

TRIAL INTERACTIVE V10.6.2 – RELEASE NOTES V1.2



1.	Table of Contents	
2.	Version History	3
3.	Purpose	4
4.	Scope	5
5.	Definitions / Acronyms	6
6.	Release Overview	7
7.	Release Schedule	8
8.	Hardware and Software Requirements	9
9.	Changes.....	10
10.	Customer Support	29
11.	Approvals	31

2. Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	31-Jan-2025	First Draft Created.
Samuel Pawar	0.2	06-Feb-2025	Added Reports: <ul style="list-style-type: none"> • Reports-173 • Reports-180 • Reports-182
Samuel Pawar	0.3	07-Feb-2025	Added Feature: <ul style="list-style-type: none"> • TTI-4113 Added Defects: <ul style="list-style-type: none"> • TRL-17307 • TRL-17392 • TRL-17445 • TRL-17476
Samuel Pawar	0.4	10-Feb-2025	Added Feature: <ul style="list-style-type: none"> • TTI-3892
Samuel Pawar	0.5	11-Feb-2025	Added Defects: <ul style="list-style-type: none"> • TRL-16811 • TRL-17258 • TRL-17341 • TRL-17323 • TRL-17476
Samuel Pawar	0.6	14-Feb-2025	Added Features: <ul style="list-style-type: none"> • TTI-2967 • TTI-3902 • TTI-3914 • TTI-4130 • TTI-4131 • TTI-4132
Samuel Pawar	0.7	19- Feb-2025	Added Defect: <ul style="list-style-type: none"> • TRL-17500
Samuel Pawar	1.0	21-Feb-2025	Added Defects: <ul style="list-style-type: none"> • TRL-16978 • TRL-17523 Removed Feature: <ul style="list-style-type: none"> • TTI-3791 Initial version finalized.
Samuel Pawar	1.1	24-Feb-2025	Updated Defect Description: <ul style="list-style-type: none"> • TRL-17500 Updated Impact / Analysis Comment: <ul style="list-style-type: none"> • TRL-17173 • TRL-17221 • TRL-17250 • TRL-17266 • TRL-17306 • TRL-17323 • TRL-17375 • TRL-17476
Samuel Pawar	1.2	26-Feb-2025	Revision update performed to add back enhancement TTI-3009 after erroneously removing.

3. 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 Release Notes. The end-users of the system can use the Release Notes to evaluate 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 the scope of the Release.



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

4. Scope

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

System In Scope	
System Name	Trial Interactive
System Version	v10.6.2
Release Type	Patch

5. 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
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
TestRail	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.

6. 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.

7. Release Schedule

Once approved for release on the date noted below, this version will be deployed to the Multi-tenant (MTI) environment during the normal maintenance windows:

Schedule (All time zones are in ET)	
Date of Release	21-Feb-2025
Estimated US MTI Upgrade Date/Time:	21/Feb/2025 9:00 PM
Estimated EU MTI Upgrade Date/Time:	21/Feb/2025 5:00 PM
Estimated China MTI Upgrade Date/Time:	28/Feb/2025 12:00 AM
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your TransPerfect Customer Success Manager.

8. Hardware and Software Requirements

The following describes the hardware and software requirements to use the Trial Interactive v10.6.2 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

9. Changes

Legend for Impacts

Trial Interactive v10.6.2 has been released with these enhanced features and defect fixes. These tables use the following definitions of functional risk and customer impact:

- **Critical** – A core function is added or updated with far-reaching functional risk or changing or impacting existing customer workflows.
- **Major** – This Defect has an impact on basic functionality or major functional risk.
- **Minor** – There may be a small impact on business in specific use cases.
- **None** – This is a cosmetic or extremely minor change with no impacts or risks.

