

# TRIAL INTERACTIVE 10.1 – RELEASE NOTES

Version 1



This controlled document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2020 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Quality Assurance Department. Other names may be trademarks of their respective owners.

# Version History

Author	Revision #	Date	Comment
Yogesh Inamdar Ankita Bora	1.0	16-July-2020	Document Creation
Jay Smith	1.1	22-Sept-2020	Update for 10.1 Release

# Trial Interactive

**TransPerfect's *Trial Interactive*** has been used successfully by TransPerfect customers for over 10 years in hundreds of Clinical Trials for the storage of critical trial documents as part of the Electronic Trial Master File. Trial Interactive's Platform is a web-based and mobile-enabled software-as-a-service (SaaS) application that provides eClinical solutions for eTMF as well as eFeasibility, Content Management, Learning Management, Study Start Up, Clinical Trial Management, and a variety of other tools used in the conduct of a Clinical Trial. The Trial Interactive Platform has the following features:

- An electronic Trial Master File archive that meets all regulatory, security, access, and storage requirements in all countries and regions.
- A fully hosted solution that is 21 CFR Part 11, Annex 11, ERES, GDPR, HIPAA, and GxP compliant.
- A single access point for all trial content and documentation for both sponsor and site personnel.
- Support of a series of TMF workflows including document import and coding, quality review, audit and inspection, document certification, and the capture of other Clinical Trial documentation.
- A thin-client, consumer-grade user interface that supports most major browsers as well as a mobile app that supports both iOS and Android phones and tablets.
- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of reviews and authoring solutions.
- A full-featured eLearning system designed specifically for GxP compliance.

## Electronic Trial Master File

Trial Interactive's electronic Trial Master File (eTMF) is a secure cloud-based solution enabling real-time collaboration for both Sponsors and CROs, supplying value and ease of use for Trial stakeholders across the board and now bringing enhanced transparency and visibility to your trial. TI eTMF can help your organization:

- Track and view study documentation in real-time;
- Check the status of TMF content at the study, country, and site-level in real-time from any location;
- Create, upload, and execute quality checks on documents within the system;

- Ensure inspection readiness through the use of the Quality Review module;
- Get better insight into your trial through Key Performance Indicator (KPI) reports; and
- Streamline processes and reduce costs.

## Study Start Up

Trial Interactive’s Study Start Up offers the real-time distribution of Essential Document packages, tracking of completion progress, IRB/EC submission, and meeting dates to supply projections of ethics approvals. This yields a faster and more realistic timeline for site activation visible to study teams. Trial Interactive SSU enables you to complete, submit, and securely host clinical trial-related regulatory documents online, significantly speeding up trial processes. The system creates efficiencies through streamlined communication between sponsors, sites, and CROs, driving time, and cost efficiencies. Cycle time metrics can be viewed to allow study teams to become more efficient in all future studies. SSU’s main features are:

- **Faster Site Activation:** TI Study Start-Up speeds the collection and finalization of essential and regulatory documents by the Study Startup Specialist to expedite site activation for national and global studies.
- **Workflows:** Fully integrated with TI eTMF, the process - from submitting regulatory packages to site activation and study management - is seamless and efficient. 21 CFR Part 11 compliance, with Audit Trail functionality and support for the country and local regulations, means improved compliance and risk mitigation throughout your site activation process.
- **Distribution, Submission, and IRB Connect:** TI Study Start-Up offers the real-time distribution of Essential Document packages, tracking of completion progress, IRB/EC submission, integration with major central IRBs, and tracking meeting dates to provide projections of approvals for a faster and more realistic timeline for site activation.

## Content Management

TI provides an online collaborative workspace, which enables collaborative and controlled document authoring and approval. Designed to include 21 CFR Part 11 compliant workflows and approvals, the solution offers an end-to-end service platform for your organization’s content management requirements. These collaborative workspaces allow users to benefit from the following solutions:

- **Study Collaborate** is a shared workspace for clinical teams to provide Sponsors, CROs, and Sites a place to manage and share documentation to be used in the Clinical Trial and ultimately published and archived in the eTMF.

- TI's Content Management System provides controlled document workflows to an organization for clinicians, quality, R&D, and other life sciences teams to collaboratively author, review, approve, distribute, and sign-off on regulated content and documents.

TI's Content Management solutions can provide your organization:

- A single place to share and collaborate on clinical documentation
- The ability to align document work streams with regulatory compliance practices for document authoring, approval, control, and related training.
- Management of the lifecycle of documentation while allowing appropriate groups to retain constant access and visibility to essential documents.
- The ability to co-author and collaborate on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.
- The ability to complete the end-to-end document process with an electronic signature for document approvals.
- The ability to follow critical processes for metadata, approval, and sign-offs by publishing directly to the TMF.

*TI 10.1 is a minor release focused on feature improvements and defect resolution. These release notes concern all major modules of Trial Interactive, including eTMF, Study Start Up, and Content Management Solutions.*

# Hardware and Software Requirements

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

<p>OS</p>	<ul style="list-style-type: none"> <li>• Windows Version 7 or higher</li> <li>• All currently supported Mac OSX releases</li> <li>• iOS and Android for myTI mobile app (see myTI release notes)</li> </ul>
<p>Browser</p>	<ul style="list-style-type: none"> <li>• Microsoft Edge: Version 20 or later</li> <li>• Google Chrome: Current release and earlier</li> <li>• Mozilla Firefox: Current and ESR releases</li> <li>• Apple Safari: Current release and earlier</li> <li>• Internet Explorer: Version 11 or later</li> </ul> <p>NOTE: Microsoft® stopped supporting Internet Explorer™ 8 and Internet Explorer™ 9 in January 2016 and will stop support for Internet Explorer™ 10 in January 2020. Beginning with the release of TI 10, we expect slight degraded performance with Internet Explorer™ 11, and no longer support Internet Explorer™ 10. Users accessing TI with this and older browsers will see in some cases a degraded experience and may have trouble using certain features.</p>
<p>Client Software</p>	<ul style="list-style-type: none"> <li>• Optional: Adobe Acrobat®, Acrobat® Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer.</li> <li>• Optional: Drag and Drop from Outlook to TI 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®.</li> </ul>
<p>Optional Add-Ons</p>	<ul style="list-style-type: none"> <li>• Optional: For SAS Datasets, SAS Viewer or compatible software must be installed. The free version is available here: <a href="https://support.sas.com/downloads/browse.htm?fil=&amp;cat=74">https://support.sas.com/downloads/browse.htm?fil=&amp;cat=74</a></li> <li>• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions)</li> <li>• Adobe Sign (Latest Adobe Document Cloud Version)</li> </ul> <p><b>NOTE:</b> The Snowbound Viewer is now deprecated in TI 10. All features of Snowbound are now available in the TI Viewer.</p>

# TI v10.1 Overview

TI v10.1 is a release focused on both new features and defect resolution. These release notes concern all major modules of Trial Interactive, including eTMF, Study Start Up, and Content Management.

