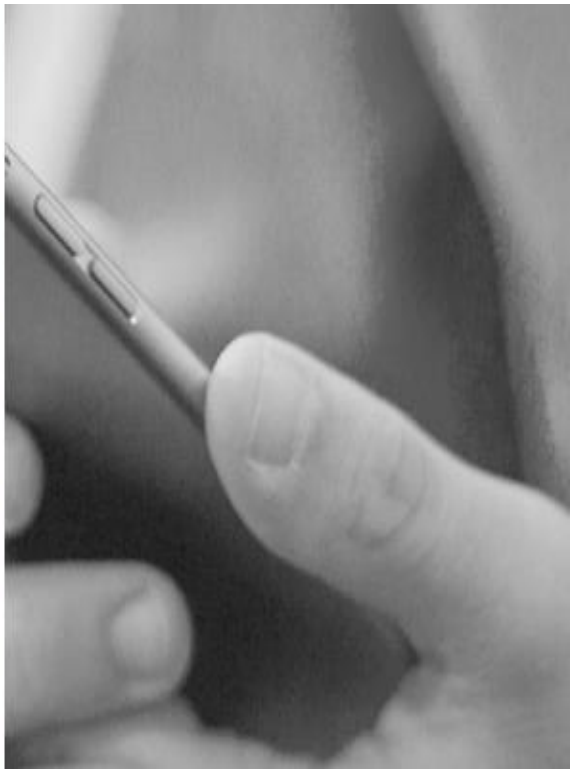
TRIAL INTERACTIVE

TRIAL INTERACTIVE V10.7– RELEASE NOTES – V1.0



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1. Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	10-Apr-2025	Initial Draft Creation
Samuel Pawar	0.2	11-Apr-2025	**Added Features:** TTI-4195, TTI-4214, TTI-4215, TTI-4216, TTI-4217, TTI-4218, TTI-4219, TTI-4220, TTI-4221, TTI-4222, TTI-4223, TTI-4224, TTI-4013
Samuel Pawar	1.0	02-May-2025	**Improvements** • Added: TTI-4202, TTI-3985, TTI-4088, TTI-4156, TTI-4127 • Removed: TTI-4185, TTI-4156, TTI-4224, TTI-3985, TTI-4088, TTI-4221, QMS-57, TTI-2864, TTI-4156 **Defect Resolutions** • Added: TRL-17059, TRL-17546, TRL-17694, TRL-17900, TRL-17845, TRL-16976, TRL-17477, TRL-17681, TRL-17789, TRL-17842, TRL-17059, TRL-12195, TRL-17931, TRL-17999, TRL-18087 • Removed: TRL-17545, TRL-17842, TRL-12195, TRL-13226, TRL-17258, TRL-17694 **Other Updates** • Open Defects table • TTI-4219: Updated Room Type
Samuel Pawar	1.1	06-Jun-2025	**Improvement:** • Updated TTI-4222 Offering Impacted. • Updated: TTI-4223 Impact Comment. **Defect Resolutions:** • Added: TRL-17269

2. 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 advance of the Upgrade Date by issuing Pre-Release Notes. The end-users of the system can use the Pre-Release Notes in evaluating if their intended use of the system will be impacted with 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 scope of the Release.

NOTE: **TransPerfect** will make commercial best efforts to minimize the differences between the Pre-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.

3. Scope

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

System In Scope	
System Name	Trial Interactive
System Version	v10.7
Release Type	Minor

4. Definitions / Acronyms

Term	Definition/Description
21 CFR Part 11	The part of the United States Code of Federal Regulations that regulates electronic records and electronic signatures.
API	Application Programming Interface
Annex 11	The European Union's guidance for using electronic records and signatures in the pharmaceutical industry.
CAPA	Corrective Action and Preventive Action
CMS	Content Management System
CRO	Clinical Research Organization
CSM	Customer Success Manager
CTMS	Clinical Trial Management System
ERES	This document provides guidance in the United States for using electronic systems, records, and signatures in clinical investigations.
eTMF	Electronic Trial Master File
GxP	An abbreviation generally accepted to refer to accepted standards of good practices.
IDP	Identity Provider
JIRA	A proprietary issue-tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management.
KPI	Key Performance Indicator
LMS	Learning Management System
MDE	Metadata Extraction
MFA	Multi-Factor Authentication
OOTB	Out of the Box
QMS	Quality Management System
SFTP	A secure File Transfer Protocol
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SQA	Software Quality Assurance
SQL	Structured Query Language
SSO	Single Sign On
SSU	Study Start-Up
TI	Trial Interactive
TP	TransPerfect
Testiny	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.

5. 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 their 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 Clinical Trial Management System (CTMS) that meets all eClinical requirements for managing and tracking clinical studies and works seamlessly with the eTMF, Content Management, Quality Management, Learning Management, Mobile app, and other Trial Interactive solutions.
- A fully hosted SaaS solution that is 21 CFR Part 11, Annex 11, ERES, HITRUST, GDPR, and GxP compliant.
- A single access point for all trial content as well as sponsor and site personnel documentation.
- Supports 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.
- Supports a series of QMS workflows, including incidents and complaints, CAPA, actions, change management, supplier audits and findings, qualifications, evidence, document change control, training management, and the capture of other Quality 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.
- Increases 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, as well as complex standardized and custom reports.
- Adaptable, built-in machine learning features such as auto-classification and metadata extraction enable AI auto-coding capabilities.
- A full-featured eLearning system designed for GxP compliance, study training, and virtual investigator meetings.
- Effectively manage the entire clinical trial process from protocol conception through closeout.

B. TRIAL INTERACTIVE – ETMF

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 300 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.

C. TRIAL INTERACTIVE – 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.
- TI 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.
- TI 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.

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 are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and ultimately shared with the eTMF.
- Site Collaborate/eISF and Remote Monitoring Rooms are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and ultimately send it to the eTMF.
- The Quality Document Management solution 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.

TI 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 TransPort, 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.

E. QUALITY MANAGEMENT SYSTEM

Trial Interactive's Quality Management System (TI QMS) is a flexible, enterprise-grade solution designed to enhance quality management across organizations, clinical trials, and supplier networks. Built on the powerful Trial Interactive platform, TI QMS provides a modern, intuitive, and fully configurable approach to handling Quality Incidents, CAPAs, Deviations, Non-Conformances, Audits, Findings, Complaints, SCARs, Effectiveness Checks, and other Quality Records. The system integrates controlled documentation, compliance training, policy management, and regulatory adherence into a single, seamless platform, empowering teams with automation, AI capabilities, and advanced analytics to drive quality excellence. Whether managing clinical trials, enterprise-wide quality initiatives, or supplier networks, TI QMS streamlines processes, enhances collaboration, and ensures regulatory readiness—all within a single, intuitive platform. TI QMS provides your organization with these capabilities:

- Integrated Quality Document Room: TI QMS operates within a controlled environment for managing, storing, and collaborating on quality documents. It ensures compliance, version control, and structured workflows, streamlining audit readiness and regulatory adherence across clinical and operational teams.
- Advanced Rich Text Capabilities: Enables precise document formatting, embedded media, and structured content, ensuring document readability and integrity. Microsoft Word tables can be reused without modification, maintaining data accuracy and consistency.
- Flexible Record Relationships for Full Traceability: Supports dynamic linking between quality records, documents, and processes, allowing back-linking of CAPAs to Audit Findings and multiple impacted SOPs for simplified policy updates and audit preparedness.
- External Collaboration & Supplier Network Integration: Provides secure, controlled access for sponsors, CROs, auditors, and suppliers, enabling seamless collaboration on Audit Findings, Compliance Documentation, and Quality Processes while maintaining data security and regulatory compliance.
- User-Friendly & Team-Centric Design: Offers a modern, intuitive user interface, reducing training time and enhancing productivity. Cross-functional collaboration is enabled through team-specific workflows, ensuring clear roles, actions, notifications, and escalation paths.
- Fully Customizable & Scalable: TI QMS is designed to adapt to your organization's needs with configurable fields, workflows, templates, and automation. It scales from a single QMS room to multiple QMS environments across departments, labs, divisions, or manufacturing plants.
- AI-Powered Automation for Efficiency: Utilizes machine learning to streamline quality management tasks, including document classification, metadata extraction, content summarization, and workflow automation, reducing manual effort and improving data accuracy. (FUTURE)

- Document Change Control: The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation.
- Training Management: The capability to fully automate the compliance training management process through the LMS, ensuring that all effective policy changes are fully understood by staff, and that they are made aware of changes through required coursework.
- Online Collaboration: 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®.
- Regulatory-Compliant eSignatures: Ensures secure, Part 11-compliant digital signatures for global regulatory adherence (FDA 21 CFR Part 11, EU Annex 11). Users can electronically or digitally sign both documents and QMS records for authentication, auditability, and integrity.
- Enterprise-Grade Compliance & Security: Built on a HITRUST-certified, HIPAA, and GDPR-compliant platform, ensuring robust access controls, audit trails, and secure electronic records management.
- Advanced Analytics & Dashboards: Offers customizable dashboards, KPIs, and real-time reporting to track compliance metrics, document status, and workflow efficiency for data-driven decision-making.
- Seamless CTMS and eTMF Integration: Designed to interoperate with Clinical Trial Management Systems (CTMS), Compliance Training Management (LMS), and electronic Trial Master Files (eTMF), ensuring alignment between clinical operations and quality management.
- Reliable, Scalable Technology: Built on a secure, high-performance infrastructure with 99.997% uptime SLA, delivering industry-leading reliability and system performance.
- Validation-Ready for Regulatory Requirements: Pre-configured workflows, automated audit trails, and validation-ready templates ensure efficient system validation with dedicated validation support staff.
- Certified Translations: The ability to send documents for certified translation through TransPerfect's GlobalLink Portal, track their status, and receive back the translated copies and certificates.

6. Release Overview

A. INTRODUCING THE QUALITY RECORDS MODULE IN COLLABORATE ROOMS

QMS-18: This feature introduces the Quality Records module, a powerful addition to the Collaborative (CMS) Room Type that enhances the way organizations track and manage their Quality Management System (QMS) records. This module provides a Dashboard and supports key record types such as Incidents, Evidence, CAPA (Corrective and Preventive Actions), Action Items, and Effectiveness Checks, with future expansions to include Change Management, Audits, and Findings.

To maintain structured governance, rooms with the Quality Records module enabled offer access control. Specific editor-level users can be restricted from creating documents and viewing in-process documentation within the Documents module, ensuring proper security.

Super Admins can enable the module through room settings, after which admins and room managers in the gain instant access, while other users require explicit permissions. With tailored actions and permissions, organizations can fine-tune access to creating Incidents, CAPAs, and restricting document creation, ensuring only the right people have the right level of control.
With this addition, teams can elevate their quality management practices, maintain compliance with ease, and drive operational excellence within the collaborative workspace.

QMS-32: As part of this enhancement, the TI Docs Room Type has been retired, and all existing TI Docs rooms will be migrated to Collaborate. The Quality Module is accessible from the “Waffle” menu, with user access controlled through the “Quality Module” action, ensuring that only authorized users—readers, editors, and room managers—can manage and oversee quality processes.

By integrating quality workflows directly into Collaborate, this update simplifies compliance management, enhances visibility, and improves efficiency in quality-related activities.

