TRIAL INTERACTIVE

TRIAL INTERACTIVE SSU V10.7 - USER GUIDE V1.0

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LIFE SCIENCES

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CONTENTS

VERSION HISTORY

Author	Revision	Date	Change History
Mansi Kandhare	1.0	29-Apr-2025	Initial Document Creation

ABOUT THIS USER GUIDE

This guide provides a comprehensive overview of the features and components of the TI Study Start-up application, enabling users to work efficiently and securely manage their tasks within the platform.

It includes instructions on the user interface, step-by-step processes, and visual aids to enhance understanding and ease of use. This guide is exclusively designed for clients who have purchased the Trial Interactive platform.

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WHAT'S NEW IN STUDY START-UP V10.7?

Incorporation of New Export Functionality:

A new export capability has been introduced for the Documents section at the Site, Country, IRB/EC, and Amendment document levels. This enhancement improves usability and ensures consistency when exporting document-related data across these levels.

Incorporation of Enhanced Contact Field Functionality in SSU:

New functionality has been introduced to improve the handling of Custom and System Contact fields in the SSU Contact Form. This enhancement ensures better clarity and consistency by implementing the following updates:

- The SSU Contact Form's Additional Info section now includes all relevant Custom fields and selected System fields from User and Contact Form Settings, provided they are not already part of General Info or Contact Information by default.
- Only fields with the Contact checkbox enabled in User and Contact Form Settings are displayed.
- System fields such as Full Name, Role Level, UserID, Username, and similar will have their Contact checkboxes turned OFF and their Readonly status turned ON.
- System fields like Site Number, Room, and Site will have their Readonly setting turned ON.

Incorporation of Unified Country List Functionality for Site Contacts:

New functionality has been introduced to align the country selection for Site Contacts with the Site configuration. Moving forward, the country list displayed for Site Contacts will be sourced directly from the Room Settings – Countries list, ensuring consistency between Sites and Site Contacts.

Incorporation of Enhanced Sub-Navigation Panel Functionality:

New functionality has been introduced to improve the flexibility and usability of the SSU sub-navigation panel. The following enhancements have been implemented:

- The panel now has a default width of 250 px.
- Users cannot expand the panel beyond the default width of 250 px.
- The panel can be resized down to a minimum width of 60 px.
- Users now have the ability to fully collapse the panel, allowing for an optimized view of the main content area.

Incorporation of Contact Details Page Enhancements in SSU:

New functionality has been introduced to streamline the Contact Details page in SSU. As part of this update, the fields Contact Type, Main Contact, and Provide Documents are now hidden from the Contact Details view, ensuring a cleaner and more focused user experience.

Incorporation of 'Copy Link' Functionality in SSU Documents:

New functionality has been introduced to enhance document accessibility in SSU. A Copy Link option has been added to the [Document] bar, allowing users to quickly copy and share direct links to specific documents for easier navigation and collaboration.

Enhancing Quality Control in Study Start-Up

For CROs utilizing TI Study Start-Up, ensuring sponsor confidence and regulatory compliance is paramount. To facilitate this, our system introduces an enhanced Sponsor Review process, allowing sponsors to oversee and approve critical site documents before full activation.

- Streamlined Oversight: Sponsors gain an exclusive Sponsor Review capability, ensuring key documents meet quality standards before activation.
- Proactive Document Control: Start-Up Specialists (SUS) can easily flag and submit documents for Sponsor Review, reinforcing compliance.
- Effortless Access & Approval: Sponsors receive a dedicated review interface, similar to the Regulatory Reviewer, to efficiently evaluate submissions.
- Actionable Decision-Making: Sponsors can approve or reject documents with ease, ensuring every site meets expectations before activation.

IRB Approval: Submission Packages

Simplify and streamline regulatory submissions with our latest SSU enhancement, now supporting IRB and Ethics Committee (EC) submission packages throughout the study lifecycle. This feature extends SSU's powerful submission tracking and management beyond Health Agencies, ensuring seamless approvals at every level.

- Expanded Submission Packages: Now create and manage IRB/EC submission packages, directly linking them to relevant sites.
- Intelligent Site-Level Approvals: When approving a submission package, users can select specific sites that have received approval, ensuring precise tracking.
- Flexible Approval Workflow: Easily approve all or select sites within a submission package, with approvals automatically cascading down to the site level.
- Global Submission Efficiency: In the European Union, a single submission package can now be assigned to multiple countries, reducing redundancy and streamlining multi-country studies.
- Multi-Country Assignments: Users can now assign multiple countries directly from the submission package profile tab, ensuring efficient global coordination.
- Automated Country-Level Updates: When a submission package is linked to multiple countries, it automatically appears in each country's records, eliminating duplication.
- Real-Time Status Synchronization: Changes in the submission package status instantly reflect across all associated countries, ensuring accurate and up-to-date regulatory tracking.

STUDY START-UP

The Start-up module is accessible to users who meet all of the following criteria:

- The Study Start-up action should be enabled in their user profile.
- The users should belong to the Site Activation Members group in the data room.

Study Start-Up Process in Trial Interactive

1. Adding contacts to sites. This includes adding:
    - Principal Investigator and other contacts
    - Start-Up Specialist
    - Regulatory Approvers
    - Site Activation Specialists
2. Sending Regulatory and Submission Packages
3. Collecting Essential/Required documents for sites, countries, and IRB/ECs.
4. Review of documents by a Start-up Specialist. Translate documents to the local language if required.
5. Review of documents by Regulatory Reviewer.
6. Site Activation and publishing documents to the eTMF.
7. Adding essential/required documents after site activation through amendments.

Basic Configurations and Settings for SSU

Confirm that the Study Start-Up configuration is double-checked by the Room Administrator. The Room Administrator should be able to:

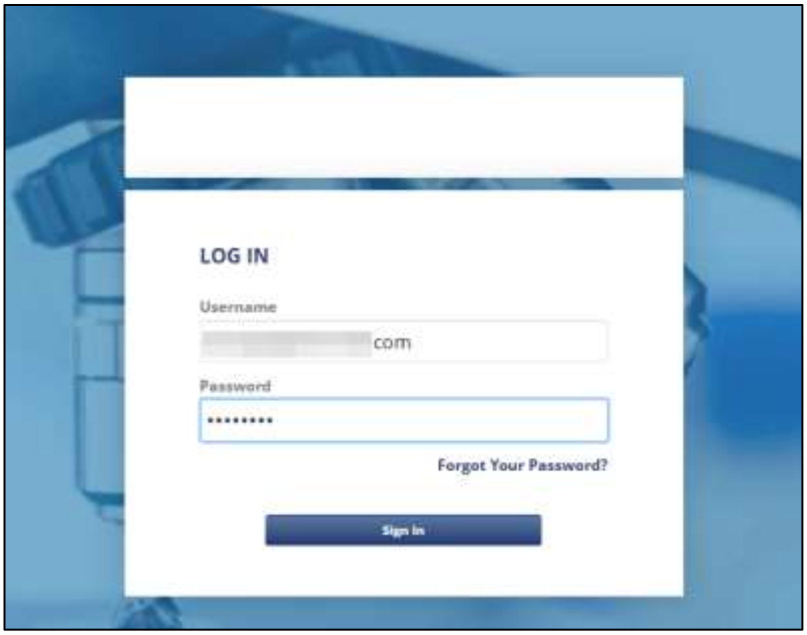
- Add Countries
- Configuring IRB/EC's
- Specifying Essential and Required Documents, etc.
- Create Sites
- Add Contacts to Sites

The Study Start-Up Settings provide users with the ability to establish global rules and configurations that are essential for the site activation process. These settings are critical for ensuring consistency and efficiency across all sites in the study and help streamline the start-up workflow.

- <u>Global Application:</u> The settings configured within the Study Start-Up Settings apply universally to all sites within the room.
- <u>Critical for Site Activation:</u> These settings define the foundational rules required for the site activation process, including regulatory requirements, documentation, and approval workflows.
- <u>Customization of Rules:</u> Administrators can customize specific settings to align with the study's needs, such as defining the required documents, setting timelines, and configuring approval processes.

To configure the SSU settings, follow the steps below.

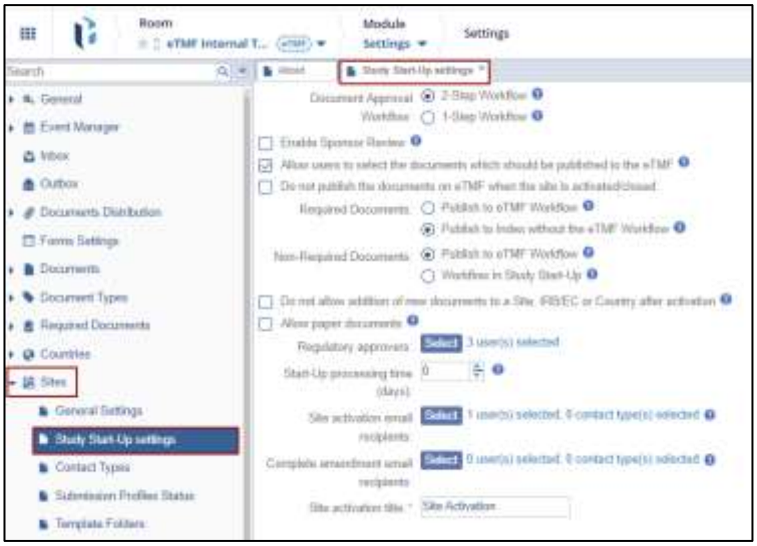
1. Please note: SSU settings are automatically configured according to the setup manual. If further adjustments are needed, Room Admins can modify them from the Settings menu. Login into Trial Interactive by entering your Username and Password.



2. Click on a room that has the Study Start-Up module enabled.

3. On the room landing page, click on the Waffle menu and select the Settings module.

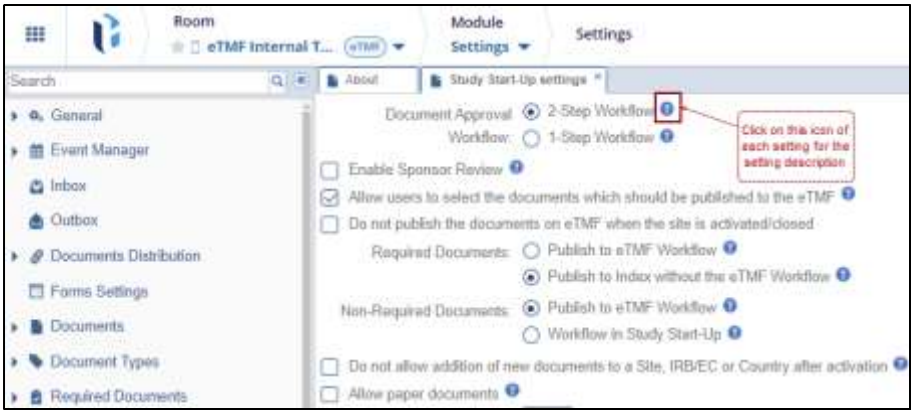
4. From the left-hand navigation pane, expand the Sites folder and select Study Start-Up settings.



5. On the Study Start-Up Settings tab, Admins can configure the following settings regarding Required and Non-Required documents.

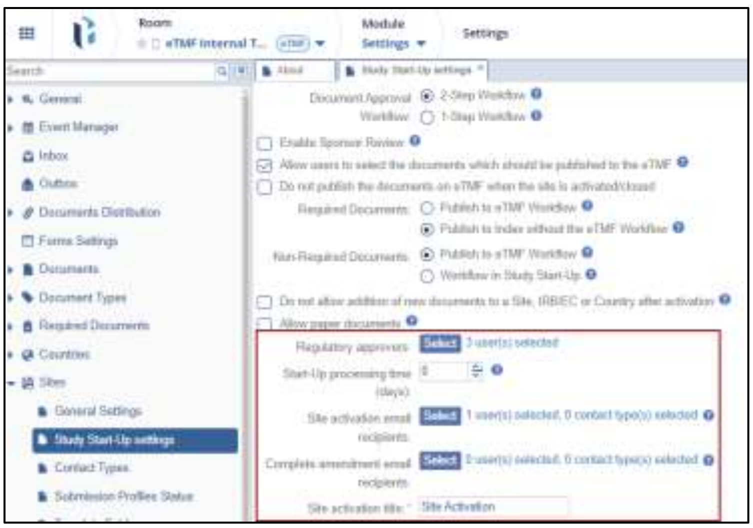
   - Document Approval Workflow: The Document Approval Workflow allows user to select the workflow type. Select any one of the workflow types by clicking on their respective radio buttons.
     - 2-Step Workflow: In this type of workflow the document should go through the two-step approval process i.e., ‘Approved by Study Start-Up Specialist’ and ‘Approved by Regulatory Reviewer.’
     - 1-Step Workflow: In this type of workflow the required documents should be approved just by the ‘Study Start-Up 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 that should be published to the eTMF: Click on the checkbox to enable the setting. If enabled the user will have the ability to select which documents to publish from SSU to the eTMF. If unchecked, all documents will automatically be published to the eTMF upon site activation.
- Do not publish the documents to eTMF when the site is activated/closed: Click on the checkbox to enable the setting. If this setting is enabled, the documents are NOT moved to the eTMF when the site is activated or closed
    - Required Documents:
        1. Publish to eTMF Workflow: When this checkbox is enabled, required documents for Site Activation undergo an additional QC step as they are published to the eTMF Workflow. This step is common for users that only have a 1-step review process in SSU.
        2. Publish to Index without the eTMF Workflow: Essential Documents will be published to the eTMF Index based on the document type auto-routing. When this checkbox is enabled, the documents are published into the eTMF index as Final. This option is common for users who have a 2-step review process in SSU.
    - Non-Required Documents: Non-required documents do not need to go through the SSU workflow. If the user wants to send them to the eTMF workflow, they can choose one of the options below based on their requirements.
        1. Publish to eTMF Workflow
        2. Publish to the Workflow in Study Start-up
- Do not allow the addition of new documents to a Site after activation: Select the checkbox to enable this setting. If enabled, no new documents can be added or imported for the activated Site, IRB/EC, or Countries in SSU.
- Allow paper documents: If enabled, SSU documents without attachments may be QC Reviewed.

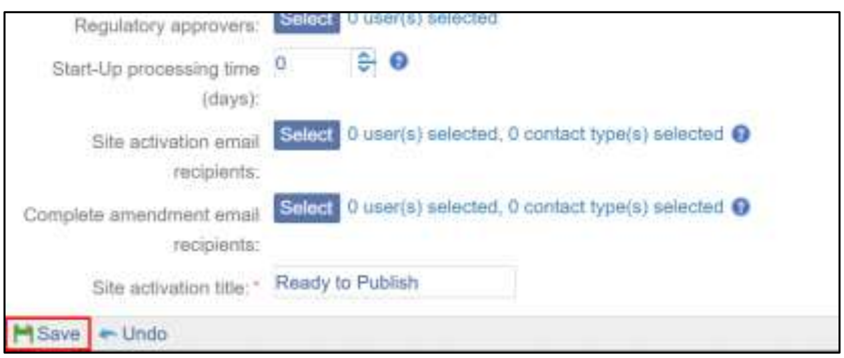


6. Configure the following additional settings.
    - Regulatory Approvers: To add regulatory approvers, follow the steps below
        - Click on the Select button.
        - On the Regulatory Approvers window, drag & drop users to the selected members' section and click on the OK button.

- Start-Up processing time: Adding the processing time enables having a buffer time required to activate a site after the IRB/EC Approval.
- Site activation email recipients: When the site is activated, recipients will get an email notification. Recipients could be a CRA, Central Lab, etc.
- Complete amendment email recipients: When the amendment is completed, recipients will get a notification email. Recipients could be a CRA, Central Lab, etc.
- Site Activation title: This is the subject line of the Site Activation email sent when a site is activated.

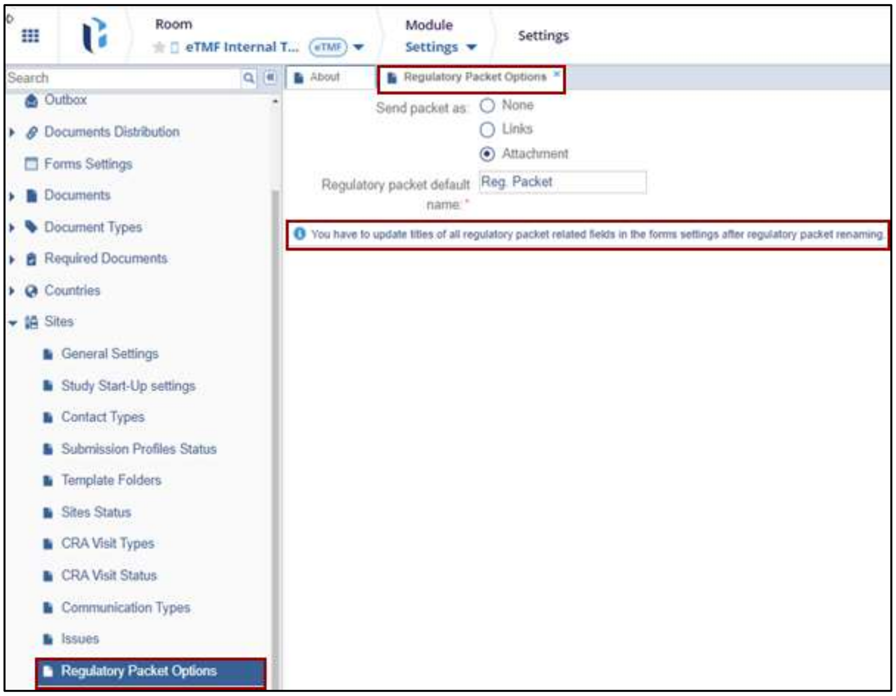


7. Once the required settings are configured, click on the Save button.



Regulatory Packet Options

Located within the Sites folder, Administrators configure how Regulatory Packets are sent to Investigative Sites. Typically, template documents are sent as links to documents stored in the TI room or as email attachments. In certain cases, documents may be sent separately, not as links or attachments, in which case the Administrator selects the ‘None’ option. Generally, Administrators choose either the 'Links' or 'Attachment' option.



CONFIGURING COUNTRIES

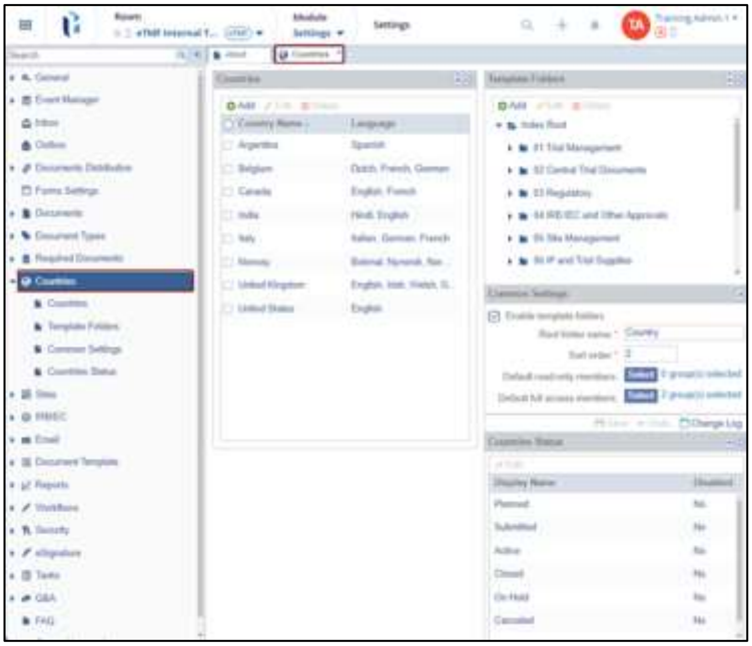
When a study includes investigative sites located in different countries, those countries need to be added to the room. As a result of this, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents and users will be able to choose the appropriate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

Countries Settings

Trial Interactive allows administrators to make changes to Countries Settings.

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.



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

Add Countries

Follow the steps below to add countries:

1. Click Add from the ribbon above the country listing.
    - The Create Country window will open.
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.

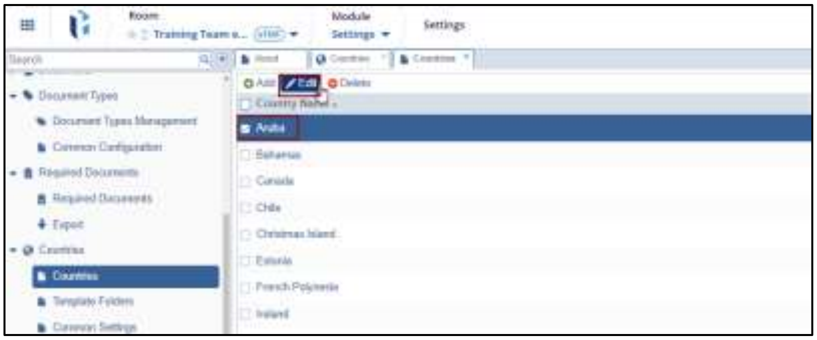
Additions and changes made here are saved automatically.

Edit Countries

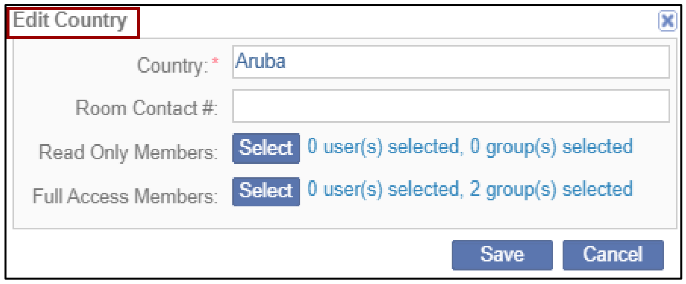
Once a country has been added to the list, you can add or change the study contact #, and adjust access to groups or users.

Follow the steps below to edit countries:

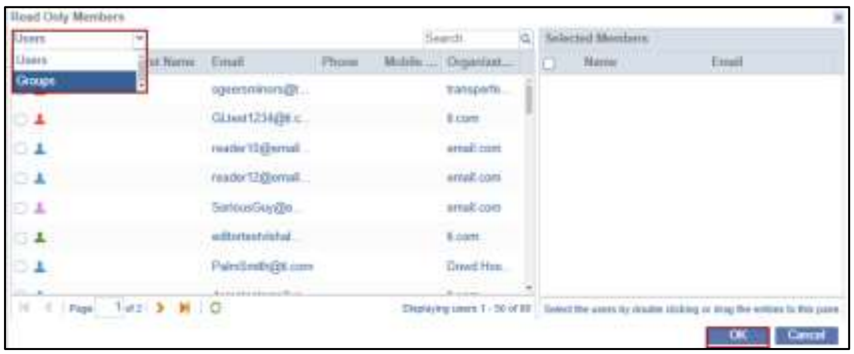
1. Select the required country from the grid to be edited. Click '**Edit'** at the top of the Countries window.



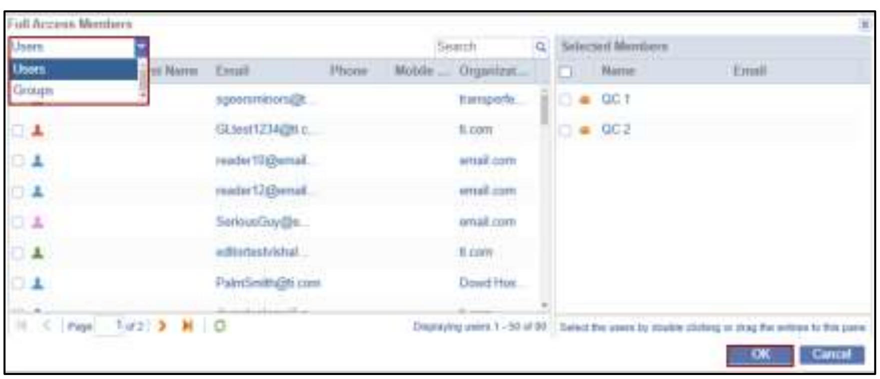
2. The Edit Country window will open.



3. Click the Room Contact# field to add the room ID.
4. Click Select next to the 'Read Only Members' option.
5. The Read Only Members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
6. Click OK.



7. Click Select next to the 'Full Access Members' option.
8. The Full Access Members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
9. Click OK.



10. Click Save on the 'Edit Countries' window.

Additions and changes made here are saved automatically.

Delete Countries

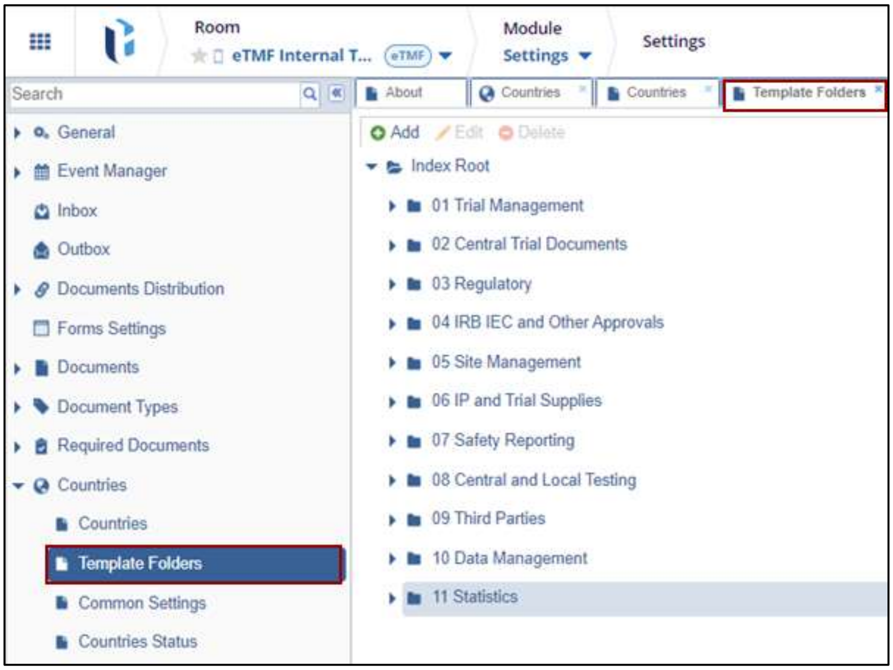
Follow the steps below to delete the countries:

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 be deleted automatically, without giving you a warning.

Note: Once documents are stored in the room's index folders, countries with associated documents cannot be deleted. However, the user can continue adding and editing entries in the Countries list as the study progresses.

Template Folders

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

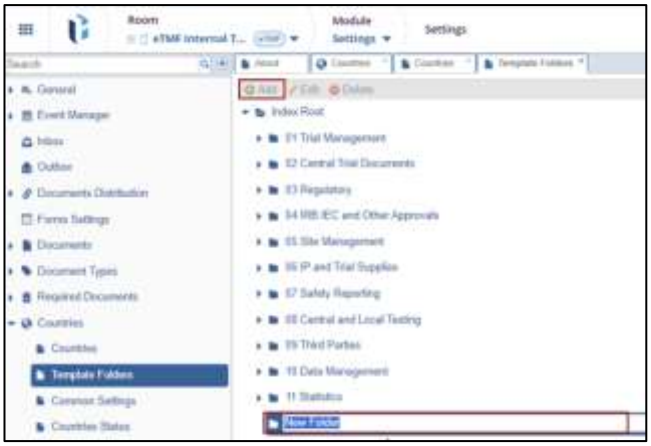


Note: The details required to complete this stage of room configuration are provided in the Configuration Manual. The folder structure is often consistent, but it is always study-specific.

Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

1. Click Add to create the folder to the 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'.



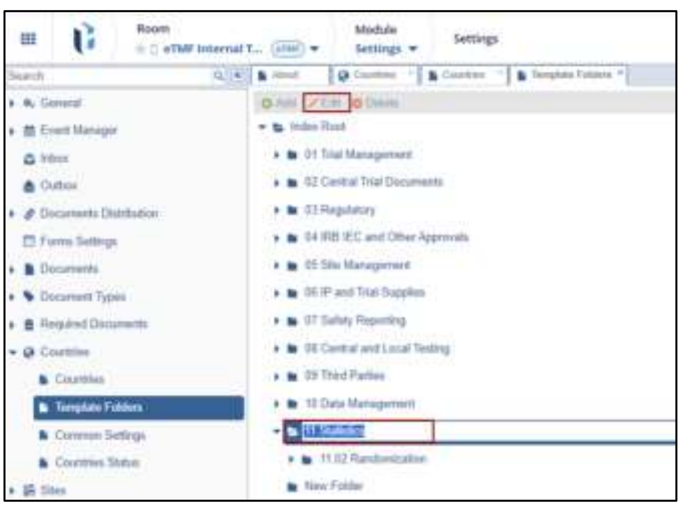
3. Type the name of the new folder name in the highlighted field.
4. Press Enter.
5. Repeat this process until you have entered all of the new folder names.

Additions and changes made here are saved automatically.

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.

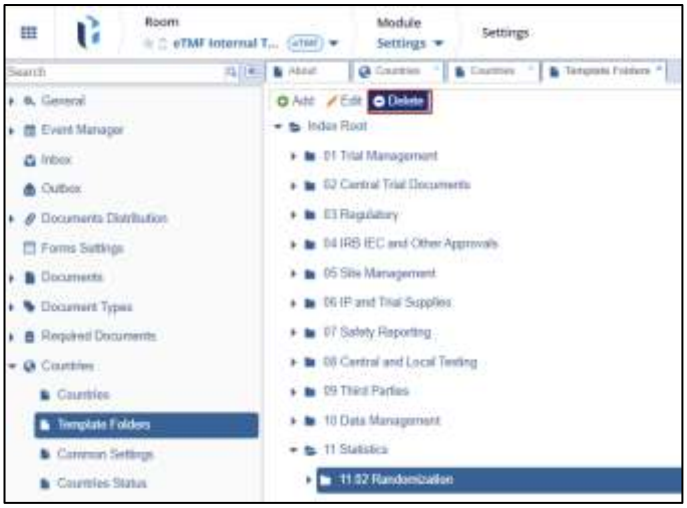


Additions and changes made here are saved automatically.

Deleting Folders

Follow the steps below to delete folders and subfolders:

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

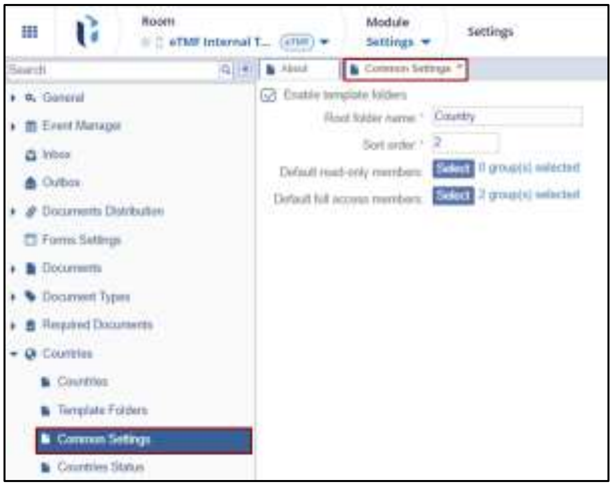


Note: Folders that contain subfolders or documents cannot be deleted.

Common Settings

In the Common Settings window, the user 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. The user can adjust the Read-Only and Full Access security settings.
5. Select the users or groups to set access. If the user can make any changes in this window, click Save.

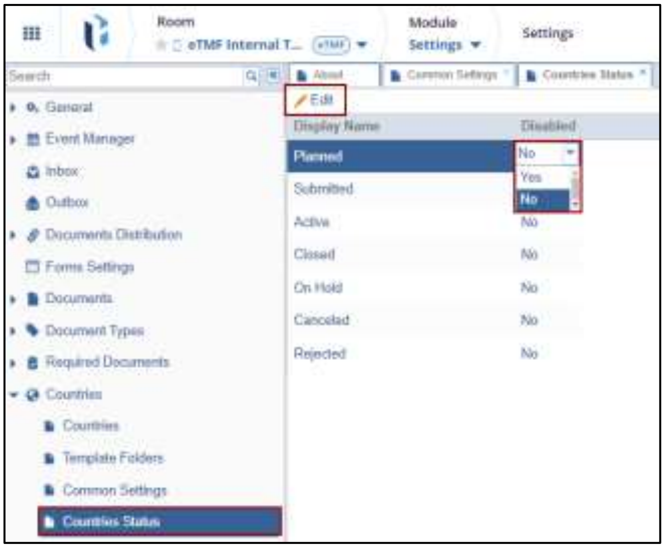


6. Click Select next to the ‘Default read-only members’ option.
7. The Default read-only members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
8. Click OK.
9. Click Select next to the ‘Default full access members’ option.
10. The Default full access members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
11. Click OK.

Countries Status

In this panel, Administrator users can edit the Display Name of the Country Status.

- Locate the status and click the Edit button on the top or double-click on the specific display name to edit.
- Country statuses can be enabled or disabled as well.
- Click on the drop-down menu from the top-right corner and select Yes or No entry to change the value.



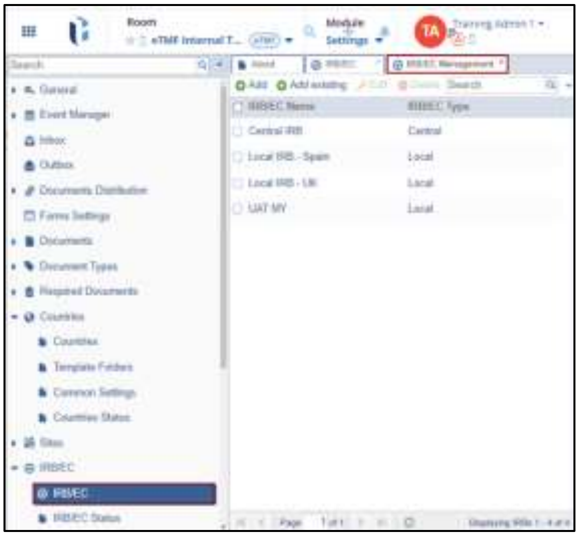
CONFIGURING IRB/EC

The IRB/EC organizations associated with the study will normally be identified and configured upon room creation.

The IRB/EC displays 2 categories IRB/EC Status and IRB/EC.

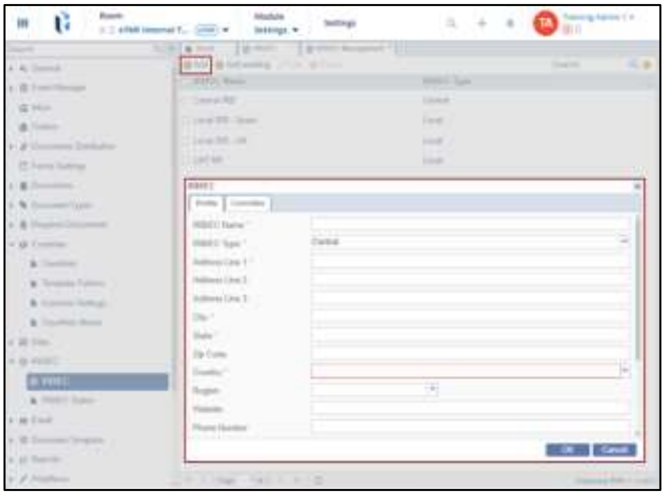
IRB/EC

The additional IRB/EC organizations can be added, edited, or deleted as needed from this menu.



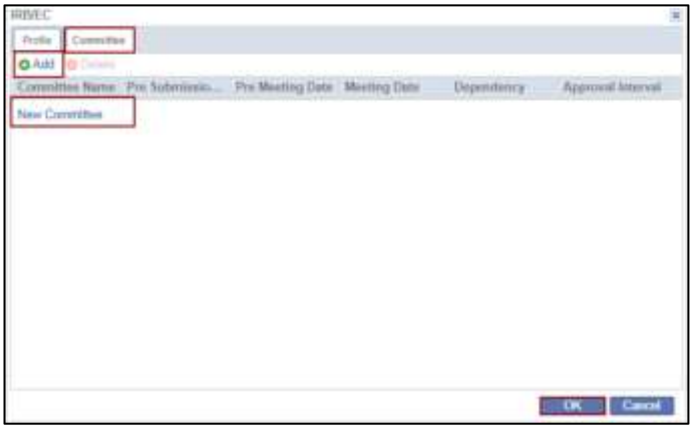
To add a new entry, follow the steps below:

1. Click the Add button. The IRB/EC window is displayed with the Profile tab by default.

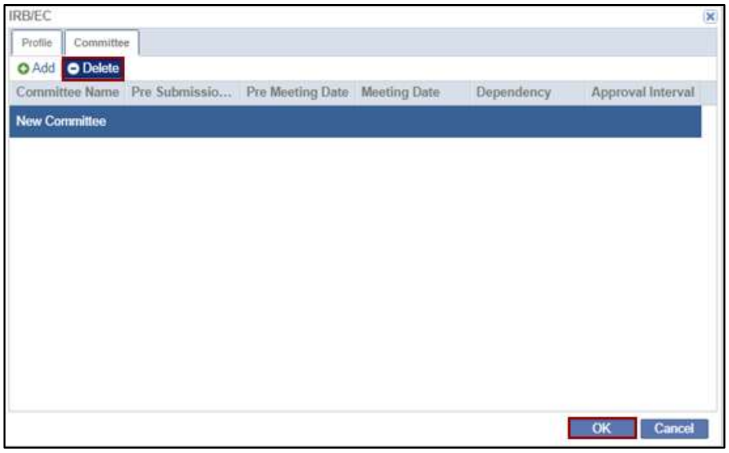


2. Fill in all the required fields and click OK within the Profile tab.
3. Click the Committee tab within the IRB/EC window.
4. Click Add. The New Committee field gets added below. Double-click to rename the Committee.

5. Click OK.

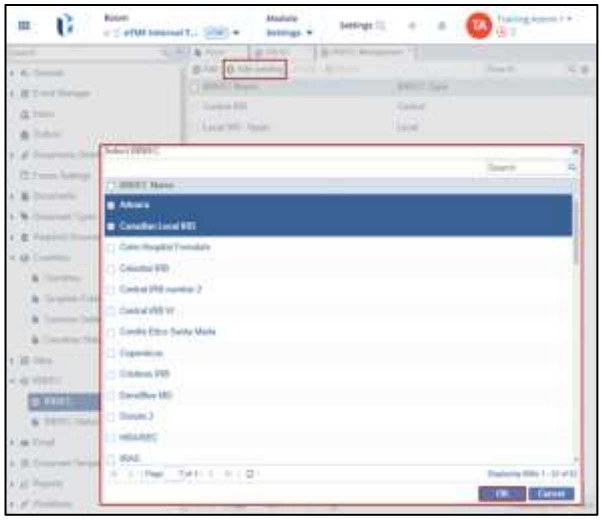


6. Select the Committee and click Delete. The created committee is removed.



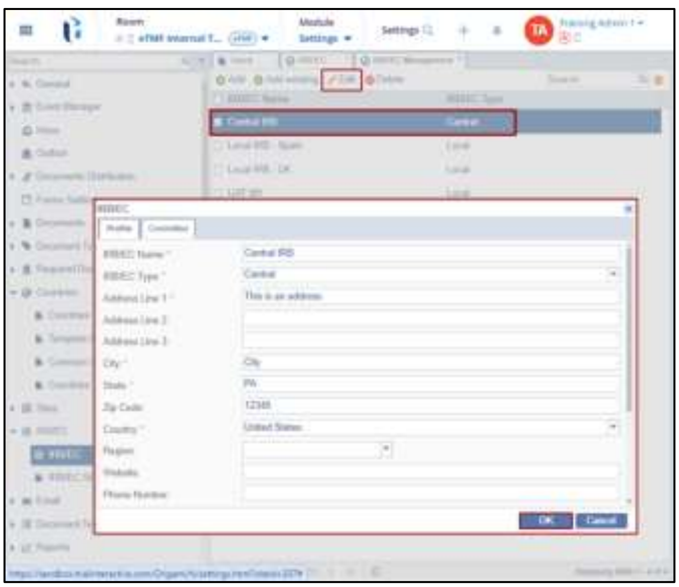
Adding Existing IRB/EC

1. Click the Add Existing button. The list of organizations stored at a domain level is displayed.
2. Locate the appropriate organization and press the OK button to add them to the room list.

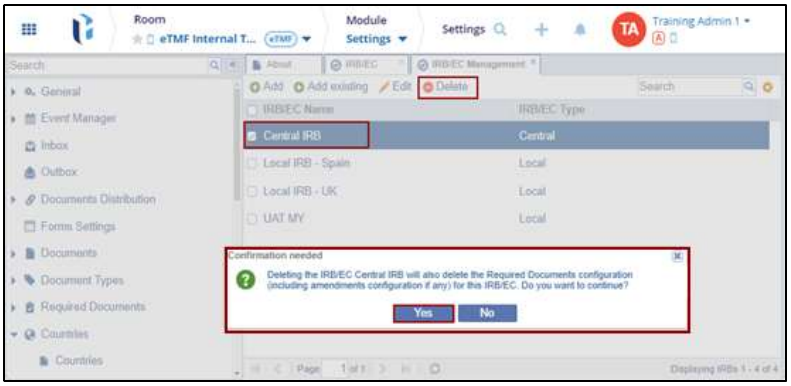


Editing Existing IRB/EC

1. Locate the IRB/EC Name and click the Edit button.
2. The IRB/EC window opens with the existing information with the editable fields.
3. Make the changes and click OK.

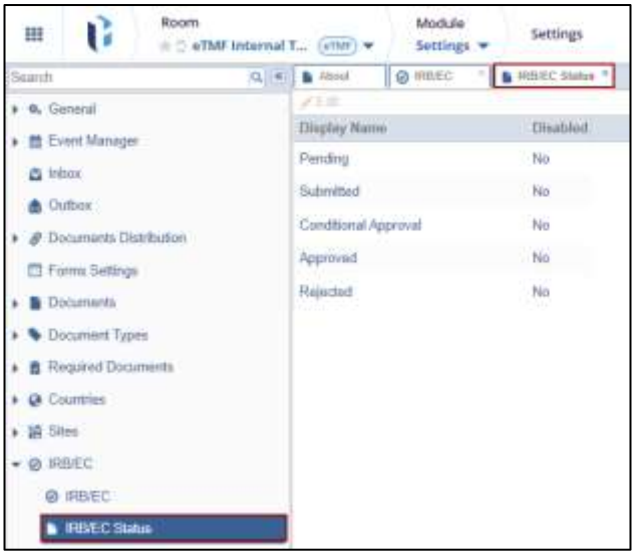


4. Locate the IRB/EC Name and click the Delete button, the selected IRB/EC gets deleted.



IRB/EC Status

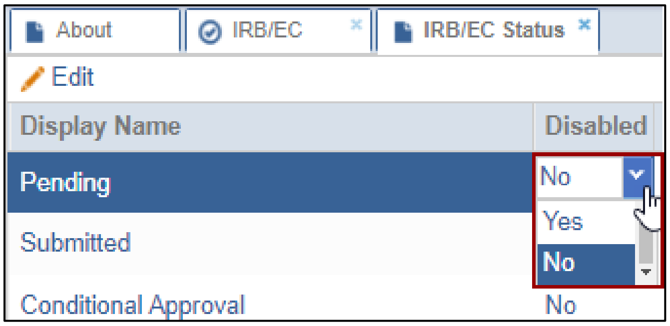
The IRB/EC Status, the users can see the statuses of the IRB/EC documents. Refer to the screenshot below:



Follow the steps below:

1. Select the Display Name in the IRB/EC Status and click the Edit button.

2. The user can see that the Disabled column gets editable and the user can see the drop-down options from where the user can assign the ‘Yes’ and ‘No’

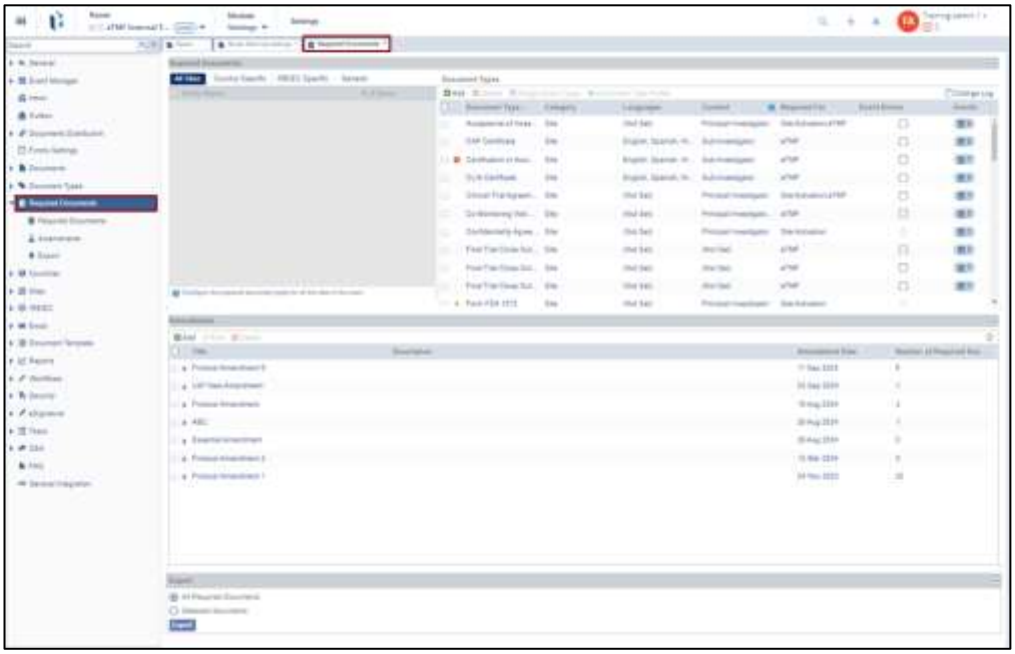


Email

Email notifications play a crucial role in keeping stakeholders informed about key activities throughout the study preparation process. These emails are automatically sent to contacts (e.g., investigators, site staff, regulatory bodies, and sponsors) to alert them about important updates, actions required, and the progress of the study.

REQUIRED DOCUMENTS

The Required Documents Settings allow Administrators to define and manage the required documents for a study. Some document types may be mandatory for all investigative sites, while others may be required only for sites in specific countries. These settings are typically configured at the start of a study but can be adjusted if needed during the study.



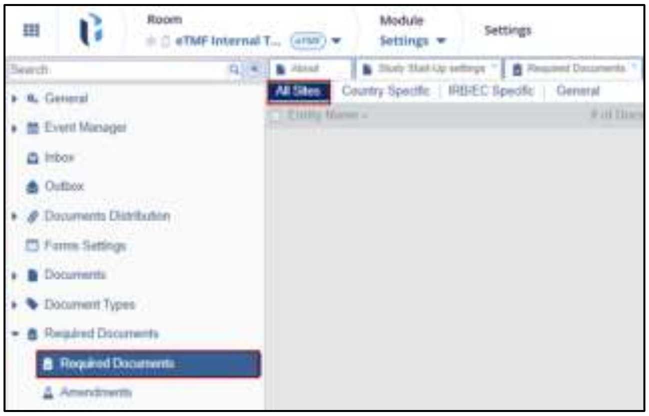
Note: It is recommended that administrators contact the Trial Interactive Project Management Team if any changes or additions are needed.

Setting Up Required Documents for All Sites

To allow users to add essential documents for sites, the document types must be configured by the administrator. Additionally, the required documents for sites can be set up through the Settings module.

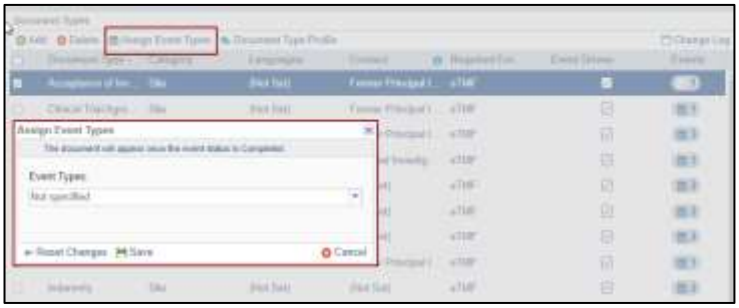
To add the required documents for All Sites, follow the steps below.

1. From the left section of the panel, the user can select the category (Sites, Country, IRB/EC, and General) of the Required Documents. By default, the All-Sites category is selected.
2. Click on the All-Sites tab.

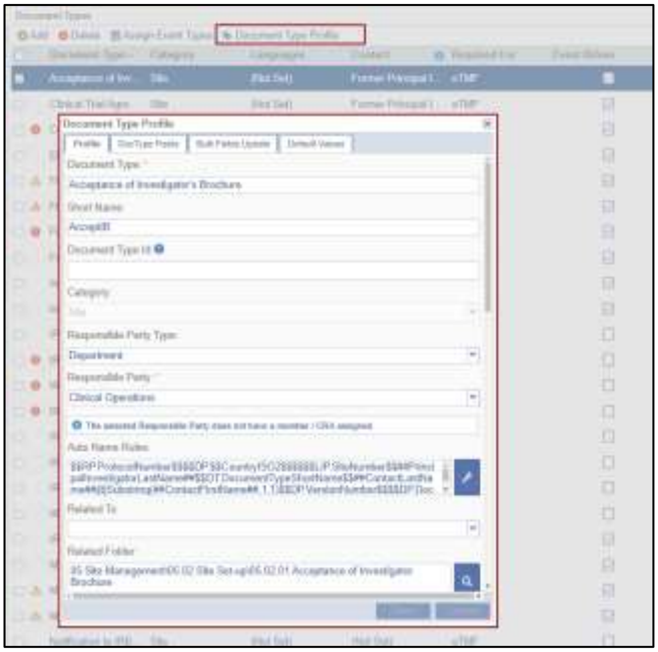


3. From the right section of the panel, named as Document Types, the user can:

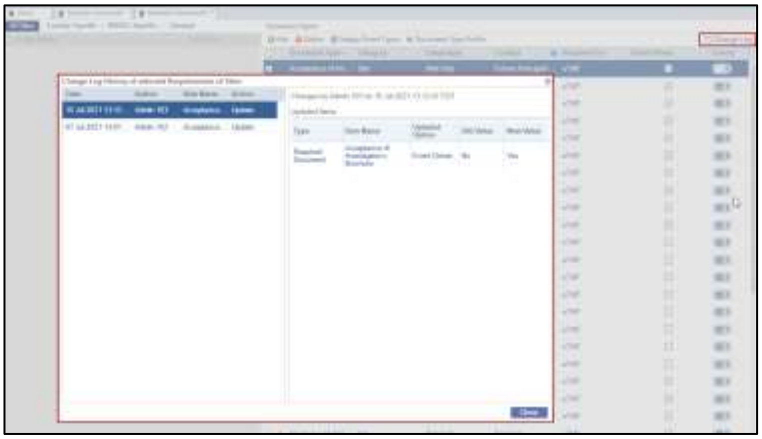
- Add or Delete a Required Document to the category selected from the left pane.
- Locate the document type and click Assign Event types which will help the users to enable Event Types.



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



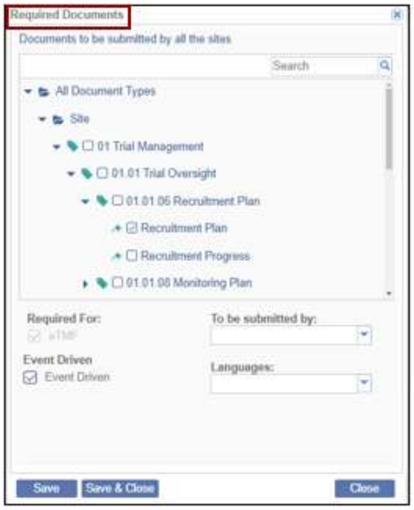
- View the activity log of the selected category from the Change Log.



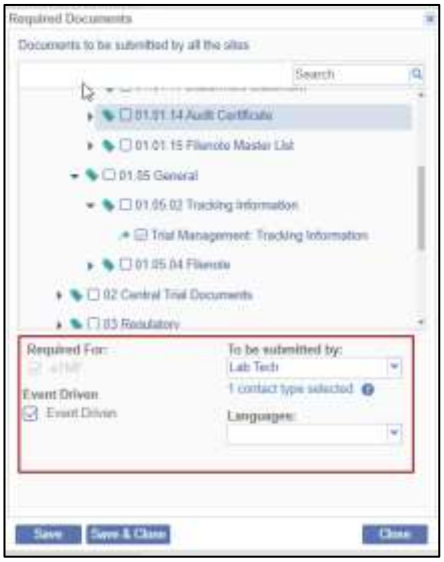
Adding Documents to the List of Documents

1. Click the relevant tab from the left panel of the Required Documents menu.
    - 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.

3. The Required Documents window is displayed to add Required Documents for All Sites under specific categories.
4. Click the folder from which you need to select the Required Documents and click the checkbox next to one or all of the documents to be required.



5. Select whether the document(s) will be required for Site Activation or eTMF by clicking the checkbox.
6. From the dropdown menus to the right, if necessary, select:
   - Required For: This is the Study Contact who is responsible for providing the selected required documents
   - 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.

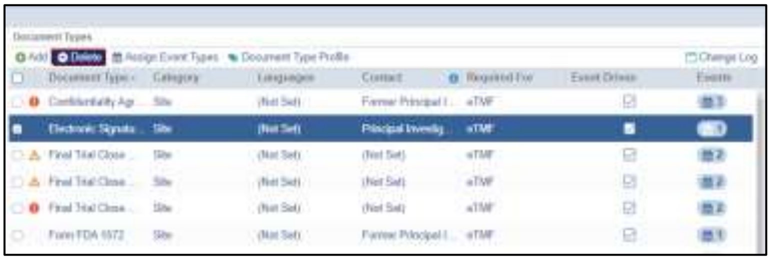
7. Click Save & Close if you have documents from only one category folder to add or click Save if you need to add more required documents.

Note: If documents are to be provided by different study contacts, click Save, then return to the documents list. Select the next set of documents, specify whether they are required for Site Activation or eTMF, choose the contact type from the dropdown, and click Save. Repeat this process until all required document types for all contacts have been added, then click Save & Close.

Deleting Documents from the List of Required Documents

To delete a Required Document:

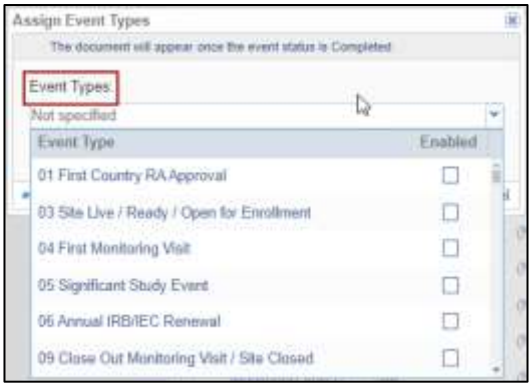
1. Click the All Sites tab from the left panel of the Required Documents Panel.
2. From the list of Required Document Types in the grid, tick the checkboxes to select the Required Document Types to be deleted.
3. Click Delete from the top ribbon bar of the Document Types window on the right.



4. The Required Document Types are removed from the list.

Assign Event types

1. The Assign Event Types will help to enable Event Types.
2. Click Assign Event Types the Assign Event Types window is displayed.
3. The user needs to select the Event Types as per the requirement.
4. Either the user can Reset Changes or Save the changes.



Document Type Profile

1. The Document Type Profile displays All fields available in the Required Documents.

2. Click Document Type Profile the Document Type Profile window is displayed.

3. The Document Type Profile displays the following sections:

- Profile
- Doc Type Fields
- Bulk Fields Update
- Default Values

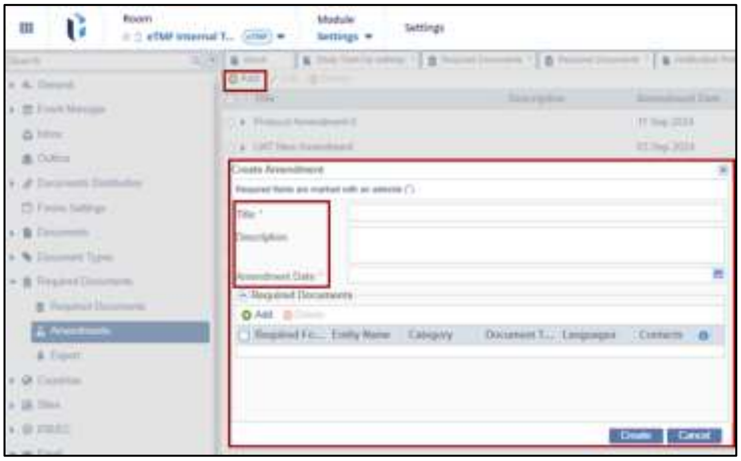
Note: To configure the Country Specific and IRB/EC Specific settings, refer to the standard steps of All Site settings detailed in the Required Documents.

Amendments

The Amendments refer to modifications or updates made to study documents, protocols, contracts, or regulatory submissions after the initial setup but before the study begins or progresses to the next phase. These amendments typically arise due to regulatory requirements, sponsor requests, site-specific needs, or protocol changes.

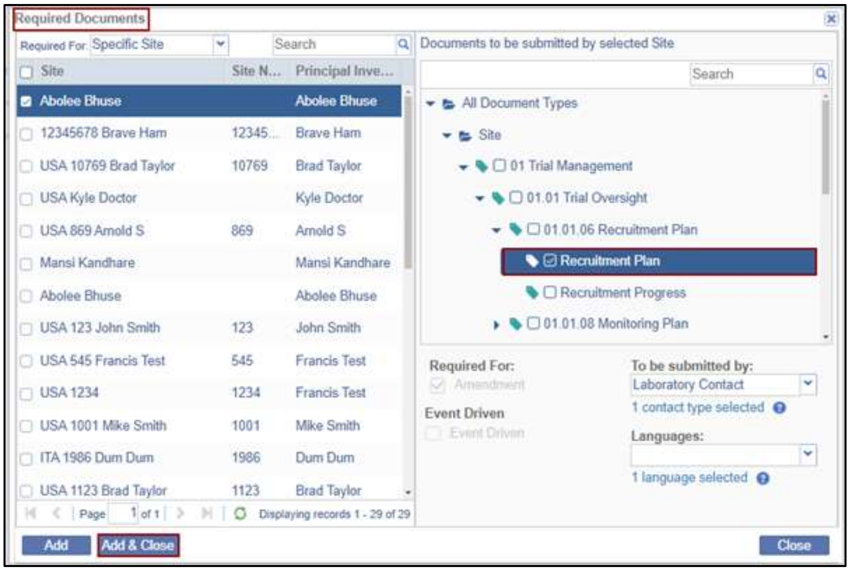
To Create an Amendment, follow the steps below.

1. Click Add, the Create Amendment window is displayed.
2. Fill in all the required fields.

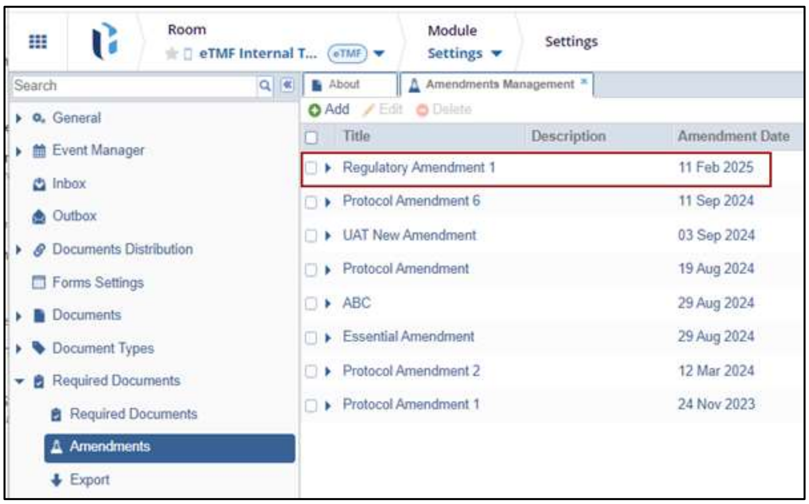


3. Click Add, within the Create Amendment window to add the Required Documents.
4. The Required Documents screen is displayed.
5. Expand the Required For field to view the options. Select the required option from the list.

6. The list of the Sites is displayed on the left pane.
7. On the right pane select the documents to be submitted by the selected Site and fill in the required fields.
8. Click Add & Close.
9. The added Required Documents are displayed within the Required Documents section on the Create Amendment window.

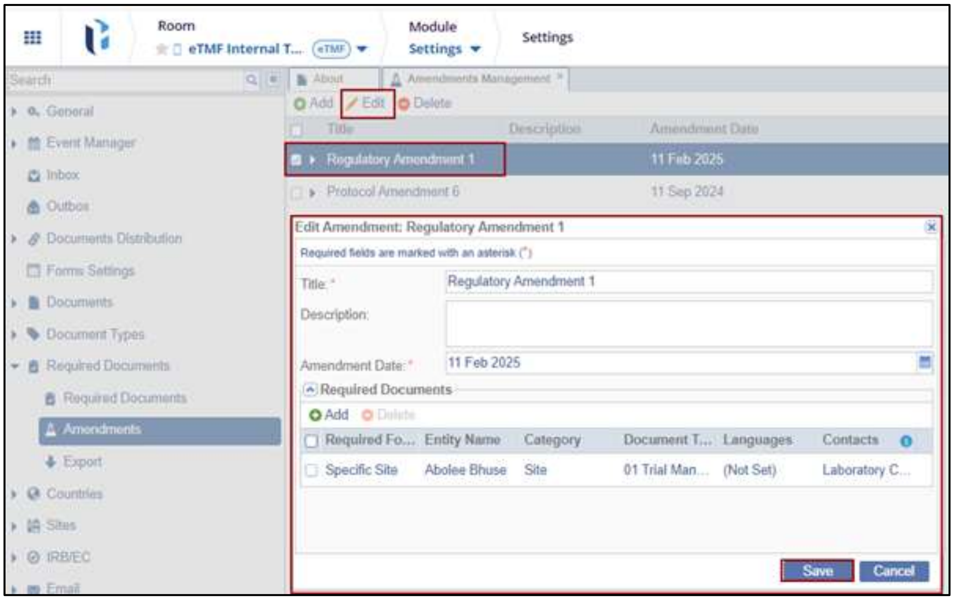


10. Click Create. The create Amendment is displayed in the grid.



To Edit and Delete the created amendment, follow the below steps:

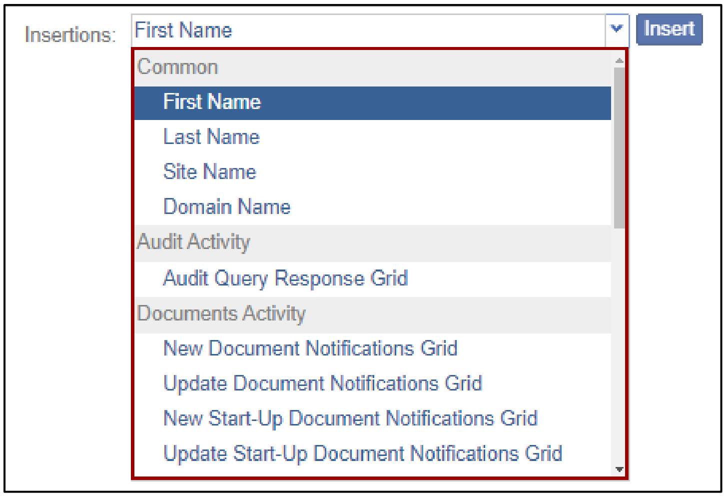
1. Locate the amendment and click the Edit button.
2. The Edit Amendment window is displayed. Make the required changes and click Save.



3. Locate the amendment and click the Delete button.
4. The Delete this Amendment dialog box is displayed. Click Yes if the user wants to delete the amendment.

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.

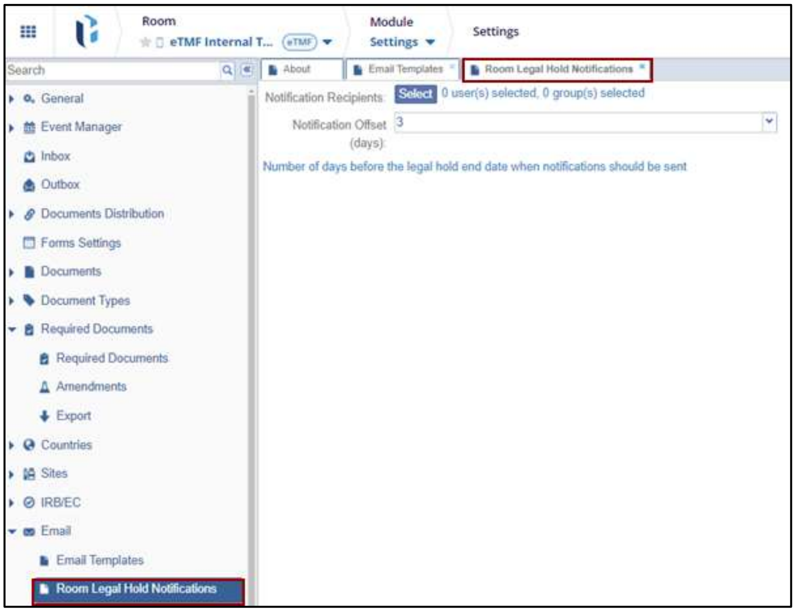


The Change Log option, located at the bottom right of the screen, displays a record of the Email Templates. It includes columns for Item Name, Setting, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

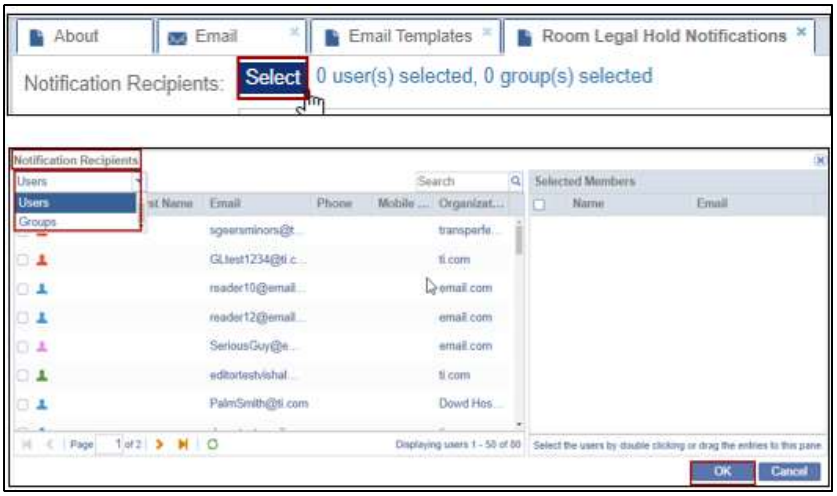
Room Legal Hold Notification

The Room Legal Hold Notification needs to be sent only when the number of days before the legal hold end date arrives.

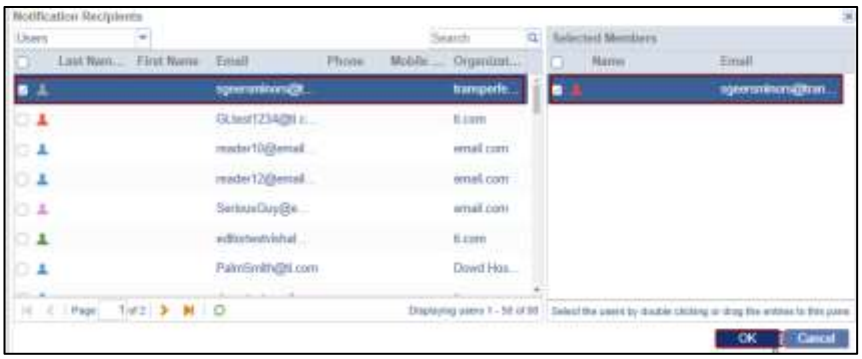


Follow the steps below:

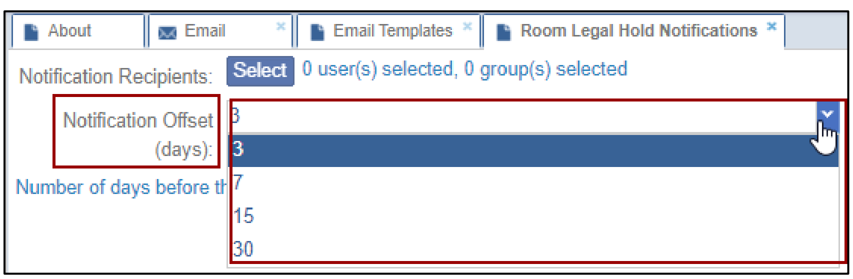
1. Click Select to set up the users who will be notified when a room is put on legal hold.
2. The Notification Recipients window opens with the list of Users/Groups.



3. Select the users by double-clicking or dragging the entries to the right pane.
4. Click OK. The selected user gets added to the right pane.



5. 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.



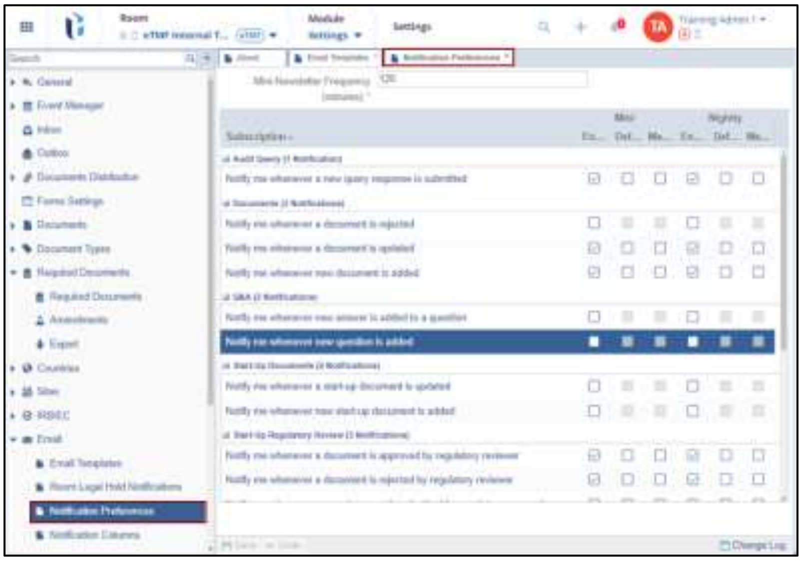
Note: Super Administrator users from the TI Service Desk can put a Legal Hold on Rooms when required.

The Change Log option, located at the bottom right of the screen, displays a record of the Room Legal Hold Notification. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

Notifications Preferences

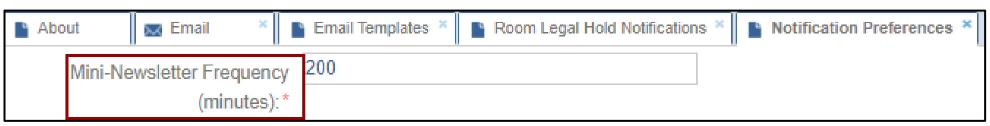
The Notifications Preferences section allows users to specify the email notifications they would like to enable for the study room.



Follow the steps below:

1. Enter the Mini newsletter Frequency (minutes) with which the Mini newsletters will be sent to the users.

   Refer to the screenshot below:

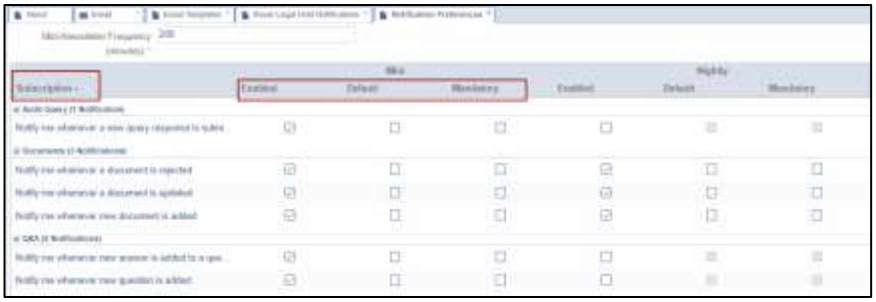


2. In the Subscription panel, enable the appropriate notifications that will be available to the room's users.

   - Using the options grid on the right of the Subscriptions window, you can select which notifications the user would receive.

     Below are the definitions of each notification type and their use:

   - Enabled: This enables users to subscribe to related notifications.
   - 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.

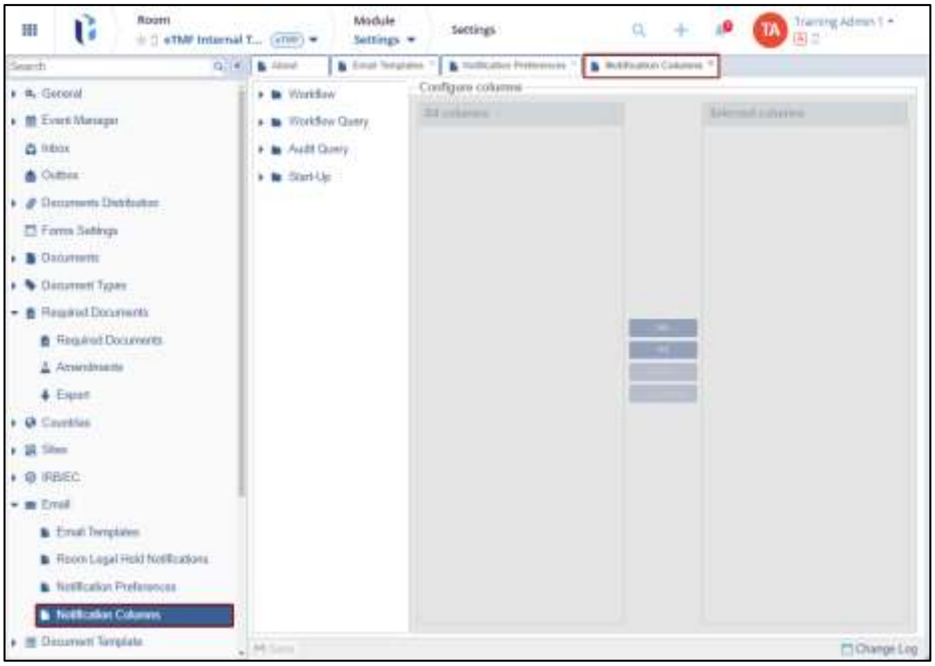


The Change Log option, located at the bottom right of the screen, displays a record of the Notifications Preferences. It includes columns for Scope, Item Name, New Value, Old Value, Updated By, Updated On (with the timestamp), and Close button.

Ensure to click Save to apply and retain any changes.

Notification Columns

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



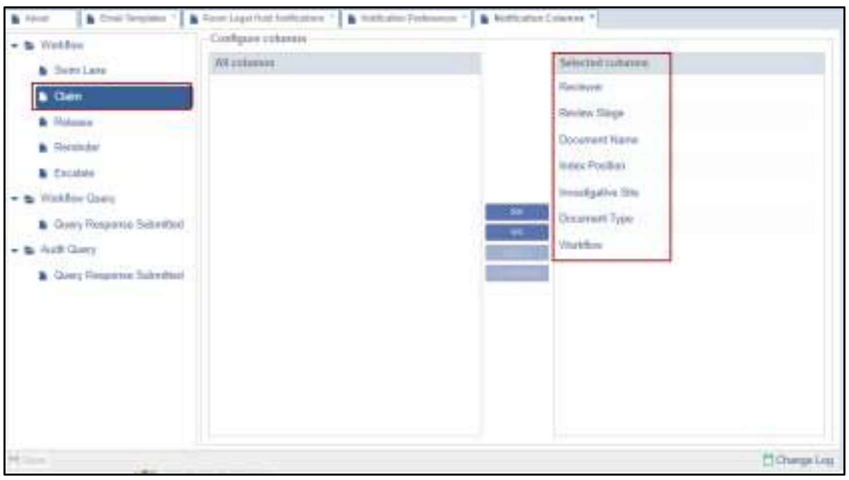
The Notification Columns are available for the following categories with sub-sections:

- Workflow
- Workflow Query
- Audit Query

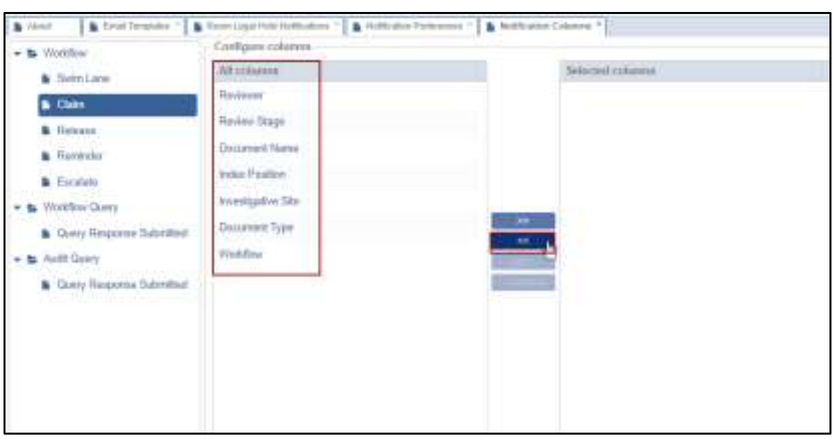
Refer to the screenshot below:

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

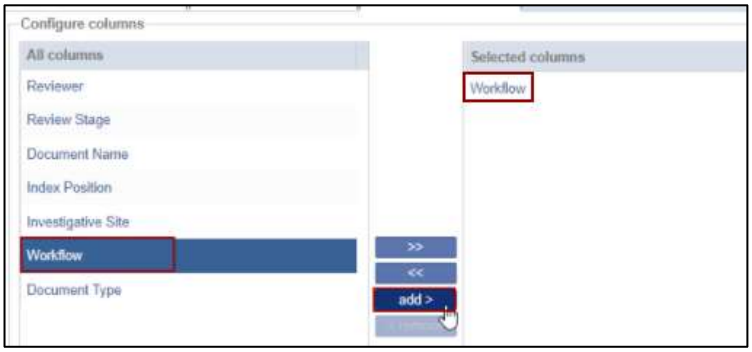
1. Expand the arrow available beside the Workflow and double-click to add the columns under the Selected Columns list.



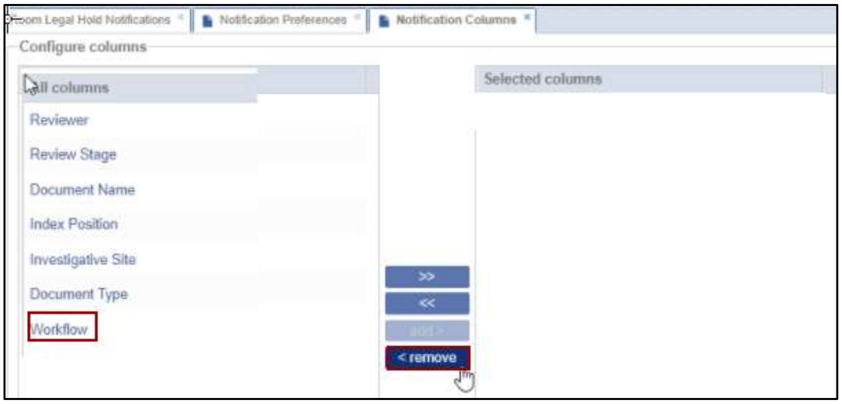
2. Click the Arrow so that the items available in the 'Selected columns' will be swapped in the 'All Columns' section.



3. Select the option from the ‘All Columns’ section and click add>. The selected option gets added to the ‘Selected Columns’ section.



4. Select the option from ‘Selected Columns’ and click <remove. The option will be removed.



The Change Log option, located at the bottom right of the screen, displays a record of the Notifications Columns. It includes columns for Setting, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

Start-Up Contacts

Once site information is entered into the TI system, the regulatory packet is automatically sent to the site members for review and action. If users are added to the Site Activation Member group, they gain the ability to submit Essential/Required Documents to the SSU module for review by the Start-Up Specialist and Regulatory Reviewer.

As a Site Activation Member, the user can:

- Monitor Document Collection: Track the progress of the Essential/Required Documents collection process to ensure all necessary documents are submitted, reviewed, and approved.
- Activate the Site: Once the required documents are collected and reviewed, the Site Activation Member can proceed with site activation, allowing the site to begin participant enrollment or other study activities.

The following are the various roles available in the SSU Module.

Role	Description
Clinical Research Associate (CRA	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.
Start-Up Specialist	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.
Regulatory Approver	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 it as necessary.
Other Site Contacts	Besides the ones mentioned above, various other site contacts can be added to a sit. Some of them are mentioned below: 1. Principal Investigator 2. Sub-Investigator 3. Pharmacy Contact 4. Laboratory Contact 5. Contracts Contact 6. Finance/Budget Contacts 7. Co-Investigator 8. Research Specialist Note: • A Principal Investigator is the most important contact for a site, as sites cannot be created without a Principal Investigator.

Role	Description
	• An SSU specialist cannot be a site contact and an SSU Specialist at the same time. Except for the CRA, all the contacts discussed in this section can be viewed from the Contacts module. You can view sites in the BY CRA view from the Sites module.

Inviting Contacts and Managing Security

In the world of clinical trials, there are diverse users, each with specific roles and responsibilities—some handle complex procedures, while others may only be responsible for reviewing and signing documents for a site. To ensure that each user can perform their duties efficiently and securely, it's essential to assign the appropriate access levels and privileges to a site.

Trial Interactive (TI) implements a streamlined process that aligns seamlessly with real-world clinical trial scenarios. It addresses key questions to define a user's role, such as:

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?

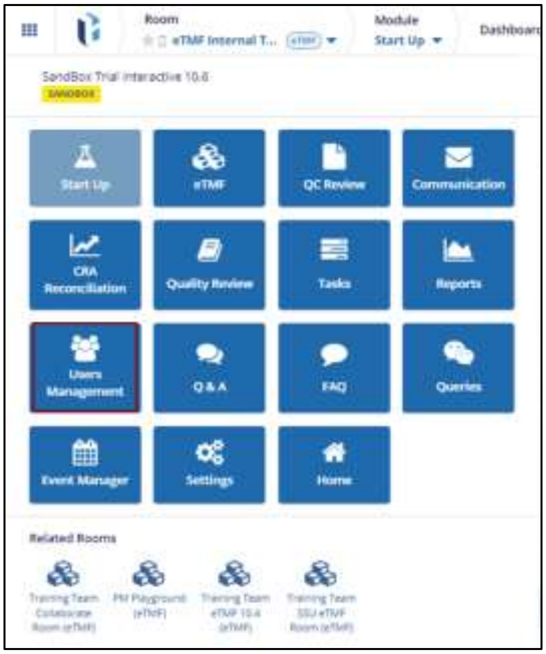
By addressing these questions, TI ensures that the user roles are well-defined and tailored to the organization's specific needs, promoting efficient site management and enhancing overall trial execution.

Trial Interactive (TI) implements the following process to assign a combination of rights and privileges to site members to enable them to carry out their responsibilities:

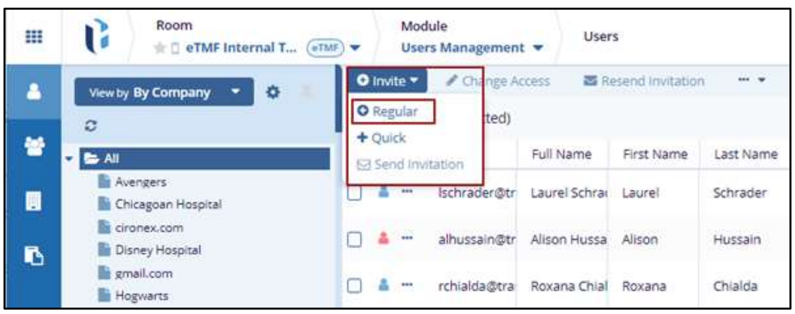
1. It allows two security privileges to be assigned to users – Editor and Reader.
2. A reader is allowed read-only access, whereas an editor can perform various other advanced functionalities like adding documents and sending documents for review to activating sites.
3. An Admin is a privileged role and is assigned to users only in specific cases discussed later in this guide.

To add users at the room level as an admin, follow the steps below.

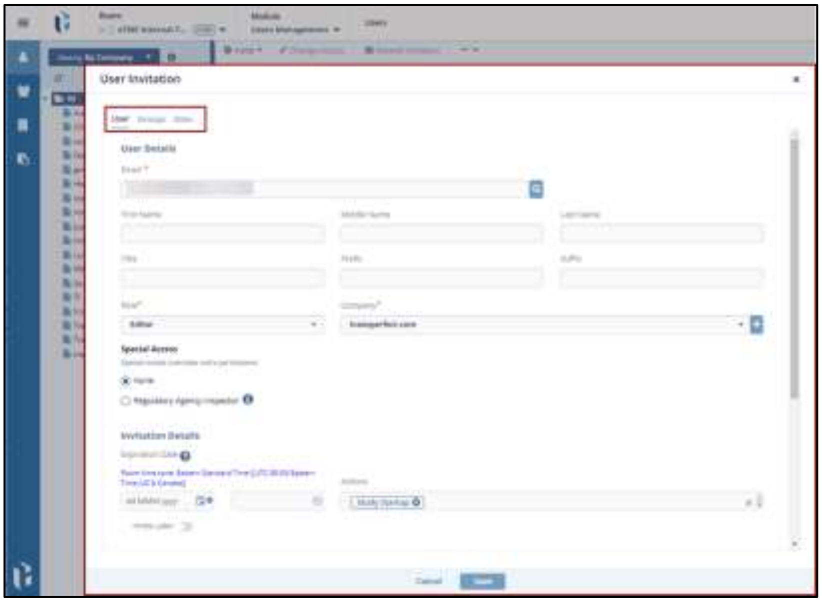
1. Login to Trial Interactive and enter the room.
2. Click on the waffle menu and select the Users Management module.



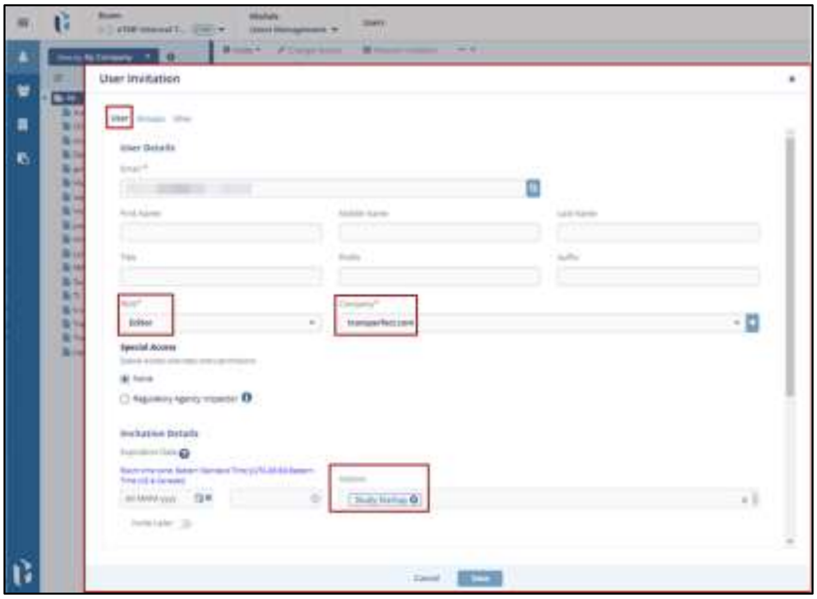
3. Click on the +Invite button and select the +Regular option.



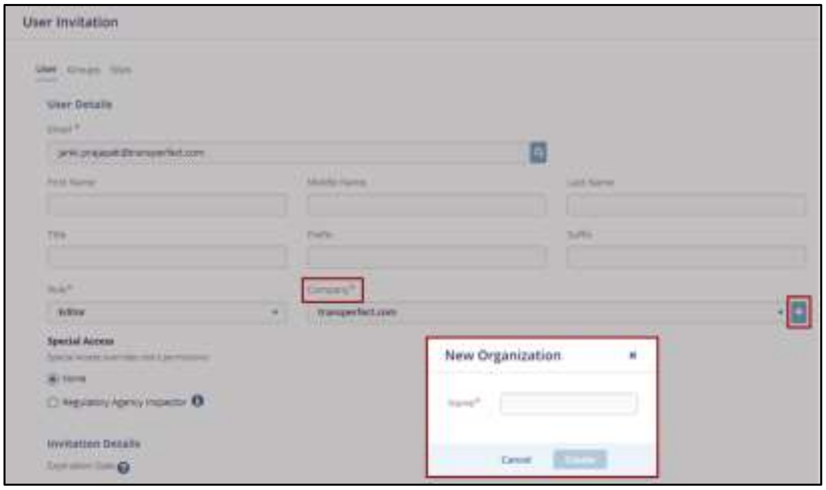
4. In the User Invitation form, the user can see three tabs:
   - User tab: Displays the user details information page
   - Groups tab: There is a list of groups a user belongs to. You can add a User to the Existing Group.
   - Sites tab: Sites where the user included as a Site Contact



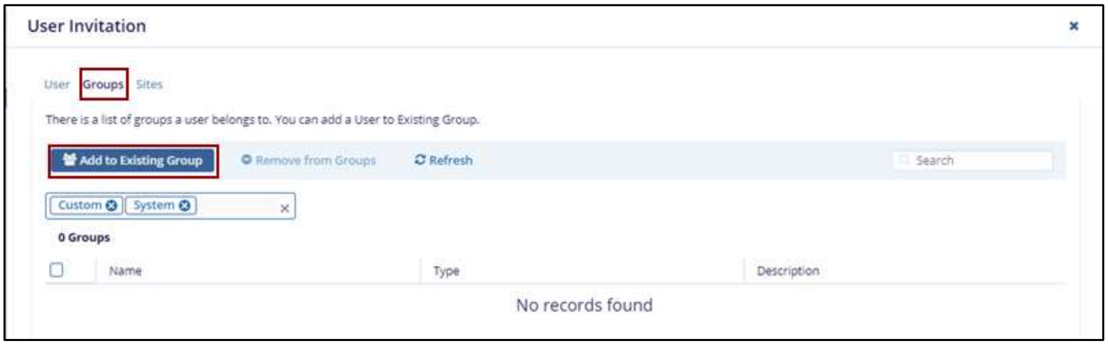
5. Fill in the required fields under the User Details section:
    a. Email
    b. Role
    c. Company
6. After entering the details, select Study Start-Up in the Actions field under the Invitation Details section.

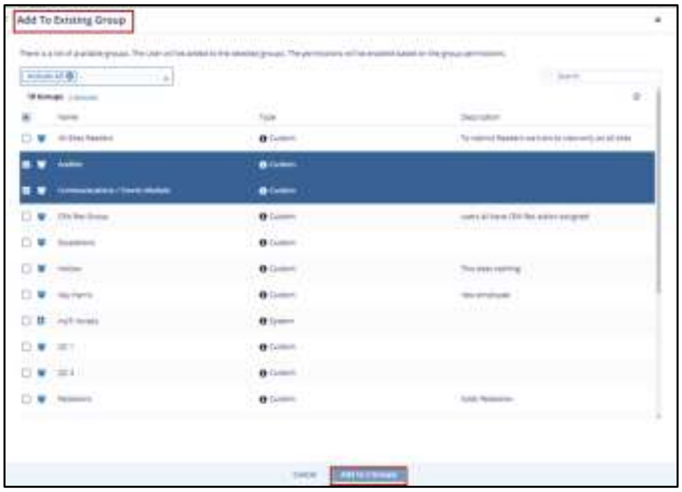


7. Clicking on the + icon available in the Company field allows the user to create a New Organization.

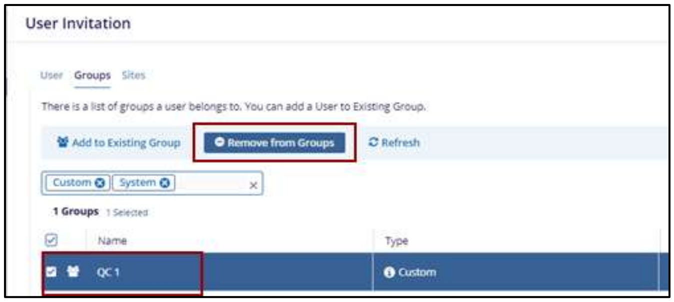


8. Click the Groups tab on the User Invitation form.
9. Click the Add to Existing Group option in the menu bar, this page is directed to the list of groups.

