

TRIAL INTERACTIVE V10.7.3

RELEASE NOTES – VERSION

V1.0



Table of Contents

1.	Version History	3
2.	Purpose	4
3.	Scope	5
4.	Definitions / Acronyms	6
5.	Release Overview	7
6.	Release Schedule	8
7.	Hardware and Software Requirements	9
8.	Changes.....	10
9.	Open Defects.....	32
10.	Customer Support	36
11.	Approvals	38

1. Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	08-Aug-2025	Initial Version: Pre-Release Notes issued.
Anuj Thapar	0.2	21-Aug-2025	Release Schedule Updated
Samuel Pawar	0.3	12-Sep-2025	<p><u>Features Added:</u></p> <ul style="list-style-type: none"> New/Enhanced Features: TTI-4167, TTI-4285, TTI-4332, TTI-4339, TTI-4359, TTI-4360, TTI-4361, TTI-4362, TTI-4363, TTI-4364, TTI-4365, TTI-4366, TTI-4367, TTI-4368, TTI-4369, TTI-4371, TTI-4372, TTI-4373, TTI-4374, TTI-4376, TTI-4377, Report-190 Defect Resolutions: QMS-1336, TRL-18272, TRL-18512, TRL-18525, TRL-18536, TRL-18562, TRL-18568, TRL-18599, TRL-18604, TRL-18643, TRL-18662, TRL-18672, TRL-18675, TRL-18680, TRL-18685, TRL-18688, TRL-18697, TRL-18699, TRL-18726, TRL-18752, TRL-18754, TRL-18833, TRL-18841, TRL-18849, TRL-18870, TRL-18878, TRL-18939, TRL-18950, RL-19018 <p><u>Features Removed:</u></p> <ul style="list-style-type: none"> New/Enhanced Features: TTI-3950 <p>Open Defects: Table added.</p>
Samuel Pawar	1.0	12-Sep-2025	Document Finalized

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	10.7.3
Release Type	Patch

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. Release Overview

This patch release includes minor, low-impact improvements and defect resolutions. Please see the table below in the next section for the release schedule.

6. 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	12-Sep-2025
Estimated US MTI Upgrade Date/Time:	12/Sep/2025 9:00 PM
Estimated EU MTI Upgrade Date/Time:	12/Sep/2025 5:00 PM
Estimated China MTI Upgrade Date/Time:	19/Sep/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.

7. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the Trial Interactive v10.7.3 platform.

System Requirements	
Operating System	<ul style="list-style-type: none"> Windows Version 7 or higher All currently supported Mac OSX releases iOS and Android for my mobile app (see myTI release notes)
Browser	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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

