Logging in and Navigating to the Study Room

1. Log in with your Username and Password.

   Warning: After three failed attempts, you will be temporarily locked out.

2. On the Home Page you will see a list of rooms to which you have access. If you see no rooms, please select *All* from the menu at the top.

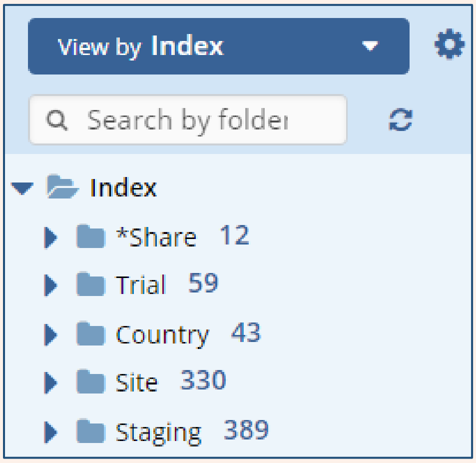
3. Click on the name of a room to enter it.

Navigating to Documents

1. If using the audit module to view a selected list of documents for review, select the Quality Review Icon.

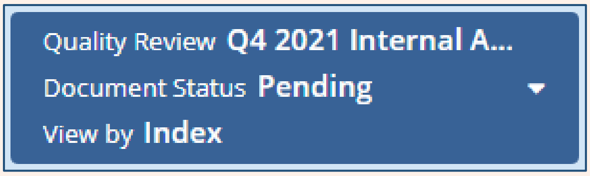
OR

2. If able to access the eTMF module, you may use the Index view to navigate directly to documents; click on the icon for the eTMF module.

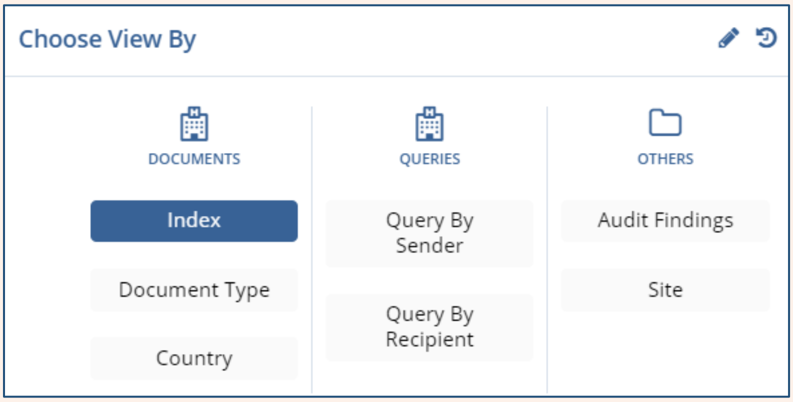


3. The selected module will open, showing the associated folder structure.

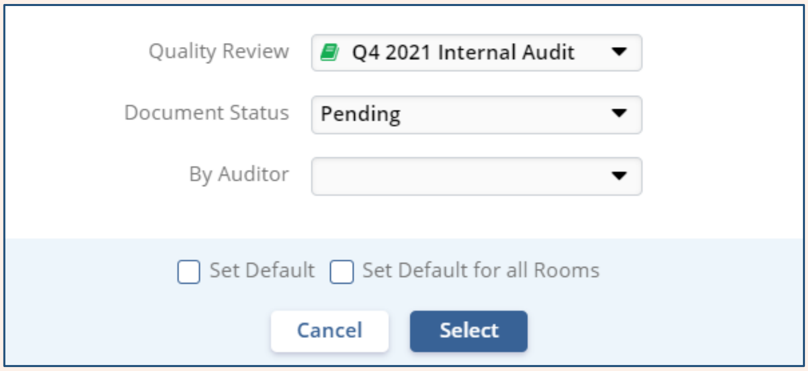
4. Use the blue selection panel to switch to a different audit if needed.



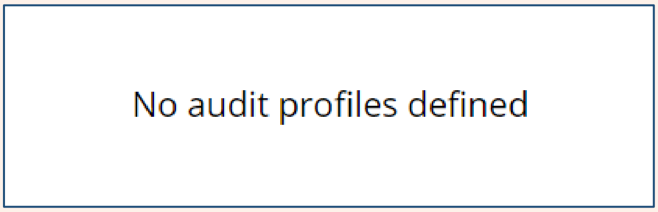
4a. Within the selection screen, first determine how documents will be shown to you (by their folder location, type, or other attributes).



