

# Trial Interactive v10.6 – Release Notes v1.0



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## 2. Version History

Author	Revision #	Date	Comment
Samuel Pawar	1.0	22-Nov-2024	Document finalized
Anuj Thapar	1.1	08-Jan-2025	Minor correction to the Impact statement of TTI-3915 and TTI-3597
Samuel Pawar	1.2	27-Jun-2025	Updated Feature ETMF-1053 to change the Online guide URL and user accessibility.

### 3. Purpose

The purpose of this document is for **TransPerfect** to disseminate information to end-users (internal and clients) prior to a system release and detail the new features and important changes. This is performed several weeks in advanced of Upgrade Date by issuing Release Notes. The end-users of the system can use the Release Notes to evaluate if their intended use of the system will be impacted by the changes introduced in the system release. The Final Release Notes are then issued once the internal Validation Package has been reviewed/approved by Trial Interactive Quality Assurance. The Final Release Notes will contain the final list of items in the scope of the Release.



**NOTE:** **TransPerfect** will make commercial best efforts to minimize the differences between the Release Notes and the Final Release Notes, but due to Trial Interactive's Agile Software Development methodology, cannot guarantee there will be no changes in scope.

## 4. Scope

The scope of this document applies to the release of the following computerized system:

System In Scope	
<b>System Name</b>	Trial Interactive
<b>System Version</b>	10.6
<b>Release Type</b>	Minor

## 5. Definitions / Acronyms

Term	Definition/Description
<b>21 CFR Part 11</b>	The part of the United States Code of Federal Regulations that regulates electronic records and electronic signatures.
<b>API</b>	Application Programming Interface
<b>Annex 11</b>	The European Union’ s guidance for using electronic records and signatures in the pharmaceutical industry.
<b>CRO</b>	Clinical Research Organization
<b>CTMS</b>	Clinical Trial Management System
<b>DICOM</b>	Digital Imaging and Communications in Medicine
<b>ERES</b>	This document provides guidance in the United States for using electronic systems, records, and signatures in clinical investigations.
<b>GDPR</b>	The General Data Protection Regulation is a set of rules laid out by the European Union regarding data privacy rights.
<b>GxP</b>	An abbreviation generally accepted to refer to accepted standards of good practices.
<b>IDP</b>	Identity Provider
<b>JIRA</b>	A proprietary issue-tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management.
<b>KPI</b>	Key Performance Indicator
<b>LMS</b>	Learning Management System
<b>MDE</b>	Metadata Extraction
<b>MFA</b>	Multi-Factor Authentication
<b>OOTB</b>	Out of the Box
<b>SFTP</b>	A secure File Transfer Protocol
<b>SLA</b>	Service Level Agreement
<b>SOP</b>	Standard Operating Procedure
<b>SQA</b>	Software Quality Assurance
<b>SQL</b>	Structured Query Language
<b>SSO</b>	Single Sign On
<b>SSU</b>	Study Start-Up
<b>TI</b>	Trial Interactive
<b>TP</b>	TransPerfect
<b>TestRail</b>	A web-based test management software that facilitates software quality assurance; it produces reports on a release candidate and documents the nature and category of bugs.

## 6. System Overview

### A. TRIAL INTERACTIVE

**TransPerfect's Trial Interactive** has been used successfully by TransPerfect customers for over 15 years in hundreds of clinical trials to store 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 and content management, Study Start-Up, and various other tools used in conducting a clinical trial.

Trial Interactive's products deliver a wide range of benefits to any organization looking to leverage new efficiencies and opportunities in Trial Master File, clinical trial management, content management, and eLearning:

- An electronic Trial Master File archive that meets all regulatory, security, access, and storage requirements in all countries and regions.
- A fully hosted SaaS solution that is 21 CFR Part 11, Annex 11, ERES, GDPR, and GxP compliant.
- A single access point for all trial content and sponsor and site personnel documentation.
- Support a series of TMF workflows, including document import and indexing, quality review, audit and inspection, document certification, remote monitoring, redaction, and the capture of other Clinical Trial documentation.
- Effective management of documents that are created internally or externally. Trial Interactive is the only solution that provides a best practice and validation-ready approach to creating, collecting, reviewing, and finalizing documents bound for the eTMF archive.
- A thin-client, consumer-grade user interface that supports most major browsers and a mobile app that supports iOS and Android devices.
- A powerful, flexible technical stack with many integration options, including an API, Event Service Bus, sFTP Dropbox, and Corporate Directory Integration with Single Sign On.
- Increased teamwork and collaboration via one global view of clinical trials, training, and supporting documentation.
- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of reviews and authoring solutions.
- Dashboards and reports that provide KPIs, measurable metrics, simple Excel exports, and complex standardized and custom reports.
- Adaptable, built-in machine learning features such as auto-classification and metadata extraction enable AI auto-coding capabilities.
- Integrations into other Trial Interactive products (GlobalLearn, myTI, CTMS) to provide a comprehensive set of solutions to effectively manage the entire clinical trial process from protocol conception through closeout.

### B. 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. Trial Interactive's eTMF can help your organization:

- Ensure quality with the ability to have a customized workflow for indexing and approval powered by AI and machine learning.

- Stay current with required document lists and placeholders based on the TMF Reference Model. Placeholders and required document lists ensure that all expected and essential documents are captured in your final TMF.
- Track timeliness with KPI metrics dashboards that measure document intake from receipt to submission through QC and finalization.
- Encourage better compliance with an eTMF that tracks responsibility and actively requests documents when they are due, supporting queries for document corrections through email or upload.
- Confirm and maintain the validity of the eTMF before inspections using quality review audit capabilities to support oversight, periodic reviews, and inspection readiness.
- Ensure overall reportable eTMF Health with Key Performance Indicator (KPI) metrics, reports, and portfolio dashboards for eTMF health, timeliness, quality, and completeness.
- Plan amendments, visits, and other key trial events and milestones while creating placeholders for the expected documents that need to be collected, including due dates and responsibility to help track eTMF health and timeliness.
- Automate the classification and metadata extraction of the TMF using powerful AI auto-coding with human-aided machine learning.
- eClinical platform interoperability provides a seamless connection and data flow between the eTMF and other critical applications such as a site portal, eISF and site binders, content management, document authoring, study startup, and clinical trial management systems.
- Email and study correspondence inbox with relevance checks captures all email correspondence for each study. Once a correspondence email is sent in, it is rendered to PDF and may be selected for inclusion in a separate interface by study staff. Attachments are checked for duplicates and are linked back to the original email. Emailing documents and site correspondence securely into the eTMF ensures GCP compliance.
- Document redaction, manipulation, and certification allow selected team members to remove personal information to meet data privacy requirements and repair, split, and merge documents. Additionally, document certification helps ensure proper paper disposal.

Additional features of the Trial Interactive eTMF include:

- A mobile content capture app that supports both iOS and Android, with support for CRA reconciliation, metadata classification, query management, training, redaction, and offline mode.
- Drag and drop emails and documents to import them automatically or drop them onto placeholders for auto-assignment.
- Full query and task management capability with three types of queries for requesting, verifying, and responding via email, web, and mobile apps.
- Automatic alerts and reminders with notifications and a daily digest.
- Built-in eSignature and digital signature solution for 21 CFR Part 11 and ER/ES compliance with pre-defined signature blocks, pages, and digital certificate.
- Universal document viewer that supports and renders over three hundred document formats.
- Multi-document view with built-in document comparisons, bulk editing, page rotation, deletion, reordering, and annotations.



- Global search provides cross-study search results for documents, document types, full-text, contacts, sites, and other record types, with facets, filtering, and other advanced features.
- Configurable grid filters, column selection, saved public/private views, and built-in reporting tools for ad-hoc exports.
- Standard and ad-hoc reports that support all metadata fields and the ability to add columns to standard reports or fully customize your exports.
- Completeness view showing TMF structure, final documents, planned documents/placeholders, and required documents.
- Configurable support for the latest TMF reference model with full auto-routing and auto-naming rules.
- Automatic duplicate document detection and comparison verifies that a document is unique and does not have a duplicate in the eTMF archive based on identical metadata or an exact copy or duplicate scan.

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### C. STUDY START-UP (SSU)

Trial Interactive Study Start-up (SSU) is a cloud-based solution to manage essential documents per the regulatory requirements for site activation and IP release. Trial Interactive SSU can help your organization:

- Send the Regulatory Package and templates to sites with the list of required documents.
- A configurable one or two-step workflow for reviewing and approving collected required documents.
- Study Start-Up makes it easy to see what documents are missing and what documents need urgent attention to avoid unnecessary delays in submission and approval.
- Study Start-Up makes it easy to see the sites most likely to activate the fastest. Identify those sites during the process so you can make sure there are no distractions in the submission and approval process.
- Set and automatically track milestones and tasks. Ensure all study start-up processes are being managed effectively and completed on time.
- Effectively track site contracts and budgets with a dedicated section for managing them.
- Create submission packages for submission to regulatory agencies.
- Get real-time updates on package submissions for realistic estimates of site activation timelines.
- Real-time distribution of required document packages, tracking progress, IRB/EC submission, and meeting dates, providing realistic timeline projections and prediction of site activation timeframes.
- Efficiently manage protocol amendments, including tracking and sending reminder emails with just a button click.
- Robust OOTB reports for cycle time calculations, missing documents, and history of collected documents.
- Automatically create sites and site contacts for sites approved in Trial Interactive eFeasibility.
- Request for certified translated copies of documents to manage your global regulatory requirements.

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## D. COLLABORATE

Trial Interactive provides an online collaborative workspace, which enables collaborative and controlled document authoring, review, 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 and document control requirements. These collaborate rooms allow users to benefit from the following solutions:

- **Study Collaborate and the CTMS Collaboration Rooms (CCR)** are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and shared with the eTMF. All CTMS documentation is generated here and auto-filed to the eTMF.
- **Site Portal and Remote Monitoring Rooms (eISF)** are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and publish it to the eTMF. Provides a simplified Site Portal and dashboards for Investigative Site personnel.
- The **Quality Document Management System (QDMS)** provides controlled document workflows to an organization for use by clinicians, quality assurance, R&D, and other life sciences teams to collaboratively author, review, approve, sign off on, make effective, train, and distribute regulated content and documents. Supports a full set of Training Management features when combined with the LMS.
- The **Safety Notifications** solution manages the tracking, storage, distribution, and acknowledgment of safety-related documents and communications, including adverse event notifications, risk assessment communications, and regulatory updates, ensuring that safety letters are managed efficiently, meet regulatory requirements, and reach the appropriate stakeholders promptly and securely.

Collaborate can provide your organization with:

- 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.
- The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation and to fully automate the training management process through the LMS.
- The ability to co-author and collaborate with other authors in real time 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 and digital signature for document approvals.
- The ability to send documents for certified translation through TransPerfect GlobalLink Portal, track their status, and receive back the translated copies and certificates.
- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.
- The ability to follow critical processes for metadata, approval, and signoffs by publishing or sharing directly with the TMF.

## 7. Release Overview

### A. ORGANIZATIONS

#### 3<sup>rd</sup> Party Vendor Support

**ETMF-214** - When handling 3<sup>rd</sup> Party Vendors in the eTMF, additional folder structures with document type classifications must be managed easily within the index. There should be a way to enter 3<sup>rd</sup> Party Vendors as Organizations within a client domain, and a way to select from these Organizations to populate folder structure and required documents for each Vendor within rooms.

This feature will implement 3rd Party Vendors within the eTMF, creating folder structures and required documents, along with metadata about these Organizations including type, subtype, service provided, address, and contact information. For customers using a CTMS, these Organizations may be shared and managed there and populated to the client domain.

This feature will implement Organizations within other room types including QMS and Site Collaborate rooms, allowing for supplier and vendor management and required documentation.

### B. USER INTERFACE

#### New Quick View Metadata Panel Interface

**TTI-2528** - For all solution offerings, this enhancement brings a new level of convenience and efficiency to the user experience with a new look and feel to the metadata quick view panel, showing all key information for each document including the Document ID, Submitted Name, and the Generated Name. Shortcuts such as claim, release, check-in, check-out, and workflow actions are now supported at the top of the panel, providing the most common actions available to the user.

A new navigation panel is available as well, providing quick access to all modules, products, and solutions as well as a clear breadcrumb showing where you are in the platform and providing additional information such as the protocol number of the trial.

For Collaborate and QMS, this feature improves collaborative reviews by enabling the display of the document metadata panel during active sessions. This feature allows participants to view essential metadata alongside the collaborative session, providing immediate context that can significantly inform and guide the review process. With key information such as metadata, info, version history, review history, queries, instructions, submitted name, document ID, generated name, and collaborate status readily accessible, collaborators can make more precise and informed contributions, leading to a more streamlined and effective review cycle. This integration represents a critical step towards a more transparent and connected review experience, ensuring all participants are aligned and fully informed throughout the collaboration.

### C. GRID VIEWS

#### Advanced Grid View Filterings

**TTI-2379** - Enhance your oversight of the room and grid view with advanced document filters. This feature provides a robust set of dropdown filters to each grid view for users to efficiently view, sort, and filter document data, optimizing the management and oversight of the eTMF, QMS, and other room types. When combined with the 'Expand' feature, documents may be quickly filtered down to just what you need to review.

For the eTMF, key filters such as zone, section, artifact, sub-artifact, index number, document type, and various dates are now available from any grid view. These filters may be saved to a private view of data or a public view that is set as the default by the administrator.

Additionally, for the QDMS a new 'Training Required' checkbox has been integrated into the metadata options to support compliance and training protocols. Streamline your reporting by exporting a comprehensive list of documents under review directly from the grid into Excel, simplifying reporting, data analysis, and tracking. This multi-faceted tool is engineered to elevate the precision and productivity of your document review processes.

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## D. TI AUTOMATE

### Intelligent Document Indexing and Metadata Extraction

**TTI-3613** - With the introduction of a new Artificial Intelligence service to TI Automate, documents may be automatically classified with their metadata extracted once uploaded to a room. This exciting new feature has the following key capabilities:

- TI Automate is pre-trained on the eTMF reference model, so no additional training is necessary. Your users are up and running with the press of a button.
- In addition to metadata, new investigative sites and new site contacts that are detected in certain documents, such as Form 1572, are automatically added with verification.
- TI Automate has a high accuracy rate that is well above 90% for structured documentation.
- Documents that come in as images are automatically OCR'd so that the required metadata may be extracted.
- For non-eTMF rooms, the metadata may be modified and mapped to meet your specific business needs. Site Collaborate and QDMS service offerings are supported for auto-classification, and new document types are easily supported.
- Over 20+ languages are supported out of the box, allowing TI Automate to translate metadata from documentation as needed.
- Just like past TI Automate capabilities, an Automate Score is assigned to each document and compared against a configurable Confidence Threshold. If the score is high enough, the document may be promoted in the workflow to allow for 'Human In The Loop' (HITL) verification.
- TI Automate is a self-training system. Documents that fail to meet the Confidence Threshold are sent for analysis and improvement.

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## E. TI ANALYTICS

### View eTMF, CTMS, LMS, and QMS KPI Dashboards, Reports, and Tabular Reports

**TTI-3285** - In 10.6, we are adding a new BI and Reporting Solution called TI Analytics.

Standard Analytics Dashboards: Current KPI dashboards will be augmented by standard KPI dashlets for CTMS, eTMF, SSU, LMS, and QMS. These dashlets will be made available using the Reporting Data Warehouse. Cross-study and cross-product dashlets are also possible to create.

