TRIAL INTERACTIVE

Trial Interactive v10.3 – User Guide Supplement

TRANSPERFECT LIFE SCIENCES

APPROVALS

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Contents

Chapter 1. Trial Interactive 10.3- Overview and Features

Hardware and Software Requirements

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

System Requirements	
Operating System	• 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 • NOTE: Microsoft® will stop supporting Internet Explorer™ 11 in January 2022. We expect degraded performance with Internet Explorer™ 11 and it is no longer supported with 10.3.
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. • 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	• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) • 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

Platform Features

Room Management

ROOM MANAGER ROLE

There are many situations in Trial Interactive that require management but do not require an administrator. For example, it may be necessary to provide a user with the ability to create and manage audits, however this manager does not need to be able to change access permission or invite new room users.

TI 10.3 introduces a new role, Manager, to allow for a set of users that may easily access most room data, both in the documents view and the settings panel, without providing these users access to change permissions or invite new users to the room.

Room Managers will be able to access everything an Administrator can, except:

- **User and Group Management**
- **Security Settings**
- **Workflow Settings**
- **No Access to Module Configuration**
- **Inbox Configuration**
- **Investigative Site Configuration**
- **Folder and Document security**
- **Email Configuration**

This role can be assigned to a user in the Users Management area of Trial Interactive. Please see the sections on inviting new users and editing user profiles in order to find steps on how to designate a user's role in your TI room.

FLEXIBLE DUPLICATE CHECKS

Introduced in 10.3 are improvements to the duplicate check function, allowing for the verification of duplicate documents within the staging area and upload folders, an indication of the checksum in the comparison metadata, as well as a more flexible duplicate check that may be triggered in the QC1 stage (instead of Final).
Enabling and configuring these options will require the assistance of the Trial Interactive Service

Desk.

Security and Privacy

RESTRICTED CONTENT

With new regulations that limit exposure to Personalized Health and Identity Information, as well as the constant concern about exposure to unblinded data, it is often difficult to indicate that a document must be redacted within a trial while preventing unauthorized individuals from seeing this document in the interim.

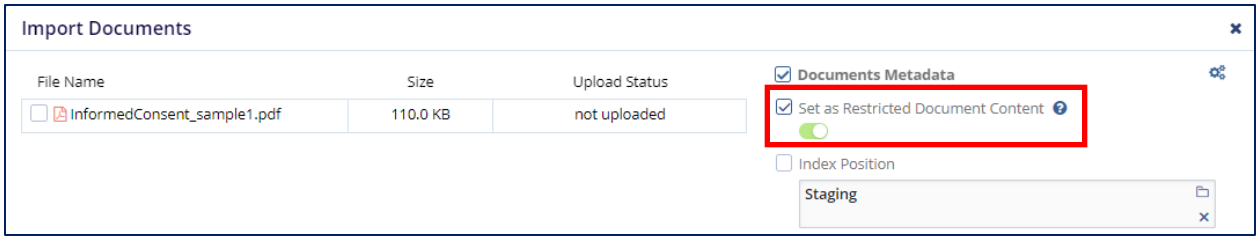
With 10.3, Trial Interactive is introducing a Restricted Content feature. This feature will allow users to indicate that a document is a 'Restrict Document.' Once restricted, only Administrator-level users or users with the redaction action on their user profile may see the unredacted copy (also referred to as the 'native' copy or 'native' version) no matter where the document moves within the room. These restricted documents will show in a new Redaction view and Redacted dashlet which shows the current queue. Users with redaction permission may then process unblinded data or documents with PII/PHI in them.
Until unrestricted by a user with redaction permissions, the content will be unavailable for any purpose within TI.

<u>In order to designate a document as containing restricted content, see the section below:</u>

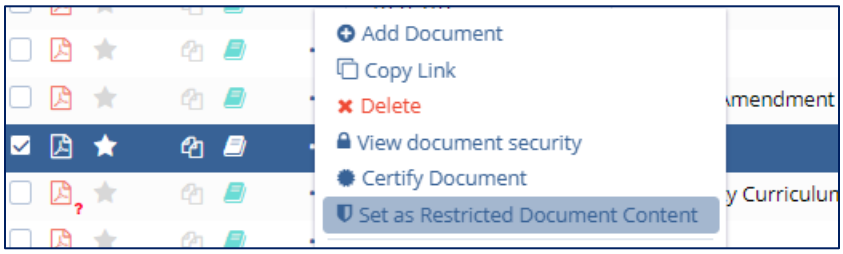
A document may be designated as 'Restricted' either during or after upload. As a best practice recommendation, we suggest that documents requiring this level of protection are designated as 'Restricted' upon upload in order to help ensure that the restricted content is not viewed by any unauthorized personnel.

During the upload (or import) process, there will be a toggle switch which, when enabled, will designate all selected documents as 'Restricted' during the upload process. The user will need to enable Documents Metadata during upload in order to activate the "Set as Restricted Document Content" option.

Please see the screenshot below.



For documents that are already in the room, users can right-click on the document or open the document action menu with the gearwheel icon on the grid. Once the menu opens, select the "Select as Restricted Document Content" option in order to designate the document as 'Restricted.' For users with the ability to edit a document's metadata, the "Restricted Document Content" toggle switch will also appear in the metadata pane.



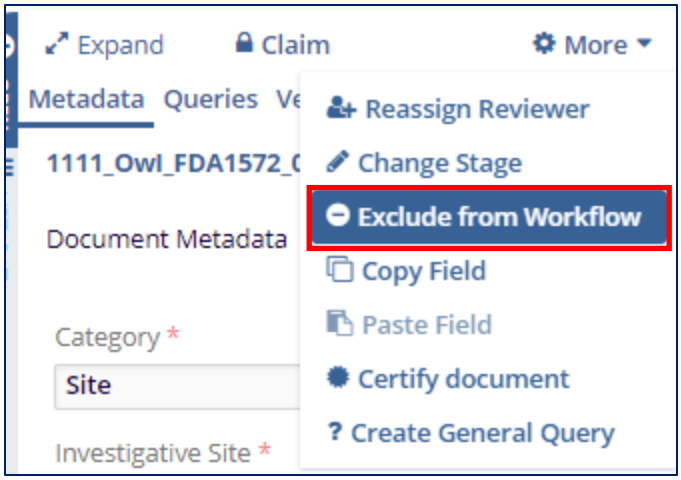
Regardless of which method is used to designate the document as 'Restricted,' a shield icon will appear on the grid as a visual reference that the document cannot be viewed prior to being redacted unless the user has sufficient privileges.