4b. Select the Quality Review to be carried out (you may have just one to choose from) and the status of documents to be displayed – choose **Pending** at the start of a new inspection.
The **By Auditor** field should display your name.

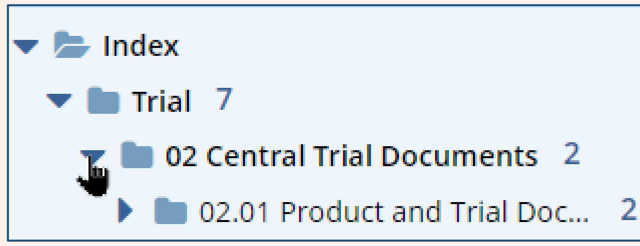


If you intend to revisit the same Quality Review in the future, you can save your preferences using 'Set Default'.

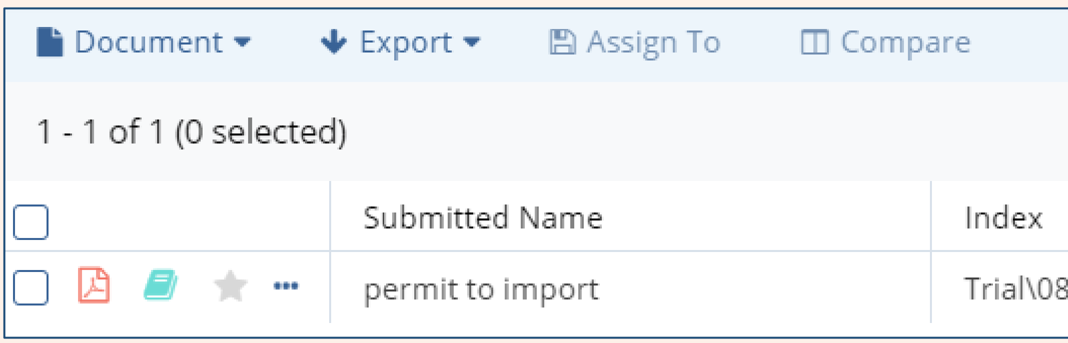


If you see no document grid and no selector, then no audit profiles have been assigned to you. Contact your inspection lead or the TMF owner to receive an assignment.

5. Click on the triangle next to any folder to see subfolders. Click on a folder name to see the contents. Documents are normally stored at the Artifact level.

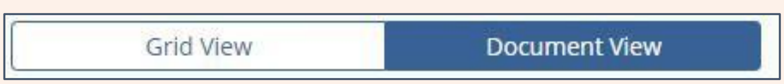


6. Selecting a file storage location will cause the relevant document grid to open, displaying files within that folder that need review.



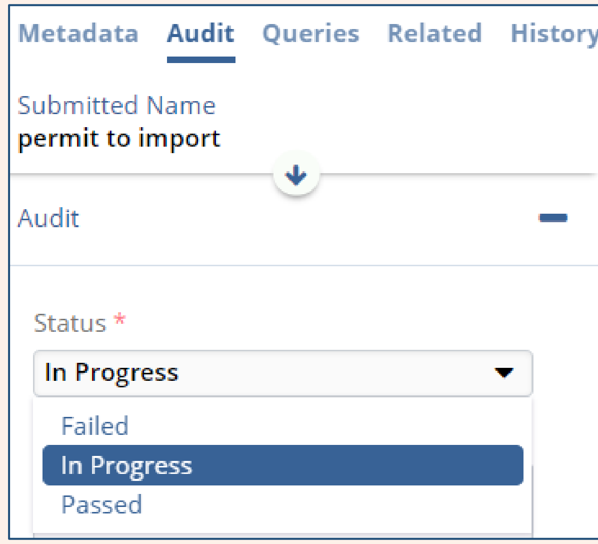
Inspecting Documents

1. Select a document by clicking on the respective checkbox and open it by selecting **Document View** at the bottom of the Grid.