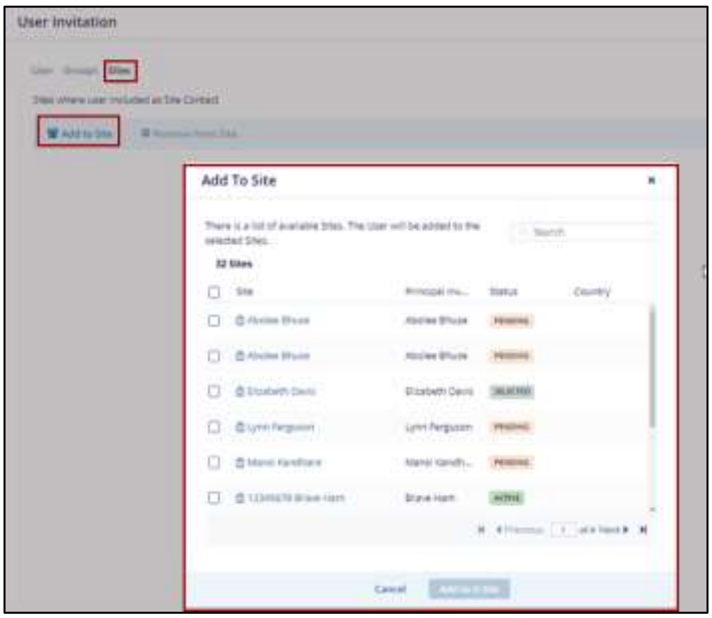




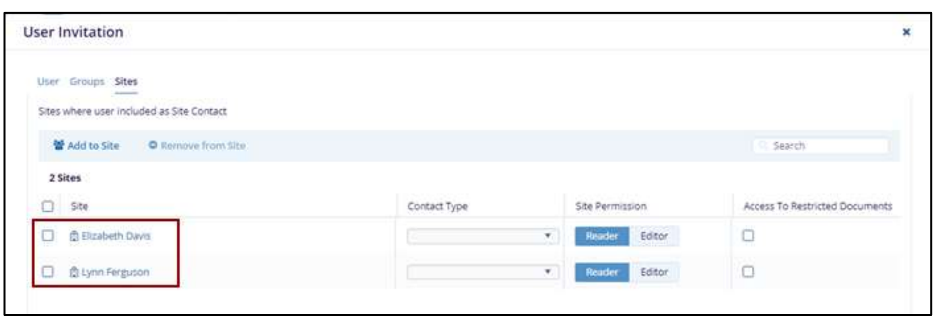
10. Select the required groups, click Add to Groups, and view the selected groups on the Groups tab.
11. Locate the groups that need to be removed and click the Remove from Groups option in the menu bar. The selected group disappears.



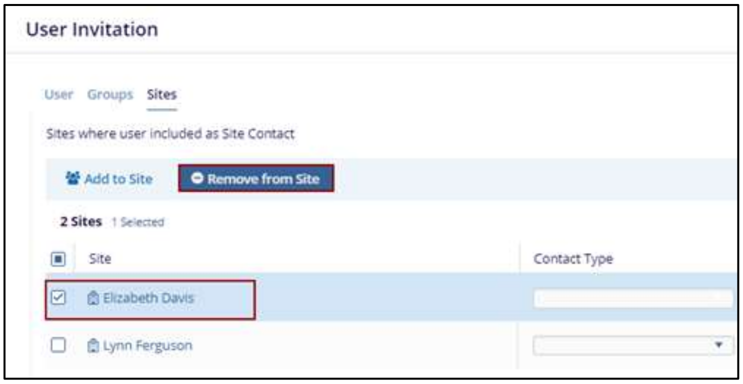
12. Click the Sites tab on the User Invitation form.
13. Click the Add to Site option the list of users is displayed on the Add To Site pop-up window.



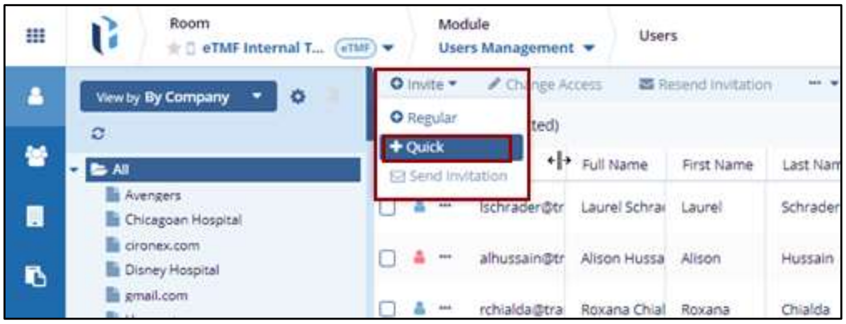
14. Select the users and click the Add to Site option at the bottom of the Add to Site pop-up window.
15. The selected users were added to the sites.



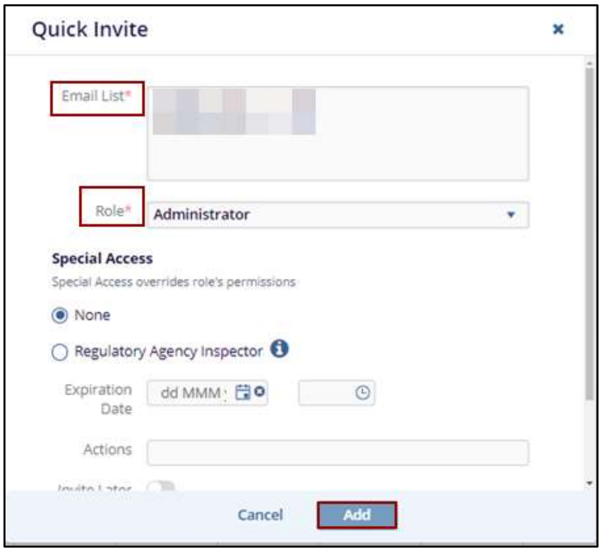
16. Locate the user that needs to be removed and click the Remove from Site option in the menu bar. The selected user disappears.



17. Click Save to save changes or Cancel to discard them.
18. Click on the +Invite button and select the +Quick option.



19. Fill in the required fields such as:
    - Email List –the list of users can be added at a time
    - Role
20. Click the Add button, the added users will be displayed in the grid.



ACCESSING STUDY START-UP MODULE

Once the basic settings and contacts are configured for Study Start-Up, users can now move forward to operate the module.

To access the Study Start-Up module, follow the steps below.

1. Navigate back to the waffle menu, and select the Start-Up module.

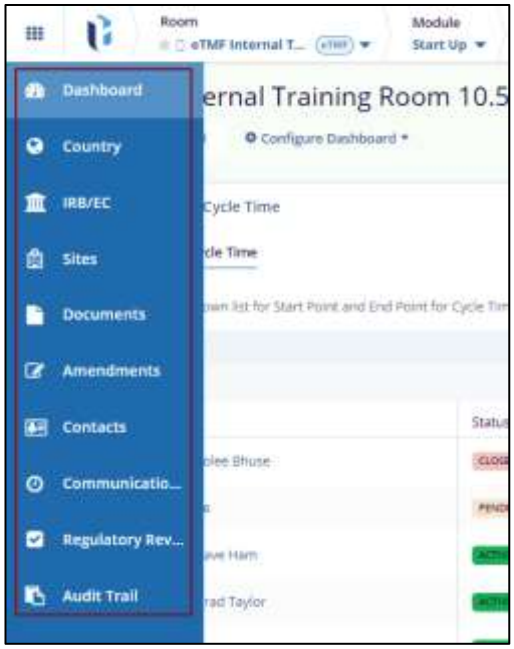
2. The Start-Up module displays the relevant dashlets.

SSU User Interface

The SSU Module in Trial Interactive (TI) provides a streamlined platform for creating, monitoring, and activating clinical trial sites. Users can add, upload, track, and review the necessary documents for site activation through this interface.

The Start-Up module includes the following sections:

- Dashboard
- Country
- IRB/EC
- Sites
- Documents
- Amendments
- Contacts
- Communication Log
- Regulatory Review
- Audit Trail



Note: The Toolbar options are available per the room settings and user access.

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.

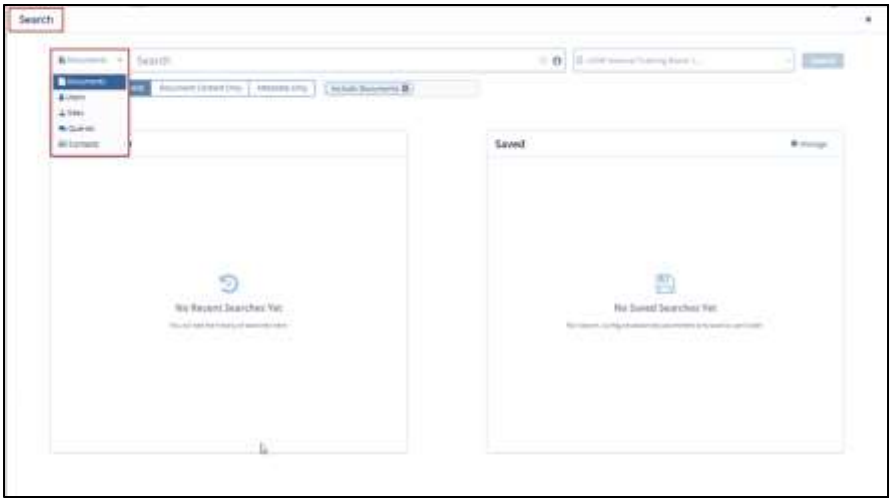
The dashlets are described here in the subsequent topics. The users can view and access the following options from the top menu bar.

The left side of the top menu bar displays the below options:

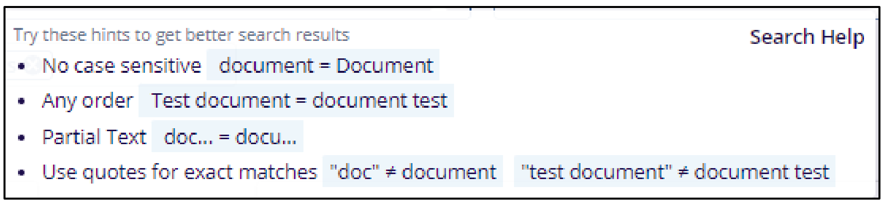
- Waffle icon: displays the modules available in the selected room
- Trial Interactive logo
- Room Name: displays the selected room name
- Module name: Selected module name in the room
- Path name: Selected path name in the room

The right side of the top menu bar displays the below options:

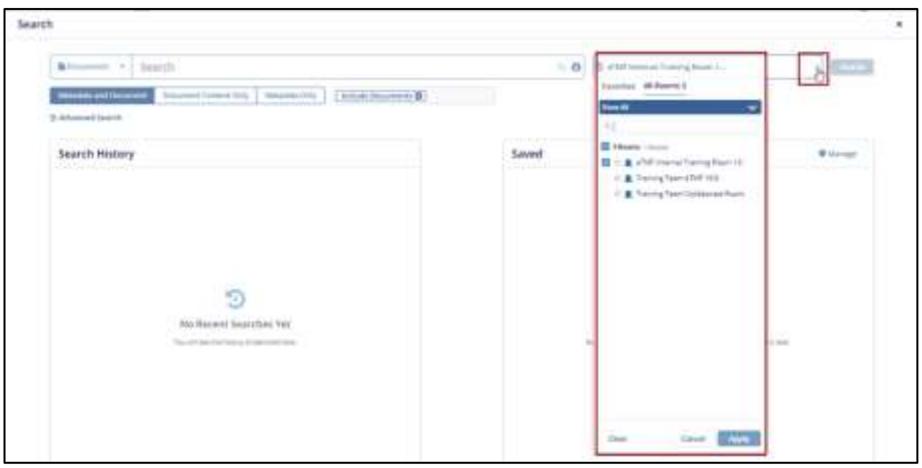
- Search icon:
    i. Click the search icon the Search pop-up window is displayed.
    ii. Expand the Documents arrow to search by Documents, Users, Sites, Queries, and Contacts.



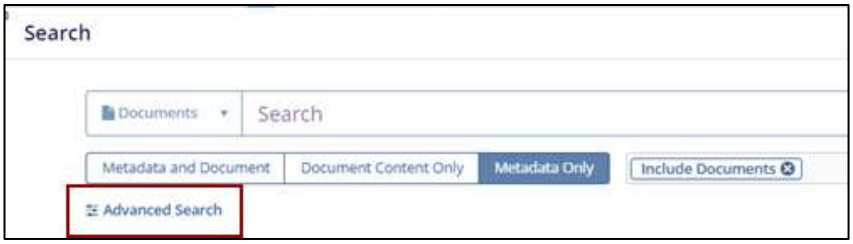
Note: Some hints to get better search results:



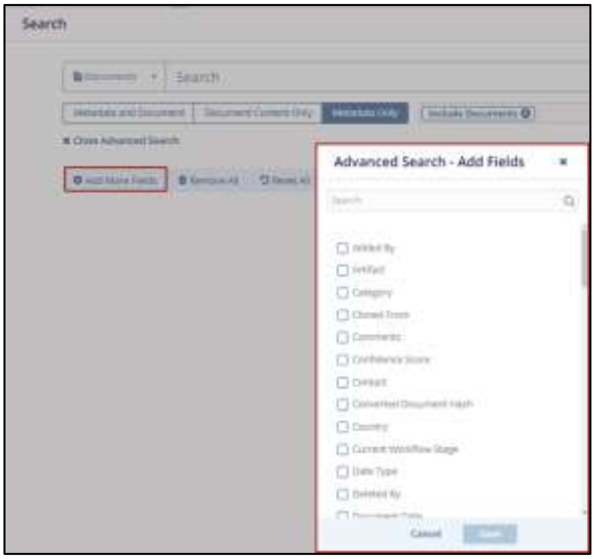
iii. The user can also search the Room by expanding the drop-down arrow shown in the screenshot below:



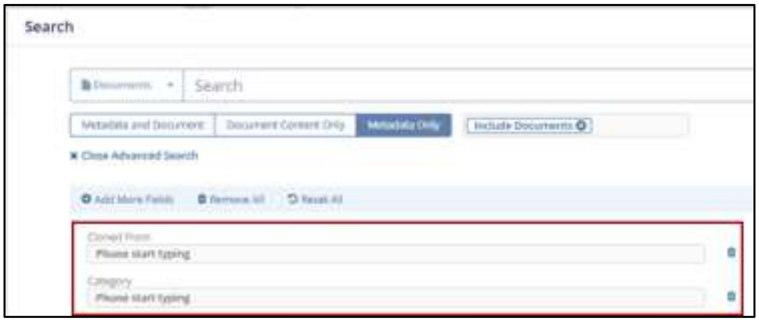
iv. Clicking the Advanced Search button in the Search pop-up redirects the user to the Advanced Search page.



v. Users can add unlimited fields as needed with the + Add More Fields button. The Advanced Search – Add Fields pop-up window is displayed.



vi. Select the fields and click the Save button.



vii. Click the Remove All option to remove the added fields.
viii. Click Reset All resets the page with the existing information.

- Add icon: Users can add the following by accessing this option:
    - Documents:
        i. Click the Documents option, the Import Documents screen is displayed.

ii. Click Browse File or Browse Folders to import documents, or simply drag and drop the required file.

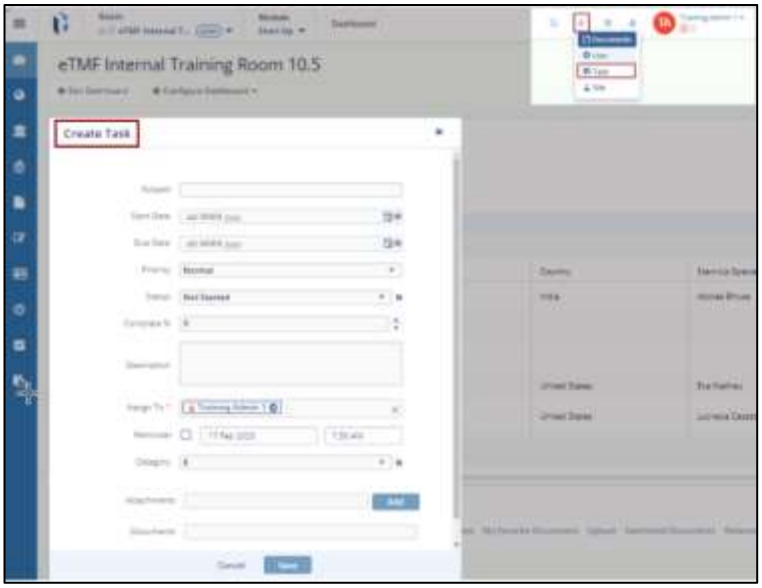
iii. Fill in the Metadata and click Import All & Apply Metadata.

iv. The user can also assign the placeholders by clicking on the Assign Placeholders option.

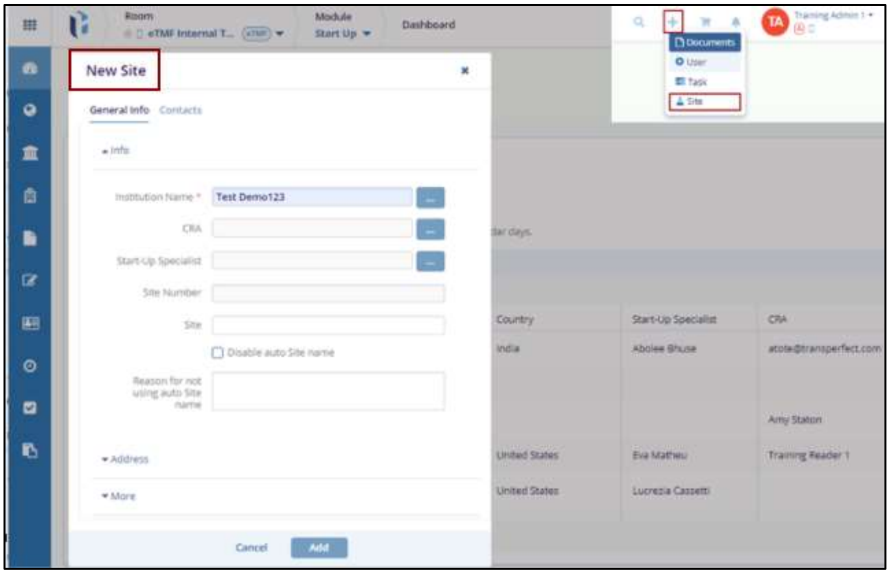
v. Apply the filters and click Import All & Apply Metadata.

- User: To learn more about User Invitation, follow the steps in Inviting Contacts and Managing Security.

- Task:
  - i. Click the Task option, the Create Task screen is displayed.
  - ii. Fill in all the required fields and click the Save button.



- Site:
    i. Click the Site option, the New Site screen is displayed.
    ii. Fill in all the required fields and click the Add button.



3. Documents Cart icon: All documents added to the cart can be viewed here.

4. Bell icon and Username: Displays the notifications and users can access the following:
    - Language Settings
    - My Profile
    - Contact Help
    - User Guide
    - Sign Out

The Dashboard allows users to customize their workspace by adding, removing, or rearranging tabs based on user preferences. Administrator-level users can configure default dashboards for users according to the user access levels. Unless restricted, users can modify their dashboards to suit the user's needs.

The dashboard includes the following edit options:

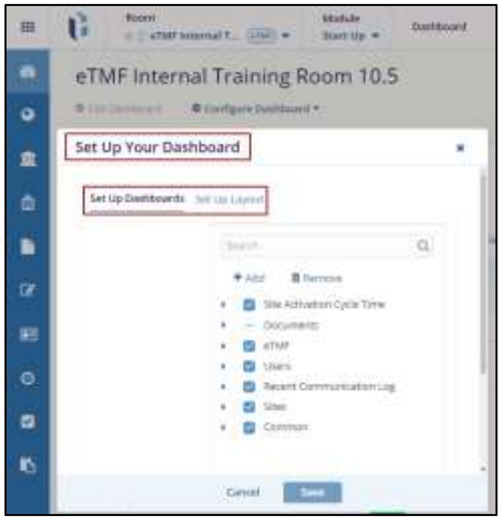
- Edit Dashboard
- Configure Dashboard

Edit Dashboard

The Edit Dashboard allows users to customize the dashboard by adding or removing tabs, reorganizing layout options, and customizing the dashboard to show the information that is most important to the user. It ensures a personalized view for better accessibility of required data.

Steps to Edit the Dashboard:

1. Navigate to the Dashboard section in the SSU module.
2. Click on the Edit Dashboard button located at the top left of the toolbar.
3. The Set Up Your Dashboard window will appear.
4. It includes the relevant options, such as:
    - Set Up Dashboards: For selecting or adding widgets.
    - Set Up Layout: For customizing the layout.

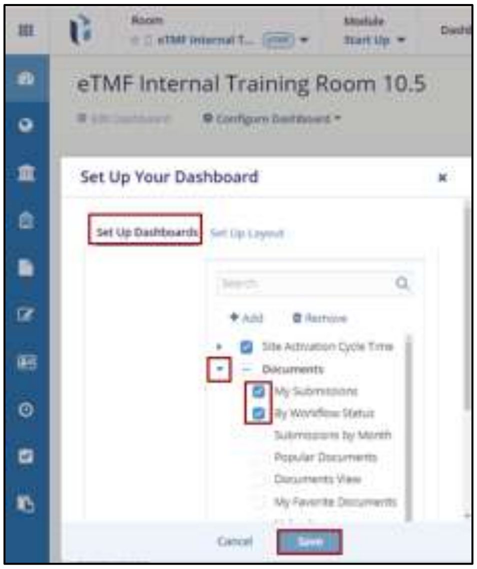


Set Up Dashboards

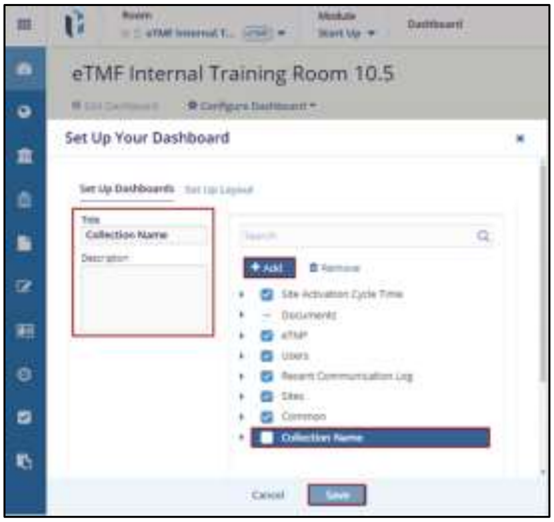
The Set-Up Dashboards allow users to customize their dashboards by adding, removing, or managing dashlets. Dashlets are individual components that display specific types of data or functionality on the dashboard, helping users personalize their view to highlight the most relevant information.

Steps to set up the dashboard.

1. On the Set Up Your Dashboard window, the Set-Up Dashboard option is displayed by default. Expand the fields using the arrow and select the required checkbox.
2. Click the Save button. The selected widgets are displayed on the dashboard.



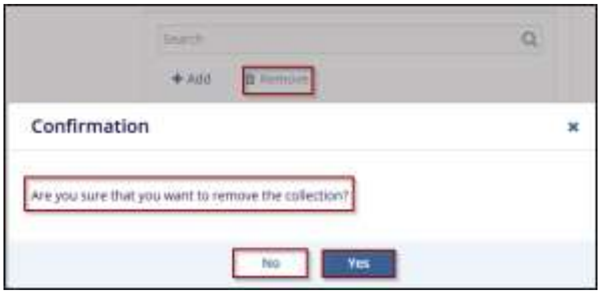
3. Click Add, and a new entry appears in the dashlet list as Collection Name. Enter the Title and Description in the left-side fields before adding the dashlet.
4. Click the Save button to add the dashlet.



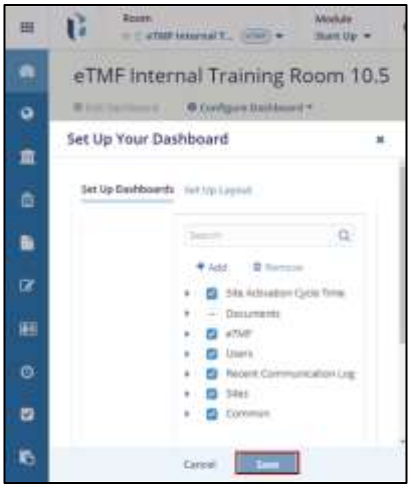
5. Click the Remove button to initiate the removal process. A confirmation window will appear with the message: 'Are you sure that you want to remove the collection?'.

   Note: The user can only remove the newly added fields and not the pre-defined fields.

6. Click Yes to confirm and remove the collection or click No to cancel the action and keep the collection.



7. Once all necessary changes are completed. Click the Save button at the bottom of the popup window to apply the changes.

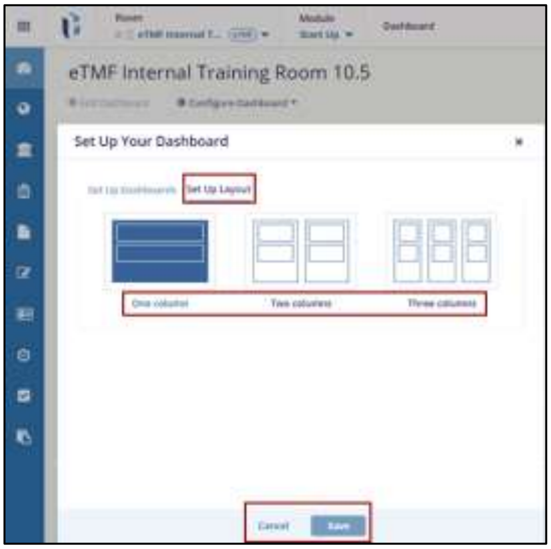


Set Up Layout

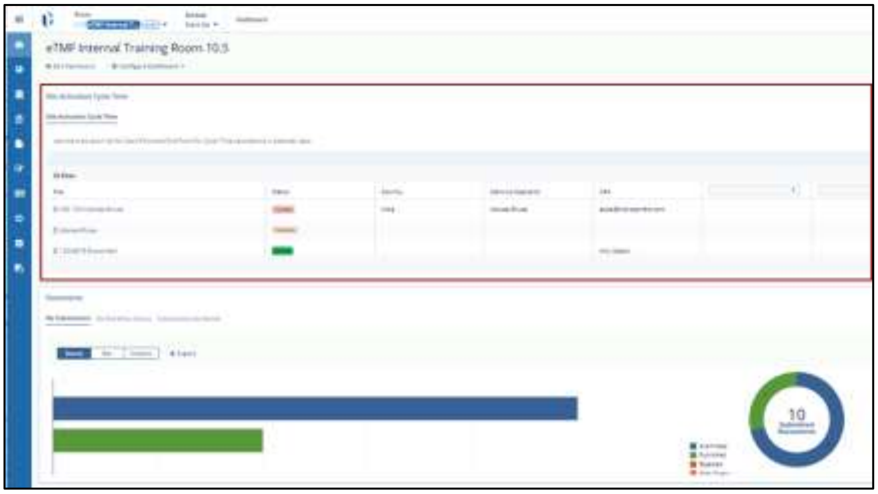
The Set-Up Layout allows users to customize the visual structure of the dashboard by choosing a column-based layout. This ensures that the dashboard is organized according to user preferences. The user has the option to select from – One, Two, or Three Columns.

Steps to set up Layout:

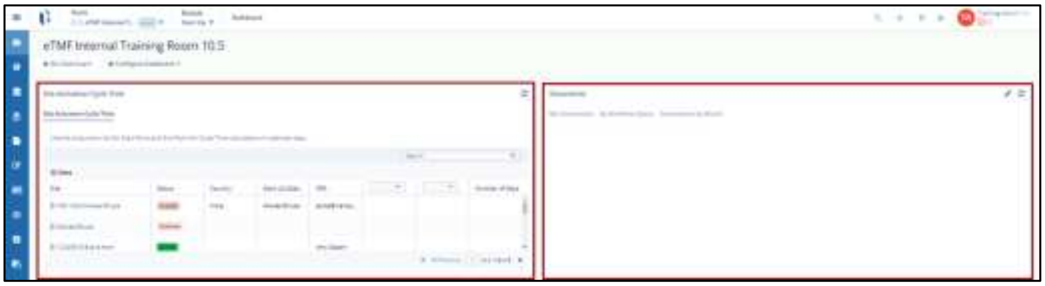
1. From the Set Up Your Dashboard window. Click on the Set-Up Layout.



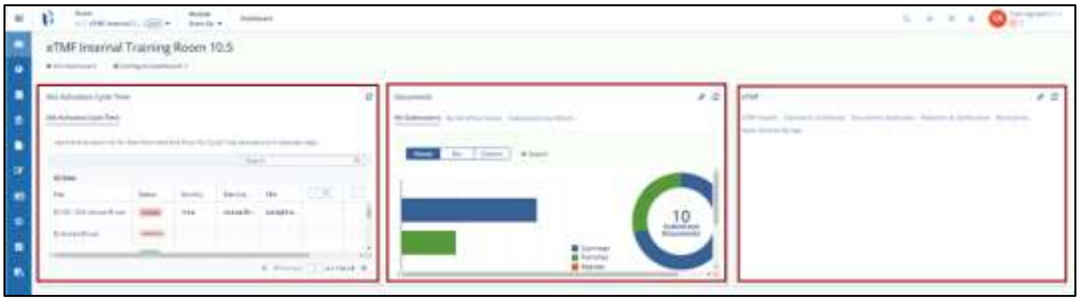
2. Select one of the available options for Layout:
   - One Column: Arrange all dashlets in a single vertical column.



- Two Columns: Splits dashlets into two evenly spaced columns.



- Three Columns: Divides dashlets across three narrower columns.



3. Click the Save button to confirm and apply the selected layout or Use the Cancel button to discard the changes.

Configure Dashboard

The Configure Dashboard helps the user to arrange the dashboard as required.

This includes two dashboards:

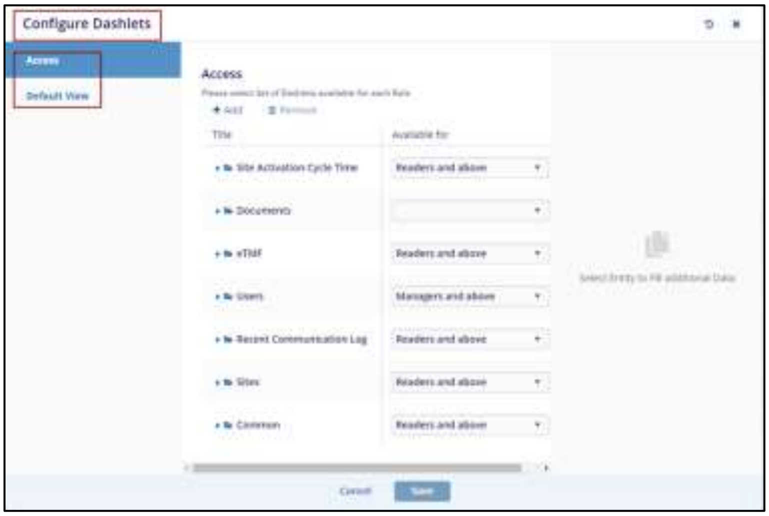
- Configure Dashlets

Configure Dashlets

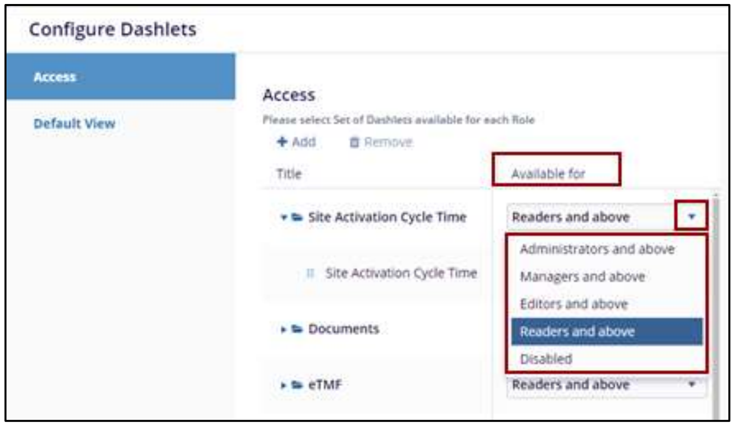
The Configure Dashlets allow administrators to manage the availability and visibility of dashlets on the dashboard for different user roles. Dashlets are individual components that display specific data or functionality, such as documents, users, or key metrics, making the dashboard customizable and role-specific.

Steps to Configure the Dashlets.

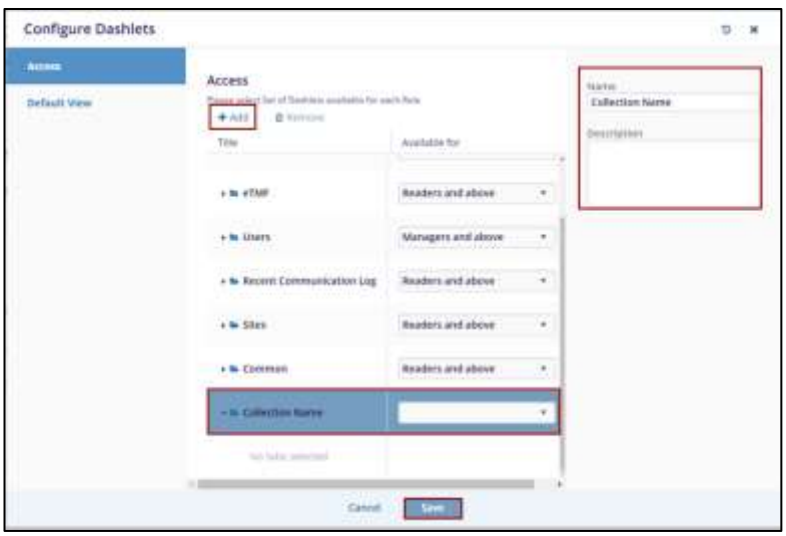
1. Click the Configure Dashboard button the user can see the dropdown menu, Configure Dashlets.
2. Click on the Configure Dashlets, and the Configure Dashlets window will pop up.
3. The Configure Dashlets window will display two tabs on the left:
    - Access: To select a Set of Dashlets available for each role.
    - Default View: To select the Default list of Dashlets for each role.



4. In the Access tab, the user can select the roles from the dropdown menu within the Available for column to assign dashlets to specific roles.

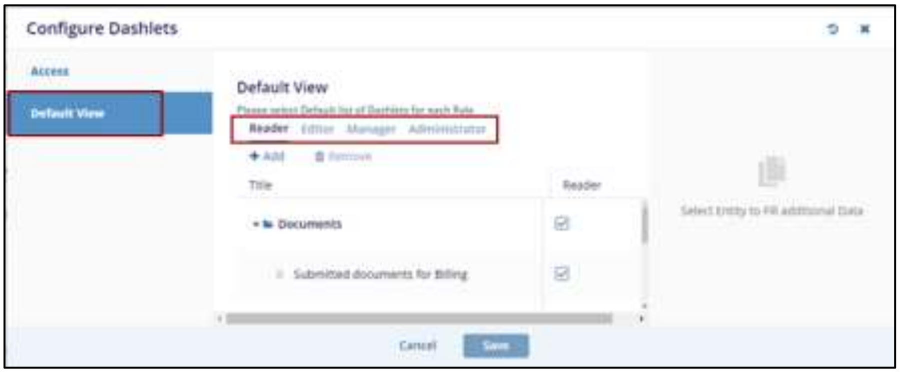


5. Click Add, and a new entry appears in the title list as Collection Name. Enter the Title and Description in the left-side fields before adding the dashlet.
6. Click the Save button to add the dashlet.



7. Click the Remove button to initiate the removal process. A confirmation window will appear with the message: 'Are you sure that you want to remove the collection?' Also, the user can only remove the newly added fields and not the pre-defined fields

8. Click the Yes button to confirm and remove the collection or click the No button to cancel the action and keep the collection.
9. Switch to the Default View tab, and select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager, and Administrator.
10. As per the roles, the titles get changed.



11. Click on the Save button at the bottom of the popup window, to save the changes, or click Cancel to discard your changes.

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.

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.

Clicking the View All Communication Log button redirects the user to the Communication Log page of the SSU module.

SITES

The Investigative Sites dashboard provides a list of sites involved in clinical trials or studies, displaying details for Expiring Sites, Site Health (CRA), Recently Updated Sites, Site Activation Status, E-Feasibility by Country, and Study Monitoring Visits.

Note: Tabs configured within the Edit Dashboard section are visible here.

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 summary of the completion status for multiple sites, allowing users to monitor site progress effectively. This tab displays 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.

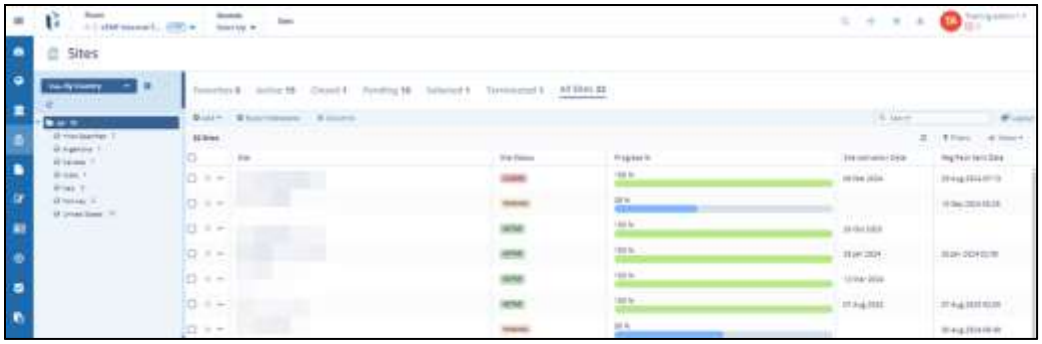
Steps to view Site Health (CRA)

1. Navigate to the Investigative Site dashboard, and click on the Site Health (CRA) tab.
2. The user can view the Site Health (CRA) Chart through the Donut, Bar, and Column view by selecting it.
   This will update the display of each site's completion status in the chosen format.
3. Use the All-Sites dropdown menu to filter which sites appear in the view. This is helpful to users if they want to focus on specific site data. It has two options: All Sites and My Sites.
4. Click on the Export button to download the data currently displayed. This option allows the user to save the information for further review or to include it in reports.

Recently Updated Sites

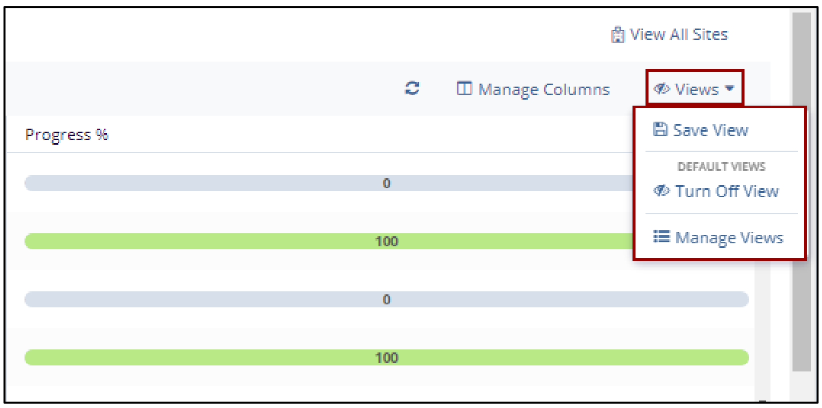
The Recently Updated Sites tab provides a list of sites that have recent updates, allowing users to monitor site progress and activity status. This tab displays details including Site, Principal Investigator, Status, and Progress %. Users can customize the display by managing columns, refreshing the 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.

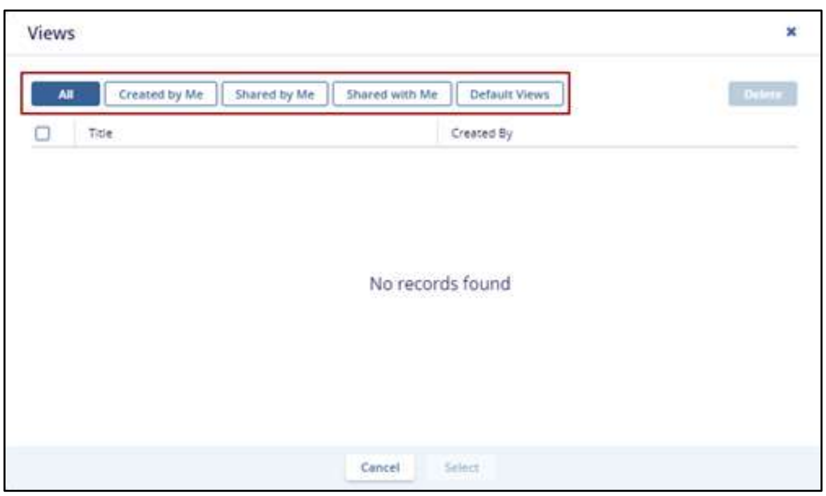
- Click View All Sites in the top right corner to navigate to the Sites page, displaying the full list of sites without filters.



- Use the Refresh button to update the information displayed in the list. This ensures the user is viewing the most current data.
- Click the Manage Columns to customize the information displayed. The user can add or remove columns that need to focus on specific details relevant to the review on the Manage Columns pop-up window.

- Click Views to manage dashboard views. Select Manage Views to customize views based on options like Created by Me, Shared by Me, Shared with Me, and Default Views.



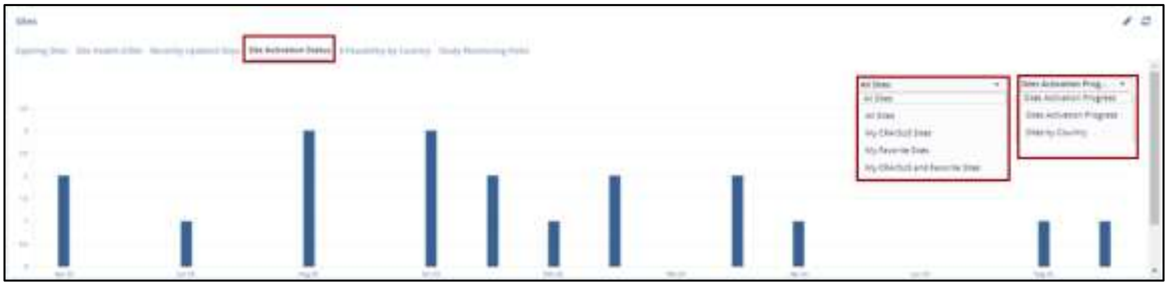


Site Activation Status

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 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 the users to focus on a subset of sites relevant to the review.

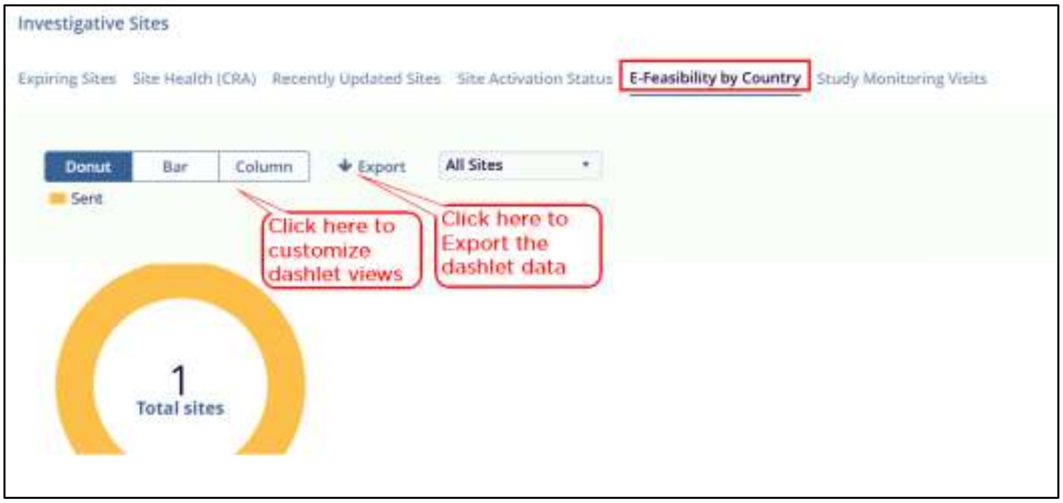
- In the Site Activation Progress dropdown menu, choose the desired Site Activation Progress type to adjust the chart based on specific activation criteria or milestones.



E-Feasibility by Country

The E-Feasibility by Country tab provides an 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 the preferred chart format by clicking Donut, Bar, or Column. This will change how the feasibility data is displayed, allowing the user to choose the visualization that best suits the 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 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 time 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.

Steps to manage study monitoring Visits:

1. Navigate to the Investigative Site dashboard, and click on the Study Monitoring Visits tab.
2. 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.
3. Select Donut, Bar, or Column to choose the preferred chart format. This will change the display of the visit data, allowing the user to view the information in a format that best suits their needs.
4. 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.
5. Click on the Export button to download the current view's data. This is useful for external analysis or reporting needs.
6. Each circular chart shows the Total visits for a specific month or 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.

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 access can edit this dashboard by pressing the Edit button with the Pencil icon at the left side of the dashboard. 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 tab provides 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.

Steps to use the common section:

1. Navigate to the Common dashboard, and click on the About this Room tab.
2. Review the welcome message and any instructions provided. This message might contain important details about study access, document requirements, and support contacts.
3. Click the Click here to get it link to download Adobe Acrobat Reader, as it is necessary to view some documents in the room.
4. If the user is an Administrator or Manager, click the Edit button with the Pencil icon in the top right corner to make changes to the welcome message.
5. Update the text with any new information or instructions, as needed.
6. After making edits, click Save to apply the changes. The updated message will be immediately visible to all users in the room or click on Cancel to discard the changes.

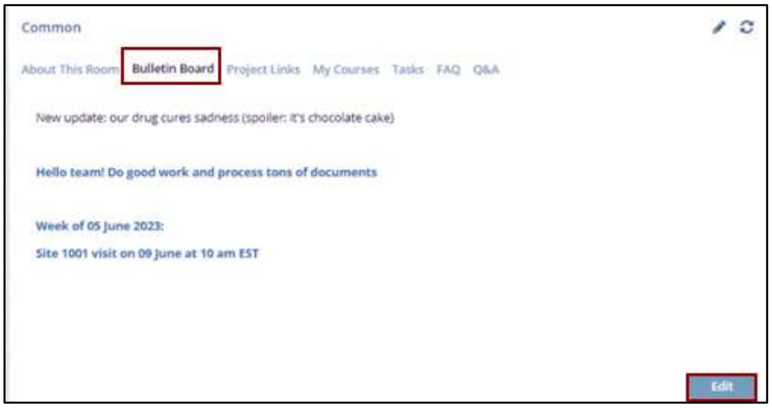
Bulletin Board

The Bulletin Board tab 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

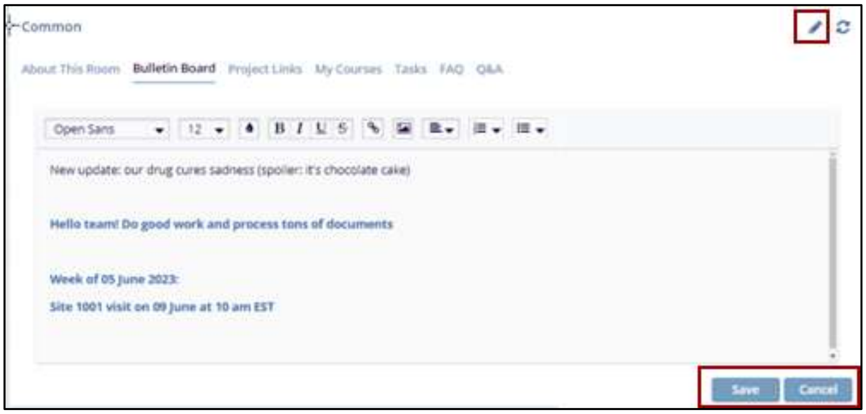
Managers have permission to edit the content in this area, ensuring that relevant information can be updated as needed.

Steps to use the Bulletin Board:

1. Navigate to the Common dashboard, and click on the Bulletin Board tab.
2. The Bulletin Board tab will display messages or updates provided by administrators. If there are no messages, it may show "No records available."
3. If the user is an Administrator or Manager and needs to add or update information, click the Edit button located at the bottom right of the screen.



4. In Edit mode, enter the message or update the wish to communicate to the team. This can include announcements, study updates, or any relevant instructions.
5. 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.

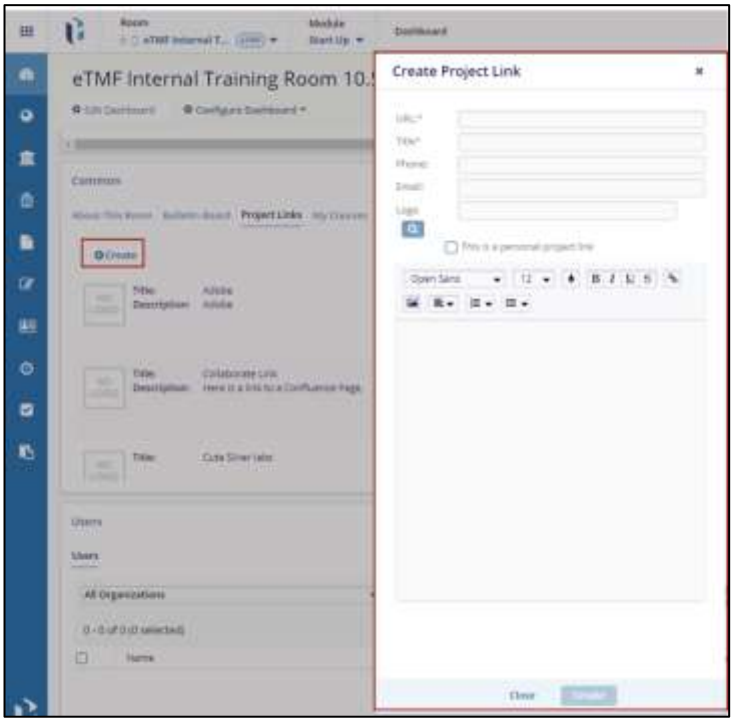


Project Links

The Project Links tab 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. Navigate to the Common dashboard, and click on the Project Links tab.

2. Click the Create button to add a new link to the tab. The Create Project Link pop-up window is displayed.



3. During the link creation process, the user 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.
4. If the user needs to modify or remove an existing link, click Edit or Delete next to the respective link. Editing allows the user to change details such as the title or URL while deleting removes the link from the tab.
5. 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 tab allows users to track and manage their tasks related to various activities. Each task is associated with specific details such as Subject, Status, Priority, Start and Due dates, and Completion percentage. This section helps users stay organized by displaying all tasks in one place and offering options to filter, sort, and update task statuses.

Steps to Manage Tasks:

1. Navigate to the Common dashboard, and click on the Tasks tab
2. Select the Status and the Assignee from their respective dropdown menus to get the task details, including the subject, status, priority, and due date to stay on top of your responsibilities.
3. If the user working on a task, update the status to reflect your progress (e.g., from Not Started to In Progress or Completed).
4. Monitor the Complete % to assess how much of the task has been finished.
5. To manage the view toggle between All Tasks and My Tasks views.
6. Click Export to download a copy of the task information for further review or reporting.

FAQ

The FAQ tab will display a list of common questions and answers related to the system, processes, or project-specific information. This section helps users quickly find answers to frequently asked questions without needing to contact support or ask team members. It can be used for both operational guidance and addressing common queries about how to use the platform or navigate through processes.

Steps to Use the FAQ tab:

1. Navigate to the Common dashboard, and click on the FAQ tab.
2. Click the + sign next to the checkbox to expand and view its answer.
3. Use the Date dropdown to sort the FAQs by their creation date (e.g., newest to oldest).
4. Use the Category dropdown to filter FAQs by categories like Regulatory Issues, Site Health, etc.
5. Use the filter option to search for keywords or phrases in the FAQ section.
6. Click Export to save the FAQ data in a suitable format.
7. Click view FAQs and take to the FAQ Module, where the user can filter questions and answer with more options.

Q&A

The Q&A tab is designed to help users post questions and receive answers related to various topics. It allows users to interact, resolve doubts, and track questions based on their status (opened or answered). This section also helps in sharing common queries that might be helpful for others.

Steps to Use the Q&A tab:

1. Navigate to the Common dashboard, and click on the Q&A tab.
2. Use the filter options on the left to view questions based on their status:
   - Opened: To see all open and unanswered questions.
   - Answered: To view questions that have been answered.
   - All: To view both open and answered questions.
3. Each question will have a title (e.g., "What's the protocol number for this study?") along with relevant details such as the Subject Matter, Company, User, and Posted Date.
4. Click the + sign next to the checkbox to expand and view its answer.
5. Click Export Q&A to download the list of questions and answers for further reference or reporting.
6. Select from the Views dropdown to sort the questions by Date or other available criteria to prioritize your review of questions.

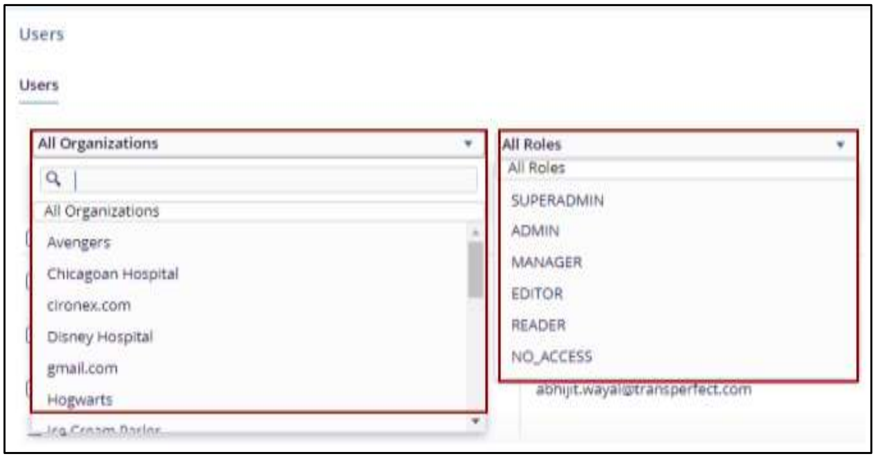

Common
Question
Subject Matter
Company
User
Posted Date
Training

Users

This tab displays available users and is added to the SSU module. Additional actions include Inviting a User, Editing the Dashlet Name, Refreshing, Managing Columns, Creating & Managing Filters, and Saving Views.

Steps to Use the Q&A tab:

1. Navigate to the Users dashboard.
2. Users can filter by Organizations and Roles using dropdowns.



3. Click the New tab to view only new users or the All tab to see all users.
4. Click +Invite the User Invitation pop-up window is displayed. Follow the steps from [Inviting Contacts and Managing Security](#).

ETMF

The eTMF (Electronic Trial Master File) dashboard provides a visual representation of trial-related document health and status. The eTMF ensures that clinical trial documents are easily accessible, properly stored, and secure.

It includes the following tabs:

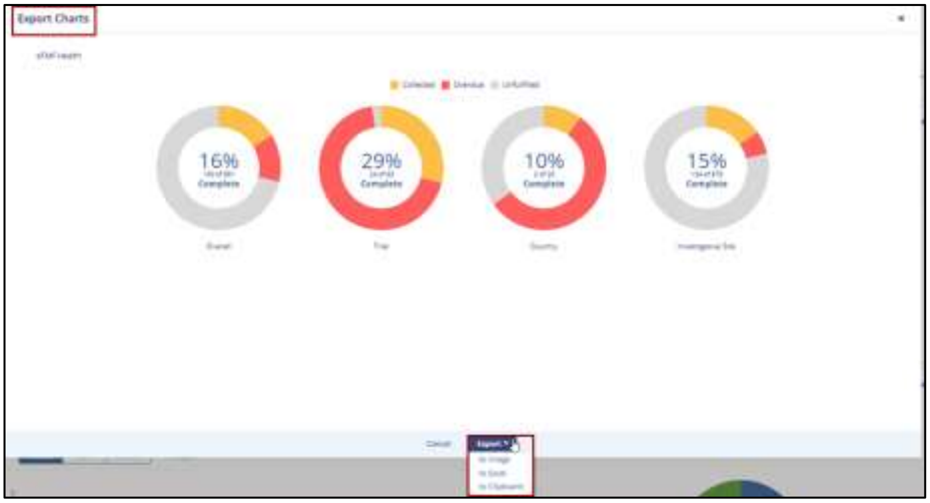
eTMF health

The eTMF Health tab provides an overview of the overall health and progress of the trial master file. It helps monitor the completeness and compliance of documents in different stages of the clinical trial by visualizing key metrics such as the percentage of completed documents in categories such as Trial, Country, Investigative Site, and overall.

Steps to view eTMF Health:

1. Navigate to the eTMF dashboard, and click on the eTMF Health tab.
2. By default, the eTMF Health tab is selected and the user can view the eTMF Health Chart through the Donut, Bar, and Column view by selecting it.
3. To export the displayed data, click Export, which allows the user to download the information for further analysis.

4. Once clicked on the Export chart window will be a popup and the user can export the data in – Image, Excel, or Clipboard format.



Claimed and Unclaimed

In the eTMF dashboard, Claimed & Unclaimed refer to the status of documents, who is responsible for them, or who has taken action on them.

Steps to view Claimed & Unclaimed Documents:

1. Navigate to the eTMF dashboard and click on the Claimed & Unclaimed tab.
2. The Claimed & Unclaimed tab is selected and the user can view the Claimed & Unclaimed Chart through the Donut, Bar, and Column view by selecting it.
3. Use the dropdown on the right to filter the documents by their workflow stage, such as 2-Step Workflow.
4. To export the displayed data, click Export, which allows the user to download the information for further analysis.

Documents Expiration

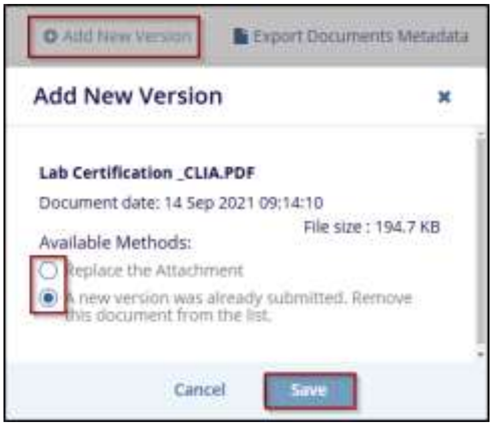
The Expired Documents tab, lists documents that are either expiring or already expired, based on the specified expiration period. The Expired Document tab allows users to track these documents, monitor their expiration, and take action.

Steps to manage Expired documents by replacing them with updated versions:

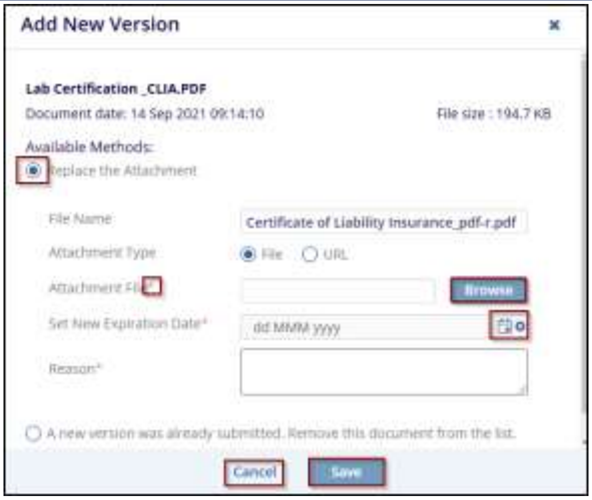
1. Navigate to the eTMF dashboard, and select the Expired Document tab.

2. The user can apply the filter to view Expired or Expiring documents. Select the option to focus on documents that are already expired or those approaching expiration.
3. Check the checkbox next to the blue arrow and click the +Add New Version button at the top-right of the dashboard.

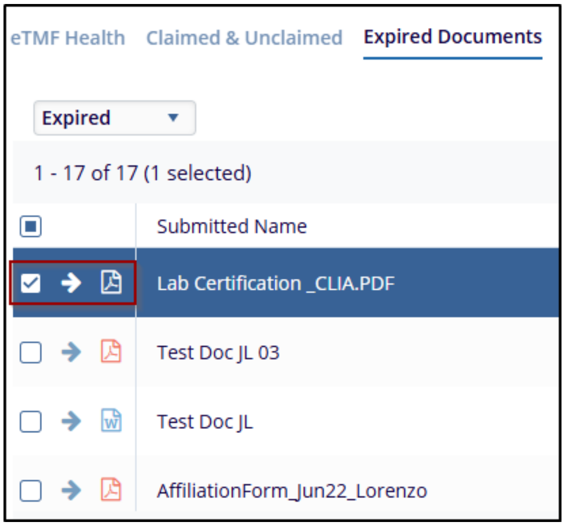
4. This will open the new Add New Version window and select the appropriate option.



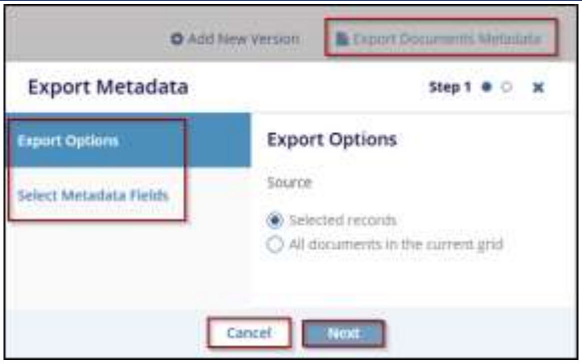
5. The options available are configurable by the room administrator in the Settings area.
6. If Replace the Attachment is chosen, click the Browse button and locate the new version of the file.
7. Set the new expiration date, and give the reason for the replacement in the comment box.
8. If the 'A new version was already submitted. Remove this document from the list. Nothing else needs to be done. The document will be removed from the list of expiring documents.
9. Press Save to save the changes or click Cancel to discard the changes.



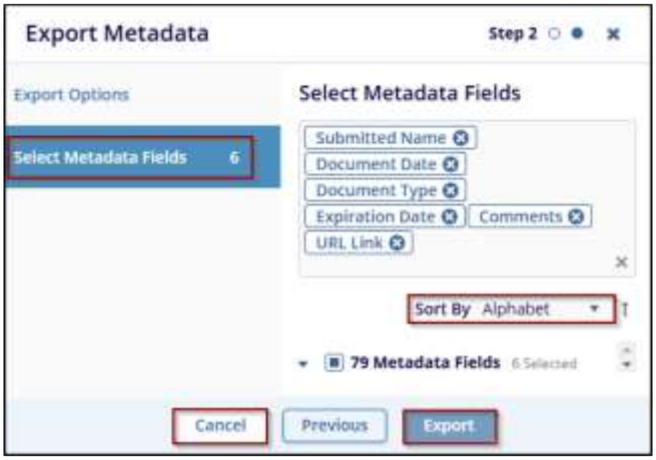
10. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
11. Click on the PDF icon will open a new window, The PDF opens in the window, allowing the user to navigate through the pages using the controls at the top (e.g., Print, Download, page Navigation arrows, zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide).



12. Click on the Export Documents Metadata button, and a new window will pop up with 2 options:
    Export option and Select Metadata fields.
13. Select the Export option will give 2 sources:
    - Selected records: Choose this option to export metadata only for specific selected documents.
    - All documents in the current grid: Choose this option to export metadata for all documents currently displayed in the grid.



14. Click Next to proceed to Select Metadata Fields, where the user can choose the metadata fields to include in the export.
15. The user can use the Sort By dropdown to sort the available metadata fields alphabetically or logically.
16. Click Export to download the document metadata file in the preferred format. Click Previous to go back or Cancel to discard changes.



Rejection and Clarification

The Rejected and In-Clarification Documents tab displays documents that have either been rejected or are currently in a state requiring clarification. These documents may need to be reviewed, corrected, and resubmitted before they can be approved and processed further in the workflow. This overview helps identify common reasons for rejection and areas where clarification is frequently needed.

Steps to Manage Rejected and In-Clarification Documents:

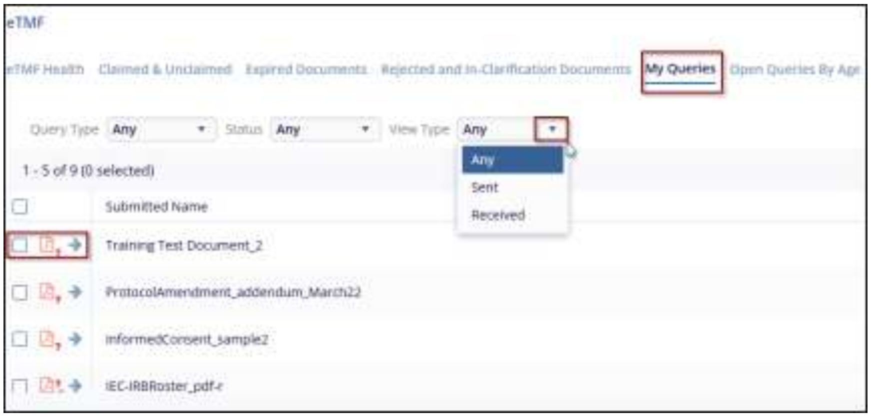
1. Navigate to the eTMF dashboard, and select the Expired Document tab to view the list of documents associated with a specific rejection or clarification reason.
2. Click on the + sign next to the reason will expand the section, and reveal individual documents, including details such as the Submitted Name, Created Date, and Comments.
3. Click on the − sign will minimize the section.
4. Additional options, like Export and Manage Columns, allow the user to export the data or customize the column view to focus on relevant information.

My Queries

My Queries in the eTMF allows the users to view and manage queries related to the documents they are working on. Queries could be either sent (by the user to someone else) or received (from others to the user). This helps to track the status of queries and allows the user to take actions such as responding to or exporting query details.

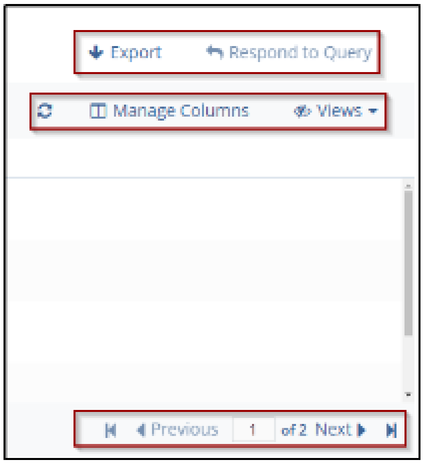
Steps to use My Queries:

1. Navigate to the eTMF dashboard, and select the My Queries tab.
2. Use the Query Type dropdown to filter the queries:
   - Select Any to view all queries.
   - Choose Sent to see the queries you have sent.
   - Choose Received to view queries you have received.
3. Review the list of documents displayed with their details (e.g., Submitted Name)
4. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
5. Click on the PDF icon will open a new window of the document which has an open query, The PDF opens in the window, allowing the user to navigate through the pages using the controls at the top.



6. If needed, click the Export button to download the query data in a suitable format (e.g., CSV or Excel) for further analysis or reporting.
7. Click on the Respond to Query option next to the relevant document. Follow the on-screen prompts to provide your response.
8. Click the Manage Columns to adjust the visible information in the table.

9. Use the navigation controls Previous and Next to switch between pages of documents.
10. Click on the Views dropdown to select different views or filtering options.
11. Click the refresh icon to update the list with any recent changes.



Open Queries By Age

The Open Queries by Age tab displays documents that are older than 30 days or more and provides a document count for easy tracking. The user can select a query type from the dropdown menu located at the top left, including Any, Workflow, or Audit options.

Steps to open queries by age:

1. Navigate to the eTMF dashboard, and select the Open Queries by Age tab.
2. Use the Query Type dropdown to filter the queries:
   - Select Any to view all queries.
   - Choose Workflow to see the action related to a specific workflow process.
   - Choose Audit to show only those that are related to audit activities.
3. Review the list of documents displayed with their details (e.g., Submitted Name)
4. Click on the + sign next to the reason will expand the section, and reveal individual documents, including details such as the Submitted Name, Created Date, and Comments.
5. Click on the − sign will minimize the section.
6. Additional options, like Export and Manage Columns, allow the user to export the data or customize the column view to focus on relevant information.

DOCUMENTS

The Documents section in the dashboard provides users with quick access to document-related actions and information.

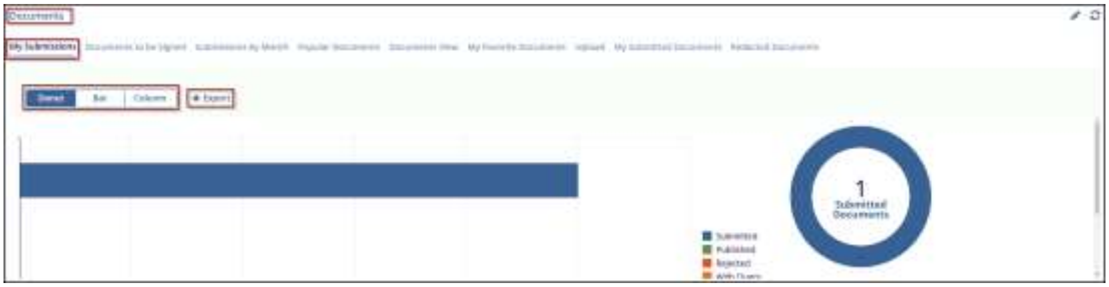
Note: Only those tabs are displayed in this dashlet that were configured within the Edit Dashboard section.

My Submissions

The My Submission dashlet will allow users to view the files that have been uploaded right from the document index.

Steps to view and manage my submissions:

1. Navigate to the Dashboard section in the eTMF module, located at the top left of the Toolbar.
2. Once clicked on Dashboard, the user can see the Document section in the dashboard.
3. By default, My Submissions is selected and it is a mandatory dashlet. In this, the user can view the Submitted Documents Chart through the Donut, Bar, and Column view by selecting it.



4. Next to Charts, the user can see the blue arrow Export button. 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.

5. Click on Cancel to discard the changes to Export Charts.

By Workflow Status

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.

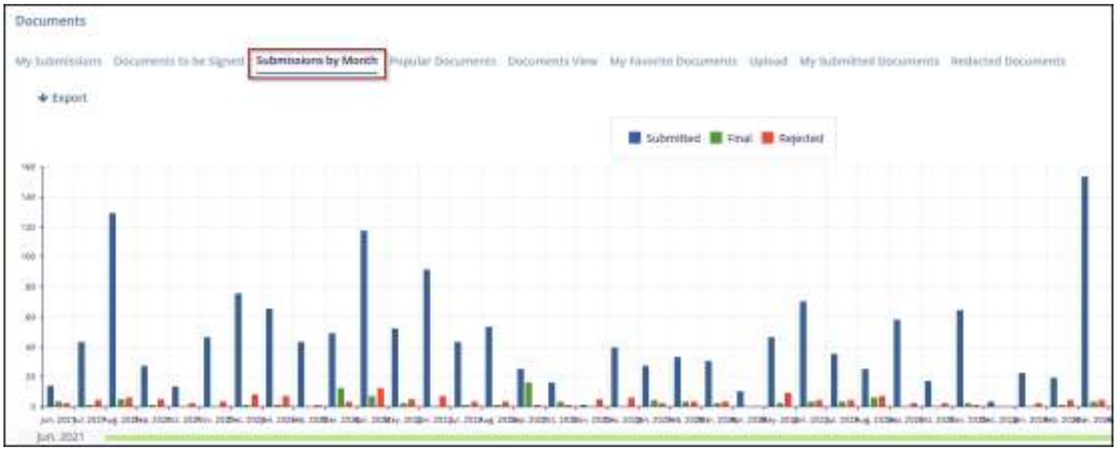
Submissions by Month

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 the final documents.

- Red represents rejected documents.



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.

Steps to view and manage Documents to be signed:

1. Click on Documents to be Signed, next to My Submissions.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.

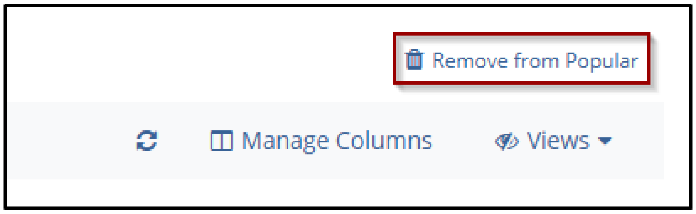
Popular Documents

In the Documents Dashboard, 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. This is similar to My Submissions.

Steps to view and manage popular Documents:

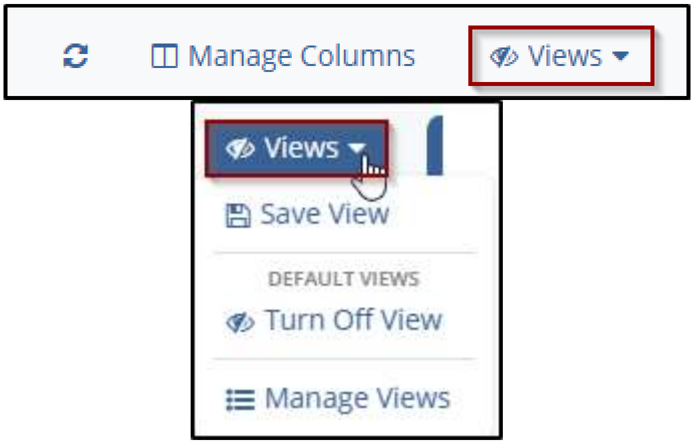
1. Click the Popular Documents, next to Submissions by month.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.

3. To remove a selected document from the Popular document list, click on the "Remove from Popular" button on the top right side of the Document dashboard.



4. To customize the columns displayed in the document list, click Manage Columns (for detailed steps please refer to My Submission (manage columns).
5. Once the changes are applied, the user can click the Refresh icon to refresh the Columns.

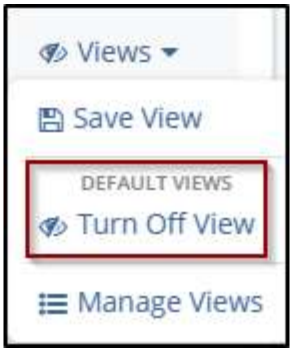
6. Use the Views option for saving views, managing, and turning off customized views.
7. Click on the Views Dropdown menu, next to the Manage columns. The user can see options Save View, Share View, Turn off View, Recent View, and Manage Views.



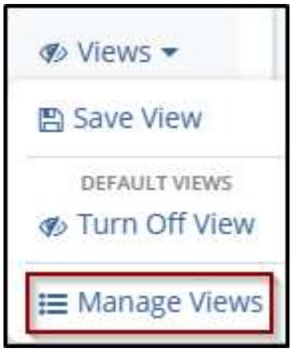
8. Click Save View from the dropdown menu, The Save Views window will pop up.

9. In the Save View window, enter a Name for view.
10. Make Default for Me: Toggle the switch to make this view the default for the user.
11. Make Default for All: Toggle the switch to make this view the default for all users.
12. To save the current view as a new view, ensure the Save As New option is enabled.

13. Click the Save button to save the current view, If the user decides not to save the view, click the Cancel button to discard changes.
14. Click Turn Off View from the dropdown menu. If the user wants to revert to the default view or disable the current saved view.



15. Click on Manage Views from the dropdown menu, Manage Views window will pop up.



16. In the Manage Views window, the user can see all available view options under tabs such as All, Created by Me, Shared by Me, Shared with Me, and Default Views. The users can browse through the views by selecting the appropriate tab.
17. Check the box next to the view to manage.
18. After selecting a view, the user can delete it by clicking the Delete button.

19. Once finished managing views, click the Cancel button to discard any changes, or click Select to apply the changes to the selected view.

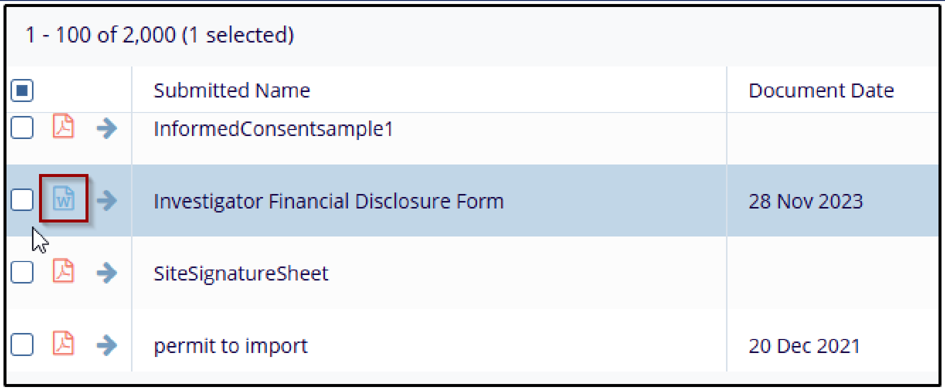
Documents View

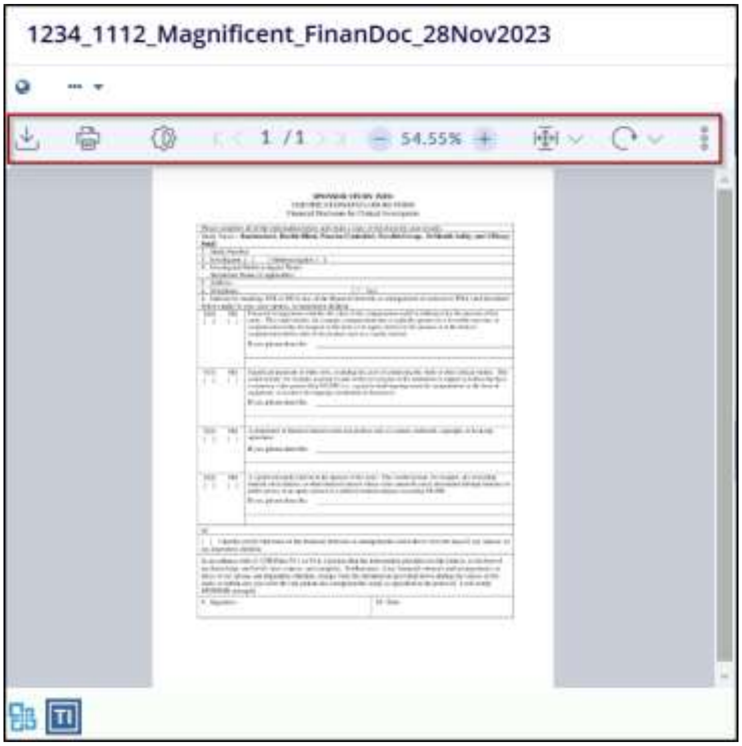
This tab displays the documents in a grid column with a selection tab for – Unread, Unclaimed, and Pending.

Steps to review documents view:

1. Click the Documents Views, next to popular Documents.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
3. To view the Document, click on the PDF icon (for detailed steps, refer Document to be Signed tab above)
4. To customize the columns displayed in the document list, click Manage Columns and select or deselect columns as required to view.

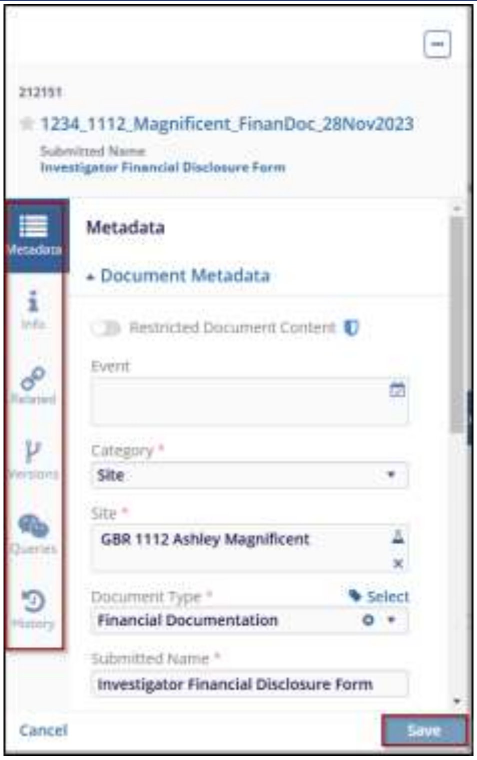
5. By clicking on the Word icon, the Word file window will open with the document, where the user can perform various actions, such as (Print, download, Page navigation arrows, Zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide).





6. On the right side of the Word file, where the user can find the document Metadata, Info, related, version, queries, and history section, after updating metadata or making any necessary changes, click Save to apply the changes. (For detailed steps refer to Documents to be signed 4th step)

   Refer to the below screenshot:



My Favorite Documents

The My Favorite Documents tab displays the list of documents that have been marked favorite from the Document Index and allows quick access to frequently used documents.

Steps to view and add documents to my favorite:

1. Click on the My Favorite Documents tab from the Documents dashboard.
2. Review the list of documents marked as favorites from the document index, displayed with their details (e.g., Submitted Name, Index, Last Updated By).
3. Click on Export to Download the document to the local system.
4. Click the star icon or the Remove from Favorites button to unmark the document as a favorite.
5. Use the pencil icon or Edit Comments option to add or update comments.
6. Delete any existing comments using the Remove Comments button.
7. Click Manage Columns to adjust the visible information in the table.
8. Use the navigation controls Previous and Next to switch between pages of documents.
9. Click the Refresh icon to update the list with any recent changes.

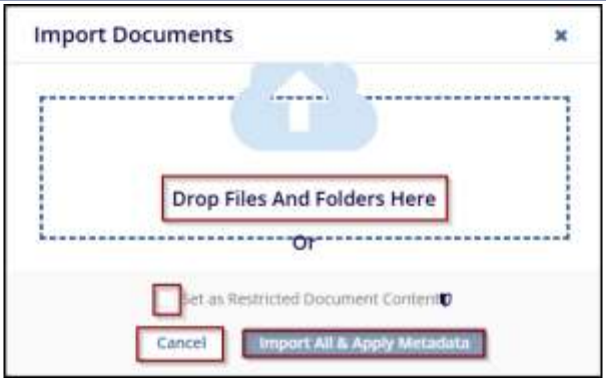
Upload

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.

Steps to upload the document:

1. Navigate to the Documents dashboard and select the Upload tab.

1. In the upload section, the user can drag and drop files directly into the designated Upload box or click on drop file and folder to Browse File or Browse Folders to locate files from the system.
2. After selecting the files, the user can set them as Restricted Document Content by checking the box if necessary.
3. Once files are ready, click Import All & Apply Metadata to complete the upload process or click Cancel to discard the changes.



Submitted Documents

The My Submitted Documents dashboard represents a user interface component that lists documents that have been uploaded or submitted by the user. This view displays a list of submitted documents, showing details such as the Submitted Name and Index.

Steps to view my submitted documents:

1. In the Documents Dashboard, select the My Submitted Documents tab.
2. Review the list of documents displayed with their details (e.g., Submitted Name, Index, Last Updated By).
3. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
4. Use the pencil icon to edit the Dashboard name at the top right corner.
5. Click Manage Columns to adjust the visible information in the table.
6. Use the navigation controls Previous and Next to switch between pages of documents.
7. Click the Refresh icon to update the list with any recent changes.

Redacted Documents

The Redacted Documents dashboard shows a set of documents that have undergone or are undergoing redaction, a process where sensitive or confidential information is removed from documents before they are shared or published.

Steps to Managing Redacted Document:

1. In the Documents Dashboard, select the Redacted Document tab, where documents undergoing redaction are listed.

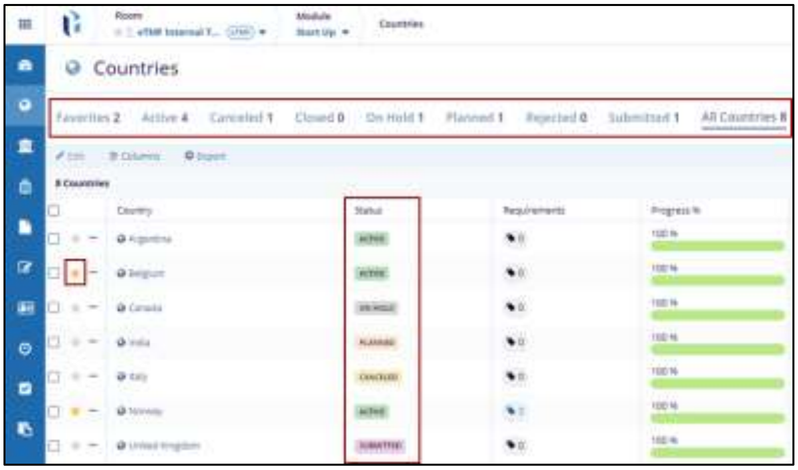
2. The user can use the status filters at the top right to sort documents by redaction stage:
    - Not Yet Started Redaction for documents pending redaction.
    - In Progress for documents currently being redacted.
    - Completed for documents where redaction is finalized.
3. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
4. The blue icon shows the document is waiting for redaction.
5. Use the pencil icon to edit the Dashboard name at the top right corner.
6. Click Manage Columns to adjust the visible information in the table.
7. Use the navigation controls Previous and Next to switch between pages of documents.
8. Click the refresh icon to update the list with any recent changes.

COUNTRY

Clinical trials are conducted globally, requiring the administrator to specify the countries where the trial is conducted and the locations of investigative sites during the initial setup and configuration.

The Start-Up Countries tab, accessible from the left toggling menu, allows document setup for countries linked to sites. The Countries Dashboard displays country statuses at the top, with a central Grid Pane for detailed viewing.

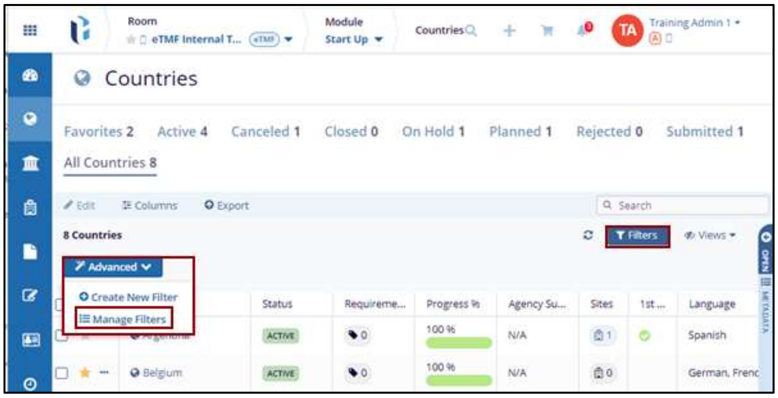
- Favorites – Shows countries marked as "Favorites."
- Active – Displays countries with the status set to "Active."
- Canceled – Lists countries with the status set to "Canceled."
- Closed – Displays countries with the status set to "Closed."
- On Hold – Shows countries currently marked as "On Hold."
- Planned – Displays countries with the status set to "Planned."
- Rejected – Lists countries with the status set to "Rejected."
- Submitted – Displays countries with the status set to "Submitted."
- All Countries – Shows all countries in the grid, regardless of status.



Manage Filters

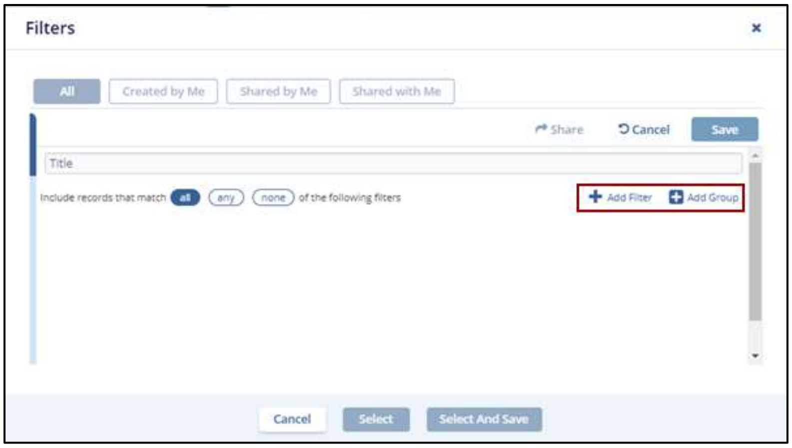
To manage the filters, follow the steps below.

1. Click on the Filters button.
2. From the Advanced dropdown on the right side, select Manage Filters.

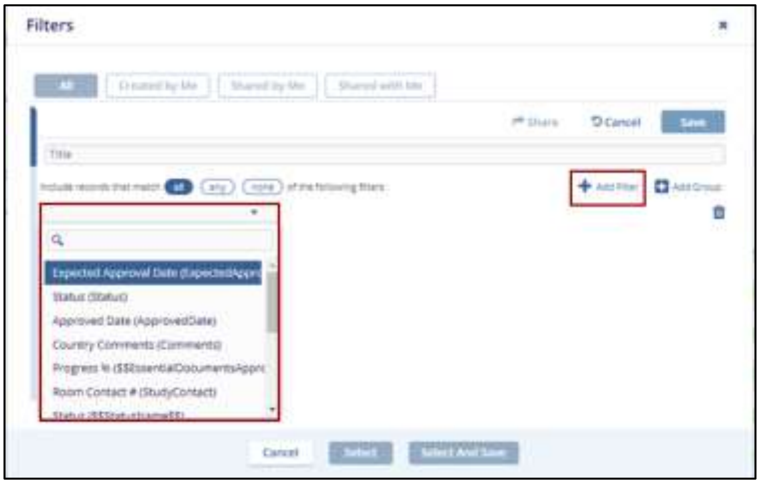


3. The Filters pop-up window is displayed. However, the below tabs are visible:
    - All
    - Created by Me
    - Shared by Me
    - Shared with Me
4. By default, the All tab is displayed.

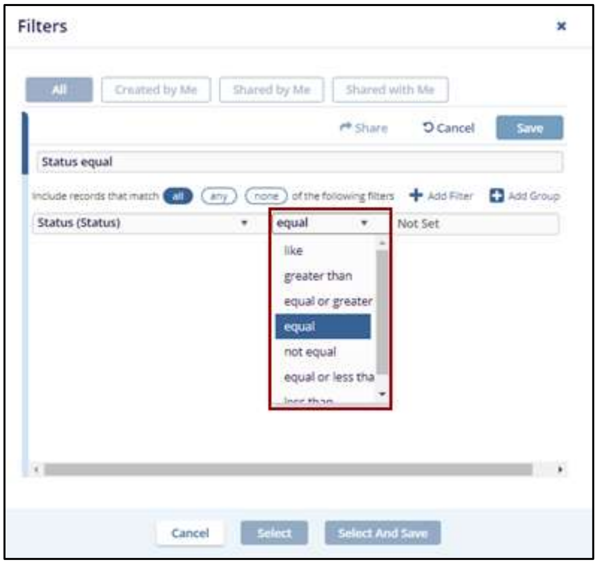
5. On the Filters window, click on the +Add button. The user is directed to the filter page where the user can Add a Filter or Group.

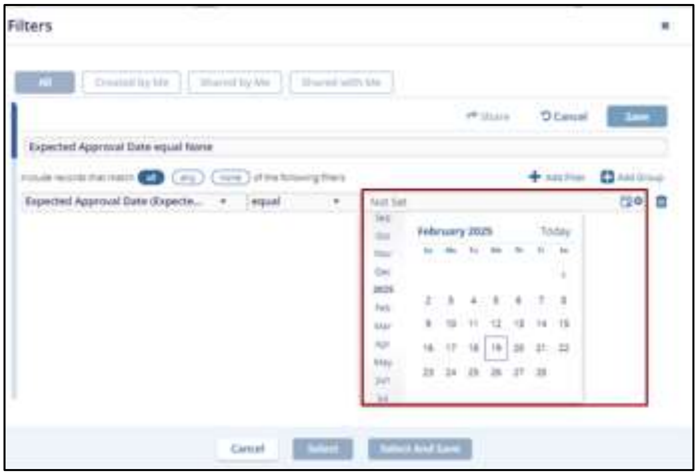


6. Click the +Add Filter option. The empty field populates on the page.
7. Select a filter option by accessing the dropdown.

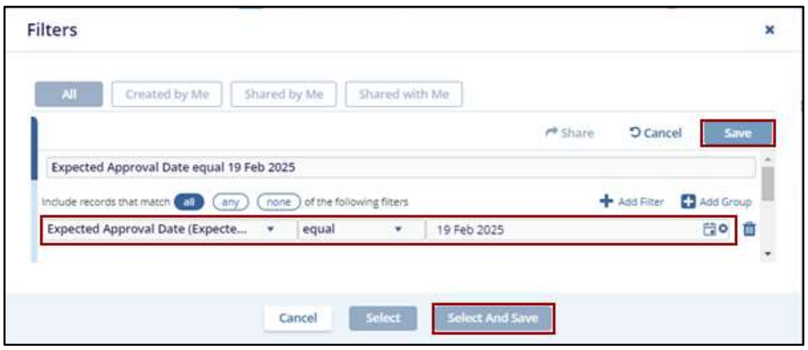


8. Select an operator from the available dropdown list. Based on the selected operator, other fields such as "Equal" and "Not Set" will be populated accordingly.





9. Configure the filter criteria and click the Save button on the top right side of the Filters pop-up window.
10. Click the Select or Select And Save buttons to apply the filters on the Countries.

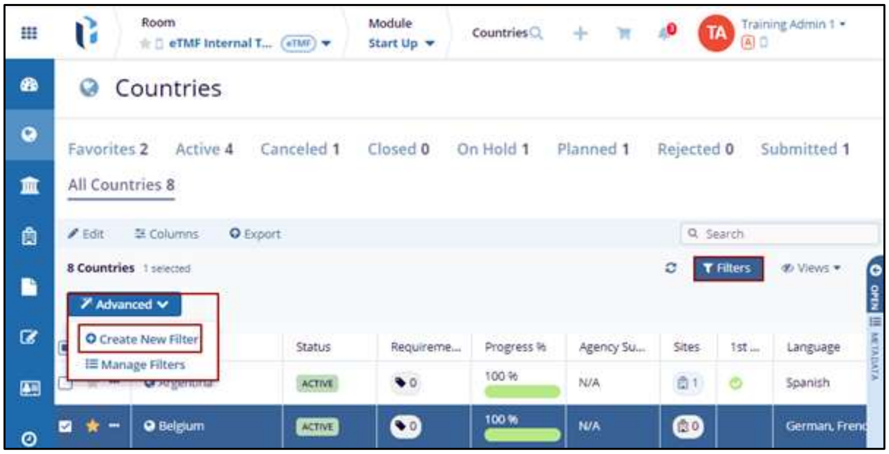


Note: The other two dropdown menu options i.e., logical operator and criteria change as per the option selected in the first dropdown menu.