## **ESTIMATED DATE OF RELEASE**

September 25, 2020

# Upgrade Schedule

Once approved for release on the date noted above, this version would be deployed to the Multi-tenant (MTI) environment during the normal maintenance windows, as noted below:

## **ESTIMATED DATE OF MULTI-TENANT (MTI) UPGRADE**

September 25, 2020

## **ESTIMATED DATE OF EU MULTI-TENANT (MTI) UPGRADE**

October 16, 2020

## **DATE OF DEDICATED CLIENT UPGRADE**

Please contact your TransPerfect Project Manager to discuss your plans for moving existing studies to, or starting new studies on, this new version.

# Platform Features

## MULTI-TENANT SSO

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

A change to the sign in page has been made to reflect the possibility of multiple providers. The Trial Interactive sign in page will now first prompt the user for their email address and, based on the domain, will either prompt for a password or redirect to the configured Identity Provider.

## OUTLOOK DRAG AND DROP

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

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

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

## CROSS-ROOM DOCUMENT SHARING

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

Each of these units broadly has its own workflows, approval cycles, and policies for the management of content. They also have separate owners who want control of the



content management and metadata policies within. When it comes to a Clinical Trial, much of this content is archived and ends up in the Trial Master File.

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

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

## eTMF Features

### RESPONSIBLE DEPARTMENT VIEWS

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

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

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

### QUERY ANY DOCUMENT

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

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

The standard query workflow process is then followed, allowing the responder to clarify the query, or respond with updated content. All back-and-forth is captured in the document audit trail as normal. Queries may now be responded to directly within the room as well as attached to an email response.

Users can see what queries are assigned to them just like they would their tasks, through a notification in the user menu, the query view, or the corresponding dashlet. They may be reminded about their queries through a message or newsletter.

Documents with open queries will show with an icon in the index and working views, and queries may be filtered by site, country, issue type, and other configurable filters. Open queries against collected and final documents also show in the 'My Queries' and 'Queries by Status' dashboards along with standard workflow and audit queries.

### STAGING AREA PREVIEW

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

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

### QUALITY REVIEW COMMENTS

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

### THREE-COLUMN DASHBOARD LAYOUT

Trial Interactive 10.1 brings back the two and three column layouts to the dashboards in addition to the single-column tabbed view introduced in TI 10. This provides more flexibility, allowing dashlets to be repositioned and configured to fit the needs of your team.

- All standard TMF dashlets are available to show in different chart styles, such as donut, and horizontal or vertical bar chart layouts.
- If project training in Global Learn is required for access it is clearly shown in an eLearning dashlet with courses listed.

- For Content Management customers, the in-progress collaborative reviews are shown, as are popular documents, favorites, approvals, and required signatures.
- Administrators can set the default dashlet layout for each user role directly from this page, defining it for all users of the eTMF room.
- Users can now create their own groups of dashlets and add it to their dashboard.

## MACHINE LEARNING METADATA EXTRACTION

The auto-classification of an eTMF document is consistently accurate when enough document identification data has been collected and the machine learning model has been trained by the clinical team.

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

Trial Interactive has been trained on a set of common eTMF document formats with a focus on 12 primary Document Types out of 32 structured essential document formats. Non-standard formats or customer-specific formats must be trained individually for best results.

## IMPROVED METADATA SEARCH

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

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

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

## DUPLICATE CHECKS

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

- Documents are now flagged as a possible duplicate if they are identical in every way to a document that already exists in the eTMF room. This functions using the documents ‘Hash Value,’ ensuring that marked documents have identical content.
- Documents are now flagged as a possible duplicate if there is a document with an identical Generated Name at any step in the QC workflow process.
- These flagged documents can be identified through an icon. Once they are claimed, the user will be prompted to compare them. Note that the user may opt to ignore the flag, for example, if the document is known to be a duplicated site document.

## CERTIFIED COPY

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

- You can upload a document in a room that has enabled certified copy, and you can verify the document uploaded and review copy certification text before providing credentials to certify the document.
- You can review a certified document and view the details related to that certification.
- If you edit a certified document, the document will no longer be a certified copy.
- The text used as the certification criteria is configurable by room, as well as the ability to define a default reason.
- This feature also works in the myTI mobile app.

## SCANNING AUTOMATION

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

With 10.1, Trial Interactive will make available our production scanning processing system. This system provides, through a simple QR code-based metadata solution, a way to quickly scan boxes of paper to be classified immediately and automatically into a Trial Interactive eTMF room. Information about the source of the document is then

filled out at the point of scan, so that the document may be processed within the TI staging area where the classification is most easily done.

## Study Start Up Features

### **ABILITY TO MARK SITES AS CLOSED**

As a Clinical Trial is completing, the investigative Sites must ultimately be closed. While not typically part of Study Start-Up, this process is very much a part of the Clinical Trial lifecycle.

With Trial Interactive 10.1 the system shall have the ability to mark Sites as closed once the trials are completed for the Sites. Once closed, these Sites will be moved to a separate folder for closed sites.

Advanced Validation for metadata fields is still available when Sites are marked as Closed.

### **SUPPORT FOR MULTIPLE TRANSLATIONS AND MULTIPLE IRB/EC APPROVALS**

Quite often, the same Document Type requires a translated version, for example, a regulatory authority may require the document in French, German, and English.

Additionally, there may be multiple IRB/ECs required in the regulatory approval workflow, and so the same Document Type may need to be recorded for each of these separate organizations.

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

- Language
- IRB/EC

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

### **ADVANCED VALIDATION**

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

With SSU 10.1, Sites can now be configured to require a set of fields to be filled out with initial site creation and require additional fields that must be filled out before the

site can be marked Active. This allows a simplified creation process, and at the same time ensures that all required information is collected prior to the Investigative Site going live.

## DOCUMENT HISTORY

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

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

# Content Management Features

## SIMPLIFIED CHECK-OUT

With CMS 10.1, Users who check-out documents for editing will now by default use the online collaborative editing feature. Users may decide if they would prefer to use their local MSOffice™ application for editing a document. Selecting this option will now open the document in the local application automatically, allowing the user to save the document for offline editing.

Once the user has completed their changes, the system will prompt the user to upload the locally saved version upon check-in.

This change will simplify the options available to users. NOTE: Any document checked-out using the online editor can always be edited later in the native MSOffice™ format.

