TRIAL INTERACTIVE

Reader User Guide v10.1

TRANSPERFECT LIFE SCIENCES

APPROVALS

Product Owner

Name: **JAY SMITH**	Title: Sr. Director, Product
Refer to the approval captured in the "Trial Interactive: v10.1 - User Guide Approval v1" on 25-Sep-2020.	

Quality Assurance

Name: **SCOTT JORDAN**	Title: Director, Quality Assurance
Refer to the approval captured in the "Trial Interactive: v10.1 - User Guide Approval v1" on 25-Sep-2020.	

VERSION HISTORY

Author	Revision #	Date	Comment
Steve Clark	1.0	25-Sep-2020	Initial document created

Contents

Chapter 1. Trial Interactive 10.1- Overview and Features

Hardware and Software Requirements

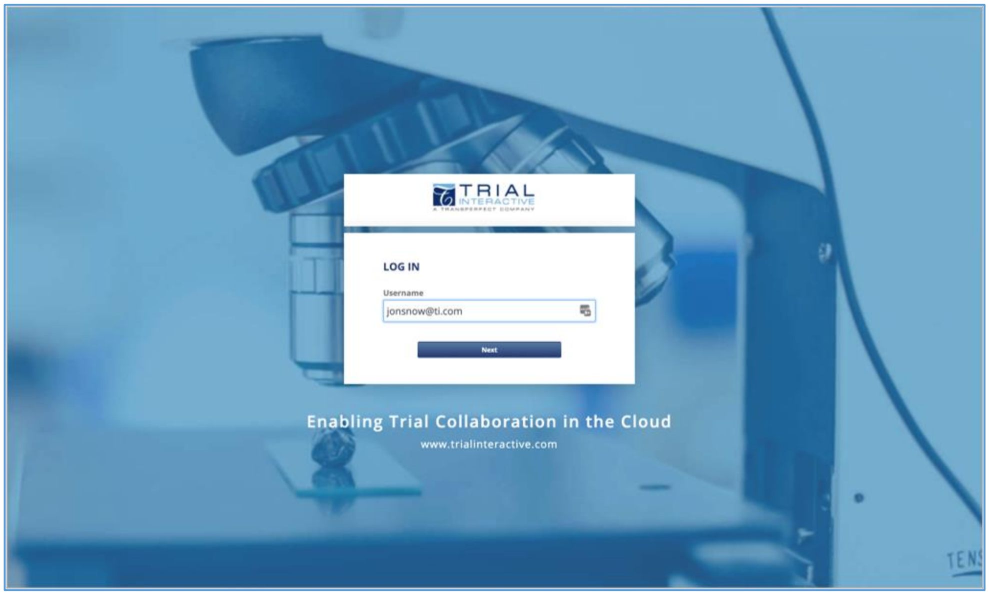
The following describes the hardware and software requirements to use the Trial Interactive eTMF platform.

OS	• Windows Version 7 or higher • All currently supported Mac OSX releases • iOS and Android for myTI mobile app (see myTI release notes)
Browser	• Microsoft Edge: Version 20 or later (officially supported versions by Microsoft only) • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • Internet Explorer: Version 11 or later NOTE: Microsoft® stopped supporting Internet Explorer™ 8 and Internet Explorer™ 9 in January 2016 and will stop support for Internet Explorer™ 10 in January 2020. Beginning with the release of TI 10, we expect slight degraded performance with Internet Explorer™ 11, and no longer support Internet Explorer™ 10. Users accessing TI with this and older browsers will see in some cases a degraded experience and may have trouble using certain features.
Client Software	• For Edit Online Support, Microsoft Office 2010 SP1 or higher is required • Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. • For SAS Datasets, SAS Viewer or compatible software must be installed. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74
Optional Add-Ons	• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) NOTE: The Snowbound Viewer is now deprecated in TI 10. All features of Snowbound are now available in the TI Viewer.

PLATFORM FEATURES

The improved version of Trial Interactive 10.1 comprises of following Platform features:

Multi-tenant SSO



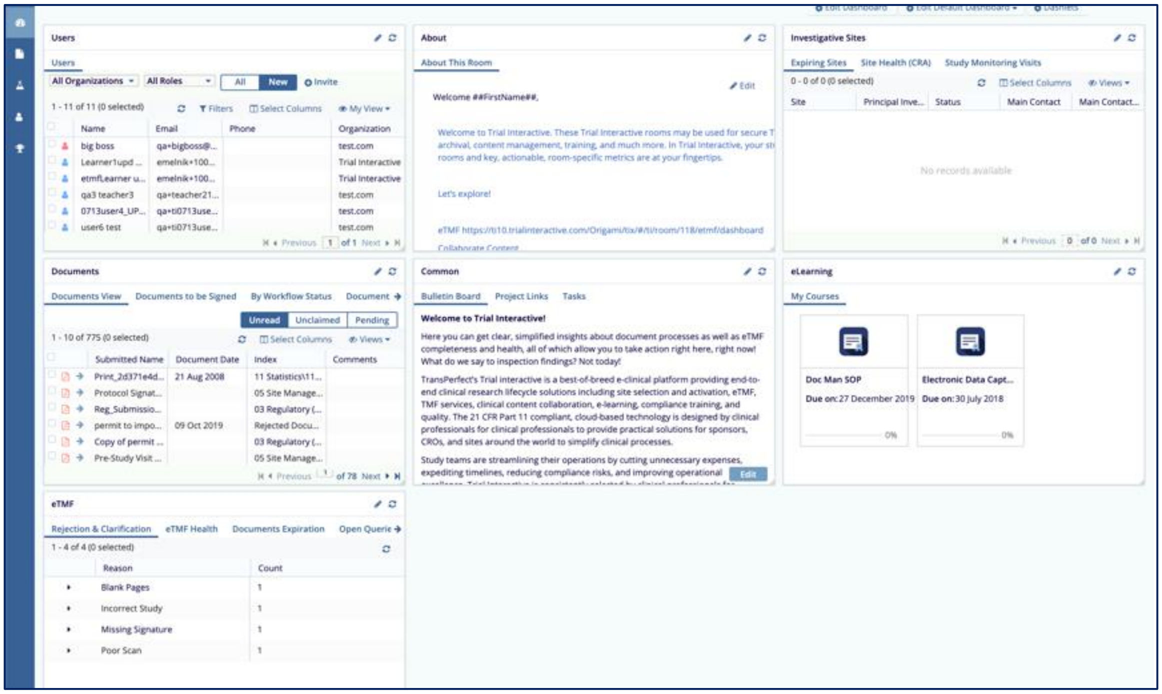
Introduced in 10.1 is support for SAML Federated Single Sign-On for the TI multi-tenant platform. Now, all customer domains on multi-tenant can be configured with single sign-on through their own Corporate Directory, as well as third party IAM providers.

A change to the sign in page has been made to reflect the possibility of multiple providers.

The Trial Interactive sign in page will now first prompt the user for their email address, and based on the domain, will either prompt for a password or redirect to the configured Identity Provider. Users who do not have SSO configured will be directed to the normal login page where they will enter their password.

Please reach out to your Trial Interactive representative to discuss setting up SSO for your organization.

Three-Column Dashboard Layout



Trial Interactive 10.1 brings back the 2 and 3 column look to the dashboards as well as the single column tabbed view introduced in TI 10. This provides more flexibility, allowing dashlets to be repositioned and configured to fit the needs of your team.

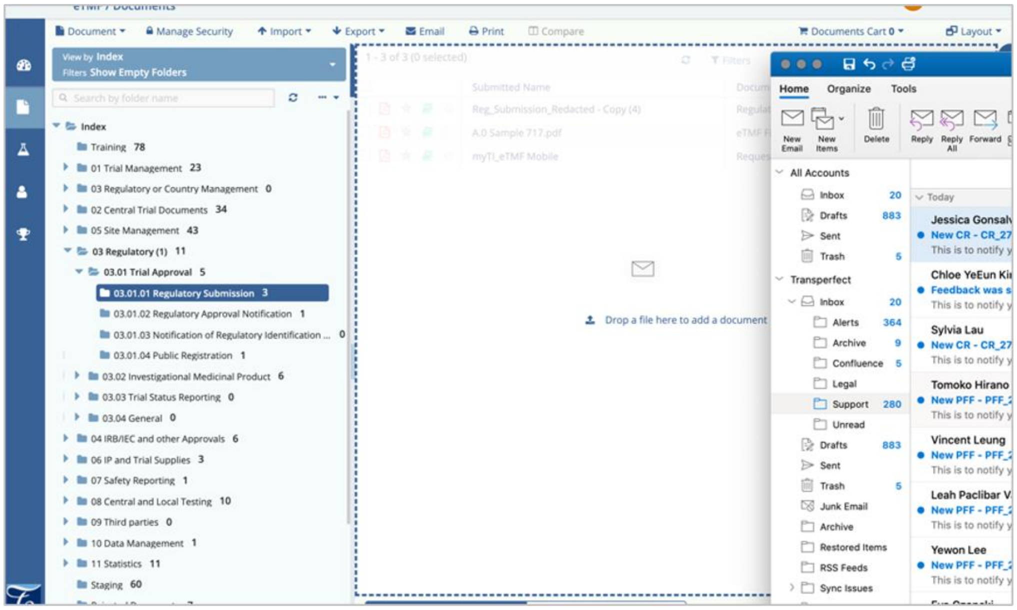
All standard TMF dashlets are available to show in different chart styles, such as donut, horizontal and vertical bar chart layouts.

If project training is required for access it is clearly shown in an eLearning dashlet with courses listed.

For Content Management customers, the in progress collaborative reviews are shown, as are popular documents, favorites, approvals, and required signatures. Finally, administrators can set the default dashlet layout for each major role directly from this page, defining it for all users of the eTMF or room.

In order to enable the multiple column layout, press the Edit Dashboard button on the dashboard and choose Setup Layout. This will enable you to choose the number of columns visible on the dashboard. This can be customized for each of the available dashboards within TI.

Outlook drag and drop



10.1 now supports Microsoft Outlook™ interoperability, fully supporting drag and drop of documents and mail messages in Windows 10™. This provides the following:

- You can drag and drop email messages from MS Outlook into TI and the email will import along with all document attachments. Once in TI, MSG files may be converted to PDF.
- You can drag and drop individual document attachments from an email into TI and the documents will import.
- You can drag and drop a single document or email message onto a folder or placeholder and it will auto-classify.
- You can drag and drop many documents or email messages into the import modal in TI and they will all load into the import box.

Certain browsers such as Mozilla Firefox™ require an Outlook plug-in to fully support this feature. Chrome, Edge, and IE 11 do not require a plug-in. Links to download the required plug-ins will be provided in the online help.

Outlook File Drag

Drag and drop Outlook items as files into any application

Read This First!

Microsoft Edge (as of Windows 10 1709) and Google Chrome (as of version 76) natively support drag and drop from Outlook on Windows. If you use one of these browsers, then this plugin is not necessary.

Overview

Outlook File Drag is an add-in for Outlook 2013 and 2016 that allows you to drag and drop Outlook items (messages, attachments, contacts, tasks, appointments, meetings, etc) to applications that allow physical files to be dropped, such as web browsers.

How does it Work?

When you try to drag and drop from Outlook, Outlook correctly identifies the format as virtual files
(CFSTR_FILEDESCRIPTORW) since the files do not exist directly on disk. Instead, they are contained in a PST file, OST file, or on an Exchange server.

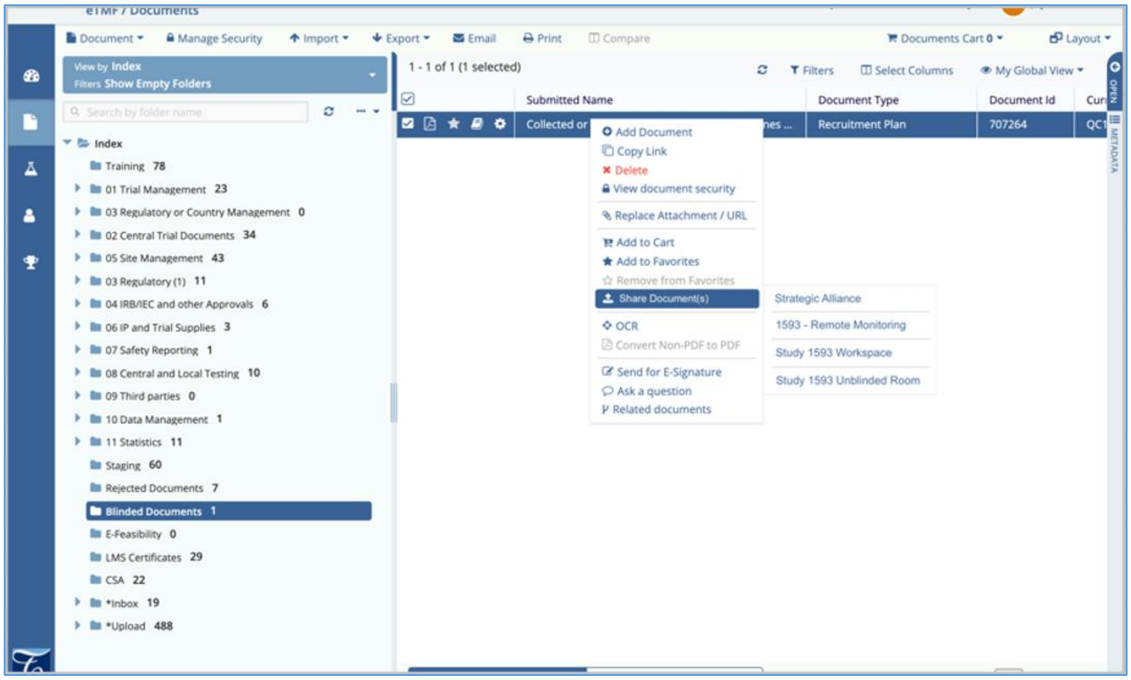
However, many applications do not support this format, such as web browsers and most .NET/Java applications.

To work around this issue, Outlook File Drag hooks the Outlook drag and drop process and adds support for physical files (CF_HDROP). When the receiving application asks for the physical files, the files are saved to a temp folder and those filenames are returned to the application. The application processes the files (such as uploading them). Outlook File Drag deletes the temp files later in a cleanup process.

Features

- Works with Chrome, Firefox, Internet Explorer, Edge, and other applications that accept files to be dropped
- Allows drag and drop into HTML5-based web applications
- Drag e-mails, attachments, contacts, calendar items, and more
- Drag multiple items at once
- Supports Unicode characters

Cross-room document sharing



Content Management in life sciences is a very complex set of relationships that happen across multiple repositories of content, owned by different business units. Clinical needs content management and a TMF system that authors and captures content generated during the planning and execution of a Clinical Trial. Other repositories exist that are owned by Quality, Regulatory, R&D, Commercial, Training, Medical Writing, and many others. Finally, quite often, Clinical needs to keep unblinded content in a separate repository as well as the ability to access site documents from remote monitoring workspaces.

Each of these units broadly has its own workflows, approval cycles, and policies for the management of content. They also have separate owners who want control of the content management and metadata policies within. When it comes to a Clinical Trial, much of this content is archived and ends up in the Trial Master File.

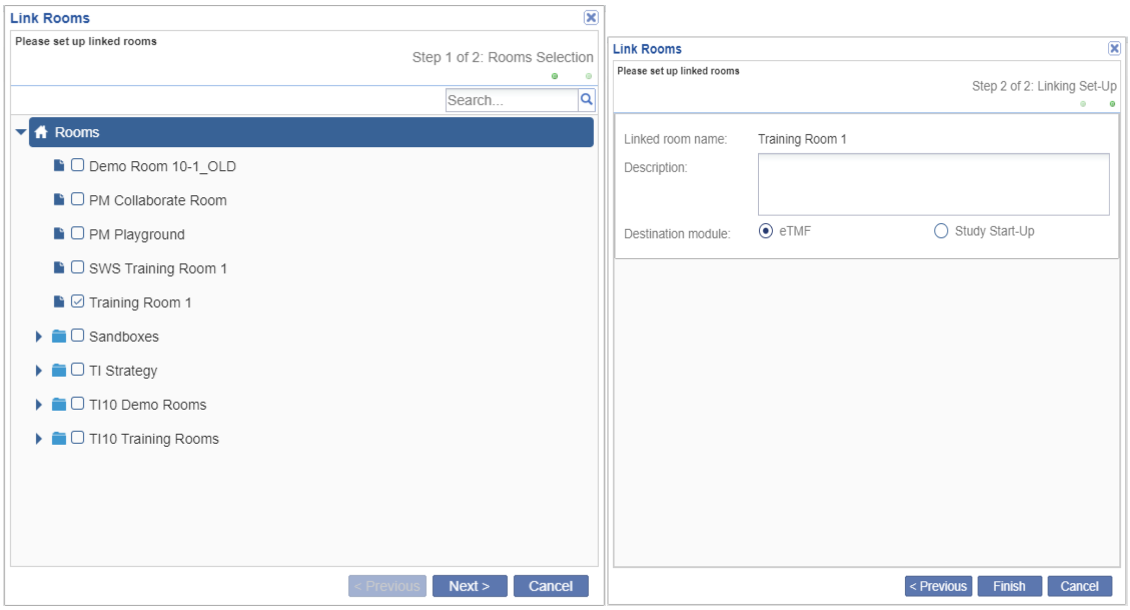
10.1 introduces the capability to share documents easily, in a controlled fashion, between TI repositories called Rooms. This sharing is configured by room and may be enabled to many rooms, to allow for multiple content sharing scenarios, including: Sharing a single document to many eTMFs, sharing from many sites to a single eTMF, and sharing from an eTMF to other groups.

The 'chain of custody' of these documents is very important to maintain. As approved document versions are shared between rooms, the document source location and destination are tracked and can be viewed. Metadata that is common between two rooms will be shared along with the content, and only users with permission may share content. However, users may not share content to rooms to which they do not have access, like the eTMF for example, to enforce a controlled document workflow between repositories.

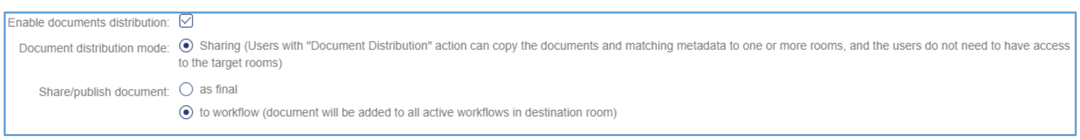
Enabling Cross-Room Document Sharing

In order to enable cross-room document sharing, the rooms must be linked. The Settings menu in TI has a new section entitled Documents Distribution.

Clicking on the Linked Rooms sub-menu and pressing the Link Rooms button will bring up the Link Rooms window. From there the user needs to drill down or search for the required room and press Next and then Finish.



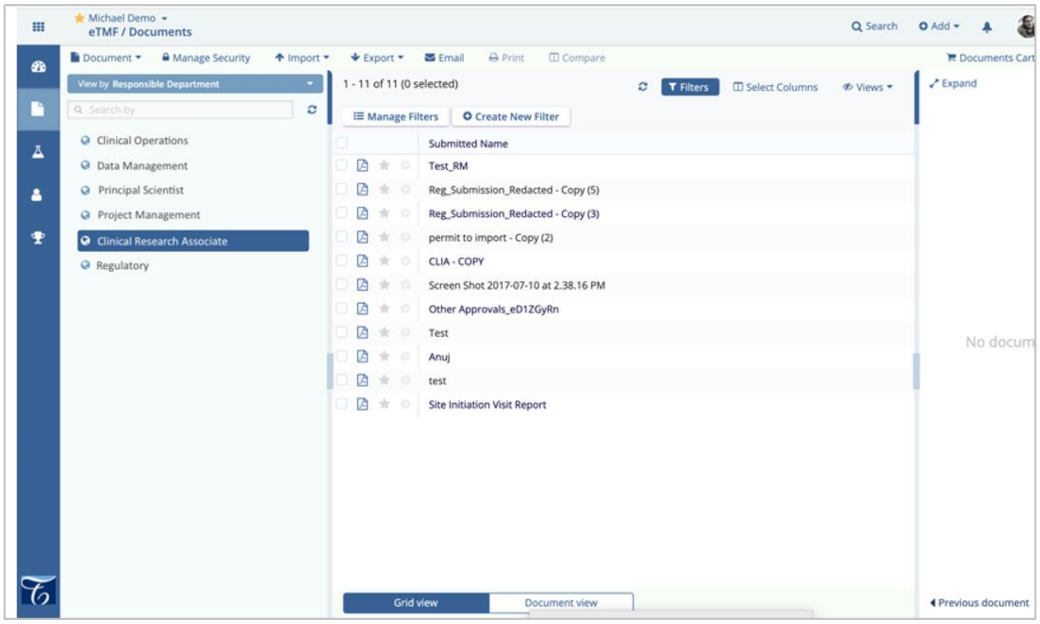
The Common Configuration sub-menu should then be opened and the user can choose whether or not to Enable Documents Distribution. Other options include whether shared document should be sent to the receiving room's QC Workflow or if they should be counted as final once shared.



eTMF FEATURES

The improved version of Trial Interactive 10.1 comprises of following eTMF features

Responsible department views

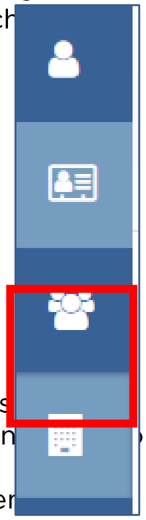


One of the business challenges with eTMF is the ability to ensure that documents are submitted in a timely fashion as the trial progresses. To ensure that this happens, it is important to know which person or department is responsible for authoring, collection, and submission of each required document and placeholder.

While CRAs are often responsible for document collection from the sites, many other documents must be collected from internal groups, regulatory authorities, IRBs/IECs, and partners.

10.1 introduces the definition of Responsible Parties and Owners to Trial Interactive. For each Document Type, the responsible group or person may be defined. These definitions may be set up using groups within the room for a flexible assignment of ownership. Once configured, an eTMF Completeness View is now available that shows the required documents, placeholders, collected, and final documents for each Responsible Department or Owner.

Setting up Responsible Departments



In order to set Responsible departments, the user should navigate to the Users Management Module. There is a new icon present on the menu at the left side of the screen which represents the Responsible Department management area.

Clicking on this will open the Responsible Department management area.

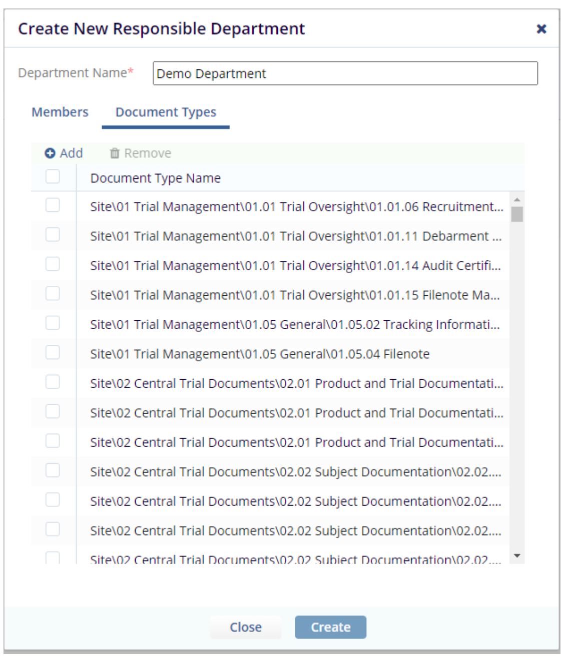
Press the Add button in order to create a new department. The user could also press the Edit button in order to make changes to a preexisting department.

Enter the Department Name.

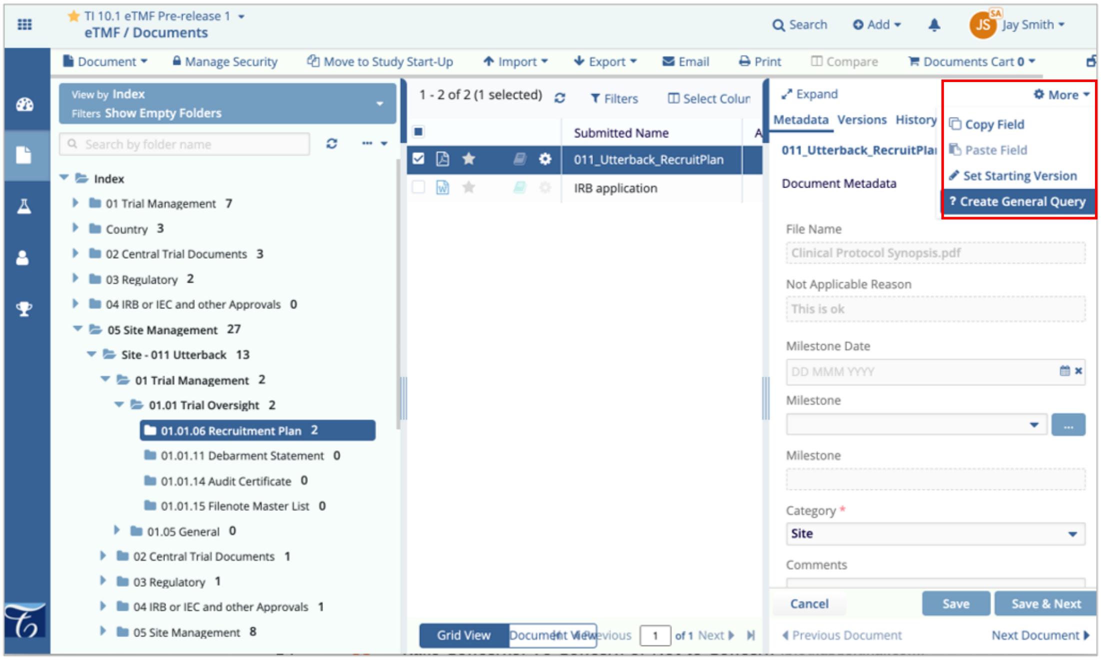
Select the Members tab to add users to the department.

Once the department members have been selected, change to the Document Types From here, the user can drill down in the folder structure to assign specific documen this department. Check the box next to the document type and press Add.
If there is no box next to the desired document type, this indicates that the documer has already been assigned to another department.

Once all required members and document types have been assigned to the department, press the Create button in order to create the department.



Query any document



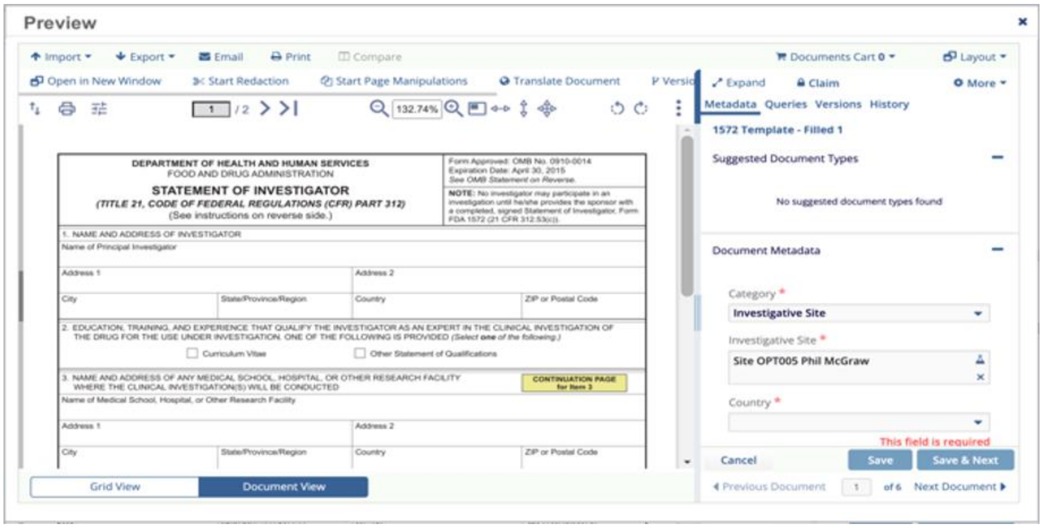
Queries are a critical feature in TI, and in 10.1, Queries will become much more flexible. Currently, queries can only be used as part of eTMF Quality Control or Quality Review, but 10.1 changes all of that. Queries can now be opened regarding a document at any time for purposes of clarification or to prompt for document replacement.

A room Admin or Document Manager can raise and resolve a query against a Collected or Final document through a simple right-click. This query may be sent to anyone in the room, including Readers and Editor roles. Once raised, the queries may be viewed by status from an All Queries view and are assigned by default to the submitter or the person who last progressed the workflow.

The standard query workflow process is then followed, allowing the responder to clarify the query, or respond with updated content. All back-and-forth is captured in the document audit trail as normal. Documents may be emailed in or attached directly to the query response from within Trial Interactive.

Users can see what queries are assigned to them just like they would their tasks, through a notification in the user menu, the query view, or the corresponding dashlet. They may be reminded about their queries through a message or newsletter. Documents with open queries will show with an icon in the index and working views, and queries may be filtered by site, country, issue type, and other configurable filters. Open queries against collected and final documents also show in the ‘My Queries’ and ‘Queries by Status’ dashboards alongside standard workflow and audit queries.

Staging area preview



In TI 10, the Working Documents view was introduced to provide a simpler, more comprehensive index for eTMF Completeness, showing not just final documents, but also collected documents, placeholders, and required documents within a standard eTMF index structure. This view also introduced the Staging Area, a separate panel that shows documents waiting to be classified via the eTMF workflow.

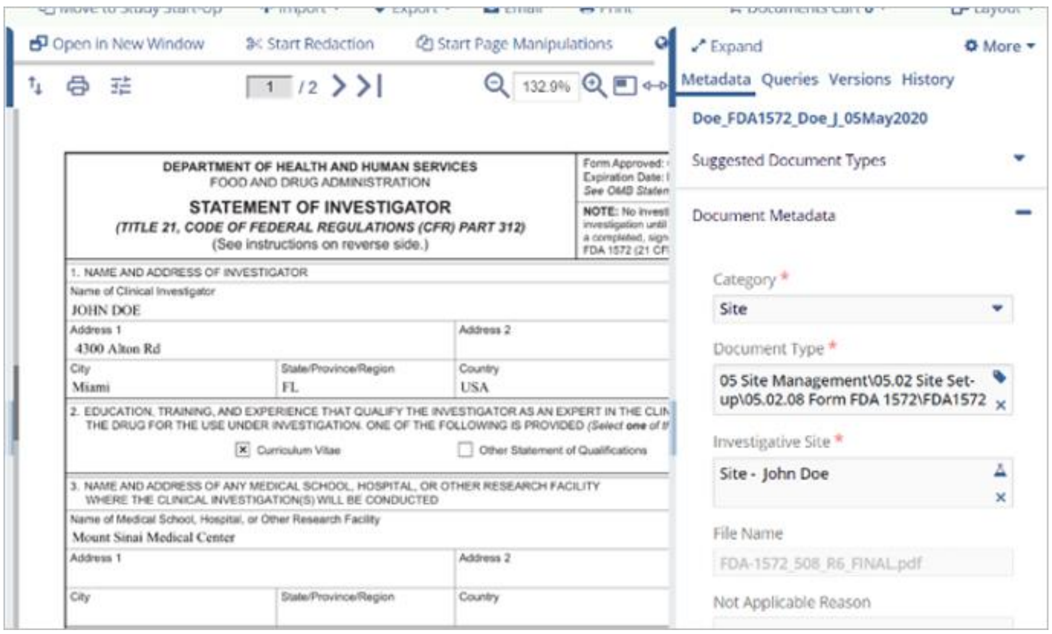
TI 10.1 introduces a simpler way to preview these documents. Selecting a document in the Staging Area and double-clicking will open the document in a preview modal window alongside its metadata. Then the document can be dragged and dropped directly into the eTMF index, into a folder or onto a Placeholder, and have Trial Interactive intelligently prompt you for the correct Document Type and other classification metadata.

Quality review comments

Improvements were made to simplify the display of Audit Comments and Audit Responses during a Quality Review by adding comments and response comments to the quality review export.

The process here hasn't changed. The export is still performed in the same way but now the Audit Comments and Audit Response Comments are available for export along with the usual audit data.

Machine learning metadata extraction



Auto-classification of eTMF documents is consistently accurate when enough document identification data has been collected and the machine learning model has been trained by the clinical team. This functionality was introduced with TI10.

In TI 10.1 the ability to recognize documents by identifying the document type and then extracting the metadata embedded within the document has been improved. This capability will identify investigator names, relevant dates, etc. and then prompt the user to verify and correct the additional pre-filled information. This capability also correctly identifies the Document Type most of the time, when properly trained.

Trial Interactive has been trained on a set of common eTMF document formats with a focus on 12 primary Document Types out of 32 structured essential document formats. Non-standard formats or customer-specific formats must be trained individually for best results. The key takeaway here is the the system will need to adequately trained to recognize documents that are new or customized for your organization or study.

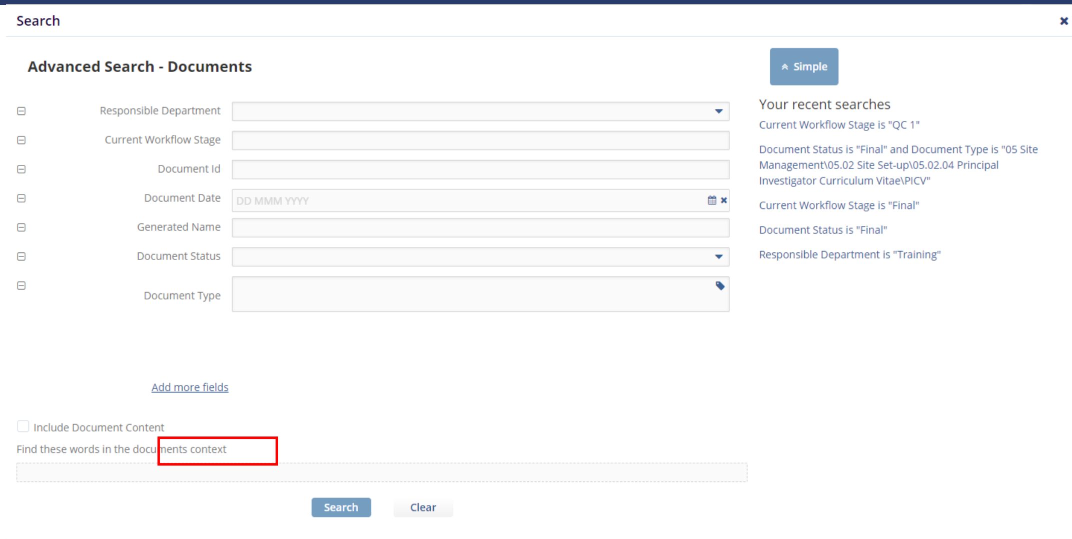
Improved metadata search

In 10.1, additional items may be searched that go beyond documents, including queries, tasks, and users. These may be selected using a simple dropdown next to the search box.

A more advanced metadata search is also available that provides the ability to search on key fields that are most common. Rooms may still be configured to limit the global search to just a few metadata fields. This improvement provides more fine- grained control to a user. For Example, a user may search against all 1572 forms in a specific Country containing a specific piece of text. Other available search fields may include:

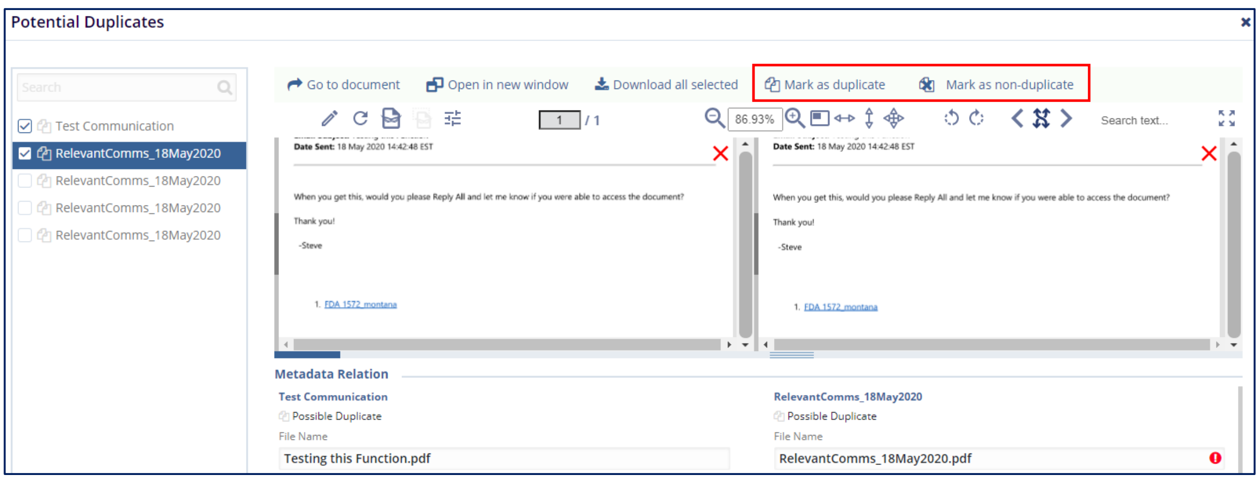
- Document ID
- Name
- Title / Submitted Name
- Submitted Date
- Investigative Site
- Country
- Within the text of the document
- Any other metadata field needed, configured in the search panel by each user.

In order to perform an Advanced search, the user would open the regular search function and press the Advanced button at the right of the search field.



In the Advanced Search window, the user can then refine their search by adding specific metadata fields.

Duplicate checks

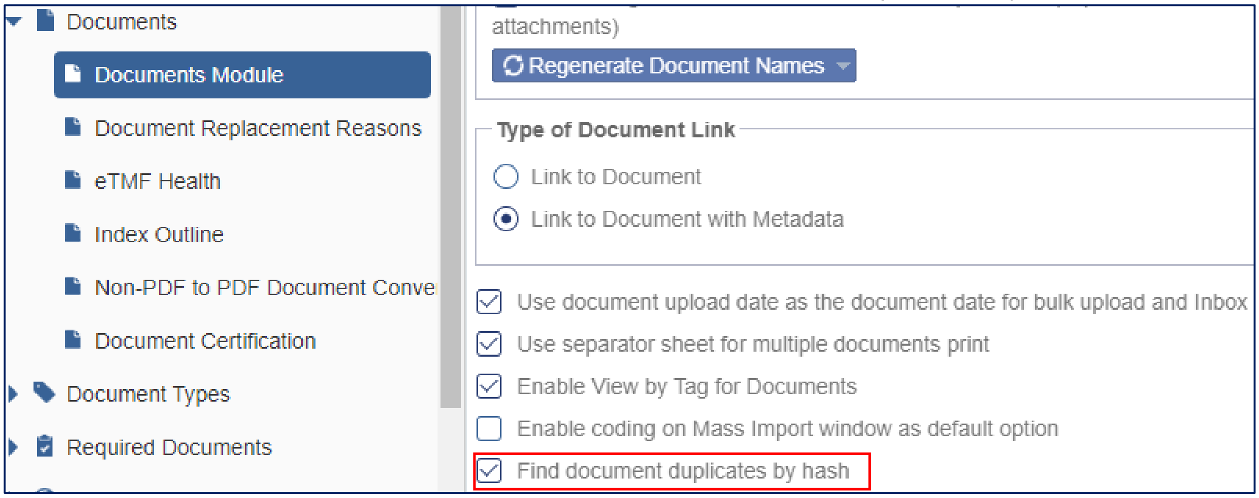


TI10 introduces more flexibility around duplicate checks, improving the process in the following ways:

- Documents are now flagged as a possible duplicate if they are identical in every way to a document that already exists in the eTMF room (they have the same hash value which means the content is identical).
- Documents are now flagged as a possible duplicate if there is a document with an identical Generated Name at any step in the QC workflow process.
- These flagged documents can be identified through an icon. Once they are claimed, the user will be prompted to compare them. Note that the user may opt to ignore the flag, for example, if the document is known to be a duplicated site document.

Enabling Detection of Potential Duplicates

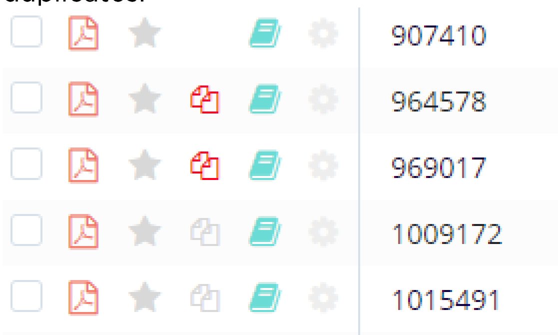
In order to enable detection of potential duplicates, an Administrator level user will need to go to the Settings menu and go to the Documents Module area of the Documents sub-menu. From here, the user can check the box labeled “Find document duplicates by hash.”



Once this setting is enabled, the room will be able to detect potential duplicates by hash value.

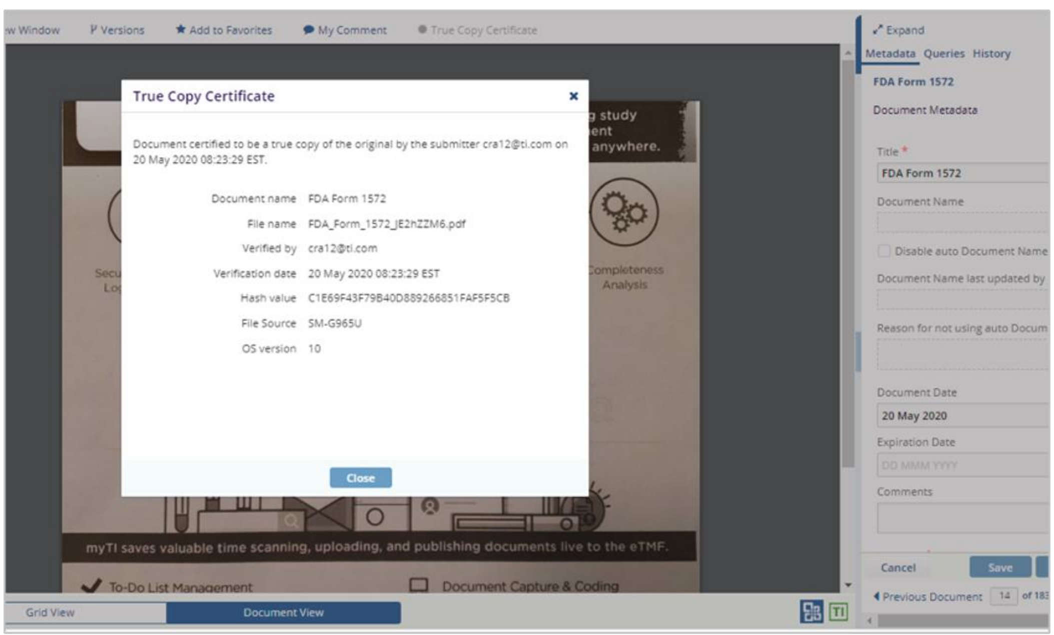
Reviewing Potential Duplicates

When a potential duplicate is detected, it will be indicated by a gray, Potential Duplicate icon. Clicking on that icon will open the window shown at the beginning of this section wherein the user can compare potential duplicate documents and indicate whether or not they are duplicates.



Documents which have been marked as duplicates will be indicated by a red version of the potential duplicate icon.

Certified copy



For situations where the original paper copy of a document may be destroyed or unavailable, TI 10.1 introduces the capability to ensure a certified copy workflow from eTMF, Collaborate, Remote Monitoring, and other room types in TI. With this feature:

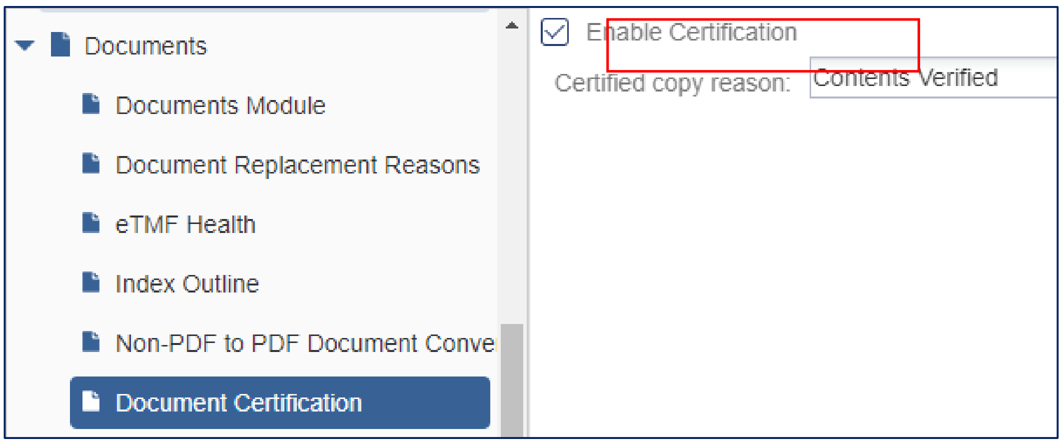
- You can upload a document in a room that has enabled certified copy, and you can verify the document uploaded and review copy certification text before providing credentials to certify the document.
- You can review a certified document and view the details related to that certification.
- If you edit a certified document, the document will no longer be a certified copy.

- The text used as the certification criteria is configurable by room, as well as the ability to define a default reason.
- This feature also works in the myTI mobile app.

Enabling Certified Copy

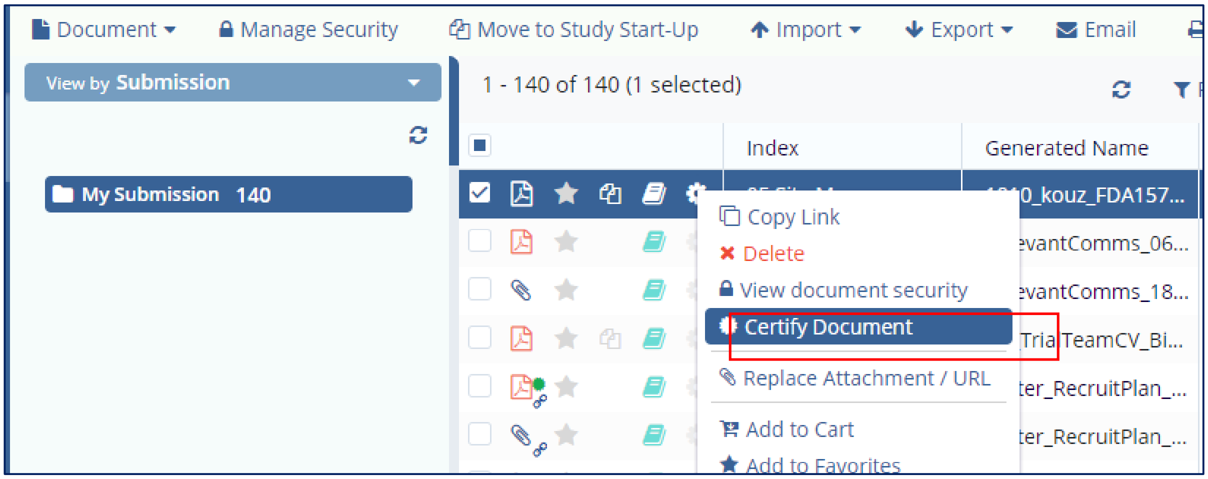
In order to enable detection of potential duplicates, an Administrator level user will need to go to the Settings menu and go to the Documents Module area of the Document Certification sub-menu.

From here, the user can check the box labeled “Enable Certification.”

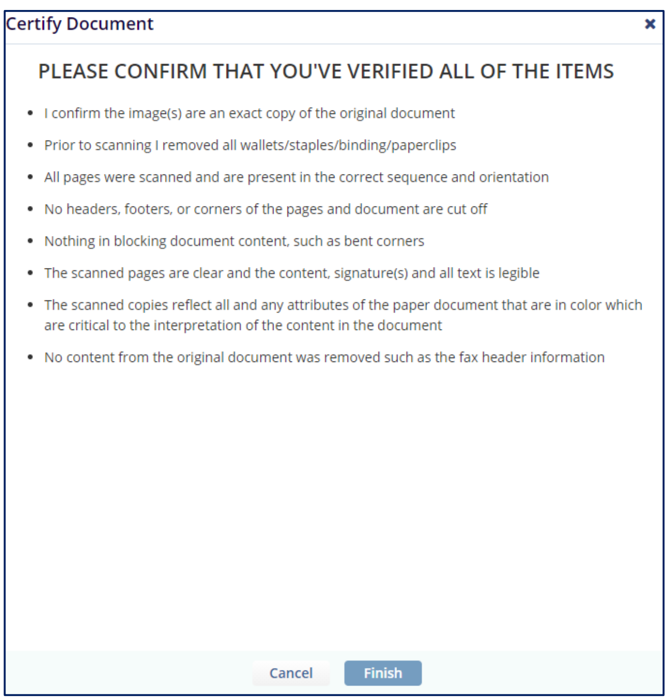


Marking a Document as Certified

Once the document has been uploaded, proceed to the Documents Module or Documents Library module and choose the Submission view under the My List column. Choose the document from the grid and open the Document Menu by clicking on the gearwheel icon or by right-clicking on a the line item in the Grid.

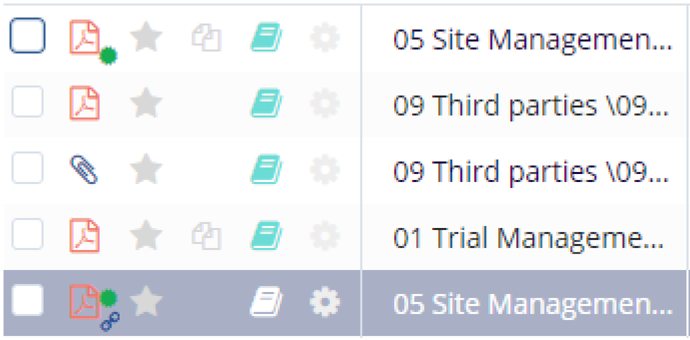


Choose Certify Document from the menu that opens. This will open the Certify Document window.



The user will need to read and agree to the conditions shown. If the document meets all of the displayed criteria, they can press the Finish button. The user will be required to confirm their identity by entering their Username and Password.

Once this is done, the document will be given the status of Certified. This is indicated in the Grid by a green dot next to the file-type icon.



Scanning automation

Trial Interactive has always been about reducing, removing, and simplifying the need for paper documentation. Both CROs and Sponsors still often need to collect paper from investigative sites, and still need a built-in process for managing paper records.

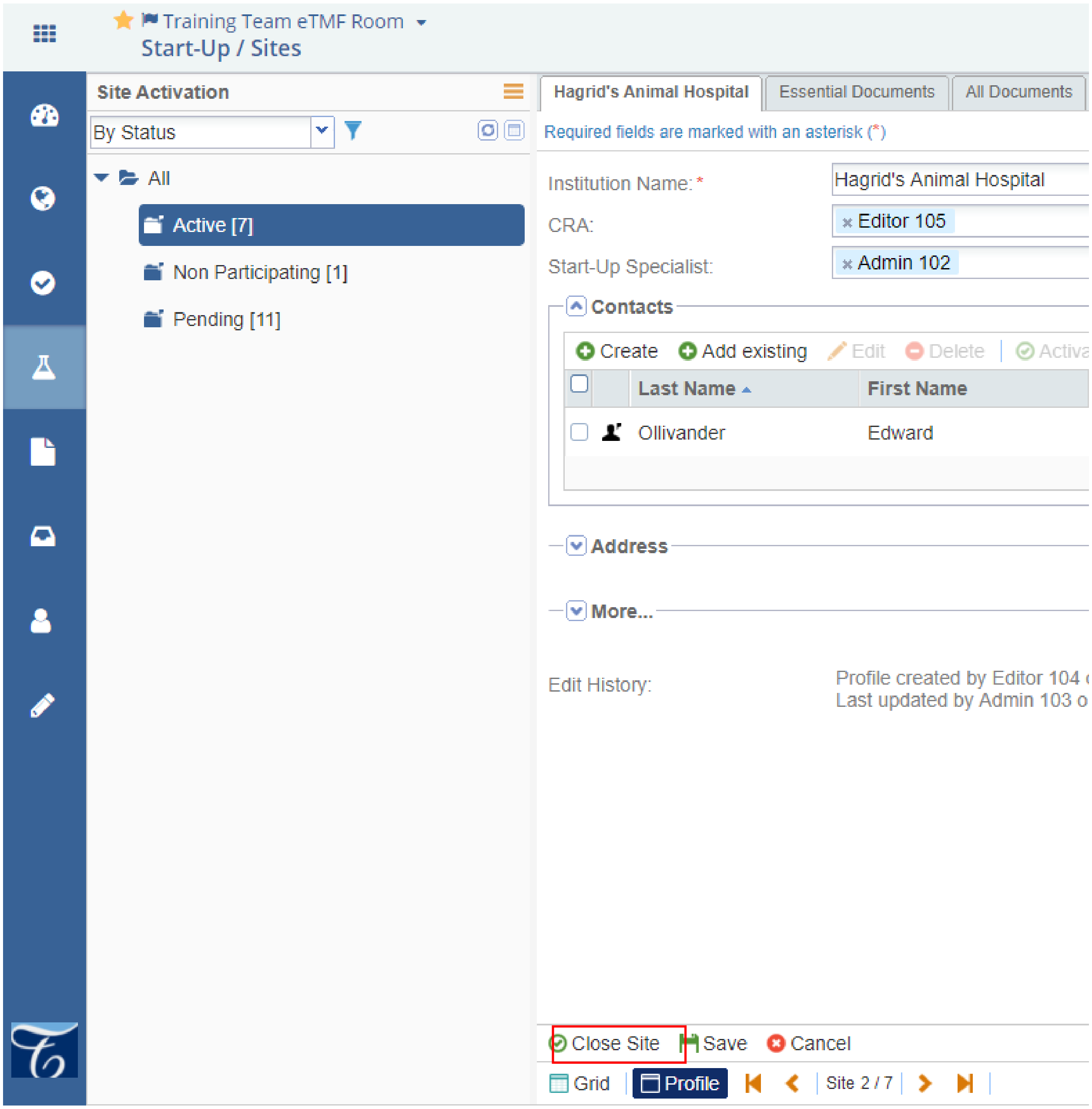
With 10.1, Trial Interactive will make available our production scanning processing system. This system provides, through a simple QR code-based metadata solution, a way to quickly scan boxes of paper to be classified immediately and automatically into a Trial Interactive eTMF room. Metadata may be filled-out either at the point of scan or within the TI staging area, depending on your process, and where the classification is most easily done.

Please reach out to your Trial Interactive Representative for a demonstration and additional information about this feature.

