TRIAL INTERACTIVE V10.7.2 – RELEASE NOTES V1.1

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1. Version History

Author	Revision #	Date	Comment
Salil Joshi	0.1	11-Jul-2025	Initial Version: Pre-Release Notes issued.
Salil Joshi	0.2	25-Jul-2025	**Features Added:** • **New/Enhanced Features**: TTI-4238, TTI-4256 • **Defect Resolutions:** TRL-16899, TRL-17334 TRL-17908, TRL-18000 TRL-18203, TRL-18242 TRL-18281, TRL-18329 TRL-18350, TRL-18407, TRL-18433, TRL-18436 TRL-18437, TRL-18461 TRL-18480, TRL-18512 TRL-18557, TRL-18561 TRL-18594, TRL-18626 • **Open Defects:** Table added. **Features Removed:** • **New/Enhanced Features:** TTI-4156, QMS-13, TTI-2864, REPORT-190, TTI-2845, TTI-3590, TTI-3754 • **Defect Resolutions:** TRL-17709, TRL-18294
Salil Joshi	1.0	25-Jul-2025	Document Finalized
Salil Joshi	1.1	11-Aug-2025	**Features Added:** • **Defect Resolutions:** TRL-18396 **Other Changes:** • The Version History table has been updated to reflect the changes made to the v10.7.2 Release Notes since the issuance of the Pre-Release Notes.

2. Purpose

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

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

3. Scope

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

System In Scope	
System Name	Trial Interactive
System Version	v10.7.2
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.
eTMF	Electronic Trial Master File
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
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 New Features, Enhancements, Reports, Open Defects 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	25-Jul-2025
Estimated US MTI Upgrade Date/Time:	25/Jul/2025 9:00 PM
Estimated EU MTI Upgrade Date/Time:	25/Jul/2025 5:00 PM
Estimated China MTI Upgrade Date/Time:	01/Aug/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 v10.7.2 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

