Trial Interactive v10.4 - Supplemental User Guide v1.0

APPROVALS

Product Owner

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Quality Assurance

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Contents

Chapter 1. Trial Interactive 10.4- 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 88 and later • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • NOTE: Microsoft® concluded support of Internet Explorer™ 11 in January 2022. We expect degraded performance with Internet Explorer™ 11 and it is no longer supported with 10.4.
Client Software	• For Edit Online Support, Microsoft Office 2016 or higher is required • For MSWord document generation, Edit Online is recommended, and all templates must be Microsoft Office 2016. • 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

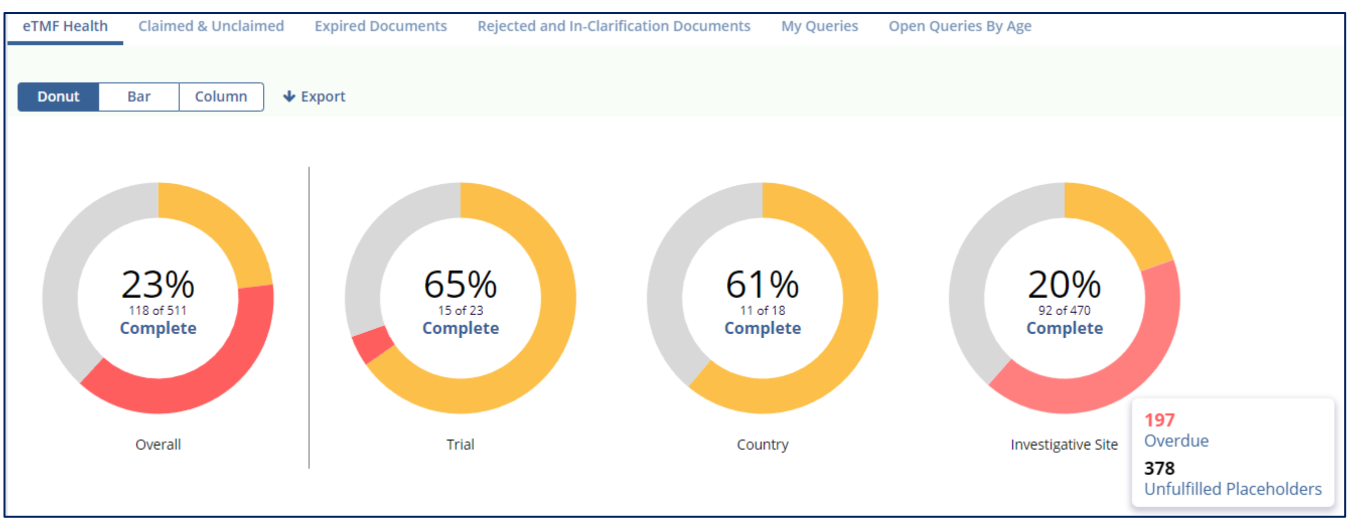
What's New in TI v10.4?

eTMF Health

ETMF-2049 - IMPROVEMENTS TO THE ETMF HEALTH DASHLET AND DOCUMENT COUNT

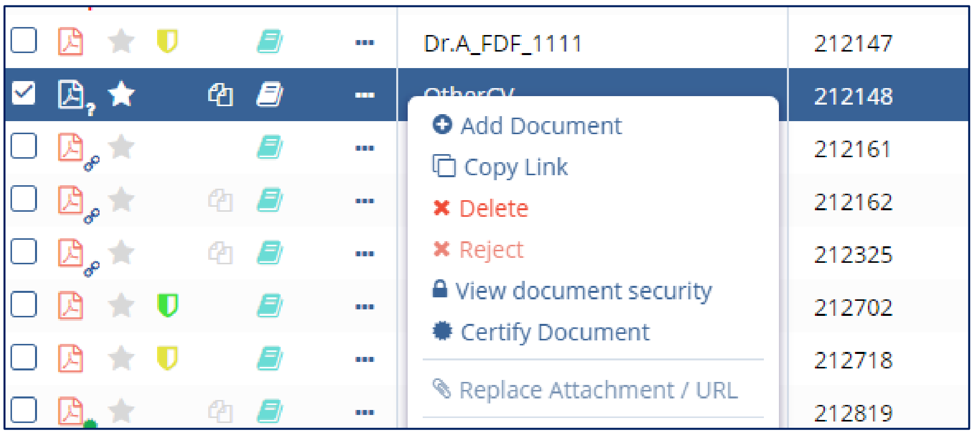
This dashlet now follows the following definitions:

- **Unfulfilled Placeholders / Missing: This is the count of placeholders that have been set up as required in the eTMF but are still waiting to be collected or marked as final. These are also referred to as Missing Required Documents, or just 'Missing'.**
- **Fulfilled Placeholders: This is the count of placeholders that have been collected, indexed, QC'd, and marked as final in the eTMF.**
- **Collected: This is the total count of final, collected documents in the eTMF, which represent not just a count of fulfilled placeholders, but also additional documents and versions collected where more than one document has fulfilled a particular placeholder or eTMF requirement. For non-TMF rooms, this metric may represent non-final documents as well depending on room configuration.**
- **Overdue: This is the total count of unfulfilled placeholders that are now past the due date set by a completed Event or milestone in the eTMF. When an Event or milestone is marked complete, the unfulfilled placeholders required by this Event are marked as due to be collected based on the Event completion date. A Due Date Period is generally added to provide time to collect and mark the documents as final, and this period is added to the completion date to determine each document's due date.**
- **Overall: This dashlet also now shows an Overall measure that sums up the entire eTMF.**



ETMF-2502 – THE ‘REJECTED’ FOLDER

- **A new setting is added to support a Rejected folder within the eTMF for Room Administrators, and a new Document Rejection function is now available to Admins, Document Managers, and Room Managers. Any documents in Upload, Inbox, Staging, and Rejected Folders are not considered to be Final. A 'Reason for Rejection' dropdown is now available for workflow documents and documents in the rejected folder/status are now excluded from eTMF health calculations.**
- **<u>NOTE:</u> Users will not be able to drag and drop documents into this folder in order to prevent awarding an erroneous status should a non-rejected document be placed in this folder.**

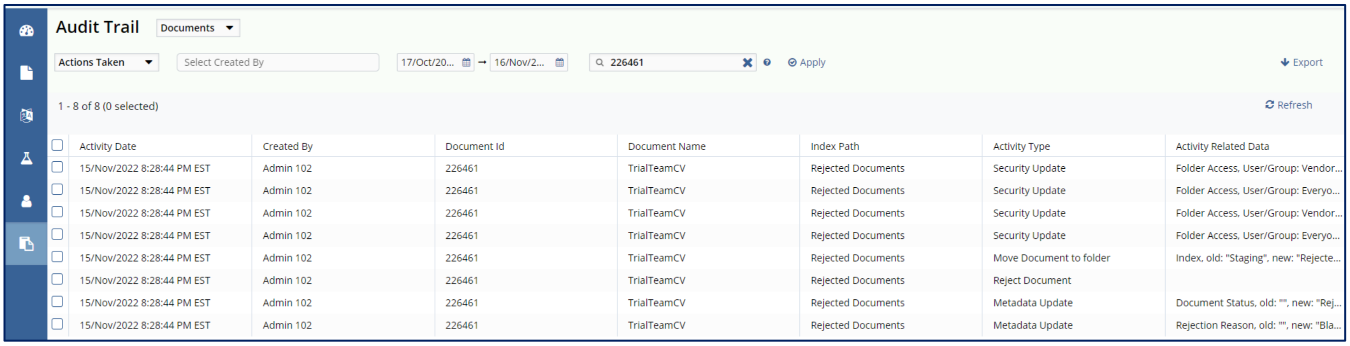


In order to reject a document outside of the standard workflow steps, the user must either be an administrator or they must have the Document Manager action enabled on their user account. For users who meet these requirements, rejecting a document can be accomplished by right-clicking on the document or by clicking on the three-dot menu in the grid and selecting the ‘Reject’ option from the document actions menu.

Audit Trail

TTI-2409 – AUDIT TRAIL ACCESS FOR REGULATORY INSPECTORS AND INTERNAL AUDITORS

While TI has provided a way to export the audit trail, an in-system interface is much simpler. This improvement is also intended to provide a straightforward way to execute UAT against 21 CFR Part 11 requirements. The interface allows searching by a date range, filtering by action type, and a search by Document ID. For additional information on how to use the Audit Trail module, please see the section on Exporting Instant Audit Trails later in this guide.