Document Module

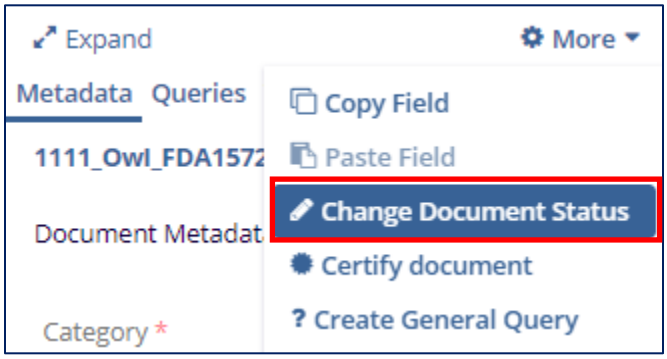
CHANGING A DOCUMENT'S STATUS

Administrator users have the ability to change a document's status as necessary. This right has been changed somewhat. Now, an administrator level user will only be able to change the status of a document if it is not a part of a document workflow in the room. For rooms in which all documents are automatically incorporated into a workflow, the administrator will need to first exclude the document from the workflow prior to changing its status. See the screenshots below:

Step 1

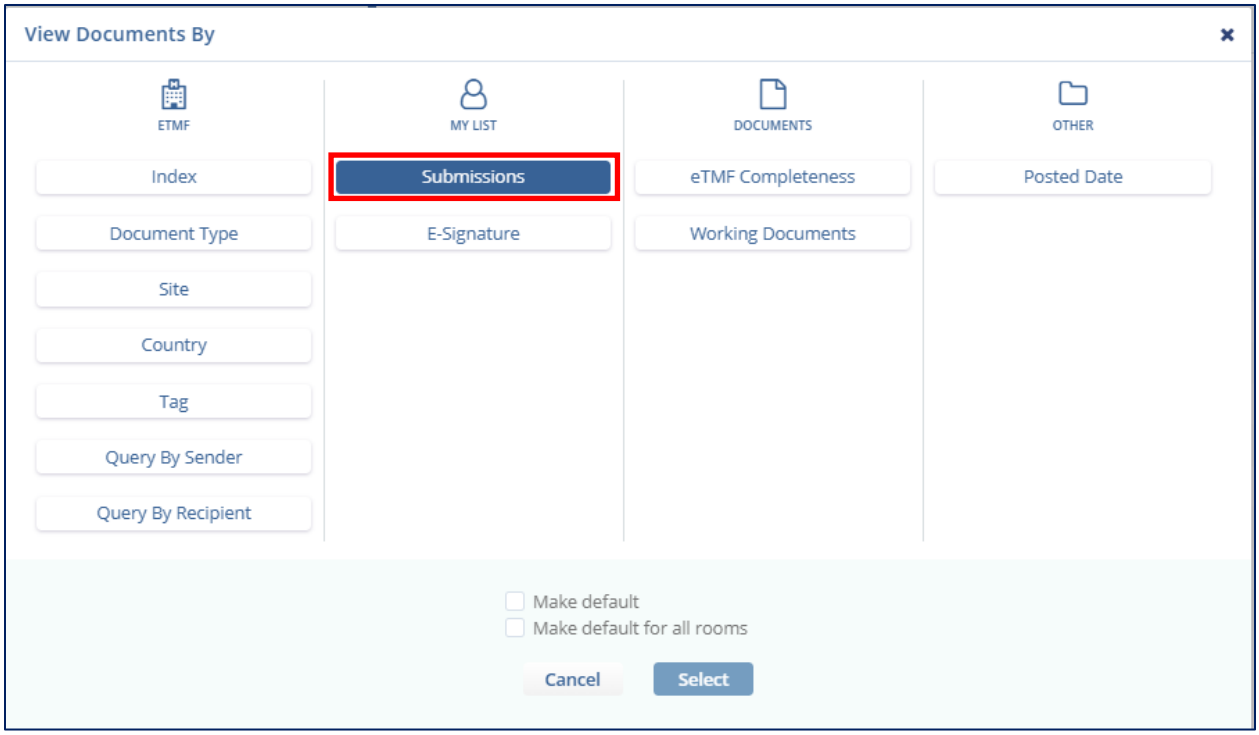


Step 2



MY SUBMISSIONS VIEW – READER ACCESS

For years now, editor and administrator level users have had the ability to view all of the documents that they have submitted to the room in one view regardless of their status or current index location. That right is being extended to readers as well. Now, reader level users will be able to navigate to the Documents Module and use the index view dropdown menu to select "Submissions" from the lists of options.



CARD VIEW

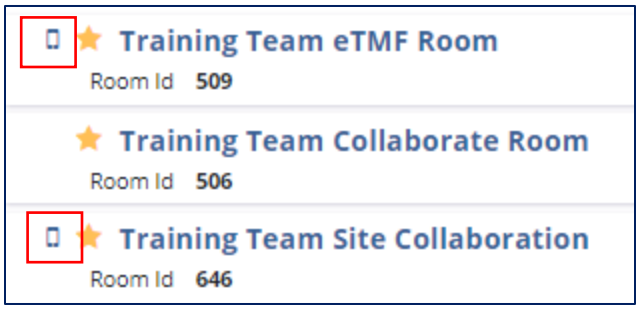
Most users are accustomed to viewing the Document Grid in Trial Interactive as a standard set of icons and configurable content on separate lines of a grid. There is now another view available to our users called "Card View." In order to enable Card View, you will need to choose the option from the view selector switch above the Document Grid. See the screenshots below.

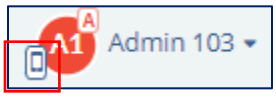
Notifications

MYTI ENABLED ROOMS

It can be difficult to remember all of the rooms for which you may have access both via the

standard online application and via myTI. To aid in that, an icon will now appear next to any room to which you have been granted access via myTI. The same icon will be available within the room as well, but it will be added to your Username Menu dot.