8. Changes

Legend for Impacts

Trial Interactive v10.7.2 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
TTI-2966	Electronic Trial Master File (eTMF)	The room search functionality has been improved to display tooltips with full field names for fields that have lengthy titles on the Configure Form. This improvement eliminates the need for horizontal scrolling to view long field names, ensuring a more user-friendly experience.	No	Yes	Minor	**Affected Users**: Editors **Impact**: This improvement has a minor impact on the room search functionality and the display of fields with long names on the Configure Form.
TTI-3327	Electronic Trial Master File (eTMF)	Currently, the query creator is not notified when a response is added to the query, requiring the creator to manually check for responses. Also, the query responder receives an email notification only once when the query is first created. The subsequent responses are available under the queries tab in the room, but do not trigger additional email notifications. With this release, the query creators will now receive email notifications when another user responds to their query. Additionally, query creators and responders will receive an email notification for each subsequent response to the initial query and also when the query is resolved.	No	Yes	Minor	**Affected Users:** All Users **Impact:** This new feature has a minor impact on receiving email notifications when a query is created, responded to, and resolved.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4114	Platform	This improvement restores the previous system behavior, allowing Admins to edit User profile data except for Name (first, middle, and last), and Email address. Additionally, when such information is edited in the User Profile section of the study room, the same shall be updated in the IAM profile for the user as well, ensuring synchronization of data.	No	Yes	Minor	**Affected Users:** Admin **Impact:** This improvement has a minor impact on the IAM functionality.
TTI-4238	Study Start-Up (SSU)	With this improvement, Study Start-up Specialists can now transition the IRB status from Conditional Approval to Approved. Additionally, the system continues to treat both Conditional Approval and Approved as valid IRB statuses for Site Activation.	No	Yes	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the IRB status changes.
TTI-4256	Platform	The latest improvement to IAM included the following key features: • Updated the password reset email link to expire after 2 hours. • Users who have not yet set up security questions and answers will now be prompted to do so when they log in or reset their password. • Super Admins can now access the password reset functionality.	No	Yes	Minor	**Affected Users:** All Users **Impact:** This improvement has a minor impact on the IAM functionality.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4286	Quality Management System (QMS)	The process for creating Incident (Quality Events) and CAPA records has been improved to auto-populate default fields during record creation, while allowing users to manually update them, if needed. Key Enhancements • The 'Initial Reporter' field is auto-filled with the record creator's name on the 'Create Incident' modal. • The Incident Date is automatically set to the current system date. • On the 'Create CAPA' modal, the 'Reported On' field is auto-filled with the current system date. • The 'Reporter' field is auto-populated with the record creator's name. • Default values apply only when creating new records. • Editing existing records does not update these fields automatically. • For automated/API-created records, default 'Reporter' fields use the system user identity.	No	Yes	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the default fields within the Incident and CAPA creation modal windows.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4298	Quality Management System (QMS)	The 'Add' button is now visible on the 'Request Clarification' modal window when sending an incident record for clarification. This improvement enables users to select recipients to whom the record should be sent.	Yes	No	Major	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the 'Request Clarification' modal window, allowing users to select recipients.
TTI-4299	Quality Management System (QMS)	Previously, only the 'Title' field in the CAPA Form was mandatory and included in coding, which could result in forms being created with just that field completed. With this enhancement, the following fields are now required and cannot be disabled through Quality Module > Settings. These fields will always appear on the form and will be included in coding: • ID • Team • Type • Initial Reporter • Identified On • Created On • Resolved By • Resolved On	Yes	No	Minor	**Affected Users:** Manager **Impact:** This improvement has a minor impact on the CAPA Form.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4300	Quality Management System (QMS)	With this improvement, users can now submit query responses through both email and the application. Upon submission, the query sender receives an immediate notification. Once a response is submitted, the query sender or a Room Manager can access the details and mark the query as resolved. Resolved queries are timestamped and linked to the user who completed the resolution for traceability. **Note**: File attachments are not supported with query responses, regardless of the submission method.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the Query Response functionality with notifications and resolutions for Incident and CAPA.
