TRIAL INTERACTIVE

TI 10.2 User Guide Supplement

TRANSPERFECT LIFE SCIENCES

APPROVALS

Product Owner

Name: **JAY SMITH**	Title: Sr. Director, Product Management
Signature: Reason for signature: Date:	 *Electronically signed by: Jay Smith* *Reason: I approve this document.* *Date: May 27, 2021 17:14 EDT*

Quality Assurance

Name: **SCOTT JORDAN**	Title: Director, QA & Systems Validation
Signature: Reason for signature: Date:	Scott Jordan *Electronically signed by: Scott Jordan* *Reason: I approve this document.* *Date: May 27, 2021 17:17 EDT*

VERSION HISTORY

Author	Revision #	Date	Comment
Steven Clark	1.0	27-May-2021	Initial creation

Contents

Chapter 1. Trial Interactive 10.2- 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 • 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 stopped support for Internet Explorer™ 10 in January 2020. We expect slight degraded performance with Internet Explorer™ 11, and no longer support Internet Explorer™ 10. Users accessing Trial Interactive with this and older browsers will see in some cases a degraded experience and may have trouble using certain features.
Client Software	• Optional: Adobe Acrobat®, Acrobat® Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. • Optional: Drag and Drop from Outlook to Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available for support of this feature on Internet Explorer® and Firefox®.
Optional Add-Ons	• Optional: 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 • 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 10.2 All features of Snowbound are now available in the TI Viewer.

Platform Features

Dashboards

DASHLET UPDATES

With the inclusion of Events, Responsible Party, Due Dates, and improved Placeholders, the eTMF Health dashlet will now show event completion (amendment, visit, milestones, etc.) with Required, Placeholder, and Overdue documents by site, country, event, and responsibility.

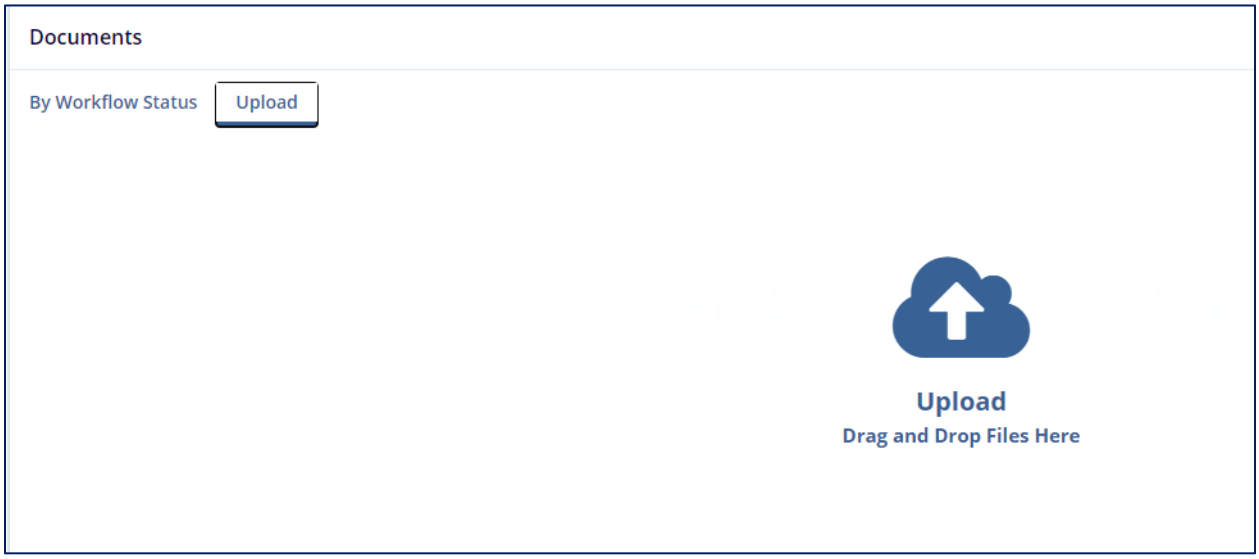
When providing a portal for Site Personnel to collaborate on a study, whether for remote monitoring, a site-specific eISF, or as a means of distributing information, it is important that users have an easy way of accessing critical documents, uploading new content, and viewing tasks and notifications.

The following dashlets were created to solve this problem by simplifying access to the site collaboration space for site personnel.

THE UPLOAD DASHLET

The Upload dashlet allows users to drop files from their desktop into the room with assistance so that documents can be quickly uploaded and indexed. The function of the dashlet is impacted by the user's specific role in the system and it will assist in directing the user's document to the correct folder as appropriate.

In order to use the Upload dashlet, simply drag a file from your computer desktop into the dashlet and press Import.

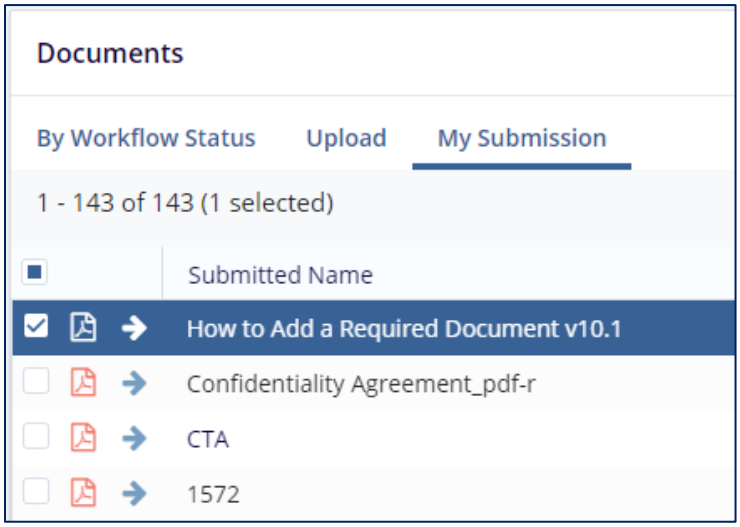


THE **MY SUBMISSION** DASHLET

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

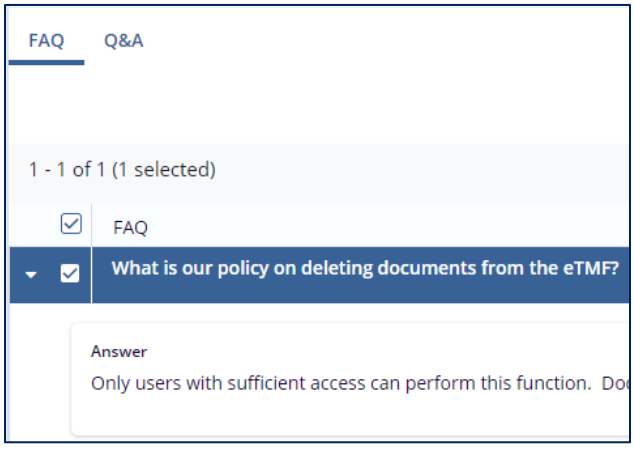
dashboard.

This operates very much like the already familiar Favorite Documents and Popular Documents dashlets. Users can click on the document type icon (PDF, Word, etc.) in order to launch a preview of the document in a separate window or click on the blue arrow to be taken directly to the document within the room's index structure.



THE FAQ DASHLET

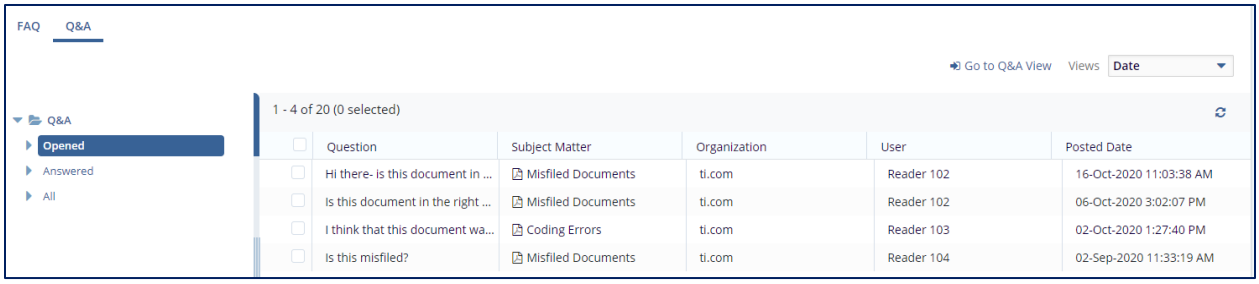
The FAQ dashlet will display a list of frequently asked questions to help users find important information even more easily. The questions will be displayed in a grid-style and the user can choose to view the answer to the question by clicking on the arrow next to the checkbox.



THE Q&A DASHLET

The Q&A dashlet will make it easier for users to view answers to their important study-related questions. Users below Administrator level access will only see their own questions posted here. Users who have been designated as Subject Matter experts will also see questions related to their

area of expertise.