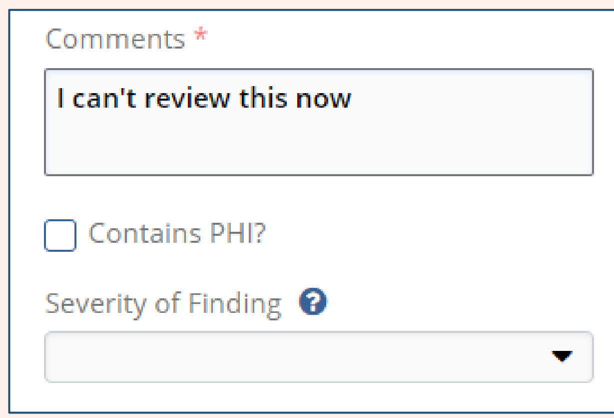


2. Expand or resize the Metadata pane located at the right-hand side of the window.
This panel will allow you to review document metadata, and to assign a 'decision' regarding your inspection.
It also contains document information such as history of actions, queries, and links to any related documents.

3. Once you reach a decision about the document under review, use the **Audit** section on the Metadata panel to assign a Status (pass, fail, or paused – actual names may vary). For your determination to be made effective, click on **Save** at the bottom of the panel.

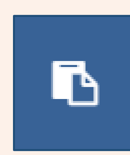


3a. **Comments** are always needed. This will provide insight on your decision or on corrective actions required.

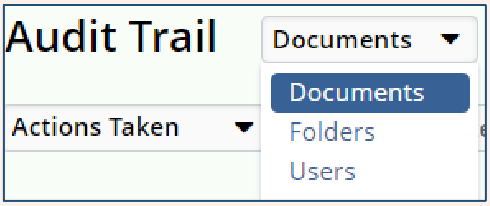


*Depending on local configuration, you may find other fields here, such as optional categorization of findings, or the option to remove a file permanently if it **contains PHI**.*

4. On top of the tools available within the Metadata panel, inspectors can use the **Audit Trail** tool to review document events and interactions.
To access it, click on the Audit Trail button on the left side of the screen.

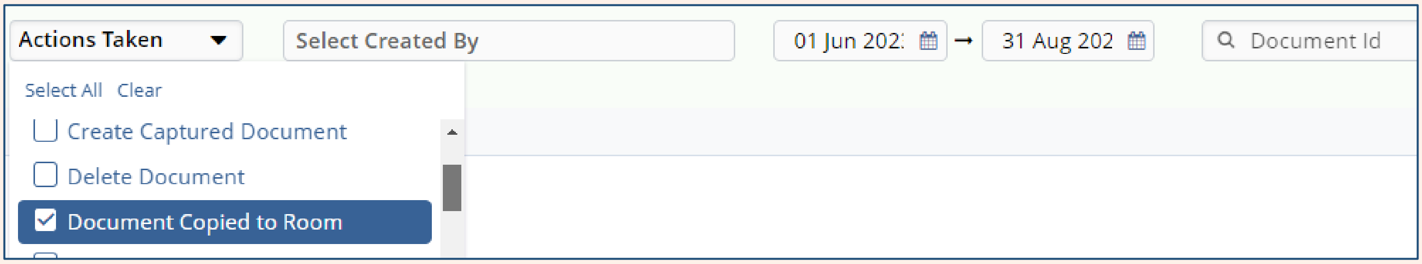


5. Audit Trail reports are created instantly and on-demand. At the top of the active screen, select the Category (Documents, Folders, or Users) of information you will be viewing.



5a. Then, set your parameters for generating a report.

*In the example below, we are looking for Documents that came into the room as copies from other rooms, regardless of user (**Created By** is left blank), in the period from 1st June to 31st August. **Document Id** is blank since we're not looking for info about a specific document, but rather wish to see all documents meeting these criteria.*



5b. Hit **Apply** to generate the report. This will appear on the same screen.

	Activity Date	Created By	Document Id
☐	13 Jun 2023 02:58:30 EDT	Editor 104	557383

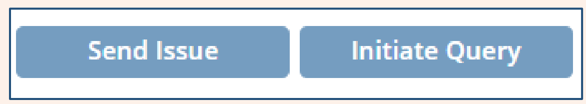
Document Name	Index Path	Activity Type	Activity Related Data
1234_038_Mama_ProtAmend_...	Site\BHS 038 Bahama Mama\0...	Document Copied to Room	Data room: Training Team