TTI-4301	Quality Management System (QMS)	The 'Form Settings' page within QMS Settings now includes an 'Order Filters' button, allowing users to configure the filter order in Search, similar to the functionality available in Room Settings > Form Settings.	Yes	No	Minor	**Affected Users:** Manager **Impact:** This improvement has a minor impact on the Form Settings page within QMS Settings.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4302	Quality Management System (QMS)	This improvement implements security updates for QMS records when they are locked. If a QMS record is locked: • Contributors, Admins, and Record owners get Edit access to the assigned subform of the current stage (if it exists). • The record claimant gets access according to the workflow configuration. • Other users get read-only access to the record and subform. • A non-null $$Access Right$$ value is now returned for Admins.	Yes	No	Minor	**Affected Users:** Manager **Impact:** This improvement has a minor impact on the QMS records that are locked.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4303	Quality Management System (QMS)	The following audit metadata fields have been added to the 'Workflow Management Grid' and 'Workflow Configuration Modal' to enhance visibility and traceability of workflow configurations. Workflow Management Grid fields • **Updated By**: Displays the user's full name who last edited the workflow. • **Updated On**: Displays the timestamp of the last modification in room format with time and date. Edit Workflow Modal fields • **Created By**: The user who initially created the workflow • **Created On**: Timestamp of creation • **Updated By**: User who last updated the workflow • **Updated On**: Timestamp of the last update.	Yes	No	Minor	**Affected Users:** Manager **Impact:** This improvement has a minor impact on the Workflow Management Grid and Edit Workflow Modal which now displays audit metadata fields.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4304	Quality Management System (QMS)	The Workflow Creation wizard is enhanced for usability by improving the field selection and simplifying timeline configuration for each stage. Field selection enhancements • All single and multi-select fields support inline search. • Alphabetical Sorting (A to Z) of dropdown values for easy navigation and usability. • A 'No results found' message is displayed when no matching value exists. Timeline Tab Enhancements • The 'Due Date' and 'Escalation Period' fields are now split into a numeric input for entering the duration and a range selector for time units with labels reflecting 'After Submission.' • Users can add multiple reminders using a numeric input box and a time unit selector, and can also delete reminders as needed.	Yes	No	Minor	**Affected Users:** Manager **Impact:** This improvement has a minor impact on the Workflow Creation modal, i.e., Add Workflow.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4305	Quality Management System (QMS)	The 'Layout Configuration' window now provides a real-time visual approximation of how the form will be rendered to the end user. Key Enhancements • The Layout Preview matches the actual end user UI that includes checkbox alignment, dropdown appearance, label placement, line spacing, position of headers, and groupings. • The layout updates in real time when field properties such as width, visibility, or type/configuration are edited, with all changes instantly reflected in the preview. • Any form control, such as radio buttons, toggles, text inputs, dropdowns, appears in preview exactly as in the end-user form. • The layout mirrors responsive rules that are applied in the actual form UI.	Yes	No	Minor	**Affected Users:** Manager **Impact:** This improvement has a minor impact on the Layout Configuration preview, which now aligns with the actual end-user UI.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4306	Quality Management System (QMS)	This enhancement allows users to add additional workflow stage participants directly through the Ad-hoc Team Assignment trigger. Additionally, notifications to participants added to the stage are now sent only when the stage is reached.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on adding a workflow stage through the Ad-hoc assignment trigger.
TTI-4307	Quality Management System (QMS)	The 'Layout Configuration' window has been enhanced with the following improvements: • A Collapsible section allowing users to expand or collapse section details by clicking on the arrow icon. • Appearance settings configured within the Quick View are now excluded from the Layout Configuration's preview area. • These improvements make it easier to manage complex layouts and ensure a user-friendly drag-and-drop process.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the 'Layout Configuration' window.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4308	Quality Management System (QMS)	The option to select all records has been reintroduced in the 'Select Record Type' multi-select modal, as well as in other modal windows where multi-select is supported. • When multi-select is enabled, an 'All' checkbox is displayed, allowing users to select all records in the hierarchy. • When multi-select is disabled, the 'All' option is not displayed.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the 'Select Record Type' and other modals where multi-selection is supported.
TTI-4309	Quality Management System (QMS)	The latest enhancement introduces a 'Save Changes' confirmation pop-up when users attempt to close the 'Layout Configuration' modal. The pop-up provides three options: • Cancel • Discard Changes • Save Changes This improvement safeguards user input and prevents accidental configuration loss when exiting the layout customization process.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on saving changes to the Layout Configuration modal.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4310	Quality Management System (QMS)	The 'Impact Value Settings' page within the Field Value Settings is enhanced for visual customization (icon, color, label) and improving the manageability of configured options in the grid. Grid View enhancements • 'ID Column' is removed from the Impact Values table • Color, Icon, and System Name columns are added. • Apply 'Sort' criteria to display values alphabetically or by priority. • The 'Enabled' toggle is maintained per Impact value. Add/Edit modal enhancements • Ability to configure Display Name, System Name, Color, and Icon while editing the field value. • Synchronization of changes to reflect in the grid with proper formatting.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on Impact Value Settings, adding visual configuration options and grid improvements.