Create New Filter

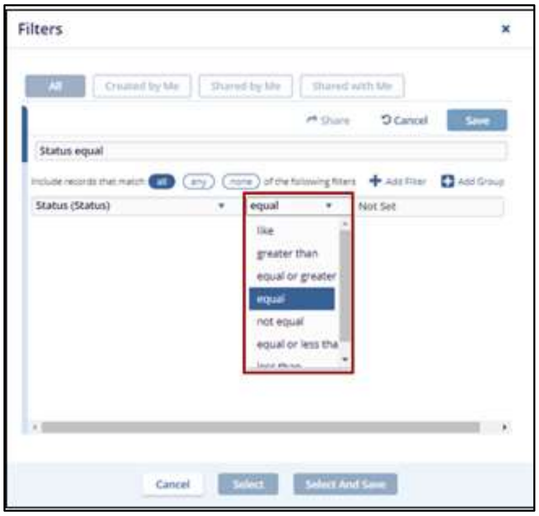
To create a new filter, follow the steps below.

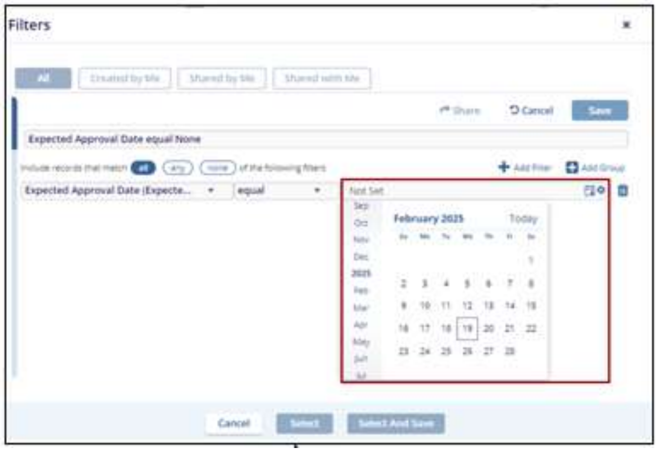
1. Click on the Filters button.
2. From the Advanced dropdown on the right side, select Create New Filter.



3. The Create Filter pop-up window is displayed.
4. Click the +Add Filter option. The empty field populates on the page.
5. Select a filter option by accessing the dropdown.

6. Select an operator from the available dropdown list. Based on the selected operator, other fields such as "Equal" and "Not Set" will be populated accordingly.

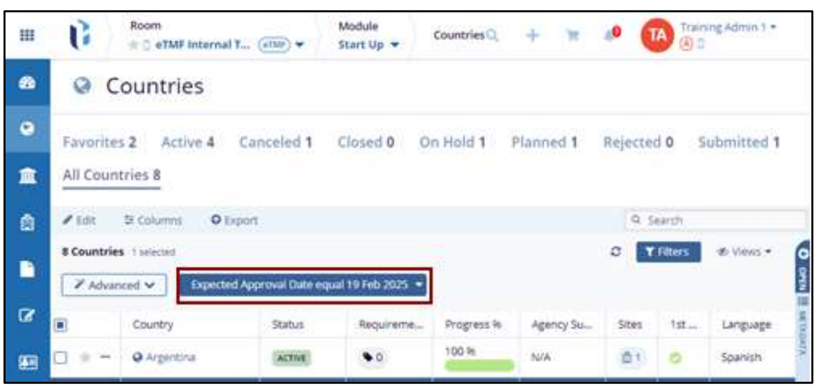




7. Click the Create button.

Note: The other two dropdown menu options i.e., logical operator and criteria change as per the option selected in the first dropdown menu.

8. The created filter is displayed in the Grid Pane.



9. Click on the filter dropdown to Select, Edit, or Delete the filter.

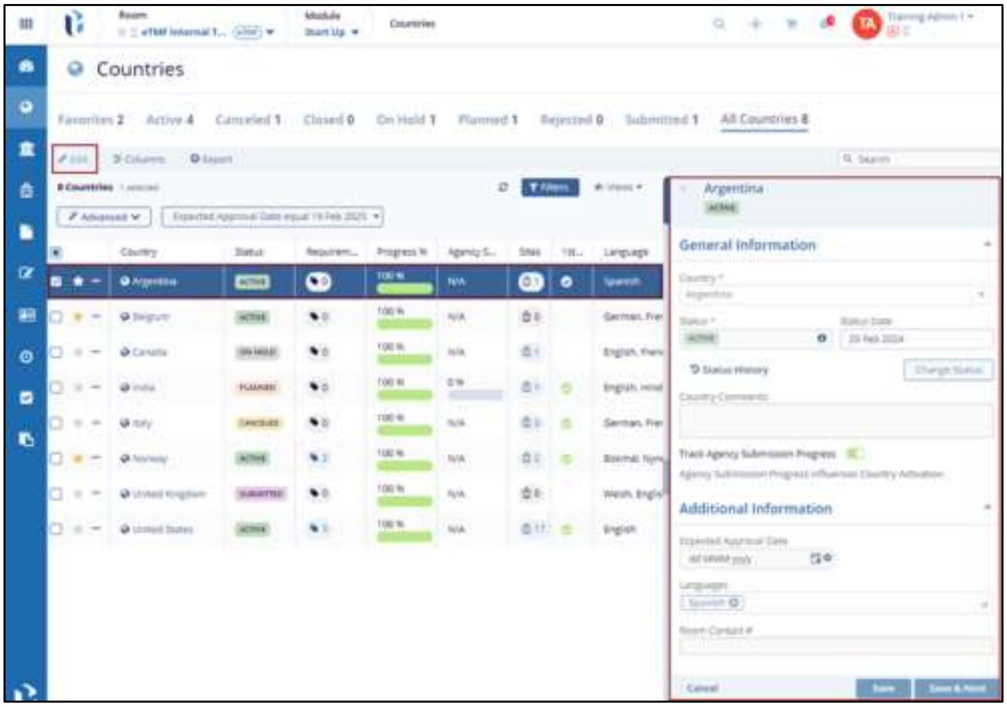
- Select – displays the countries added based on the created filter.
- Edit – displays the Update Filter pop-up window to edit the created filter. Additionally, the Cancel, Run, Save & Run, and Save As New buttons are displayed at the bottom of the Update Filter pop-up window.
  - Run – This filter will be replaced in the current view without saving. The user must save the view separately by clicking on save view.
  - Save & Run – These filter changes will be saved and then updated in the current view.
  - Save As New – These filter changes will be saved as the new view and the original filter will be replaced by what's in the current view.

- Delete – The created filter disappears from the grid view.

Editing Country

To edit the country, follow the steps below.

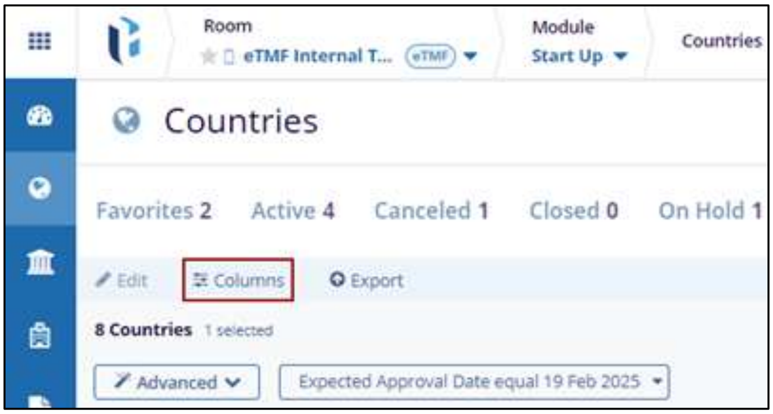
1. Locate the country for editing and click the Edit button.
2. The metadata panel is displayed on the right side of the screen.
3. Edit the information as per the requirement and click Save to save the edited information. However, the Save & Next button directs the user to the next country.



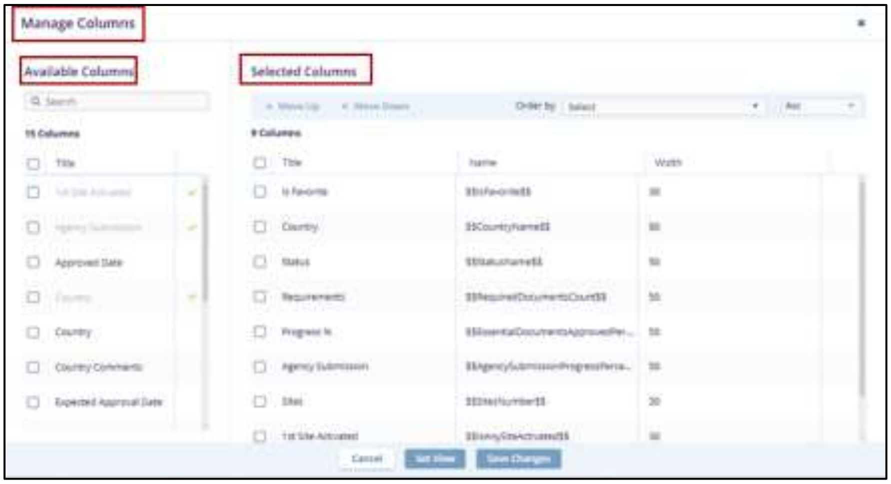
Columns

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:

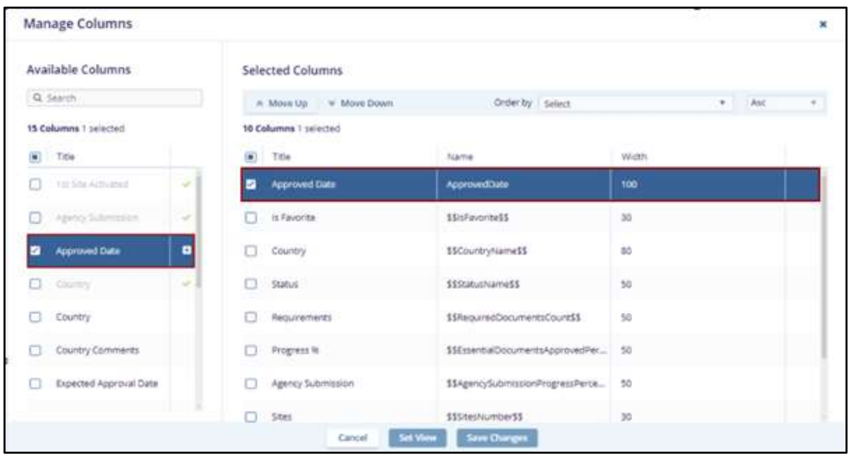
1. Click the Columns button displayed in the top left corner of the screen. This opens the Manage Columns popup window.



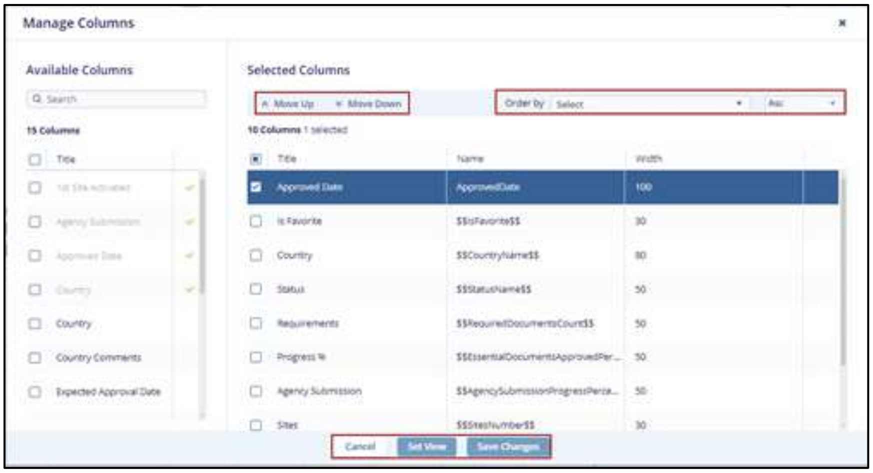
2. On the Manage Columns window, the "Available Columns" section lists the column titles, while the "Selected Columns" section shows the chosen columns.



3. Select the required checkbox(es) and click the Plus icon next to the chosen title in the "Available Columns" section.



4. Click on the ‘Move Up’ and ‘Move Down’ arrow to rearrange the order.
5. Select the ‘Order by’ option and select either ‘Ascending’ or ‘Descending’
6. Click an appropriate option from the following – Cancel, Set View, or Save Changes as required.



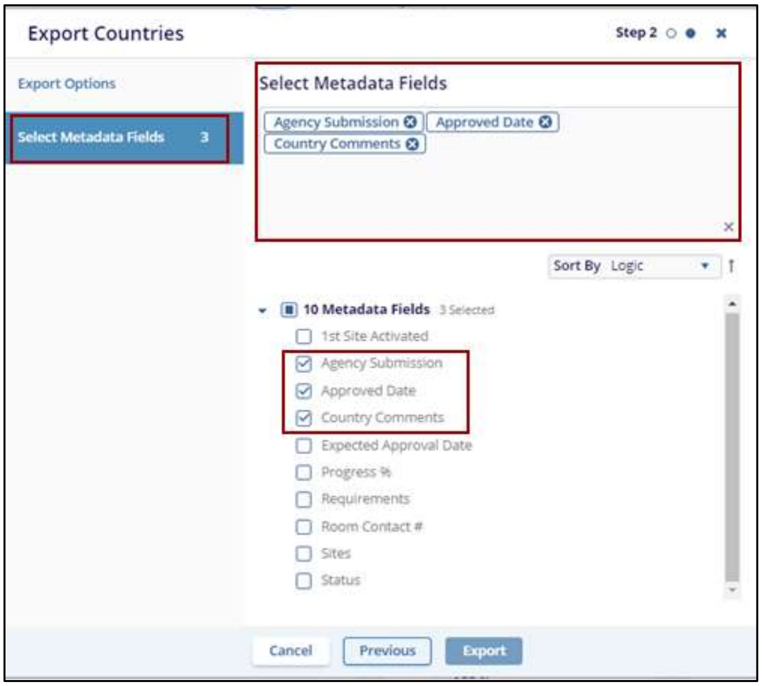
Export

Follow the steps below to export the countries in the Country module.

1. Click the Export button. The Export Countries pop-up window is displayed.
2. The Export Countries display the 'Export Options' tab and the 'Select Metadata Fields' tab.

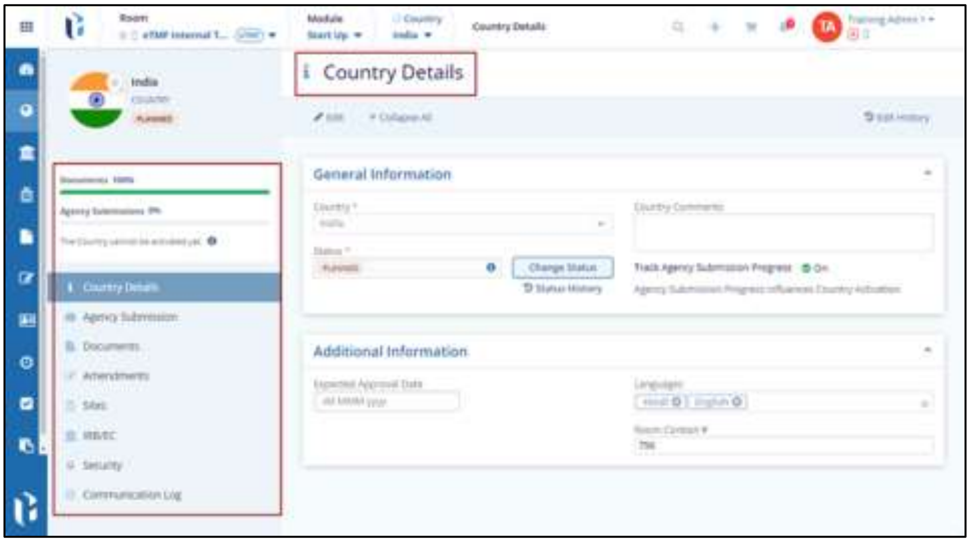
3. The Export Options displays the below options. The user can choose the option as per the requirement.
    - Selected Record (s)
    - All contacts in the current grid
    - All contacts in the room
4. Choose the option for export and click the Next button.

5. The Select Metadata Fields page is displayed, with 10 Metadata Fields available by default.
6. Tick the checkbox for the required metadata. The selected metadata fields will appear in the "Select Metadata Fields" box.
7. Click Export to export the data, Previous to return to the previous page, or Cancel to discard the changes.



Country Details

The Country Details 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.



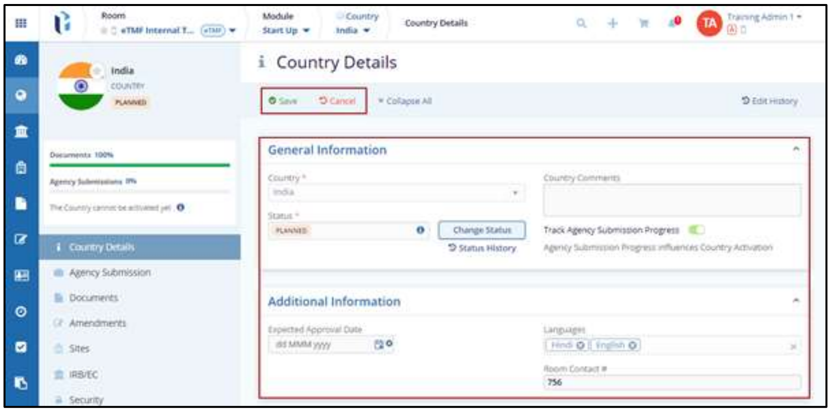
Edit details

The user can view the following edit options on the Country Details page.

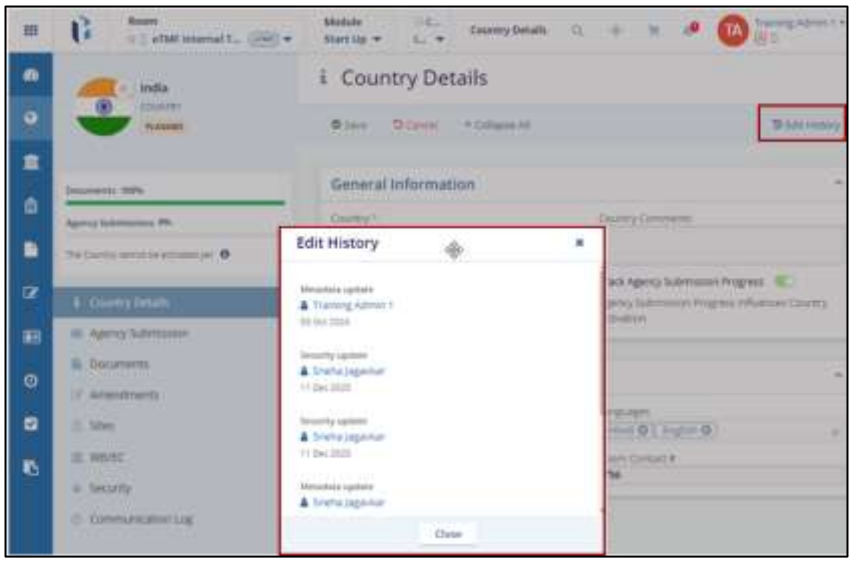
- Edit - Edit fields in General Information and Additional Information for the Country.
- Edit History - The user can only view the details of the history and cannot make any changes.

Steps to Edit Country details:

1. Click on the Edit button at the top of the grid. It will enable all fields as shown in the below image.
2. Edit the options as per the requirement and click on the Save button.



3. On the top right side of the page, click the Edit History button to view past edits.



Change Status

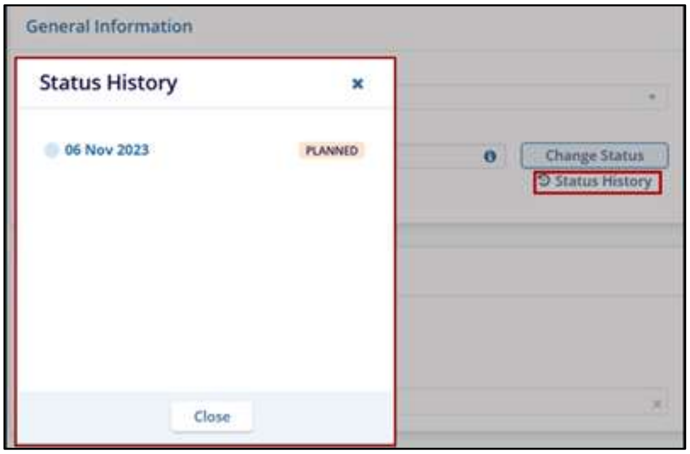
The user can change the status of a country by following the steps below:

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.



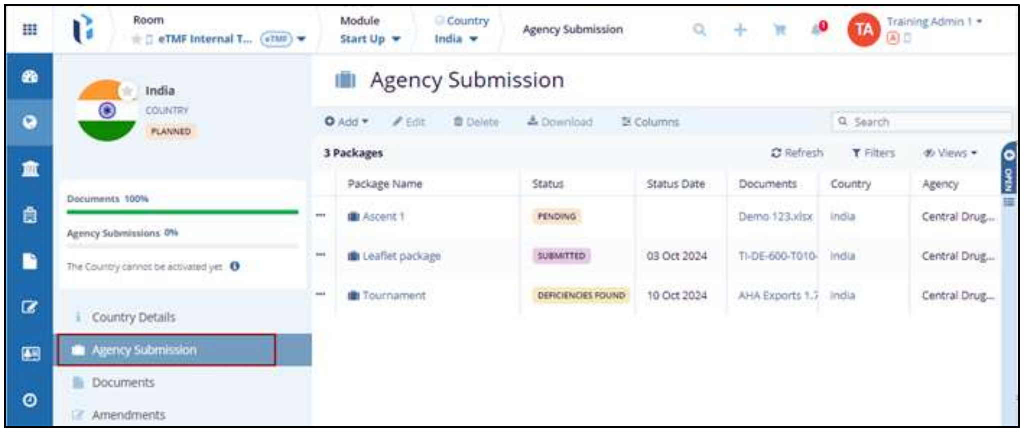
Agency Submissions

The Agency Submission module streamlines the approval process for activating clinical study sites. Users can create submission profiles, specifying agency details, submission status, required documents, and submission dates. Packages can include documents from various sources (eTMF, SSU, Site, Country, IRB, or disk). Admins and editors manage profiles, perform QC reviews, and track multiple submissions per country. If a package is rejected, new submissions can be made. Approved documents remain in the submission package but are not transferred to the eTMF.

Defining Health Agencies

Health agencies must be defined at the domain level before adding submission profiles and downloading packages. These agencies are then associated with sites.

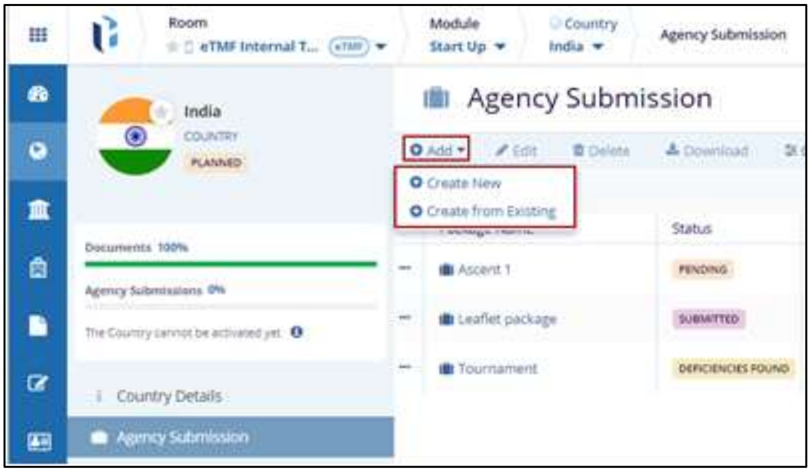
Note: Contact the help desk to create Health Agencies if they are not already created.



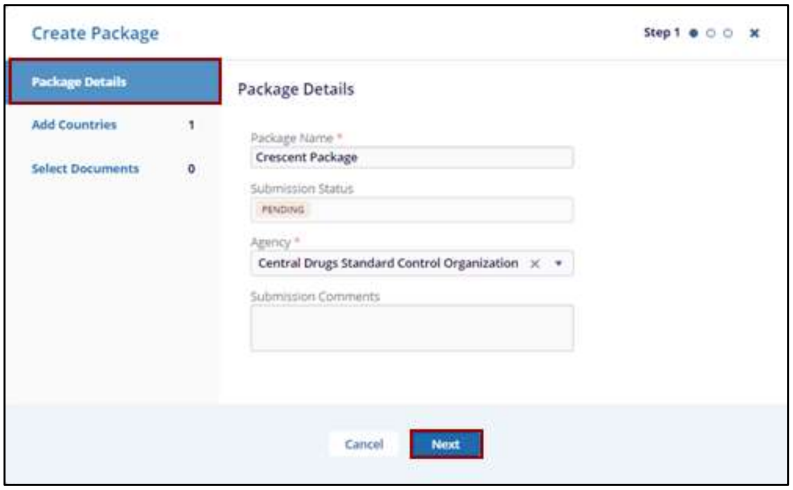
Add Agency Submission

Follow the below steps to add the agency:

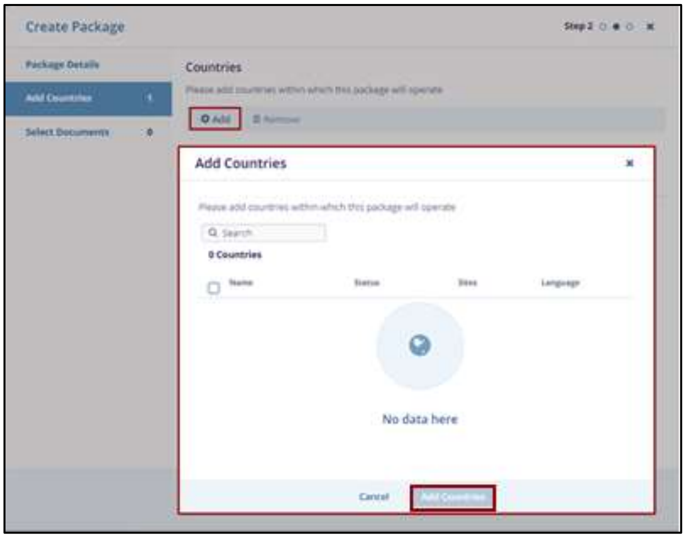
1. Click the Agency Submission option on the Country Details page. This opens the Agency submission Page.
2. Click the drop-down arrow next to the Add button. The Create New and Create from Existing options are displayed.



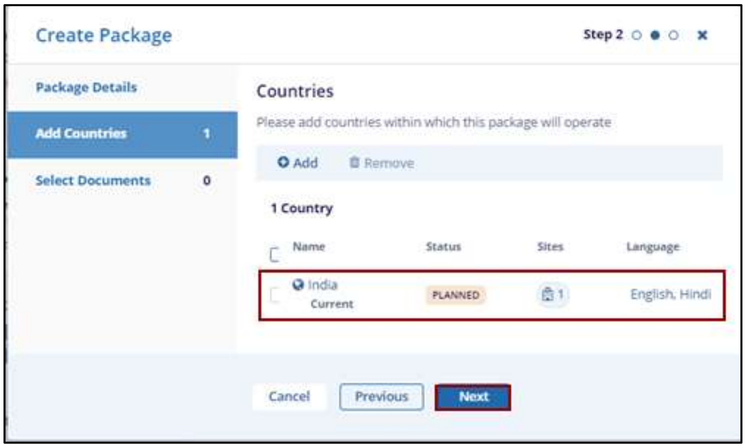
3. Click the Create New option. The Create Package pop-up window is displayed.
4. In the Package Details tab, fill in the required fields - Package Name, and Agency.
5. Click the Next button at the bottom of the popup window.



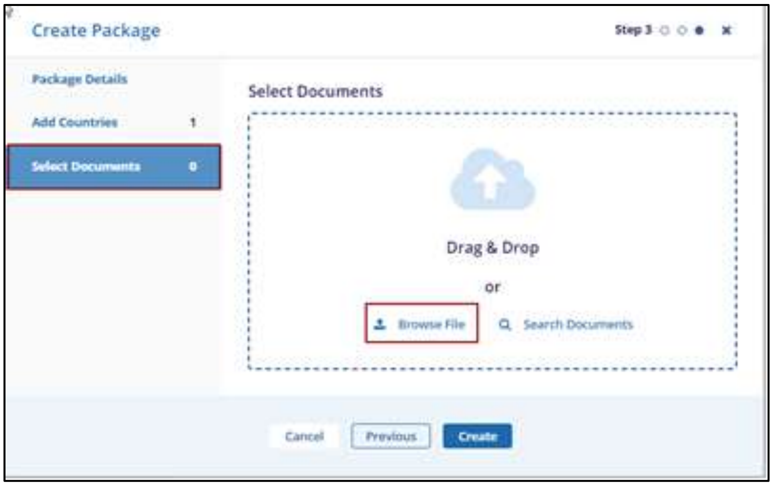
6. This opens the Add Countries tab, click on the +Add button to add a country.
7. The Add Countries pop-up window is displayed.

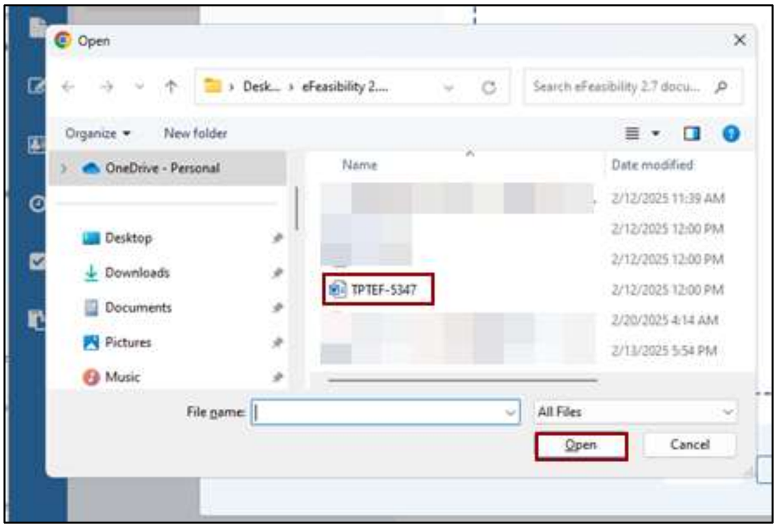


8. Click Add Countries, and the added country is displayed within the Add Countries tab.
9. Click on the Next button once the required countries within the package have been added.

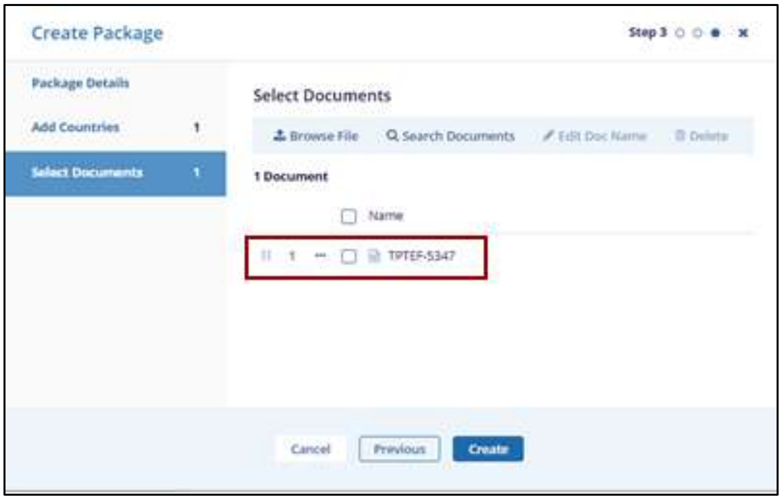


10. This opens the Select Documents tab. Select an appropriate option – Browse Files OR Search Documents.
11. Click on the Browse Files option, select a document from the system, and click on Open.

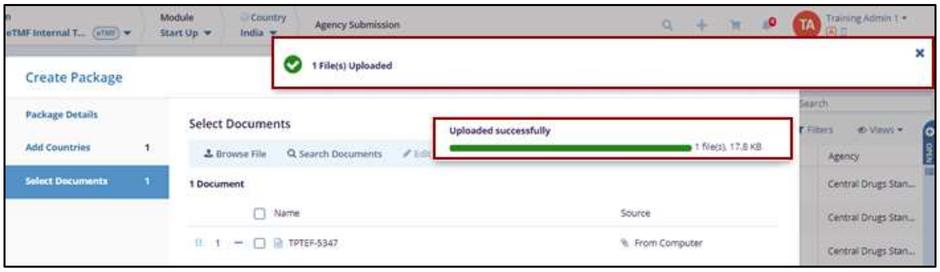




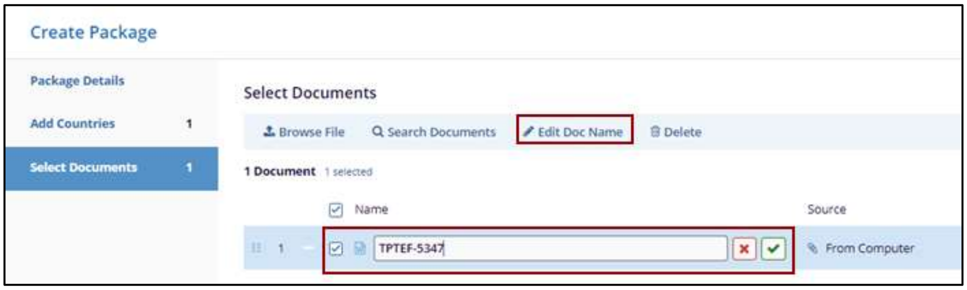
12. The selected document is added to the Select Documents tab.



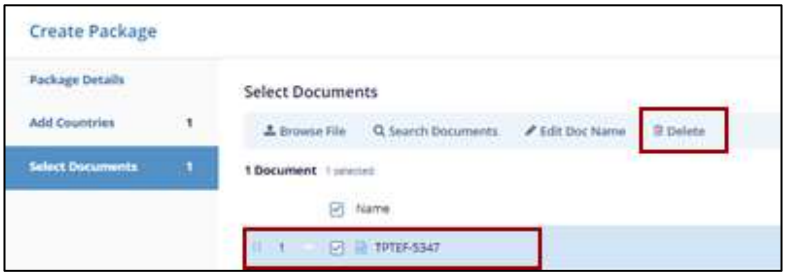
13. The notification message is displayed on the top right side of the screen.



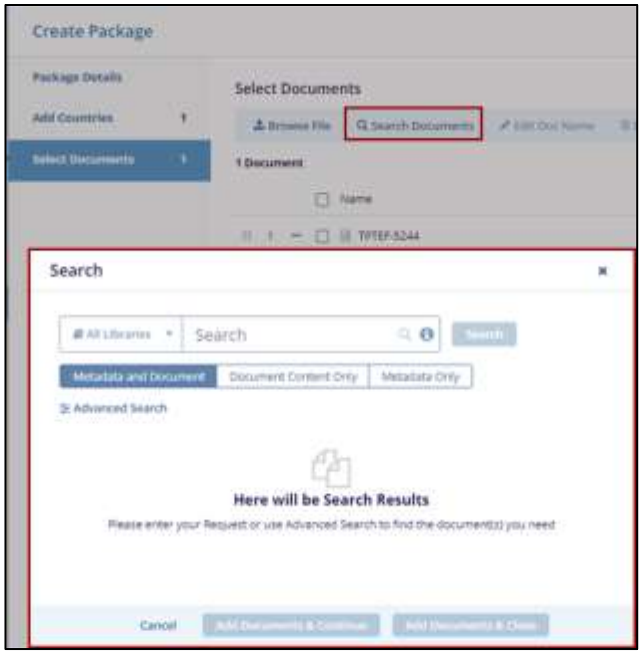
14. Once the document is uploaded, select the document click on the Edit Doc Name, make the required changes, and click the Tick mark beside the document.



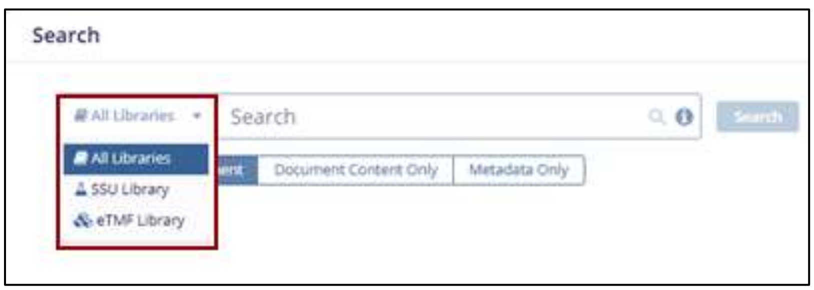
15. Select the document and click Delete the button to discard the action.



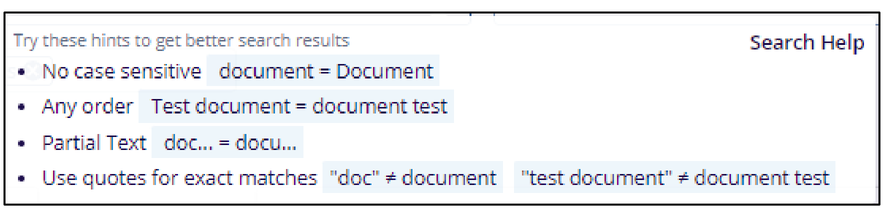
16. Click the Search Documents tab the Search pop-up window is displayed.



17. Expand the All-Libraries arrow to search from SSU Library or eTMF Library.

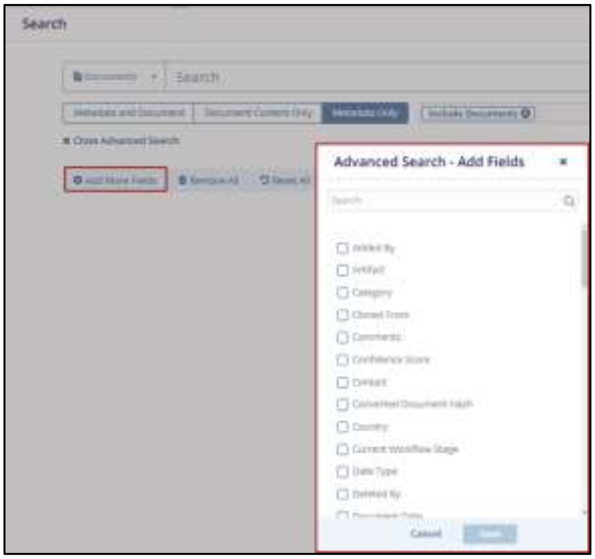


Note: Some hints to get better search results:

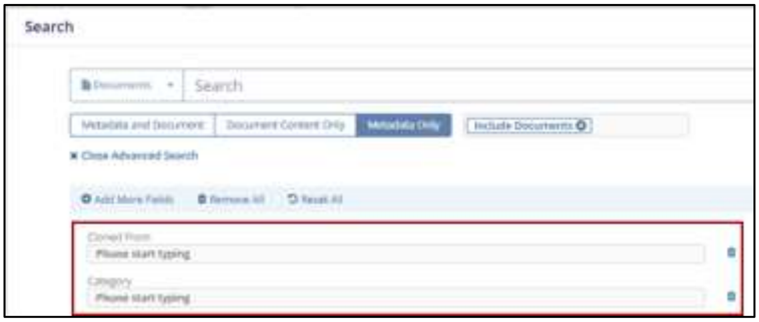


18. Clicking the Advanced Search button in the search pop-up window redirects the user to the Advanced Search page.

19. Users can add unlimited fields as needed with the + Add More Fields button. The Advanced Search – Add Fields pop-up window is displayed.



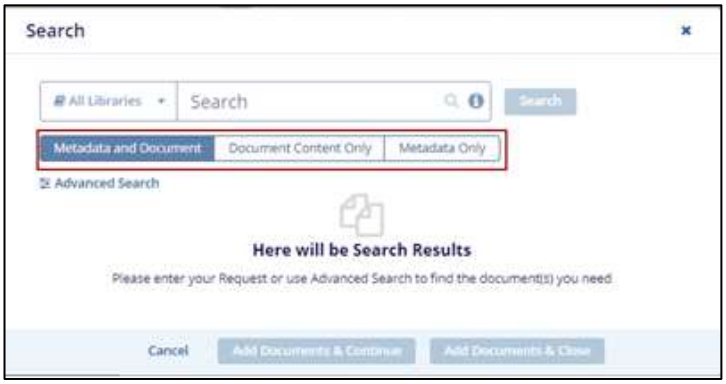
20. Select the fields and click the Save button.



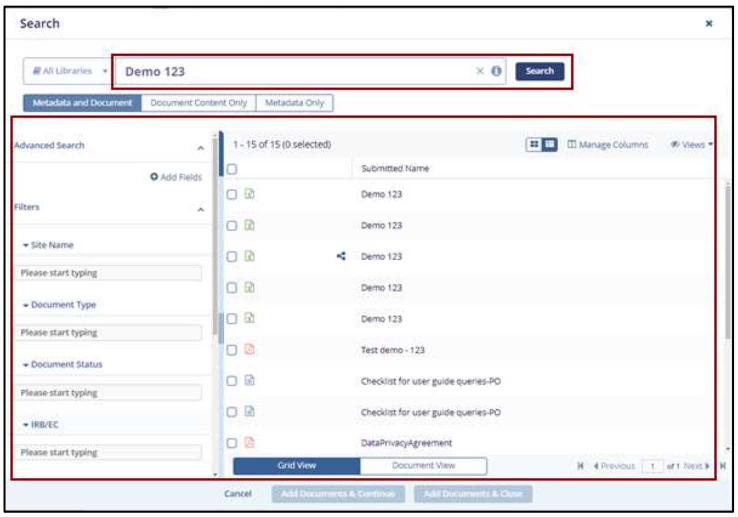
21. Click the Remove All option to remove the added fields.
22. Click Reset All resets the page with the existing information.

23. The Search pop-up window displays the below three tabs by default.
    - Metadata and Document
    - Document Content Only
    - Metadata Only

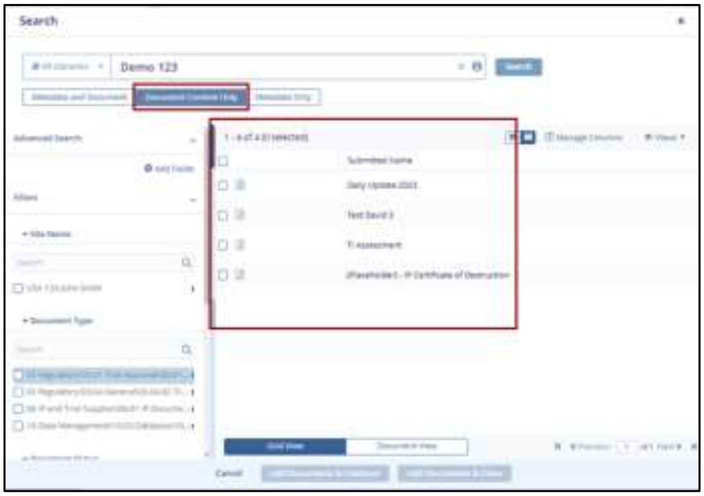
Note: The Metadata and Document tab is pre-selected by default. Choose Document Content Only or Metadata Only if you want to filter the results accordingly.



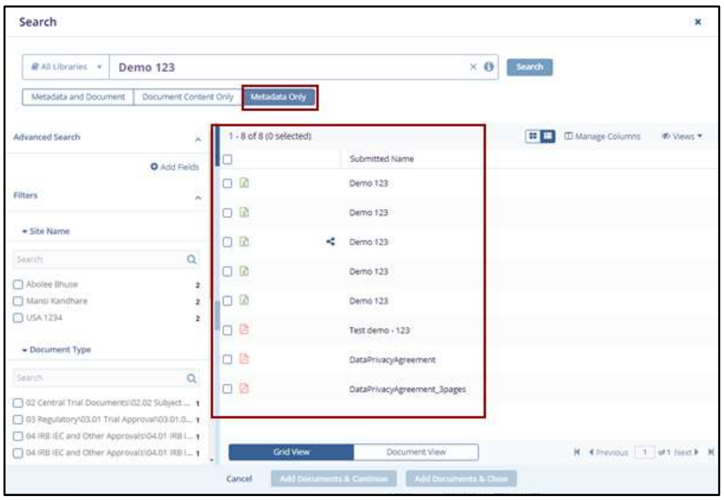
24. Enter the document name in the Search field and click Search. The searched document is displayed with the Metadata on the left side.



25. Click the Document Content Only tab it will display the document based on the content only.

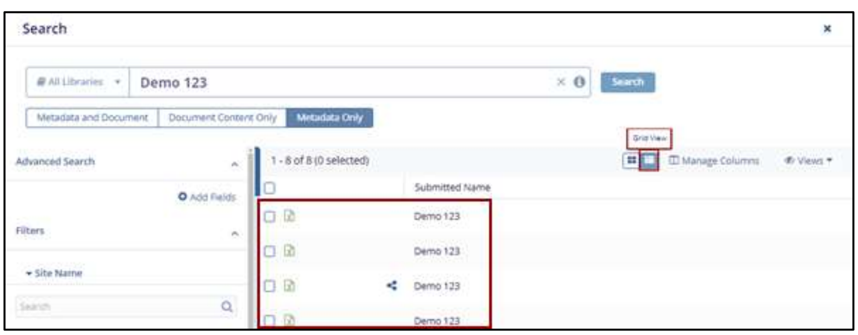


26. Click the Metadata Only tab it will display the document having metadata.

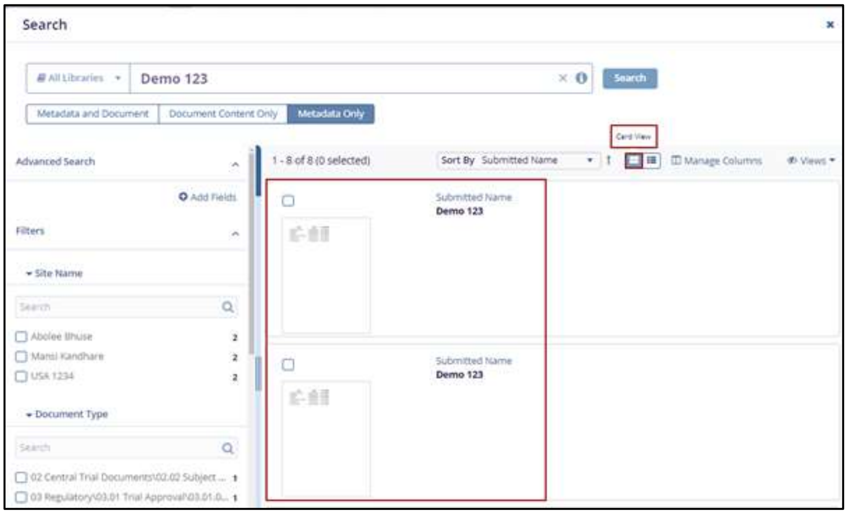


27. The users can view the views in two ways:

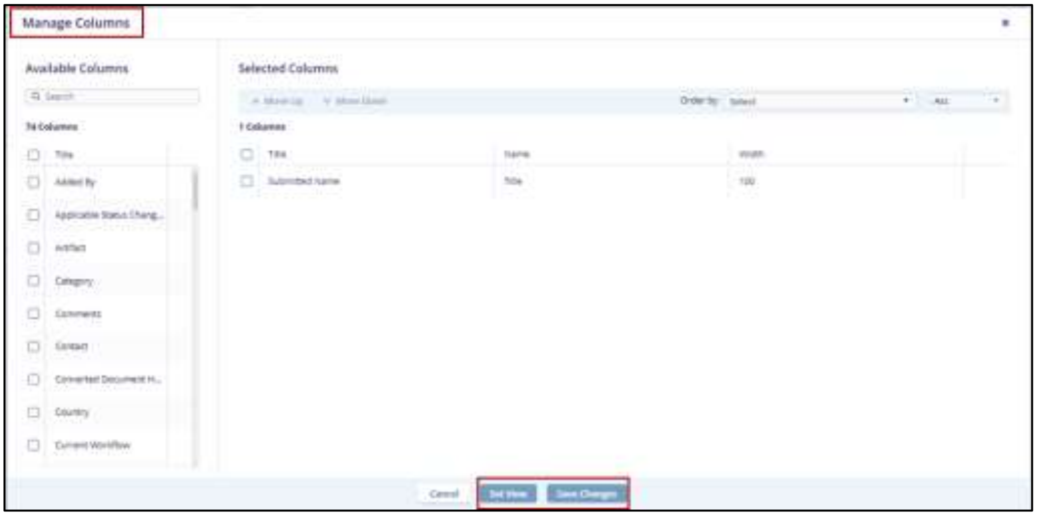
- Grid View



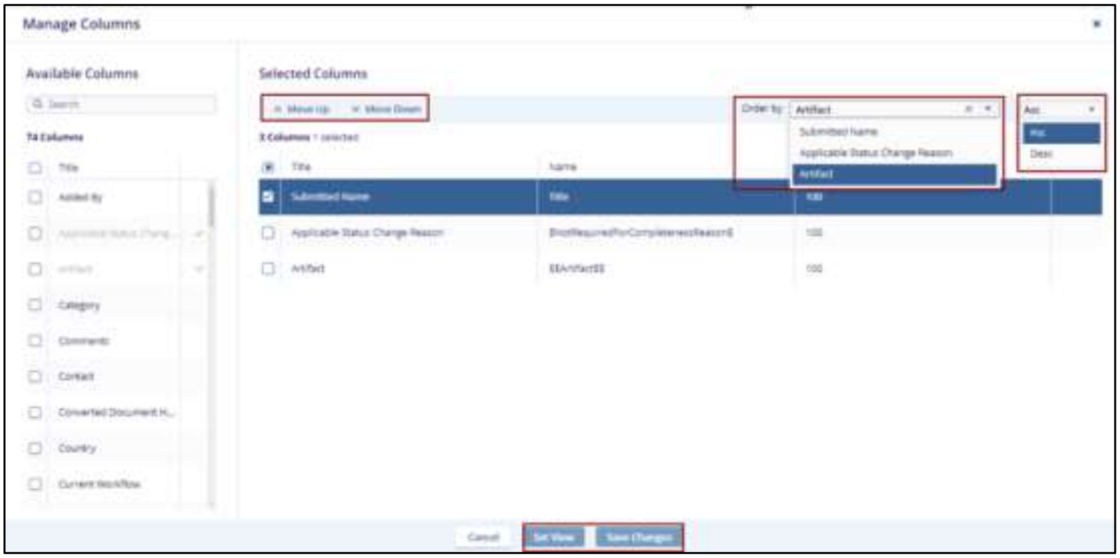
- Card View



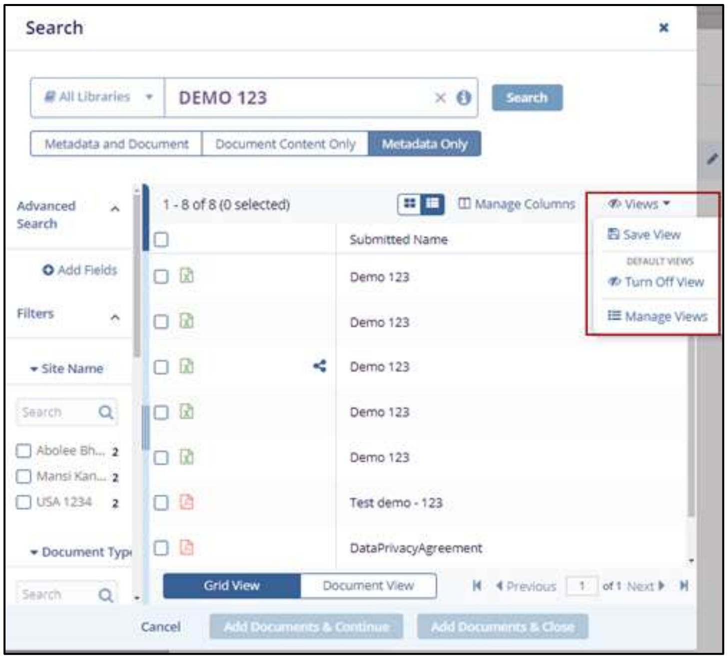
28. Click the Manage Columns to customize the information displayed. The user can add or remove columns that need to focus on specific details relevant to the review on the Manage Columns pop-up window.
29. Save View to save the current selection as a new view, or click Save Changes to apply the modifications to the existing view.

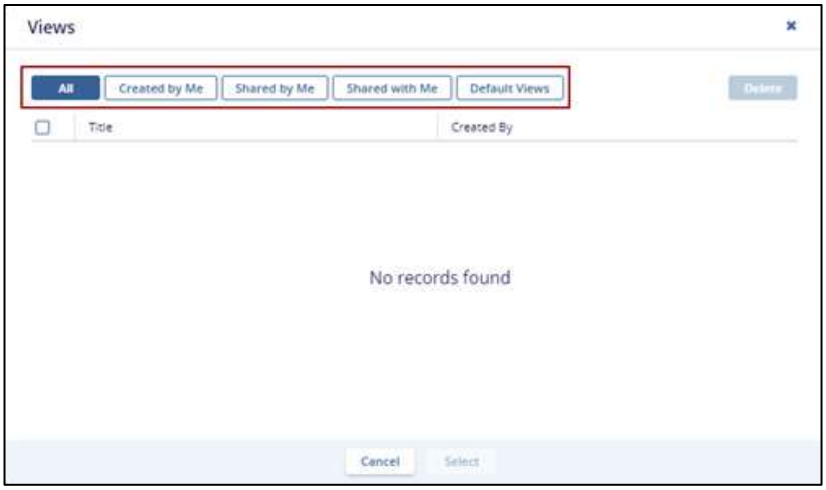


30. Use the Move Up and Move Down arrows to adjust the position of the columns.
31. Use the Order By option to sort the selected columns in Ascending or Descending order.
32. Save View to save the current selection as a new view, or click Save Changes to apply the modifications to the existing view.



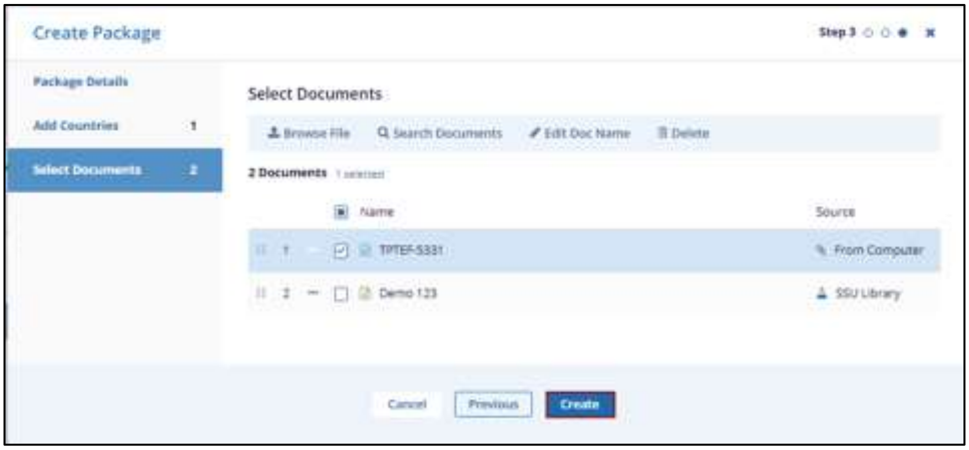
33. Click Views to manage the search views. Select Manage Views to customize views based on options like Created by Me, Shared by Me, Shared with Me, and Default Views.



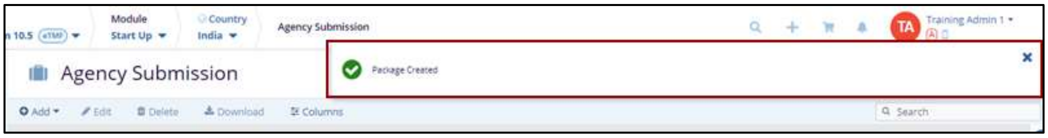


34. Click Add Documents & Continue will display the notification message at the top right of the screen and will continue on the same page to add the documents.

35. Click Add Documents & Close will close the Search pop-up window.
36. Click Create on the Create package pop-up screen.



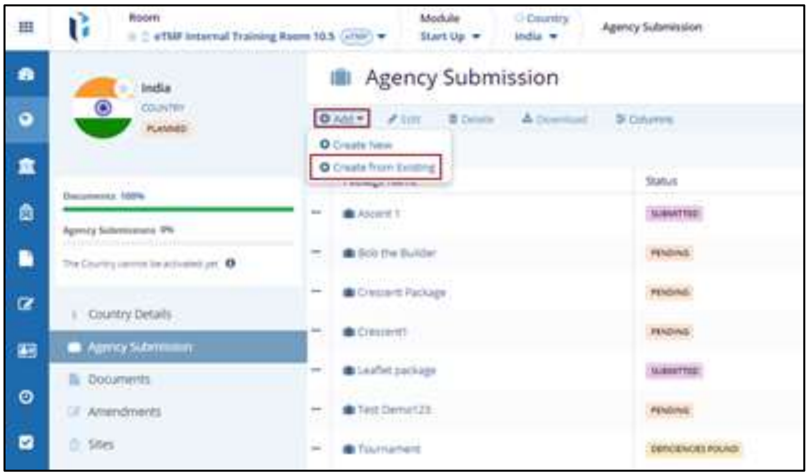
37. The Package Created notification message is displayed at the top right of the screen.



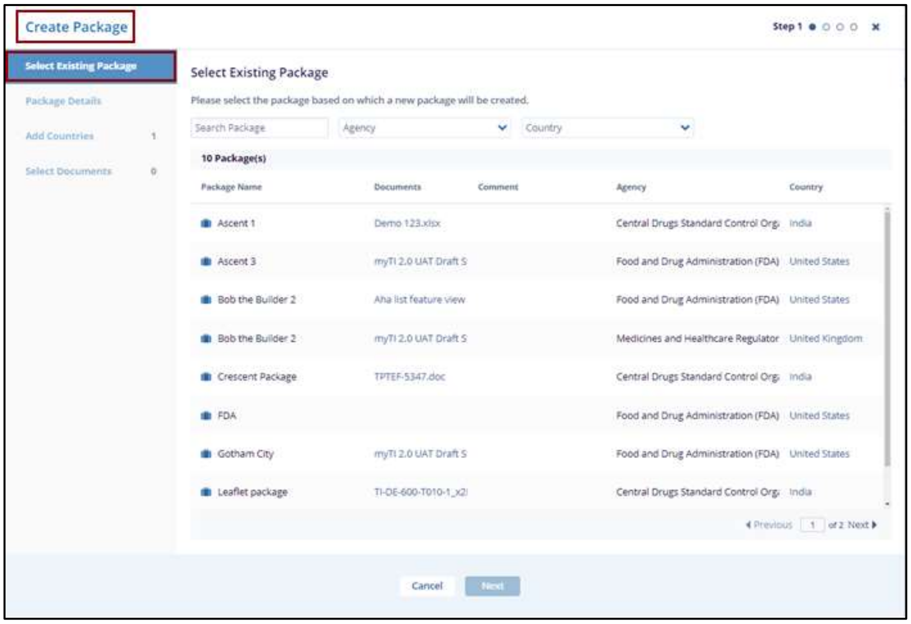
Creating Package from Existing

Follow the below steps to add the existing agency:

1. Click the drop-down arrow next to the Add button. The Create New and Create from Existing options are displayed.
2. Click the Create from Existing option. The Create Package pop-up window is displayed.



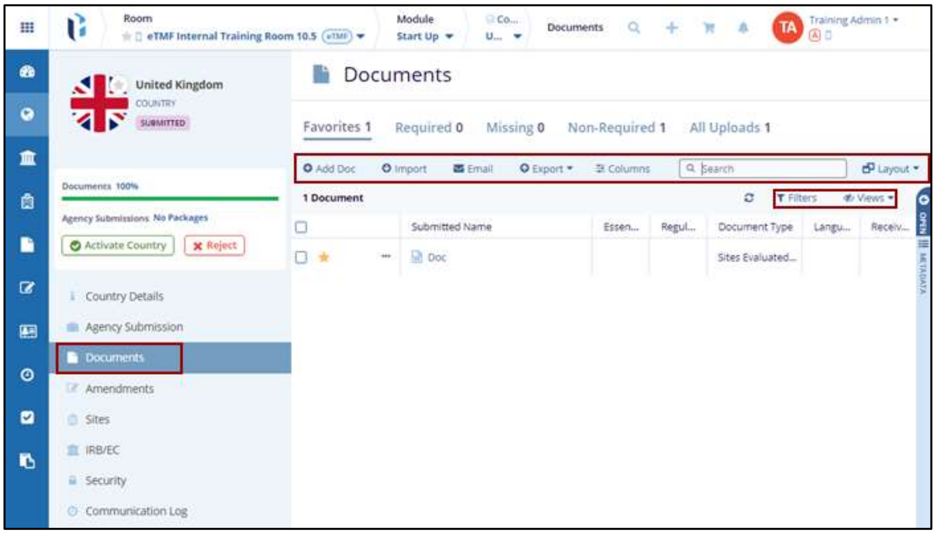
3. In the Select Existing Package, the list of existing packages is displayed.
4. Select the package based on which a new package will be created and click Next.



Follow the steps in the [Add Agency Submission](#) section to update the Package Details, Add Countries, and Select Documents sections for the existing package.

Documents

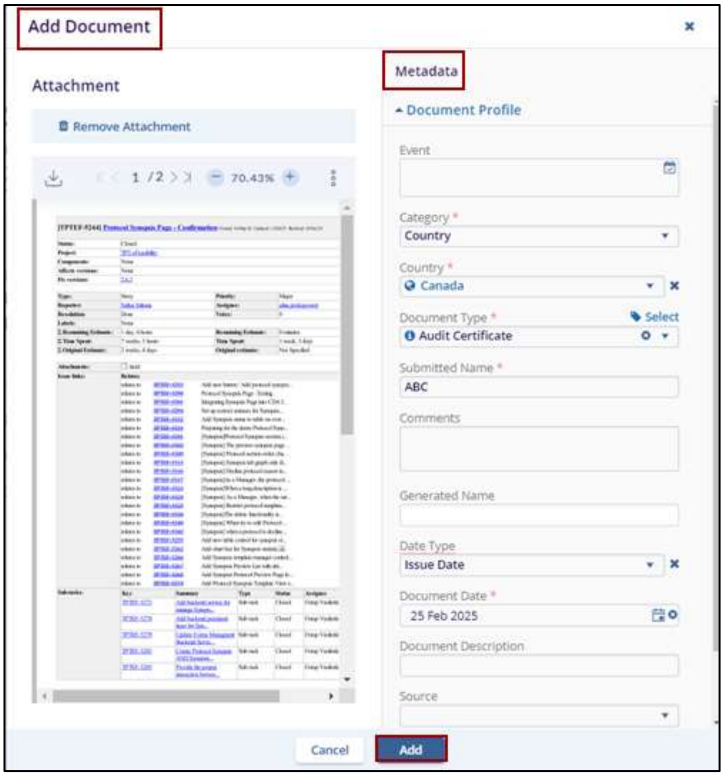
The Documents tab on the Country Details page assists the user in Importing, Adding Docs, Email, Exporting, Manage Columns, Search, Views, and creating Filters.

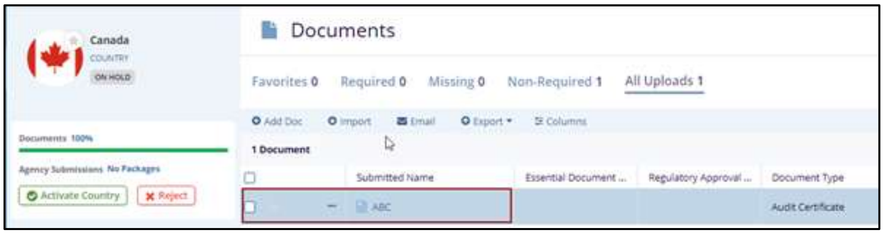


Add Required Doc

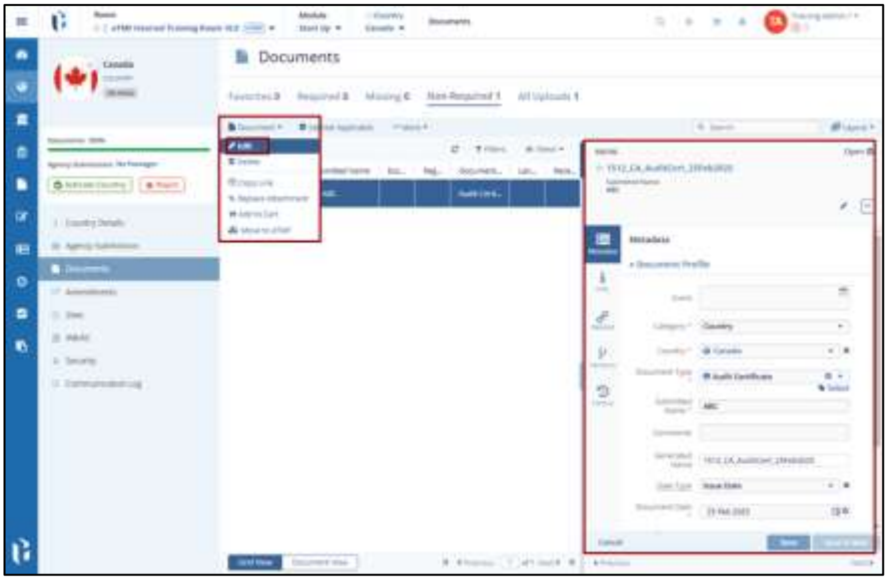
Follow the steps below to add a required document to the country.

1. Click the Add Doc button displayed in the top menu bar, this opens the Add Document popup window.
2. Drag & Drop the required files or click the Browse File option.
3. Select the file from the Windows Explorer and click Open. The selected files get uploaded.
4. Fill in the metadata and click ADD. The document is added to the country.

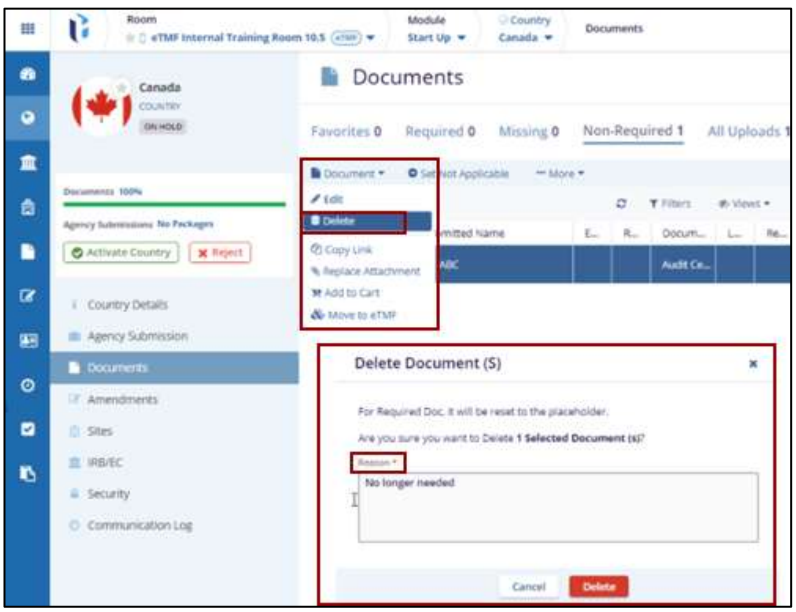




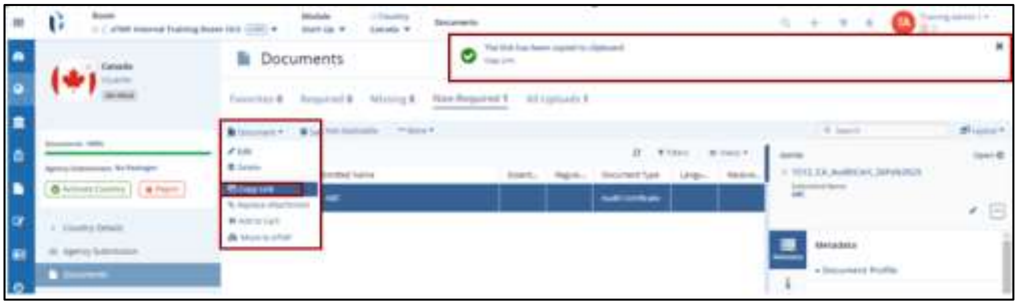
5. Locate the document and click the Document drop-down to edit the document.
6. Click the Edit option, the metadata panel is opened on the right side of the screen.



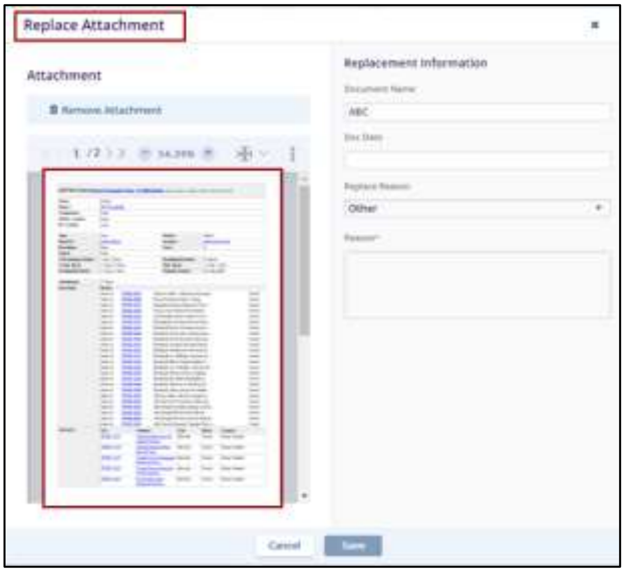
7. Edit the fields and click the Save button on the metadata panel the edited fields get updated.
8. Locate the document and click the Document drop-down arrow.
9. Click the Delete option, and the Delete Document(s) pop-up window is displayed with the Reason box.



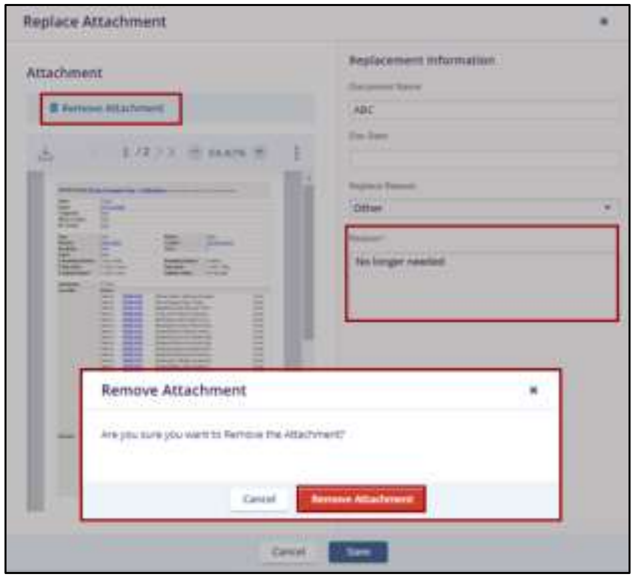
10. Locate the document and click the Document drop-down arrow.
11. Click the Copy Link option, the notification message is displayed on the top right of the screen.



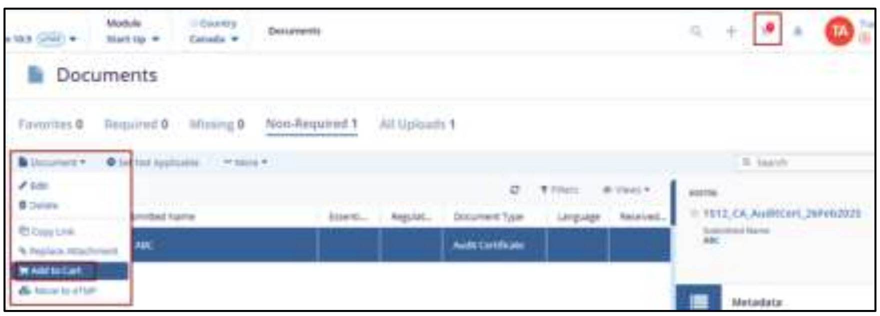
12. Locate the document and click the Document drop-down arrow.
13. Click the Replace Attachment option. The Replace Attachment pop-up window is displayed with the existing attachment.



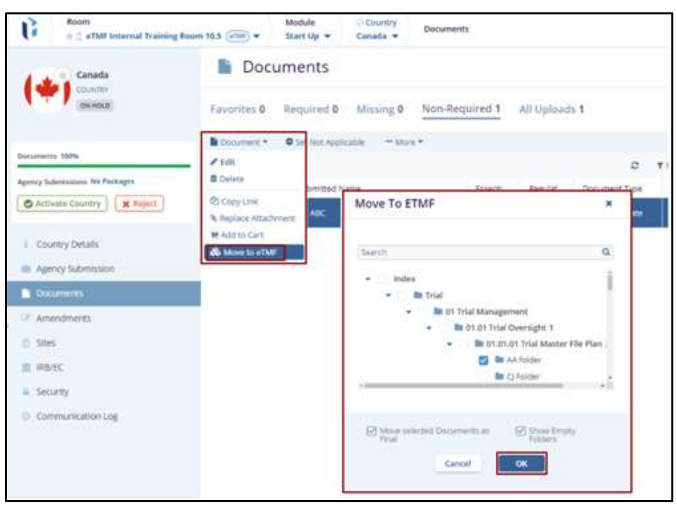
14. To remove the attachment, the user needs to provide a reason in the Reason box and click Remove Attachment.
15. The Remove Attachment pop-up window is displayed with the Cancel and Remove Attachment buttons.
16. Now the user can attach the new document attachment as per the requirement and then click the Save button.



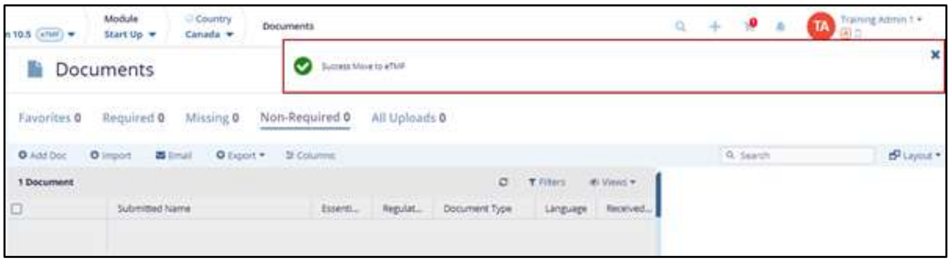
17. Locate the document and click the Document drop-down arrow.
18. Click the Add to Cart option. The selected document gets added to the cart.



19. Locate the document and click the Document drop-down arrow.
20. Click the Move To eTMF option. The Move To eTMF pop-up window is displayed with the list of the available folders in eTMF.
21. Select the appropriate folder from the list and click the OK button.



22. The Success Move to eTMF notification message is displayed on the top right of the screen.

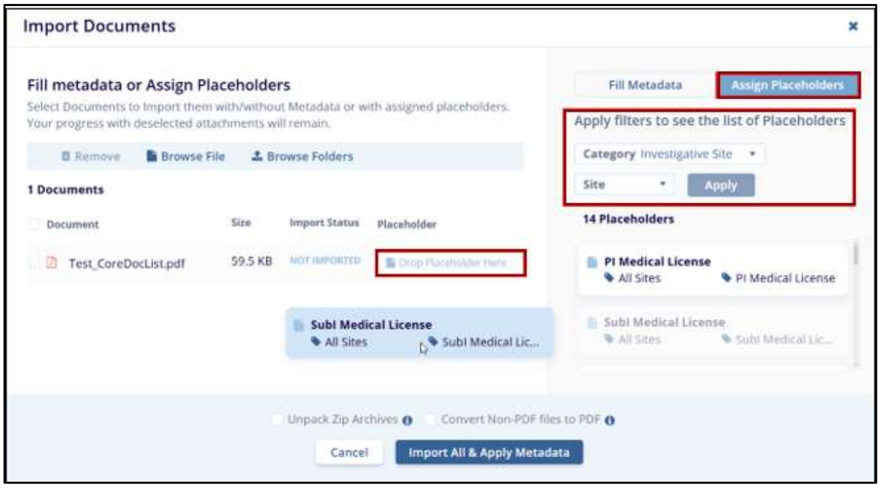


Import Documents

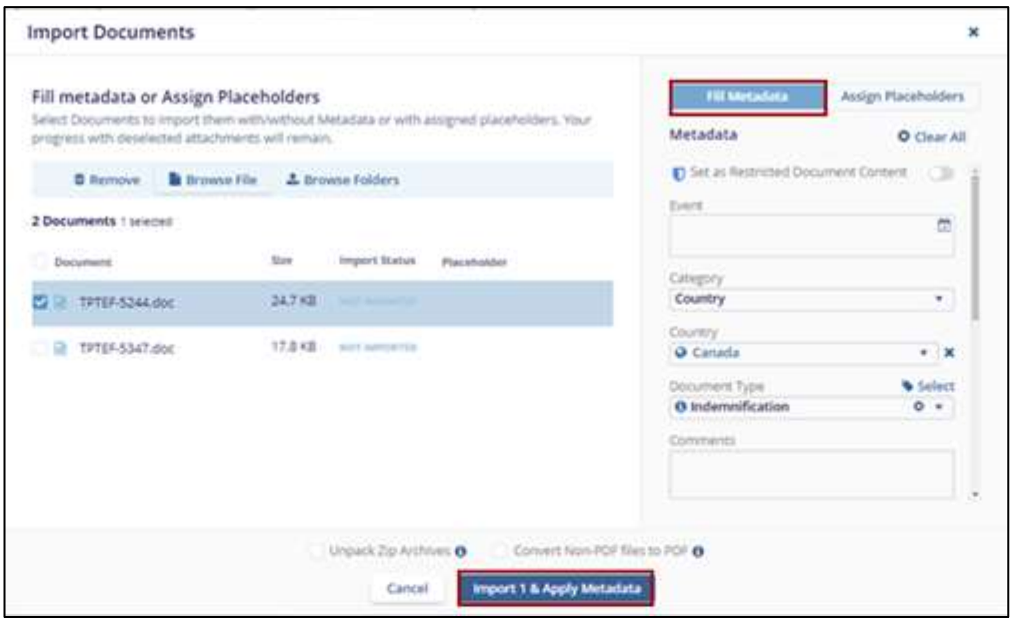
To Import Documents, follow the steps below.

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. Apply the relevant filters within the Assign Placeholders tab.
4. Drag & Drop the necessary placeholder in the designated area.



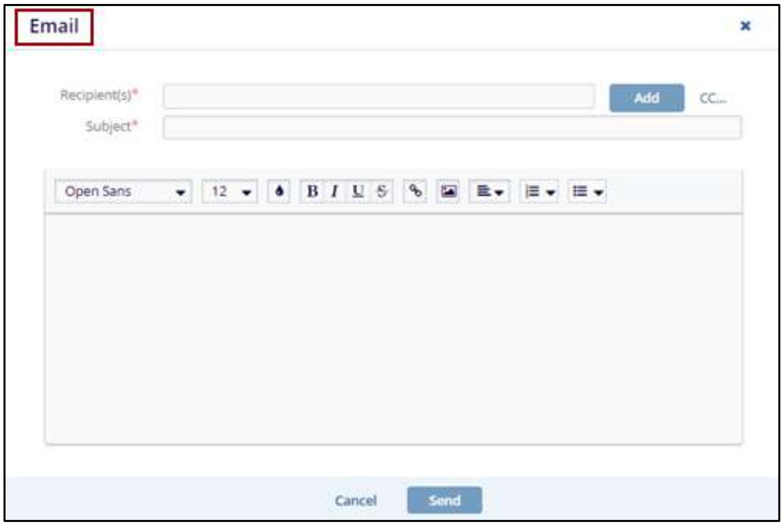
5. Click on the Fill Metadata tab where the Country, Category, and Document Type fields are by default selected.
6. Click on the Import All & Apply Metadata button at the bottom of the popup window.



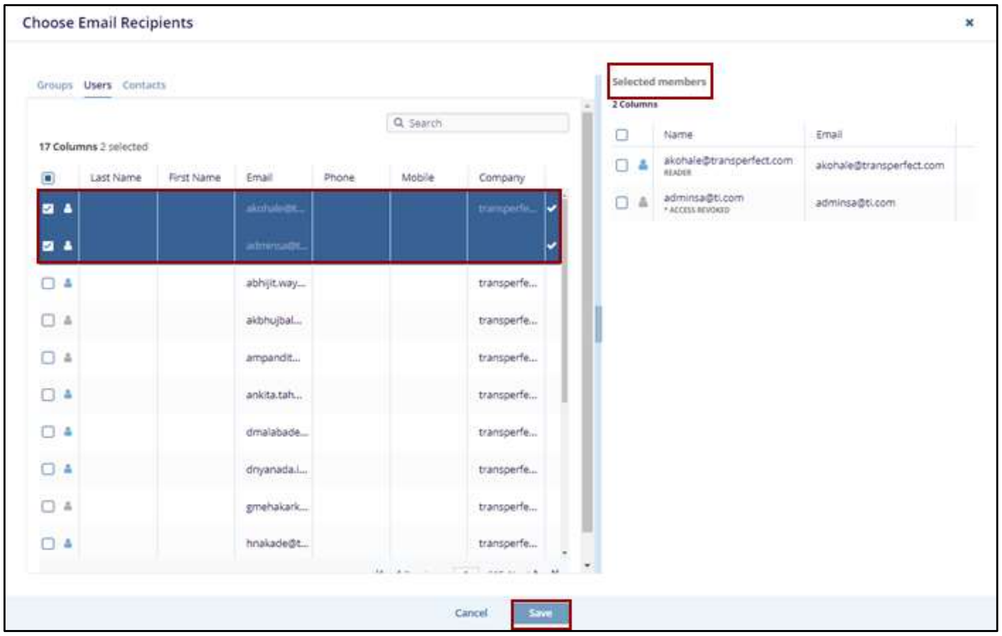
Email

Follow the steps below to send an email to the recipient(s)

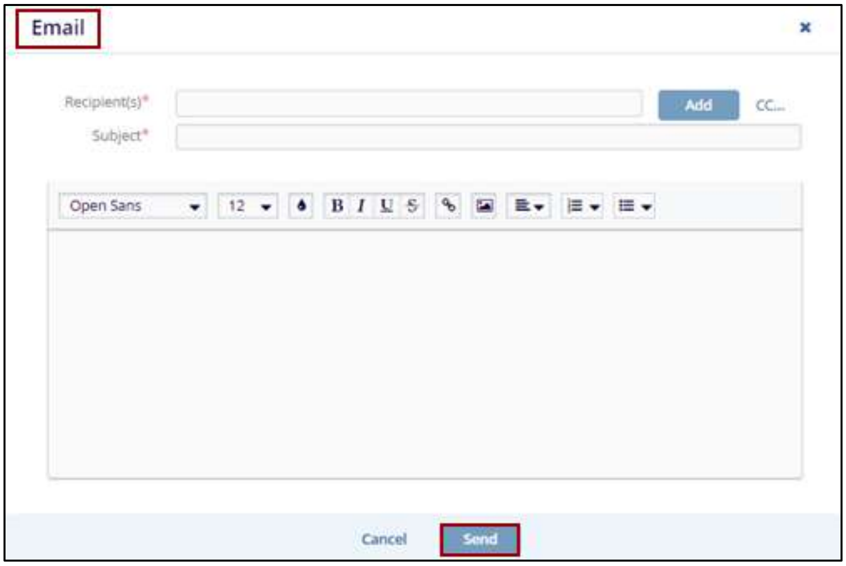
1. Click the Email button displayed in the top menu bar. This opens the Email popup window.



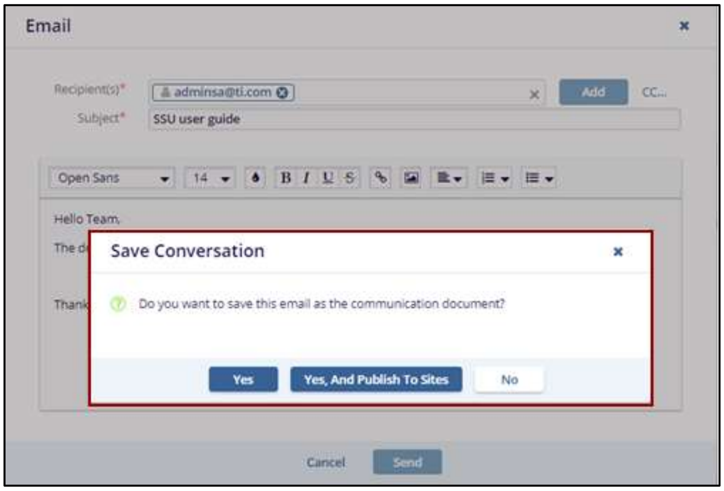
2. Enter the details in the mandatory fields – Recipients, Subject.
3. Click the Add button beside the Recipient(s) and the Choose Email Recipients pop-up window is displayed with the Users, Groups, and Contacts list.
4. Double-click on the Users, Groups, and Contacts from the list. The selected users were added to the right pane (Selected members) of the Choose Email Recipients screen.
5. Click the Save button.



6. Write the mail in the body text box provided below.
7. Click the Send button at the bottom of the popup window.



8. Click the appropriate option – Yes, Yes, And Publish to Investigative Sites, No displayed in the Save Conversation popup window.

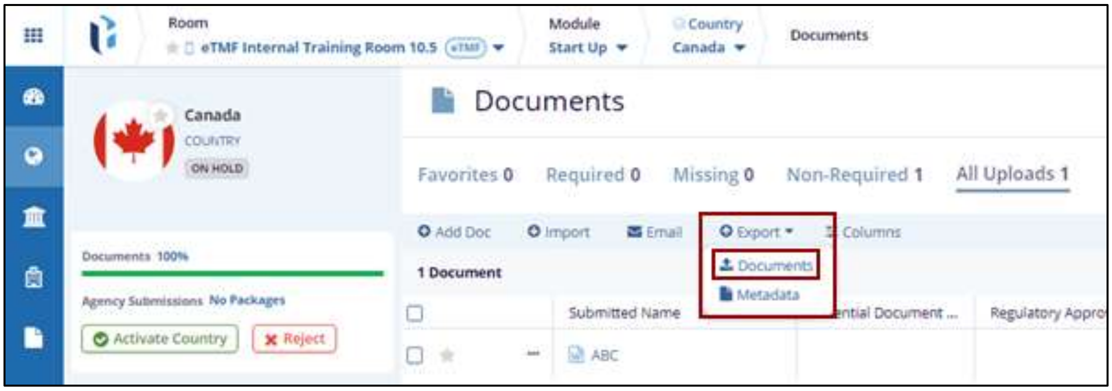


Export

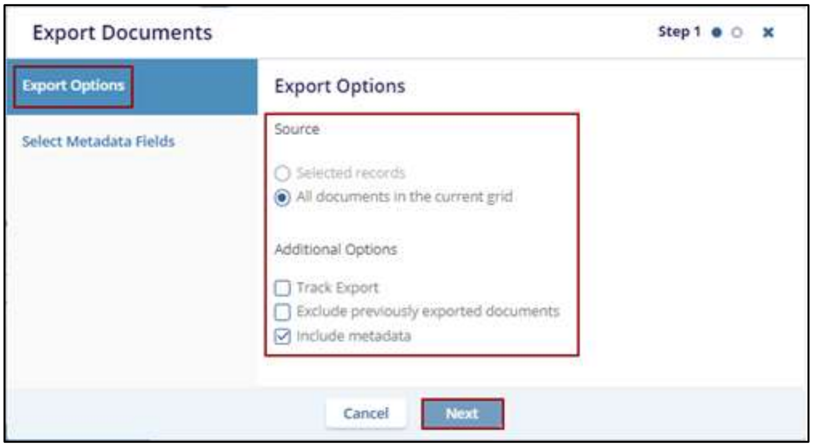
Follow the steps below to export the documents in the Country module.

Exporting Documents

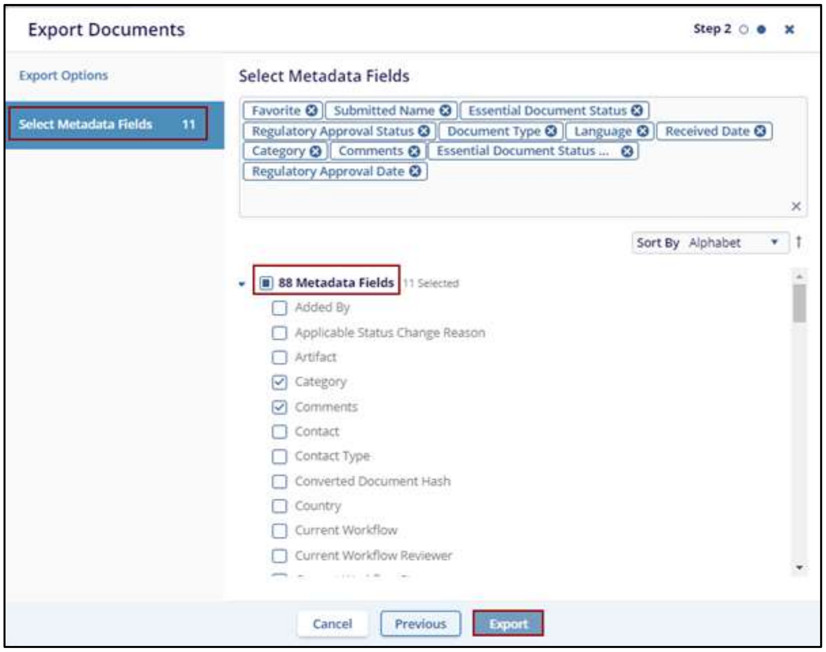
1. Click the Export button displayed on the top menu bar and select the Documents option.



2. The Export Documents pop-up screen is displayed with the 'Export Options' and 'Select Metadata Fields' tab.
3. On the Export Options window, select Source and Additional Options.
4. Click on the Next button.

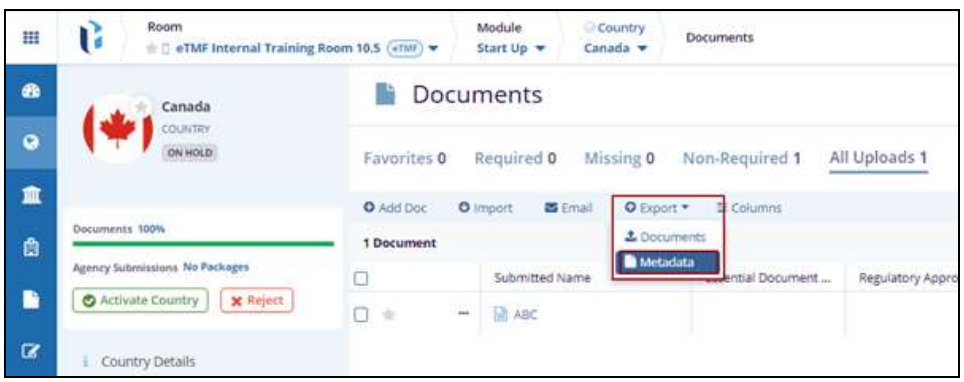


5. On the Select Metadata Fields screen, select the required metadata fields by clicking on the checkboxes.
6. Click on the Export button and the notification message is displayed on the top right side of the screen.

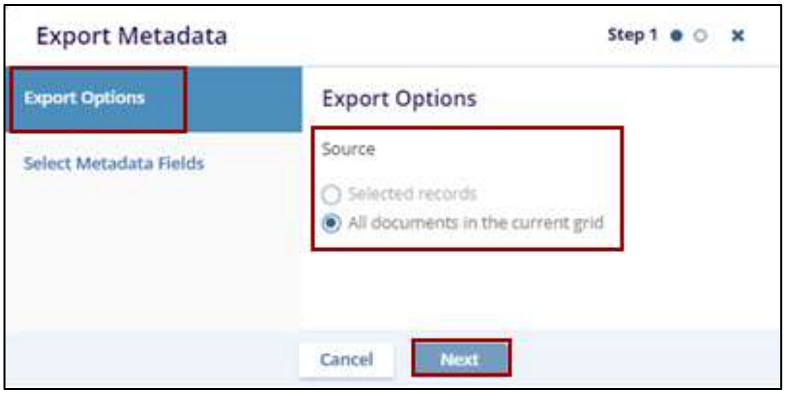


Exporting Metadata

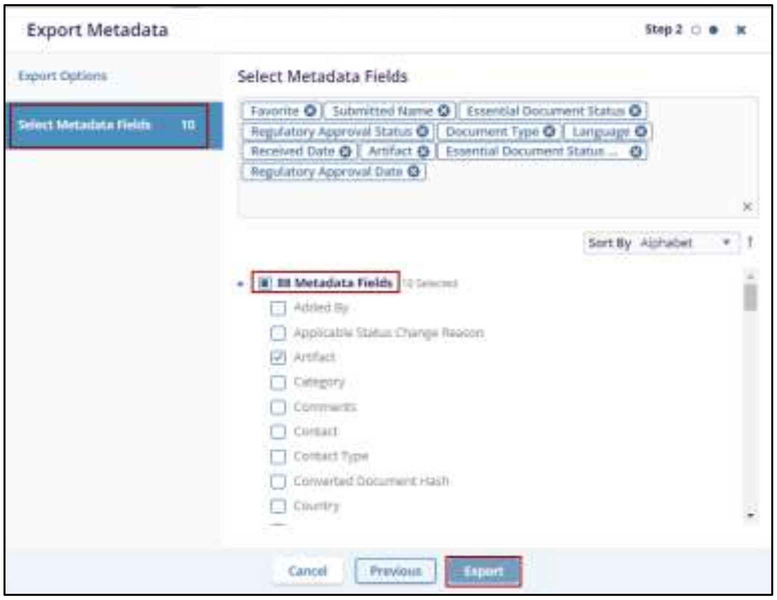
1. Click the Export button displayed on the top menu bar and select the Metadata option.