## ROLE-BASED CONTENT VIEWS

When Editors are looking for documents, they typically want to see the latest, most CURRENT, draft version, so they know what's in progress, what needs to be reviewed, and what is currently approved and effective. They will be able to see the latest edits.

Conversely, when Readers are looking at documents, they will see the current, EFFECTIVE version.

In 10.1, TI CMS will provide users with the most logical views for each role, showing Readers the EFFECTIVE version, and Editors the CURRENT version.

## SIMPLIFIED WORKFLOW START

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

## FLEXIBLE CONTROLLED DOCUMENT STATES

For Controlled Documents, there may be a need to make a document Effective immediately or make a document Effective with or without a Periodic Review Period.

With 10.1, Document managers will be able to control what does or does not apply to a document providing the ability to meet the business requirements of the document with ease. Document owners will be able to:

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

## IMPROVED WORKSPACE NAVIGATION

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

Within the Document Repository, users can click on the collaborative icon to take them to that document in the Collaborative workspace. Users can click on the workflow icon to go directly to the document and its status in the Document Lifecycle.

## COLLABORATE WITHIN A CONTROLLED DOCUMENT WORKFLOW

In CMS 10.1, Document Owners have more workflow choices for their Controlled document.

Workflows can be created for business needs providing review steps that allow a document edit, approval steps which will provide an approval event in the document history as well as an E-Signature step to obtain signatures on the document.

## VERSION LABELS

Upon document upload, users will be able to set the initial version in Trial Interactive allowing the document in Trial Interactive to be able to inherit previously defined versions.

Trial Interactive will allow for the initial version of a draft document to be set as 0.1. The control of the document version labels will allow organizations to easily follow their own procedure for document management.

## ADDITIONAL DESIGNATION FOR TI E-SIGN

Roles can be defined and leveraged during the E-Signature step. The standard definitions will create consistency across all signatures.

During the creation of the E-Signature request, each signer can be associated with a role for the document. This allows not only the user's title, and reason for the signature to be displayed as part of the E-Signature record but the role of the person in the lifecycle of the document.

Title and Role inclusion in the E-signature step provide a high level of visibility and clarity for each signer of a controlled document.

## COLLABORATE WITH OUTSIDE USERS

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

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

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

## CANCEL CHECK-OUT

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



## SITE USER RESTRICTIONS

In Content Management, eISF, and Collaborate rooms, this improvement will restrict users assigned to sites so that they can only see their assigned sites in the Investigator site list when adding documents or updating document metadata in our TI Collaborate rooms.

This provides an additional security measure eliminating other site names or numbers from site-specific users.

# Reporting Features

## IMPROVED TI STANDARD AND AD HOC REPORTS

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

The following reports have been added in 10.1:

- **SSU Document History Report** - This new report provides a complete history from the time the document is uploaded in TI SSU module through various approval stages.
- **Document Placeholder Report** - This new report provides the complete history of any placeholders created, modified, or deleted in the TI system.
- **Quality Review Report** - This new report displays the history documents (passed and failed) through the Quality Review module in TI.
- **Inventory and Completeness Report - Site** - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Site category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- **Inventory and Completeness Report - Country** - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Country category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- **Inventory and Completeness Report - Trial** - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Trial category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- **Inventory Report - Staging and Upload** - The new report shall display the inventory all documents for all categories that are available in the staging and

inbox folder. This report will help take inventory of documents which are available in the system but have not been coded yet.

# Features and Enhancements

Trial Interactive v10.1 is planned for release with these enhanced features. This table uses the following definitions of customer Impact:

- **CRITICAL** - A core functionality returns invalid results or does not function as expected.
- **MAJOR** - This Defect has an impact on basic functionality.
- **MINOR** - There may be a small impact on business in specific use cases.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-94	TRL-28, TIIG-718	<p>Introducing the ability to auto-code documents using metadata found in the subject line of an incoming email. Users sending in emails can now specify the following fields, separated by semi-colons:</p> <ul style="list-style-type: none"> <li>* Category - (example: general, country, site)</li> <li>* Site (site number .. 001, US342)</li> <li>* Document Type (document type short name)</li> </ul> <p>For example: site;002;fdf</p>	MINOR	<p>Admin only.</p> <p>This feature provides a more streamlined way to integrate email systems and auto-code information.</p>

