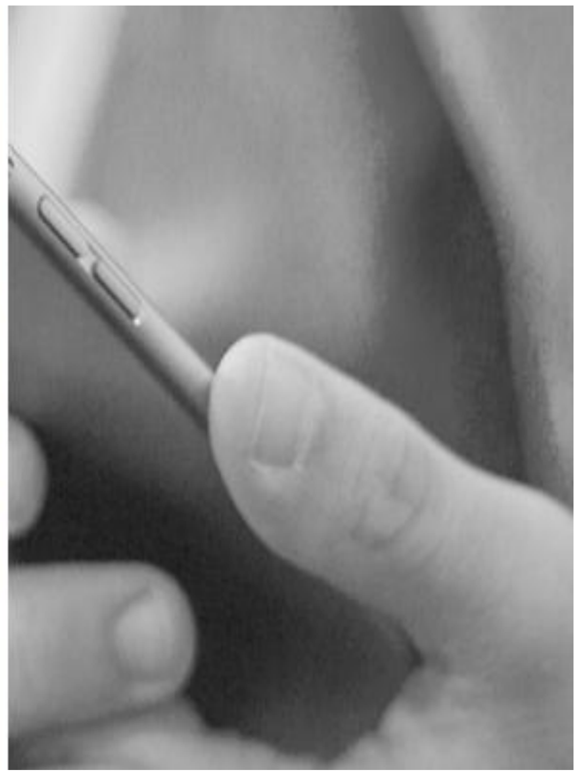
TRIAL INTERACTIVE V10.8 - RELEASE NOTES V0.2



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1. Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	22-Sep-2025	Pre-Release Notes
Samuel Pawar	0.2	21-Nov- 2025	**Added Features:** • ETMF-993, TTI-3167 • TTI-4137, TTI-4490 • TTI-4453, TTI-4454 • TTI-4455, TTI-4456 • TTI-4457, TTI-4458 • TTI-4465, TTI-4466 • TTI-4469, TTI-4474 • TTI-4475, TTI-4476 • TTI-4477, TTI-4480 • TTI-4481, TTI-4482 • TTI-4484, TTI-4485 • TTI-4487, TTI-4489 • Report-220 **Removed Features:** • ETMF-865, TTI-3791 • TTI-4320, TTI-4349 **Added Defect Resolution and Open Defect table:**

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 by the changes introduced in the system release. The Final Release Notes are then issued once the internal Validation Package has been reviewed/approved by Trial Interactive Quality Assurance. The Final Release Notes will contain the final list of items in 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 that 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	10.8
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.
CRO	Clinical Research Organization
CSM	Customer Success Manager
CTMS	Clinical Trial Management System
DICOM	Digital Imaging and Communications in Medicine
ERES	This document provides guidance in the United States for using electronic systems, records, and signatures in clinical investigations.
GDPR	The General Data Protection Regulation is a set of rules laid out by the European Union regarding data privacy rights.
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
eTMF	Electronic Trial Master File
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 GlobalLink, 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 Events, 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. COUNTRY-LEVEL IRB DOCUMENT CONFIGURATION

ETMF-237 This enhancement enables the configuration and management of IRB Required Documents at the Country level, addressing the limitation of only being able to set up documents at the Study or Site level. Teams can now define country-specific document requirements, such as Country Insurance without relying on dummy document types or manual filing, ensuring accuracy and efficiency.

A new **"Countries" radio button** in the Required Documents setup allows admins to select all countries at once or choose specific ones. Different documents can be assigned to different countries (e.g., Document A for all countries, B for Canada, C for the USA and Germany), providing flexibility to reflect real regulatory variations. Once configured, placeholders automatically appear under each IRB's Required Documents tab, organized by country.

When IRB or Site approvals occur, these documents are auto-filed into the correct Country category in the eTMF, ensuring proper organization and compliance.

By allowing IRB document setup to the country level, this feature removes manual workarounds, strengthens compliance alignment, and streamlines activation processes empowering teams to manage global studies more efficiently and accurately.

B. TI VIEWER ENHANCEMENT: PDF PORTFOLIO DOCUMENT SUPPORT

TTI-3167 This enhancement enables full viewing support for PDF Portfolio documents in both the Original Viewer and the TI Viewer by upgrading the rendering engine to ARender 2023.6.0**.** Previously, PDF Portfolios—commonly generated from email correspondence with embedded attachments—could not be opened in TI, preventing users from reviewing important content needed for eTMF filing and compliance.

With this upgrade, users can now open PDF Portfolio files directly within TI and view their embedded documents without errors, ensuring complete visibility into all information packaged in the portfolio. This improvement strengthens document accessibility, reduces manual workaround steps, and ensures that all supporting materials included in portfolio-style PDFs can be reviewed and filed correctly.

C. QUERY MANAGEMENT IN SSU

TTI-3544 This enhancement introduces a formal Query Management system in SSU, enabling Start-up Specialists and Regulatory Reviewers and Sponsors to raise, track, and resolve queries on submitted documents before approval. Previously, SSU lacked a structured process for managing clarifications, making tracking and audit compliance difficult.

Users can now **raise queries during their review stages** and triggering notifications via TI and email. Queries can be answered either in TI or by replying to the email, with all actions recorded in a complete audit trail. Once resolved, the issuer can close the query, allowing the document to move forward. Documents with open queries cannot be approved, ensuring all issues are addressed beforehand. Query history is retained when documents move to eTMF.

All queries follow a Pending → In-Progress → Resolved lifecycle and appear in the dedicated Query Module that displays both open and closed items. Start-up Specialists and Regulatory Reviewers can assign queries to Site Contacts, CRAs, Document Submitters, or other roles to ensure targeted follow-up.

By embedding structured query handling into SSU, this feature streamlines communication, enforces review controls, and strengthens audit readiness.

D. ETMF EVENT BASED ON CTMS MILESTONE STATUS

TTI-3595 This feature introduces **interoperability between CTMS milestones and eTMF event triggers**, enabling a more automated, activity-driven approach to event creation and placeholder management. Previously, milestone tracking and eTMF event setup were handled separately, requiring manual updates and increasing the risk of misalignment between operational timelines and regulatory documentation. By linking milestone status changes directly to eTMF triggers, this update establishes a seamless cross-system workflow that improves accuracy, consistency, and speed.

Users can configure **Event Trigger mappings** using a unique combination of Milestone Name and Organizational Level (Study, Country, Site). Standard milestone templates are supported across levels, while study-specific milestones can be mapped manually. Once defined, CTMS sends real-time milestone status updates to eTMF:

- **In Progress** milestones become available in the TI Event Manager, signaling the start of activities.
- **Completed milestones** trigger event creation and document placeholder generation in TI.
  Planned and completion dates, classifications, risk levels, and document type references are synchronized to ensure accurate event configuration.

By introducing milestone-driven triggers, this feature eliminates manual placeholder setup, ensures timely alignment between study operations and documentation, and lays the foundation for a unified, cross-application study management experience between CTMS and eTMF.

E. RISK SCORING

TTI-3980 This enhancement introduces **foundational risk scoring capabilities** in eTMF, enabling clinical teams to proactively identify and prioritize high-risk documents and placeholders. With risk scoring, teams gain clear visibility into high-impact areas, allowing for smarter monitoring and earlier interventions.

Administrators can now configure numeric risk values (0–100) for each document type based on regulatory criticality. The system automatically groups scores into High (≥ 80, Red), Medium (40–79, Amber), and Low (< 40, Green) categories. Risk scores are calculated in real time whenever documents or placeholders are created or their document types are updated. These scores are displayed as color-coded indicators and numeric values in key grid views (status, workflow, reviewer, site, country, etc.), allowing users to filter and sort by risk level to focus on the highest-priority records first.

A new **Risk Score View** provides a dedicated workspace to group documents by risk level, while a dashboard dashlet highlights unfulfilled placeholders by risk category, offering drill-down navigation for immediate action. Site profiles also display a site-level risk roll-up, helping users assess overall site compliance exposure at a glance.

By embedding risk visibility across eTMF, this feature also allows users to perform Quality Reviews and QC workflows based on risk levels. This enables studies to take a risk based approach to their TMF activities while maintaining consistent quality standards across studies.

F. QMS RECORD DEPENDENCY & CLOSE CONDITIONS CONFIGURATIONS

TTI-4207 This enhancement introduces **configurable Close Conditions** that prevent records (e.g., Incidents, CAPAs) from being closed while related records or queries remain unresolved. Previously, records could be closed prematurely, creating traceability gaps and compliance risks. With this update, dependency checks are enforced automatically during closure, ensuring all required actions are completed first.

Admins can configure Close Conditions at the classification or record type level, with options to inherit or customize settings. Conditions include:

- **Related Records** – Block closure if selected related record types remain open.

- **Queries** – Block closure if any associated queries are unresolved.

Checks run on any transition to a Closed state. If dependencies are unmet, closure is blocked and a popover tooltip lists the specific blocking items, with direct links for resolution. A new Close Conditions panel in Settings simplifies setup, and the related records UI now displays clearer parent–child relationships.

By enforcing dependency checks, this feature prevents premature closure, maintains traceability, and provides clear user feedback to resolve open items efficiently.