Legend for Offerings

- Electronic Trial Master File (eTMF)
- Study Start-Up (SSU)
- Collaborate (CMS)
- Quality Management System (QMS)
- Platform

A. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-2967	Platform	<p>This improvement in the Room Search functionality enhances the Manage Saved Searches interface by adding more clarity in the Shared With column across all tabs.</p> <p>Now, the column will display the User/Group with whom the search is shared, in addition to the existing values of "By ME" (for searches shared by the current user) and "With ME" (for searches shared by the current user).</p>	No	Yes	Minor	<p>Affected Users: Editor and Above.</p> <p>Impact: This improvement has a minor impact on the Room Search (Manage Save Searches)</p>
TTI-3009	Trial Master File (eTMF)	<p>To address compliance risks and enhance transparency, a dedicated audit trail entry has been added for purged documents. This ensures a complete and traceable record of deletion activities and provides details for restoration.</p> <p>Users with access to the audit trail will be able to view records of purged documents and filter entries by the "Purge" action for better tracking.</p> <p>The Audit Trail Event Activity for Purge will show the old and new values for ALL Deleted Document metadata changes in the Activity Related Data.</p>	No	Yes	Minor	<p>Affected Users: All Users</p> <p>Impact: This improvement has a minor impact on the purged documents in Audit Trail.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>Deleted documents will also show 'Reason for Deletion' as part of this change.</p> <p>Additionally, it also simplifies restoration efforts by providing essential information, such as Document ID, Generated Name, and Submitted Name.</p> <p>All Audit Trail Activities for Deleted Documents (CRUD) should provide:</p> <ul style="list-style-type: none"> • Activity Date/Time • Created By • Document ID • Document Name • Index Path • Activity Type • Activity Related Data 				
TTI-3783	Trial Master File (eTMF)	<p>This improvement in the Communication module adds the submitted document name at the top of the metadata panel, even after metadata has been selected. This ensures users always have context on the document they are working with, making it easier to understand and input the correct data.</p>	No	Yes	Minor	<p>Affected User: All Users.</p> <p>Impact: This improvement has a minor impact on the Communication module's metadata by displaying the submitted document name.</p>
TTI-3890	Trial Master File (eTMF)	<p>This improvement enables TI Automate to support multiple libraries, allowing clients to create and manage tailored document types, indexes, and workflows.</p>	Yes	No	Minor	<p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>Each library can be configured separately to meet specific client requirements, with documents being routed to the correct library based on Client ID and room.</p> <p>The system ensures that the correct library is selected during document upload, either automatically based on configuration or through user selection.</p>				Automate's flexibility, enabling clients to manage their documents according to unique needs and enhancing the overall user experience.
TTI-3892	Study Start-Up (SSU)	<p>With this improvement, only Super-Admins will have the ability to delete active sites that do not have associated documents.</p> <p>Before performing this action, Investigative Sites (IS) must be created and activated. Note that these Investigative Sites should not have any associated documents. Also, an Editor-level user cannot delete active sites.</p>	No	Yes	Minor	<p>Affected User: Super-Admins.</p> <p>Impact: This improvement enhances security and control by restricting the deletion of active sites to Super-Admins only.</p> <p>It ensures that only sites without associated documents can be deleted.</p>
TTI-3902	Platform	<p>This enhancement improves navigation in Search Results for Placeholders and Deleted Documents. The "Open in Room" and "Open in New Tab" buttons will now redirect users to the eTMF Completeness view for</p>	No	Yes	Minor	<p>Affected User: All Users.</p> <p>Impact: This improvement has a minor impact on the Search Results page, specifically affecting the</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>Placeholders and the Deleted Documents view for Deleted Documents.</p> <p>Additionally, the "Go to Folder" option will be disabled for these document types to streamline the user experience.</p>				<p>interaction with Placeholders and Deleted Documents.</p> <p>The buttons "Open in Room" and "Open in New Tab" will now redirect to the appropriate views (eTMF Completeness view and Deleted Documents view).</p>