8. Changes

Legend for Impacts

Trial Interactive v10.7.3 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
QMS-13	QMS	<p>This feature introduces Configurable Grid Views, allowing users to create, save, and manage custom data grid views with specific filters, sorting, column selections, and "expand all" settings.</p> <p>Each view appears as a tab above the grid, with options to add new views via a "+" button and manage them (rename, delete,</p>	Yes	No	Major	<p>Affected User: Editor and Above.</p> <p>Impact: This feature has a major impact on Grid Configuration in the Quality Management System.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>and favorite) through the "... " menu. Views support individual search, filter, and sort settings, and users can export the current view to CSV or XLSX formats.</p> <p>Additional features include column visibility control, drag-and-drop tab reordering, view reset and management, and responsive design with modals and dropdowns for smaller screens or overflow tabs.</p>				
TTI-4167	QMS	<p>This feature introduces the ability for Process Owners to enter stage-specific instructions when starting a workflow stage. These instructions provide contributors with clear guidance on what is expected of them and are visible in both workflow history and notification emails, improving communication and clarity throughout the workflow process.</p> <p>Instructions can be entered directly in the Ad-Hoc Assignment modal or added later through the Workflow tab. When present, they appear in a dedicated "Instructions" button and can be viewed in a popover or edited by authorized users. Only record owners and administrators can add or edit instructions, while others may only view them. Instructions are also included in stage-start notification emails for assignees.</p>	Yes	No	Minor	<p>Affected User: Editor and Above.</p> <p>Impact: This feature has a minor impact on workflow stage execution, ensuring contributors receive stage-specific guidance and reducing ambiguity in task completion.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4285	QMS	<p>The improvement now offers greater flexibility in configuring workflows, allowing users to decide on Team or Ad-Hoc assignments from the initial stage.</p> <p>This enhancement supports use cases where the assessment stage can be skipped or merged with the first stage, streamlining the process and reducing unnecessary steps in the workflow setup.</p>	Yes	No	Minor	<p>Affected User: Editor and Above.</p> <p>Impact: This improvement has a minor impact on the Team or Ad-Hoc Assignments Workflow.</p>
TTI-4317	QMS	<p>The improvement now includes the capability to use the form designer to add in-line instructions directly within field layouts.</p> <p>This allows administrators to insert labels, descriptions, or guidance text, such as using a label field to highlight relevant points in the form. These instructions are defined as part of the form itself, helping users understand what is expected while filling out specific fields.</p>	Yes	No	Minor	<p>Affected User: Manager-level user.</p> <p>Impact: This improvement has a minor impact on the Form Designer to enter the instructions for the user directly in line fields layouts.</p>
TTI-4332	QMS	<p>The "Restrict Document Creation" (RDC) setting has been updated to align more closely with the Reader experience when the "Show only Final or Effective documents to Readers" provision is enabled.</p> <p>Previously, Editors with RDC applied could still see all document versions, including drafts, access document history, and view</p>	No	Yes	Critical	<p>Affected Users: Editor and Above.</p> <p>Impact: This feature has a critical impact on document access control and ensures RDC user permissions mirror the intended Reader experience.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>non-effective documents. This behavior did not match the expected Reader restrictions.</p> <p>With this enhancement, Editors with RDC now:</p> <ul style="list-style-type: none"> • Cannot create new documents (unchanged) • Cannot see non-effective documents; only effective versions are visible (updated) • Cannot access newer draft versions; only effective versions are accessible (updated) • Cannot participate in Document Reviews (unchanged) • Cannot see the Document History (updated) 				
TTI-4339	eTMF	<p>This enhancement updates the Contact metadata field in TI eTMF so that users can attribute documents to inactive site Contacts, not only those marked as Active. Previously, the Contact dropdown only displayed site staff with an Active status, limiting the ability to associate historic documents with the correct individual.</p> <p>With this update, deactivated contacts are now selectable in the Contacts metadata dropdown. This improvement supports a wide range of real-world use cases, including:</p> <ul style="list-style-type: none"> • Filing historic documents associated with 	No	Yes	Minor	<p>Affected User: All Users.</p> <p>Impact: This feature has a minor impact on document attribution in eTMF, ensuring that historic and reconciled documents can be correctly linked to the appropriate site Contacts, regardless of their active status.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>site staff who are no longer active.</p> <ul style="list-style-type: none"> Associating documents for staff who remain at a site but are no longer working on a specific study. Reconciling documents during trial rescue, migration, or post-QC activities. Linking historic training records from LMS to staff who are no longer active. 				
TTI-4359	QMS	<p>The "Estimated Time" field in Action Items has been updated from a numeric field to a text field. This change allows users to enter descriptive values (e.g., "2 days", "1 week") instead of being limited to numbers.</p>	Yes	No	Major	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a major impact on Action Item configuration, improving flexibility in recording time estimates.</p>
TTI-4360	QMS	<p>The "Cancelled" view has been updated to improve security and clarity. Previously, this view was visible to all roles, and cancelled records could surface in other views.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> The "Cancelled" view is hidden from roles below Room Manager. Cancelled records display exclusively in the "Cancelled" view and are not shown in any other views. Direct access to a cancelled record URL now enforces security (403 Forbidden or redirect for unauthorized users). 	Yes	No	Major	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a major impact on record visibility and enforces stricter access control for cancelled records.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<ul style="list-style-type: none"> Permissions are updated: <ul style="list-style-type: none"> Room Manager / Admin / Super-Admin → Can access the “Cancelled” view; cancelled records appear only there. Editors and Readers → No access to “Cancelled” view; cancelled records remain hidden elsewhere. 				
