TRIAL INTERACTIVE

TRIAL INTERACTIVE COLLABORATE - USER GUIDE V1.0

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LIFE SCIENCES

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CONTENTS

VERSION HISTORY

Author	Revision	Date	Change History
Salil Joshi	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 Collaborate 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 TI COLLABORATE V10.7?

This section provides an overview of new features and improvements in Trial Interactive Collaborative Workspace v10.7.

Large Files Support in TI Rooms

As usage of Collaborate has increased, users now require the ability to store and access larger files, including Word documents, ZIP files, and SAS datasets, with sizes up to 20GB for archival purposes.

TI rooms now allow storage of files up to 20GB; however, files must be uploaded to the room using WinSCP, SFTP, or similar methods. Typically, the large files involved will be ZIP and SAS files. Any file larger than 2GB will automatically download to the client desktop instead of opening in the browser. Additionally, any movie files (AVI, MP4, MOV) will continue to play directly using the original viewer.

COLLABORATE OVERVIEW

The Collaborate module is a central hub for collaborative authoring, approvals, and e-signatures.

Trial Interactive provides an online collaborative workspace, which enables collaborative and controlled document authoring, review, and approval. Designed to include 21 CFR Part 11 compliant workflows and approvals, the solution offers an end-to-end service platform for your organization's content management and document control requirements. The TI Collaborate rooms allow users to benefit from the following solutions:

- Study Collaborate and the CTMS Collaboration Rooms are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and ultimately shared with the eTMF.
- Site Collaborate/eISF and Remote Monitoring Rooms are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and ultimately send it to the eTMF.
- The Quality Document Management solution provides controlled document workflows to an organization for use by clinicians, quality assurance, R&D, and other life sciences teams to collaboratively author, review, approve, sign off on, make effective, train, and distribute regulated content and documents.

TI Collaborate can provide your organization with:

- A single place to share and collaborate on clinical documentation.
- The ability to align document work streams with regulatory compliance practices for document authoring, approval, control, and related training.
- The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation and to fully automate the training management process through the LMS.
- The ability to co-author and collaborate with other authors in real time on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.
- The ability to complete the end-to-end document process with an electronic and digital signature for document approvals.
- The ability to send documents for certified translation through TransPerfect TransPort, track their status, and receive back the translated copies and certificates.
- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.
- The ability to follow critical processes for metadata, approval, and signoffs by publishing or sharing directly with the TMF.

Solutions within the Room Type

Trial Interactive QDMS

The Trial Interactive QDMS leverages the TI Content Management functionality in-built Document Type management and configurable folder structure to provide a Quality Document Management System solution for controlled QMS documentation.

Trial Interactive eISF

Trial Interactive's eISF solution reduces administration and improves speed and compliance for site personnel, CRAs, and study teams. Digital investigative site binder processes maintain certified copies of source file documentation and essential documents required for each clinical study. A seamless, connected eTMF allows for automatic indexing of essential documents to the TMF. The ability to conduct remote site monitoring, when needed, recommended by the FDA and EMA, helps CRAs work more efficiently in today's increasingly virtual environment while reducing travel expenses.

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

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

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

There are two types of rooms associated with Collaborative Workspace.

1. TI Docs
2. TI Collaborate

TI Docs and TI Collaborate both can edit the documents online. TI Collaborate acts as a Content management tool that is linked to the TMF. TI Collaborate asks, 'Is this a TMF document?' while publishing the documents. With TI Collaborate, the users can also publish the documents to any other room that is not associated with Collaborative Workspace.

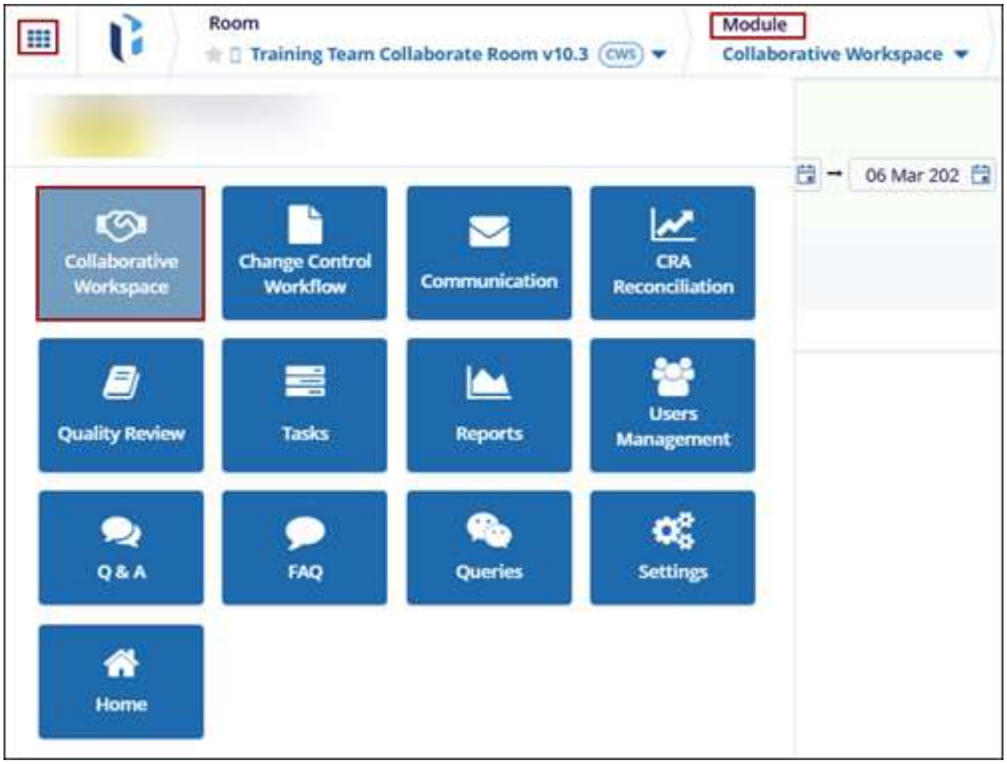
While TI Docs doesn't have any link to TMF, nor can it publish the same to any other room. However, the documents can be copied to other rooms.

Important: To enable the Collaborative Workspace room, contact the Service Desk.

To access the Collaborative Workspace module in Trial Interactive, follow the steps below.

1. Login to Trail Interactive with the appropriate Username and Password.
2. Select the TI Collaborate room from the list of assigned rooms on the TI landing page.

3. The Collaborative Workspace option can also be accessed from the Waffle menu and the Modules dropdown.



COLLABORATE ROOM SETTINGS

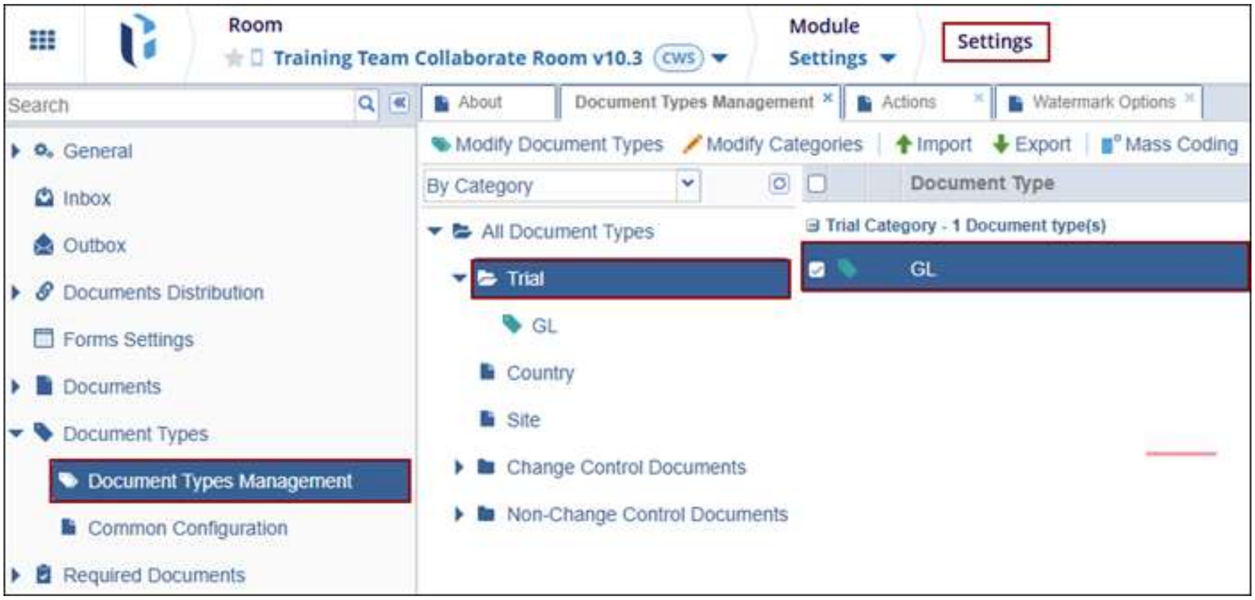
This section describes the Room Settings that impact the collaborative room types.

Document Types and Change Control Workflow

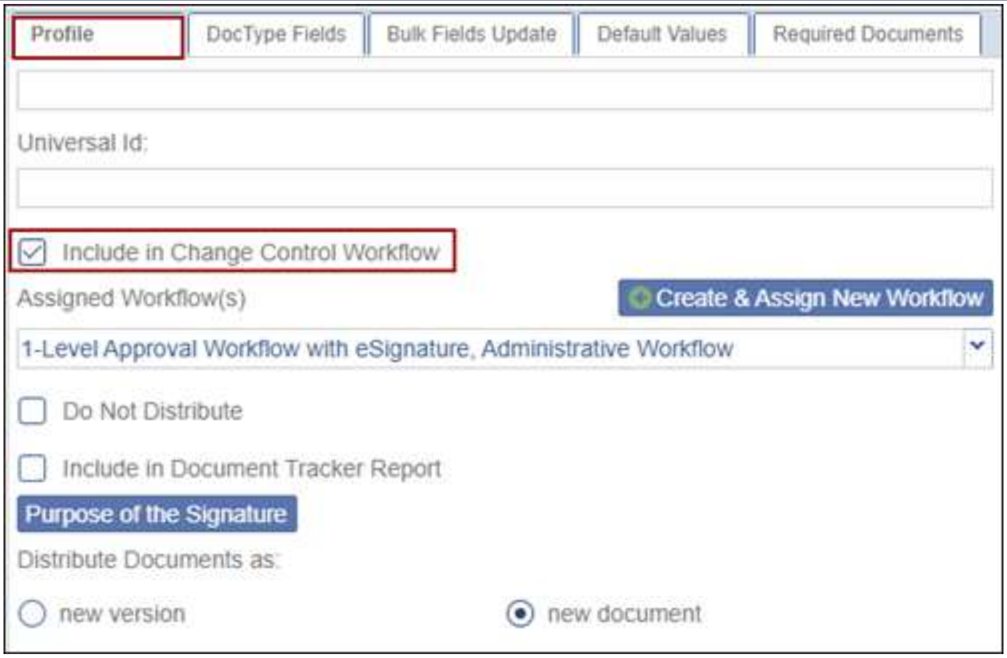
In the Room Settings, document types requiring a Change Control workflow can be defined. As a result, when users upload documents, they can select a 'Workflow' document type either manually or by uploading to a folder designated for Workflow documents. The uploaded document will then be automatically set to require a Change Control workflow for versioning.

To configure the document types and change the control workflow, follow the steps below.

1. Navigate to the Settings > Document Types > Document Types Management section.
2. Expand the required document type category and select the required document type.



3. Click on the Profile tab and check the Include in Change Control Workflow checkbox.
4. Click on the Assigned Workflows dropdown and select the Change Control or Administrative workflows.
5. Click on the Save button.



Note: If the approval workflows are predefined and the user initiates one, the approval workflow window opens directly without displaying the workflow selection wizard.

Workflow Settings

In Workflow Settings, Admins configure key details such as workflow statuses, potential issues, timelines, and workflow group members. The workflow setup is outlined in the room's configuration manual and established during room creation. To ensure accuracy and consistency, it is strongly recommended that the Trial Interactive Service Desk handle any changes to the room's workflow settings.

Admins can configure the following within the workflow settings.

Common Settings

Admin can adjust the following in the Common Settings section:

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

Default Ranges Configuration

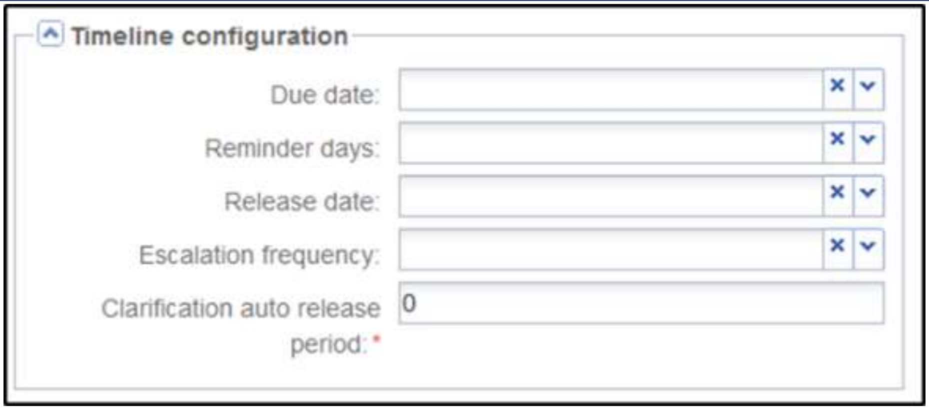
In this section, users can specify date ranges that would apply to the workflow. TI recognizes that different workflows may have varying review and submission periods. To accommodate this, it allows users to specify multiple values, separated by semicolons. These values will populate the corresponding dropdown menu during workflow creation, allowing users to select the most suitable option.

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

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

Timeline Configuration

If the user specifies values in the timeline, they will be automatically applied during workflow creation.



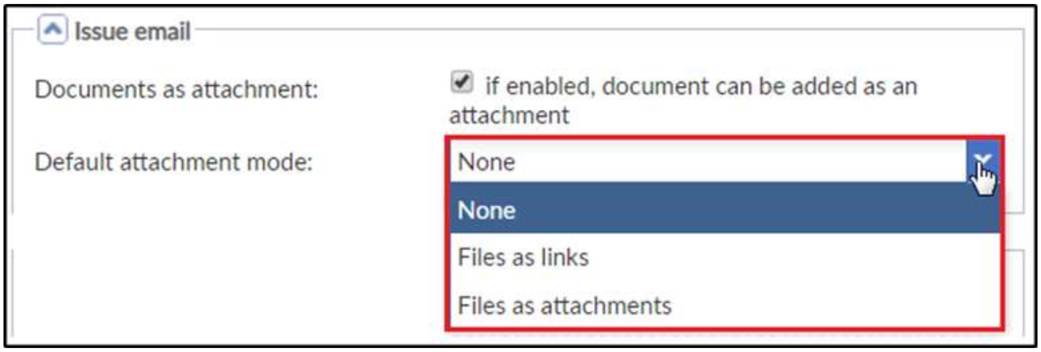
- If the user specifies values in the timeline, the values will be automatically set for the user at the time of workflow creation.
- If the user changes their mind during creation, the user can select values as needed, overriding those set in the timeline configuration.
- The configurations are optional here except for the Clarification auto-release, which means a document that is pending for clarification will be automatically released if it was not released back to the workflow by the reviewer within the defined time.
- Users can delete timeline values from a Workflow profile as well as for existing workflows by clicking the cross icon next to the fields in the Timeline Configuration panel or from the Timeline tab in a Workflow Profile Editor.

Issue Email

From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session.

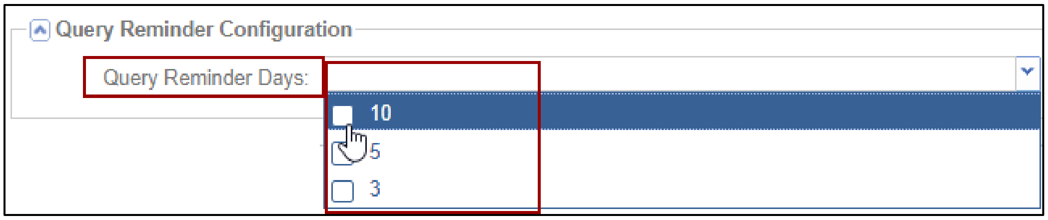
To configure the Issue Email settings, follow the steps below.

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



Query Reminder Configuration

In the Query Reminder Configuration section, room Administrators can configure a schedule by which reminder emails will be sent.

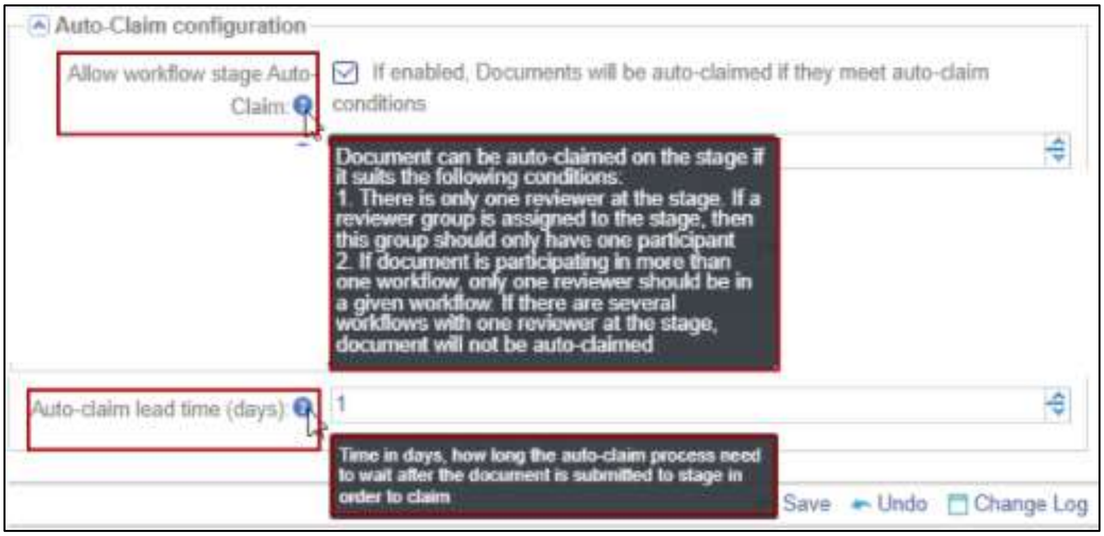


Auto Claim Configuration

Administrators will need to enable the configuration from this panel to enable the auto-claiming of the document.

To configure Auto Claim Configuration, follow the steps below.

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



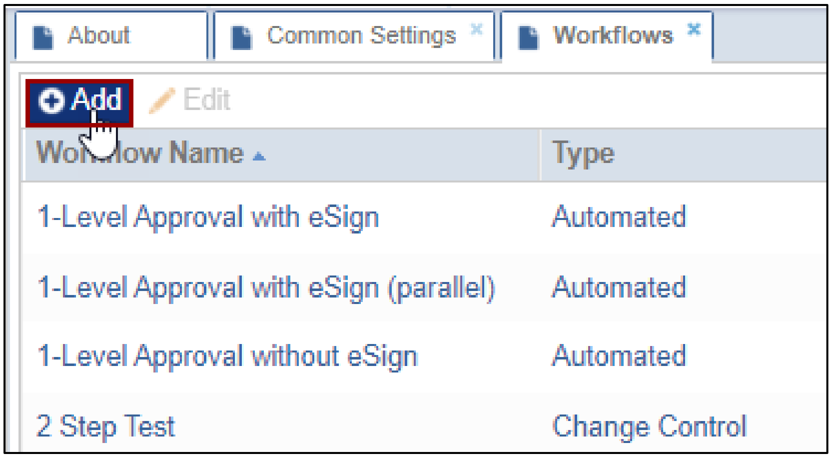
Note: If there is only one reviewer in a workflow the documents will be auto-claimed by the system and assigned to the lone reviewer for review.

Workflows

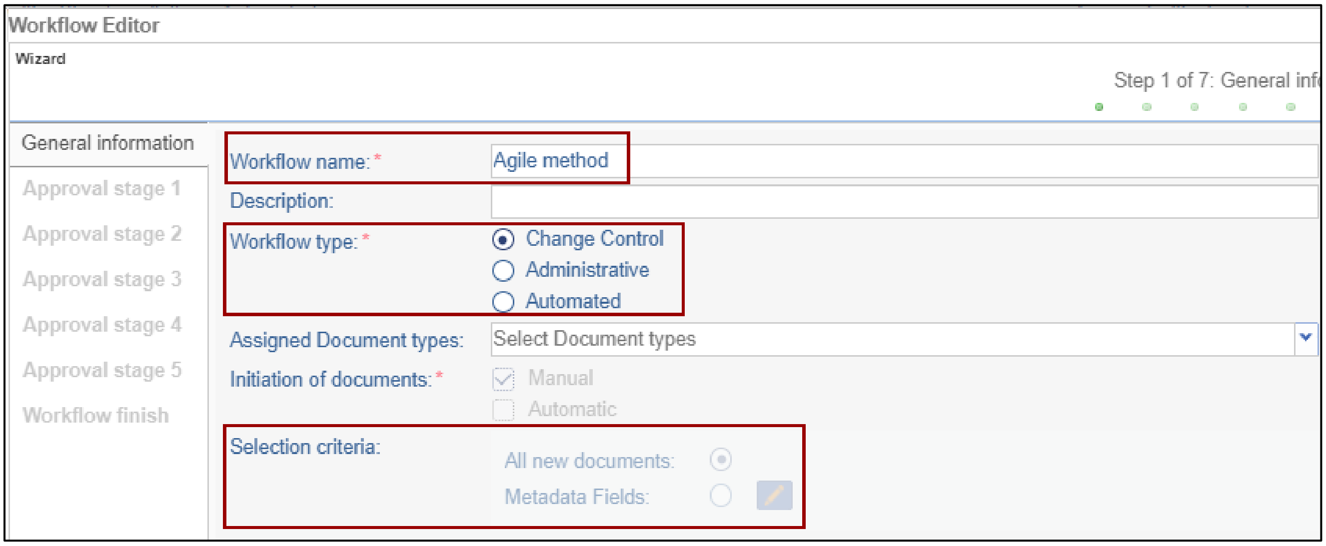
There are 2 types of Workflows 1-step Workflow and 2-step Workflow.

To create a Workflow, follow the steps below:

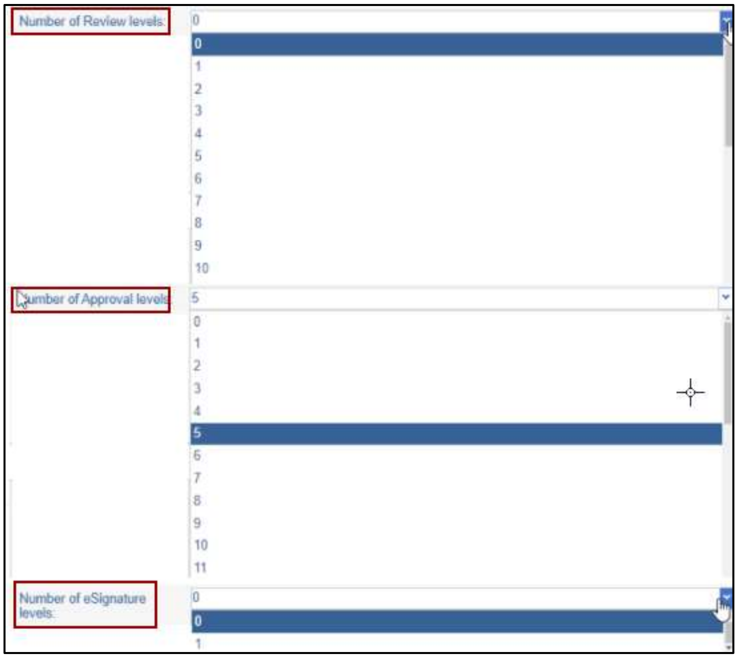
1. Click the Add button from the grid. The Workflow Editor window will open.



2. Enter the Workflow name, select the Workflow type, and Initiation of documents.
3. Add the Selection Criteria as either 'All new documents' or 'Metadata fields' that need to be reviewed.

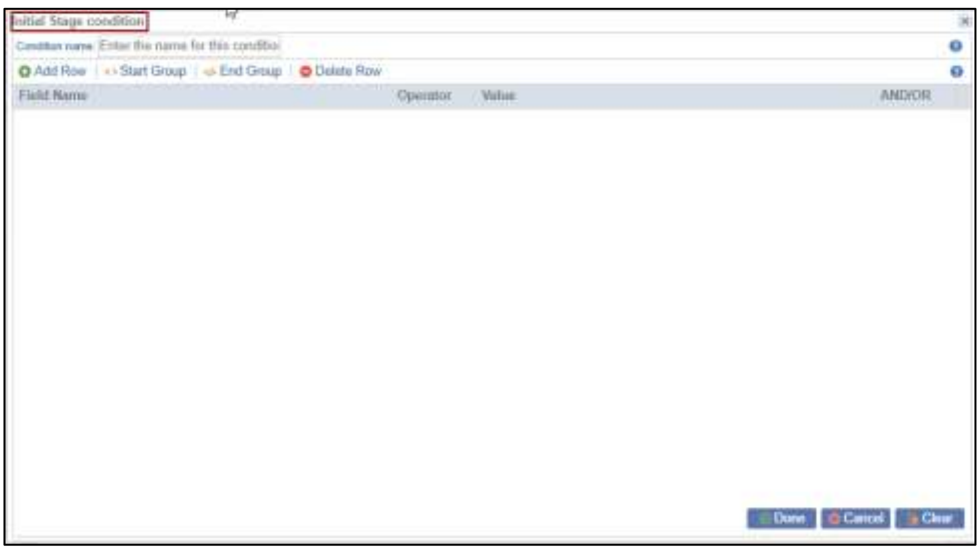


4. Select the number of Review Levels, Approval Levels, and eSignature levels.



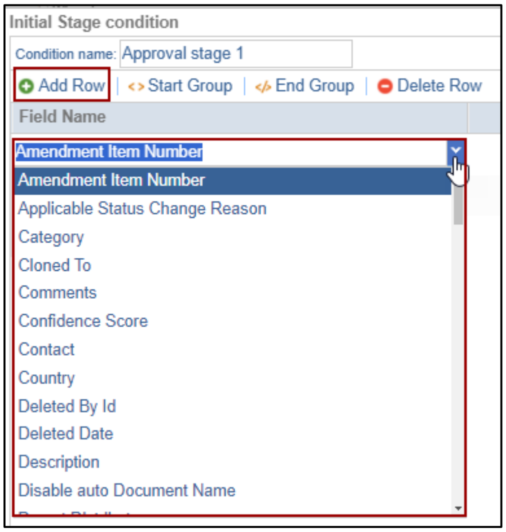
5. Click on the +Add button on the Initial Stage section.

6. The Initial Stage condition pop-up window is displayed. The user can apply a condition to select documents for review as per a particular condition.



7. Enter the Condition name in the blank field.

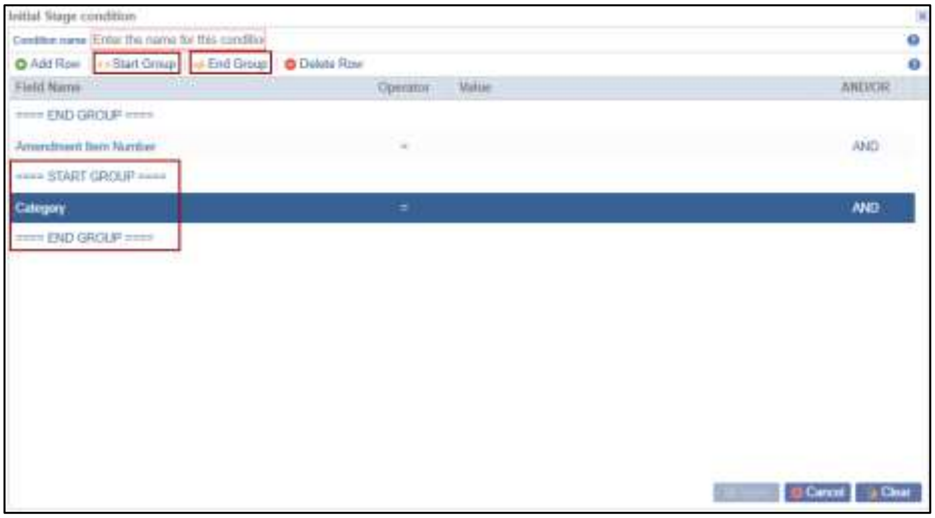
8. Add multiple conditions by clicking the Add button the field gets added below the Field Name.



9. To decide their sequence filter documents with the green arrow keys. Use And / Or operators to have all / either of the conditions to execute.

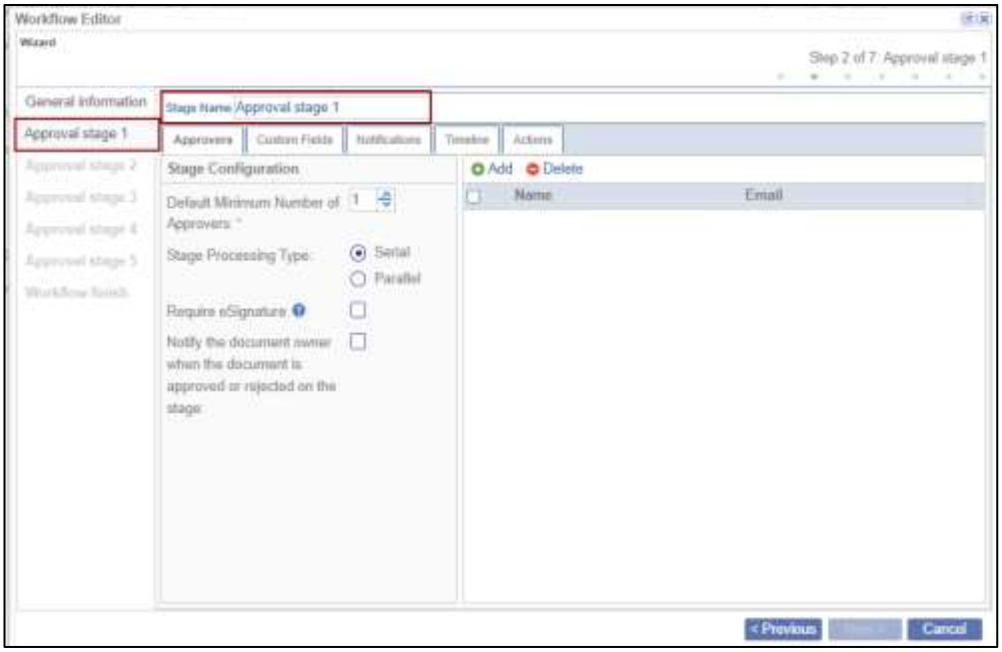
10. Documents uploaded by the site contact on a particular site visit date would be added to the workflow. The details of each condition are as below:

11. Click Start Group button to start the group by adding the category. Clicking on the End Group button the started group gets over.



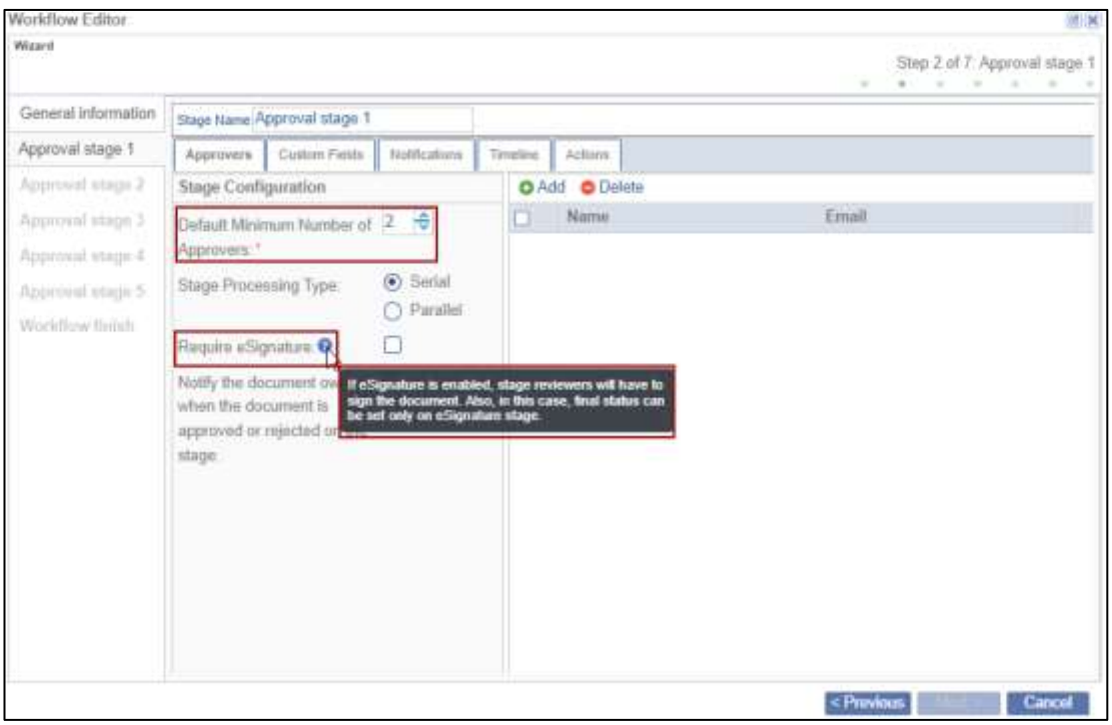
12. To delete an added row, select the row and click Delete Row button.
13. Click on the Apply button to apply the condition.

14. Click on the Next button. This opens the configuration wizard of the first stage of the workflow.

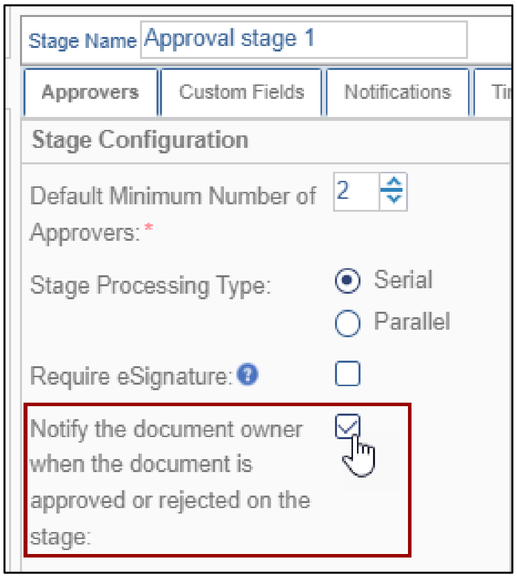


Approvers Tab:

1. Change the Stage Name, if desired. Click the Approvers tab. Refer to the screenshot above.
2. Increase or decrease the number of approvers as per the requirement and set the stage processing type as Serial or Parallel.
3. Check the 'Require eSignature' check box to route the document for eSignature.

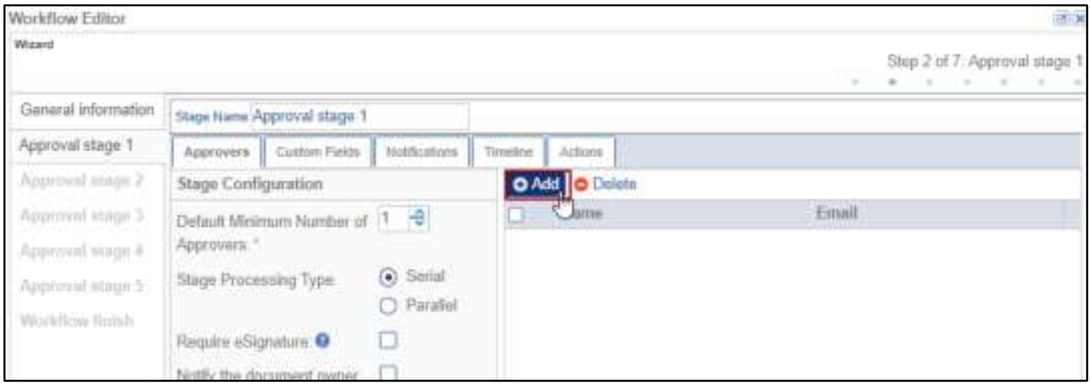


4. Check the 'Notify the document owner when the document is approved or rejected on the stage' checkbox to notify the owner about the document status whether 'Approved' or 'Rejected'

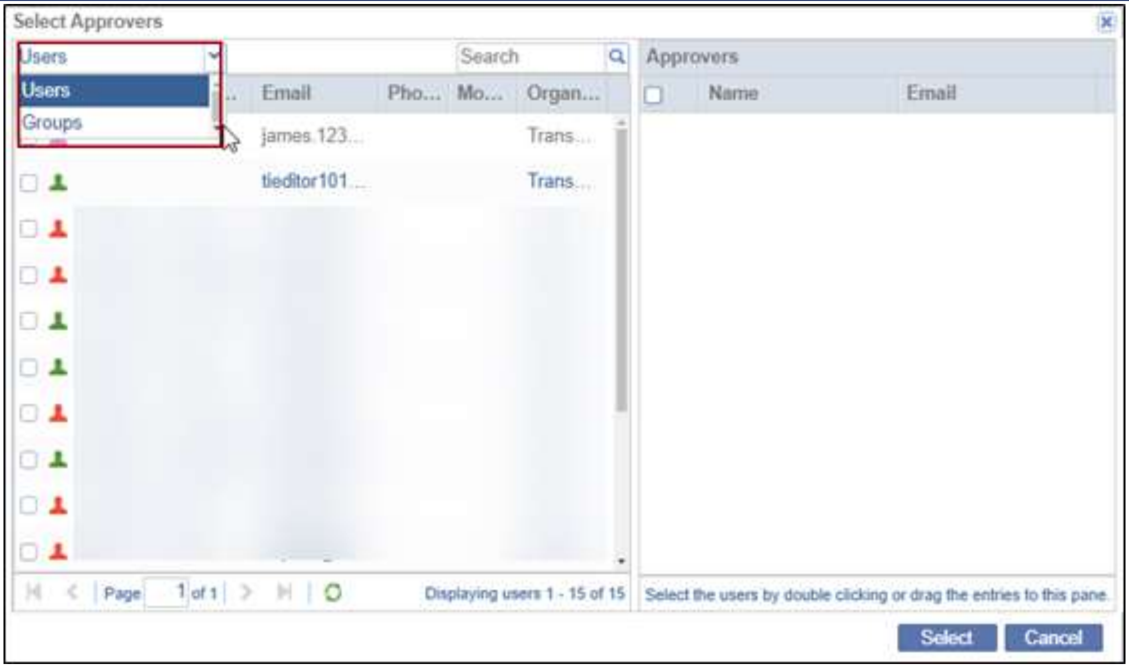


5. This allows the user to add users/groups as reviewers of the documents for a particular stage in the workflow.

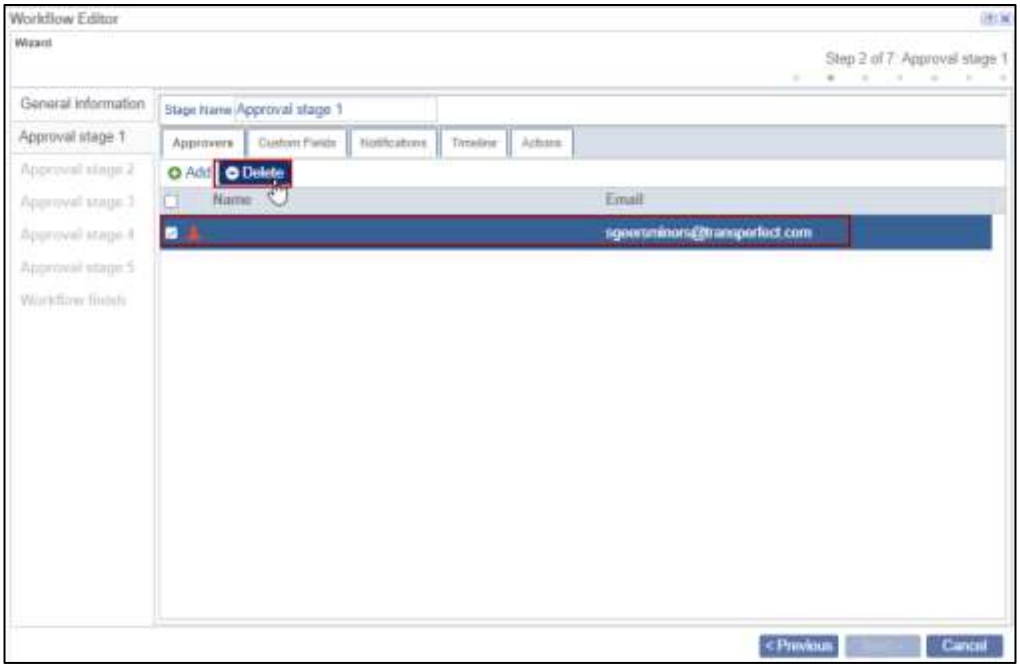
   Note: It is recommended to add a Group to save configuration time.



6. Select the user/group from the list. The selected user/group moves to the Approvers tab on the right side.
7. Click on the Select button.

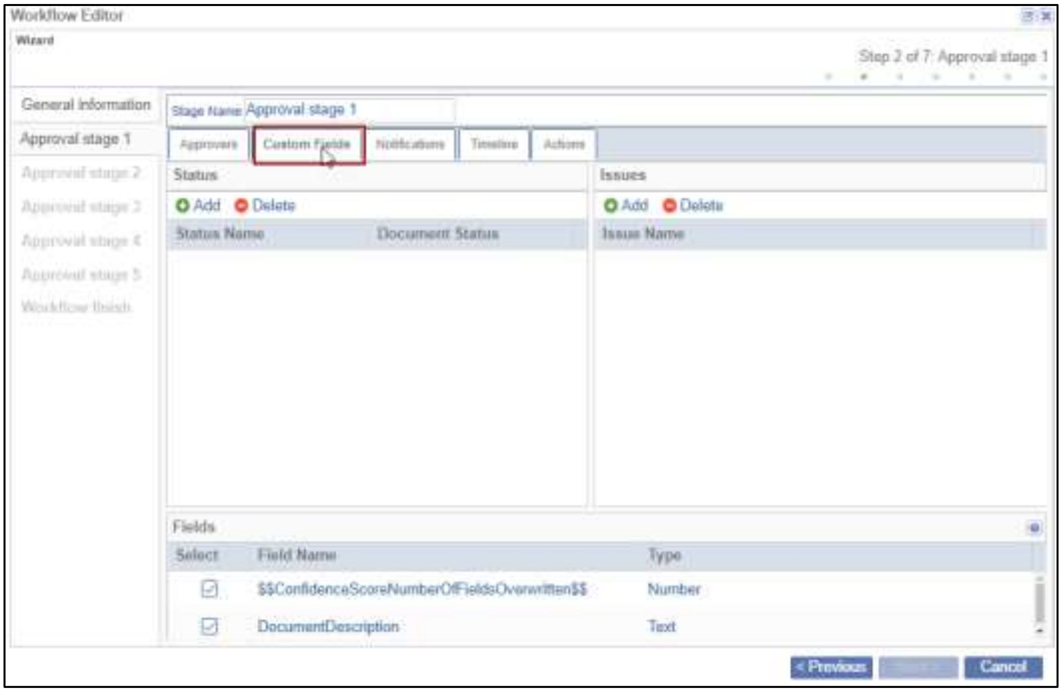


8. Click the Delete button to delete the selected users/groups.



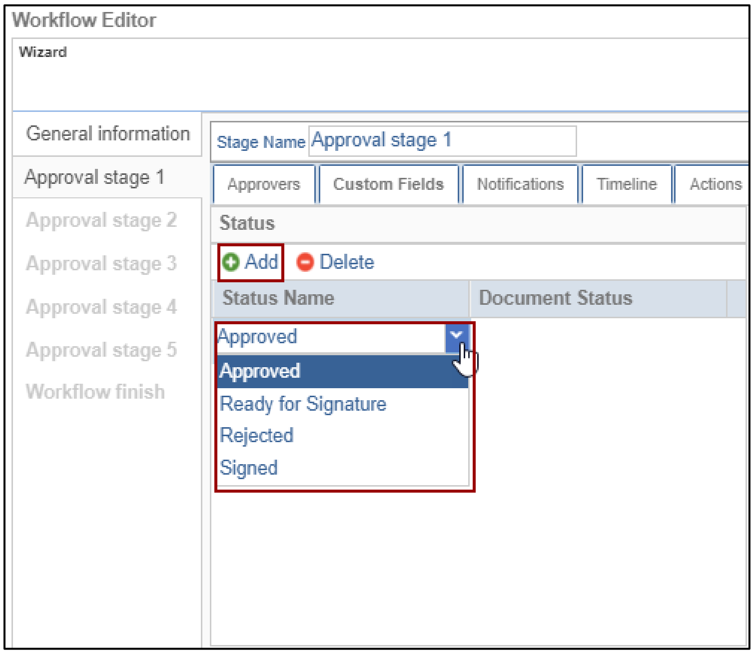
Custom Fields Tab:

1. Click the Custom Fields tab that displays the Status and Issues panels.

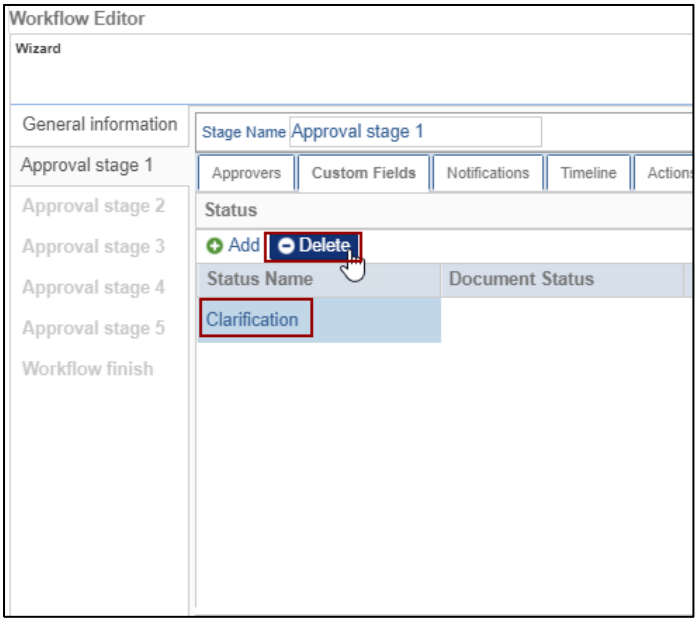


2. Click Add below the 'Status' section. The empty field gets added below the 'Status Name' with the following status:

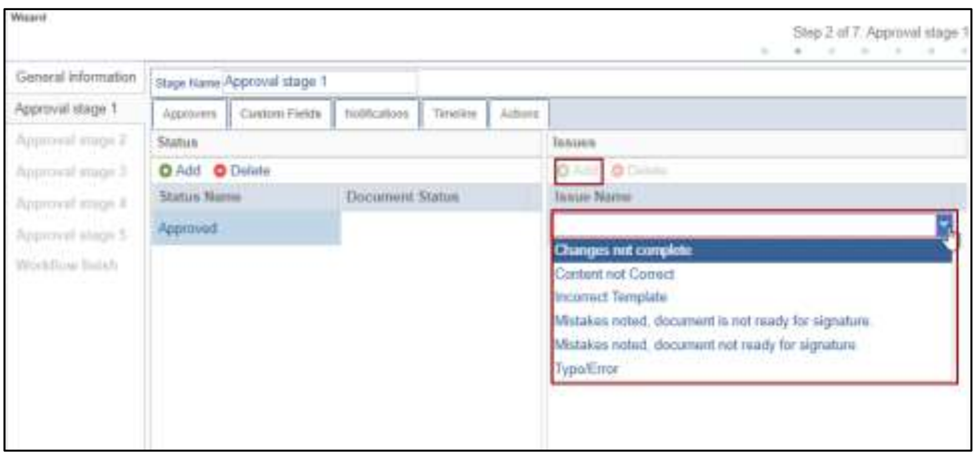
   - Approved
   - Ready for Signature
   - Rejected
   - Signed



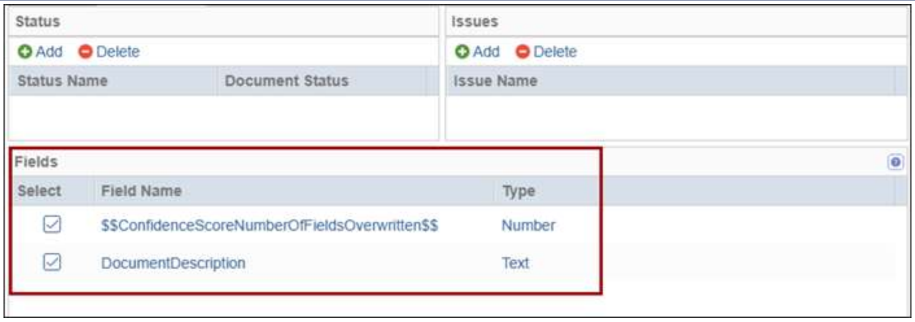
3. Click the Delete button to delete the selected Status Name.



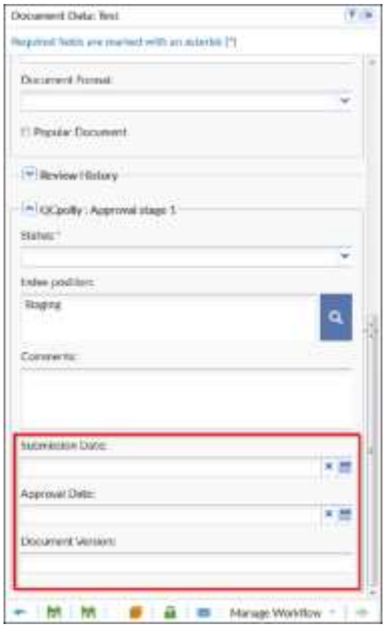
4. Click Add below the 'Issues' section. The empty field gets added below the 'Issue Name' with the List of issues.
5. Click the issues to assign the reasons in case the reviewer rejects a document/asks for clarification.



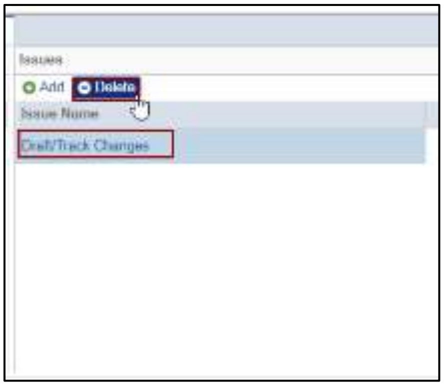
6. To make metadata fields, as required, available for a workflow configuration, proceed to Fields section and select the Workflow Fields, as required.
   - These fields will appear in the Fields panel at the bottom of the Custom Fields tab. Tick the fields as required for the review. Refer to the screenshot below:



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



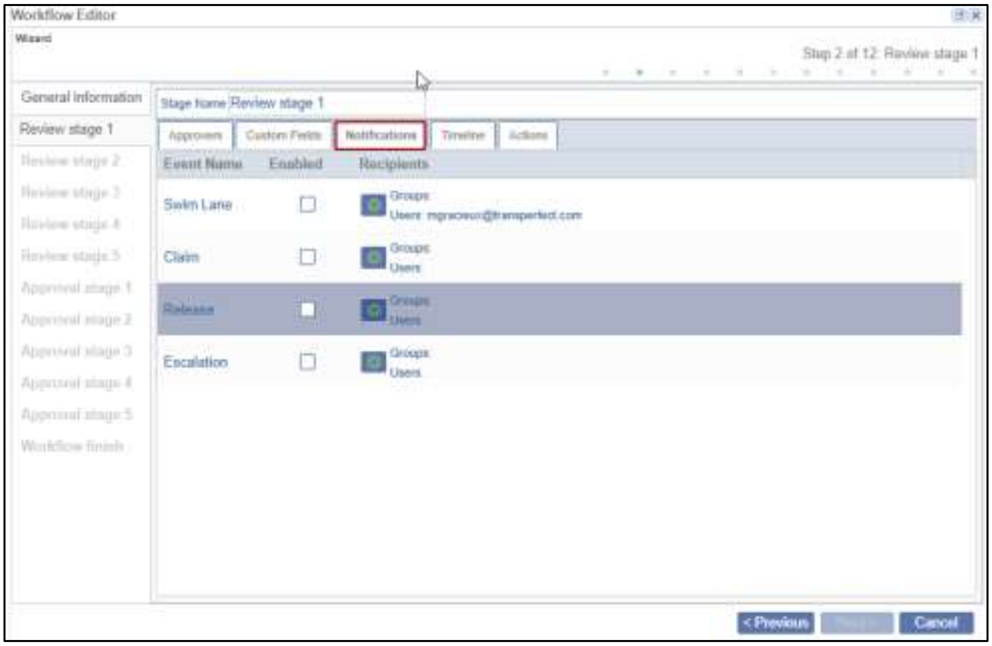
7. Click the Delete button to delete the selected Issues Name.



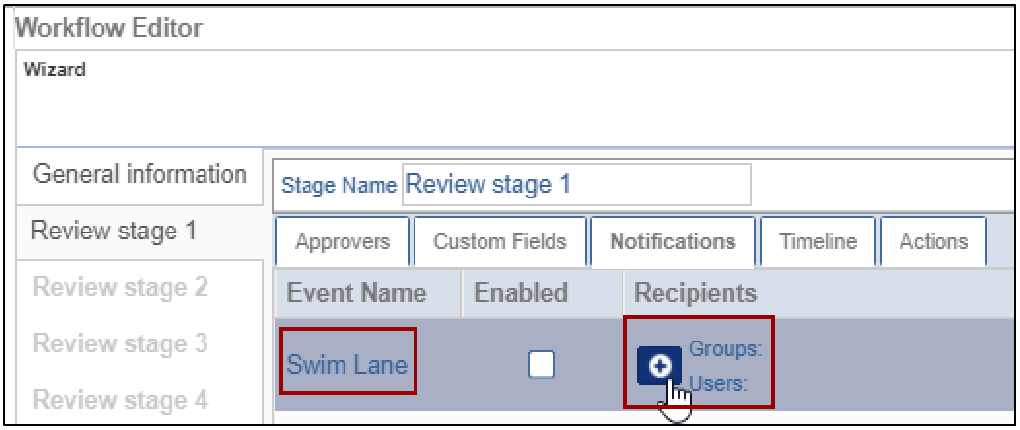
Notifications Tab:

In the Notifications tab, the user can allow for email notifications to be enabled for the event names listed. For users who want to be notified only in case of Swim Lane, Claim, Release, or Escalation, Users/Groups can be added accordingly.

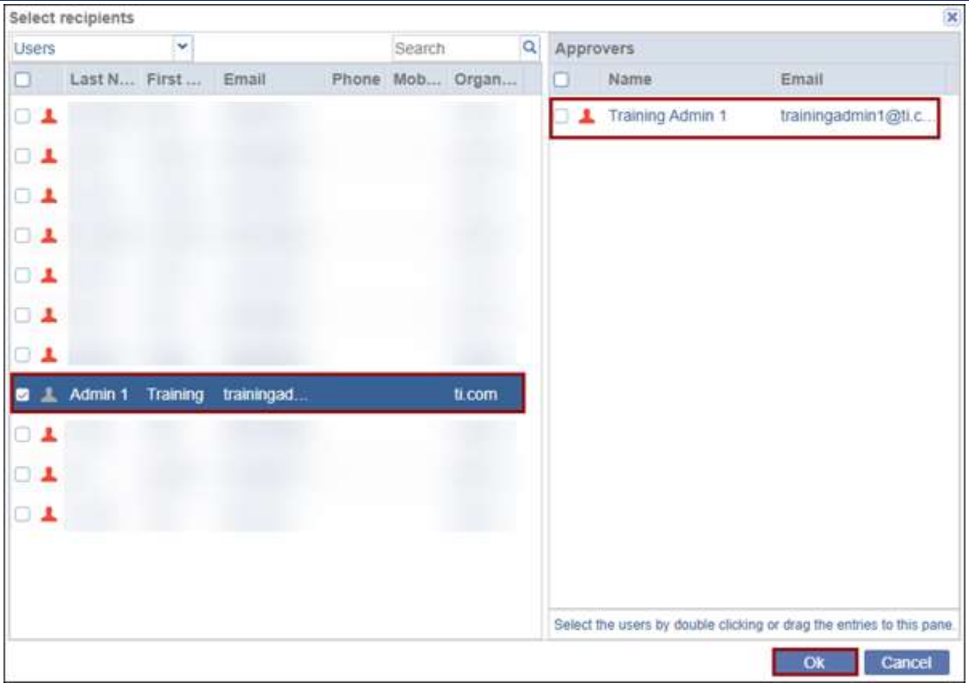
1. Click on the Notifications tab.



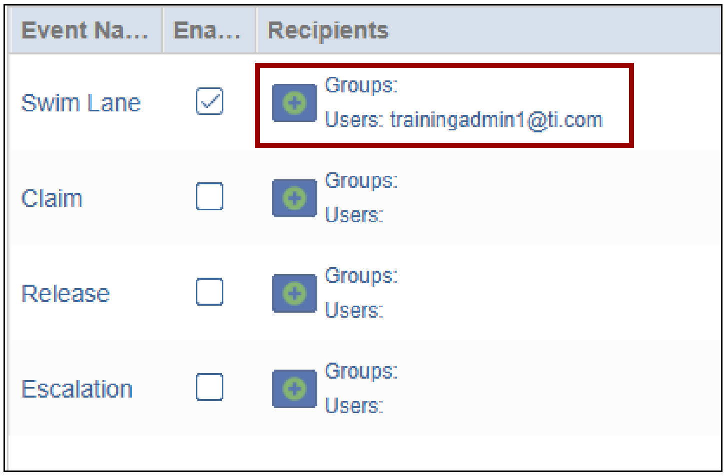
2. To add the Users/Groups to the specific Event Name, click the + (plus) icon available beside the event name.



3. The Select Recipients pop-up window is displayed with the list of Users/Groups.
4. Select the users/groups by double-clicking or dragging the entries to the right pane and clicking OK.

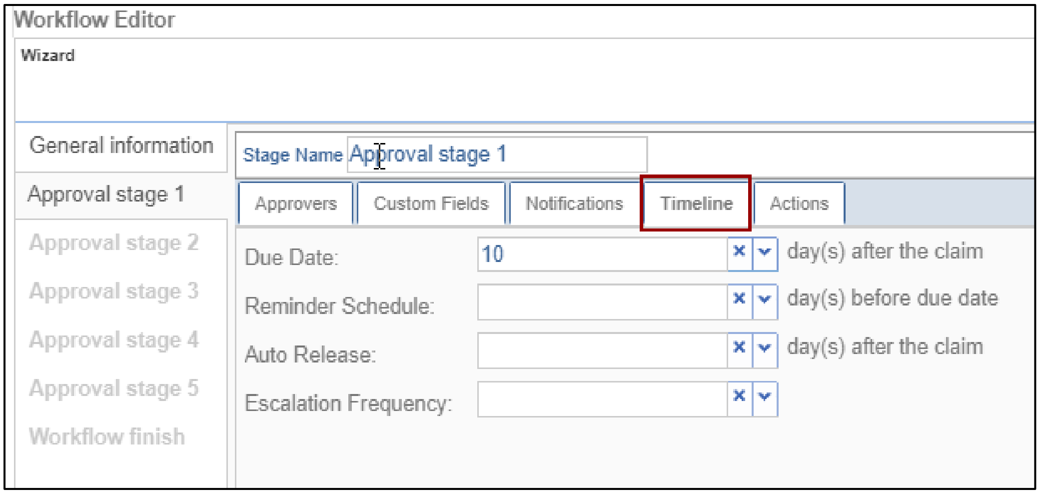


5. The added users/groups are displayed on the 'Workflow Editor' pop-up window.

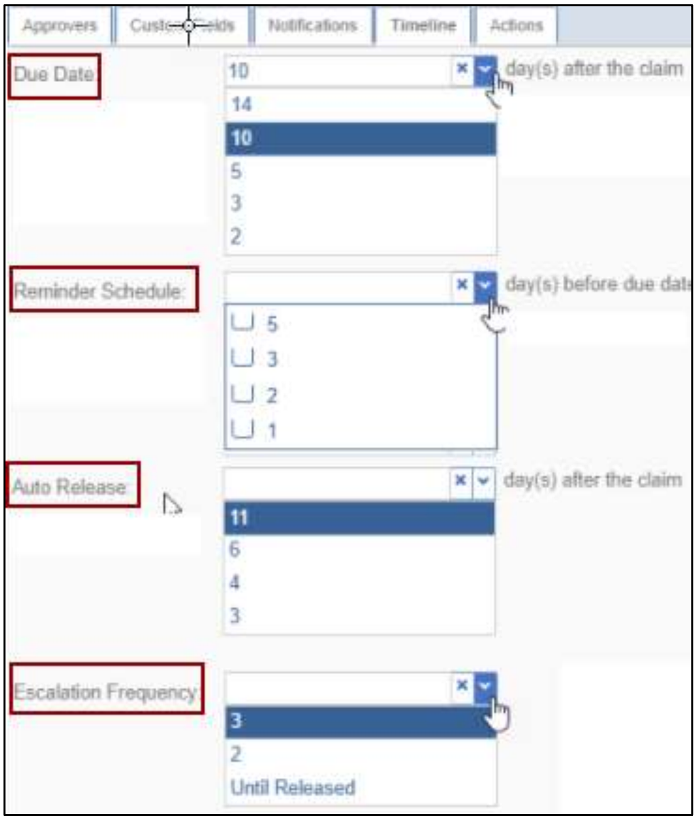


<u>Timeline Tab:</u>

In case values are configured in Timeline Configuration in Common Settings, the values would be populated by default in the Timeline tab. Users may choose to override the previously set configurations if desired.

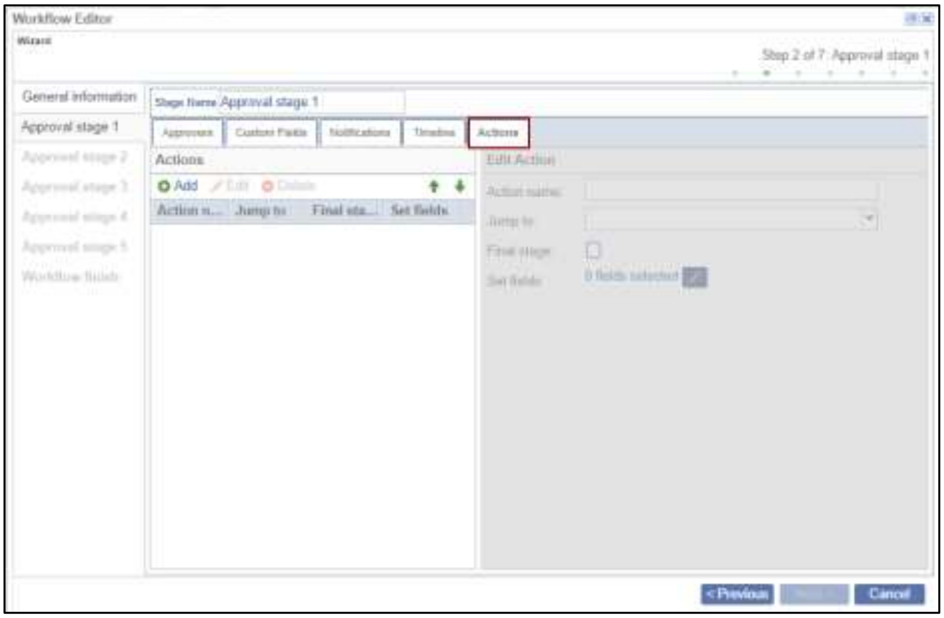


1. The Due Date displays the days once the document is claimed.
2. The Reminder Schedule displays the days before the due date comes.
3. The Auto Release displays the days after claiming the document.
4. The Escalation Frequency decides to escalate the document until the release.



<u>Actions Tab:</u>

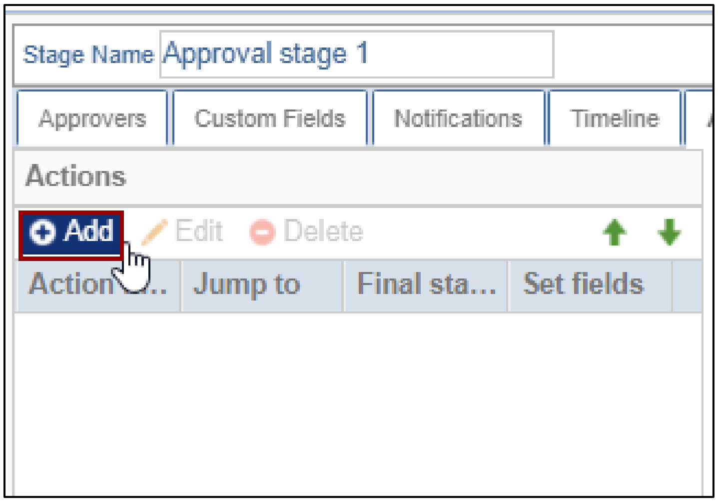
Actions is an optional tab allowing for complex workflow building. It enables a workflow to have a jump. A specific document can jump to a certain stage. For example, a Form FDA 1572 after QC1 review, can jump to a stage 3 review, where Regulatory Affairs performs a 2nd review on the document. While efficient for complex workflows, it is not required for regular workflow creation.



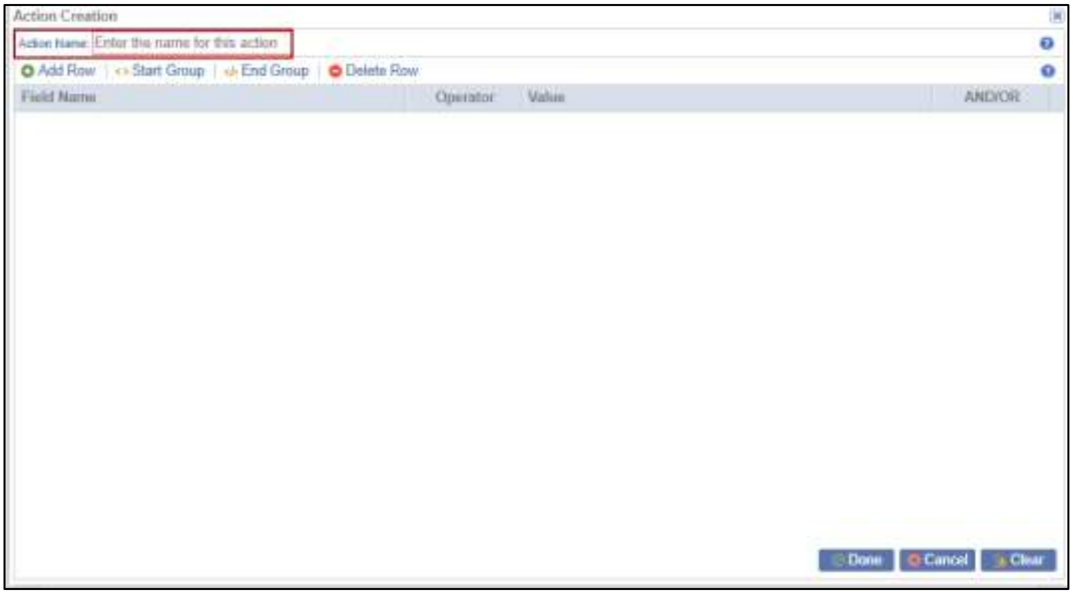
Add Action

To configure the Actions tab, follow the steps below.

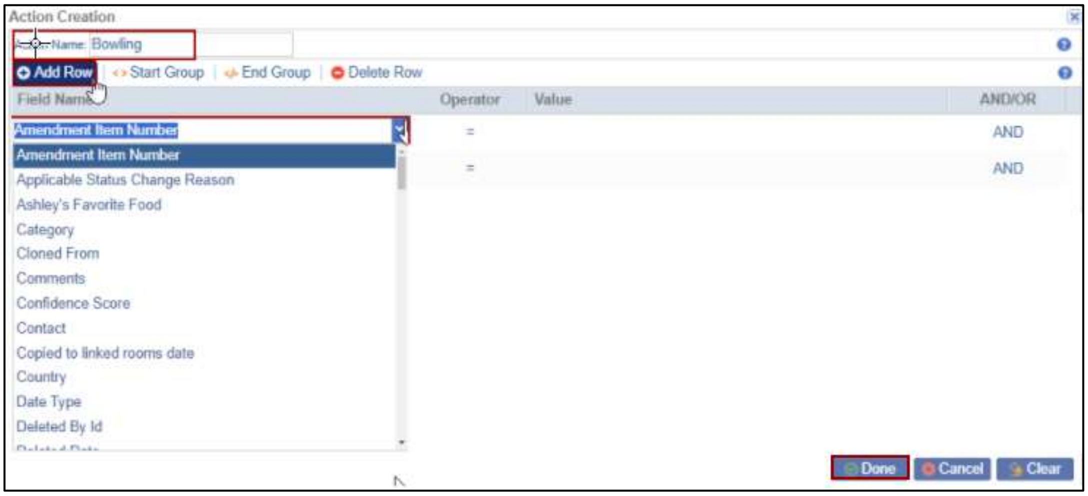
1. Click **Add** in the 'Actions' tab.



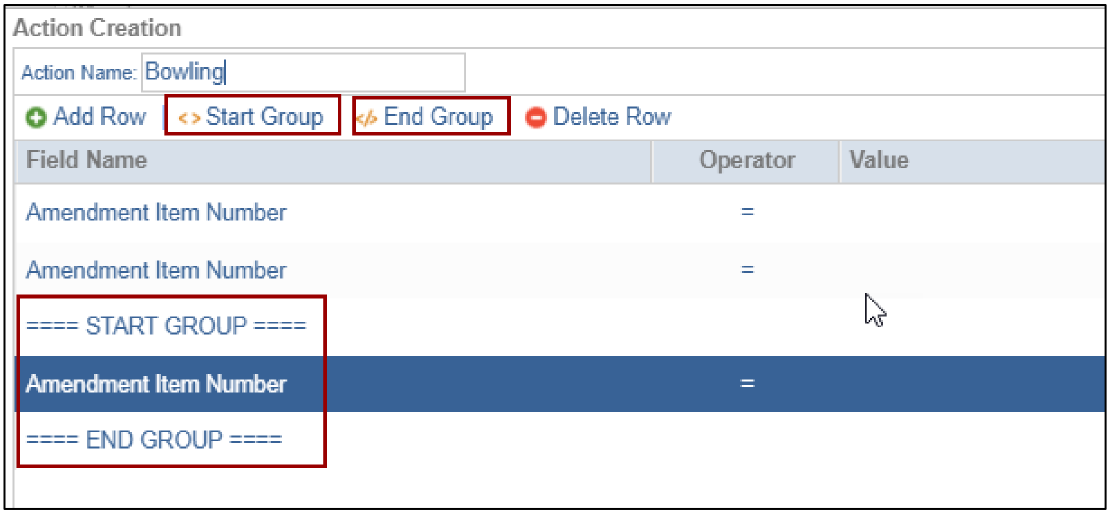
2. On the 'Action Creation' pop-up window, enter a name for the Action Creation.



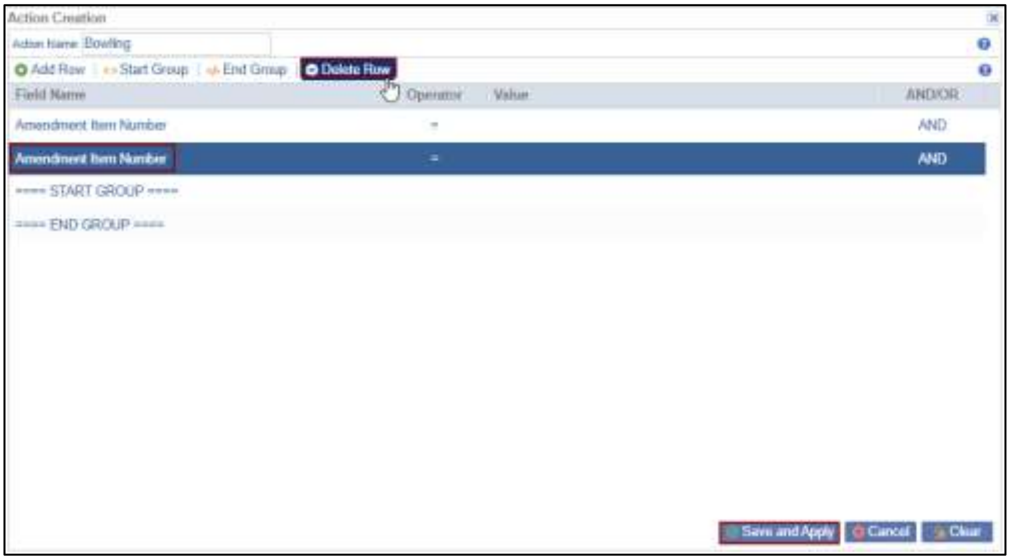
3. Click the Add Row button to add a row below the ‘Field Name’ with the drop-down options. Once the row is added, click on the Done button.



4. Click Start Group to start the group by adding the category by clicking the End Group the started group gets over.

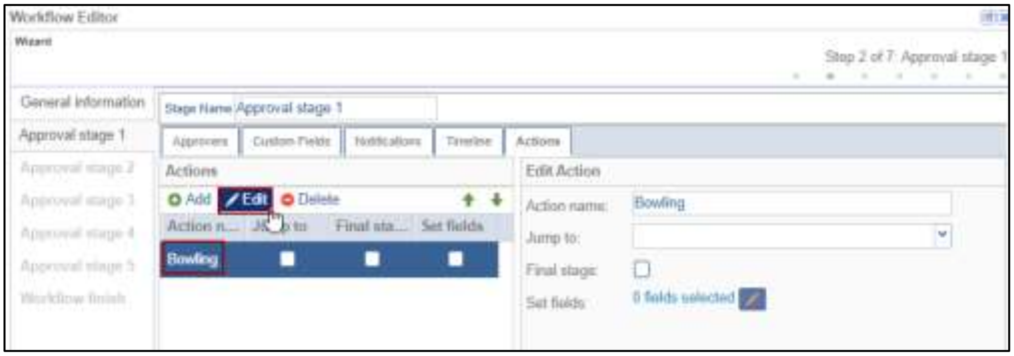


5. Select the row and click the Delete button.
6. Click the Save and Apply button.

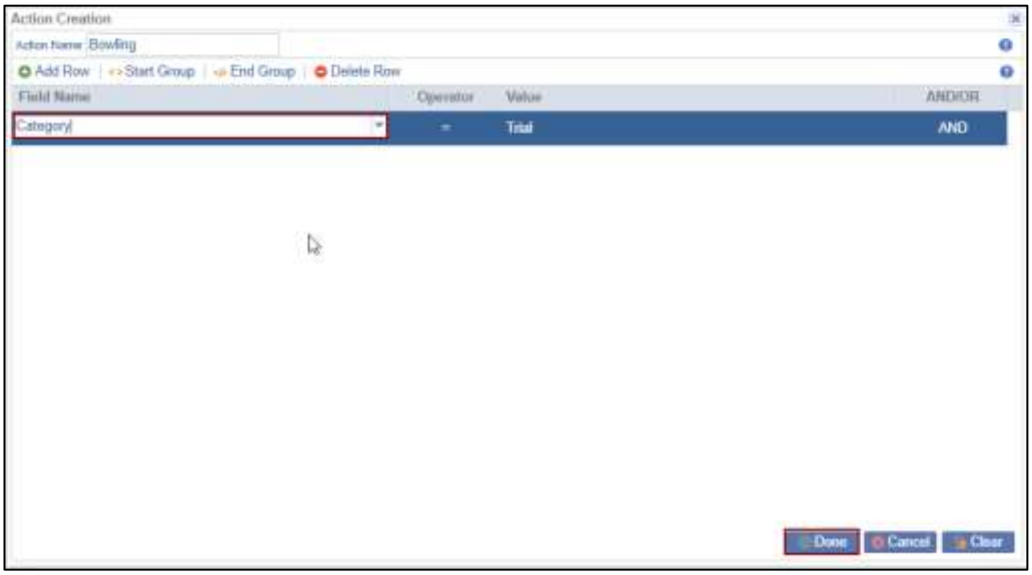


Edit Action

1. Select the action and click the Edit button. The 'Action Creation' pop-up window opens.

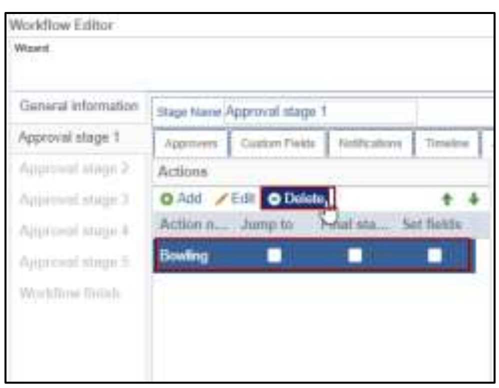


2. Make edits and click on the Done button.

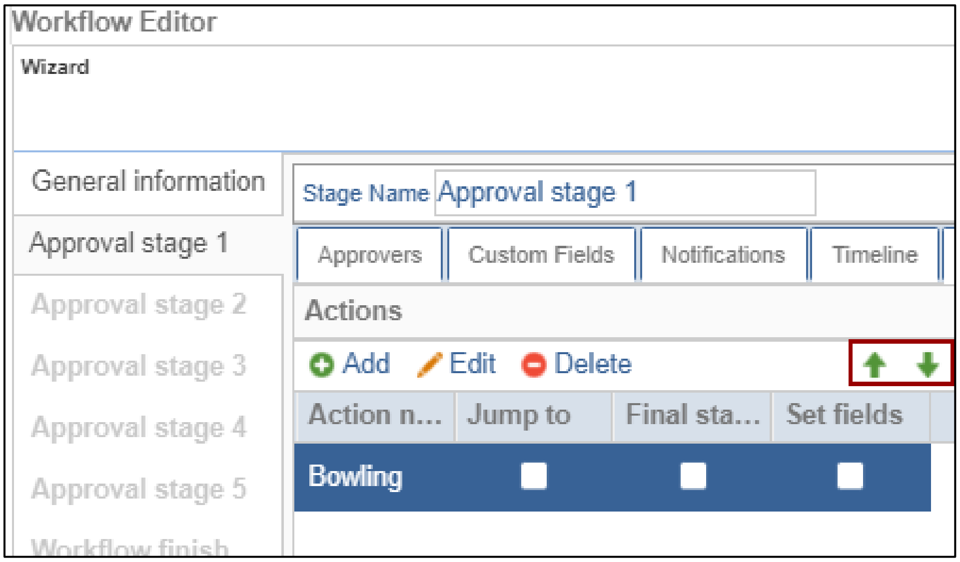


Delete Action

1. Select the action and click on the Delete button the selected action gets deleted.

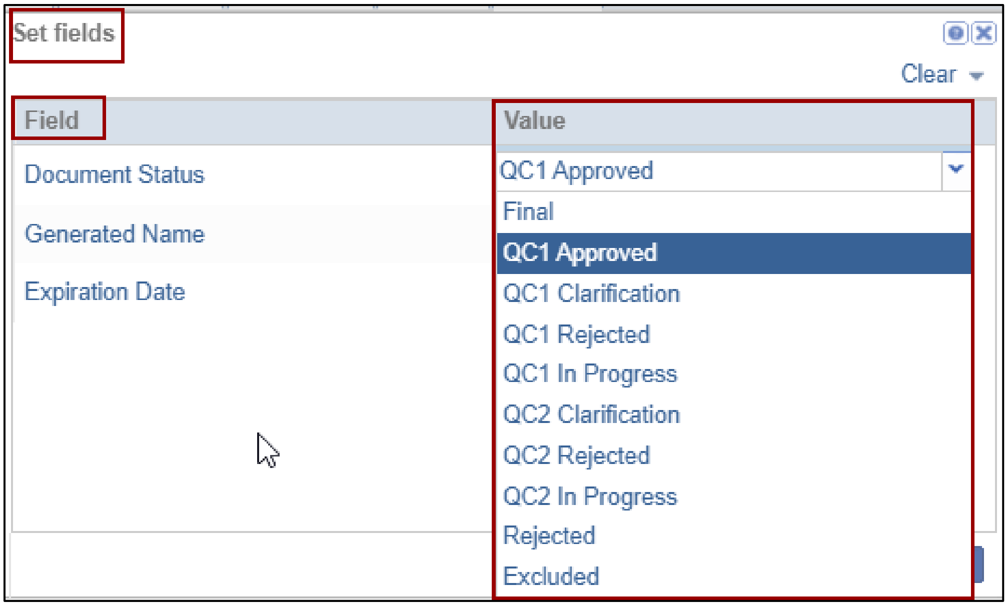


2. The Move Up and Move Down arrows help the user to move the actions as per the requirement.



Edit Action Tab

1. On the right side of the 'Workflow Editor' pop-up window within the Edit Action panel, the user can see the following actions:
   - Action name: the user adds the action name is displayed
   - Jump to: the user can select the Approval Stages that are displayed in the drop-down list
   - Final stage: if the checkbox is checked the user directly moves to the Final stage of the Workflow
   - Set fields with edit icon:
2. Click the edit icon and the Set fields pop-up window is displayed with the 2 columns 'Field' and 'Value.' The field column has 3 fields by default:
   - Document Status
   - Generated Name
   - Expiration Date
3. Double-click on the field in the Value column. The drop-down options are displayed select the appropriate value and click Save.



4. Click Next after reviewing all tabs and repeat these steps for each approval stage.

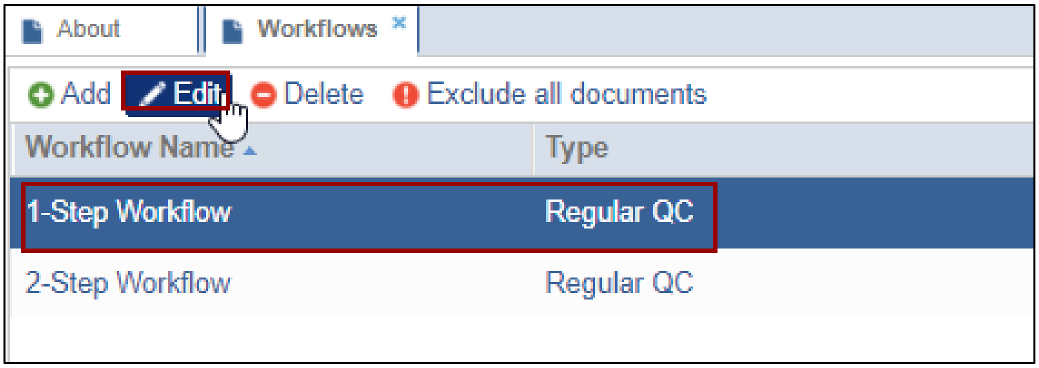
   Note: Settings, such as approvers, notifications, and timelines, may vary by stage.

5. When finished, click on the Next button.
6. The Workflow Finish step is the final stage.
   - Any workflow errors will be displayed here and must be resolved.
   - If no errors are found, click Finish to complete the process.

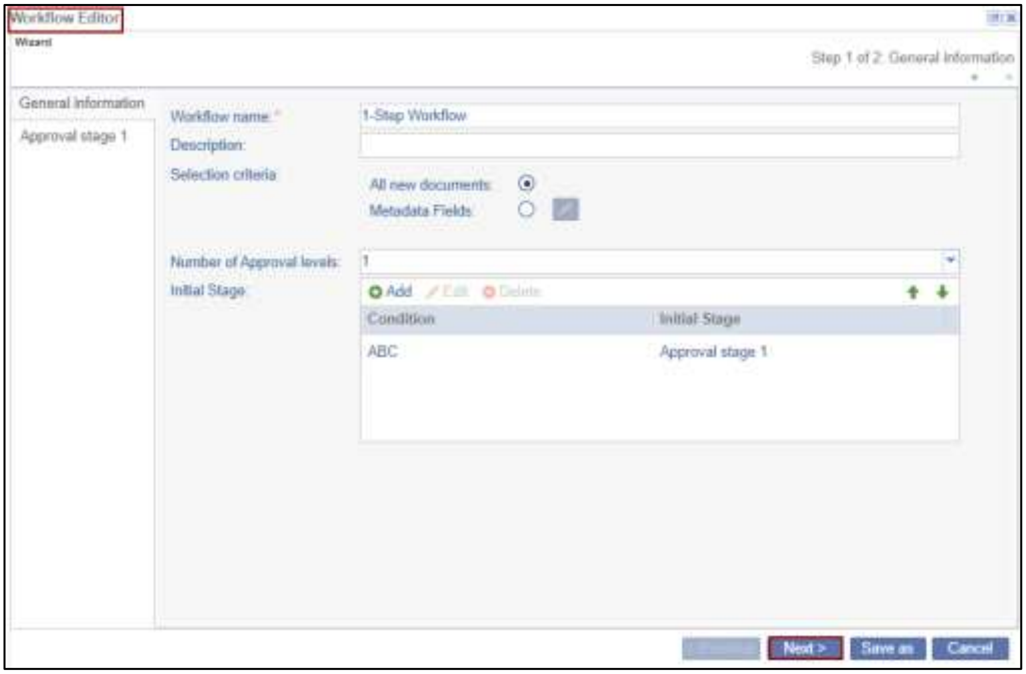
Editing an Existing Workflow

To edit and existing workflow, follow the steps below.

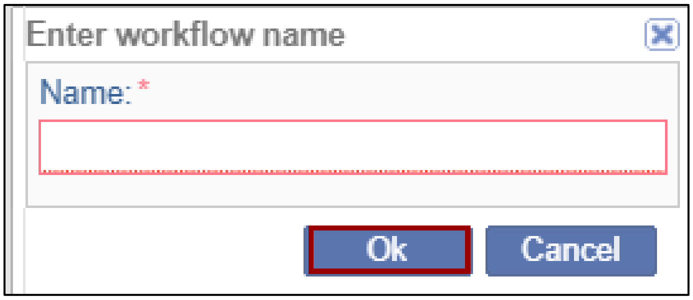
1. Click the Edit button the 'Workflow Editor' pop-up window is displayed.



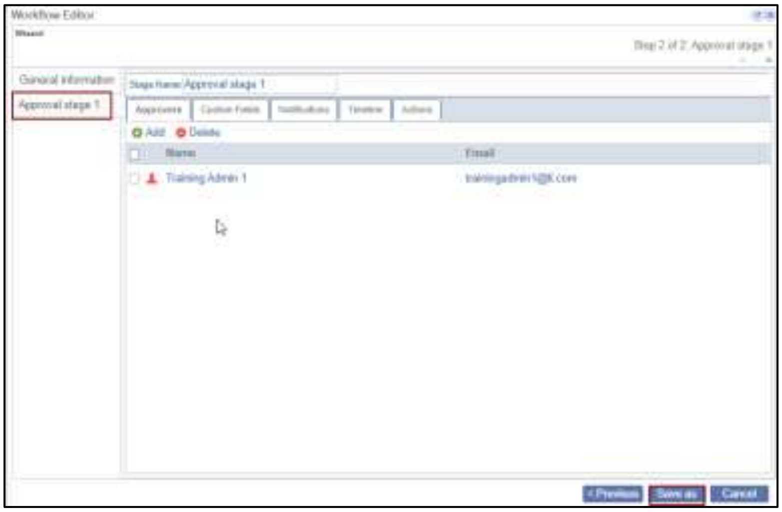
2. Edit the required fields and click Next will proceed to the 'Approval Stage 1' information page.



3. Edit the required fields and click Save As to save the workflow under a new name.



4. Click on the Save as button.



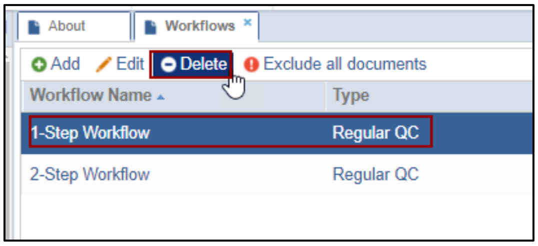
Note: Editing of an existing workflow should be executed with caution because any saved changes require a new and revised workflow to be created. As a result, only Super Administrators can edit an existing workflow. To request workflow changes, contact the TI Service Desk.

Deleting an Existing Workflow

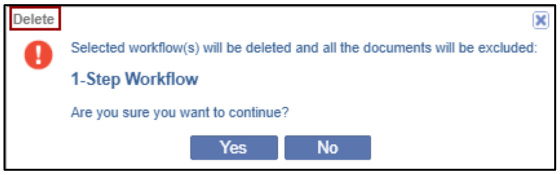
Deleting an existing workflow will result in the removal of any related status from documents previously processed as a part of the deleted workflow.

To delete an existing workflow, follow the steps below.

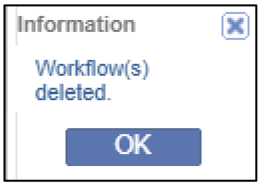
1. Select a workflow from the list to delete and then click Delete from the top menu.



2. The Delete pop-up window is displayed.



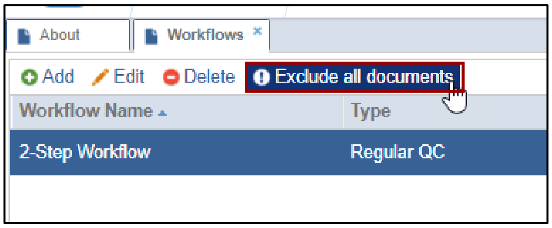
3. If clicked Yes, the Information dialog is displayed.



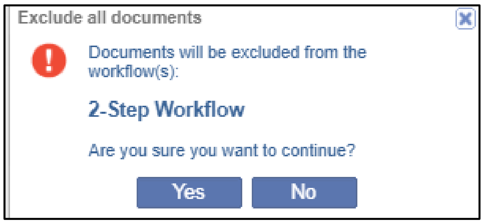
Exclude all documents

The documents associated with the workflow will be excluded from it.

1. Click Exclude all documents button.



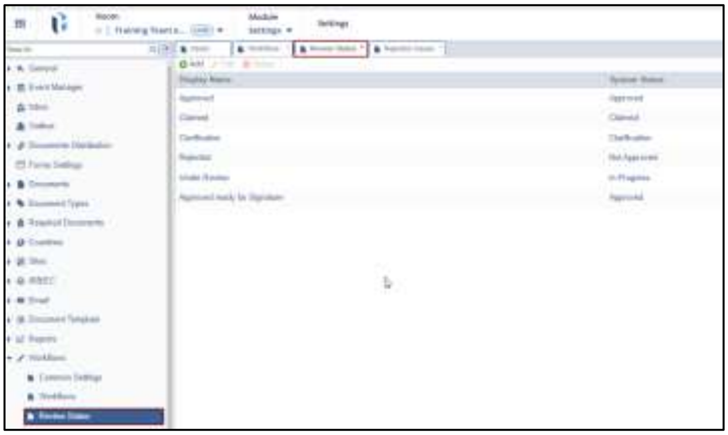
2. The Exclude all documents dialog is displayed.



3. If clicked Yes, the Information dialog is displayed.

Review Status

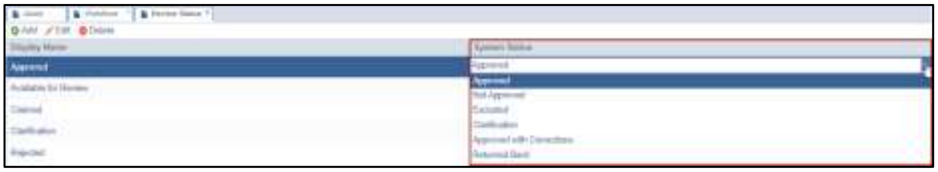
Administrators can create review statuses to assign to documents at each stage of the workflow. The Display Name is the status name visible on the user interface, while the System Status refers to the predefined values assigned to the review status. Regardless of the Display Name, documents will be routed to the appropriate workflow folder in QC Review or My Reviews based on the System Status.



Add Review Status

1. On the Review Status screen, click on the Add button.
2. Enter the Display Name.

3. Double-click the System Status field, click the dropdown arrow, and select the System Status from the list.



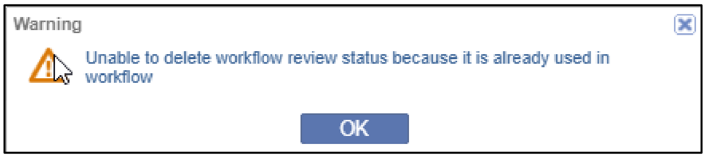
Editing Review Status

1. Select the required Review Status/Display Name to be edited and click Edit.
2. The Review Status field becomes editable.
3. Make the required changes.
4. Double-click the System Status field, click the dropdown arrow, and select the System Status from the list.

Deleting Review Status

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

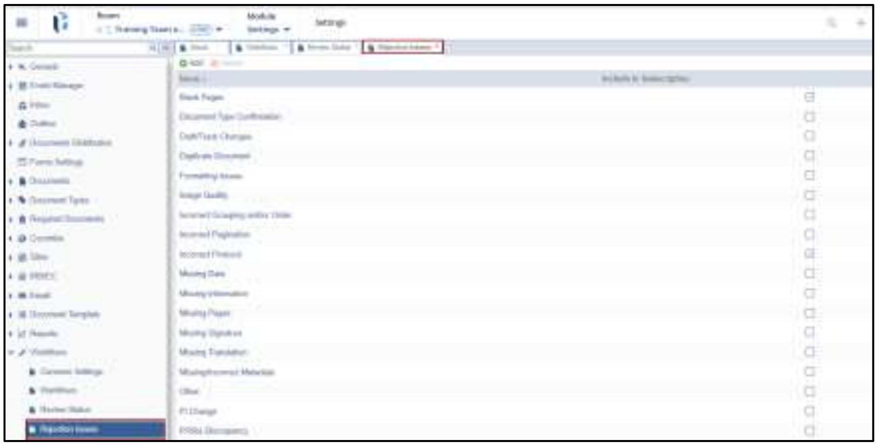
3. If the selected status is in use within a workflow, a pop-up dialog will appear. If the selected workflow is not in use, it will be deleted.



Rejection Issues

When adding a status to the workflow, if the user reports an issue, the issue will be added to the status in the Custom Field.

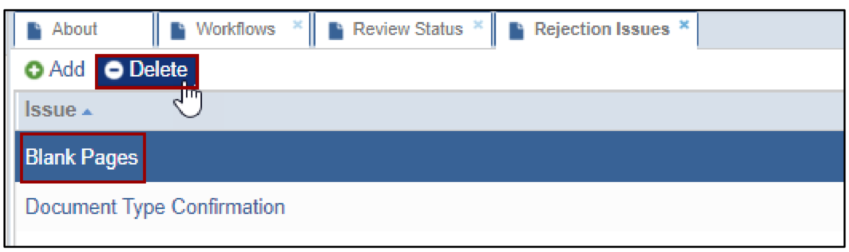
The reported issues will be added to the Rejection Issues section. Existing issues will also be marked and added under the Issue Name in the Custom Field.



To add rejections issues, follow the steps below:

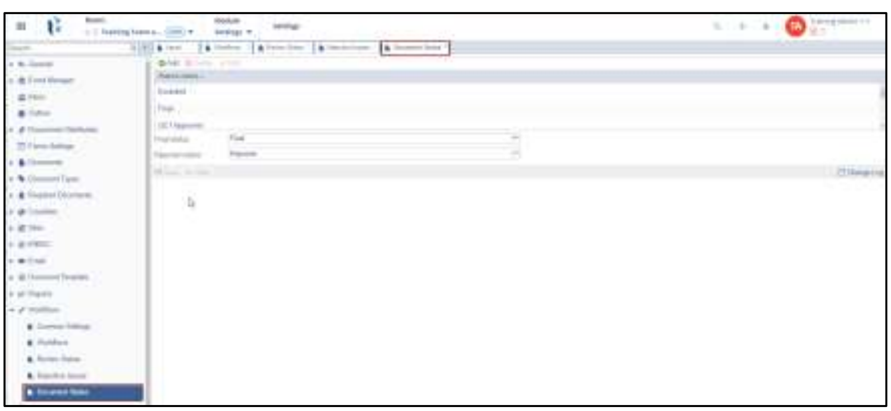
1. Click Add, the field gets activated and the user can add the Issue.

2. Select the issue and click Delete. The selected issue will disappear from the list.



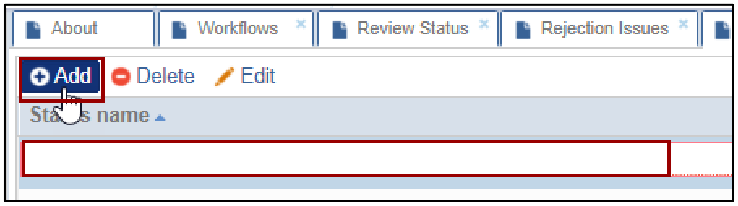
Document Status

Document Status displays the status names that have been assigned to the documents.

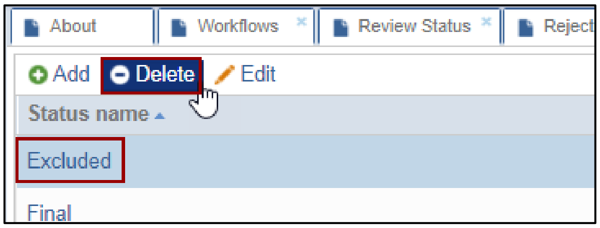


To add Document status, follow the steps below.

1. Click Add to add the ‘Status name’.

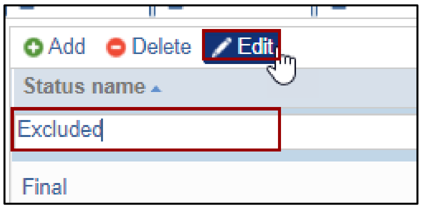


2. Click on the Delete button to delete the selected status name.



3. Click on the Yes button on the ‘Delete Item Configuration’ dialog box.

4. Select the Status name and click Edit. The selected field gets editable.



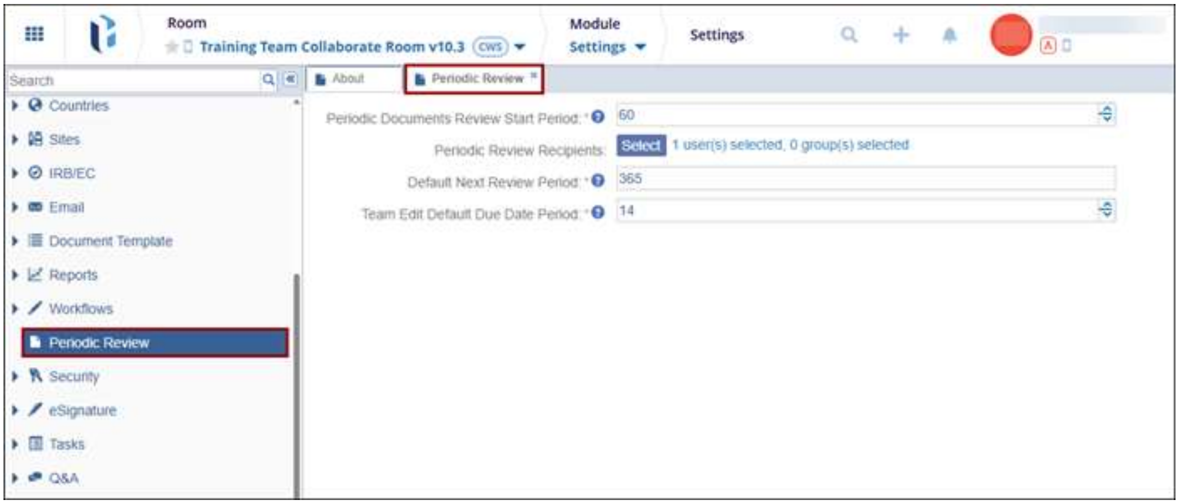
5. The Final Status and the Rejected Status fields display the status that the user wants to associate.

Periodic Review

The Periodic Review settings enable admins to configure key aspects of the document review process. Admins can specify the number of calendar days before the review due date when a document should be included for periodic review. They can also assign individual users or user groups as reviewers and define the time frame after which an effective document requires its next review. Additionally, admins can set the due date period for completing shared document edits.

To configure the periodic review settings, follow the steps below.

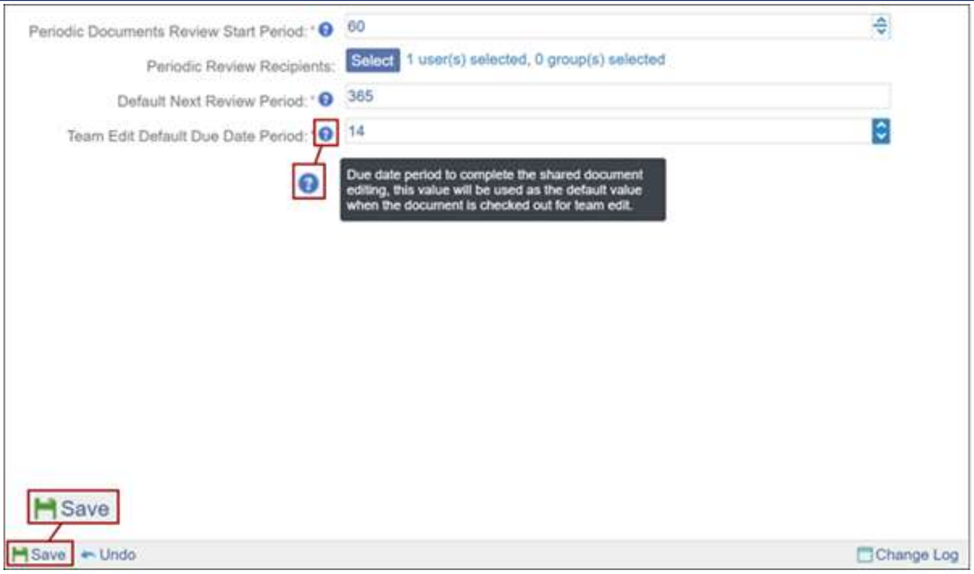
1. Click on the waffle icon and select the Settings module.
2. Select the Periodic Review option from the left-hand navigation pane.



3. Within the Periodic Review tab, configure the following settings by defining the number of days and users in their respective fields.

    a. Periodic Documents Review Start Period: This period is the number of calendar days before the periodic review due date when the document should be added for the periodic review. Click on the Up and Down arrows to define the number of days.
    b. Periodic Review Recipients: These users or the group of users will be responsible for reviewing documents in a periodic review process. Click the Select button to add the required groups and/or users.
    c. Default Next Review Period: This period is the number of calendar days after which the effective document requires the next review. Define the default next review period in days using the up and down arrows.
    d. Team Edit Default Next Review Period: This is the due date period to complete the shared document editing. The value mentioned in this field will be the default value when the document is checked out for team edit.

4. Click on the Save button once the Periodic Review settings are configured.



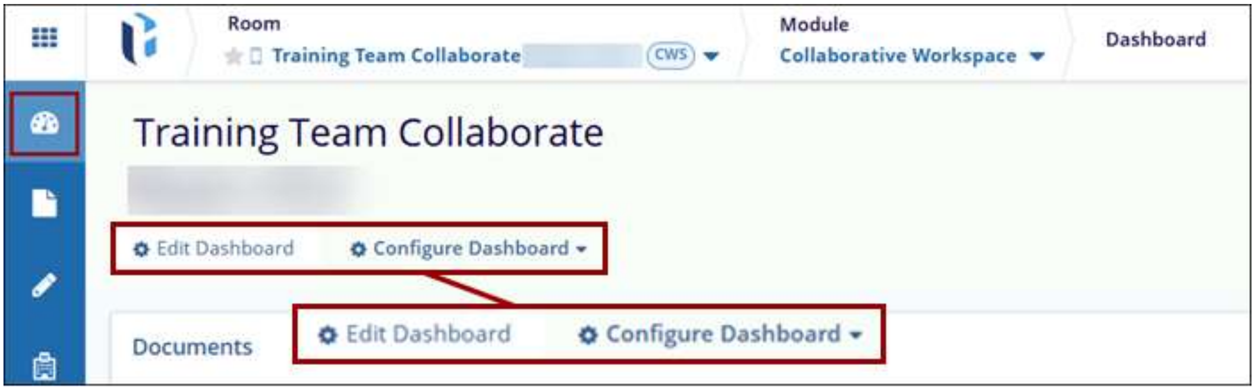
Note: Click on each settings tooltip to view the settings description.

DASHBOARD

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

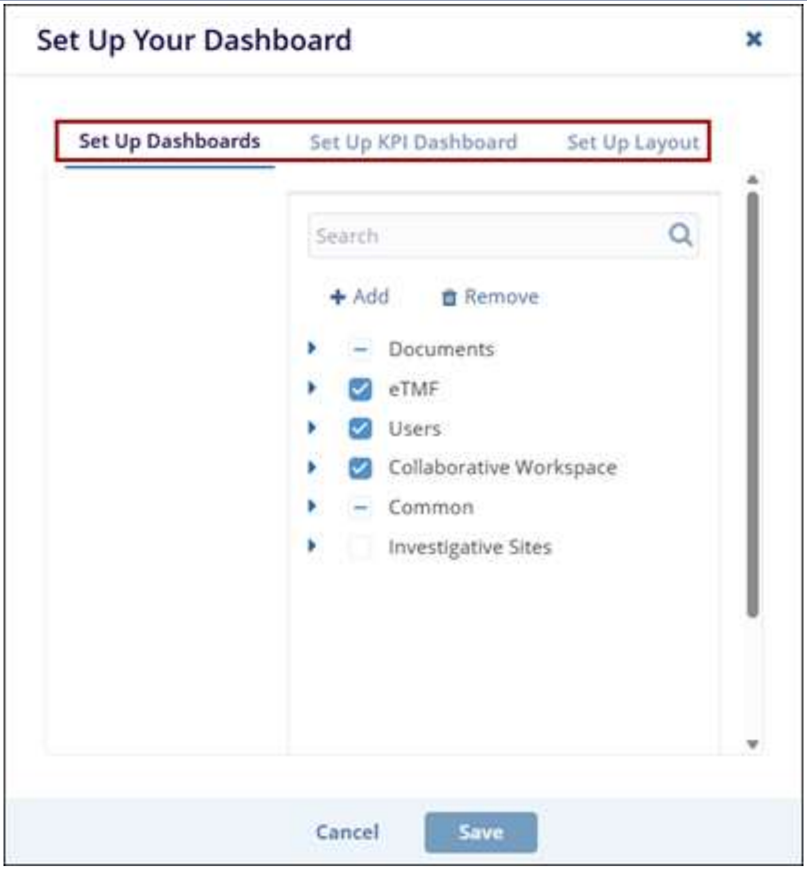


Edit Dashboard

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.