B. ENHANCED RECORD TYPE MANAGEMENT

QMS-28: The Record Type Settings feature introduces a structured and efficient approach to managing record-related workflows, forms, and configurations within the system. Designed to streamline record type management, this functionality provides administrators with the ability to create, edit, and configure record types, authority types, workflows, and teams in a centralized interface.

By categorizing record types in a hierarchical tree structure based on predefined main topic classifications, users can easily navigate and manage record-related processes. This feature mirrors the existing Document Types settings but is specifically tailored to enhance record workflow configurations. In this way, for the main type ‘CAPA’, there can be defined sub-types such as ‘CAPA Plan’, ‘SCAR’, ‘Continuous Improvement Plan’, ‘Risk Mitigation Plan’, etc. Each of these sub-types can have its own workflow, forms, fields, teams, and general configurations, allowing great flexibility.

Users can define key record details, including naming conventions, workflow rules, due dates, and field settings, through a dedicated Fields Tab. The system also supports import/export capabilities and maintains a change log for version tracking and compliance. Automated notifications and structured workflows ensure seamless record processing, enhancing transparency and operational efficiency.

By offering a systematic approach to record management, this feature improves compliance, streamlines workflow execution, and enhances collaboration across teams, ultimately driving efficiency in record handling and decision-making.

C. TEAM MANAGEMENT

QMS-21: This feature introduces **Team Management**, allowing users to create and manage teams responsible for **Records and Documents**. Teams can be assigned **authority types** for workflow stages, record approvals, and other system-configured action items. Users can add or remove team members, link teams to specific record or document types, and manage authority levels, ensuring structured collaboration and compliance.

Teams can be associated with specific document types (for responsible departments) and record types (for QMS workflows). By streamlining team assignments and authority configurations, this feature enhances efficiency, accountability, and workflow automation within the system.

D. RECORD TYPE SETTINGS

QMS-28: The new **Record Type Settings** feature introduces a centralized and structured interface for creating, managing, and configuring record types and their associated workflows, forms, and fields. Designed to mirror the familiar Document Types settings, this functionality focuses specifically on record-related workflows and offers enhanced configurability **for Quality Administrators** and system managers.

Users can navigate a **hierarchical tree structure** that organizes record types by predefined categories based on forms designated as “main topic” in the Form Settings. This structure provides clarity and consistency across the system, supporting robust configuration at both top-level and subtype levels.

Through this interface, users can manage multiple aspects of record types, including:

- Creating, editing, and deleting types and subtypes under each form category.
- Importing and exporting record type configurations.
- Managing workflows, teams, naming rules, and field behaviors per record type.
- Viewing and auditing changes via the built-in change log.

This feature ensures seamless configuration of all elements involved in record lifecycle management, supporting compliance, traceability, and process efficiency.

E. STRUCTURED WORKFLOW MANAGEMENT

QMS-30: The **QMS Workflow Management** feature introduces a structured and configurable approach to defining and managing quality workflows within the Quality Management System. With a **dedicated Workflow Settings Page**, users gain a centralized interface to configure and manage workflows, ensuring seamless control over processes.

The feature enables workflow creation, allowing users to define workflow names, profiles, descriptions, record types, and stages while leveraging a wizard-based setup that guides them step by step through the configuration process. Organizations can customize workflow stages and statuses**,** assign role-based permissions**,** and designate responsible teams or individuals for each stage to ensure accountability. Additionally, users can link forms to specific workflow stages, controlling field visibility and validation to enforce data integrity. To further enhance efficiency, advanced notification options support group-based alerts and escalation levels, ensuring timely communication and issue resolution. By standardizing workflow

management, this feature enhances traceability, governance, and compliance**,** providing organizations with a seamless way to structure and optimize quality processes.

F. INCIDENT MANAGEMENT

QMS-20: The Incident Management feature introduces a structured approach to capturing, investigating, and resolving quality issues within the Quality Management Module. Serving as the centralized entry point for quality concerns, the Incident Form ensures that reported issues are accurately documented, assessed, and swiftly escalated as needed. By seamlessly integrating with Investigations, Action Items, and CAPA (Corrective and Preventive Actions), this feature empowers organizations to proactively manage risks, drive compliance, and enhance overall product and service quality.

Incidents are categorized as Main Types, with the option to include Sub Types for better organization and tracking. The workflow-driven approach ensures that incidents progress through assessment, investigation, assessment, root cause analysis, and corrective action implementation, helping to prevent recurring issues. Key fields such as Record Type and Team allow organizations to configure workflows and assign responsibilities effectively.

Additionally, automated notifications, real-time dashboards, reports, and analytics provide visibility into issue trends, ensuring proactive resolution and continuous improvement. Integrated audit trails and compliance tracking help maintain detailed records, supporting regulatory adherence and quality assurance.

By offering a systematic and structured process for incident resolution, this feature enhances quality control, risk management, and overall operational efficiency, allowing organizations to maintain high standards in product and service delivery.

QMS-53: The **Incident Workflow Processing** feature streamlines incident management by automating submission, validation, and assignment. It enhances compliance, improves transparency, and reduces manual intervention.

When an originator submits an incident, the system verifies its type and record type to check for a predefined workflow. If a match is found, the record enters the workflow; otherwise, the originator is notified.

Role-based access controls ensure data integrity. The originator's access is downgraded to read-only, while team members gain controlled visibility. Assigned authorities can manage incidents via the **Assignments View**, ensuring accountability.

This workflow-driven approach enables efficient incident tracking, structured collaboration, and proactive issue resolution through automated transitions and notifications.

G. INCIDENT RECORD SECURITY DESIGN SPECIFICATION

QMS-49: The Incident Record Security Design Specification introduces a robust and flexible access control model to support the upcoming Records module within the Quality Management System (QMS). This design ensures that sensitive quality records—such as Incidents, Investigations, and CAPAs—are securely managed throughout their lifecycle, with permissions dynamically adjusted based on user roles, team assignments, and workflow progression.

At its core, this feature enforces record-level security, ensuring each incident record has individualized access rules. Users gain visibility and edit rights based on their roles (e.g., Admins, Process Owners), direct assignments (e.g., Investigators, Workflow Participants), or actions taken within the system. Room-level settings allow Super Admins to activate the Records module and configure access at a granular level, while supporting the separation of privileges between the Records and Documents modules.

Upon creation, incident records automatically grant access to key stakeholders, including the Originator, Process Owner, and Room Admins. As the incident progresses through the workflow, permissions are adapted in real-time, ensuring originators transition to a read-only role, while team members and stage-specific contributors gain access aligned with their responsibilities. Special provisions allow external Investigators to participate without compromising broader system visibility.

Additionally, clear rules govern record deletion and obsolescence, balancing administrative control with data integrity. Draft records can be deleted by Originators and Admins, while workflow-submitted records can only be marked obsolete by authorized users.

This security design supports scalable, audit-ready governance of quality records, enabling organizations to maintain strict data confidentiality, ensure proper accountability, and streamline compliance. By embedding permission logic into the incident lifecycle, this feature fosters a secure, transparent, and collaborative environment for managing quality events.

H. CAPA WORKFLOW PROCESSING

QMS-42: The CAPA Workflow Processing feature optimizes **Corrective and Preventive Action (CAPA)** management by issue identification, root cause analysis, and action tracking. It enhances compliance, accountability, and efficiency, ensuring a structured resolution process for quality incidents.

When a CAPA is initiated, the system validates the issue, assigns responsible parties, and tracks corrective and preventive actions through a predefined workflow. Each stage supports role-based access, ensuring secure collaboration and controlled visibility. The system automatically notifies assigned users, guiding them through investigation, corrective measures, and verification steps.

With workflow-driven automation, real-time tracking, and documented traceability, this feature improves regulatory compliance, prevents recurring issues, and strengthens overall quality management.

I. ACTION ITEM WORKFLOW PROCESSING

TTI-2993: The **Action Item** Workflow Processing feature optimizes Corrective and Preventive Action (CAPA) management by supporting the creation of **Action Items.** This enhances compliance, accountability, and efficiency, ensuring a structured action plan and management process for quality incidents and CAPAs.

When an Action Item is initiated, the system validates the issue, assigns responsible parties, and tracks task execution through a predefined workflow. Each stage supports role-based access, ensuring secure collaboration and controlled visibility. The system automatically notifies assigned users, guiding them through the execution of the action item.

J. QMS WORKFLOW ENGINE ENHANCEMENTS FOR DYNAMIC ROLE ASSIGNMENT BASED ON METADATA

TTI-2846 This release introduces a powerful enhancement to the QMS Workflow Engine that dynamically configures and assigns QMS Roles based on the type and category of each record. Designed to ensure the

right people are involved at each stage of a CAPA or investigation, the new functionality integrates **Record Types**, **Workflows**, **Teams**, and **Forms** to drive intelligent, metadata-based user assignments.

Now, when initiating a workflow (e.g., CAPA, Investigation), the system uses the record's metadata—such as **Type** and **Category**—to automatically determine the correct **Teams** and associated **Authority Types** (Process Owner, Contributor, Approver). This ensures that the appropriate users are pre-filled in each workflow step, streamlining the investigation process and reinforcing compliance by including the right participants at the right time.

For instance, a CAPA categorized under "Technology" would automatically involve the Head of IT and Technical Support as lead investigators, ensuring a faster, more accurate response aligned with the organization's quality protocols.

This enhancement empowers QA administrators to configure dynamic review groups that are automatically assigned to workflow steps based on record metadata such as category, type, and subtype. The system supports hierarchical mapping of Record Types and uses these to determine the appropriate Teams and Authority Types for each workflow.

Within each Team, users can be assigned one or more Authority Types—such as Process Owner, Contributor, or Approver—representing the specific role or "hat" they wear in the context of a given record. These Authority Types are further defined by their level of involvement (Assigned, Escalation, Informed), ensuring accurate participation across the workflow lifecycle. Workflow Configuration Profiles provide granular control over workflow behavior, including step order, visibility of fields, authority-to-action mappings, and targeted notifications. When a workflow is launched, the system automatically identifies the relevant team members for each step, streamlining participation and improving compliance. Additionally, if only one user is assigned to a workflow role, the system implicitly assigns the task to them; if multiple users are assigned, a claim mechanism is enabled. Built-in edit checks help prevent configuration errors, ensuring reliability without blocking setup progress.

7. 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)	
Estimated Date of Release	02-May-2025
Estimated US MTI Upgrade Date/Time:	02-May-2025 9:00 PM
Estimated EU MTI Upgrade Date/Time:	02-May-2025 5:00 PM
Estimated China MTI Upgrade Date/Time:	09-May-2025 9:00 AM
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your **TransPerfect** Customer Success Manager.

8. Hardware and Software Requirements

The following describes the hardware and software requirements to use the Trial Interactive v10.7 platform.

System Requirements	
Operating System	• Windows Version 7 or higher • All currently supported Mac OSX releases • iOS and Android for my mobile app (see myTI release notes)
Browser	• Microsoft Edge: Version 88 and later • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • NOTE: TI Sign requires that pop-up blockers be disabled for the Trial Interactive domain.
Client Software	• For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally. • For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred). • Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. • Optional: Drag and Drop from Outlook to Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available to support this feature on Internet Explorer® and Firefox®.
Optional Add-Ons	• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) • Optional: SAS Viewer or compatible software must be installed for SAS Datasets. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74

9. Changes

Legend for Impacts

Trial Interactive v10.7 has been released with these enhanced features and defect fixes. These tables use the following definitions of customer Impact:

- **Critical**: A core functionality returns invalid results or does not function as expected.
- **Major**: This Defect has an impact on basic functionality.
- **Minor:** There may be a small impact on business in specific use cases.
- **Blocker:** A Blocker defect refers to a critical issue that completely prevents further progress in development or testing.