TTI-4361	QMS	<p>This improvement ensures that actions performed by Additional Participants (such as comments, status updates, or file uploads) are visible in Workflow history. Previously, these activities were logged only in Record History, leaving gaps in Workflow visibility and audit trails.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> Stage History (Workflow tab): Additional Participant actions now log with timestamp, user name, activity type, and comment. Workflow History (Workflow tab): The same entries are mirrored to provide a complete cross-stage chronology. Record History: No change; continues to capture all actions. 	Yes	No	Major	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a major impact on audit visibility and ensures Additional Participant activity is fully traceable within Workflow history.</p>
TTI-4362	QMS	<p>This improvement introduces the ability for authorized users to control record visibility at the time of workflow submission and while a record is in progress. Users can now toggle</p>	Yes	No	Major	<p>Affected Users: Manager Level User.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		whether a record is shared with the entire team or restricted to assigned users only, ensuring more precise control over sensitive content. All changes are fully auditable. Permissions: A “Manage Record Security” action (existing or reused) grants access to this control. By default, Room Managers/Admins can use it, along with any users who have explicit permission and record access.				Impact: This feature has a major impact on access control and enhances record security during workflows.
TTI-4363	QMS	<p>This improvement refines the behavior when a CAPA or Incident is submitted, but no applicable workflows exist.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> CAPA Submission (from metadata panel): The Submit button is disabled if no workflow is found. Hovering displays a tooltip with the message: <i>“No workflow found for this CAPA: Change Record Type. Contact your administrator or the service desk at help@trialinteractive.com”</i> Incident Submission (from metadata panel): The tooltip reads: <i>“No workflow found for this Incident: Change Record Type. Contact your administrator or the service desk at help@trialinteractive.com”</i> CAPA Submission (during creation): Pressing Create & Submit shows an error: <i>“CAPA cannot be submitted. No workflow</i> 	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on submission behavior, improving clarity of error handling and preventing invalid submissions.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p><i>found for this CAPA. Possible Resolutions: Change Record Type, Contact your administrator or the service desk at help@trialinteractive.com”</i></p> <ul style="list-style-type: none"> Incident Submission (during creation): Error reads: <i>“Incident cannot be submitted. No workflow found for this Incident. Possible Resolutions: Change Record Type, Contact your administrator or the service desk at help@trialinteractive.com”</i> 				
TTI-4364	QMS	<p>This improvement ensures that record ownership is preserved when a record is cancelled. Previously, cancelling a record cleared the owner/lead metadata, causing the owner to lose access.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> The record owner/lead metadata is no longer cleared during cancellation. Record owners retain access to cancelled records for history and reference purposes. 	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on cancellation behavior and improves historical accuracy and owner visibility.</p>
TTI-4365	QMS	<p>This improvement enhances usability by allowing users to copy the link of related records directly from the Related Records panel. Previously, record IDs were displayed but could not be quickly copied for reference.</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on usability and</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>With this enhancement:</p> <ul style="list-style-type: none"> A Click to Copy Link tooltip/icon appears when hovering over a related record ID. Clicking copies the full link to the clipboard and shows a brief confirmation (e.g., “Copied”). Functionality applies to all types of related records (CAPA, Action Item, Effectiveness Check, etc.) in both expanded and collapsed views. Aligns behavior with existing ID copy options elsewhere in the system. 				improves efficiency for users referencing related records.
TTI-4366	QMS	<p>This improvement standardizes the default sizing and resizing behavior of columns across all listing grids. Previously, layouts varied between grids, resulting in inconsistent and sometimes inefficient column widths.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> Initial Width: Column size according to content. If the total column width is less than the available space, the system distributes extra space equally across adjustable columns. Minimum Width: Columns cannot be resized or auto-sized below 100 px. Maximum Width: Auto-sizing is capped at 400 px; manual resizing has no limit. If extra space remains, it is redistributed among all adjustable columns. 	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on grid usability by ensuring consistent layouts while preserving flexibility for user customization.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<ul style="list-style-type: none"> Consistency: Fixed-width columns are excluded from resizing adjustments, ensuring stability. 				
TTI-4367	QMS	<p>This improvement ensures that the “Reason” field is captured in the Audit Trail when a user responds No to an Effectiveness Check trigger. Previously, the Reason entered by the approver was not displayed, creating gaps in audit visibility.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> When an approver selects No for an Effectiveness Check trigger and provides a Reason, the Reason is now logged in the Audit Trail. This ensures consistency between user actions and audit records. 	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on audit accuracy and improves the traceability of Effectiveness Check decisions.</p>
TTI-4368	QMS	<p>This improvement enhances the visibility of Additional Participant activity in workflows. Hovering over an Additional Participant card now displays their status, date, and comment.</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on the Workflow tab and improves transparency of participant contributions.</p>