Using Queries

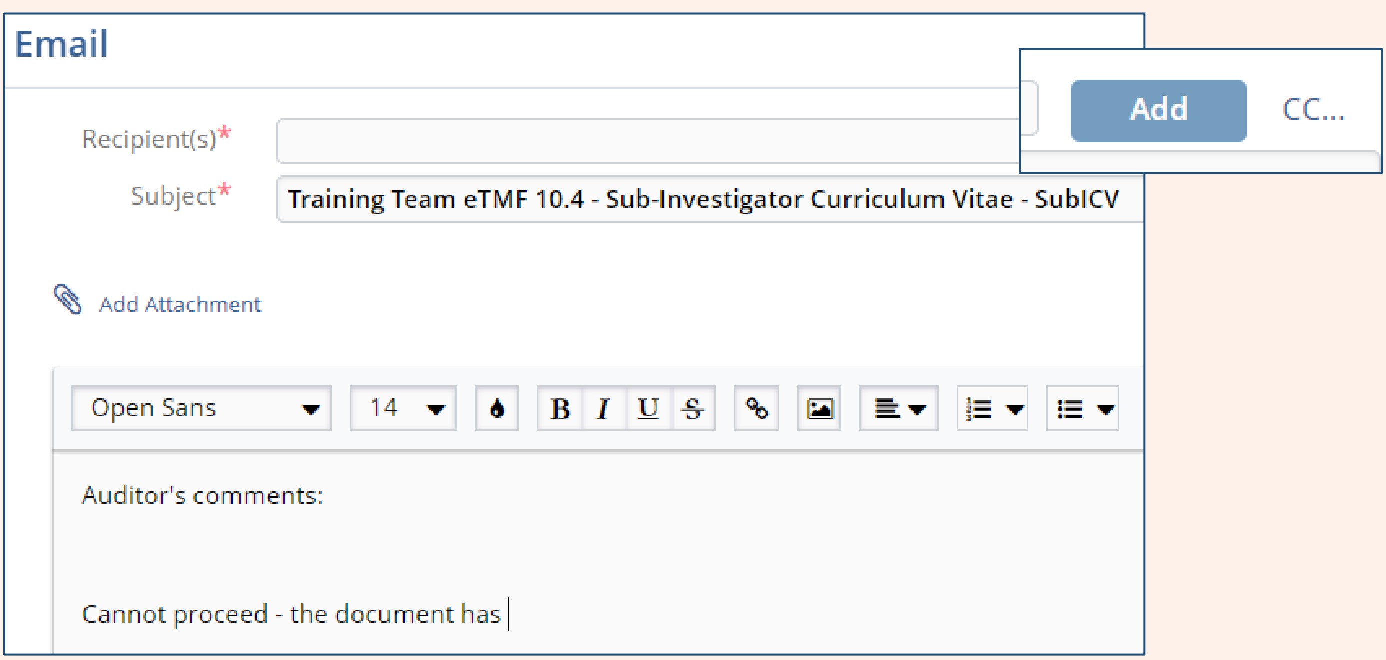
Queries may be used by an inspector only if the working Room has this function enabled.

1. When reviewing a document, you may occasionally find an issue that needs action by the TMF team before you can reach a determination (finding/no finding). In such cases, you may find it useful to launch a **Query**.

2. Within the Metadata panel, under **Audit**, locate the **Initiate Query** button.



3. Queries work just like e-mails. Your message will be partially pre-filled. Adjust the content to your needs and select one or more recipients in the top bar (you can type names or use the **Add** button to select from a pool of users).



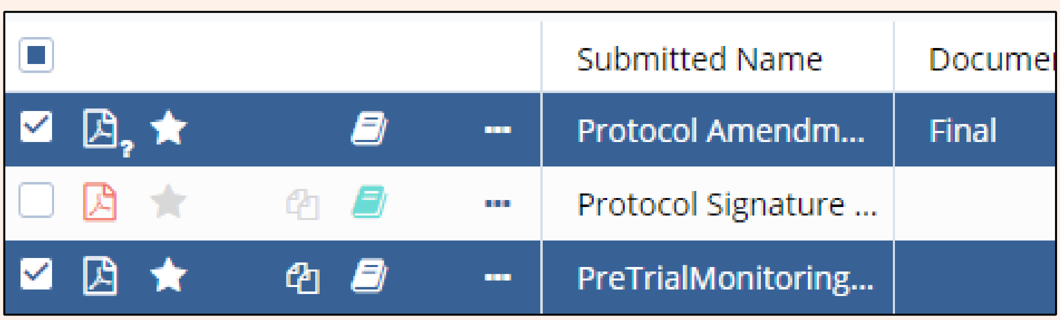
4. Before submitting your query, choose if/how to include a copy of the relevant document (options may vary). Then hit **Send Query**.