Legend for Offering/Room Types

- 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
QMS-3	QMS	This feature introduces the **CAPA (Corrective and Preventive Action) workflow** in the **Quality Management Module**, providing a structured approach to identifying, investigating, and resolving quality issues. The CAPA workflow ensures that non-conformities, incidents, and deviations are effectively managed, reducing risks and	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the CAPA functionality in the Quality Management Module.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		improving compliance with industry standards. **Key Features:** • **CAPA Process:** Guides users through a systematic approach to issue resolution, from identification to verification. • **Issue Identification & Investigation:** Captures and analyzes non-conformances, incidents, and deviations to determine root causes. • **Corrective & Preventive Actions:** Implements measures to eliminate root causes and prevent future issues. • **Verification & Effectiveness Checks:** Ensures that actions taken successfully resolve issues through follow-up assessments. • **Documentation & Compliance:** Maintains detailed records of CAPA activities, ensuring transparency and regulatory adherence.				
QMS-7	QMS	This feature introduces **Evidence Attachment** functionality in the Quality Management Module**,** allowing users to add supporting evidence to quality records such as incidents and CAPAs. Users can now **upload files, attach URLs and search & Link** the evidence	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Evidence functionality in Quality Management Module.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		to ensure complete and accurate documentation. **User Actions:** • **Incident authors** can add evidence during record creation to include all relevant documentation. • **Reviewers** can add evidence during the review process for completeness and accuracy. • **Investigators** can add evidence to document the investigation process thoroughly. • **QA managers** can upload evidence for CAPAs to ensure all supporting documents are attached.				
QMS-8	QMS	This improvement introduces a **user-friendly incident viewing interface** in the **Quality Management Module**, allowing originators, submitters, and investigators to efficiently track and manage incidents relevant to their roles. Users can now easily access incidents they have reported, those assigned to them, and their favorite incidents through a simplified view designed for quick navigation. Supervisors and QA roles have expanded access, including visibility into workflow	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the incident viewing interface in the Quality Management Module**.**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		stages, ensuring better oversight and tracking. Additionally, users with **Edit, Manager, or Admin permissions** will have full access to all records for reporting and monitoring purposes. This enhancement streamlines incident management, improves visibility, and ensures users can efficiently focus on their specific responsibilities**.** **<u>Users Actions</u>** • **Originators** can view all reported incidents to track their status. • **Investigators** can access assigned incidents for prompt investigations. • **QA reviewers** can monitor incidents in different workflow stages. • **Users** can save incidents as favorites for quick access. • **Users with Edit, Manager, or Admin permissions** can access all records for tracking and reporting.				
QMS-12	QMS	This improvement enhances the Quick View (QV) panel that allows users to quickly access and interact with incident records. It provides a streamlined interface to view, edit, and manage incident details without navigating away from the current page. The panel can be	Yes	No	Minor	**Affect Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Quick

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		resized, and users have the option to open the full record page from the QV panel. The QV panel includes different tabs such as Metadata, Record History, Related, and Workflow for detailed navigation. **Key Enhancements:** • **Quick Access to Incidents:** Users can open the QV panel by clicking on a record, which slides in from the right. • **View and Edit Mode:** The panel opens in read-only mode by default, with an option to switch to **edit mode** for users with the proper permissions. • **Multiple Tabs for Easy Navigation:** Users can navigate between Metadata, Record History, Related, and Workflow tabs for detailed insights. • **Resizing Capability:** The QV panel can be resized to adjust the view according to user preference. • **Full Record Page Access:** Users can open the complete incident record from the QV panel by clicking the **"**Open Full Page**"** button or the record icon**.** • **Action Buttons in Edit Mode:** Includes Save, Cancel, and Close options in the Metadata tab to manage updates effectively.				View panel in the Quality Management Module**.**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
QMS-15	QMS	The Quick View (QV) panel in the Quality Management System (QMS) enables users to efficiently access and manage incident records without leaving the current page. A key enhancement is the Record History tab, which allows users to track changes, providing a clear audit trail of all updates made to a record. This tab ensures transparency and facilitates compliance by displaying a chronological log of modifications, including timestamps and user actions. Users with the appropriate permissions can navigate through Metadata, Record History, Related, and Workflow tabs for detailed record insights. The QV panel is resizable and includes an "Open Full Page" option for a more comprehensive view. Validation measures ensure data integrity, and action buttons within the Metadata tab support editing, saving, and reverting changes.	Yes	No	Minor	**Affected User:** Editor and Above. **Impact:** This feature has a minor impact on the history record in the Quality Management System.
QMS-18	QMS	This feature introduces a new module, **"Quality Records,"** in **Collaborative Workspace (CWS) Room Type** to enhance Quality Management System (QMS) tracking. This module will provide a **dashboard** and support various record types, including **Incidents, Evidence, CAPA (Corrective and**	Yes	No	Minor	**Affect Users:** Editor and Above. **Impact:** This improvement has a minor impact on the "Quality Records" in the Collaborative Workspace (CWS) Room Type.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Preventive Actions), Action Items, and Effectiveness Checks, with future expansions to include Change Management, Audits, and Findings**.** Additionally, **in** Collaborate rooms that have the 'Quality Records' module enabled, it will also be necessary to limit access to the 'Create Documents' in the document's module for specific editor level users who have been given access to the Quality Records.				
QMS-19	QMS	This feature introduces **Form Management** in the **Quality Management Module**, providing a structured approach to configuring and managing forms used in Quality workflows. The **Form Settings** page offers a centralized view of all forms, allowing users to define relationships, customize field settings, and ensure forms align with organizational needs. With support for **Main Topics and Sub Topics**, users can create dynamic form structures that adapt to various stages of the quality process. **Key Features:** • **Form Settings Page:** Provides an overview of all forms within the Quality module, displaying key details like field count, related forms, and module association.	Yes	No	Major	**Affect Users:** Editor and Above. **Major:** This improvement has a major impact on the Form Management in the Quality Management Module.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• **Topic Type Management:** Supports **Main Topics** (parent forms) and **Sub Topics** (child forms), allowing structured relationships between forms. • **Field Configuration & Customization:** Enables users to add, edit, and reorder fields, with support for multi-column layouts and rich text fields. • **Visibility & Validation Controls:** Allows marking fields as **required or optional** and setting advanced validation rules for data integrity. • **Related Forms Management:** Establishes relationships between Main and Sub Topics, ensuring proper form connections within workflows. • **Form Configuration Modal:** Provides an easy-to-use interface for arranging and customizing form layouts to suit business needs.				
QMS-20	QMS	This feature introduces **Incident Management** in the **Quality Management Module**, providing a structured approach to capturing, investigating, and resolving quality issues. The **Incident Form** serves as the entry point for quality concerns, ensuring reported issues are properly documented, assessed, and escalated as needed. Verified incidents trigger	Yes	No	Minor	**Affect Users:** Editor and Above. **Major:** This improvement has a minor impact on the Incident Management in the Quality Management Module.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Investigations to determine root causes, which may result in Non-Conformances or CAPAs with assigned Actions to drive corrective and preventive measures. **Key Features:** • **Incident Capture & Tracking:** Establishes a structured process for reporting and managing quality concerns. • **Topic Type Management:** Incidents are categorized as Main Topics and can include Sub Topics to maintain structured relationships. • **Workflow-Driven Incident Handling:** Incidents transition through investigation, root cause analysis, and corrective action implementation. • **Field Configuration & Customization:** Users can define key fields such as Record Type and Team, impacting workflow responsibilities. • **Non-Conformance & CAPA Integration:** Ensures incidents lead to appropriate corrective and preventive actions. • **Automated Notifications & Analytics:** Provides real-time visibility into issue trends, ensuring proactive resolution. • **Audit Trails & Compliance Tracking:** Maintains a detailed record of incidents to ensure regulatory adherence.				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
QMS-21	QMS	This feature introduces **Team Management**, allowing users to create and manage teams responsible for **Records and Documents**. Teams can be assigned **authority types** for workflow stages, record approvals, and other system-configured action items. Users can add or remove team members, link teams to specific record or document types, and manage authority levels, ensuring structured collaboration and compliance. The **Team Listing screen** provides a centralized view of all teams, displaying key details such as **team name, member count, description, and purpose** (e.g., Responsible Parties, QMS). Teams can be associated with **specific document types** (for responsible departments) and **record types** (for QMS workflows). By streamlining team assignments and authority configurations, this feature enhances efficiency, accountability, and workflow automation within the system.	Yes	No	Minor	**Affect Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Team Management in the Quality Management Module.
QMS-22	QMS	Users with the Approver or Contributor role can now initiate records from Incidents, including Non-Conformance/Deviation, CAPA, Action Items, Effectiveness Checks, and more. These newly created records will be	Yes	No	Major	**Affect Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		automatically linked to the original incident, ensuring seamless association. This enhancement also establishes parent-child dependencies, meaning a child record's status can determine whether the parent record can progress to completion within the workflow. For example, a CAPA Plan linked to an Incident must be completed before the Incident can be closed. This capability improves record management, workflow control, and compliance tracking across the system.				**Impact**: This improvement has a major impact on the Initiate Records from Incident.
QMS-25	QMS	This feature added a configurable product list under room settings, allowing clients to define products specific to their business. The system will not include a default list, ensuring full customization. When cloning a room or settings file, the product list from the source will be replicated to maintain consistency. This update enhances flexibility and ensures room setups align with business needs.	Yes	No	Minor	**Affect Users:** Editor and Above. **Impact:** This Improvement has a minor impact on the customization of the product list in the Quality Management system.
QMS-27	QMS	This feature introduces an **Impact** field with configurability. Admins can now customize the field by changing its label, adding new options, and disabling it as needed. This	Yes	No	Minor	**Affect Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		update provides greater flexibility in tailoring the Impact field to fit specific business requirements.				**Impact:** This Improvement has a minor impact on the configuration the Impact field.
QMS-28	QMS	The new **Record Type Settings** feature enables users to create, manage, and configure record types within the system. This structured interface allows for the management of record types and their associated workflows, forms, and field settings. This feature mirrors the functionality available in the Document Types settings but is specifically tailored for managing record-related workflows and forms. Record types are displayed in a hierarchical tree structure categorized by pre-defined categories based on forms with the “main topic” type. • **Structured Interface**: Enables users to manage record types and their associated workflows, forms, and fields • **Tree Structure View**: Displays record types in a hierarchical tree categorized by predefined main topic forms. • **Entity Selection**: Users can select a form (entity) for which they can configure record types.	Yes	No	Minor	**Affect Users:** Editor and Above. **Impact:** This Improvement has a minor impact on the Record Type Settings.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis

		• **Full Record Type Management**: Allows users to create, edit, or remove record types and subtypes.
		• **Import/Export Capabilities**: Provides options to import/export configurations for easier setup and migration.
		• **Change Log Tracking**: Maintains a change log for transparency and tracking modifications.
		• **Configuration Panel**:
		  ○ Define key details for record types, including naming rules, workflows, and due dates.
		  ○ Manage field visibility, requirements, and validations through a dedicated **Fields Tab**.
		• **Comprehensive Configuration Capabilities**: Supports configuring Record Types, Authority Types, Workflows, Forms, and Teams.
		• **Quality Administration Support**: As a Quality Administrator, users can configure Record Types to create and manage Record Type workflows efficiently.				