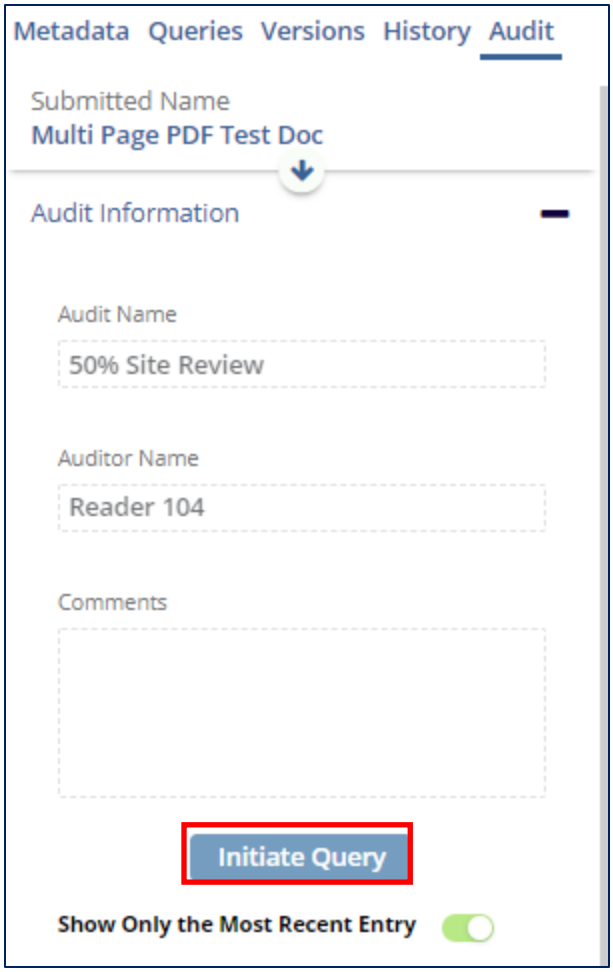




Quality Review Audits

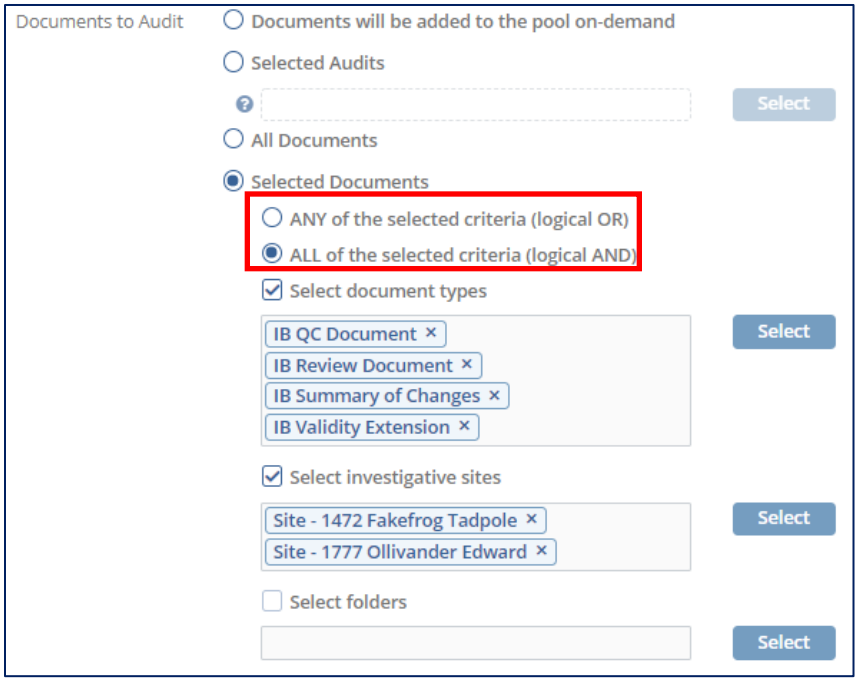
AUDIT RESPONDER QUERIES

Audit Responders in Trial Interactive will now have the ability to initiate a query in order to assist them in correcting a document which has been failed in an audit. The Audit tab of the metadata panel has been updated with an Initiate Query button which will allow the user to send a query to any group, user, or contact associated with the study room. For more information on creating, responding to, or resolving a query, please see the associated section of the User Guide.



IMPROVED AUDIT FILTERS

When creating an audit profile, users have many options for designating which documents should be included in the resulting audit (see the related section of the Guide). Users who choose the "Selected Documents" option are presented with the ability to select document types, investigative sites, and index folders. There is now also an option to select whether 'ANY' or 'ALL' of the chosen criteria should be used in gathering documents for the audit.



AUDIT SECURITY

Administrators have always had access to all Quality Review Audit profiles. In 10.3, Editors and Room Managers now have access to audit profiles where they are listed as the Audit Manager, in order to provide for more control over who can view and update Audits. For more information about how to view or update an audit profile, please see the related section of the User Guide.

REGULATORY AGENCY INSPECTOR VIEWS

In a prior version of TI, Regulatory Agency Inspector users' access was limited to viewing only the audit created for them by the room administrators and any documents which were required would have to have been added to that audit but a room editor or administrator. TI v10.2.4 restored these users' access to the document module. With this update, users with Regulatory Agency Inspector access can now navigate the documents index if they need to review a document which is not included in the audit created for them.