Activity Date	Created By	Document Id	Document Name	Index Path	Activity Type	Activity Related Data
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Security Update	Folder Access, User/Group: Vendor...
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Security Update	Folder Access, User/Group: Everyo...
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Security Update	Folder Access, User/Group: Vendor...
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Security Update	Folder Access, User/Group: Everyo...
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Move Document to folder	Index, old: "Staging", new: "Rejecte...
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Reject Document	
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Metadata Update	Document Status, old: "", new: "Rej...
15/Nov/2022 8:28:44 PM EST	Admin 102	226461	TrialTeamCV	Rejected Documents	Metadata Update	Rejection Reason, old: "", new: "Bla...

Quality Review Audit

ETMF-2327 – COPYING AN EXISTING AUDIT

Users of Trial Interactive often need to run the same quality review audit multiple times, changing a few details such as the participating auditors. You may also need to change the audit scope after an audit has started, but do not wish to impact the current audit.

There are now two options:

- **<u>Duplicate an Existing Audit:</u> Use this option when you wish to duplicate an existing audit, running the same scope again but with different users involved. You may update the scope in the new audit if you need, but once it is published, no further scope changes can be made.**
  - **To duplicate an existing audit, select the audit from the list of existing audits and press the 'Duplicate' button in the menu bar above the list.**

Duplicate   Add   Edit   Disable   Complete   Delete   Publish Documents

12 Audits 1 Selected

Name	Status	Description	Frequency
2021 Full Audit Review	ACTIVE	Full audit of all submitted docum	
December 2021 Full Audit Review	ACTIVE	Review of all submitted documer	
Q4 2021 Internal Audit	ACTIVE	Q4 Audit of all submitted docum	2w
2022 Full Audit Review	ACTIVE	Full Audit of all documents in roc	
Q1 2022 Internal Audit	ACTIVE	Q1 Audit of all submitted docum	
Q2 2022 Internal Audit	DISABLED	100% of all submitted document	
RAI 2	ACTIVE	100% of currently available unau	
Rosana Test Audit	COMPLETED	50% of all documents in the roor	
Copy of Demo Audit June 2022	COMPLETED		
Partner Audit 2022	DISABLED	This is a partner audit for all doc	
Q3 2022 Internal Audit	ACTIVE	Audit of all submitted document	
Copy of Q4 2021 Internal Audit	DRAFT	Q4 Audit of all submitted docum	2w

- **Documents from Selected Audits: Use this option when you want to create a new audit that contains the documents from prior audits. This allows you to choose from the existing users involved in those audits, and merge and include all the same sets of documents from those prior audits.**

Additionally, this improvement:

- **Simplifies the duplication of existing audits, providing an option to easily do this so that audits may be managed through a regular maintenance cycle.**
- **Corrects the audit scope for audits using the 'Do not include already audited documents' feature, limiting this scope to only Active and Completed audits, and ignoring Disabled audits.**
- **Adds 'Disabled' and 'Completed' statuses for audits, allowing an improved tracking of audit statuses.**
- **Restricts updates to the Audit Scope for existing active audits, requiring duplication of the current audit instead.**
- **Improves the descriptions and tooltips on the Audit Scope page.**

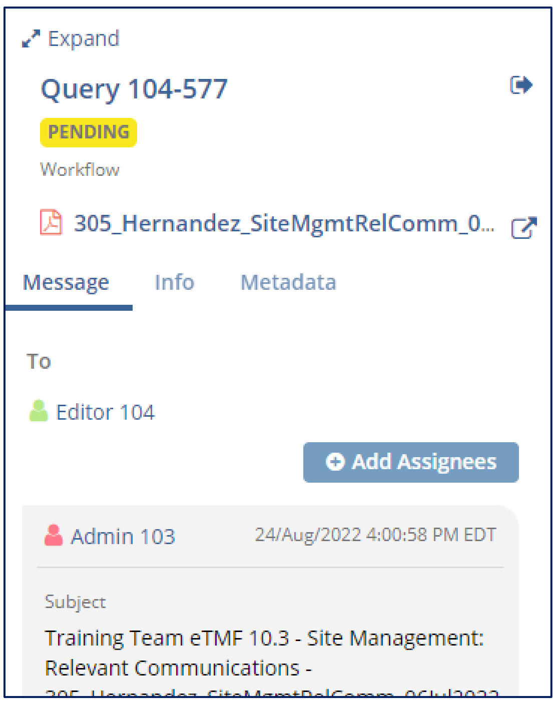
ETMF-2340 - AUDIT MANAGERS WITH THE MANAGER ROLE CAN EDIT DOCUMENT METADATA DURING AN AUDIT.