G. REGIONS IN SSU

TTI-4271 This enhancement introduces the concept of Regions within SSU to support **EUCTR's two-level submission** process Part I (regional submission) and Part II (country submissions) for CTIS. Previously, SSU only tracked submissions at the country level, which aligned with Part II but did not support regional coordination or the role of a Reporting Member State (RMS). With this release, SSU can now manage both regional and country-level submissions, aligning the platform with the EUCTR regulatory model.

At the domain level, **CTIS regions (27 EU + 3 additional countries)** are predefined. A new CTIS column and CTIS tab are added to the Country Overview page, enabling region management. By default, all countries are marked as MSC (Member State Country), and Editors can propose and confirm one country as the RMS, which is visually flagged. Once confirmed, only Admins can change the RMS designation, and ownership of any existing regional submission packages is automatically transferred to the new RMS.

The RMS can create and manage Regional Submission Packages at the region level, while other member countries can view these packages in a read-only format. Proposed RMS countries can also initiate regional submissions before confirmation, supporting flexibility during setup. This structure ensures Part I submissions are tracked at the region/RMS level, while Part II continues at the country level, enabling accurate, EUCTR-compliant submission management.

H. QMS ENABLE MULTIPLE QUERIES DURING INVESTIGATIONS

TTI-4334 This enhancement introduces the ability for multiple queries to be raised during an investigation or other workflow steps, overcoming the previous limitation of a single workflow query. Record participants—including Admins, Record Owners, Stage Assignees, and Additional Participants—can now create **General Queries** that are not tied to a specific workflow stage. This improvement enables broader collaboration across teams without blocking stage progression.

General Queries appear alongside workflow queries in the Queries tab and can be created at any point after the record's first submission and before final closure. These queries operate independently of stage transitions, with standard actions available such as Respond, Back to Pending, Resolve, and Add Recipients. To ensure governance, unresolved queries do not prevent stage completion but will trigger a confirmation modal before approval or completion, and no record can be closed while queries remain unresolved.

With dedicated UI changes, users see an always available Add Query button (unless the record is Draft, Cancelled, or Closed), a clean recipient picker with no pre-filled groups, and clear notifications to all relevant participants. This enhancement strengthens investigation workflows by improving visibility, ensuring unresolved questions are addressed, and fostering more effective collaboration across stakeholders.

I. QMS DUE DATE CONFIGURATION FLEXIBILITY

TTI-4453 This enhancement introduces greater flexibility and control in how due dates are assigned across QMS records. Previously, all due dates were automatically calculated from a fixed period defined at the Record Type level, which limited use cases where teams needed manual flexibility (e.g., Action Items) or preferred different timing strategies based on the record classification.

With this release, administrators can now configure whether due dates are auto-calculated or manually entered, at both the Record Classification and Record Type levels. Record Types can inherit settings from their parent classification or override them as needed, allowing organizations to standardize due date behavior for some record families while enabling exceptions for others. When auto-calculation is enabled, the system sets the due date automatically when the record is submitted into workflow and maintains read-only control. When auto-calculation is disabled, users can enter due dates during record creation, while post-submission changes continue to follow the existing Change Due Date action to preserve audit accountability.

By providing configurable due date behavior, this enhancement eliminates manual workarounds, supports varied operational approaches across different record types, and maintains audit integrity while giving teams the flexibility they need to align due date handling with their internal processes.

J. QMS QUERIES DASHLET ON DASHBOARD

TTI-4454 This release introduces a dedicated Queries Dashlet to the QMS Dashboard, giving teams a clear and actionable overview of all open and resolved queries across investigations, CAPAs, quality events, and other record workflows. Previously, users needed to open individual records to find or track queries, making it difficult to manage follow-ups, prioritize work, or ensure timely closure.

The Queries Dashlet consolidates this information into one workspace. Two tabbed views help users immediately focus on what matters:

- Assigned to Me shows queries where the user is responsible to respond.
- My Submissions shows queries the user has raised and may be awaiting responses on.

Compact filters make it easy to slice by record type, team, role, query type, status, or date ranges—while smart sorting highlights items that are overdue or require urgent review. Each line item includes direct navigation links to both the query and the associated record, ensuring fast resolution and reducing delays. Users can also export their filtered view to Excel for team reporting, audits, issue review meetings, or handoffs.

By putting query visibility front and center, this enhancement strengthens collaboration, reduces turnaround times, and improves oversight across QMS record workflows helping teams maintain compliance while working more efficiently.

K. SHOW ADDITIONAL PARTICIPANTS IN WORKFLOW STAGES

TTI-4455 This update improves visibility and clarity within workflow-driven records by expanding how Additional Participants are displayed during stage progression. Previously, the system only surfaced participants who were still pending action, which made it difficult to understand who had already completed their part or contributed comments. As a result, users often lacked full context when making decisions or advancing a stage.

With this enhancement, the trigger has been renamed to “Show Additional Participants,” and now displays every participant on the stage including those who have already completed their review along with their status and any recorded comments. The list is neatly organized to highlight pending items first while still allowing users to see the complete participation history at a glance. This improves transparency, supports clearer decision-making, and strengthens record traceability.

By enabling full visibility of participant involvement, this enhancement reduces ambiguity, helps reviewers quickly confirm completion, and reinforces a more accountable and collaborative workflow experience across QMS records.

L. WORKFLOW PREVIEW & PRE-ASSIGNMENT FOR UPCOMING STAGES

TTI-4456 This enhancement improves workflow readiness by enabling users to see and set stage responsibilities before the workflow reaches those stages. Previously, assignments for upcoming stages were often left unset until the moment the stage opened, resulting in last-minute reassignments, delayed approvals, and confusion about who was responsible for the next action.

With the new Show Upcoming Stages & Assignments workflow trigger, authorized users are prompted to review and update assignments at the right time when the record transitions into a configured status. A clear “Assign Users” modal displays each upcoming stage in order, showing the current default assignees and participants along with the option to modify or reset them. Ownership logic respects existing claim behaviors, ensuring full consistency with organizational workflow design.

By enabling early assignment, this feature reduces bottlenecks, strengthens accountability, and ensures the right people are prepared before their stage begins. Teams benefit from smoother workflow transitions, fewer reassignments, and improved overall process efficiency.

M. AUTO-FOCUS ON ACTIVE WORK STAGE FOR ASSIGNED USERS

TTI-4457 This enhancement improves efficiency and clarity when working within records by automatically directing users to the area where they are responsible to take action. Previously, Assignees and Additional Participants had to manually search through sections to locate their workflow stage, often leading to delays, missed updates, and navigation errors.

Now, when an assigned user opens a record with an active stage, the system immediately expands and highlights the relevant section collapsing surrounding content to reduce noise and bringing the user’s work into clear view. A subtle visual accent draws attention to the exact area requiring input, helping users orient themselves quickly and take action without hesitation. Once the user interacts with the panel, the system respects their layout and does not interfere further.

This enhancement reduces confusion, accelerates task completion, and ensures users always know exactly where to go when entering a record—resulting in faster workflows and fewer errors across teams.

N. STREAMLINED CREATION OF RELATED QMS RECORDS

TTI-4458 This enhancement improves clarity and usability when adding follow-up records such as CAPAs, Action Items, and Effectiveness Checks. The previous Initiate button was often misunderstood and required users to navigate additional screens to choose record types, leading to unnecessary clicks and user errors.

The updated Add Related action makes this process more intuitive. A clean popover menu provides one-click access to the most common related record workflows, and Effectiveness Checks are now surfaced as a first-class option, helping teams treat them as intentional follow-up activities rather than hidden Action Item variants. The selected record type opens directly into its creation modal with the appropriate classification already selected, and once saved, the system automatically links the new record and updates the Related section without any additional setup required.

By simplifying the interaction and clarifying intent, this enhancement reduces mis-clicks, accelerates corrective and follow-up action workflows, and ensures more consistent linkage between records—supporting better traceability, audit readiness, and workflow efficiency.

O. CAPA & QUALITY EVENT ROLLUP REPORT IN MS WORD FORMAT

TTI-4482 This enhancement introduces the ability for QA teams to generate CAPA and Quality Event reports in MS Word, allowing users to produce a complete, editable, and externally shareable rollup report. Previously, CAPA data had to be manually consolidated from multiple screens, limiting the ability to prepare polished reports for audits, inspections, or stakeholders without system access.

With this improvement, users can export a structured Word document that includes a standardized header, a summary table of CAPA fields, related action details, and rich text sections such as corrective and preventive actions, root cause analysis, and final approvals. Optional Action Items can be included, and the Word format allows teams to add signature blocks or apply additional formatting as needed.

This enhancement ensures clearer documentation, reduces manual report preparation, and provides QA teams with a streamlined, audit-ready output that supports both internal collaboration and external distribution.

