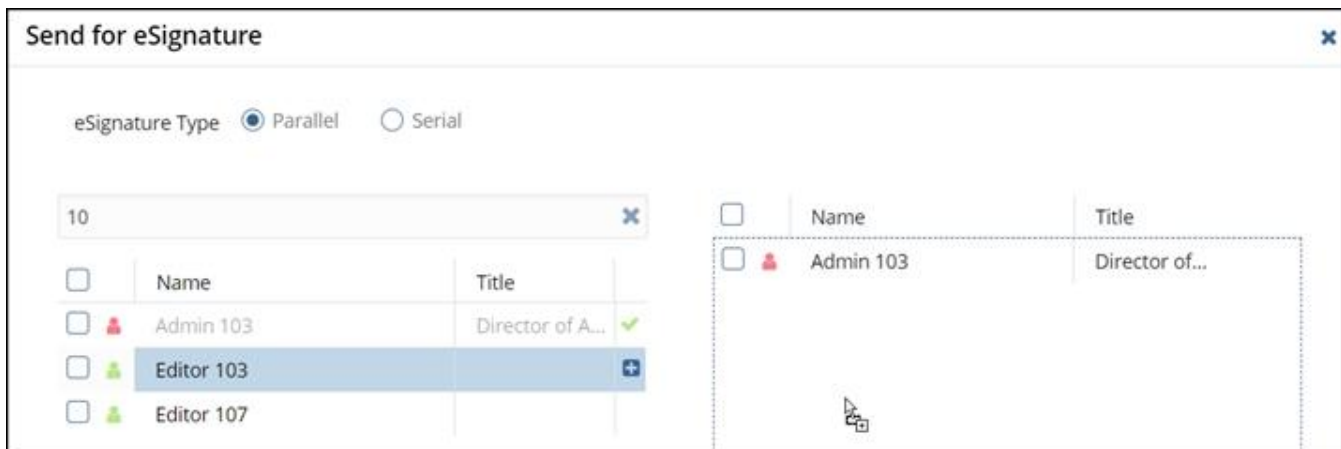




2. Click on the **Create eSignature Request** button.



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.



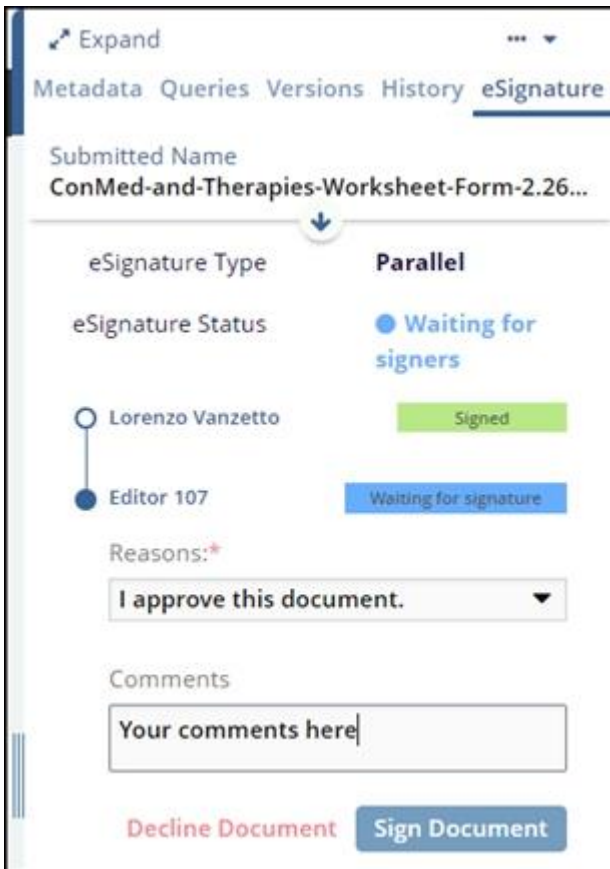
4. The selected users are required to sign and will be notified by email that their signature on the document is pending.  
**Note:** Specific steps at this point may vary based on the eSignature vendor configured for use in the room. Please see additional materials as necessary.

## 213. 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.



Expand

Metadata Queries Versions History **eSignature**

Submitted Name  
ConMed-and-Therapies-Worksheet-Form-2.26...

eSignature Type **Parallel**

eSignature Status **Waiting for signers**

Lorenzo Vanzetto **Signed**

Editor 107 **Waiting for signature**

Reasons:  
I approve this document.

Comments  
Your comments here

**Decline Document** **Sign Document**

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.

## 214. Non-Approval of Documents

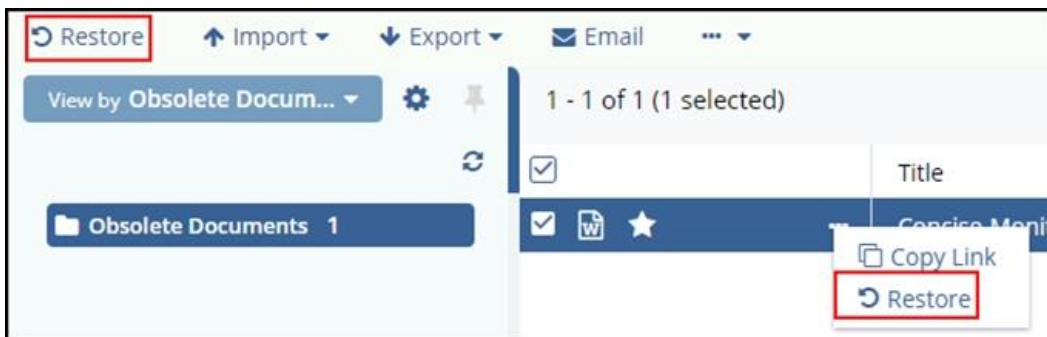
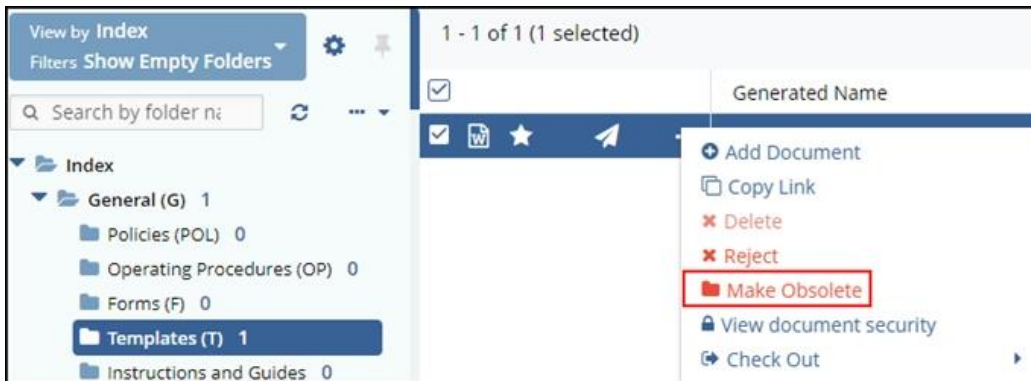
Documents can be rendered ineffective, for example, when the format is not correct, in multiple ways. Of course, an approver can refuse to move the document forward, or a signature workflow can be neutralized when someone refuses to sign.

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

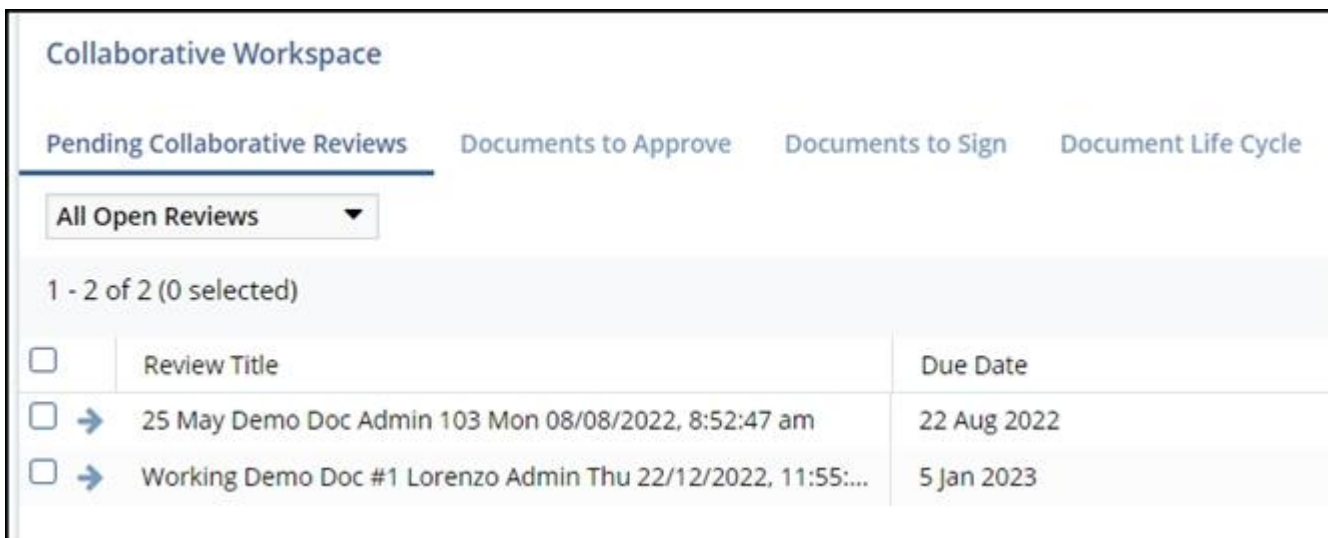
The Collaborative Workspace grouping of dashlets is exclusive to TI Collaborate rooms and contains dashlets that give the user quick access to lifecycle tools and documents.

See the following subsections for a description of these dashlets and their functions.

---

### 215. 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).

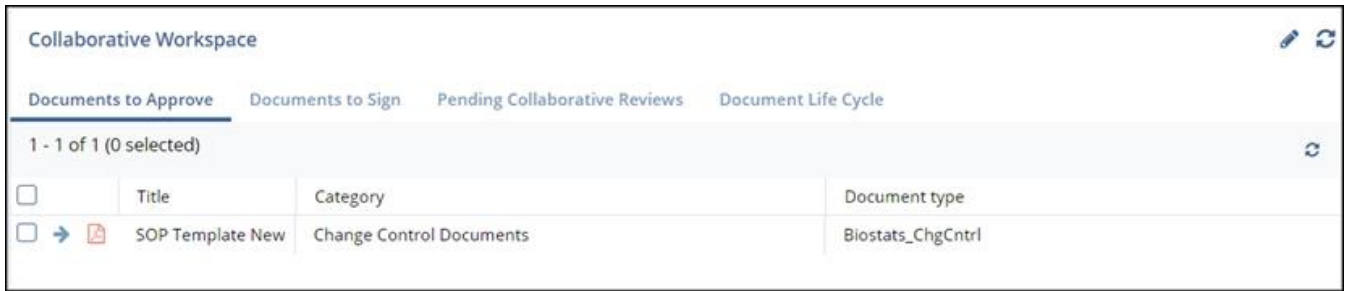


The screenshot shows the 'Collaborative Workspace' dashlet with the 'Pending Collaborative Reviews' tab selected. A dropdown menu is set to 'All Open Reviews'. Below the dropdown, it indicates '1 - 2 of 2 (0 selected)'. A table lists two pending reviews with checkboxes, review titles, and due dates.

<input type="checkbox"/>	Review Title	Due Date
<input type="checkbox"/> →	25 May Demo Doc Admin 103 Mon 08/08/2022, 8:52:47 am	22 Aug 2022
<input type="checkbox"/> →	Working Demo Doc #1 Lorenzo Admin Thu 22/12/2022, 11:55:...	5 Jan 2023

## 216. Dashlet – Documents to Approve

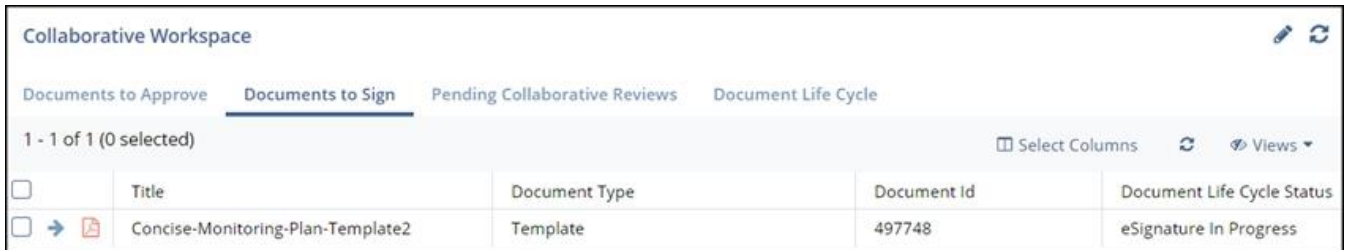
This dashlet displays the list of documents that are pending the user’s approval in TI. Note that if the user belongs to a pool of approvers of the same level, docs may be approved without the user’s intervention. Click on an entry in this list to open the document approval interface.



Collaborative Workspace			
Documents to Approve Documents to Sign Pending Collaborative Reviews Document Life Cycle			
1 - 1 of 1 (0 selected)			
	Title	Category	Document type
<input type="checkbox"/>	SOP Template New	Change Control Documents	Biostats_ChgCntrl

## 217. 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..).



Collaborative Workspace				
Documents to Approve Documents to Sign Pending Collaborative Reviews Document Life Cycle				
1 - 1 of 1 (0 selected)				
	Title	Document Type	Document Id	Document Life Cycle Status
<input type="checkbox"/>	Concise-Monitoring-Plan-Template2	Template	497748	eSignature In Progress

## 218. 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.

**Collaborative Workspace** ✎ ↻

Documents to Approve   Documents to Sign   Pending Collaborative Reviews   Document Life Cycle

Status Approved ▼

1 - 1 of 1 (0 selected) Select Columns   ↻   Views ▼

	Title	Category	Document type	Life Cycle Status
<input type="checkbox"/>	<a href="#">→</a> SOP #3	Change Control Documents	ClinOps_ChgCntrl	Approved

## 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.

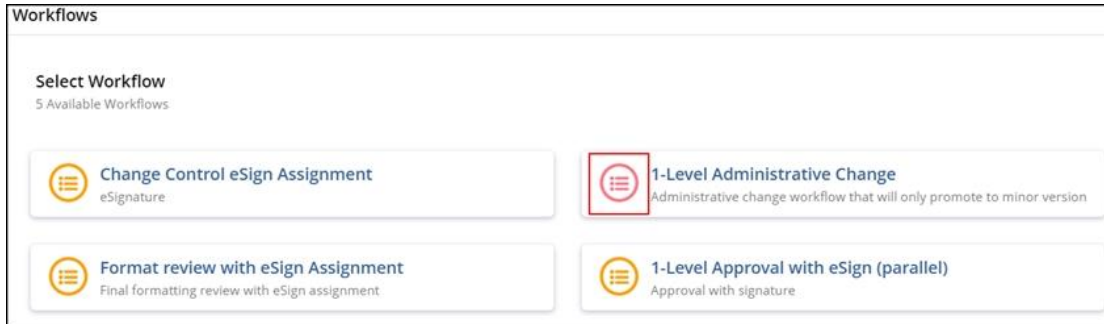
Make the necessary small change(s) and check the document in.

1. The document will be indicated as ready for workflow (paper plane icon).

<input type="checkbox"/>		Generated Name	Document Owner	Working Version
<input type="checkbox"/>	  ...	Other	Admin 103	1.0
<input type="checkbox"/>	   ...	Informed Consent Form_ICF	Lorenzo Vanzetto	1.1
<input type="checkbox"/>	   ...		Lorenzo Vanzetto	0.1

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).

- Set up the workflow and carry out the review and approval as normal (see previous chapter on Review and Signature Workflows).



- You can verify the document update in the document's Versions panel. The Effective Date and (where applicable) Review Period fields are unchanged.



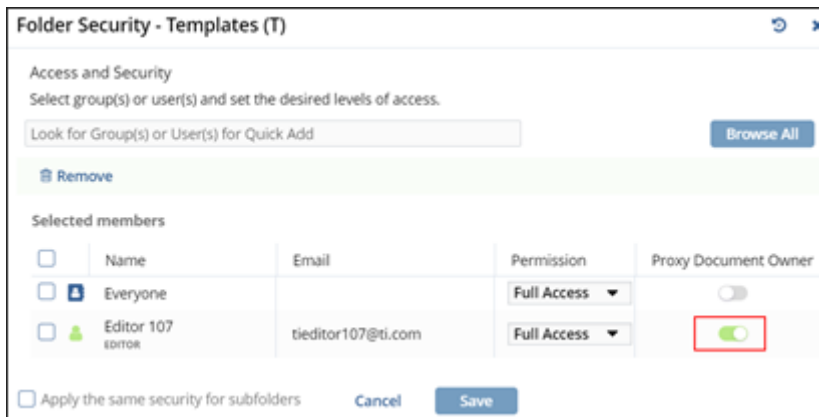


## 219. Additional Document Owner Privileges

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:

Expand More ▾

Metaddata Queries Versions History

**CTA**

Document Type ✕  
Change Control

File Name CTA.pdf

Sender Name

Sender Address

Document Status ▾

Published Date DD MMM YYYY 📅 ✕

Published By

Country ▾

Document Owner Admin 103 ▾


Additional Document Owners

Effective Period ▴ ▾

Effective Immediately

**Additional Document Owners** ✕

🔍 Search

Full Name	Email
 Editor 107	tieditor107@ti.com

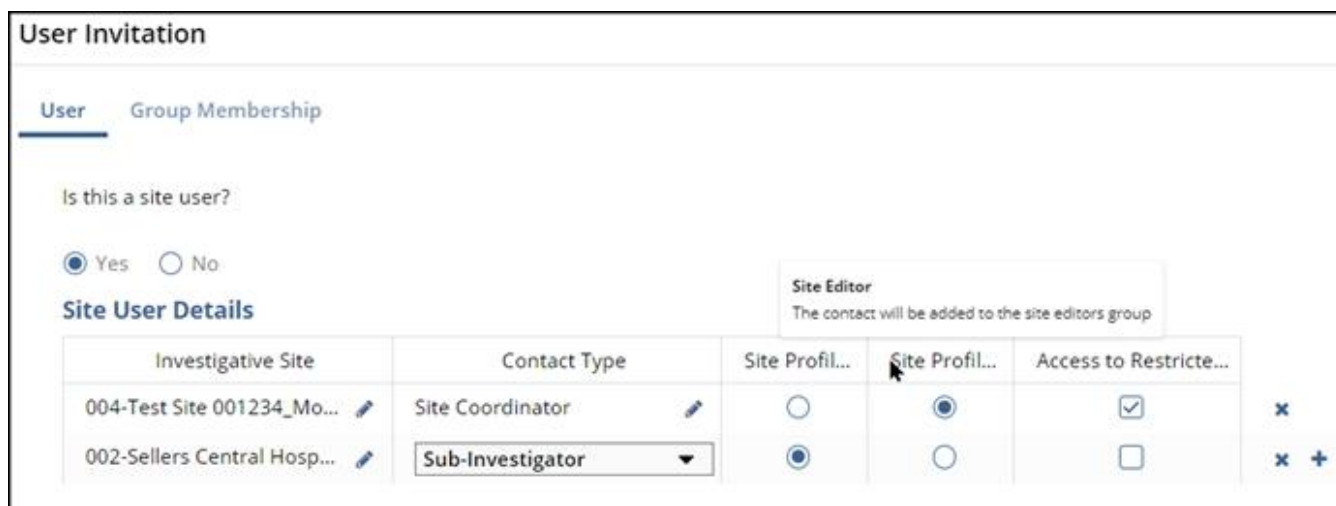
## eISF

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.

## 220. 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.










**User Invitation**

**User** | Group Membership

Is this a site user?

Yes  No

**Site User Details**

Investigative Site	Contact Type	Site Profil...	Site Profil...	Access to Restrict...	
004-Test Site 001234_Mo... 	Site Coordinator 	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>	
002-Sellers Central Hosp... 	Sub-Investigator 	<input checked="" type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	 

**Site Editor**  
The contact will be added to the site editors group

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.

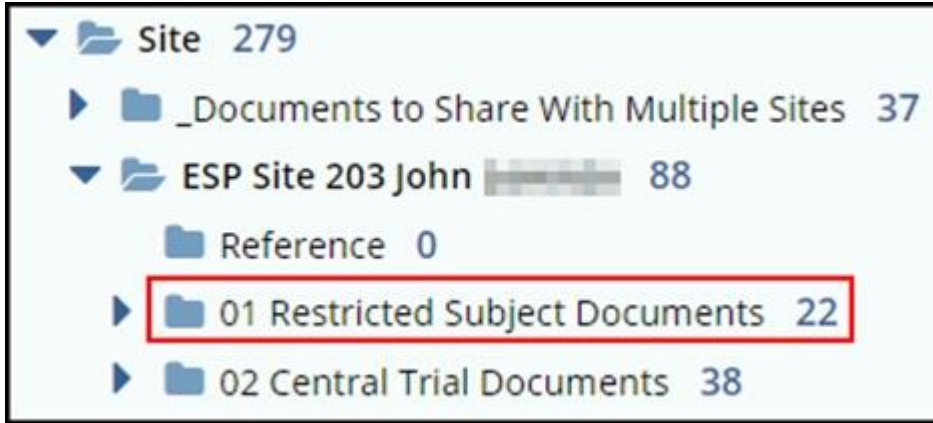
Specific permissions are assigned to users in this category based on predetermined site template-folder security configuration. This will allow users to be provided the correct security profile right away upon creation and gain immediate access to the Site Collaborate room, reducing time-to-access.

*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.

## 221. 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.

---

## 222. 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 16: 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.

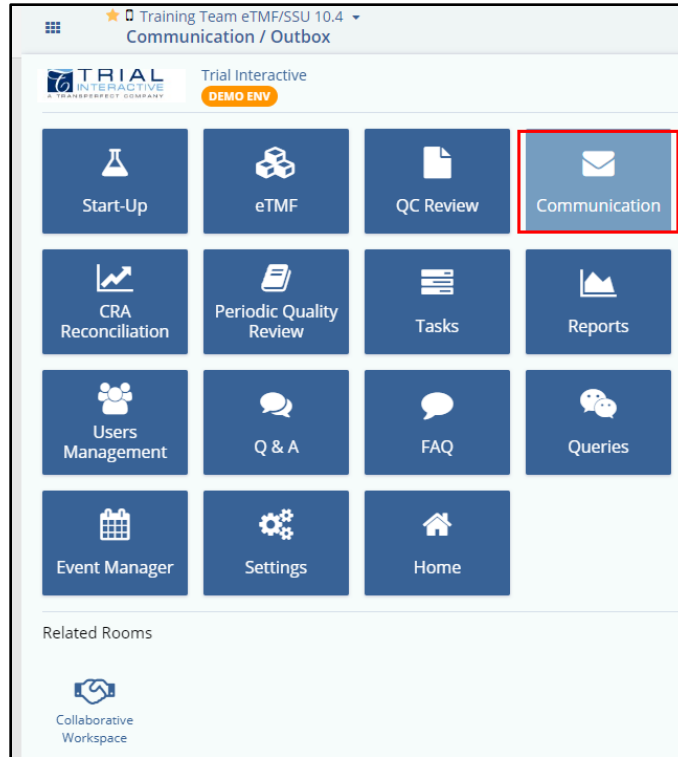


Figure 1: Communication Module

### 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:

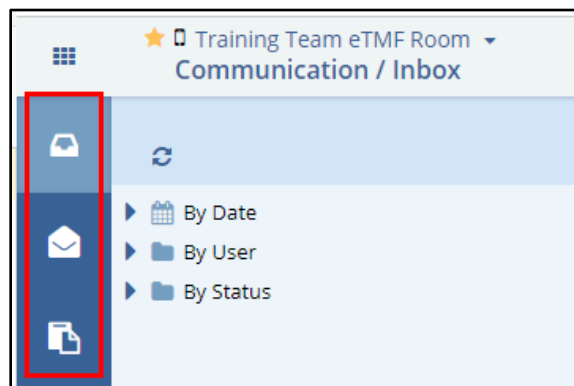


Figure 2: Inbox and Outbox module

### Communication Inbox

From this area, you can perform the following functions:

- The Inbox Settings
- The Inbox Process

## 223. Reviewing Communications

Follow the steps below to review communications and mark them as relevant or non-relevant.

1. Navigate to the Communications module.
  - o The communications will be displayed in the following categories:
    - a. By Date
    - b. By User
    - c. By Status

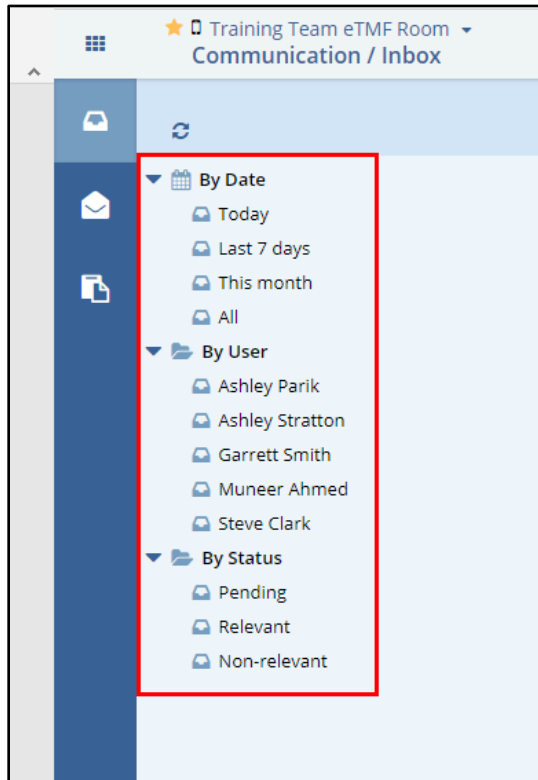


Figure 3: Inbox Folders

2. Choose whichever category you would like (By Status is recommended for this process).
  - o The communications will load in the grid.
3. Select a communication in Pending status.
  - o The communication's details will load in the metadata pane.

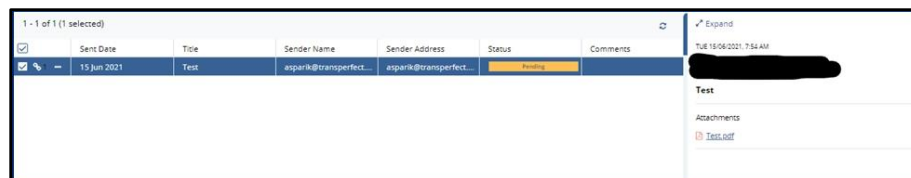


Figure 4: Communication Metadata Tab

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.



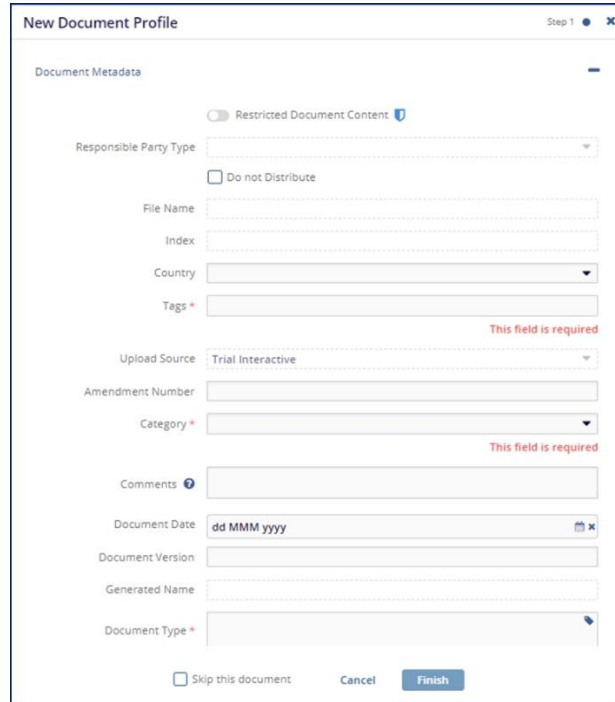


Figure 6: new Document Profile

- 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.

---

#### 224. 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:

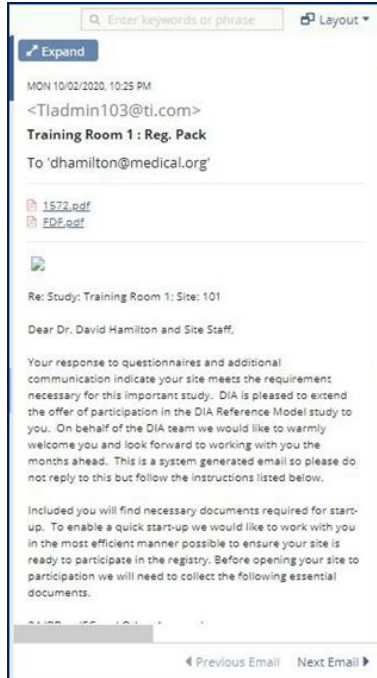


Figure 7: Communication outbox

## 225. 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:

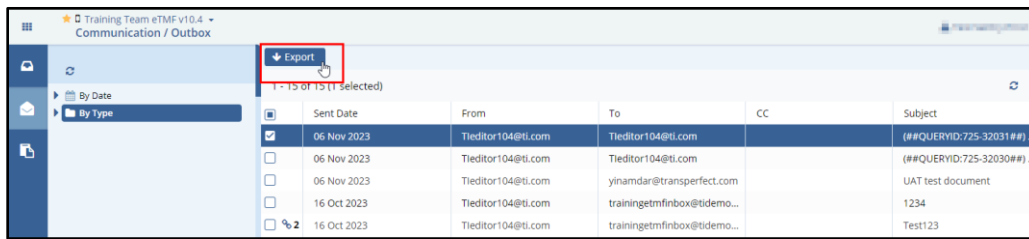


Figure 8: Communication Export

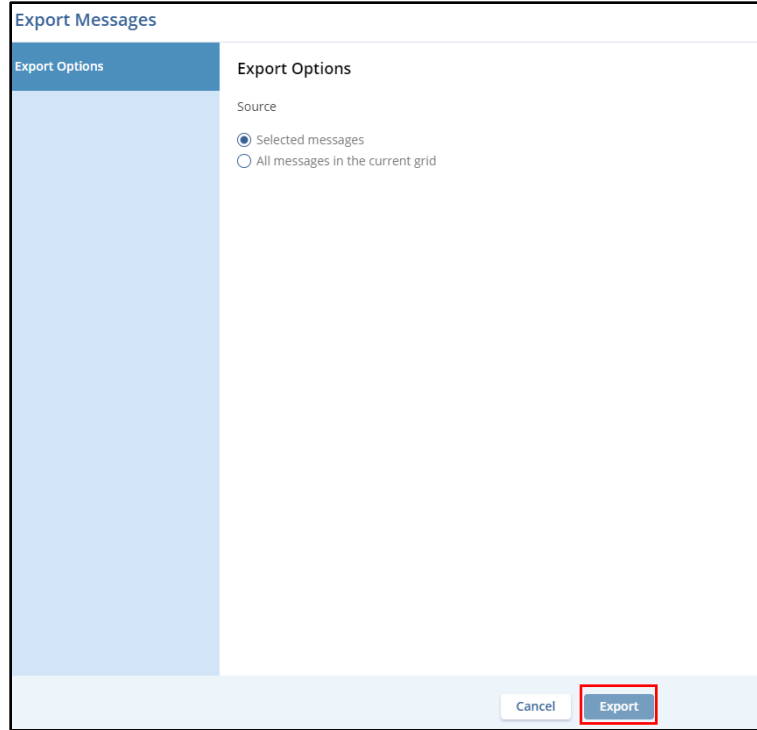


Figure 9: Export Message Page

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.

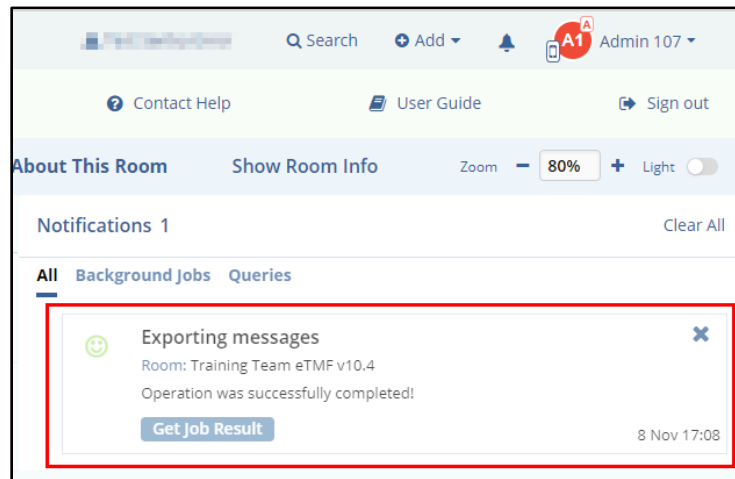


Figure 10: Exporting Notification

## CHAPTER 17: 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.

## 226. 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.

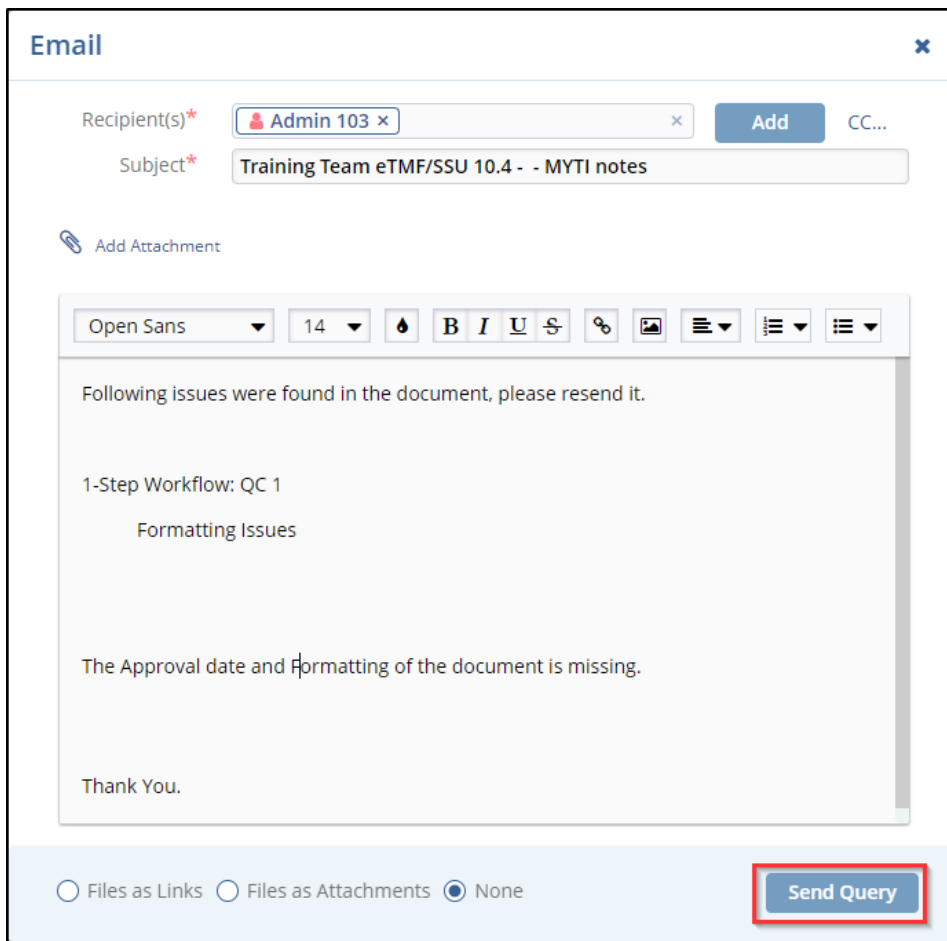
The screenshot shows a web interface for managing trial metadata. At the top, there are tabs for 'Metadata', 'Queries', 'Versions', and 'Related'. Below these is a 'History' section with a 'Submitted Name' field containing 'MYTI notes'. A dropdown arrow is visible below the name. The main form area is titled '1-Step Workflow: QC 1'. It contains several sections:
 

- Status\***: A dropdown menu currently showing 'Clarification'.
- Issues\***: A list of issues, with 'Formatting Issues' selected and marked with an 'x' for removal.
- Index**: A text box containing the path 'Trial\04 IRB or IEC and other Approvals\04.04 General\04.04.01 Relevant Communications'.
- Comments**: A text area containing the text 'The Approval date is missing. Formatting of the document is missing.'.

 At the bottom of the form, there are three buttons: 'Send Issue', 'Create Query' (highlighted with a red box), and 'Save & Next'. Below the form is a 'Workflow History' section with 'Cancel', 'Save' (highlighted with a red box), and 'Save & Next' buttons.

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.

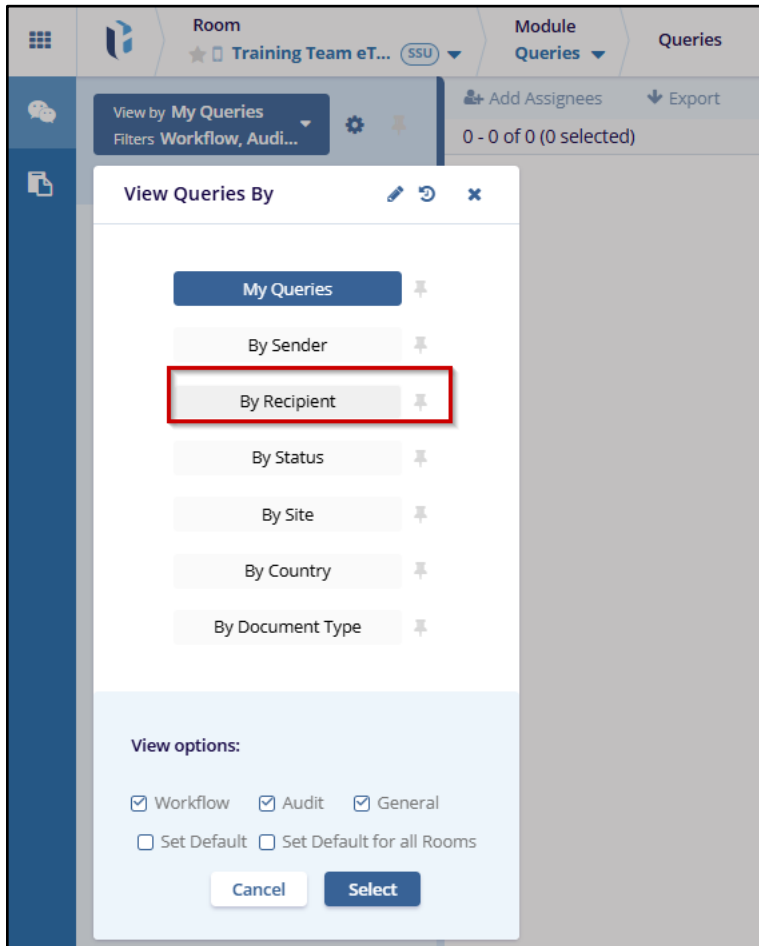
To respond to a query from inside the system:

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.

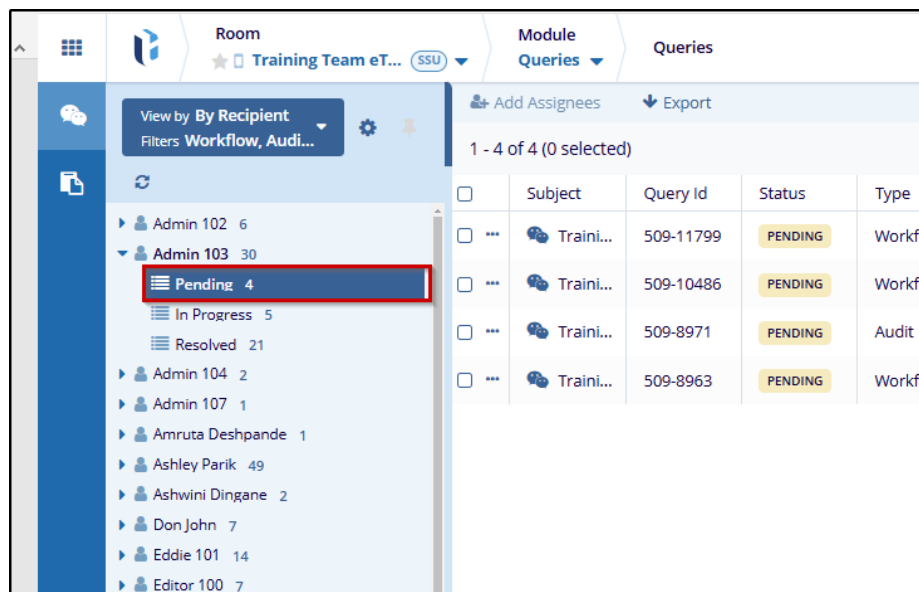
The screenshot displays the Trial Interactive dashboard interface. At the top, there is a navigation bar with a grid icon, the Trial Interactive logo, and breadcrumb navigation: Room (Training Team eT... SSU) > Module (eTMF) > Dashboard. Below the navigation bar, the main content area is titled 'Trialinteractive DEMO'. It features a grid of 16 blue buttons with white icons and text labels: Start-Up, eTMF, QC Review, Communication, CRA Reconciliation, Periodic Quality Review, Tasks, Reports, Users Management, Q & A, FAQ, and Queries. The 'Queries' button is highlighted with a red border. Below the grid, there is a 'Related Rooms' section with two entries: 'Training Team eTMF Room (eTMF)' and 'Training Team Collaborate v10.4 (eTMF)'. A partial sidebar on the right shows 'ew My P'.



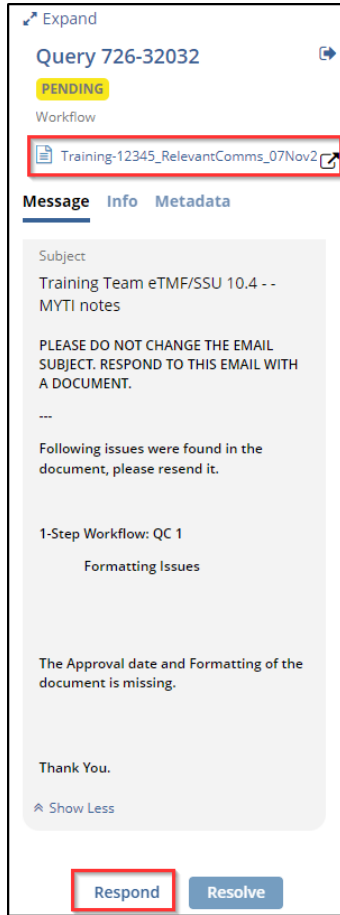
2. Choose the 'By Recipient' view from the dropdown menu at the top-left.



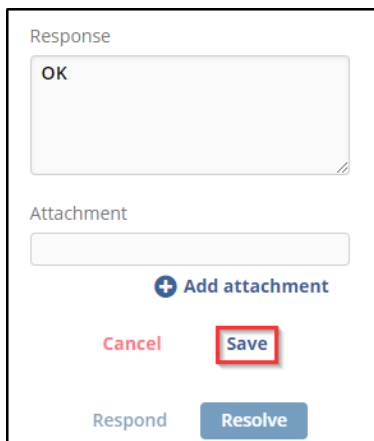
- a. Users who have access to view queries for multiple users will need to expand their own list by clicking on the arrow next to their username.



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.

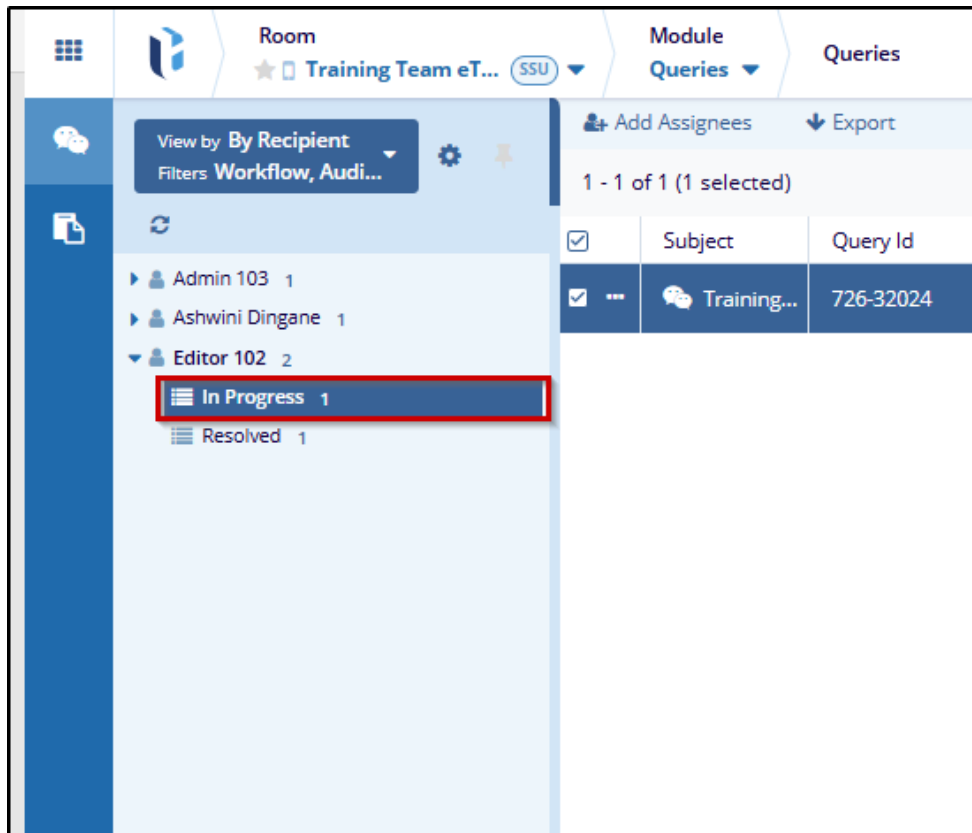
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

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.

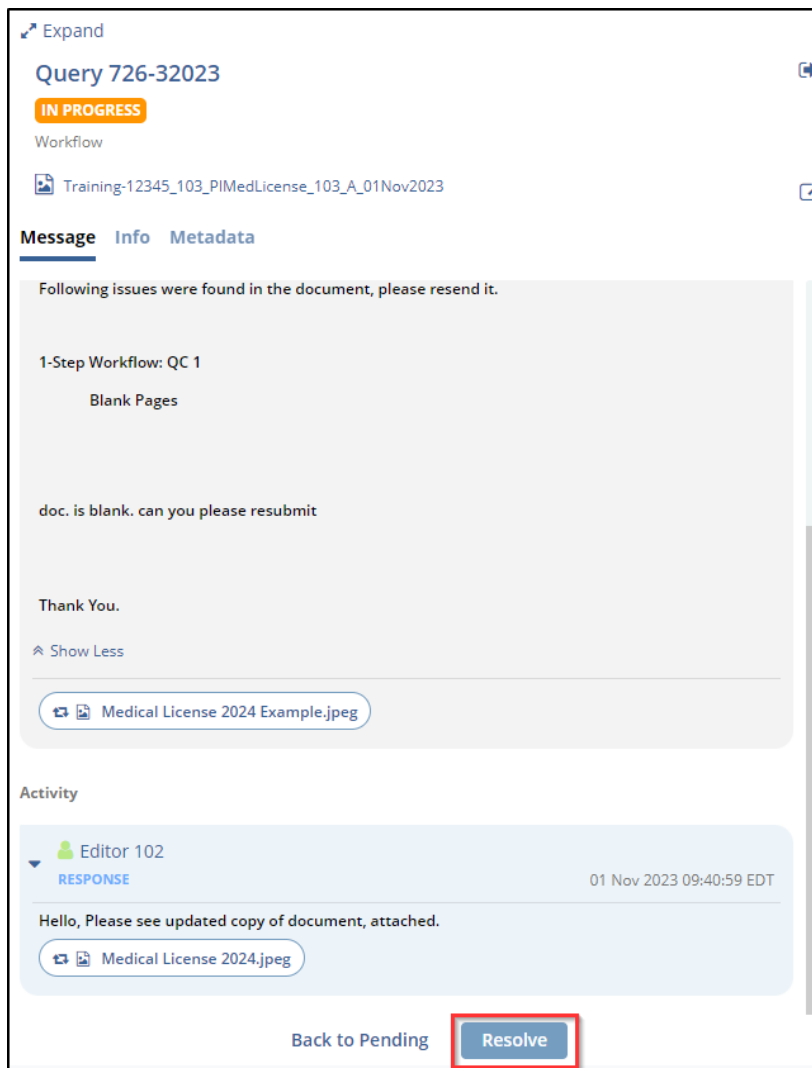
To resolve a query, follow these steps:

- Locate the 'In Progress' query
  - a. Pending queries can be resolved too but the status indicates that no response has been received.



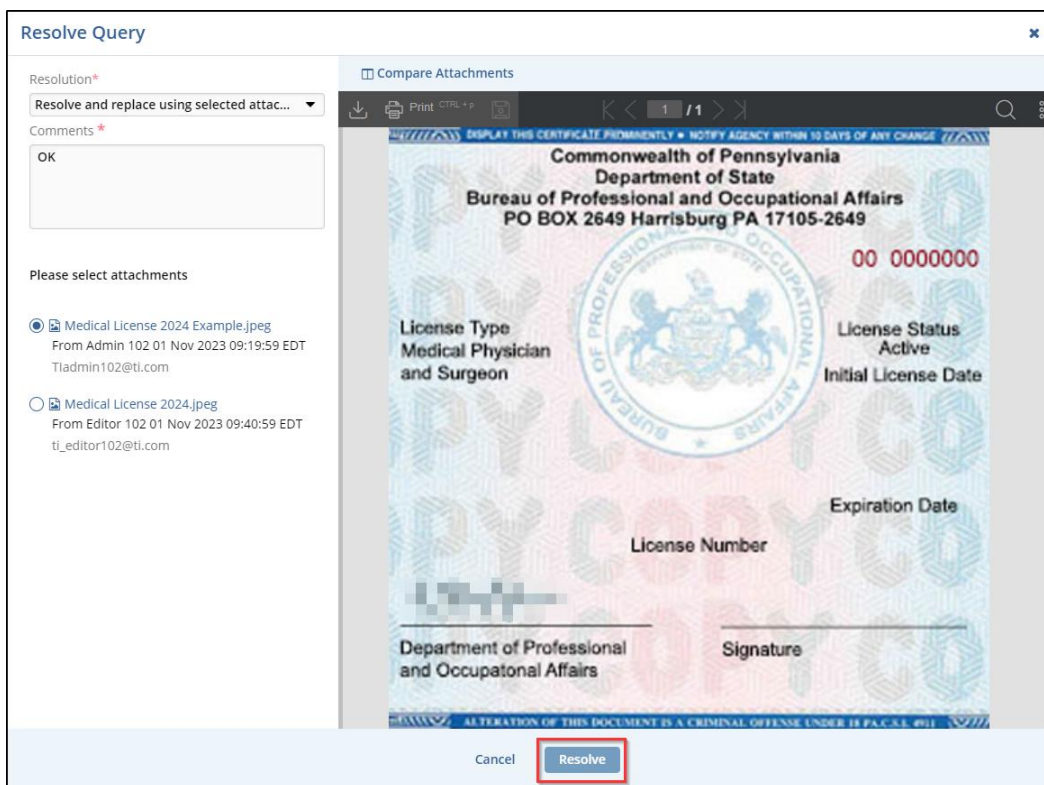


- Click on the query in the grid.
  - a. The metadata panel loads in the metadata panel.
  - b. For users who opt to perform these steps from other locations in the system, you may have to select the Query tab of the metadata panel.
  - c. The query response will appear lower down in the panel and is 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.

## 227. 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

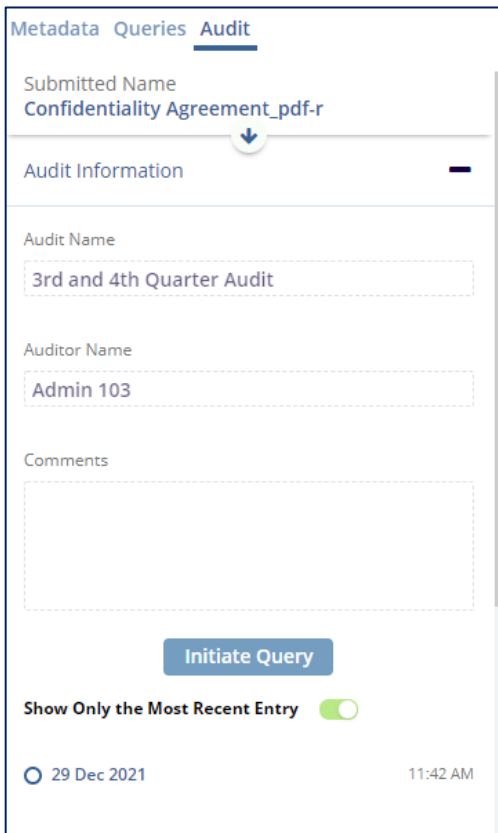
second, and likely more common usage, would be when the document has been failed and the Audit Responder needs to correct any audit findings.

### *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



The screenshot shows a software interface with three tabs: 'Metadata', 'Queries', and 'Audit'. The 'Audit' tab is selected. Below the tabs, the 'Submitted Name' is 'Confidentiality Agreement\_pdf-r'. A dropdown arrow points to the 'Audit Information' section, which is expanded. This section contains three input fields: 'Audit Name' with the value '3rd and 4th Quarter Audit', 'Auditor Name' with the value 'Admin 103', and 'Comments' which is empty. Below these fields is a blue 'Initiate Query' button. At the bottom of the panel, there is a toggle switch for 'Show Only the Most Recent Entry' which is turned on, and a timestamp '29 Dec 2021 11:42 AM'.

- 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:

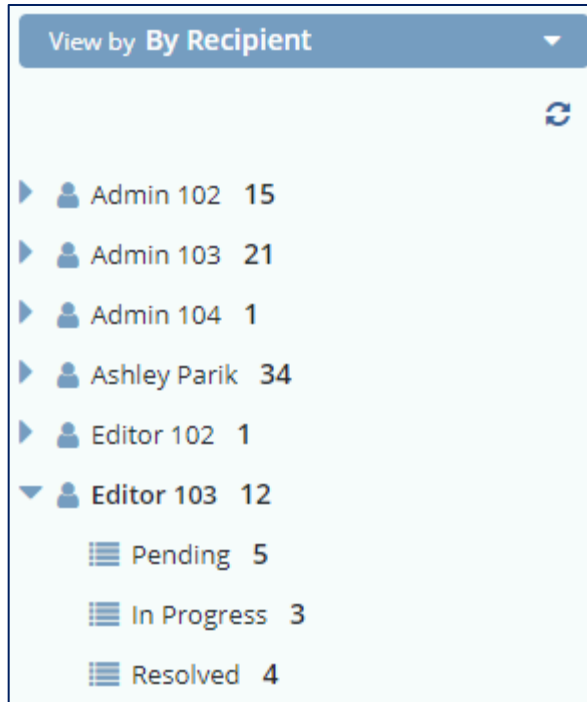
Responding to a query can happen from multiple locations in the system:

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

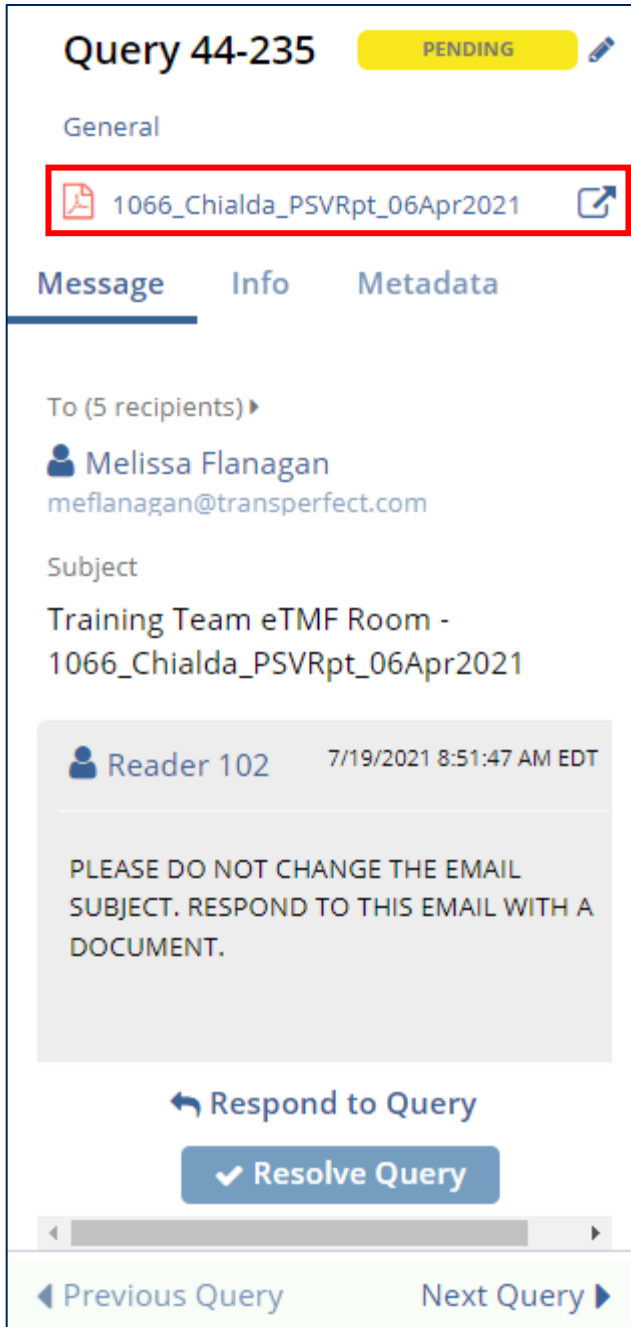
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

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.

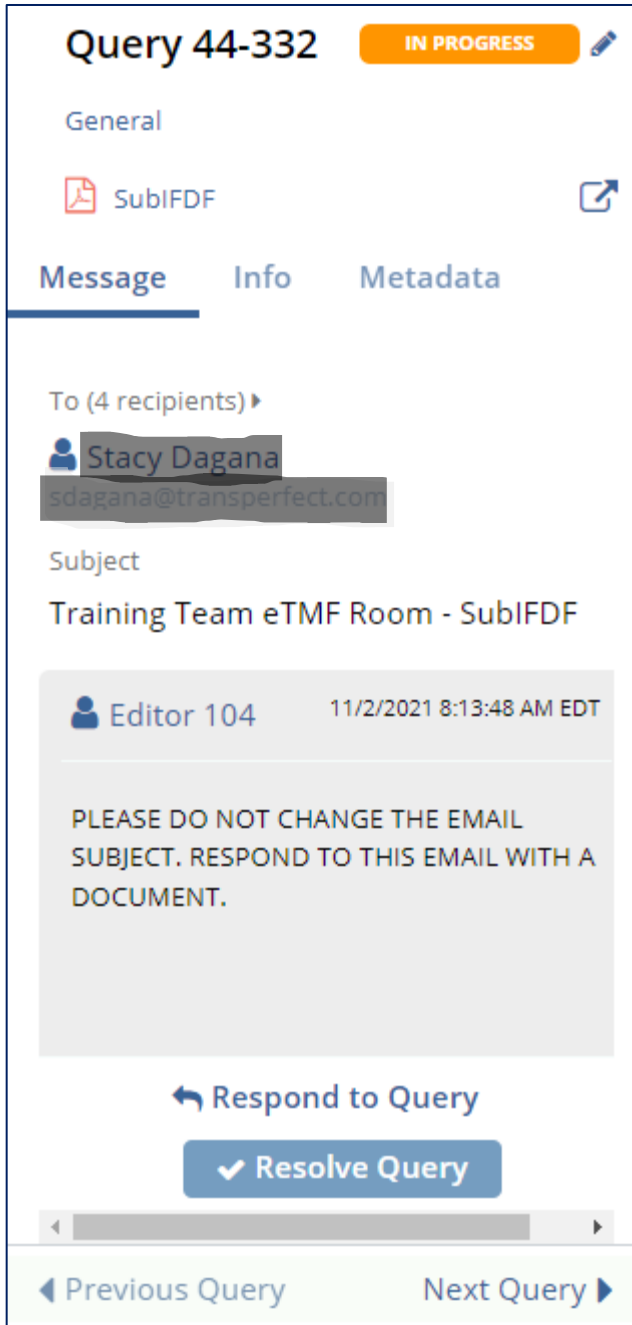
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:


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.



**Query 44-332** IN PROGRESS 


General

 SubIFDF 


**Message** Info Metadata

---


To (4 recipients) ▶

 **Stacy Dagana**  
sdagana@transperfect.com

Subject  
Training Team eTMF Room - SubIFDF

 Editor 104 11/2/2021 8:13:48 AM EDT

PLEASE DO NOT CHANGE THE EMAIL SUBJECT. RESPOND TO THIS EMAIL WITH A DOCUMENT.

 **Respond to Query**

✓ Resolve Query

◀ Previous Query      Next Query ▶

- 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'

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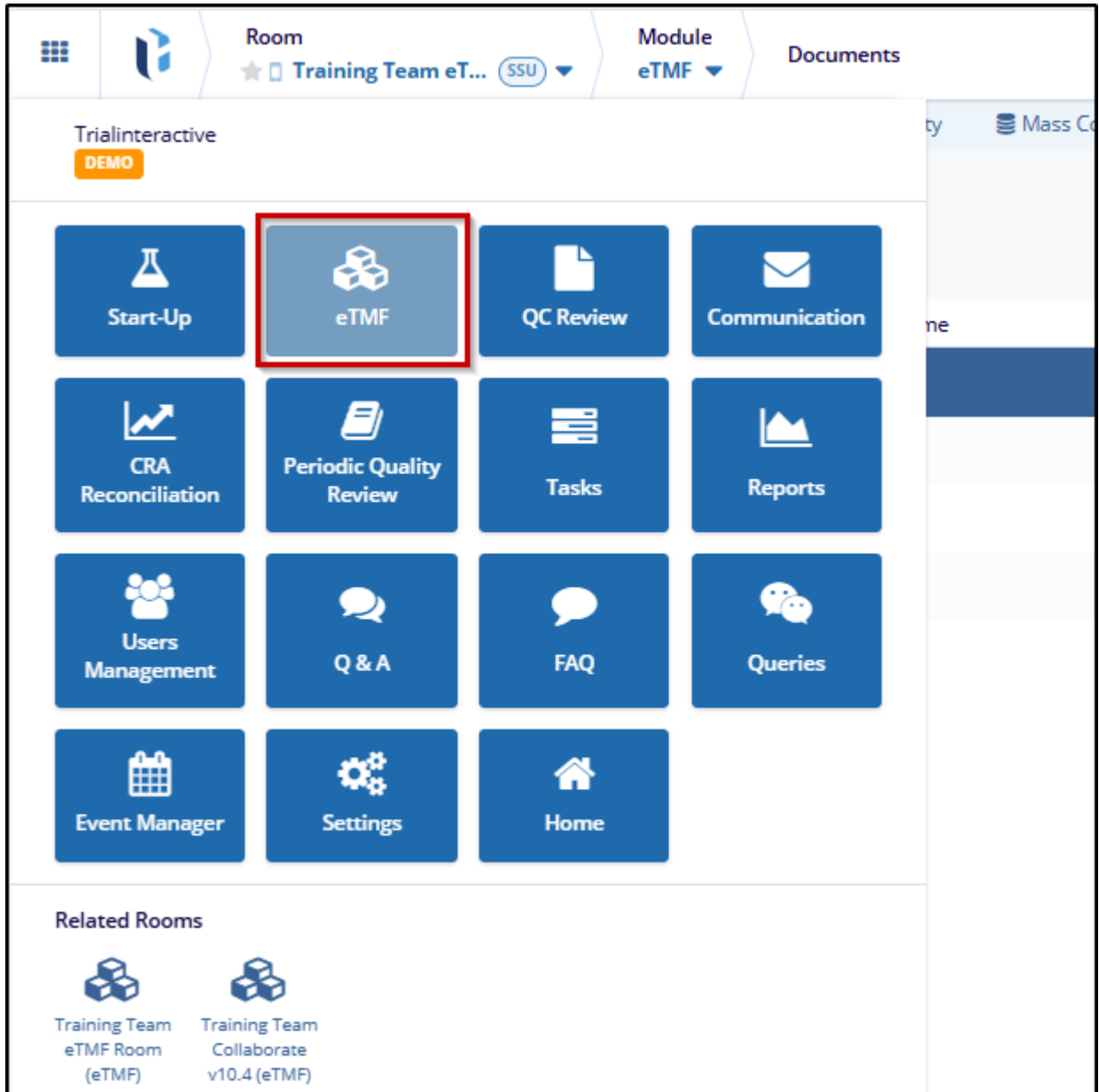
## 228. General Queries

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*

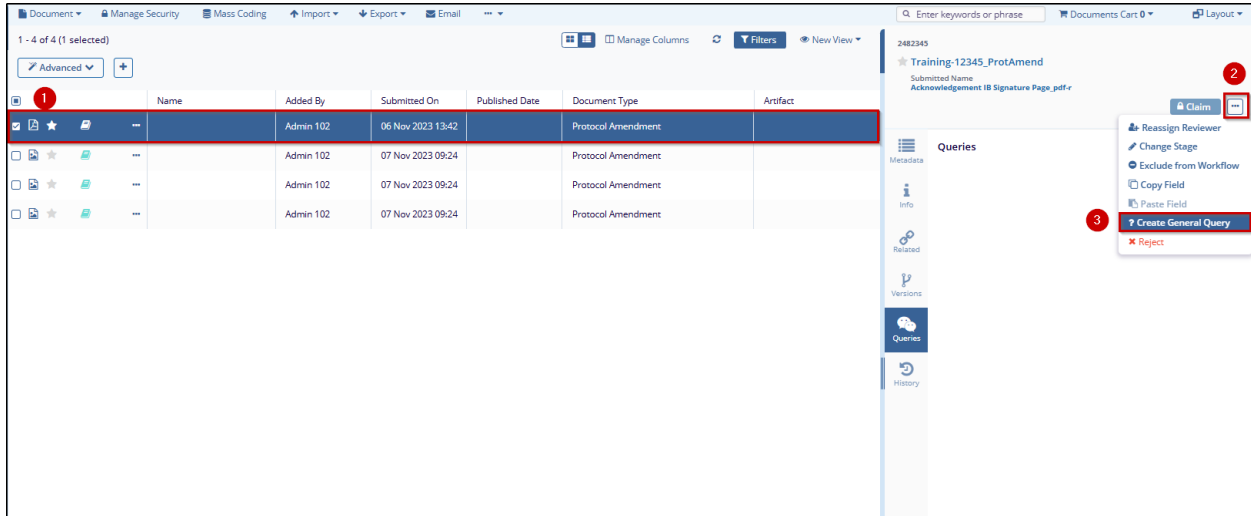
All Trial Interactive users can issue general queries against any document or document placeholder in the eTMF. In order to open a general query on a document, follow the steps below:

1. Login to the room and navigate to the eTMF Documents module.



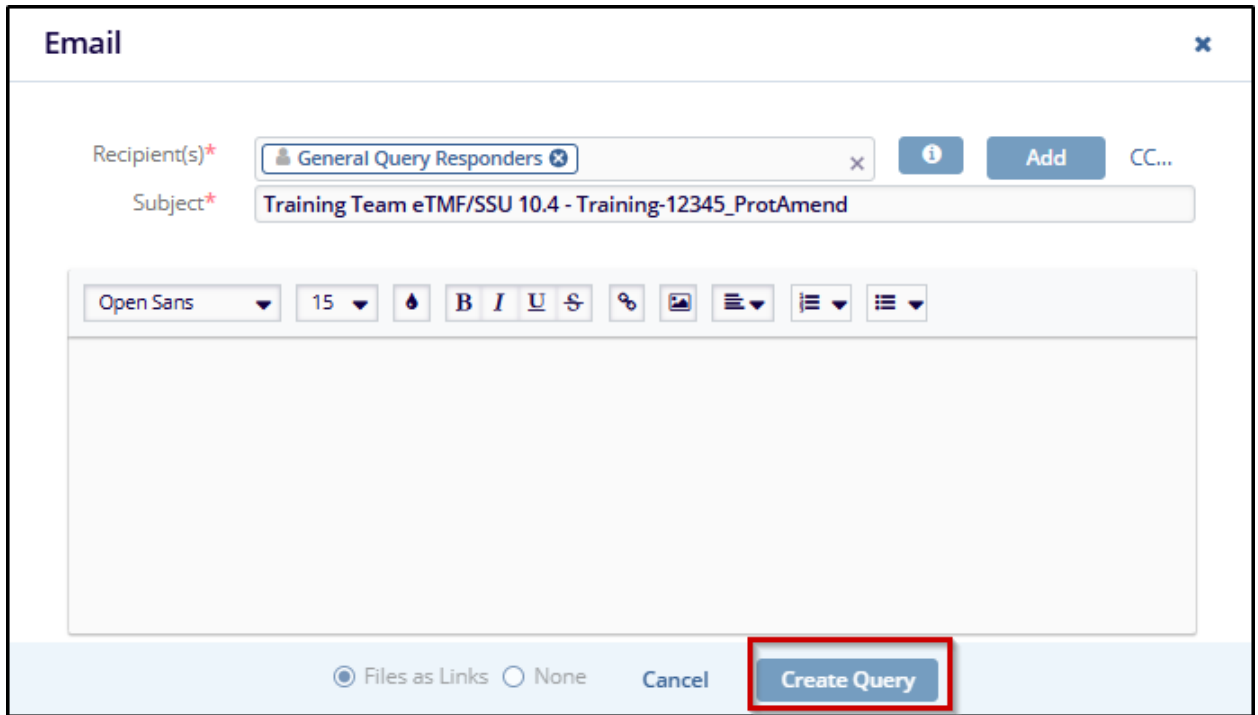
2. Locate the document in question either using the search function or by drilling down in the index panel to select the appropriate index location for the document.
3. Click on the document in the grid and open the Metadata Pane at the right side of the screen.
4. Once the Metadata Pane has loaded, 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.

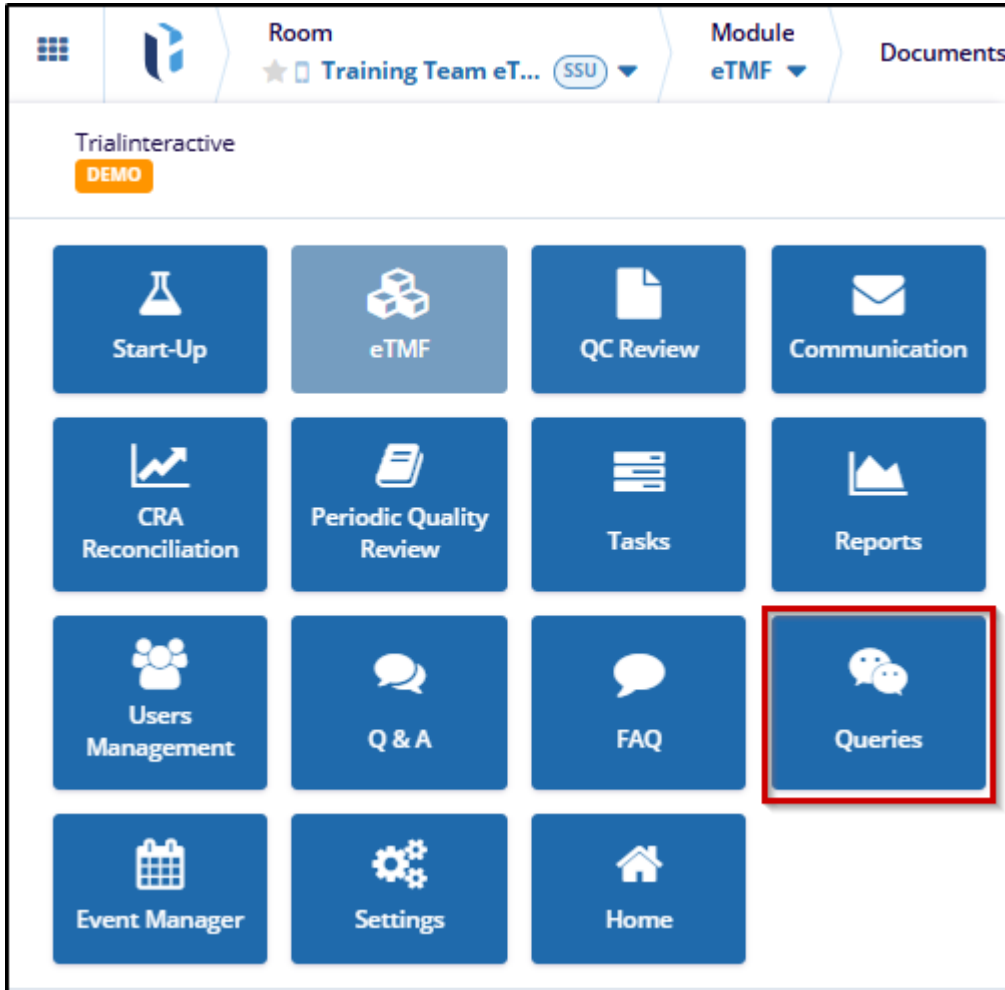
Responding to a query can happen from multiple locations in the system:

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

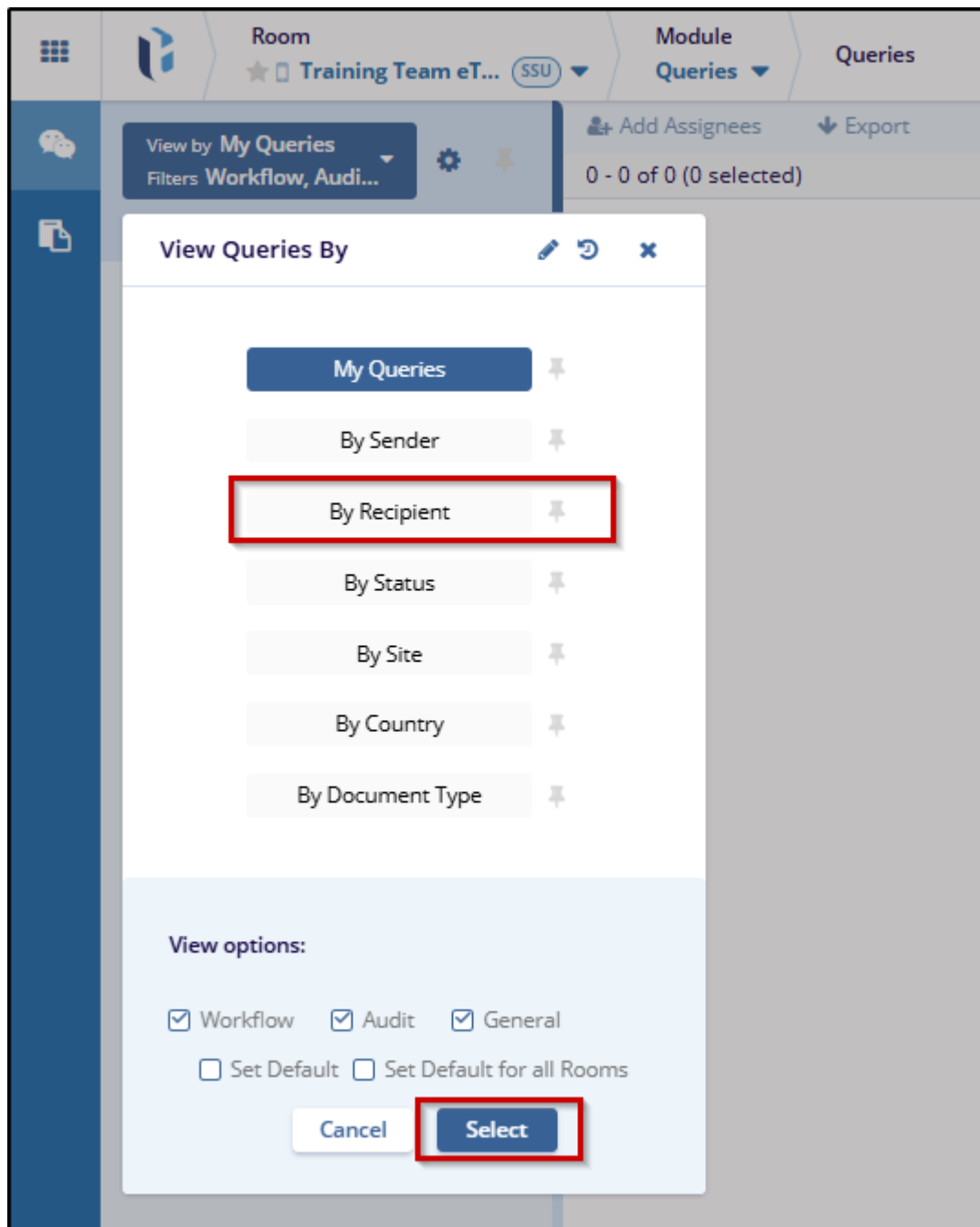
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

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.

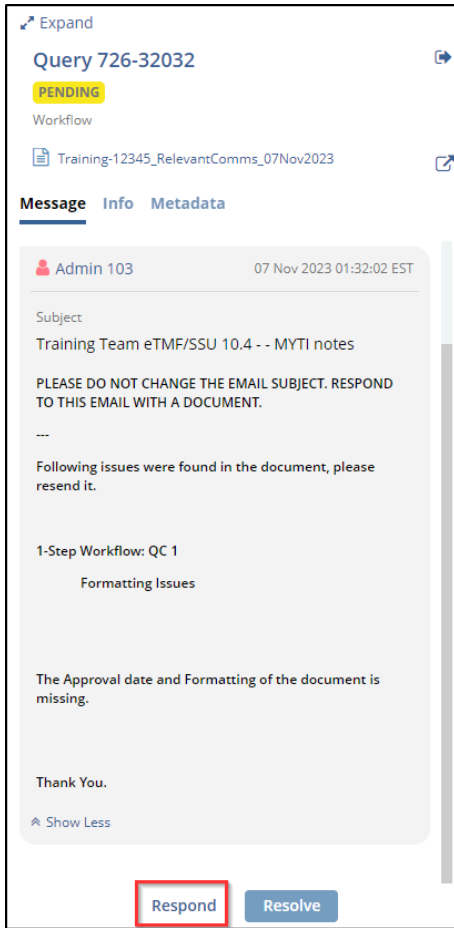


2. Choose the 'By Recipient' view from the dropdown menu at the top-left.
  - a. Users who have access to view queries for multiple users will need to expand their own list by clicking on the arrow next to their username.

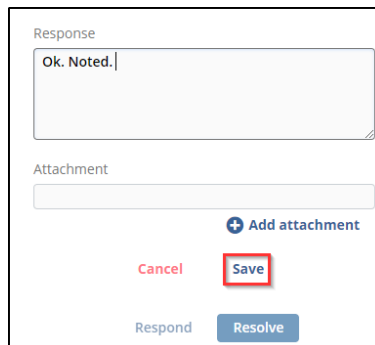


3. Select your Pending queries.
  - a. This will cause the documents grid to populate.
4. Select the document whose query you wish to review and respond to.
  - a. The metadata panel will populate with the query information.
  - b. For other areas of the system, choosing the document will also cause 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.

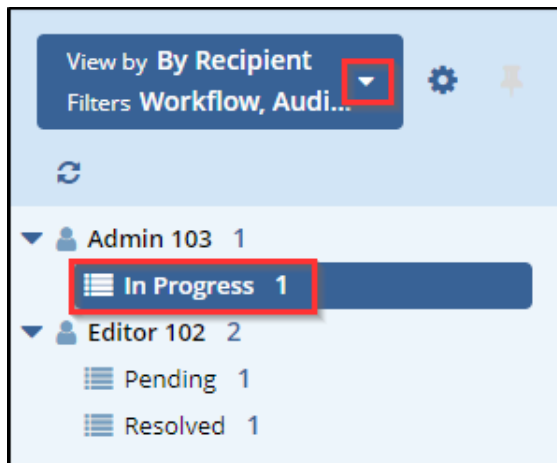
'Working' a query can happen from multiple locations in the system. The user who opened the query can review the query process from the following areas:

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

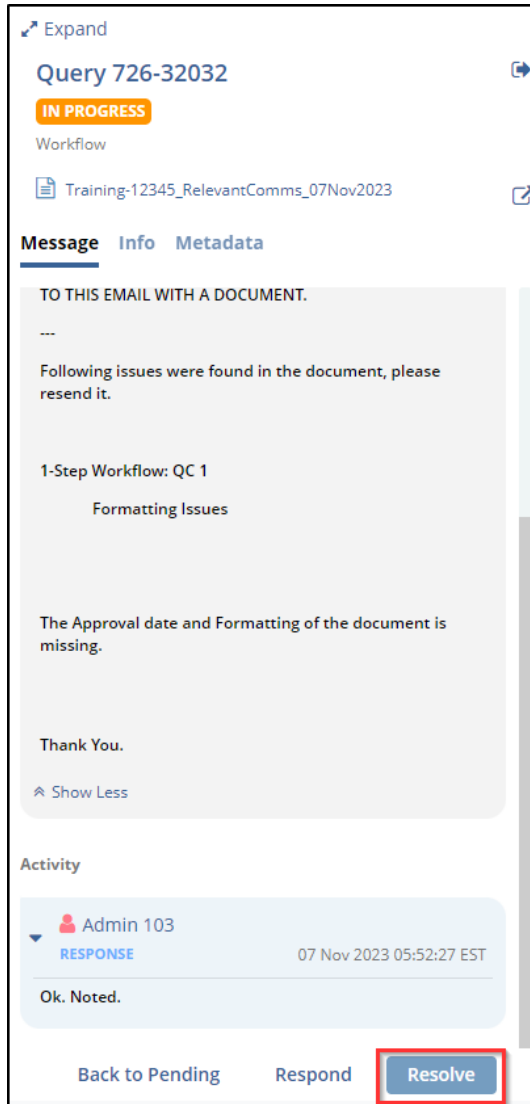
These instructions will direct the user based on the assumption that the query is being tracked and worked from the Queries module of the study room but the steps below are appropriate to any of the areas mentioned above.

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.

**Resolve Query**
✕

---

Resolution\*

Resolve
▼

Comments \*

Done.

Cancel
Resolve



---

## 229. 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:

Metadata Queries Versions History

Submitted Name  
Certificate of Liability Insurance\_pdf-r


Is this document missing a page? Unable to determine if it's complete.

Thank You.