To Edit the Dashboard, follow the steps below.

1. Navigate to the Dashboard section in the Collaborative Workspace module.
2. Click on the Edit Dashboard button located at the top left of the toolbar.
3. The Set Up Your Dashboard window opens and displays the following options
    - Set Up Dashboards: For selecting or adding widgets.
    - Set Up KPI Dashboard: For managing key performance indicators.
    - Set Up Layout: For customizing the layout.

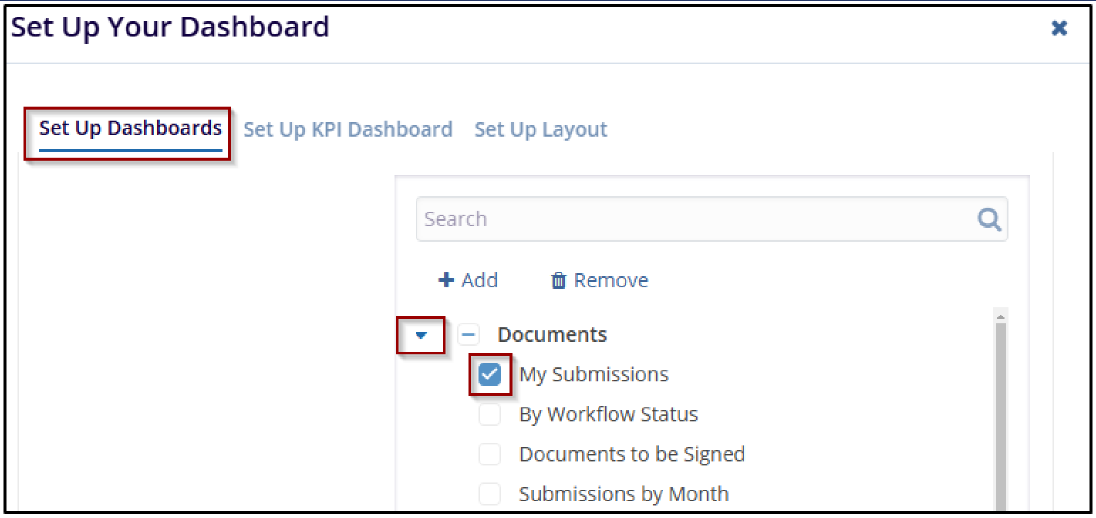


Set Up Dashboards

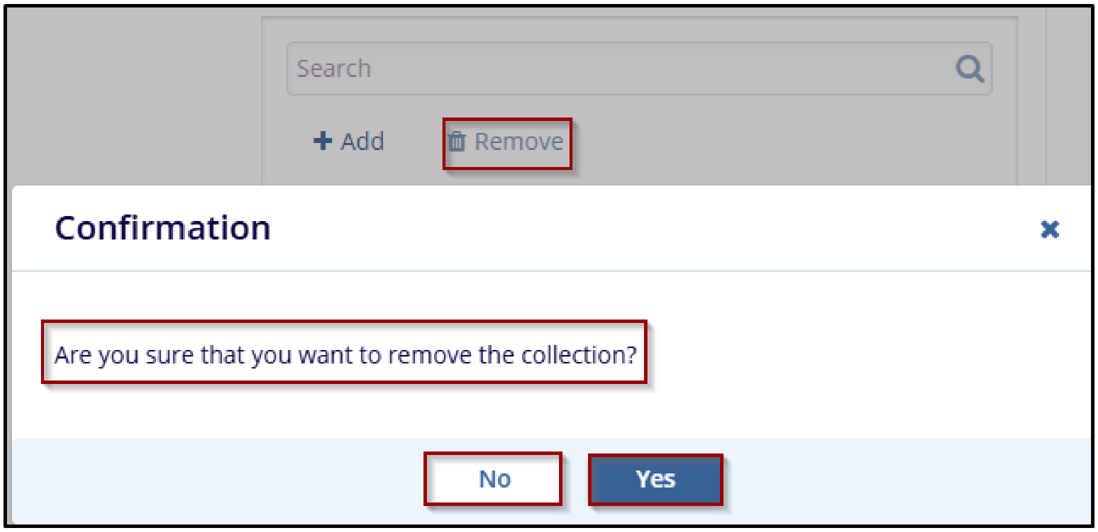
The Set-Up Dashboards tab allows users to customize their dashboards by adding, removing, or managing dashlets. Dashlets are individual components that display specific types of data or functionality on the dashboard, helping users personalize their view to highlight the most relevant information.

Steps to set up the dashboard.

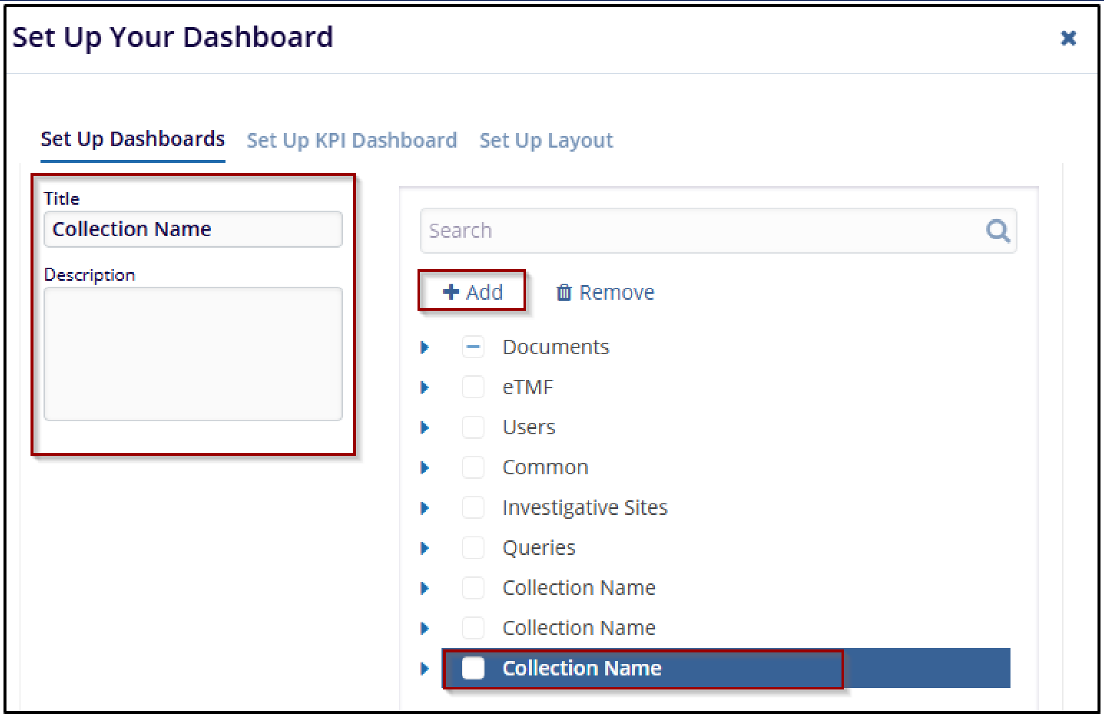
1. On the Set Up Your Dashboard window, click on the Set-Up Dashboard tab and expand the fields using the arrow, and select the required checkbox.



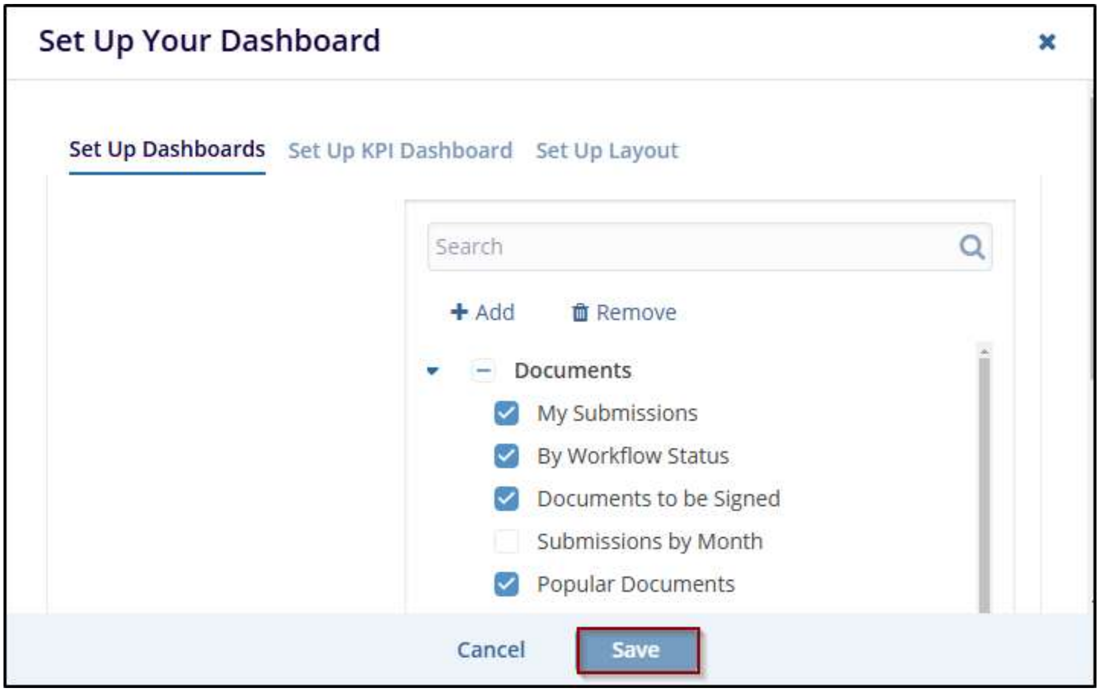
2. Click the Remove button to initiate the removal process. A confirmation window will appear with the message: 'Are you sure that you want to remove the collection?'. Also, the user can only remove the newly added fields and not the pre-defined fields.
3. Click Yes to confirm and remove the collection or click No to cancel the action.



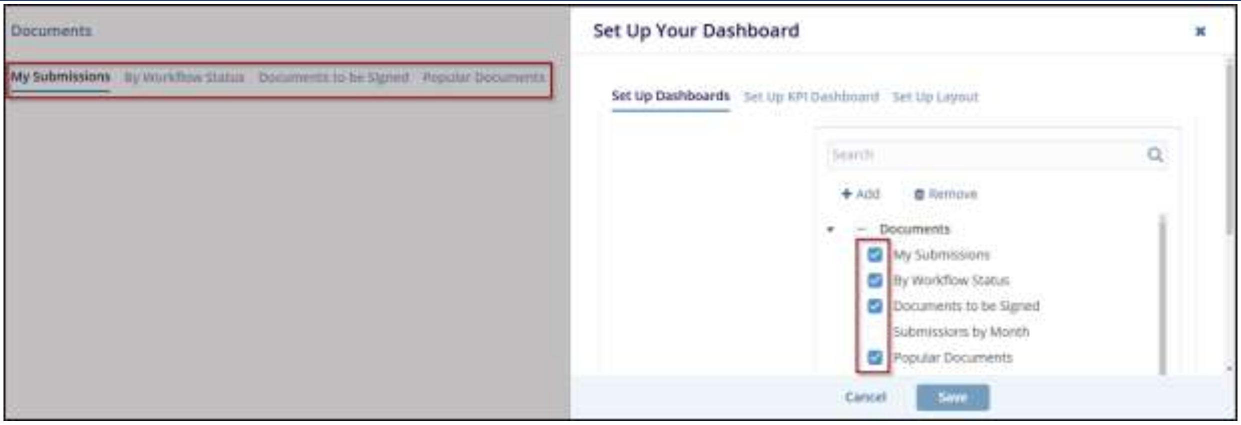
4. Click on the Add button, and a new entry will appear under the list of available dashlets as (collection Name). While adding a new dashlet, mention the Title and Description in the left-side fields.



5. Once all necessary changes are completed, click the Save button to apply the changes.



Note: The checkbox(s) selected for each dashlet from the set up your dashboard window will only display those tabs in the Dashboard.

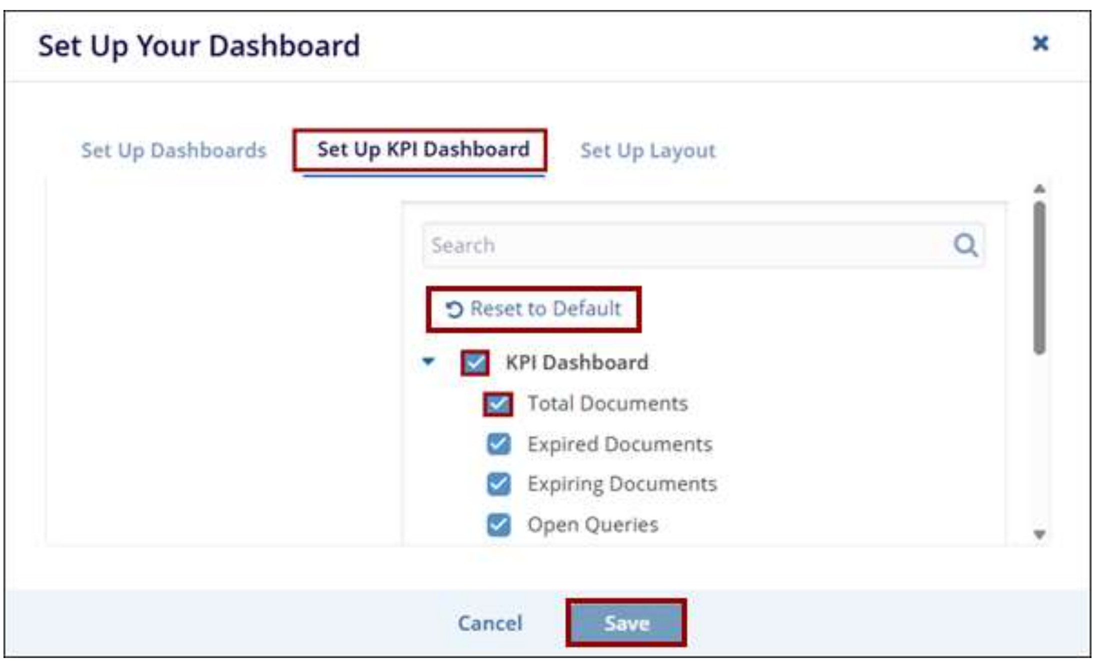


Set Up KPI Dashboard

The Set Up KPI Dashboard allows users to configure key performance indicator (KPI) metrics on the user's dashboard. The selected dashlets are displayed on the top right corner of the screen.

Steps to set up the KPI dashboard.

1. Click on the Set Up KPI Dashboard tab on the Set Up Your Dashboard window.
2. Expand the KPI Dashboard fields using the arrow and select the required checkbox.
3. Click on Reset to Default to revert all KPI configurations to the original system-defined settings
4. Once all necessary changes are completed. Click the Save button to apply the changes or click the Cancel button to discard changes.



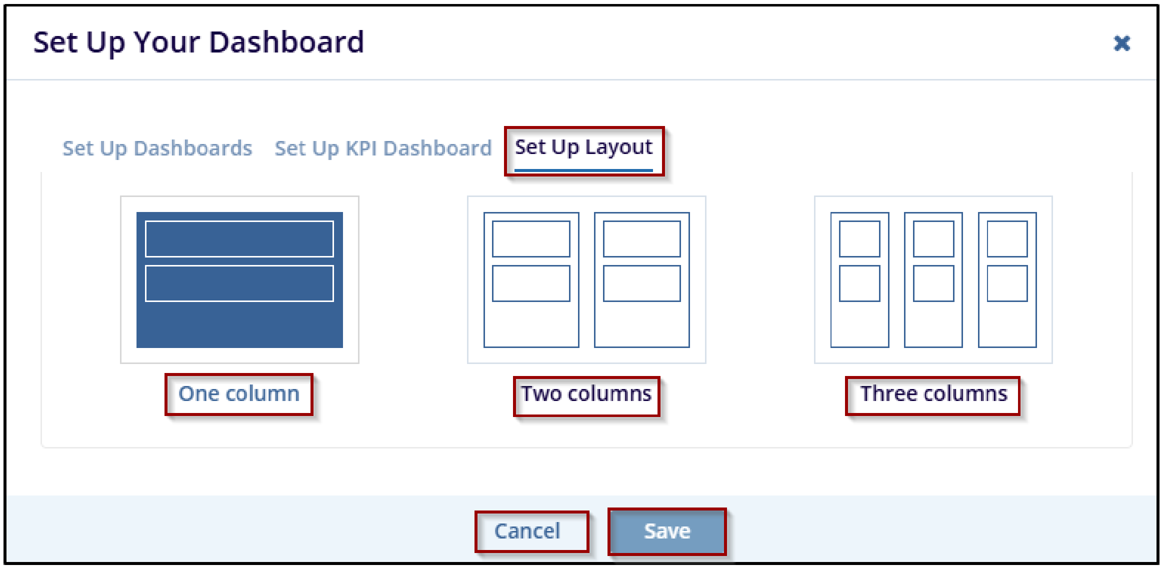
5. The selected tabs are displayed on the top right of the screen.

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 tab.
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 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 KPIs

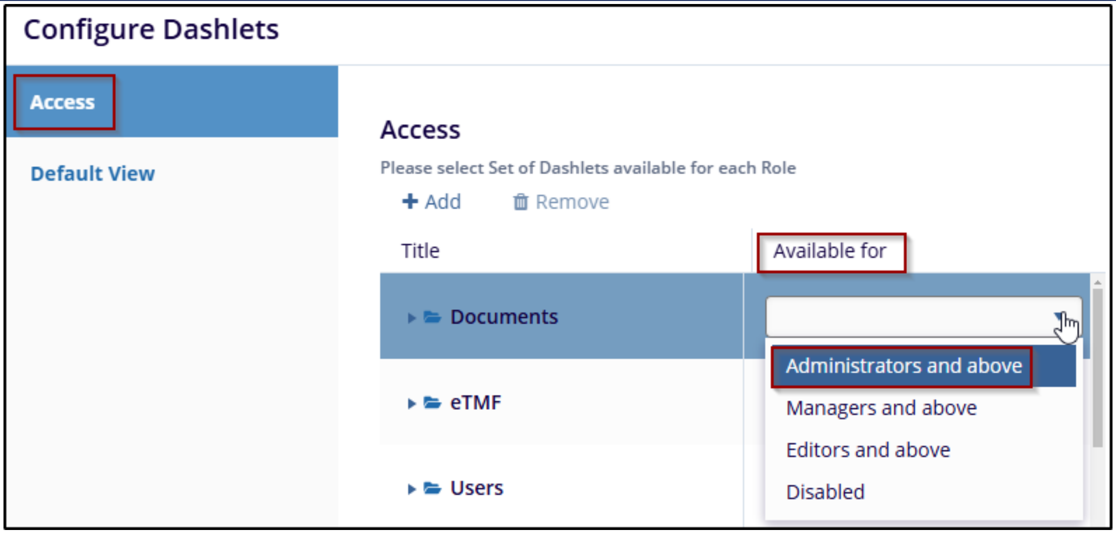
Configure Dashlets

The Configure Dashlets allows 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.

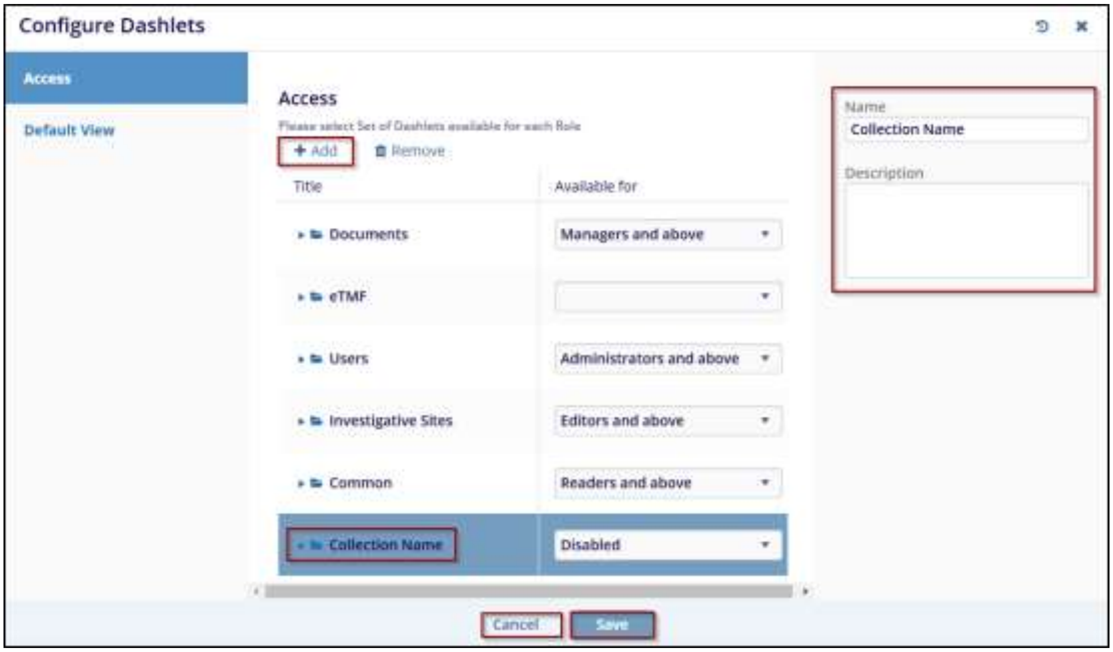
Steps to Configure the Dashlets.

1. Click the Configure Dashboard button next to the Edit Dashboard button. The dropdown menu displays the Configure Dashlets, and Configure KPIs options.
2. Select the Configure Dashlets option, and the Configure Dashlets window will open.
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.

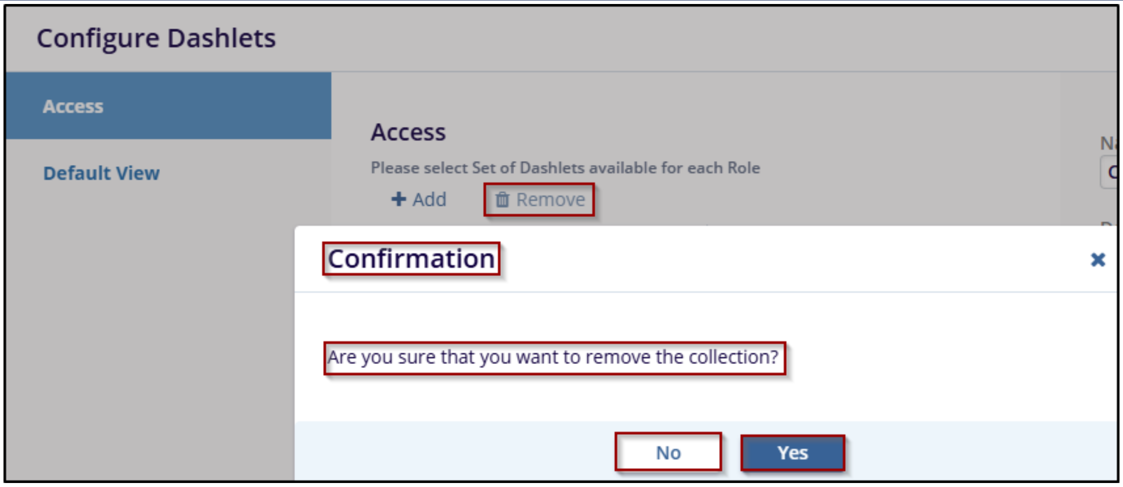
4. In the Access tab, select the roles from the dropdown menu under the Available for the column to assign dashlets to specific roles.



5. Click on the Add button, and a new entry will appear under the list of available dashlets as (collection Name). While adding a new dashlet, the user has to mention the Name and Description in the right-side fields.



6. Click the Remove button to initiate the removal process. Users can only remove the newly added fields and not the pre-defined fields.
7. On the Confirmation popup, click the Yes button to confirm and remove the collection, or click the No button to cancel the action.



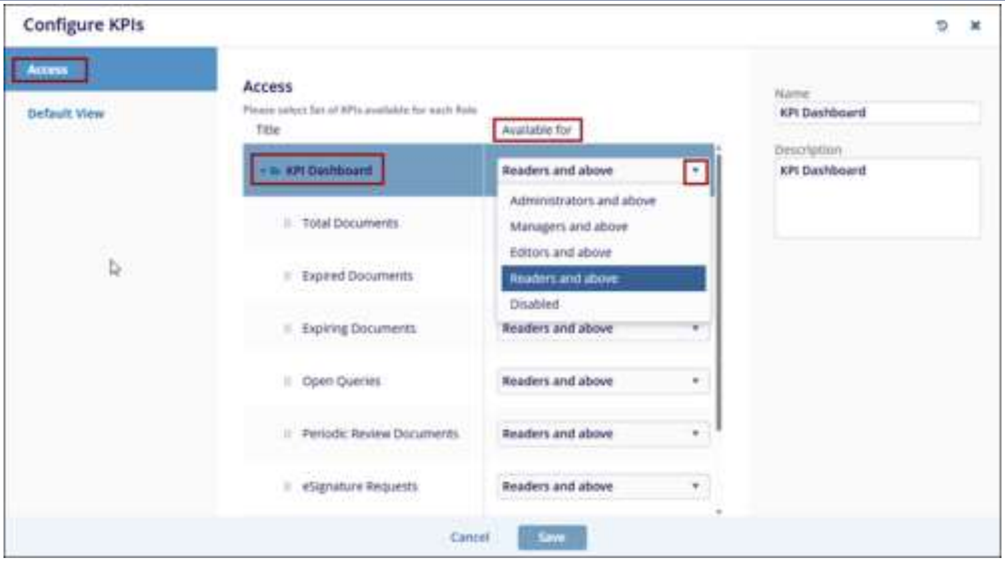
8. Switch to the Default View tab, and select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager, and Administrator.
9. Click on the Save button to save the changes or click Cancel to discard the changes.

Configure KPIs

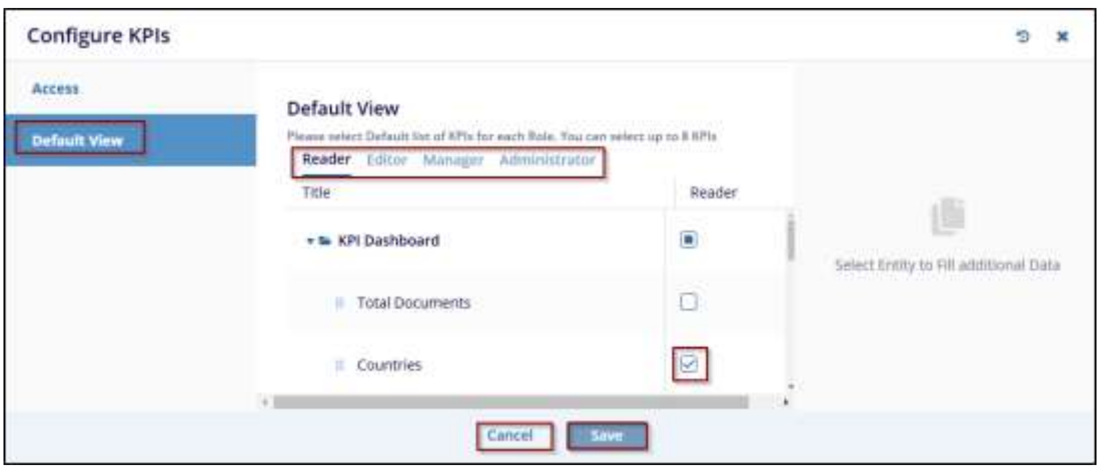
The Configure KPIs allow administrators to manage the key performance indicators (KPIs) displayed on the user dashboard. It enables role-based customization of KPI metrics, ensuring that users see the most relevant data based on their responsibilities.

Steps to set up the Configure KPIs:

1. Click the Configure Dashboard button and select the Configure KPIs option.
2. The Configure KPIs 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.
3. On the Access tab, expand the KPI Dashboard fields using the arrow and select the roles from the dropdown menu under the Available for the column to assign dashlets to specific roles.



4. Switch to the Default View tab, and select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager, and Administrator.



5. Click on the Save button to save the changes or click Cancel to discard the changes.
6. The selected tabs are displayed on the top right of the screen.

Documents

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

My Submissions

The My Submission dashlet allows 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 Collaborative Workspace 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. Click on the Export button next to charts to export data in – Image, Excel, or Clipboard format.

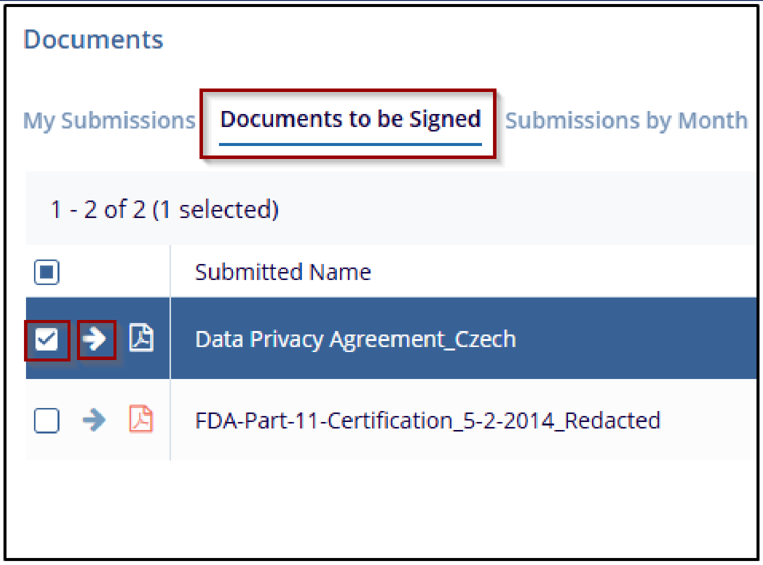
5. Click on Cancel to discard the changes.

Documents to be Signed

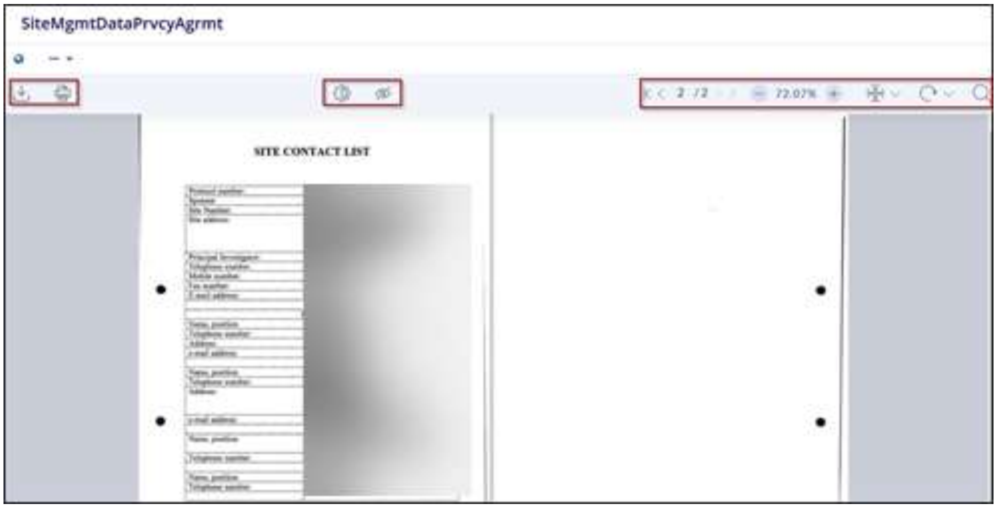
In the Documents section, select Documents to be Signed from the options at the top. This view will display a list of documents awaiting signatures, along with details like the document's submitted name and current signer status.

Steps to view and manage Documents to be signed:

1. Click on the Documents to be Signed tab.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document.
3. Click on the blue arrow (Go to the document), which will navigate to the document index.

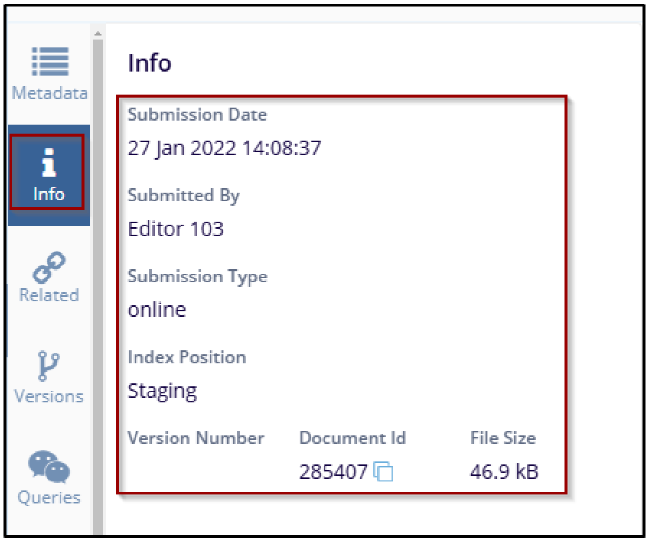


4. Click on the PDF icon to open a new window, The PDF opens in the window, allowing the user to navigate through the pages using the controls at the top (e.g., Print, Download, Page Navigation arrows, Zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide).

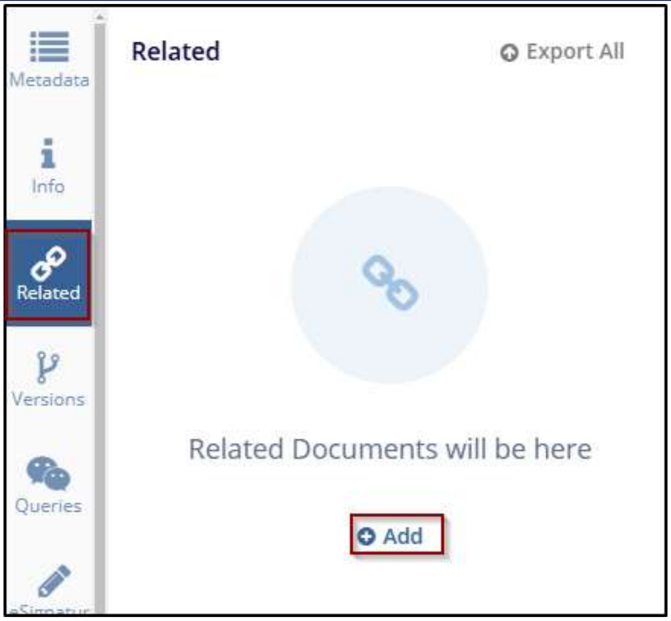


5. The metadata panel on the right side of the PDF window displays detailed document information, such as Document ID, Document name, submitted name, Metadata, Info, Related, Versions, Queries, signature, and History.
6. Click on the Metadata Tab.
   - Document Metadata holds metadata details as needed, select or modify the category, site, contact, and document type from the dropdown menus, fields marked with an asterisk (*) are mandatory
   - Add or update comments related to the document.
   - Save changes using the Save button or cancel to discard the changes.
   - Workflow History shows the last history record.

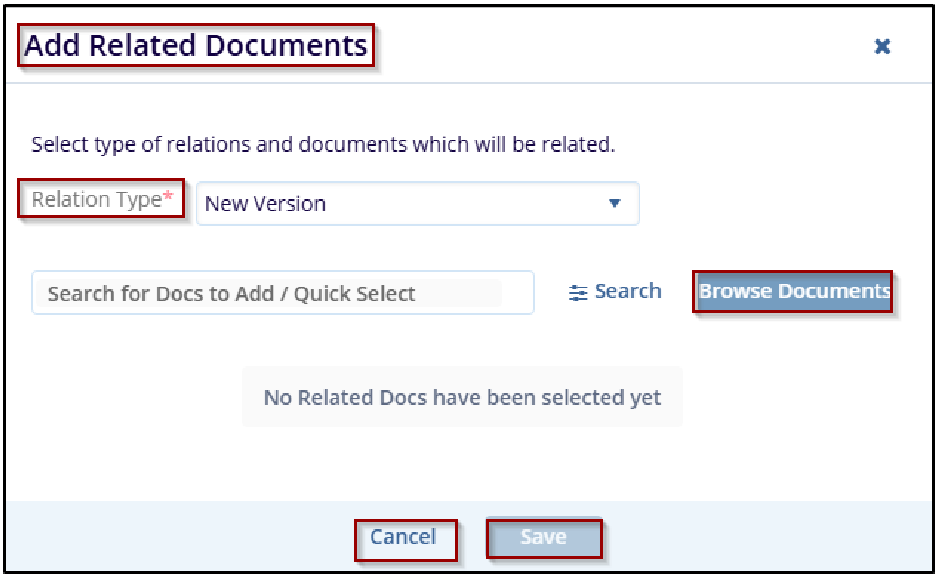
7. Click on the Info Tab to view the Submission date, Submitted by, Submission type, Index position, Version Number, etc.



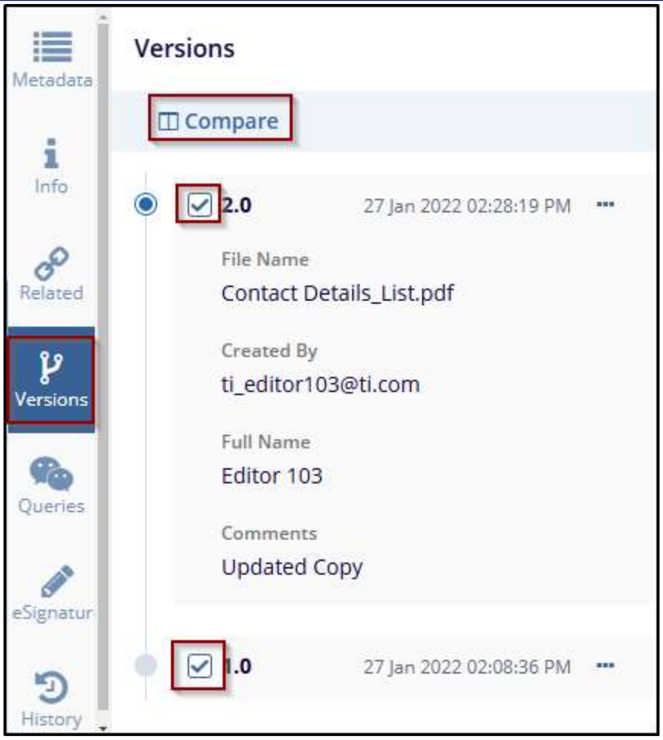
8. Click on the Related Tab and perform the following.
    - Click the + Add button to open a new window to add related documents.



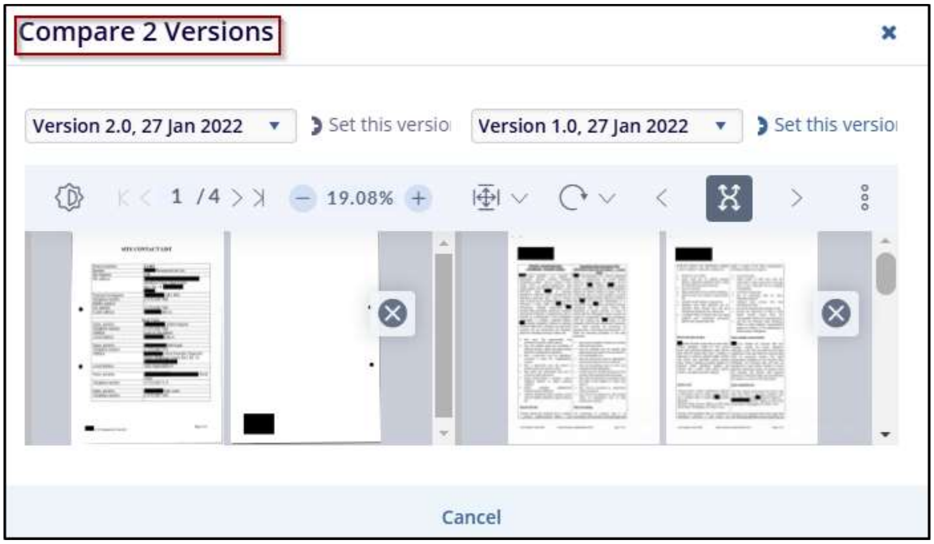
- From the pop-up window, select the relation type from the dropdown menu, and by clicking on the browser document, the document will be browsed from the document index folder and click on save to apply the changes or click the cancel to discard the changes.
- Use the Export All option at the top-right to download all related documents as a batch.



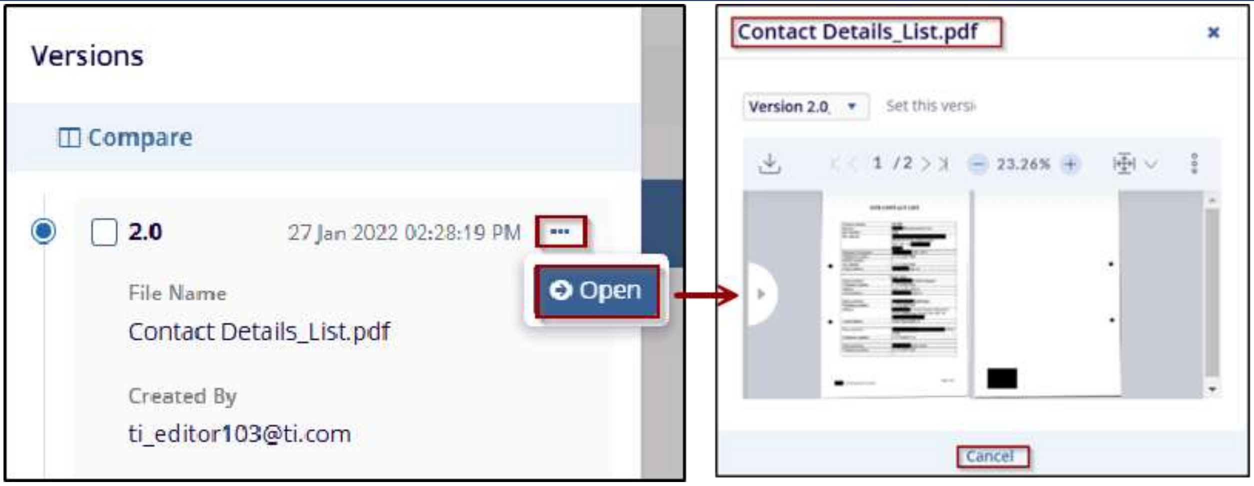
9. Click on the Version Tab and perform the following.
    - Check both the checkbox to select the version and use the Compare option to identify changes between both versions.



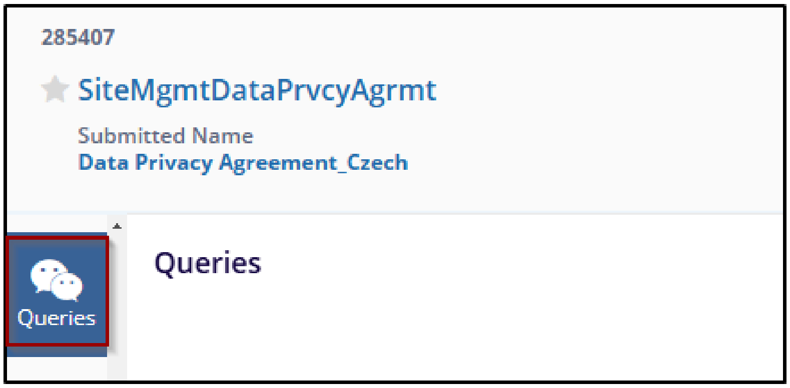
- Click the compare option to open a new Compare 2 Version window.



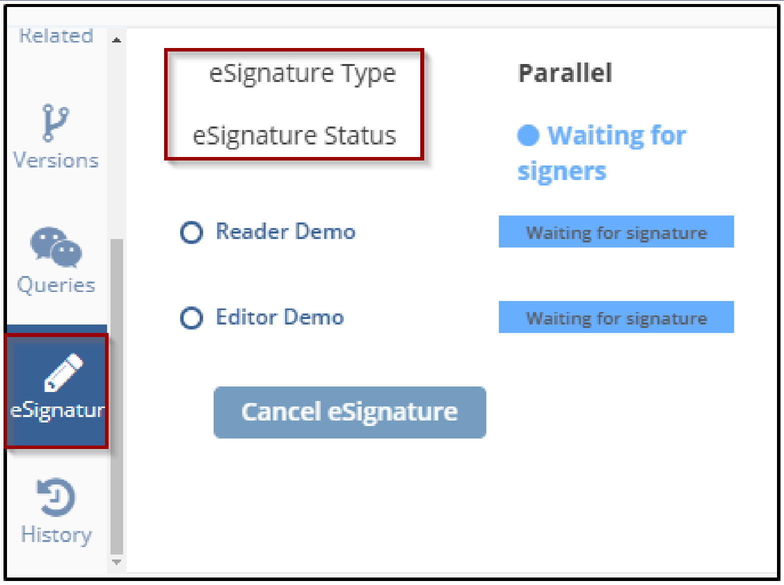
- Click on three dots (...) next to the version number gives the option to open the contact details PDF, and click the cancel to close it.



10. Click on the Queries Tab and it will address the document-related queries in this section.

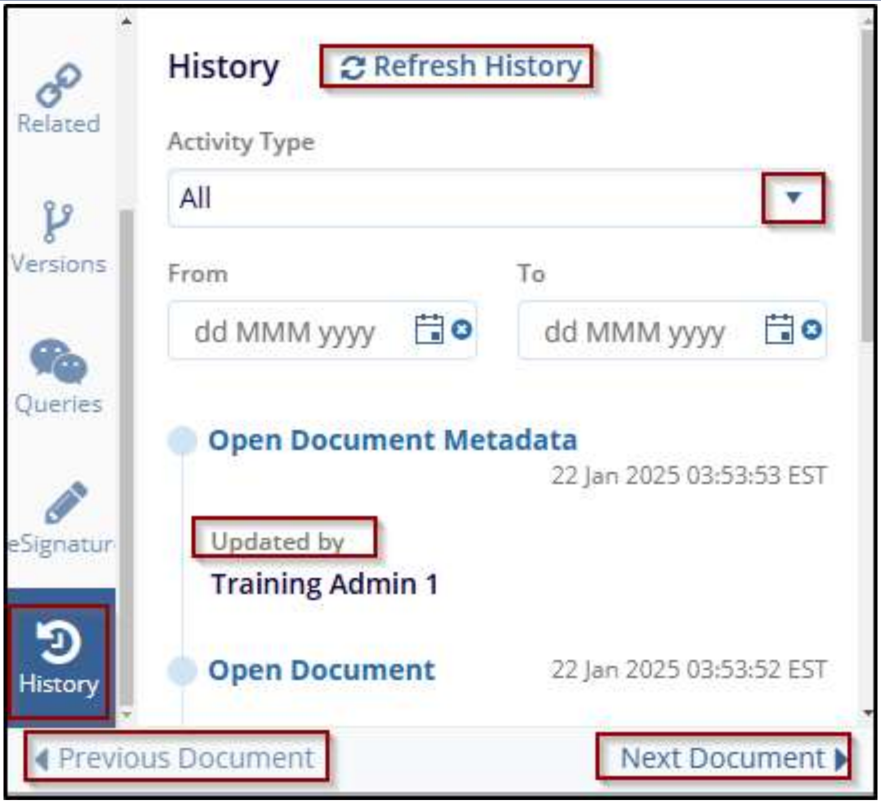


11. Click on the eSignature Tab.
    - The user can check and review the eSignature type workflow, and eSignature status.



- Click the Cancel eSignature button to stop the current eSignature process, a confirmation pop-up appears with the message: *'Are you sure you want to cancel the eSignature process?'*

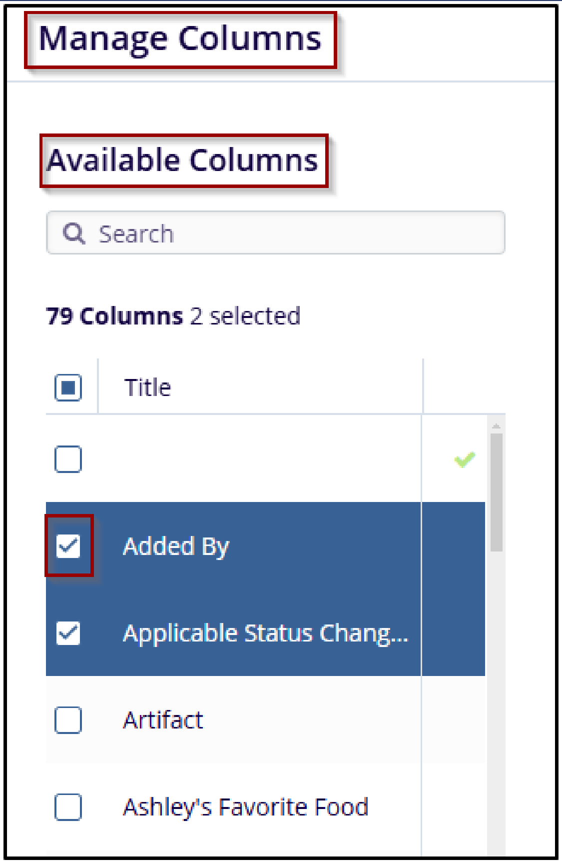
12. Click on the History Tab.
    - View the history of the document, that is updated by and with dates. The user can filter activities by Activity Type or specify a date range using the From and To fields. Use the Refresh History option to update the log with the latest actions.



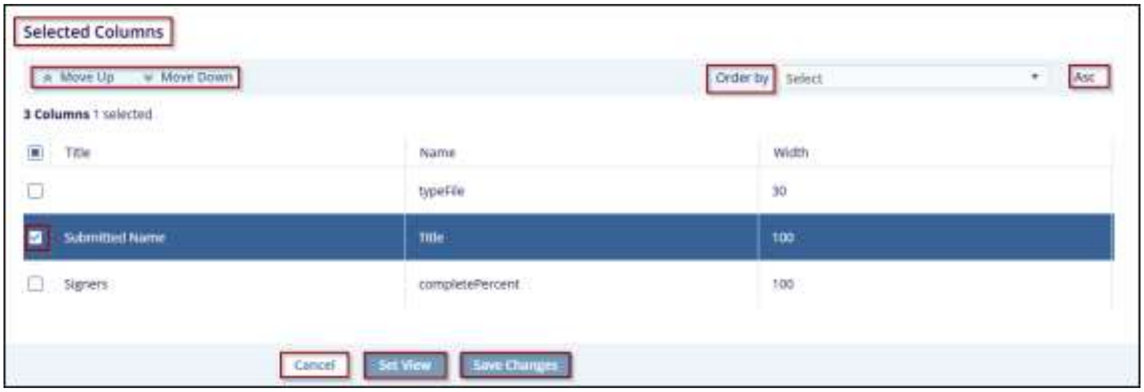
- Use the Previous Document and Next Document buttons to navigate to other documents in the queue or list.

13. To customize the columns displayed in the Document Dashboard, click the Manage Columns, and a new window will pop up.

14. On the left side of the manage column window, a list of Available Columns is used to add a title to the table.
15. Users can use the search bar to find columns. Check the checkbox available for the title that the user wants to add to their view.



16. In the Selected Columns section, the user can use the Move Up and Move Down buttons to reorder the columns in the selected list. For each selected column, the user can see its Title, Name, and Width.
17. Use the Order by dropdown menu to select a column for sorting the data. Choose whether the user wants the sorting to be Ascending or Descending.
18. After customizing the columns, click on Save Changes to apply the settings or the user can click Set View to apply and see the updated view. If the user wants to discard the changes, click on the Cancel button.
19. To set the current selections and order as the default view, click Set View. After finalizing the column selections and order, click Save Changes to apply them to the document view.



20. Once the changes are applied, the user can click the Refresh icon to refresh the Columns.

Submissions by Month

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

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

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

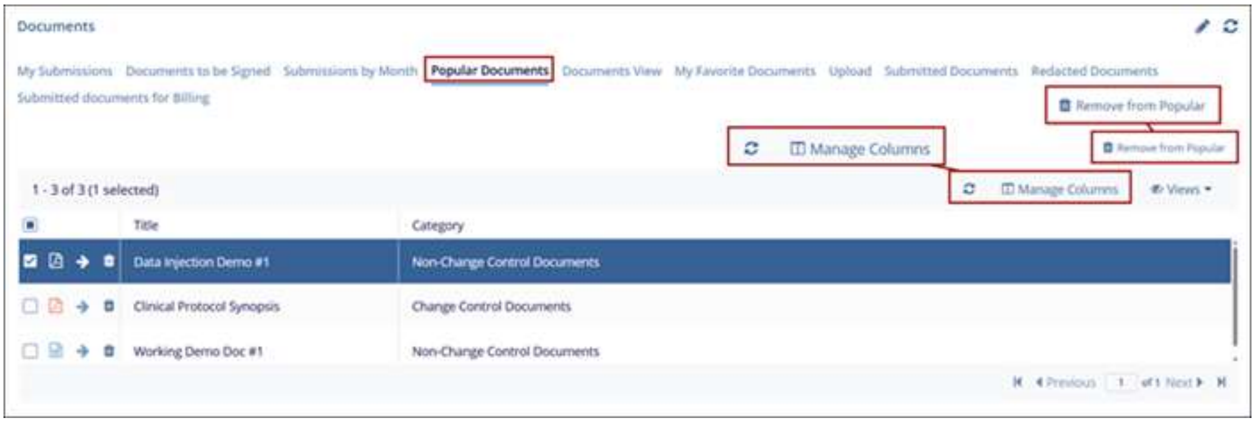
Popular Documents

In the Documents dashlet, 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.

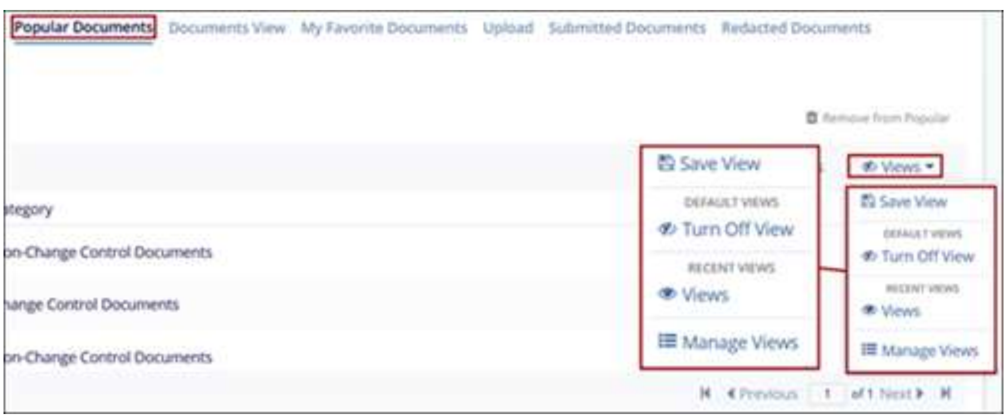
Steps to view and manage popular Documents:

1. Click the Popular Documents, next to Submissions by month.

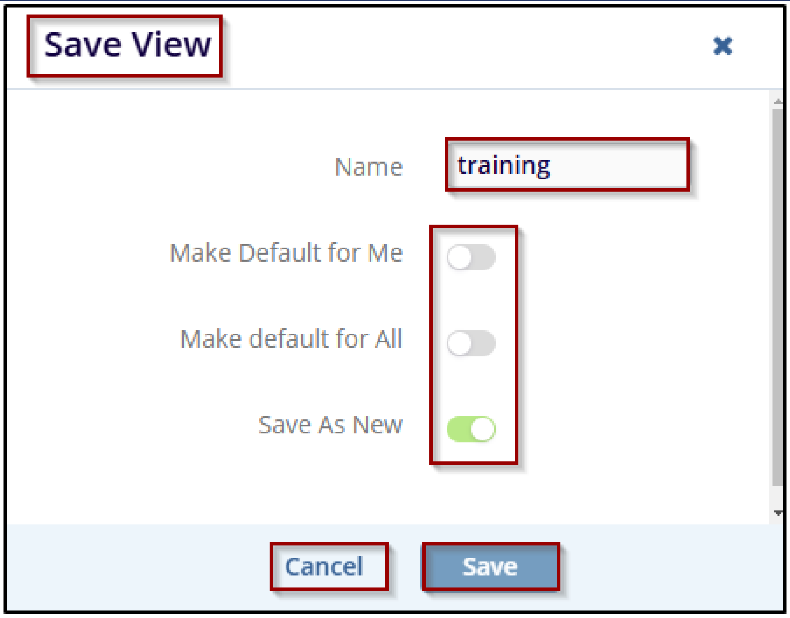
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
3. To remove a selected document from the Popular document list, click 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.



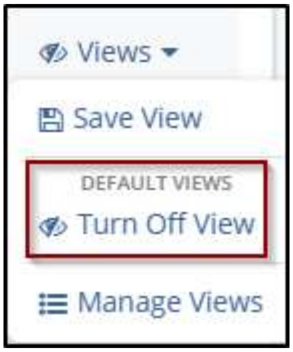
6. Use the Views option for saving views, managing and turning off customized views
7. Click on the Views Dropdown menu, next to the Manage columns. The user can see options Save View, Share View, Turn off View, Recent View, and Manage Views.



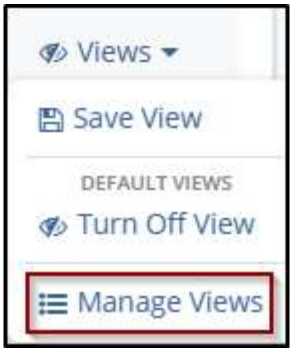
8. Click Save View from the dropdown menu, The Save Views window will pop up.
9. In the Save View window, enter a Name for view.
10. Make Default for Me: Toggle the switch to make this view the default for the user.
11. Make Default for All: Toggle the switch to make this view the default for all users.
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.

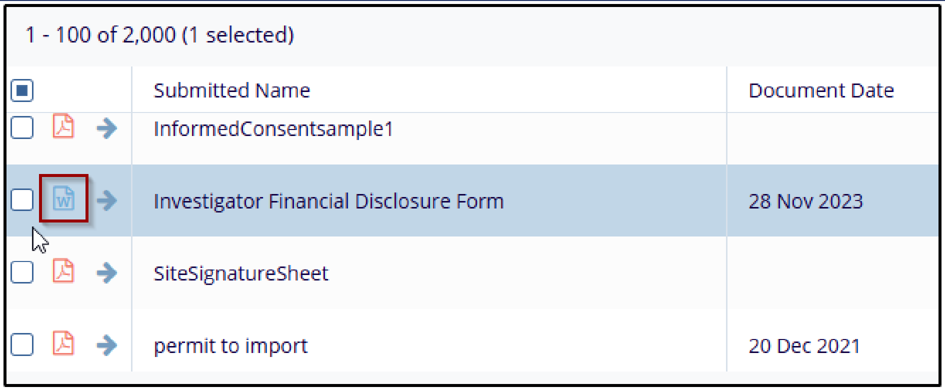
Documents View

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

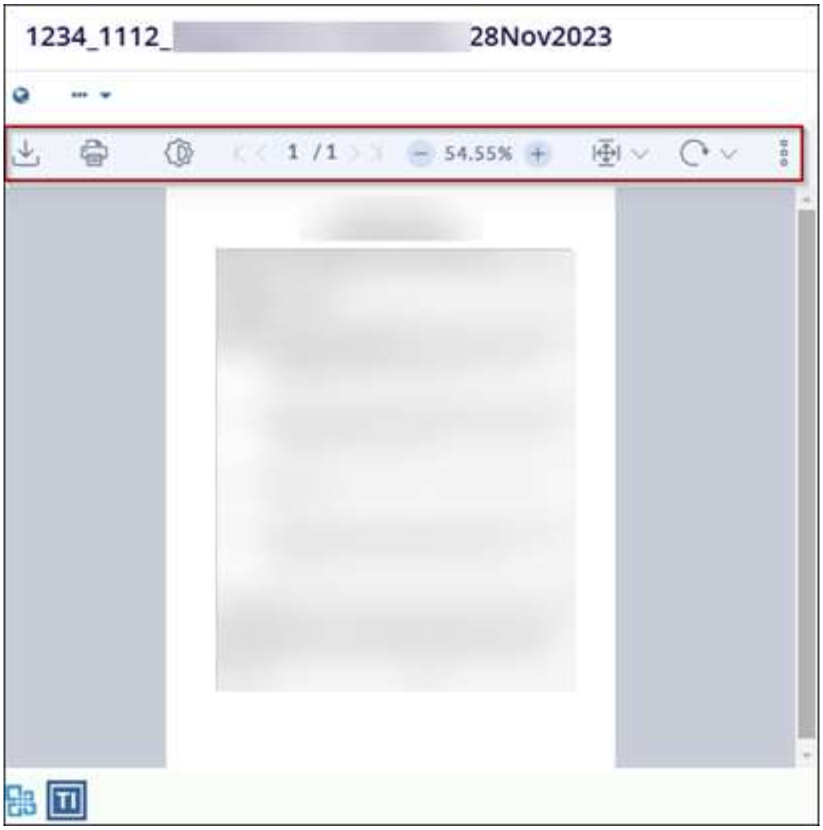
Steps to review documents view:

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.

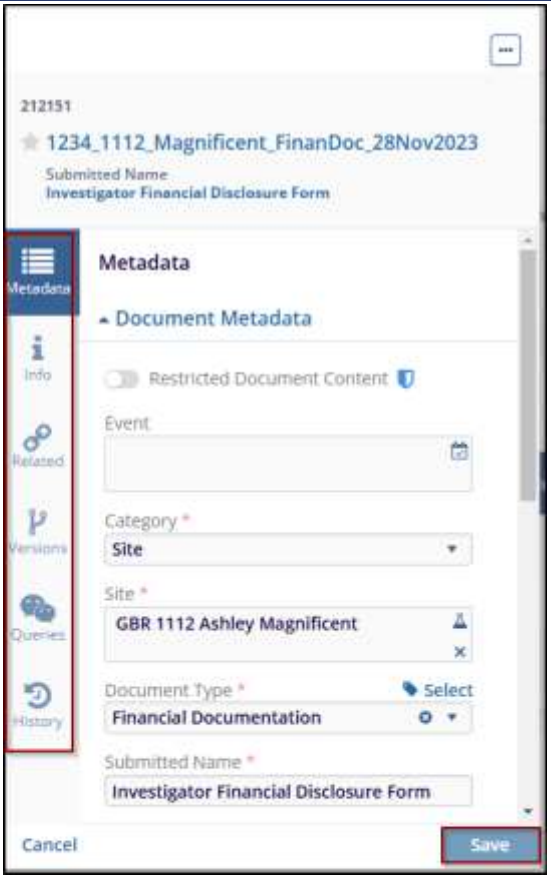
5. Clicking on the Word icon and the Word file will open with the TI document viewer.



6. Perform various actions, such as (Print, download, Page navigation arrows, Zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide).



7. Within the Metadata panel, access the Info, related, version, queries, and history sections, make any necessary changes, and click Save to apply the changes.



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.

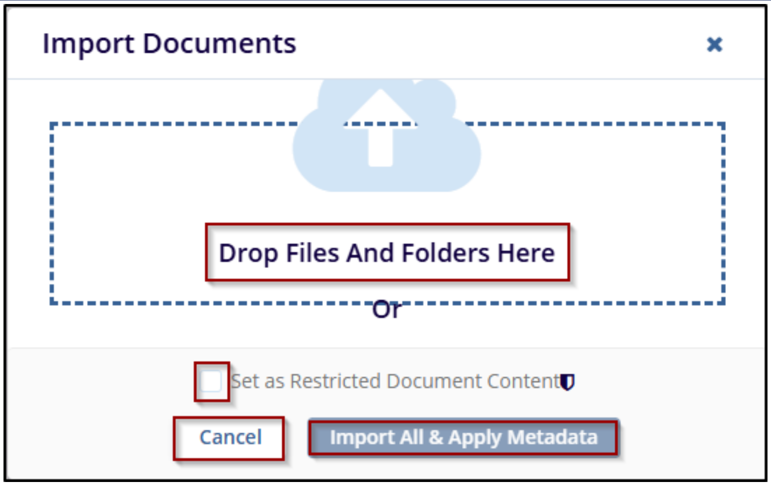
Upload

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.

2. 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.
3. After selecting the files, the user can set them as Restricted Document Content by checking the box if necessary.
4. Once files are ready, click Import All & Apply Metadata to complete the upload process or click Cancel to discard the changes.



My 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

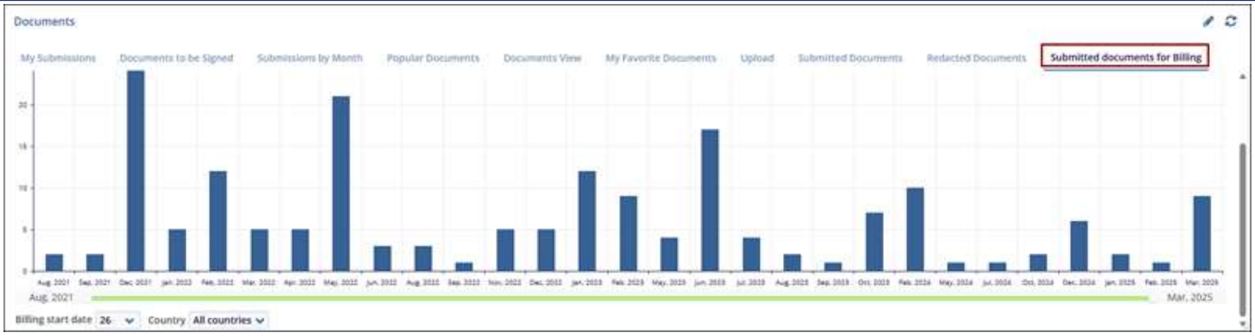
The Redacted Documents dashboard shows a set of documents that have undergone or are undergoing redaction, a process where sensitive or confidential information is removed from documents before they are shared or published.

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.

Submitted Documents for Billing

The Submitted Documents for Billing dashlet displays the number of submitted documents within the date range starting from the 26th to the 25th of each month, by default. Additionally, users can filter document submissions by specific countries, including site-level documents for those countries.


Documents
My Submissions
Documents to be Signed
Submissions by Month
Popular Documents
Documents View
My Favorite Documents
Upload
Submitted Documents
Redacted Documents
Submitted documents for Billing
Aug. 2021
Mar. 2025
Billing start date
26
Country
All countries

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.

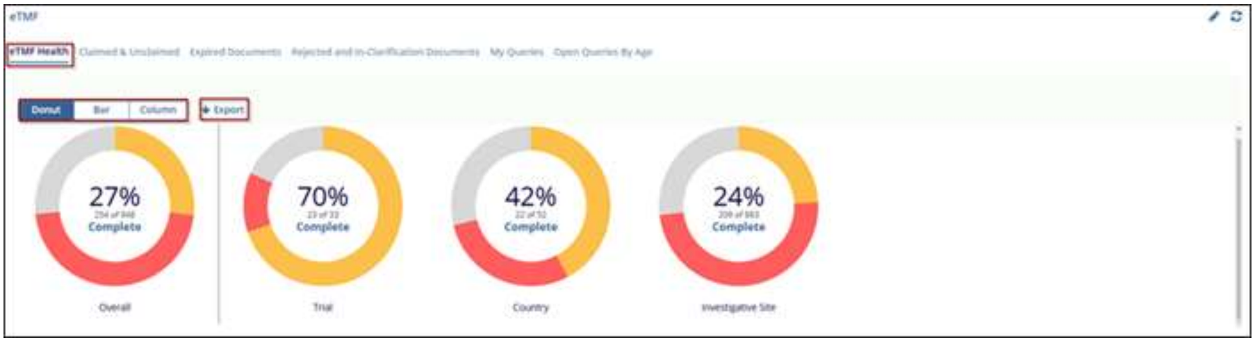
It includes the following tabs:

eTMF Health

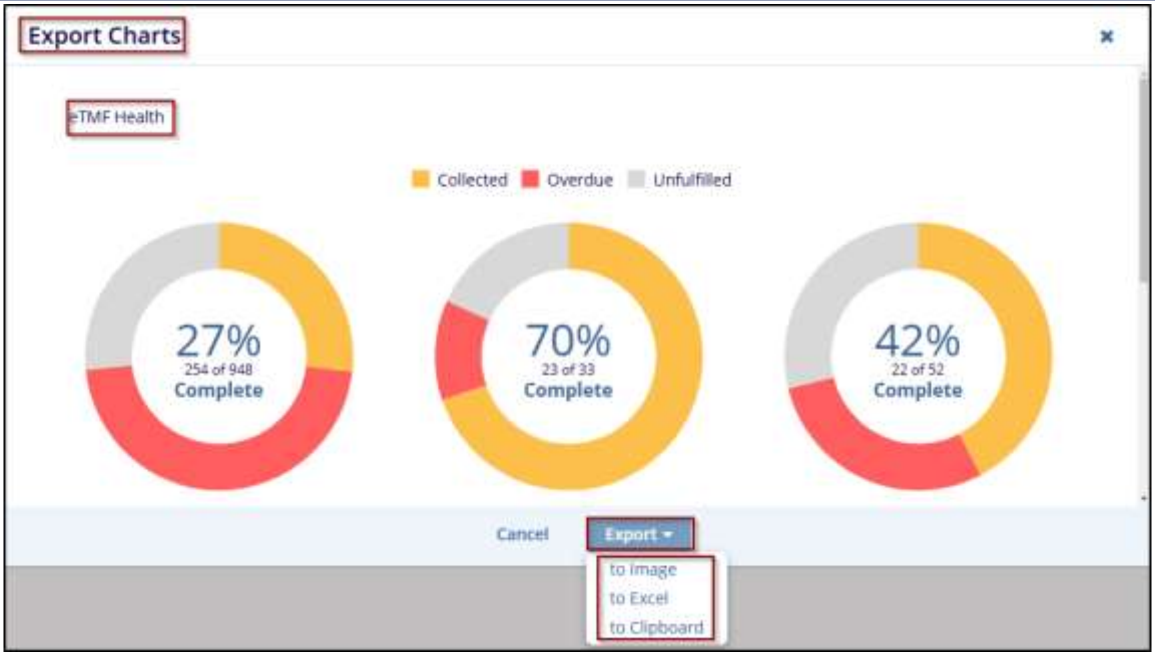
The eTMF Health tab provides an overview of the overall health and progress of the trial master file. It helps monitor the completeness and compliance of documents in different stages of the clinical trial by visualizing key metrics such as the percentage of completed documents in categories such as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

In the eTMF dashboard, Claimed & Unclaimed sections 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.

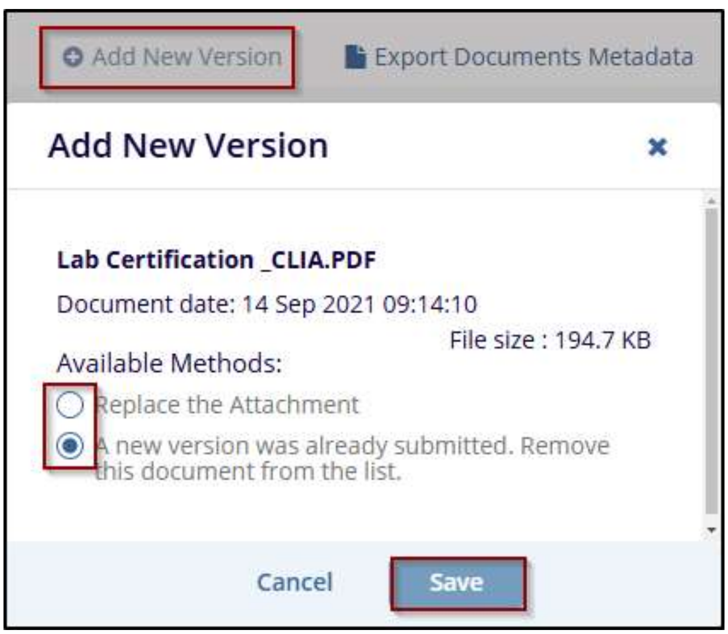
Expired Documents

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:

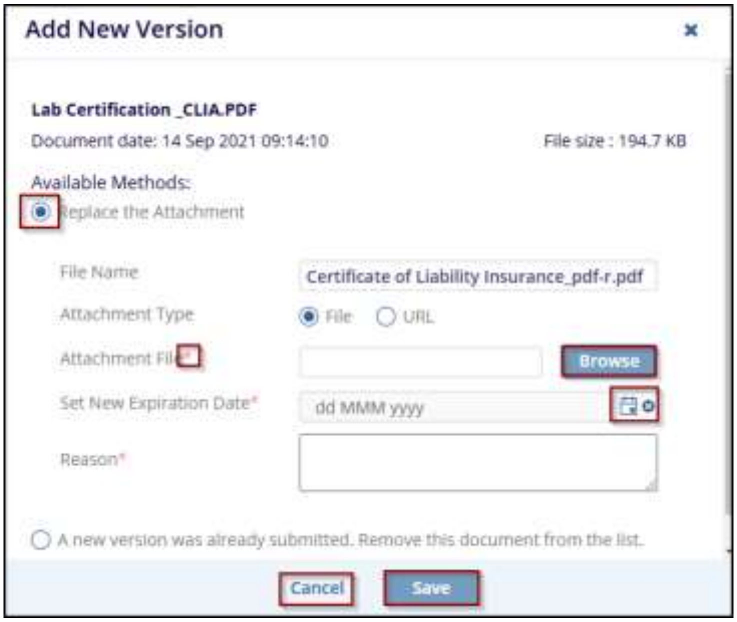
1. Navigate to the eTMF dashboard, and select the Expired Document tab.
2. The user can apply the filter to view Expired or Expiring documents. Select the option to focus on documents that are already expired or those approaching expiration.
3. Check the checkbox next to the blue arrow and click the +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.

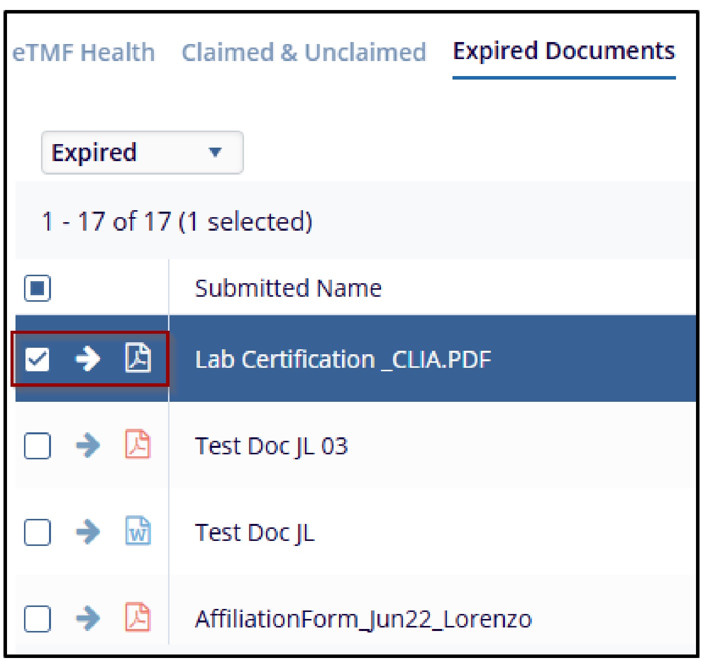


5. The options available are configurable by the room administrator in the Settings area.
6. If Replace the Attachment is chosen, click the Browse button and locate the new version of the file.
7. Set the new expiration date, and give the reason for the replacement in the comment box.

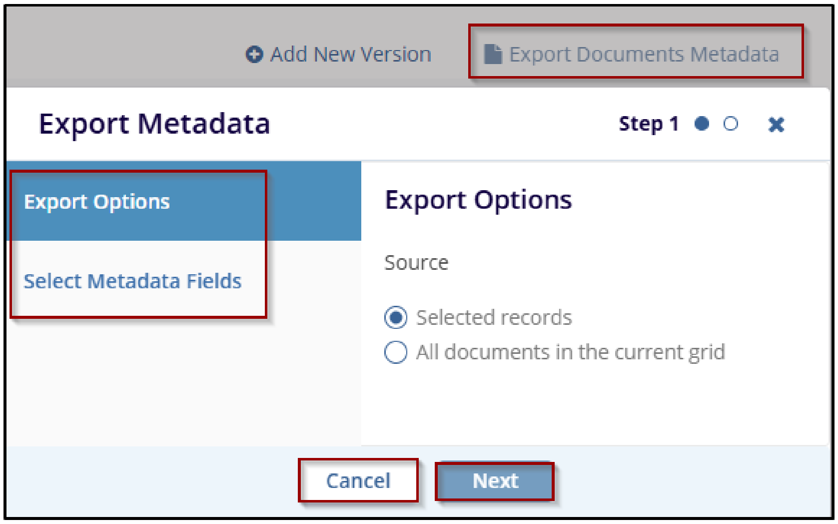
8. If the ‘A new version was already submitted. Remove this document from the list. Nothing else needs to be done. The document will be removed from the list of expiring documents.
9. Press Save to save the changes or click Cancel to discard the changes.



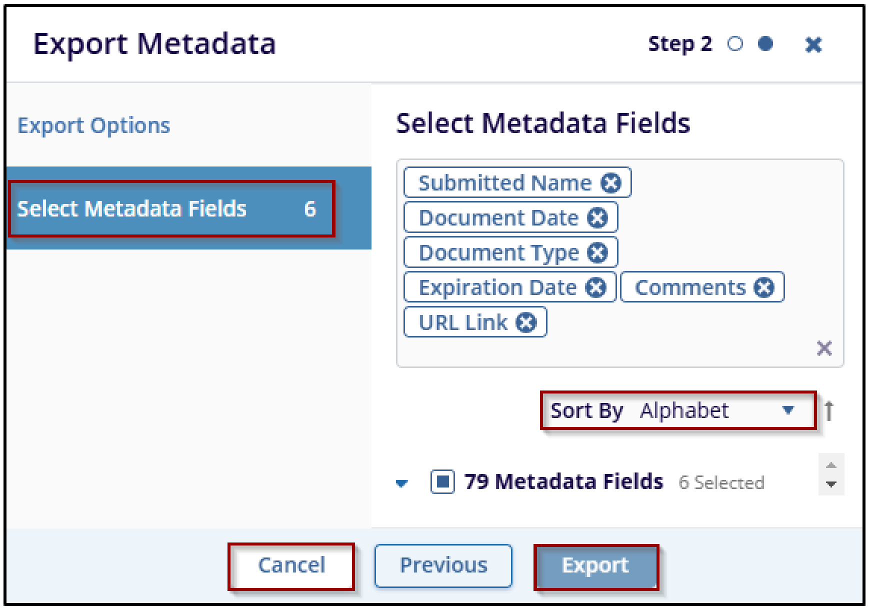
10. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
11. Click on the PDF icon will open a new window, The PDF opens in the 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, if the user wishes to go back click on the Previous button or click Cancel to discard the changes.



Rejected and In-Clarification Documents

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:

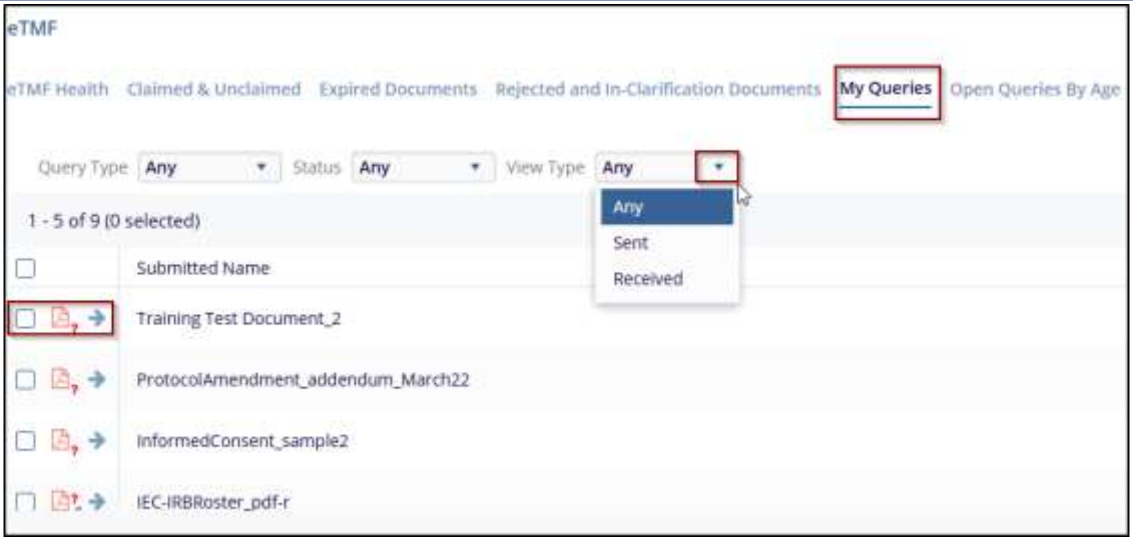
1. Navigate to the eTMF dashboard, and select the Expired Document tab to view the list of documents associated with a specific rejection or clarification reason.
2. Click on the + sign next to the reason will expand the section, and reveal individual documents, including details such as the Submitted 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

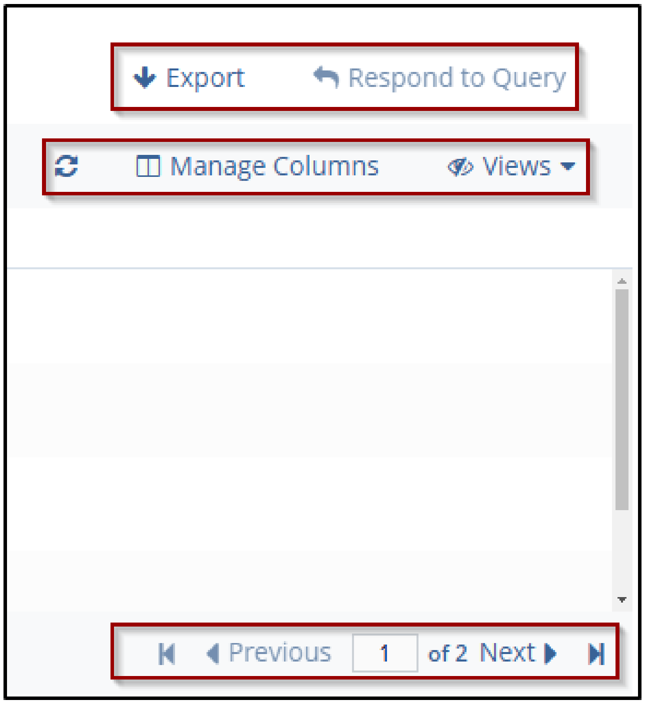
My Queries in the eTMF allows the users to view and manage queries related to the documents they are working on. Queries could be either sent (by the user to someone else) or received (from others to the user). This helps to track the status of queries and allows the user to take actions such as responding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

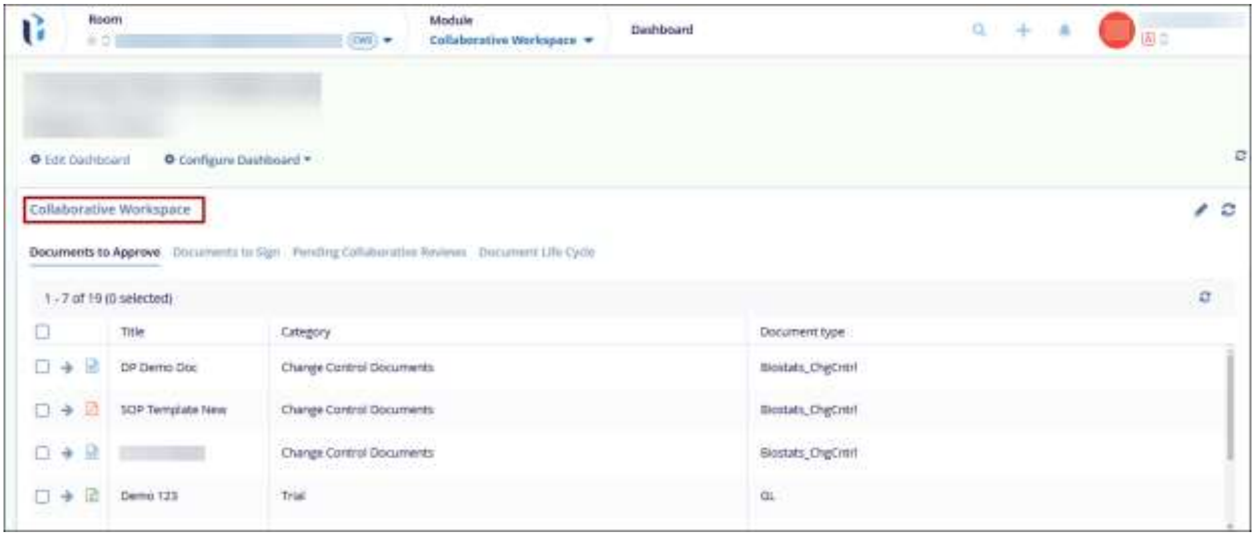
1. Navigate to the eTMF dashboard, and select the Open Queries by Age tab.
2. Use the Query Type dropdown to filter the queries:
    - Select Any to view all queries.
    - Choose Workflow to see the action related to a specific workflow process.
    - Choose Audit to show only those that are related 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.

Collaborative Workspace

The Collaborative Workspace group of dashlets is exclusive to TI Collaborate rooms and includes dashlets that provide users the visibility and access to documents required to be approved and electronically Signed. Additionally, users get clarity on the pending collaborative reviews and the document life cycle.

To access the Collaborative Workspace dashlets, follow the steps below.

1. Login to a Collaborate room or select the Collaborative Workspace module from the Modules dropdown.
2. Navigate to the bottom of the Dashboard page to access the Collaborative Workspace dashlet.



Users can access the following dashlets exclusive to the Collaborative workspace.

Documents to Approve

The Documents to Approve dashlet displays a list of documents that require users' approval. If the user belongs to a pool of approvers of the same level, documents may be approved without user intervention.

To access the documents to approve, select the document and click on the arrow to open the documents in the document view.

Documents to Sign

This dashlet shows a list of workflow documents awaiting the user's signature in TI. Some documents may require serial signatures and will only appear once it is the user's turn to sign.

To access the document for signature, select the document and click on the arrow to open the document signature interface, which utilizes the implemented signature engine (TI Sign, Adobe Sign, etc.)

Pending Collaborate Reviews

This dashlet displays all documents that are currently open in Team Edit mode for collaborative review by the current user.

Users can choose to view the documents pending review for All users (default) by selecting the All Open Reviews option. Additionally, users can select the My Pending Reviews option to view documents only for themselves.

To access the documents pending collaborative review, click on the arrow to open the Collaborative Review tab from the documents metadata panel.

Document Life Cycle

This dashlet displays documents based on their review status. Users can select a review status from the dropdown options and view documents in that particular status. For example, documents in the below-mentioned review status can be filtered and displayed.

- Any
- Pending
- Review In Progress
- eSignature Requests
- eSignature in Progress
- eSignature Completed
- Rejected
- Approved
- Effective
- Periodic Review Required
- Periodic Review Overdue
- Periodic Review in Progress
- Obsolete

Common

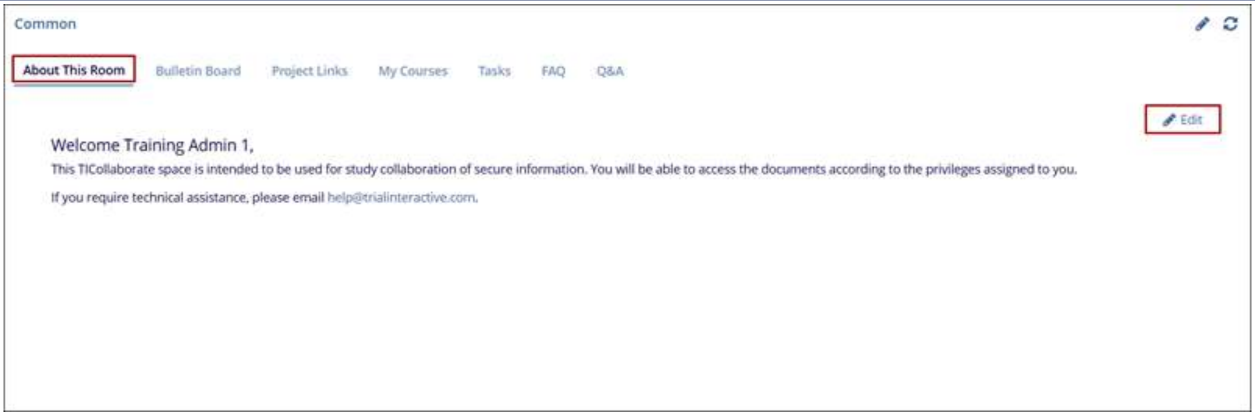
The users can view and modify the room's Welcome message, which is displayed to all users upon accessing the room. This message area serves as a space for sharing essential information about the study, such as updates, reminders, or key details. Only users with Administrator or Manager access can edit 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. 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.
4. Update the text with any new information or instructions, as needed.



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.
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 etc.

3. If the user working on a task, update the status to reflect the 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 the review of questions.

DOCUMENTS LIBRARY

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

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

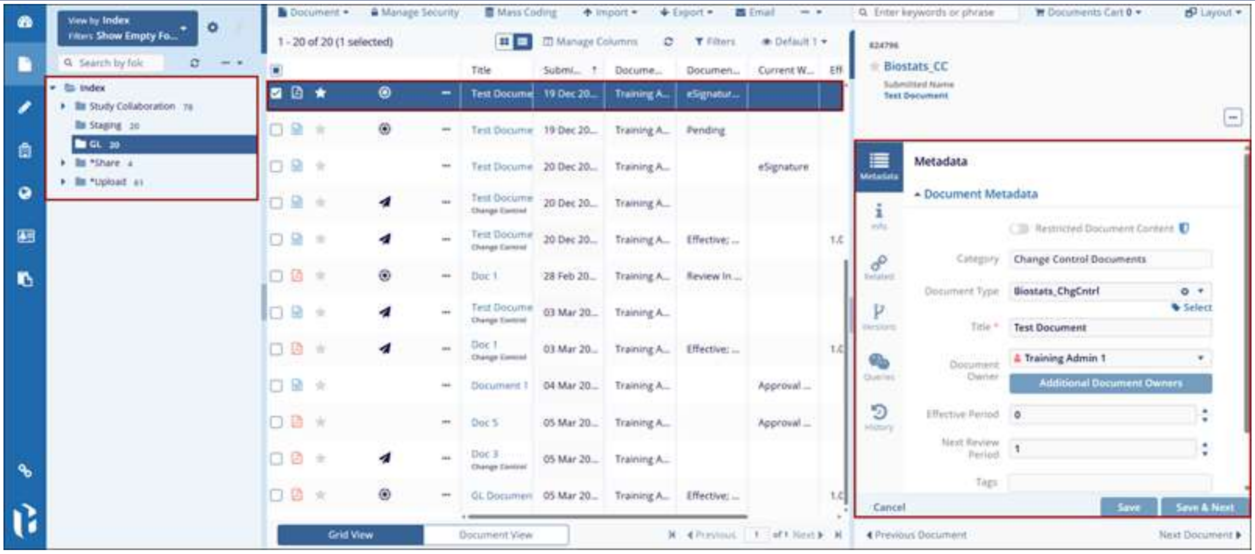
To comply with eTMF Completeness, users can track the progress right from the document.

To access the documents library modal, follow the steps below.

1. Select the Collaborative Workspace module from the Module dropdown.
2. Click on the Documents modal from the left-hand navigation menu.

The Room Index

The Room Index is structured as a tree-like system, with the Index as the root folder. It consists of parent and child folders, which can either be cloned during room creation or created from scratch. Each Trial Interactive room can have a completely customized index structure, as no two index configurations are necessarily identical. Documents emailed to a room's inbox address are stored in each user's Inbox folder unless the room is configured otherwise. Documents uploaded directly to the room without metadata appear in each user's Upload folder, while those uploaded with metadata are placed in the default folder location, typically the Staging folder. Depending on room configuration, documents can also be uploaded directly to other index folders. If a folder contains subfolders, clicking the arrow next to the folder or double-clicking it will expand and display the child folders. Similarly, an expanded folder can be collapsed by clicking the arrow next to it. Viewing documents within a folder requires selecting the folder, which then displays the stored documents in the documents grid at the center of the screen. Selecting a document from the grid loads its metadata in the Metadata Pane on the right side of the screen. In addition to the Metadata tab, the Metadata Pane may also include Workflow, Queries, Versions, History, and eSignature tabs, depending on the document's context.



Configuring the Index Structure

The index structure of a room will be cloned from an existing room or a client-specific template room. Normally, any changes to the standard layout would be indicated in the configuration manual and addressed before the room is used. However, administrator-level users can make changes to the room index structure.

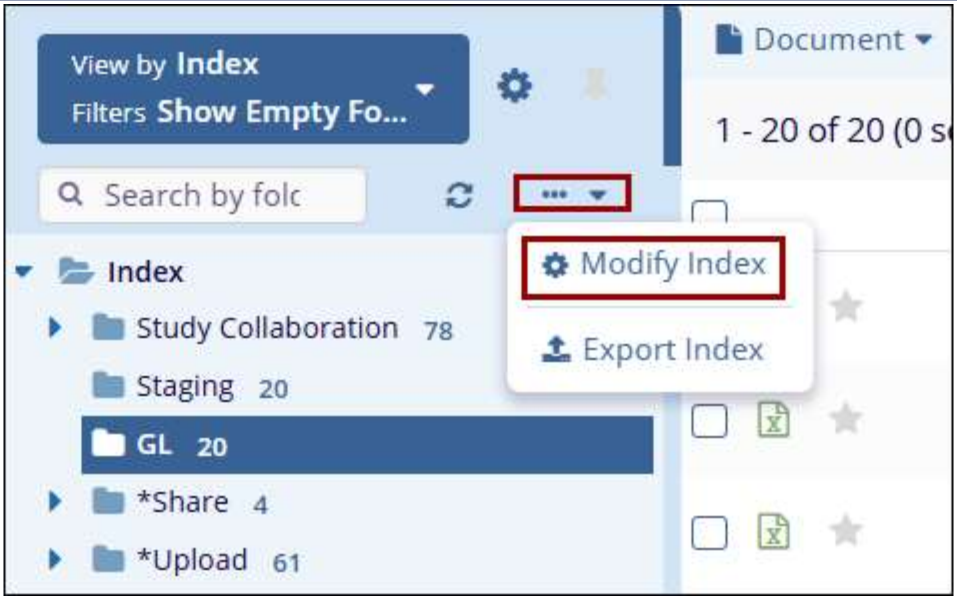
Note: It is recommended to be fully trained by a Trial Interactive Product Trainer to ensure the changes need to be made. Deleting a folder containing documents will immediately delete all of the documents within. It is highly recommended that to work with the Trial Interactive Service Desk if to make any alterations to the index structure of a study room.

Add New Folders

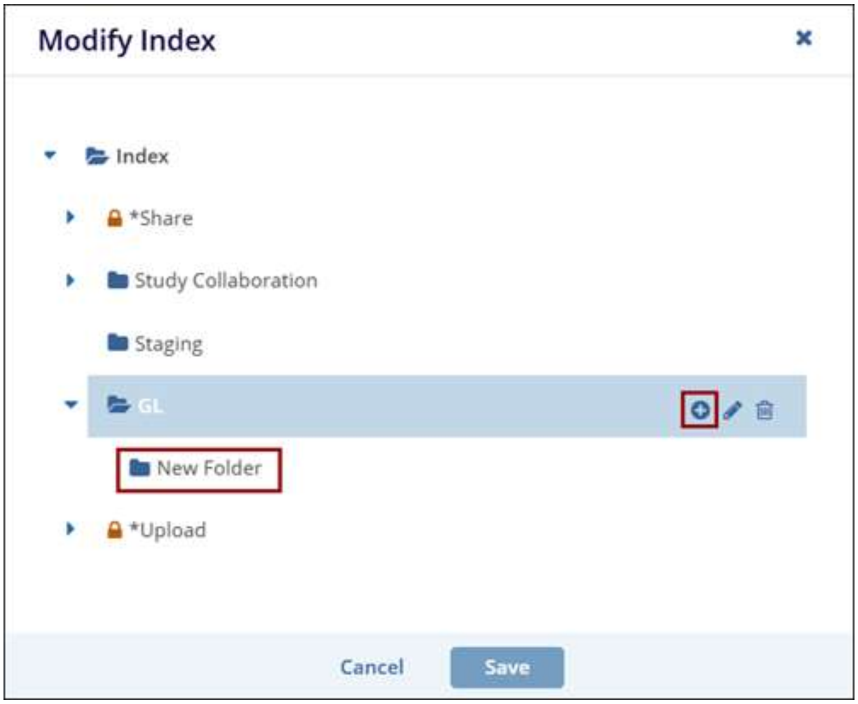
Administrator-level users can add new folders to the index structure of the documents module from the Index pane. There is a three-dot menu under the view selector menu.

To add new folders, follow the steps below.

1. Click on the three-dot menu and select the Modify Index option from the dropdown options. The Modify Index window opens.



2. Hover over the parent folder, or hover over the index to create a new sub-folder, and click the + icon to add a new folder.
   Note: The index structure may appear different from the one shown in the image above since index structures can be customized on a room-by-room basis.
3. When the folder is created, name the folder and press the Enter Key to save the name.
4. Perform any other desired index modifications and click on the Save button.

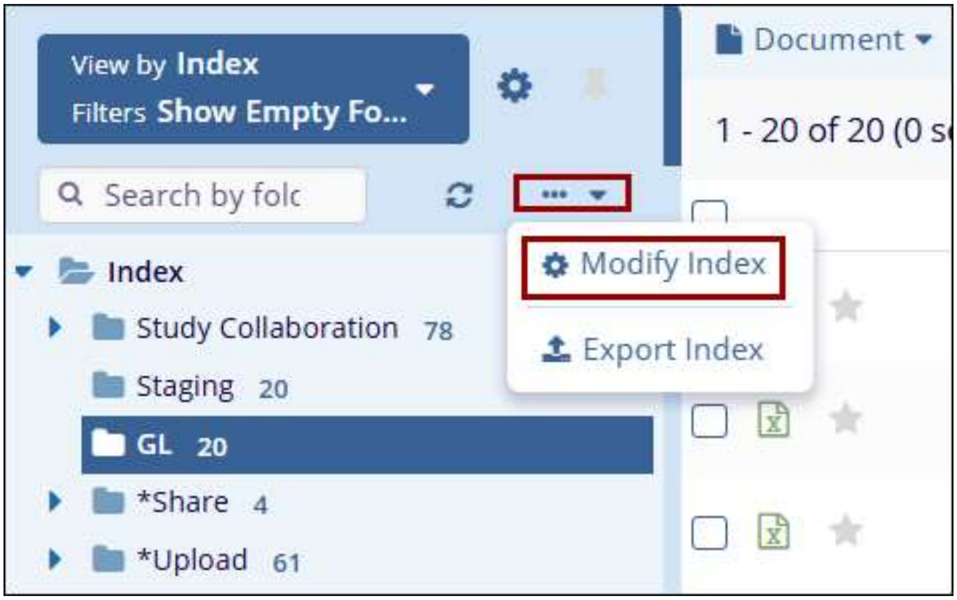


Edit or Delete an Existing Index Folder

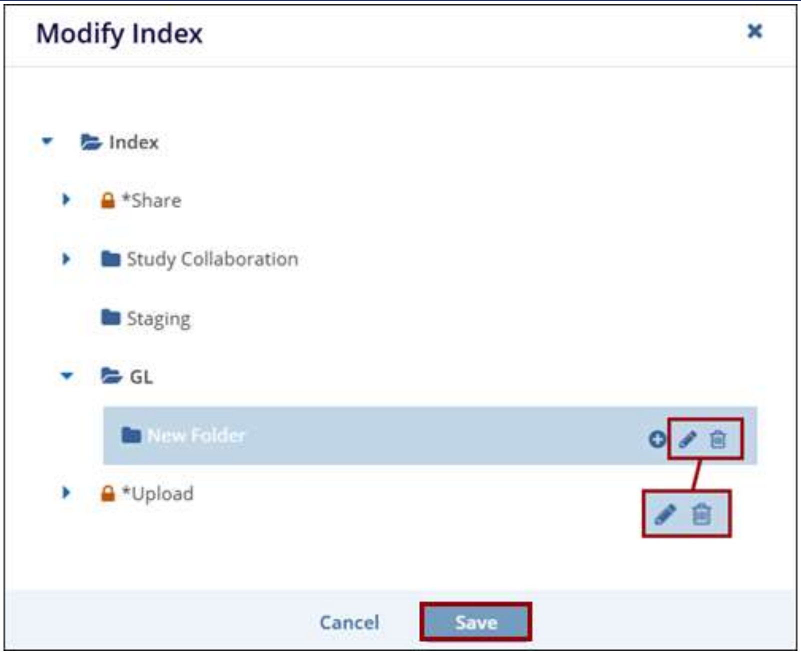
Administrator-level users can delete or edit the names of existing folders to the index structure of the documents library module from the Index pane by accessing the three-dot menu under the view selector menu.

To edit or delete an index folder, follow the steps below.

1. Click on the three-dot menu and select the Modify Index option. The Modify Index window opens.



2. Click on the edit (pencil) icon and modify the folder name.



3. Click on the Delete icon and confirm the folder deletion by clicking on the OK button on the Folder Deletion confirmation popup.

4. Perform any other desired index modifications and click on the Save button.

Note: It is recommended to be fully trained by a Trial Interactive Product Trainer to ensure the changes need to be made. Deleting a folder containing documents will immediately delete all of the documents within. It is highly recommended that to work with the Trial Interactive Service Desk if to make ANY alterations to the index structure of a study room.

Edit Country and Site Level Folders

The country and site-level folders are greyed out and are not editable from the Modify Index window. These folders are controlled by the template folder settings.

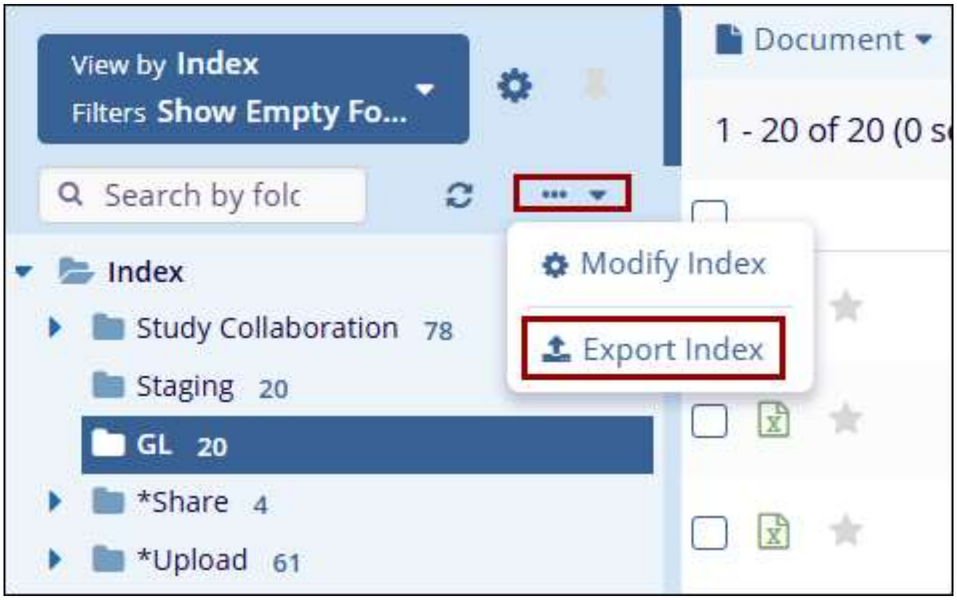
Note: Refer to the Countries Template Folder and Site Template Folder settings from the Settings module.

Exporting the Index Structure

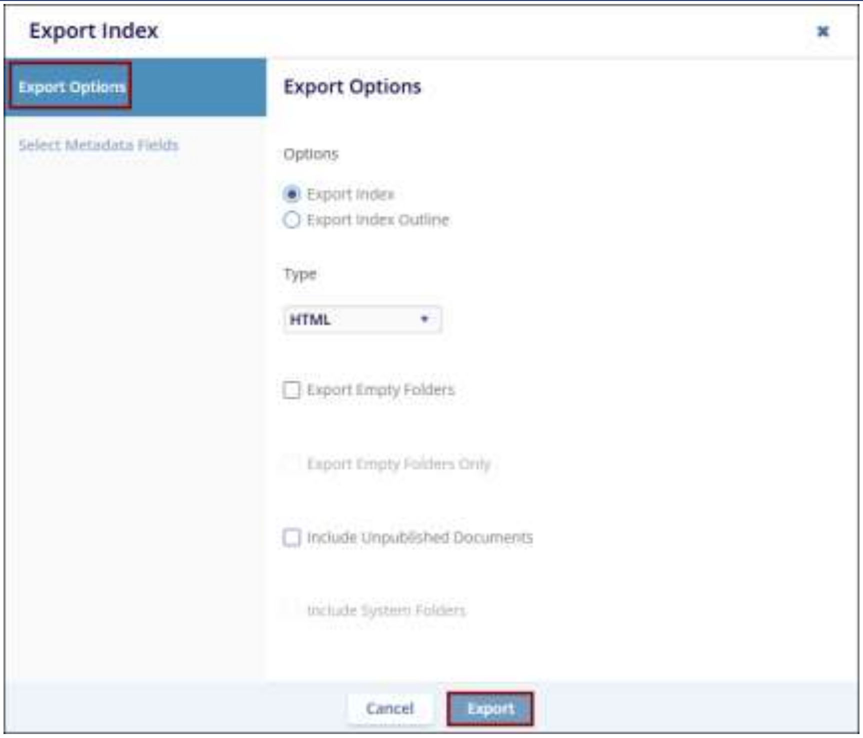
Export index allows to export the index structure of the room. Users can choose to export the index for the chosen folder or only the index outline. The index can be exported in either HTML, Microsoft Excel or Microsoft Word format. Besides these, users can also choose to export empty, or system folders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

To export the index, follow the steps below:

1. Click on the three-dot menu and select the Modify Index option from the dropdown options. The Export Index window opens.