Create and Customize Interactive Visualizations and Dashboards: TI Reporting domains are made available to provide sophisticated 'live' dashboard customization capabilities in TI. This will allow us to easily create for clients custom and scheduled dashboards tabular reports and data exports from a single fully managed cloud-based BI service.

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## F. IDENTITY AND ACCESS MANAGEMENT

An updated Identity and Access Management component is rolling out, providing global authentication and authorization for the TI platform, all TI users, and all applications and modules. This component will support the following new capabilities:

- New Users will only need to register once on the TI Platform to access all TI products, studies, and environments.
- Each dedicated environment keeps its own preferences regarding password requirements, timeouts, and expirations.
- Supports configuration of multiple SSO systems for a single application and set of users.
- Easily activate multiple options for Sign On, including Single Sign On, Multi-Factor (MFA) using text message or app, One-Time Password (OTP), and familiar SSO options such as MS Teams and Okta.

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## G. CENTRAL HELP PORTAL

### A Single Portal to Access All Documentation, Help, Training, and Support

**ETMF-1053** - A central portal that all customers can access, providing them with the latest help, videos, job aids, ideas, tickets, and requests. This portal will have the following features:

- The portal will be completely secure, accessible to users, and available from every product and every dedicated instance.
- All online help will be made available centrally for all TI modules and customer solutions
- Users will have access to the Manage Engine service desk ticketing system for their tickets and the creation of new tickets
- All Service Requests will be made available, with 'self-serve' custom forms for Archive requests, Site Updates, User Updates, and all other formal requests.
- The latest product release notes will be made available, as well as PDF documentation.
- For Focus Group members, access to the Idea portal will be provided.

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## H. CONTACT START AND END DATES

### Track contacts accurately for more precise expired document reporting.

**TTI-3305** - During a clinical trial, site personnel change often at the site, and investigators may participate in a trial for a brief period, and then hand the responsibility to another investigator. This makes tracking required documents somewhat challenging at times, and the expiration of medical licenses and similar documents should be aware of when an investigator joined or left the site staff to ensure documents are not marked as required when they are not needed.

For these reasons, a Contact in the eTMF will now support start and end dates to improve both required and expired document tracking. These start and end dates may be inherited from the CTMS, or they may be set on individual contacts within the eTMF. Once set, these dates are compared against document expirations, ensuring that expiring documents are not tracked for a Contact that has already left the trial (or has not yet joined).

## I. QUALITY REVIEW FAILURE REASONS

**TTI-3597** - When a particular document fails during a Quality Review Audit, the system currently prompts for a free text reason for failure. While this free text allows for description, it does not provide for a simple, configurable list of failure reasons like the one supplied during normal QC. This enhancement will add this list, prompting the auditor for a specific reason for failure that may be more easily tracked, managed, and reported.

## J. COLLABORATE: CTMS LETTER WORKFLOWS

### **Simplified Visit Report and Letter Workflows, Back-to-Back Comparison of Regenerated Reports with Accept/Reject Capability**

**TTI-3731** - Monitoring Trip Reports and Letters requires a clear, concise workflow. At times, the report must be regenerated from the original data. In these cases, it must be simple to compare the differences and comments between the new and previous versions, and easily accept or reject the changes and comments. This is now also possible with letters, and letter workflows support a clear signature and allow the option for the letter to be quickly reviewed and sent.

After a visit report has been regenerated from the original data, this enhancement provides the capability to compare, accept, reject changes, and view comments between the new and previous versions of the visit report.

## K. COLLABORATE: VIEW ACTIVE DOCUMENT REVIEWS FROM ONE PLACE

### **Introducing a Consolidated View of Currently Active Workflows and Documents You Are Editing**

**TTI-3344** - This feature removes the "Collaborative Workspace" submodule for Collaborate/QMS/EDMS Room Types and enhances the "Documents" module with new views. The Index view shows all documents in various workflow stages, allowing review workflows to be created from drafts. The Currently Editing view replaces Collaborative Workspace views, showing all documents a user is engaged with, including offline and collaborative tasks. A new 'Recents' view shows documents that were recently edited by the current user, and a Planned view provides all required documents needed completion for that user based on their Responsible Party. Other updates include reorganized views and metadata quick view panel enhancements, focusing on QDMS and Site Collaborate solutions.

## L. COLLABORATE: TEAM EDIT INSTRUCTIONS AND REVIEW UPDATES

**TTI-3727** - This new enhancement introduces the ability to set the name of the collaborate review and provide specific instructions, along with a notification, when initiating a collaborative review session. This is especially beneficial for subsequent review rounds, allowing the review initiator to guide participants' focus—such as directing attention to a particular section—which streamlines the process and eliminates redundant efforts.

An additional enhancement elevates collaboration by empowering all review participants, not just owners and admins, to provide their review comments back, with a notification, when they've completed their reviews.

Finally, if an incorrect effective date is set, the Document Owner may now resend the original document through the approval workflow after changing key pieces of metadata, such as the effective date.

## M. COLLABORATE: WORKFLOW OPTIONS BASED ON BUSINESS NEEDS

### **Automated Processing Room Workflow with Workflows Configured by Document Type**

**TTI-3816** - In this Collaborate/QDMS enhancement, documents introduced into the system are instantly engaged in an automated processing workflow, optimizing the initial handling and processing stages. This automatic workflow ensures that no document coming into the room is left unmanaged or untracked. However, recognizing the need for flexibility, the system allows for manual reassignment to alternative workflows, accommodating unique document requirements or changes in project direction.

With this enhancement, workflows and their templates may now be associated with specific Document Types. This provides a greater degree of control over what workflows each specific document type may be engaged in. Additional controls are added to clarify what CTMS workflows and templates may be associated with Visit Reports and Letters.

Finally, in Collaborate / QMS rooms, Document Owners and Proxy Owners may now exclude a document from a workflow, and they are immediately prompted for the new desired workflow based on the Document Type.

## **N. COLLABORATE: SEND SAFETY LETTER ACKNOWLEDGEMENTS**

### **Safety Letters and Other Critical Site Documents in the TI Safety Solution**

**TTI-2975** - This enhancement, focused on the Safety Letter tracking solution, introduces a streamlined 'Read and Understand' acknowledgment feature, which significantly simplifies the process of confirming the review of critical documents at a Site. With this capability, users can electronically acknowledge new documents such as CIOMS, DSURs, Investigator Brochures and other critical documents, ensuring the timely confirmation of safety issues and avoiding manual follow-ups. With just a click, notifications are sent to all relevant parties, who can then acknowledge and confirm its receipt. Each acknowledgment is logged as a separate record, maintaining a transparent and traceable record of who has reviewed and understood the document. This system additionally supports the cancellation and replacement of the acknowledgment.

## **O. SSU: SPONSOR OVERSIGHT**

**TTI-3539** - For CROs using TI Study Start-Up, Sponsors are required to review and approve the first few sites before all Sites can be activated. This is required as the Sponsors want to oversee the process.

- The system shall support an additional level of QC check for documents called 'Sponsor Review'
- The system shall allow the Start-up Specialist (SUS) to push any documents for Sponsor Review.
- The system shall provide a new view for the Sponsor (just like the regulatory Reviewer) to access the documents available for review
- The Sponsor shall have the ability to approve or reject the documents submitted for review.

## **P. SSU IRB APPROVAL: SUBMISSION PACKAGES**

**TTI-2988** - SSU supports creating, tracking and managing Submission Packages for Health Agencies. However, submissions are required to be made to IRBs and Ethics Committees throughout the lifecycle of the Study.

With this enhancement, SSU will expand the concept of Submission Packages to IRBs/ECs.

- The system shall allow creating of Submission Packages for IRBs associating them with Sites.
- The Submission Packages shall have different status.
- When approving the Submission Package, the system shall prompt the User to identify the Sites for which the approval has been received.
- The system shall allow approving all or some Sites associated with the Submission Package

- Approval for submission packages shall trickle down to sites IMPROVEMENTS SUBMISSION PACKAGES

In the European Union, a single submission package is created that is used for multiple countries. This new feature provides a way to assign a submission package to multiple countries.

- When creating a submission package, or when editing it, the User has the ability to assign multiple countries in the submission package profile tab.
- When multiple countries are chosen, this submission package automatically shows in each of those countries.

When the status of the submission package is changed, it automatically shows the status for all the countries associated with that submission package.

## Q. REPORT UPDATES

The following reporting improvements have been made:

### Updated Feature:

- **Audit Summary Report:** Includes the percentage quality of the quality review
- **Document Submission Inventory Workflow Report:** Includes the Organization name to provide the name of the company the user belongs to
- **Placeholder Report:** Now includes information about the assignee for each placeholder, and a listing of all documents linked.
- **Document Review Report:** Many new fields have been added.
- **Queries Report:** Editor users can now view all queries.
- **UPDATED All Reports:** Manager role may now configure the reports dashboard.
- **UPDATED All Reports:** Now contain a description of the report.

### New Feature:

- **Index/Filing Structure Report:** Provides a validated snapshot of a TI Room’s current configuration for both the index and document types
- **Controlled Documents Report:** Provides comprehensive details of controlled documents
- **Acknowledgments Report:** Provides details on the current set of acknowledgments.

## R. TECHNICAL UPDATES

The following technical improvements are made to Trial Interactive:

- TI now supports a new content store, supporting much larger file sizes and improved performance.
- TI now supports an upgraded database service and UI cache, improving performance and scalability.
- TI now supports a Universal Document ID (UDID) for all Document Types and all rooms, allowing for a simpler association and management of document classification.
- TI Viewer: A new version of the TI Viewer is now included, supporting bulk page rotations and an improved user interface
- TI Editor: An updated version of the TI Editor is now included, supporting back-to-back document comparison, better commenting within tables, and many other capabilities



- TI now supports the detection and reporting of problematic files, including encrypted files, Portfolio PDFs, password-protected documents, and digitally signed PDFs.

## 8. Release Schedule

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

Schedule (All time zones are in ET)	
<b>Date of Release</b>	22-Nov-2024
<b>Estimated US MTI Upgrade Date/Time:</b>	22/Nov/2024 9:00 PM EST
<b>Estimated EU MTI Upgrade Date/Time:</b>	22/Nov/2024 9:00 PM CET
<b>Estimated China MTI Upgrade Date/Time:</b>	29/Nov/2024 8:00 AM CST
<b>Date of Dedicated Client Upgrade:</b>	All times are in the local time zone to the hosting country. For information about upgrading your dedicated instance to this new version, please contact your <a href="#">TransPerfect</a> Customer Success Manager.

## 9. Hardware and Software Requirements

The following describes the hardware and software requirements to use the Trial Interactive v10.6 platform.

System Requirements	
<b>Operating System</b>	<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 my mobile app (see myTI release notes)</li> </ul>
<b>Browser</b>	<ul style="list-style-type: none"> <li>Microsoft Edge: Version 88 and 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>NOTE: TI Sign requires that pop-up blockers be disabled for the Trial Interactive domain.</li> </ul>
<b>Client Software</b>	<ul style="list-style-type: none"> <li>For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally.</li> <li>For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred).</li> <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 Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available to support this feature on Internet Explorer® and Firefox®.</li> </ul>
<b>Optional Add-Ons</b>	<ul style="list-style-type: none"> <li>DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions)</li> <li>Adobe Sign (Latest Adobe Document Cloud Version)</li> <li>Optional: SAS Viewer or compatible software must be installed for SAS Datasets. 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> </ul>

## 10. Changes

### Legend for Impacts

Trial Interactive v10.6 has been released with these enhanced features and defect fixes. These tables use the following definitions of functional risk and customer impact:

- **Critical** - A core function is added or updated with far-reaching functional risk or changing or impacting existing customer workflows.
- **Major** - This Defect has an impact on basic functionality or major functional risk.
- **Minor** - There may be a small impact on business in specific use cases.
- **None** - This is a cosmetic or extremely minor change with no impacts or risks.

### Legend for Offerings

- Electronic Trial Master File (eTMF)
- Study Start-Up (SSU)
- Collaborate (CMS)
- Quality Management System (QMS)
- Platform

### A. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
ETMF-214	Platform	<p>This improvement introduces a comprehensive system for managing organizations within the TI platform, applicable across eTMF and Collaborate rooms. Users can now represent organizations, vendors, suppliers, and other third parties as folders within the room index, complete with binders, folder hierarchies, and required placeholders.</p> <p><b><u>Key features include:</u></b></p>	Yes	No	Major	<p><b>Affected Users:</b> Admins and above</p> <p><b>Impact:</b> This improvement has a major impact on managing organizations within the TI platform. For eTMF, folders no longer need to be manually created, but instead vendors and third parties</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p><b>Organization Management:</b> Add, modify, or remove organizations and their associated metadata such as status, type, subtype, and services provided. These organizations are available for all rooms under the Domain and are stored centrally so can be re-used across several trials or the QDMS.</p> <p><b>Binder and Hierarchy Support:</b> Create and manage binders and binder hierarchies to reflect organizational structures.</p> <p><b>Security and Permissions:</b> Enhanced security settings allow for controlled access and modification rights based on user roles (Room Managers, Admins, Super-admin).</p> <p><b>Document Management:</b> Configure required document placeholders and document types specific to each organization, supporting languages and auto-routing.</p>				<p>are added centrally, with the TTI-3597 required folders and placeholders created automatically in the eTMF.</p> <p>NOTE: Initially, organizations must be created through a service desk ticket. This will be improved in a future release.</p>
ETMF-542	Platform	This feature improves the general look-and-feel of the standard email notifications for Trial Interactive, adding a header, footer, and clear buttons for actionable links to end-users.	Yes	No	None	<p><b>Affected Users:</b> All users.</p> <p><b>Impact:</b> This improvement has a very minor impact on email look and feel, adding a header and footer along with clearer fonts and buttons. It has been evaluated with all major email systems; older systems may have some</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
ETMF-1053	Platform	<p>To enhance data security, the Online Guide within the TI application now has a newly updated look-and-feel, with improved navigation and a more comprehensive index.</p> <p><b>Enhancements:</b></p> <ul style="list-style-type: none"> <li>• <b>New URL for Online Guide:</b> The User Guide URL has been updated to a secured location, "<b>guide.trialinteractive.com</b>", and is now accessible to the users.</li> <li>• <b>Updated 'Help' Button:</b> The 'Help' button within TI/eTMF now redirects users to the new URL, providing seamless access for users.</li> <li>• <b>Gradual Deprecation of Old URL:</b> The previous URL <b>tiug.trialinteractive.net</b> remains available temporarily for users not yet upgraded to version 10.6 (or GL 2.5, CTMS 2.1). Once upgraded, users will be redirected to the new secure portal, with the old URL phased out accordingly.</li> </ul>	No	Yes	Minor	<p>minor issues with display, but this is not expected. NOTE: Any email transmission issues should be reported immediately to the TI Service Desk.</p> <p><b>Affected Users:</b> All Users</p> <p><b>Impact:</b> This Improvement has a minor impact on the Online Guide.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
ETMF-1100	Platform	This feature enhances the TI Viewer to allow users to rotate all pages in a file with a single click, significantly improving document editing efficiency. Issues such as unsaved rotations, the inability to delete multiple blank pages, timeouts when rotating more than five pages, and overall performance during page rotations have been resolved. These updates ensure a smoother and faster experience when modifying documents in the TI Viewer.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This Improvement has a minor impact on the TI Viewer Rotation functionality. NOTE: This improvement only allows all pages in a file to be rotated at once. If only some of the pages should be rotated, they must still be done one at a time. This will be improved in a future release.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
ETMF-1853	Collaborate (CMS)	<p>Currently, users can only claim a workflow step from views directly associated with workflows. This improvement has streamlined this process now user can claim a workflow step from any of the views within the “<b>Index</b>” or “<b>Document Repository</b>”.</p> <p>For Collaborate, the Claim should be available from the Index or Document Repository views.</p> <p>The <b>Claim</b> button will only be visible if the user has an active workflow step assigned for the document. If the workflow step has already been claimed or completed by another user, a message will appear upon clicking the <b>Claim</b> button, informing the user that the step has been completed by another individual.</p> <p><b><u>New Workflow Action Buttons Introduced:</u></b></p> <ul style="list-style-type: none"> <li>• Claim</li> <li>• Release</li> <li>• Team Edit Status Updates</li> <li>• Check Out</li> <li>• Check In</li> <li>• Start Workflow</li> <li>• Sign</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Collaborate.</p>