Events

EVENTS MANAGER

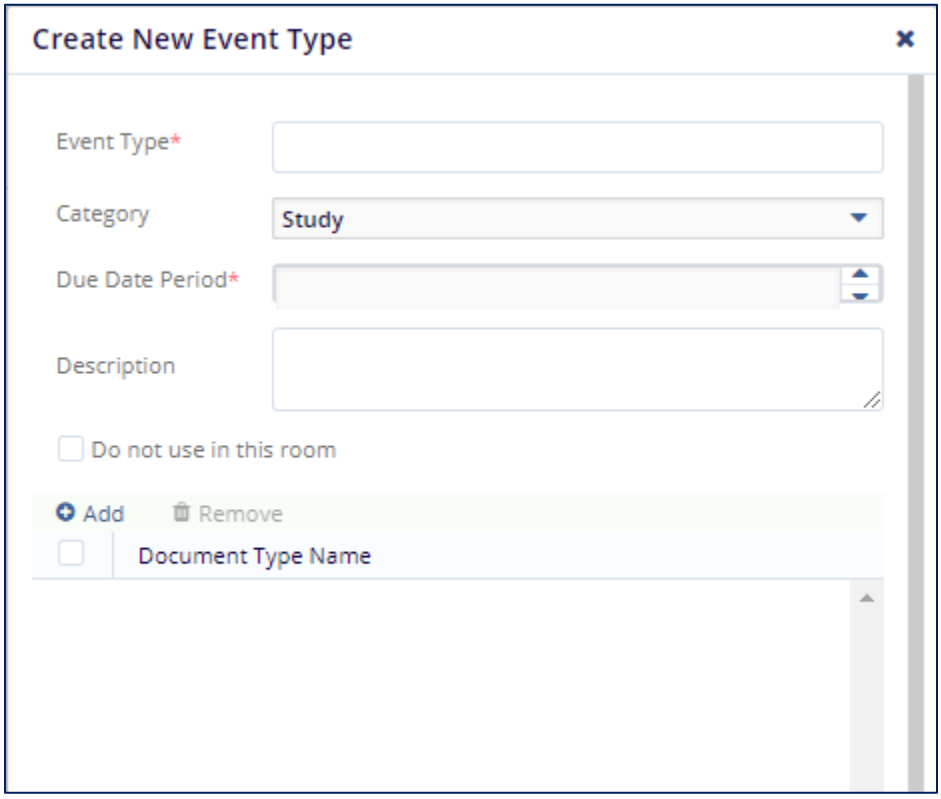
The Event Manager was created as a new way to manage amendments, milestones, visits, and other events that occur during a Clinical Trial. It is important to have a simple way to recognize clinical events as they happen in order to get the most accurate picture of eTMF Health. That way, as amendments, visits, and other activities occur, the eTMF 'knows' what documents are needed in association with those events and can even plan them, including the responsible party and due date.

Events may now be applied to the eTMF Required Document and Placeholder definitions, providing a simple way to manage the milestones of a study, applying the planned documents automatically, and improving the quality of the measurement of eTMF Health.
Placeholders are defined and applied as a part of amendments, milestones, visits, and other trial activities. Sites and countries may be included or removed as necessary.

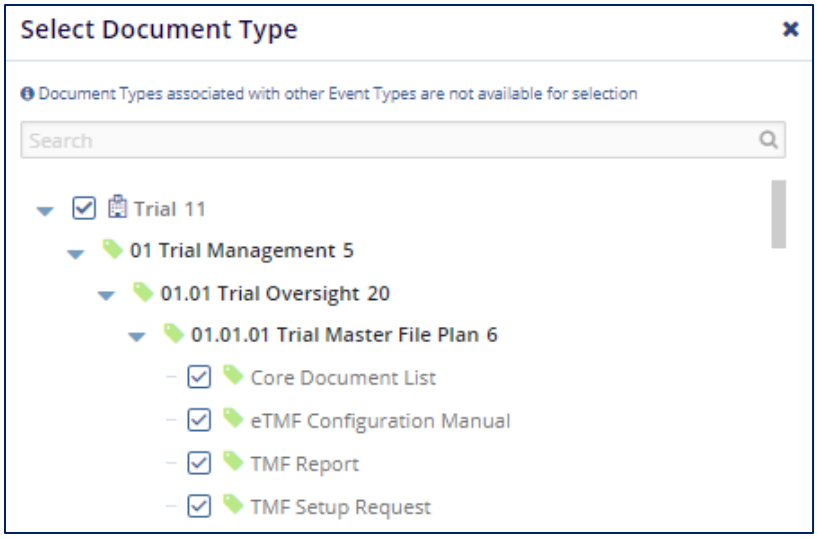
CREATING AN EVENT TYPE

Prior to creating a specific event in the system, we must first ensure that the type of event has been created. If your room has come prepopulated with event types based on those created by default in the system or milestones cloned from another room, you can certainly use those. However, there will sometimes be an occasion where a custom event may be of use. In order to create an event, follow the steps below:

1. **Select the Event Types area of the Event Manager. This is indicated by a gearwheel icon on the far left of the screen.**
2. **Click on the "Add" button in the menu bar above the list of events already in the room. The "Create New Event Type" window will open.**



3. **Fill out the required fields.**
    a. **The Event Type field allows you to name the new event.**
    b. **Category indicates whether this is related to a Study, Country, or Site level event.**
    c. **The Due Date Period field allows you to indicate how much time users have to submit the documents after the event has taken place.**
4. **Use the "Add" button above the Document Type Name field in order to open the Select Document Type window.**



5. **You can search for the document type via the search bar at the top of the window or by drilling down in the index structure until the correct document type entry is shown.**
6. **Check the box next to the correct document type(s) and click Select to add the selected document type(s) to the event being created.**
7. **Once all document types have been added, press the Create button to create the event type.**

CREATING AN EVENT

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

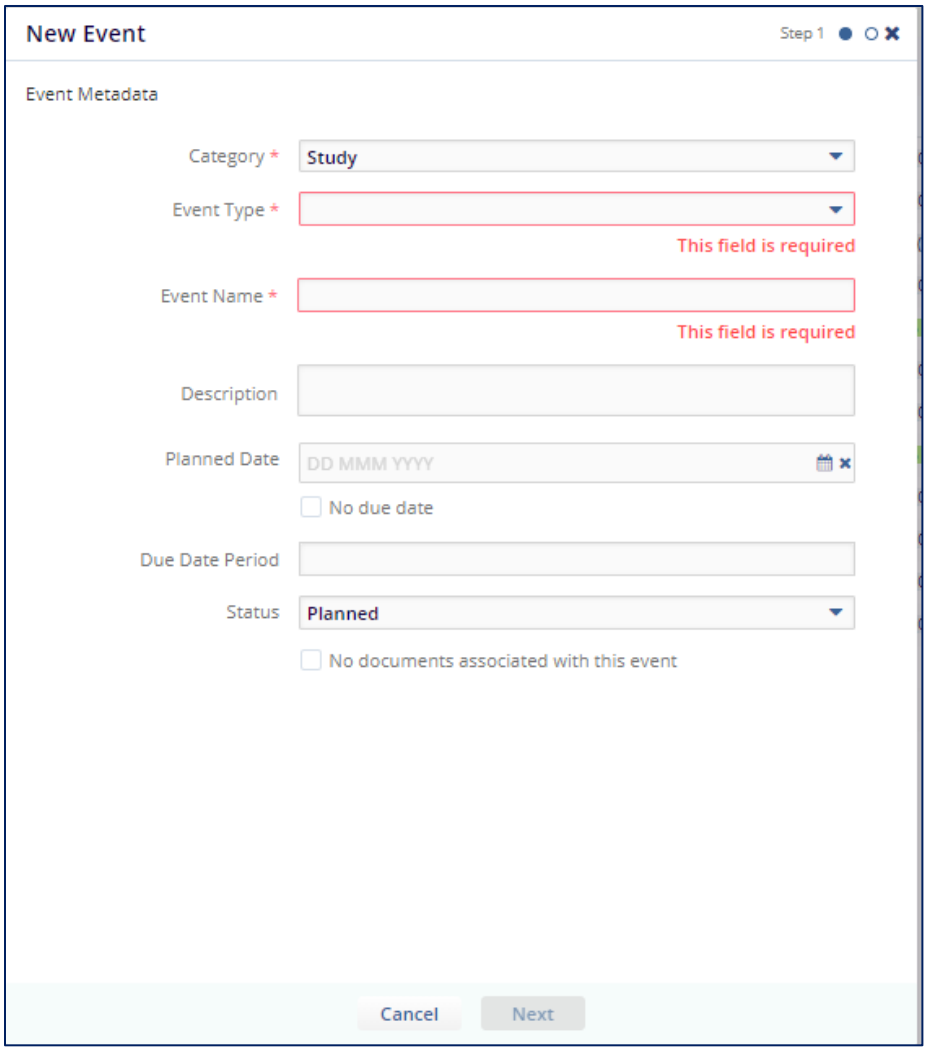
Events can be created using the following steps:

1. **Access the Events module. Any previously created events should be displayed in the window.**
2. **Click on the "Add" button in the menu bar above the list of events. The "New Event" window will open.**
3. **Using the Category field, indicate whether the event being planned is a Study, Country, or Site level event.**
4. **Choose the Event Type from the dropdown menu.**
5. **Give the event a name and fill out any other fields as desired.**
    a. **The planned date field will be critical to tracking the timeliness of event document submissions.**
    b. **The Due Date Period should be automatically populated based on the value**

entered during the creation of the Event Type.

c. **The Status field can be used to indicate whether an event is being planned or has already been completed. Most events will be created with a status of "Planned"**

6. **Press "Next"**

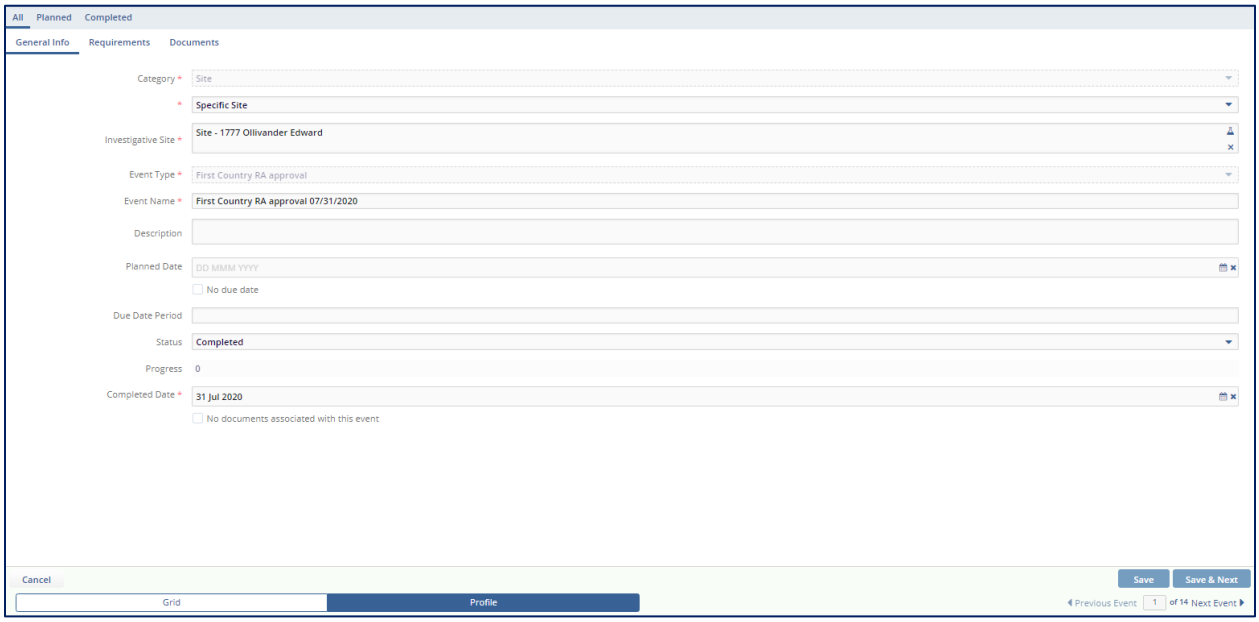


7. **The next screen allows the user to confirm whether all required document types for this event are displayed. The list will be populated based on the values chosen during the creation of the Event Type.**
   a. **If another document type is required, the user can press the "Add" button in the menu bar above the right panel. This will open the "Add Required Document Types" window.**
      i. **Use the Search bar or manually drill down in the folder structure to locate the required document type and press "Add".**
8. **Once all required document types have been added to the event, press "Finish" to complete the event creation process. The event will be displayed in the list of created events.**

MODIFYING AN EVENT

Follow these steps in order to modify an existing event:

1. **Access the Events module. Any previously created events should be displayed in the window.**
2. **Select the event to by modified and, using the toggle switch at the bottom of the screen, press "Profile." The event profile will open.**
3. **The event profile has three tabs:**
    a. **General Info: This tab includes the name of the event, any impacted sites or countries, the due date, etc.**
    b. **Requirements: This tab allows the user to adjust the required documents associated with the event.**
    c. **Documents: This tab allows the user to see which documents have been collected or are still outstanding.**
4. **Only the General Info tab has a save button. Be sure to save any changes made to this tab prior to exciting the view or else the changes will be lost.**

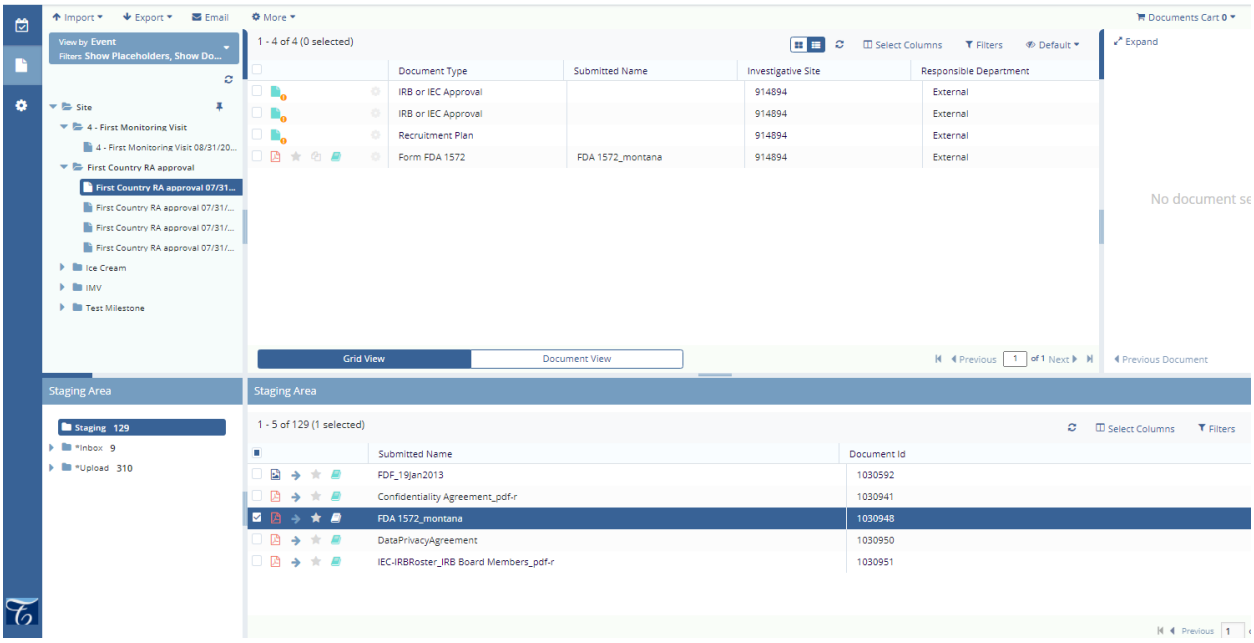


ASSIGNING DOCUMENTS TO EVENT PLACEHOLDERS

Once an event has been created, documents which have been submitted to the room can be assigned to the placeholders generated by the creation of the event so that they can count toward event completion and eTMF health. In order to assign a document to an event placeholder, follow the steps below:

1. **Select the Documents area of the Event Manager. This is indicated by a page icon.**

2. **The user can change their view of the Documents area using the "View by" dropdown menu. The available completeness views are the same as those available in the eTMF Documents module with the exception of "View by Event." We will be addressing the "View by Event" view in these instructions.**
3. **Using the index pane at the left side of the screen, drill down to the Event in question and click on it in order to show the missing and collected documents in the central "Grid" pane.**
4. **If it is not already expanded, click on the "Open Staging Area" button at the bottom of the screen in order to access those documents currently housed in the Staging, Inbox, and Upload folders.**
5. **Click on the document location and locate the document which applies to the placeholder displayed in the upper portion of the screen.**
6. **Click and drag the appropriate document from the lower panel onto the document placeholder in the upper panel.**
7. **The document will be coded based on the placeholder metadata.**
8. **Press the Refresh button above the Grid or in the Index pane in order to see the selected document in place of the Placeholder that was filled.**



Queries

OPENING A GENERAL QUERY

Trial Interactive v10.1 introduced the ability for Administrator level users to issue general queries against any document in the eTMF. Now, in 10.2, this ability has been given to all users regardless of access level. In order to open a general query on a document, follow the steps below:

1. **Login to the room and navigate to the eTMF Documents module.**
2. **Locate the document in question either using the search function or by drilling down in the index panel to select the appropriate index location for the document.**
3. **Click on the document in the grid and open the Metadata Pane at the right side of the screen.**
4. **Once the Metadata Pane has loaded, click on the "More" menu at the top-right corner of the pane to display additional document actions.**
    a. **Please note that administrators and editors may have additional functions in this area.**
5. **Select the "Create General Query" option. This will open the Email window.**
6. **Readers will not be able to select an individual recipient of their query. Instead, the General Query Responder group will be the dedicated recipients of these queries. At this point, Editors and Administrators will be able to select the appropriate recipient.**
7. **Compose the email and, when done, press "Create Query" to send the message to the selected recipients.**
    a. **These queries can be tracked using the Query by Sender or Query by Recipient views, or via the My Queries dashlet on the dashboard.**

ADDING A USER TO THE GENERAL QUERY RESPONDERS GROUP

There will now be a system generated group called General Query Responders available in the Groups area of the Users Management module. Administrator level users will be able to add any Editor or Administrator level user to this group. Readers are not eligible for inclusion in this group.