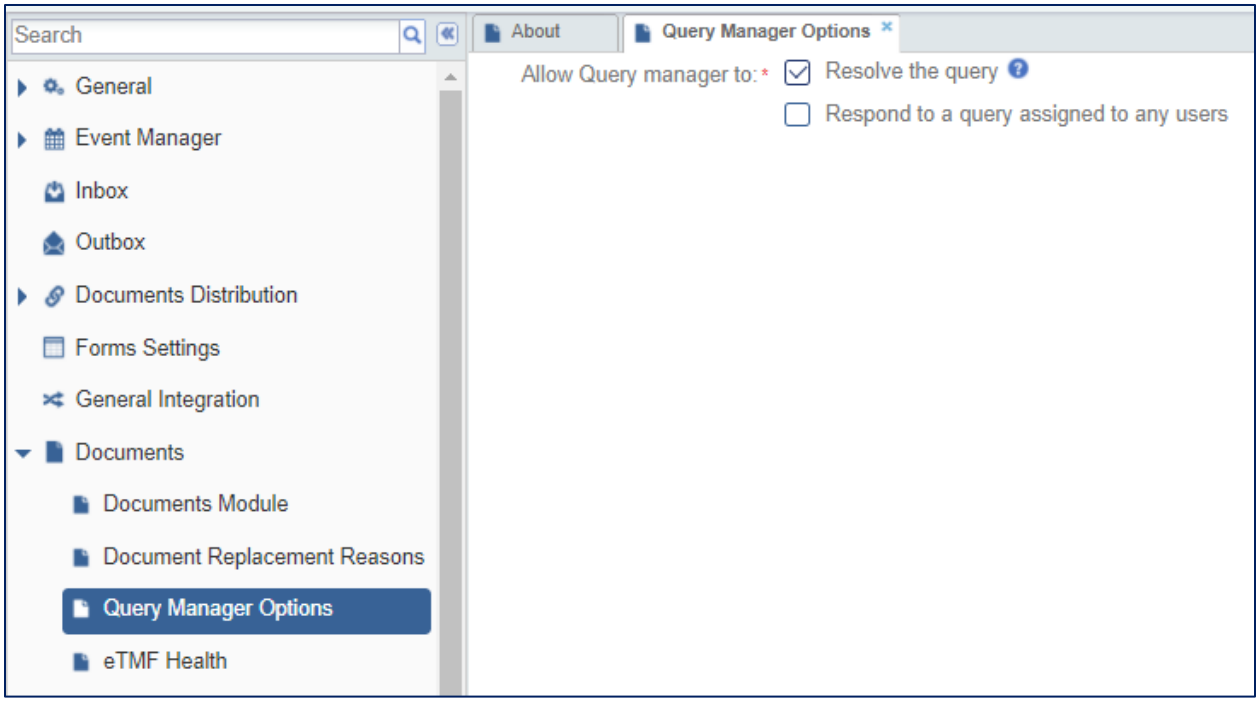
Query

QUERY MANAGER

The Query Manager group and its function is discussed at greater length in another area of this guide but, with TI v10.2.4, we added additional customization options to this group's function within the room. Room administrators can now choose whether those users added to the Query

Manager group can respond to queries, resolve queries, or do both. This is contained in a new menu in the Settings module.

See the screenshot below:



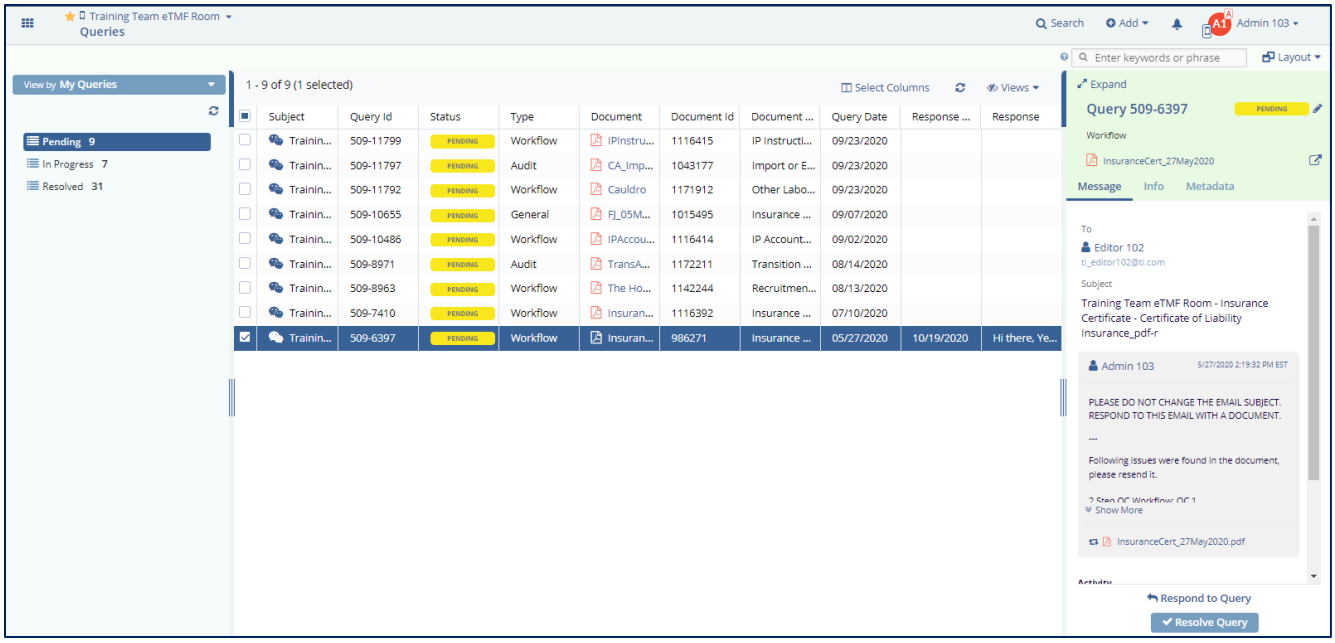
QUERIES MODULE

There are multiple ways to access a query in Trial Interactive but, depending upon your role in the related study room, you may have to access Workflow Queries, General Queries, and Audit Queries. Historically, these have always been managed through the user's viewing options in the Documents module of the eTMF. In TI v10.3, a Query Management Module has been introduced, with the following capabilities:

- **The ability to sort and view queries By Sender, By Recipient, and, for those with higher levels of access, the ability to limit queries to only those related to themselves.**
- **Once a view has been chosen, users will be able to view queries by their current status.**
- **The ability to work a query through to resolution and to take any appropriate action associated with the query.**
- **Query Managers will be able to**
- **An update to the Queries by Age Dashlet with Query Management capabilities.**

The Queries module may be accessed from the Navigation Grid or 'Waffle' in the upper-left corner of the screen. All users should be able to access the Queries module without additional actions

or permissions applied to their account.