ETMF-2305	Collaborate (CMS)	<p>This improvement adds flexibility and control to the document review process. This update extends the Comment-Only Review functionality, which currently exists as a part of TI CTMS report workflow process, to our Collaborative Review Workflow, as well as providing more configurable options within Workflow Configuration.</p> <p><b>Key Improvements:</b></p> <ol style="list-style-type: none"> <li> <b>Comment-Only Review for Collaborative Review Workflow:</b> <ul style="list-style-type: none"> <li>A new "<b>Comment Only Review</b>" toggle is available in the <b>Approval Stage</b> of the <b>Workflow Creation Window</b>. This allows administrators to enable or disable Comment-Only Review for each workflow.</li> <li>When enabled, Document Reviewers in the <b>Collaborative Review Workflow</b> can provide comments on the document but will be restricted from making any content changes. This ensures the integrity of the original document is preserved.</li> </ul> </li> <li> <b>Extended Control for CTMS Visit Reports:</b> <ul style="list-style-type: none"> <li>Reviewers accessing <b>CTMS Visit Reports</b> with Comment-Only permissions will now be able to add in-line comments but will be unable to edit or change the report's content. This feature is</li> </ul> </li> </ol>	Yes	No	Minor	<p><b>Affected Users:</b> Editor and above</p> <p><b>Impact:</b> This improvement gives additional flexibility to the options currently available for users who wish to restrict reviewer access to modify documents during the review process.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>now configurable within the Workflow settings, adding flexibility to different review scenarios.</p> <p>3. <b>Restriction on Offline Editing in Comment-Only Workflows:</b></p> <ul style="list-style-type: none"> <li>To prevent unauthorized content changes, <b>offline editing</b> is now disabled for any document in a Comment-Only Workflow. Reviewers will be able to access the document online to provide feedback without the risk of altering the document’s content.</li> </ul> <p>4. <b>Document Owner Permissions:</b></p> <ul style="list-style-type: none"> <li>After Document Reviewers have added comments in the Workflow review process, the <b>Document Owner</b> can view all the comments and retains the ability to make necessary updates or changes to the document content.</li> </ul> <p>This enhancement provides better control and security in document reviews, ensuring that the comment-only review process is seamless and efficient while safeguarding against unintentional or unauthorized document modifications.</p>				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2379	Platform	<p>This improvement introduces advanced filtering capabilities in the TI grid view, enabling users to easily filter and export documents while viewing the entire folder hierarchy. Filters are saved with the current view and offer options based on metadata field types. All filtered views can be exported, enhancing document management efficiency within the platform. When combined with the 'Expand' feature, documents may be quickly filtered down.</p> <p>For the eTMF, key filters such as zone, section, artifact, sub-artifact, index number, document type, and various dates are available from any grid view. These filters may be saved to a private view of data or a public view that is set as the default by the administrator.</p> <p>For the QDMS a new 'Training Required' checkbox has been integrated into the metadata options to support compliance and training protocols.</p>	Yes	Yes	Major	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a major impact on the filters in the TI grid view.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2528	Platform	<p>This enhancement brings a new level of convenience and efficiency to collaborative reviews by enabling the display of the document metadata panel during active collaborate sessions. This feature allows participants to view essential metadata in real time, providing immediate context that can significantly inform and guide the review process.</p> <p>With key information such as metadata, info, version history, review history, queries, instructions, submitted name, document ID, generated name, and collaborate status readily accessible, collaborators can make more precise and informed contributions, leading to a more streamlined and effective review cycle.</p>	Yes	Yes	Critical	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a critical impact on the Collaborate Module (Metadata panel during active sessions)</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2796	Trial Master File (eTMF)	<p>This update introduces a streamlined process for handling form 1572 documents in the TI platform. When a form 1572 is uploaded, the system will automatically detect the document type and launch a guided wizard to extract and match metadata with existing sites and contacts.</p> <p>The system will prompt users to confirm matches or create new entries if no matches are found. Users with the appropriate privileges can create new sites or contacts directly through the wizard, while those without privileges will receive guidance on the next steps. The 1572 document will be classified and indexed with metadata, and confidence scores provided by the system.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editors and above</p> <p><b>Impact:</b> This improvement has a major impact on 1572 documents in the TI platform.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2899	Trial Master File (eTMF), Collaborate (CMS), Study Start Up (SSU)	This enhancement now allows Admins to manage site access directly from the user management screens. This update simplifies the process by enabling both user addition to a room and site access configuration in one place. This functionality is available for Site Portal, Site Collaborate/eISF, Safety Notification, and Remote Monitoring Room service offerings.	No	Yes	Minor	<p><b>Affected Users:</b> Admins and above.</p> <p><b>Impact:</b> This improvement has a minor impact on the User Management module. NOTE: While Site Users may now change sites using the new Sites tab on the User Profile, Site security options, including access to the restricted folder, must still be managed separately after the user has been initially invited to the room.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2911	Collaborate (CMS)	<p>This enhancement enhances the Collaborative Review feature to allow review owners to customize the review name when initiating a review. Previously, the review name defaulted to the document's title, especially when using a document template.</p> <p>With this update, users can now configure auto-naming rules for the collaborative review, and if needed, they may modify the review name at the start, providing greater flexibility and control over review naming. They can also add instructions, which will be sent out to all reviewers in a notification, providing additional information about a review. This improvement addresses the limitation of being restricted to the template title and allows for the inclusion of custom or generated names.</p>	Optional	Yes	Minor	<p><b>Affected Users:</b> Editor and above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Collaborate. Note that the auto-naming rules may now be configured for the collaborative review if desired or overridden as needed when starting the review.</p>

TTI-2936	Platform	<p>With this improvement, users will now see a clear indication when a document is digitally signed, with accompanying informational text guiding them to download the document to verify the signature using Adobe Acrobat or Reader.</p> <p>Additionally, the system now handles watermark errors on digitally signed documents more gracefully, providing clear messages explaining why watermarks or OCR cannot be applied.</p> <p>A new field called "Document Issues," has been added to indicate issues with digitally signed documents, which can also be exported for reporting purposes.</p> <p>Additional data available in that field includes:</p> <ul style="list-style-type: none"> <li>• <b>IsSigned</b> - indicates the document is digitally signed</li> <li>• <b>IsPasswordProtected</b> - indicates the document is password protected.</li> <li>• <b>IsPortfolio</b> - indicates the document is a Portfolio PDF</li> <li>• <b>isOCR</b> - indicates the document has OCR text available for search and extraction</li> </ul>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Collaborate and eTMF Modules. Note the following:</p> <ul style="list-style-type: none"> <li>• If MSOffice documents are password protected, they may still be opened using the TI Editor, which will prompt the user for the password.</li> <li>• Digitally signed documents will not be processed for OCR by default as that would invalidate the eSignature.</li> <li>• Portfolio PDF documents cannot be viewed using the TI Viewer or TI Editor as this is a proprietary format. They must be downloaded and opened in a desktop version of Adobe Acrobat.</li> </ul>
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TTI-2975	Collaborate (CMS)	<p>This improvement enhances the capability to support Acknowledgments within the Site Portal, eISF, or Safety rooms, allowing users to assign documents to others for sign-off or Read &amp; Acknowledge.</p> <p>Users can upload Safety Letters and configure metadata, distribute these letters to both Site Users as well as other users within the room, and manage contact and site information within the Safety Letter Distribution room.</p> <p>This enhancement supports the Read and Acknowledge (R&amp;A) feature to electronically acknowledge new documents such as CIOMS, PSURs, DSURs, Investigator Brochures and other critical documents, ensuring the timely confirmation of safety issues and avoiding manual follow-ups. Notifications are sent to all relevant parties, who can then acknowledge and confirm receipt. Each acknowledgment is logged as a separate record, maintaining a transparent and traceable audit of who has reviewed and understood the document. This system additionally supports the cancellation and replacement of the acknowledgment, as well as manual and automatic email reminders.</p> <p>The update also includes four additional 'R&amp;A' views to show the status of Acknowledgments, a quick view panel update that lists out the status by site and contact, the ability to configure who at each Site should receive the notification, reminders for acknowledgments, managing document replacements, and</p>	Yes	No	Major	<p><b>Affected Users:</b> Editors and Above, with the 'Acknowledge' permission.</p> <p><b>Impact:</b> This improvement has a major impact on Safety Workflows. Note the following:</p> <ul style="list-style-type: none"> <li>• Site Users who are the recipients of the acknowledgement will have security on the document automatically updated to provide them Reader access with the ability to download the document.</li> <li>• If security is changed on the parent folder of documents that have been sent for acknowledgement, the Site Users may lose access to view them.</li> <li>• Once the acknowledgements have all been completed, it is recommended in eISF rooms to copy/clone</li> </ul>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		tracking all acknowledgments through a standard report and audit trail.				the document to all sites included in the acknowledgement. Future versions of TI will make this an automated process.

TTI-2988	Study Start-Up (SSU)	<p>This new feature streamlines the management of IRB Submission Packages and Approvals in multi-IRB environments:</p> <p><b>IRB Submission Packages:</b> Users can now create, replicate, and manage IRB Submission Packages, with the ability to associate specific sites, select relevant documents, and track package statuses (Pending, Submitted, Approved).</p> <p><b>Site Association:</b> The system prompts users to associate sites when creating or replicating submission packages and allows new sites to be added to already submitted packages.</p> <p><b>Approval Flexibility:</b> Users can approve all or some sites within a submission package, and approval dates are recorded in the Site Profile under IRB Approval Date.</p> <p><b>Handling Multiple IRBs:</b> Sites associated with multiple IRB Submission Packages will receive submission and approval dates from the first package, ensuring accurate and consistent tracking.</p> <p><b>Custom Approval Management:</b> The system allows for flexible handling of Central and Local IRB approvals, including marking site-specific approval dates and updating them independently of the main IRB profile.</p> <p>These enhancements provide greater flexibility and accuracy in managing IRB submissions and approvals, particularly in complex multi-IRB scenarios.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on IRB Submission Packages and Approvals in Multi-IRB Environments.</p>
TTI-2997	Collaborate (CMS)	<p>This enhancement supports an Automatic Processing workflow capability for specific</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>solution offerings, such as Collaborate or Quality Management rooms. Admins can now configure rooms so that any document entering the room—whether newly created, uploaded, emailed, or shared—is automatically entered into a default Automatic Processing workflow. Different automatic processing workflows may be chosen based on a metadata value or document type. Document owners and proxy owners have the flexibility to change the workflow of a document that has already entered the automatic workflow to a different predefined workflow by excluding the document from the workflow, which will provide a way of launching the workflow wizard automatically to assign appropriate reviewers and approvers. Once a document is approved and Final in the automated workflow, it will be auto-routed to a destination folder and may be then sent through a review process (checkout and check in) and launched into another workflow manually or automatically and configurable by Document Type.</p> <p>The system restricts each document to only one workflow at a time. Additional safeguards ensure that certain workflows, such as Change Control and Administrative workflows, cannot be used as the automatic 'Processing' workflow.</p>				<p><b>Impact:</b> This improvement has a minor impact on the Collaborate Rooms. Automated workflows support all auto-routing features of eTMF rooms, allowing for a manual classification of all incoming documents. The Automate AI may also be enabled, allowing for automatic classifications in eISF, Safety, QDMS, and other Collaborate rooms.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3095	Platform	<p>This improvement provides capabilities for identifying and handling password-protected documents and Portfolio PDFs within the TI system. Users will now see clear indications in the document list when a document is password protected, with additional support for automatically attempting to open MSOffice files in the TI Editor, where users will be prompted to enter the password. For documents that cannot be viewed directly in the system, such as Portfolio PDFs, users will receive a message explaining the issue and providing guidance on how to view the document.</p> <p>A new "Document Issues" field in the grid view has been added to indicate whether a document is password protected or a Portfolio PDF, with this information also available in exported reports. Additionally, the system now gracefully handles watermark and OCR errors on digitally signed documents, providing users with clear instructions on how to verify signatures.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on Document Handling in TI.</p>

TTI-3178	Trial Master File (eTMF), Collaborate (CMS), Quality Management System (QMS), Study Start Up (SSU),	<p>This enhancement upgrades the TI Editor with additional capabilities.</p> <p><b>Key Enhancement:</b></p> <ul style="list-style-type: none"> <li>• <b>Comments within tables:</b> The comments feature has been improved to support the selection of text within a table and the addition of a comment, so that the comment appears anchored to the text and not just to the entire table.</li> <li>• <b>Document Comparison:</b> Enhanced document comparison allows users to view differences between two versions, with the option to Accept or Reject changes in the updated document.</li> <li>• <b>New Button for Document Editing Mode:</b> A convenient toolbar button now allows quick switching between Editing, Reviewing, and Viewing modes.</li> <li>• <b>Support for Page Color in Document Editor:</b> Users can now customize page colors, adding more flexibility and personalization when formatting documents.</li> <li>• <b>Goal Seek Functionality in Spreadsheet Editor:</b> The new Goal Seek feature enables users to perform "what-if" analyses, aiding in data-driven decision-making.</li> <li>• <b>Partial Support for Bidirectional Text:</b> A crucial enhancement for users working with right-to-left languages,</li> </ul>	Yes	Yes	Minor	<p><b>Affected Users:</b> Reader and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the TI Editor.</p> <p>NOTE: For CTMS Visit Reports, the Editor has been improved to support comments added by reviewers within the questionnaire tables. For certain report designs, it may be necessary to modify the visit reports in order to support comments within these tables. Please contact your CSM for more details on this procedure</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>improving text alignment and readability</p> <ul style="list-style-type: none"> <li>• <b>Screen Reader Support:</b> Achieving Section 508 Compliance, this accessibility feature ensures an inclusive experience for visually impaired users.</li> <li>• <b>Support for SVG Graphics:</b> SVG handling is now supported, allowing for scalable vector graphics with no loss of quality.</li> </ul>				
TTI-3200	Collaborate (CMS), Quality Management System (QMS)	<p>This improvement enhances the grid view filter experience, making it easier to view, sort, filter, and export collaborative review information. Users can now apply filters through intuitive drop-down menus with multi-select options.</p> <p>The system now logically combines multiple filters (AND) and values within a filter (OR). Additionally, tabbed views allow for quick access to different filter configurations, and a new 'Training Required' checkbox has been added to the metadata for easier reporting.</p> <p>These filters are fully supported by saved grid views, so multiple custom views may be created with different selections of Columns and Filters for each, along with default selections for each different index view.</p>	Yes	No	Major	<p><b>Affected Users:</b> Reader and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Collaborate grid views.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3255	Collaborate (CMS)	<p>This release introduces significant enhancements to streamline workflow management in Study Collaborate and Quality Management Solutions.</p> <ol style="list-style-type: none"> <li><b>Automatic Processing Workflow:</b> Support for an Automatic Processing workflow has been added, allowing documents to be automatically pushed into the room default workflow when added to the room.</li> <li><b>Document Type Associations:</b> The system now associates document types directly with workflows and templates, adhering to the "Rule of 1." This improves usability by limiting the number of workflows and templates per document type that the user needs to choose from when starting a new document workflow. Specific options for default review groups, training requirements, approvers, and workflow configurations can also be preset.</li> </ol> <p>These updates aim to enhance user experience and ensure compliance within clinical and life sciences settings.</p>	Yes	No	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Collaborate Room.</p>