2. On the Export Index window, perform the following.
    1. Select Export Index or Export Index Outline by clicking on the radio buttons.
    2. Select HTML, Microsoft Excel, or Microsoft Word from the Type dropdown options.
    3. Click on the Export Empty Folders checkbox to retrieve empty folders as well.
    4. Click on the Export Empty Folders Only checkbox to retrieve just the empty folders.
    5. Click on the Include Unpublished Documents checkbox to retrieve unpublished documents.
3. Click on the Export button.



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

5. On the Job Result window, click on the Export Results link.

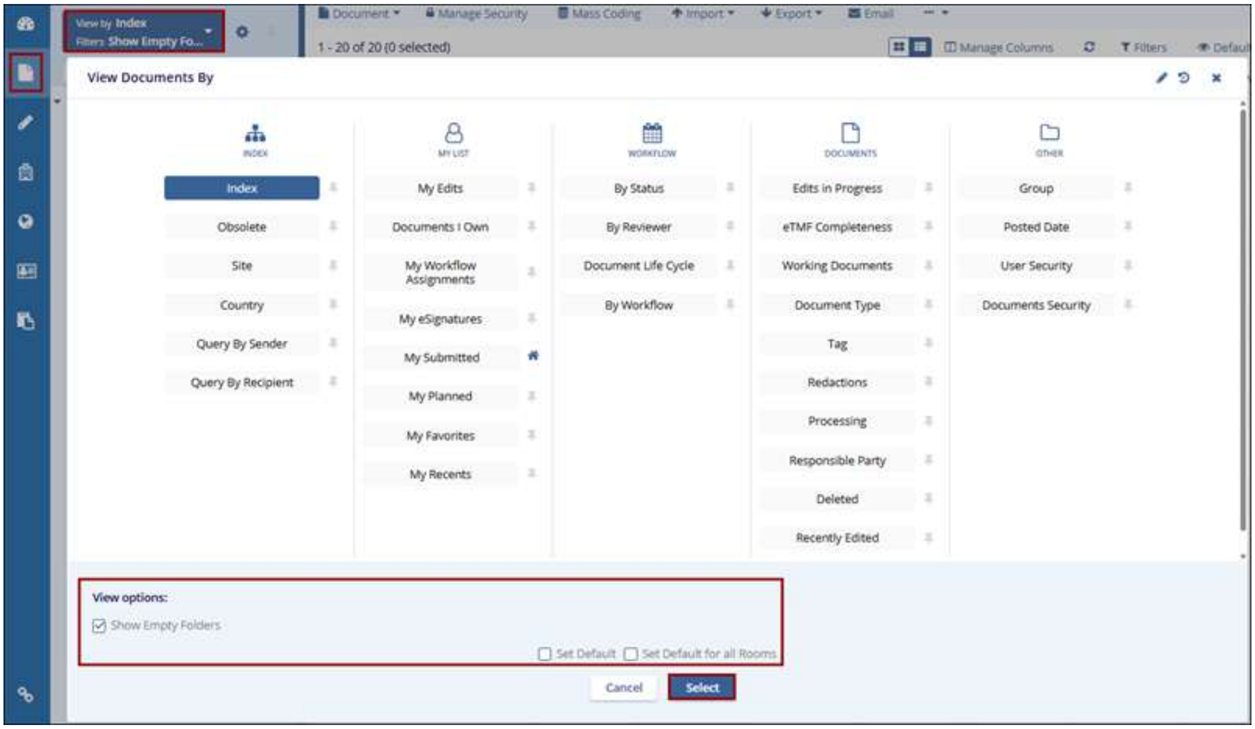
Views

The Views functionality enables users to customize the left-hand navigation pane in the Documents module and select documents based on specific categories.

Apply a View

To access and apply different views, follow the steps below:

1. Open the Documents Library modal from the left-hand navigation pane and click the View By dropdown. The index view is applied by default.
2. On the View Documents By screen, choose a view from the available categories.
3. Click the pin icon to pin a view if needed.
4. Use the View Options to customize the selected view.
5. Click on the Select button once, the require view and view option is selected.

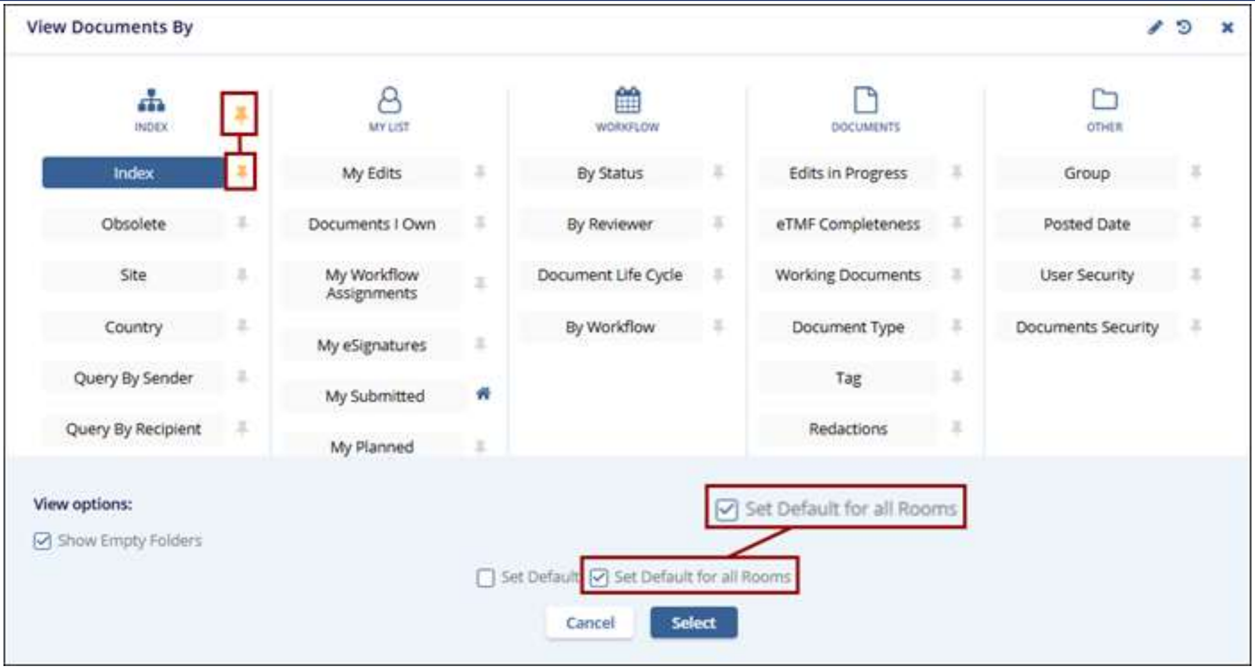


Note: View Options differ based on the view selected.

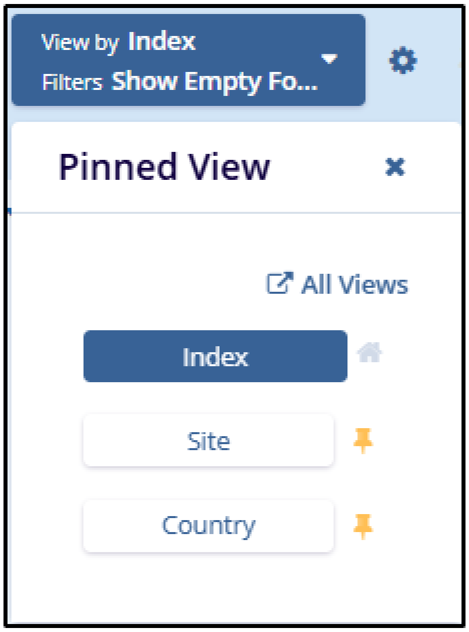
Pin and Set Default View

To pin and set a default view, follow the steps below.

1. Select a view and check the Set Default for all Rooms checkbox to make that view default across rooms.



2. Click the pin icon to pin the view. Pinned views appear in the View By dropdown. To view all available options, click the All Views button.

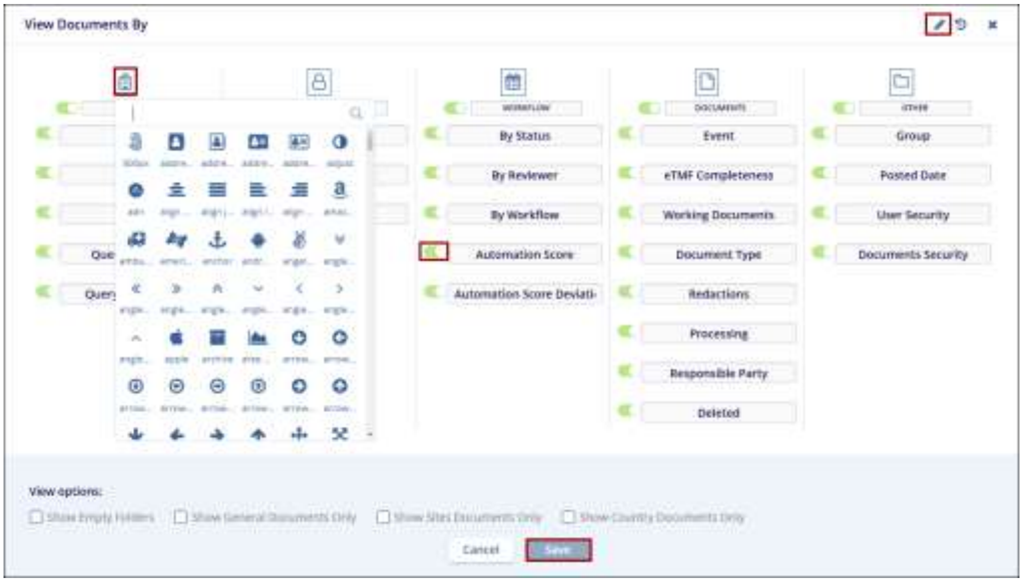


Edit View Documents By screen

To edit the View Documents By screen, follow the steps below.

1. Open the View Documents By screen and click on the Edit icon.

2. Click on the Group Name icon and select an icon from the available list to have a different icon for the group.
3. Enable or disable the toggle switch of a Group Name and View Name to control their visibility.
4. Modify the Group or View Name if required.
5. Click on the Save button once all the changes are made.



6. Click on the Change Log icon to view the Change Log History.

View Descriptions

Each view is organized into different groups.

- Index: Displays all documents in the room based on their index location.
- Obsolete: Displays all documents that are marked as obsolete.
- Site: Shows documents organized by their site association.
- Country: Displays documents grouped by their country association.
- Query By Sender: Organizes queries by the sender. Users will see different queries depending on their access level. Administrators can view all queries in the room or

choose to see only their own. Other users will only see their queries unless granted additional privileges.

- Query By Recipient: Organizes queries by the recipient. Depending on the user's access level, administrators can view all queries or choose to see only their own, while other users will only see their queries unless granted additional privileges.
- My Edits: Organizes documents by Team Edit, Online Edit, Offline Edit, and Overdue.
- Documents I Own: Organizes and displays documents bifurcated by the folders where the user has uploaded documents.
- My Workflow Assignments: Displays documents organized by workflows that the user is a part of.
- My eSignatures: Displays documents requiring eSignature, allowing users to perform eSignature-related functions.
- My Submitted: Shows documents that the user has submitted or uploaded.
- My Favorites: Displays documents marked as favorites by the user.
- My Recent: Organizes and displays documents based on the recently accessed documents by the user.
- By Status: Groups documents by their Change Control and Administrative QC Workflow Assignments.
- By Reviewer: Shows documents currently claimed by QC workflow personnel. Administrators can reassign claimed documents to other reviewers.
- Document Life Cycle: Categorizes documents by their current state in the life cycle of the document processing.
- By Workflow: Organizes documents by their workflow association.
- Edits in Progress:
- eTMF Completeness: Organizes documents and placeholders by the related entity (e.g., Study, Countries, Sites, or IRB/EC).
- Working Documents: Focuses on missing documents and placeholders, allowing users to drag documents onto placeholders for coding and fulfillment. The Staging, Upload, and Inbox folders are available from the lower panel.
- Document Type: Organizes documents according to their assigned document types.
- Tag: A metadata field that links documents. This view groups documents by their assigned tags, with one document potentially linked to multiple tags.
- Redactions: Shows documents identified as containing protected content, organized by the state of their redaction.
- Processing: Shows documents bifurcated within the following categories.

- Optical Character Recognition
- Page Count
- PDF Conversion

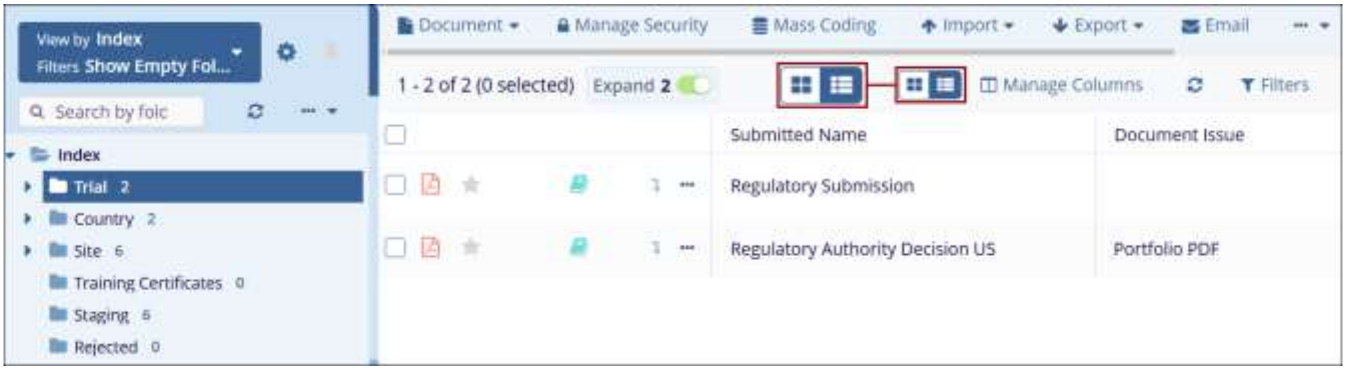
- Responsible Party: Displays collected and missing documents organized by their Responsible Party association, requiring responsible parties to be in use in the room.
- Deleted: Displays all deleted documents, with options to restore or permanently purge them from the system.
- Recently Edited:
- Group: Displays documents organized by their affiliated group.
- Posted Date: Shows documents organized by the date they were added to the study room.
- User Security: Groups documents by their affiliated security access group.
- Documents Security: Organizes documents that have specific document-level security applied.

Documents Grid Views

Immediately above the Documents Grid are the Grid and Card View options which allow the user to switch between Grid View and Card View.

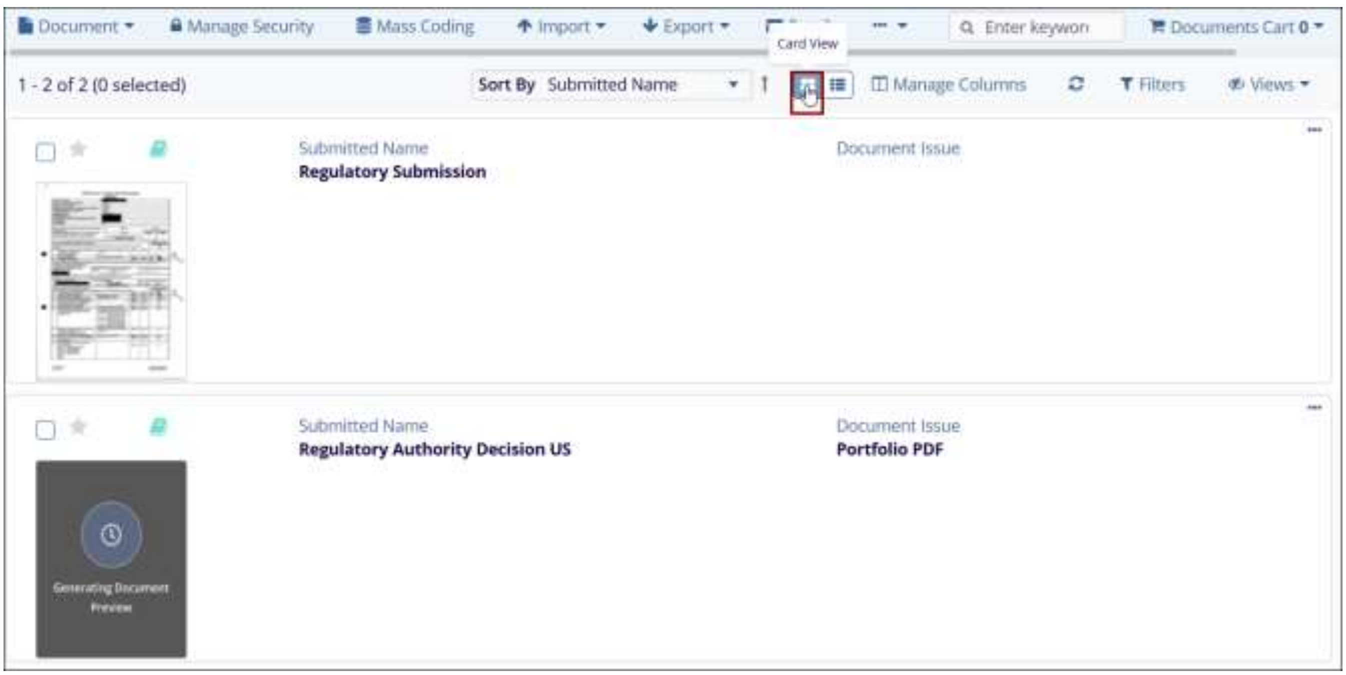
To apply different views to the Documents modal, follow the steps below.

1. Select a folder with documents in it and the documents will be listed in the Documents Grid.
2. Navigate to the top section of the Documents modal and switch between Grid View and Card View by selecting the respective view buttons.



3. Click on the Grid View icon to view all documents within a folder in a list format.

4. Click on the Card View icon to view documents within a folder as individual cards. Each card represents a document and includes key information and a thumbnail image to visually represent the document's content.



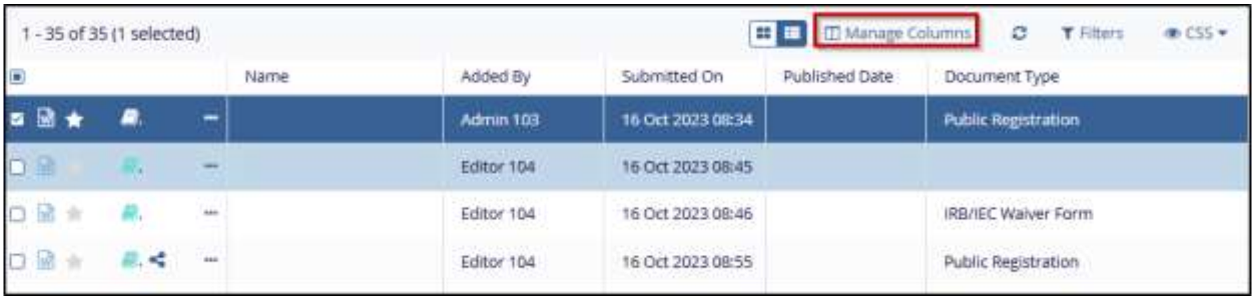
Manage Columns

Users can configure which columns are displayed in the Document Grid irrespective of the Card or Grid View selected. This function is not limited to the Documents library module and any grid in the system can be configured to the users' preferences.

<u>Manage Columns – Card View</u>

To manage columns within the Card View, follow the steps below.

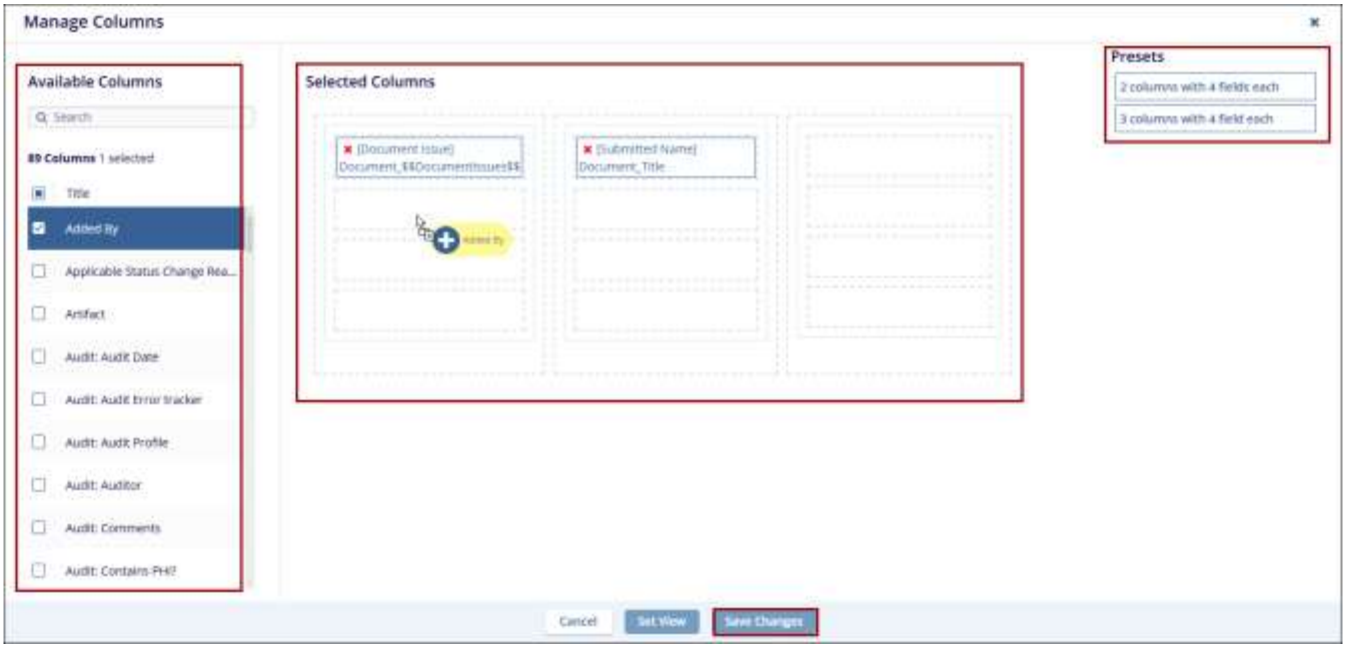
1. Click the Manage Columns button from the top-right corner of the documents grid. This opens the Manage Columns window.



2. The Manage Columns window will open which displays the following panels:

    a. Available Columns Panel: This panel displays the list of all available columns in a room.
    b. Selected Columns Panel: This panel displays the list of all columns that are selected and added from the Available Columns.
    c. Presets:

3. To add a column to the Selected Columns pane from the Available Columns pane, drag & drop a column within the selected preset in the Selected Columns panel.
4. Alternatively, double-click on the columns in the Available Columns to add to the Selected Columns.
5. To remove the columns, click on the x icon of a particular column within the Selected Columns section.
6. Rearrange the columns sequence by dragging and dropping the columns into the desired order.
7. Click on the Save Changes button.



8. On the Save View popup window, perform the following

    a. Name: If the view is new, provide a unique name. For an existing view, leave the name unchanged, if required.
    b. Make Default for Me: Choose whether this view shall be set as default by enabling the toggle switch.
    c. Make Default for All: (Admins Only) Select whether this view should be the default for all users in the room. Users can change their default view later, but this will initially set the view for all users.
    d. Save As New: Decide whether to save this as a new view by enabling the toggle switch. For editing an existing view, do not select the option to save it as a new view.

9. Click on the Save button.
10. Once saved, the view will be listed in the available views, which can be accessed from the Views dropdown menu at the top-right of the Grid.

Once the view(s) are configured, users can perform the following

- Save View
- Share View
- Manage Views

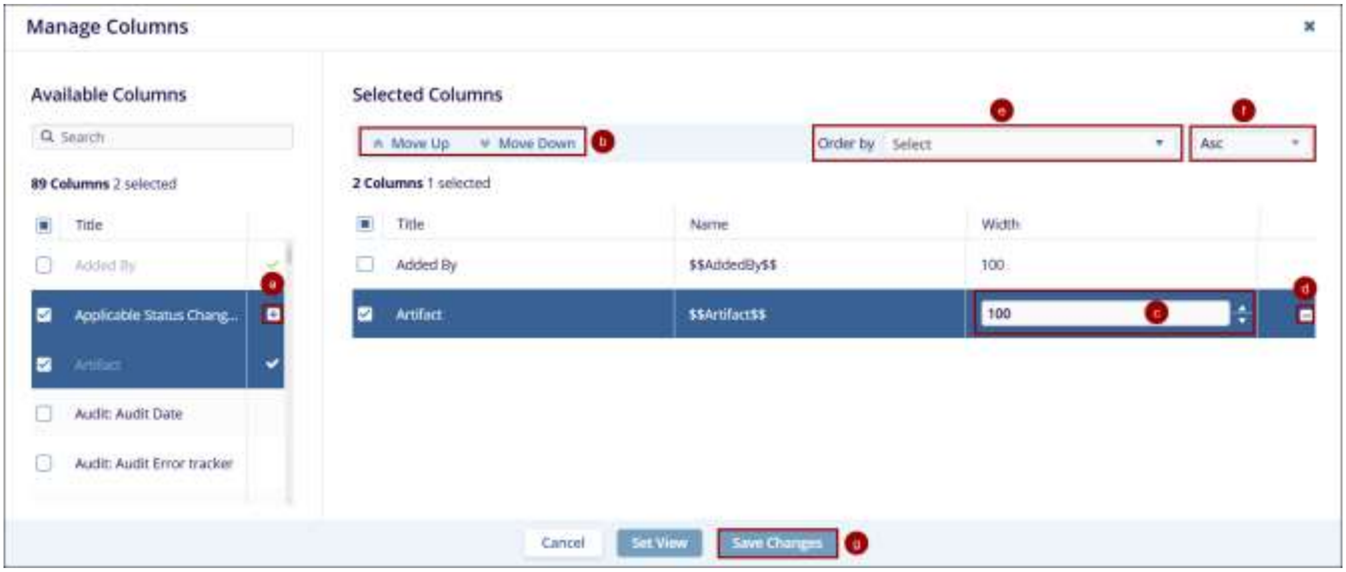
Manage Columns – Grid View

To manage columns within a Card View, follow the steps below.

1. With the Grid View selected, click on the Manage Columns button.

2. On the Manage Columns screen, perform the following

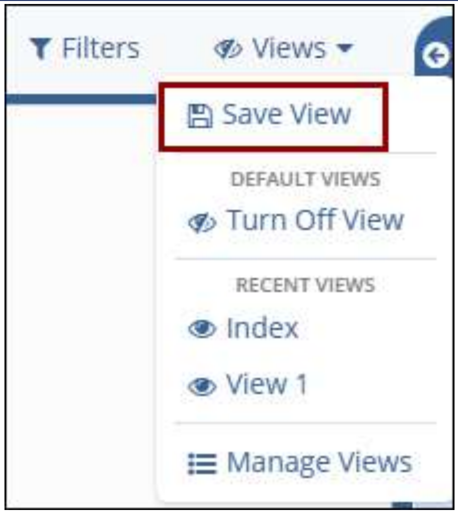
    a. Select column headers from the Available Columns section and add them to the Selected Columns section.
    b. In the Selected Columns section, select a column and click on the Move Up and Move Down arrows to re-arrange the order of the columns.
    c. Adjust the width of the column by increasing or decreasing the value.
    d. Click on the - sign to remove the column from the Selected Columns list.
    e. Click on the Order by dropdown and select the criterion from the available dropdown options.
    f. Sort the columns in Ascending and descending order by selecting the necessary option.
    g. Click on the Save Changes button.



Save View

To Save the view using another method follow the steps below.

1. On the Documents screen, click on the Views dropdown and select Save View option.



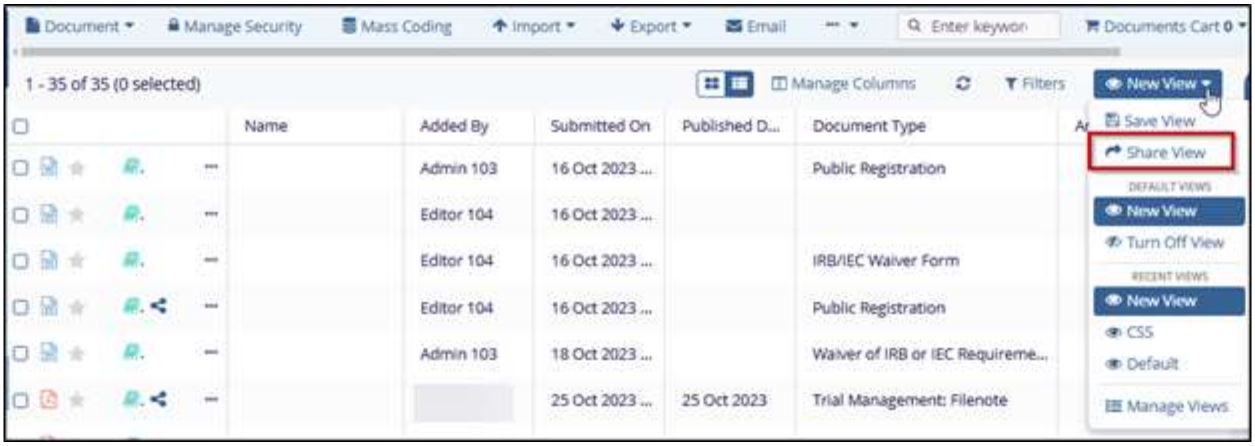
2. Make the necessary configurations within the Save View popup as mentioned above.
3. Once the view is saved, it will be available in the list of all views. This list is accessible from the Views dropdown menu at the top-right of the Grid.

Share View

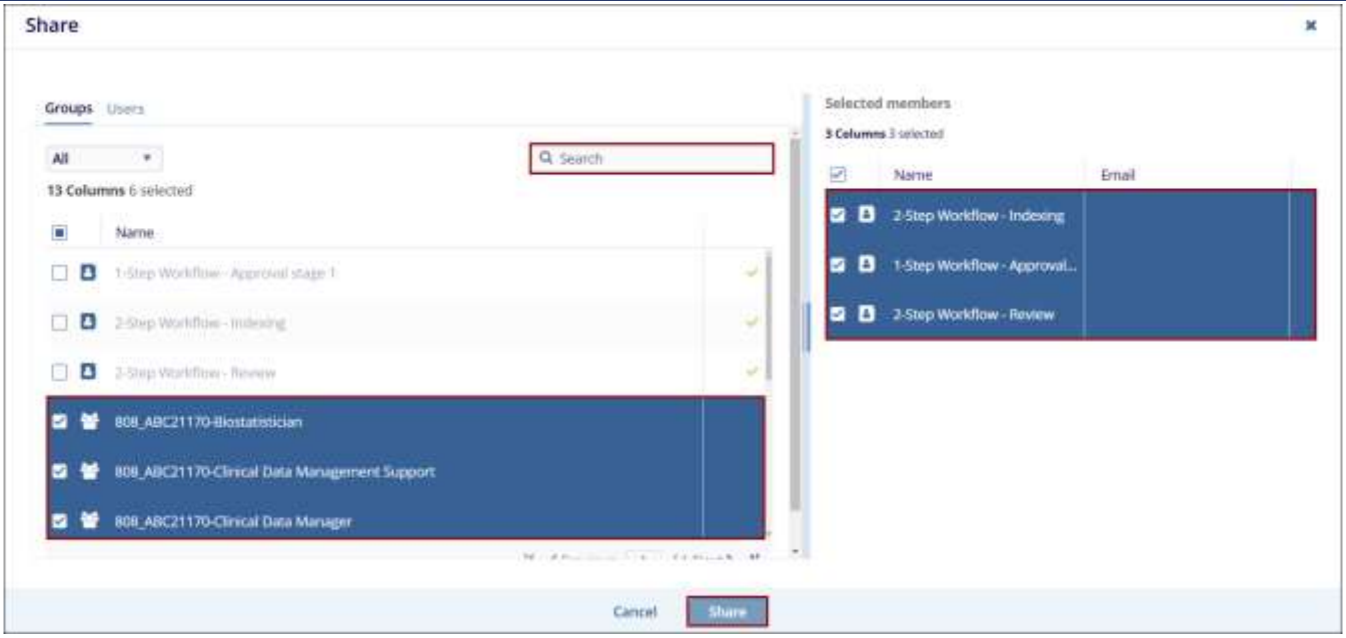
Once the view has been saved, it can be shared with any other room user. This is particularly useful when a new team member is brought on, as they may not be familiar enough with Trial Interactive to easily find the necessary information via the Grid.

To share the view, follow the steps below.

1. Open the View menu at the top-right of the Grid and select the Share View option. This opens the Share window.



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

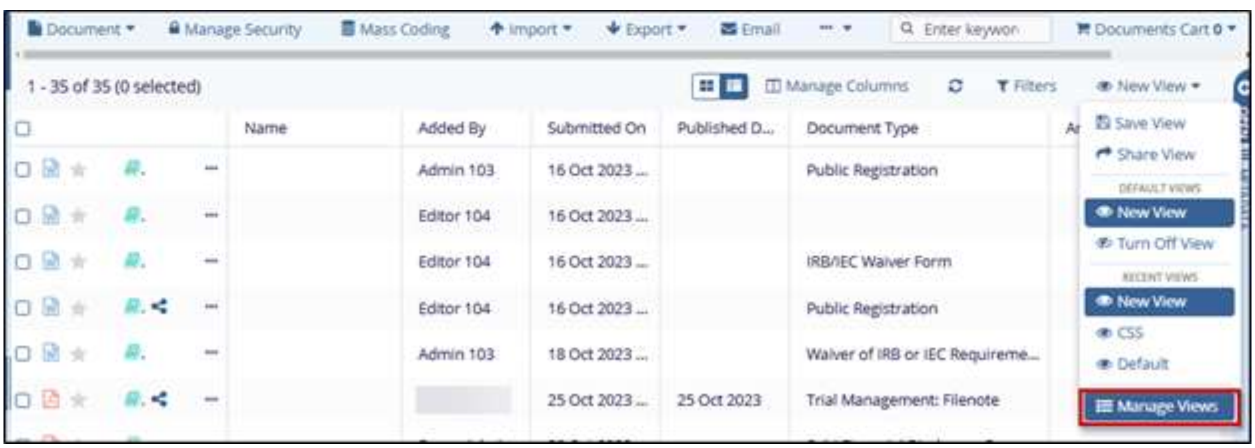


Manage Views

If the room has multiple views created in a room, and if they are visible to all users, it is possible to see all the views in a room.

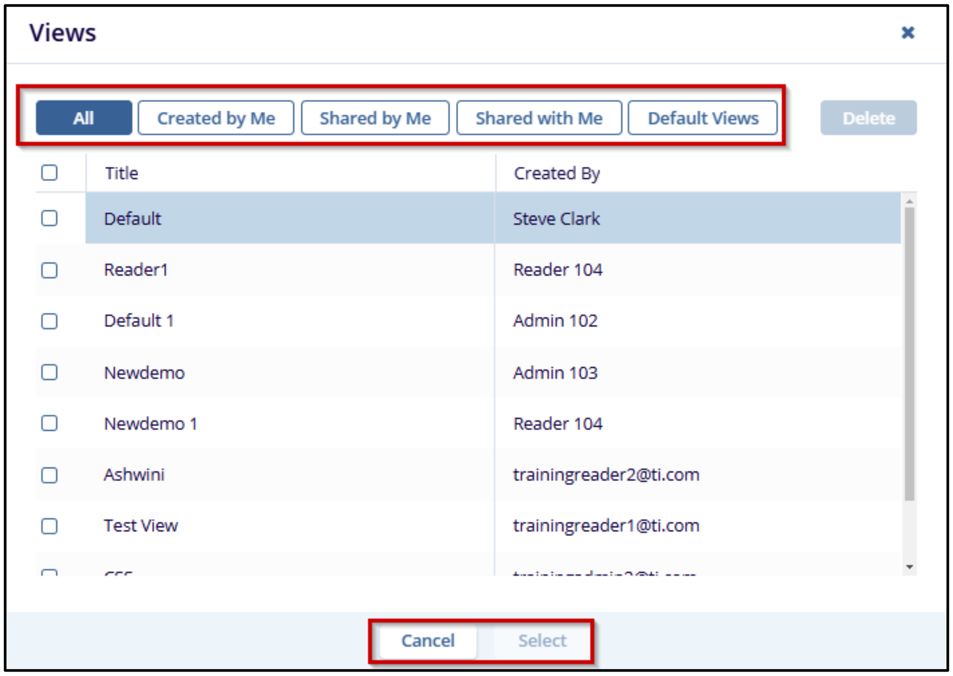
To display all views, follow the steps below.

1. Select the Manage Views option from the from the Views dropdown.



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

e. Default Views: This displays the list of all default views.



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

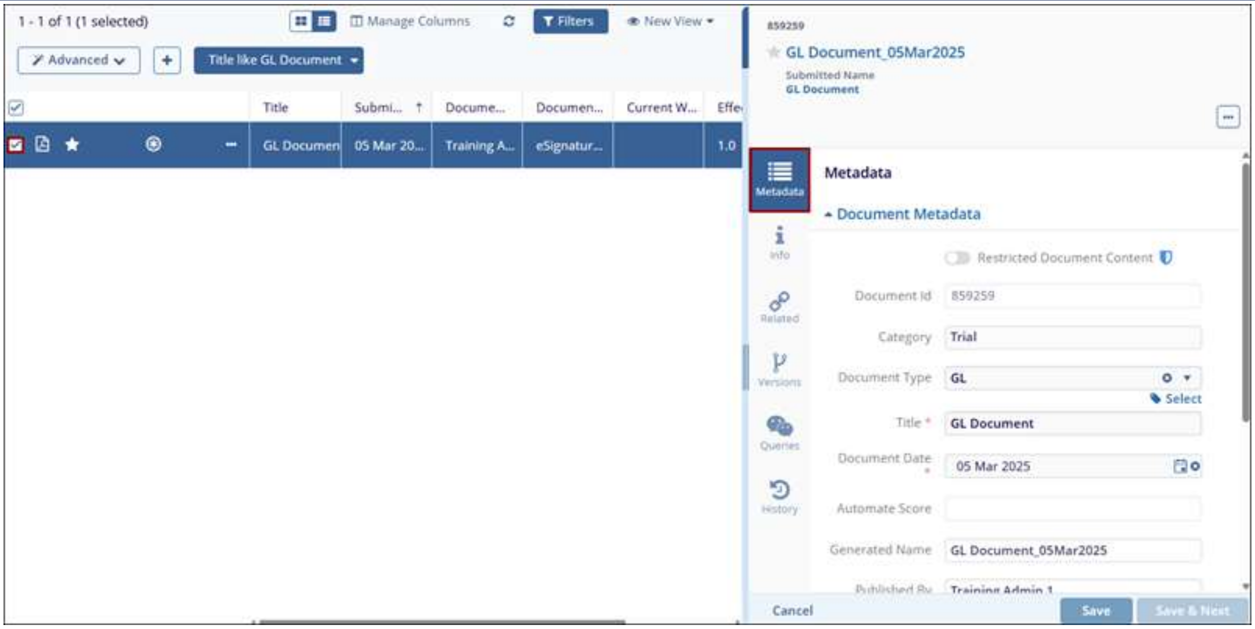
Preview and View a Document and its Metadata

The Document Metadata panel allows users to view the document metadata and the document in separate panels in the Collaborative Workspace/Document's Library module.

Viewing Document Metadata

To access the Document Metadata, follow the steps below:

1. From the Documents Library module, select the document from the grid.
2. Click on the Hide arrow to open the Metadata Panel.
3. The Metadata Pane opens and displays the Document Metadata by default.



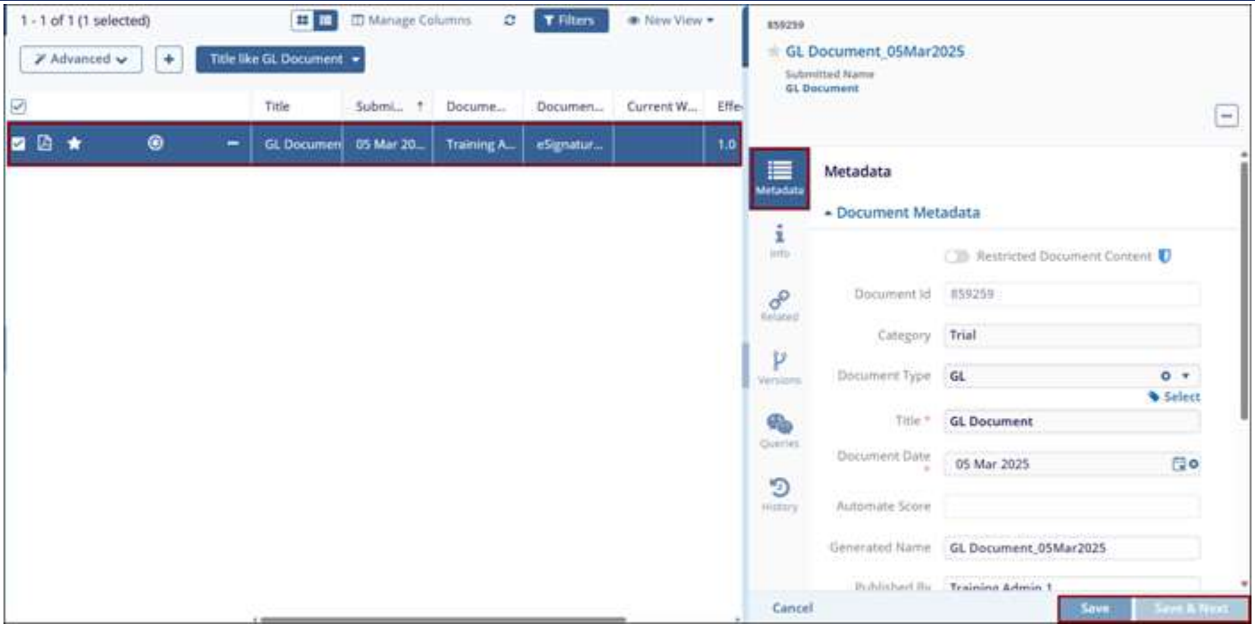
Editing Document Metadata

Users with appropriate access levels can edit document metadata as follows:

- Administrator-level users can edit metadata for all documents.
- Editor-level users and Manager-level users with Document Manager permission can edit metadata for all documents.
- Editor and Manager-level users can edit metadata for non-final documents.
- Reader-level users do not have permission to edit metadata for any document.

To edit document metadata, follow the steps below.

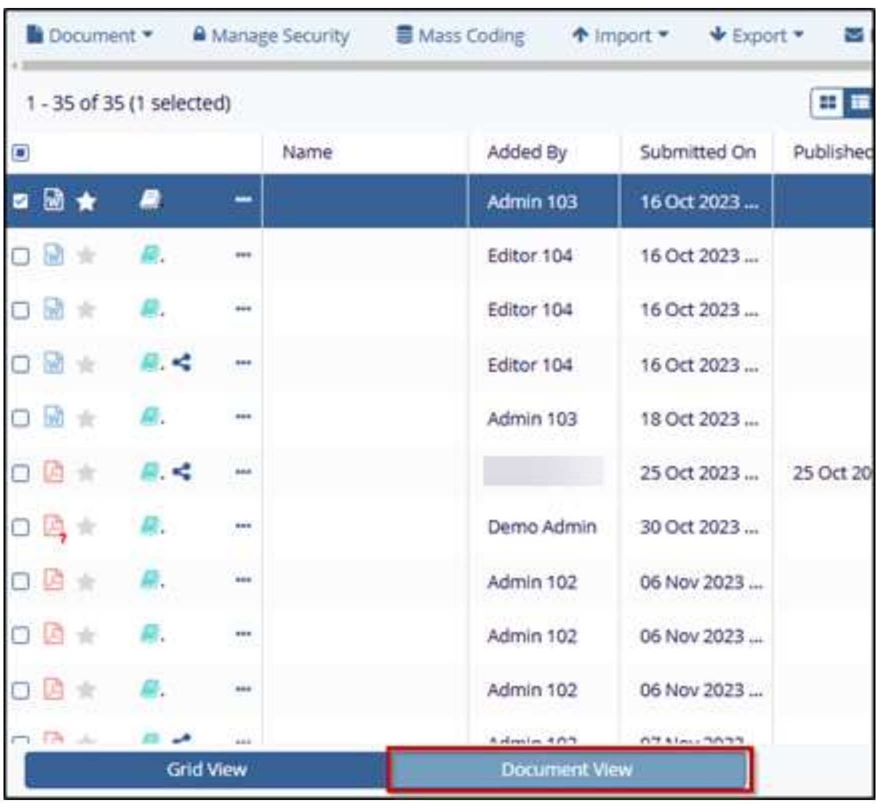
1. Select a document by checking the checkbox.
2. Modify the fields in the metadata panel.
3. Click Save to apply the changes.
4. Click Save & Next to edit metadata for the next document in the grid.



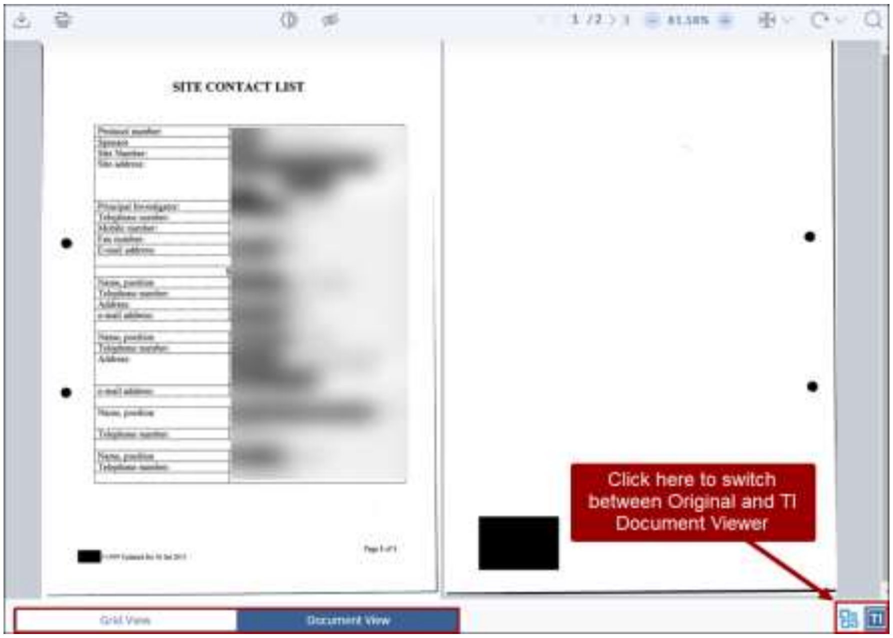
Viewing Documents in Document Viewer

To view the documents in the document viewer, follow the steps below.

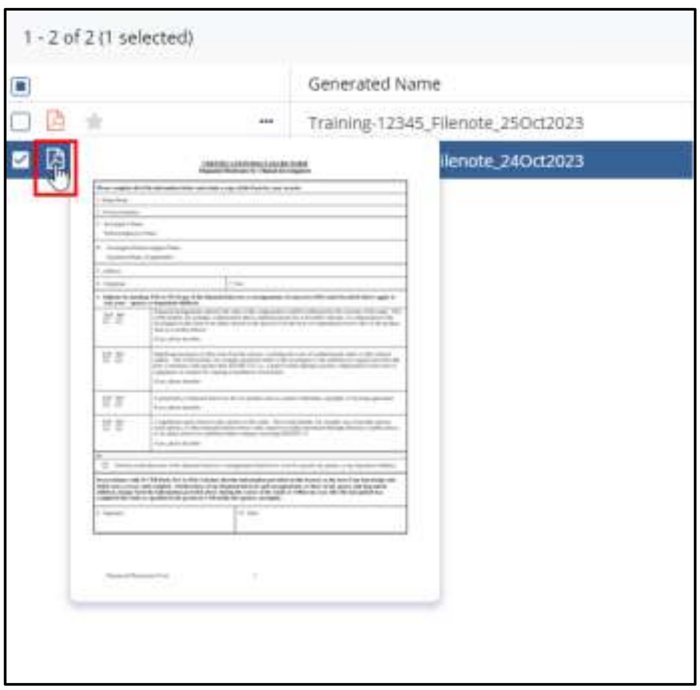
1. Select a document from the grid by clicking on the checkbox.



2. Click on the Document View tab at the bottom of the grid. The Document and viewed in the Original as well as the TI Document Viewer.



Note: Documents can also be previewed by hovering over the document icon within the grid view as in the screenshot below.

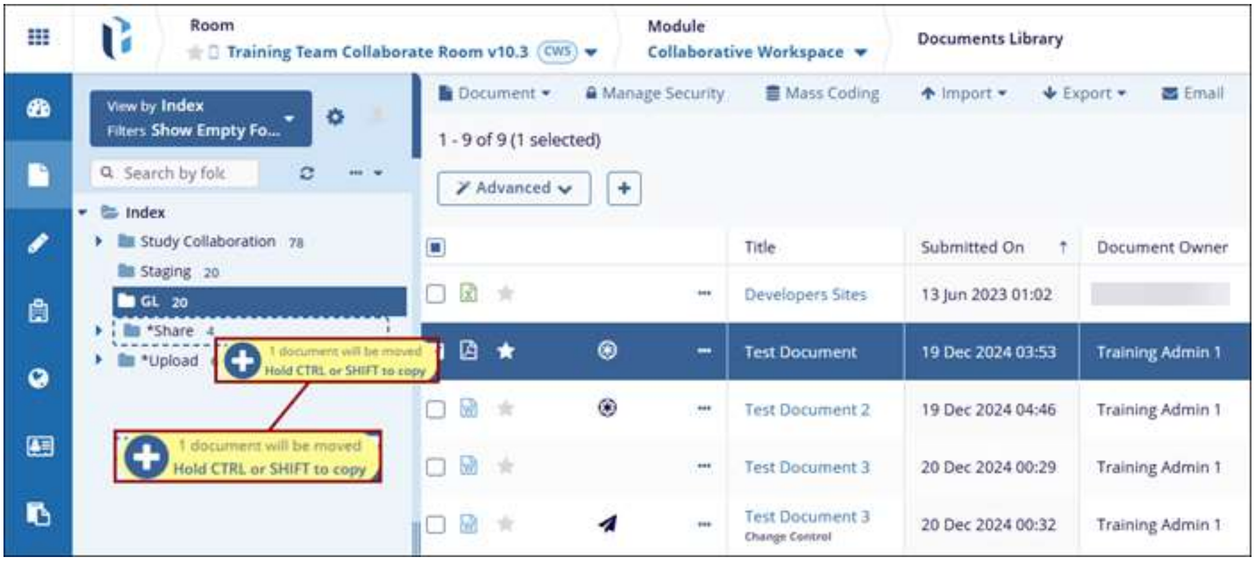


<u>Copying or Moving Documents</u>

Users with necessary access permissions can drag and drop documents from one folder to another. Dragging and dropping documents across folders will not alter the metadata applied to the document. However, if a document manually copied from one folder to another, users need to re-code the document.

To move documents to other folders, follow the steps below.

1. Select the document(s) to be copied or moved from the grid.
2. Drag and drop the document to the intended folder in the Index Pane.



Grid Filters

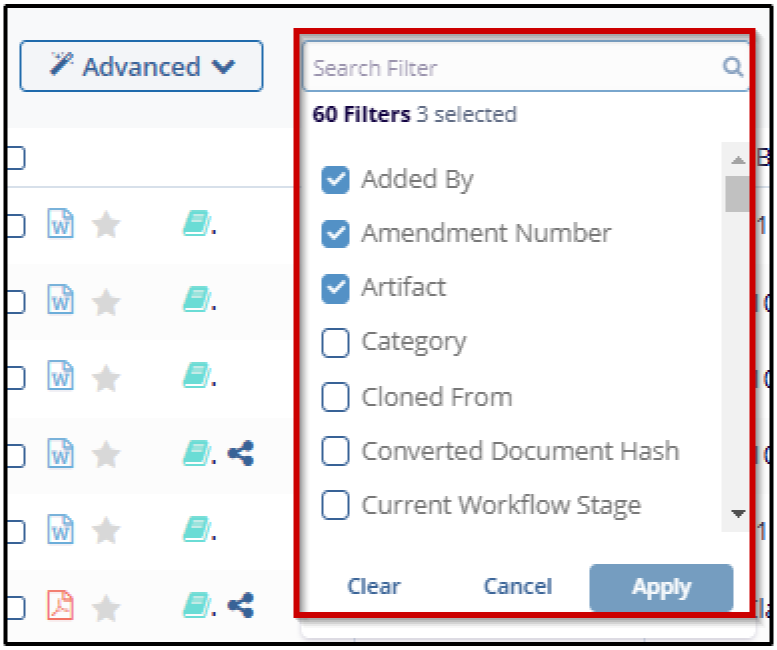
This section explains the filters in the document grid.

Document Library Filters

To apply standard and advanced filters, follow the steps below.

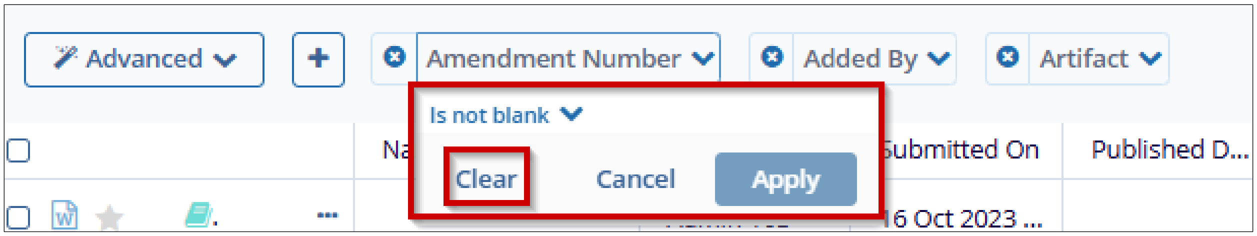
1. In the Collaborative Workspace module, click on the Filters option.
2. Two options appear: Advanced and +. Click the + icon to add a filter.

3. Within the dropdown menu with various field names, select the desired filter fields and click on the Apply button.



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

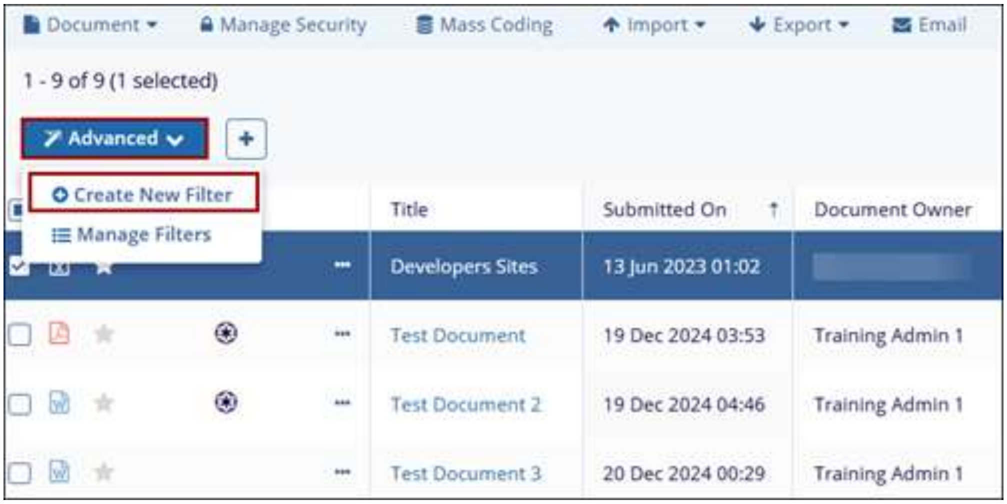
5. To remove a filter, select the Clear option within the filter dropdown.



Creating a New Filter

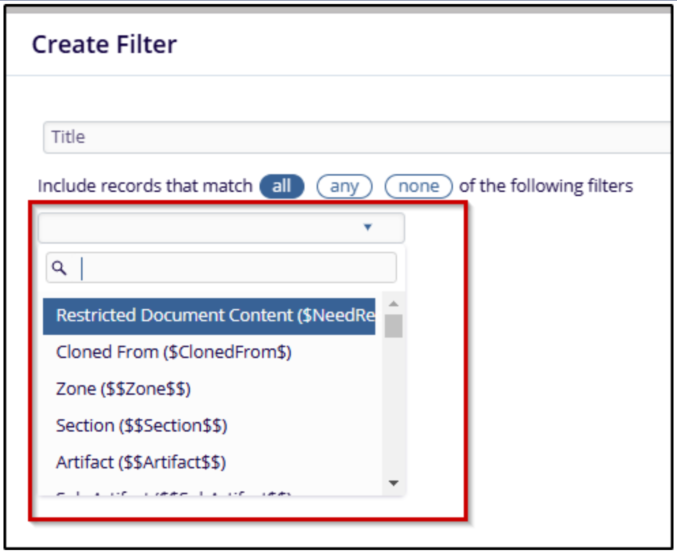
To create a new filter, follow the steps below.

1. Click on the Advanced button and select the + Create New Filter option above the documents grid. The Create Filter window opens.



2. On the Create Filter screen, enter a title for the filter and click the + Add Filter button.

3. Click the dropdown and select a field to apply filters for.



4. Select the logical operator and enter the value for the selected field.

5. Click on the Create button.

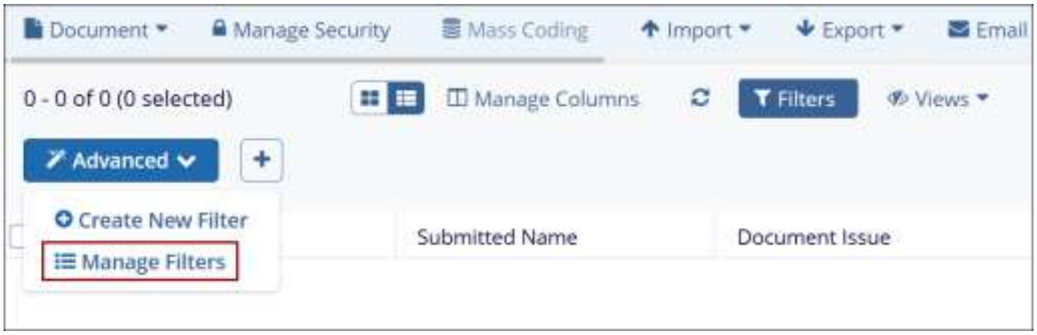
6. The filter will appear above the grid. Select the filter to apply it to the grid contents

Add Existing Filters or Manage Filters

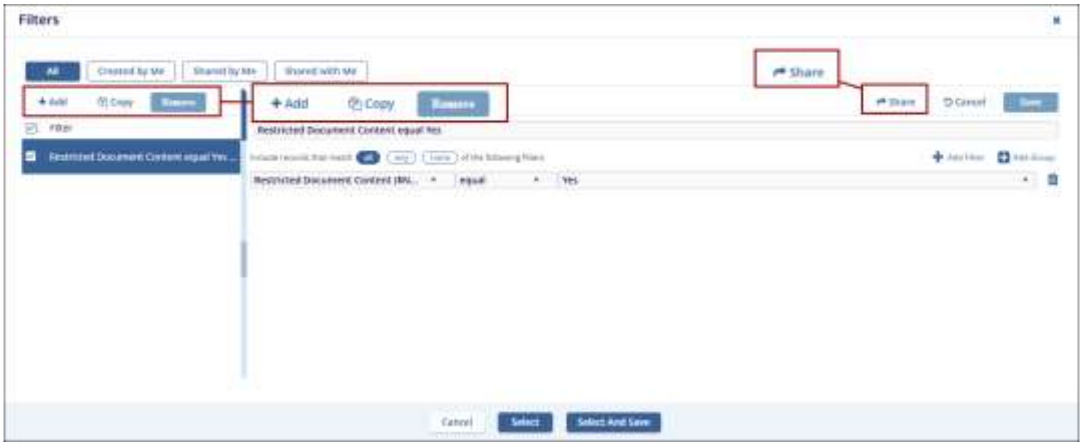
Manage filters allow users to view and share the created filters.

To manage the existing filters, follow the steps below.

1. Click on the Advanced button and select the Manage Filters option.



2. On the Filters screen, select the filter and it appears in the right pane with +Add, Copy, Remove and Share options enabled.

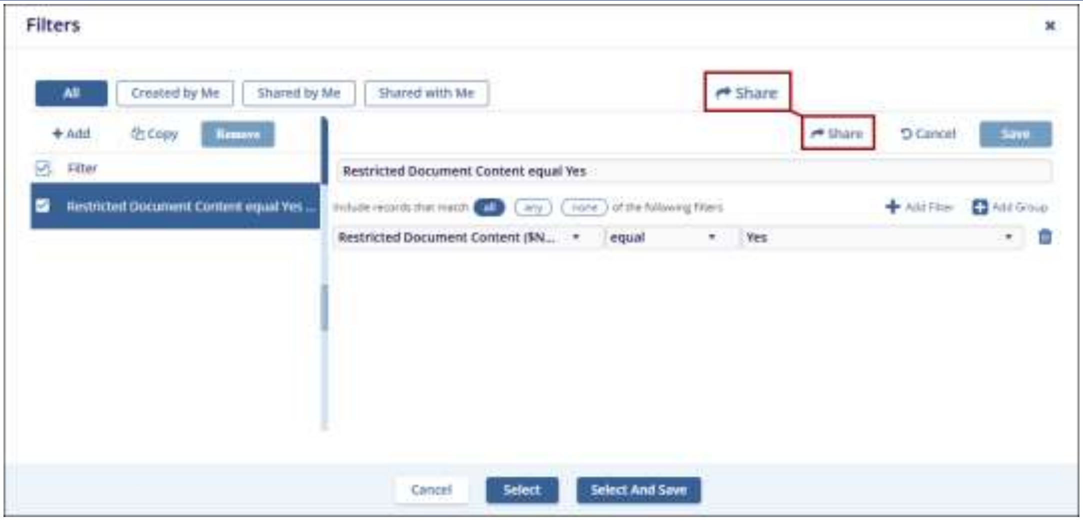


Users can perform the following activities on the filters in the Manage Filers window:

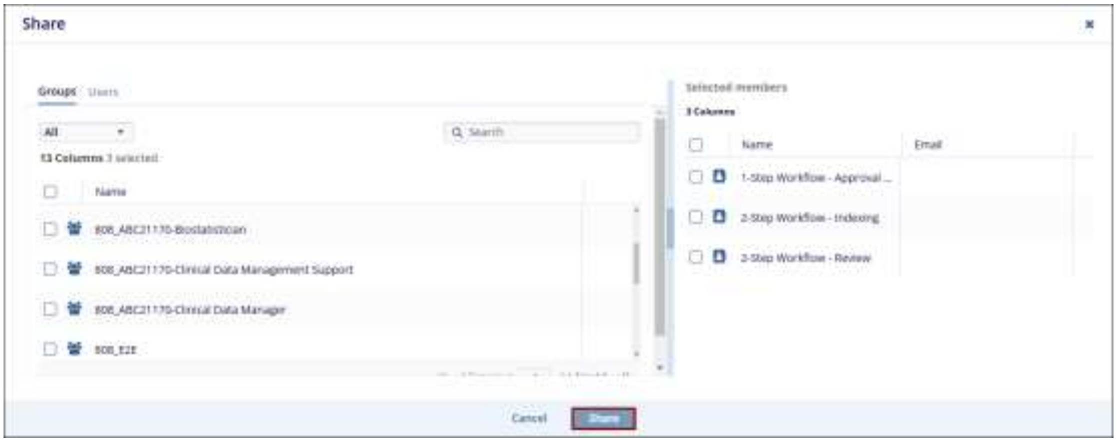
<u>Share Filters</u>

To share a filter, follow the steps below.

1. Select a filter and click on the Share button. The Share window opens.



2. Select the Users / Groups by accessing the respective sections and add them to the Selected member's section.
3. Click on the Share button once the necessary users and/or groups are added.



Remove Filters

To remove filters, follow the steps below.

To remove the filters, follow the steps below.

1. Select the filter from the list.
2. Click on the Remove button to remove the filter from the list.

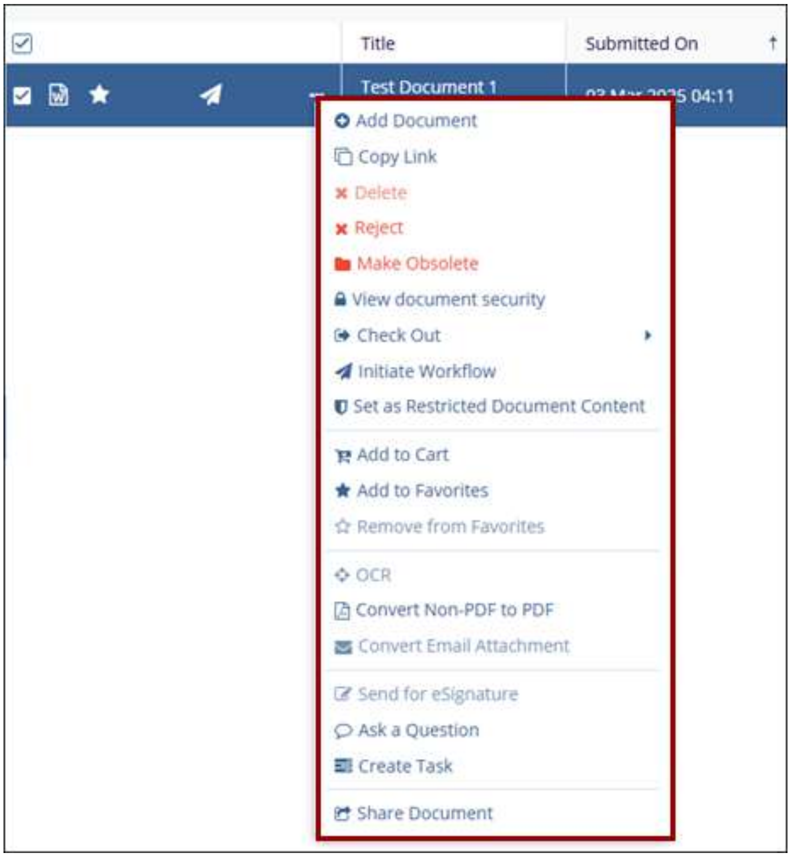
View Shared Filters

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

- All
- Created by Me
- Shared by Me
- Shared with Me

Document Activities Menu

The Document Activities Menu provides access to various actions based on the user's access rights. To open this menu, select a document or placeholder from the Grid and either right-click or click on the three-dot menu.



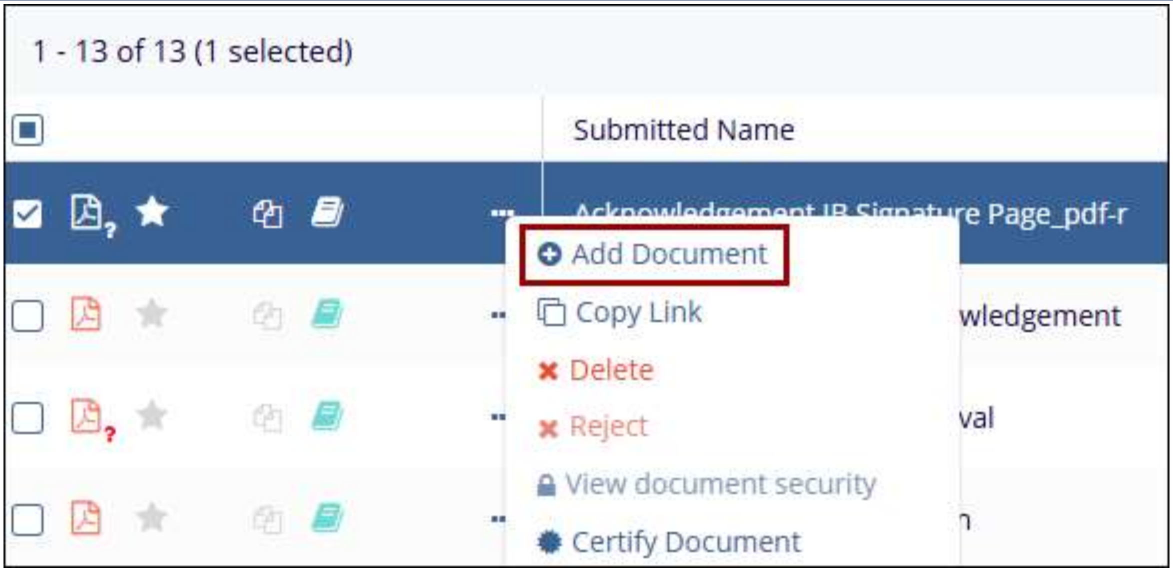
Note: The view displayed above is that of a Room Administrator. The options available will vary based on the individual user access rights.

Add Document

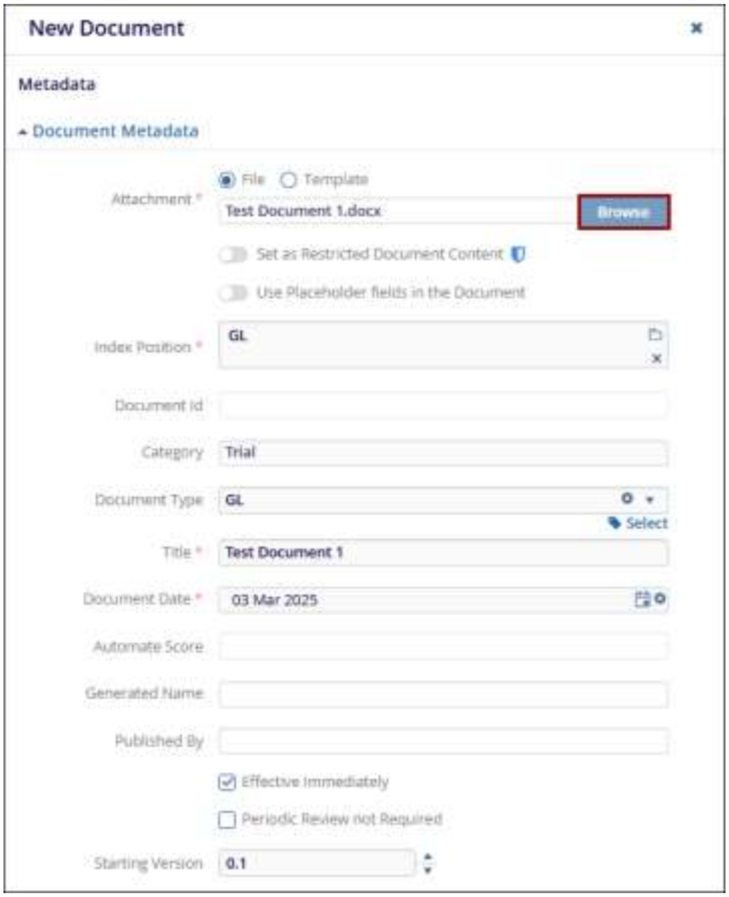
Users with sufficient access (editors and above) can open the Document Activities Menu and select the Add Document option to upload a single document. In locations within Trial Interactive where this is an option, the system will open an import interface that will apply the coding relevant to the placeholder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

To add a document, follow the steps below

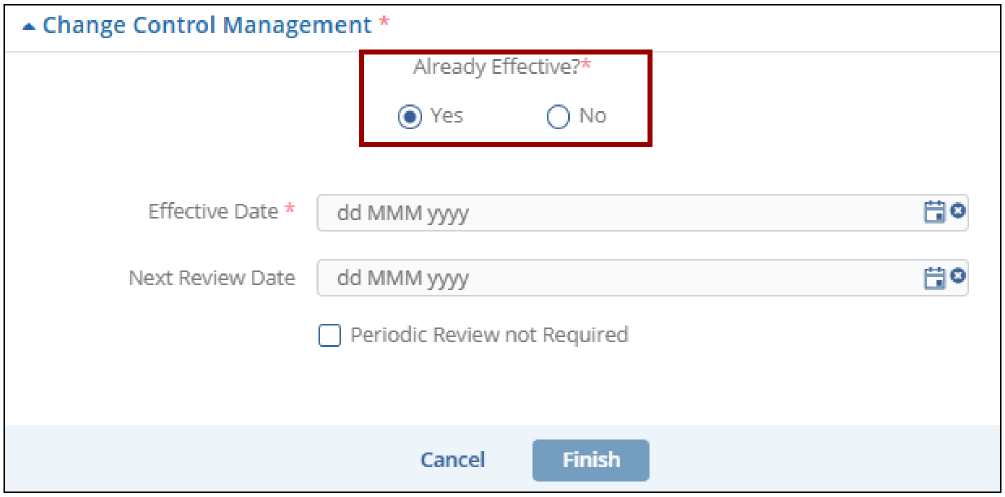
1. Click on the three-dot menu and select the +Add Document option.



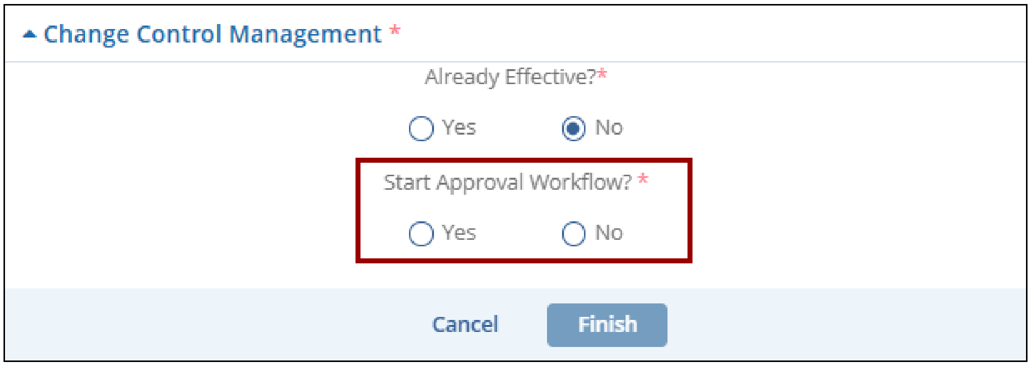
2. On the New Document form, select whether the uploaded document will be a File or Template.
3. Click on the Browse button and select a file to upload.
4. Fill in all the mandatory metadata fields highlighted with a red asterisk (*) mark in the Document Metadata section.



5. Navigate to the Change Control Management section and select either Yes or No in the Already Effective* section.
6. If Yes, specify the Effective Date, Next Review Date, and whether periodic review is required or not.



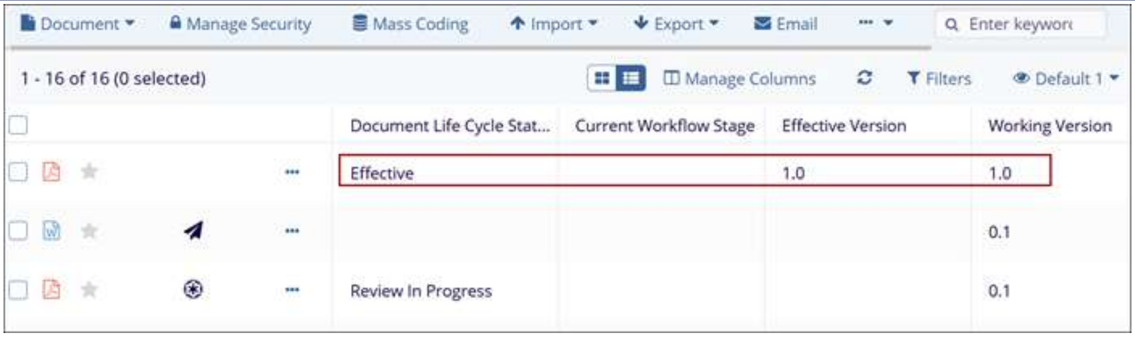
7. If No, then select either Yes or No in the Start Approval Workflow* section.



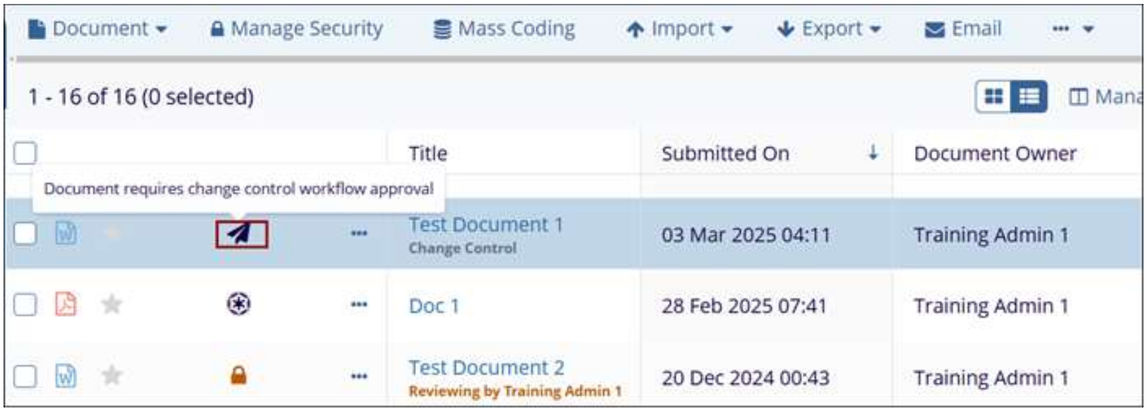
8. Once all the required details are added, click on the Finish button.

Note

- If ‘Already Effective = Yes’ is selected, the Document Life Cycle Status column shows ‘Effective,’ and the Effective and Working Version columns display the updated version number.
- The effective document can be routed through an administrative workflow and a periodic review process.



- If Start Approval Workflow = Yes, the document is highlighted with a paper plane icon indicating the document requires a change control approval workflow.

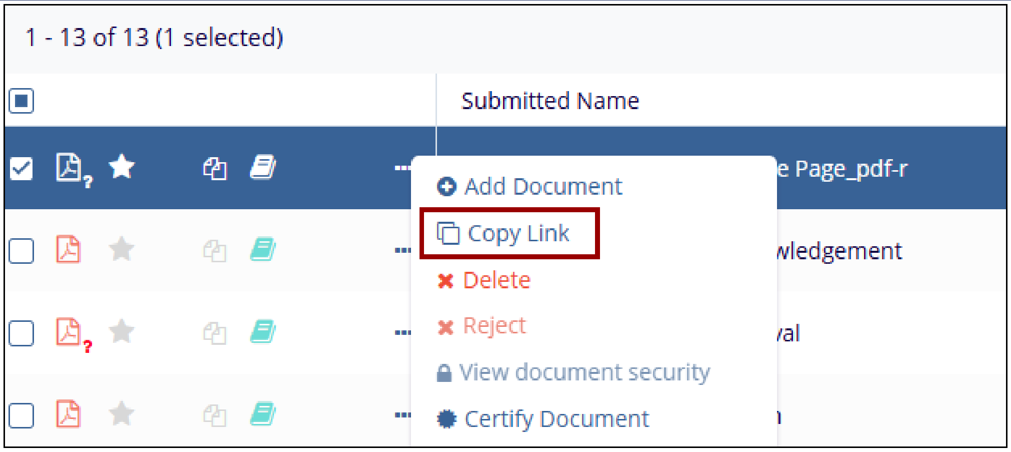


Copy Link

If referencing a specific document to another room user for review, the Document ID Number can be provided or the Document Activities menu can be opened to select Copy Link, which will copy a direct URL link to the clipboard. Anyone using the link must have sufficient access to the study room in order to view the document.

To copy the link, follow the steps below.

1. Select a document by clicking on the checkbox.
2. Select the Copy Link option.

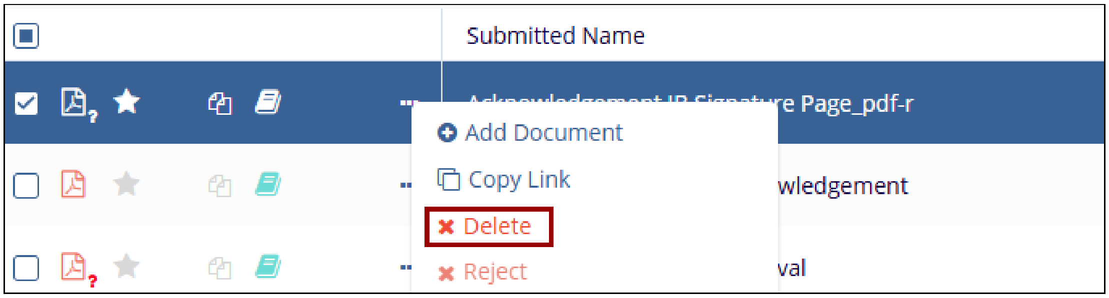


Delete

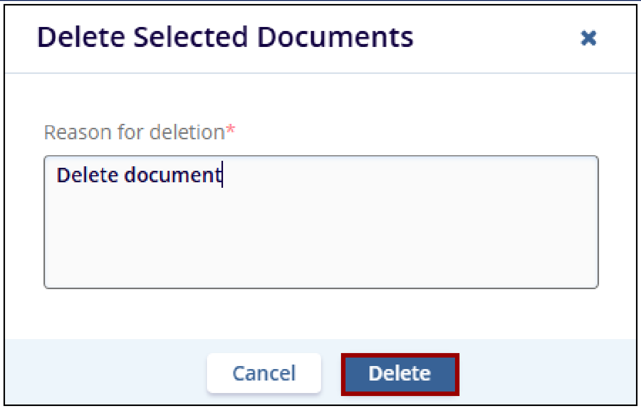
Administrator-level users can select Delete from the Document Activities menu for any document in the room, except those currently claimed for review in an Audit Response or the QC Workflow. Editor and Manager-level users can delete documents only if they uploaded the document and it has not been claimed by the QC workflow. Once a document is marked as final, Editor and Manager-level users cannot delete it unless additional permissions are granted.

To delete documents, follow the steps below.

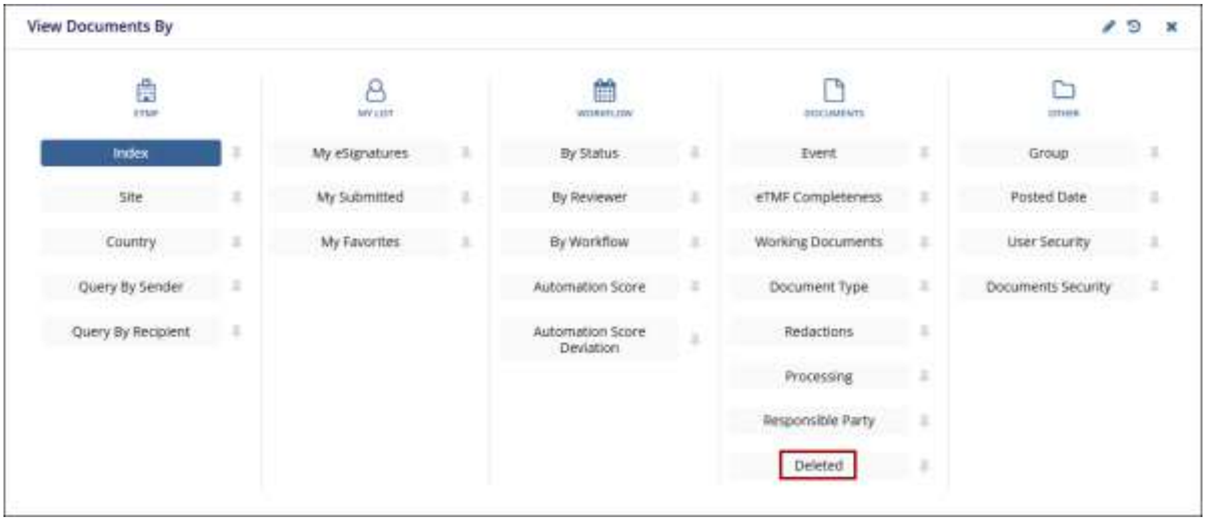
1. Select a document and click on the Delete button from the document activities menu.



2. Enter the reason for deletion on the confirmation popup and click on the Delete button.



3. Deleted documents can be viewed in the Deleted Documents section of the Documents module, which is accessible only to Administrators.

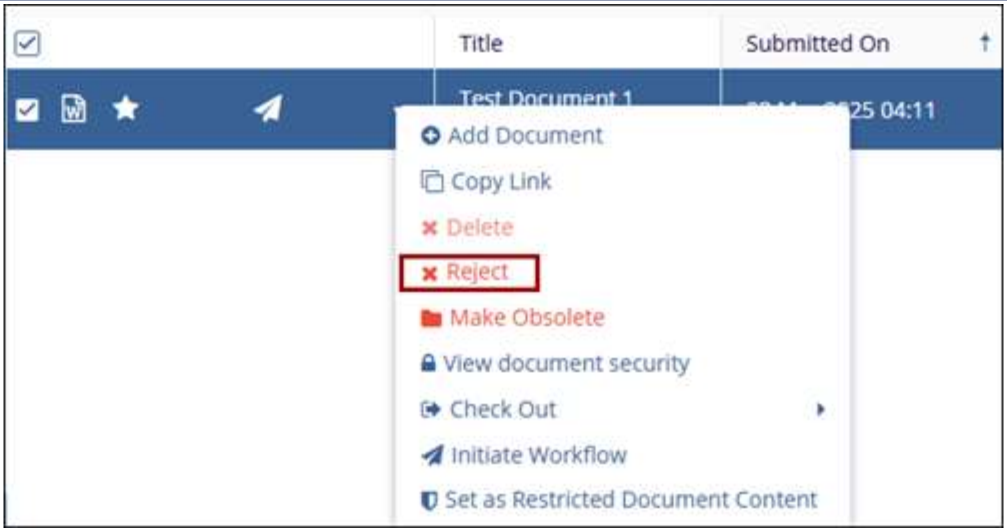


Reject

Admins, Document Managers, and Room Managers can reject a document. Any documents in Upload, Inbox, Staging, and Rejected Folders are not considered to be Final. A Reason for Rejection dropdown allows specifying a reason for workflow documents and documents in the rejected folder/status are now excluded from eTMF health calculations.

To reject a document, follow the steps below.

1. Select a document by clicking on the checkbox.
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:

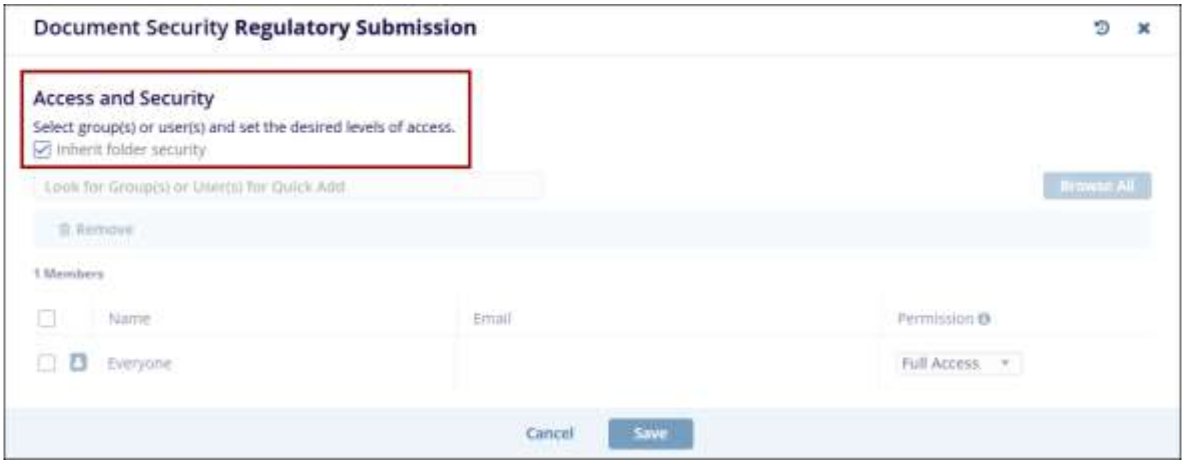
- Users will not be able to drag and drop documents into this folder to prevent awarding an erroneous status should a non-rejected document be placed in this folder.
- To reject a document outside of the standard workflow steps, the user must either be an administrator or they must have the Document Manager action enabled on their user account.

View Document Security

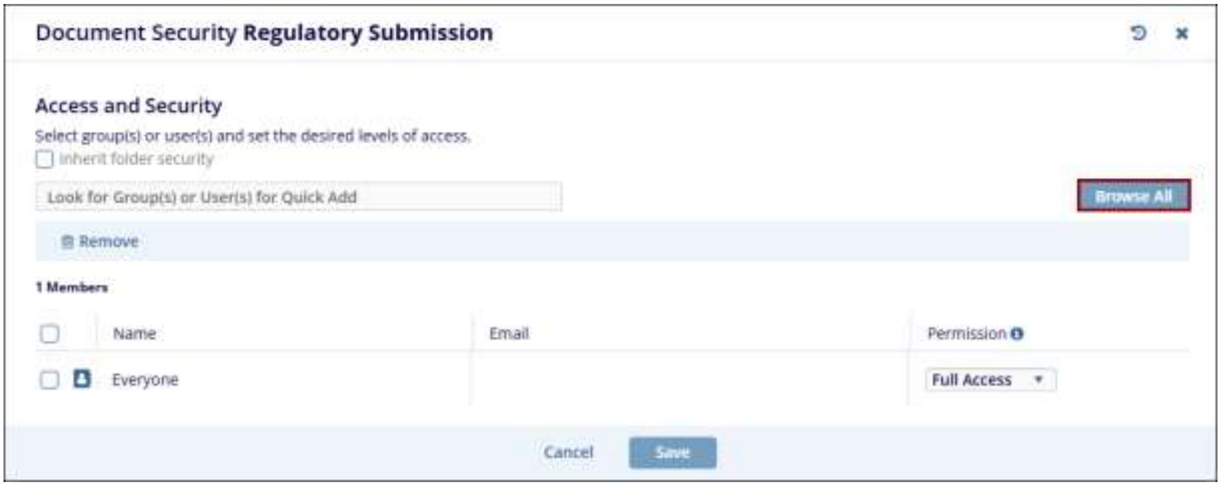
Administrator-level users can apply specific document-level security via the Document Activities menu. Selecting View Document Security will open the Document Security window.

To view the document security, follow the steps below.

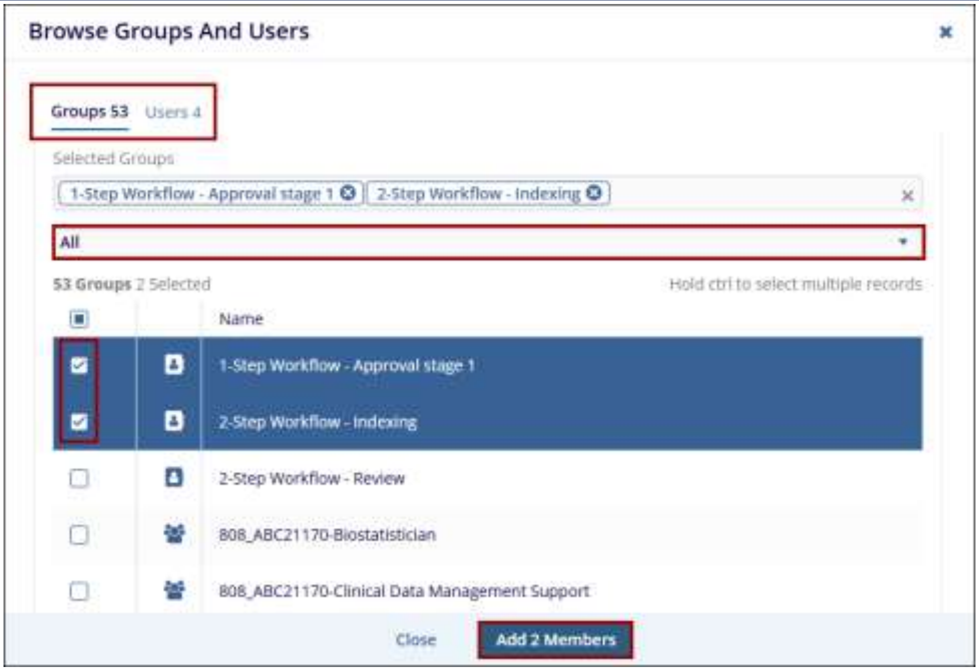
1. Click on the three-dot menu and select the View Document Security option.
2. The Documents Security window will display the users or groups with the access permissions by default if the Inherit folder security is enabled.



3. To add additional users or groups, disable the Inherit folder security setting and click on the Browse All button.



4. In the Browse Groups and Users window, switch between the Groups and Users tabs and select the desired groups or users.
5. On the Groups tab, use the dropdown menu to filter groups by category.
6. After selecting the required groups or users, click the Add (number of members) Members button.



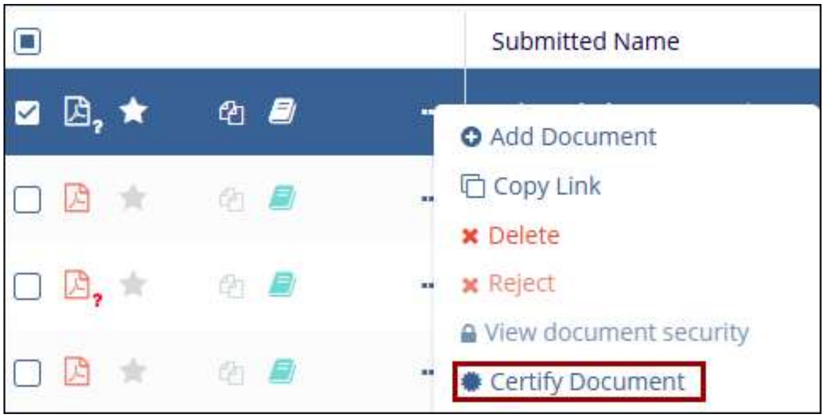
7. After adding the groups or users, click the Permissions dropdown to assign the appropriate access level, such as Full Access, View Only, or No Access and click on the Save button.

Certify Document

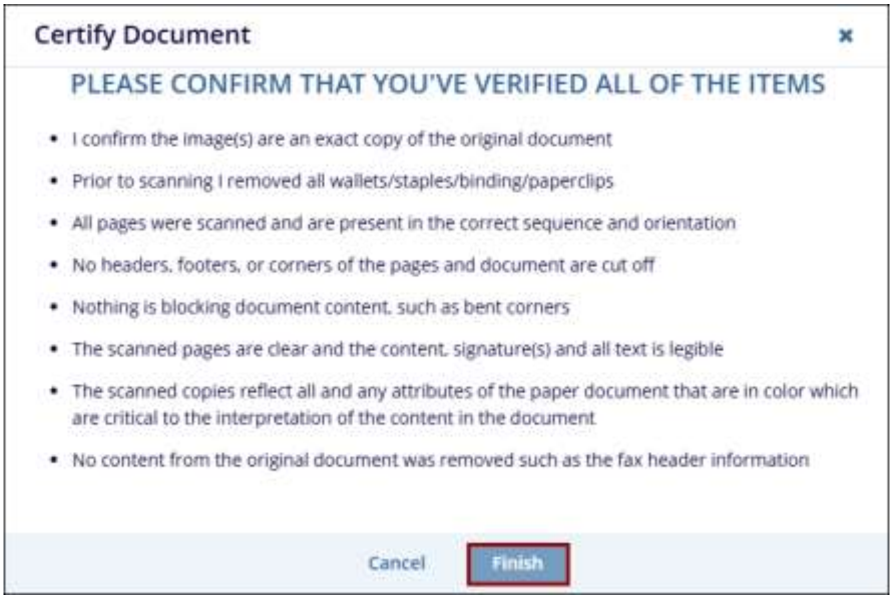
For studies in which the document certification option is in use, a user can either choose to indicate that a document is a certified copy upon upload or it can be done via the Document Activities Menu.

To certify a document, follow the steps below:

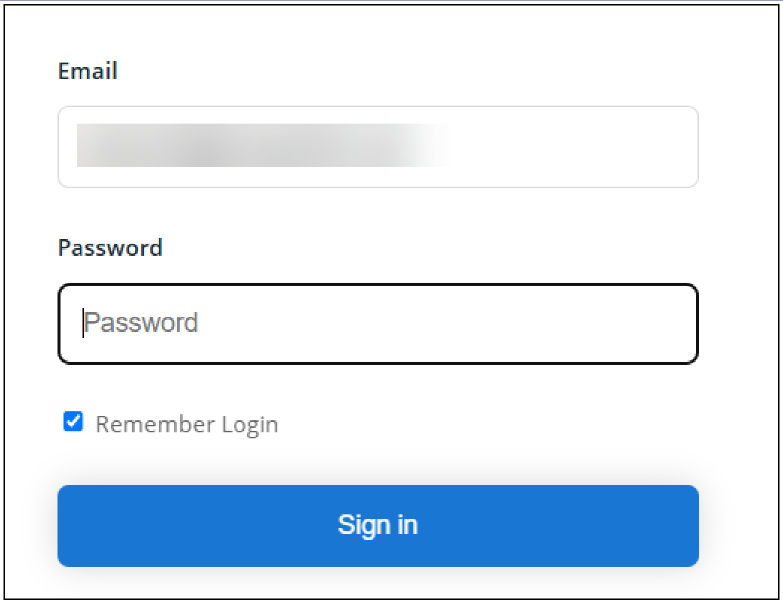
1. Open the Document Activities menu by right-clicking on a document or using the three-dot icon on the grid.
2. Select Certify Document



3. Read the criteria and press Finish if the document meets all expectations.



4. Use the username and login to complete the process.

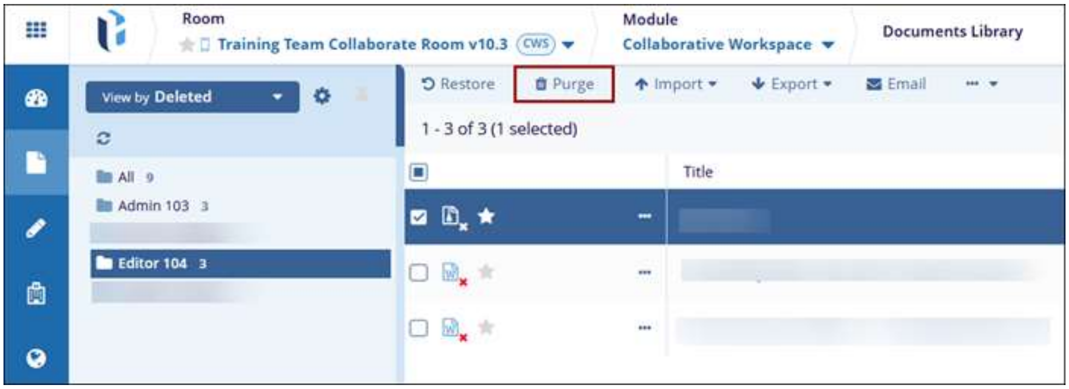


Purging a Deleted Document

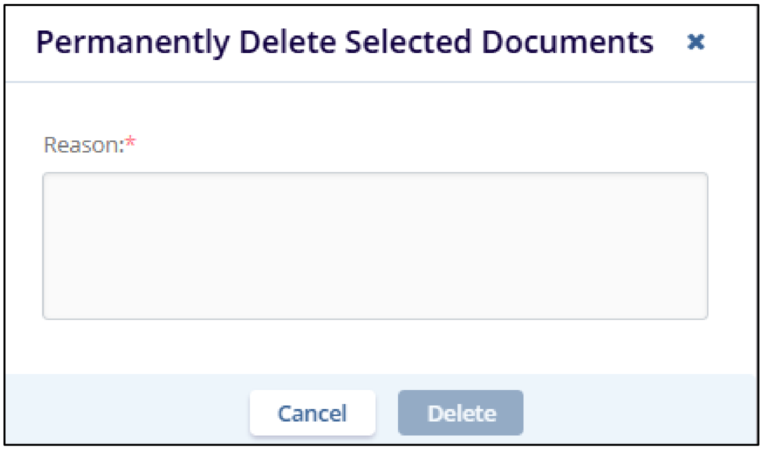
Once a document has been deleted, an administrator-level user will be able to navigate to the Deleted Documents view of the Documents module and, if desired, purge the document. Most deleted documents do not need to be purged from a study room unless necessitated by an internal SOP. However, some documents,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

To purge a document, follow the steps below:

1. Navigate to the Deleted Documents view.
2. Locate the document that was deleted. Documents are sorted by the user who deleted them and additional column selection and filtering are available as in other areas of the system.
3. Click on the Purge button.



4. Mandatorily provide a reason on the Permanently Delete Selected Documents popup.
5. Press the Delete button on the confirmation popup.

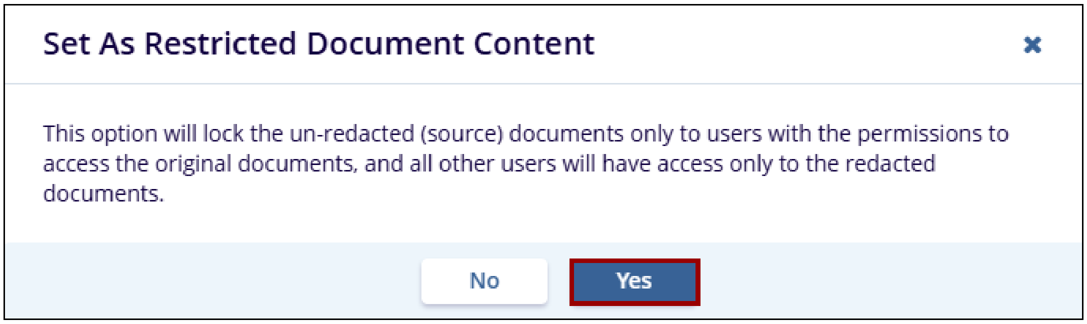


Set as Restricted Document Content

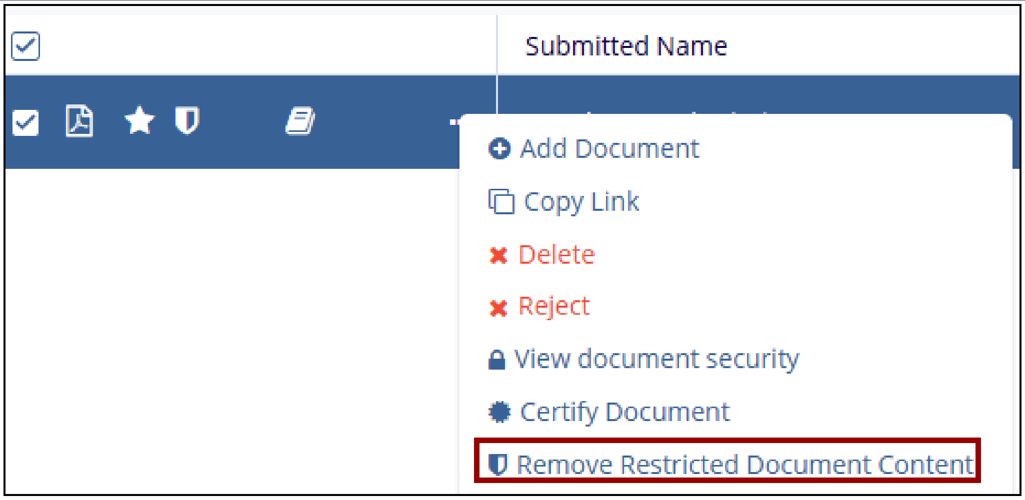
The Set as Restricted Document Content option locks the un-redacted (source) documents only to users with the permissions to access the original documents. All other users will have access only to the redacted documents.

To enable this setting, follow the steps below.

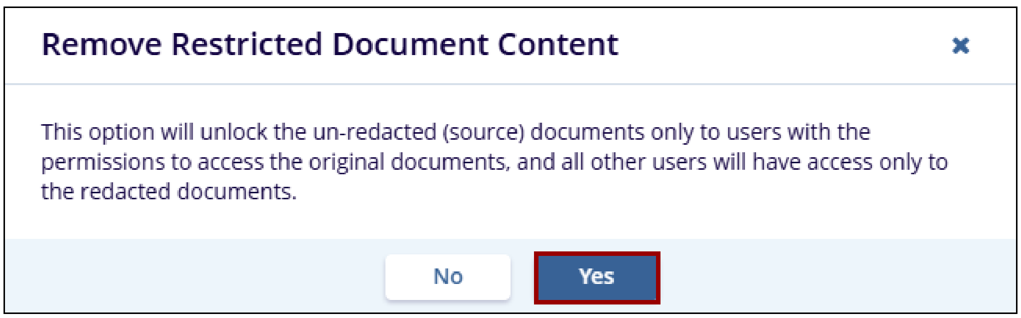
1. Click on the three-dot menu and select the Set as Restricted Document Content option.
2. On the Set As Restricted Document Content popup, click on the Yes button.



3. To remove the restricted documents content, click on the three-dot menu and select the Remove Restricted Document Content option.



4. On the Remove Restricted Document Content popup, click on the Yes button.

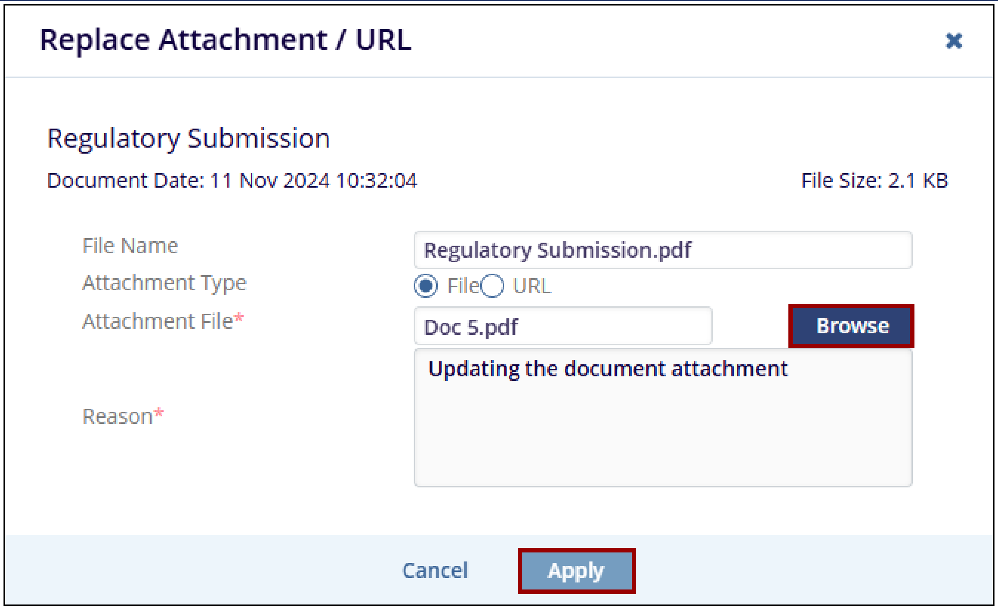


Replace Attachment/URL

This option enables users to replace the current uploaded document attachment or URL link with a new one.