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-252	TRL-24	When clicking on the last record in a list, the 'Next Document' button shows as disabled, and when on the first in the list, the 'Previous Document' button shows as disabled.	MINOR	All Roles. Minor User Experience Improvement.
ETMF-709	TRL-12	In the CRA Reconciliation Module, a new Room Setting, 'Include recommended (non-required) documents for CRA Reconciliation for a Site' Option is added.	MAJOR	Editor Role. Major Impact, when this new Room Setting is enabled, 'Collected' CRA Reconciliation View, as well as eTMF Completeness View, now returns all Site documents, required or not. This option is disabled by default, but if enabled it is recommended that CRAs be trained on the improvement.
ETMF-730	TRL-6	In the eTMF room, a user opening a confidentiality agreement showed the window title as 'Confidentiality Agreement' instead of the specific title of the agreement.	MINOR	Editor and Admin. A minor user experience improvement, this allows more flexibility of this feature, allowing this to be used for other requirements that users must confirm.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-737	TRL-19	In Content Management rooms, an improvement is made for users to navigate documents from Index to Document life cycle or the collaborative view. Links will also navigate user from collaborative view to the index folder as well as Document Lifecycle view to the index folder.	MINOR	All Roles. All users will have links to navigate to the same document in different modules.
ETMF-757	TRL-23	In Content Management Room, there is an improvement with document check-out. Now, upon selecting 'My Edit -> Edit Online' in the grid view, document will open automatically in the document view.	MINOR	Editors. With this improvement, User Navigation for document check-out -> Edit Online has been enhanced.
ETMF-669	TRL-3	The Document API has been improved with the following metadata fields-Visit Number, Milestone Date, Visit Date, Comments, TMF Readiness Date, Wet Ink Received, and Duplicate Check. In addition, new documents created via the API will return a Document ID and may be updated at any time with additional metadata. Documents will also be checked for duplication, returning the Document ID of the duplicate.	MINOR	API Only. With this improvement, eTMF and CTMS integration is improved.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-705	TRL-37	Trial Interactive 10.1 brings back the 2 and 3 columns look to the dashboards as well as the single-column tabbed view introduced in TI 10.	MAJOR	All Roles. Enhancements have been introduced to the Dashboard dashlets. This improvement is purely user interface and is disabled by default. It will have no impact on current functionality until explicitly enabled by customer configuration.
ETMF-707	TRL-1106	A feature has been improved where documents in TI can be scanned using QR code and stored at a central, globally accessible location for QC. Slip sheets are inserted to separate the documents, rooms, sites, and box numbers.	MINOR	API Automation only. With this, the users can scan an entire box of documents, run different processes, QC the documents, and store them in a central globally accessible location.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-343	TRL-39	<p>Now Supported for MTI:</p> <ul style="list-style-type: none"> <li>* Users will be prompted for email, and domains are compared. If SSO enabled, the user is redirected to IDP in modal and they may enter their credentials and will be signed into TI.</li> <li>* Users may also sign into their IDP directly, then follow a link directly to TI and will be authenticated directly and placed within TI.</li> <li>* If Users follow a deep link to TI, they must still enter their email address and click login, and they will then be signed in.</li> </ul>	MAJOR	All Users. The new feature improves the security level with the new two-step login facility. Must be configured separately by Trial Interactive staff.
ETMF-394	TIUI-216, TIUI-290, TIUI-816	Tasks have been updated in TI10 to include an improved listing, with tagging and the ability to associate TMF documents directly with a Task.	MINOR	All Users. This minor change makes it easier to include a TI document in a task.
TISW-102	TRL-1108	A feature has been added where the editors or above users can drag and drop an email with or without attachment from the desktop outlook as an MSG file attachment to a TI study room (index folder/grid/bulk documents import window).	MAJOR	Editor and Admin. Major impact, this new feature provides more flexibility in capturing email correspondence and attachments to TI rooms.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-461	TRL-554	A feature has been improved where the system identifies and flags 'possible duplicate' when a new document is imported into the system or emailed into TI. The system generates a document hash for every new document imported that helps to compare for any duplicates.	MAJOR	All Users. Major impact and must be turned on in room configuration, this helps in checking for possible duplicates in the initial upload or during the workflow and verifies both metadata duplicates as well as checksum (identical) matches.
ETMF-561	TRL-1663	A feature has been improved where users with editor access and above can share documents and related metadata from one source room to multiple target rooms with the destination document inheriting the audit trail and workflow history of the source document.	MAJOR	Editor and Admin. Impacts the sharing of documents between rooms only and must be enabled specifically between linked rooms.
ETMF-604	TRL-21	Improvement has been made to allow users to select multiple documents from the expired list and remove them from within the expired document dashlet.	MINOR	All Users. This makes it easier for users to remove multiple expired documents at once from the dashlet.



Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-715	TRL-767	In Content Management rooms, there is an improvement where the editors will always be allowed to view the Current or Draft versions of a controlled document in the document view while readers will be allowed to view only the Effective version of the controlled documents.	MAJOR	Editors. Enhances the user experience of the editors managing controlled documents. This is a possible major impact that is enabled automatically but only impacts Content Management rooms, it has no impact on eTMF rooms.
ETMF-716	TRL-764	Improvement has been made in a Content Management room where, for a controlled document, readers will have access to see only the Effective Version of the document (Documents that are approved and have Effective Status) but not the draft versions while Editors and Admins will have full access to view and edit those documents.	MINOR	Readers. Impacts the readers in the content management room in the viewing of Controlled Documents. This is a possible major impact that is enabled automatically but only impacts Content Management rooms, it has no impact on eTMF rooms.
ETMF-722	TRL-26	Improvement is made to a function in a content management room, where the controlled documents that do not need periodic review or effective timeframe are allowed. These documents will be final or effective upon approval and also documents may not need a periodic review timeframe.	MINOR	Editors Only. Minor impact, provides immediate Effective status or ability to not require a periodic review timeframe on controlled documents

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-740	TRL-763	With this enhancement, the status of Active sites can now be changed to Closed. Closed sites would not be considered when amendments are created. Also, the system shall allow advanced validation when a site status is changed to Closed.	MINOR	Study Start-Up, Admins, and Editors. Members of the Site Activation team would have the ability to mark sites as closed.
ETMF-742	TRL-38	With this improvement, Admins can assign select metadata fields related to site profiles to be enforced when sites are activated. Thus, any critical data that might not have been captured when site profiles are created would be mandated before the sites are activated.	MINOR	Study Start-Up, Editor, and Admin. This improvement allows making select metadata fields as required before a site can be activated. Minor impact, must be configured first.
ETMF-743	TRL-762	This improvement will allow users to view the document upload and review history for all documents uploaded in the TI SSU module.	MINOR	Study Start-Up, All Users. Complete document history would now be available for documents uploaded in the Study Start-Up module. Minor impact.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-753	TRL-1099	Improvement has been made to the controlled document workflows in Content Management rooms in which a workflow can include a step that will allow for the document to be edited and a new version created as part of the workflow.	MAJOR	Editor, Admin. This expands the workflow capability to include a review step, which allows for editing/finalization of a document as part of the workflow. Major Impact but for Content Management rooms only.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-755	TRL-5	<p>Updated UI of 'View Documents By' menu with the following changes:</p> <ol style="list-style-type: none"> <li>1. Columns made of same width size</li> <li>2. Audit fields moved to the bottom of the view selector</li> <li>3. View mode options moved into the view mode action components</li> <li>4. Ability to change View Groups title and icons</li> <li>5. 'Show Index' functionality added for 'By Site' and 'By Country' views</li> <li>6. Ability to select view modes by double-clicking</li> <li>7. Disabled selecting 'Show CWS / TMF Documents Only' if Show Index selected in By Site view mode</li> <li>8. eTMF completeness view fixes:               <ol style="list-style-type: none"> <li>i) Removed 'Show Empty Folders' option from completeness view.</li> <li>ii) Made missing and placeholders options selected by default.</li> </ol> </li> </ol>	MAJOR	<p>All Users.</p> <p>The view selector checkboxes are now moved to the bottom of the modal, with support of double-click to select the view. Major Impact as these UI/UX changes immediately go into effect, but no change in system functionality is made here, all views work exactly the same.</p>