Event Manager Enhancements

The Event Manager allows for the creation of Events to track a specific list of document types that must be collected. The following improvements are included in 10.3.

DOMAIN LEVEL EVENT TYPES

Event types, as discussed elsewhere in the User Guide, are configurable on a room-by-room basis and users with sufficient access can create new event types, as necessary. However, with this improvement, a generic list of standard event types can be created at the domain level for each of our clients. Now, when you need a new room, you will be able to configure the available event types along with the rest of the settings pertinent to your new room. In order to customize this domain level list of event types, please reach out to your TI representative or the Trial Interactive Service Desk.

ADD EVENT

Many users are already familiar with adding a document, a task, or a new user to a room via the 'Add' button near the username menu at the top-right corner of the screen. We have added Event to the list in that menu so that users can now create an event from anywhere in the system.

EVENT TYPE DESCRIPTION

When choosing which event type to use while creating a new event, users must select from a dropdown menu showing all of the names of the events available for the chosen category (Study, Country, or Site). This list now includes the descriptions associated with the event types, making it easier to find the correct event type for the event being created.

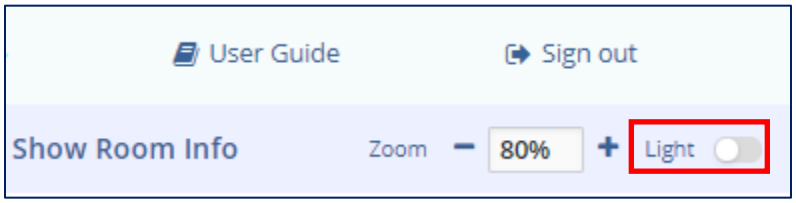
For more information about creating events, please see the associated section in the User Guide.

User Interface

DARK MODE

As everyone spends more time staring at screens, eye strain can get worse. Support of a 'Dark Mode' as a user preference can make it easier to parse information.
With 10.3, Trial Interactive introduces a Dark Mode to TI, a simple user preference that can switch the case colors to something less glaring at night, and to some, more pleasant to the eye.

In order to enable Dark Mode, go to the Username menu at the top-right corner of the screen and toggle the Light/Dark switch next to the zoom indicator. See the screenshot below.