QMS-30	QMS	A new feature for configuring QMS (Quality Management System) workflows, including a dedicated Workflow Settings Page, enhanced	Yes	No	Minor	**Affected Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		creation tools, and a guided wizard for customizing stages, statuses, notifications, permissions, and actions. This streamlines workflow management for record types, ensuring full control over QMS processes. **Key enhancements** • **Workflow Management Settings Page**: Provides a centralized interface to configure and manage QMS workflows. • **Expanded Workflow Creation**: Enables users to define workflow names, profiles, descriptions, record types, and workflow stages. • **Wizard-Based Setup**: A step-by-step approach for configuring workflows, making setup easier and more intuitive. • **Stage and Status Management**: Allows users to define and manage QMS workflow stages and statuses. • **Permissions and Authority Assignment**: Configure role-based permissions and assign responsible teams or individuals to workflow stages. • **Forms and Field Configuration**: Link forms to workflow stages and control field visibility, required-ness, and validation.				**Impact:** This improvement has a minor impact on the QMS Workflow Configuration.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• **Advanced Notification Options**: Supports group-based notifications and escalation levels for enhanced communication.				
QMS-31	QMS	The feature introduces the ability to **open Queries on QMS records**, including **Incidents, CAPAs, and Action Plans**, improving communication and resolution within workflows. When a workflow stage is set to **"Clarification" status**, the stage claimant can send queries to previous stage participants or designated recipients. Recipients gain **view-only access** to the main record and sub-records (if not already granted), while automated **email notifications** ensure timely responses. **Key Enhancements** • **Query Initiation & Permissions** – The "Send Clarification" button is available when a record is claimed in a stage configured for clarification. Only the current stage claimant can trigger a query, and users must send a query before setting the record to "Clarification." • **Query Creation Workflow** – Clicking "Send Clarification" opens a modal window with an auto-filled email template, allowing users to add	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Queries in Quality Management System.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		recipients, modify the subject, and provide additional comments. Default recipients include the previous stage claimant or record originator (for first-stage workflows). • **Access Rules** – Recipients without prior access to the record receive **view-only** access to the main record and its associated sub-records. • **Status Change Validation** – If a query is open, users receive a confirmation prompt before transitioning out of "Clarification" status, ensuring queries are resolved before workflow progression. • **Email Configuration & Notifications** – A dedicated email template is used for query notifications, with placeholders for key details (Record Name, Type, Status, Link, Sender Info). Emails are sent instantly upon query initiation. • **Query Response & Resolution** – Recipients can respond to queries via email or within the application, with instant notifications to the query sender. The query sender or room manager can mark the query as resolved. File attachments are not supported in query responses.				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
QMS-32	Collaborate	This improvement introduces a **Quality Module** within the Collaborate Room Type to streamline quality management processes. Initially, this module will support Complaints/Incidents Management, Investigations, CAPA Record, and Report Generation. The Quality Module will not be enabled by default for our Collaborate customers, and will function similarly to the SSU module in eTMF and is accessible from the "Waffle" menu. User access is controlled through the "Quality Module" action, ensuring that only authorized users (readers, editors, and room managers) can view and manage compliance-related tasks.	Yes	No	Minor	**Affect Users:** Editor and Above. **Impact:** This Improvement has a minor impact on the Quality Module within the Collaborate Room types
QMS-33	QMS	This improvement introduces a **Quality Approval Form** to streamline the incident approval process. This form ensures that incidents are properly reviewed and approved by QA Approvers before closure, improving compliance and accountability. The **Quality Approval Form** functions as a **Sub Topic form**, automatically linked to Main Topic forms at the final stage of the incident workflow. It does not appear in the Record	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the **Quality Approval Process** by introducing the **Quality Approval Form** at the end of the workflow.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Types list but remains a static, related form within workflows and record configurations.				
QMS-34	QMS	This enhancement enhances the **Incident Management lifecycle**, we have introduced an **Investigation Form** that enables contributors to investigate newly opened incidents. This form ensures that incidents are thoroughly assessed at the beginning of the workflow, facilitating better tracking and resolution. The **Investigation Form** is a **Sub Topic form**, which means it can only be linked as a child to Main Topic forms. It does not appear as an independent form type in the Record Types list but functions as a **static, related form** within workflows and record configurations. This ensures that every incident includes an investigation step early in the process.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the **Incident Management Lifecycle** by introducing the **Investigation form** at the beginning of the workflow.
QMS-35	QMS	This enhancement enhances the **Incident Management lifecycle** by introducing an **Assessment Form** that enables QA Approvers to assess completed incidents. This form ensures that incidents are thoroughly evaluated at the end of the workflow, facilitating better tracking and resolution.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Incident Management Lifecycle by introducing the Assessment Form at the end of the workflow.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		The **Assessment Form** is a **Sub Topic form**, meaning it can only be linked as a child to **Main Topic forms**. It does not appear as an independent form type in the **Record Types** list but functions as a static, related form within workflows and record configurations. This ensures that every incident includes an assessment step before closure.				
QMS-39	QMS	This improvement disables document types assigned to another team in the Add Document Types modal.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the document types that are assigned to another team in the Add Document Types Modal.
QMS-40	QMS	The Audit Trail now includes a full history of Quality Records, enhancing compliance and visibility for administrators. This update adds QMS Topics, Activities, and Actions to the Audit Trail interface, allowing administrators to track modifications, approvals, and key events.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Audit trail in the Quality Management System.
QMS-41	QMS	The feature supports searching for various QMS topics, including Incidents, CAPA, Action	Yes	No	Minor	**Affected Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Plans, and Evidence, directly from the room search interface. Previously, QMS-related records could only be searched at the room level. Now, users with access to the QMS module will see a new "QMS Records" segment, where they can select the primary record type to search, defaulting to "Incident." The search functionality will support facets based on form settings configurations, ensuring tailored filtering options. The search results will display in a configurable data grid similar to the existing views' data grids, and clicking a record will open the familiar metadata panel for detailed information. This update indexes key QMS module records, including main topics like Incident, CAPA, and Action Items, as well as sub-records like Assessment, Investigation, and QA Approval. The fields indexed for search are determined by the form settings configuration under "Searches," while filters are based on the "Filters" configuration.				**Impact:** This improvement has a minor impact on the searching functionality in QMS topics.
QMS-42	QMS	This feature introduces CAPA (**Corrective and Preventive Action**) as a structured process in quality management aimed at **identifying, addressing, and preventing** the recurrence of	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the CAPA in

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		non-conformities, incidents, or other quality issues. **Key Steps in CAPA:** • **Identification** – Recognizing and documenting the issue. • **Investigation** – Determining the root cause through analysis. • **Corrective Action** – Implementing solutions to eliminate the cause. • **Preventive Action** – Taking proactive measures to prevent future occurrences. • **Verification** – Assessing the effectiveness of actions taken. • **Documentation** – Maintaining records of all CAPA activities for compliance and traceability.				the Quality Management System.
QMS-46	QMS	This feature introduces the ability to formally close a resolved incident within the Quality Management System (QMS), marking the end of the incident lifecycle. The Close Incident action becomes available only after the associated workflow has been fully resolved, ensuring that no open tasks remain before closure. To maintain control and integrity, only authorized users. Admins and users with the	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on incident management processes within the Quality Management system, adding a formal closure mechanism to enhance control,

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Approver Authority Type from the assigned team are permitted to perform this action. Upon initiating closure, the user must provide a Closure Comment (mandatory), after which the system automatically captures the Closure Date and the User who performed the action. These details are recorded in both the Audit Trail and the Incident Metadata for full traceability. Once an incident is closed: • An email notification is sent to all relevant users, including team members, workflow participants, and users involved via queries. • The incident becomes locked from further modifications, unless reopened by an Admin. This update ensures proper lifecycle management of incidents, enhances accountability, and provides clear communication across teams.				transparency, and communication.
QMS-47	QMS	This feature enables the cancellation (termination) of an incident during the workflow process in the Quality Management System. Cancellation removes the incident from the active workflow, unassigns all users,	Yes	No	Minor	**Affected Users: Editor and Above.** **Impact**: This improvement has a minor impact on incident lifecycle management,

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		and moves the record to a designated **"Canceled"** folder for clear separation. The **Cancel Incident** action can be performed under the following conditions: • **Workflow Users** assigned to the current stage can cancel the incident **only if explicitly permitted in the workflow settings**, and **only after claiming the record**. This option is not available once the workflow is fully completed. • **Admin Users** can cancel incidents at **any time**, regardless of workflow progress. Upon cancellation: • The incident is removed from workflow tracking. • All assigned users are unassigned. • The record is relocated to the **Canceled** folder for reference. An **email notification** is sent to all team members, including the Originator. Notably, **Admin users** and **Query Recipients** do not receive this notification. Cancellation details—including **Cancellation Date**, **Canceled By**, and **Reason for Cancellation**—				providing a controlled mechanism for terminating incidents when necessary and ensuring visibility and traceability of canceled records within the Quality Management system.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		are stored in both the **Audit Trail** and the **Incident Metadata** to ensure full traceability.				
QMS-48	QMS	This enhancement introduces administrative functionality that allows authorized users to manage and correct workflow records for incidents without interrupting related quality processes. Specifically, users can now change the record type, update the assigned team, and perform realignment of workflow responsibilities to ensure accurate routing and team ownership. **Key Action: Change Record Type & Assigned Team** Authorized users can initiate the Change Type and Team action directly from the record header. This opens a modal with the following configurable fields: • **Title** • **Record Type** (dropdown filtered by form-specific configurations) • **Assigned Team** (dropdown with all system-configured teams) • **Reason** (mandatory for audit tracking) **Behavioral rules:** • When a new Record Type is selected, the	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on incident management in the Quality Management system, enabling efficient administrative control for maintaining workflow accuracy and team alignment.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		system automatically populates the Assigned Team if a default mapping exists in the Record Type Settings. • The default can be overridden, and users may freely assign a different team. • Based on the changes, the system evaluates whether the workflow should continue as-is, reset, or be replaced, ensuring proper alignment with the new configuration. This feature provides necessary administrative flexibility to correct misclassified records or adjust team responsibilities during active workflows.				
QMS-49	QMS	This release introduces a comprehensive security model for managing Incident Records within the upcoming Records module of the Quality Management System (QMS). The feature ensures that each incident record is protected through record-level security, granting access based on user roles, group memberships, direct assignments, and workflow stages. Key functionality includes: • **Default Access Rules:** Upon creation, incident records are accessible to the	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Incident Record Security Design Specification.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Originator, Process Owner, Room Admins, and Super Admins. These users have edit access by default, with the Originator's access downgraded to read-only once the record enters workflow. • **Workflow-Aware Permissions:** As incidents progress, permissions are dynamically adjusted. Stage participants gain access based on workflow settings, while completed stages restrict contributor access to view-only. • **Investigator Access:** Investigators assigned outside of incident teams receive view-only access to relevant records and sub-forms. • **Deletion and Obsolescence:** Draft records can be deleted by Originators and Admins. Once submitted to workflow, only Admin roles can mark a record as obsolete. • **Creation Privileges:** Admin-level users can create incidents by default; Editor-level users require a specific "Create Incident Record" action privilege.				
QMS-50	QMS	This feature supports auto-numbering by major record type classification. For Example: • CAPA – **CAP-12345**	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Auto-