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

TTI-4311	Quality Management System (QMS)	The record creation modal is now improved by adding step validation and button order alignment.
		
		General Info tab enhancements
		
		• Immediate validation when the user clicks the 'Next' button at the bottom of Step 1.
		• Prevents transition to Step 2 if any required fields are missing or invalid.
		• Displays error message listing all invalid fields, and allows progress only when all required fields are filled.
		
		Add Evidence Tab enhancements
		
		• Footer buttons are rearranged to display in the following sequence
		
		    o Cancel
		    o Previous
		    o Create Draft
		    o Create & submit for Review
			Yes	No	Minor	**Affected Users:** Editors
						
						Impact: This improvement has a minor impact on the record creation modal, enhancing usability and clarity.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4312	Quality Management System (QMS)	Previously, users were able to create a new item using an existing Item ID when that ID had been modified. A validation check has been implemented to ensure Item IDs remain unique during item creation.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on the creation of item IDs.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4313	Quality Management System (QMS)	A chip-based user display, role-specific labeling, and contextual interactions for assigned users and additional participants are introduced to improve the clarity and interactivity of workflow stage cards. Assigned Users Section • Plain user names are replaced with user chips that include avatar, name, and role-based tag. • If the stage is unclaimed, the section displays as 'Authorized Users' with a list of eligible claimants. Once claimed, it updates to 'Assigned User', showing only the selected user. Additional Participants Section • Status colored chips for selected participants that include avatar, name, and status indicator. • Chat bubble icon to view comments. • Unique color coding for chips reflecting statuses.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This enhancement has a minor impact on the user interface of the Workflow Stage cards.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-4314	Quality Management System (QMS)	Previously, the Additional Authority Level users received notifications for the first workflow stage, even though they did not have access to the record. With this improvement, in workflows where the Ad-hoc assignment is enabled, the system now ignores Additional Authority Levels from the first stage of the workflow.	Yes	No	Minor	**Affected Users:** Editors **Impact:** This improvement has a minor impact on triggering email notifications to additional authority-level users when ad-hoc assignment is enabled.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
QMS-448	Quality Management System (QMS)	In the Record Types Management module, when a user attempts to delete a Record Type that is currently assigned to existing Incident or CAPA records, the system deletes the Record Type without displaying any warning or confirmation message.	Minor	This bug had a minor impact on the Record Types Deletion. The resolution ensures that a warning is displayed before confirming the record type deletion.
TRL-15435	Electronic Trial Master File (eTMF)	When attempting to add documents in the Related Documents tab, users receive a message indicating that the document was added successfully. However, the document does not appear in the Related Documents list.	Minor	This bug had a minor impact on adding documents to the Related Documents tab. The resolution restores the correct system behavior.
TRL-16899	Collaborate (CMS)	In the grid view, the alignment between rows and columns becomes distorted when the header row is oversized.	Minor	This bug had a minor impact on the columns' display in the Grid. The resolution ensures that the alignment between rows and columns remains properly aligned.
TRL-17141	Collaborate (CMS)	When uploading a single document and applying a provided template, the system does not retain the document's original font. This issue also persists after the Workflow or E-Signature process is completed, with the font reverting from Calibri to Times New Roman.	Minor	This bug has a minor impact on the retention of the document's original font size. The resolution restores the correct system behavior.
TRL-17334	Electronic Trial Master File (eTMF)	Disabling a contact caused the 'Contact' metadata field to display as 'Not Specified' in the document metadata panel, effectively removing the selected contact from the field.	Major	This bug had a major impact on the 'Contact' metadata field. The resolution ensures that when a contact is deactivated, the 'Contact' field displays '(contact name) Deactivated' instead of 'Not Specified'.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17609	Study Start-Up (SSU)	An issue was observed in an SSU-enabled room, where editors in eTMF were able to replace an attachment.	Critical	This bug had a critical impact on the editor's ability to replace an attachment. The resolution restricts editors to replacing an attachment.