Please see the section on adding users to groups for step-by-step instructions.

THE QUERY MANAGER GROUP

There will now be a system generated group called Query Manager. Users added to this group

will be able to view and manage all QC Workflow related queries via the Query by Sender and Query by Recipient views in the Documents module. Only Editor and Administrator level users can be added to this group.

Please see the section on adding users to groups for step-by-step instructions

Metadata

TYPE-AHEAD FIELDS

When faced with a text metadata field, it can be difficult, especially for those new to a team, to decide exactly what should be entered into the field or perhaps the spelling of a particular word might be especially difficult. Trial Interactive v10.2 introduces the ability for a metadata field to learn values previously entered into it and to suggest those words when a user fills in the field for another document.

New rooms built after the release of TI v10.2 will have this function enabled by default. For those who whish to enable this for existing rooms, please see the section of the main user guide regarding the Forms Settings menu. Now, in the Forms Settings menu, there will be a Suggestions column. Once the checkbox is checked, the field will begin learning and suggesting values for future entry.

TMF Reference Model 3.2

REFERENCE METADATA

The standard set of TMF metadata is 'mappable' from Trial Interactive document types but it has not been available directly in the User Interface. Providing this information allows for better metadata exports and improves classification.
For eTMF rooms, this metadata is now included with each document type in a set of virtual fields. Fields now include:

- **Zone**
- **Section**
- **Artifact**
- **Sub-Artifact**
- **Index Number**
- **Description**
- **Instructions**

These fields will simplify the full implementation of sub-artifacts, particularly important for the TMF Reference Model v3.2.

Additionally, when selecting a document type, the Instructions field is now made available as fly-over help.

Finally, these fields are all fully reportable and are made available in standard views, grid view metadata exports, standard reports and archives.

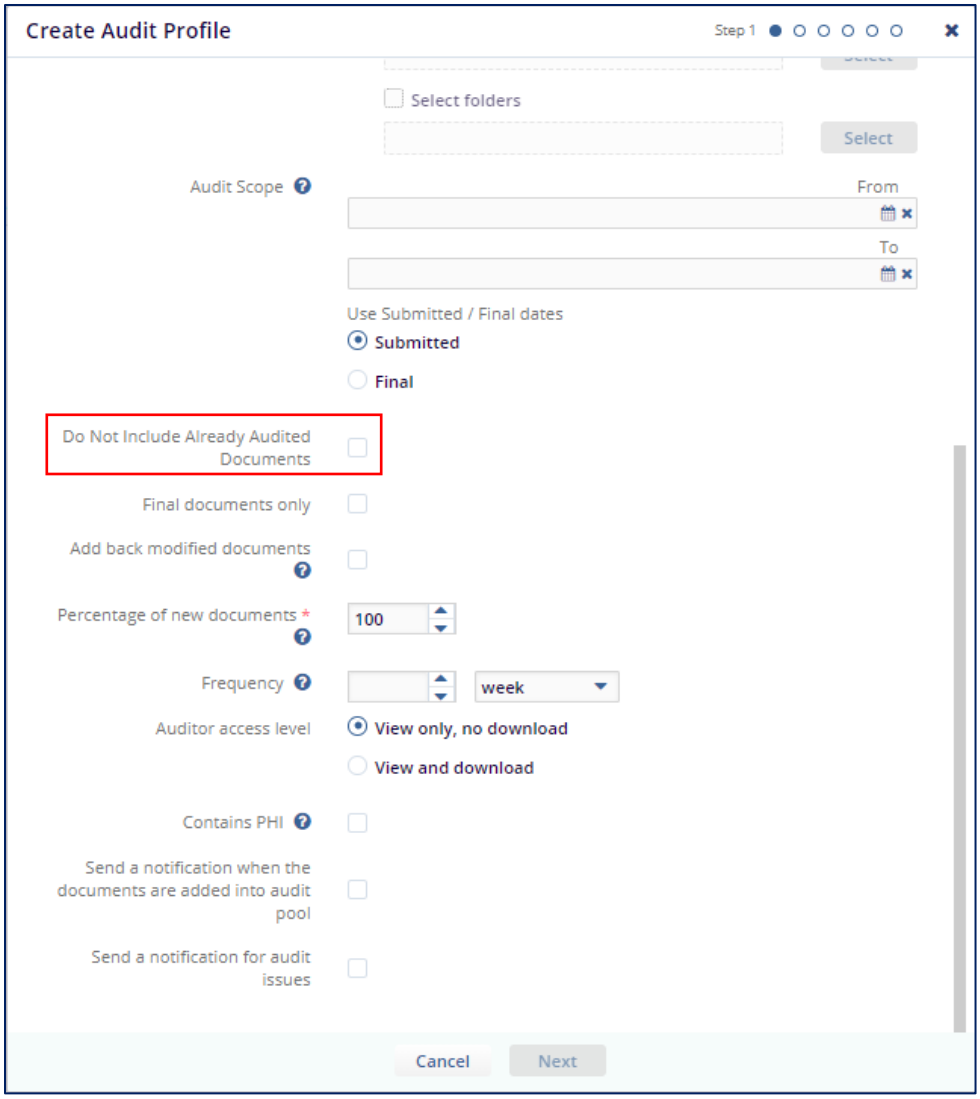
Quality Review

Trial Interactive v10.2 includes two especially important improvements to our Quality Review module:

EXCLUDE ALREADY AUDITED DOCUMENTS

Previously, it has not be possible to ensure that all documents added to an audit had not already been reviewed in a prior audit. Now, when creating an audit, there will be a checkbox labeled "Do not include already audited documents." When checked, this will ensure that all documents added to the new audit will be those which have never been a part of a previous audit in the room.

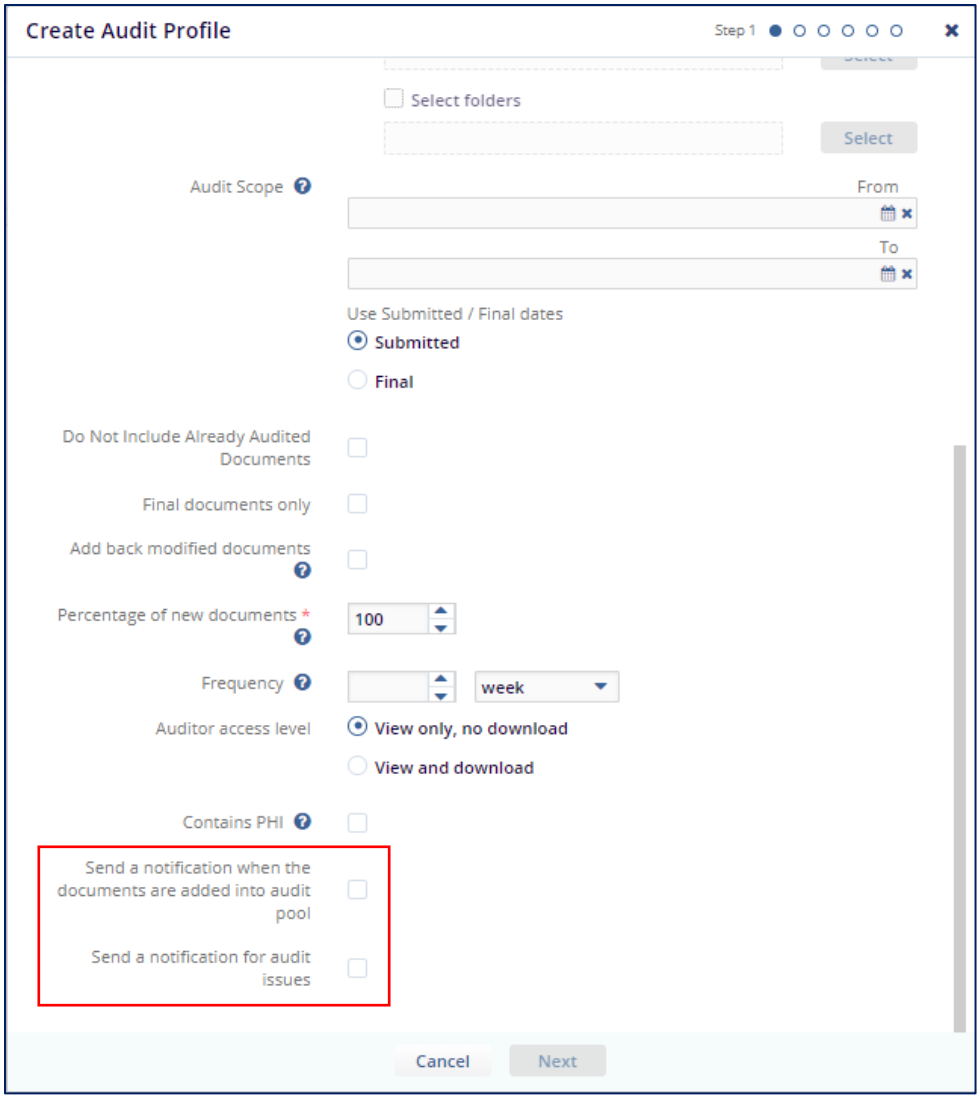
See the screenshot below:



For a full description of how to create an audit, please refer to the Quality Review section in the main User Guide or to the associated Job Aids and Videos.