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• Incident- **INC-12345** • Action Plan – **ACT-12345**				Numbering for Incident, CAPA, and Action Item.
QMS-53	QMS	This feature ensures a structured and automated process for submitting and managing incident records within the QMS workflow. An incident record enters the workflow when the originator submits it for review, either during creation or after the record has been created. Upon submission, the system checks for a matching workflow based on the incident topic type and record type via an API: • If a matching workflow is found, the incident is successfully submitted and enters the workflow. • If no matching workflow is found, the originator receives an error message: *"No workflow found for this incident. Please contact your administrator or the service desk"* **Access & Workflow Assignment** Once the incident enters the workflow: • The originator's access is changed to read-only. • Team members associated with the record type gain read access. • The assigned authority can locate assigned incidents via the "Assignments View."	Yes	No	Major	**Affected Users:** Editor and Above. **Impact:** This improvement has a major impact on the Incident Workflow Process.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2421	QMS	With this feature, Managing Quality Records is now more efficient with the introduction of a cleaner, two-column metadata panel view. This update ensures that key metadata is accessible at a glance, reducing the need for excessive navigation while deemphasizing attached content, which may not always be relevant for metadata-based records. **Flexible Layout and Improved Navigation** • **Configurable Field Placement** – Organize metadata fields across multiple collapsible sections for a more intuitive layout. • **Enhanced Related Records Grid** – A refined grid view simplifies the way related records are displayed, improving readability and efficiency. • **Adaptive Viewing Experience** – Easily toggle between the expanded metadata panel and the standard panel, adjusting the view based on room and document type.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the two columns in the metadata panel.
TTI-2846	QMS	The QMS Workflow Engine supports configurable review groups, ensuring the correct investigators, reviewers, and quality approvers are automatically assigned based on Document Type and Category. This enhancement streamlines workflow	Yes	No	Major	**Affected Users:** Editor and Above. **Impact:** This improvement has a major impact on the QMS Workflow Engine.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		management by pre-filling the appropriate users when initiating records like CAPAs, Investigations, and Incidents. **Key Features:** • **Automated Role Assignment** – Based on metadata, the system selects the correct group of investigators, reviewers, and approvers. • **Configurable Review Groups** – QA Admins can define groups based on issue type, such as IT-related or laboratory-related investigations. • **Pre-filled Workflow Steps** – When a workflow is initiated, the relevant users are automatically populated in the workflow steps, reducing manual input and improving efficiency.				
TTI-2847	QMS	A new wizard-driven workflow assignment feature allows Quality Reviewers to initiate investigations on incidents after they are created and submitted. This enhancement provides a structured approach to assigning responsible parties at each stage of the workflow, ensuring clarity, accountability, and streamlined processing. **Key Updates** • **Guided Workflow Assignment**: Quality Reviewers can use a wizard to assign	Yes	No	Minor	**Affected User:** Editor and Above. **Impact:** This improvement has a minor impact on the Incident Workflow.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		responsible parties for each stage of an incident investigation**.** • **Configurable Workflow Steps**: Steps in the workflow can be customized in system settings**,** similar to document workflows in the eTMF system. • **Rich Text Instructions**: Reviewers can add detailed instructions for each step using a rich text editor to provide clear guidance. • **Status Tracking**: Incident authors can track the status of their submitted incidents and see when an investigation begins. • **Email Notifications**: Assigned users receive automated email alerts when they are added to an incident, ensuring prompt awareness of responsibilities.				
TTI-2848	QMS	The feature includes pre-configured Quality Management dashlets that can be added to any dashboard, providing real-time visibility into Quality Record To-Dos and Tasks, including Incidents, CAPAs, and Action Items. **Key Features:** • **Task Overview** – Displays active workflows for the three most important document types (Incidents, CAPAs, Action Items) to help users track pending tasks and team throughput. • **Advanced Filtering** – Users can filter by	Yes	No	Minor	**Affected User:** Editor and Above. **Impact:** This improvement has a minor impact on the Quality Management Dashlets.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		date range, type, organization, status, category, document type, and assignee for targeted task management. • **Grouping Options** – Tasks can be grouped by type, organization, status, category, document type, and assignee for better organization and prioritization. This enhancement ensures efficient task tracking, improves workflow visibility, and enables better workload management for QA teams.				
TTI-2993	QMS	The **Action Item Workflow (WF)** ensures a structured process from initiation to quality approval**,** consisting of two primary stages: Implementation and Quality Approval**.** The workflow supports claiming, reassignment, clarification, and cancellation to streamline processing. **Action Item Creation & Workflow Initiation** **Users Allowed to Create:** Any user with editor permissions or higher**.** • **Workflow Initiation:** Users submit an **Action Item** for review upon creation or after record creation. • **System Response:** ○ If a **matching workflow** is found, the Action Item enters the **Implementation Stage**. ○ If no workflow is found, an error message is displayed:	Yes	No	Minor	**Affected User:** Editor and Above. **Impact:** This improvement has a minor impact on the Action Item Workflow (WF)**.**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		"No workflow found for this Action Item. Please contact your administrator or the service desk" **Permissions & Access:** • The **originator's access** is downgraded to **read-only**. • **Team members** linked to the record type receive **read access**. • Assigned authorities use **"My Assignment"** to locate assigned Action Items. **Workflow Stages** **Notifications & Assignment:** • System notifies the assigned authority when the record enters this stage. • Email notification includes comments from the originator. **Claiming the Stage:** • Must be manually claimed before taking action. • Once claimed, the following buttons appear: "Complete," "Clarification," and "Cancel." • The claimant gains edit access to the record. • If the claimant differs from the process owner, the system updates the process				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		owner field. **<u>Quality Approval Stage</u>** **Stage Initiation & Notification:** • System notifies the assigned authority when the record enters this stage. • The "Start Review" button appears for manual claiming. **<u>Claiming the Stage:</u>** • Once claimed, a Quality Review form appears. • The following buttons are enabled: "Approve," "Clarification," "Reject," and "Cancel." • Claimant gains edit access to the incident and subforms. • Edit permissions extend to associated topics based on role settings.				
TTI-3679	QMS	To establish a robust Quality Management System (QMS), the following modules and submodules are introduced to support key workflows such as Incidents, CAPAs, and Action Items. These modules are designed to function independently while also integrating into a comprehensive quality management framework. Create the following Modules / Submodules: • For Incidents (Dashboard, Incidents, CAPA, Action Item, Effectiveness Checks, Organizations, Contacts, Audit Trail)	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Modules and Submodules in the Quality Management System.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3680	QMS	The feature introduces workflow-driven security, allowing users to access records dynamically based on their role in a workflow, rather than static security groups. Roles such as Submitter, Supervisor, Investigator, Reviewer, and Quality Assurance gain permissions through Authority Types (Owner, Contributor, Approver, Reader), ensuring controlled access. Teams enable flexible record permissions, with the least restrictive access for records and the most restrictive for documents. A bulk security UI simplifies permission management, while workflow approvals, notifications, and external user collaboration enhance efficiency. This ensures secure, traceable, and compliant Quality Management processes.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Overall Roles and Permissions, including Editors and Authority.
TTI-4013	Collaborate	This enhancement increases the **maximum supported video file size** in the **TI Viewer** from **100 MB to 2 GB**. Video files are commonly used in TI for **training sessions**, **instructional content**, and **meeting recordings**. With the increase in video resolution and size, many users struggle to compress files effectively. This improvement ensures that users can **upload, store, and playback** larger video content smoothly.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement has a minor impact on the video size in TI Viewer.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-4085	Collaborate	This improvement enhanced support for handling large files in TI rooms, allowing storage of files up to 20 GB. These files, such as ZIP archives and SAS datasets, must be uploaded to the room by a Solutions Engineer using WinSCP, sFTP, or similar transfer tools. Files larger than 2GB will automatically download to the user's desktop when accessed. Supported movie file formats (AVI, MP4, MOV) will continue to play directly using the original viewer.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on supporting larger files in TI rooms.
TTI-4127	Platform	This feature introduces an integration between the Customer Portal, managed by ZS, and Trial Interactive (TI) systems to enhance task visibility and streamline workflow execution for end users. The portal serves as the primary entry point for users to access and complete key actions within TI and, in future phases, GlobalLearn (GL). Upon logging into the portal via SSO, users are presented with a personalized "My To Do List" populated with tasks retrieved in real-time from TI's DMS and eTMF modules. A secure REST API (GET) call is made through the AWS API Gateway, with Oauth 2.0 authentication, to fetch pending tasks. The returned JSON response is rendered as actionable cards or buttons in the user	Yes	No	Minor	**Affected Users:** SuperAdmin and Above. **Impact:** This improvement has a minor impact on enabling seamless task visibility and redirection from the Client Portal to TI rooms.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		dashboard, each redirecting to the corresponding task in TI or GL. **Key Functionalities:** **<u>Displayed Tasks (Phase 1):</u>** **TI QDMS:** • Documents pending Approval • Documents pending Signature • Documents pending Collaborative Review **TI eTMF:** • Queries assigned to the user **Note**: LMS training tasks and QC review items are excluded in this initial phase and will be considered for a future release. **<u>Returned Metadata:</u>** For each task retrieved from TI, the following metadata is displayed in the Client Portal: **Document Tasks (Approval, Signature, Review):** • Document Title, Category, and Type • Approval Due Date, Assigned Date, Completed Date • Approval Status				