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-767	TRL-536	The global search is improved with a short set of metadata fields.	MINOR	All users. Minor Impact, the global search is made more flexible with additional selections and fields. The normal and advanced search acts the same now.
ETMF-768	TRL-1658	The quality review coding panel is improved with new sections related to the audit.	MAJOR	Quality Review Module, All Users. Major Impact, the new button 'Audit' explores Audit Profile Name, Auditor, and Auditor's Comments. This aids the user to understand the Audit activities.
ETMF-773	TRL-765	The foreign language strings are updated for all languages.	MINOR	All Users. Minor Impact, an updated foreign language translation is included to provide multi-language support of the user interface.
ETMF-790	TRL-962	In a Content Management room, an improvement has been made to allow Editor and above level users to be collaborators to any review and edit online any room document even though they may not have direct access to the document or folder in the document reside.	MAJOR	Editor and Admin. This will facilitate editors and admins to collaborate and review documents online for a controlled timeframe as part of a collaborative review. Major impact on Content Management rooms only.
ETMF-791	TRL-1689	In a Content Management room, a cancel check-out is made available to users with the Admin level.	MINOR	Admin Only. The Admins now can cancel check-out of documents as needed. Minor impacts.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-794	TRL-1711	The support for 'Open in local office' is no longer available in the collaborative authoring. To edit a document offline, simply check it out, select 'Edit Document Offline', and it will open in your local MSOffice application. Once finished, check the document in, and it will prompt you for the new file, version increment, and comment.	MAJOR	Editor, Admin. With this improvement, the users now only have two options for 'My Edit': 'Using Online Editor', or 'Edit Content Offline'. Major impact, this feature is now deprecated in favor of the 'Edit Online' capability that works directly in the browser, and the simpler 'Edit Document Offline' which provides the same capability for offline edit in native MSOffice™ applications.
ETMF-800	TRL-1691	Improved site security now allows users to see only the investigative sites to which they have access.	MAJOR	Readers, Editors: The improved version now helps the users only to see the sites they are assigned in the investigative sites when updating the metadata, adding a new document to a folder, and importing a new document to a folder. Major Impacts and must be enabled to take effect.
ETMF-717	TRL-553	Improvement has been made that will allow document owners or editors with document manage privilege to initiate a workflow for a controlled document upon document upload without a document edit.	MINOR	Editor, Admin. Minor impacts, the improved version helps the users to initiate a controlled workflow without requiring a document edit. This only impacts Content Management rooms.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-898	TRL-1913	<p>Improvements are made to resolve data-based inconsistency with displaying 'Audit Comments' and 'Audit Response' for the Audit Export Windows:</p> <ol style="list-style-type: none"> <li>1) Added 'Audit: Comments' and 'Audit: Response Comments' metadata fields to 'Export Audit by View' by default,</li> <li>2) Removed duplicate display of 'Audit:' fields within the 'Select Columns' Window (previously, were placed on the top grayed-out, and again at the bottom),</li> <li>3) Corrected mismatch found on 'Status' selection availability from 'Export All Audits' Window,</li> <li>4) Adjusted so that 'Audit: Response Comments' field is only available for selection in the grid when Document Status is Issues Resolved.</li> </ol>	MINOR	Quality Review module, Editor, Admin. The improved version helps the users to perform Audit activities with some added features. Major Impacts on Quality Review users only.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-774	TRL-1328	Improvement has been made that allows users to create a query on final documents, view queries from anywhere in TI, and generally support queries separately from the workflow.	MAJOR	Editor, Document Manager, Admin. The improved version enhances the query functionality. May have a major impact on eTMF processes but must be enabled to take effect.
ETMF-785	TRL-1426	Improvement has been made in the system that provides the ability to associate a user role to a TI e-signature.	MINOR	Editor, Admin. Minor Impacts, the improved version enhances the information recorded with the TI Signature.
ETMF-786	TRL-1690	The system now displays full text in the Grid view and Metadata Panel (if applicable) for a field value when the user hovers on available fields.	MINOR	All Users. Minor Impacts, the improved version helps users to get entire information about a document in the metadata.
ETMF-611	TRL-545	The 'By Department' and 'Documents' views are introduced, to provide a simplified way for admins and users to see which placeholders and required documents they must submit. This assists the eTMF team in ensuring the timeliness and quality of all document submissions to the eTMF.	MAJOR	Editor, Admin. The improved version provides users with an enhanced document view. May have a major impact on the eTMF processes but must be configured to take effect, as Document Types must be associated with Responsible Departments.



Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-571	TRL-1914	An improvement is available now wherein, the certified copy process is enabled from the Trial Interactive user interface, the myTI mobile app, and both may optionally require a user eSignature.	MINOR	All Users. Minor Impacts, this feature only impacts those enabling Certified Copy in the room, for the purpose of certifying that a physical copy of a document is identical to the paper copy.
ETMF-784	TRL-2034	In Content Management rooms, a feature has been improved where Editors will be allowed to set the initial version number of a document when adding or importing a document. Admins will be allowed to correct/update the 'set versions' of a document.	MINOR	Editor and Admin. Minor Impact, this improvement will help facilitate editors and admins in Content Management rooms to manage document versions.
ETMF-867	TRL-2035	In the Working Documents view, documents in the staging area may now be previewed.	MINOR	All Users. Minor impact, the improved feature now allows the users to preview the documents in the staging area. The documents open alongside the metadata.
ETMF-891	TRL-2097	An improvement has been made in redaction security where the editors who have redaction permission are able to see both the original and the redacted PDF (default view).	MINOR	Admins, Editors. Minor impact, this provides better security for unredacted versions and makes it simpler for users with the Redaction permission to see the results of their update.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-770	TRL-2096	An improvement has been made to provide automation using machine learning to auto-classify and extract metadata automatically from documents when they are uploaded into a room. The metadata found is assigned to the fields that have been trained in the model, but the document must still be claimed, and a CDS must verify the content prior to moving the document forward in the workflow.	MAJOR	All Users. Major impact. This feature provides the basic capability to extract metadata from documentation and automatically assign it to the metadata fields prior to the QC1 workflow step. Prior to implementation, this feature must be enabled and the specific document types must be trained by Trial Interactive staff.
ETMF-913	TJR-1634	New Report - SSU Document History Report  This new report provides a complete history from the time the document is uploaded in the TI SSU module through various approval stages.	MINOR	All Users: This new report would be useful in tracking the complete history of documents uploaded and approved in the TI SSU Module.
ETMF-914	TJR-1801	New Report - Document Placeholder Report  This new report provides the complete history of any placeholders created, modified, or deleted in the TI system.	MINOR	All Users: This new report will help TI users to maintain controls and checks for any placeholders created and/ or removed in the TI system.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-915	TJR-1886	<p>New Report - Quality Review Report</p> <p>This new report displays the history documents (passed and failed) through the Quality Review module in TI.</p>	MINOR	All Users: This new report will help provide an audit history of all documents that have been processed under quality review/ audit.
ETMF-916	TJR-1555	<p>New Report - Inventory and Completeness Report - Site</p> <p>The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for the Site category. The report shall also provide the Zone, Section, and Artifact details related to each document type.</p>	MINOR	All Users: This new report shall be an improvement over the existing reports enabling the users to get the complete information for all essential and non-essential documents pertaining to Sites in one single report.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-917	TJR-1556	<p>New Report - Inventory and Completeness Report - Country</p> <p>The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for the Country category. The report shall also provide the Zone, Section, and Artifact details related to each document type.</p>	MINOR	All Users: This new report shall be an improvement over the existing reports enabling the users to get the complete information for all essential and non-essential documents pertaining to Countries in one single report.
ETMF-918	TJR-1557	<p>New Report - Inventory and Completeness Report - Trial</p> <p>The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for the Trial category. The report shall also provide the Zone, Section, and Artifact details related to each document type.</p>	MINOR	All Users: This new report shall be an improvement over the existing reports enabling the users to get the complete information for all essential and non-essential documents pertaining to Trial in one single report.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-919	TJR-1562	<p>New Report - Inventory Report - Staging and Upload</p> <p>The new report shall display the inventory of all documents for all categories that are available in the staging and inbox folder. This report will help take inventory of documents that are available in the system but have not been coded yet.</p>	MINOR	All Users: This new report shall be an improvement over the existing reports enabling the users to get the complete information for all essential and non-essential documents that have been uploaded in the system but not yet reviewed.
ETMF-920	TJR-1467 TJR-1444	<p>The following two reports are being enhanced and would no longer display records pertaining to inactive sites.</p> <p>All Expiring Documents Expired Documents in 60 days</p>	MINOR	All Users: With this improvement Inactive Sites would no longer be considered for this report
ETMF-921	TJR-1859	The Workflow Query by Query Submitter is being enhanced and will now display the Query Recipient against each query.	MINOR	All Users: This is an improvement in the existing report whereby the report would now display the Query Recipient against each query.
ETMF-922	TJR-1894	The Audit Users Report will now display deleted users and users for whom access has been revoked.	MINOR	All Users: With this improvement, the report would now display deleted users and users for whom access has been revoked.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-923	TJR-1894	The Audit Inactive Users Report hall now display deactivated users.	MINOR	All Users: With this improvement, this report shall now display deactivated users.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-924	TJR-1893	<p>The following inventory and completeness reports are being retired shortly and would no longer be available as TI Standard Reports.</p> <ul style="list-style-type: none"> <li>eTMF Missing Required Documents - Country Level</li> <li>eTMF Missing Required Documents - General Level</li> <li>eTMF Missing Required Documents - Site Level</li> <li>Inventory - Required Documents by Country</li> <li>Inventory - Required Documents by Site</li> <li>Inventory - Required Documents by General</li> <li>eTMF Completeness Report - Site Documents</li> <li>eTMF Completeness Report - General Documents</li> <li>eTMF Completeness Report - Country Documents</li> <li>Inventory of Documents - Country Level</li> <li>Inventory of Documents - Site Level</li> <li>Inventory of Documents - General Level</li> </ul>	MINOR	<p>The retired reports have now been clubbed together to provide four basic reports for ease of use. These reports would now be replaced by the following reports:</p> <ul style="list-style-type: none"> <li>Inventory and Completeness Report - Site</li> <li>Inventory and Completeness Report - Country</li> <li>Inventory and Completeness Report - General</li> <li>Inventory Report - Staging and Upload</li> </ul> <p>The new reports shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders). The reports shall also provide the Zone, Section, and Artifact details related to each document type.</p> <p>For ease of transition, these legacy reports would continue to remain available under a separate tab for a limited time period.</p>

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-925	TJR-1892	<p>The following reports would no longer be available.</p> <p>Documents Requiring Clarification Rejected Documents Inventory</p>	MINOR	<p>These reports are duplicate reports and are available under the KPI reports tab under the following names:</p> <p>Document Clarification Inventory - KPI Report Document Rejection Inventory - KPI Report</p>
ETMF-926	TJR-1891	<p>The following reports are being retired shortly and would no longer be available as TI Standard Reports.</p> <p>Audit: Failed Documents Audit: Failed Documents Without Response</p>	MINOR	<p>This report is being replaced by a single Integrated Quality Review Report</p> <p>For ease of transition, these legacy reports would continue to remain available under a separate tab for a limited time period.</p>
ETMF-541	TRL-22	<p>If a room has 'Accept email from ANY non-participant' or 'Accept email from non-participants with these specific email domains' setting enabled for a study room, there has to be a way to place the email address of the sender in the 'submitted by' metadata.</p>	MINOR	<p>Minor Impact. This configuration will provide the submitted by attribute for all incoming emails.</p>



Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-719	TRL-654	The initiation and completion of a periodic review as part of the Controlled Document Life cycle will be available in the document history.	MINOR	Minor impact, this improvement provides additional detail in the workflow history to show the initiation and completion of a periodic review.
ETMF-723	TRL-27	For content management rooms, controlled documents when published to a TMF or shared to another room will be able to be set as always send as new document or send as new version of an existing document.	MINOR	For rooms that are published to TMF, or set up with shared documents, controlled documents will need to be assessed and determined if new versions for new documents will be sent.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-879	TRL-1414	Restrictions are added to the Reassign Reviewer option. Currently, Admins are able 1) to assign documents to themselves and 2) to Reviewers who already reviewed the document. There is already a restriction in the normal Workflow to prevent Reviewers from reviewing the same documents for multiple stages. The Reassign Reviewer option should have the same restriction to prevent this from happening. When User tries to assign QC2 Reviewer as same as QC1 Reviewer, then TI will prompt asking whether they want to proceed further.	MINOR	Minor. Impacts only a specific set of circumstances when reassigning QC1.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
REPORT-8	TJR-1879	<p>With this improvement, all TI users will now have access to OOTB standard reports using Jasper Reports solution. TI Reports will no longer support reporting solutions based on legacy Izenda Reports. In order to ensure smooth migration of any custom reports created using Izenda reports solution please contact your Project Manager.</p> <p>Additionally, ad-hoc reports will be enabled for all clients by default.</p>	MAJOR	<p>All Users: All users will now only have access to Jasper Reports in the TI Reporting platform.</p> <p>Clients using legacy Izenda reports are requested to contact their Project Managers to ensure a smooth transition. Additionally, ad hoc reports would be enabled for all users by default.</p>
ETMF-931	TJR-1587	This new report provides a summary of documents (counts) submitted for all Content rooms with a breakthrough at different workflow stages.	MINOR	All Users: All users will now have access to this CWS report.
ETMF-931	TJR-1588	This new report shall provide details of all documents submitted in a CWS room along with complete version history for these documents.	MINOR	All Users: All users will now have access to this CWS report.
ETMF-932	TJR-1635	This new report shall allow users to monitor the status of all documents in the TI Docs rooms.	MINOR	All Users: All users will now have access to this CWS report.