TRL-17661	Platform	A warning message was displayed while adding Super Admin users to the TI Analytics group. 'Task Completed with issues, and the users don't get added.'	Major	This bug had a major impact on adding Super Admin users to the TI Analytics group. The resolution ensures that Super Admin users can be added to the TI Analytics group without any errors.
TRL-17908	Electronic Trial Master File (eTMF)	An issue is observed where users with revoked access can still be assigned to queries under the Quality Review module.	Minor	This issue has a minor impact on the 'access revoked' user, which can be added to queries. The resolution restores the correct system behavior.
TRL-17940	Platform	The following fields remain empty in the Domain Settings User Form Settings due to IAM • MFA Registered • Password Date • Password Expiration Date • Is Locked	Minor	This bug has a minor impact on the Domain User interface. Removing unused fields will improve clarity and reduce potential confusion. The resolution restores the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18000	Electronic Trial Master File (eTMF)	An issue occurred where the 'Certified Copy Reason' field did not appear when users imported new documents and selected 'Yes' for the certified document option.	Minor	This bug had a minor impact on the reason for certified documents. The resolution ensures that users can see the 'Certified Copy Reason' field when a new document is imported with the certified document option as 'Yes'.
TRL-18122	Collaborate (CMS)	A system error is displayed when a user generates a Follow-up Letter and selects the 'Edit with New Version' option, attempting to save the document as a Major Version.	Major	This bug had a major impact on editing follow-up letters. The resolution ensures that the Follow-up Letter is saved successfully as a Major Version without any errors.
TRL-18203	Study Start-Up (SSU)	The Document Cart in the SSU module did not function as expected. • The cart failed to open in a pop-up window. • Added documents were not visible in the cart. • Drag-and-drop functionality did not work. In the previous version, the documents were visible in the cart, but the cart still cannot be closed, and drag-and-drop remained non-functional.	Minor	This bug had a minor impact on the Document Cart and its associated functionalities in the SSU module. The resolution restores the correct system behavior for the Document Cart and its associated functionalities.
TRL-18242	Electronic Trial Master File (eTMF)	When adding a single document using the 'Add Document' option, the 'Date Type' field remained blank in the document's metadata panel even after selecting the appropriate 'Category' and 'Document Type'.	Major	This bug had a major impact on the on the 'Date Type' metadata field. The resolution ensures that the Date Type field reflects the configured default value upon selecting the Document Type.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18246	Electronic Trial Master File (eTMF)	When a file is downloaded as a PDF, it incorrectly uses a random series of characters as the file name instead of the original file name.	Minor	This bug has a minor impact on the downloaded PDF file name. The resolution restores the correct system behavior.
TRL-18276	Electronic Trial Master File (eTMF)	An issue was observed in the document versioning display. The document correctly showed version 2.0 in the grid view, but the Version tab continued to display version 1.0, confusing the current version of the document.	Major	This bug had a major impact on the Documents Library page. The resolution ensures that the Version tab now correctly reflects the updated version, ensuring consistency across all views.
TRL-18281	Electronic Trial Master File (eTMF)	Selecting the 'Copy Field' option did not immediately make the metadata fields selectable. The fields only became selectable after users either manually clicked into a field or navigated to a different document and returned. A similar issue occurred when users selected the 'Cancel Copy Field' option.	Minor	This bug had a minor impact on the copying of the metadata fields. The resolution ensures that the metadata fields are copied when the 'Copy Field' option is selected.
TRL-18329	Platform	Users are unable to submit the documents into the room via email (Inbox Submission), despite having active access. When attempting to send a document to the study inbox, the user is getting the failure message that "You are not authorized to submit the documents for this study".	Minor	This bug has a minor impact when users are submitting the documents via email (Inbox Submission). Correct system behavior will be restored.