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• URL Deep Link to the Document • Workflow Details (Name, Reviewer, Stage, Stage Status) • Document ID, Owner, Version, Effective Date • File Name, Language, Page Count, Last Updated By • Working Version, Training Required/Needed, Submitted On. **eTMF Queries:** • Query Text, Type, ID, and Date • Related Document Title • All associated document metadata as listed above				
TTI-4154	QMS	The User handler has been updated to support return avatars for all users, not just the current user. This enhancement improves flexibility in profile management.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Profile management.
TTI-4165	QMS	This improvement introduces the ability to reassign a workflow stage to another team member within the same team. The new "Reassign" option is available in the workflow stage interface and allows reassignment under controlled conditions. **Key Functionality:**	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Reassignment Functionality for the Workflow Stage.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• Reassignment is limited to users within the same team. • Only authorized users (Super Admin, Admin, and Record Owner) can perform this action. • Reassignment actions are logged with timestamps for audit trail purposes. • The UI dynamically updates to reflect the new assignee.				
TTI-4177	QMS	This improvement introduces a standardized set of status tracking fields to QMS records, which will capture information related to status changes during workflows or manual closing/cancellation of records: • StatusDate • StatusComments • StatusChangedById • StatusChangedByName These fields will be automatically populated based on the latest status update and will be displayed in grids. Additionally, the existing fields **ResolvedById** and **ResolvedDate** have been converted into virtual fields, with values now sourced from	Yes	No	Low	**Affected Users:** Editor and Above. **Impact:** This improvement has a low impact on the new status system fields to QMS parent forms.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		the Workflow Log table, specifically where Workflow Status = 3 (Approved). A new field, **Resolved Comment,** has also been added to capture comments related to resolution.				
TTI-4178	QMS	This improvement updates the QMS Audit Trail filter to use the **ID** field instead of **Record ID** when filtering entries.	Yes	No	Major	**Affected Users:** Editor and Above. **Impact:** This improvement has a major impact on the QMS Audit Trail for ID filter.
TTI-4179	QMS	This improvement adds **validation** to the **Metadata Criteria** modal in the Quality record to ensure correct and complete input before saving or proceeding.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the QMS Audit Trail for ID filter.
TTI-4180	QMS	This improvement ensures that the **title of an Advanced Validation rule** updates correctly when the When or Equals fields are modified. Previously, the title remained unchanged after saving updates to the criteria.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Advanced Validation rule of the title.
TTI-4181	QMS	With this improvement, in QMS Workflow Creation, the Access Permissions for All Forms on each stage should be set as Read by	Yes	No	Minor	**Affected Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		Default & user can change this if needed. Currently default value is EDIT.				**Impact:** This improvement has a minor impact on the Access permission for all forms in QMS workflow creation.
TTI-4182	QMS	This improvement updates the Initiate Record modal to trigger data reloading only after the record has been successfully initiated, avoiding unnecessary reloads during the modal interaction.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Initiate record modal.
TTI-4183	QMS	This improvement implements a **dedicated audit trail view** in the User module to display activity log entries related to **Teams** within the QMS system. **Key Features**: • New audit scope selector for **Users** • Additional filter options: ○ **Include Subform** ○ **Actions Taken** ○ **Created By** ○ **Date Range** ○ **Record ID** **Tracked Activities**: • Create Team (with name and description) • Remove Team • Add/Remove User to/from Team • Assign/Unassign Record Type to/from Team • Assign/Unassign Team Authority Type to	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement has a minor impact on the Audit Trail for Team Changes.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		User (e.g., Process Owner, Contributor, Approver, Escalated, Notified) **View Columns**: • Activity Date • Created By • ID • Name • Activity Type • Activity Related Data The audit trail also includes an **export option**. When **Subform activity** is included, it displays related **Create** and **MetaUpdate** actions with their associated parent record data.				
TTI-4184	QMS	This improvement disables coding for a set of read-only fields in the CAPA Form that are auto-populated by the system. These fields are now excluded from the Coding and included only in the Grid view: • Created By • Created On • Current Workflow • Current Workflow Reviewer • Workflow Stage • Stage Status • Updated By • Updated On • ID • Resolved By	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on some fields from the CAPA form.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• Resolved On • Status				
TTI-4186	QMS	This improvement introduces **separate Edit buttons** for each form **Incident**, **Assessment**, **Investigation**, and **Quality Approval** within the Incident Workflow. Previously, a single common Edit button applied to all forms in a stage.	Yes	No	Minor	**Affected User:** Admin and Above. **Impact:** This improvement has a minor impact on the Incident Workflow edit functionality.
TTI-4187	QMS	This improvement sets the **Format** field in the **Sequential Numbering** as **required**. Users must now provide a valid format when enabling sequential numbering for a record type.	Yes	No	Minor	**Affected User:** Editor and Above. **Impact:** This improvement has a minor impact on the Sequential numbering for incidents.
TTI-4188	QMS	This improvement enforces validation to ensure the **Auto Name Pattern** field is **required** when the **"Use Auto naming Rules"** option is enabled.	Yes	No	Minor	**Affected User:** Editor and Above. **Impact:** This improvement has a minor impact on the Auto-naming Rules.
TTI-4189	QMS	This improvement hides the **Default Values** tab in the Record Types Settings for Version One**.**	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement has a minor impact on the Record

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
						Types setting for the default values tab for version one.
TTI-4190	QMS	This improvement fixes the UI behavior in the Coding Panel Preview**,** where Boolean and Choice elements (e.g., Custom Single Choice, Custom Multiple Choice, Custom Radio Button) previously appeared as **text fields**. These elements now render correctly according to their field type.	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement has a minor impact on the Form Settings – Code Panel Preview.
TTI-4191	QMS	This improvement removes the **Record Types** option from **Quality Module > Settings**, as it is already available under **Room Settings**, avoiding redundancy in configuration access points.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Record Type present in Settings.
TTI-4192	QMS	This improvement adds a **grid zero state** to the **States** and **Actions** tabs on the **Stage Page** in the Workflow Wizard.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Workflow Wizard – Stage Page.
TTI-4193	QMS	This improvement updates the default security behavior for newly created Incident, CAPA, and Action Item records, ensuring role-based access is automatically and accurately applied throughout the record lifecycle.	Yes	No	Major	**Affected Users:** Admin and Above. **Impact:** This improvement has a major impact on the

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis

		Key Behaviors:
		At Record Creation:
		• Originator, Room Admin, and Super Admin are granted Editor access.
		• No other users have access while the record is in draft mode.
		On Workflow Submission:
		• Originator access is downgraded to Reader.
		• Room Manager and the assigned Team (based on Record Type) receive Reader access.
		• Stage Claimant receives Editor access to the subform record and is designated as:
		  ○ Record Owner for Incident
		  ○ CAPA Lead for CAPA
		• Claimant retains Editor access unless the owner/lead changes.
		• Additional Contributors added at this stage will have Editor access to subforms.
		• Upon stage completion, Claimant and Contributors are downgraded to Reader.
		Evidence Access:
		• Any user with Reader access to the record and Editor access to the room can create Evidence records (until the record is closed).
		Related Record Access:
		• Same as Evidence—allowed for users with Reader record access and Editor
						changes to default security for incident /CAPA/ Action Items.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis

		room access, while the record status is not closed.
		CAPA Creation Rules:
		• Requires CAPA Create Action
		• Requires access to the referenced record
		• User must be a member of the assigned team on the referenced record
		• Upon workflow entry:
		  ○ CAPA team is added to Incident ACL
		  ○ Incident team is added to CAPA ACL
		Action Item Creation Rules:
		• Requires Editor access to the record
		• Requires access to the referenced record
		• Same rules apply whether the Action Item is for Incident or CAPA
		• Upon workflow entry:
		  ○ The Action Item team is added to the Incident or CAPA ACL
		  ○ Incident or CAPA team is added to the Action Item ACL.				

TTI-4194	QMS	This improvement introduces automatic **Due Date population** for **Incident**, **CAPA**, and **Action Item** records based on the **record type configuration**. **Key Behavior**: • A new required field **"Due Date"** has been added to the General section of the Record Type configuration (root node).	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement has a minor impact on the due date for Incident, CAPA, and Action Item.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis

		• The default value is 14 days and can be overridden at the node level.
		• When a record is created, the Due Date is auto-calculated as:
		  ○ Record creation date + configured due date period
		• Upon entering the workflow, the Due Date is recalculated as:
		  ○ Workflow start date + configured due date period
		• Any previously entered manual due date will be overwritten during workflow entry.
		• The Due Date field remains editable and can be manually changed by users with edit access.				

TTI-4195	QMS	This update improves **workflow security logic** for **Incident**, **CAPA**, and **Action Item** records. When a record enters a workflow, the system now determines related records using a more structured approach: • Identify the **root parent record**. • Include all **nested CAPA and Action Item** records under that parent. • Filter Draft record This ensures that workflow permissions are applied accurately across the full hierarchy of related items.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Security improvement for Incident. CAPA, and Action Item.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-4197	QMS	This improvement adds a **view-only Workflow field** to the Record Type Settings for **CAPA**, **Incident**, and **Action Item** forms. The field displays the list of **Workflows** where the selected record type is currently assigned. This field is informational only and cannot be edited.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the workflow view only field for Incident, CAPA, and Action Item.
TTI-4198	QMS	This improvement introduces a **caching service** to **preload data** required for displaying grid columns in **Incident**, **CAPA**, and **Action Item** views. This ensures that grid content loads accurately and efficiently, enhancing the user experience.	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact**: This improvement has a minor impact on the Incident & CAPA & Action Item grids.
TTI-4200	QMS	This improvement refines the behavior of the **"Set Action"** button in **Advanced Validations** for specific cases where the action was not being applied or updated correctly.	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement has a minor impact on the **"**Set Action**"** button in Advanced Validations.
TTI-4202	QMS	This improvement ensures that every record created in the system—whether it's an **Incident**, **CAPA**, or **Action Item**—has a **unique Record ID** that's automatically generated. This ID helps users easily identify and track each record.	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement has a minor impact on the Record ID Management.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		To support this, Admins must set up the **Record ID format** and **starting number** for each record type from the **Record Type Settings** in the system. For example, Incident IDs might look like `INC-001`, `INC-002`, and so on. Going forward, users will not be able to create a record unless this setup is complete. If a format is missing, the system will show a message guiding the user to update the settings. The system will also show an example format as a placeholder, like `INC-{{###}}` for Incidents, to help set things up. An info icon is available next to the format field for guidance.				
TTI-4214	SSU	This improvement updates the **Export** option for the **Documents** section in the **Site**, **Country**, **IRB/EC**, and **Amendment**. The changes enhance usability and consistency when exporting document-related data from these levels.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement has a minor impact on document management workflows at the Site, Country, IRB/EC, and Amendment levels by improving export behavior.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-4215	SSU	This improvement enhances the handling of **Custom** and **System Contact fields** in **SSU** by refining the way data is pulled from **User** and **Contact Form Settings**. The SSU Contact Form now clearly distinguishes between general and additional information and ensures proper visibility and behavior of relevant fields. Key changes include: • The **Additional Info** section in the SSU Contact Form now includes all Custom fields and only those System fields that are not already displayed under **General Info** or **Contact Information**. • Only fields with the **"Contact"** checkbox enabled in either the **User Form Settings** or **Contact Form Settings** will be shown. • For System fields such as **Full Name, Role Level, Userid, Username**, and so on, the "Contact" checkbox is now disabled, and Read-only is enforced. • Fields such as Site Number, Room, Site**,** etc., are automatically set to Read-only**.**	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement has a minor impact on the Custom and System Contact field in the SSU Form Setting.
TTI-4216	SSU	This improvement updates the behavior of the **Site Contact** form by aligning its **Countries list** with the configuration from **Room Settings**. Going forward, the Site Contact form will only display countries that are explicitly added under **Room Settings > Countries**, ensuring consistency with the behavior already implemented for **Site**.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement has a minor impact on the Site Contact – Countries list.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-4217	SSU	This improvement enhances the **sub-navigation panel** behavior in **SSU** by improving content visibility and usability. Previously, the fixed-width panel limited the user's ability to adjust the layout. The following changes have been applied: • The panel now defaults to a width of **250 px**. • The panel **cannot** be expanded beyond the **default width** of 250 px. • The panel **can be resized down to 60 px**, allowing for a more compact view. • Users can now **fully collapse** the panel, providing maximum space for viewing content.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement has a minor impact on the Sub Navigation behavior in SSU.
TTI-4218	SSU	This improvement removes the **'Contact Type'**, **'Main Contact'**, and **'Provide Documents'** fields from the **Contact Details** screen in **SSU**.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement has a minor impact on the minor impact on Contact details screen in SSU.
TTI-4219	SSU	A **"Copy Link"** option has been added to the **[Document] bar** in the **SSU/Documents** section. This enhancement allows users to quickly copy a direct link to a document, improving efficiency when sharing or referencing specific files.	No	Yes	Major	**Affected Users:** Editor and Above. **Impact:** This improvement has a major impact on the Copy Link functionality in the SSU/Documents screen.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-4220	eTMF	This improvement addresses a UI fix in the **Acknowledgement** tab. When using the **"Add Users to Acknowledgement"** modal, the header has been updated to display **"Add Users to [Acknowledgement Name]"** for clarity.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Acknowledgement tab.
TTI-4222	eTMF, Collaborate	An **"Edit"** button has been added to the **Coding Panel** within the **Quality Review** module, specifically for the **Metadata** and **Audit** tabs. This enables users with permission to edit metadata, to update relevant fields from within the panel by clicking on an edit button first.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement has a minor impact on the Quality Review Module regarding the edit.
TTI-4223	eTMF, Collaborate	This improvement enhances the **Document History** view for large documents. Key updates include: • **Paging** has been introduced to improve performance and responsiveness when loading document history. • The **Activity Type filter** has been updated to a **multiselect control**, allowing users to filter by multiple activity types at once instead of only one.	No	Yes	Minor	**Affected Users:** Editor and Above. **Note:** Due to different user abilities between eTMF and Collaborate room types, this improvement impacts Editor users and above in Collaborate rooms but only Administrators in eTMF rooms. **Impact:** This improvement has a minor impact on the Document History view.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
REPORT-186	QMS	The Listing Report for Incidents, CAPA, and Action items displays all configurable fields related to the report for the following columns. • Title • Type • Team • Impact • Product name • Initial Reporter • Due Date • Date of Incident • Customer (Organization) • Reported on • Awareness date • Description • Comments • URL field (Evidence field) Furthermore, the report displays sub-records associated with the incident, whether CAPA or Action, with appropriate indicators.	No	Yes	Minor	**Affected Users**: All Users **Impact**: The Listing Report for Incidents, CAPA, and Action has a minor impact on the Reports module and displays all configurable fields along with CAPA and action records associated with the incident with appropriate indicators.
REPORT-187	QMS	The 'Overdue CAPA Report' displays the following information when a reporting incident is present and CAPA is overdue. • ID • Type	No	Yes	Minor	**Affected Users**: All Users **Impact**: The introduction of the 'Overdue CAPA Report' has a minor impact on the Reports module and displays