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)	
Date of Release	21-Nov-2025
Estimated US MTI Upgrade Date/Time:	12/Dec/2025 9:00 PM
Estimated EU MTI Upgrade Date/Time:	05/Dec/2025 9:00 PM
Estimated China MTI Upgrade Date/Time:	19/Dec/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 in order to use the Trial Interactive v10.8 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 v10.8 has been released with these enhanced features and defect fixes. These tables use the following definitions of customer Impact:

- **Blocker:** A Blocker defect refers to a critical issue that completely prevents further progress in development or testing.
- **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

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	Comment / Impact Analysis
ETMF-237	SSU	This feature introduces the ability to configure IRB Required Documents at the Country level, enabling study teams to define and manage country-specific document requirements for IRB/EC submissions. This enhancement ensures proper categorization, auto-filing, and compliance by aligning required documents with country regulations. **Key Features:** • **Country-Level Configuration:** Allows users to assign required documents at the country level in addition to study and site levels. • **Flexible Document Assignment:** Enables selection of all countries at once or individual countries for document	Yes	Yes	Minor	**Affected Users:** Admin and Above. **Impact:** This feature has an impact on IRB Documents at the Country Level.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		requirements. • **Radio Button for Countries:** Adds a new option in the Required Documents setup for IRB-specific configuration. • **Placeholders for Required Documents:** Automatically generates placeholders under the Required Documents tab for each country's IRB requirements. • **Auto-Filing in eTMF:** Ensures approved IRB documents are automatically filed under the correct country category in the eTMF. • **Dynamic Updates:** Automatically creates required document placeholders when new countries are added to a study. • **Efficiency in Setup:** Supports quick setup with a "Select All Countries" option for global requirements.				
ETMF-993	eTMF	This enhancement introduces a configurable option in the Communication Inbox that allows users to mark documents as Relevant without completing metadata fields. When this setting is enabled at the Room level, users with Reader, Editor, or Admin access can select single or multiple communications and mark them as Relevant, and the documents will move directly into the Staging or QC queue defined in the room's workflow configuration. This behavior is also supported during Mass Coding. To support processing and tracking, documents marked as Relevant include source information indicating they originated from the Communication Inbox. When required metadata is skipped, the system provides a user warning before submitting, ensuring users understand that workflow routing may depend on metadata applied later in the process. This enhancement streamlines triage activities for teams who need to identify relevant communications quickly while allowing coders or service teams to complete metadata entry later in the workflow.	Yes	No	Minor	**Affected User:** All Users. **Impact**: This enhancement impacts Communication Inbox processing and relevant document routing.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
ETMF-2168	Platform	This enhancement delivers a redesigned Web Help experience with a modern look and feel, adding support for solution-offering home pages, comprehensive search, and a unified landing that surfaces Topics, Job Aids, and Videos at a glance. The site supports multiple languages and enables the UI to deep-link to specific topics for context-sensitive help, ensuring users can jump directly to relevant guidance from within the product.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This feature has an impact on the Web Help experience.
TTI-3167	eTMF	This enhancement adds support for viewing PDF Portfolio documents in both the Original Viewer and the TI Viewer by upgrading the rendering engine to ARender 2023.6.0. PDF Portfolio files, which often include email correspondences with embedded attachments, can now be opened directly within TI without errors. Users can view the full content of the portfolio, including embedded files, ensuring that all information captured in these PDFs is accessible and can be reviewed as part of the eTMF documentation process.	No	Yes	Minor	**Affected User:** All Users. **Impact:** This enhancement impacts document viewing by enabling full support for PDF Portfolio files in TI.
TTI-3544	SSU	This enhancement introduces a formal Query Management system in SSU, enabling **Start-up Specialists** and **Regulatory Reviewers** to raise, track, and resolve queries on submitted documents before approval. With this update, users can raise queries during their respective review stages. When a query is raised, notifications are sent via TI and email. Queries can be answered within TI or by replying to the email, with all actions recorded in the audit trail. Once resolved, the issuer can close the query, allowing the document to proceed to approval. Documents with open queries cannot be approved, ensuring issues are addressed before filing. All queries follow the **Pending → In-Progress → Resolved** lifecycle, are displayed in the **Query Module**, and their history is retained when documents move to eTMF. **Key Features** • **Query Lifecycle** – Raise queries on submitted or pending	No	Yes	Minor	**Affected User:** Editor and Above. **Impact:** This Improvement has an impact on the formal Query Management system in SSU.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		documents; document status updates to *Clarification*. • **Flexible Responses** – Respond within TI or via email; all interactions audited. • **Role-Based Assignment** – Start-up Specialists and Regulatory Reviewers can assign queries to Site Contacts, CRA, Document Submitters, and other relevant roles. • **Approval Control** – Documents with open queries cannot be approved; visual grid indicators highlight queried documents. • **Unified View & History** – Queries appear in the Query Module alongside eTMF queries, with complete history retained during document transfer.				
TTI-3590	eTMF	This improvement adds a time component to the “Published Date” field in order to facilitate accurate time zone conversion, and should be adjusted in all places applicable.	No	Yes	Minor	**Affected Users**: All Users. **Impact**: This improvement has a minor impact on the time component of the “Published Date” field.
TTI-3595	eTMF	This enhancement introduces **interoperability between CTMS milestones and eTMF event triggers**, enabling a more automated and activity-driven approach to event and placeholder creation. By establishing seamless milestone-based interoperability, the system can now automatically initiate eTMF events when key study milestones reach defined statuses, eliminating manual tracking and improving cross-system alignment. Through this interoperability, users can configure event triggers using unique combinations of Milestone Name and Organizational Level (Study, Country, Site). Once defined, the system listens for CTMS status updates and automatically pushes the relevant milestone data to TI (eTMF) when trigger conditions are met.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact:** This feature has an impact on eTMF event creation and milestone-driven placeholder management through CTMS–eTMF interoperability**.**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		Key Capabilities • **Event Trigger Mapping:** Define or retrieve triggers using a unique Milestone Name + Level combination, with support for standard templates at Study, Country, and Site levels. • **Milestone Status–Driven Triggers:** *In Progress* status makes milestone data available in TI Event Manager, while *Completed* status triggers event and placeholder creation in eTMF. • **Document Association:** Only milestones with document type references and "Completed" status push data to TI; non-document milestones are excluded. •				
TTI-3725	eTMF	With this Improvement, Users can now easily **copy the URL of a related document** directly from the panel by: • Hovering over the **document ID** and clicking to copy the link. • Using the new **"Copy Link"** option in the three-dot menu.	No	Yes	Minor	**Affected User:** All Users. **Impact:** This Improvement has a minor impact on the Related document link.
TTI-3827	SSU	This enhancement introduces Sponsor Review notifications, aligned with existing Regulatory Review notifications. Sponsor users can now receive alerts when documents are submitted for sponsor review, approved, or rejected, ensuring timely visibility into sponsor-driven review processes.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact**: This enhancement impacts notification handling by enabling alerts specific to Sponsor Review actions.
TTI-3980	eTMF	This release introduces foundational risk scoring to help teams focus monitoring efforts on high-risk areas and implement corrective or preventative measures early in the process. By assigning a risk score (0–100) to documents and placeholders based on document-type criticality, the system surfaces clear, color-coded indicators across key views. This enhancement	Yes	Yes	Major	**Affected Users:** Editor and Above **Impact**: This feature has an impact on risk-based

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		enables teams to prioritize high-impact items, allocate resources efficiently, and address potential compliance issues before they escalate. **Key Capabilities** • **Document-Type Risk Model (Admin-Configurable):** Assign numeric risk values (0–100 in increments of 10) to document types; the system groups score as High (≥ 80, Red), Medium (40–79, Amber), and Low (< 40, Green). • **Real-Time Scoring:** Risk scores are calculated and updated immediately when a document or placeholder is created or its document type changes. • **Grid Enhancements:** Risk score columns (pill + numeric value) with filtering and sorting are available. By default, the column is enabled in "View by Risk Level**"**; it can be added to other key views (e.g., status, workflow, reviewer, site, country) as needed. • **Risk Score View:** Dedicated view for grouping by High / Medium / Low scores. (Per 10/2/25 agreement, placeholders are not shown in this view though they are scored elsewhere.) **Affected modules:** • Document types management • Document settings page (module enable/disable) • Document Grids/Coding Panel • Document/Doctype export • Room Creation • Document review module				monitoring, prioritization, and audit readiness in eTMF**.**
TTI-4069	Collaborate	This enhancement allows the **"Use Placeholder fields in the Document"** toggle to be edited even after a document has been added. Previously, users could only set this toggle during upload, and any missed configuration required deleting and re-adding the document, resulting in the loss of associated history and version	No	Yes	Major	**Affected Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		details. With this update, users can now modify the toggle post-upload, reducing rework and improving flexibility. Additionally, the default state of the toggle is now set to **ON**, ensuring consistency for QDMS and Collaborate rooms where placeholders are frequently used to automate document headers.				
TTI-4099	eTMF	This enhancement introduces a search option in the Quality Review Module (QRM), enabling users to quickly locate specific documents within the audit profile grid. **Key Features** • **Search Bar Implementation:** Search bar added above the audit profile grid in QRM, available to all users. • **Searchable Fields:** Supports search by Generated Name, Document Date, Section, Document Type, Sub-Artifact, Index Number, and Document ID. • **Search Flexibility:** Both partial and exact matches are supported. • **Integration with Filters/Sorting:** Search works seamlessly with existing filters and sorting options.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts the Quality Review Module by enabling faster document retrieval through search functionality.
TTI-4137	eTMF	This enhancement adds support for rotating multiple pages at once within the TI Viewer (ARender). Users with edit permissions can now select several pages in a PDF and apply a single rotation action, rather than rotating each page individually or rotating the entire document. This update streamlines document preparation and improves efficiency when working with multi-page PDFs that require consistent orientation adjustments.	No	Yes	Minor	**Affected Users**: Editor and Above. **Impact:** This enhancement impacts PDF editing by enabling multi-page rotation within the TI Viewer.
TTI-4152	eTMF	This enhancement enables extracted metadata to be displayed in the indexing panel even when document classification is not returned, allowing users to review, select, and map useful metadata during document indexing. **Key Features**	No	No	Minor	**Affected Users:** All Users. **Impact:** This enhancement impacts the document indexing process by ensuring extracted