Feature	Ticket(s)	Description	Impact	Comment / Impact Analysis
ETMF-932	TJR-1661	This new report shall track all documents in TI Docs which are currently under collaboration.	MINOR	All Users: All users will now have access to this CWS report.
ETMF-932	TJR-1663	This new report shall Track all documents with effective versions.	MINOR	All Users: All users will now have access to this CWS report.

# Fixed Defects

Trial Interactive 10.1 has been released with these defect fixes. This table uses the following definitions of customer Impact:

- **CRITICAL** - A core functionality returns invalid results or does not function as expected.
- **MAJOR** - This Defect has an impact on basic functionality.
- **MINOR** - There may be a small impact on business in specific use cases.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-1882	Users experienced conflict in the document versions. Actual versions and the displayed versions are shown varied.	MINOR	All Users. The bug fix removes the UI limitations with document versioning. This restores the correct system behavior with a minor impact.
TRL-2010	While changing the site status from pending to active, the system displayed a message as ' User does not have permissions to perform this operation. 'However, the site status was changed.	MINOR	Editor, Admin. Minor Impact. This issue was stipulated with erroneous system UI. The bug fix restores the correct system behavior with a minor impact on users.
TRL-2106	Issue with mass coding the site status. During Mass Coding the field Status doesn't show. They both show in the Coding panel, but not in the Mass coding.	MINOR	Editor, Admin. Minor Impact. The bug fix restores the mass coding to its correct. The status field is removed from mass coding only in case if SSU module is enabled for a room.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-1910	While filling the registration form if a user types the country name instead of selecting it from the dropdown list, the system shows a country error.	MINOR	All Users. This bug fix restores the correct system behavior to its normal removing the country error.
TRL-1954	While uploading a document the tag filed set as required is getting not set in the upload window. However, no error happens with the upload.	MINOR	All Users. This bug is restricted to the UI level only. The bug fix restores the correct system behavior.
TRL-1741	A user invited to a study room gets a message showing they do not have access to the room.	MINOR	All Users. This issue occurred due to pending users that were re-sent an invitation. They must be set to active in order to complete their activation. This has been resolved.
TRL-2072	When an auditor tries to export Audit by view on an empty index it gets exported, but the system displays a message as 'File was not generated'.	MINOR	Editor, Admin. The bug fix removes the incorrect message. This restores the system behavior.
TRL2074	The users when try to search a document with some keywords and select the document, it doesn't open the document often.	MINOR	All Users. The bug fix removes the error in search and select. This restores the system behavior.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-2249	The users experienced non-working edit checks for the sub-condition in the 'Edit Advanced Fields Validation'	MINOR	Editors, Admin. The bug was stipulated to data level due to older, now-invalid field definitions. The bug fix restores the system behavior.
TRL-1835 TRL-1735	The users experienced the absence of the document viewer icons when they changed the document grid preview. Also, the changed preview was not saved in several instances.	MINOR	Editors, Admin. This was a minor bug. The bug fix restores the document viewer icons to their correct place irrespective of the document grid preview. The changed view is saved correct.
TRL-1880	The users were not able to remove the title filed from the eTMF health dashlet. Also, the fields added to the gird from settings were not available for selection in the same dashlet.	MINOR	Editors, Admin. This was a minor bug. The bug fix restores the correct operations in the eTMF Health Dashlet.
TRL-2107	Users with Reader/Editor level access are not able to download the documents using document cart/export option when DRM is enabled. Also, the download button was not available in the TI viewer.	MINOR	Readers, Editors. This was a minor bug. This issue was produced only when the folder security was selected to view only with DRM disabled. The bug fix restores the download and the download button to its correct place.
TRL-2069	There are duplicate user folders created inside 'Inbox' folders when user sends submission to room inboxes.	MINOR	Editors, Admin. This was a minor bug. The bug fix restores the folder structure. Duplicate folders reflection is removed to establish the correct system behavior.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TIUI-1248	When comparing documents, it is no longer possible to Edit metadata values from the comparison popup.	MINOR	Admin  Minor impact with a workaround. The new comparison modal does not allow editing directly here, the user must edit metadata in the usual way.
TIUI-3484	The TI 10 User Interface is optimized for many screen sizes, but it may not be optimal for users with larger monitors. (Resolved with a new zoom feature to control the responsive UI more easily.)	MINOR	All Users  Minor Impact. Since the user interface is fully responsive and resizable, users can solve this by simply changing the Zoom In / Zoom Out setting on their browser and adjust to the size they prefer.
TRL-808	When an SSO user attempted to sign on, they were placed in a loading state because their account was locked.	MINOR	All Users Minor Impact. SSO users whose accounts are locked will now see the appropriate error message prior to making an SSO attempt.
TRL-2069	Duplicate user folders created inside INBOX folders during inbox submissions due to auto-coding feature.	MINOR	All Users Minor Impact. Auto-coding feature caused the erroneous creation of duplicate folders in the Inbox. This has been corrected.



Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-1686	A document that was locked in the workflow was deleted by a different user, and the document name length went beyond the field length, creating an error.	MINOR	All Users Minor Impact. This rare scenario has been addressed and correctly handled in the software.
TRL-1954	Tag Field not Marked as Required when Uploading File.	MINOR	All Users Minor Impact. The required attribute has been corrected for the Tags field.
TRL-1067	Unable to Display PDF XFA Forms using the both the original Viewer and the TI Viewer. This is a known issue in the PDF plug-ins supported by all major browsers.	MINOR	All Users Minor Impact with workaround. PDF XFA Forms cannot be displayed by the standard PDF plug-ins supported by all major browsers, they are only supported using Adobe Acrobat®. TI Viewer cannot support XFA forms. For more information: <a href="https://helpx.adobe.com/livecycle/kb/xf-pdf-forms-policy-protected-documents-not-displayed.html">https://helpx.adobe.com/livecycle/kb/xf-pdf-forms-policy-protected-documents-not-displayed.html</a> WORKAROUND: These forms may be downloaded directly from either the TI or Original Viewer and opened in Adobe Acrobat®.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-712	<p>Users were having trouble loading PDF documents in original viewer on Chrome. Typically, the first page of the PDF will display, followed by a series of grey dots representing the missing pages. Occasionally it will also show the first page as blank. This is a known issue in the Chrome® PDF plug-in viewer.</p>	MINOR	<p>All Users                      Minor Impact with workaround.                      Upon investigation, this is an issue with the Google-installed PDF Viewer, designated as the Original viewer in TI. It appears to occur in PDF documents that have been optimized for fast web view.                      WORKAROUND: These PDFs may be downloaded directly from either the TI or Original Viewer and opened in Adobe Acrobat®.</p>
TRL-264	<p>Dashboard: "Site Health" was not available to Admins, because they are not CRA contacts.</p>	MINOR	<p>All Users                      Minor impact, this has been addressed and this dashboard is now available to Admins.</p>
TRL-2760	<p>Discrepancy in the Workflow Dashboard due to the number documents that are Final not tallying with those that have been changed by the admin to a non-final status.</p>	MINOR	<p>All Users                      Minor impact, when documents are finalized in the workflow and then admin changes the status to anything Non-Final, these documents will now be treated as final in the dashlet.</p>
TRL-2862	<p>Site number is missing on auto generated name unless the Site is reselected again.</p>	MINOR	<p>All Users                      Minor impact, the logic has been fixed and the generated name now updates the site number correctly.</p>

