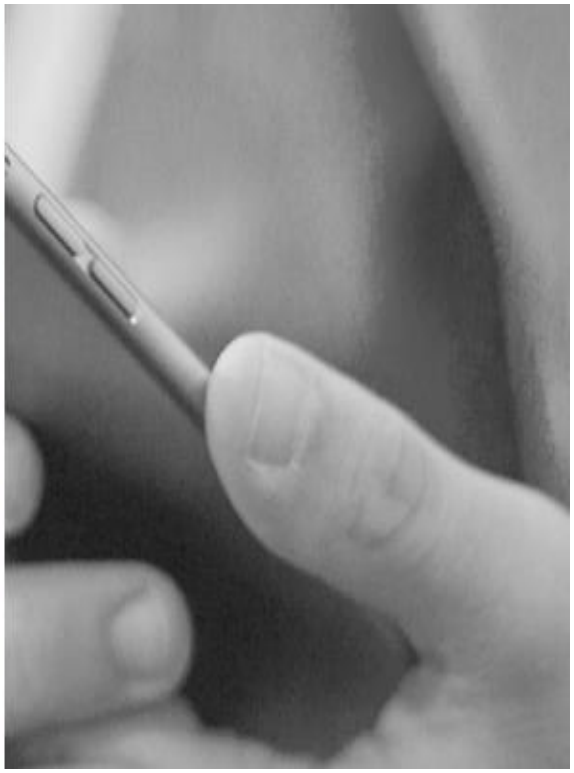
TRIAL INTERACTIVE

TRIAL INTERACTIVE V10.8 - PRE-RELEASE NOTES V0.1



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1. Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	22-Sep-2025	Pre-Release Notes

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. MASS CODING FOR SSU INBOX DOCUMENTS

ETMF-865 This enhancement introduces the ability to mass code documents received via email and stored in the SSU Inbox, bringing the Inbox fully in line with existing bulk upload capabilities. Previously, Study Start-up Specialists had to code and assign Inbox documents individually, slowing down high-volume workflows and adding unnecessary manual steps.

With this release, users can **select multiple Inbox documents at once** and perform bulk actions such as assigning them to specific Sites and applying metadata (e.g., Document Type, Version, Date). A familiar multi-select checkbox and bulk action menu mirrors the document upload interface, while existing permissions and validation rules ensure data integrity and compliance.

By extending bulk coding to the Inbox, this feature transforms SSU document handling, eliminating repetitive work, accelerating processing times, and empowering teams to focus on strategic, higher-value activities.

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 EVENTSBASED 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. CTMS VISIT REPORT MANAGEMENT – INTEROPERABILITY AND TRANSITION SUPPORT

TTI-4320 This enhancement introduces updates to support the improved CTMS Visit Report management process while continuing to maintain the existing Collaborate Room-based workflow for a defined

transition period. The new process enables visit reports to be generated directly within CTMS, including a built-in review and eSignature cycle, and published to eTMF, Blinded eTMF, or Collaborate rooms.

To provide customers sufficient time to migrate, the existing Collaborate-based approach will remain available for up to one year, configurable on a study-by-study basis. While most customers are expected to transition all studies at once, exceptions for older studies can be accommodated individually. The platform also supports scenarios where eTMF, Blinded eTMF, or Collaborate rooms may not yet exist, ensuring publishing flexibility during the transition.

New visit reports are generated fully within CTMS and, once approved, can be published through one of four options:

- Publish to eTMF
- Publish to Blinded eTMF (if available)
- Publish to Collaborate for optional post-processing
- Continue using the legacy Collaborate workflow for select studies

By supporting both approaches concurrently, this update allows teams to adopt the new CTMS Visit Report process at their own pace while ensuring continued operational stability across all studies and publishing destinations.

I. 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

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	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
		of all countries at once or individual countries for document 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-865	SSU	This enhancement introduces the ability to mass code documents received via email and stored in the Inbox, bringing Inbox functionality in line with the existing bulk upload capabilities. Previously, users could only apply metadata in bulk when uploading documents directly. Any documents received through email had to be coded and assigned individually, which was time-consuming and inefficient for high-volume study start-up workflows. With this release, users can now select multiple documents in the Inbox and perform bulk actions, including: • Assigning the selected documents to a specific	No	Yes	Minor	**Affected Users:** Editor and Above. **Impact:** This feature has an impact on Inbox document processing workflows**.**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		Site • Applying **metadata in bulk** (e.g., Document Type, Version, Date) • Leveraging a **multi-select checkbox and bulk action menu** similar to the existing document upload interface The feature adheres to existing permissions and validation rules for document handling to ensure data integrity and compliance.				
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-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	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
		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 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.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
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. **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. •	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**.**
TTI-3725	eTMF	With this Improvement, Users can now easily **copy the URL of a related document** directly from the panel by:	No	Yes	Minor	**Affected User:** All Users.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		• Hovering over the **document ID** and clicking to copy the link. • Using the new **"Copy Link"** option in the three-dot menu.				**Impact:** This Improvement has a minor impact on the Related document link.
TTI-3791	Platform	This enhancement increases the maximum supported size for MS Office documents in TI Editor (Only Office), enabling users to open, view, and edit files up to 300 MB.	No	Yes	Minor	**Affected Users:** All Users. **Impact**: This enhancement impacts the handling of MS Office documents by enabling users to work with files up to 300 MB in TI Editor (Only Office).
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 enables teams to prioritize high-impact items, allocate resources efficiently, and	Yes	Yes	Minor	**Affected Users:** Editor and Above **Impact**: This feature has an impact on risk-based monitoring, prioritization, and audit readiness in eTMF**.**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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 scores 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.)				
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 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	No	Yes	Major	**Affected Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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-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** • **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	No	No	Minor	**Affected Users:** All Users. **Impact:** This enhancement impacts the document indexing process by ensuring extracted metadata is always visible and usable, even if document classification fails.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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.				
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. • **Portal Integration (Future):** IAM portal will support direct self-service updates for end users while preserving role-based restrictions.	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
		• **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.	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