TTI-4369	QMS	<p>This improvement enhances usability in the Quick-View panel by preserving section expansion states and scroll behavior for a more consistent user experience. Previously,</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>collapsed or expanded sections reset when switching modes or tabs, disrupting workflow.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> Section State: Expansion/collapse choices are preserved when switching between Edit and Read-Only, and when navigating away from Metadata and back. Scroll Behavior: Scroll position is preserved only when toggling Edit ↔ Read. On tab changes, scroll resets to the top as expected. Session Scope: State is stored per user/record for the current session. A refresh or new session resets to default (top section expanded, others collapsed, scroll top). Applies across all record types (Quality Event, CAPA, Action Item, etc.) and any QV entry point. 				<p>Impact: This feature has a minor impact on the Quick-View panel and improves efficiency by reducing repetitive navigation.</p>
TTI-4371	QMS	<p>This improvement enhances navigation by allowing related records (e.g., CAPA, Action Item, Effectiveness Check) to open in a new browser tab directly from the Related Records tab in the Quick-View panel. Previously, clicking a related record replaced the current view, forcing users to reopen the parent record.</p> <p>With this enhancement:</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on navigation and significantly improves efficiency for users reviewing parent and child records side by side.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<ul style="list-style-type: none"> Clicking a related-record card opens the full record view in a new tab, keeping the parent QV panel open. Hover state adds subtle elevation and background tint; pressed state applies a darker tint for activation feedback. Keyboard accessibility is supported: pressing Enter on a focused card opens it in a new tab. 				
TTI-4372	QMS	<p>This improvement ensures consistency when adding assignees to queries. Previously, the “Select” button was missing during the Add Assignees step, even though it was available during initial query creation.</p> <p>With this enhancement:</p> <ul style="list-style-type: none"> A ‘Select’ button is now displayed when adding additional assignees to an existing query. The behavior is consistent with the query creation flow, improving usability and reducing confusion. 	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This feature has a minor impact on query management and improves user experience when assigning participants.</p>
TTI-4373	QMS	<p>This improvement improved clarity and reduced unnecessary clutter during record creation. System-managed read-only fields are now excluded from new-record forms.</p> <ul style="list-style-type: none"> System Read-Only Fields: Fields such as Created By, Created On, Resolved By, 	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This improvement has a minor impact on record-creation workflows. It prevents user confusion by showing only relevant fields while ensuring</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>and Closed On will no longer appear during record creation—even if included in form configuration.</p> <ul style="list-style-type: none"> Custom Read-Only Fields: Custom read-only fields defined by admins remain available in create forms, allowing users to view prefilled or default values (still non-editable). Post-Creation Visibility: All read-only fields (system and custom) remain visible in the Metadata panel after the record is created. 				that all read-only values remain accessible post-creation.
TTI-4374	QMS	<p>To improve workflow configuration, a dedicated control for selecting Stage Status values has been added. In Workflow → <i>Add Action</i>, users can now filter conditions using a structured Stage Status dropdown. The control supports multiple predefined statuses (e.g., <i>Approved</i>, <i>Available for Review</i>, <i>Claimed</i>, <i>Clarification</i>, <i>In Progress</i>, <i>Cancelled</i>). Each status is displayed with a clear label and color coding, ensuring consistency with record views.</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This improvement has a minor impact on workflow configuration. It simplifies the setup of workflow conditions by providing a dedicated, standardized selection control for Stage Status.</p>
TTI-4376	QMS	<p>This improvement updated the user selector controls to display user avatars instead of generic icons, ensuring a more intuitive and personalized experience when assigning or viewing users.</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This improvement has a minor impact on the icons with avatars in user selectors.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4377	QMS	<p>This improvement updated the QMS record history to improve clarity when tracking additional participants in workflows. Now, the system records the following distinct activities in the record audit trail:</p> <ul style="list-style-type: none"> <i>Workflow – Add Additional Participants</i> <i>Workflow – Remove Additional Participants</i> <p>The “Add User to Group” activity is now only logged at the user profile level, not within the QMS record history.</p>	Yes	No	Minor	<p>Affected Users: Manager Level User.</p> <p>Impact: This enhancement ensures that record-level audit trails more accurately reflect participant changes in workflows, providing clearer oversight and traceability.</p>
Report-190	QMS	<p>This feature introduces the ability to output CAPA records into standardized formats, enhancing collaboration and documentation flexibility for QA teams. QA professionals can now generate CAPA records into a structured report. The report includes a standard header with the TI logo, a populated table of CAPA fields at the top, followed by section headings that map to rich text fields from the CAPA record. Action Item records can optionally be included, either as part of the main report or as a separate report.</p>	No	Yes	Minor	<p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on a CAPA Report with an optional Action Item as a Rollup Report.</p>
Report-195	eTMF	<p>This feature adds the submission/upload date to the Document Submission By Status report, enabling oversight roles to quickly verify when documents were uploaded by team members within a date range.</p>	No	Yes	Minor	<p>Affected User: All Users.</p> <p>Impact: This improvement has a minor impact on the Submission/Upload date to the Document Submission.</p>