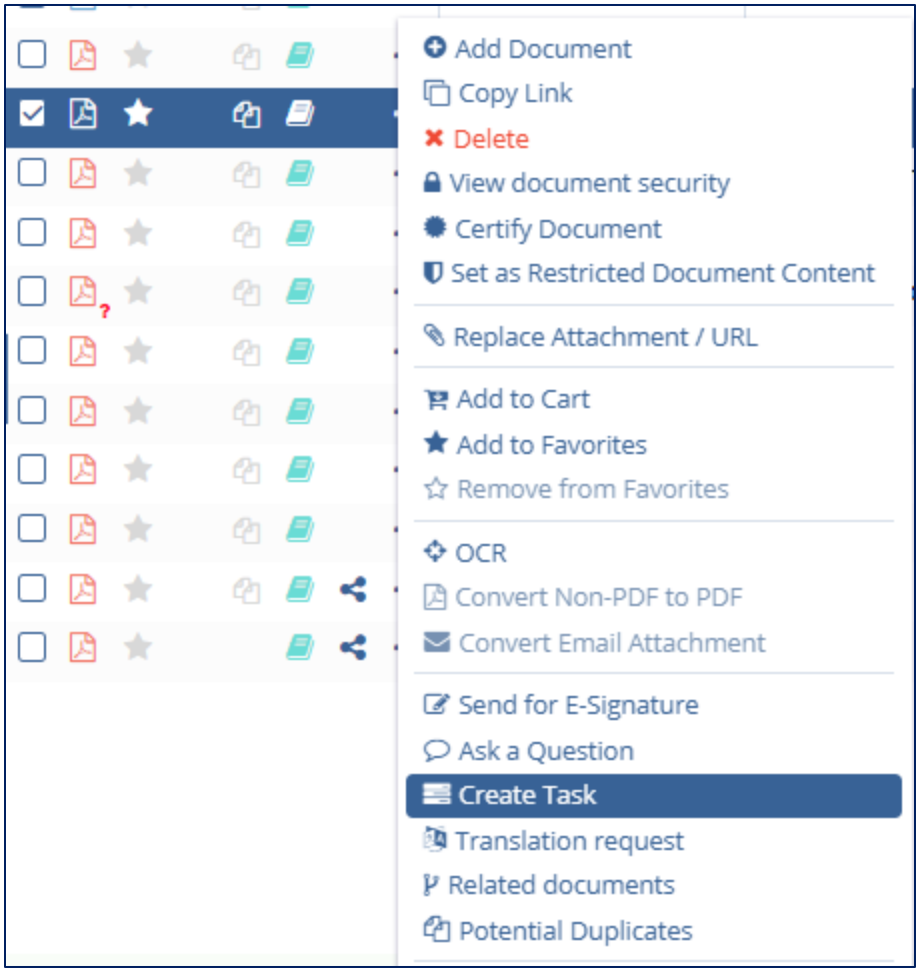


Tasks

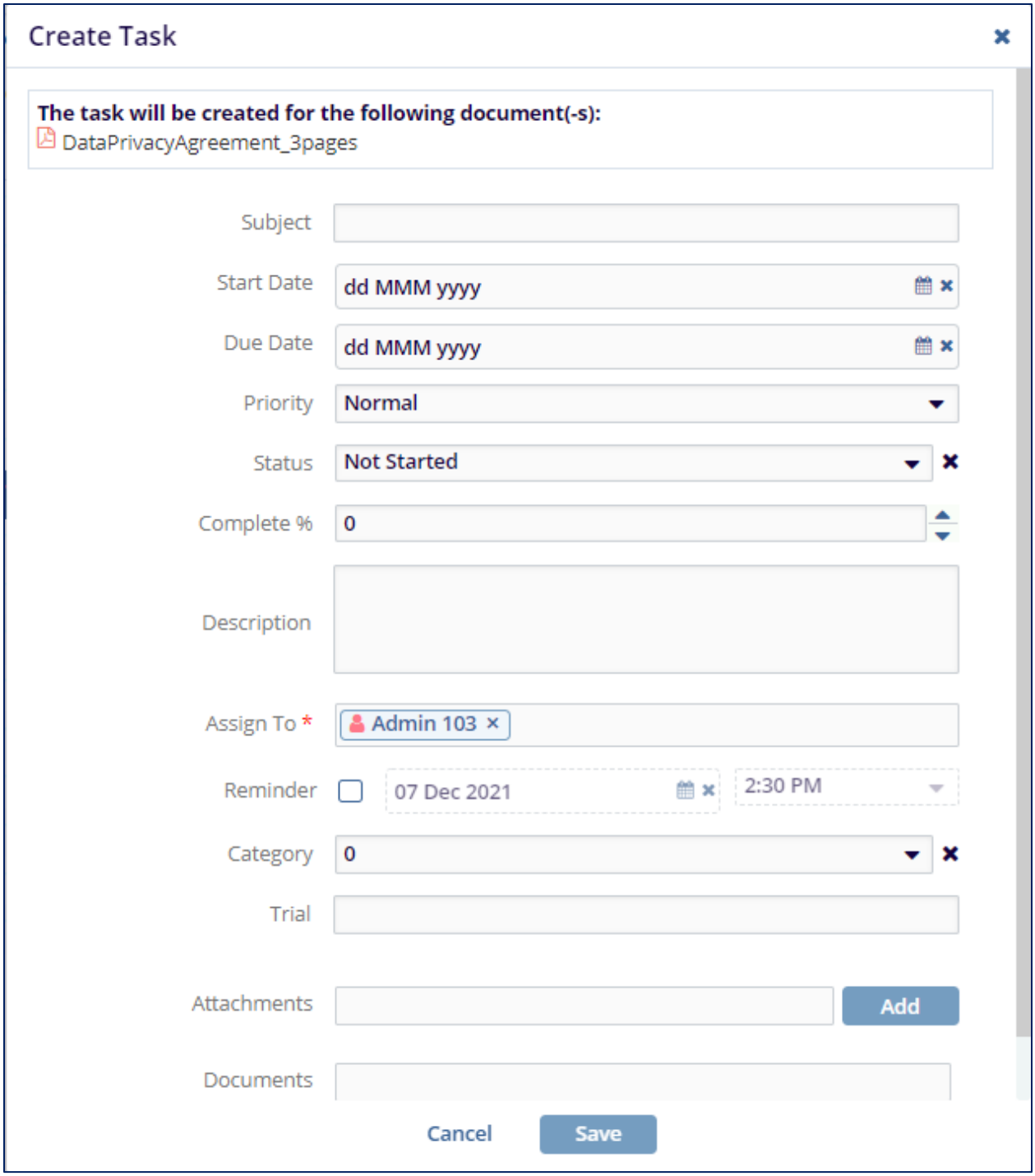
DOCUMENT-BASED TASKS

TI v10.3 introduces the ability to create a task in relation to a specific document. For additional information regarding tasks in Trial Interactive, please see the associated section in the User Guide.

In order to create a task associated with a document, open the document menu either by right-clicking on the document in the grid or by clicking on the three dots on the item line in the grid. When the window opens, choose the "Create Task" option.



The Create Task window will open, and it will indicate that the task is being created in association with the chosen document. Fill in any required information as well as any necessary additional fields and then press "Save" in order to complete the process and create the task. Users with the "Assign Task" action on their user account can create tasks and assign them to other users in the room.



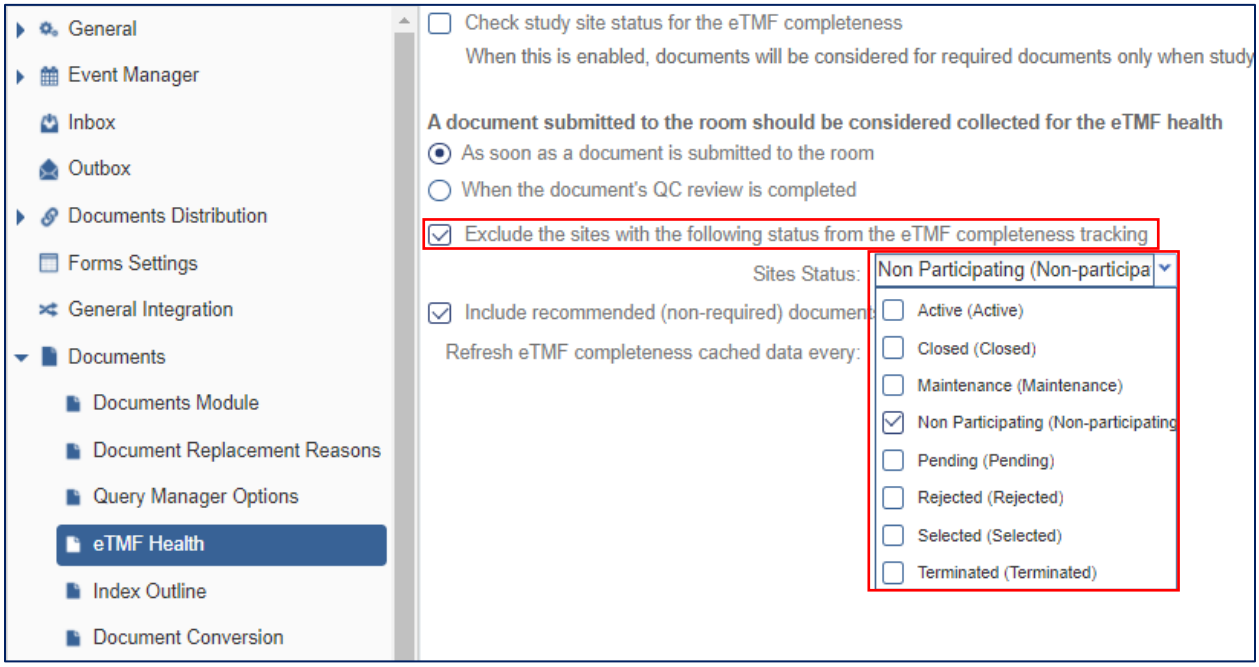
eTMF Health – Site Status

INACTIVE SITES

With the TI v10.2.4 patch, TI introduced the ability for room administrators to decide whether or not inactive sites should be counted in eTMF Health calculations. In order to exclude sites of a certain status from the eTMF completeness tracking, follow the steps below. As always, any changes made to your room's setting should be communicated to your TI Project Manager so that the Change Log can be maintained correctly.