Subject Training Team eTMF 10.2 - Insurance Certificate - InsuranceCert\_04Aug2021

To tireader102@ti.com

From Editor 103

Attachments  InsuranceCert\_04Aug2021.pdf

Response from Reader 102 20 Dec 2021, 2:53 PM

Resolve Query

Return back to Pending

This record is not editable

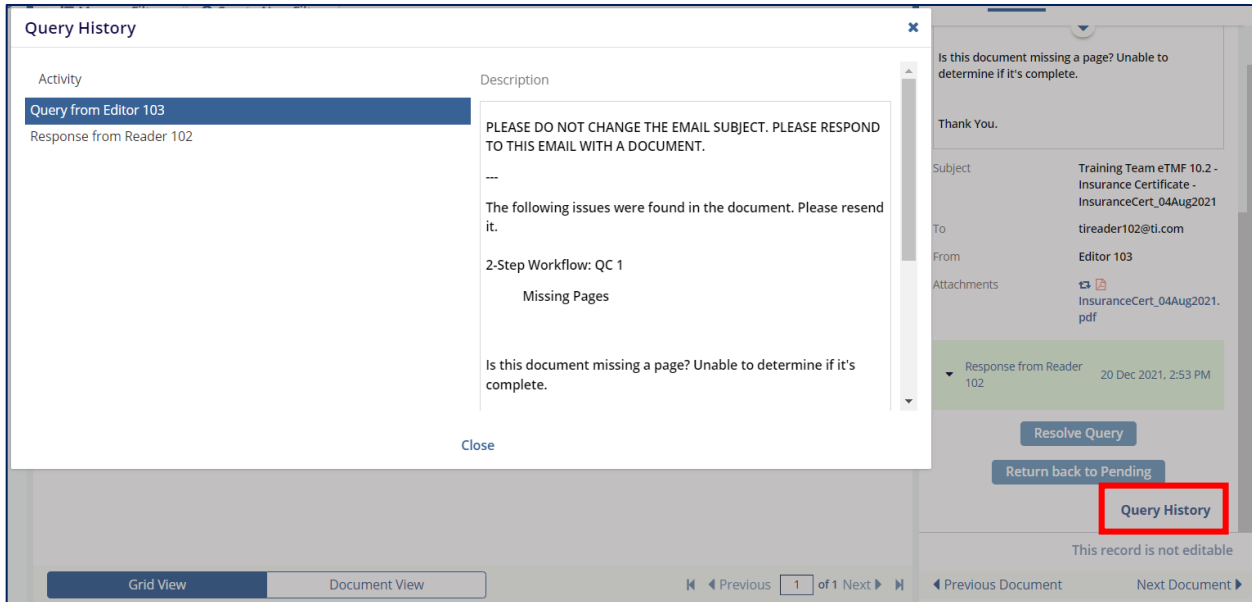
◀ Previous Document Next Document ▶

- 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:

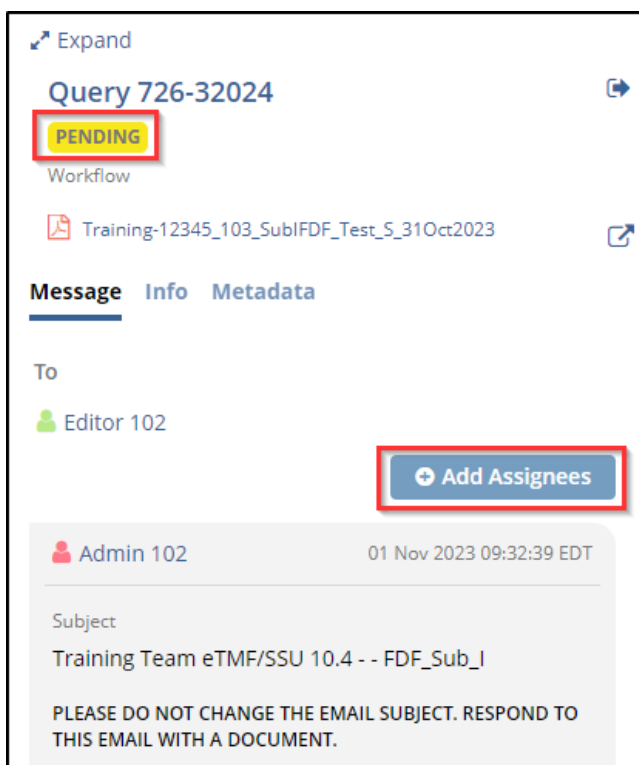


From the Query History window, select the required query activity from the left pane and the details of the history displays in the right pane.

### Reassigning a query to a new recipient

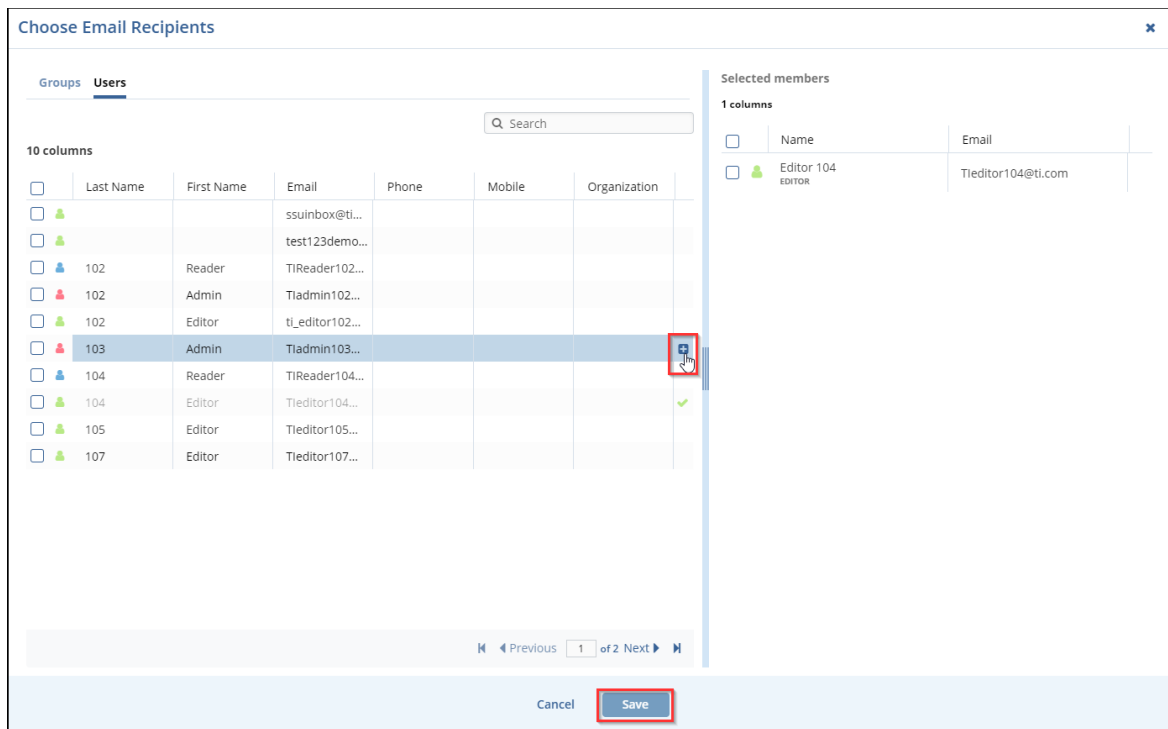
Administrator users and those users who are added to the Query Managers group can add an additional recipient to a query. Users can perform this action by locating the query in the Queries module. follow the steps below to reassign a query to a new recipient.

1. Click the **Add Assignees** button in the metadata panel on the right.

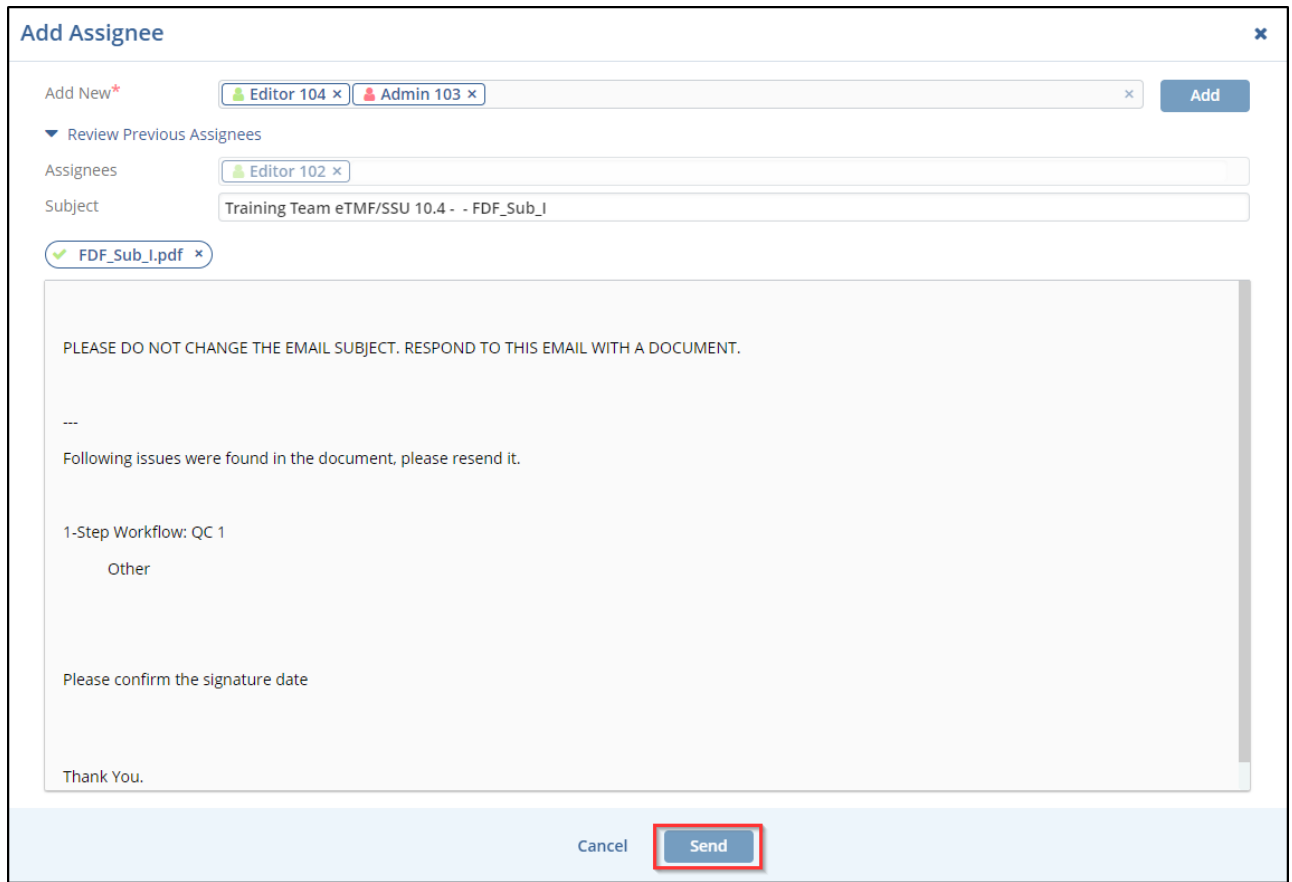


2. This opens the Add Assignee popup window.
3. Click the **Add** button displayed in the top right corner of the popup window.

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 18: 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.

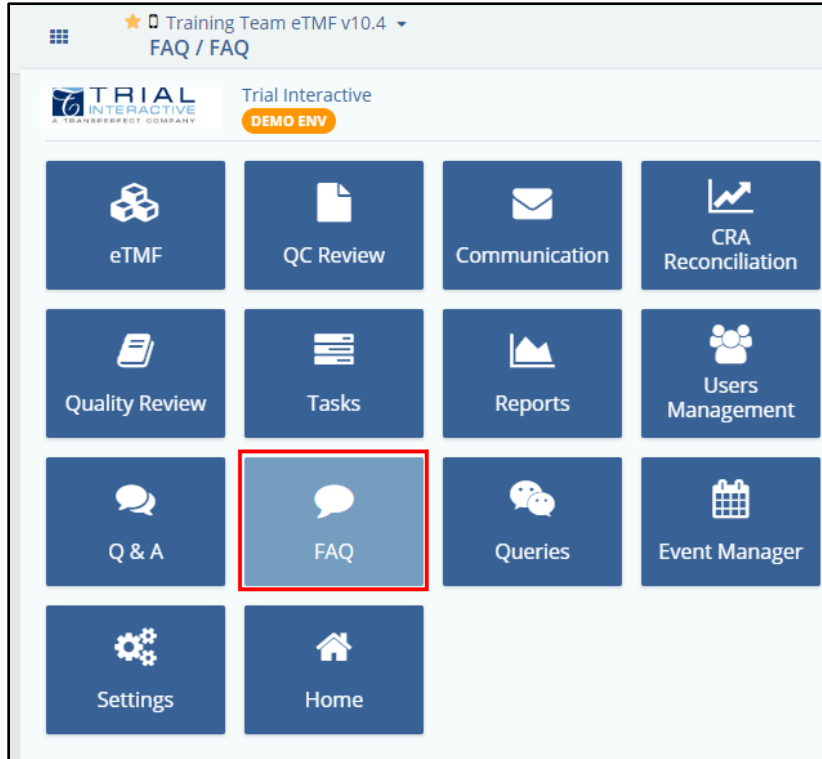


Figure 1: FAQ Module

## 230. Adding **FAQ** Categories

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

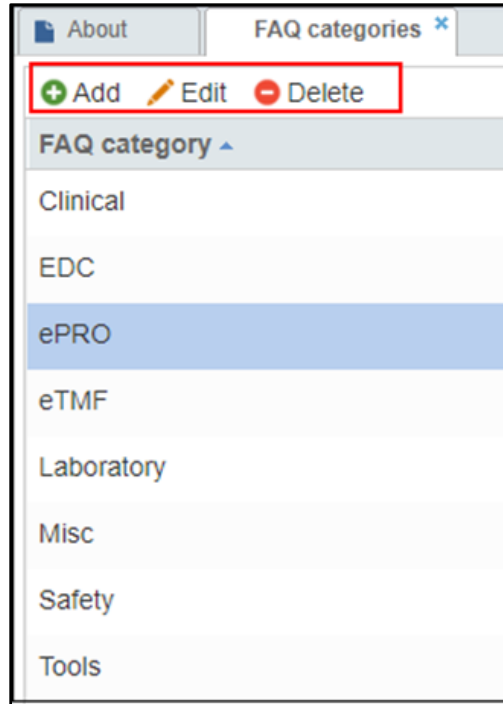


Figure 2: Setting FAQ (Add, Edit, Delete)

3. Click Save after making any changes.

---

### 231. 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.

---

### 232. 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



### 233. 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

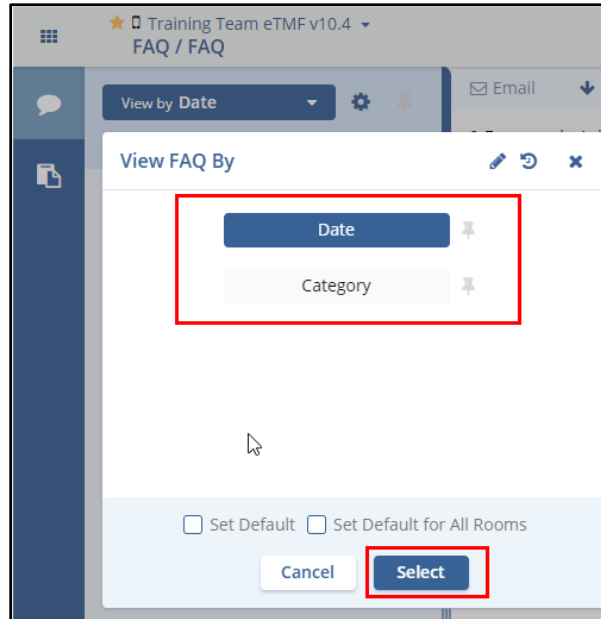


Figure 3: View FAQ by

Note: You can make a view default by checking the Make Default option

### 234. 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.

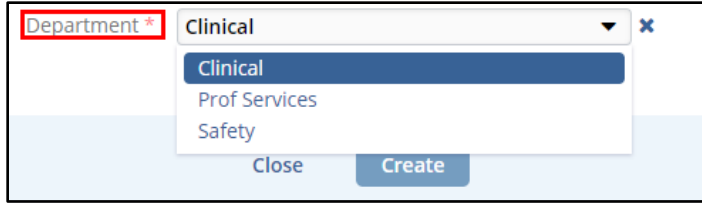


Figure 6: FAQ Department

5. Click the 'Create' button available at the bottom of the Create New FAQ window.

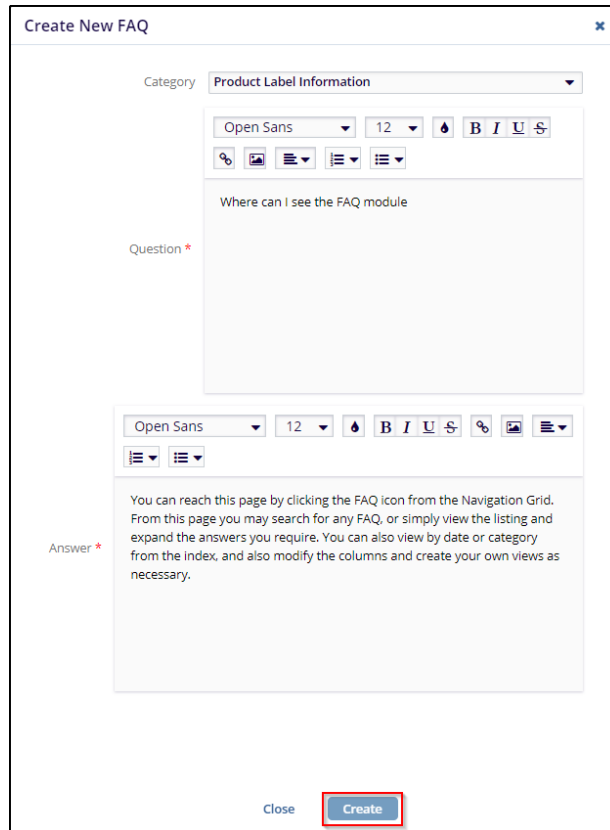


Figure 7: FAQ page

**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

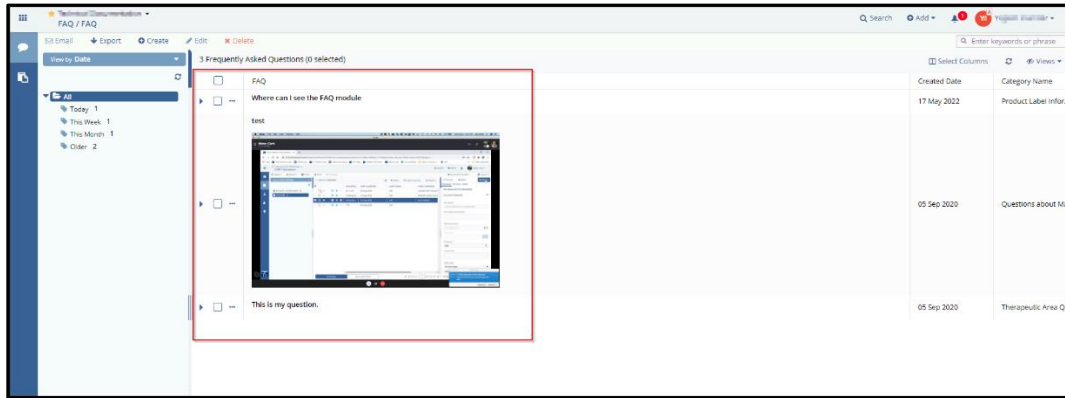


Figure 8: FAQ View

### 235. Edit FAQs

To Edit FAQ-

1. Select any of the FAQs available from the list.

2. Click the  button available from the top ribbon bar

This will open an 'Edit FAQ' window as shown in the screenshot below-

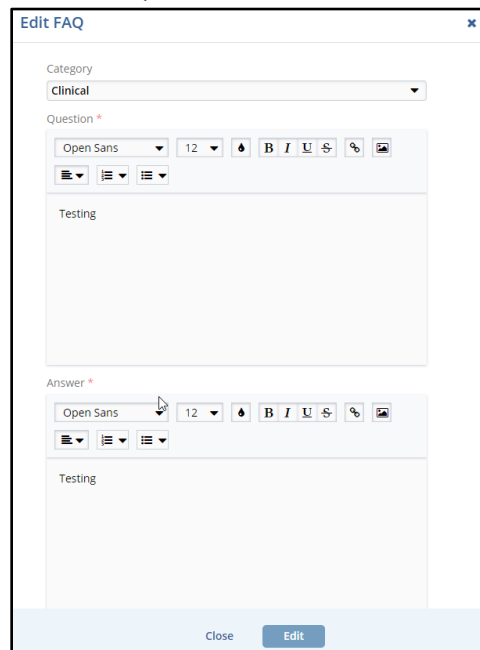
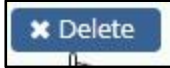


Figure 9: FAQ Edit

3. Once you make the essential changes in the FAQ click the Edit button available at the bottom.

### 236. 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.

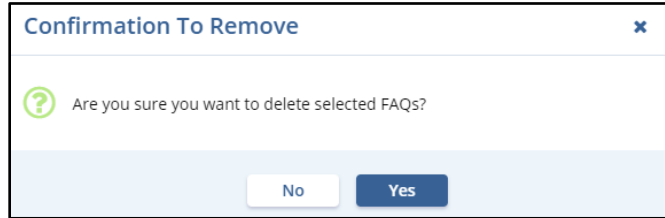


Figure 10: FAQ Delete Confirmation Message

3. Click Yes to make the deletion successful.

**Note:** The success of deletion can be seen as a notification message.

## 237. 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.

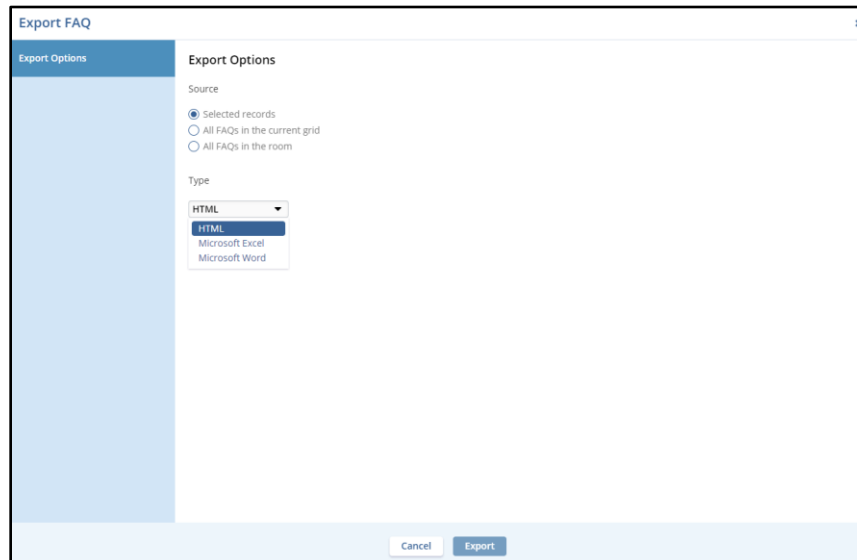


Figure 11. Export FAQ Options

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.

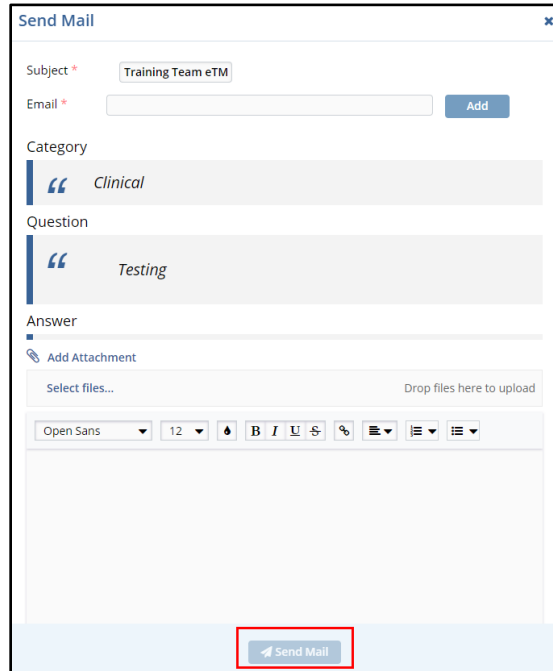


Figure 12: FAQ Email Page

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 19: 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:

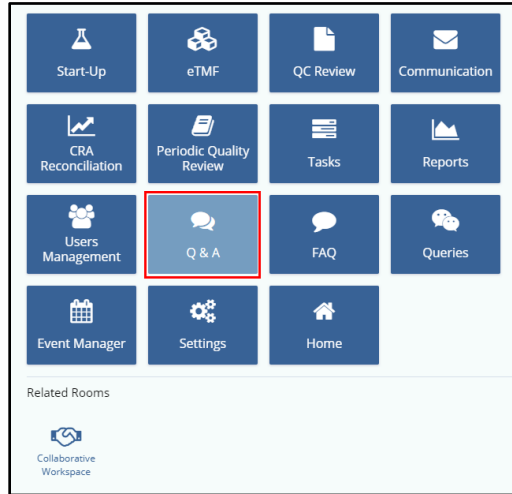


Figure 1: Q&A Module

### 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.

---

#### 238. 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.

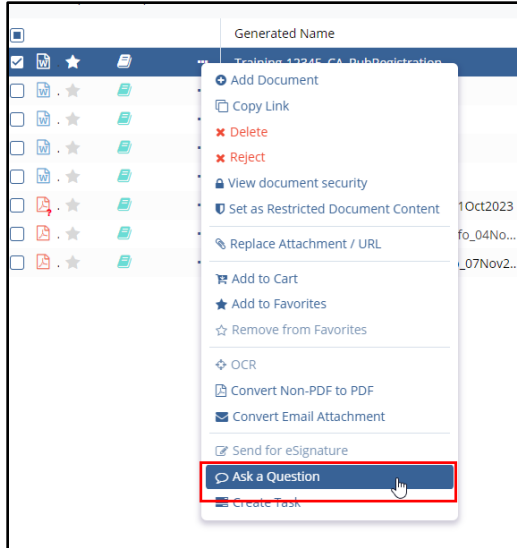


Figure 2: Ask a Question option

3. Click **'Ask a Question.'**
  - a. The Ask a Question window will open.

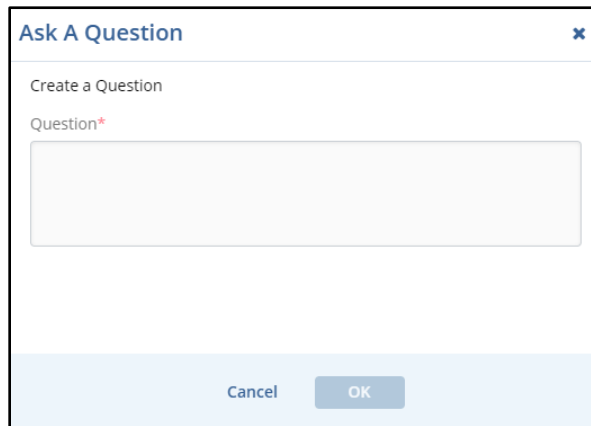


Figure 3: Ask A Question page

- 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.

### 239. 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:

2. Navigate to the **Q&A** module.



3. Click the 'Ask a Question' button in the menu bar above the index panel.
  - a. The Ask a Question window will open.

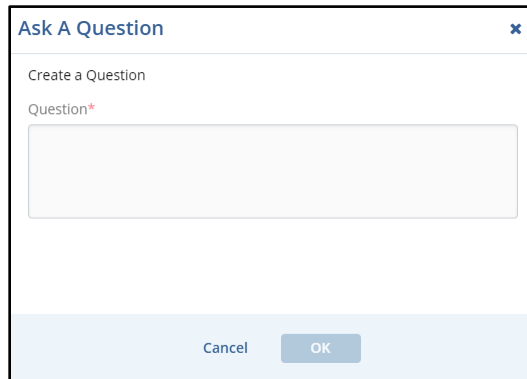


Figure 4: Ask a Question page

- b. The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.
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.

### 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.

- This will open the **Create Answer** window.

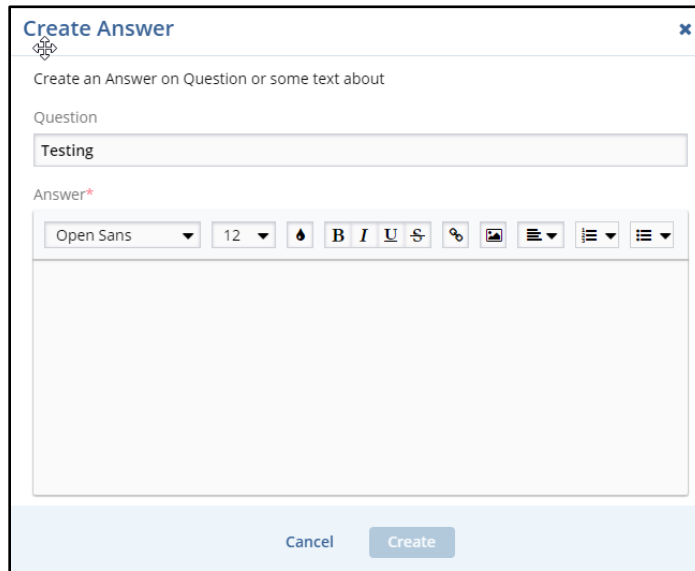


Figure 6: Create Answer

- Type your answer in the box and press **Create** button.

### Converting a Question into an FAQ Entry

- Locate the question which needs to be converted to an FAQ entry.
- Click on the arrow to expand the line and view the available answers.
  - Only answered questions can be converted.
- 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.
- Click the '**Convert to FAQ**' button
  - This will open

**Convert to FAQ** [Close]

Question\*

Do we currently have an SOP governing which document upload method we should be using?

Answer\*

Open Sans 12 [Bold] [Italic] [Underline] [Strikethrough] [Link] [Image] [Bulleted List] [Numbered List] [Table]

Yes.

Cancel Create

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.

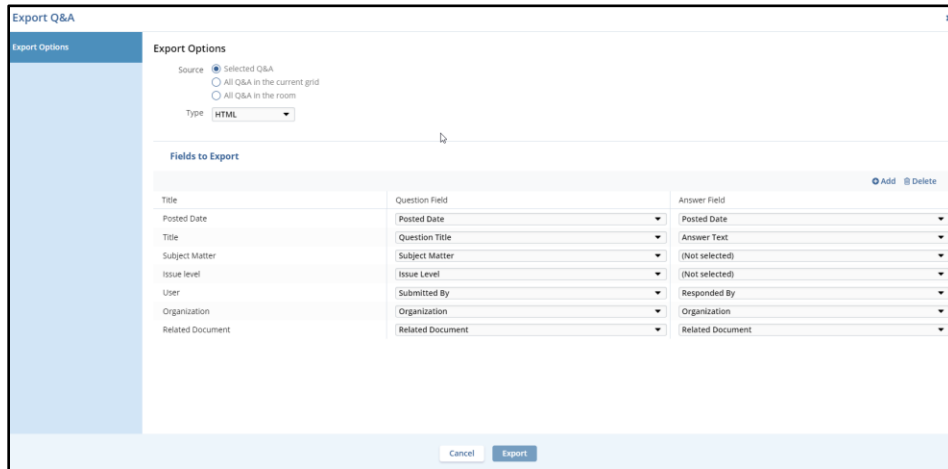
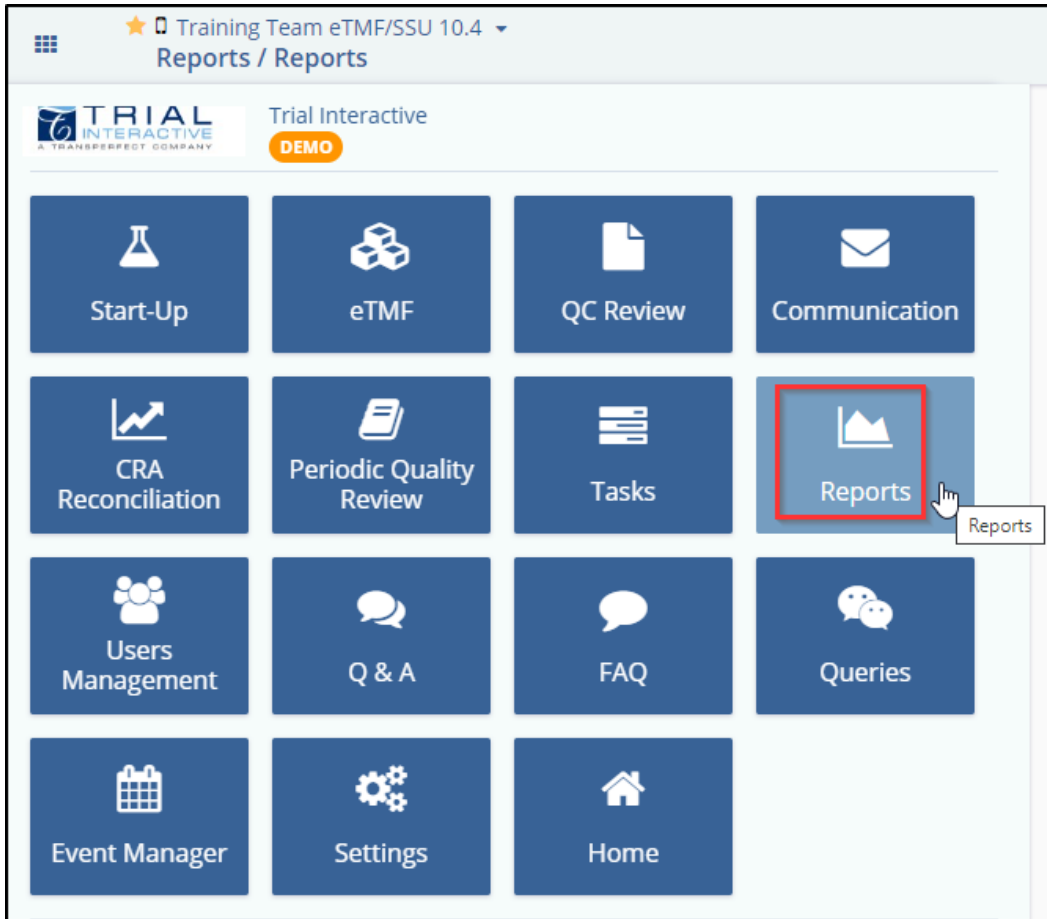


Figure 8: Export Q&A page

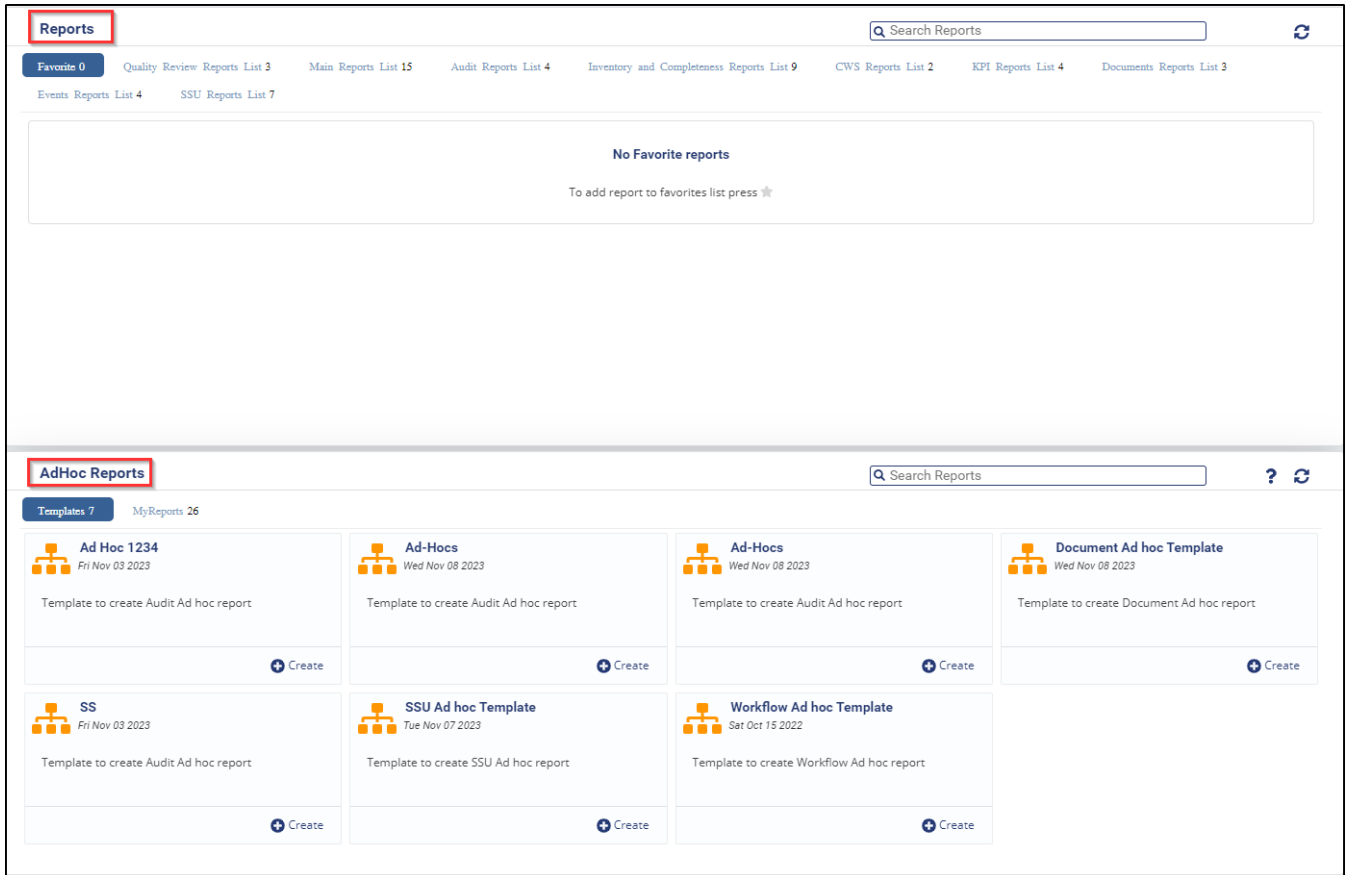
3. Select the Q&A Source and the export Type.
4. Indicate which fields should be exported.
5. Press **'Export'** Button.

## CHAPTER 21. REPORTS

The Reports module can be accessed by clicking the Reports application from the Navigation Grid. Refer to the screenshot below:

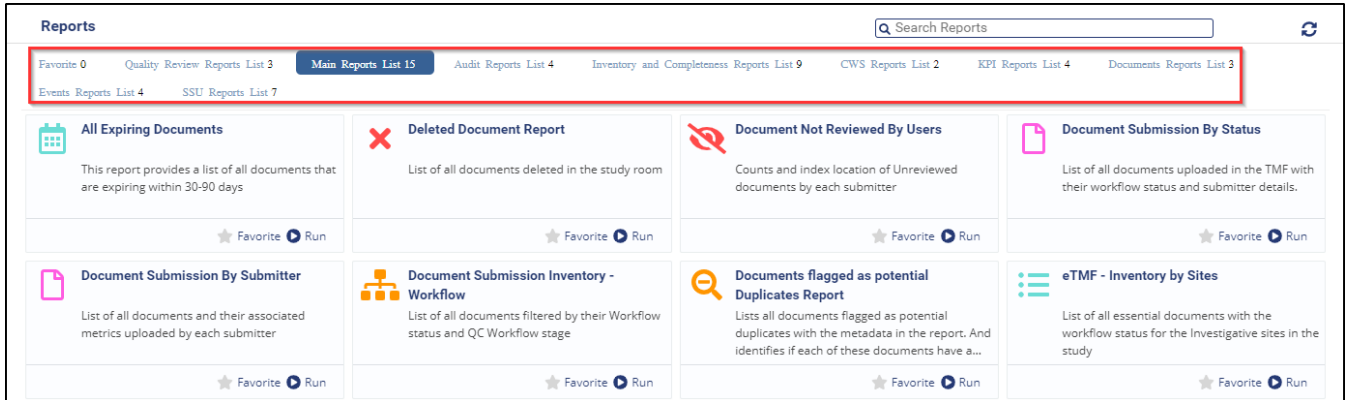


The Reports Dashboard consists of the various dashlets which gives a summary of the reports of the room.  
Refer to the screenshot below:

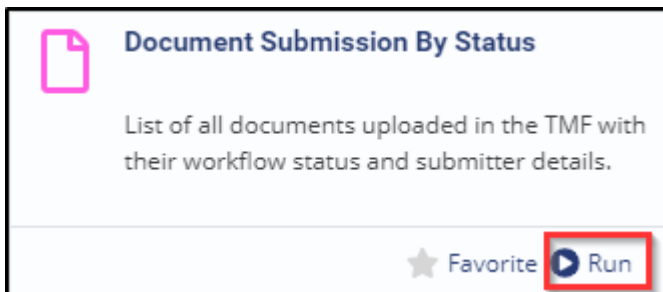


## Viewing Reports from the Report List

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 a study room.

The Trial Interactive Collaborate solution, also known as Shared Workspace, is a Clinical Collaborative Workspace Solution for clinical teams to provide Sponsors, CROs, and Sites a place to share and author documentation to be used in the Clinical Trial and ultimately archived in the eTMF.


An integral part of TI Collaborate, TI Collaborative Authoring will provide end-users the capability of directly editing MS Word, Excel, and Power point documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

There are two types of rooms associated with Collaborative Workspace

3. TI Docs
4. 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 any other 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

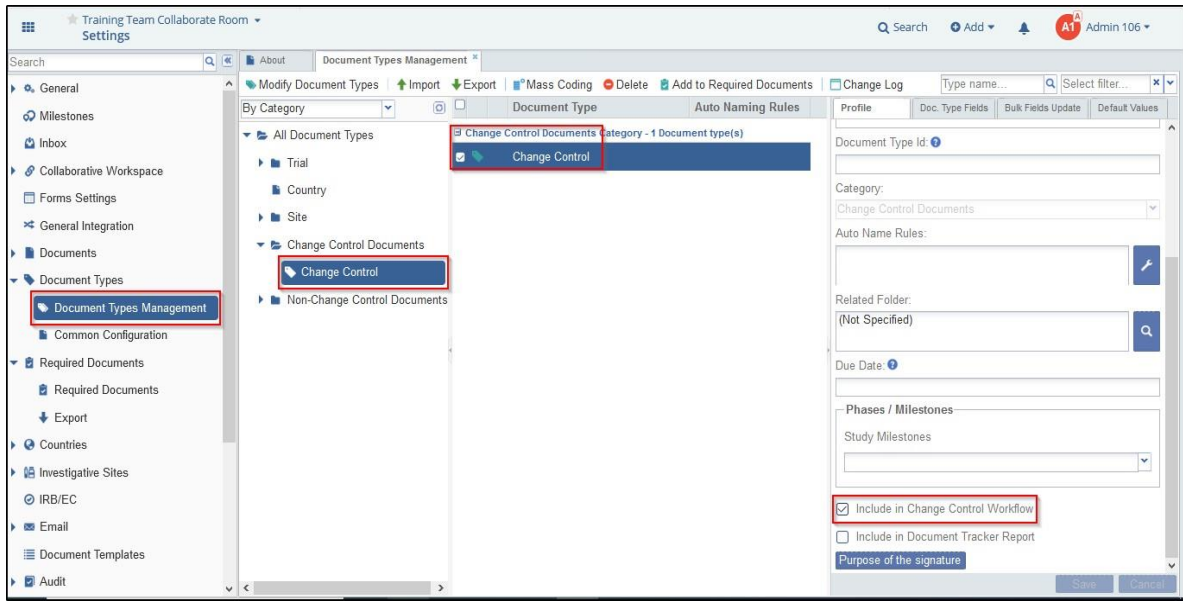
The room configurations that impact the room types TI Docs and TI Collaborate are described below.

5. Document Type - The document types settings can be configured via **Settings>DocumentTypes>All Document Types**. Refer the screenshot below.

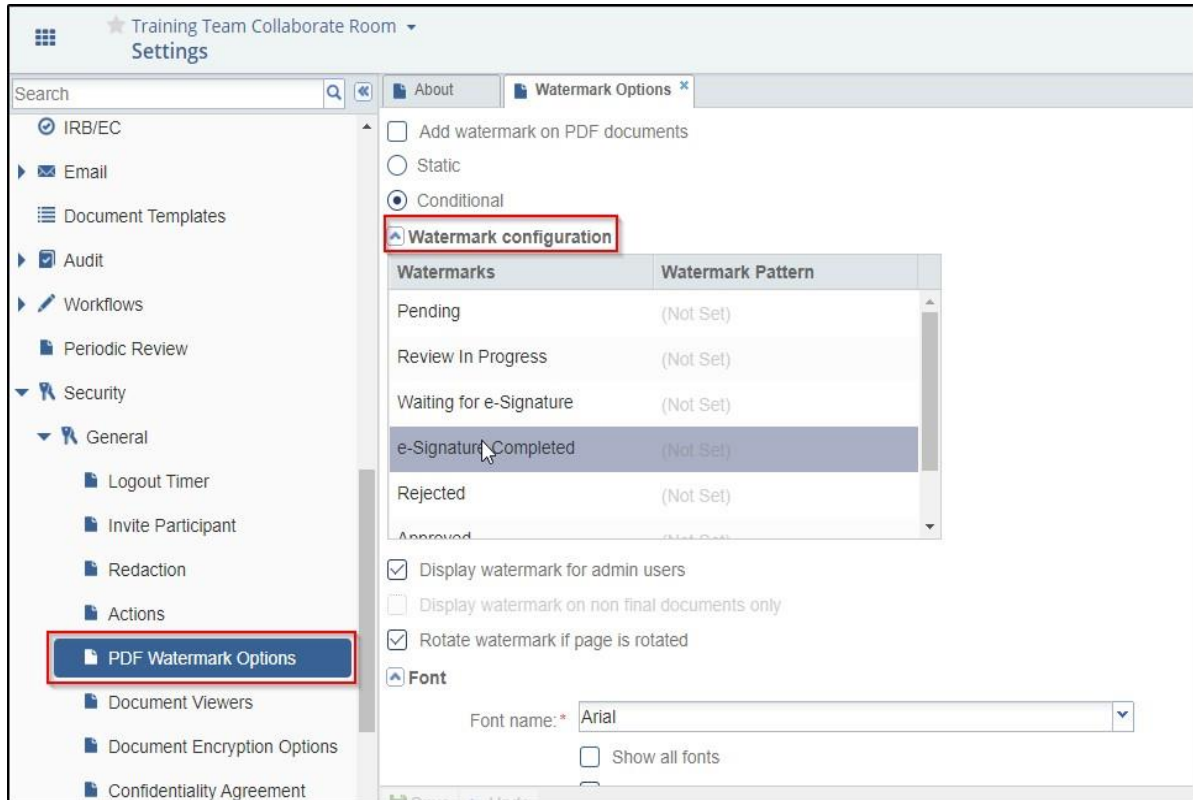


The screenshot displays the 'Document Types Management' interface. On the left sidebar, the 'Document Types' menu item is highlighted with a red box. The main content area shows a tree view of categories, with 'All Document Types' selected and highlighted with a red box. Below this, a table lists document types, including 'All Hands Me...', 'General', 'Guess Access...', 'Meeting Infor...', 'New Hire Info...', 'TOC', 'Account Status', 'Action Tracker', 'Agenda', and 'Audit Certificate'. The table has columns for 'Document Ty...' and 'Auto N...'. The interface also includes a search bar, a 'Settings' header, and various navigation tabs like 'About', 'Document Types', and 'Workflows'.

- 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.



7. **PDF Watermark-** To insert a PDF watermark, go to **Settings> Security>General> PDF Watermark Options** and select the Watermark Configuration. Refer the screenshot below.

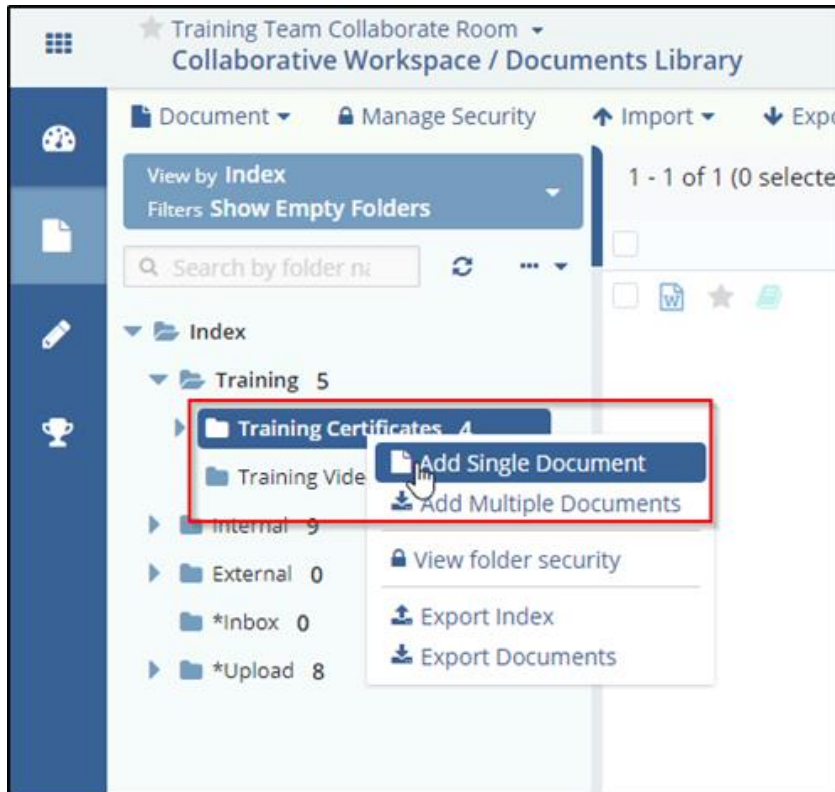


8. **Converting Documents -Non PDF to PDF-** To convert non PDF documents to PDF, go to **Settings>Documents>Non PDF to PDF Document Conversion** and select the conversion type. Refer the screenshot below.

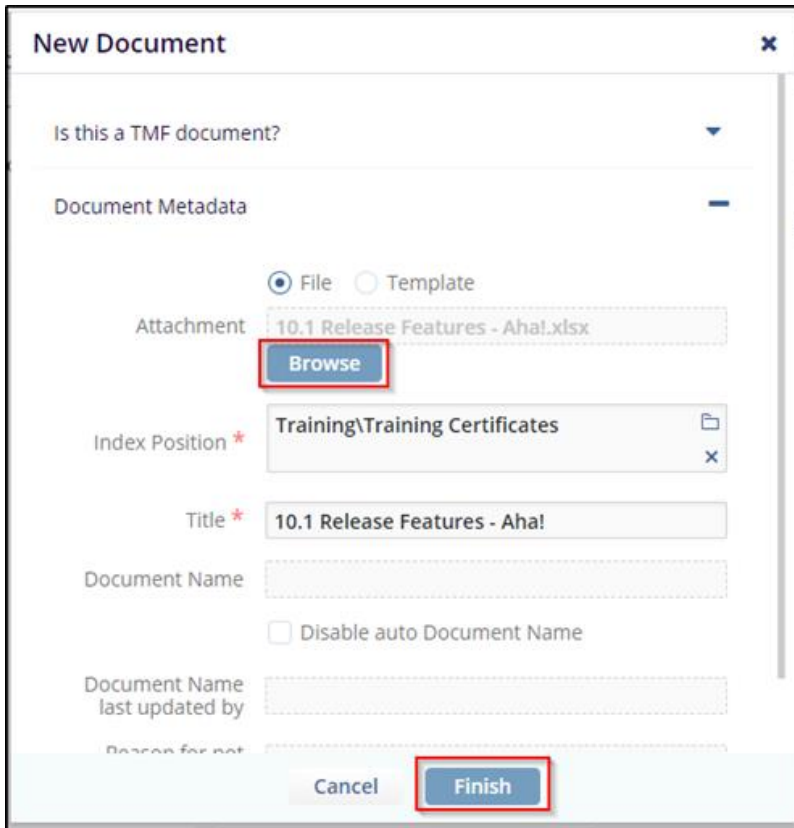
## Document Upload

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:

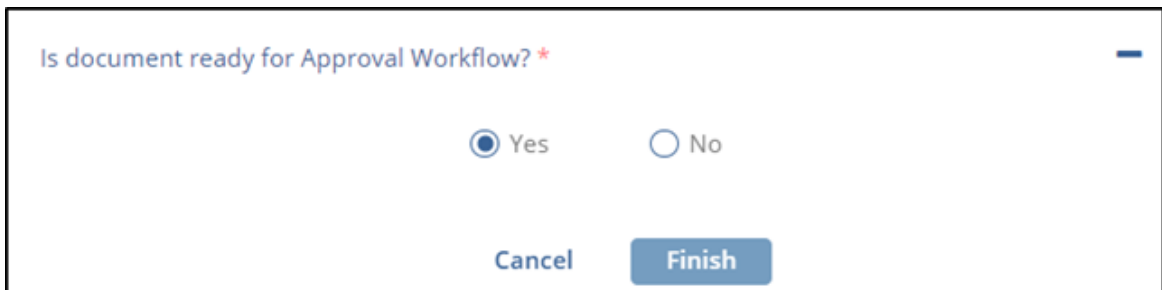
5. Start by navigating to the Document Library Index view, then select the desired upload location (folder) and right-click on it to start adding documents. Refer to the screenshot below.



- 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.

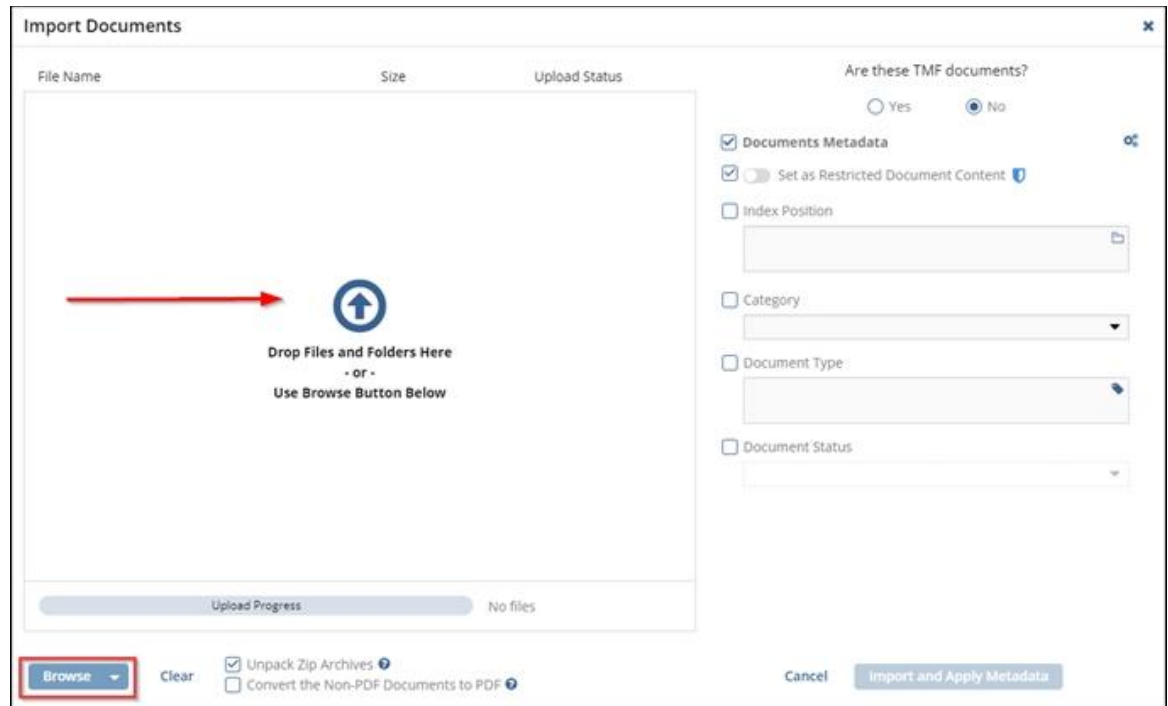


- Additionally, when adding a single document, it is possible to define whether the document is ready for a Workflow - that is, we don't expect changes to be made to the content prior to review and approval. Selecting 'Yes' as shown in the screenshot below, will allow the document to be assigned to review and/or signature workflows immediately after upload.



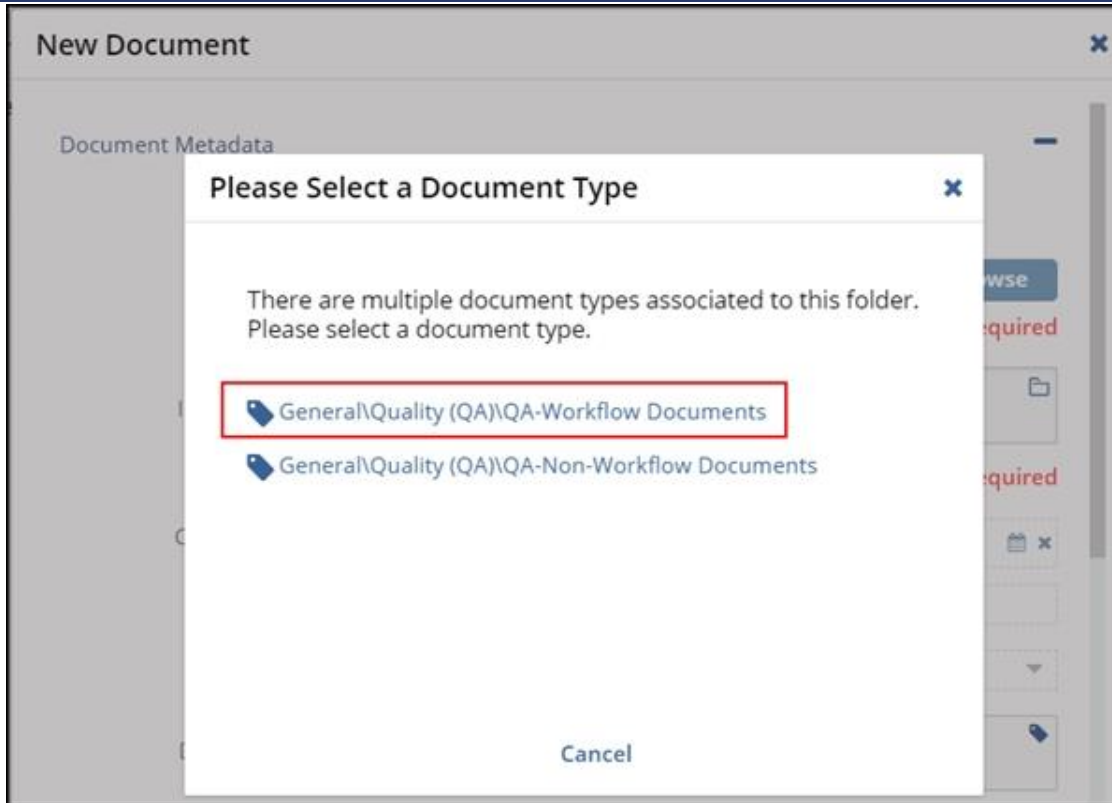
- In case multiple documents are needed at once for upload,

- Choose the 'Add Multiple Documents' option.
- A different upload window opens. *(Notice the ability shown in step #3. To define documents as ready for workflow is lost using this method).*
- Drag documents into the white space on the left (or Browse your device contents).
- 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.
- Click on '**Import**' or '**Import and Apply Metadata**' when ready to begin the file upload.



### Change Control Documents

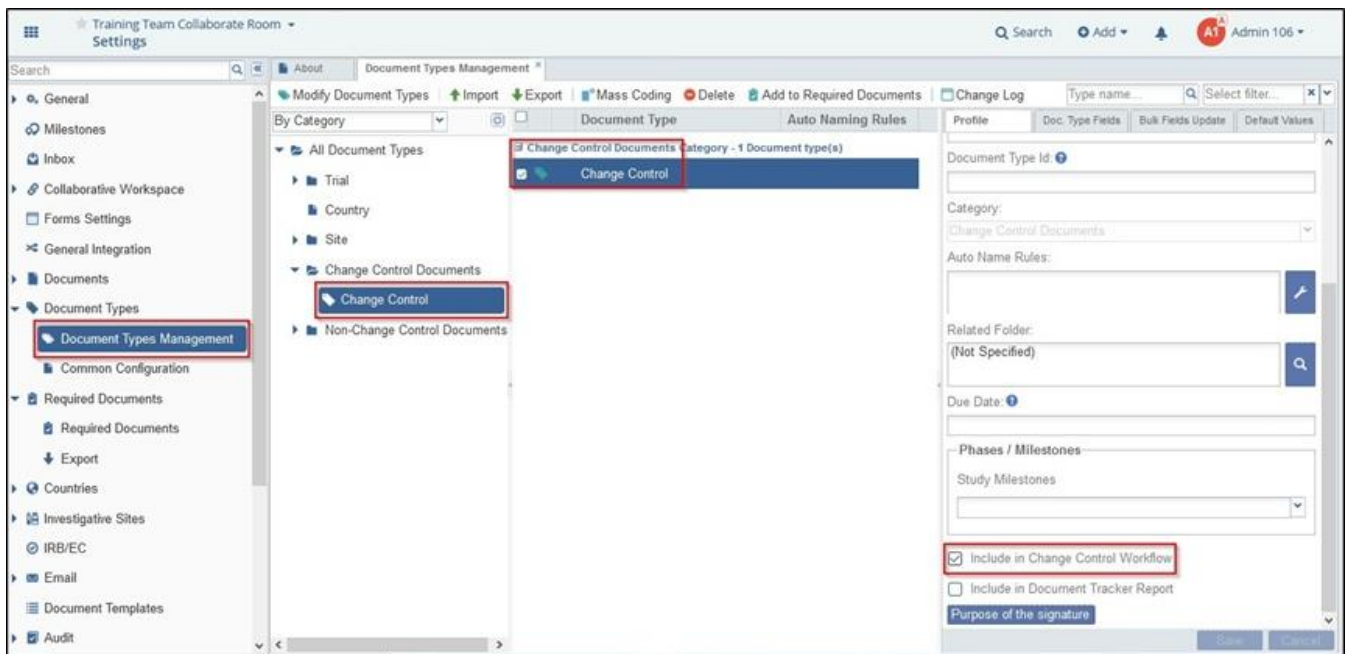
Document types requiring a Change Control workflow can be defined in room settings, with the effect that users uploading documents can select a 'Workflow' document type (either by manually applying a selection or uploading documents to a folder supporting Workflow documents only) the uploaded document 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.

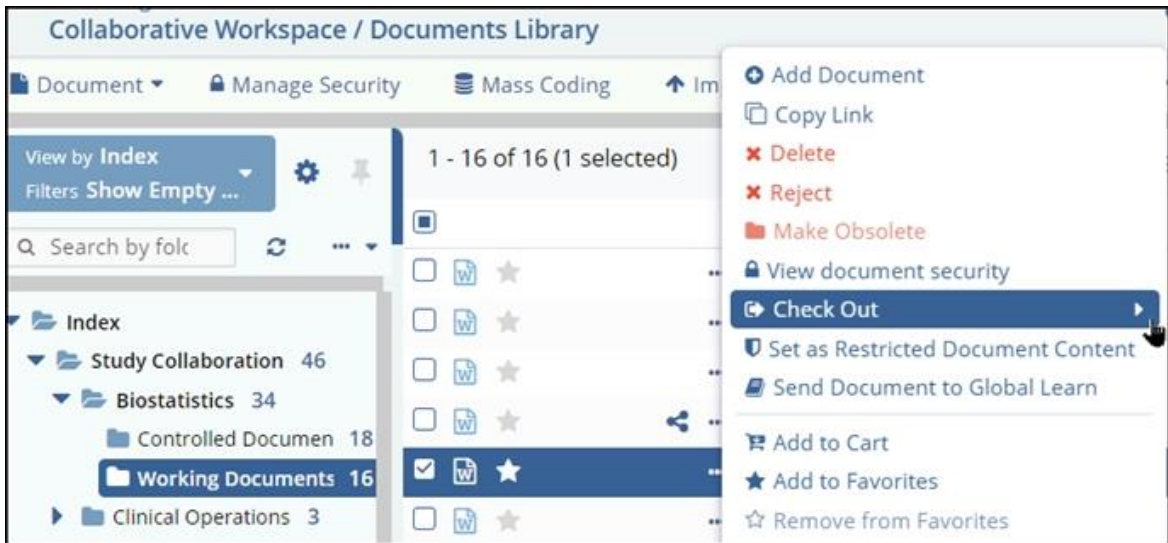
Collaborators in Team Edit can annotate a document with responses and comment threads, as well as integrated online chat. No local software installation is necessary.

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.

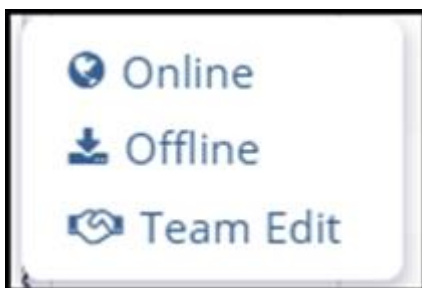
## 240. Checking Out and Editing

Editing of a document begins with the check-out process.

3. 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.

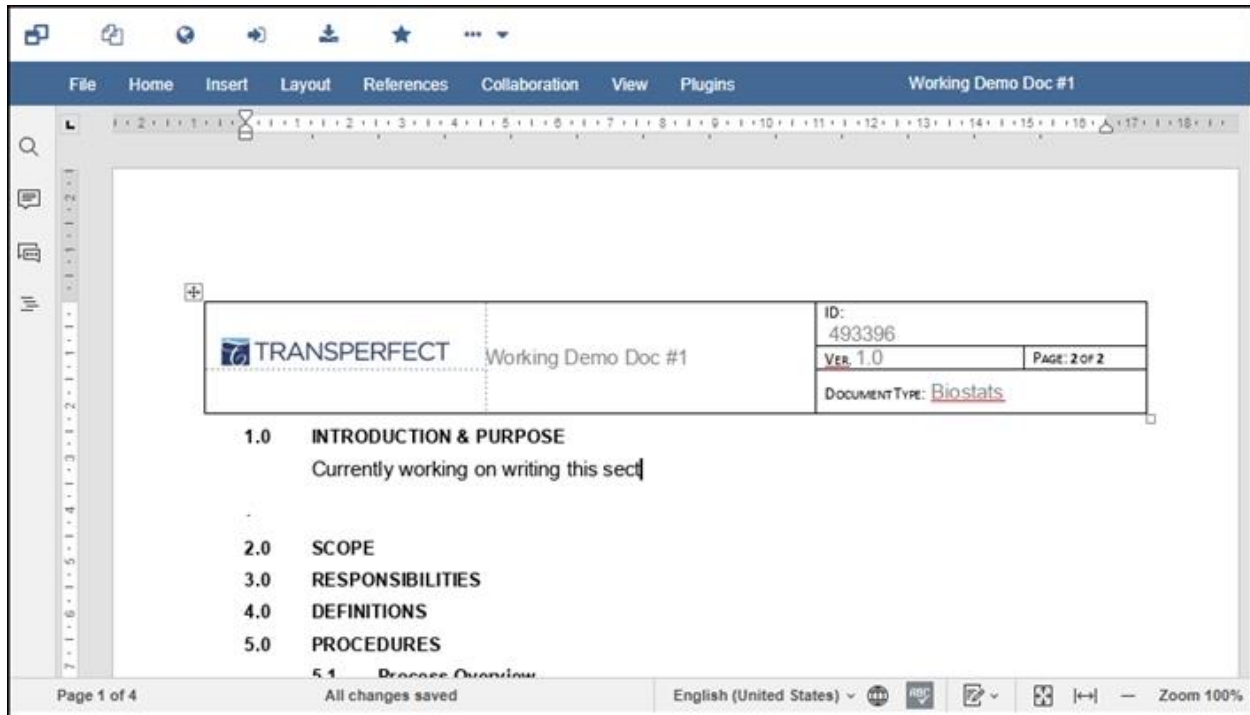


4. Select from the available check-out options according to your preference: Online (Individual Online Authoring), Offline (Individual Offline Authoring outside of TI), or Team Edit (simultaneous team collaboration).



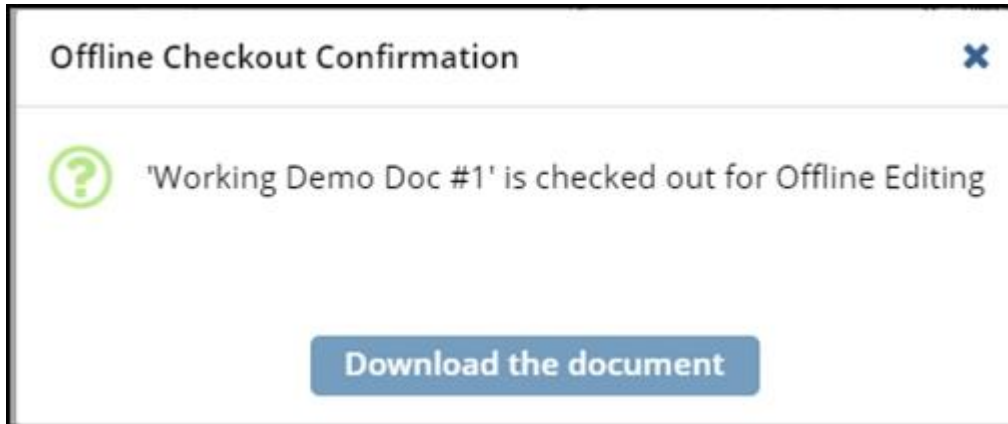
Online

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.

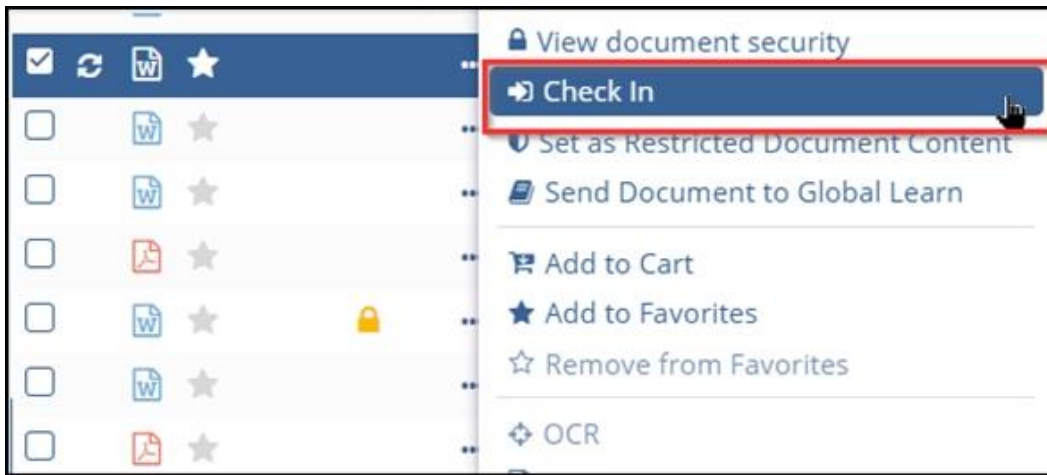


**Note:** We suggest always downloading the document when using this method. This ensures you are working on the most up-to-date version of the document.

*Checking In*

When a user has finished applying their changes, they will need to check the document back in.

5. A Check-In button can be found in the Document Action Menu.

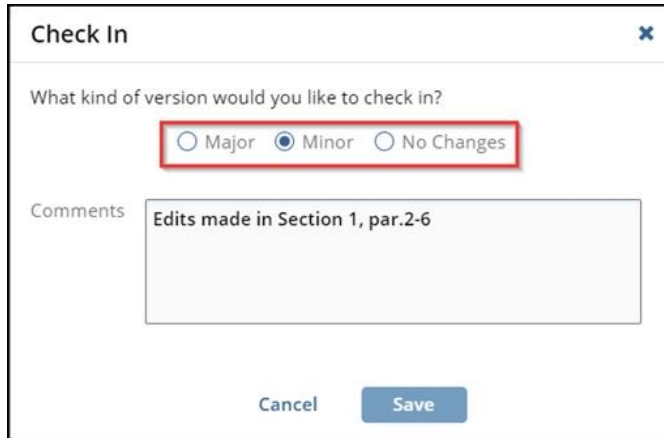


6. (For Online Edits only), users can opt to click on the Check In button above the Document Viewer instead.



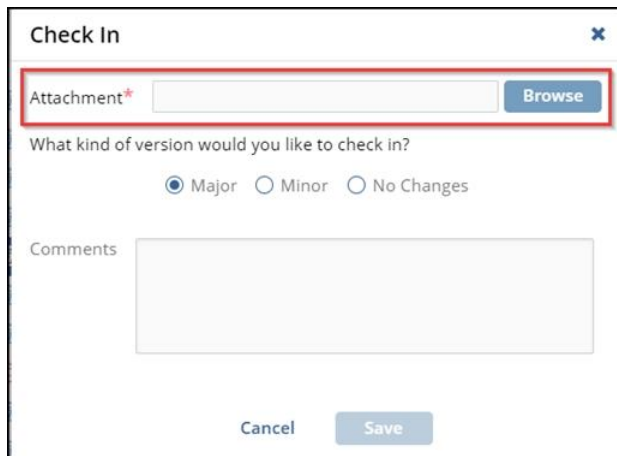
7. Users can then choose from three options:

- 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.

8. 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.



## 241. Team Edit

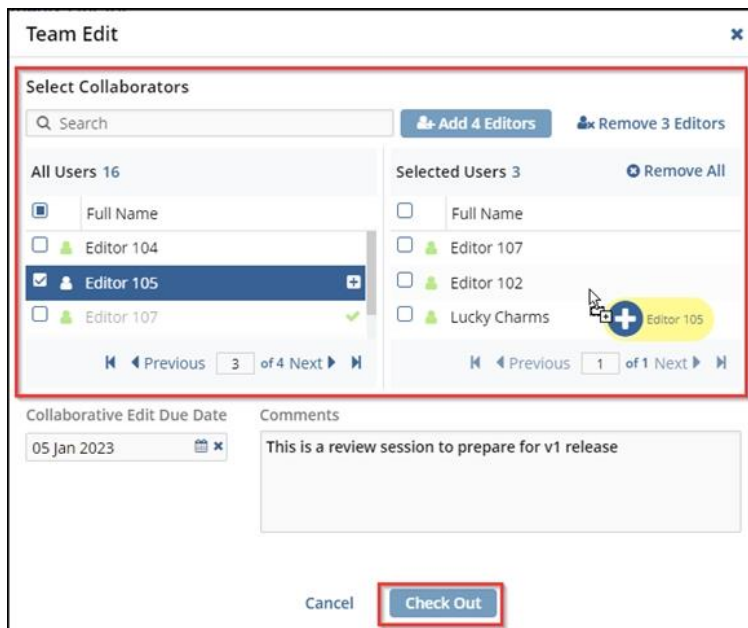
This option creates an online editing session involving multiple users, who can all work on the document simultaneously and see each other's changes in real-time.

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.

- To initiate a collaborative edit, check out the document using the **Team Edit** option.



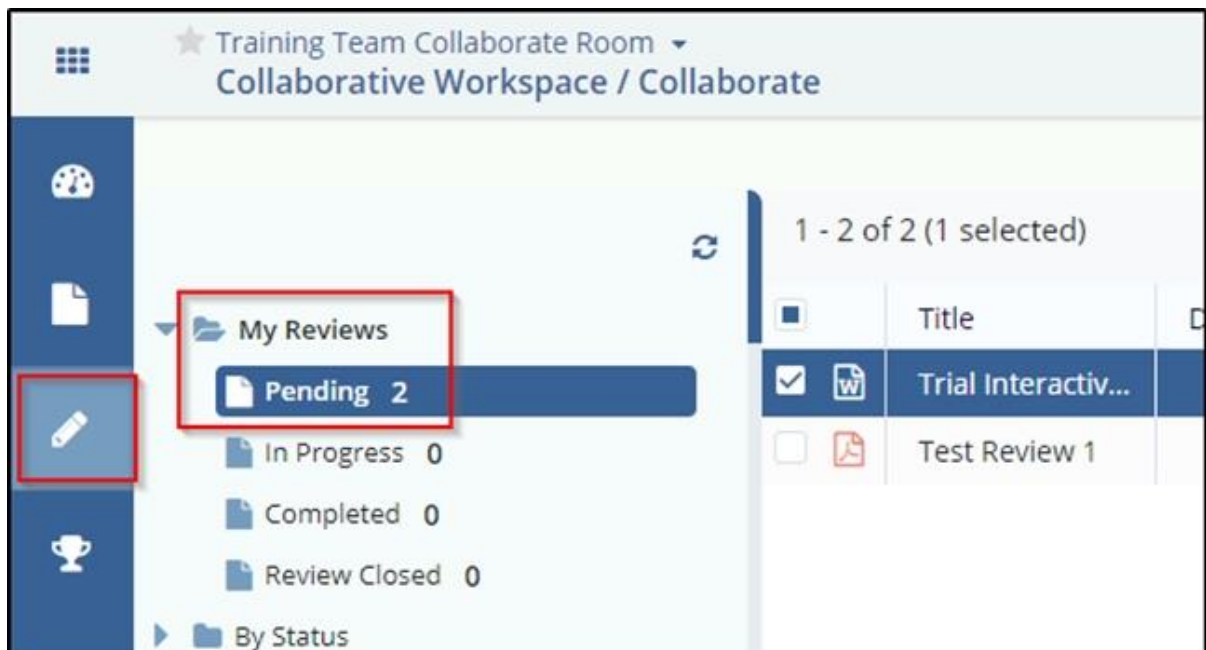
**Note:** The 'Add All Editors' option will automatically add to the review all editor users who have Edit rights in the folder where the document is located.

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.

5. Click the **Check-Out** option to initiate the team Edit session.
6. 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:



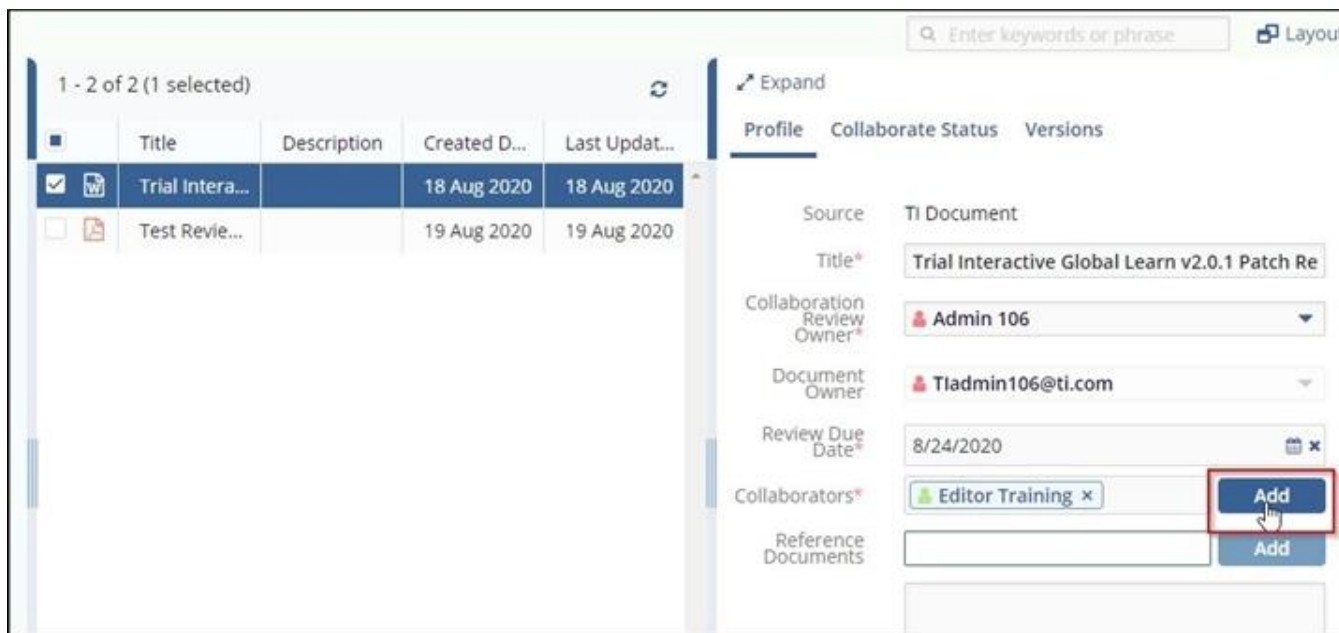
- The Collaborate module, accessed via the vertical navigation bar to the left of the screen in TI
- The Pending Collaborative Reviews dashlet, which displays all ongoing reviews assigned to the user
- The email notification received when added to the edit, which contains a direct link to the document 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:

3. Clicking on the Add button next to Collaborators, a selection menu will open. Reviewers can then be added.
4. 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.

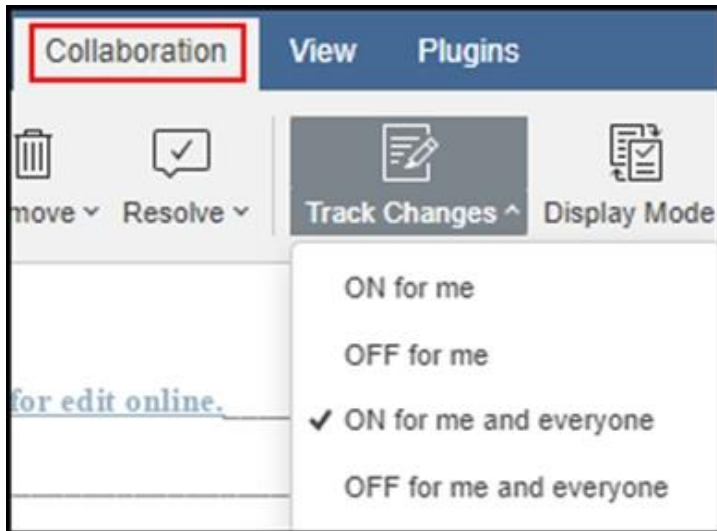
**ENROLLMENT LOG**

Protocol#: Test for edit online. PI: \_\_\_\_\_  
 Protocol Title: \_\_\_\_\_ Site #: \_\_\_\_\_

■ Editor 107  
 3/23/2023 10:08 am ✓ ✕  
 Inserted: writing

Subject ID	Date Consent Signed	Gender	Race	Ethnicity	Was Subject Randomized	Treatment Arm / Group	Subject Status (Withdrawn or Completed)	Explanation if subject not complete study Comment
1		M F			Y N			

**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.



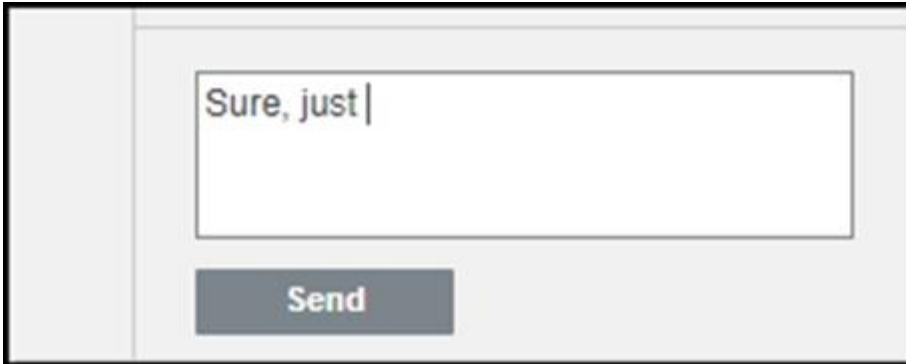
Users can also chat with each other if they are working on the document at the same time.