TRL-18331	Electronic Trial Master File (eTMF)	Users encountered a 'Task Cancelled' message while exporting documents from the search results, and the document was not downloaded.	Major	This bug had a major impact on exporting documents from search results. The resolution ensures that documents are downloaded without any errors.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18350	Collaborate (CMS)	Users are encountering an issue where the breadcrumb trail at the top of the interface continues to display 'Sites', resulting in an inconsistency. However, the left panel correctly displays the site breadcrumb as 'Vendors'.	Minor	This bug has a minor impact on the Breadcrumb trail that does not match renamed toolbar items. The resolution restores the correct system behavior.
TRL-18359	Electronic Trial Master File (eTMF)	The 'Create Audit Profile' modal displayed the column headers that were misaligned with the data columns in the room, affecting the readability and usability of the data.	Major	This bug has a major impact on the 'Create Audit Profile' UI. The resolution ensures that the columns and headers are properly aligned, ensuring productivity and usability.
TRL-18366	Collaborate (CMS)	The 'Versions' tab in the metadata panel of certain documents is not displaying correctly. When attempting to access the document versions, error messages are displayed.	Major	This bug has a major impact on the document versions. The resolution restores the correct system behavior.
TRL-18390	Electronic Trial Master File (eTMF)	Reader users assigned the role of Auditor encountered a UI inconsistency where the 'Audit' tab in the metadata panel of an audited document incorrectly displayed the following message along with an active 'Edit' button. 'The record is not editable.'	Minor	This bug had a minor impact on the 'Audit' tab of an audited document in the Quality Review module.
TRL-18391	Electronic Trial Master File (eTMF)	When accessing a document under the In Progress status via the Quality Review > Audit section, the Edit button on the Audit tab does not function as expected. The editable fields are visible, but pressing the Edit button does not trigger any action.	Minor	This bug had a minor impact on the auditors' ability to edit details in the Audit tab. The resolution ensures that the fields become editable after pressing the Edit button.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18396	Electronic Trial Master File (eTMF)	When attempting to open an attachment from a query response in the room, the attachment appears blank and cannot be viewed.	Minor	This bug has a minor impact on viewing the attachment from the query response. The resolution restores the correct system behavior.
TRL-18397	Platform	While creating a Custom Workflow, selecting Metadata criteria as Document Type does not persist. After progressing through the workflow setup steps, the selected Document Type value is reset, requiring users to reselect the criteria or preventing the intended condition from being applied.	Critical	This bug had a critical impact on configuring metadata-based custom workflows. The resolution ensures that the selected Document Type criteria are now retained throughout the workflow creation process.
TRL-18407	Platform	In some cases, when a room name is updated, the change is not reflected in the linked room. The linked room continues to display the old room name instead of the updated one.	Minor	This bug has a minor impact on room synchronization. The resolution restores the correct system behavior.
TRL-18410	Collaborate (CMS)	When users upload a PDF document with placeholder fields enabled, attempting to check out the document results in a server error. This issue does not occur with Word documents; checkout works correctly when placeholders are enabled for Word files.	Critical	This bug has a critical impact on PDF document handling. The resolution restores the correct system behavior.
TRL-18427	Electronic Trial Master File (eTMF)	An issue was observed where the 'GetContactProfile' returned the user's full name instead of the contact's name. This happened if the contact is locally stored with a different First or Last name.	Minor	This bug had a minor impact on retrieving the contact profile details. The resolution restores the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18433	Electronic Trial Master File (eTMF)	An issue was observed where the 'GetDocumentByView' did not take into account the locally stored contact names.	Minor	This bug had a minor impact on the locally stored contacts. The resolution ensures that the 'GetDocumentByView' takes into account locally stored Contact Names
TRL-18436	Electronic Trial Master File (eTMF)	User observed in the eTMF > Documents Module that, if users attempt to adjust the column sizes, after a few times, the column headers become misaligned with the rest of the content.	Minor	This bug has a minor impact on the alignment of columns in the eTMF module > Documents tab. Correct system behavior will be restored.
TRL-18437	Electronic Trial Master File (eTMF)	An issue was identified where metadata was not visible to users in the 'Query By Sender' view.