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		• **Metadata Display with UDID, No Mapping:** Extracted metadata is shown in the indexing panel when a document has a UDID but no mapping, allowing users to populate fields and configure expected mappings. • **Metadata Display without UDID:** When classification fails, extracted metadata such as date, site, country, protocol, version, category, and contact is displayed with a low confidence score. • **Simplified Mapping:** Users can map metadata fields without being forced to select an entity, reducing confusion when the document type is undefined. • **Dynamic Refresh:** Once a user inputs the document type, the system refreshes and maps the proper fields automatically based on configuration.				metadata is always visible and usable, even if document classification fails.
TTI-4156	Platform	This enhancement introduces an end–user–facing profile form that allows users to edit their own account information, while maintaining strict control over identity fields through IAM SuperAdmin and application admins. The form can be accessed from integrated applications via a new tab, modal, or embedded iframe, with updates communicated across applications and IAM. **Key Features** • **IAM SuperAdmin Control:** Only IAM SuperAdmin can update the user name and email address (email updates subject to impact/risk analysis). • **Application Admin Control:** Application admins can update job titles, supporting eSignature and application-specific requirements. • **User Control:** End users can update personal details such as address and phone number directly in the profile form. • **Synchronization:** Updates are communicated via SQS to all connected applications and IAM.	No	Yes	Minor	**Affected Users:** Super Admin. **Impact:** This enhancement impacts user profile management by enabling end users to edit their own non-identity data while ensuring identity fields remain under admin control.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		• **Portal Integration (Future):** IAM portal will support direct self-service updates for end users while preserving role-based restrictions. • **API & UI Support:** Secure API and user interface allow authenticated users to view and edit permitted fields without VPN restrictions.				
TTI-4196	QMS	This enhancement introduces the ability to **return all valid workflow actions** available to the logged-in user for a record at its current stage. Action availability is now determined **server-side**, ensuring accurate permissions and reducing UI complexity. Two **virtual fields** — $$AllowRecordClose$$ and $$AllowRecordCancel$$ — have been added to record entities to indicate whether a user can close or cancel a record. This ensures consistent enforcement of workflow rules and improves security. **Key Features** • Returns valid workflow actions per user and stage. • Server-side evaluation replaces UI checks. • Adds $$AllowRecordClose$$ and $$AllowRecordCancel$$ virtual fields. • Ensures consistent, secure action handling.	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact**: This enhancement impacts workflow handling by centralizing action validation on the server, improving security, reducing UI dependency, and ensuring consistent availability of close and cancel actions across modules.
TTI-4207	QMS	This enhancement introduces configurable Close Conditions at both the classification and record-type levels, allowing administrators to prevent records (e.g., Incident, CAPA) from being closed when related records or queries remain unresolved. By enforcing these dependency checks at the point of closure, the system ensures that no record is prematurely resolved while dependent actions or investigations are still open. This helps maintain end-to-end traceability and supports stronger compliance controls. **Key Capabilities** • **Configurable Close Conditions:**	Yes	No	Major	**Affected Users:** Editor and Above. **Impact**: This feature has an impact on Incident, CAPA, and Quality Event closure workflows, improving traceability and compliance.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		◦ **Related Records:** Prevent closure while selected related record types remain open. Admins can select one or more related record types (across classifications such as QE, CAPA, Action Item). ◦ **Queries:** Prevent closure if any queries associated with the record are still open. • **Flexible Configuration Levels:** ◦ **Classification Level:** Apply Close Conditions to all record types within a classification (e.g., all CAPA records). ◦ **Record Type Level:** Option to **inherit** from classification or define **custom Close Conditions** for a specific record type. • **Closure Checks:** ◦ Checks run on any action that moves a record to a Closed state (e.g., Close, Complete/Close, workflow transitions). ◦ If conditions are not met, closure is blocked, and users see a popover tooltip listing the specific blocking items (e.g., related record IDs, query subjects) with links. • **UI Enhancements:** ◦ New **Close Conditions** configuration panel under *Settings → Form Settings → Record Types → Profile*. ◦ **Improved related records panel UI** with clear parent–child visualization.				
TTI-4224	eTMF	This enhancement ensures that the Export button is hidden for Readers and Editors in SSU when the “Enable export (for readers/editors)” setting is turned off in Room Settings. Previously, the button was still visible and triggered an unauthorized action warning when used. The behavior is now aligned with eTMF > Documents, where the Export button is properly hidden under the same configuration.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact**: This enhancement impacts export configuration by ensuring Readers and Editors no longer see the Export option when it is disabled in settings.

<table>
<tr><th>Feature ID</th><th>Offering Impacted</th><th>Description</th><th>Config Change?</th><th>Enabled by Default?</th><th>Impact</th><th>Comment / Impact Analysis</th></tr>
<tr><td>TTI-4263</td><td>QMS</td><td>This enhancement introduces control over available Record Types and improves usability by renaming the action to a “Create” button. When users click the button, they can select from a dropdown of enabled record types (e.g., Quality Event, Safety Event, IT Issue) before the form opens, with the selected type pre-populated. Administrators can enable or disable record types as needed, ensuring new records follow updated workflows while legacy workflows remain intact.</td><td>No</td><td>Yes</td><td>Major</td><td>Affected Users: Editor and Above.

Impact: This enhancement impacts record creation by allowing administrators to control which record types are available and by streamlining the user experience for creating Quality Records.</td></tr>
<tr><td>TTI-4271</td><td>SSU</td><td>This enhancement introduces the concept of Regions within SSU to support EUCTR’s two-level submission process, Part I (regional submission) and Part II (country submissions) for CTIS (Clinical Trials Information System). The current SSU structure supports tracking only at the country level, which aligns with Part II submissions but does not address regional coordination requirements.

With this release, CTIS is pre-defined as a region with a clear structure to support regional submissions and Reporting Member State (RMS) coordination. This enables SSU teams to manage and track Part I submissions at the region level while maintaining Part II submissions at the country level, reflecting the actual EUCTR regulatory process.

Key Capabilities
Predefined Regions:
CTIS regions (27 EU + 3 additional countries) are predefined at the domain level.
A new ‘CTIS’ column is added to the Country Overview page, along with a CTIS tab for managing regional settings.
RMS Designation:
All countries are marked as MSC (Member State</td><td>No</td><td>Yes</td><td>Minor</td><td>Affected Users: Editor and Above.

Impact: This enhancement impacts submission management by enabling regional submissions, RMS assignment, and package visibility across member countries to meet EUCTR requirements.</td></tr>
</table>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		Country) by default. ◦ Editors can propose and confirm one country as the RMS, which is visually flagged with an RMS ID. ◦ RMS designation can be changed only by Admin users after confirmation, and ownership of regional submissions is reassigned automatically. • **Regional Submissions:** ◦ RMS can create and manage Regional Submission Packages at the region level. ◦ Regional packages are visible to all member countries in the region as read-only. ◦ If the RMS changes, ownership of existing regional packages is automatically transferred to the new RMS. • **Submission Alignment:** ◦ This structure supports **Part I submissions** at the RMS/Region level and **Part II submissions** at the country level, in line with EUCTR requirements. ◦ Proposed RMS can also initiate submissions before confirmation, ensuring process flexibility				
TTI-4295	eTMF	This enhancement introduces the ability to copy events within a study room**,** allowing users to quickly duplicate existing events and their configurations for other sites or countries. By enabling event cloning, study teams can avoid repetitive manual creation of recurring events such as monthly activities, protocol amendments, and monitoring visits. This improvement reduces setup time, ensures consistency across study configurations, and minimizes the risk of errors during event creation.	No	Yes	Minor	**Affected Users:** Admin and Above. **Impact:** This enhancement impacts event management by simplifying event setup and improving efficiency for study teams.
TTI-4319	Platform	This enhancement replaces the sFTP archive process with a secure archive solution**,** ensuring all exports are encrypted with a 24-character strong password and validated with checksums. Files are stored on the cloud, accessible through pre-signed URLs or VPC-restricted archives with strict cleanup.	Yes	Yes	Minor	**Affected Users:** Admin and Above. **Impact:** This enhancement impacts archive and export