4. A yellow icon will appear any time a new message is received.





5. Use the box at the bottom of the panel to reply.

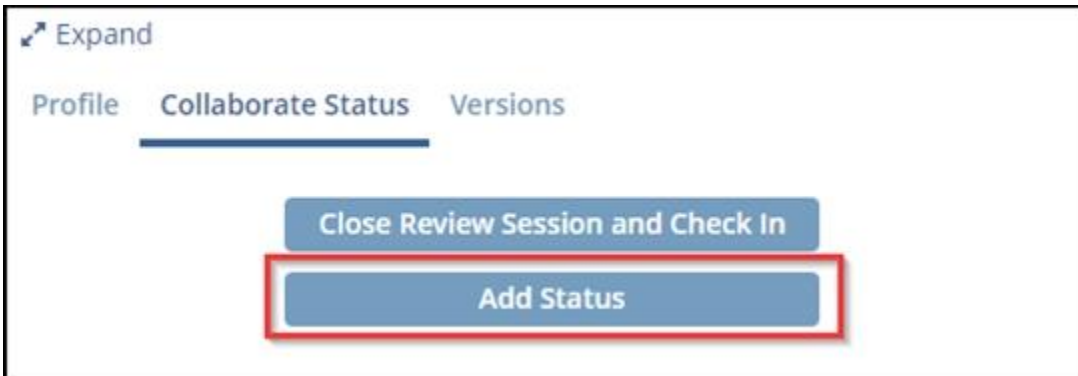


6. Chat History is discarded when the users log off.

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.

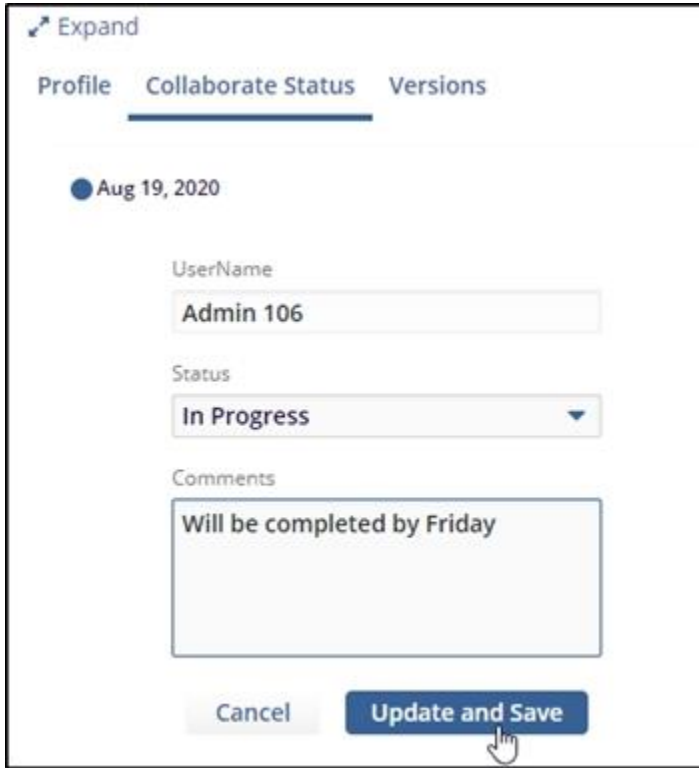
To do so, follow the steps below:

1. Expand the Metadata Panel, and click on the Collaborate Status tab.
2. Click on the **Add Status** button.

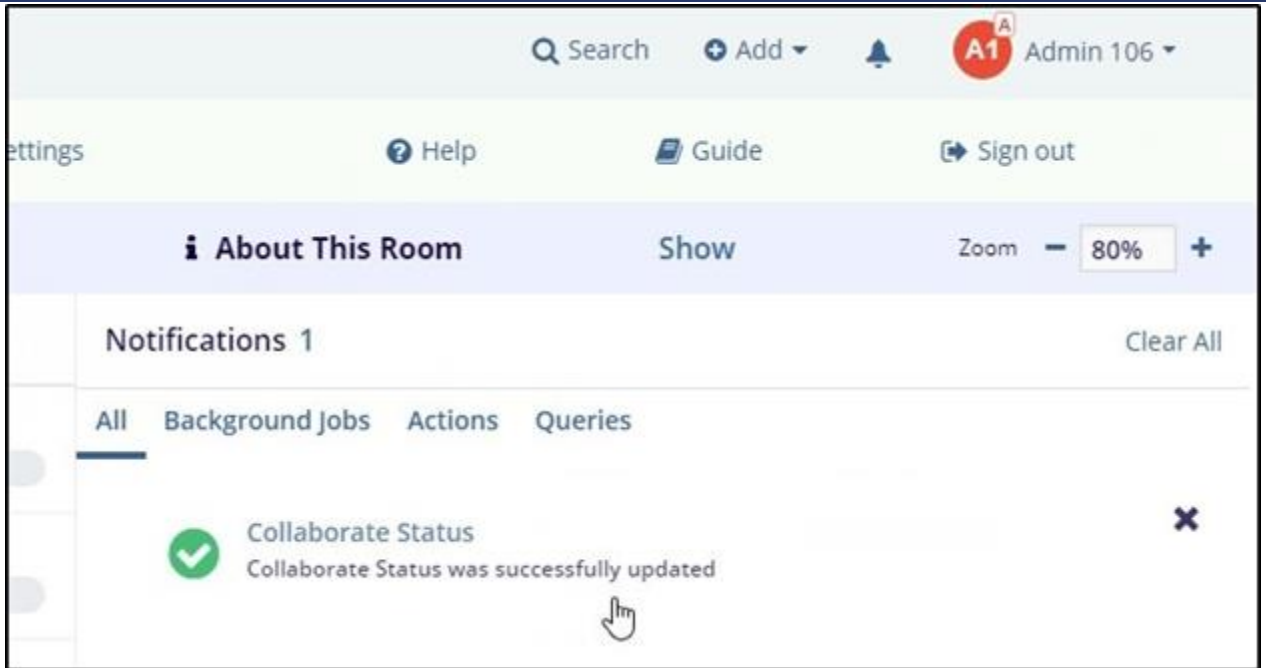


3. The status selection window opens. Choose the status from Pending, In Progress, or Completed, and (optionally) insert comments to provide updates on the work performed. Refer to the screenshots below.

- Click on the Update and Save button to make your change effective.



- You will be notified by a pop-up that your status was correctly added.

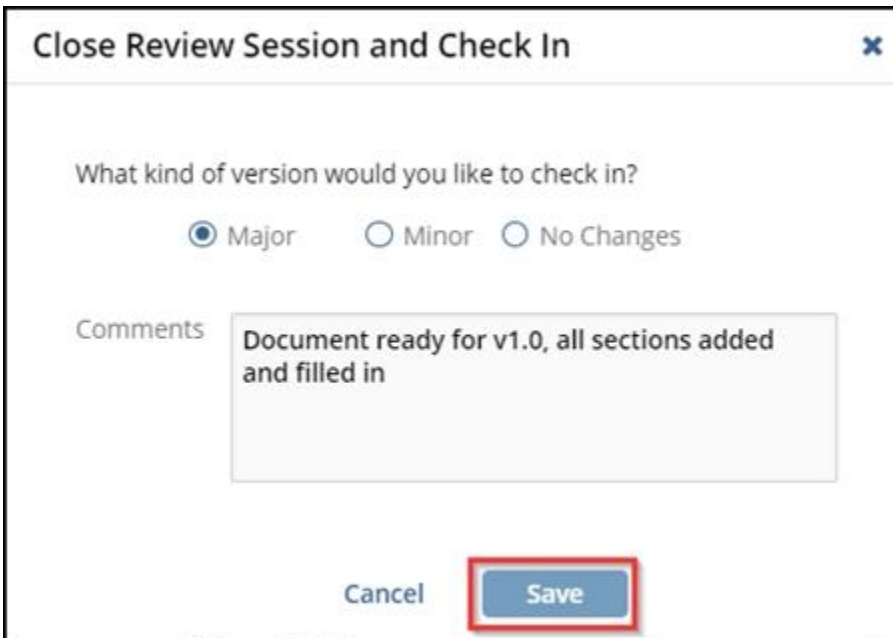
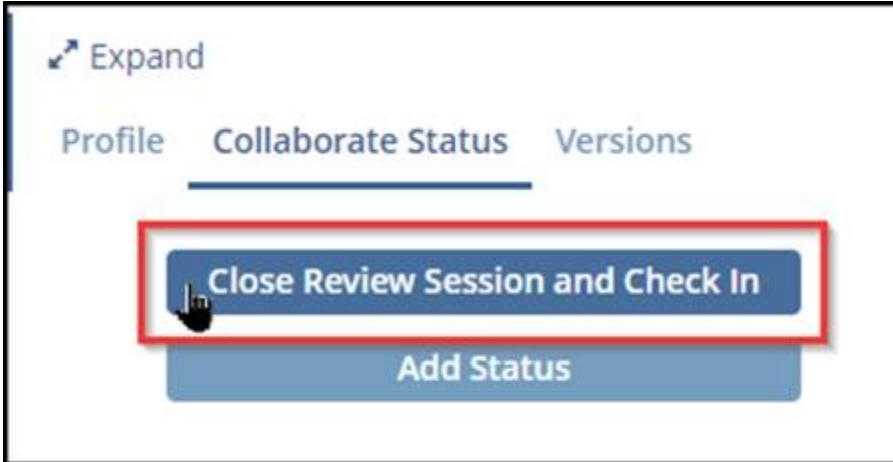


### *Closing a Team edit*

Once work on a document is complete, only the Collaboration Review Owner can close the session and check in the document.

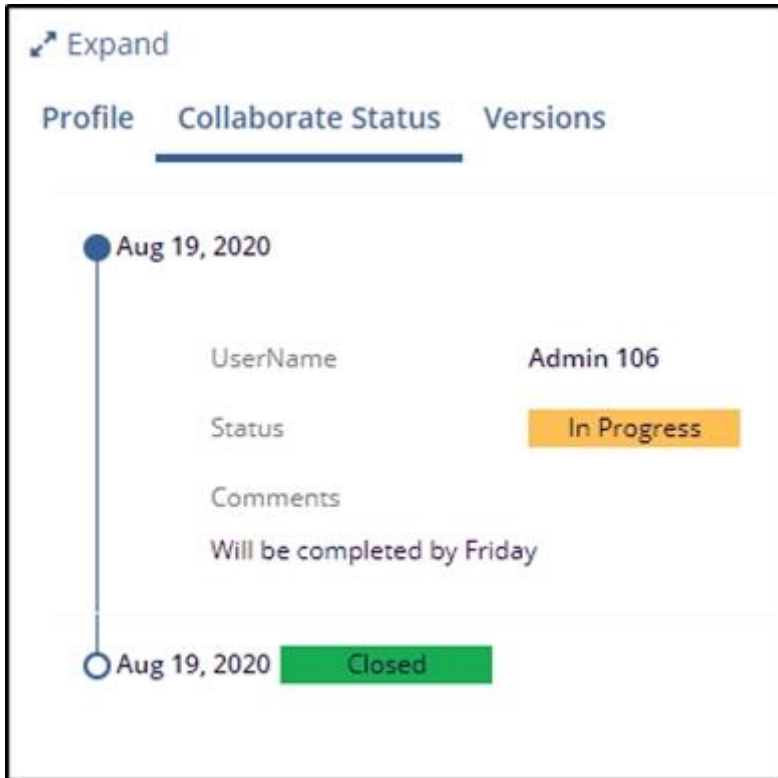
To do that, follow the steps below:

5. Click the Close Review Session and Check In button under the Collaborate Status.
6. A pop-up window appears.
7. Complete the check-in information by adding the type of revision and any comments, and then click Close Review Session and Check-In.





- 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.



Submitted Name  
**Concise-Monitoring-Plan-Template2**

Version history timeline:

- Version 2.0 (Effective)
  - Compare More info Open Download
- Version 2.0 (Approved, Promoted from v. 1.1)**
  - Compare More info Open Download
  - Version Label: 2.0
  - Version Date: 2 Mar 2023, 6:19 AM
  - Comments: Version is promoted from version 1.1
- Version 1.0 (Effective)
  - Compare More info Open Download
- Version 0.1
  - Compare More info Open Download

**Compare**

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.

Expand

Metadata Queries **Versions** History eSignature

Submitted Name  
ConMed-and-Therapies-Worksheet-Form-2.26.19

Version 1.0  Compare More info Open Download

Version Label 1.0

Version Date 14 Feb 2023, 2:17 PM

Comments

**ConMed-and-Therapies-Worksheet-Form-2.26.19** Lorenzo Vanzetto Tue 17/01/2023, 10:42:17 am

Closed By **Lorenzo Vanzetto**  
(Major Versions)

Comments

Collaboration Start Date 17 Jan 2023, 10:42 AM

Collaboration Owner **Lorenzo Vanzetto**

Collaboration Editor 107  
Participants Editor 103

Version 0.1  Compare More info Open Download

Compare

## Review and Signature Workflows

This section explains the procedure to follow to review and sign a documents.

### 242. Setting Up a Workflow

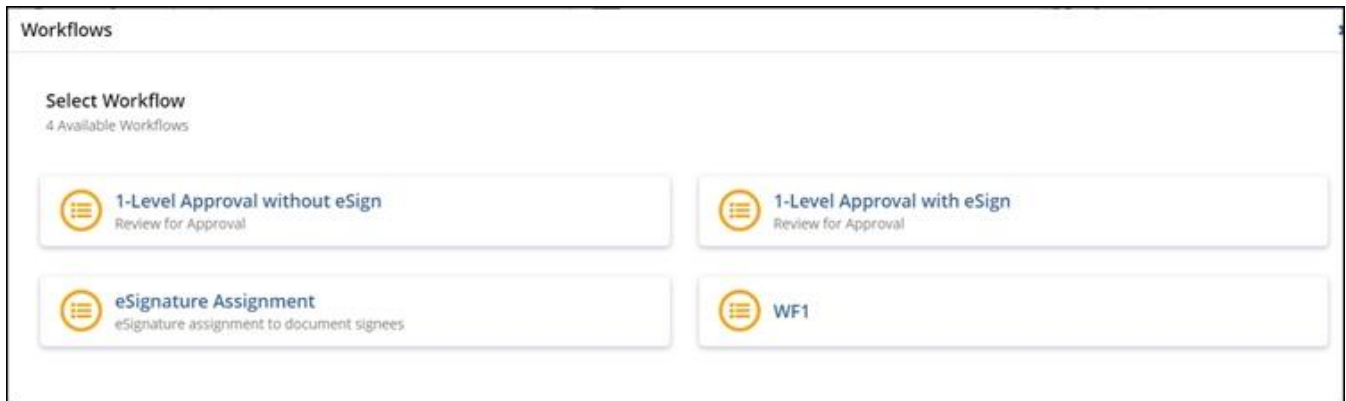
Documents requiring Change Control can be submitted for review or signature workflows either upon submission to TI or after content is generated/edited in TI.

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.

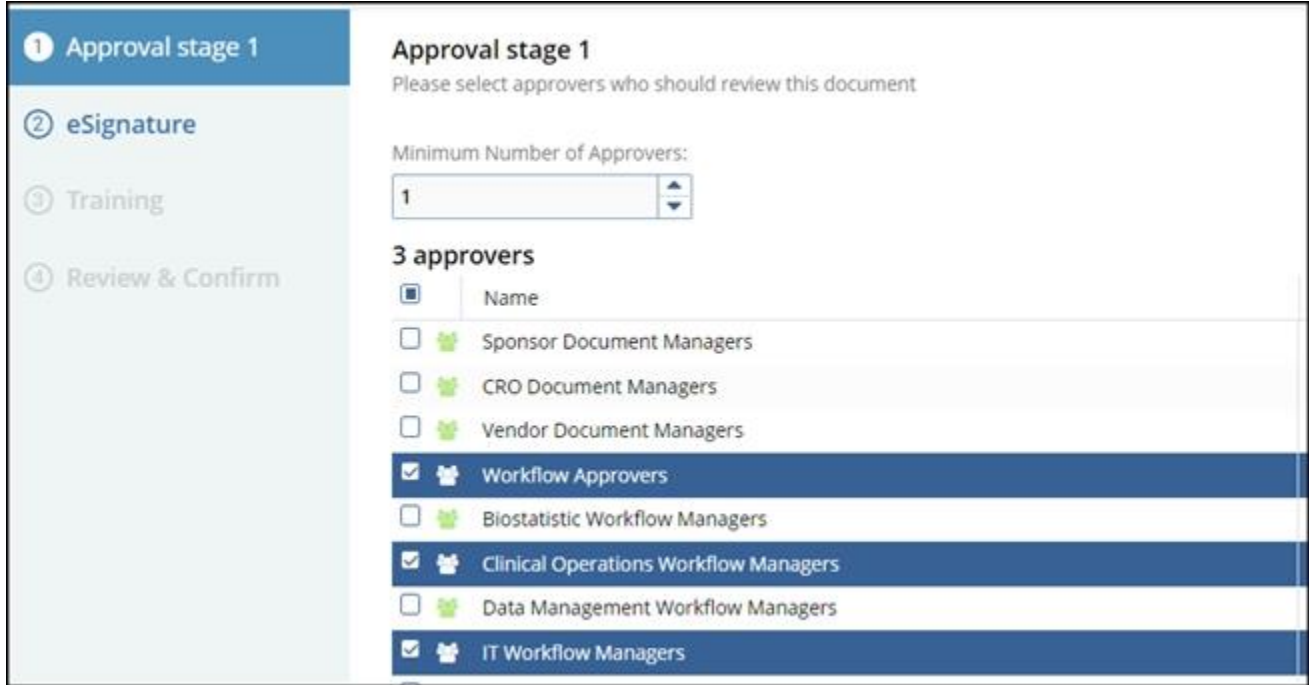


The Document Owner or Proxy Document Owner (as designated in the folder security settings) will select one of the workflows available in the room.



*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.

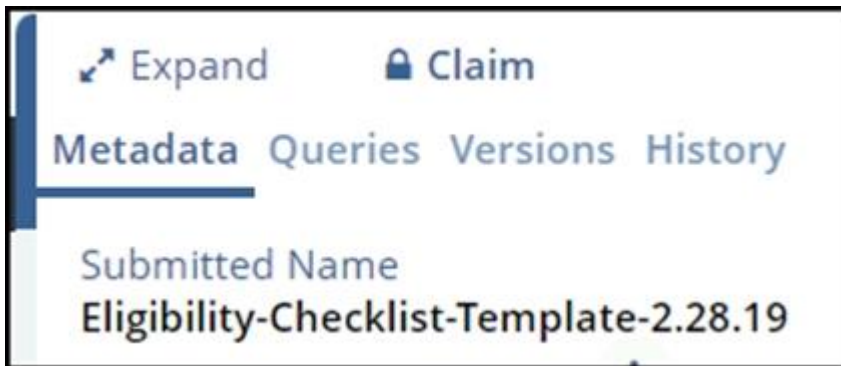
**Important:** *It is our recommendation that users should, where possible, reach out to the Trial Interactive Service Desk whenever assistance is needed in workflow creation or maintenance.*



## 243. Approving a Document

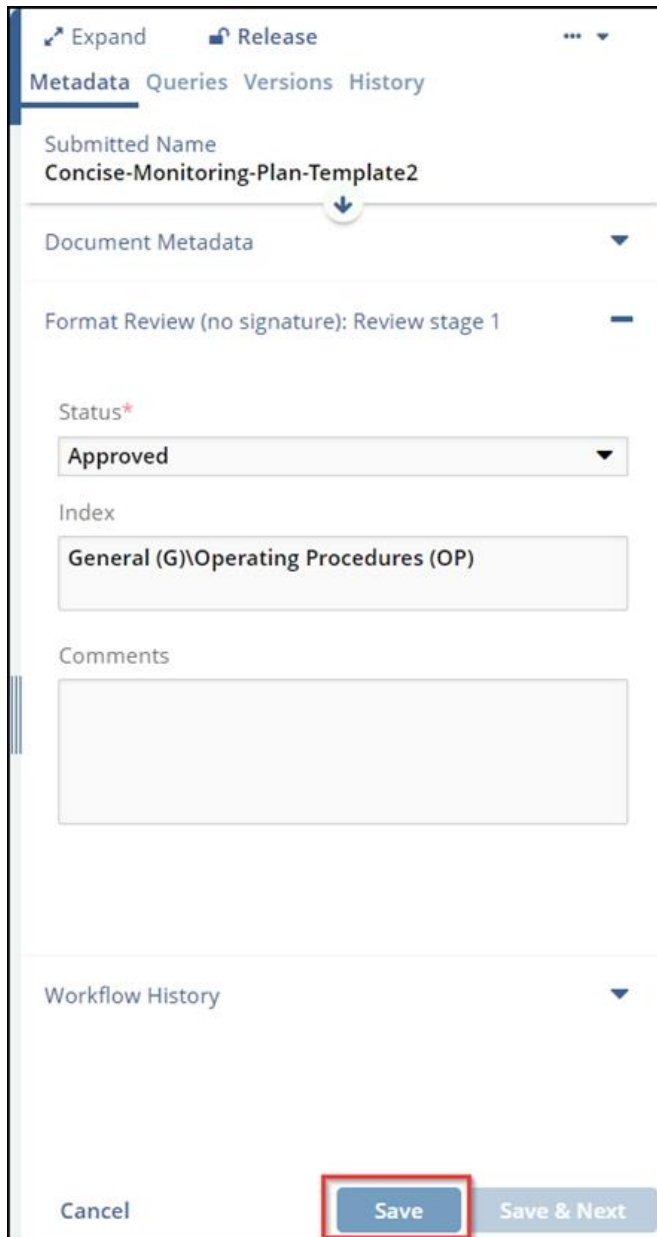
To review and approve a document, first navigate to it using one of the methods available (email link, Documents to Approve dashlet, or Document Library views).

5. 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.
6. 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).*

7. 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.
8. 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.



The screenshot shows a document review interface. At the top, there are tabs for 'Metadata', 'Queries', 'Versions', and 'History'. The 'Submitted Name' is 'Concise-Monitoring-Plan-Template2'. Below this is a section for 'Document Metadata' and a 'Format Review (no signature): Review stage 1' section. The 'Status\*' dropdown menu is set to 'Approved'. The 'Index' field contains 'General (G)\Operating Procedures (OP)'. There is a large text area for 'Comments'. At the bottom, there are three buttons: 'Cancel', 'Save' (highlighted with a red box), and 'Save & Next'.

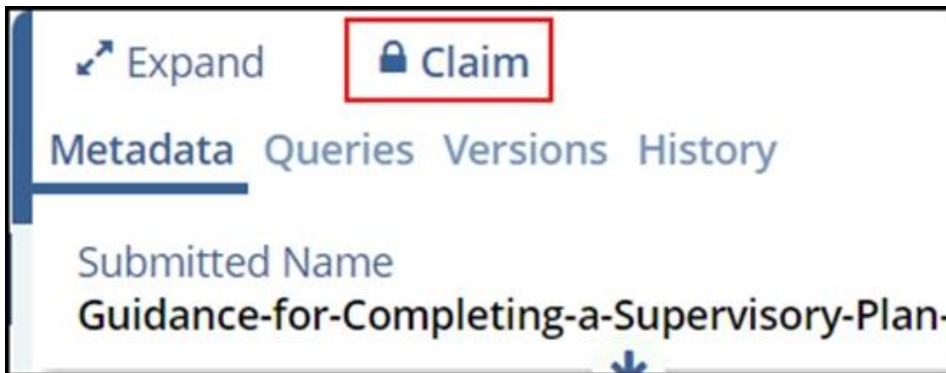
244. Setting Up eSignature

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.

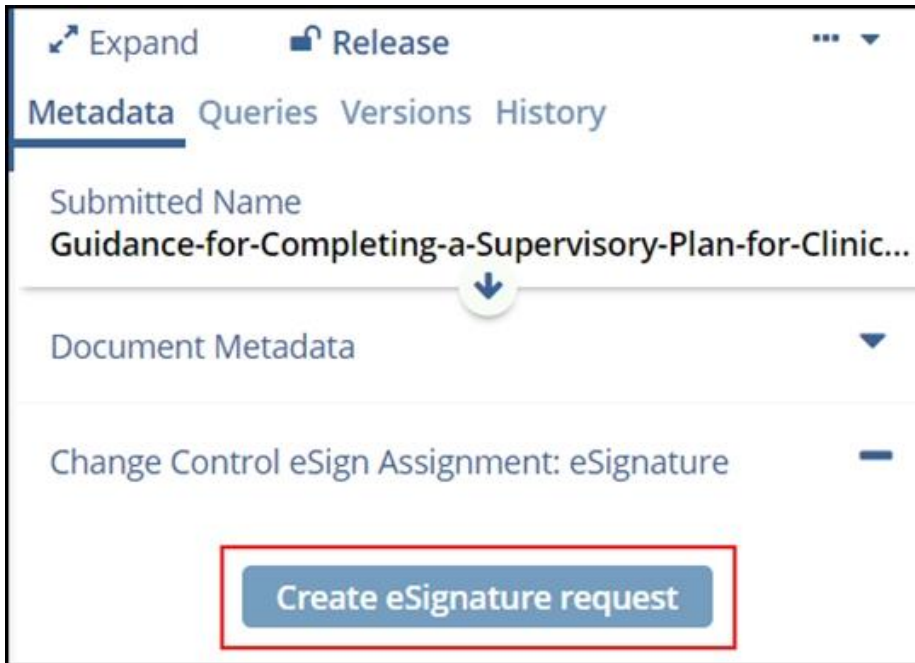


5. Select and Claim the document you wish to have signed (screenshot below).

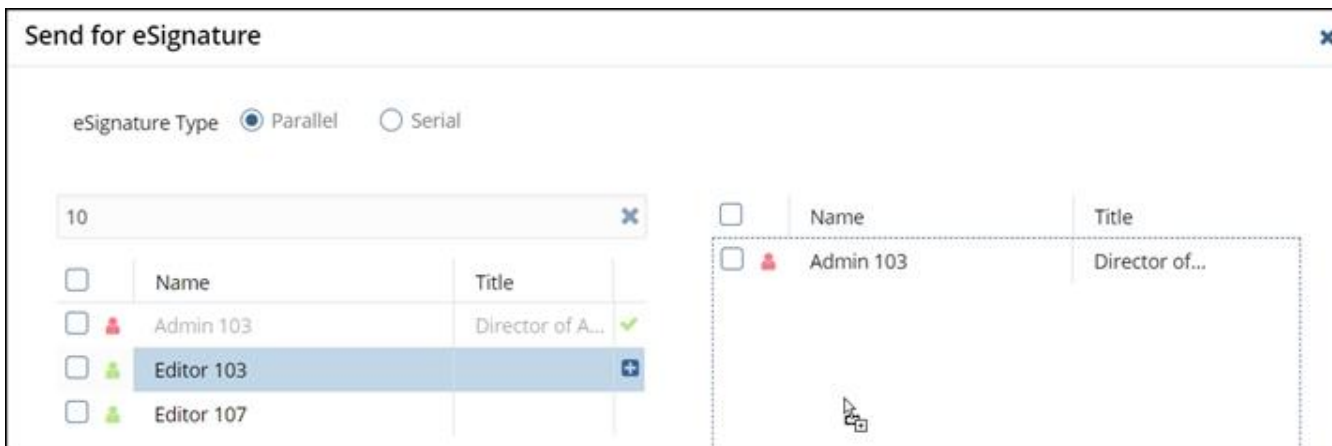




- Click on the **Create eSignature Request** button.



- 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.



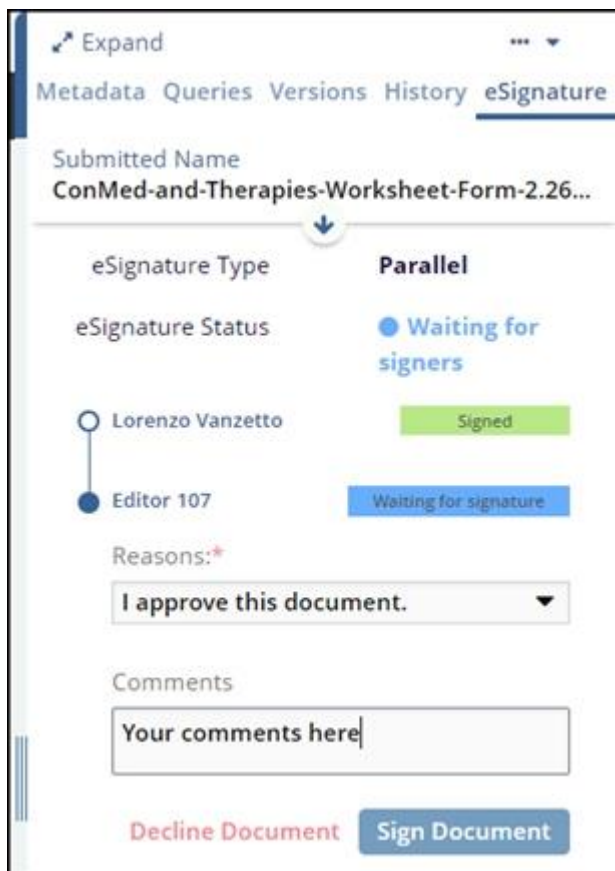
- The selected users are required to sign and will be notified by email that their signature on the document is pending.  
**Note:** Specific steps at this point may vary based on the eSignature vendor configured for use in the room. Please see additional materials as necessary.

## 245. 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.

4. You will find a tab called eSignature. This displays the current status of the signature workflow, including the name of the required signatories.
5. Choose a Reason from the related dropdown, add any comments you may have, then click on **Sign Document**. See the screenshot below.



6. After clicking on Sign Document, a window will open up where you will be able to apply your eSignature using your chosen eSignature provider.

## 246. Non-Approval of Documents

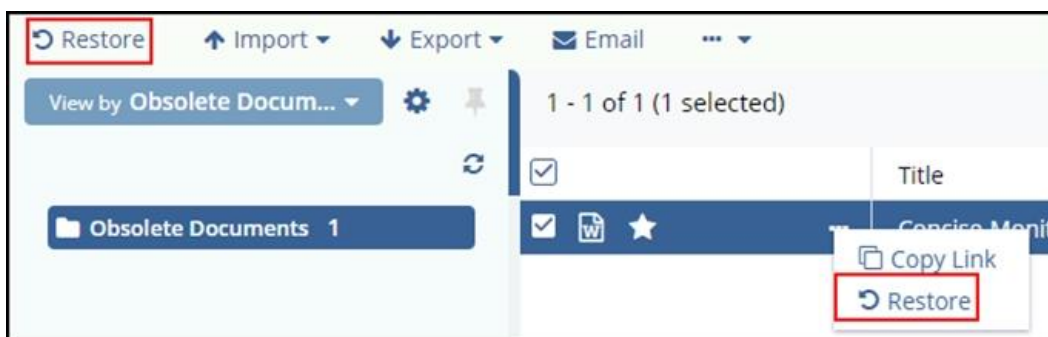
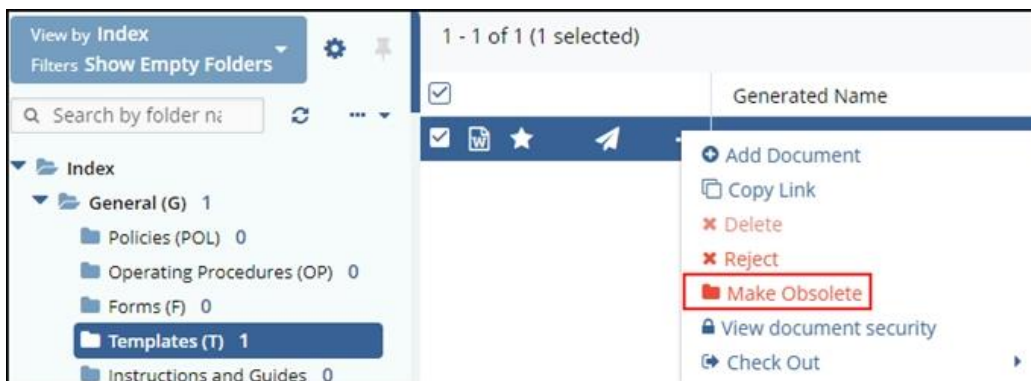
Documents can be rendered ineffective, for example, when the format is not correct, in multiple ways. Of course, an approver can refuse to move the document forward, or a signature workflow can be neutralized when someone refuses to sign.

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

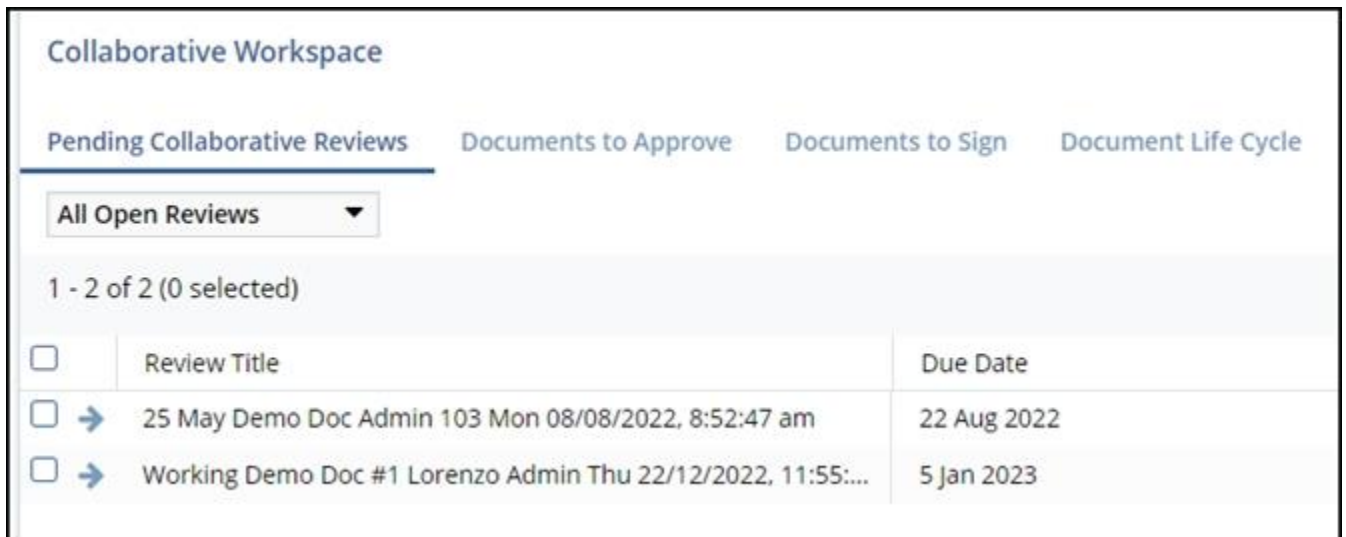
The Collaborative Workspace grouping of dashlets is exclusive to TI Collaborate rooms and contains dashlets that give the user quick access to lifecycle tools and documents.

See the following subsections for a description of these dashlets and their functions.

---

### 247. Dashlet – Pending Collaborative Reviews

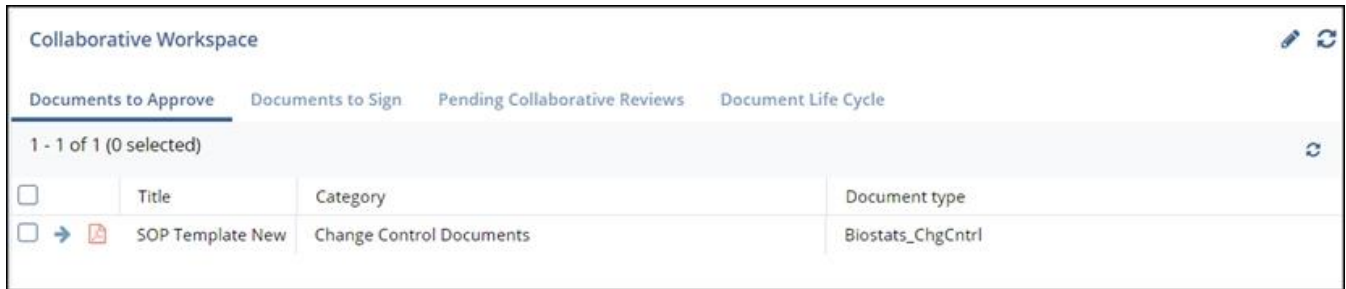
This dashlet displays all documents that are currently open in Team Edit mode for collaborative review by the current user. You can choose to view the documents pending for review for All users (default) or only for yourself by selecting My Pending Reviews. Click the dropdown located above the grid within 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).



Collaborative Workspace		
Pending Collaborative Reviews		
Documents to Approve		
Documents to Sign		
Document Life Cycle		
All Open Reviews		
1 - 2 of 2 (0 selected)		
<input type="checkbox"/>	Review Title	Due Date
<input type="checkbox"/> →	25 May Demo Doc Admin 103 Mon 08/08/2022, 8:52:47 am	22 Aug 2022
<input type="checkbox"/> →	Working Demo Doc #1 Lorenzo Admin Thu 22/12/2022, 11:55:...	5 Jan 2023

### 248. 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.

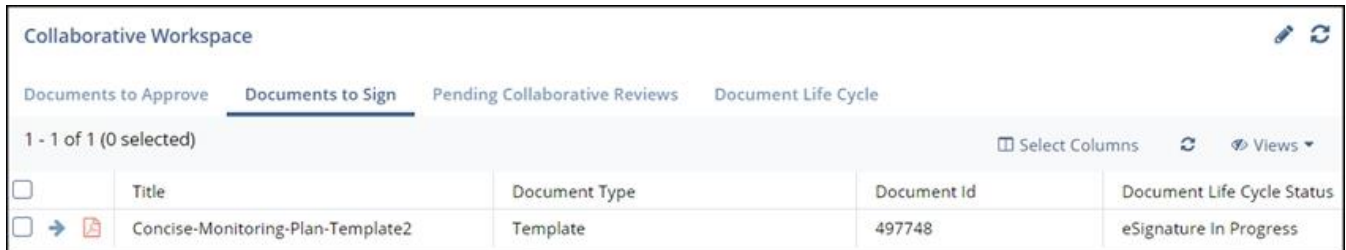


The screenshot shows a 'Collaborative Workspace' interface with a tabbed menu. The 'Documents to Approve' tab is active. Below the tabs, it shows '1 - 1 of 1 (0 selected)'. A table lists one document:

<input type="checkbox"/>	Title	Category	Document type
<input type="checkbox"/>	SOP Template New	Change Control Documents	Biostats_ChgCntrl

### 249. 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..).



The screenshot shows a 'Collaborative Workspace' interface with a tabbed menu. The 'Documents to Sign' tab is active. Below the tabs, it shows '1 - 1 of 1 (0 selected)'. A table lists one document:

<input type="checkbox"/>	Title	Document Type	Document Id	Document Life Cycle Status
<input type="checkbox"/>	Concise-Monitoring-Plan-Template2	Template	497748	eSignature In Progress

## 250. 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.

**Collaborative Workspace** ✎ ↻

[Documents to Approve](#)
[Documents to Sign](#)
[Pending Collaborative Reviews](#)
[Document Life Cycle](#)

Status Approved ▼

1 - 1 of 1 (0 selected) ☐ Select Columns ↻ Views ▼

	Title	Category	Document type	Life Cycle Status
<input type="checkbox"/>	<a href="#">→</a> <a href="#">📄</a> SOP #3	Change Control Documents	ClinOps_ChgCntrl	Approved

## 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.

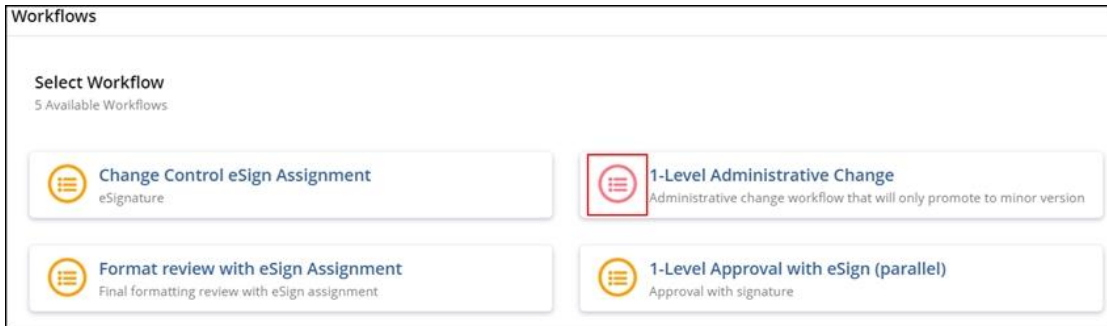
Make the necessary small change(s) and check the document in.

- The document will be indicated as ready for workflow (paper plane icon).

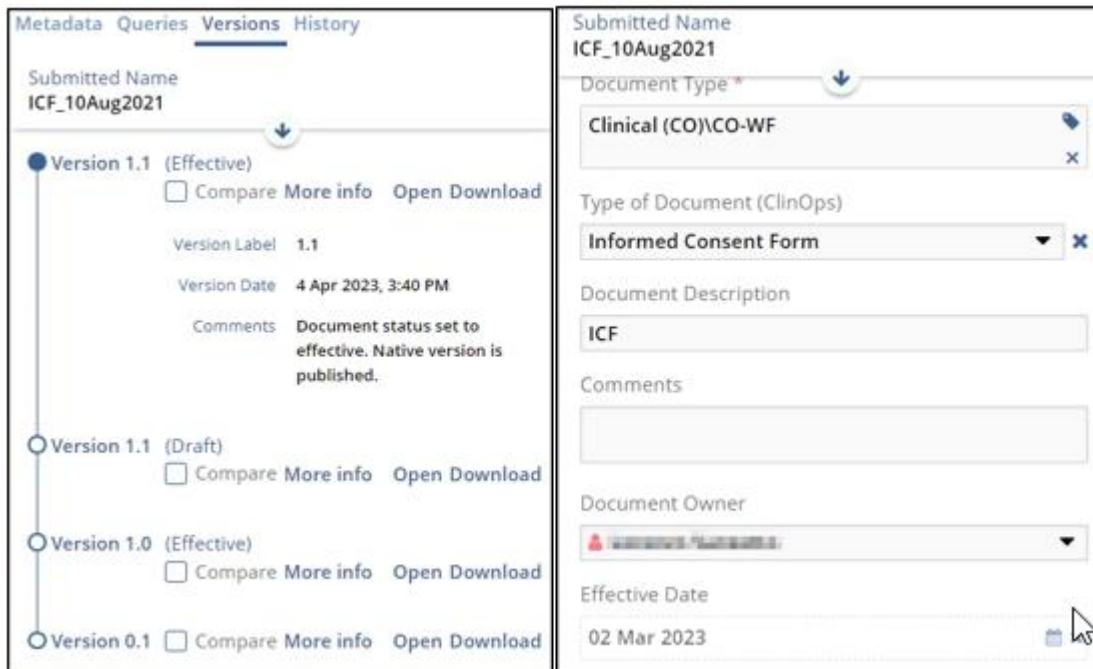
<input type="checkbox"/>		Generated Name	Document Owner	Working Version
<input type="checkbox"/>	  ...	Other	Admin 103	1.0
<input type="checkbox"/>	   ...	Informed Consent Form_ICF	Lorenzo Vanzetto	1.1
<input type="checkbox"/>	   ...		Lorenzo Vanzetto	0.1

- 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).

- Set up the workflow and carry out the review and approval as normal (see previous chapter on Review and Signature Workflows).



- You can verify the document update in the document's Versions panel. The Effective Date and (where applicable) Review Period fields are unchanged.



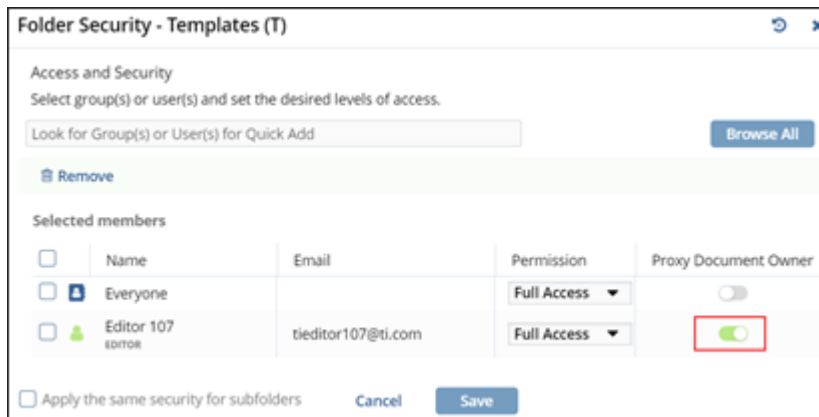


## 251. Additional Document Owner Privileges

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:

7. Navigate to the Documents Library in your Content Management room.
8. Locate the folder whose security settings you wish to adjust.
9. Right-click on the folder and select View Folder Security.
10. Select the Group or User who should be added to this folder's security and move them to the right side of the window.
11. Once they are there, you will need to give the Group or User the Proxy Document Owner permission, as shown in the screenshot below.
12. 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:

Expand More

OPEN METADATA

Metadata Queries Versions History

CTA

Document Type: Change Control

File Name: CTA.pdf

Sender Name: [Empty]

Sender Address: [Empty]

Document Status: [Empty]

Published Date: DD MMM YYYY

Published By: [Empty]

Country: [Empty]

Document Owner: Admin 103

**Additional Document Owners**

Effective Period: [Empty]

Effective Immediately

Additional Document Owners	
Full Name	Email
Editor 107	tieditor107@ti.com

## 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 Startup Process in Trial Interactive

1. Setting up the configurations
  - a. Configuring Study Start-Up Setting
  - b. Adding Countries
  - c. Adding IRB/ECs Setting Required/Essential Documents for Countries
  - d. Setting Required/Essential Documents for IRB/EC
  - e. 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 Specialist
  - 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. Translate documents to the local language if required
8. Review of documents by Regulatory Approve
9. Site Activation and publishing documents to the eTMF
10. Adding essential/required documents after site activation through amendments.

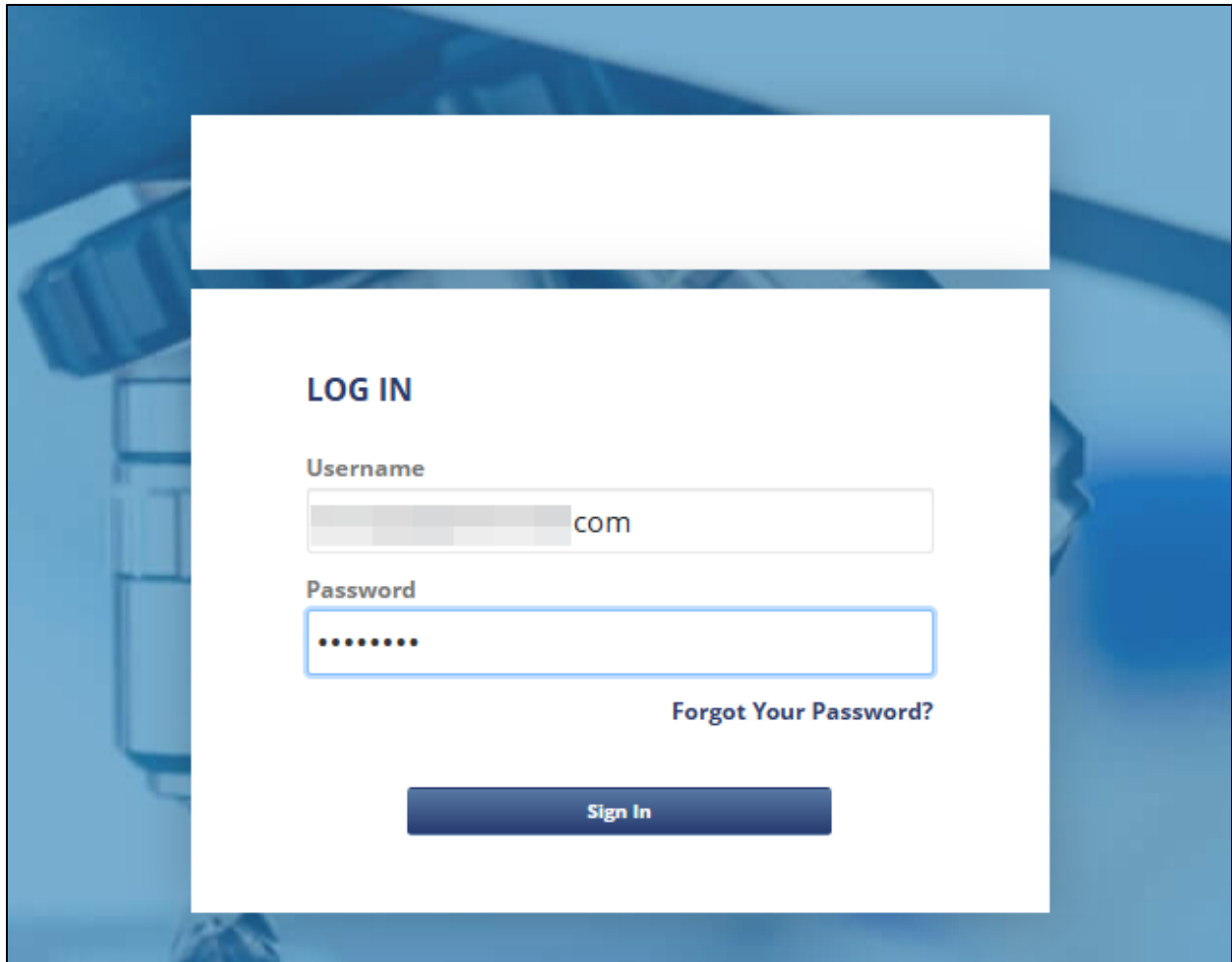
### Basic Configurations and Settings for SSU

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 role team member or by your TI implementation team.

The Study Start-Up Settings allows you to set up rules that would be critical for a site activation process. These settings are global and are applicable to all sites in the room.

To configure the SSU settings, follow the steps below.

1. Login into Trial Interactive entering the Username and Password.

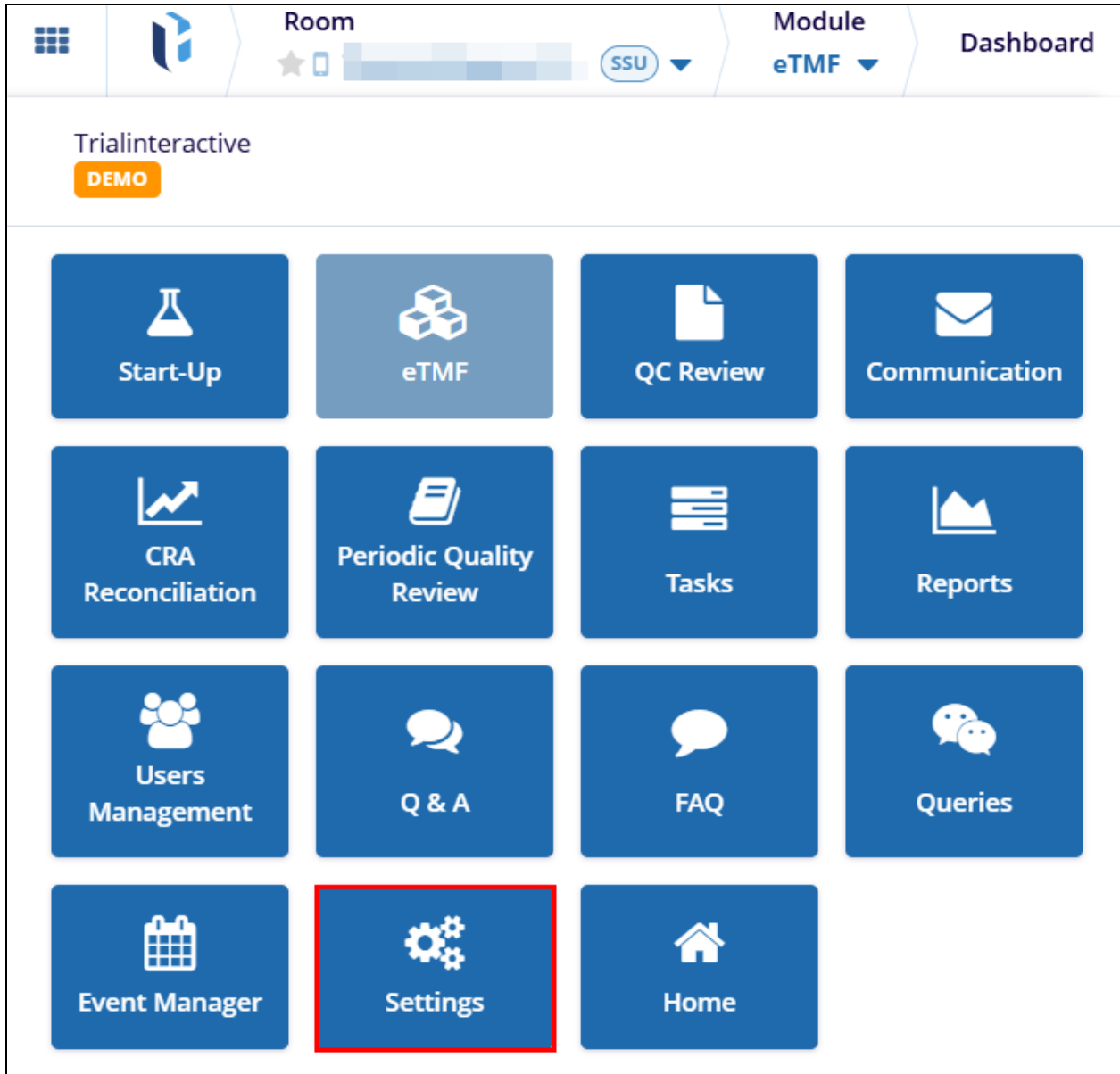


2. Click on a room

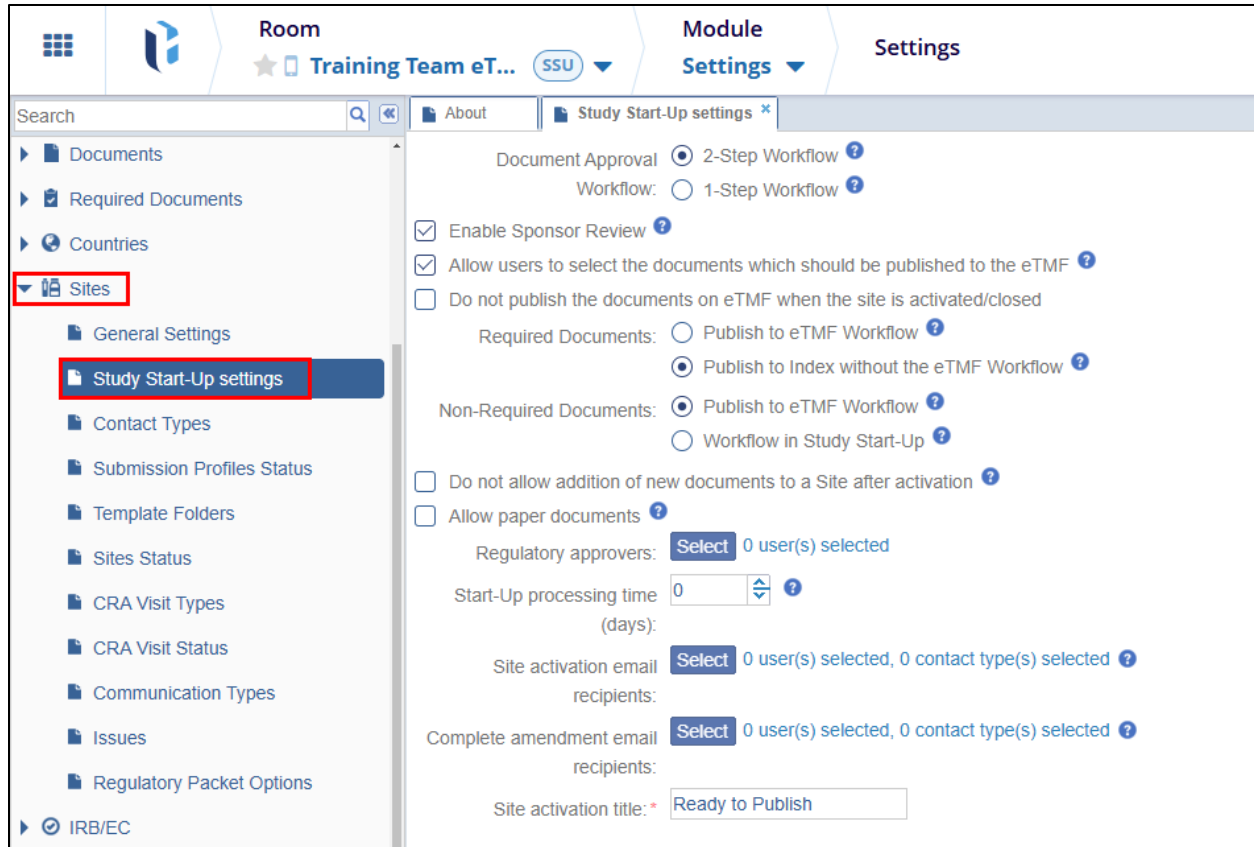
The screenshot displays three room landing pages in a list view. Each page shows a room ID, protocol number, TI client, and last visit date. Below this, there are several statistics: Countries, Pending Sites, Active Sites, Total, and a grid of counts for different statuses. The first room (SSU) has 201 total counts, the second (CWS) has 10, and the third (SSU) has 1,091. The status counts include Collected, Missing, Required Coding, Final, Expired, Expiring, Open Queries, and Rejected.

Room ID	Protocol #	TI Client	Last Visit	Created	Countries	Pending Sites	Active Sites	Total	Collected	Missing	Required Coding	Final	Expired	Expiring	Open Queries	Rejected
[Redacted]	[Redacted]	[Redacted]	10 Nov 2024	22 Oct 2022	7	9	7	201	30	469	76	37	0	0	2	4
[Redacted]	[Redacted]	[Redacted]	9 Nov 2024	25 Oct 2022	-	-	-	10	0	0	0	0	0	0	0	0
[Redacted]	[Redacted]	[Redacted]	9 Nov 2024	30 Jan 2020	31	29	14	1,091	95	720	850	159	28	0	69	55

3. On the room landing page, click on the Waffle menu and select the **Settings** module.



- From the left-hand navigation pane, expand the Sites settings and select the Study Start-Up Settings.

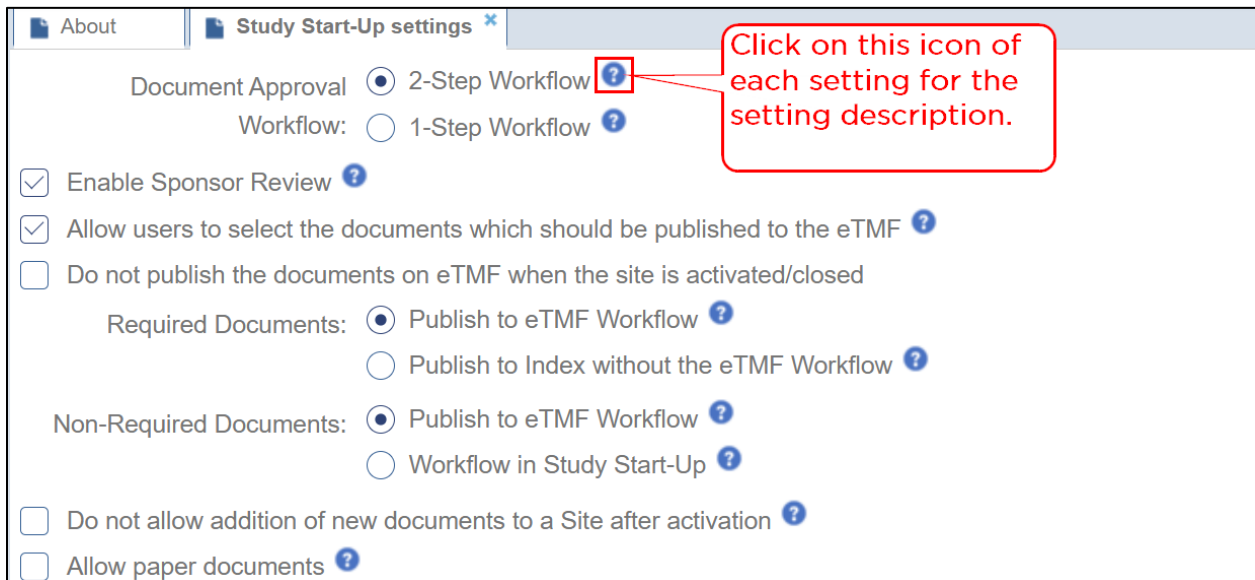


5. On the Study Start-UP Settings tab, configure the following settings regarding required and non-required documents on the Site Activation.

- **Document Approval Workflow:** The Document Approval Workflow allows users to select the workflow type. Select any one of the workflow types by clicking on their respective radio buttons.

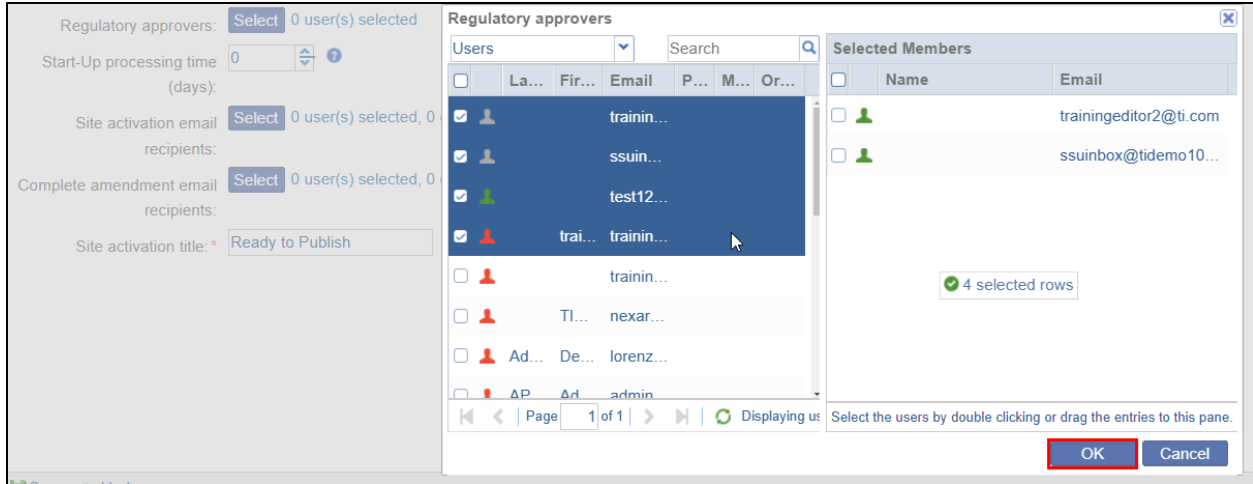
  - a. **2-Step Workflow:** In this type of workflow the document should go through the two-step approval process i.e., Approve by Study Startup Specialist and Approve by Regulatory Reviewer
  - b. **1-Step Workflow:** In this type of workflow the required documents should be approved just by the Study Startup Specialist
- **Enable Sponsor Review:** Click on the checkbox to enable the setting. If enabled documents can be submitted for additional Sponsor Review.
- **Allow users to select the documents which should be published to the eTMF:** Click on the checkbox to enable the setting. If enabled it affects the site activation/non-participating process.
- **Do not publish the documents on eTMF when the site is activated/closed:** : Click on the checkbox to enable the setting. If this setting is enabled, the Required and Non-Required Documents settings are disabled.

- **Required Documents:** Select any one of the Required Documents settings from the below options.
  - a. Publish to eTMF Workflow: Essential Documents will be added to the default folder – **Staging.**
  - b. **Publish to Index without the eTMF Workflow:** Essential Documents will be published to the eTMF Index based on the document type auto routing
- Non-Required Documents: Select any one of the Non-Required Documents settings from the below options.
  - a. Publish to eTMF Workflow: Non-Essential Documents will be added to the default folder – **Staging.**
  - b. Workflow in Study Start-Up: Depends on the Document Approval Workflow settings.
- **Do not allow addition of new documents to a Site after activation:** Select the checkbox to enable this setting. If enabled, no new document can be added or imported for the activated site in SSU.
- **Allow paper documents:** If enabled, SSU documents without attachments may be QC Reviewed. The Regulatory Reviewer can approve multiple documents.



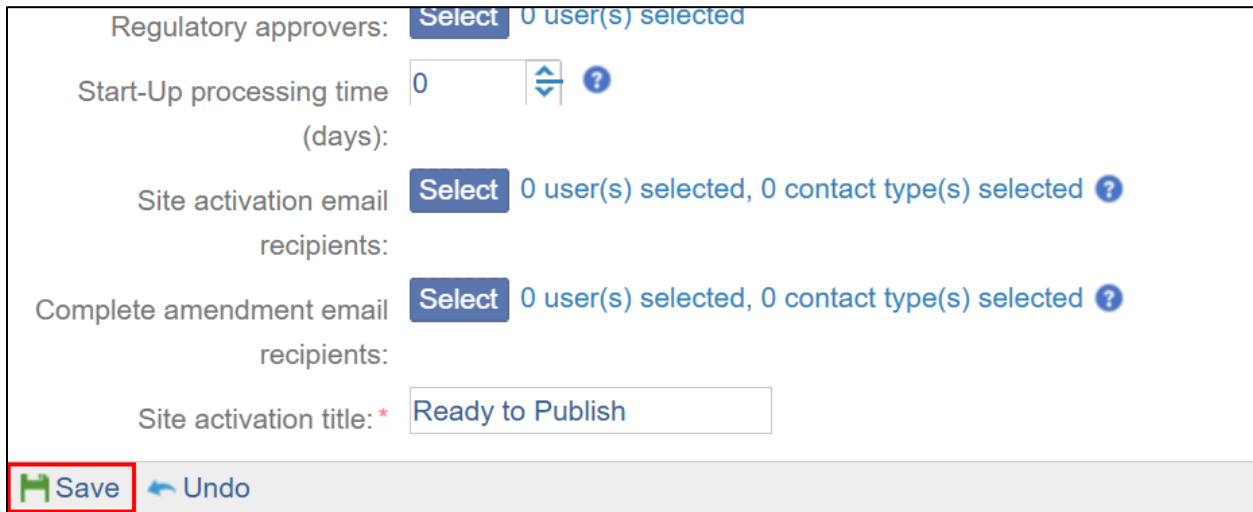
6. Configure the following additional settings.
  - Regulatory Approvers: To add regulatory approvers, follow the steps below
    - a. Click on the Select button.
    - b. On the Regulatory Approvers window, drag & drop users to the selected members section and click on the OK button.





- **Start-Up processing time:** Adding the processing time enables having a buffer time to activate a site after the IRB/EC Approval.
- **Site activation email recipients:** Add recipients who will receive a site activation notification email. Follow the standard process of adding Regulatory approvers.
- **Complete amendment email recipients:** Add recipients who will receive a amendment completion notification email. Follow the standard process of adding Regulatory approvers.
- **Site Activation title:** Mandatorily enter a site activation title.

7. Once the required settings are configured, click on the Save button.

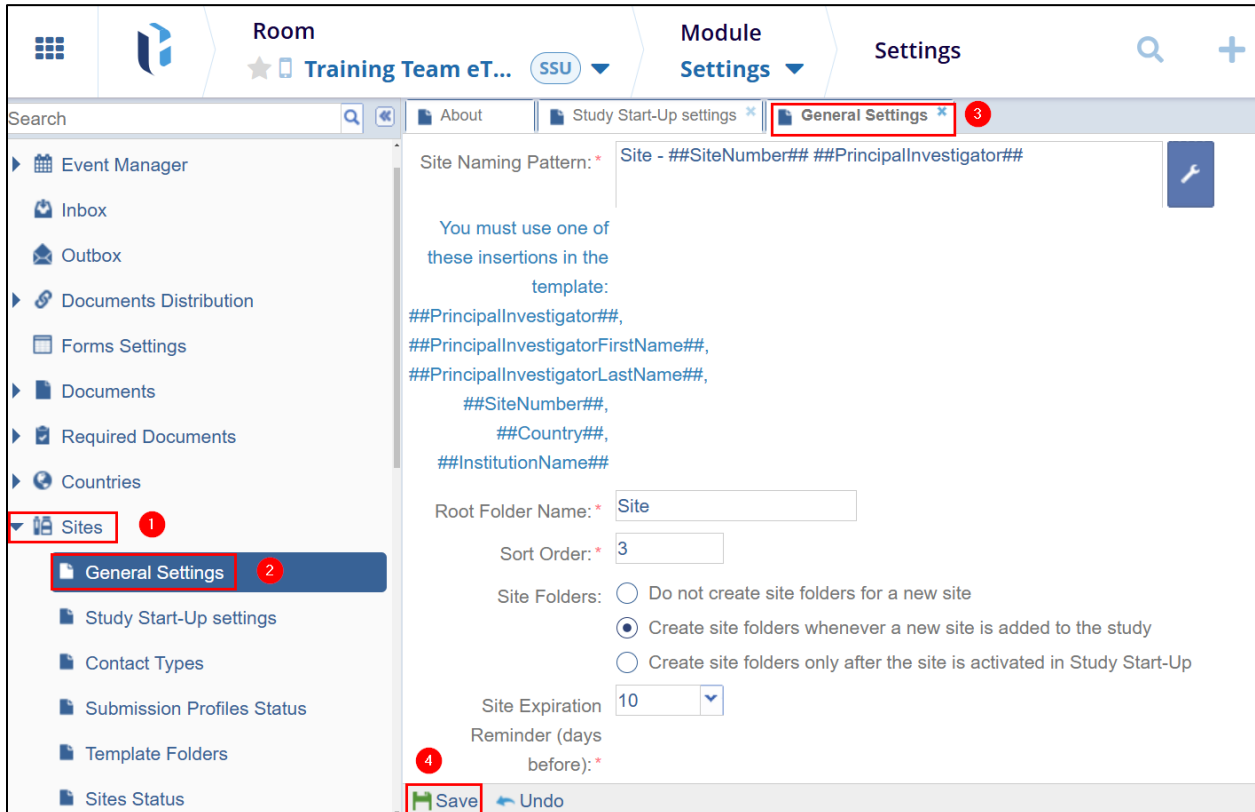


## General Settings

The General Settings allow users to set up rules that would be critical for a site creation process. These settings 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. On the Settings module, expand the Sites option in the left-hand navigation pane.
2. From the collapsed dropdown, click **General Settings**.
3. Configure the settings on the General Settings tab.
4. Click on the **Save** button at the bottom of the window.



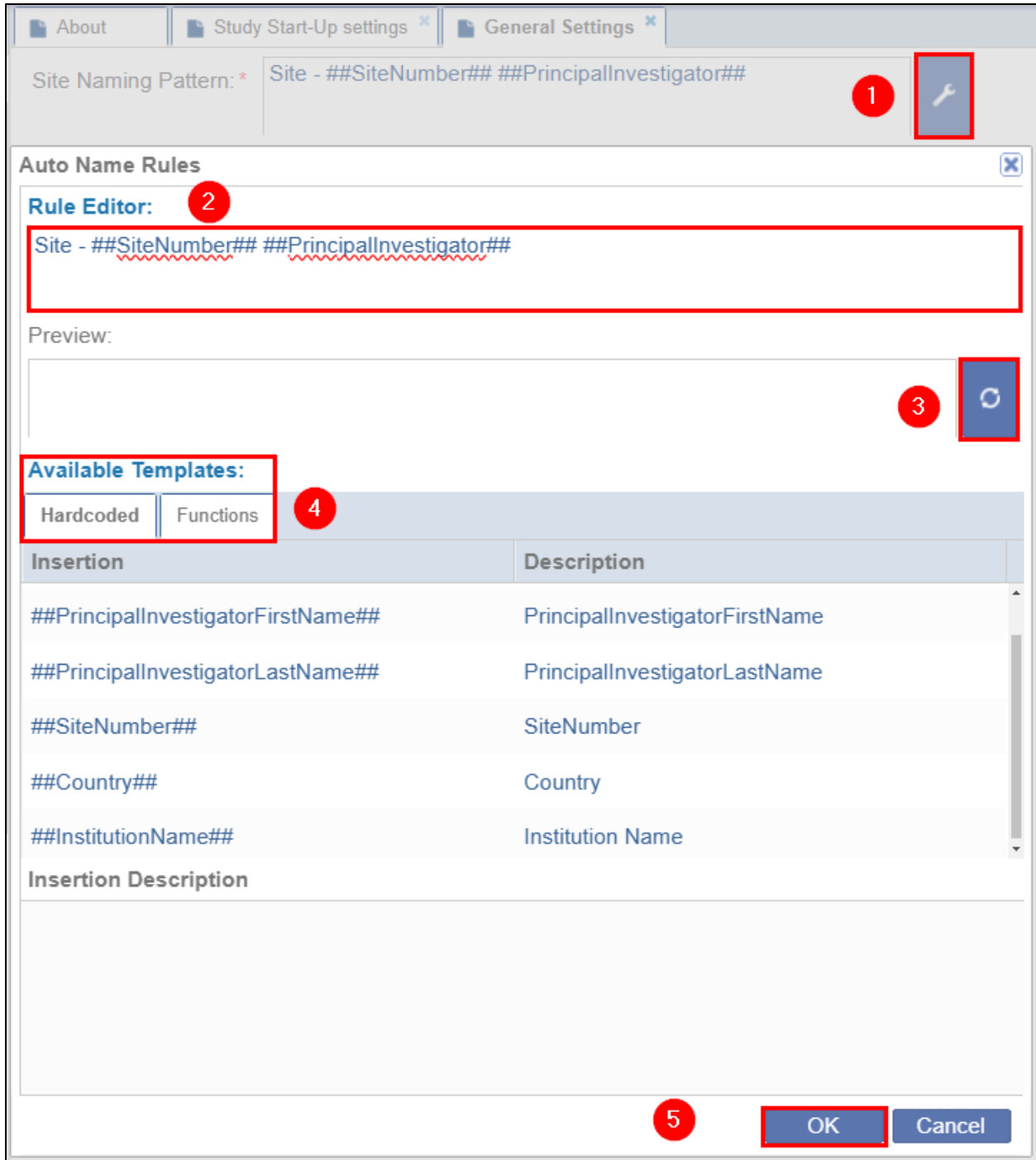
The General settings window allows the following to be defined.

### 252. Site Naming Pattern

The investigative site naming pattern is set as per the prescribed pattern of the organization.

To set the naming pattern, follow the steps below.

1. Click the wrench icon displayed at the end of the Investigative Site Naming Pattern.
2. On the Auto Name Rules window, define the rule for naming the investigative sites.
3. Review the same by clicking the refresh icon available after the preview box.
4. Fill in the essential details from the available templates (choose Hardcoded/Functions by toggle screen)
5. Click the OK button at the button to save and execute the naming pattern.



### 253. 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.

To add a root folder name, follow the steps below.

1. Click in the field.
2. Type the root folder name.
3. Hit the Enter key on the keyboard

Root Folder Name: \*

## 254. Sort Order

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.

To configure sort order, follow the steps below

1. Click in the field.
2. Type the number of the client’s preference.
3. Hit **Enter** on the keyboard.

Sort Order: \*

## 255. 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.

To configure sort order, select any one option by clicking on an options radio button.

1. Do not create site folders for a new site
2. Create site folders whenever a new site is added to the study
3. Create site folders only after the site is activated in Study Start-Up

Site Folders:

Do not create site folders for a new site

Create site folders whenever a new site is added to the study

Create site folders only after the site is activated in Study Start-Up

## 256. Site expiration reminder period

The options here allow users to set the number of days before a site's expiration and when notifications will be sent out to the users who are selected as the 'Expiring sites notification recipients.

To set site expiration reminder period, select the time period in days by accessing the field dropdown.

Site Expiration    
 Reminder (days  
 before): \*

### 257. Expiring Sites Notification Recipients

To add recipients for the expiring sites notifications, follow the steps below.

1. Click the Select button to select the users/groups receiving the notification reminder email.
2. Double-click the users or drag and drop them to the right pane to add them to the recipients' list.
3. Click on the OK button.

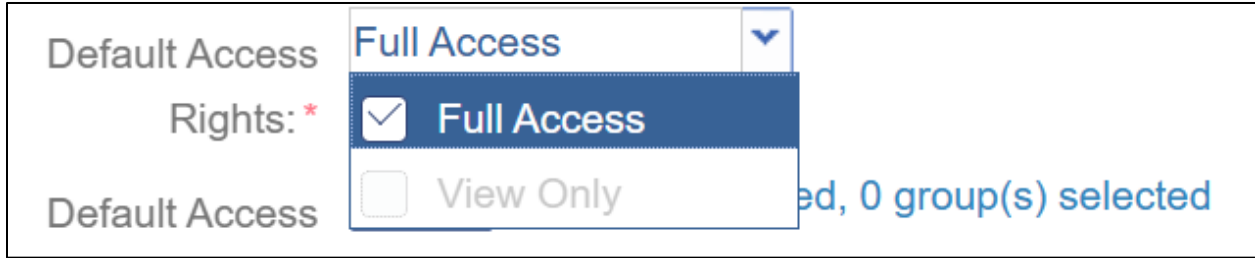
### 258. Default Access Rights and Members

This option allows users to enable default access rights and the members who possess them. To enable the default access rights, follow the steps below.

1. Click the checkbox available before the Enable Default Right Access option.

**Enable Default Access Rights**

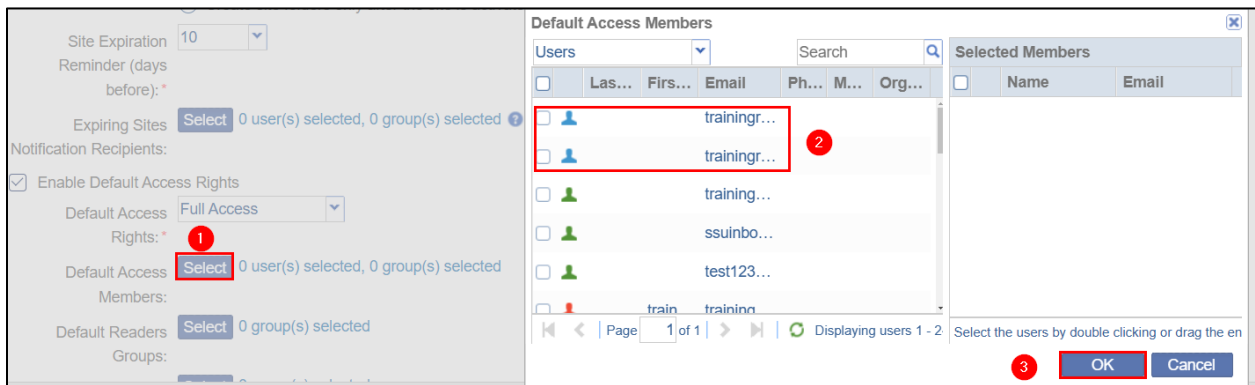
2. Access the Default Access Rights dropdown and select either Full Access or View Only.



### 259. Default Access Members

To add default access members, follow the steps below.

1. Click the Select button that opens the Default Access Members popup.
2. Double-click the users or drag and drop them to the right pane to add them to the Selected Members list.
3. Click on the OK button.

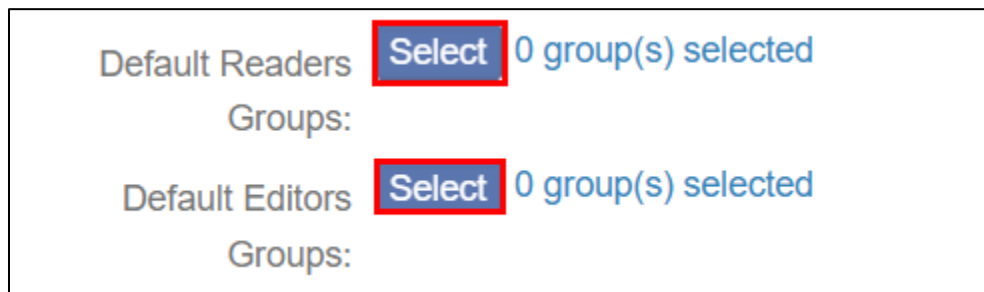


### 260. Default Readers and Editors Groups

These options allow you to set the default access to readers and editors groups.

To configure the default readers and editors' groups, follow the steps below.

1. Click the Select button available after the options Default Readers/Editors Groups.
2. Double-click the users or drag and drop them to the right pane to add them to the Selected Members list.
3. Click on the OK button.



### 261. Enable site users and site user template security

To enable this setting, click on the 'Enable site users and site user template security' checkbox.

Enable site users and site user template security

**!** Before you enable this setting, make sure the Site template folders are configured, and for each folder, the default security is assigned; and also the protected and staging folders are assigned.

## Configuring Countries to Data Room

### 262. Add Country

To add countries from where the sites will be enrolling to the study, follow the steps below.

1. From left hand navigation pane of the Settings module, expand the Countries option.
2. Click on the Countries option.
3. On the Countries screen, click on the +Add button.
4. On the Create Country form, select the Country\* from the dropdown options and specify the Room Contact in the respective field.
5. Click on the Create button once the required details are specified.

Country Name	Language
<input checked="" type="checkbox"/> Bahamas	English
<input type="checkbox"/> Belgium	Dutch, French, German
<input type="checkbox"/> Canada	English, French
<input type="checkbox"/> India	Hindi, English

**Create Country**

Country: \* Belarus

Room Contact #:

Create Cancel

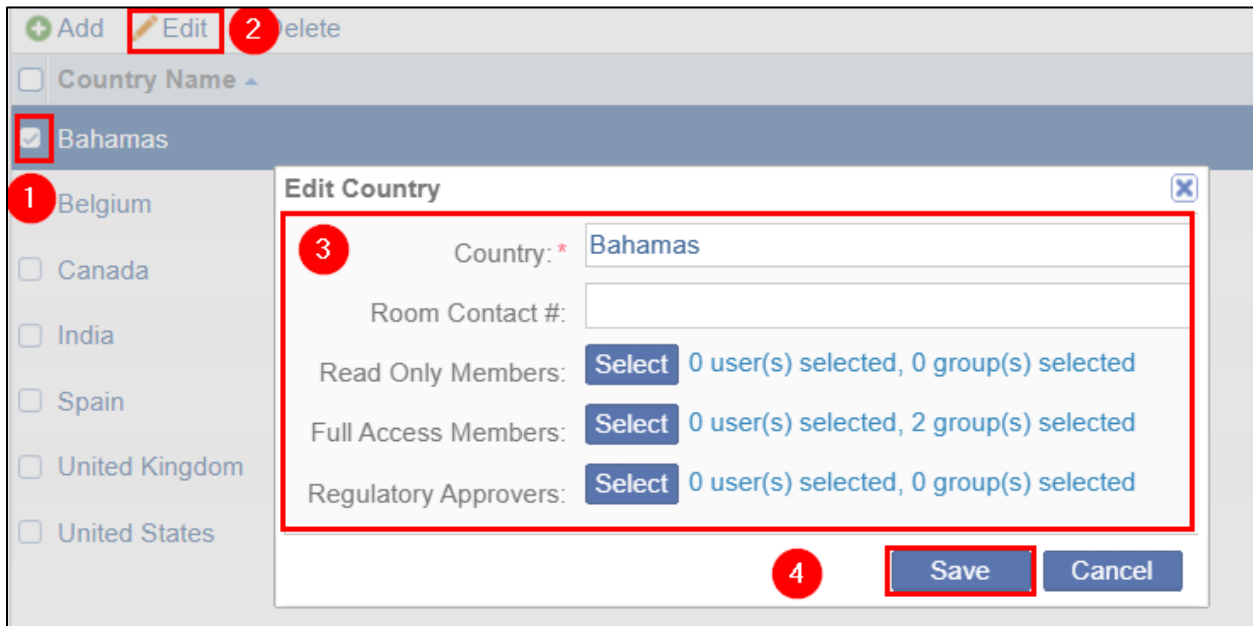
**Note:** Repeat the same procedure to add multiple countries.

### 263. Edit a Country

To edit a country, follow the steps below.