Manager level users who are added to an audit as a document reviewer can, when full permission is granted, now make edits to some document metadata. Editor level users were granted this permission in a prior upgrade and it has now been extended to Manager level users.

Query

ETMF-591 - ABILITY FOR QUERY MANAGERS, ADMINISTRATOR USERS, AND QUERY CREATORS TO ADD ASSIGNEES TO A QUERY AND SEND IT TO SOMEONE ELSE WITHOUT HAVING TO CLOSE IT.

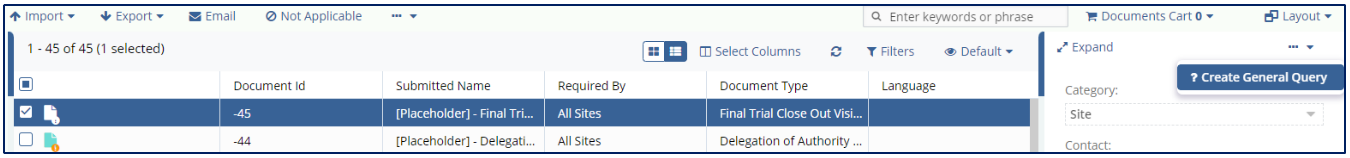
Prior to TI v10.4, if a query was sent to the wrong recipient or if the recipient was unable to assist, the query had to be closed and another, identical query, had to be opened. This is no longer the case. Now, Administrator users and those users who are added to the Query Managers group can add an additional recipient to a query. Users can perform this action by locating the query in the Queries module and pressing the Add Assignees button in the metadata panel on the right.



ETMF-834 – ABILITY TO RAISE A DOCUMENT REQUEST QUERY ON A PLACEHOLDER OR REQUIRED DOCUMENT.

A significant business challenge with eTMF is ensuring that documents are submitted in a timely fashion as the trial progresses. To ensure that happens, it is important to be able to request a document from the user who is responsible for providing it. TI will now allow 'document request' queries to be opened against placeholders

and required documents, providing a simple means to track this as a task that must be completed by the responsible user or department.

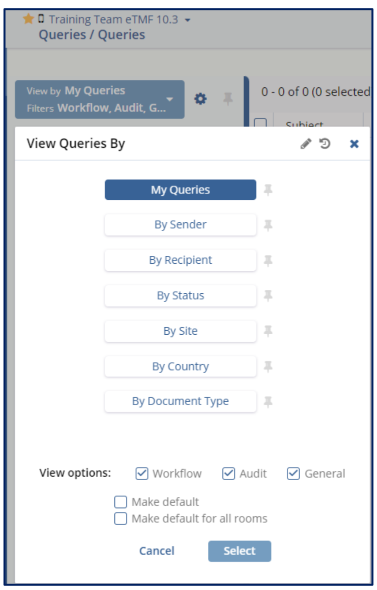


ETMF-2319 - BOTH MANAGERS AND ROOM ADMINS MAY NOW BE ASSIGNED THE QUERY MANAGER ROLE.

Up until now, the Query Manager role has been envisioned as an Editor level function. With TI v10.4, this functionality will now be accessible to Manager and Administrator level users.

ETMF-2339 - MORE QUERY MODULE VIEWS INCLUDING BY SENDER, RECIPIENT, DOCUMENT TYPE, STATUS, SITE, COUNTRY, AND MY QUERIES.

With the launch of the Queries module, users have asked for more ways to view their queries and to sort the available queries in the room for tracking purposes and we have responded by adding several new views to the 'View By' menu above the index panel.