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		Users can view and manage their export history, download links, and passwords from their profile, while super admins have domain-level visibility. Notifications alert users when exports are complete. This update improves security, streamlines delivery, and removes reliance on sFTP.				operations by providing secure, encrypted, and trackable delivery through the cloud instead of sFTP.
TTI-4321	eTMF	This enhancement updates the service offering label from "SSU" to "SSU/eTMF" when a room includes both SSU and eTMF. Previously, the label displayed only "SSU," which confused users working in the eTMF module. So, the Room type label was changed in rooms where the service offering is selected as SSU.	No	Yes	Minor	**Affected Users:** All Users. **Impact**: This enhancement impacts service offering visibility by ensuring the tag accurately reflects rooms that include both SSU and eTMF.
TTI-4334	QMS	This enhancement introduces support for multiple queries during investigations and other workflow steps, allowing record participants to create "General Queries" that are not tied to a workflow stage. This enables broader collaboration without blocking stage progression and ensures all queries are tracked before a record can be closed. **Key Features** • **Who Can Create:** Admins, Record Owner, current Stage Assignees, and Additional Participants. • **When Allowed:** After the record's first submission and before final Closed status; not available for Draft, Cancelled, or Closed records. • **Stage Impact:** General Queries do not block stage progression. Before Approve/Complete, a confirmation modal lists unresolved queries. Records cannot move to Closed until all queries are resolved. • **Recipients:** No default groups; creators select Users and/or Groups manually.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts investigation workflows by enabling multiple queries to be raised and resolved independently, ensuring improved collaboration and compliance before records are closed.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		• **Query Type:** Appears as “General” in the Queries tab and exports, alongside stage queries. • **User Flow:** ○ Add Query button always visible (except in Draft/Cancelled/Closed). ○ Create a Query dialog identical to stage queries, with an empty recipient list. ○ On Save → status = Pending, recipients notified, creator subscribed to responses. ○ Actions supported: Respond, Back to Pending, Resolve, Add Recipients.				
TTI-4346	eTMF	This enhancement allows Editors in eTMF rooms to view the “History” tab in document metadata, providing transparency into all updates made to a document throughout its lifecycle. Editors with Regulatory Inspector access will not see the History tab, maintaining the restricted view for inspection purposes.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts document metadata visibility by extending History tab access to Editors in eTMF while preserving restrictions for Regulatory Inspectors.
TTI-4354	eTMF	This enhancement introduces the ability to save metadata mapping configurations directly from the coding panel**.** When a document type has no existing mapping, metadata entered during manual coding will be captured and stored in Automate settings for future use. **Key Features** • Unmapped Document Detection: The system identifies when a document type lacks existing mappings and alerts the user during coding. • Metadata Capture: Metadata field mappings entered during manual coding are recorded and linked to the document type. • Mapping Persistence: Captured mappings are automatically	No	No	Minor	**Affected Users:** Admin and Above. **Impact:** This enhancement impacts Automate metadata management by enabling mappings to be created dynamically during coding, reducing repetitive setup and improving efficiency.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		saved into Automate settings, ensuring they are immediately available for subsequent documents of the same type.				

TTI-4355	QMS	This enhancement improves the Auto naming rule builder by replacing technical ID fields with user-friendly display values. Users can now generate names that include readable values such as Owner or Team instead of raw database keys, making record titles clearer and easier to search.
		Key Features
		• Hide Technical ID Fields: Internal key fields (e.g., Owner ID, Team ID) are suppressed in the rule builder, except for record IDs.
		• Expose Display-Value Tokens: New user-friendly tokens are available, including Owner, Team, Record Type, Status, and Workflow Stage.
		• Runtime Rendering: Tokens output the current display value (e.g., "Jane Doe", "Product Team") instead of GUIDs.
		• Backward Compatibility:
		  ○ Existing rules with ID tokens automatically migrate to display-value tokens.
		  ○ New records adopt display values in generated names.
		  ○ Historical names remain unchanged.
			Yes	No	Minor	**Affected Users:** Manager Level Users.
						
						Impact: This enhancement impacts record auto naming by ensuring generated names use readable display values instead of raw IDs, improving usability and searchability.

TTI-4383	QMS	This enhancement introduces a new Records Queries sub-module for QMS records and renames the existing Queries module to Document Queries. The update provides a consolidated workspace for record-level queries, improving visibility and triage for QA staff and investigators. Existing *Queries* renamed to Document Queries, retaining current functionality. New Records Queries sub-module created for QMS record queries (Quality Events, CAPAs, Action Items). Both sub-modules are accessible under the parent Queries menu for easy navigation.	Yes	No	Minor	**Affected Users:** Manager Level Users. **Impact:** This enhancement impacts query management by centralizing record-level queries into a dedicated workspace, improving visibility, consistency, and efficiency.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4384	QMS	This improvement ensures that once an Incident is closed, it becomes fully read-only and cannot be edited by any user, including admins and record owners. It prevents post-closure modifications	Yes	No	Major	**Affected Users**: Managers and Above. **Impact:** This improvement has an impact on the closed incidents.
TTI-4387	QMS	This enhancement introduces a preview panel for evidence items, allowing users to review supporting content directly without needing to download or navigate away. **Key Features** • **Attachments:** Displays a document preview for supported formats such as PDF and images. • **External Links:** Shows a link card with title, URL, and favicon for quick reference. • **System Documents:** Provides a preview of whether the user has access permissions. • Restricted Access: ○ If a user does not have permission, the evidence entry is still visible. ○ Content is blocked, and a notification explains that access is restricted.	Yes	No	Minor	**Affected Users:** Manager Level Users. **Impact**: This enhancement impacts evidence review by reducing navigation, enabling quick inline previews, and clearly enforcing access restrictions.
TTI-4388	QMS	This enhancement introduces dynamic trigger display behavior during stage transitions, adjusting the UI based on the number of active triggers. This ensures a cleaner, more focused experience and prevents overcrowded modal layouts. **Key Features** • **Single Trigger Enabled:** Displays a single modal with the relevant trigger content only. • **Multiple Triggers Enabled**: Opens a wizard-style modal where each trigger is presented as a separate step. ○ Step titles match trigger names. ○ Navigation supported with Next and Back buttons.	Yes	No	Minor	**Affected Users:** Manager Level Users. **Impact:** This enhancement impacts stage transition workflows by simplifying trigger display, reducing UI clutter, and improving usability through dynamic single- or multi-trigger handling.

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

		• **Usability:**
		  ○ Consistent styling and input validation across both single and multi-trigger flows.
		  ○ Trigger order preserved based on workflow configuration.				