2. The Export Documents pop-up screen is displayed with the ‘Export Options’ and ‘Select Metadata Fields’ tab.
3. On the Export Options window, select Source.
4. Click on the Next button.



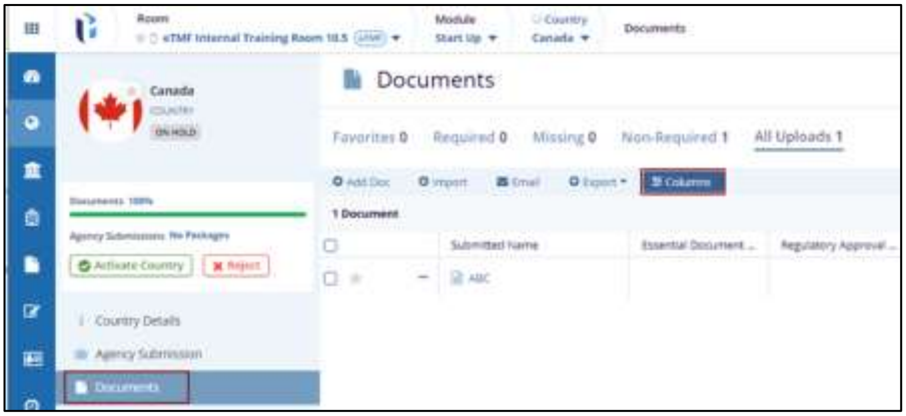
5. On the Select Metadata Fields screen, select the required metadata fields by clicking on the checkboxes.
6. Click on the Export button and the notification message is displayed on the top right side of the screen.



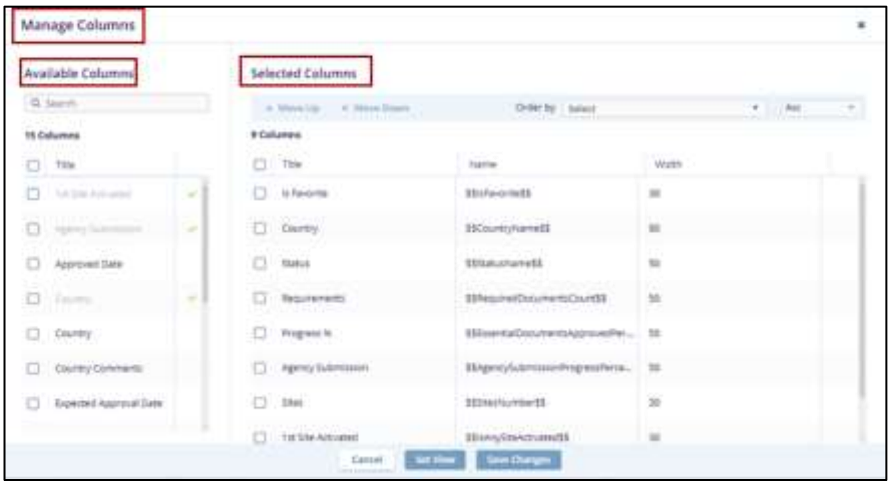
Columns

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:

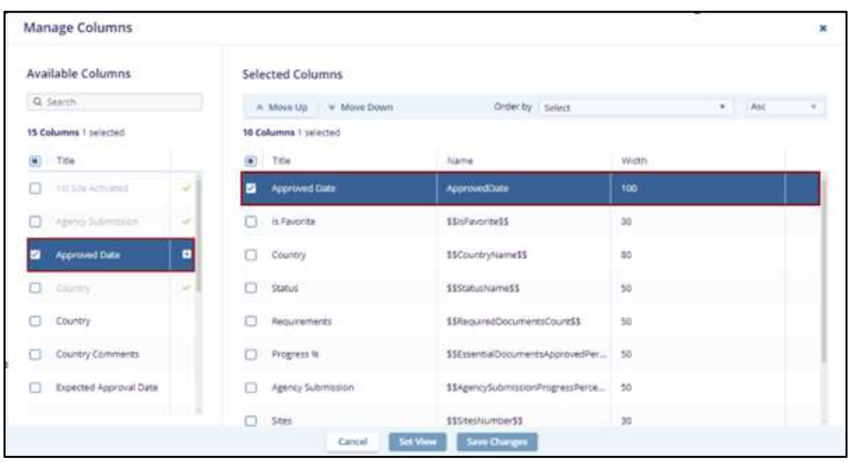
1. Click the Columns button displayed in the top left corner of the screen. This opens the Manage Columns popup window.



2. On the Manage Columns window, the "Available Columns" section lists the column titles, while the "Selected Columns" section shows the chosen columns.

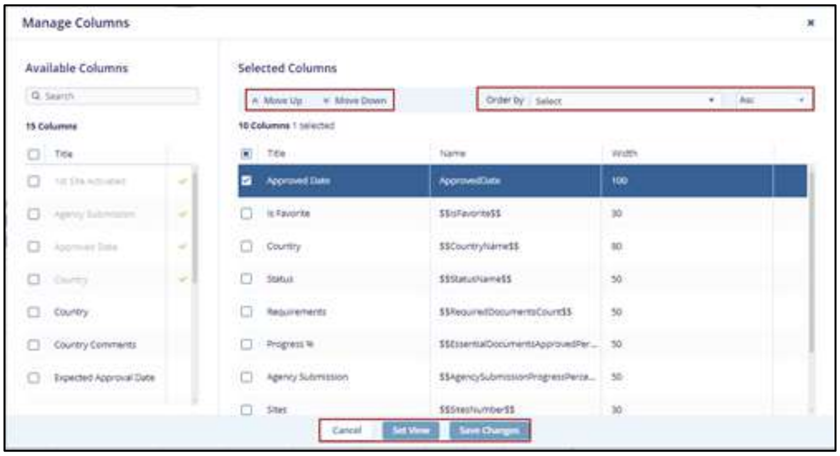


3. Select the required checkbox(es) and click the Plus icon next to the chosen title in the "Available Columns" section.



4. Click on the 'Move Up' and 'Move Down' arrow to rearrange the order.
5. Select the 'Order by' option and select either 'Ascending' or 'Descending'

6. Click an appropriate option from the following – Cancel, Set View, or Save Changes as required.



Filters

To know more detailed information about filters please refer to this link - [Manage Filters] and [Create New Filter].

Views

To know more detailed information about views please refer to this link - [Popular Documents].

Amendments

Once a clinical trial begins, protocol amendments often require sites to submit additional essential documents. These documents can only be specified through Amendments, which can be created for Investigative Sites, Country Amendments, and IRB/EC.

Columns

To know more detailed information about columns please refer to this link - [Columns].

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

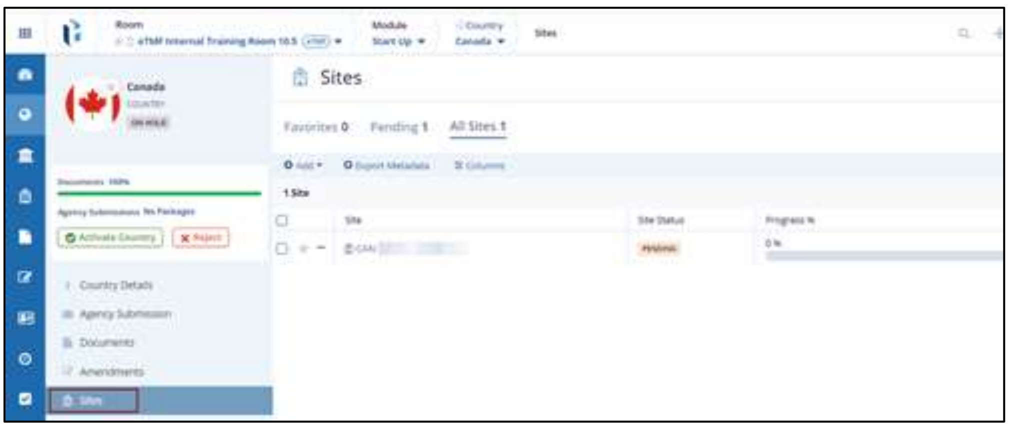
To know more detailed information about views please refer to this link - Popular Documents.

Sites

The Sites tab in the Country module displays all sites associated with the selected country. From this page, users can:

- Add and Import site lists
- Export metadata
- Manage Columns to customize the view
- Search for specific sites
- Manage and Create New Filters for better organization

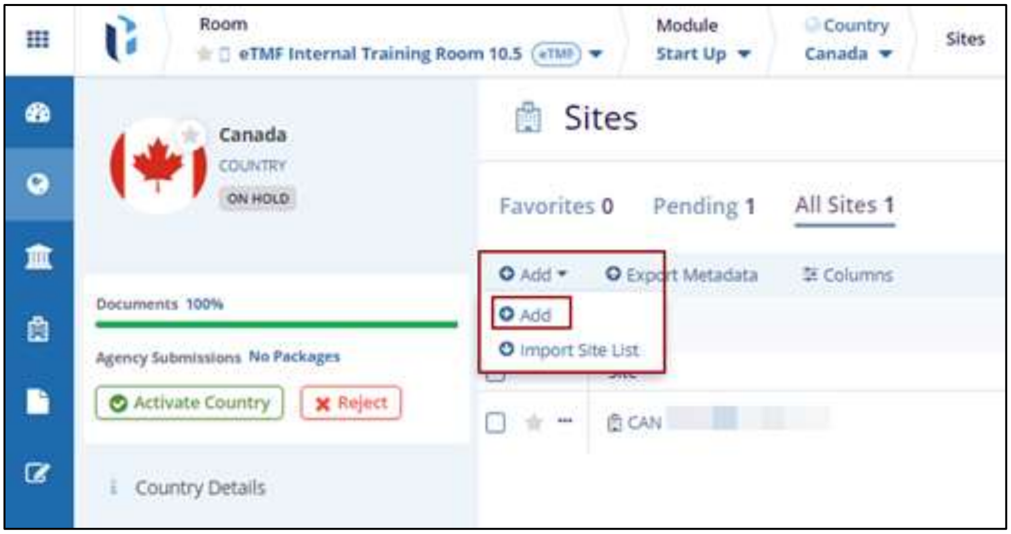
This tab provides a centralized interface for viewing and managing sites linked to a country.



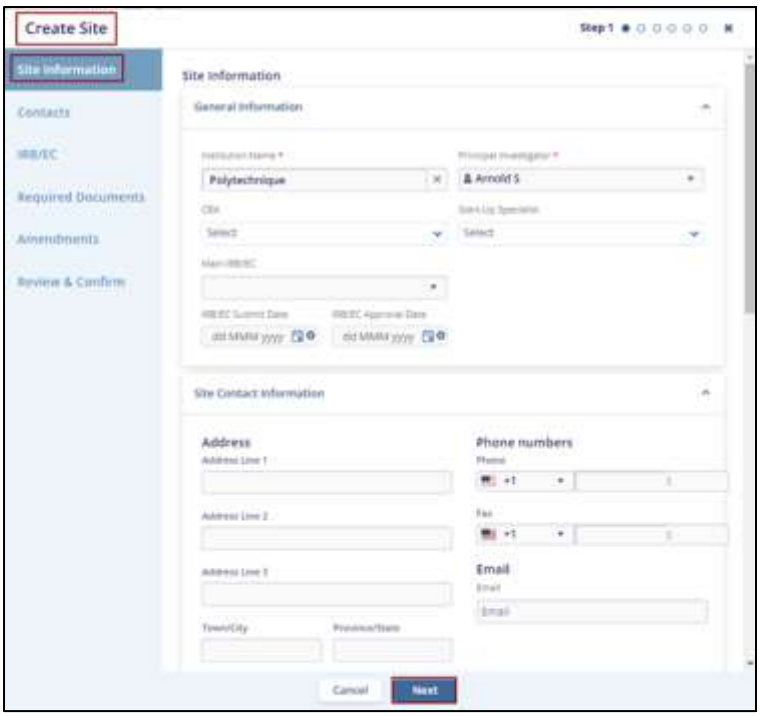
Adding Sites

Follow the steps below to add the site:

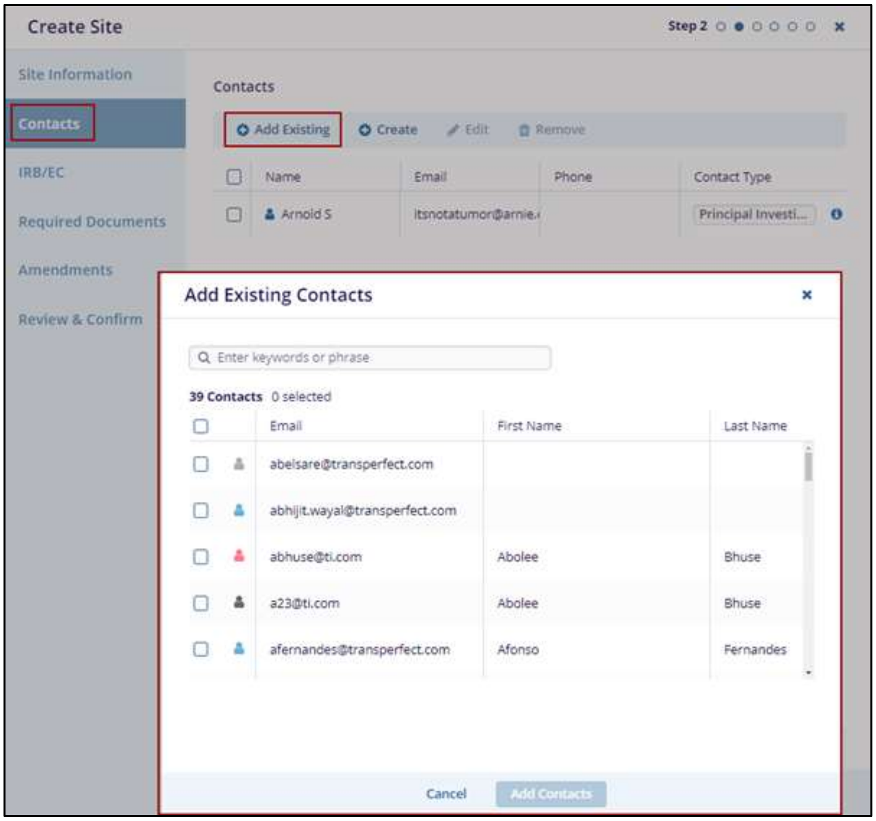
1. Click the drop-down arrow beside the Add button.
2. Click the Add button. The Create Site pop-up window is displayed.



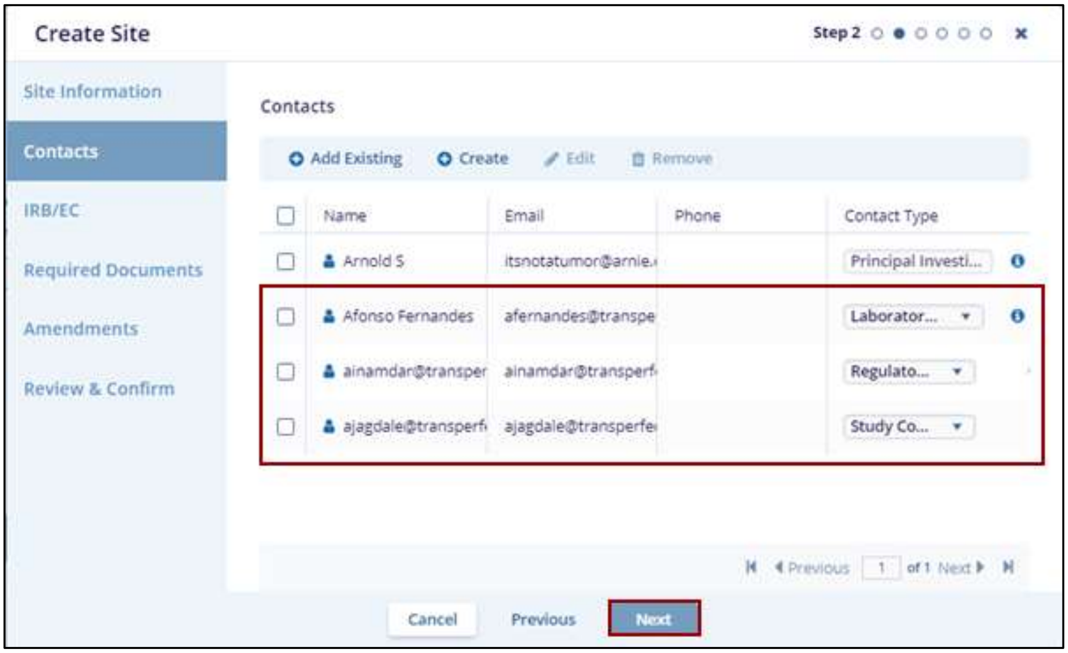
3. Fill in all the required fields within the Site Information tab and click the Next button.



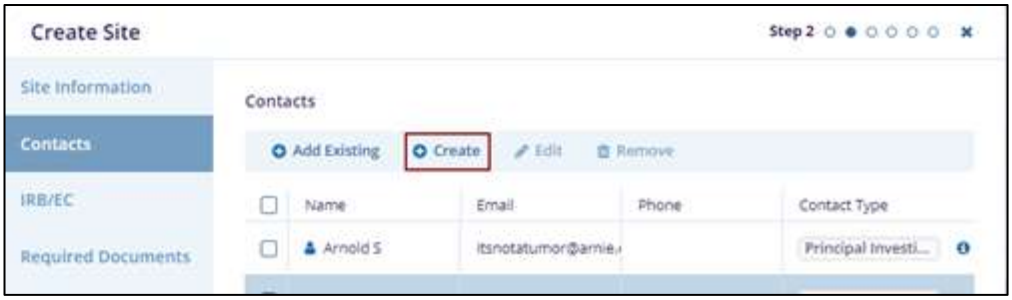
4. The **Contact's** tab is displayed on the Create Site pop-up window.
5. Click the Add Existing button. The Add Existing Contacts pop-up window is displayed with the list of the contacts.



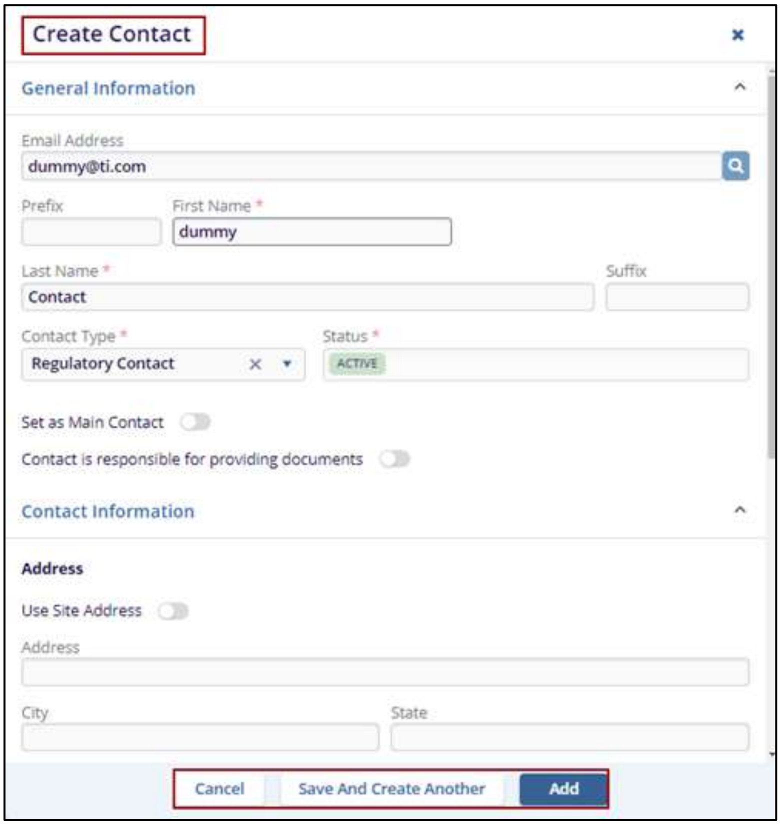
6. Select the contacts and click Add Contacts button at the bottom of the Add Existing Contacts pop-up window.
7. The selected contacts get added to the Contacts tab.

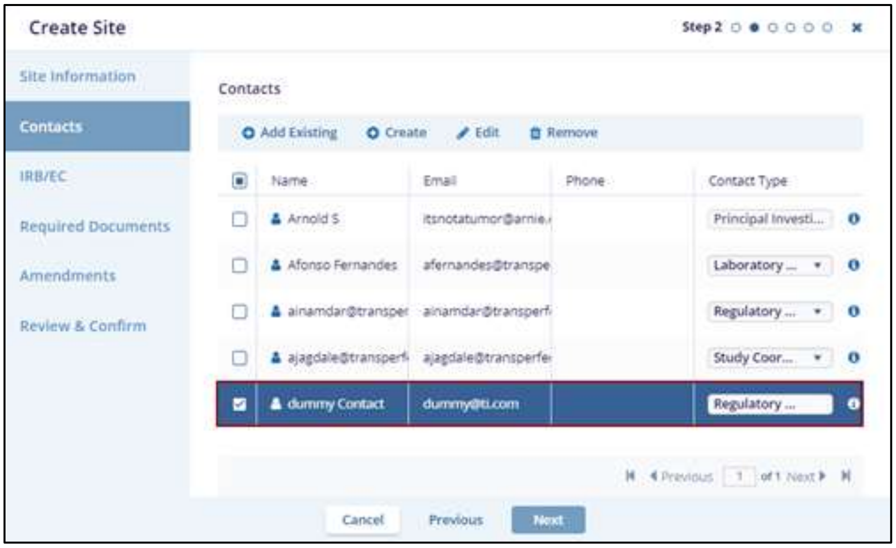


8. Click the Create button on the Create Site pop-up window.

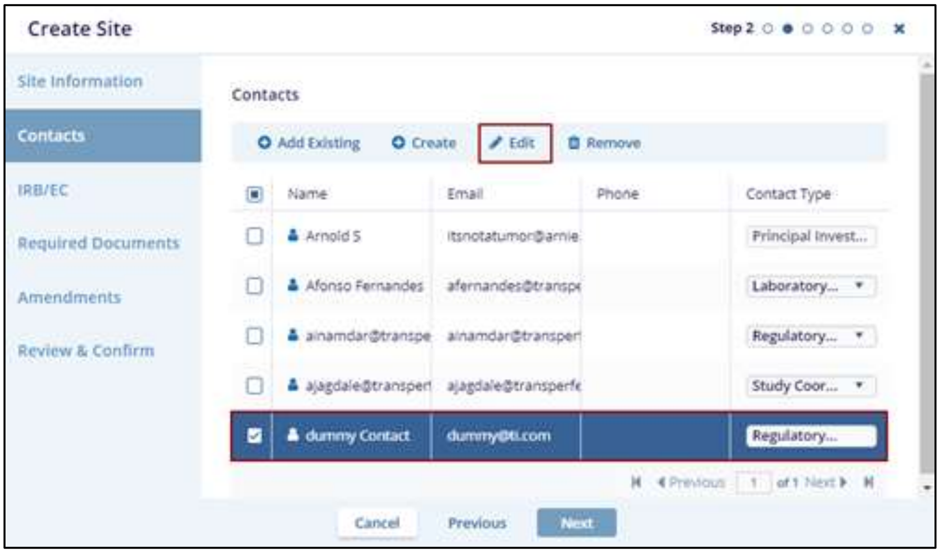


9. The Create Contact pop-up window is displayed with the Cancel, Save And Create Another, and Add buttons.
10. Fill in all required fields in the General Information, Contact Information, and Additional Information sections.
11. Click Add to save the contact, or click Save and Create Another to save the current contact and add a new one, and Cancel to discard the changes.
12. The newly added contact will appear on the Contacts page.

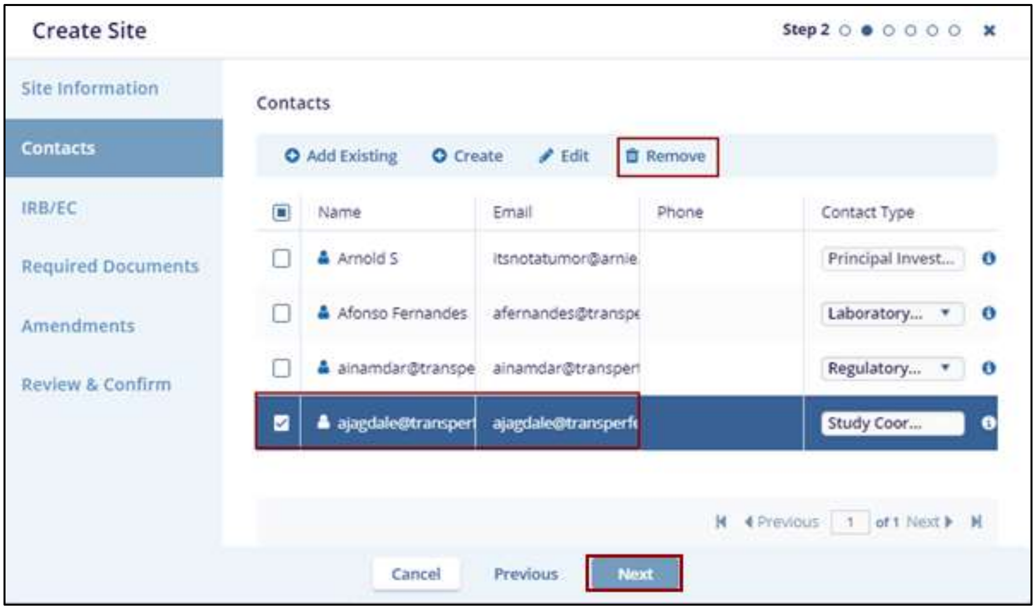




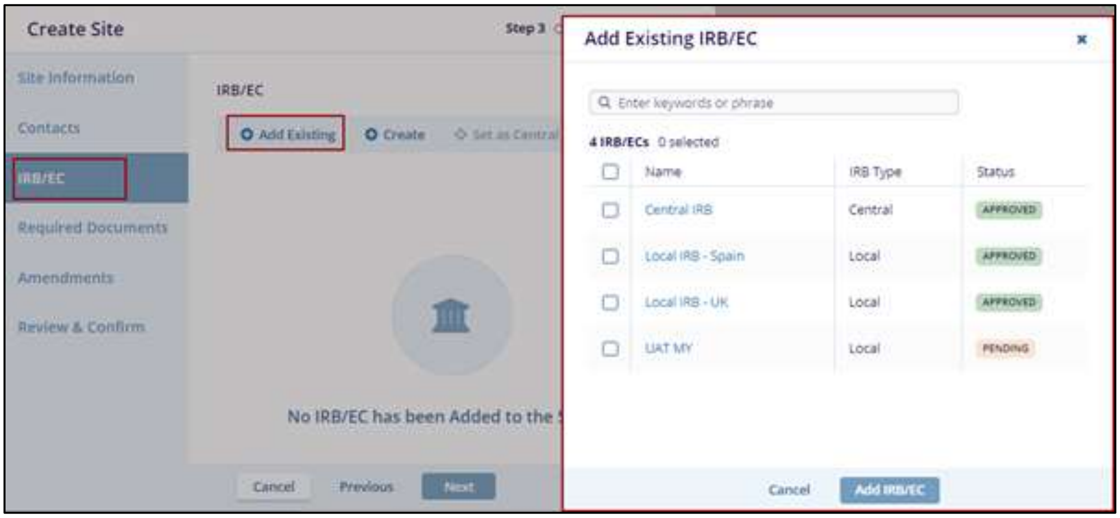
13. Locate the contact and click the Edit button.



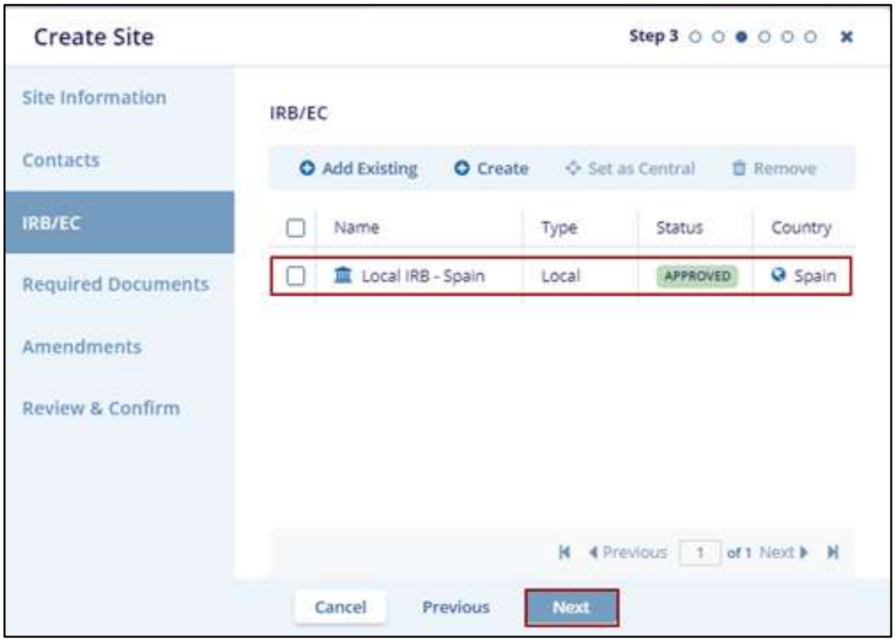
14. The Edit Contact pop-up window is displayed. Edit the required fields and click the Save button.
15. Locate the contact and click the Remove button. The selected contact disappears from the page and click the Next button.



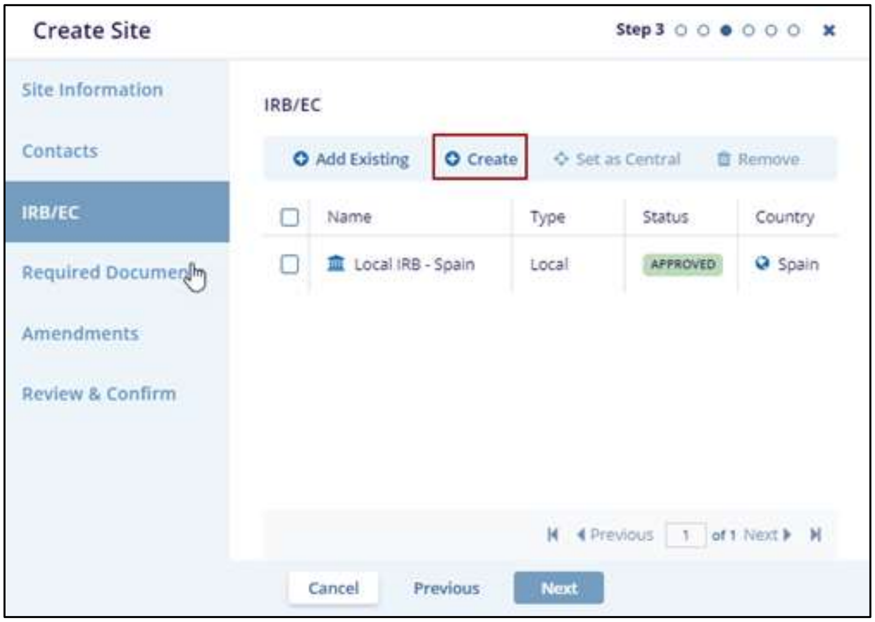
16. The IRB/EC tab is displayed on the Create Site pop-up window.
17. Click the Add Existing button. The Add Existing IRB/EC pop-up window is displayed with the list of the IRB/ECs.



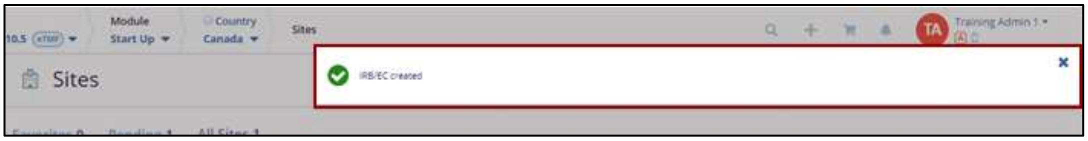
18. Select the IRB/EC from the list and click the Add IRB/EC button at the bottom of the Add Existing IRB/EC pop-up window.
19. The selected IRB/EC displays on the Create Site page.



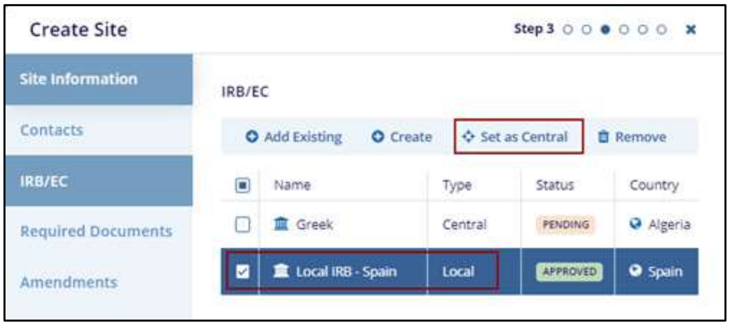
20. Click the Create button on the Create Site pop-up window.

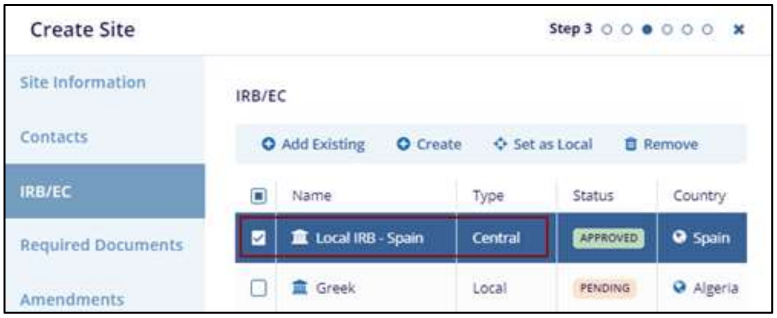


21. The Create IRB/EC pop-up window is displayed with the Cancel, Save And Create Another, and Create IRB/EC buttons.
22. Fill in all required fields in the General Information, IRB/EC Contact Information, Additional Information, Meeting Frequency, and Submission Deadline sections.
23. Click Create IRB/EC if the user wants to create it, or click Save and Create Another to save the current IRB/EC and add a new one, and Cancel to discard the changes.
24. Click Create IRB/EC the notification message 'IRB/EC Created' is displayed on the top right side of the screen.

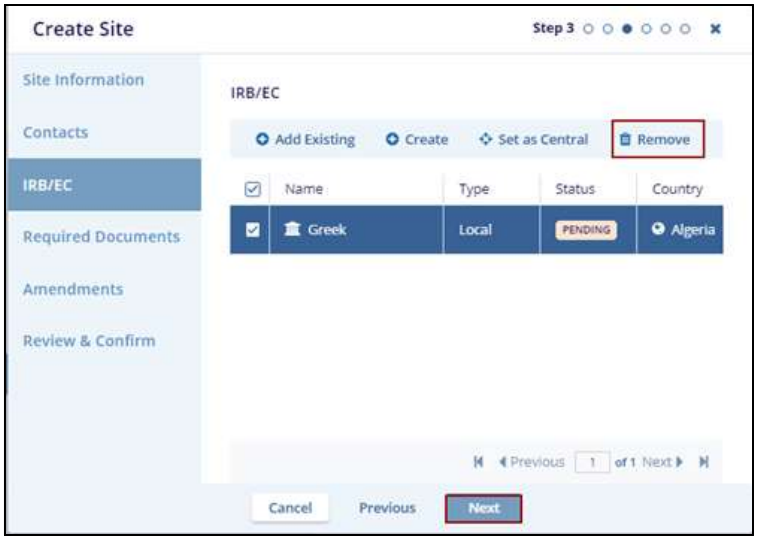


25. Locate the IRB/EC with the type as Local and click the Set as Central button. The type of the selected IRB/EC changes to the Central.



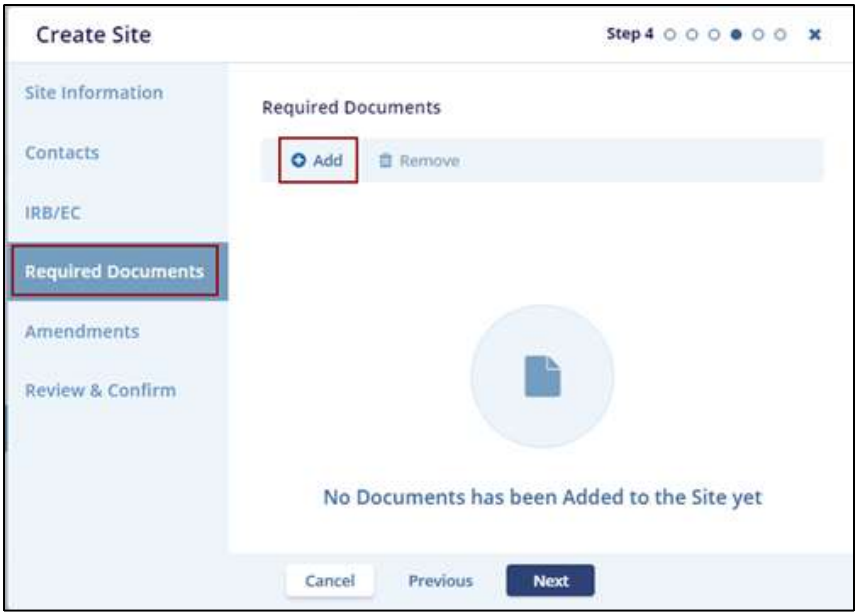


26. Locate the contact and click the Remove button. The selected IRB/EC disappears from the page.

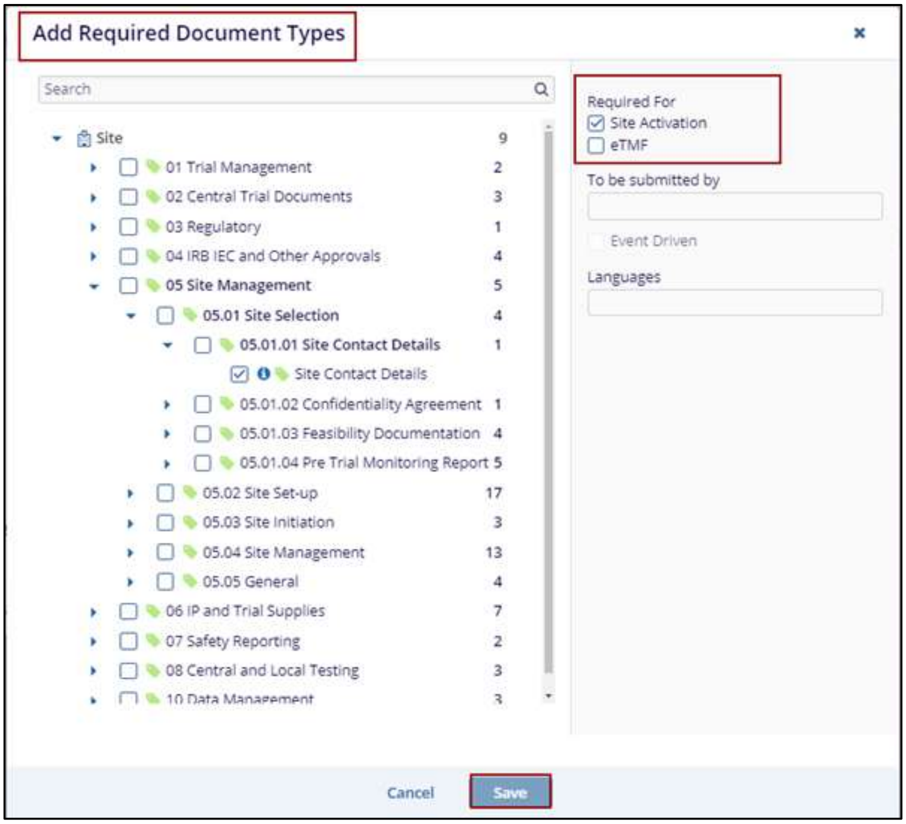


27. Click the Next button. The Required Documents page is displayed on the Create Site pop-up window.

28. Click the Add button. The Add Required Document Types screen is displayed.

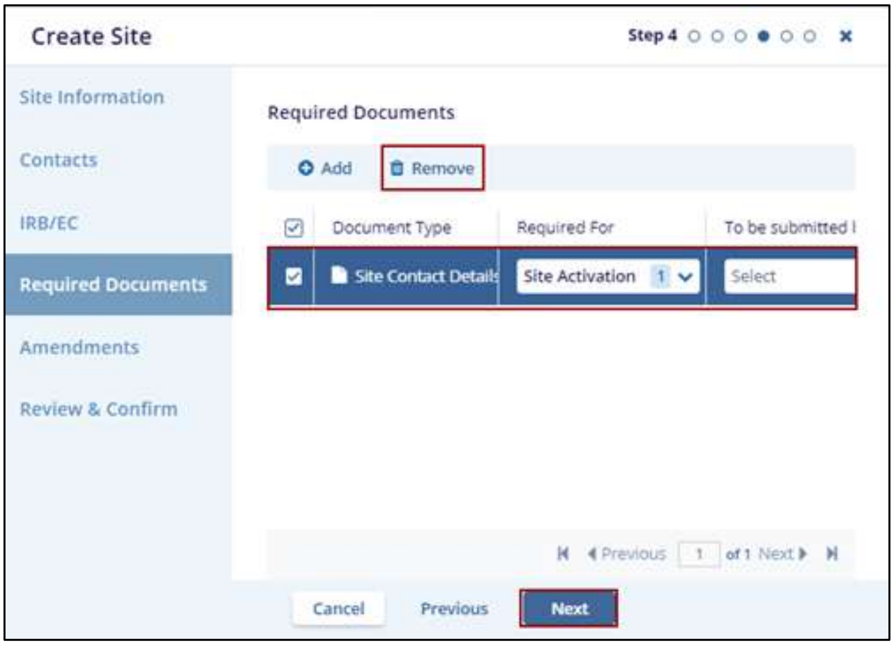


29. Select the necessary document from the list determine whether it is required for Site Activation or inclusion in the eTMF and click the Save button.

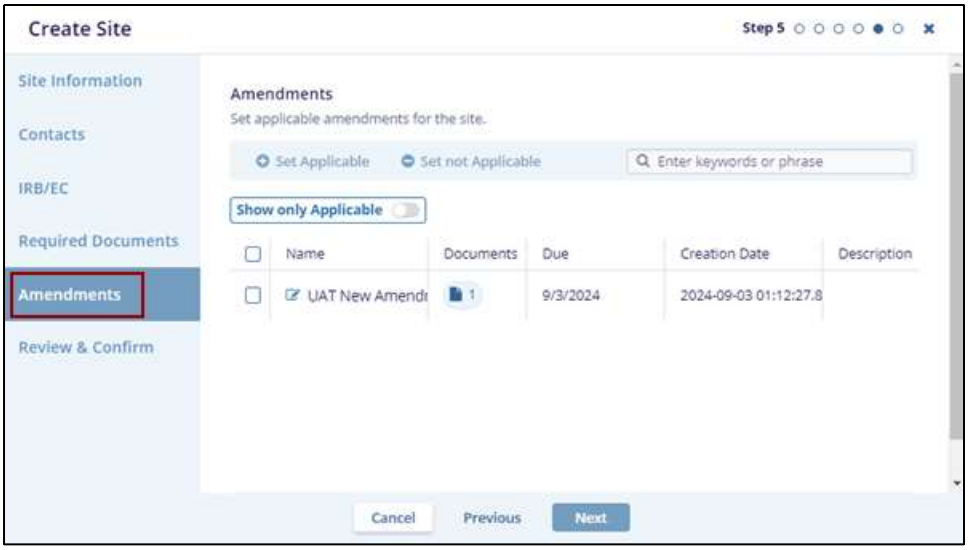


30. The added document is displayed on the Create Site page.

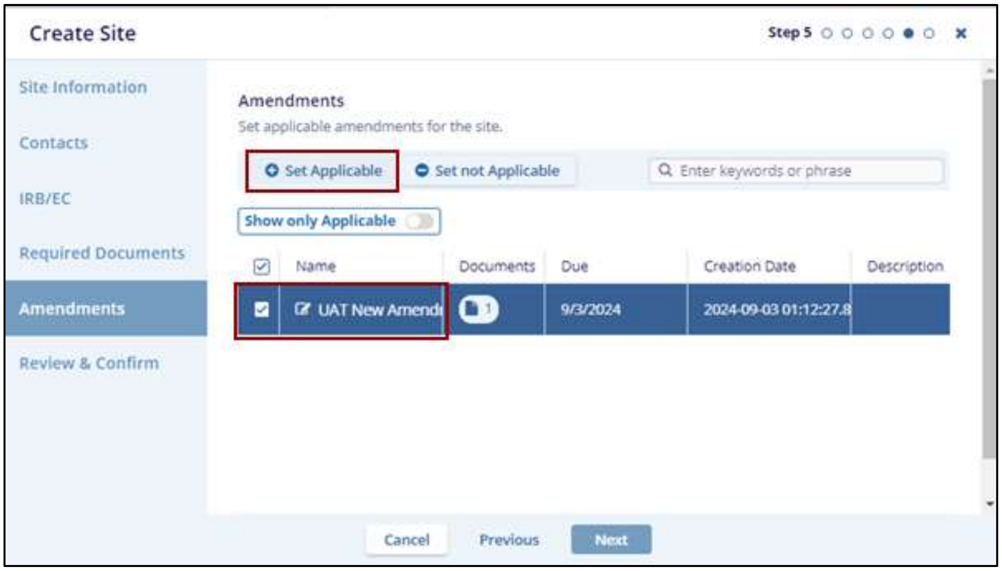
31. Locate the contact and click the Remove button. The selected Document Type disappears from the page.

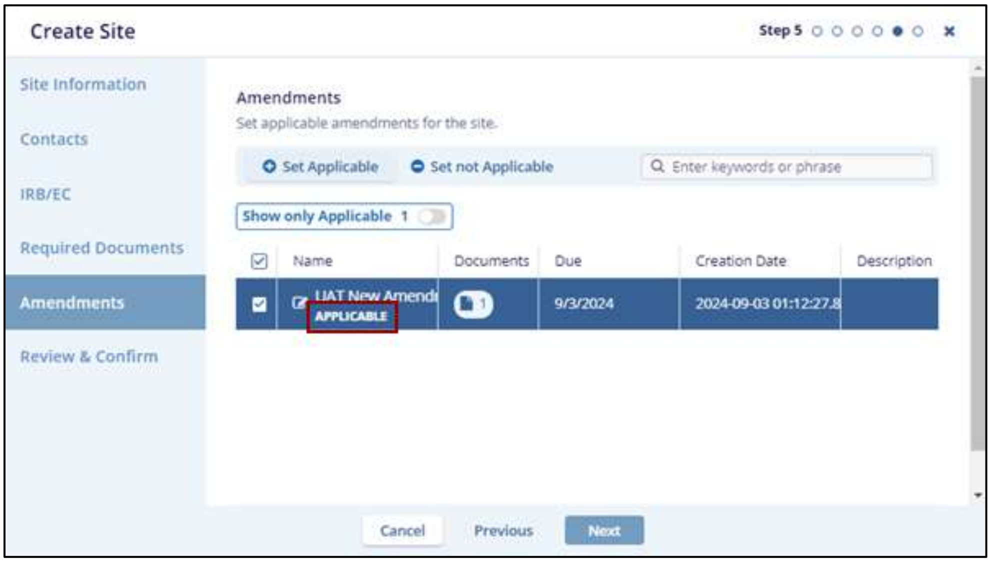


32. Click the Next button. The Amendments page is displayed on the Create Site pop-up window.

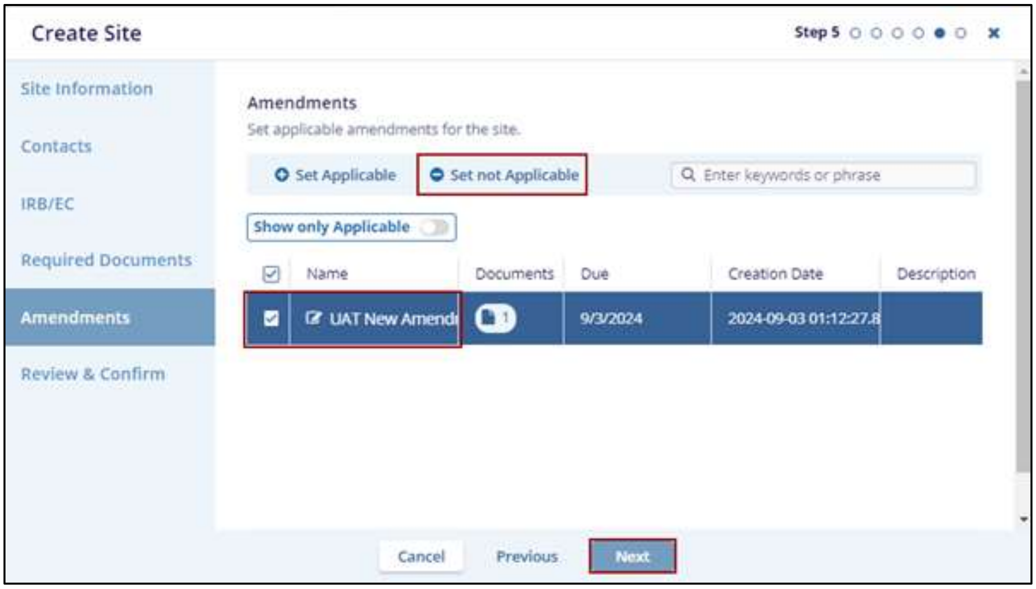


33. Locate the Amendment and click Set Applicable, the Applicable word is displayed right below the selected Amendment.

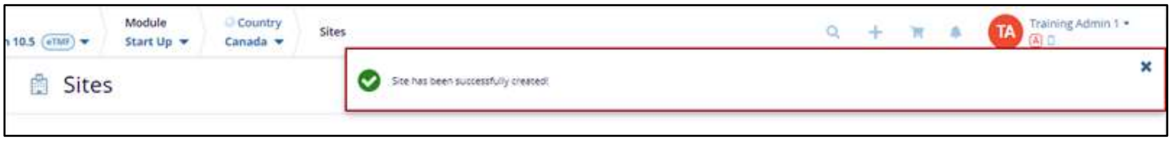




34. Locate the amendment and click Set not Applicable, the selected amendment is set to not applicable and the word Applicable disappears.

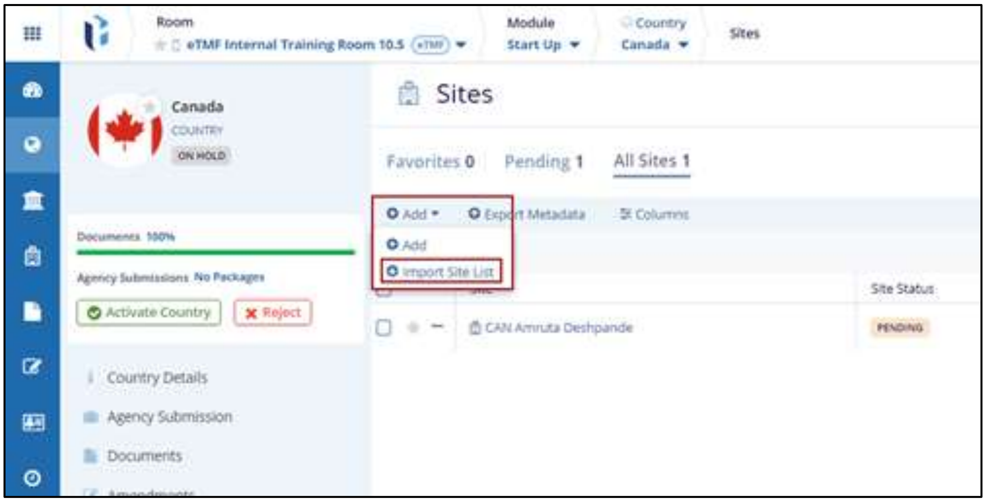


35. Click the Next button. The Review & Confirm page is displayed on the Create Site pop-up window.
36. Ensure by reviewing the information that is added while creating the site and clicking the Create button.
37. The notification message 'Site has been successfully created' is displayed on the top right side of the screen.

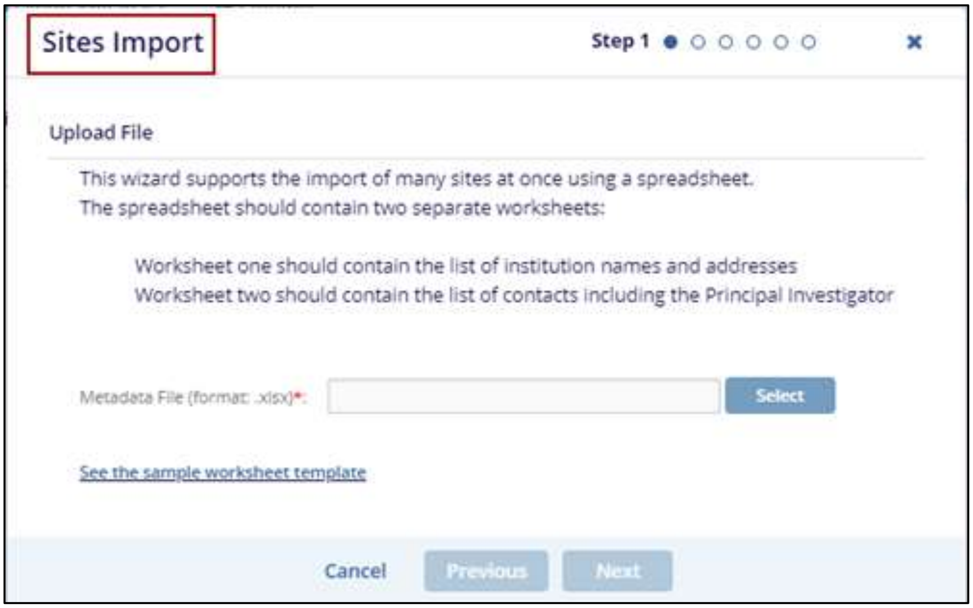


Import Site List

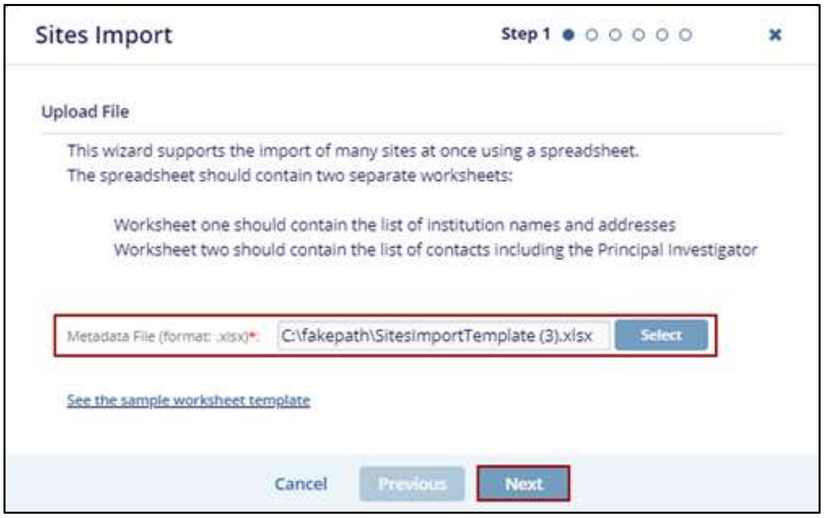
1. Click the drop-down arrow beside the Add button and click the Import Site List button.



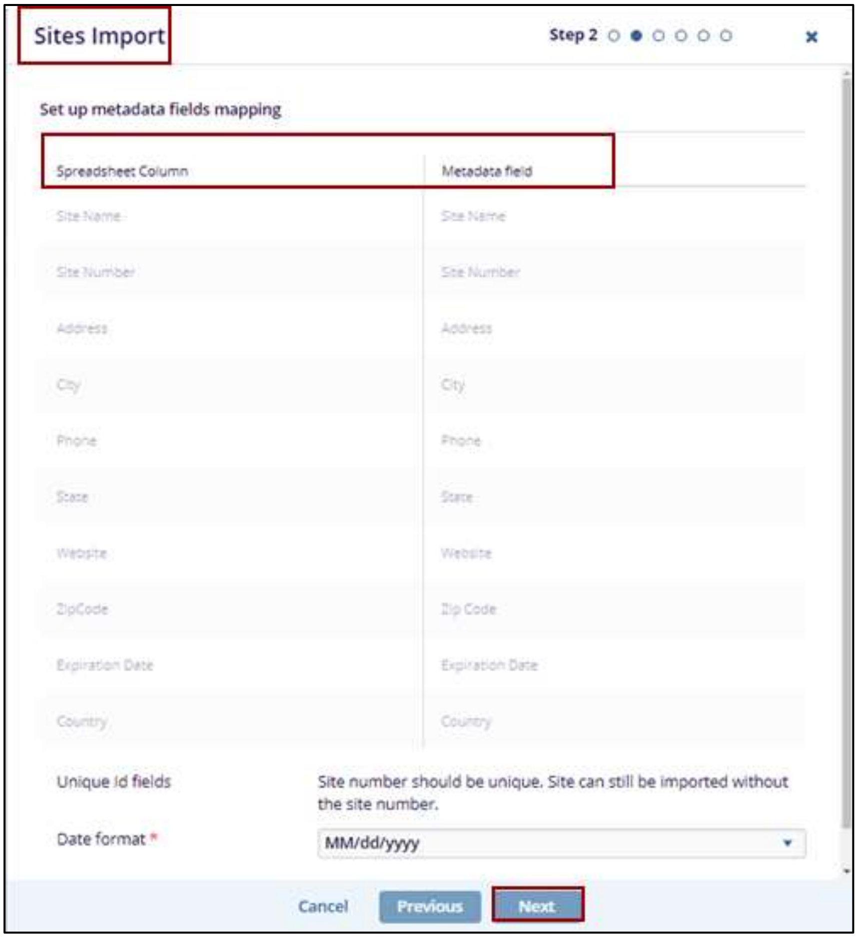
2. The Sites Import pop-up window is displayed.



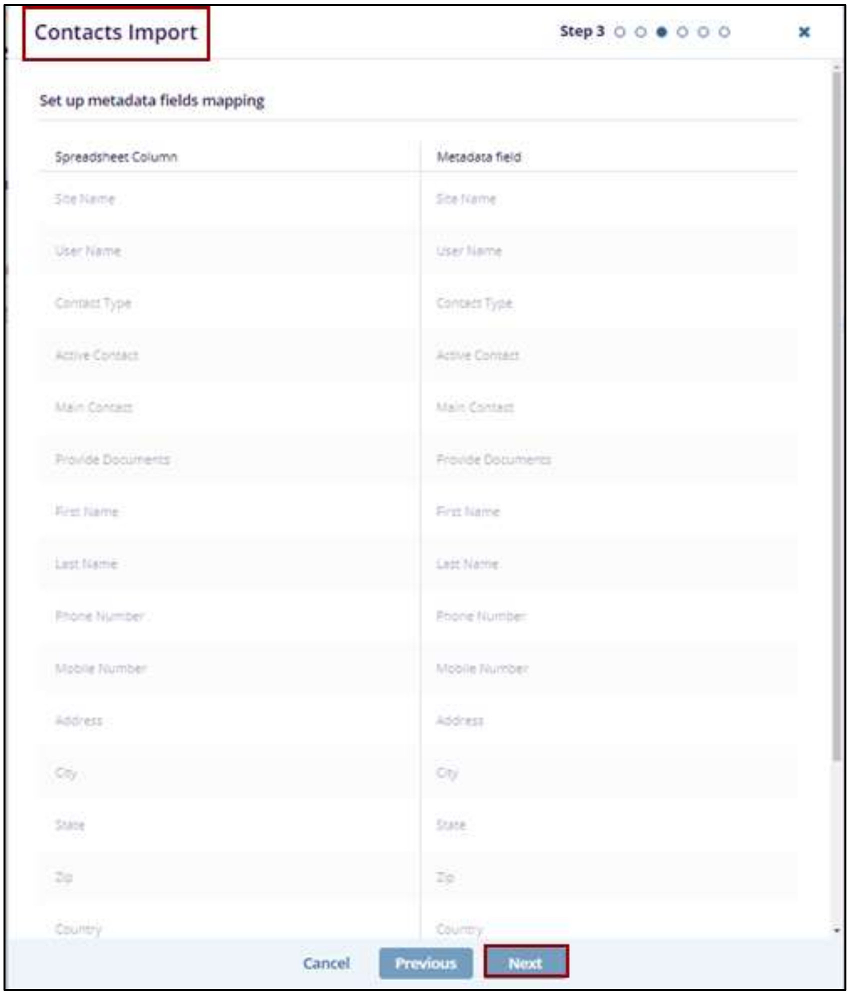
3. Click the Select button and select the document from Windows Explorer which should be a .xlsx file and click the Next button.



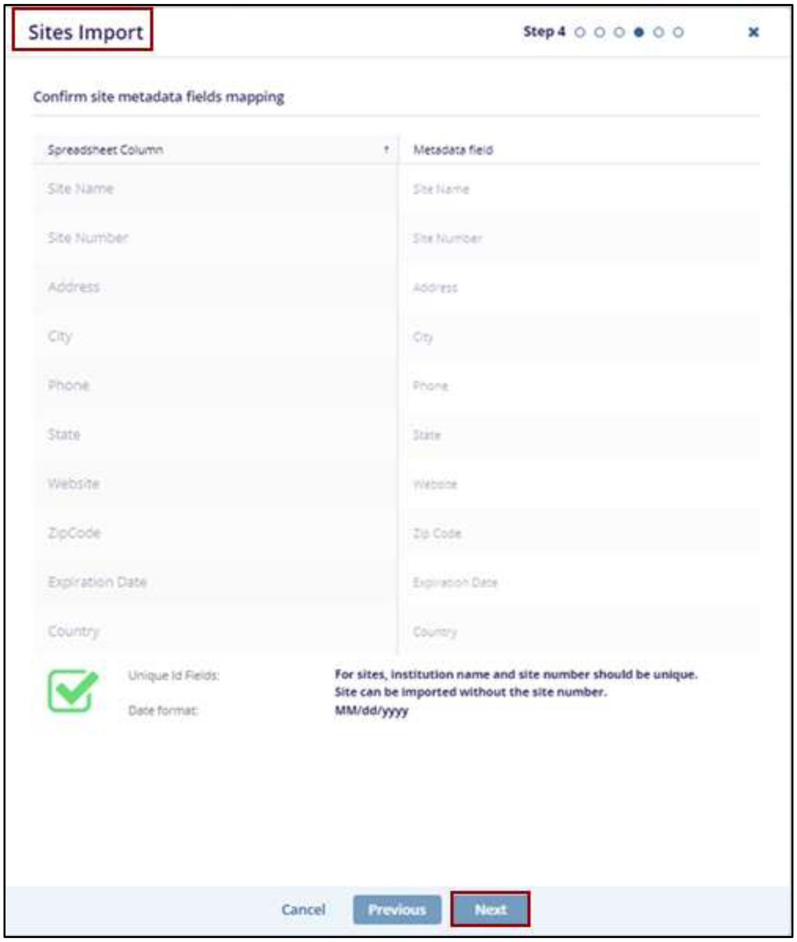
4. The Sites Import pop-up window is displayed with two columns Spreadsheet Column and Metadata Field.



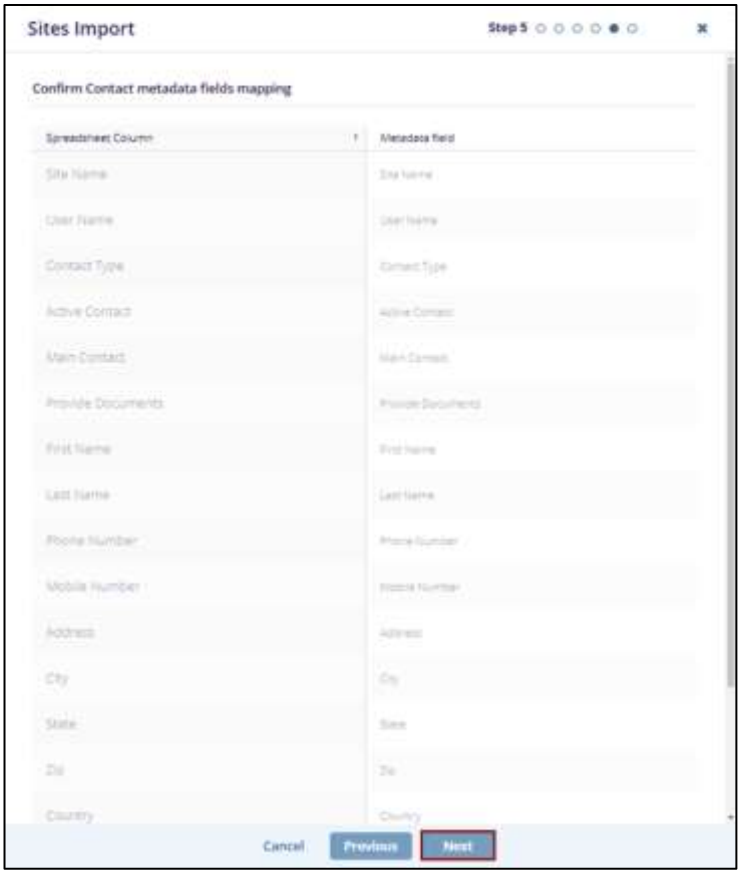
5. Click the Next button and the Contacts Import page is displayed with the contacts information and click the Next button.



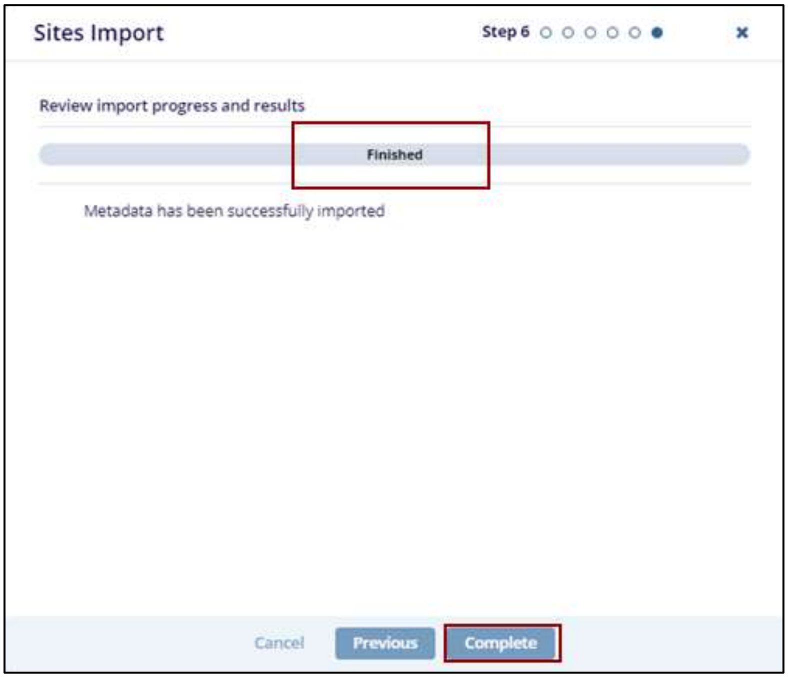
6. Click the Next button and the Sites Import page is displayed with the contact information and click the Next button.



7. Confirm that the Contact metadata fields are mapping and click the Next button.



8. The Information pop-up window is displayed with the message and OK button.
9. Click the OK button and the Sites Import pop-up window displays the Finished bar click the Complete button.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

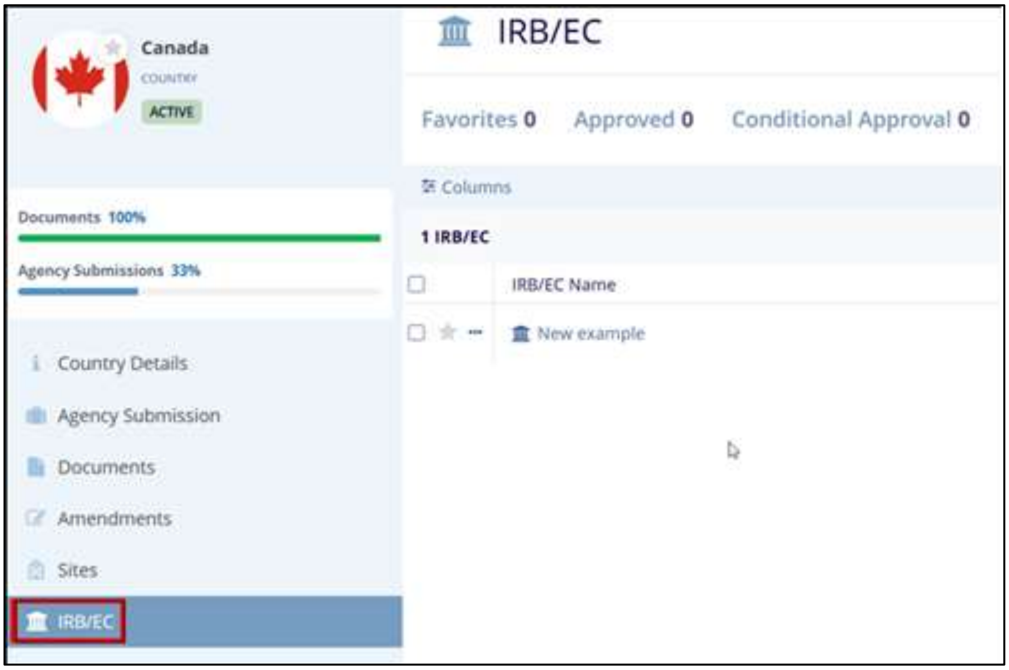
To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

IRB/EC

The IRB/EC tab in the Country module lists all IRBs/ECs associated with a specific country. Users can edit, manage columns, search, manage, and create filters on this page. The grid pane displays key details, including IRB/EC Name, Status, Progress, and Address. Refer to the screenshot below for reference.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

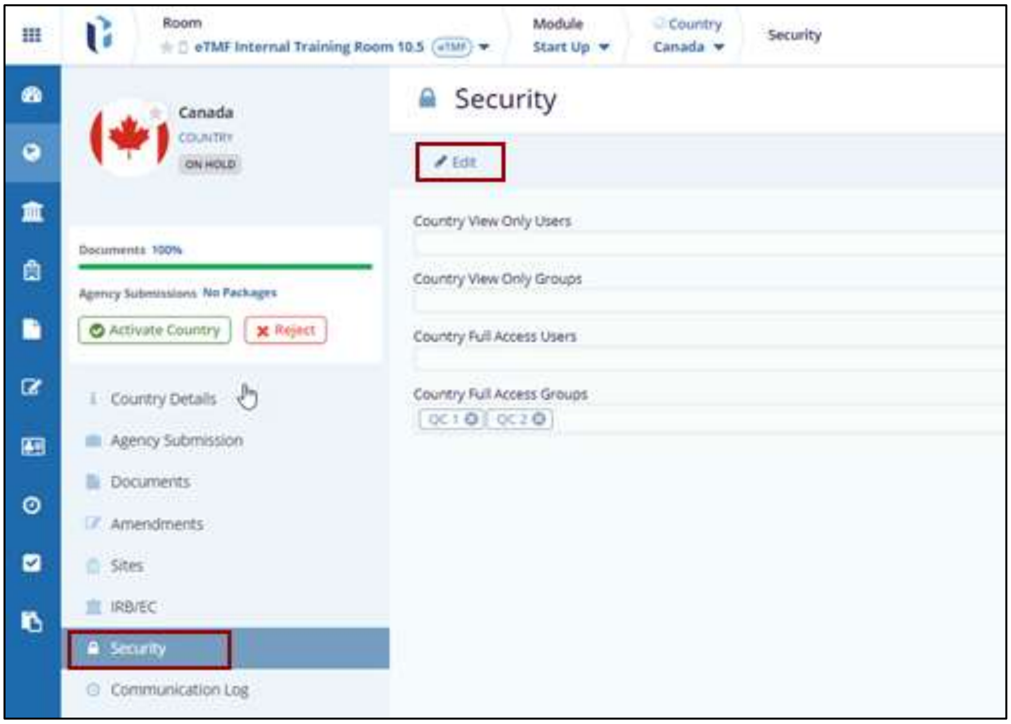
To know more detailed information about views please refer to this link - Popular Documents.

Security

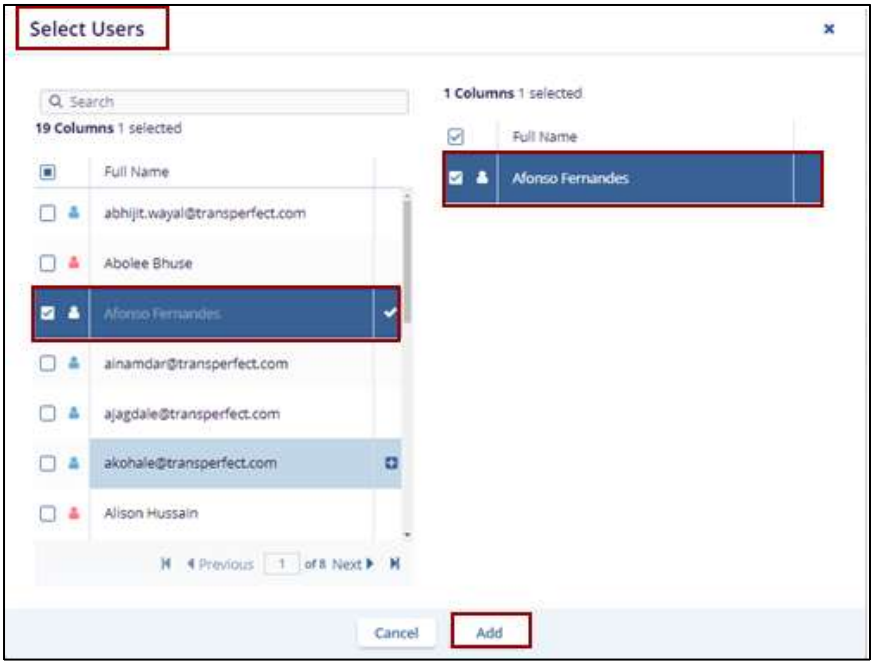
The Security page in the Country module allows users to configure access permissions, granting either full access or country-specific access to selected users and groups. Users can only edit the fields displayed on the page.

Follow these steps to set security for users and groups:

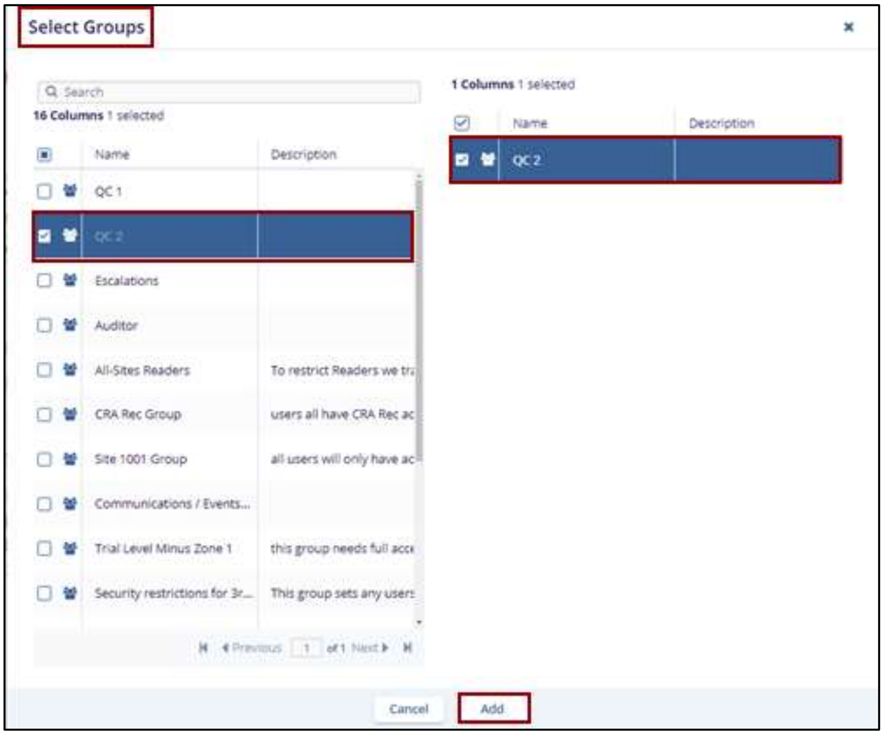
1. Click on the Security tab of the Country module. This opens the Security page in the center of the screen.
2. Click the Edit button displayed in the top left corner. This enables the four fields to apply security for users and groups.



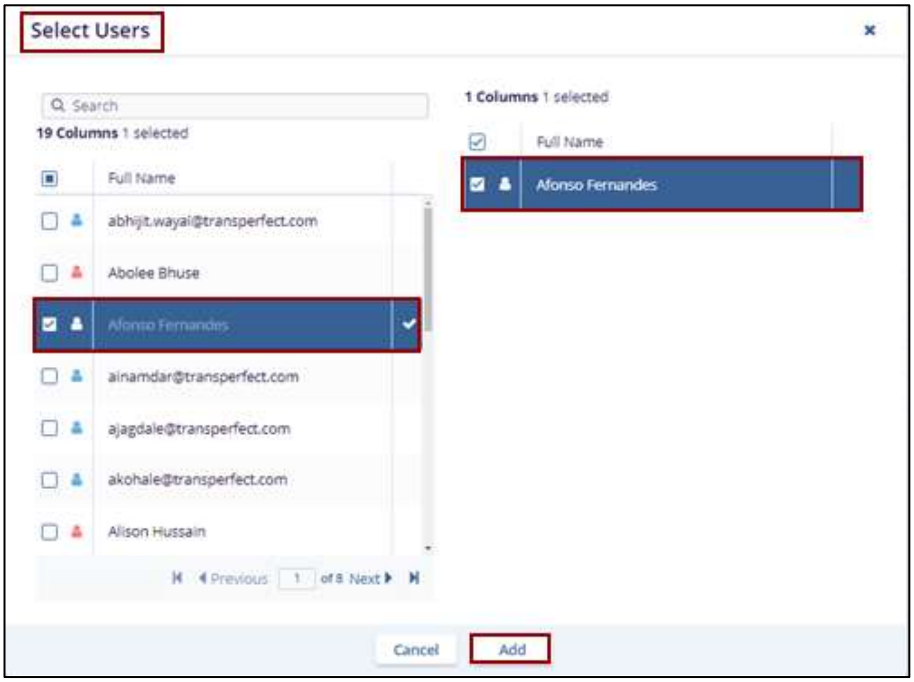
3. On the Country View Only Users field, click on the three-dot menu. This opens the Select Users popup window.
4. Select the checkbox(s) of the users whom you want to add to view only the country. Click the Plus sign next to the name. OR Drag and drop the name to the right-side pane. The selected names 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.



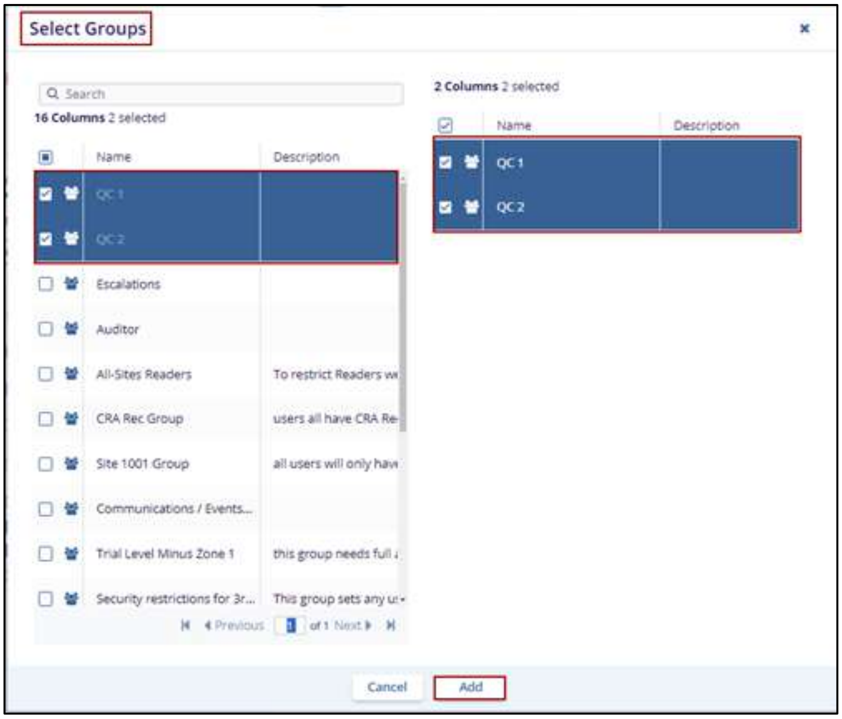
6. Click the three-dot menu displayed next to the Country View Only Groups field. This opens the Select Groups popup window.
7. Select the checkbox(s) of the users whom you want to add to only view the country. Click the Plus sign next to the name. OR Drag and drop the name to the right-side pane.
8. Click the Add button at the bottom of the popup window.



9. On the Country Full Access Users field, click on the three-dot menu. This opens the Select Users popup window.
10. 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.
11. Click the Add button at the bottom of the popup window. The selected names are reflected in the Country Full Access Users field.



12. Click the three-dot menu displayed next to the Country Full Access Groups field. This opens the Select Groups popup window.
13. 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.
14. Click the Add button at the bottom of the popup window.

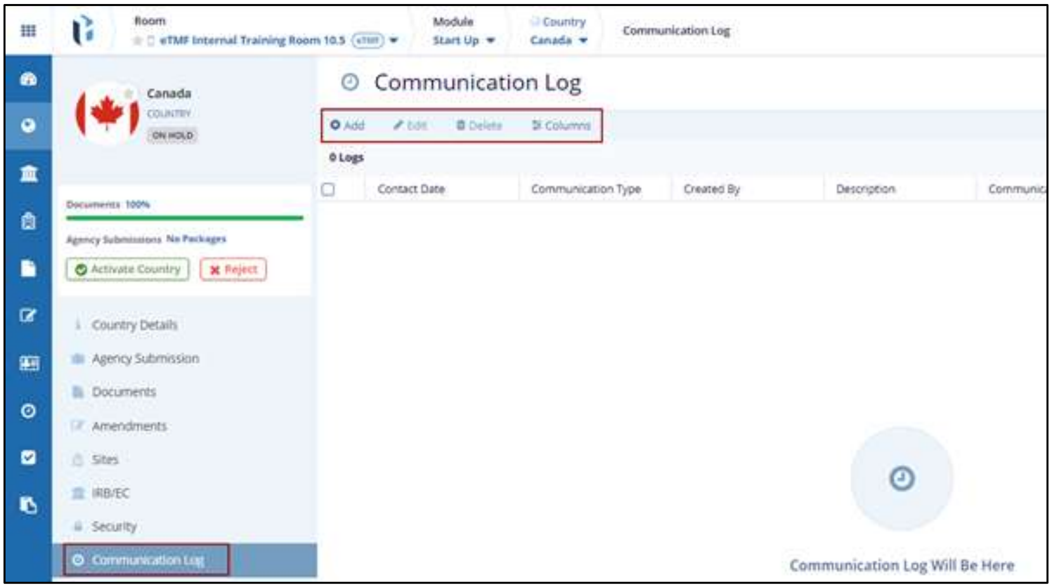


15. Click the Save button displayed at the top left of the screen.

16. A notification is displayed on the right side of the screen, mentioning changes have been made to the Country.

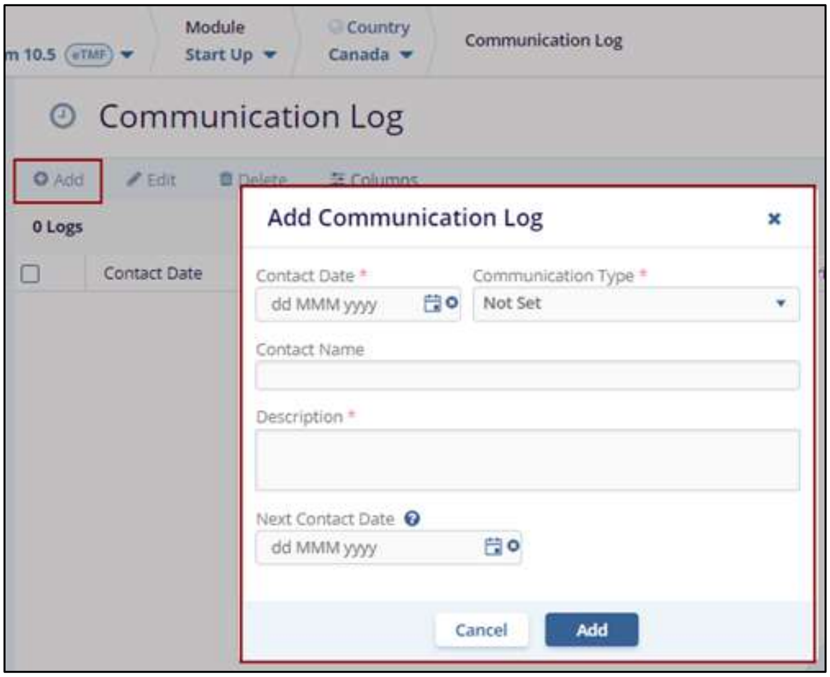
Communication Log

The Communication Log displays a record of communications over time to track document collection from the appropriate personnel. Users can Add, Edit, Delete, Manage Columns, Search, Manage, and Create Filters on this page.

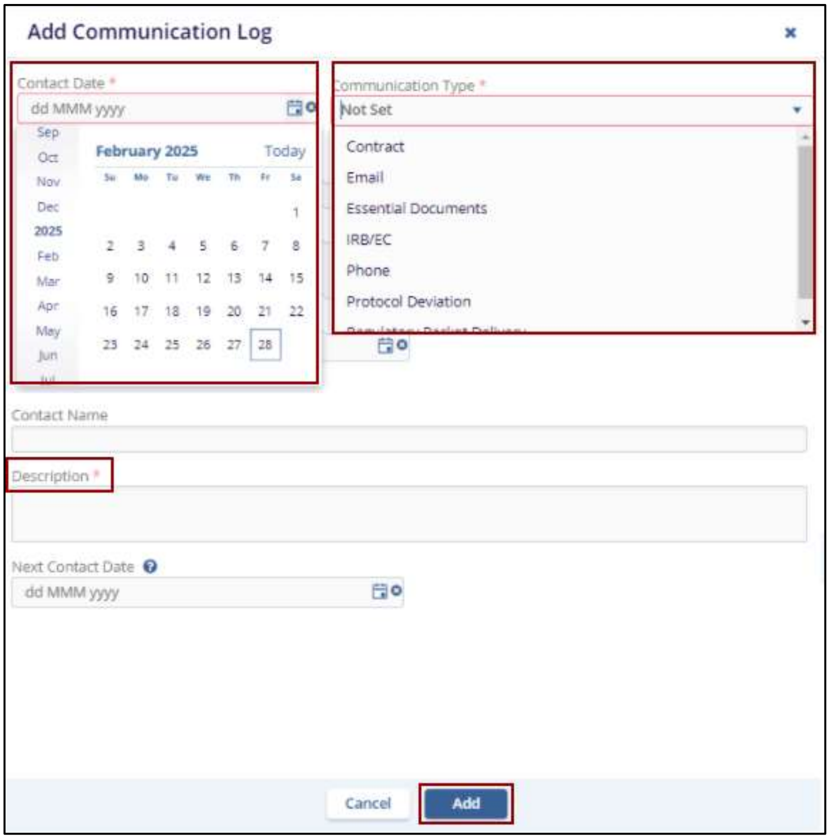


Add Log

1. Click the Add button displayed on the top menu bar. The Add Communication Log pop-up window is displayed.

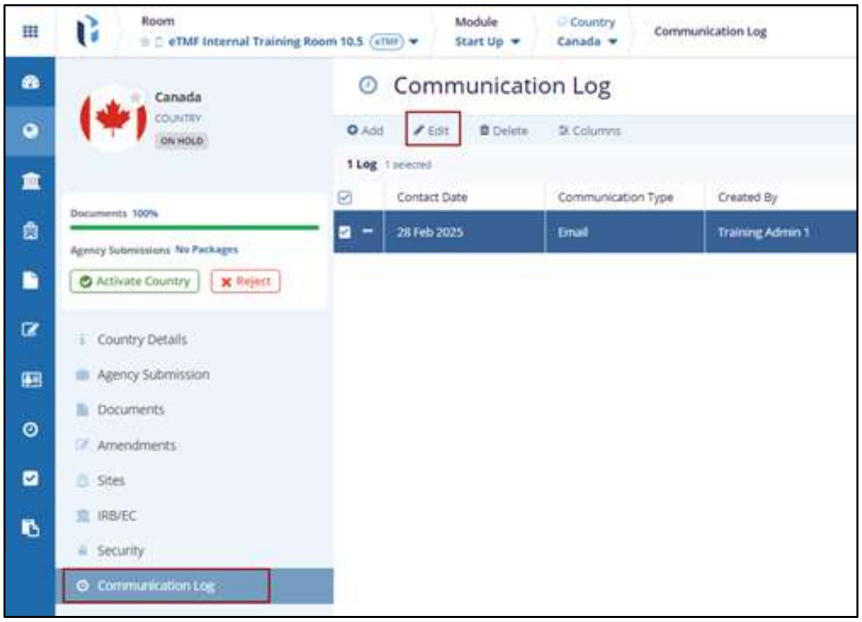


2. Fill in all the required fields such as the Contact Date by clicking the Calendar Icon and Communication Type by clicking its dropdown menu.
3. Enter the details in the Description field.
4. Click the Add button at the bottom of the popup window.

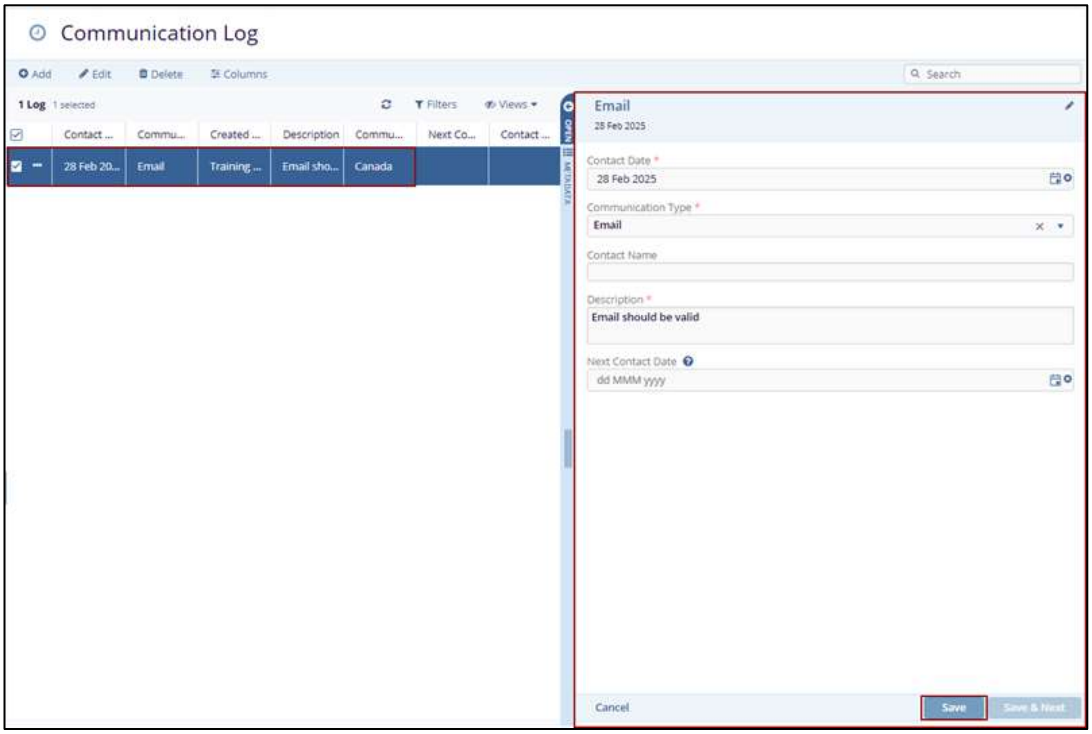


Edit Log

1. Select the checkbox of the communication 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.

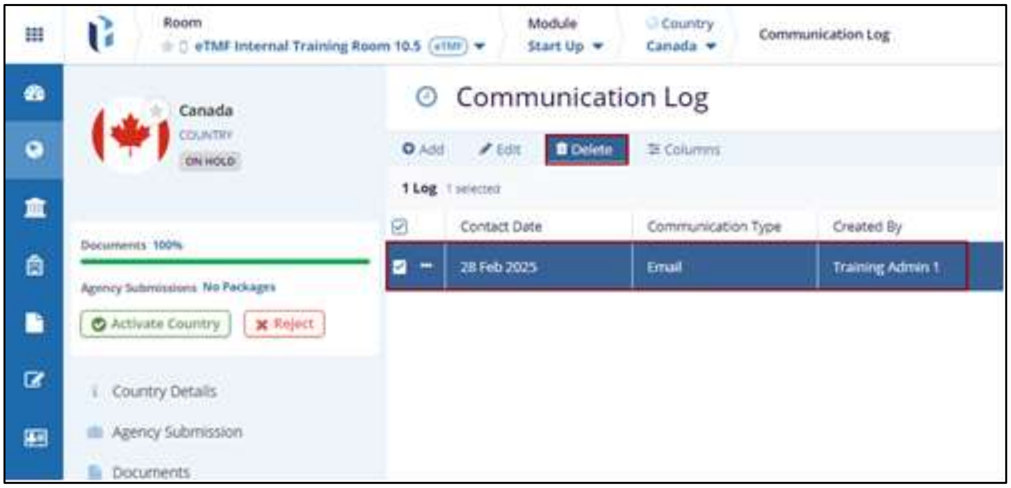


3. Make the changes in the required fields and click the Save button at the bottom of the metadata panel.
4. The saved changes are reflected in the grid pane.