TTI-3914	Study Start-Up (SSU)	This enhancement enhances the SSU module by adding a Required By column to the grid in the Required tab under Documents> Specific Amendment > Site/Country/IRB >.	No	Yes	Minor	<p>Affected User: All Users.</p> <p>Impact: This improvement has a minor impact on the Required tab in the SSU module.</p>
TTI-3916	Study Start-Up (SSU)	The 'Fill Metadata' tab in the Documents import section now includes the default selections for Country, IRB/EC, and IS Name when importing documents. Previously, the 'Country' field was left empty by default, even when the 'Country' category was selected in the import modal.	No	Yes	Minor	<p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on the default selection of Country, IRB/EC, and Is Name for the Metadata Tab.</p>
TTI-3956	Collaborate	The enhanced Read & Acknowledge feature now includes key UI enhancements and additional functionalities to ensure a seamless user experience.	Yes	No	Minor	<p>Affected Users: Editors and Above.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/ Risk	Comment / Impact Analysis
		Key Features <ul style="list-style-type: none"> View and select Study Name/ Protocol Number and Product Name(s) while selecting Site and User Recipients. Apply filters such as Study Name, Protocol Number, and Product Name to sort and refine the site list. Bulk Update contacts to eliminate the manual effort of setting multiple site users as recipients responsible for acknowledging the document. Multi-select functionality for selecting contacts and users to eliminate the effort of adding one record one at a time. Display users who have read and acknowledged a document with clear indications and a tooltip. Include the document title in the email subject line, providing clear evidence in the Communications module. Add a column chooser and filters in the acknowledgements panel, including custom fields from the site entity along with filters and fields that can display Product, Study, and Country details. Restrict acknowledgers from viewing document history or audit information for sites they do not have access to. Capability to include Contacts in User 				Impact: This improvement has a minor impact on the Send for Read & Acknowledge form and Sites modal.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>Groups, allowing for bulk notifications to many users who may not have user accounts.</p> <ul style="list-style-type: none"> • Capability to include the attachment in the bulk email notification for safety events. • Ensure that notifications are sent also to users, converted from contacts, who are not yet activated. 				
TTI-3974	Trial Master File (eTMF)	<p>TI Automate now includes robust reprocessing capabilities for handling changes to the model, metadata mappings, and configurations. Super admins can reprocess selected or all documents to apply updated settings, ensuring consistent and accurate results across the system.</p> <p>UI Functionality:</p> <ul style="list-style-type: none"> • Super admins can initiate reprocessing via a dedicated interface with filtering options. • A confirmation dialog ensures controlled and deliberate execution of reprocessing tasks. 	Yes	No	Minor	<p>Affected User: Super Admins</p> <p>Impact: This improvement has a major impact on document reprocessing workflows, providing super admins with greater control and accuracy when applying updates to prompts or configurations.</p>
TTI-3984	Trial Master File (eTMF)	<p>This improvement prevents access to the “Query” tab when the “Inspector Access” toggle is enabled. This ensures proper</p>	No	Yes	Minor	<p>Affected Users: Inspector Role.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>segregation of permissions and avoids unintended interactions.</p> <p>In this state, the “Query” tab is either visibly disabled or hidden from the user interface. If users attempt to access the tab directly via a URL or bookmark, they are redirected to the default landing page or shown an appropriate error message. When the toggle is off, authorized users can access the “Query” tab as usual.</p>				<p>Impact: This improvement has a minor impact on accessing the Query Tab.</p>
TTI-4113	Platform	<p>To ensure that every active site has an assigned Principal Investigator (PI) contact, the system now prompts admins when revoking access for a PI Contact who is also the Site User at an active site. If the admin attempts to revoke access for such a user, a prompt appears:</p> <p>“Do you want to revoke this user but maintain them as the PI Contact at this site?”</p> <ul style="list-style-type: none"> • If Yes, the user’s site access is revoked, but they remain assigned as the PI contact. • If No, another prompt appears: “If you wish to revoke this user, you must first assign another Contact as the PI at this site.” 	No	Yes	Minor	<p>Affected User: Admin and Above.</p> <p>Impact: This improvement has a minor impact on the process of revoking a PI contact who is also the Site user for an active site.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		The admin must assign a new PI contact before proceeding with the revocation.				