TTI-4390	QMS	This enhancement updates the **QMS Grid behavior** so that the Metadata Panel is no longer opened by default when navigating to CAPA, Quality Event, or Action Item grids. Previously, the panel opened automatically with a "No Records" message even when no record was selected, creating confusion and leaving unnecessary empty space when closed. With this change, the grid now loads in full width by default, providing a cleaner and more accurate view of records. **Key Features** • Metadata Panel remains closed by default on initial navigation. • Grid displays full width without empty space when no record is selected. • Improves usability and visual consistency across QMS modules.	Yes	No	Minor	**Affected Users:** Manager Level Users. **Impact:** This enhancement impacts the **QMS Grid view** by improving layout behavior and usability, ensuring the grid loads correctly without an empty metadata panel when no record is selected.
TTI-4391	QMS	This enhancement adds Close Date and Close Comment fields to CAPA, Quality Events, and Action Items. These fields will be automatically populated when a record is closed and will be visible in both the metadata panel and the grid.	Yes	No	Major	**Affected Users:** Manager Level Users. **Impact:** This enhancement improves record tracking and visibility by ensuring closure details are consistently captured and displayed.
TTI-4392	QMS	This enhancement updates the edit behavior so that when a user clicks Edit from any tab other than Metadata, the system automatically redirects them to the Metadata tab. This ensures a	Yes	No	Minor	**Affected Users:** Manager Level Users.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		consistent editing experience and prevents confusion when making changes.				**Impact:** This enhancement improves usability by streamlining the editing process and directing users to the correct location for metadata updates.
TTI-4395	QMS	This enhancement extends Room Clone so the destination room inherits form configurations and third-party organization folder structures, reducing manual setup effort and ensuring consistency across rooms. **Key Features** **Form Settings & Field Sizes** Clone for all enabled forms, including: • Layout: sections, groups, field order, column layout/widths, placement. • Visibility & Requiredness: field flags and availability in filters, search, and coding panel. • Advanced Validation: rules, constraints, dependencies. • Descriptions/Help: tooltip vs inline display and formatting. • Related Forms (static): main ↔ sub-topic links, display names, and layout overrides. **Third-Party Organization Folders** • Clone the full folder hierarchy under vendor/third-party area. • Preserve folder names, root folder naming patterns, and sort order. • Inherit hierarchy and permissions, but exclude folder content.	Yes	No	Major	**Affected Users:** Manager Level Users. **Impact:** This enhancement impacts room setup by extending cloning to include form configurations and third-party folder structures, reducing manual setup effort and ensuring consistent layouts and hierarchies across rooms.
TTI-4400	eTMF	This enhancement automates the creation and management of customer-specific prompt libraries during Automate enablement. Each customer now receives a unique library ID, and the system prompts users to select a library template during setup. The library is then automatically created and associated with the	Yes	No	Minor	**Affected User:** Superadmin. **Impact:** This enhancement has an impact on Automate enablement and customer library setup processes.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		customer's environment, reducing manual effort and ensuring consistent configuration.				
TTI-4415	eTMF	This enhancement enables organizations to implement risk-based quality control by leveraging document **Risk Scores and Risk Levels within workflow settings**. Users can now define conditional workflow rules that route documents through different workflow paths depending on their assessed risk. High-risk documents can be configured to undergo additional review steps or validations, while low-risk documents can follow simplified or expedited workflows, helping teams focus resources where they matter most. **Key Capability:** • Risk Score & Risk Level Fields in Workflow Settings: These fields are now available for use when defining workflow conditions, allowing administrators to set thresholds and configure conditional routing, skipping, or modification of workflow steps based on risk assessments.	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This feature has an impact on workflow configuration, quality control routing, and risk-based document processing**.**
TTI-4418	Platform	The platform has standardized password requirements to enhance security and align with industry best practices. Passwords must now be a minimum of 12 characters and support all special characters, providing users with greater flexibility in creating secure passwords. support all special characters • Password length went from 8 to 12 • Password expiration set to 60 days • Password reset went from 60 minutes to 120 minutes • Password locking went from 5 attempts to 3	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This feature has an impact on user authentication and security settings.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4453	QMS	This enhancement adds flexibility to how due dates are assigned in QMS records. Administrators can now choose to either auto-calculate due dates based on a defined period or allow users to enter due dates manually. The setting is available at the Record Classification level and can be inherited or overridden at the Record Type level. When Auto-Calculate is enabled, the due date is set automatically when the record enters workflow and remains read-only. When disabled, the due date is manually entered during record creation and becomes read-only after submission. Any post-submission changes continue to use the existing Change Due Date action to maintain audit integrity.	Yes	No	Major	**Affected Users:** Editor and Above **Impact:** This enhancement has an impact on due date configuration and record workflow behavior by allowing either auto-calculated or manually entered due dates, depending on administrative setup.
TTI-4454	QMS	This enhancement introduces a new **Queries Dashlet** on the QMS Dashboard to provide users with centralized visibility into all queries across QMS records. The dashlet includes two tabs **Assigned to Me** and **My Submissions** allowing users to quickly identify queries they are responsible for responding to, as well as queries they have raised. Inline filters and sortable columns support quick search and prioritization, while direct links allow users to open the associated query or record for immediate action. An export option is available for reporting and follow-up tracking.	Yes	No	Major	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts query review and follow-up processes by providing a centralized view and faster navigation for outstanding queries.
TTI-4455	QMS	This enhancement updates the workflow trigger that displays Additional Participants on a stage. The trigger has been renamed from **“Pending Participants”** to **“Show Additional Participants”** to reflect broader visibility. When executed, the trigger now opens a view showing **all** additional participants assigned to the stage not only those pending along with their current status and latest comments. The participant list is read-only and sorted to show Pending users first, followed by Completed users, with alphabetical ordering within statuses. If no additional participants exist on the stage, the trigger does not appear	Yes	No	Major	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts workflow review and visibility by allowing users to see the full list of participants involved in a stage, not just those pending completion.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4456	QMS	This enhancement introduces a new workflow trigger, **Show Upcoming Stages & Assignments**, allowing authorized users to preview upcoming workflow stages and pre-assign the Owner, stage assignees, and Additional Participants before the stage begins. When the trigger executes, a modal displays upcoming stages in sequence, showing current default assignments with the ability to edit or reset to system defaults. Pre-assigned values are stored and carried forward when the workflow progresses. No notifications are sent at the time of pre-assignment; standard notifications continue to trigger only when the stage actually starts. Visibility and editing are controlled by existing **Manage Record Assignments** permissions.	Yes	No	Trivial	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts workflow configuration and stage preparation by allowing users to define assignments earlier and reduce delays when stages open.
TTI-4457	QMS	This enhancement introduces automatic focus on the user's assigned workflow section when opening a record. If the viewer is assigned to the current workflow stage (as an Assignee or Additional Participant) and the stage is active, the system will automatically expand and highlight the relevant section while collapsing others. The section scrolls into view and displays a temporary visual highlight to draw attention. Once the user interacts with the panel (expanding/collapsing sections), the interface respects the user's manual state until the page is reloaded. Users who are not assigned to the active stage see the record in its default state.	Yes	No	Major	**Affected Users:** Editor and Above **Impact:** This enhancement impacts workflow execution and user navigation by reducing the time needed to locate active stage responsibilities.
TTI-4458	QMS	This enhancement replaces the **Initiate** button on record pages with a new **Add Related** action that provides a clearer and more direct way to create related records. When selected, a popover menu presents quick-create options for **CAPA**, **Action Item**, and **Effectiveness Check** (listed as its own option even though it is an Action Item subtype). Choosing an option opens the standard Create modal with the appropriate classification pre-selected, and upon saving, the newly created record is automatically linked as a Related record. The Related panel updates immediately, and an audit entry is logged documenting the creation.	Yes	No	Major	**Affected Users:** Editor and Above. **Impact:** This enhancement impacts related record creation workflows by making record linkage easier, faster, and more explicit.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4465	eTMF	This improvement standardizes Dark Mode colors across the TI platform to ensure consistent backgrounds, panels, and interface elements when the dark theme is enabled.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This enhancement impacts the visual interface by improving Dark Mode color consistency.
TTI-4466	eTMF	This improvement updates the SSU contact workflow by keeping key contact fields read-only during redaction, while allowing the Email field to remain editable. If the email is updated to match an existing contact without an IAM ID, all fields become editable for redaction. Required disabled fields no longer block Add, Create, or Save actions.	No	Yes	Major	**Affected Users:** Editor and Above. **Impact:** This improvement impacts contact redaction behavior and field availability in the SSU workflow.
TTI-4469	Platform	This improvement enhances OCR processing by enabling automatic routing of documents to the appropriate ABBYY OCR server based on the selected target language. When a room is configured for automated or manual OCR and the target or default language is Chinese, Japanese, or Korean, the OCR job is now submitted to the CJK OCR server. All other languages continue to use the standard OCR server. New configuration options have been added to support CJK server settings, ensuring more accurate OCR results and eliminating the need for manual configuration changes by Solution Engineers.	No	No	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts OCR processing by enabling automatic language-based server selection.
TTI-4474	eTMF	This improvement updates the visibility rules for the Site Health (CRA) Dashlet. The dashlet can now be viewed by users with eTMF or SSU access who are assigned to a site as a CRA, have the CRA action enabled, are readers or editors of the site profile, or are Admin users. This provides clearer and more flexible access to site health information.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts dashlet visibility and site-level access control.
TTI-4475	eTMF	This improvement delivers several UI updates across multiple dashlets. The Billing Dashboard now includes the Billing Start Date field, and the “Submitted Documents” metric has been	No	Yes	Minor	**Affected Users:** All Users.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		removed to streamline reporting. The eTMF Health Dashlet has been updated with a new green color scheme for clearer status visibility. Additionally, a “General” option has been added to the filters in the Open Queries by Age Dashlet to support broader filtering.				**Impact:** This improvement impacts dashboard usability and filtering across multiple dashlets.
TTI-4476	eTMF	This improvement enhances the Quick View panel by adding a Workflow tab**.** When a document is in workflow, the new “Workflow” tab is displayed alongside metadata and coding information, giving users quick access to workflow details directly from the Quick View panel.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts document review by adding workflow visibility to the Quick View panel.
TTI-4477	eTMF	This improvement adds user feedback when attempting to drag and drop documents that cannot be moved in the Working Documents view. When a missing or collected document is dragged to another folder, the interface now displays a clear visual indicator, such as a crossed-out cursor, to show that the action is not allowed, ensuring users understand that the document cannot be relocated.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts document handling by providing clear feedback when drag-and-drop actions are not permitted.
TTI-4480	Study Start Up	This improvement updates the history record for documents moved from SSU to eTMF. The history entry now displays the title “Moved from SSU to eTMF,” and the description clearly indicates whether the document was moved automatically as part of a site, country, IRB/EC, or amendment activation process, or moved manually by a user.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement impacts document history tracking and movement transparency between SSU and eTMF.
TTI-4481	eTMF	This improvement replaces the simple contact-to-user conversion form with the standard New User invitation modal. Contact details are prefilled, roles are restricted as before, and email validation populates existing user information when applicable. IAM fields remain read-only when IAM integration is enabled.	No	Yes	Minor	**Affected Users:** Admin and Above. **Impact:** This improvement impacts user creation by aligning contact-to-user