5. Your recipient(s) will be notified and be able to provide a response. You can track a query in the document Metadata panel, but you will also be notified via e-mail of any progress.

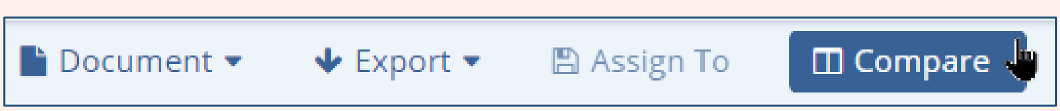
Helpful Tools 1: Comparing Documents

When looking at a list of documents, especially if they refer to the same doc type, individual, or functional area, you may want to compare their contents.

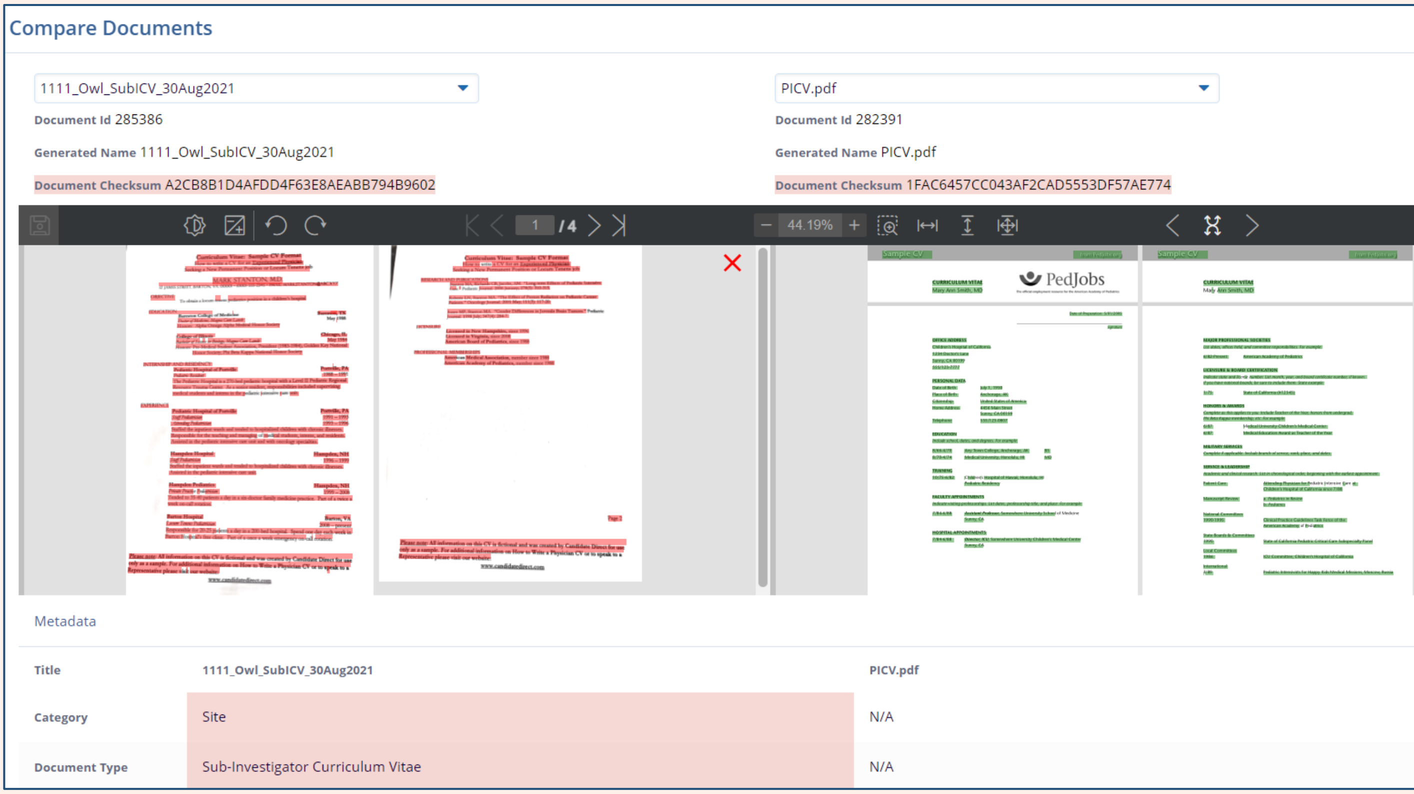
1. To do so, first select multiple documents via their checkboxes.