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		• Team • Impact • Organization • Opened date • CAPA Lead • Due date • Close requirements • Plan descriptions • URL • Record status Additionally, the 'Overdue CAPA Report' displays the associated action items with proper indicators along with the report status, including Cancelled, Submitted and Claimed.				information when CAPA is overdue and reporting incidents are present with associated action items, with proper indicators.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14119	SSU	In the SSU – Amendments section, the "Complete Amendment" button was not displayed after all required documents were approved. Users had to manually refresh the page for the button to appear.	Minor	This issue had a minor impact on the Complete Amendment functionality. **Correct system behavior has been restored.**
TRL-16559	eTMF	When a CTMS room is cloned from a source room, the Workflows defined for the Doctypes are not carried over to the new room.	Minor	This issue had a minor impact on the Complete Amendment functionality. **Correct system behavior has been restored.**
TRL-16883	Collaborate	In the MTI US instance, clicking the Link to Collaborate Profile in the collaborator email redirects users to the room but does not open the document directly.	Major	This issue had a major impact on the Link to Collaborate Profile. **Correct system behavior has been restored.**
TRL-16892	Platform	Change log history for Template Folders sometimes displays null dates.	Minor	This issue had a major impact on the change log history for the Template Folders dates. **Correct system behavior has been restored.**
TRL-16959	eTMF	Mass Coding is incorrectly requiring users to provide a Reason for Change even when Causality Tracking is not enabled.	Minor	This issue had a minor impact on the Mass Coding. **Correct system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16976	Collaborate	When a document is checked out and checked back in (either through Edit Offline or Edit Online) without making any changes, the **Next Review Date** is automatically updated, even though it should remain unchanged. The issue occurs after uploading a document, making it effective on the current or a past date, and then performing a check-out and check-in action without edits.	Blocker	This issue has an impact on the next Review date has visibility. **Correct system behavior has been restored.**
TRL-17059	Collaborate	A Super Admin (SA) user is experiencing an issue where no folders are displayed in the index view for a specific room. The display appears empty, and the “Show Empty Folders” option is greyed out.	Major	This issue has a major impact on the Super Admin user’s ability to navigate and access folders in the specified room. **Correct system behavior has been restored.**
TRL-17254	eTMF	Users sometimes encountered a **server error** when attempting to export from the **Communication Outbox** in a specific room.	Minor	This issue had a minor impact on the Communication Outbox while exporting. **Correct system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17269	eTMF, SSU	In ETMF or SSU rooms, the "Copy" and "Share" buttons in the Documents Cart are not displayed as expected based on the document distribution configuration. **Issue 1:** When the **"Enable documents distribution"** option is disabled and a document is added to the cart by a Super Admin, the **"Copy"** button is expected but the **"Share"** button is shown instead. **Issue 2:** When the **"Enable documents distribution"** option is disabled and an **Editor** adds a document (with full access) to the cart, no action button is shown; the **"Copy"** button should appear. **Issue 3:** When the **"Enable documents distribution"** option is enabled and the **Editor** has the "documents distribution" action, adding a document to the cart does not display any action button; the **"Share"** button should appear.	Major	This issue had a major impact on the availability of document cart actions based on room settings. Inconsistent visibility of the "Copy" and "Share" buttons could confuse users and limit proper document handling. **Correct system behavior has been restored**
TRL-17277	Platform	User noted that the Trial Interactive UI prompts users to change their password even when **IAM integration** is enabled.	Minor	This issue had a minor impact on the IAM integration. **Correct system behavior has been restored.**
TRL-17398	eTMF	In the Quality Review module, document status changes (e.g., from *In Progress* to *Passed*) are not consistently saved. Although a pop-up confirms the update, the document often remains in the original status and location. The issue occurs sporadically, requiring users to repeat the update process multiple times for it to take effect.	Major	This issue has a major impact on the Document Status in the Quality Review Module. **Correct system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17447	Platform	Users are reporting that the Audit Comment column appears blank when auditing documents, even though the Comment Metadata Field is filled with the reason. This issue is not room- or query-specific and has been observed across multiple rooms.	Major	This issue had a major impact on the Audit Comment Column data visibility. **Corrected system behavior has been restored.**
TRL-17477	Platform	In CCR rooms, when sending a document for signature with the CRA selected as the Author and the CSM as the Reviewer, the system intermittently removes one of the signers during the first attempt. The Reviewer, although initially added, disappears after being selected. This issue is difficult to consistently replicate and appears to occur only during the first document signature process.	Major	This issue had a major impact when sending documents for signature in the CCR room.
TRL-17484	Platform	When creating a new CCR room by importing the settings file **from** the source room, the **Visit Report** and **Unblinded Visit Report** workflows were configured incorrectly, with the eSignature stage appearing before the Review stage**.** When the room is created by **cloning** the same source room, the workflow order is correct.	Blocker	This issue had an impact on the Incorrect Workflow Stage While Using the Settings File. **Corrected system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17546	Collaborate	Users reported that during collaborative review sessions in the Trial Interactive interface, all user comments are visible. However, when downloading the document using the Download icon, some comments, specifically from a few users, are missing from the downloaded .docx file. 1. When downloading via File > Download as Docx, all comments are correctly included. 2. When downloading using the **Download** icon directly, some comments are missing in the resulting file.	Minor	This issue had a minor impact on viewing comments for the Collaborate users when downloading the document using the Document icon. **Correct system behavior has been restored.**
TRL-17681	Platform	Users noted that after the TI version update, notifications triggered by actions in the room are not appearing under the notification area (bell icon). Although users still receive the initial pop-up notification, the notification is not retained or displayed in the notification list. This issue has been observed in both the MTI US and EU environments.	Minor	This issue had a minor impact on the user's ability to track recent actions via the notification center. **Correct system behavior has been restored.**
TRL-17726	Platform	The **study profiles between CTMS and MTI-Stage** do not match. Out of 15 studies created for the UAT dry run and only 5 have corresponding profiles on the MTI Stage. One urgent study, *Intense Oversight*, is missing its profile and corresponding CCR. The root cause is that the system uses **Study Name** to identify unique records instead of the **unique study identifier** from CTMS, leading to missing or skipped profile creation when duplicate study names exist across domains.	Blocker	This issue had an impact on the Study Profile between CTMS and MTI-Stage. **Corrected system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17740	Collaborate	In the **Create R&A - Select Sites** screen, when selecting a site that has no contacts with the **'Contact is responsible for Read & Acknowledge Documents'** setting, the **'Go to Contacts'** link is unclickable, and the expected **tooltip** does not appear on hover over the red triangle icon.	Major	This issue had a major impact on the "Go to Contacts" link and the tooltip visibility in the Select Site Screen. **Corrected system behavior has been restored.**
TRL-17745	eTMF	When using the **Export Room Archive** feature with the **'Final Documents Only'** option and selecting a specific date range,the system exports **were innacurate.**	Major	This issue had a major impact on the Audit Comment Column data visibility. **Corrected system behavior has been restored.**
TRL-17789	Platform	In a specific room, when attempting to edit the Visit Letter Workflow (eSignature only), the page freezes and becomes unresponsive, preventing users from modifying or closing the workflow settings. A page refresh is required, but even after refreshing, the workflow remains stuck at the loading stage.	Blocker	This issue has an impact on workflow configuration usability for Visit Letter Workflows involving eSignature. **Corrected system behavior has been restored.**
TRL-17804	Platform	A user's email address update in Prod IAM was successfully reflected in LDAP and another application. But not in MTI US.	Blocker	This issue had an impact on the updated email address in the Prod IAM, which is not reflected in MTI US. **Corrected system behavior has been restored.**
TRL-17845	eTMF	In **Users Management**, Administrator-level users can view **Super Admin** accounts v**iewing by the Action** functionality. This behavior is inconsistent .	Major	This issue has a major impact on user visibility restrictions in Users Management. **Corrected system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17900	eTMF	Users are experiencing an issue where the **Query ID column remains empty** when viewing documents in the **Index view** of the Document Library. Although the Query ID field is added via **Manage Column**, it does not populate for documents associated with a query. Notably, the Query ID displays correctly when using **Query by Sender** or **Query by Recipient** views.	Major	This issue had a major impact on Query ID visibility in Index View. **Corrected system behavior has been restored.**
TRL-17931	eTMF	When submitting a Translation Request for a document, the required metadata fields 'Project Start Date' and 'Country' do not appear in the metadata panel or Document Column after submission. Although both fields are marked as required during the creation of the Translation Request and can be updated prior to submission, the values are not reflected post-submission in the expected areas.	Minor	This issue has a minor impact on the Project Date and Country issue in the Translation Request. **Corrected system behavior has been restored.**
TRL-17999	Platform	When a contact is created in CTMS without an email, TI assigns a random placeholder email as expected. However, if the email is later updated in CTMS, the change is **not reflected in TI** or in the linked CCR/eTMF rooms. Although the **SiteContactUpdate** message includes the correct email, TI fails to process or apply the update.	Critical	This issue has a critical impact on the email address updates from CTMS, which is not reflected in TI. **Corrected system behavior has been restored.**
TRL-18087	eTMF	The system allows users to send **Translation Requests** without entering the two fields marked as **required**. Despite the required field indicators, the system does not enforce validation and permits submission without completing them.	Major	This issue has a major impact on the translation request required fields. **Corrected system behavior has been restored.**