1. Select a country by clicking on the checkbox.
2. Click on the Edit button.
3. On the Edit Country screen, make edits to the following fields.

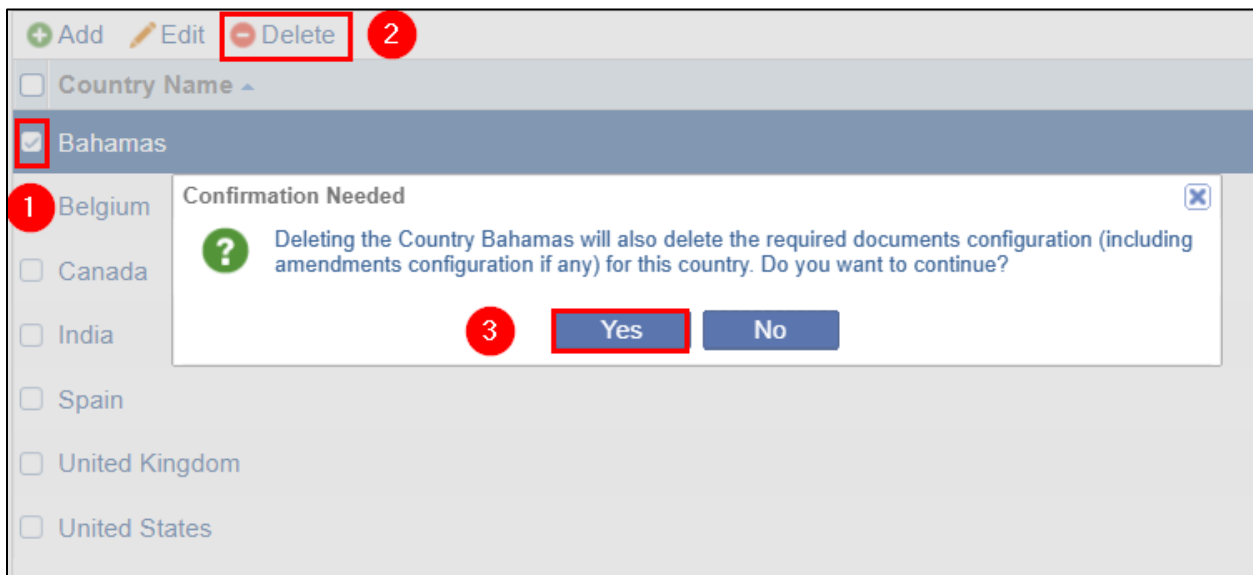
4. Click on the Save button.



## 264. Delete a Country

To delete a country, follow the steps below.

1. Select a country by clicking on the checkbox.
2. Click on the Delete button.
3. Click on the Yes button on the 'Confirmation Needed' popup.



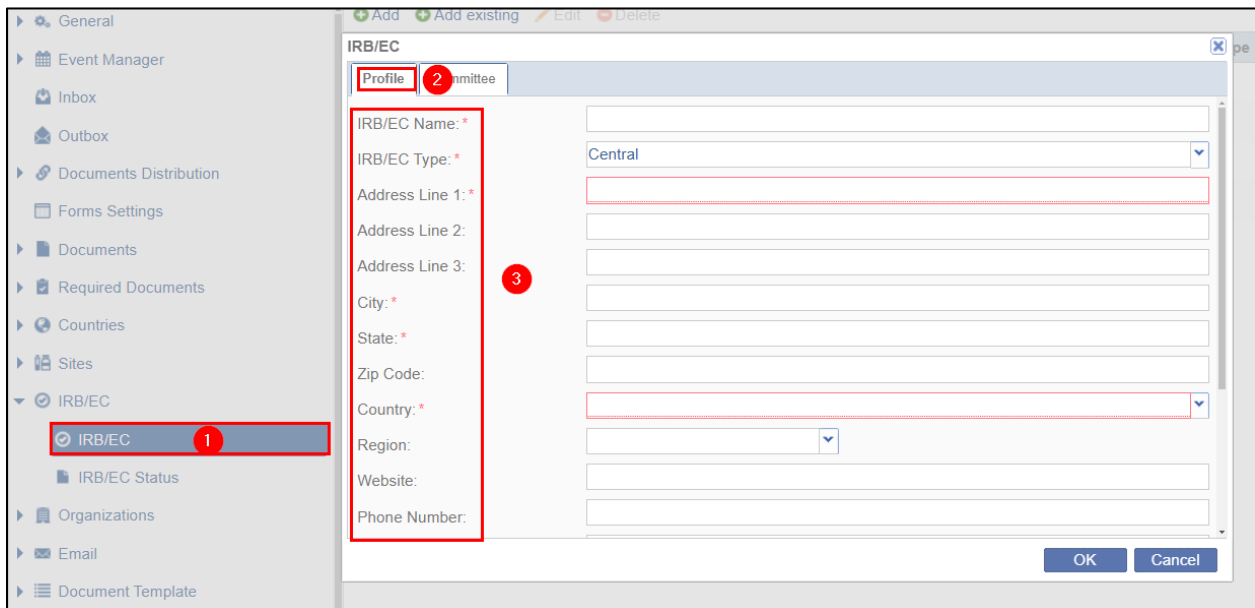


## Configuring IRB/EC

### 265. Add new IRB/EC

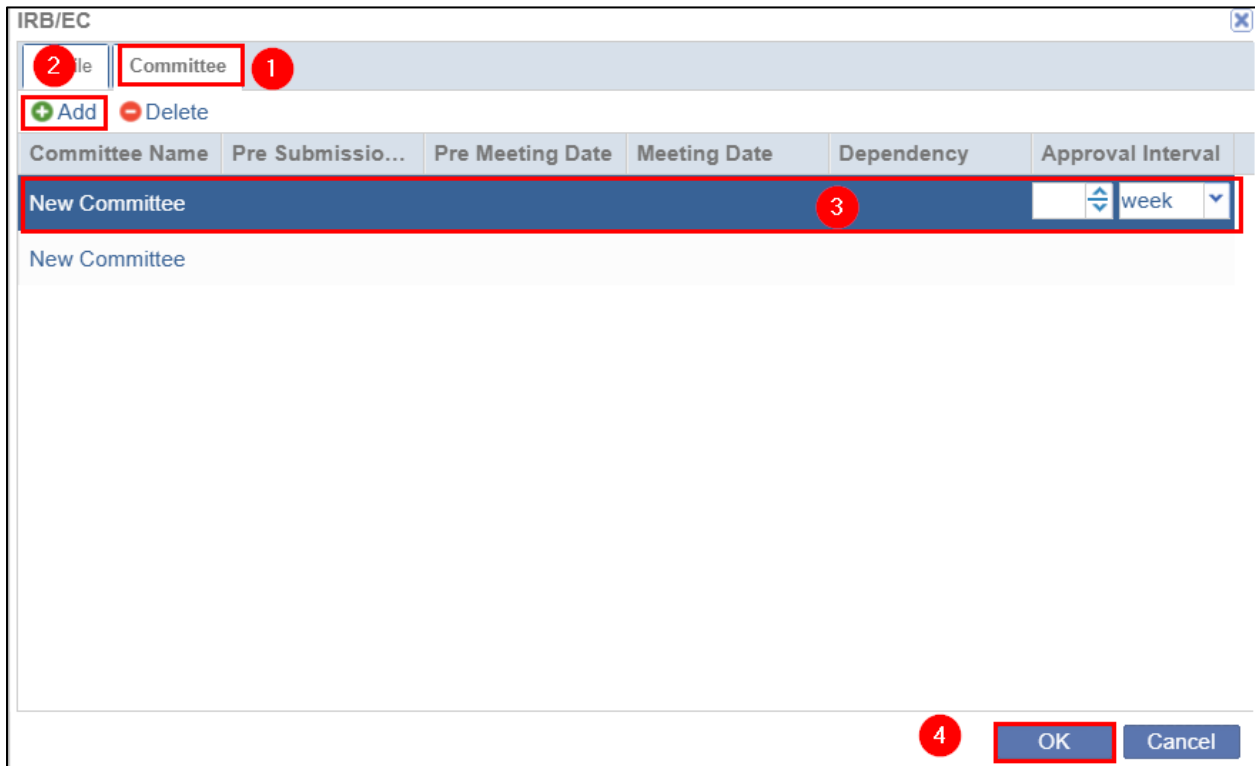
To add IRB/ECs as required by sites, follow the steps below.

1. From the left-hand navigation pane on the Settings screen, expand the IRB/EC setting and select the IRB/EC option.
2. Click on the **+Add** button from the top menu bar.
3. On the IRB/EC form, click on the Profile tab and enter the following details
  - a. IRB/EC Name: \*
  - b. IRB/EC Type: \*
  - c. Address Line 1: \*
  - d. Address Line 2:
  - e. Address Line 3:
  - f. City\*
  - g. State\*
  - h. Zip Code
  - i. Country\*
  - j. Region
  - k. Website
  - l. Phone Number
  - m. Email address
  - n. **Approval Cycle:** This is the IRB/EC's processing time and can be denoted in days/weeks/months.
  - o. **Buffer Time:** This is the extra time IRB/EC may need to approve the documents.
  - p. **Meeting Frequency:** This denotes the meeting frequency of the IRB/EC, which could be daily/weekly/monthly/yearly.
  - q. **Submission Deadline:** This denotes the submission deadline in the day/week/month/year before the IRB Meeting Date.



4. Click the Committee tab in the popup.
5. Click on the +Add button which will add a new row to an ethics committee named 'New Committee.'

6. Double-click each field in the row to enter the details for the committee
7. Click on the OK button.

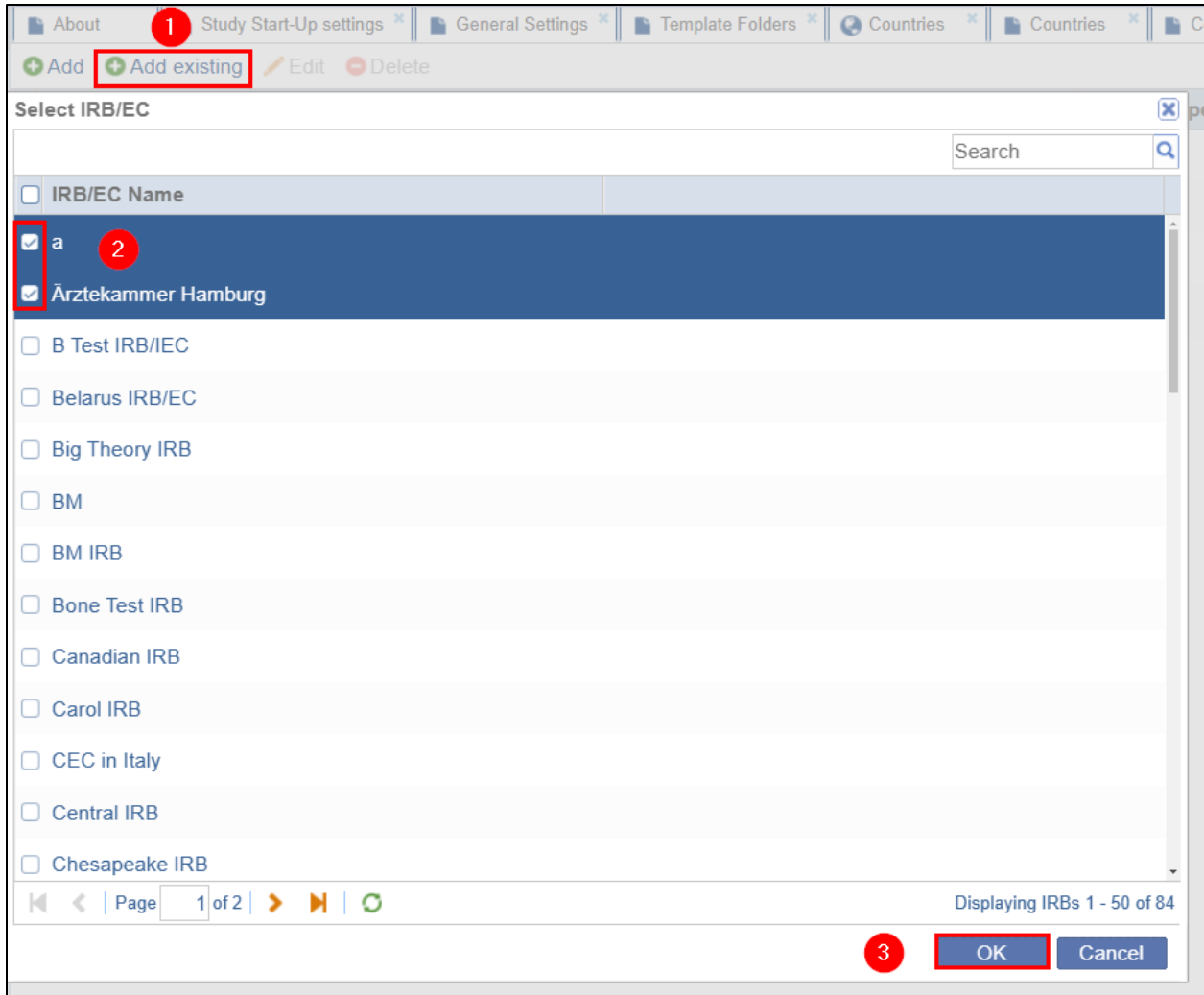


The screenshot shows a dialog box titled "IRB/EC" with a close button in the top right corner. At the top, there is a "Title" field containing the text "Committee". Below the title bar, there are two buttons: "+Add" and "-Delete". A table with the following columns is displayed: "Committee Name", "Pre Submissio...", "Pre Meeting Date", "Meeting Date", "Dependency", and "Approval Interval". The first row of the table is highlighted in blue and contains the text "New Committee" in the "Committee Name" column and "week" in the "Approval Interval" column. Below the table, the text "New Committee" is visible. At the bottom right of the dialog box, there are two buttons: "OK" and "Cancel".

## 266. Add Existing IRB/EC

To add an existing IRB/EC, follow the steps below.

1. On the IRB/EC page, click on the +Add Existing button.
2. Select the required number of IRB/EC's by clicking on the checkboxes.
3. Click on the OK button.



## 267. Edit an IRB/EC

To edit an IRB/EC, follow the steps below.

1. Select an IRB/EC by clicking on the checkbox.
2. Click on the Edit button.
3. Access the Profile and Committee tabs and make the required edits.
4. Click on the OK button.

## 268. Delete IRB/EC

To delete an IRB/EC, follow the steps below.

1. Select an IRB/EC by clicking on the checkbox
2. Click on the Delete button
3. Click on the Yes button on the Confirmation Needed popup.

## Setting Up Required Documents for Countries

For a user to upload collected essential documents for countries, the document types for the same need to be set up by the administrator.

To set up the required documents, follow the steps mentioned below.

1. From the left-hand navigation pane of the Settings module, expand the Required Documents setting and select the Required Documents option.
2. Click on the **Country Specific** tab.
3. Select a country by clicking on the respective checkbox to open the 'Required Documents' panel.

Entity Name	# of Docs
<input checked="" type="checkbox"/> Bahamas	4
<input type="checkbox"/> Belgium	1
<input type="checkbox"/> Canada	22
<input type="checkbox"/> India	20
<input type="checkbox"/> Spain	18
<input type="checkbox"/> United Kingdom	9
<input type="checkbox"/> United States	3

4. On the Document Types panel, click on the **+Add** button.

Document Ty...	Category	Languages	Contact	Requir...
Confidentiality ...	Site	(Not Set)	(Not Set)	Site Act...
Form FDA 1572	Site	(Not Set)	(Not Set)	Site Act...
PI Curriculum ...	Site	(Not Set)	(Not Set)	Site Act...
PI Financial Di...	Site	(Not Set)	(Not Set)	Site Act...

5. On the Required Documents form, select any one of the options by clicking on their respective radio buttons.

- **Investigative Site:** To submit investigative site documents specific to countries.
  - **Study:** To submit government-approval documents of the country.
6. Select documents as required from the collapsible tree structure listing the documents.
  7. Check any one of the following checkboxes from the 'Required For' section.
    - Site Activation
    - eTMF
  8. Add the required submitters in the 'To be Submitted by' field.
  9. Select the language from the 'Languages' dropdown.
  10. Click on the Save & Close.

**Required Documents**
✕

Country level documents and the documents to be provided by all the sites from the country (**Bahamas**)

Provided By:  Site 5  
 Study

🔍

▼

**All Document Types**

- ▼ **Site**
  - ▶  01 Trial Management
  - ▶  02 Central Trial Documents 6
  - ▶  COI
  - ▶  03 Regulatory
  - ▶  04 IRB or IEC and Other Approvals
  - ▶  05 Site Management

**Required For:**  
 Site Activation 7  
 eTMF

**Event Driven**  
 Event Driven

**To be submitted by:**  
 8  
 4 contact types selected ⓘ

**Languages:**  
 9

Save

Save & Close 10

Close

## 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 by the administrator. The Required Documents for Sites can also be set up from the Settings module.

To add the required documents for all Sites, follow the steps below.

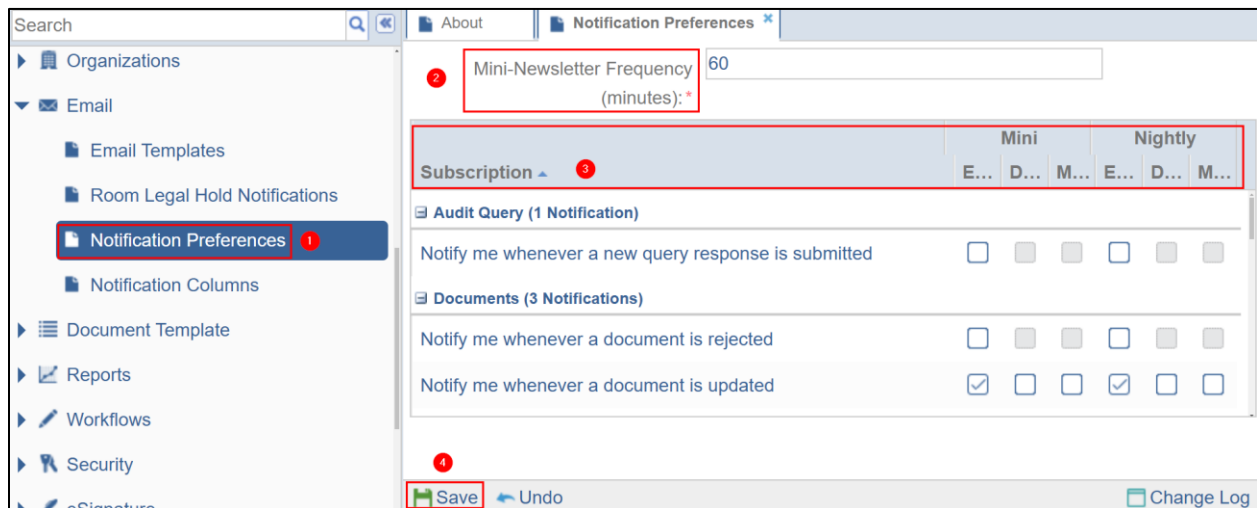
1. From the left-hand navigation pane of the Settings module, expand the Required Documents setting and select the Required Documents option.
2. Click on the **All-Sites** tab.
3. Perform the similar steps detailed in the [Setting Up Required Documents for All Countries](#) section.

## Setting Up Notifications

Contacts in SSU can receive notifications via emails for the regulatory packets sent out, for documents collected and approved, and for site activation. The administrator can set up notification preferences for Start-Up Documents and Regulatory Review

To setup notifications, follow the steps below.

1. From the left-hand navigation pane on the Settings Module, expand the Email dropdown and select Notification Preferences
2. Configure the Mini-Newsletter Frequency by entering the minutes in the respective field.
3. Enable or disable the options as required by selecting or deselecting the respective checkboxes.
4. Click on the Save button once the required options are enabled or disabled.



## Start Up Contacts

Once site information is entered in TI, the regulatory packet is sent to site members. If users are added to the Site Activation Member group, they can submit Essential/Required Documents to the SSU module for review by the

Start-Up Specialist and Regulatory Reviewer. As a Site Activation Member, a user can monitor the progress of Essential/Required Document collection and activate the site when needed.

The following are the various roles available in the SSU Module.

Role	Description
<b>Clinical Research Associate (CRA)</b>	A Clinical Research Associate (CRA) is responsible for conducting clinical trials and managing key site-related functions, including site initiation, protocol compliance, site visits, adherence to good clinical practices, data integrity, and ensuring the protection and safety of study participants. During site visits, the CRA adds documents to the site. To be designated as a CRA at a site, they must have editor access in the room.
<b>Start-Up Specialist</b>	As part of the Site Activation Member group, the Start-Up Specialist serves as the initial reviewer of SSU documents. Documents can be sent to a specific SSU email, imported, or individually attached in Trial Interactive. The Start-Up Specialist reviews each document, approving or rejecting it, and forwards it to the Regulatory Reviewer for final review. After the Regulatory Reviewer approves all Essential/Required Documents at each site, the Start-Up Specialist will activate the site. A Start-Up Specialist can hold either Editor or Admin access in the room
<b>Regulatory Approver</b>	The Regulatory Approver is the final reviewer of SSU documents. (Email notifications can be configured to alert the Regulatory Approver when documents are pending review.) The Regulatory Approver reviews each document in the Regulatory Review section of the SSU module, approving or rejecting as necessary.
<b>Other Site Contacts</b>	Besides the ones mentioned above, various other site contacts can be added to a sit. Some of them are mentioned below: <ol style="list-style-type: none"> <li>1. Principal Investigator</li> <li>2. Sub-Investigator</li> <li>3. Pharmacy Contact</li> <li>4. Laboratory Contact</li> <li>5. Contracts Contact</li> <li>6. Finance/Budget Contacts</li> <li>7. Co-Investigator</li> <li>8. Research Specialist</li> </ol> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• A Principal Investigator is the most important contact for a site, as sites cannot be created without a Principal Investigator.</li> <li>• 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.</li> </ul>

## Inviting Contacts and Managing Security

The world of clinical trials involves many users whose responsibilities range from handling various complex procedures to users who only review and sign documents on a site. To enable them 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 to a 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 specific roles in a site?
3. Does the user need to oversee the complete site activities, or is it enough for the user to only be a contact 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 members to enable them to carry out their responsibilities:

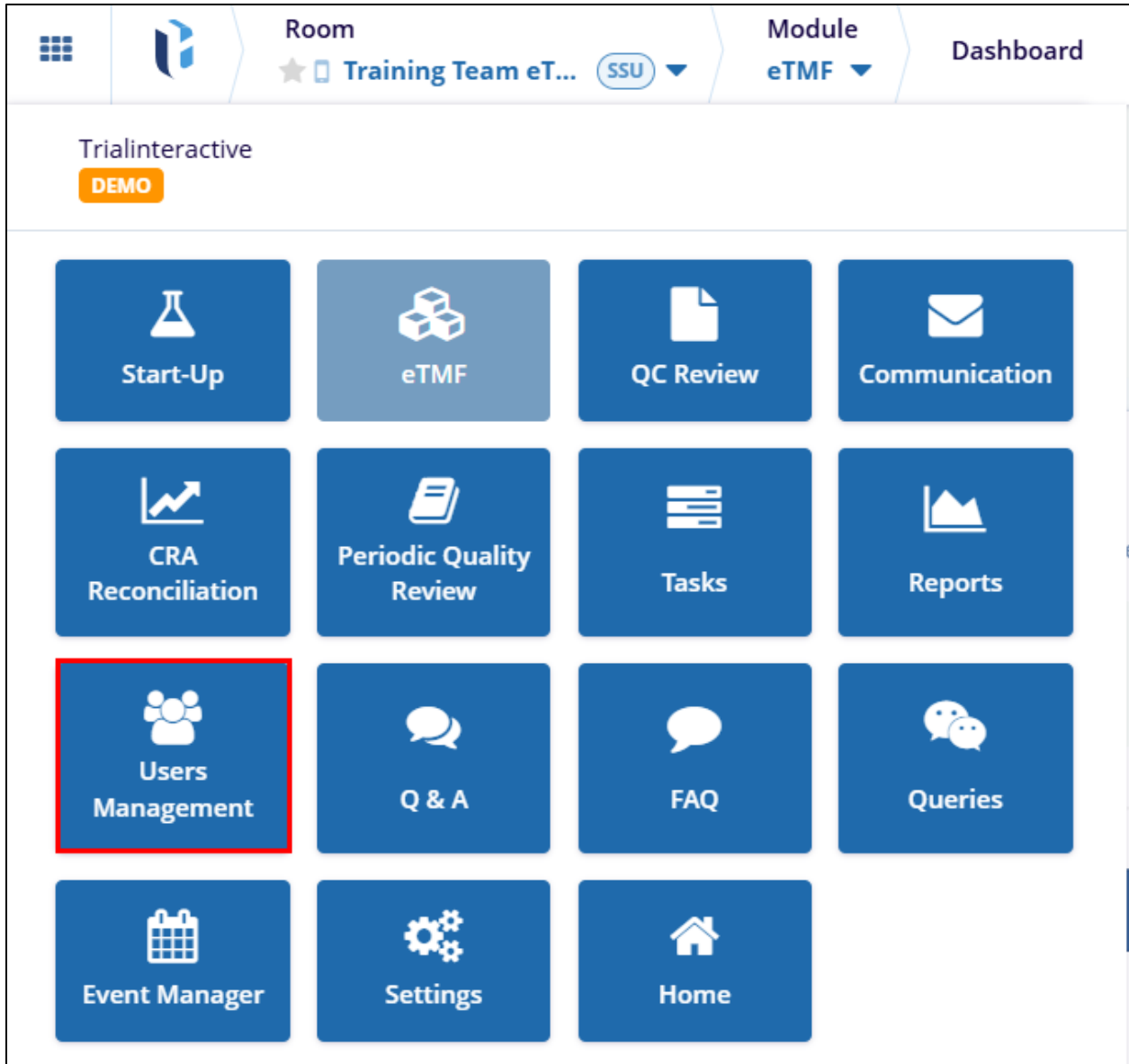
1. It allows two security privileges to be assigned to users – Editor and Reader.
2. A reader is allowed read-only access, whereas an editor can perform various other advanced functionalities like adding documents and sending documents for review to activating sites.
3. An Admin is a privileged role and is assigned to users only in specific cases discussed later in this guide.

The security privileges can be assigned at two levels.

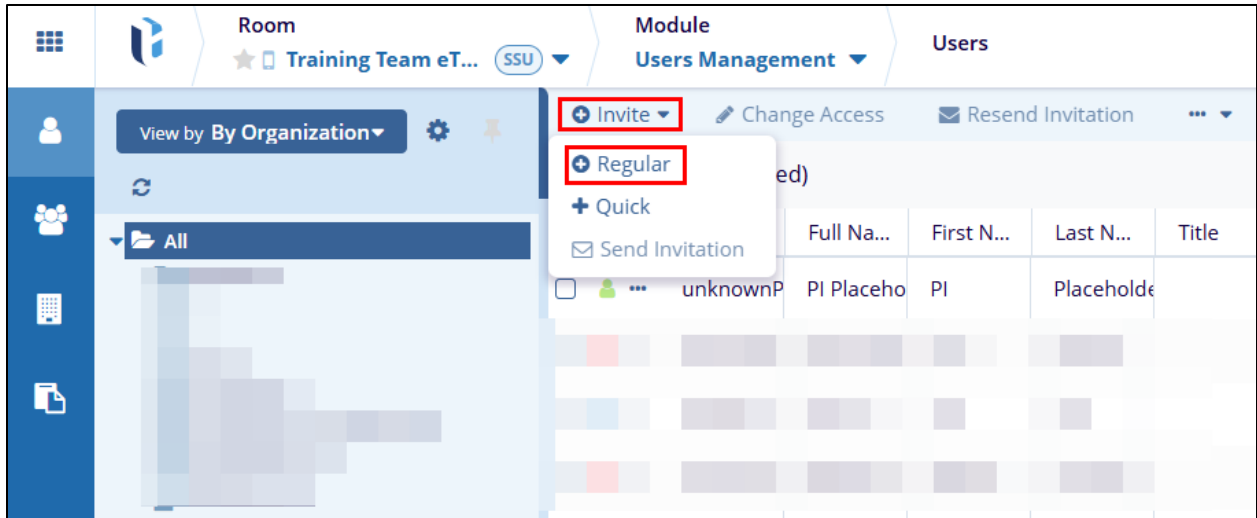
**At Room Level:** To assign privileges to a user in a room, the admin has to provide access to the user by inviting the user to the room. On inviting, the user receives an invitation mail in their registered email ID to join the room.

To add users at the room level as an admin, follow the steps below.

1. Login to TI and enter the room.
2. Click on the Waffle menu and select Users Management module.



3. Click on the **+Invite** button and select the **+Regular** option.



4. On the User Invitation form, mandatorily add the following details
  - a. Role
  - b. Company
5. Once these details are entered, add Study startup in the Actions field.
6. Click on the Save button once all the details are entered.

### User Invitation

**User** Groups

Email \*

First Name  Middle Name  Last Name

Title  Prefix  Suffix

Role\* Editor Company\* transperfect.com

**Invitation Details**

Expiration Date

Room time zone: Eastern Standard Time [(UTC-05:00) Eastern Time (US & Canada)]

Actions Study Startup

Cancel Save

**Note:** For Study Start-Up roles, the user needs to at least be an Editor and above in the room.

**At Site Level:** Within a site, the following types of users can be added as site contacts:

- Users belonging to a room to which the site belongs.
- Users belonging to a room to which the site does not belong.
- 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.

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 be added 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 on a site. To make things easy, you can directly add the user 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).
- 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.

## Accessing Study Startup Module

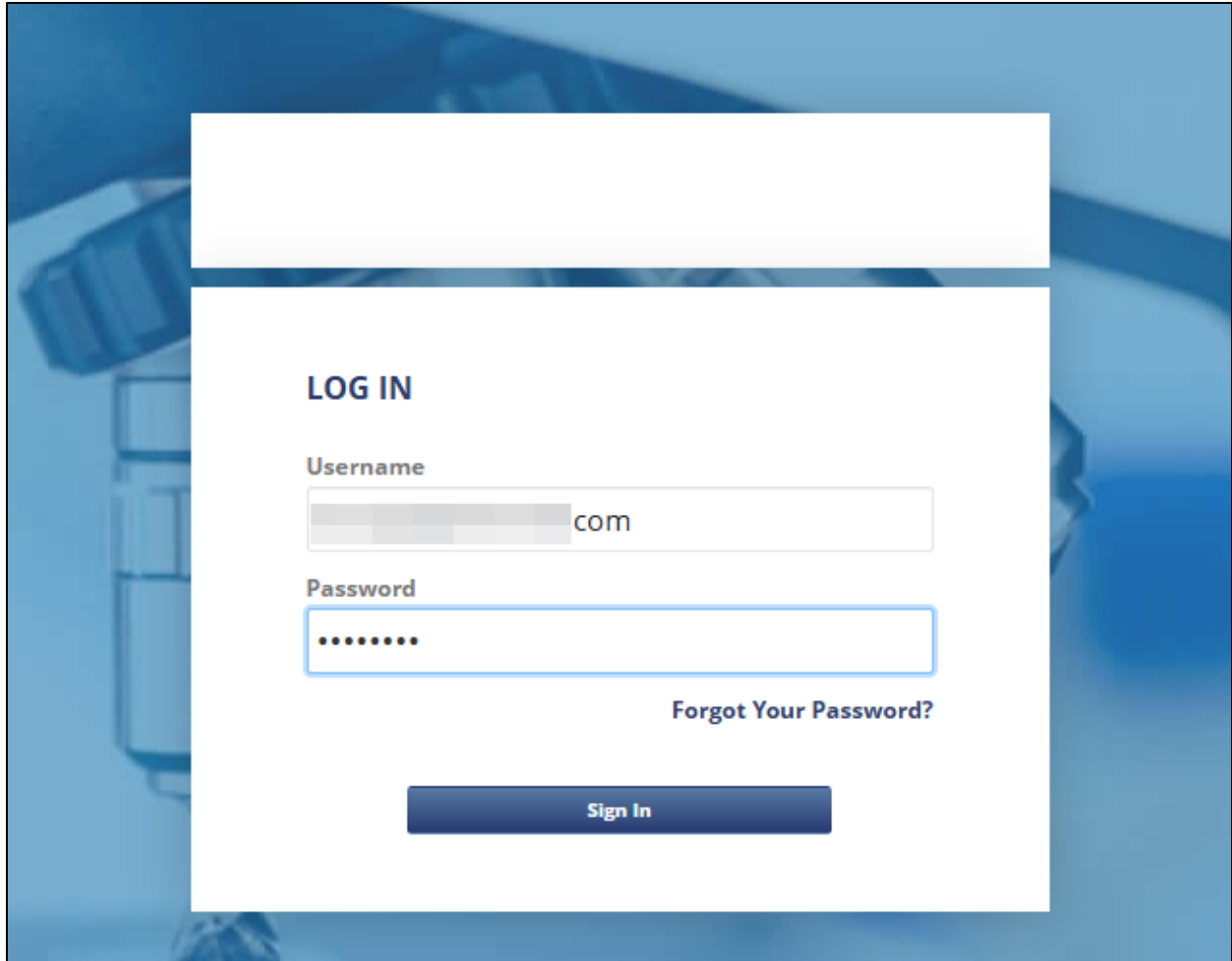
Once the basic settings and contacts are configured for Study Start-Up, users can now move forward to operate the module. The Study Start-Up Module comprises the following topics.

1. Accessing the Study Start-Up Module
2. The SSU User 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

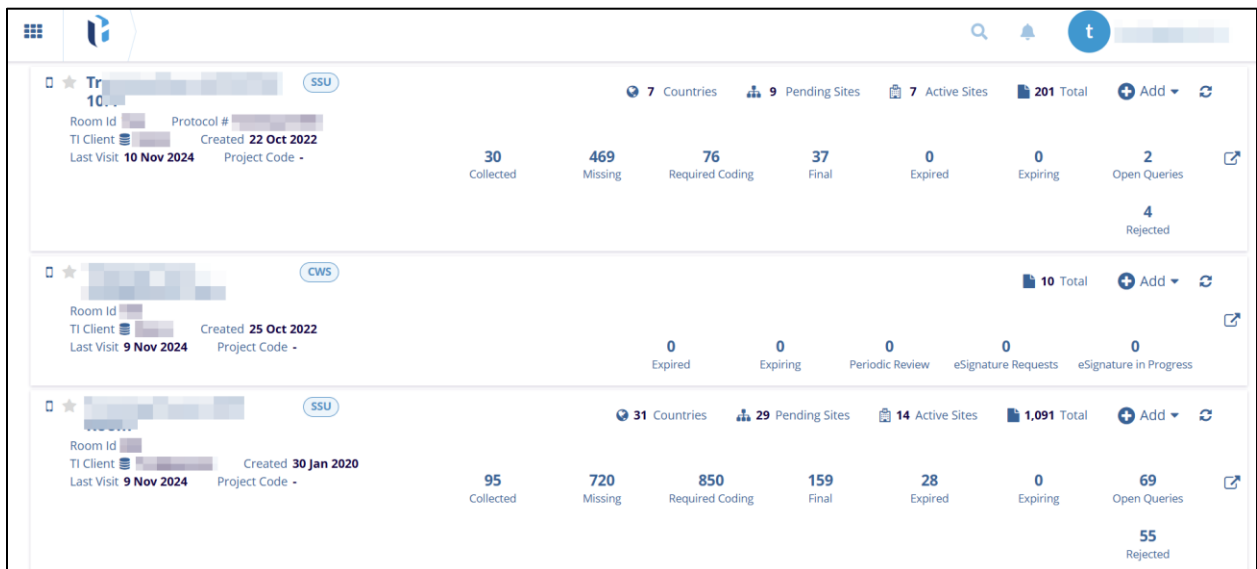
Each of these topics with their subtopics is described in detail in the subsequent sections.

To access the Study Startup module, follow the steps below.

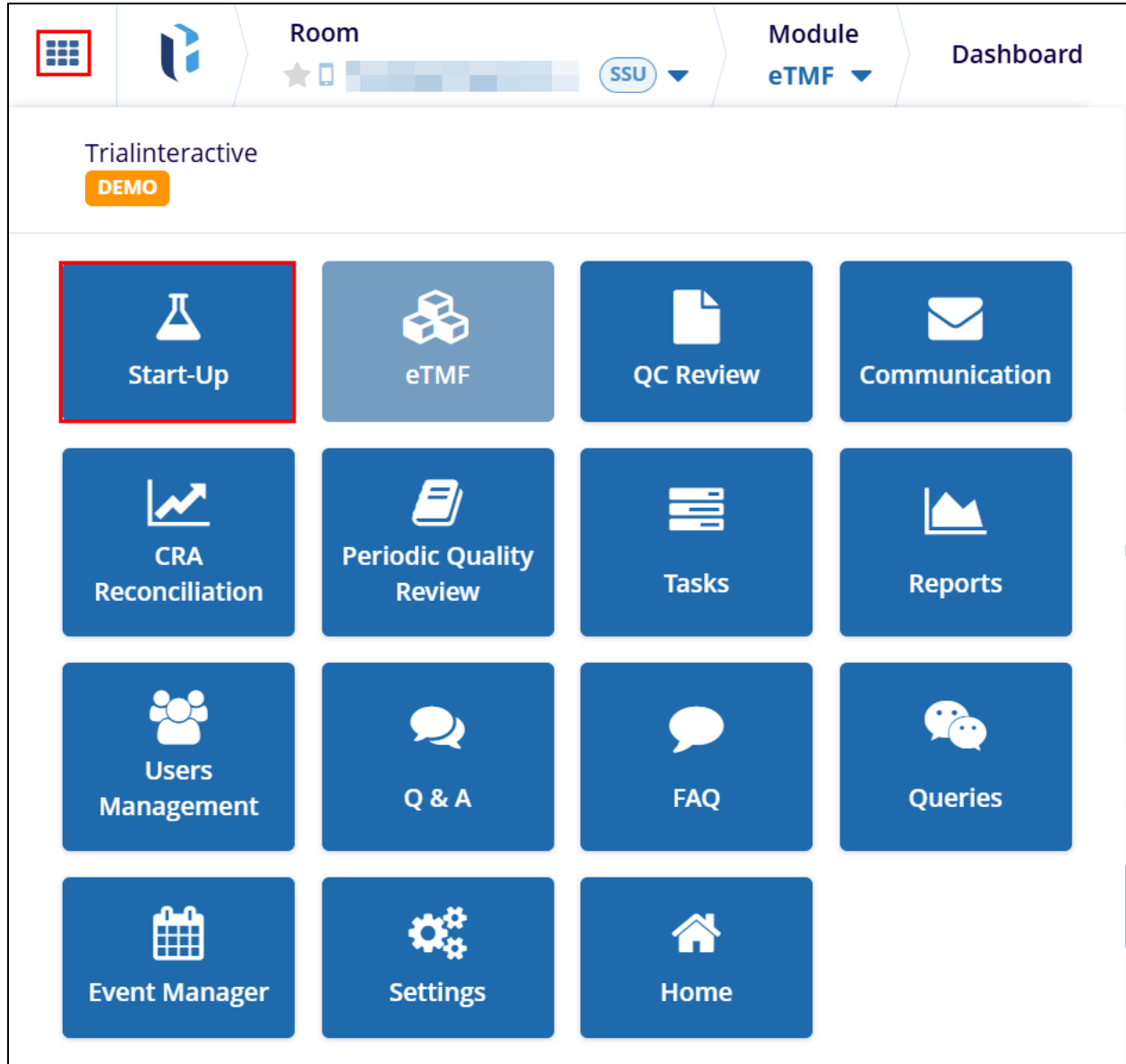
1. Login to Trail Interactive using the application link.



2. Click on a room.



- On the rooms landing page, click on the Waffle menu and select the **Start-UP** option.



- The Start-Up module opens with relevant dashlets and modals

### SSU User Interface

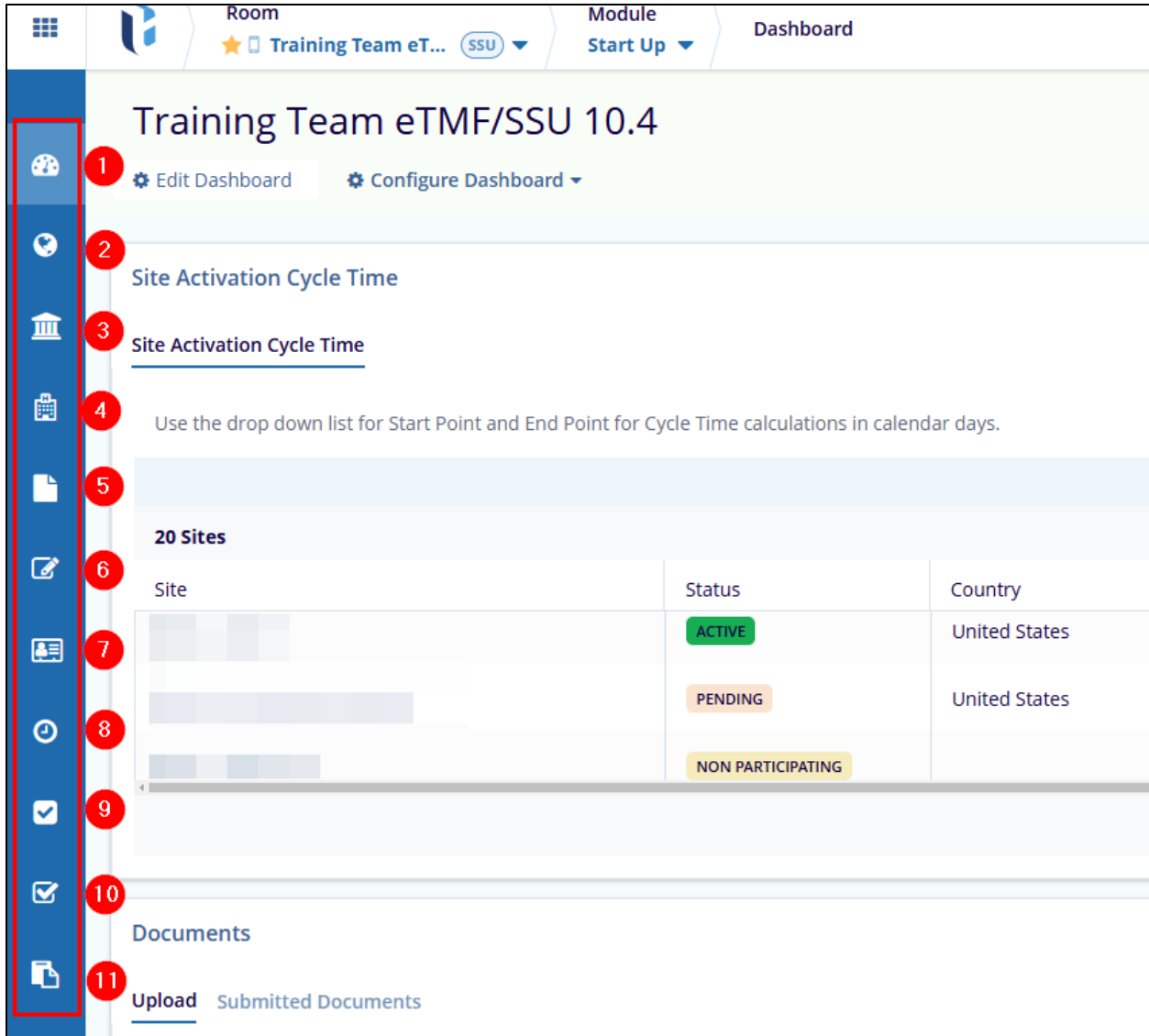
The SSU Module in Trial Interactive (TI) provides a streamlined platform for creating, monitoring, and activating sites essential for clinical trials. Through this interface, users can add, upload, and track the progress of documents needed for site activation, as well as review them.

Refer to the table below to understand various modals and options available in SSU.

Sr No	Modal	Description
1	Dashboard	Users have the ability to manage and edit the dashboard.

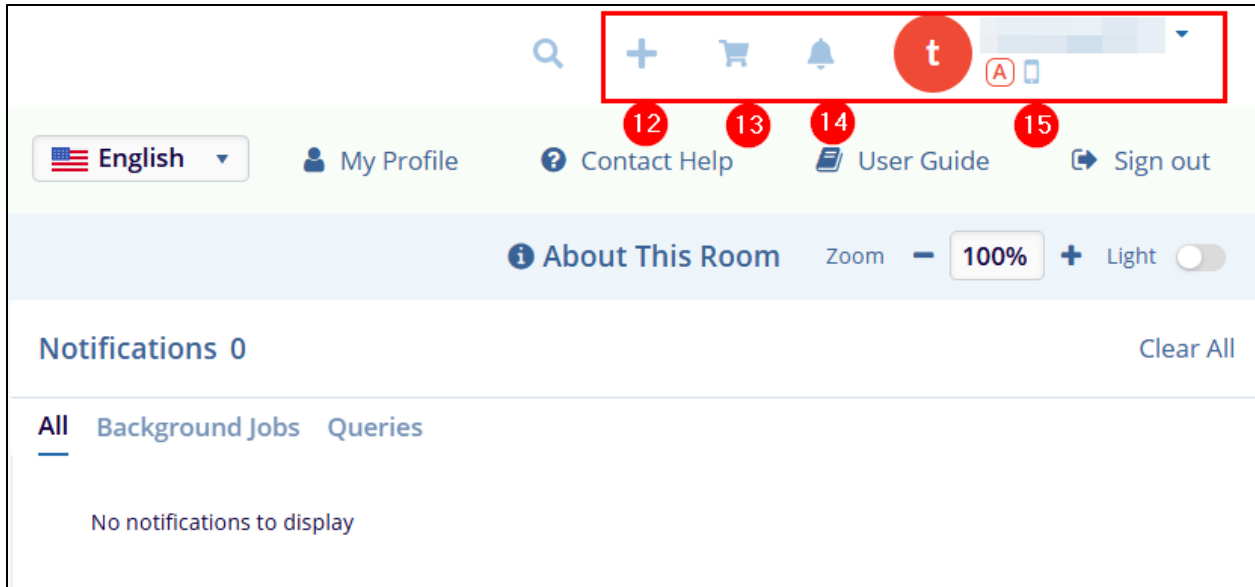
2	Country	Here, users can view and edit the country profile, as well as collect and review documents associated with each country.
3	IRB/EC	Here, users can view and edit the IRB/EC profiles, collecting and reviewing documents specific to each IRB/EC.
4	Sites	In this section, users can create sites and contacts, filter views by status, country, start-up specialist, IRB/EC, and CRA, and perform actions such as exporting, importing, deleting, and editing sites. It also allows mass coding of site metadata, adding documents, sending regulatory packets, and managing contact security within sites.
5	Documents	Here, users can view, add, and track all documents collected at the SSU site.
6	Amendments	Users can add, view, and apply filters to amendments displayed in the grid.
7	Contacts	In this section, users can view contact details based on their access level at the site.
8	Communication Log	Here, users can view, add, delete, and edit the communication log according to their SSU access level at the site.
9	Regulatory Review	Users with regulatory reviewer access can review documents assigned to them.
10	Sponsor Review	Users with sponsor reviewer access are able to review their assigned documents
11	Audit Trail	This section allows users to view the audit trail for all documents uploaded and processed within the SSU.





Additionally, users can access the following options from the top menu bar.

Sr No	Action	Description
12	Add	Users can add the following accessing this option <ul style="list-style-type: none"> <li>• Documents</li> <li>• User</li> <li>• Task</li> <li>• Site</li> </ul>
13	Documents Cart	All documents added to the cart can be viewed here.
14	Notifications	Users can view the notifications here.
15	Username Dropdown	With the User name dropdown, users can access the following <ul style="list-style-type: none"> <li>• Language Settings</li> <li>• My Profile</li> <li>• Contact Help</li> <li>• User Guide</li> <li>• Sign Out</li> </ul>



## Dashboard

The Overview Dashboard, which consists of a number of different dashlets, 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.

## Site Activation Cycle Time

The Site Activation dashlet provides an overview of the available sites with their status in the SSU module. 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.

- Input filter for start and end points for calculations.
- Heat map to highlight performing and under-performing sites.
- Option to export the data.



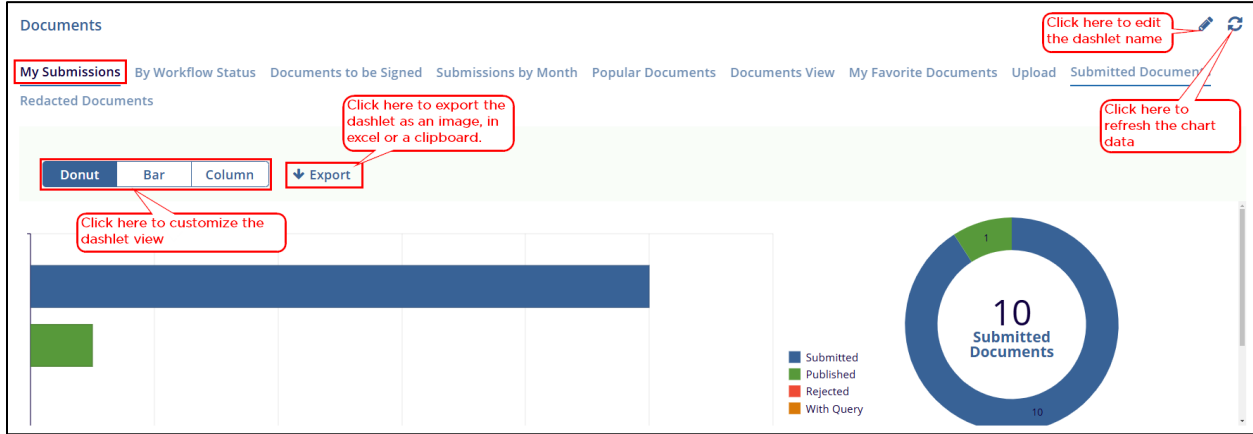
## Documents

The Documents dashlet provides an overview of the documents with the following tabs.

**Note:** Only those tabs are displayed in this dashlet that were configured within the Edit Dashboard section.

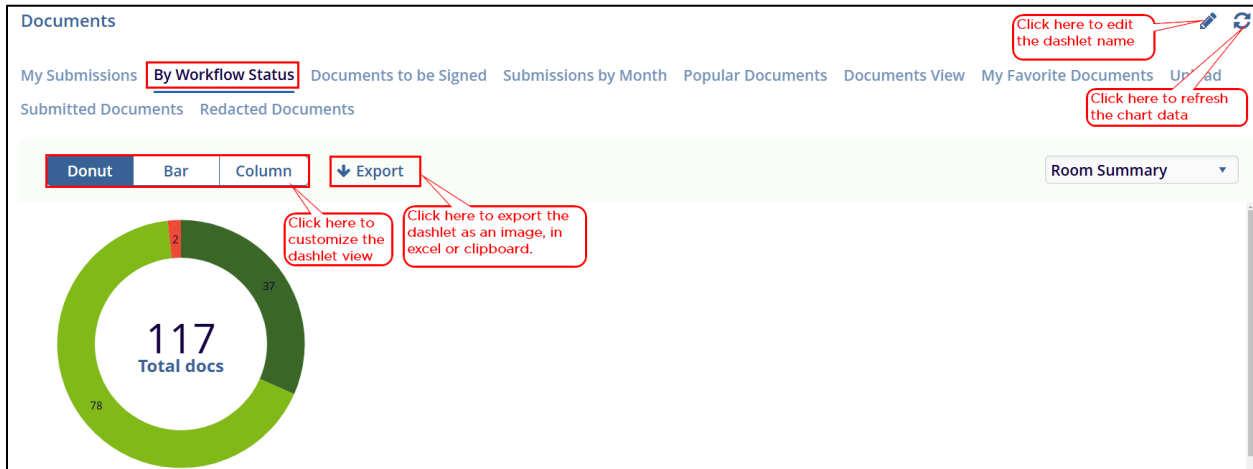
### 269. My Submissions

This dashlet displays the documents submitted by the user in a form of donut chart.



### 270. By Workflow

This dashlet 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.



### 271. Documents to be signed

This tab displays the documents in a grid pane that are to be signed by that specific user.

My Submissions By Workflow Status **Documents to be Signed** Submissions by Month Popular Documents Documents View

My Favorite Documents Upload Submitted Documents Redacted Documents

1 - 4 of 4 (0 selected)

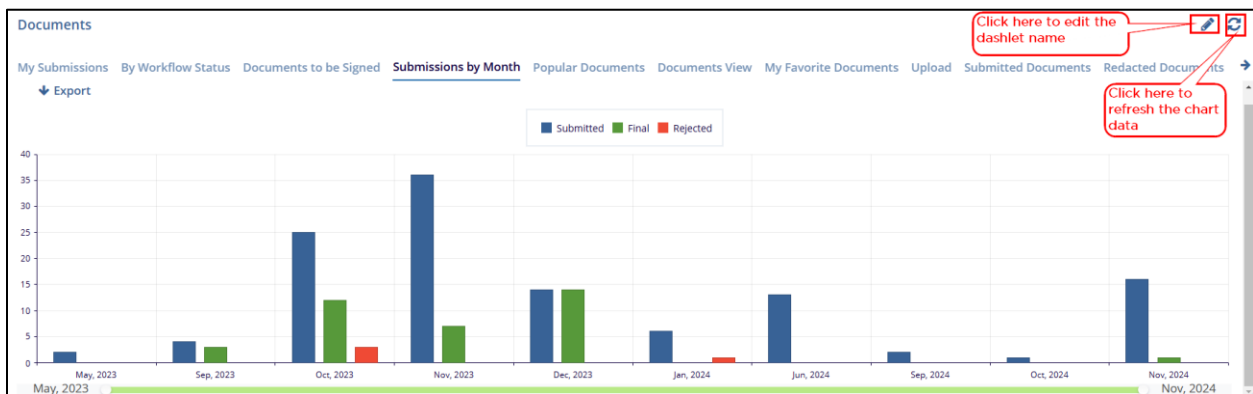
Submitted Name	Signers
<input type="checkbox"/> →  Prot_000	
<input type="checkbox"/> →  F01-202-S01 Protocol Signature Page	
<input type="checkbox"/> →  Dr. K 1572	
<input type="checkbox"/> →  Contact Details_List	

[Click here to refresh the chart data](#)
[Manage Columns](#)
[Views](#)

[Click here to add or remove the dashlet columns](#)
[Click here to customize the dashlet views](#)

## 272. Submissions by Month

This tab displays a graph bar for the submissions done in the last six months.



## 273. 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.

My Submissions By Workflow Status Documents to be Signed Submissions by Month **Popular Documents**

Documents View My Favorite Documents Upload Submitted Documents Redacted Documents

1 - 2 of 2 (0 selected)

Remove from Popular

Click here to refresh the dashlet data

Click here to add or remove the dashlet columns.

Manage Columns

Views

Click here to customize dashlet views

Submitted Name	Category
aha_list_features_231...	

## 274. Documents View

This tab displays the documents in a grid pane with a selection tab for – Unread, Unclaimed, and Pending.

My Submissions By Workflow Status Documents to be Signed Submissions by Month Popular Documents **Documents View**

My Favorite Documents Upload Submitted Documents Redacted Documents

Unread Unclaimed Pending

Click here to switch between the tabs.

Click here to refresh the dashlet data

Manage Columns

Views

Click here to manage dashlet columns

Click here to customize the dashlet views

Submitted Name	Document Date	Index	Document Comments
Minute of Meeting - 2nd Ma...	26 Oct 2023	Site\Site - 1234 A A\05 Site ...	
Minute of Meeting - 2nd Ma...	09 May 2023	Site\Site - 1234 A A\05 Site ...	
Prot_000	27 Sep 2023	Country \Canada\04 IRB or ...	

## 275. My Favorite Documents

This tab displays the documents that are marked as favorites by the user.

My Submissions By Workflow Status Documents to be Signed Submissions by Month Popular Documents

Documents View **My Favorite Documents** Upload Submitted Documents Redacted Documents

Select a document and access these options to perform the corresponding action.

Export Edit Comments Remove Comments Remove from Favorites

0 - 0 of 0 (0 selected)

Click here to refresh chart data

Manage Columns

Views

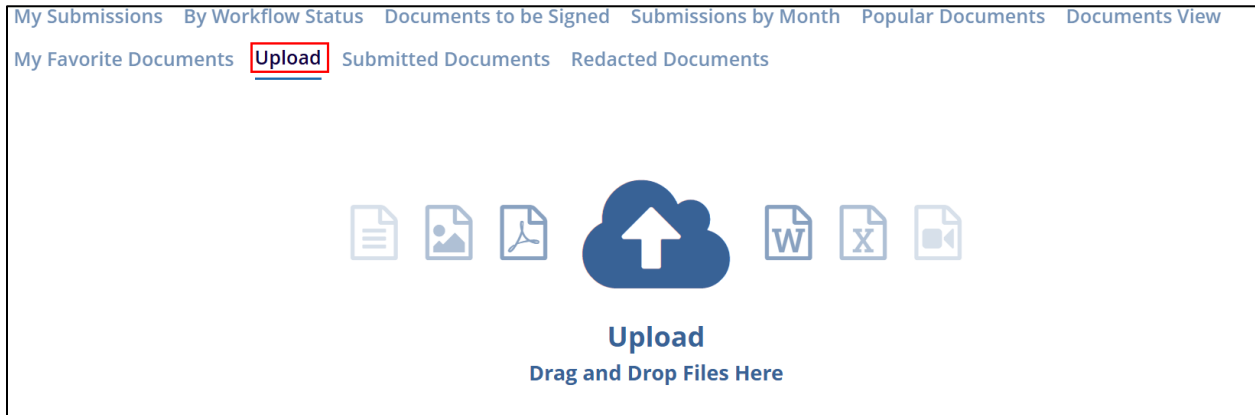
Click here to add or remove the dashlet columns.

Click here to customize dashlet views.

Submitted Name	Index	Comment

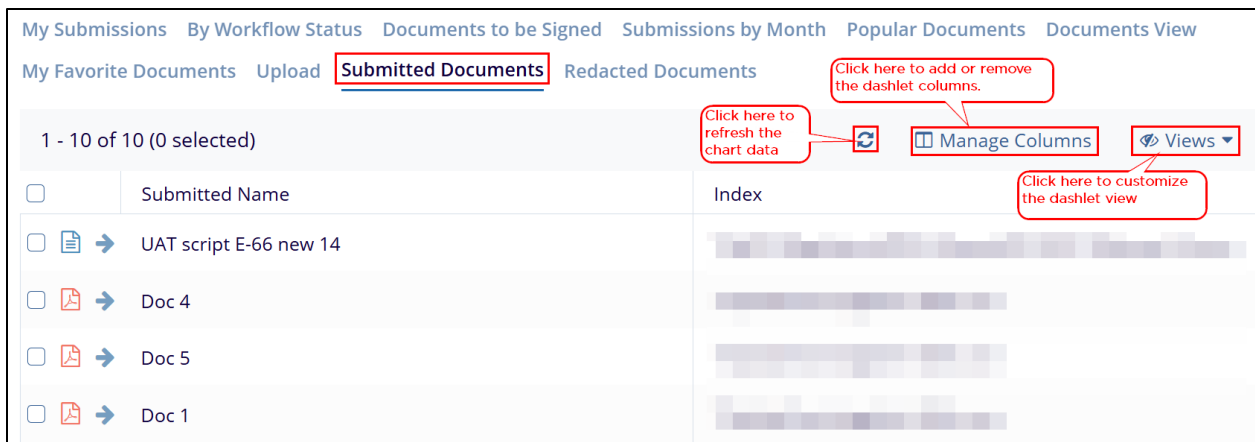
## 276. Upload

This dashlet allows the user to drag & drop or manually upload the document in the designated area.



## 277. Submitted Documents

This dashlet displays the documents that the user submits.



## 278. Redacted Documents

This tab displays the documents that the user redacts.

My Submissions By Workflow Status Documents to be Signed Submissions by Month Popular Documents →

Documents View My Favorite Documents Upload Submitted Documents **Redacted Documents**

Click here to switch between the tabs. **Not Yet Started Redaction** In Progress Completed

0 - 0 of 0 (0 selected) Click here to refresh the chart data **Manage Columns** **Views** ▼

<input type="checkbox"/>	Submitted Name	Document Date	Index	Document Comments

Click here to manage the dashlet columns. Click here to customize the dashlet view.

### 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.

**Recent Communication Log**

View All Communication Log

21 Communication Logs

Date	Type	Description	Contact Name	Communication En...
25 Jan 2024	Regula...	E-Delivery of Reg. pack to the site	Principal Investigator	Demo Site 10.5
12 Oct 2023	Regula...	E-Delivery of Reg. pack to the site	PI Placeholder	Test Site #2
11 Dec 20...	Phone	na	PI Placeholder	Amendment 2024

Clicking the **View All Communication Log** button redirects the user to the Communication Log page of the SSU module.

**Communication Log**

View By Communicati... Columns  Layout

21 Logs Filters Views ▼

<input type="checkbox"/>	Contact Date	Communication Ty...	Created By	Description	Communication En...	Next Contact Date	Contact Name
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
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<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							

All 21  
 Email 3  
 Phone 2  
 Regulatory Packet Delivery 16

## 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:** Tabs configured within the Edit Dashboard section are visible here.

### 279. Expiring Sites

This tab displays the sites that are going to expire.

**Investigative Sites**

**Expiring Sites** | Site Health (CRA) | Recently Updated Sites | Site Activation Status | E-Feasibility by Country

Study Monitoring Visits

0 - 0 of 0 (0 selected)

Click here to refresh the dashlet data | Click here to add or remove the dashlet columns | Click here to customize dashlet views

Expiration Date	Site	Principal Inve...	Status	Main Contact	Main Contact ...
-----------------	------	-------------------	--------	--------------	------------------

### 280. Site Health CRA

This tab displays the health of a site in a Donut, Bar, or 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.

**Investigative Sites**

Expiring Sites | **Site Health (CRA)** | Recently Updated Sites | Site Activation Status | E-Feasibility by Country | Study Monitoring Visits

Donut | Bar | Column | Export | All Sites

Completion Percentage	Count	Status
0%	0 of 13	Complete
0%	0 of 27	Complete
0%	0 of 16	Complete
9%	2 of 22	Complete
7%	3 of 45	Complete
1%	1 of 153	Complete

### 281. Recently Updated Sites

This tab displays the sites that the user recently updated. The sites are displayed in the grid with the Site Name, Principal Investigator, Status, and Progress columns. The user can Edit the dashlets name, Refresh, Manage Columns, and save Views for this tab. Clicking the View All Sites button displayed in the right corner redirects the user to the Sites page of the SSU module.



Expiring Sites Site Health (CRA) **Recently Updated Sites** Site Activation Status E-Feasibility by Country Study Monitoring Visits

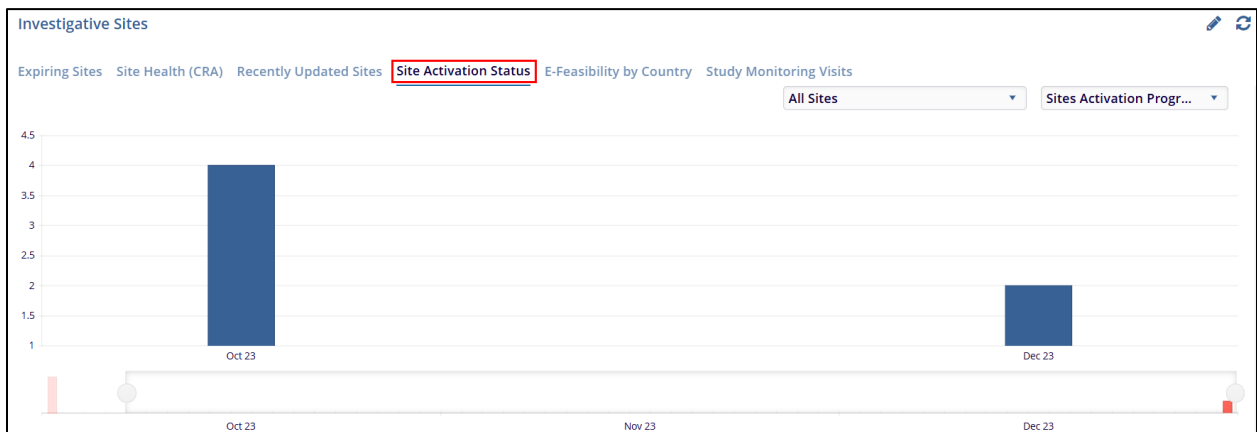
[View All Sites](#)

1 - 20 of 20 (0 selected) Manage Columns Views

Site	Principal Investigator	Status	Progress %
Site - Admin 103	Admin 103	Selected	<div style="width: 7%;"><div style="width: 7%;"></div></div> 7
USA 001 PI Placeholder	PI Placeholder	Active	<div style="width: 100%;"><div style="width: 100%;"></div></div> 100

## 282. 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.



Click on the bar view data at the individual month level.

Expiring Sites Site Health (CRA) Recently Updated Sites **Site Activation Status** E-Feasibility by Country Study Monitoring Visits

Oct 2023 > **Site Activated** All Sites Sites Activation Progr...

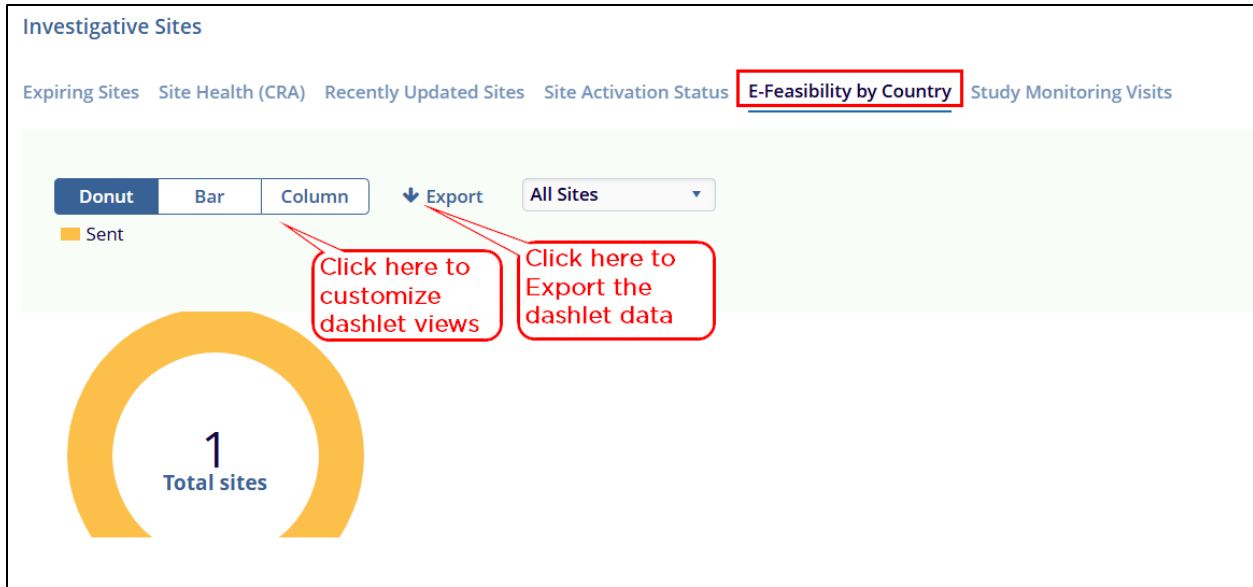
1 - 4 of 4 (0 selected) Manage Columns Views

Site	Progress %	Site Activation Date
<input type="checkbox"/> USA 001 PI Placeholder	<div style="width: 100%;"><div style="width: 100%;"></div></div> 100 %	
<input type="checkbox"/> Site - 004 PI	<div style="width: 100%;"><div style="width: 100%;"></div></div> 100 %	
<input type="checkbox"/> Site - 004 PI	<div style="width: 100%;"><div style="width: 100%;"></div></div> 100 %	
<input type="checkbox"/> Site - 002 PI Placeholder	<div style="width: 100%;"><div style="width: 100%;"></div></div> 100 %	12 Dec 2023

Previous 1 of 1 Next

## 283. E-Feasibility by Country

This tab displays the E-Feasibility by Country.





## 284. Study Monitoring Visits

This tab displays an overview of the past six months of the monitoring visits. The tab displays the data in a Donut, Bar, or 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.




## 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.

Common  

[About This Room](#) [Bulletin Board](#) [Project Links](#) [My Courses](#) [Tasks](#) [FAQ](#) [Q&A](#)

 Edit

---

Welcome to the  This Trial Interactive room is a place for secure eTMF and Study Information. You will be able to access the documents according to the participation privileges assigned to you.

You will need Adobe's Acrobat Reader software version 7.0 or later to view many of the documents in Trial Interactive. [Click here to get it.](#)

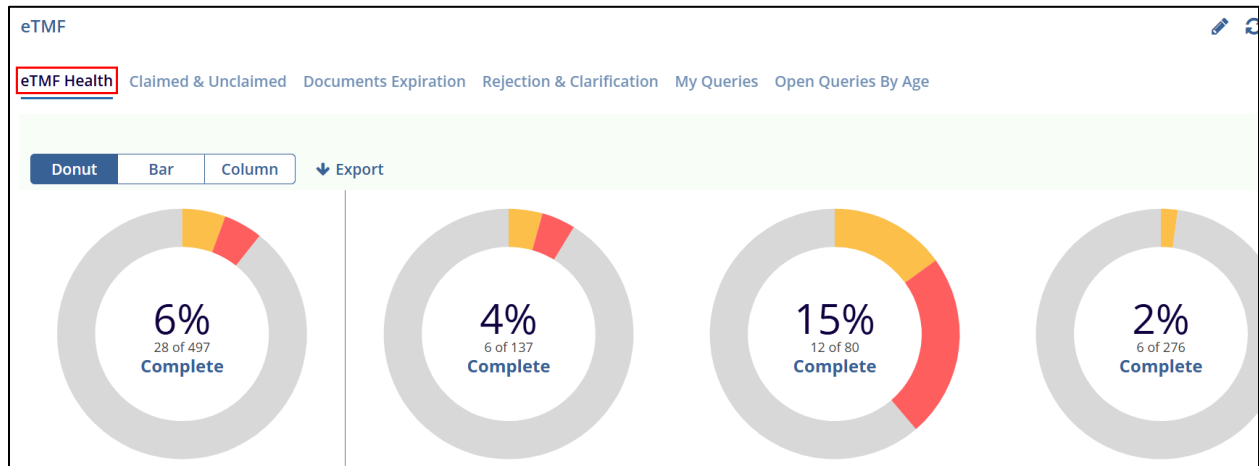
If you require technical assistance accessing a site, please email [help@trialinteractive.com](mailto:help@trialinteractive.com)

Dashlet	Description
<b>Bulletin Board</b>	The administrators set this up to provide messages to the team, which can be information regarding a room or problems within a study. Administrators and managers can edit it.
<b>Project Links</b>	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.
<b>My Courses</b>	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 that, when clicked, will take the user to that course in Global Learn.
<b>Tasks</b>	<p>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.</p> <p>All Tasks lists all the tasks belonging to the selected assignee.</p> <p>My Tasks lists all the tasks pending recently, today, or are overdue.</p> <p>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.</p>
<b>FAQ</b>	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.
<b>The Q&amp;A</b>	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 questions posted here. Users who have been designated as Subject Matter experts will also see questions related to their area of expertise.

eTMF

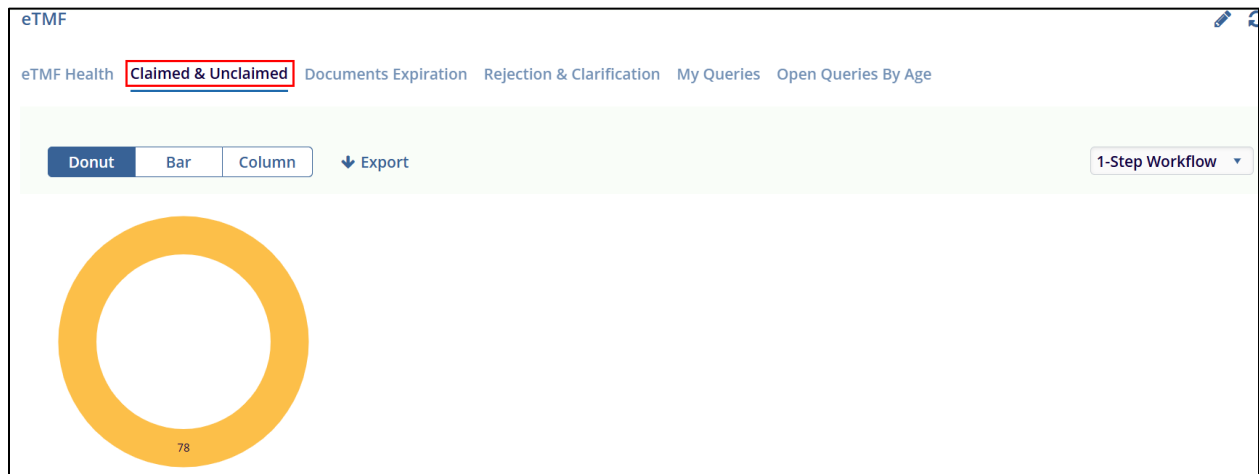
285. eTMF health

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 or can copy it to Clipboard. The user can also edit the name of the dashlet by clicking the **Pencil** icon displayed in the right corner.



286. 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 data.



### 287. 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 Versions to the document, Export document metadata, Manage Columns, Manage and Create New Filter, and 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.

### 288. 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 the submitted Name, Created Date, and Document Comments. For each dropdown arrow, the user can Export, Refresh, and Manage Columns and Views.

	Reason	Count
+	Blank Pages	2
+	Duplicate Document	2
+	Incorrect Protocol	1

### 289. My Queries

This tab displays the documents that have 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, and Save Views in this dashlet.

eTMF Health Claimed & Unclaimed Documents Expiration Rejection & Clarification **My Queries**

Open Queries By Age

Query Type **Any** Status **Any** View Type **Any** Export Response

1 - 1 of 1 (0 selected) Manage Columns Views

<input type="checkbox"/>	Submitted Name
<input type="checkbox"/>	Protocol Template

### 290. Open Queries By Age

This tab displays the queries that are 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.

eTMF Health Claimed & Unclaimed Documents Expiration Rejection & Clarification **My Queries**

**Open Queries By Age**

**Any**

1 - 1 of 1 (0 selected)

Age	Count
+ 30 days and older	2

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.

1 - 1 of 1 (1 selected)

Age	Count
- 30 days and older	2

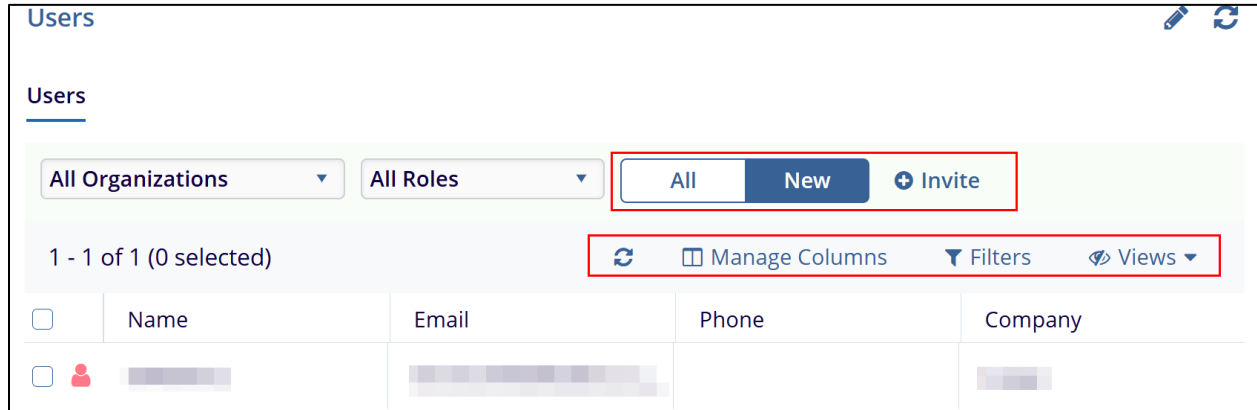
In Progress 2

<input type="checkbox"/>	Submitted Name
<input type="checkbox"/>	FDF Sub I

Export Manage Columns Views

## Users

This tab displays the users available and is added to 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.



The screenshot shows the 'Users' dashboard interface. At the top, there is a title 'Users' with edit and refresh icons. Below the title, there is a filter section with two dropdown menus: 'All Organizations' and 'All Roles'. To the right of these are three buttons: 'All', 'New', and '+ Invite'. Below the filter section, there is a status bar showing '1 - 1 of 1 (0 selected)' and four buttons: 'Refresh', 'Manage Columns', 'Filters', and 'Views'. Below the status bar, there is a table with columns: 'Name', 'Email', 'Phone', and 'Company'. The table contains one row with a user icon, a redacted name, a redacted email, and a redacted phone number.

## Edit Dashboard

This button is displayed in the top left corner. By clicking this button, the user can do the following:

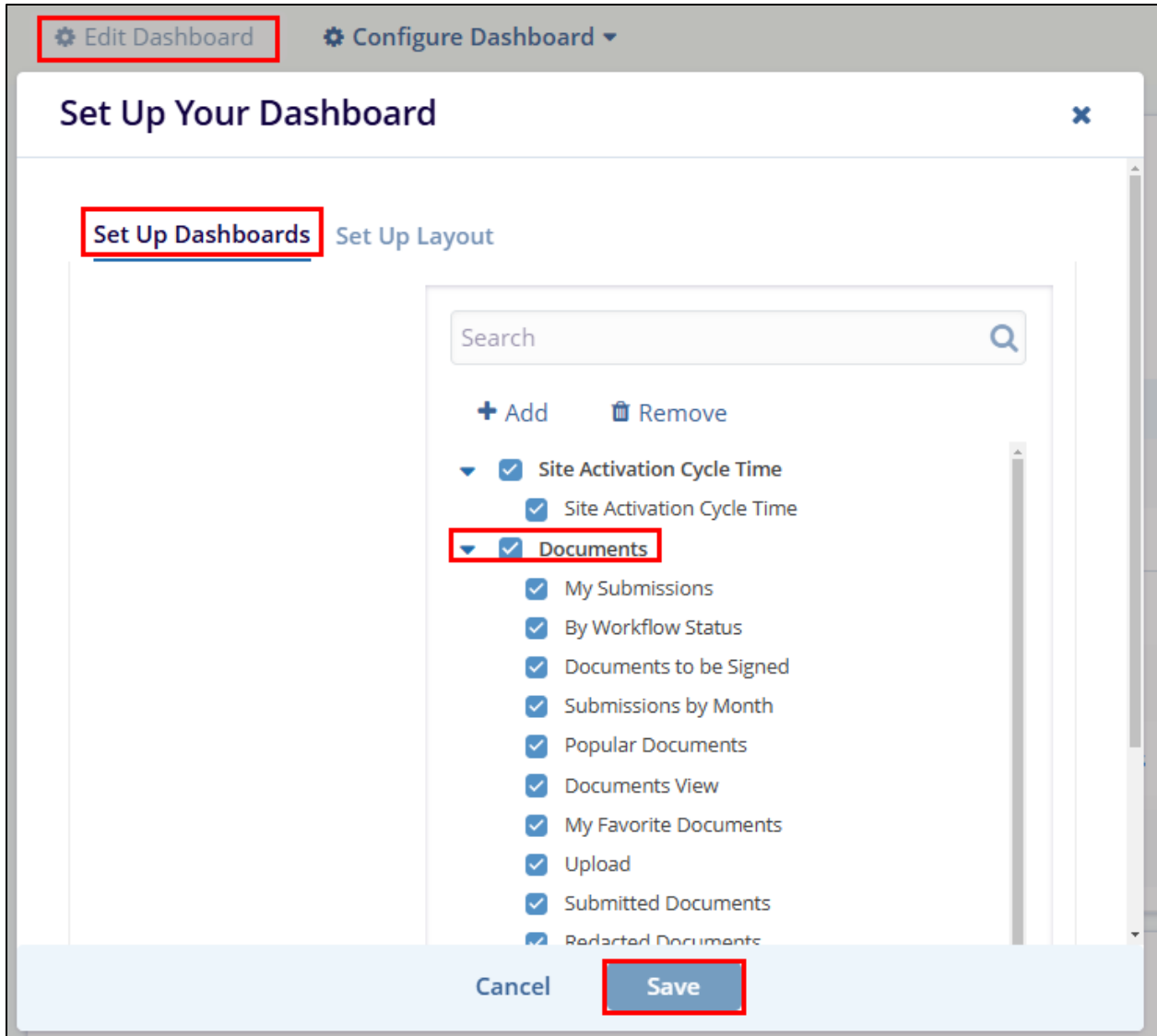
- **Set Up Dashboards**
- **Set Up KPI Dashboards**
- **Set Up Layout**

### Set Up Dashboards

Here, the user can set up their dashboard as required. Follow the steps below to set up 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.

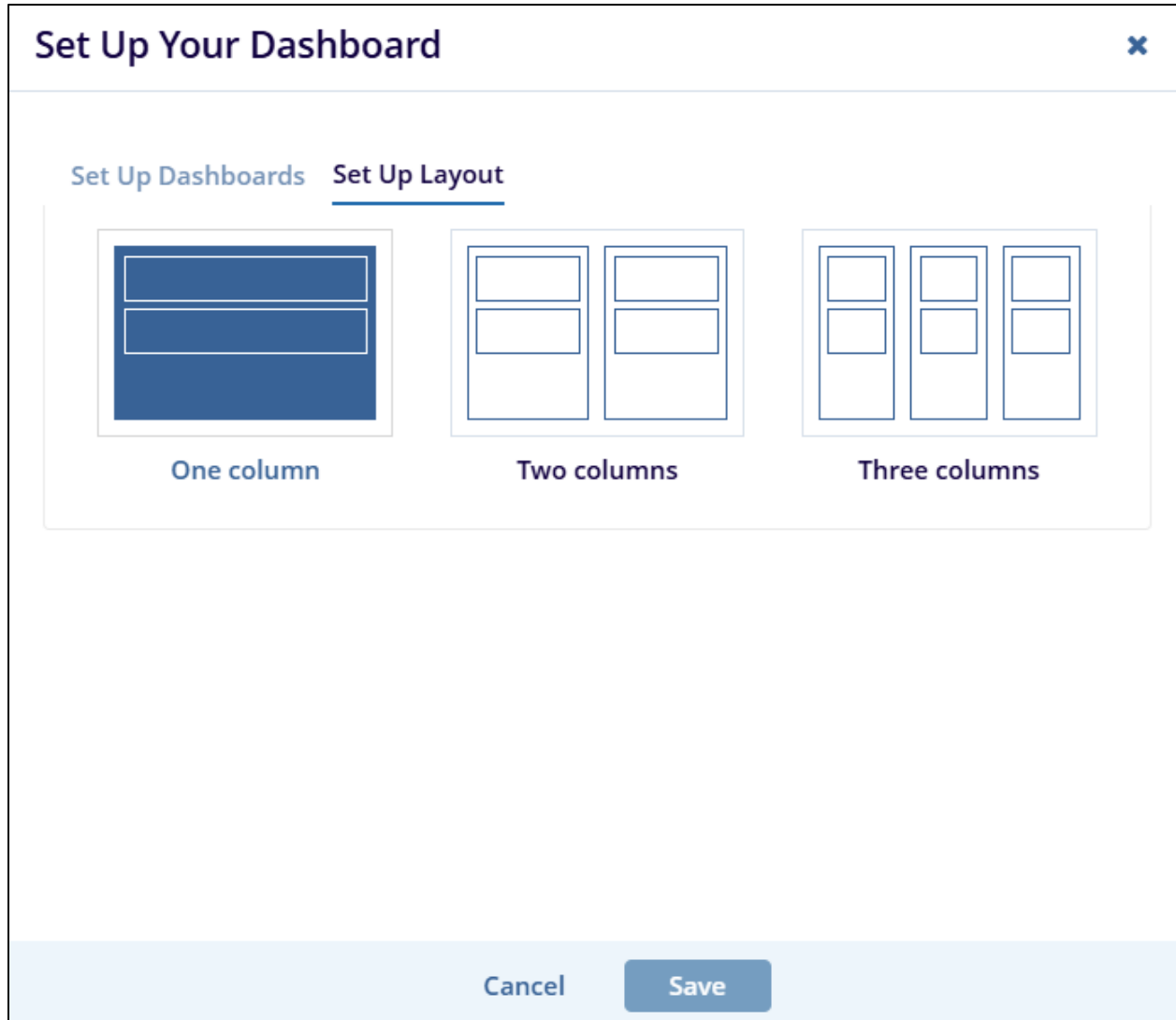
**Note:** While adding a new dashlet, the user has to mention the Title and Description in the left side fields. Also, the user can only remove the newly added fields and not the pre-defined fields.