2. At the top of the active area, find the **Compare** button. Click once.



3. Documents are shown side-by-side, and differences highlighted automatically.

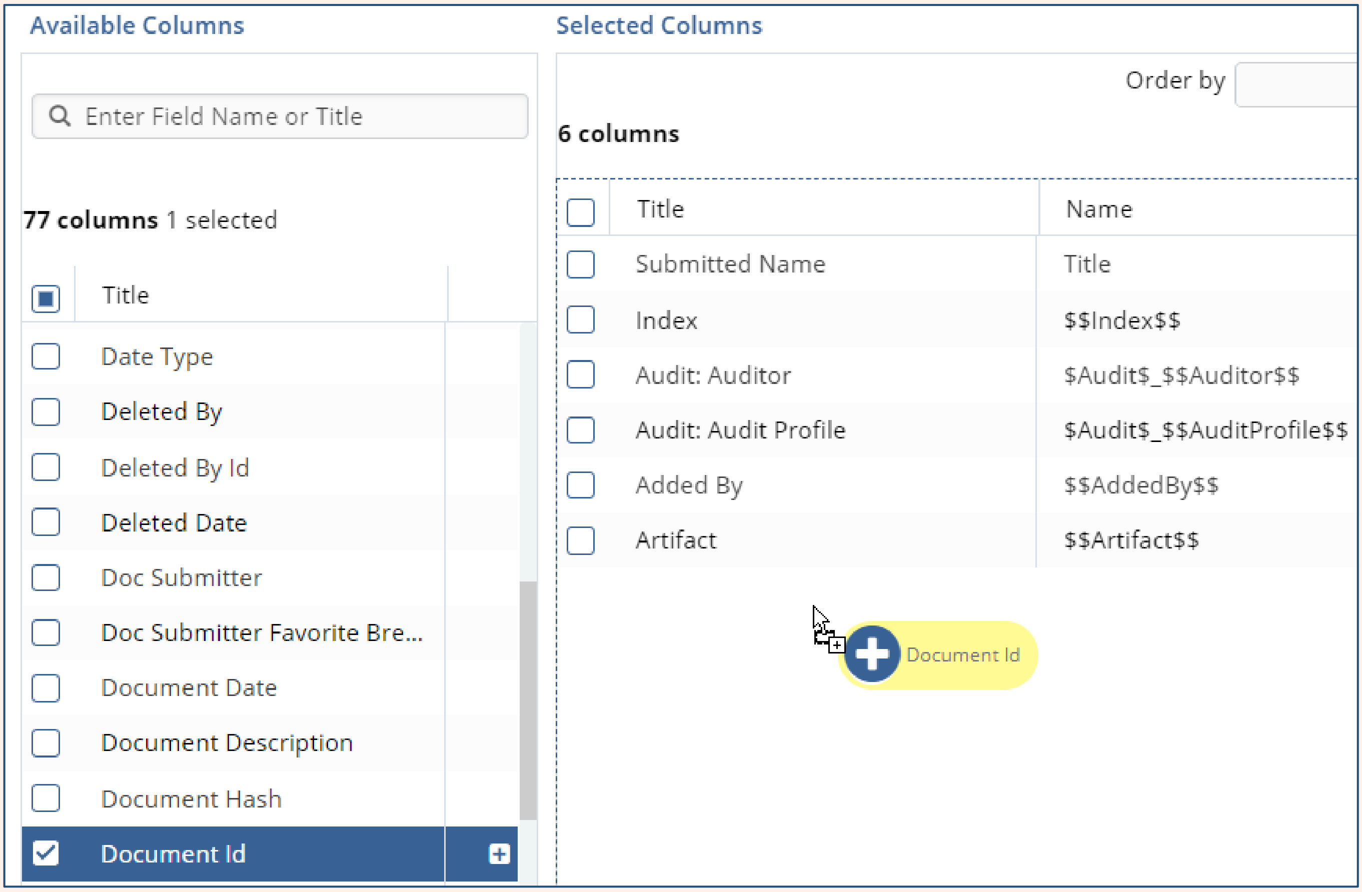


Helpful Tools 2: Columns and Filters

In Trial Interactive, information (documents metadata) is shown under columns, with each grid having a default selection of these. However, users can customize their grid in order to view their preferred information assortment at-a-glance.