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3285	Platform	<p>This feature introduces new TI Analytics module for cross study dashboards. This enhancement enables dynamic and interactive dashboards to support key clinical trial metrics and surpass competitive offerings.</p> <p><b>Key Features:</b></p> <ul style="list-style-type: none"> <li>• <b>eTMF KPI Dashboard Upgrade:</b> The cross study KPI dashboards available with v10.5.5 will be replaced with new KPI analytics dashboards in Q1 2025.</li> <li>• <b>New Layout:</b> The new KPI analytics dashboards will have a layout with different tabs for distinct categories, instead of showing all dashlets on one screen.</li> <li>• <b>New Chart Types:</b> TI Analytics will have new chart types not available earlier including Funnel Charts and Sankey Diagrams.</li> </ul>	Yes	No	Minor	<p><b>Affected Users:</b> Admin Users.</p> <p><b>Impact:</b> Since TI Analytics are cross-study dashboards, these are not enabled by default for all users.</p> <p>In the initial roll out phase, TI will invite users for Early Adopter Program of this new feature before its general availability in Q1 2025.</p> <p>If you wish you participate in the Early Adopter Program, please contact your Customer Service Manager.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3305	Platform	<p>This Improvement improves site contact management and document expiration handling in the TI system:</p> <p><b>Manual Entry of Activation/Deactivation Dates:</b> Users can now manually enter start and end dates when activating or deactivating a site contact. This ensures that the system accurately reflects when a contact is associated with or removed from a study.</p> <p><b>Improved Expired Document Dashlets:</b> The Expired Document Dashlet now respects these manually entered dates, only displaying expired documents relevant to the active period of the site contact. Documents associated with deactivated contacts will no longer appear after the specified end date.</p> <p><b>Enhanced Contact Management:</b> Users can now manage site contact details more efficiently from both the Site and Contacts modules, with improved functionality for exporting contact-level fields and updating contact information during the coding process.</p> <p><b>CTMS Integration:</b> Contacts coming over from the CTMS will inherit their start and end dates.</p> <p>These enhancements streamline site contact management, reduce clutter in the Expired Document Dashlet, and improve overall efficiency in handling site contacts and related documents.</p>	No	Yes	Major	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on on-site contact management and document expiration handling in the TI system</p>

TTI-3344	Platform	<p>With this improvement, the Collaborate and QMS room types have been updated to provide a more intuitive content management experience within the Documents module. The Collaborative Workspace submodule is still available but is deprecated, to be removed in the next minor TI release. This submodule is now replaced with enhanced views integrated into the Documents module. Key views include:</p> <p><b>Index View:</b> Displays all documents in various workflow stages within the Room Index.</p> <p><b>Currently Editing:</b> Replaces the Collaborative Workspace submodule and 'Checked Out By Me' view, showing documents users are actively engaged with (e.g., Author, Editor, Reviewer). Includes Team Edits, Online Edits, Offline Edits, and Overdue documents.</p> <p><b>Documents I Own:</b> Shows all documents within the index tree where the current user is either an Owner or a Proxy Owner.</p> <p><b>My Workflow Assignments:</b> A 'By Status' view but only showing documents specific to the current user.</p> <p><b>My eSignatures:</b> An 'eSignatures' view but specific to the current user.</p> <p><b>My Planned:</b> Displays both manual and required document placeholders assigned to the user through the Responsible Department / Responsible Party feature, providing an interface to drag and drop documents for placeholder assignment, or uploading content for placeholder fulfillment.</p> <p><b>My Recents:</b> Displays the most recent documents the current user has edited.</p>	Yes	No	Major	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a Major impact on the Collaborate Module. Because of the nature of this user interface change, the Collaborative Workspace submodule still exists but is now deprecated and will be removed in the next minor version of TI. These new views must be enabled by each user to truly take full advantage of this additional flexibility.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p><b>Edits in Progress:</b> The equivalent of the 'Currently Editing' view but shows everyone's current edits across the room.</p> <p>These updates align the interface with the working styles of content management users, providing more relevant and accessible views. Additionally, metadata panel updates have been implemented to support these new views.</p>				

TTI-3385	Platform	<p>This feature integrates improved artificial intelligence into Trial Interactive to enhance the existing document indexing and metadata extraction feature. This upgrade allows for automated document type identification and metadata extraction using advanced AI, improving the accuracy and efficiency of document processing in eTMF rooms and other service offerings.</p> <p><b>Key features</b></p> <p><b>Automated Document Processing:</b> AI is now used to automatically detect document types and extract relevant metadata to calculate a confidence score and extract a rationale for why the system chose a particular document type.</p> <p><b>Manual Intervention for Unmatched Data:</b> The system handles cases where sites, organizations, or contacts do not match existing records, creating draft contacts when necessary and prompting users for changes in principal investigators.</p> <p><b>Flexible Workflow Integration:</b> Documents are automatically processed through the MDE queue after OCR, with the ability to promote or hold documents based on confidence thresholds.</p> <p><b>Enhanced Metadata Management:</b> The system now supports room-specific document training, failure modes, and multiple document types, ensuring that extracted metadata is accurate and tailored to specific needs.</p>	Yes	No	major	<p><b>Affected Users:</b> Editors and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on Metadata Extraction by using Improved Artificial Intelligence</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p><b>Efficient Error Handling:</b> Documents that fail to meet confidence thresholds or encounter errors are sent to a queue for further review by engineers, ensuring continuous improvement and accuracy.</p> <p>This integration marks a significant step forward in automating and improving document management workflows within Trial Interactive, leveraging the latest in AI technology to enhance performance and accuracy.</p>				

TTI-3386	Study Start-Up (SSU)	<p>We have introduced a new feature to streamline the management of submission packages across multiple countries, particularly for EU submissions:</p> <ul style="list-style-type: none"> <li>• <b>Assign Multiple Countries:</b> Users can now assign a single submission package to multiple countries directly from the submission package profile tab, simplifying the process and ensuring consistency.</li> <li>• <b>Automatic Linking:</b> Once a submission package is assigned to multiple countries, it will automatically reflect in each of those countries, linking the package to their respective submission processes.</li> <li>• <b>Status Synchronization:</b> Any changes to the status of a submission package will automatically update across all associated countries, maintaining consistent status information.</li> <li>• <b>Efficient Management:</b> The system allows for easy addition or removal of countries from a submission package, with updates promptly reflected across all associated countries.</li> <li>• <b>Country Profile Integration:</b> Submission package details, including status and country associations, are now visible in the country profiles, ensuring transparency and easy access to information.</li> </ul> <p>This update enhances the efficiency and accuracy of managing submission packages across multiple countries, particularly in complex, multi-country submission processes.</p>	Yes	No	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Submission Packages assigned in multiple countries. It streamlines the process where a Regulatory Authority is used for submissions for multiple countries.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3398	Trial Master File (eTMF)	With this new feature, TI now enables a Contact Form for managing Contacts across all sections of the application, replacing the previously used User Form. This update standardizes contact management throughout the platform for improved consistency and efficiency. A quick-view panel is also provided in the Contacts and Sites submodule for simpler editing and access.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Site Contacts.</p>
TTI-3407	Platform	This improvement implements a database upgrade to enhance the performance of the TI system.	Yes	No	Critical	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on database upgrade.</p>



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3408	Platform	<p>This feature enables content storage in an added content platform, delivering enhanced scalability and security. Support for an added content store includes the following capabilities:</p> <ul style="list-style-type: none"> <li>• Support for files up to 5 TB in size (must be uploaded through a service desk ticket)</li> <li>• Support for the TI Editor, TI Viewer, and Automate AI with content Integration to TI IAM for authentication and authorization</li> <li>• in-place and in-transit encryption with Improved monitoring of content changes</li> <li>• Configuration and backup of content with features such as versioning, encryption, immutability, checksum verification, restore, and disaster recovery (DR)</li> <li>• Support for multi-region access points, content migration, streaming, performance optimization, and cloud caching</li> <li>• Version and Rendition control table implemented in Trial Interactive</li> </ul>	Yes	No	Critical	<p><b>Affected Users:</b> SuperAdmin</p> <p><b>Impact:</b> Although there are no user impacts, this improvement has a major technical impact on the platform.</p>

TTI-3539	Study Start-Up (SSU)	<p>This feature enables the system to allow sponsors to review and approve sites before CROs can approve them.</p> <p><b>Key Features:</b></p> <ul style="list-style-type: none"> <li>• <b>Sponsor Review Workflow:</b> Introduces a new Sponsor Review stage, adding an additional level of document quality control (QC) before site activation.</li> <li>• <b>Configurable Workflows:</b> Sponsors can be included in both one-step and two-step workflows through settings configurations.</li> <li>• <b>Sponsor-Specific Role:</b> A new Sponsor Oversight role is added, restricting sponsor access to only the documents meant for their review, similar to the Regulatory Inspector in the Audit Module.</li> <li>• <b>Manual Document Submission:</b> Start-up Specialists (SUS) can select and manually push documents for Sponsor Review. Only documents that have passed prior QC stages can be submitted for sponsor approval.</li> <li>• <b>Multiple Iterations:</b> The system allows multiple submissions of documents to the sponsor, even if the entity is not fully complete.</li> <li>• <b>Sponsor Approval Status:</b> Documents sent for sponsor review will have a dedicated Sponsor <b>Approval Status</b>.</li> </ul>	Yes	No	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This feature has a minor impact on Sponsor Oversight for Site Activation.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3550	Trial Master File (eTMF)	<p>Sites with pending sponsor approval cannot be activated by the SUS.</p> <ul style="list-style-type: none"> <li> <b>Sponsor Dashboard View:</b> Sponsors will have access to an SSU dashboard, where they can view and filter documents by sites, countries, IRBs, and document status.                     </li> </ul>				
		<p>This update enhances the Contacts management capabilities within TI Rooms by allowing Admins and Managers to edit contact information directly from the main Contacts view. Previously, this functionality was restricted to Superadmins.</p> <p>Admins and Managers can now modify contact details such as Name, Address, and other relevant fields. However, the ability to change the Contact Email address remains restricted and cannot be modified by Admins or Managers.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Manager and Above.</p> <p><b>Impact:</b> This Improvement has a minor impact on the Contacts.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3567	Platform	<p>This improvement introduces the "Smart Breadcrumbs" feature in the TI product User Interface, designed to significantly enhance navigation across the platform. This update replaces the static breadcrumb system with an interactive, dynamic navigation structure, allowing users to seamlessly switch between different applications, modules, and submodules. Users can now click on breadcrumbs to navigate to any previous point in their workflow, with each breadcrumb displaying a dropdown menu that offers additional navigation options within the same level.</p> <p>The Smart Breadcrumbs feature is context-sensitive, ensuring that users can switch between related elements, such as studies, sites, or contacts while maintaining their current state or data context. This update is integrated consistently across all modules and applications within TI, providing a cohesive and user-friendly experience.</p>	No	Yes	Major	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the eTMF User Interface.</p>
TTI-3597	Trial Master File (eTMF)	<p>This improvement added a mandatory picklist of failure reasons in the quality review audit process. This dropdown, prepopulated with 13 common failure reasons, standardizes the reporting of quality review rejections. This improvement improves consistency and clarity in documenting review failures.</p>	Yes	Yes	Minor	<p><b>Affected User:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on Quality Review audit reporting</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3613	Platform	<p>A powerful enhancement to TI Automate that leverages machine learning to classify and extract metadata on uploaded documents. This feature streamlines the QC process, allowing users to trust and validate machine-extracted metadata more efficiently and supporting a 'human in the loop' approach to document QC.</p> <p><b>Key highlights include</b></p> <ul style="list-style-type: none"> <li>• A confidence score for extracted fields that is configurable at the domain. Users can choose which data is most crucial for weighting their confidence score.</li> <li>• A view of all extracted data alongside the document and the ability to accept or update the information extracted.</li> </ul> <p>Multi-language support: TI Automate supports over twenty languages including but not limited to English, Spanish, French, German, Italian, Portuguese, Dutch, Japanese, Chinese, and Korean.</p>	Yes	No	Major	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This feature has a minor impact on the AI classification and extraction.</p>
TTI-3615	Trial Master File (eTMF), Study Start-Up (SSU)	<p>With this improvement, users can now open and view EML documents in the TI Viewer when sent via the submission inbox or imported into the system. Previously, EML files displayed issues in rendering specific characters from the email subject. This enhancement resolves those issues, ensuring consistent display of email content in TI Viewer.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users</p> <p><b>Impact:</b> This issue has a minor impact on the EML Document in the TI viewer.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3637	Study Start-Up (SSU)	<p>With this update, the system now allows assigning a Health Agency to multiple countries, addressing the specific needs of regions like the EU, where some Health Agencies manage submissions across multiple countries.</p> <p>This change facilitates more efficient and accurate management of submissions that involve regional Health Agencies overseeing multiple countries.</p>	Yes	No	Minor	<p><b>Affected Users:</b> SuperAdmin.</p> <p><b>Impact:</b> This improvement has a minor impact on SSU Countries and deals with configuring the countries with the Regulatory Authorities.</p>
TTI-3727	Collaborate (CMS)	<p>This enhancement allows review owners to enter specific instructions or comments when creating a collaborative review session. These instructions will be visible to all assigned users when they access the review in the collaborative review panel.</p> <p>In addition, reviewers will receive the instructions via email along with the review link, ensuring clear communication and guidance throughout the review process.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Collaborative Review Session.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3731	Collaborate (CMS)	<p>This enhancement streamlines the process of managing CTMS Letters, from creation to distribution and eTMF publication. Letters now automatically enter a workflow upon generation, with assignments based on document type or CTMS configuration.</p> <p>Document owners can edit and finalize letters directly within the workflow without needing to manually start it, and can modify documents without Track Changes enabled by default. For clients with specific business needs, an optional review/approval step can be added between editing and e-signature, utilizing the MVR Approvers Group with options for comments or tracked changes.</p> <p>The workflow also automates document conversion to PDF and initiates a self-sign eSignature step, allowing owners to sign the document and download the final PDF directly. Future updates will include email functionality for document distribution with configurable reply-to options.</p>	Yes	No	Minor	<p><b>Affected Users.</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on UI to support CTMS Letters in CCR workflows.</p>
TTI-3739	Platform	This improvement introduces a new Trial Interactive Logo in our platforms.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on TI Platform</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3746	Trial Master File (eTMF), Study Start-Up (SSU)	<p>An improvement has been made to enable Editor-level users to perform Mass Coding operations, even when Causality Tracking is enabled. Previously limited to Admins and Room Managers, Mass Coding is now extended to Editor-level users, improving efficiency in handling large volumes of data.</p> <p>For final documents, Mass Coding is restricted to Editors with Document Manager action, Managers, and Admins. When applying Mass Coding to non-final documents in study rooms with Causality Tracking enabled, users must provide a reason for changes, ensuring consistency across mixed document selections.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the mass coding for editor-level users.</p>
TTI-3749	Study Start Up (SSU)	<p>This new feature alerts the Start-up Specialist when a Site Contact has been assigned a dummy email address. Upon detection of a system assigned dummy email address, an exclamation alert icon will be displayed on the Contacts screen for the email address with a tooltip stating that the email address is invalid and prompting the necessary course of action.</p> <p>This is important because the lack of a real email ID can cause issues when the Start-up Specialist converts a Site Contact to a user or sends out a regulatory package to the Site Contact.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This new feature has a minor impact on the Study Start-Up Contacts management.</p>