STUDY START UP FEATURES

The improved version of Trial Interactive 10.1 comprises of following features:

Ability to mark sites as Closed



As a Clinical Trial is completing, the investigative Sites must ultimately be closed. While not typically part of Study Start-Up, this process is very much a part of the Clinical Trial lifecycle. With Trial Interactive 10.1 the system shall have the ability to mark Sites as closed once the trials are completed for the Sites. Once closed, these Sites will be moved to a separate folder for closed sites. Advanced Validation for metadata fields is still available when Sites are marked as Closed.

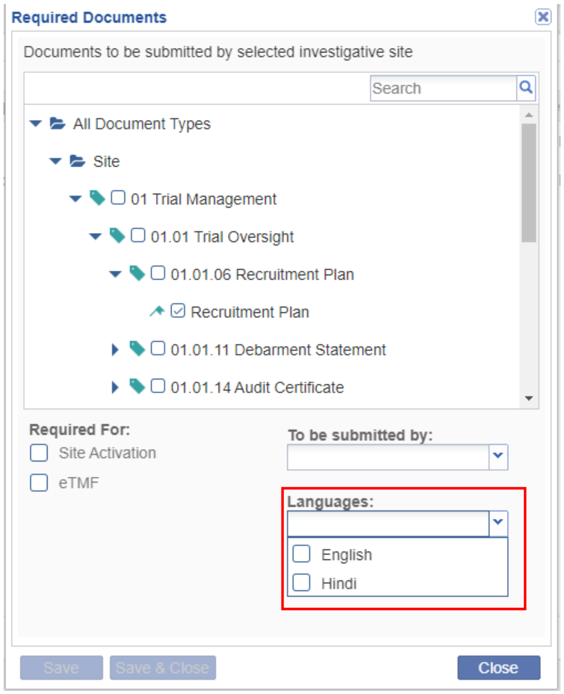
Sites marked as Closed will still appear on eTMF completeness reports but documents from these sites will not be shown on expired/expiring documents reports or dashlets. Additionally, new amendments will not be applied to Closed sites.

Marking a Site as Closed

If Study Start Up has been enabled in a room, any changes to a site's status must be made from the Study Start Up module. To do so, simply navigate to SSU in the Navigation Grid and open the Sites area. (See the screen shot above)

Select a site from the list of Active sites and double-click or select the site and click Edit in the menu-ribbon above the grid. This will open the site profile. As seen in the screen shot above, a user with sufficient privileges to edit the site (Editor or Admin) will be able to mark the site as closed.

Support for Multiple Translations and Multiple IRB/EC Approvals



Quite often, the same Document Type requires a translated version, for example, a regulatory authority may require the document in French, German, and English. Additionally, there may be multiple IRB/ECs required in the regulatory approval workflow, and so the same Document Type may need to be recorded for each of these separate organizations.

For this reason, in SSU 10.1 a document type may now be set up as required document multiple times. They can now be set up as required documents more than once based on:

- Language
- IRB/EC

This improves support for European agencies, as well as supporting the process where more than one Ethics Committee may be required for a specific Country or Site's activation.

In order to perform this task, follow the standard procedure for designating a document as required. Simply select multiple languages from the drop down menu in the Required Documents window where possible.

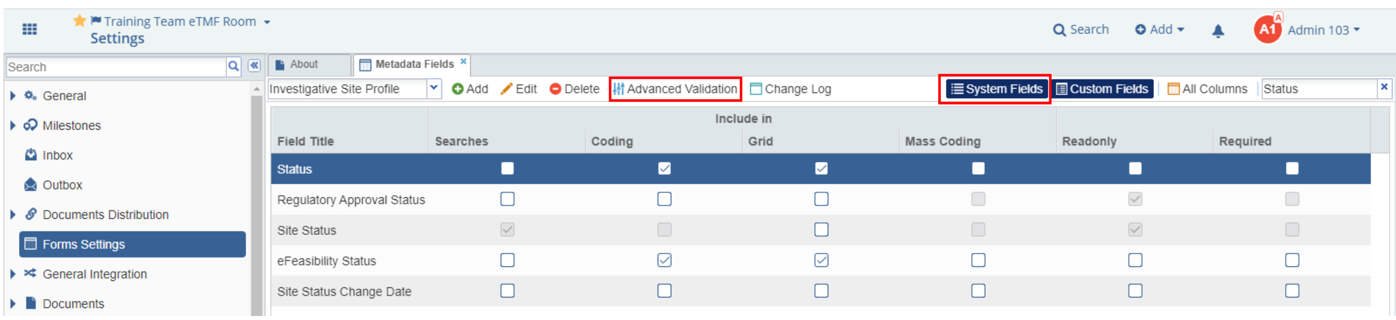
Advanced Validation

When a site is created the Sponsor/CRO may have only limited information about the site, and often cannot complete all the required fields. However, the Sponsr/CRO will ultimately gather more information that must be included before the Site can be marked Active.

With SSU in 10.1, Sites can now be configured to require a set of fields to be filled out with initial site creation and require additional fields that must be filled out before the site can be marked Active. This allows a simplified creation process, and at the same time ensures that all required information is collected prior to the Investigative Site going live.

To set this up, an Administrator level user will need to go to the Settings menu and to the Forms Settings area of that menu.

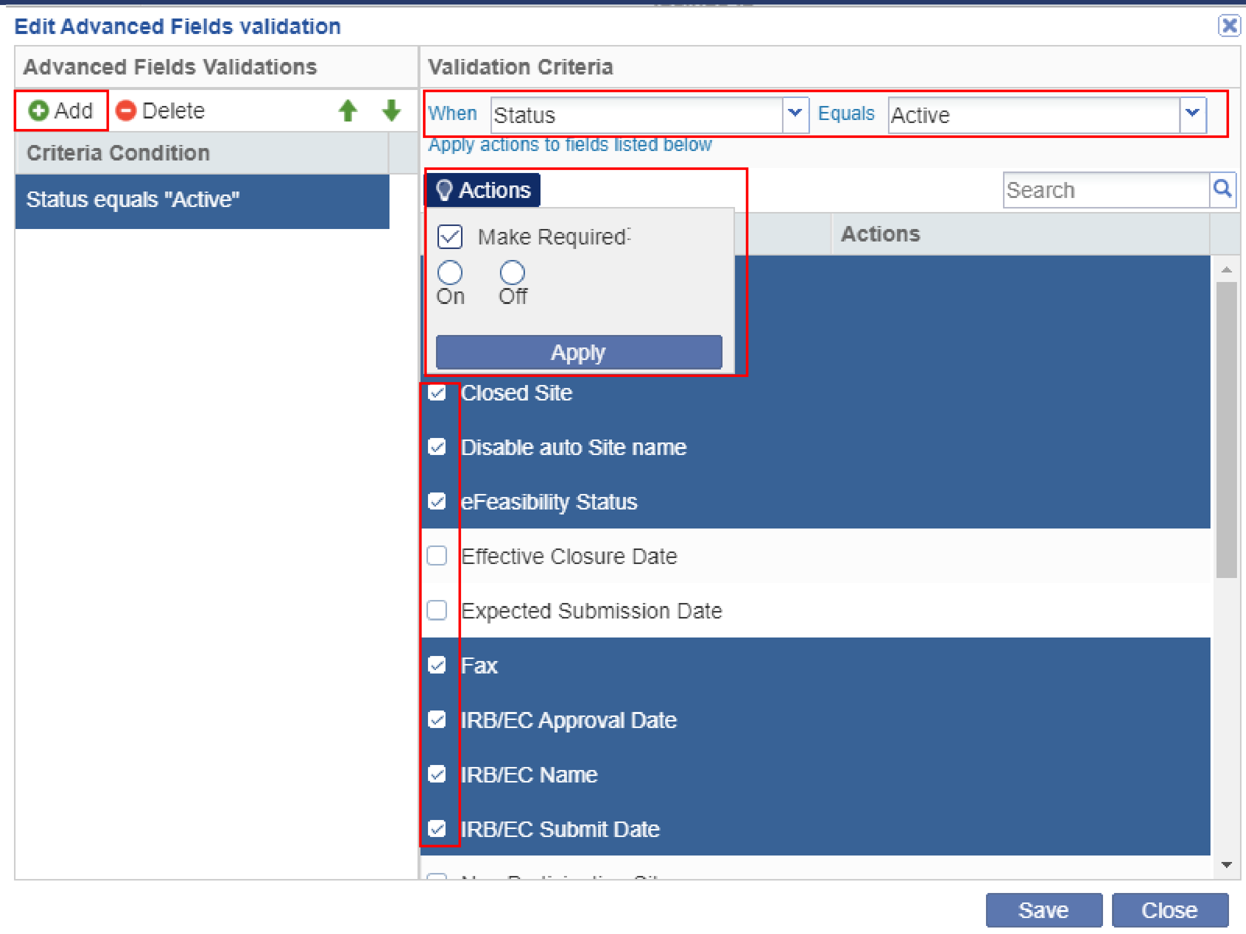
From there, the user will need to select Investigative Site Profile from the drop-down menu above the Grid. It is likely that nothing will appear. If desired the user can click the option for System Fields above the Grid to display all fields.



The user should select Advanced Validation. This will open the Edit Advanced Fields Validation window.
Pressing Add will begin the process of creating an advanced validation requirement.

Select the field (in this case, “Status”) and the value (“Active”).

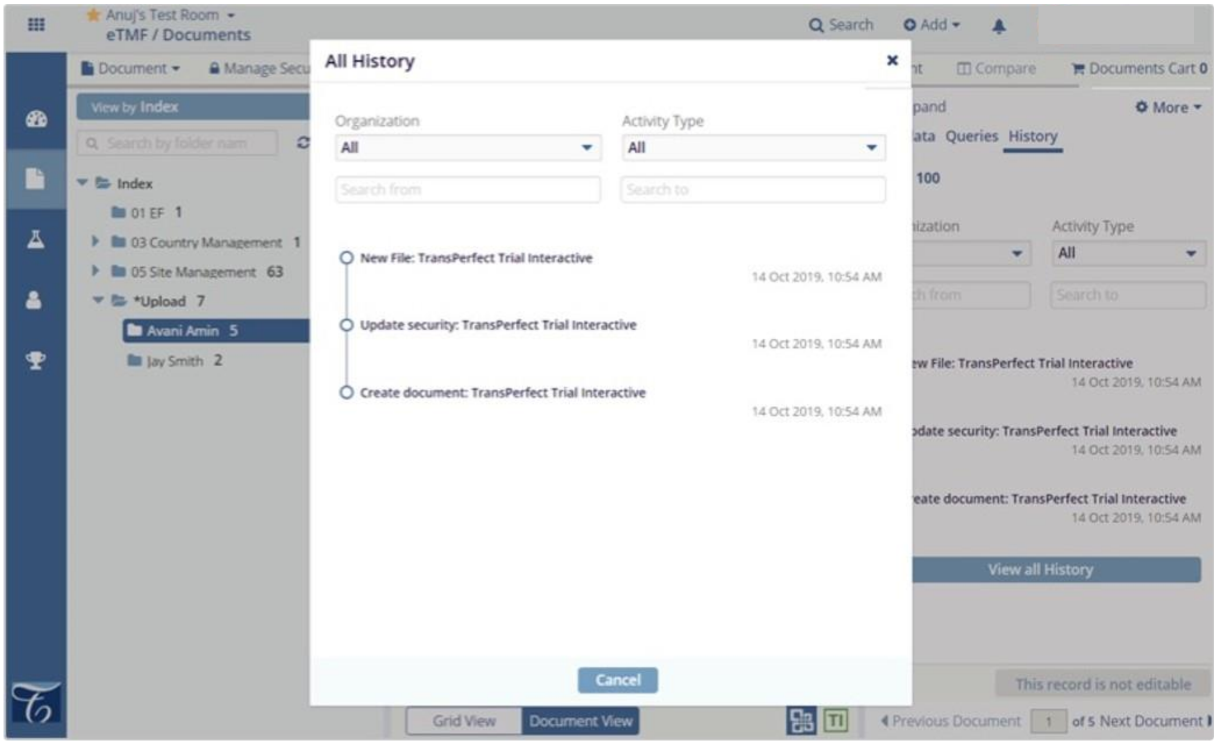
Choose which metadata fields should be required upon site activation by clicking the appropriate checkboxes. Then, press the Actions button and select “Make Required.”



Press Save to close the window.

**The user will also have to press the Save button at the bottom-left of the Forms Settings window in order to keep the changes. **

Document History



During the course of Study Startup, Documents must go through a standard process before they are considered approved. With SSU 10.1, Users now have the ability to view the complete history of the documents in SSU. This includes:

- Submitted By
- Submitted Date
- Start-up Specialist Approver
- Start-up Specialist Approval Date
- Regulatory Approval Date
- Regulatory Reviewer

This information will be accessible at the bottom of the metadata pane when a document has been highlighted in the Grid. Simply click the View all History button to see the expanded history.

CONTENT MANAGEMENT FEATURES

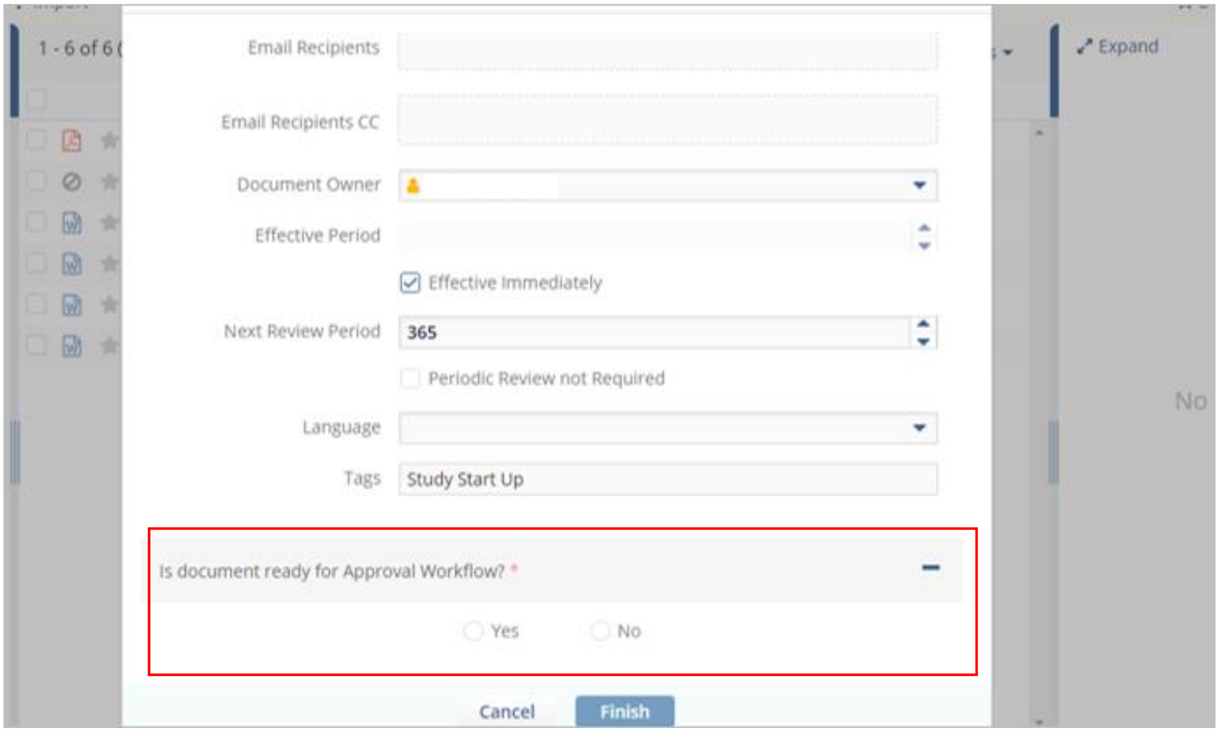
Trial Interactive 10.1 comprises of following Content Management features:

Role-based content views

When Editors are looking for documents, they likely want to see the latest, most current, draft version so that they know what's in progress, what needs to be reviewed, and what is currently approved and effective.

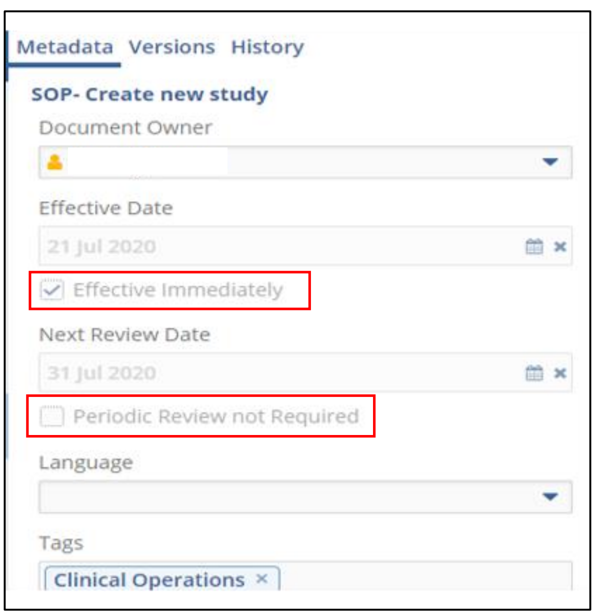
Conversely, when Readers are looking at documents, they will see the current, effective version. In 10.1, the TI CMS will provide users with the most logical views for each role, showing Readers the effective version, and Editors the current version.

Simplified workflow start



No longer will a document need to go through a round of editing prior to being able to start a workflow. With CMS 10.1, upon upload, the user will be able to set a document as ready for workflow and the workflow can be initiated right after saving. Immediate approvals and E-signatures can be obtained.

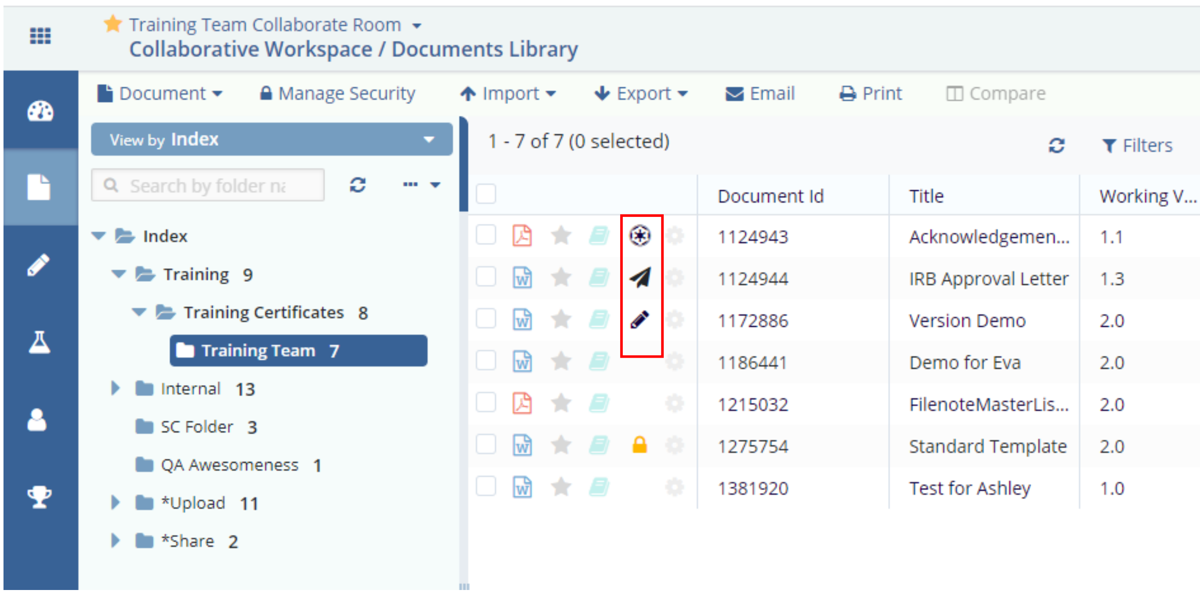
Flexible controlled document states



For Controlled Documents, there may be a need to make a document Effective immediately or make a document Effective with or without a Periodic Review Period. With 10.1, Document managers will be able to control what does or does not apply
to a document providing the ability to meet the business requirements of the document with ease. Document owners will be able to:

- Control the duration of a document's Effective Period and Periodic Review Period; and
- Set a document to be Effective immediately after approval with or without a Periodic Review Period.

Improved workspace navigation



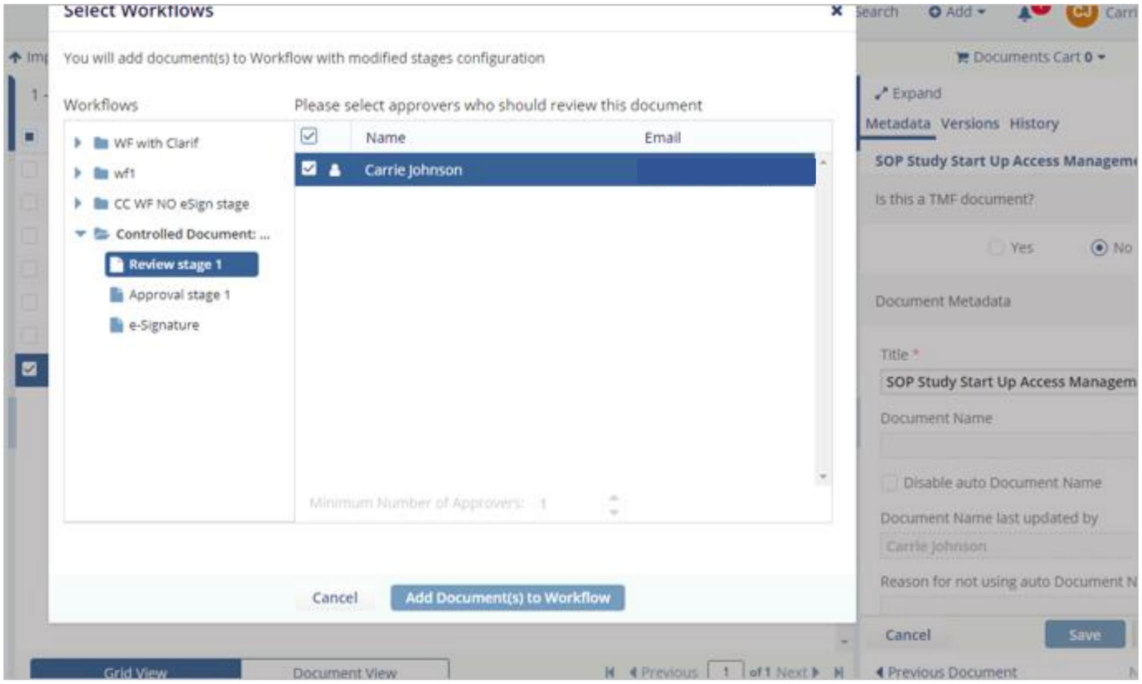
Now users can easily navigate between the Document Repository and Collaborative workspace or Document Lifecycle for a single document.

Within the Document Repository, users can click on the collaborative icon to take them to that document in the Collaborative workspace.

Users can click on the Workflow icon to go directly to the document and its status in the Document Lifecycle.

Within the Collaborative workspace click on the paper airplane icon on the document row to send the document immediately to a workflow review.

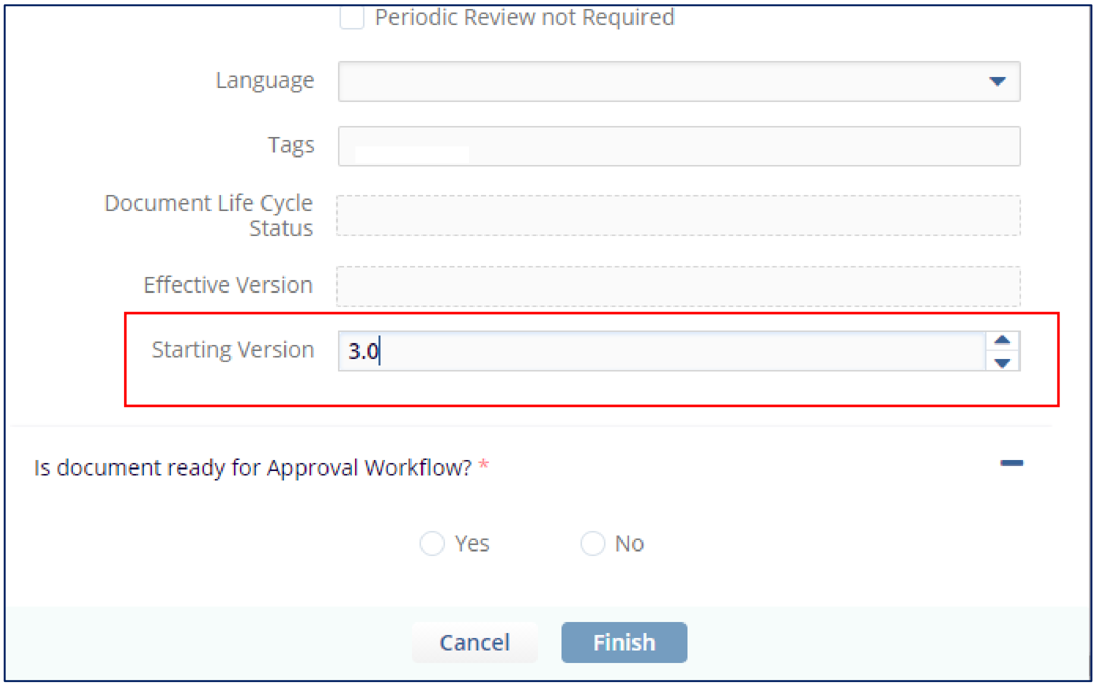
Collaborate within a controlled document workflow



In CMS 10.1, Document Owners have more workflow choices for their Controlled document. Workflows can be created for business needs providing review steps that allow a document edit, approval steps which will provide an approval event in the document history as well as an E-Signature step to obtain signatures on the document.

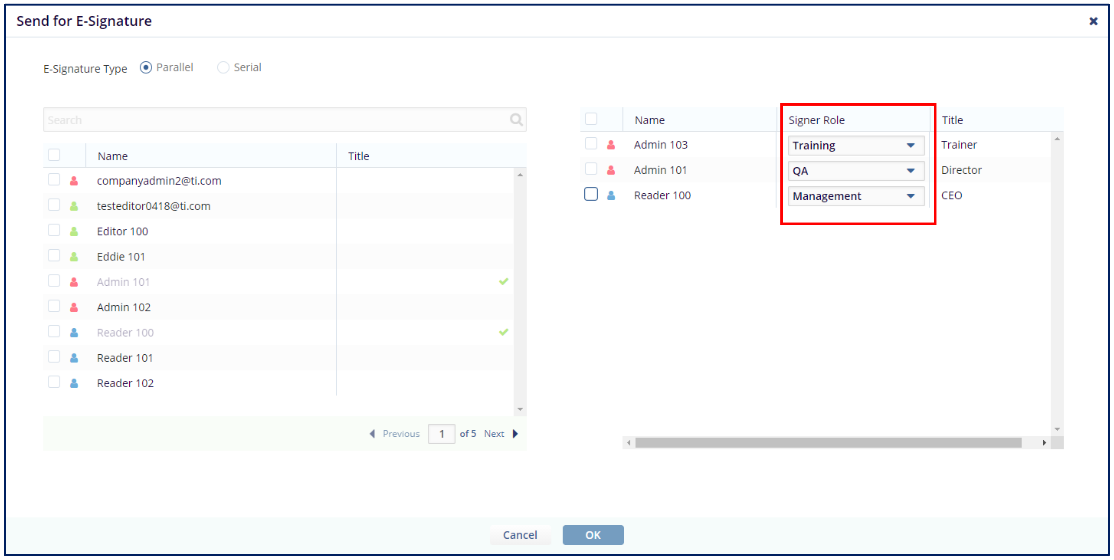
Creating and initiating a workflow are covered more in-depth later in this document.

Version labels

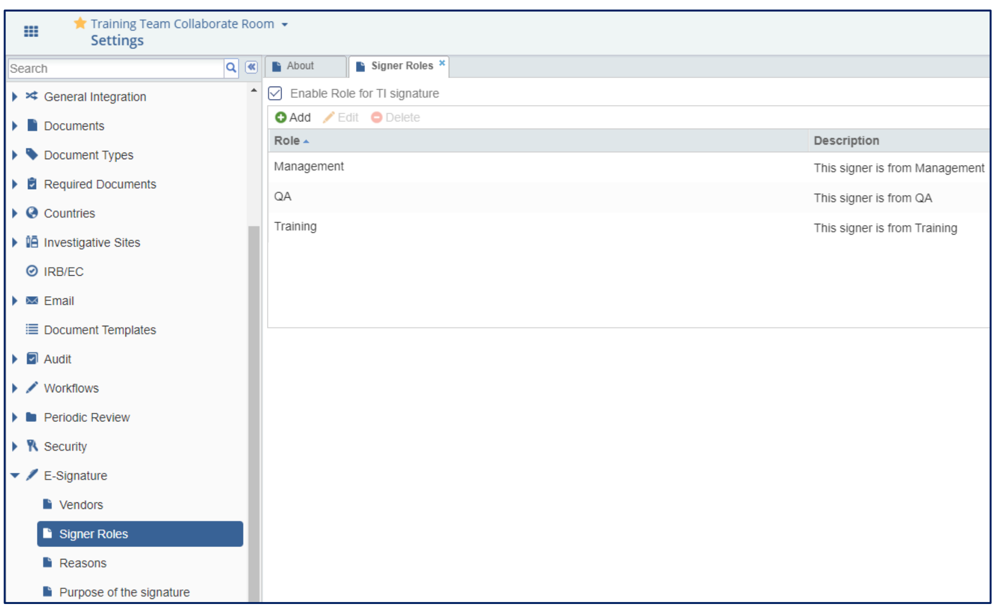


Upon document upload, users will be able to set the initial version in Trial Interactive allowing the document in Trial Interactive to be able to inherit previously defined versions. Trial Interactive will allow for the initial version of a draft document to be set as 0.1. The control of the document version labels will allow organizations to easily follow their own procedure for document management.

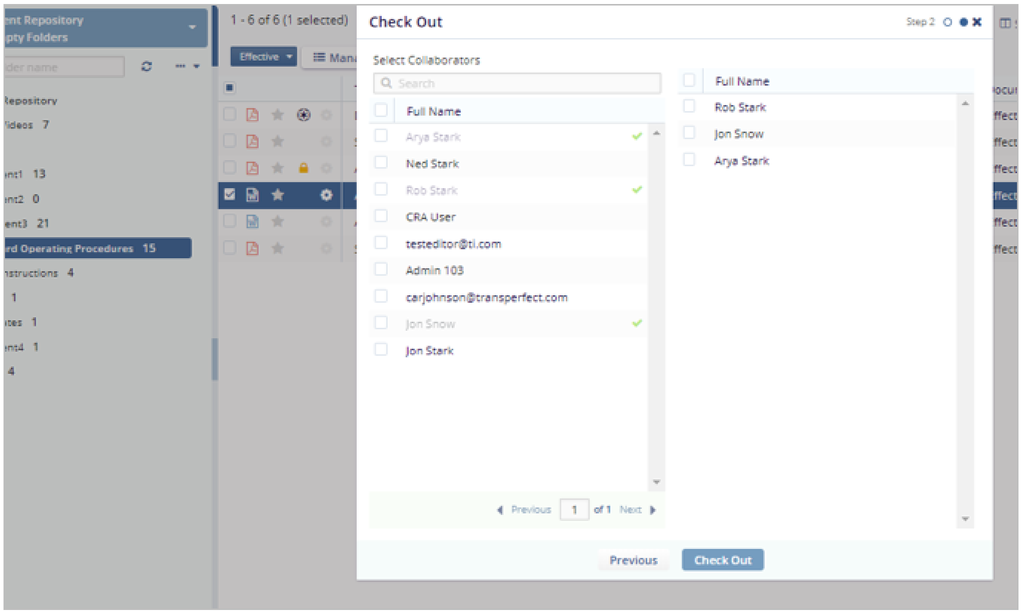
Additional designation for TI e-sign



Roles can be defined and leveraged during the E-Signature step. The standard definitions will create consistency across all signatures. During the creation of the E-Signature request, each signer can be associated with a role for the document. This allows not only the user's title, and reason for the signature to be displayed as part of the E-Signature record but the role of the person in the lifecycle of the document. Title and Role inclusion in the E-signature step provide a high level of visibility and clarity for each signer of a controlled document.
Roles can be enabled and defined from the E-Signature area of the Settings Menu as shown in the screen shot below.



Collaborate with outside users

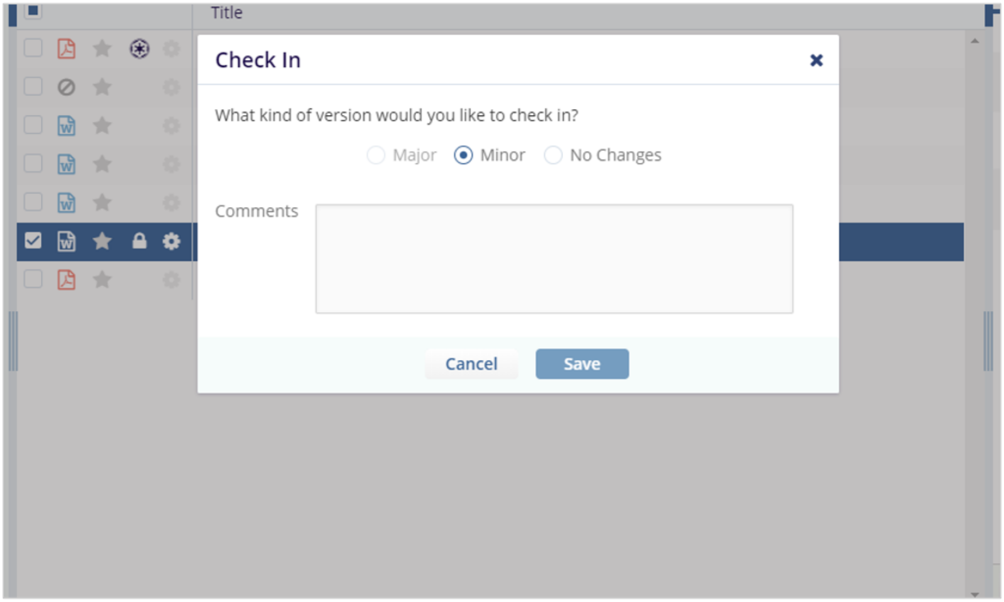


This improvement will allow document collaboration to occur with room participants that may not have direct access to the document in the document repository.

Documents can be managed in a folder by one set of users and then, as needed for collaborative review, new users can be invited and their edits limited to only within the collaborative review.

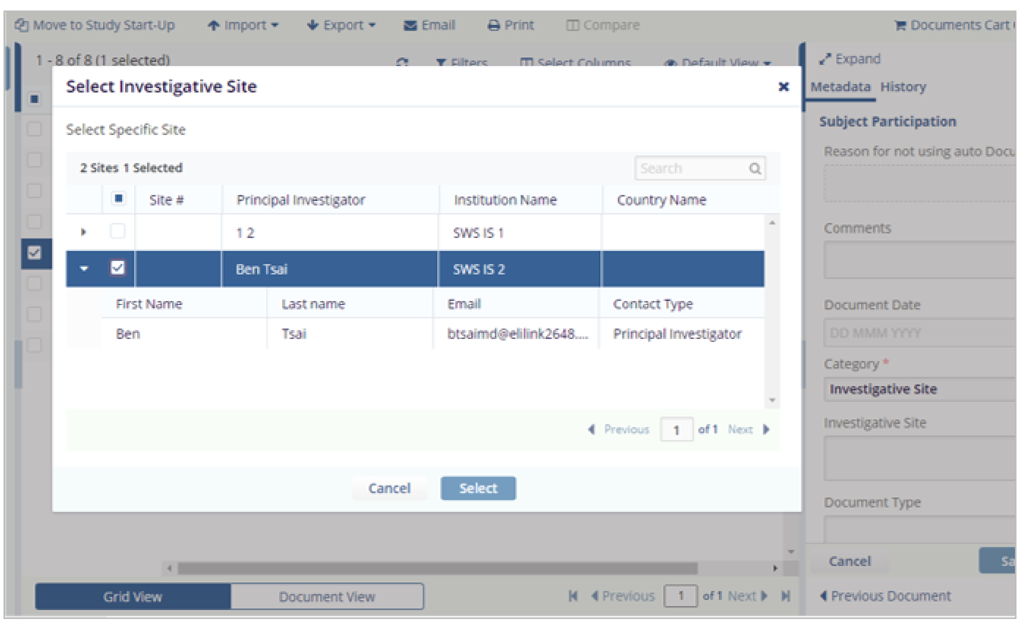
This provides an easy way to gain input from subject matter experts, outside organizations, or other departments in a controlled timeframe without leaving the document open and editable for all the editors at all times.

Cancel check-out



This improvement will allow room administrators in a Content Management room to check back in a document checked out by another user. In cases where a user may unexpectedly be unavailable or unresponsive a room admin can free up the document locked by a collaborative edit or an individual edit.

Site user restrictions



This improvement will restrict users assigned to sites to only see their assigned sites in the Investigator site list when adding documents or updating document metadata. This provides an additional security measure eliminating other site names or numbers from site-specific users.

REPORTING FEATURES

Improved TI Standard and Ad hoc Reports

In TI 10.1, all TI users will now have access to OOTB standard reports using Jasper Reports solution. TI Reports will no longer support reporting solutions based on legacy Izenda Reports. Additionally, ad-hoc reports would be enabled by default for all users with access to the TI Reports module.

The following reports have been added in 10.1:

- SSU Document History Report - This new report provides a complete history from the time the document is uploaded in TI SSU module through various approval stages.

- Document Placeholder Report - This new report provides the complete history of any placeholders created, modified or deleted in the TI system.

- Quality Review Report - This new report displays the history documents (passed and failed) through the Quality Review module in TI.

- Inventory and Completeness Report - Site - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Site category. The report shall also provide the Zone, Section and Artifact details related to each document type.

- Inventory and Completeness Report - Country - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Country category. The report shall also provide the Zone, Section and Artifact details related to each document type.

- Inventory and Completeness Report - Trial - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Trial category. The report shall also provide the Zone, Section and Artifact details related to each document type.

- Inventory Report - Staging and Upload - The new report shall display the inventory all documents for all categories that are available in the staging and inbox folder. This report will help take inventory of documents which are available in the system but have not been coded yet.

Chapter 2. Signing into Trial Interactive

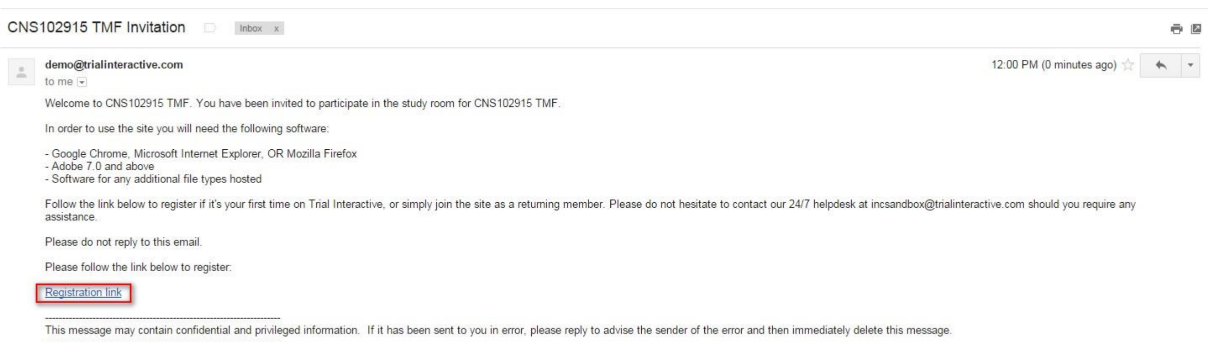
This section includes basic information that will help you get started with Trial Interactive 10.1.

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

Receiving and Responding to Room Invitation

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

Figure 1: Room Invitation Email



CNS102915 TMF Invitation Inbox x

demo@trialinteractive.com
to me

12:00 PM (0 minutes ago)

Welcome to CNS102915 TMF. You have been invited to participate in the study room for CNS102915 TMF.

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

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

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

Please do not reply to this email.

Please follow the link below to register:

Registration link

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

Click the Registration link near the bottom of the message, and you are directed to the Trial Interactive user account registration page. Follow on to the User Registration page *(page 36)* for the complete process.

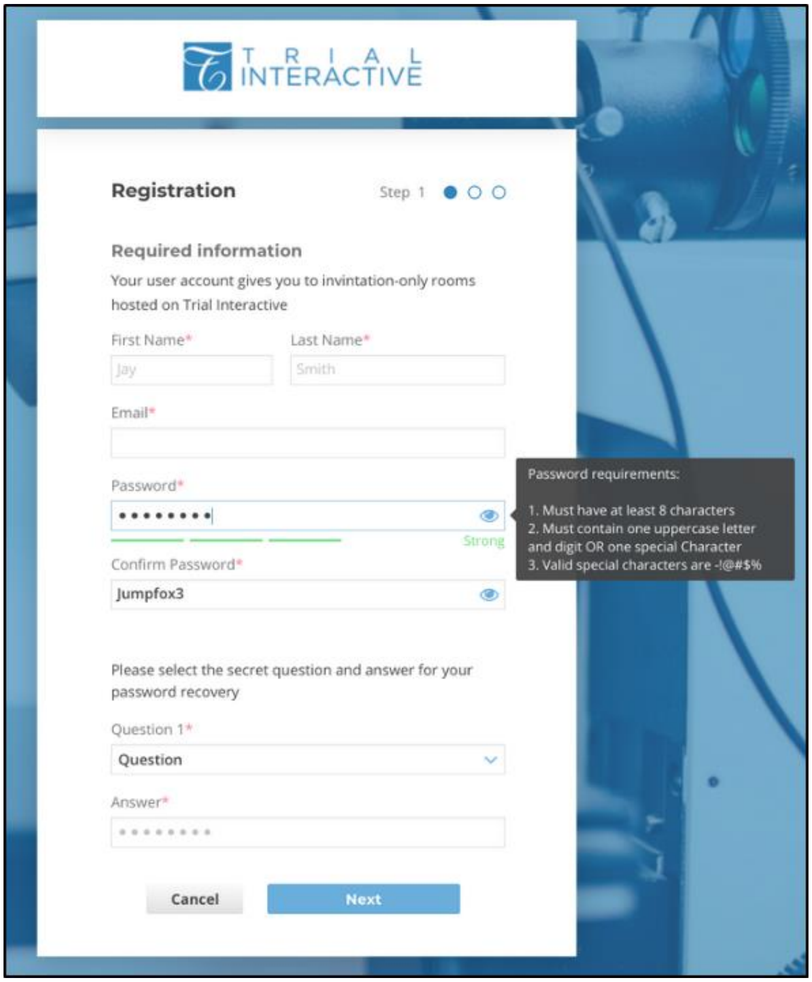
User Registration

Important:

1. **You register to the application only once as a first-time user** when you are invited to a room *(page 36)* through an email.
2. Once you register, you can sign into your room.
3. If you are invited to other rooms hereafter, you need not register again, but need to sign in to access the rooms.
4. For all subsequent invitations to rooms, you are notified by emails.

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

Step 1: Registration - Required Information



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

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

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

Step 2: Registration - Optional Information

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

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

Step 3: Registration - Custom Information

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

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

Signing in on Subsequent Visits

To log in to Trial Interactive

1. Using your preferred internet browser, navigate to http://www.trialinteractive.com
2. Click the **Client Login** button located at the top right corner of the page.
3. The Trial Interactive Login page with links to a suite of e-clinical solutions offered by TransPerfect Life Sciences appears. Click the links to delve further into the solutions provided by TransPerfect Life Sciences or log in.
4. Enter the **Username** and **Password**. The **Username** is the full email address that was submitted by the client-appointed Administrator.
5. Click **Login**.

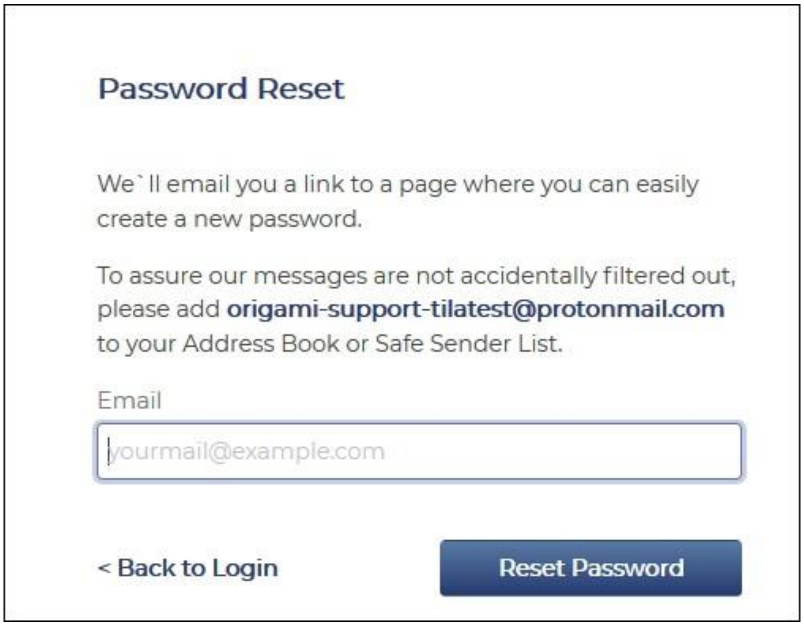
   If you are logging in the first time, the Trial Interactive Homepage *(page 40)* for the account associated with the login username appears, else you are redirected to the same location in the application that you were in upon subsequent login.

   Note: *You can bookmark* ***http://www.trialinteractive.com*** *on your browser for easier access to the Trial Interactive corporate homepage. By accessing Trial Interactive through this site, you will consistently see news and new information about Trial Interactive.*

Requesting a Password Reset

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

Users do not need to contact the Help Desk. In most cases, the user can



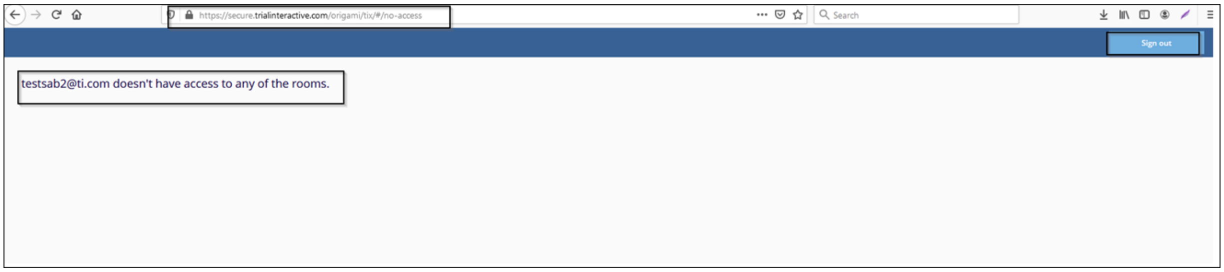
perform the Password Reset operations without any outside help.

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

Signing in without access to rooms

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

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



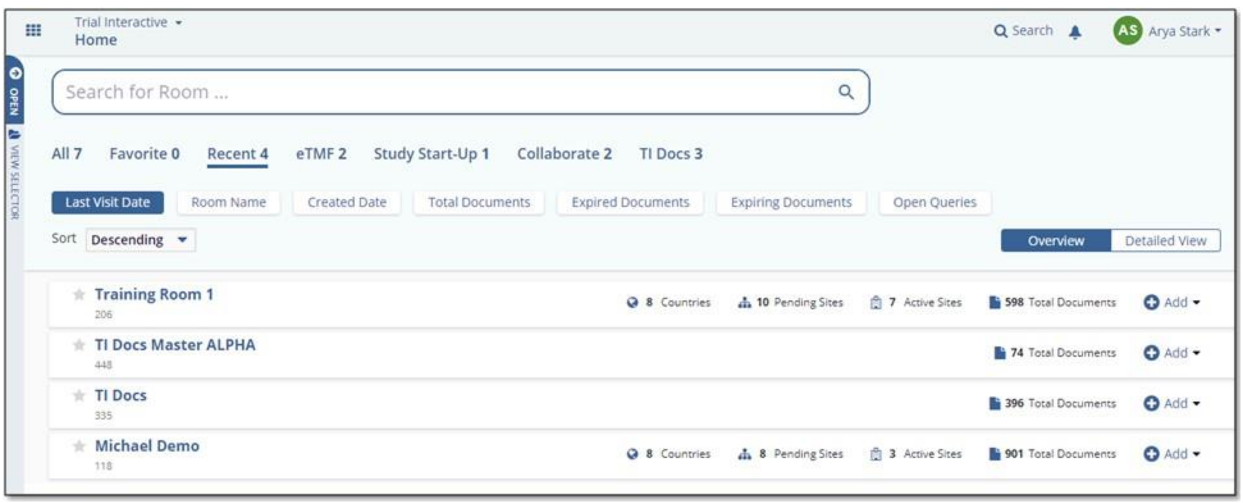
Click the Sign Out button to redirect to the standard login page.

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

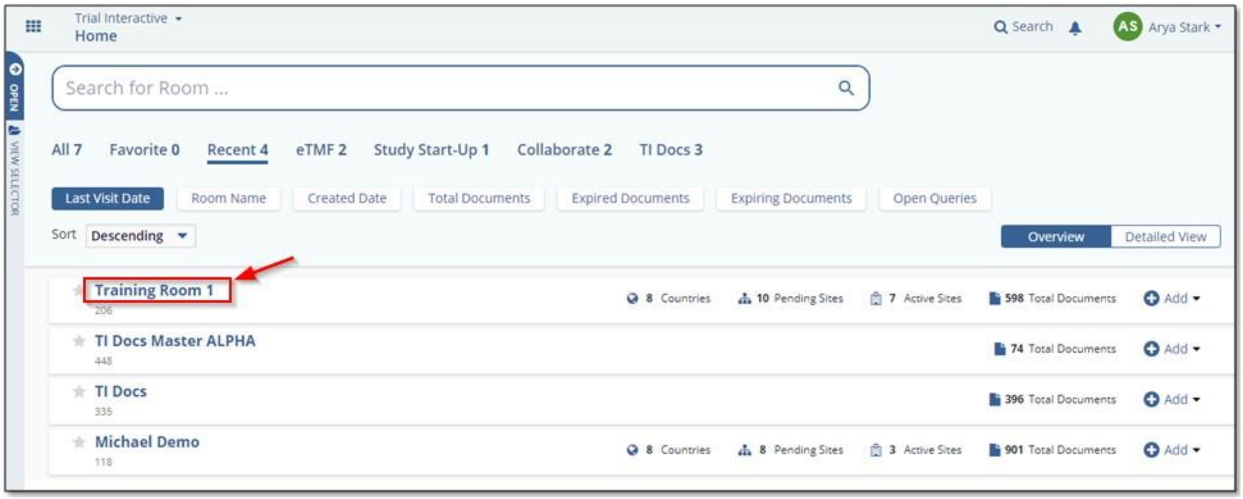
Chapter 3. The Trial Interactive Home Page

This section helps you access rooms as well as Overview and Detailed summary of rooms.

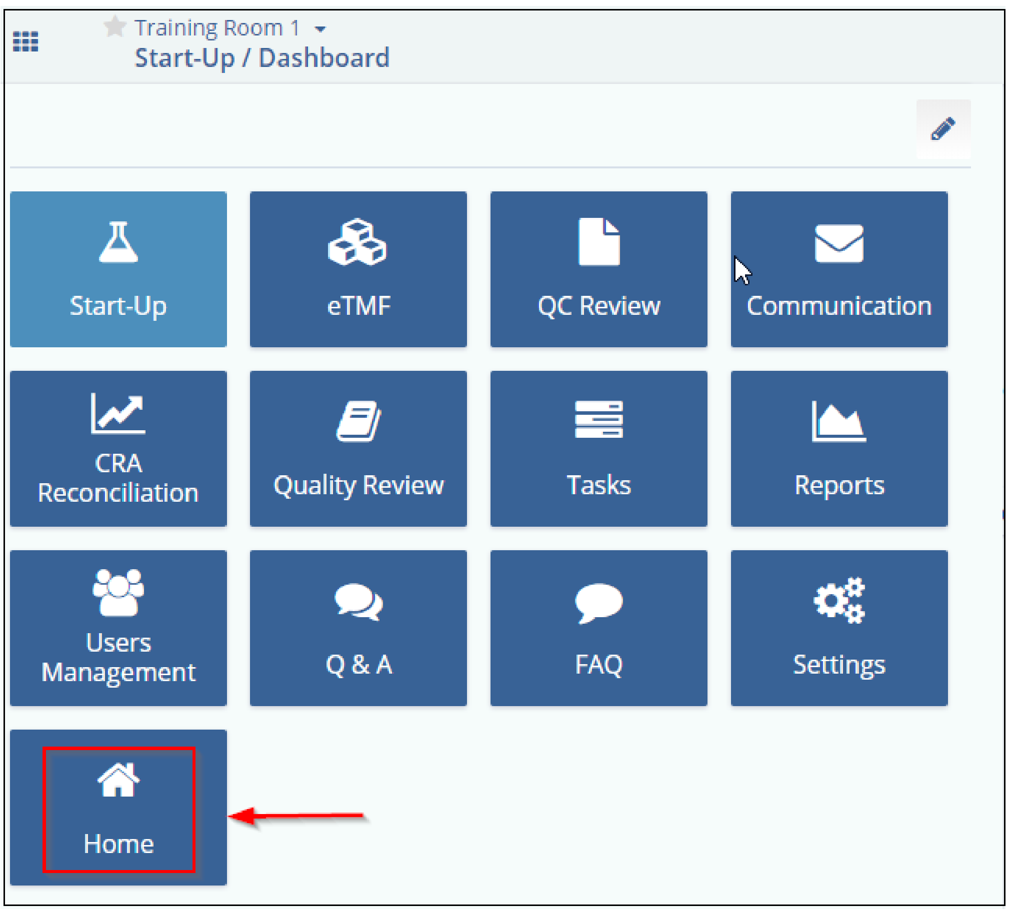
After signing in to Trial Interactive, you are landed on the Trial Interactive Home Page as shown in the screenshot below:



Click the required Room Name to enter a room.