1. To start customizing your view, find and click the **Manage Columns** button at the top of the grid.

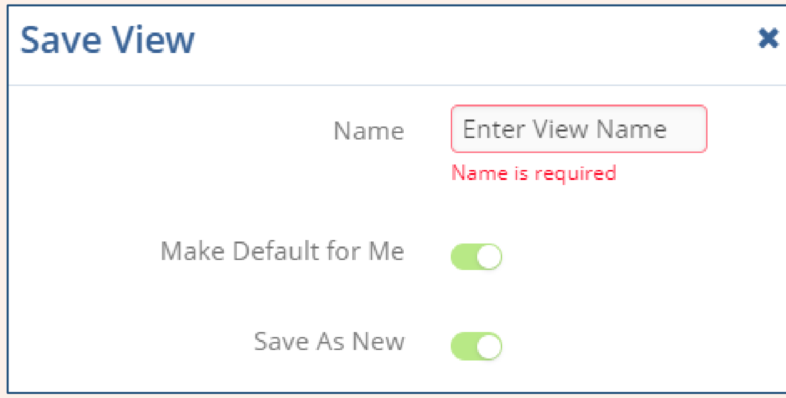
2. The column management windows allows you to select what metadata will display in the grid for each document, by picking a column (displayed on the left) and moving it to the active area (displayed in the middle). The arrangement thus created is called a *View*.



3. You can rearrange your selected columns freely, using the **Move** buttons at the right of the active area (you need to have selected at least one column for this to work).

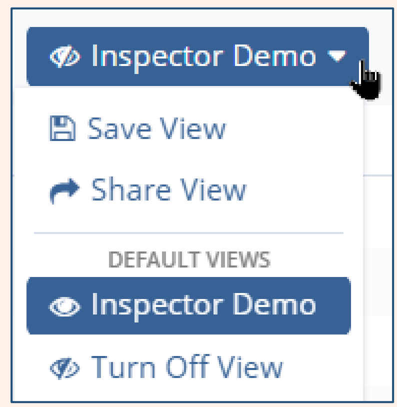
You may also remove columns by returning them to the area on the left. Once you are satisfied with your selection, hit **Save**.

4. Saving your selection **as default** is recommended, as this will display it every time you access the same grid. Notice that a unique name is required for each column arrangement you create.



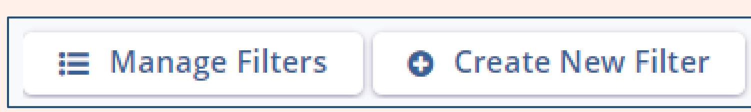
*Pro Tip: use **Set** to view your new arrangement in the grid without committing to it (no save).*

5. Access the Views dropdown at the top-right of the grid to switch on/off your personal view, and optionally to Save, Share, or Manage your views.

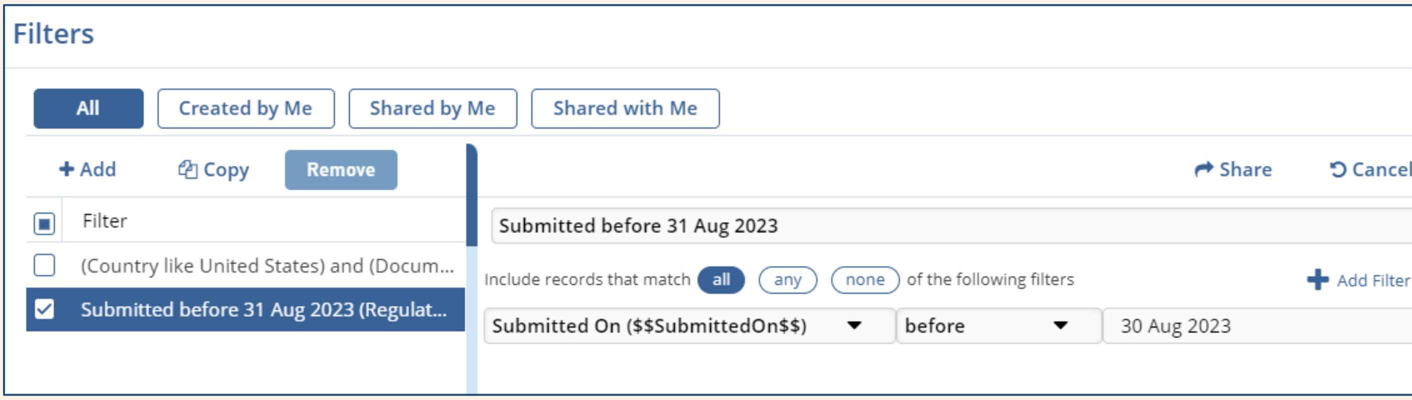


6. Similar but distinct from Views, **Filters** can be created to reduce visual clutter and only focus on the documents you need right now. You'll find the related button at the top of your Grid, towards the right.