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3760	Study Start-Up (SSU)	<p>With this release, the Trial Interactive CTMS will disable specific status update options for Sites (Active, Rejected, Non-Participating) and Countries (Submitted, Active, Rejected) for SSU integrated studies.</p> <p>When integrated these specific Status updates for sites and countries will be exclusively managed by SSU and CTMS will receive such status updates from SSU.</p> <p>This feature aims to provide users with a clear distinction between activities done in CTMS and SSU.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This new feature has a minor impact on the TI SSU and CTMS Interoperability.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3762	Trial Master File (eTMF)	<p>This improvement addresses a significant issue regarding document finalization and management in eTMF Room Types. Previously, editors who submitted documents and were considered document owners were able to finalize documents without following the designated workflow by using the "Replace as Attachment" function in the Final Document Index. This posed a compliance risk, as editors could upload new documents as final records, potentially violating (GCP) R3 guidelines.</p> <p>The original implementation allowed editors to replace expired final documents through the Expired Document View, but feedback from customers has clarified that this capability should not be extended to general document finalization.</p> <p><b>Enhancements:</b></p> <ul style="list-style-type: none"> <li>In eTMF Room Type ONLY, remove the ability for all base editors who is the document owner to replace an attachment in the final doc index. Additionally, should restrict making any change to final document metadata.</li> <li>In eTMF Room Type ONLY, allow editors with 'Document Management' action to continue to replace attachments for final documents.</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This update enhances compliance and system security by ensuring that only authorized users with the correct permissions can make changes to final documents, while preventing base editors from bypassing workflows or altering final records.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3786	Platform	This improvement finalizes the IAM integration in the US MTI Production environment, enhances the TI login page, and introduces several critical configuration changes in preparation for production rollout.	No	Yes	Critical	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This feature has a critical impact on IAM in US MTI Production.</p>
TTI-3792	Platform	A new setting has been added to allow users to hide the banner by selecting “Do not show again.” However, when a new version of the banner is published, the “do not show again” setting will be reset, ensuring that users who previously opted to hide the banner will see the updated content.	No	Yes	None	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on settings.</p>

TTI-3811	Trial Master File (eTMF)	<p>This release introduces a new feature that allows <b>Super Admins</b> to view the JSON response returned from TI Automate directly from the metadata panel. This enhancement enables Super Admins to easily access and review structured data in a separate window or modal.</p> <p><b>Key Features:</b></p> <p><b>User Role and Permissions:</b></p> <ul style="list-style-type: none"> <li>• Only users with the "<b>Super Admin</b>" role will have access to this functionality.</li> <li>• The "<b>View Response</b>" button is visible only to Super Admins and can be accessed exclusively from the metadata panel.</li> </ul> <p><b>Accessing the JSON Response:</b></p> <ul style="list-style-type: none"> <li>• A "<b>View Response</b>" button has been added to the metadata panel, visible only to Super Admins.</li> <li>• Clicking this button will open the JSON response in a separate resizable window or modal.</li> </ul> <p><b>Window/Modal Specifications:</b></p> <ul style="list-style-type: none"> <li>• The JSON response will be displayed in a structured, readable format (e.g., pretty-printed with indentation).</li> <li>• The window or modal is resizable and allows scrolling to ensure the entire JSON response is viewable.</li> <li>• Basic functionality like copying the JSON to the clipboard is available.</li> <li>• A "<b>Close</b>" button is provided to exit the window or modal.</li> </ul> <p><b>Error Handling:</b></p>	No	No	Minor	<p><b>Affected Users:</b> SuperAdmins</p> <p><b>Impact:</b> This feature enhances the ability of Super Admins to easily access and review JSON data, improving system transparency and efficiency.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3813	Trial Master File (eTMF)	<ul style="list-style-type: none"> <li>If the JSON response cannot be retrieved, an error message will be displayed with an option to retry.</li> <li>Users without the <b>Super Admin</b> role will not be able to see or access the <b>"View Response"</b> button.</li> </ul> <p>In this update, the confidence score section will now display the required metadata fields for all non-1572 documents. The fields shown are selected based on the mapping settings, ensuring that users see relevant and necessary metadata for each document.</p> <p>Additionally, for metadata fields related to sites, a visual indicator (e.g., checkmark or warning icon) will indicate whether the metadata has been successfully extracted and matched with system values. Fields like document date, type, and category will display a checkmark if data is returned from the AI or remain visually marked otherwise.</p> <p>The mapping settings are configurable, allowing users to select which metadata fields should appear in the confidence score section. A user-friendly interface has been designed to make it easy to distinguish between successfully matched and unmatched fields, all while maintaining optimal performance, even with multiple documents.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the TI Automate confidence score and metadata extracted for non-1572 documents.</p>

TTI-3815	Platform	<p>The latest upgrade to the TI Viewer improves the user experience, document interaction, editing, and viewing capabilities.</p> <p><b>Key Enhancements:</b></p> <ul style="list-style-type: none"> <li>• <b>Rotate Multiple Pages at Once:</b> Users can now rotate all pages in the file simultaneously and save the document, enhancing efficiency when modifying content.</li> <li>• <b>Redaction Panel UI:</b> The redaction panel has been revamped, featuring separate buttons for rule-based and manual redaction applications, allowing for the efficient, automated redaction of PHI or PII within documents.</li> <li>• <b>Enhanced Sticky Note Editing with Image Support:</b> Sticky notes now support images, allowing users to copy and paste visuals directly into notes, offering more dynamic ways to share information.</li> <li>• <b>Hyperlink Enhancements:</b> A quick menu now appears when selecting text, enabling the creation of hyperlinks to specific pages or external URLs. Users can easily set a page target or input a URL to create seamless links.</li> <li>• <b>Full XFA Document Support:</b> TI Viewer now fully supports PDFs containing dynamic forms (XFA), ensuring a smooth viewing experience of non-modifiable fields in form-based PDFs.</li> </ul>	No	Yes	Major	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on TI Viewer.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<ul style="list-style-type: none"> <li>• <b>Quick Menu for Text Selection:</b> Selecting text now triggers a Quick Menu under the cursor, enabling fast actions like copying, highlighting, and underlining, speeding up document interactions.</li> <li>• <b>Set a Zone as a Hyperlink Target:</b> Users can now set specific areas as hyperlink targets, extending the hyperlink feature for more precise document navigation.</li> </ul>				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3816	Collaborate (CMS)	<p>In this new Collaborate/QDMS configuration, documents introduced into the system are instantly engaged in an automated processing workflow, optimizing the initial handling and processing stages. This automatic workflow ensures that no document coming into the room is left unmanaged or untracked. However, recognizing the need for flexibility, the system allows for manual reassignment to alternative workflows, accommodating unique document requirements or changes in project direction.</p> <p>With this enhancement, workflows and their templates may now be associated with specific Document Types. This provides a greater degree of control over what workflows each specific document type may be engaged in. Additional controls are added to clarify what CTMS workflows and templates may be associated with Visit Reports and Letters.</p> <p>Finally, in Collaborate / QMS rooms, Document Owners and Proxy Owners may now exclude a document from a workflow, and they are immediately prompted for the new desired workflow based on the Document Type.</p>	No	Yes	MINOR	<p><b>Affected Users:</b> Editor and above</p> <p><b>Impact:</b> This improvement grants users additional flexibility to exclude documents from automated workflows.</p>



TTI-3821	Collaborate (CMS), Quality Management System (QMS)	<p>This enhancement provides a warning rather than a restriction when a user attempts to launch an Admin workflow for a document that was previously eSigned. This ensures that users are aware that no new eSignature will be generated, while still allowing them to proceed with administrative updates as needed.</p> <p><b>Key Changes:</b></p> <ol style="list-style-type: none"> <li><b>Warning Message:</b> When a user attempts to send an eSigned document into an Admin workflow that does not require eSignature, they will now receive a warning. The message will inform them that the workflow allows updates but will not generate a new final document with updated placeholder fields since there is no eSignature step involved.</li> <li><b>Warning Message:</b> "You are about to send the e-signed document to an administrative workflow that does not support e-signatures. Would you like to proceed?"</li> <li><b>User Confirmation:</b> The user must confirm by selecting "Yes" to proceed with the Admin workflow. This confirmation ensures that the user understands that the workflow will update the document without generating a new e-signed final version.</li> </ol>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This Improvement has a minor impact on the Admin Workflow.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3826	Study Start-Up (SSU)	<p>4. <b>Effective Document Handling:</b> Even though a new administrative version is not signed, any administrative changes made will still be considered Effective since the original signed document is already in place. The administrative update can be disseminated and trained on without the need for a new eSignature.</p> <p>5. <b>GlobalLearn LMS Update:</b> Once the administrative updates are completed, the latest PDF rendition (without a signature) will be pushed to GlobalLearn, ensuring that users are trained on the most up-to-date version of the document, even without a new eSignature.</p> <p>The improvement now allows <b>Editor-level</b> users to edit both the metadata and status of submission packages when the status is one of the following: <b>Deficiencies Found, Deemed Approved, and Approved with Conditions.</b> Additionally, Editor-level users can edit the submission packages themselves under these same status conditions.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Country Submission Packages.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3840	Collaborate (CMS)	This feature introduces a flag for users when a document is being sent for eSignature when the document is a PDF form with fillable fields. This ensures that the document cannot be edited after signature.	No	Yes	Minor	<b>Affected Users:</b> All Users. <b>Impact:</b> This improvement has a minor impact while sending the document in e-signature.
TTI-3841	Trial Master File (eTMF), Study Start-Up (SSU)	This feature enhances the 'Mass Import' window where 'Fill Metadata' will be default option for eTMF and Collaborate rooms. For SSU, the default option would be to 'Assign Placeholders' while mass importing documents. Both options will be available in all rooms, this simple determines the default tab.	Yes	Yes	Minor	<b>Affected Users:</b> Editor and Above. <b>Impact:</b> This improvement has a minor impact on the SSU and eTMF mass import functionality.
TTI-3842	Trial Master File (eTMF)	This feature allows the import metadata feature to read the starting version field and then set the document version accordingly.	No	Yes	Minor	<b>Affected Users:</b> Editor and above. <b>Impact:</b> This improvement has a minor impact on document versioning.
TTI-3843	Trial Master File (eTMF)	Starting from version 10.6, the ' <b>Mass Coding</b> ' feature is now available for Manager and above users even when the " <b>Enable Causality Tracking for final documents</b> " option is set.	No	Yes	Minor	<b>Affected Users:</b> Manager and above. <b>Impact:</b> This improvement has a minor impact on the mass coding.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3844	Trial Master File (eTMF)	This feature enhances the document revert functionality by granting <b>Superadmin</b> and <b>Admin</b> users the ability to restore the original non-OCR version of a document directly from the UI. Previously, only the Document Owner had access to this feature due to pre-set conditions. With this improvement, Superadmin and Admin now have the necessary permissions to perform the restore of the original, non-OCR document.	No	Yes	Minor	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on Document revert functionality.</p>

TTI-3845	Study Start-Up (SSU)	<p>This update improves the handling of Site Contact changes in the Study Start-Up (SSU) process, particularly during Site Activation. It provides flexibility for managing Site Contact replacements or role changes while ensuring valid documents are maintained. The system now allows Start-Up Specialists (SUS) to change Site Contacts, even when documents are already associated, and offers options for handling the existing Site Contact and their documents.</p> <p><b>Key Enhancements</b></p> <ul style="list-style-type: none"> <li>• When selecting or changing Site Contacts, the system displays the current role of the Site Contact, improving clarity during the update process.</li> <li>• SUS can now replace a Site Contact, even if documents have been collected, without restrictions.</li> <li>• Options for Managing Site Contacts: <ul style="list-style-type: none"> <li>○ <b>Delete Option:</b> If the SUS chooses to delete the existing Site Contact, the system retains the associated documents and moves them to the 'Non-Essential Documents' tab.</li> <li>○ <b>Role Reassignment:</b> SUS can assign a new role to the existing Site Contact being replaced, and the already collected documents will transfer to the Site Contact's new role.</li> </ul> </li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This enhancement is available for all SSU users managing Site Contacts during the Site Activation process.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<ul style="list-style-type: none"> <li>○ <b>Deactivate:</b> If the SUS chooses to deactivate the existing Site Contact, the system retains the associated documents and moves them to the 'Non-Essential Documents' tab.</li> <li>● Any extra documents that do not fit the new role's requirements are automatically moved to the 'Non-Essential Documents' tab, ensuring proper document management.</li> </ul> <p><b>Benefits</b></p> <ul style="list-style-type: none"> <li>● Greater flexibility for updating Site Contacts during Site Activation.</li> <li>● Ensures documents are retained and properly categorized, even when Site Contacts are replaced or their roles change.</li> </ul>				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3848	Platform	<p>To optimize efficiency and reduce costs, the system will now ensure that only documents without OCR are sent for processing.</p> <p><b>Key Enhancements:</b></p> <ul style="list-style-type: none"> <li>• While processing PDFs for attributes such as password protection and live status, the system will now also check if the document has OCR.</li> <li>• The system will loop through each page of the document to search for extractable text. If text is found, the document will be marked as OCR and a status update will be applied, indicating that the determination was made by the system.</li> <li>• Documents identified as OCR will not be included in the OCR processing queue, ensuring that only non-OCR documents are sent for further processing.</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the OCR documents.</p>
TTI-3859	Study Start-Up (SSU)	<p>With this improvement, the country created without the <b>Submission Package</b> will now display "N/A" in the column, instead of showing 100% progress.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the country in Study Start-Up.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3860	Study Start-Up (SSU)	With this improvement, the layout for the <b>'Review and Confirm'</b> step during site creation has been updated to improve user experience. Additionally, the style for all <b>'read-only' fields</b> has been unified for consistency across the interface. This change enhances clarity and ensures a more cohesive visual presentation throughout the site creation.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor <b>impact</b> on the <b>'Review and Confirm'</b> step of the site creation process in SSU. It enhances the visual consistency and layout without affecting the overall functionality or user workflow.</p>
TTI-3861	Study Start-Up (SSU)	<p>This feature Improvement has implemented additional file upload validations to prevent users from getting stuck or losing progress when attempting to upload unsupported files. The system now checks for the following:</p> <ul style="list-style-type: none"> <li>• <b>File size:</b> Files larger than 1.8 GB are not allowed.</li> <li>• <b>File format:</b> The following file formats are restricted: ASPX, EXE, ASP, PBD, JSP, JSPX, DO, JAR, WAR, EAR, HTM, HTML, XHTML, SHTM, SHTML, JS, VBS.</li> <li>• <b>Folders:</b> Folder uploads are not supported.</li> </ul> <p>These validations ensure that users receive immediate feedback on any upload issues, allowing them to correct mistakes and continue without losing progress.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This update has a minor impact on the file upload process. Users will now receive immediate feedback if a file exceeds the size limit (1.8 GB), is in a restricted format, or if a folder is mistakenly uploaded.</p>