Note: Once inside a room, you can reach this page from the Main Navigation *(page 53)* by clicking the **Navigation Grid** icon. Refer to the screenshot below:



You can do the following from the Trial Interactive 10.1 Home Page:

1. View Rooms

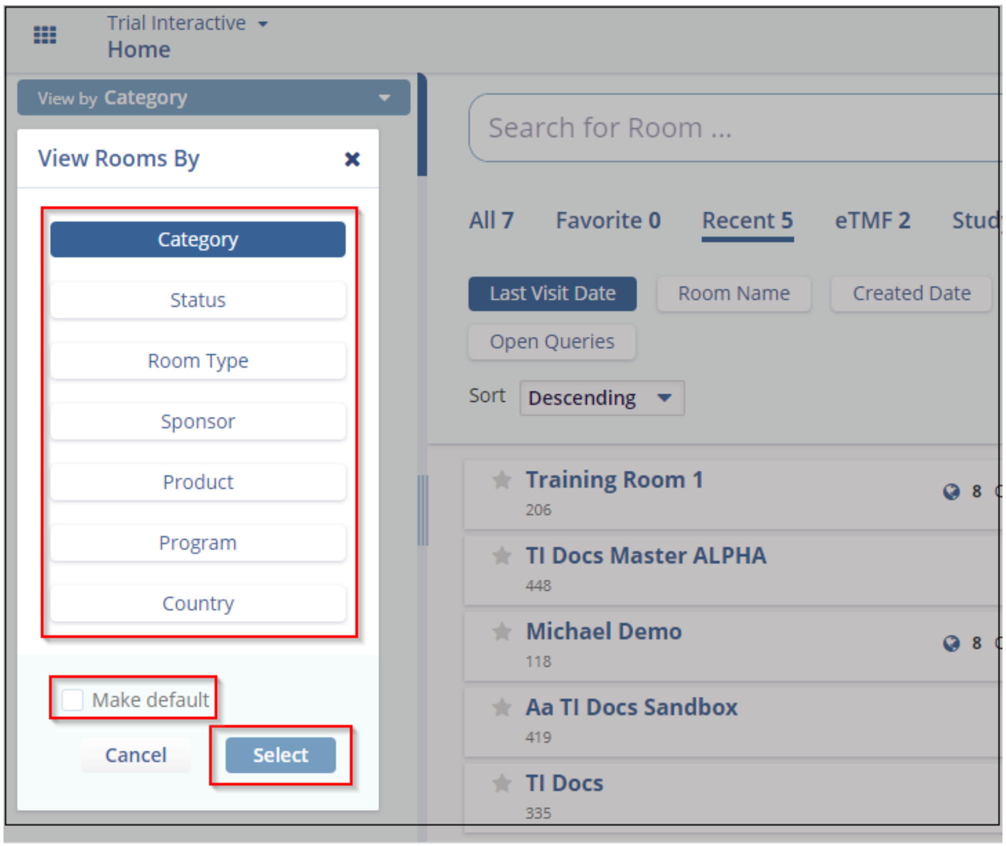
2. Search for Studies, Sponsors, and Sites across all rooms
3. Cross Study Document Search
4. Get a Summarized Overview of rooms
5. Get a Detailed View of rooms
6. Upload Documents to a Room
7. Add Users to a Room
8. Filter and Sort Rooms
9. View and Mark favorite rooms

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

Room View

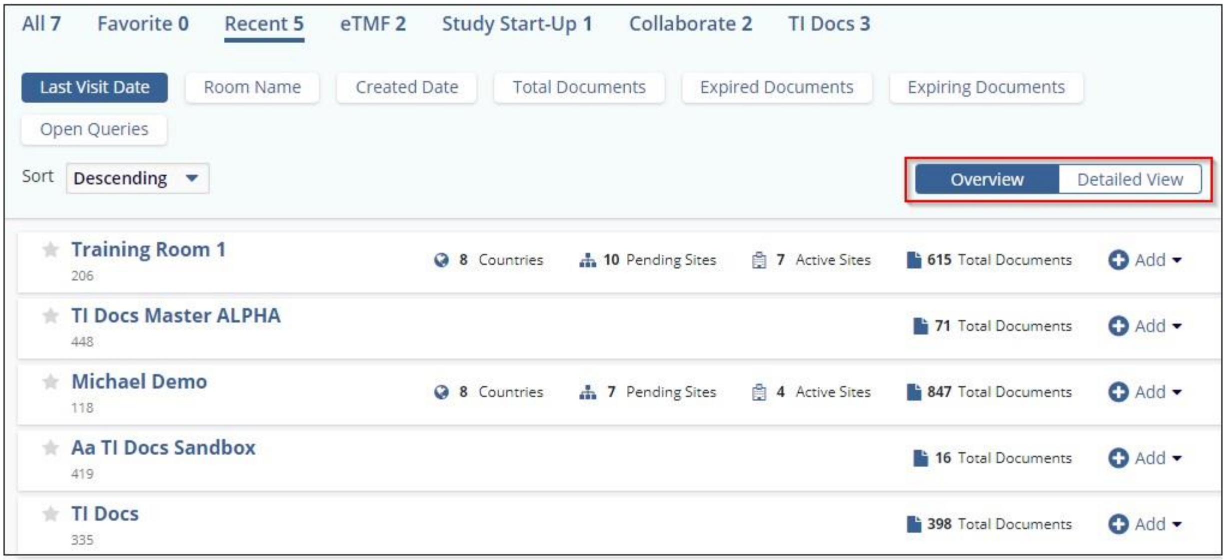
TI Home page provides you with the different views through which you can filter rooms.

Filter categories are placed in the left pane. If it is closed then click on Open like shown in below screenshot to open it.



Viewing Room Details

You can also view the details of the room and the related information by clicking the 'Overview' or 'Detailed View' to the extreme right of the



home page. Refer to the screenshot below:

Besides TI Home Page, the Room Details can also be viewed from the User Menu *(page 56)* after entering a room.

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

Room Search and Accessing a Trial Interactive Room

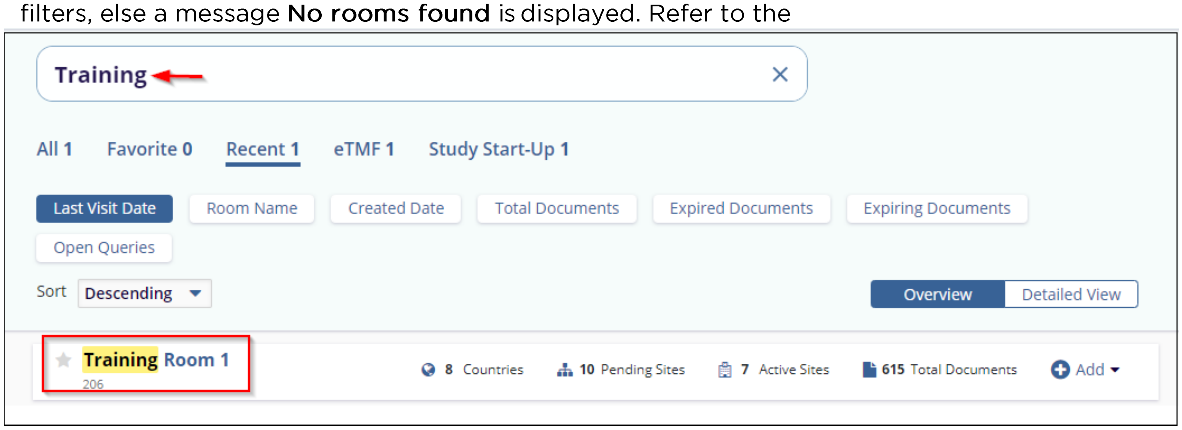
Room Search

Trial Interactive allows you to search for rooms easily in

cases you have access to hundreds of rooms. To perform

a room search:

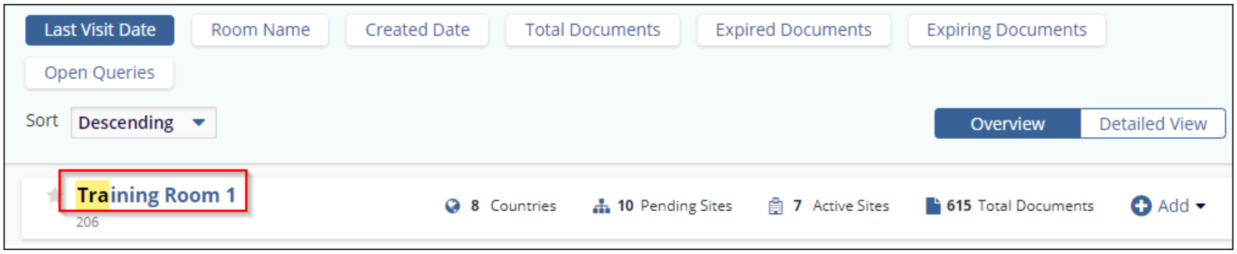
1. Enter the required room name in the **Search box** at the top of the page and press **Enter** on your keyboard.
2. Rooms matching the search criteria are displayed in the panel below the filters, else a message **No rooms found** is displayed. Refer to the



screenshot below:

Accessing a Trial Interactive Room

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

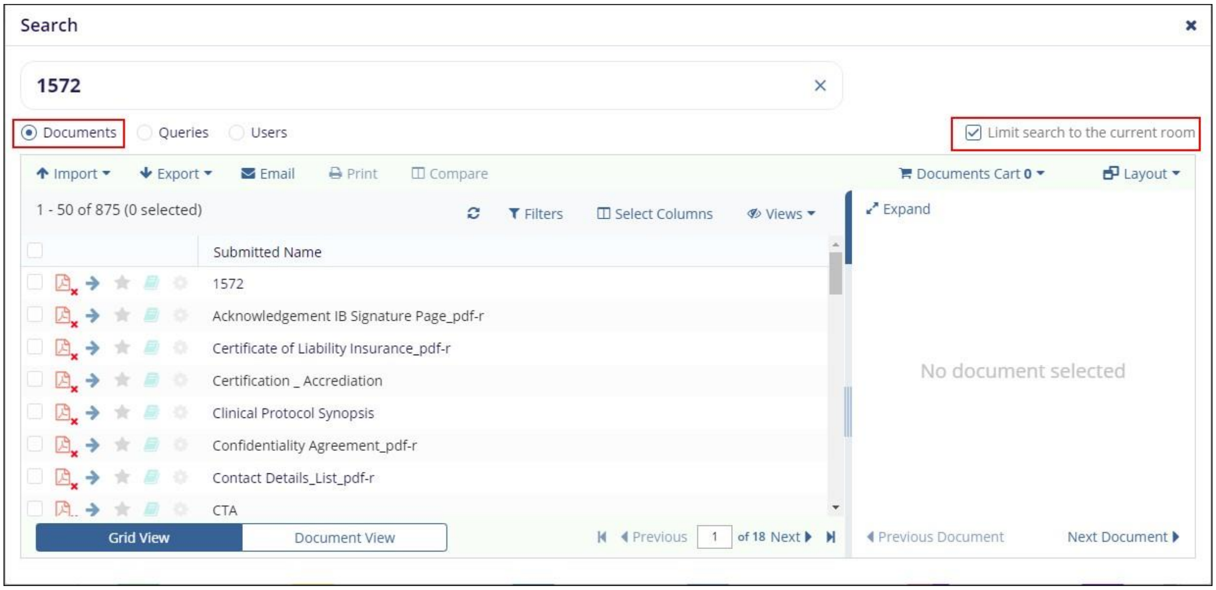


Cross Study Document Search

Documents Search

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

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
2. The **Search** window appears, which consists of the following sections:
   a. The **Search** textbox.
   b. The **Documents**, **Queries**, and **Users** radio buttons (these are available only when a search is being performed from within a room)
   c. The **Limit search to the current room** checkbox.
3. Select the **Documents** radio button. The documents grid appears below.

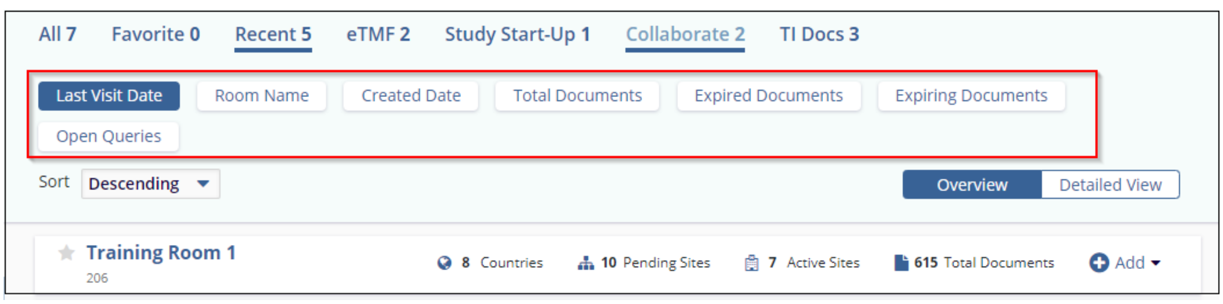


You can perform the following action from the Search Window:

1. Code the document
2. Import and Export the document
3. Email document
4. Compare documents

TI Home Page Filters

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



The filters consist of the following main filters:

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

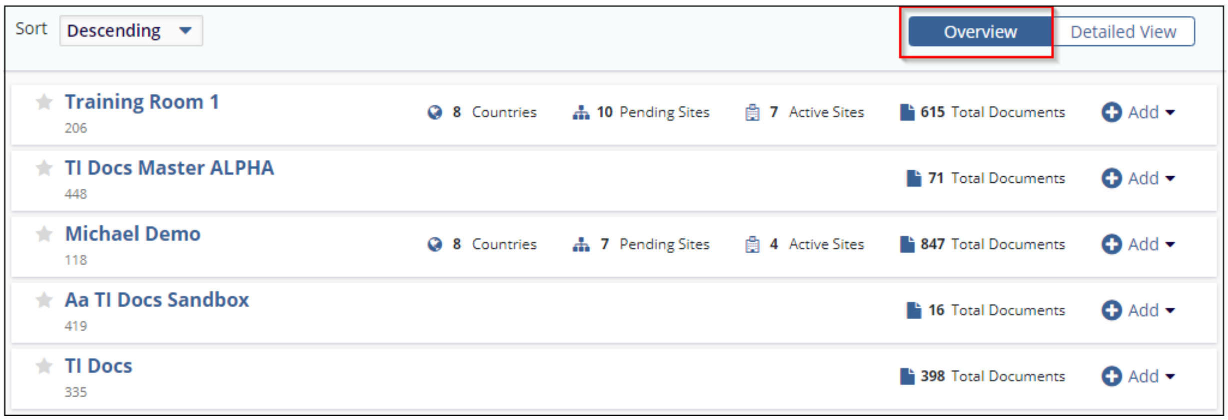
Below these main filters, TI Home Page provides **Additional Sortings** which allows you to sort the room as per the options in the sortings. *These Additional Sortings varies with every main filter.*

Summarized (Overview) View of Rooms

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

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

Refer to the screenshot below:



Countries

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

Active Sites

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

Pending Sites

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

Total Documents

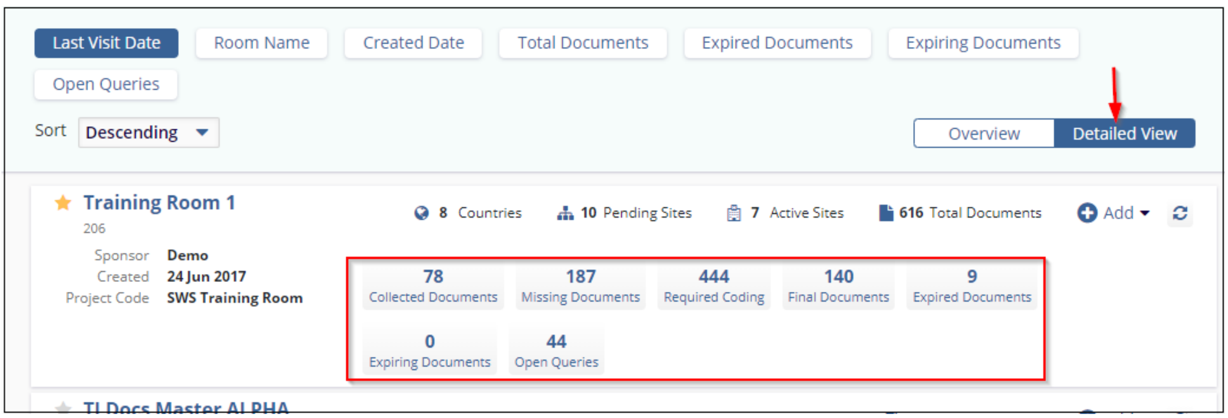
The number next to **Total Documents** link shows the **total count** of documents pertaining to a room.

Detailed View of Rooms

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

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

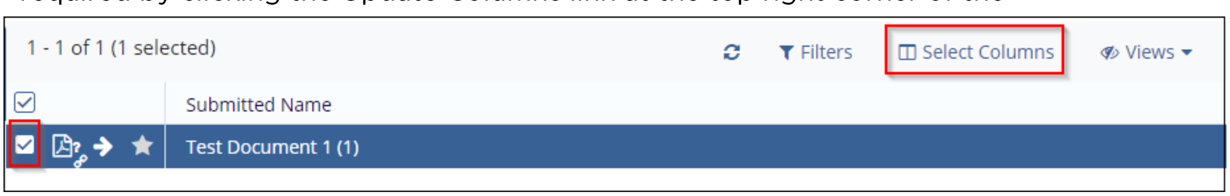
screenshot below:



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

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

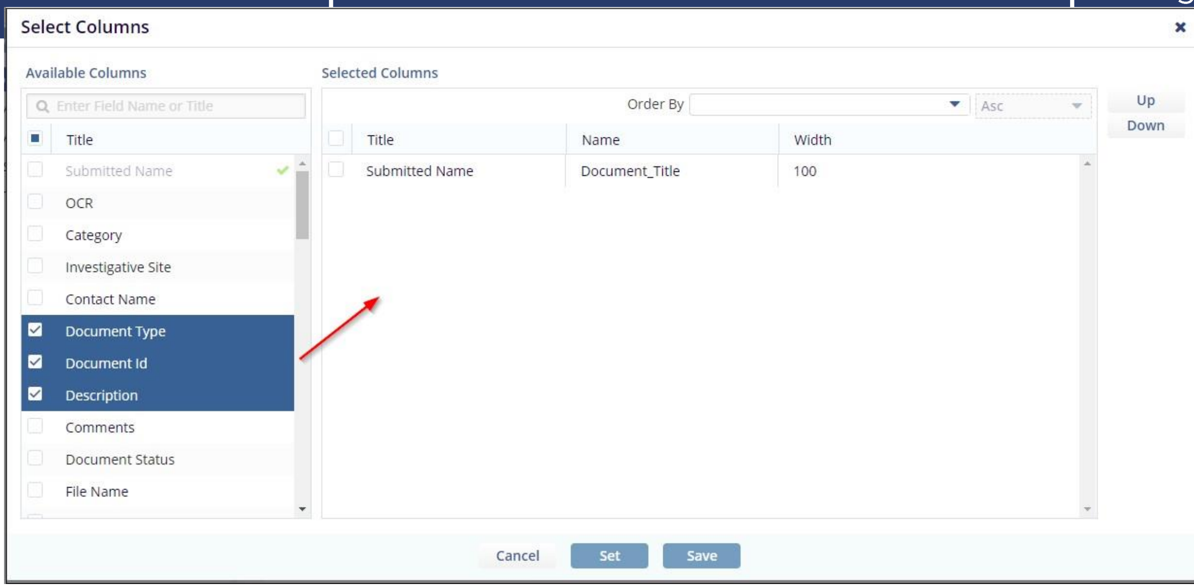
Besides, you can also configure the columns in the Document window as required by clicking the Update Columns link at the top right corner of the

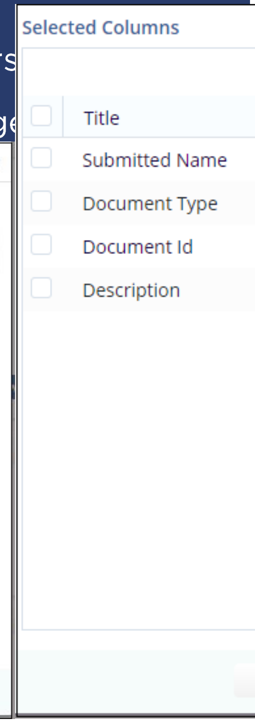


window. Refer to the screenshot below:

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

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

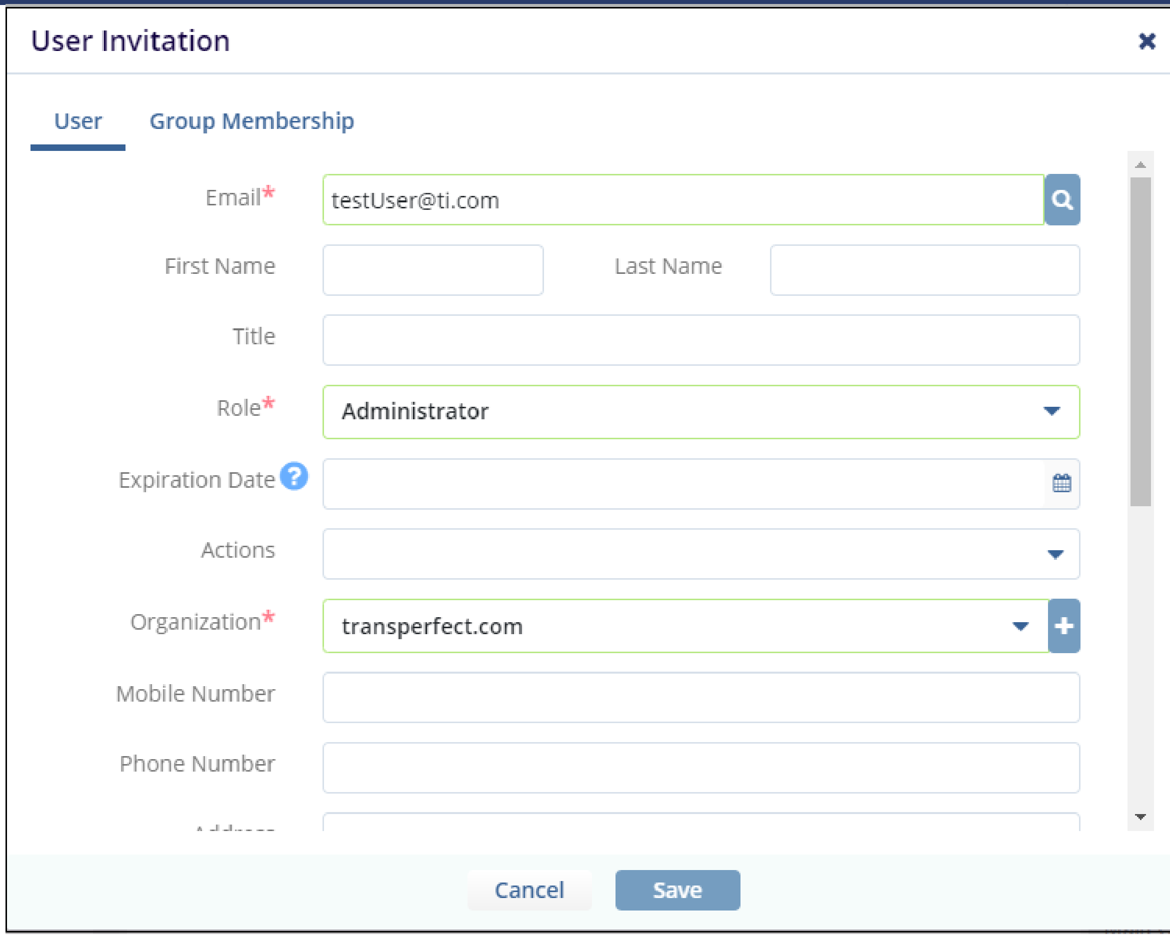




Add Users to a Room

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

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

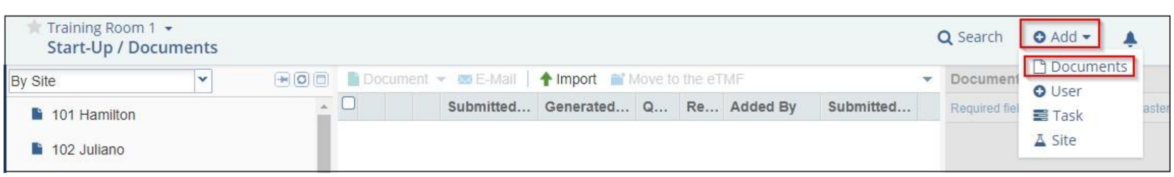


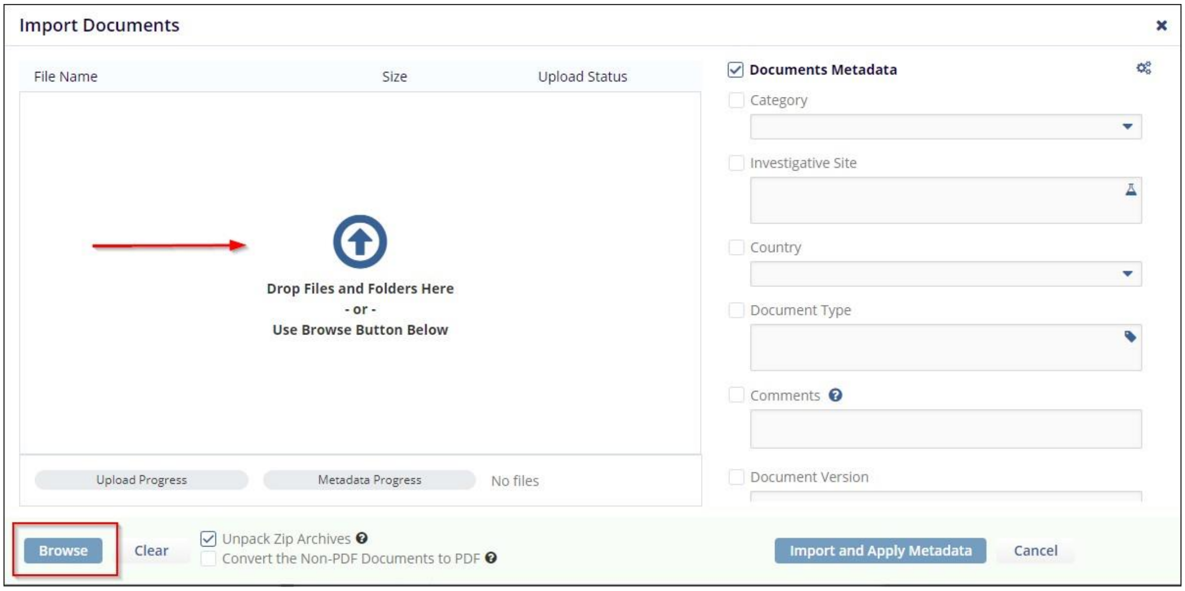
3. You can choose to select multiple rooms to add users to by clicking **Add** button next to the Room textbox.
4. Enter the **Email Address** of the user, assign **Role** to the user, select **Actions** to assign to users.
5. Select the **Groups** to add users to the group. You can select multiple groups.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

Upload Documents to a Room

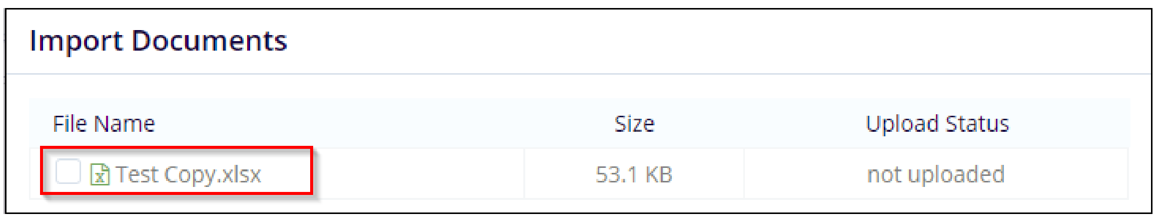
Follow the steps below to upload documents to a room from the Home Page:

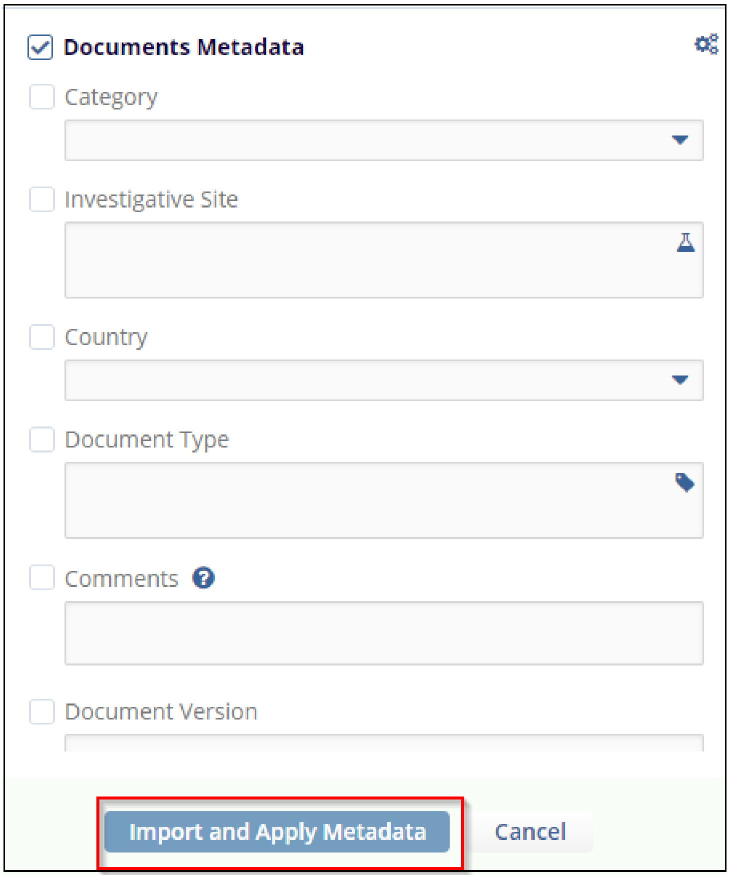
1. Click  dropdown at the extreme right of the Room Name on the home page to reveal the options.
2. Select the **Document** option from the dropdown list that appears.
3. Drag and drop the files OR click Browse at the bottom of the page to navigate to the required document to be uploaded. See below screenshots:





4. Once the document is added, click on the **Import and Apply Metadata** button to import the document.



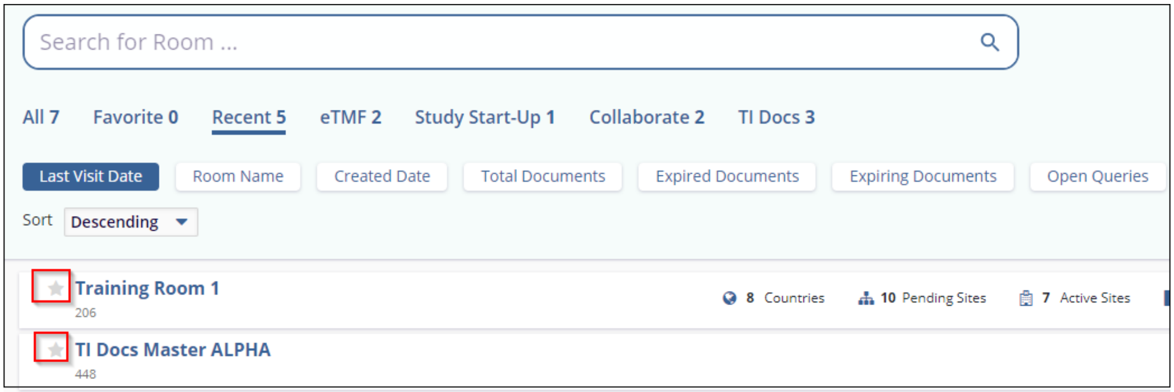


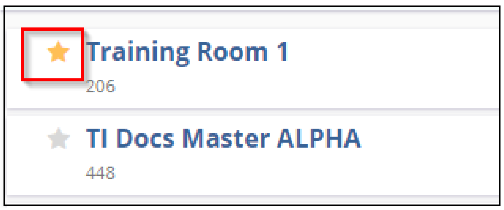
5. Once the document uploading is completed, the system displays a notification to the user regarding the same.

Marking Favorite Rooms

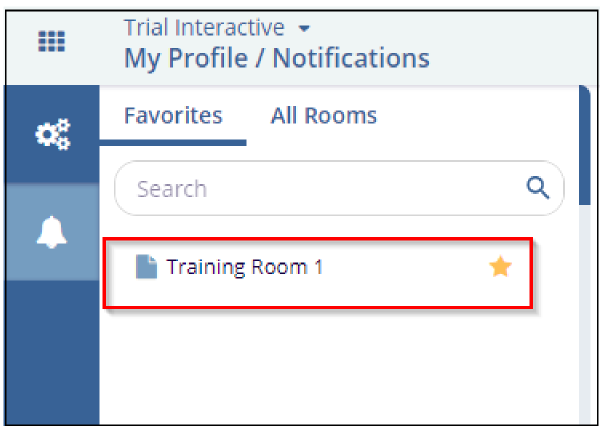
Many users are granted access to more than one Trial Interactive room. Users can make particular rooms easier to locate by marking the room or rooms as Favorites. This can be done in two ways.

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





2. On entering a study room, you can add it to Favorites by clicking the star at the top left corner of the page where the room name is displayed. The room can easily be removed from the list by clicking the star again. Refer to the screenshot below: The list of all rooms to which you are assigned is also available through the user profile.
   a. Navigate to **My Profile Settings** from the User menu.
   b. Select **Notifications** from the menu on the left.
   c. Click the golden star to the right of the room names to mark the selected rooms as **Favorites**.

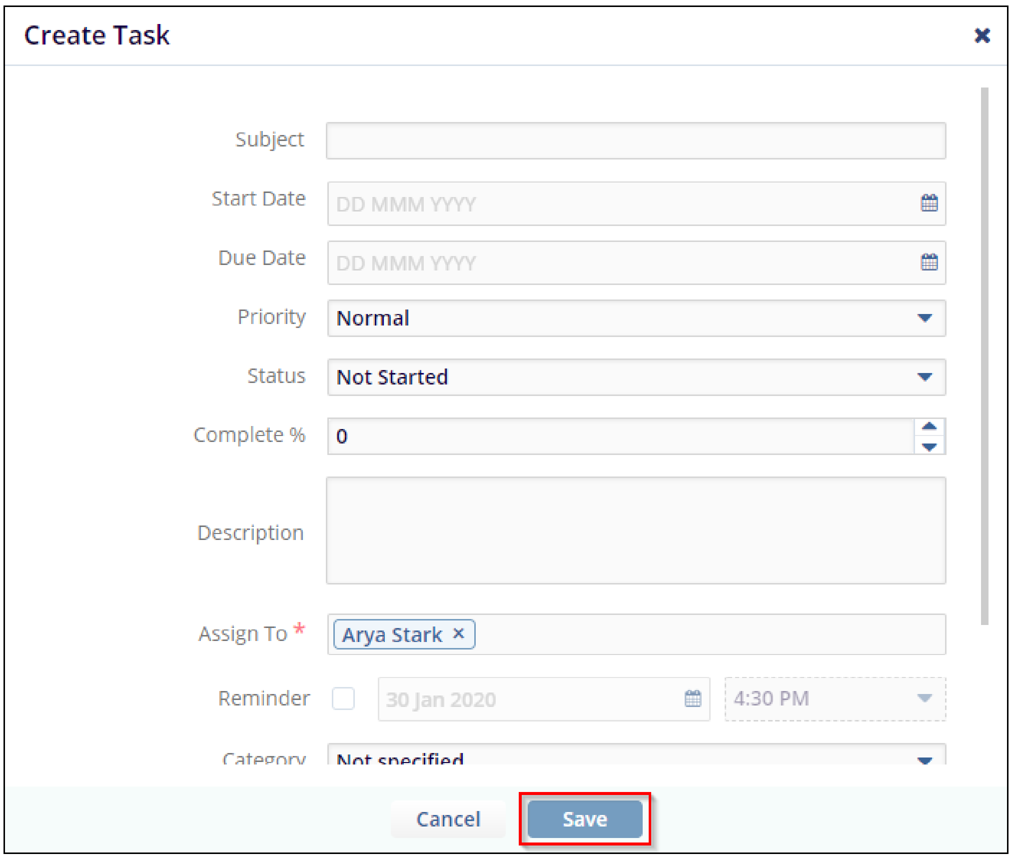


Adding Tasks to a Room

To add documents to a room:

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

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



4. Click **Save** when all the information is filled.

Chapter 4. Main Navigation and Inter-Room Navigation

Know how to access applications from within Trial

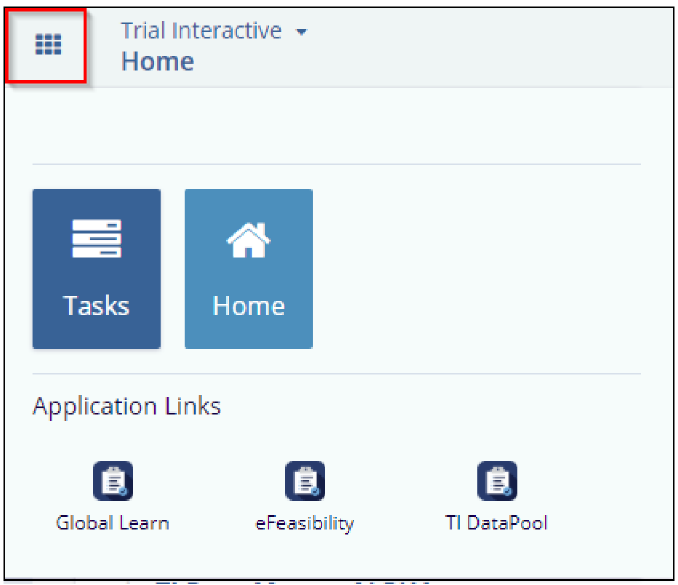
Interactive and navigate between rooms. From here,

find more details on the following:

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

Main Navigation from Home Page

Main Navigation from the Home Page can be accessed by clicking the Four Dots located at the top left corner of the page marked in Red box in the screenshot below:

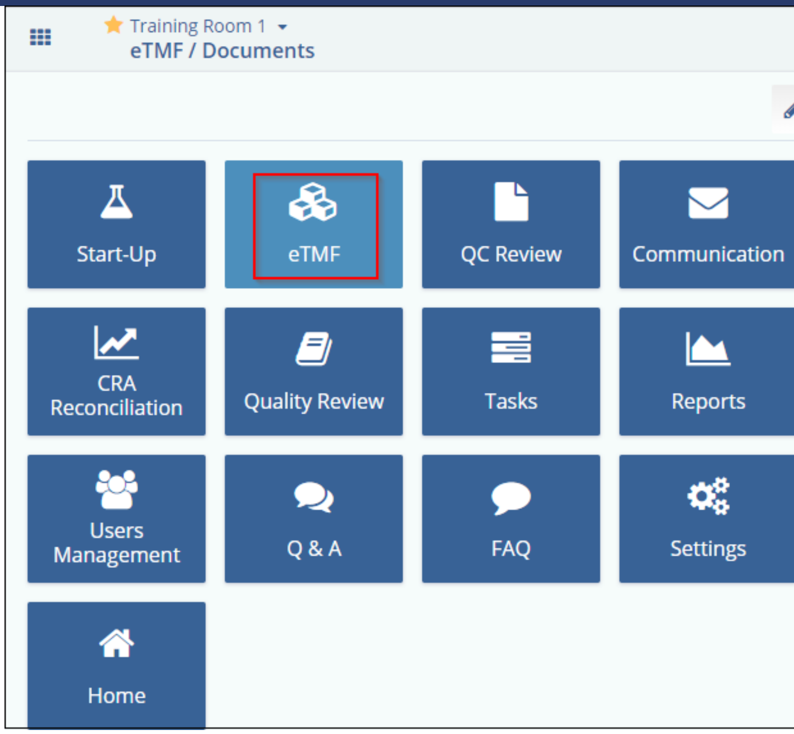


You can access the Home Page and Tasks application from the Main Navigation. Besides applications, you can also access other Application Links from the Main Navigation of the Home Page. These application links take you to the website of the respective links.

Main Navigation from within a Room

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

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



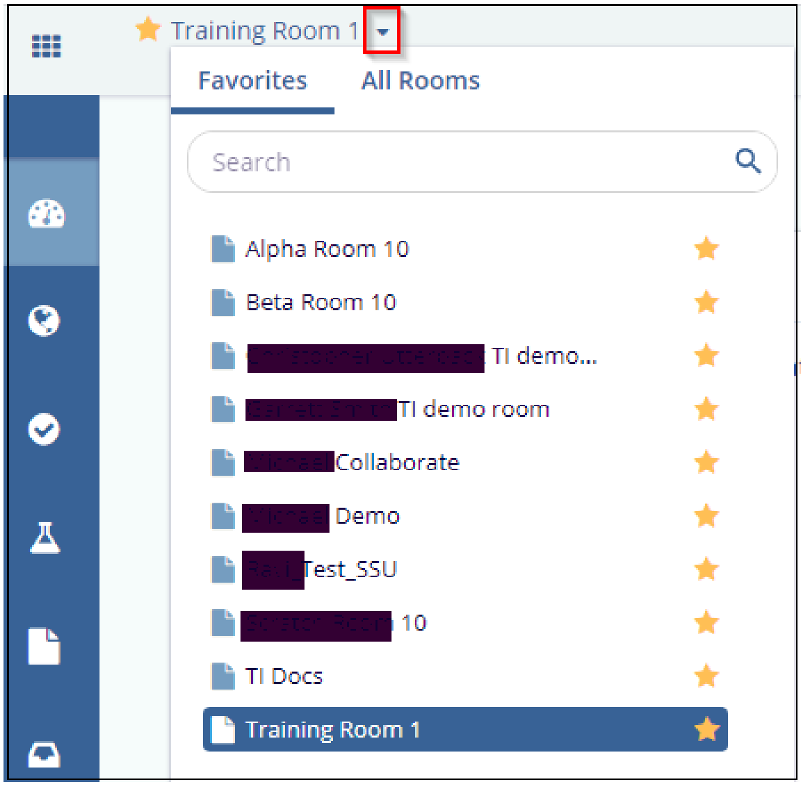
The different modules that can be viewed from a particular Main Module depend on the functionality that can be allowed from the particular Main module. Within Trial Interactive, you can view the following Main Modules:

1. Home *(page 40)*
2. Tasks *(page 429)*
3. Trial Interactive eTMF and the Documents Module *(page 199)*
4. Quality Control
5. Start-Up
6. Audit/Quality Review *(page 346)*
7. Communication *(page 431)*
8. Q&A *(page 438)*
9. FAQ *(page 29)*
10. Reports *(page 498)*
11. Collaborative Workspace *(page 451)*

Navigating between Rooms

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

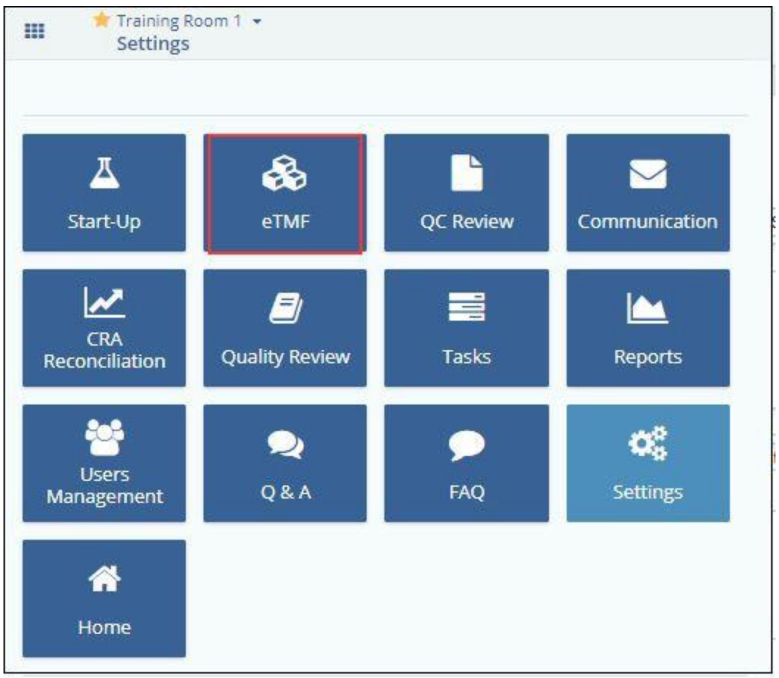
Click the arrow next to the room name. Select a room from the dropdown list that appears. Refer to the screenshot below:


Training Room 1
Favorites
All Rooms
Search
Alpha Room 10
Beta Room 10
[redacted] TI demo...
[redacted]TI demo room
[redacted]Collaborate
[redacted] Demo
[redacted]Test_SSU
[redacted] 10
TI Docs
Training Room 1

Chapter 5. Trial Interactive eTMF and the Documents Module

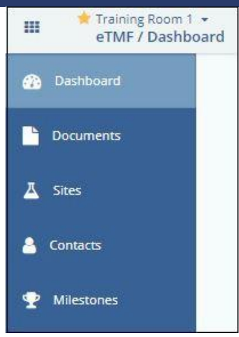
The Trial Interactive eTMF Application acts as a central access point to not only Clinical Trial Documents *(page 222)* but also to eTMF Sites *(page 291)*, Contacts, eTMF Completeness, and CRA Reconciliation Reports *(page 308)*, reports in the form of Dashlets for all clinical trial activities, and also to IRB Integration and Potential Sites *(page 291)*.

You can access this module from the Main Navigation *(page 53)*. Refer to the screenshot below.



Once you enter the application, you have access to various modules within it and can toggle between the:

1. Dashboard Dashlet View
2. Documents
3. Sites
4. Contacts
5. Milestones etc. from the menu bar on the left. Refer to the screenshot below:



All these views can be enabled for you by the Super Admin through the Room Settings (page 85), and are discussed in separate topics.

Dashboard Dashlets

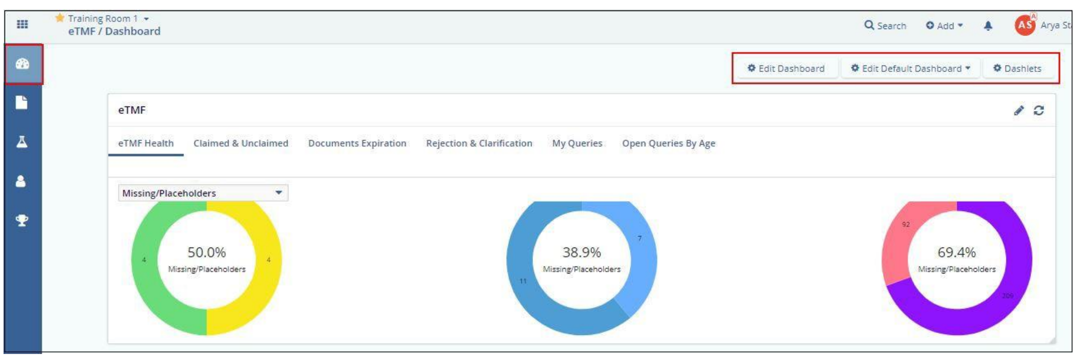
Know how to configure the dashboard and dashlets in a room.
All Trial Interactive dashboards are primarily composed of dashlets. As a user, you can configure your dashboards to suit your preferences, views, and convenience for efficient performance.
Individual users in Trial Interactive have the option to arrange their Dashboard views. Arranging your dashboard views include deciding:

1. The layout of the dashlets on your dashboard by moving them around,
2. The dashlets to view along with their distribution on the dashboard, and
3. The configuration of each dashlet.

Dashlets

A dashlet is a component in a dashboard with functionalities of its own. A dashlet may provide information on a particular feature in the form of a report, a graph, or a description on a particular topic. Dashlets are independent of each other and are contained in a dashboard. In a way of its own, they play a significant role in the look and feel of a dashboard.

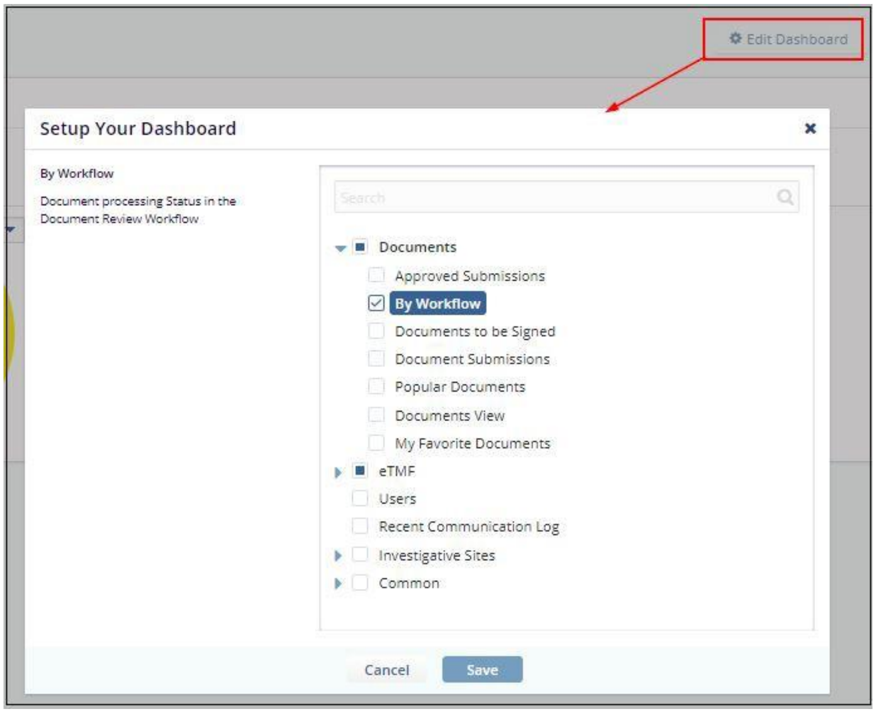
To visit a Room Dashboard, click Dashboard from the left menu from the eTMF module. Refer to the screenshot below:



Dashboard Settings

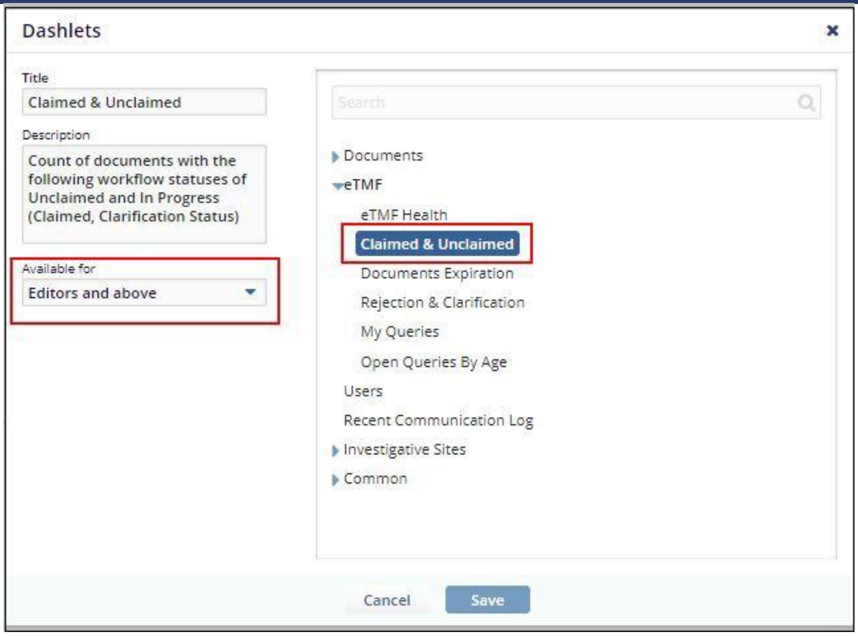
As one of the sub-section of General room setting tabs, the Administrator will see the Dashboard Setup box. An Administrator can change the information that will be available to users in the room when they access their Dashboard.

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



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

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



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

From the Dashboard Settings, the following activities are available:

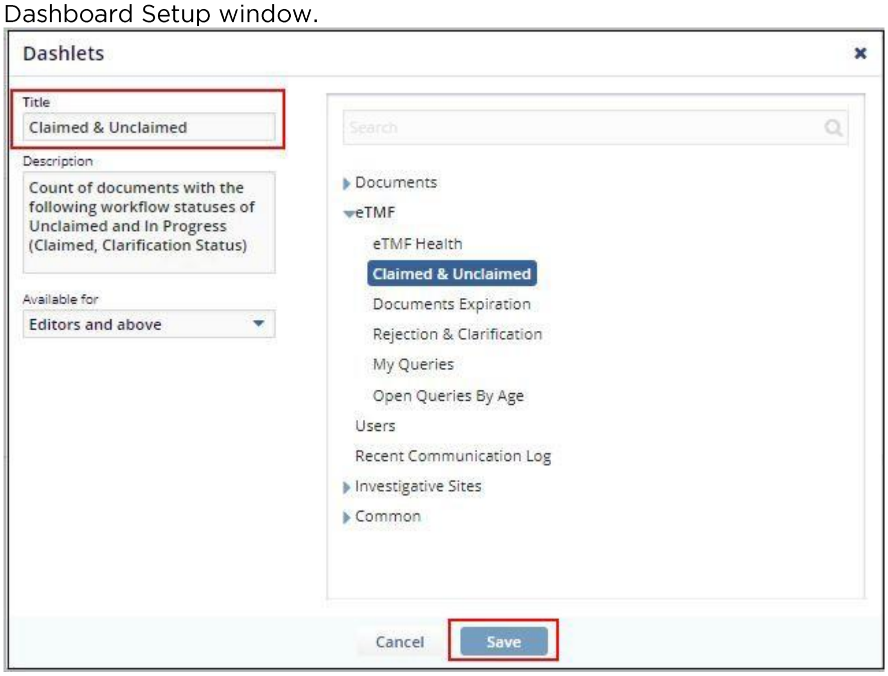
1. Renaming a dashlet
2. Default Dashboard Setup

Above activities are discussed in details in the sections below.

Renaming a dashlet

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

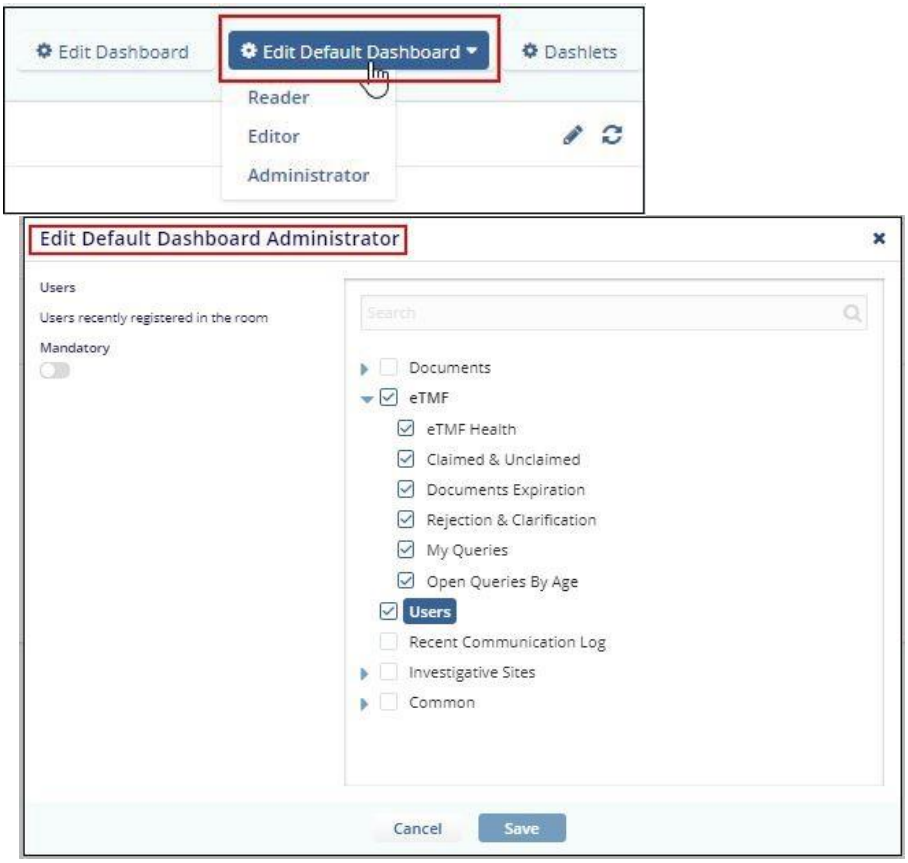
1. Double-click the name of a dashlet that you want to rename from the Dashlet column of the Dashboard Setup window.