AUDIT NOTIFICATIONS

In prior versions of TI, some audit-related notifications were being sent even when the option to send notifications was not selected. In TI v10.2 we are introducing a second checkbox regarding audit notifications. Users can now better select which, if any, audit notifications they would like sent regarding both newly created and existing audits. See the screenshot below:

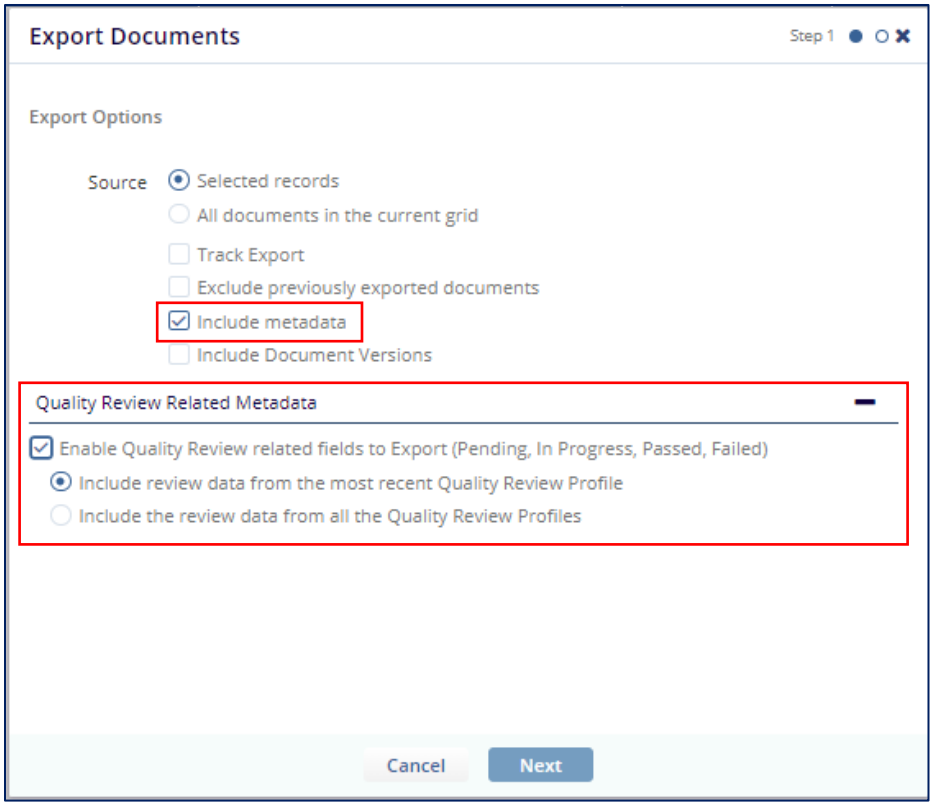


EXPORT AUDIT DETAILS

Exporting documents along with the associated metadata has been a function in TI for years but, prior to TI v10.2, users were not given the option to export audit-related information in a general document export. Now, when performing an export, the user is given the option to include this information.

When choosing to export audit-related metadata, users can choose to include information related to all audits in which this document has been reviewed or they can limit the information to only the most recent audit.

See the screenshot below:



eTMF Best Practice

CAUSALITY TRACKING

It is crucial to keep track of all final documents in the system and to have a record of any changes made to those documents if necessary. Now, whenever a final document's metadata is altered, typically to correct an error introduced during the document coding process, the user will be prompted to enter a reason for the change. This will allow more complete reporting where changes to final document metadata are concerned.

INSTANT AUDIT TRAILS

Auditors often ask for immediate access to the audit trail of a specific document or set of documents. It is critical to be able to provide this information immediately and respond to the audit request.

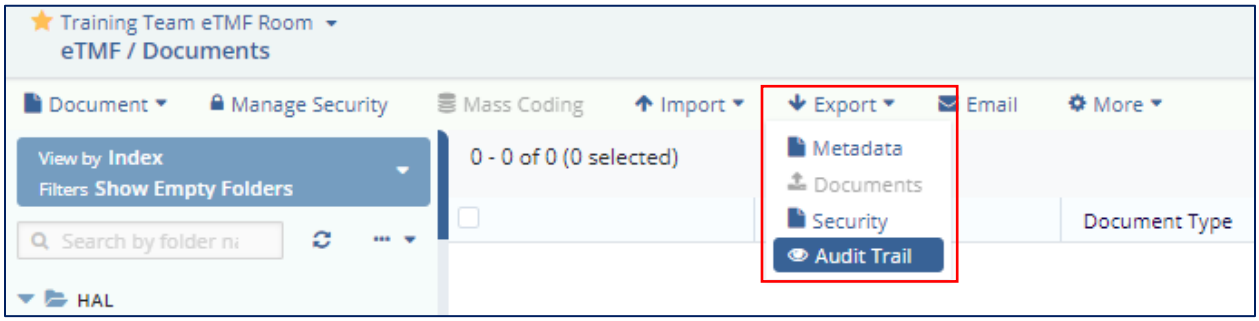
To that end, Trial Interactive now provides this capability through an audit trail export feature. This export feature allows for users to report audit information according to the following criteria:

- **All documents in a room,**
- **Current list of documents in the grid,**

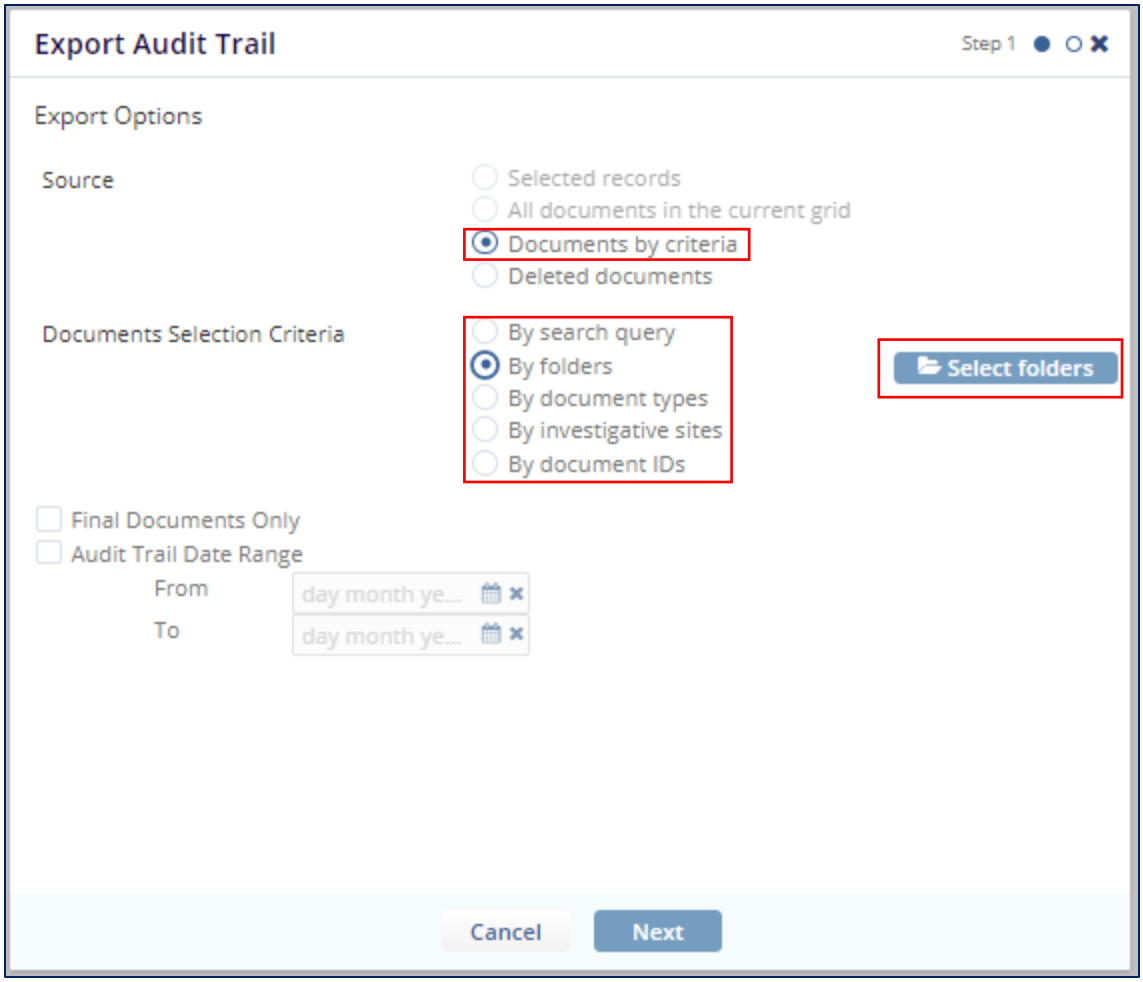
- **A specific search query,**
- **A specific folder, site, document type, or Document ID, or**
- **A range of dates**
- **This feature also provides the flexibility to easily export this information to an Excel spreadsheet for review.**