1. **Navigate to the Settings Module → Documents → eTMF Health menu**
2. **Enable the "Exclude the sites with the following status from the eTMF completeness tracking" option by checking the box.**
3. **Select which statuses should cause a site to be removed from completeness tracking by using the dropdown menu.**

See the screenshot below:



Translation

CERTIFIED TRANSLATIONS

When writing clinical documents, particularly those going to clinical sites, it is often necessary to translate them formally to the local language. Because of the possibility of misunderstanding, it is necessary for documents such as patient consents to go through a certified translation process.

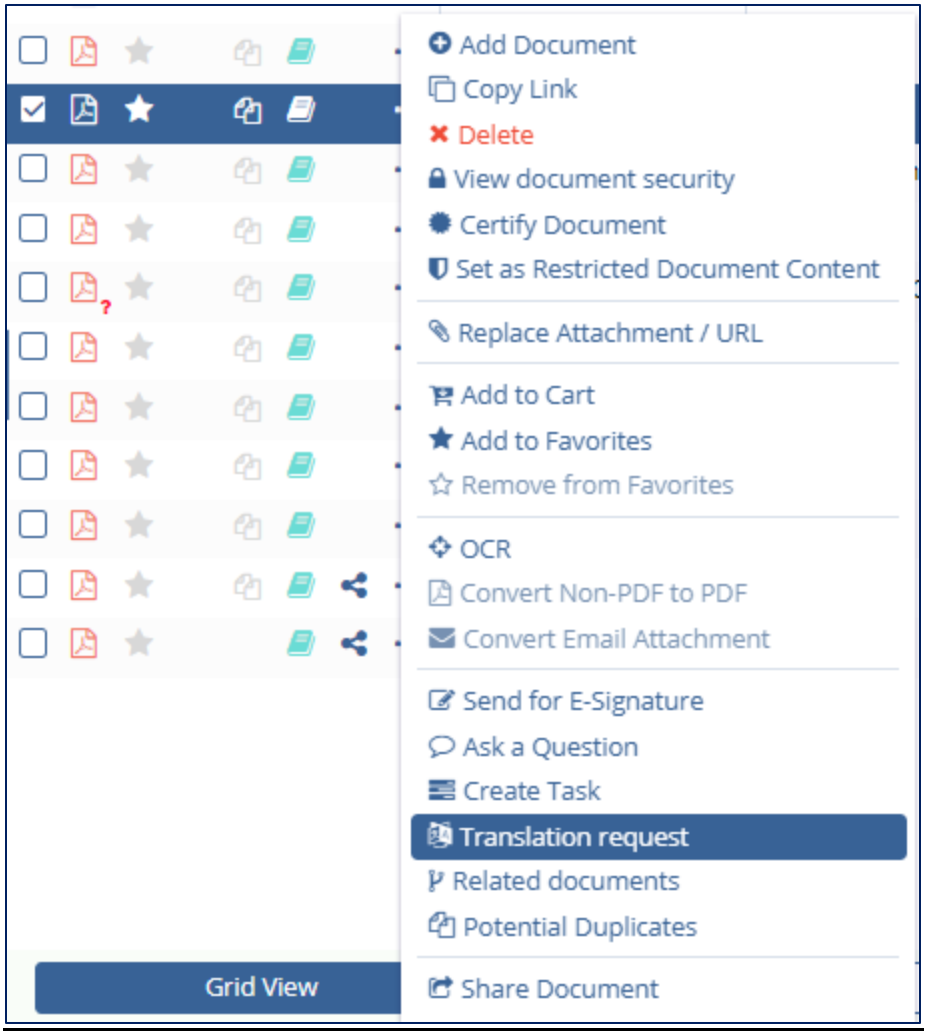
Trial Interactive has incorporated our Certified Translation capability into our trial support solutions, making the request for a certified translation significantly easier. Once sent, this translation will be processed and returned to your document library with the appropriate language set in the document metadata.

In order to activate this feature in your Trial Interactive study rooms, please contact your TI representative or reach out to the Service Desk.