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. The Delete Communication Log (s) dialog box is displayed with the Cancel and Delete buttons.
3. Click Delete in the Delete Record popup window.

Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

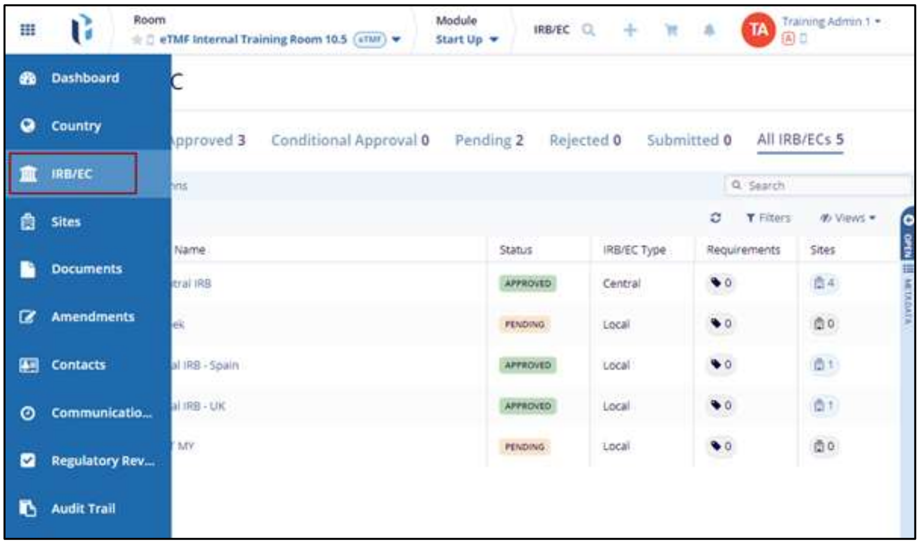
Views

To know more detailed information about views please refer to this link - Popular Documents.

IRB/EC

Clinical trial sites must follow IRB/EC protocols to ensure efficient and effective operations. While organizations are encouraged to use central IRBs over multiple local IRBs, the choice depends on the research enterprise, particularly for multi-site trials.

Trial Interactive accommodates both central and local IRBs, offering flexibility for multi-site trials. While a single central IRB is recommended, multiple IRBs/ECs may be necessary. Trial Interactive enables users to add and specify IRB/ECs as needed.

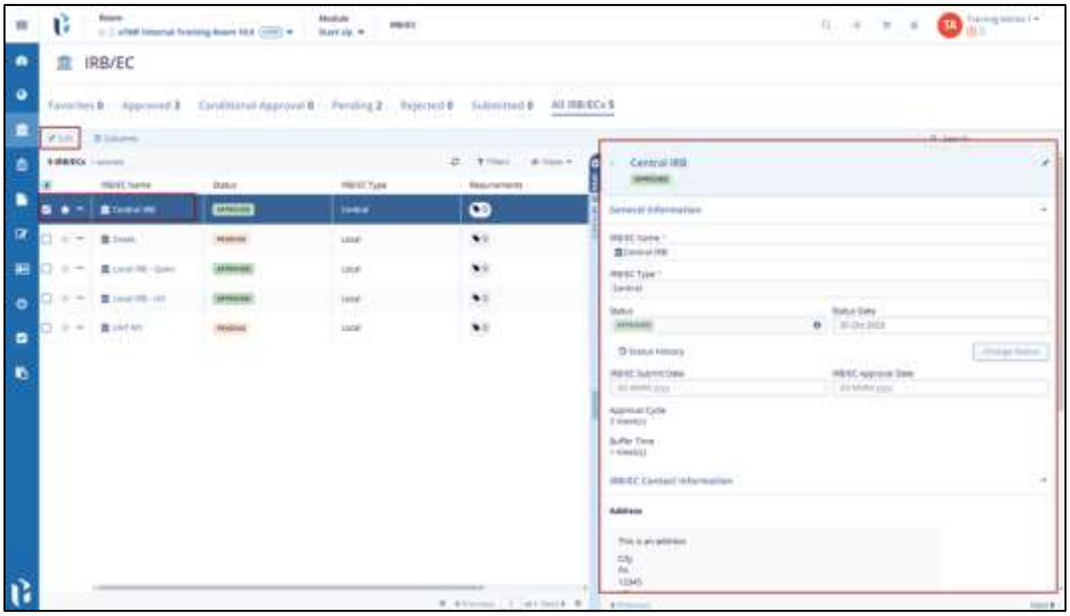


Clicking the IRB/EC tab from the toggling menu bar on the left lists the IRB/ECs available to the room. The IRB/EC dashboard consists of the Grid pane in the center with the following columns to view and edit:

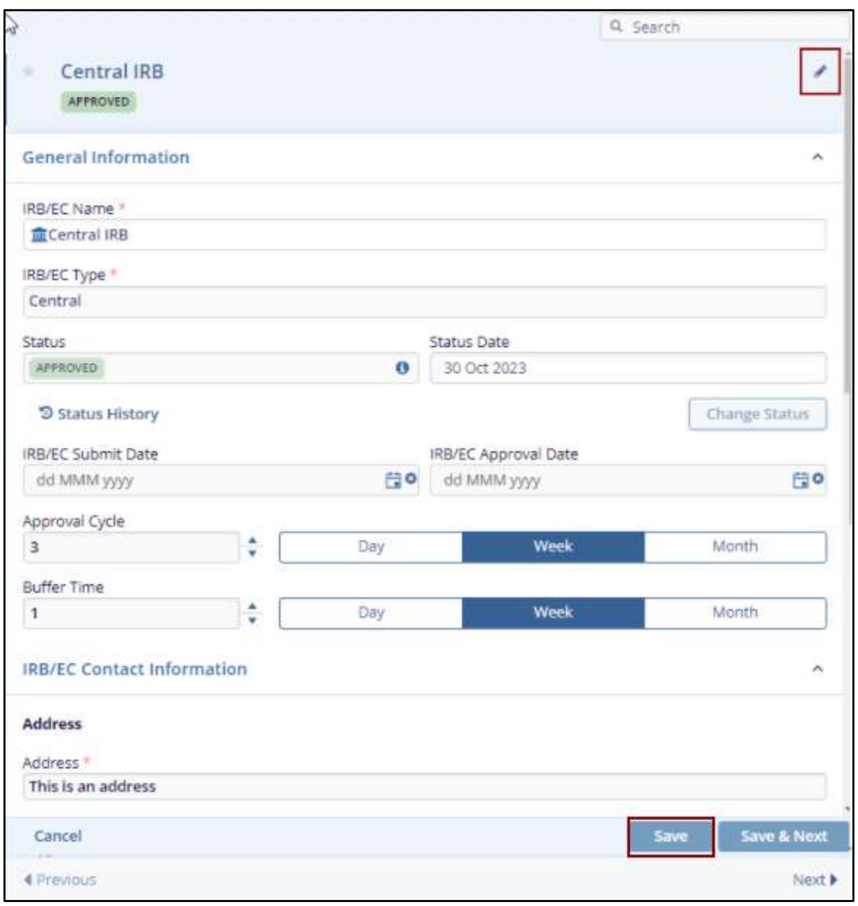
- IRB/EC Name
- Status – Displays if the IRB/EC is Approved, Submitted, Pending, or Conditional Approval.
- IRB/EC Type – Displays if the IRB/EC is Central or Local.
- Progress – Displays the percentage of required documents collected for each IRB.
- Sites – Displays the number of sites linked to the IRB/EC.
- Address – Displays the address of the IRB/EC.

Edit Log

1. Select the checkbox of the IRB/EC 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. Click the Edit icon available on the top right in the metadata panel then only the fields get editable. 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.



Columns

To know more detailed information about columns please refer to this link - [Columns](#).

Show Filters

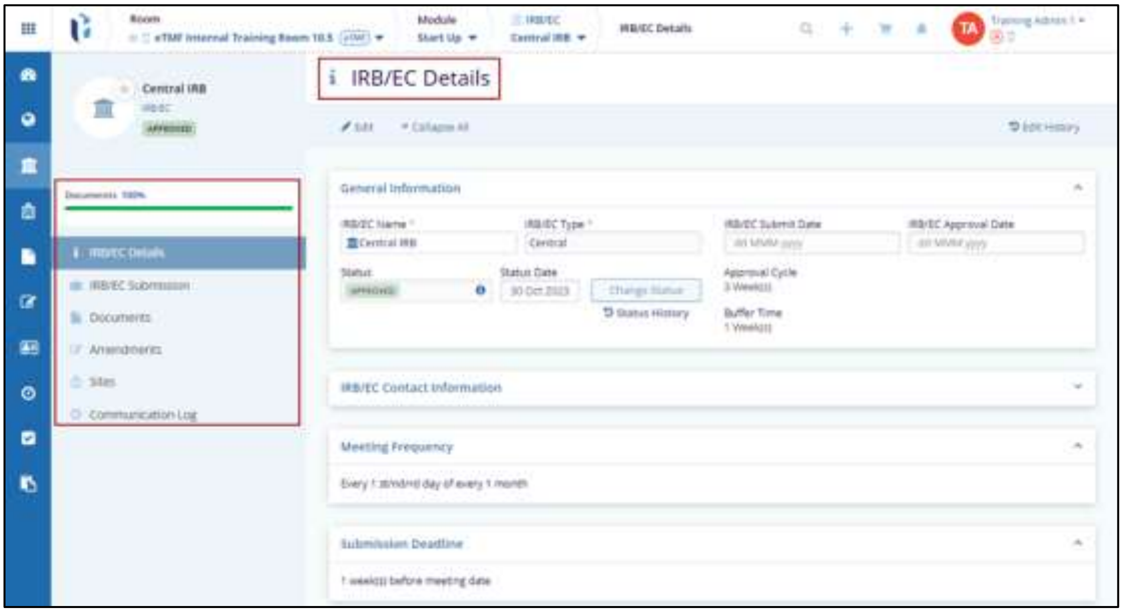
To know more detailed information about filters please refer to this link - [Manage Filters](#) and [Create New Filter](#).

Views

To know more detailed information about views please refer to this link - [Popular Documents](#).

IRB/EC Details

The IRB/EC Details page displays a progress bar for - the Documents. Below the progress bar, the page displays the tabs/links for IRB/EC Submission, Documents, Amendments, Sites, and Communication log. Refer to the screenshot below.



Edit details

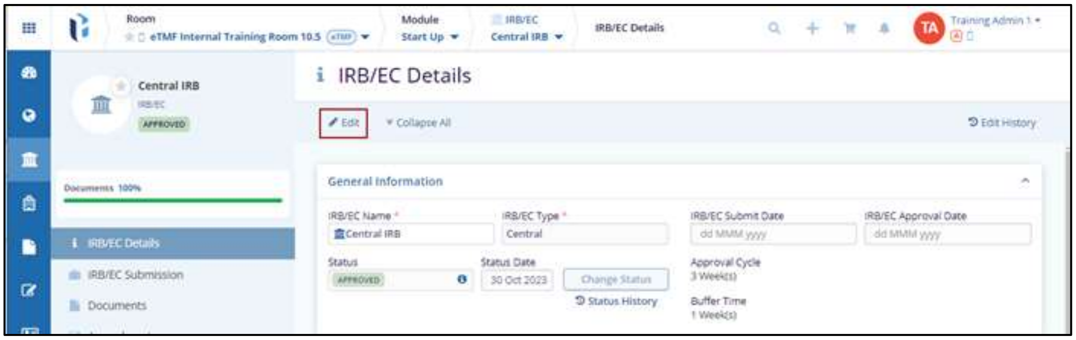
The user can view the following edit options on the Country Details page.

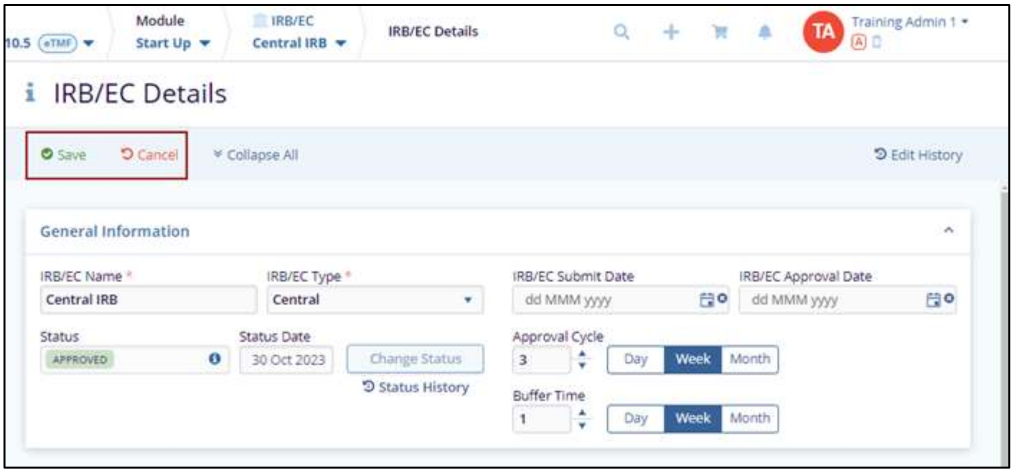
- Edit - Edit fields in General Information, IRB/EC Contact Information, Meeting Frequency, and Submission Deadline for the IRB/EC.
- Expand All – Expands the sections for General Information, IRB/EC Contact Information, Meeting Frequency, and Submission Deadline.
- Edit History - The user can only view the details of the history and cannot make any changes.

Steps to Edit Country details:

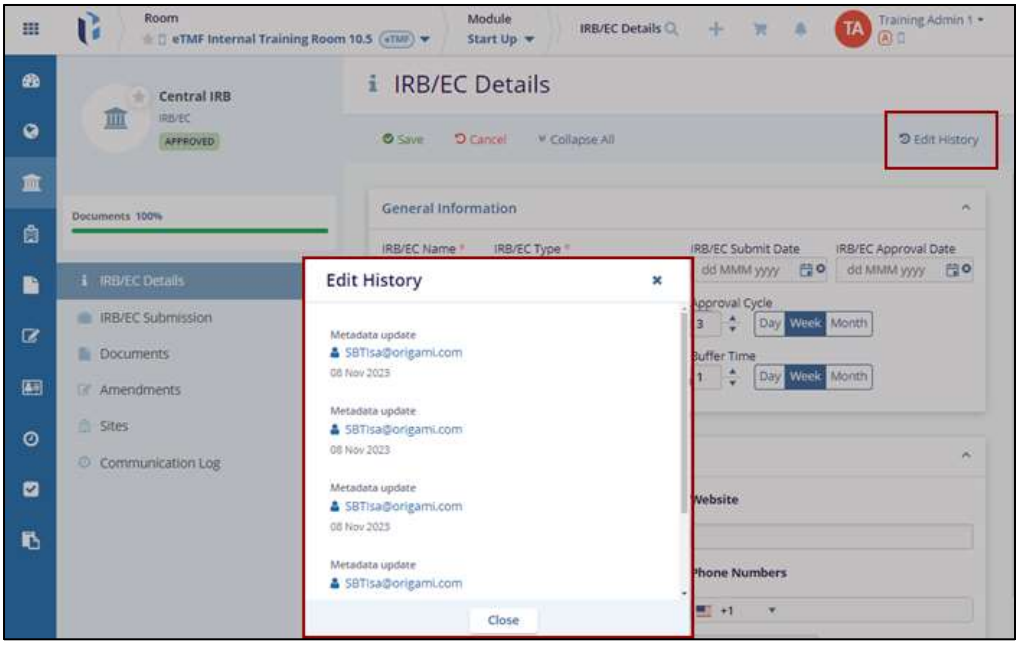
1. Click on the Edit button at the top of the grid. It will enable all fields as shown in the below image.

2. Edit the options as per the requirement and click on the Save button to save the changes and Cancel to discard.





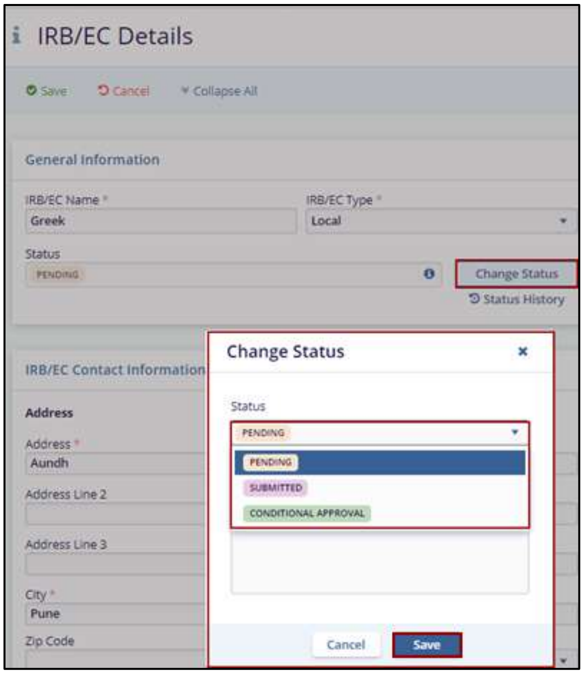
3. On the top right side of the page, click the Edit History button to view past edits.



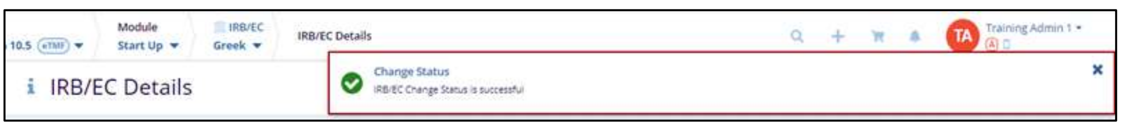
Change Status

The user can change the status of a country by following the steps below:

1. Click the Change Status button displayed on the IRB/EC 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.



5. The notification message is displayed as ‘IRB/EC Change Status is successful’.

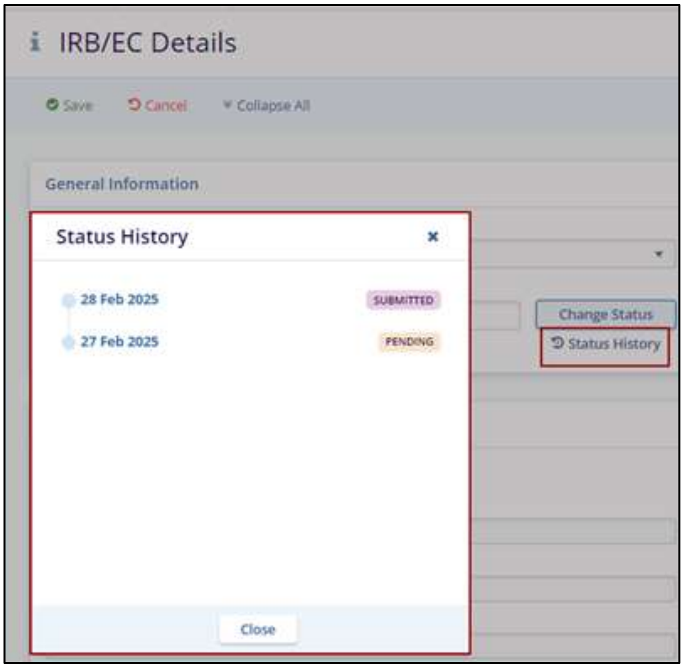


6. Click the Save button on the top of the menu bar on the IRB/EC Details page.

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 IRB/EC Details page.

Note: The user can only view the history and cannot edit any information in the table displayed.



The notification message is displayed as 'Current IRB/EC was successfully updated!'.

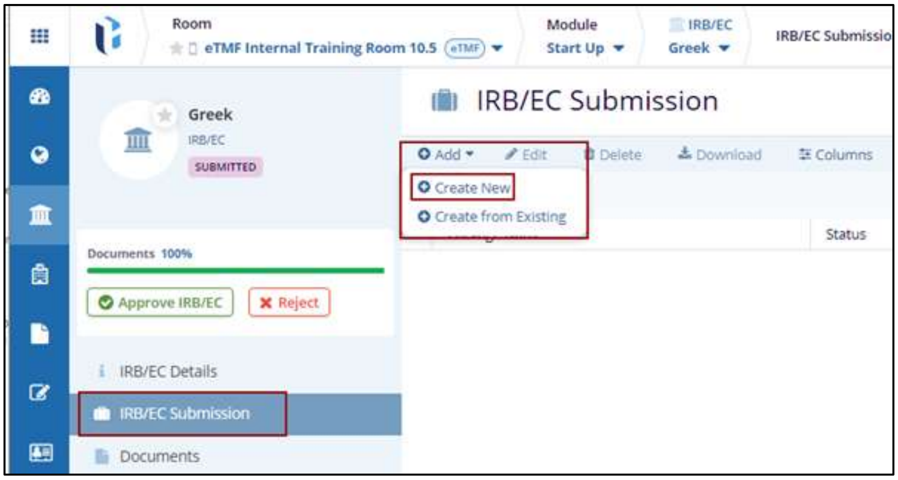
IRB/EC Submission

An IRB/EC Submission refers to the process of submitting a research study for ethical review and approval before conducting research. This is required to ensure the protection of participants' rights, safety, and well-being.

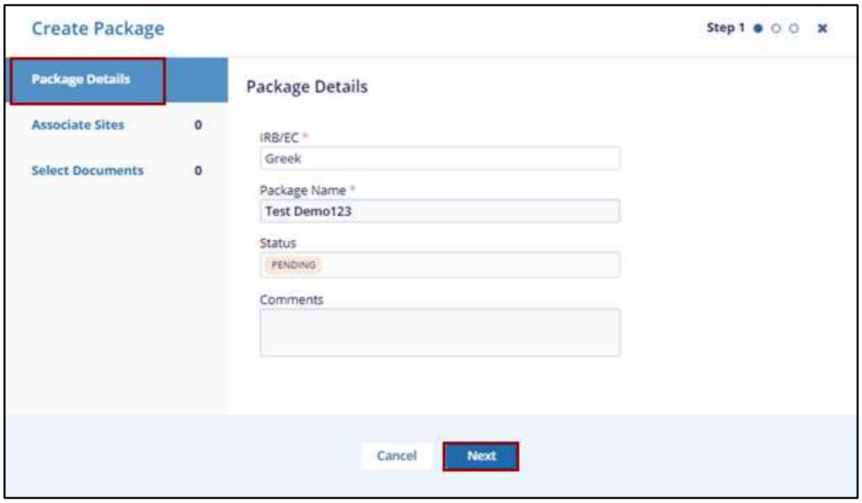
Add Additional IRB/EC

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.

1. Click the IRB/EC Submission option on the IRB/EC Details page. This opens the IRB/EC Submission Page.
2. Click the drop-down arrow next to the Add button. The Create New and Create from Existing options are displayed.



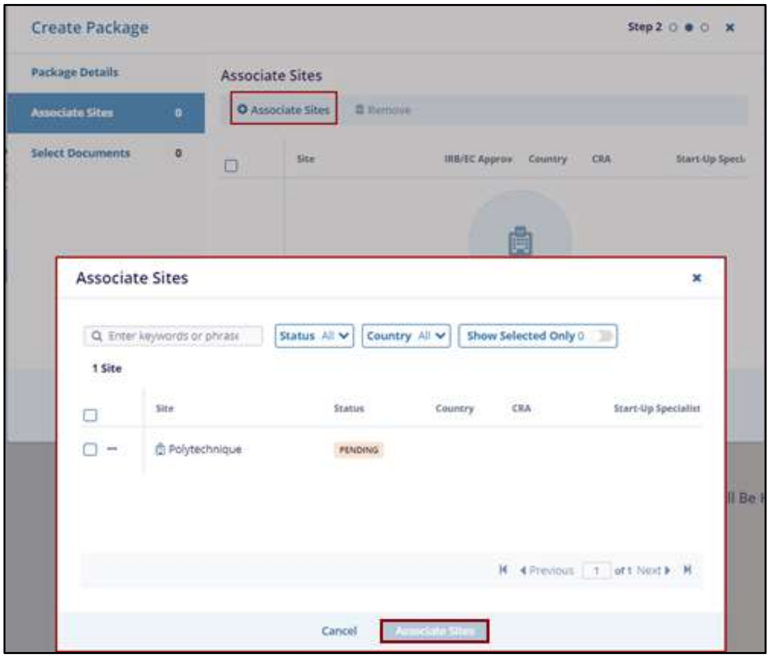
3. Click the Create New option. The Create Package pop-up window is displayed.
4. In the Package Details tab, fill in the required fields – IRB/EC, and Package Name
5. Click the Next button at the bottom of the popup window.



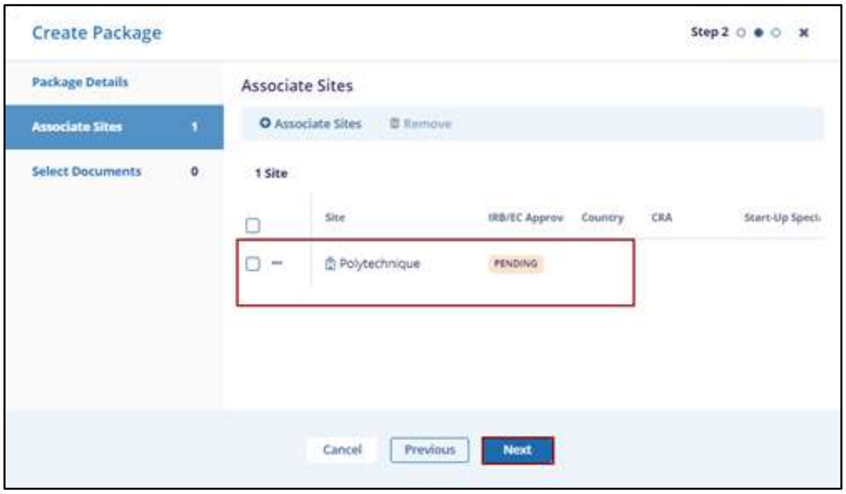
6. This opens the Associate Sites tab, click on the + Associate Sites button.
7. The Associate Sites pop-up window is displayed.

This section will cover the following features:

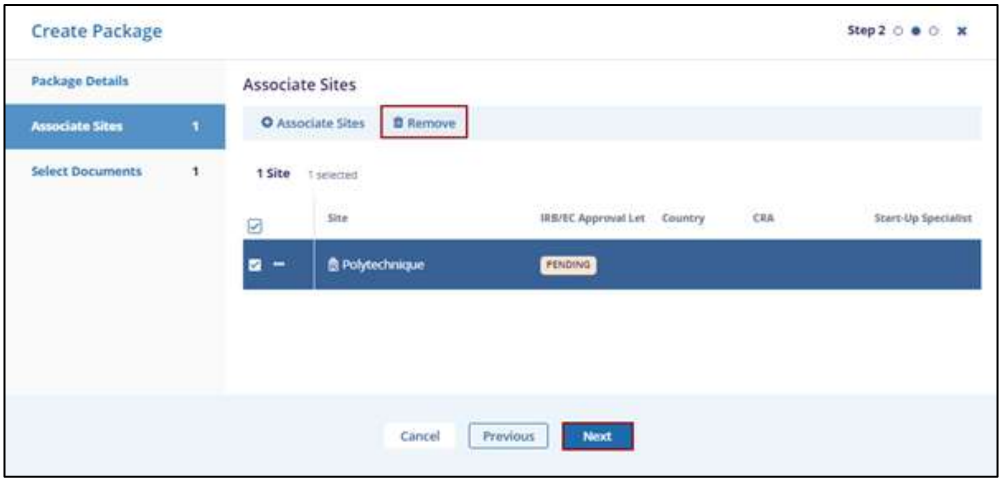
- Status: Allows users to filter sites based on their selected status.
- Country: Enables users to specify a country as needed.
- Show Selected Only: A toggle button that displays only sites filtered by Status and Country.



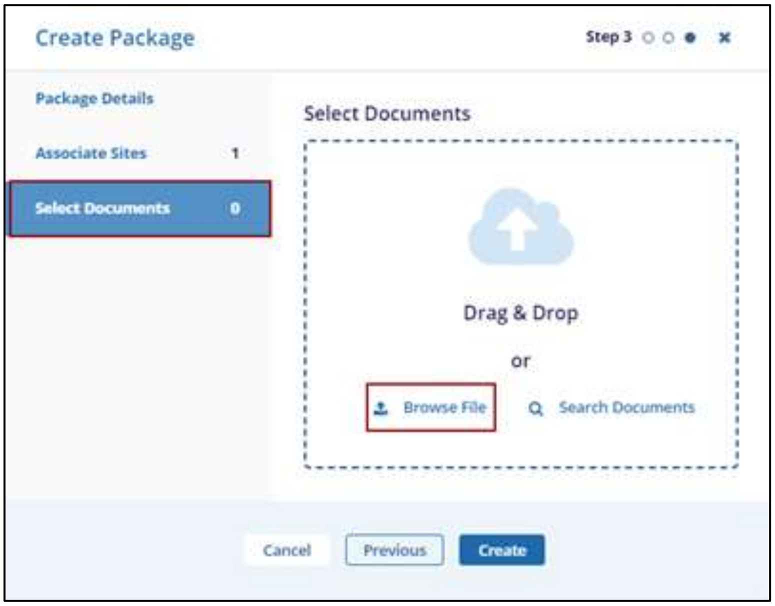
8. Click Associate Sites, and the associated site is displayed within the Associate Sites tab.
9. Click on the Next button.

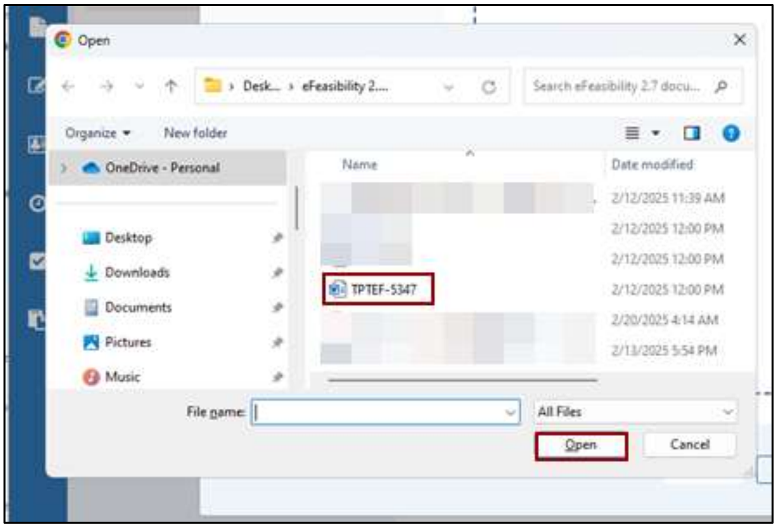


10. Locate the Site and click the Remove button. The associated site is removed from the Create Package.

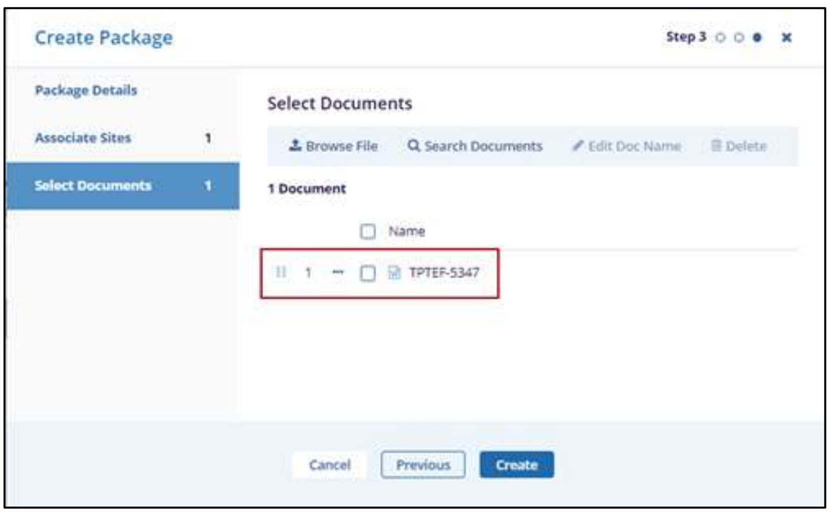


11. This opens the Select Documents tab. Select an appropriate option – Browse Files OR Search Documents.
12. Click on the Browse Files option, select a document from the system, and click on Open.



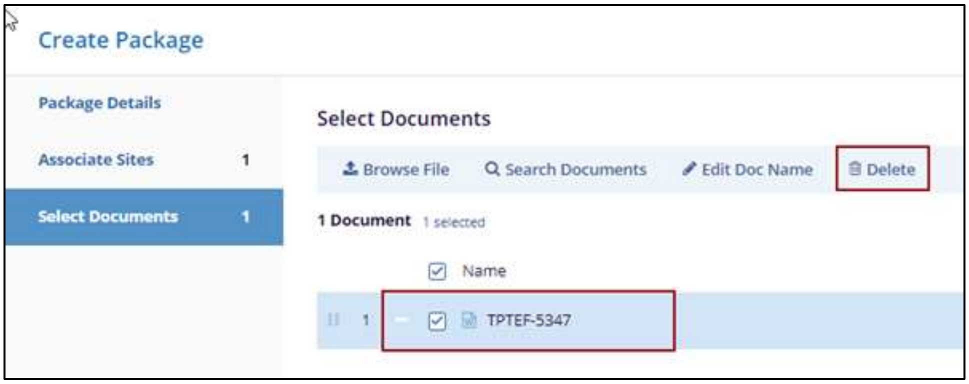


13. The selected document is added to the Select Documents tab.

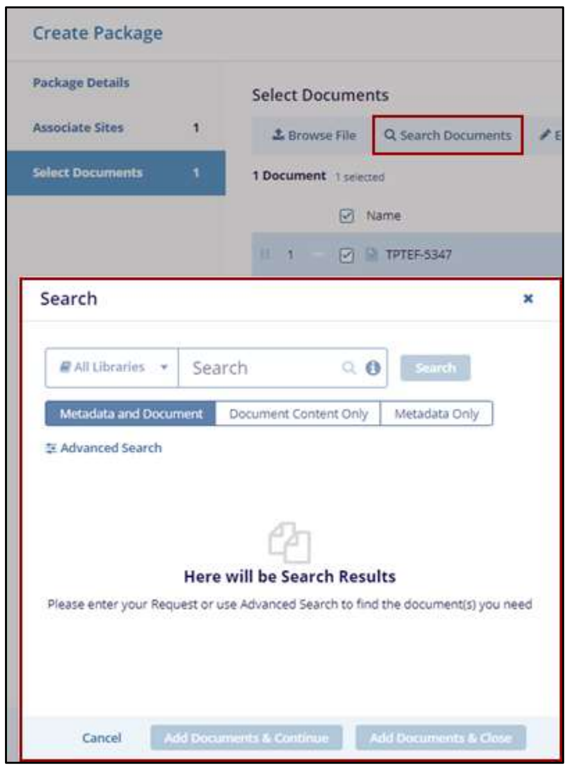


14. Once the document is uploaded, select the document click on the Edit Doc Name, make the required changes, and click the Tick mark beside the document.

15. Select the document and click Delete the button to discard the action.

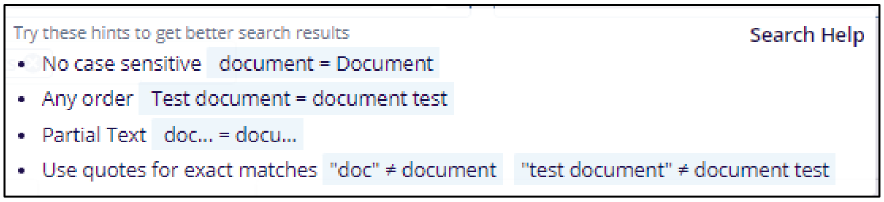


16. Click the Search Documents tab the Search pop-up window is displayed.

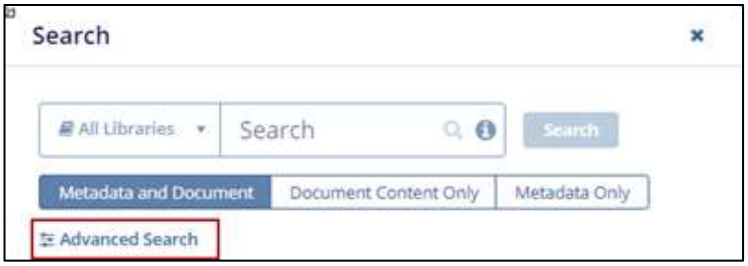


17. Expand the All Libraries arrow to search from SSU Library or eTMF Library.

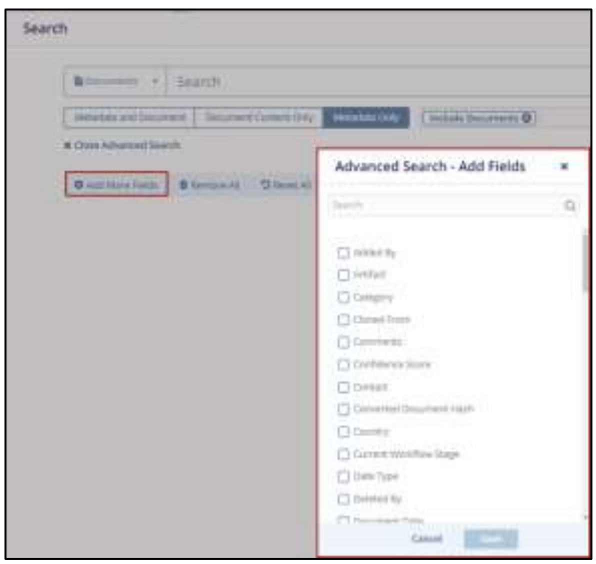
Note: Some hints to get better search results:



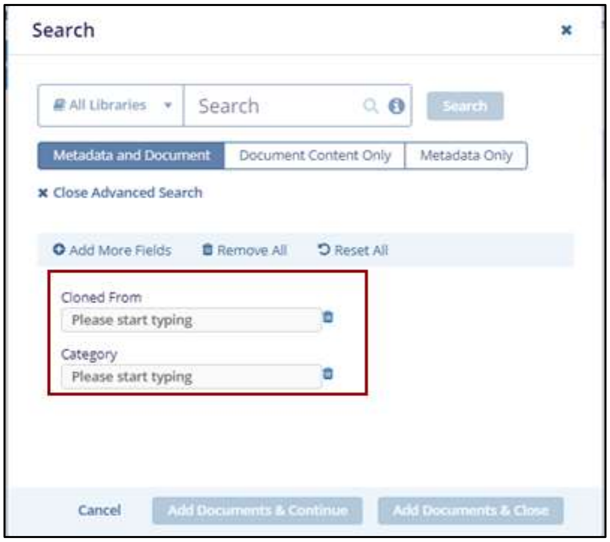
18. Clicking the Advanced Search button in the search pop-up window redirects the user to the Advanced Search page.



19. Users can add unlimited fields as needed with the + Add More Fields button. The Advanced Search – Add Fields pop-up window is displayed.



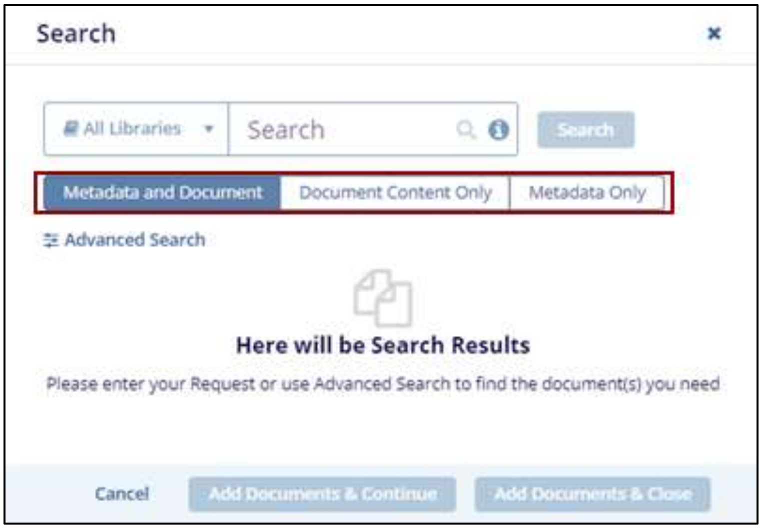
20. Select the fields and click the Save button. The selected fields added to the Search page.



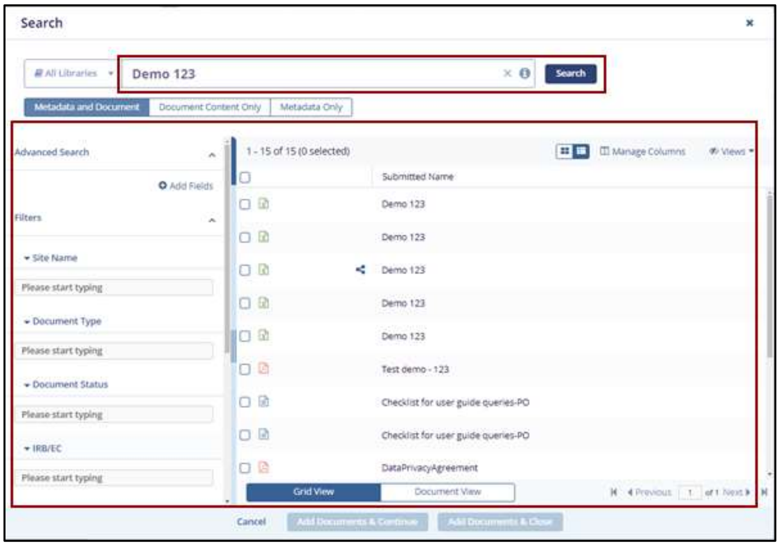
21. Click the Remove All option to remove the added fields.
22. Click Reset All resets the page with the existing information.

23. The Search pop-up window displays the below three tabs by default.
    - Metadata and Document
    - Document Content Only
    - Metadata Only

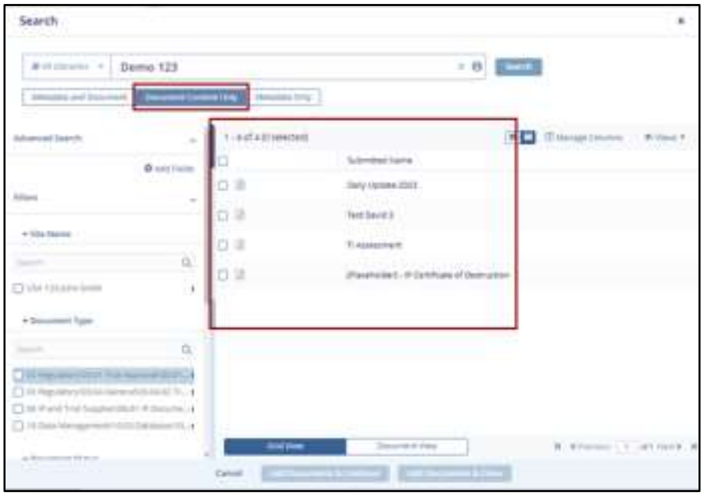
Note: The Metadata and Document tab is pre-selected by default. Choose Document Content Only or Metadata Only if you want to filter the results accordingly.



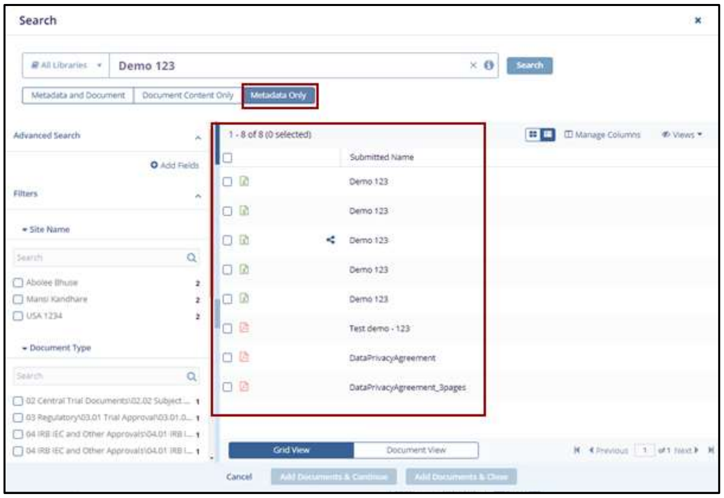
24. Enter the document name in the Search field and click Search. The searched document is displayed with the Metadata on the left side.



25. Click the Document Content Only tab it will display the document based on the content only.

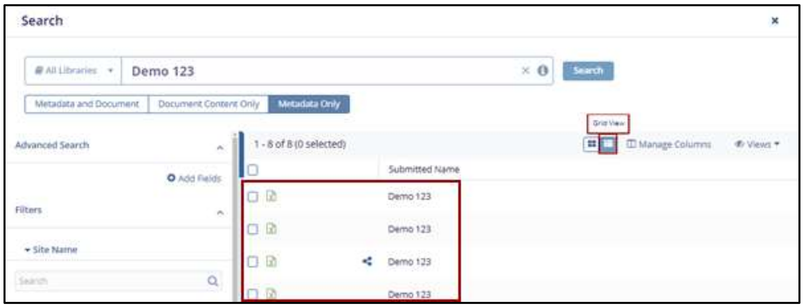


26. Click the Metadata Only tab it will display the document having metadata.

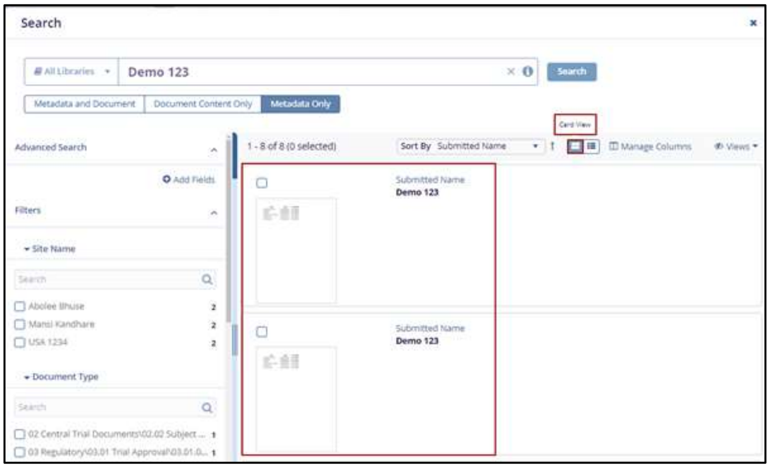


27. The users can view the views in two ways:

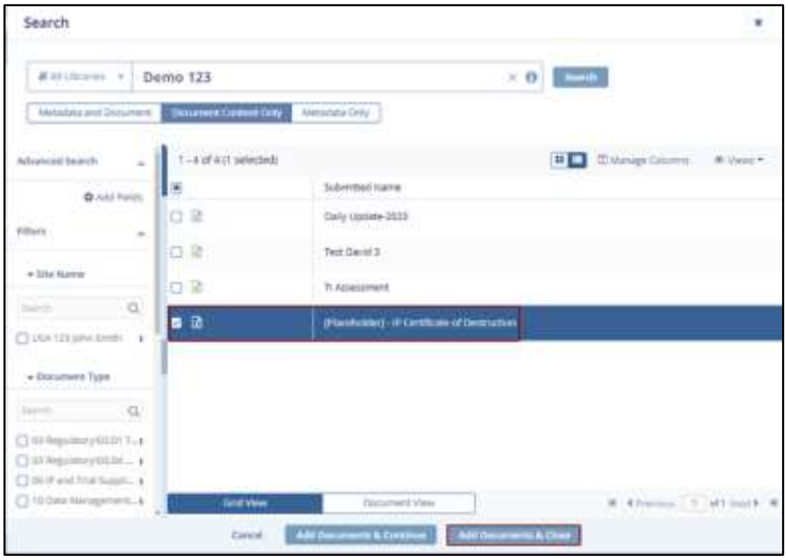
- Grid View



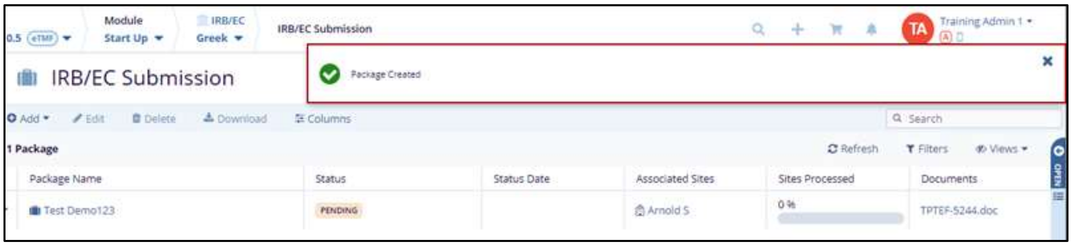
- Card View



28. Select the document and click Add Documents & Continue or Add Documents & Close button as per the requirement.



29. Click Add Documents & Close will close the Search pop-up window.
30. Click the Create button. The notification message is displayed on the top right side of the screen.



Columns

To know more detailed information about columns please refer to this link - Columns.

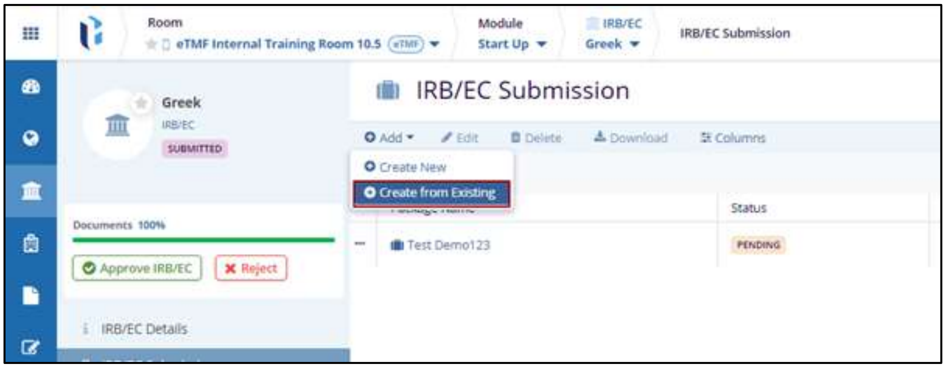
Views

To know more detailed information about views please refer to this link - Popular Documents.

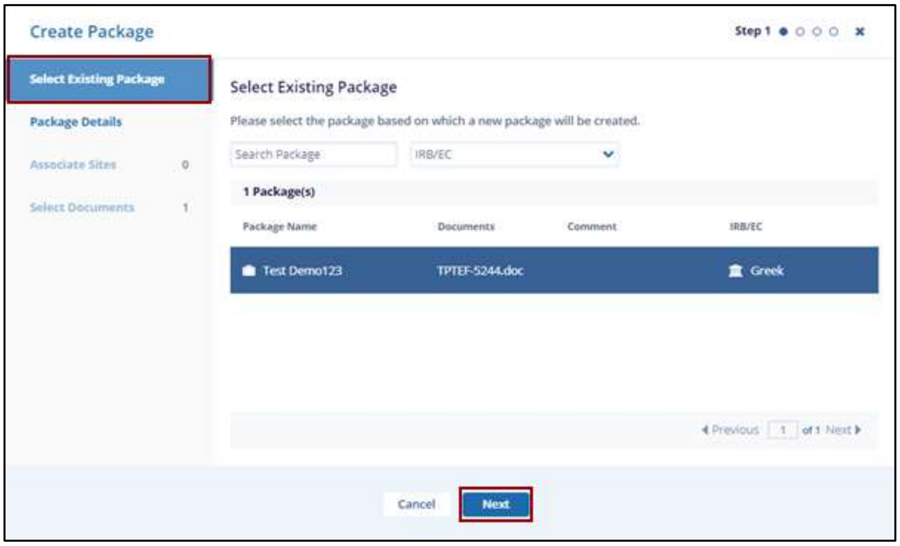
Creating IRB/EC from Existing

Follow the below steps to add the existing agency:

1. Click the drop-down arrow next to the Add button. The Create New and Create from Existing options are displayed.
2. Click the Create from Existing option. The Create Package pop-up window is displayed.

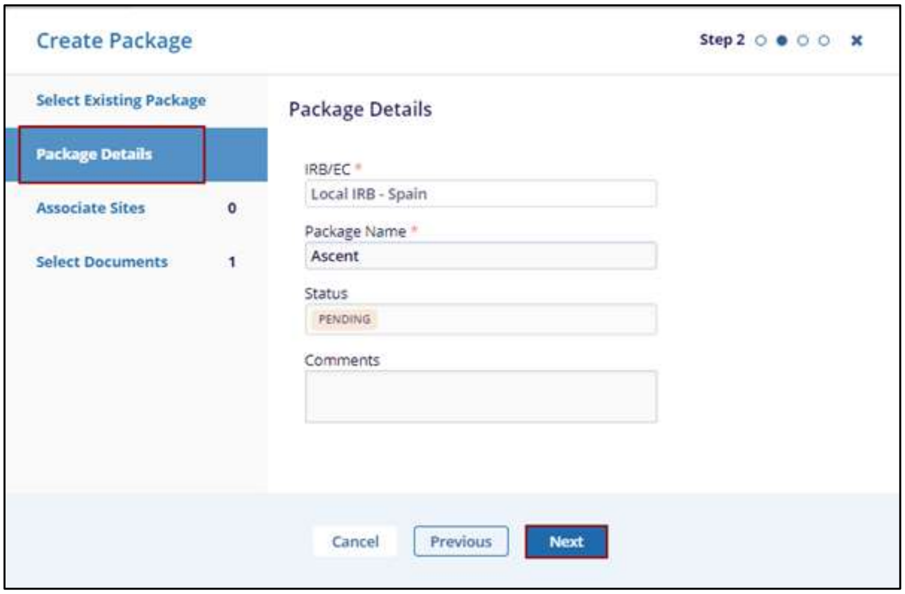


3. In the Select Existing Package, the list of existing packages is displayed.
4. Select the package based on which a new package will be created and click Next.



5. In the Package Details tab, fill in the required fields – IRB/EC, and Package Name.

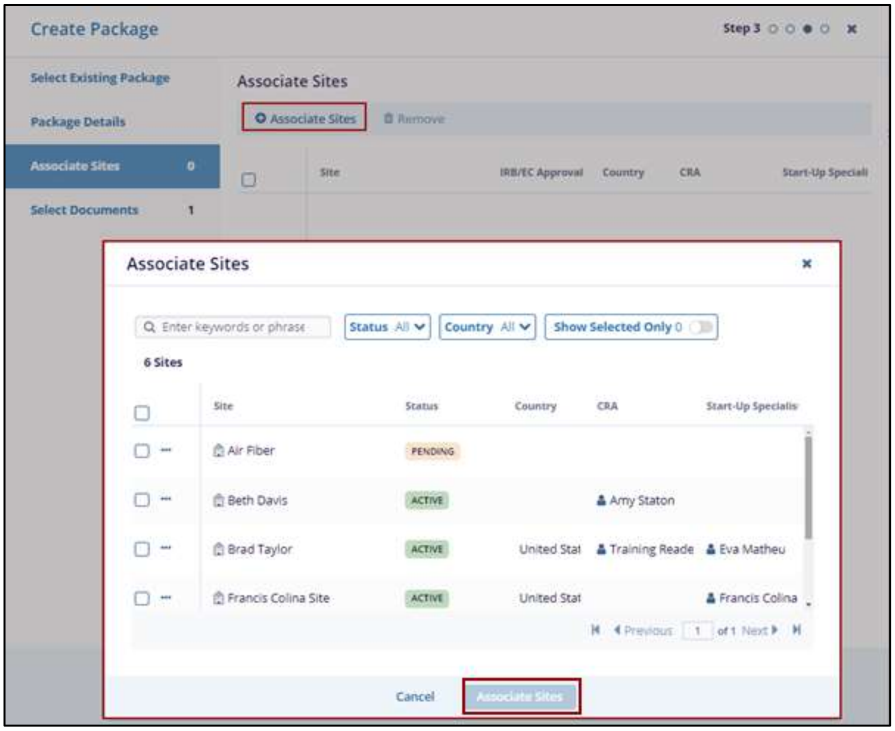
6. Click the Next button at the bottom of the popup window.



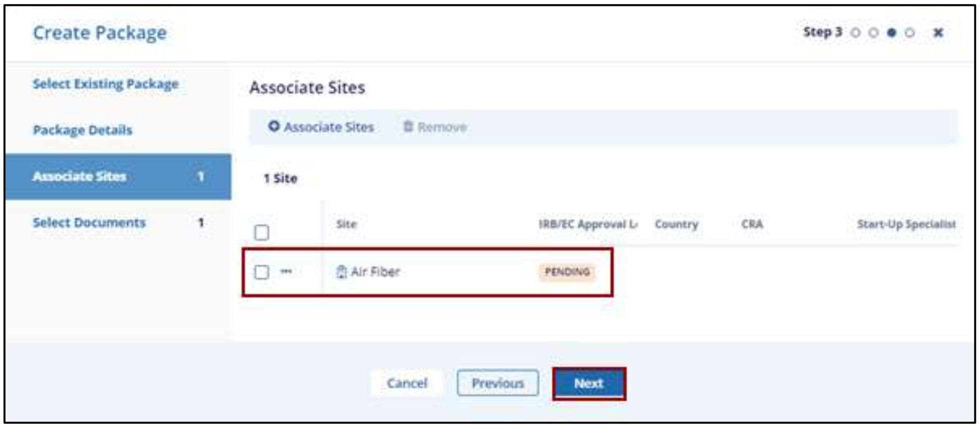
31. This opens the Associate Sites tab, click on the + Associate Sites button.
32. The Associate Sites pop-up window is displayed.

    This section will cover the following features:

    - Status: Allows users to filter sites based on their selected status.
    - Country: Enables users to specify a country as needed.
    - Show Selected Only: A toggle button that displays only sites filtered by Status and Country.

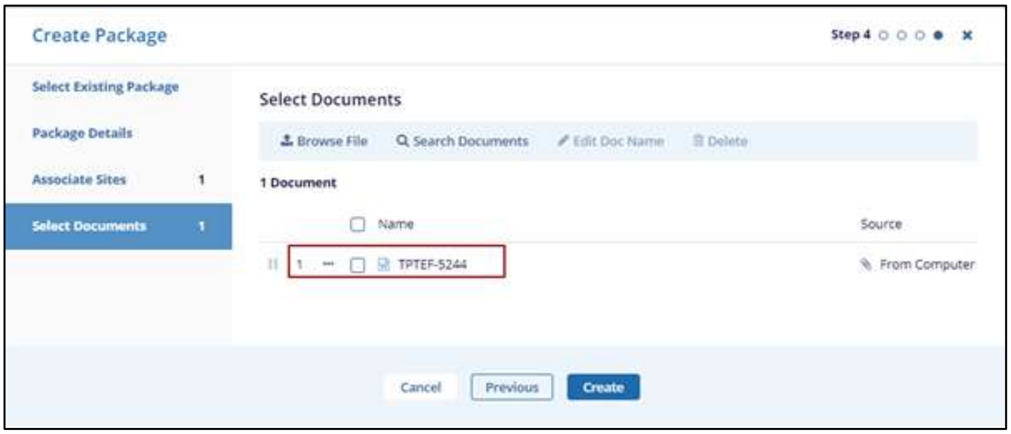


33. Click Associate Sites, and the associated site is displayed within the Associate Sites tab.
34. Click on the Next button.

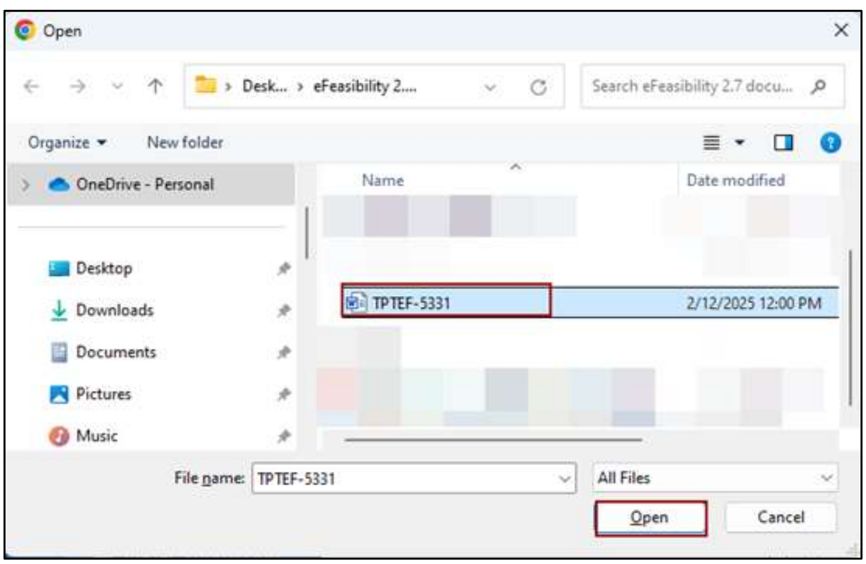


35. Locate the Site and click the Remove button. The associated site is removed from the Create Package.

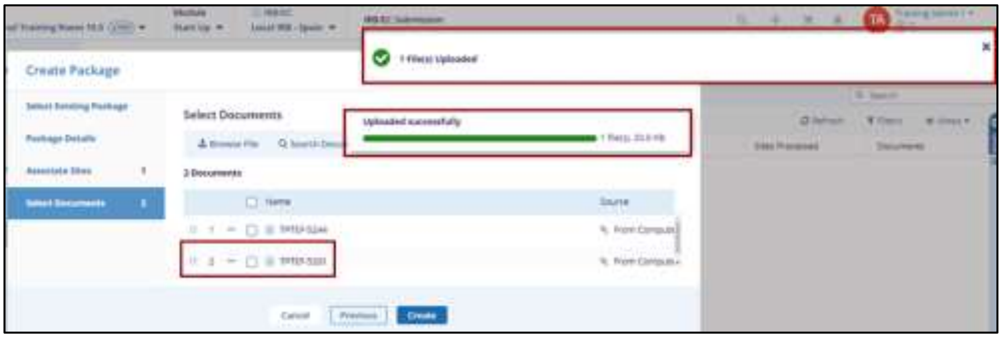
36. This opens the Select Documents tab. As the user is adding the existing package the Site is already associated with the package.



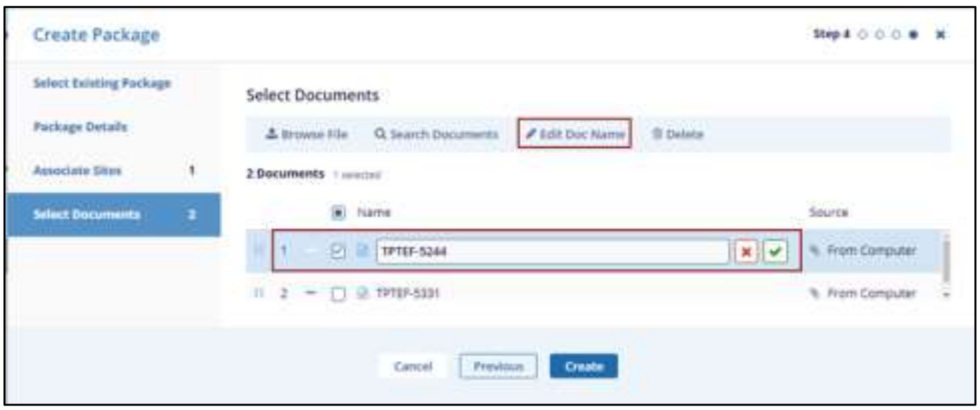
37. If user want to associate another Site, then click the Browse Files on the top menu bar.
38. Select a document from the system, and click on Open.



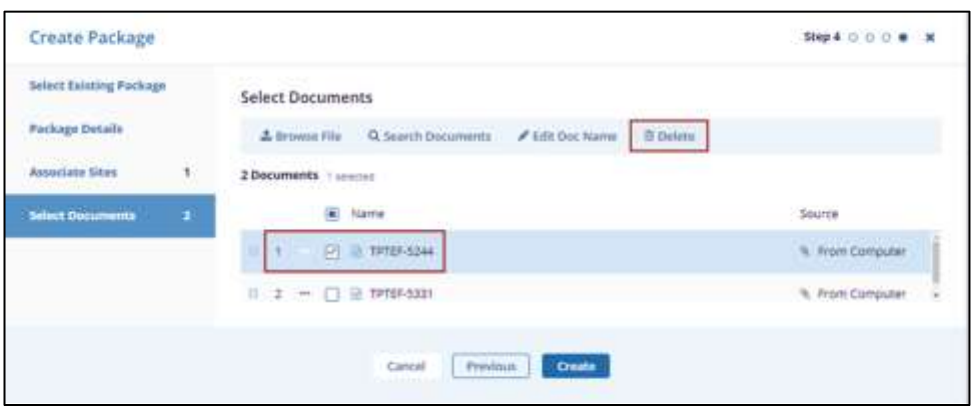
39. The selected file is uploaded in the Select Documents section and the notification message is displayed on the screen.



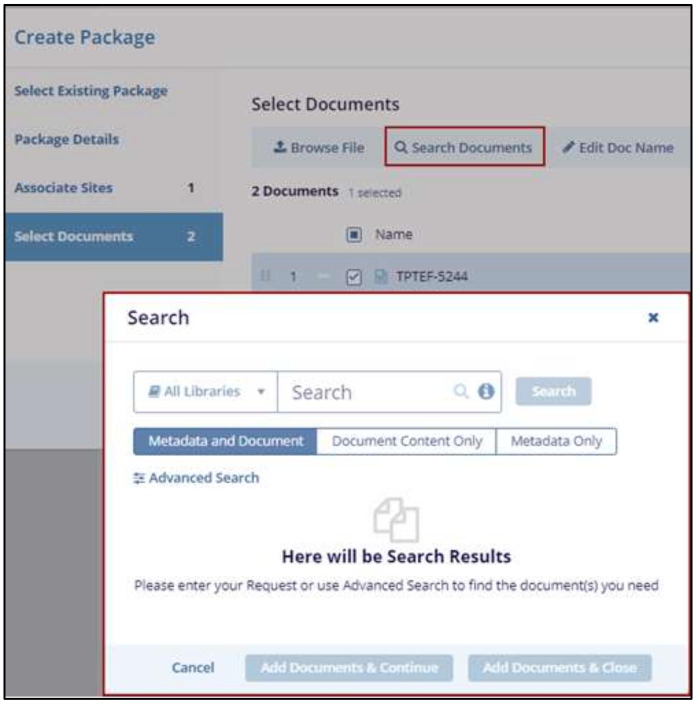
38. Once the document is uploaded, select the document click on the Edit Doc Name, make the required changes, and click the Tick mark beside the document.



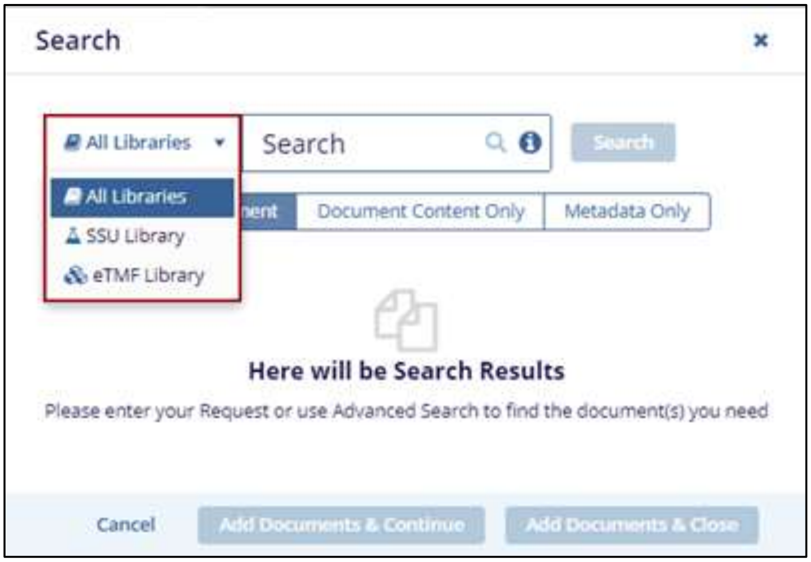
39. Select the document and click Delete the button to discard the action.



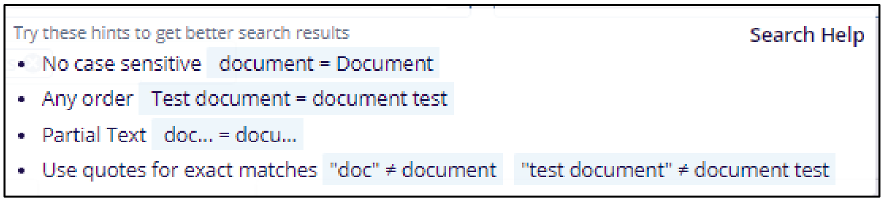
40. Click the Search Documents tab the Search pop-up window is displayed.



41. Expand the All-Libraries arrow to search from SSU Library or eTMF Library.



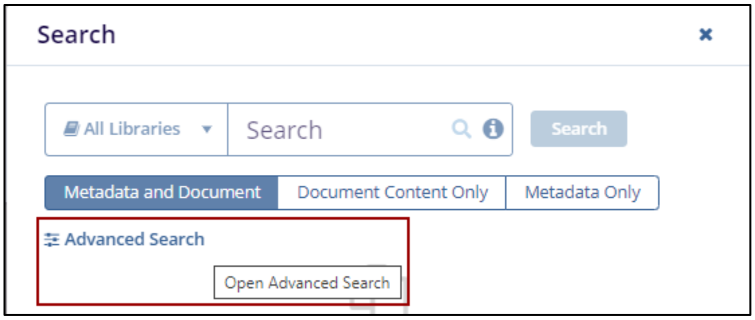
Note: Some hints to get better search results:


Try these hints to get better search results

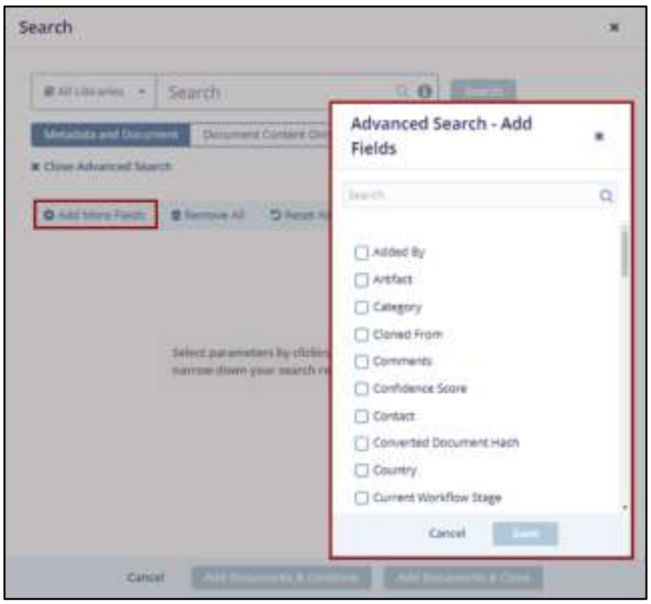
Search Help

- No case sensitive document = Document
- Any order Test document = document test
- Partial Text doc... = docu...
- Use quotes for exact matches "doc" ≠ document "test document" ≠ document test

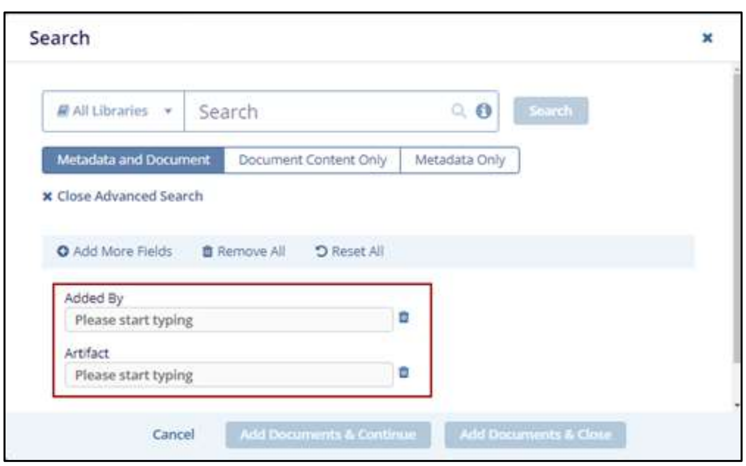
42. Clicking the Advanced Search button in the search pop-up window redirects the user to the Advanced Search page.



43. Users can add unlimited fields as needed with the + Add More Fields button. The Advanced Search – Add Fields pop-up window is displayed.



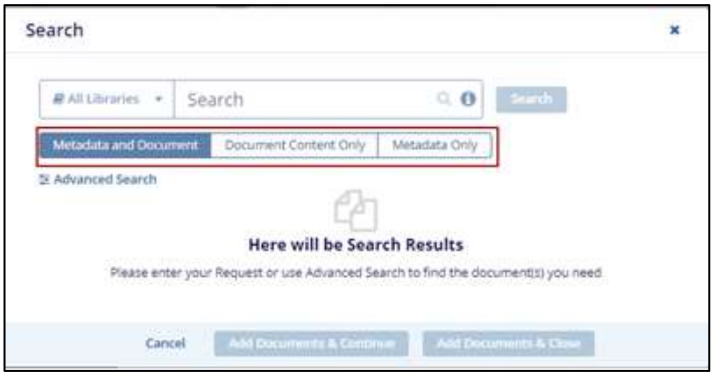
44. Select the fields and click the Save button on the Advanced Search – Add Fields.



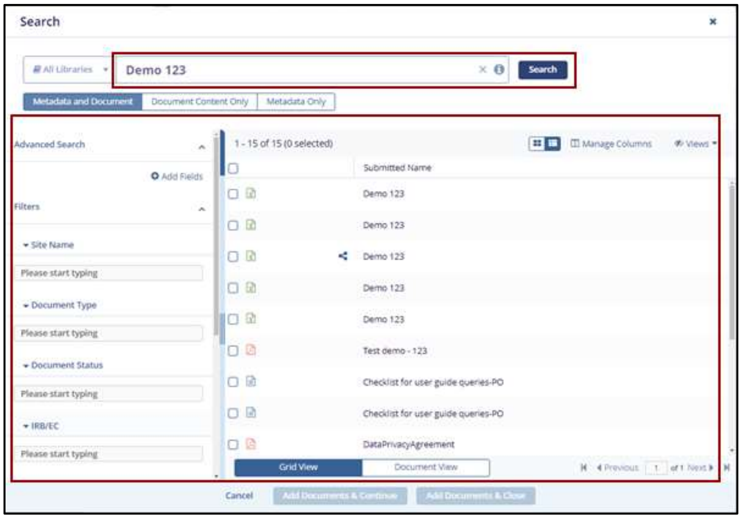
45. Click the Remove All option to remove the added fields.
46. Click Reset All resets the page with the existing information.

47. The Search pop-up window displays the below three tabs by default.
    - Metadata and Document
    - Document Content Only
    - Metadata Only

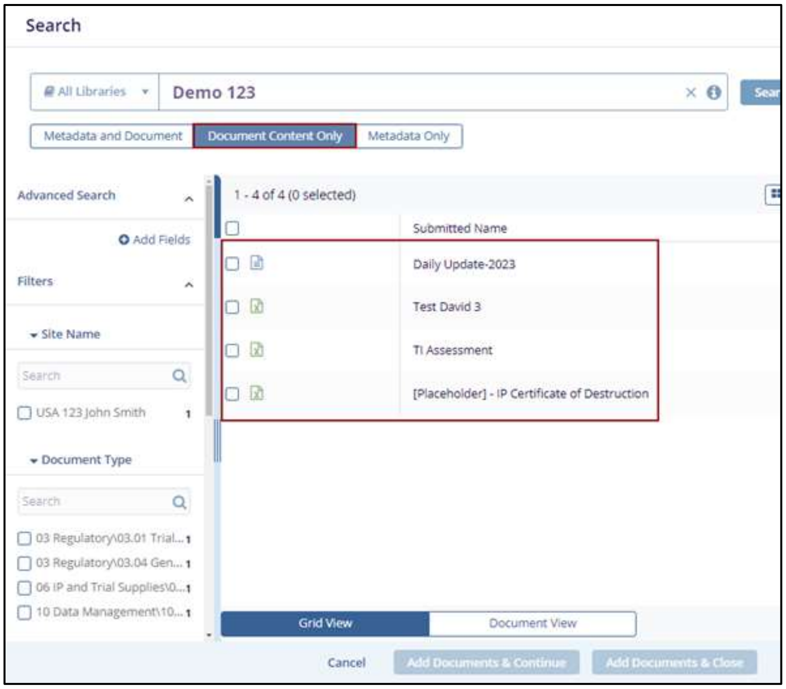
Note: The Metadata and Document tab is pre-selected by default. Choose Document Content Only or Metadata Only if you want to filter the results accordingly.



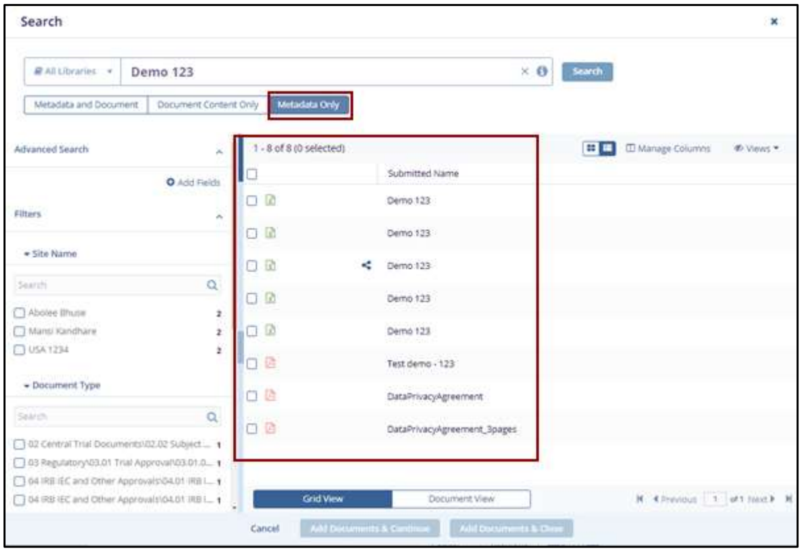
48. Enter the document name in the Search field and click Search. The searched document is displayed with the Metadata on the left side.



49. Click the Document Content Only tab it will display the document based on the content only.

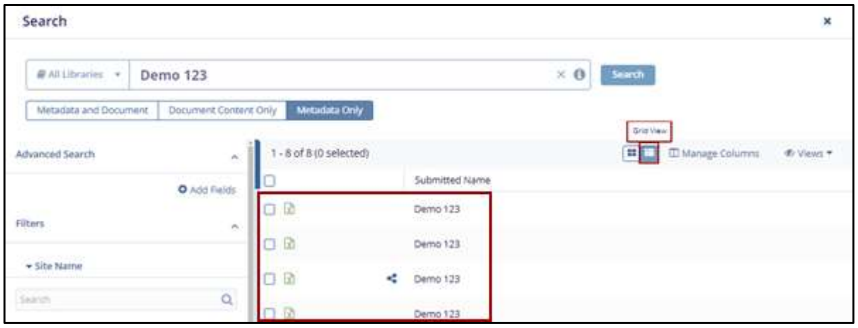


50. Click the Metadata Only tab it will display the document having metadata.

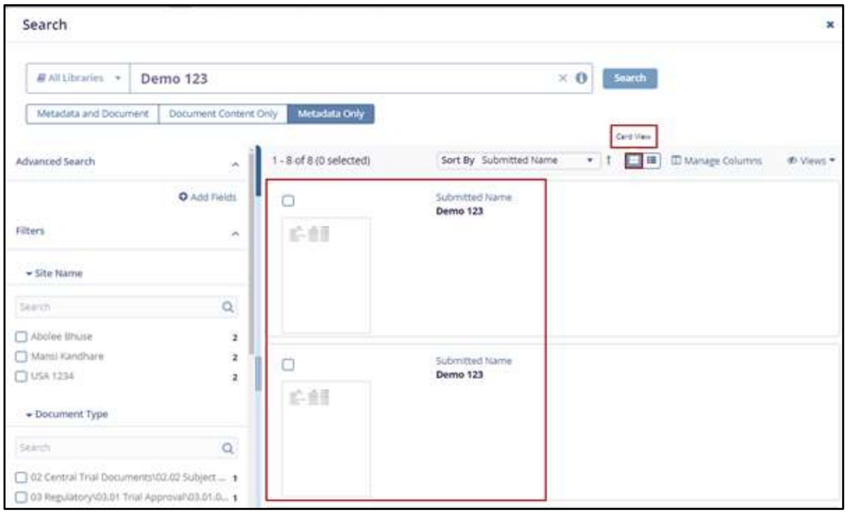


51. The users can view the views in two ways:

- Grid View

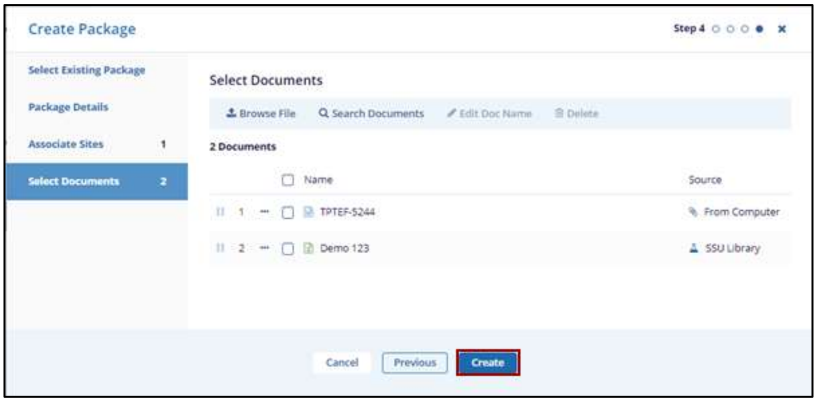


- Card View



52. Click Add Documents & Continue will display the notification message at the top right of the screen and will continue on the same page to add the documents.

53. Click Add Documents & Close will close the Search pop-up window.
54. Click Create on the Create package pop-up screen.



55. The Package Created notification message is displayed at the top right of the screen.

Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Editing a Package

1. Click on the package name the Package Details page is displayed.

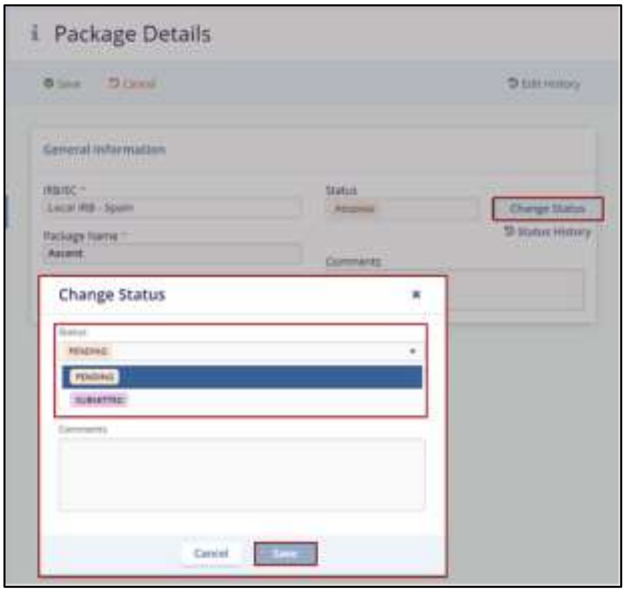
2. Click on the Edit button displayed on the top menu bar. The Package Name field get editable on the General Information page with the Save and Cancel buttons.

3. Make the changes in the required fields and click the Save button displayed on the top menu bar.
4. Click Cancel button to discard the changes.

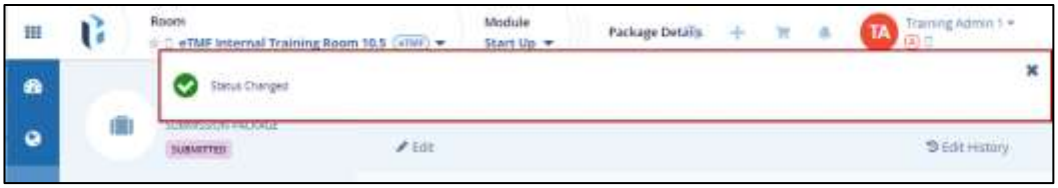
Change Status

The user can change the status of a country by following the steps below:

1. Click the Change Status button displayed on the Package 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.



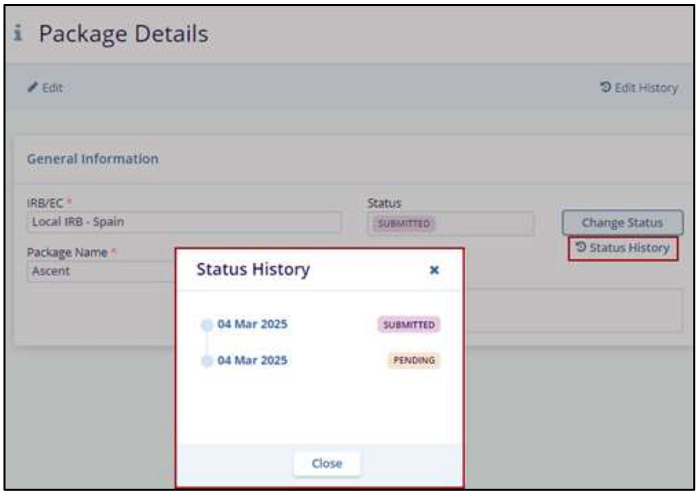
5. The notification message is displayed as 'Status Changed'.



Status History

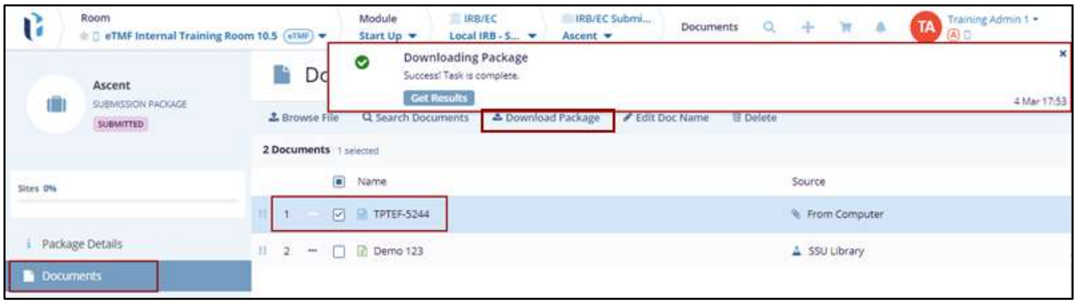
A Status History button is displayed below the Change Status button. Click the button to view the name of the user who made the changes on the IRB/EC Details page.

Note: The user can only view the history and cannot edit any information in the table displayed.

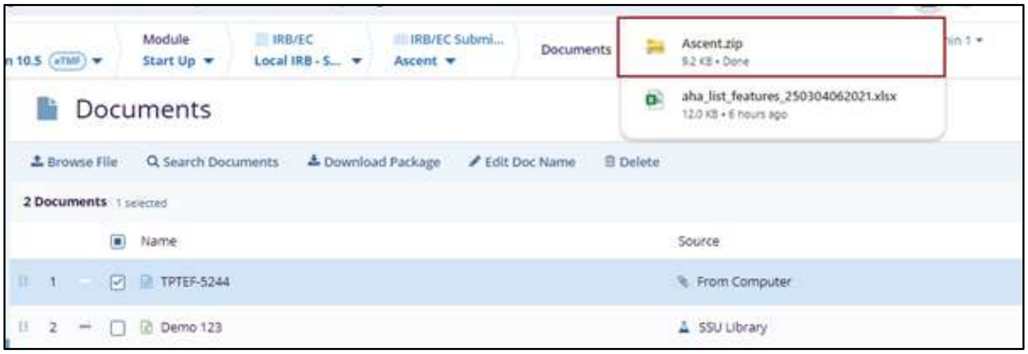


Documents

1. Select the document that is added to the selected package and click the Download Package button.
2. The package is downloaded notification message is displayed on the top right of the screen.

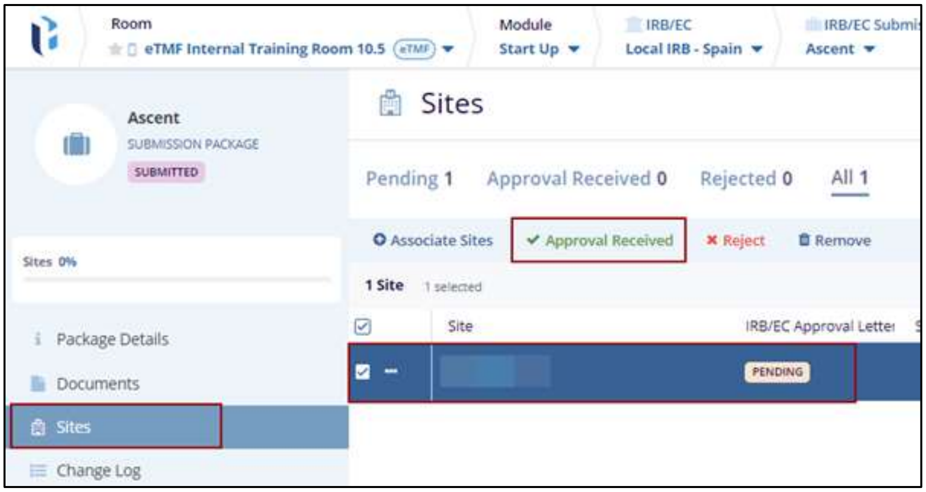


3. Click on the Get Results button on the notification message. The zip file of the selected package is downloaded.

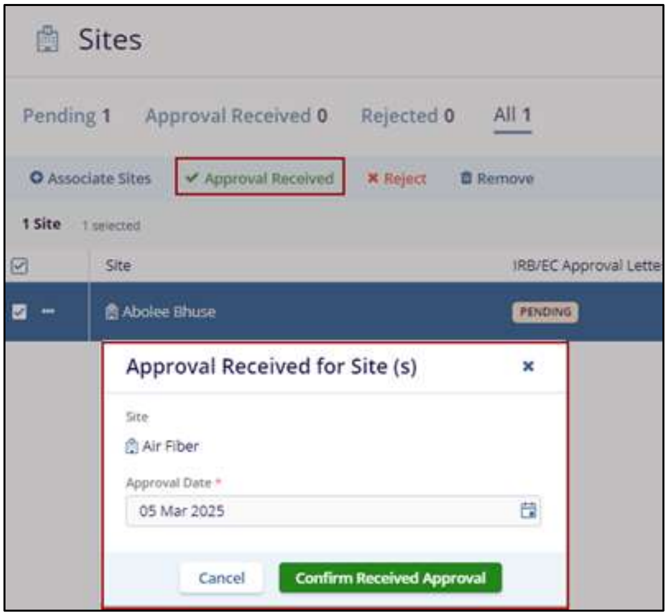


Sites

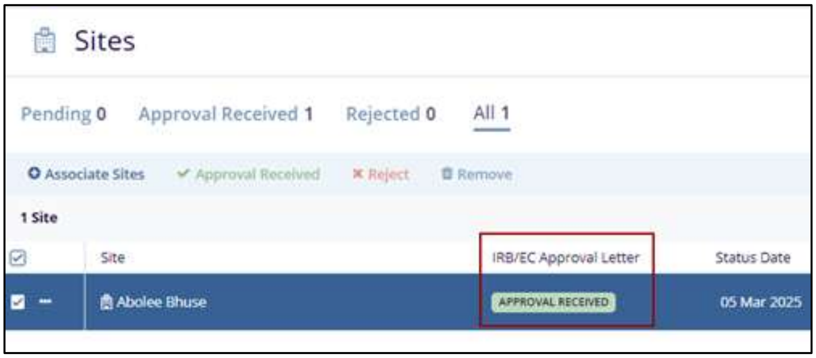
1. Select the associated site of the selected package and click the Approval Received button on the top menu bar.