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

Default Dashboard Setup

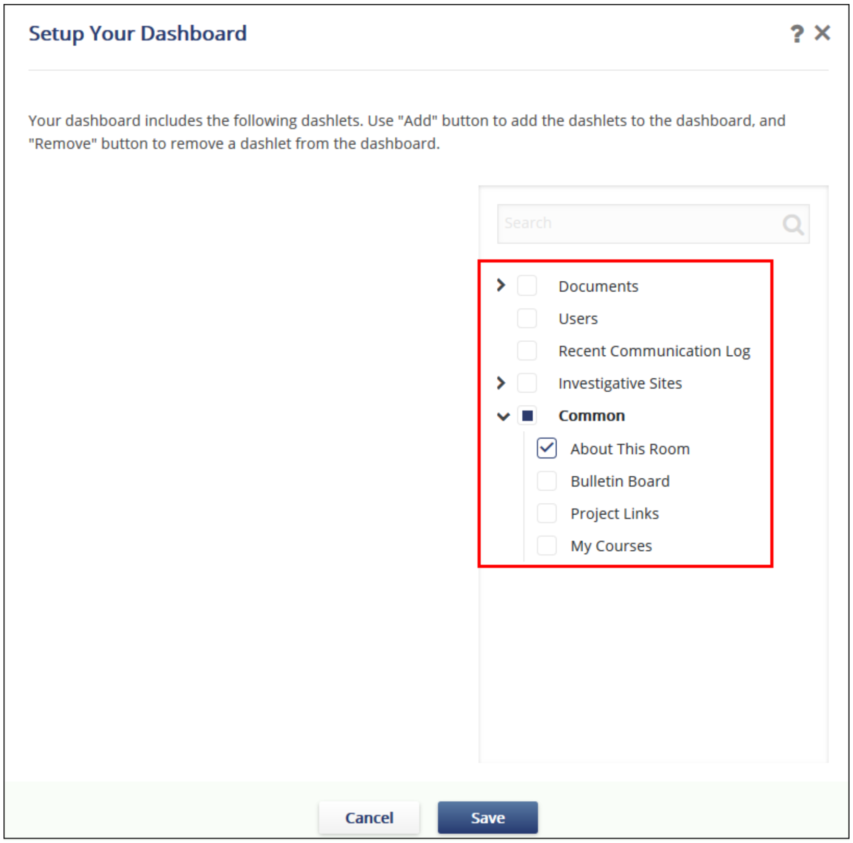
You can set the default dashboard for the minimum level role by clicking the button at the bottom of the Dashboard Setup panel. The Default Dashboard Setup window opens. Make the appropriate choices as required and click OK.



Configure Dashboard

The ***Configure Dashboard*** icon at the top right corner of the Dashboard page opens the **Setup Your Dashboard** window which lists out the dashlets available for a particular dashboard.

Refer to the screenshot below:



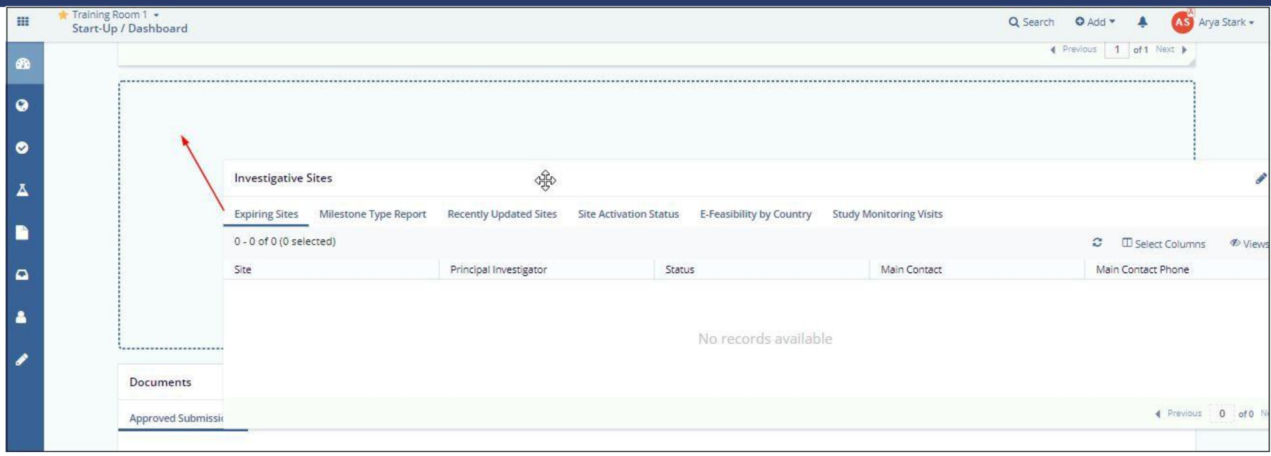
The dashboard is divided into the following parent dashlets which have child dashlets associated with each of them:

1. Documents
2. Users
3. Recent Communication Log
4. Common

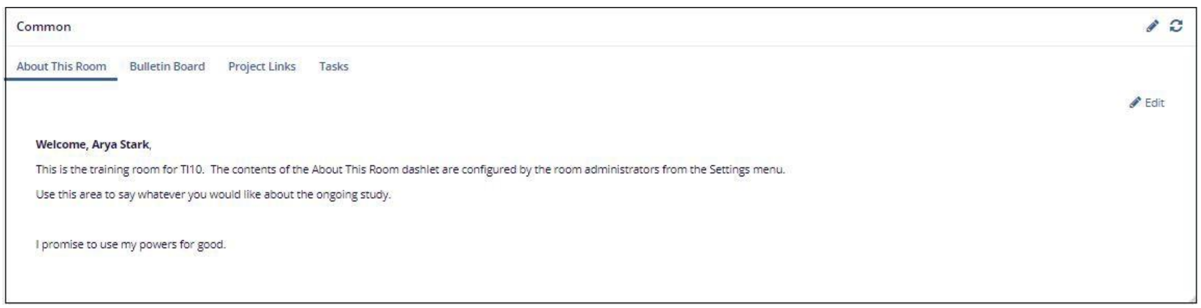
   Click the arrow next to the required parent dashlets to revel the child dashlets to add them to the dashboard as shown in the screenshot above. On selecting the dashlets, click Save and the dashlets appear on the dashboard.

Laying Dashlets in your dashboard

To arrange the dashlets, simply drag-and-drop them to a location of your choice on your dashboard. This is demonstrated below:



Dashlet – Common Grouping



The Common Dashlet gives an overview of the room and the related information to the room. Administrators can rename the dashlet by clicking the Edit icon from the top of the right corner of the dashlet and refresh the dashlet by clicking the Refresh icon.

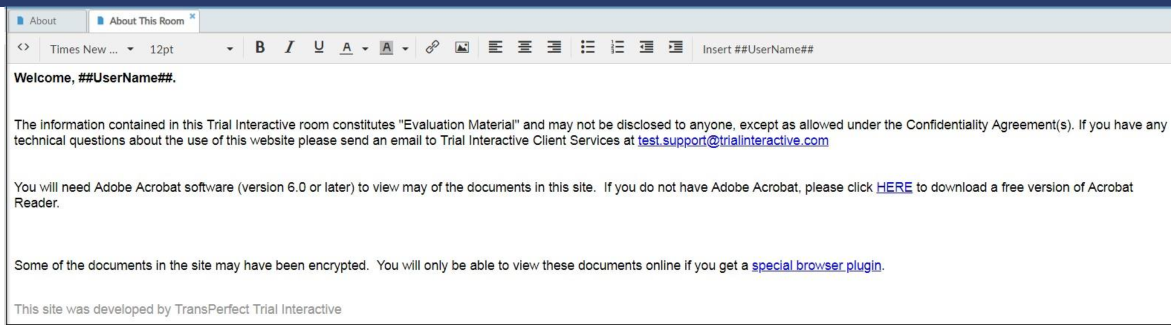
The following tabs are available in the dashlets:

1. About The Room
2. Bulletin Board
3. Project Links
4. Tasks

Each of these is discussed in the separate topics. Click the topics on the left to open the topic.

About This Room

In this window, the user can see and change the information contained in the room's Welcome message, which is the message that all users see when they access the room. This space can be used to share important information about the study once the study is in full swing, and the welcome message is no longer necessary. Once you have made the desired changes, click Save in the lower-left corner of the box.
You can view the Change Log History by using the Change Log button that is directly available on the bottom right corner of the About this Room dashlet.

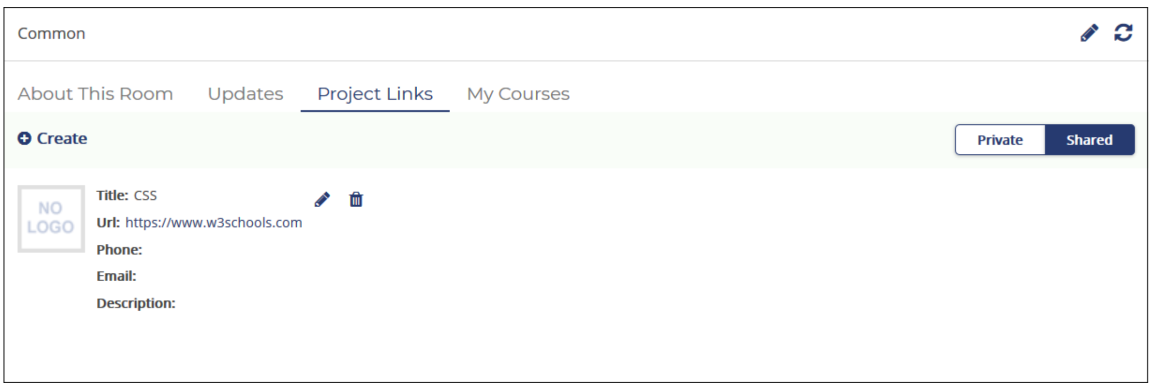


Dashlet Common - Bulletin Board

This is set up by the administrators to provide messages to the team which can be information regarding a room or problems within a study. It can be configured only by the administrators, and the reader can only see the information but could not edit.

Dashlet Common - Project Links

The Project Links tab displays the links to different systems that are used for the study and their contact information.



Note: *The project links are displayed in the tab only when you select the Shared button located at the right of the tab.*

Following activities are available for the administrators in the Project Links tab:

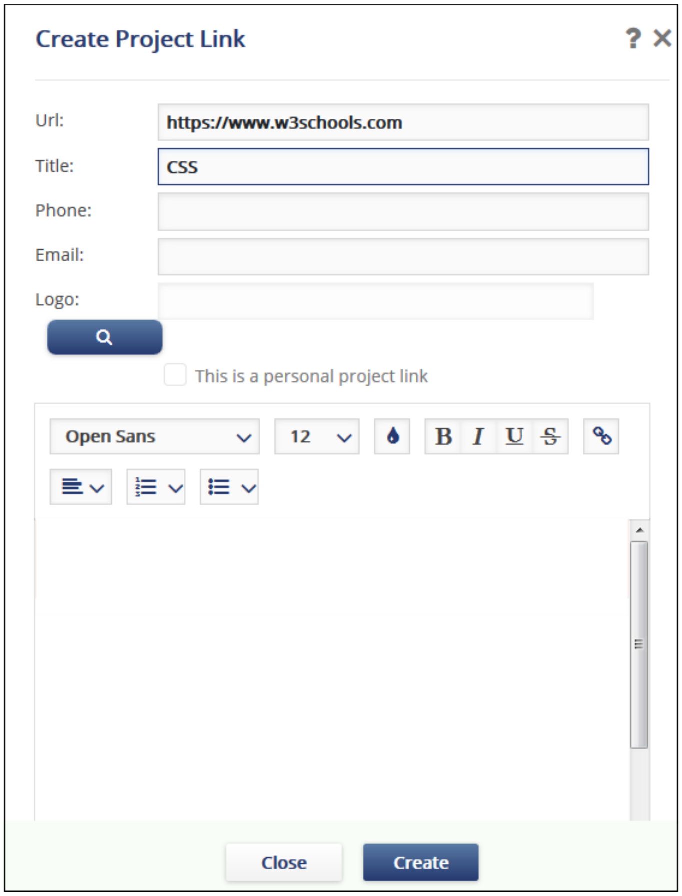
1. Adding a new link
2. Editing a link
3. Deleting a link

Each of these activities is discussed in the sections below:

Adding a new link

To add a new link:

1. Click the **Create**  button from the top left corner of the tab.
2. The **Create Project Link** window appears.
3. Enter the URL, Title, Contact details, Email, Logo, and any description.
4. Click **Create** at the bottom of the window. The link is added to the Project List. Refer to the screenshot below:



Editing a link

Click the Edit icon next to the link. Follow the on-screen instructions and edit the required details.

Deleting a link

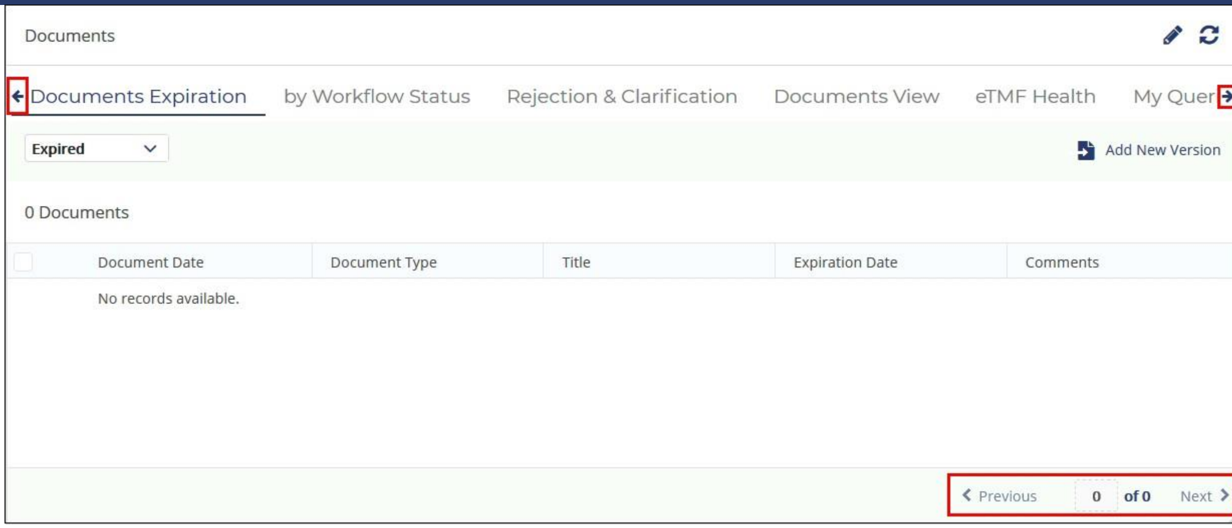
Click the Delete icon next to the link. Follow the on-screen instructions to delete the link.

Dashlet Common - My courses

This displays the courses you are assigned to and is configured by the administrator.

Dashlet – Documents Grouping

The Documents Dashlet gives an overview of the all documents and their related activities in a room. Refer to the screenshot below:



The dashlet provides the Right and Left arrows to the extremes of the dashlet to allow you to navigate to the sub- dashlets dashlets contained in the Document Dashlet.

Besides, for every dashlet of the Documents Dashlets, you can also use the Previous and Next arrows to move among the documents in the dashlet as shown in the screenshot above.

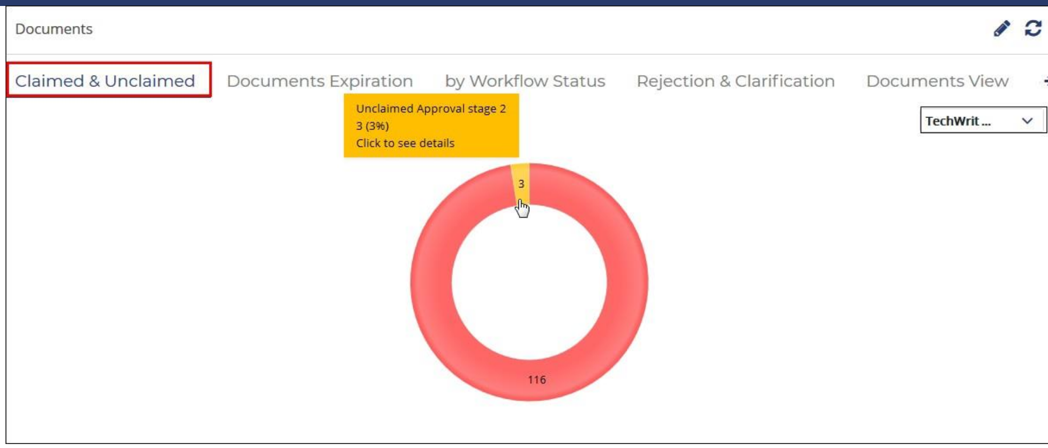
The Documents Dashlet contains the following tabs related to documents:

1. Claimed & Unclaimed
2. Documents Expiration
3. By Workflow Status
4. Rejection and Clarification
5. Documents View
6. eTMF Health
7. My Queries
8. Documents Submissions
9. Open Queries by Age
10. Popular Documents
11. Pending Documents Review
12. Unread
13. My Favorite Documents
14. Milestones Timeline
15. Milestone Type Report
16. Tasks

Each of these is discussed in separate topics. Select a topic from the left pane to open it.

Dashlet - Claimed & Unclaimed

The Claimed vs Unclaimed Documents dashlet provides a count of all documents that are in workflow and are either claimed, unclaimed, or in progress. You can further click on each slice of the interactive donut chart to obtain further detailed information.
The dashlet also provides the dropdown to select the workflow as required and displays the Donut Chart as per the selected workflow. Refer to the screenshot below:

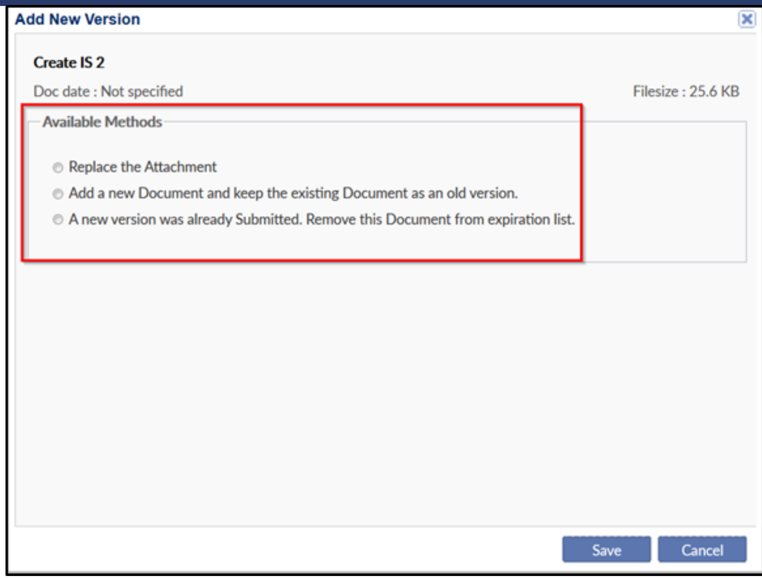


Dashlet - Documents Expiration

The Documents Expiration dashlet lists the expiring and expired documents as specified in the expiration period (N). The dashlet has two views that can be selected through an Expired dropdown. To set the views, click the Expired dropdown located on the top left corner. Refer to the screenshot below:

Click the Add New Version button from the top right corner of the dashlet to replace a document.

This opens the Add New Version window which provides the available methods to replace an attachment, or adds a new document and retain it alongside the older version or remove the older version if a new version is already submitted. Refer to the screenshot below:

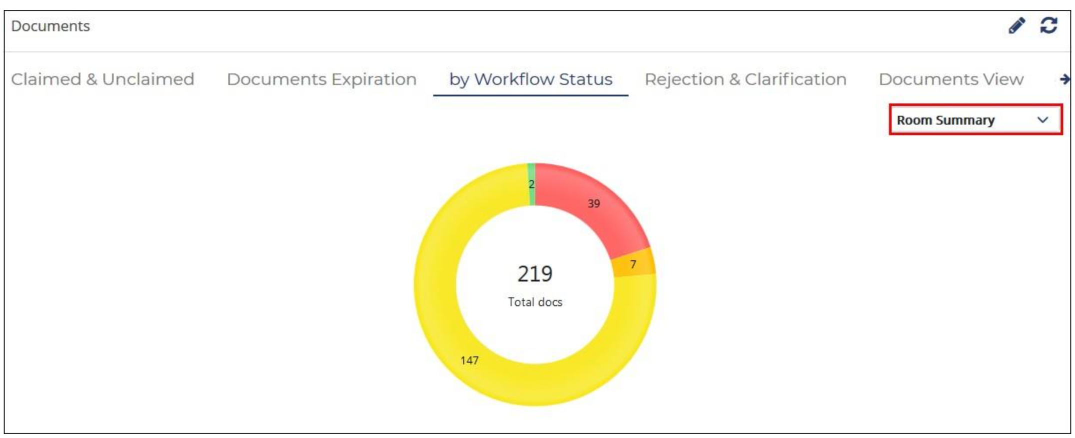


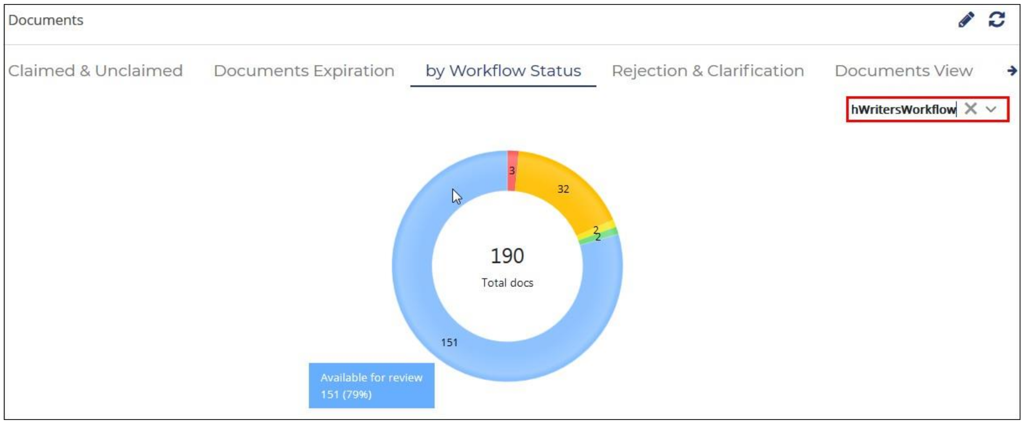
Dashlet - Documents by Workflow Status

The Documents by Workflow Status dashlet displays the document processing status in the document review workflow through a donut chart. By changing the dropdown menu, you can view the document processing status:

1. As a complete Room Summary, or
2. As workflow stages defined.

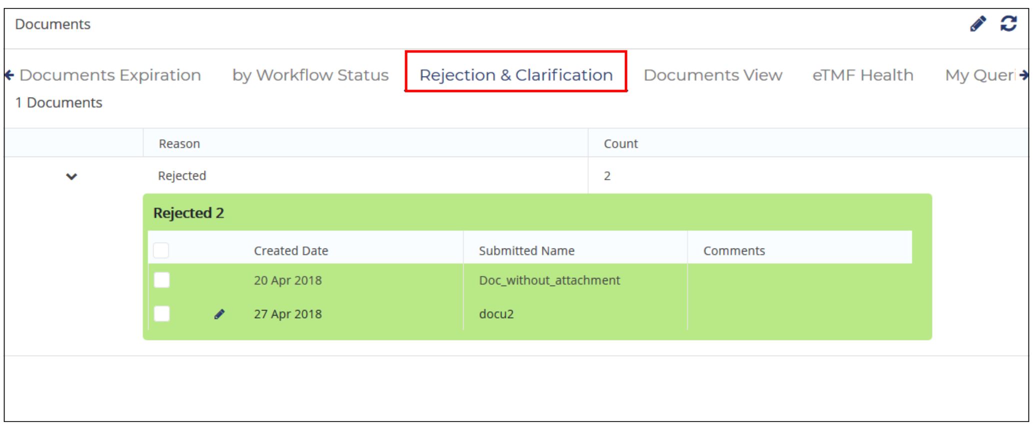
Refer to the screenshots below:





Dashlet - Documents Clarification and Rejection

The Documents Rejection and Clarification dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.
You can further double-click on the count to view the list of documents associated with a particular rejection or clarification reason. Refer to the screenshot below:

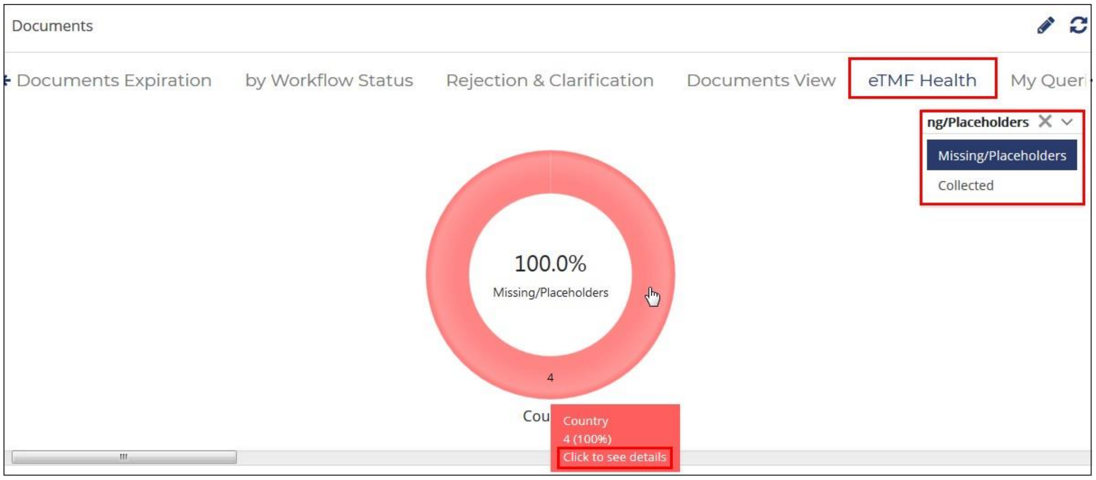


Dashlet - eTMF Health

The eTMF Health dashlet displays a donut chart that indicates what percentage of required eTMF documents are either collected or currently missing. From the top right corner of the donut chart, Administrator users can manually set the chart type to be displayed.
Hovering the mouse over the donut chart shows a popup with a more detailed progress percentage for the category of the documents.

Click a donut to drill down to the lowest level to list the missing/placeholder documents. Additionally, you can use the

Add Placeholder button to conveniently upload a missing document/placeholder or to edit a placeholder right off the dashlet. To



view any changes, refresh the chart to update the missing documents list. Refer to the screenshot below:

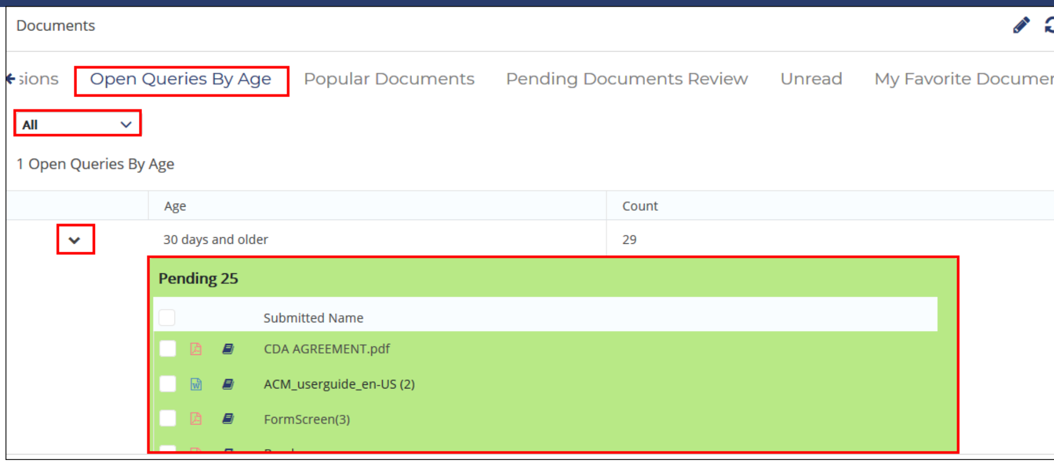
Dashlet - My Queries

The My Queries dashlet gives a list of documents based on their query types. The query types could be All, Workflow, or Audit. Refer to the

screenshot below:
Click the All dropdown to toggle between different views to view the queries.

Dashlet - Open Queries by Age

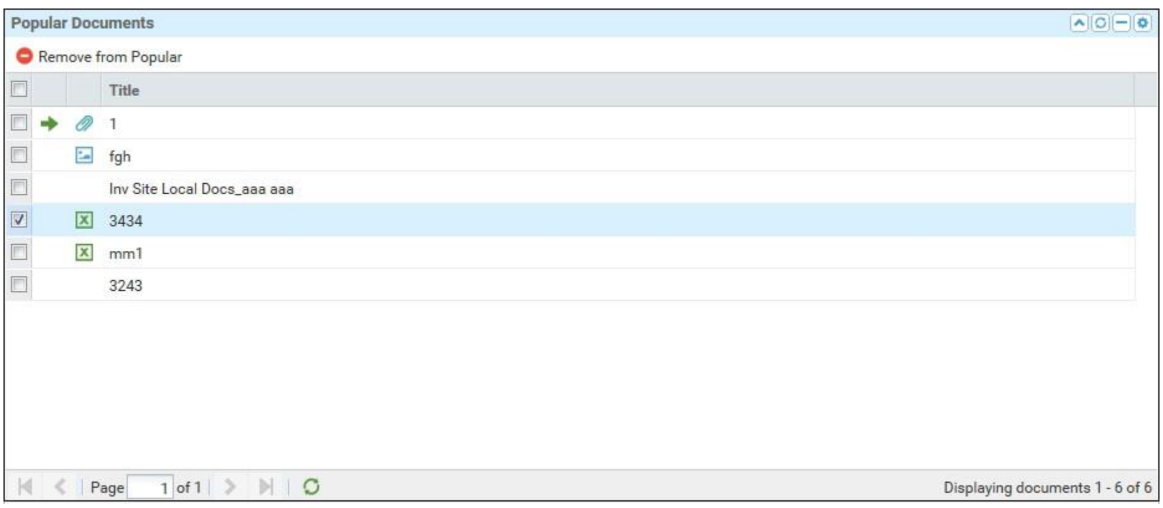
The Queries by Age dashlet conveniently displays those documents that are 30 days and older in age and also provides a documents count. The query types could be All, Workflow, or Audit. Click the arrow next to the age to reveal the queries listed in the query type. Refer to the screenshot below:



Dashlet - Popular

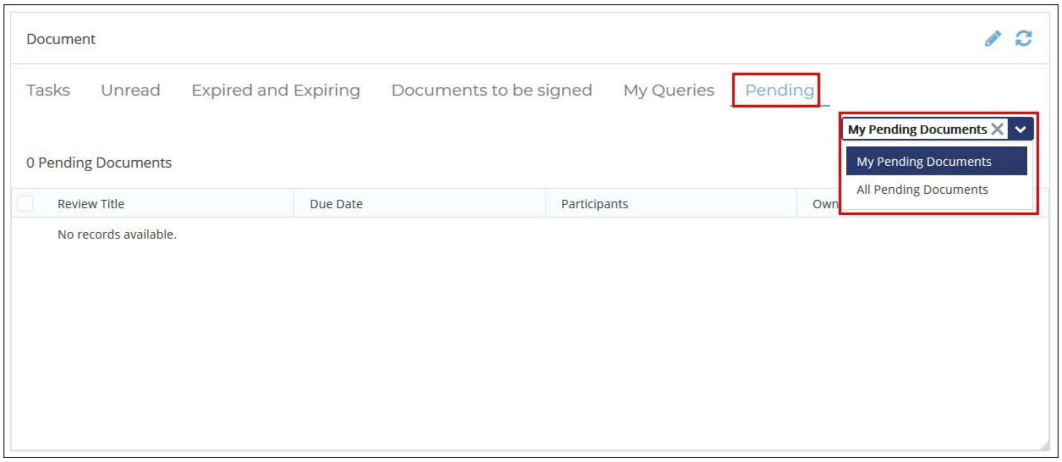
The **IP Release Documents** dashlet displays the list of documents that have been **marked as popular *(page 289)*** by an Admin or Editor through the Document Cart and which are used frequently.

To remove a document from the Popular list, click Remove from Popular button on the dashlet. To view the document, click the icon. Refer to the screenshot below:



Dashlet - Pending Documents Review

The Pending Documents Review dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for All users, or only for yourself through My Review. Refer to the screenshot below:

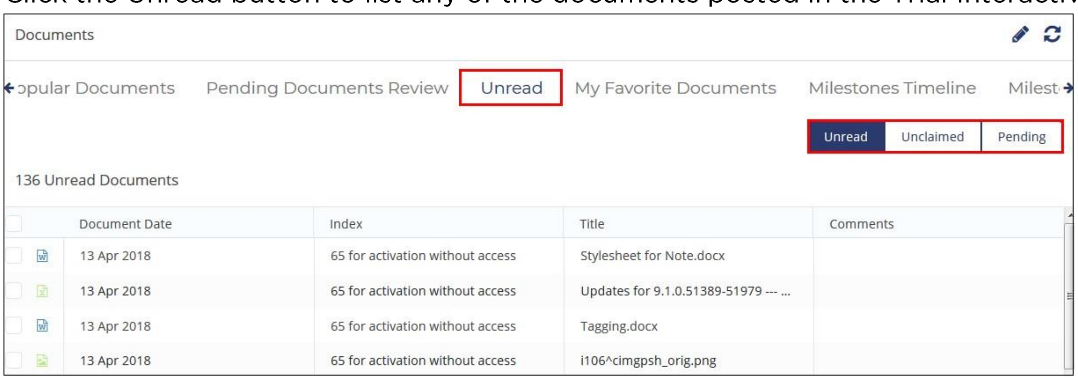


Click the All Pending Documents dropdown from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

1. **My Pending Documents**: This displays the list of all pending documents that are assigned to you for review.
2. **All Pending Documents**: This displays the list of all pending documents that are pending for review in a room.

Dashlet - Unread

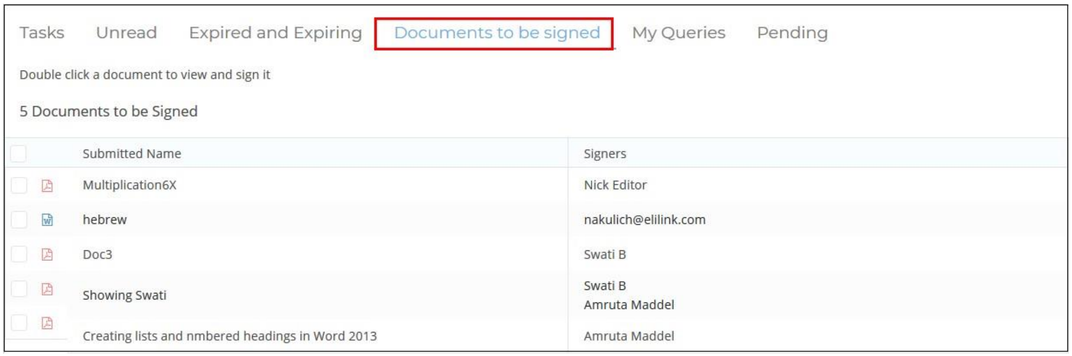
The Unread dashlet shows the three different views of documents in eTMF module - Unread, Pending, and Unclaimed. Refer to the screenshot below:
Click the Unread button to list any of the documents posted in the Trial Interactive site that



has not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of.
Click the Unclaimed button to get a list of documents that have not been claimed for review.
Click the Pending button to get a list of documents that are yet to be reviewed.

Dashlet - Documents to be Signed

The Documents to be Signed dashlet gives a list of document pending for signature. Refer to the screenshot below:

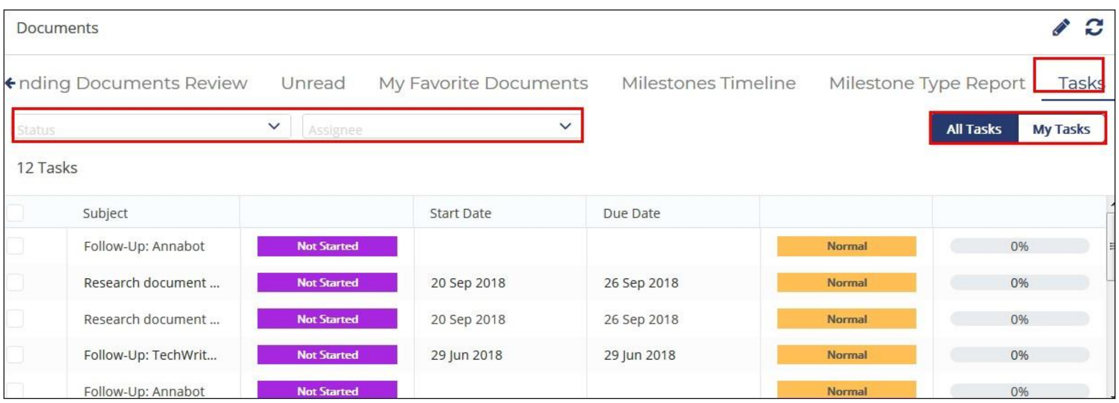


Dashlet - Milestone Type Report

The Milestone Type Report dashlet gives the percentage of missing/placeholder documents or collected documents for a particular milestone type associated with a site in the form of a bar graph.

Dashlet - Tasks

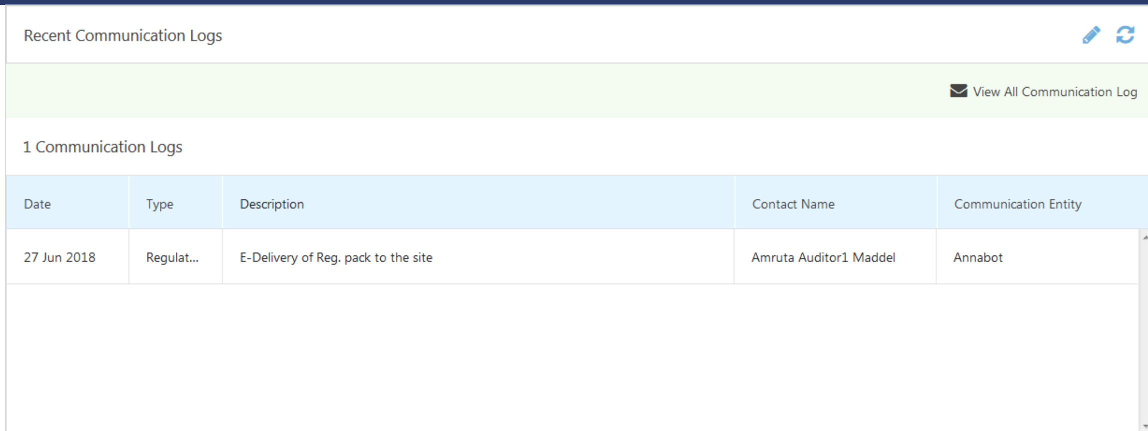
The Tasks dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the Status and the Assignee from their respective drop-downs to get the task details.
All Tasks lists all the tasks belonging to the selected assignee.
My Tasks lists all the tasks pending recently, today, or are overdue.



You can also export selected tasks or all tasks in the current grid by clicking the Tasks Export icon located on the top right corner of the dashlet. After the export job is over, you can retrieve the job result from the Notifications (page 64) by clicking Get Job Result which then downloads the export job as a .xlsx file on your hard disk.

Dashlet - Recent Communications Log

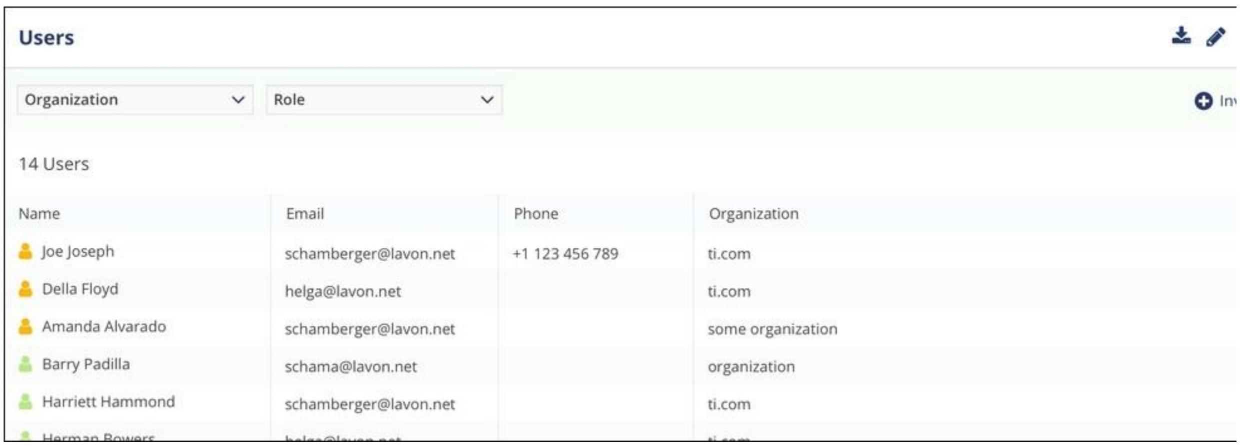
The Recent Communication Logs dashlet gives a list of all communications made during the site start-up and activation stage.
Clicking the View All Communication log link from the top right corner of the dashlet to view the list of all communication log. Refer to the screenshot below:



You can also rename the dashlet by clicking the Pencil icon to the right of the dashlet and refresh the dashlet by clicking the Refresh icon.

Dashlet - Users

The Users dashlet provides a helpful option that lists new users or all users in a study with filters to sort users by organization and by their organization and access level (role). You can also invite a new user here by clicking the Invite button placed in the upper right corner. Double-clicking the icon next to the Last name opens the Edit User popup to allow editing of the user profile. Refer to the screenshot below:

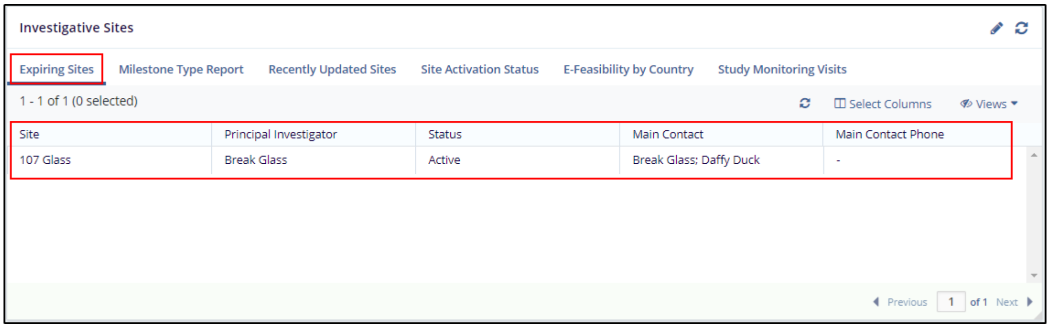


The Investigative Sites dashlet display the overview of Sites in the form of Pie Chart. The dashlet contains the following tabs for the related to the sites:

1. **Expiring**: Display the details and count of expired sites in the form of Pie Chart.
2. **E-Feasibility by Country**: Display the count and details of sites based on E-Feasibility by Countries.
3. **Study Monitoring Visits**: Display the count of sites based on the Study Monitoring Visits.
4. **Recently Updated**: Display the count of all recently updated sites.

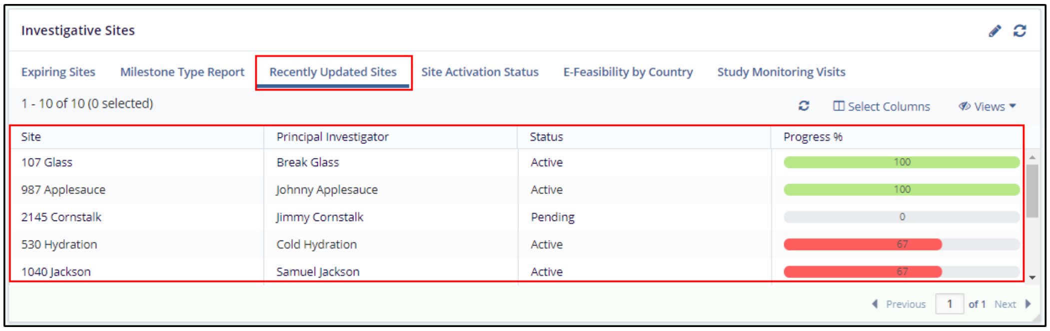
Dashlet - Expiring Sites

The Expiring Sites dashlet gives a list of all sites that are expiring in a future date. Refer to the screenshot below:



Dashlet - Recently Updated Sites

The Recently Updated Sites gives the activation progress of all sites in a room. Hover the mouse over the Progress % column to view the list of documents that are missing to complete the site activation. Refer to the screenshot below:

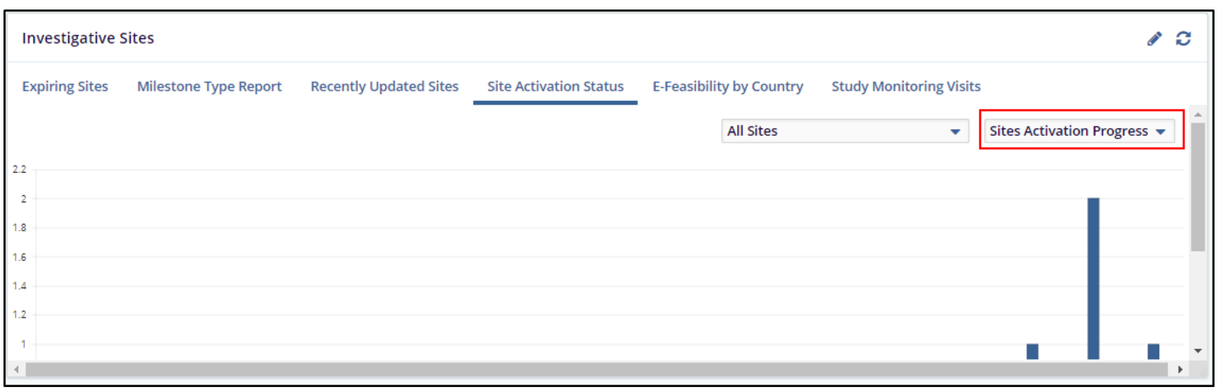


Dashlet - Site Activation Status

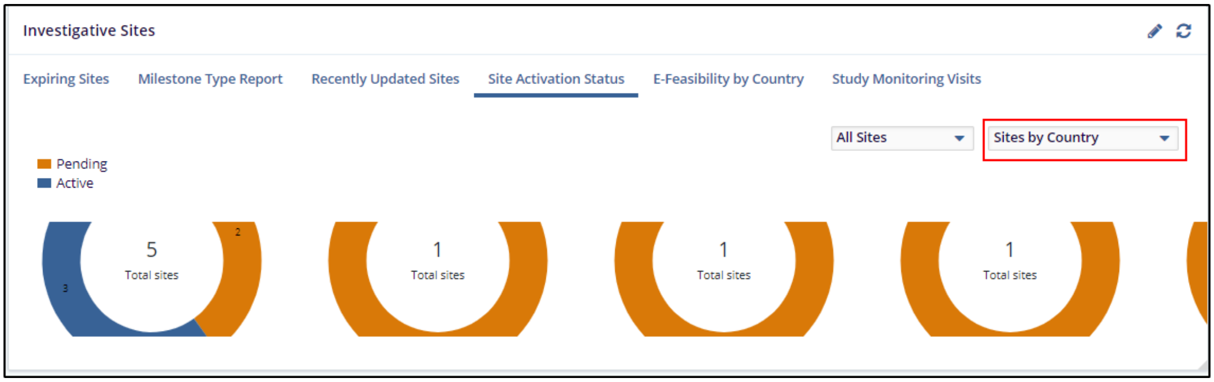
This dashlet offers three views – Sites By Country, e-Feasibility By Country, and Sites Activation Progress.

Select the Site By Country view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshots below:

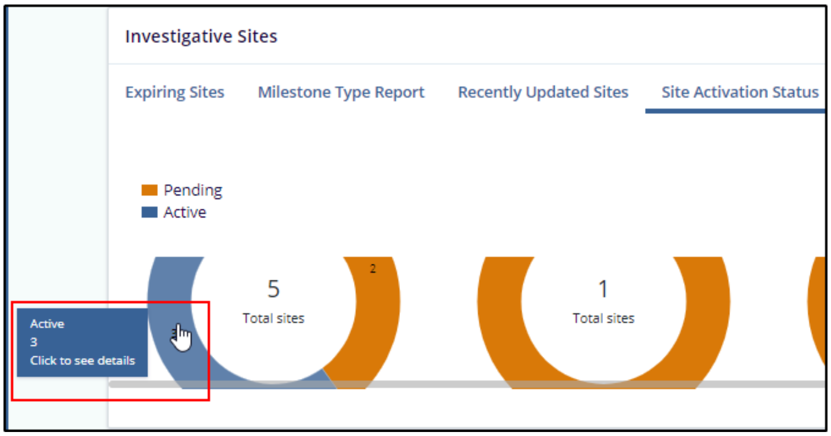
Site Activation Progress Screenshot -



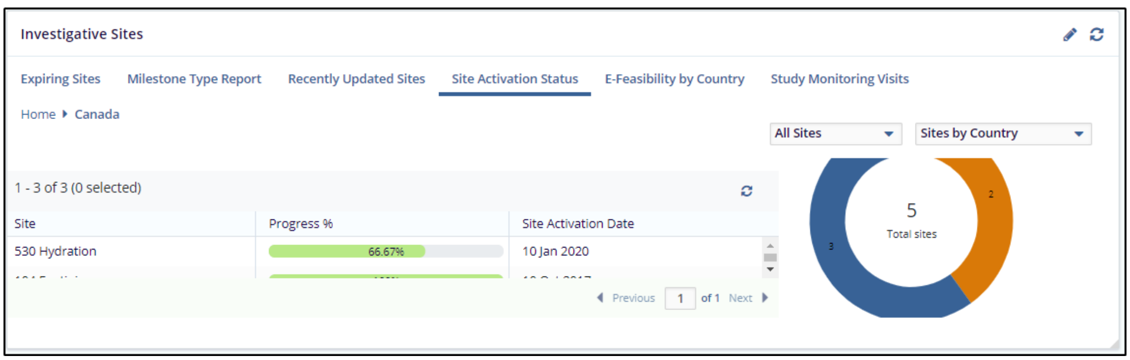
Sites by Country Screenshot -



Hover the mouse on any part of the chart to view the details of the site, see below -

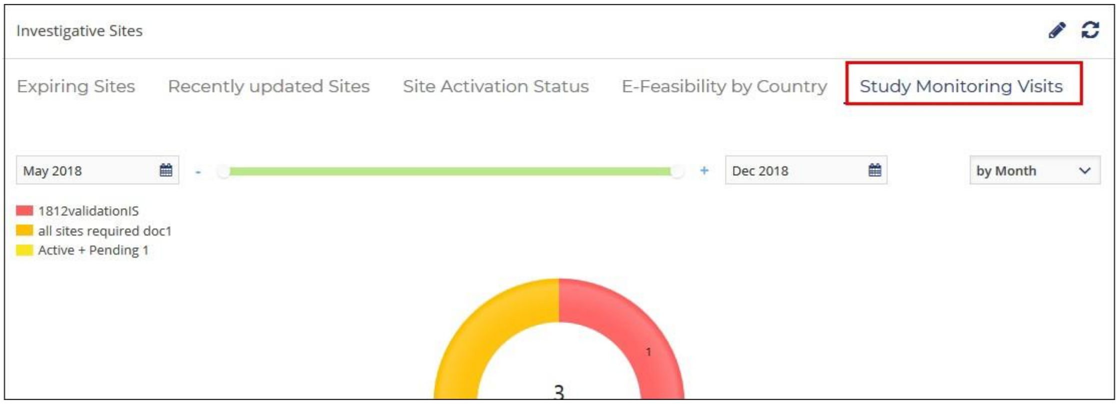


Drilldown to the specific site, see below -



Dashlet - Study Monitoring Visits

The dashlet Study Monitoring Visits provides two different views study monitoring visits – Monitoring Visits By Month, and Monitoring Visits By Country, in the form of a donut chart. This dashlet can be configured to display the Visit Date instead of the Created Date through the Configure Dashlet feature as discussed above. Refer to the screenshots below:



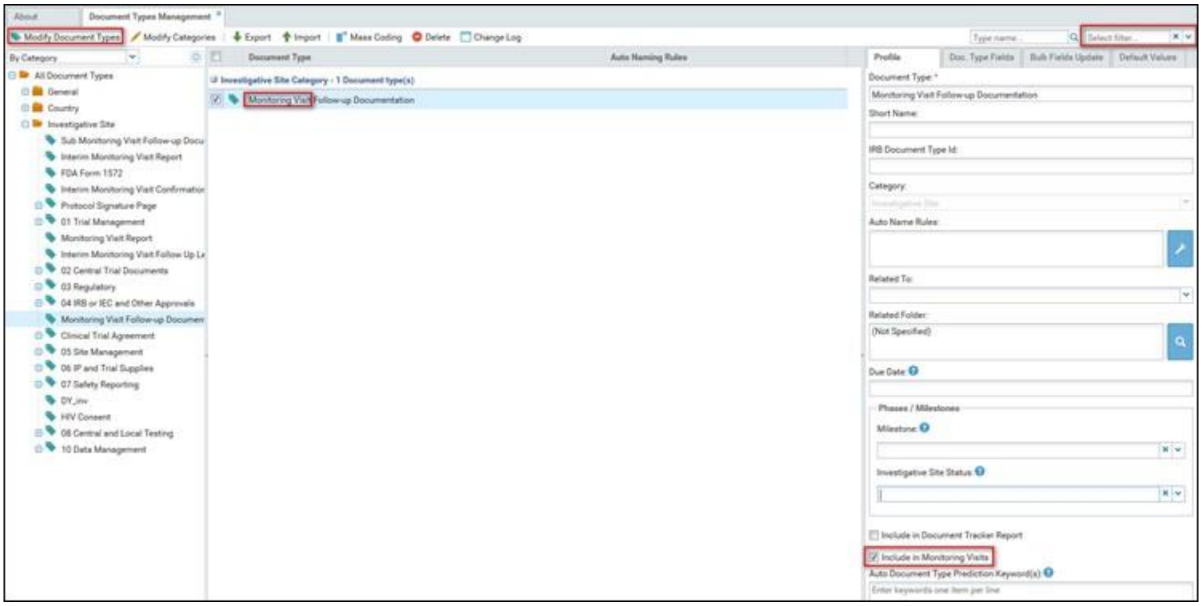
The dashlet provides the Date Ranges to filter the sites. Besides selecting dates in the date columns, you can also scroll the bar between the ranges to filter the sites.