TTI-3862	Study Start-Up (SSU)	<p>This feature improvement introduces several improvements to the file uploading process for IRB &amp; Agency Submissions, enhancing usability and user control:</p> <ul style="list-style-type: none"> <li>• <b>Cancel Upload Option:</b> Users can now cancel file uploads mid-process without waiting for completion. A Cancel button has been added to the upload popover for greater control. There are some cases when the user uploads bigger files mistakenly that can be controlled with this functionality.</li> <li>• <b>Popover Title Update:</b> The popover title has been updated from "Uploading Document(s)" to "Uploading File(s)" for clarity.</li> <li>• <b>Grid Display During Upload:</b> When files are dragged for upload, an overlay will appear. Once the files are dropped, the grid becomes visible.</li> <li>• <b>Rounded Corners:</b> The drag-and-drop zone now features 5px rounded corners for a more modern and visually appealing interface.</li> <li>• <b>Error/Warning Notification Timing:</b> Notifications with a Show Details button will no longer auto-dismiss. They will remain visible for up to 500 seconds, ensuring users have ample time to review details.</li> <li>• <b>Drag &amp; Drop Focus State:</b> A focus state will now be applied to the drag-and-drop zone before the files are dropped.</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the file uploading in IRB &amp; Agency Submissions.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3869	Study Start-Up (SSU)	This enhancement enables users to add documents directly in the Study Start-Up (SSU) module without automatically syncing those documents to the eTMF (electronic Trial Master File). When users add a document through the SSU - Documents section using the 'Add' button in the Document bar, the document will be available in SSU.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This Improvement has a minor impact on the SSU Document functionality.</p>
TTI-3870	Study Start-Up (SSU)	This enhancement allows users to easily assign an existing Site Contact as the Principal Investigator (PI) for a site. When changing the PI, the system now enables seamless replacement of the current PI with an existing contact. If the new PI is already a contact at the site, the system will notify the user that the existing contact will be removed from their previous role upon assignment as PI.	No	Yes	Critical	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This Improvement has a minor impact on the SSU Document functionality.</p>
TTI-3871	Study Start-Up (SSU)	<p>To enhance consistency and user experience, the text in all Delete/Remove modals has been standardized across the platform. This ensures that users receive a clear and uniform message whenever they perform deletion or removal actions, reducing confusion and maintaining a professional interface.</p> <p>This improvement has been applied in various areas such as the Country Section, IRB/EC section, Site section, Document Section, and Communication section.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on deleting and Removing modules in the study start-up.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3872	Study Start-Up (SSU)	The ' <b>Import Status</b> ' column has been added to the 'Import Documents' modal in the Study Start-Up (SSU) module. This new column provides users with a clear view of the status of each document during the import process, allowing for easier tracking and management of document imports	No	Yes	Minor	<b>Affected Users:</b> Editor and Above.  <b>Impact:</b> This improvement has a minor impact on the "Import Documents" Modal.
TTI-3873	Study Start-Up (SSU)	The button that allows users to link system documents to a package has been renamed from " <b>Search and Add Documents</b> " to " <b>Search Documents</b> ". This change has been applied across both Agency Submissions and IRB Submissions. The updated button text and corresponding icon are now reflected in the following areas: <ul style="list-style-type: none"> <li>• Wizard (zero state)</li> <li>• Wizard (toolbar)</li> <li>• Document section after package creation (toolbar)</li> </ul>	No	Yes	Minor	<b>Affected User:</b> Editor and Above.  <b>Impact:</b> This improvement has a minor impact on both Agency Submissions and IRB Submissions.
TTI-3874	Study Start-Up (SSU)	The button styles for editing document names in both IRB and Agency Submissions have been updated for a more streamlined and consistent user experience. The new design includes updated icons and buttons, making it easier to identify the save (green checkmark) and cancel (red cross) actions when renaming documents.	No	Yes	Minor	<b>Affected User:</b> All Users.  <b>Impact:</b> This improvement has a minor impact on both IRB and Agency Submissions.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3875	Study Start-Up (SSU)	<p>The ability to change the Principal Investigator (PI) in the Investigative Site Coding panel and Details page has been enhanced. Users can now easily replace the current PI with a new one by using the “<b>Change</b>” button.</p> <p>Additionally, a “<b>Create Contact</b>” option has been added to the dropdown, allowing users to quickly create a new PI if needed. Once a new PI is assigned, the previous PI will automatically be replaced.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Principal Investigator inside the Investigative site.</p>
TTI-3882	Study Start-Up (SSU)	<p>The “Ext” (extension) field in the phone number input section of the Study Start-Up (Create Site page) has been corrected to display properly. Previously, the field appeared misaligned or incorrectly formatted. This update ensures the “Ext” field is visually consistent with the rest of the phone number input.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Create Site (Site Contact Information) Modal.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3883	Study Start-Up (SSU)	<p>With this improvement, the error message for document uploads in the Study Start-Up (SSU) module has been improved when a single document with a conflict is uploaded. Previously, the message handling in such cases was not clear.</p> <p>The system will additionally prompt the SUS to act on the conflicting document. The actions available would include; Skip, Reset Document Type, Replace.</p> <p>With this update, users will now receive a more specific and informative message, detailing the conflict and its cause, and provide options to fix the conflict.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Add a document modal in the study start-up.</p>
TTI-3888	Trial Master File (eTMF), Collaborate (CMS), Quality Management System (QMS), Study Start Up (SSU)	<p>The search query has been optimized to improve result accuracy and reduce redundancy. By refining query logic, unnecessary parentheses have been removed, similar groups are now merged, and the IN operator is used for multiple OR conditions where applicable. These enhancements ensure more efficient data retrieval, faster workflows, and an overall improvement in customer satisfaction.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the search functionality.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3891	Platform	This enhancement optimizes database performance to improve user interface speed and reduce response times. Users will experience a faster and more responsive application, enhancing overall usability.	No	Yes	Major	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a Critical Impact on the Database performance for a faster user interface and response time.</p>
TTI-3892	Trial Master File (eTMF), Study Start Up (SSU), Collaborate (CMS)	This improvement allows SuperAdmins to delete an Active Site that has no associated documents.	No	Yes	Minor	<p><b>Affected Users:</b> Super Admin.</p> <p><b>Impact:</b> This improvement has a minor impact on Deleting the Active Sites.</p>
TTI-3893	Collaborate (CMS)	A 'Go to Index' button is now available in R&A Views to let users quickly return to the Index. The Index view also has a new 'R&A' tab to help users verify acknowledgements. This update makes it easier to move between R&A, Collaborate, and Index views for a smoother workflow.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above</p> <p><b>Impact:</b> This feature Introduced the “Go to Index” button in R&amp;A, Collaborate, and Index Views.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3894	Platform	<p>The <b>"Copy/Share"</b> button in the Document Cart is now renamed to <b>"Copy"</b> in Collaborate rooms under the following conditions:</p> <ul style="list-style-type: none"> <li>When the <b>"Publishing"</b> distribution mode is selected.</li> <li>When the <b>"Sharing"</b> distribution mode is selected and <b>"Enable documents distribution"</b> is disabled.</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Document Cart.</p>
TTI-3895	Platform	<p>This improvement provides Admins with a confirmation notification—<b>"User access was revoked successfully"</b>—when revoking a user’s access in User Management.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Revoking the User Access in the User Management.</p>
TTI-3896	Platform	<p>This enhancement adds a tooltip for the <b>'Share Document'</b> action in the document context menu when it’s disabled. Users with sharing permissions will now see an explanation on hover, offering clarity on why the action is unavailable.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Share Document functionality in the Context menu.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3897	Platform	<p>A new in-app tooltip has been added to the Search panel, providing users with tips for constructing effective search patterns. This tooltip explains:</p> <ul style="list-style-type: none"> <li>• Searching with full words in any order, allowing partial matches for the last word (e.g., document test).</li> <li>• Using partial matches for single words (e.g., doc).</li> <li>• Using quotes to find exact matches (e.g., "test document" for precise results, excluding variations like document test or doc).</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Search Functionality.</p>
TTI-3898	Trial Master File (eTMF)	<p>In the Event Manager's <b>Documents</b> tab, users can no longer add a manual placeholder with a category different from the Event's category. The system now pre-fills the category to match the Event and restricts changes. If only one DocType exists for the Event, it will also be pre-filled. An error message will display if an invalid DocType is selected.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on adding the placeholders in the event manager position.</p>
TTI-3899	Platform	<p>With this improvement, when the <b>'Make default for all rooms'</b> option is selected, both <b>default and pinned views will</b> be saved together. This ensures that pinned view preferences are consistently applied across all rooms.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Pinned View.</p>



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3900	Platform	The <b>Deleted Document View</b> now displays the count of deleted documents in both the <b>User</b> folder and the <b>All</b> folder, providing users with a clear overview of deleted items across folders.	No	Yes	Minor	<b>Affected Users:</b> All Users. <b>Impact:</b> This improvement has a minor impact on the Deleted Document View.
TTI-3901	Platform	This enhancement improves the <b>Room Switcher</b> UI design, offering users more detailed information about each room. The updated design enhances navigation and provides greater context, making it easier for users to select the correct room.	No	Yes	Minor	<b>Affected Users:</b> All Users. <b>Impact:</b> This improvement has a minor impact on the Room Switcher UI Design.
TTI-3903	Platform	KPI cards: <b>Collected, Required, Final, Expired, Expiring, Open Queries, Periodic Review,</b> and <b>eSignature</b> cards, are now clickable. Selecting a card opens a modal with a searchable list of elements, similar to the Sites KPI cards. This enhancement enables easier access and navigation within KPI data.	No	Yes	Minor	<b>Affected Users:</b> All Users. <b>Impact:</b> This improvement has a minor impact on the KPI Cards.
TTI-3905	Platform	This improvement adds a warning for the <b>Activate/Deactivate</b> action in <b>User Search</b> , notifying users that the action may take some time to complete.	No	Yes	Minor	<b>Affected Users:</b> All Users. <b>Impact:</b> This improvement has a minor impact on the Activate/Deactivate action.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3906	Platform	This enhancement removes the <b>User Time zone</b> from all application areas, including <b>My Profile</b> and all-time fields in <b>Room</b> and <b>Domain</b> .	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the User Time zone of the application including the User Profile.</p>
TTI-3907	Study Start-Up (SSU)	This enhancement ensures label consistency in <b>SSU Amendment Details</b> when only one progress bar appears in the left panel. A <b>"Documents"</b> label is now displayed before the percentage when a single progress bar is shown,	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the SSU Amendment Details when only one progress bar appears.</p>
TTI-3908	Trial Master File (eTMF)	This improvement enables scrolling for the <b>Audit Owner</b> in the <b>Quality Review Audit Module</b> when viewing lists of selected items in a disabled audit profile. This allows easier access to all items, even when the list exceeds the field's viewable area.	No	Yes	Minor	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Quality Review Audit Module.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3909	Platform	This improvement restricts <b>Room-level Time Zone Settings</b> to <b>Super Admins</b> only, due to its impact on dates (e.g., Effective Date, Next Review Date). Other users can view the current Room Time Zone but cannot make changes. Additionally, Super Admins are now prompted to provide a reason when switching the Room Time Zone, ensuring clarity and accountability for any changes.	Yes	No	Minor	<p><b>Affected Users:</b> SuperAdmin.</p> <p><b>Impact:</b> This improvement has a minor impact on the Room-level Time Zone Settings.</p>
TTI-3910	Study Start-Up (SSU)	This improvement ensures that <b>Country, Status, and Sites</b> are always included in <b>SSU Grid Views</b> for Countries, regardless of settings in <b>Form Settings &gt; Countries</b> . These key fields are now hardcoded into the grid and cannot be excluded, although other columns remain user-configurable.	No	Yes	Minor	<p><b>Affected Users:</b> Admin and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the SSU Grid views for Country, Status, and Sites.</p>
TTI-3911	Platform	This enhancement combines the <b>Site Status</b> and <b>Status</b> fields into a single field in the <b>Site Profile</b> form. Additionally, the <b>Site Name</b> and <b>Site ID</b> fields are now merged for a more streamlined view.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Site Profile Form.</p>
TTI-3915	Study Start-Up (SSU), Trial Master File (eTMF)	This enhancement restricts Placeholder Assignment during ZIP Import with the Unpack option in <b>SSU/eTMF</b> . When Unpack is <b>ON</b> , users can no longer drag and drop placeholders onto a ZIP file, ensuring proper import handling	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the assignment of documents to placeholders.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3917	Trial Master File (eTMF)	This improvement hides SSU-specific fields in the Manage Columns option within the eTMF/Countries grid. Fields like Requirements, Progress %, Agency Submission, Expected Approval Date, Activation Date, 1st Site Activated, and Track Agency Submission Progress are now removed from view. Additionally, a tooltip has been added in Form Settings > Country to indicate that these fields are specific to SSU, helping users understand their absence in the eTMF/Countries grid.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the SSU Specific Fields.</p>
TTI-3918	Study Start-Up (SSU)	This enhancement updates progress bars in <b>SSU</b> to display only integer values. The change applies to progress bars and popups in the <b>Site Profile, IRB/EC Profile, Country Profile, and Amendment Profile</b> , ensuring consistent and clear percentage displays across profiles.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Progress Bar in SSU.</p>
TTI-3920	Study Start-Up (SSU)	This enhancement adds <b>IRB/EC tabs</b> to both <b>Site</b> and <b>Country</b> levels, ensuring consistency with other entities in SSU, such as the tabs for sites at the IRB and country levels.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the <b>IRB/EC tabs</b> at both <b>Site</b> and <b>Country</b> levels</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3921	Study Start-Up (SSU)	With this improvement, Users are now guided to select a <b>Central IRB/EC</b> or <b>Local IRB/EC</b> as appropriate when adding an IRB. The new selection logic ensures that only one IRB can be designated as central for each site, providing clear options for IRB assignments.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the IRB Type Selection logic.</p>
TTI-3923	Platform	This enhancement sends the notification for blinded reviewer users without document access after an eSignature. The notification now confirms the successful eSignature, ensuring users receive relevant feedback even without document access.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the notification after eSignature.</p>
TTI-3924	Platform	This improvement Re-label CRA with MyTI access action name (to "Mobile CRA"), to indicate they are restricted CRA	No	Yes	Minor	<p><b>Affected Users:</b> CRA users.</p> <p><b>Impact:</b> This improvement has a minor impact on the CRA with MyTI access action.</p>
TTI-3925	Platform	This enhancement adds a visual indicator after a user clicks " <b>Sign Document</b> ", showing that the signing process is in progress. This improvement helps prevent confusion.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Sign Document notification.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3926	Platform	This enhancement updates the User Interface Component Framework to Kendo version 15, bringing improved functionality, performance, and compatibility.	No	Yes	Minor	<b>Affected Users:</b> All Users.  <b>Impact:</b> This improvement has a minor impact on the User Interface Component Framework.
TTI-3928	Study Start-Up (SSU)	<p>This enhancement standardizes the Status field placement for Agency/IRB Submission by positioning it below the Package Name field for consistency across the system. The updated placement applies to:</p> <ul style="list-style-type: none"> <li>• Package Details</li> <li>• Package Details with Additional Info shown</li> <li>• Package Details after Package Creation</li> </ul> <p>This ensures a uniform layout in all relevant views.</p>	No	Yes	Minor	<b>Affected Users:</b> All Users.  <b>Impact:</b> This improvement has a minor impact on the Agency/IRB Submission status.
TTI-3929	Study Start-Up (SSU)	This update changes the logic in <b>Agency &amp; IRB Submissions</b> to allow users to delete only one package at a time, enhancing control and accuracy during package deletion.	No	Yes	Minor	<b>Affected Users:</b> Editor and Above.  <b>Impact:</b> This improvement has a minor impact on the logic in Agency & IRB Submissions.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3930	Study Start-Up (SSU)	This improvement removes <b>All Docs Counters</b> during actions such as <b>Activate (Approve)</b> , <b>Reject entities</b> , and <b>Change Terminal Statuses</b> , streamlining the interface and focusing attention on primary action details.	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on all Documents.</p>
TTI-3931	Study Start-Up (SSU)	<p>This enhancement introduces color-coded buttons for Approval (green) and Rejection (red) actions to improve visual clarity and consistency. The updated button colors are applied to:</p> <ul style="list-style-type: none"> <li>• Approve/Reject IRB/EC</li> <li>• Activate/Reject Site</li> <li>• Activate/Reject Country</li> <li>• Complete Amendment</li> </ul> <p>These color cues help users quickly identify action options.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the color-coded buttons for approval and rejection entities.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3932	Study Start-Up (SSU)	<p>This enhancement improves the Drag &amp; Drop Zone for Import, aligning it with IRB and Agency Submissions updates. Key changes include:</p> <ul style="list-style-type: none"> <li>• Added Focus State for the Drag &amp; Drop zone, visible before file drop.</li> <li>• Updated behavior to show an overlay when dragging files; the grid becomes visible once files are dropped.</li> <li>• Rounded corners to 5 px for a refined look.</li> </ul> <p>These improvements provide a more intuitive and consistent drag-and-drop experience.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Drag &amp; Drop functionality.</p>