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
QMS-1336	QMS	When users attempt to download the Sample Import Template from the Record Types Management section for each Record Type, the link is incorrectly redirecting to an old version of the User Guide page.	Major	This bug had a major impact on the Record Types Management section when downloading the Sample Import Template. Correct system behavior has been restored.
TRL-16377	Platform	When users searched for a document created in a room with a particular time zone, the document profile section within the quick view panel of the document displayed the submission date with a different time zone.	Minor	This bug had a minor impact on the display of time zones for the submission date of a document. Correct system behavior has been restored.
TRL-18272	Platform	User noticed an issue where a user with the "Administrator" role was added as a Site Contact with the contact type "Principal Investigator" in the specific room. This violates system configuration rules, which restrict assigning site contact roles to users above the "Editor" role. Additionally, inconsistent role visibility was observed: in the User Management grid view, the role displays as "Administrator", but in the user profile view, the role disappears, and "Administrator" is not available in the drop-down list.	Minor	This defect had a minor impact on system integrity, allowing a restricted role to be assigned as a Site Contact and causing inconsistent role visibility in User Management. Correct system behavior has been restored.
TRL-18294	Platform	Users have noticed an issue where general queries can be sent to revoked users, and those users are receiving the query emails even after revoking their access.	Minor	This bug had a minor impact on the Revoked Users. The Revoked users should not be selectable for queries, and they should not receive any query email notification from the room. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18512	Platform	Users received a “Download Failed” error when attempting to open files in the Document Template section. The issue occurred for all templates (Word, Excel, and PowerPoint), and while the files downloaded successfully, they could not be viewed in the pop-up window.	Blocker	This bug had an impact on viewing document templates within the application. Correct system behavior has been restored.
TRL-18525	Platform	Folder security was not applied to sub-folders when a user dragged and dropped folders into the room. The last child sub-folders did not inherit security from the parent folder, preventing users (e.g., Editor role) from viewing documents in those folders.	Major	This bug had a major impact on folder security inheritance, restricting user access to documents in sub-folders. Correct system behavior has been restored.
TRL-18536	Platform	<p>In the MTI EU environment, a warning message “The operation finished with issues” appeared when replacing the attachment for the Final documents. The document was successfully replaced when created by the same user, but the warning still displayed. For Final documents created by other users, the Replace Attachment/URL option was greyed out and could not be selected.</p> <p>When viewing the version history of Final documents submitted by other users, the warning message “User does not have access to this document” was displayed.</p>	Minor	This bug had a minor impact on document replacement and version history access, leading to confusion for users when handling Final documents. Correct system behavior has been restored.
TRL-18562	Platform	Documents were routed to the incorrect workflow step in a specific room. The workflow was configured so that documents with the “Document Format” metadata field populated (Paper/Electronic) should route to Step 2, while documents with the field left empty should route to Step 1.	Major	This bug had a major impact on workflow routing, preventing documents from being sent to the correct workflow step and causing inconsistencies with the “Document Format” metadata field. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
		However, documents sent via the communication module and marked as relevant were incorrectly routed to Step 1, despite having the field populated. Additional investigation showed the “Document Format” field was not functioning correctly: keyword lookup values returned an error, the field defaulted to “Electronic” for some document types, and existing documents reflected inconsistent values.		
TRL-18568	Platform	<p>The user noticed an issue in MTI EU instances where the export fails when all metadata fields are selected. The export works successfully when only a few metadata fields are selected, but if all fields are included, particularly when “Metadata Fields” and “Required Fields” are selected together, the report fails to generate.</p> <p>The export report should generate successfully even when all metadata fields are selected.</p>	Critical	This defect had a critical impact on reporting functionality, preventing users from generating exports when all metadata fields were included. Correct system behavior has been restored.