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-2637	Site Folder disappears after all documents have been reconciled. Additionally, site placeholders and documents are missing from the completeness views after they have been reconciled.	MINOR	Editors, CRA Group Minor impact. In the CRA Module, the documents are given the "Not Specified" status during the reconciliation. Afterwards, they no longer appear in the CRA module index and the completeness views. This is corrected.
TRL-2450	Sorting user by organization does not work properly under User management/Groups	MINOR	Admins Minor Impact, this logic is fixed in the User Interface.
TRL-2711	Cannot resolve a query if a document is locked and the query was opened during an audit.	MINOR	Editor, Admin Minor Impact, this is addressed in code for Audit Queries.
TRL-2039	A User receives a warning message while changing site Status from pending to Active.	MINOR	Admin. This is a minor issue caused by a mistaken warning message, and this message no longer appears.
TRL-1628	This was an issue with the duplicate check error message, where the message was not providing the User with the generated name.	MINOR	Editors, Admin. This was a minor bug. The bug fix restores the correct filename in the duplicate error message.

# Known Defects

Trial Interactive 10.1 has been released with these known issues. This table uses the following definitions of severity:

- **CRITICAL** - A core functionality returns invalid results or does not function as expected.
- **MAJOR** - This Defect has an impact on basic functionality.
- **MINOR** - There may be a small impact on business in specific use cases.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-305	When changing the Document Type, default values that were set in certain fields are not refreshed with new default values if the new Document Type's fields have different default values set.	MINOR	Editor, Admin  Minor Impact. This only causes an issue when there are Document Types with different default values for the same field, and the Document Type is changed.
TRL-311	When selecting a different Document Type in a Content Management room, the Investigative Site field is blanked out during edit if the document has already been determined to be an eTMF Document and inherit eTMF metadata.	MINOR	Editor, Admin  Minor Impact, this only affects Users who are changing the Document Type in a Content Management room for a document that has already been indicated to be an eTMF Document.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-314	When viewing the Manage Security panel and searching in the folder listing, the search does not work consistently.	MINOR	All Users  Minor Impact, this only occurs on the Manage Security panel and is inconsistently seen.
TRL-407	When approving a document in a Controlled workflow, if the document is viewed it does not open directly but instead takes the user to the standard grid view instead of showing the document in the My Reviews view.	MINOR	All Users  Minor Impact, this provides the grid view listing the document but requires that the user reopen the document to view it.
TRL-416	A minor User Interface issue appears when viewing the User panel. A scrollbar incorrectly appears, making it necessary to scroll to view all Users.	MINOR	Admin  Minor Impact, most of the Users are displayed, and the view can be easily scrolled. This is a minor UI issue only.
TRL-423	When clicking a Close or Close All button from the User Menu Notification panel, the background jobs are being erroneously cancelled.	MAJOR	All Users  Minor Impact. Workaround for this issue is to wait for the process to complete before clicking on Close.
TRL-564	When viewing the Working Documents view, collected documents that share the same Document Type will intermittently show in an expandable row instead of an integrated grid view.	MINOR	Editor, Admin  Minor Impact, this only affects certain documents with specific attributes in an intermittent fashion, and does not impact system function.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TRL-2021	When declining to sign an eSignature when using DocuSign, TI responds incorrectly with "Document was successfully signed" as an erroneous informational message.	MINOR	All Users  Minor Impact, this does not impact the signing, it only impacts the message that is received upon return to Trial Interactive.
TRL-2045	The Original Document Viewer, under certain conditions, is blocking pop-up windows on Internet Explorer. Specifically, when attempting to approve a document when in the document view.	MAJOR	All Users  Minor Impact, this only occurs in the Original Viewer, and only when a popup appears and in an inconsistent way.
TIUI-2379	When viewing the Unread document dashlet, if the document is a URL type document, it is not removed from an unread state and continues to show in the dashlet.	MINOR	All users  Minor issue, this only impacts URL documents which are quite rare.
TIUI-2444	When using View Filters, if a particular field contains BLANK values, attempting to filter when the values are NONE will still show the records that are blank, which may be confusing when filtering result sets.	MINOR	Editor, Admin  Minor issue, it is difficult to distinguish between blank and null values, but this only impacts the filtering, not the data.
TRL-2793	When reassigning Auditors during a Quality Review, the list of Audits shows up as missing an expand or collapse arrow making it difficult to select from the list.	MINOR	Admin  Minor Impact, it is still possible to easily select an audit without these arrows.

Ticket(s)	Description	Impact	Comment / Impact Analysis
TIUI-2800	When exporting the FAQ entries, the text is correct, but it contains formatting tags that must be removed.	MINOR	Editor, Admin  Minor impact. These tags may easily be removed after export, and they do retain formatting information.
TRL-2804	If a Query is opened on a document, and then the document is deleted, instead of the User navigating to the Deleted Document view with the selected document opened in the Document View, a 'No Document Selected' message is displayed.	MINOR	All Users  Minor Impact, this occurs from the My Queries dashlet only and occurs in a rare case only.
TIUI-3082	When a user is set as a Regulatory Approver in a particular Country, they are provided access to all of the IRBs instead of just the ones that pertain to that Country.	MINOR	Editor, Admin  Minor impact as it is rare as users should not have access to these IRBs in any case.
TIUI-3387	When emailing a document, if there are more than 10 recipients in the To field, the System will only show the first 10 selected.	MINOR	Editor, Admin  Minor Impact. The Email addresses remain, they are simply not viewable in this interface.
TIUI-3465	When setting a document to be published to another room, if the document already has a Document Type set, setting it to publish then back again will erase the prior Document Type setting. It will need to be reset again manually.	MINOR	Admin  Minor Impact. This only occurs in a specific case where there is a published document type already set.