### Set Up Layout

This tab helps the user select and set up a layout for the entire Dashboard. The user has the option 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.





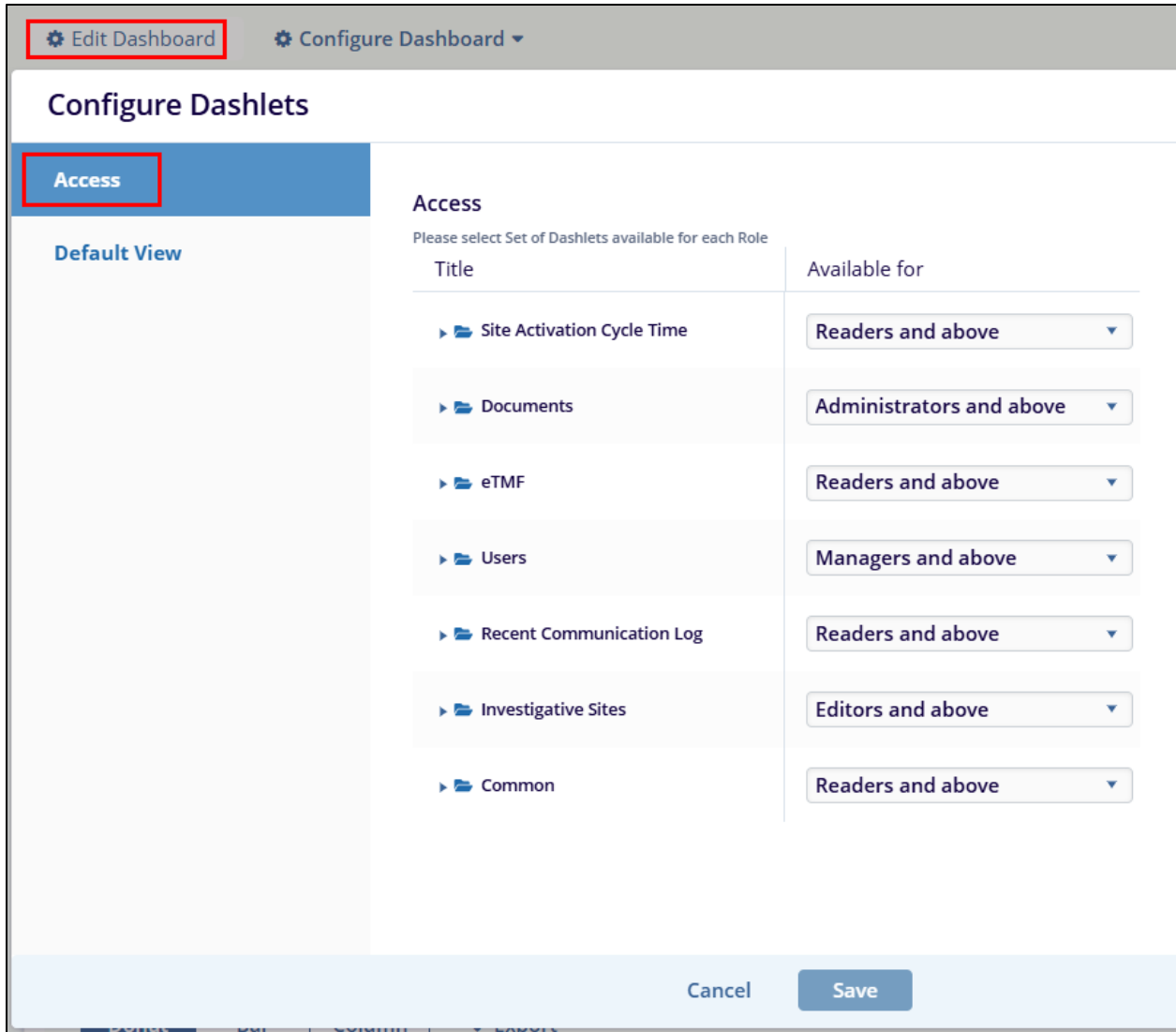
### Configure Dashboard

The Configure Dashboard helps the user to arrange the dashboard as required. The user has one option for configuring the dashboard – Configure Dashlets.

#### Configure Dashlets

To configure dashlets, follow the steps below.

1. Click the **Configure Dashboard** button displayed next to the 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. In 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.

### Configure Dashlets ↺ ✕

**Access**

Default View

#### Default View

Please select Default list of Dashlets for each Role

Reader
Editor
Manager
Administrator

+ Add
 🗑 Remove

Title	Reader
▶ Site Activation Cycle Time	<input checked="" type="checkbox"/>
▶ eTMF	<input type="checkbox"/>
▶ Recent Communication Log	<input checked="" type="checkbox"/>
▶ Common	<input checked="" type="checkbox"/>

Select Entity to Fill additional Data

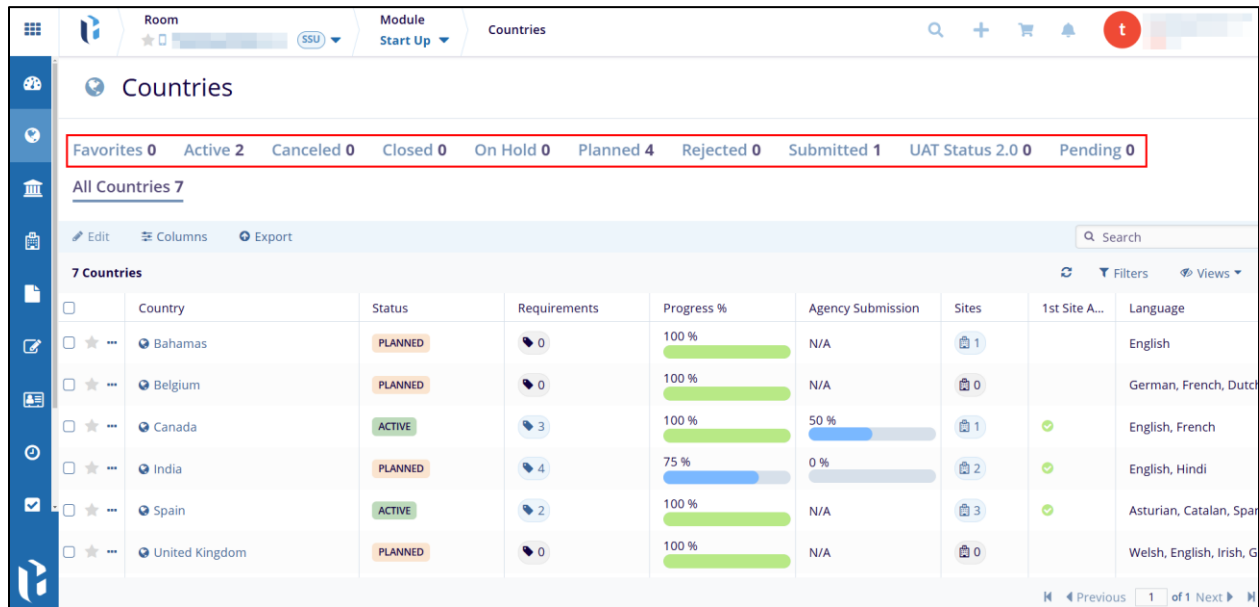
Cancel
Save

## 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 located in the country during its initial setup and configuration. The following section discusses:

1. Viewing and editing country profiles
2. Viewing documents

The Start-Up Countries tab, accessed from the toggling menu bar on the left, allows you to set up 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.



## Viewing Countries

Countries in which the sites are located can be viewed from the list of countries appearing in the grid pane. The list of countries appearing in the grid pane is displayed without applying any filters. Follow the steps below to Manage Filters and Create a New Filter for the Countries module.

### 291. Manage Filters

To manage the filters, follow the steps below.

1. Click on the Filters button.
2. From the Advanced Dropdown, select **Manage Filters**.

**Countries**

Favorites 0 Active 2 Canceled 0 Closed 0 On Hold 0 Planned 4 Rejected 0 Submitted 1

UAT Status 2.0 0 Pending 0 All Countries 7

Edit Columns Export Search

7 Countries Filters Views

Advanced +

- Create New Filter
- Manage Filters

Status	Requirements	Progress %	Agency Sub...	Sites	1st S...	Language
PLANNED	0	100 %	N/A	1		English

Previous 1 of 1 Next

3. On the Filters window, click on +Add button.

**Filters**

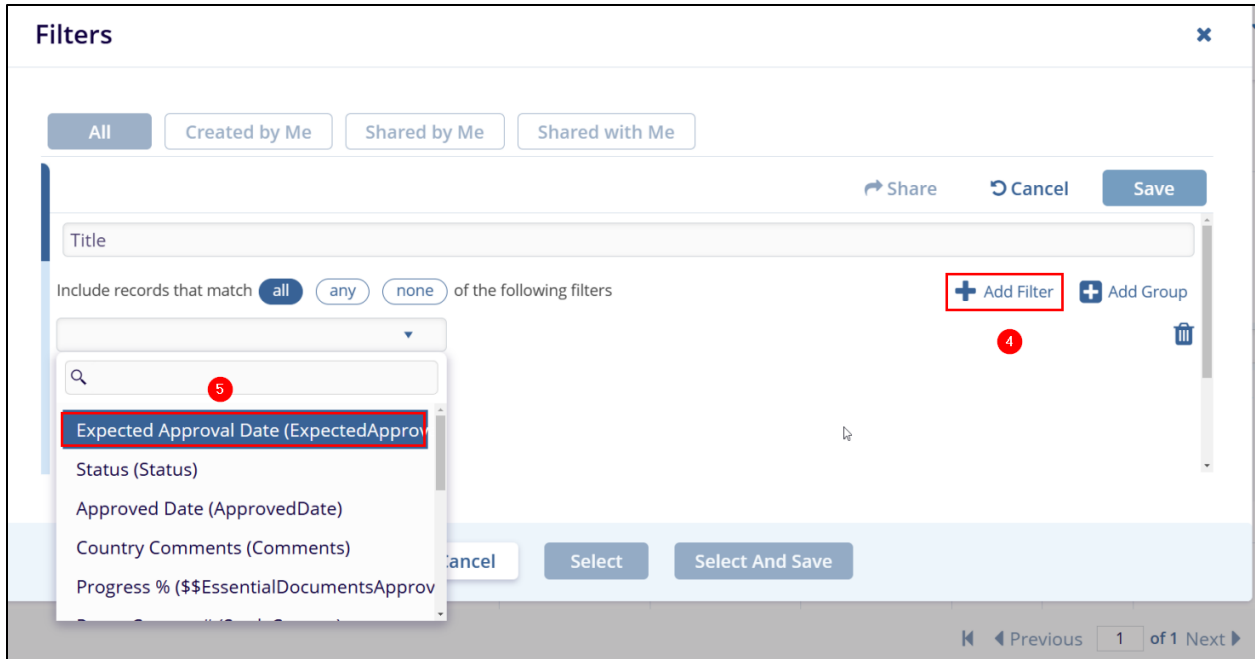
All Created by Me Shared by Me Shared with Me

+ Add Copy Remove Only one filter may be selected

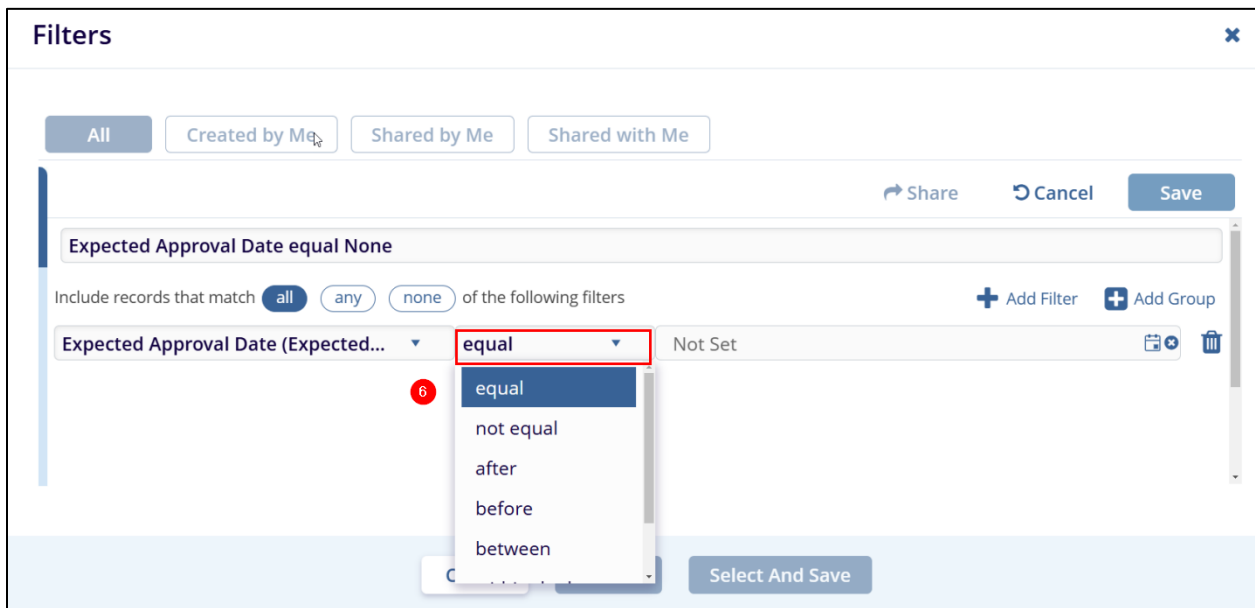
- Filter
- Status equal (Admin 103)

Cancel Select Select And Save

4. Click on the +Add Filter button.
5. Select a filter option by accessing the dropdown.



6. Select a logical operator from the available dropdown list



7. Configure the filter criteria.
8. Click on the Save button.

**Note:** The other two dropdown menu options i.e., logical operator and criteria change as per the option selected in the first dropdown menu.

9. Click the **Select** or **Select And Save** buttons to apply the filters on the Countries.

## 292. Create New Filter

To create a new filter, follow the steps below.

1. Click on the Filters button.
2. From the Advanced Dropdown, select **Manage Filters**.

**Countries**

Favorites 0 Active 2 Canceled 0 Closed 0 On Hold 0 Planned 4 Rejected 0 Submitted 1

UAT Status 2.0 0 Pending 0 All Countries 7

Edit Columns Export Search

7 Countries Filters Views

Advanced +

Create New Filter 2 Manage Filters

Status	Requirements	Progress %	Agency Sub...	Sites	1st S...	Language
PLANNED	0	100 %	N/A	1		English

3. Click the **Add Filter** button displayed in the right corner.
4. Select a filter from the available list.
5. Add a logical operator
6. Set the filter criterion
7. Click on the Create button.

**Create Filter**

Expected Approval Date equal None 3

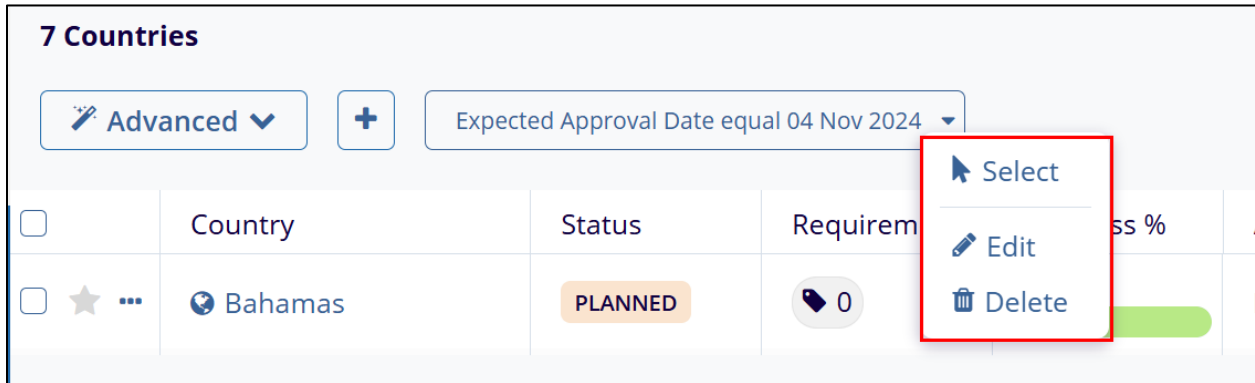
Include records that match all any none of the following filters + Add Filter + Add Group

Expected Approval Date (Expected... 4 equal 5 Not Set 6

Cancel Create 7



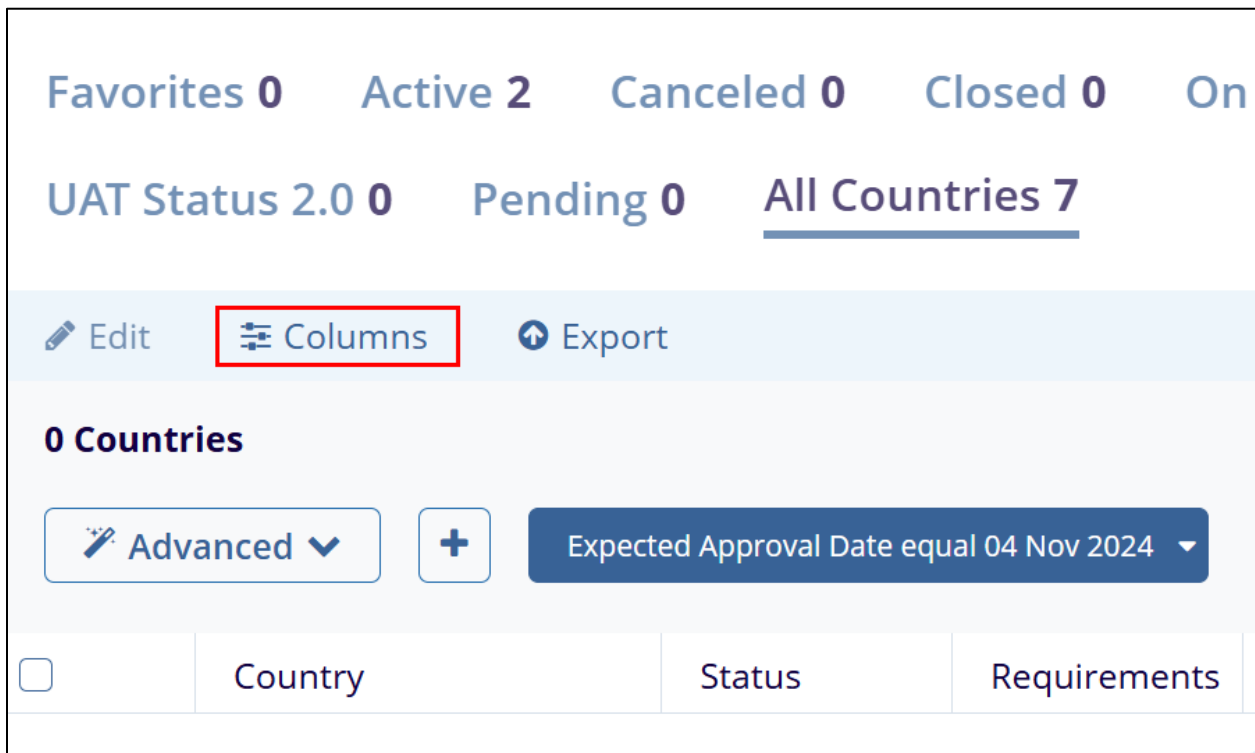
8. The Created filter is displayed in the Grid Pane. Click on the filter dropdown to edit or delete the filter.



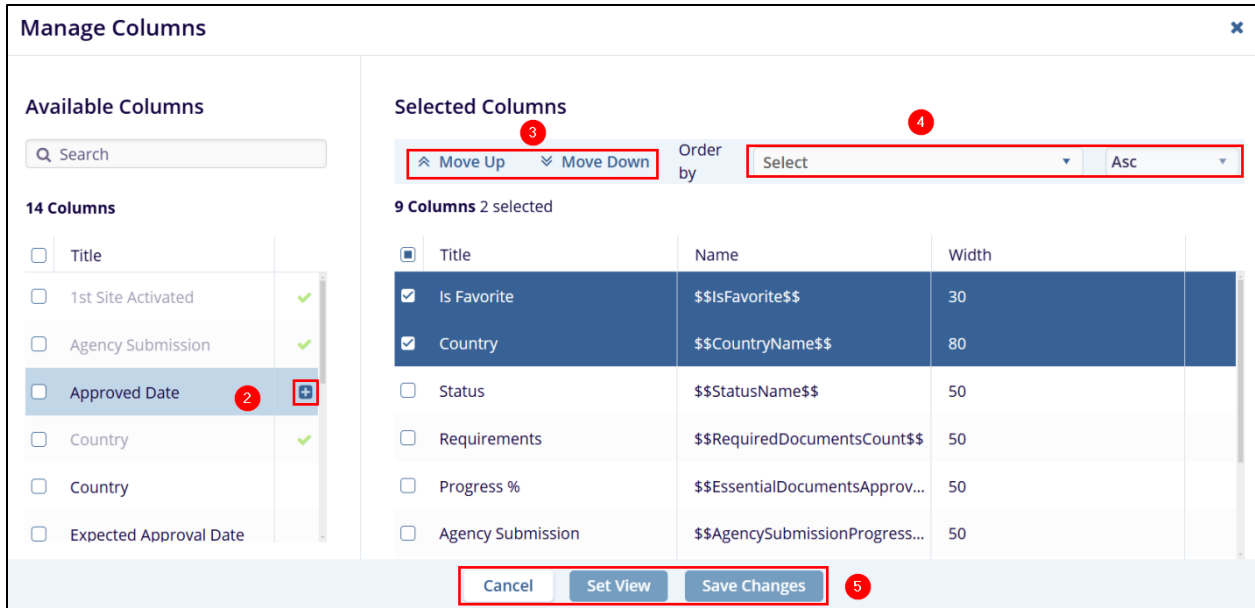
### 293. Columns

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.

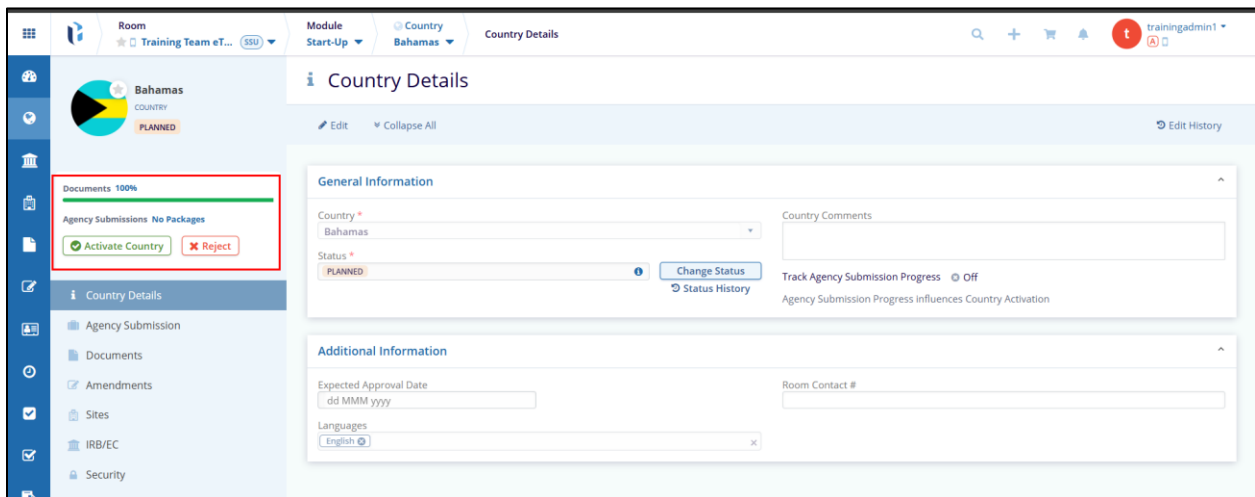


2. On the Manage Columns window, select the required checkbox(s) and click the **Plus** icon in the Available Columns section.
3. Click on the Move Up and Move Down arrow to rearrange the order.
4. Select the 'Order by' option and select either 'Ascending' or 'Descending'
5. Click an appropriate option from the following – **Cancel**, **Set View**, or **Save Changes** as required.



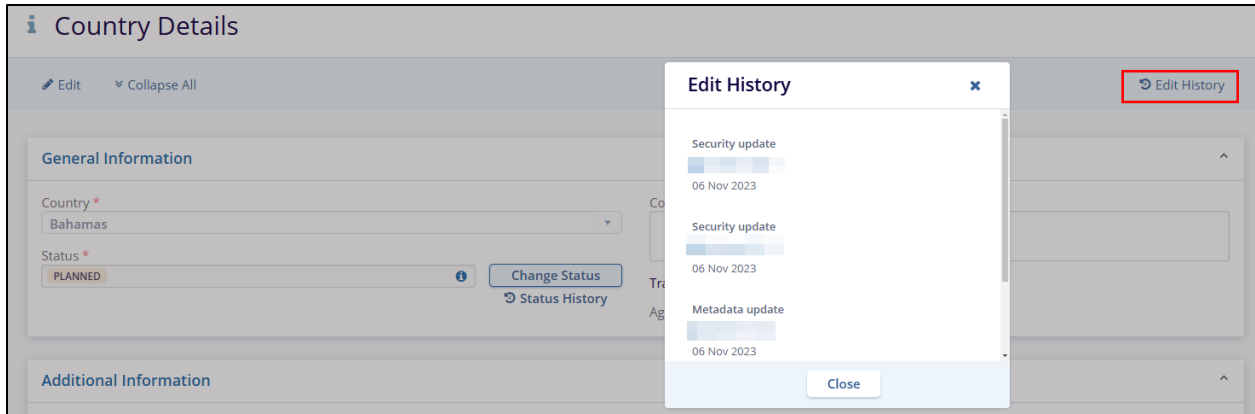
### The site's Current View

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.



### 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.

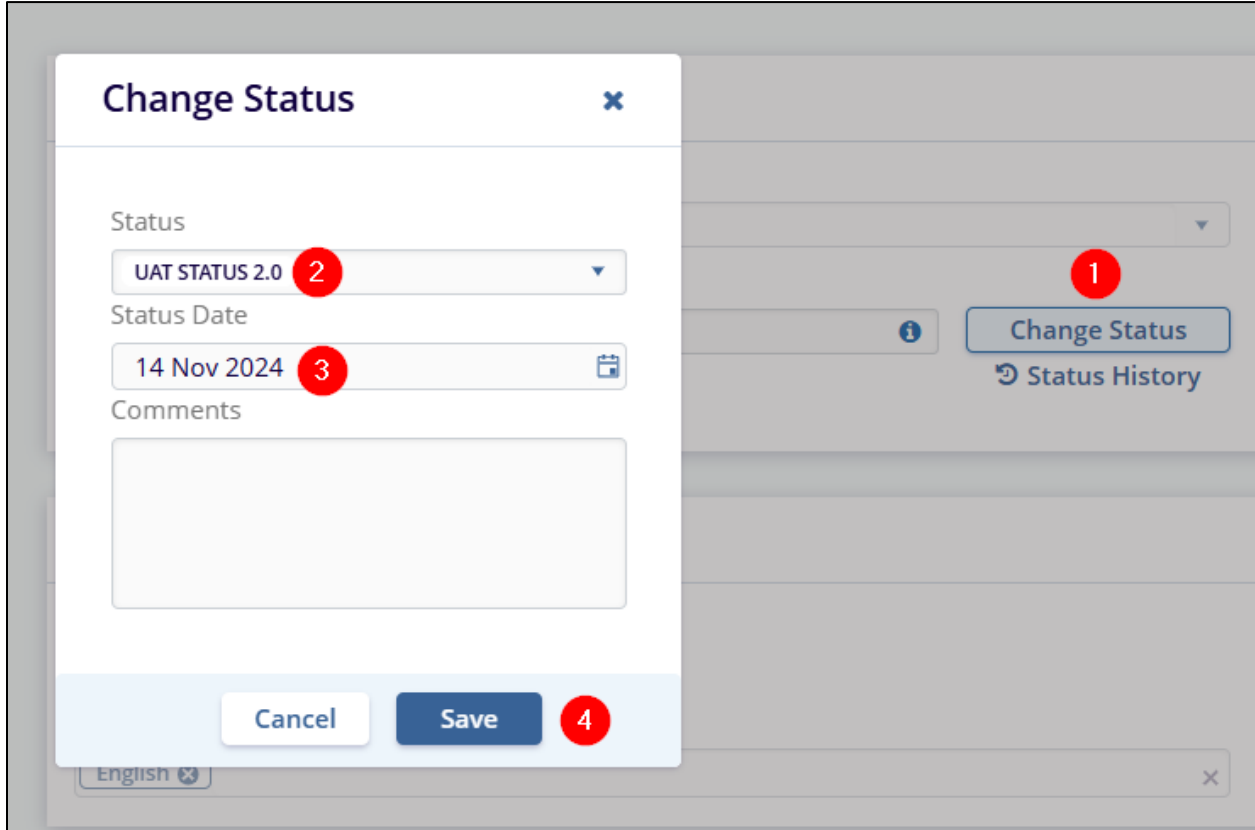


**Note:** The user can only view the details of the history and cannot make any changes.

### Change Status

The user can change the status of a country by following the steps below:

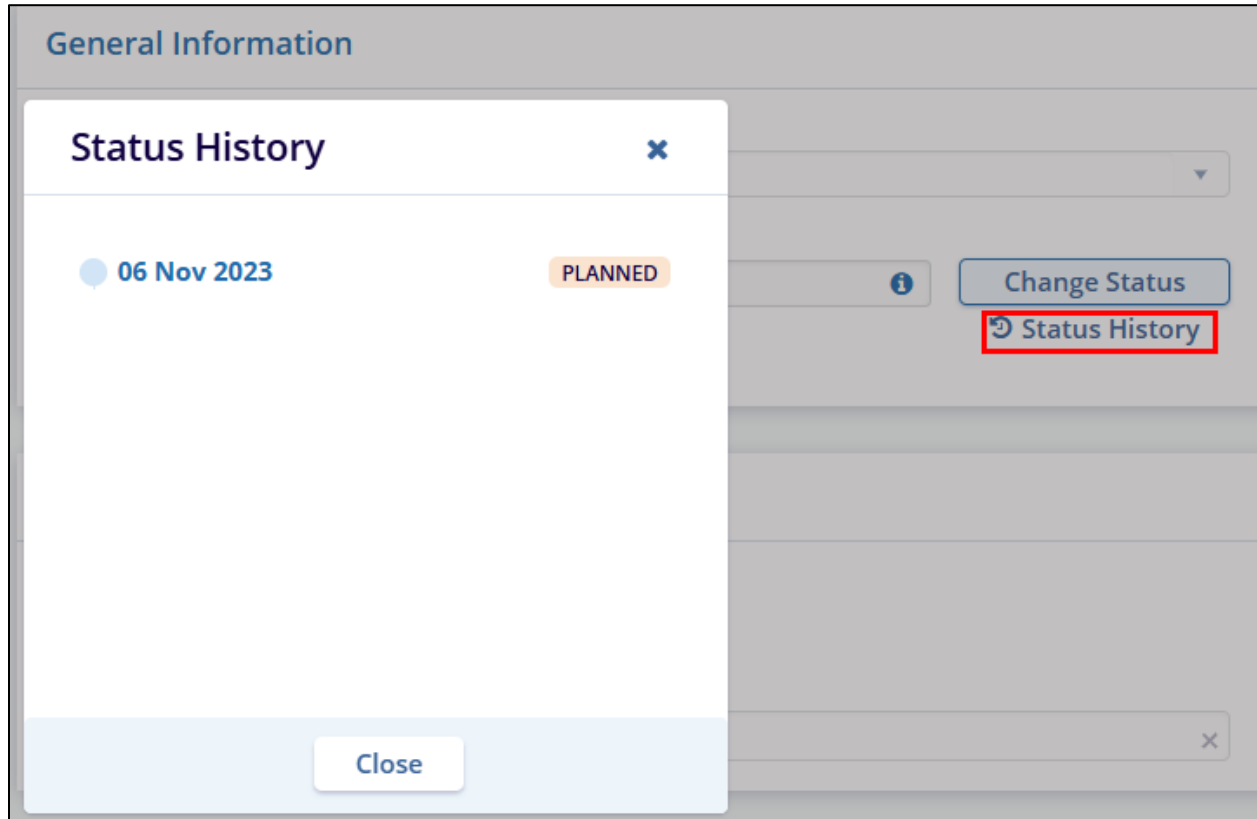
1. Click the **Change Status** button displayed on the Country Details page. This opens the Change Status popup window.
2. Select the appropriate status from the dropdown menu of the Status field.
3. Select the Status Date by clicking the **Calendar** icon. Mention comments if required in the box below.
4. Click the **Save** button at the bottom of the popup window.



## 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 on the Country Details page.

**Note:** The user can only view the history and cannot edit any information in the table displayed.



## Agency Submissions

It is common practice to associate health agencies with sites and send submission packages to them for their approval. Sites can't be activated for the clinical study unless the agency approval is received. A study may have multiple health agencies located in various countries. These agencies may have more comprehensive site activation submission packages involving hundreds of documents that 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 as agency name, country, status of submission, documents to be included in the submission profile, date when the package was submitted, and also the status of the submission package.

A submission package can contain documents from the eTMF, SSU, Site, Country, 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.

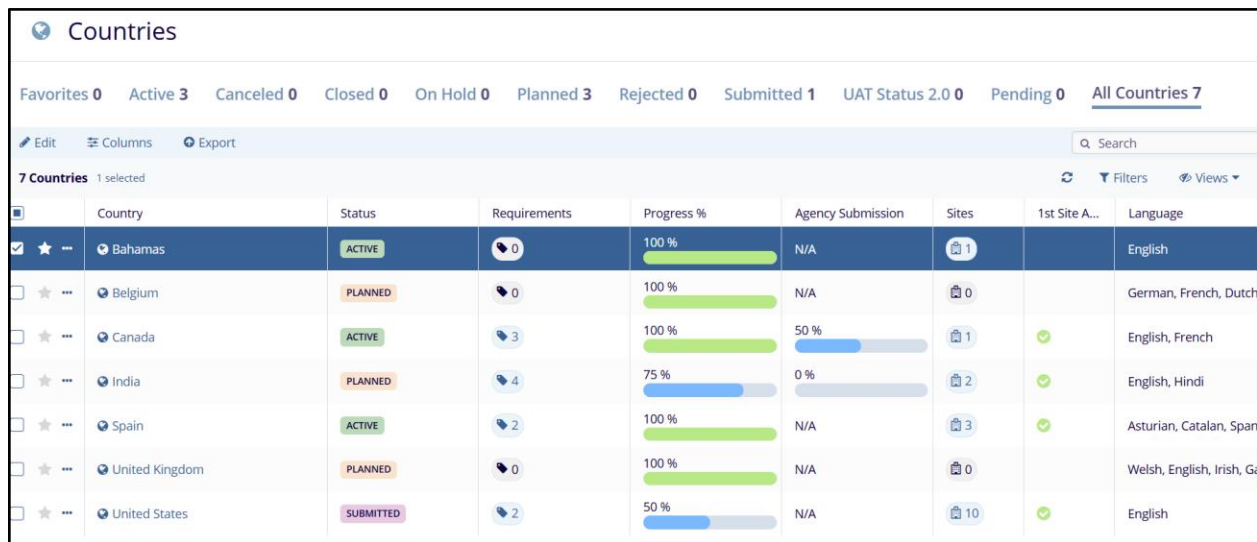
### Defining Health Agencies

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 help desk 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.

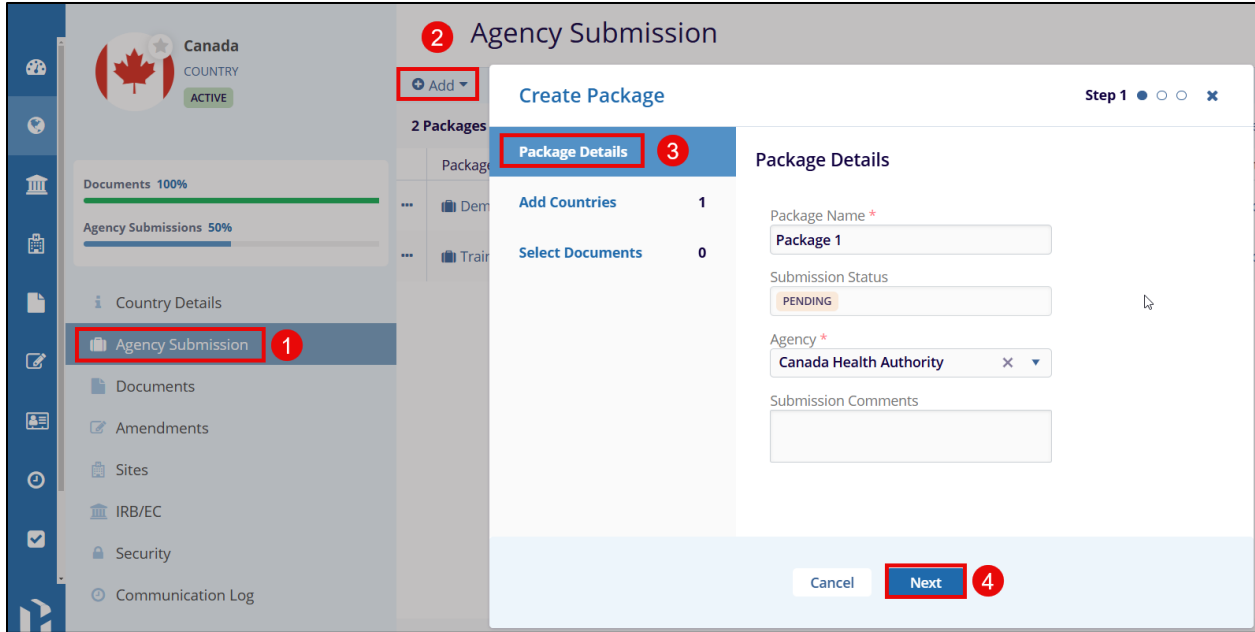


Country	Status	Requirements	Progress %	Agency Submission	Sites	1st Site A...	Language
Bahamas	ACTIVE	0	100 %	N/A	1		English
Belgium	PLANNED	0	100 %	N/A	0		German, French, Dutch
Canada	ACTIVE	3	100 %	50 %	1	✓	English, French
India	PLANNED	4	75 %	0 %	2	✓	English, Hindi
Spain	ACTIVE	2	100 %	N/A	3	✓	Asturian, Catalan, Span
United Kingdom	PLANNED	0	100 %	N/A	0		Welsh, English, Irish, Ga
United States	SUBMITTED	2	50 %	N/A	10	✓	English

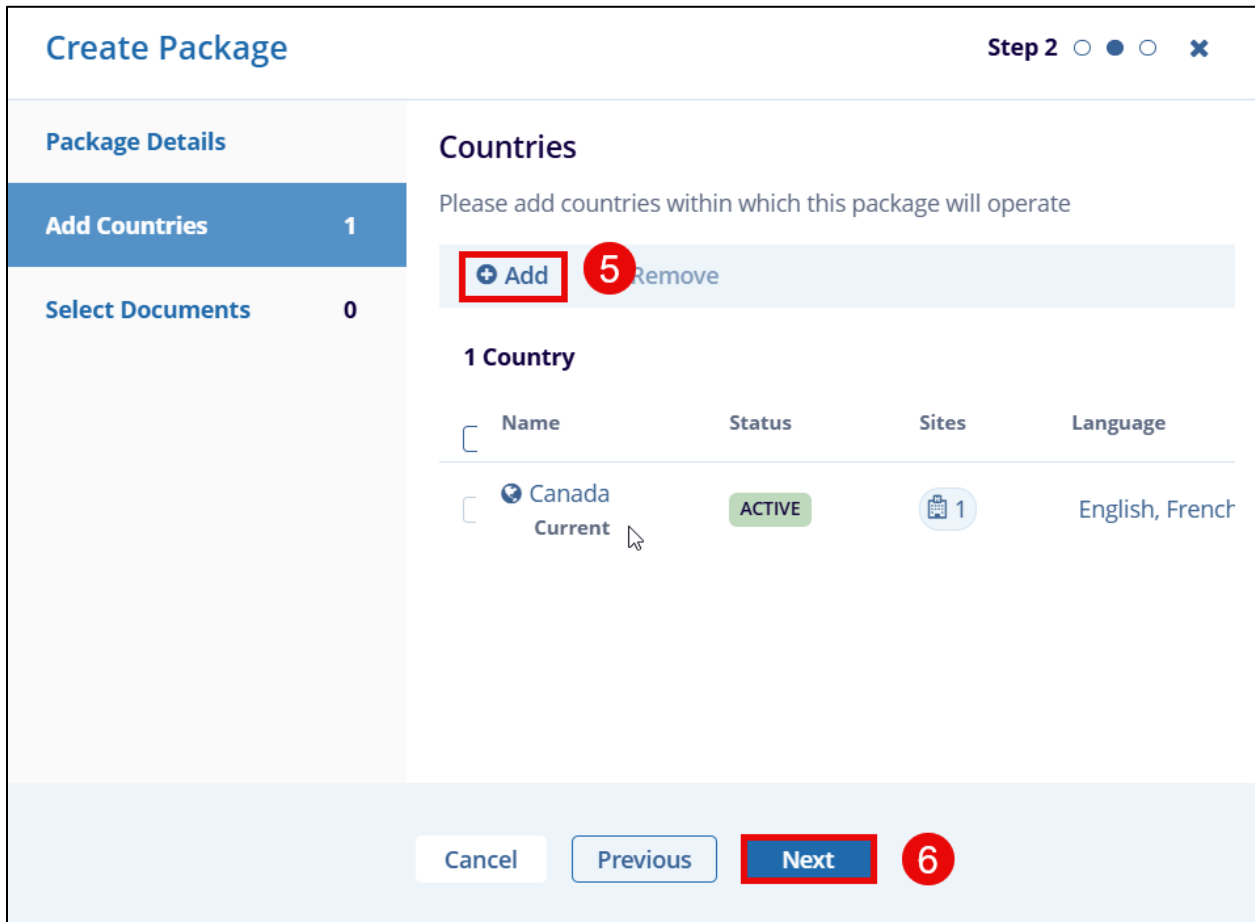
## 294. Add Agency Submission

As mentioned above, the user can add an agency submission for a country. Follow the steps below for the same.

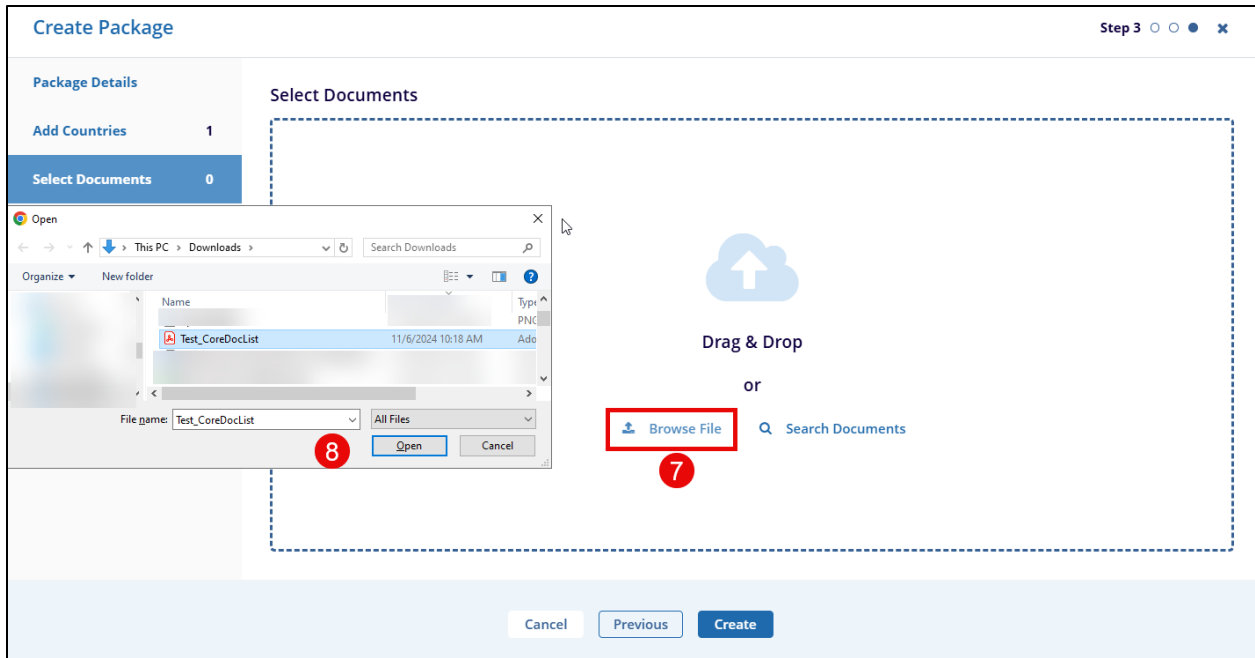
1. Click the Agency Submission option on the Country Details page. This opens the Agency submission Page.
2. Click the **Add** button displayed in the left corner of the top menu bar. This opens the Create Package popup window.
3. In the General Information tab, enter the details for the fields marked with an asterisk - **Package Name, Agency, and Country**.
4. Click the **Next** button at the bottom of the popup window.



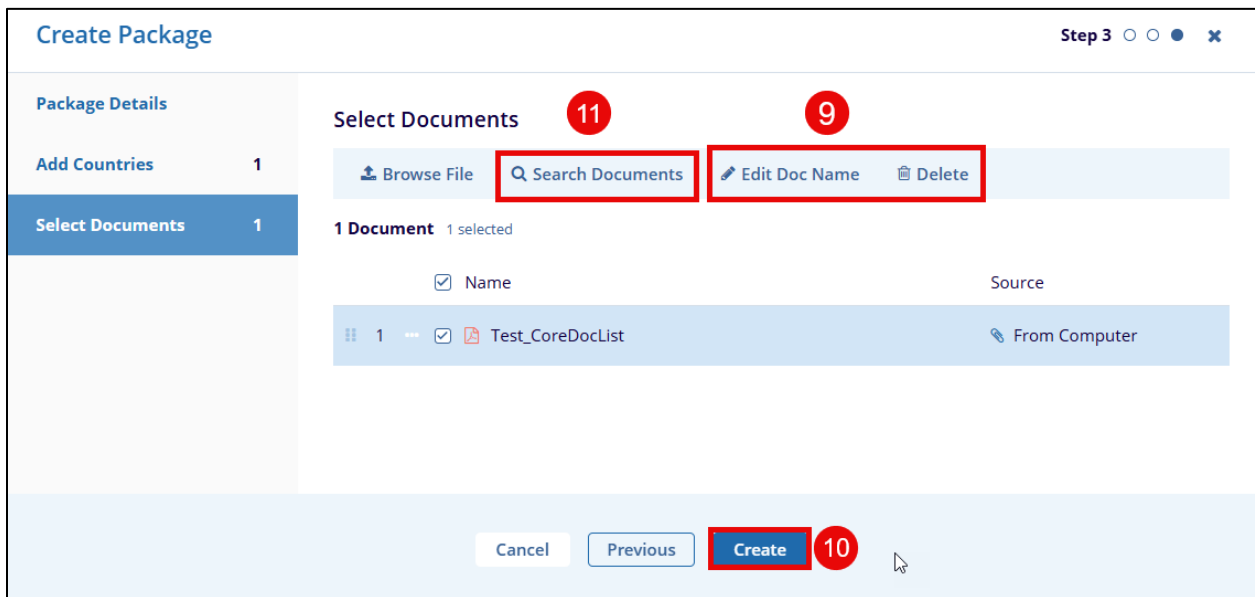
5. This opens the Add Countries tab, click on the +Add button to add a country.
6. Click on the Next button once the required countries within the package have been added.



7. This opens the Select Documents tab of the Create Package popup window. Select an appropriate option – Browse Files OR Search Documents
8. Click on the Browse Files option, select a document from the system, and click on Open.



9. Once the document is uploaded, select the document and click on the Edit Doc Name and Delete button to perform the relevant actions.
10. Click on the Create button to successfully create a package.
11. Click on the Search button to retrieve documents based on the search criteria

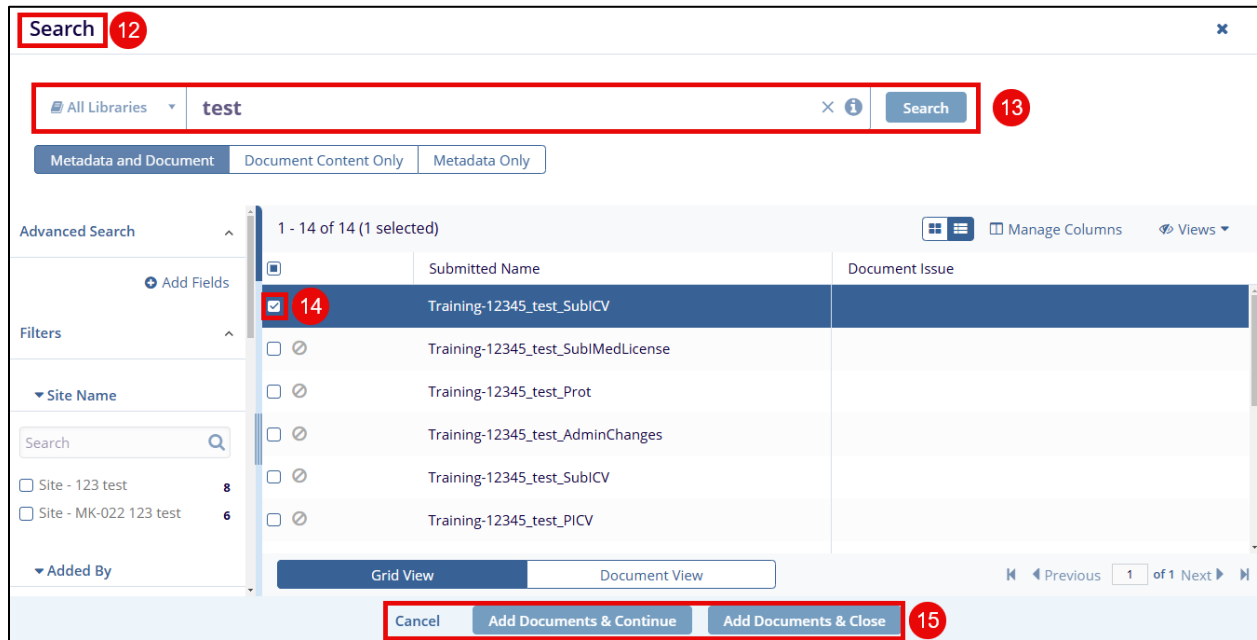


12. If the Search option is selected, it opens the Search popup window.

13. Enter a name in the Search field, and click on the Search button on your keyboard. Below the search field are three tabs displayed
  - Metadata and Document,
  - Document Content Only
  - Metadata Only.

Note: 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.

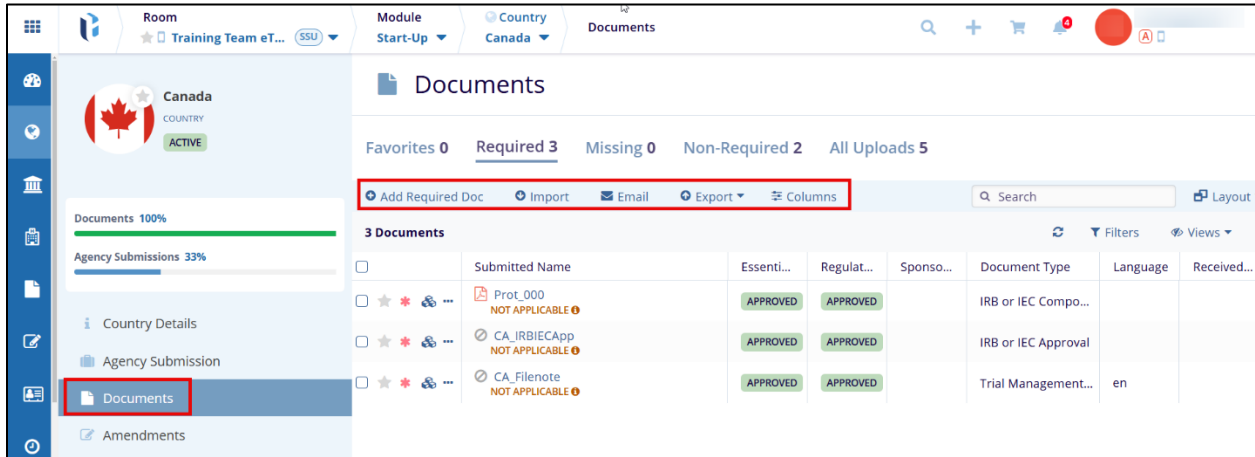
14. Select the checkbox(s) of the documents.
15. Click either of the buttons displayed at the bottom of the window – **Add Documents & Continue** or **Add Documents & Close**.





## Documents

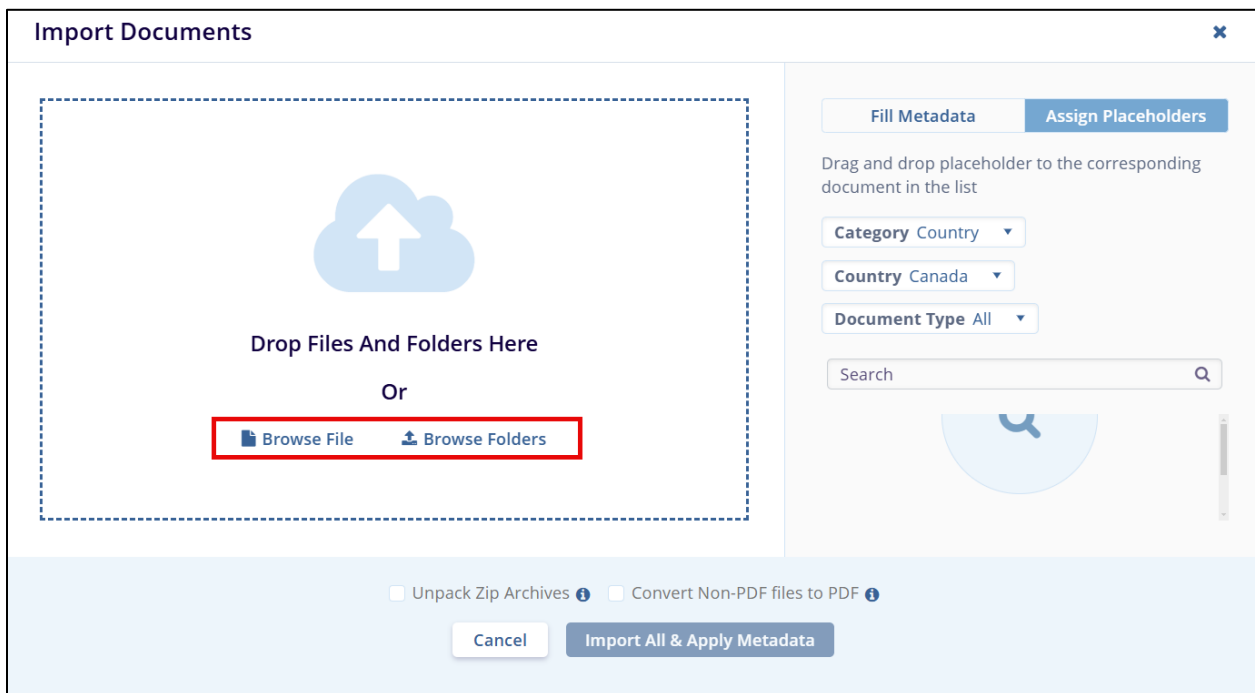
The Documents tab on the Country page assists the user to Import, Add Required Docs, Email, Export, Manage Columns, Search, Apply, and create new Filters.



### 295. Import Documents

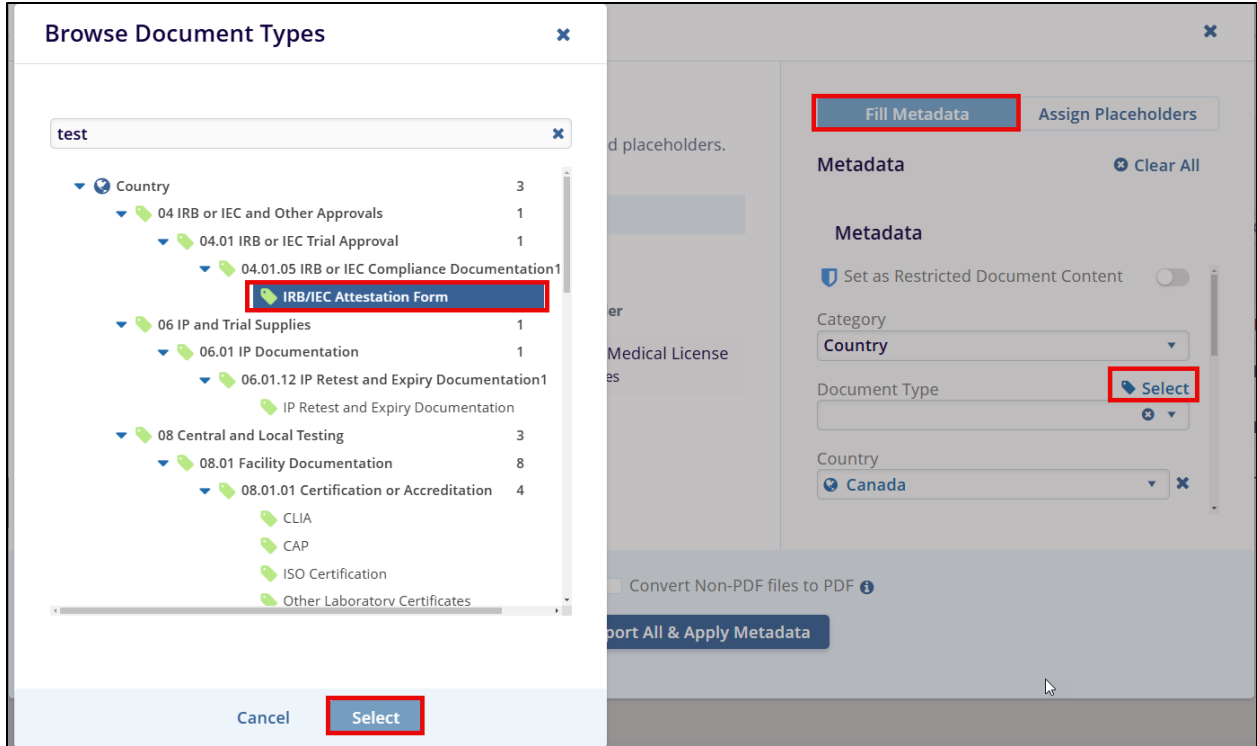
To Import Documents, follow the steps below.

1. Click the **Import** button displayed on the top menu bar. This opens the Import Documents popup window.
2. Drag & Drop the required files or click the **Browse File/ Browse Folders** option.

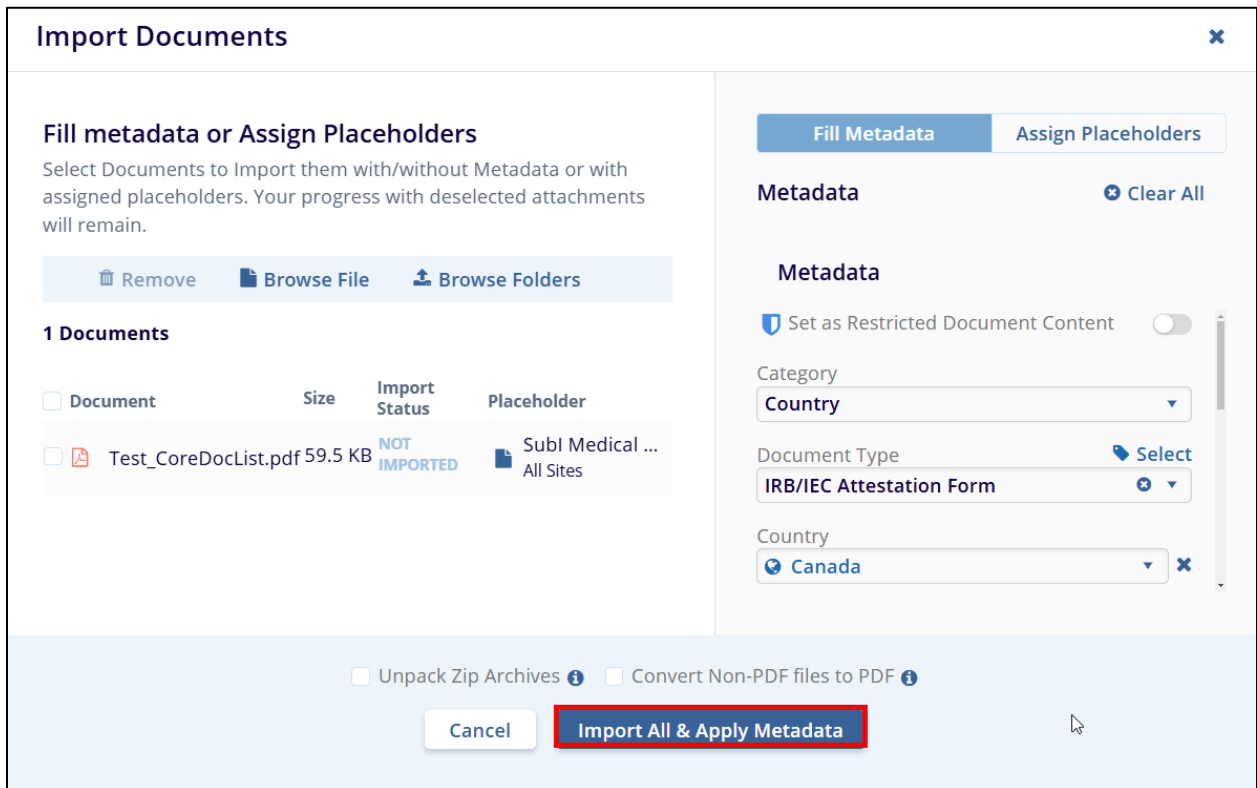


3. Click on the Assign Placeholders tab and apply the relevant filters.
4. Drag & Drop the necessary placeholder in the designated area.

5. Click on the Fill Metadata tab where the Country and Category fields are by default selected.
6. Scroll down to view the Document Type field. Click the **Tag** icon to display a Select Document Type popup window.
7. Expand the dropdown and select the appropriate type. Click the **Select** button.



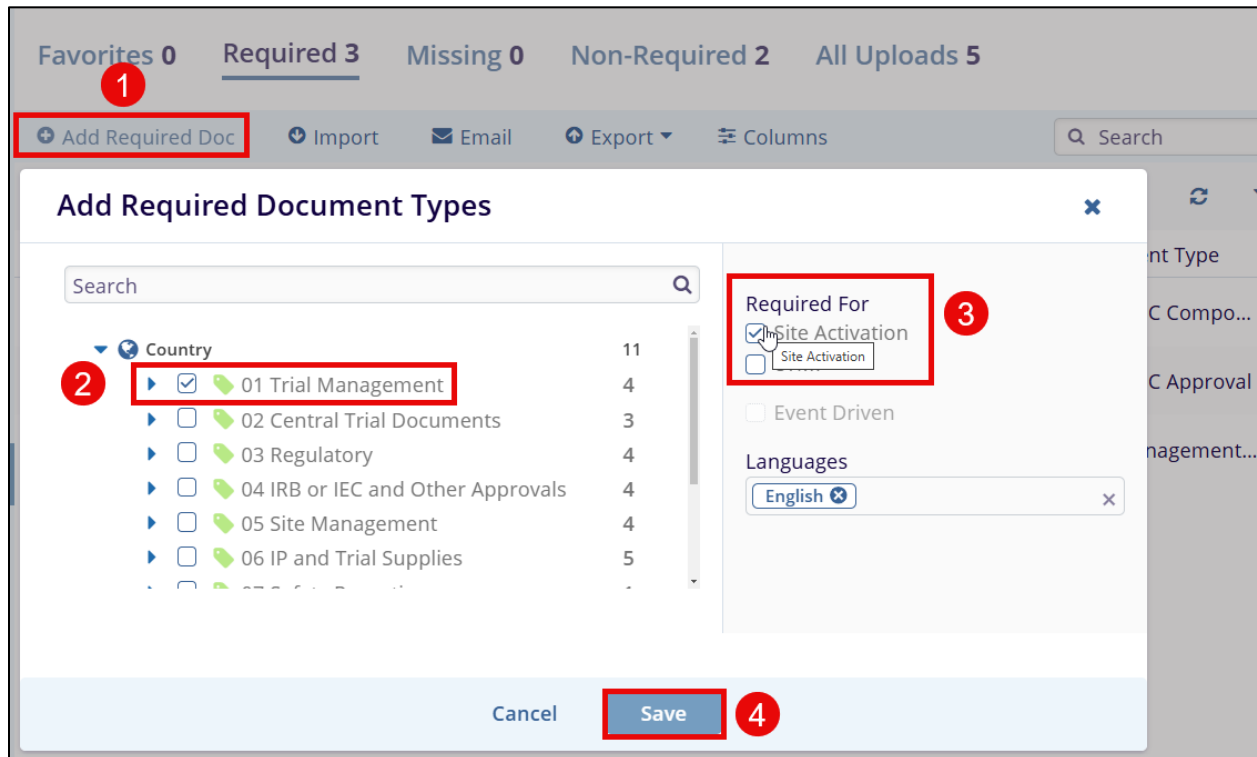
8. The selected document type is reflected in the field.
9. Click on the Import All & Apply Metadata button at the bottom of the popup window.



## 296. Add Required Doc

Follow the steps below to add a required document to the country.

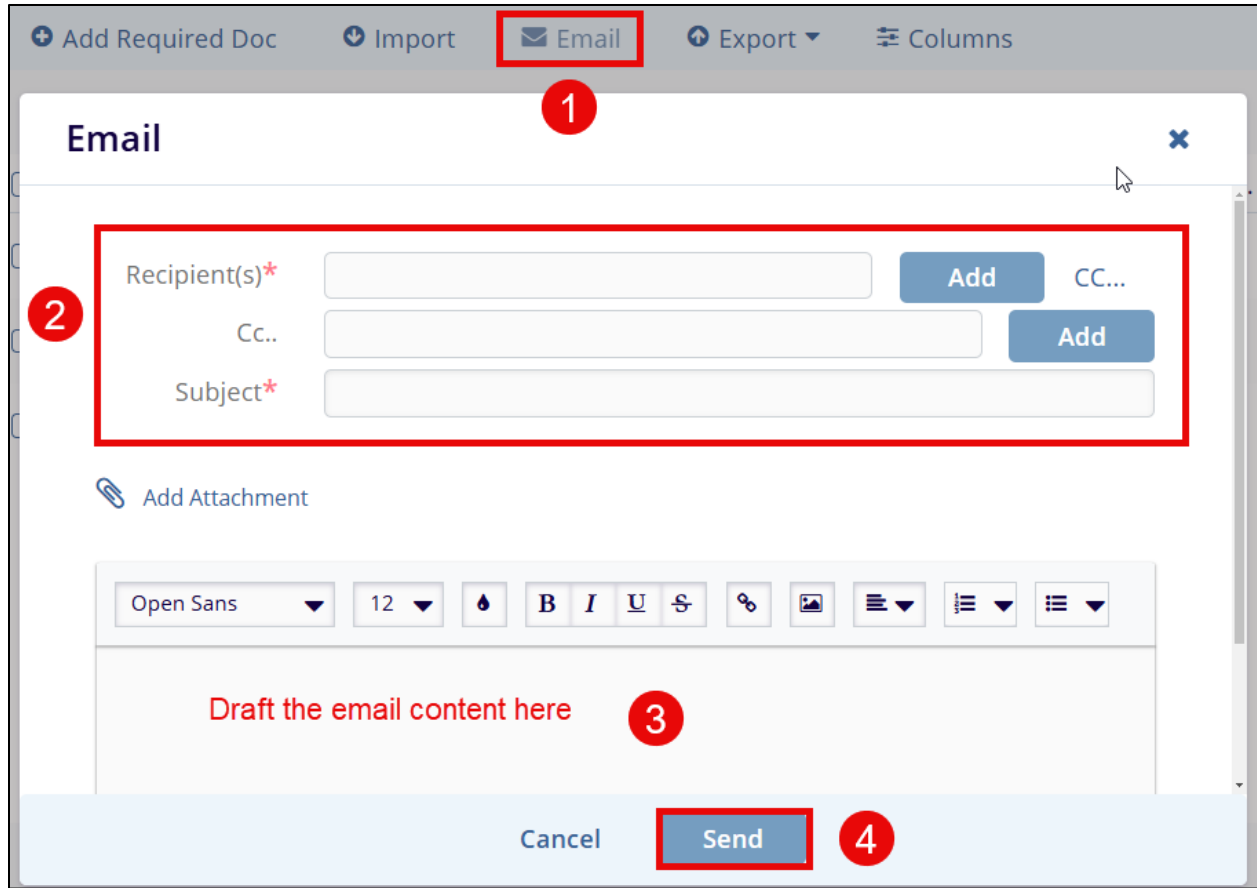
1. Click the **Add Required Doc** button displayed in the top menu bar. This opens the Add Required Document Types popup window.
2. Expand the dropdown of the Country and select an appropriate checkbox from the available list.
3. Select at least one checkbox from the 'Required For' section on the right 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.



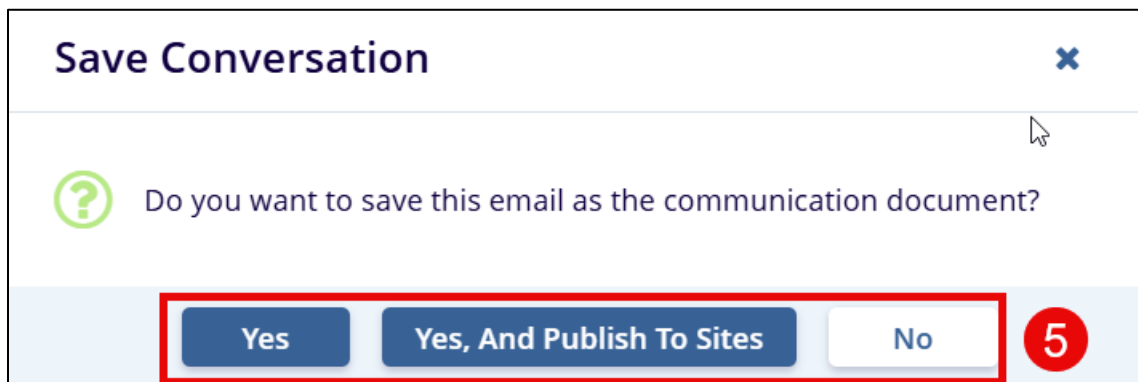
## 297. Email

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 at the bottom of the popup window.



5. Click the appropriate option – **Yes, Yes, And Publish to Investigative Sites, No** displayed in the Save Conversation popup window.

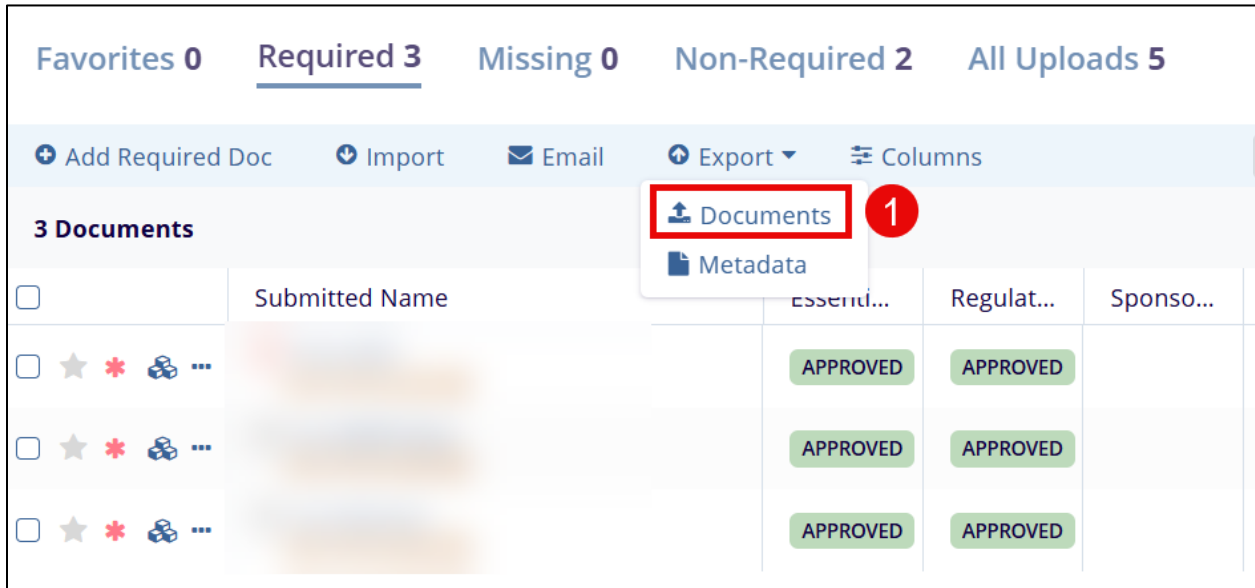


## 298. Export

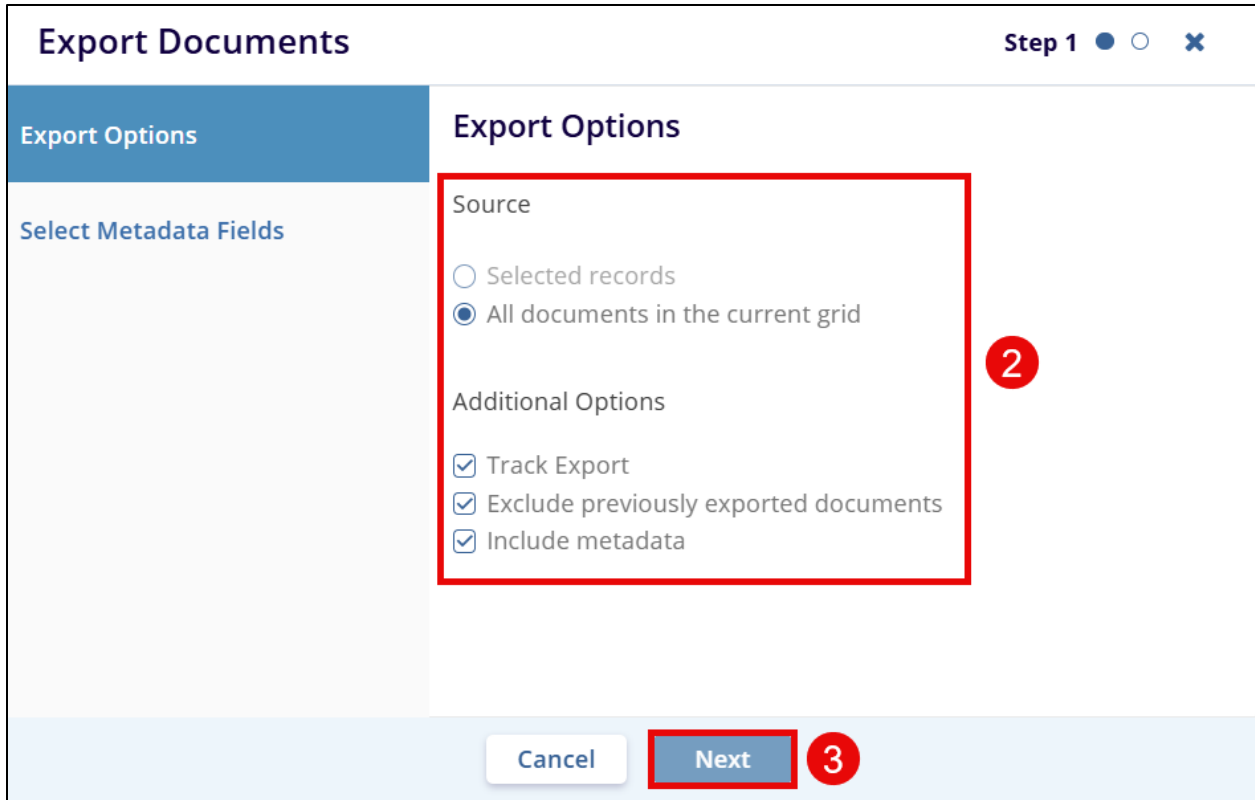
Follow the steps below to export the documents in the Country module.

### Exporting Documents

1. Click the **Export** button displayed on the top menu bar and select the Documents option.



2. On the Export Options window, select Source and Additional options
3. Click on the Next button.



4. On the Select Metadata Fields screen, select the required metadata fields by clicking on the checkboxes.
5. Click on the Export button.

### Export Documents Step 2 ○ ● ✕

**Export Options**

- Select Metadata Fields 14

#### Select Metadata Fields

Favorite ✕ Submitted Name ✕ Essential Document Status ✕

Regulatory Approval Status ✕ Sponsor Approval Status ✕

Document Type ✕ Language ✕ Received Date ✕ Added By ✕

Amendment Number ✕ Applicable Status Change Reason ✕

Essential Document Status Date ✕ Regulatory Approval Date ✕

Sponsor Approval Date ✕

Sort By Alphabet ▾ ↑

▼ ■ **73 Metadata Fields** 14 Selected

- Added By
- Amendment Number
- Applicable Status Change Reason

Cancel
Previous
Export 5

**Exporting Metadata**

1. Click the **Export** button displayed on the top menu bar and select the Metadata option.

**Favorites 0**
**Required 3**
**Missing 0**
**Non-Required 2**
**All Uploads 5**

➕ Add Required Doc
⬇️ Import
✉️ Email
⬆️ Export ▾
☰ Columns

**3 Documents**

- 
- ★ \* 🔄 ...
- ★ \* 🔄 ...
- ★ \* 🔄 ...

Submitted Name	Essend...	Regulat...	Sponso...
	APPROVED	APPROVED	
	APPROVED	APPROVED	
	APPROVED	APPROVED	

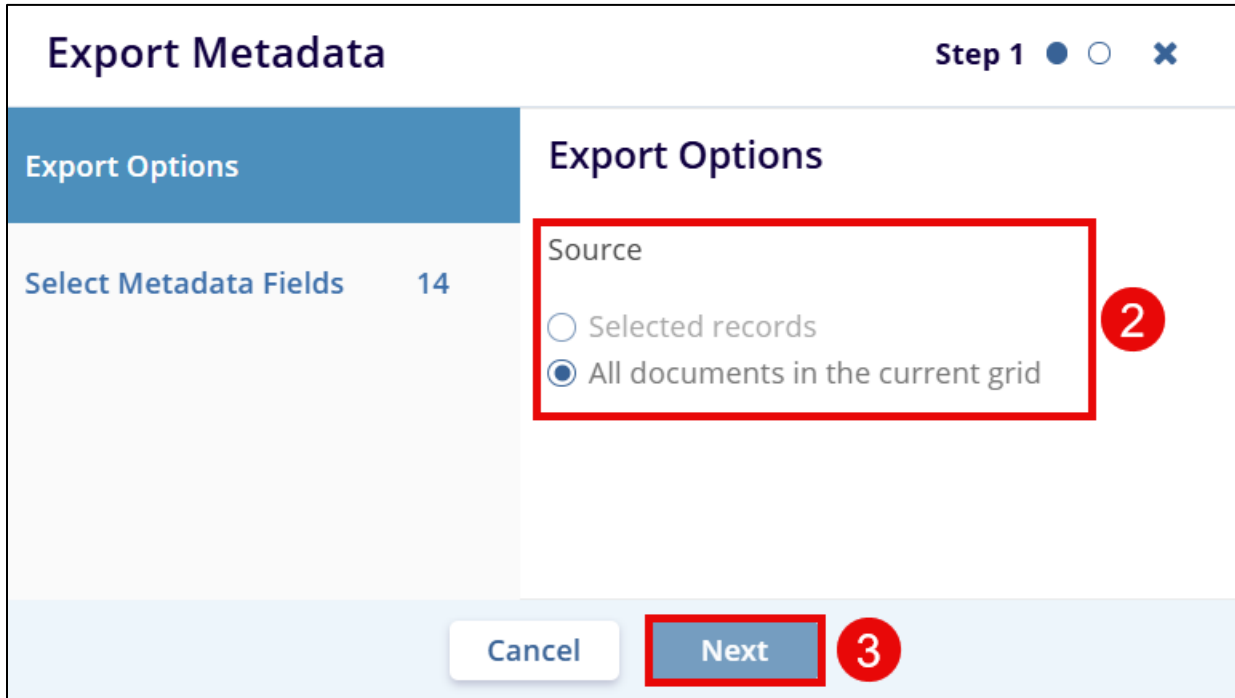
📁 Documents

- 📄 Metadata

1



2. On the Export options screen, select a Source option.
3. Click on the Next button.



4. On the Select Metadata Fields screen, select the required metadata fields by clicking on the checkboxes.
5. Click on the Export button.

### 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.

Site	Site S...	Progress %	Site...	Reg...	IRB...	Start-Up S...	CRA
<input type="checkbox"/> <span>★ ...</span> Site - MK-022 123 tes	ACTIVE	100 %	13 D...	29 N...			abc def

### IRB/EC

The IRB/EC tab in the Country module displays the IRB/ECs linked to the particular Country. On 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.