		Key Capabilities
		• **Configurable Close Conditions:**
		  ○ **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	No	Yes	Minor	**Affected Users:** Editor and Above.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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.				**Impact**: This enhancement impacts export configuration by ensuring Readers and Editors no longer see the Export option when it is disabled in settings.
TTI-4263	QMS	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.	No	Yes	Major	**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.
TTI-4271	SSU	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	No	Yes	Minor	**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.

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

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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. 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.	Yes	Yes	Minor	**Affected Users:** Admin and Above. **Impact:** This enhancement impacts archive and export operations by providing secure, encrypted, and trackable delivery through the cloud instead of sFTP.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4320	Collaborate	This enhancement introduces changes to accommodate the new CTMS Visit Report management process**,** while ensuring continued interoperability between CTMS, eTMF, Blinded eTMF, and Collaborate rooms during a defined transition period. The new process leverages an improved report generation directly within CTMS**,** including review and eSignature cycles, and supports publishing the final approved visit report to multiple TI room types. To allow customers sufficient time to migrate, the existing Collaborate-based workflow will remain available for up to one year, allowing study-by-study configuration flexibility. Most customers are expected to transition all studies simultaneously, but exceptions for older studies can be managed individually. **Key Capabilities** • **New Visit Report Generation:** ○ Improved generation within CTMS with integrated review and eSignature cycles. ○ Produces a final approved visit report ready for publishing. • **Flexible Publishing Options (per study):** ○ **eTMF:** Publish final report to the eTMF room. ○ **Blinded eTMF:** Publish to a Blinded eTMF room if available. ○ **Collaborate:** Publish to a Collaborate room for optional post-processing. ○ **Legacy Collaborate Workflow:** Continue using the existing Collaborate workflow for older studies if needed.	Yes	No	Minor	**Affected Users:** Editor and Above. **Impact: This feature has an impact on** visit report generation, publishing workflows, and transition planning for CTMS–TI interoperability.

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

		• **Transition Flexibility:**
		  ○ Existing functionality is maintained at the **study level**, enabling exceptions where needed.
		  ○ The platform accommodates cases where eTMF, Blinded, or Collaborate rooms may not yet exist.
		  ○ Study-level settings determine whether a Collaborate will be used.
		This dual approach ensures a smooth transition to the new CTMS Visit Report process while preserving operational continuity for ongoing studies.				

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.	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.	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

		• **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.
		• **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.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4349	eTMF	This enhancement introduces a **Human-in-the-Loop (HITL) feedback system** that automatically captures human corrections to Automate outputs, such as overwritten or newly added metadata and sends them back along with confidence scores for prompt refinement and accuracy improvement**.** In addition, the system now supports customer-specific prompt libraries**,** created automatically during Automate enablement and identified by unique library IDs. These libraries start from a standard template but evolve independently based on customer-specific feedback patterns, enabling adaptive learning for different document types and use cases. Administrators can manage libraries through a dedicated interface with version control and rollback options. Feedback submissions run in the background without affecting processing performance and scale to hundreds of customers, providing a foundation for continuous, customer-specific optimization of Automate.	No	No	Minor	**Affected User:** Admin and Above. **Impact:** This feature has an impact on Automate accuracy improvement, customer prompt management, and feedback-driven model optimization**.**
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.	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
		• Mapping Persistence: Captured mappings are automatically 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	Yes	No	Minor	**Affected Users:** Manager Level Users. **Impact:** This enhancement impacts query management

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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.				by centralizing record-level queries into a dedicated workspace, improving visibility, consistency, and efficiency.
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.

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

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

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	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.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		when no record is selected. • Improves usability and visual consistency across QMS modules.				
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 consistent editing experience and prevents confusion when making changes.	Yes	No	Minor	**Affected Users:** Manager Level Users. **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	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

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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.				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 customer's environment, reducing manual effort and ensuring consistent configuration.	Yes	No	Minor	**Affected User:** Superadmin. **Impact:** This enhancement has an impact on Automate enablement and customer library setup processes.
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	Yes	No	Minor	**Affected Users:** Admin and Above. **Impact:** This feature has an impact on workflow configuration, quality control routing, and risk-

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		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.				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 14 characters and support all special characters, providing users with greater flexibility in creating secure passwords.	No	Yes	Minor	**Affected Users:** All Users. **Impact:** This feature has an impact on user authentication and security settings**.**
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.

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)

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

Customer Focus Group

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:	