TTI-3933	Study Start-Up (SSU)	<p>This enhancement enhances the "Publish Docs" section in Activation/Change Terminal Status with refined wording and a new default option. Changes include:</p> <p>String Updates:</p> <ul style="list-style-type: none"> <li>• "Do not publish any documents" updated to "Do not Publish Documents".</li> <li>• "Select Documents to be Published to eTMF" updated to "Select Documents to be Published".</li> </ul> <p>Modal-Specific Wording:</p> <ul style="list-style-type: none"> <li>• In activation and status change modals for Site, IRB/EC, and Country:</li> <li>• Site: "Publish All Site Documents" with context (e.g., Site, Site Completed Amendments, Country, and IRB/EC Documents if any).</li> <li>• IRB/EC: "Publish All IRB/EC Documents" with context (e.g., All IRB/EC and IRB/EC Completed Amendments if any).</li> <li>• Country: "Publish All Country Documents" with context (e.g., All Country and Country Completed Amendments if any).</li> <li>• <b>Default Option Change:</b> Set default to "Do not Publish Documents" for clarity.</li> </ul> <p>These updates improve clarity and consistency across publishing actions, except in the Complete Amendment modal.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Publish Docs Section.</p>
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Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3938	Platform	<p>This improvement removes review documents from automatic PDF conversion in Collaborate and QMS rooms, preventing disruptions during the review process.</p> <p>Review documents will only be converted to PDF if required before the eSignature stage for providers that do not support signing Word documents.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on Collaborate and QMS Room.</p>
TTI-3939	Platform	<p>This feature allows users to hide the maintenance banner and prevent it from showing for specific users. This feature ensures that users do not miss any new messages even if they have opted not to show the maintenance banner again.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the User Experience.</p>
TTI-3940	Platform	<p>The study profile interface now removes the edit dialog and 'Change Status' option from the coding panel, simplifying navigation.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Domain Admin.</p> <p><b>Impact:</b> This improvement has a minor impact on the Study Profile.</p>
TTI-3941	Platform	<p>An 'Expand All' toggle has been added to the 'Add to Events' and 'Completeness' views, enhancing document review efficiency. This helps users easily locate and access other documents within the same folder.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the 'Add to Events' and 'Completeness' views'.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3947	Study Start-Up (SSU)	To improve user understanding, a message has been added to indicate that when an IRB/EC is marked as Central at both the room and site levels, the Submit and Approval Date can only be modified in the IRB/EC profile. These fields will be read-only at the site level, ensuring clarity during edits.	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the IRB/EC.</p>
Report-31	Trial Master File (eTMF)	The Expired Document Report Title is being changed and will no longer state it is for 60 days to reflect the actual data in the report.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Expired Documents Report.</p>
Report-106	Trial Master File (eTMF)	In this update, a new column has been added to the Audit Summary Report that displays the percentage quality of a quality review. This addition provides users with a clear metric to evaluate the overall quality of each audit.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the</p> <p><b>Impact:</b> The new quality percentage column in the Audit Summary Report helps users quickly gauge the effectiveness of quality reviews, improving audit oversight and decision-making.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-119	Trial Master File (eTMF)	<p>In this report, the column previously labelled as ‘<b>Document Signature Date</b>’ in the Document Submission Inventory Workflow Report has been renamed to ‘Document Date’ to align with the metadata field it represents.</p> <p>Also, the Document Submission Inventory Workflow Report will include a column for the Organization name to provide the name of the company the user belongs to.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Reduces confusion and improves clarity by aligning column names with corresponding metadata fields</p>
Report-123	Trial Master File (eTMF)	<p>The existing placeholder report has been enhanced to include information about the assignee for each placeholder.</p> <p>This update allows users to easily identify who is responsible for any queries linked to specific placeholders, improving the efficiency of tracking responsibilities and follow-up actions.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact;</b> Enhances accountability and streamlines the process of query resolution by clearly identifying the responsible assignee for each placeholder in the report.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-127	Trial Master File (eTMF)	A new functionality has been developed to identify and list all documents linked within a study room.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Enhances efficiency by restoring the ability to easily identify and manage linked documents within study rooms, reducing time spent on manual checks and improving overall usability.</p>
Report-136	Trial Master File (eTMF)	The system now includes a standard report called the Index/Filing Structure Report. This report provides a validated snapshot of a TI Room’s current configuration for both the index and document types. It consolidates index and document type information into a single, comprehensive report, allowing users to view the entire index outline alongside the document type assignments for each index location.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Enhances the ability to verify and review the current configuration of TI Rooms by providing a clear and comprehensive view of index structures and document type assignments, improving accuracy and efficiency in managing filing structures.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-137	Trial Master File (eTMF)	<p>A controlled new feature is being introduced to allow Editor users to view all queries in the Queries Report, similar to Admins. Currently, Editors can only see their queries.</p> <p>This enhancement provides broader visibility without granting the additional permissions associated with Query Manager and Document Manager roles, which would allow them to edit final documents and close other users' queries.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Improves visibility of all queries in the Queries Report, enhancing oversight and collaboration, while maintaining appropriate control over document editing and query management.</p>
Report-145	Collaborate, (CMS), Trial Master File (eTMF)	<p>During a recent discussion with an internal client, it was highlighted that the current reports do not adequately provide details on controlled documents. In response, a User Requirements Specification (URS) has been drafted for the development of a new standard Out-Of-The-Box (OOTB) report for Collab/TI Docs.</p> <p>This report is designed to better support and display comprehensive details of controlled documents, addressing the gaps identified in the existing reporting capabilities.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Enhances the ability to manage and review controlled documents by providing more detailed and comprehensive reporting, thereby improving document oversight and compliance tracking.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-146	Trial Master File (eTMF)	Report descriptions are updated to provide the necessary details and will be incorporated to ensure that the reports are more informative and aligned with user needs.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Improves clarity and usability of reports by providing updated and accurate descriptions, enhancing the overall user experience and understanding of report functionalities.</p>
Report-148	Platform	<p>Currently, the Jasper interface allows configuration of report dashboards for Admin, Editor, and Reader level users, but this functionality is not available for users with Manager level access. To address this gap, the system will be enhanced to allow Jasper Reports Admins to configure the reports dashboard for Manager level users.</p> <p>This update will enable the configuration of a specific list of reports for users with Manager level access, ensuring they have access to the necessary reports aligned with their role.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users</p> <p><b>Impact:</b> Expand functionality by allowing customized report dashboard configurations for Manager-level users, improving their access to relevant reports and enhancing overall system usability.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-152	Trial Master File (eTMF)	<p>To support the new eTMF Lite offering, there is a critical need to allow Managers access to reports. Since there is no Admin role in eTMF Lite, the highest access level for client users is Manager, making it essential for this role to have full report access.</p> <p>The system will be updated to ensure Managers in eTMF Lite rooms have the necessary access to reports, while Editor and Reader roles will have limited access as defined in the CM table.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> Ensures Managers can fully access and utilize reports, providing the necessary tools for oversight and management in the absence of an Admin role. Limited access for Editors and Readers will maintain appropriate security and role-specific functionality.</p>
Report-155	Trial Master File (eTMF)	<p>To improve the existing document review process, the report has been enhanced to include the following new columns: DOC ID, DOC TITLE, DOC DATE, DOC SUBMISSION DATE, SUBMITTED BY, QC1 APPROVED DATE, QC1 REVIEWER, QC2 APPROVED DATE, and QC2 REVIEWER.</p> <p>Additionally, the report will now calculate the number of days between key document milestones.</p>	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This enhancement provides greater detail and transparency in the document review process, enabling better tracking of document timelines and improving the efficiency of quality control and review stages.</p>



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-156	Trial Master File (eTMF)	<p>To improve the reporting experience in TI, a <b>Document Description</b> column in the Inventory and Completeness Reports is essential. This addition will provide users with detailed descriptions of each document directly within the reports, eliminating the need to open documents individually for review.</p> <p>The system is updated to include the <b>Document Description</b> column in these reports, enabling all users to quickly identify and understand the content and purpose of each document. This enhancement will improve efficiency in report generation and review processes.</p>	No	Yes	Minor	<p><b>Affected User:</b> All Users.</p> <p><b>Impact:</b> This enhancement adds the <b>Document Description</b> column to Inventory and Completeness Reports, offering clearer context for each document.</p>
Report-158	Collaborate (CMS)	<p>The improved Acknowledgements Report now displays the Contact User details, Site, Country details, Time and Dates and link to the acknowledged document with the document statuses.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and above.</p> <p><b>Impact:</b> This report makes the acknowledgement capability more convenient for report tracks.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-160	Trial Master File (eTMF)	To address feedback, an identifier or specific area in the Reports Module will be added to help users easily distinguish Custom Reports from Standard 'Out of the Box' (OOTB) Reports. Currently, the only way to identify Custom Reports is by referencing the work order for their creation, which is inefficient and leads to confusion. The new feature will include a visual identifier, such as an icon, label, or tag, next to each report title, clearly indicating whether it is a Custom Report or an OOTB Report.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Custom Reports.</p>
Report-161	Study Start-Up (SSU)	The Budgets and Contracts Report provides a consolidated view of budget and contract information across studies and sites, listing essential details such as study name, site details, document title, facility, status, and key dates. This report allows users to filter by study, site, status, or facility, sort columns for easy organization, and export data in multiple formats, including CSV and Excel. Real-time updates ensure the latest information is accessible, and access is restricted to users with appropriate permissions.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This report improves budget and contract tracking by centralizing data in a single view and allowing for flexible data export and real-time updates.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-162	Trial Master File (eTMF)	The ADHOC Reports Widget has been removed from the Cross-Study level reporting dashboard for MTI US and MTI EU users. This change streamlines the dashboard by eliminating the widgets in these regions.	Yes	No	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> MTI US and MTI EU users will no longer see the ADHOC Reports Widget on the Cross-Study reporting dashboard, improving focus and reducing clutter in the interface</p>
TTI-3224	Trial Master File (eTMF)	This report allows export functionality for users to view several pending and in-progress queries by recipient name.	No	Yes	Minor	<p><b>Impact:</b> This enhancement has a minor impact on the pending and in-progress query accessibility.</p>