When you select the 'By Country' option from the dropdown at the top right corner, you will finally be able to view the documents for the particular country. Click the section on the donut chart to delve further for the country documents.

The Study Monitoring Visits dashlet is connected to the Document Type Settings. Therefore, Administrator users can go to SettingsàDocumentTypesàDocumentTypesManagement, *(page 105)* and assign or modify document types. Through the configuration box, users can manually specify whether to include the document in the Monitoring Visits or not.

If you choose to include a new document type, the Study Monitoring Visits dashlet will be updated to reflect the change.

For your convenience, a search box and a filter option are also available in the Document Type Management section in the Settings. These features help users track which documents, and how many documents are needed to be collected for specific document types. Refer to the screenshot below:



Dashlet - Collaborative Review

The Collaborative Review dashlet gives you an overview of all the documents that are in a Collaborative Review. Refer to the screenshot below:
The following dashlets are available in the Collaborative Dashlet:

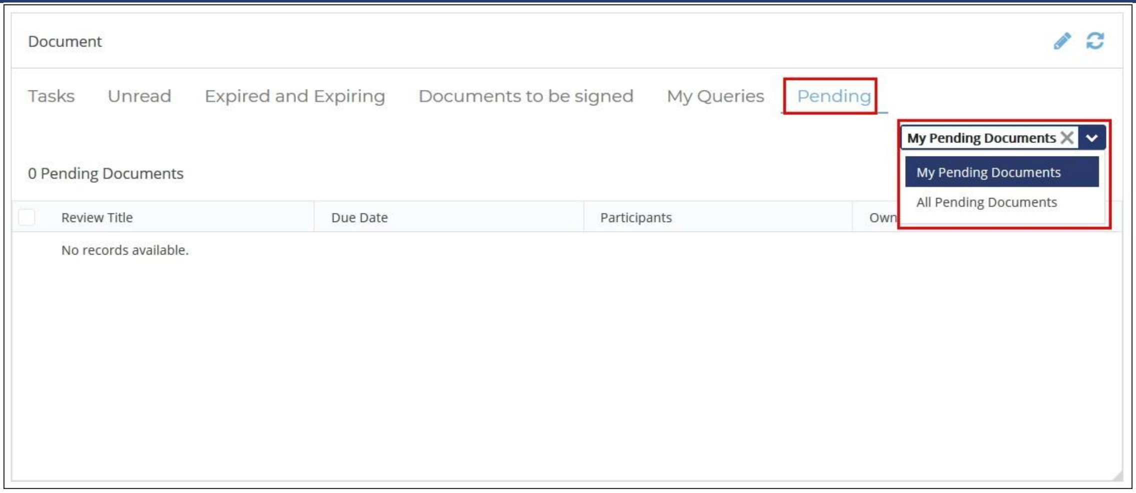
1. Documents to Approve
2. Documents to Sign
3. Pending Documents Review
4. Collaborative Documents

Dashlet - Documents to Approve

This dashlet displays the list of all documents that are pending for approval in TI Collaborative. Click the document to open the document for approval.

Dashlet - Pending Documents Review

The Pending Documents Review dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for All users, or only for yourself through My Review. Refer to the screenshot below:



Click the All Pending Documents dropdown from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

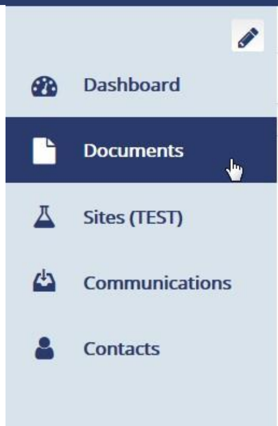
1. **My Pending Documents**: This displays the list of all pending documents that are assigned to you for review.
2. **All Pending Documents**: This displays the list of all pending documents that are pending for review in a room.

Dashlet - Collaborative Documents

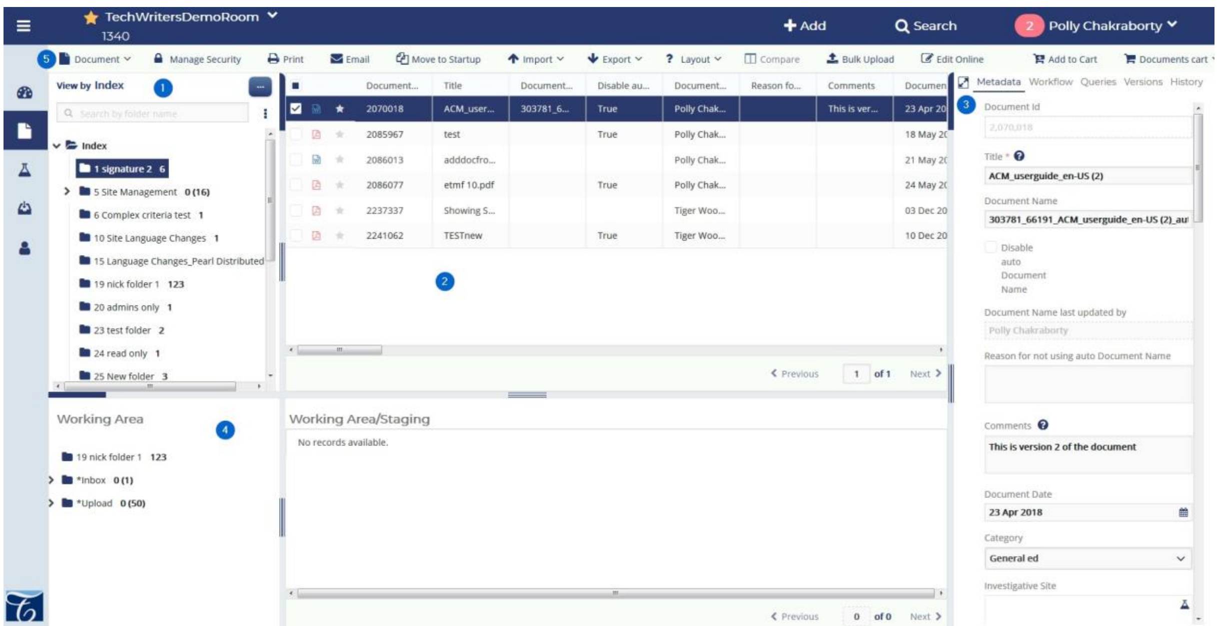
The Collaborative Documents dashlet displays the list of all collaborative documents. From this dashlet, you can also create a new Collaborative Profile by clicking the Create Profile button located at the top right corner of the dashlet.

Documents View

The Trial Interactive eTMF Documents is the central repository for all the clinical trial documents in their original digital format with Digital Signatures *(page 255)* wherever applicable, records, or documents converted from one format to another like paper documents, images converted to PDFs *(page 255)*, besides videos and recordings pertaining to trials.
Here, you can configure and store trial master file 'essential documents' pertaining to clinical trials, view and edit documents attachments, manage security privileges on them, import and export documents and their metadata, mail them to other users besides many others.
To comply with eTMF Completeness, you can track the progress right from documents collection to the finalization of a document through Milestones and assignments of Tasks to authorized personnel. Besides, this application also provides you with the facility to post Questions and Answers along with the generation of FAQs for further insight.
The documents are then subjected to Quality Control, and Quality Review checks as specified by the FDA.
You can access the Documents View by clicking the Documents icon from the menu bar at the left of the dashboard. Refer to the screenshot below:



Clicking the **Documents icon** from the menu bar at the left leads you to the **Documents dashboard**.
Refer to the screenshot below:



Refer to the table below for more description on each numbered part.

Table 1: The Documents View

No.	Part Name	Description
1.	The Room Index *(page 224)*	The Room Index consists of folders organized into a tree-like structure starting with **Index** as the root folder.
2.	The Documents Grid *(page 241)*	Select a chid folder from the Index to populate and view its documents in the Documents Grid.
3.	The Document Data Panel *(page 261)*	Tick a checkbox next to a document in the Documents Grid to populate the Document Data Panel.
4.	The Working Area *(page 259)*	Shows the record of the document currently working in.
5.	The Top Ribbon Bar *(page 269)*	Access various functionalities required for eTMF operations from here.

Click the links in the table below for more details on each part or section.

Documents Module Settings

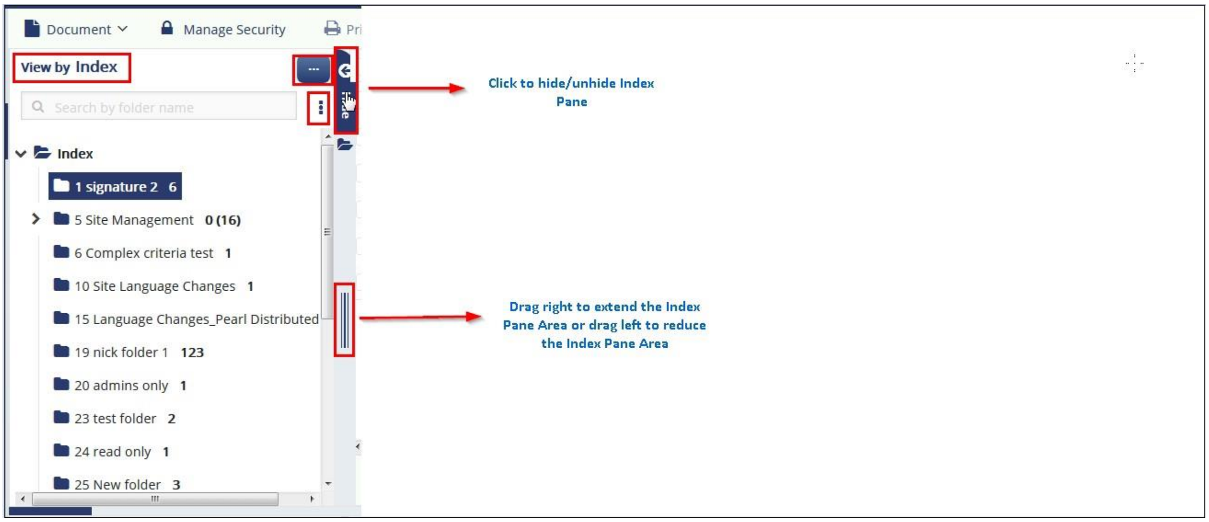
Important:

- *All documents added/imported to a room get populated in the Upload folder by default unless the Default index position is specified in the document settings.*
- *Documents emailed to the room will find its way to the Communication Inbox or the eTMF Inbox as per the room settings.*

The settings that need to enable for a document are discussed in detail in the Settings → Documents → Documents Module. *(page 97)*

The Room Index

- The Room Index consists of folders organized into a tree-like structure starting with **Index** as the root folder.
- The Index consists of **parent and child folders** and can either be cloned during room creation or created from scratch.
- The Index Folders are categorized as per the **Document Types** specified from the Room Settings and consist of three main categories – **General**, **Country Management**, and **Site Management**.
- **Documents emailed to a room get stored in the room's Inbox folder.**
- **Similarly, all documents imported are populated in the Upload folder.**
- If a folder contains subfolders, you can **expand** it to list its content by clicking the expand arrow icon next to a collapsed folder.
- Similarly, you can **collapse** an Index folder by clicking the collapse arrow icon next to an expanded folder.
- To locate documents in a child folder, you drill down to the last child folder and click on it.
- The documents in the child folder populate in the **Documents Grid**.
- Tick a checkbox in the Documents Grid to view its metadata in the **Metadata tab** of the **Right Panel**.
- Besides the Metadata tab, the **Right Panel** also consists of the **Workflow, Queries, Versions, History, and eSignature tabs**.



From the Index Pane:

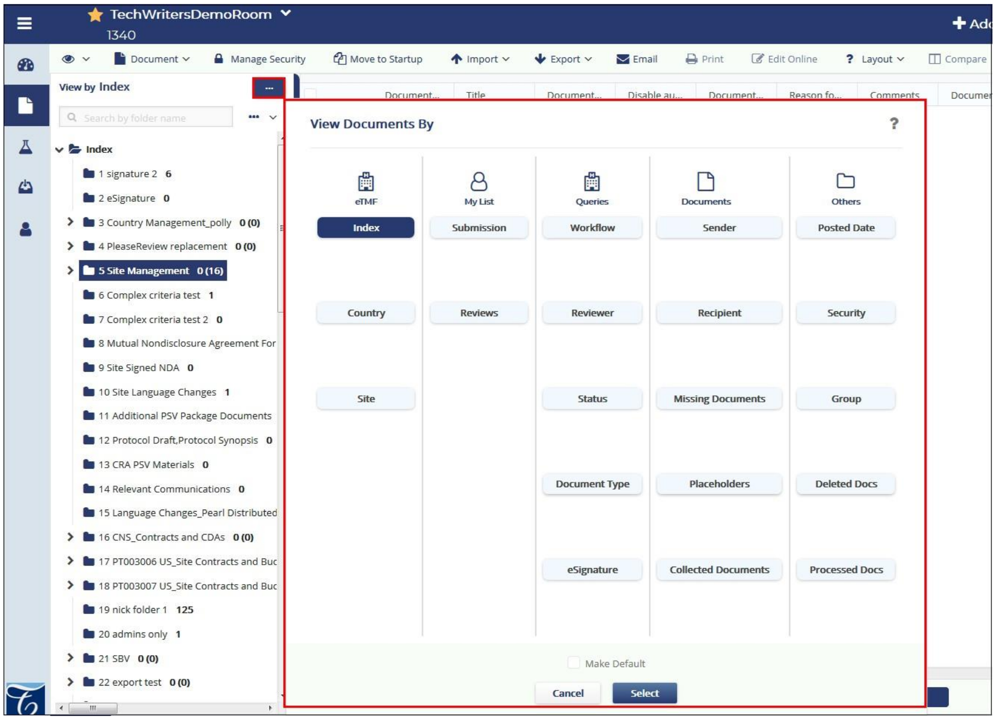
- View the room's folder structure *(page 225)*
- Search and navigate to sub-folders *(page 241)*
- Modify Index Structure *(page 238)*
- Export Index *(page 240)*
- Refresh Index *(page 240)*
- View Security on an Index Folder
- Export documents from an Index Folder
- Add documents to an Index Folder *(page 297)*
- Index Outline Settings and By Index View *(page 101)*

Choose View - Viewing the Room's Index Structure

You can view a room's index and its documents from the Index Pane of the room. From the Index Pane, you have access to various kinds of views to the folder structure. The default view provided by the system is By Index.

To toggle between the various views of the Index Structure:

1. Click the **Choose View** button on the Index Pane.
2. This opens the **View Documents By** popup with various view options. Refer to the screenshot below:



Tip: *Select a view and tick the* ***Make Default*** *checkbox to make that view the default view. You will then see the documents sorted and grouped by the view you marked as default every time you visit the room.*

Each of the view options are discussed in separate topics available from the left pane of this help.

By Index and Index Outline Settings

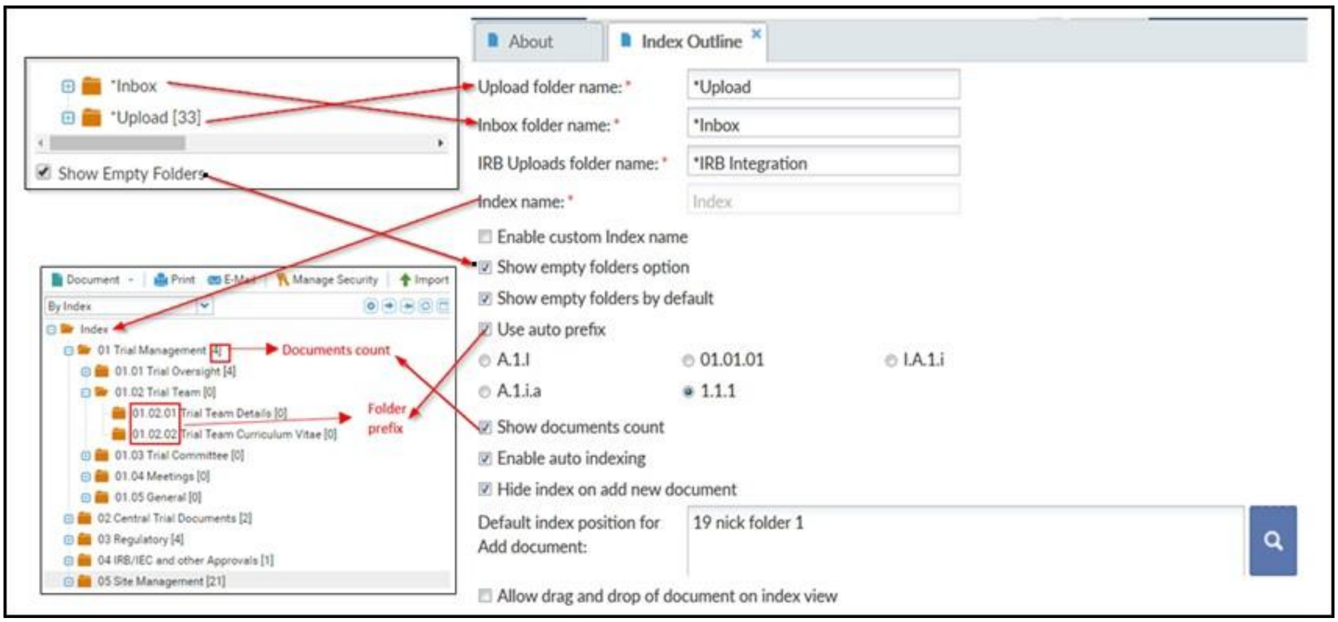
Important: ***Index Outline is a group of settings that Administrators should leave unchanged. The settings here are those chosen by the client during the initial room setup. Before making changes here, consult with the Project Manager and/or the Client Services Team.***

On creating the index, as an administrator, you can decide on a number of functions and appearances related to the Trial Interactive room's index from the Main Navigation ->Settings -> Documents Module -> Index Outline. You can change the names of the Upload folder, the Index folder, and the IRB Uploads folder if so requested by the client.
The following settings are configured from the Index Outline:

- By Index View
- Changing the Index Name
- Empty Folders Options
- Hide Index on add new document
- Auto Indexing

Each of these sections is discussed in detail in the sections below.

By Index View



The All View(By Index) shows the full folder index of the room with child pages. If a folder contains sub-folders, it can be expanded to list its content by clicking the expand icon.
If a user emails documents to the room, such documents get stored in the Inbox folder of the room. Similarly, all documents imported are populated in the Upload folder.

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

Auto Prefix

The folders in a room index are numbered, and the subfolders follow a standard numbering system. These folder numbers are called as Folder Prefixes, whose settings can be decided from the **Auto Prefix** option in the **Settings -> Documents Module -> Index Outline**.

Activate or inactivate Auto Prefixing of folders in the room's index by ticking the Use auto prefix checkbox. If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index. Auto prefixing inserts the client's requested prefix of numbers or letters to identify the levels of the folders in the index. Click the radio button for the prefix pattern requested by the client.

Documents Count

Numbers in parentheses after the folder names indicate how many documents are available to you in each folder. Click a folder to open the documents contained in it in the Document Grid.

By showing Documents count, by ticking the Show documents count checkbox in the settings, users in the room will see a number in brackets that indicate how many documents are in each index folder.

Changing the Index Name

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

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

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

Empty Folders Options

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

You can enable or disable the Show Empty Folders Option. By showing that option, users in the room will see this checkbox at the bottom of the room's folder index.

Another option sometimes called for by the client is to show empty folders all the time. If that is the case with the room you're configuring, click this box – Show Empty Folders by default. Then, the room's full index will always show in the documents view, whether the folders are empty or not.

Hide Index on add new documents

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

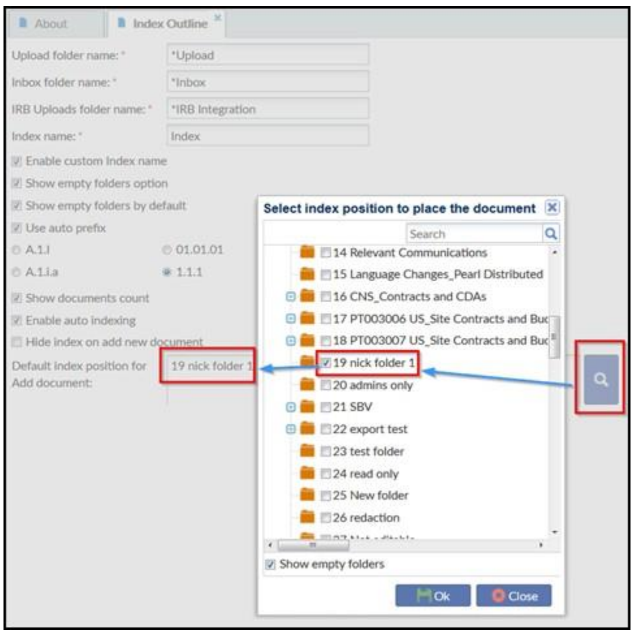
If this setting is enabled:

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

Auto Indexing

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

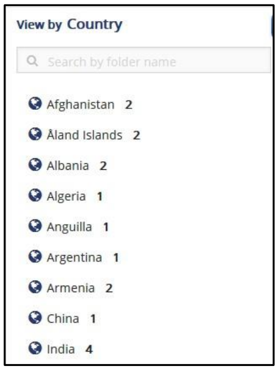
1. Click the magnifying glass. The full index list appears.



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

By Country

From this view, you can access all documents and placeholders of the Category Country having a country name metadata specified in its Country Field. When you access this view from within the Documents sub-module, you see all eTMF documents of the category Country. Refer to the screenshot below:



Under each country as a parent folder, the documents are further categorized by its Document Types.

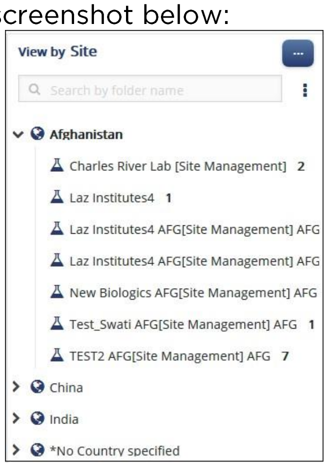
You can also view the category country documents in the By Index (page 225)view under the Country folder (the name that you provide to this folder depends on your room settings).

For more details on how to set up this folder and its hierarchy follow on to Chapter Countries (page 380). To know more about Site-Specific Country Category documents proceed to Site -> By Country view.

By Site

From this view, you can access all documents and placeholders associated with the Investigative Sites. Sites are places where clinical studies are conducted. This view shows the segregation of Investigative Site as located in various countries.

All sites belonging to a particular country are listed under their specific country. Click a site name to list the documents belonging to the site in the Document Grid. Refer to the screenshot below:



The configurations for an Investigative Site can be setup from **Settings -> Investigative Sites** ***(page 133)***. The dashlets related to Investigative Sites are:

1. Expiring Sites
2. Recently updated sites
3. Site Activation Status
4. Site Activation Progress
5. Sites Activation by Country
6. Study Monitoring Visits By Country

eTMF Completeness

This view lists collected, missing documents and acts as a placeholder for missing documents that do not fall under the required documents section.

From within the Document Grid or from the Add Placeholder dropdown on the top ribbon, placeholders can be created, edited, deleted for a document. Documents can be attached to placeholders or missing documents from the Add Document located on the top ribbon bar or by dragging and dropping them from the Windows Explorer.

The system:

1. Creates a new document from placeholder and missing documents
2. Does not allow to change the category and related metadata if placeholder ID is present for documents.
3. Allows the user to assign placeholders to milestone histories from the **Create Placeholder** window. Refer to the screenshot below:

By Posted Date

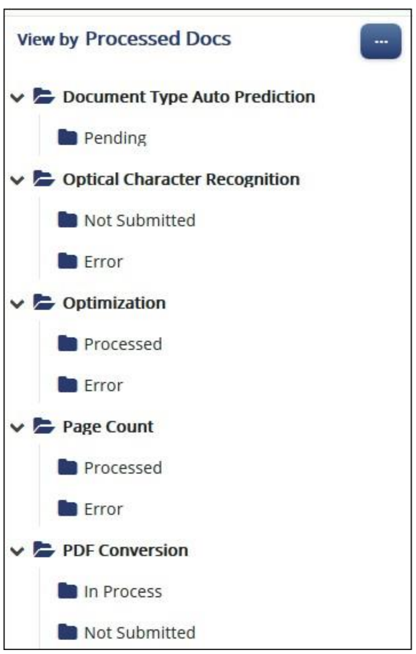
In the By Posted Date view, the documents are grouped as per the days they were posted/imported/added. Folders by posted dates are created. Clicking each folder displays the documents posted on that particular day. Refer to the screenshot below:

By Security

The By Security view shows all the documents based on the security accesses provided to users and group of users. Documents are segregated under folders by the name of users showing the level of their access. Refer to the screenshot below:

Processed Documents

All the documents that traverse through various processes in a study can be viewed from here. Refer to the screenshot below.



Some examples of processes in a study that the documents need to pass through are **OCR**, **Optimization**, **PageCount**, **PDFConversion**, **PDFFixation**, **PublishtoeTMF**, and **DocumentTypeAutoPrediction**. The documents are listed under each process in this. Under each process, the documents are further categorized into **Not Submitted**, **Pending**, **Processed**, and **Error**.

For example, as a user, you might want to submit documents for PDF Conversion. All the documents that were converted into PDF will appear under the Processed->PDF Conversion folder. If some documents could not be converted into PDF due to some error, they will appear under the

Error folder. The documents that were not submitted for PDF Conversion will appear under the Not Submitted folder, and those that are still pending for conversion will appear under the Pending folder.

Similarly, all documents that are published from a Shared Workspace to its eTMF room get recorded under Publish to eTMF sub-folder in the Processed folder.

Exporting and Refreshing Index

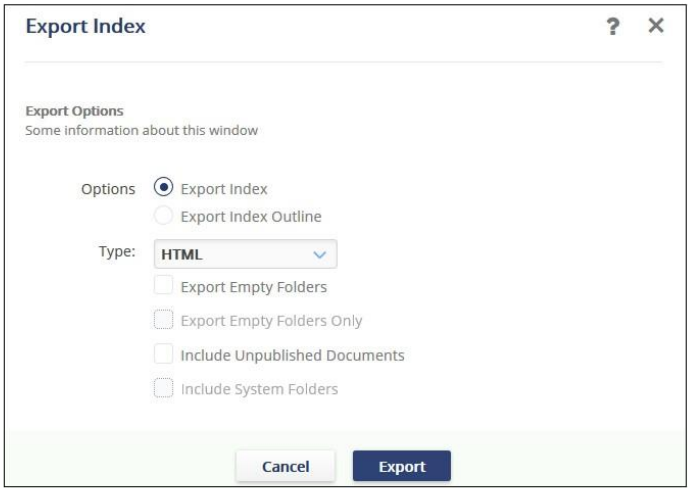
Exporting Index

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

To export index:

1. Click the Export Index 

from the popup and export the index as per the actions required. Refer to the screenshot below:



Index Search

In the Search box below the View By Index pane, enter the name of the folder you want to search. Press Enter or click the magnifying lens icon to reveal matching contents.

Click the Cross next to the right of the search box to delete the search criteria.

The Documents Grid

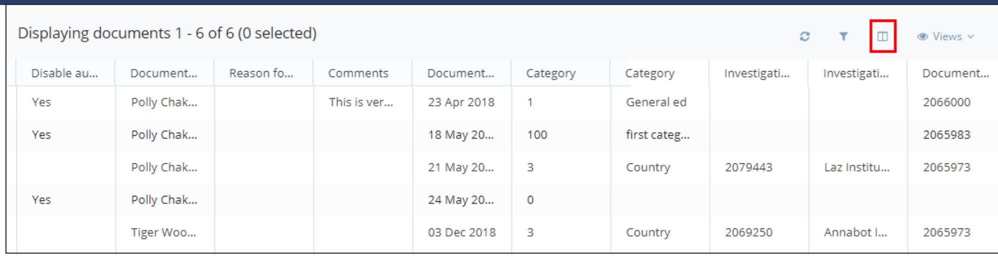
You can perform the following from the Documents Grid.

- Preview and Viewing a document and its metadata *(page 243)*
- Access the Document Context menu on a document by the mouse right-click *(page 249)*
- Configure the Documents Grid *(page 241)*
- Copy or move documents *(page 245)*

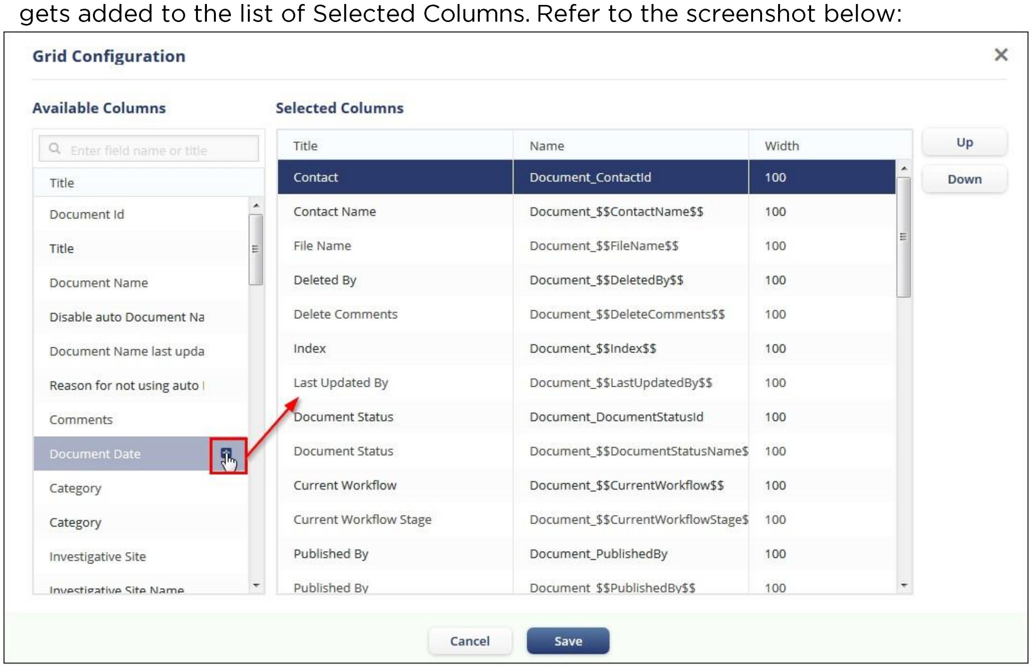
Configuring the Document Grid

Through this option, you can decide which columns to display or hide from the Document, Workflow, or Audits Grid. Thus, you can decide exactly what information you want to see and configure the grids accordingly to suit your view.

1. Navigate to the **eTMF/Documents** module.
2. Click the **Update Columns** icon from the top right corner of the documents grid. Refer to the screenshot below:



3. The **Grid Configuration** window opens which displays the following panels:
   a. **Available Columns Panel**: This panel display the list of all available columns in a room.
   b. **Selected Columns Panel**: This panel displays the list of all columns that are selected and added from the Available Columns.
4. To add a column to the **Selected Columns** pane from the **Available Columns** pane, hover the mouse over the column name in the Available Columns. The **+** sign appears next to the column name.
5. Click the **+** sign to add the column to the **Selected Columns.** The column gets added to the list of Selected Columns. Refer to the screenshot below:



6. Alternatively, you can also **double-click** the columns in the Available Columns to add to the Selected Columns.
7. After adding the columns to the Selected list, they are **greyed out** in the Available Columns list and a **small green tick** appears to the next of the column name as shown in the screenshot below:

8. Similarly, you can remove the columns from the Selected Columns list by clicking the - icon that appears next to the column name on hovering the mouse over the column OR double-click the column to remove it from the list.
9. Besides adding and deleting columns, you can also change the sequence of the columns by clicking the **Up** or **Down** 

buttons located at the extreme right of the window.
10. Click **Save** to save to changes.

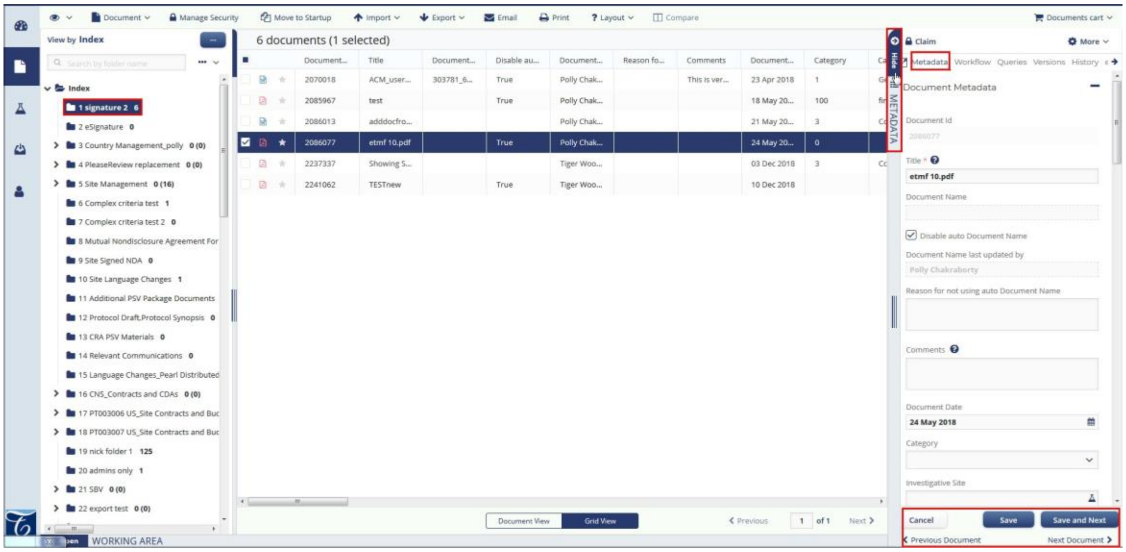
Previewing and Viewing a Document and its Metadata

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

Viewing Document Metadata

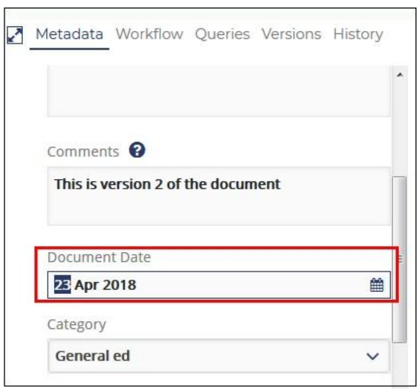
To access the Document Metadata, follow the steps as below:

1. From the **Documents** module, select the document from the grid.
2. Hover the mouse over the bar to the right of the grid. The **Metadata Viewer** display with the **Open** text on it.
3. Click the viewer to open the **Metadata Panel**. *Notice that when you open the metadata panel, the Metadata Viewer bar changes the **Open** text to **Hide** clicking which you can hide the metadata panel*
4. The **Document Data Panel** opens which displays the **Document Metadata** by default. Refer to the screenshot below:



As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The icons at the bottom of the panel provide access to several essential functions, such as saving changes and updates in the metadata panel as shown in the screenshot above.

Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings -> General Information (page 58)section. Refer to the screenshot below:

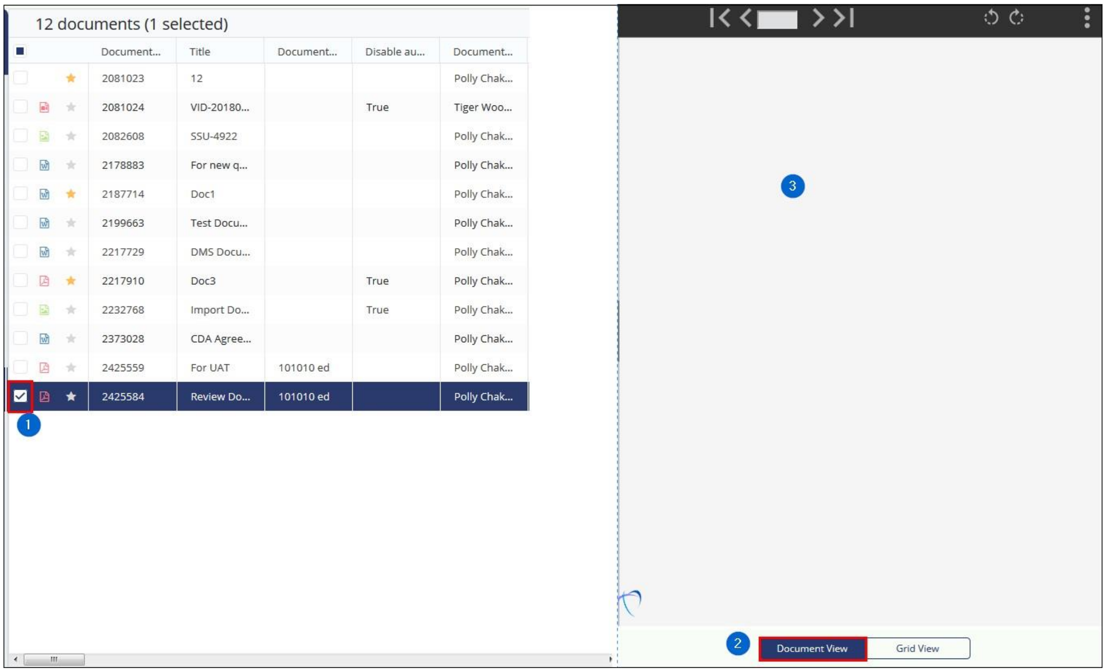


Previewing a document

To preview the selected document:

1. Select the checkbox next to the document.
2. Click the **Document View** button at the bottom of the grid.

3. The document opens in the Arender view. Refer to the screenshot below with the sequence of

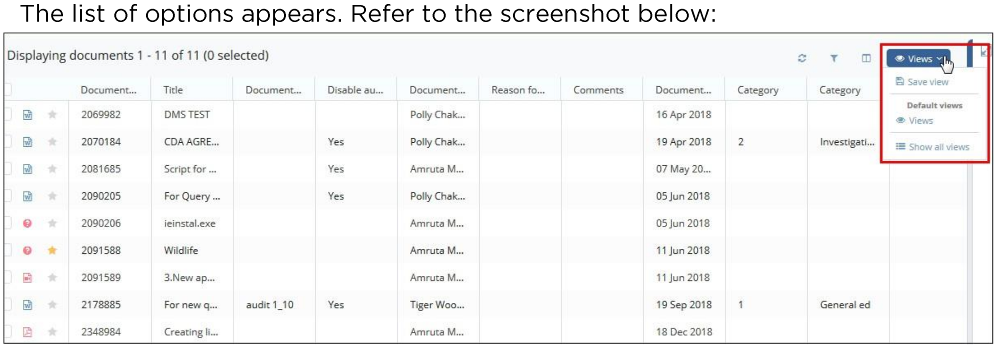


steps in number denoted:

Documents Grid Views

While in a specific folder, the user may want to filter the columns and view only the columns that are required. This can be done by customizing the grid view. You can create your own view and set that particular view as a default view so that you can view only that information which is required in the grid.
Besides, you can also apply filters to the grid and save the view for future use. To set and customize a view:

1. Navigate to the **eTMF/ Documents** view.
2. Select the required folder and update the columns *(page 241)* as needed. The documents grid gets updated as required.
3. Click the **Views** dropdown at the top right corner of the grid.
4. The list of options appears. Refer to the screenshot below:

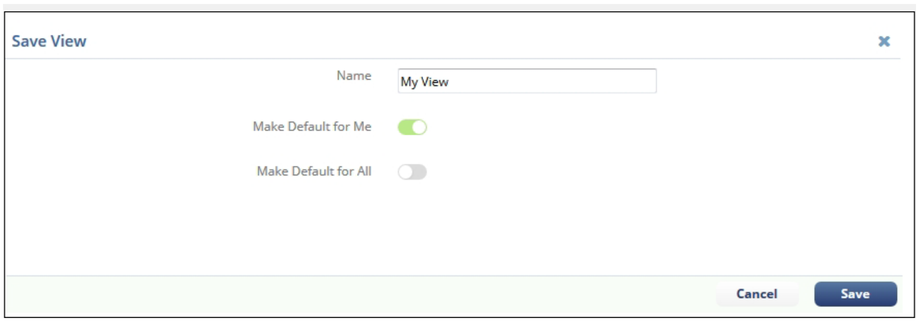


5. You can perform the following actions:
   a. Save View
   b. Set Default View
   c. Show all views
   d. Share the Views

Each of these is discussed in the sections below:

Save Views

After updating the columns in the grid, click **Views → Save View**. The **Save View** window opens. Refer to the screenshot below:



Enter the name of the view and enable the options by clicking the toggling buttons below for the default view. You can either make the view default for you or for all the users who accesses the folder to which the view has been set. Click Save to save the changes.

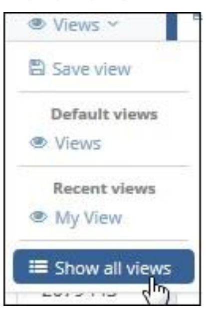
On saving, you can see the name of the view and columns also gets

updated. Every time you visit the folder, you can select the view for the grid. Refer to the screenshot below:

Show All views

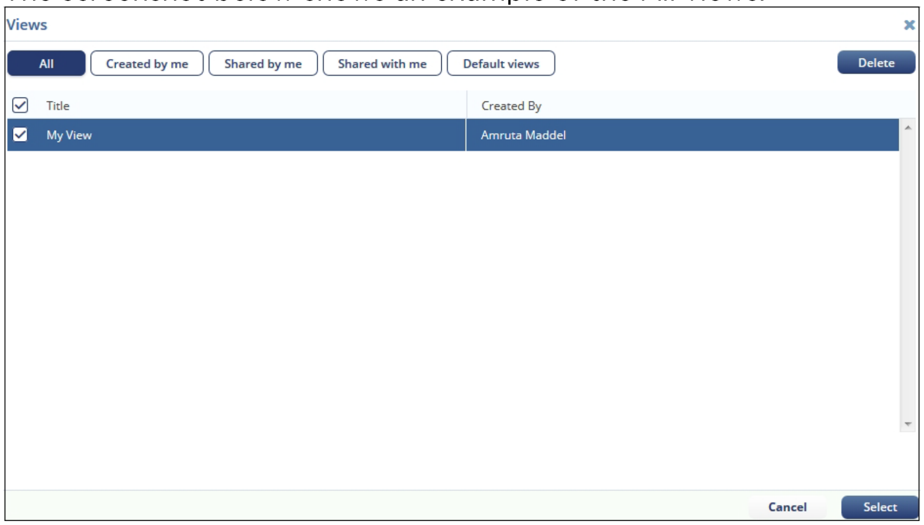
If the room has multiple views created in a room, and if they are visible to all users, you can view all the views in a room. To display all views:

1. Click **Show All Views** from the from the Views dropdown. Refer to the screenshot below:



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

The screenshot below shows an example of the All views:



Note: *The **Delete** and **Select** buttons are enabled only when you select a view from the list.*

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

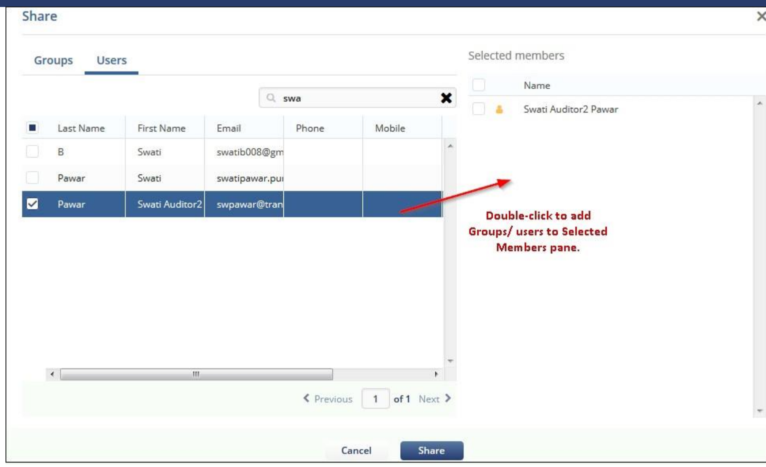
Share Views

Note: *This option is enabled in the Views dropdown only when you select a view created from the list.*

To share view:

1. Select a view you want to share from the list of views. The selected name of the view displays.
2. Now, click the **Views** dropdown. The list of options appears.
3. Click **Share View.** Refer to the screenshot below:

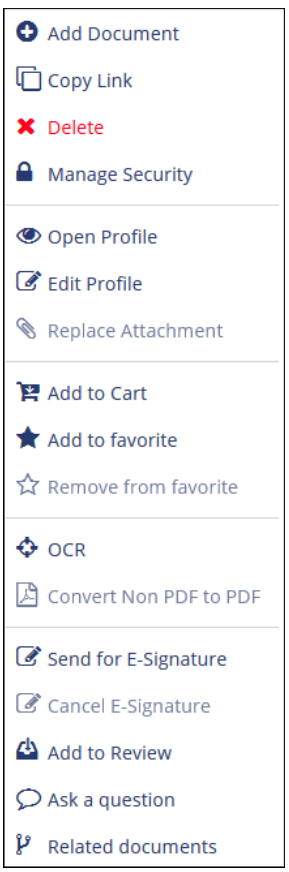
4. The **Share window** opens.
5. Select the **Groups** or **Users** to whom you want to share the view. Double click the user from the left pane to add them to the Selected members pane.
6. After selecting Gorpus/Users, click **Share**. Refer to the screenshot below:



7. This shared view now displays under the list of Shared by me in the Show All Views.

Documents Context Menu

You can perform the horde of activities on a document from the Document Actions (page 269) as well as by right- clicking on a document in the Document Grid.
Refer to the screenshot below to get a list of actions possible from the Documents Context Menu. Each of the functionalities is discussed in separate topics available from the left panel of this topic help.

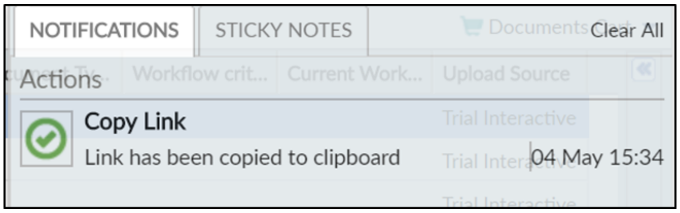


Copy Link

Clients might need to copy a document link through the Document dropdown in the eTMF module. They can choose the type of document link to copy through theCopy Link Settings option.

Once the Copy Links settings are made, follow the steps as below to copy a link:

1. Navigate to the **Documents** Module.
2. Select the required document from the grid and right-click on it.
3. Click **Copy Link** to **copy the link to a documen**t, or to **copy the link to a document with metadata** and anotification about the same is



received. Refer to the figure below:

Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings, the document will either open up in the browser for you to read, or the link will take you to the eTMF room and open the document and its metadata for you to view. **Copying and pasting the link of an empty document shall display the message ‘This document profile does not have an associated document’.**

Adding and Removing Favorites

Adding Favorites

Click Add to favorite from the Documents Context Menu menu to mark a document as favorite. Similarly, click Remove from favorite from the right-click menu to unmark document as favorite.

Besides, you can also click a Star to the left of a document to mark/unmark it as a favorite.

Ask a Question

This allows you to create a question related to a particular subject. Click the link Ask a Question *(page*)to lead you to the topic

Note: You can also perform this action from the **Documents Actions** ***(page 269)*** dropdown on the top menu bar.

Convert Non PDF to PDF

Convert Non PDF to PDF and PDF fix

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

e-Signature

This section discuss the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

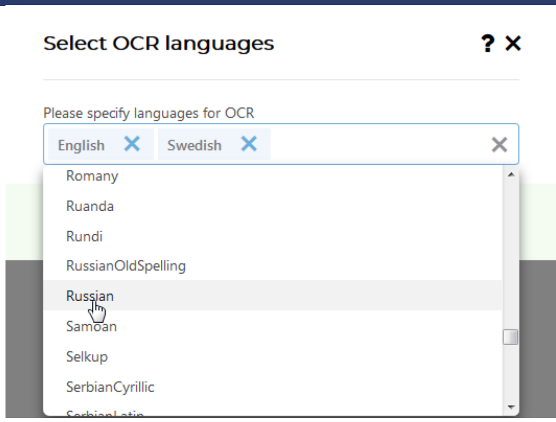
OCR

This allows you to choose the language for OCR.

OCR can also be performed from the **Documents Actions dropdown** *(page 269)*

on the top ribbon bar. To specify languages for OCR:

1. Right-click on the required document from the grid. The **Document Context Menu** popup appears.
2. From the Context Menu, select **OCR**.
3. The **Select OCR languages** popup appears.
4. Click the textbox and select the languages as applicable from the dropdown.



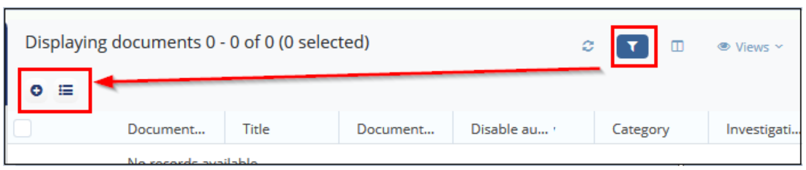
5. Click **Ok.**

PDF Fix

Grid Filters

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

1. Click the **Filter** icon above the document grid.
2. The Filter options are enabled at the top left corner of the documents grid. Refer to the screenshot

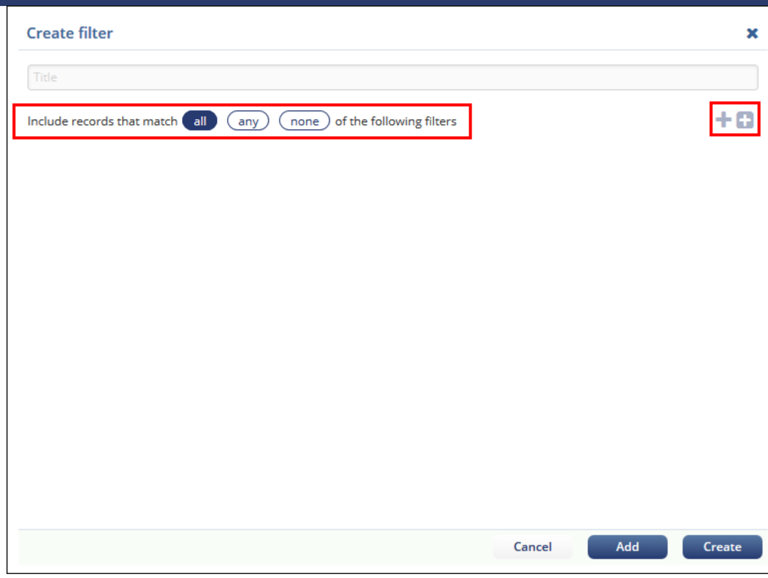


below:
3. From the enabled options, you can perform the following:
   a. Create New Filter
   b. Add Existing Filter/Manage Filter

   Each of these is discussed in the separate sections below:

Creating New Filter

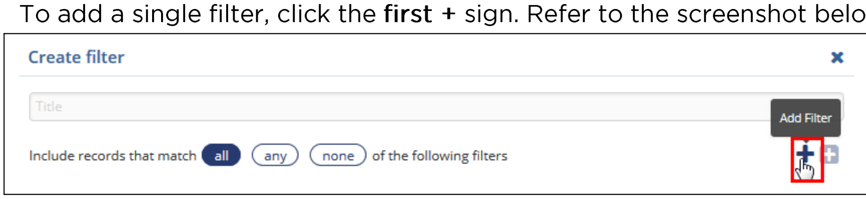
1. Click the **+** sign above the documents grid.
2. The **Create Filter** window opens. The window displays the following:
   a. A textbox that displays the **Title** for the filter selected.
   b. The options for matching the filter records. Refer to the screenshot below:



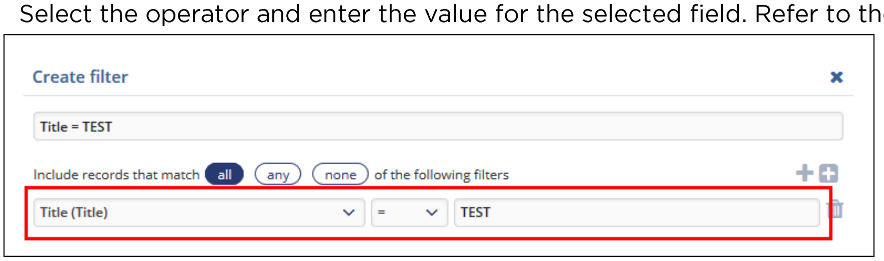
3. Notice that there are two **+** plus signs to the right of the window which allows you to create a **single filter** and **group of filters.**

Adding Single Filter

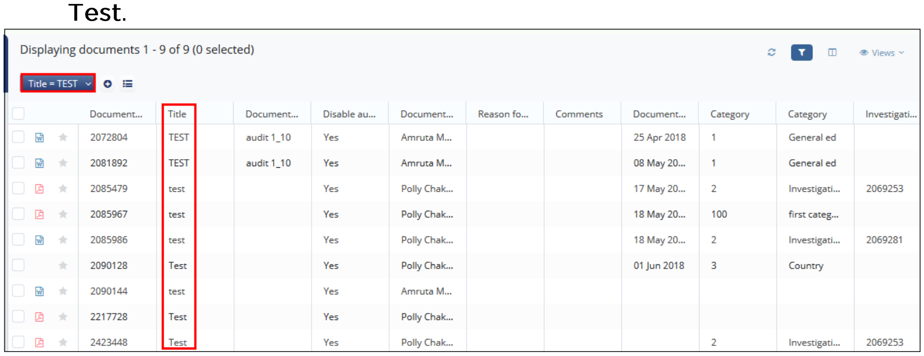
4. To add a single filter, click the **first +** sign. Refer to the screenshot below:



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



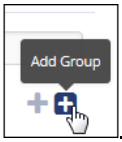
7. Click **Add** if you wish to display the filter in the current view or click **Create** if you want to save the filter and use it later.
8. After creating a filter, when you select the filter and apply it for the document grid, the search results display accordingly. The screenshot below shows an example of the filter result applied for the **Title** = **Test**.