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
						conversion with the standard invitation process.
TTI-4482	QMS	This improvement introduces a rollup Quality Event report, with optional CAPA items, that can be generated into an MS Word document using Jasper. QA users can now export a Quality Event (and related CAPA record, when selected) into a structured report that includes key metadata fields, action details, due/completed dates, owners, evidence document titles, and rich text sections such as root cause, corrective and preventive actions, and final approvals. The report uses a standard header (TI-branded), presents core fields in a summary table followed by sectioned narrative content, and is designed for readability and external sharing with stakeholders who do not have system access, while allowing further editing and formatting in Word.	Yes	No	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts Quality Event and CAPA reporting by enabling rollup MS Word reports suitable for review, collaboration, and external distribution.
TTI-4484	eTMF	This improvement enhances notifying users when mass coding is finished. When the user uses mass coding for documents, the progress indication is displayed, also there is a notification when the update is finished and When the user uses mass coding for sites the window just closes without any notification. The changes are applied for mass coding in: SSU -> Sites SSU -> Contacts SSU -> Sites -> Contacts eTMF -> Documents eTMF -> Sites eTMF -> Contacts eTMF -> Sites -> Contacts	No	No	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts site mass coding by providing clear completion feedback to users.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4485	eTMF	This improvement adds the ability to include FAQ metadata when exporting FAQ records. Additional fields configured in the FAQ Form Settings can now be selected and included during export, ensuring all relevant FAQ data is captured and shared as needed.	No	Yes	Minor	**Affected Users:** Admin and Above. **Impact**: This improvement impacts FAQ exports by allowing inclusion of additional metadata fields.
TTI-4487	Collaborate	This improvement updates the TI Viewer to prevent page manipulation on published documents. The “Start Page Manipulation” button is no longer displayed for published files, ensuring that users cannot reorder pages once the document has reached its published state.	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This improvement impacts document viewing by removing page-manipulation options for published documents.
TTI-4489	Collaborate	This improvement restores the “Enable Mass Import for Editors” room setting for CWS rooms. Since the Import button is now available again for Editors, this setting has been re-added under Settings → Document → Documents Module, allowing administrators to control whether Editors can perform mass imports in CWS environments.	Yes	No	Major	**Affected Users:** Admin and Above. **Impact:** This improvement impacts CWS room configuration by restoring control over mass import permissions for Editors.
TTI-4490	eTMF	This improvement updates the Audit Trail for Users by presenting Recent Search activity in a more user-friendly format. Search details are now displayed clearly to help users better understand and interpret recorded search actions.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This improvement impacts Audit Trail readability for Recent Search activity.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
Report-205	eTMF	This enhancement updates the **Placeholder Report** to improve visibility and oversight by consolidating data and adding key columns. The report now includes: • **Placeholder Aging Count** – Displays the number of days between the creation date and the current date, allowing users to identify placeholders older than a set threshold (e.g., 60 days). • **Fulfilled Status** – Indicates whether a placeholder has been fulfilled. • **N/A Status** – Indicates whether a placeholder has been marked as not applicable. The report has also been enhanced to include both manually created and system-generated placeholders, providing a single, comprehensive view for tracking and analysis.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This enhancement improves placeholder tracking and reporting**,** enabling more effective oversight, aging analysis, and status monitoring through one consolidated report.
Report-220	SSU	This Improvement has added two fields, “Sponsor Approver (Name) and Sponsor Approval Date at the end of the SSU Document History Report.	No	Yes		**Affected Users:** All Users. **Impact:** This improvement impacts the SSU Document History Report.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
QMS-674	QMS	Users noted that the Due Date filter in Room > Quality > Filters does not display the Room Time zone, causing potential confusion.	Minor	This bug had a minor impact on Due Date visibility as the Room Time Zone was not displayed. The resolution ensures that the Due Date now reflects the correct Room Time Zone.
QMS-675	QMS	Users noted that in the Room Search > Quality Records, the Due Date field in Advanced Search does not display the Room Timezone.	Minor	This bug had a minor impact on Due Date visibility in Room Search as the Room Time Zone was not displayed in Advanced Search. The resolution ensures that the Due Date now reflects the correct Room Time Zone.
TRL-12195	Platform	Users noted an issue with a specific room in the MTI US instance, where Regulatory Packet emails sent from the room to the Main Contact are not using the correct email domain configured at the room level. Instead, the system is incorrectly pulling the email domain from the cross-study level, leading to misaligned sender information.	Minor	This bug had a minor impact on Regulatory Packet emails as the incorrect email domain was used. The resolution ensures that the room-level domain is now applied correctly.
TRL-13555	Platform	User noted an issue MTI US instance reporting an issue during document coding. When the user selects Category: Site and then Investigative Site, the Site field becomes grayed out, and the site details disappear upon choosing the document type. However, once the document is approved, the Investigative Site details reappear. Additionally, the user encounters a "Network Error"	Minor	This issue has a minor impact on the visibility of Site details. Correct system behavior has been restored.
TRL-14887	SSU	In the SSU module, advanced validation fails to function when the IRB/EC Submit Date or Approval Date fields are used as part of the validation criteria.	Minor	This issue has a minor impact on advanced validation functionality. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16300	Platform	Users reported that font changes made while editing a document offline are not retained upon check-in. When a user checks out a document, updates the font style offline, and checks it back in as a minor version, the changes are not saved—the font reverts to its previous state.	Minor	This bug has a minor impact on formatting consistency, as offline font changes are not preserved during check-in. Correct system behavior has been restored.
TRL-17187	Platforms	In the MTI US instance, there is an issue where the text color 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 has been restored.
TRL-17202	eTMF	User noted that document dates appear inconsistently across the Original Viewer, TI Viewer, and downloaded files, with each showing a different date for the same document. This affects a large number of documents.	Major	This bug had a major impact on document date accuracy. The resolution ensures that document dates are displayed consistently across the Original Viewer, TI Viewer, and downloaded files.
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 has a minor impact on the eTMF completeness view. Correct system behavior has been restored.
TRL-17649	eTMF	An issue was observed where certain characters in the exported Excel files were not properly encoded.	Major	This bug had a major impact on the character encoding in the exported files. The resolution ensures that all views exported into Excel files are encoded properly.
TRL-17709	eTMF	Several sites with ‘non-participating’ status were incorrectly displaying ‘No’ in the ‘Non-Participating Site’ column within the grid.	Minor	This bug had a minor impact on the non-participating sites. The resolution ensures that sites with ‘Non-Participating’ display as ‘Yes’ in the ‘Non-Participating Site’ column.
TRL-17922	Collaborate	An issue was identified in the application’s user interface where dark mode was not applied consistently, with some sections still showing white backgrounds despite dark mode being enabled.	Minor	This bug has a minor impact on the application’s UI. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18108	eTMF	When a placeholder within an event is marked as Not Applicable, there is a brief window before the page refreshes where the user can select the placeholder and upload a document. This results in an event document being successfully added to a placeholder that is designated as Not Applicable. Once saved, the document inherits the Not Applicable status, and there is no available action in the UI to remove or update this status.	Minor	This bug had a minor impact on adding documents to a placeholder. The resolution restricts users from adding a document to a non-applicable placeholder.
TRL-18201	eTMF	User noted that assigning one user to multiple queries in MTI US is automatically cancelled without any error message. The issue occurs only in specific MTI US rooms	Minor	This bug had a minor impact on query assignment actions. The resolution ensures that users can be assigned to multiple queries without cancellation and that the system behaves consistently across instances.
TRL-18208	eTMF	User noted that a database error occurs when applying an advanced filter in the *View by Workflow → Status* view.	Major	This bug had a major impact on the advanced filtering functionality. The resolution ensures that users can apply date-based and workflow-stage filters in the Status view without encountering database errors.
TRL-18281	eTMF	Users facing an issue in MTI US where clicking “Copy Field” does not immediately make the metadata fields selectable. They only become selectable if we manually click on a field or switch to another document and come back. Similarly, clicking “Cancel Copy Field” does not immediately remove the copy icons from the metadata fields. The icons only disappear after refreshing the view or manually interacting with the fields.	Minor	This bug has a minor impact on the Copy Field and Cancel Copy Field functionality. Correct system behavior has been restored.
TRL-18285	Platform	The user noted that when a CAPA is claimed in the QMS workflow, the process owner receives an excessive number of notifications, exceeding 100, for a single action. This occurs after adding a team to the QMS room and creating and claiming a CAPA, with notifications continuing for approximately 20 minutes.	Major	This bug had a major impact on workflow notifications. The resolution ensures that users receive only the appropriate single notification when a CAPA is claimed, preventing repeated or duplicate alerts.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18297	Platform	User noted that system users are visible in Open Search but correctly hidden in the User module. Open Search is not applying the system-user filtering logic, causing inconsistent visibility across rooms.	Minor	This bug had a minor impact on user visibility consistency. The resolution ensures that Open Search follows the same filtering rules as the User module so system users are not displayed.
TRL-18348	eTMF	The 'Select Metadata' option in the communication inbox export was incorrectly displayed and grayed out.	Major	This bug had a major impact on exporting communication inbox records. The resolution ensures that the 'Select Metadata' field does not appear while exporting the records.
TRL-18367	Collaborate	Editor users could not see the 'Copy' option by default, even if they had access to the document while accessing the document cart.	Critical	This bug had a critical impact on accessing the document cart option. The resolution ensures that the 'Copy' option within the document cart is available for editors.
TRL-18467	eTMF	User noted that translation requests can be submitted without providing the Project Start Date and Country fields, even though both fields are marked as mandatory.	Major	This bug had a major impact on mandatory field validation for translation requests. The resolution ensures that users cannot submit a translation request unless all required fields, including Project Start Date and Country, are completed.
TRL-18472	eTMF	User noted that sorting the Contact column triggers a warning pop-up displaying a "Database error" message.	Critical	This bug had a critical impact on column sorting functionality. The resolution ensures that sorting the Contact column works correctly without triggering database errors.