**B. DEFECT RESOLUTIONS**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-12533	eTMF	A user encountered an error when attempting to regenerate site-level document names.	MINOR	This bug had a minor impact on name regeneration. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13180	eTMF	Users noted that the page count functionality does not work properly for two documents on the platform.	Minor	All Users: This issue affected the document module's page count functionality. The correct system behavior has been restored.
TRL-13335	eTMF	A user indicated that they did not receive an expected notification from the system with regard to document signature.	MINOR	This bug had a minor impact on notification emails. Correct system behavior has been restored.
TRL-13622	eTMF	Some users noted that they were unable to select views of the documents grid.	MINOR	This bug had a minor impact on document grid views. Correct system behavior has been restored.
TRL-13786	Platform	Users viewing documents in different time zones indicated that they saw a discrepancy in the values displayed.	MINOR	This bug had a minor impact on timestamp display. Correct system behavior has been restored.
TRL-13796	Collaborate	Users indicated that several documents had been assigned the incorrect effective date.	MINOR	This bug had a minor impact on metadata display. Correct system behavior has been restored.
TRL-13989	eTMF	Users reported an error where, upon signing a blinded report without access to the required folder, the document appears unsigned for the reviewer but is marked as approved.	Major	Reviewers. This issue impacts the integrity of the signing process for blinded reports. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13962	eTMF	Users noted that when exporting specific file types, the resulting data had repeated information.	MINOR	This bug had a minor impact on metadata export. Correct system behavior has been restored.
TRL-13976	eTMF	Users indicated that some documents were not converting to PDF as expected despite long waits.	MINOR	This but had a minor impact on PDF conversion. Correct system behavior has been restored.
TRL-14074	Platform	Users noted that the Service Offering field was producing unexpected output.	MINOR	This bug had a minor impact on metadata display. Correct system behavior has been restored.
TRL-14130	SSU	A user was attempting to assign a user as a Start-Up Specialist and encountered a Network Error.	MINOR	This bug had a minor impact on SSU user assignments. Correct system behavior has been restored.
TRL-14144	eTMF	Users in a specific room noted that they were not able to manage their grid views as expected.	MINOR	This bug had a minor impact on grid view functionality. Correct system behavior has been restored.
TRL-14145	eTMF	Users noted that the eSignature reason field was disabled in their room unexpectedly.	MINOR	This bug had a minor impact on eSignature settings. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14159	eTMF	Users noted that they received a system notification with incorrect spelling.	MINOR	This had a minor impact on notifications. The issue was corrected.
TRL-14193	eTMF	Users attempting to perform an index export from the Settings area experienced an error.	MINOR	This bug had a minor impact on Index Export functionality from the Settings area. Correct system behavior has been restored.
TRL-14206	Platform	Users are experiencing significant slowness in the MTI US room when performing folder searches. The GetFolderIndexTree call is taking approximately 1.6 minutes to execute.	Major	The delay in folder search functionality disrupts workflow efficiency in the MTI US room. <b>Correct system behavior has been restored.</b>
TRL-14208	Collaborate (CMS)	When a user updates the title of a document, it does not save.	Minor	All users. Impacts indexing and editing of document metadata. Correct system behavior has been restored.
TRL-14279	eTMF	In “View Edit History” modal, a user’s entry in the change log had the first name duplicated in “Updated By” column.	Minor	Change Log was not reflecting the real user’s name. Correct system behavior has been restored.
TRL-14293	eTMF	Value for “event driven” was not passed correctly and resulted in inaccurate placeholder counts in the eTMF Health dashlet.	Major	Editors and above. Discrepancy of true placeholder count could affect reporting. Correct behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14397	eTMF	Users noted that when the date format is set to DD-MMM-YYYY, metadata exports display dates in the format YYYY-MM-DD instead of the expected format.	Minor	All users. This issue impacts the consistency of date formatting in metadata exports. Correct system behavior has been restored.
TRL-14456	eTMF	Document cart displays email option even when disabled in settings.	Minor	Editors and above. This issue impacts the actions available in the document cart.
TRL-14457	Platform	Intermittent performance issues which resulted in page not loading.	Critical	All users. Impacted daily use of the system as certain pages would not load.
TRL-14547	eTMF	The event manager change log was displaying an inaccurate value.	Major	SuperAdmins. This impacts the ability for SuperAdmins to trace back certain fields in the event log. <b>Correct system behavior has been restored.</b>
TRL-14770	eTMF	Users in a specific client environment were noting issues with completing electronic signatures using TI Digital Sign for Serial signature requests.	MINOR	This bug had a minor impact on TI Digital Sign functionality in a specific environment. Correct system behavior has been restored.
TRL-14772	eTMF	Users were getting a Network Error when attempting to click on a site contact at the Domain Level in a specific client environment.	MINOR	This bug had a minor impact on Domain level navigation. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14831	Collaborate	Users noted that the 'Go to Document Profile' button specifically for generated Site Visit Reports was not taking them into the CCR as expected.	MINOR	This bug had a minor impact on the Visit Report UI. Correct system behavior has been restored.
TRL-14841	eTMF	Users noted that the "Reassign Reviewer" option is missing when attempting to reassign reviewers for certain documents. This issue occurs even though the documents are in an active workflow and have not been rejected or finalized. The problem could not be reproduced in a test environment under similar conditions.	Minor	Reviewers. This issue had a minor impact on the ability to reassign document reviewers. Corrected system behavior has been restored.
TRL-14846	eTMF	For two specific users in one specific room, the activity log was not generating automatically. This issue was not reproducible in any other environment for any other users.	MINOR	This bug had a minor impact on Activity Log generation. Correct system behavior has been restored.
TRL-14852	eTMF	Metadata for six final documents disappeared in a specific room after an admin user updated certain metadata fields (excluding category, site, and country). Required fields such as "Category" should prevent saving without input, yet documents were saved with missing required metadata.	Major	Admin users. This issue impacts data integrity by allowing documents to be saved with missing required metadata fields. Correct system behavior has been restored.
TRL-14853	eTMF, Study Start-Up (SSU)	The system does not display the option to select the site stage folder when a site editor with the rights to upload site-related documents tries to upload documents to a site.	MINOR	Editor and above. This bug has a minor impact on the Site Documents Management. The resolution resets the correct system behavior.



Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14866	Study Start-Up (SSU)	There is a defect in the date picker. It gets closed automatically when a user tries to click it from the Reg Pack Send Date in the Site Edit window.	MINOR	Editor and above. This bug has a minor impact on the system user interface and was stipulated to Chrome browser users only. The resolution restores the correct system behavior.
TRL-14868	eTMF	The users experienced the inability to remove the metadata for documents approved in a workflow.	MINOR	Editor and above. This bug has a minor impact on the document management. The resolution restores the correct system behavior.
TRL-14881	eTMF, Study Start-Up (SSU)	The users experienced the inability to update the Address of a closed site. The system displays a warning and users aren't able to update without adding the Effective Closure Date & Closure Comments.	MINOR	Editors and above. This bug has a minor impact on the Site Management. The resolution resets the correct system behavior.
TRL-14888	eTMF	Users were unable to expand document types by clicking on the document type name	Major	All users. This issue impacts user efficiency when interacting with document types in the metadata section. Correct system behavior has been restored.
TRL-14901	SSU	In the SSU module "Move to eTMF icon" was missing in the document tab linked to the Investigative Site	Major	All Users: The user had a workaround to go to the Documents section to manually move the document. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15020	SSU	Users reported an issue when creating a new site contact, the option “Contact is responsible for providing documents” appears to be enabled initially. However, after the contact is created, this option shows as disabled, contrary to the user’s selection during the creation process.	Major	Admin and Above. This issue had a minor impact on creating the new site contact. Correct system behavior has been restored.
TRL-15109	eTMF	In Document Type Management, the change log only displays the username of the person who made changes, without reflecting the actual changes made. This discrepancy was noted post-upgrade in MTI US and EU instances	Major	Editor and Above. This issue had a minor impact on the Document Type management. Correct system behavior has been restored. Ensuring the username and actual changes are recorded in the log.
TRL-15170	eTMF	Received the ticket by users, reporting an issue where a document, already included in an Audit Profile, was moved to a different index folder. After this move, the document no longer appears in the previously assigned Audit Profile, and the audit icon is missing for that document.	Major	Editor and Above. This issue had a minor impact on the documents that were present in the Audit profile. Correct system behavior has been restored.
TRL-15187	eTMF	Users experience an intermittent error message, “failed to get token,” after completing a document signature using TI Digital Sign. Although the document signature is completed, the error message misleads users into thinking that the signature process is incomplete. This confusion arises because, in TI Digital Sign, signatures are not visible on the document until all required signatures are completed.	Major	Admin and Above. This issue has an impact on the TI Digital Sign functionality. Correct system behavior has been restored, and the error message no longer appears after completing signatures.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15285	eTMF	When exporting TMF metadata from a TMF room, the “Rejection Reason” column intermittently appears blank, despite the Rejection Inventory KPI report showing the correct rejection reason. Upon investigation, it was found that the metadata export inconsistently populates this field, leading to a blank entry in one instance and a correctly populated entry in another. This discrepancy affects users relying on consistent rejection data across TMF exports and reports.	Minor	All Users. This issue had a minor impact on the TMF metadata exports and reports. Correct system behavior has been restored.
TRL-15297	eTMF	The User observed mismatch in published dates in grid and while exporting the documents.	Minor	All Users: The issue occurred due to multiple/ duplicate documents. Correct system behavior has been restored
TRL-15314	eTMF	In a client’s dedicated instance, a user encounters a <b>Server Error</b> when attempting to search within a room. Upon clicking the search icon, the system begins to load but fails to complete the search operation, resulting in a server error message.	Critical	All Users. This defect prevents users from performing searches within the room in the impacted environment. Correct system behavior has been restored.
TRL-15346	SSU	When a user adds in required countries in amendment settings, it does not appear in Amendment Tab in SSU. Only the first selected country would appear on the top and every subsequent countries would be blank.	Major	All Users: This issue had a major impact on correctly seeing all the countries in the Amendment tab. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15393	eTMF	Users experienced an issue where the reason for Metadata changes were not visible in the UI of the audit trail.	Minor	All Users: This defect had a minor impact as the Users were able to see the reason for metadata changes in the exported report but not in the UI. Correct system behavior has been restored.
TRL-15728	SSU	The user reported an issue with a specific amendment which is applicable only to the United States. However, it is also appearing on the France site.	Minor	All Users. This issue has a minor impact on the amendment that was displayed incorrectly on the site. Correct system behavior has been restored.
TRL-15783	eTMF	<p>In the MTI US Instance (v10.5.5), there is a discrepancy in audit trail exports for deleted documents:</p> <ul style="list-style-type: none"> <li>• <b>Audit Trail Module:</b> Deletion activities and comments are missing unless the document has been restored.</li> <li>• <b>Documents Module (Export &gt; Audit Trail):</b> Shows deletion details, including comments.</li> </ul> <p>Additionally, deleted documents display Deleted Date and Deleted By under Activity Type as "Metadata Update" rather than "Delete Document," which may confuse.</p>	Major	Admin and Above. This inconsistency in audit trail exports could lead to confusion and incomplete records, especially for regulatory or auditing purposes, where a consistent view of document deletion activity is essential. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15875	Platform	Duplicate entries appear when executing the stored procedure in a client’s staging environment on the server, affecting report accuracy. Request to remove duplicates from the database.	Critical	This issue has a minor impact on Duplicate entries in the Databases. Correct system behavior has been restored.
TRL-15893	eTMF	Users noted that searching by the 'file name' system field yields no results, despite the room being indexed and the field included in searches, resulting in inconsistent search behavior.	Major	All Users. This issue has a minor impact on the search functionality. Correct system behavior has been restored.
TRL-15954	eTMF	A user reported receiving three duplicate signature emails from a client’s Research Document Library room within a three-minute timeframe. This unexpected repetition of notifications could lead to confusion and impacts user experience by creating unnecessary email clutter.	Minor	This issue has a minor impact on the signature emails from the impacted environment. Correct system behavior has been restored.
TRL-15975	eTMF	In a specific client room, amendments are counted at the top of the site but are not visible in the table. Other rooms display amendments correctly. A 503 error message appears in the browser console for the affected room.	Minor	All Users. This issue has a minor impact on the Amendments for specific rooms. Correct system behavior has been restored.
TRL-16064	eTMF	Users observed that when setting up a new event type in the event manager module, the screen displays the incorrect text "Customer Sandbox."	Minor	Admin and Above. This issue has a minor impact on the Event Module. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16071	eTMF	A user noted an error when moving a document type from a sub-category to the parent category. The error message displayed “Database Error”.	Blocker	All Users. This issue has a minor impact on modifying document types. Correct system behavior has been restored.
TRL-16182	eTMF, SSU	Users encounter an issue when attempting to publish documents from eTMF to SSU, as the “Move to eTMF” option is currently greyed out, preventing document transfer.	Major	All Users. This issue had a minor impact on publishing documents from eTMF to SSU. Correct system behavior has been restored.
TRL-16690	CMS	Users were experiencing an issue with removing the eSignature process when excluding a document from the workflow.	Major	All Users: The issue had a minor impact where the signature process remained attached to the document even when the document was removed from the workflow. Correct system behavior has been restored.

## 11. Open Defects

Trial Interactive v10.6 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) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16668	SSU	'Status History' does not display values in the agency submission profile.	Minor	Editor and above
TRL-16084	SSU	When editing a Contact, their name does not get updated in the contact modal interface.	Minor	Editor and above
TRL-16585	eTMF	Intermittent failure when opening attachments from a task.	Minor	Editor and above
TRL-12873	eTMF	Inconsistencies in metadata updates when mass coding records from the document grid.	Minor	Editor and above
TRL-16378	Platform	When performing a domain search across rooms, the system currently doesn't align with the user's browser timezone.	Minor	All users. This could impact how timestamps and time-based filters are displayed.
TRL-11642	Platform	When searching for a document using its full name, results populate correctly. However, when searching with only part of the document name, poor results are returned.	Minor	All users. Impacts the search experience.
TRL-16629	eTMF	Intermittent errors when attempting to revoke access for user who is also a Principal Investigator for a site	Minor	Admins and above.
TRL-14716	eTMF	In the Quality Review Module, when viewing "By Auditor" option, usernames are not visible.	Minor	All users. This impacts filtering by specific auditors.
TRL-9918	eTMF	In the Processed Documents view, if a source document is deleted after conversion, it does not appear in the "Processed" folder. This	Minor	Editors and above.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
		creates inconsistencies in document tracking and visibility post-conversion.		
TRL-6990	eTMF	The 'Import Documents' dialog does not support adding single or multiple .msg files. This prevents users from uploading email files directly, limiting document import functionality.	Minor	Editors and above.
TRL-6573	Platform	In the Folder Selection forms, previously selected Protected and Staging folders are not preselected as expected. This requires users to manually reselect these folders, leading to inefficiencies in the workflow.	Minor	Admin and above
TRL-16668	SSU	'Status History' does not display values in the agency submission profile.	Minor	Editor and above



## 12. Customer Support

### A. REPORTING ISSUES WITH THE RELEASE

Once **TransPerfect Trial Interactive** releases a system into a Production environment, the Support Service department is responsible for providing Clients and Authorized Users with technical support via phone or email. This support shall consist of commercial best efforts by **TransPerfect** to provide the User or the Client's designated personnel or helpdesk, with but not limited to the following:

- Error corrections and temporary workarounds
- Technical assistance relating to the operation of the system
- Processing service requests
- Processing configuration change requests

**TransPerfect** will respond by the levels of priority, as reasonably determined by **TransPerfect**. Support Services will be available at all times via phone and email from **TransPerfect** Service Desk centers set forth below:



#### Phone



#### Email



#### Business Hours

Phone	Email	Business Hours
US: 888-391-5111 (TOLL-FREE)	<a href="mailto:help@trialinteractive.com">help@trialinteractive.com</a>	Available twenty-four (24) hours a day, seven (7) days a week, three-hundred-sixty-five (365) days a year
European Union, Madrid, Spain +44 (20) 45182755	<a href="mailto:eu.help@trialinteractive.com">eu.help@trialinteractive.com</a>	Monday – Friday, 9 AM – 6 PM CET.
China +86 (755) 66856062	<a href="mailto:cn.help@trialinteractive.com">cn.help@trialinteractive.com</a>	Monday – Friday, 9 AM – 6 PM Beijing Time

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## B. REQUESTING FUTURE ENHANCEMENTS

If you would like to submit requests for enhancing the system, please submit your ideas through one of the following methods:



### Customer Success Manager (CSM)

Your PM can submit Ideas to our Perfective Change Management on your behalf



### Focus Group

Meet with other Trial Interactive customers for an immersive Focus Group:

- Focus Group
- Early Access
- Hosted Beta
- Usability Studies

## 13. Approvals

### Product Owner

Name: Jay Smith	Title: Sr. Director, Product Management
Signature:	
Reason for signature:	
Date:	

### Quality Assurance

Name: Scott Jordan	Title: Director, QA & Systems Validation
Signature:	
Reason for signature:	
Date:	