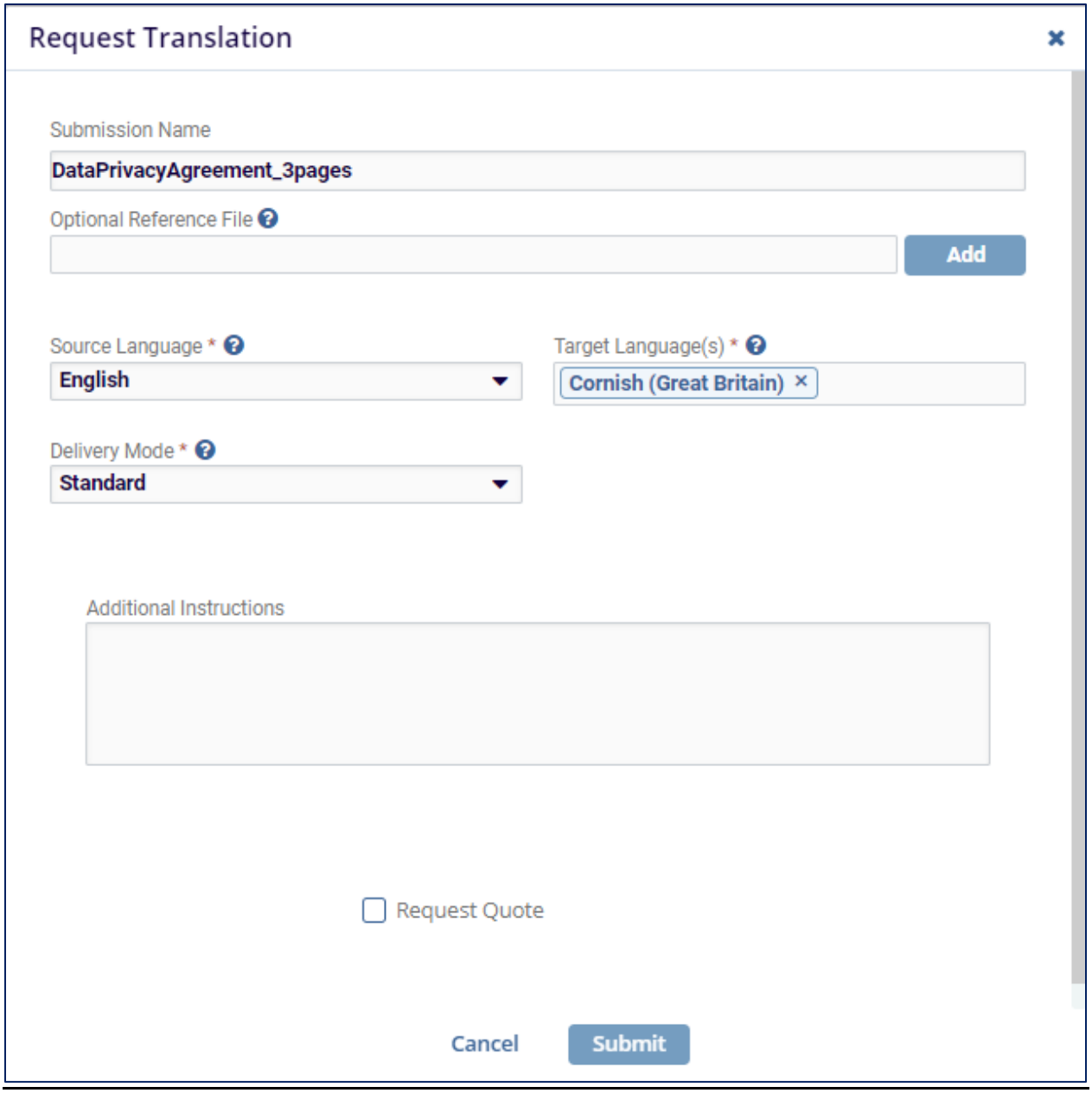
Once The translations feature is active in your room, sending a document for translation is fairly straightforward.

<u>Requesting Translation of a document:</u>

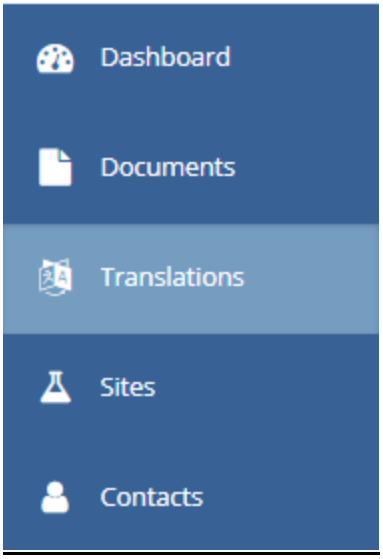
1. **Log in to the room in which the document is stored.**
2. **Navigate to the document and right-click on the line item or use the three-dot icon on the grid line.**
    a. **This will open the document action menu.**
3. **Select the "Translation Request" option.**



4. **Once the Request Translation window opens, fill in the required information and add any additional information, reference files, or instructions.**



5. **(Optional) If you would like to receive a translation quote prior to requesting that a translation be completed, check the "Request Quote" box and press "Submit."**
6. **If you are requesting a translation instead of a Quote, press "Submit" to send the request.**
7. **Translation requests can be monitored in the Translations module by clicking on the Translations icon in the left-hand.**



Once a translation is complete, the file will be added to the study room automatically and the correct language will be indicated in the document metadata. The translation will also be automatically linked to the source document for future reference.

Reports

New Cross-Study Reports

With 10.3 Trial Interactive customers would have three standard out-of-the-box cross –study reports available. These cross-study reports will be available only to authorized Users, who are added to a special security group. Please reach out to your TI Representative or the TI Service Desk in order to request access to these reports for members of your study team as appropriate.

AUDIT SUMMARY REPORT

This new cross study report displays the summary results of Audits/ Quality Reviews across multiple studies.

QUERY HISTORY REPORT

A new cross study report to display all transactions related to Queries that have happened the previous day across multiple rooms.

REJECTED DOCUMENT REPORT

This report displays the rejected documents over the previous day across multiple studies.

DOCUMENT REPLACEMENT REPORT

This report displays a list of all documents that have been replaced in the last 30 days in the study room. The new report has been added to the reports dashboard for all Users.

Portfolio KPI Dashboards

SELECT RELEVANT HEAT-MAP METRICS

With this improvement, study Admins can choose the metrics to be displayed in the Heatmaps for KPI Dashboards. The selections made by study Administrators would be applicable for all Users of the study room.

CONFIGURABLE TARGET PERIOD

Room administrators will be able to adjust the Target Period for the Heatmaps (KPI Dashboard). This can be done from the Settings area of your Trial Interactive room. For assistance in making changes to room settings, please reach out to your Trial Interactive representative or to the TI Service Desk.

SELECT ALL / UN-SELECT ALL

With this improvements Users can easily select or de-select all options in the filters for Portfolio Dashboards without having to individually selecting the options. Each KPI dashboard dashlet has an individually configurable filter in order to make it easier to control what information is shown at any given time. With 10.3 users will have the option to select or unselect all from within the filter.

Trial Management

CTMS INTEGRATION

A Clinical Trial Management System has the capability to track all trial activities as well as the collection of documents and evidence that must ultimately be published to the eTMF. As reports and letters are completed, they must be captured in the eTMF as the final record.

Trial Interactive 10.3 introduces the following capabilities for both eTMF and Content Management rooms:

- **All Studies, Sites, Countries, Contacts, and other data is automatically updated in the TI eTMF, ensuring a single point of truth for both systems.**
- **Sites and Contacts created in the CTMS will trigger the creation of Required Documents in TI.**
- **The TI CTMS can create and publish Monitoring Reports, Letters, and many other trial-related documents from source data and deposit them in a TI room for review and approval, and then publish them to the eTMF archive for safekeeping.**