To replace an existing attachment or URL with a new one, follow these steps:

1. Click the three-dot menu and select the Replace Attachment / URL option.
2. In the Replace Attachment / URL window, choose either the File or URL option.
3. If the File option is selected, upload the new document into the Attachment File* field.
4. If the URL option is selected, enter the new URL in the URL* field.
5. Provide a reason for replacing the attachment or URL.
6. Click the Apply button after adding the new attachment or URL.



Add to Cart

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

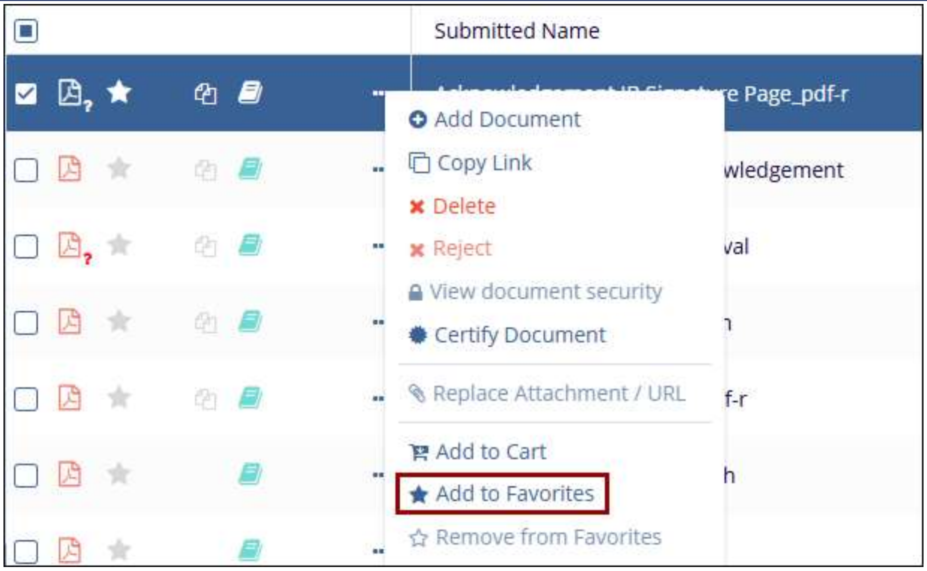
Refer to the [Documents Cart](#) section for detailed steps to manage documents from the Documents Cart.

Add to Favorites

Marking a document as a favorite makes it appear in the My Favorite Documents dashlet on the dashboard and provides a direct link to the document from that dashlet.

To mark a document as a favorite, follow the steps below.

1. Click the star icon on the document line in the grid.
2. Additionally, open the Document Activities menu by right-clicking or clicking on the three-dot icon and selecting Add to Favorites.



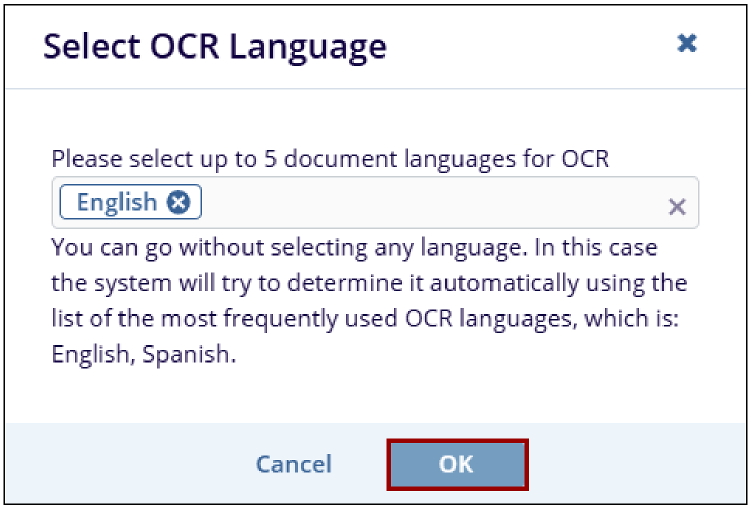
3. Similarly, select Remove from Favorites. Option to remove the document from the favorites list.

OCR and Revert OCR

Some functions, such as text-specific redaction, require that the document has OCR (Optical Character Recognition) applied.

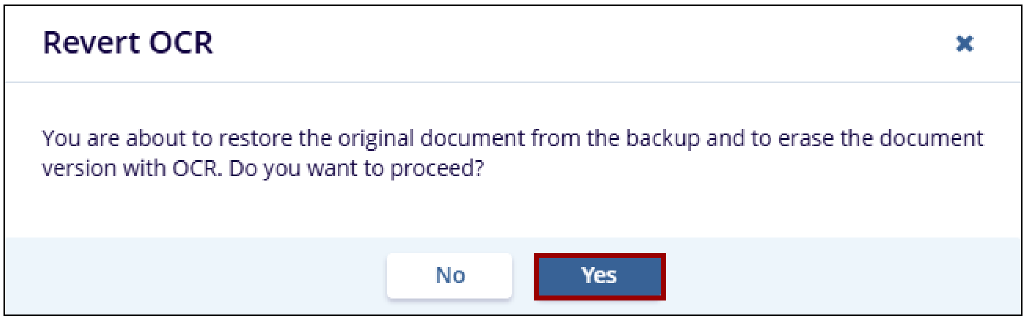
To apply OCR to a document, follow the steps below.

1. Select the OCR option from the Document Activities menu.
2. On the Select OCR Language popup, select up to 5 languages for the OCR.
3. Click on the OK button.



4. Once the document is successfully processed, the OCR column within the documents grid displays the processed status.

5. To revert OCR, select the Revert OCR option from the Document Activities menu.
6. On the Revert OCR confirmation popup, click on the Yes button.



7. Once OCR is successfully reverted, the OCR column within the documents grid displays the corresponding status.

Convert Non-PDF to PDF

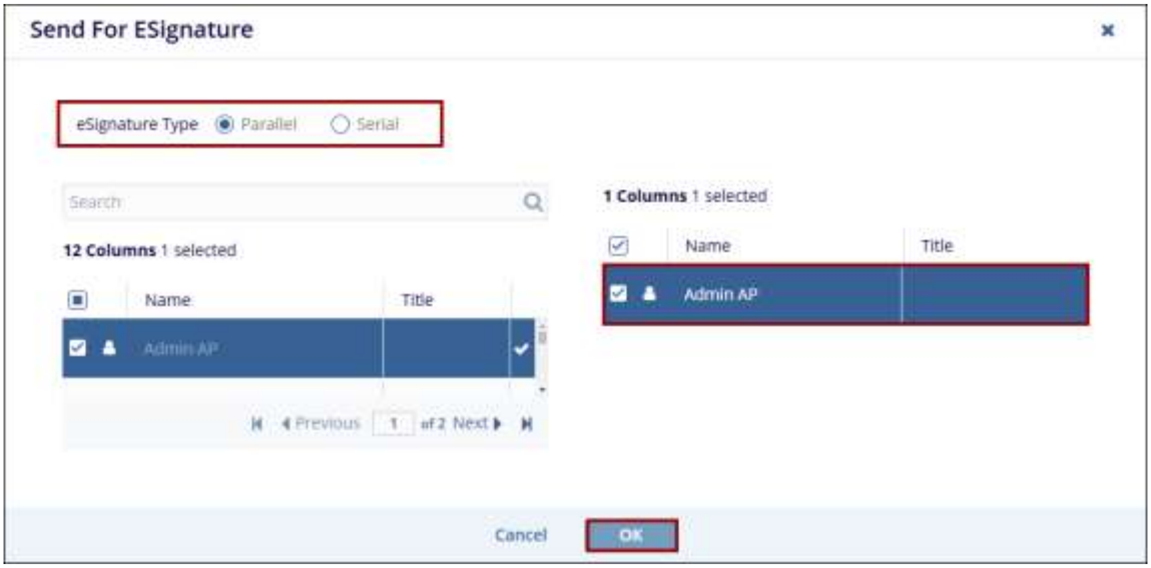
To convert non-PDF files into PDF files, follow the steps below.

1. Select the Convert Non-PDF to PDF option from the Document Activities menu.
2. Access the View by dropdown and select the Processing view.
3. Expand the PDF Conversion folder and select the Processed sub-folder to view the document converted into a PDF file.

Send for eSignature

To send a document for eSignature through the document activities menu, follow the steps below.

1. Select the Send for eSignature option from the Document Activities menu.
2. On the Send for eSignature screen, select the eSignature type as Parallel or Serial.
3. Add the users to whom the document is to be sent for eSignature.
4. Click on the OK button.



Note: To understand the eSignature process in detail refer to the eSigning Document section.

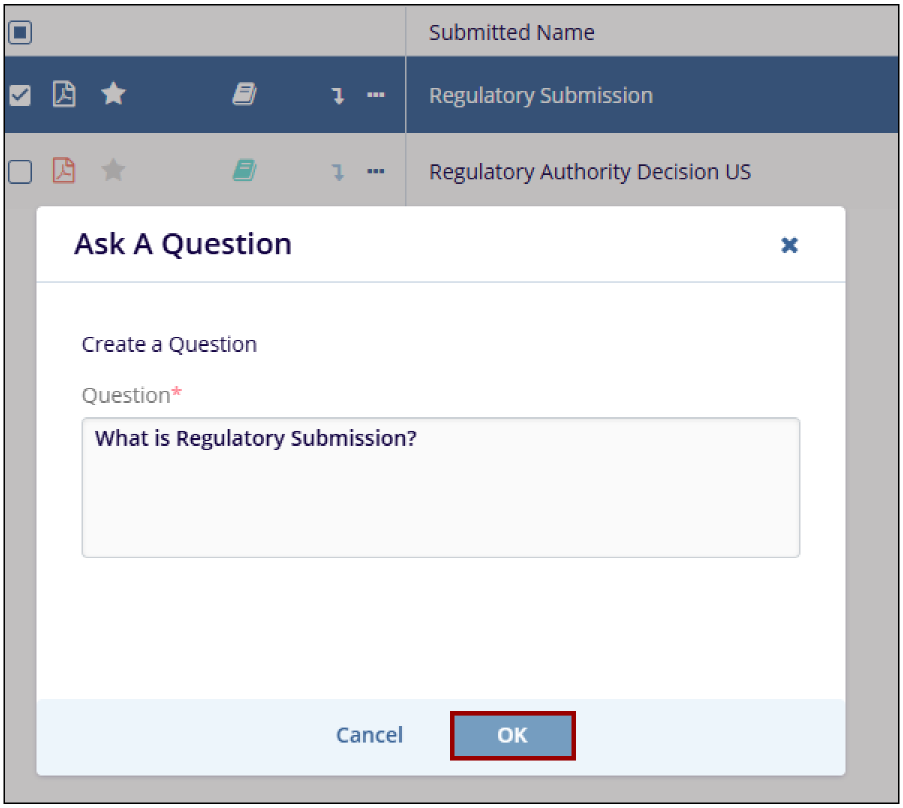
Ask a Question

This option allows users to submit a document-specific question directly to the Q&A module of the room.

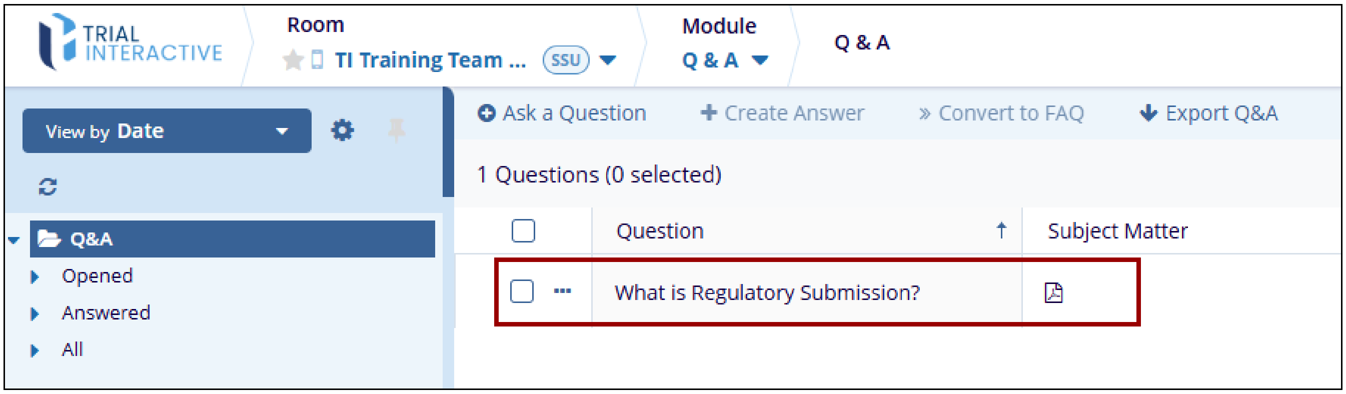
To submit a document to Q&A module, follow the steps below.

1. Select the Ask a Question option from the Document Activities menu.

2. Within the Ask a Question dialog box, enter the question into the respective field and click on the OK button.



3. Once successfully created, the question displays in the Q&A module.

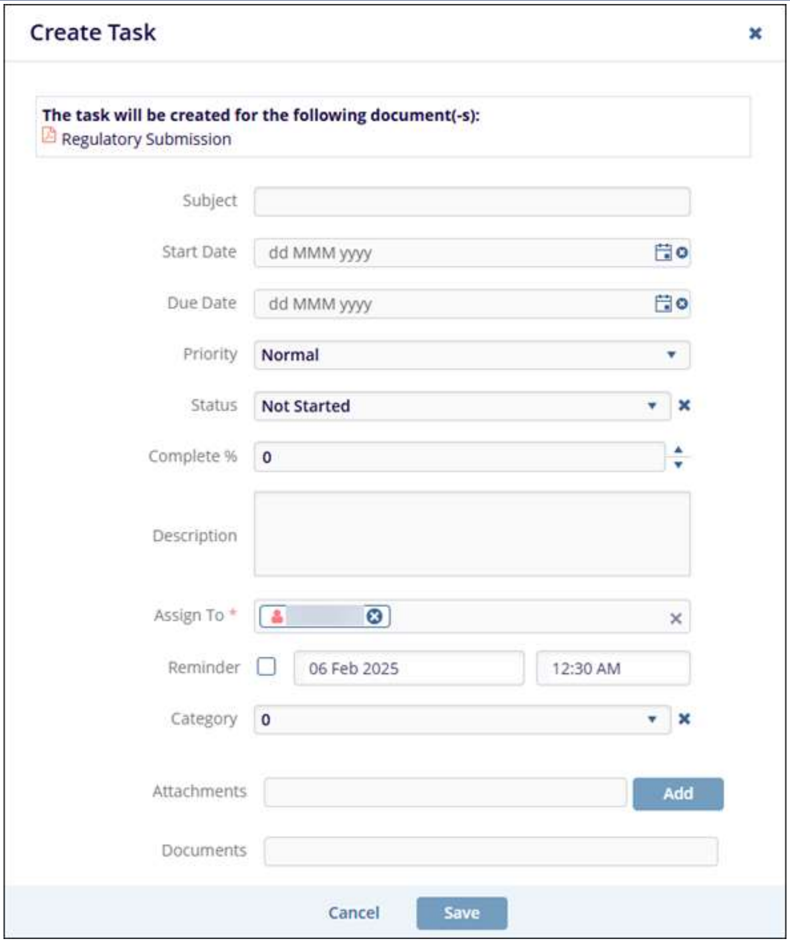


Create Task

To create a task, follow the steps below.

1. Select the Create Task option from the Document Activities menu.

2. On the Create Task form, fill in the necessary details and click on the Save button.

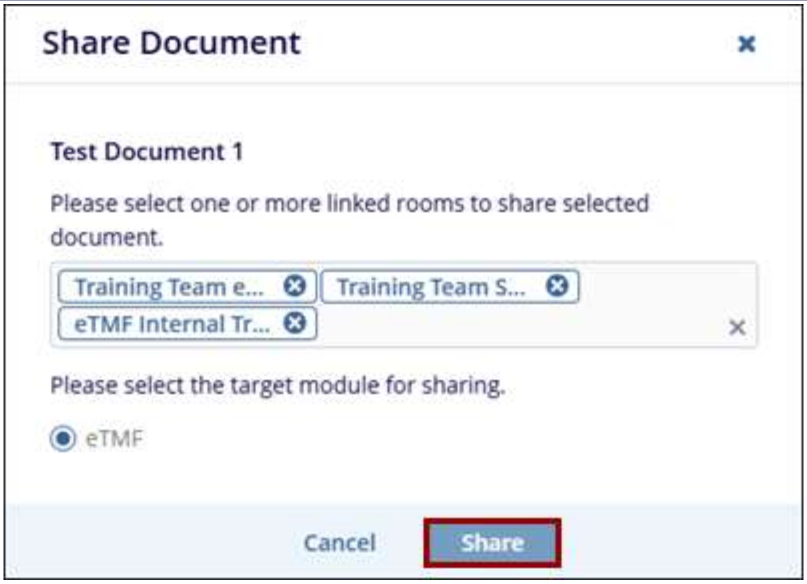


Share Document

With the Share Document functionality, users can share a document to other rooms assigned them.

To share a document, follow the steps below.

1. Click on the three-dot menu and select the Share Documents option.
2. On the Share Document popup window, specify one or more linked rooms.
3. Select a target module for sharing.
4. Click on the Share button.


Share Document
Test Document 1
Please select one or more linked rooms to share selected document.
Training Team e...
Training Team S...
eTMF Internal Tr...
Please select the target module for sharing.
eTMF
Cancel
Share

Document Metadata Panel

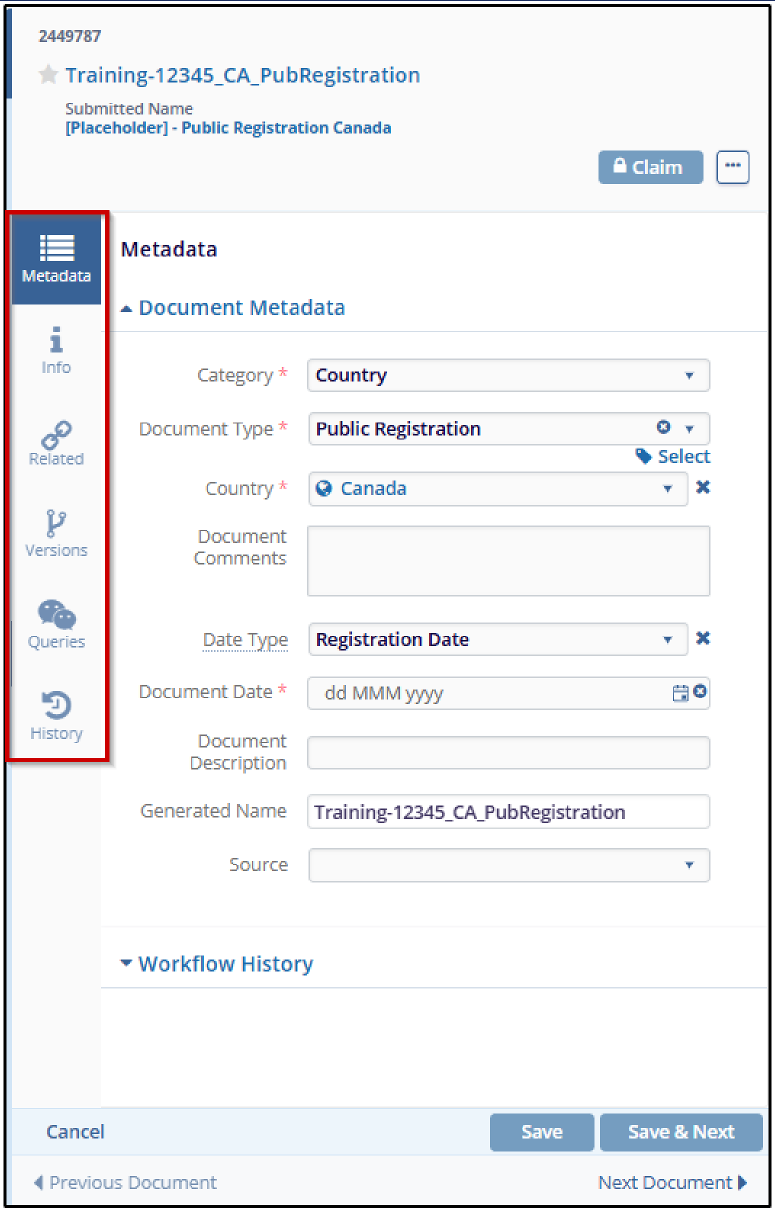
From the metadata panel located at the right of the documents grid, users can view the following tabs after selecting a document from the grid.

- Metadata
- Info
- Related
- Versions
- Queries
- History tab
- eSignature tab
- Workflow History

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

Users can expand or hide this panel by hovering the mouse to the right of the grid and clicking the Open/Hide arrow.

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

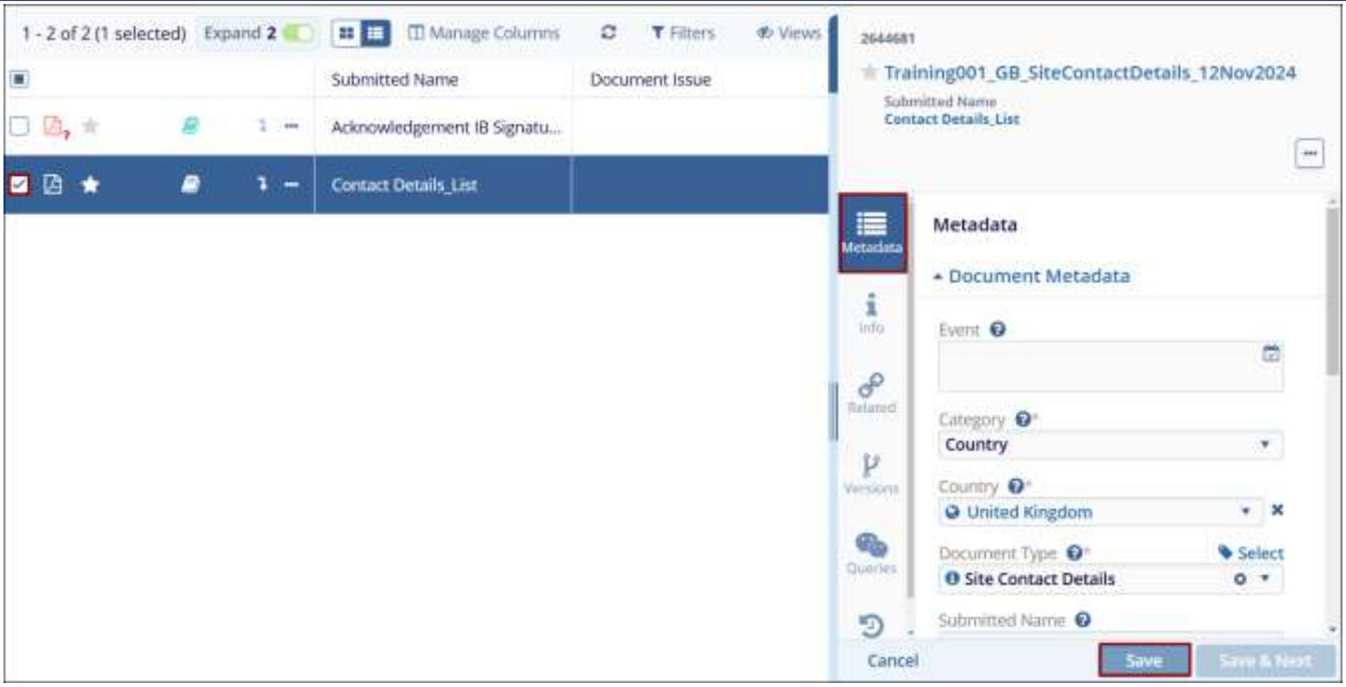


Metadata tab

The Metadata tab in the Metadata panel displays all details entered during the document addition process. Users with the required permissions can edit metadata fields.

To edit the metadata fields, follow the steps below.

1. Select a document by checking the box.
2. Open the metadata panel
3. Make necessary edits in the metadata tab.
4. Click on the Save button.



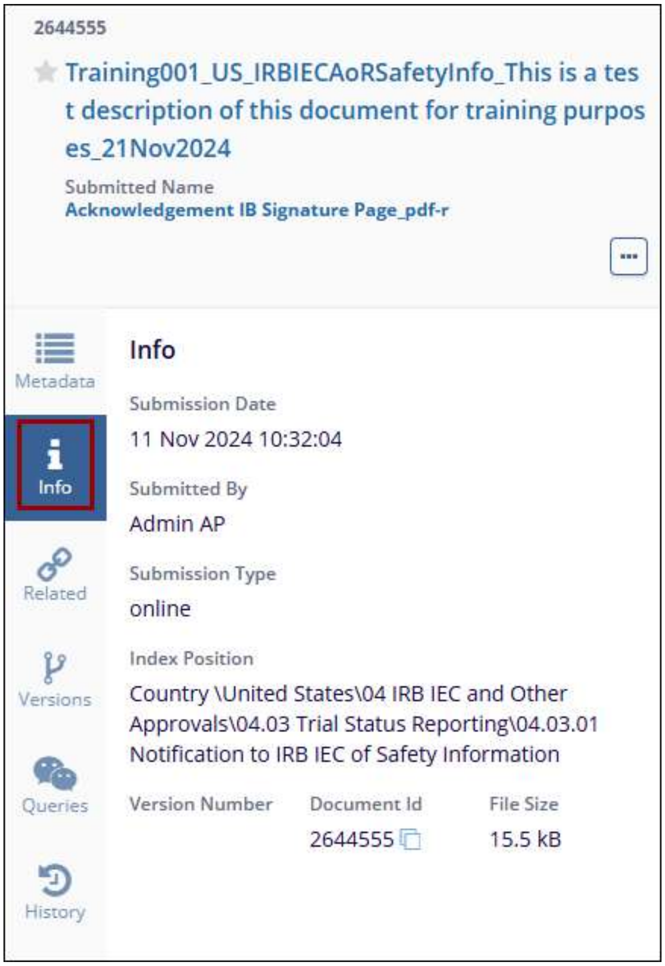
5. Additionally, click on the horizontal ellipsis (three-dot menu) to access the following options.

- Copy Field
- Paste Field
- Certify Document
- Create General Query
- Reject

Info tab

The Info tab within the Metadata panel of a document provides a comprehensive overview of key document details. This tab includes essential document information that helps users track document details. The information includes the following.

- Submission Date: The date when the document was added to the system.
- Submitted By: The name of the user who uploaded or submitted the document.
- Submission Type: The method or category under which the document was submitted
- Index Position: The assigned position of the document within the structured index
- Version Number: The current version of the document
- Document ID: A unique identifier assigned to the document
- File Size: The size of the document file, displayed in bytes, kilobytes (KB), or megabytes (MB).

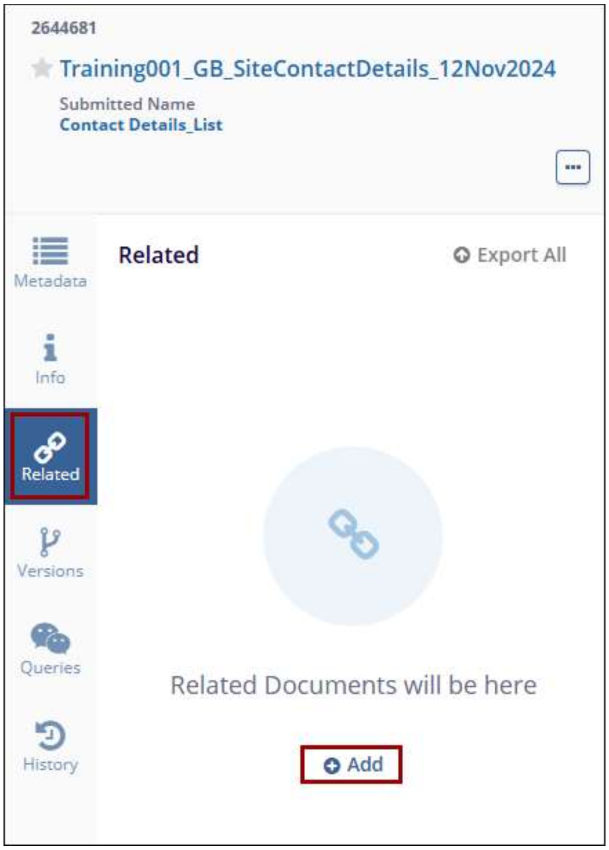


Related Tab

The Related tab in the Metadata panel displays all documents associated with a specific document. Users can also add additional related documents from this section.

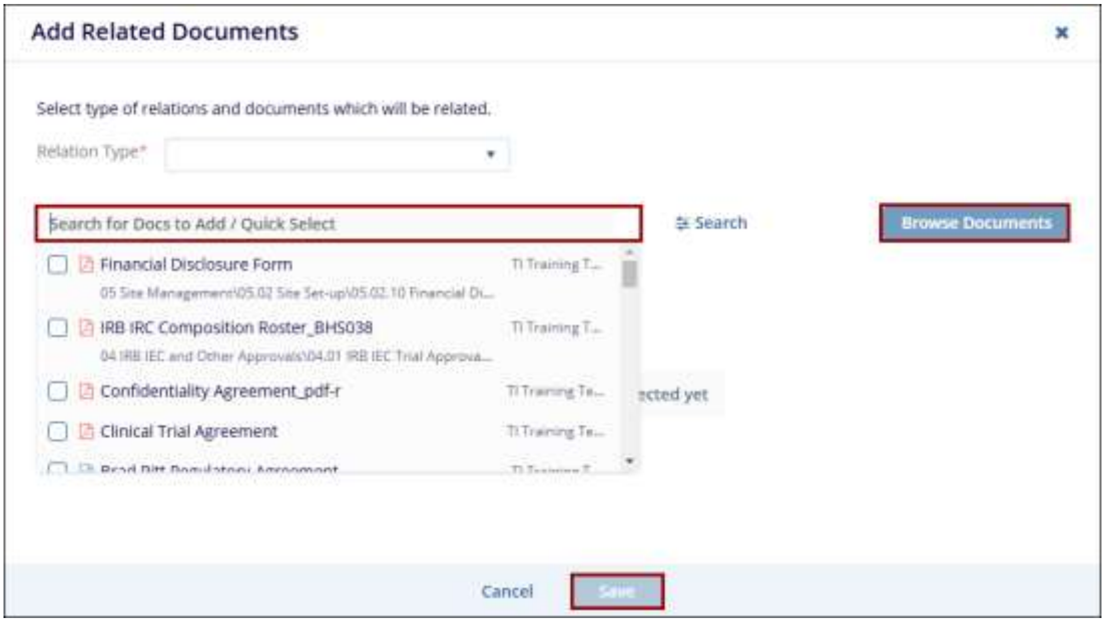
To add a related document, follow the steps below.

1. Click on the +Add button within the Related tab.



2. Select the Related Type from the dropdown options and the document using the Quick Select functionality else click on the Browse Documents button.

3. Once the necessary documents are added, click on the Save button.

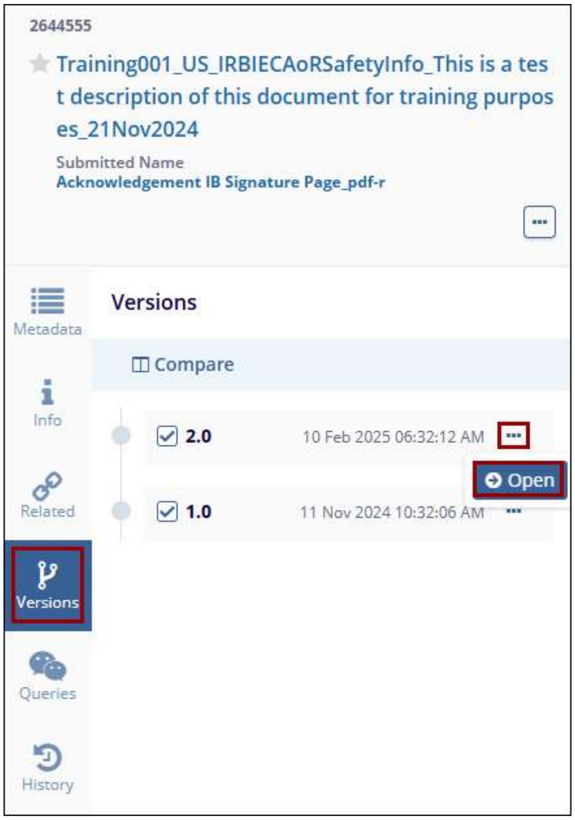


Versions Tab

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

To view the different versions, follow the steps below.

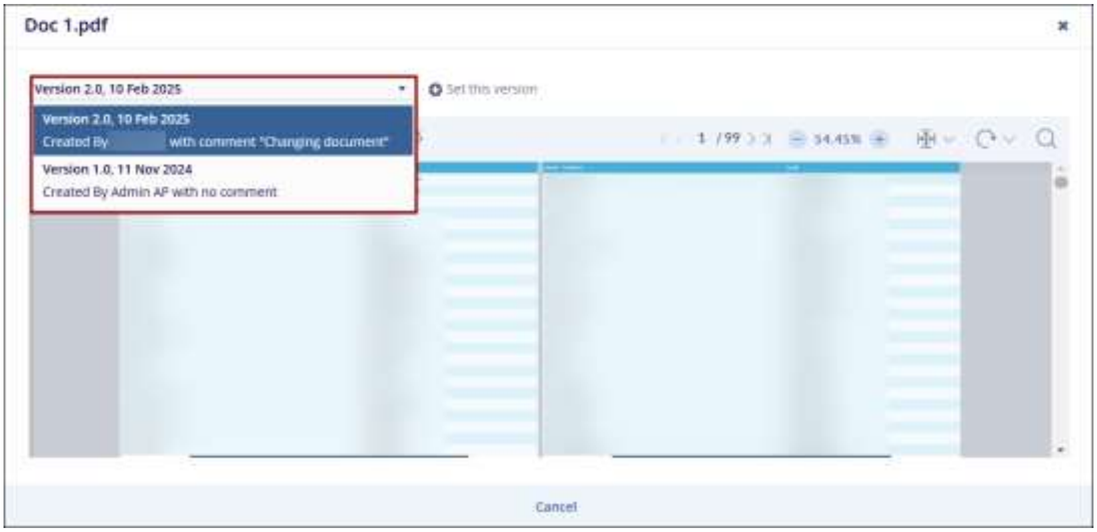
1. Select a document from the grid and click the Versions tab from the Metadata panel.
2. Click on the horizontal ellipsis (three-dot) icon and select the Open option to view the document in the TI Document Viewer.



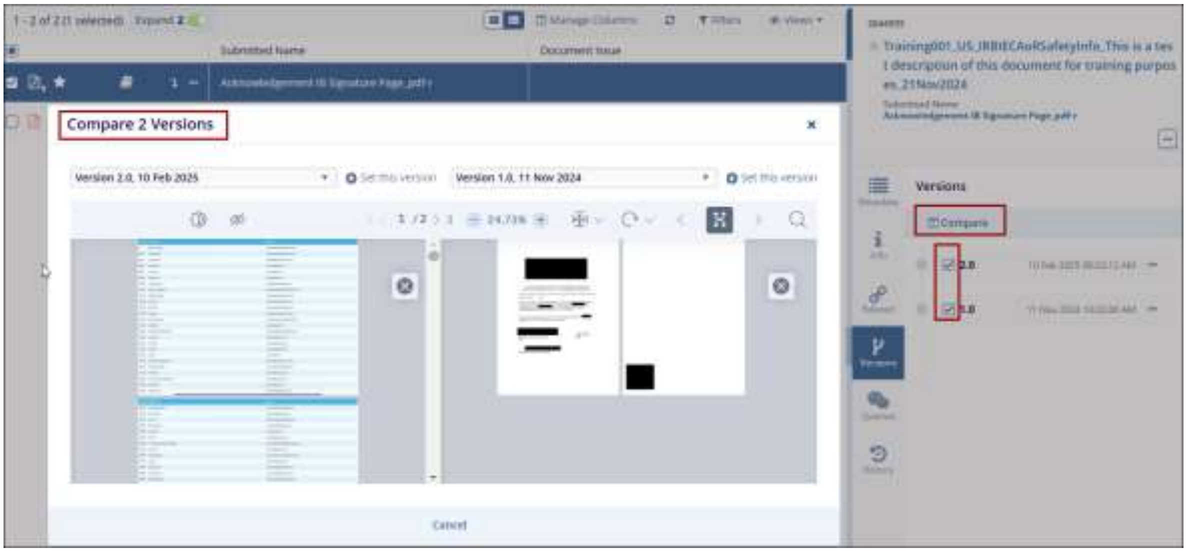
3. Click on the dropdown menu to access the different document versions.
4. Click on the Set this version button, to set a specific version as the active one.
5. Access the Navigation menu that allows the user to:

- Download
- Print
- Zoom in/out
- Adjust brightness, contrast, and colors
- Adjust height and width
- Rotate
- Navigate through pages

- Search

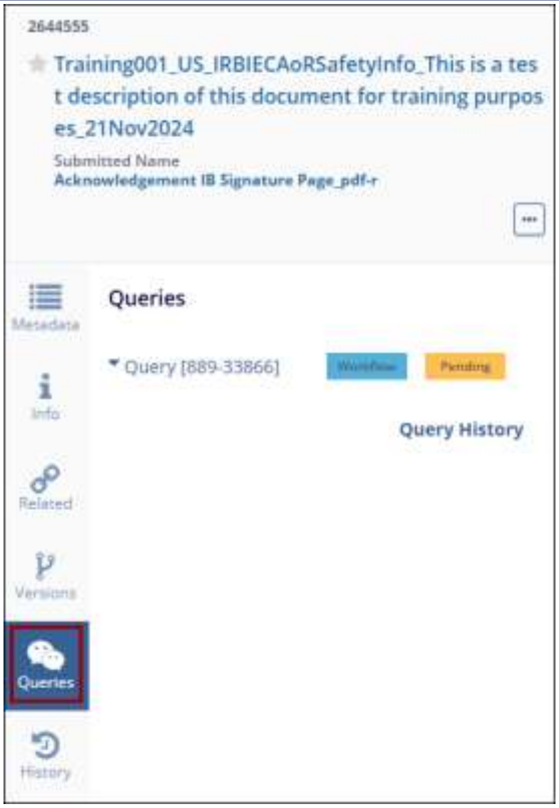


6. Select the documents and click on the Compare button to display documents from both the versions in a side-by-side view.



Queries

This tab is visible only if a query is assigned to the users. Users can perform all query-related activities from the metadata panel.

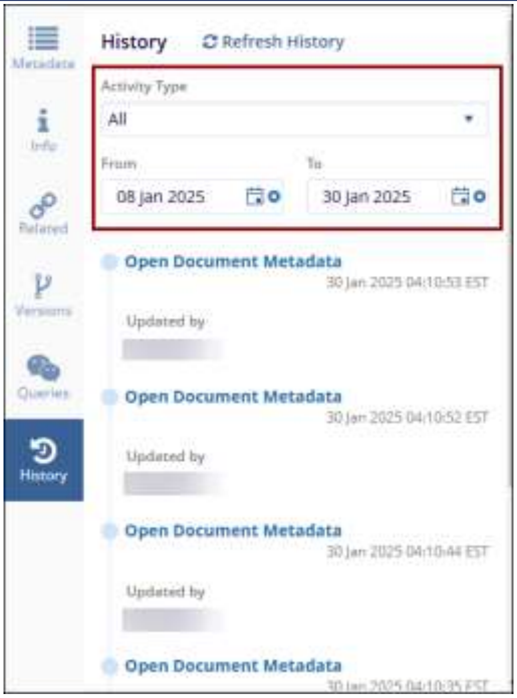


History Tab

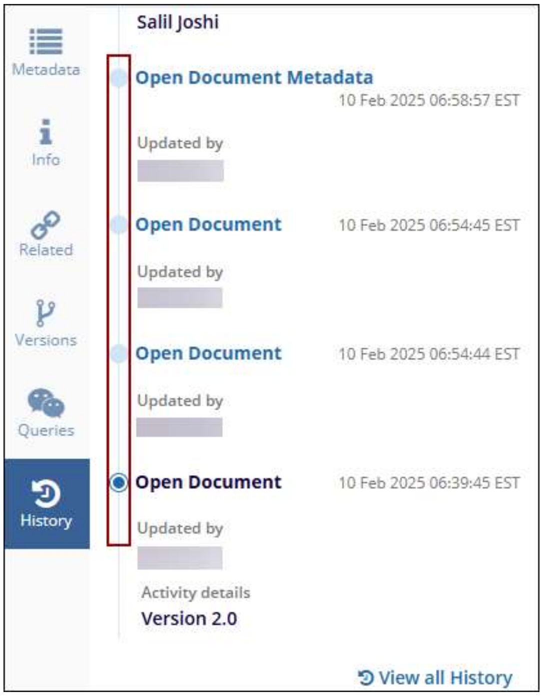
The History tab gives an overview of the document's history. The History tab displays the top five entries of the activities performed on the document. Here, users can apply the Activity Type and From & To filters to view the history of a document. Additionally, users can view the entire document history by selecting the View all History option.

To access and perform various functions within the History tab, follow the steps below.

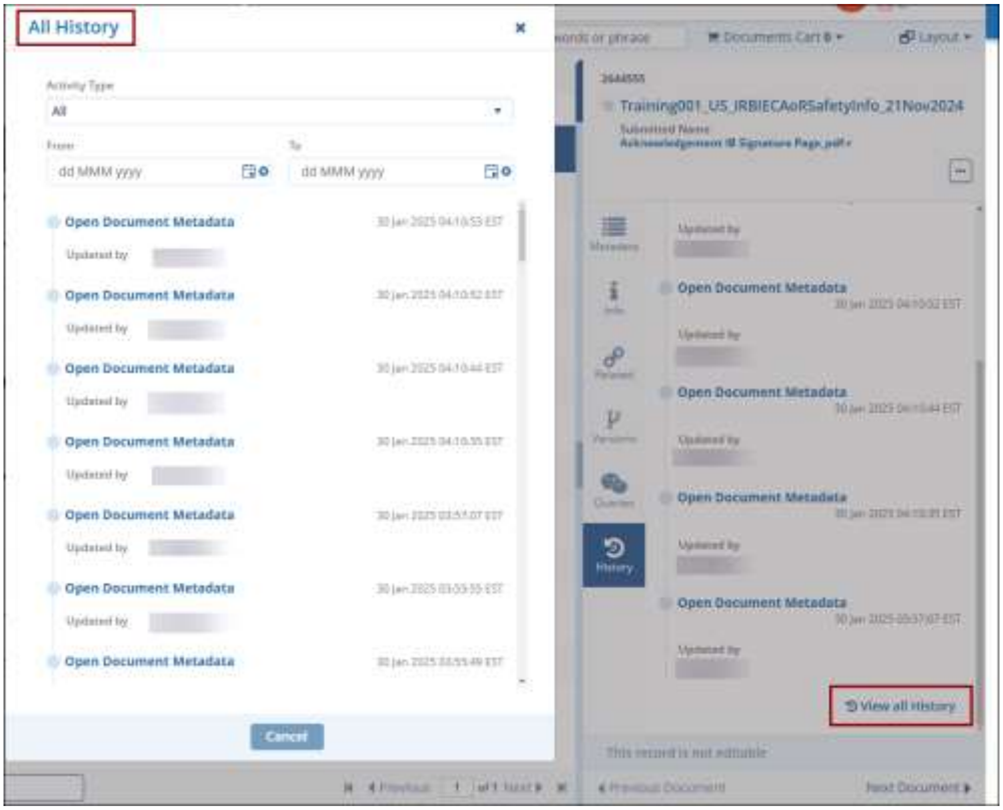
1. Select a document from the grid and click the Versions tab from the Metadata panel.
2. Apply the following filters to and filters to view the history of specific activities and time range.
    - Activity Type: Use this drop-down to view the document history by the activity performed on it.
    - From & To: Use this filter to view the document history within the set date range.



3. Every activity in the History panel is denoted by a node. Click the node to view the description, date, time, and name of the person who performed the activity on the document.



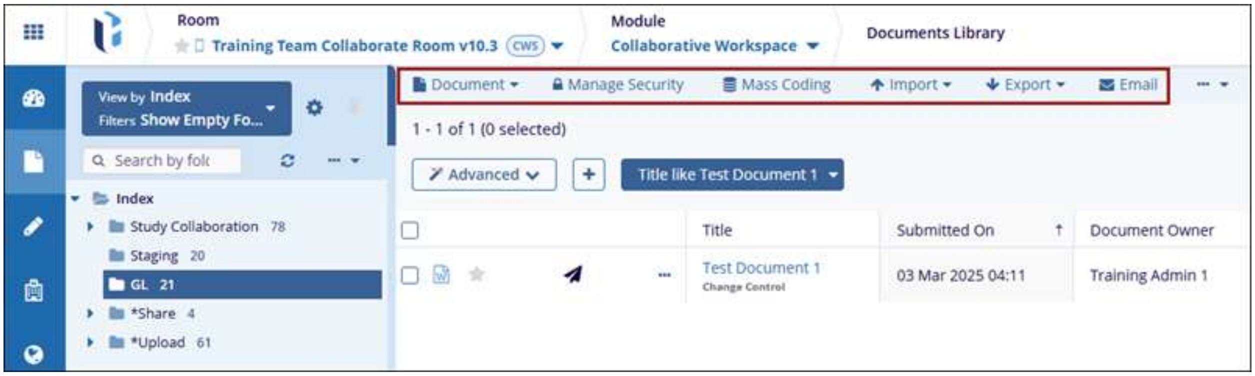
4. Click on the View All History button to display the complete history of a document and filter the document history based on the Organization, Activity Type, and Duration.


All History
Activity Type
All
From
dd MMM yyyy
To
dd MMM yyyy
Open Document Metadata
Updated by
Open Document Metadata
Updated by
Open Document Metadata
Updated by
Open Document Metadata
Updated by
Open Document Metadata
Updated by
Open Document Metadata
Updated by
Open Document Metadata
Cancel
Documents Cart
Layout
Training001_US_IRBIECAoRSafetyInfo_21Nov2024
View all History
This record is not editable
Previous Document
Next Document

Documents Library - Top Menu Ribbon

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

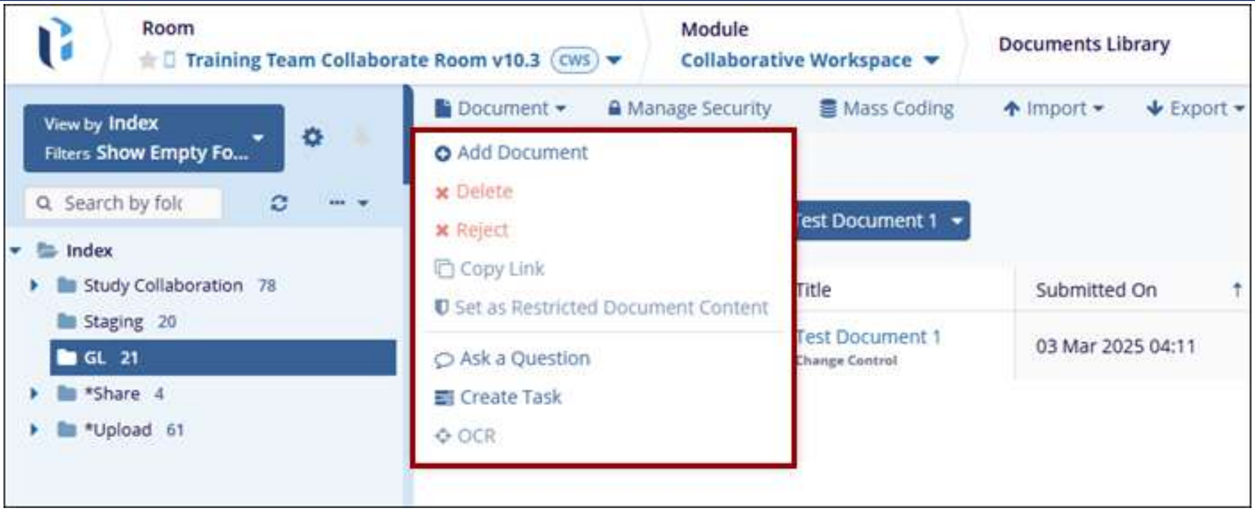
- Document Activities
- Manage Security
- Mass Coding
- Import
- Export
- Email
- Print
- Compare
- Local Search
- Documents Cart



Document

The options available in this dropdown menu are only available once a document has been selected in the grid and are a subset of the options available in the Document Activities menu mentioned in the section above.

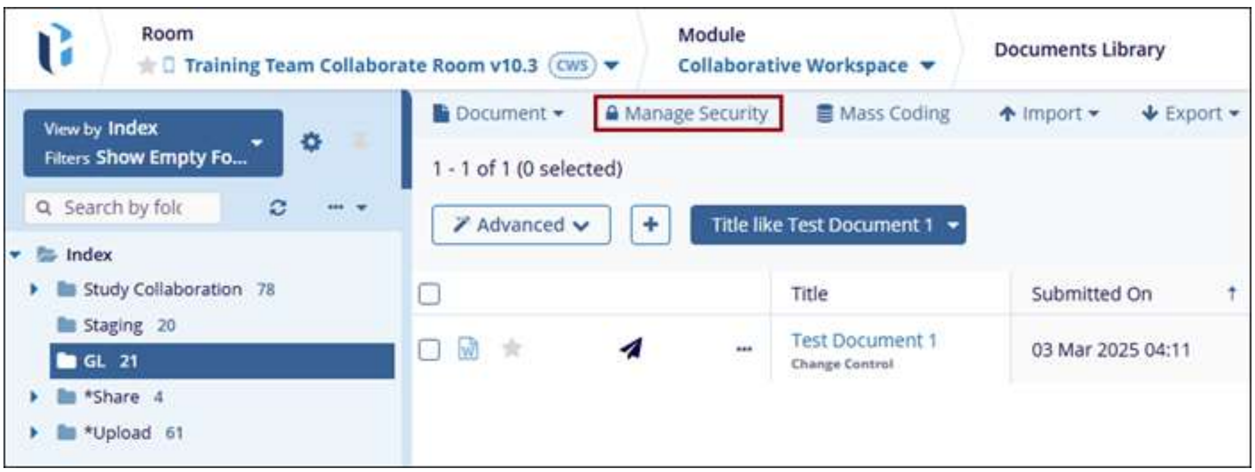
Refer to the Document Activities Menu section for a more detailed description of these options.



Manage Security

To manage folder security, follow the steps below.

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

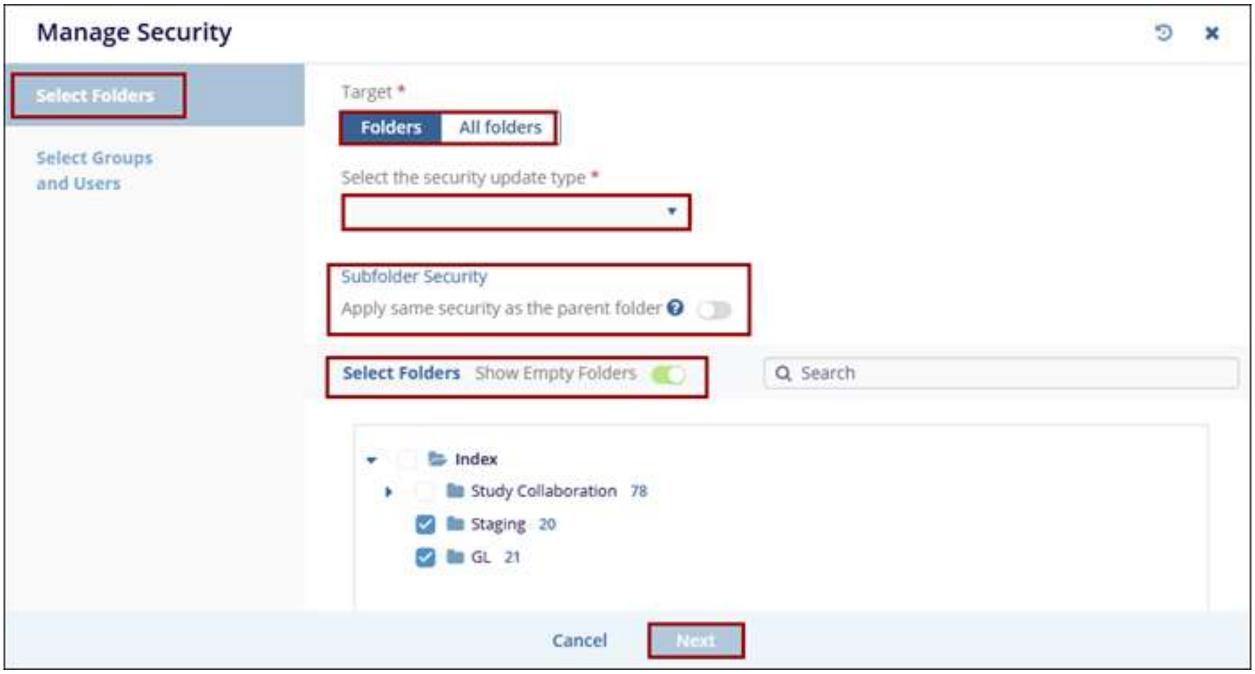


2. Within the Target* section, click on the Folders tab and select the folders to apply security to. To search for a specific folder, enter the search term in the search box.
3. Click on the All Folders button to apply security to all the folders.
4. Select whether or not the changes should apply to all subfolders or only to the folders specifically chosen by accessing the Apply same security to the parent folder toggle switch.
5. Enable or disable the Show Empty Folders toggle switch to display and hide empty folders respectively.
6. Select a security type by accessing the Select the security update page* dropdown options.

   - Update existing security: This option leaves all current security definitions in place and adds on any new definitions set in step two of the manage security process.

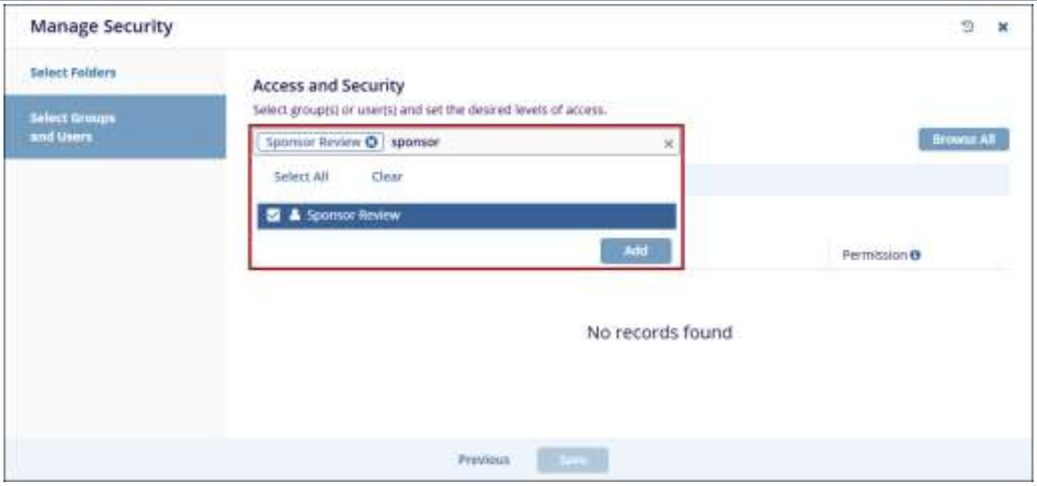
- Overwrite existing security: This option erases all current security definitions and replaces them entirely with the definitions set in step two of the manage security process.
- Remove from existing security: This option leaves intact any security definitions already assigned but removes access for any group(s) or user(s) specified in step two of the manage security process.
- Restrict access to administrators only: This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.

7. Click on the Next button.

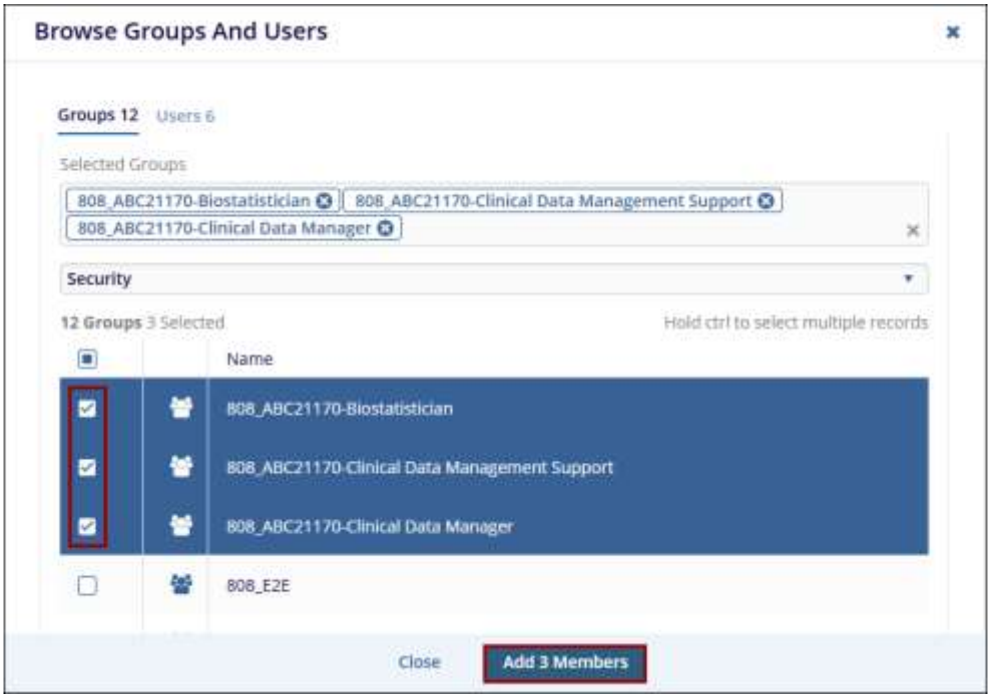


8. On the Select Groups and Users screen, perform the following

- Enter a keyword related to the users or groups, select the required groups and users from the dropdown options and click on the Add button.



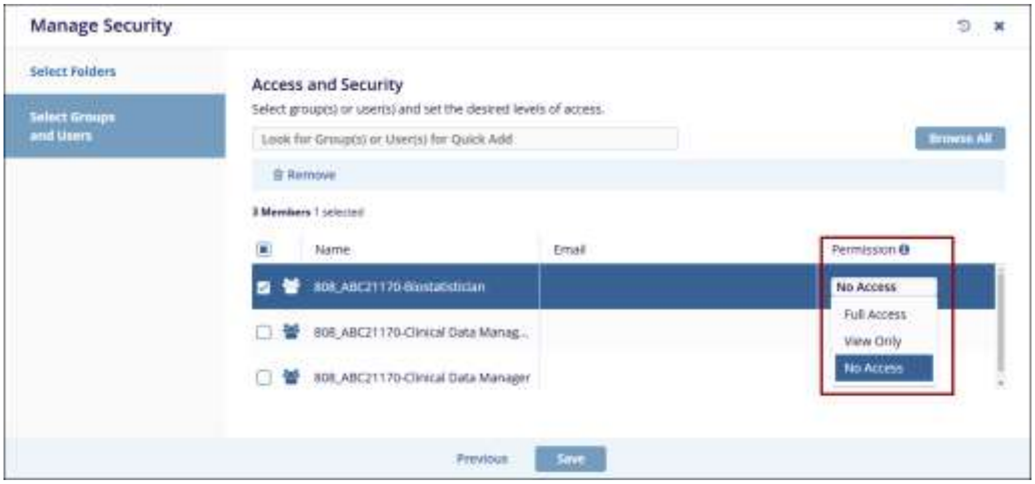
- Additionally, click on the Browse All button and select the required users and groups by navigation to their respective tabs.



- Once the required groups and users are added, click on the Permissions dropdown and provide the necessary permissions.

    1. Full Access: Users have unhindered access-level-appropriate access to the documents.
    2. Read-Only Access: Users can only view the documents.
    3. No Access: These users will not even see this folder on their room index and cannot access any associated files.
    4. No Watermark: This option will only appear for rooms in which the watermark option is enabled. It allows the selected user to view the documents in the chosen folders without the watermark.

5. Proxy Document Owner (For collaborate rooms): This allows the specified user to act as a document owner for any documents contained in the selected folders.



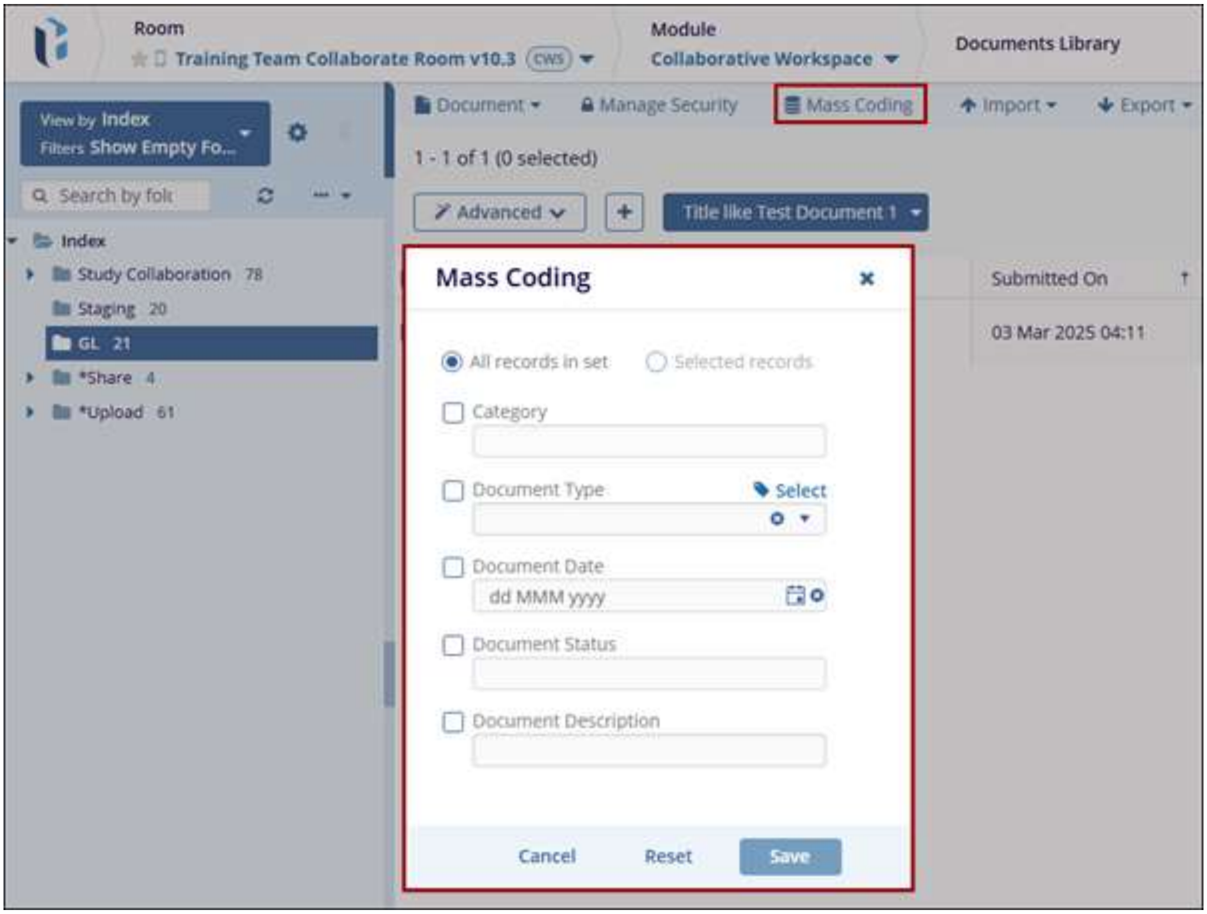
9. Once all the changes are made, click on the Save button.

Mass Coding

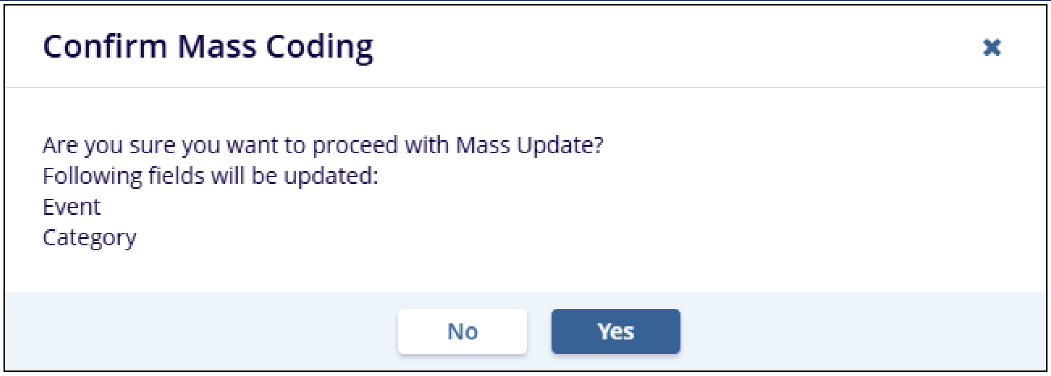
The Mass Coding function, allows the user to apply metadata to multiple documents at the same time. A room can be configured to allow both Causality Tracking and Mass Coding.

To apply mass coding, follow the steps below.

1. Click on the Mass Coding button displayed in the top menu bar to open the popup window to mass code all documents in grid.
2. Otherwise, select an individual document and clicking on the Mass Coding button.
3. Mandatorily enter the reason in the Mass Coding Reason* field
4. Additionally, select the fields to update by clicking on their respective checkboxes.
5. Click on the Save button displayed at the bottom of the popup window.



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



Important

- If no document is selected from the grid, the Mass Coding window displays All Records in set selected by default.
- If an individual document is selected, the Selected Records radio button is selected by default.
- Alternatively, the user can also drag-drop the documents in document cart and select the Mass Coding option from the Actions dropdown menu.

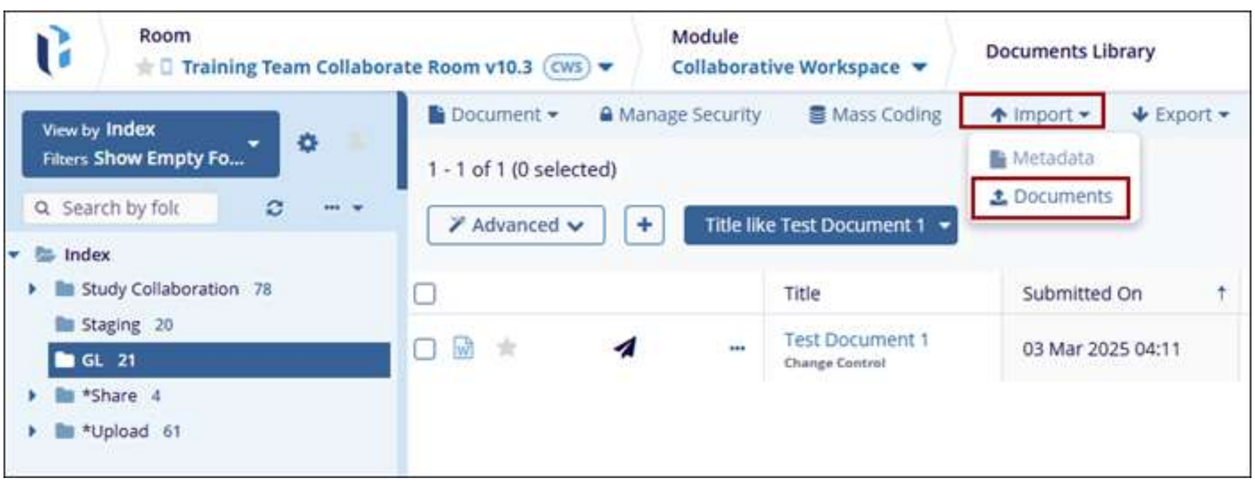
Import

The Import function allows users to add multiple documents into the room, where permissible, the function also allows for the import of metadata.

Documents

To import documents, follow the steps below.

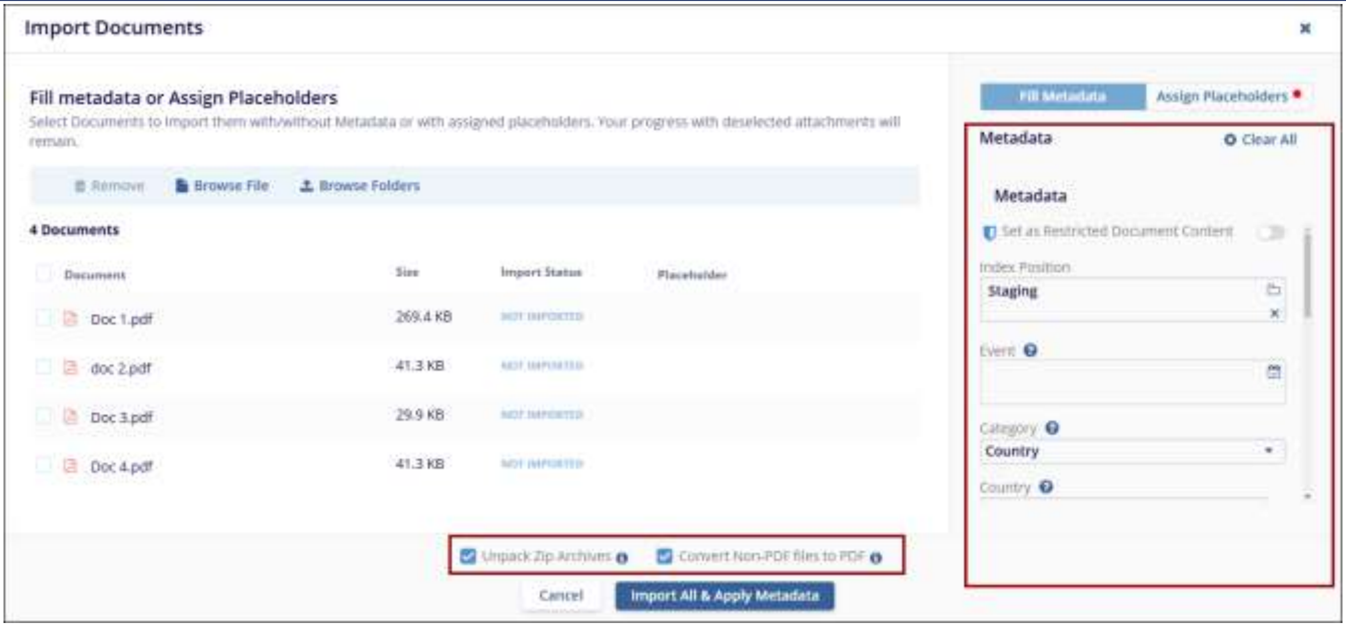
1. Click on the Import button from the top menu bar and select Documents options. This opens the Import Documents window.



2. On the Import Documents window, add single or multiple documents using the drag & drop functionality or manually upload the documents by selecting Browse File or Browse Folders.

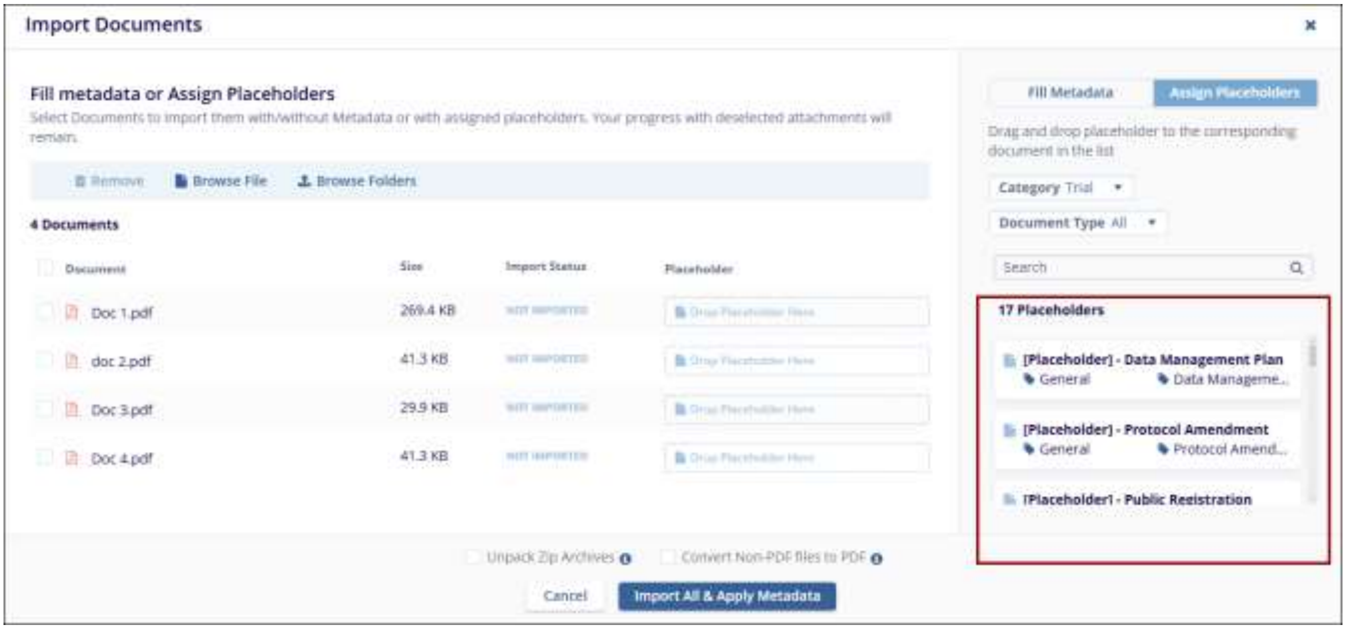
3. Once the documents are uploaded, add the necessary information in the Fill Metadata tab.
4. Select the following checkboxes

   a. Unpack Zip Archives: Enable this option if a ZIP folder is uploaded and the documents within the ZIP folder need to be uploaded as separate documents.
   b. Convert Non-PDF files to PDF: Enable this option to convert any file format into PDF files.

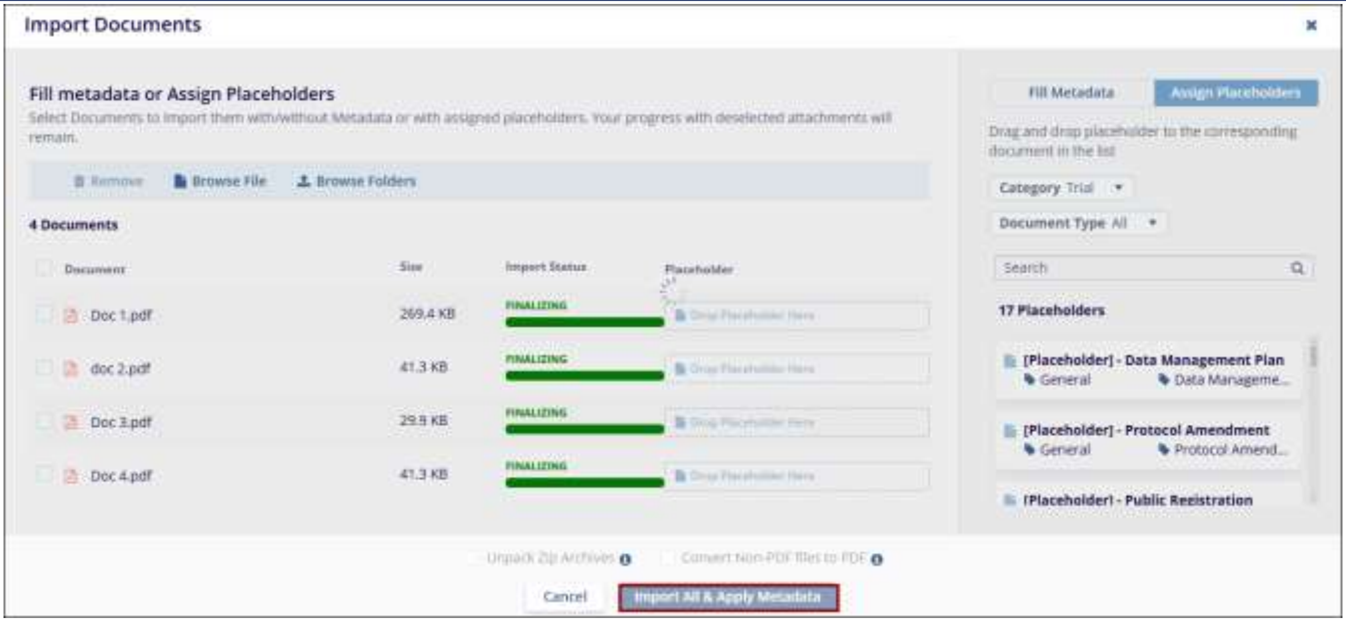


5. If metadata fields are not added, navigate to the Assign Placeholders tab and drag & drop the placeholders within the designated area.

   Note: If Category, Country and Document Type is selected within the Fill Metadata tab the Assign Placeholders tab will display the placeholders by default.



6. Click on the Import All & Apply Metadata button once the metadata fields are updated or the placeholders are assigned.



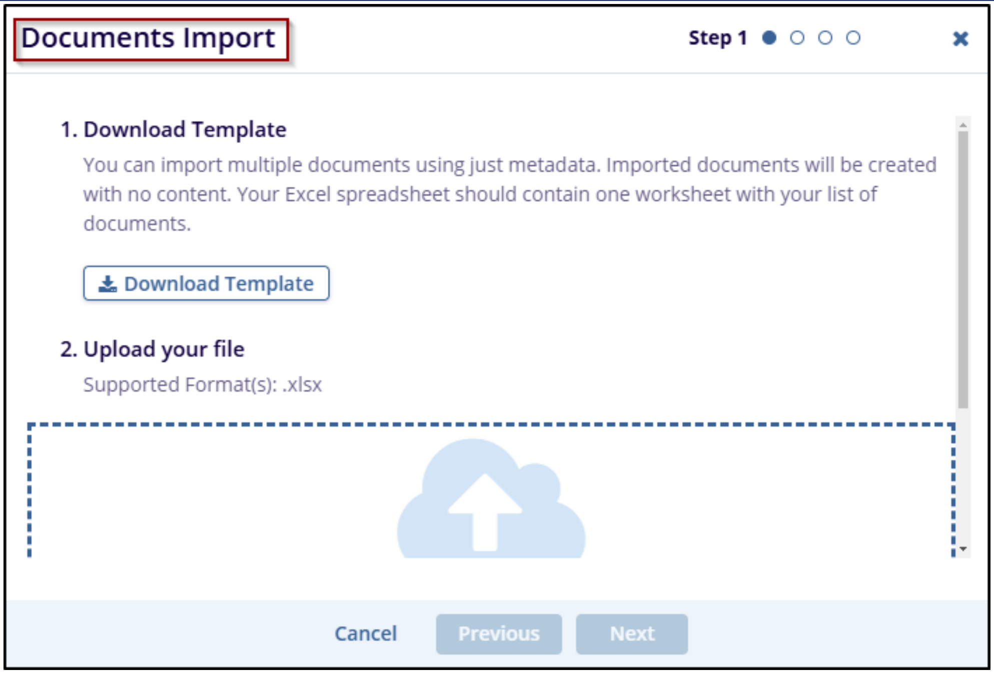
Note: If the metadata is applied to only a few of the documents, only those documents will be uploaded to the room.

Metadata

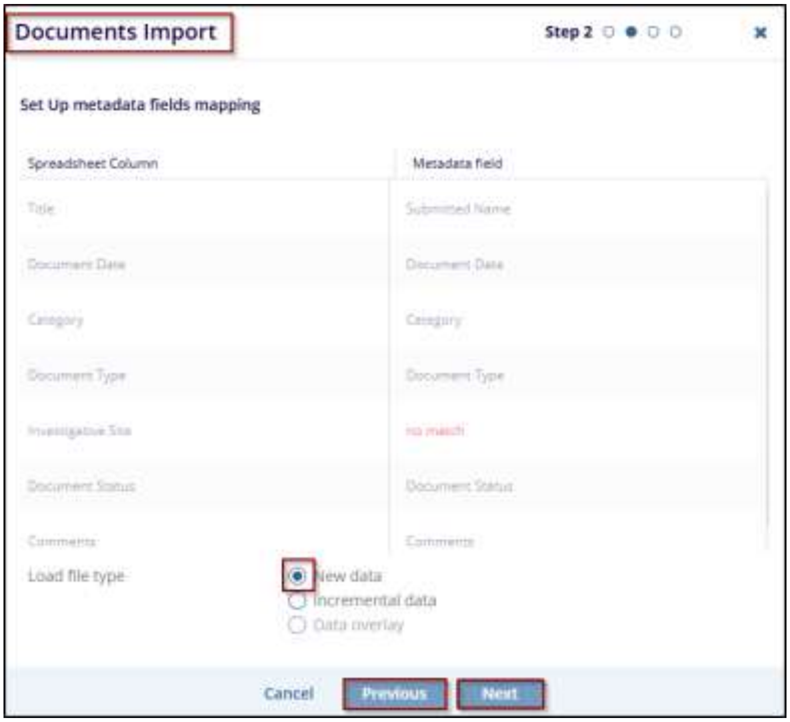
The metadata Import option allows users to import metadata associated with documents, such as document type, category, country, or other key data. It enables the system to update or create metadata records in bulk, ensuring that documents are properly categorized and searchable.

To import the metadata, follow the steps below.

1. Click on the Import button, and select the Metadata option. The Document Import window opens.
2. In the Document Imports window, click on Download Template to get a pre-formatted file that contains the required metadata fields.
3. Open the downloaded template and fill in the necessary details as per the systems guidelines.
4. Under the Upload Your File section, locate the Browse button. Click Browse to open the file explorer.
5. Select the appropriate file or folder containing the metadata information.
6. Once selected, the system will display the chosen file. Click Next to proceed.



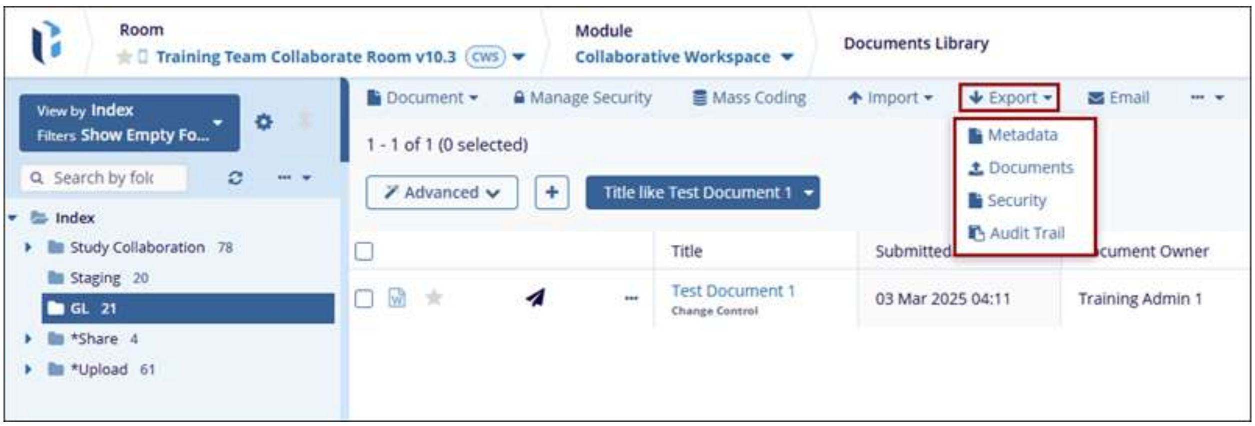
7. The system displays a Metadata Fields Mapping screen, ensuring that each column from the uploaded file is correctly mapped to the system's metadata fields.
8. Once the mapping is correctly set, click Next to proceed. If any errors are detected, click on the Previous button and go back to correct them.
9. Once confirmed, proceed by clicking Next to Import the data.



10. Click OK to View the results.

Export

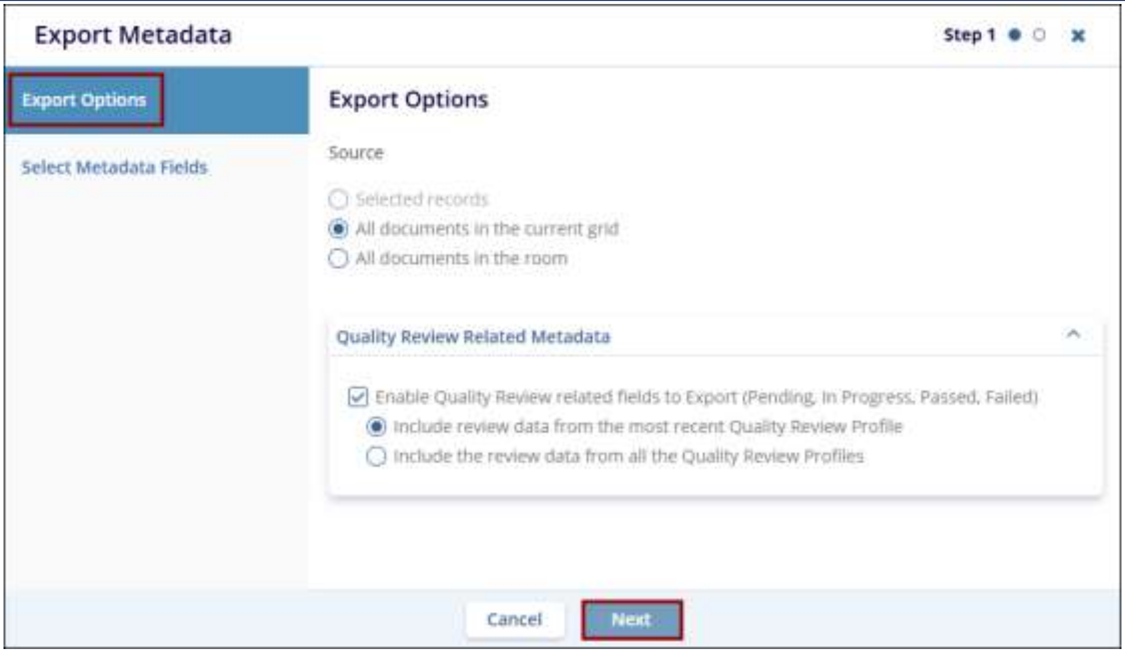
The Export function allows users to export either selected or all documents that are currently present in the grid. Like the Import function, this export can export documents, metadata, or both. Users with sufficient access will be able to export security and audit trial information.



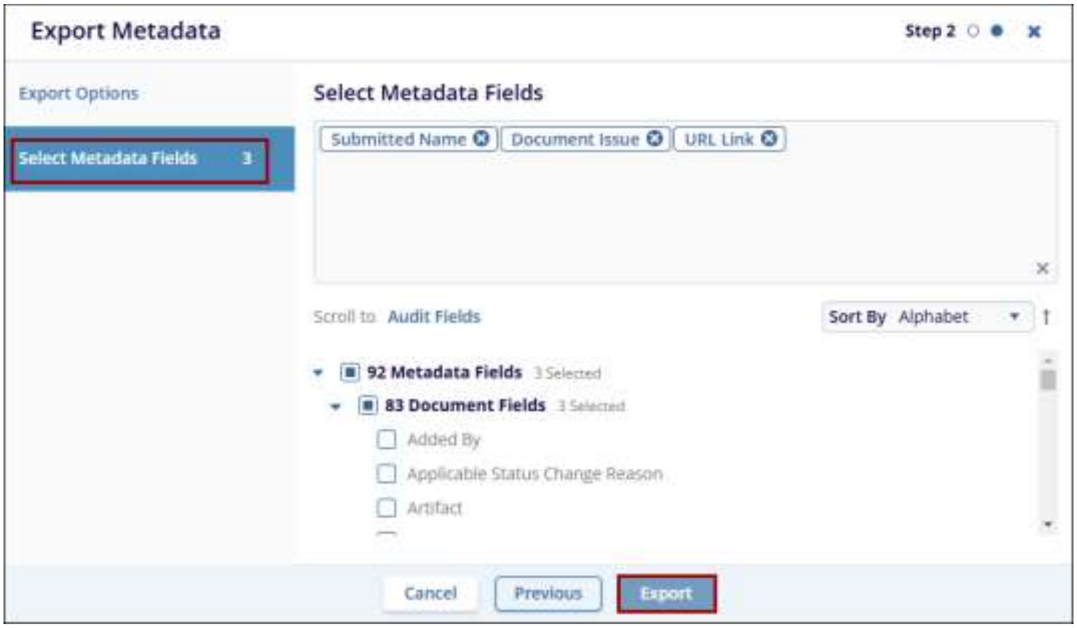
Metadata

To export Metadata, follow the steps below.

1. Click on the Export button and select the Metadata option. The Export Metadata window opens.
2. In Step 1, Select any one option from the Source options.
   - Selected records
   - All documents in the current grid
   - All documents in the room
3. Choose whether or not the export should include Quality Review (audit) related Metadata. If yes, indicate whether all information should be provided or only the information from the most recent audit.
4. Click on the Next button.



5. In Step 2, select the required metadata fields and click on the Export button.



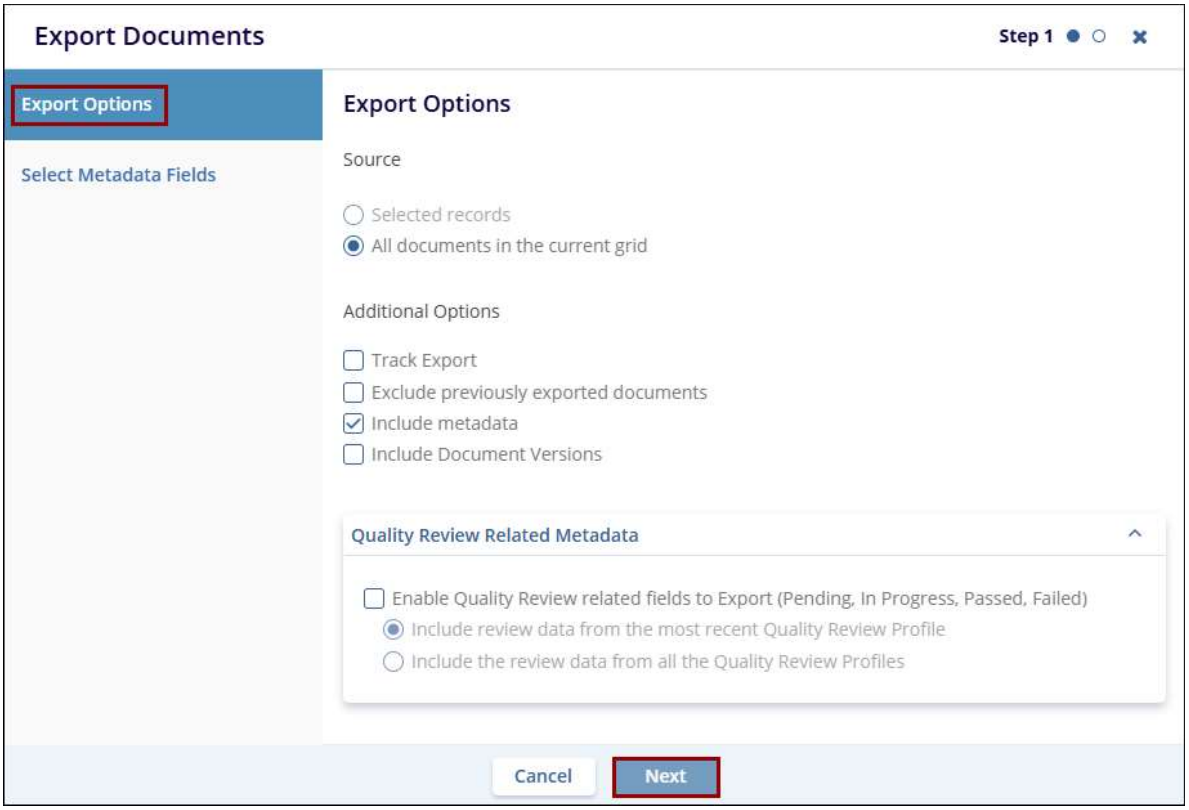
Documents

To export Documents, follow the steps below.

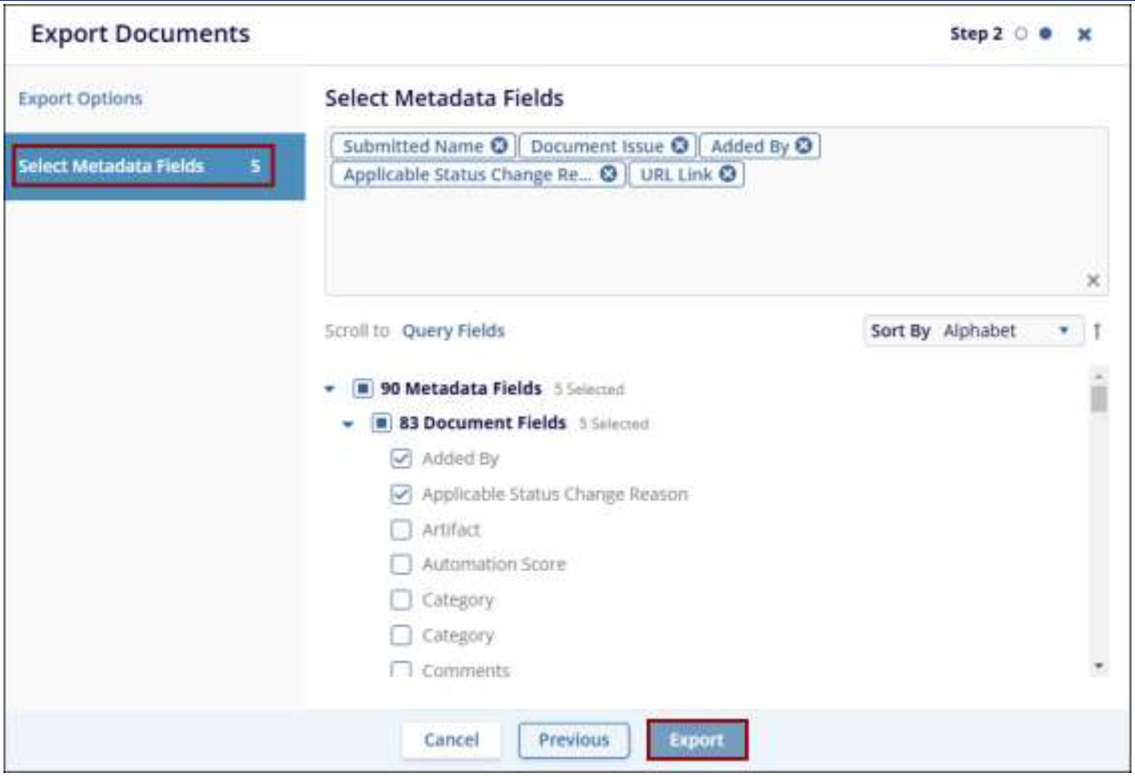
1. Click on the Export button and select the Documents option. The Export Documents window opens.

2. In Step 1, Select any one option from the Source options.
    - Selected records
    - All documents in the current grid

3. From the Additional Options section, select the required options. These options will vary depending on user access rights.
    - Track Export
    - Exclude previously exported documents
    - Include Metadata
    - Include Document Versions
4. If the Include Metadata option is selected, choose whether or not the export should include Quality Review (audit) related Metadata.
    - If yes, indicate whether all information should be provided or only the information from the most recent audit.
5. Click on the Next button.



6. In Step 2, select the required metadata fields and click on the Export button.

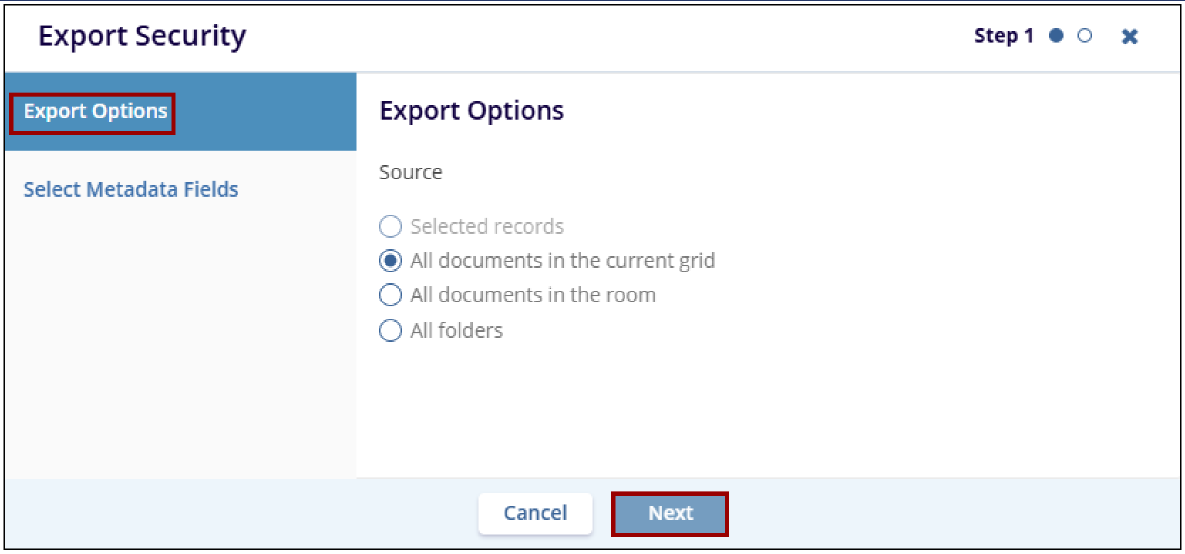


7. Click on the Get Job Results button to download the file.

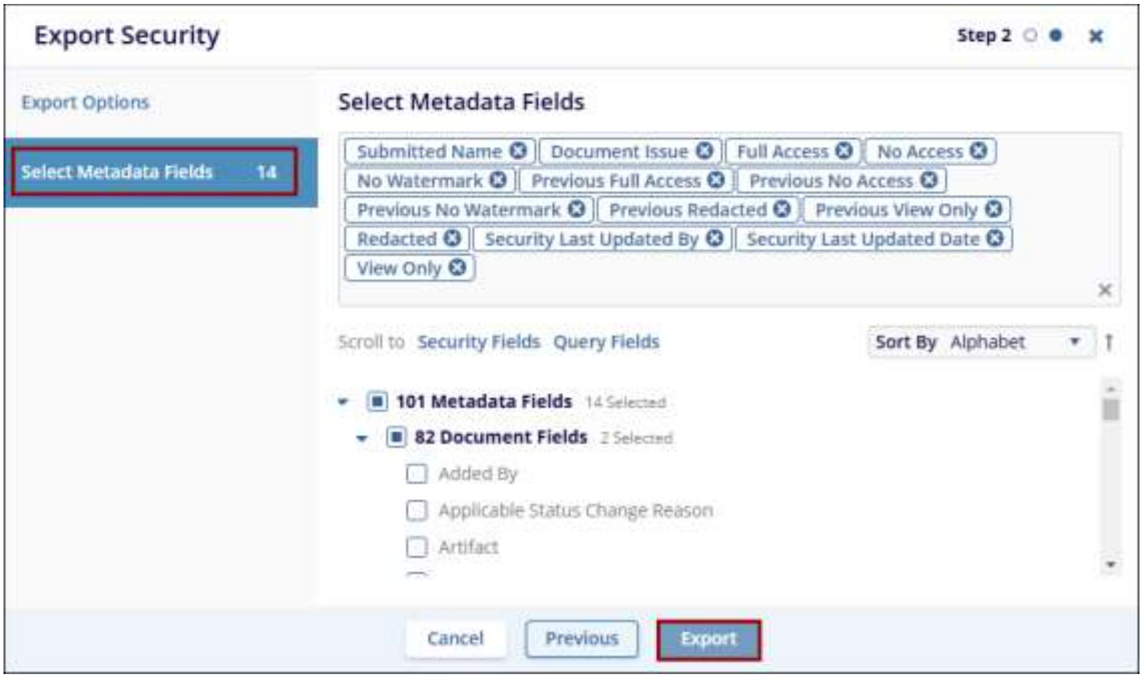
<u>Security</u>

To export Security Information, follow the steps below.

1. Click on the Export button and select the Security option. The Export Security window opens.
2. In Step 1, Select any one option from the Source options.
    - Selected records
    - All documents in the current grid
    - All documents in the room
    - All Folders
3. Click on the Next button.



4. In Step 2, select the required metadata fields and click on the Export button.



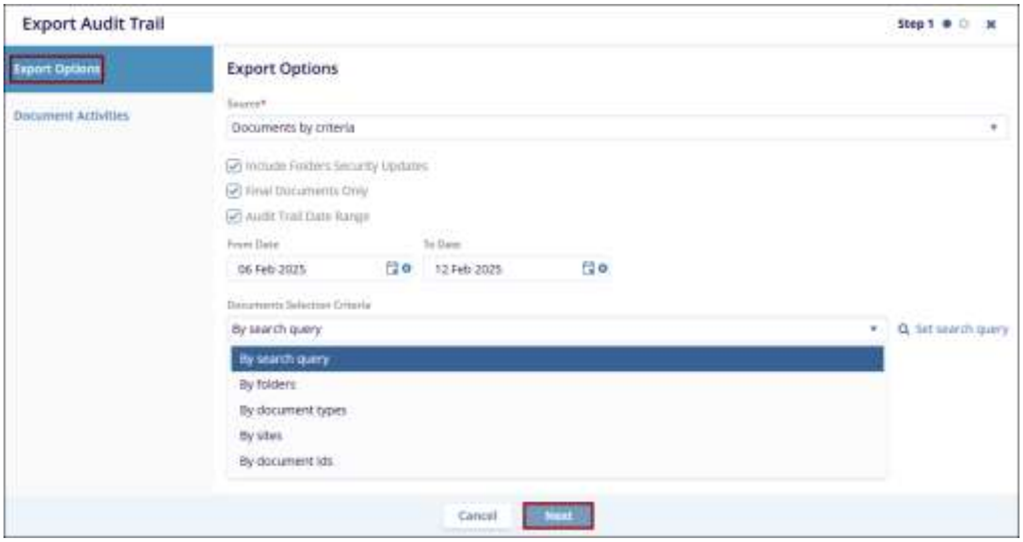
5. Click on the Get Job Results button to download the file.

<u>Audit Trials</u>

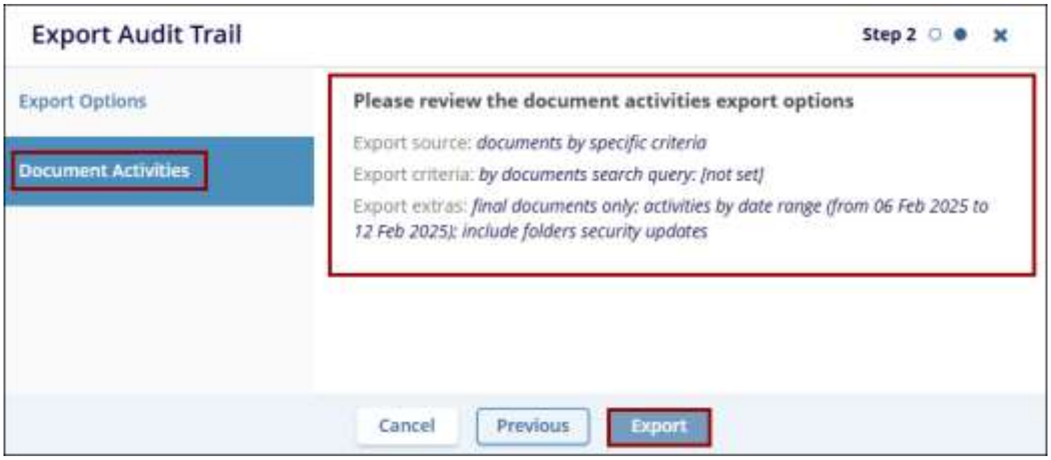
To export the audit trail, follow the steps below.

1. Click on the Export button and select the Security option. The Export Security window opens.

2. In Step 1, click on the Source* dropdown and select the required option.
    a. All documents in the current grid
    b. Documents by criteria
    c. Deleted documents
3. Select one or multiple options by clicking on the checkbox.
    a. Include Folders Security Updates
    b. Final Documents Only
    c. Audit Trail Date Range
4. If the Audit Trail Date Range is selected, specify the From Date and To Date.
5. If Documents by Criteria is selected, specify the Document Selection Criteria by accessing the dropdown options.
6. Click on the Next button.



7. In Step 2, review the document activities export options and click on the Export button.



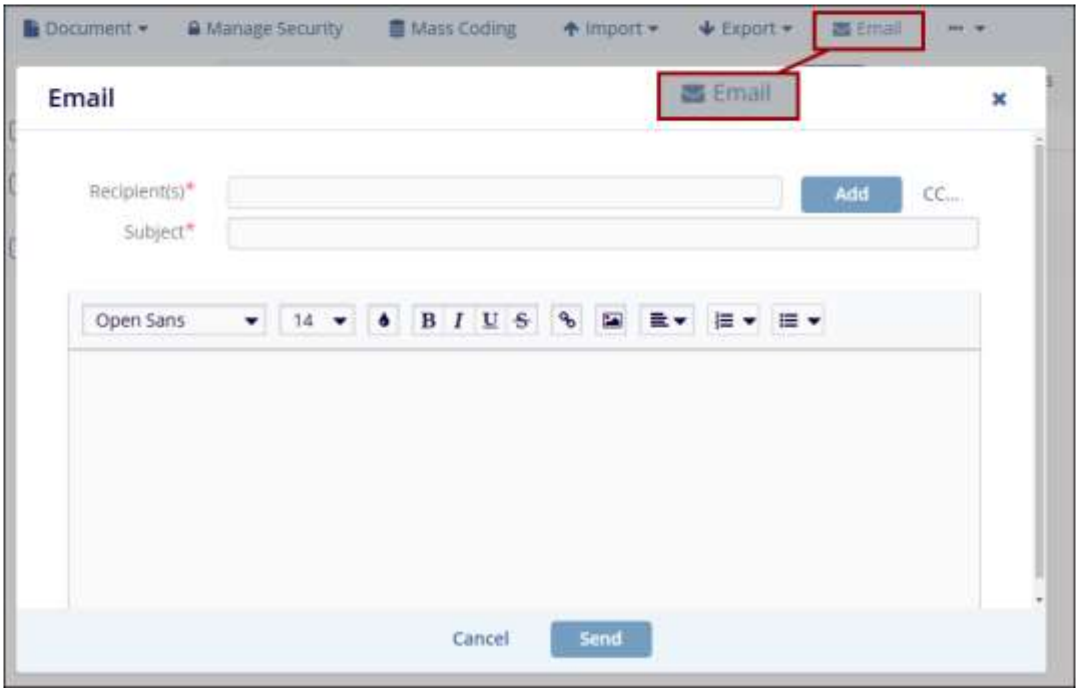
8. Click on the Get Job Results button to download the file.