TRL-18599	Platform	Users noted that when exporting document metadata in a specific room, the Contact Name field was missing for some documents. This occurred despite the field being correctly populated and visible when viewed directly from the room.	Major	This bug had a major impact on the Contact Name field visibility when exporting the document in a specific room. Correct system behavior has been restored.
TRL-18604	Platform	Documents submitted via email are not appearing under the expected Index Position and are instead categorized under <i>Staging</i> . Additionally, attempts to update the default Index Position in document settings trigger a warning error.	Major	This bug had a major impact on the Document Index Position. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18643	Platform	User noted that in a room, documents submitted outside the defined Audit Scope were included in the audit. The issue was reproducible across multiple instances, where documents submitted one day past the scope were incorrectly included in audit results.	Major	This bug had a major impact on the accuracy of audit scope validation, as documents outside the defined period were incorrectly included in the audit. Correct system behavior has been restored.
TRL-18662	Platform	User encountered a database error when uploading a document in a specific room on the MTI US Instance. The issue is isolated to this room and appears to have started after the recent upgrade.	Major	This defect had a major impact on document upload functionality in the specific room. Correct system behavior has been restored.
TRL-18672	Platform	In a specific TI instance, when dark mode was enabled, the font color of documents appeared in blue instead of white, reducing readability. The font color only changed to white after clicking inside the document.	Minor	This bug had a minor impact on document readability in dark mode. Correct system behavior has been restored.
TRL-18673	Platform	In the previous version, the drag-and-drop functionality for moving documents between folders in the Folder View was not working. When users attempted to drag a document from one folder to another, the action was unresponsive, and the document was not moved.	Major	This bug had a major impact on document management usability. The drag-and-drop functionality has been restored, and documents can now be moved between folders as expected. Correct system behavior has been restored.
TRL-18675	Platform	The 'Document Submission Inventory – Workflow' report is a standard study-level report run on the MTI US Instance, and when we run the query in the DB end, the user gets an error message for a specific room.	Major	This bug had a major impact on report generation, preventing users from retrieving workflow submission data at the study level. Correct system behavior has been restored.
TRL-18680	eTMF	User has reported an issue that in the previous version, the Document Module is experiencing a problem where column names are not displaying correctly and must be manually expanded to be viewed properly.	Major	This bug had a major impact on the column names in the Document Module. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18685	Platform	The system does not allow the same Sequential Numbering pattern to be applied to multiple document types within the same room. When attempting to configure identical numbering patterns, an error appears. In the previous version, sequential numbering was applied at the document type level, but the current behavior enforces uniqueness at the room level.	Critical	This bug had a critical impact on the document numbering setup for customers using consistent patterns across document types. Correct system behavior has been restored.
TRL-18688	Platform	Users with revoked access to a room were still receiving email notifications for General Query resolution. This occurred when a user with the <i>Access Revoked</i> role remained part of the <i>General Query Responders</i> group.	Major	This bug had a major impact on email notifications, as revoked users continued to receive updates they should no longer have access to. Correct system behavior has been restored.
TRL-18697	eTMF	User noted that when trying to view the document via domain-level search (TI View), the document shows a blank screen. However, the same document loads properly when accessed through the room-level search (TI View).	Minor	This issue had a minor impact on viewing the document when performing a domain-level search. Correct system behavior has been restored.
TRL-18699	Platform	Users are facing an issue with the search functionality. Even after updating the form settings under Settings. When users try to save the changes, the system keeps spinning indefinitely and does not complete the save operations.	Major	This bug had a major impact on search functionality. Correct system behavior has been restored.