7. Once you enable Filters, two buttons will show: **Manage** and **Create** Filters.

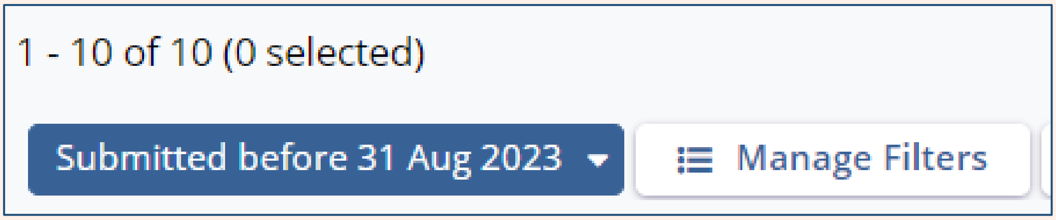


8. Click on **Manage Filters** to display all existing, applicable filters. You can use this window to activate (**Select** button), review settings for, and edit filters.



9. If there is no filter that matches your needs, you may create a new one via **Add** or using the button **Create New Filter** on the grid.
Just add one or more criteria based on metadata (see image above), then **Save**.

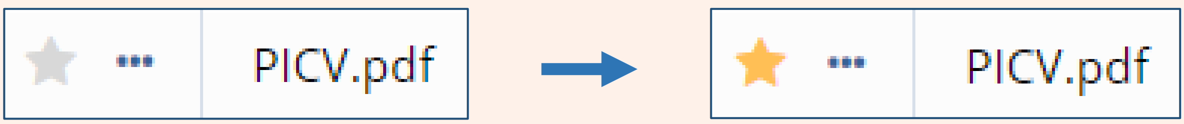
10. Once selected or saved, a filter is immediately applied, and will be displayed next to the filters action buttons. Click on the filter name to **Deselect** it.



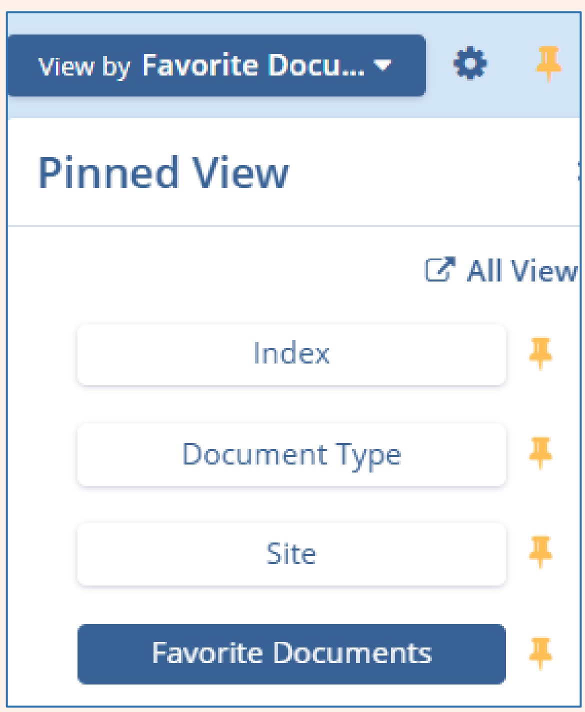
Helpful Tools 3: Favorite Documents

You may find yourself returning frequently to some documents that are archived in the eTMF. Maybe they represent an important reference point, or they guide you in your decision process.
*Whatever the reason, you can mark documents as **Favorites** to easily find them again and again.*

1. Any document can be marked as a Favorite. Just click on the grey star near a document's name.



2. Once a document has been Favorited, it can be easily located using the View called Favorite Documents in the eTMF module. Un-favorite documents any time by clicking on their gold star.



End of document