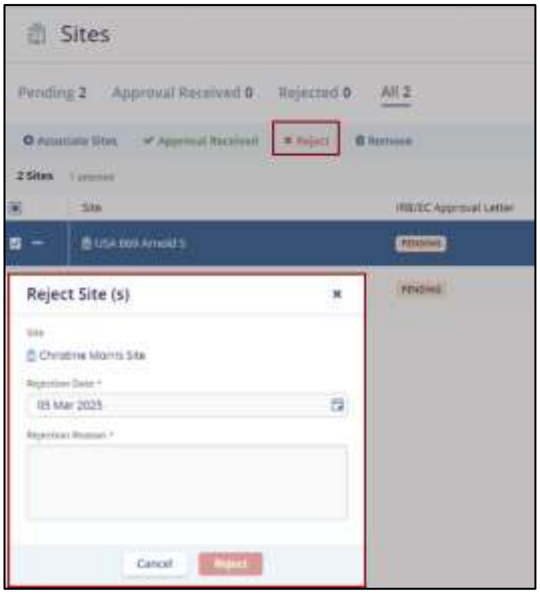
2. The Approval Received for Site (s) pop-up window is displayed with the Cancel and Confirm Received Approval buttons.



3. Click the Confirm Received Approval button to confirm the approval. The IRB/EC Approval Letter column displays the Approval Received status for the selected site.
4. Click the Cancel button to discard the changes.

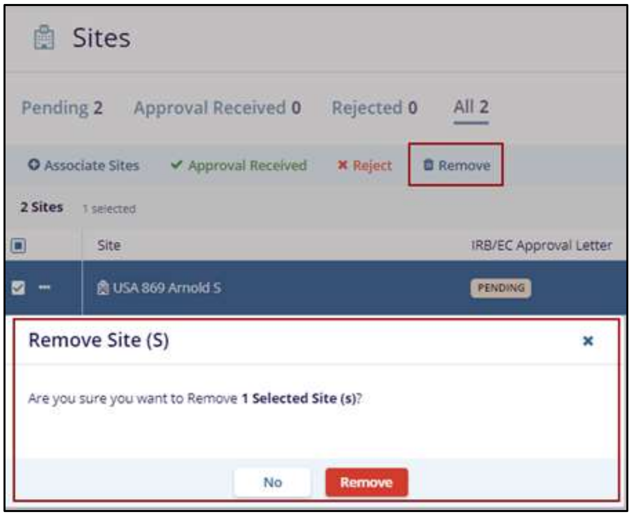


5. Locate the Site and click the Reject button on the top menu bar. The Reject Sites (s) pop-up window is displayed with the Cancel and Reject buttons.



6. Click the Reject button once the user enters the Rejection Reason in the box.
7. Click the Cancel button to discard the changes.

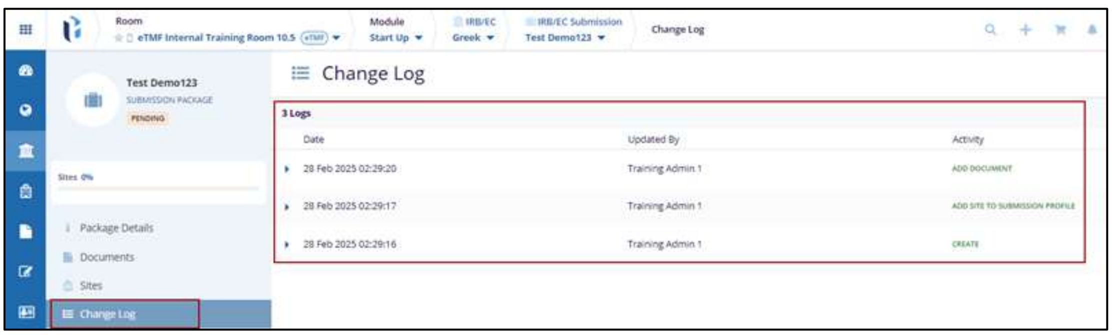
8. Locate the site and click the Remove button on the top menu bar. The Remove Site (s) pop-up window is displayed with the No and Remove buttons.



9. Click the Remove button the selected site gets removed from the grid.

Change Log

A Change Log is a file that records all notable changes made to a package. It helps users understand what has changed in different versions of the package.



Documents

To know more detailed information about views please refer to this link - Documents

Amendments

To know more detailed information about views please refer to this link - Amendments

Sites

To know more detailed information about views please refer to this link - Sites

Communication Log

To know more detailed information about views please refer to this link - Communication Log

SITE

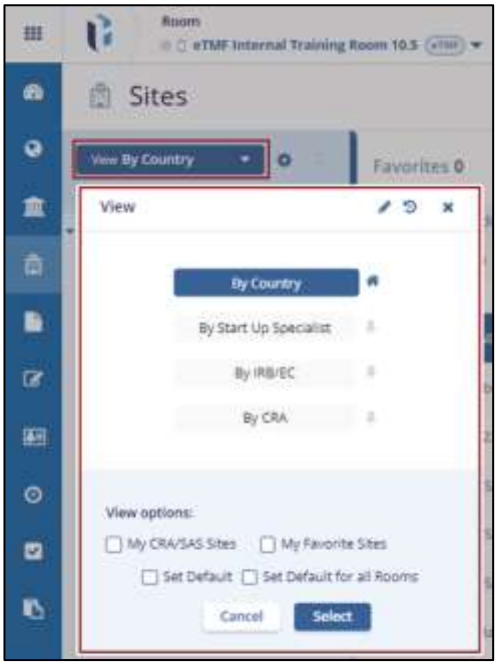
The Sites Module in the Study Start-Up (SSU) process refers to the set of activities involved in identifying, evaluating, selecting, and activating clinical trial sites.

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.

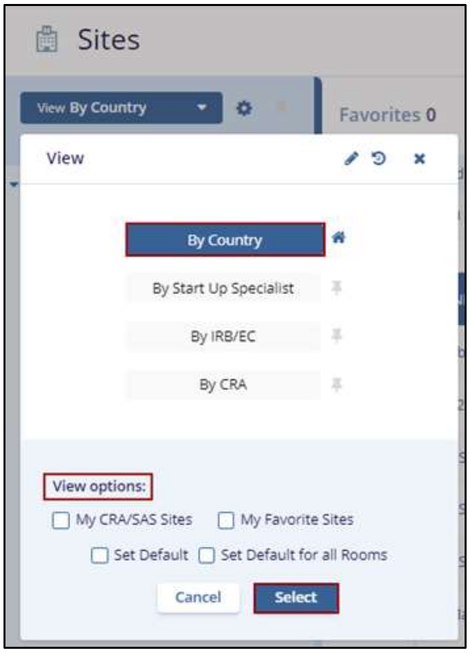
Views:

Users can customize views as needed, and the grid view adjusts accordingly to display relevant information.

1. On the left side of the Sites screen in the index panel click the View By drop-down arrow.
2. The View pop-up window is displayed with the views.



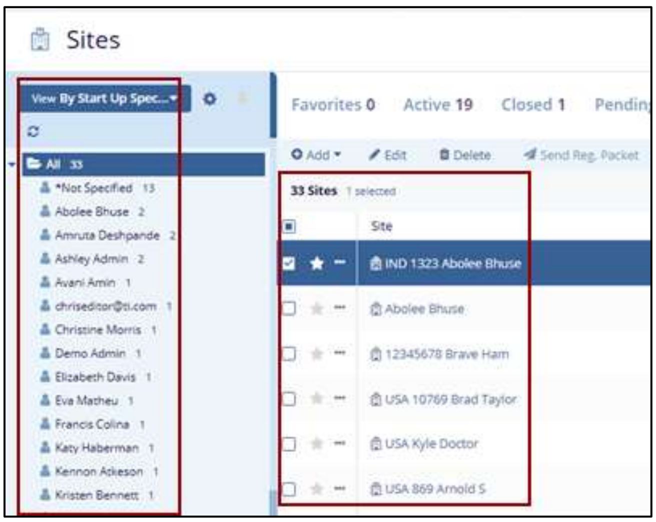
3. Select the By Country view, optionally check the desired 'View Options' at the bottom of the View pop-up, and click the Select button.



4. The Index panel displays the Country list and the associated sites on the right side.

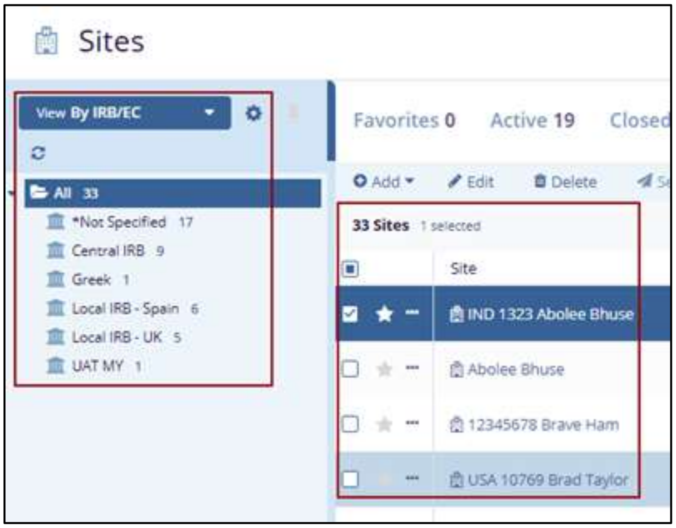
5. Select the By Start Up Specialist view, optionally check the desired ‘View Options’ at the bottom of the View pop-up, and click the Select button.

6. The Index panel displays the Start Up Specialist Users list and sites on the right side.



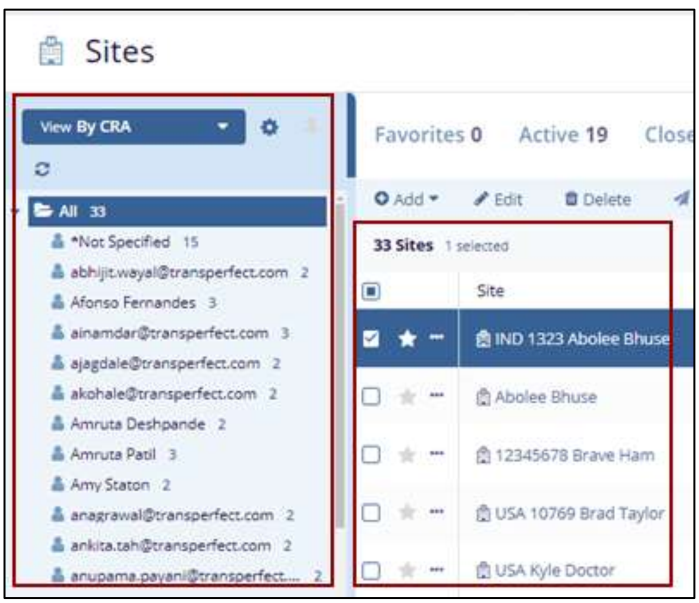
7. Select the By IRB/EC view, optionally check the desired 'View Options' at the bottom of the View pop-up, and click the Select button.

8. The Index panel displays the IRB/ECs list and sites on the right side.



9. Select the By CRA view, optionally check the desired ‘View Options’ at the bottom of the View pop-up, and click the Select button.

10. The Index panel displays the CRA Users list and sites on the right side.



Buttons on the Current view

The data room supports hundreds of sites, allowing users to toggle between sites where they are a CRA, a Start-Up Specialist, or view all sites. Users can refresh the current view with the Refresh Current View button. Room administrators can configure the grid layout using the Configure Grid button to set default columns and sorting options. While all users can show or hide columns, only administrators can make additional columns available for viewing.

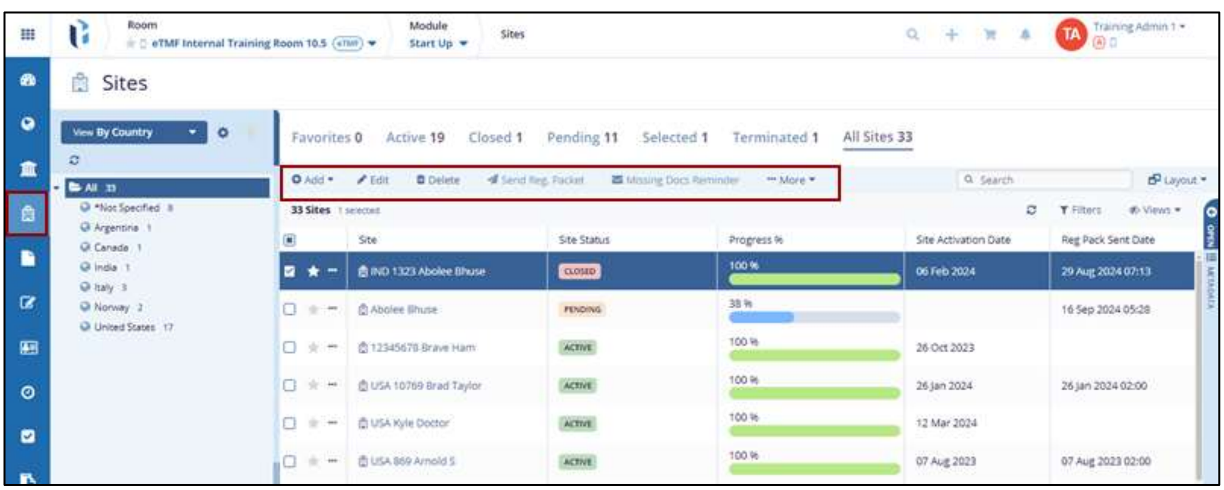
- Settings: Check the relevant option from the list and click Save and Reload.

- Pin View button: The Pin View feature allows users to save and quickly access a specific grid configuration, ensuring a consistent display of selected columns and sorting preferences across sessions.

- Refresh Button: The Refresh Current View button updates the displayed data, ensuring users see the latest site information without changing their current filters or settings.

On the Sites page, users have the following options:

- View Sites – Browse available sites.
- Add Sites – Add new sites to the data room.
- Import – Upload site data in bulk.
- Edit – Modify site details.
- Delete – Remove selected sites.
- Sending Reg. Packet – Send regulatory packets to sites.
- Reminder for Missing Docs – Notify sites about missing documents.
- Managing Security – Configure site access permissions.
- Export Metadata – Download site metadata.
- Columns – Customize column visibility in the grid.
- Mass Coding – Apply bulk updates to multiple sites.



Add Sites

Sites can be newly created or imported from existing sites linked to the same sponsor across different rooms within a domain, which is particularly useful for managing sites across multiple locations.

To know more detailed information about Add Sites please refer to this link - Adding Sites.

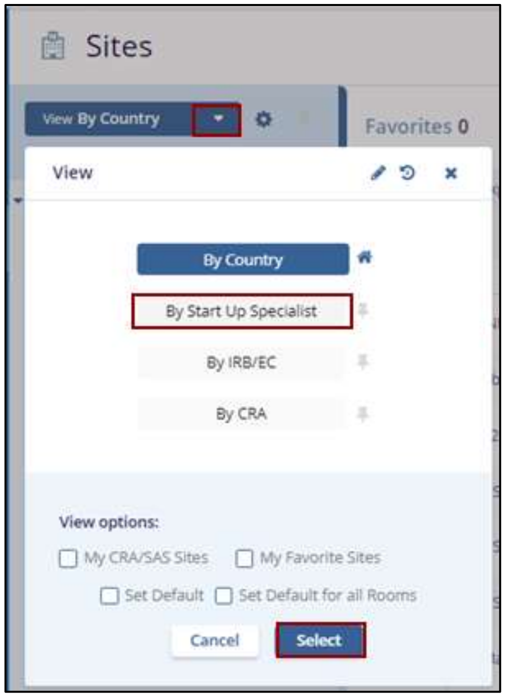
Import Site List

To know more detailed information about Import Site List please refer to this link - Import Site List.

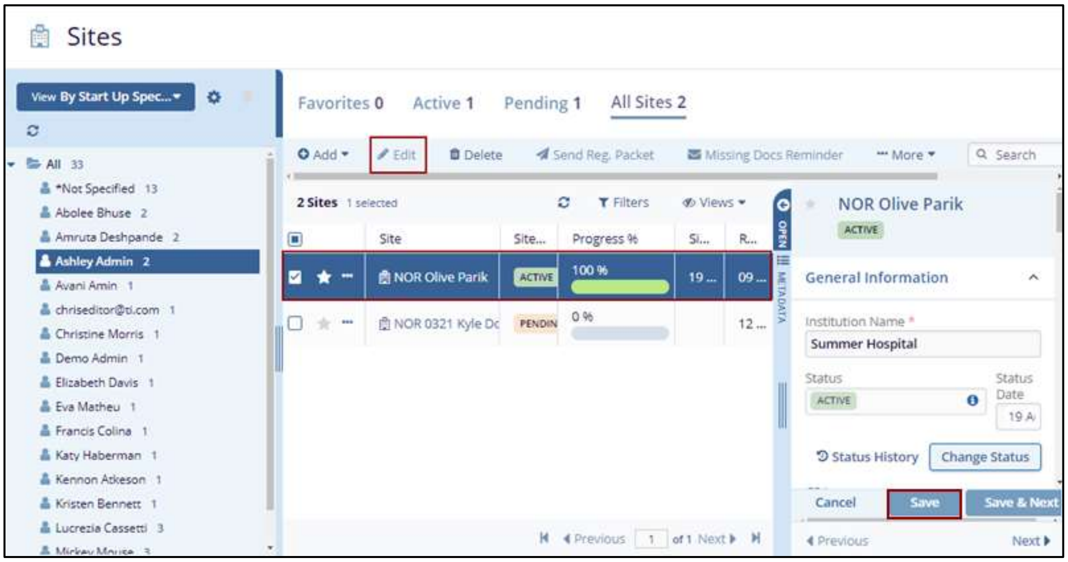
Edit Site

To edit site profiles, follow the steps below.

1. Access the View By dropdown, select 'By Start-Up Specialist' and click on the Select button.



2. Select a site profile and click the Edit button in the menu bar 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 changes get saved.



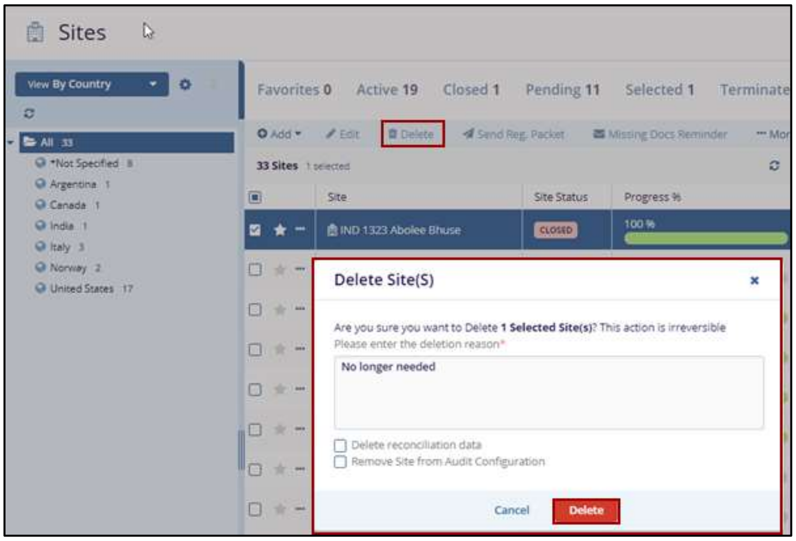
Delete Site

To delete a site, follow the steps below

1. Select a site from the list by clicking on the checkbox and click the Delete button from the top menu ribbon.
2. The Delete Site(S) popup window is displayed with deletion reason box.
3. Optionally enable or disable the following by selecting or deselecting the checkboxes
    1. Delete Reconciliation Data

2. Remove Site from Audit Configuration

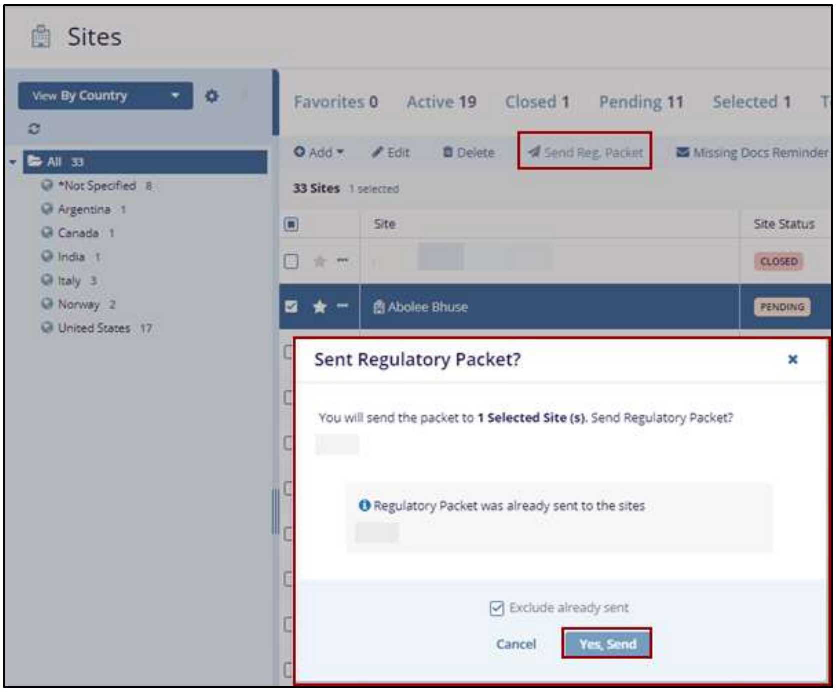
4. Click on the Delete button.



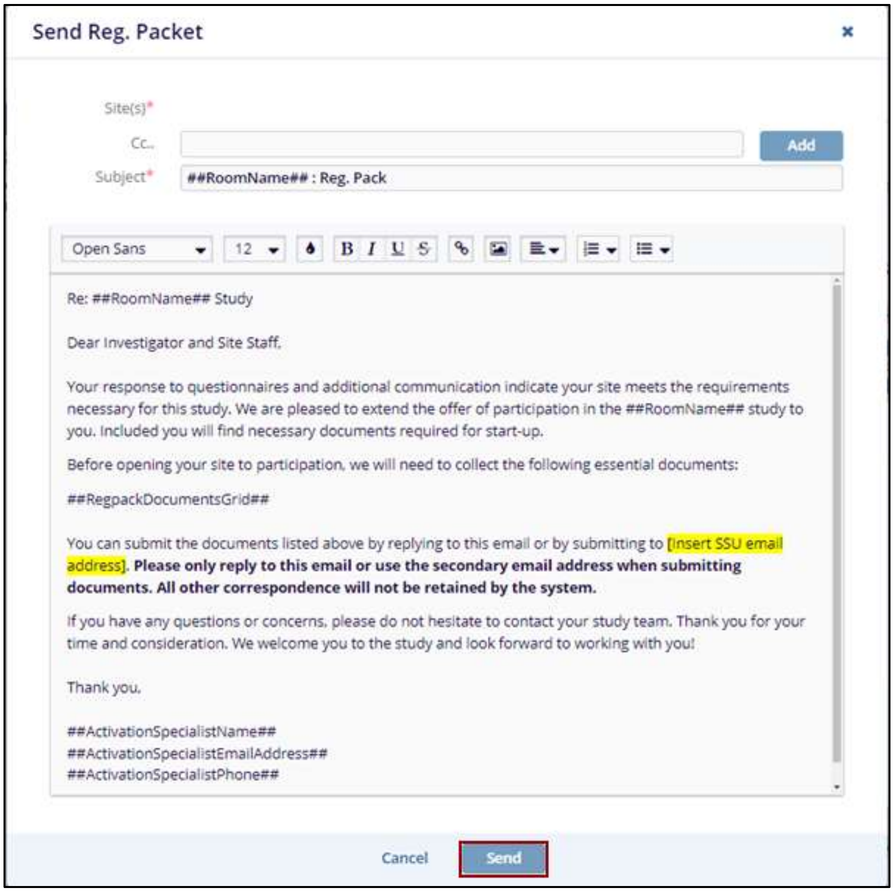
Send Reg. Packet

To send a regulatory packet, follow the steps below.

1. Select a site by clicking on the checkbox and click on the Send Reg. Packet button on the top menu bar.
2. The Sent Regulatory Packet? Popup window is displayed with the checkbox 'Exclude already sent' and Cancel and Yes, Send buttons.
3. Click on the Yes, Send button to send the regulatory packet and Cancel button to discard the changes.

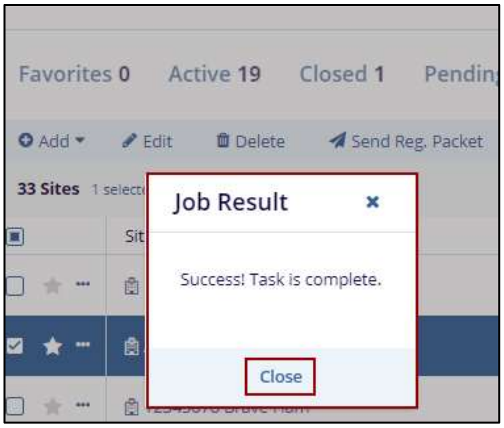


4. The Send Reg. Packet email screen, click on the Send button.



5. The Send Regulatory Packet notification message is displayed on the top right side of the screen with the Get Results button.

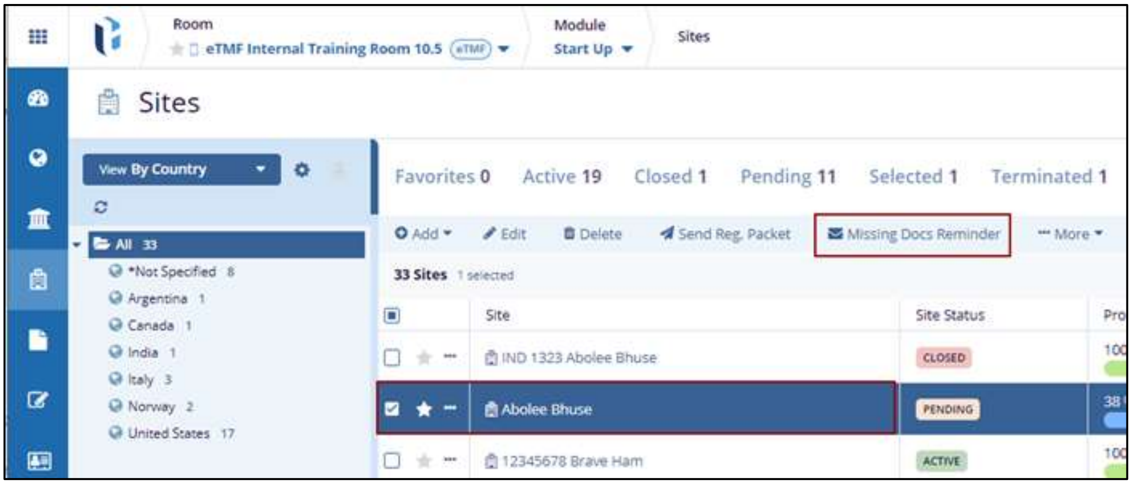
6. Click the Get Results button. The Job Result pop-up message is displayed on the screen.
7. Click the Close button to close the job result window.



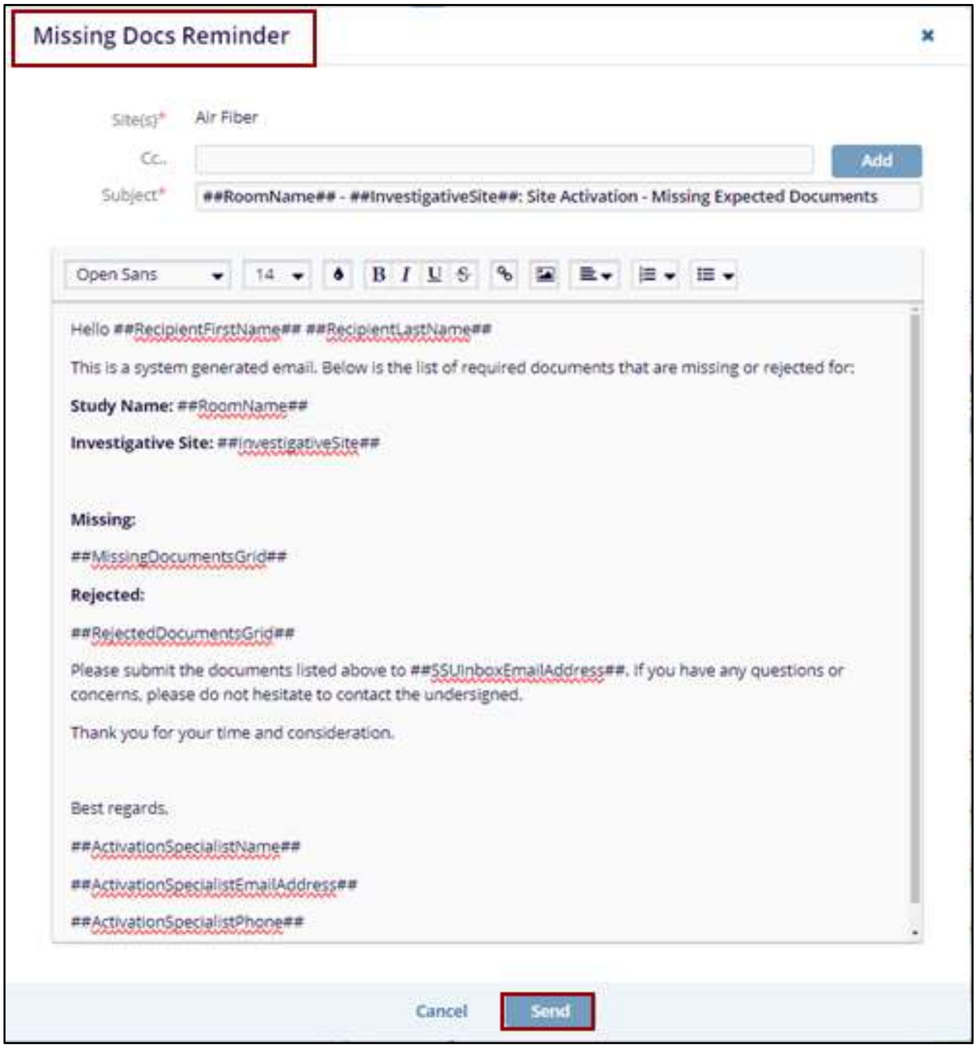
Missing Docs Reminder

To send a reminder for missing documents, follow the steps below.

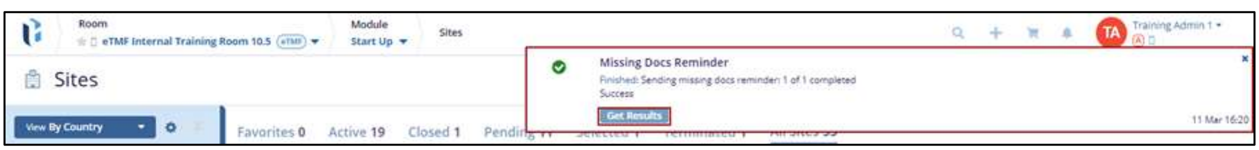
1. Select a site by clicking on the checkbox and click on the Missing Docs Reminder button on the top menu bar.



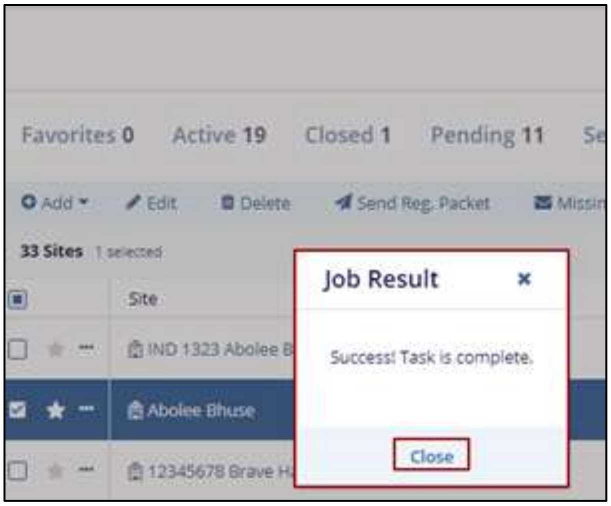
2. The Missing Docs Reminder email pop-up window is displayed, enter the required details and click on the Send button.



3. The Missing Docs Reminder notification message is displayed on the top right side of the screen with the Get Results button.



4. Click the Get Results button. The Job Result pop-up message is displayed on the screen.
5. Click the Close button to close the job result window.



More

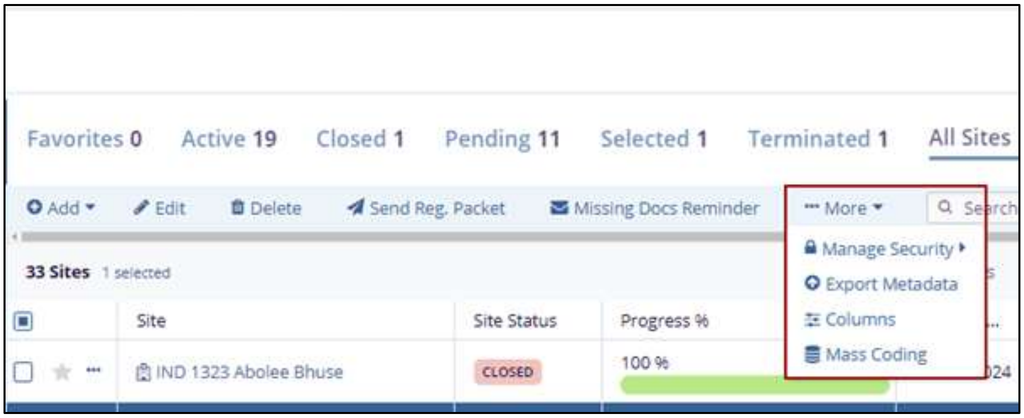
The More drop-down provides access to the below options:

- Manage Security
- Export Metadata
- Columns
- Mass Coding

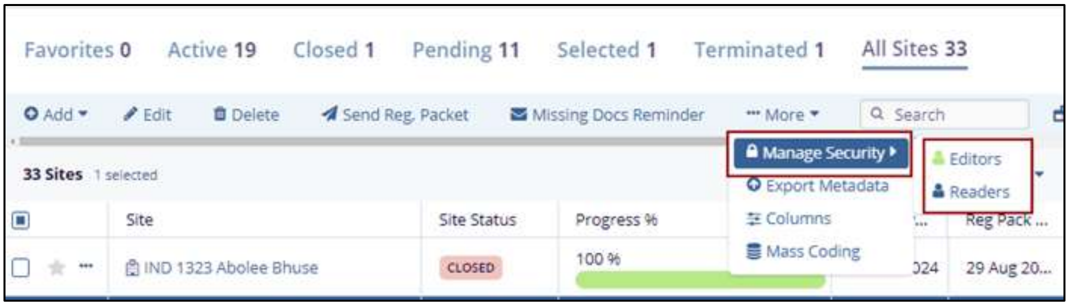
Managing Security

To manage security, follow the steps below.

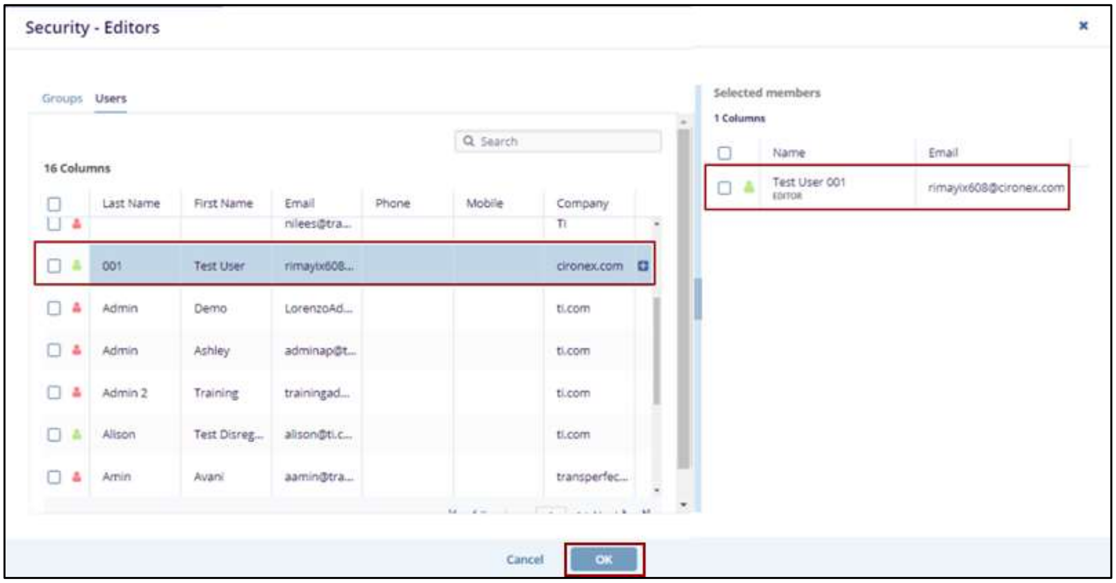
1. Select a site by clicking on the checkbox and click the More dropdown button and select Manage Security option.



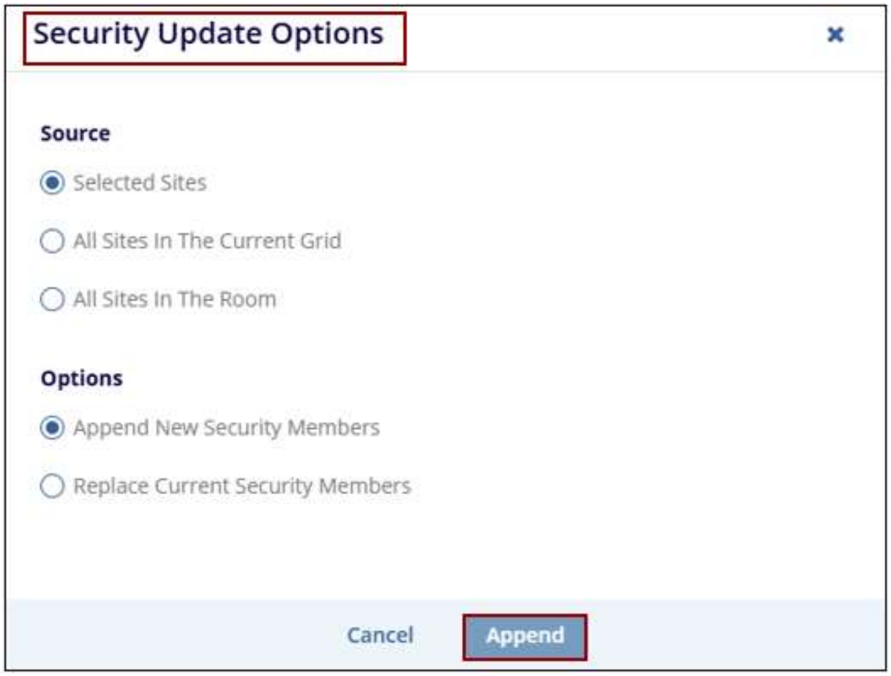
2. The Manage Security option displays two options – Editors and Readers.
3. Select Editors from the two options displayed.



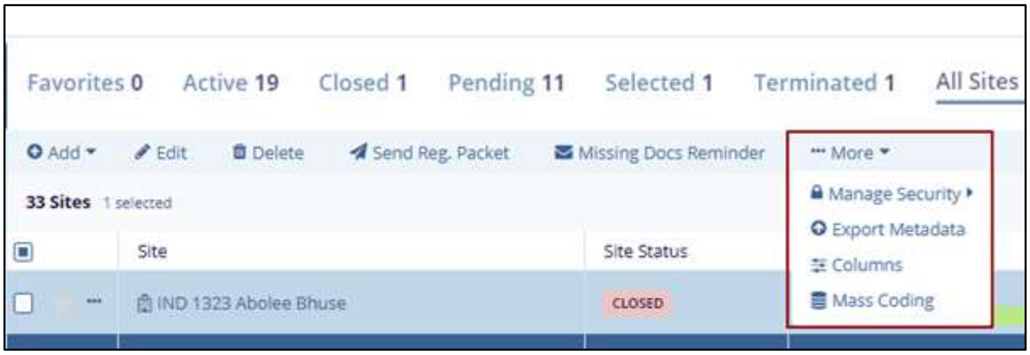
4. The Security – Editors screen is displayed with the Groups and Users tab, hover the mouse over the names to highlight in blue and view the Plus icon next to each username.
5. Click the Plus icon to view the name on the right side – Selected Members pane on the right side. The user can also drag and drop the name if required.
6. Click the OK button displayed at the bottom of the popup window



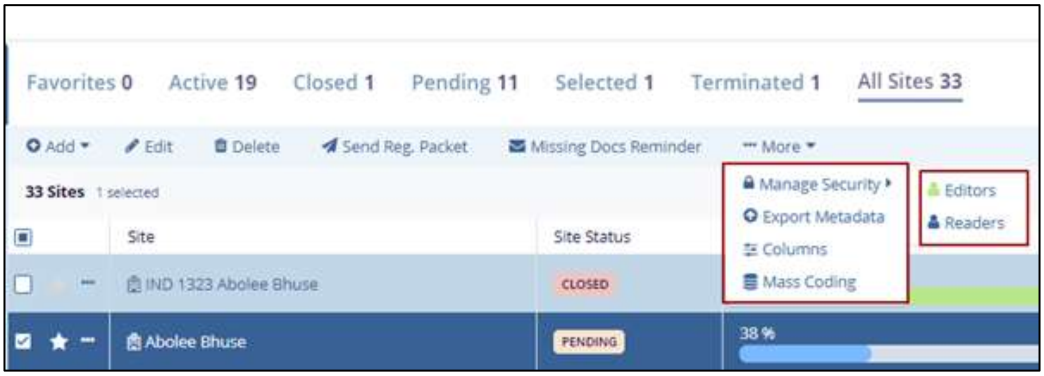
7. A Security Update Options popup window is displayed with Cancel and Append buttons.
8. Select the appropriate radio buttons for – Source and Options.
9. Click the Append button displayed at the bottom of the popup window.



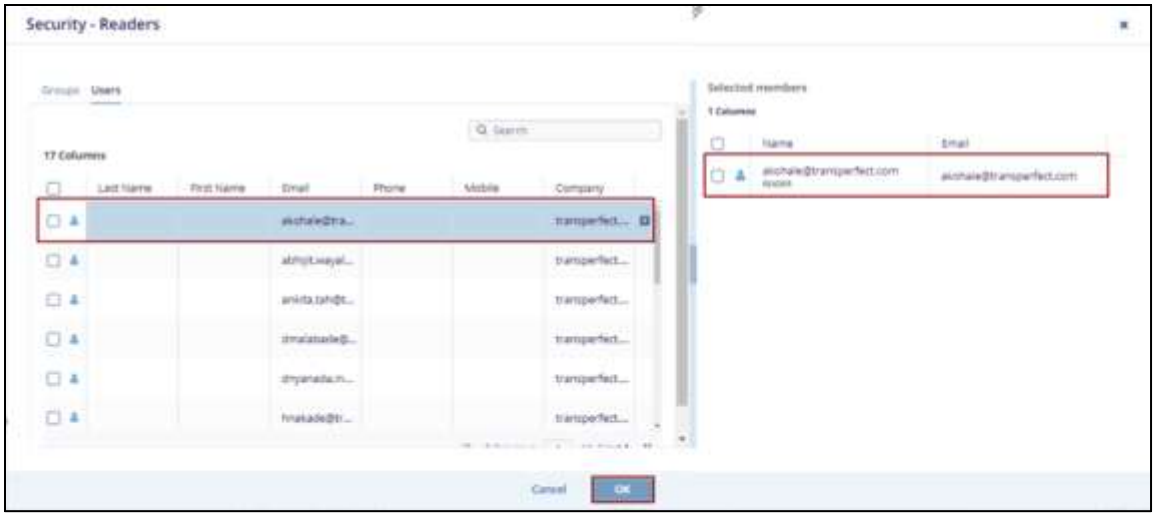
10. Select a site by clicking on the checkbox and click the More dropdown button and select Manage Security option.



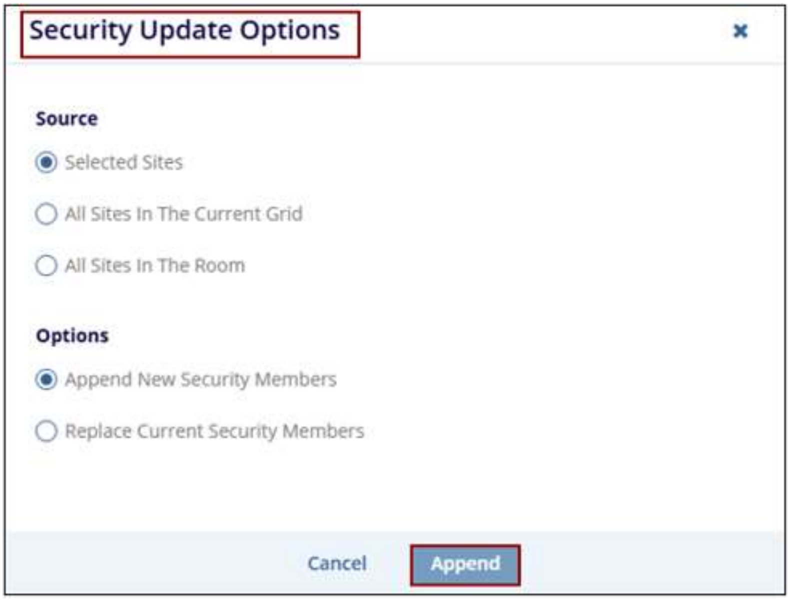
11. The Manage Security option displays two options – Editors and Readers.
12. Select Readers from the two options displayed.



13. The Security – **Reader's** screen is displayed with the Groups and Users tab, hover the mouse over the names to highlight in blue and view the Plus icon next to each username.
14. Click the Plus icon to view the name on the right side – Selected Members pane on the right side. The user can also drag and drop the name if required.
15. Click the OK button displayed at the bottom of the popup window.



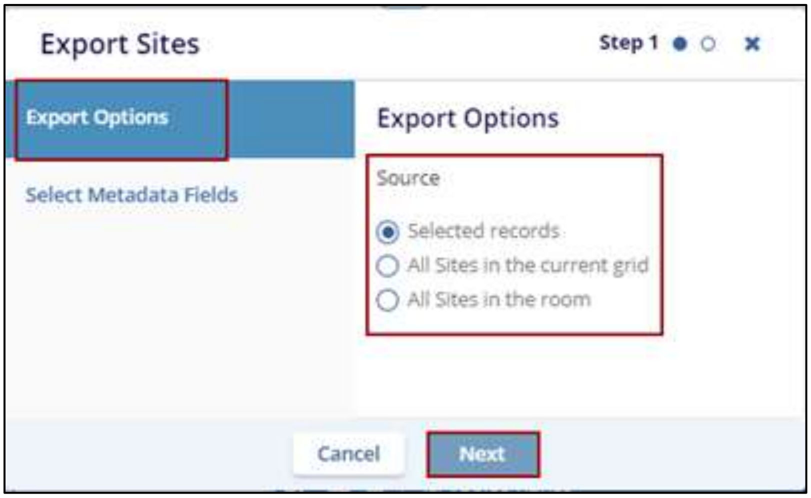
16. A Security Update Options popup window is displayed with Cancel and Append buttons.
17. Select the appropriate radio buttons for – Source and Options.
18. Click the Append button displayed at the bottom of the popup window.



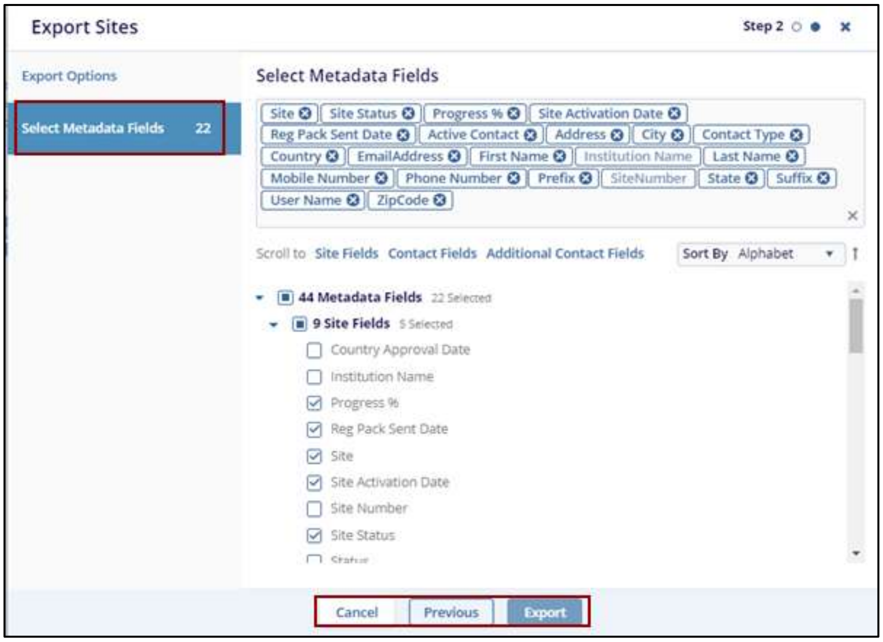
Export Metadata

1. Select a site by clicking on the checkbox and click the More dropdown button and select Export Metadata option.

2. Select the Export option will give 3 sources:
    - Selected records: Choose this option to export metadata only for specific selected sites.
    - All Sites in the current grid: Choose this option to export metadata for all sites currently displayed in the grid.
    - All Sites in the room: Choose this option to export metadata for all sites displayed in the room.



3. Click Next to proceed to Select Metadata Fields, where the user can choose the metadata fields to include in the export.
4. The user can use the Sort By dropdown to sort the available metadata fields alphabetically or logically.
5. Click Export to download the document metadata file in the preferred format. Click Previous to go back or Cancel to discard changes.



6. The Exporting Sites notification message is displayed on the top right side of the screen with the Get Results button.

7. Click the Get Results button and the Exported metadata file gets downloaded.

Columns

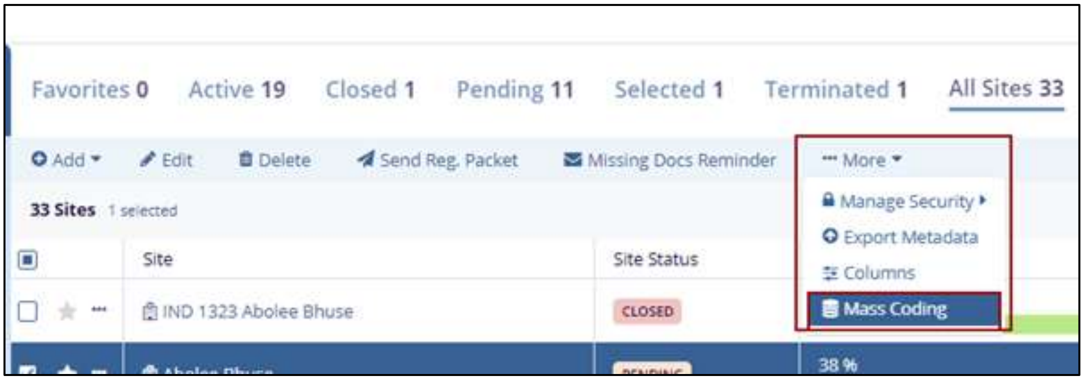
To know more detailed information about columns please refer to this link - [Columns].

Mass Coding

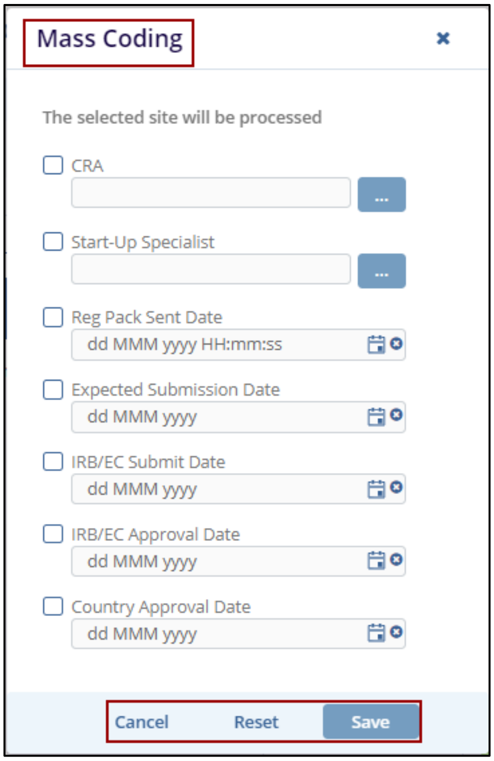
Mass coding for metadata fields of Investigative sites is enabled after room administrators configure the relevant fields in the room's Form Settings during the initial setup.

To mass code sites, follow the steps below.

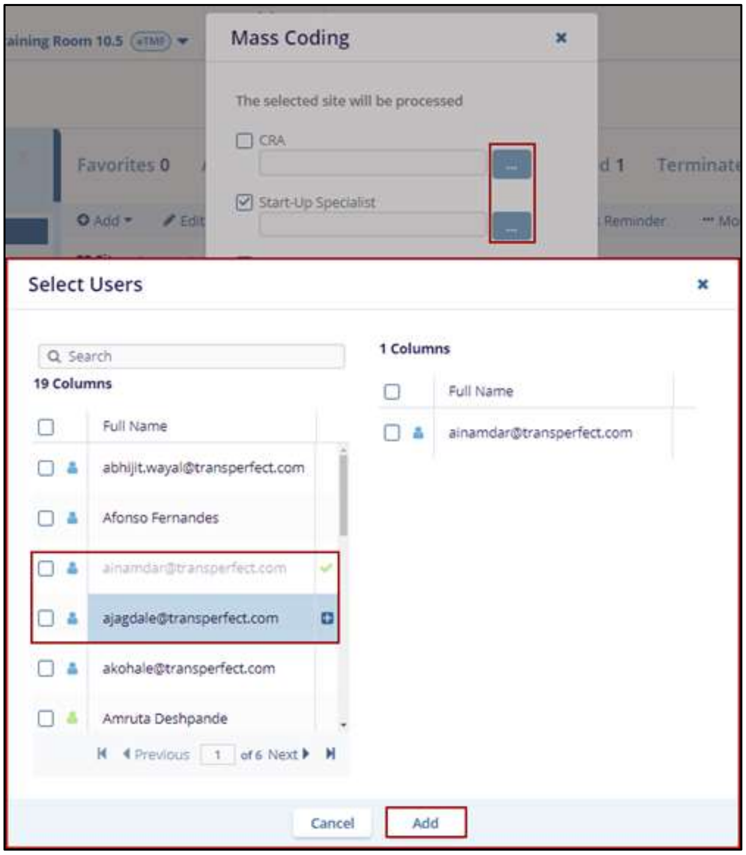
1. Select a site by clicking on the checkbox and click the More dropdown button and select Mass Coding.



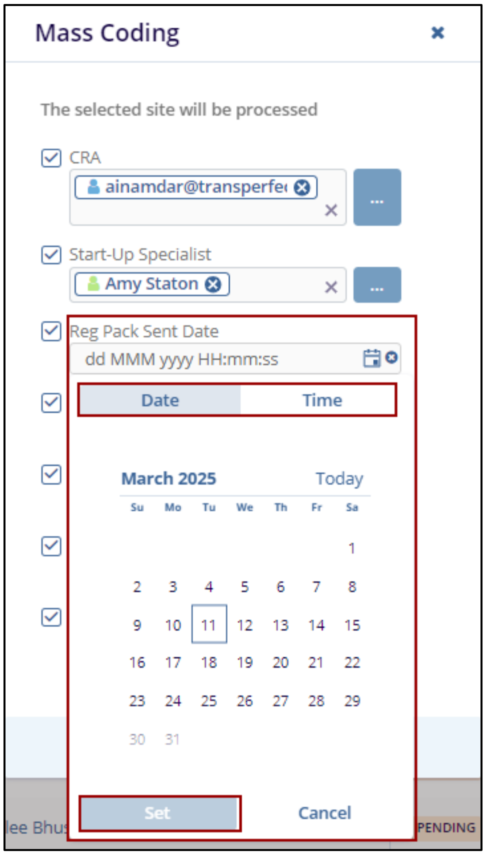
2. The Mass Coding pop-up window is displayed with the Cancel, Reset, and Save buttons.



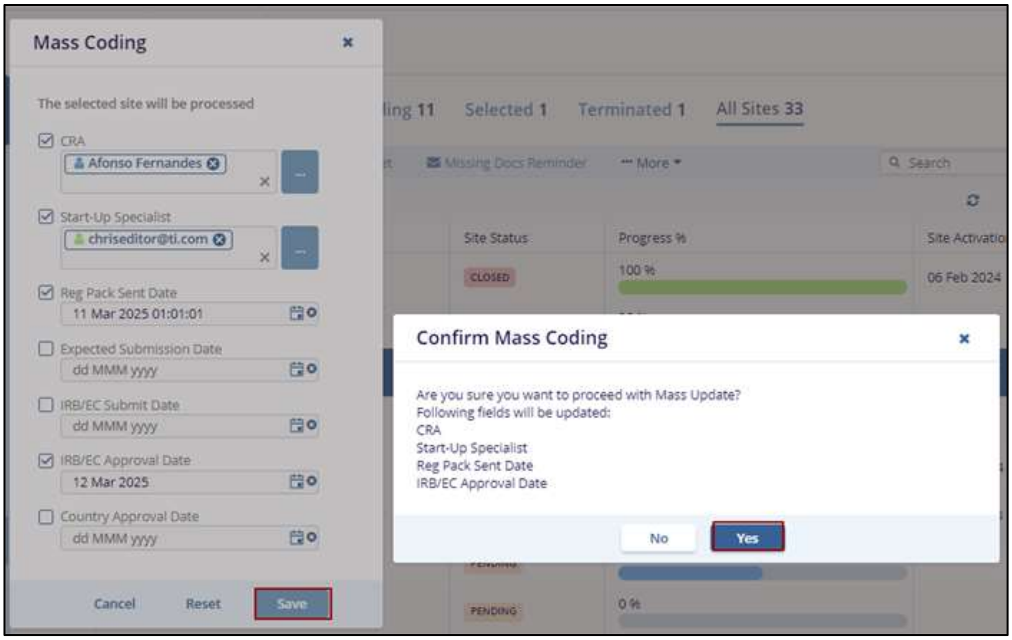
3. Select the three-dot menu for the CRA and Start-Up Specialist fields. This opens the Select Users window.
    - Hover the mouse to view the user in blue color and click the Plus icon next to the name.
    - The selected names are reflected on the right side of the Select Users window.
    - Click the Add button displayed at the bottom of the Select Users window.
    - The selected users are reflected in the required fields.



4. If required, select the checkbox(s) for the below date fields and click the Calendar icon next to those fields, select an appropriate Date and Time, and click on the Set button on the Calendar view.
    - Reg Pack Sent Date
    - Expected Submission Date
    - IRB/EC Submit Date
    - IRB/EC Approval Date
    - Country Approval Date



5. Click the Save button displayed at the bottom of the popup window to save the changes.
6. Click Reset button, if user wants to reset the previously added information and Cancel button to discard the changes.
7. The Confirmation Mass Coding pop-up window is displayed with No and Yes buttons.
8. Click Yes, in the Confirmation window displayed on the screen.

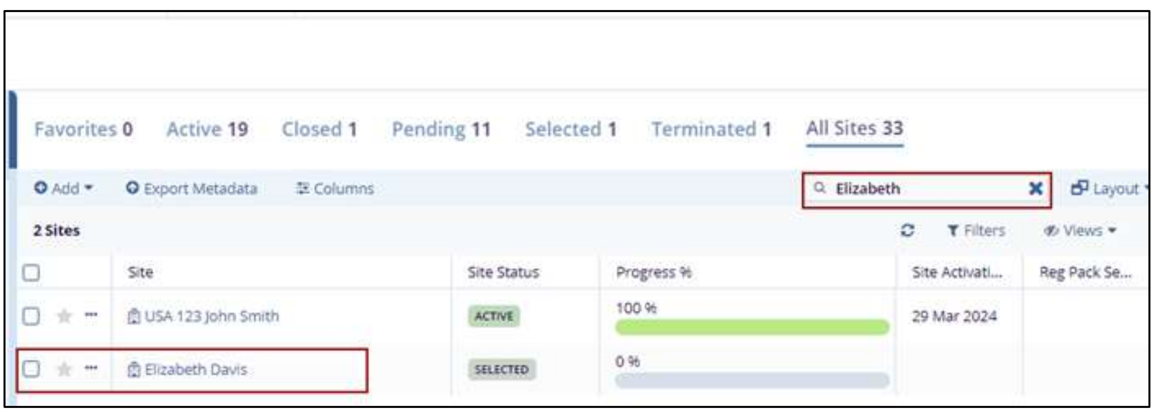


9. The coding changes will be added to the site profiles.

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.

Sites Search

To search for sites from the grid pane, enter a search pattern in the Search textbox in the top ribbon bar and click the magnifying lens icon or press Enter. The system will display sites matching the pattern from both the Grid Pane columns and site profiles, including related contacts.

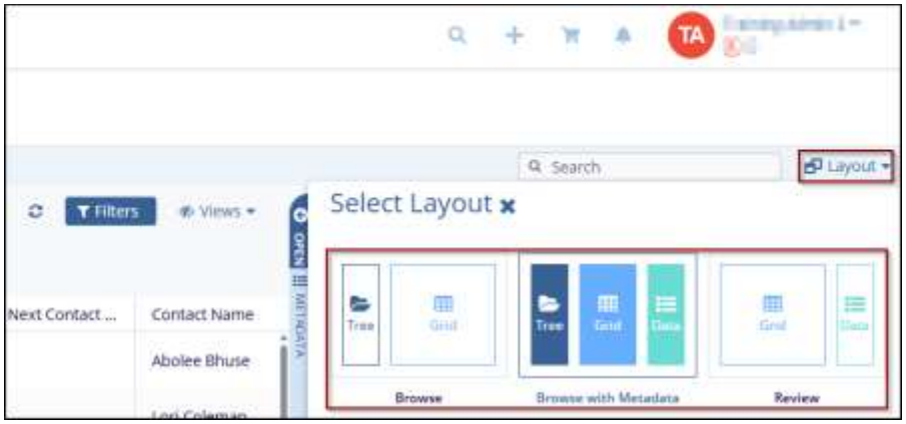


Layout

The Layout provides users with different data viewing options. The choice of layout can help enhance user experience by making the data easier to navigate or manage.

To apply a layout view, follow these steps:

1. At the top-right click on the Layout button. This will open a menu displaying available layout options.
2. From the layout options displayed, select the one that best suits the user's needs:
   Browse: this is the default view for browsing data.
   Browse with Metadata: this option displays data along with associated metadata, which may be useful for understanding the context of the data.
   Review: it is likely a review or approval view, useful for reviewing data before finalizing it.



Filters
To know more detailed information about filters please refer to this link - [Manage Filters] and [Create New Filter].

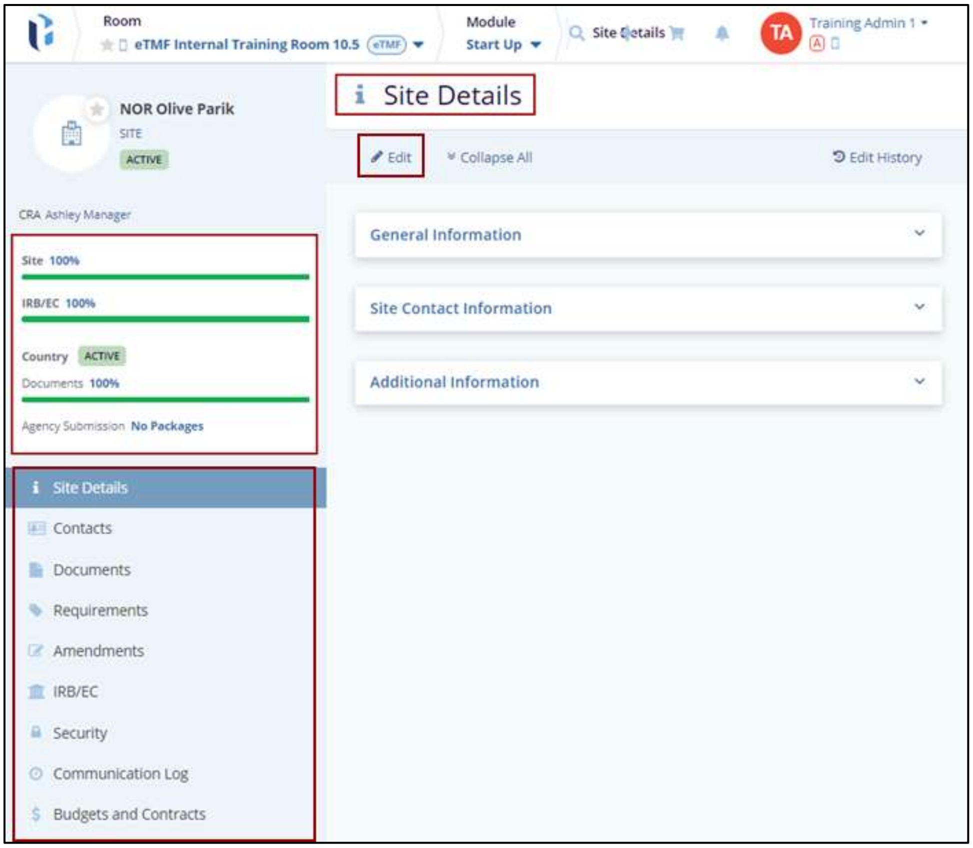
Views
To know more detailed information about views please refer to this link - [Popular Documents].

Site Details
The Site Details page, displays a progress bar for the Site, Country, and IRB/EC, along with an activation notice based on the percentages shown.

- Contacts
- Documents
- Requirements
- Amendments
- IRB/EC
- Security
- Communication Log
- Budgets and Contracts of the site

Follow the below steps:

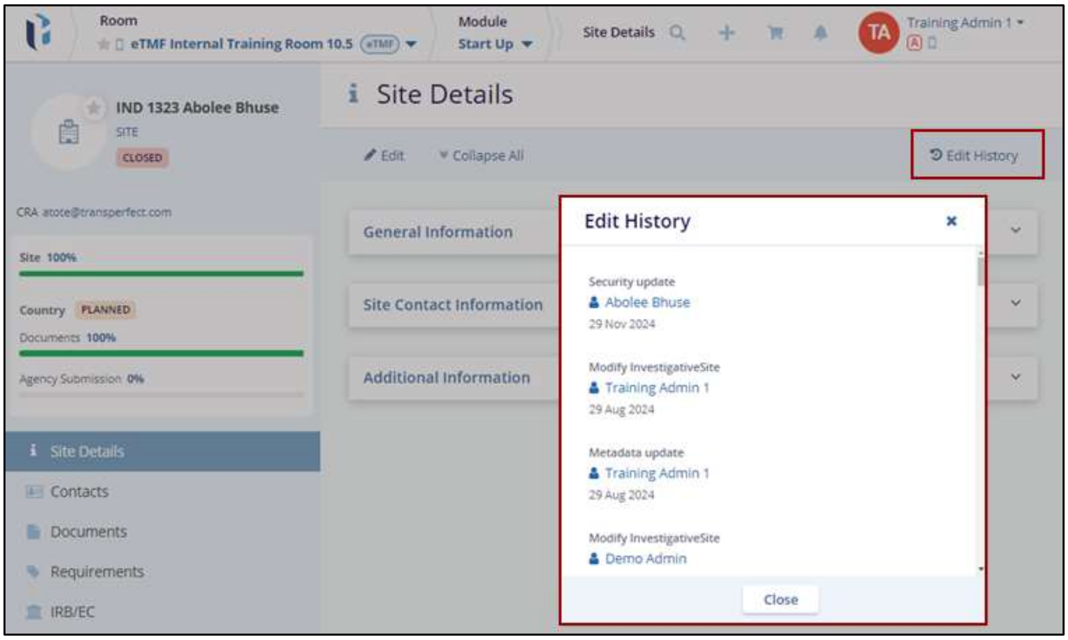
1. To open the Site Details page, click on the name of the site from the grid to open its Site Details window and click on the Edit button.



2. Fill in all the required fields within the General Information, Site Contact Information, and Additional Information section on the Site Details page.

3. Click the Edit History icon displayed at the top menu bar on the right side. The 'Edit History' pop-up window is displayed.

Note: The information here cannot be edited.

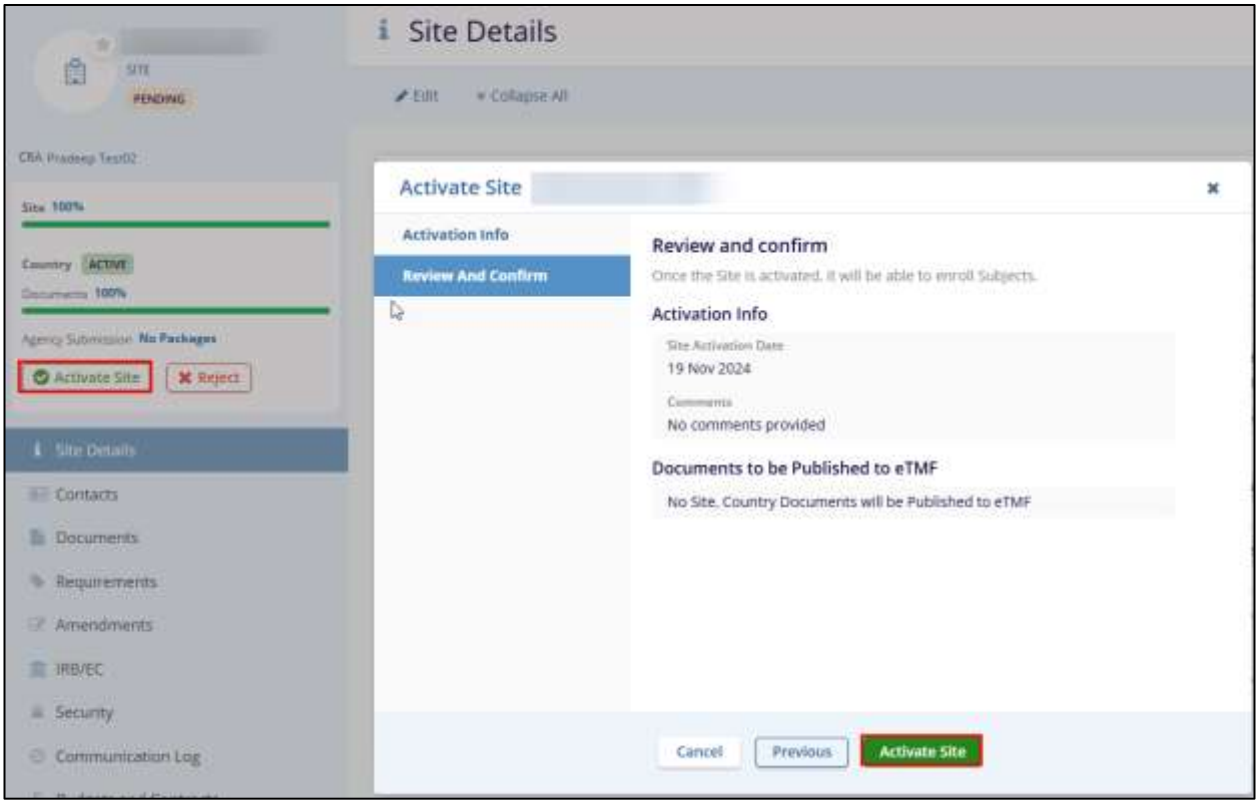


Steps to Site Activation

A site can be activated once all essential documents are submitted, approved, and the Essential Documents Progress Bar reaches 100%. Only Site Activation Members can activate the site, triggering automatic naming, routing, and filing of documents in the finalized eTMF. Administrators can configure these automation settings in Study Start-Up. The Activate/Reject button appears on the Site Profile Dashboard upon final approval by the Start-Up Specialist and Regulatory Reviewer.

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.

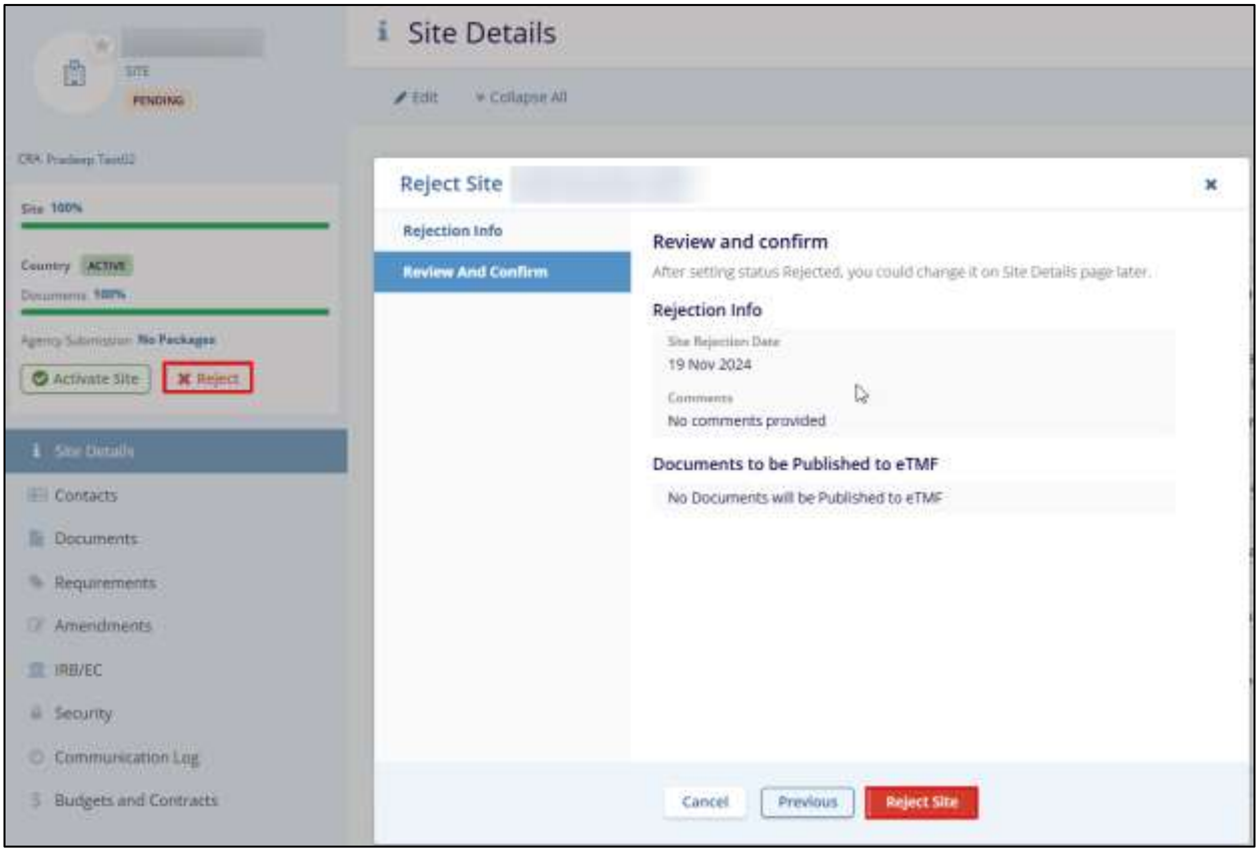


Note: The site information and users specific to the SSU site can be imported by TI if the information is provided in a formatted Excel. In addition, sites and users can be added to the site grid.

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:

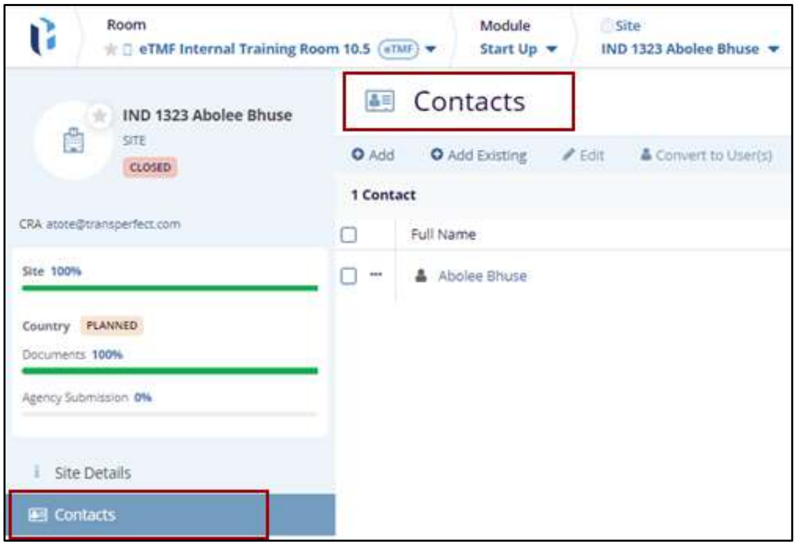
- If during site activation system cannot move the documents to eTMF for some reason, such documents will not be moved, and the user will be warned about it. In that case site will not be activated. The reasons why docs cannot be moved to eTMF are duplications found and cannot determine Index position.
- 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.

Contacts

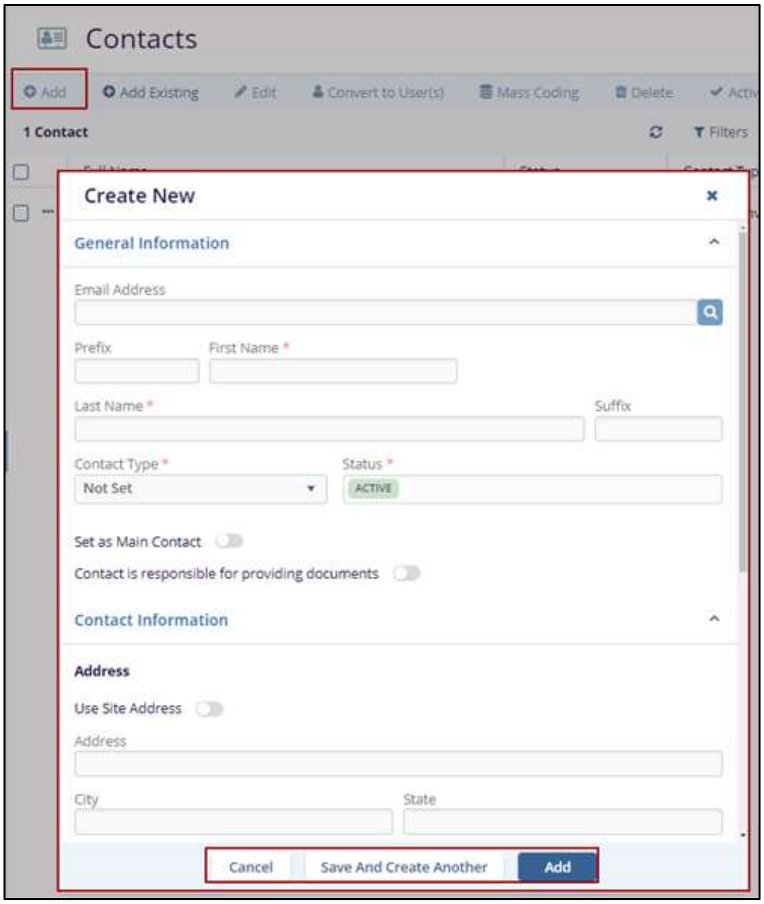
Contacts for sites typically include key individuals responsible for site operations, communication, and compliance. These may include Principal Investigators, Site Coordinators, Regulatory Contacts, and Administrative. Each contact is assigned specific roles, ensuring smooth site management, regulatory adherence, and efficient communication.

Add Contacts

1. Click Contacts on the left side of the screen in the index panel. The contacts page is displayed.

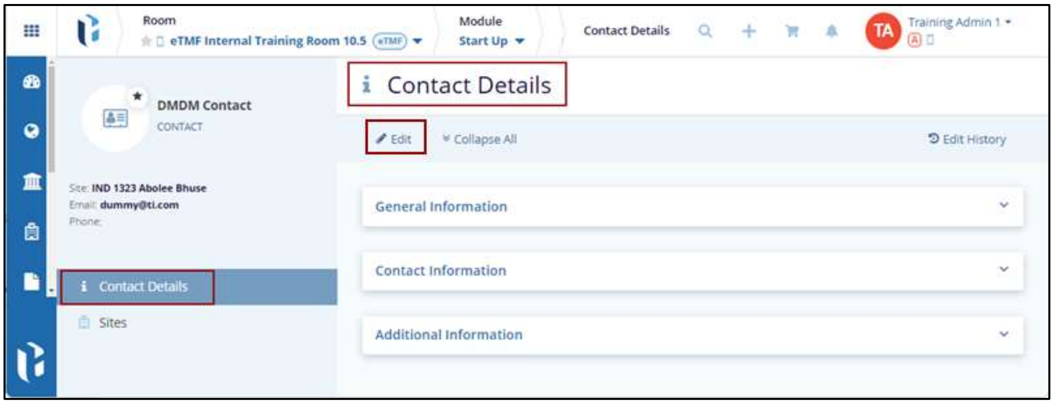


2. Click the Add button on the top menu bar. The Create New pop-up window is displayed with Cancel, Save And Create Another, and Add buttons on the bottom Create New pop-up window.

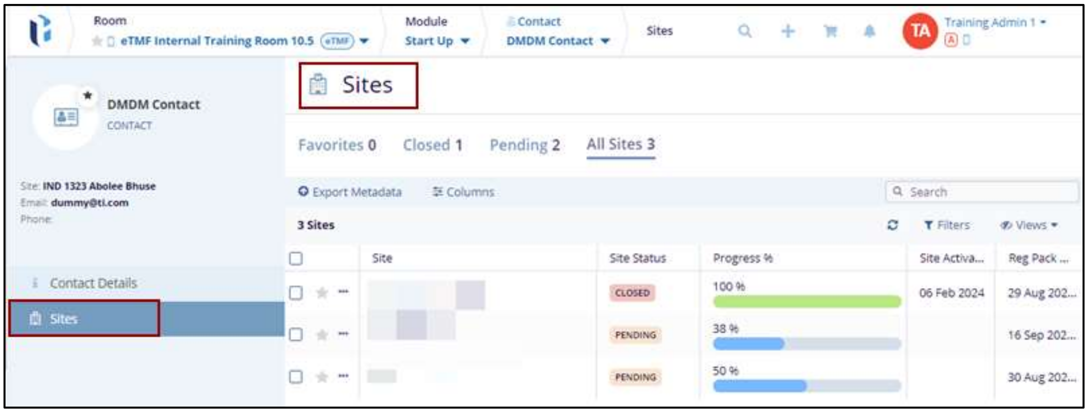


3. Fill in all the required fields in the General Information, Contact Information, and Additional Information sections.
4. Click Add to save the contact, or click Save and Create Another to save the current contact and add a new one, and Cancel to discard the changes.
5. The Contact Added notification message is displayed on the top right side of the screen and the added contact will appear on the Contacts page.

6. Click on the name of the newly created contact the Contact Details page is displayed with the existing information.
7. Click Edit to edit the information as per the requirement and click Save to save the changes and Cancel to discard the changes.

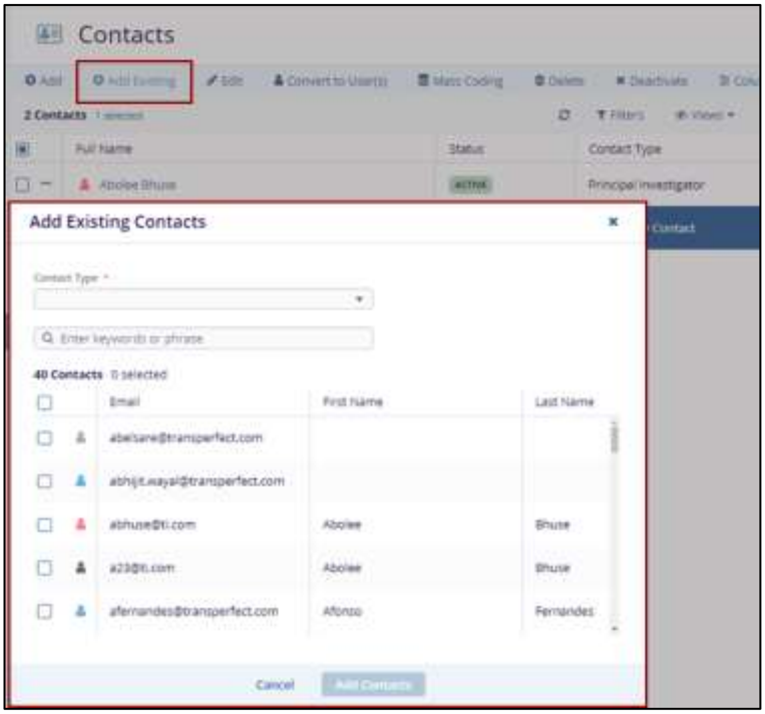


8. Click on the Sites on the left side in the index panel. The Sites page is displayed with the Site associated with that particular user.



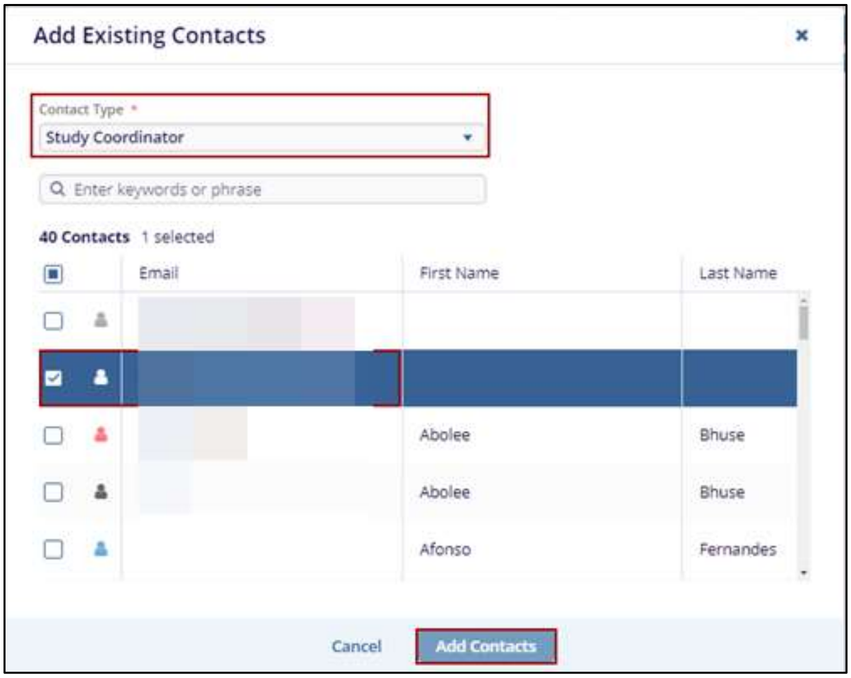
Add Existing Contacts

1. Click the Add Existing button. The Add Existing Contacts pop-up window is displayed with the list of the contacts.

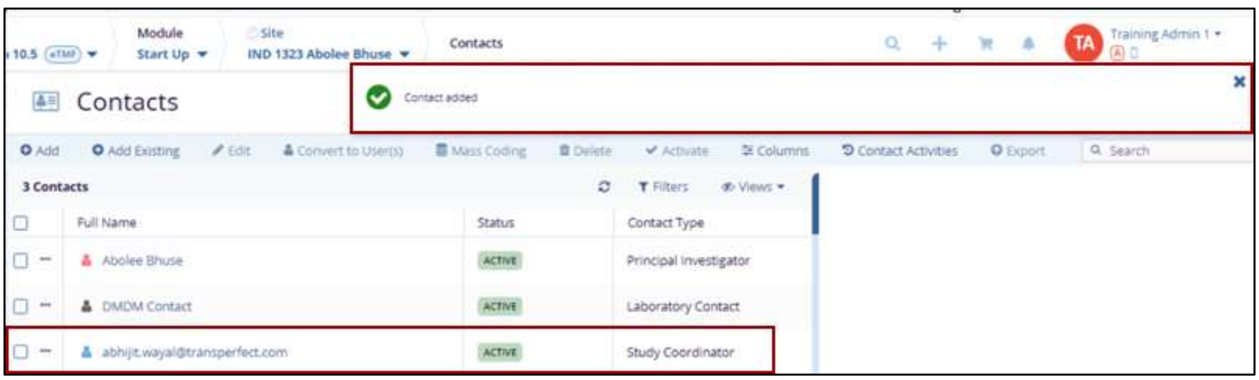


2. Expand the drop-down arrow of the Contact Type and select the type.

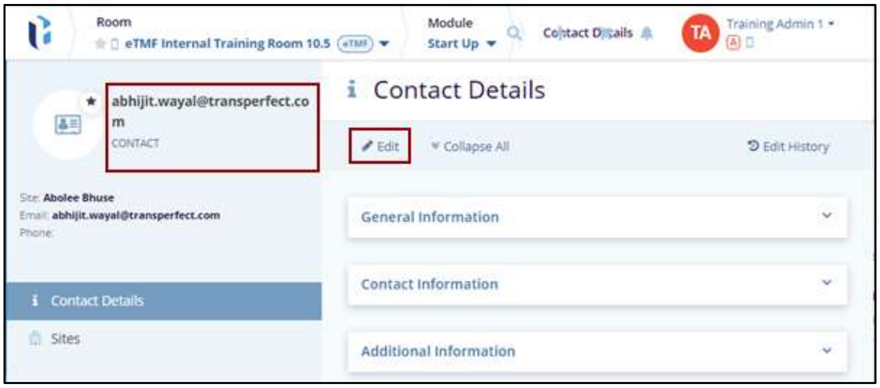
3. Select the User's Email ID from the list within the Add Existing Contacts pop-up window and click the Add Contacts button.



9. The Contact Added notification message is displayed on the top right side of the screen and the added contact will appear on the Contacts page.

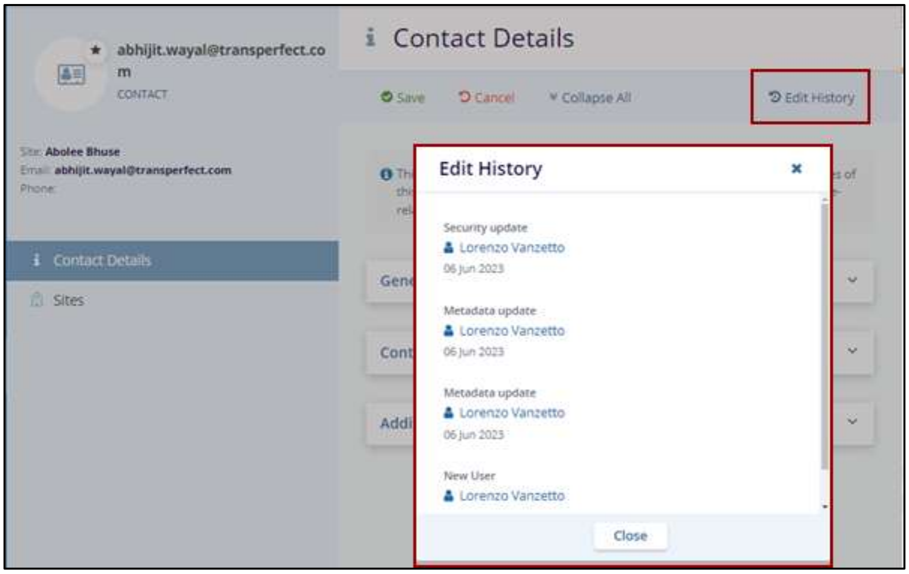


10. Click on the name of the newly created contact the Contact Details page is displayed with the existing information.
11. Click Edit to edit the information as per the requirement and click Save to save the changes and Cancel to discard the changes.

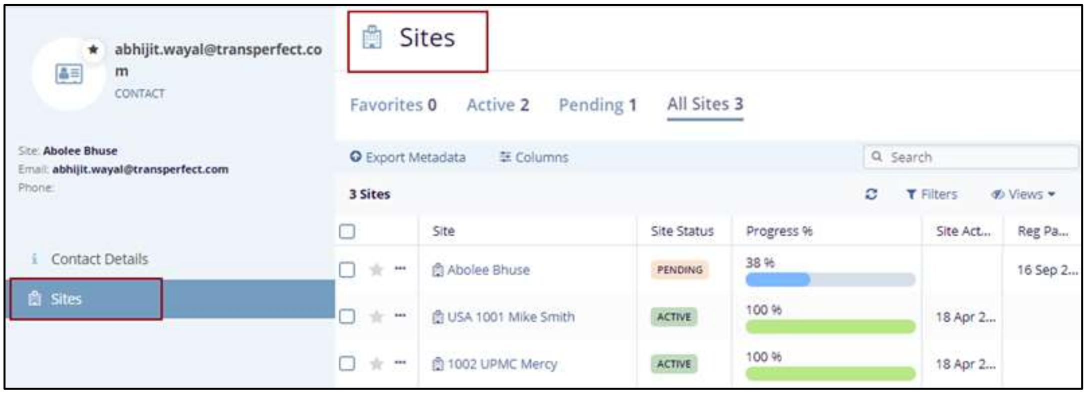


12. Click the Edit History icon displayed at the top menu bar on the right side. The 'Edit History' pop-up window is displayed.