Email

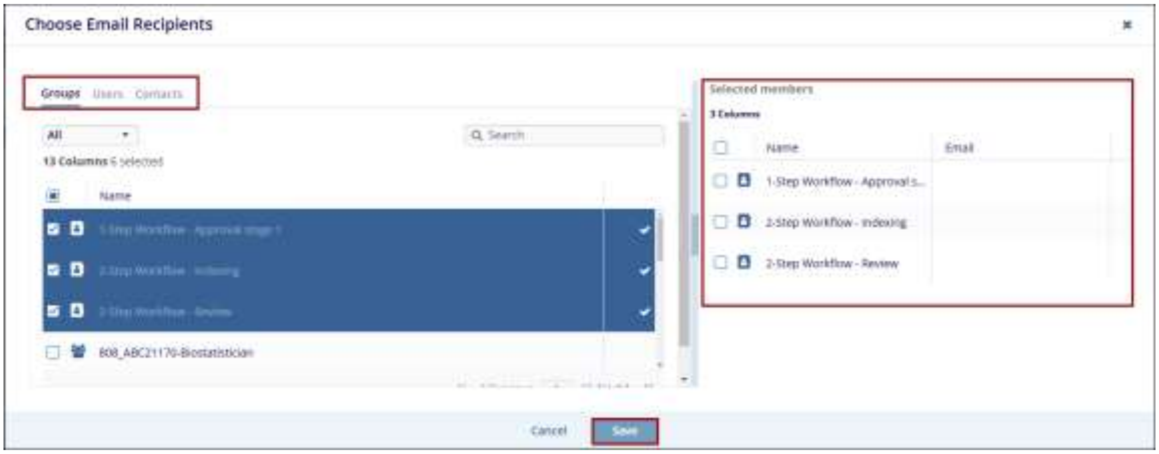
The email function allows users to send an email to another room user or contact which can be a document-related email or other.

To send an email, follow the steps below.

1. Select the documents by clicking on the checkboxes.
2. Click on the Email button. This opens the Email window.

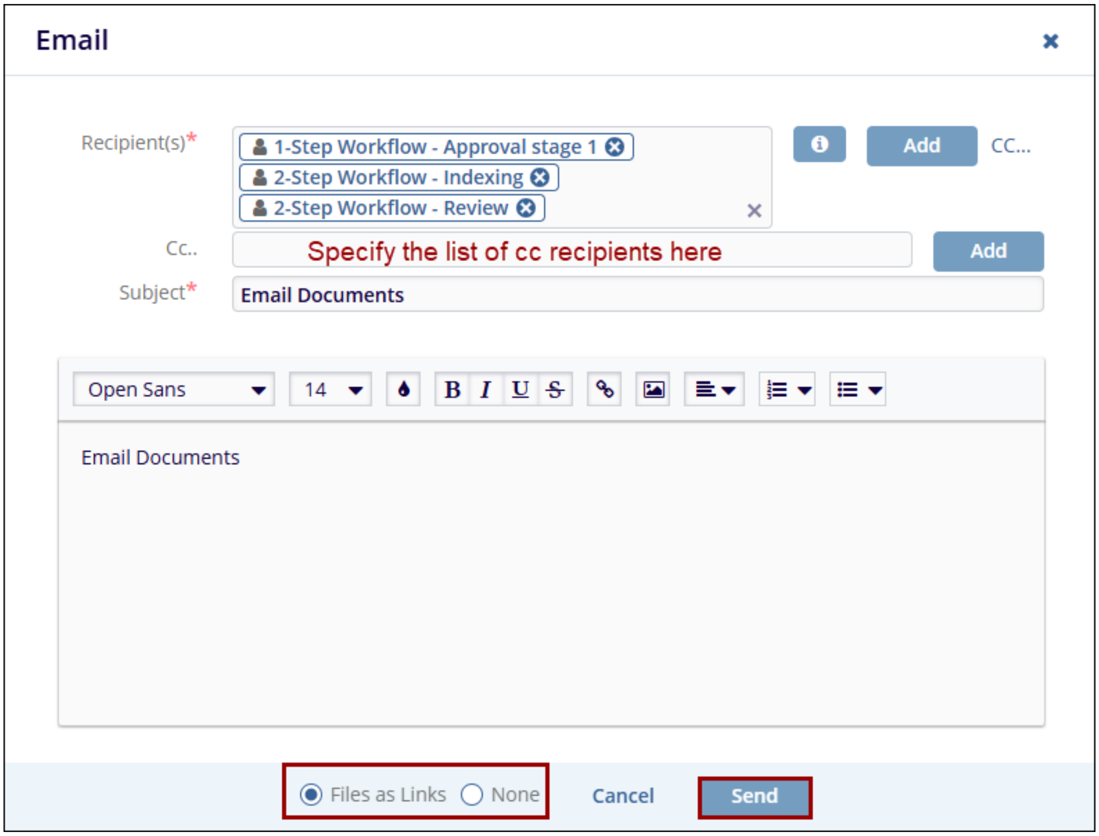


3. Click on the Add button.
4. On the Choose Email Recipient screen, navigate to the Groups, Users, and Contacts tab and add them to the Selected Members section.
5. Click on the Save button.



6. Additionally, click the CC button to specify the list of CC recipients.

7. Add the email subject and text.
8. Select the Files as Links radio button to share documents as links or select None if not required.
9. Click on the Send button.

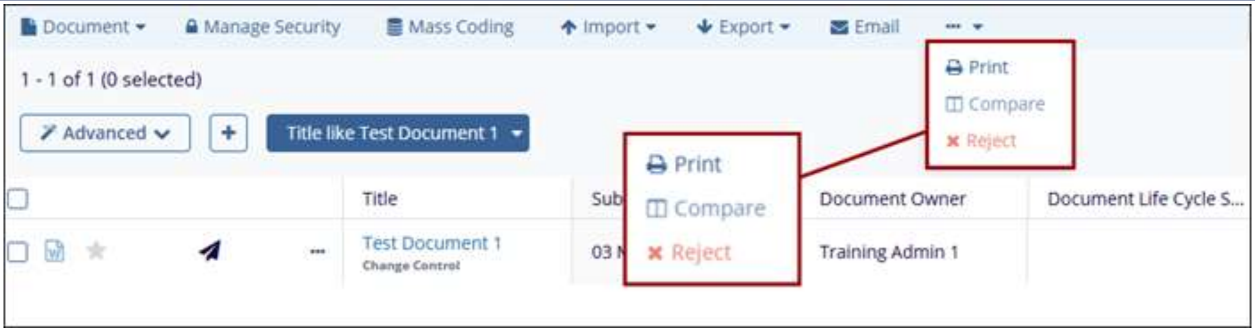


Print

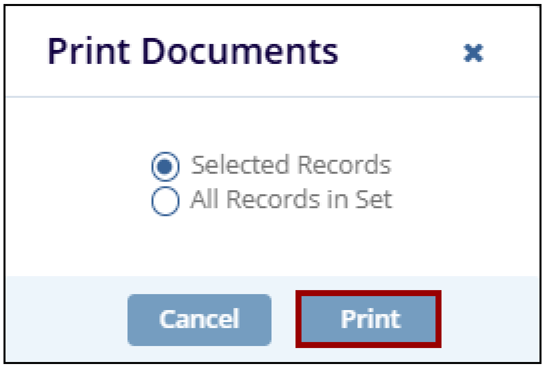
The Print function does not print the selected documents but merges them into a single PDF file which can then be downloaded or printed by the user.

To merge multiple documents into a single PDF file, follow the steps below.

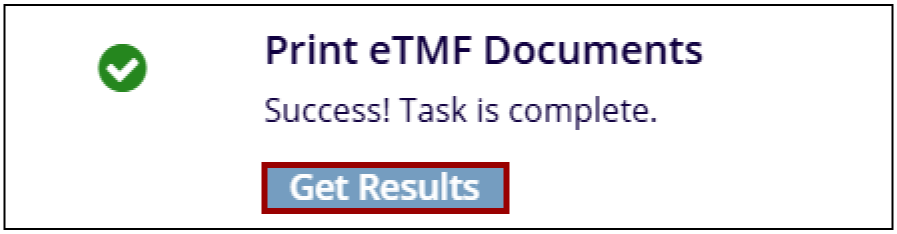
1. Select multiple documents by clicking on their checkboxes.
2. Click on the three-dot menu and select the Print option.



3. On the Print Documents popup select either Selected Records or All Records in Set radio button and click on the Print button.



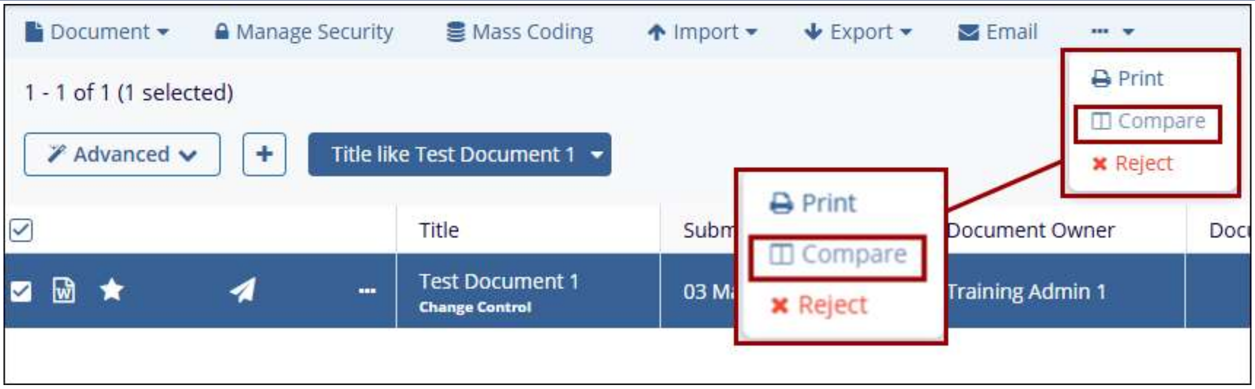
4. On the Print eTMF Documents success message popup, click on the Get Results button and a new tab will open displaying a single PDF file with pages merged from both documents.



Compare

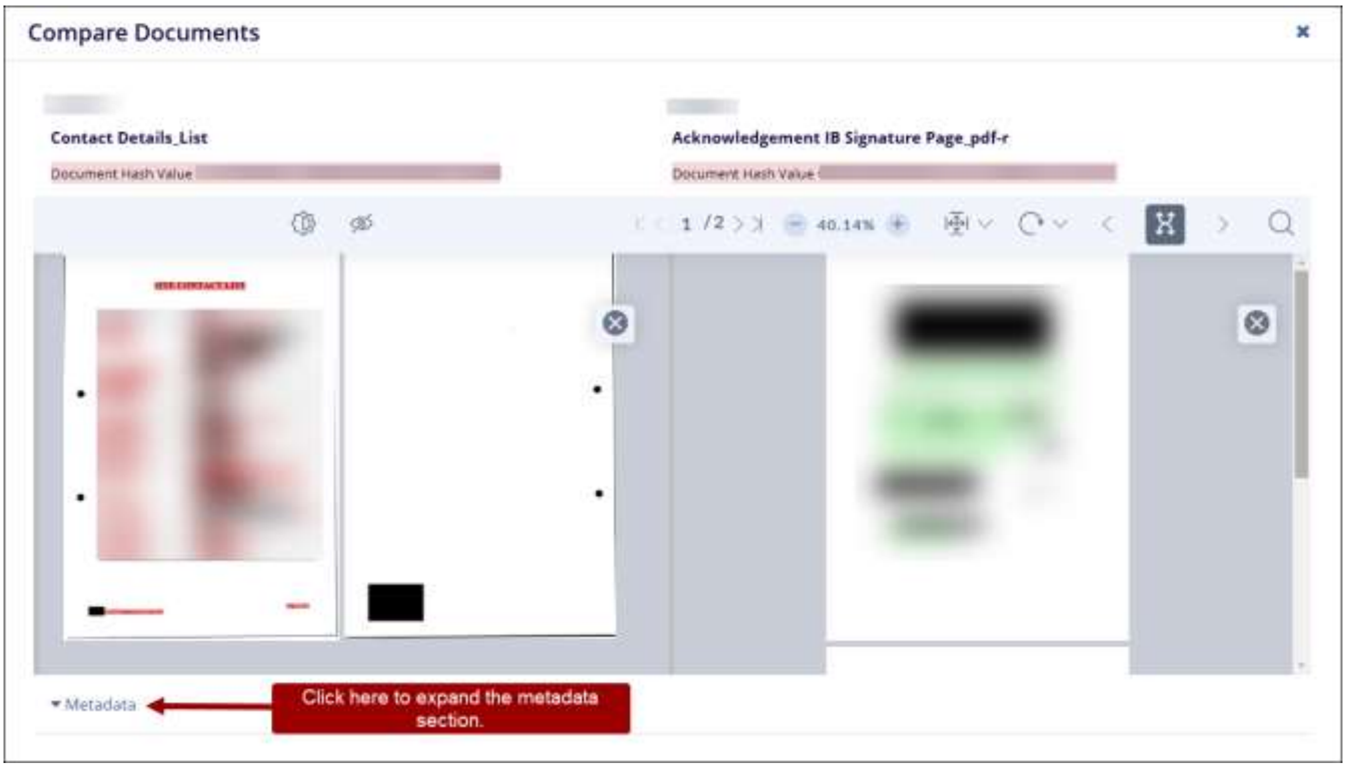
To compare documents, follow the steps below.

1. Selecting two documents
2. Click on the three-dot menu and select the Compare option.



3. The selected documents will appear side-by-side in a pop-out window along with any associated metadata.

4. Expand the metadata section to view and edit the document metadata.



Search

Above the documents grid, next to the documents cart, is a search bar. This is a local search and will search the currently selected index folder for relevant documents.

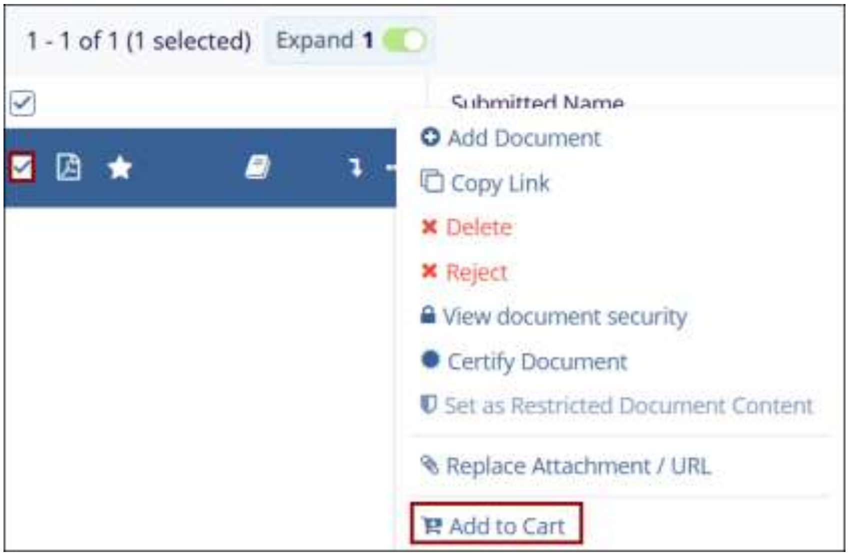
Documents Cart

The functions available to a user in the document cart will depend on their access level. Users can add documents from various locations to the cart and perform actions such as Export, Mass Coding, Email, and others.

Adding documents to the Documents Cart

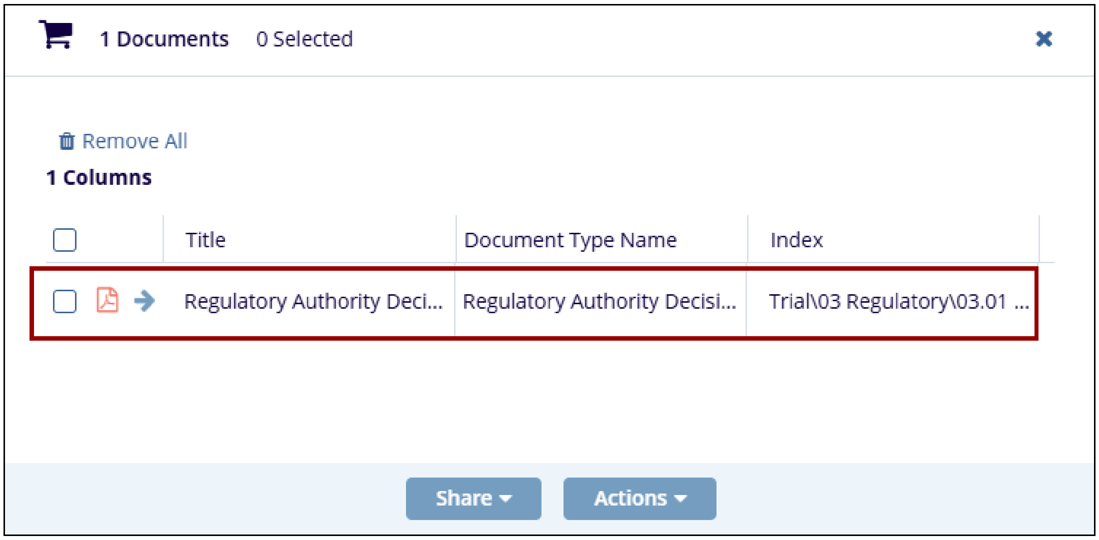
To add documents to the cart, follow the steps below.

1. Locate the document which is to be added to the Document Cart and select the checkbox next to it.
2. Right-click and select the Add Selected to the Cart option.



3. Else, drag the document(s) to the documents cart.

4. Once a document is added, it will automatically update to reflect the number of documents available in the cart.

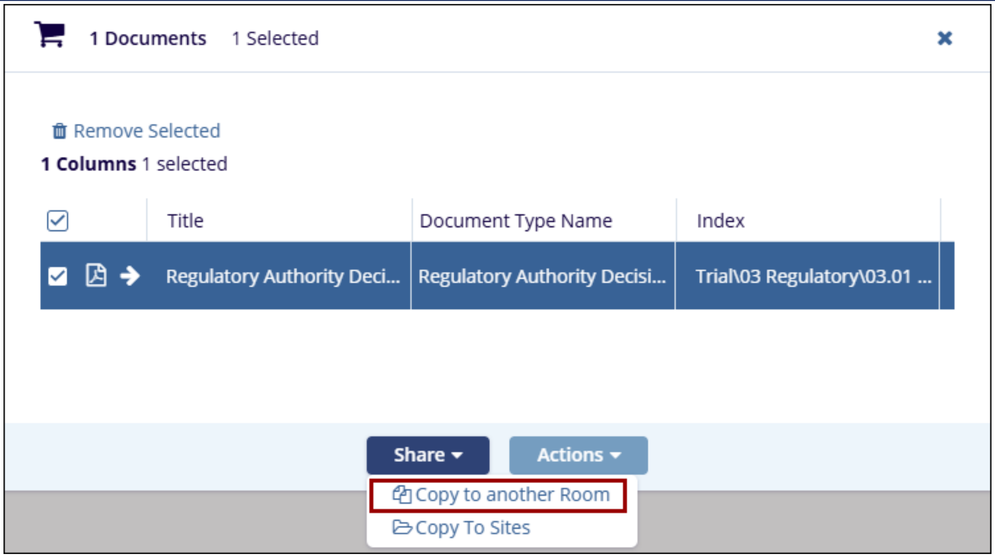


Copy to another room

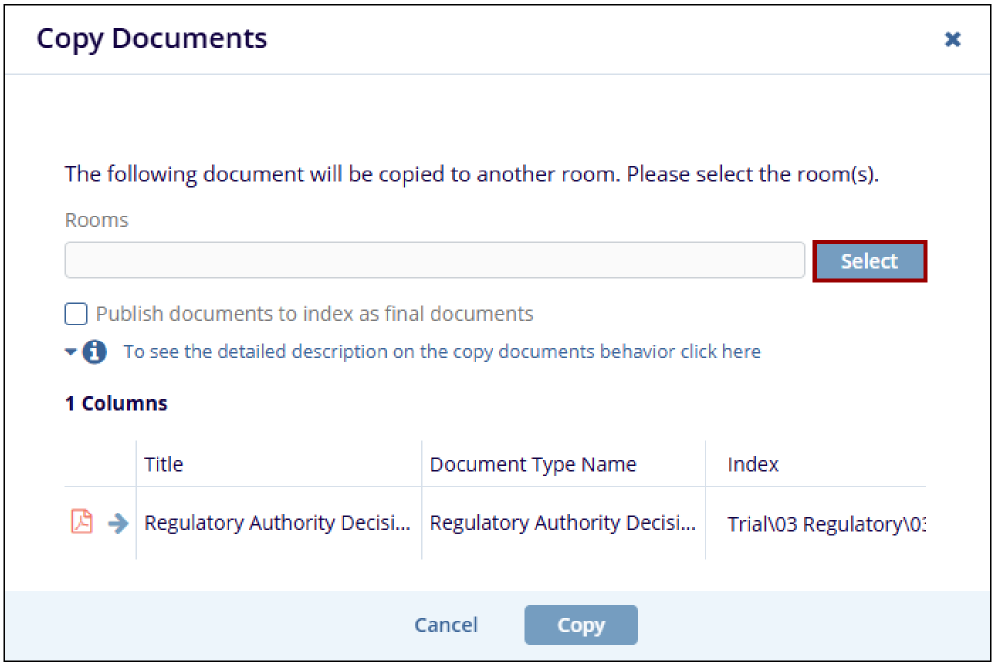
Trial Interactive allows Cross-Study Copy of Documents through this functionality. When users select the Copy to Other Rooms option from the Documents Cart, selected documents as well as their metadata will be copied to other rooms.

To copy documents to another room through the Documents Cart, follow the steps below.

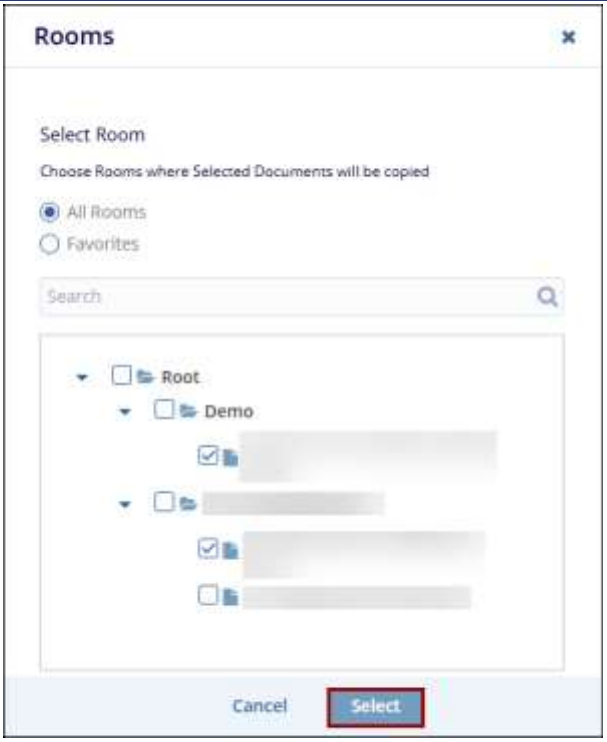
1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. Select the documents to copy to other rooms.
3. Click on the Share dropdown and select the Copy to another Room option.



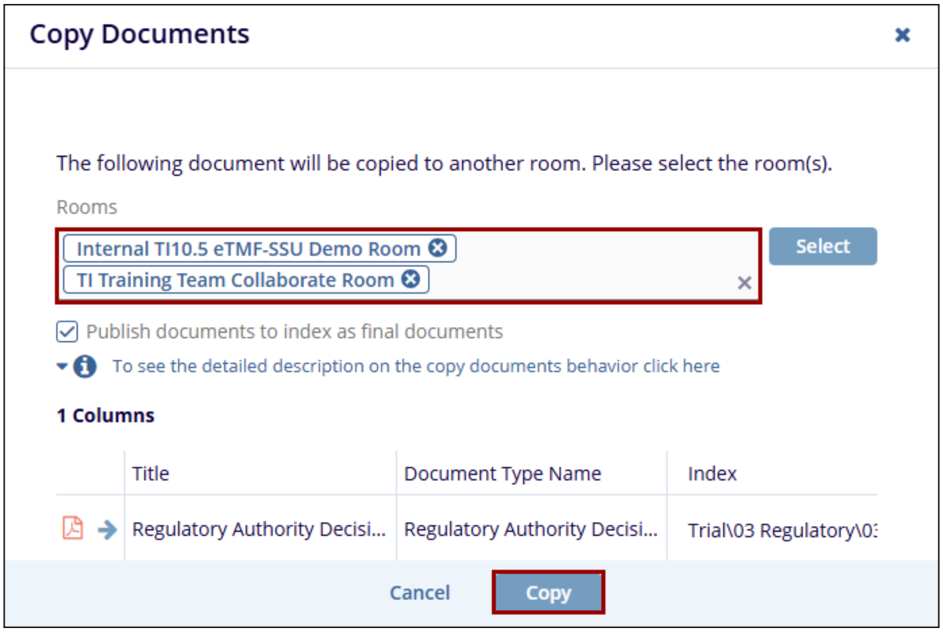
4. On the Copy Documents screen, click on the Select button to add rooms.



5. On the Rooms screen, select the required rooms and click on the select button.



6. To publish documents to the index as final documents without going through the workflow, check the Publish documents to the index as final documents checkbox.
7. Once the rooms are specified, click on the Copy button.

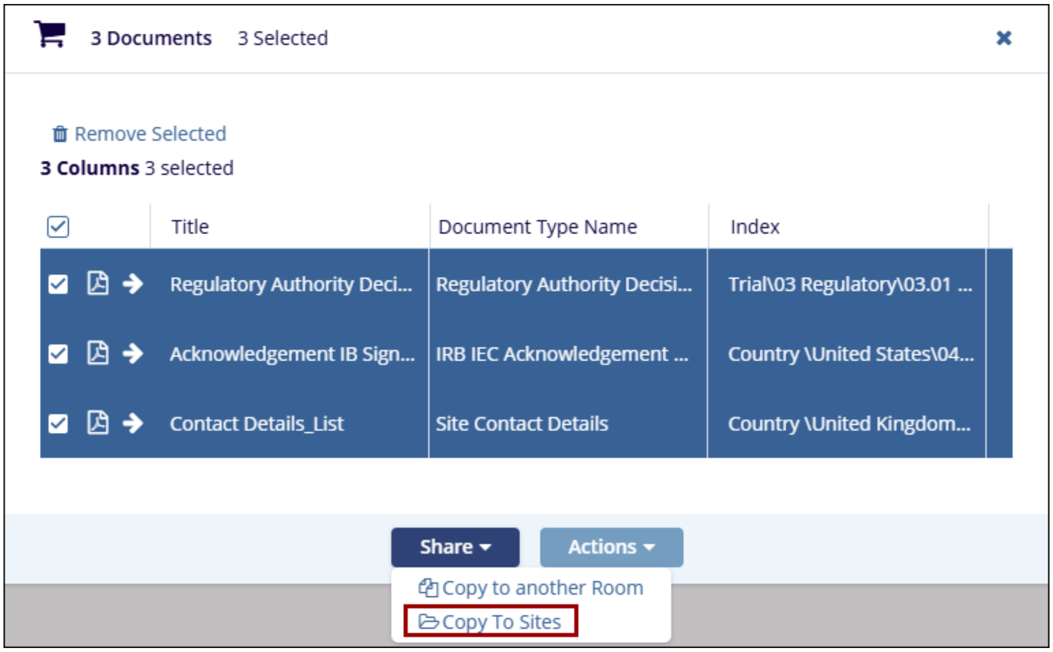


Copy To Sites

Administrators can access the documents cart to avoid copying documents such as training documents individually across different investigative sites.

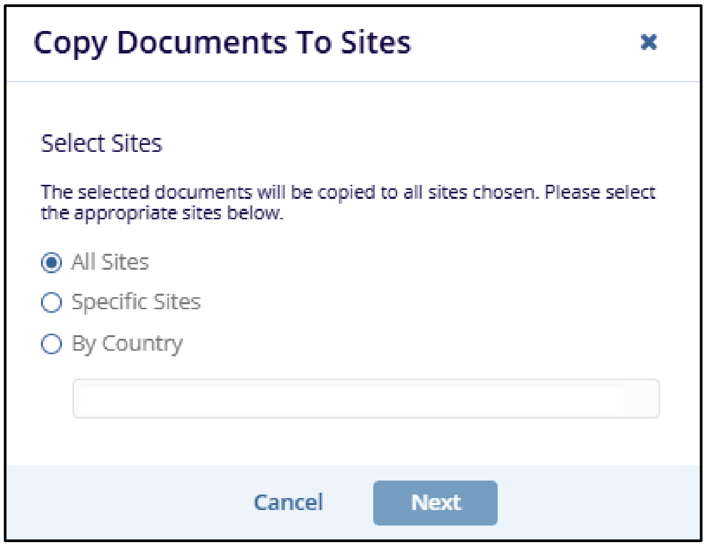
To copy documents to sites, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. Select the documents to copy other Investigative Sites.
3. Click on the Share dropdown and select Copy to Sites option.

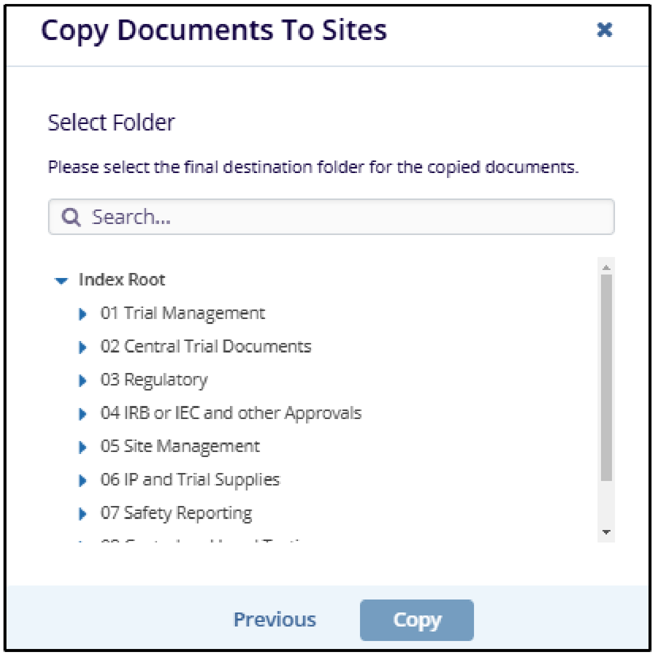


4. On the Copy Documents to Sites window, select sites pertaining to specific criteria by clicking on the radio buttons.

    a. Select the All Sites options, and click on the Next button to select the folder to which the documents will be copied.
    b. Select the Specific Sites options, and click on the Next button to select the folder to which the documents will be copied.
    c. Select the By Country option and select a country from the dropdown options.



5. Click on the Next button once the criterion is selected
6. Select a folder and click on the Copy button. The documents are copied to the Investigative Site folder.

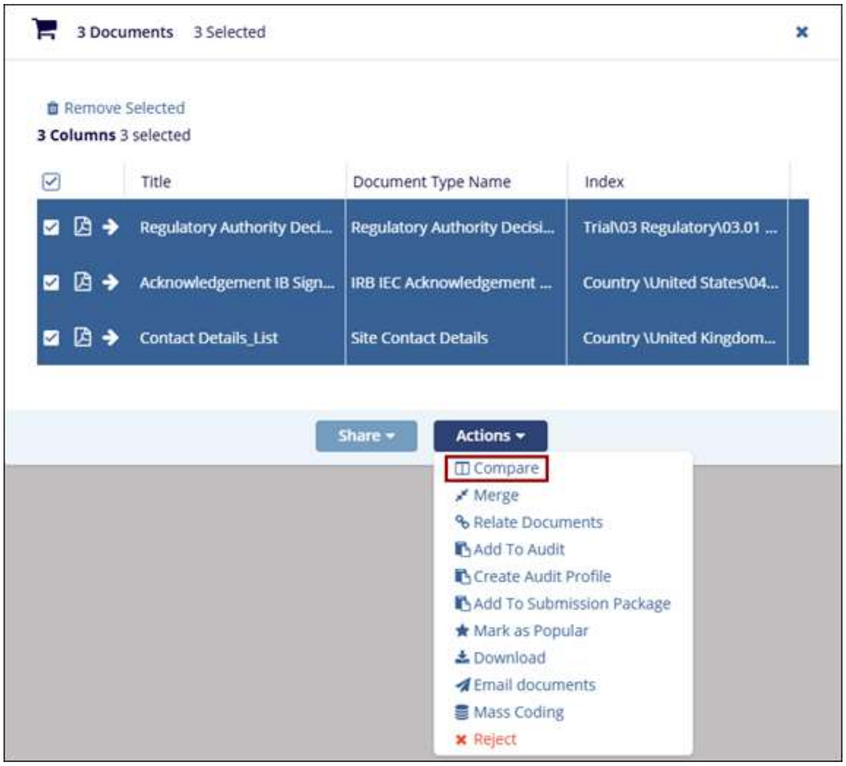


Compare

To compare documents, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.

2. On the Documents Cart window, click on the Actions dropdown and select the Compare option.

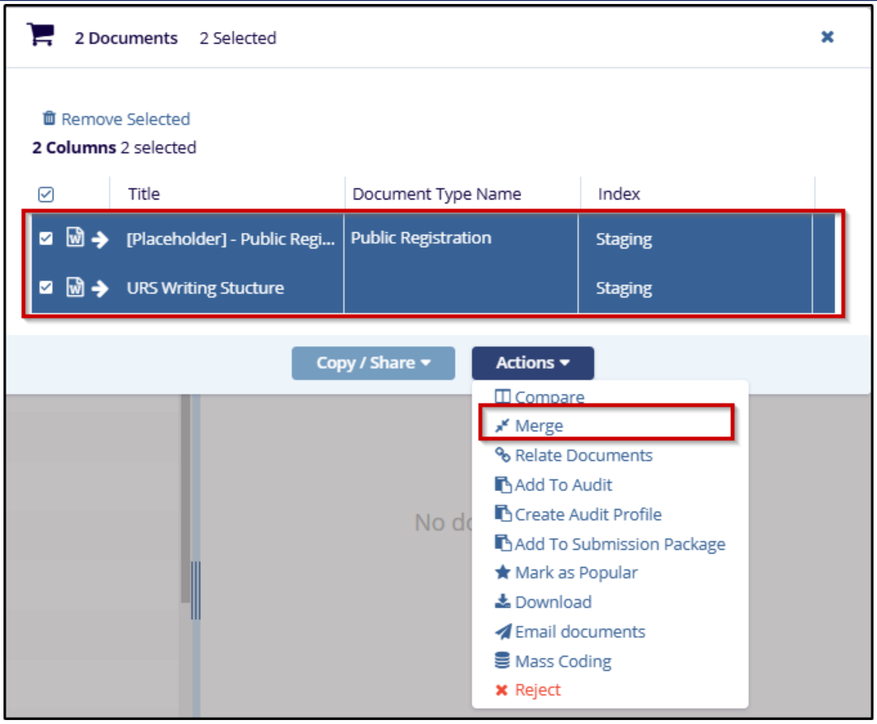


3. Refer to the [Compare](#) section for additional information.

Merging documents

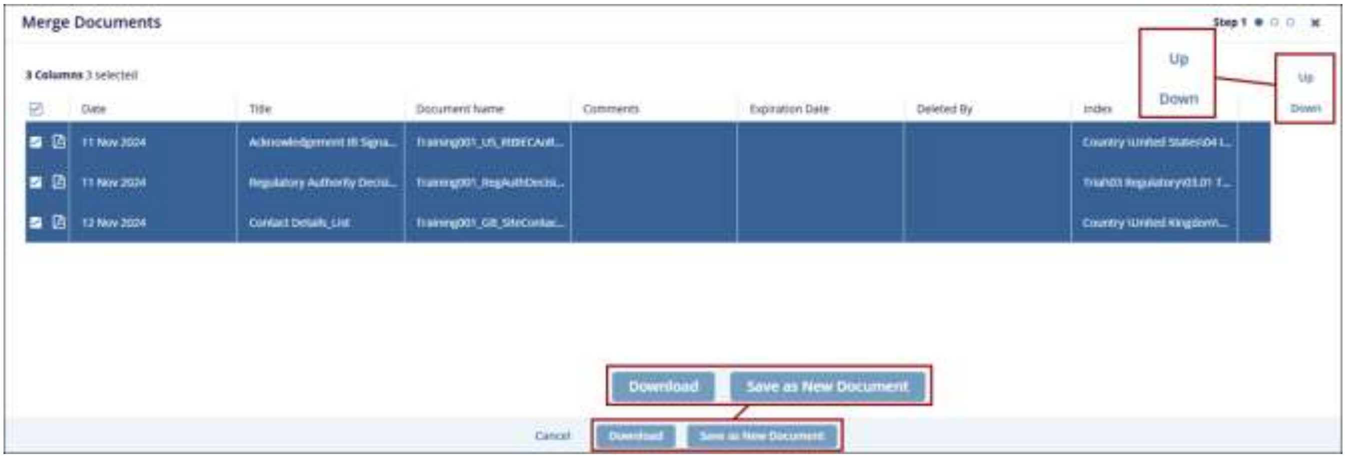
Users with Administrator, Manager, and Editor access can merge two or more documents into one document.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Merge option.

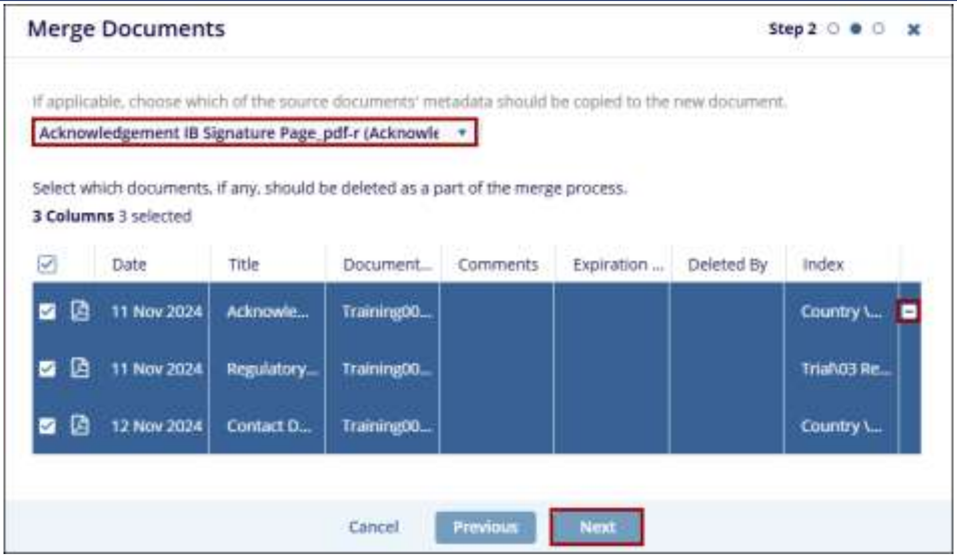


3. On the Merge Documents screen, access the Up and Down buttons on the right side to rearrange the order of documents in the correct order of appearance in the final document.
4. Click on either Download or Save as New Document.

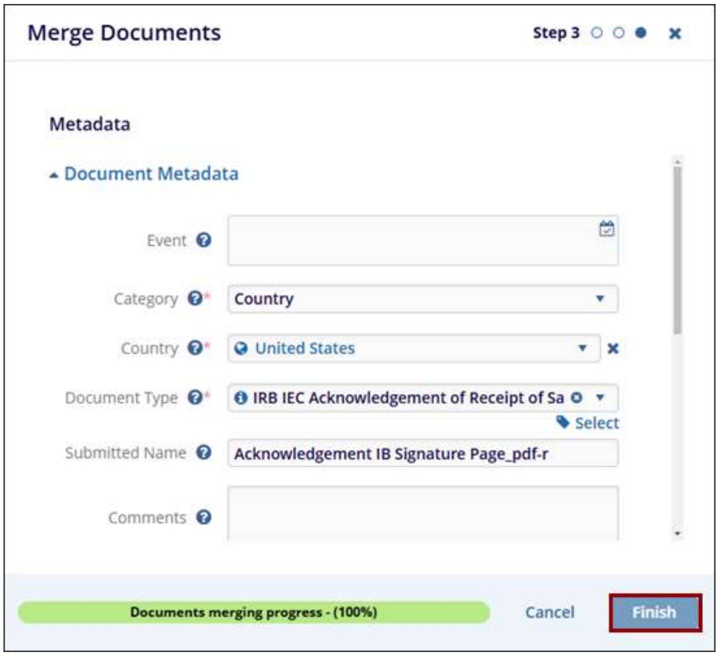
   - Download: It will download all documents merged as one PDF file.
   - Save as New Document: This creates the merged file as a new document in the study room.



5. If Save as New Document is selected, access the dropdown and select a source document whose metadata should be copied to the new document.



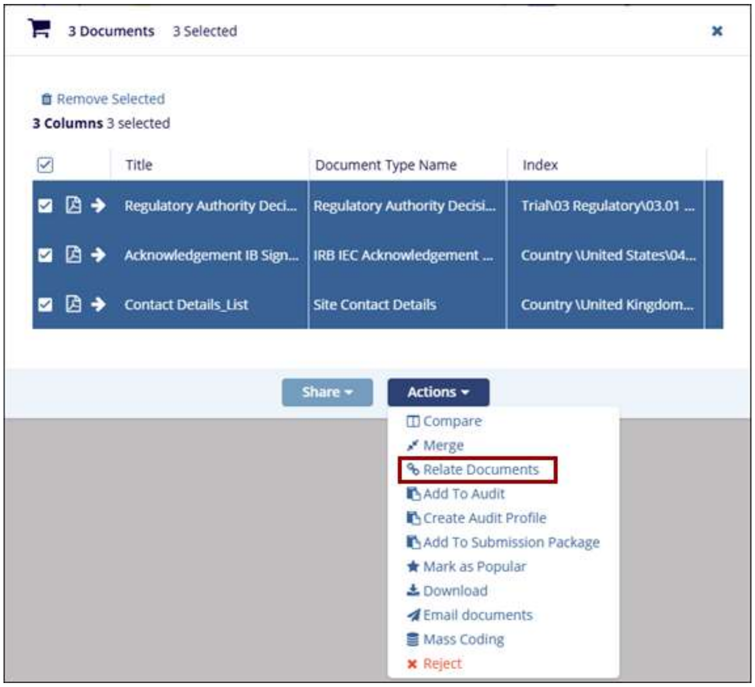
6. Click on the Next button.
7. On the Merge Documents screen, confirm the metadata for the merged document and click on the Finish button.



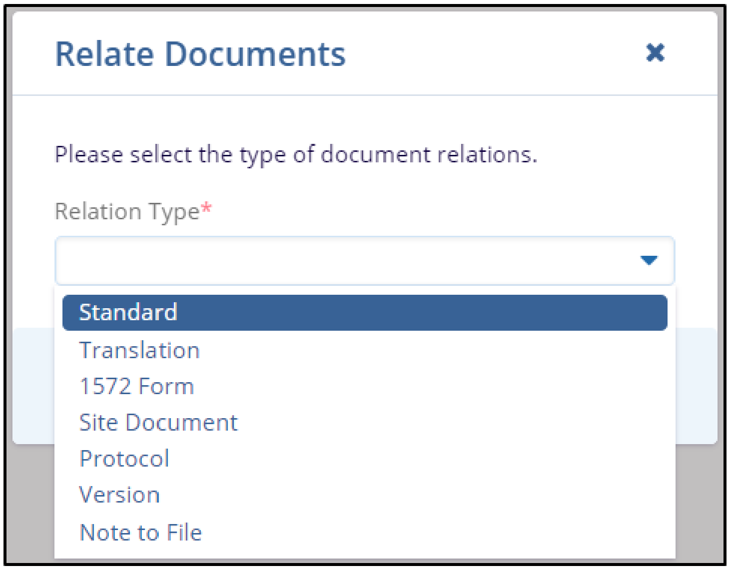
Related documents

Users with Editor and Administrator access related the documents with this option.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Related Documents option.



3. On the Relate Documents window, select the appropriate option from the dropdown menu.



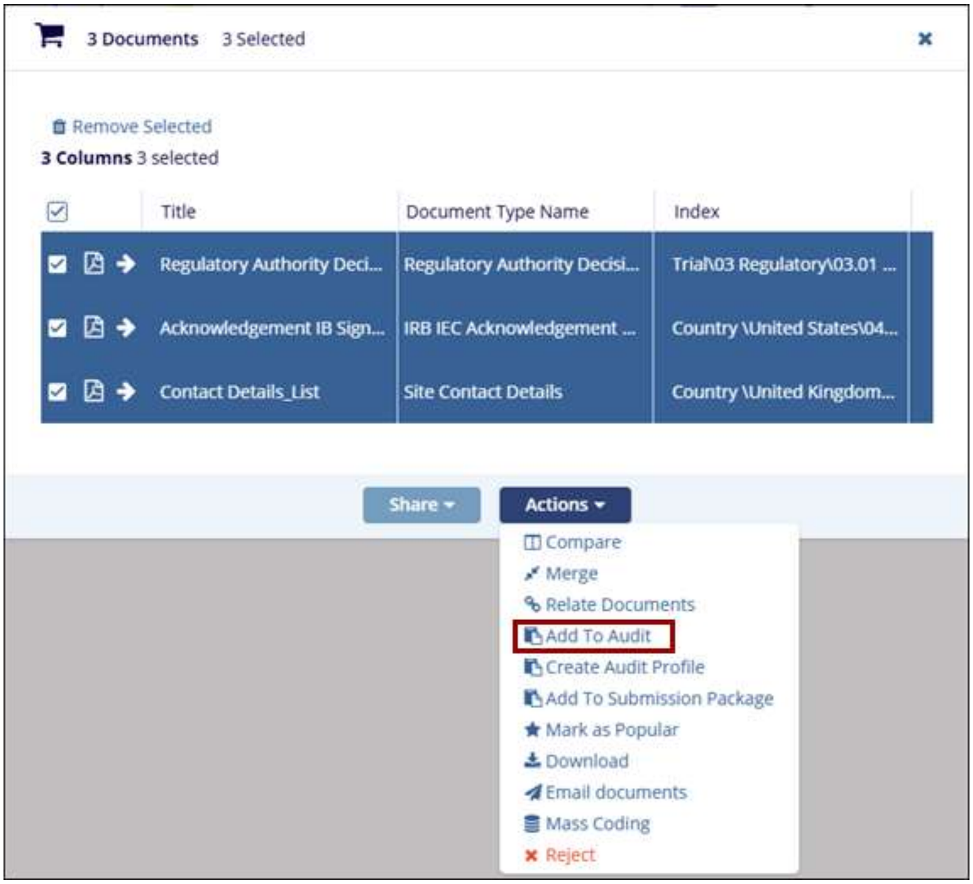
4. Click on the Save button to complete the related documents process. A notification Documents related is displayed in the top right corner of the screen.

Adding documents to an Audit

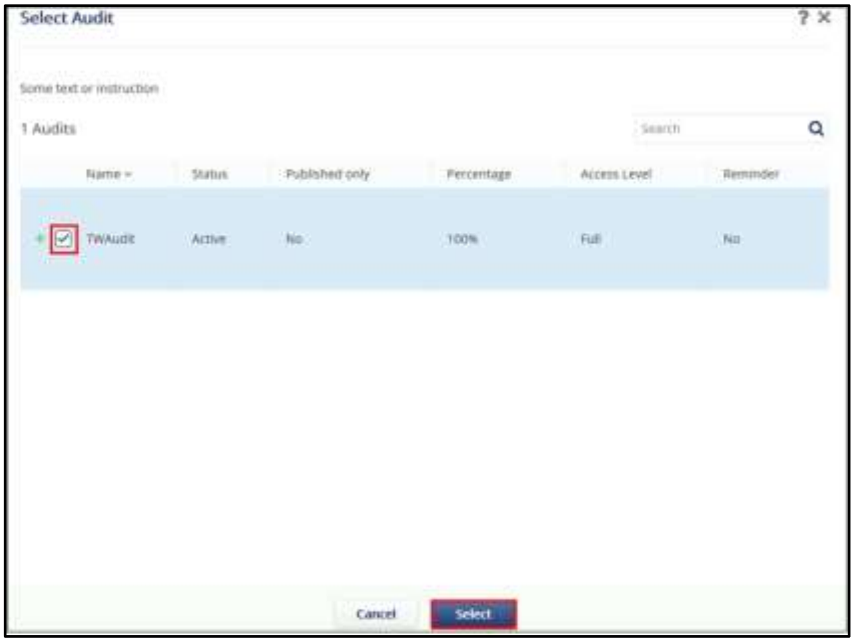
Administrator, Manager, and Editor users can add documents to the cart from the grid and include them in an existing audit by using the Add to Audit option.

To add documents to an audit, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Add To Audit option.



3. On the Select Audit window, select the Audit to add documents to.
4. Click on the Select button.



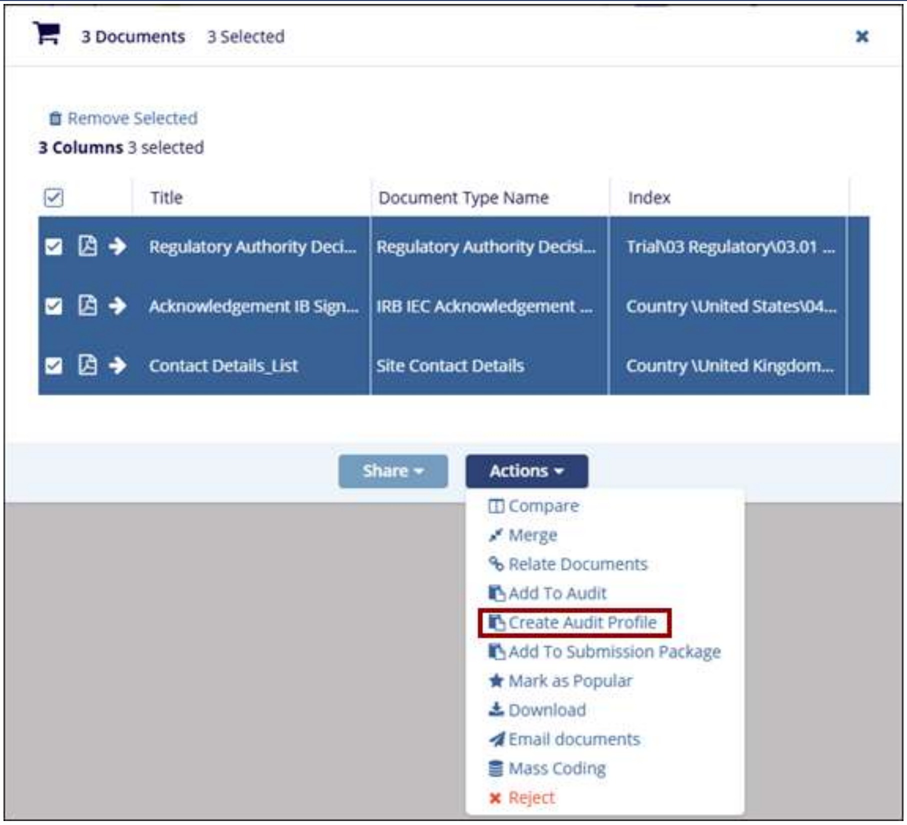
Note: The audits displayed are those that have been created in the Quality Review module specifically to have documents added to them in this manner.

Create an Audit Profile

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

To create an audit profile, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Create Audit Profile option.



3. The Create Audit Profile popup opens.
4. On the Create Audit Profile form, create an audit by adding the necessary by following the instructions.

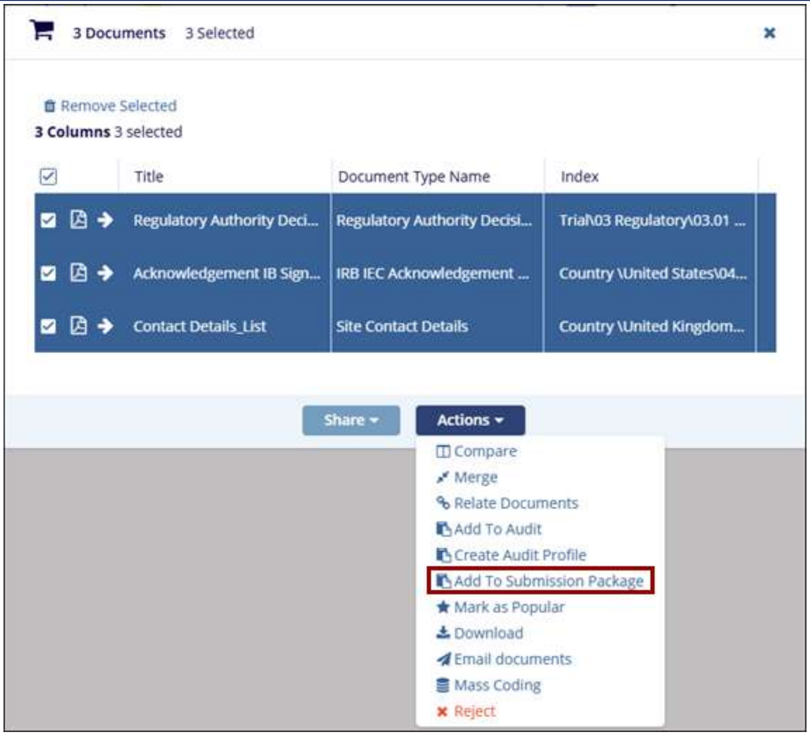
Adding Documents to a Submission Package

Administrators, managers, and editors can add documents to the cart from the grid to include them in a start-up submission package by using this option.

Note: This option will only be available in rooms where Study Start-Up is enabled.

To add documents to the submission package, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Add to Submission Package option.



3. On the Select a Submission window, choose a submission package and click on the Select button.

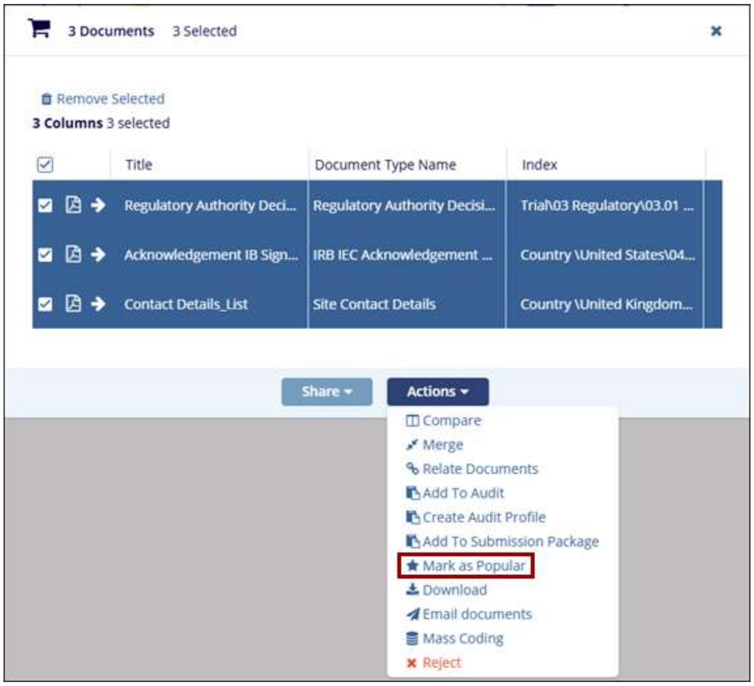
Marking documents as Popular

Administrator, Manager, and Editor users can mark certain documents as popular using this option.

To mark documents as popular, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.

2. On the Documents Cart window, click on the Actions dropdown and select the Mark as Popular option.

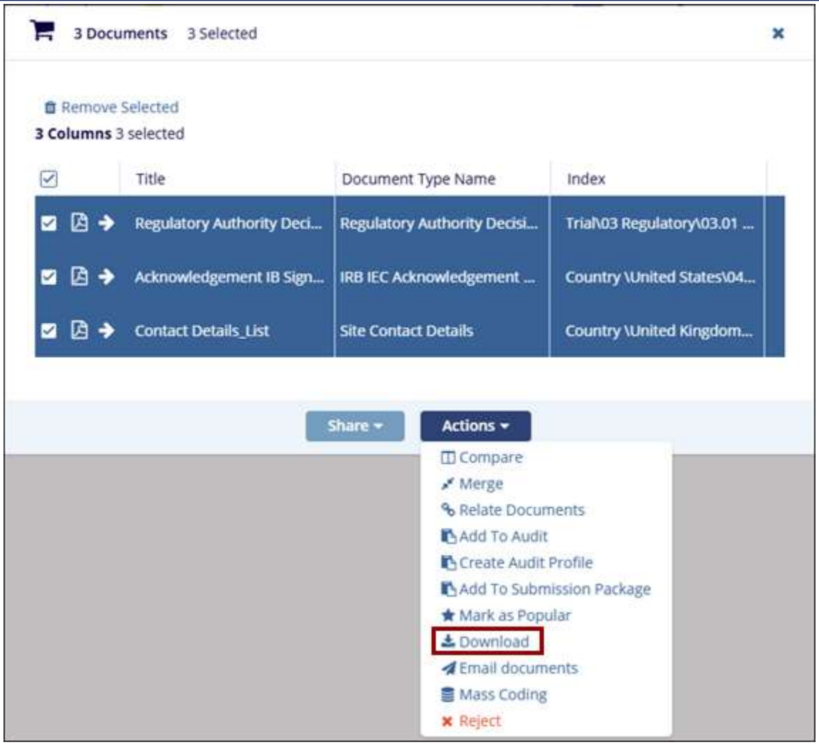


3. A success message appears stating the documents are successfully marked as popular.

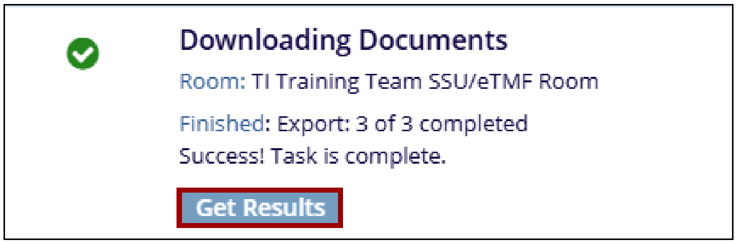
4. The documents can be viewed on the Popular Documents dashlet.

Downloading documents

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Download option.



3. On the success message popup click on the Get Results button.

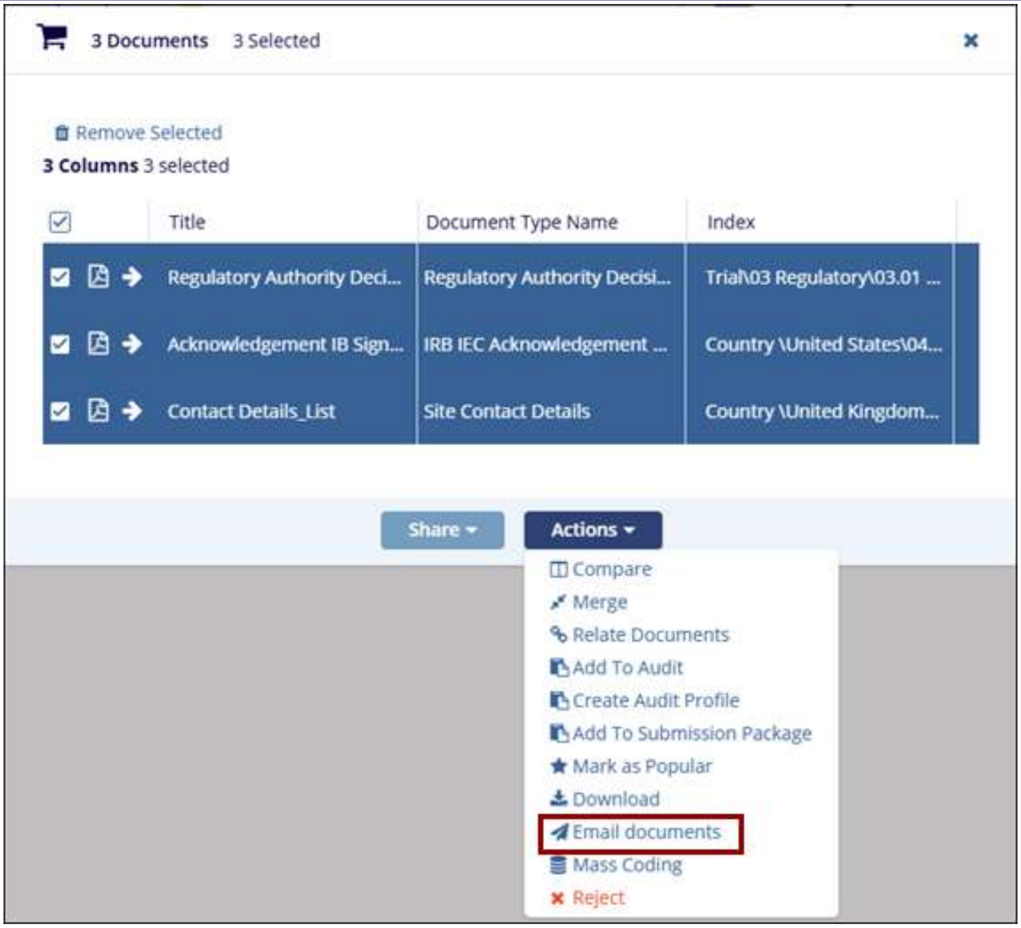


Email

The email function allows users to send an email to another room user or contact. This could be a document-related email or not.

To send an email, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Email Documents option.



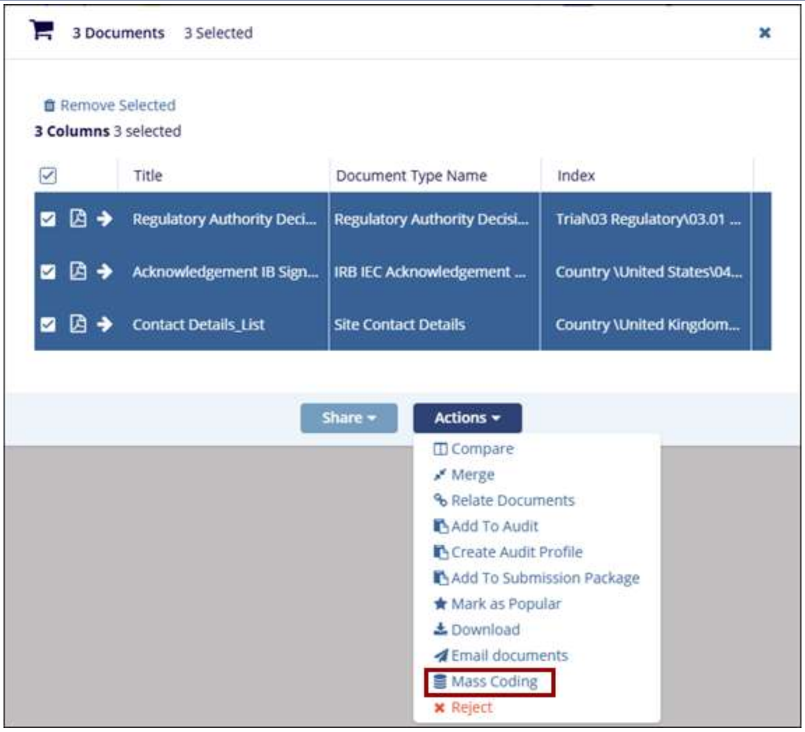
3. Refer to the Email section for the standard steps of sending an email to another user or a contact from another room.

Mass Coding

The Mass Coding function, allows the user to apply metadata to multiple documents at the same time. If the Causality Tracking feature is enabled in the room, then Mass Coding will be disabled.

To apply Mass Coding, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Mass Coding option.

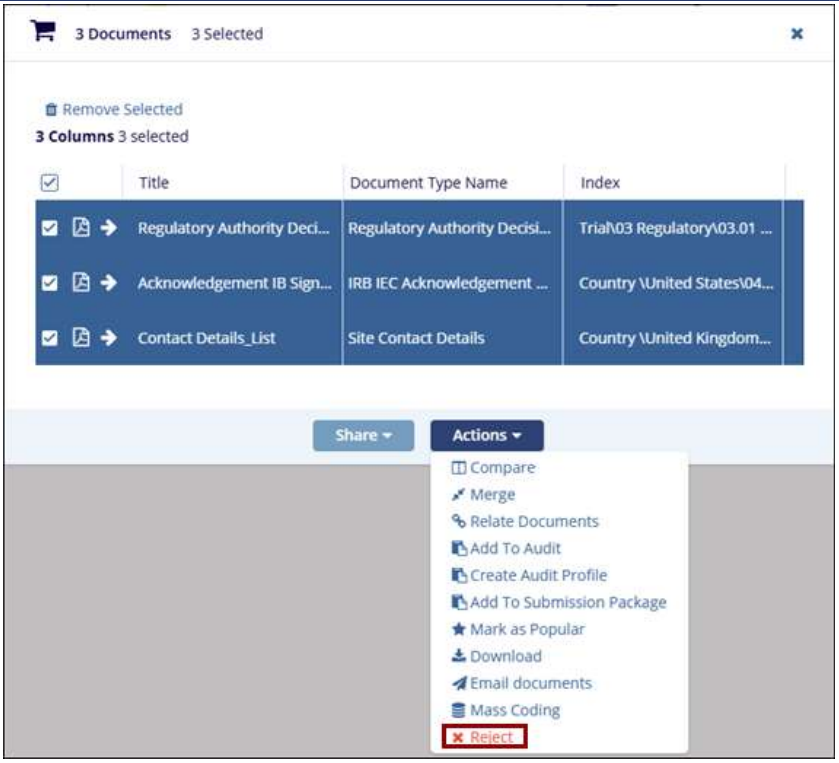


3. Refer to the standard steps of mass coding documents detailed in the Mass Coding section.

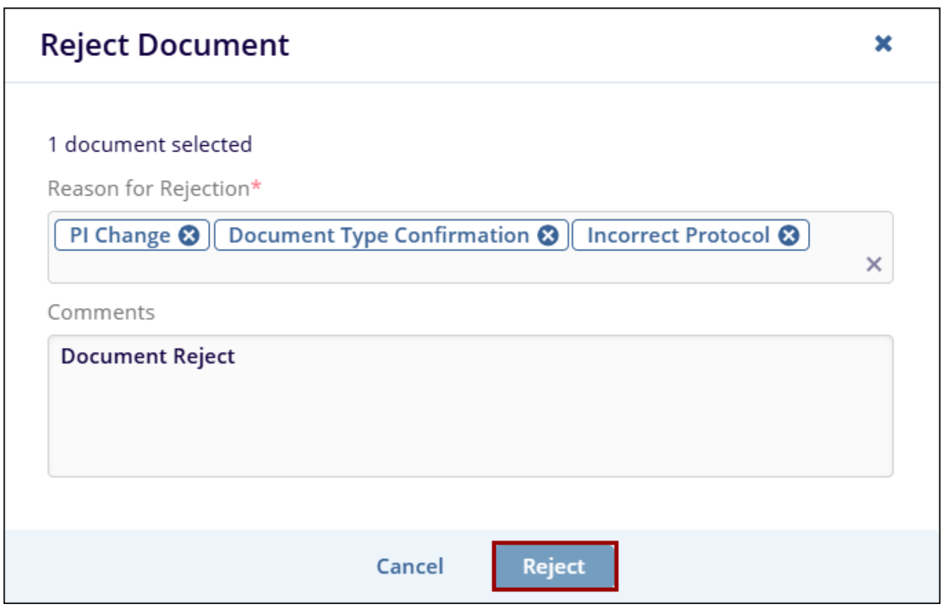
Reject

To Reject a document through the documents cart, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Reject option.



3. On the Reject Document screen, add the rejection reason and click on the Reject button.

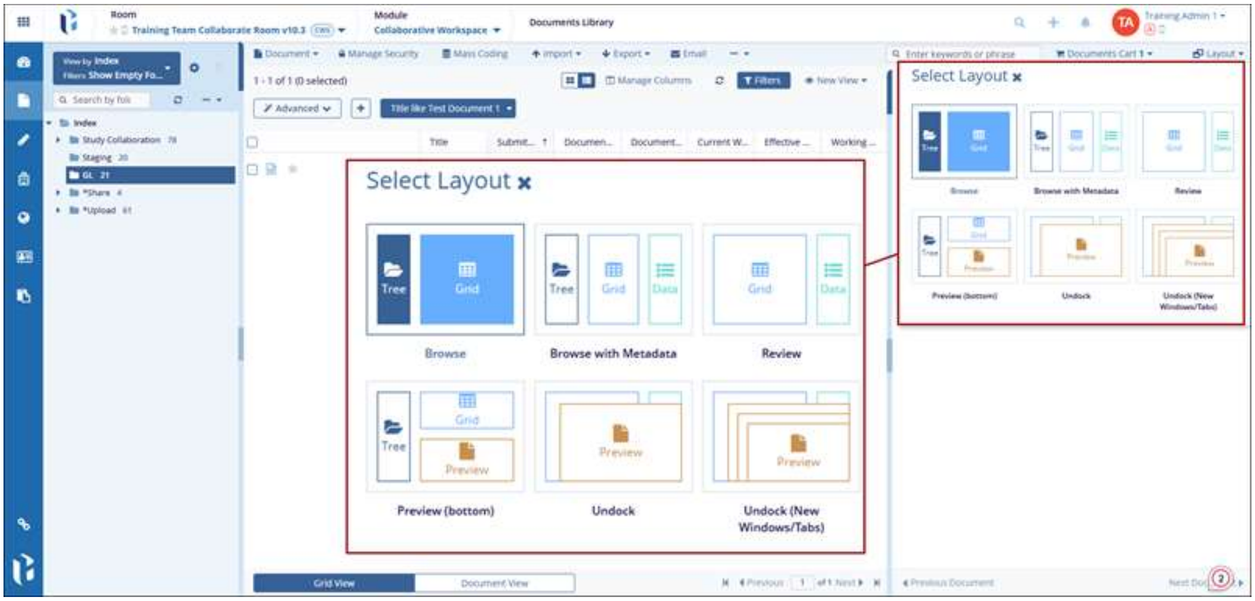


Layout

The layout menu, above the metadata pane, allows the user to choose from several page potential layouts.

- Browse

- Browse with Metadata
- Review
- Preview (bottom)
- Undock
- Undock (New Windows/Tabs)



Content Editing and Versioning

Document editing and versioning in TI Collaborate follows a check-in and check-out process. The various methods of content editing and versioning provide the ability to track changes across multiple document versions while enabling users to edit content efficiently. This functionality is available through various editing methods

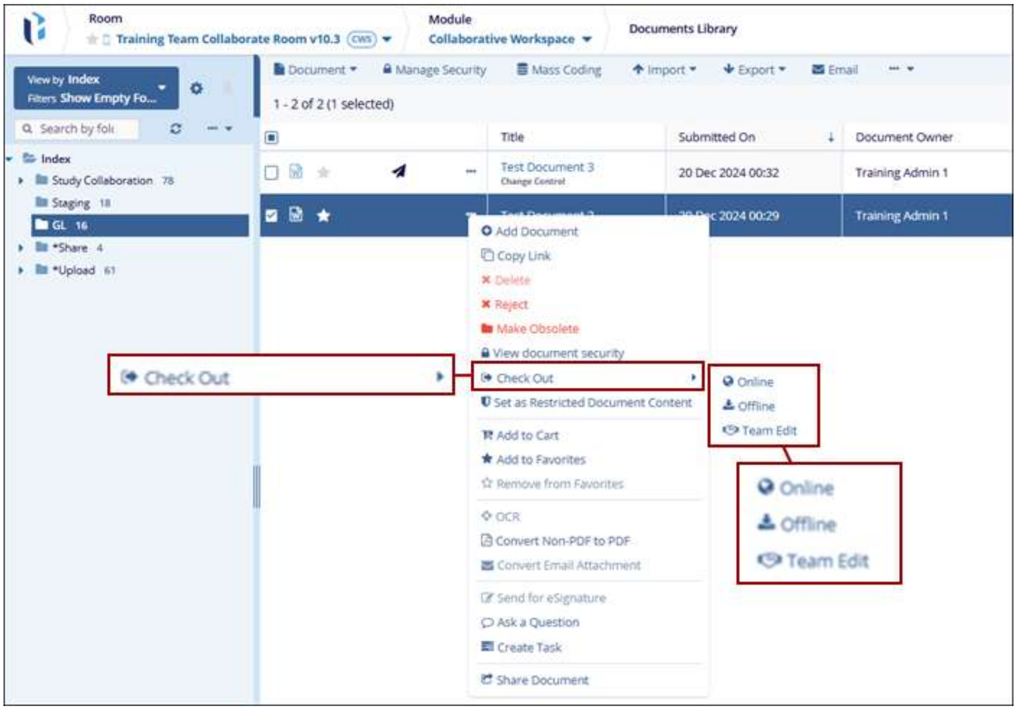
- Online Edits: Using the Online Edit functionality, users can make changes to documents directly within TI. However, users need to save the edits manually.
- Offline Edits: The Offline Edit functionality allows users to download the document on their systems and upload the updated documents back into the collaborate room.
- Team Edits: This option enables multiple collaborators to edit a document simultaneously. Team members edit documents along with adding comments and responses.

Checkout and Edit

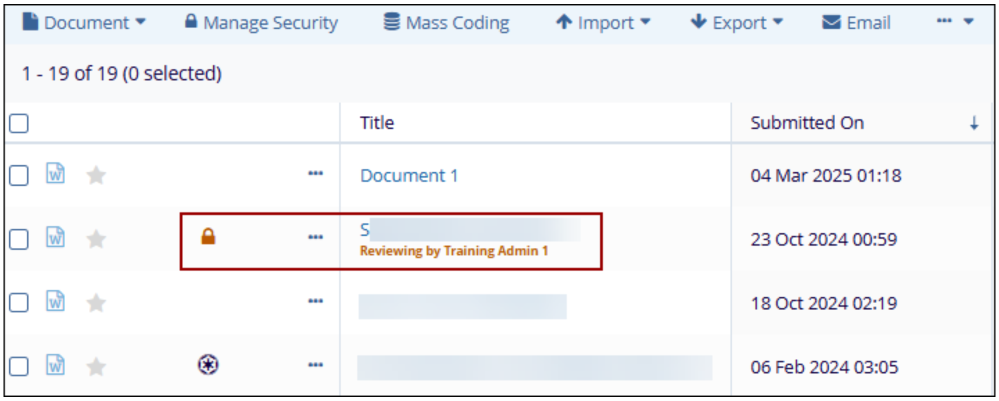
The document edit process begins with checking out a document from the Documents Library module.

To check out and edit a document, follow the steps below.

1. Within the Documents Library modal, click on the horizontal ellipsis (three-dot menu) icon of a document.
2. Select the Check Out option.
3. Select any one of the following checkout options.
    a. Online
    b. Offline
    c. Team Edit



4. Once a document is checked out, the document is highlighted with a lock icon with the reviewer's name.

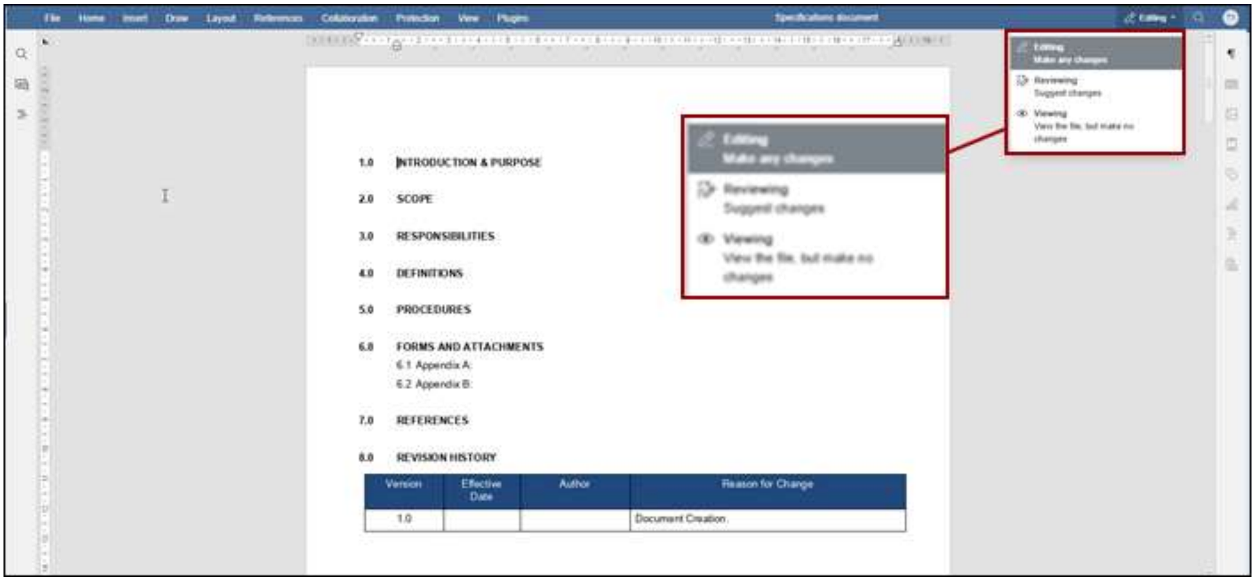


Online

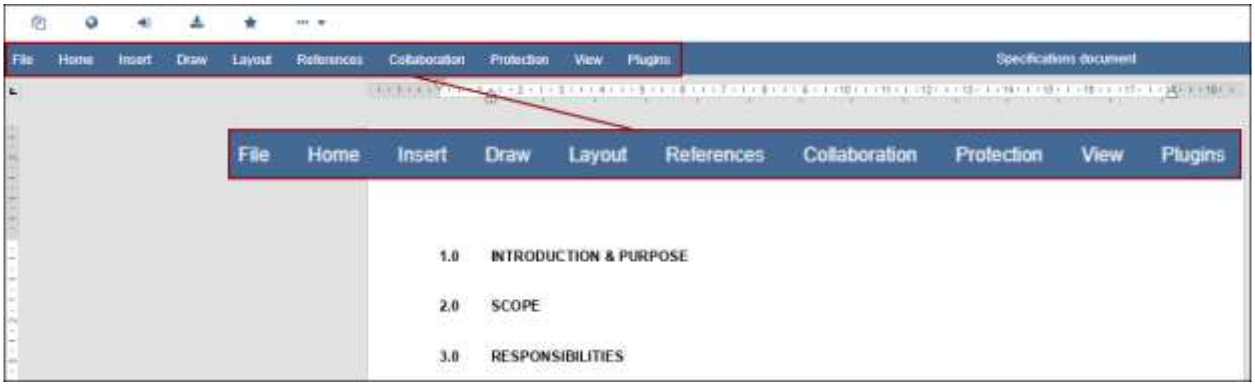
This option is intended to be used by those who would like to edit the document within TI without downloading the file. Choosing this option will immediately open the Document Viewer in Edit Mode, where the user can perform any necessary changes to the document. While checked out, the document is locked for all other users, preventing inadvertent overwriting or conflicting edits. Other users will be able to view and download the current effective version of the document, but they will not be able to check it out until it has been checked back in.

To edit a document online, follow the steps below.

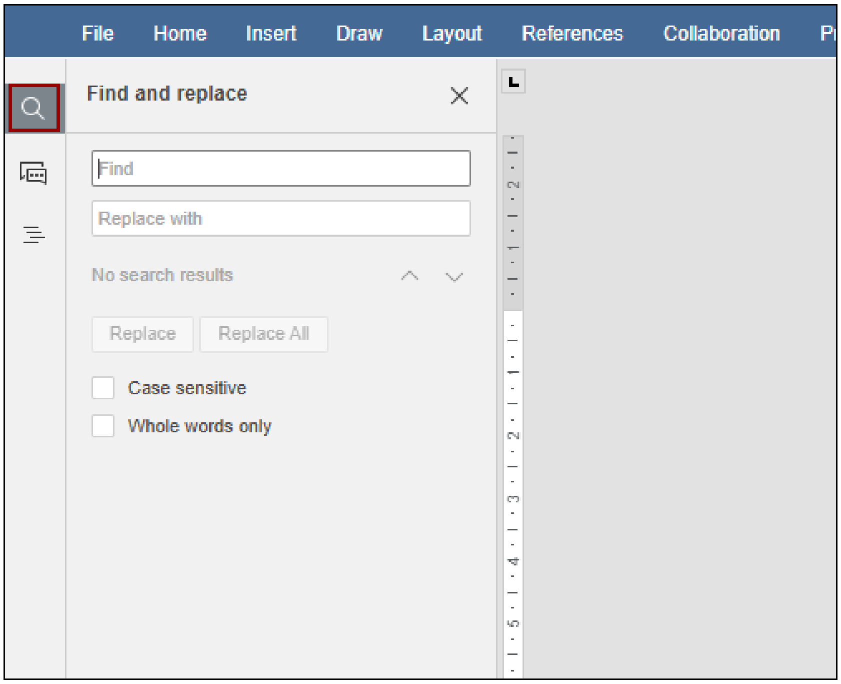
1. Check out a document to edit and select the Online option.
2. Click on the Editing mode menu in the top right and select any one option.
    a. Editing: This option allows users to make any changes in the document.
    b. Reviewing: This option allows users to suggest changes to the document.
    c. Viewing: This option allows users to view the file without making any changes to the document.



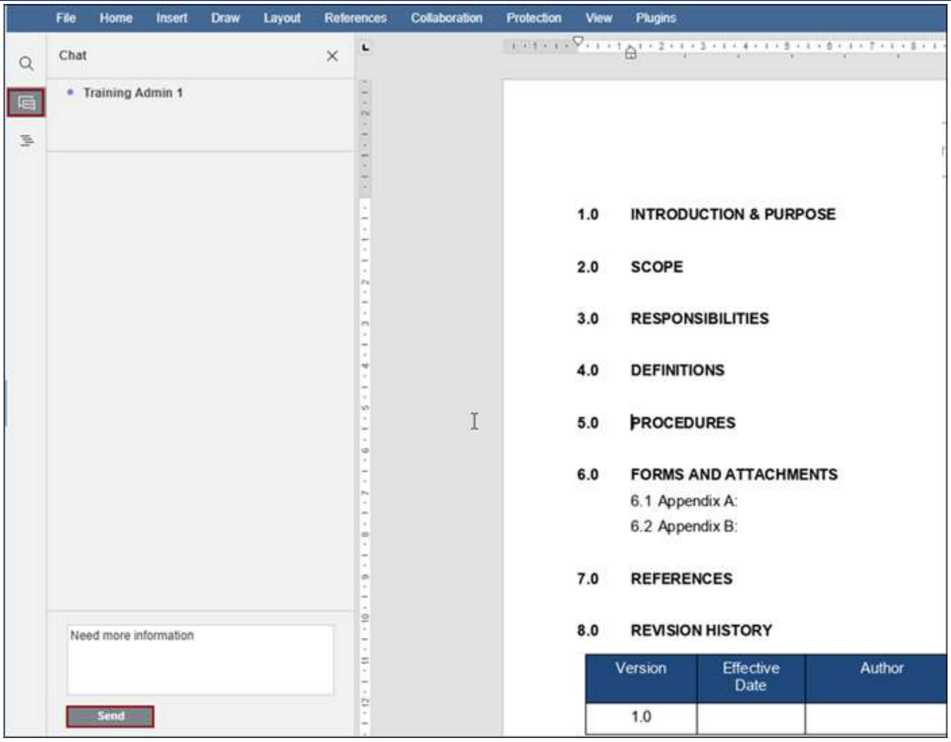
3. Accessing the toolbar at the top of the Document Viewer to access options like File, Home, Insert, Draw, Layout, References, Collaboration, Protection, View, and Plugins etc. to make edits to the document.



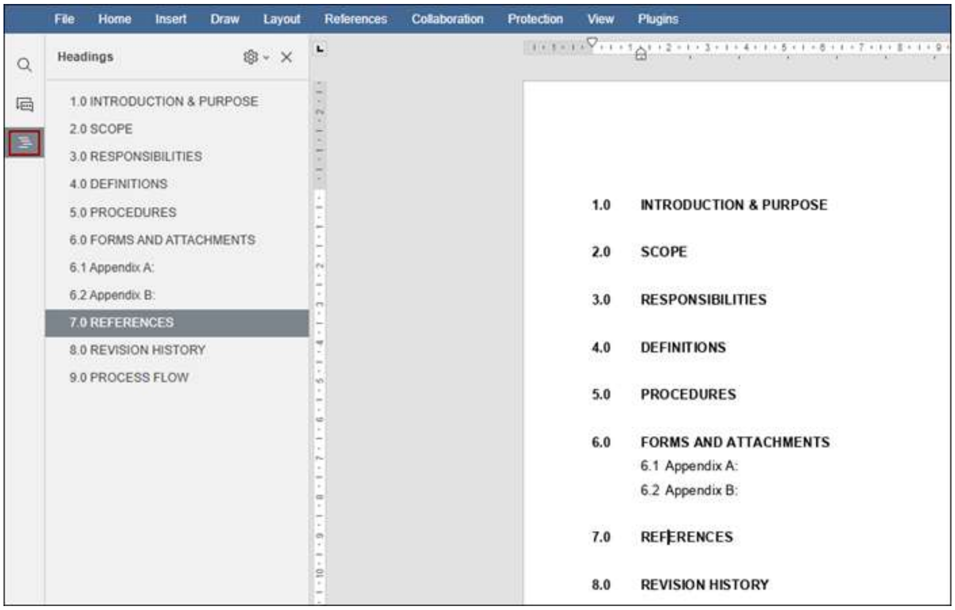
4. From the vertical toolbar on the left side of the editor, select the following options.
   a. Find: Click on the Find icon to search for specific text and replace it with alternative text.



   b. Chat: Select this option to chat with other collaborators responsible for reviewing the document.



c. Headings: Select this option to view the document's structured outline.

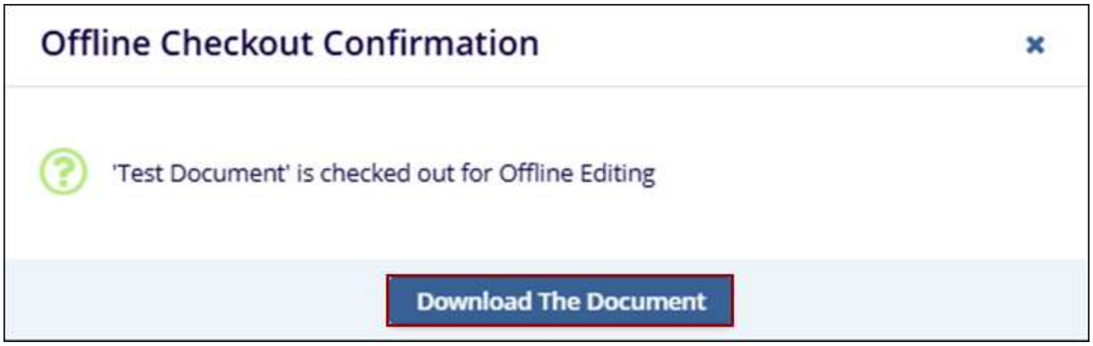


Offline

This option offers the user a chance to download the document to their computer. The user will then make any changes required using their preferred, locally installed software and upload an updated copy to the Collaborate room. When checking out a document offline, the document is immediately locked, and the system prompts the user to (optionally) download the document.

To edit a document offline, follow the steps below.

1. Check out a document to edit and select the Offline option.
2. On the Offline Checkout Confirmation popup, click on the Download the Document button to download the copy into the system.



Note: It is recommended to download the document during offline edits to ensure working on the most up-to-date version of the document.

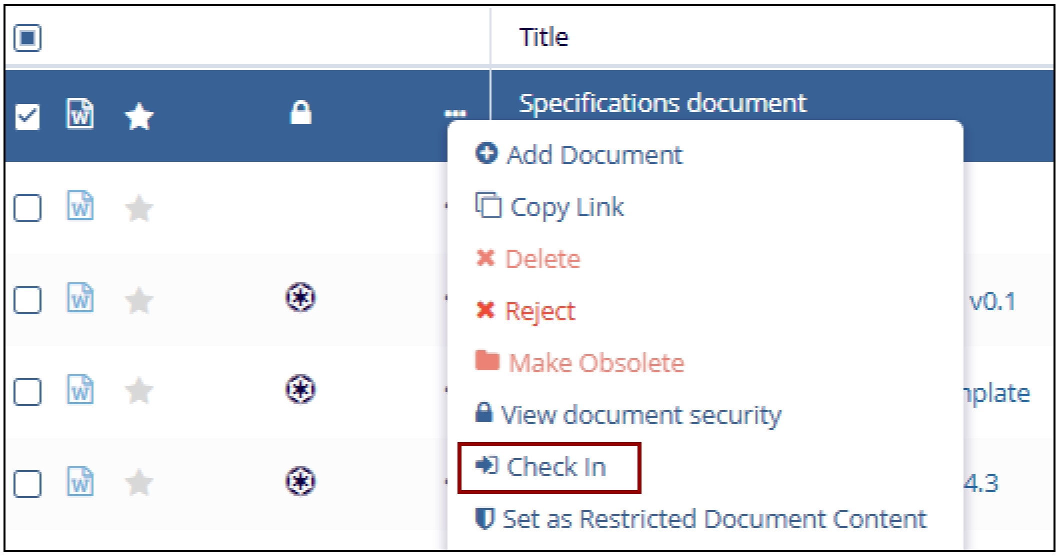
Check-In

When a user has finished editing the document, they need to check in the document.

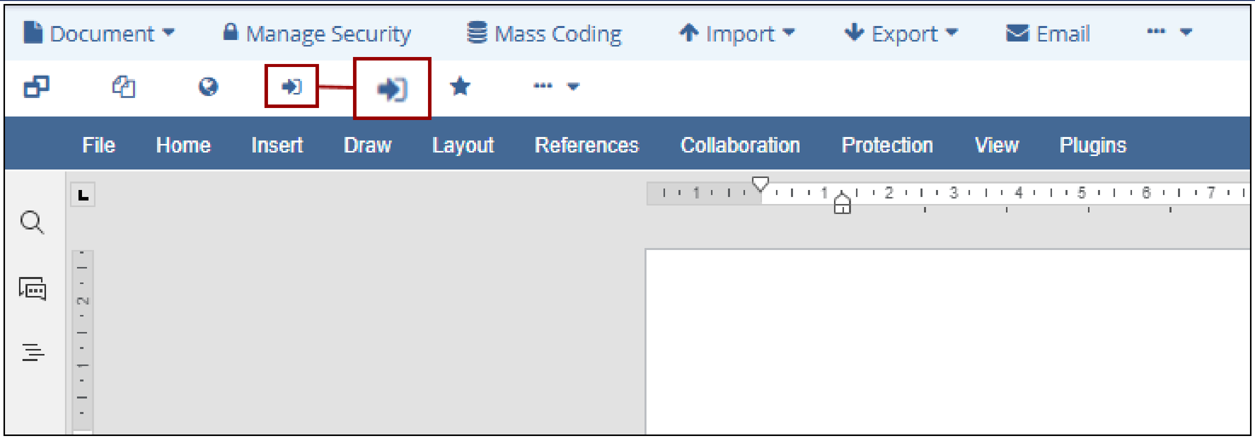
<u>Check-In for Online edits</u>

To check in a document for online edits, follow the steps below.

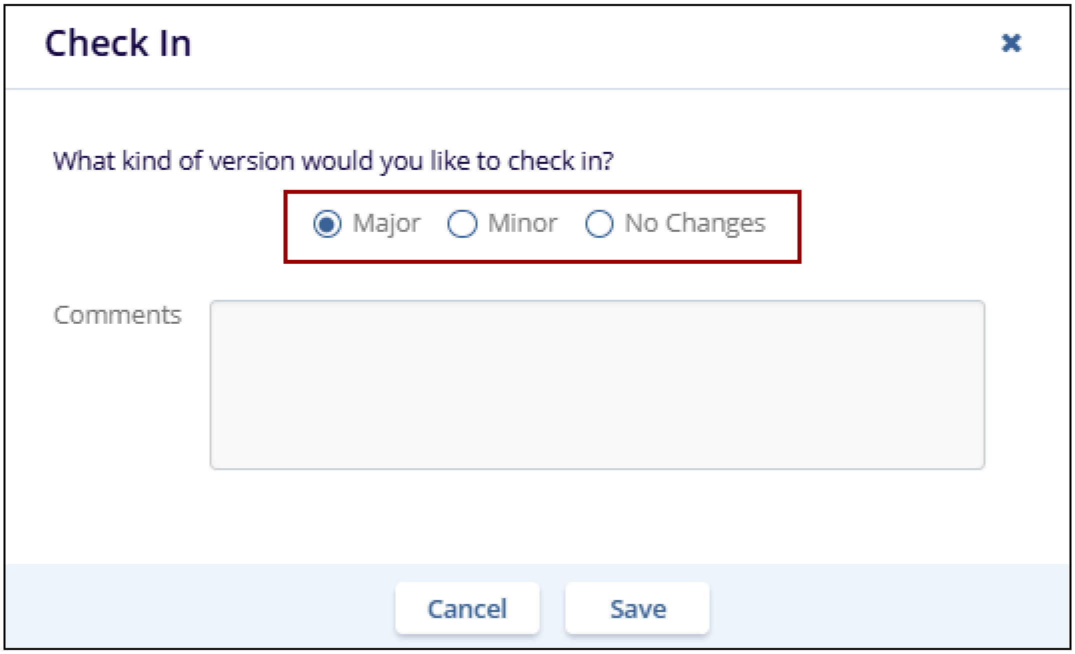
1. Click on the horizontal ellipsis (three-dot menu) icon of a checkout document and select the Check-In option.



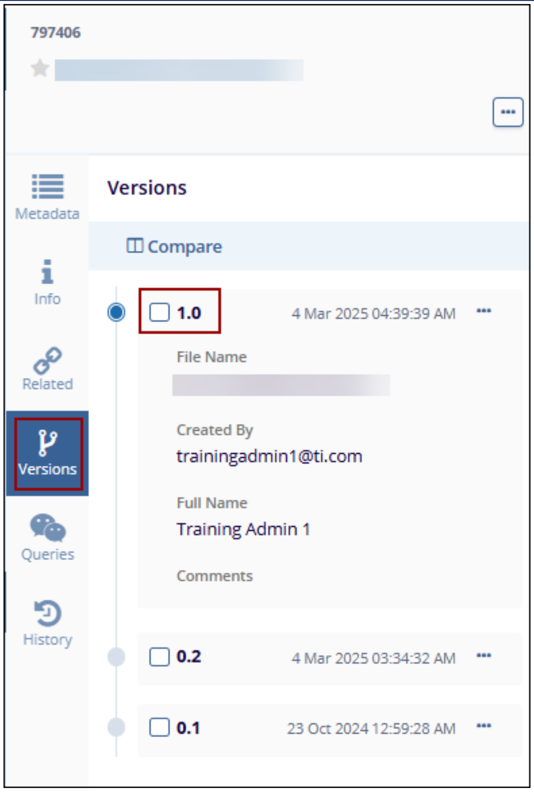
2. Otherwise, navigate to the Document View and click on the Check In button to check in the document from the Document Viewer.



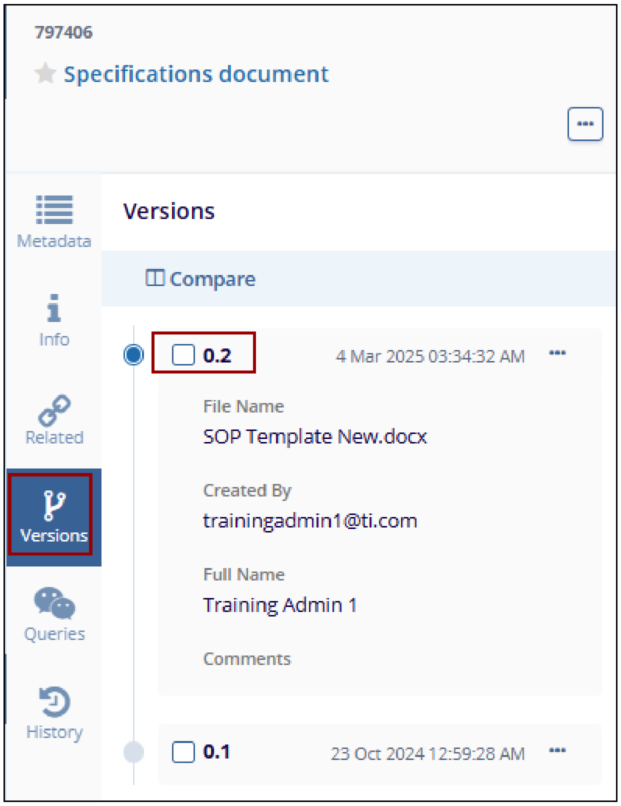
3. On the Check In popup, select any one of the options by clicking on the radio buttons, optionally enter a comment, and click on the Save button.
    a. Major
    b. Minor
    c. No Change



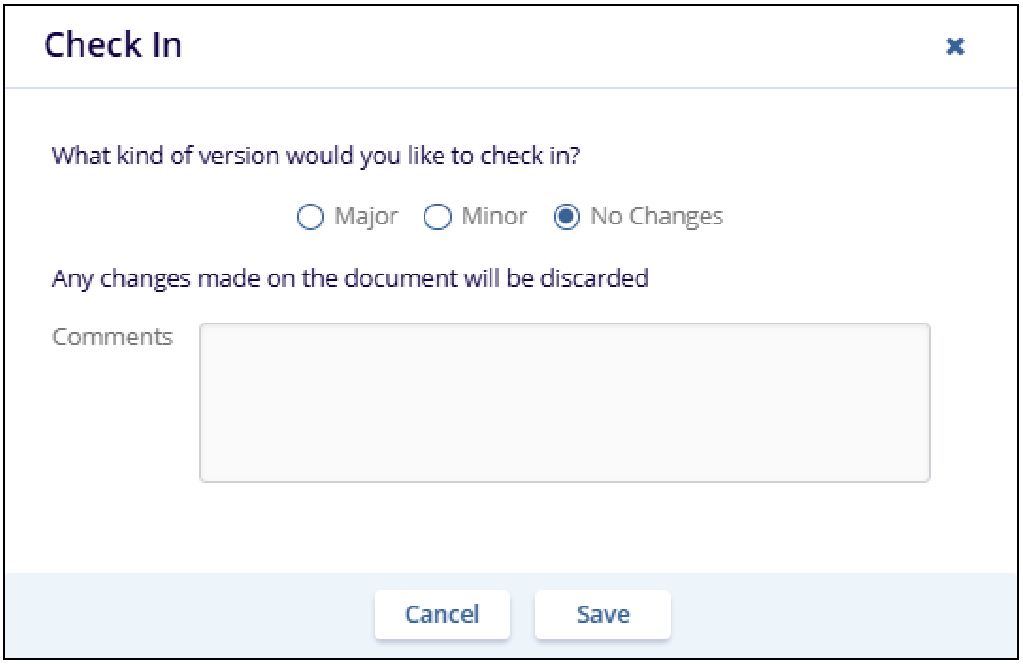
4. If Major is selected, the document is updated to a new major version and is displayed in the document metadata panel.



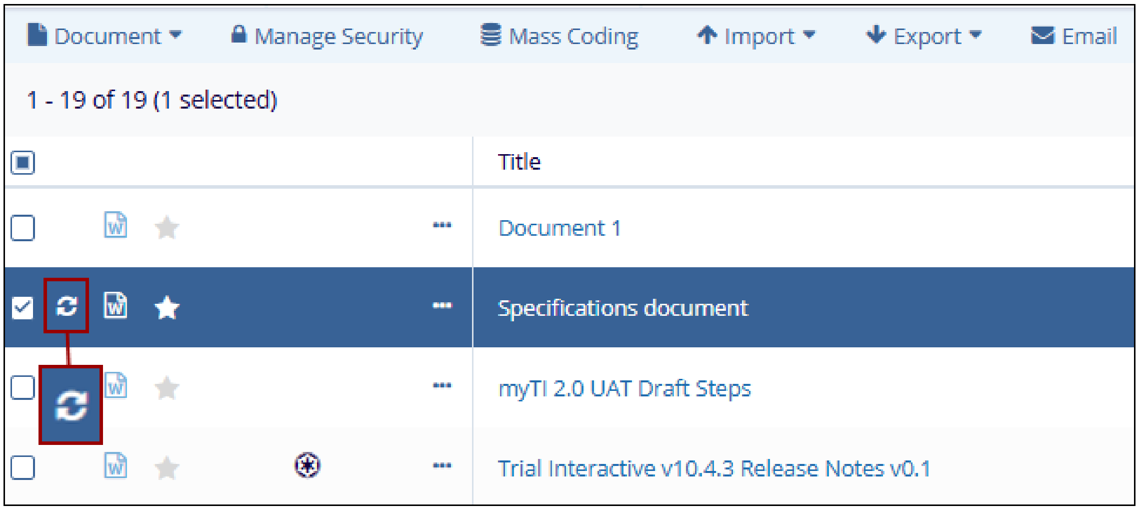
5. If Minor is selected, the document is updated to a new minor version and is displayed in the document's metadata panel.



6. If the No Changes option is selected, the edits are discarded and the document remains in its previous state and version.

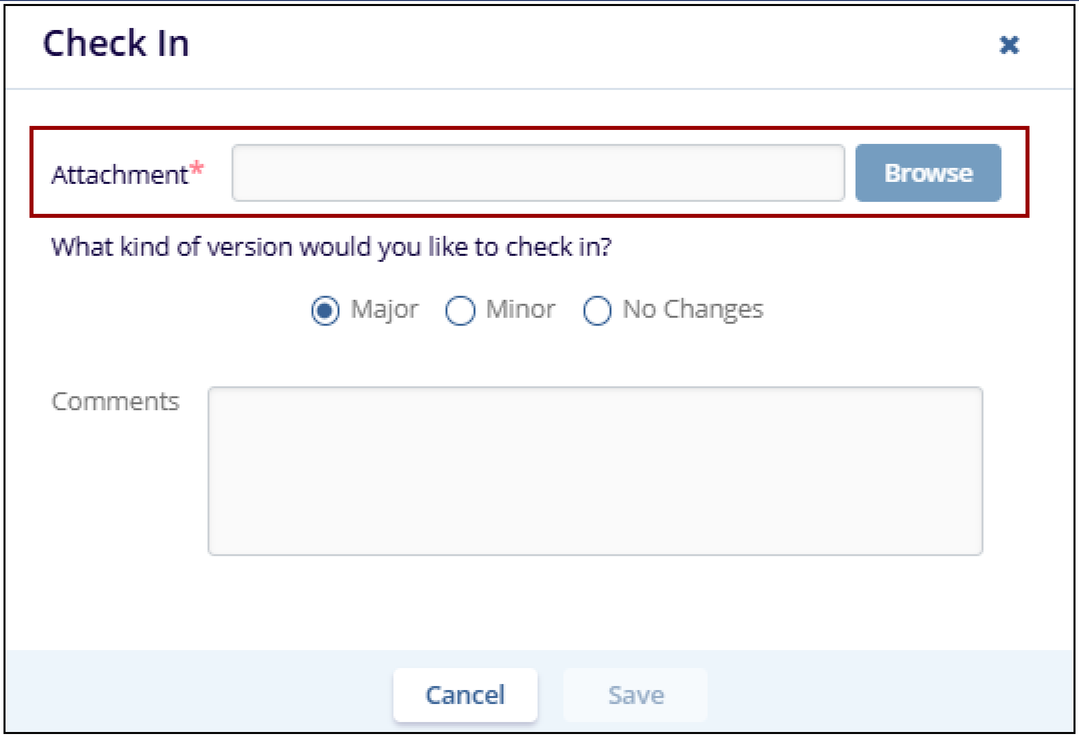


7. Click on the refresh icon within the Grid View.



Check-in for Offline edits

For Offline edits, users need to upload the locally edited document in the Attachment* section by clicking on the Browse button.


Check In
Attachment*
Browse
What kind of version would you like to check in?
Major
Minor
No Changes
Comments
Cancel
Save

Team Edits

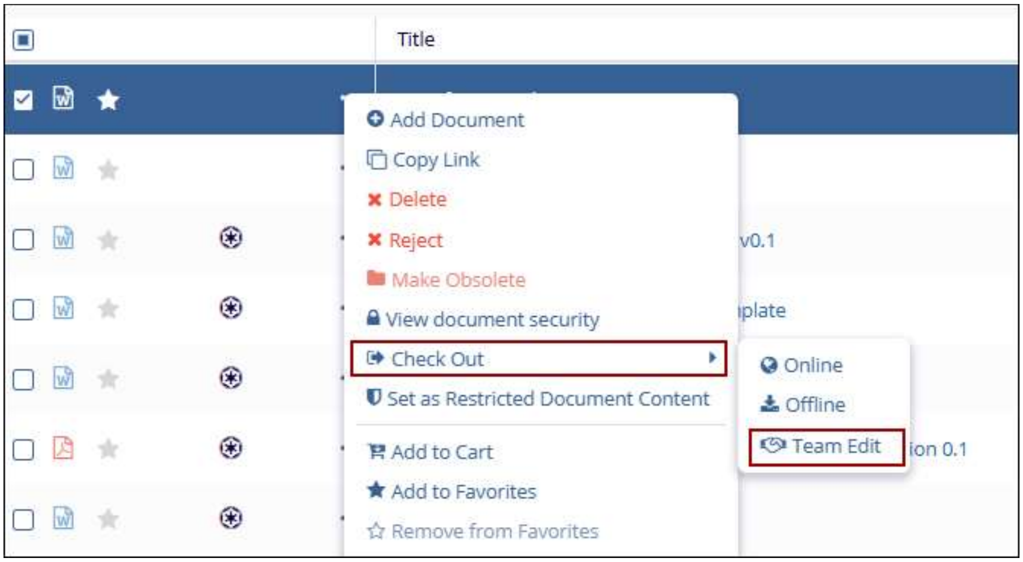
This option creates an online editing session involving multiple users, who can all work on the document simultaneously and see each other's changes in real time.