TRL-18720	Platform	When uploading a document to a folder with multiple Document Types in the previous version, the system prompts the user to select a Document Type at the start of the process. However, after completing metadata entry and clicking the Finish button, the system prompts the user to select the Document Type again before completing the upload.	Minor	This bug had a minor impact on the document upload process by displaying the “Please Select a Document Type” prompt twice. This may confuse users and suggest the initial selection was not retained. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18726	Platform	On the MTI Stage instance, event triggers are generating events when a Country Status is updated in CTMS. However, the created events do not have document placeholders, even though the event trigger setup includes document type configuration.	Blocker	This issue has an impact on generating the placeholders for created events. Correct system behavior has been restored.
TRL-18752	Platform	User has reported that the Mass Coding to Document types Functionality is currently not working.	Critical	This issue has an impact on mass coding functionality in the Document Types Management Section. Correct system behavior has been restored.
TRL-18754	Platform	Users observed an issue when exporting unpublished and closed rooms. The exported file shows the total document count as zero, but when we check in the database, the documents are indeed present in the room. However, in the UI, the Total Documents column appears empty.	Major	This bug had a major impact on the Document Count when exporting Unpublished and Closed Rooms. Correct system behavior has been restored.
TRL-18833	Platform	Users were unable to check in a document. When attempting to attach a file and complete the check-in, a warning message appeared stating: <i>"The operation finished with issues."</i>	Major	This bug had a major impact on document check-in functionality, preventing users from successfully attaching files and completing the process. Correct system behavior has been restored.
TRL-18841	Platform	A mismatch has been identified in the Groups column of the Audit User List report. The group values displayed in the eTMF system & Audit User List report do not match those shown in the report, leading to inconsistent user group information.	Major	This issue has a major impact on the value of the group column that is not matching in the eTMF system and the Audit User List Report. Correct system behavior has been restored.
TRL-18849	Platform	Users noticed that when opening queries through the KPI Dashboard (Open Queries) and switching between different queries, the Queries tab in the metadata panel does not refresh or update.	Major	This bug had a major impact on the Queries tab in the metadata panel, which does not refresh or update. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18870	eTMF	Users are encountering an issue in the previous version where, in the Completeness View, if the user filters placeholders in alphabetical order and then sets a placeholder to 'Not Applicable', the page refreshes, and the placeholder list reverts to its original order.	Major	This bug had a major impact on sorting the Completeness View. Correct system behavior has been restored.
TRL-18878	eTMF	Deactivated contacts were not displaying correctly in the Contact metadata field. When a document was associated with a contact that was later deactivated, the dropdown showed “Not Specified” instead of the deactivated contact's name.	Minor	This bug had a minor impact on document attribution, as deactivated contacts were not properly visible in the metadata field. Correct system behavior has been restored.
TRL-18939	Platform	User was unable to update a Site Contact’s first and last name at a specific site. The system returned error code 14116: <i>“This contact email address already exists in the system with a different name.”</i> However, database checks confirmed that the email address exists only for a single user.	Major	This bug had a major impact on Site Contact management, preventing updates to user details despite no duplication in the system. Correct system behavior has been restored.
TRL-18950	Platform	User observed that the assigned sequential number functionality is not working as expected. When cloning a document to a different document type, the assigned case number (previously labelled as Sequential Number) does not update and remains the same as the source document. As a result, cloned documents carry the original assigned number instead of generating a new one.	Major	This issue has a major impact on document numbering, as cloned documents are not receiving unique sequential numbers after a document type change. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-19018	Platform	An issue was identified in User Management where the Title field entered during user creation would disappear once the user was invited. Although the Title initially appeared saved (and was visible in reports for some users), it was not retained in the user profile. Testing confirmed that in both live and test rooms, the Title value was removed immediately after saving the invited user and refreshing the page.	Major	This bug had a minor impact on User Management, causing user profile data to be incomplete. Correct system behavior has been restored.