10. Open Defects

Trial Interactive v10.7 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
QMS-448	QMS	In the **Record Types Management**, when a user attempts to delete a **Record Type** that is assigned to existing **Incident or CAPA records**, the system currently does **not provide any warning or confirmation message**. The deletion proceeds, and the **Type field in those Incident/CAPA records is silently cleared**, which may lead to confusion or data inconsistency**.**	Minor	This issue has a minor impact on the Record Types Deletion. **Correct system behavior will be restored.**
QMS-674	QMS	In the Quality module, when an Admin-Level user navigates to the Filters section and creates a new filter using the **Due Date** field, the system does not display or apply the **Room Time zone** for the Due Date value.	Minor	This issue has a minor impact on the due date filter in the Quality Module. **Correct system behavior will be restored.**
QMS-675	QMS	In the Quality Records search view within a QMS Room, when an Admin Level user adds the **Due Date** field through Advanced Search, the system does not display or apply the **Room Time zone**	Minor	This issue has a minor impact on the search results for “Due Date” in Quality Records. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
QMS-816	QMS	In the **Form Settings** for the **Action Item** form, when a user selects the **Title** field, the system allows exclusion of the field from Coding. However, the **Title** field is a mandatory core field and should not be allowed to be excluded from Coding.	Minor	This issue has a minor impact on the Action Item Title field. **Correct system behavior will be restored.**
QMS-820	QMS	In the Record Types Management section, when a **Super Admin User** unchecks the **"Inherit from Incident"** checkbox for **Due Date** and **Auto Name Pattern**, changes the values, and then rechecks the checkbox, the system does not reset the values to **OFF** as expected.	Minor	This issue has a minor impact on the expected value behavior for inherited settings in Record Types Management. **Correct system behavior will be restored.**
QMS-828	QMS	When a new room is created from a template, the **"Starts from"** field in the Sequential Numbering section is incorrectly set to **0**, even though the minimum value should be **1**. After updating the value to 1, the field remains highlighted in red**.**	Minor	This issue has a minor impact on the default value validation and UI feedback in the Sequential Numbering configuration. **Correct system behavior will be restored.**
QMS-829	QMS	When a room is created from a **template** or when a room is created **without the QMS module**, the **Format** field for **CAPA** and **Action Item** record types is incorrectly set to **0** in the Sequential Numbering section.	Minor	This issue has a minor impact on the default configuration of Format values for CAPA and Action Item record types. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
QMS-830	QMS	In Record Types Management, when a Super Admin enters a format in the Sequential Numbering – Format field using the example pattern shown (e.g., INC- {{###}}), the system does not allow the value to be saved. After saving, the Format field is cleared, turns red, and appears empty, indicating an error, even though the input matches the expected example format.	Minor	This issue has a minor impact on configuring Sequential Numbering formats in Record Types Management. **Correct system behavior will be restored.**
QMS-831	QMS	For rooms created from a template or without QMS, the **Team** field in Processing Configuration shows **[0]** instead of being empty.	Minor	This issue has a minor impact on the Team field. **Correct system behavior will be restored.**
QMS-870	QMS	In the TI Viewer, when a user opens an Incident record with attached Evidence and navigates through the pages, a pop-up appears with the message: **"Do you want to save annotation(s)?"** This confirmation dialogue is triggered by the TI viewer and interrupts the viewing experience.	Minor	This issue has a minor impact on the document viewing experience in the TI Viewer. **Correct system behavior will be restored.**
TRL-9793	Platform	The user noted that the Grid view becomes misaligned when scrolling through a large number of records.	Minor	This issue causes the grid columns to go out of alignment during scrolling, affecting readability. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-11642	Platform	When users perform a document search by entering the full name of the document, the search results populate correctly. However, when users search using only a partial name of the document, no results are returned. This issue is inconsistent with expected behavior, where partial searches should retrieve matching documents.	Minor	This issue has a minor impact on the search functionality. **Correct system behavior will be restored.**
TRL-13226	eTMF	When entering a date in the metadata panel, the cursor did not auto-move from the year to the month field, requiring manual adjustment.	Minor	This issue had a minor impact on data entry. **Correct system behavior will be restored.**
TRL-15019	eTMF	User has noted that the Manager-level users are automatically assigned group actions upon creation, even if not added to any group.	Minor	This issue causes new Manager-level users to receive default group actions that cannot be removed, despite not being associated with a group. **Correct system behavior will be restored to prevent unintended action assignments.**
TRL-15324	eTMF	Editor-level users in the "General Query Responder" group are unable to assign queries, as the "Add Assignee" option is greyed out in the General Query module.	Minor	This issue has a minor impact on assigning the queries for editor-level users. **Correct system behavior will be restored.**
TRL-15397	Platform	The user has noted that the signature in a Document is viewable in the Original viewer but not in the TI Document viewer.	Minor	This issue has a minor impact on viewing the document in the TI document viewer. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15435	eTMF	Users are experiencing an issue where documents added to the Related Documents tab do not appear after being added. Although the system displays a success message, the tab remains empty and does not show the added document.	Minor	This issue has a minor impact on adding the document to the related documents tab. **Correct system behavior will be restored.**
TRL-16345	Platform	In the Setting - client management user noted that not all controls are displayed on the organization tab when editing.	Minor	This issue has a minor impact on the organization's control visibility. **Correct system behavior will be restored.**
TRL-16899	Collaborate	The user noticed an issue in MTI US that the alignment for Rows and Columns in the grid view is jumbled if we oversize the header row.	Minor	This issue has a minor impact on the Alignment in the grid view for rows and Columns. **Correct system behavior will be restored.**
TRL-17141	Platform	There is an issue where, upon uploading a single document using a user-provided Word template, the system does not retain the original font formatting. After the document is uploaded and processed through the Workflow or E-Signature stages, the font changes from Calibri to Times New Roman.	Minor	This issue has a minor impact on the font formatting consistency. **Correct system behavior will be restored.**
TRL-17167	eTMF	User noted that password password-protected documents are sometimes not opening in the TI viewer.	Minor	This issue has a minor impact on accessing the password-protected document in TI Viewer. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17187	Platforms	In the MTI US instance, there is an issue where the text colour in the footer cannot be changed to black when editing fillable fields using the Content Control settings. Even after updating the color to black and saving the changes, the footer text remains grey.	Minor	This issue has a minor impact on the Content Control Setting. **Correct system behavior will be restored.**
TRL-17321	eTMF	In the system, when a contact is deactivated from a site, the metadata updates correctly to show "Not Specified." However, the contact's name remains in the Document Name, as defined by the auto-naming rule. Even after regenerating the names from Room Settings, the Document Name does not update to reflect the removal of the deactivated contact.	Minor	This issue has a minor impact on the Metadata updates for contacts. **Correct system behavior will be restored.**
TRL-17467	Platform	We are facing an issue in the MTI instance where a specific document in a reported room cannot be opened in either TI or Original View. Additionally, when exporting the checksum file via SFTP, the document details are missing.	Minor	This issue has a minor impact on accessing the document in TI and the Original Viewer. **Correct system behavior will be restored.**
TRL-17469	eTMF	Some documents are unable to be opened and viewed via the TI Viewer. Issue was unable to be replicated with OnlyOffice.	Minor	This issue has a minor impact on accessing the document in TI Viewer. **Correct system behavior will be restored.**
TRL-17545	eTMF	In the **ETMF Completeness View**, the **Sub-I contact's first name** is displayed incorrectly on the placeholder in the room.	Minor	This issue had a minor impact on the eTMF completeness view. **Correct system behavior has been restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17709	eTMF	Users have encountered an issue in the MTI US instance, where several sites with a status of "Non-participating" are incorrectly showing as "No" in the Grid view, instead of Yes.	Minor	This issue has a minor impact on the Site with Non-Participating Status. **Correct system behavior will be restored.**
TRL-17732	Platform	In the MTI US instance, users are unable to select all sites in the Safety Letter Acknowledgement screen when performing bulk actions. When selecting sites from search results, only the sites on the first page are retained. Upon navigating to the next page, previously selected sites are automatically deselected. In some cases, it might be 3-4 pages of sites.	Minor	This issue has a minor impact on selecting all sites from the search results when sending the document for reading and acknowledgement. **Correct system behavior will be restored.**
TRL-17857	eTMF	Users are facing an issue where recent documents are not appearing in results when using both Room-level Search and Keyword Search. These counts are not reducing or progressing even after resubmission.	Minor	This issue has a minor impact on the Room Search and Keyword Search. **Correct system behavior will be restored.**
TRL-17876	eTMF	Users are encountering an issue in the MTI US instance in the previous version. While reviewing the audit trail for certain revoked user accounts, they observed that these accounts were revoked earlier. However, the system still allows them to be added to a group, despite their status being marked as "revoked".	Minor	This issue has a minor impact on adding a revoked user to the group. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17908	eTMF	The user has reported an issue in the MTI US instance where users with revoked access can still be assigned to queries under the Quality Review module.	Minor	This issue has a minor impact on the access revoked user, that can be added to queries. **Correct system behavior will be restored.**
TRL-18000	eTMF	Users are facing an issue when importing a new document and selecting 'Yes' for the Certified Document option; the Certified Copy Reason field does not appear, even though a reason has been configured in the settings. However, when certifying an existing document in the room, the Certified Copy Reason field appears correctly. Users also tested this in the MTI US instance, where the Certified Copy Reason field does not appear for either new or existing documents.	Minor	This issue has a minor impact on the Certified Copy Reason field. **Correct system behavior will be restored.**
TRL-18047	Collaborate	In MTI US, users have reported an issue where, upon adding both Editor- and Admin-level users to the Quality Editor group, only Editor-level users appear as selectable options when assigning an additional document owner in the metadata. Admin users are not displayed in the selection list. Additionally, periodic review notifications are being correctly sent to the document owner and all Editor-level users within the Quality Editor group. However, Admin users within the same group are not receiving these notifications.	Minor	This issue has a major impact on the Quality Editor group when adding both editors and admins. **Correct system behavior will be restored.**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18077	eTMF	A user with **Editor** access reported being unable to view the **CRA Reconciliation Module Reports**. The issue was verified using a Super Admin account, where the reports were visible. The user's access was reviewed, confirming that they had **Editor** permissions with actions like Page Manipulation, Communication, Event Manager, and CRA Reconciliation enabled. The issue appears to be user-specific.	Minor	This issue has a minor impact on the ability of specific users to access CRA Reconciliation Module Reports. **Correct system behavior will be restored.**

11. 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 Client 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 according to 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

US: 888-391-5111 (TOLL-FREE)	help@trialinteractive.com	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	eu.help@trialinteractive.com	Monday – Friday, 9 AM – 6 PM CET.
China +86 (755) 66856062	cn.help@trialinteractive.com	Monday – Friday, 9 AM – 6 PM Beijing Time

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 CSM can submit Ideas to our Perfective Change Management on your behalf

Focus Group

Meet with other Trial Interactive customers for an immersive CEP Forum:

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

12. Approvals

Product Owner

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

Quality Assurance

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