Set up Team Edits

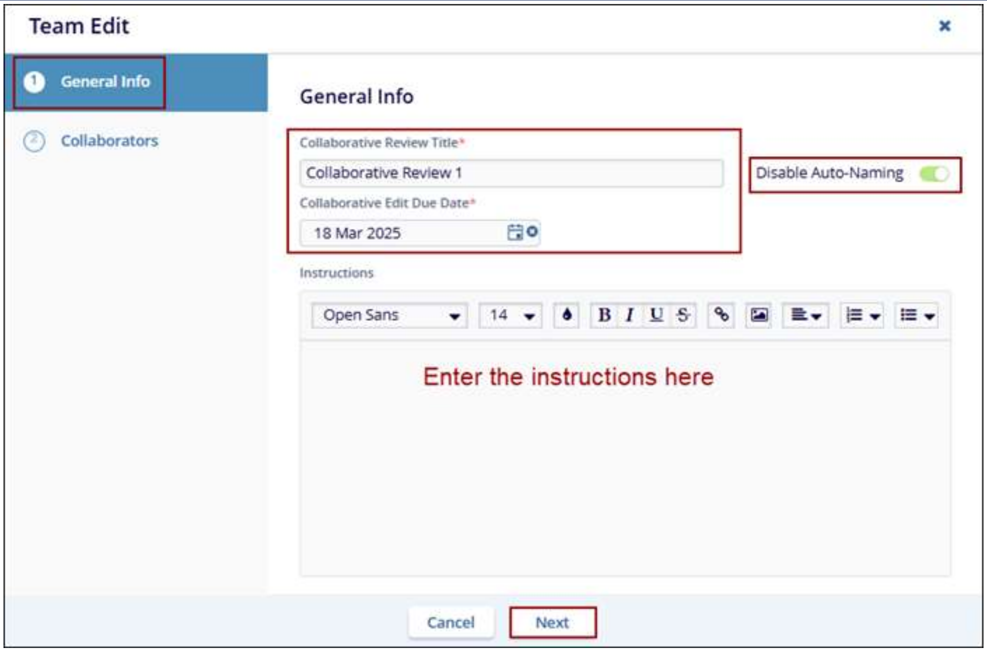
The user who creates the team editing session will be identified as the Collaborative Review Owner and can define which users will take part in the collaborative edit. The owner of the session can be reassigned later, if necessary, via the metadata panel in the collaborative editing module.

To set up team edits, follow the steps below.

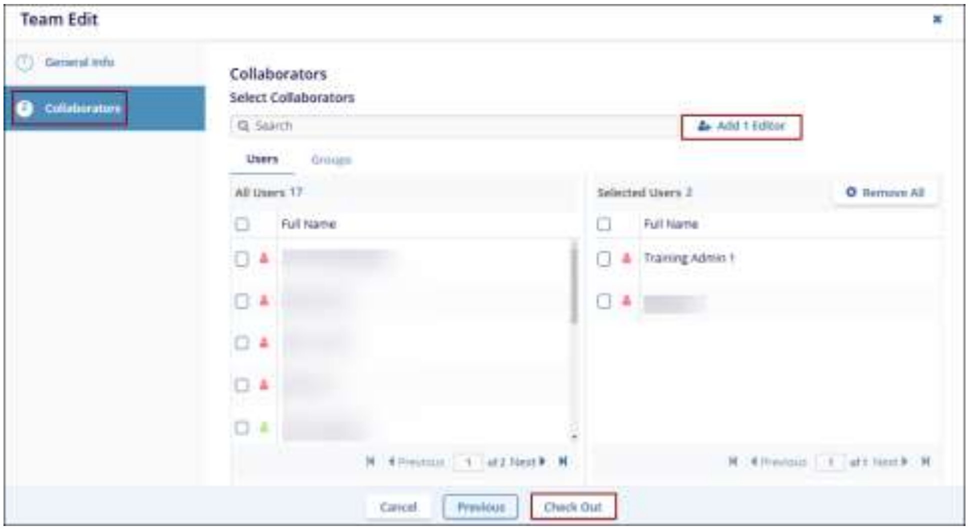
1. Check out the document to edit from the Documents Library and select the Team Edit option. The Team Edit window opens.



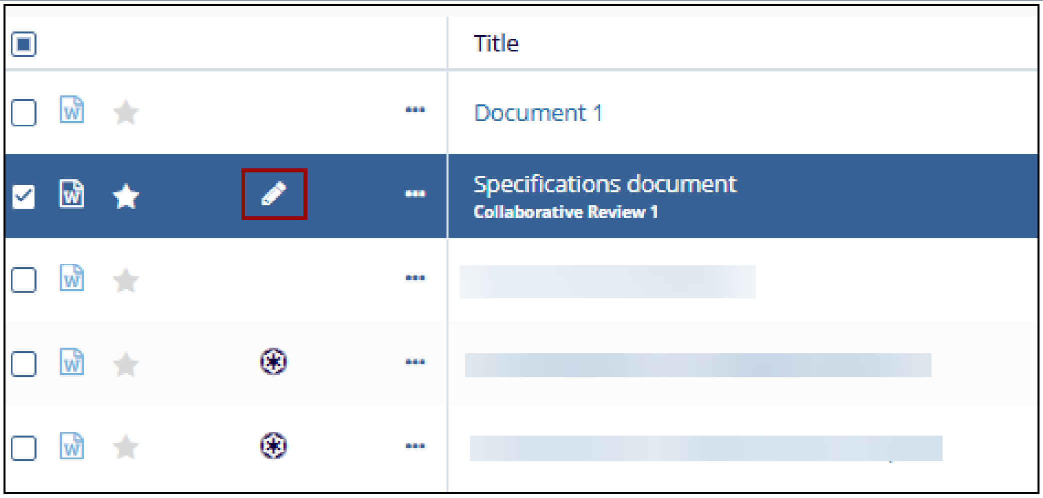
2. Within the General Info section, perform the following and click on the Next button.
    a. Assign a due date for the collaborative review by overriding the default date.
    b. Disable the Disable Auto-Naming toggle switch to personalize the review title.
    c. Optionally add the review instruction into the text box.



3. Within the Collaborators section, add the required number of collaborators from the All Users section to the Selected Users section.
4. Additionally, click on the +Add 1 Editor button to select all editor users with edit rights to the folder where the document is located.
5. Once the collaborators are added, click on the Check Out button.



6. The checked-out document for team editing is highlighted stating the document is in a collaborative review.

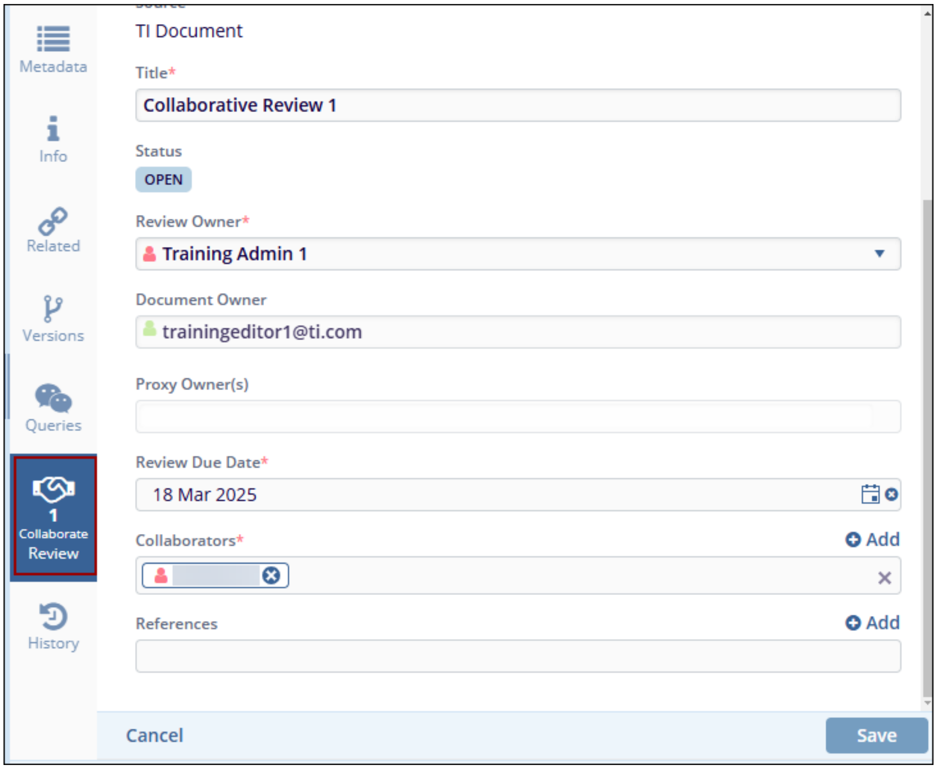


Participate in Team Edit

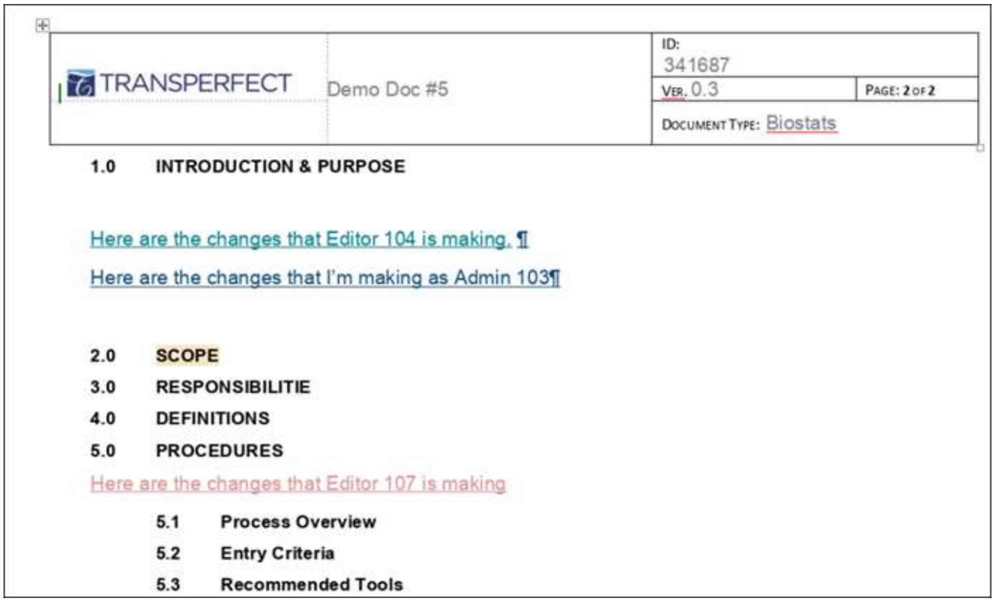
Collaborators participating in a team edit can simultaneously edit documents in the Document Viewer. Additionally, the Collaborate Review owner can make changes to the team editing session setup via the metadata panel.

To add or remove collaborators and collaboratively edit a document, follow the steps below.

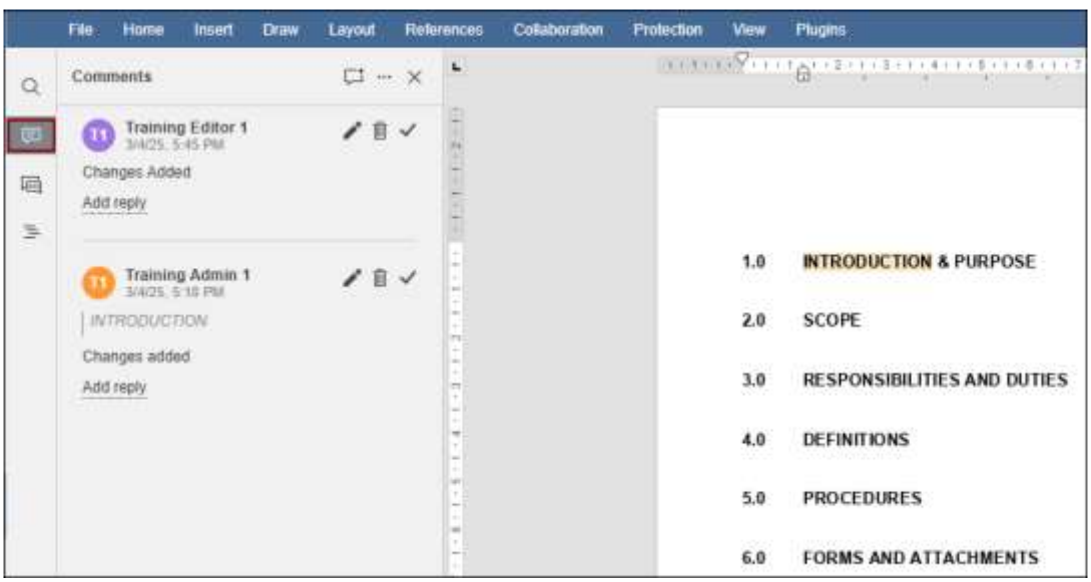
1. Navigate to the documents metadata panel and select the Collaborate Review tab.
2. Click on the Review Owner* dropdown and assign a different review owner.
3. Access the Collaborators* dropdown and add additional collaborators to the review.



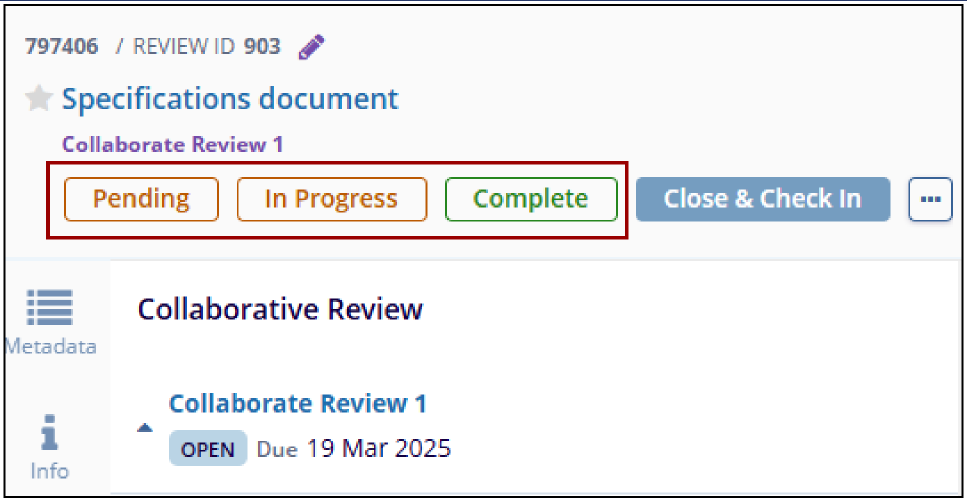
4. Click on the Document View to access the document in edit mode. Multiple users can make changes in real time, with each collaborator marked in a different ink.



5. Click on the Comments button from the vertical toolbar to add comments that can viewed by other collaborators as well.



6. Navigate to the documents metadata panel and update the review status by selecting Pending, In Progress, or Complete options.



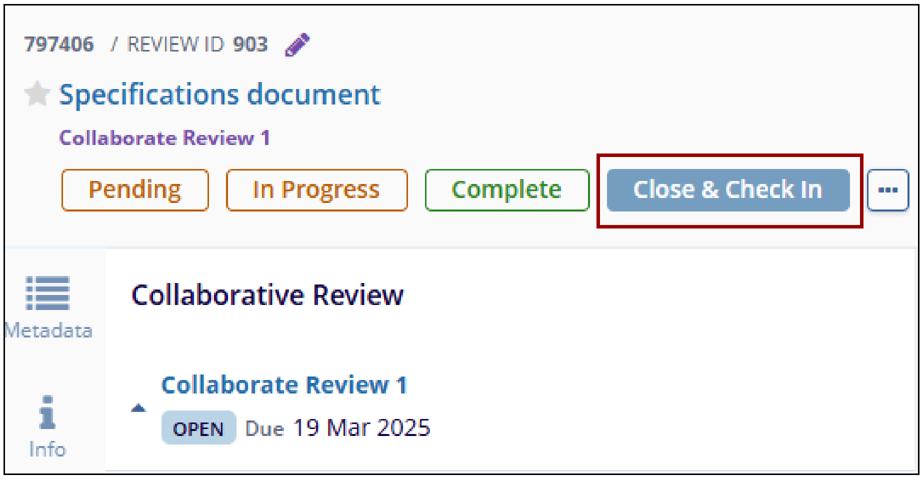
Closing a Team Edit

Once the collaborators have completed editing the document, any one of the collaborative reviewers can close the session and check back in the document. A team edit can closed directly from the documents metadata panel from the Documents library and from the Collaborate modal.

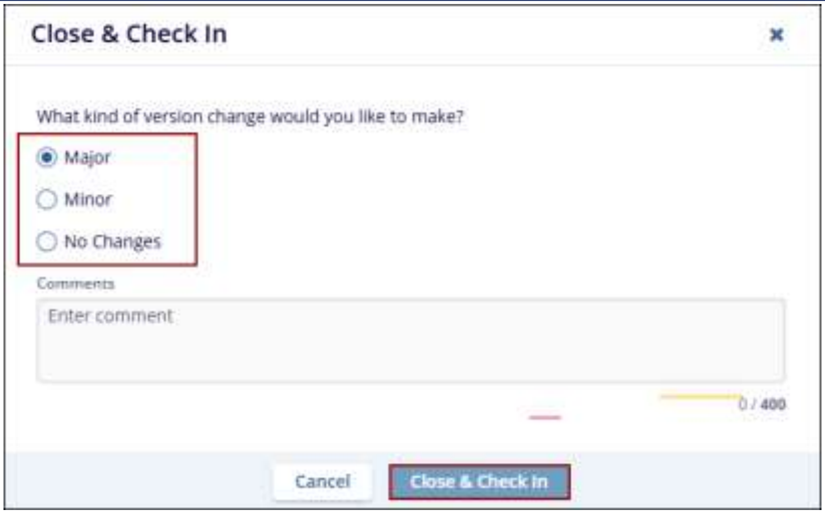
<u>Method 1</u>

To close a team, edit, follow the steps below.

1. Click on the Close & Check In button from the documents metadata panel.



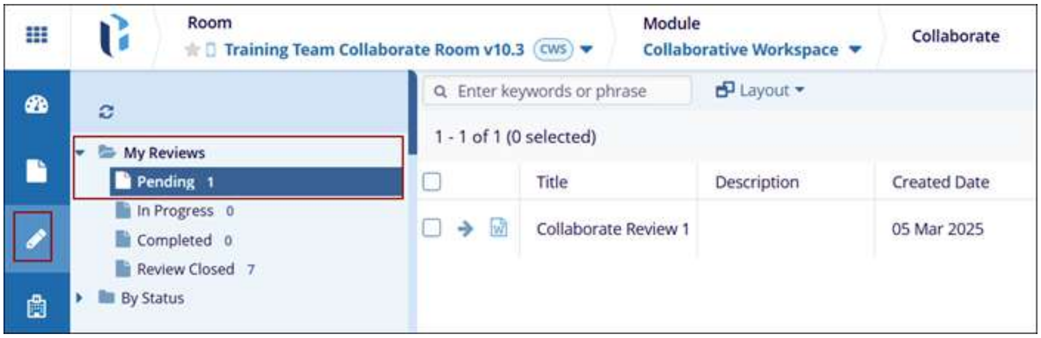
2. On the Close & Check-In popup, select any one of the version change options, optionally enter comments, and click on the Save button.



Method 2

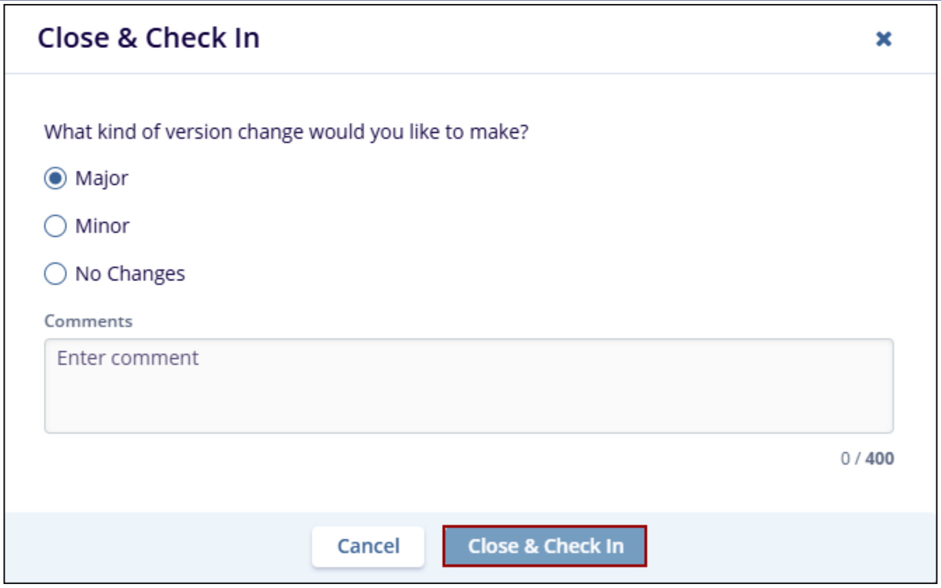
To close a team edit through the Collaborate modal, follow the steps below.

1. Navigate to the Collaborate modal and expand the My Reviews > Pending folder.

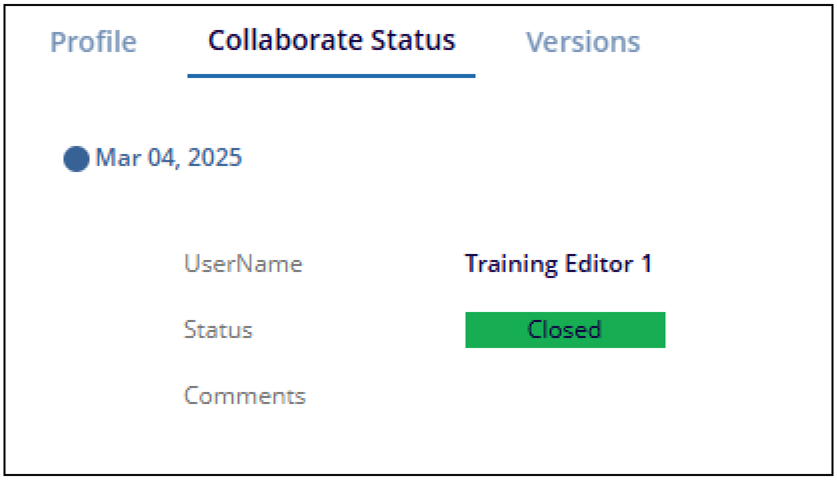


2. Select the review and click on the Collaborate Status tab from the quick view panel on the right-hand side.

3. Complete the check-in process by adding the type of revision and any comments, and then click Close Review Session and Check-In.



4. The Collaborate Status tab will display the status as closed with the User Name and Comments, if any.

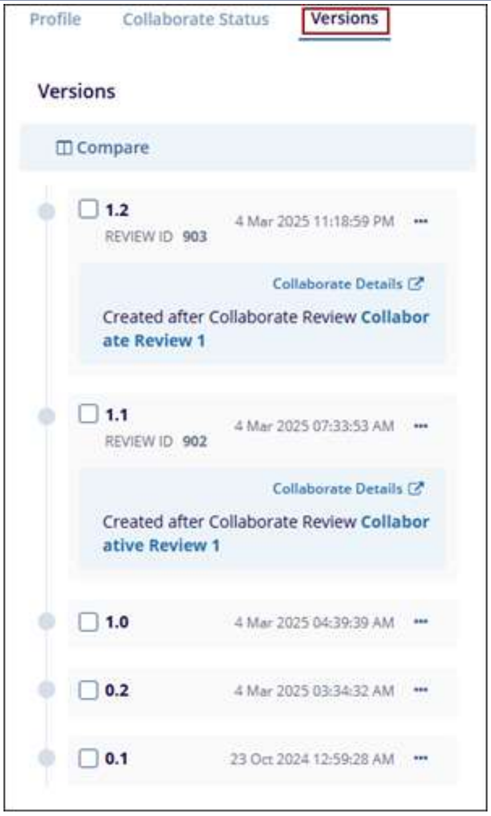


Documents and Collaboration Review

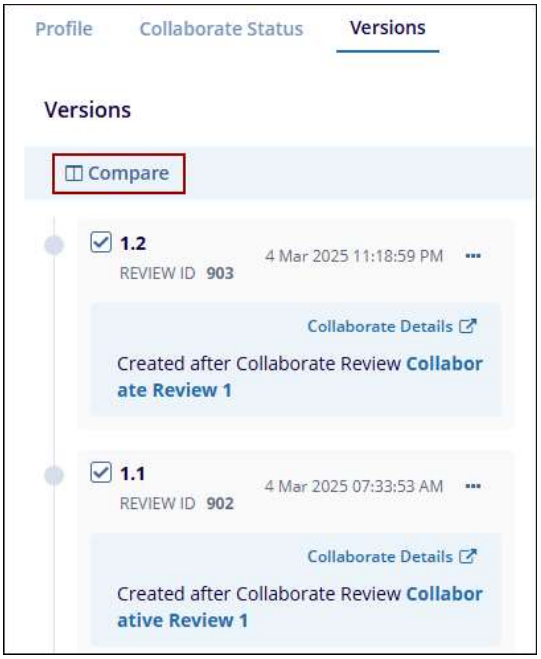
All edits, regardless of method, are tracked as part of a document's history. Versions of the document can be viewed and compared in the Versions tab of the Metadata panel.

To view the collaborate review history, follow the steps below.

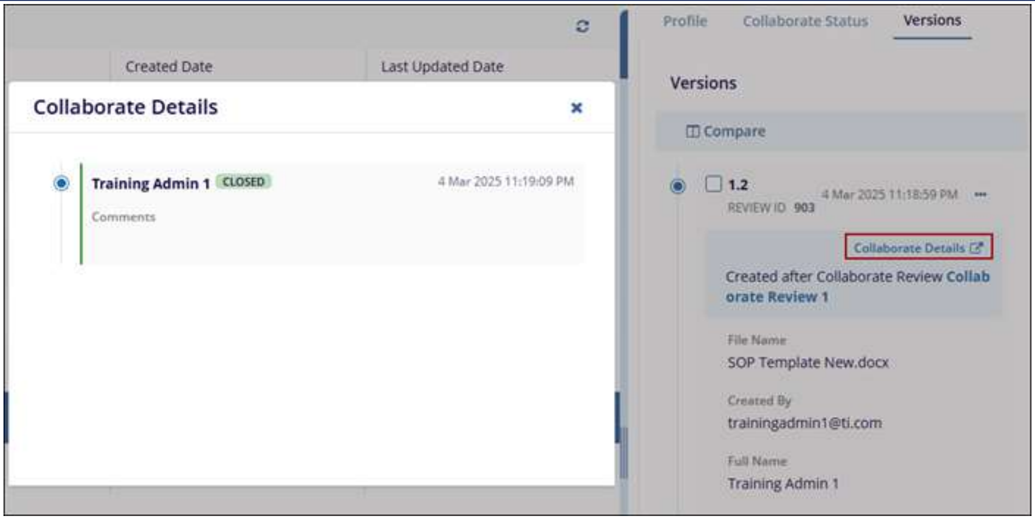
1. Click on the Versions tab from the quick view panel to view the document versions.



2. Select two document versions and click on the Compare button to view the document versions in a side-by-side view.



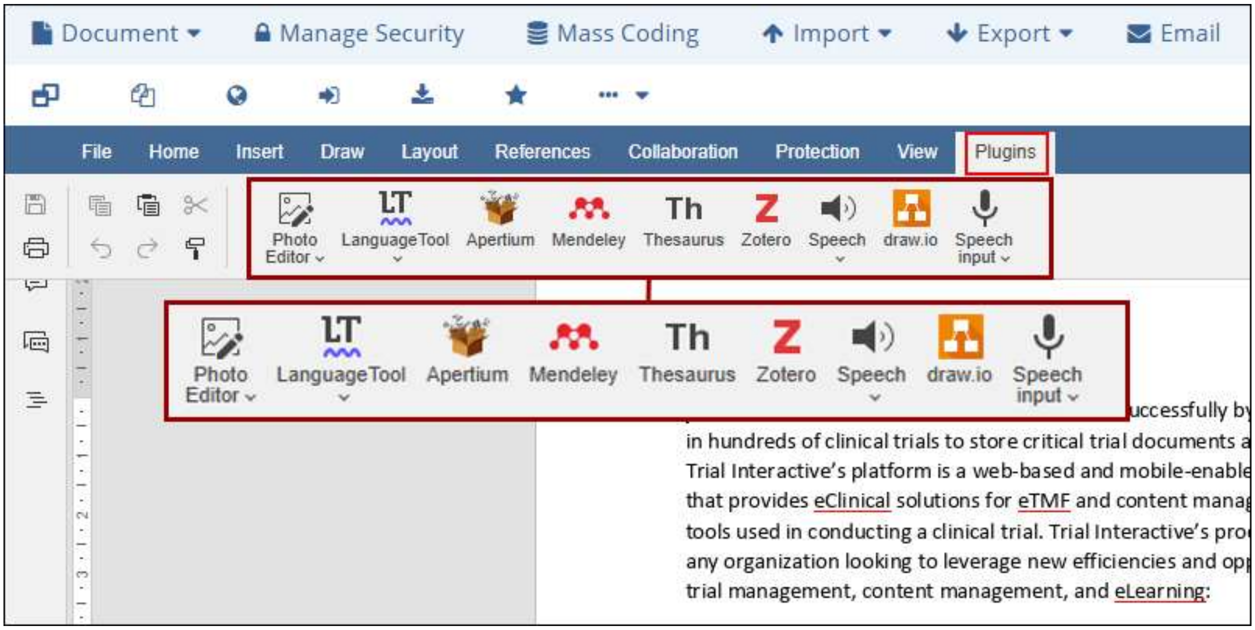
3. Click on the Collaborate Details link to view the review details in a different popup window.


Created Date
Last Updated Date
Collaborate Details
Training Admin 1
CLOSED
4 Mar 2025 11:19:09 PM
Comments
Profile
Collaborate Status
Versions
Versions
Compare
1.2
REVIEW ID 903
4 Mar 2025 11:18:59 PM
Collaborate Details
Created after Collaborate Review Collab orate Review 1
File Name
SOP Template New.docx
Created By
trainingadmin1@ti.com
Full Name
Training Admin 1

Only Office Plugins

The OnlyOffice Workspace is a robust productivity suite featuring word processing, spreadsheets, presentations, and collaboration tools. These tools are essential for streamlining organizational processes. Plugins, as integrated extensions, add extra functionality to the software, allowing users to customize and expand OnlyOffice's capabilities to meet specific needs.

Note: To access the plugins, check out a document for online editing and navigate to the Plugins menu in the toolbar at the top of the document viewer while in editing mode.



List of Only Office Plugins

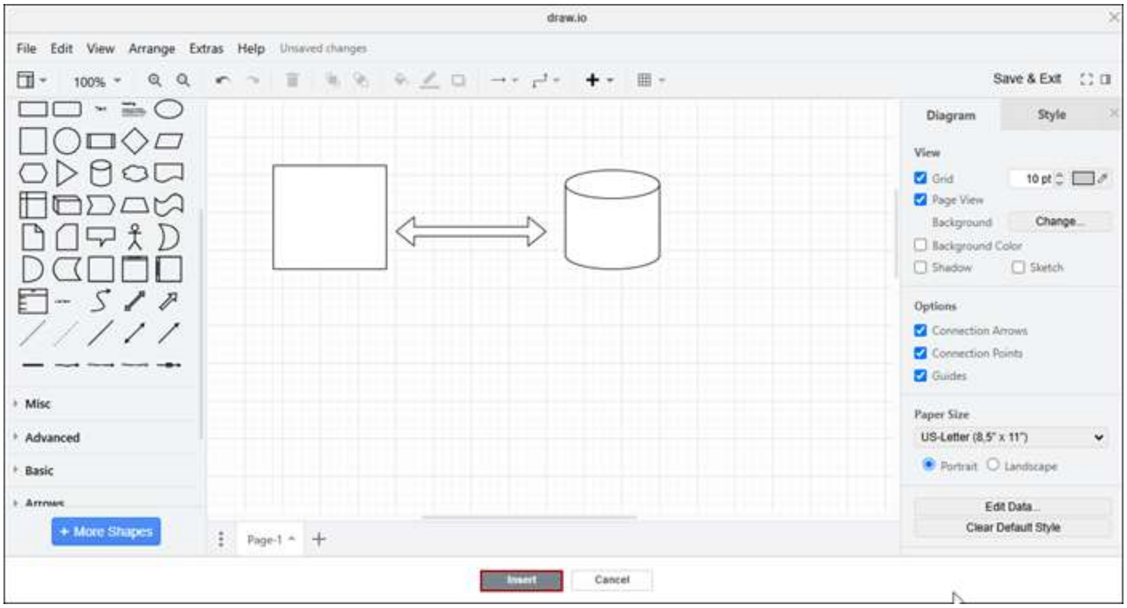
Trial Interactive now supports the use of various plugins within OnlyOffice, enabling users to integrate additional features and functionalities directly into the platform.

Important

1. To access the ONLYOFFICE Docs user guide, [Click here]
2. To access the ONLYOFFICE Document Editor user guide, [Click here]
3. To access the ONLYOFFICE Spreadsheet Editor user guide, [Click here]

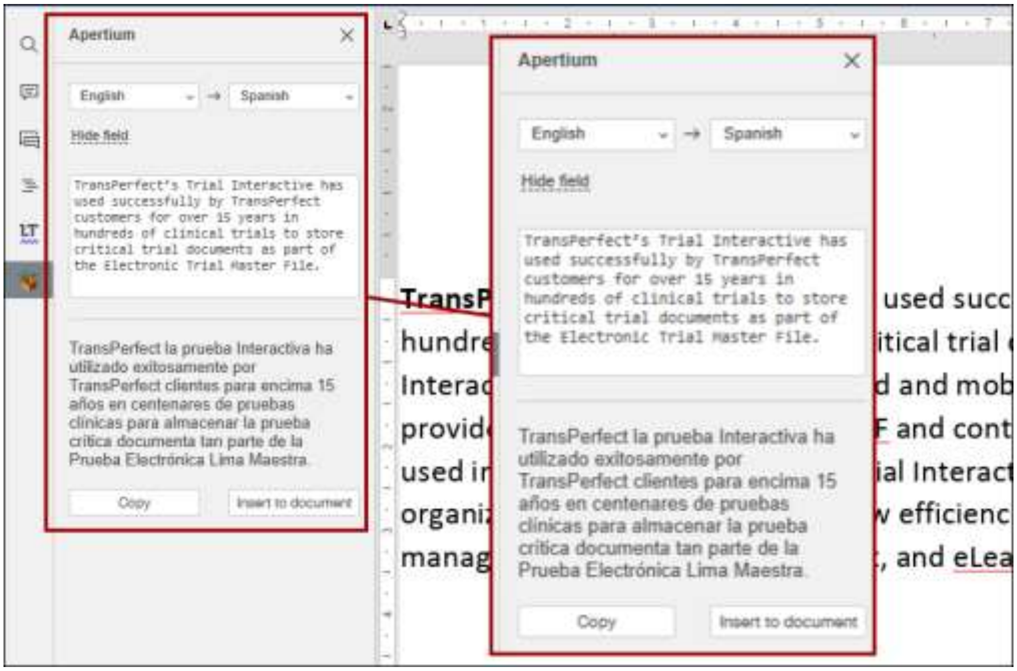
Draw.io

The Draw.io plugin for OnlyOffice allows users to create and edit diagrams, flowcharts, mind maps, and other visual representations. The plugin integrates draw.io, an open-source diagramming application that allows users to create a wide variety of diagrams: flow charts, mind maps, Venn diagrams, infographics, network and architecture diagrams, UML diagrams, etc. Ideal for project management, software design, and business documentation, the Draw.io plugin boosts productivity by keeping all the visual and textual content in one place. This way, users can work with such diagrams without leaving the editor interface or launching any additional applications.



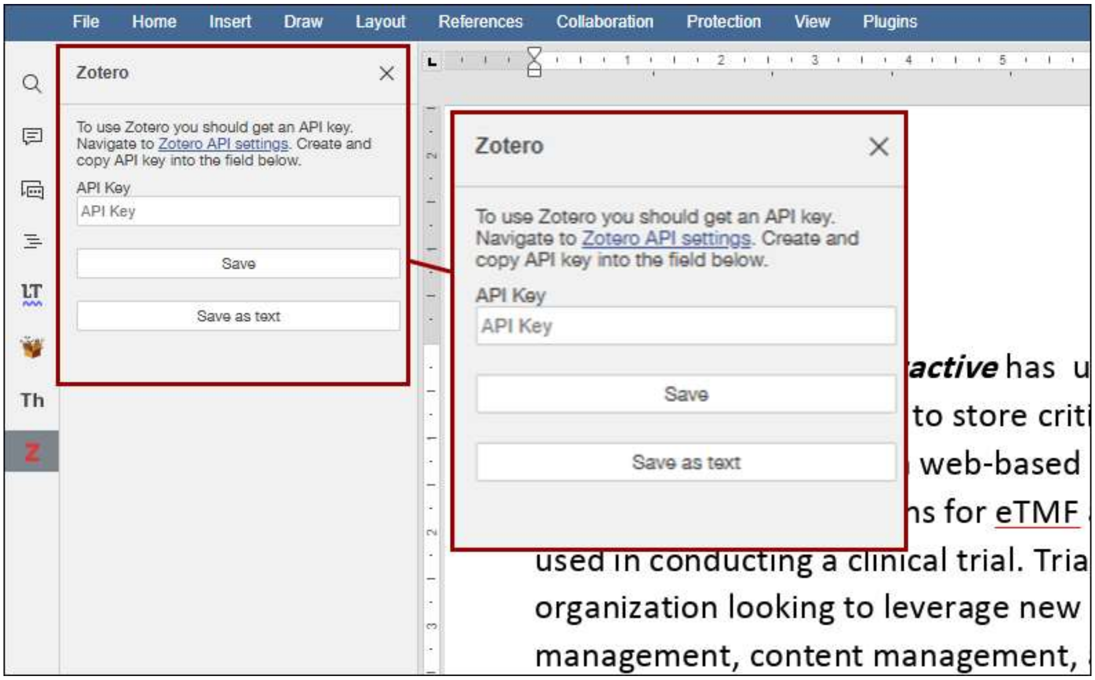
Apertium

The Apertium plugin for OnlyOffice offers a robust, open-source machine translation tool supporting multiple languages. This free platform allows users to translate text seamlessly within documents, making it an excellent solution for businesses and teams collaborating across languages.



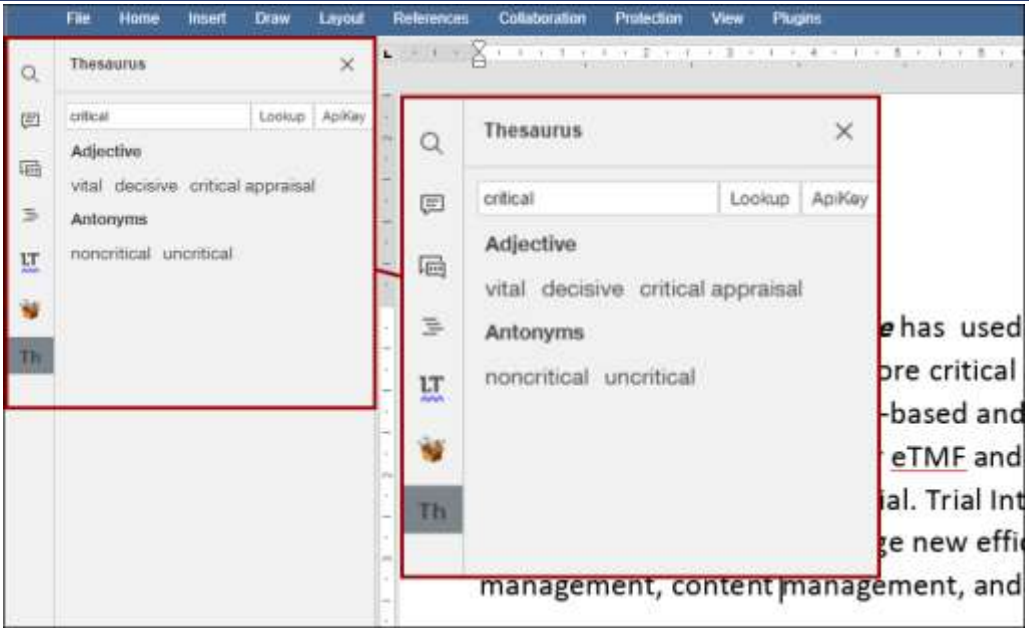
Zotero

Zotero is a free, open-source reference management tool designed to act as the personal research assistant. It helps you collect, organize, cite, and share research sources with ease. The Zotero plugin for OnlyOffice integrates this powerful tool directly into the document editor, enabling seamless management of references while working on documents. With Zotero, users can save references from library catalogs, research databases and websites. Additionally, users can add PDFs, images, audio and video files, snapshots of webpages, and write annotations and attach them to the citations. Users can also create bibliographies using a wide range of major citation styles.



Thesaurus

The Thesaurus plugin for OnlyOffice allows users to easily find and replace words with synonyms directly within the editor. This enhances vocabulary and improves writing quality by providing quick access to word alternatives, enabling more refined and diverse content without leaving the workspace.

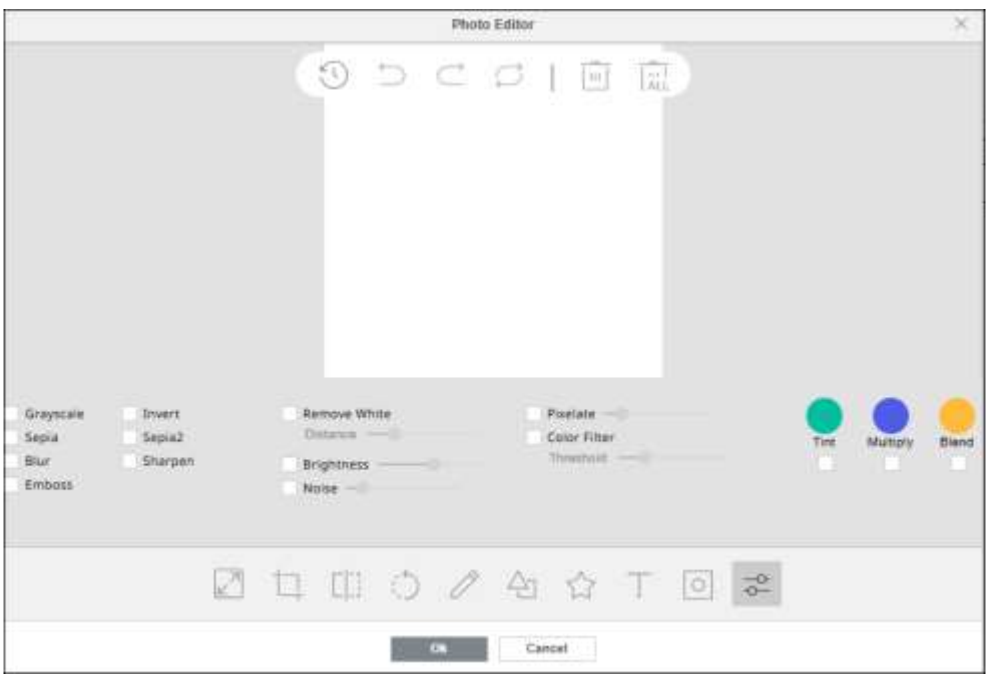


Talk

Talk: Talk is an instant messenger that provides real-time communication between co-workers. It offers all the traditional features a user can expect from a messenger i.e., history archiving, file transfer, multi-user chat support, search function and emoticons etc.

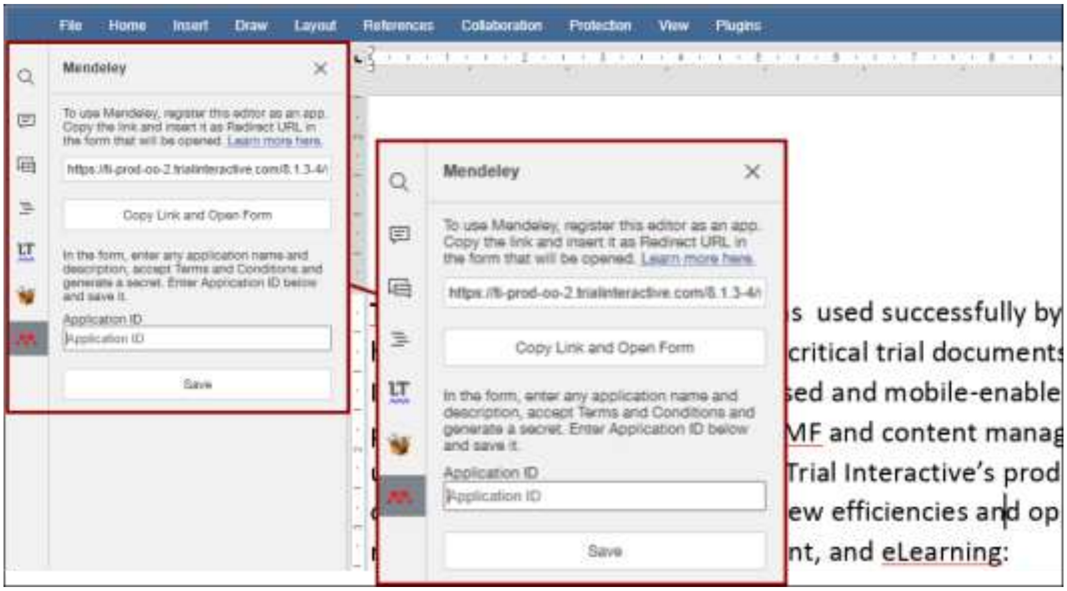
Photo Editor

The Photo Editor plugin for OnlyOffice enables users to edit images directly within the document editor. It offers features like cropping, resizing, flipping, rotating, drawing lines and shapes, adding icons and text, applying masks, and using filters such as Grayscale, Invert, Sepia, Blur, Sharpen, and Emboss, simplifying the process of enhancing visuals.



Mendeley

The Mendeley plugin for OnlyOffice integrates a powerful reference management tool allowing users to insert citations, manage references, and create bibliographies seamlessly. This plugin streamlines the citation process and ensures accurate referencing directly within documents.



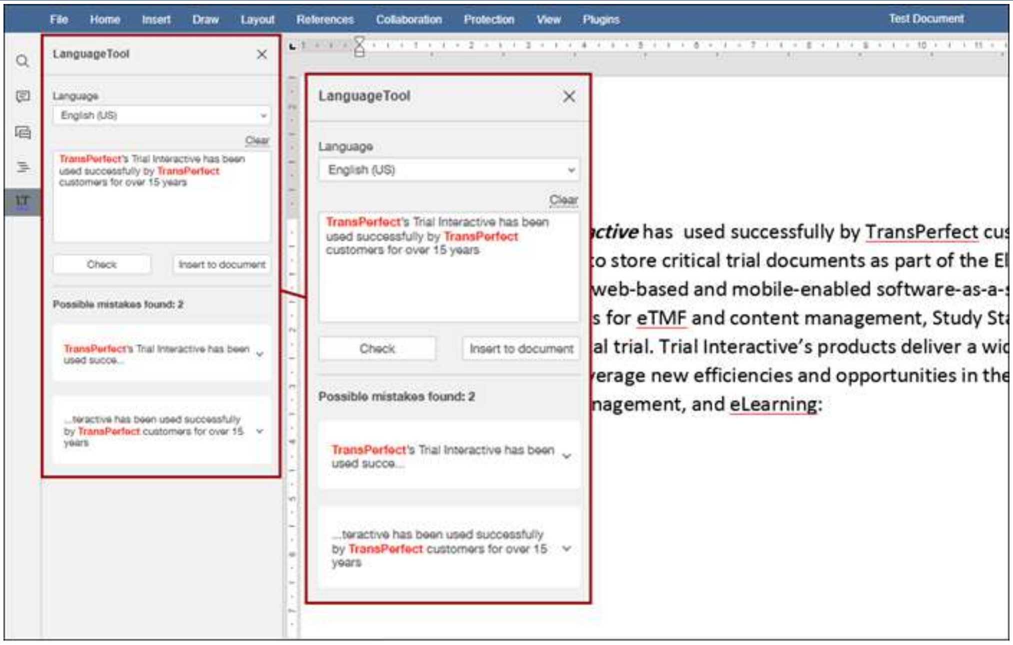
Auto Complete

The AutoComplete plugin for OnlyOffice enhances productivity by predicting and suggesting words or phrases as users go on typing. The AutoComplete helps save time, reduces errors, and ensures consistent terminology, making it particularly useful for repetitive tasks or handling professional documents efficiently.

Language Tool

The LanguageTool plugin for OnlyOffice provides advanced grammar, style, and spell-checking capabilities in multiple languages. It helps users improve the quality of their writing by identifying errors and suggesting corrections directly to the editor, ensuring polished and professional documents with ease.

To use the language tool, highlight the text, select the Language Tool plugin from the top toolbar, and click the Start button.

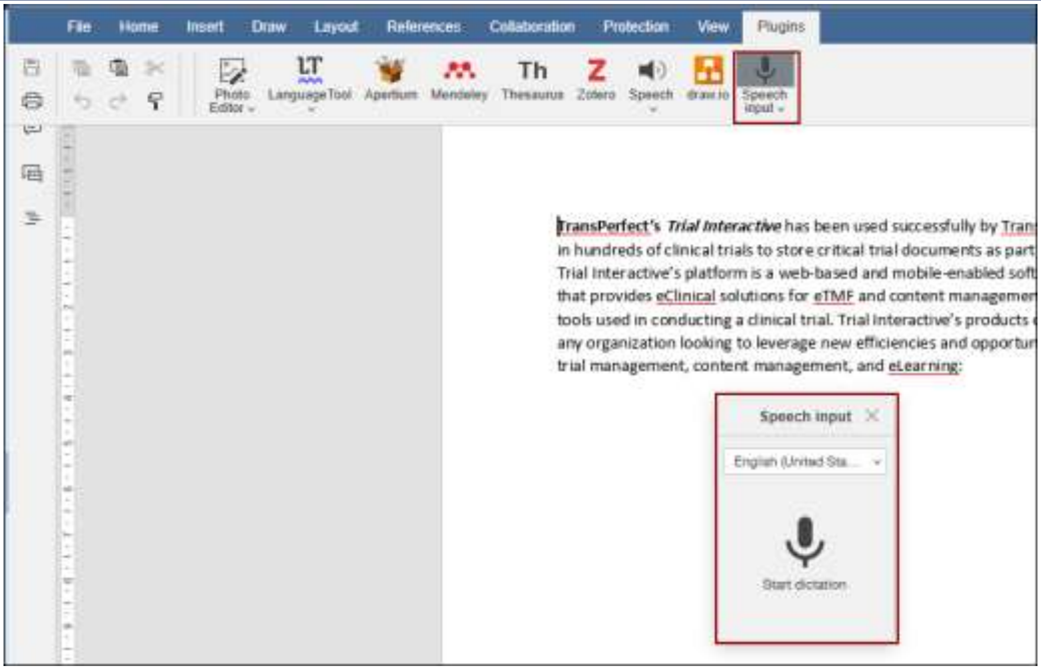


Speech

Speech: The Speech plugin for OnlyOffice converts text to speech, enabling users to listen to their documents being read aloud. This feature is ideal for proofreading, accessibility, and multitasking, helping users catch errors, improve content flow, or review documents hands-free directly within the editor.

Speech Input

The Speech Input plugin in OnlyOffice enables users to convert speech into text effortlessly. The Web Speech API recognizes spoken words and inserts them directly into documents, streamlining productivity and minimizing typing effort. The plugin supports multiple languages, including English, French, German, Italian, Spanish, Portuguese, Turkish, Chinese, and more.

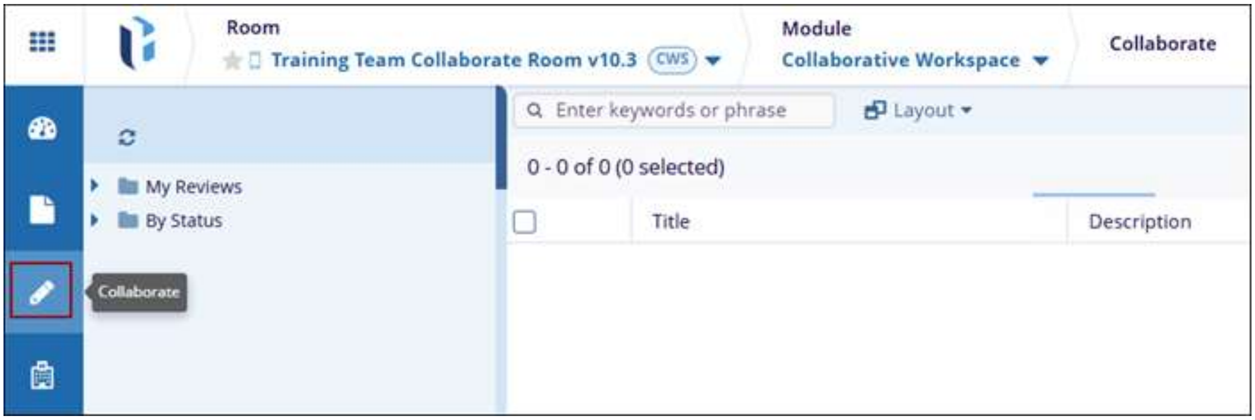

File
Home
Insert
Draw
Layout
References
Collaboration
Protection
View
Plugins
Photo Editor
LanguageTool
Apertium
Mendeley
Thesaurus
Zotero
Speech
draw.io
Speech input
TransPerfect's Trial Interactive has been used successfully by Tran
in hundreds of clinical trials to store critical trial documents as part
Trial Interactive's platform is a web-based and mobile-enabled soft
that provides eClinical solutions for eTMF and content managemen
tools used in conducting a clinical trial. Trial Interactive's products
any organization looking to leverage new efficiencies and opportu
trial management, content management, and eLearning:
Speech input
English (United Sta...
Start dictation

COLLABORATE MODAL

The Collaborate modal in the Collaborative Workspace displays and provides access to Collaborative Team Edit sessions. These sessions are categorized based on the user's participation and their status. Additionally, users can view and update the session profile, manage collaboration status, and access different versions of the collaboration review.

To access the Collaborate modal, follow the steps below.

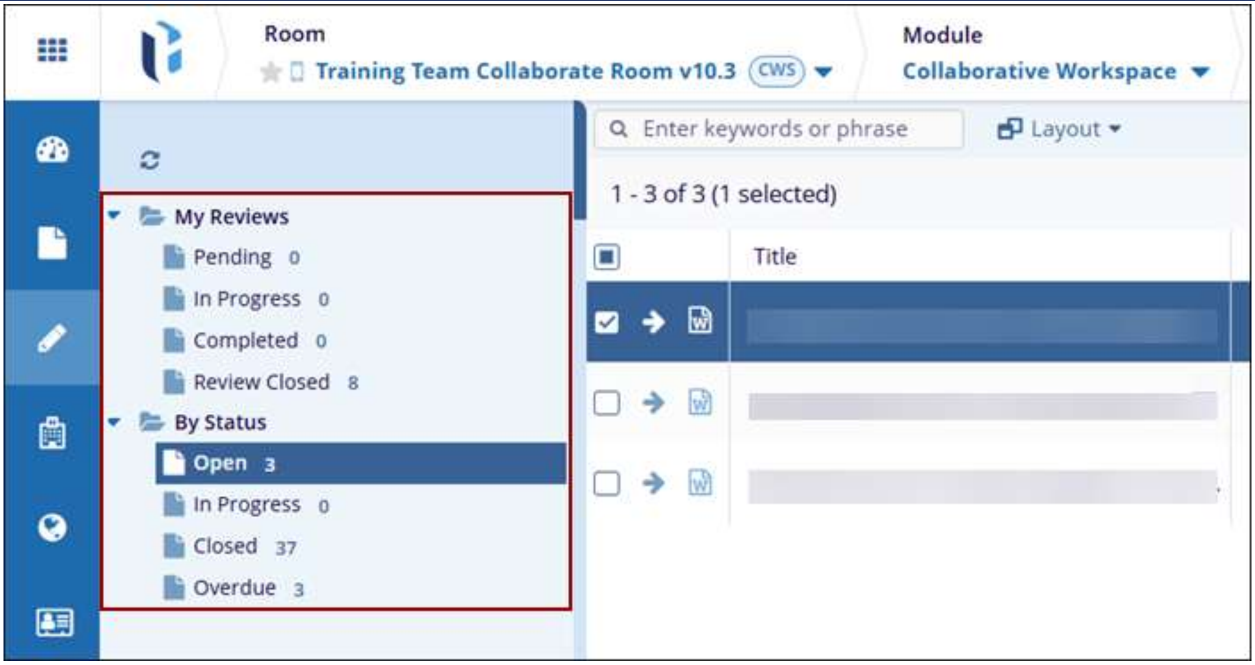
1. Click on the Collaborative Workspace from the module's dropdown.
2. Click on the Collaborate modal from the left-hand navigation menu.



Collaborate Views

To view documents within a collaborative session by different criteria, follow the steps below.

1. Expand the My Reviews and By Status folders.
2. Under My Reviews folder, select the following sub-folders.
   a. Pending
   b. In Progress
   c. Completed
   d. Review Closed
3. Under By Status folder, select the following sub-folders
   a. Open
   b. In Progress
   c. Closed
   d. Overdue

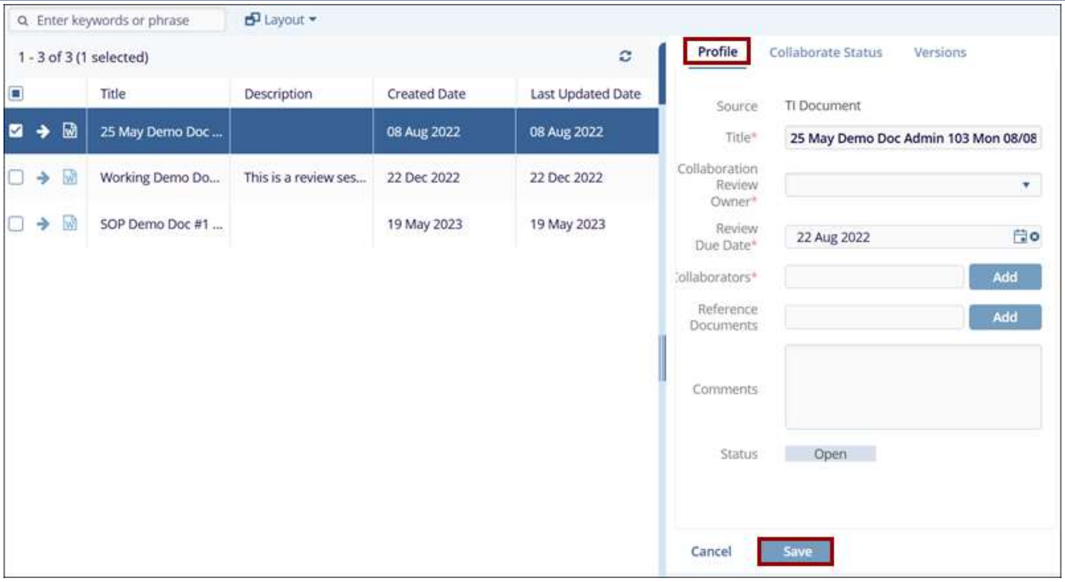


Collaborate Metadata Panel

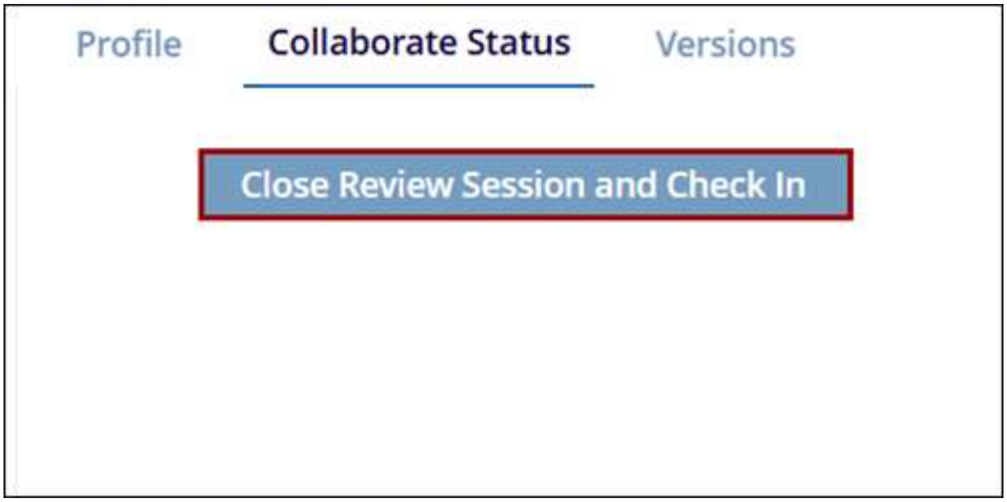
The metadata panel of a document in a collaborative session allows users to view and update the profile details, close the session, check back in the updated document, and access different versions of the document.

To access the metadata panel of a collaborate document, follow the steps below.

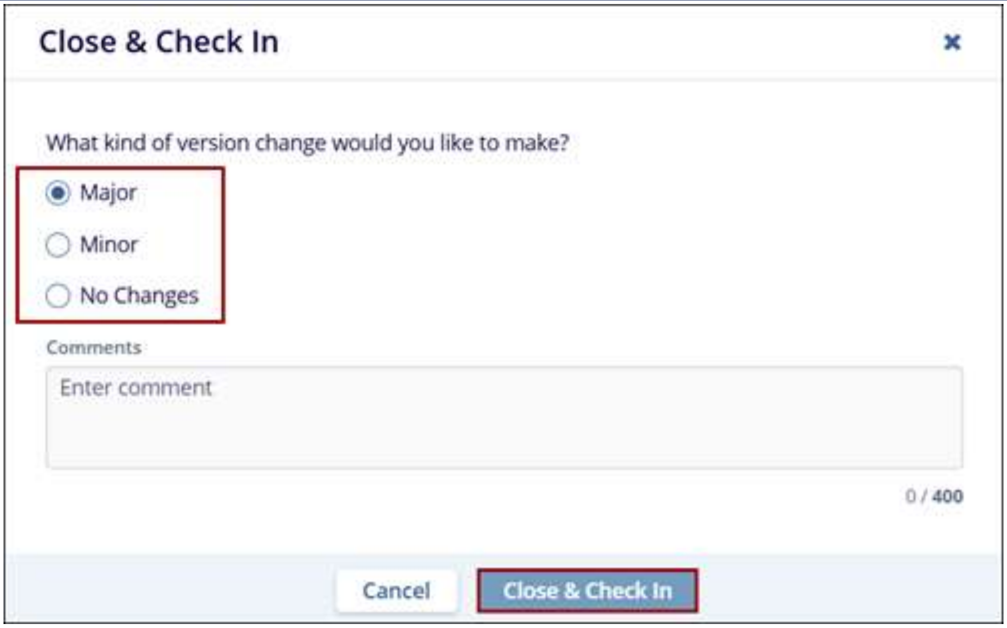
1. Select a collaborate document and expand the metadata panel.
2. Click on the Profile tab, update the following details if required, and click on the Save button.
   a. Title*
   b. Collaboration Review Owner*
   c. Review Due Date*
   d. Collaborators*
   e. Reference Documents
   f. Comments



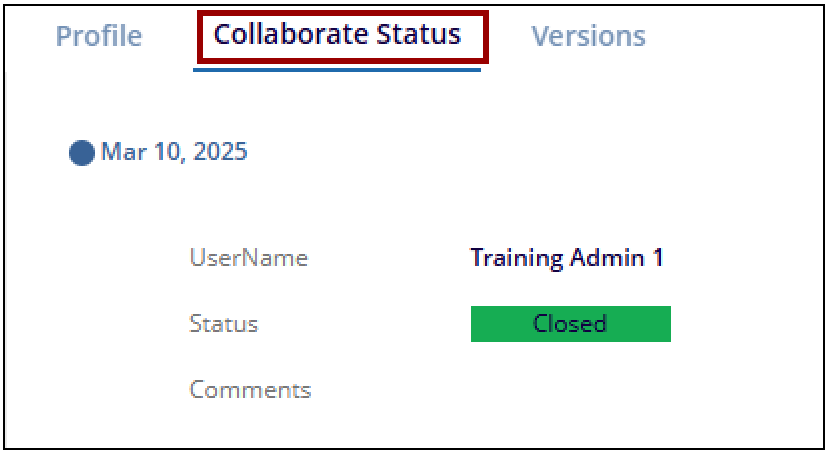
3. Select the Collaborate Status tab and click on the Close Review Session and Check In button.



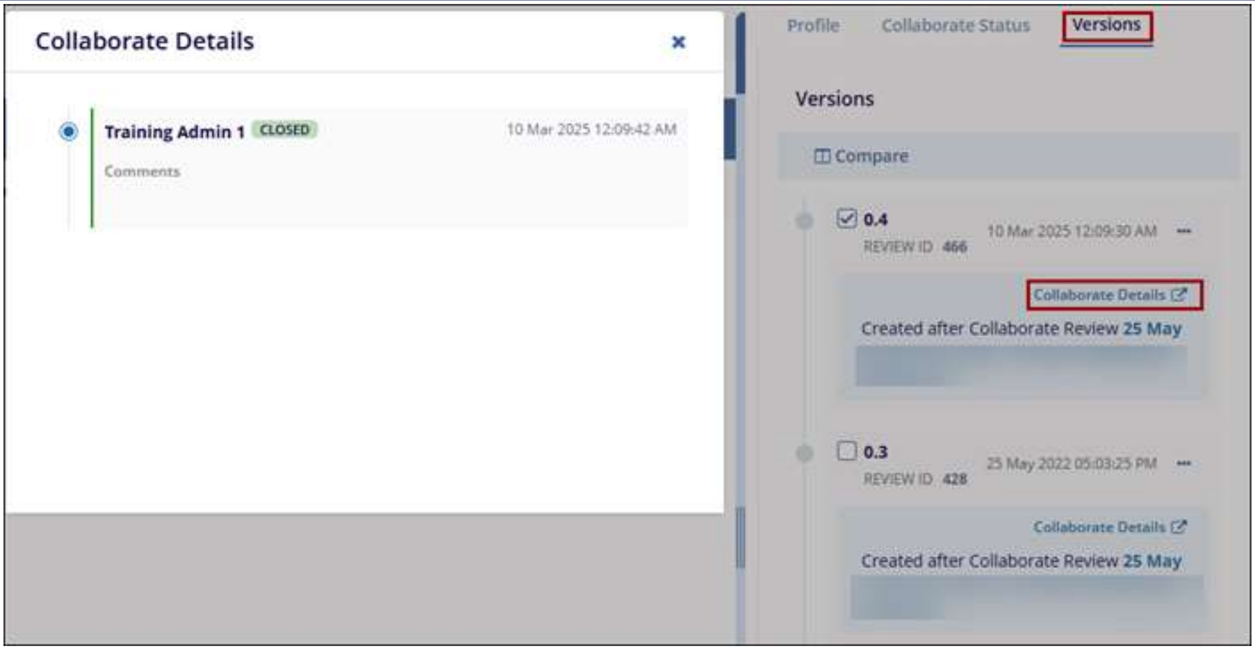
4. On the Close & Check In window, select a version change option and click on the Close & Check In button.



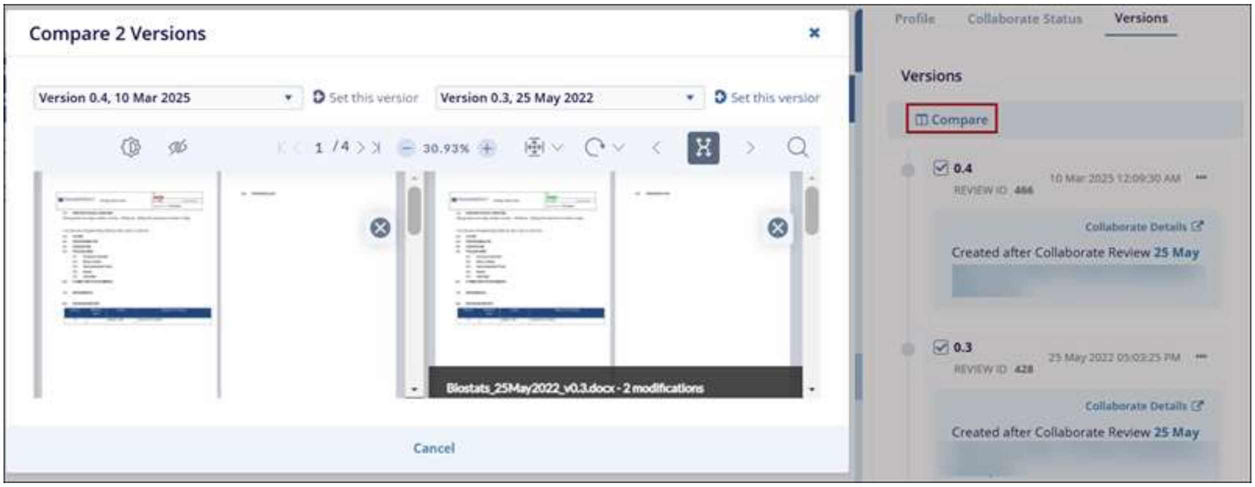
5. Once the session is successfully closed, the Collaborate Status tab displays the review status as Closed along with the user's name.



6. Navigate to the Versions tab to view the version-specific details. Click on the Collaborate Details tab to view the collaborate review details in a separate popup.



7. Select two versions and click on the Compare button to display a side-by-side view of both versions.



APPROVAL WORKFLOWS

This section explains the procedure to initiate the change control and administrative approval workflows and electronically sign a document.

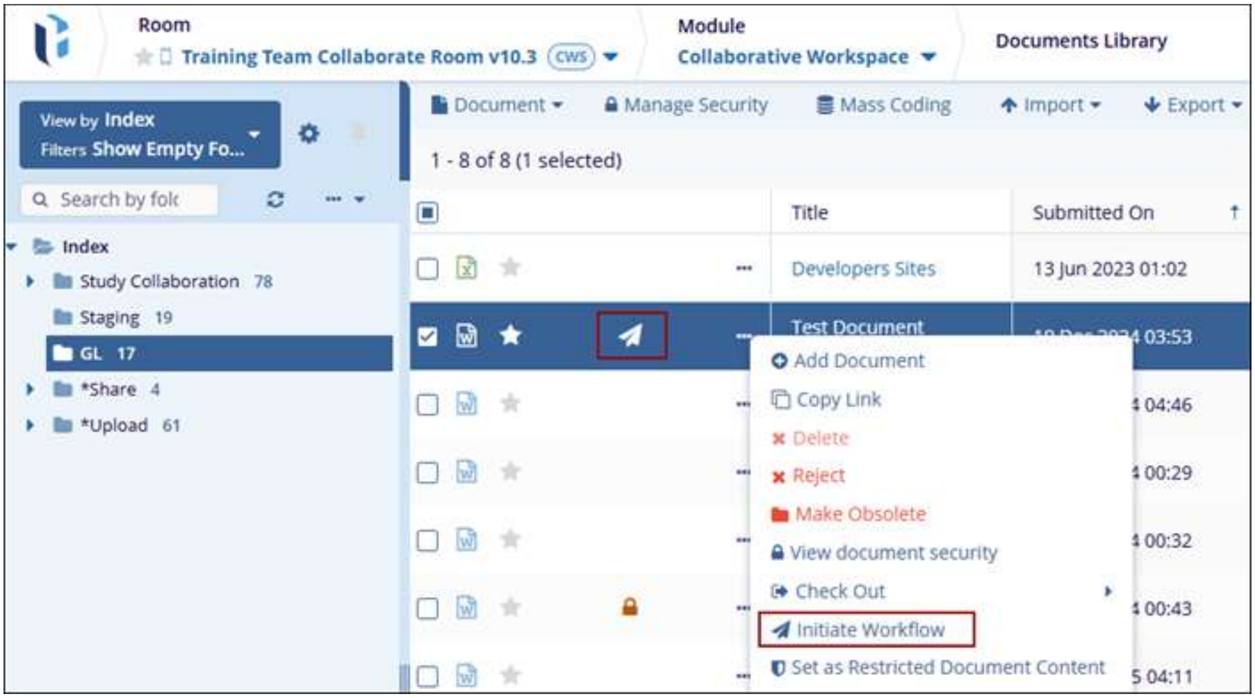
Change Control Workflow

Documents requiring change control can be submitted for review or signature workflows either upon submission to TI or after content is generated/edited in TI. Users with editor and above access can initiate a workflow.

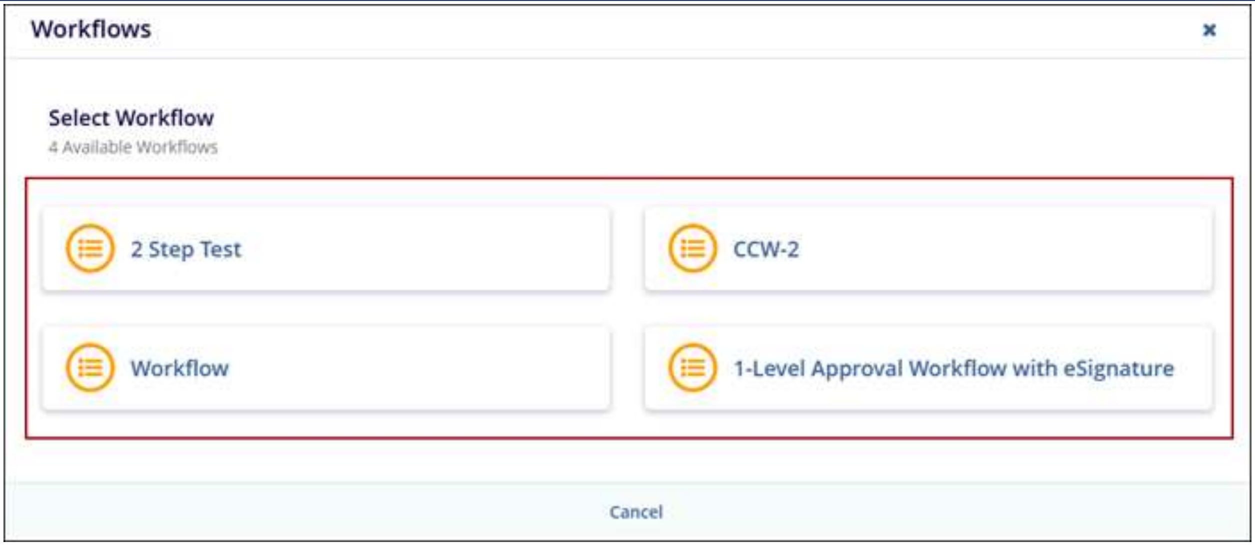
Initiate Workflow

To initiate a workflow for a controlled document, follow the steps below.

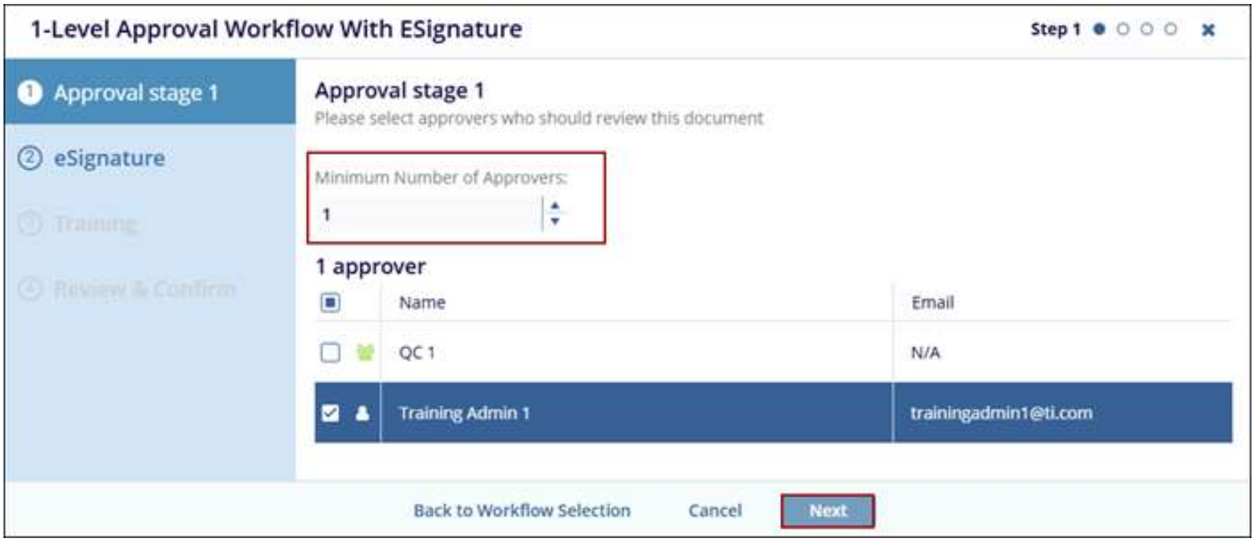
1. Navigate to the Documents Library modal within the Collaborate Room and expand the necessary folder to access the document.
2. Click on the paper plane icon which indicates the document is ready for workflow or select the three-dot menu and select the Initiate Workflow option.



3. On the Workflows wizard, select the appropriate workflow for the specific document type.

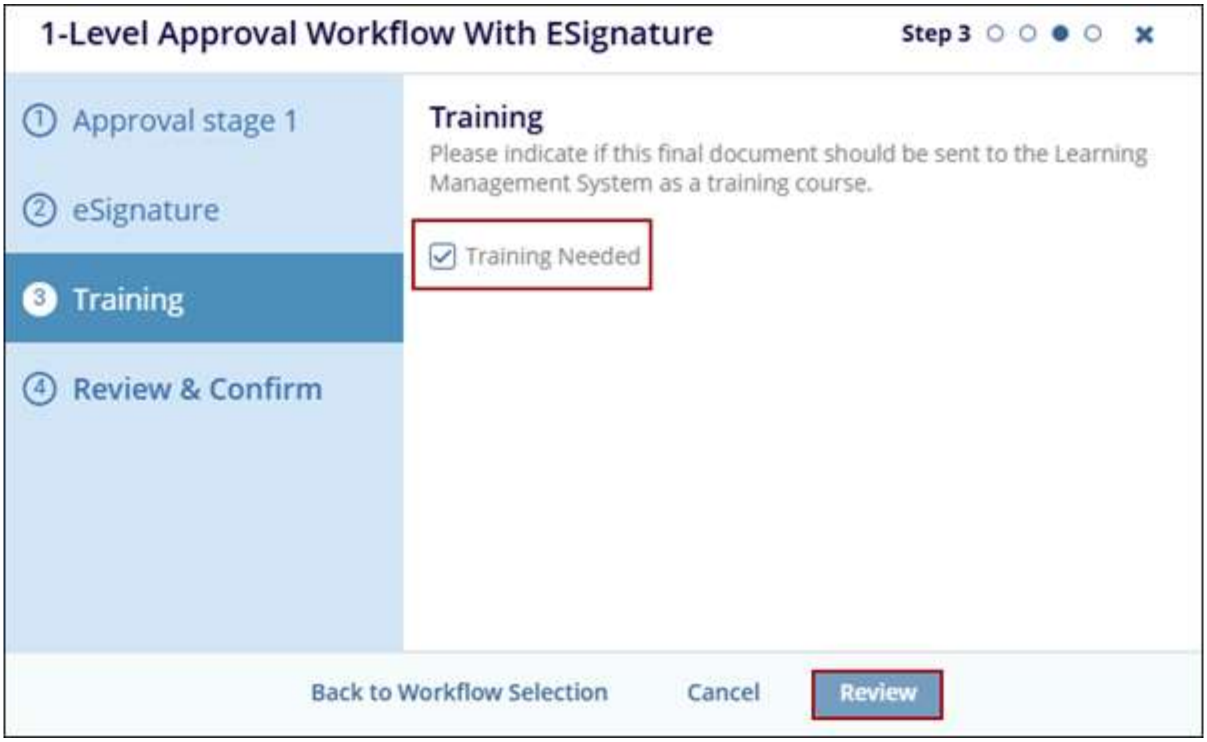


4. Specify the number of approvers to complete a stage in the workflow in the Minimum Number of Approvers section and click on the Next button.



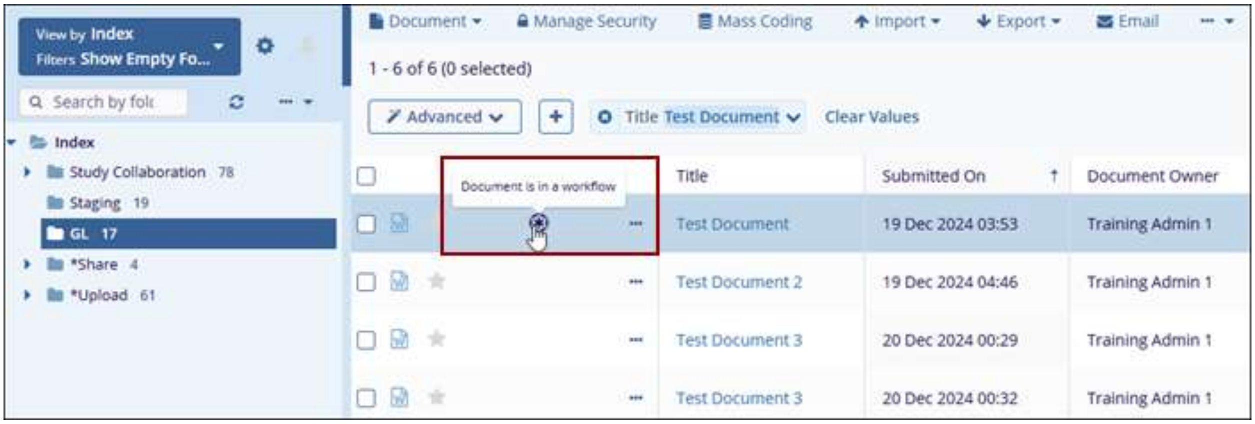
5. Within the eSignature step, select the signers who should review the document and click on the Next button.

6. On the Training step, check the Training Needed checkbox if users are required to complete training in GlobalLearn when the new version becomes effective and click on the Review button.



7. In the Review & Confirm step, verify the details and click on the Add Document(s) to the Workflow button for users to begin the review.

8. Once the document is successfully added to the workflow, the icon in the grid changes, indicating the document is under review.



Important

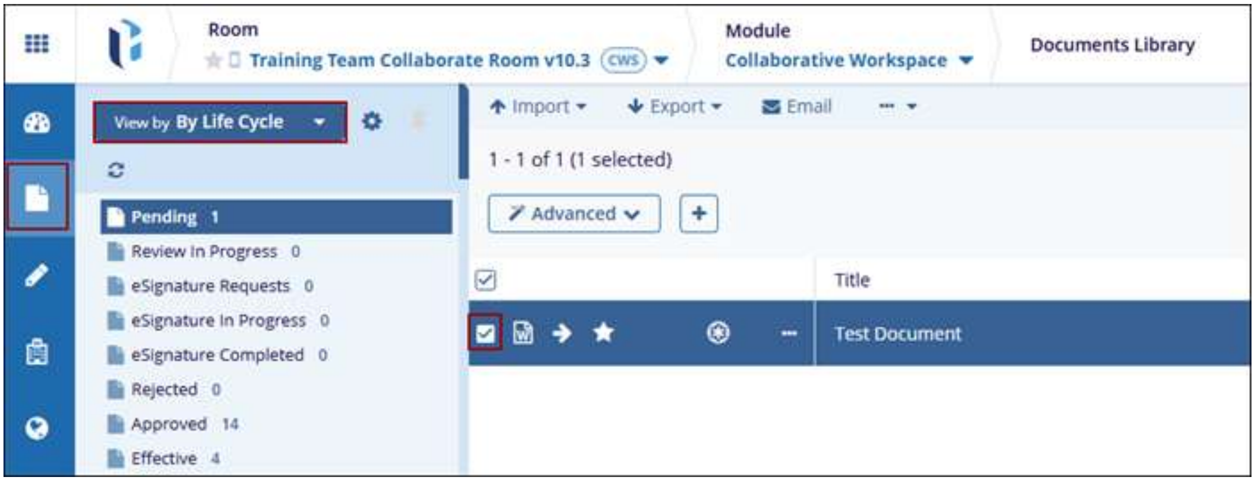
- The Change Control workflows enabled via Settings > Workflows > Workflows are displayed in the Workflows wizard and available for selection.
- The wizard for a specific workflow shows the number of steps configured during its creation, which may vary depending on the workflow.

Claim a Document in a Workflow

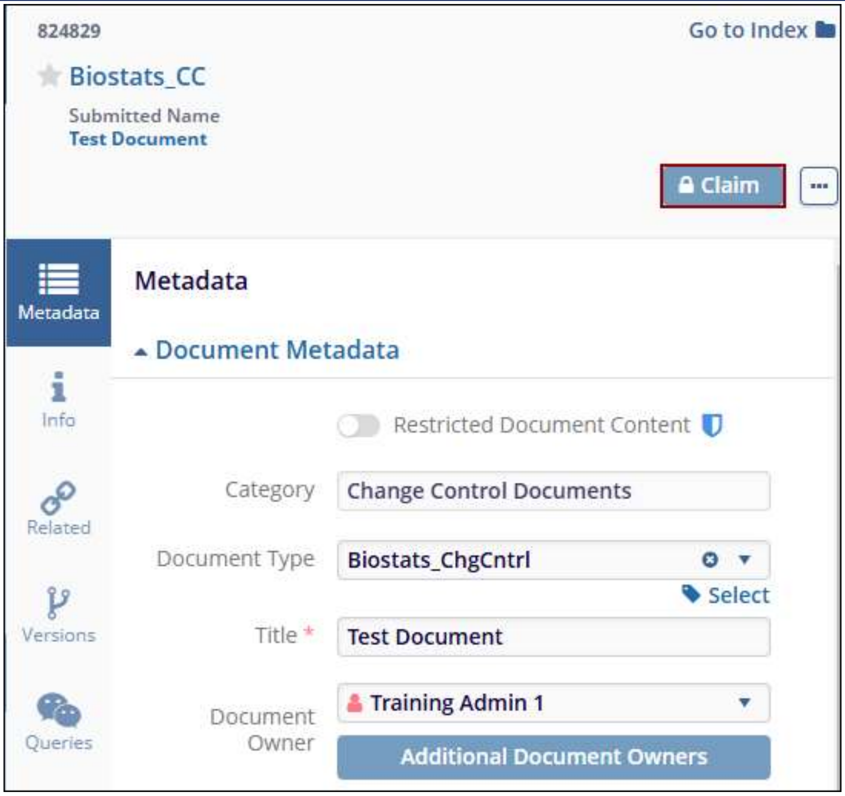
The section describes the procedure to locate and claim a document which is sent for review through a workflow. To locate and claim a document, users must have access to the collaborate room and should be participants in the ongoing document review process.

To locate and claim a document, follow the steps below.

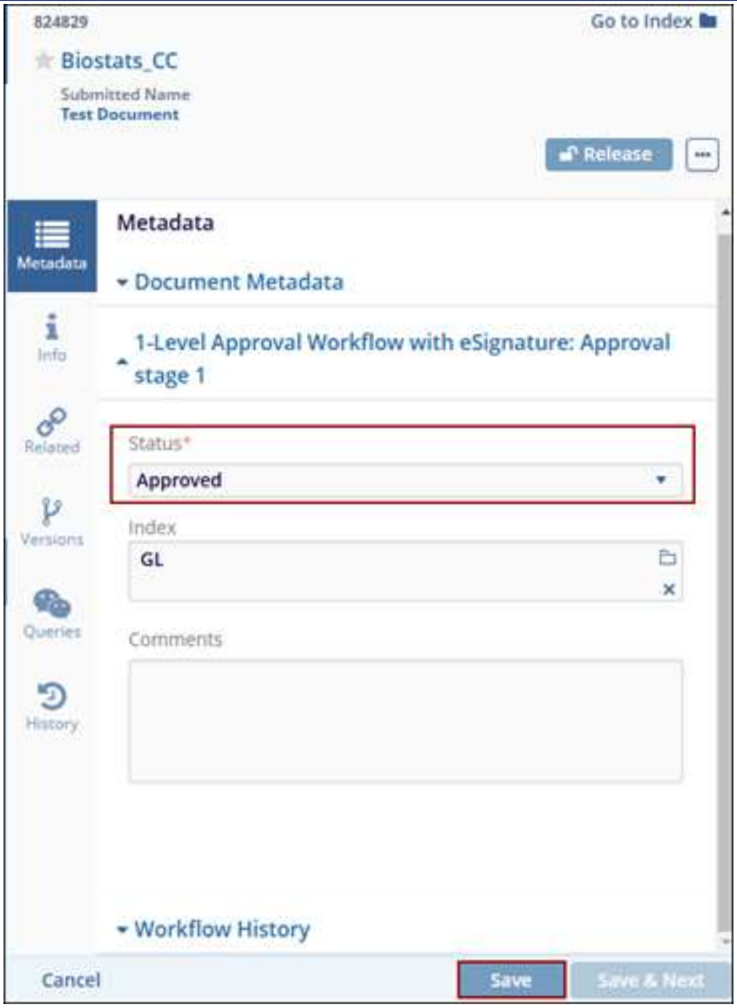
1. Navigate to the Documents Library modal, and set the view to 'Document Life Cycle'.
2. Click on the Pending folder and select the document.



3. Navigate to the metadata panel of the document and click on the Claim button.



4. Review the document and mandatorily add a status from the available dropdown options.
5. Click on the Save button so that the document moves to next stage of approval or signature.



Important

- Documents to claim can also be accessed from the Documents to Approve and Document Life Cycle sections from the Collaborative Workspace dashlet.
- Pending Documents have at least one stage of review in the workflow.
- Documents need to be claimed before sending an eSignature request.

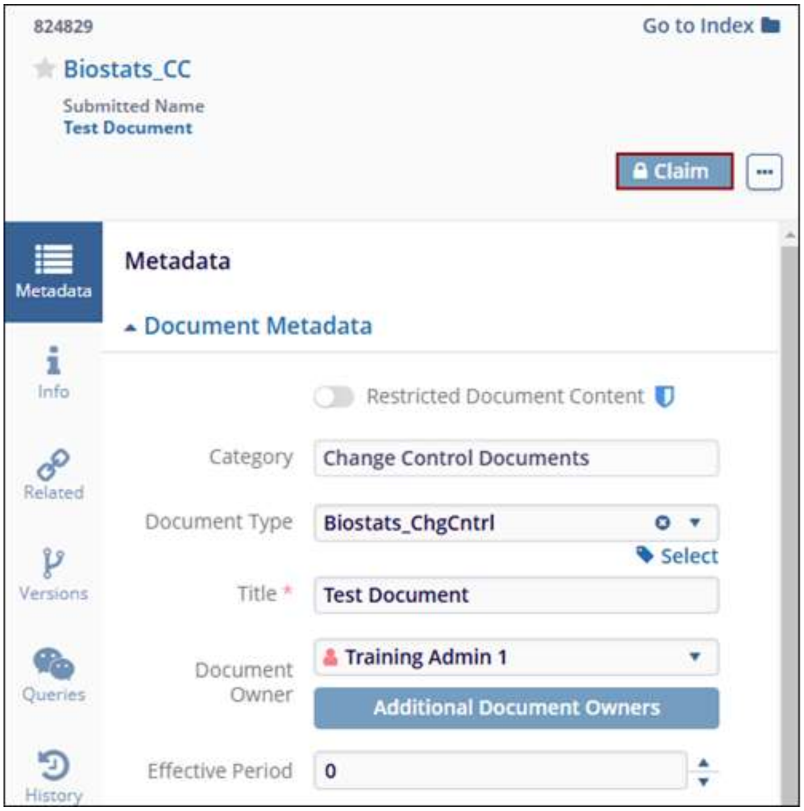
Create eSignature Request

Once the Pending documents are claimed, eSignature request can be created and the document can be sent for eSignature to the appropriate users.

To create eSignature request, follow the steps below.

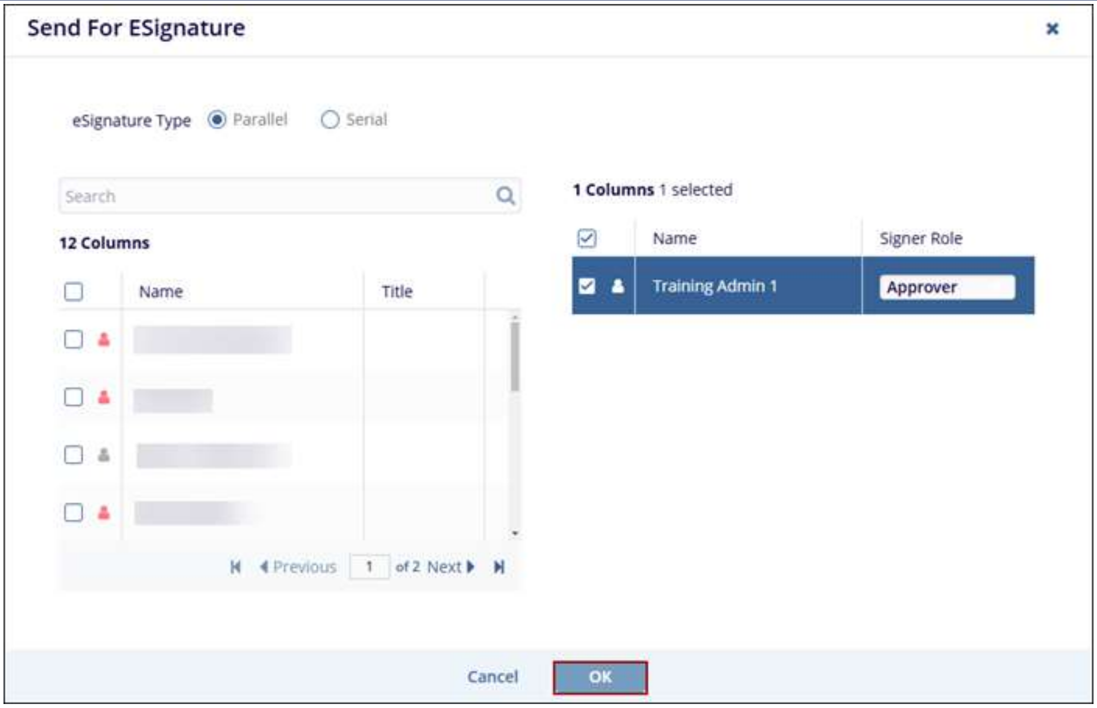
1. Navigate to the Documents Library modal, and set the view to 'Document Life Cycle'.
2. Click on the eSignature Requests folder and select the document.

3. Navigate to the metadata panel of the document and click on the Claim button.



4. Click on the Create eSignature Request button.

5. Move the requested signatories into the right column of the 'Send for eSignature' panel, assign a signer role, and click on the OK button.



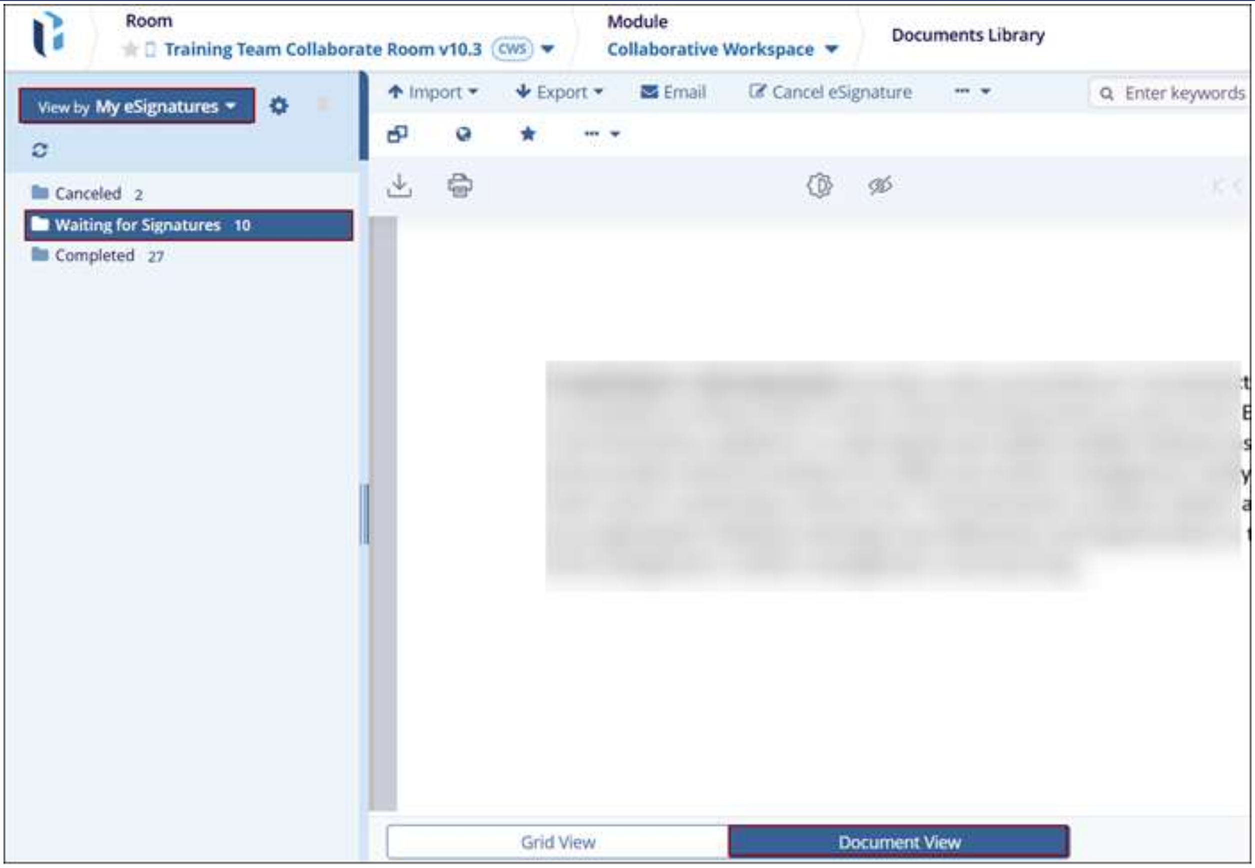
6. A success message is displayed indicating the specified users are required to sign the document and are notified by email that the eSignature is pending.

Sign a Document

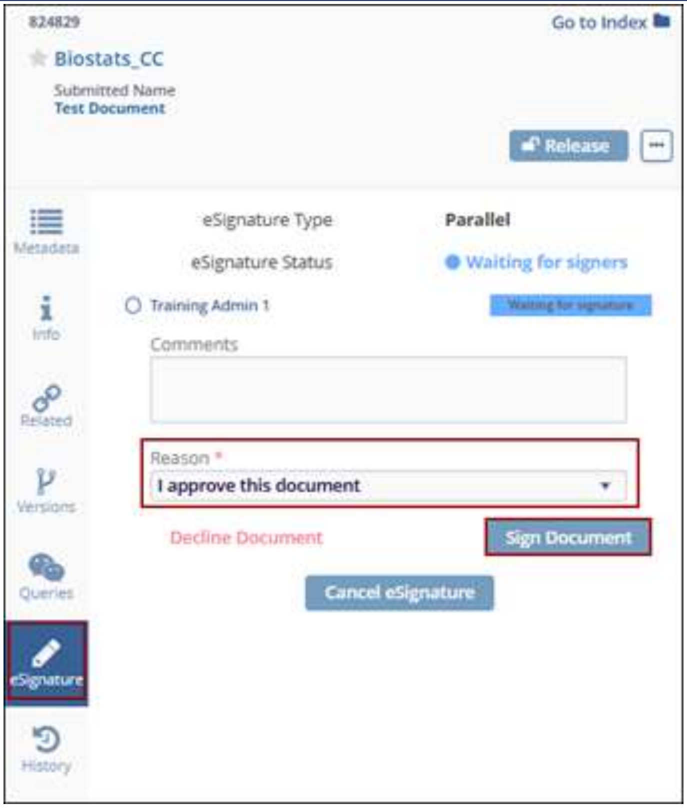
To sign a document, follow the steps below.

1. Navigate to the Documents to Sign tab within the Collaborative Workspace dashlet.
2. Select the document to eSign and click on the arrow.

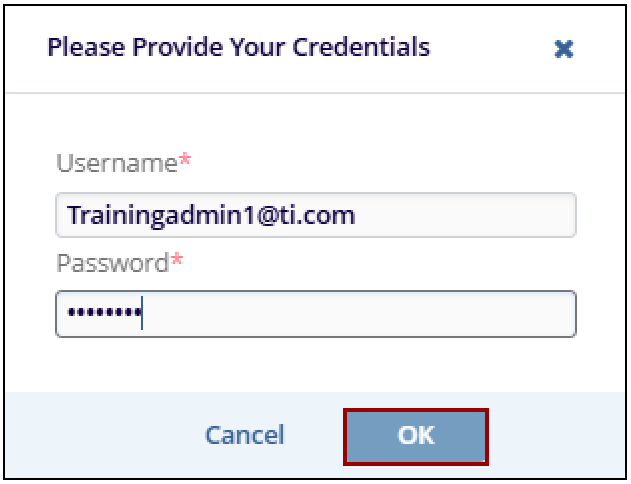
3. The Document View opens by default with My eSignature view applied and the Waiting for Signatures folder selected.



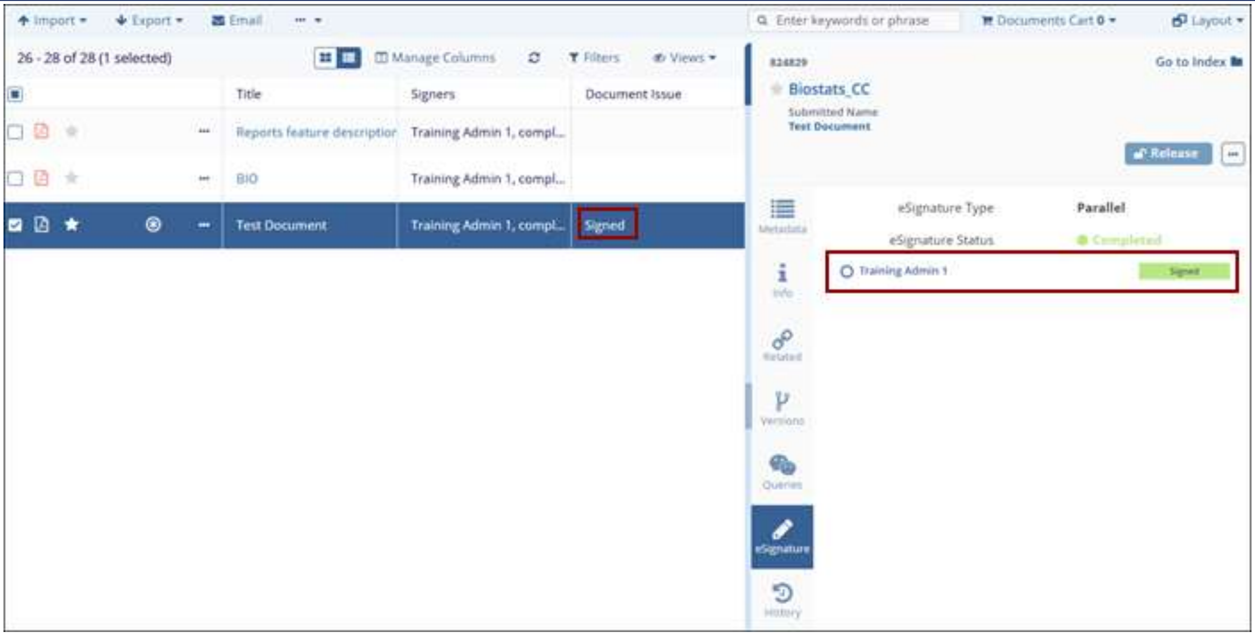
4. Select the eSignature tab in the metadata panel and enter a reason from the available dropdown options.
5. Click on the Sign Document button.



6. On the 'Please Provide Your Credentials' popup, mandatorily enter the Username* and Password*.
7. Once the user's name and password are entered, click on the OK button.



8. Once the document is signed successfully, the metadata panel displays the status as Completed and the Document Grid displays the status as Signed.

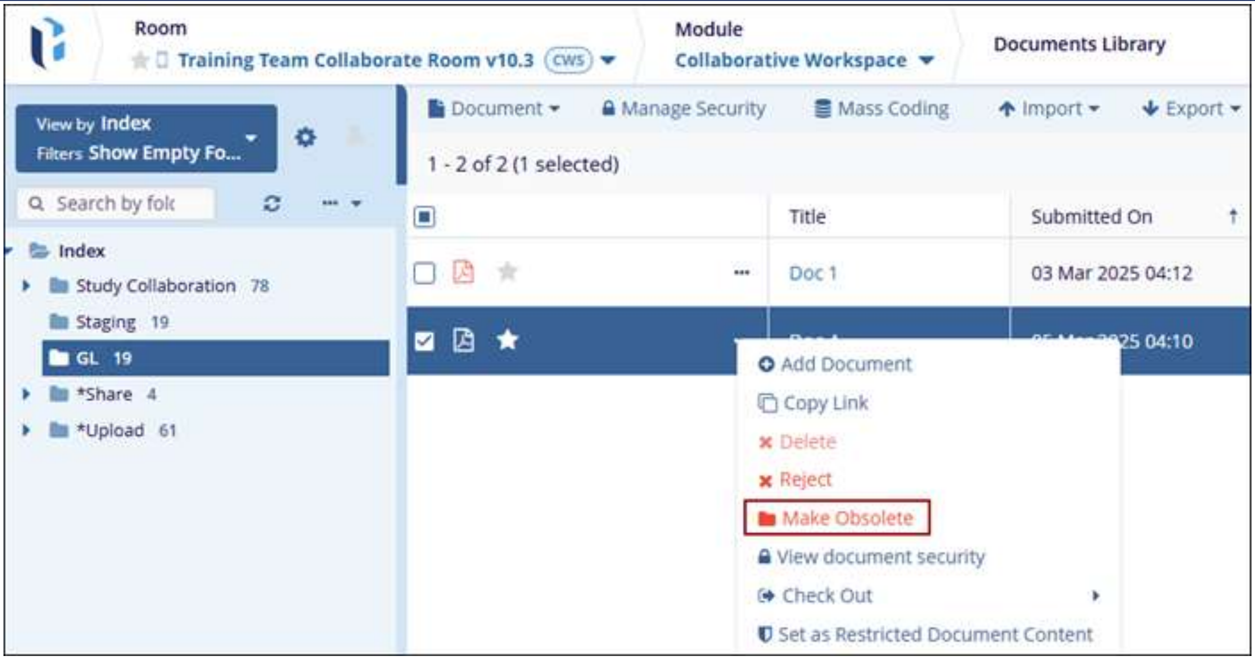


Non-Approval of Documents

It is also possible to mark a controlled document obsolete. Once a document is marked as obsolete will not be eligible for editing or workflows. However, the document history and properties will remain intact. Additionally, the obsolete documents can be restored in case they were rendered obsolete in error.