Displaying documents 1 - 9 of 9 (0 selected)

Title = TEST

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

9. Similarly, you can add group filters to apply for the document grid and search for the results by clicking the second + sign 

. Proceed further as discussed above to add group filters.

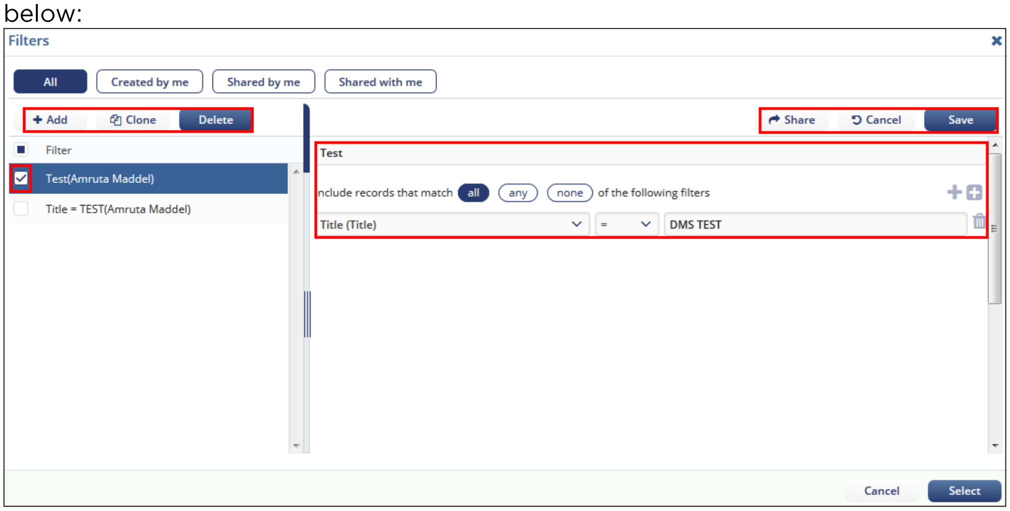
Add Existing Filters / Manage Filters

Manage filters allows you to view and share the created filters by you and by others. When you click the Manage Filters  icon above the documents grid, the Filters window opens. Refer to the screenshot below:

ilers window:

3. Delete Filters **Sharing Filters** To share a filter:

1. Select the filters from the list of filters in the **Filter** window.
2. The selected filter appears in the right pane of the window and the buttons **Clone**, **Delete**, **Share**, **Cancel**, and **Save** are enabled. Refer to the screenshot below:



3. After selecting a filter, click the **Share** button. The **Share** window opens.
4. Select the **Users / Groups** to whom you want

to share the filter and click **Share**. **Deleting Filters**

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

Viewing Shared Filters

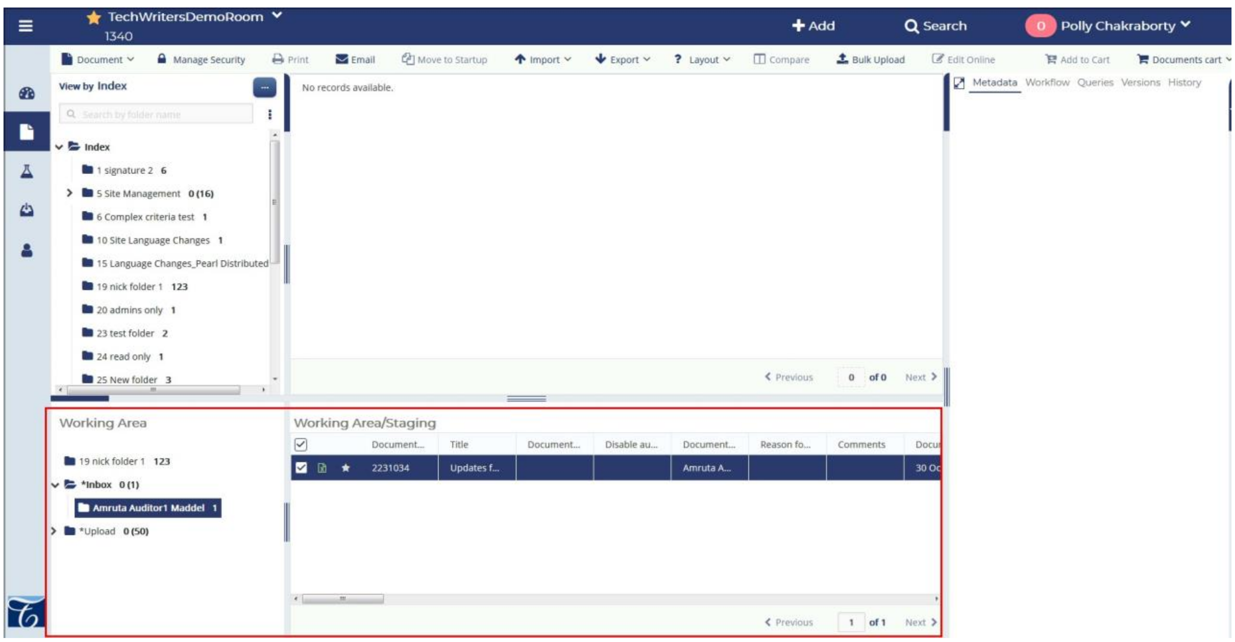
You can view the filters that are **created by you**, **shared by you** and that are **shared with you** by clicking the required tabs in the Filters window.

The Working Area and Grid

When you open the **eTMF/Documents** module, the following appears:

1. The Room Index *(page 224)*
2. The Documents Grid *(page 241)*
3. The Working Area and Grid

In Trial Interactive 10, the eTMF index is separated from the working folders which include Working Documents, Rejected Documents, Uploaded, and Emailed documents. Users can perform various actions like document coding, document replacing and attaching, adding documents to workflow or auditetc. from this Working Area. The folders in the working area are hardcoded and any documents coming in the room, either by uploading or emailing are available for further process or actions from this Working Area. Refer to the screenshot below:

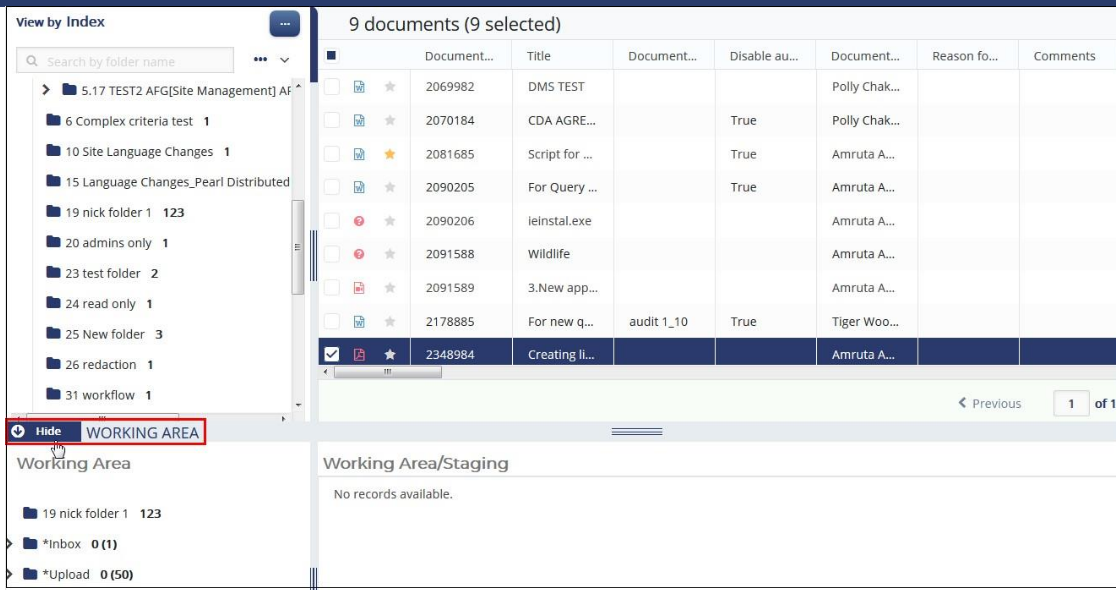


Besides working on documents, you can also drag and drop the documents from the Working Area to the required eTMF folders above like for the Country and Site views, the user can easily drag and drop documents from the working folders into missing documents and placeholders in the eTMF.

Note: *Documents can be dragged only out of Working Area but not into the Working Area.*

Hiding or Unhiding the Working Area/Staging panel

To hide or unhide the Working Area, hover the mouse over the bar above the Working Area. The Hide - Working Areabar appears. Refer to the screenshot below:



Hiding the Working Area

You can also drag the Working Area/Staging to the extreme left to hide the Work Area. Refer to the screenshot below:

Similarly, you can also drag the Working Area/Staging Area up to increase the size of the window and the number of documents count in the grid.

The Document Data Panel

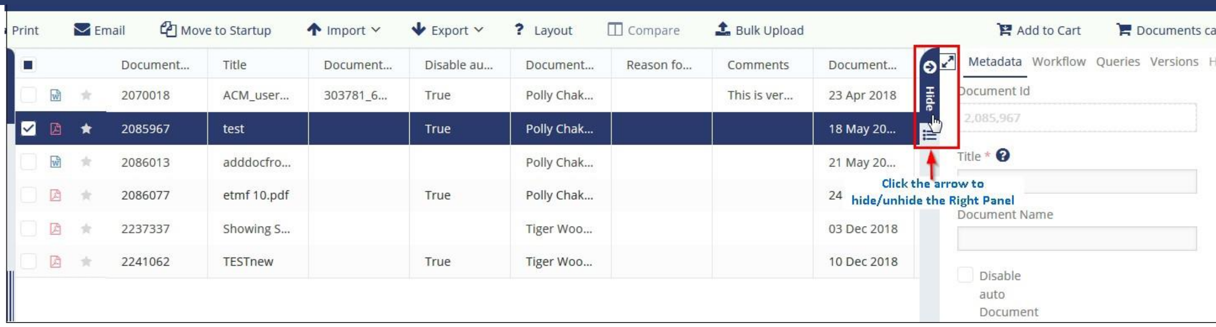
The Right Panel opens by default in the **eTMF Documents Module** when you click **Documents** from the left pane.

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

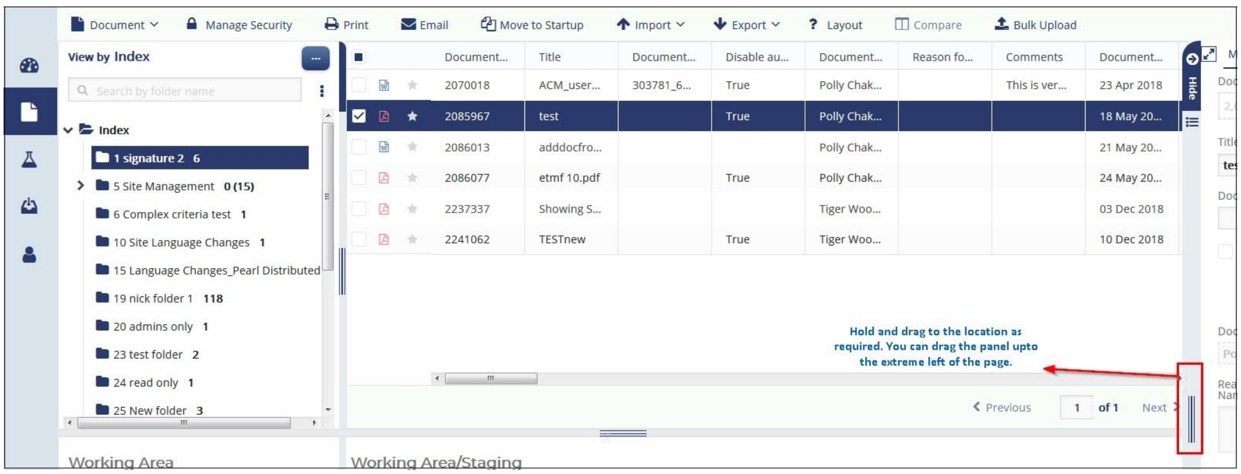
1. Metadata panel
2. Workflow panel
3. Queries panel
4. Versions panel
5. History panel
6. eSignature panel

Each of the functionalities above is discussed in separate topics available from the left panel of this help.

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

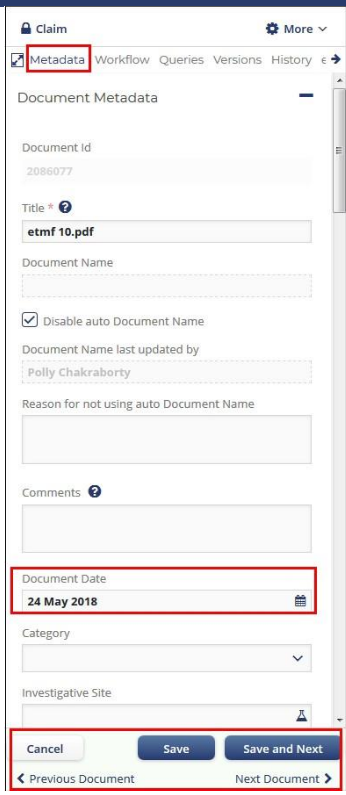


Besides, you can also hold the panel and drag it to the extreme left of the page. Refer to the screenshot below:



Metadata Panel

Metadata Panel is activated by default when you select a document.
As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The buttons at the bottom of the panel provide access to several essential functions, such as saving changes and moving to the next document in the metadata panel. Refer to the screenshot below:



Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings → General Information (page 60) section.

You can also shuffle back and forth between documents in the grid by clicking the Previous Document and Next Document links at the bottom of the Metadata panel.
The Metadata Panel also provides the Claim button and the More (Settings) icons at the top of the panel to allow you to claim documents in workflow and perform various actions on the document.

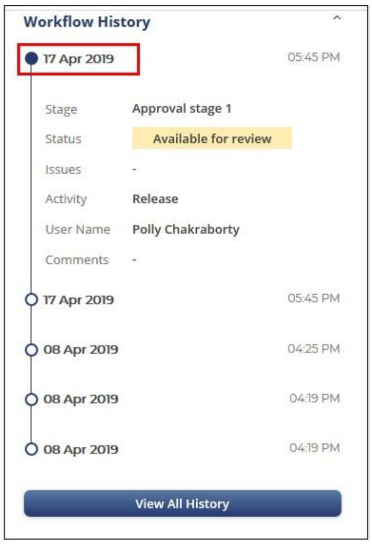
Workflow Panel

You can do the following from the Workflow Panel:

1. Claim Documents in a workflow
2. View the Workflow History
3. Initiate a Query
4. Release a document from a workflow'
5. Reassign Reviewer
6. Exclude document from a workflow

The Workflow panel displays all the details of the document workflow.

Click the Date to view from the Workflow History section to view the full history of the



document in a workflow as shown in the screenshot below:

Queries Panel

From the Queries tab, you can not only view the queries received but also can resolve them. You can view queries in TI by various methods:

1. **Query Email:** By the Query Responder from the query email received in his/her inbox
2. **By Recipient View**: The Query Responder can view the queries received under the By Recipient view if the said query responder has access to such a TI room and documents related to the query.
3. **By Sender View**: The Reviewer can view the queries from the By Sender view if such a reviewer is the creator and sender of the query.
4. **By Reviewer**: This view is available only for admins and such a user can view the queries sent and responded by all the reviewers. (add to profiling for admins)

5. **By Reviews**: The reviewer can view all the queries from the By Reviews view which he/she has initiated.

eSignature panel

The eSignature Panel:

1. Allows sending the document for eSignature if it is not initiated for eSignature yet.
2. Display the status of the document eSignature if it is initiated for eSignature.

Besides eSignature Panel, you can also send the documents for eSignature from the **Document Context Menu** ***(page 249)***by right-clicking on a document.

Cancel eSignature

If the document is waiting for eSiganture, the eSignature Panel displays the status of the document as shown in the screenshot below:

Select the eSignature and click the Cancel E-Signature button at the bottom of the eSignature Panel if you wish to cancel the eSignature of any document. Click Yes on the pop-up that appears to confirm the cancellation.

The Top Ribbon Bar

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

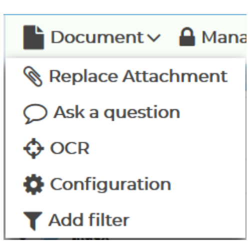
- The Document Actions
- Manage Security on documents
- Print
- Email
- Move to Startup
- Import
- Export
- Comparing Documents
- Documents Cart
- Dashboard Layout

Refer to the screenshot below:

Each of the above functionalities is discussed in separate topics available from the left panel of this help.

Document Actions

You can perform the horde of activities on a document by from the Document Drop down located on the top ribbon bar of the eTMF



Documents Dashboard.

Each of the functionalities is discussed in sections below:

Replace Attachment

To replace a document attachment or URL:

1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.

2. The dropdown appears.
3. Select **Replace Attachment / Add URL**.
4. The **Replace Attachment / Add URL** popup window opens.
5. Select the **File** radio button to replace an attachment, or select the **URL** radio button to replace the URL
6. To attach a document click **Browse** and select the required document from the Explorer, whereas to replace a URL ????
7. Enter the reason for replacement.
8. Click **Apply**

1. Click **Ok**.

Export

Documents can be exported from:

1. The **Export** dropdown from the top ribbon bar
2. The **Documents Cart**
3. The **Download documents** when opening a document in the **Original Viewer**

   Three options are available for Administrators from the **Export Dropdown** on the top ribbon bar - **Metadata**, **Documents**, and **Security**. Refer to the screenshot below:

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

Exporting Metadata

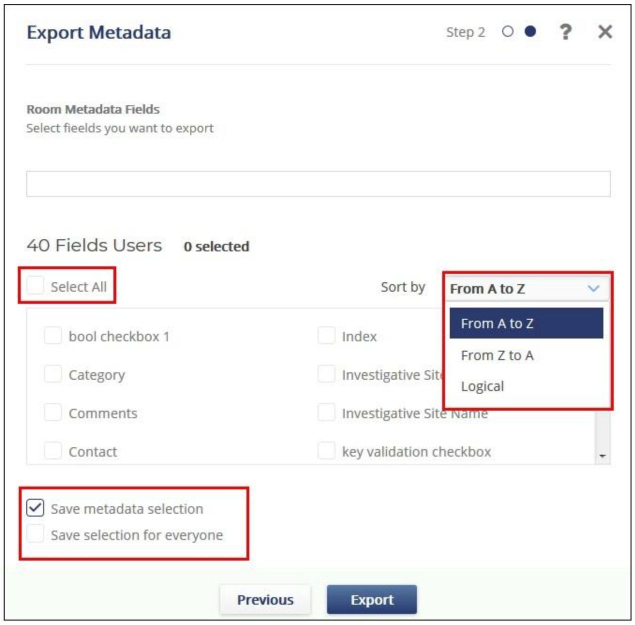
This function gives you a compressed file with the information you requested in XLSX spreadsheet file To export metadata,

1. Click the **Metadata** option from the **Export** dropdown on the top ribbon bar. The **Export Metadata** window opens. Refer to the screenshot below:

2. Select the **Source** options as required and click **Next**.
3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
   a. **Select All**: Tick this checkbox if you wish to select all metadata fields.

b. **Sort By**: Select the options as required from this dropdown to view or select the metadata fields.

4. Also, Notice the two checkboxes below the metadata fields. Select the **Save metadata selection** checkbox if you wish to save the selection for the current user and **Save selection for everyone** if you wish to save the selection for all users. Refer to the screenshot below:

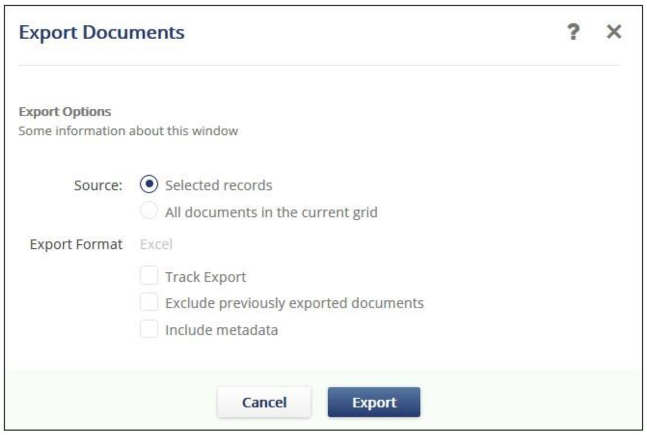


5. Click **Export**.

Exporting Documents

Exporting documents is the same as downloading documents from the Documents Cart.

You can **track an export**, **exclude previously exported documents**, or **include metadata during export**. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.



The documents or selected documents get exported in a .zip file. The .zip will include the following:

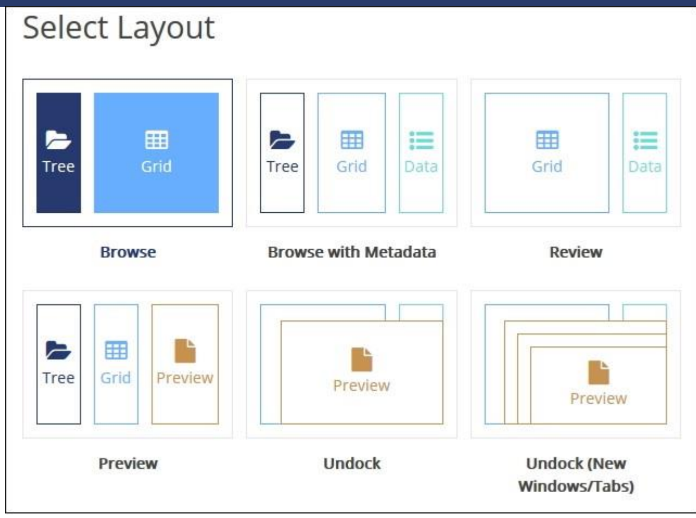
1. A **folder with the exported documents** in it.
2. An **excel worksheet** with the metadata, if you happen to export metadata.
3. A **.log** file which opens in Notepad to give the list of previously exported documents that were excluded during export. Here again, you have to select the option to exclude previously exported documents to enable this.
4. An **ErrorsLog.xml** file that includes details of documents that fail to export. To view the exported

file, navigate to the Notifications *(page 64)*.

Layout

You can change the layout view of the grid by clicking the Layout option from the top ribbon bar. Follow the steps below to change the layout of the gird.

1. Navigate to **eTMF Documents module.**
2. Select the **Layout** option from the top ribbon bar. The **Select Layout** popup opens. Refer to the screenshot below:



3. Select the required layout and the document grid sets it layout as selected.

Compare

Documents can be compared from in the following ways:

1. From the top ribbon in the eTMF Documents module.
2. From the Documents Cart *(page 285)*. To compare documents,

1. From the **eTMF Documents** module, select the folder from the Index to open the documents in the grid.
2. Select the required documents to compare and click the **Compare** 

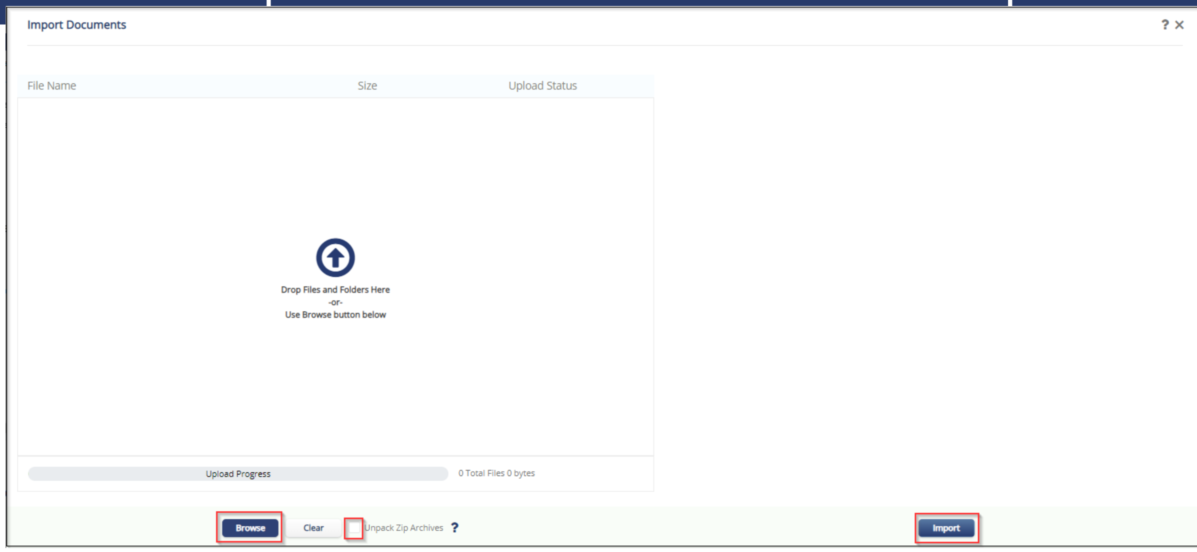
option from the top ribbon bar.
3. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the viewer chosen by you. You can also expand the metadata fields on the bottom using the double-caret bar to compare documents metadata conveniently at once.

Bulk Uploading

Besides Importing documents, you can also upload documents in a bulk to the room. Follow the steps below to bulk upload documents in a room.

1. Navigate to **eTMF Documents** module.
2. Click the **Bulk Upload** 

option from the top ribbon bar. The **Import Documents** window opens.
3. Following the on-screen instructions, either drag-and-drop files from your computer into the upload panel or use the
Browse button on the window to select documents to upload. Refer to the screenshot below:



4. Choose **Unpack Zip-archives** if you wish to extract files from an attached zip folder.
5. Tick the checkboxes for documents to be uploaded and click **Import**.
   These documents are uploaded to the upload folder. You can later edit the metadata of these documents from the Metadata Panel *(page 262)*as required.

Documents Cart

Perform various functions from here like **copying documents to rooms or sites, comparing, merging, or linking**

documents besides many more.

Users select documents to add to the Document Cart either from the Documents Context Menu *(page 249)* or by selecting documents from the grid and then clicking the Add to Cart button from the top ribbon menu.

The Documents Cart 

icon is located on the upper right-hand corner of the document grid and works just like a shopping cart.

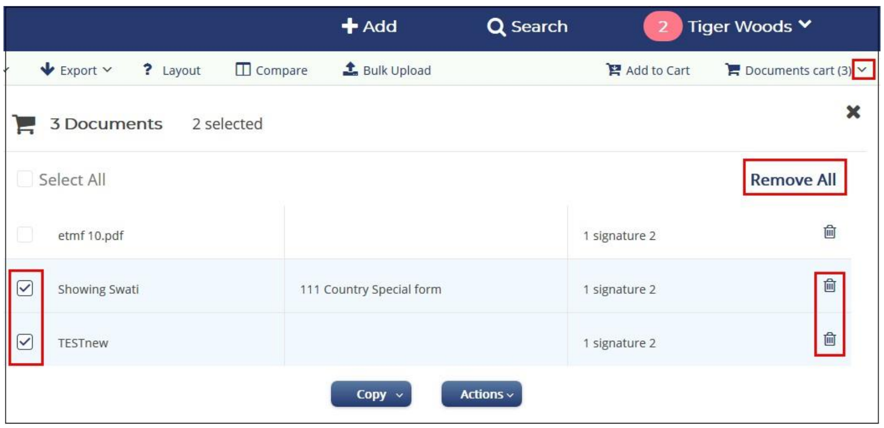
Adding documents to the Documents Cart

1. Locate the document which is to be added to the Document Cart and select the checkbox next to it. Now the process of addition can be done in two ways.
   a. Click **Add to Cart** from the upper right-hand corner.
   b. Right-click and select **Add Selected to the Cart** option.
2. Once a document is added, it will automatically update to reflect the number of documents available in the cart. Refer to the screenshot below:

Removing documents from the Documents Cart

Follow the steps below to remove documents from the Documents Cart:

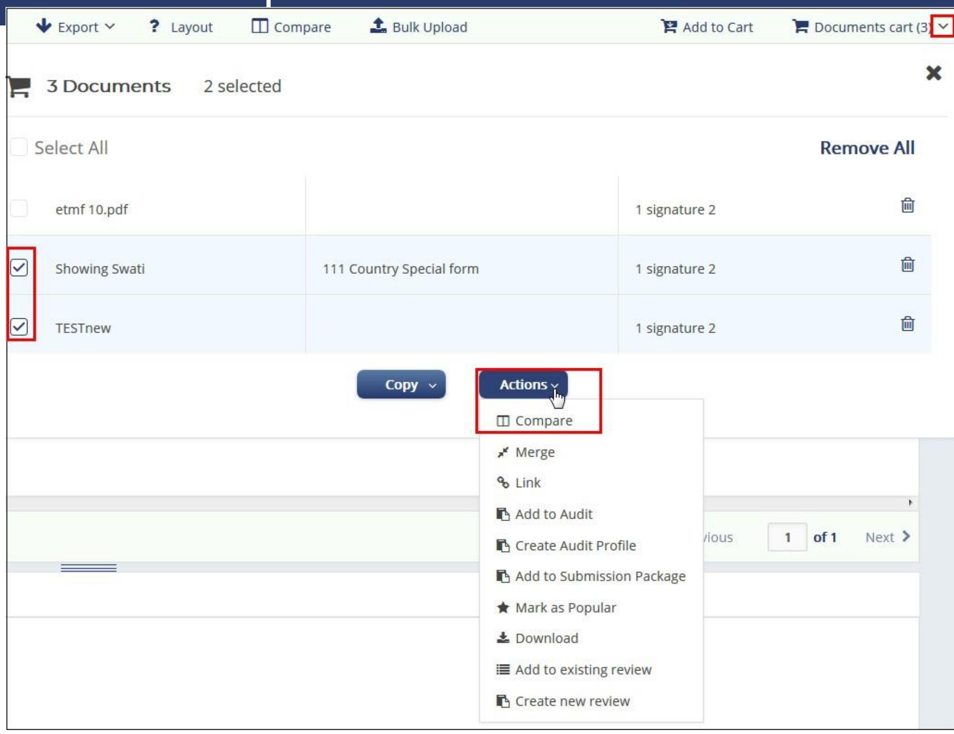
1. Click the arrow next to the **Documents Cart**. A popup window opens.
2. Select the checkboxes next to the documents and click Delete button to the right of the selected documents.
3. If you wish to remove all the documents, click the **Remove All** button. Refer to the screenshot below:



Compare Documents

The Compare Documents tool in Documents Cart lets you view and compare two or three documents at the same time by placing those side by side. You can use the ABBYY Optical Character Recognition (if that is enabled for you) to support the comparison of documents from document scans and images.

1. Add required documents to the Documents Cart. *(page 282)*A pop-up window opens.
2. Select the documents from the list you wish to compare.
3. Click **Actions** at the bottom of the window and then select **Compare**. Refer to the screenshot below.



4. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the **Arender** view. Refer to the screenshot below:
5. To facilitate easy and seamless comparison of documents:
   a. The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
   b. The **documents scroll at once in sync** with each other when you drag the scroll bar to facilitate easier viewing and comparison if you have activated the 'Synchronize document scrolling' from the toolbar.
   c. The system displays appropriate messages when two documents are identical.
   d. The print and download options for comparison are available to you only if you have **Full Access** to the documents.

Sites

This allows you to locate the Unique Sites using the combination of Study Name and Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. **When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.**

Note:*If the system finds matching conditions like the site, IRB number and IRB document type in the Study Start- up Site Profile, the documents for the imported site will be uploaded into* *the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which are discussed below.*

Chapter 7. Searches

In this section we discuss Document and Advanced Search, Cross Study Search, Search for Users, Sites, Clinical Data and Room Search

Each of the searches is discussed in separate topics available in the left panel of this help topic.

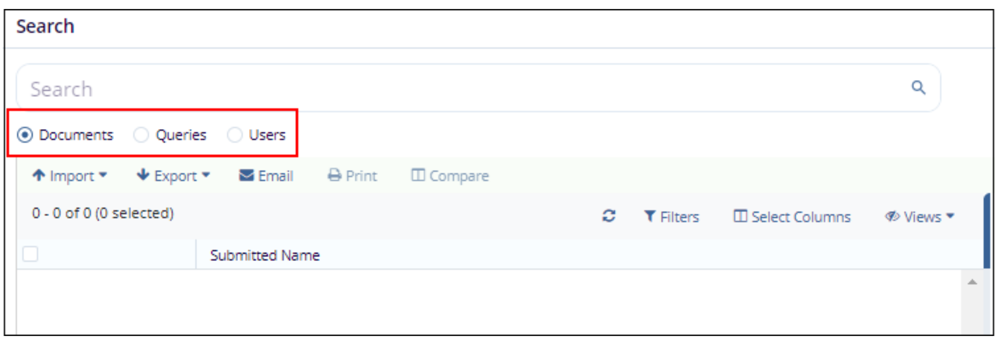
Documents Search

We can perform two types of searches on documents:

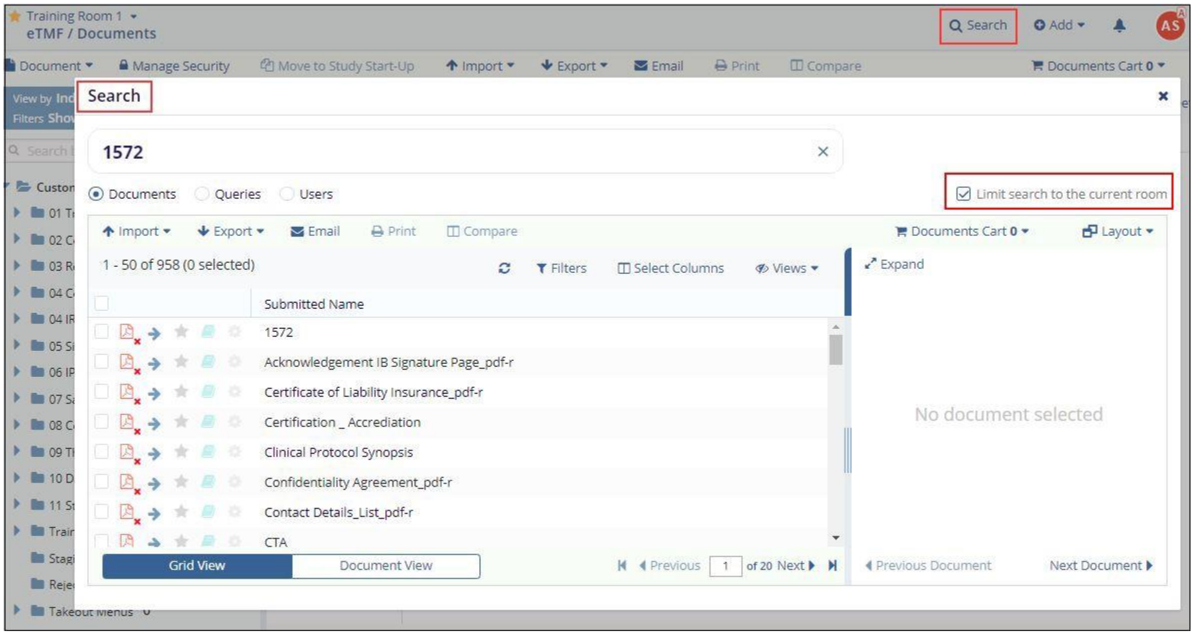
1. **Cross Room Search:** When you search for documents across all studies that you have access to, you are performing a cross-study search. You can execute this search from the **Home Page Search** functionality.
2. **Documents Search:** When you search for documents from within a room or study, check the box **Limit search to the current room**. Refer to the screenshot below:

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

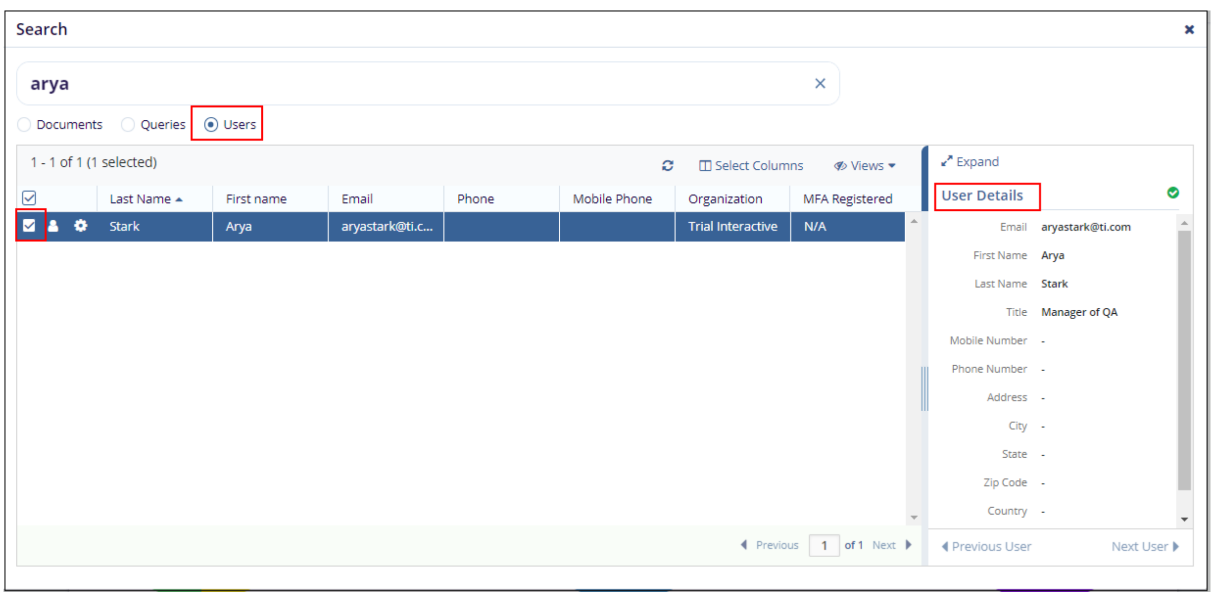
1. Navigate to the Home Page or a Trial Interactive room as required.
2. Click the Search icon from the blue bar located on the top of the dashboard.
3. The Search popup appears.
4. Select **Documents** from the options of Documents, Queries, and Users, Refer to the screenshot below:



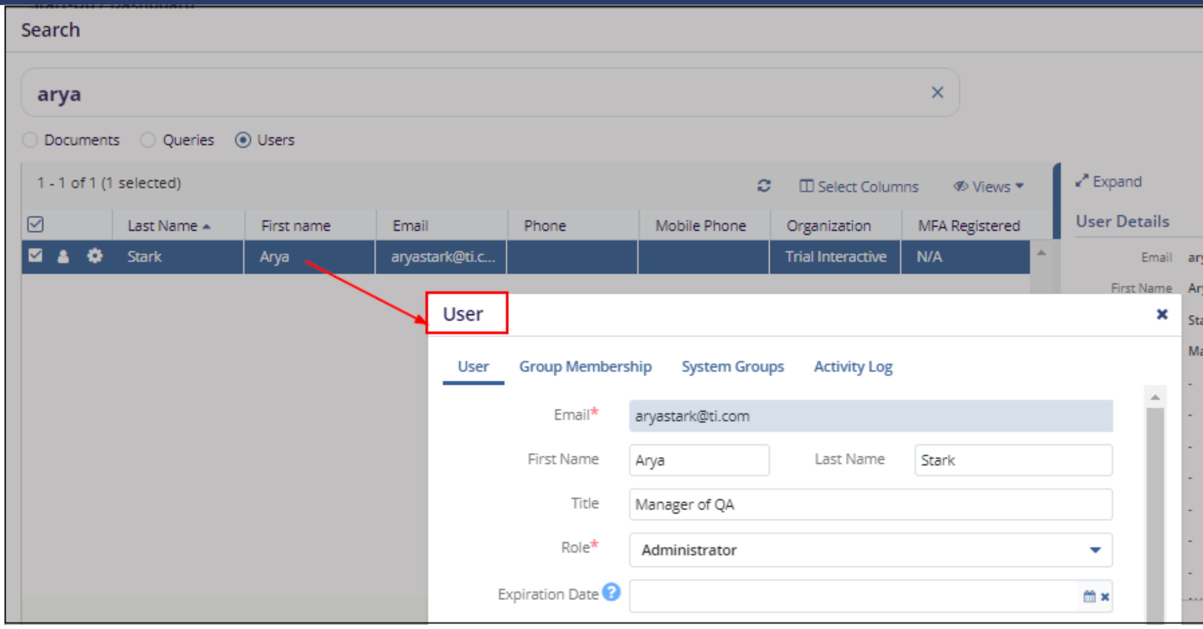
5. Enter the search criteria in the **Search box**.
6. As soon as the text is entered in the Search box, the search process starts.
7. Documents matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:



8. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
9. Hover the mouse over the **Document icon** to get a preview of the documents.
10. Click the document icon. The document **Metadata** panel opens in the right pane.
11. Similarly, select the **User** option to perform the user search. When the results are displayed and the user selects any record, User Details are displayed in the right pane.



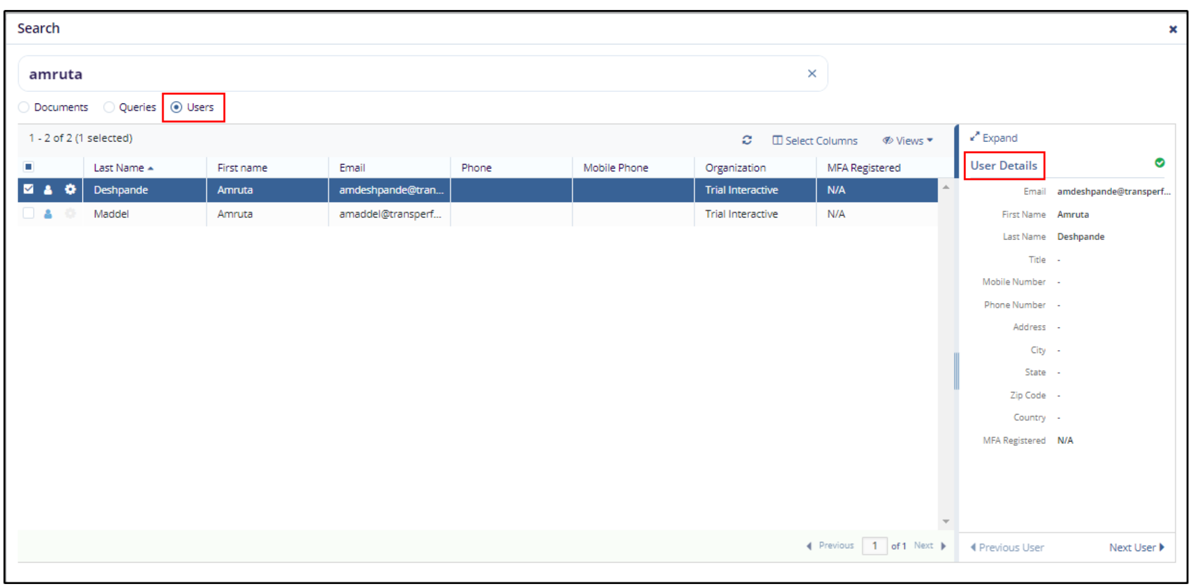
If more details are required then double click the record and **User** popup screen appears in which more **User Details**, **Group Membership**, **System Groups**, and **Activity Log** details are available.



Searching Users

To search for users, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
2. The **Search** window appears. Select **Users** from the options given.
3. Enter the user name in the **Search** textbox at the top of the window. This displays the user in the **Records** section if available. Refer to the screenshot



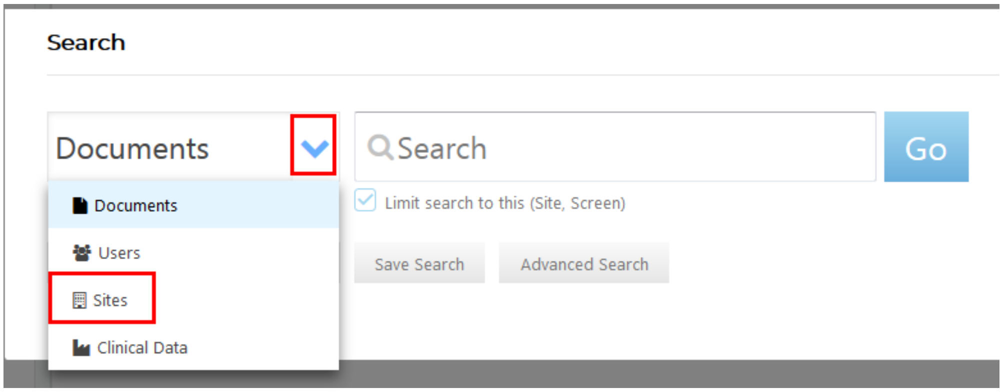
below:

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

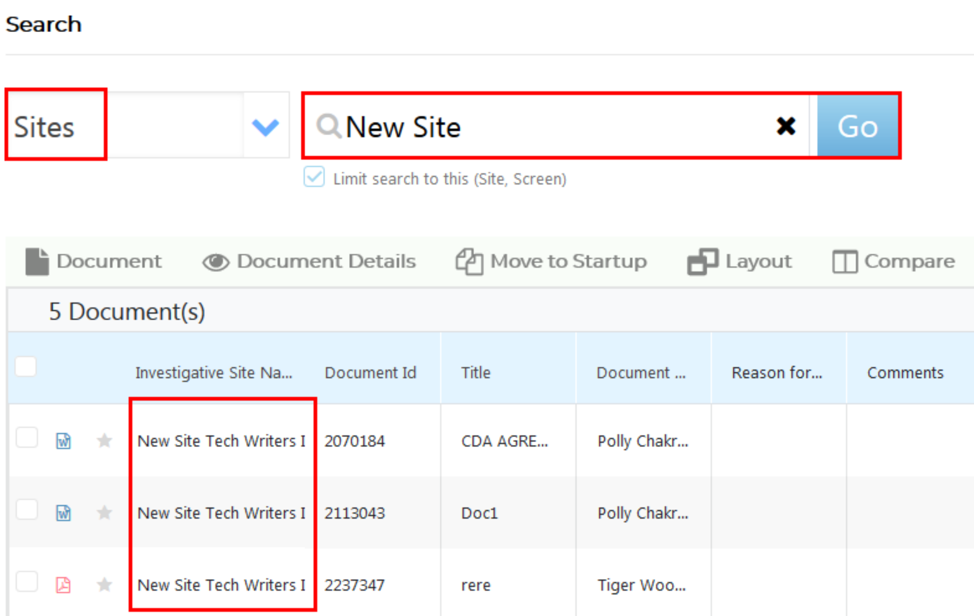
Searching Sites

To search for sites, follow the steps as below:

1. From the Home Page, or from within a room as appropriate, click the **Search** icon located on the blue bar.
2. The **Search** popup appears.
3. From the **Documents** dropdown, click **Sites**. Refer to the screenshot below:



4. Enter the site name in the **Search box** next to the dropdown and click **Go** or press **Enter**.
5. The sites matching the search criteria are displayed in the **Grid** below the **Search box** else a message **No records available** is displayed. Refer to the screenshot below:



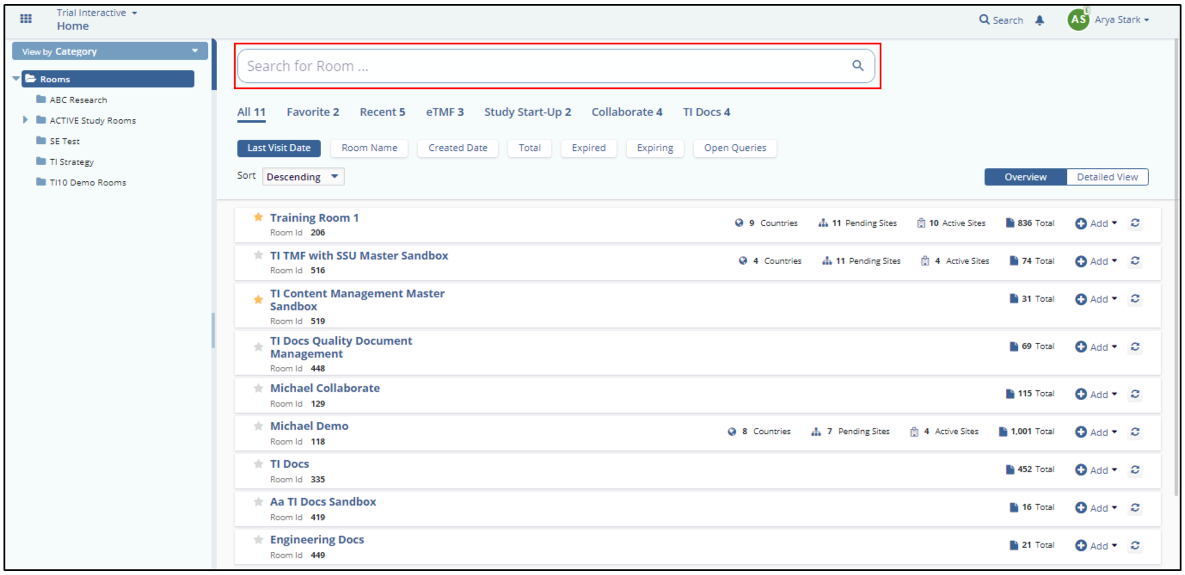
6. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
7. Notice that the top ribbon bar is also available above the Grid which provides the functionalities like **Document**, **Document Details**, **Move to Startup**, **Layout**, **Compare**, and **Add to Cart**.

   Each of these functionalities is discussed in the respective sections.

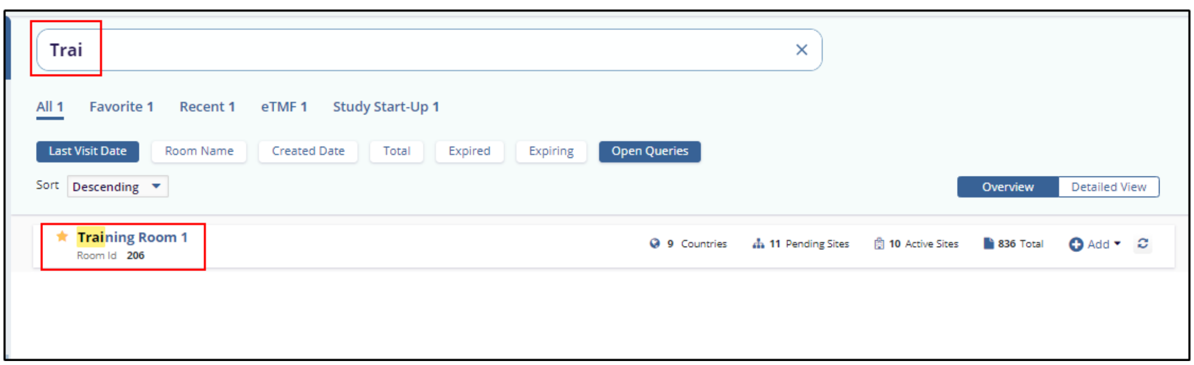
Room Search

To search for a room, follow the steps as below:

1. The **Search** textbox is located on the home page to perform the room search. Refer to the screenshot below:



2. On the home page of the application, all the rooms are displayed and the user can use this search functionality to easily search for the desired room.
3. Enter the room name in the search textbox and search starts automatically as and when the text gets entered in it. Refer to the screenshot below:



Chapter 10. CRA Reconciliation

This section helps you find the details about the CRA Reconciliation Reports that allows CRA to take decisions regarding further site visits.

Trial Interactive 10.1 helps the CRA to reconcile documents

during their site visits through the Site Report. You can reach

this page from Main Navigation →CRA Reconciliation. Refer to

the screenshot below: The module has the following sections:

1. Documents: This module allows the CRA to mark the documents as verified, missing in eTMF, missing in ISF, or add the placeholder for an expected document as a part of the reconciliation process.
2. Reports: This module allows the CRA to create CRA Report which will include all the documents reviewed by the CRA since the last report created by him/her.

   Each of the above modules is discussed in separate topics and can be accessed from the left pane of this help.

Documents Reconciliation

For performing Site Visits, CRAs needs to take some important decisions regarding documents for sites:

1. Which documents need to be added to both eTMF and site binder
2. Which documents need to be added to site binder from eTMF
3. Which documents need to be added from site binder to eTMF

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

Note: *Only **Pending** and **Active** sites are available for the reconciliation process*

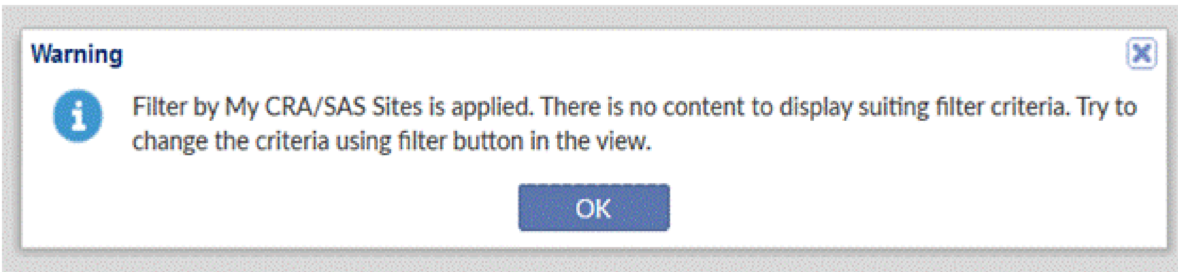
Important:

- *Missing documents cannot be marked as reviewed.*
- *Only CRAs can perform this step. Admin users will not be able to mark documents as Reviewed.*
- *The CRA needs to have **CRA Reconciliation Action** enabled under the user profile.*

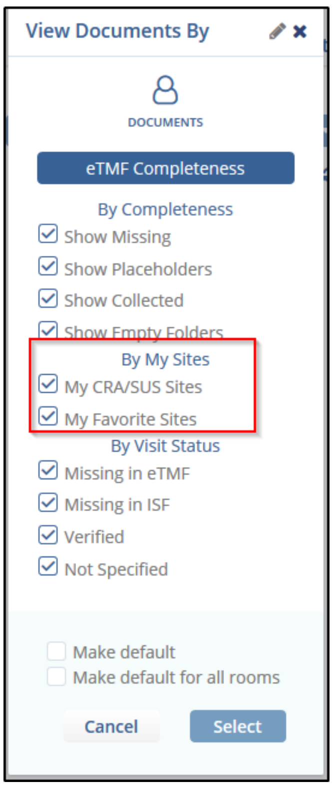
Follow the steps below to reconcile documents:

1. Navigate to **Main Navigation** →**CRA Reconciliation** Refer to the screenshot below:
2. The **Document View** opens as shown in the screenshot below:

3. Notice if you receive warning as shown in the screenshot below:

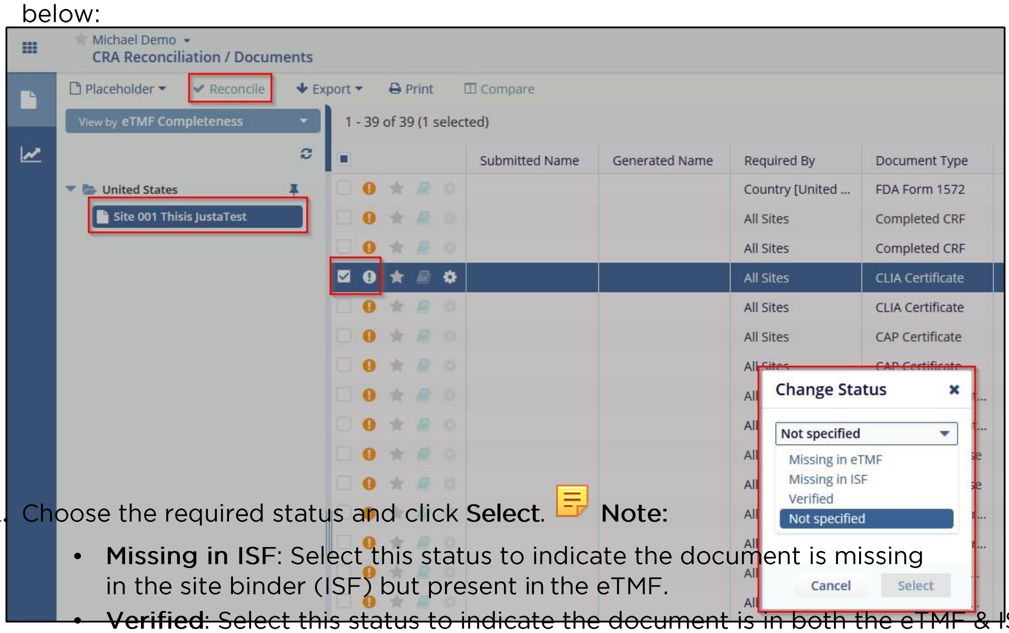


4. If the warning is displayed, click the **Filter** icon below the view and uncheck **My CRA/SAS Sites** or **My favorite sites**
   from the filter. Refer to the screenshot below:
5. Click **Apply**.