Additionally, placeholders were not displayed in the 'Event' view. | Major | This bug had a major impact on the display of metadata and placeholders within the 'Query By Sender' and 'Event' views, respectively. The correct system behavior will be restored. |
| TRL-18461 | Electronic Trial Master File (eTMF) | An issue persists in TI Analytics, where the Zoom In and Zoom Out are not working as expected. While zooming in, the visual size remains the same, and while zooming out, the visuals are hidden, and no scroll bar can be seen to view the hidden visuals. | Minor | This bug has a minor impact on the Zoom in and Zoom Out in TI Analytics. The resolution ensures that the Zoom in and Zoom Out work as expected. |
| TRL-18480 | Platform | Users are unable to add or edit Advanced Validation settings from both the Document Types and Forms settings. When attempting to apply a validation rule (e.g., making one field required based on another field's value), the system becomes unresponsive upon clicking 'Apply'. The settings are not saved or updated. | Minor | This bug has a minor impact on validation rule configuration for Document Types and Forms. Correct system behavior will be restored. |

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18489	Collaborate (CMS)	The following issues were observed while sending documents for the Read & Acknowledgement process. • Although the correct number of contacts was displayed, users were unable to select them. • Selecting all contacts across multiple pages sometimes resulted in only a partial list being carried forward. • The contact search functionality did not return the expected results.	Critical	This bug has a critical impact on the Read & Acknowledgement process. The resolution removes all inconsistencies and resets the correct system behavior.
TRL-18493	Collaborate (CMS)	Users reported an issue where the 'Pending' folder within the 'R&A as Received' view indicated one pending document. However, upon clicking the folder, no document was displayed in the list.	Major	The bug has a major impact on the display of documents in the pending folder within the 'R&A as Received' view. The resolution ensures that the number of documents displayed accurately reflects the pending count.
TRL-18505	Platform	When a contact is a site user and is updated for address within an SSU room, the changes appear correctly in the application but are not reflected in IAM.	Critical	This bug had a critical impact on the data synchronization between the application and IAM. The resolution ensures that updates to the contact are correctly reflected in the application and IAM.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18507	Platform	An issue was identified where the user title updated from the eSignature window was not reflected in IAM. The change appeared correctly within the application, but not in IAM.	Major	This bug had a major impact on the data synchronization between the application and IAM. The resolution ensures that users in Origami and IAM have the same title.
TRL-18512	Collaborate (CMS)	An issue was observed where clicking on any file icon within the 'Document Template' section of the Settings module displayed a 'Download Failed' message and the file could not be opened.	Blocker	This bug impacted the documents display and download within the Document Template section. The resolution ensures that users can click on any template file icon in the Document Template section and view or download the document.
TRL-18557	Collaborate (CMS)	While attempting to send a document for Read & Acknowledge, deselecting a site does not remove the associated contacts, and they continue to appear on the R&A Recipients list.	Minor	This bug has a minor impact on the display of deselected site contacts. Correct system behavior will be restored.
TRL-18561	Collaborate (CMS)	Users are encountering an issue where some of the previously signed documents do not display the 'Signed' status in the documents grid.	Minor	This bug has a major impact on the display of the 'Signed' status for some documents. Correct system behavior will be restored.
TRL-18594	Collaborate (CMS)	The 'Include All' dropdown incorrectly displayed one empty search box on the 'Search' window when 'Documents' was selected as the search entity.	Minor	This bug had a minor impact on the search functionality at the room level. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18626	Electronic Trial Master File (eTMF)	While attempting to edit the Satellite Site field, no dropdown window was displayed. Additionally, a similar issue occurred for any metadata field with the field type as Keyword Lookup.	Minor	This bug had a minor impact on the keyword lookup metadata fields. The resolution ensures that keyword metadata fields can be selected and dropdown options are displayed.