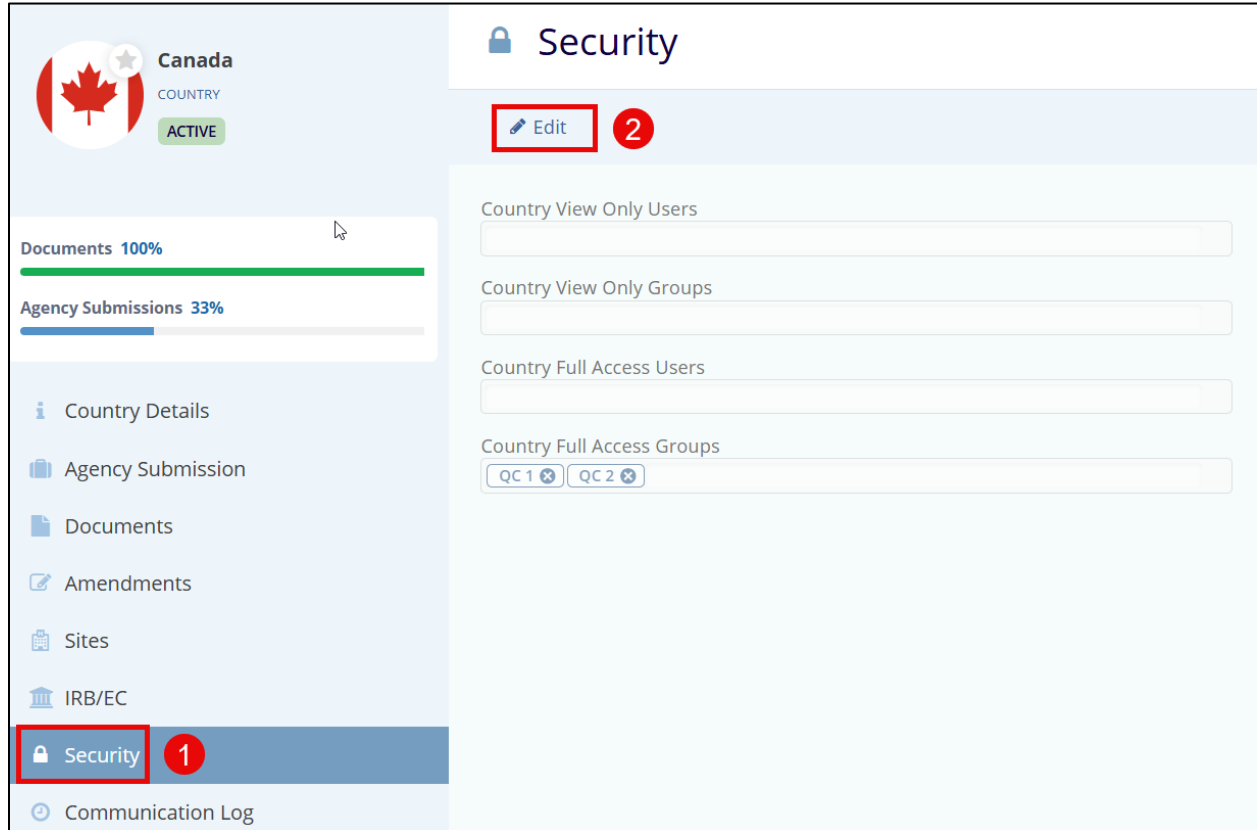
IRB/EC Name
<input type="checkbox"/> <span>★ ...</span> New example

### Security

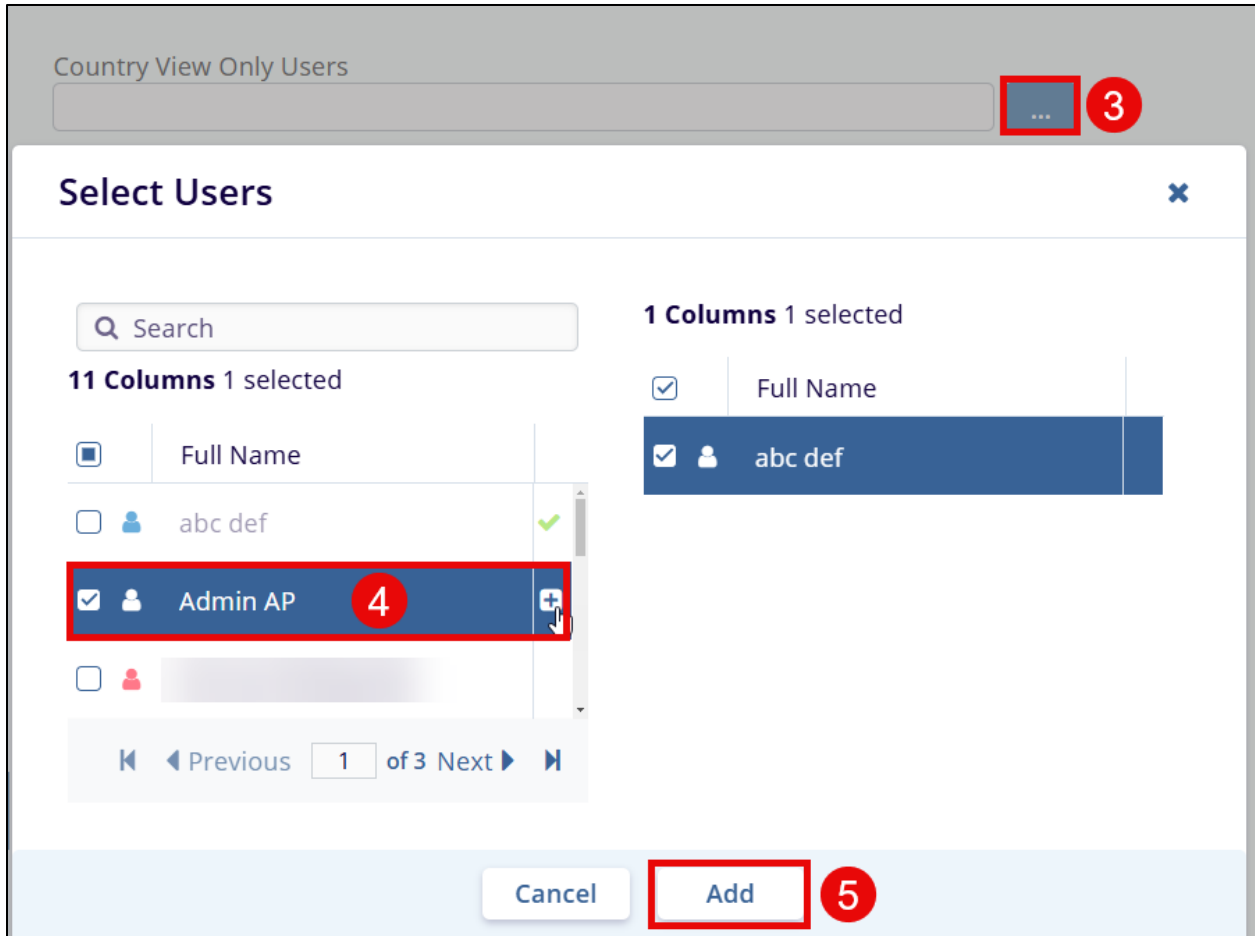
The Security page in the Country module helps the user create security to view full access and only country access to specific users and groups. The user can only edit the fields displayed on the page. Follow the steps below to set the security for the users and groups:

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.

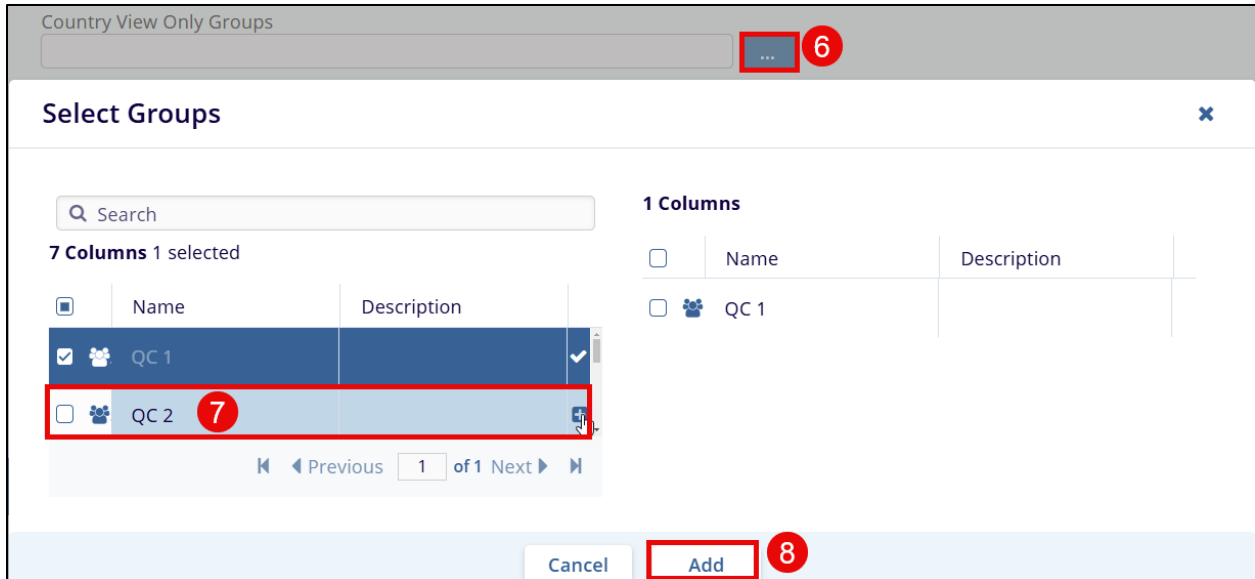
e



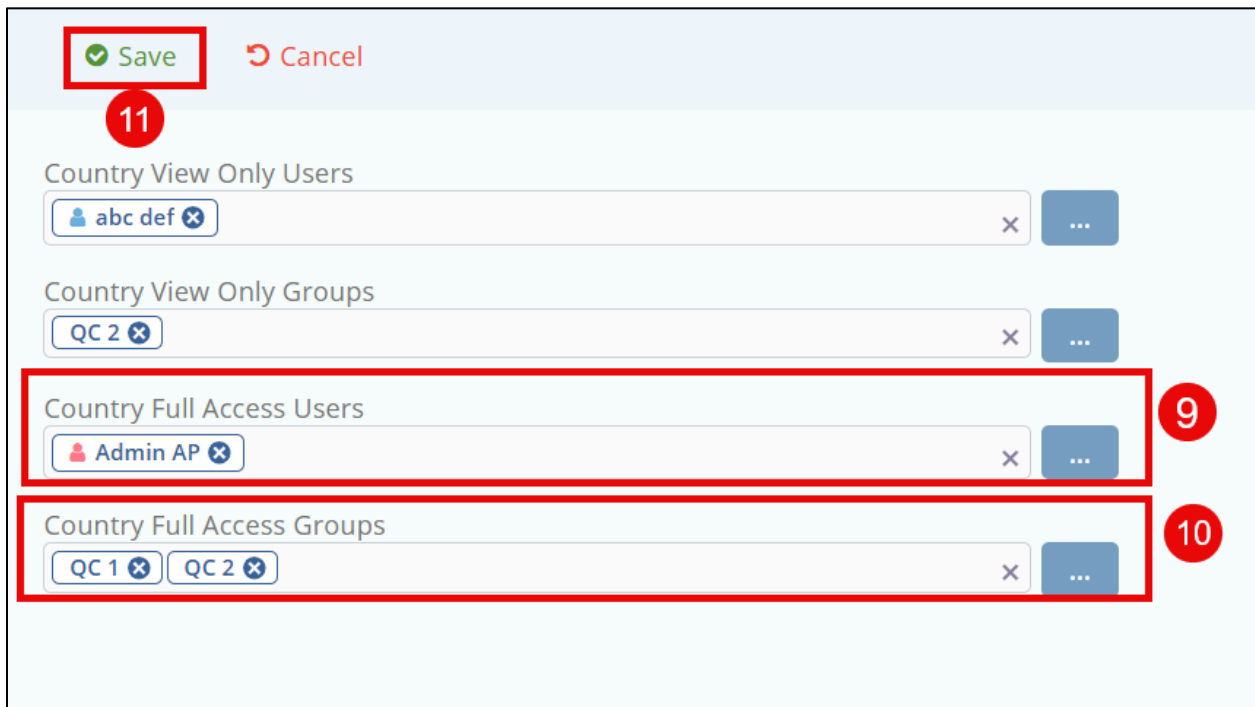
3. On the Country View Only Users field, click on the **three-dot** menu. This opens the Select Users popup window.
4. Select the checkbox(s) of the users whom you want to add to view only the country. Click the **Plus** sign next to the name. OR Drag and drop the name to the right-side pane. The selected names are reflected in the right-side pane. Also, the selected names in the left pane are greyed out.
5. Click the **Add** button at the bottom of the popup window. The selected names are reflected in the Country View Only Users field.



6. Click the **three-dot** menu displayed next to the **Country View Only Groups** field. This opens the Select Groups popup window.
7. 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.
8. Click the **Add** button at the bottom of the popup window.



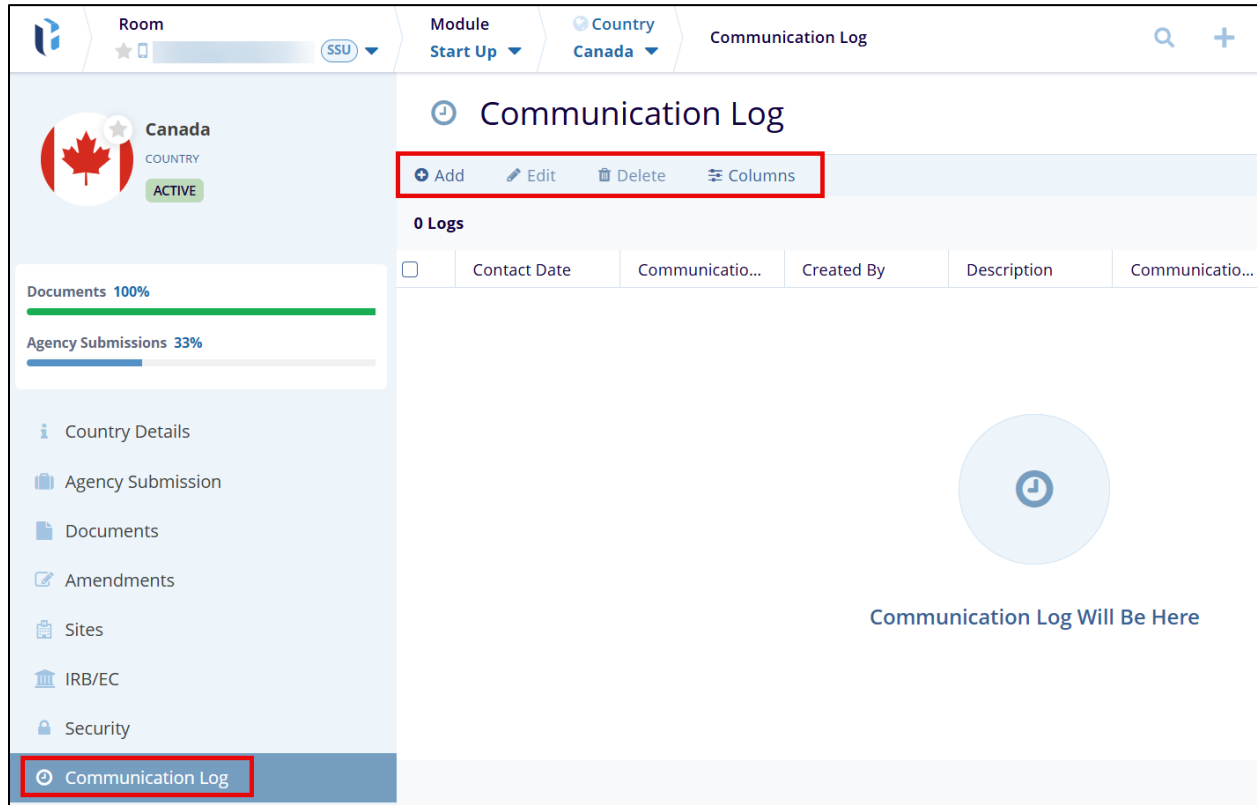
9. Follow steps 3-5 to add Country Full Access Users.
10. Follow steps 6-8 to add Country Full Access Groups.
11. Click the **Save** button displayed at the top left of the screen.



12. 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.



The screenshot shows the 'Communication Log' page in the Trial Interactive application. The top navigation bar includes 'Room', 'Module Start Up', and 'Country Canada'. The left sidebar contains a navigation menu with 'Communication Log' highlighted. The main content area features a toolbar with 'Add', 'Edit', 'Delete', and 'Columns' buttons. Below the toolbar, there is a table with the following columns: 'Contact Date', 'Communication...', 'Created By', 'Description', and 'Communication...'. The table currently shows '0 Logs'. A large circular icon with a clock symbol and the text 'Communication Log Will Be Here' is centered in the table area.

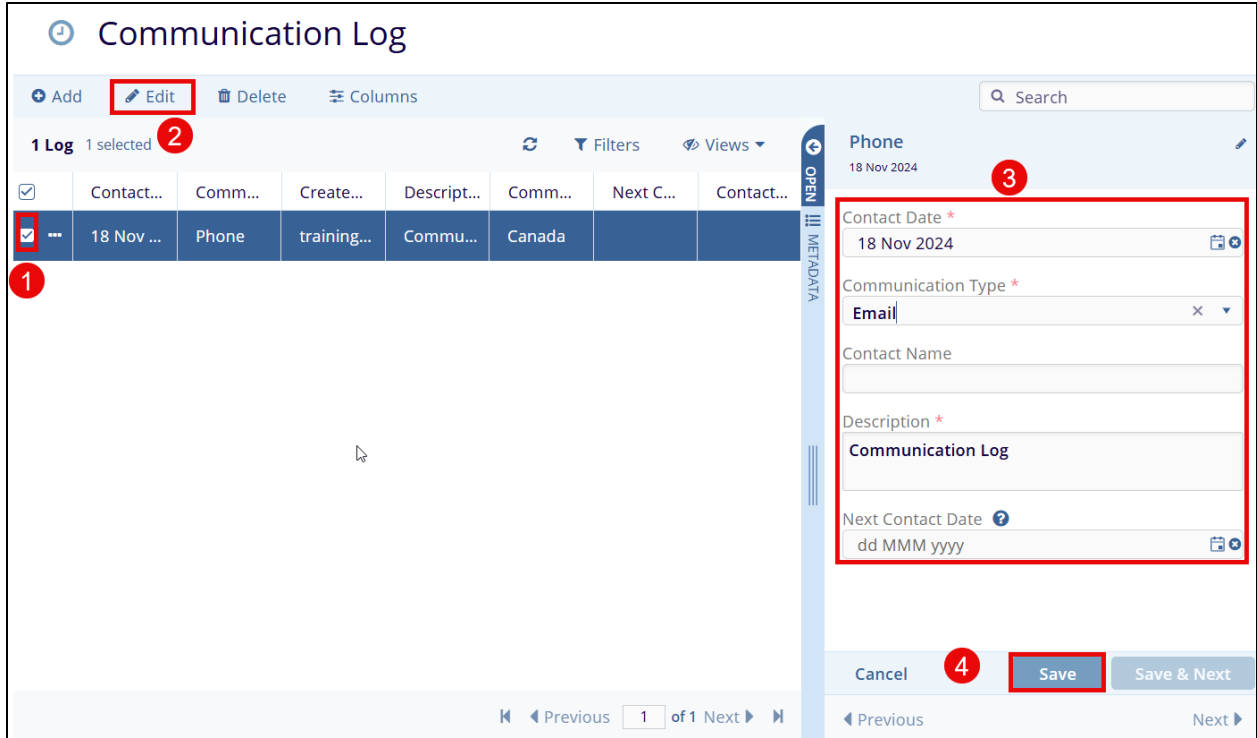
### 299. Add Log

1. Click the **Add** button displayed on the top menu bar.
2. On 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. Optionally add the Contact Name
5. Enter the details in the Description field.
6. **Optionally**, Enter the details in the Contact Name and Next Contact Date fields.
7. Click the **Add** button at the bottom of the popup window.

### 300. Edit Log

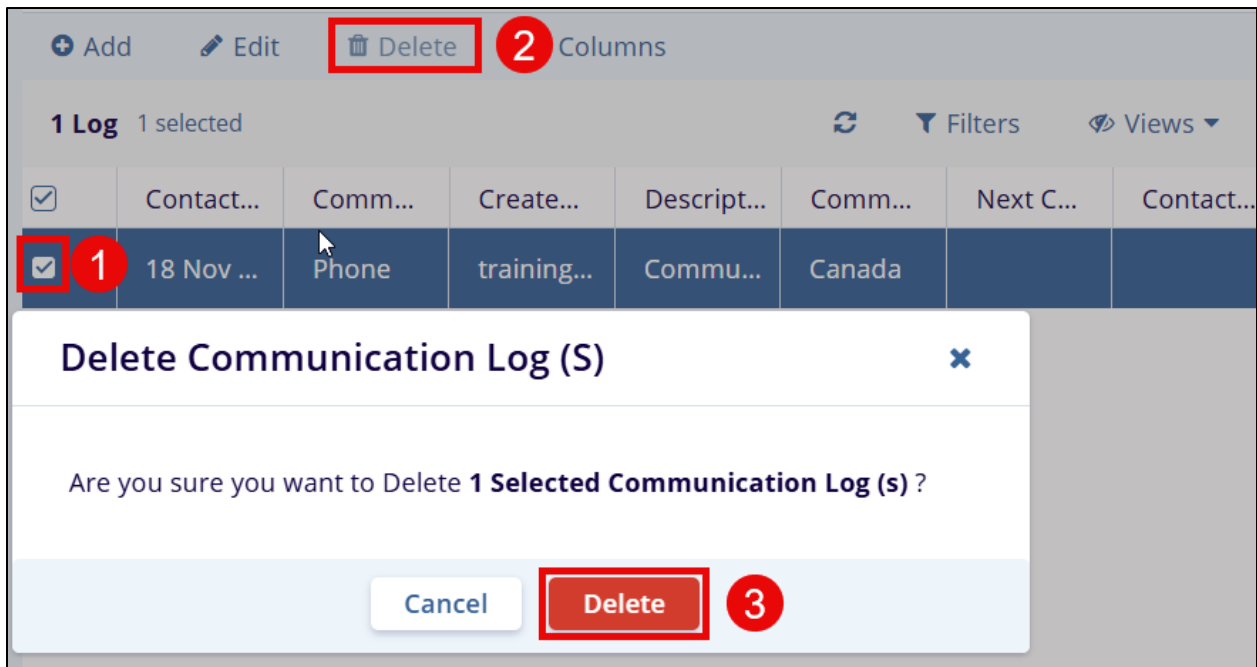
1. Select the checkbox of the log to edit.
2. Click the **Edit** button displayed on the top menu bar. This opens a metadata panel on the right side of the screen.
3. Make the changes in the required fields and click the **Save** button at the bottom of the metadata panel.
4. The saved changes are reflected in the grid pane.





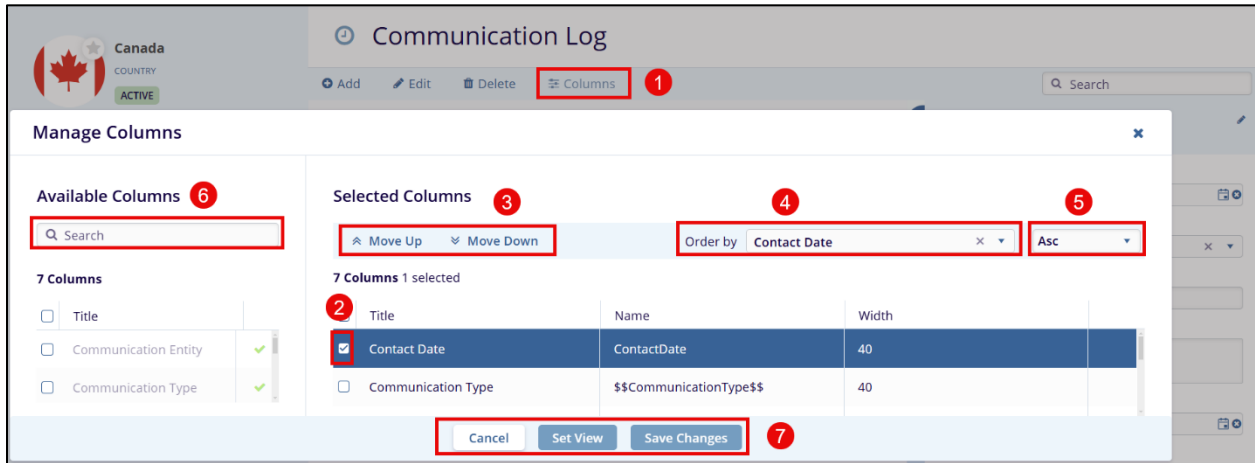
### 301. Delete Log

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.



### 302. Manage Columns

1. Click on the Columns option from the top menu bar
2. Select the column title by clicking on the Checkbox
3. Click on the Move Up and Move Down buttons to rearrange to columns' order.
4. Select an Order By filter from the available dropdown option.
5. Select Ascending or Descending to sort the columns.
6. Search for a specific column by entering the search term in the Available Columns search box.
7. Click on either the Cancel, Set View, or Save Changes button.



### 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

### Add Additional IRB/EC

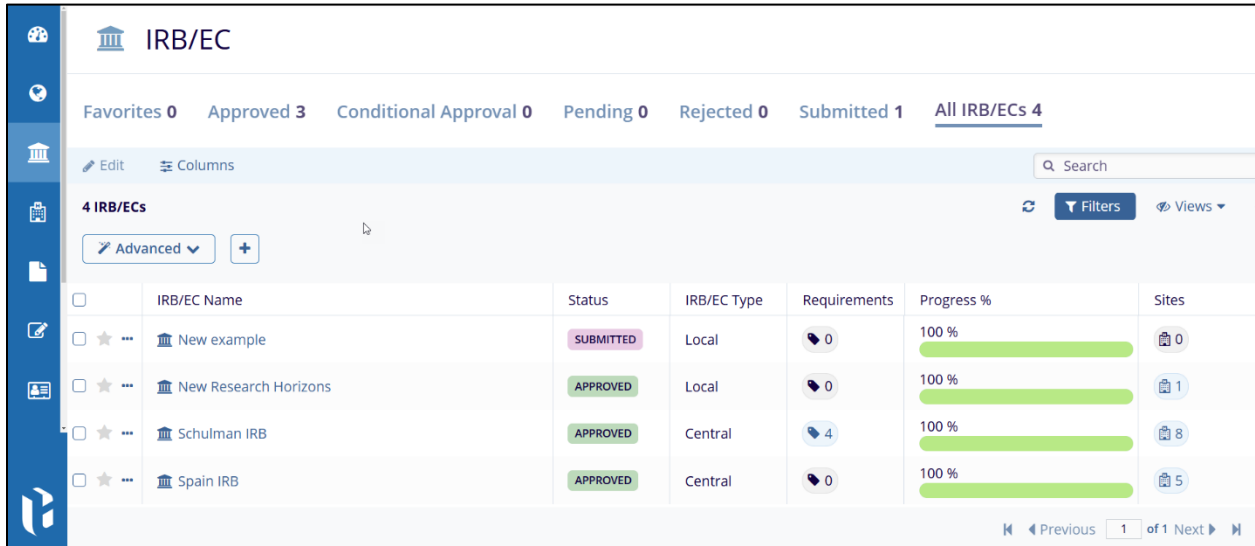
Users can specify more than one IRB/EC for a site from within the Sites module of SSU. Proceed to the section Add Additional IRB/ECs for more details on this.

### 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.
- **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.



## 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 and enables all four fields to be edited –
  - General Information
  - IRB/EC Contact Information
  - Meeting Frequency
  - Submission Deadline
  - Additional Information
4. Make the changes in the required fields and click the **Save** button displayed at the bottom of the metadata panel.

**IRB/EC**

[Favorites 0](#)
[Approved 3](#)
[Conditional Approval 0](#)
[Pending 0](#)
[Rejected 0](#)
[Submitted 1](#)
[All IRB/ECs 4](#)

**2** [Edit](#) [Columns](#)

4 IRB/ECs 1 selected [Filters](#) [Views](#)

[Advanced](#) [+](#)

	IRB/EC Name	Status	IRB/...	Requ...	Progress %	Sites
<input checked="" type="checkbox"/>	<b>1</b> <a href="#">New example</a>	SUBMIT	Local	0	100 %	0
<input checked="" type="checkbox"/>	<a href="#">New Research Horizons</a>	APPROV	Local	0	100 %	1
<input type="checkbox"/>	<a href="#">Schulman IRB</a>	APPROV	Central	4	100 %	8
<input type="checkbox"/>	<a href="#">Spain IRB</a>	APPROV	Central	0	100 %	5

**3** **New example** SUBMITTED

- General Information
- IRB/EC Contact Information
- Meeting Frequency
- Submission Deadline
- Additional Information

**4** [Cancel](#) [Save](#) [Save & Next](#)

Previous 1 of 1 Next

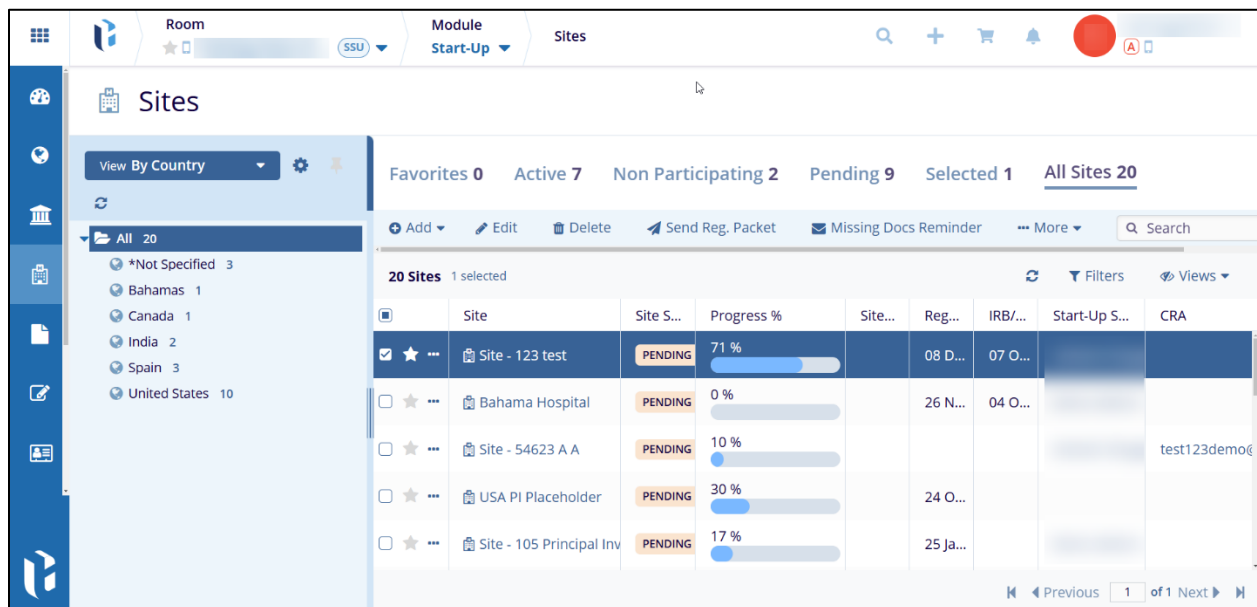
## Site

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 and approve 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 list of sites in the grid pane. Refer to the screenshots below.



Besides the above, users can also add required documents or regulatory approvers specific only to a particular site and add room users to sites by providing them with appropriate security accesses. These will be discussed in subsequent sections.

Sr No	Part	Description
1	Site Activation	Users can choose the current view.
2	Add	add New Investigative Sites and Contacts one at a time.
3	Edit	Allows to edit the sites.
4	Delete	Allows to delete the Investigative Site.
5	Send Reg. Packet	Allows to send the regulatory packets to the specific sites.
6	Missing Docs Reminder	Allows the user to send an email regarding the missing expected documents to the recipient.

Sr No	Part	Description
7	More <ul style="list-style-type: none"> <li>Manage Security</li> <li>Export Metadata</li> <li>Mass Coding</li> <li>Columns</li> </ul>	<ul style="list-style-type: none"> <li>Allows to provide security roles to users on the site.</li> <li>Allows to export the sites in the room.</li> <li>Allows to add Metadata to the multiple selected sites.</li> <li>Allows the user to manage the columns to be viewed in the grid.</li> </ul>
8	Filters	Allows users to manage and create new filters.

## Creating Sites and Additional Contacts

Users can create sites using any one of the methods below.

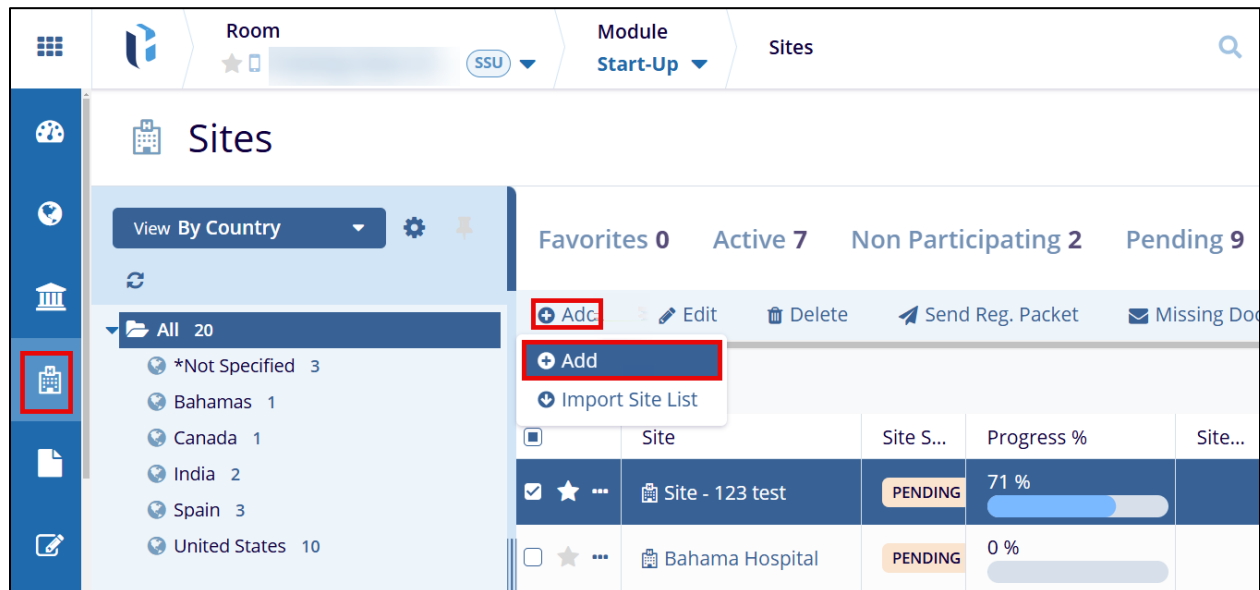
### 303. Adding each site and contact individually

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.

So users might want to create sites with the same name but different metadata like contacts, addresses, 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 and available.

To create sites, follow the steps below:

1. Click on the Sites modal from the left-hand navigation pane and click on the **+Add** button from the top menu bar and select +Add option.



2. On the Create Site form, add the following details as a part of Step 1: Site Information and click on the Next button.
  - General Information
    - Institution Name\*

- Principal Investigator\*
- CRA
- Start-Up Specialist
- Main IRB/EC
- IRB/EC Submit Date
- IRB/EC Approval Date
- Site Contact Information
  - Address
  - Phone Numbers
- Additional Information
  - Site Number
  - Site
  - Disable Auto Site Name
  - Reason for not using the auto site name
  - Expiration Date
  - Status
  - Preferred Communication Mode
  - Reg Pack Sent Date
  - Expected Submission Date
  - Site Activation Date
  - eFeasibility Status
  - Effective Closure Date
  - Do not inherit security from the template folders
  - Other
  - Country Approval Date
  - Status Date
  - Organization Name
  - Alternative Site Address(es)
  - Pharmacy Address(es)
  - Laboratory Address(es)

**Create Site**
Step 1 ● ○ ○ ○ ○ ○ ○ ×

Site Information

Contacts

IRB/EC

Required Documents

Amendments

Review & Confirm

**Site Information**

**General Information** ^

Institution Name \*

Principal Investigator \*

333 222
▼

CRA

Select
▼

Start-Up Specialist

Select
▼

Main IRB/EC

▼

IRB/EC Submit Date

dd MMM yyyy
📅

IRB/EC Approval Date

dd MMM yyyy
📅

Cancel

Next

3. Add the following details as a part of Step 2: Contacts and click on the **Next** button.

- Add an existing contact by selecting the +Add Existing button
- Create a new contact by selecting the +Create button
- Select a contact and click on the Edit button to make changes to the existing contact.
- Select a contact and click on the Delete button to remove the contact.

**Create Site**
Step 2 ○ ● ○ ○ ○ ○ ○ ×

Site Information

Contacts

IRB/EC

Required Documents

Amendments

Review & Confirm

**Contacts**

+ Add Existing
+ Create
✎ Edit
🗑 Remove

	Name	Email	Phone	Contact Type
<input checked="" type="checkbox"/>	333 222	test213123@ti.com		Principal Investigator

⏪ Previous
1 of 1
Next ⏩

Cancel

Previous

Next

4. Add the following details as a part of Step 3: IRB/EC

- Add an existing IRB/EC by selecting the +Add Existing button
- Create a new IRB/EC by selecting the +Create button



- Select an IRB/EC and click on the Set as Central button
- Select an IRB/EC and click on the Set as Local button
- Select an IRB/EC and click on the Edit button to make changes to the existing IRB/EC.
- Select an IRB/EC and click on the Remove button to remove an existing IRB/EC.

**Create Site** Step 3

Site Information

Contacts

**IRB/EC**

Required Documents

Amendments

Review & Confirm

IRB/EC

+ Add Existing + Create + Set as Central Remove

<input checked="" type="checkbox"/>	Name	Type	Status	Country	Address
<input checked="" type="checkbox"/>	New example	Local	SUBMITTED	Canada	Any street

Cancel Previous **Next**

5. Add the following details as a part of Step 4: Required Documents and click on the **Next** button.
  - Click on the +Add button to add the required documents
  - Select a required document and click on the Remove button.

**Create Site** Step 4

Site Information

Contacts

IRB/EC

**Required Documents**

Amendments

Review & Confirm

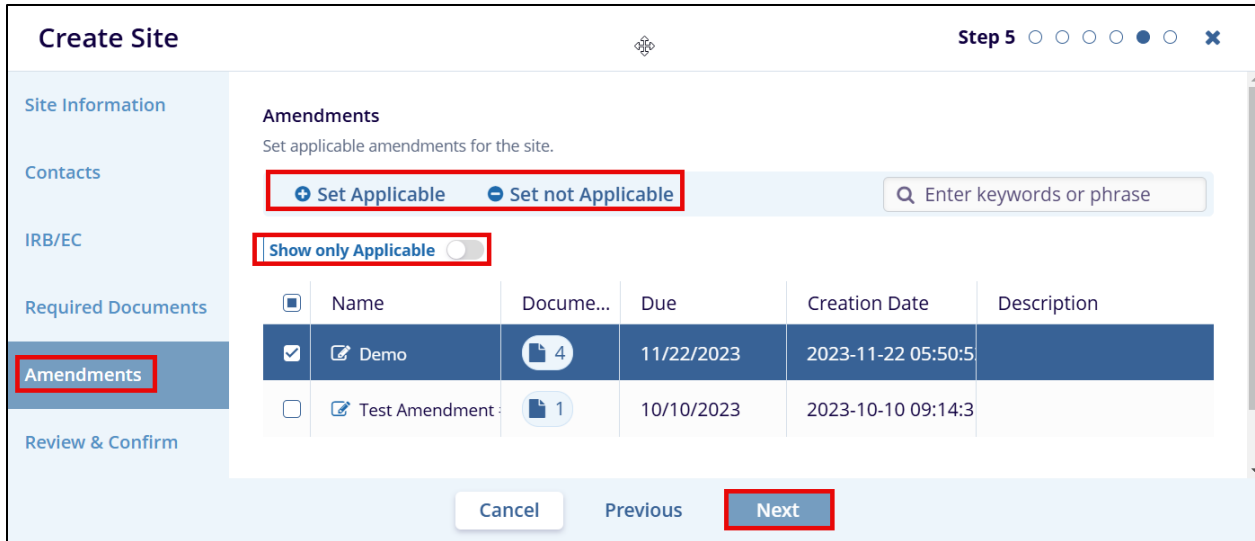
Required Documents

+ Add Remove

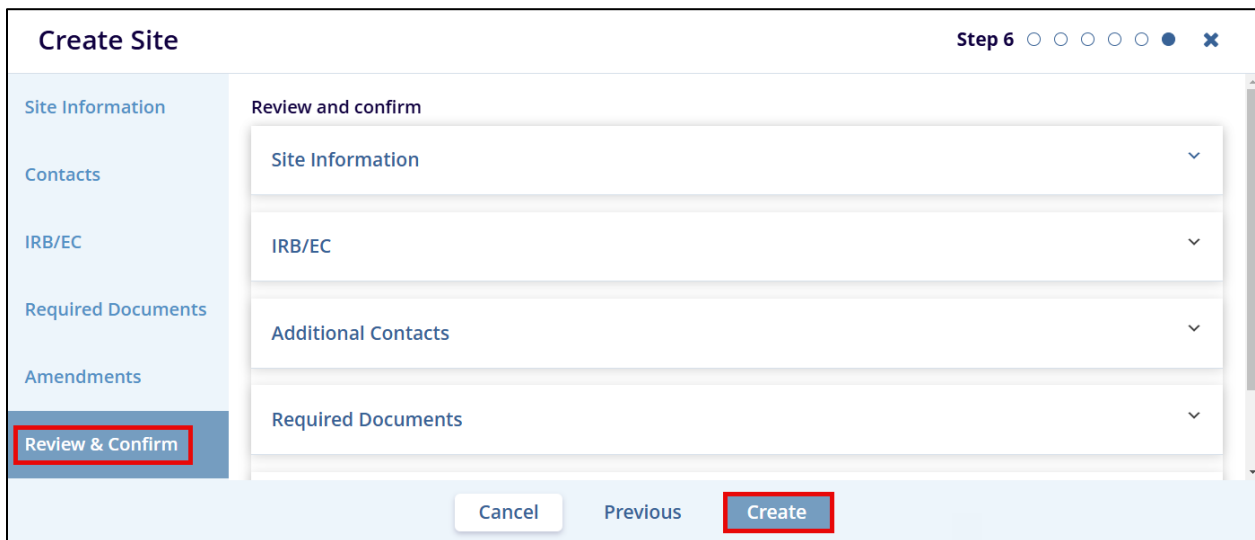
<input checked="" type="checkbox"/>	Document Type	Required For	To be submitted by	Languages
<input checked="" type="checkbox"/>	Recruitment Plan	Site Activation 1	Select	Select
<input type="checkbox"/>	Debarment Statement	Site Activation 1	Select	Select
<input type="checkbox"/>	Audit Certificate	Site Activation 1	Select	Select
<input type="checkbox"/>	List of audits	Site Activation 1	Select	Select

Cancel Previous **Next**

6. Add the following details as a part of Step 5: Amendments and click on the Next button.
  - Select an existing amendment and click on +Set Applicable.
  - Select an existing amendment and click on -Set Not Applicable.
  - Enable the 'Show only Applicable' toggle button to display only the applicable amendments.



7. Verify all the information in Step 6: Review and Confirm and click on the Create button.



### 304. Importing Sites and Site Contacts

This feature is beneficial if users 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.

To import sites and contacts, follow the steps below.

1. Click on the Sites modal from the left-hand navigation pane, click on the +Add button from the top menu bar, and select the Import Site List option.

The screenshot shows the 'Sites' management interface. At the top, there are navigation elements: 'Room' (Training Team eT...), 'Module' (Start-Up), and 'Sites'. The main header is 'Sites'. Below it, there's a 'View By Country' dropdown and a refresh button. A list of countries is shown: \*Not Specified (3), Bahamas (1), Canada (1), India (2), Spain (4), and United States (10). The 'Sites' icon in the left navigation menu is highlighted with a red box. A dropdown menu is open, showing 'Add' and 'Import Site List' (highlighted with a red box). Below the dropdown is a table of sites:

<input type="checkbox"/>	Site	Site S...	Progress %
<input checked="" type="checkbox"/>	Site - 123 test	PENDING	71 %
<input type="checkbox"/>	Bahama Hospital	PENDING	0 %
<input type="checkbox"/>	Site - 333 222	PENDING	0 %

- On the Site Import screen, click on the **'See the sample worksheet template'** hyperlink to download the template.

**Sites Import**
**Step 1** ● ○ ○ ○ ○ ○ ○
✕

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**Upload File**

This wizard supports the import of many sites at once using a spreadsheet.  
The spreadsheet should contain two separate worksheets:

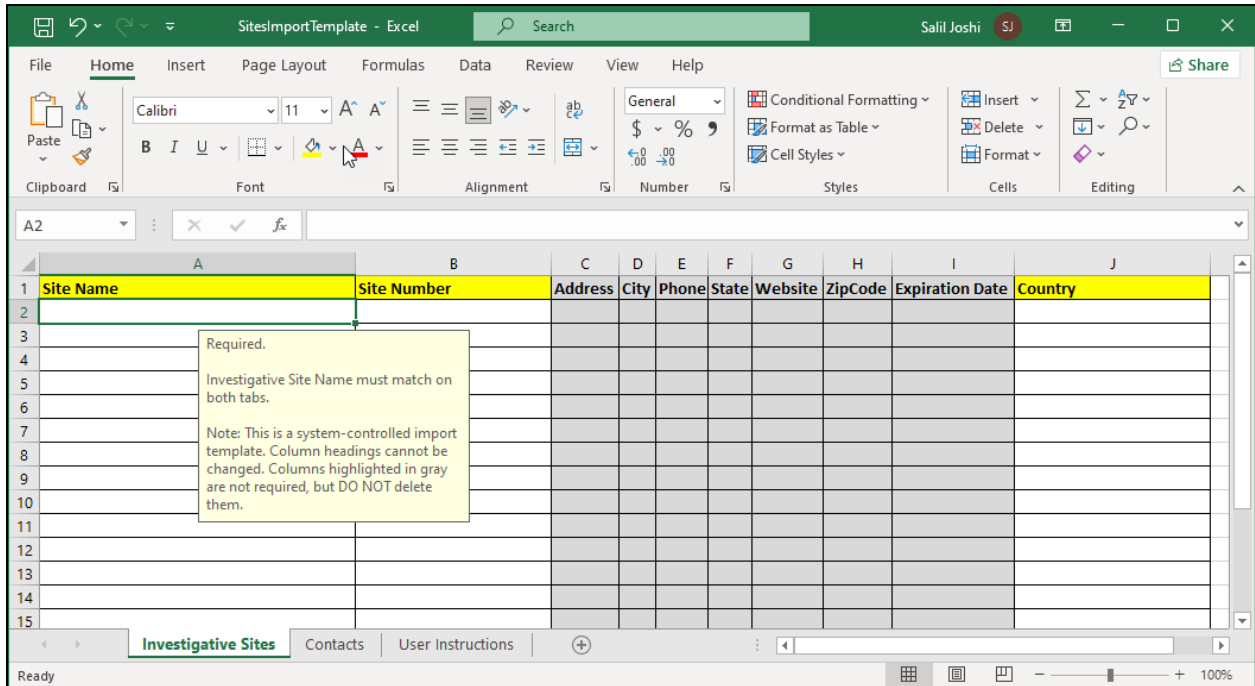
- Worksheet one should contain the list of institution names and addresses
- Worksheet two should contain the list of contacts including the Principal Investigator

Metadata File (format: .xlsx)\*:  Select

[See the sample worksheet template](#)

Cancel
Previous
Next

3. The worksheet consists of three sheets – 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 sites and their contacts and create the sites. The sites thus created appear in the grid for you to view.



## Important

- The Investigative Sites sheet cannot be left blank.
  - While importing sites, it is compulsory to specify the Principal Investigator, without which sites will not be imported.
  - Start-up specialists and CRA cannot be imported. You will need to add these later and can use Mass Coding for the same
  - Sites with the same names cannot be imported.
  - Fields such as First Name and Last Name in the Contacts sheet cannot be left blank, as the system will 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.
  - Main contact/s should be specified as they are the ones to receive the email when the regulatory packets are sent.
  - 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 and set 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).
  - If the 'Active Contact' field is left blank, the contact will be deactivated by the system. You may choose to activate the contact later if required.
  - If a site and its contacts are already imported, then more contacts can be added to the site only manually or through the API.
  - Data that was not imported can be mass-coded for multiple sites later (follow on to Mass Coding of Sites for further details).
4. In Step 1, Click on the Select button select the updated .xlsx file and click on the Next button.

**Sites Import**
Step 1 ● ○ ○ ○ ○ ○ ○
✕

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**Upload File**

This wizard supports the import of many sites at once using a spreadsheet.  
The spreadsheet should contain two separate worksheets:

- Worksheet one should contain the list of institution names and addresses
- Worksheet two should contain the list of contacts including the Principal Investigator

Metadata File (format: .xlsx)\*: C:\fakepath\SitesImportTemplate.xlsx
Select

[See the sample worksheet template](#)

Cancel
Previous
Next

5. In Step 2, setup the metadata field mapping and click on the **Next** button.

## Sites Import

Step 2
○ ● ○ ○ ○ ○ ○
✕

---

Set up metadata fields mapping

Spreadsheet Column	Metadata field
Site Name	Site Name
Site Number	Site Number
Address	Address
City	City
Phone	Phone

Cancel
Previous
Next

6. In Step 3, setup the metadata field mapping for contacts and click on the **Next** button.

**Contacts Import**
Step 3 ○ ○ ● ○ ○ ○
✕

Set up metadata fields mapping

Spreadsheet Column	Metadata field
Site Name	Site Name
User Name	User Name
Contact Type	Contact Type
Active Contact	Active Contact
Main Contact	Main Contact
Provide Documents	Provide Documents
First Name	First Name

Cancel
Previous
Next

7. In step 4, confirm site metadata field mapping and click on the Next button.



## Sites Import

**Step 4** ○ ○ ○ ● ○ ○ ✕

---

**Confirm site metadata fields mapping**

Spreadsheet Column <span style="float: right;">↑</span>	Metadata field
Site Name	Site Name
Site Number	Site Number
Address	Address
City	City
Phone	Phone

Cancel
Previous
Next

8. In Step 5, confirm contact metadata field mapping and click on the Next button.

## Sites Import

**Step 5** ○ ○ ○ ○ ● ○

✕

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### Confirm Contact metadata fields mapping

Worksheet Column	Metadata field
Site Name	Site Name
User Name	User Name
Contact Type	Contact Type
Active Contact	Active Contact
Main Contact	Main Contact
Provide Documents	Provide Documents

Cancel
Previous
Next

9. On the Information popup, click on the OK button.

## Information

✕

?

While the import is in progress, you can close the wizard. The import progress will appear at the Notifications area.

Do not ask me again

OK

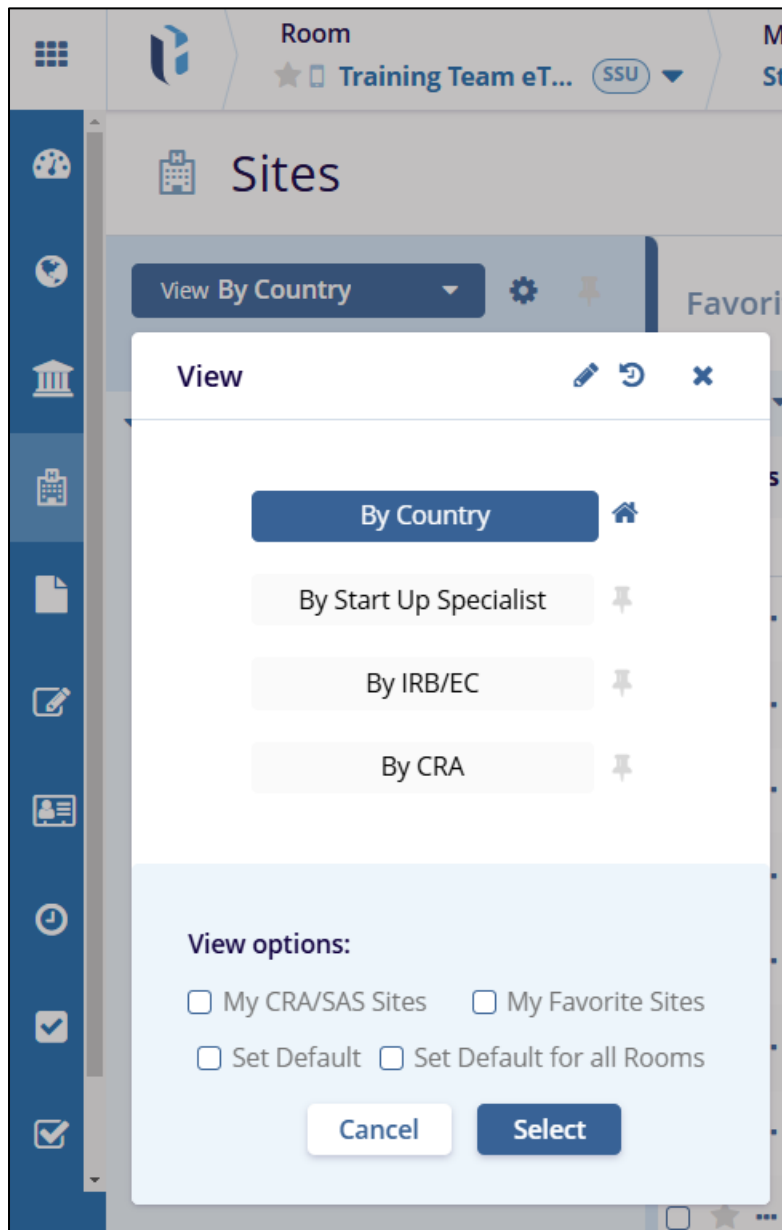
10. Click the **Complete** button in the Review import progress and results.

### Viewing Sites

Sites can be viewed from the list of sites appearing in the grid pane. The user can choose to filter the sites appearing in the grid by selecting the filters from the current view dropdown, as shown below.

#### The Site Current View

The Current View Dropdown offers four views:



View	Description
------	-------------

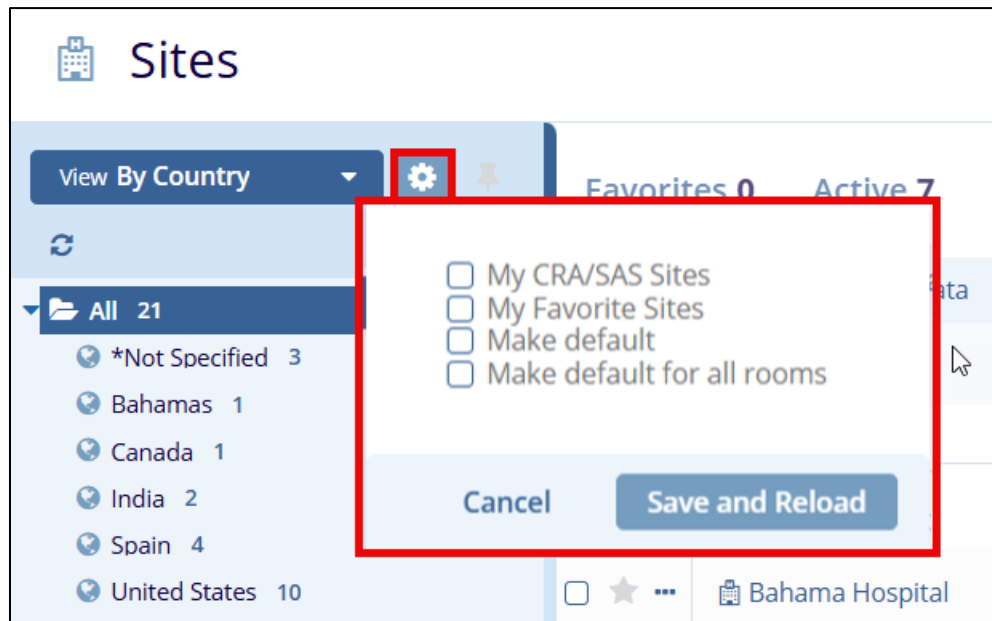
By Country	This view reveals a list of countries, and when you select a particular country from the list, you see all investigative sites related to this country. Not Specified status indicates that a country is not specified in the investigative site’s profile.
By Start-Up Specialist	This view displays a list of data room users with Start-Up Specialist designation. When you select a particular user from this list, you will see all sites where this user is set as a 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	RBs 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 all investigative sites with local IRB specified in their profiles.
By CRA	This view displays a list of data room users with CRA designation. When you select a 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 in their profiles.

### Buttons on the Current view

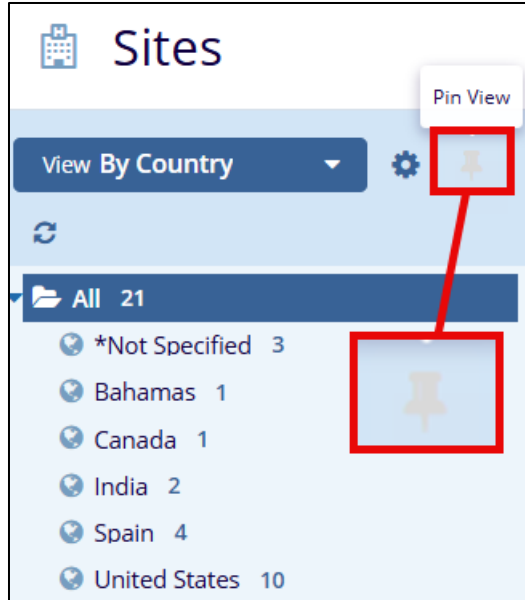
Some studies require that a data room house hundreds of sites. The user can toggle the display between the sites where the user is a CRA, a Start-Up Specialist, or All Sites.

The user can refresh the current view by clicking the Refresh Current View button. Through the Configure Grid button, the room administrator can decide the columns that team members need to 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



2. Pin View button



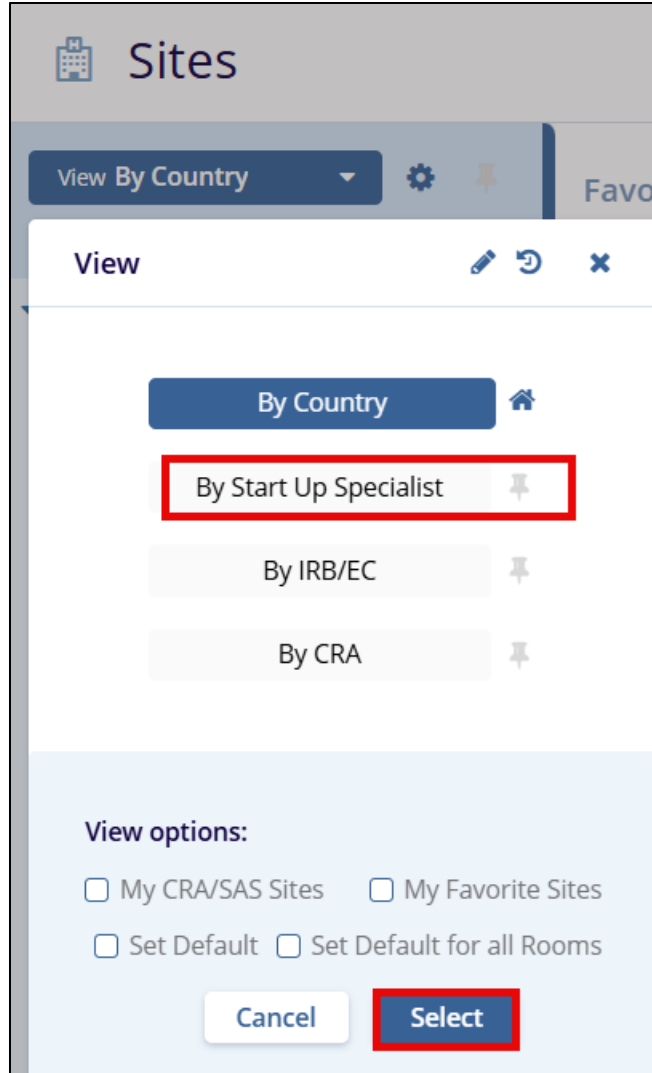
3. Refresh Button



**View and Edit Site Profiles**

To view and edit site profiles follow the steps below.

1. Access the View By dropdown, select 'By Startup Specialist' and click on the Select button.



2. Select a site profile and click the **Edit** button in the menu ribbon to open the Site Profile in the metadata panel on the right side of the screen.
3. Make edits to the site details and click on the Save button.

The screenshot displays the 'All Sites 21' view in the Trial Interactive application. At the top, there are navigation tabs for Favorites (0), Active (7), Non Participating (2), Pending (10), Selected (1), and All Sites (21). Below these are action buttons: Add, Edit (highlighted with a red box), Delete, Send Reg. Packet, Missing Docs Reminder, and More. A search bar is also present.

The main area shows a table of 21 sites. The first site, 'Site - 123 test', is selected and its details are shown in a right-hand pane. The table columns include Site, S..., Progress %, S., R., I..., Star..., and CRA. The 'Site - 123 test' row shows a progress bar at 71% and a 'PENDING' status. The details pane for this site includes a 'General Information' section with fields for Institution Name (marked with a red asterisk), Status (set to PENDING), and a 'Change Status' button. Navigation buttons for 'Previous' and 'Next' are visible at the bottom of the details pane.

4. To open the Site Details page, double-click a site from the grid to open its Site Details window and click on the **Edit** button
5. 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 whether the site can be activated, depending on the percentage displayed for each field. Below the progress bar, the user can navigate to:
  - a. Contacts,
  - b. Documents,
  - c. Requirements,
  - d. Amendments,
  - e. IRB/EC,
  - f. Security,
  - g. Communication Log and
  - h. Budgets and Contracts of the site.

6. Make changes in the General Information, Site Contact Information, and Additional Information tabs and click on the Save button.

**Note:**

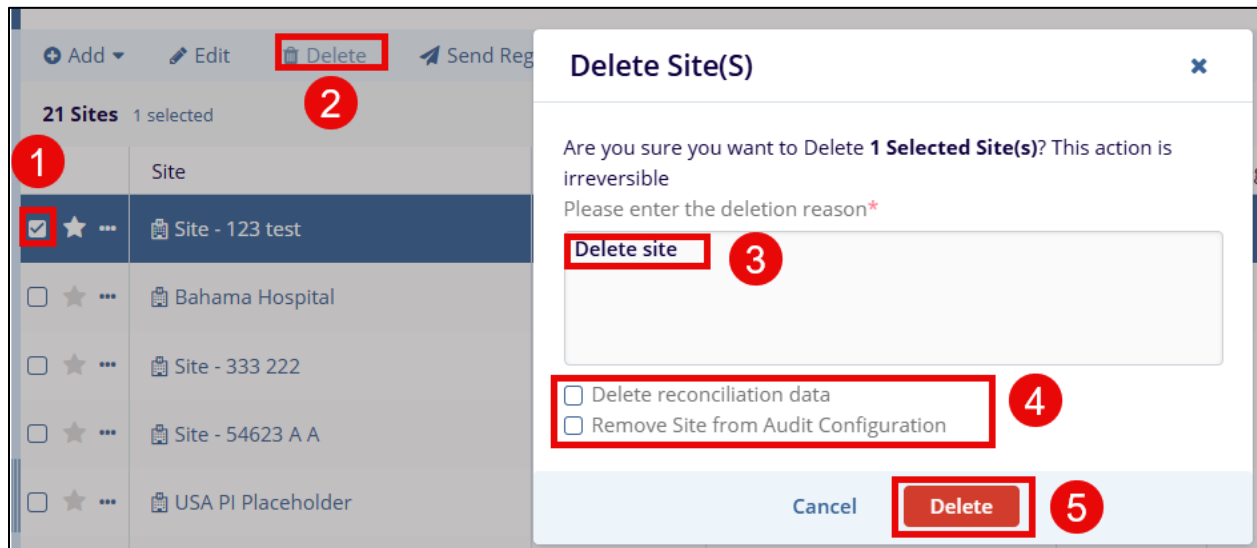
- If no IRB/EC Submit Date and Expected Submission Date are specified in the site profile, the system will not display them in the right panel.
- Instead, it will project the Next Pre-Submission Deadline Date based on the meeting schedule specified in the IRB/EC profile.
- The system will use the Next Pre-Submission Deadline Date to display the Projected IRB/EC Approval 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 next to the Expected Submission Date field.



## Delete Site

To delete a site, follow the steps below

1. Select a site from the list by clicking on the checkbox
2. Click the **Delete** button from the top menu ribbon.
3. On the 'Delete Site(S) confirmation popup, mandatorily enter a reason for deletion.
4. Optionally enable or disable the following by selecting or deselecting the checkboxes
  1. Delete Reconciliation Data
  2. Remove Site from Audit Configuration
5. Click on the **Delete** button.



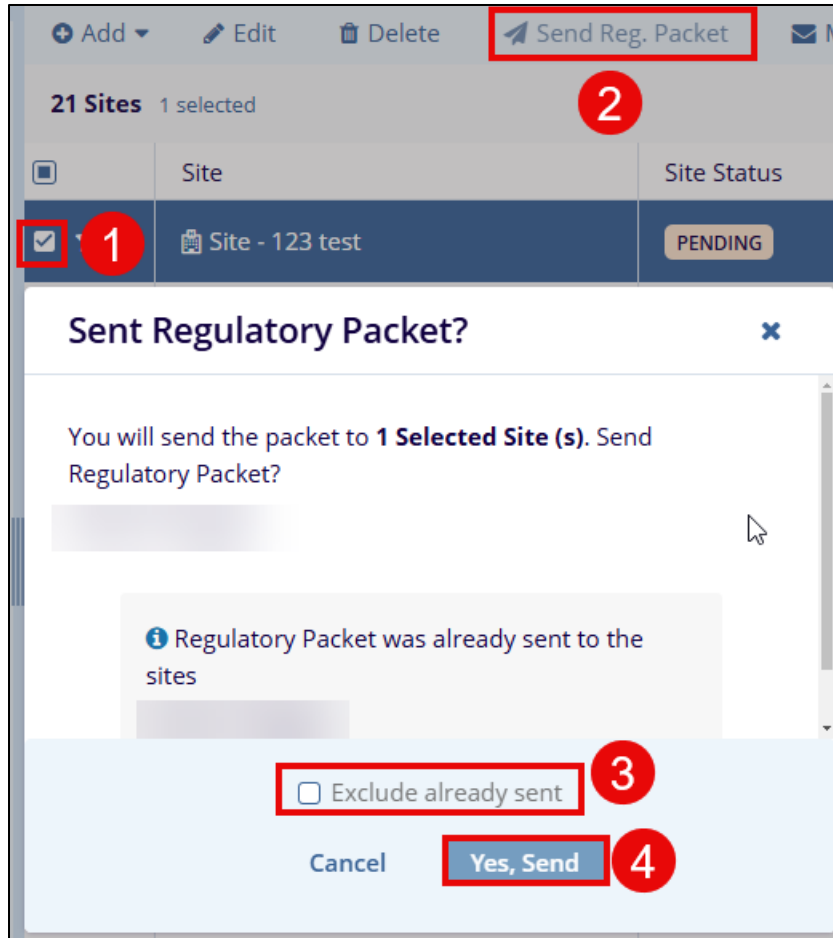
### Note:

- Sites cannot be deleted if they have already collected documents and the user receives a warning message about the same in the popup window.
- To delete a site, its documents must first be deleted.

## Send Reg. Packet

To send a regulatory packet, follow the steps below.

1. Select a site by clicking on the checkbox,
2. Click on the Send Reg. Packet button.
3. On the 'Sent Regulatory Packet?' popup, click on the 'Exclude already sent' checkbox.
4. Click on the **Yes, Send** button.



5. On the Send Reg. Packet email screen, click on the **Send** button.

**Send Reg. Packet**
✕

Site(s)\*

Cc..  Add

Subject\*

Open Sans
16
🔥
B I U S
🔗
🖼
☰
☰
☰

Re: ##RoomName## Study

Dear Investigator and Site Staff,

Your response to questionnaires and additional communication indicate your site meets the requirement necessary for this important study. **CLIENT NAME** is pleased to extend the offer of participation in the ##RoomName## study to you. On behalf of the **CLIENT NAME** team we would like to warmly welcome you and look forward to working with you the months ahead. This is a system generated email so please do not reply to this but follow the instructions listed below.

Included you will find necessary documents required for start-up. To enable a quick start-up we would like to work with you in the most efficient manner possible to ensure your site is ready to participate in the registry. Before opening your site to participation we will need to collect the following essential documents.

##RegpackDocumentsGrid##

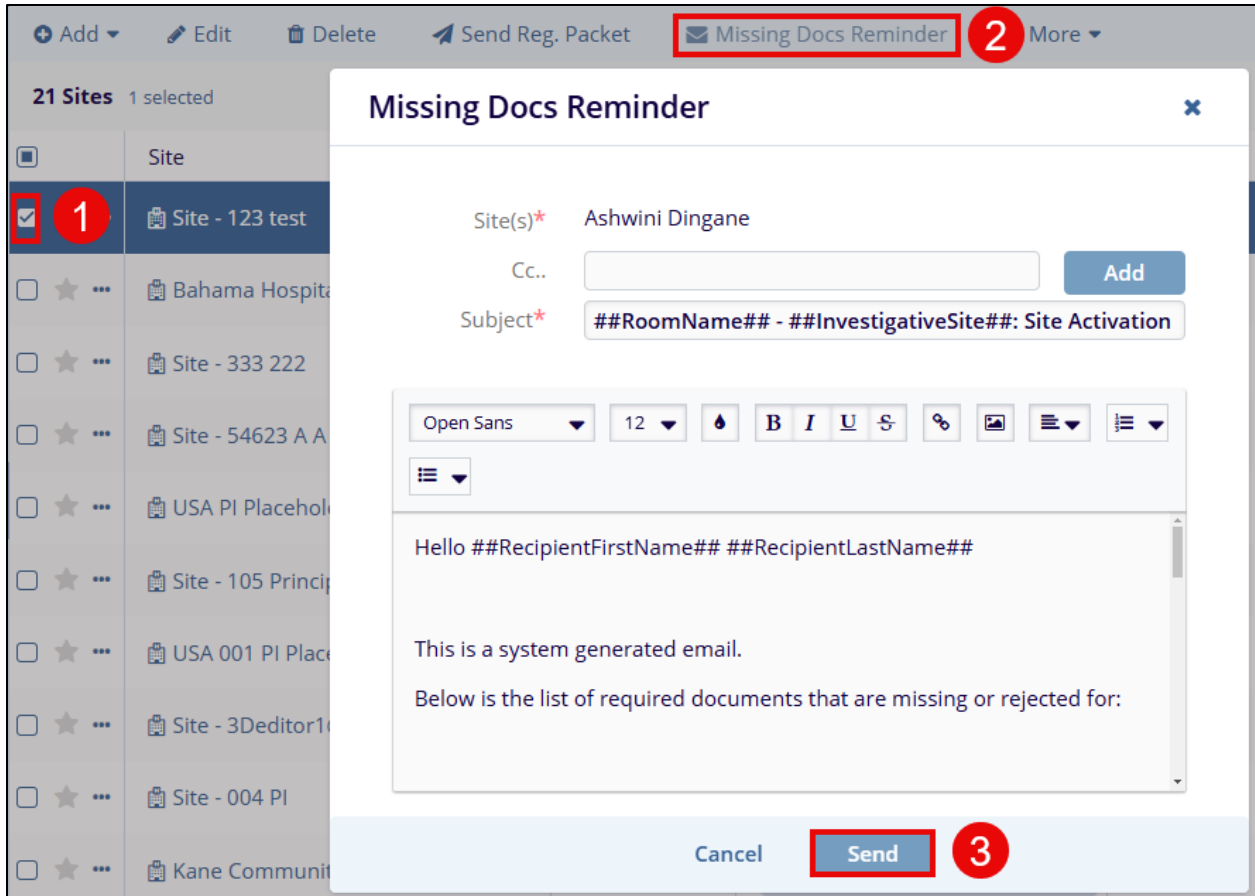
Please submit the documents listed above to @.com.

Cancel
Send
5

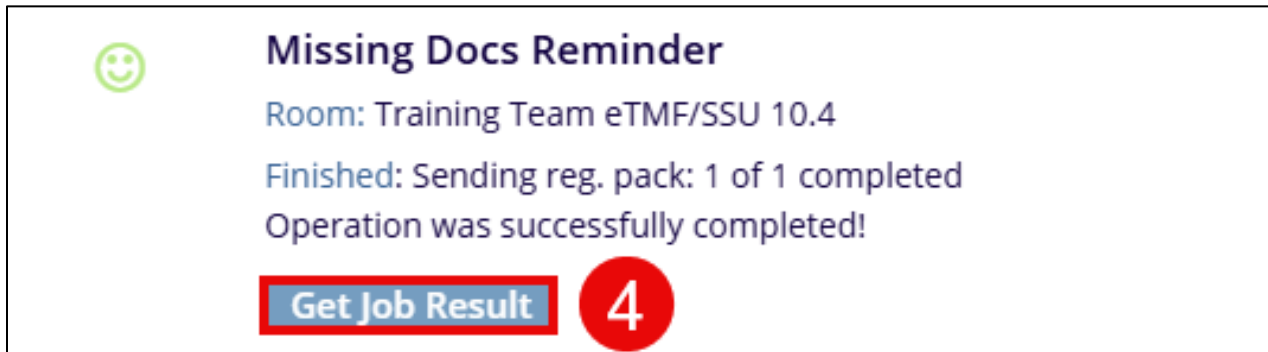
### Missing Docs Reminder

To send a reminder for missing documents, follow the steps below.

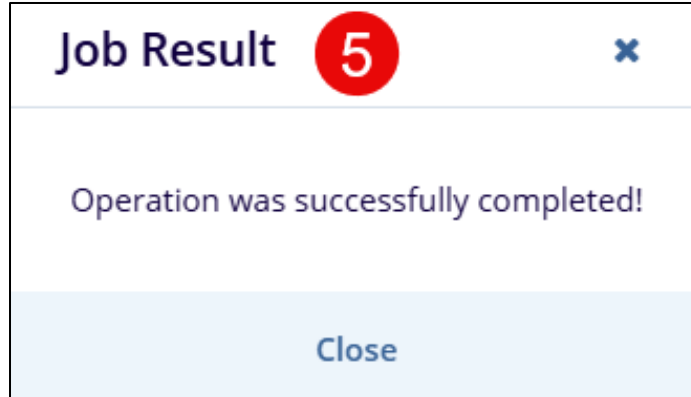
1. Select a site by clicking on the checkbox
2. Click on the Missing Docs Reminder button.
3. On the 'Missing Docs Reminder' email, enter the required details and click on the Send button.



4. The Missing Docs Reminder success popup click on the Get Job Result button.



5. The Job Result popup displays the success message.



### Managing Security

We have already seen in the section Accessible functionalities for SSU Users the types of security privileges provided by the Trial Interactive system to the users and contacts of investigative sites. Security privileges can be provided for all sites in a data room, as well as from within the Study Start-Up Sites section.

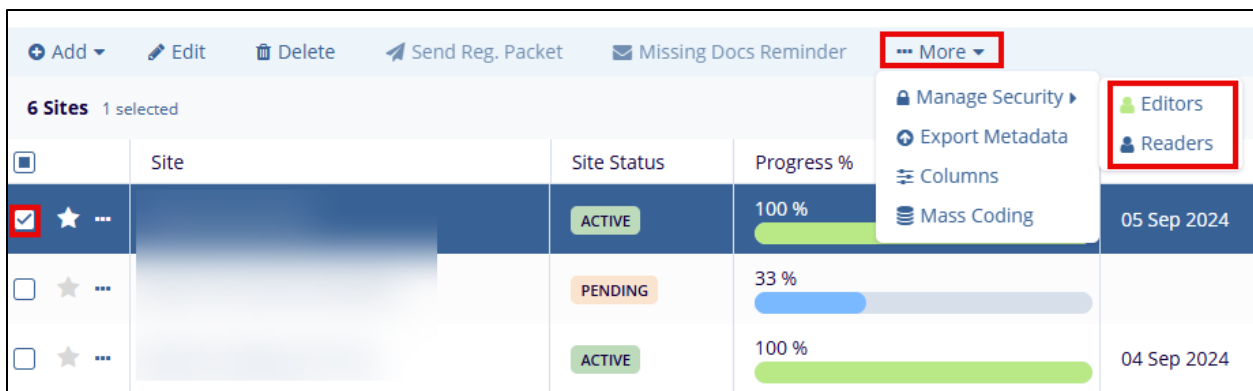
Access to users for all sites can be provided by adding the site users to the Default editors/readers group or by making them Default access members of sites.

From within the SSU Sites section, the administrator can view and provide security privileges to users for site/s from two locations:

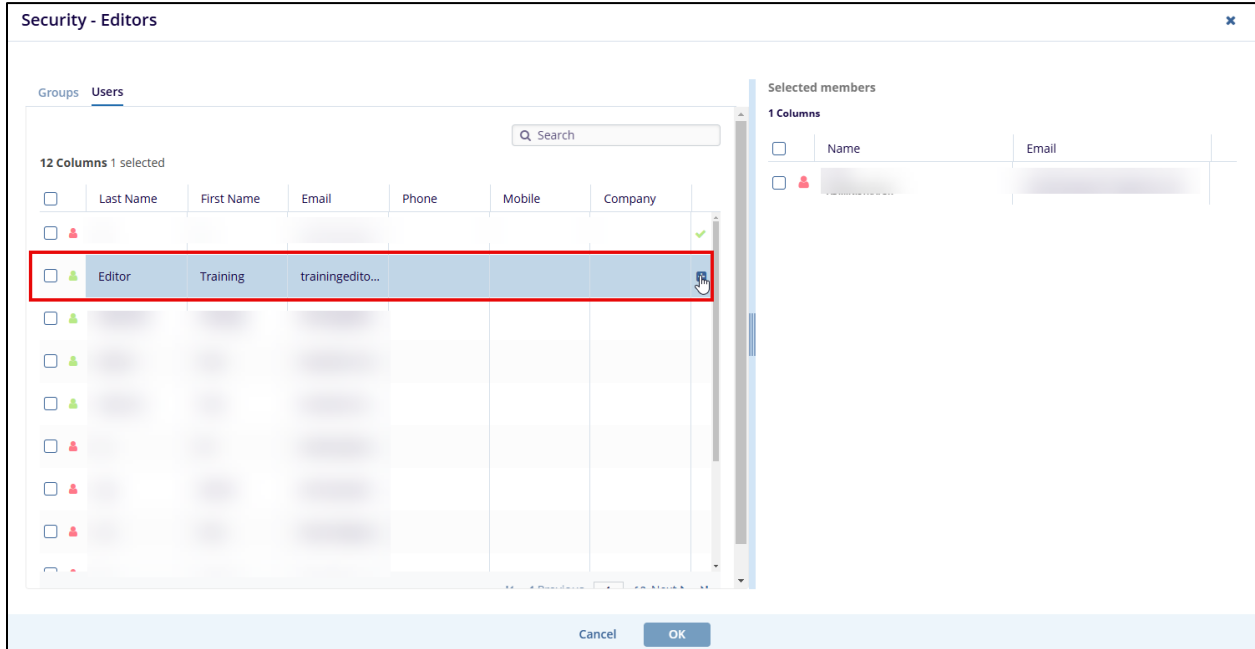
**Note:** The Administrator has to be a site member like an SSU Specialist, Co-Investigator, or Site Activation Member to be able to manage the security of sites from within the SSU Sites section.

To manage security, follow the steps below.

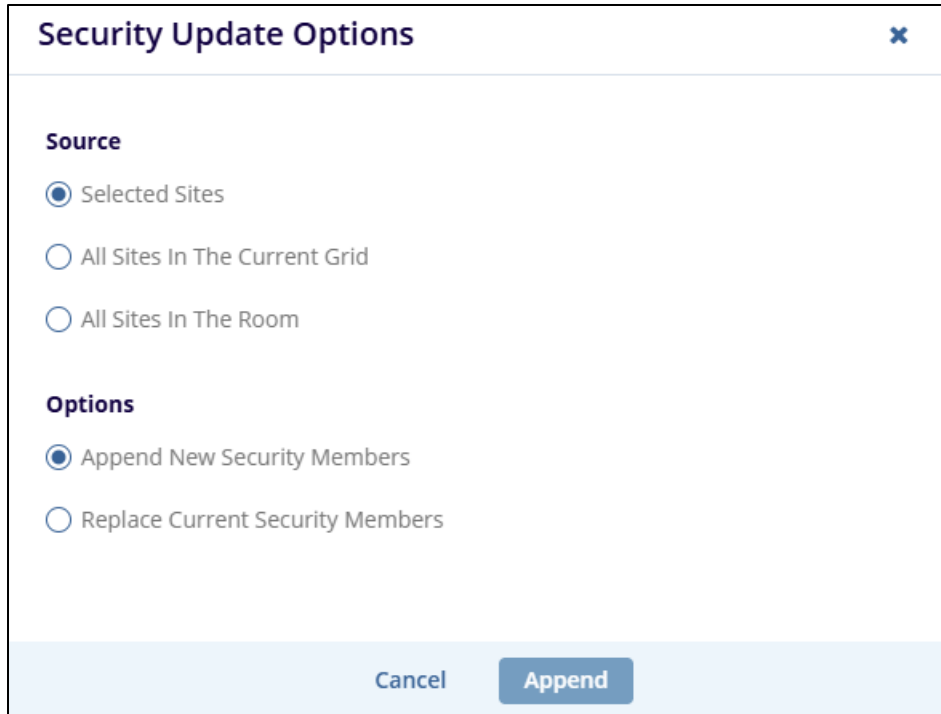
1. Select a site by clicking on the checkbox.
2. Click the More dropdown button and select Manage Security
3. Two options are displayed – **Editors and Readers**. From the Grid Pane, the administrator can assign Editor and Reader accesses to users/groups of users, thereby making them contacts of multiple sites. By selecting the checkboxes next to the site names in the grid, the administrator can make the selected users/group members to multiple sites at one time. This is helpful if contacts will have the same privileges on multiple sites.
4. Select **Editors** from the two options displayed.



5. On the 'Security – Editors' screen, 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 on the right side – Selected Members pane. The user can also drag and drop the name if required.
7. Click the **OK** button displayed at the bottom of the popup window



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.



11. If the **Readers** option is selected – a ‘Security Readers’ popup window is displayed.
12. Follow the **standard steps** to manage the security for readers.

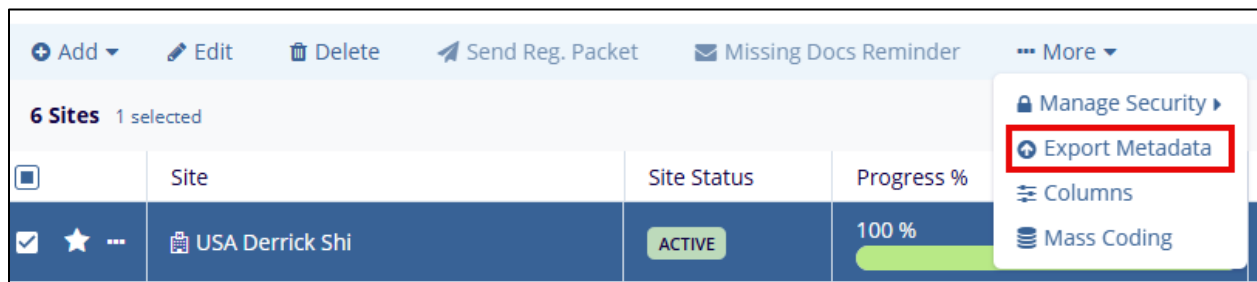
**Important**

- From within a Site Profile, the administrator can assign Editor and Reader access to users/groups of users for only the particular site whose profile they are 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.
- The procedure to add users to default editors/readers groups is described in detail in the User Management section.