6. The list of folders appears in the view.
7. Click the appropriate folder to display the list of sites.
8. Select the appropriate site from the selected folder to get the list of **missing**, **collected**, and **placeholder documents** in the grid.
9. while reconciliation, each document will fall into one of the three scenarios as below:
   a. ***If the document is in the ISF but not showing in the eTMF:***
      a. Click **Add Placeholder** (or if applicable, upload/email the document to the eTMF).
      b. Complete the known required fields and click **Finish** (metadata can be added/edited once the document is collected).
      c. Once all the actions are done, click the **Reconcile** button and proceed to step 11.
   b. ***If a document is in the eTMF not present in the ISF:***
      a. Click the document(s) and click the **Reconcile** button.
   c. ***When the document is in both eTMF and the ISF***
      a. Click the document and then click the **Reconcile** button.

10. Click the **Reconcile** button from the top ribbon bar to change the status of the document. The **Change Status** pop-up opens. Refer to the screenshot below:



11. Choose the required status and click **Select**. **Note:**
   - **Missing in ISF**: Select this status to indicate the document is missing in the site binder (ISF) but present in the eTMF.
   - **Verified**: Select this status to indicate the document is in both the eTMF & ISF.
   - **Not specified** Select this status to clear a previously assigned status.

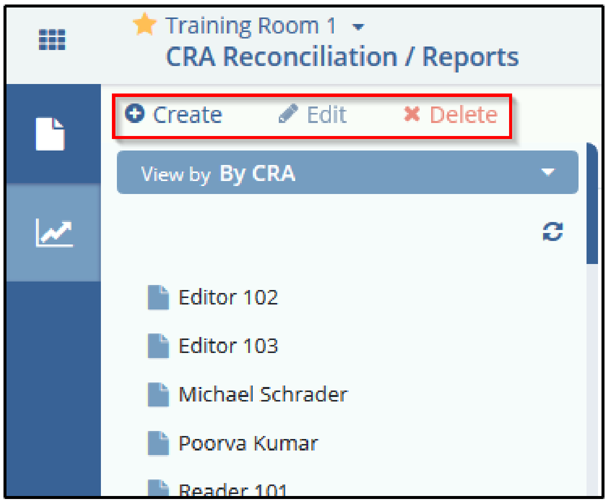
12. Once the **Reconcile** process is complete, you can see the status of the document with the date. Refer to the screenshot below:
13. This site is then available for the creation of the CRA TMF Reconciliation Report in the **Report** view.

Creating and Viewing the CRA TMF Reconciliation Report

CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. You can access this page from Main Navigation → CRA Reconciliation → Reports View. On entering the dashboard, you can find the list of reports generated displayed in the grid. You can choose to view the reports By Site, By Visit Type, or By CRA from the current view panel on the left. Clicking a report from the grid populates the report metadata in Reconciliation Data panel located at the extreme right of the dashboard. You also have the option to Create edit, or delete a CRA Reconciliation TMF Report from the Create, Edit, or Delete icons located on the top ribbon. Refer to the screenshot below:

Creating CRA TMF Reconciliation Report

1. Once the **Reconciliation** process is complete, you can create the CRA TMF Reconciliation report from the
Reconcilia



tion Report module.

2. Select the appropriate filter from the Current View. The Previous reports will populate in the grid.
3. Select the appropriate site and click **Create** from the top ribbon bar to run a new report.
4. The **Create CRA TMF Reconciliation**window populates with documents from the latest reconciliation. Complete the required fields.

   Note: *The Visit Type will be populated in the dropdown only if it is created from Settings → Investigative Sites → CRA Visit Types. (page 140)* Refer to the screenshot below:

5. Fill in the appropriate details and click **Create.**
6. You will receive a **notification** that the **Site Report** is created successfully and displayed in the grid.

Editing CRA TMF Reconciliation Report

1. Select the required **site** from the **Reports** module and click the **Edit** button on the top ribbon bar.
2. The **Modify CRA TMF Reconciliation** popup opens.
3. Edit the required details and click **Save** when finished.

Deleting CRA TMF Reconciliation Report

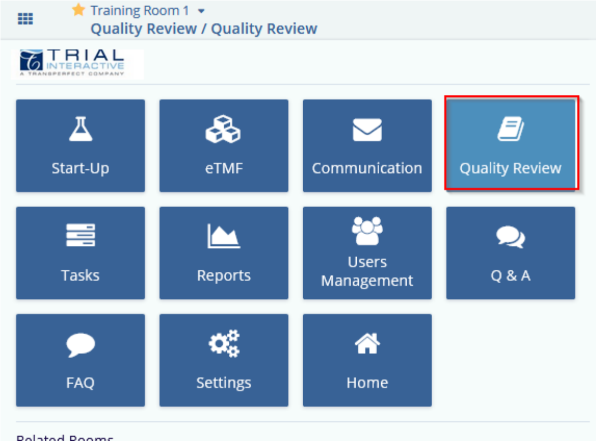
1. Select the required **site** from the Current View and click the **Delete** button on the top menu bar.

2. Click **Yes** on the confirmation popup that appears if you wish to delete the report from the list.

Chapter 12. Quality Review

This section helps you understand the Quality Review/Audit application in Trial Interactive that allows creating Quality Review profile, recording auditor's review and comments on various documents added for audit in a trial.

As a Trial Interactive user, you can access the **Quality Review Application** from the **Main Navigation**:



From here we discuss the following:

1. Performing Quality Review
2. Performing Quality Review Response
3. Responding to Quality Review Queries
4. Resolving Queries Raised during Quality Review

Performing Audits

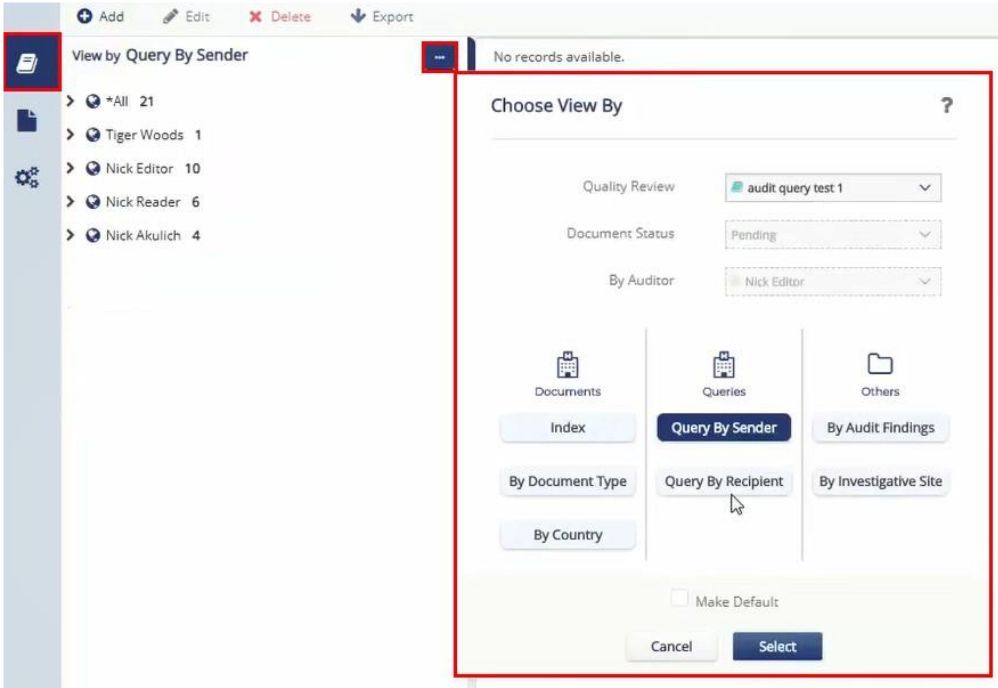
If you are assigned the Auditor or Audit Manager action in your trial room, the audit feature is available to you when you click the Quality Review module in the toggling menu bar.

The Quality Review module has the following views:

- **Audit**: This allows you to perform audits
- **Documents**: This allows you to assign documents for audits
- **Settings**: This allows you to configure settings for Quality Review Follow the steps below to perform audits:

1. As a user with Auditor duties, log in to a room and click the **Quality Review** icon from the Main Navigation. The user can access **Audits**, **Audit Documents**, and **Audit Settings** through the panel on the left.
2. Click the **Audit** view from the left panel. The Audit view opens.

3. Click **three dots** from the left pane. The **Choose View By** popup appears as shown in the



screenshot below:

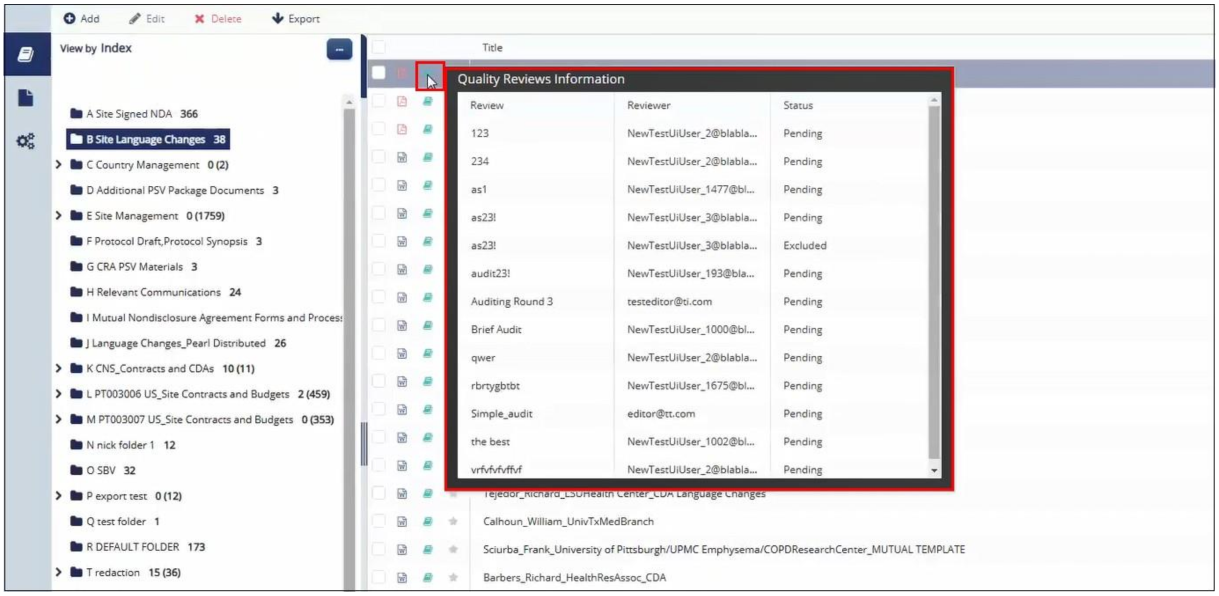
4. Click the **Quality Review** dropdown to select an active audit from the list.
5. The user can also choose to view the available audit documents *By Document Type*, *By Country*, *and By Investigative Site*, *Audit Findings*, *Query By Sender, and Query By Recipient*. Select views to be displayed.
6. The corresponding folders display based on the selection made by the user. Drill down and select the available folders.

Available documents will be displayed in the grid.

The Auditor has another means to filter the audit documents.

1. Once the Audit is chosen, click the **Document Status** dropdown.
2. Select **Pending** from the list.
3. Select the auditor from the **By Auditor** dropdown.
4. Click the **Select** button. Index folder containing documents **Pending Audit** populate in the Index View. Refer to the screenshot below:
5. Open folders to locate documents published and assigned for audit.
6. Notice the **Quality Review Information** icon next to the document icon in the document grid.
7. Click the icon to open the Audit Panel in the Metadata Panel. Also, notice that the **Quality Review Information popup**

displaying the audit status of the selected document. Refer to the screenshot below:



8. Open the document in the viewing panel.
9. Examine the document and its metadata to determine if it meets the established audit criteria.
10. From the **Metadata panel** to the right, click the dropdown arrow at the right end of the **Status** field. The status options appear.
11. Click the appropriate **Status**.

    If the document contains **Protected Health Information** (PHI) and you want to delete and fail the document attachment for audit, tick the **Contains PHI?** checkbox.

    Note: *To enable the Contains PHI? field, you will need to enable the feature when setting up the Audit under* *Document Audit Settings (page 347)*

    On ticking this, the document automatically acquires a failed status and displays a warning regarding the removal of the attachment from the document.

    Click Remove file to proceed. The system deletes the attachment in the backend and displays the Refresh icon next to the document in the grid.

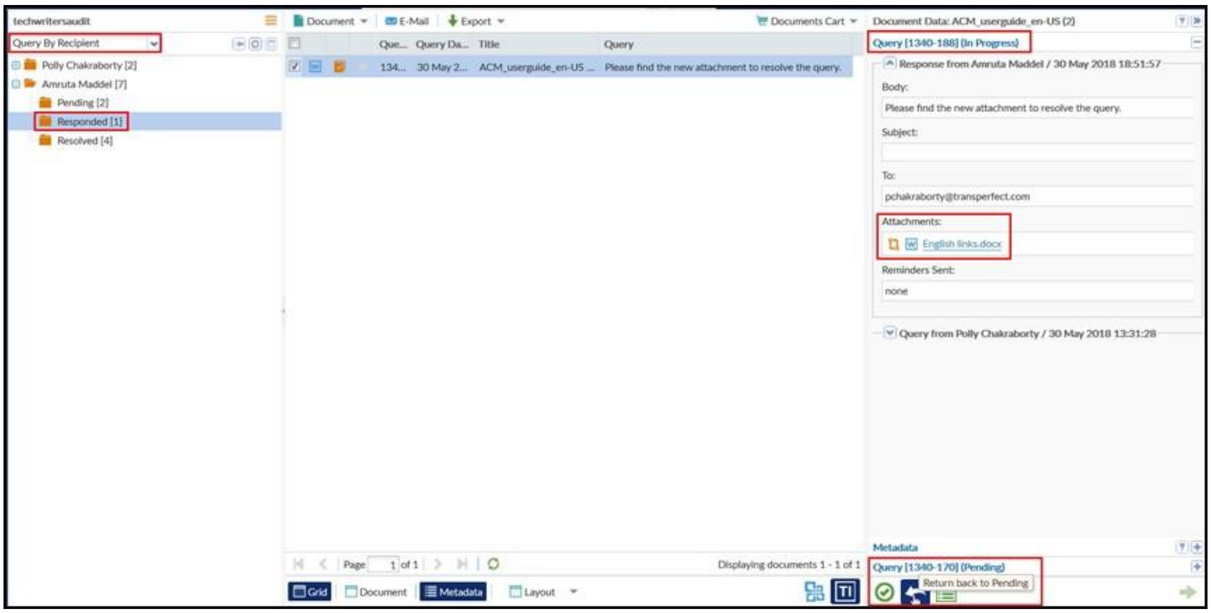
    On clicking the Refresh icon, the document disappears from the grid and moves to the Audited folder.
12. Insert comments as appropriate.
13. Click the **Save** button, or the **Save and select next button** in the lower toolbar of the window.

Note: *Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your Audit Criteria*

14. To view audited documents, filter the documents by Audited from the panel on the left.
15. The audited documents appear in the grid with their respective statuses. Documents failed due to the content of PHI appear in the grid without the attachment and acquire a failed status.

Resolving Queries Raised during Audit

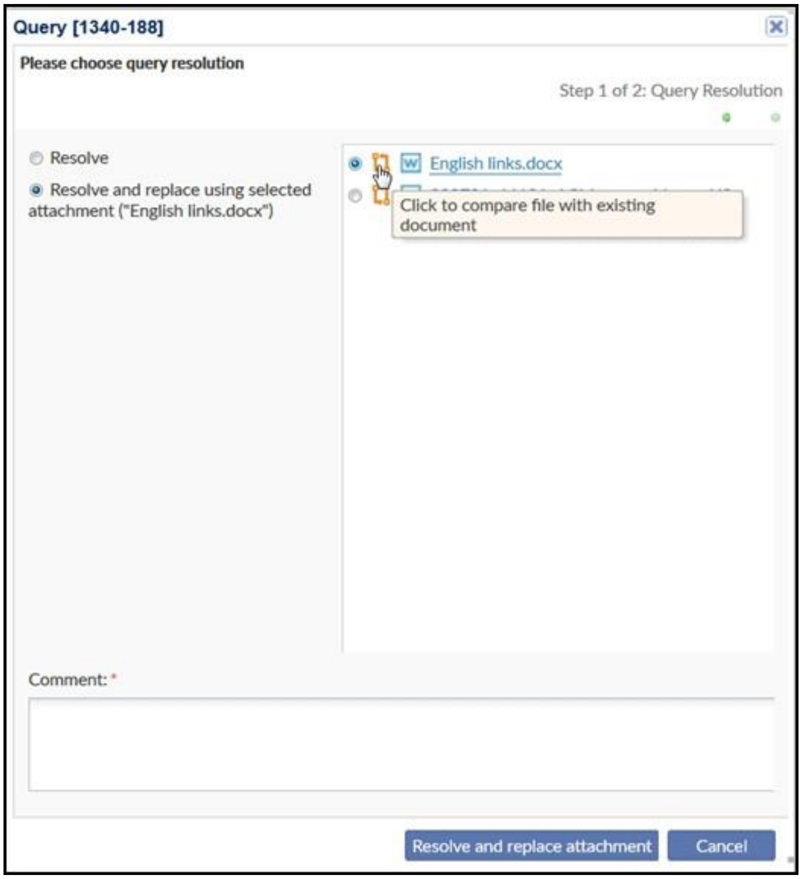
The user who receives the email responds back with an attachment to resolve the query. You can view the responded query in the Responded folder of Query By Recipient view under the selected audit. Refer to the screenshot below:



To resolve queries raised during audit:

1. Navigate to the **Query By Recipient** view.
2. Select a query from the grid on the right.
3. Click the **Metadata** button from the bottom of the grid. This will open the Document Data Panel.
4. Click the **Resolve** button from the bottom of the **Document Data Panel**. If the resolution is not acceptable, you can click the **Return to Pending**button from the bottom of the metadata panel. The document returns back to the **Pending** folder and can be resent for query again.
5. This will open the **Query** window to comment and resolve the query.

6. Enter the **comments** and click the **Resolve** button or **Resolve and replace attachment** button on the window as per your selection. Refer to the

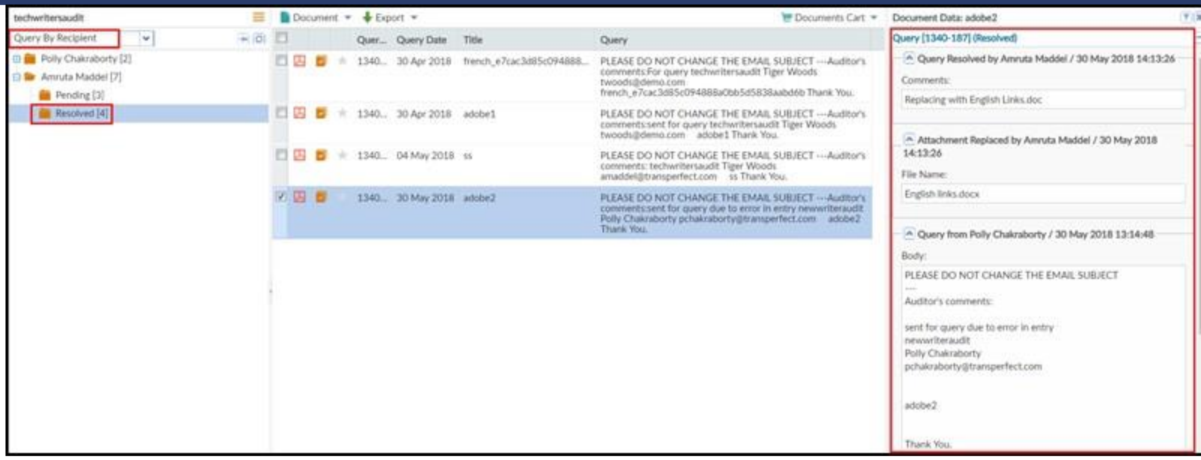


screenshot below:

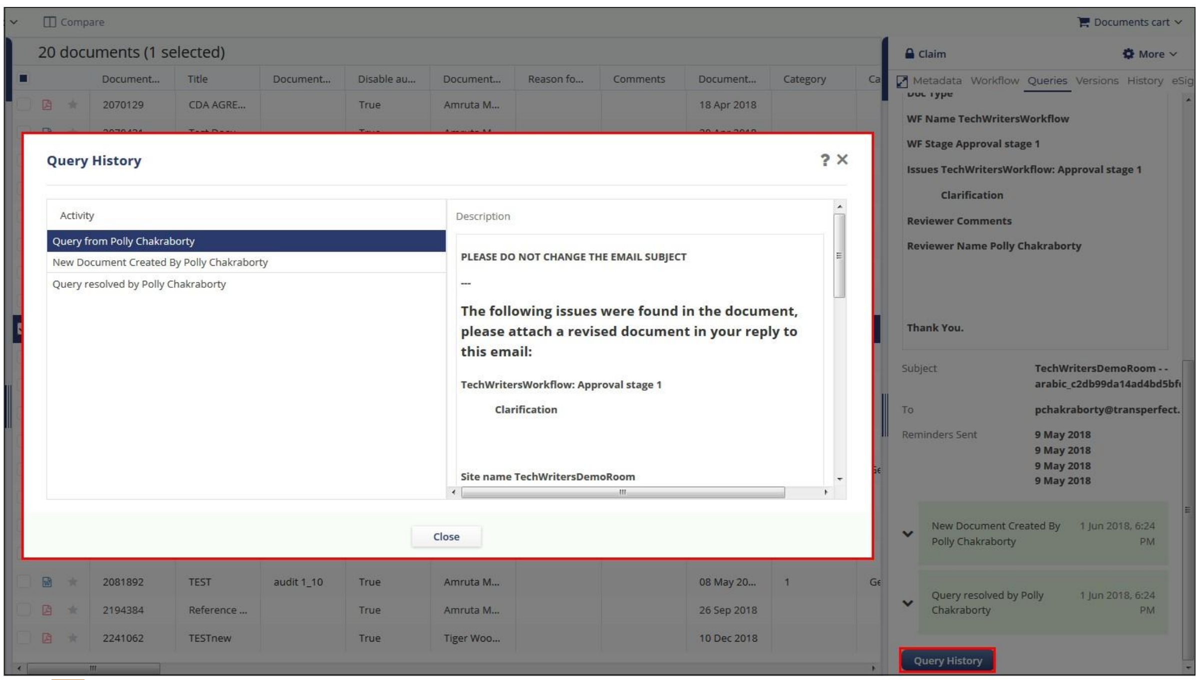
   a. **Resolve**: This option will just mark the query as resolved without any additional actions.
   b. **Resolve and replace using selected attachment**: This option allows you to replace the existing attachment with the one which is received as a part of the query response. Select the document from the right pane and click the **Compare** icon to compare the attachment received with the document in audit.

      If you are satisfied with the response received, enter your comments and click Resolve and replace attachment button.

7. This will resolve the query and the query will now move automatically to the **Resolved** folder under the name of the auditor.
8. Click the **Resolved** folder from the **Index Pane** to view the resolved query. Refer to the screenshot below:



9. You can click the Query History icon at the bottom of the Document Data Pane for a query to view the Query History in a window that pops up.



Note: *To know how to view a deleted queried document, proceed to section Deleted Queried Documents.*

Chapter 13. Sites, Required Documents, Countries and Contacts

In this section, we discuss the Sites, Required Documents that are required for site activation, Country Documents, and Contacts.

Sites

You can access the Sites module by clicking Sites icon on the left menu bar in the eTMF/Documents module. The Sites module is used for site management purposes and allows the administrator to track the progress of the sites. It gives detailed information on all investigation sites available in a room By Status, By CRA, By Country.

You can perform various other activities associated with a site, such as:

1. Retrieving Site Details
2. Adding, Editing, and Deleting sites
3. Importing, and Exporting Sites
4. Mass Coding metadata for sites
5. Managing Security.

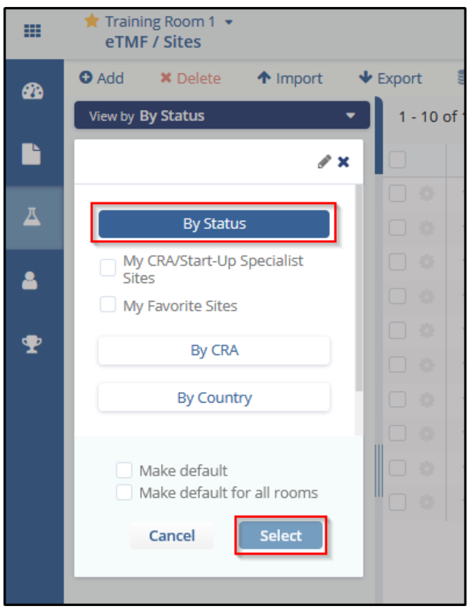
Each of the above is discussed in the separate topics and can be accessed from the left pane of this help.

Site Views

This section discusses about the various views of the Sites module.

By Status

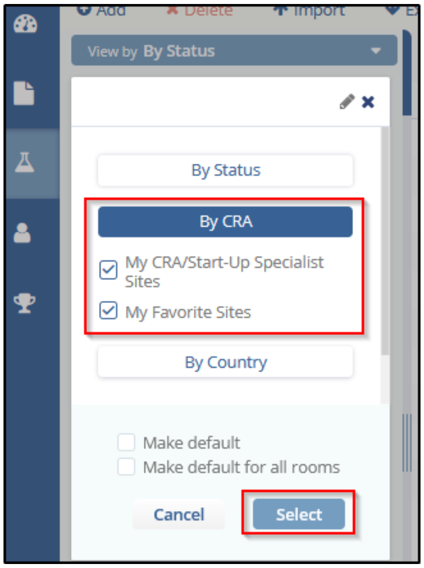
Select By Status from the dropdown in the Index Pane of Sites Dashboard. Refer to the screenshot below:



This will populate the data of all the sites available in the room based on their progress report in the right pane of the dashboard.

By CRA

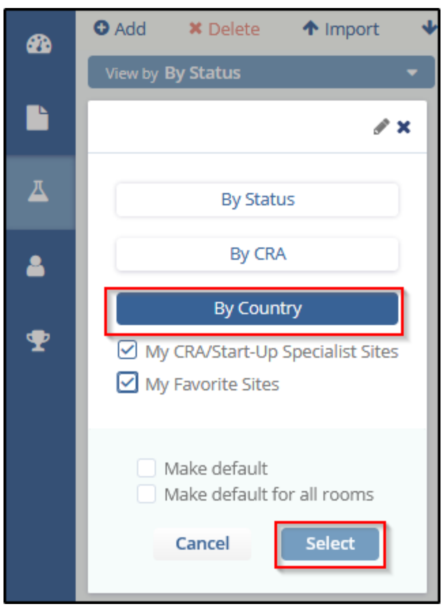
Select By CRA from the dropdown in the Index Pane of Sites Dashboard. Refer to the screenshot below:



This will populate the Clinical Research Associate (CRA) for the available sites in the Index Pane on the left. Click the name of a CRA to populate the site details associated with that particular CRA in the right pane.

By Country

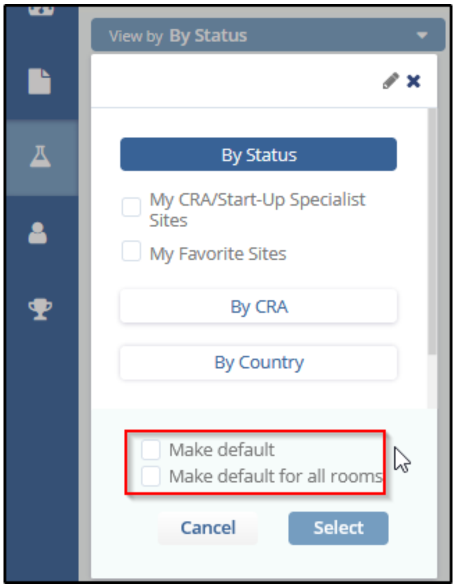
Select By Country from the dropdown in the Index Pane of Sites Dashboard. This will populate the countries where the studies are being conducted in the Index Pane on the left. Click the name of a country to



populate the site details associated with that particular country in the right pane. Refer to the screenshot below.

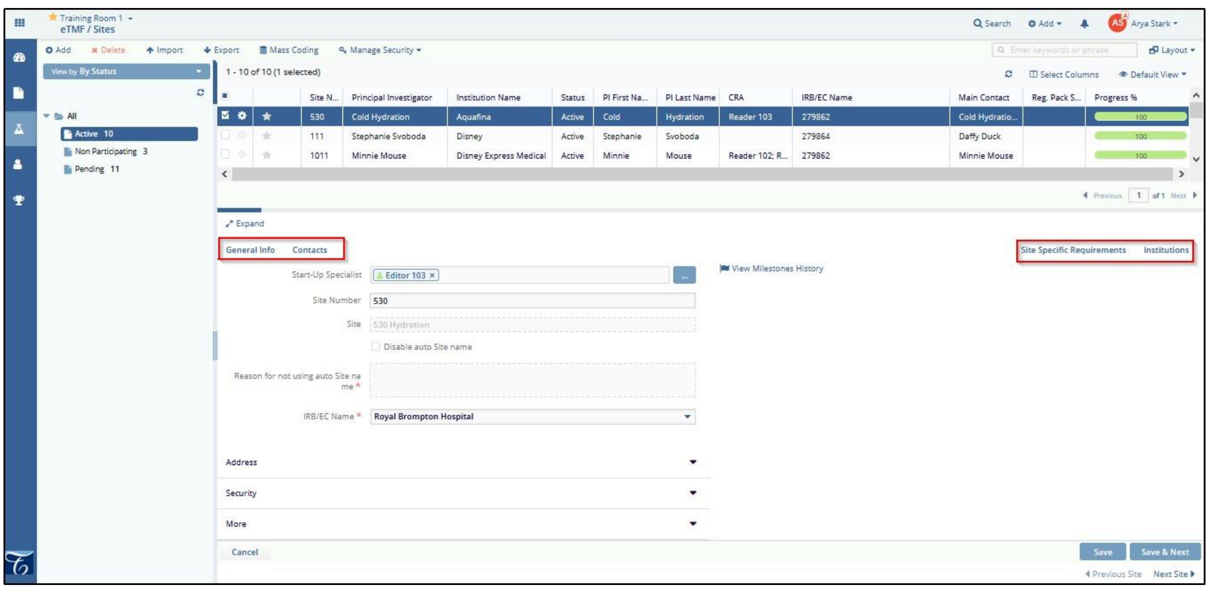
Make a view default

To make any site view default and default for all rooms check one of the two options available in the index dropdown. Refer to the screenshot below.



Site Profile

Select a site from the grid and the Site Profile is displayed at the



bottom of the grid. This will allow you to fill all the metadata related to the selected sites. Refer to the screenshot below:

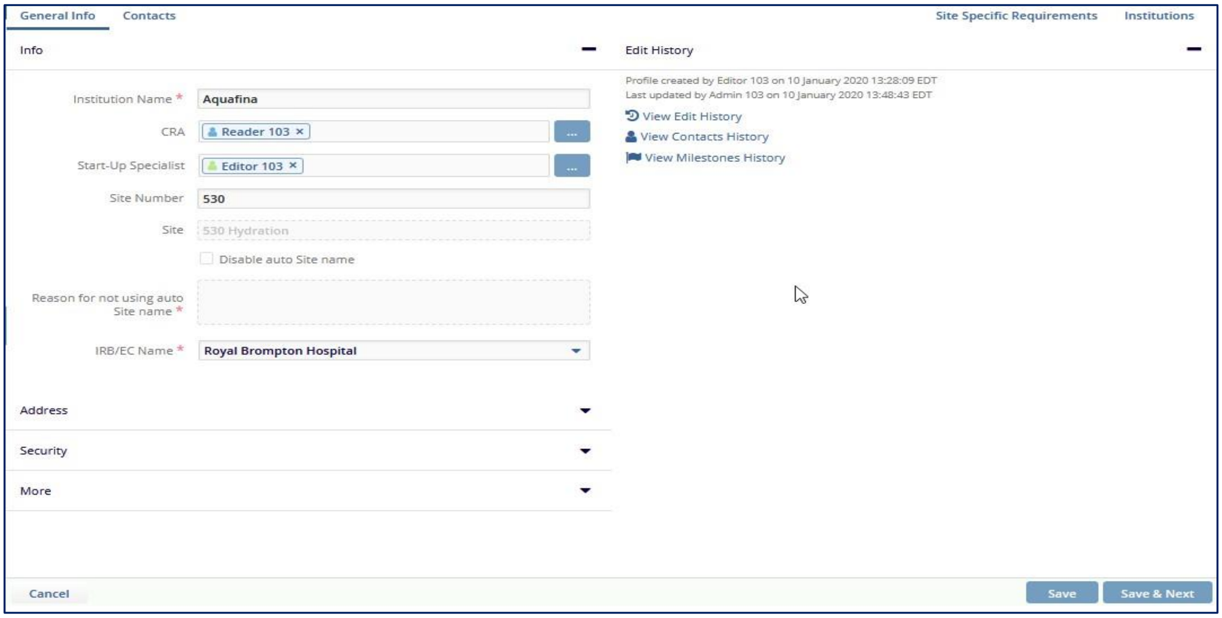
The Site Profile window provides the following:

1. General Info tab
2. Contacts tab
3. Specific Requirements tab
4. Institutions

   Each of the tabs is discussed in the separate topics.

Site Profile - General Info

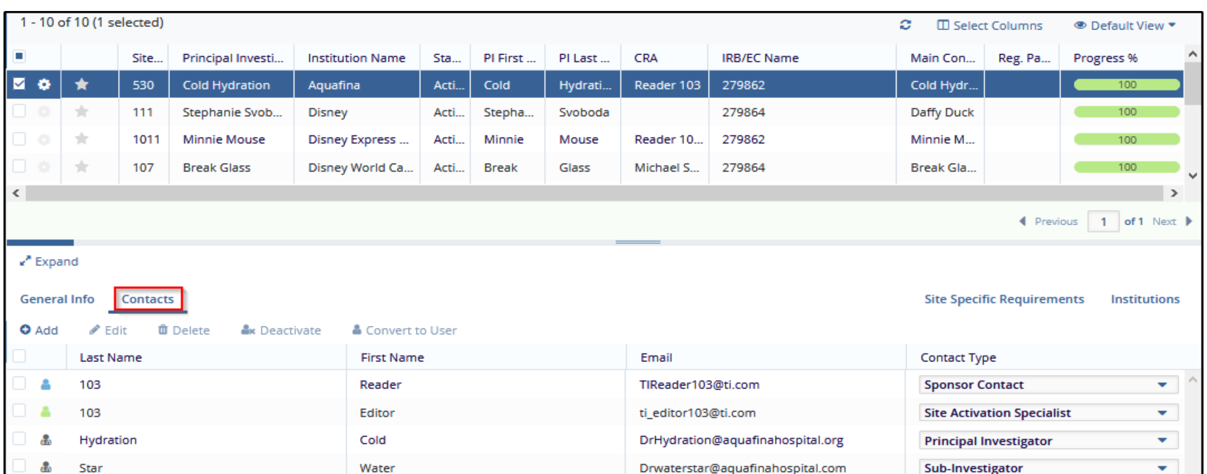
This tab displays the general information of the site.
After selecting a site, click the General Info tab to edit the general details of the site. Click the arrow next to the required section of the General Info to update. Refer to the screenshot below:



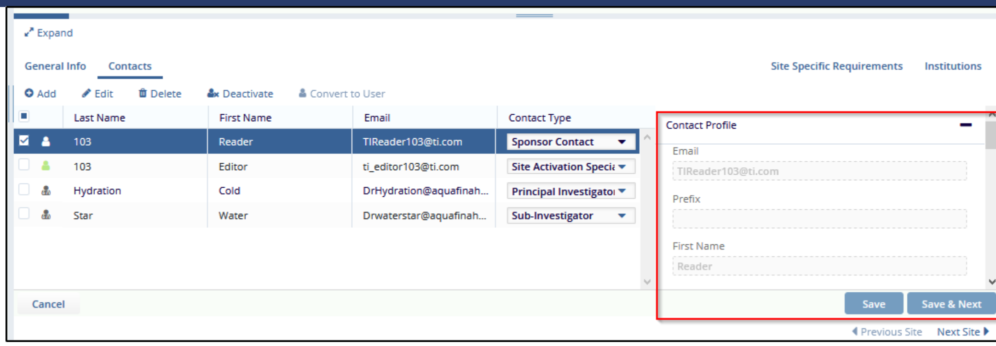
When you click the arrow, the section fields get enabled and the arrow turns to - sign as shown in the screenshot below. Similarly, you can update the fields in the other sections of your choice.

Site Profile - Contacts

This section displays the list of contacts that are added to a site. From here, you can add, edit, delete, deactivate contacts and also change the contact to another level. Refer to the screenshot below:



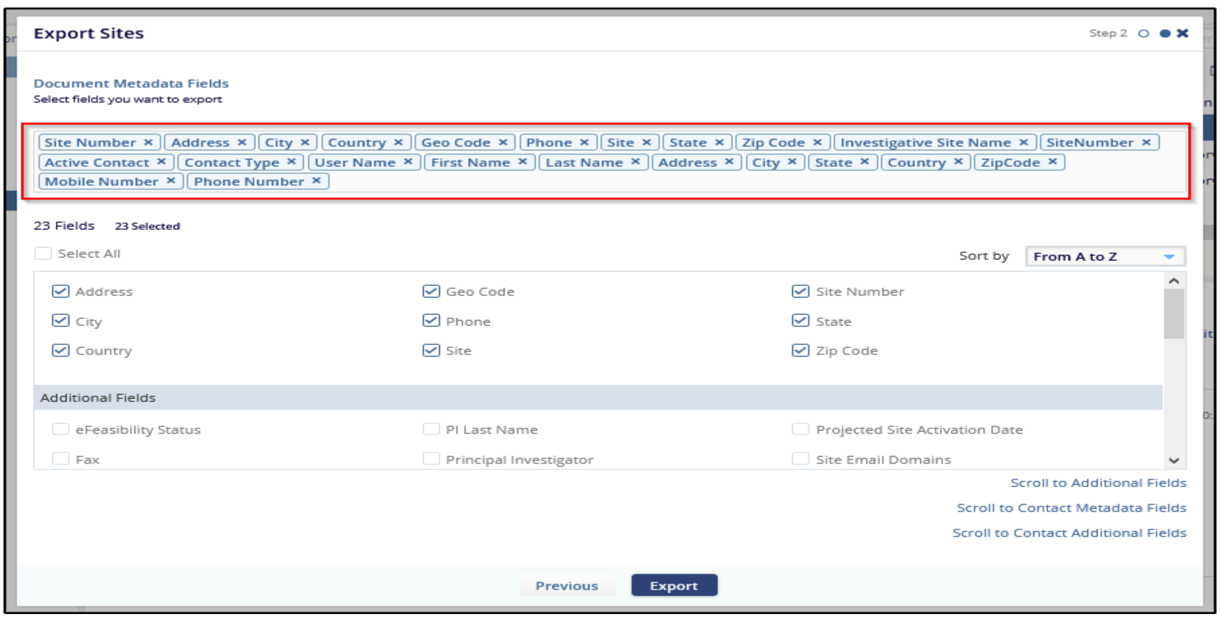
Double click the user to open the Contact Profile to the right of the contacts tab. This allows you to edit the contact details of the user. Once all the details are updated, click Save to save the changes. Refer to the screenshot below:

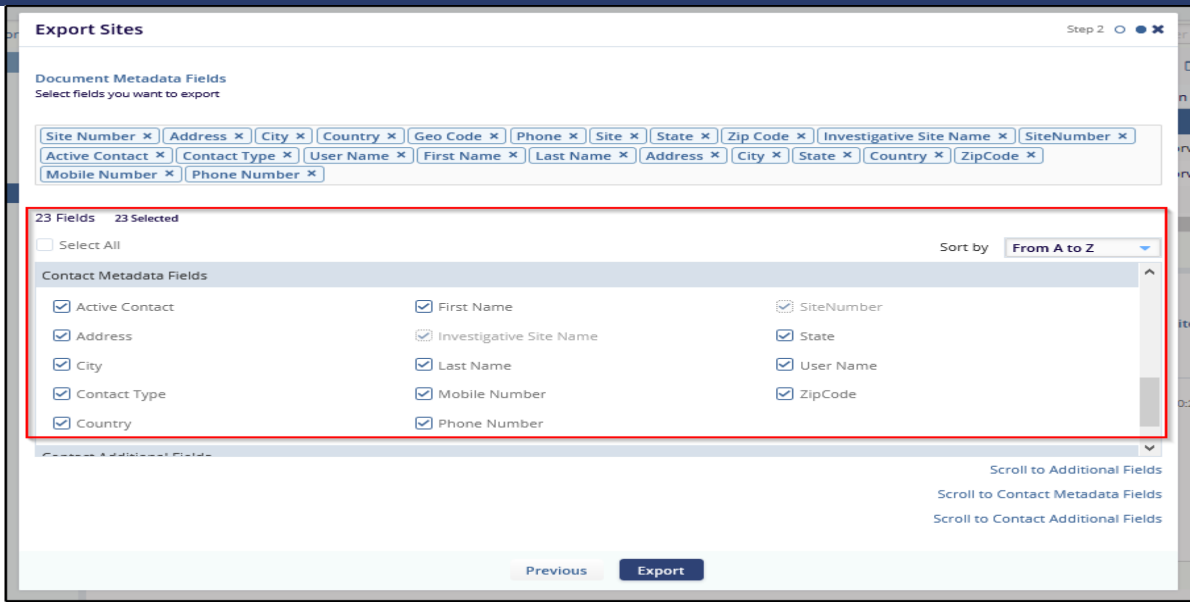


Exporting Sites

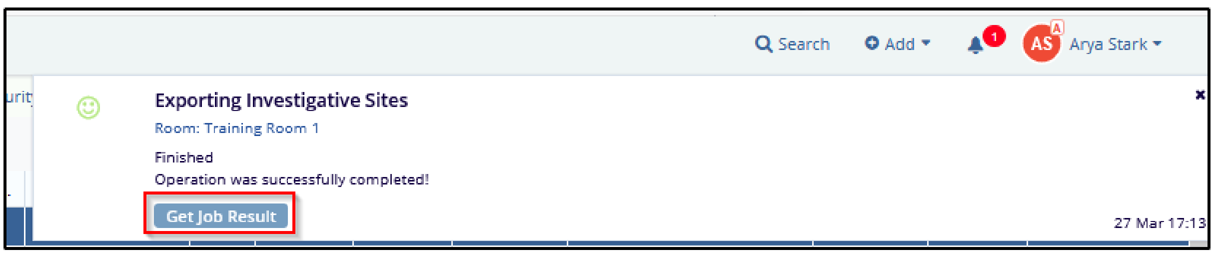
You can also export site metadata through the Export window that appears on clicking the Export icon on the ribbon. You may export sites selected from the right panel, or all the sites in the current grid or room. To export site data, it is mandatory to select the Site Metadata Fields as shown below:
You can export the additional fields in either alphabetical or logical order of selection.

Similarly, to export site contact data, you need to select Contact Metadata fields as shown below:





The export result is also populated in the **Notifications.** Click **GetJob Result** to view the excel file.



.

Contacts

A clinical trial includes a varied range of people with different profiles, who are a part of the study. Such people are a valuable source of information and are required at various stages of the study. Trial Interactive helps to maintain the detailed profile of such people as Contacts for a study. Some examples of contacts could be the Principal Investigator, Sponsor, Co-Investigator, regulatory authorities, authorities in the IRB.

You can access the **Contacts** module by clicking the **Contacts** icon on the menu bar at the left. The **Contacts module** gives detailed information on all contacts available in a room **By Site**, **By IRB/EC**, **By Country**, and **By Contact Type**. From this section you can do the following:

1. View Contacts
2. Mass Coding for Contacts
3. Convert to Users
4. Contact Data

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

View Contacts

This section gives you an overview of the different types of contacts:

By Site

Select By Site from the dropdown in the Index Pane on the left of the Contacts Module. This will reveal all the sites available in the room.

Click a site. This will populate the data of all the contacts available for the particular site in a room in the right pane of the dashboard.

By Country

Select By Country from the dropdown in the Index Pane of the Contacts Dashboard.
This will list all the countries with the sites where the studies are being conducted in the Index Pane on the left. Clicking a country to expand the dropdown will reveal the sites under it.
Click a site to populate the contact details associated with the site in the right pane.

By IRB/EC

Select By IRB/EC from the dropdown in the Index Pane of Contacts Dashboard. This will populate the IRBs associated with the sites in the Index Pane on the left. Clicking an IRB will expand the dropdown to reveal the sites associated with it.
Click a site to populate the contact details associated with the site in the right pane.

By Contact Type

Select By Contact Type from the dropdown in the Index Pane of Contacts Dashboard. This will populate the contact types associated in the room in the Index Pane on the left.
Clicking a contact will list the contact details associated with a particular site in the right pane of the dashboard.

Countries

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

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

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

.

Chapter 14. e-Signature

This section discuss the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

e-Signature

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

Vendors

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

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

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

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

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

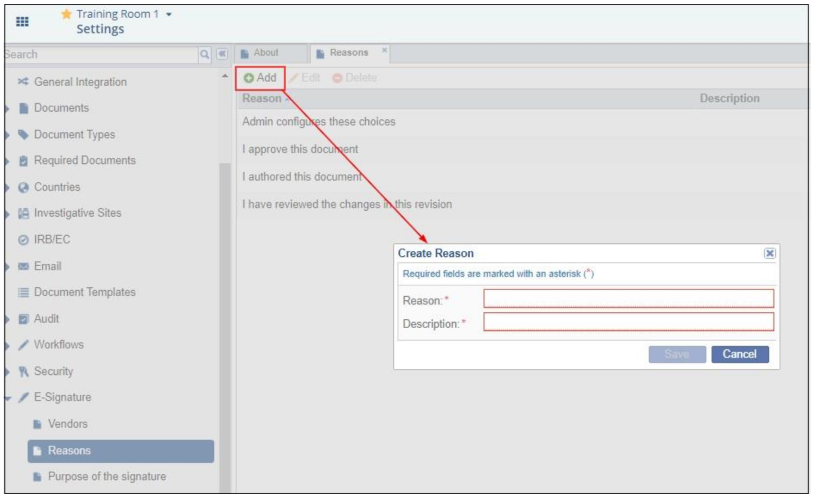
3. An Administrator can choose to enable or disable the use of an e-signature for users in a room by selecting the **None** option from the dropdown.
4. Click **Save** if you make any changes here.

Note: *If the **E-signature** is enabled, the e-Signature Action is automatically added in the **Actions** pane as discussed in* *Edit User (page 72)**. To see the addition, refresh the room in the browser.*

Reasons

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

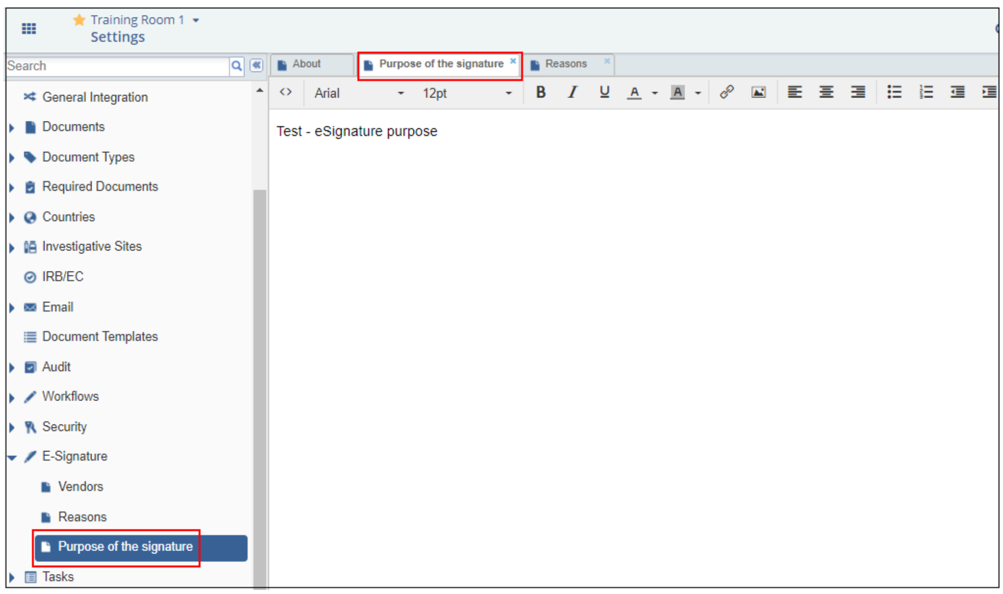
1. Navigate to **Main Navigation**-> **Settings**-> **E-Signature**-> **Reasons**. Refer to the screenshot below:



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

Purpose of the e-signature

Purpose of the e-Signature is an additional text to display on the top of



the send to e-signature form. Refer to the screenshot below:

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

Assigning Users to prepare an e-Signature Envelope

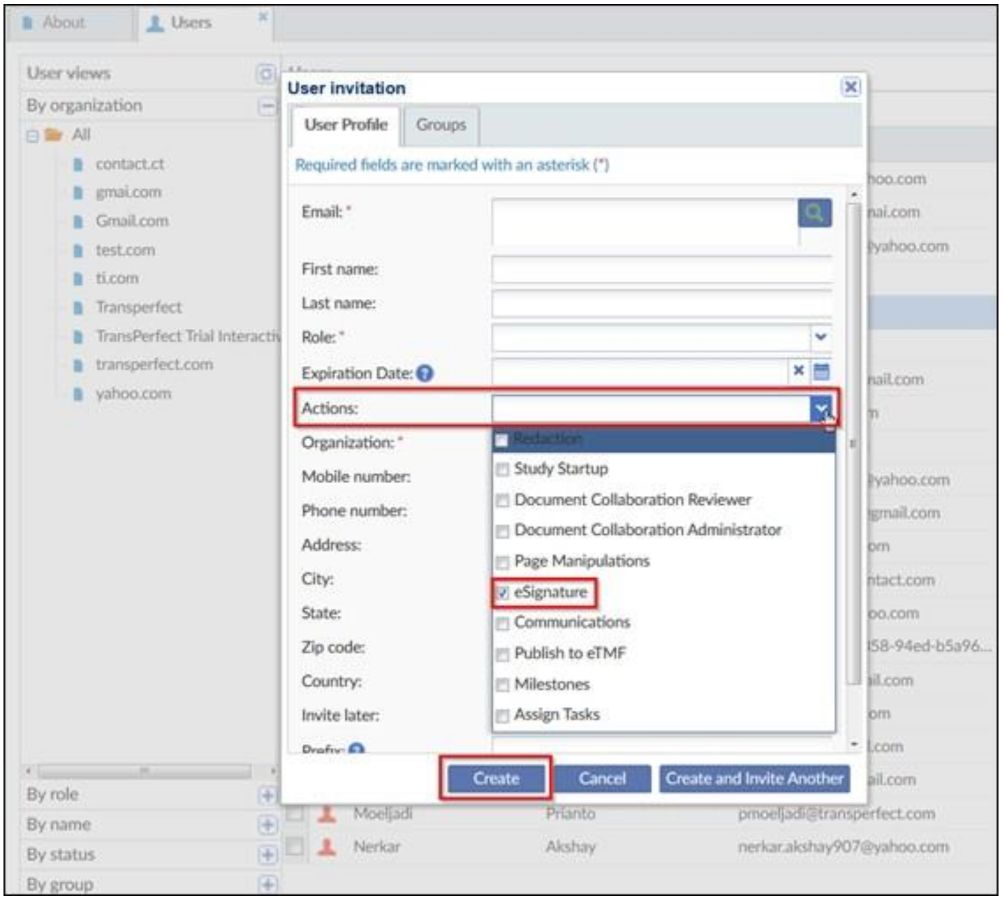
1. Click the desired room in your TI session. Click **Settings** from the Main Navigation to populate the room settings.
2. Navigate to **Settings -> Security-> Users**. A panel listing all users will be

displayed in the right pane. Alternatively, you may arrive on the same page from the **Main Navigation -> Users management**.