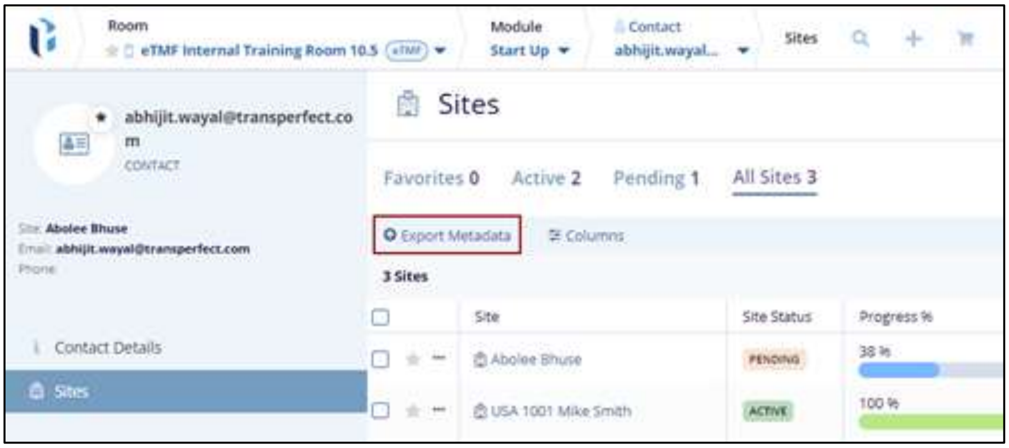
    Note: The information here cannot be edited.



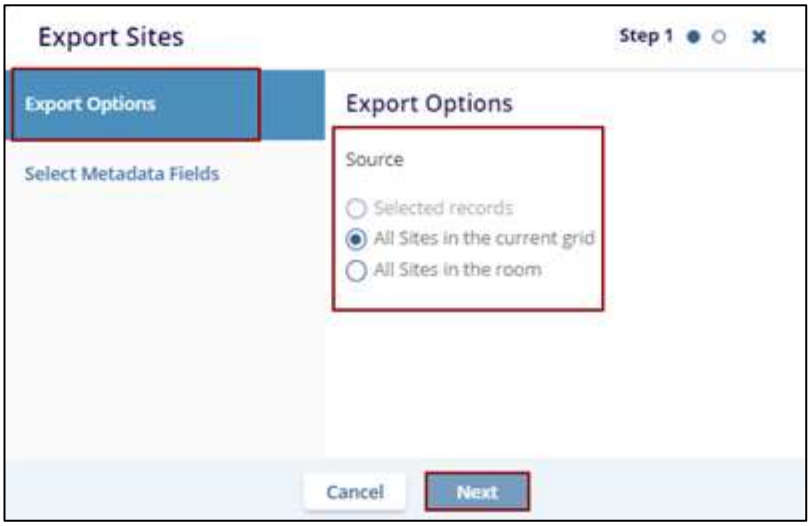
13. Click on the Sites on the left side in the index panel. The Sites page is displayed with the Site associated with that particular user.



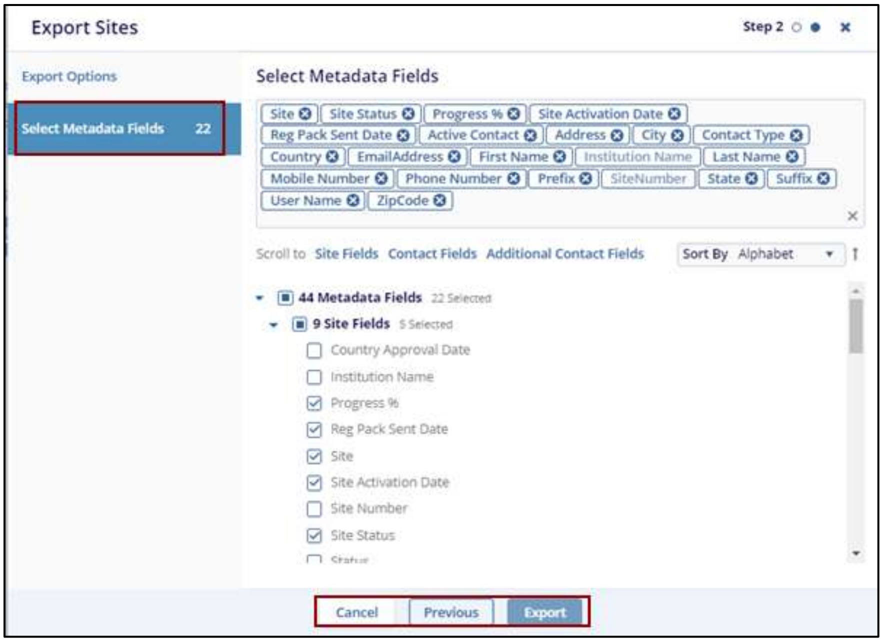
14. Click on the Export Metadata button, and Export Sites window will pop up with 2 options:
    Export option and Select Metadata Fields.



15. Select the Export option will give 3 sources:
    - Selected records: Choose this option to export metadata only for specific selected sites.
    - All Sites in the current grid: Choose this option to export metadata for all sites currently displayed in the grid.
    - All Sites in the room: Choose this option to export metadata for all sites displayed in the room.



16. Click Next to proceed to Select Metadata Fields, where the user can choose the metadata fields to include in the export.
17. The user can use the Sort By dropdown to sort the available metadata fields alphabetically or logically.
18. Click Export to download the document metadata file in the preferred format. Click Previous to go back or Cancel to discard changes.

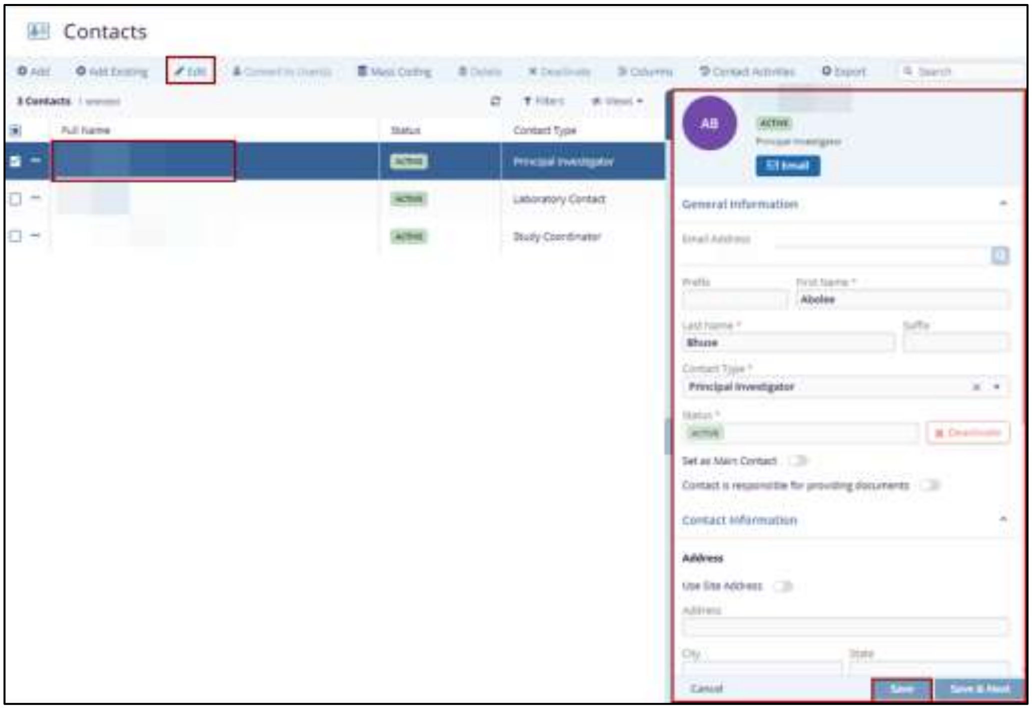


8. The Exporting Sites notification message is displayed on the top right side of the screen with the Get Results button.

9. Click the Get Results button and the Exported metadata file gets downloaded.

Edit Contact

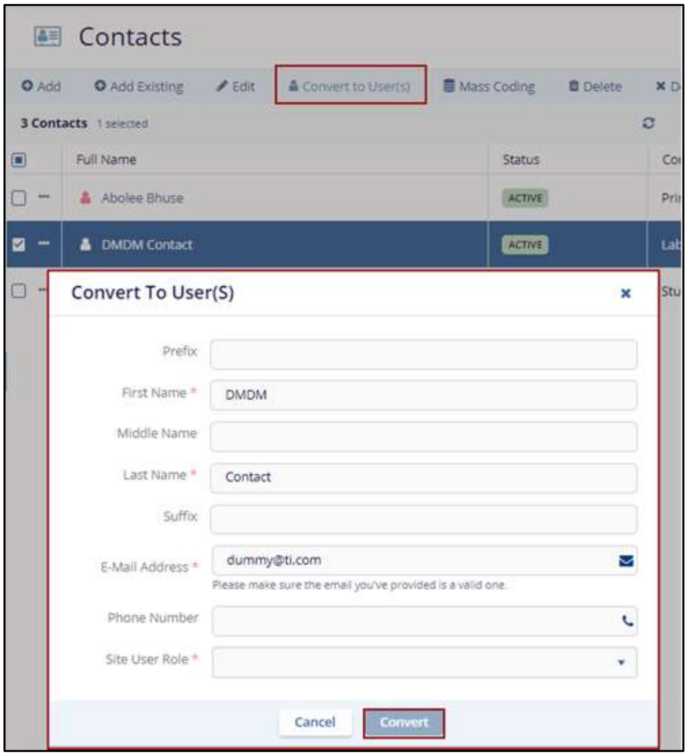
1. Select a contact and click the Edit button in the menu bar to open the Contact Profile in the metadata panel on the right side of the screen.
2. Make edits to the contact details and click on the Save button. The changes get saved.



Convert to User(s)

The Convert User(s) function updates an existing user's role to the selected role in the Site User Role field within the Convert Users pop-up window.

1. Select a contact and click the Convert to User(s) option on the top menu bar.
2. The Convert to User(s) pop-up window is displayed with the Cancel and Convert buttons.
3. Fill in all the required fields and click the Convert button.

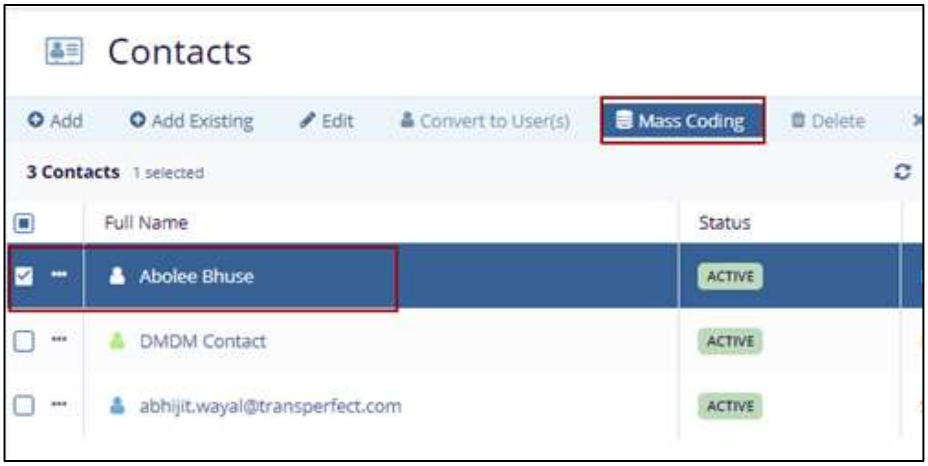


4. The selected contact user gets converted to the selected user.

Mass Coding

The Mass coding functionality allows users to apply metadata updates in bulk to all or selected contacts.
To apply mass coding to all or selected contacts, follow the steps below.

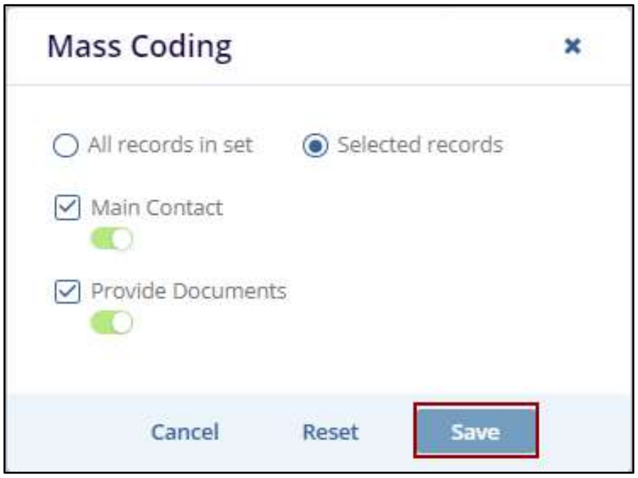
1. Select a single or multiple contacts by clicking on their respective checkboxes.
2. Click on the Mass Coding button from the top menu bar.



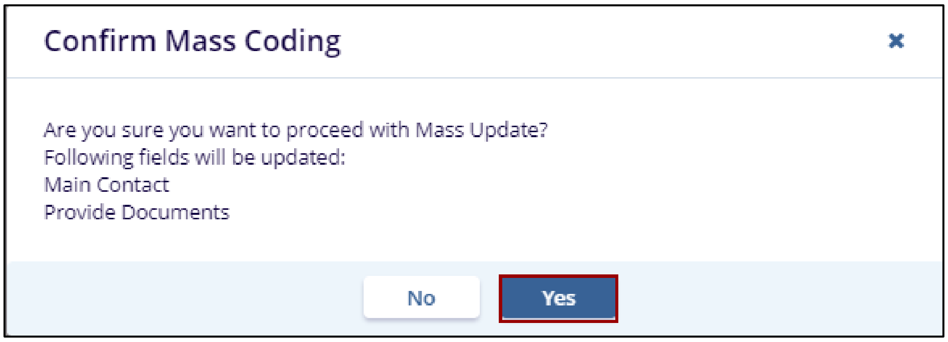
3. On the Mass Coding window, select the following option by clicking on its radio button.

- All Records in set: The metadata updates will apply to all contact records.
- Selected records: The metadata updates will apply to selected contacts.

4. Check or Uncheck the Main Contact checkbox and enable or disable the toggle switch to designate the contact as the main contact.
5. Check or Uncheck the Provide Documents checkbox and enable or disable the toggle switch.
6. Click on the Save button.

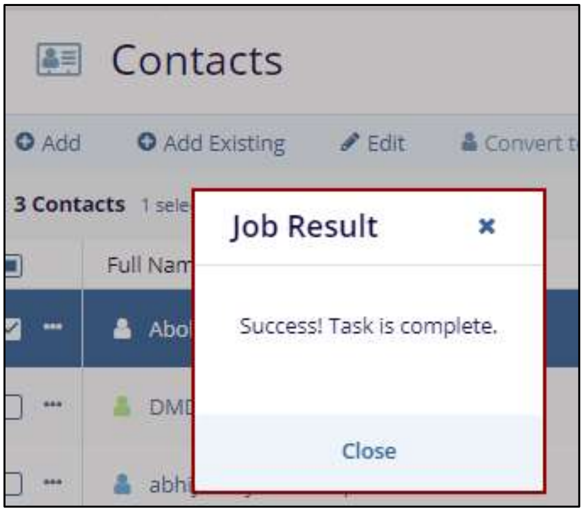


7. On the Confirm Mass Coding popup, click on the Yes button.



8. On the success message popup, click on the Get Results button.

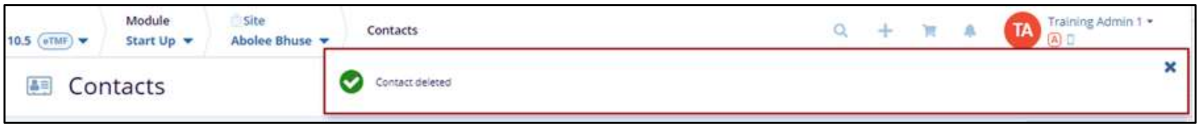
9. Once the task is complete, the Job Result pop-up window is displayed and the contacts screen displays the updated metadata fields and columns.



Delete Contact

To delete a contact, follow the steps below:

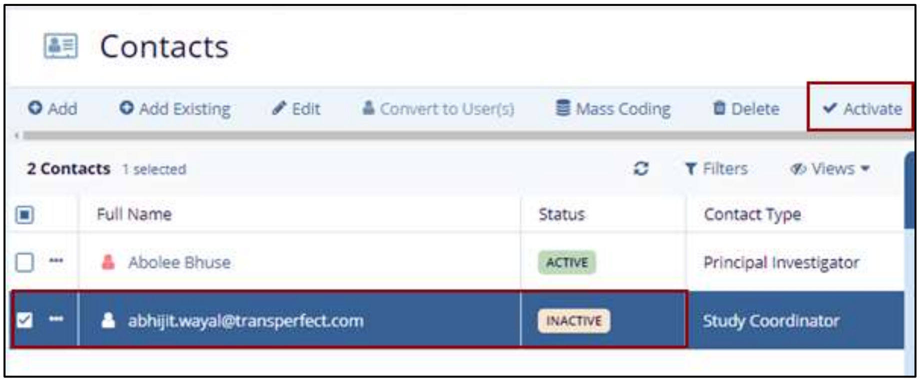
1. Select a contact from the list by clicking on the checkbox and click the Delete button from the top menu ribbon.
2. The Delete Site(S) popup window is displayed with the message including Cancel and Delete buttons.
3. Click on the Delete button. The notification message is displayed on the top right of the screen.



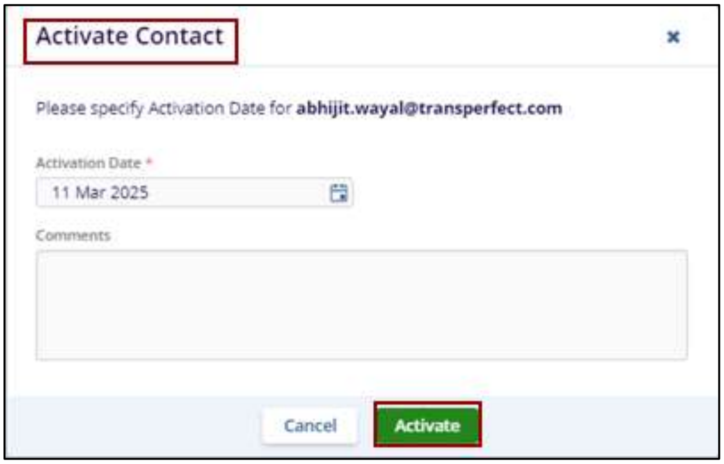
Activate Contact

To activate a contact, follow the steps below:

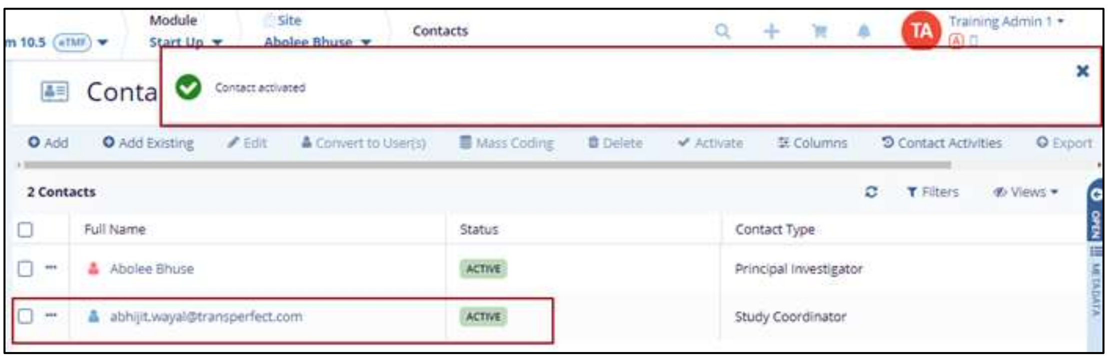
1. Select the contact that is in the Inactive status, the metadata panel is displayed on the right side of the screen.
2. Click the Activate button on the top menu bar.
   Note: The user can click the Activate button available in the metadata panel.



3. The Activate Contact pop-up window is displayed with Cancel and Activate buttons.
4. Fill in the required fields and click the Activate button.



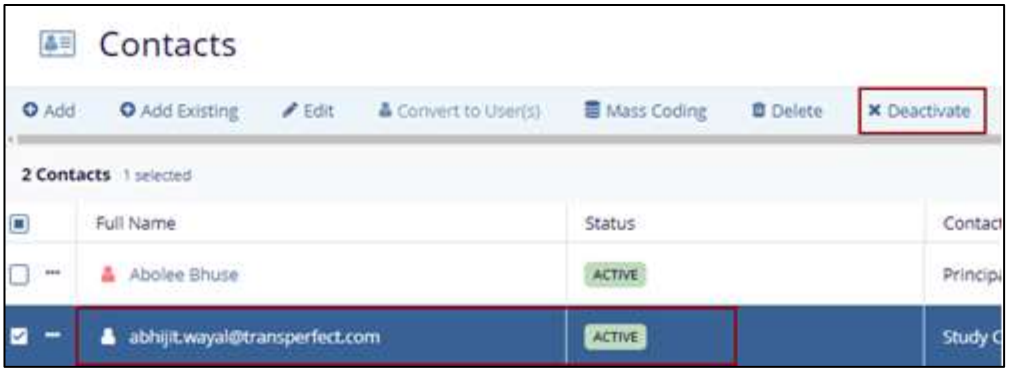
5. The selected contact gets activated and the notification message is displayed on the top right side of the screen and the status column displays the Active status.



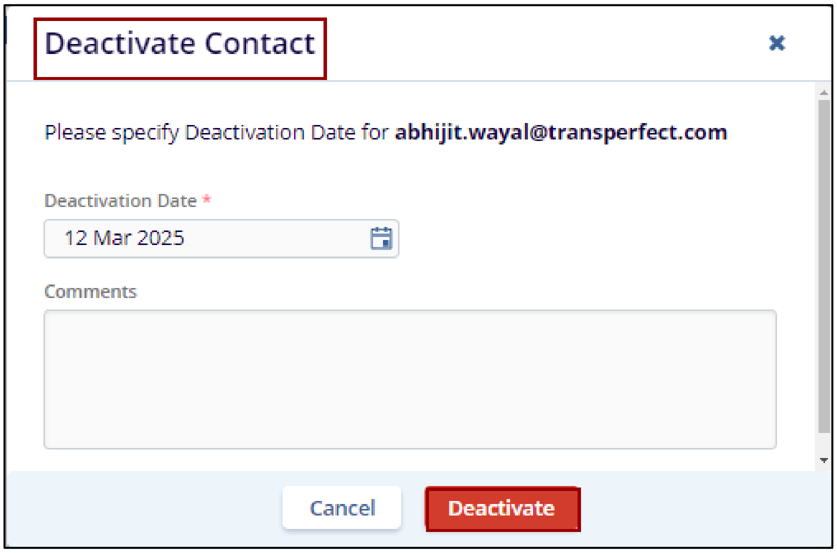
Deactivate Contact

To deactivate a contact, follow the steps below:

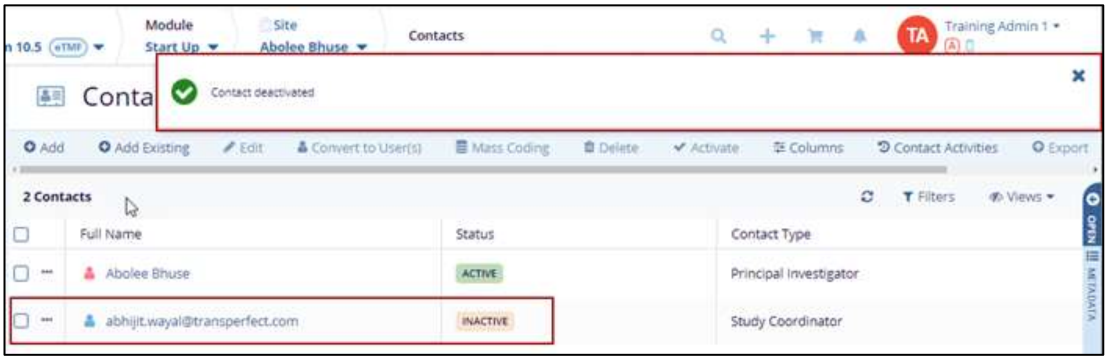
1. Select the contact that is in the Active status, the metadata panel is displayed on the right side of the screen.
2. Click the Deactivate button on the top menu bar.
   Note: The user can click the Deactivate button available in the metadata panel.



3. The Deactivate Contact pop-up window is displayed with Cancel and Deactivate buttons.
4. Fill in the required fields and click the Deactivate button.



5. The selected contact gets deactivated and the notification message is displayed on the top right side of the screen and the status column displays the Inactive status.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

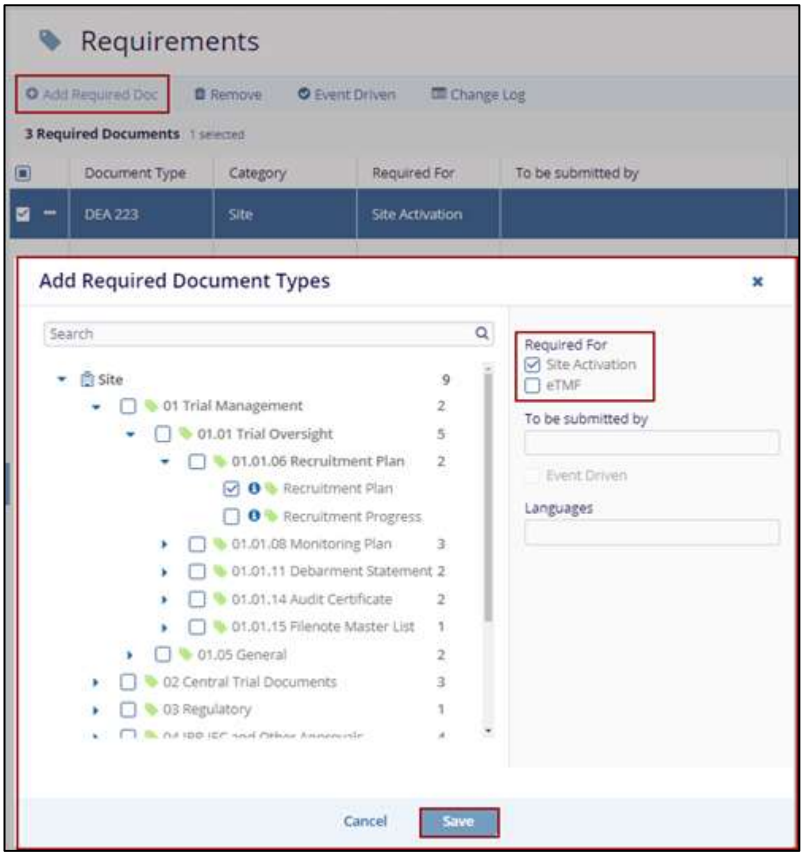
Documents

To know more detailed information about documents please refer to this link - [Documents]

Requirements

Follow the steps mentioned below to add required document:

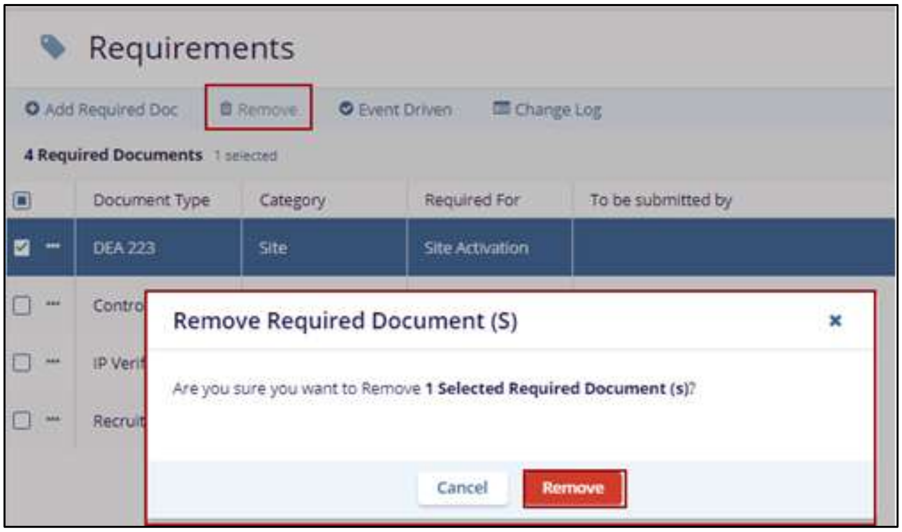
1. Select the checkbox of the contact and click Add Required Document on the top menu bar.
2. The Add Required Document Types pop-up window is displayed with the Sites, check the checkbox from the list and mark the site is required for: Site Activation or eTMF.



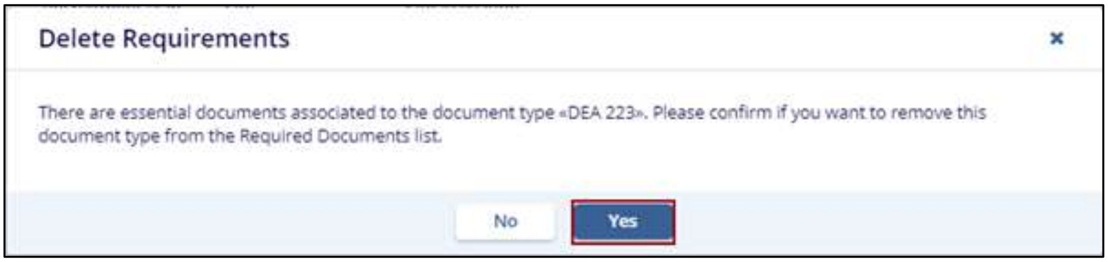
3. The notification is message is displayed on the top right side of the screen.

Remove

1. Select the site and click the Remove button above on the top menu bar.
2. The Remove Required Document(s) with the Cancel and Remove buttons.



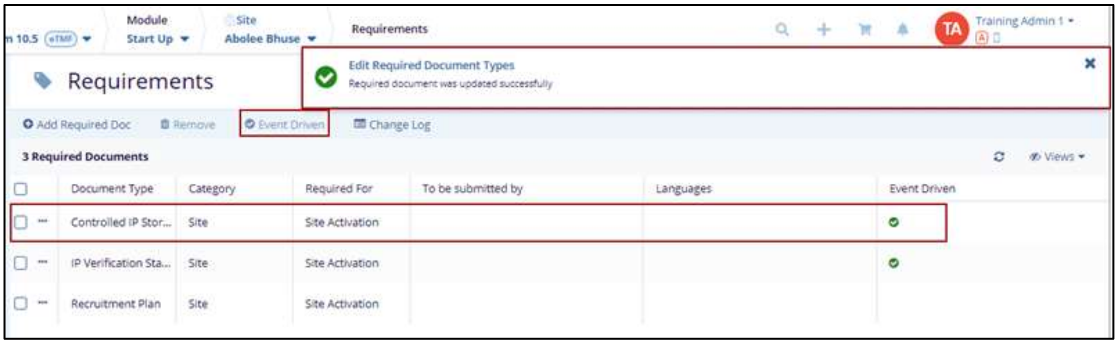
3. Click the Remove button, the Delete Requirements pop-up window with the No and Yes buttons.



4. Click Yes button the notification is message is displayed on the top right side of the screen.

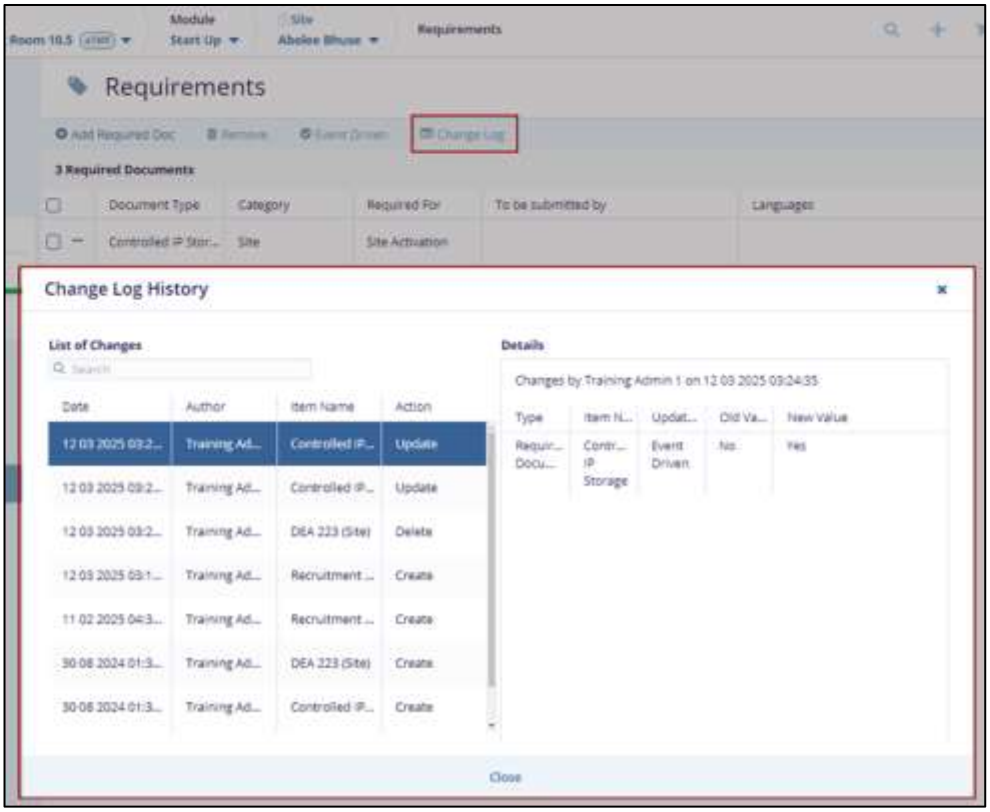
Event Driven

1. Select the site and click the Event Driven button above on the top menu bar.
2. The notification is message is displayed on the top right side of the screen and the Green tick is displayed within the Event Driven column.



Change Log

1. Click the Change Log button on the top menu bar.
2. The Change Log History pop-up window is displayed with the list of changes and details.



Views

To know more detailed information about views please refer to this link - [Popular Documents](#).

Amendments

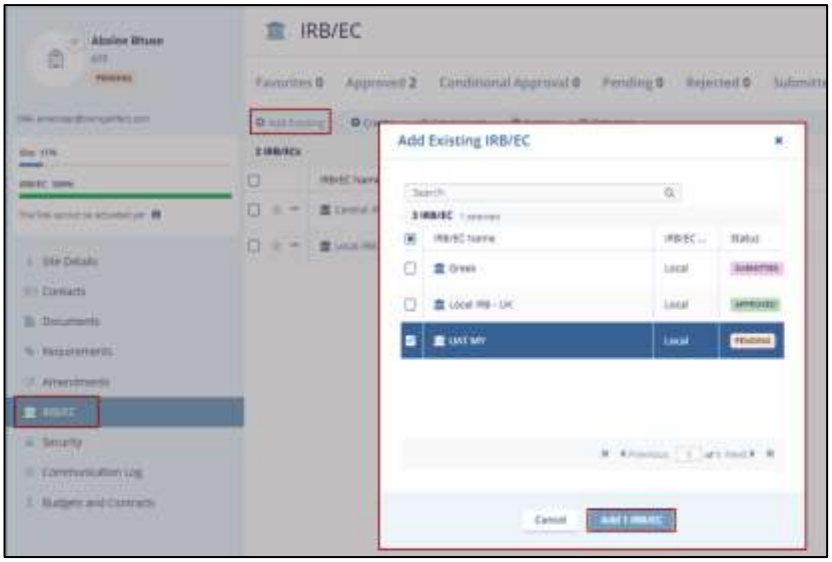
To know more detailed information about Amendments please refer to this link - [Amendments](#)

IRB/EC

Add Existing

Follow the steps below to add an existing IRB/EC to the list of institutions:

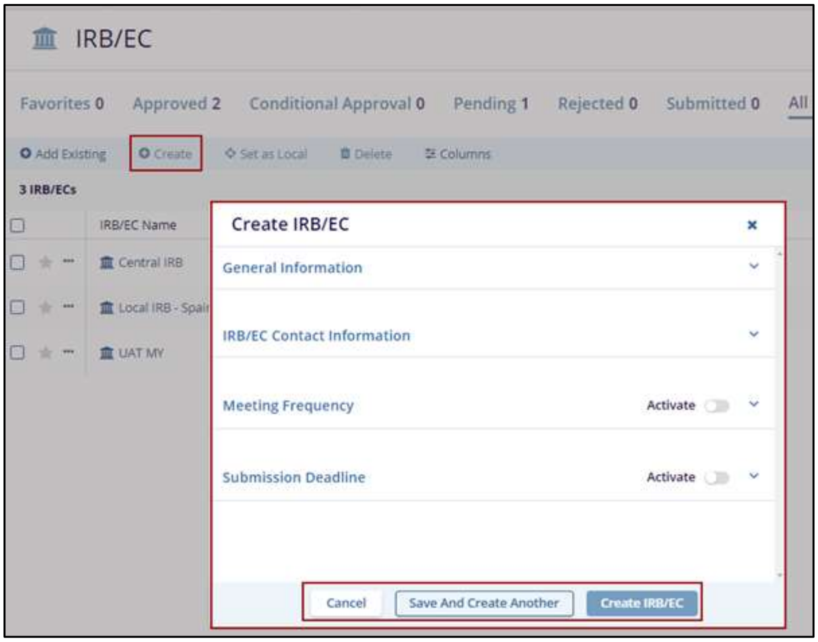
1. Click the Add Existing button displayed on the top menu bar. This opens the Select IRB/EC popup window.
2. Select the checkbox of the required IRB/EC and click the Select button displayed at the bottom of the popup window. The selected IRB/EC is added in the grid.



Create 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. Click 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
2. Click the Create IRB/EC button displayed at the bottom of the popup window.
3. If the user wants to create another IRB/EC at the same time, click Save and Create Another button.

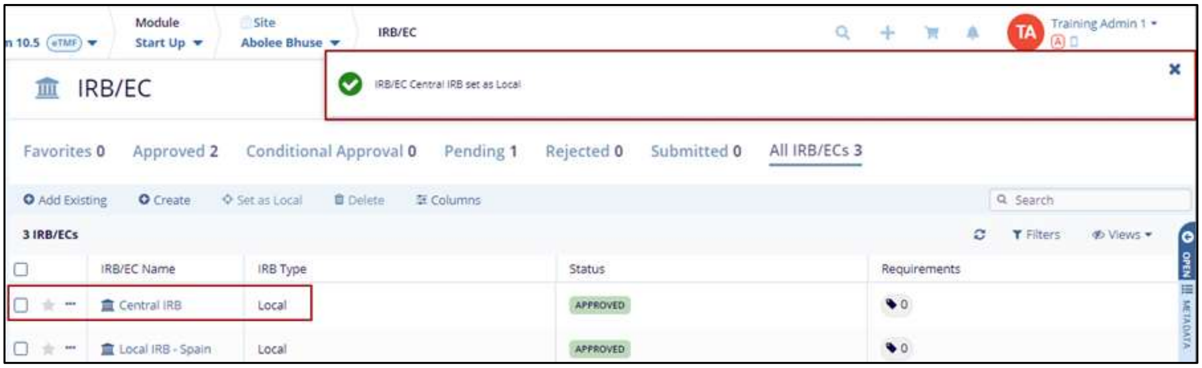


Set as Local

Follow the steps below to set IRB/EC as local:

1. Select the IRB/EC that have the IRB Type different than Local.

2. Click the Set as Local option on the top menu bar.

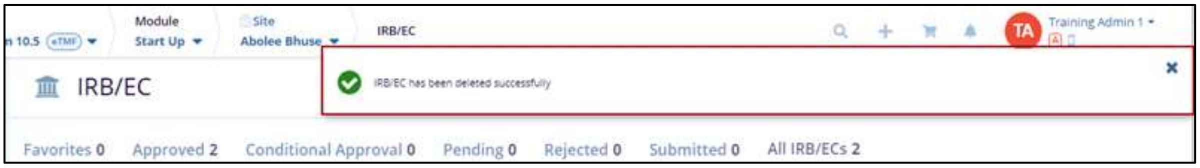


Delete

Follow the steps below to set IRB/EC as local:

1. Select the IRB/EC and click the Delete button on the top menu bar.
2. The Delete IRB/EC (s) pop-up window is displayed with Cancel and Delete buttons.

3. The notification is message is displayed on the top right side of the screen.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - [Popular Documents](#).

Security

To know more detailed information about security for sites please refer to this link - [Security](#)

Communication Log

To know more detailed information about communication log please refer to this link - [Communication Log](#)

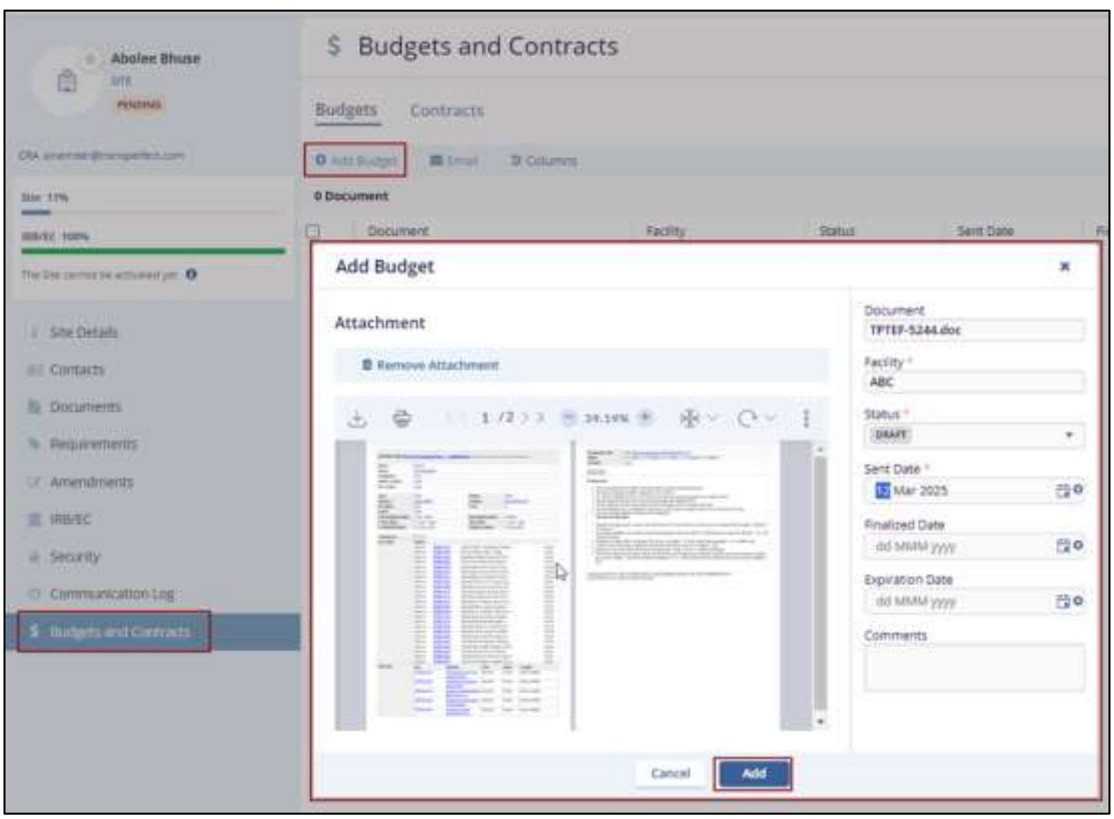
Budgets and Contracts

Budgets and Contracts manage financial agreements and legal terms between the site and sponsor. This includes site budget negotiations, contract execution, and amendments. The process ensures compliance, transparency, and alignment on costs, payment terms, and responsibilities before site activation.

Add Budget

Follow the steps below:

1. Click the Add Budget option, the Add Budget pop-up window is displayed on the screen with Cancel and Add buttons.
2. Click the Browse File option and add the attachment and fill in all the required fields.
3. Click the Add button, the attached document is displayed in the grid.

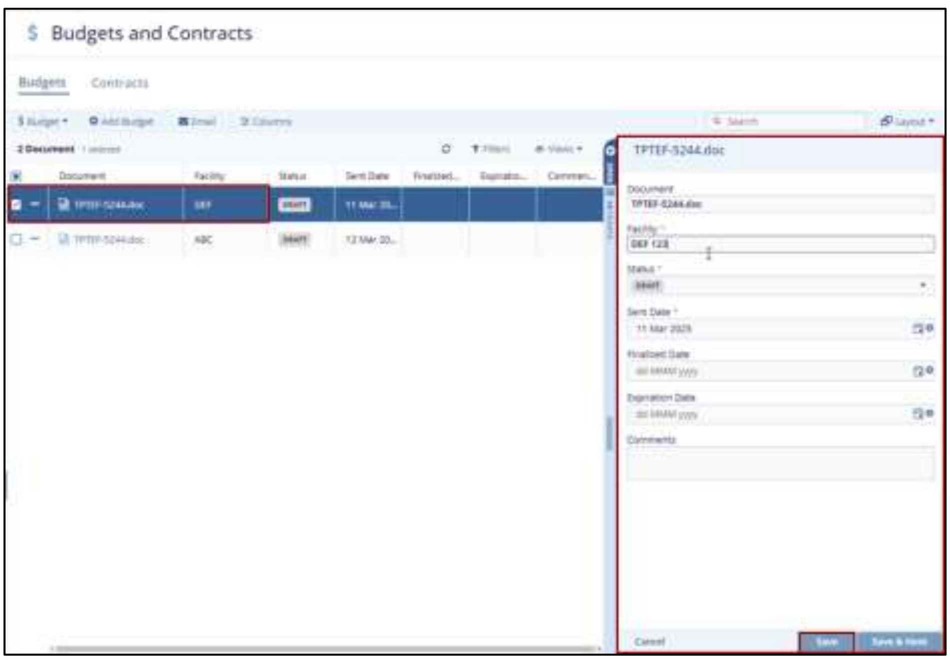


Budget

Follow the steps below to Edit the Budget and Contract:

1. Select the document and expand the Budget drop-down and click the Edit option.

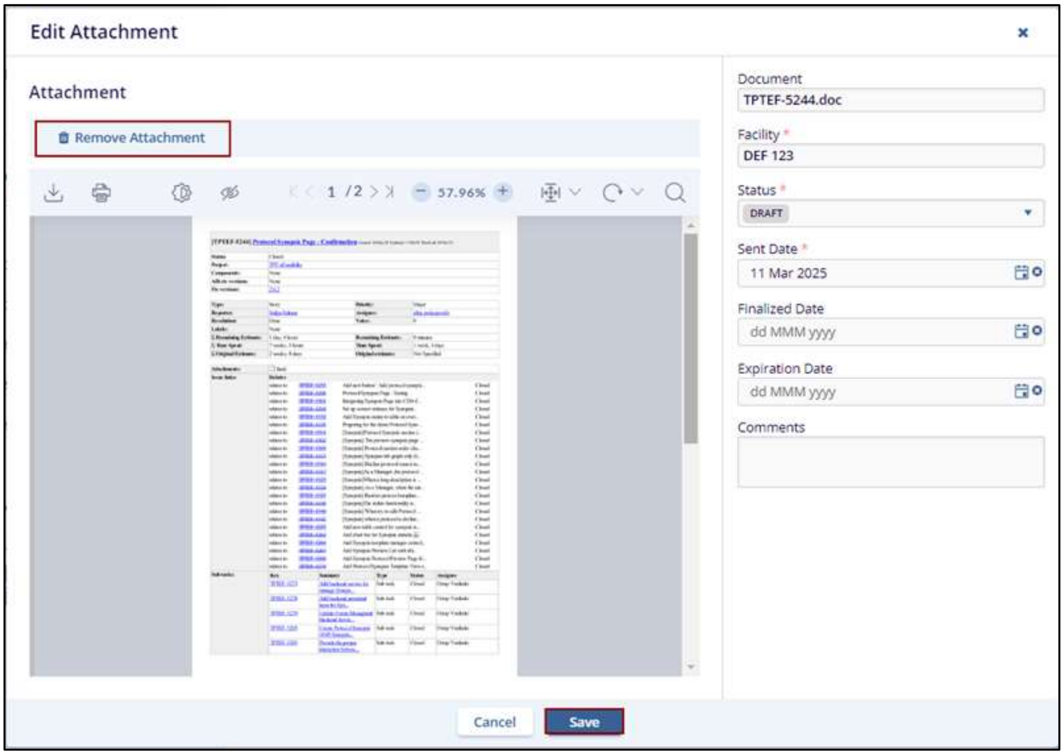
2. The metadata panel gets opened on the right side of the screen make the edits and click Save at the bottom in the metadata panel.



Follow the steps below to Edit Attachment the Budget and Contract:

1. Select the document and expand the Budget drop-down and click the Edit Attachment option.

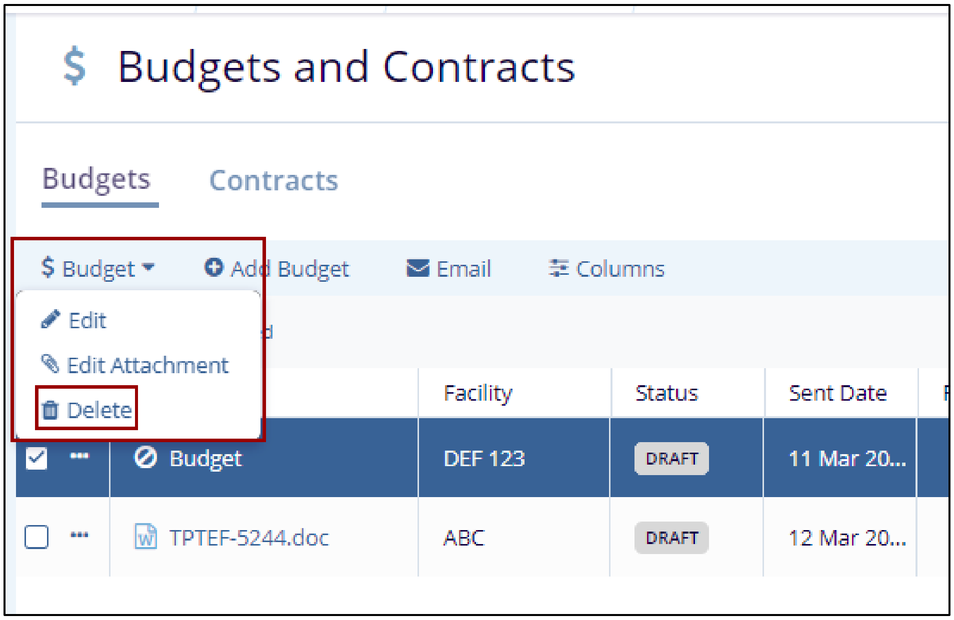
2. The Edit Attachment pop-up window is displayed.
3. Click Remove Attachment to remove the existing attachment.



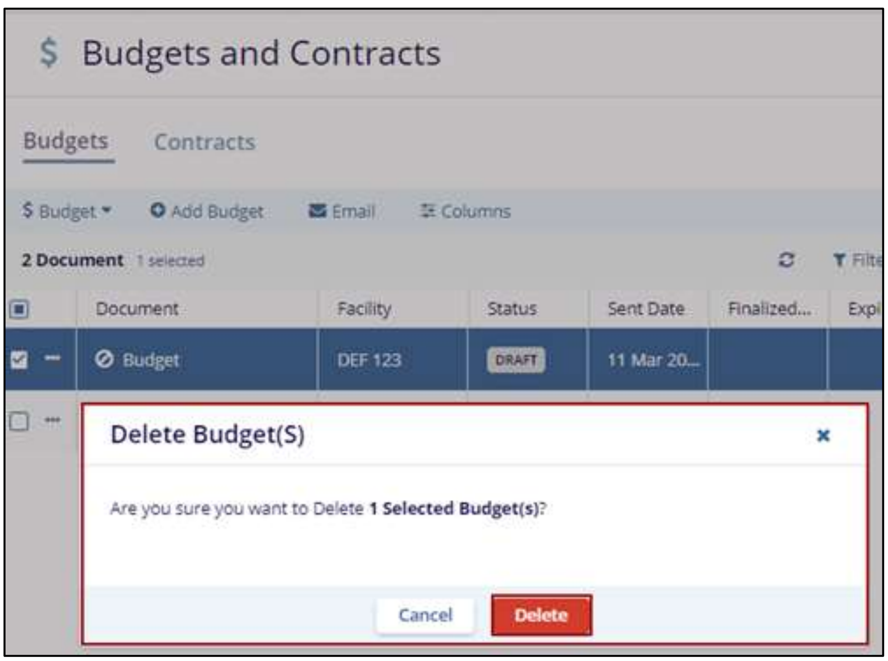
4. The Remove Attachment pop-up window is displayed with the Cancel and Remove Attachment buttons.
5. Click the Remove Attachment button. The existing attachment gets removed.
6. Click the Save button with or without attachment.

Follow the steps below to Delete the Budget and Contract:

1. Select the document and expand the Budget drop-down and click the Delete option.



2. The Delete Budget(s) pop-up window is displayed with the Cancel and Delete buttons.
3. Click the Delete button and Cancel button to discard the changes.

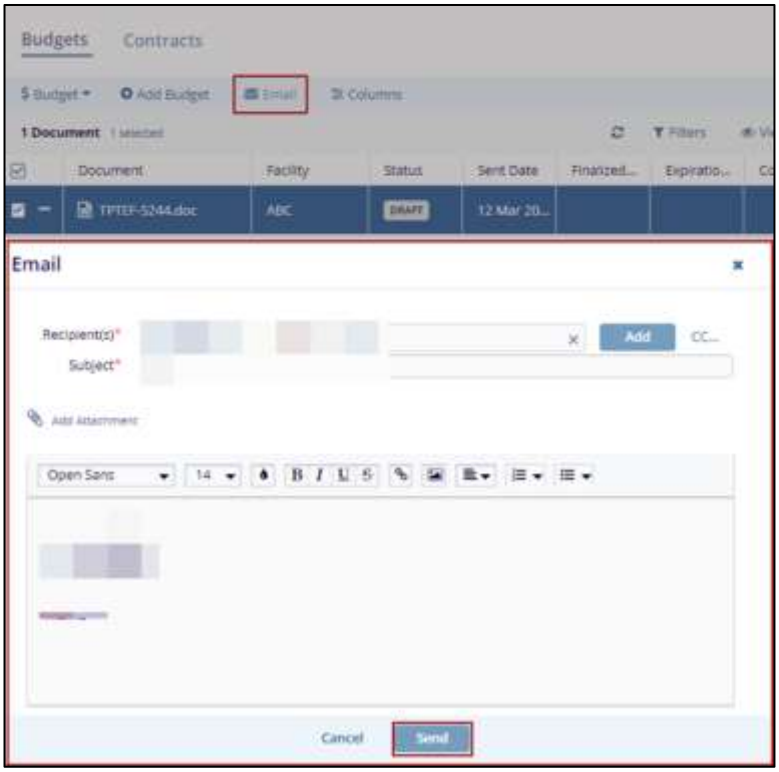


4. The notification message is displayed on the top right side of the screen.

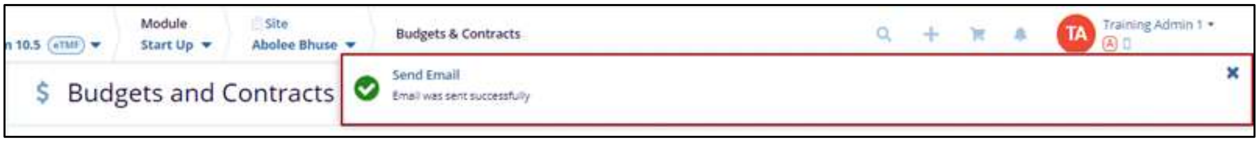
Email

Follow the steps below to Email the Budget and Contract:

1. Click the Email button on the top menu bar.
2. The Email pop-up window is displayed fill in all the required fields and click Send button.



3. The Save Conversation pop-up window is displayed with the Yes, Yes, And Publish To Sites, and No buttons.
4. Click the Yes button. The notification message is displayed on the top right side of the screen.



Columns

To know more detailed information about columns please refer to this link - [Columns](#).

Show Filters

To know more detailed information about filters please refer to this link - [Manage Filters](#) and [Create New Filter](#).

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

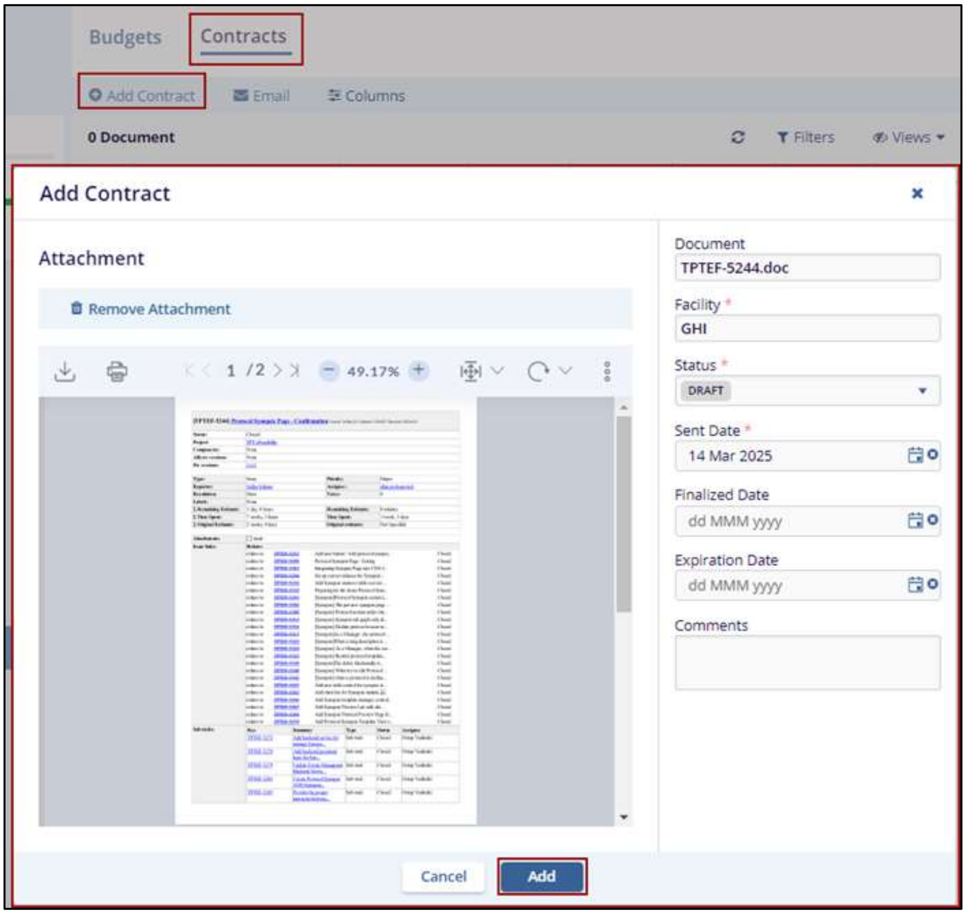
To know more detailed information about views please refer to this link - Layout.

Contracts

Add Contract

Follow the steps below:

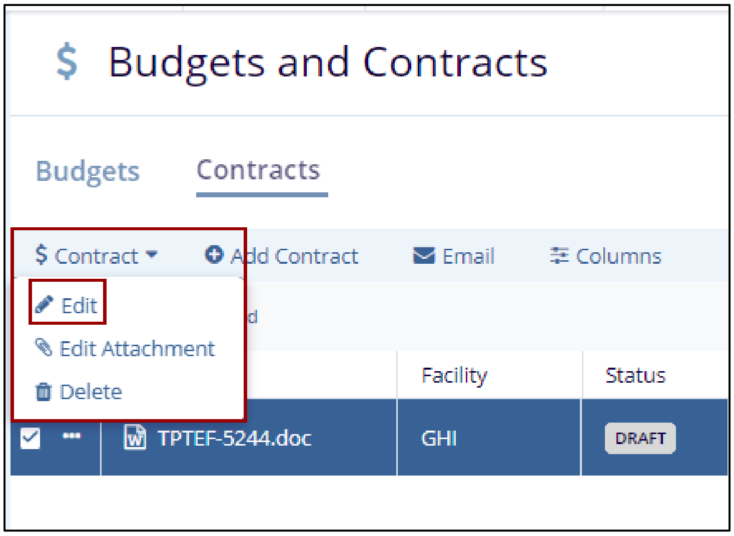
1. Click the Add Contract option, the Add Contract pop-up window is displayed on the screen with Cancel and Add buttons.
2. Click the Browse File option and add the attachment and fill in all the required fields.
3. Click the Add button, the attached document is displayed in the grid.



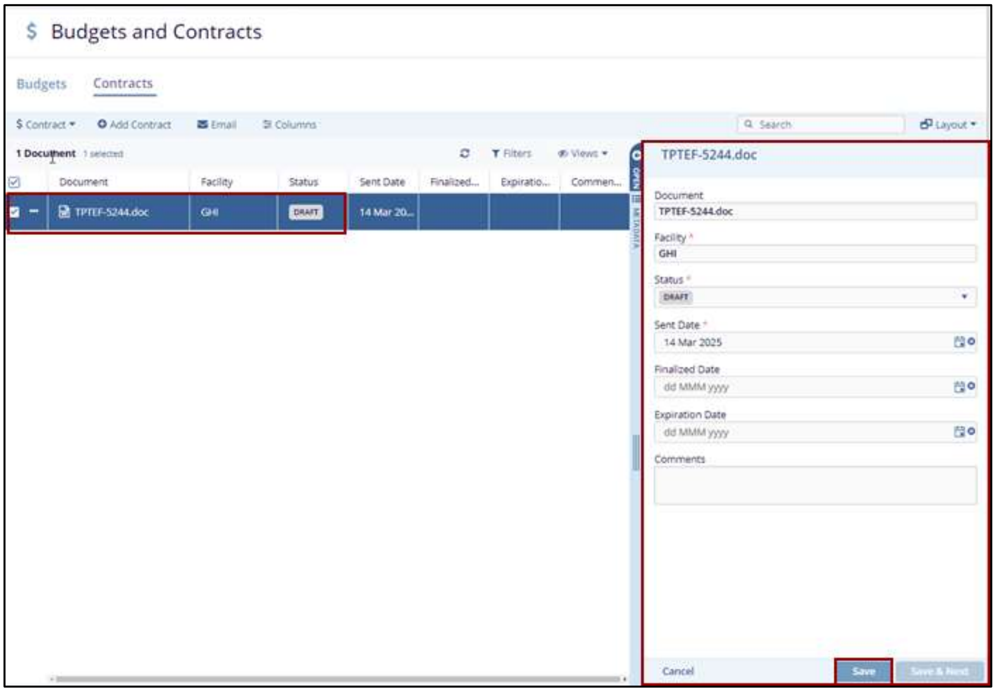
Contract

Follow the steps below to Edit the Budget and Contract:

1. Select the document and expand the Contract drop-down and click the Edit option.

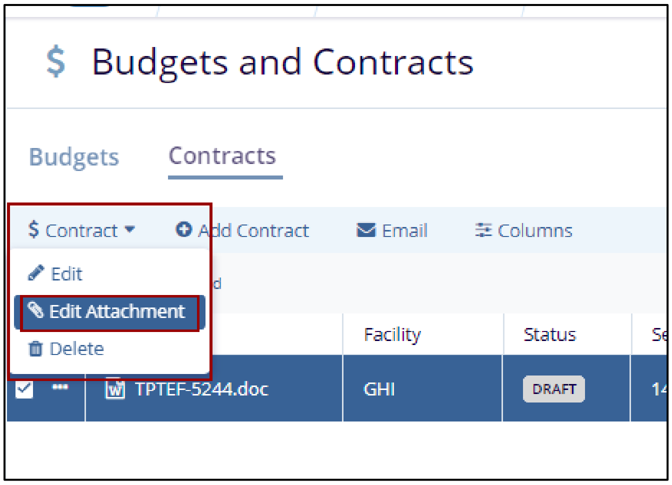


2. The metadata panel gets opened on the right side of the screen, make the edits, and click Save at the bottom in the metadata panel.

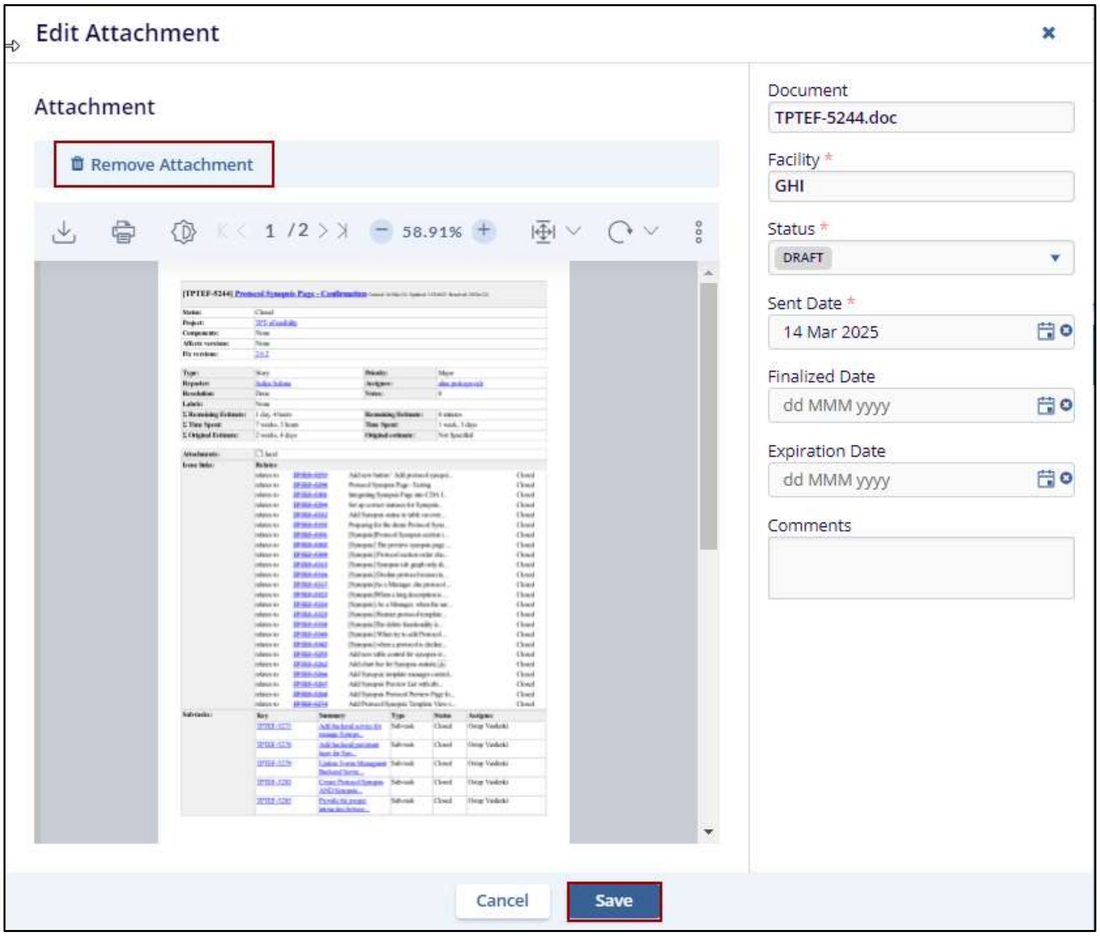


Follow the steps below to Edit Attachment the Budget and Contract:

1. Select the document and expand the Contract drop-down and click the Edit Attachment option.



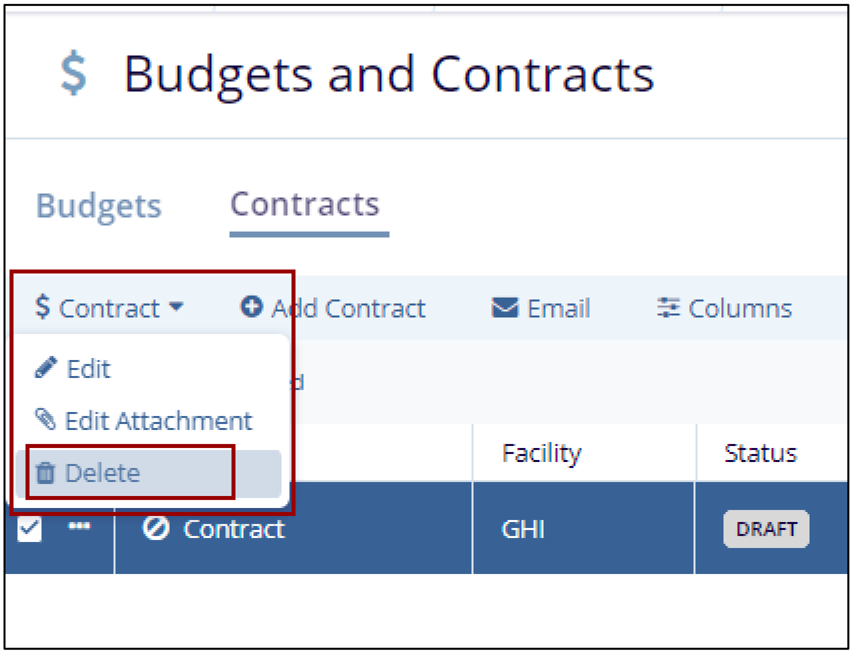
2. The Edit Attachment pop-up window is displayed.
3. Click Remove Attachment to remove the existing attachment.



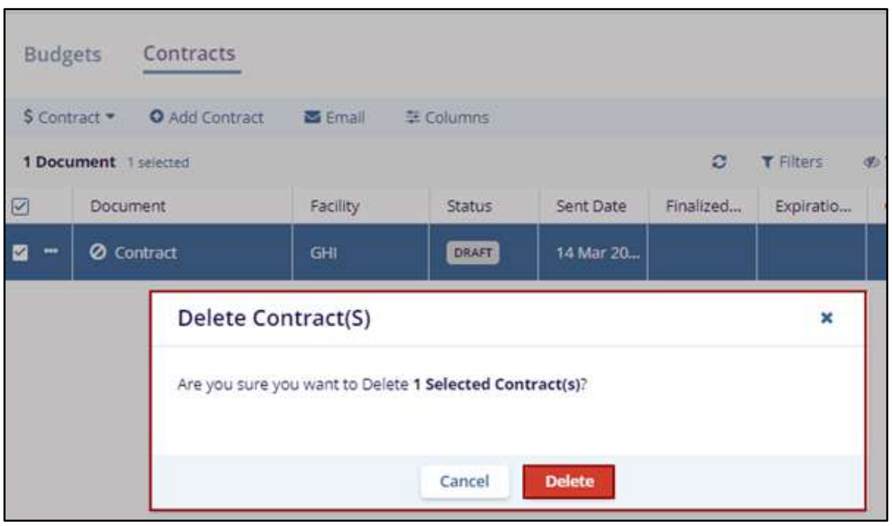
4. The Remove Attachment pop-up window is displayed with the Cancel and Remove Attachment buttons.
5. Click the Remove Attachment button. The existing attachment gets removed.
6. Click the Save button with or without attachment.

Follow the steps below to Delete the Budget and Contract:

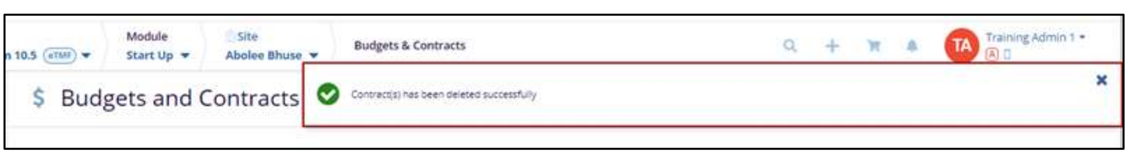
1. Select the document and expand the Contract drop-down and click the Delete option.



2. The Delete Budget(s) pop-up window is displayed with the Cancel and Delete buttons.
3. Click the Delete button and Cancel button to discard the changes.



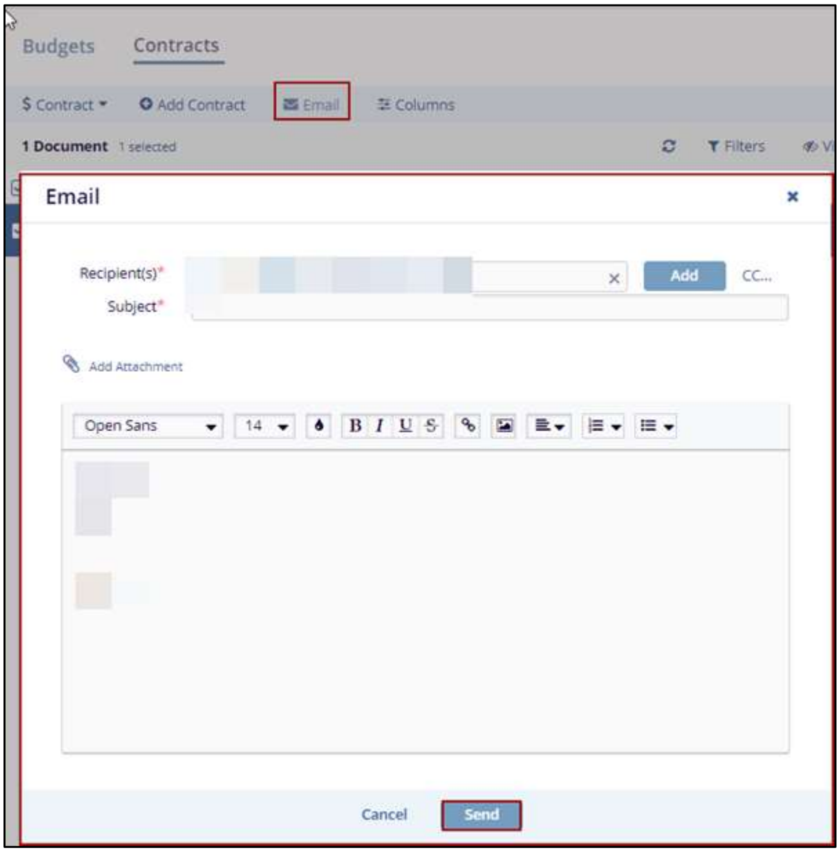
4. The notification message is displayed on the top right side of the screen.



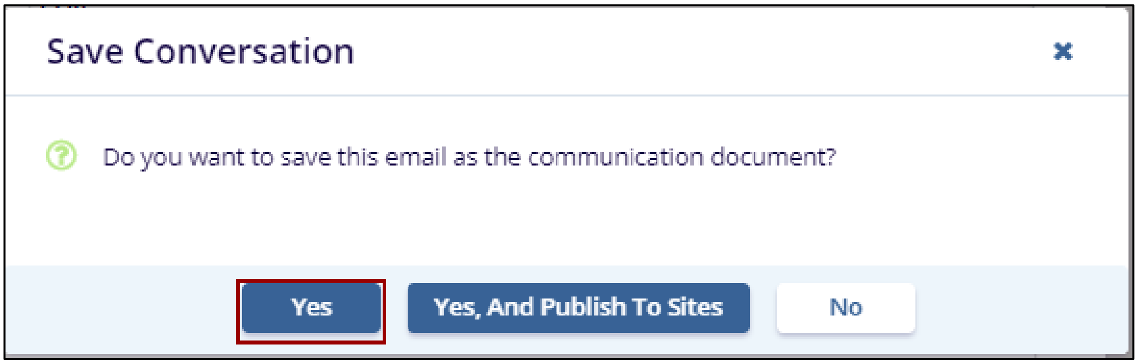
Email

Follow the steps below to Email the Budget and Contract:

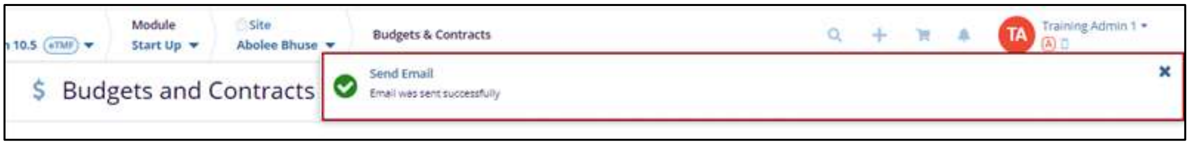
5. Click the Email button on the top menu bar.
6. The Email pop-up window is displayed fill in all the required fields and click Send button.



7. The Save Conversation pop-up window is displayed with the Yes, Yes, And Publish To Sites, and No buttons.



8. Click the Yes button. The notification message is displayed on the top right side of the screen.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

To know more detailed information about views please refer to this link - Layout.

DOCUMENTS

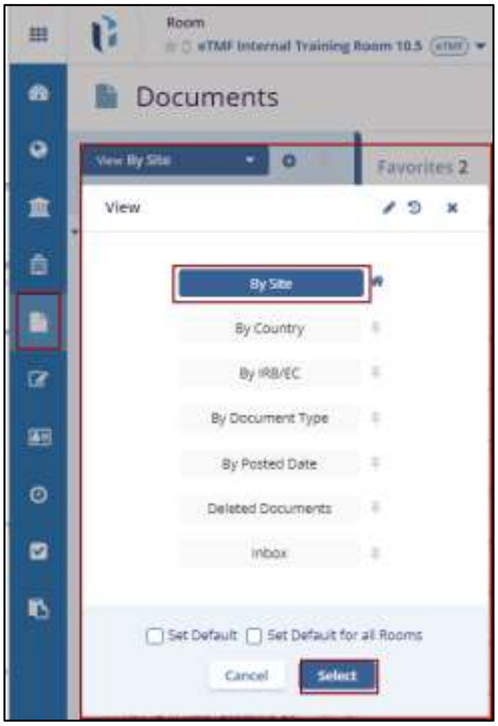
The Document tab from the toggling menu bar leads the user to the Documents dashboard. Typically, the Documents module is the route through which most Editors will access and view documents for a Start-Up study. This module acts as a central repository for all documents added to the various components 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.

View By options

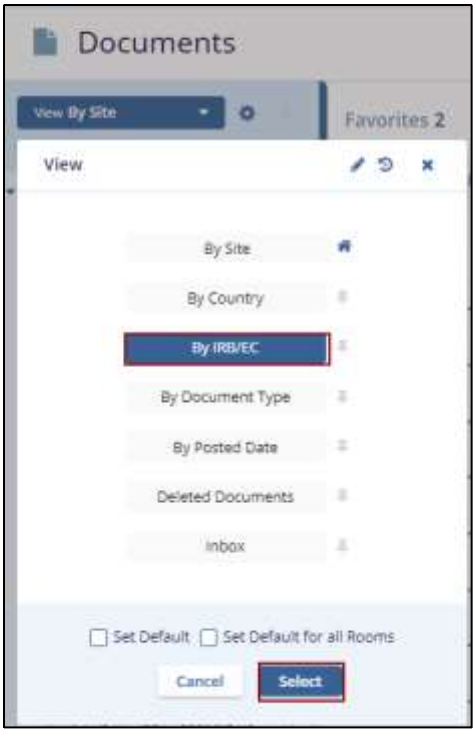
The Current View Dropdown offers seven views. Click the View By dropdown menu to view the options. Click the Select button displayed at the bottom of the window to view the specific documents.

- 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.

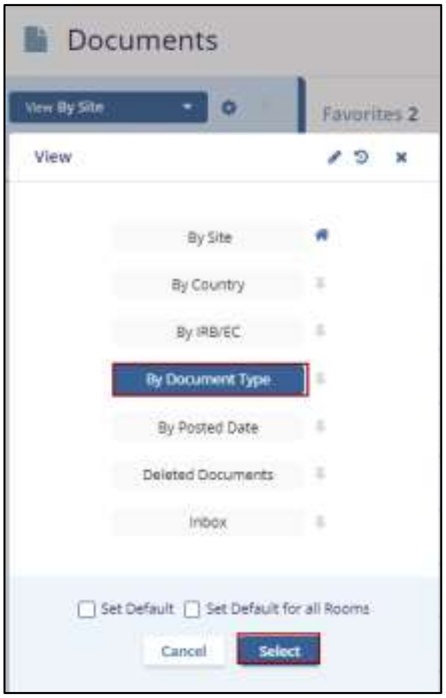


- By Country: Selecting the By Country option lists the countries to which documents have been added. Documents added through the Countries tab can be located here. Clicking a country will display the documents submitted to the country along with their review status in the grid pane.

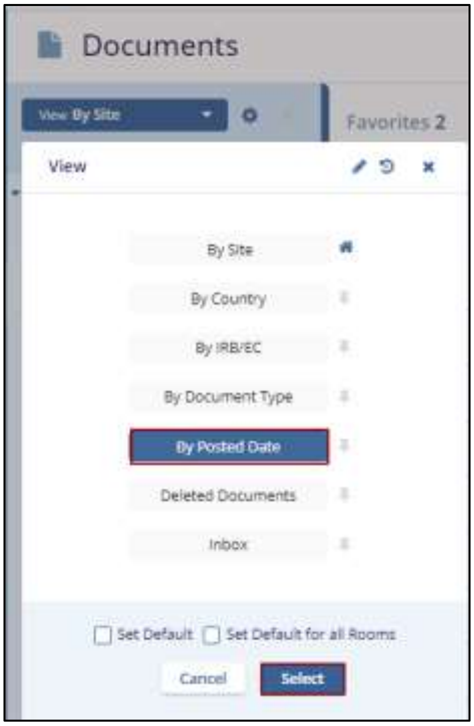
- By IRB/EC: Selecting the By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC will display the documents submitted to the institution along with their review status in the grid pane.



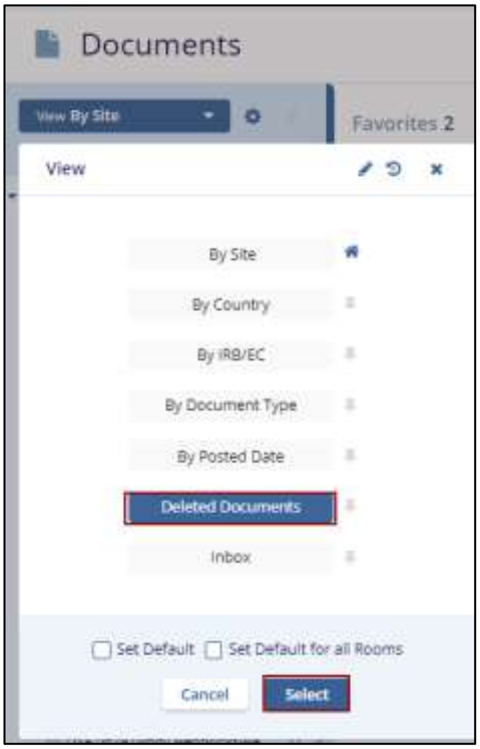
- By Document Type: Selecting the By Document Type option lists the various document types available to the study start-up. Clicking a document type will display the documents submitted by that type, along with their review status, in the grid pane. Refer to the screenshot below:



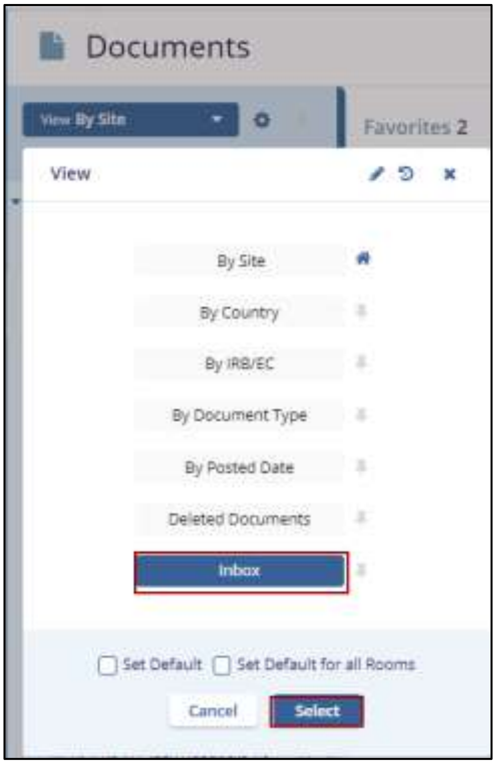
- By Posted Date: Selecting the By Posted Date option lists the dates on which documents were submitted to the sites, countries, and IRB/ECs. Clicking a date will display the documents submitted on that day, along with their review status in the grid pane.



- 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.



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.

Import

The Import button helps the user to add a document. To know more detailed information about views please refer to this link - Import Documents.

Export

The Export button helps the user to export the existing data/document. To know more detailed information about views please refer to this link - Export.

Email

To know more detailed information about views please refer to this link - Email.

Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

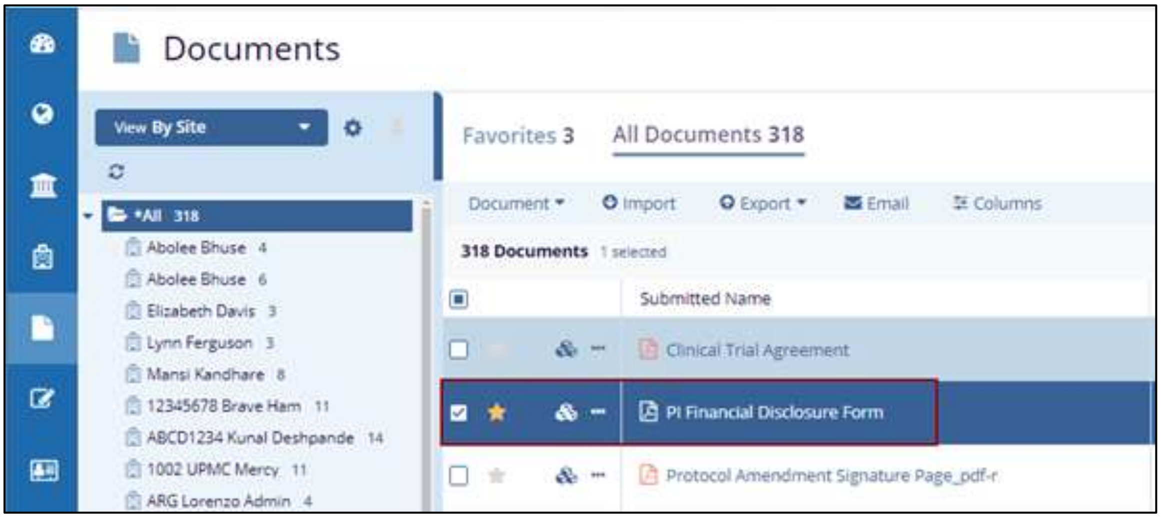
To know more detailed information about layout please refer to this link - Layout.

Document Dropdown

The Document button and its dropdown options appear only when a document is selected via its checkbox. Each available option in the dropdown provides specific actions related to document management, which are covered in the following topics.

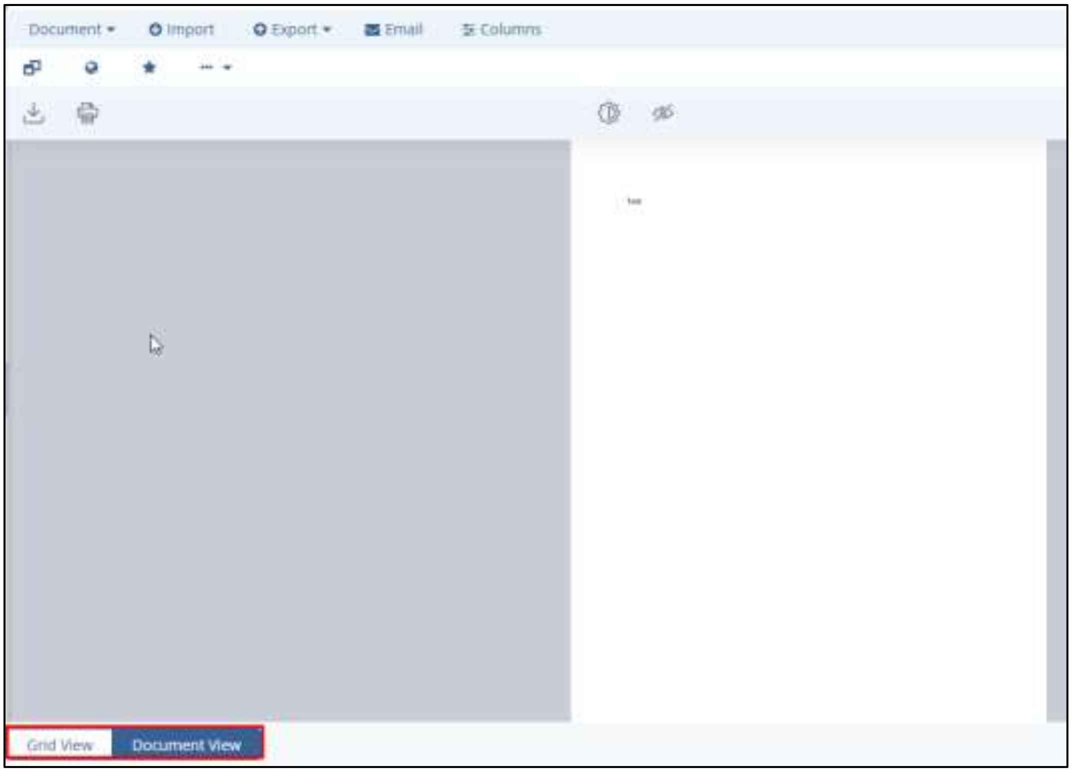
Add to Favorites

Click the Star icon next to the document checkbox to add it to Favorites—the grey star will turn yellow. Alternatively, use the three-dot menu to access the same option.



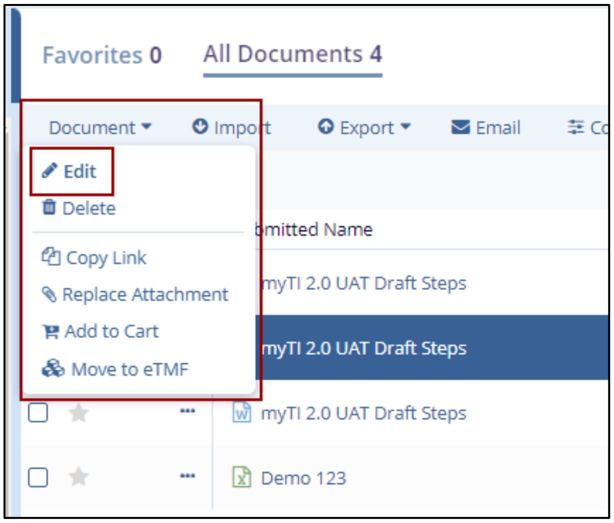
Open Document

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.

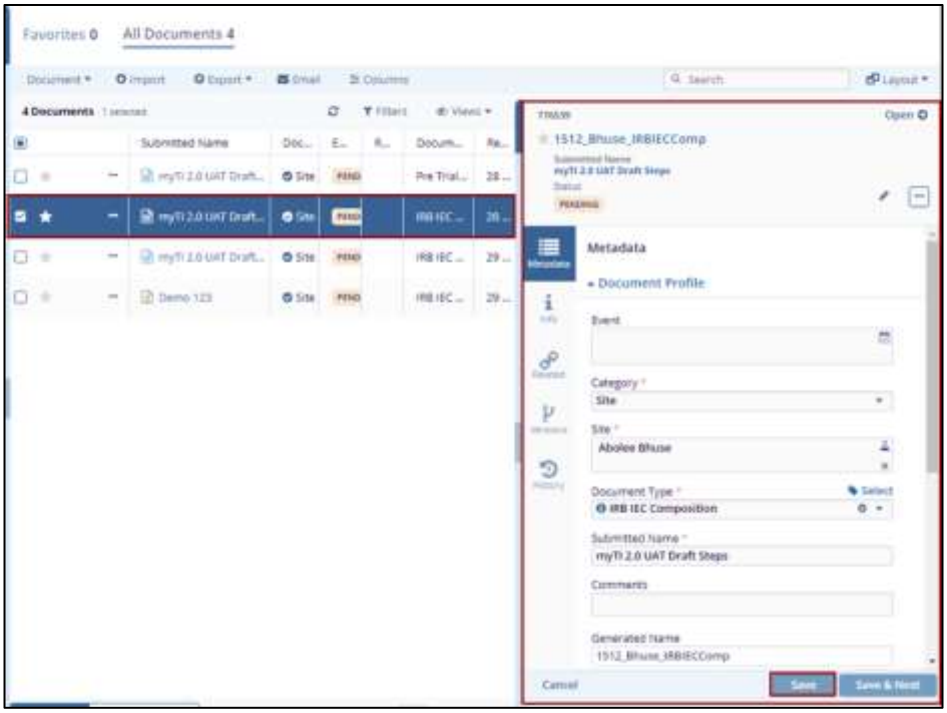


Edit

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.