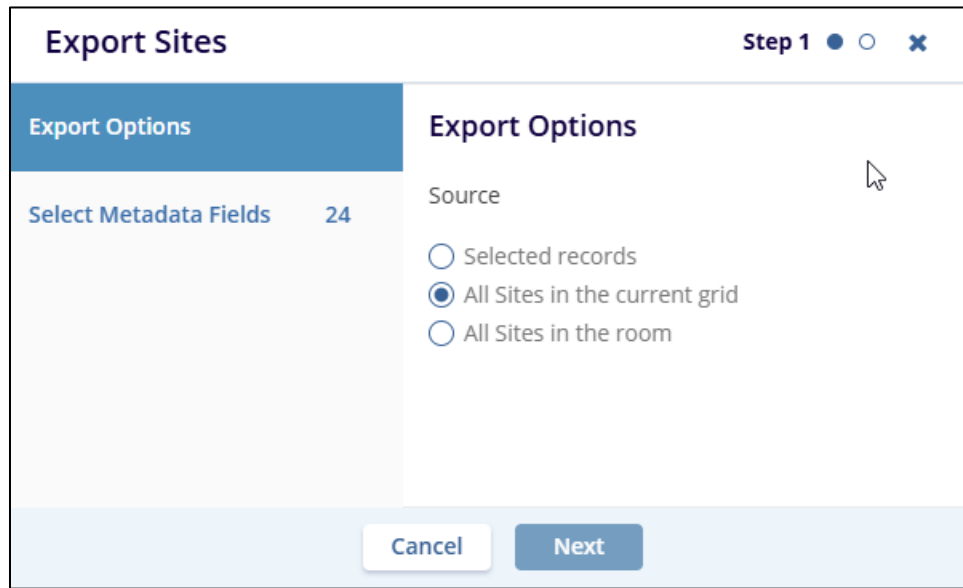
**Exporting Metadata**

To export the site details, follow the steps below.

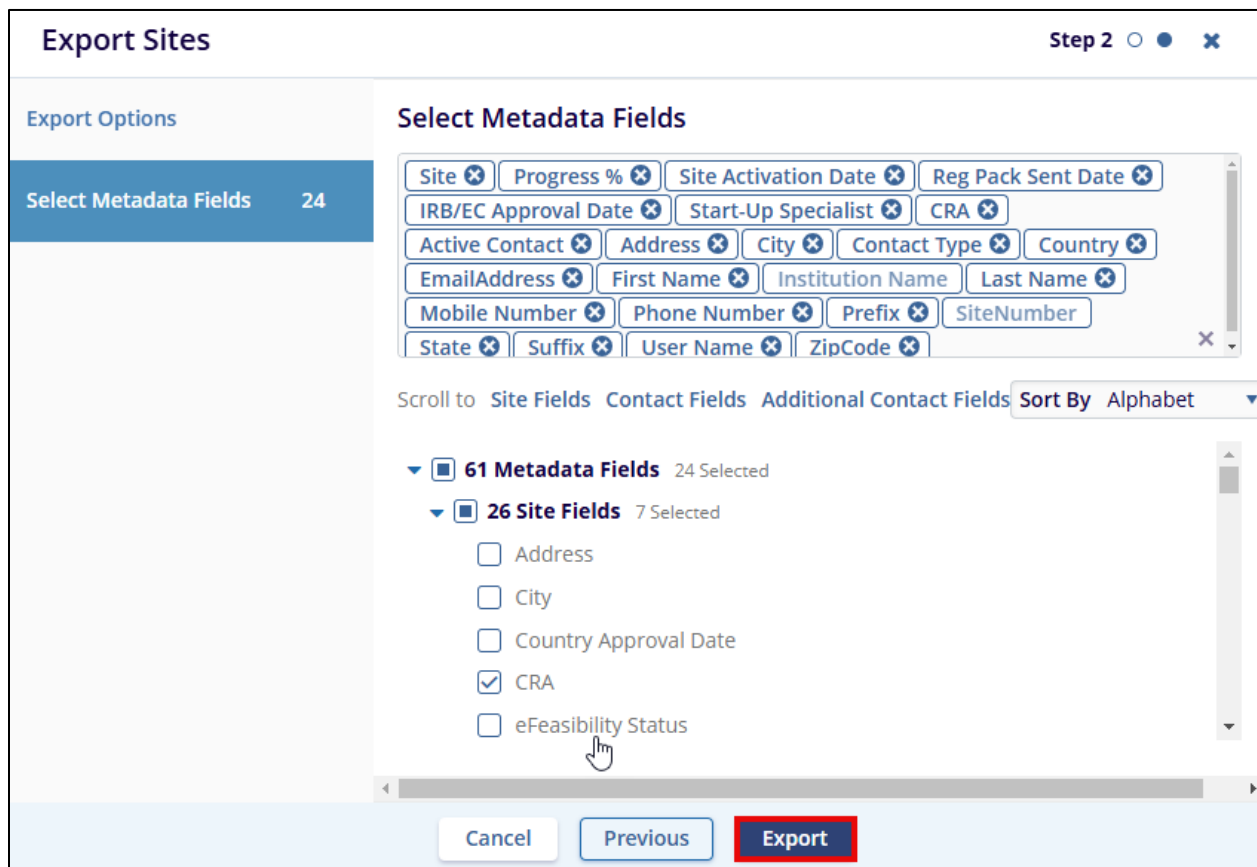
1. Select a site by clicking on the checkbox.
2. Click the More dropdown button and select Manage Security



- On the Export Options screen, select a source by selecting the radio button and click on the Next button.



- On the Select Metadata Fields, add the required number of metadata fields and click on the Export button.



- On the Exporting Site success message popup, click on the Get Results button.





## Exporting Sites

Room:

Success! Task is complete.

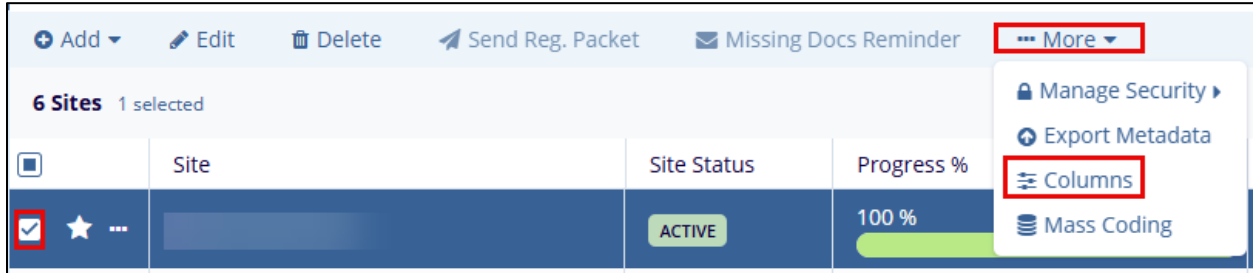
[Get Results](#)

6. Save the Microsoft Excel Worksheet into the system.

## Columns

To Manage Columns, follow the steps below.

1. Select a site by clicking on the checkbox.
2. Click the More dropdown button and select Columns.



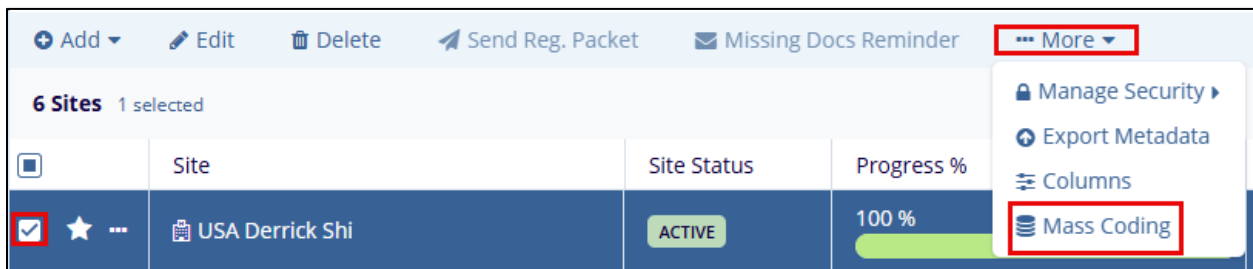
3. Follow the standard steps to configure columns detailed in the [Columns](#) section.

## Mass Coding

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, follow the steps below.

1. Select a site by clicking on the checkbox.
2. Click the More dropdown button and select Mass Coding.



3. The Mass Coding window displays the following fields:

- Mass coding Reason\*
- CRA
- Start-Up Specialist
- Reg Packet Sent Date
- Expected Submission Date
- IRB/EC Submit Date
- IRB/EC Approval Date
- Country Approval Date

### Mass Coding ✕

The selected site will be processed

Mass Coding Reason \*

Enter Reason

CRA  ...

Start-Up Specialist  ...

Reg Pack Sent Date  📅 ✕

Expected Submission Date  📅 ✕

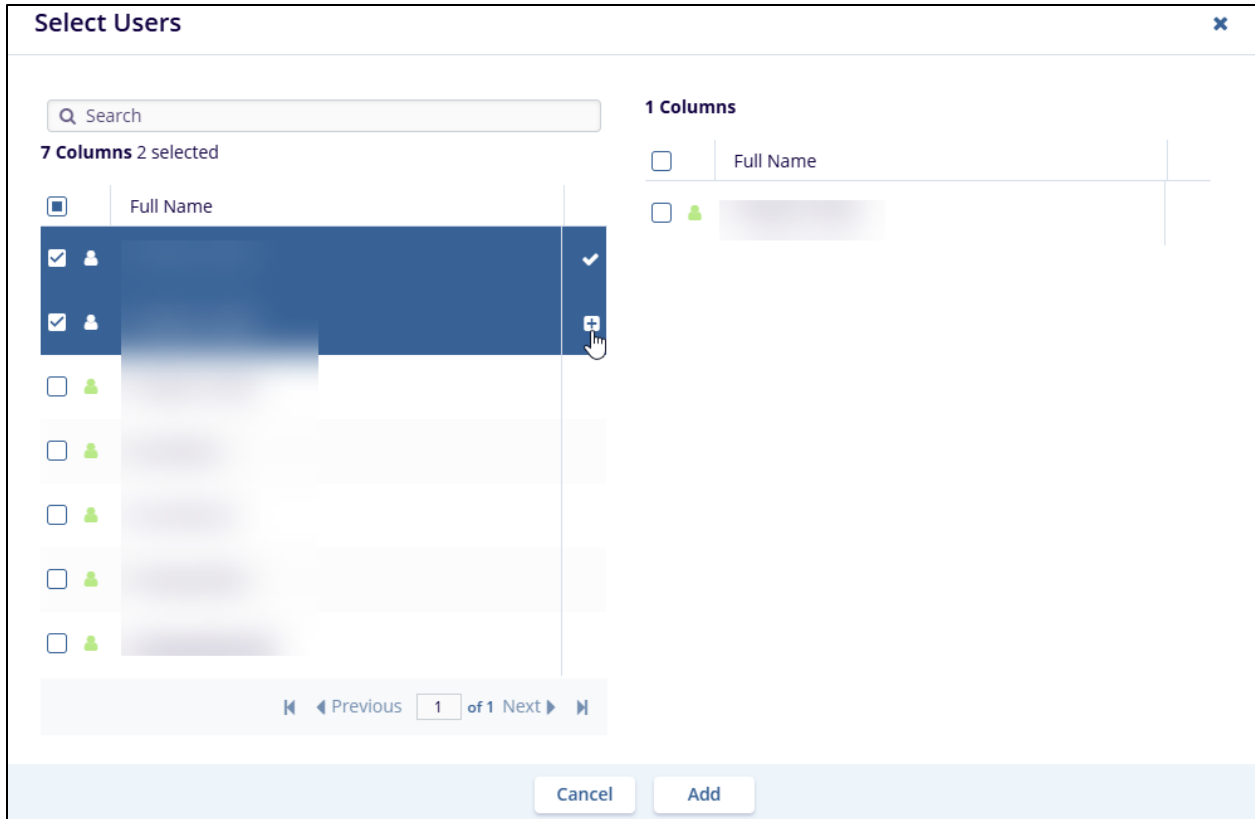
IRB/EC Submit Date  📅 ✕

IRB/EC Approval Date  📅 ✕

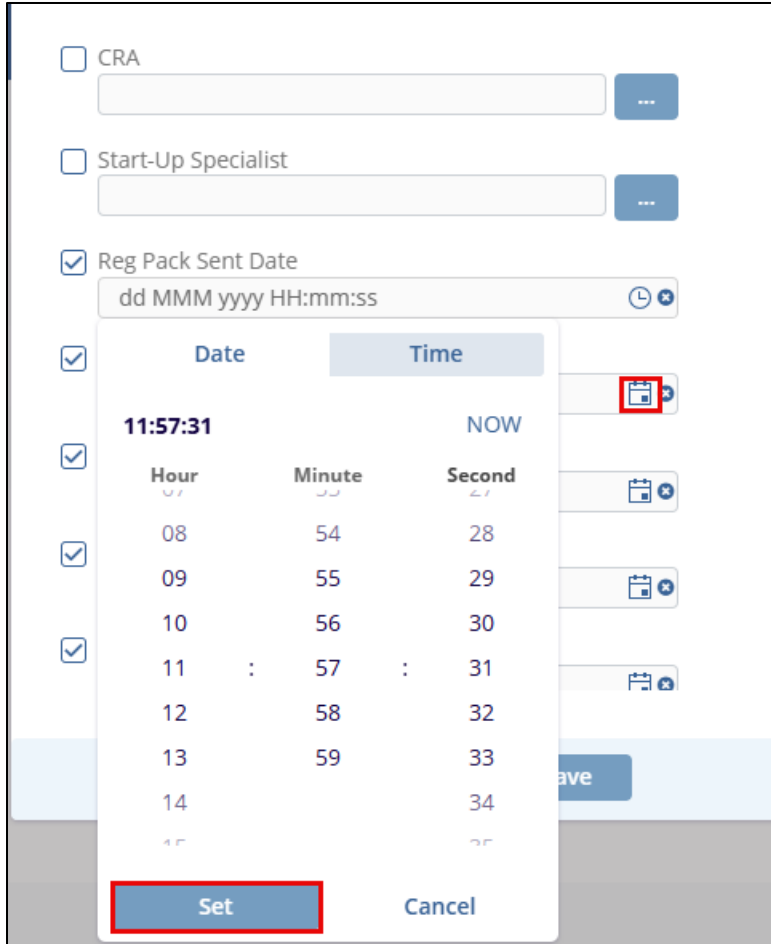
Country Approval Date  📅 ✕

Cancel
Reset
Save

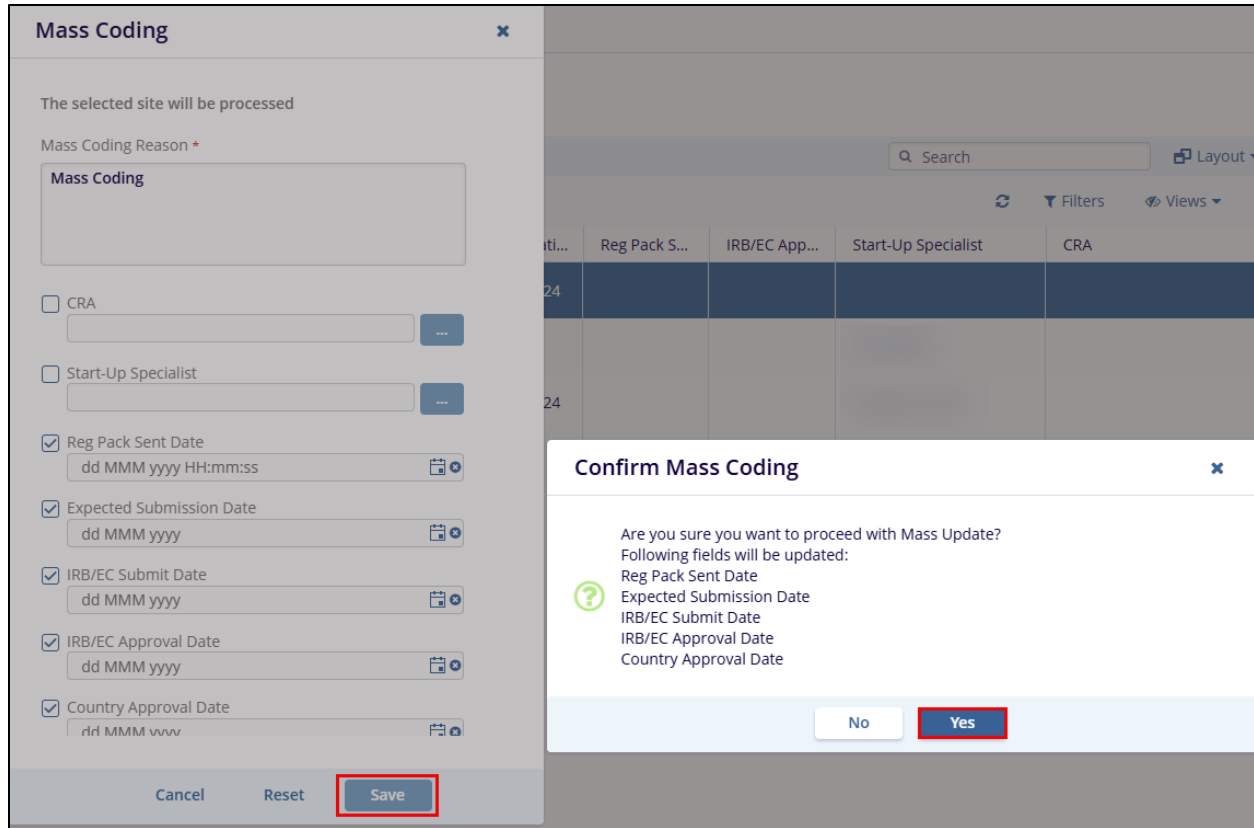
4. The Expiration Date field format is pre-defined and cannot be edited.
5. Select the three-dot menu for the CRA and Start-Up Specialist fields. This opens the Select Users window.
  - Hover the mouse to view the user in blue color and click the Plus icon next to the name.
  - The selected names are reflected on the right side of the Select Users window.
  - Click the Add button displayed at the bottom of the Select Users window.
  - The selected users are reflected in the required fields.



6. If selected, the checkbox(s) for the date fields, click the calendar icon next to these fields, select an appropriate date, and click on the **Set** button.



7. Click the Save button displayed at the bottom of the popup window.
8. Click Yes in the Confirmation window displayed on the screen.



9. 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.

### Searching for Sites

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 Grid Pane, but 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.

[Favorites 0](#)   [Active 2](#)   [Pending 4](#)   [All Sites 6](#)

Add ▾   Export Metadata   Columns      Layout

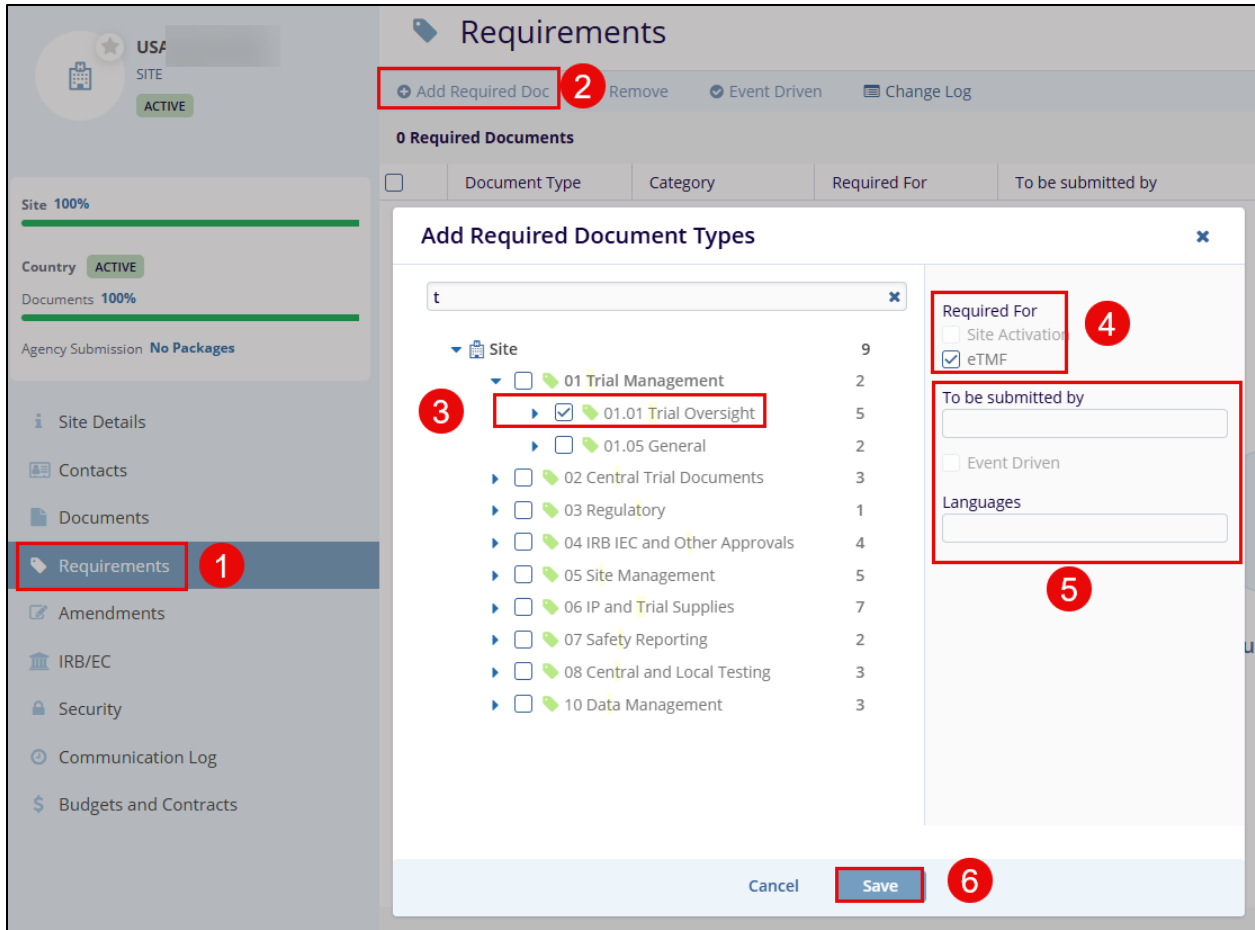
2 Sites   Filters   Views ▾

<input type="checkbox"/>	Site	Site S...	Progress %	Site...	Reg...	IRB...	Start-Up S...	CRA
<input type="checkbox"/>	★ ... USA	ACTIVE	100 %	05 S...				
<input type="checkbox"/>	★ ... USA	ACTIVE	100 %	04 S...				

### Setting up Site Specific Required Documents

The required documents specific only to a particular site can be set up through the Requirements button located on the left pane of the Sites Profile dashboard. This is discussed below:

1. Double-click the site from the Grid Pane to open the Sites Profile window and click the **Requirements** tab displayed on the left side of the screen of the Site Details window. This opens the Requirements window.
2. Click the **Add Required Doc** button from the top menu bar in the window.
3. Select the document types as required from the collapsible tree.
4. Select at least one of the checkboxes for 'Site Activation' and 'eTMF' to enable the Save button in the popup window.
5. (Optional) Select the contact(s) from 'To be submitted by' and 'Languages' dropdowns.
6. Click the **Save** button to add the required document type.



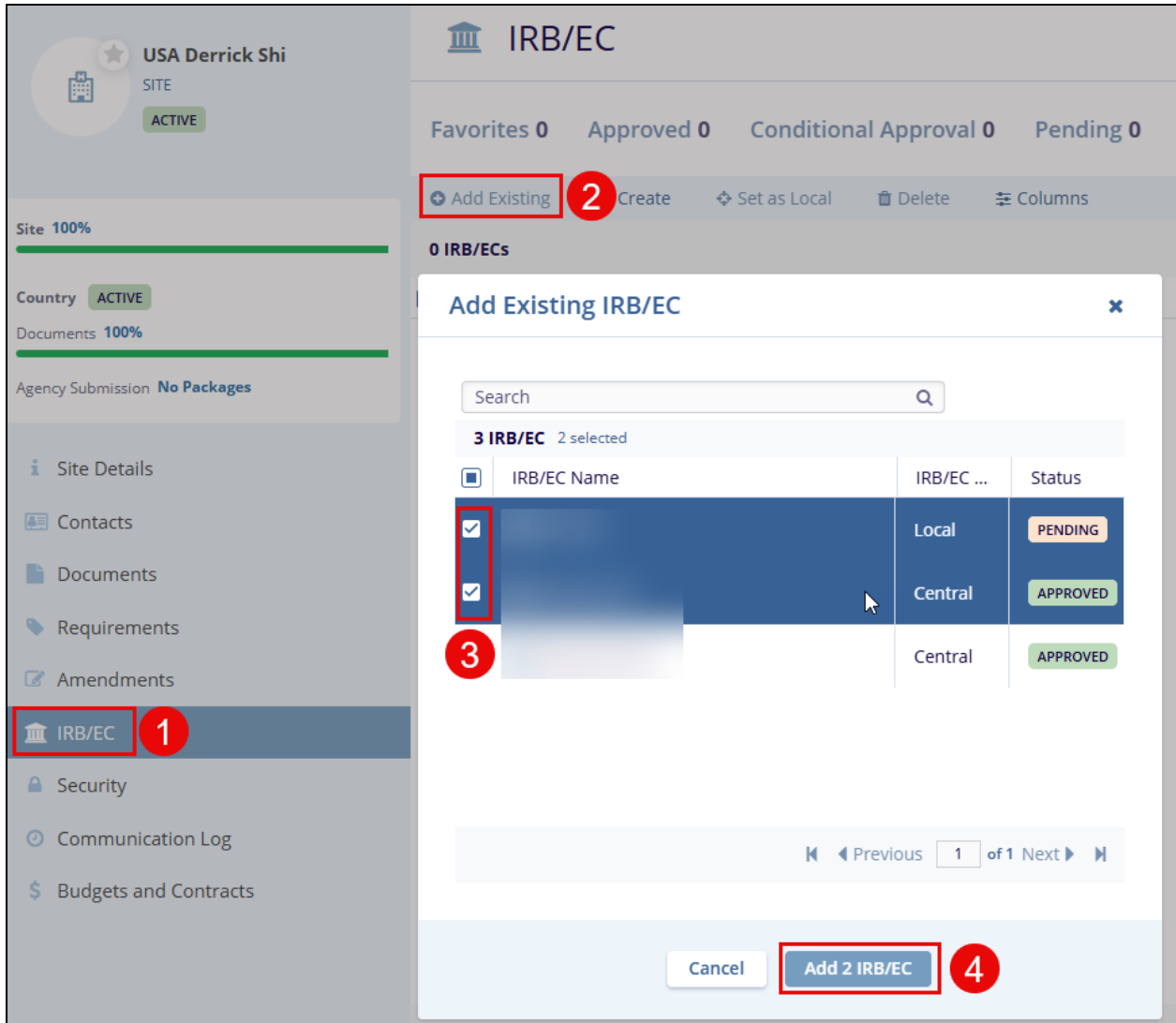
### Add Additional IRB/ECs

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.

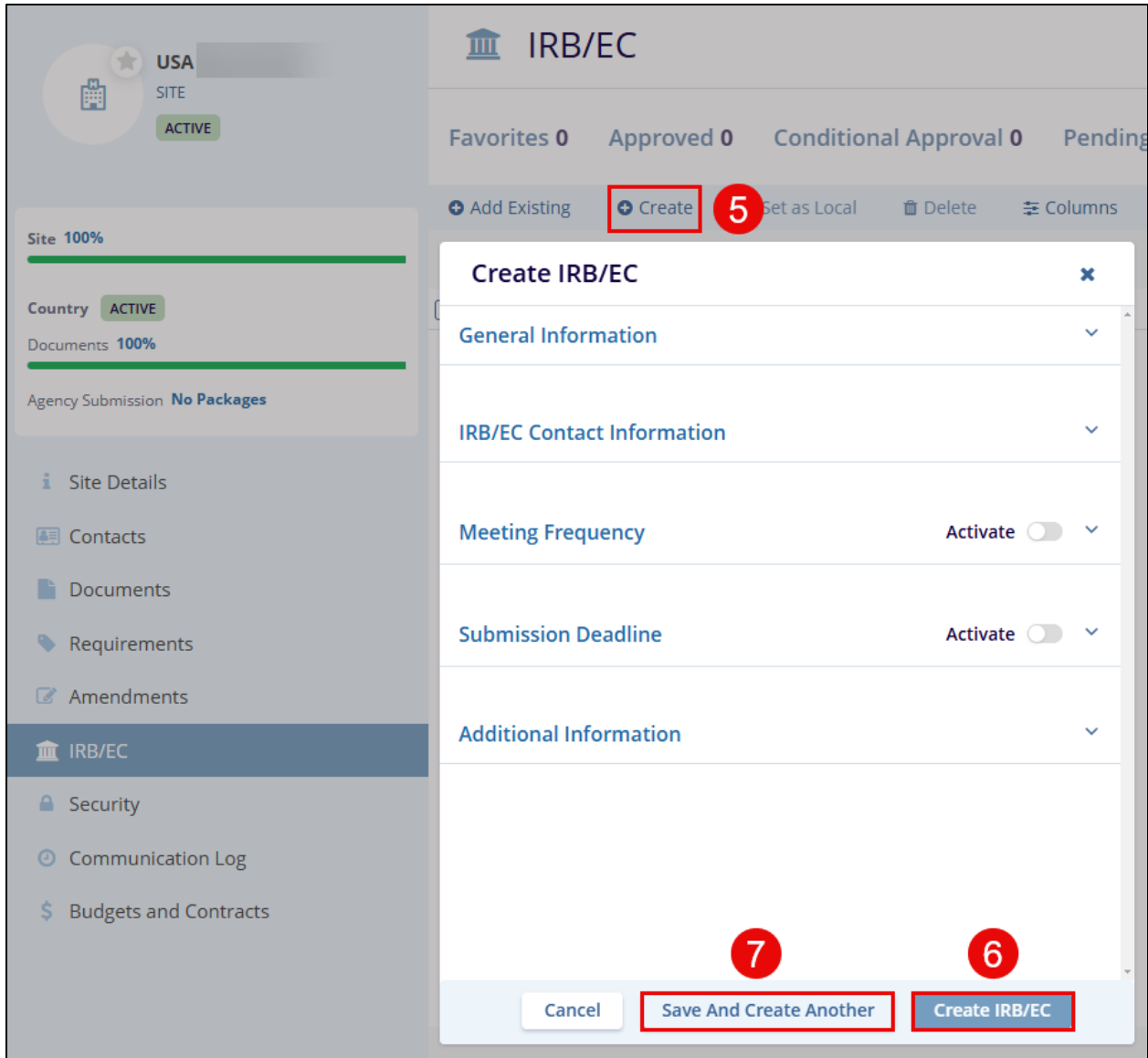
In the Site profile, you will be able to specify only one IRB/EC of any type. In case you need to provide additional IRB/ECs, proceed with the steps below:

1. From the Grid Pane, double-click the site for which additional IRB/ECs need to be specified and select the **IRB/EC** tab from the left pane.
2. The top menu bar displays two options – **Add Existing** and **Create**.
3. 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.
4. Click on the Add (number) IRB/EC button.





5. If clicked 'Create' – a 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 in their respective sections
  1. IRB/EC Name
  2. IRB/EC Type
  3. Address
  4. City
  5. State
  6. Country
6. Click the **Create IRB/EC** button displayed at the bottom of the popup window.
7. If the user wants to create another IRB/EC at the same time, click **Save and Create Another button**.



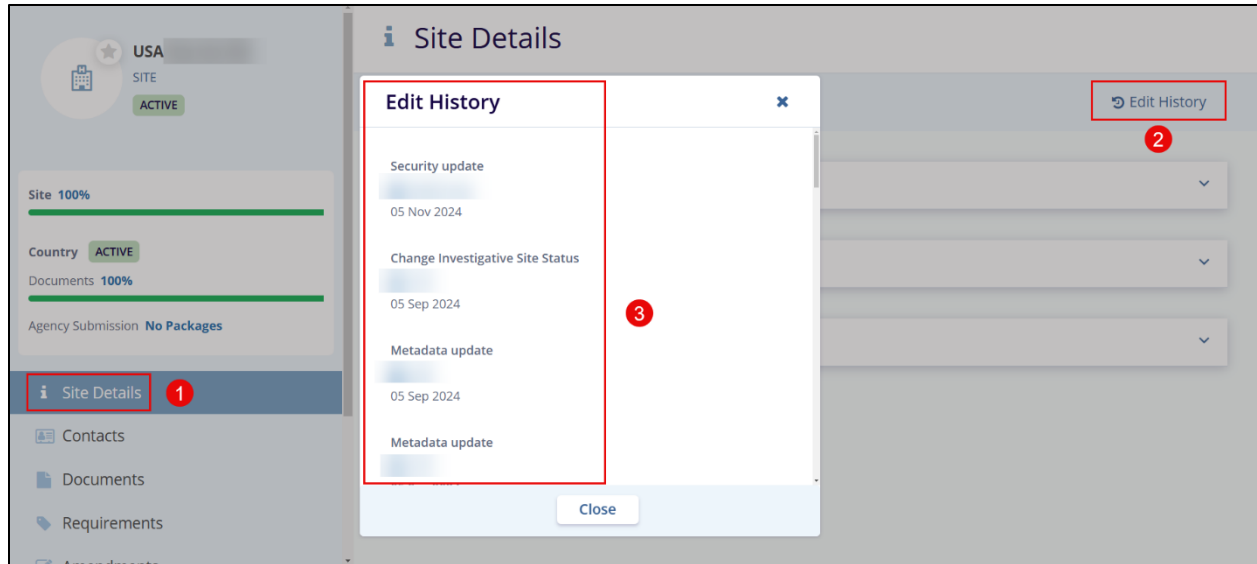
## Edit History

From a site profile window, you can also view histories related to site edits, contact activities, and milestones.

### 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.
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.

**Note:** The information here cannot be edited.



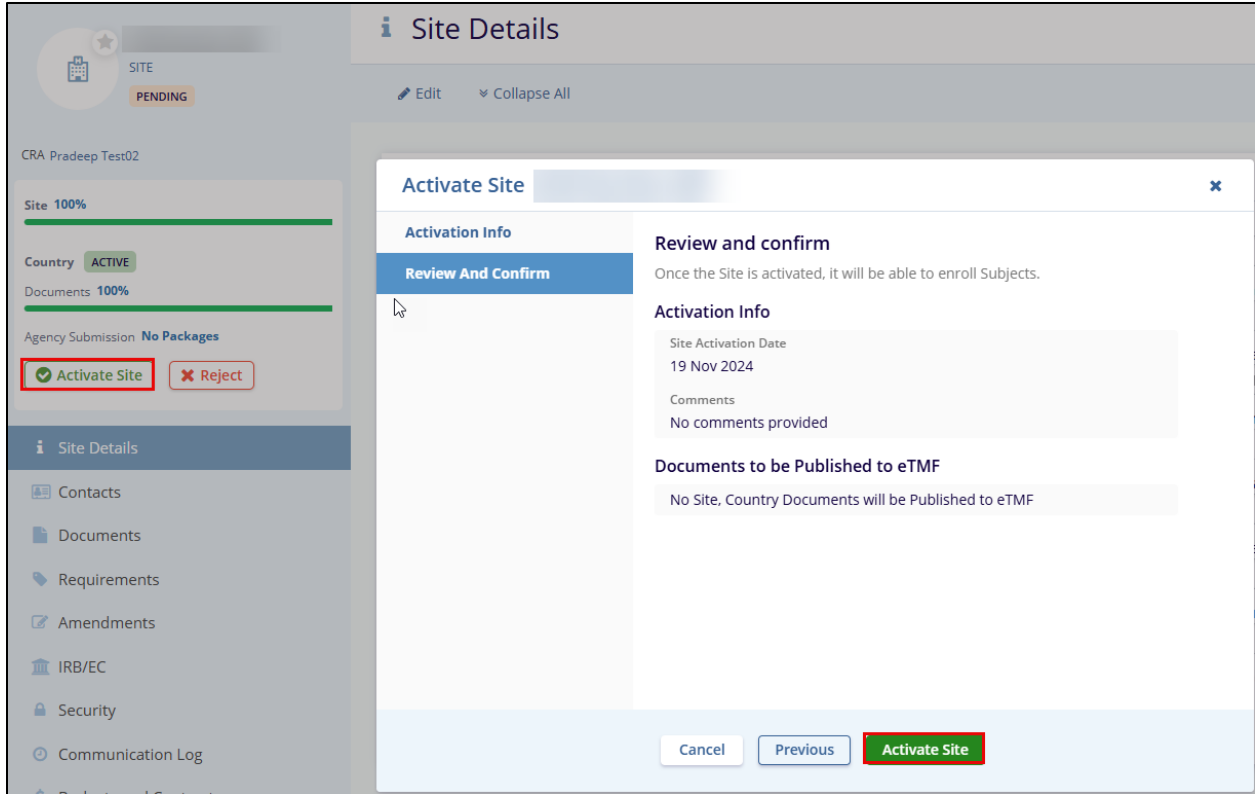
## Steps to Site Activation

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, the 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 a site in the Trial Interactive Study Start-Up module, a series of steps must be followed.

1. Select a site that displays the 'Pending' status. This opens the Site Details page.
2. Click the Activate Site button displayed on the left side below the Country name. This opens the Activate Site popup window.
3. Select the 'Site Activation Date' by clicking the Calendar icon.
4. Select the appropriate required radio button for the documents to publish to eTMF.
5. Enter the details in all the fields marked with an asterisk \* in the right-side panel – Site Activation Fields.
6. Click the **Next** button.
7. Review and confirm the details in the popup window and click the Activate Site button.

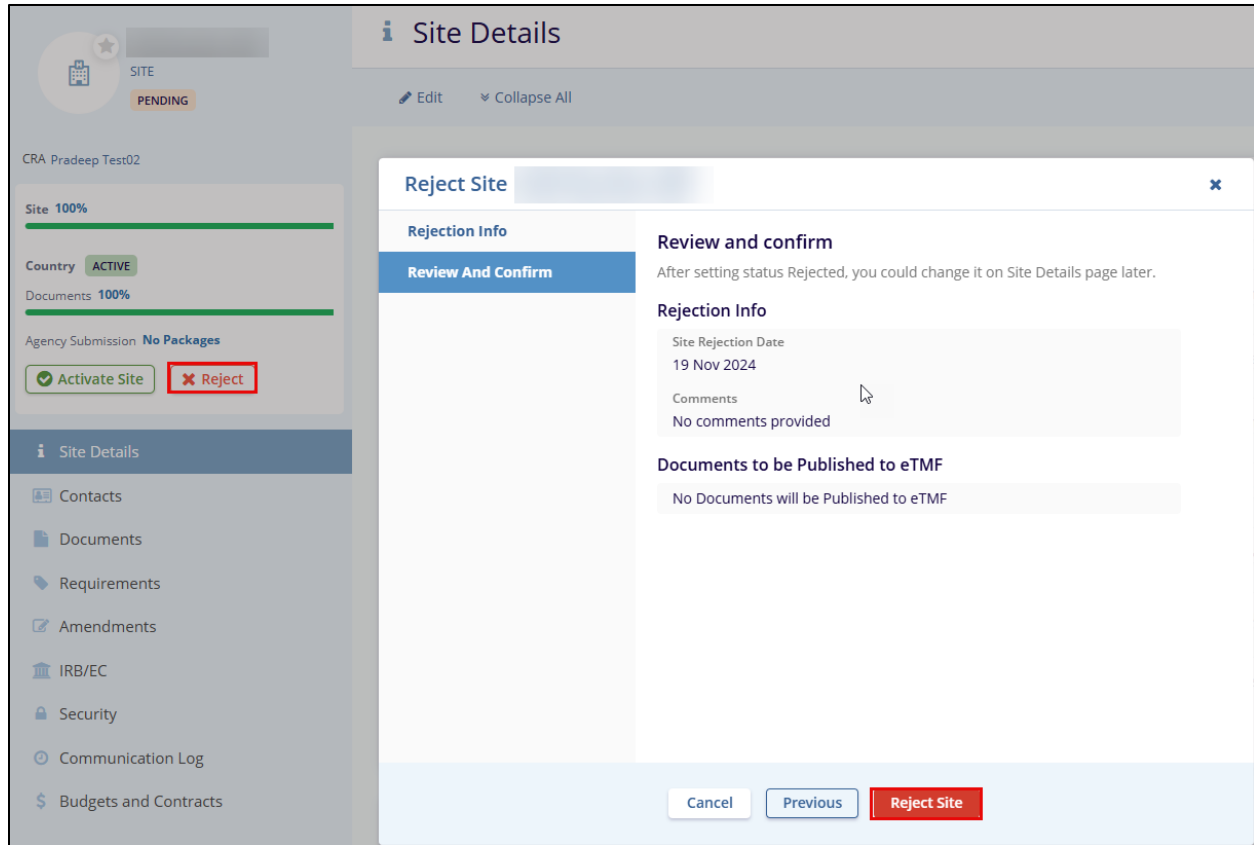


**Note:** The site information and users specific to the SSU site can be imported by TI if the information is provided in a formatted Excel. In addition, sites and users can be added to the site grid.

### Steps to Site Rejection

To activate a site in the Trial Interactive Study Start-Up module, a series of steps must be followed:

1. Select a site that displays the 'Pending' status. This opens the Site Details page.
2. Click the **Reject** button displayed on the left side below the Country name.
3. On the Rejection Info screen, enter a rejection reason and click on the Next button
4. On the Review and Confirm step, click on the Reject Site button.



**Important:**

- If during site activation system cannot move the documents to eTMF for some reason, such documents will not be moved, and the user will be warned about it. In that case site will not be activated. The reasons why docs cannot be moved to eTMF are duplications found and cannot determine Index position.
- 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 has now disappeared, and the site name appears under the Active folder in the Current window. Refer to the screenshot below.

## 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.

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.

---

### 305. 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.

- **By Site:** electing 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 in the grid pane.
- **By Country:** Selecting the By Country option lists the countries to which documents have been added. Documents added through the Countries tab can be located here. Clicking a country will display the documents submitted to the country along with their review status in the grid pane.
- **By IRB/EC:** Selecting the By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC will display the documents submitted to the institution along with their review status in the grid pane.
- **By Document Type:** Selecting the By Document Type option lists the various document types 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:
- **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 documents submitted on that day, along with their review status in the grid pane.
- **Deleted Document:** Selecting this option lists the documents that were deleted from the sites.
- **Inbox:** Selecting this option lists out the documents that are in the Inbox folder of the user.

---

### 306. Documents Grid Panel

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.

#### *Import*

The Import button helps the user add a document to the Documents section.

1. Click the Import button displayed in the top menu bar.
2. On the Import Document window, drag and drop the required files OR click the Browse File/Browse Folders option and upload the required file from the system.
3. The Import Documents popup window displays two options – Assign To Placeholders and Fill Metadata & Import.
4. The Assign to Placeholder – select the appropriate Category from the dropdown menu and the associated fields.
5. Click on the Apply button.
6. From the results, drag & drop the placeholder.

**Note:** The category selected here changes the options displayed in the next step.

7. Click on the, Fill Metadata & Import – enter the details in the fields marked with an asterisk (\*).
8. Click the Import & Apply Metadata button displayed at the bottom of the popup window.

Import Documents ✕

### Fill metadata or Assign Placeholders

Select Documents to Import them with/without Metadata or with assigned placeholders. Your progress with deselected attachments will remain.

Remove
Browse File
Browse Folders

**1 Documents** 1 selected

<input type="checkbox"/> Document	Size	Import Status	Placeholder
<input checked="" type="checkbox"/> Test_CoreDocList.pdf	59.5 KB	NOT IMPORTED	

Fill Metadata
Assign Placeholders ●

**Metadata** 7 Clear All

**Metadata**

Event

Category

Site

Document Type Select

Unpack Zip Archives ?
 Convert Non-PDF files to PDF ?

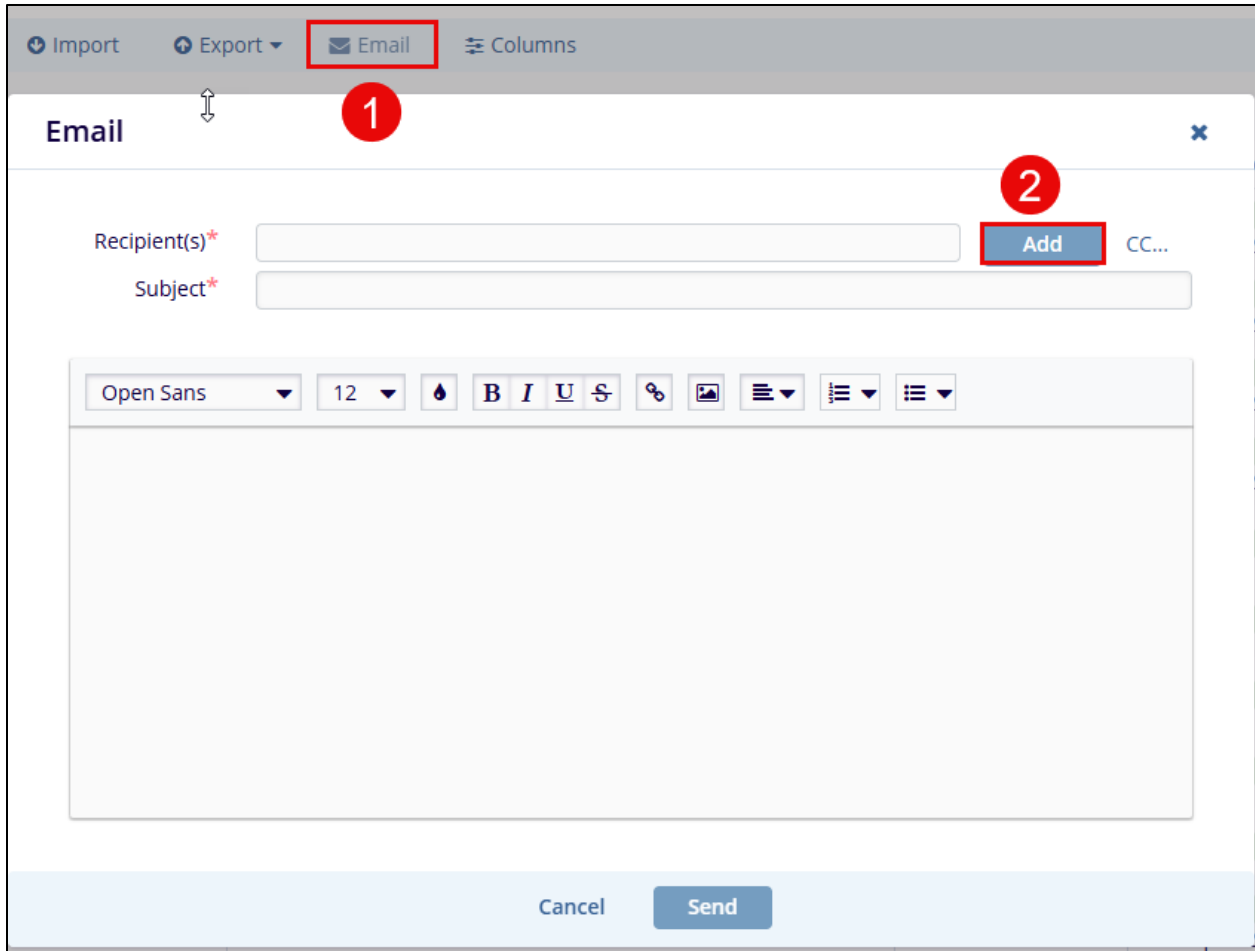
Cancel
Import 1 & Apply Metadata
8

### Email

The Email tab helps the user to send emails to other users.

1. Click the **Email** button displayed in the top menu bar.
2. Click the **Add** button displayed at the right corner of the popup window.





3. Drag drop the user(s) to the right pane.
4. Click the Save button displayed at the bottom of the popup window.

**Choose Email Recipients**

Groups Users Contacts

13 Columns 1 selected

	Last Name	First Name	Email	Phone	Mobile	Company
<input checked="" type="checkbox"/>	Admin					3
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						

Selected members

0 Columns

	Name	Email
<input type="checkbox"/>		

Admin

No records available

Cancel **Save** 4

5. Enter the **Subject** in the Subject field (mandatory).
6. Enter the content in the body text field.
7. Click the **Send** button.

**Email**

Recipient(s)\*  Add CC...

Subject\* **test email** 5

Open Sans 14 B I U S

Notification Email 6

Cancel **Send** 7

### Export

The Export button helps the user to export the data in an Excel sheet.

1. Click on the Export button from the top menu bar
2. Refer to the [Export](#) section for the standard steps to export the data.

### Columns

This option helps the user to select the required columns to be displayed in the grid pane of the Documents section.

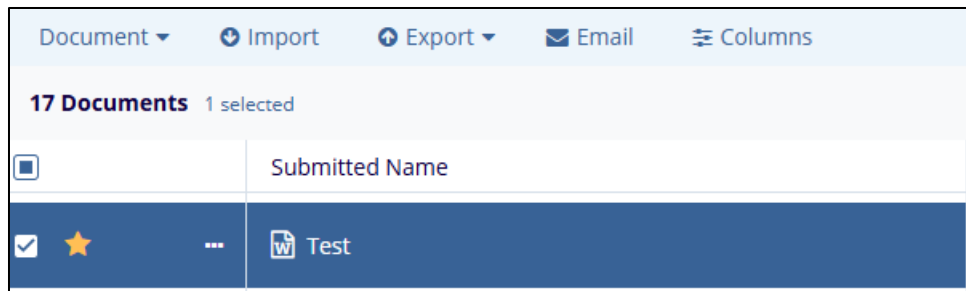
1. Click on the Export button from the top menu bar
2. Refer to the [Columns](#) section for the standard steps to manage columns.

## 307. Document Dropdown

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 is discussed in the subsequent topics.

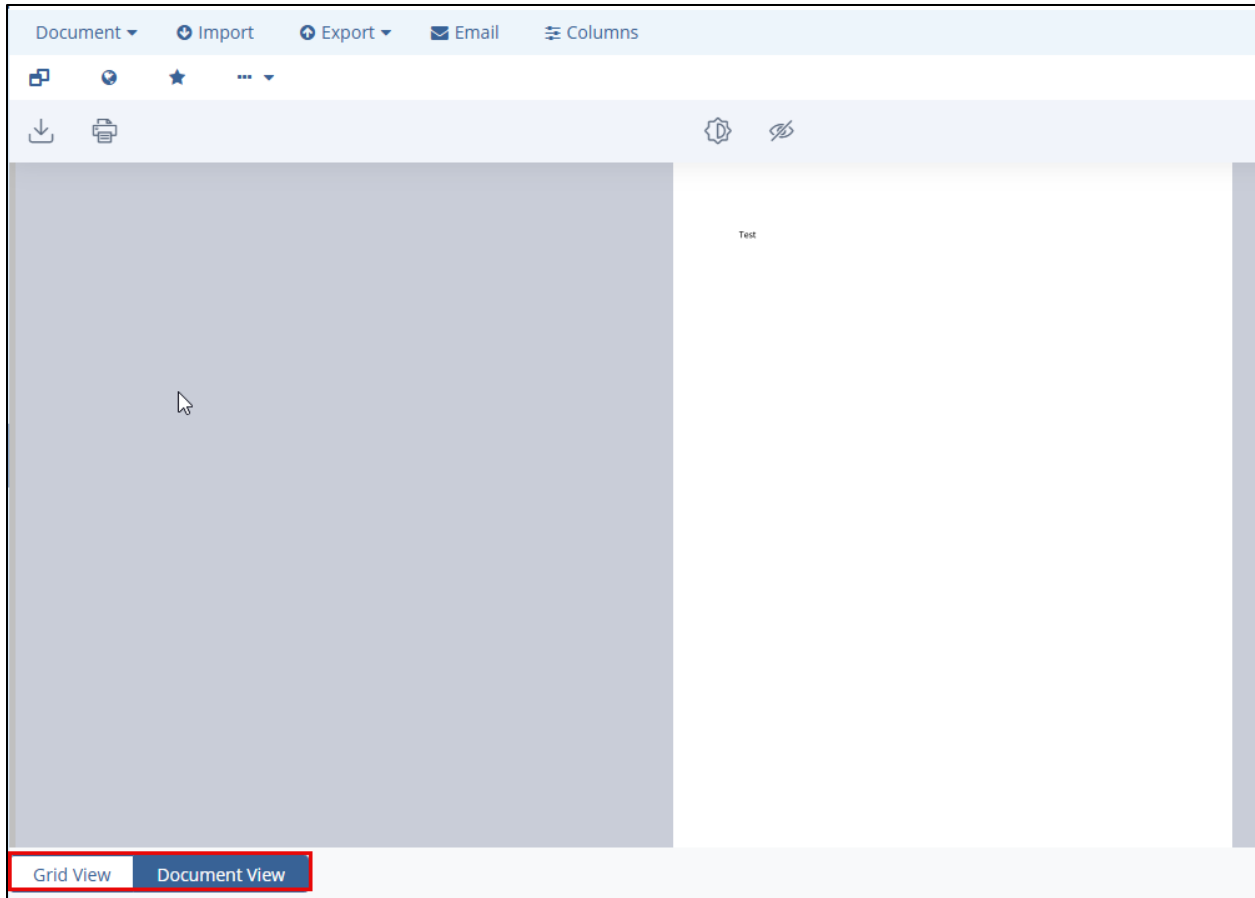
### Add to Favorites

Click the **Star** icon next to the checkbox of the document to add the document to Favorites. The Grey star becomes Yellow. 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.



### *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.

Submitted Name	Essential ...	Regulator...	Document Type	Language	Received ...
PROTOCOL-AMENDMENT-TRACKING-LOG_V0...	APPROVED 07 Oct 2023	APPROVED 07 Oct 2023	Site Contact Details		07 Oct 2023
Patch Release Notes Structure.	APPROVED 13 Oct 2023	APPROVED 17 Oct 2023	Recruitment Plan		13 Oct 2023
TI v10.5 UAT rough Draft 3rd October	APPROVED 17 Oct 2023	APPROVED 17 Oct 2023	IRB or IEC Approval		17 Oct 2023
OtherCV	APPROVED 31 Oct 2023	PENDING	PI Curriculum Vitae		31 Oct 2023

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.

**Set Document As Not Applicable**

Are you sure you want to set Status **NOT APPLICABLE** to the document **Dr. A 1572**?  
Please enter the reason

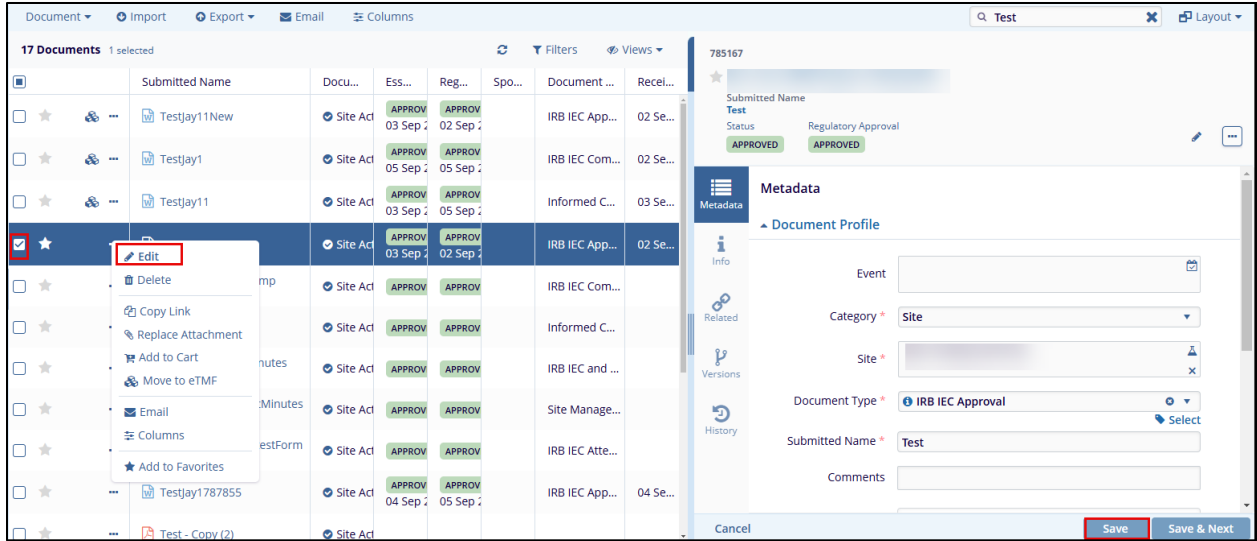
Reason\*

No Longer Required.

Cancel    **Set Not Applicable**

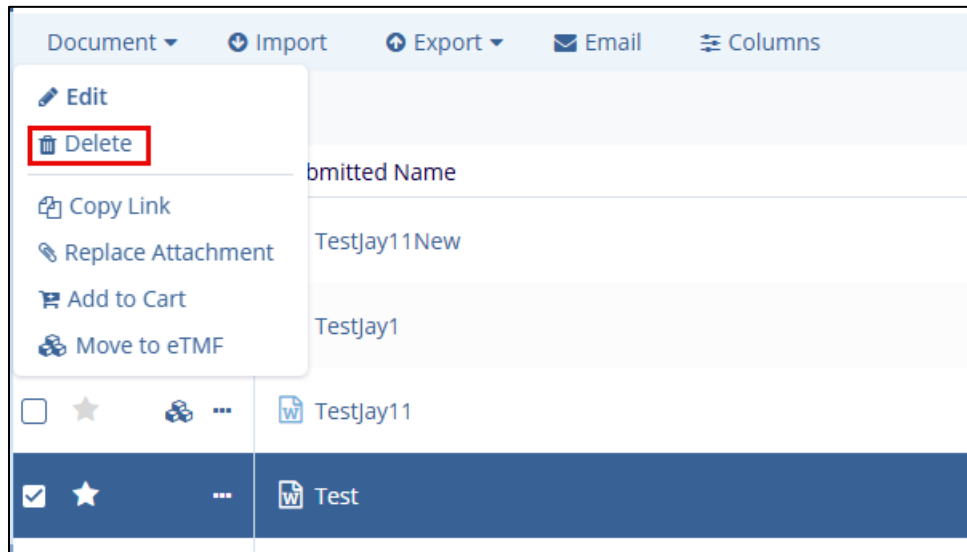
*Edit*

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 opened 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.

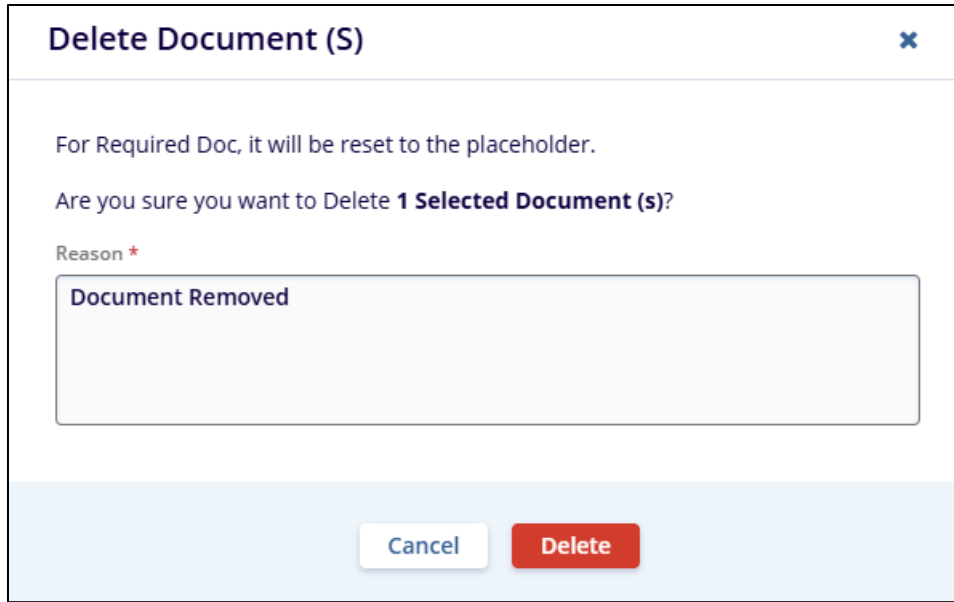


### Delete

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.



4. A popup window is displayed. Enter a reason in the empty field (mandatory) and click on the Delete button.

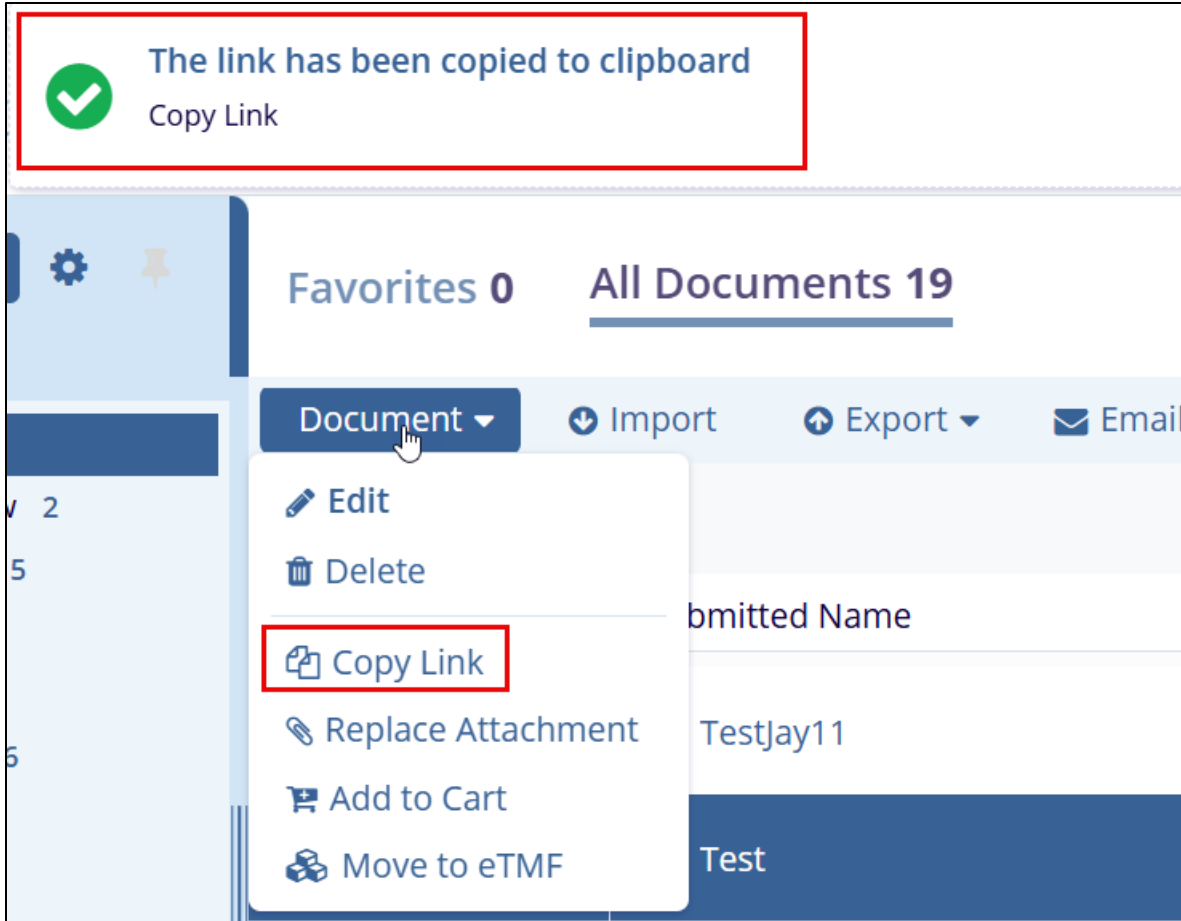


*Copy Link*

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.
6. Paste the copied URL in the browser tab.
7. The document opens in the browser for you to read.

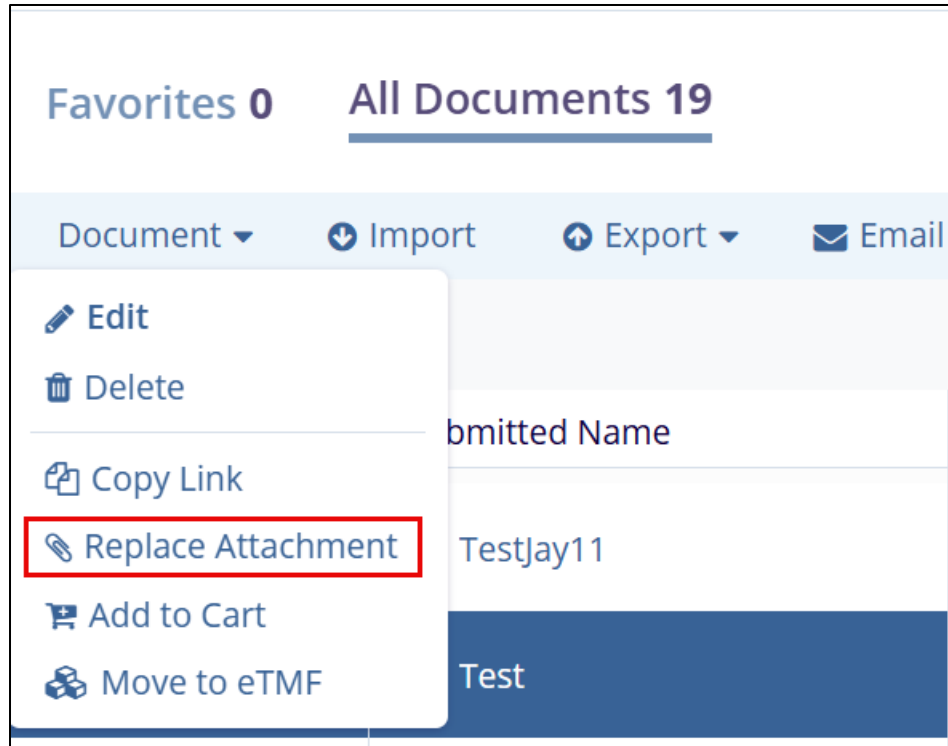


### Replace Attachment

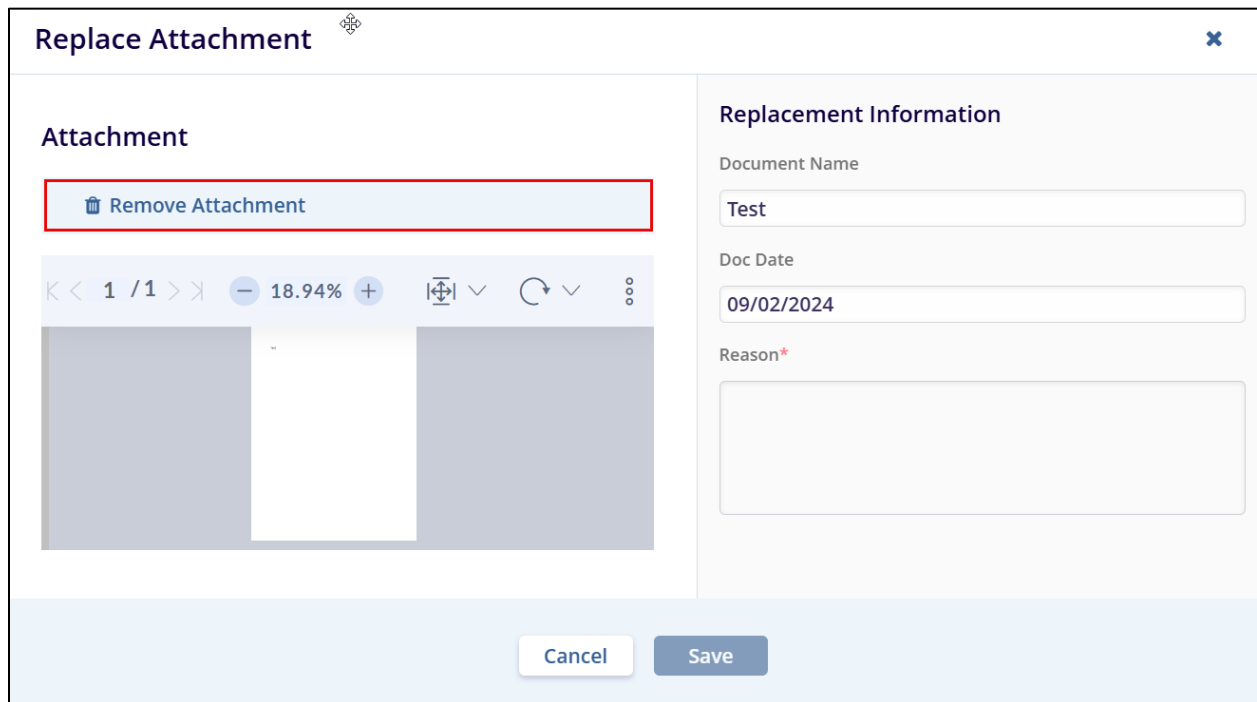
You can replace the attachment with a document type if it is not approved by using this feature.

1. Select the checkbox of the document that needs the 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.





4. The Replace Attachment popup window is displayed.
5. Remove the existing attachment by clicking on the Remove button.



6. Click the Attach URL option.
7. Paste the link in the field – Link to External Document.
8. Click the Save button displayed at the bottom of the popup window.

### Replace Attachment

✕

#### Attachment

Upload File

Attach URL

Link to External Document

http://www

#### Replacement Information

Document Name

Test

Doc Date

09/02/2024

Reason\*

Updating links

Cancel

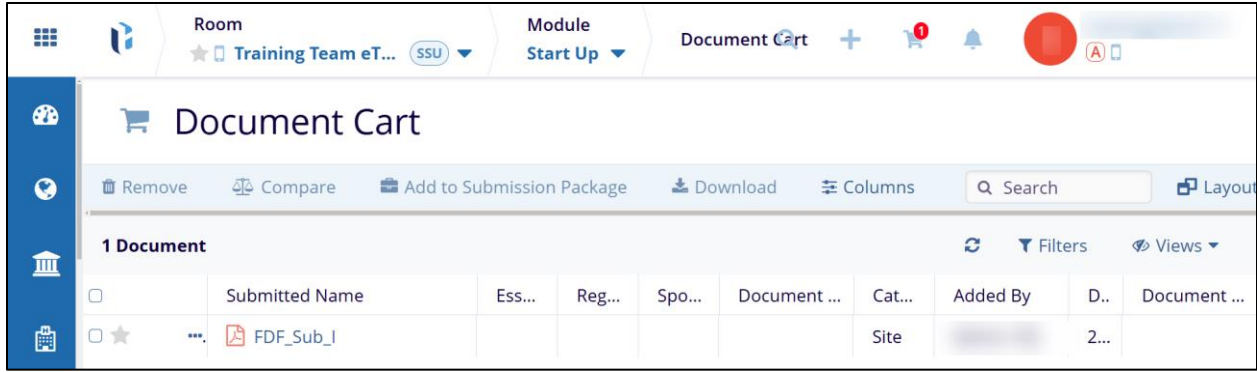
Save

**Note:** Click on the Upload File tab and upload documents following the standard document upload steps.

### Add to Cart

Users 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.

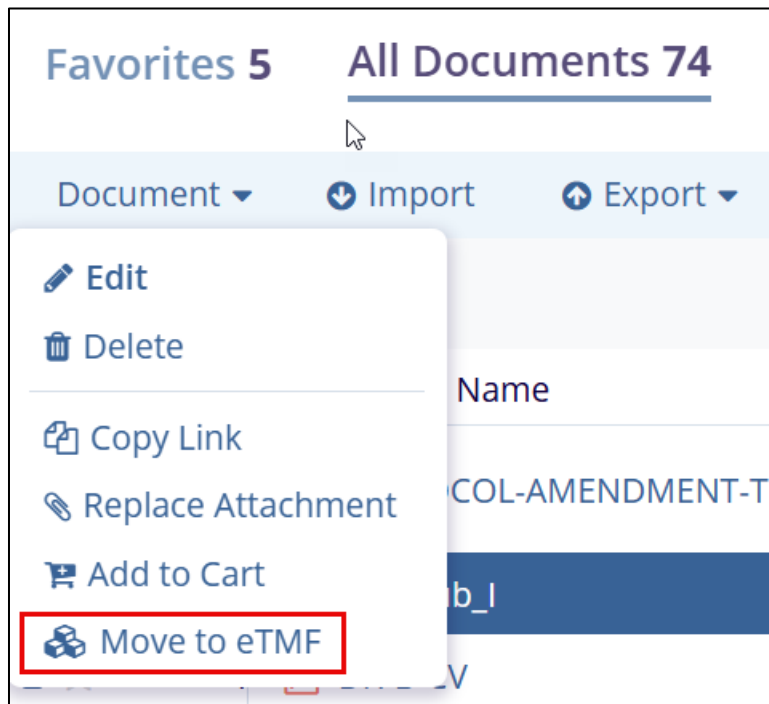
1. Select the checkbox of the document that needs to be added to the cart.
2. Click the dropdown menu of the **Document** button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the **Add to Cart** option.
4. The Document Cart icon displays a number in the top right corner.
5. Click the Document Cart icon to view the document details in the grid pane.
6. The user can Remove, Compare, and Add Documents to the Submission Package, Download, Manage Columns, Manage and Create Filters, and Save Views in the grid pane.



*Move to eTMF*

Users 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.



4. A Move to ETMF popup window is displayed.
5. Expand the appropriate dropdown. 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.

## Move To ETMF ✕

Search 🔍

- ▼  Index
  - ▼  Trial
    - ▶  01 Trial Management 1
    - ▶  02 Central Trial Documents
    - ▶  03 Regulatory
    - ▶  04 IRB or IEC and other Approvals
    - ▶  05 Site Management
    - ▶  06 IP and Trial Supplies
    - ▶  07 Safety Reporting

Move selected Documents as Final     Show Empty Folders

## 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 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.

### 308. 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. On the Amendments Management window, click on the **+Add** button.

The screenshot shows the Trial Interactive interface. At the top, the 'Room' is 'Training Team eT...' and the 'Module' is 'Settings'. The left sidebar shows a navigation menu with 'Required Documents' expanded to show 'Amendments' selected. The main area displays the 'Amendments Management' window with a table of existing amendments. The '+Add' button is highlighted with a red box and a '4' in a red circle. The 'Amendments' option in the sidebar is highlighted with a red box and a '3' in a red circle. The 'Settings' module is highlighted with a red circle and a '1'. The 'Add', 'Edit', and 'Delete' buttons are highlighted with a red circle and a '2'. The 'Title' column header in the table is highlighted with a red circle and a '4'.

Title	Description
<input type="checkbox"/> Country Amendment	
<input type="checkbox"/> 10.5 Amendment	
<input type="checkbox"/> Demo	
<input type="checkbox"/> New Amendment	This is an example
<input type="checkbox"/> Amendment 2024	
<input type="checkbox"/> Amendment 4	
<input type="checkbox"/> test3	
<input type="checkbox"/> Test Amendment #2	
<input type="checkbox"/> Test1	

5. Fill in the details as required.
6. Click Add in the Required Documents panel in this window.

**Create Amendment**
✕

Required fields are marked with an asterisk (\*) 4

**Title: \***

**Description:**

**Amendment Date: \***

📅

⬇️ **Required Documents**

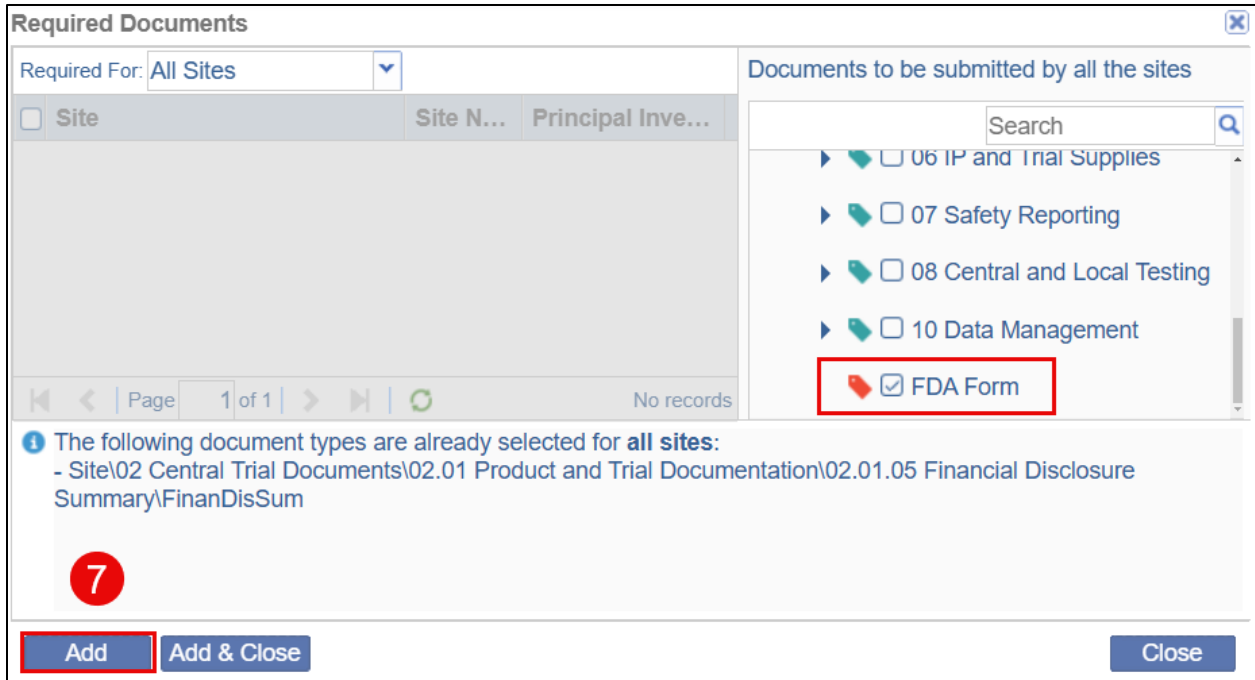
+ **Add**
- **Delete**

<span style="color: red; font-weight: bold; border: 1px solid red; border-radius: 50%; padding: 2px 6px;">5</span> Required Fo...	Entity Name	Category	Document T...	Languages	Contacts <span style="float: right;">?</span>
<input checked="" type="checkbox"/> All Sites	Site	Site	02 Central Tri...	(Not Set)	(Not Set)

Create
Cancel

7. The Required Documents window opens.

- From the Required For dropdown in the left panel, select an option as required (All Sites, Specific Site, Specific IRB/EC, or Specific Country).
- From the right panel above, in the 'Provided by' section, select a radio button.
- Below in the right panel, select the required documents that are needed after the site activation.
- Select an appropriate option from the dropdown menu of the 'To be Submitted by' and 'Languages' fields.
- Click the 'Add' and 'Close' button to reflect the changes in the 'Create Amendment' window.
- The procedure to add the documents is the same as described in the earlier section of Basic Configuration for SSU.



8. Click the Create button to create the amendment.

### 309. Add Amendments from the modal

To add amendments from the modal follow the steps below.

1. In the SSU module, select Amendments from the left hand navigation pane.
2. Click on the +Add button.

Room [SSU] Module Start Up Amendments

## Amendments

Favorites 0 Site 9 Country 2 IRB/EC 0 All Amendments 12

**+ Add**

**12 Amendments** 1 selected

Name	Documents	Doc completion	Due
★ ... Country Amendment	1	100 %	23 Nov 2023
★ ... 10.5 Amendment	0	100 %	14 Nov 2023
★ ... Demo	0	0 %	22 Nov 2023

- On the Create Amendment window, enter the necessary details in the Step1: Amendment Information and click on the Next button.



## Create Amendment

Step 1 ● ○ ○ ✕

**Amendment Information**

Required Documents

Review & Confirm

### Amendment Information

Title \*

Amendment Date \*  📅

Description ↔

Cancel
Next

4. Add the Required number of documents in Step 2: Required Documents and click on the Next button.

## Create Amendment

Step 2 ○ ● ○ ○ ✕

Amendment Information

**Required Documents**

Review & Confirm

### Required Documents

+ Add Required Doc
🗑 Remove

**1 Document Type** 1 selected

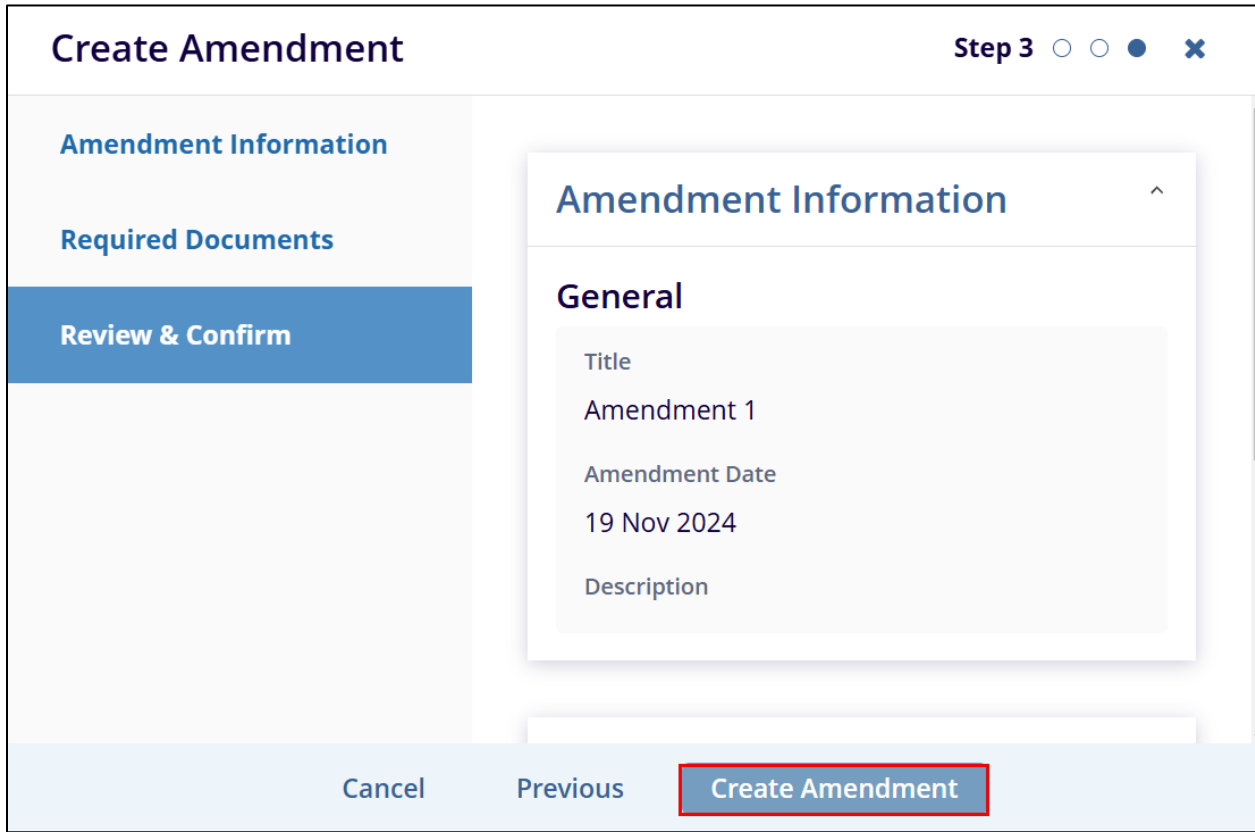
<input checked="" type="checkbox"/>	Document Type	Requir...	Entity ...	Categ...	To be ...	Langu...
<input checked="" type="checkbox"/>	COI	Specifi...	📄 Bah...	Site	<span style="background-color: white; color: #4a86e8; padding: 2px 5px; border-radius: 3px;">1</span>	<span style="background-color: white; color: #4a86e8; padding: 2px 5px; border-radius: 3px;">Sel... ▾</span>

⏪ ◀ Previous 1 of 1 Next ▶ ⏩

Cancel
Previous
Next

Click here to add the required documents

5. Confirm all the details in Step 3: Review and Confirm and click on the Create Amendment button.



**Create Amendment** Step 3 ○ ○ ● ✕

**Amendment Information**

**Required Documents**

**Review & Confirm**

**Amendment Information** ^

**General**

Title  
Amendment 1

Amendment Date  
19 Nov 2024

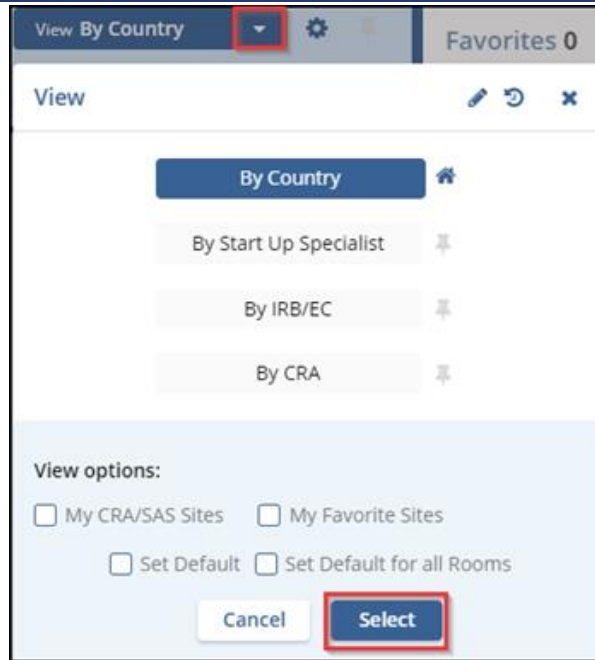
Description

Cancel Previous **Create Amendment**

### 310. Viewing Amendments and Adding Documents

To view amendments for a site/s and countries, navigate to the Sites section and follow the steps below.