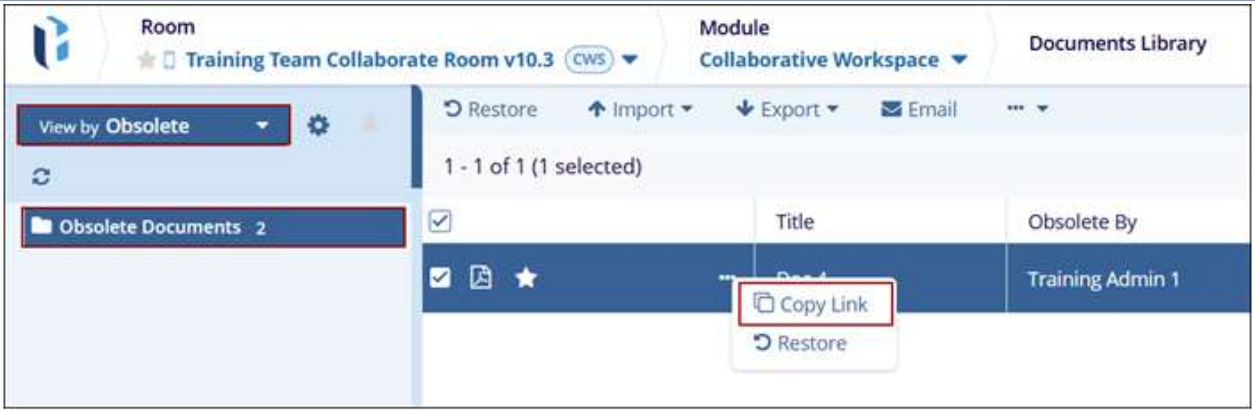
To mark a document as obsolete, follow the steps below.

1. Click on the three-dot menu of a document to mark as obsolete.
2. Select the Make Obsolete option.



3. On the Make Document(s) Obsolete popup, mandatorily enter a comment and click on the Confirm button.

4. To view the obsolete documents, set the view to display only the obsolete documents.
5. Click on the three-dot menu and select the Restore option to add documents back to their initial location.


Room
Training Team Collaborate Room v10.3
CWS
Module
Collaborative Workspace
Documents Library
View by Obsolete
Restore
Import
Export
Email
1 - 1 of 1 (1 selected)
Obsolete Documents 2
Title
Obsolete By
Training Admin 1
Copy Link
Restore

Administrative Workflows

Effective Documents can be routed through an administrative workflow. Effective versions of controlled documents will sometimes require a minor housekeeping change after approval. These changes should not impact the effectiveness of the document. An example of this type of change would be correcting a minor typo. It would be inconvenient to use the full versioning workflow in correcting such a trivial error, and this is why TI Collaborate includes a feature called Administrative Workflow.

The key difference between an Administrative Workflow and a standard Approval Workflow is that the administrative workflow will appear as a minor version change. Still, the Effective date and Periodic Review timeframe will remain unchanged from the currently effective version.

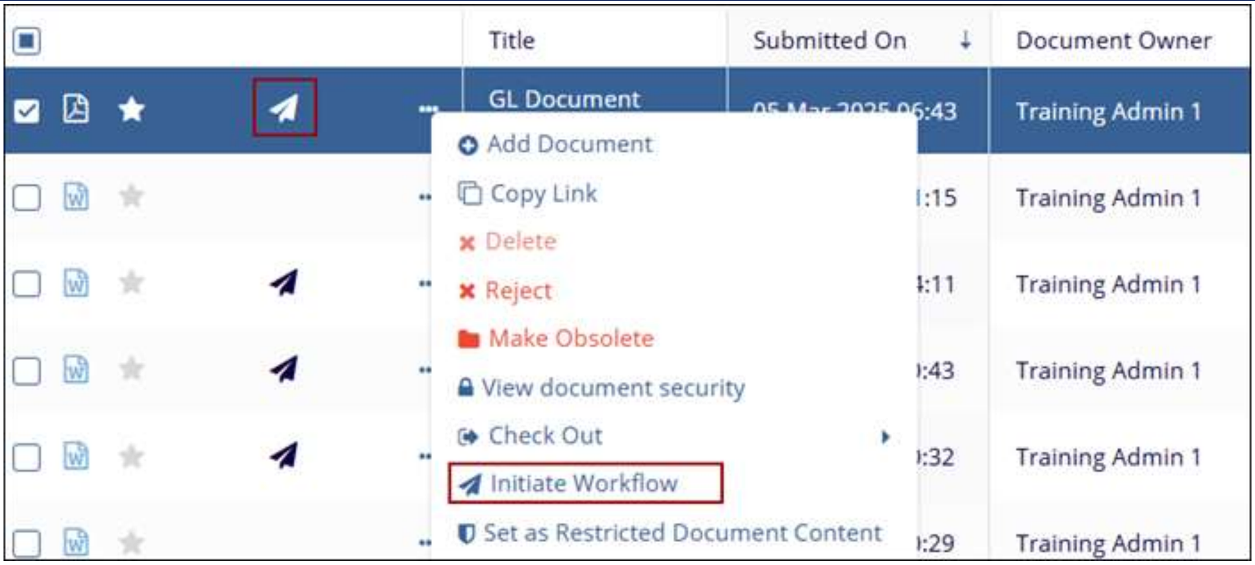
To carry out an Administrative Workflow correction, the user must be added to the related group in a room.

Initiate a Workflow

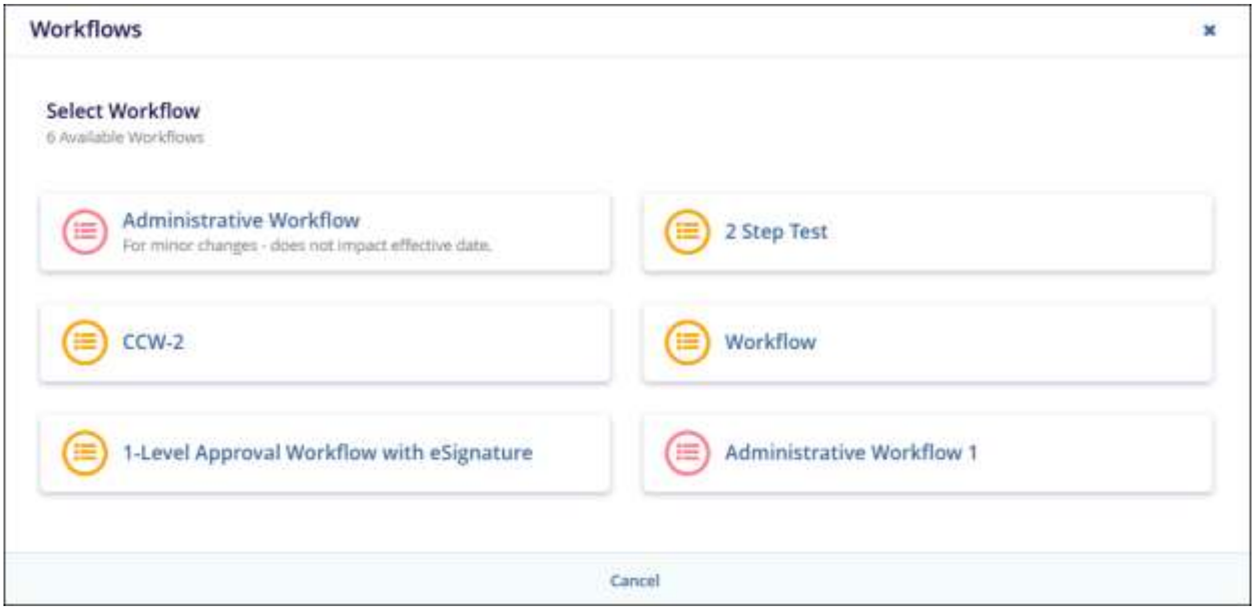
To initiate an administrative workflow, follow the steps below.

1. Check out an effective document and check back in the updated version.

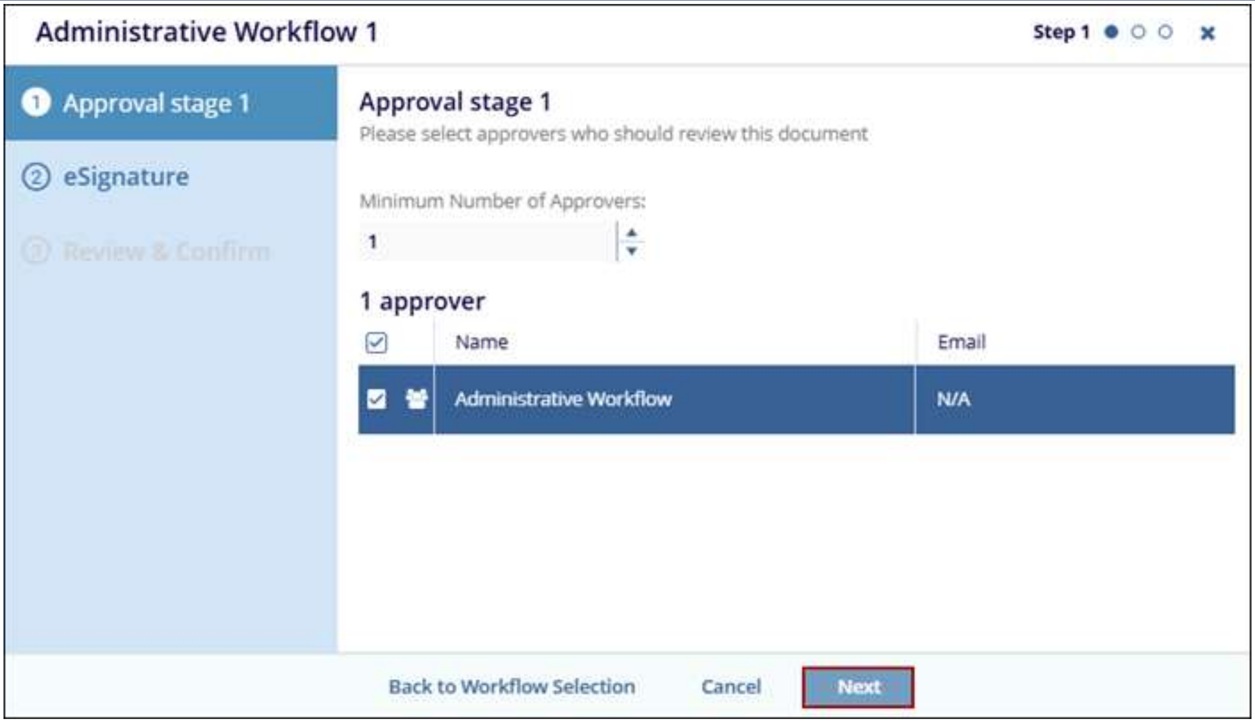
2. Click on the paper plane icon which indicates the document is ready for workflow or select the three-dot menu and select the Initiate Workflow option.



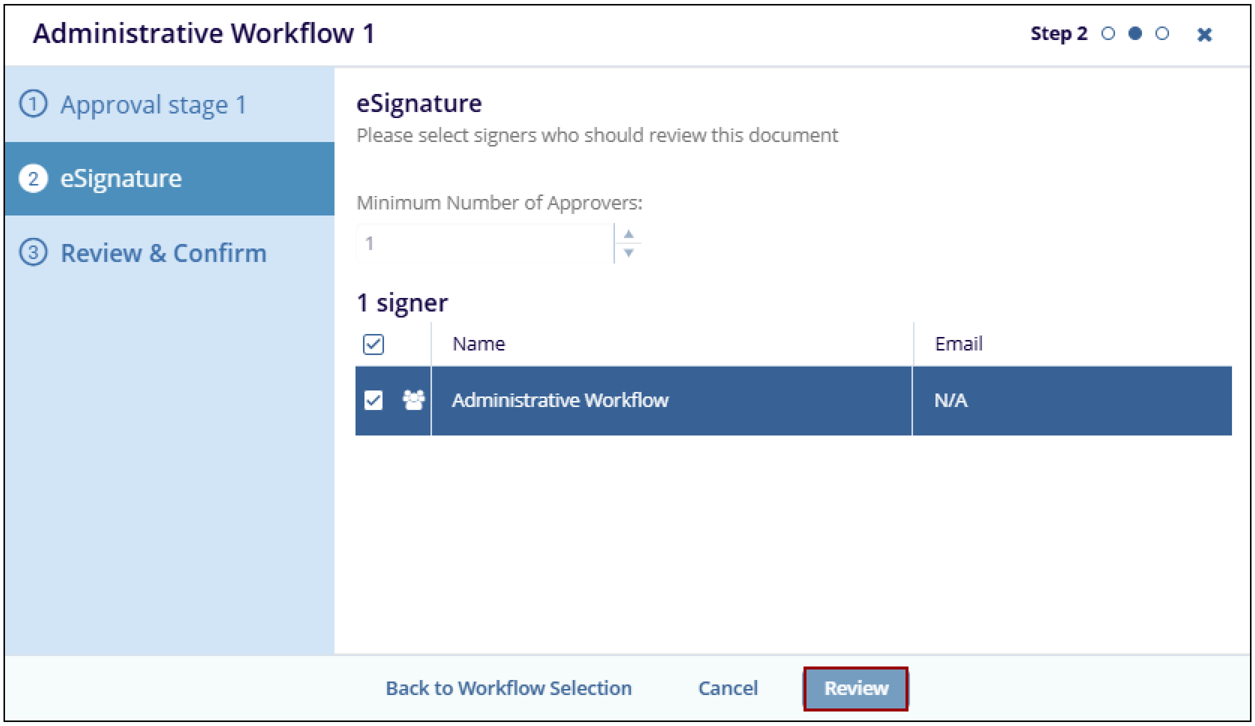
3. On the Workflows wizard, select the appropriate workflow for specific document type.



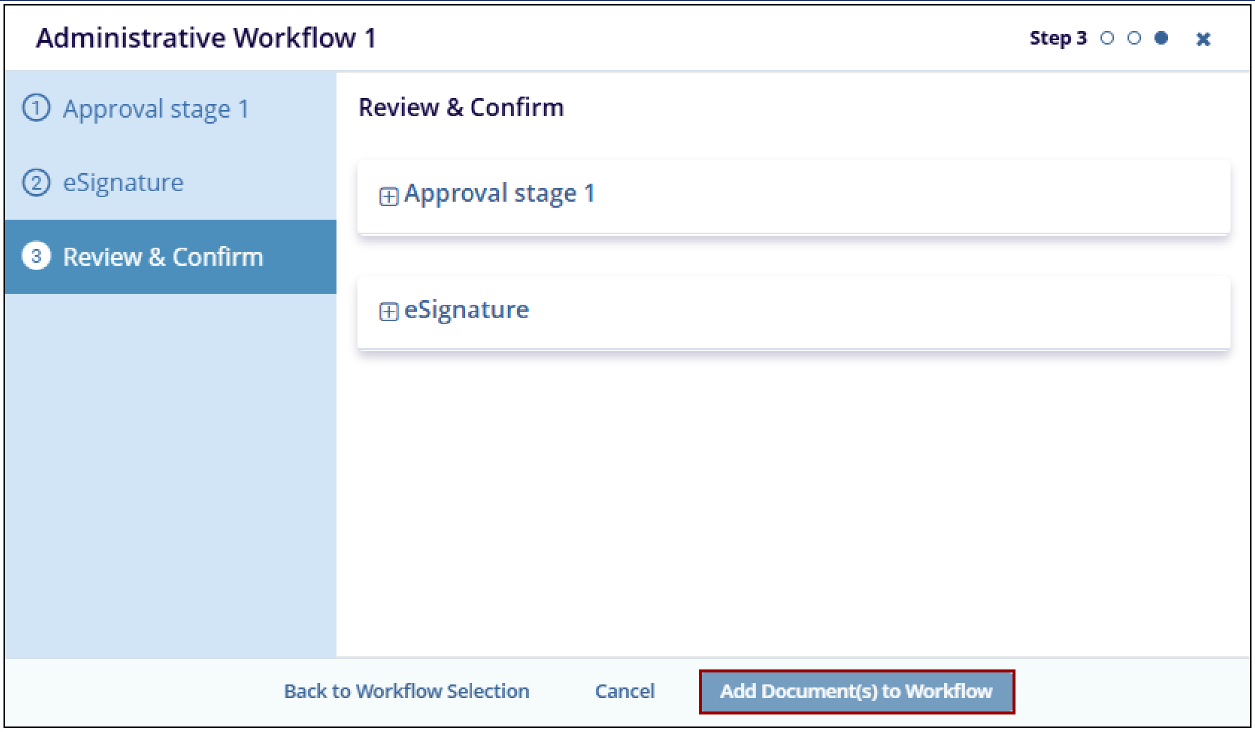
4. Specify the number of approvers to complete a stage in the workflow in the Minimum Number of Approvers section and click on the Next button.



5. Within the eSignature step, select the signers who should review the document and click on the Review button.



6. In the Review & Confirm step, verify the details and click on the Add Document(s) to the Workflow button for users to begin the review.

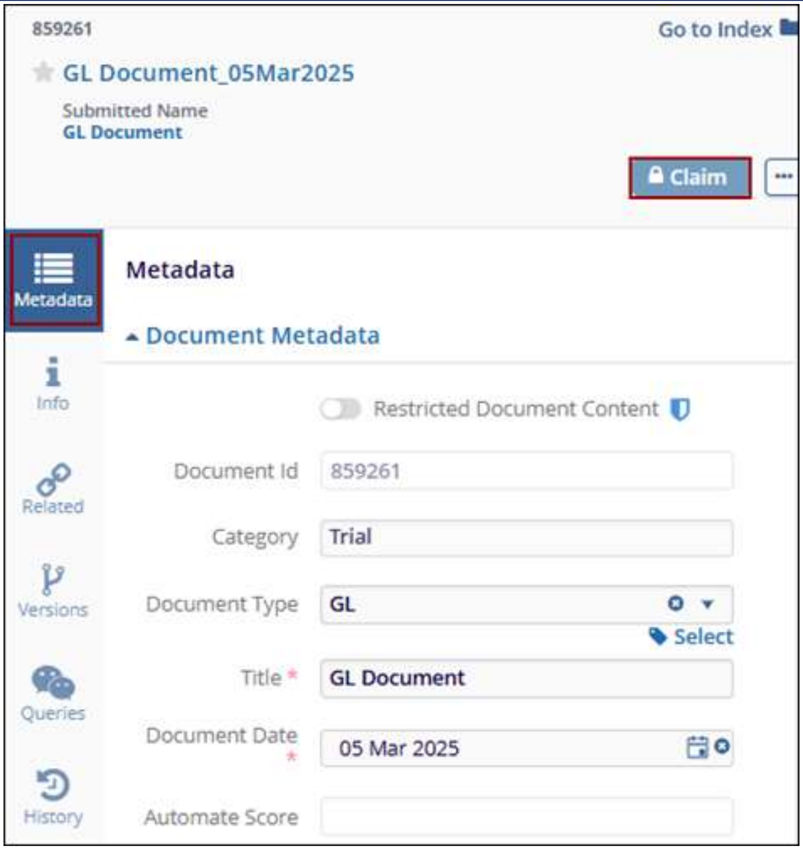


Locate and Claim a Document

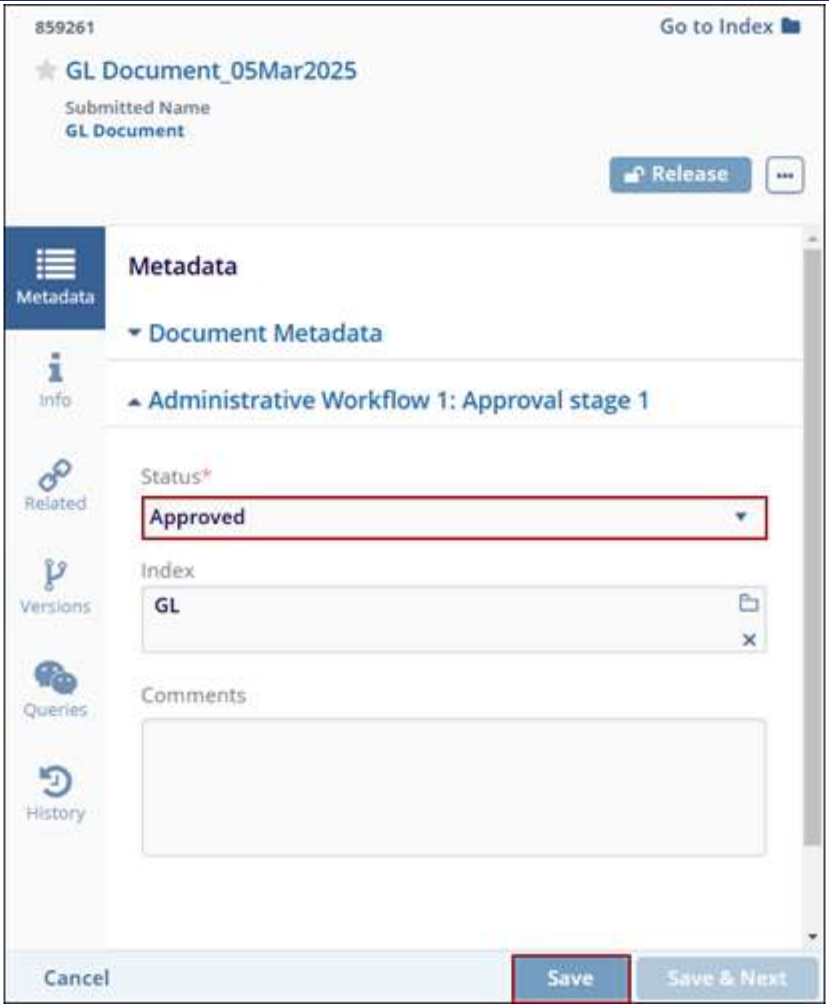
To locate and claim a document in an administrative workflow, follow the steps below.

1. Navigate to the Documents Library modal, and set the view to 'Document Life Cycle'.
2. Click on the Pending folder and select the document.

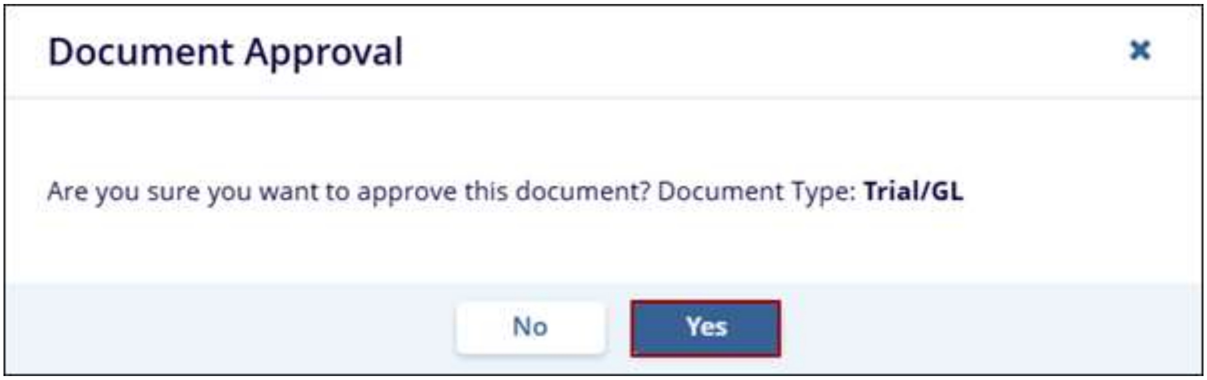
3. Navigate to the metadata panel of the document and click on the Claim button.



4. Review the document and mandatorily add a status from the available dropdown options.
5. Click on the Save button so that the document moves to the next stage of approval or signature.



6. On the Document Approval confirmation popup, click on the Yes button.



Important

- Documents to claim can also be accessed from the Documents to Approve and Document Life Cycle sections from the Collaborative Workspace dashlet.
- Pending Documents have at least one stage of review in the workflow.

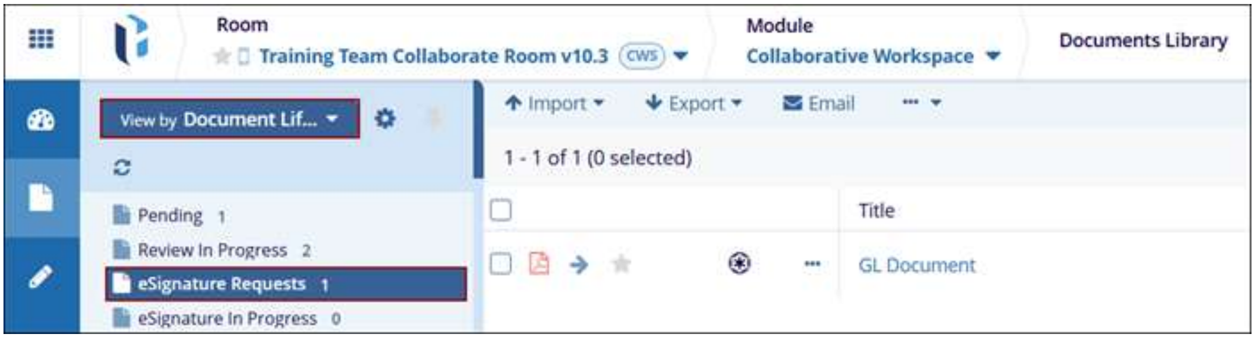
- Documents need to be claimed before sending an eSignature request.

Create eSignature Request

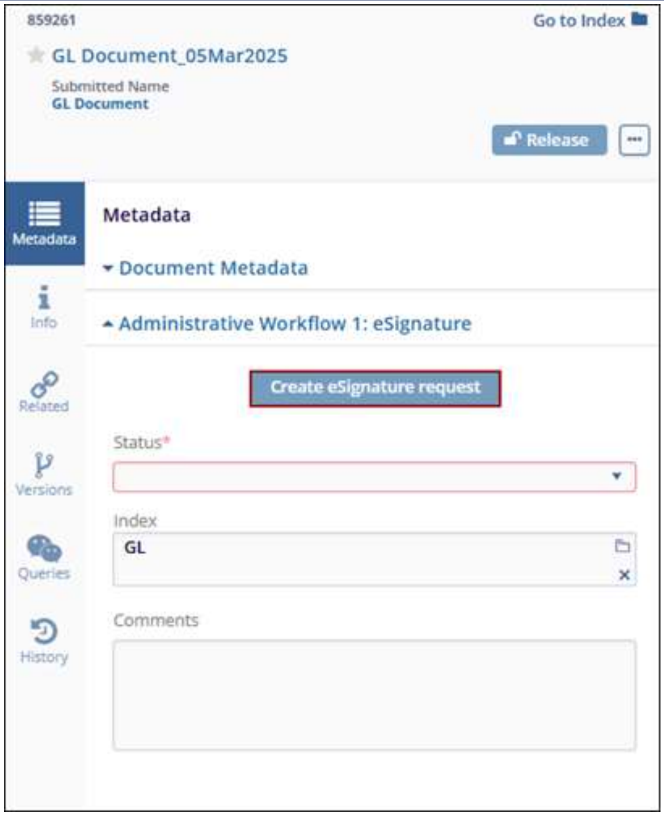
Once the Pending documents are claimed, an eSignature request can be created and the document can be sent to the appropriate users. Once the document is successfully claimed, it can be located in the eSignature Requests folder.

To create eSignature request, follow the steps below.

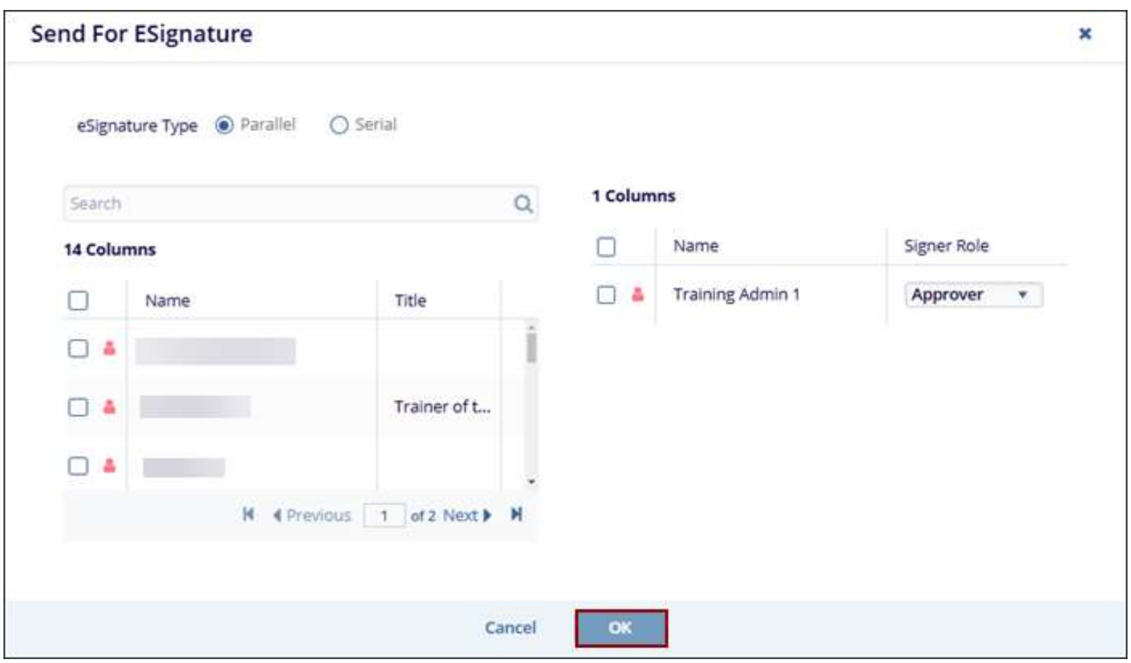
1. Navigate to the Documents Library modal, and set the view to 'Document Life Cycle'.
2. Click on the eSignature Requests folder and select the document.



3. Navigate to the metadata panel of the document and click on the Claim button.
4. Click on the Create eSignature Request button.



5. Move the requested signatories into the right column of the 'Send for eSignature' panel, assign a signer role, and click on the OK button.



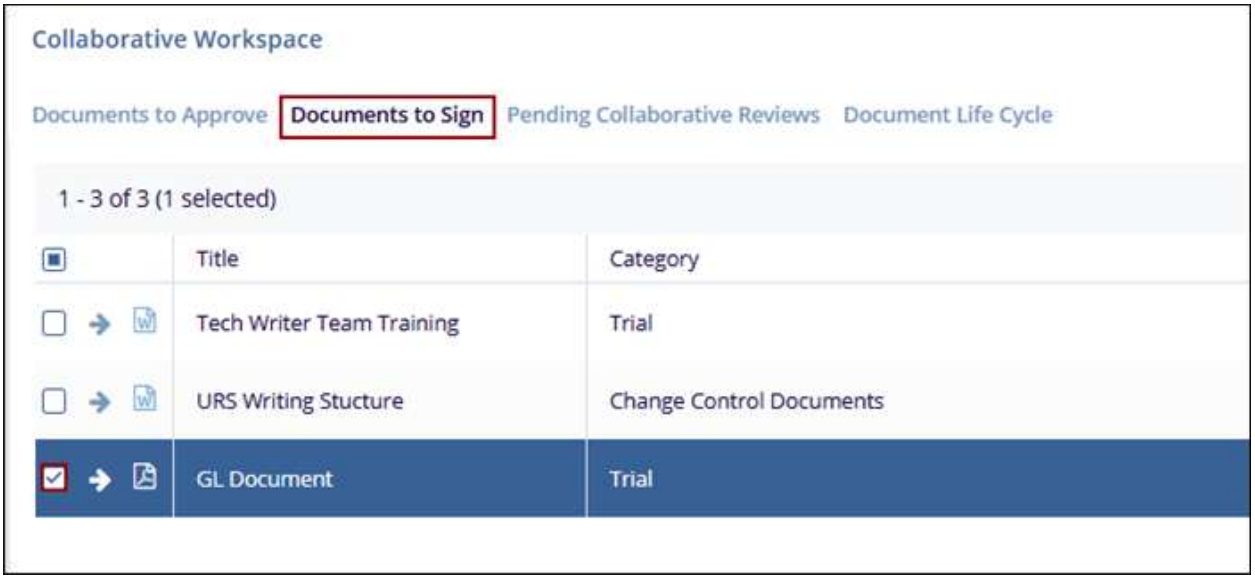
Note: Signatories specified during workflow creation are selected by default.

6. A success message is displayed indicating the specified users are required to sign the document and are notified by email that the eSignature is pending.

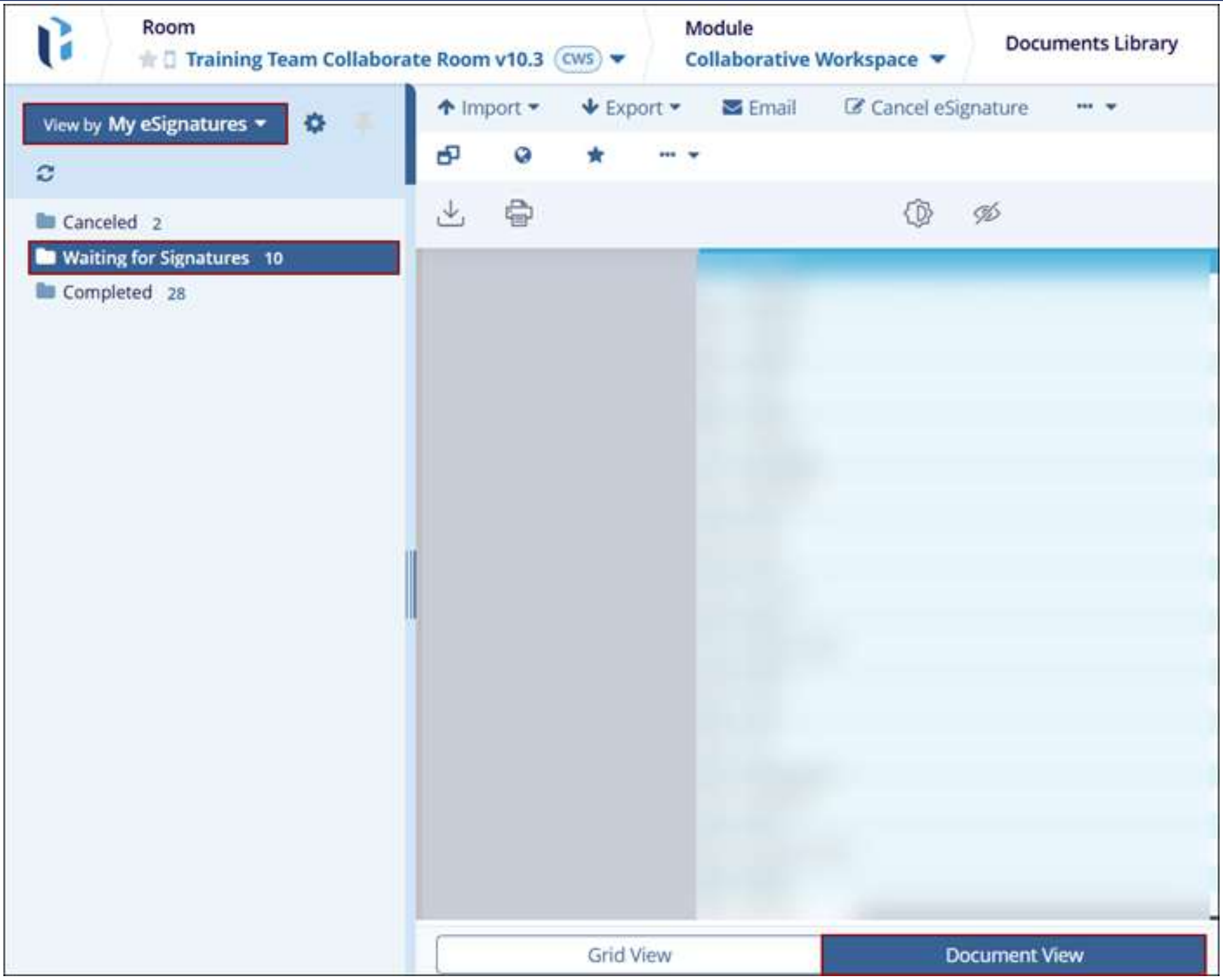
Sign a Document

To sign a document, follow the steps below.

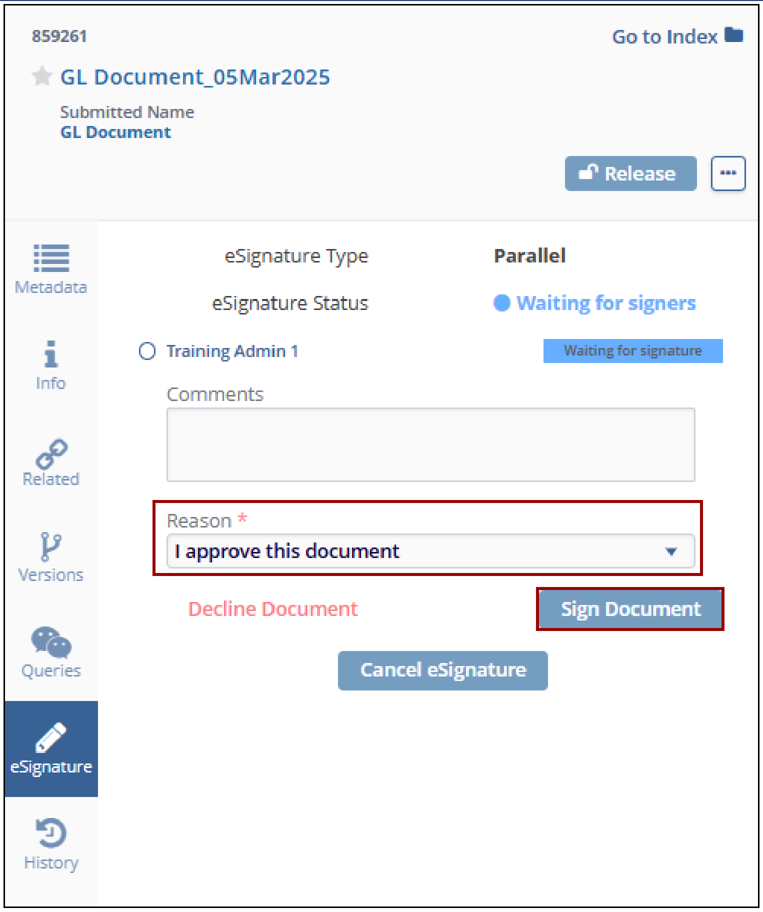
1. Navigate to the Documents to Sign tab within the Collaborative Workspace dashlet.
2. Select the document to eSign and click on the arrow.



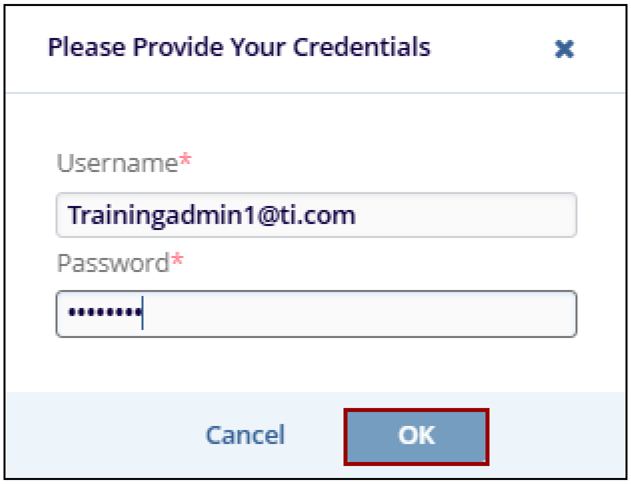
3. The Document View opens by default with the My eSignature view applied and the Waiting for Signatures folder selected.



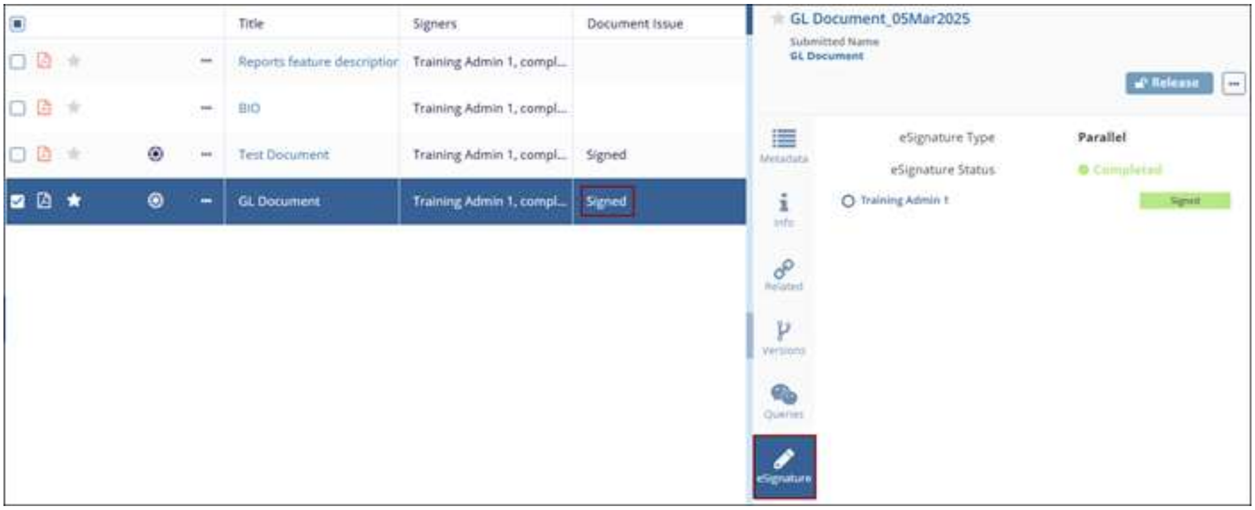
4. Select the eSignature tab in the metadata panel and enter a reason from the available dropdown options.
5. Click on the Sign Document button.



6. On the 'Please Provide Your Credentials' popup, mandatorily enter the Username* and Password*.
7. Once the user's name and password are entered, click on the OK button.



8. Once the document is signed successfully, the metadata panel displays the status as Completed and the Document Grid displays the status as Signed.



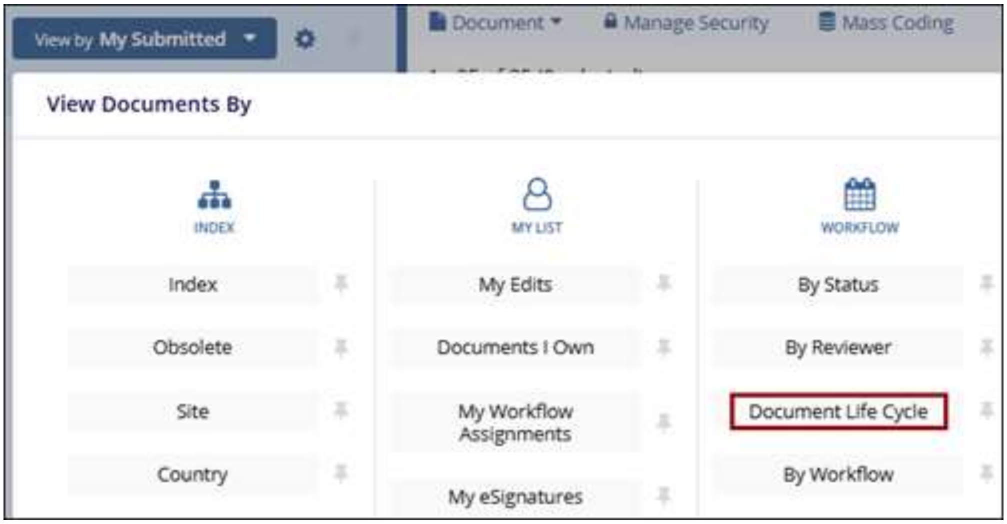
9. The signed documents can be located in the Completed folder within the Document Life Cycle view.

Periodic Review of Documents

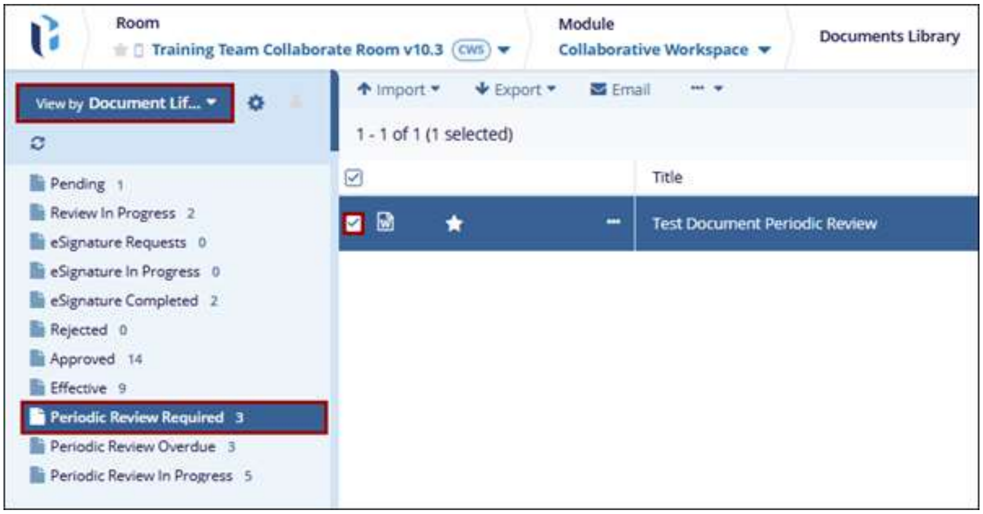
The Periodic Review process determines users or groups of users responsible for reviewing a document after a specific time to ensure the document is correct i.e., after every year or two years. Within TI Collaborate, Admins can define the period when a document requires periodic review along with the reviewers.

To complete a periodic review of documents that do not require a change, follow the steps below.

1. Click on the View by dropdown and select the Document Life Cycle view.

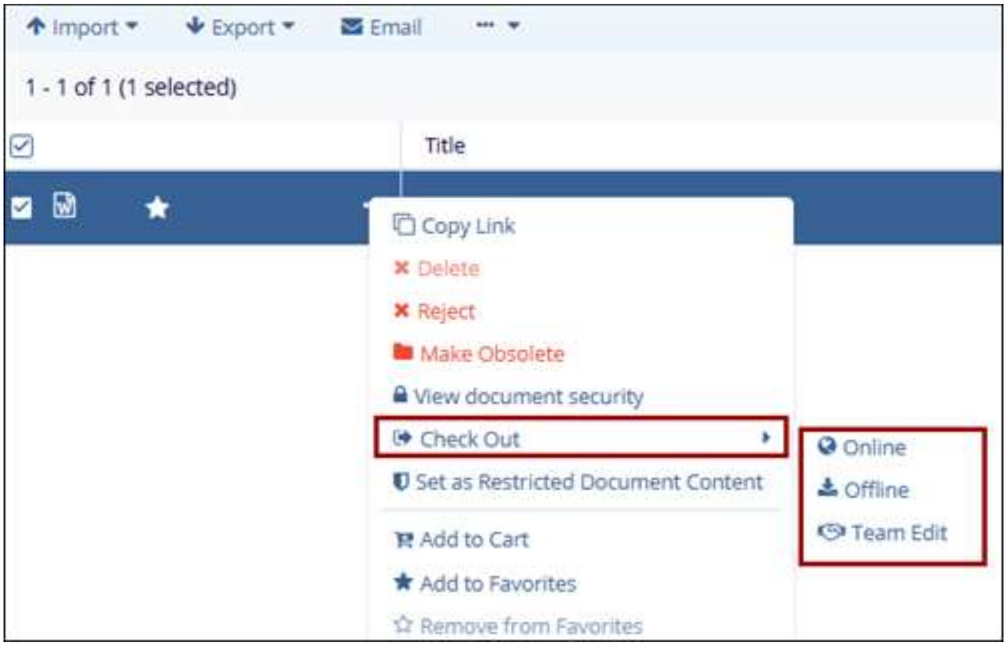


2. Open the Periodic Review Required folder and select the document.

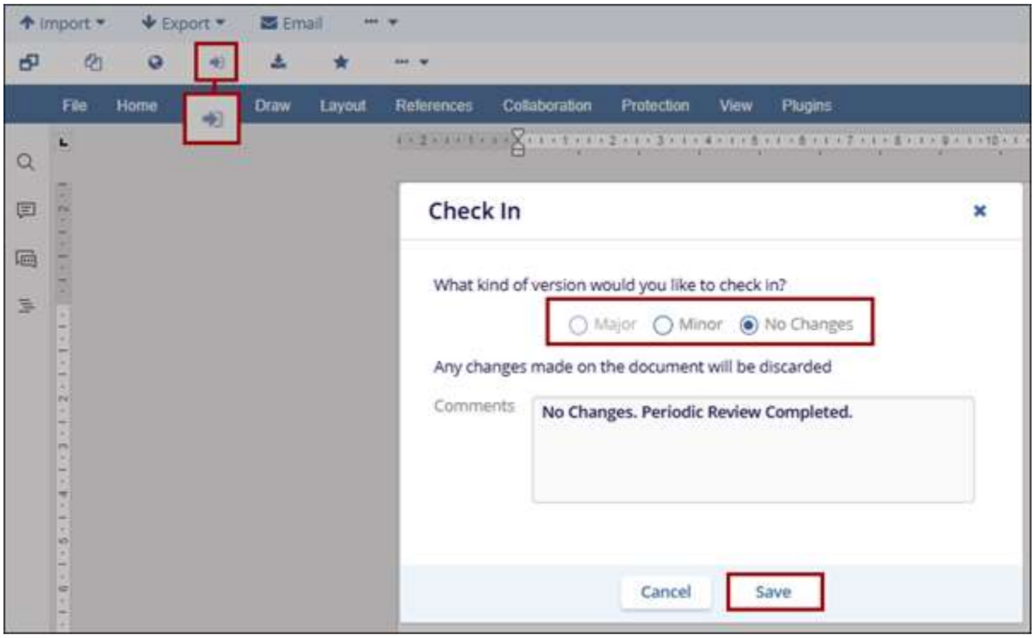


3. Click on the horizontal ellipsis icon (three-dot menu), and select the Check Out option.

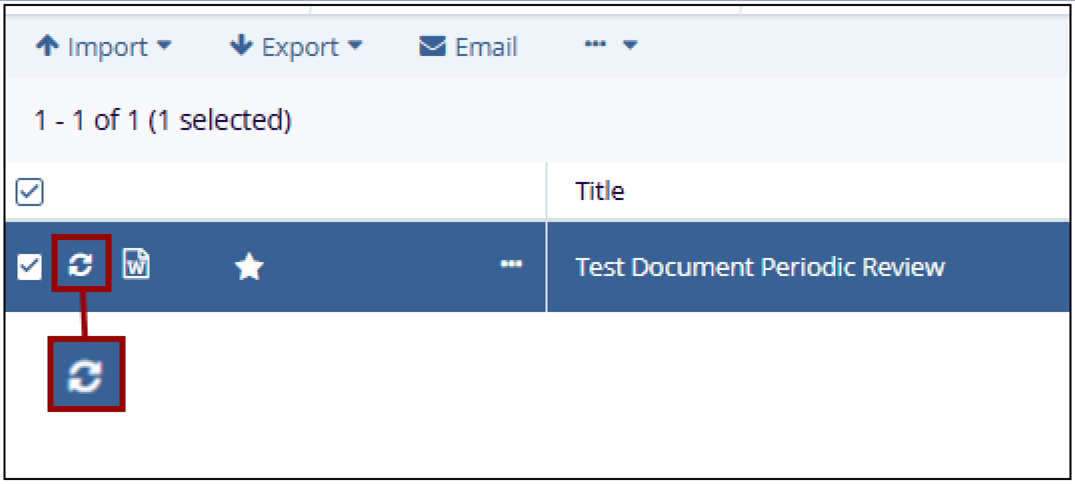
4. Select an edit method i.e., Online, Offline, and Team Edit.



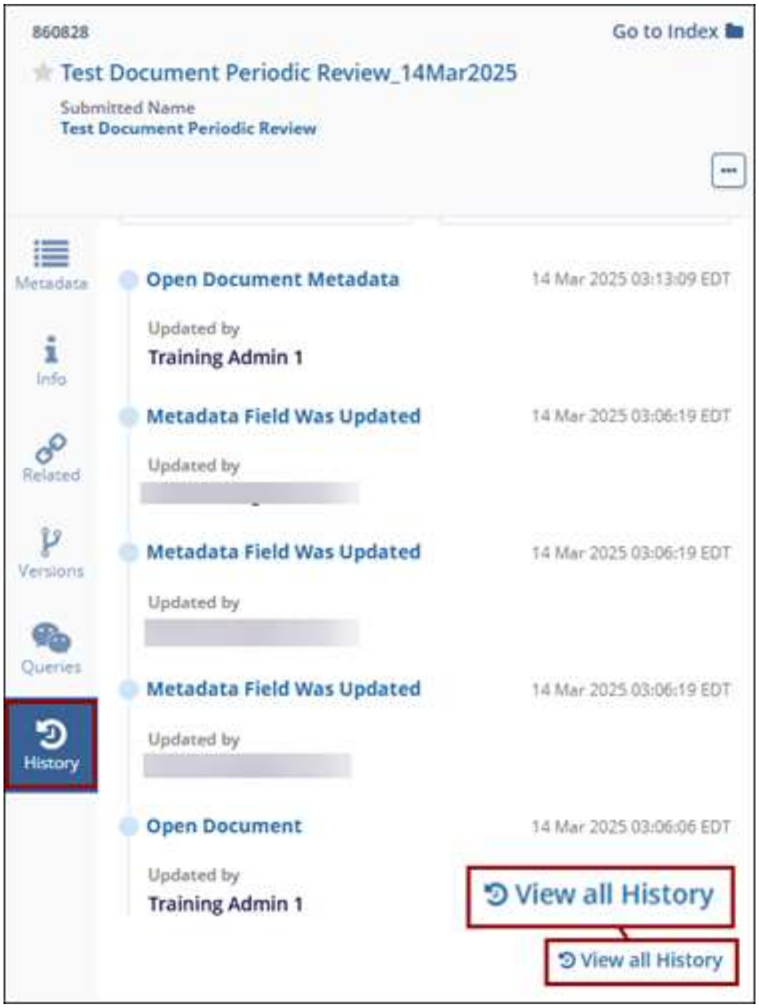
5. Once the edits are made or no change is required click on the Check In button.
6. Select the No Change option and add a comment.
7. Click on the Save button.



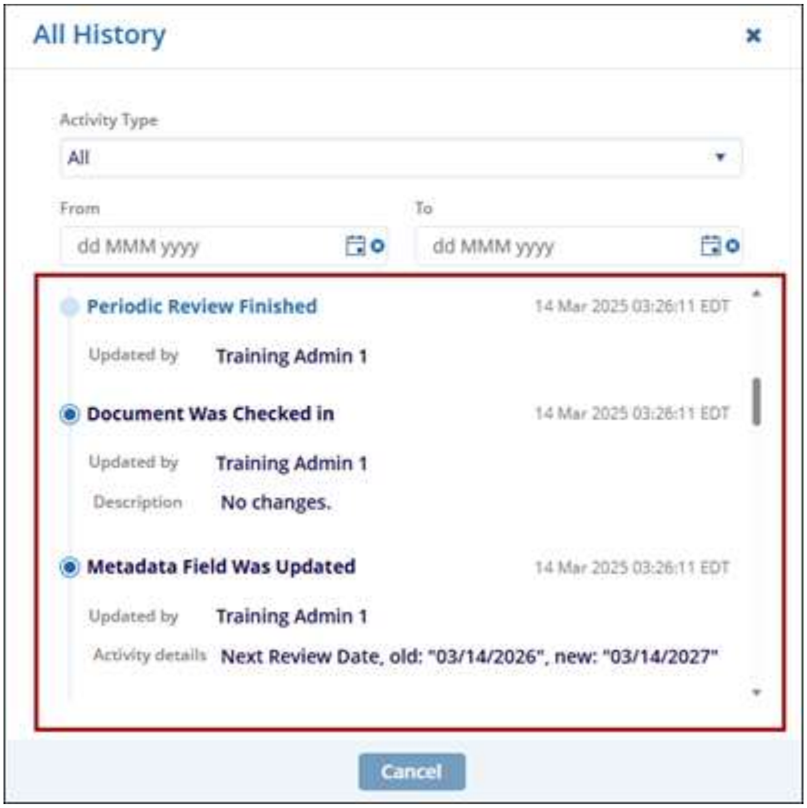
8. Navigate to the Grid View and click on the Refresh button.



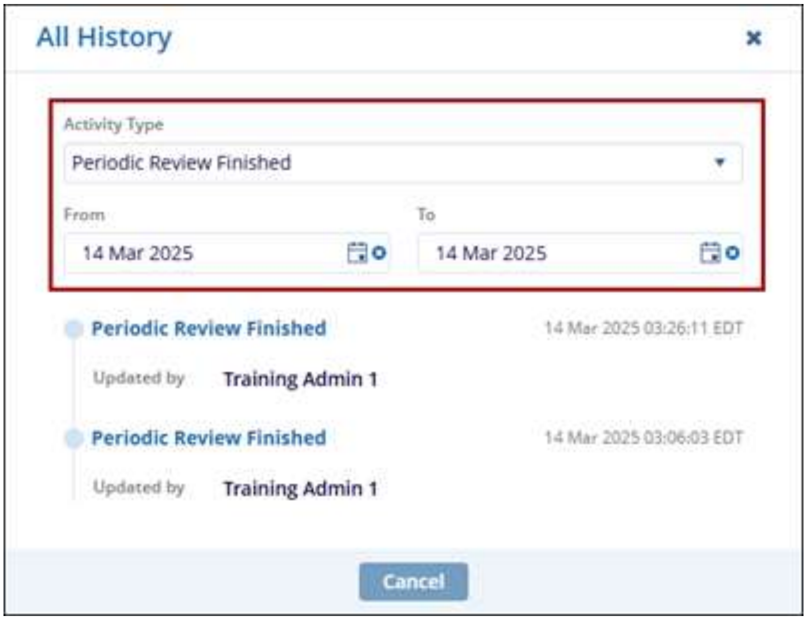
9. Navigate to the History tab documents metadata panel and click on the View all History button.



10. On the All History tab, view all the periodic review actions.



11. To view specific actions for a specific period, add a criterion from the Activity Type dropdown and specify the From and To dates.



Important

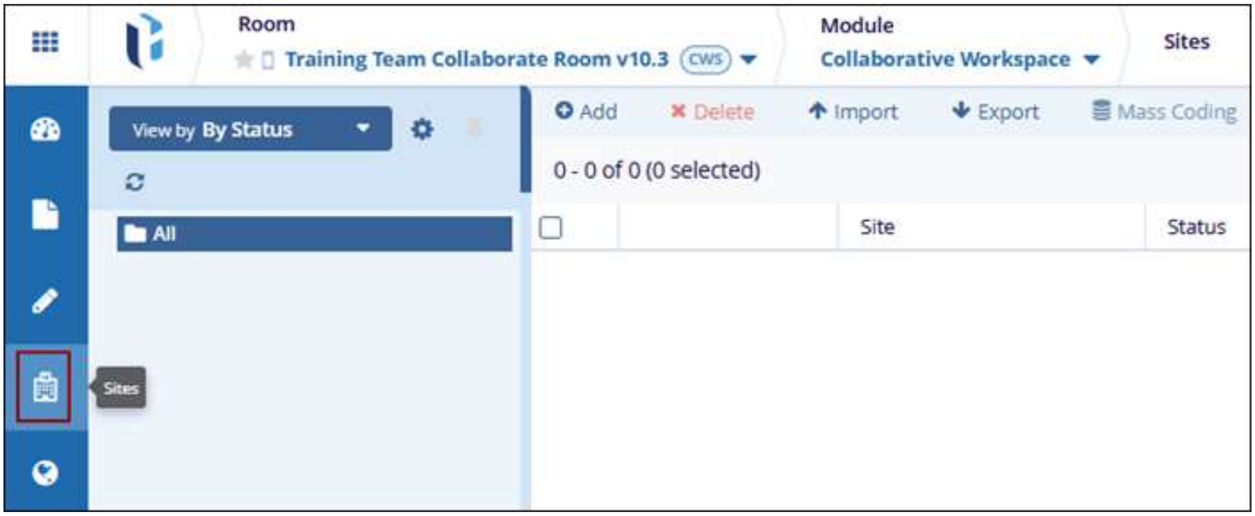
- Documents, once effective, can be routed through the periodic review process.
- Online checkout option is recommended for documents that do not require a change.
- For documents that do require changes, the document would be revised per the usual process and sent through the appropriate workflow for approval/ up version. In that case, the periodic next review date would be generated based on that document's new approval date.
- Periodic Review does not apply to documents that are not configured for the Change Control Workflow at the Document Profile Level.
- If a major or minor version is checked in during a periodic review, the document can be located in the Periodic Review In Progress folder and routed through the approval workflow.

SITES

This section provides detailed instructions on adding, deleting, importing, and exporting data, performing mass coding, managing security settings, and customizing columns. It also includes comprehensive guidance on General Information, Contacts, and Site Visits.

To access the Sites modal in the Collaborative Workspace, follow the steps below.

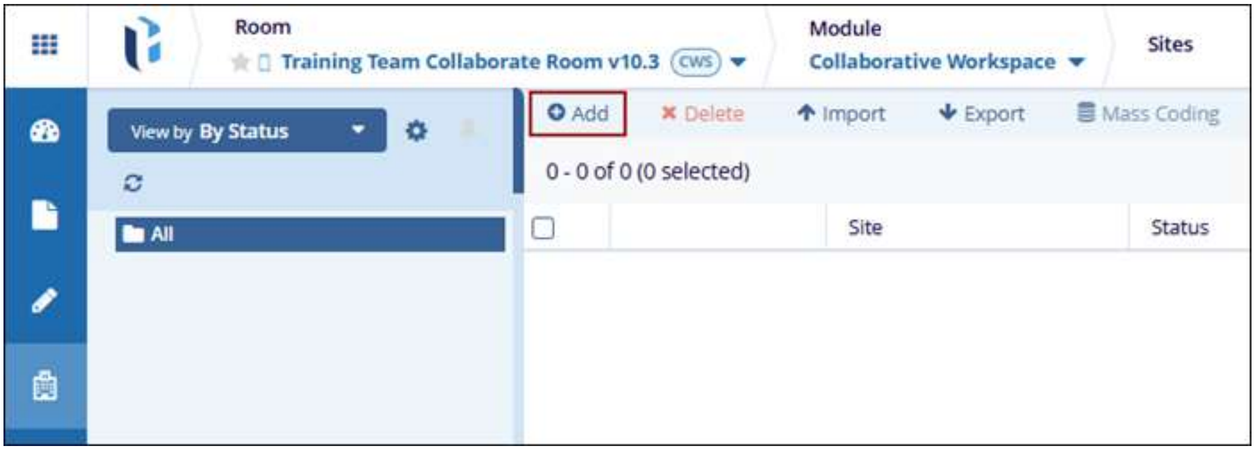
1. Select the Collaborative Workspace module from the Module dropdown.
2. Click on the Sites modal from the left-hand navigation menu.



Add Sites

To add new sites, follow the steps below.

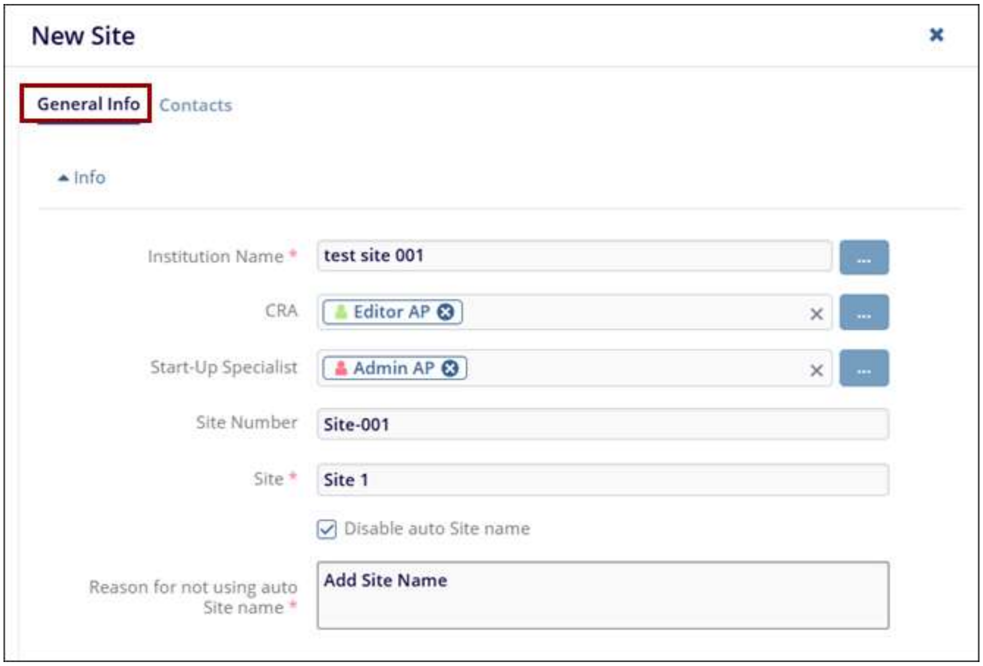
1. Click on the Sites modal from the left-hand navigation pane within the Collaborative Workspace module.
2. Click the +Add button to create a new site. This opens the New Site form.



3. In the General Info tab, expand the following sections and add the necessary information.

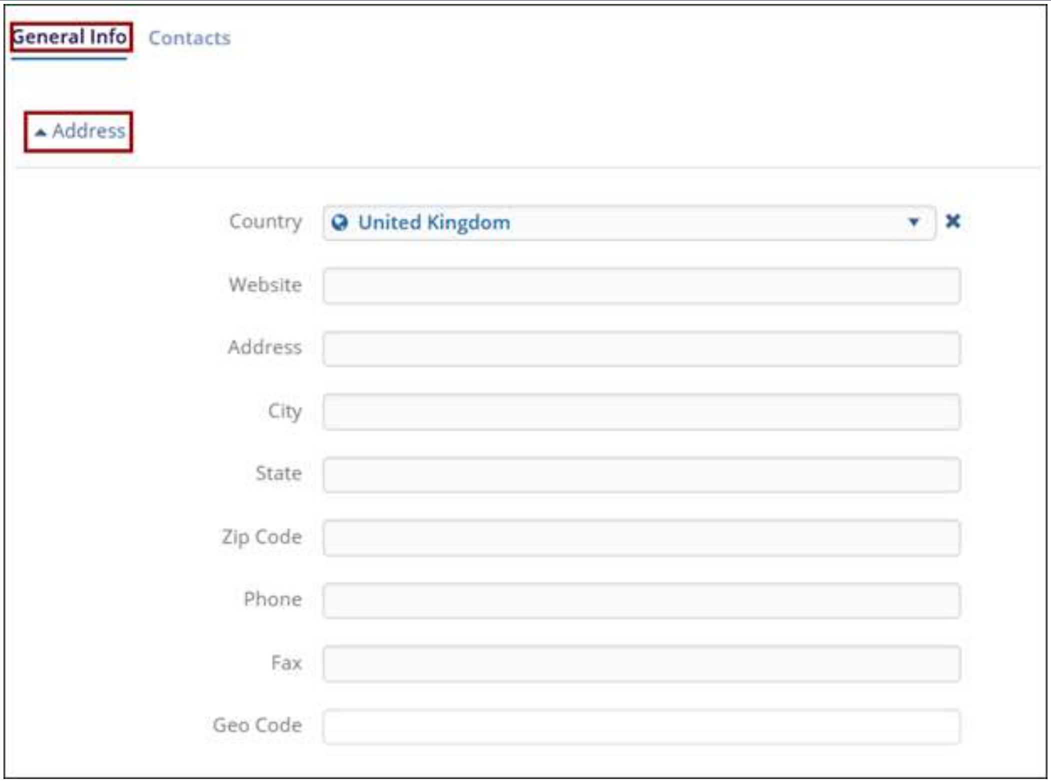
- Info: Add information to the following fields.

    1. Institution Name*: Mandatorily add the institution name from available options.
    2. CRA: Select users from the dropdown options as CRAs
    3. Start-Up Specialist: Select users from the dropdown options as Start-Up Specialists.
    4. Site Number: Enter the site number.
    5. Site*: Mandatorily enter the site name if Disable auto Site Name is disabled.
    6. Disable auto Site Name: Check the checkbox to manually add the site name or vice versa.
    7. Reason for not using the auto site name: Mandatorily provide a reason for not using the site if Disable auto Site Name is disabled.



- Address: Add information to the following fields.

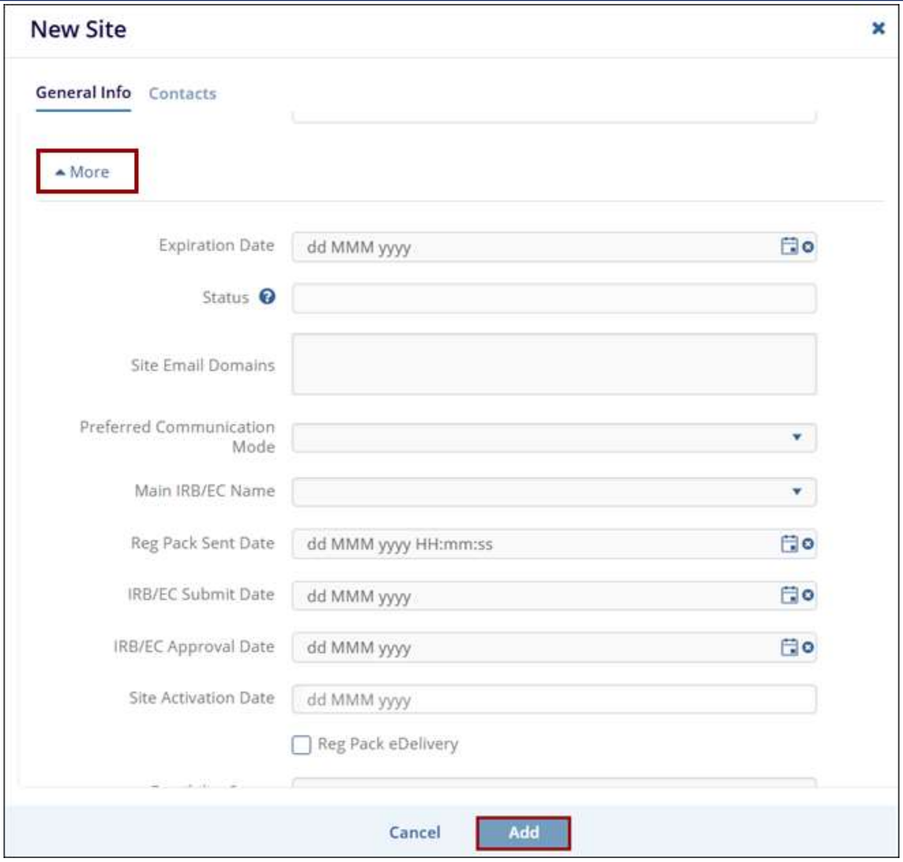
    1. Country: Select a country from the dropdown options.
    2. Website: Add a website
    3. Address: Add the address to the respective field
    4. City: Enter a city for the site
    5. State: Enter a state for the site
    6. Zip Code: Enter the ZIP Code for the site
    7. Phone: Enter phone number for the site
    8. Fax: Enter the fax number for the site
    9. Geo Code: Enter the geocode for the site.



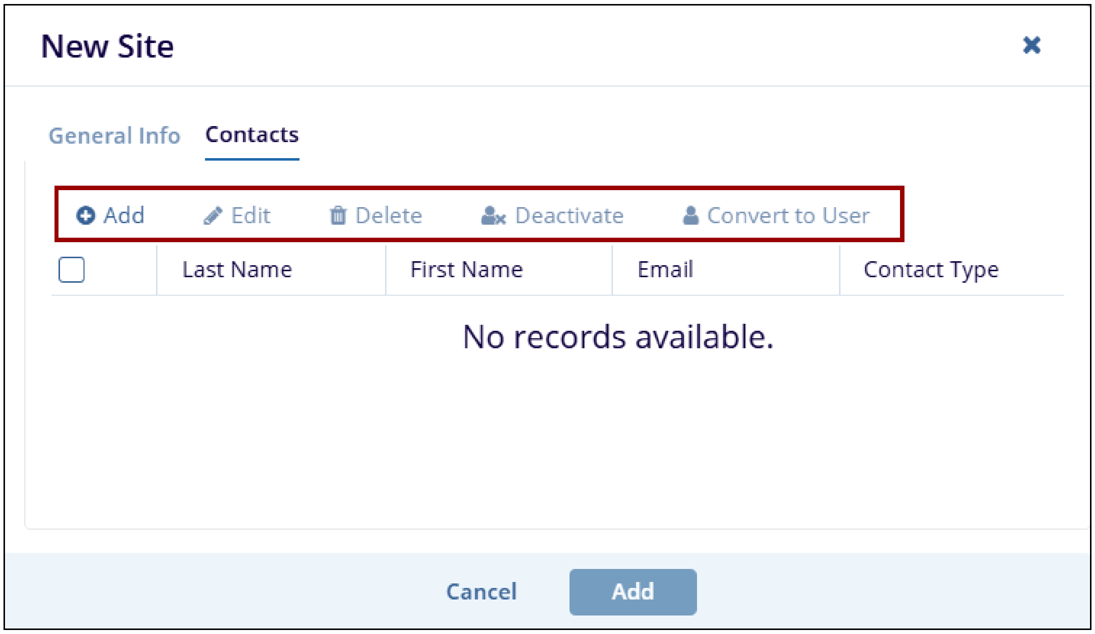
- More: Add information to the following fields.

  1. Expiration Date
  2. Status
  3. Site Email Domains
  4. Preferred Communication Mode
  5. Main IRB/EC Name
  6. Reg Pack Sent Date
  7. IRB/EC Submit Date
  8. IRB/EC Approval Date
  9. Site Activation Date
  10. Reg Pack edelivery
  11. eFeasibility Status
  12. Effective Closure Date
  13. Address Line 2
  14. Address Line 3
  15. Email
  16. Other
  17. Country Approval Date
  18. Status Date
  19. Organization Name

4. Once the necessary details are specified, click on the Add button.

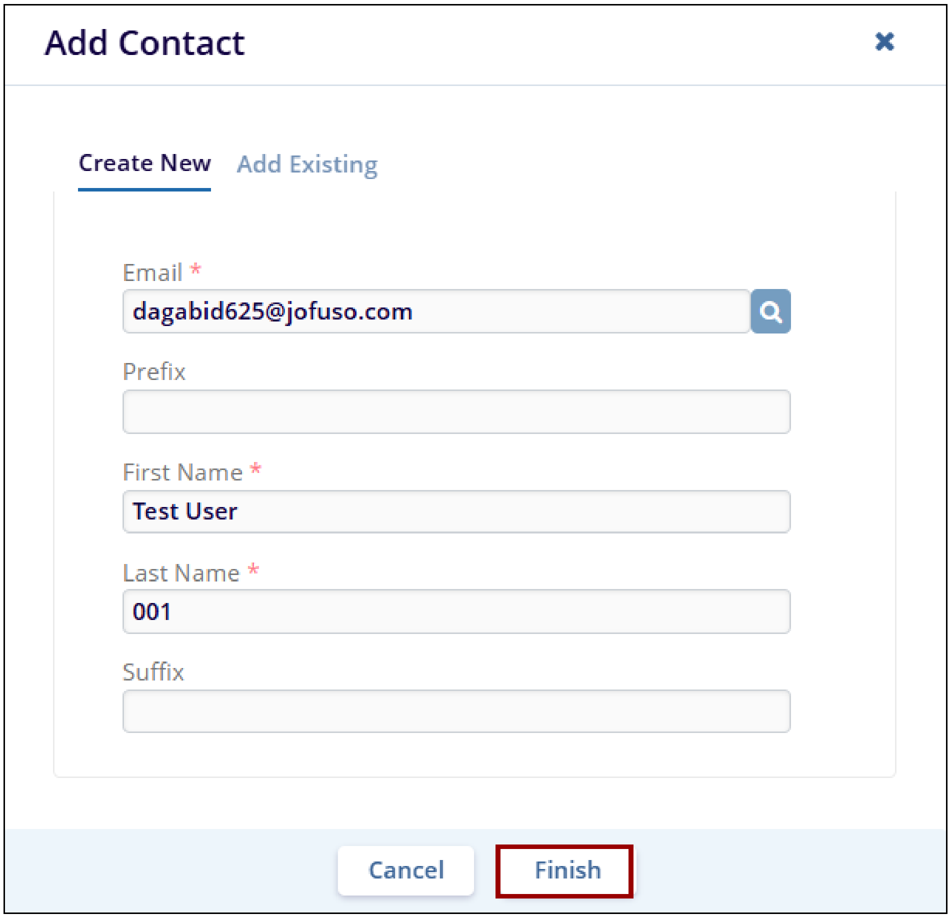


5. On the Contacts tab, perform the following to configure the list of contacts within the site.



- Add Contacts: To add contacts, follow the steps below.

    1. On the Contacts tab, click on the +Add button.
    2. On the Add Contact form, add details to the mandatory metadata fields.
    3. Click on the Finish button.
    4. To add existing contact, switch to the Add Existing tab.

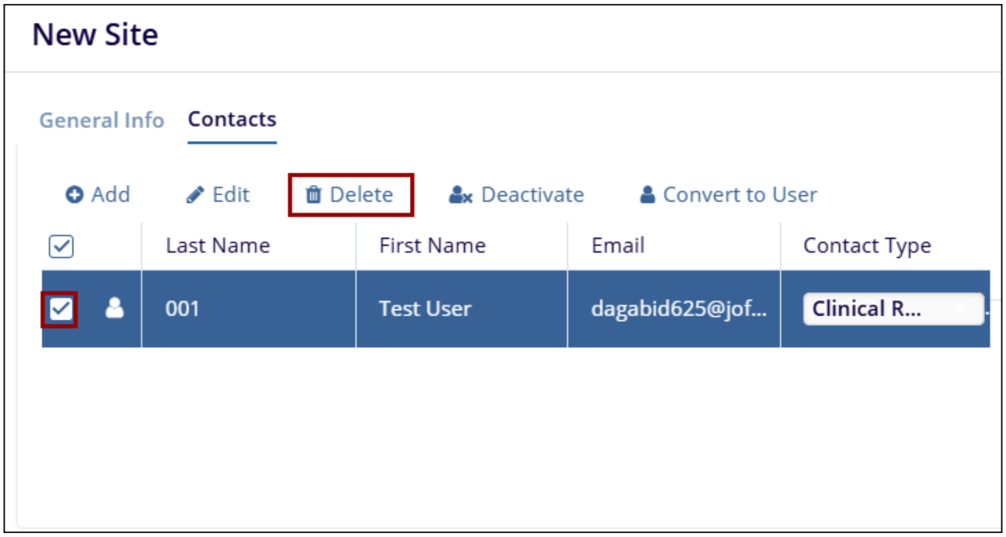


- Edit Contact: To edit a contact, follow the steps below.

    1. Select the contact within the contacts list.
    2. Click on the Edit button from the top menu bar.
    3. On the Edit Contacts screen, make the necessary changes.
    4. Once the details are modified, click on the Edit button at the bottom of the Edit Contacts screen.

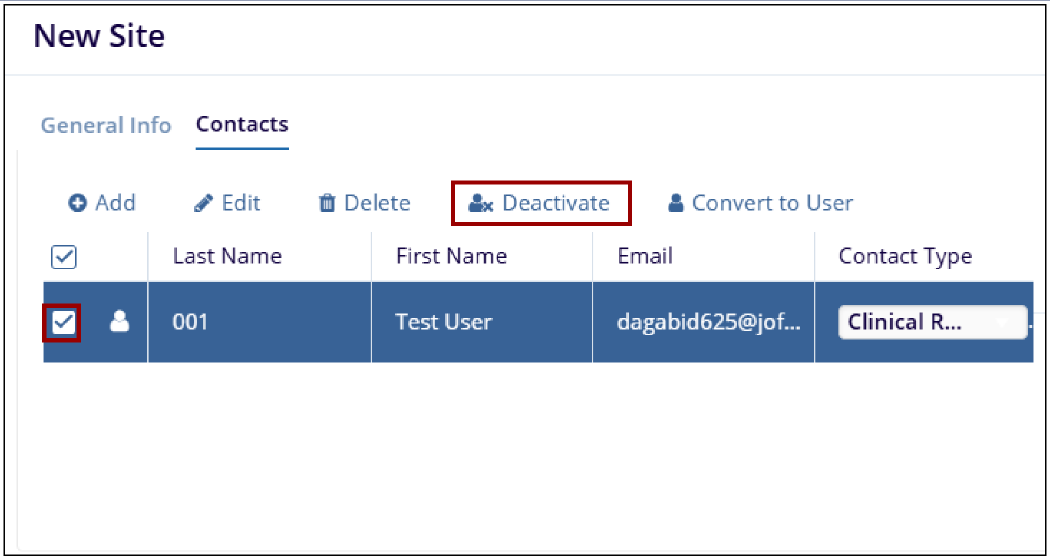
- Delete Contact: To a contact, follow the steps below.

  1. Select the contact within the contacts list.
  2. Click on the Edit button from the top menu bar.



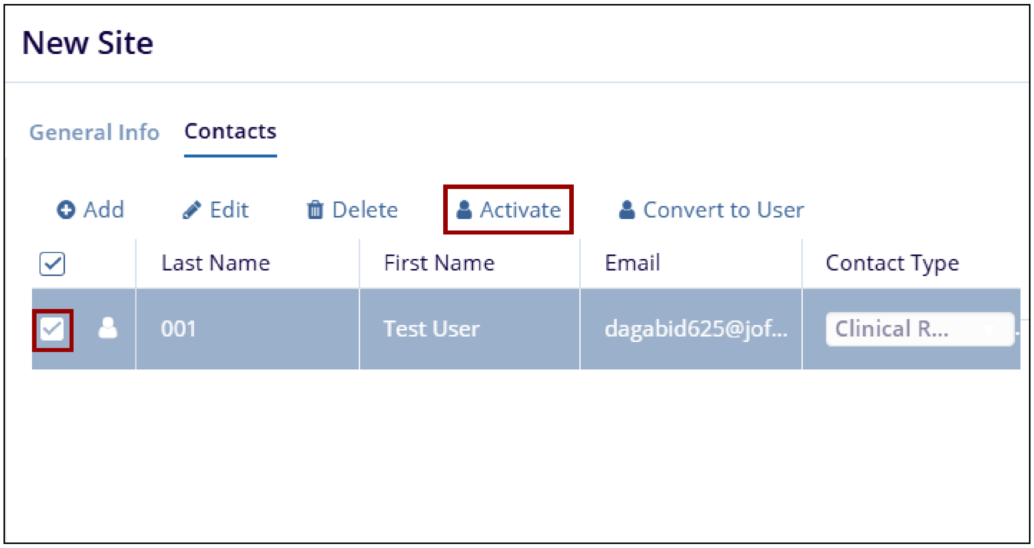
- De-activate Contact: To deactivate a contact, follow the steps below.

  1. Select the contact within the contacts list.
  2. Click on the De-activate button from the top menu bar.



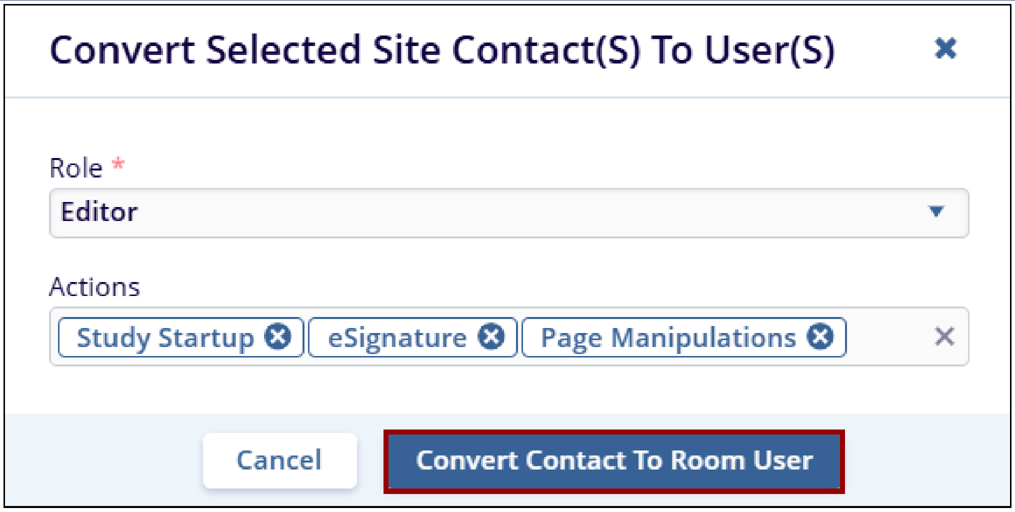
- Activate Contact: To activate the contact, follow the steps below.

  1. Select the contact within the contacts list.
  2. To activate, the contact, click on the Activate button from the top menu bar.



- Convert to User: To convert a contact into a user, follow the steps below.

  1. Select the contact within the contacts list.
  2. Click on the Convert to User button from the top menu bar.
  3. On the Convert Select Site Contacts screen, provide a role and the actions to the user and click on the Convert Contact to Room User button.

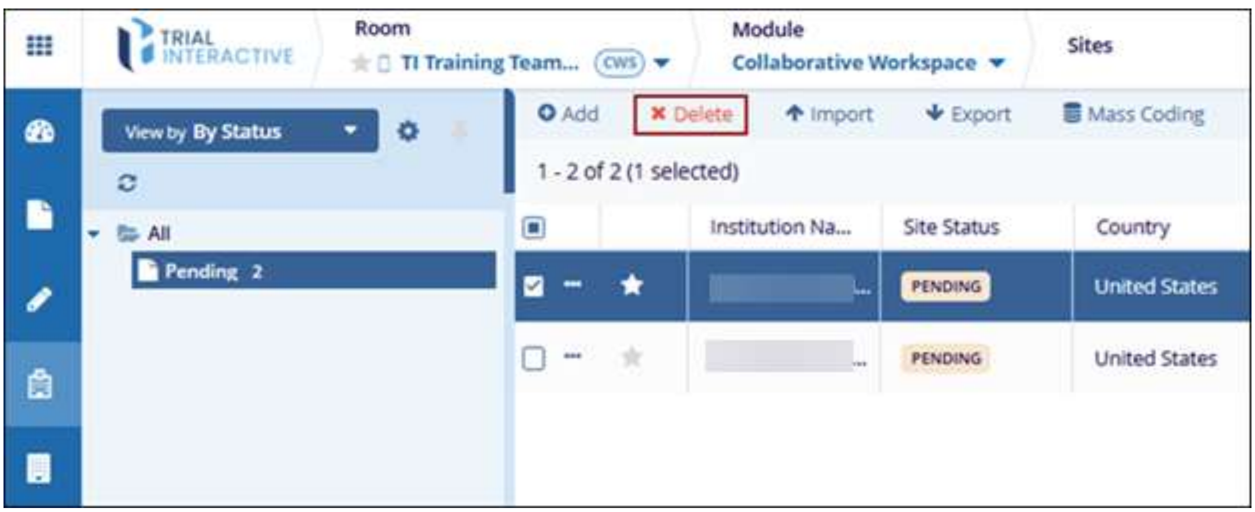


6. Once the General Info and Contact Details are added, click on the Add button.

Delete Site

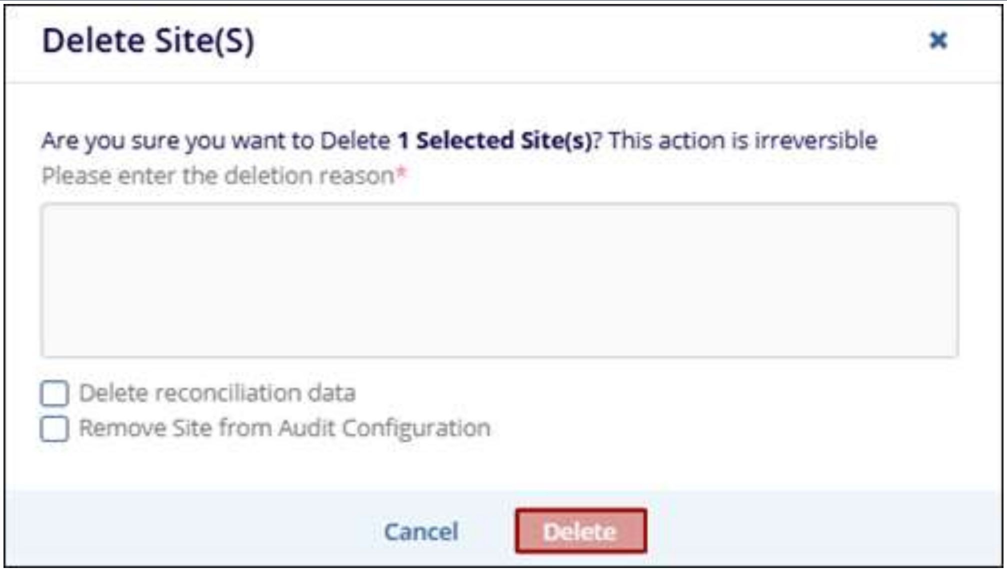
To delete a site, follow the steps below.

1. On the Sites screen, check the box next to the site to delete,
2. Click on the Delete button.



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

4. Click the Delete button to confirm the deletion.

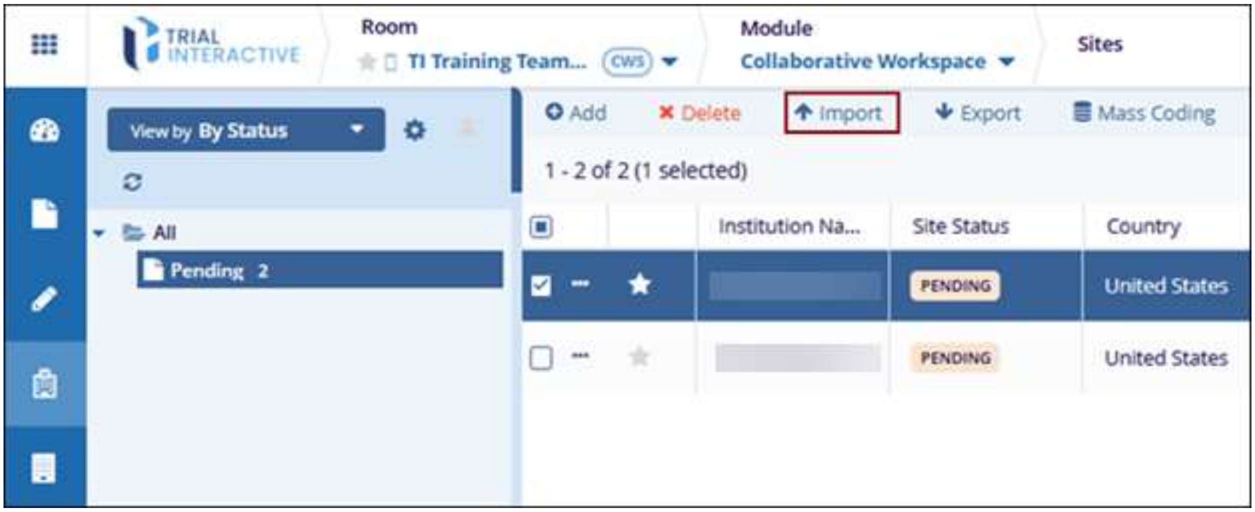


Note: This action is irreversible, and a confirmation message will indicate the site has been deleted.

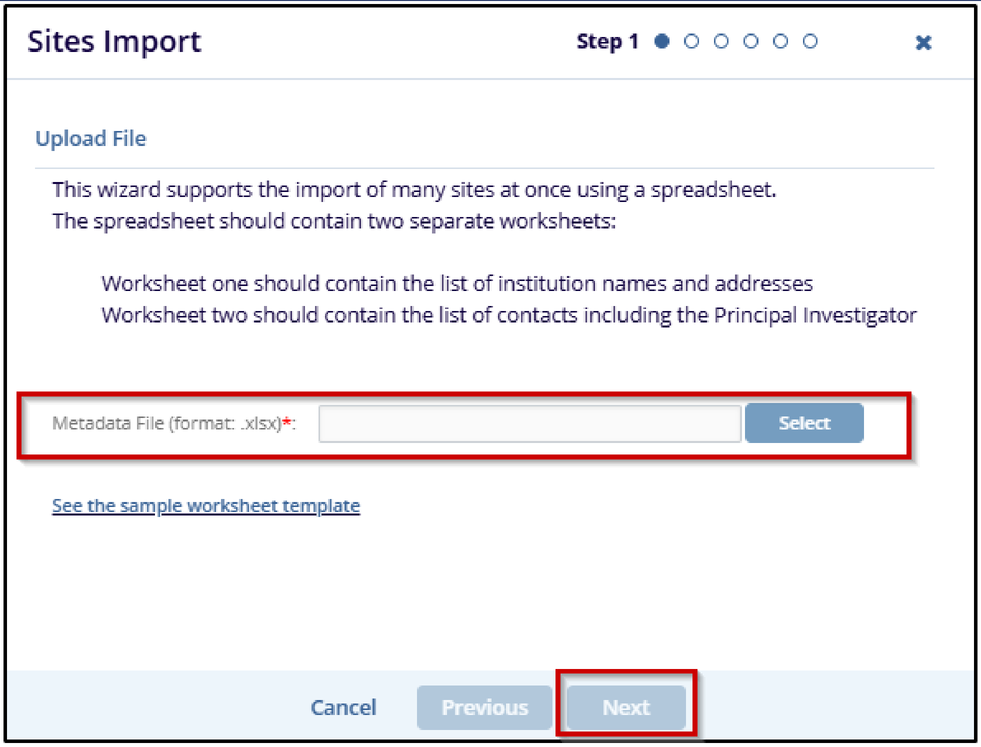
Import Sites

To import sites from the Collaborative Workspace module, follow the steps below.

1. On the Sites screen, click the Import button from the top menu bar.



2. On the Sites Import dialog, click on the See the sample worksheet template to download a template and enter the necessary details.
3. Click Select to upload a metadata file in .xlsx format. Ensure that the spreadsheet contains two worksheets.
    - The first worksheet should list investigative site details.
    - The second worksheet should list contacts.

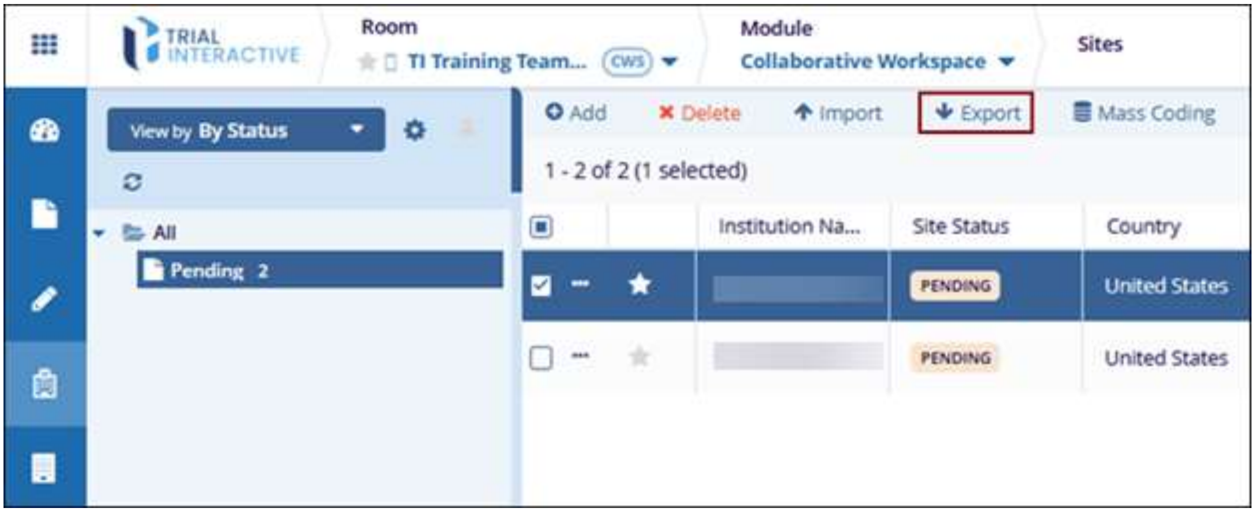


4. After selecting the file, click Next to proceed with the import process.

Export Sites

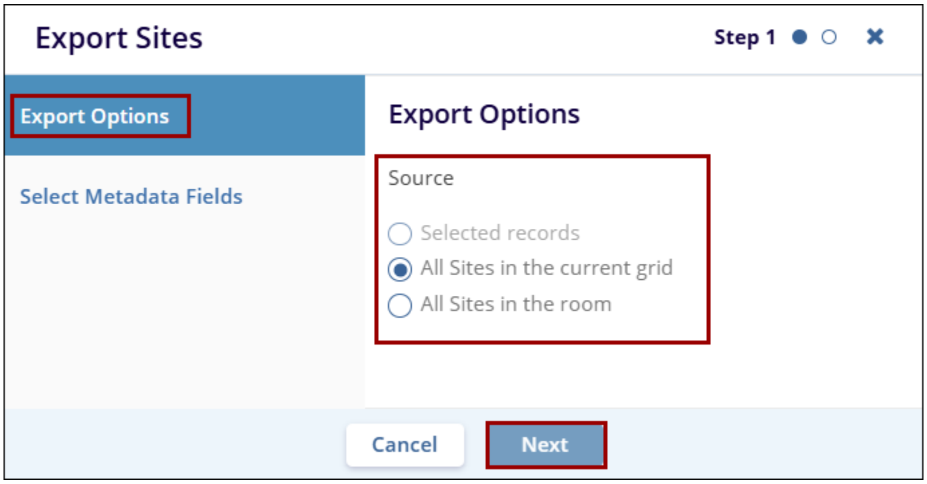
To Export sites, follow the steps below.

1. Click the Export button at the top of the screen to export all sites in the grid. To export specific sites, check the box next to the site name.

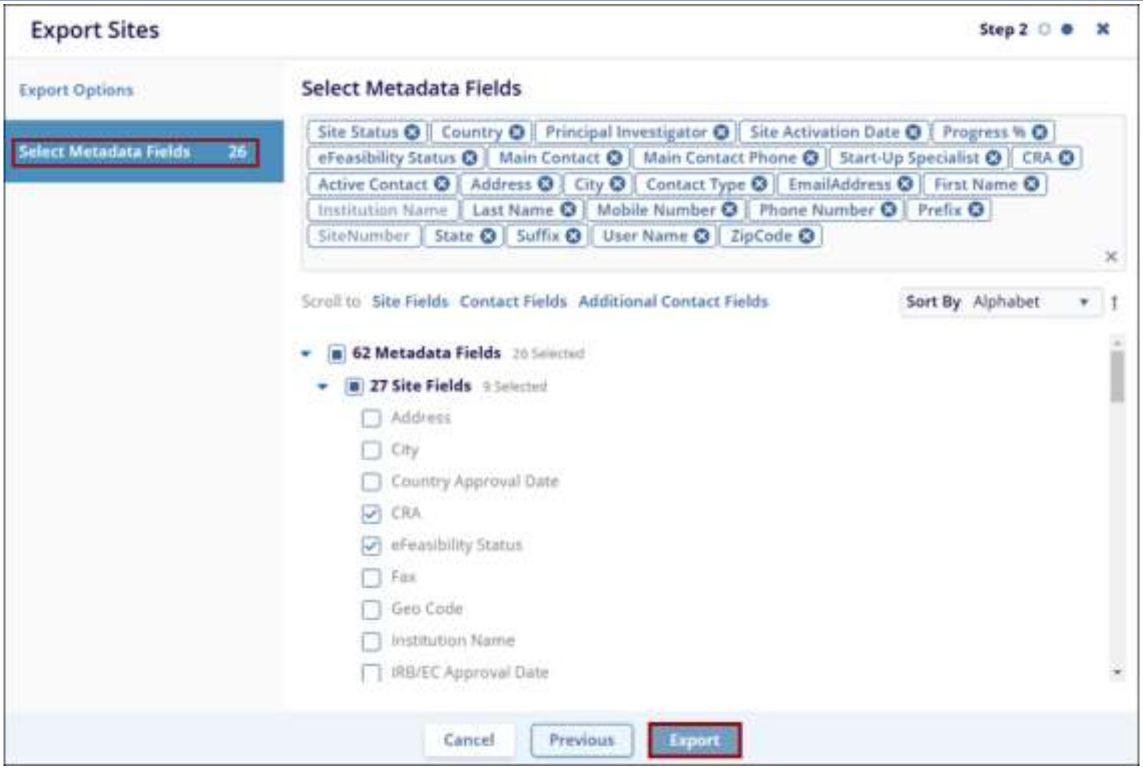


2. On the Export Sites dialog, under Export Options, select one of the following sources and click on the Next button.

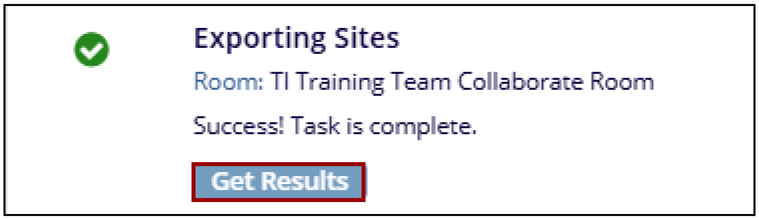
   - Selected records
   - All Sites in the current grid
   - All Sites in the room



3. In Step 2, choose the metadata fields to include in the export file and click on the Export button to finalize and start the export.

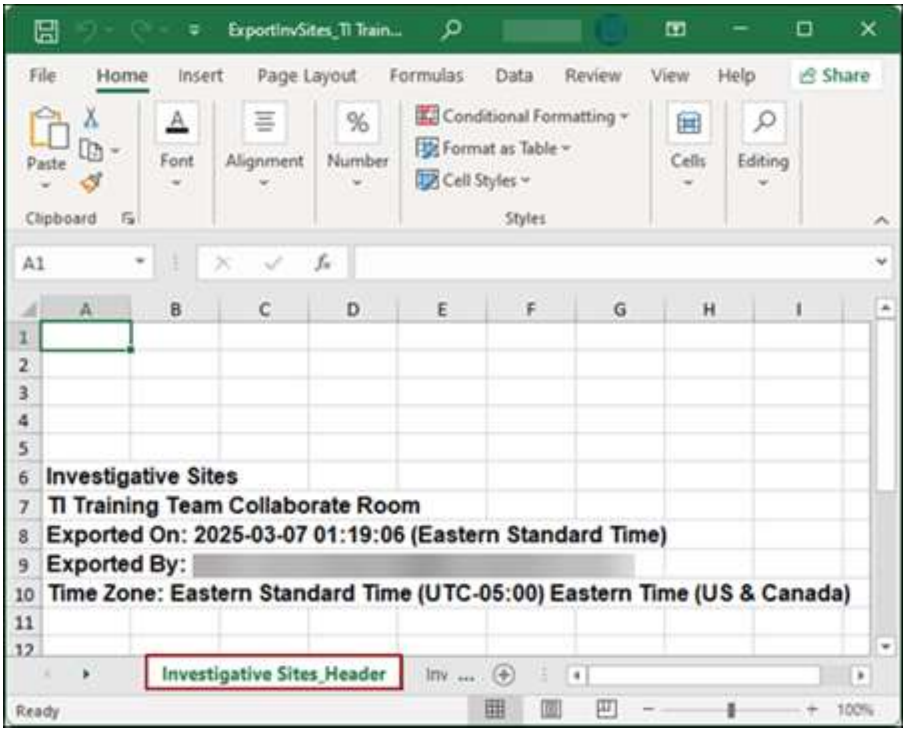


4. On the Export Sites success message popup, click on the Get Results button and download the export file into the system as Microsoft Excel Worksheet.