In order to export an audit trail, follow the steps below:

1. **Navigate to the eTMF Documents module.**
2. **Select the Export dropdown menu from the options above the Grid.**
3. **Select the Audit Trail option as shown in the screenshot below.**



4. **The Export Audit Trail window will open.**
5. **Select the Documents by Criteria option.**
    a. **This will activate the Documents Selection Criteria area of the window.**
6. **Select which option you would like using the radio buttons.**
7. **If you have chosen the By document IDs option, you can enter the document ID numbers in the field below. For all other options, press the associated blue button to the right of the chosen option to continue and select specific criteria as shown in the screenshot below.**



8. **Choose the appropriate criteria and press the Select button.**
9. **When you have indicated all necessary criteria, press Next to continue.**
    a. **A confirmation window will open showing you the selected criteria.**
10. **Review the selected criteria and, if they are correct, press Export.**
11. **A message will be displayed when the export is ready for download.**
12. **Press Get Job Results to download the file.**

Machine Learning

AUTO-FILING ETMF

Additional improvements are made for the identification and extraction of metadata to help to further auto-file the eTMF, including the following:

The extraction of all metadata, classification of the document, along with the assignment of Document Type, Site, Contact, Date, and other metadata pulled from the document.

The selection of the correct Site and Contact defined within the eTMF room.

Study Start-Up Features

ADD ANY SITES TO AMENDMENTS

Previously in TI, when a new site was created, it would automatically be added to the most recent amendment but not to prior amendments. Now, room administrators will have the ability to add a newly created site to any amendment, making it easier to ensure that all required documents are accounted for and collected in a timely manner.

IMPROVED SITE ACTIVATION DATE TRACKING

Routinely, a site's activation date may have to be recorded after the fact. In prior versions of TI, sites have been tied to an automatically generated activation date which was not always representative of the date that the site came online. Trial Interactive now allows a Start-Up Specialist to track the site activation date by setting it manually, overriding the default date set automatically by the system. This will help provide consistent metrics for cycle time and allow for accurate reporting.

For a more detailed discussion of the site activation process, please see the site activation section of the users guide. The ability to manually indicate a site's activation date is added to the Set Investigative Site Status window underneath the Comment field.

UPDATED PROGRESS FOR ESSENTIAL DOCUMENTS

It is critical to have an accurate idea of how close a site is to activation and key to that is knowing exactly how many documents are still outstanding or may still require review for final approval. To that end, SSU will now differentiate between documents which have been reviewed and those which are still pending approval. This will allow for users to have a more accurate understanding of how close each site is to submitting all of the documentation required for site activation.

When viewing Pending sites in Study Start Up, the Progress % column shows the site's progress towards activation. For more information, hover over the progress bar. The following information

will be displayed:

- **% of documents approved by QC Review (Study Start Up Specialist)**
- **% of documents approved by the Regulatory Reviewer**
- **A list of any documents still waiting to be collected.**

EMAIL PREVIEW, CC, AND REPLY TO REGULATORY PACKAGES

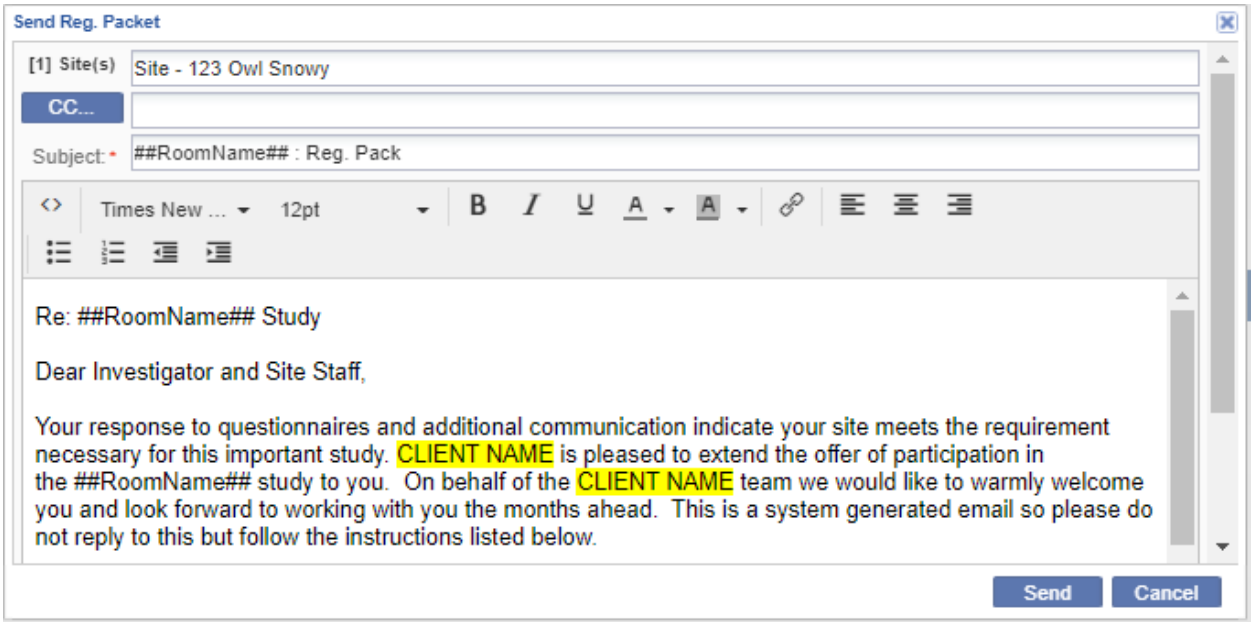
Easy and effective communication with sites is important to the site activation process. In order to help maximize efficiency in these communications, we have made a number of alterations in the emailing of regulatory packages to sites and in how those documents may be returned for processing. Trial Interactive now allows Start-Up Specialists to preview regulatory packet emails in order to see if any edits are required. Users can edit these emails prior to sending to them and to copy additional contacts if necessary.

Also, new to SSU in this release is the ability of sites to submit these documents simply by replying to the regulatory packet email that they received. This will facilitate timely receipt of documents and help ensure that the site activation process goes as smoothly as possible.

A more detailed discussion of the process for sending the Regulatory Packet to a site is contained in the Study Start Up User Guide but the following, abbreviated, discussion may be of assistance.

In order to Preview a Regulatory Packet Email, follow these steps:

1. **From the Grid in the SSU Sites module, select a site.**
2. **Press the Send Reg Packet button located above the Grid.**
3. **A preview window will now open allowing the user to confirm the body of the email and make any edits as necessary.**
    a. **This includes adding another recipient by pressing the CC button and selecting from the list shown. See the screenshot below:**



4. **When you have completed any required changes to the email template, press Send to send the email to the site.**

Of additional interest with regard to the Regulatory Packet email is that, in prior versions of Trial Interactive, site contacts would be required to send any completed documents to the Study Start Up Inbox in order for them to be received by the system. Now, in TI v10.2, the site will be able to reply directly to the Regulatory Packet email in order to submit their documents.

Content Management Features

SIMPLIFIED SITE SECURITY - SITE COLLABORATION ROOMS

When providing site users access to a study, it is important that security is automatically assigned to ensure that users can complete their tasks, such as document upload, certification, redaction, indexing, reconciliation with the regulatory binder, and sharing to the eTMF while preventing access to material that they are not authorized to see.

Upon creation of a new user, a designation of Site User can be made along with the assignment of the site. Specific permissions are assigned to these users based on a predetermined site-template-folder security configuration. This will allow users to be provide the correct security profile right away to provide them immediate access to the Site Collaborate room.

Given the security required in a Site Collaboration room, the creation of new users in this room will be handled by the Trial Interactive Service Desk in accordance with your previously defined

security setup. To have a site-specific user added to a Site Collaboration room, please reach out to your Trial Interactive representative or directly to the Service Desk.