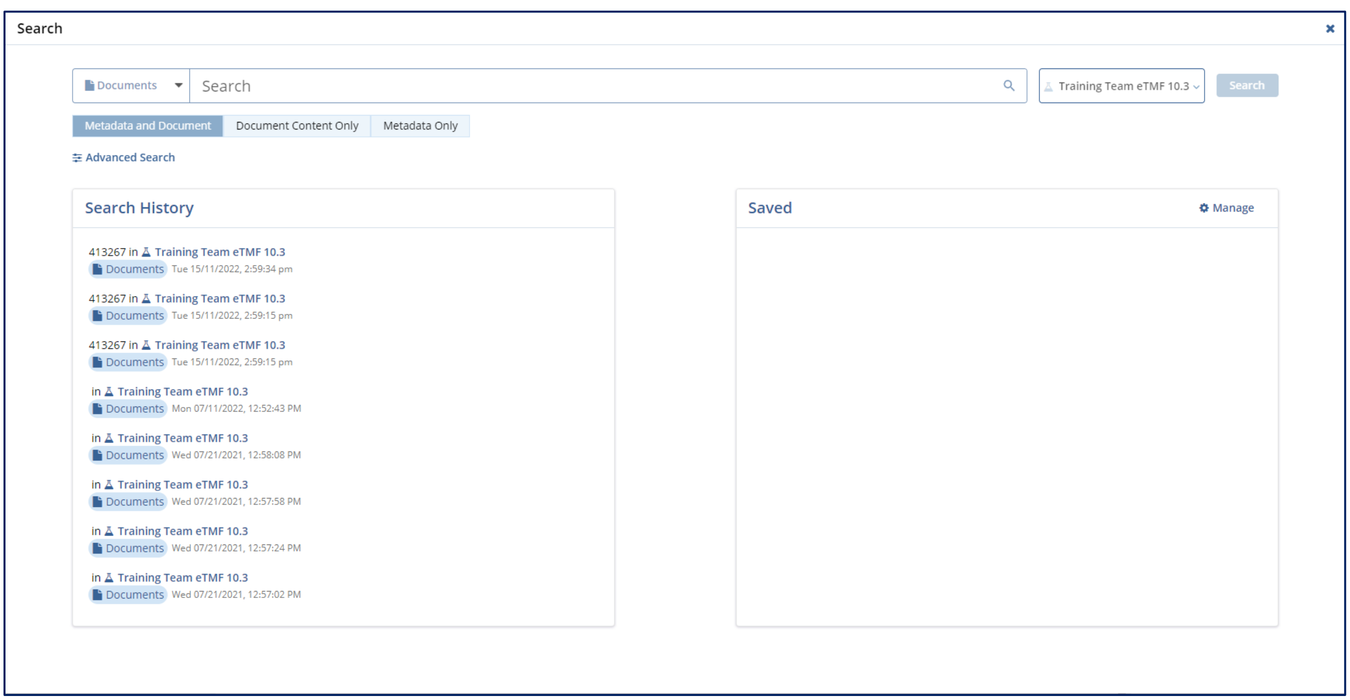


Search

ETMF-747 - TRIAL INTERACTIVE NOW SUPPORTS A CROSS-ROOM, FULL-TEXT INDEXED, SEGMENTED, AND FILTERED SEARCH CAPABILITY, WITH SUPPORT FOR ALL RECORD TYPES AND FACETS, INCLUDING DOCUMENT TYPES AND METADATA FIELDS

This new search interface has the following powerful capabilities:

- **Record-Type search based on topic and record-type, allowing for searching of documents, users, queries, and other segments.**
- **Filters based on any document metadata, implemented as facets to allow simplified fast filtering of search results.**
- **A new full-text index based on automatic text extraction and OCR.**
- **Support for full metadata searching within a room and across multiple rooms.**
- **Integrated selection of saved and recent searches, with rapid re-searching.**
- **Continued support of the custom grid view for search results with integrated exports, compare, document cart, and other actions.**
- **Continued support of instant document review with metadata panel from the search screen.**
- **Actionable result set based on record type, with easy navigation to the document.**
- **Continued support of flexible search terms and wildcards.**



Notifications

ETMF-2040 - ADD NEW NOTIFICATIONS FOR WHEN A DOCUMENT IS REJECTED AND WHEN A QUERY IS RESPONDED TO AND RESOLVED

A set of notifications are added in this release to let the user know when an important action has occurred:

- **Notifications have been added for when a query is responded to and resolved. There are now notifications for when a query is either responded to or resolved. The person that raised a query can now get a notification when a user answers the query, without a need to enter the room. The person that responded to the query can now get a notification when the query is resolved.**