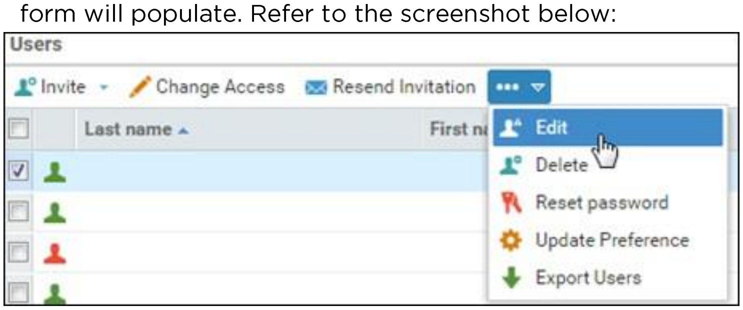
3. Click the **Invite** dropdown located on the top left corner of the user list pane. Select the invite option from the list. A **User Invitation** form will be populated.

   Fill in the fields marked with an asterisk (*), at minimum, to invite the desired user.

   From the **User Profile** tab click the **Actions** dropdown menu to select the **eSignature** option and click **Create** to assign your user to prepare the eSignature package. Refer to the screenshot below:



4. For existing users, select the user from the user list by clicking the checkbox adjacent to the list populated in the right pane.
5. Click the dropdown next to the dots and click **Edit** option. An **Edit User** form will populate. Refer to the screenshot below:



6. Click the **Actions** dropdown menu and select the **eSignature** option by ticking the checkbox.
7. Click **Save** to prepare the existing user for the e Signature package.

The user added will receive an email from Trial Interactive asking them to register in order to comply with e Signature feature.

TI eSignature

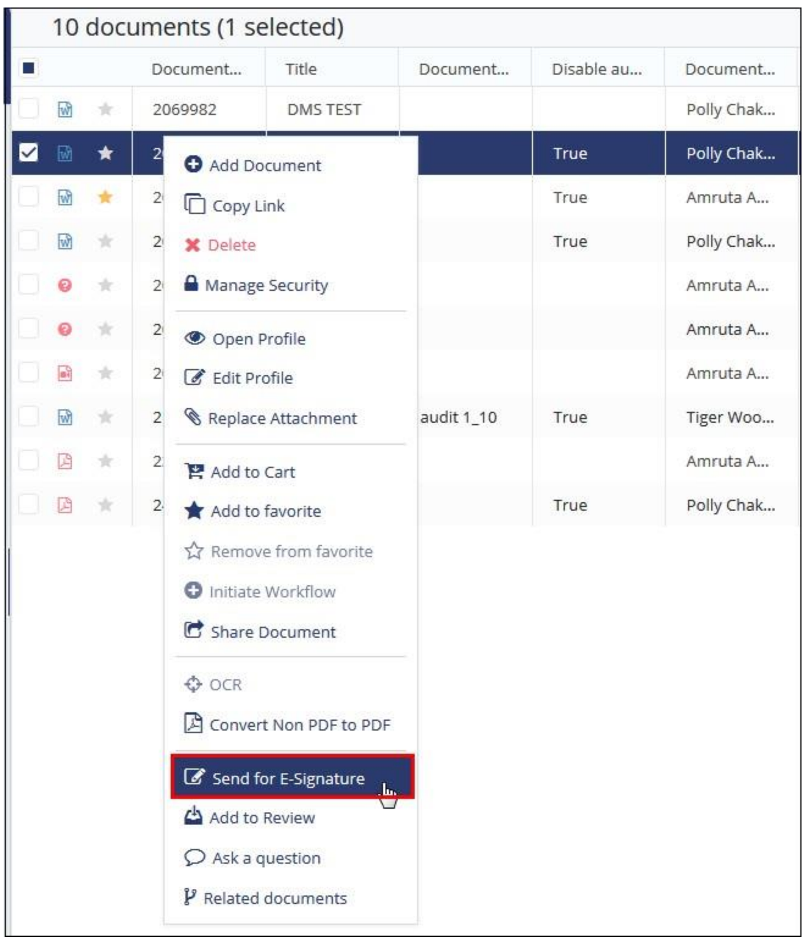
For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) to sign the documents.

This section includes the following sections:

1. Assigning signers to the documents *(page 415)*
2. Signing the documents in TI -eSignature if you are a signer *(page 417)*

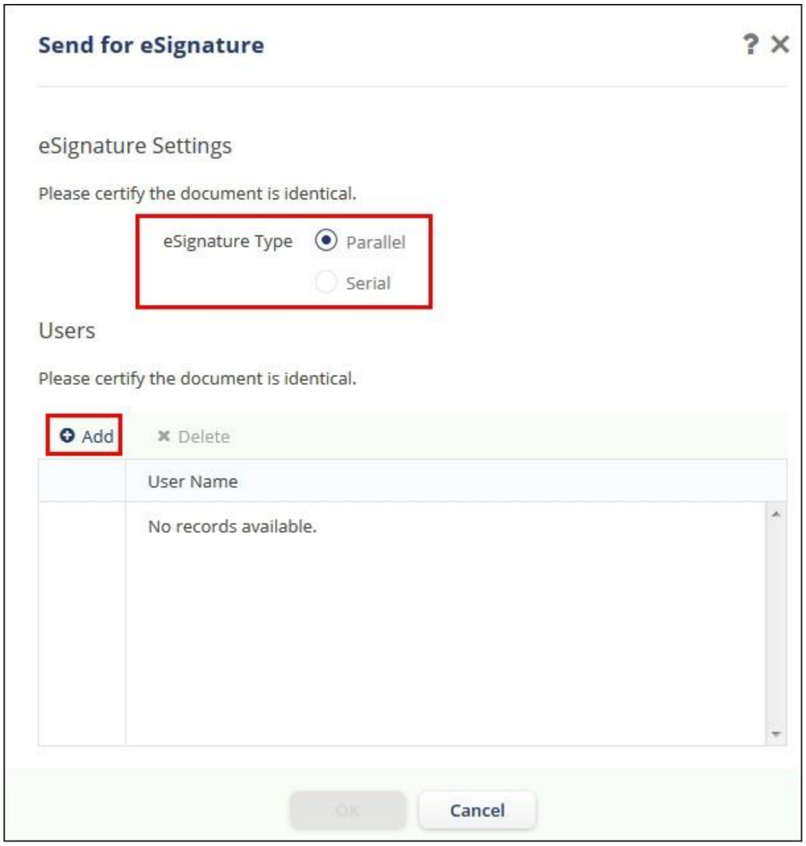
TI eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right-click the desired document and click **Send for e-signature**. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel *(page 268)* to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. Refer to the screenshot below:



Signing the documents in TI - eSignature

If you are assigned to electronically sign a document, you can sign the documents in the following ways:

- From the Documents to be signed dashlet
- From the eTMF/Documents view

Each of the ways is discussed in the sections below:

Signing Documents from the Documents to be Signed Dashlet

1. When you are assigned a document for eSignature, navigate to the room **Dashboard** and scroll to find the **Documents to be signed** *(page 215)* dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display. Refer to the screenshot below:

   You can also proceed to the **eTMF/Documents** module or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane.

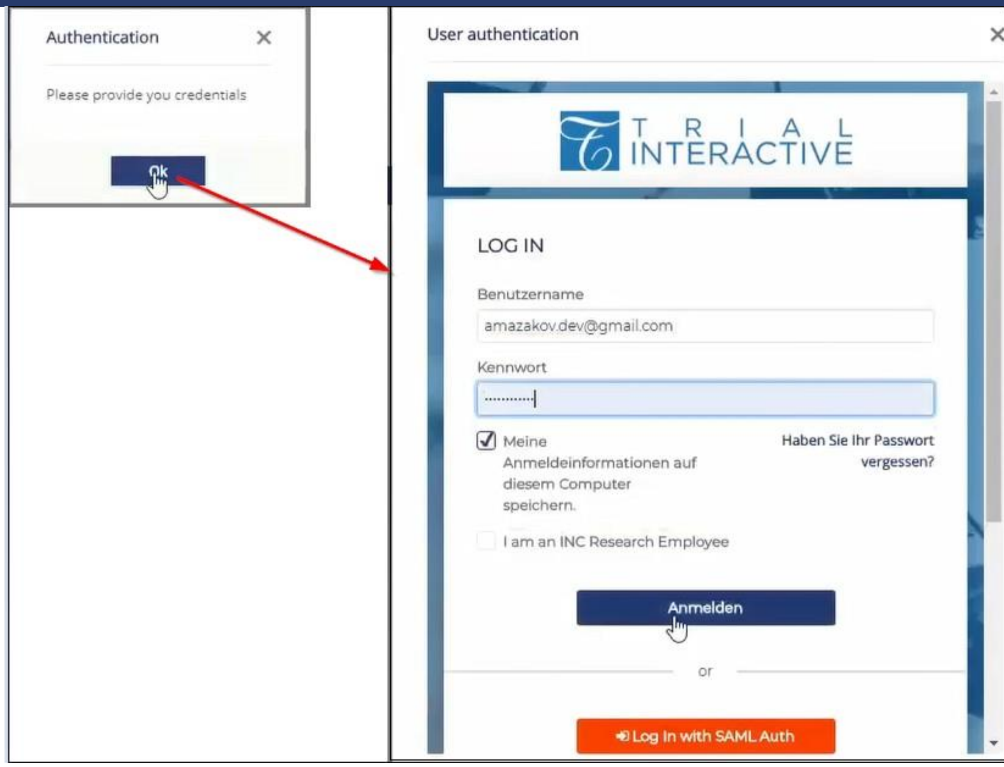
Note:

- *Completed signatures cannot be canceled.*
- *Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.*
- *Once a document is canceled from e-signature, no one can sign the document until it is resent again.*

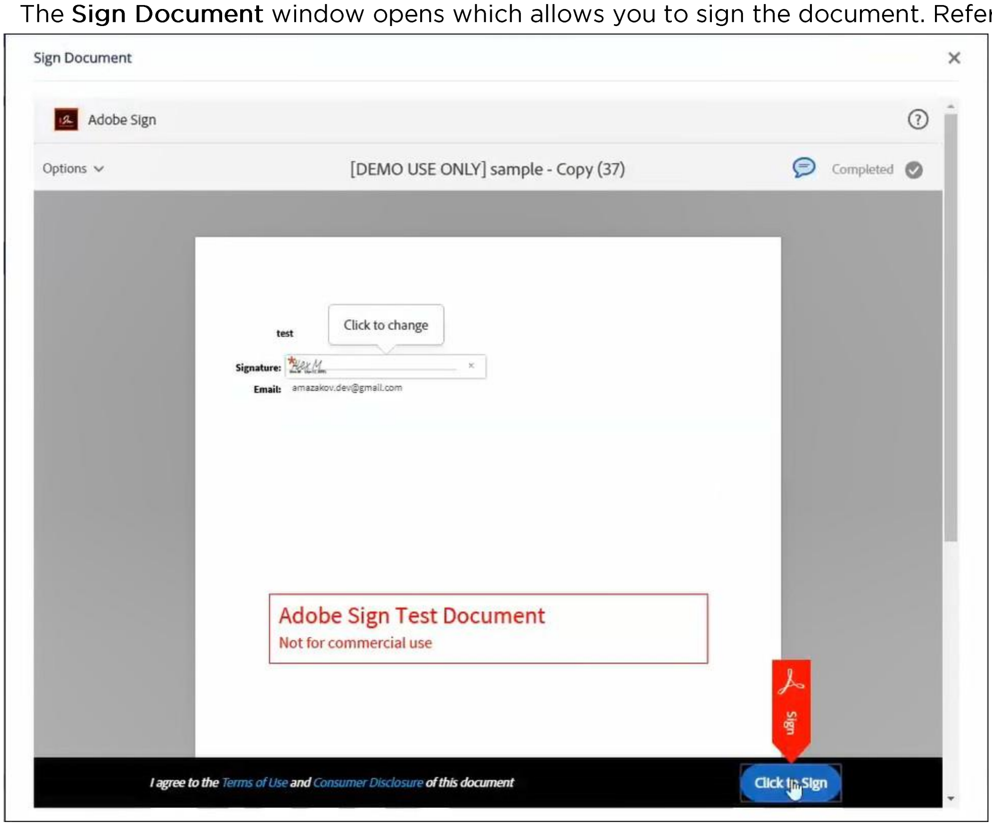
Signing Documents from the eTMF/Documents view

1. Navigate to the **eSignature view** and click the **Waiting for Signature** folder to locate the document to be signed as shown in the screenshot above section.
2. Select a document and open the **eSignature Panel** to the right. The Waiting for eSignature status appears next to your name.
3. Click the username to expand the details. Refer to the screenshot below:

4. Enter all the required details and click **Sign Document** button.
5. A window opens asking you for Authenticating your credentials opens.
6. Click **OK** to authenticate your credentials. Refer to the screenshot below:



7. Once you are authenticated, you are directed to the confirmation dialog box asking for signing.
8. Click **OK**.
9. The **Sign Document** window opens which allows you to sign the document. Refer to the



screenshot below:

10. Click the Blue button at the bottom right corner of the window to sign the document.
11. If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all the signers have finished signing. Refer to the screenshot below:

12. Open the signed document to find that a page with the signer's name and contact details, date of e-signing the document is appended as the last page to the document. In the case of multiple e-signers, a page for every signer is appended.

Note: *Signature Page will be added to PDF documents only after all signers have finished signing the document.*

13. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under **e- Signature Documents** view. You can see the status of the eSignature as **Completed** in the eSignature Panel.

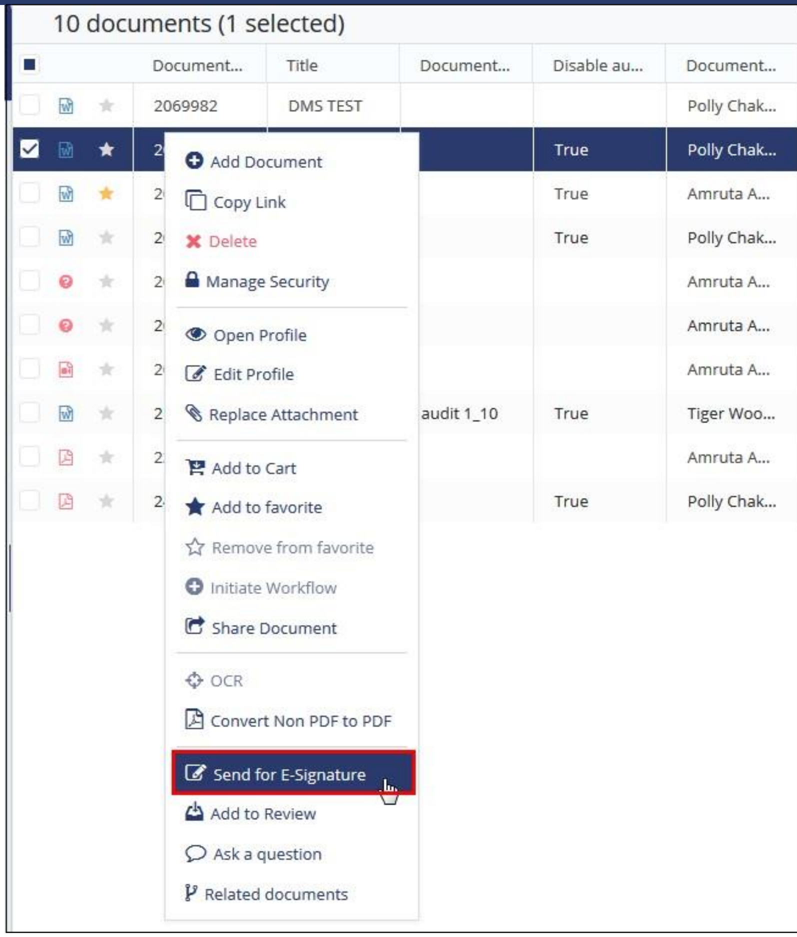
Adobe eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

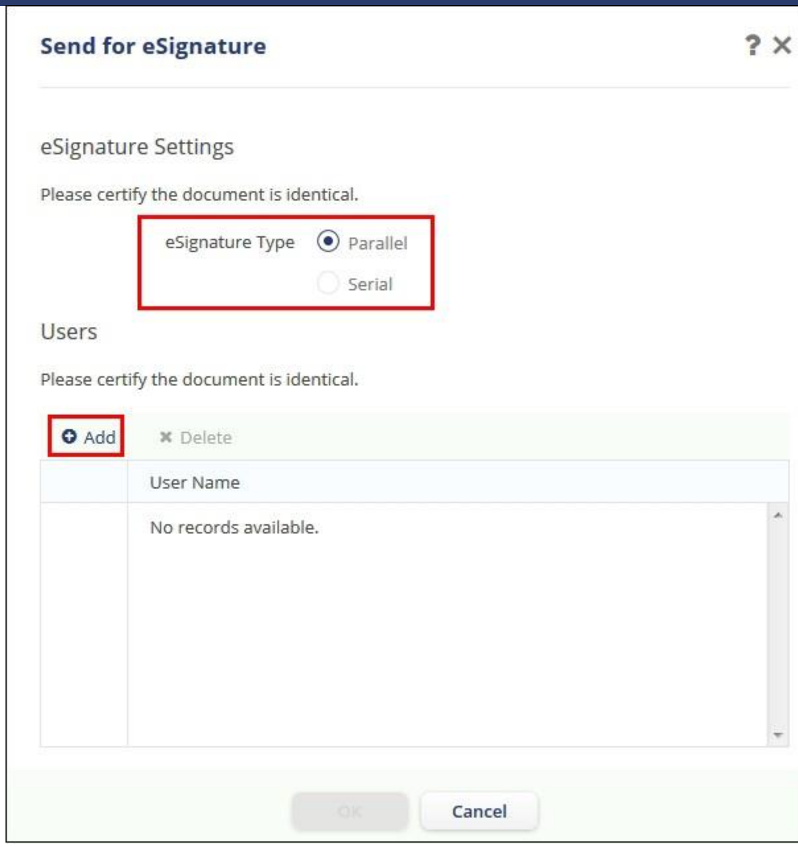
Adobe eSignature - Assigning signers to the documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right-click the desired document and click **Send for e-signature**. Refer to the screenshot below:



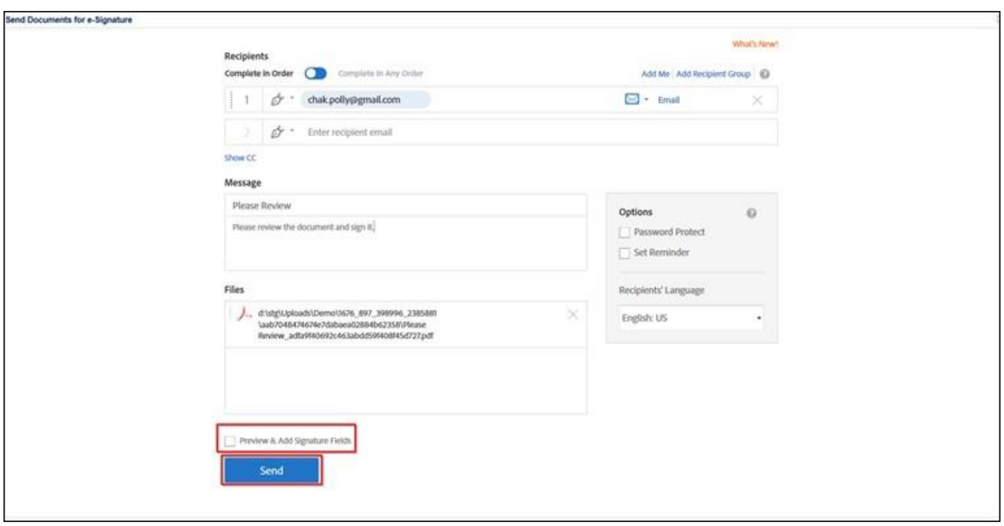
Alternatively, you can also send the document for eSignature from the eSignature Panel *(page 268)* to the right.

3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:



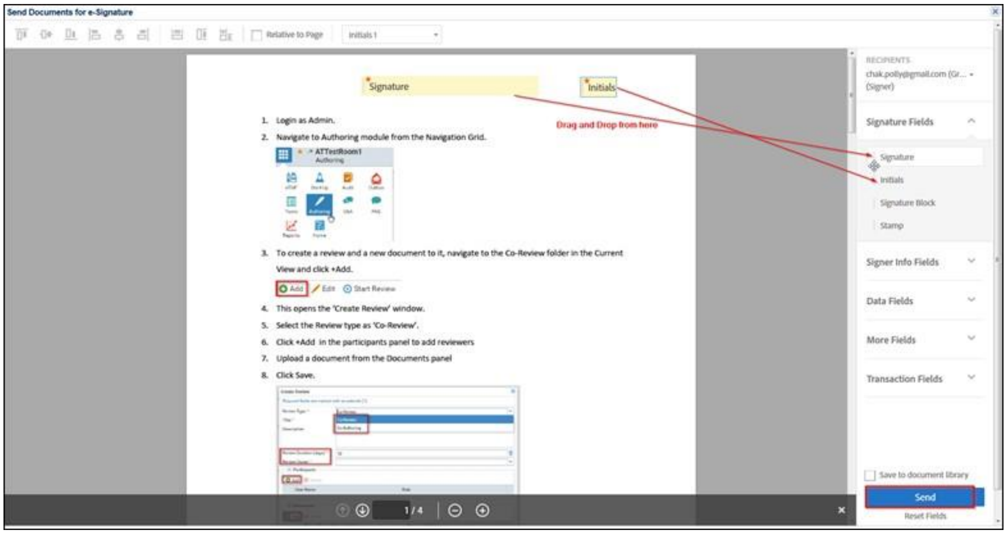
If you wish to assign a sequence in which your signers should sign the document, select the Serial option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. Recipient window with the list of email ids of signers enlisted opens.
7. Tick the **Preview & Add Signature Fields** checkbox located at the end of the page to determine the placement of signatures on the document.
8. Click **Next**. Refer to the screenshot below:



9. From the Recipients field select the signer and, drag and drop the fields on your document from the right menu option that you wish to include in the signature.

10. Repeat the above step for every e-signer.



11. Click the **Send** button located on the bottom right corner of the window to complete the signer assignment process. The system will trigger an email to the signers designated by you with a link to the document for eSignature.

    You may also review the documents to be signed, along with the signer details, in your dashboard under the Documents to be signed dashlet. Refresh the page to view the latest updates.

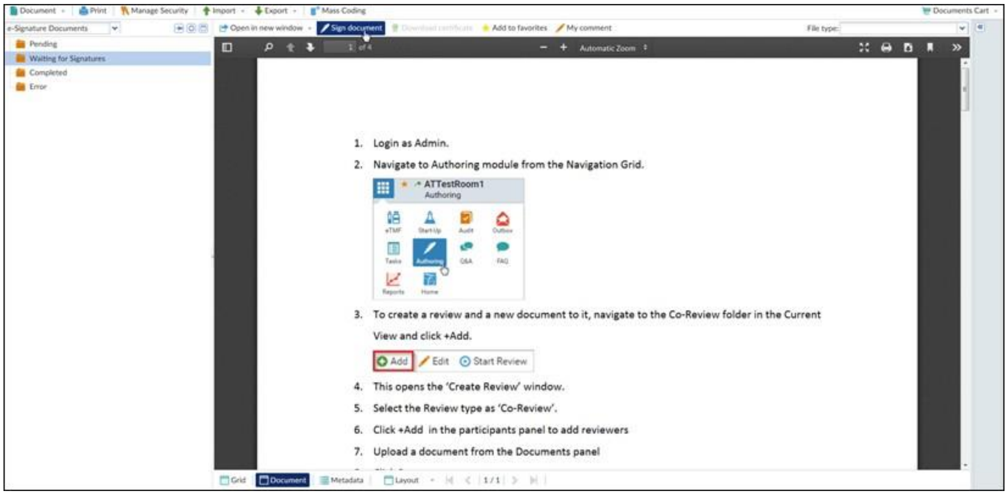
Signing the documents in Adobe Sign

If you are assigned to electronically sign a document, follow the steps mentioned here:

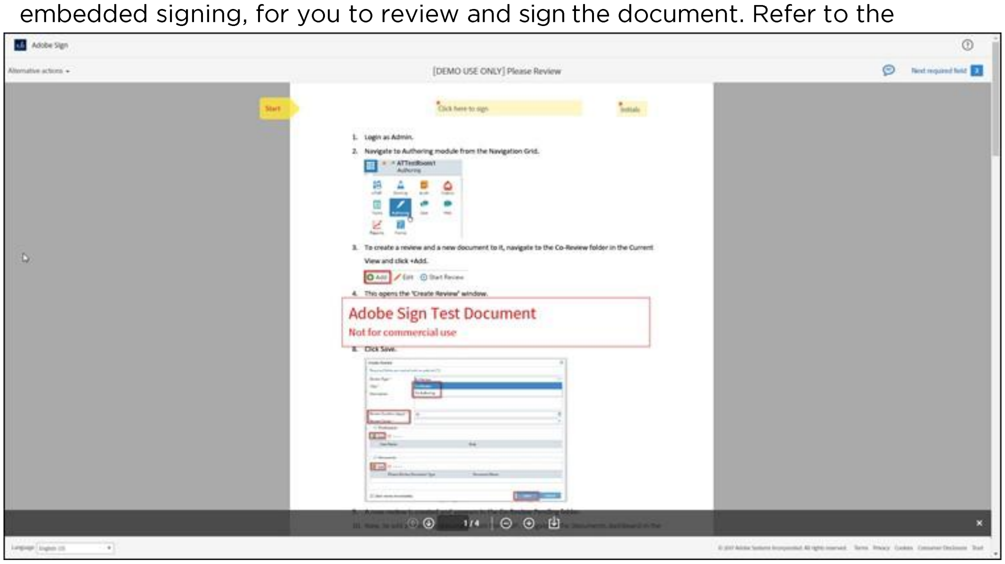
1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document. Alternatively, click the **Dashboard** tab and navigate to the **Documents to be signed** dashlet.
2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

    You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature**view in the Index pane. Either way, click **Sign Document** to begin the review and signing process.

    If you are assigned to sign using the Serial signature, a place where you are supposed to sign will be highlighted in the document. Refer to the screenshot below:

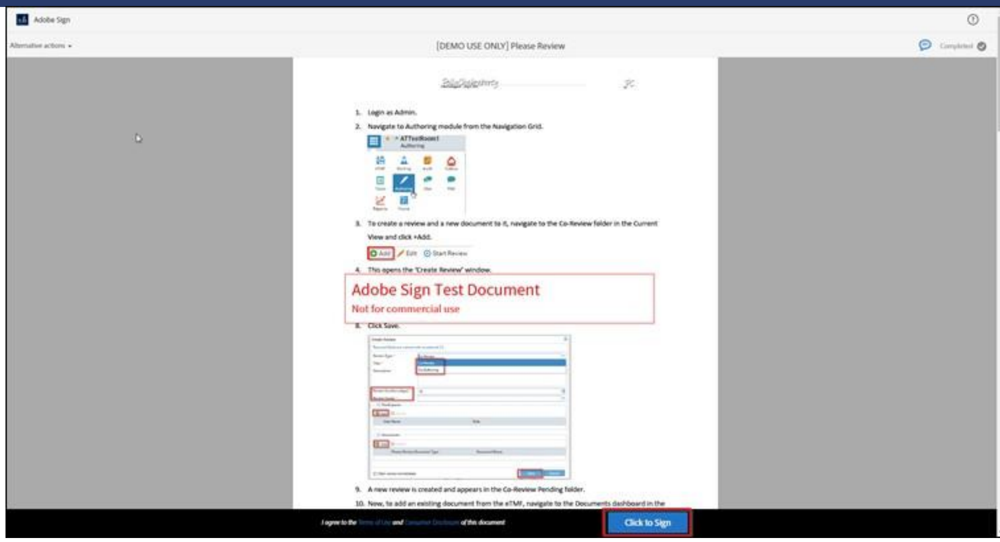


3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.
4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document. Refer to the



screenshot below:

5. Hit **Click here to sign** box. You will be prompted to choose your style for the signature (font, size, etc.)
6. Enter your signature and other details as required. Click **Apply.**
7. This will insert your signature. Hit **Click to Sign**. Refer to the screenshot below:



8. The document will move to the **Completed** folder under **e-Signature Documents**.

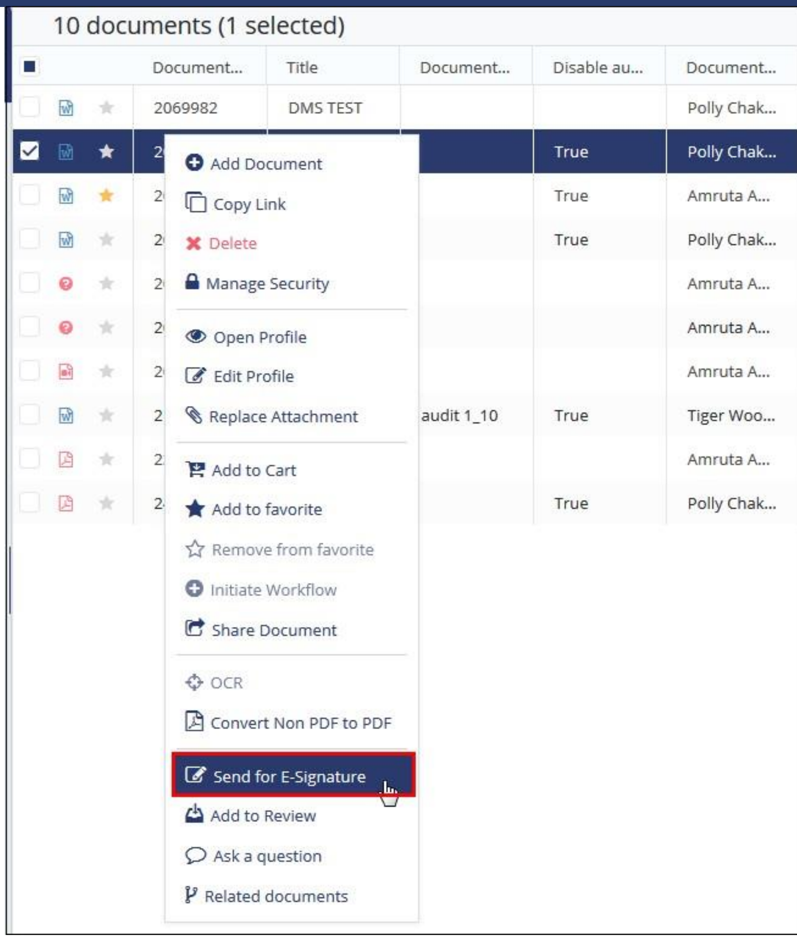
DocuSign eSignature

This sections includes the following sections:

1. Assigning signers to the documents
2. Signing the documents in Adobe Sign if you are a signer

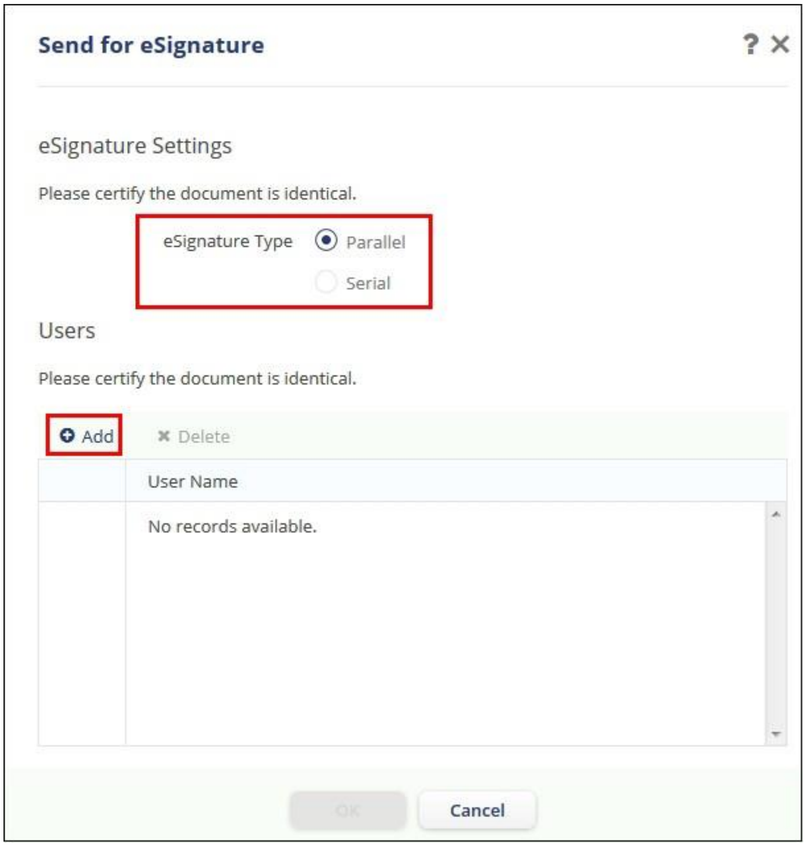
DocuSign - Assiging Signers to the Documents

1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
2. Right-click the desired document and click **Send for e-signature**. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel *(page 268)* to the right.

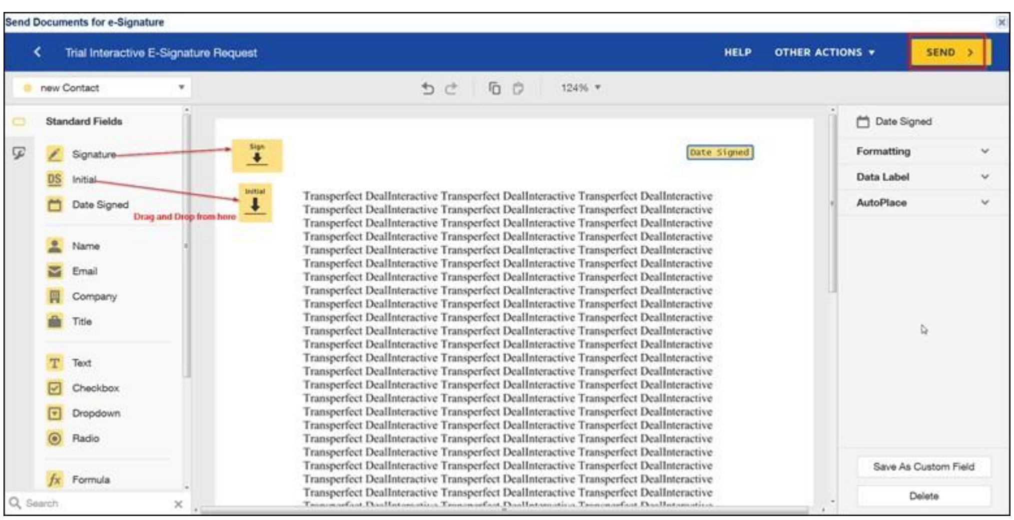
3. The **Send for eSignature** dialog box opens.
4. Select the **eSignature Type** and assign the users for the document eSignature by clicking the **Add** button. You may add one or more signers to the document. Refer to the screenshot below:



If you wish to assign a sequence in which your signers should sign the document, select the Serial option to decide the sequence.

5. Click the **OK** button after adding the desired signers.
6. A document preview window to determine the placement of the signatures with the designated recipient list on the left will display.

   Select the desired recipient. Then drag and drop the fields on your document from the left menu option that you wish to be included in



the signature. Repeat the above step for every e-signer. Refer to the screenshot below:

Click the Send button located on the top right corner of the window to complete the signer assignment process.

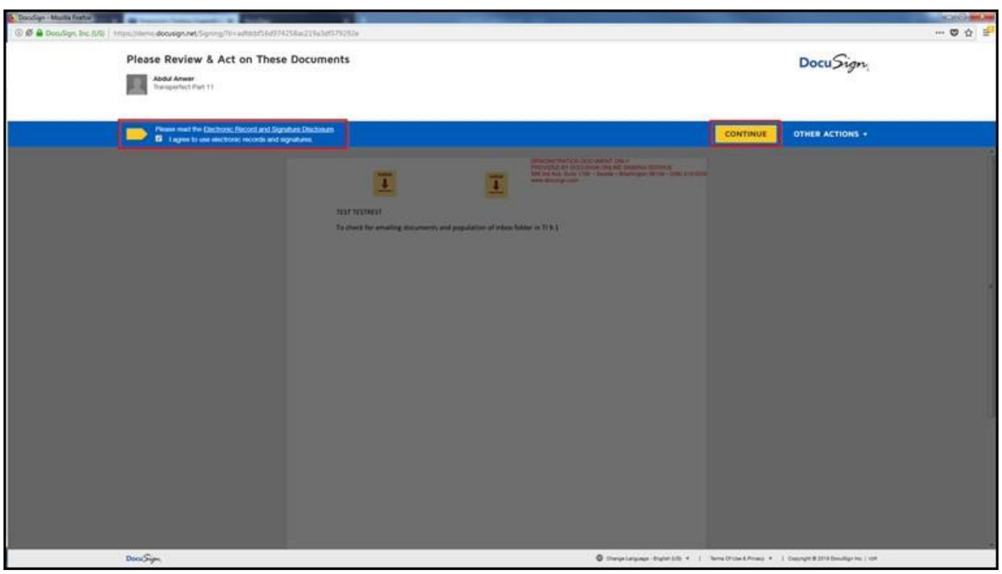
The system will trigger an email to the signers designated by you with a link to the document for eSignature.

You may also review the documents to be signed, along with the signer details, in your dashboard under the Documents to be signed dashlet. Refresh the page to view the latest updates.

Signing the Documents in DocuSign

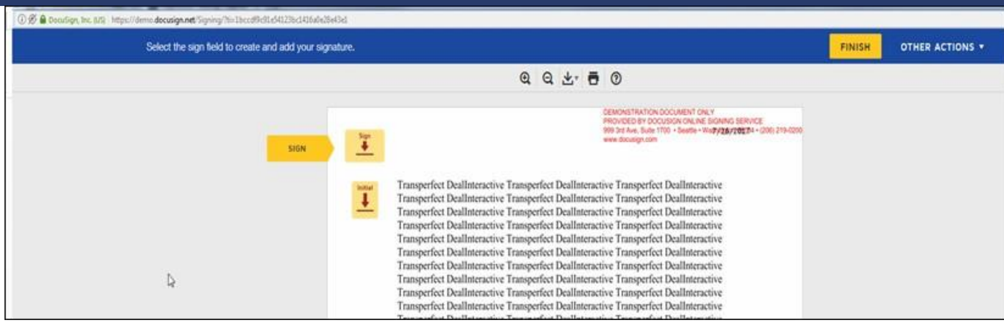
If you are assigned to electronically sign a document, follow the steps mentioned here:

1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room. Alternatively, click the **Dashboard** tab in the eTMF module and scroll down to find the **Documents to be signed** dashlet.
2. Click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.
3. You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature**
   Documents view in the Index pane. Either way, click Sign Document to



begin the review and signing process. Refer to the screenshot below:

Click Continue. If you are assigned to sign using the Serial signature, a place where you are supposed to sign will be highlighted in the document. Click the sign icon. You will be prompted to choose your style for the signature (font, size, etc.). Refer to the screenshot below:



Click Finish to complete the eSignature process.

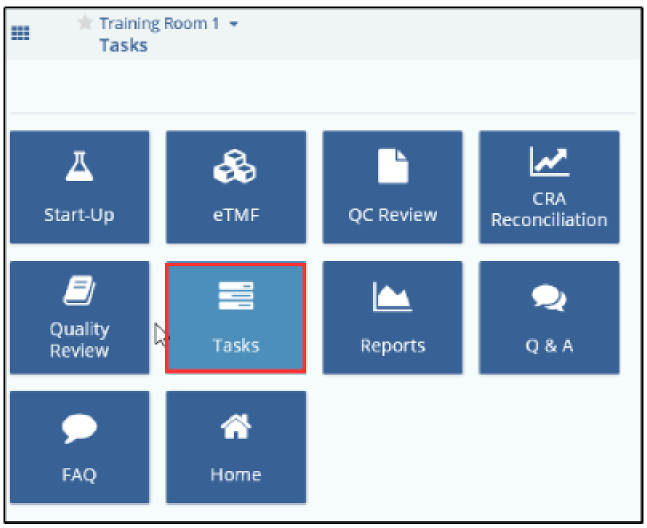
Chapter 15. Tasks

This section explains the tasks application that allow users to manage their Trial Interactive tasks for their rooms.

They are given an option to add, edit, delete, and export tasks. Additionally, administrators can adjust the number of days before a task's deadline for a user to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task.

As a Trial Interactive administrator, you can access Tasks as mentioned below:

1. **Enter the room** for which you want to create tasks from the **Home** page
2. Click the **Main Navigation – >App switcher**.
3. The popup with all the applications appear
4. Click **Tasks** icon.
5. You are taken to the **Tasks** page. Refer to the screenshot below:



The **Task Module** is explained in detail in separate section.

Tasks

The Administrator would need to set up certain configurations for tasks in a room from **Main Navigation → Room Settings**

→Tasks. These configurations are listed below:

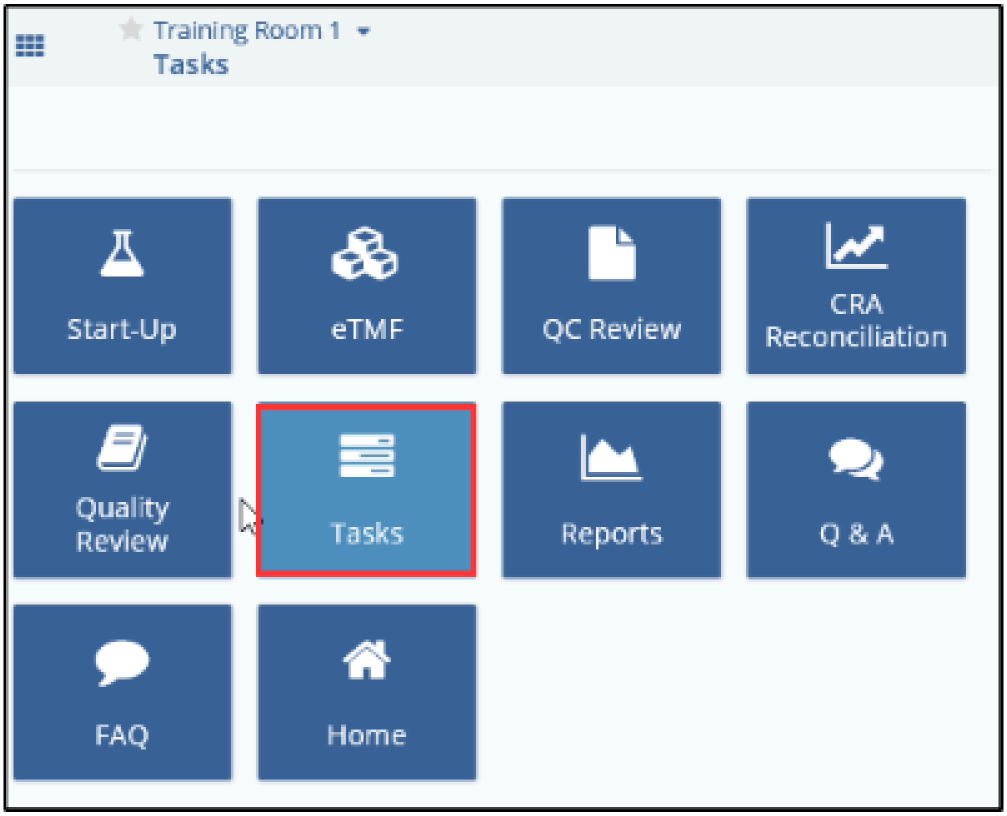
1. Tasks
2. Tasks Category

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

Tasks

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

the screenshot below:

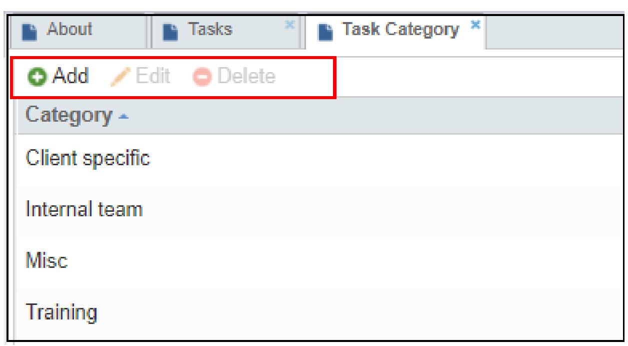


3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.

Task Category

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

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



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

Chapter 24. Reports

This section helps you know about getting the Reports for the room activities.

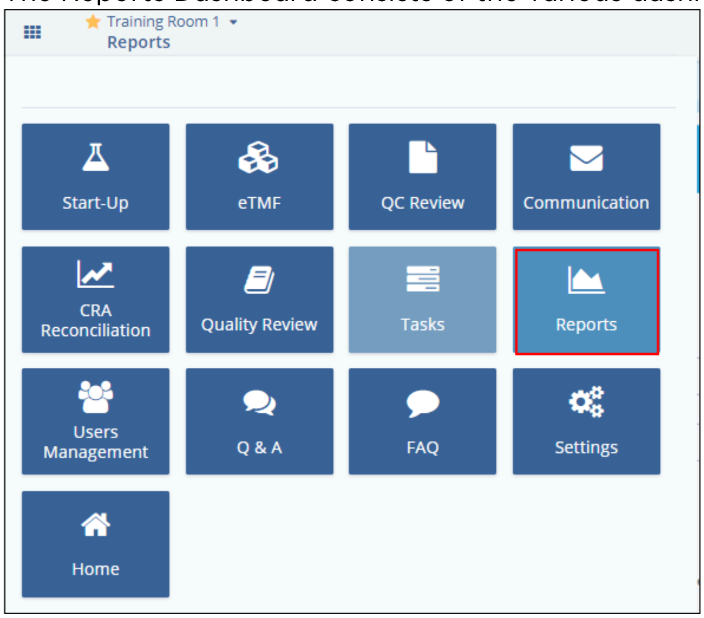
Room Administrators have the option to turn on Reports and make them available to other users. If Reports are activated, you will see an icon in the Navigation Grid.

Reports Dashboard

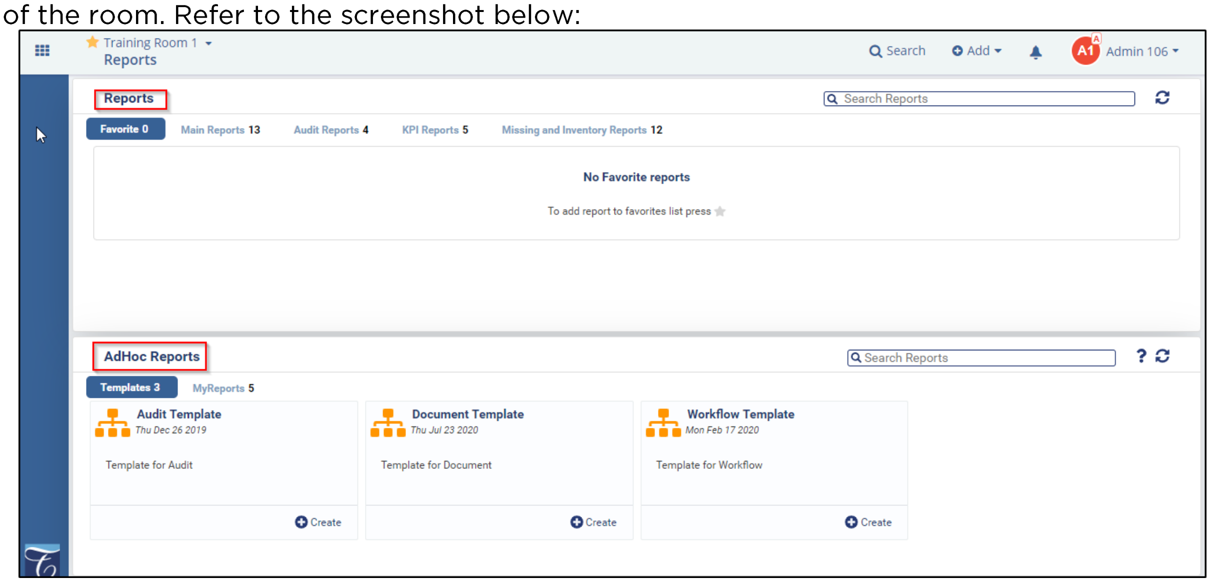
As an Administrator user, you have an option to turn on Reports for other level users to access and view.

You can reach this page by clicking the Reports application from the Main Navigation. Refer to the screenshot below:

The Reports Dashboard consists of the various dashlets which gives a summary of the reports



of the room. Refer to the screenshot below:



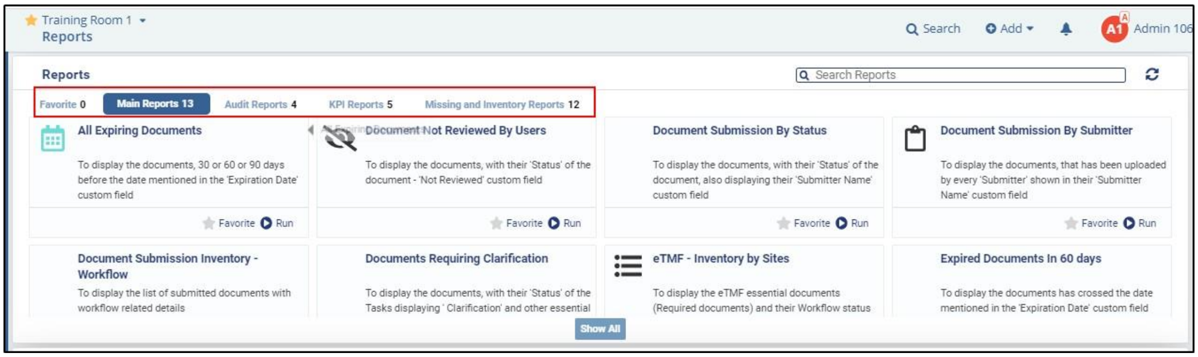
From the Reports Dashboard you can do the following:

1. Generate Reports from the Reports List.
2. Export the Reports.
3. Design a new dashboard
4. Update Results

Each of these is discussed in the seperate topics in this help.

Viewing Reports from the Report List

From the Reports Dashboard, click the reports category marked in red in below screenshot. The below list of the reports are from the Main Reports category.



Select any report and click on Run button to view the desired report.

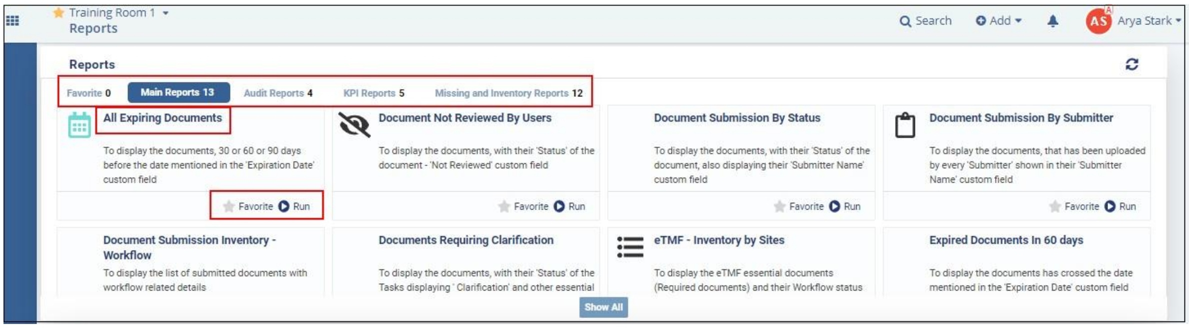
Typically, report builds are based on specific sponsor requests.

Note: *For further assistance on other features of reports, please get in touch with the Support team of Trial Interactive.*

Generating Reports

Reports are categorized by their types at the top and users can choose the category to view the list of reports available in that category. Below screenshot shows an example of Main Reports. From the Reports List page, choose the report to be run and click on the Run button to open it.

Any report can also be made favorite by clicking on the Favorite button.



For a particular report, you can do the following:

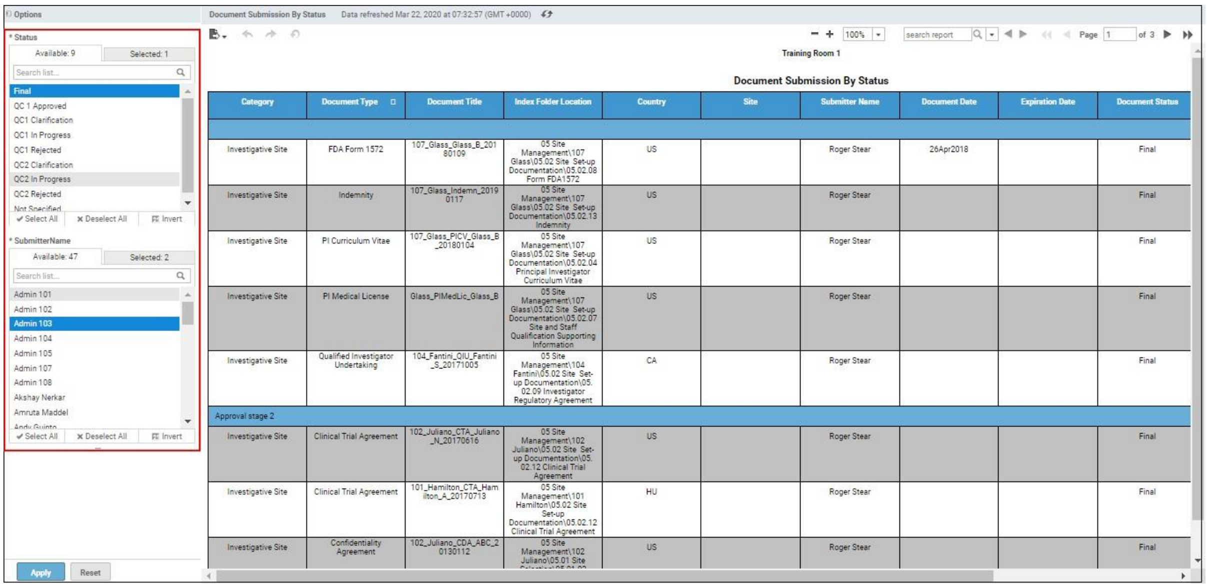
1. Apply Filters
2. Adding and deleting fields in a report
3. Print Reports
4. Download Reports

Each of these is discussed in the sections below.

Applying Filters

You can apply filters for a report if you wish to view and generate the report with only specific information. You can apply filters for a report by clicking the Show Filters button in the menu bar. This enables the Filter Field, Operator, and Value(s), Blank fields to allow you to select the filters for a report.

Select the single or multiple filter fields for which you want to get the



reports. An example below shows a filter applied for generating a report for the open queries of a particular Status and Submitter:

You can also apply multiple filters as well by using the operator conditions to view the required results.

Exporting Reports

You can export the reports in the following formats:

1. CSV
2. Microsoft Excel
3. Microsoft Word
4. XML
5. Open Office Document
6. Rich Text Format (RTF)