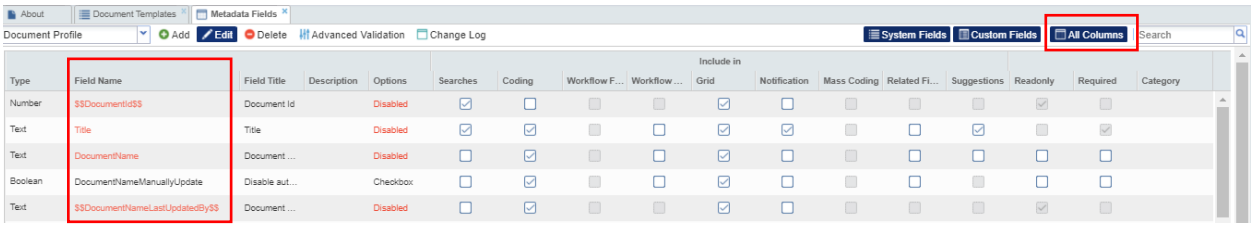
SITE USER IDENTITY VERIFICATION

In order to prevent unauthorized users requesting and gaining access to a site's data, site users are assigned to their site, and a secure PIN code can also be *optionally* required as part of the request for access. Site administrators that are part of a restricted site group can view the PIN code and include the PIN as part of a new user access request. Trial Interactive Service Desk personnel always verify the PIN code as part of granting access to the site.

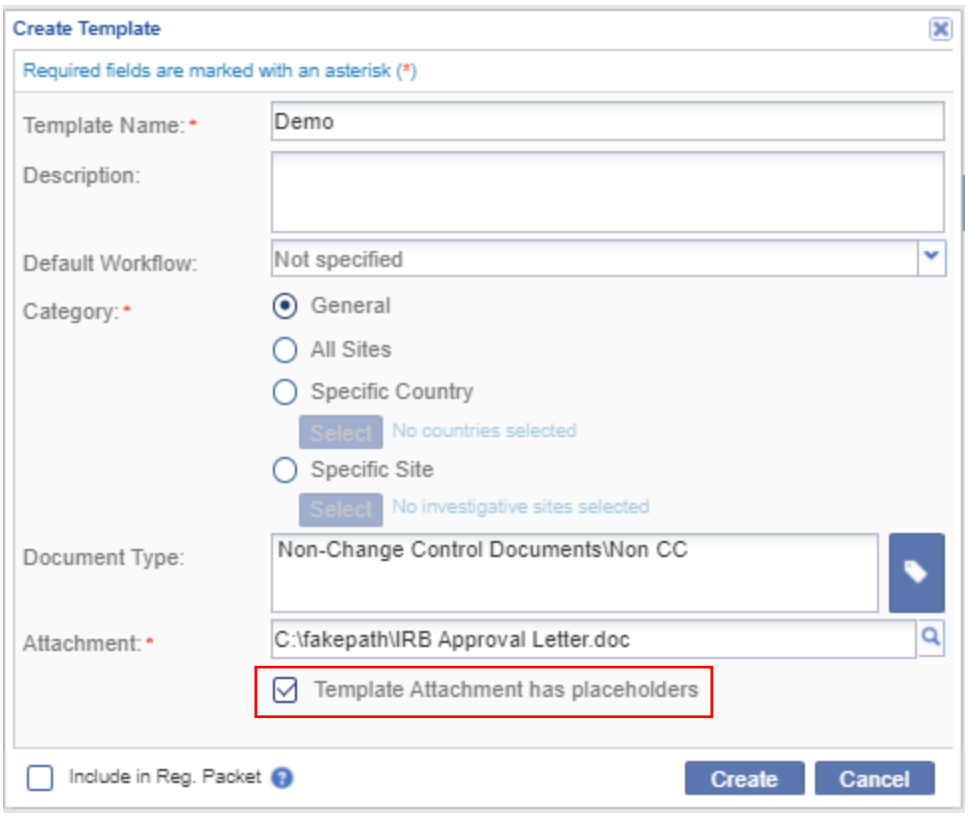
HEADERS FOOTERS AND WATERMARKS

Controlled document workflows often require that headers, footers, watermarks, and other fields to be filled in automatically when the document moves to an effective status. Users can now select document templates that have defined form fields that will automatically populate with metadata information from the document profile.

These template documents can be created in Microsoft Word™ using the Content Control options in the Developer menu tab. Values for these fields can be located in the Settings module by navigating to the Forms Settings menu. Select the All Columns option as shown in the screenshot below. The Field Name column will contain the necessary values in order to create the data injection field in Word™.



Once a template document has been created, it can be uploaded to the Document Template menu in the room's Settings module. The process follows the directions laid out in the User Guide section on Settings with one exception. As shown in the screenshot below, the Create Template window now has a field labeled "Template Attachment has Placeholders" which will need to be checked upon uploading a document intended containing data injection fields.



Controlled documents can populate values such as document name, document identifier and other document specific values into the document itself, ensuring that the document and the document's information match. These may be applied in the header, the footer, another location on the document, or the watermark itself. This streamlines the document finalization process as users do not have to manually populate key document information. Templates with the metadata values added as controlled fields will allow for the metadata injection.

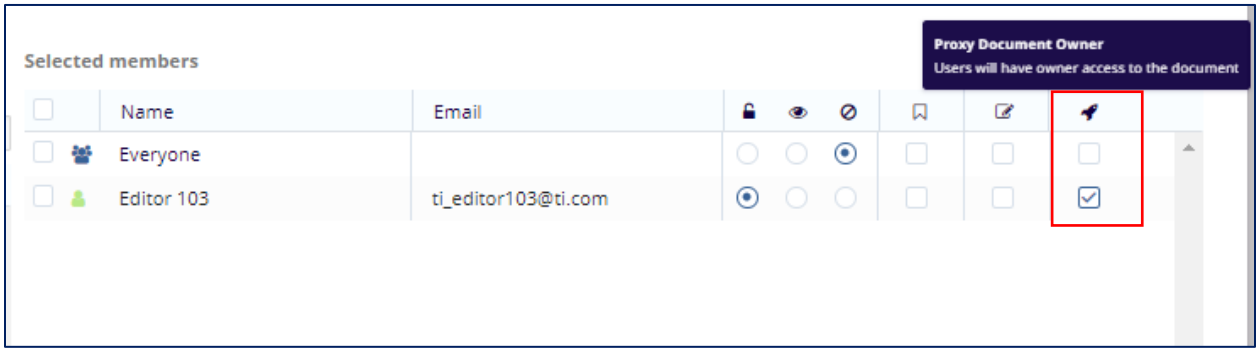
Once a document has been created in the Content Management room (see the related section in the Content Management User Guide), the document will have to be checked out or otherwise opened in a content review session in order for the fields to be automatically filled.

IMPROVED DOCUMENT OWNER PRIVILEGES

In many cases, the user listed as the Document Owner will not be the only one who needs to have permission to send a document for review and initiate a workflow. To that end, we are introducing a new folder security feature called Proxy Document Owner. Any user indicated as a proxy document owner via the folder security settings can then perform document owner functions for the documents in that folder.

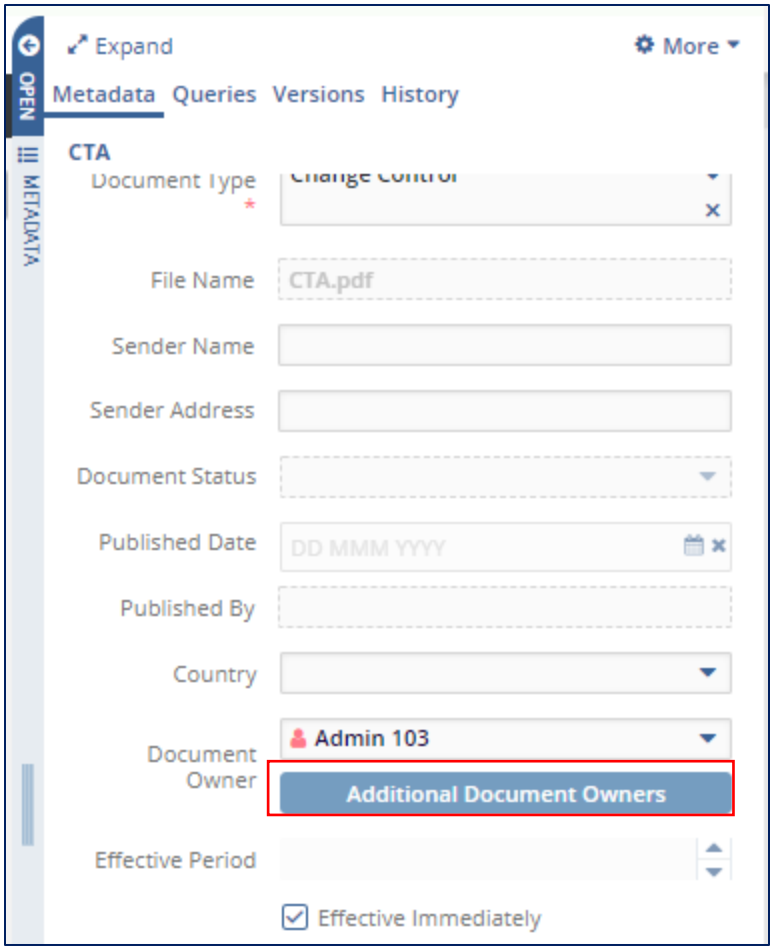
In order to assign a user as a Proxy Document Owner, follow the steps below:

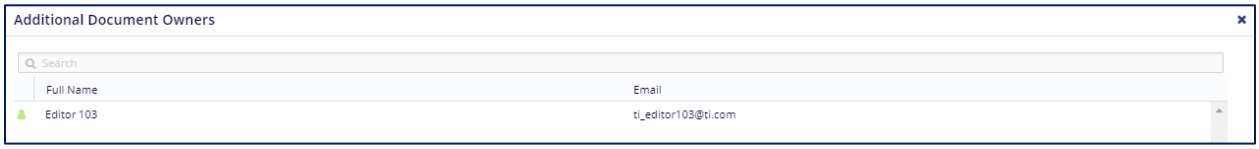
1. **Navigate to the Documents Library in your Content Management room.**
2. **Locate the folder whose security settings you wish to adjust.**
3. **Right-click on the folder and select View Folder Security.**
4. **Select the Group or User who should be added to the folder security and move them to the right side of the window.**
5. **Once they are there, you will need to give the Group or User the Proxy Document Owner permission as shown in the screenshot below.**
6. **Press Save to complete the process.**



For a more detailed discussion of folder security, please see the related section in the User Guide.

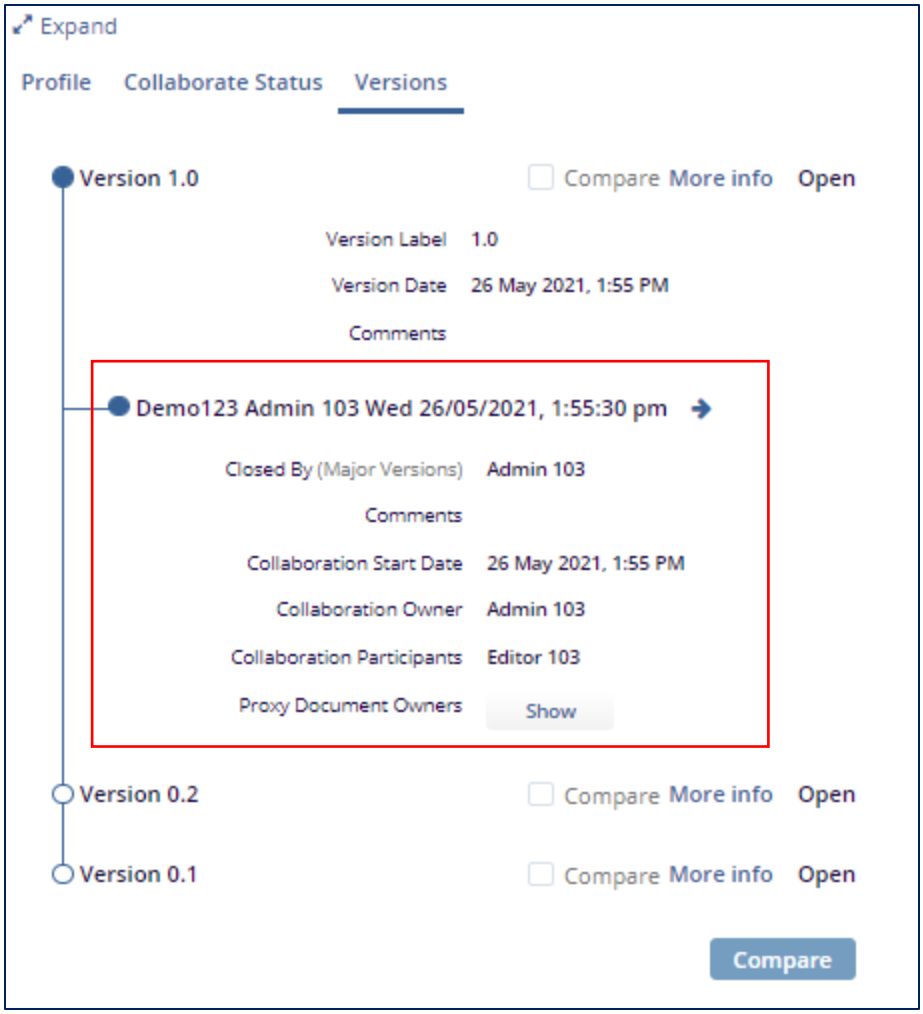
Once a user has been assigned as a Proxy Document Owner, they will appear on the list of Additional Document Owners found in the Metadata Pane for any document in the folder. Please see the screenshots below:





IMPROVED DOCUMENT COLLABORATION VISIBILITY

When viewing the document library, it is important that any collaborative review session that is currently active on a document is easily seen. Now, information from a closed collaborative review will now be displayed as a part of the Versions tab in the document's metadata panel.



Users can see what version was created, who participated in the review and when the collaborative review occurred with the Collaborative review information, putting all of the document history in one place.

Additionally, we have introduced the ability to mark a change-controlled document as Obsolete with a simple right-click on the document in the Grid. The document will be moved from the Index view of the Documents Library and will be stored in the new Obsolete Documents view. Documents which are checked out or undergoing a workflow review cannot be either deleted or marked as Obsolete.

ADMINISTRATIVE WORKFLOWS

Effective versions of controlled documents will often require a minor housekeeping change after approval. These changes should not impact the effectiveness of the document. An example of this type of change would be the correction of a minor typo. It would be inconvenient to use the full versioning workflow in correcting such a trivial error and so we have introduced the

Administrative Workflow.

For a more detailed discussion of workflow creation, please see the related area of the User Guide. However, it is our recommendation that users should, where possible, reach out to the Trial Interactive Service Desk whenever assistance is needed in workflow creation or maintenance.

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

Reporting Features

UPDATES TO EXISTING COMPLETENESS REPORTS

In this release existing reports are updated to include additional data now available. These changes include the following:

- **All Completeness reports will also list the associated Events like Milestones, Amendments, and Visits. These frequently accessed reports are crucial for users interested in finding out the state of the eTMF and this update will ensure that users will continue to have access to all relevant information in one location.**

- **Completeness reports will also list the Responsible Party, Due Date, and Event Planned date for collecting documents. This will make it easier to track down required documentation and to ensure that all parties are meeting document submission expectations.**

- **Improved logic for differentiating between Essential Documents and Placeholder Documents.**

- **Improved logic for differentiating between Collected and Missing Placeholder Documents helping users to get a clear idea of which documents are outstanding.**

COMPLETENESS - SITE CATEGORY REPORT

Often, CROs and Sponsors need to run reports specific to one or more of the sites associated with the study in order to identify missing documents or take stock of the inventory of collected

documents. This release introduces an input filter for selecting one or more of the sites for which the report needs to be generated. Additionally, the report will also list the site contacts as a new field. These improvements will make it even easier for our users to generate targeted data as needed.

DELETED DOCUMENTS REPORT

CROs and Sponsors have a need to track all documents that have been deleted from the study. Tracking this is important not only to ensure that such deletions are not misused but also so that the information can be produced for auditing purposes.

A new standard report is available for TI users containing the following information:

- **Document Details: Document name, ID, who submitted the document and when it was submitted.**
- **Deletion Details: Who deleted the document and on what day it was deleted.**
- **Reason: The report will include the reason entered by the user who deleted the document.**
- **Status: The report will indicate what status the document was in at the time of deletion.**

PORTFOLIO HEALTH

Completeness, Quality and Timeliness are the three pillars of eTMF health. With 10.1 TI introduced portfolio-level dashboards including new dashlets for use in monitoring the health and quality of eTMF.

A new dashlet is now available for Sponsors and CROs to monitor eTMF completeness across multiple studies.

Users will have filters available to break apart the data by Studies, Categories of documents (Sites, Country, Trial) and by the Status of documents, enabling our customers to be inspection ready at all times.

DATA TABLE IN PORTFOLIO DASHLETS

All dashlets in the portfolio dashboard will now display data in tabular form along with the graphical representation currently available. Now, users can see detailed information in addition to gaining a quick impression of the health of a study room or several related rooms with a glance.

UPLOAD FILTER FOR QUALITY AND TIMELINESS DASHLETS

Documents can be uploaded to an eTMF using different sources such as myTI, Inbox Submission, or direct upload to the eTMF via the room interface. Sometimes, one or more of these methods of upload are more efficient for different organizations. In order to monitor quality and timeliness, it becomes important to be able to analyze data by the upload source.

The system now has the ability to filter the data displayed in dashlets pertaining to timeliness and queries, in the Portfolio Dashboard, with the document upload source, allowing our users to determine if any particular way of getting documents into the room is more efficient than the others for their team.