9. Open Defects

Trial Interactive v10.7.3 has been released with these known issues. This table uses the following definitions of severity:

- **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.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
QMS-674	QMS	User noted that when visiting the room and adding the due date filter. The Due Date filter in QMS Room does not display the room's time zone.	Minor	This issue has a minor impact on the Room Time-zone for Due Date in Filters. Correct system behavior will be restored.
QMS-675	QMS	In QMS Room Search, the Due Date field does not display the room's timezone. When adding the Due Date field in Advanced Search for Quality Records, the timezone is missing.	Minor	This issue has a minor impact on displaying accurate due dates in QMS Room Search. Correct system behavior will be restored.
TRL-9793	Platform	The User noted that the Grid View becomes misaligned when there are many records.	Minor	This issue has a minor impact on the Grid View when there are many records. Correct system behavior will be restored.
TRL-11642	Platform	User reported that when they are searching for the full name of the document, it's populating. But when they search it with half of the submitted name, it's not populating.	Minor	This issue has a minor impact on the document search with a partial name. Correct system behavior will be restored.
TRL-16300	Platform	Users are encountering an issue with font changes. When the user checks out the document offline, downloads the file, and makes font changes (e.g.,	Minor	This issue has a minor impact on the font styles in a document after

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
		changes to Basis Grotesque Pro), and then checks it back in, the changes are not retained. The font reverts to Source Serif Pro.		checking in and out. Correct system behavior will be restored.
TRL-16345	Platform	In the Domain Settings, users observed that not all controls are displayed on the organization tab when editing.	Minor	This issue has a minor impact on the organization's control visibility. Correct system behavior will be restored.
TRL-17477	Collaborate	An issue was observed while sending documents for signature in the CCR Rooms. When selecting CRA as the document Author and CSM as the document Reviewer, the system automatically removes one of the signers.	Minor	This issue has a minor impact on sending documents for signature in the CCR rooms. Correct system behavior will be restored.
TRL-17959	eTMF	The 'Page Count' column within the grid view displays '0' for some documents even if the documents have multiple pages. This issue has been observed in the "View by Processing > Page Count> Processed". Users observed that it appears that the page count is only displayed for PDF and DOC file types. Other formats, such as .msg, .pub, .xls, and so on, do not show any page count.	Minor	This issue has a minor impact on the page count display. Correct system behavior will be restored.
TRL-17945	Platform	Users are experiencing multiple issues when attempting to update a rejected report using the Edit with Comparison functionality. The observed behavior does not align with expectations, and several features appear non-functional. <ul style="list-style-type: none"> Issue 1: When one user is editing the report and another user opens the same report, the Discard and Save Changes buttons are displayed, even though the second user did not initiate editing. 	Minor	This defect impacts report editing and version control, limiting the usability of the Edit with Comparison feature. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
		<ul style="list-style-type: none"> Issue 2: The scrollbar does not function, preventing users from scrolling beyond the first page of the report. Issue 3: New reports generated via Edit New Version still display old edits instead of resetting. 		
TRL-18461	eTMF	Users noted that the zoom in/out functionality in TI Analytics is not working as expected. When zooming out to 70%, the visuals remain the same size instead of decreasing proportionally. When zooming in (page width greater than 1020px), visuals are hidden, and no scroll bar appears to allow access to the hidden visuals.	Minor	This issue has a minor impact on the TI Analytics zoom in/out functionality. Correct system behavior will be restored.
TRL-18462	eTMF	Users are not receiving email notifications when a document is uploaded, despite the corresponding settings being configured in the room.	Minor	This issue has a minor impact on triggering email notifications when documents are uploaded. Correct system behavior will be restored.
TRL-18506	Platform	User received the following error message: "Replace document content is not applicable for hybrid storage," when attempting to check in a document in the room.	Minor	This issue has a minor impact on Document Management as it prevents users from completing the check-in process. Correct system behavior will be restored.
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 will be restored.
TRL-18932	Platform	Users noted that the Signer Role and Reason fields are misaligned in the eSign request. When a signer with a long job title signs the document, the Signer Role and Reason shift to the right and appear out of alignment.	Minor	This issue has a minor impact on the display alignment of Signer Role and Reason fields in eSign requests. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18997	Platform	<p>Client requested an export of all final Portfolio PDF documents with specific metadata fields (Document ID, Index Location, Submitted On, Published Date, Submitted Name, Document Issue, and Document URL).</p> <p>The export cannot be performed from the UI due to issues with the Document Issue field. The field is virtual and mapped to a numerical value, but applying this filter results in a database error.</p> <p>In addition, the Document Issue field is not available as a filter in advanced room search, leaving no way to query all Portfolio PDF documents for export.</p>	Minor	This issue has a major impact on the Document Issues field. Correct system behavior will be restored.
TRL-19025	SSU	<p>Users noted that when enabling the “Contact is responsible for providing documents” toggle in the SSU Site, a warning pop-up appears stating “Contact conflicts detected”, and the changes are not saved.</p>	Minor	This issue has a major impact on enabling responsibility for document provision in SSU Site contacts. Correct system behavior will be restored.

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: Senior Director, Product Management
Signature: Reason for signature: Date:	

Quality Assurance

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