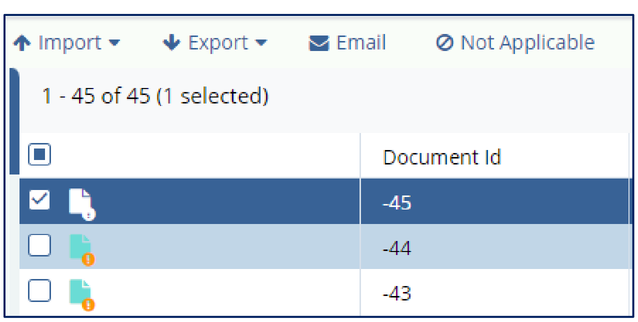
- **There is now a notification available for when a document has been rejected. This is an optional notification available to admins, managers, and others with access to the Rejected folder, as well as to the user who submitted the document.**

Placeholders

ETMF-708 – CAPABILITY FOR AN ADMINISTRATOR AND DOCUMENT MANAGER TO MARK PLACEHOLDERS AND REQUIRED DOCUMENTS AS 'NOT APPLICABLE', OR 'APPLICABLE' WITHIN THE ETMF.

Placeholders and Required Documents are useful to indicate what documents are necessary for eTMF completeness. But quite often, a document is not needed and does not need to be collected for the trial. TI v10.4 introduces the ability to disable a specific required document or placeholder directly in the working and completeness views.

Users can mark the document placeholder as 'Not Applicable' by pressing the button in the menu bar above the grid. Once done, the user is prompted for the reason, which is recorded in the audit trail and available in the grid. If the document is required later, the disabled placeholder may be marked as 'Applicable' and re-enabled.



CTMS Interoperability

ETMF-2196 - CAPABILITY TO PROPAGATE SITE VISITS FROM THE CTMS TO TRIAL INTERACTIVE ETMF AND COLLABORATE ROOMS USING EVENTS.

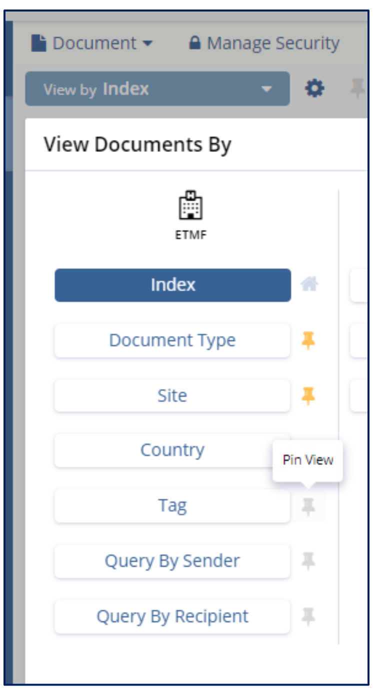
A Clinical Trial Management System has the capability to track all trial activities as well as the collection of documents and evidence that must ultimately be published to the eTMF. As milestones and activities are completed, they often result in final documentation that must be archived. Additionally, documents must often be associated with trial records for viewing and distribution to the study teams. Trial Interactive will introduce the following capabilities:

- **All Visit Status changes configured in the CTMS will trigger Visit Events in the eTMF. These Events may then trigger required documents and placeholder creation in TI.**

User Interface

ETMF-2193 – THE ABILITY TO 'PIN' EXISTING VIEWS USING A PINNED ICON IS ADDED TO THE 'VIEW BY' MENU.