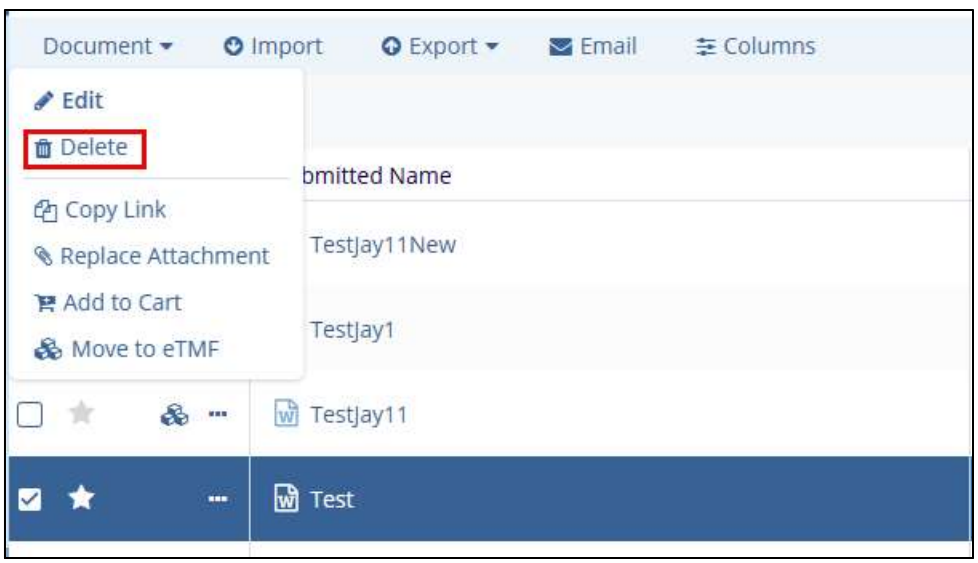


4. The metadata panel is opened on the right side of the screen.
5. Make the required changes in the doc and click the Save button displayed at the bottom of the metadata panel.

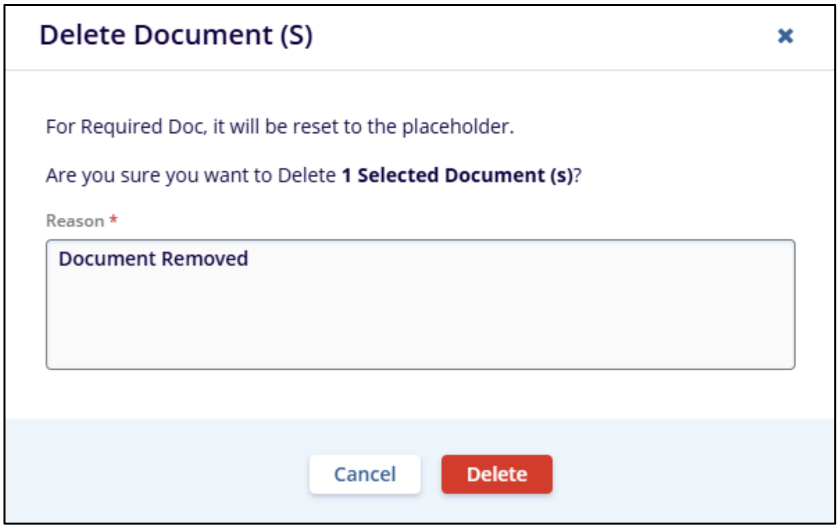


Delete

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.

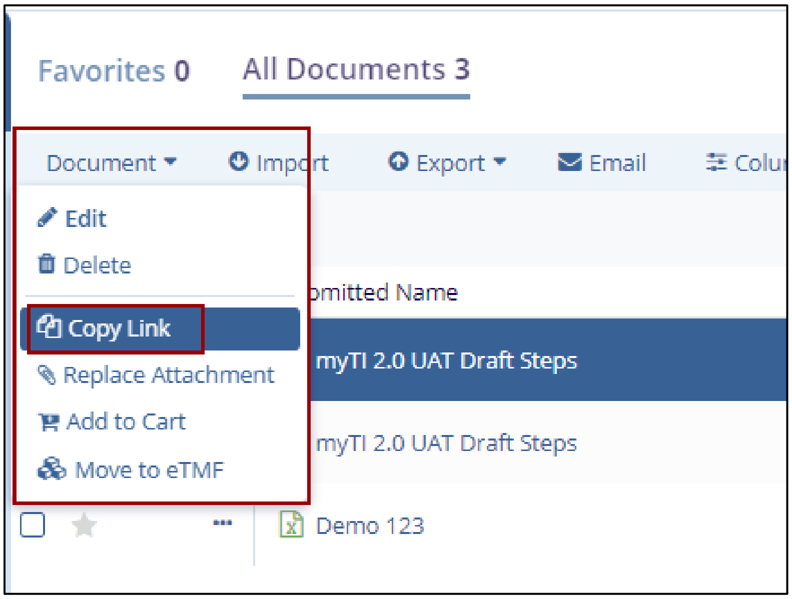


Copy Link

This option allows the user to copy the document link or copy the link along 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 and select the Copy Link option.

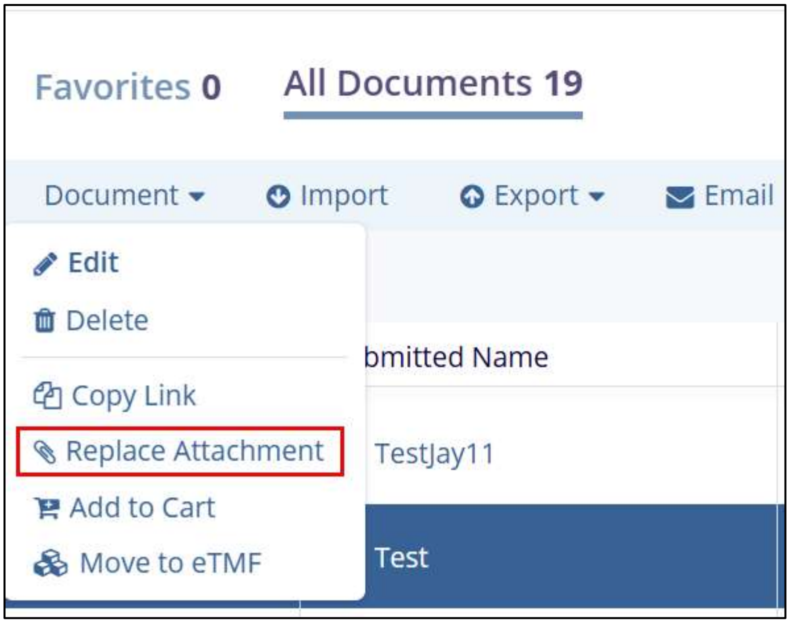


3. The document URL gets copied to the clipboard.
4. A notification about the same is displayed at the bottom right corner of the screen.

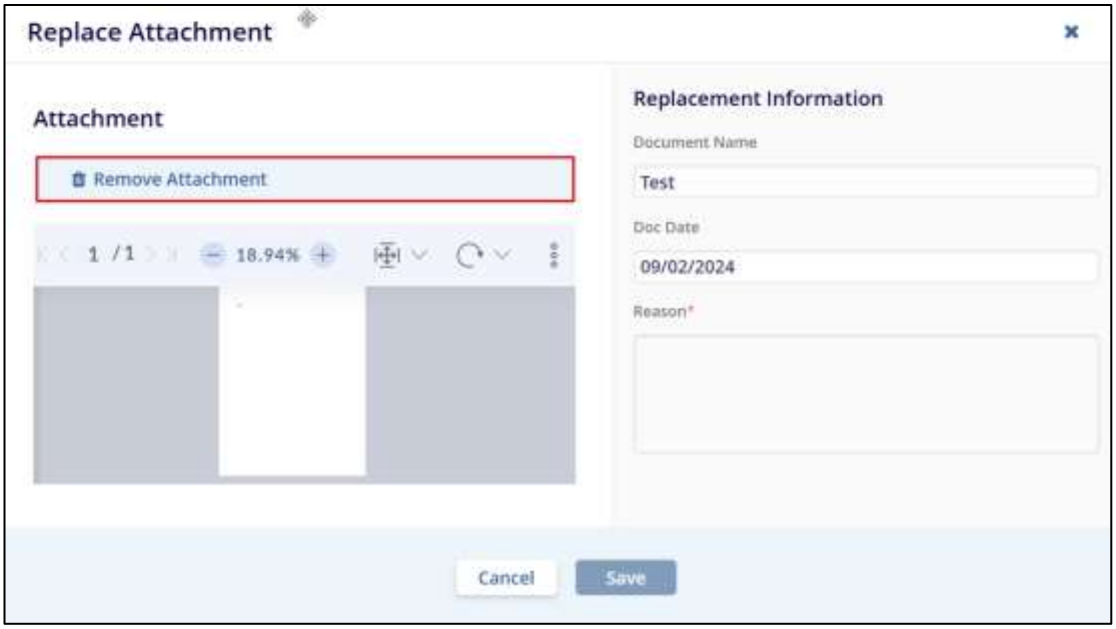
Replace Attachment

You can replace the attachment with a document type if it is not approved by using this feature.

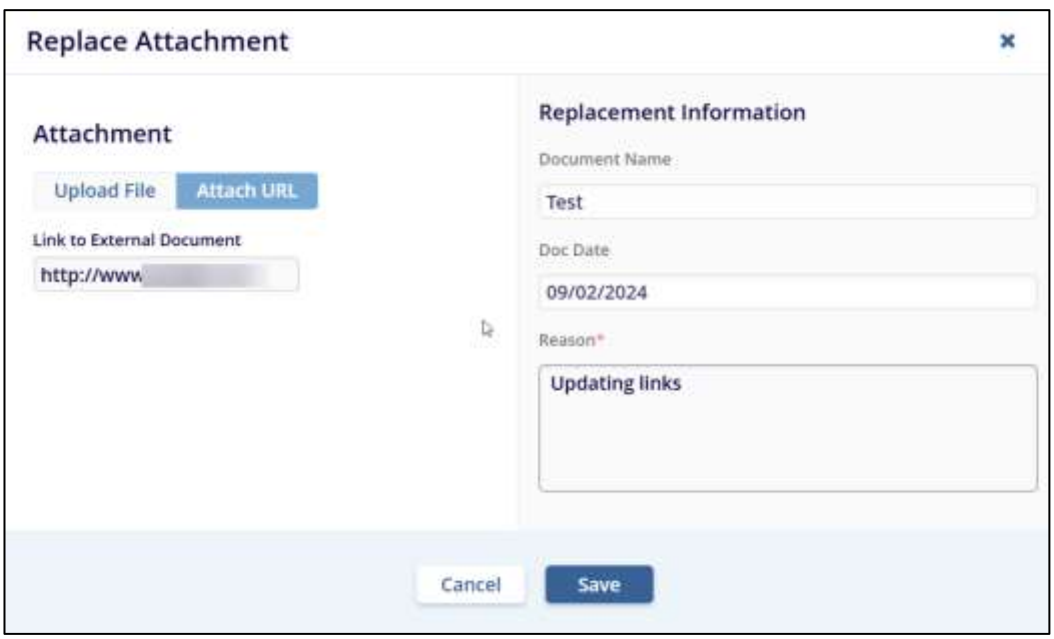
1. Select the checkbox of the document that needs the attachment replaced.
2. Click the dropdown menu of the Document button OR click the three-dot menu next to the checkbox of the selected document.
3. Select the Replace Attachment option.



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.

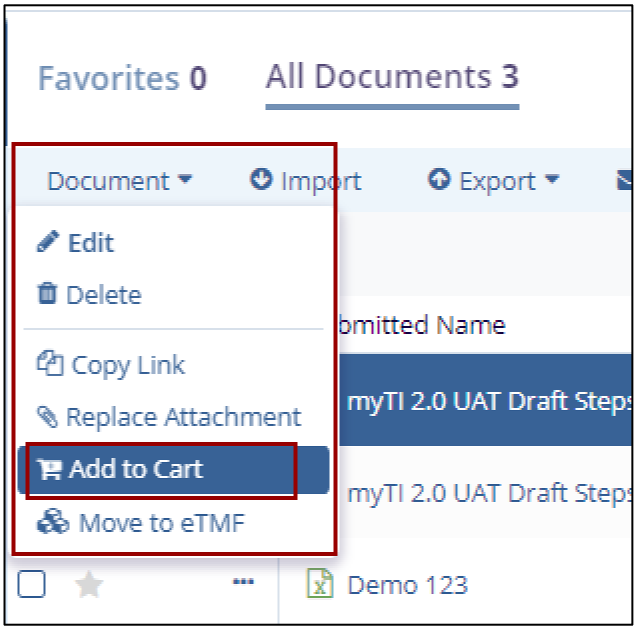


Note: Click the Upload File tab to upload documents by following the standard document upload process.

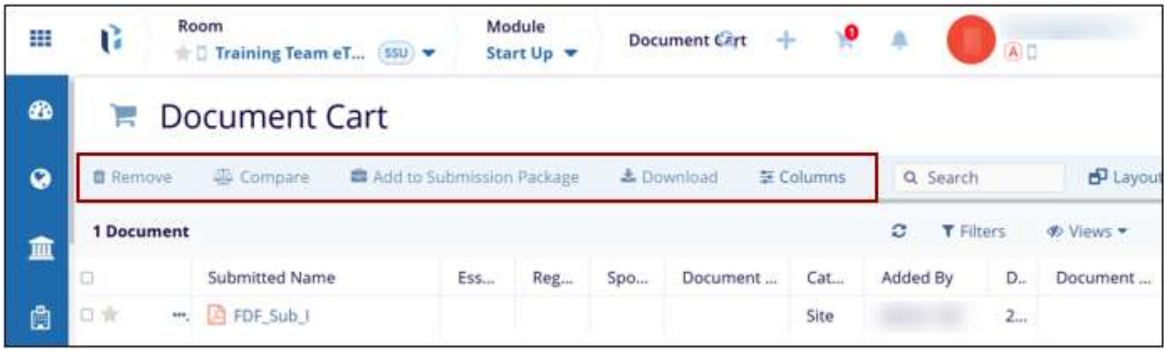
Add to Cart

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. The Document Cart icon displays a number in the top right corner.



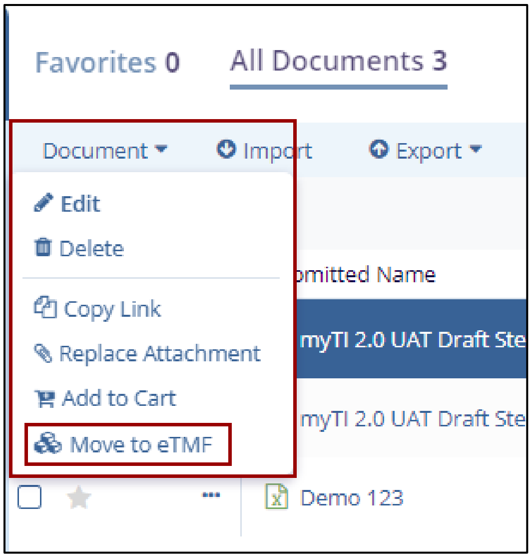
4. Click the Document Cart icon to view the document details in the grid pane.
5. The user can Remove, Compare, and Add Documents to the Submission Package, Download, Manage Columns, Manage and Create Filters, and Save Views in the grid pane.



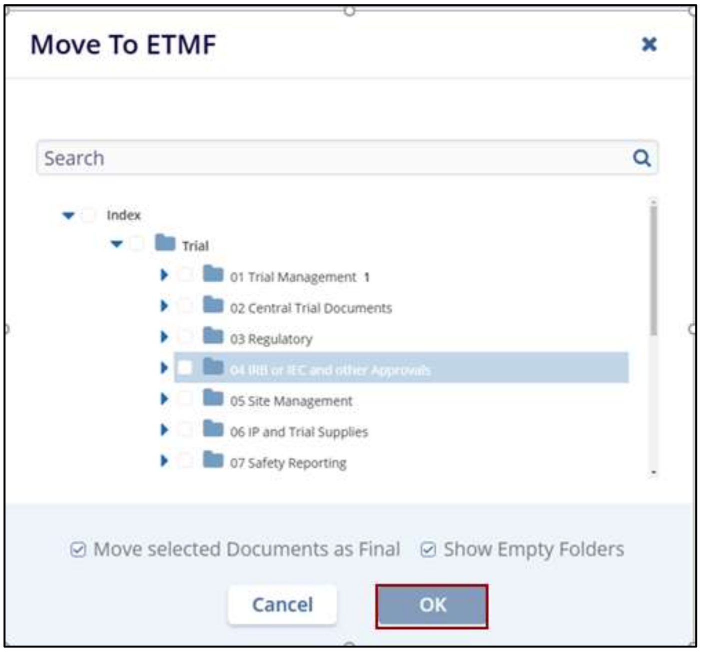
Move to eTMF

Users can move a selected document to the eTMF by clicking the Move to eTMF button in the top menu bar. This opens the Select Index Position pop-up window for document placement.

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.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

To know more detailed information about layout please refer to this link - Layout.

AMENDMENTS

After a site is activated and the clinical trial begins, protocol amendments are common. Depending on the amendment type, additional essential documents may be required. These documents cannot be added directly to the site but must be specified through Amendments, which can be created for Investigative Sites, Country Amendments, and IRB/EC.

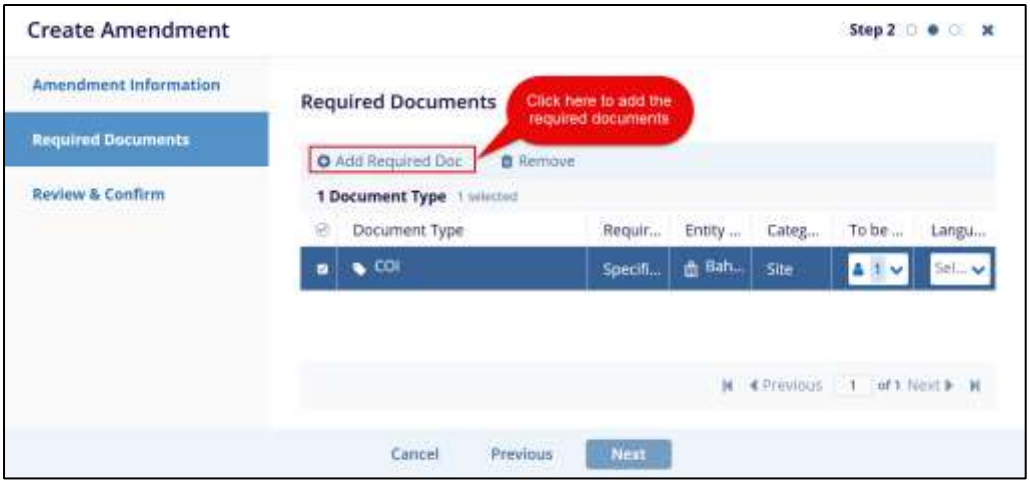
Add Amendments

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.

3. On the Create Amendment window, enter the necessary details in Step 1: Amendment Information and click on the Next button.

4. Add the Required number of documents in Step 2: Required Documents and click on the Next button.



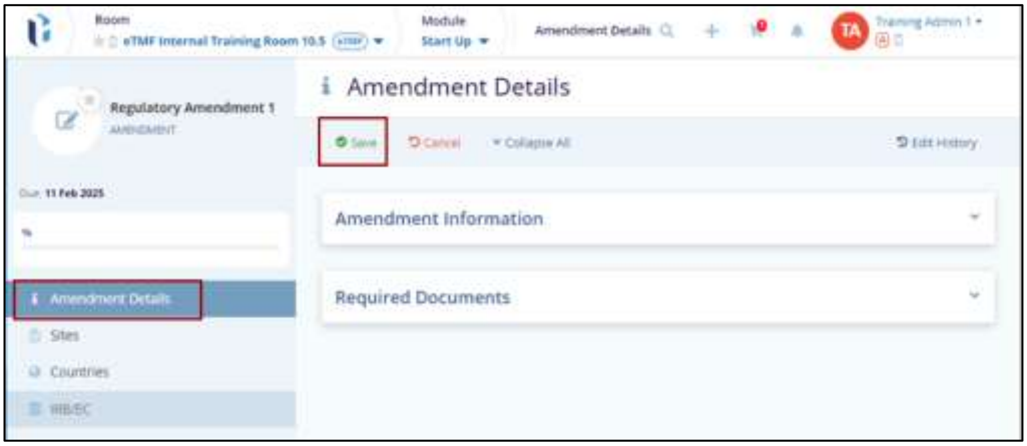
5. Confirm all the details in Step 3: Review and Confirm and click on the Create Amendment button.

Amendments Details

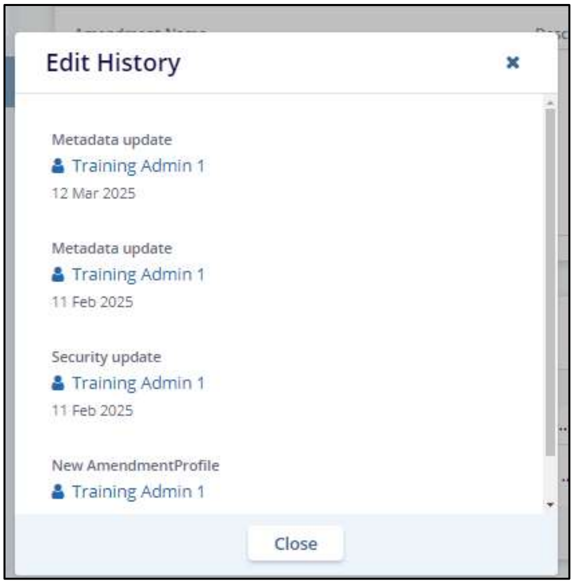
Edit

1. Select the document to be edited and click the Edit option.
2. The Amendment Information and Required Documents section fields are editable.

3. Make the edits and click the Save option to save the changes and the Cancel option to discard the changes.

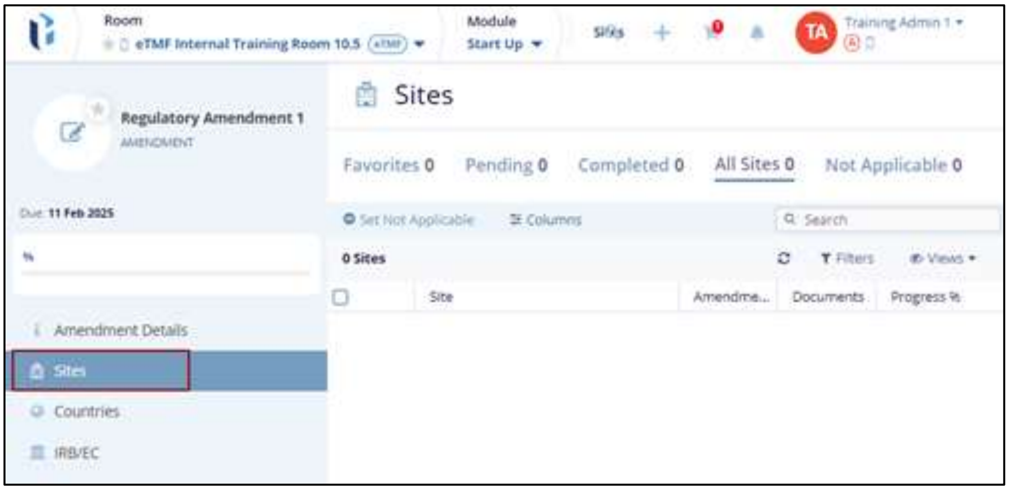


4. On the top right side of the page, click the Edit History button to view past edits.



Sites

The user can mark an Amendment as Applicable or Not Applicable based on the requirements.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

To know more detailed information about layout please refer to this link - Layout.

Countries

The user can view the Amendment that is associated with the countries.

Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

To know more detailed information about layout please refer to this link - Layout.

IRB/EC

The user can view the Amendment that is associated with the IRB/EC.

Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

Layout

To know more detailed information about layout please refer to this link - Layout.

Contacts

The Contacts tab, accessed from the left toggling menu, stores all messages exchanged during the study start-up process for site activation. In the Communication tab, users can view three panels: Current View, Grid Pane, and Communication Data.

To know more detailed information about contacts please refer to this link - Contacts.

COMMUNICATION LOG

The communication log helps the user by displaying communications that have occurred over time, allowing them to collect different documents from the appropriate personnel. The user can add, edit, delete, manage columns, search, and create or manage filters on this page.

View Dropdown

The View Dropdown allows users to select options based on requirements such as By Communication, and By Date.
The View dropdown includes these views:

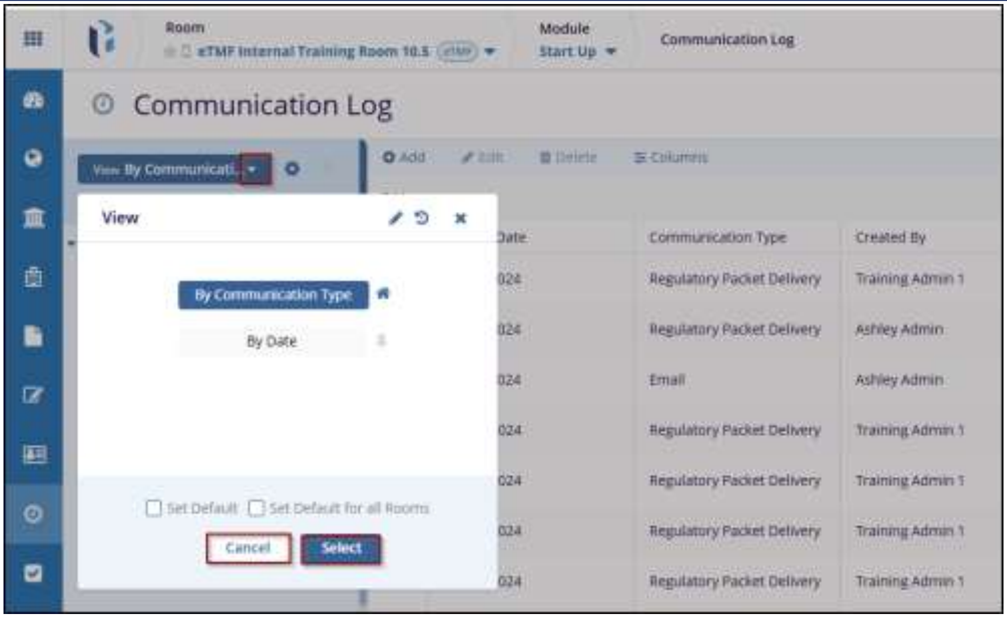
- By Communication Type: This refers to the categorizing document based on communication.
- By Date: This refers to organizing or categorizing documents or sites based on the dates of their review statuses. It allows users to filter and view documents according to a specific date.

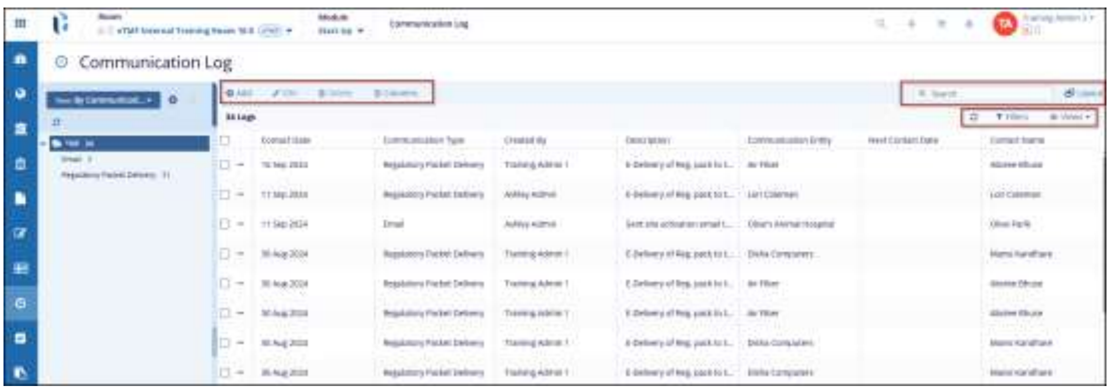
Additional filter:

- Set Default: This will set the selected view as the default for the current session.
- Set Default for All Rooms: This will set the selected view as the default for all rooms, not just the current room.

To apply View options, follow these steps:

1. Navigate to Communication Log from the left-side panel, click on the dropdown menu, View window will display.
2. Select any available options from View.
3. Select the checkbox to set the default view.
4. Click Select to apply the changes or click Cancel to discard changes and retain previous settings.
5. After clicking on the Select button, it will display a folder that will be dependent on the selection of View by option.

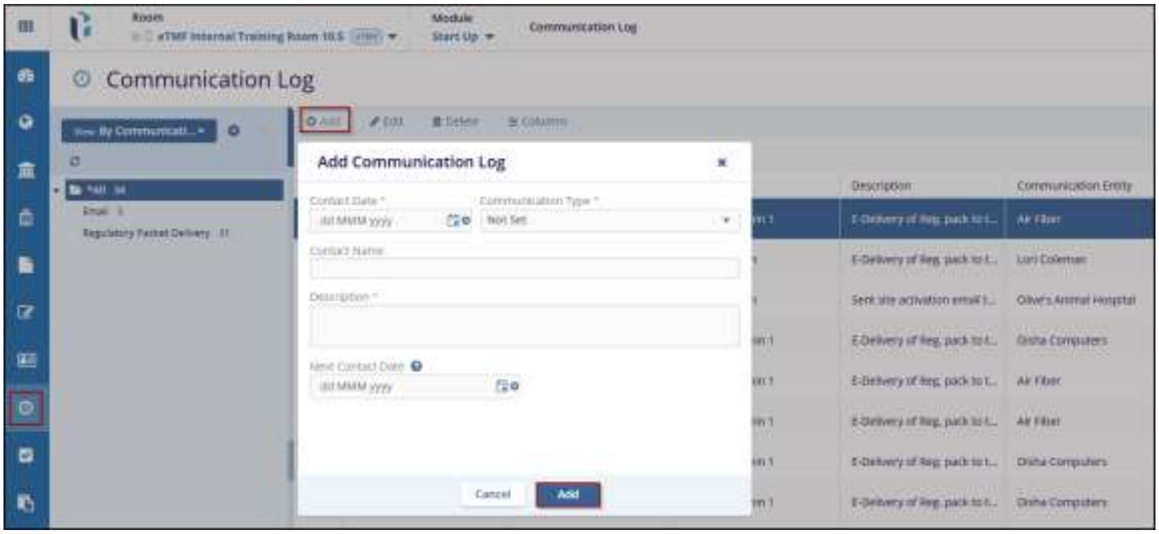




Add

To Add a new Communication Log, follow these steps:

1. Click the Add button displayed on the top menu bar, this will open the Add Communication Log 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 window.

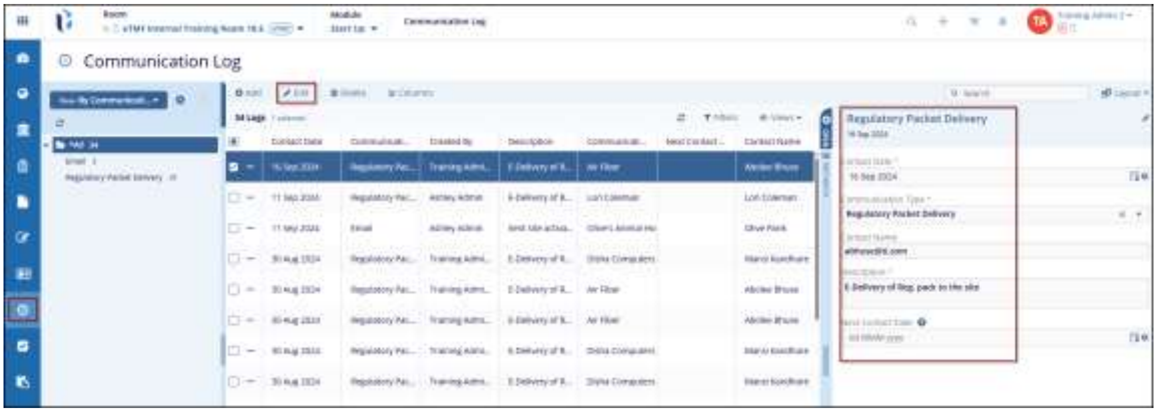


Edit

The edit button allows the user to Modify the Communication Log.

To Edit the Communication Log, follow these steps:

1. Select a checkbox of the log that is to be edited. This enables the Edit button on the top menu bar.
2. Click the Edit button from the top menu bar. Thai opens the metadata panel on the right side of the screen.
3. Click the Pencil icon displayed in the top right corner of the metadata panel.
4. Make the required changes and click the Save button displayed at the bottom of the metadata panel.

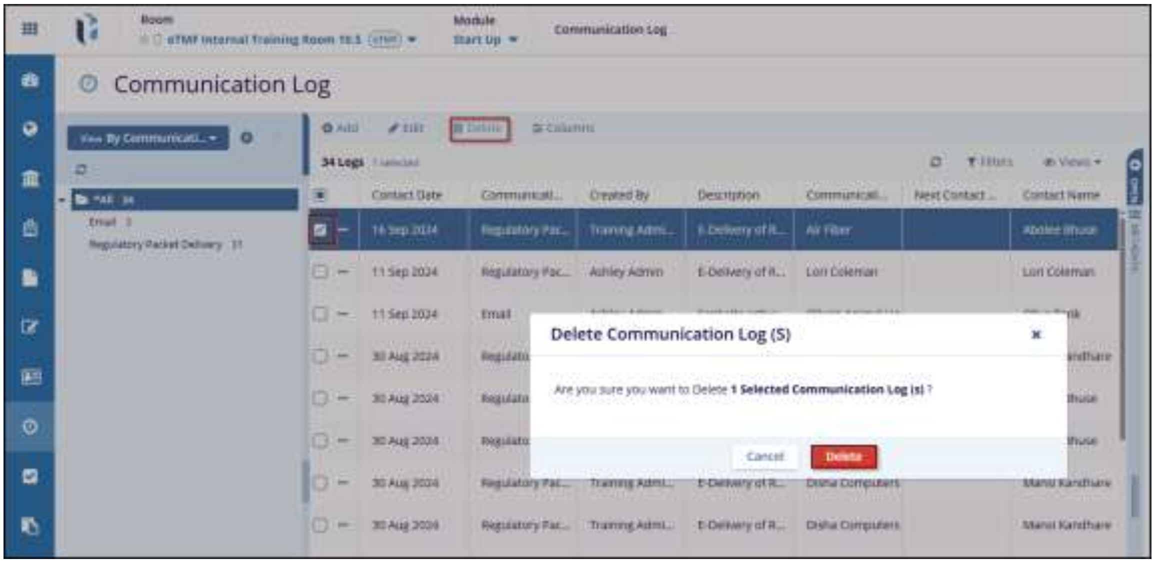


Delete

The delete button allows the user to Delete the Communication Log.

To Delete the Communication Log, follow these steps:

1. Select the log that is to be deleted.
2. Click the Delete button displayed in the top menu bar. This opens the Delete Record popup window.
3. Click the Delete button displayed at the bottom of the popup window.



Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

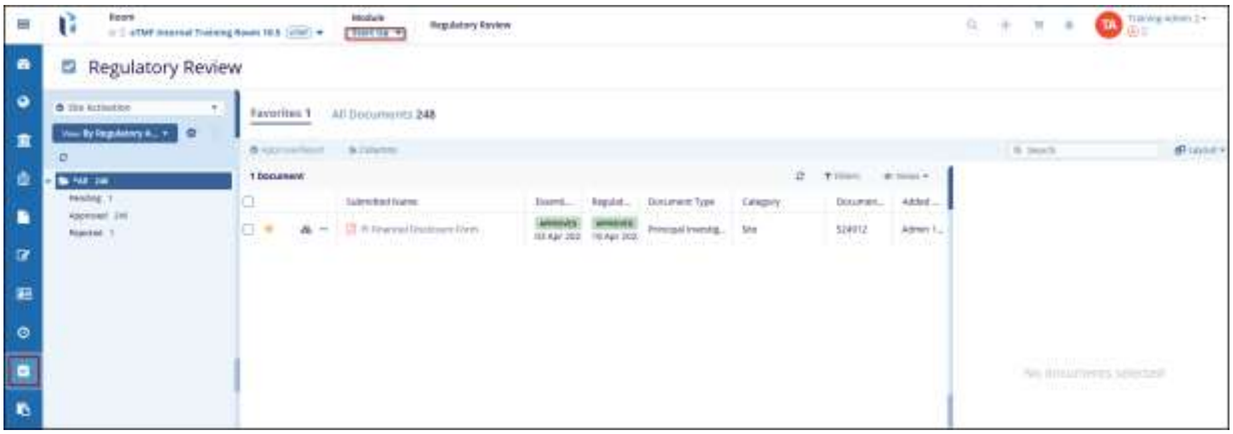
Layout

To know more detailed information about layout please refer to this link - Layout.

REGULATORY REVIEW

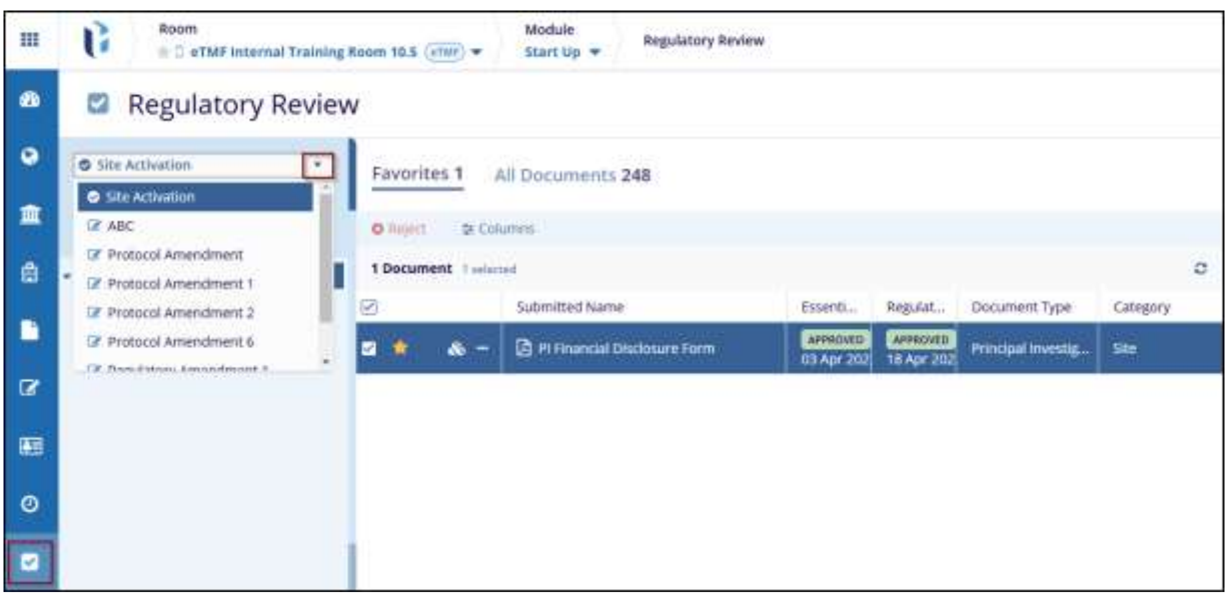
The Regulatory Review module allows users to view the review statuses of documents submitted for regulatory review, as well as review and approve the documents. The procedure for approving documents by the regulatory reviewer is discussed after a summary of the dashboard.

Click the Regulatory Review tab from the left menu bar to access the Regulatory Review dashboard. The dashboard consists of the Views panel on the left, the Grid pane in the center, and the Document Data panel on the right.



Site Activation Dropdown

A Site Activation Dropdown is a user interface element that allows users to select and apply available site activation options.



View Dropdown

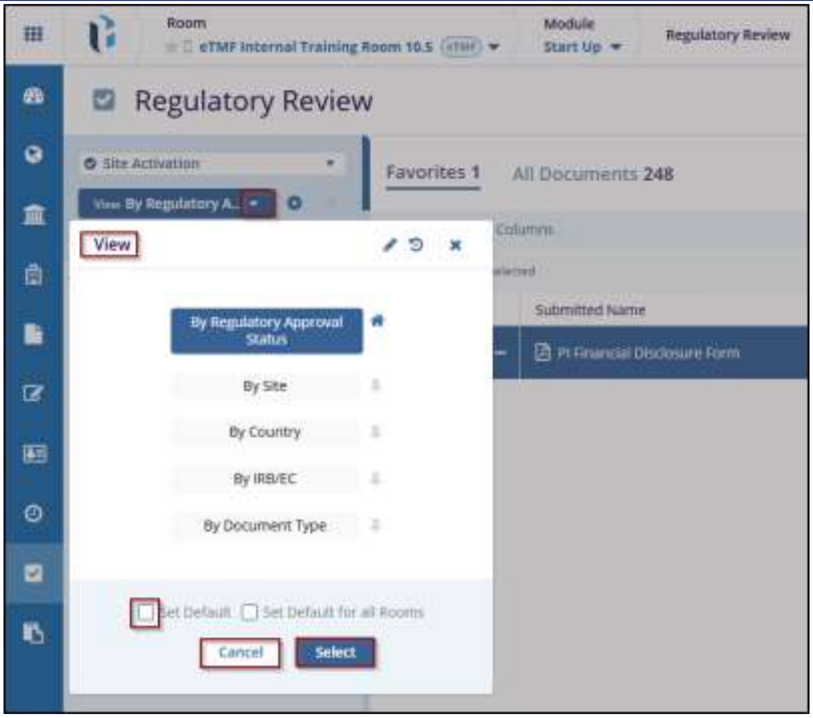
The View Dropdown allows users to select options based on requirements such as By Regulatory Approval Status, By Site, By Country, IRB/ EC, and Document Type.

The View dropdown includes 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 their 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.
- By Country: The By Country option lists 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.
- 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.

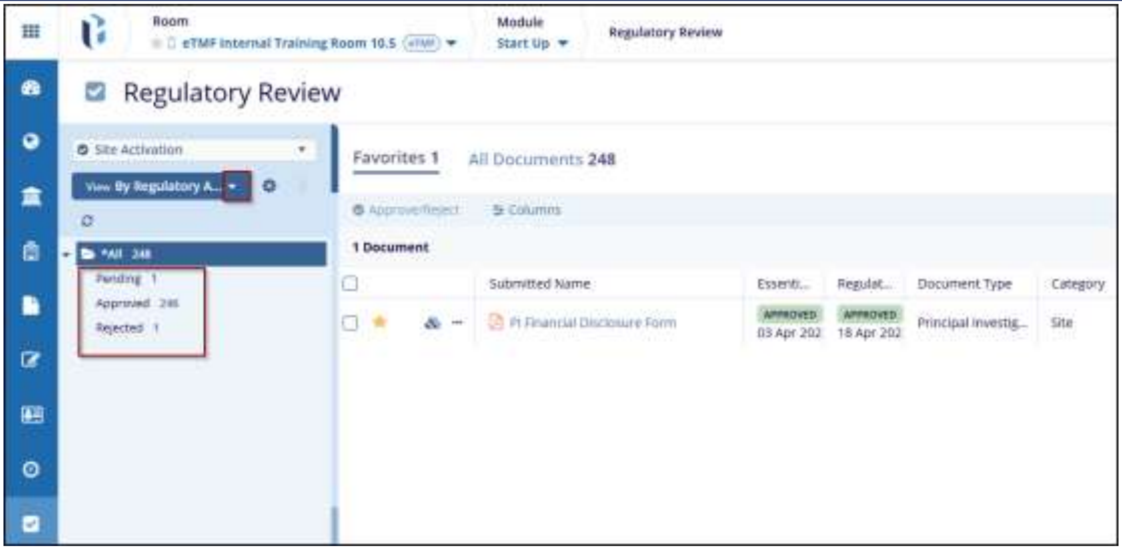
Additional filter:

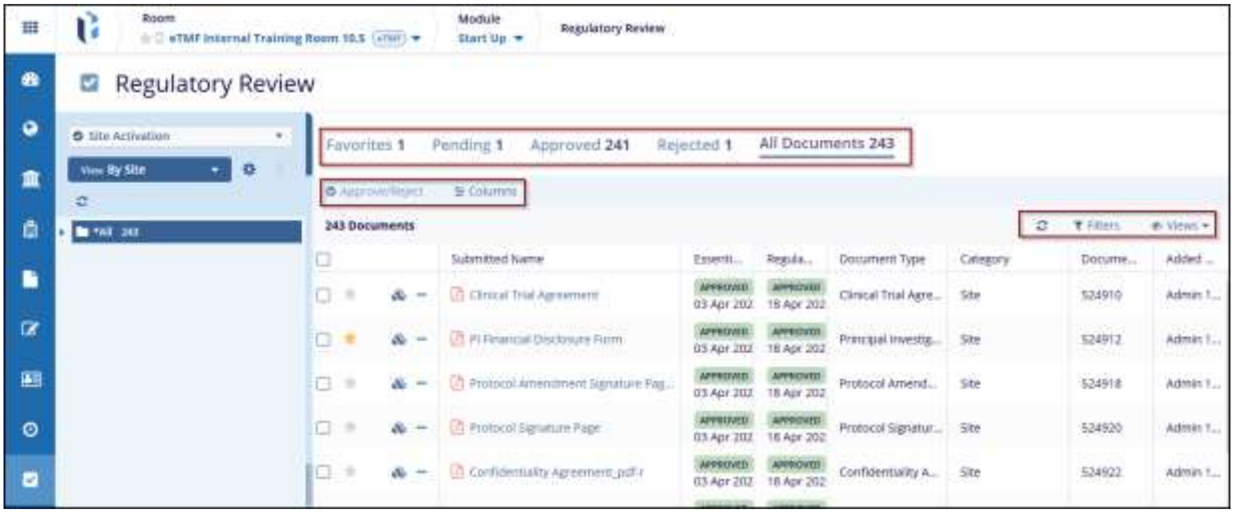
- Set Default: This will set the selected view as the default for the current session.
- Set Default for All Rooms: This will set the selected view as the default for all rooms, not just the current room.



To apply View options, follow these steps:

1. Click on the dropdown menu, View window will display.
2. Select any available options from View.
3. Select the checkbox to set the default view.
4. Click Select to apply the changes or click Cancel to discard changes and retain previous settings.
5. After clicking on Select, status options become visible, as per the selected By Regulatory Approved Status it will show Pending, Approved, and Rejected, each displaying the documents result in a grid view.
6. The Folder Dropdown display will depend on the selection of View by option and Site Activation.





Favorites: This Tab contains documents that have been marked as favorites for quick access.
Pending: This Tab holds documents that are awaiting review or approval.
Approved: This Tab contains documents that have been reviewed and officially approved.
Rejected: This Tab stores documents that have been reviewed but not approved.
All Documents: This holds all documents, regardless of their status.

Columns

To know more detailed information about columns please refer to this link - Columns.

Show Filters

To know more detailed information about filters please refer to this link - Manage Filters and Create New Filter.

Views

To know more detailed information about views please refer to this link - Popular Documents.

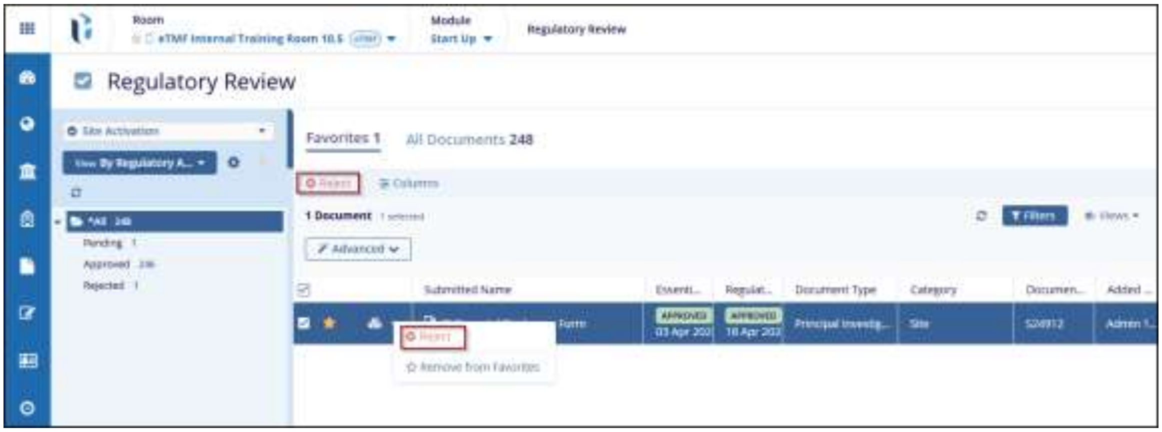
Layout

To know more detailed information about layout please refer to this link - [Layout](#).

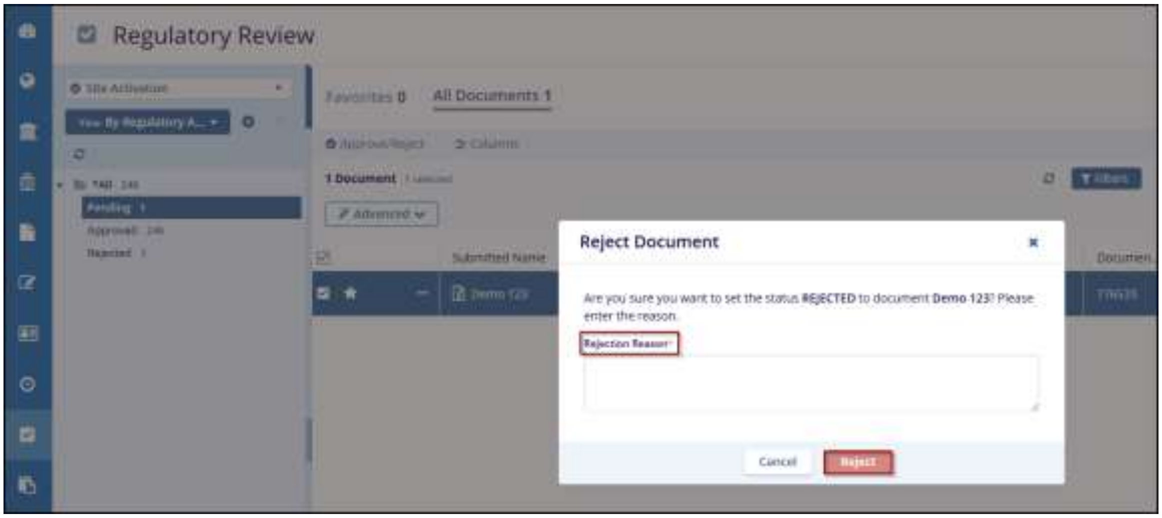
Reject

A new setting is added to support a Rejected folder within the Room for Administrators, and a new Document Rejection function is now available to Admins, Document Managers, and Room Managers. Any documents in 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.
To reject a document, follow these steps:

1. Select a document by clicking on the checkbox and the Reject Button will be available at the Top menu bar.
2. Right-click on the document or the three-dot menu in the grid and select the Reject option from the document actions menu.



3. Provide a rejection reason on the Reject Document popup and click on the Reject button.



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.
- 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.

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.

To view the Metadata Panel, follow these steps:

1. Select a document by clicking on the checkbox and the Metadata Panel on the right-hand side will open, displaying detailed information about the selected document.
2. In the Metadata Panel, review the following:
    - Submitted Name and Status.
    - Document associated with the Status.
    - Metadata This section refers to information regarding the query, such as Document Profile, and Review History. This includes data that provide additional context to the query.
    - The info section provides general details about the document, such as the Submission Date, Submitted By, Submission Type, and Version Number. It often includes the most relevant metadata related to the particular case or record.
    - Related is used to reference related documents that are connected to the main Document. This could include relationships with others and tasks that are relevant for follow-up.
    - **Version's** tab displays the File name, Created By, Full Name, and Comments of selected documents.
    - History holds the updated data of documents.

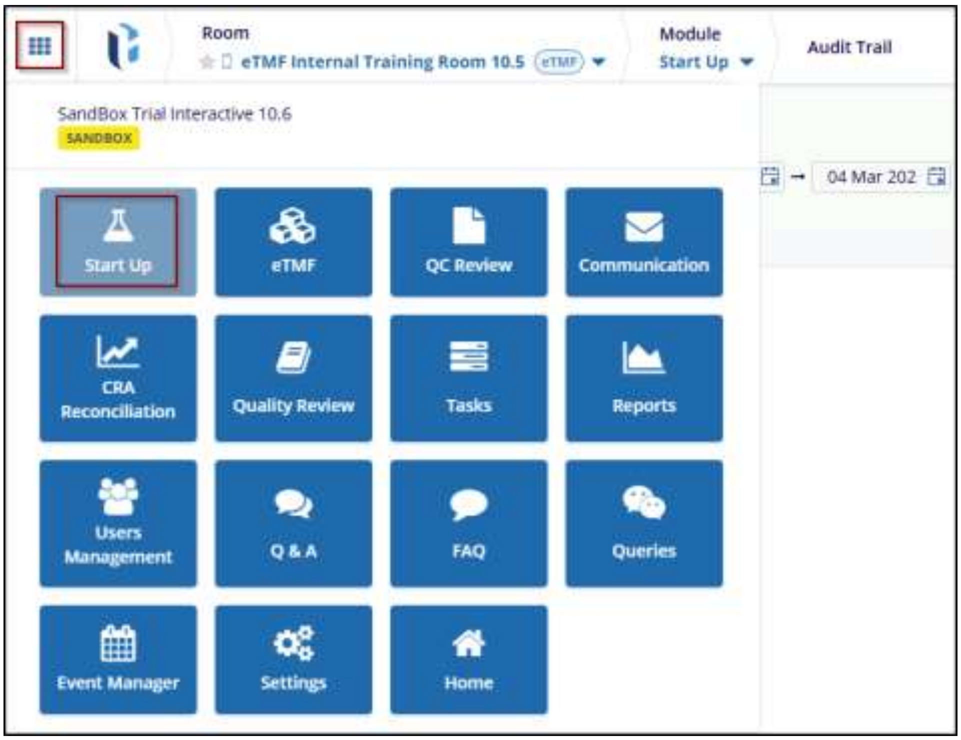
AUDIT TRAIL

The Audit Trail provides a comprehensive record of all actions performed on documents within a study room. This is designed to help users track activities for auditing and compliance purposes. Users can filter the audit trail by various criteria to efficiently retrieve specific records. The changes made in a document by all users are displayed within the Audit Trail.

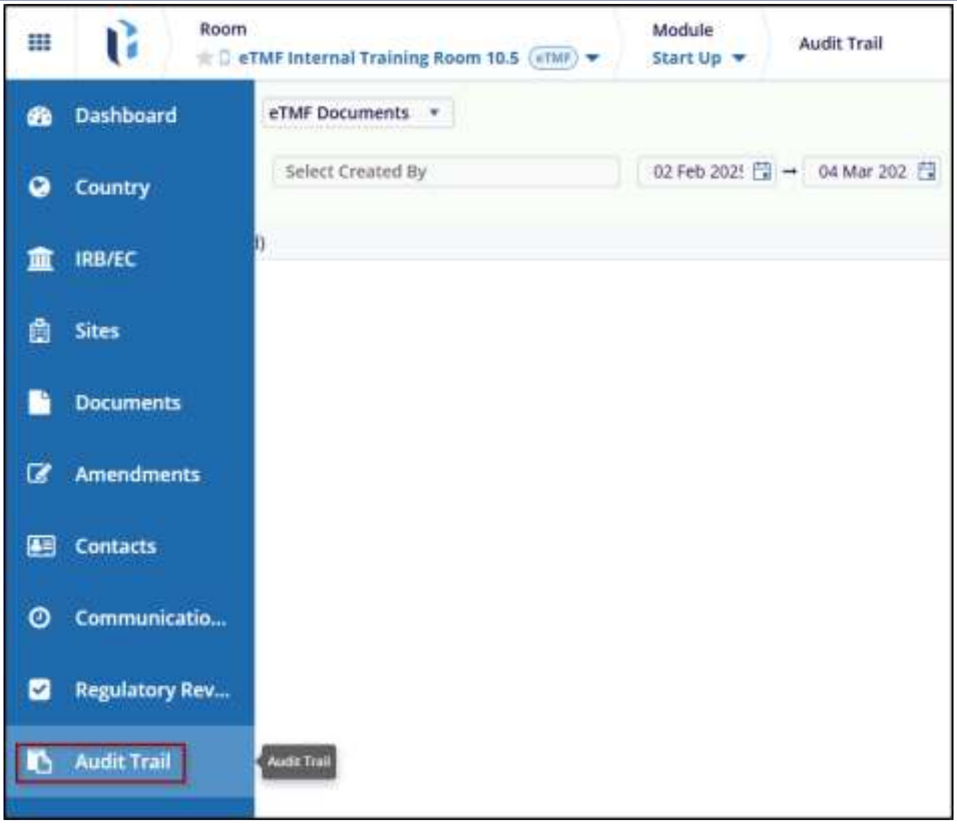
Note: By default, the audit trails grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.

To access the Audit Trail modal within the Start-Up module, follow the steps below:

1. Navigate to the Start-Up module from the navigation grid.



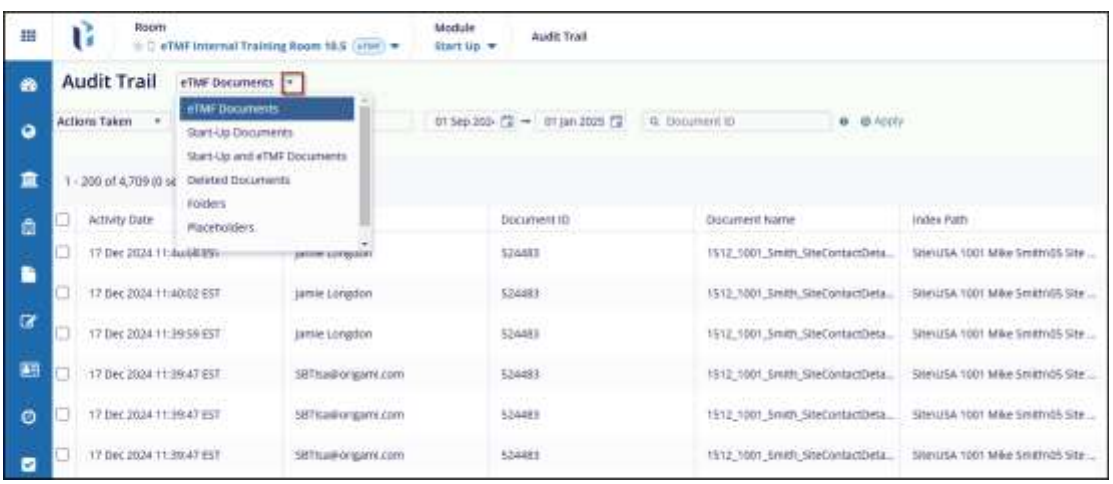
2. On the Start-Up screen, navigate to the left-hand menu and select the Audit Trail modal.
3. The Audit Trail screen displays options to apply certain filter criteria and export the audit trail details.



Audit Trail Process

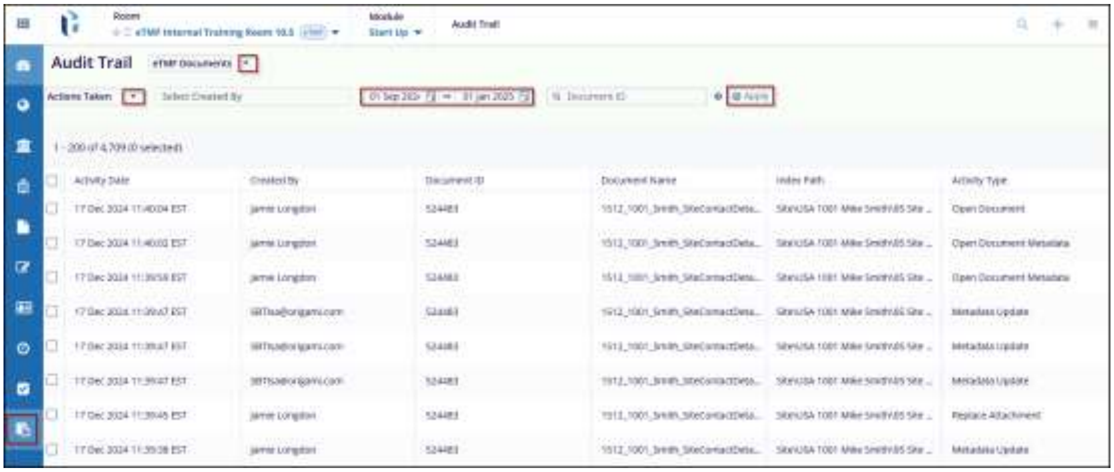
To retrieve the audit trail, follow the steps below:

1. On the Audit Trail screen, specify a parameter from the available dropdown options i.e., eTMF documents, Start-Up Documents, Start-Up and eTMF Documents, Folders, Placeholders, and Users.



2. Click on the Actions Taken dropdown and select or deselect actions by clicking on their respective checkboxes.
3. Specify one or multiple users in the Select Created By box.

4. Add the From and To dates by clicking on the calendar icon.
5. Add Document IDs separated by commas to retrieve data restricted to the specified document IDs.
6. Click on the Apply button.

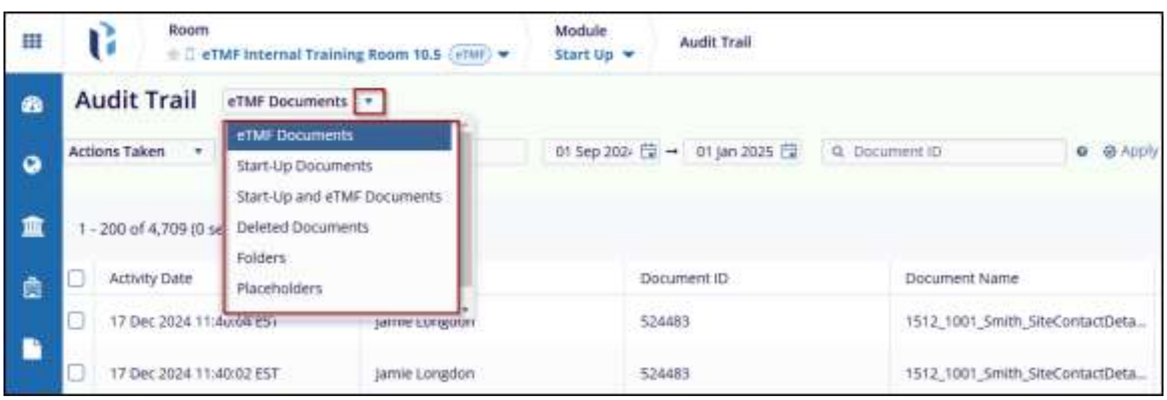


7. The Audit Trail screen displays data based on the applied filters and parameters.

Audit Trail Parameters

Users can retrieve the audit trail based on selected parameters. The options in the "Actions Taken" dropdown are displayed according to the chosen parameter.

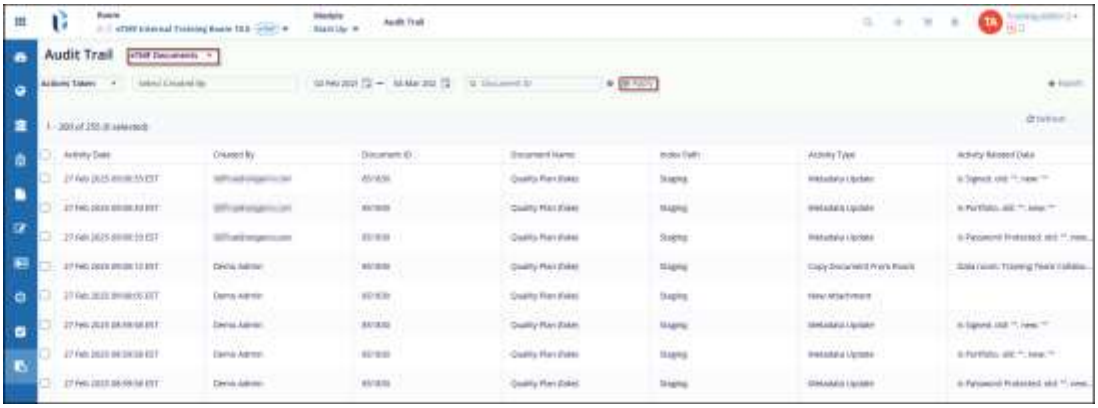
- eTMF Documents
- Start-Up Documents
- Start-Up and eTMF Documents
- Folders
- Placeholders
- Users
- Deleted Documents



1. User Interface for eTMF Documents: When the audit trail for eTMF documents is retrieved, the data is presented in the following columns.

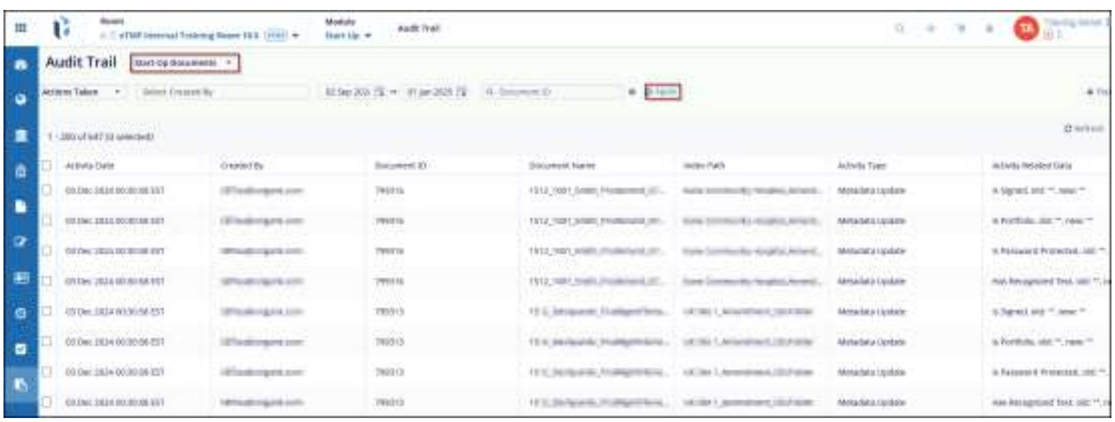
   - Activity Date
   - Created By

- Document ID
- Document Name
- Index Path
- Activity Type
- Activity Related Date.



2. User Interface for Start-up Documents: When the audit trail for Start-up Documents is retrieved, the data is presented in the following columns.

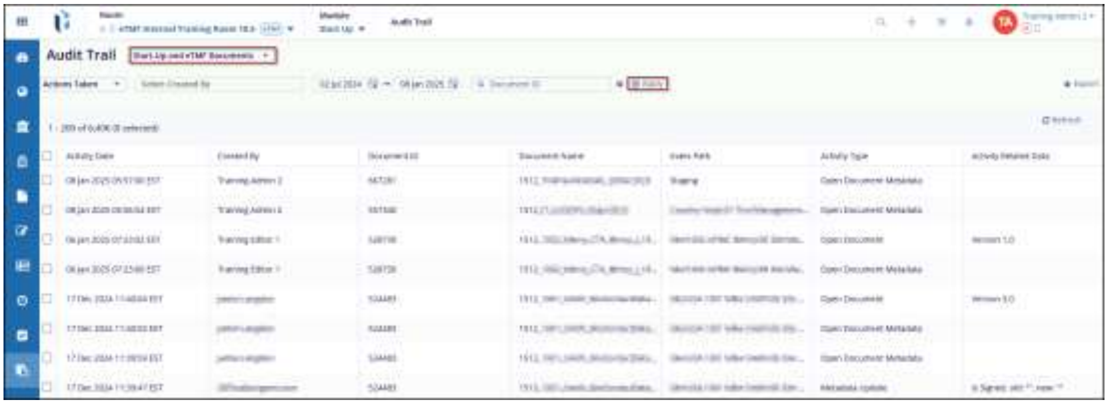
   - Activity Date
   - Created By
   - Document ID
   - Document Name
   - Index Path
   - Activity Type
   - Activity Related Date



3. User Interface for Start-Up and eTMF documents: When the audit trail for Start-Up and eTMF Documents is retrieved, the data is presented in the following columns.

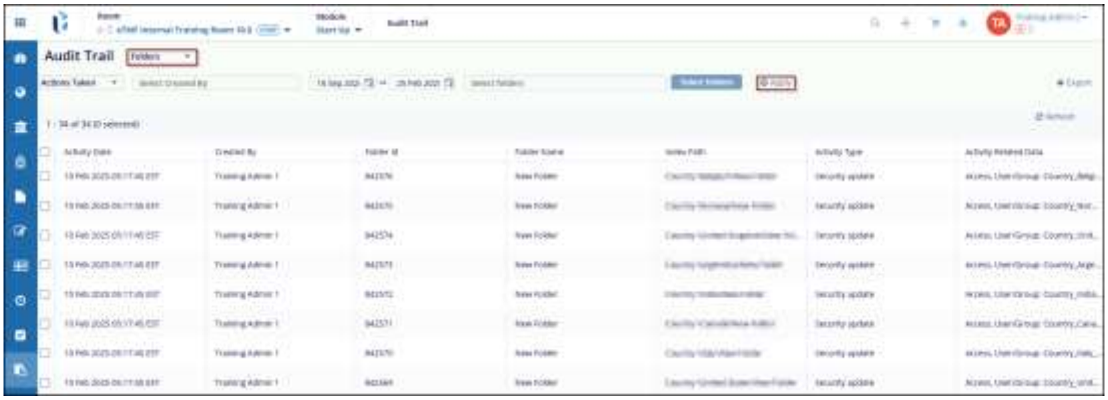
   - Activity Date
   - Created By
   - Document ID
   - Document Name

- Index Path
- Activity Type
- Activity Related Date



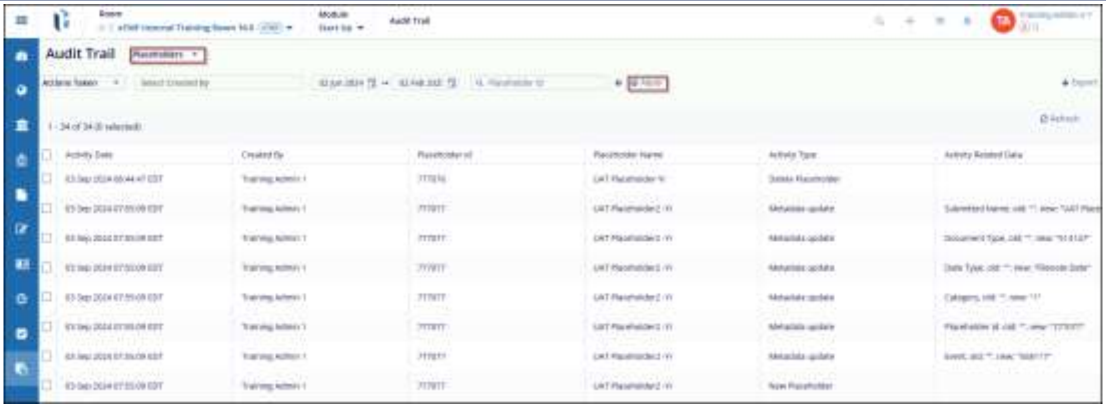
4. Folders: When the audit trail for Folders is retrieved, the data is presented in the following columns.

    - Activity Date
    - Created By
    - Folder ID
    - Folder Name
    - Index Path
    - Activity Type
    - Activity Related Date



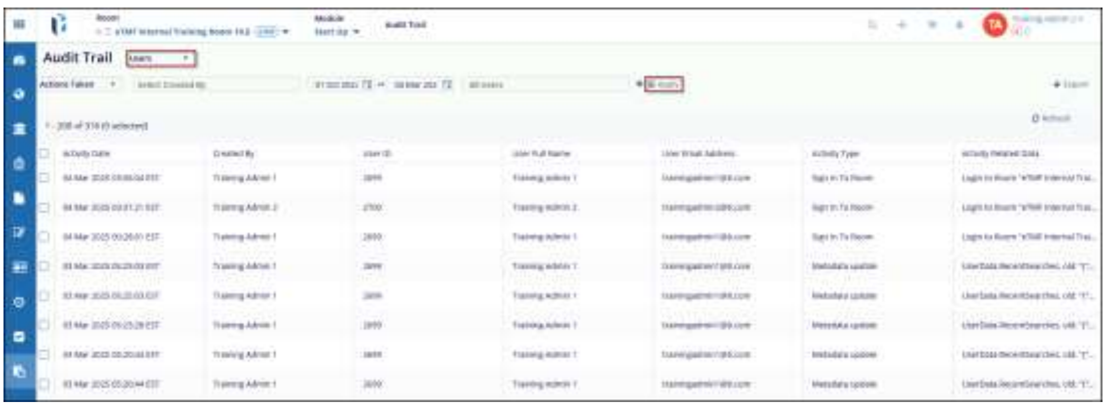
5. Placeholders: When the audit trail for Placeholders is retrieved, the data is presented in the following columns.

    - Activity Date
    - Created By
    - Placeholder ID
    - Placeholder Name
    - Index Path
    - Activity Type
    - Activity Related Date



6. Users: When the audit trail for Users is retrieved, the data is presented in the following columns.

    - Activity Date
    - Created By
    - User ID
    - User Full Name
    - User Email Address
    - Activity Type
    - Activity Related Data

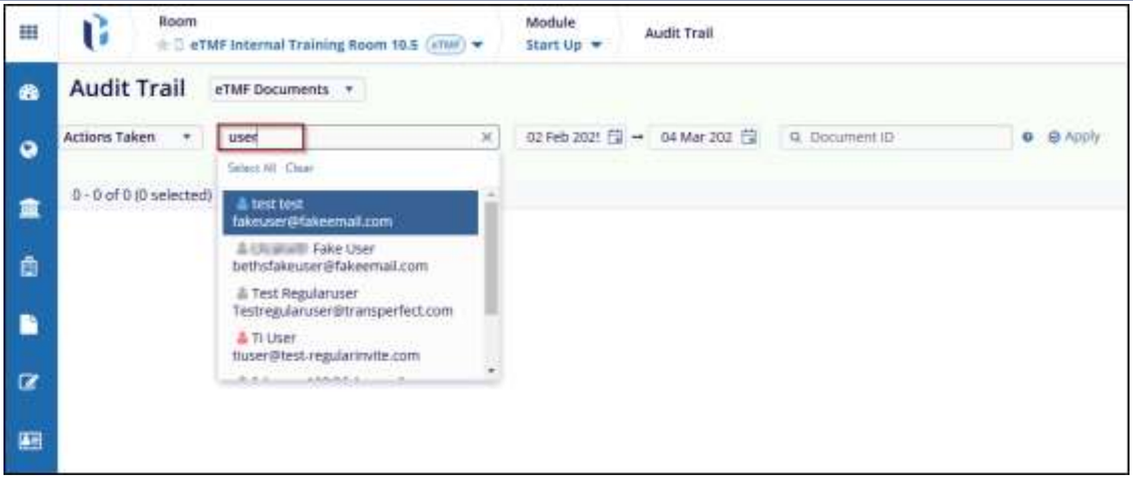


Audit Trail Filters

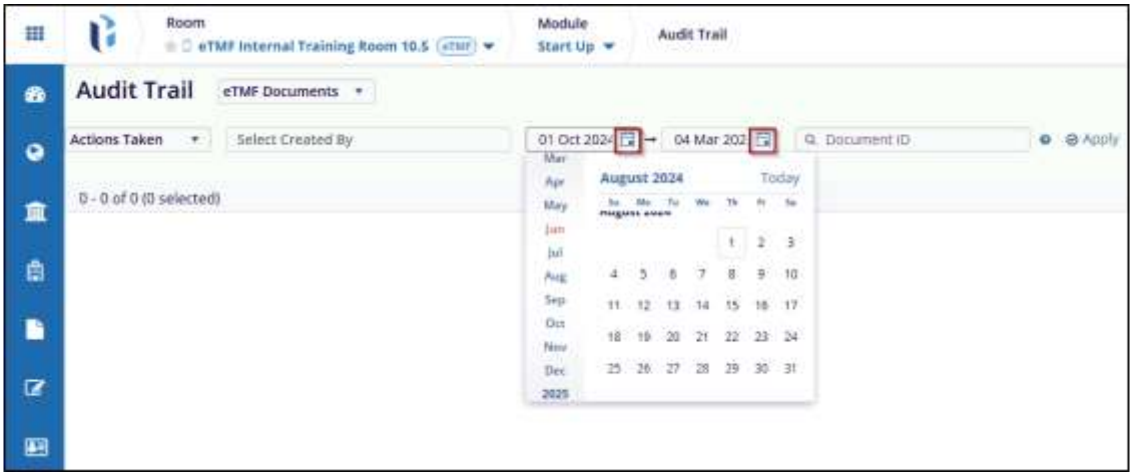
Users can apply additional filters to the selected parameter. The following filters are available in the Audit Trail modal, allowing users to retrieve specific data.

1. Actions Taken: This dropdown displays a list of actions to be selected from the dropdown menu for filtering the audit trail as per the selected parameter. The Actions Taken dropdown populates and displays actions depending on the parameter selected. Users can either select all actions or select specific actions by clicking on their respective checkboxes.

2. Select Created By: In the Select Created By field, users can specify one or more usernames associated with document creation in eTMF. When a username is selected, the Audit Trail screen filters and displays records corresponding to the specified user.

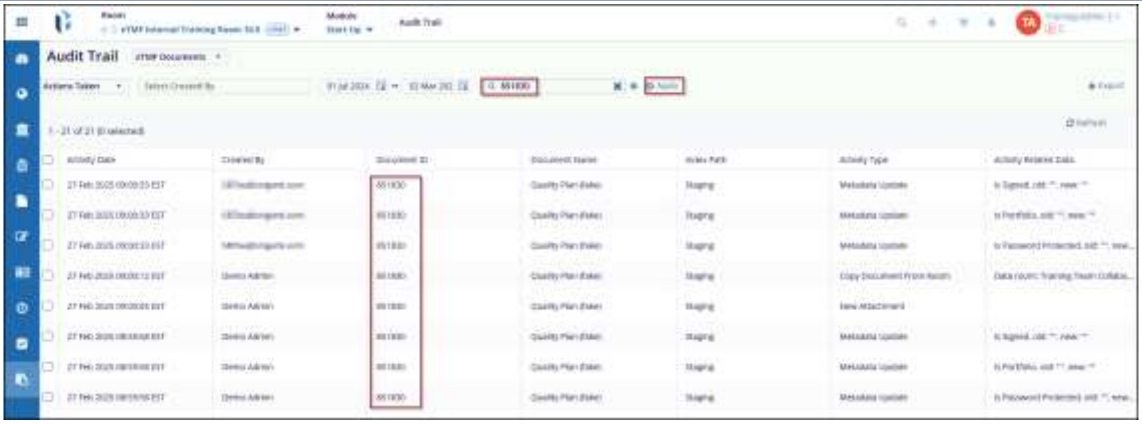


3. Date Filters: Users must enter start and end dates in their respective fields to search for a document. By default, the start date is set to the previous month, and the end date is set to today. To select dates, click on the calendar icon. Once the dates are chosen, click the Apply button on the right side to view the search results. Users can also select dates from the previous year by scrolling up in the Months field.



4. Document ID Filter: The Document ID field allows users to retrieve audit trials for a specific document by entering its ID number, separated by commas. After entering the document ID, users must click the Apply button on the right side to view the search results.

   Note: The Document ID Filter is applicable only for eTMF Documents, Start-Up Documents, and Start-Up and eTMF Documents.

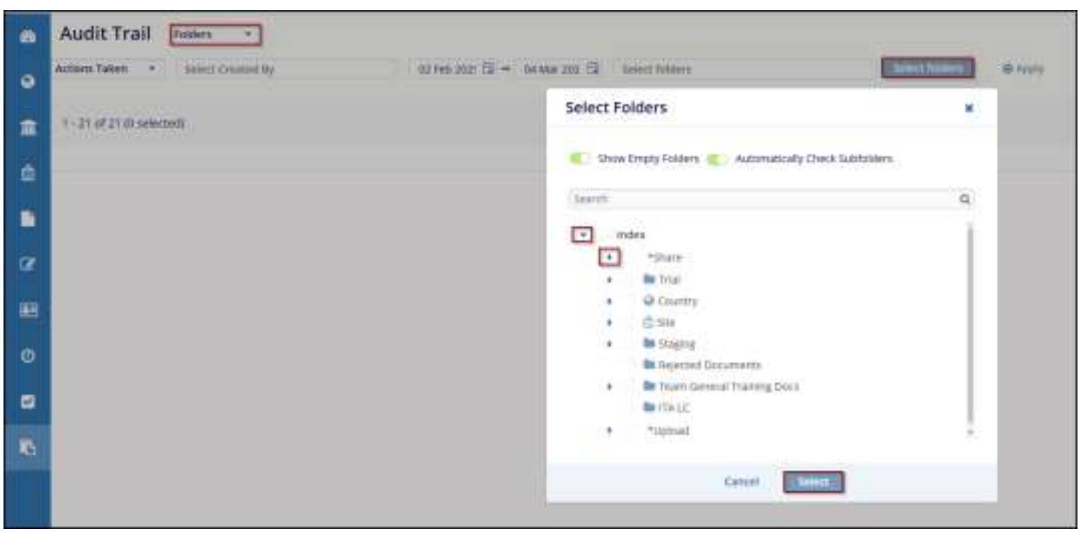


5. Select Folders: The Select Folders field allows users to specify certain folders and retrieve the audit trail for those specified folders.

   Note: The Select Folders Filter is applicable only for the Folders parameter.

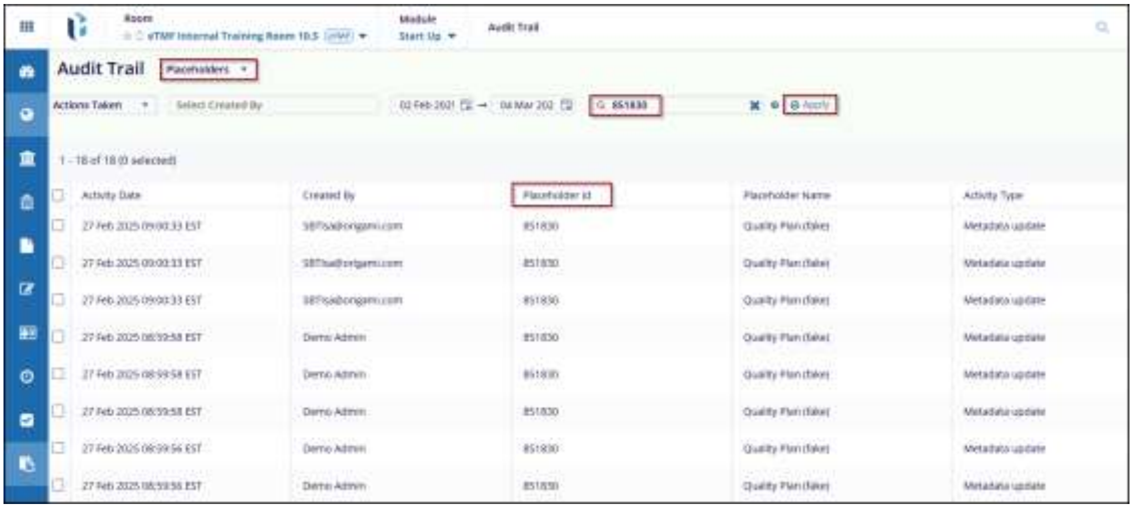
   To specify folders, follow the steps below:

   1. Select Folders as the parameter.
   2. Click on the Select Folders button.
   3. On the Select Folders screen, expand the desired category and select the folder.
   4. Toggle on the Show Empty Folders switch to display empty folders.
   5. Enable the Automatically Check Subfolders toggle switch to automatically select folders associated with the parent category.
   6. To search for a specific folder, enter the search term in the Search box.
   7. Click on the Select button.



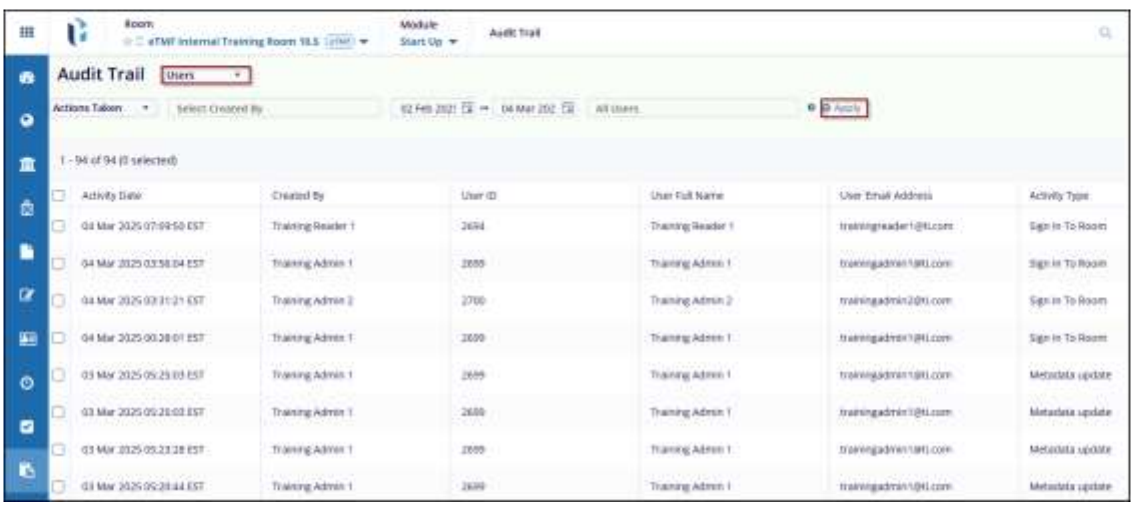
6. Placeholder ID: The Placeholder ID field allows users to retrieve audit trials for a specific placeholder by entering its ID number, separated by commas. After entering the placeholder ID, users must click the Apply button on the right side to view the search results.

Note: The Placeholder ID filter is applicable only for the Placeholder's parameter.

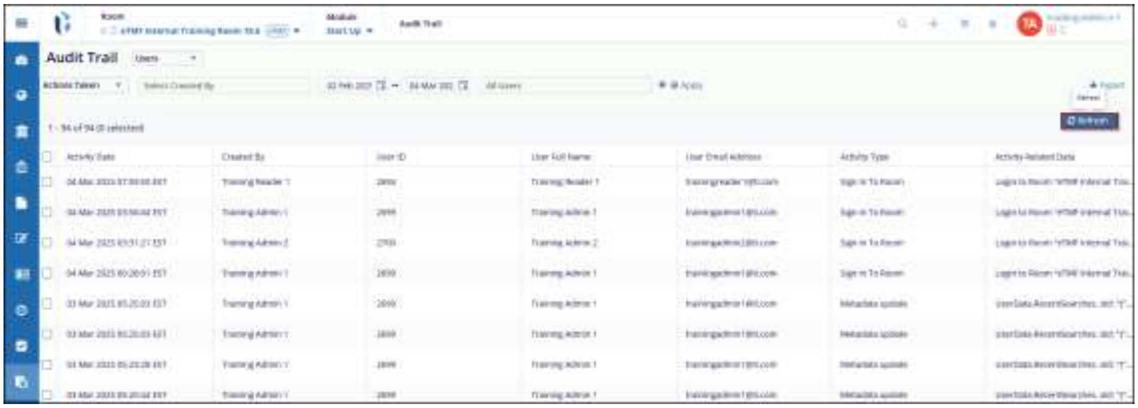


7. All Users: The All-Users field allows users to retrieve audit trails for specific users by entering multiple user names. After specifying user names, users must click the Apply button on the right side to view the search results.

   Note: The All-Users filter is applicable only for the User's parameter.



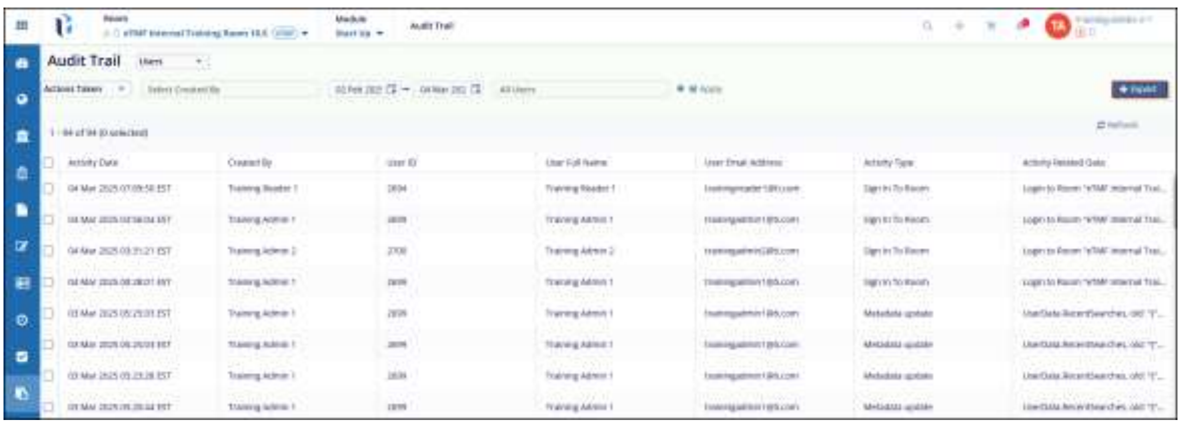
8. Refresh: The Refresh button is visible and accessible when the audit trail results are displayed. When a parameter or a filter is updated, users need to click the Refresh button to update the audit trail records as per the newly applied filters and parameters.



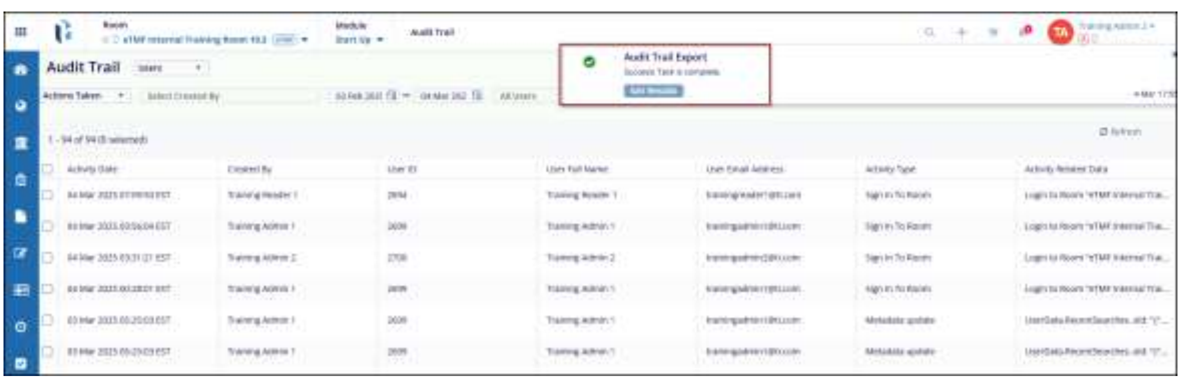
Export Audit Trail

To export the Audit Trail data, follow the steps below.

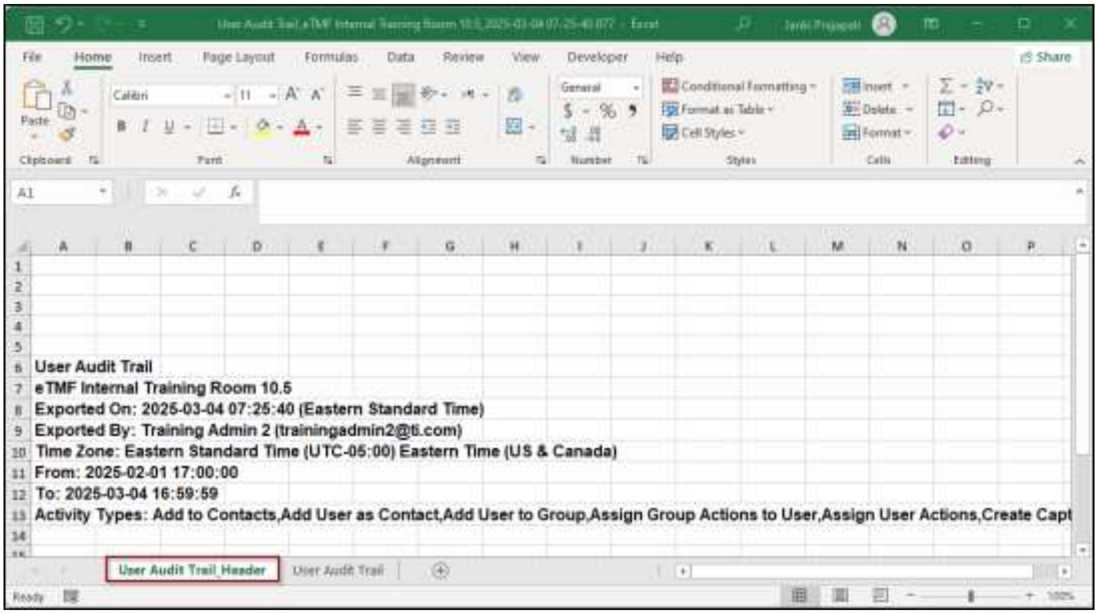
1. On the Audit Trail screen, click on the Export button.



2. On the Audit Trail Export popup displaying the success message, click on the Get Results button.



3. Download the Microsoft Excel Worksheet containing the export data into the local system.
4. On the downloaded file, click on the Document Audit Trail Header tab to view the header-related details.



5. Click the Use Audit Trail sheet to access audit trail details.