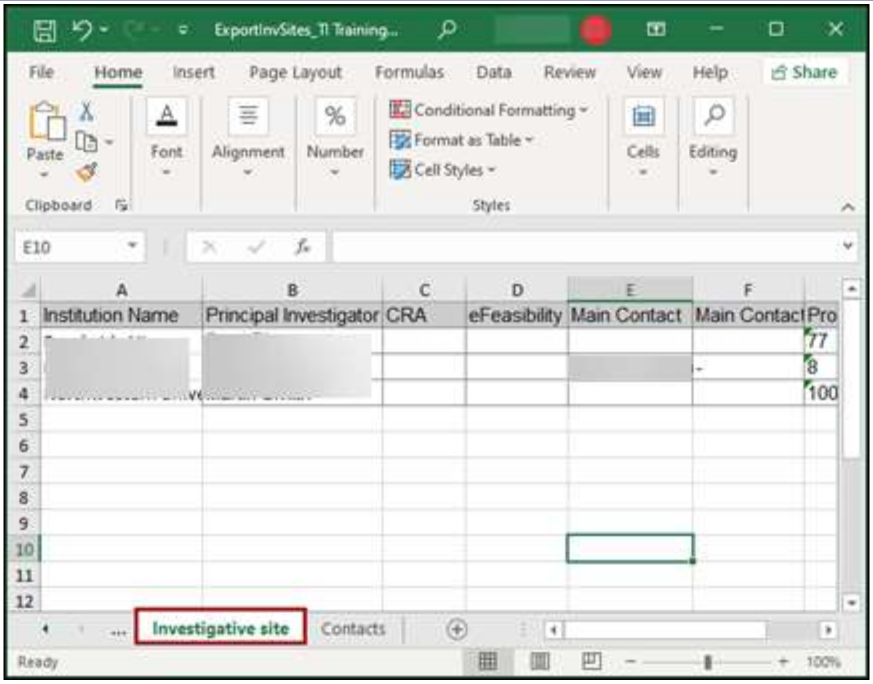
5. Within the downloaded file, click on the Investigative Sites_Header tab to view details such as

    1. Room Name
    2. Exported On
    3. Exported By
    4. Time Zone



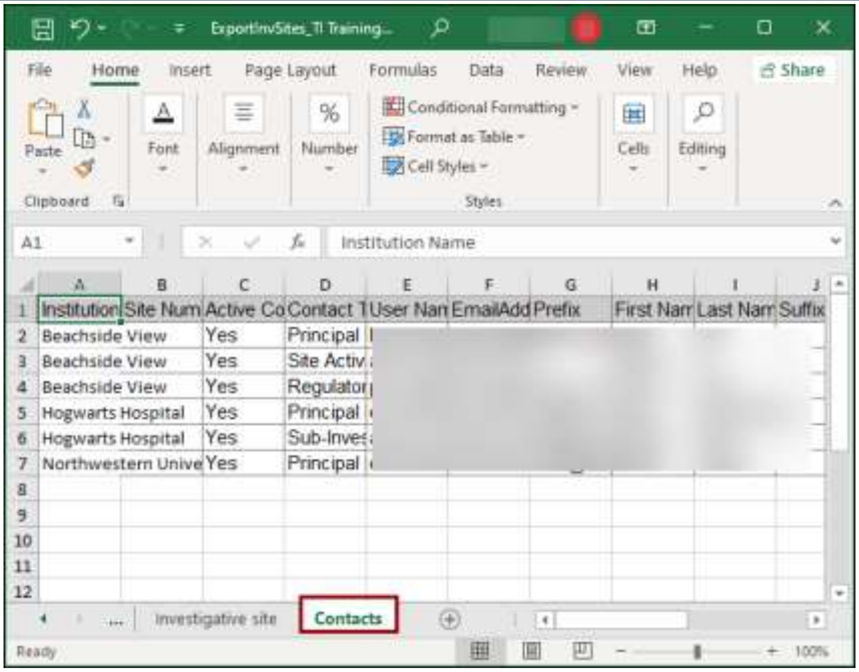
6. Click on the Investigative site tab to view the following details.

    1. Institution Name
    2. Principal Investigator
    3. CRA
    4. eFeasibility
    5. Main Contact
    6. Main Contact Phone
    7. Progress
    8. Site Activation Date
    9. Status
    10. Start-Up Specialist



7. Click on the Contacts tab to view the following details.

    1. Institution Name
    2. Site Number
    3. Active Contact
    4. Contact Type
    5. User Name
    6. Email Address
    7. Prefix
    8. First Name
    9. Last Name
    10. Suffix
    11. Address
    12. City
    13. State
    14. Country
    15. Zip Code
    16. Mobile number
    17. Phone number

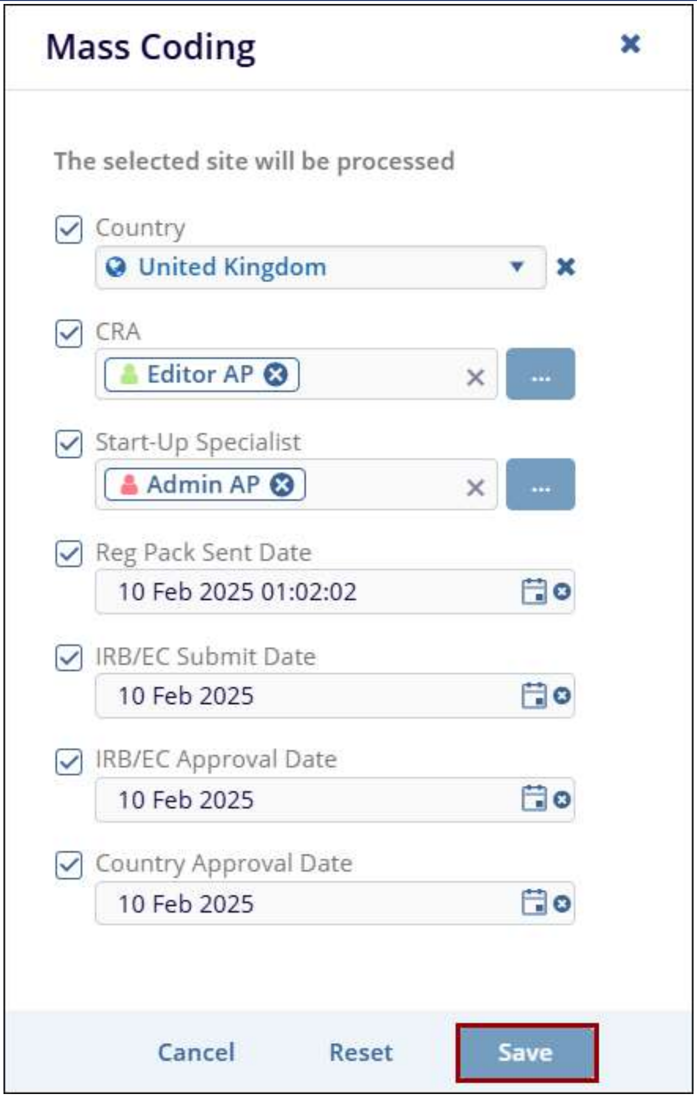


Mass Coding Sites

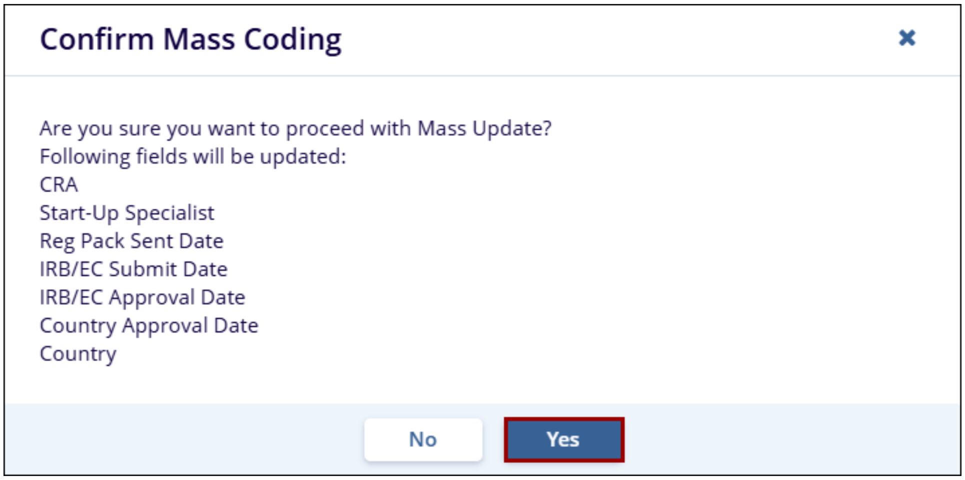
To perform mass coding for sites, follow the steps below.

1. Select the site(s) to apply mass coding by checking the box next to the site name.
2. Click Mass Coding at the top of the screen.

3. In the Mass Coding dialog, select the relevant fields to code, such as Country, Expiration Date, CRA, Start-Up Specialist, or any other applicable fields, and fill in the details.
4. Once all information is entered, click on the Save button to apply the mass coding to the selected site(s).



5. On the confirmation popup, click on the Yes button.

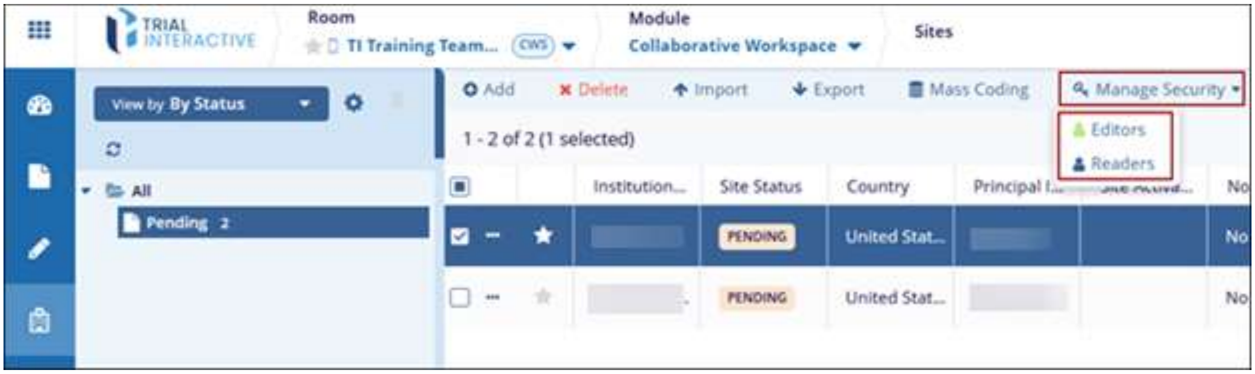


Manage Security of Sites

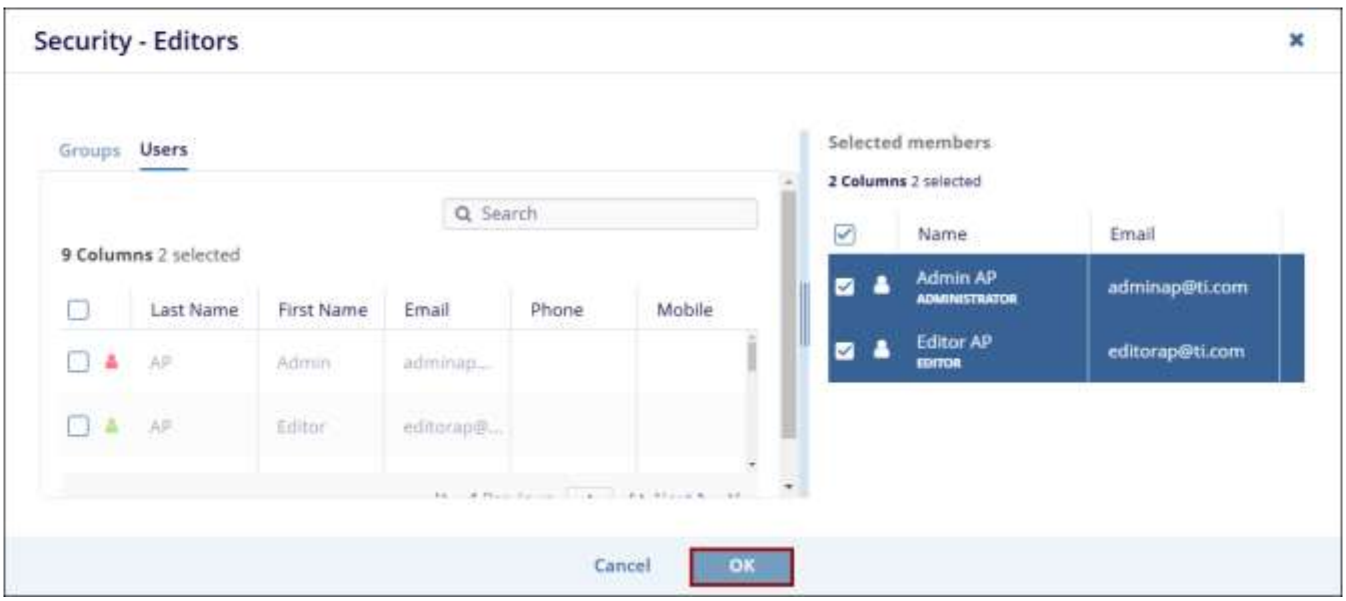
To manage security settings for sites, follow the steps below.

1. Check the box next to the site to manage security settings.

2. Click on the Manage Security button at the top of the screen, and choose either Editors or Readers to manage permissions.



3. In the Security - Editors or Security - Readers dialog, switch to the Users or Groups tab.
4. Select the user(s) or group (s) by checking the box next to their name in the user list and add them to the Selected Members section.
5. Click on the OK button.



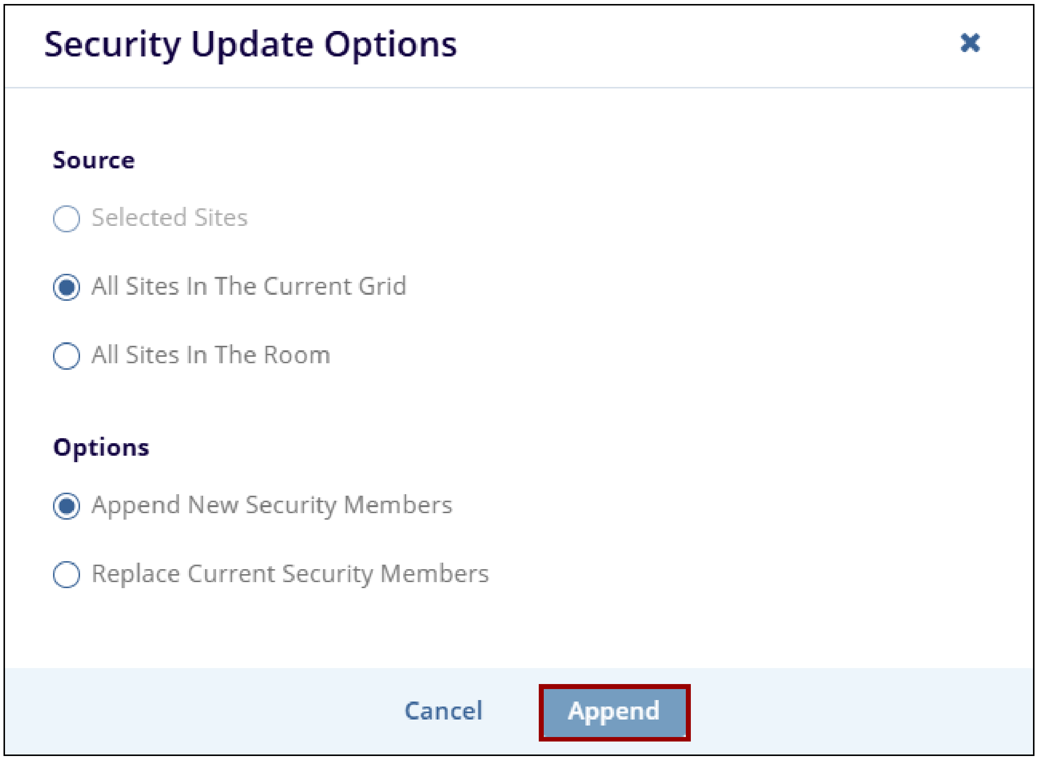
6. On the Security Update Options popup, select the options by clicking on their respective radio buttons.

    1. Source
        1. Selected Sites

        2. All Sites In The Current Grid
        3. All Sites In The Room

    2. Options
        1. Append New Security Members
        2. Replace Current Security Members

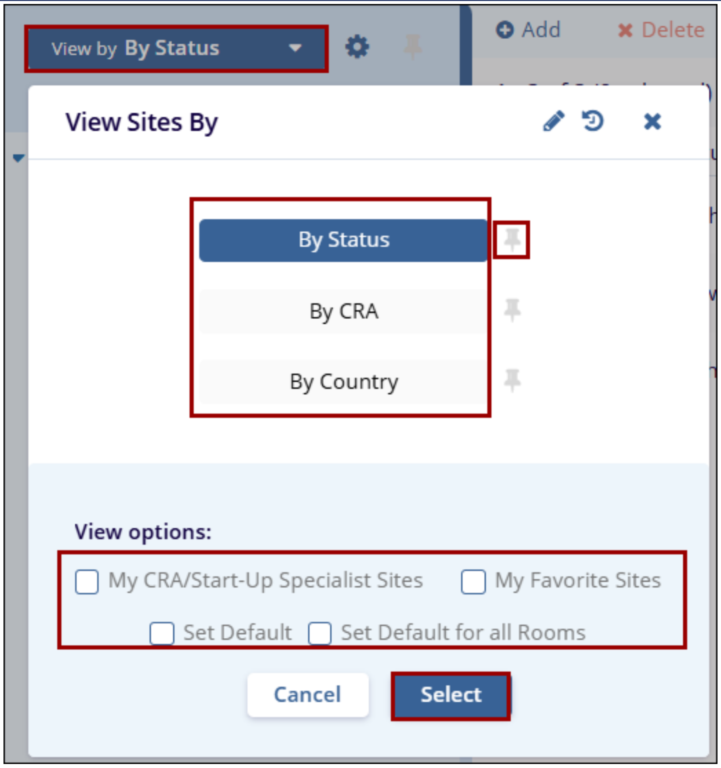
7. Once the necessary, click on the Append (for append new security members) or Replace (for replace current security members) button.



Site Views

To access and configure the site views, follow the steps below.

1. On the Sites screen, click on the View by dropdown.
2. On the View Contacts By window, select a view by clicking on the view name.
    a. By Status: Displays the contacts grouped by the site.
    b. By CRA: Displays the sites grouped by the associated CRA.
    c. By Country: Displays contacts grouped by their country association.
3. Click on the pin icon to pin a view and this view is selected once user access the Sites modal.
4. Select the different view options by checking the box before their name.
5. Click on the Select button once the desired view is selected.

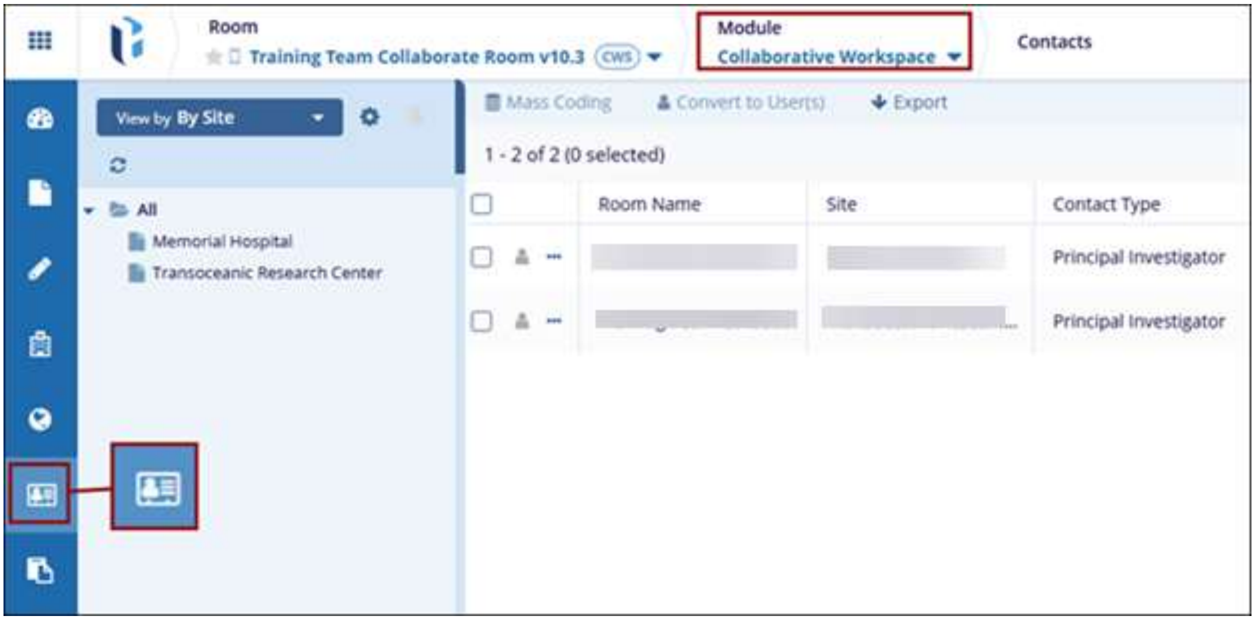

View by By Status
Add
Delete
View Sites By
By Status
By CRA
By Country
View options:
My CRA/Start-Up Specialist Sites
My Favorite Sites
Set Default
Set Default for all Rooms
Cancel
Select

CONTACTS

The contacts assigned to a site are shown in the Contacts modal within the Collaborative Workspace module. Users with the necessary access permissions can edit contacts, apply mass coding, convert contacts into users, and export contact details and metadata.

To access the contacts modal within the eTMF module, follow the steps below.

1. Click on the modules dropdown and select the Collaborative Workspace module.
2. From the left-hand navigation menu, select the Contacts modal.
3. The Contacts screen displays the contacts configured within the site and its associated data in the following columns.
    a. Room Name
    b. Site
    c. Contact Type
    d. Main Contact
    e. Email Address
    f. Full Name
    g. Provide Document
    h. Status



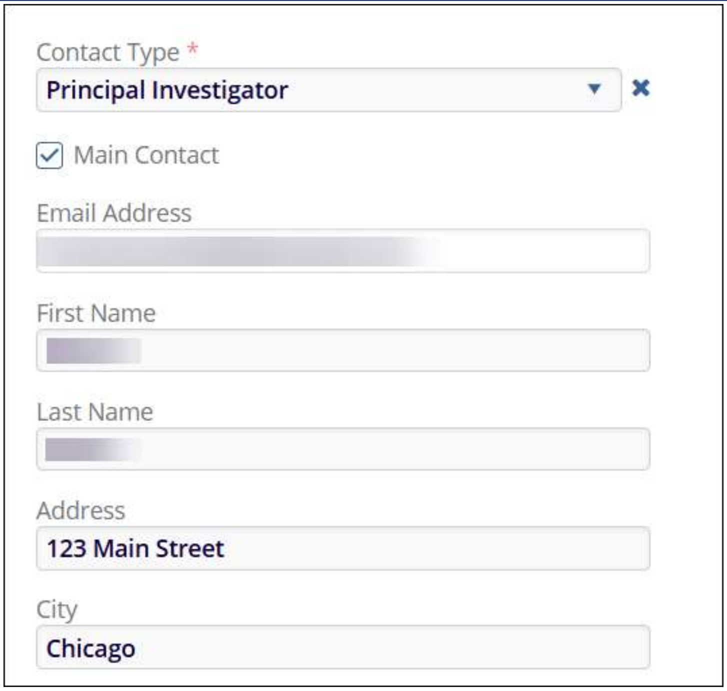
Edit Contacts

To edit contacts, follow the steps below.

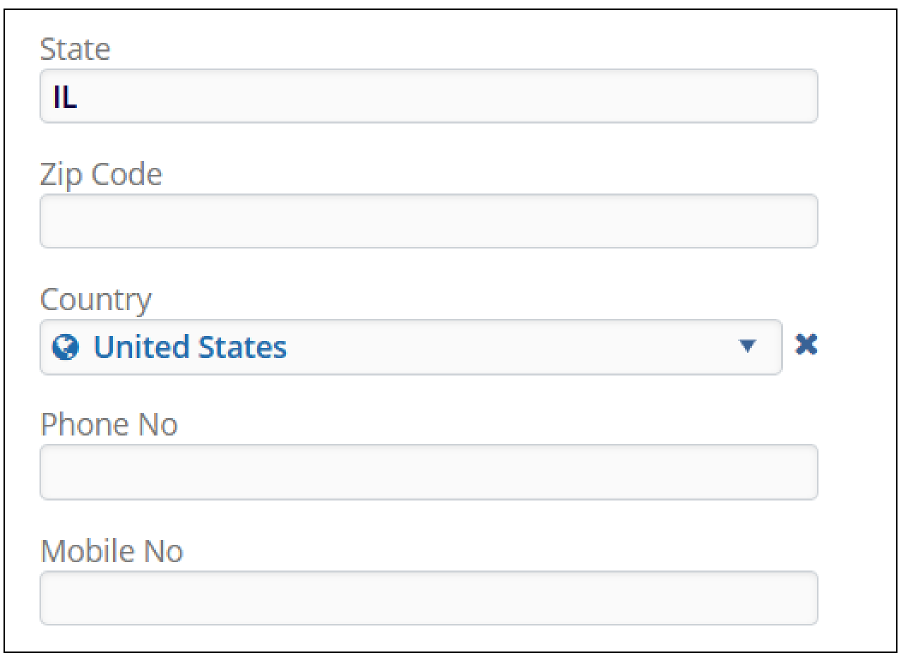
1. Click on the checkbox next to the contact.

2. Within the metadata panel on the right-hand side, make changes to the following metadata fields.

    a. Contact Type*: Select a contact type from the dropdown list.
    b. Main Contact: Check or uncheck the Main Contact checkbox to designate the contact as a main contact. If selected, the Main Contact column in the contacts screen will display Yes and vice versa.
    c. Email Address: This field is non-editable.
    d. First Name: Enter or update the contact's first name.
    e. Last Name: Enter or update the contact’s last name.
    f. Address: Enter or update the contact’s address.
    g. City: Enter or update the contacts city.



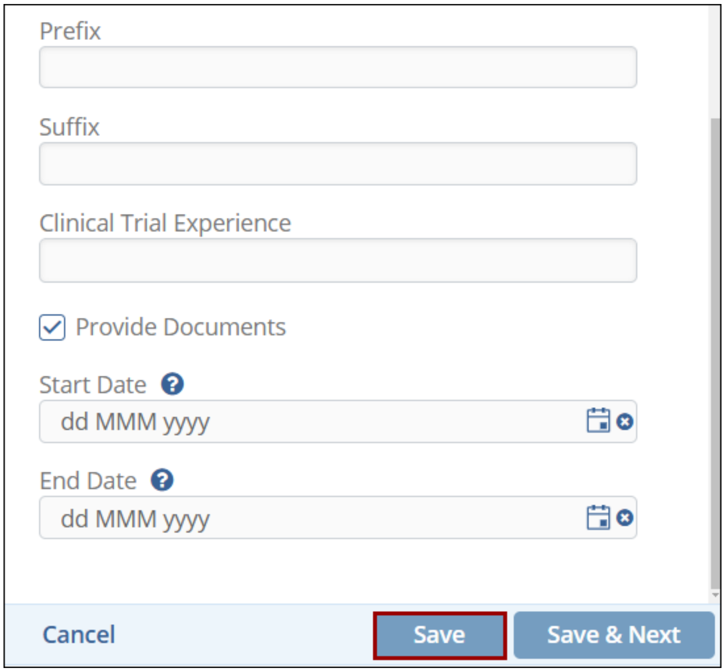
h. State: Enter or update the contact’s state.
i. Zip Code: Enter or update the contact's zip code.
j. Country: Select a country from the dropdown list.
k. Phone No: Enter or update the contact phone number.
l. Mobile No: Enter or update the contact's mobile number.



m. Prefix: Enter or update the contact’s prefix.
n. Suffix: Enter or update the contact’s suffix.

o. Clinical Trial Experience: Enter or update the contact's clinical trial experience.
p. Provide Documents: Check or uncheck the Provide Documents checkbox to enable or disable this setting. If selected, the Provide Document column in the contacts screen will display Yes and vice versa.
q. Start Date: Select or update the start date using the calendar icon. This indicates when the contact started working at the site.
r. End Date: Select or update the end date using the calendar icon. This indicates when the contact stopped working at the site.

3. Once all the changes are made, click on the Save button.

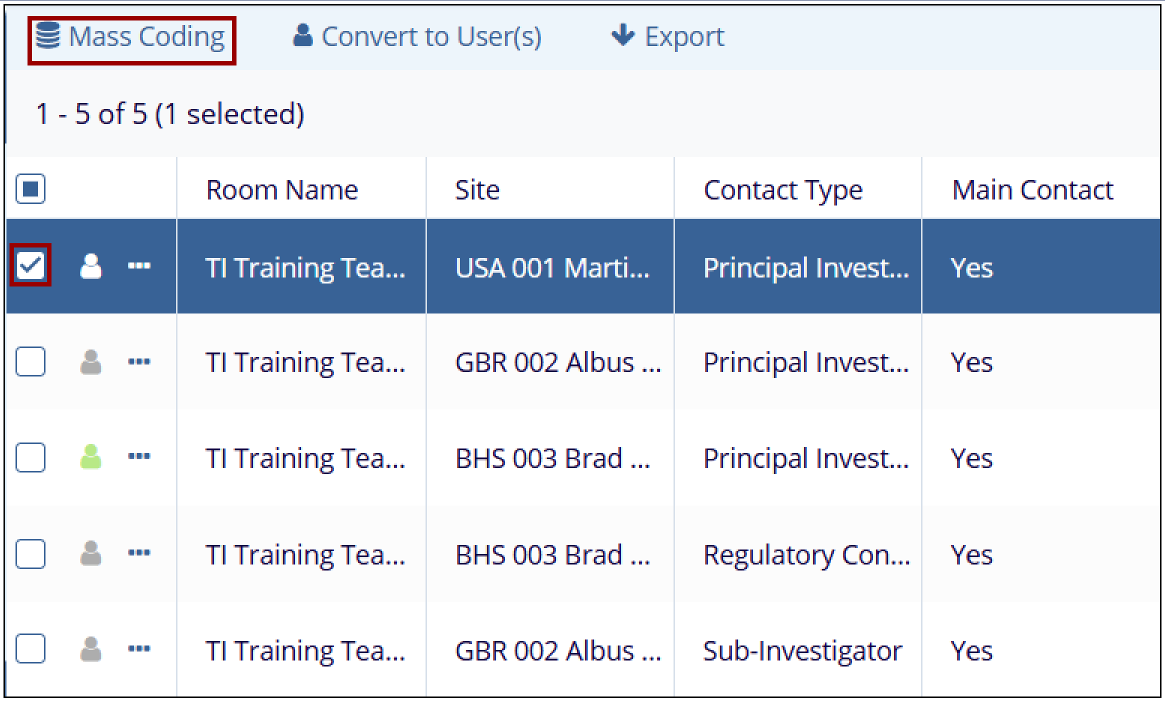


Mass Coding

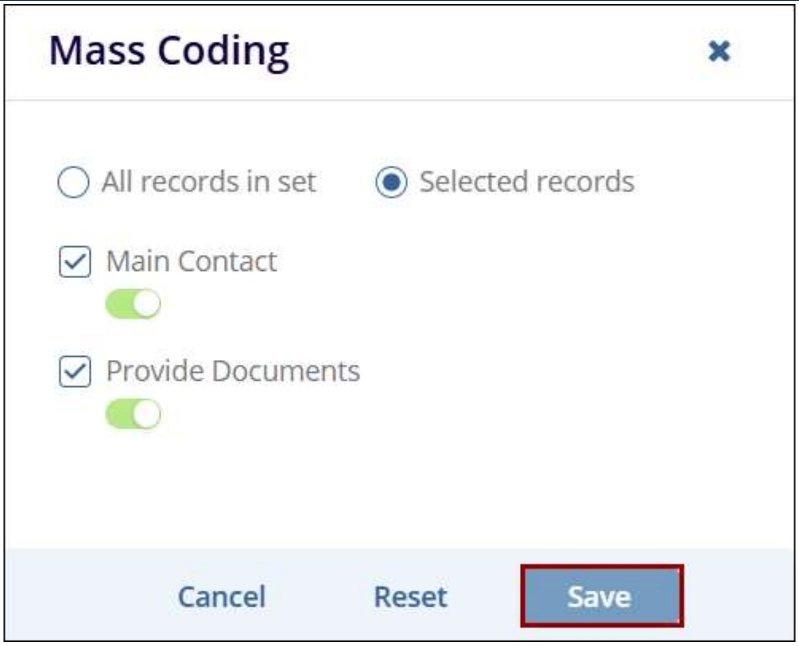
The Mass coding functionality allows users to apply metadata updates in bulk to all or selected contacts.

To apply mass coding to all or selected contacts, follow the steps below.

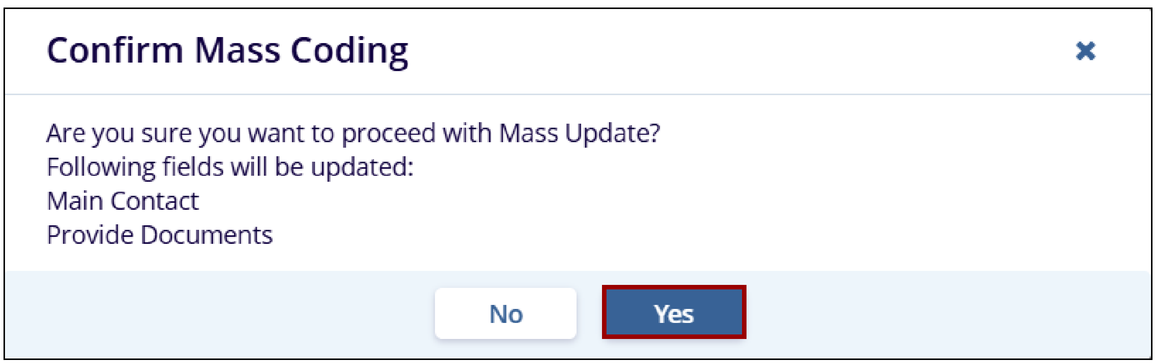
1. Select a single or multiple contacts by clicking on their respective checkboxes.
2. Click on the Mass Coding button from the top menu bar.



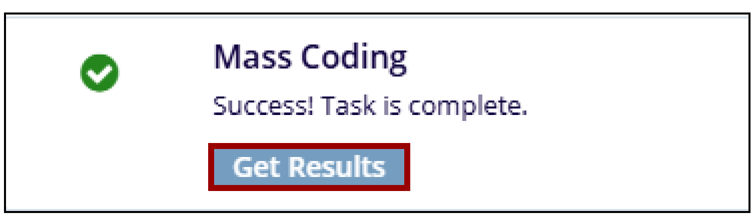
3. On the Mass Coding window, select the following option by clicking on its radio button
    a. All Records in set: The metadata updates will apply to all contact records
    b. Selected records: The metadata updates will apply to selected contacts.
4. Check or Uncheck the Main Contact checkbox and 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 Contacts screen displays the updated metadata fields.

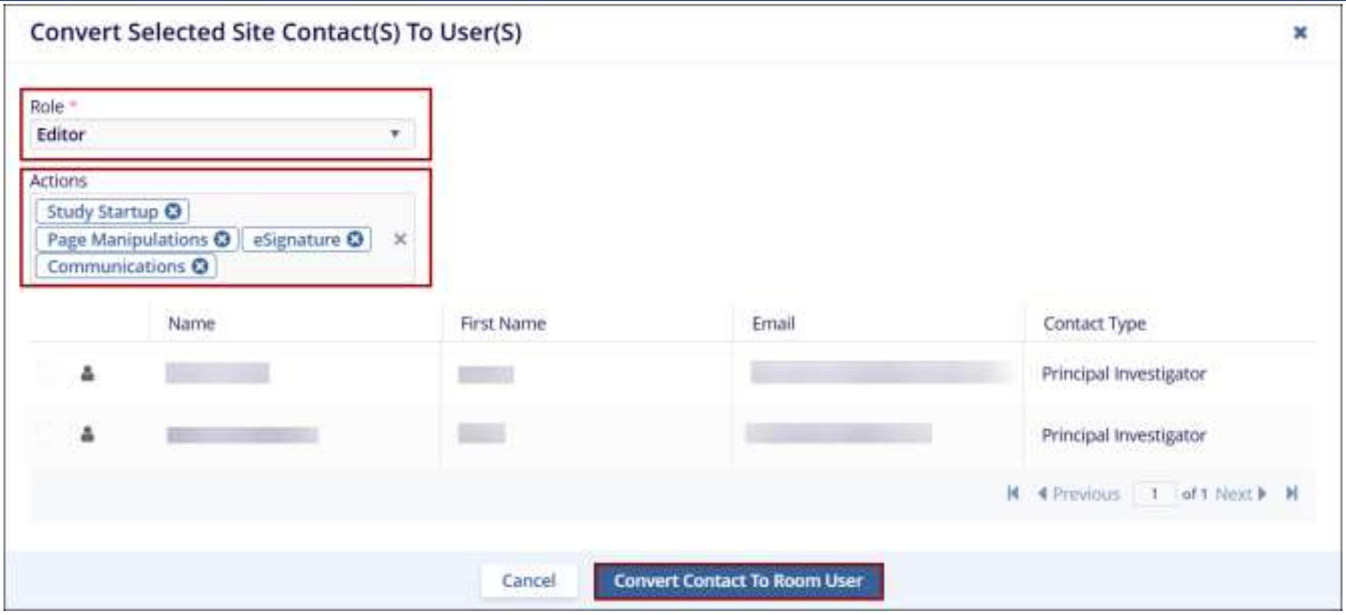
Convert to Users

Administrators have the capability to convert contact(s) to room user(s).

To convert a contact to a user, follow the steps below.

1. Select a single or multiple contacts by clicking on their respective checkboxes.
2. Click on the Convert to User(s) button from the top menu bar.

3. On the Convert Selected Site Contact(S) To User(S) window, click on the Role* dropdown and select Editor or Reader.
4. Click on the Actions dropdown and select the actions that the user would be allowed to perform in addition to the basic rights associated with their user access role. Note: The Actions dropdown displays options based on the role selected.
5. Click on the Convert Contact to Room User button.



6. Once the contact is successfully converted to a user, it is displayed in the users list within the User Management module.

Export

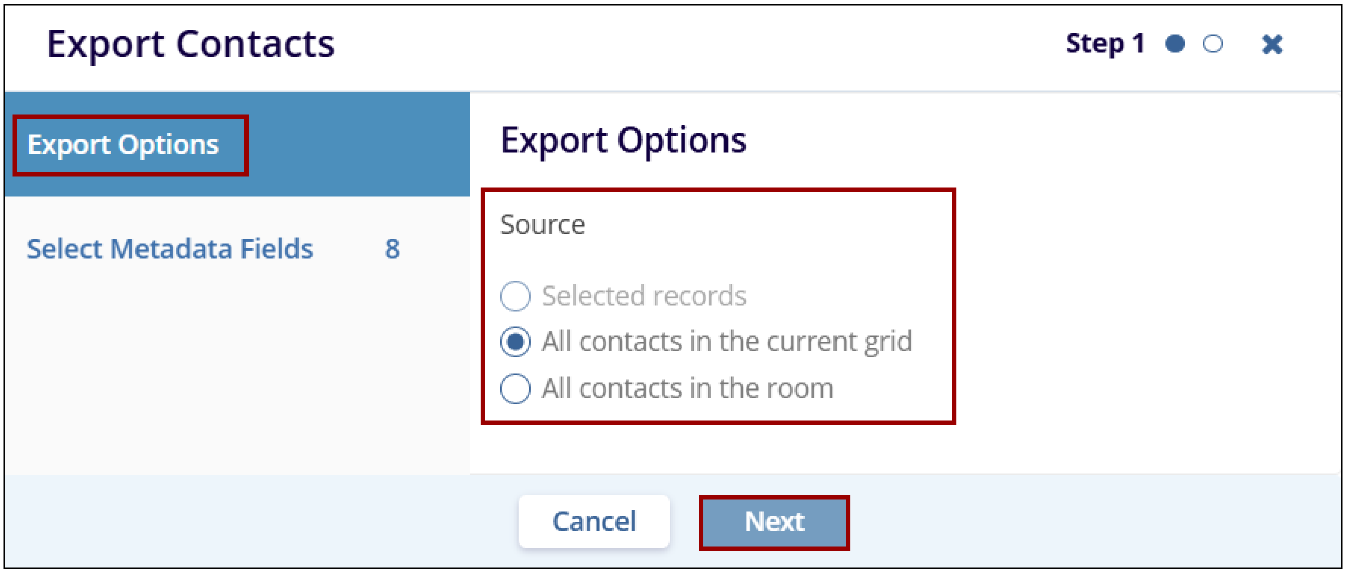
To export contacts, follow the steps below.

1. On the Contacts screen, select users or click the Export button in the top menu bar.

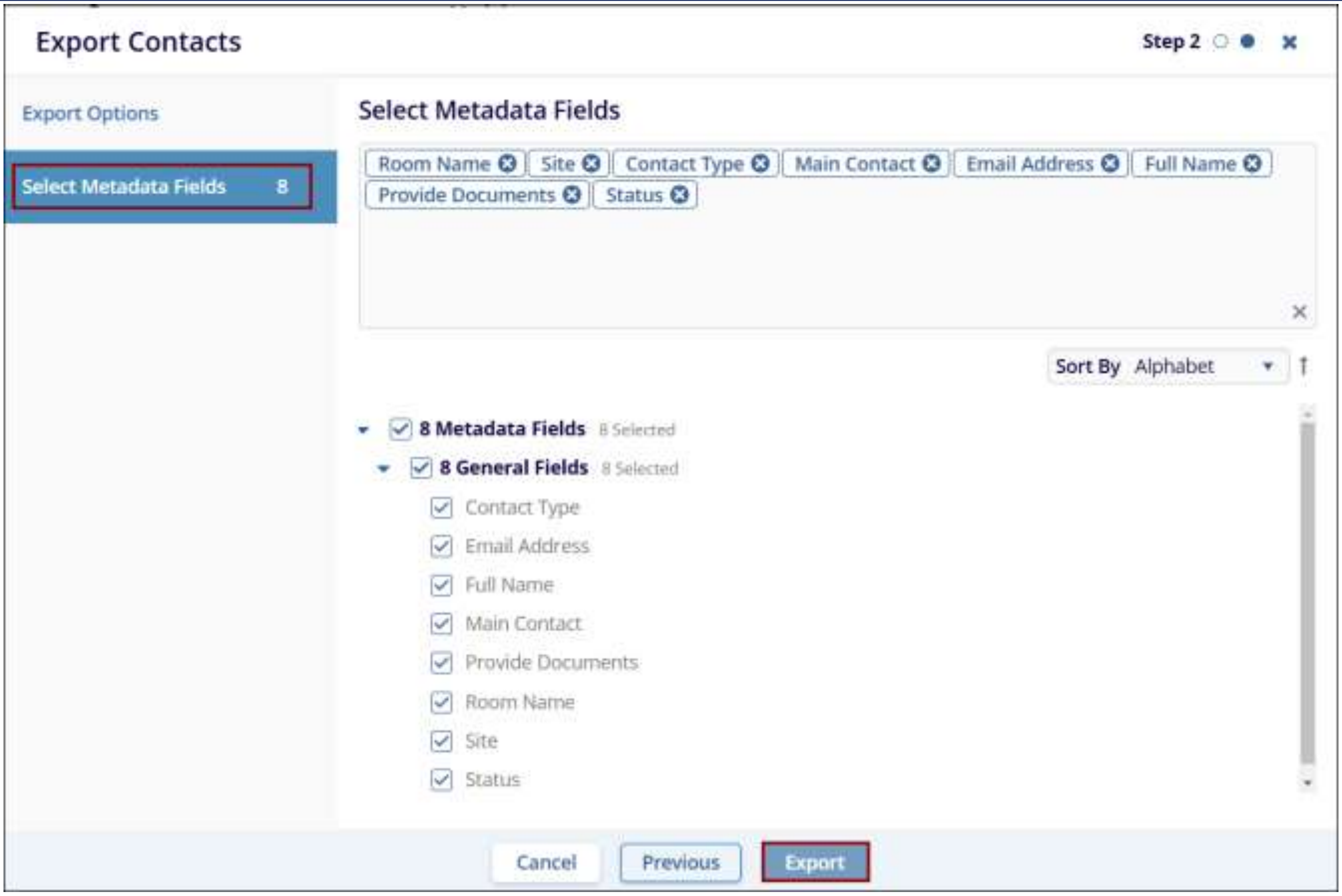
2. On the Export Contacts screen, select any one of the export options and click on the Next button within Step 1.
    a. Selected records
    b. All contacts in the current grid

c. All contacts in the room

Note: If no contacts are selected, the Selected records radio button will be grayed out.

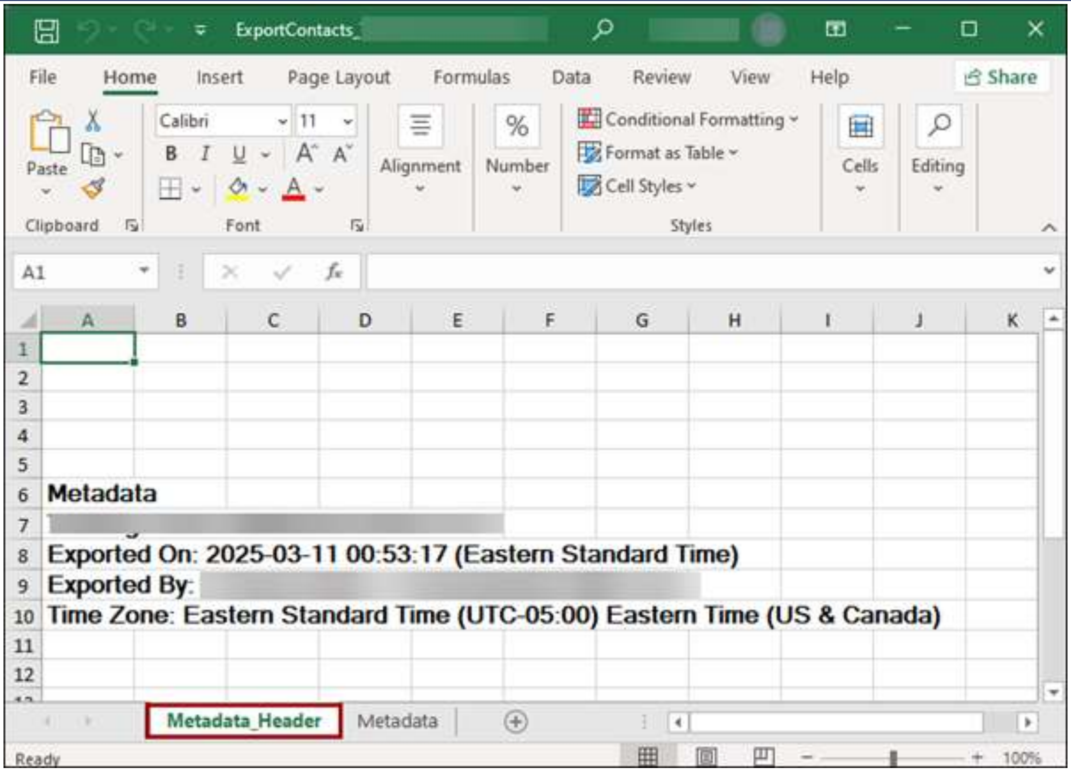


3. Within the Step 2, select the required metadata fields and click on the Export button.

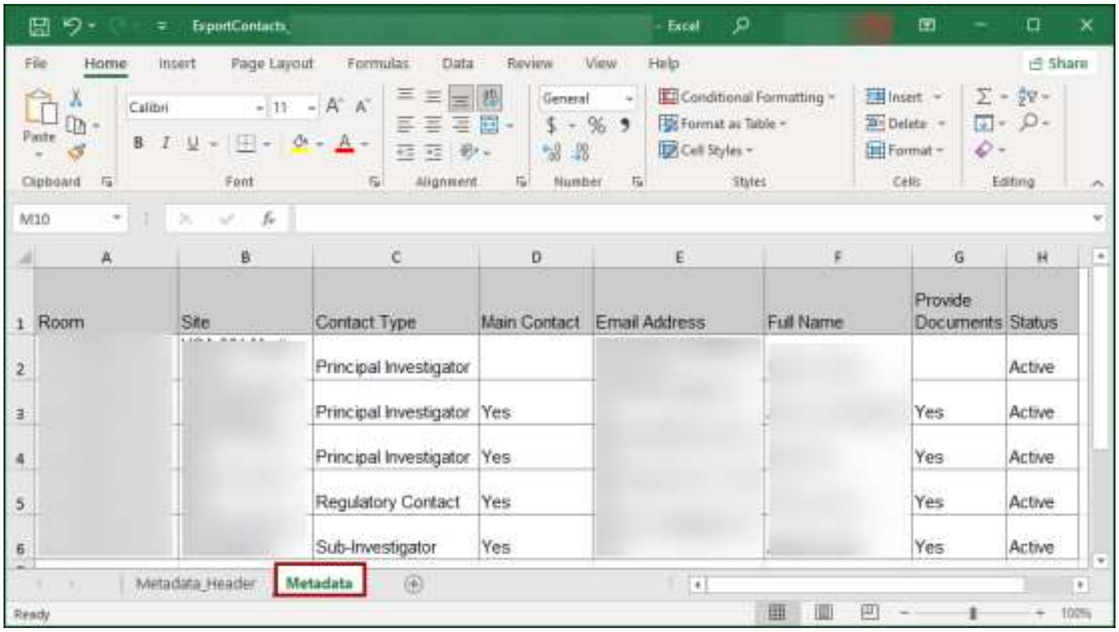


4. On the Export Contacts popup, click on the Get Results button and download the Microsoft Excel Worksheet on the system.

5. On the downloaded file, click on the Metadata_Header tab to view the header details i.e.,
    a. Room name
    b. Exported On
    c. Exported By
    d. Time zone



6. Click on the Metadata tab, to view the contact details and the metadata.



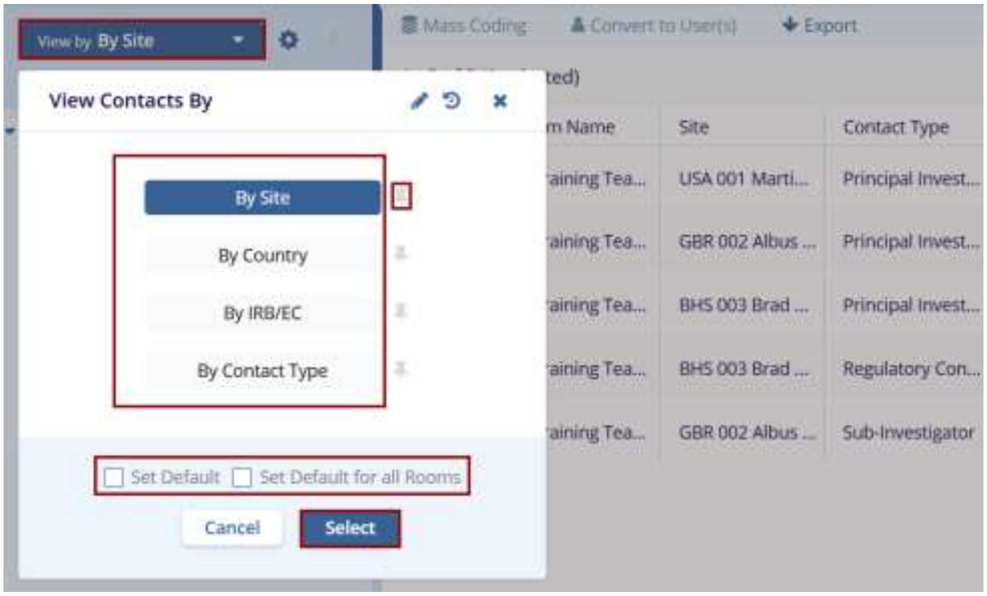
Contact Views

To access and configure the contact views, follow the steps below.

1. On the Contacts screen, click on the View by dropdown.
2. On the View Contacts By window, select a view by clicking on the view name.

    a. By Site: Displays the contacts grouped by the site.
    b. By Country: Displays contacts grouped by their country association.
    c. By IRB/EC: Displays contacts grouped by the IRB/EC.
    d. By Contact: Displays contacts grouped by the Contact Type.

3. Click on the pin icon to pin a view and this view is selected once user access the Contacts modal.
4. Check the Set Default checkbox to set the view as a default and Set Default for all Rooms to apply the view to all rooms.
5. Click on the Select button once the desired view is selected.



Customize Contacts views

Users can customize the contacts screen view by Managing columns and configuring views.

To manage columns and views on the Contacts screen, refer to the standard steps detailed in the Manage Columns section.

COUNTRIES

To access the countries modal, follow the steps below.

1. Click on the modules dropdown and select the Collaborative Workspace module.
2. From the left-hand navigation menu, select the Countries modal.
3. The Countries screen displays the configured organizations and their associated data in the following columns.

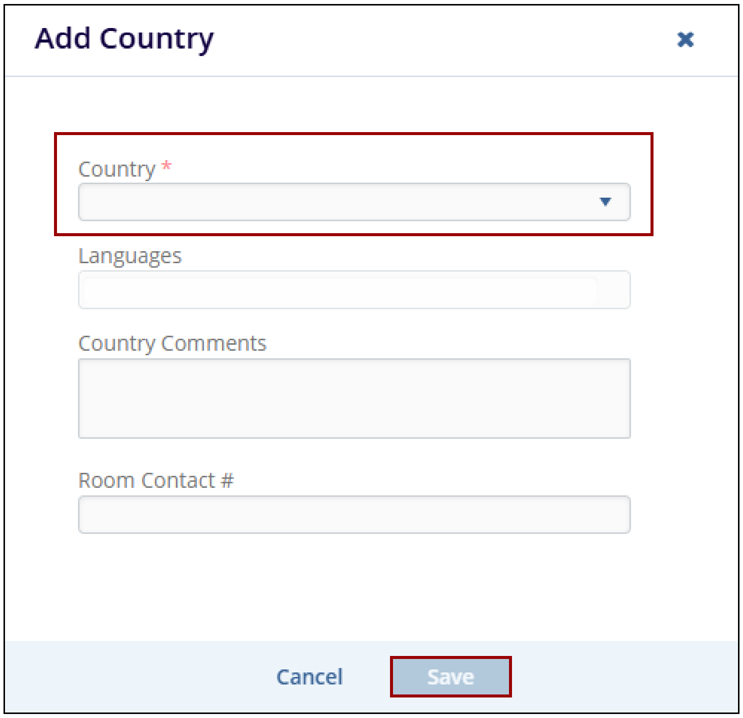
    a. Country
    b. Status
    c. Sites
    d. Language

Add Countries

To add a country, follow the steps below.

1. In the Collaborative Workspace module, go to the sidebar and click on the Countries modal.
2. Click on the +Add button at the top of the grid.

3. In the Add Country form, select a country from the Country drop-down list.
4. Optionally, fill in additional details i.e., Languages, Country Comments, and Room Contact # etc.



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

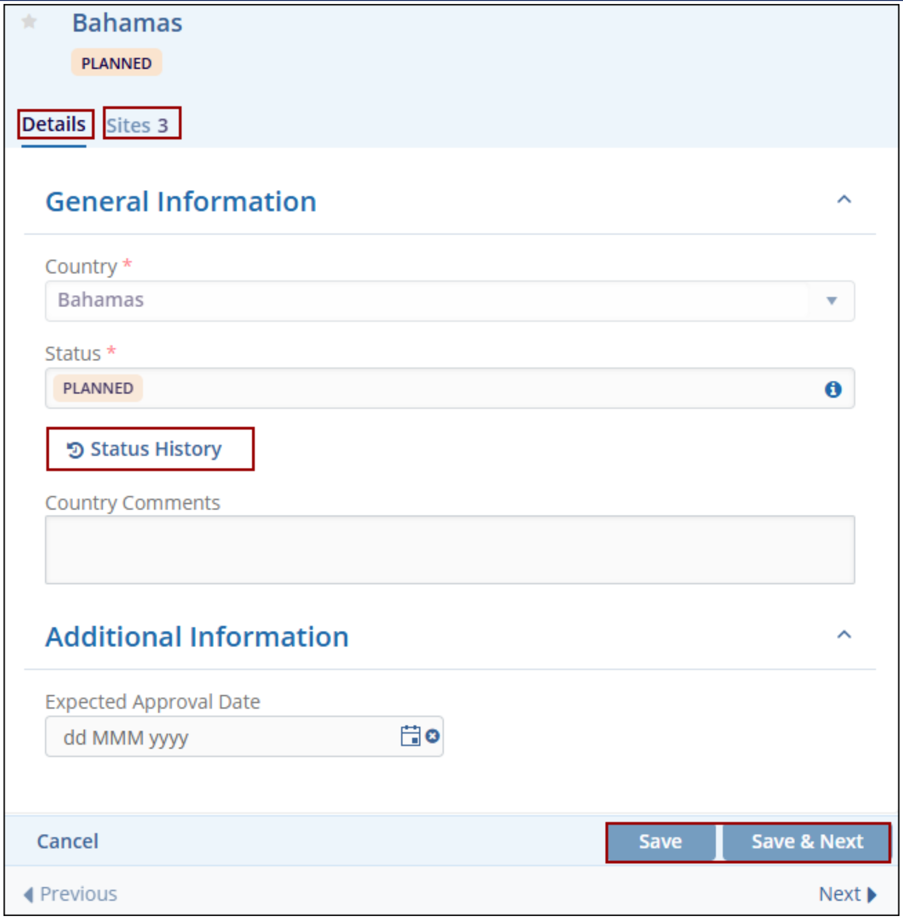
Edit Countries

To edit a country in the Collaborative Workspace module, follow one of the methods below.

Method 1

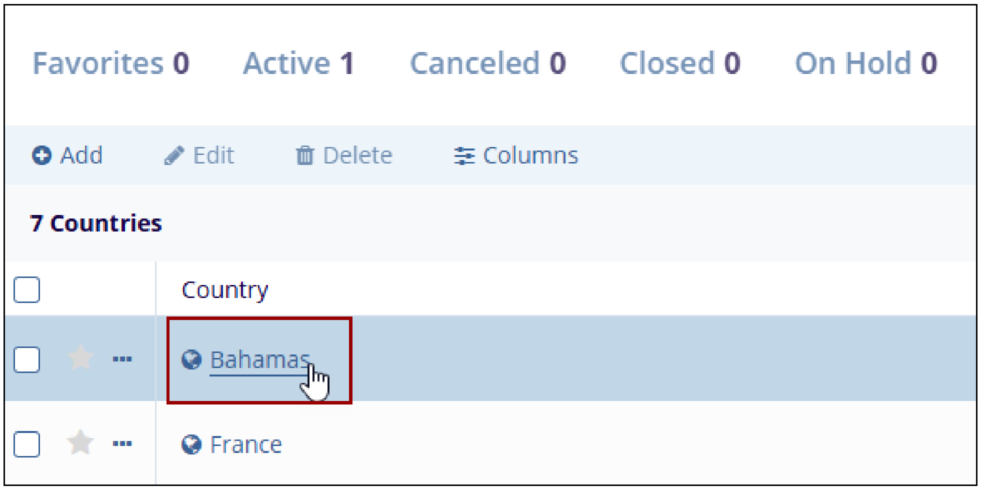
1. On the Countries screen, select the country to edit by checking the box next to its name.
2. Click on the Edit button. This opens the Edit Country panel on the right side of the screen.

3. In the Edit Country panel, make the necessary changes under the Details tab.
   - Under General Information, update the Country name and Status if needed.
   - Add or modify Country Comments as required.
   - In Additional Information, set or update the Expected Approval Date.
4. Click on the Sites tab to view the sites associated with the country.
5. Click on the Status History button to view the status changes and users responsible for changing the status.
6. Once the desired changes are made, click on the save button Save to apply the updates, or Save & Next button to edit the next country in the list.



Method 2

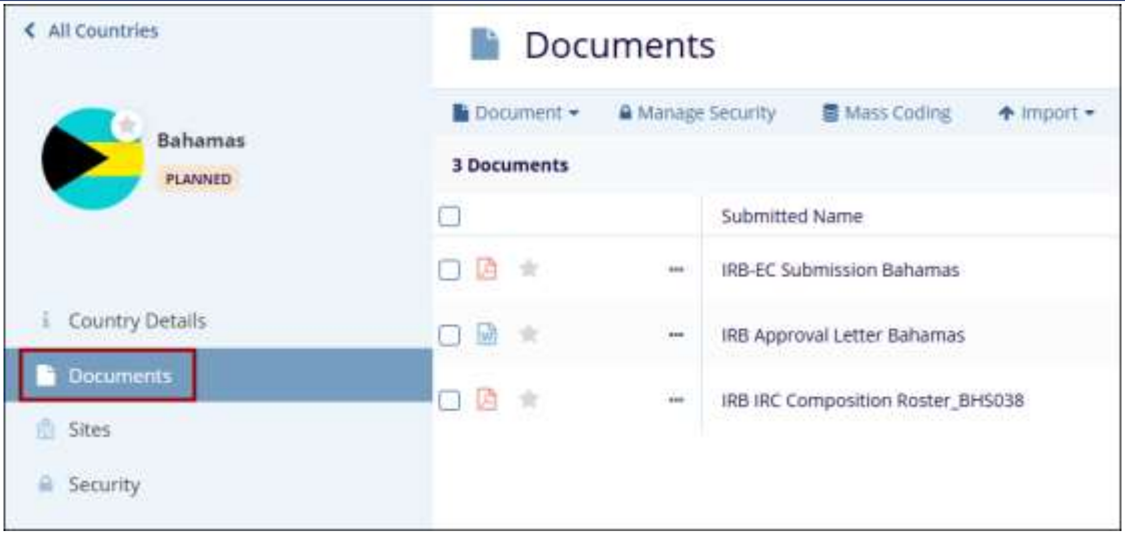
1. On the Countries screen, click on the country name to edit.



2. On the Country Details screen, Click on the Edit button.

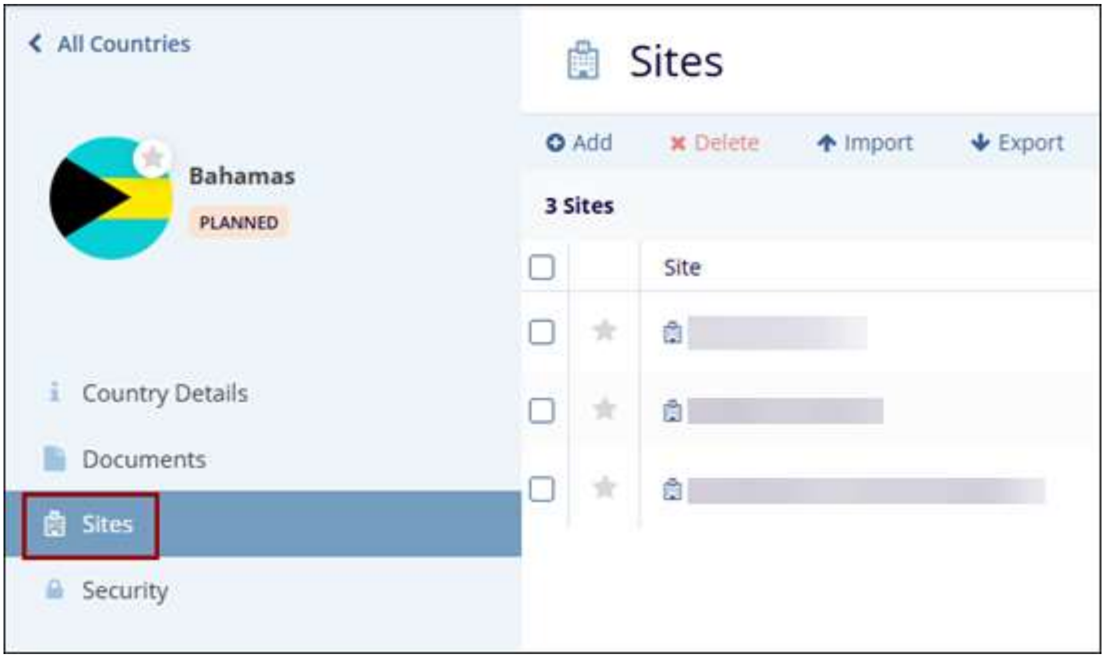
3. Make changes to the General and Additional Information sections and click on the Save button.

4. Click on the Documents tab from the left-hand navigation pane to add documents and access other functions.



Note: Refer to the [Documents Library - Top Menu Ribbon] section to add documents and perform the other functions.

5. Click on the Sites tab from the left-hand navigation pane to add and access other functions.



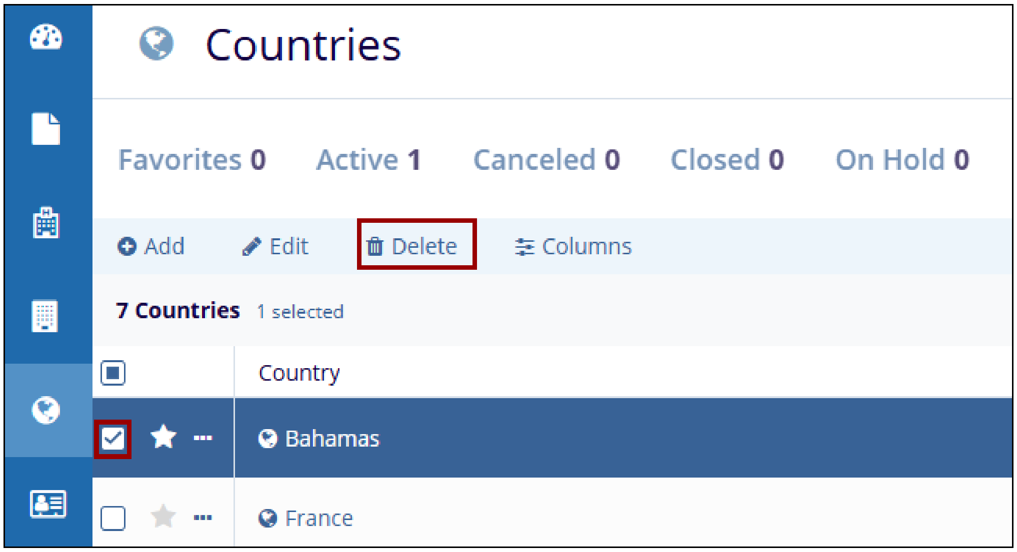
Note: Refer to the Sites section to add sites and perform the other functions.

6. Click on the Security tab from the left-hand navigation pane to grant users, the necessary access permissions.

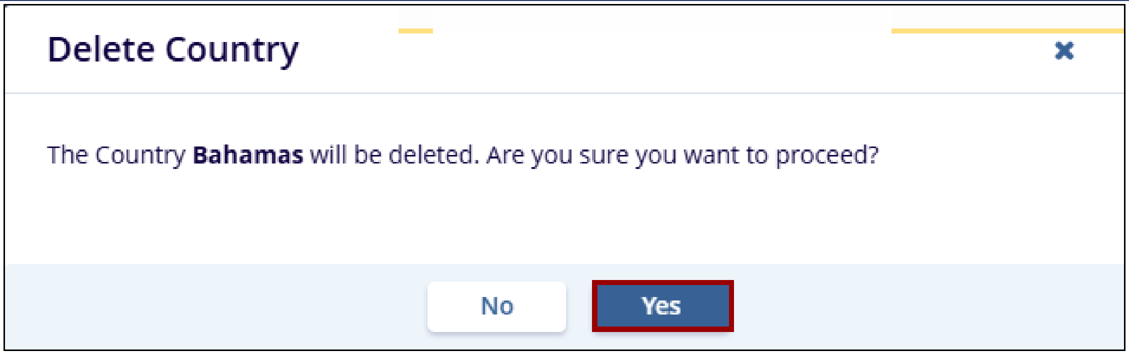
Delete Countries

To delete a country in the Collaborative Workspace module, follow the steps below.

1. On the Countries screen, select the country to delete by checking the box next to its name.
2. Click on the Delete button.



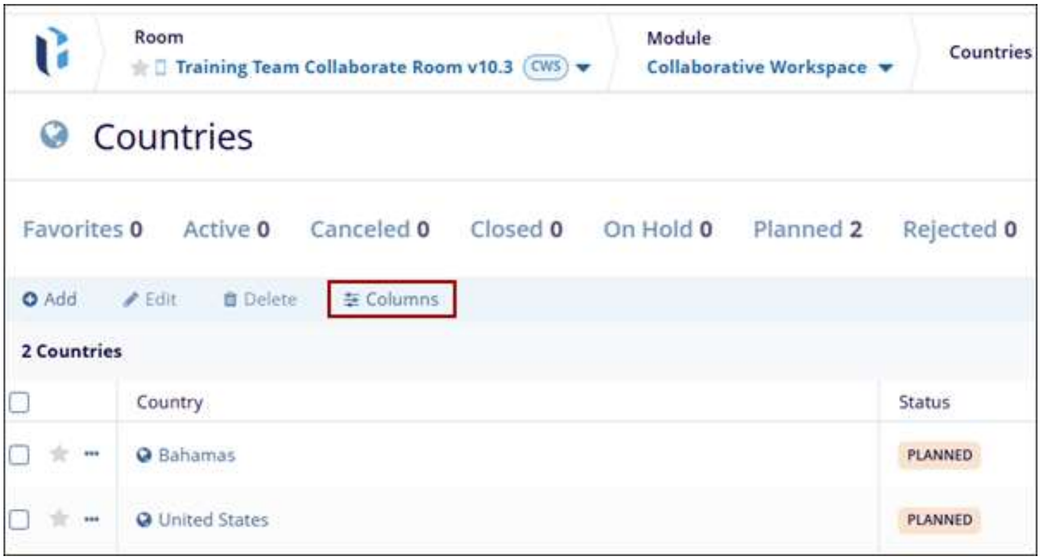
3. On the Delete Country confirmation popup, click on the Yes button.



Manage Columns

To Manage columns within the countries screen, follow the steps below.

1. On the Countries screen, click on the Columns button in the toolbar at the top of the grid.



2. To manage columns and views on the Countries screen, refer to the standard steps detailed in the [Manage Columns](#) section.

AUDIT TRAIL

An Audit Trail is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed 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 Collaborative Workspace module, follow the steps below.

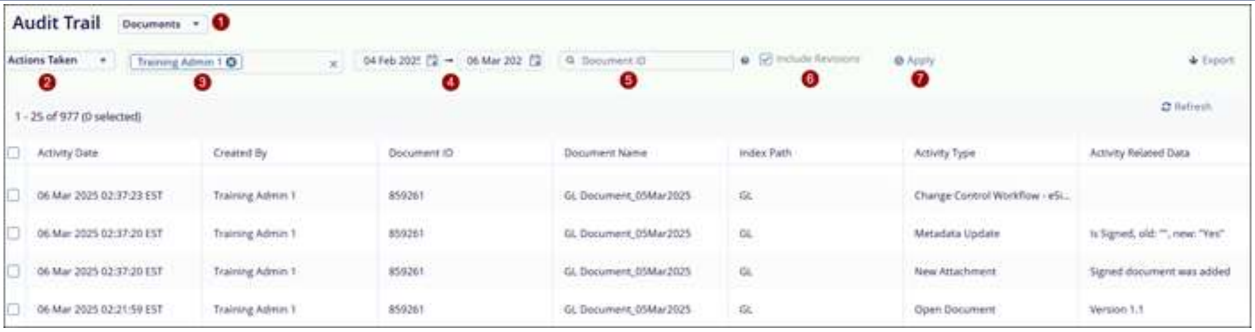
1. Click on the Module dropdown and select the Collaborative Workspace option.
2. On the Collaborative Workspace screen, navigate to the left-hand menu and select the Audit Trail modal.

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., Documents, Deleted 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. Check the Include Revisions checkbox for the Documents and Deleted Documents parameter.
7. Click on the Apply button.



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

Note: Refer to the sections below to understand filters, parameters, and other actions within the Audit Trail modal.

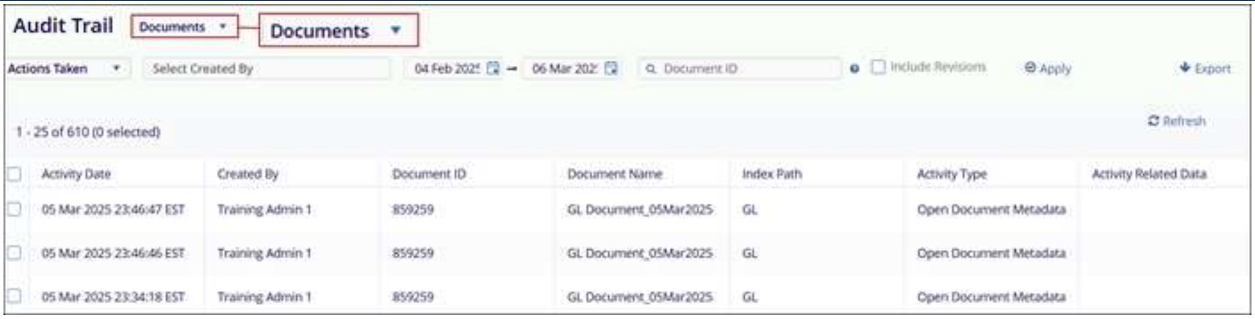
Audit Trail Parameters

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

- Documents
- Deleted
- Folders
- Placeholders
- Users

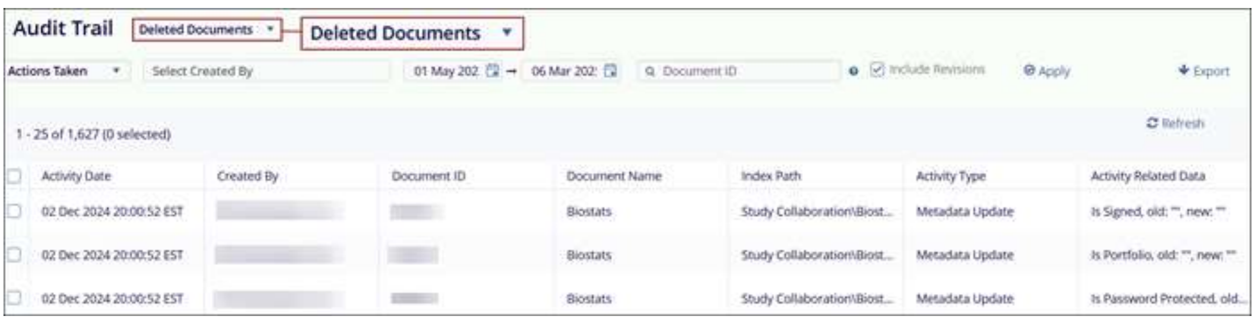
1. User Interface for Documents: When the audit trail for collaborate documents is retrieved, the data is presented in the following columns.

    a. Activity Date
    b. Created By
    c. Document ID
    d. Document Name
    e. Index Path
    f. Activity Type
    g. Activity Related Date



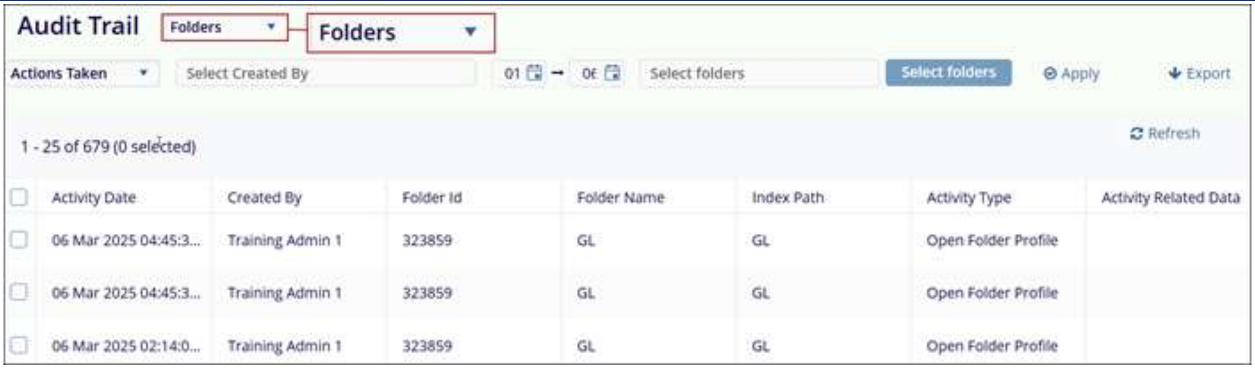
2. User Interface for Deleted Documents: When the audit trail for Deleted Documents is retrieved, the data is presented in the following columns.

   a. Activity Date
   b. Created By
   c. Document ID
   d. Document Name
   e. Index Path
   f. Activity Type
   g. Activity Related Date



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

   a. Activity Date
   b. Created By
   c. Folder ID
   d. Folder Name
   e. Index Path
   f. Activity Type
   g. Activity Related Date

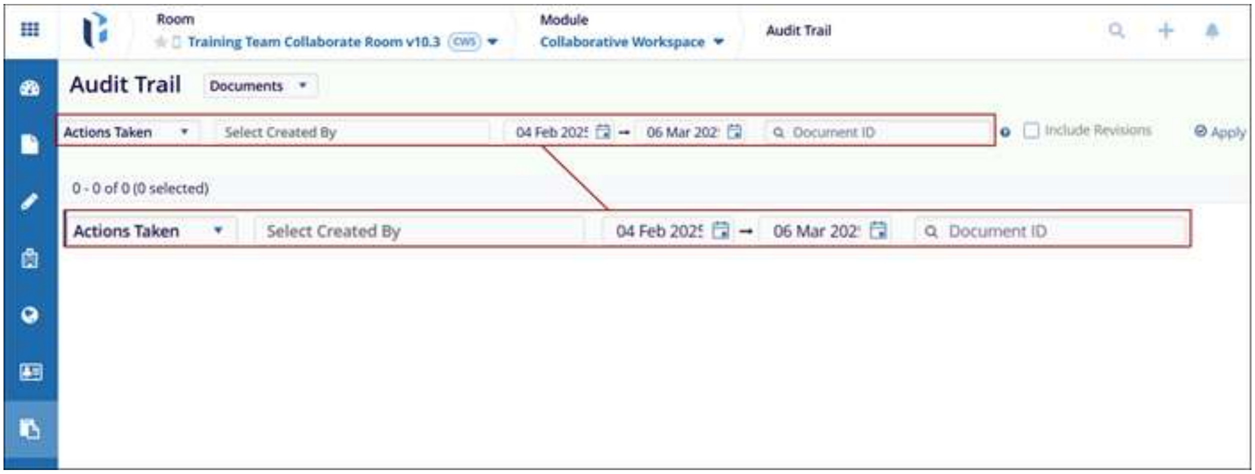


4. Placeholders: When the audit trail for Placeholders is retrieved, the data is presented in the following columns.
    a. Activity Date
    b. Created By
    c. Placeholder ID
    d. Placeholder Name
    e. Index Path
    f. Activity Type
    g. Activity Related Date

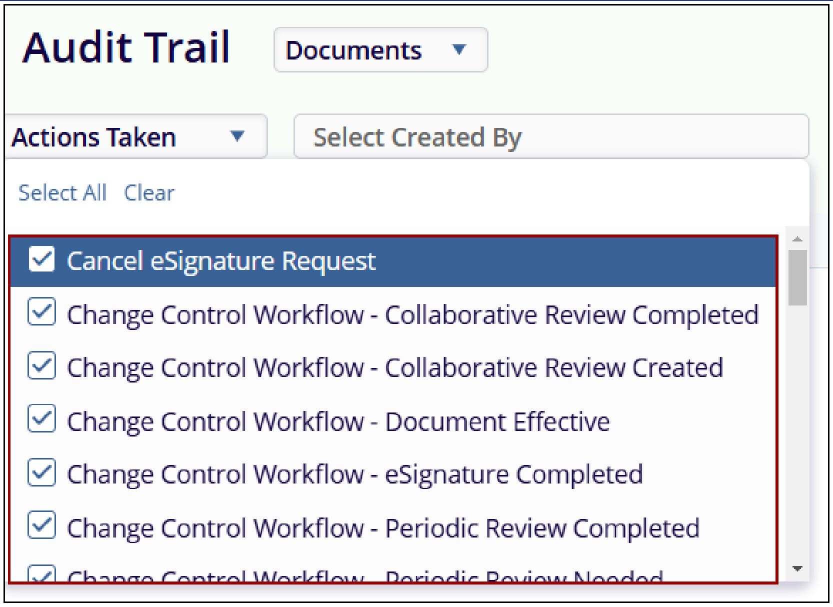
5. Users: When the audit trail for Users is retrieved, the data is presented in the following columns.
    a. Activity Date
    b. Created By
    c. User ID
    d. User Full Name
    e. User Email Address
    f. Activity Type
    g. Activity Related Data

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.



Following are the actions associated with each parameter.

- Documents
  - Cancel Signature Request
  - Change Control Workflow-Collaborative Review Completed
  - Change Control Workflow-Collaborative Review Created
  - Change Control Workflow-Document Effective
  - Change Control Workflow-eSignature Completed
  - Change Control Workflow-Periodic Review Completed
  - Change Control Workflow-Periodic Review Needed
  - Change Control Workflow-Periodic Review Started
  - Check In Document after Editing
  - Check Out Document after Editing
  - Copy Document From Room
  - Delete Attachment
  - Delete Document
  - Document Edit Mode Switched
  - Document Shared from Room
  - Document Shared to Room
  - Edit Document Online Accessed
  - Move Document to folder
  - Metadata Update
  - eSignature
  - Export Document
  - Lock Document Profile
  - New Attachment
  - New Document Profile
  - Open Document
  - Open Document Metadata

  - QC Workflow – Approve Document
  - QC Workflow – Claim Document
  - QC Workflow – Release Document
  - QC Workflow – Swim Lane
  - Replace Attachment
  - Save Document
  - Security Update
  - Send eSignature Request
  - Set Document Start Version
  - Unlock Document Profile
  - Update Default Field Value

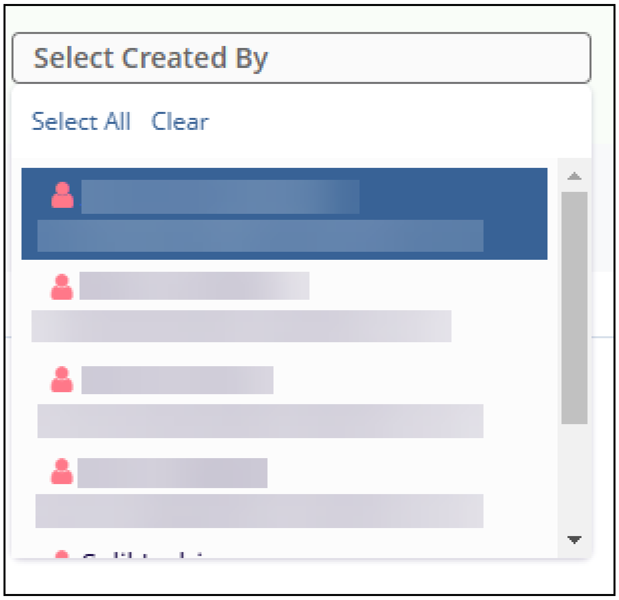
- Deleted Documents
  - Change Control Workflow-Collaborative Review Completed
  - Change Control Workflow-Collaborative Review Created
  - Check In Document after Editing
  - Check Out Document after Editing
  - Delete Document
  - Edit Document Online Accessed
  - Move Document to folder
  - Metadata Update
  - Lock Document Profile
  - New Attachment
  - New Document Profile
  - Open Document
  - Purge Document
  - Security Update
  - Unlock Document Profile
  - Update Default Field Value

- Folder
  - Change Control Workflow – Document Approved
  - Edit Folder
  - Metadata Update
  - Check Out
  - New Folder
  - Open Folder Profile
  - Security Update
  - Check In
  - Update Document Sort Order in a folder

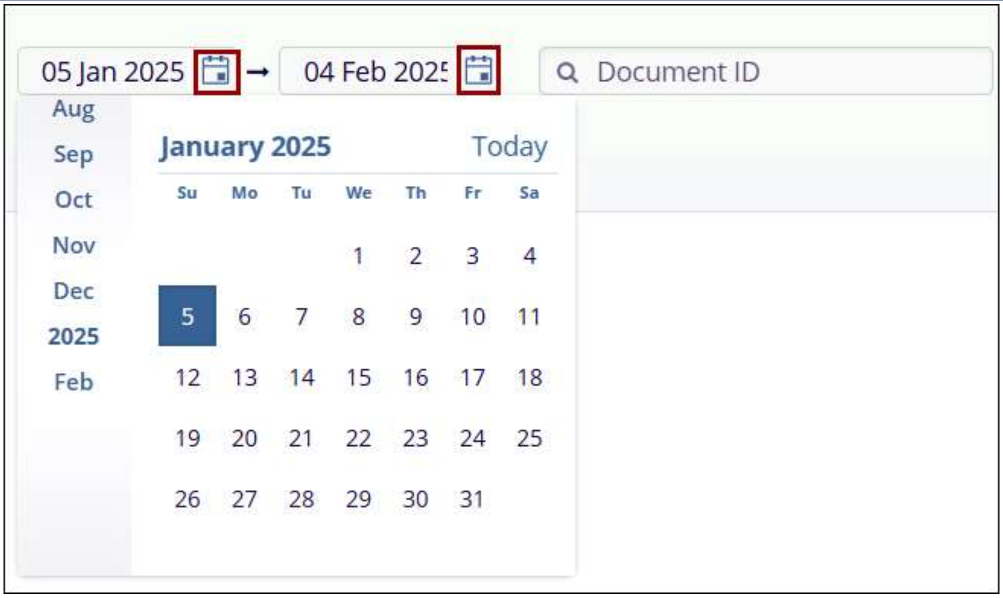
- Placeholder
  - Delete Placeholder
  - Metadata Update
  - Security Update

- Users
    - Assign Group Actions to User
    - Assign User Actions
    - Edit User
    - New User
    - Pending User
    - Remove User from Group
    - Reset Password
    - Sign In to Room
    - User Access Level Update
    - User Invitation
    - User Registration
    - User was deactivated
    - User was reactivated

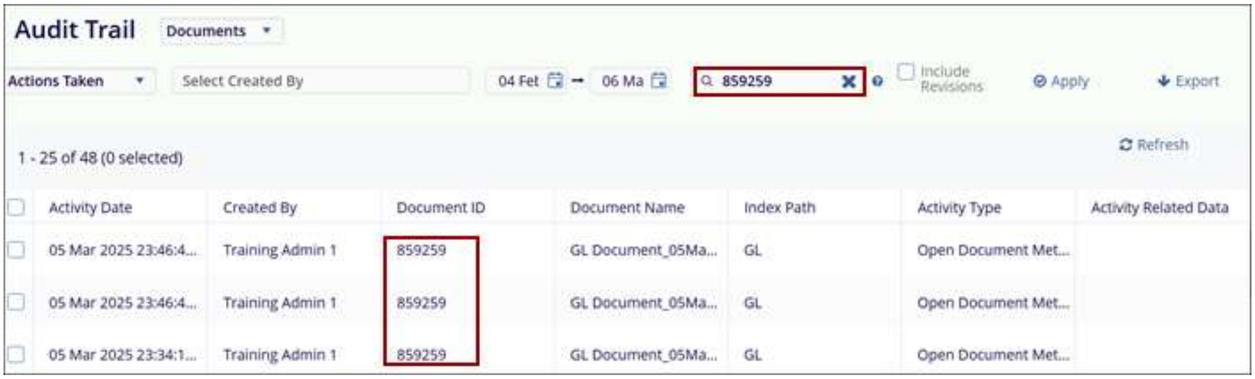
2. Select Created By: In the Select Created By field, users can specify one or more usernames associated with document creation. When a username is selected, the Audit Trail screen filters and displays records corresponding to the specified user.



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 trial 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.



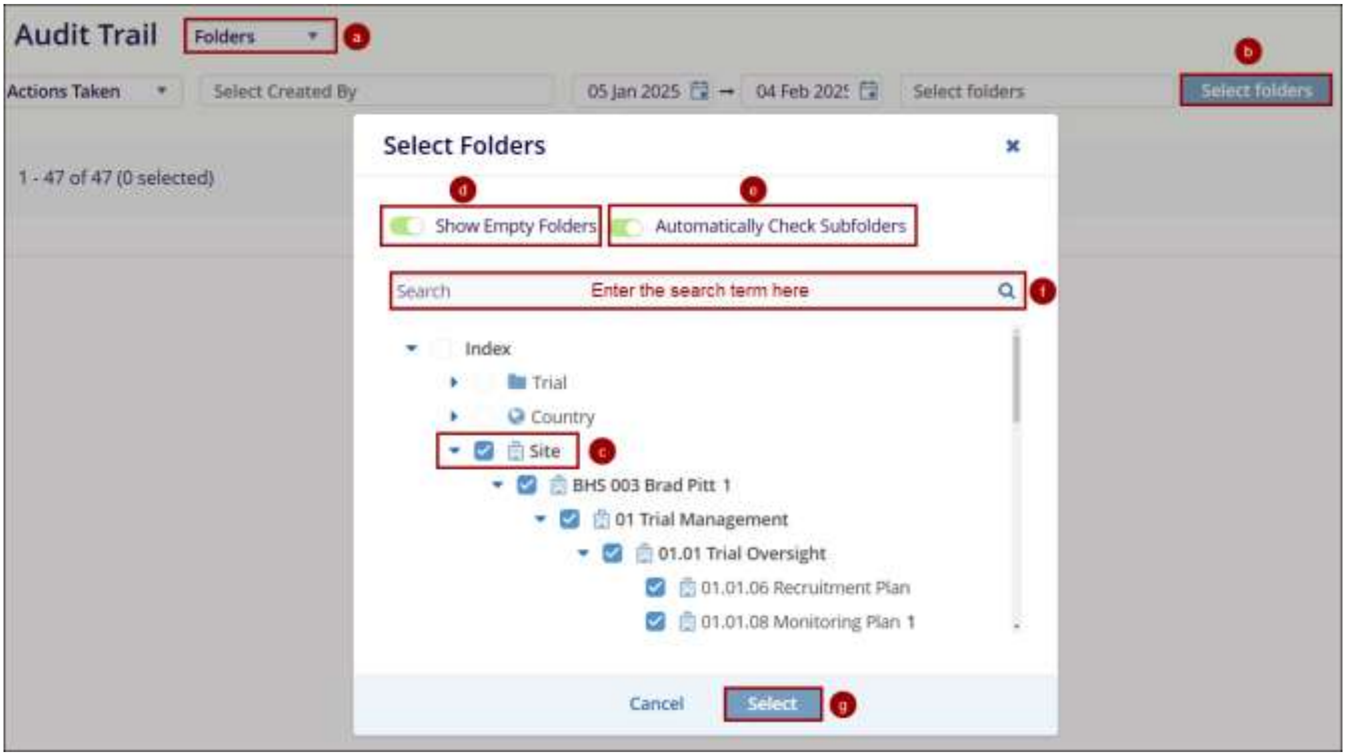
Note: The Document ID Filter is applicable only for Documents and Deleted Documents.

5. Select Folders: The Select Folders field allows users to specify certain folders and retrieve the audit trail for those specified folders.

   To specify folders, follow the steps below.

   a. Select Folders as the parameter.
   b. Click on the Select Folders button.
   c. On the Select Folders screen, expand the desired category and select the folder.
   d. Toggle on the Show Empty Folders switch to display empty folders.
   e. Enable the Automatically Check Subfolders toggle switch to automatically select folders associated with the parent category.
   f. To search for a specific folder, enter the search term in the Search box.

g. Click on the Select button.

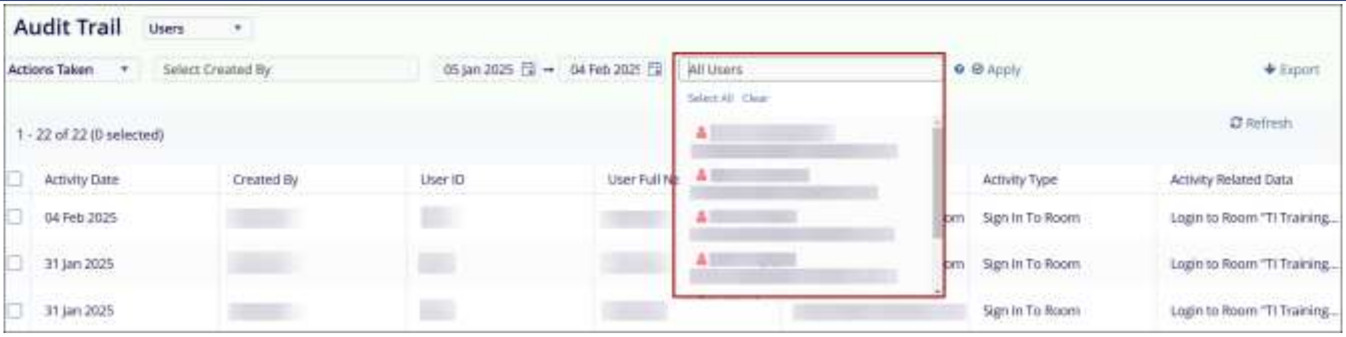


Note: The Select Folders Filter is applicable only for the Folders parameter.

6. Placeholder ID: The Placeholder ID field allows users to retrieve audit trial 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 filter 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.



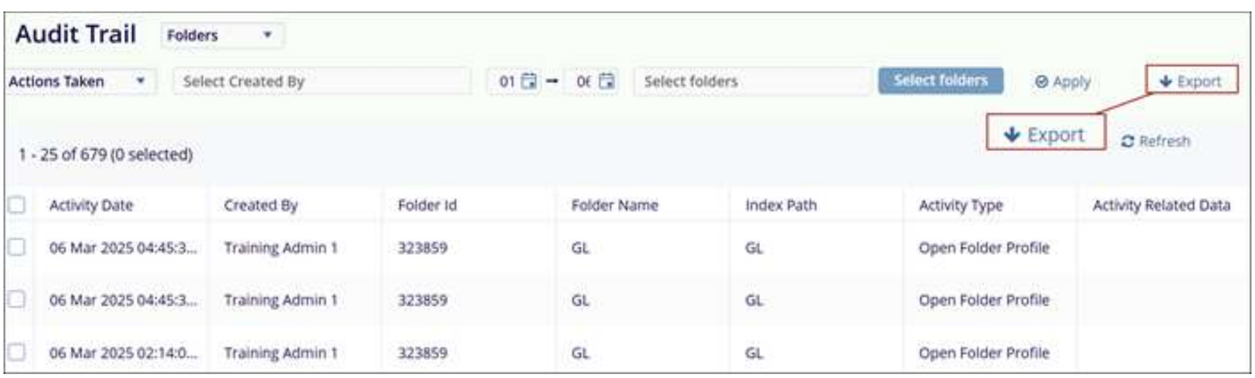
Note: The All Users filter is applicable only for the User's parameter.

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.

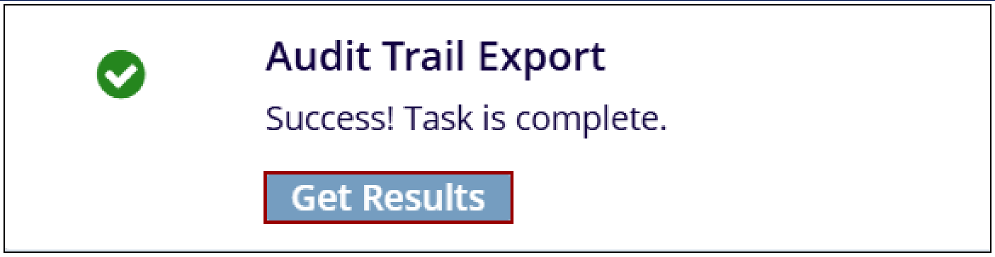
Export Audit Trail

To export the Audit Trail data, follow the steps below.

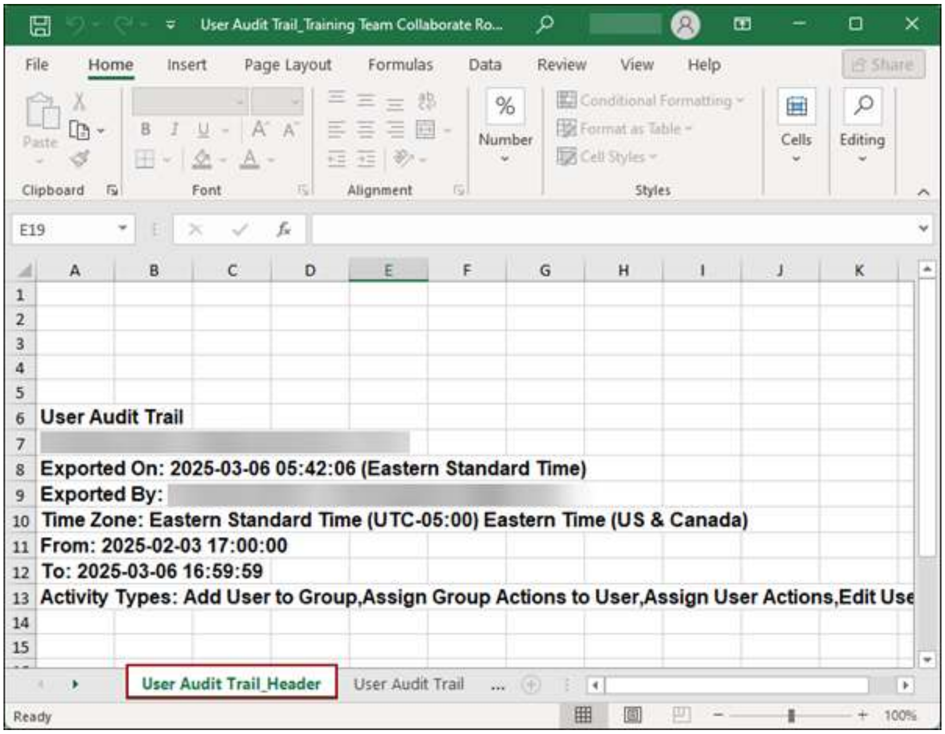
1. On the Audit Trail screen, click on the Export button.



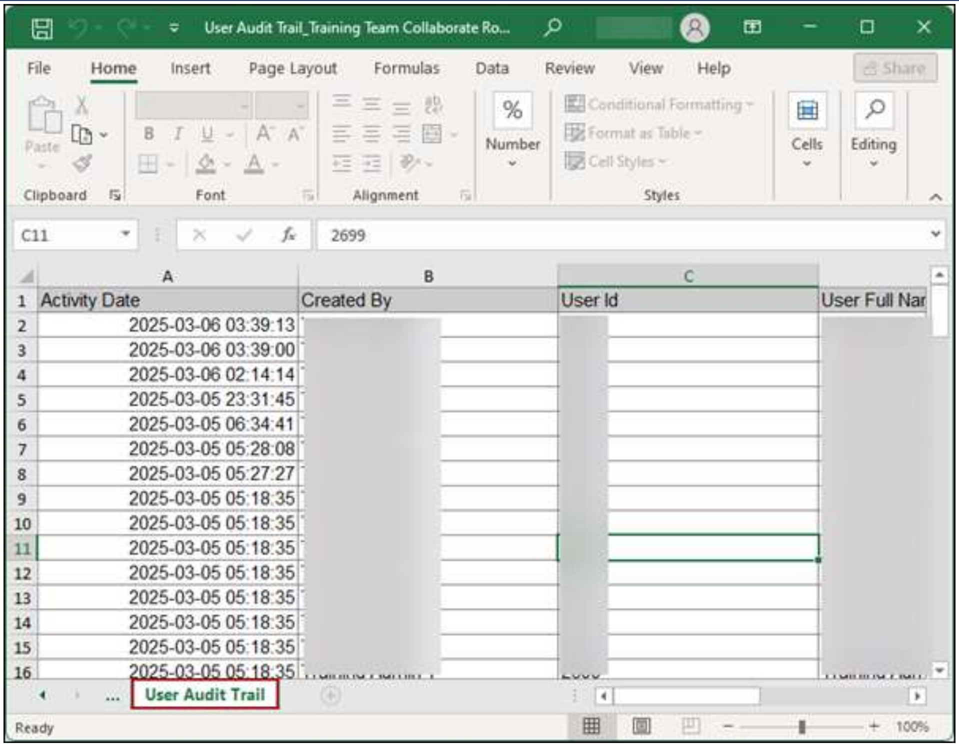
2. On the Audit Trail Export popup displaying the success message, click on the Get Results button to download MS Excel Worksheet containing the export data.



3. On the downloaded file, click on the Audit Trail_Header tab to view the header related details.



4. Click the Audit Trail tab to access audit trail details.


User Audit Trail_Training Team Collaborate Ro...
File
Home
Insert
Page Layout
Formulas
Data
Review
View
Help
Share
Paste
Clipboard
Font
Alignment
Number
Conditional Formatting
Format as Table
Cell Styles
Styles
Cells
Editing
C11
2699
Activity Date
Created By
User Id
User Full Nar
2025-03-06 03:39:13
2025-03-06 03:39:00
2025-03-06 02:14:14
2025-03-05 23:31:45
2025-03-05 06:34:41
2025-03-05 05:28:08
2025-03-05 05:27:27
2025-03-05 05:18:35
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User Audit Trail
Ready
100%

SAFETY LETTER MANAGEMENT SOLUTION

This solution description provides a high-level description of the Safety Letter Management solution. This description is designed to inform TransPerfect personnel and to facilitate discussions between customer-facing TransPerfect personnel and existing customers. It is intended to be used in conjunction with the Safety Letter Management solution configuration manual to provide a complete overview of the solution.

Overview

Trial Interactive's Safety Letter Management solution provides a validated, dedicated repository to electronically store and track safety letters and investigative site acknowledgments for products that are being studied in clinical trials. It provides a mechanism for sponsors to ensure that responsible staff members at their investigative sites have been notified and proactively acknowledge the notification in a validated, secure repository. The solution also enables a review team to follow essential processes for information collection and document access.

Safety Letter Management Solution

A Safety Letter Management solution is essential for tracking pharmacovigilance (PV) and other product safety notices because it ensures the continuous monitoring of the safety profile of drugs or other medical products during clinical trials as well as on the market. The primary goals of the Safety Letter Management solution are to store and provide information about safety notices related to adverse product events. The Safety Letter Management solution within TI is just one piece of a multi-layered safety system.

What does the solution do?

- Utilizes Site Module to build out investigative sites, add contacts, and assign acknowledgment responsibility to contact(s) at investigative sites.
- Leverages acknowledgments in the system to ensure all safety event-related documents have been viewed and acknowledged by the appropriate site personnel
- Offers an optional workflow and document management process to author, collaborate on, and approve letters for distribution.
- Full 21CFR11 compliant audit trail, tracking user, document, and workflow actions
- Provides streamlined, configurable folder structure for storing and managing safety letters within the system.
- Provides flexibility to include a mechanism for external distribution of safety letters via attachment, tracked in the communication module, for sites or users who will not be acknowledged within the system.
- Leverages configuration to support storage of over 250 file types
- Documents are stored with consistent naming conventions based on configurable metadata, allowing safety/clinical team members and site personnel to easily identify the study, safety database ID, event date, and other relevant information simply by viewing the document name.
- Provide notification and direct document links to site personnel when they are

required to acknowledge a document.
- Provides a central view for all outstanding, overdue, and completed acknowledgments for sites and for sponsor/CRO personnel.
- Report to show compliance data by investigative site.
- Mechanism for clinical/safety personnel to cancel, resend, and/or send reminders to responsible site personnel directly from the document.

System/Technical Requirements

- Standard Trial Interactive browser requirements apply to the Safety Letter Management Solution.
- It is assumed that the system has no practical limit to the number of authorized users who are asked to acknowledge documents and/or are accessing them within the room.
- This solution has TransPort Translations enabled to easily request a certified translation of any documentation.
- This solution can perform a Quality Review for oversight.

High-level technical capabilities:

- Users can view, and modify metadata on documents within a workflow if desired and configured
- Users can Copy/move documents between rooms if desired and configured
- Users can perform translation requests for certified translations if desired and configured
- Users can run reports on Inventory, KPIs, User Access
- Ability to access Audit Trail
- Ability to add or remove user access
- Ability to designate site contact as required to perform acknowledgments in the system.
- Ability for Sites to be chosen based on Site-level metadata search when sending acknowledgment requests, with users auto-populated based on their acknowledgment designation in their contact profile. Additional users can be added as/if desired.
- Ability to send acknowledgment documents via built-in email mechanism to one or multiple site contact personnel, with tracking in the communications outbox module.

Solutions available for interoperability:

- Translations Portal
- GlobalLearn
- TI Connector
- eTMF
- eISF

Target Audience and Business Use Cases

Target Audience and Intended Users

With Life Sciences Sponsors and CROs being the target audience, the Business Lead will understand the requirements for continuous safety letter management, acknowledgments, and tracking.

The audience of this solution depends on the organization but may include the following groups.

- Pharmacovigilance staff including safety coordinators
- Medical monitor/medical SMEs
- Product Management
- Regulatory Staff
- Clinical Team Members
- Other Study Team Members
- Sponsor (when utilized by a CRO)
- CRA/Monitors (for oversight with sites)

Business Use Cases

In clinical research, sponsors need to track safety letter acknowledgments with investigative sites for several critical reasons:

1. Regulatory Compliance: Sponsors are required to adhere to regulatory guidelines set by authorities like the FDA, EMA, and others. These agencies mandate that all safety information, such as updates on adverse events, product recalls, or safety warnings, be communicated to all parties involved in the clinical trial, including investigative sites. Tracking the acknowledgment of safety letters ensures that the sponsor complies with these regulations.
2. Subject Safety: The primary goal of clinical trials is to ensure the safety of participants. Safety letters typically contain crucial updates on potential risks or newly discovered adverse events related to the investigational product. Tracking whether the investigative sites have received and acknowledged these safety updates helps ensure they are implementing necessary changes to protect participants.
3. Proper Site Response: Investigative sites must take appropriate actions in response to safety concerns, whether that means adjusting protocols, modifying informed consent documents, or monitoring subjects more closely. By tracking acknowledgments, sponsors can verify that sites are aware of safety issues and are acting accordingly.
4. Documentation and Auditing: Sponsors are required to maintain accurate records for auditing purposes. If there is ever a question about whether safety information was communicated properly, being able to track acknowledgments from the investigative sites provides a documented trail to demonstrate that the sponsor fulfilled their obligations.
5. Effective Communication: Ensuring that safety letters are acknowledged by investigative sites helps facilitate ongoing communication between sponsors, sites, and other stakeholders. This contributes to smooth operations and helps identify any potential gaps in information or misunderstandings.

6. Risk Management: In clinical trials, it's important to anticipate and mitigate risks, including those related to participant safety. Tracking safety letter acknowledgments is a form of proactive risk management, ensuring that everyone involved in the study has the latest safety information and is aligned on how to respond to any emerging issues.
7. By properly tracking these acknowledgments, sponsors help ensure the integrity of the study, safeguard participants, and maintain compliance with industry regulations.

Example Use Case:

Contract Research Organization – tracking for single or multiple studies for their Sponsor

A Sponsor has contracted their CRO to manage the distribution of safety letters to investigative sites that are participating in their clinical trial(s). When events occur, they are tracked and managed by the CRO Safety (Pharmacovigilance) team within their Safety Database (Argus, ArisG, and Veeva Safety as examples). These cases have strict timelines that they are required to meet for reporting, depending on the seriousness of the event and other factors. After the event has been recorded, the investigative sites that are presently utilizing the study drug are required to be notified of the safety event. The Safety Letter Management solution provides a secure and compliant method to record the acknowledgement requests to sites and their response. It provides the CRO and Sponsor with the ability to provide proof to regulatory bodies that the notifications were made and that the sites viewed the material.