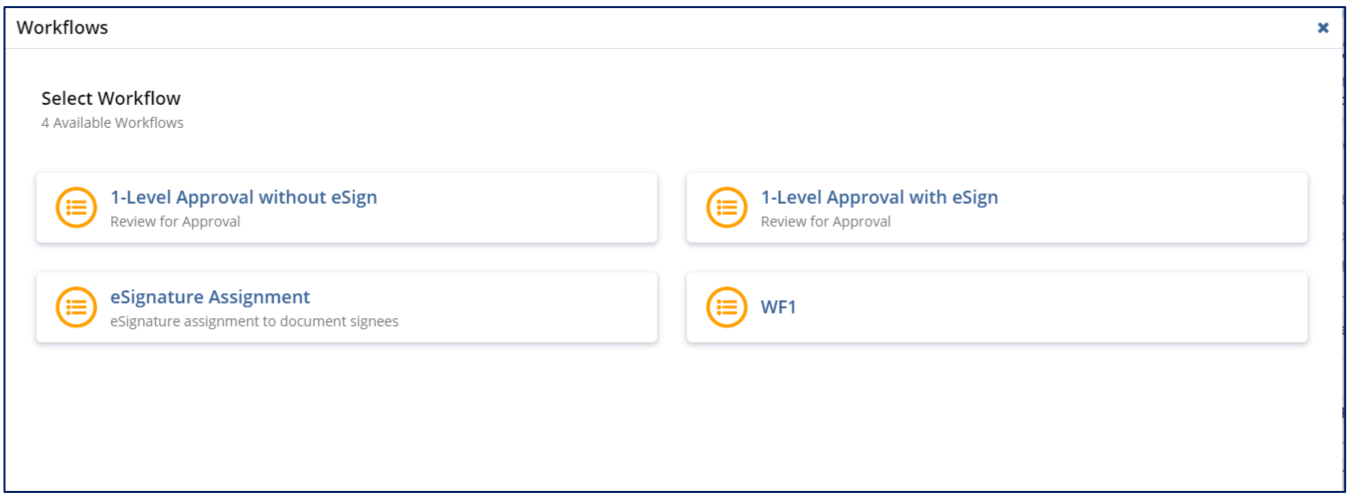
This improvement allows users to select which views they prefer rather than always having to choose from all of the available views. Once pinned, when clicking on the 'View by' dropdown menu, users are presented with only those views they have pinned, providing a faster way to switch to their preferred views Documents module. This can be modified at any time.



Content Workflows

TTI-2485 – IMPROVE THE 'INITIATE WORKFLOW' PANEL, SUPPORTING A SIMPLER, MULTI-STEP WORKFLOW DEFINITION WITH THE SELECTION OF WORKFLOW, REVIEWERS, APPROVERS, AND SIGNATURES.

When starting a workflow on a new document, there are often multiple steps involved that include the selection of the workflow, the reviewers, the approvers, and the signers. This improvement to the workflow wizard supports a simpler, multi-step workflow definition with the selection of workflow, reviewers, approvers, and signatures.



Application Programmers Interface

TTI-2574 - IMPROVE EMAIL SUBJECT LINE AUTO-CODING BY SUPPORTING ADDITIONAL METADATA INCLUDING CATEGORY, SITE, COUNTRY, DOCUMENT DATE, AND DOCUMENT TYPE.

The Inbox Auto-Coding feature was introduced some time ago but now we are introducing more functionality to it.

In order to user this functionality, once enabled in the room:

The user must send the email with the subject line in the prescribed format for the email auto-coding feature to work as expected. The user should separate the metadata using a semicolon and maintain the appropriate spacing for the Document Type.

The standard format is as follows: [Category;Document Type] or [Category;Document Type Short Name;Site Number] or [Category;Document Type;Site Number;Document Date;Country Code]

The first element will be assigned to a category, the second element to document type, and the 3rd to the site. If Category is Site, then there will be up to 5 metadata fields expected for Email subject-line auto coding. 3rd metadata will always be Site # and 4th will be Document Date.

Examples:

site;Financial Disclosure Form;US001

site;FDF;US001

site;fdf;002;2022-02-05;ALB

country;FDF;2011-02-01;ALB

trial;Trial Master File Plan

trial;TMFPlan

TTI-2622 - THROUGH THE API WEB SERVICES, THE CAPABILITY TO UPDATE METADATA FIELDS CONFIGURED FOR THE DOCUMENT TYPES THAT ARE CUSTOM IN THAT ROOM.

When uploading final eTMF documents from another content system or CTMS, users want to be able to send all document metadata fields defined in a room through the API, so they can have flexibility in how they develop their content interfaces. This improvement will support the following capabilities:

- **Required Fields: If the option *'Accept documents upload without the required metadata?'* is enabled in the room, the *AddDocumentForSite* API Web Service will accept documents with metadata that do not contain all required fields.**

- **Custom Fields: If the option *'Accept documents upload without the required metadata?'* is enabled in the room, the *AddDocumentForSite* API Web Service will accept documents with custom metadata. These additional metadata fields can contain text, numbers, picklists, and any value currently supported. If invalid data types or undefined picklists are sent, the field will not be set.**

- **Error handling: If the option *'Accept documents upload without the required metadata?'* is enabled on the room, invalid fields, field values, or missing required fields will be indicated in warnings and error responses to the API call, providing the caller details on the invalid fields that failed to be set successfully.**

Reports

REPORT-47 - EVENT LISTING REPORT

With 10.4 a new standard report is available that lists all the events set up in the study room. The report provides relevant information including: Event Name, Category, Event Type, Event Status, Status, Progress, Planned Date, Completed Date, Due Date, Due Date Period, Country, and Investigative Sites. Users can filter this report by Category, Status, Country, and Investigative Sites. Additionally, users shall be able to sort the data by events' Planned Date and Due Date. With this report, users can more easily identify past and upcoming events and make their plans accordingly.