1. Click the 'View By' dropdown and choose the Country option. Click the Select button.



2. Select a required Country. This opens the sites assigned to that Country.
3. Click on the Site name that displays 100% progress to open the Site Details page.

Site	Site Status	Progress %	Site Act...	Reg Pac...	IRB/EC A...	Country	IRB/EC Name	Start-Up Specialist	CRA
Site - 004 PI	ACTIVE	100 %	16 Oct 20...			India			

4. Click the Amendments tab displayed on the left corner of the screen. This opens the Amendments page.
5. Click on a required Amendment name where documents have to be added. This opens the Amendment Details page.
6. Click on the Documents tab displayed in the left corner. This opens the Documents page with a grid with a column mentioning the missing documents.
7. Click the '+' icon displayed next to the checkbox before the Submitted Name. This opens the Add Document popup window.

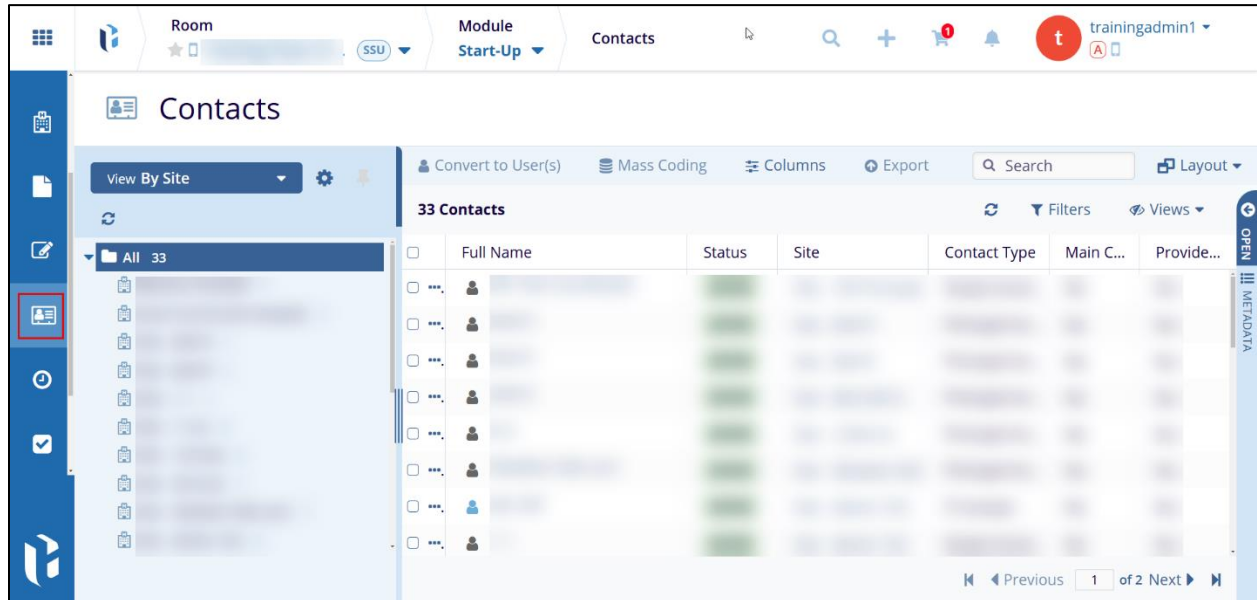
Submitted Name	Generated Name	Document Type	Essential Doc...	Regulatory Ap...	Added By	Received Date
Protocol Approval Document		Protocol Approval Document	MISSING			
Protocol		Protocol	MISSING			
Protocol QC Document		Protocol QC Document	MISSING			
Test Document 101_translation	Training-12345_P1_ProtQCDoc	Protocol QC Document	PENDING		Admin 103	22 Nov 2023
FoldersAndFilesTruncations	Training-12345_P1_ProtAppDoc	Protocol Approval Document	PENDING		Admin 103	22 Nov 2023

8. Upload the required file from your system OR attach the appropriate required URL.
9. The added documents are displayed in the grid pane.

**Note:** 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.

## Contacts

The Contacts tab, accessed from the toggling menu bar on the left, holds all the messages sent and received with a study start-up to activate a site. Opening the Communication tab, the user can see three panels: **Current View**, **Grid Pane**, and **Communication Data**. Refer to the screenshot below.

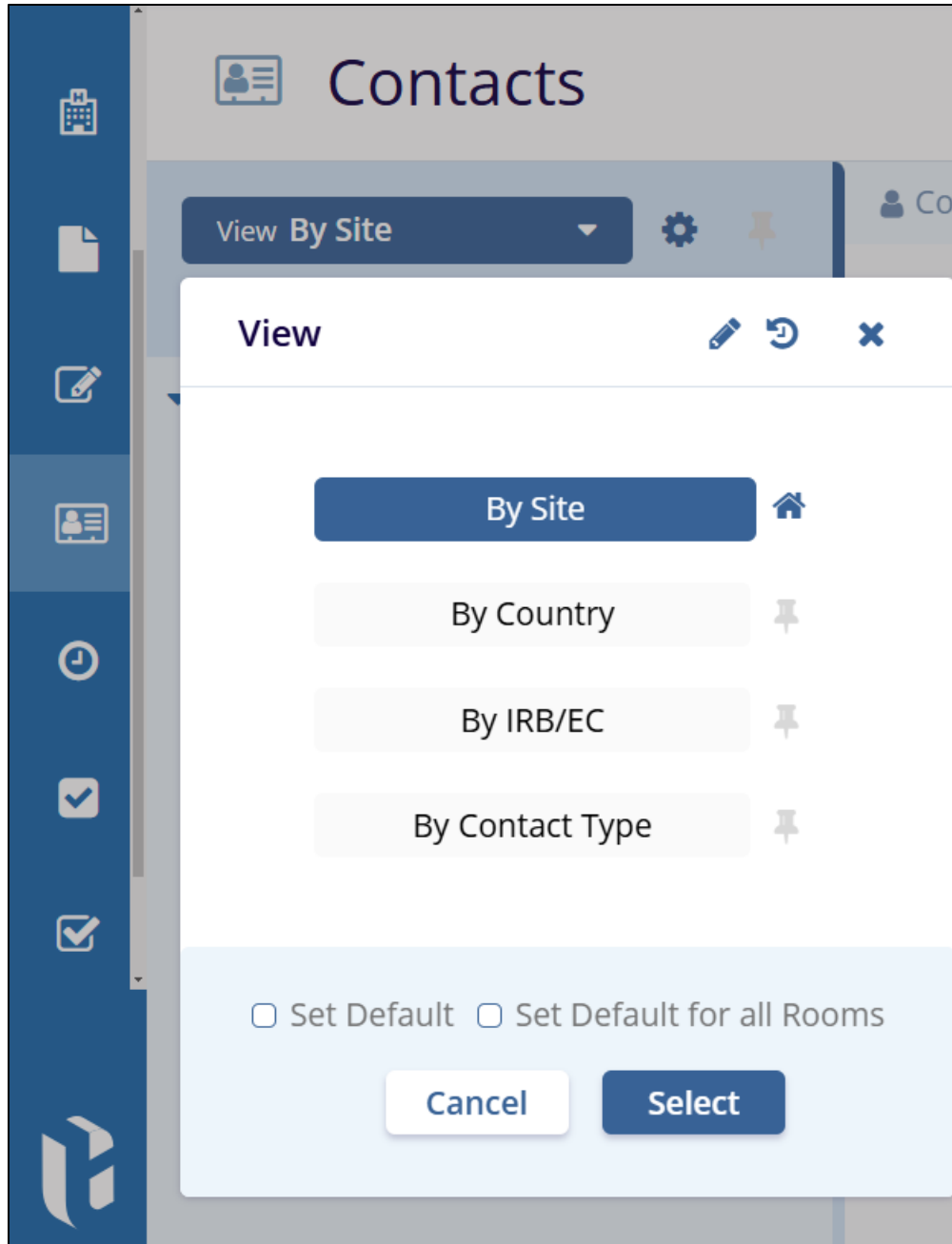


**Note:** The Contacts Log section from Sites, Countries, and IRB/EC provides the same functionality as that available in the Communication section.

### 311. 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 that 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 the 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.

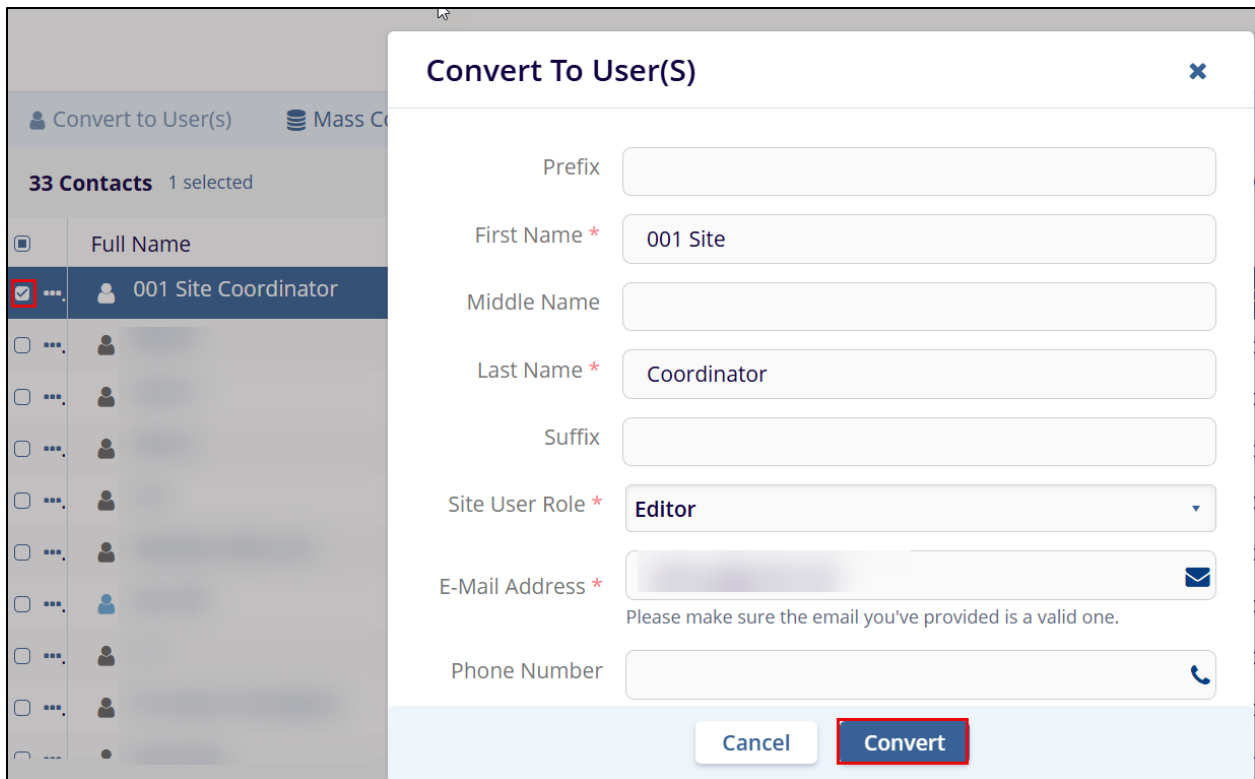
## The Top Menu Bar

The Menu bar on the top displays buttons for various functionalities. Refer to the screenshot below.



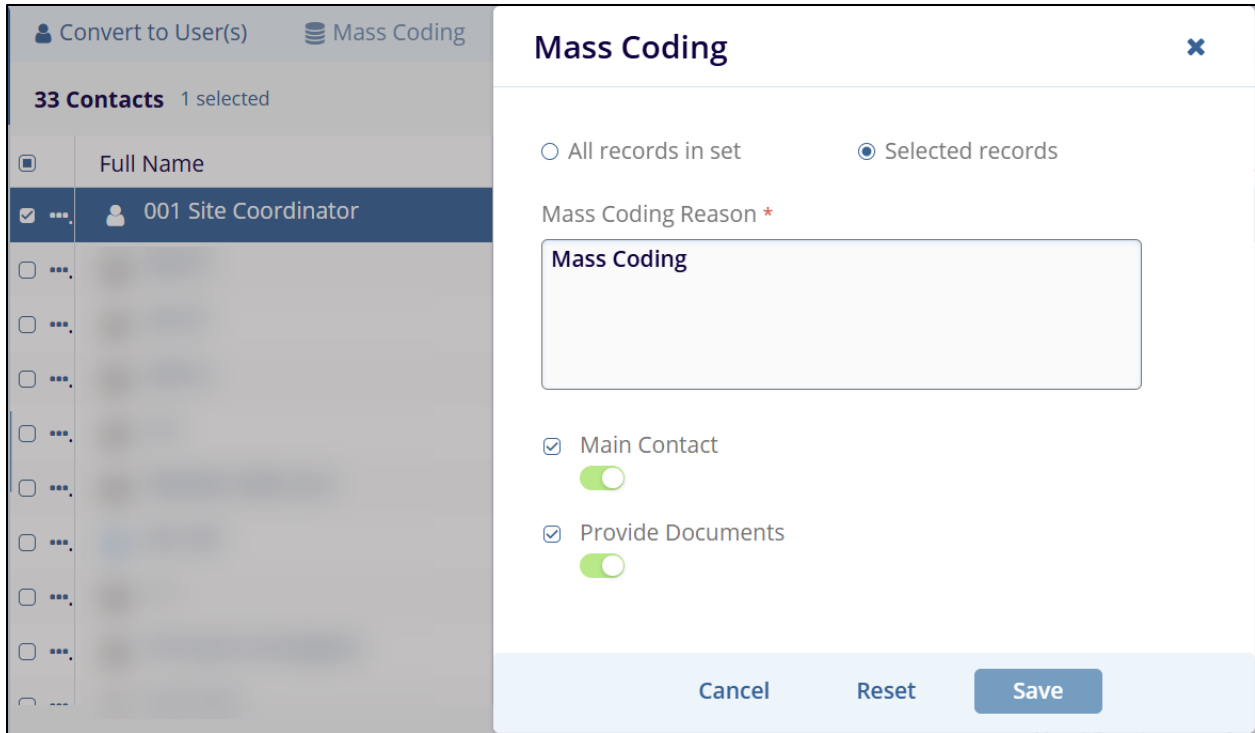
## Convert to User(s)

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 screenshot below.



## Mass Coding

1. Click the **Mass Coding** option from the top menu bar to enable you to set all contacts in the grid pane or only select 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:

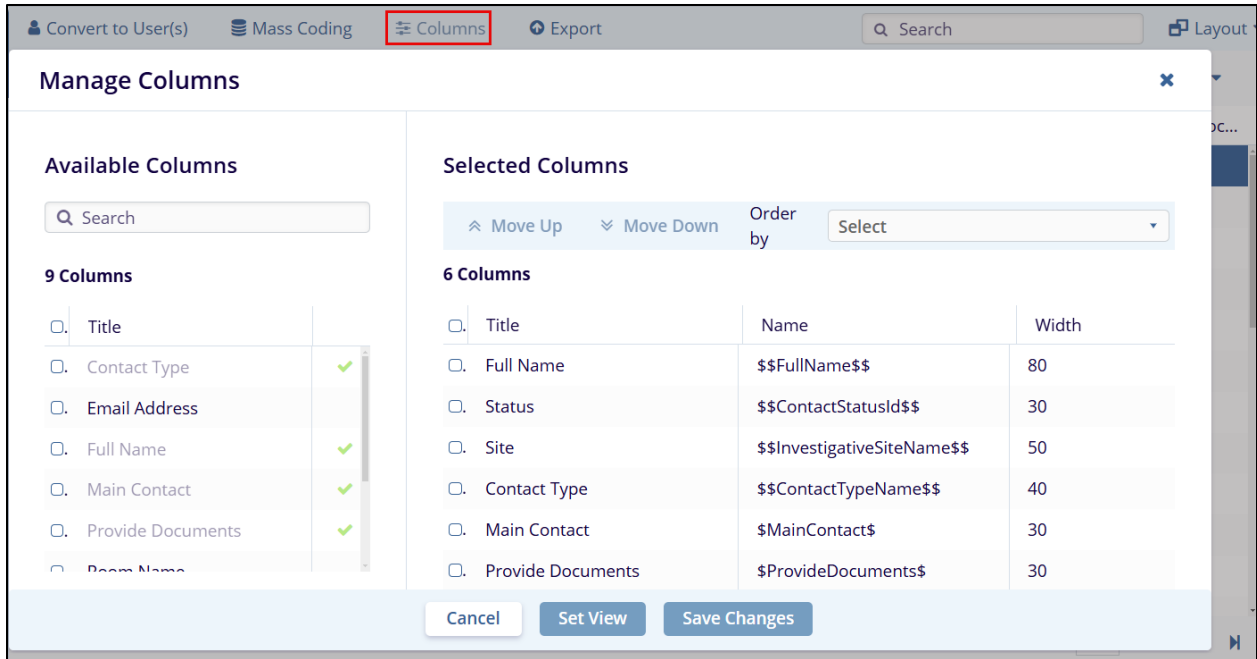


### Columns

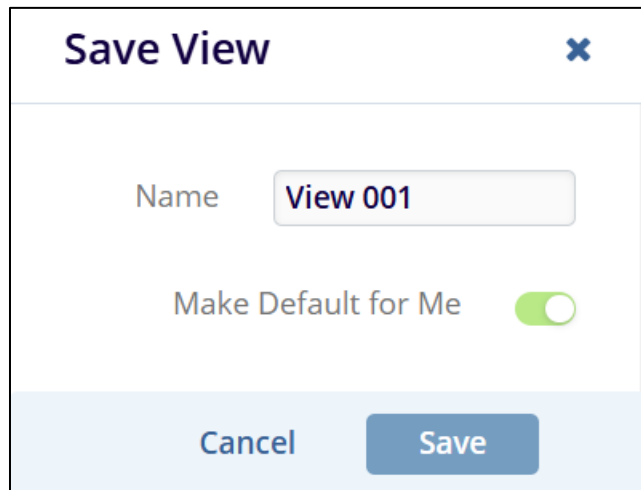
This option helps the user to select the required columns to be displayed in the grid pane of the Documents section.

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.



### 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.

<span>Convert to User(s)</span> <span>Mass Coding</span> <span>Columns</span> <span>Export</span> <span>Search</span>						
<b>33 Contacts</b> 1 selected <span>Filters</span> <span>Views</span>						
	Full Name	Status	Site	Contact ...	Main ...	Provi...
<input checked="" type="checkbox"/>	001 Site Coordinator	ACTIVE	Site - 105 Princ	Study Co...	No	No
<input type="checkbox"/>	004 PI	ACTIVE	Site - 004 PI	Principal...	No	No

3. The metadata panel displays the contact details.

OC

**001 Site Coordinator**

ACTIVE

Study Coordinator

✉ Email

**General Information**

Email Address

Prefix  First Name \*


Last Name \*  Suffix

Contact Type \*

Status \* ACTIVE Activation Date

◀ Previous
Next ▶

- Double-click on the contact and make the required changes on the Contact Details screen.
- Click the **Save** button to save the changes.



**001 Site Coordinator**  
CONTACT

Site: **Site - 105 Principal Investigator**  
Email:   
Phone:

**Contact Details**

Sites

### Contact Details

[Save](#) [Cancel](#) [Collapse All](#) [Edit History](#)

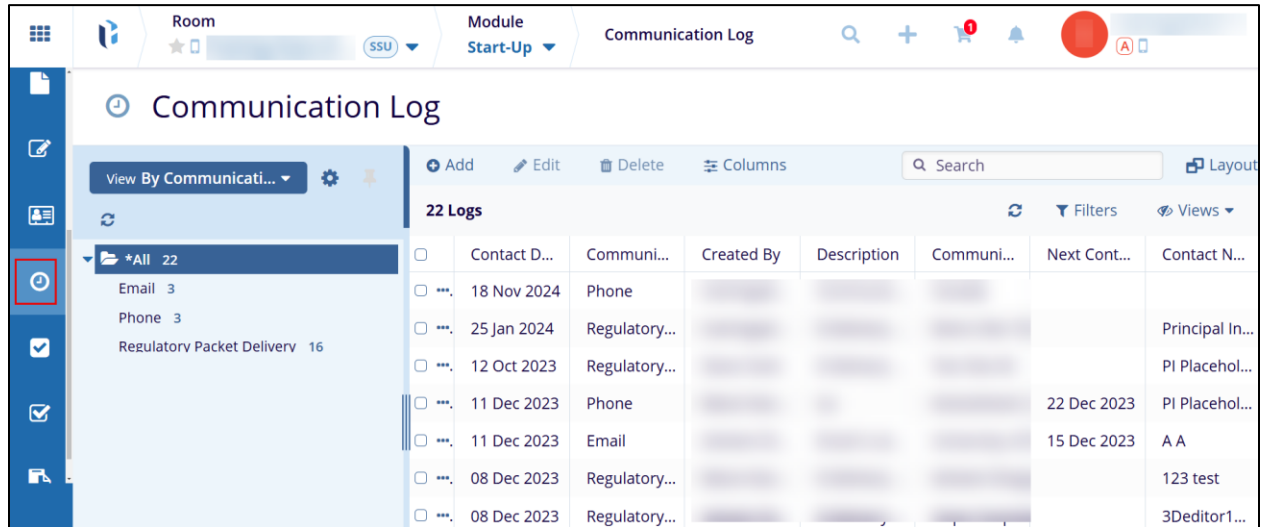
**General Information** ▾

**Contact Information** ▾

**Additional Information** ▾

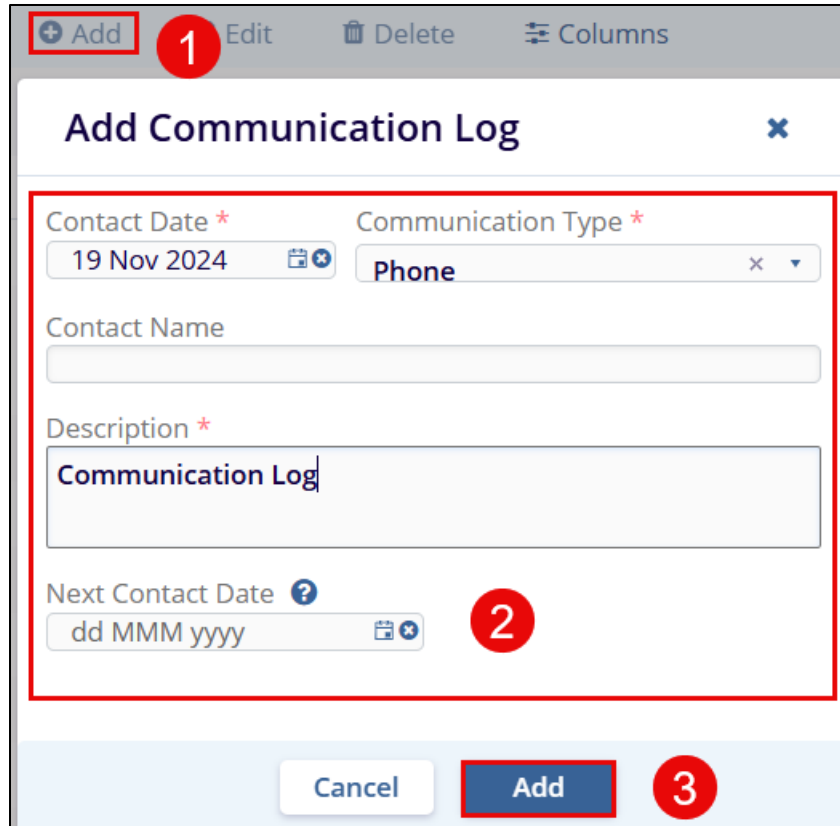
## Communication Log

The communication log helps the user by displaying the communications that happened over a while 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.



### 312. Add

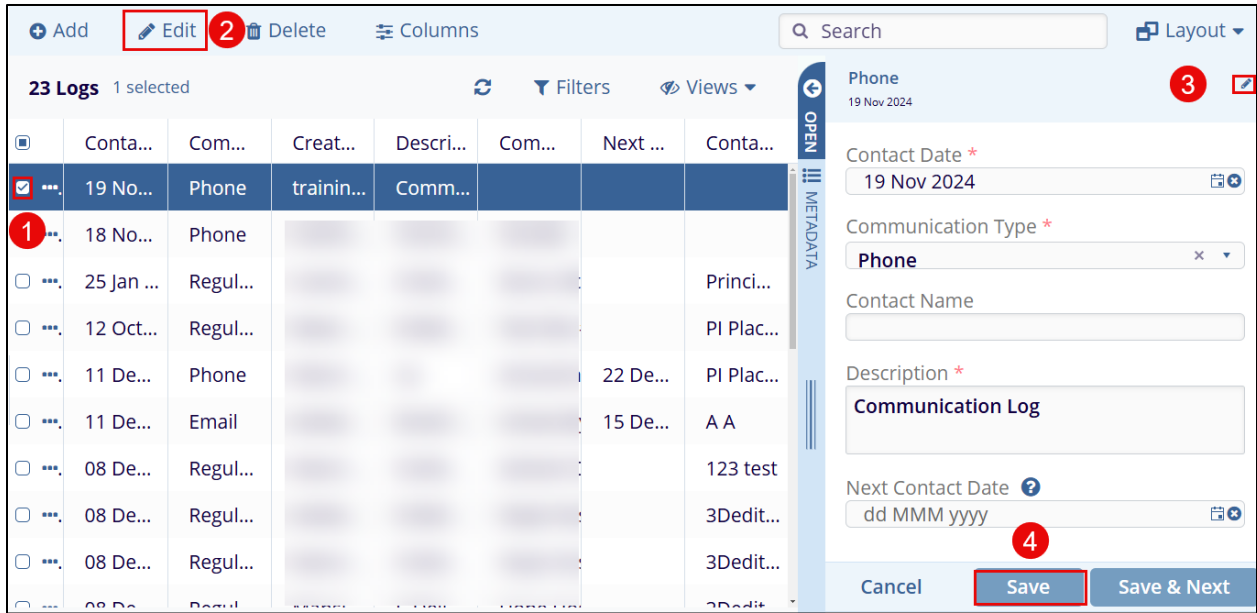
1. Click the **Add** button displayed on the top menu bar. This opens the Add Communication Log popup window.
2. Enter the details in the fields:
  - Contact Date
  - Communication Type
  - Description.
  - Contact Nam
  - Next Contact Date
3. Click the **Add** button displayed at the bottom of the popup window.



The screenshot shows a modal window titled "Add Communication Log" with a close button (X) in the top right. At the top, there is a menu bar with buttons: "Add" (highlighted with a red box), "1 Edit" (with a red circle containing the number 1), "Delete", and "Columns". The form fields are: "Contact Date \*" (with "19 Nov 2024" and a calendar icon), "Communication Type \*" (with a dropdown menu showing "Phone"), "Contact Name" (empty text field), "Description \*" (with "Communication Log" and a cursor), and "Next Contact Date ?" (with "dd MMM yyyy" and a calendar icon). At the bottom, there are "Cancel" and "Add" buttons (the "Add" button is highlighted with a red box), and a red circle containing the number "3" is positioned to the right of the "Add" button. A red box also encloses the "Contact Date", "Communication Type", "Contact Name", "Description", and "Next Contact Date" fields.

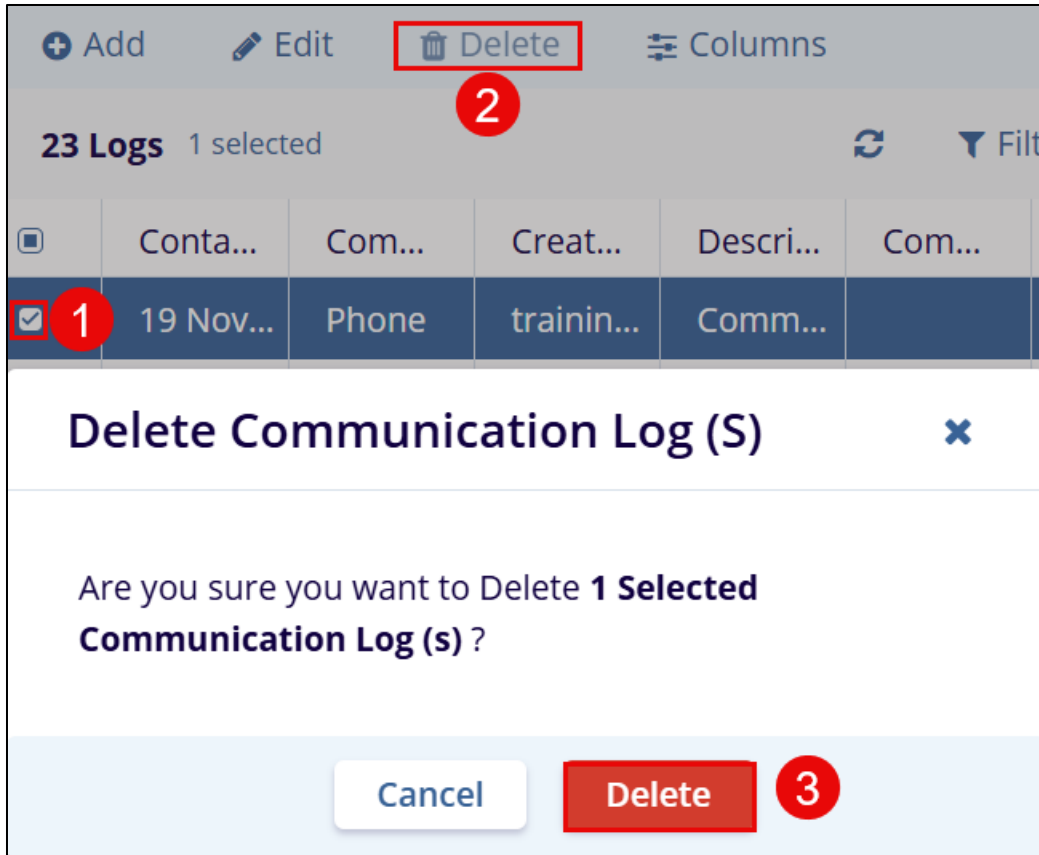
### 313. Edit

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. This 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.



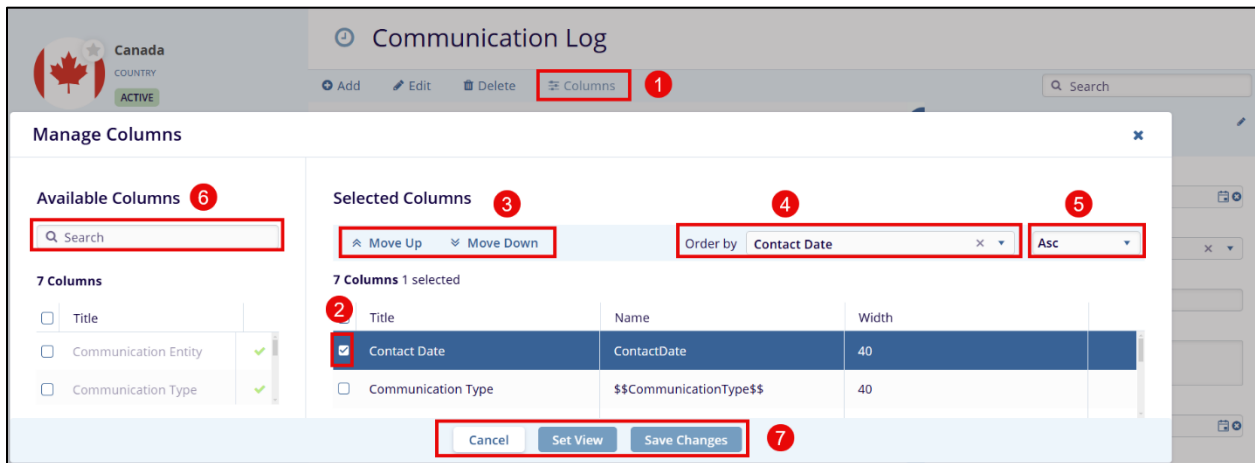
### 314. Delete

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.



### 315. Columns

1. Click on the Columns option from the top menu bar
2. Select the column title by clicking on the Checkbox
3. Click on the Move Up and Move Down buttons to rearrange to columns' order.
4. Select an Order By filter from the available dropdown option.
5. Select Ascending or Descending to sort the columns.
6. Search for a specific column by entering the search term in the Available Columns search box.
7. Click on either the Cancel, Set View, or Save Changes button.



## 316. Filters

### Manage Filters

On the Communication Log screen, click on the Filters button and follow the standard steps to manage filters detailed in the [Manage Filters](#) section.

### Create New Filter

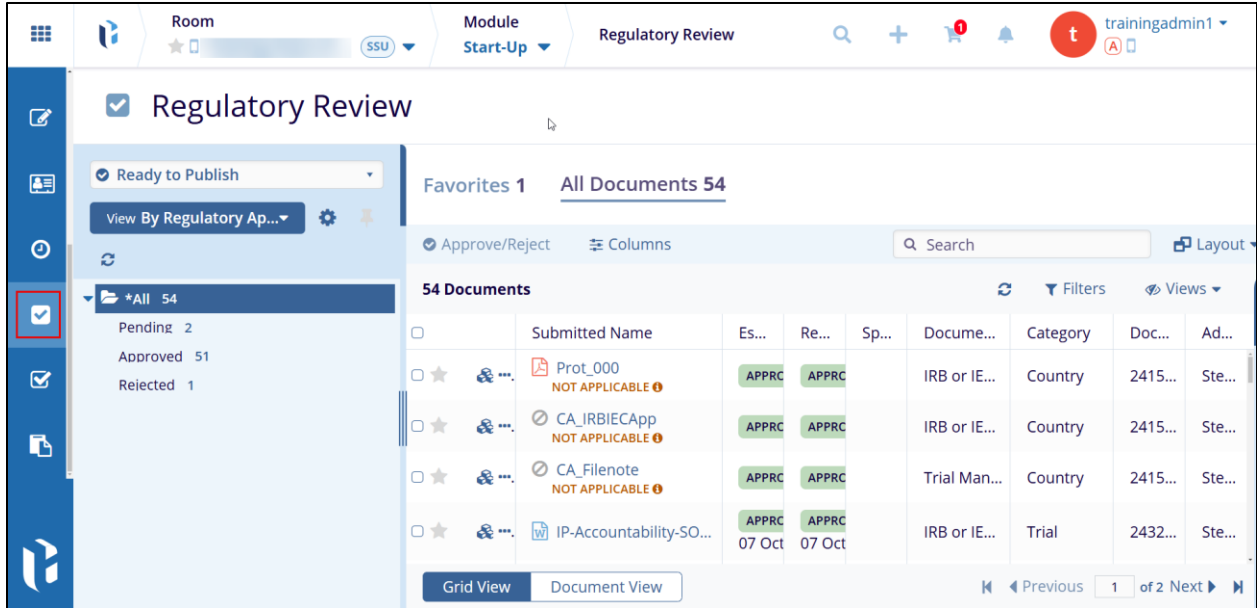
On the Communication Log screen, click on the Filters button and follow the standard steps to manage filters detailed in the [Create New Filter](#) section.

## 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 summary 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 the **Document Data** panel on the right.





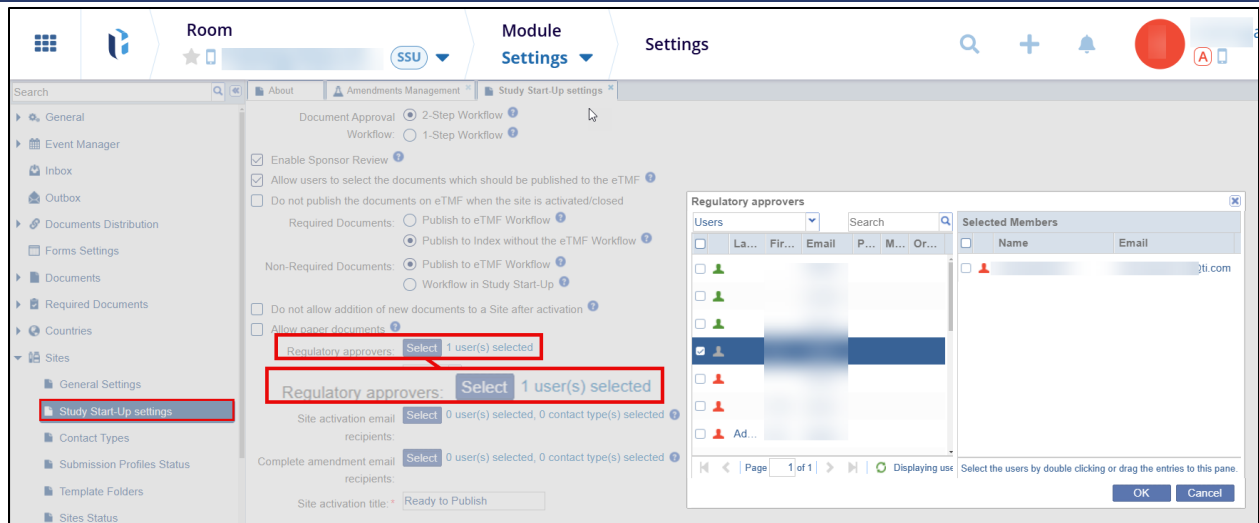
### 317. Adding Regulatory Approvers

A Regulatory Approver can be a Global Regulatory Approver, Country, or Site Regulatory Approver. As a Global Regulatory Approver, you can perform the functions at all sites within a study room. As a Country Regulatory Approver, you can perform the functions at all sites in a specific country (ies). Lastly, as a Site Regulatory Approver, you can only perform the functions at the site(s) a room Administrator assigns.

**To add Global Regulatory Approver, follow the steps below:**

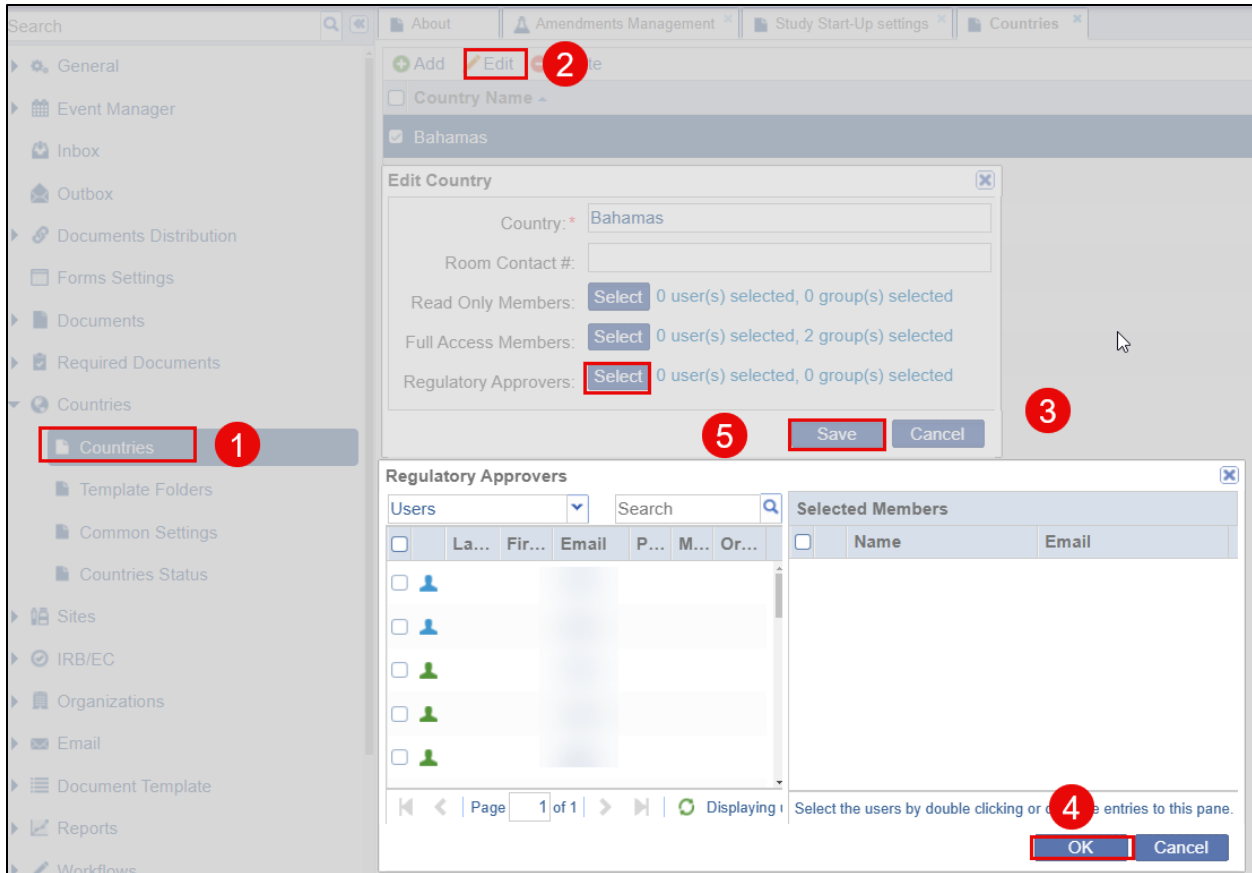
1. Navigate to **Settings**.
2. On the left-side panel, navigate to **Sites> Study Start-Up settings**.
3. Next to Regulatory approvers, click on **Select**. Add user(s) by either double-clicking on the user on the left-hand side to move to the Selected Members on the right-hand side or by dragging and dropping the user from the left-hand side to the Selected Members on the right-hand side.

**Note:** Users added as Regulatory Approvers from here will be available as Regulatory Approvers to all the sites in the room.



**To add a Country Regulatory Approver, follow the steps below:**

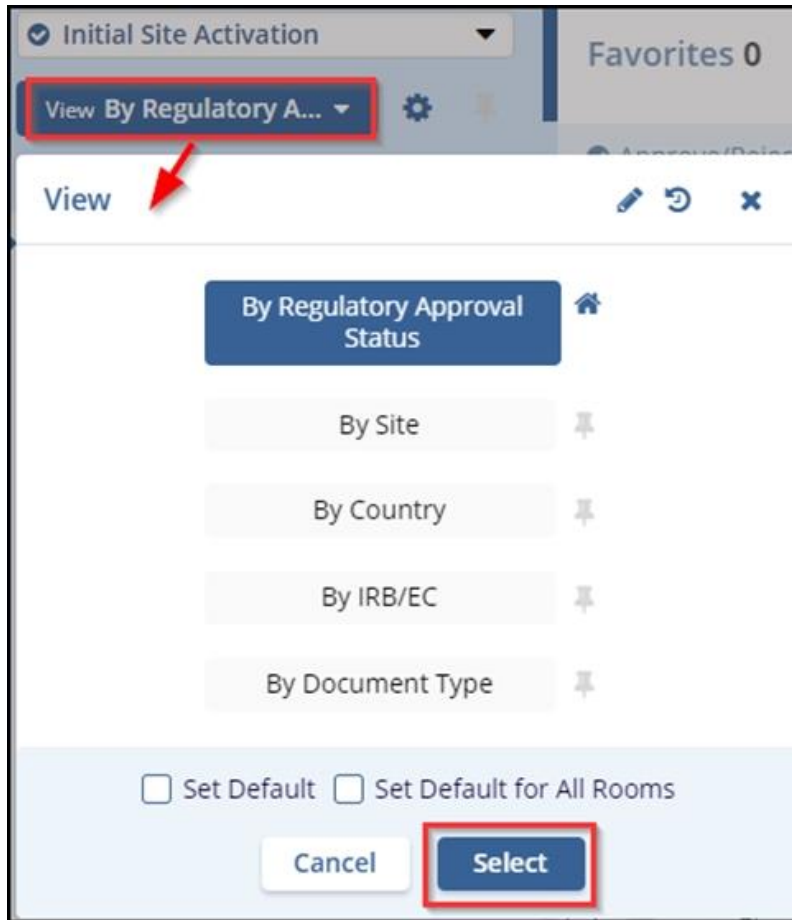
1. Navigate to **Settings -> Countries -> Countries**.
2. Check the box next to the country and then click **Edit**. (If the Country is not listed, click **Add** to create a new country).
3. Next to **Regulatory Approvers**, click **Select**. Add user(s) by either double-clicking on the user on the left-hand side to move to the **Selected Members** on the right-hand side or dragging and dropping the user from the left-hand side to the **Selected Members** on the right-hand side.
4. Click **Select** to open the Regulatory Approvers windows and add the users. Click **OK**.
5. Click **Save**.



**To add a Site Regulatory Approver, follow the steps 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 or dragging and dropping the user from the left-hand side to the **Selected Members** on the right-hand side.
4. Click **Save**

318. Current View

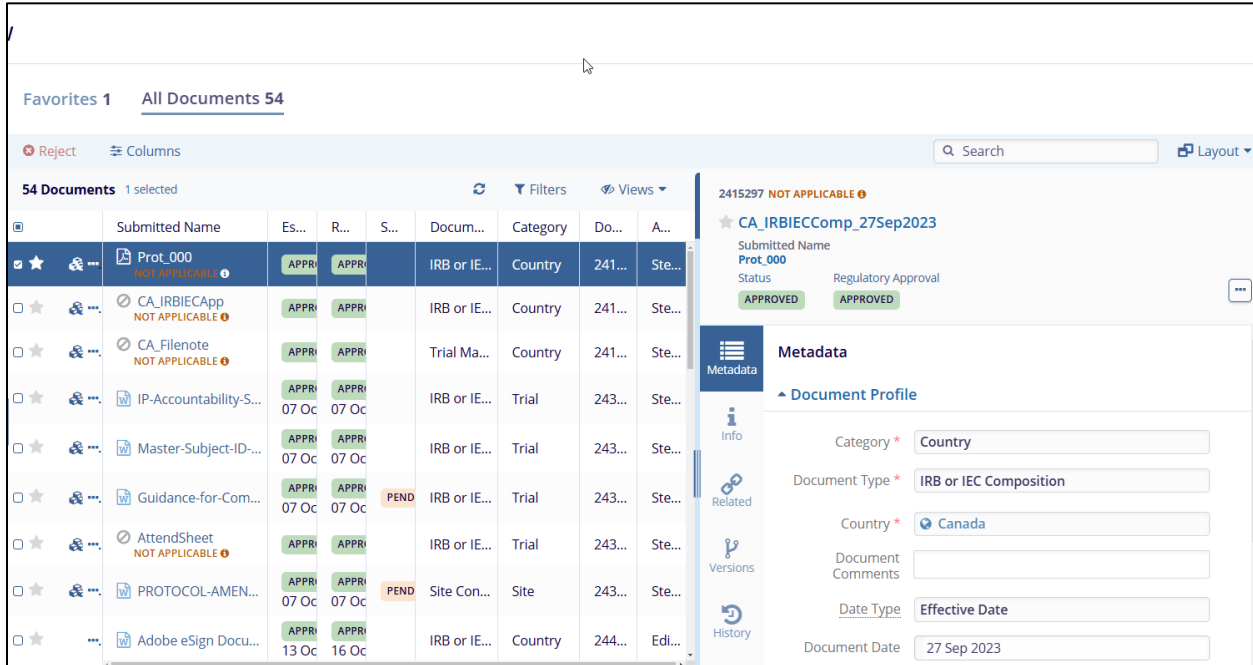


The Current View Dropdown offers five views:

- **By Regulatory Approval Status:** The By Regulatory Approval Status groups all the documents as 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. The review 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 along with their review status in the grid pane.
- **By IRB/EC:** The By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC from the left pane will display the documents submitted to the institution along with their review status in the grid pane. Refer to the screenshot below:
- **By Document Type:** The By Document Type option lists 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.

### 319. 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.



The screenshot displays the 'All Documents' section with 54 documents listed in a grid. The selected document, 'CA\_IRBIECComp\_27Sep2023', is shown in a detailed view on the right. The metadata panel includes fields for Category (Country), Document Type (IRB or IEC Composition), Country (Canada), Date Type (Effective Date), and Document Date (27 Sep 2023). The grid shows columns for Submitted Name, Status (APPR, PEND), and various document details.

Submitted Name	Es...	R...	S...	Docum...	Category	Do...	A...
Prot_000 NOT APPLICABLE	APPR	APPR		IRB or IE...	Country	241...	Ste...
CA_IRBIECApp NOT APPLICABLE	APPR	APPR		IRB or IE...	Country	241...	Ste...
CA_Filenote NOT APPLICABLE	APPR	APPR		Trial Ma...	Country	241...	Ste...
IP-Accountability-S...	APPR	APPR		IRB or IE...	Trial	243...	Ste...
Master-Subject-ID...	APPR	APPR		IRB or IE...	Trial	243...	Ste...
Guidance-for-Com...	APPR	APPR	PEND	IRB or IE...	Trial	243...	Ste...
AttendSheet NOT APPLICABLE	APPR	APPR		IRB or IE...	Trial	243...	Ste...
PROTOCOL-AMEN...	APPR	APPR	PEND	Site Con...	Site	243...	Ste...
Adobe eSign Docu...	APPR	APPR		IRB or IE...	Country	244...	Edi...

The user can switch between the Grid and the Document Data Panel by clicking any of the buttons located at the bottom of the Grid pane.

### 320. How to Regulatory Review a Document with Attachments

Once the regulatory reviewer receives an email stating about a pending review, they log 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 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 approval.
2. Select the checkbox of the file that displays Pending status.
3. Click the Document View button displayed at the bottom of 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 appropriate.
6. Click the Reject or Approve button displayed at the bottom of the popup window.

The screenshot displays the 'Document Preview' window. On the left, a PDF document titled 'STATEMENT OF INVESTIGATOR' is open. The document contains sections for 'DEPARTMENT OF HEALTH AND HUMAN SERVICES', 'STATEMENT OF INVESTIGATOR', and 'INSTRUCTIONS FOR COMPLETING FORM FDA 1572'. The right sidebar shows document details: ID '2489814', title 'Training-12345\_102\_FDA1572\_102\_A\_09Nov 2023', submitted name 'FDA 1572\_montana', and status 'Regulatory Approval' with 'APPROVED' and 'PENDING' buttons. Below this is a 'Metadata' section with a 'Document Profile' and fields for 'Category' (Site), 'Document Type' (Form FDA 1572), 'Site' (Kane Community Hospital), and 'File Name' (FDA 1572\_montana.pdf). At the bottom of the preview area are 'Cancel', 'Reject', and 'Approve' buttons.

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.

### 321. Regulatory Review of Paper Documents/Documents without attachments

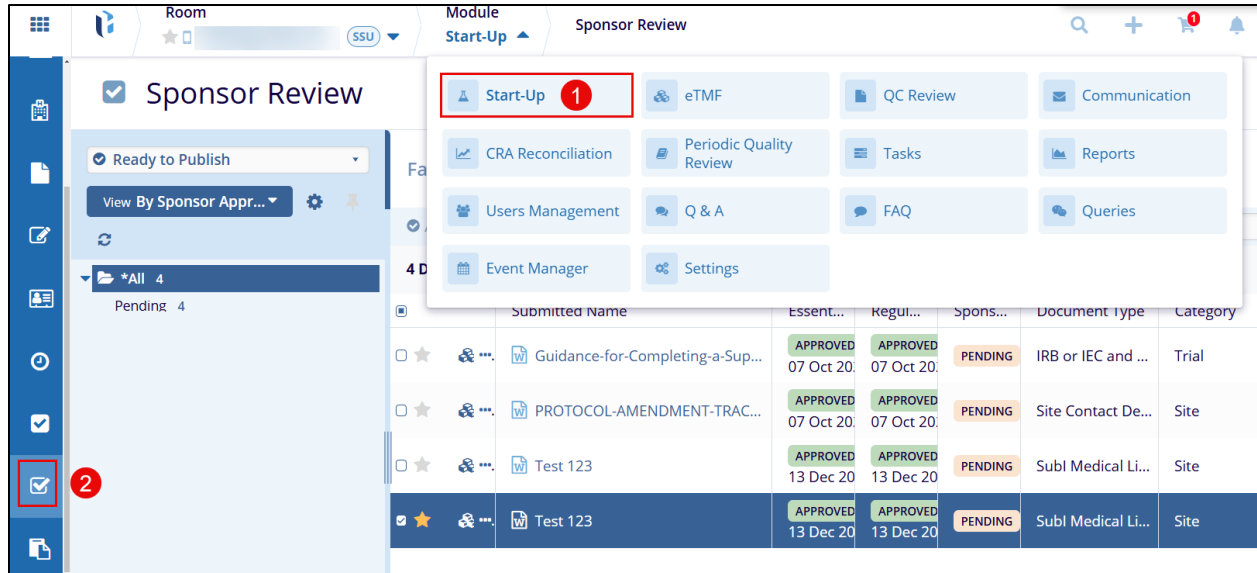
As discussed in earlier sections, paper documents go without attachments. In such a case, the Approve and Reject buttons will be placed above the Regulatory Review documents grid, so it will not be required to open the document in a viewer to approve/reject it. The rest of the approval/ rejection process remains the same.

## Sponsor Review

### 322. Accessing Sponsor Review

To access the sponsor review, follow the steps below.

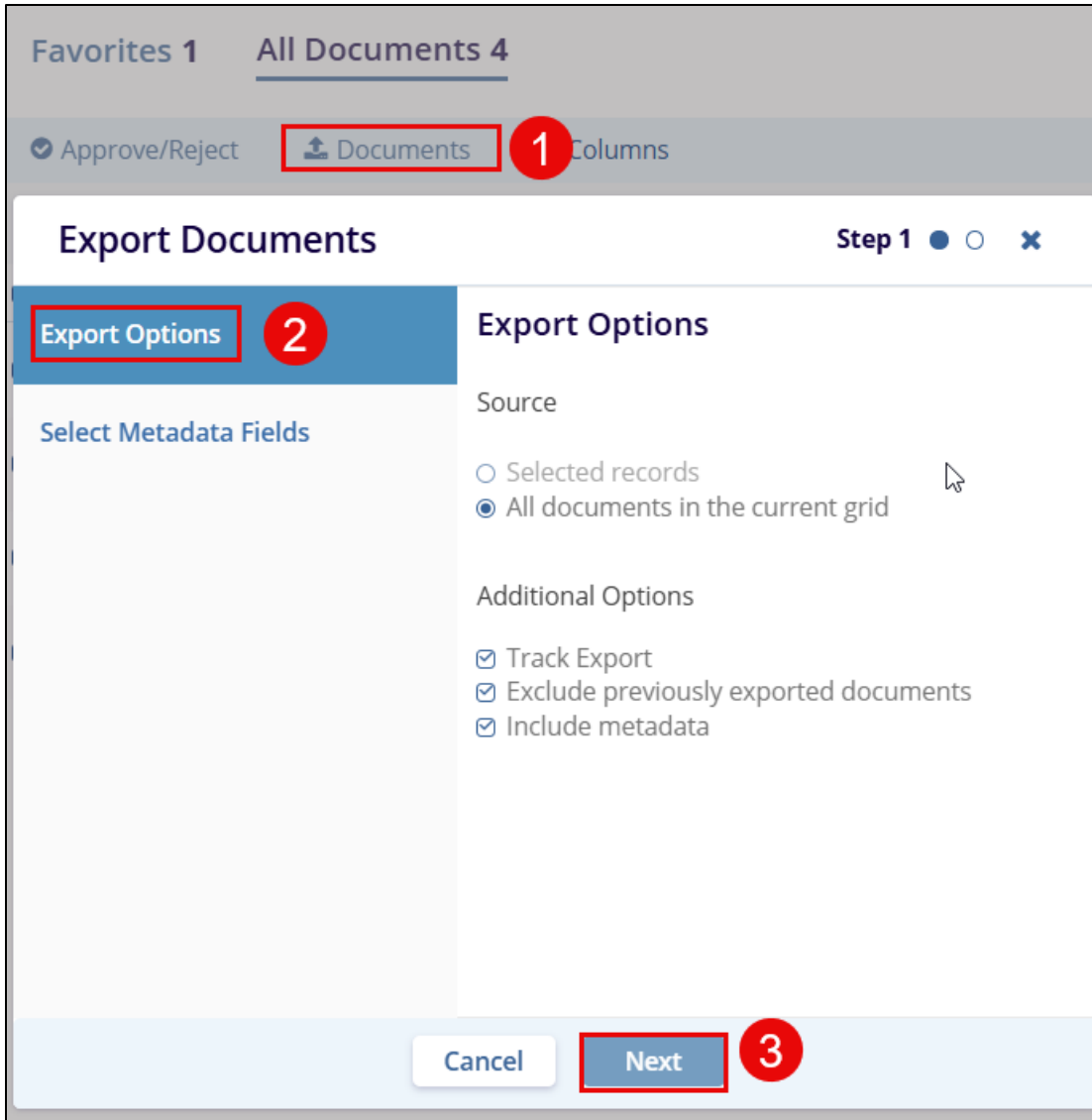
1. Select the Study Start-Up module
2. From the left-hand navigation pane, click on the Sponsor Review modal.



### 323. Documents

To upload documents, follow the steps below.

1. Click on the Documents button from the top menu bar
2. On the Export Options screen, add Source and Additional options.
3. Click on the Next button.



4. Select the metadata fields and click on the Export button.



## Export Documents

Step 2
○ ● ✕

Export Options

Select Metadata Fields 12

### Select Metadata Fields

Favorite ✕
Submitted Name ✕
Essential Document Status ✕

Regulatory Approval Status ✕
Sponsor Approval Status ✕

Document Type ✕
Category ✕
Document Id ✕
Added By ✕

Essential Document Status Date ✕
Regulatory Approval Date ✕

Sponsor Approval Date ✕

Sort By Alphabet
▼
↑

▼ 73 Metadata Fields 12 Selected

- Added By
- Amendment Number
- Applicable Status Change Reason
- Artifact
- Category
- Contact Name
- Contact Type
- Converted Document Hash

Cancel
Previous
Export
4

### 324. Columns

To manage columns, select columns from the top menu bar and follow the steps detailed in the [Columns](#) section.

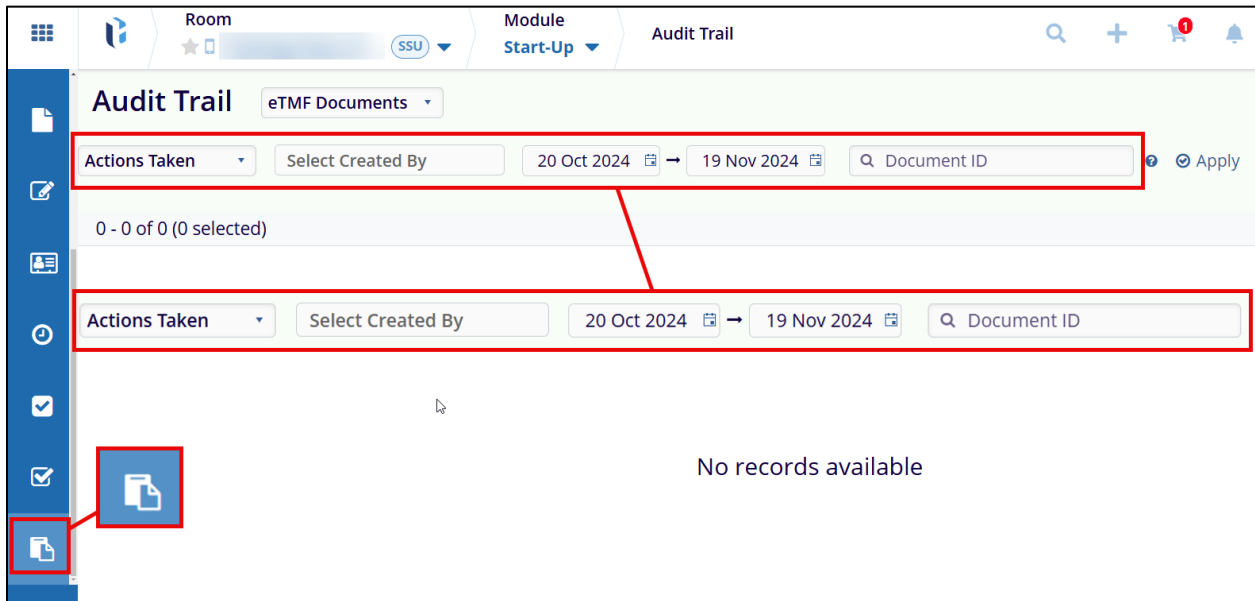
## Audit Trail

An 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 the username in the ‘Select Created By’ field and clicking the Apply button displayed in the top right corner.

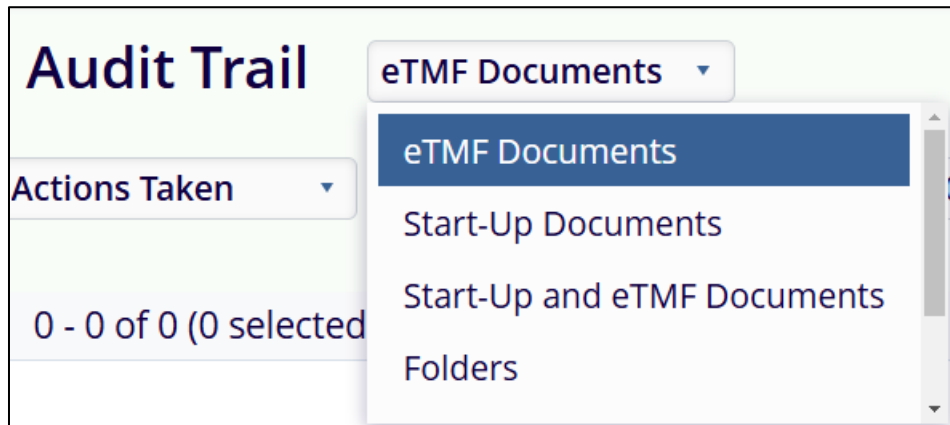
### 325. Filters for Audit Trail

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.



### 326. 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.

### 327. User Interface for eTMF 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.

Activity Date	Created By	Document ID	Document Name	Index Path	Activity Type	Activity Related Data
15 Nov 2024 04:41:1...		2449794		Staging	Open Document Met...	
15 Nov 2024 04:41:0...		2449793		Staging	Open Document Met...	
15 Nov 2024 04:41:0...		2449787		Staging	Open Document Met...	
15 Nov 2024 04:39:2...		2449793		Staging	Open Document Met...	

### 328. User Interface for Start-Up and eTMF Documents

This feature helps the user to search and apply filters combined for the eTMF and Start-Up modules.

Activity Date	Created By	Document ID	Document Name	Index Path	Activity Type
19 Nov 2024 07:07:4...		2489814			Open Document
19 Nov 2024 07:07:4...		2489814			Open Document Met...
19 Nov 2024 07:07:1...		2489814			Open Document
19 Nov 2024 07:07:0...		2489814			Open Document Met...
18 Nov 2024 00:14:0...		2647863			SSU - New Essential ...

### 329. 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.

**Audit Trail** Folders ▾

Actions Taken ▾  ×  →

1 - 50 of 399 (0 selected)

<input type="checkbox"/>	Activity Date	Created By	Folder Id	Folder Name	Index Path	Activity Type
<input type="checkbox"/>	18 Nov 2024 06:20...		2648041	New Folder	Site\Site - 333 222\...	New InvestigativeS...
<input type="checkbox"/>	18 Nov 2024 06:20...		2648039	10.05.04 Filenote	Site\Site - 333 222\...	New InvestigativeS...
<input type="checkbox"/>	18 Nov 2024 06:20...		2648038	10.05.02 Tracking I...	Site\Site - 333 222\...	New InvestigativeS...
<input type="checkbox"/>	18 Nov 2024 06:20...		2648037	10.05.01 Relevant ...	Site\Site - 333 222\...	New InvestigativeS...
<input type="checkbox"/>	18 Nov 2024 06:20...		2648036	10.04.01 System A...	Site\Site - 333 222\...	New InvestigativeS...

### 330. 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 ▾

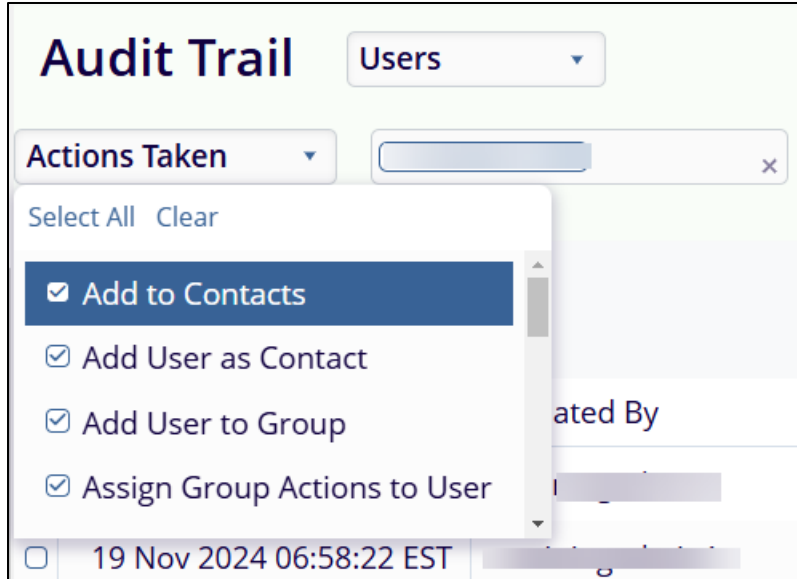
Actions Taken ▾  ×  →

1 - 50 of 126 (0 selected)

<input type="checkbox"/>	Activity Date	Created By	User ID	User Full Name	User Email Address	Activity Type
<input type="checkbox"/>	19 Nov 2024 06:58...		6092			Add User to Group
<input type="checkbox"/>	19 Nov 2024 06:58...		6092			Add User to Group
<input type="checkbox"/>	19 Nov 2024 06:57...		6092			Sign In To Room
<input type="checkbox"/>	19 Nov 2024 06:48...		6092			Sign In To Room
<input type="checkbox"/>	19 Nov 2024 04:20...		6092			Sign In To Room

### 331. 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.



## Filters

The following filters are available in Audit Trail

### 332. 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.

### 333. 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. Users can select dates from the previous year too, by scrolling up on the Months field. Refer to the screenshot below.

### 334. 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.

### 335. Export

The user can export the Audit Trail in an Excel sheet for reference. Follow the steps below to export.

- Click the Export button displayed in the right corner to view the details of the audit trail in an Excel sheet.
- Click on the Get Job Result button displayed in the notification in 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.
- The Activity Related Data column displays the activities carried out over a document.

### 336. 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, the sponsor, or the CRO forwards an initial regulatory documents packet for collecting the documents from various contacts on 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 by 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, the administrator can set up email templates and document templates for specific document types as required.

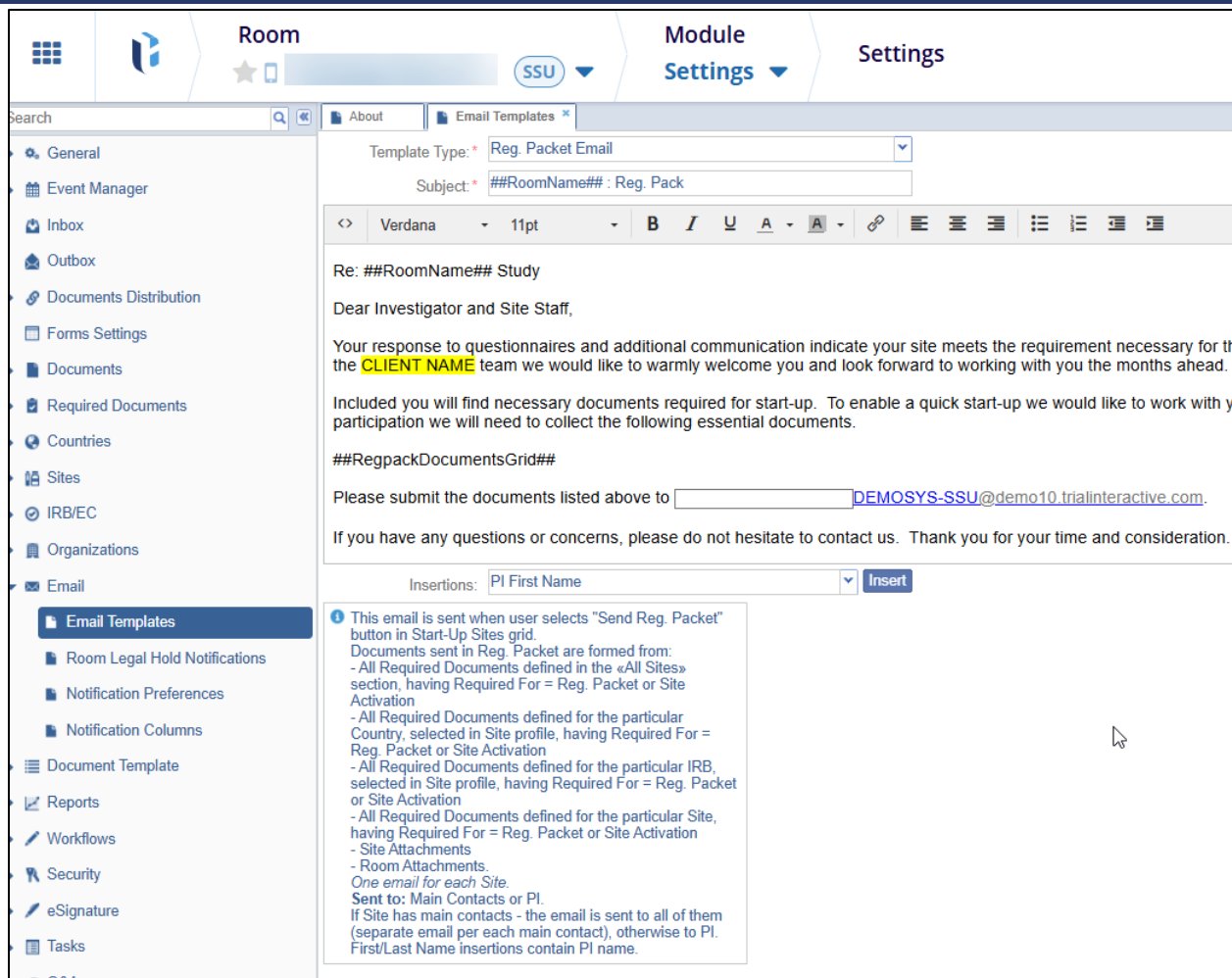
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### 337. Setting Up Email Templates

The administrator can set up the body of the email template from the room's settings. By default, the system 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, proceed as 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 on 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 insertions in the email body for the PI name, Domain Name, Room Name, and Investigative Site details by choosing appropriate options from the Insertions dropdown and clicking Insert next to the dropdown.
9. Click Save to commit the changes.

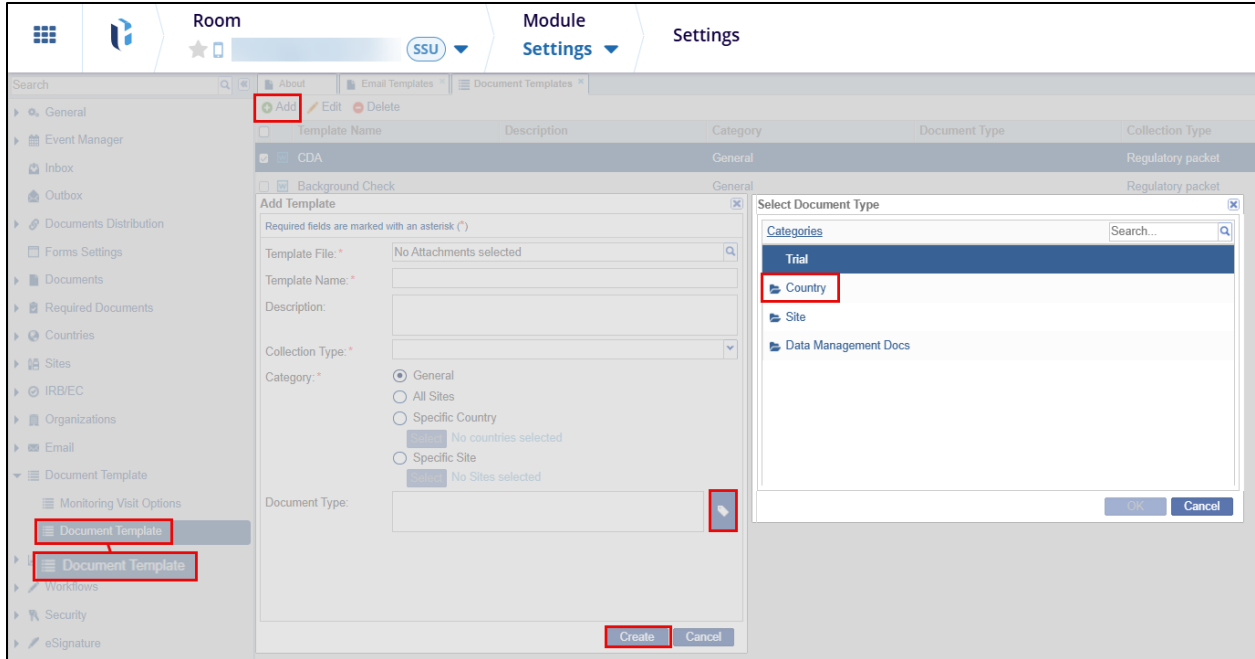


### 338. Setting Up Document Templates

To set up document templates, follow the procedure below:

1. Navigate to the **Settings**.
2. Select the Document Templates from the left panel.
3. The Document Templates window opens on 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 countries or sites 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.



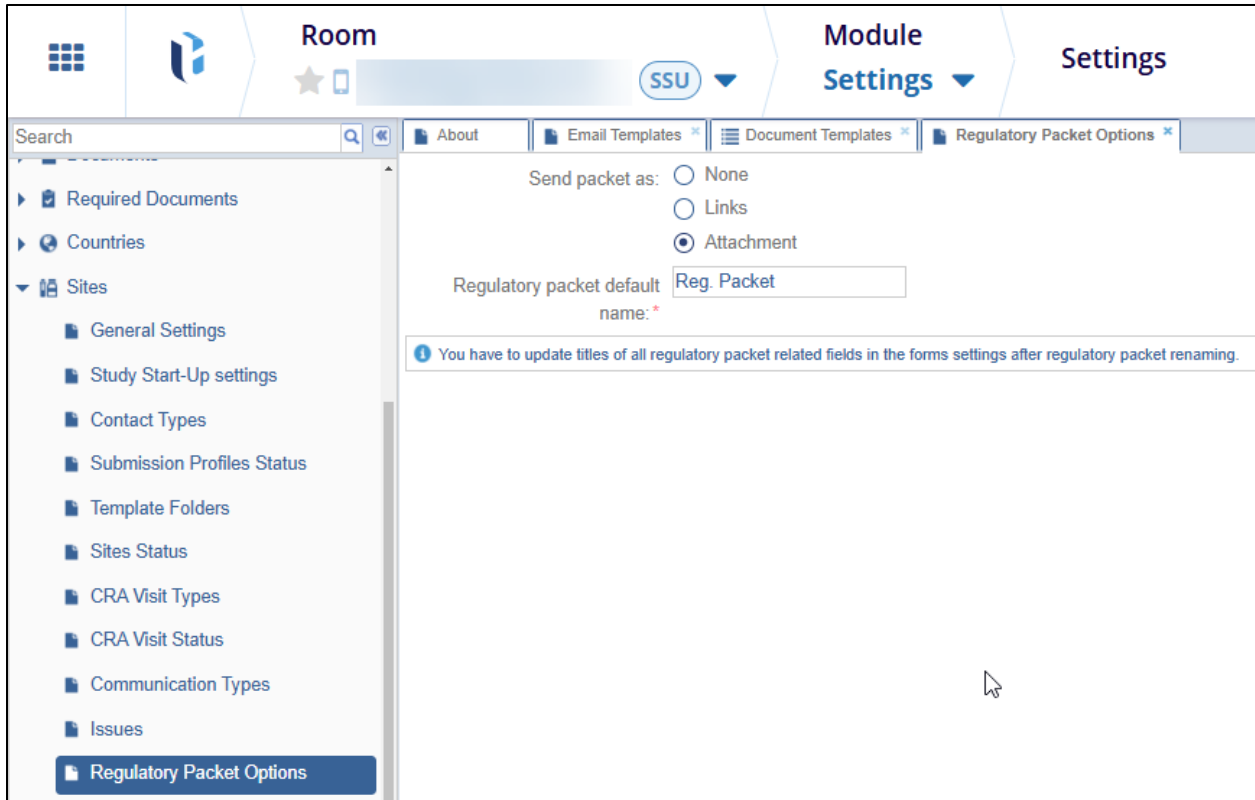


### 339. Sending Regulatory Packets

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 the standard steps detailed in the [Send Reg. Packet](#) section.

### Collecting Required and Non-Required Documents

Once the document requirements are configured, documents can enter the room through three methods depending on preference and access:

1. Via a unique SSU email address
2. Via Mass Import
3. Via individual document attachment

As mentioned earlier, all the sites, countries, and IRB/ECs require the 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-essential documents, and add/edit communication logs. The procedure to add documents is the same for sites, countries, and IRB/ECs.

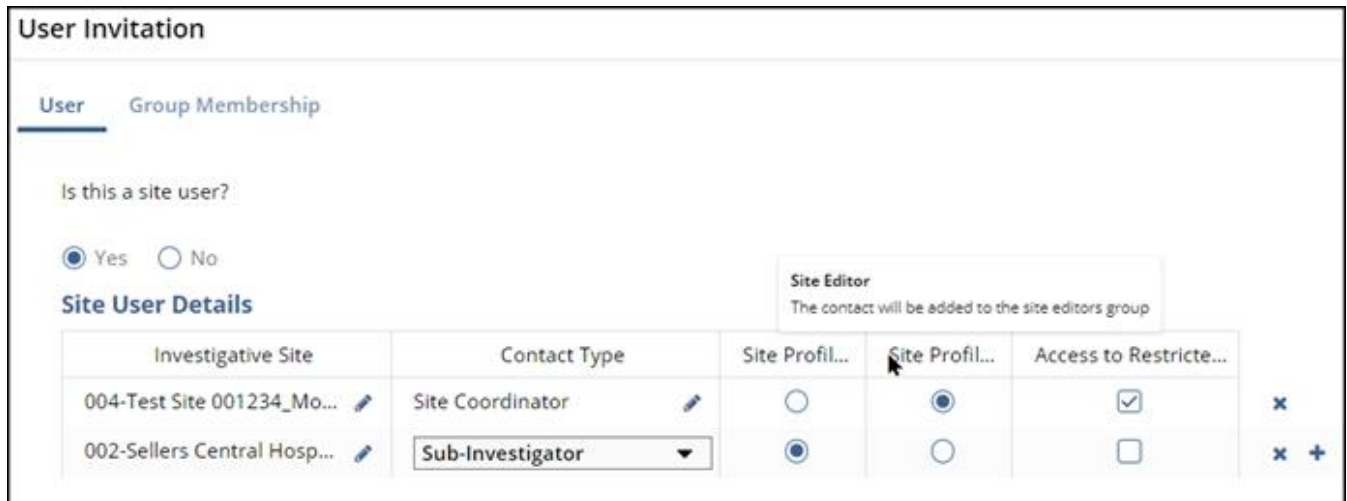
## eISF

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.

### 340. 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.










**User Invitation**

**User** | Group Membership

Is this a site user?

Yes  No

**Site User Details**

Investigative Site	Contact Type	Site Profil...	Site Profil...	Access to Restrict...	
004-Test Site 001234_Mo... 	Site Coordinator 	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>	
002-Sellers Central Hosp... 	Sub-Investigator 	<input checked="" type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	 

**Site Editor**  
The contact will be added to the site editors group

6. Select Yes under “Is this a Site User?”
7. Choose an Investigative Site, followed by the Contact Type to be assigned to the user for that Site.
8. Select whether the user should have Reader- or Editor-type access to the Site.
9. Mark the Access to Restricted Folder box if you wish the user to have access to the site Subject Documentation and other source documents.
10. You can repeat these steps for multiple Sites. Use the ‘+’ button at the right to add a new line.

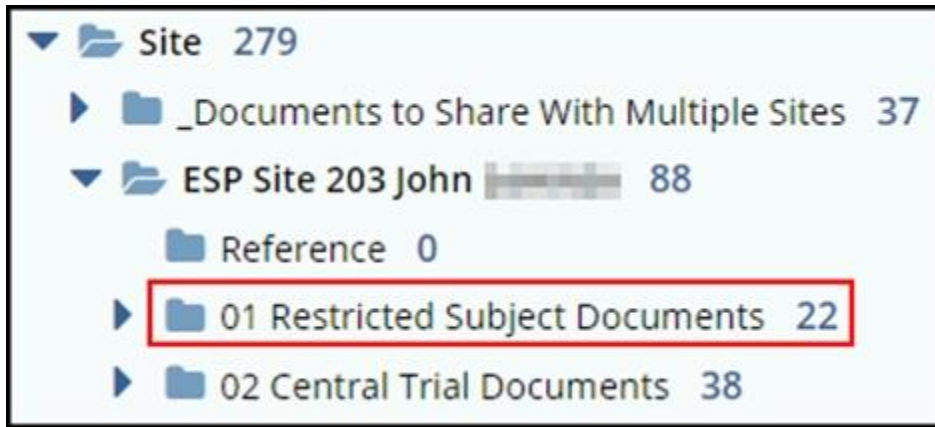
Specific permissions are assigned to users in this category based on predetermined site template-folder security configuration. This will allow users to be provided the correct security profile right away upon creation and gain immediate access to the Site Collaborate room, reducing time-to-access.

*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.

### 341. 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.

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### 342. 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.