TRL-18477	eTMF	User noted that several queries are not loading in the WCT instance. The affected queries do not open, and no related error logs or failed HTTP responses appear in the HAR file.	Major	This bug had a major impact on query accessibility. The resolution ensures that all queries load correctly in the WCT instance and that users can open each query without errors.
TRL-18508	Platform	Users noted that when inviting an existing Origami user through IAM, the updated details (address, role, and organization) are not saved. After adding the user to the room, the information does not update in User Management.	Major	This bug had a major impact on IAM user detail updates. The resolution ensures that updated user information is correctly saved and reflected in User Management when adding existing users to a room.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18520	Platform	A user reported that while reviewing the room, several shared documents display "System Account Account" in the Shared By field, instead of the actual username who shared the document.	Minor	This issue has a major impact on the Shared By field. Correct system behavior has been restored.
TRL-18542	eTMF	When a serial e-signature request was sent using TI-Sign as the selected e-signature method, only the first signer received a notification. Subsequent signers did not receive notification emails after the previous signer completed their signature.	Minor	This bug had a minor impact on the TI e-Signature. The resolution ensures that notifications are triggered to subsequent users when the first user has signed the document.
TRL-18572	Platform	User noted that attempting to check out a specific document results in **a** “Server error” (500) message. Investigation showed that the file the system is trying to access does not exist in the S3 bucket, while related review documents do exist. This discrepancy causes the checkout process to fail for this document only.	Critical	This bug had a critical impact on document checkout functionality. The resolution ensures that the system correctly references existing files in S3 and that users can check out documents without encountering server errors.
TRL-18663	eTMF	A warning message stating ‘Client contact type does not exist’ was displayed while creating a contact as part of updating document metadata, even though the contact type existed in the sites section.	Major	This bug had a major impact on creating contacts. The resolution recognizes the existing contact type and allows contact creation during the metadata updates.
TRL-18674	eTMF	Documents that were either rejected or approved and released during the approval workflow did not appear in the ‘By Status’ view.	Minor	This bug had a minor impact on viewing documents in the ‘By Status’ view. The resolution ensures that the released document appears under the correct folder within the ‘By Status’ view.
TRL-18686	Platform	User noted that after upgrading to the previous version, the SSU Document Cart can be opened and documents can be added, but there is still no option available to close the Document Cart.	Major	This bug had a major impact on SSU cart usability. The resolution ensures that users can close the Document Cart properly after adding or reviewing documents.
TRL-18795	eTMF	The width of the ‘Column’ field in the Grid view could not be expanded. Modifying the width setting to a higher value did not result in any visible change.	Minor	This bug had a minor impact on the ‘Column’ field in grid view. The resolution now allows the Column field to resize correctly when its width is increased.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18833	Platform	User noted that they are unable to check in a document. When attempting to attach a file and complete the check-in process, a warning message appears stating: "The operation finished with issues."	Major	This bug had a major impact on document check-in functionality. The resolution ensures that users can successfully attach files and check in documents without encountering warning messages.
TRL-18886	Collaborate	The 'Use Placeholder fields in the Document' toggle appeared temporarily disabled after clicking Finish when uploading a document. This occurred only while the page was loading.	Major	This bug had a major impact on document uploads. The resolution ensures the toggle stays enabled consistently.
TRL-18907	Platform	User noted that the "Create new document from selected thumbnails" option appears in the Arender viewer and needs to be hidden. As confirmed, this option originates from the viewer itself and is not part of TI functionality.	Minor	This bug had a minor impact on the viewer interface. The resolution ensures that the unwanted Arender option is hidden so users do not see or attempt to use functionality that TI does not support.
TRL-18940	eTMF	When navigating to Filter > Advanced > Manage Filters, selecting an existing filter and attempting to align the columns caused the screen to refresh, preventing any further action.	Major	This bug had a major impact on the Advanced Filters feature. The resolution ensures that users can complete the necessary actions without the system triggering a screen refresh.
TRL-19000	Collaborate	Users reported an issue in MTI US, where the selected index position is displayed as a numerical value instead of the expected text when submitting a document. It occurs only in the specific Room from the previous version.	Major	This issue had a major impact on the index position display during document submission in the specific Room.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-19009	eTMF	Users experienced inconsistent behavior when using the search functionality. • When performing a search using the Search by Folder search bar, the results are initially displayed correctly. However, after navigating through the breadcrumbs and returning to View by Index, the system did not display the full folder index. It continued to show only the folders returned from the previous search. • The search bar appeared empty, with no trace of the previous search term.	Minor	This bug had a minor impact on the search functionality within the ‘View By Index’ view. The resolution restores the correct system behavior.
TRL-19018	Platform	User noted that the Title field entered during user invitation does not save. After adding the user and refreshing the page, the Title disappears. The issue is reproducible in other rooms.	Major	This bug had a major impact on user profile data accuracy. The resolution ensures that the Title field is properly saved and retained when inviting users.
TRL-19025	SSU	When users attempted to enable the Contact is responsible for providing documents option for certain contacts within an SSU site, a warning message: ‘Contact conflicts detected’ was displayed, and the changes were not saved.	Major	This bug had a major impact on configuring contacts within an SSU site. The resolution ensures that the toggle can now be enabled without showing the warning message, and the changes are saved.
TRL-19051	Platform	User noted that creating a new room triggers the error “Topic with such a name already exists” even though the topic name does not exist in the instance. The issue is reproducible with different room names during testing.	Critical	This bug had a critical impact on room creation. The resolution ensures that rooms can be created successfully and that the system correctly validates existing topic names.
TRL-19075	Collaborate	When users updated a pre-existing effective document, the Effective Date field did not auto-populate after the document was checked back in and the associated workflow was completed.	Minor	This bug had a minor impact on the documents' effective date. The resolution ensures that the ‘Effective Date’ field is populated when the existing effective document is updated.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-19119	SSU	When attempting to edit the Additional Information in a Site, the details were not editable.	Minor	This bug had a minor impact on updating a site's additional information. The resolution ensures that the additional site information can now be modified.
TRL-19150	Platform	User noted that a pending-invited user is receiving notifications from a specific Room despite not having room access. The user has not received confirmation on why notifications are being triggered for someone who does not yet have access to the room.	Major	This bug had a major impact on notification accuracy. The resolution ensures that users without room access, including those in pending invitation status, do not receive notifications from the room.
TRL-19160	Collaborate	An issue was identified where changes made during online editing were not saved when the document was checked out.	Major	This bug had a major impact on editing documents in online mode. The resolution ensures that all changes made during online editing are now saved correctly.
TRL-19218	Major	User noted that when replacing an attachment in an SSU-enabled room, the page freezes after selecting the new file. The loading icon spins indefinitely, and the attachment cannot be replaced until the page is refreshed.	Major	This bug had a major impact on attachment replacement functionality. The resolution ensures that users can successfully replace attachments without the page freezing.
TRL-19221	Collaborate	Subjects and Due Dates were missing in the generated Site Visit Report, thereby requiring a manual entry.	Critical	This bug had a critical impact on the CTMS Site Visit Reports. The resolution ensures that Subjects and due dates are auto-populated in Visit Reports based on the entries made in CTMS.
TRL-19225	Collaborate	Users experienced an issue when viewing video files in the TI Viewer. • After uploading and playing a video, the playback would automatically pause after some time. • When attempting to resume, the video restarted from the beginning instead of continuing from the paused position. • Additionally, when users skipped forward in the video, it would initially play but then pause and restart from the beginning.	Critical	This bug had a critical impact on viewing videos in TI Viewer. The resolution ensures that users can view videos in TI Viewer without any issues.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-19247	eTMF	Users were receiving blank audit issue emails without any of the expected audit issue details, such as Room Name, Audit Profile Name, Document Name, Category, Investigative Site, Index Position, and Issue Description.	Major	This bug had a major impact on the audit issue email notifications. The resolution ensures that the Audit issue email notifications include all relevant details.
TRL-19284	Platform	User noted that site name changes made in CTMS are not syncing to the linked eTMF rooms. Although the CCR reflects the updated site names correctly, the corresponding eTMF rooms continue to display the old names. The issue is reproducible across the linked rooms.	Major	This bug had a major impact on site data synchronization. The resolution ensures that site name updates made in CTMS automatically sync to both CCR and all linked eTMF rooms.
TRL-19338	Collaborate	User noted that their grid view continuously resets to a narrow layout each time the page is refreshed. The issue appears to be user-specific and is not reproducible for others.	Major	This bug had a major impact on grid view usability. The resolution ensures that a user's preferred grid column width is retained and does not reset on page refresh.
TRL-19391	Platform	User noted that newsletter update notifications are still being sent even though all notifications are disabled in the affected rooms. The issue occurs for multiple users	Major	This bug had a major impact on notification accuracy. The resolution ensures that newsletter update notifications are not sent when notification settings are disabled.
TRL-19432	Collaborate	When using the 'Add Document Cart' option to move a document within the same room, the metadata from the original folder is no longer carried over to the copied document.	Major	This bug had a major impact on moving documents within the room through the document cart. The resolution ensures that the copied document automatically inherits all metadata from the original folder.
TRL-19591	Platform	Users reported an issue in the Event Manager where the document type count displayed within the event type section becomes incorrect when scrolling down after selecting an event type. The count temporarily shows inaccurate values, creating a display glitch.	Major	This issue has a major impact on the document type count display within the event type section.

10. 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 in accordance with 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)

Customer Focus Group

Your CSM can submit Ideas to our Perfective Change Management on your behalf	Meet with other Trial Interactive customers for an immersive Focus Group Forum: • Focus Group Q&A • Early Access • Hosted Beta • Usability Studies

11. Approvals

Product Owner

Name: Jay Smith	Title: Vice President, Product Management
Signature: Reason for signature: Date:	

Quality Assurance

Name: Conor McCabe	Title: Senior QA Specialist
Signature: Reason for signature: Date:	