REPORT-48 - EVENT PAST DUE REPORT

TI Users need a standard report that provides a listing of events that are not complete and are past their planned date. With 10.4 a new standard report listing past-due events is made available to users. The report lists the Event Name, Category, Event Type, Event Status, Status, Progress, Planned Date, Country, and Investigative Sites. Users can filter this new report by Category, Country, and Investigative Site. Additionally, users can sort by events' planned and due dates.

REPORT-53 - POTENTIAL DUPLICATES REPORT

With 10.4 TI Users will have access to a new standard report that lists all documents that have potential duplicates. The report provides details (Zone, Section, and Artifact) for the potential documents. This report helps treat duplicate documents, which is critical to eTMF health.

REPORT-62 - AUDIT USERS CROSS-STUDY REPORT

With v10.4 the existing study-level standard report for invited and active users as well as their room/module access levels is now available at a cross-study level. This report helps with due diligence in user activity and avoids the necessity of maintaining a separate sheet outside of the system to give the same information. Cross-study reports are not available by default for all users due to security reasons and access to such reports should be requested through the Project Manager.

TTI-2572 - AUDIT INACTIVE USERS CROSS-STUDY REPORT

With v10.4 the existing study-level standard report for users who have not logged into the system for over 120 days, is available at a cross-study level. This report helps with due diligence in user activity and avoids the necessity of maintaining a separate sheet outside of the system to give the same information. Cross-study reports are not available by default for all users due to security reasons and access to such reports should be requested through the Project Manager.

REPORT-21 - DOCUMENT METADATA CHANGES REPORT UPDATES

Improvements have been made to the Document Metadata Changes report so that it now tracks changes to the document metadata regardless of the status of the document. Prior to this improvement, only metadata changes to the documents in the final status were tracked. This improvement helps TMF managers to identify commonly made metadata mistakes and frequent defaulters, highlighting underlying training needs.

REPORT-66 - INVENTORY AND COMPLETENESS REPORT UPDATES

A minor but important improvement has been made to existing inventory and completeness reports (all categories) whereby these reports shall now provide the additional details below:

- **Document Submitted Name**
- **Document Submission Date**
- **Document Link**

REPORT-28 - FINAL DOCUMENTS REPORT UPDATES

The Final Documents report has been modified so that the report shall show 'Submission Name' instead of 'Document Title' and shall have 'Document Date' instead of 'Document Signature Date.'

REPORT-67 - HEATMAP FOR RESOLVED QUERIES REPORT UPDATES

The logic for color coding the resolved queries in the heat maps in the cross-study portfolio dashboards is being revised. With this change if the In-Progress and Pending queries are at 0%, the resolved queries, also being at 0%, will now be reflected in green color as this is the true representation.

REPORT-39 - ALL DOCUMENT ACTIVITY REPORT UPDATES

With TI 10.4, the 'All Document Activities' report now displays an additional column providing the email ID (user ID) of the person performing the activity.

REPORT-16 - ETMF PORTFOLIO COMPLETENESS DASHLET

- **Portfolio Dashboards now have a new dashlet for eTMF completeness. The dashlet displays the following breakdown:**
- **Required Documents**
- **Submitted Documents**
- **Missing Documents**

The dashlet allows users to filter the results based on the document categories (Site, Country, and Trial). This new dashlet helps CROs and Sponsors monitor the completeness view for a portfolio of studies.

ETMF-1924 - TIMELINESS OF QUERIES DASHLET

With TI v10.4 a new dashlet is available that allows users to apply filters to calculate the time taken from:

- **The time a query is raised to the time a response is received,**
- **The time Response is received to the time the query is resolved.**
- **The time a query is raised to the time it is resolved.**

This new dashlet helps query managers identify bottlenecks for faster query resolution.