9. Open Defects

Trial Interactive v10.7.2 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
TRL-13555	Platform	While coding the document by selecting the category as 'Site' followed by 'Investigative Site,' and upon choosing the document type, the site field becomes grayed out, and the site details disappear. However, when the document is approved, the investigative site details reappear in the field. Additionally, users also encountered a 'Networking Error' while approving the document.	Minor	This issue has a minor impact on the visibility of Site details. Correct system behavior will be restored.
TRL-16300	Collaborate (CMS)	When users check out a document for offline use, make changes, such as modifying the font style, and then check the document back in, those changes are not retained.	Minor	This bug has a minor impact on the font styles in a document after 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-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 has a minor impact on the display of time zones for the submission date of a document. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17477	Collaborate (CMS)	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 bug has a minor impact on sending documents for signature in the CCR rooms. Correct system behavior will be restored.
TRL-17709	Electronic Trial Master File (eTMF)	Users are encountering an issue where Sites with the 'Non-Participating' status are incorrectly showing as 'No' in the "Non-Participating Site" column.	Minor	This bug has a minor impact on the sites with 'Non-Participating' status showing incorrectly as 'No' in the Sites list. Correct system behavior will be restored.
TRL-17922	Collaborate (CMS)	An issue was identified in the application's user interface where dark mode was not applied consistently, with some sections still showing white backgrounds despite dark mode being enabled.	Minor	This bug has a minor impact on the application's UI. Correct system behavior will be restored.
TRL-17959	Electronic Trial Master File (eTMF)	The 'Page Count' column within the grid view displays '0' for some documents even if the documents have multiple pages. This issue is encountered when the 'View By Processing' is set and the 'Processed' folder is selected.	Minor	This bug has a minor impact on the page count display when the 'Processing' view is set. Correct system behavior will be restored.
TRL-18130	Platform	When a document is sent for serial e-signature (MSB), the e-signature status next to each user's name appears as 'Unknown' in the e-signature tab. The expected status should be 'Waiting for Signature' until the user completes the action.	Minor	This bug has a minor impact on the User E-Signature status. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18272	Electronic Trial Master File (eTMF)	A user with the Administrator role was added as a Site Contact with the contact type Principal Investigator, which violates system configuration rules, which restrict Site Contacts to users with roles no higher than Editor. Additionally, the user's role is displayed inconsistently as 'Administrator' in the User Management grid view, but is not shown in the user's profile and is not available in the role drop-down list.	Minor	This bug has a minor impact on adding Administrators as site contacts. Correct system behavior will be 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 has a minor impact on the access control for revoked users. Correct system behavior will be restored.
TRL-18295	Platform	Users are facing issues with the Document Type Configuration of the TI Automate, where some document types weren't listing the Extracted Field Name, though the universal IDs are provided.	Minor	This issue has a minor impact on Document Type Configuration (TI Automate). Correct system behavior will be restored.
TRL-18462	Electronic Trial Master File (eTMF)	Users are not receiving email notifications when a document is uploaded, despite the corresponding settings being configured in the room.	Minor	This bug has a minor impact on triggering email notifications when documents are uploaded. Correct system behavior will be restored.
TRL-18506	Platform	An error message is encountered when attempting to 'Check-In' a document in a specific room. 'Replace document content is not applicable for hybrid storage",	Minor	This bug has a minor impact on Document Management as it blocks users from completing the check-in process. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-18525	Electronic Trial Master File (eTMF)	While dragging and dropping a document into a folder where security is set with editor and reader access, the last child folder does not inherit the parent folder's security. This resulted in editor users not being able to view documents.	Minor	This bug has a minor impact on the sub-folders inheriting the parent folder's security. Correct system behavior will be restored.
TRL-18542	Platform	When a serial e-signature request is sent using TI-Sign as the selected e-signature method, only the first signer receives a notification. Subsequent signers do not receive notification emails after the previous signer completes their signature.	Minor	This issue has a minor impact on the serial e-signature workflow using TI-Sign. 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)

Customer Focus Group

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

11. Approvals

Product Owner

Name: Anuj Thapar	Title: Senior Product Manager
Signature: Reason for signature: Date:	

Quality Assurance

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