TTI-4130	Trial Master File (eTMF)	This update introduces the Mass Coding action in the Site Contacts section of the eTMF and SSU modules . Previously available in the eTMF/Contacts module , this functionality is now extended to the site profile, allowing users to efficiently apply bulk coding actions to multiple site contacts at once.	No	Yes	Minor	<p>Affected Users: Admin and Above.</p> <p>Impact: This improvement has a minor impact on Mass Coding actions in Site Contacts.</p>
TTI-4131	Trial Master File (eTMF)	This enhancement improves the visibility of checked-out documents for Team Edit by reflecting the status not only in the grid but also in the Quick View (QV) panel header . When a document is checked out for team editing, an icon will now appear in the QV panel, and the Title will include Team Edit information, providing users with a clear and consistent indication that the document is in use for team collaboration.	No	Yes	Minor	<p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on the Metadata Quick View Panel Headers.</p>
TTI-4132	Trial Master File (eTMF)	With this improvement, the room name display limit has been increased from 20 to 40 characters , allowing over 95% of current room names to be fully visible.	No	Yes	Minor	<p>Affected Users: All Users.</p> <p>Impact: This Improvement has a minor impact on the room name characters.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-163	Trial Master File (eTMF)	An improvement has been made to the Documents on the Completed Event report, to remove documents in the rejected status.	No	Yes	Minor	Affected Users: All Users. Impact: Users can now view only applicable data for this report.
Report-168	Trial Master File (eTMF)	An improvement has been made to the Timeliness Report, adding a column named 'Organization' to assist users in determining timeliness by organization.	No	Yes	Minor	Affected Users: All Users. Impact: Users can now more easily determine timeliness by organization.
Report-172	Trial Master File (eTMF)	This improvement makes several string changes within the TI report descriptions. Included in this are the removal of the words 'in the TI Docs room' where appropriate and the addition of the words 'in the eTMF'.	No	Yes	Minor	Affected Users: All Users. Impact: This change makes report descriptions more accurate.
Report-173	Trial Master File (eTMF), Collaborate	An improvement has been made to ensure the following reports Audit Summary Report, Documents Flagged as Potential Duplicates Report, Linked Documents report, Open Queries Report, and so on are visible for OOTB collaborate room templates on the Stage, Sandbox, and MTI environments:	No	Yes	Minor	Affected Users: All Users. Impact: This improvement has a minor impact on report visibility, ensuring the reports are now accessible in the specified environments.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
Report-180	Collaborate	An improvement has been made to the Controlled Document Information Report by removing the 'Division' column.	No	Yes	Minor	Affected Users: All Users. Impact: This improvement has a minor impact on the Controlled Document Information Report.
Report-181	Trial Master File (eTMF), Collaborate	This improvement allows users to manually select dates on the Document Activity Report.	No	Yes	Minor	Affected Users: All Users. Impact: Users no longer have to choose from 30, 60, or 90 days and can select more accurate dates.
Report-182	Trial Master File (eTMF)	<p>An improvement has been made to the Queries Report to improve the logic of the "Aging of Queries" column. This column calculates the duration between when a query was raised and the current date for open queries.</p> <p>However, for closed queries, the calculation now uses the formula: Query Age = Query Closed Date – Query Date, ensuring the age is fixed at the time of closure.</p> <p>For open queries, the calculation remains: Query Age = Current Date – Query Date.</p>	No	Yes	Minor	Affected Users: All Users. Impact: This improvement has a minor impact on the accuracy of the query age calculation for closed queries.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14219	Trial Master File (eTMF)	In the User Management section, sorting users by the Organization column does not function correctly. When attempting to sort the user list in ascending or descending order by Organization, the expected order is not achieved.	Minor	This issue had a minor impact on the sorting functionality in User Management. Correct system behavior has been restored.
TRL-15000	Trial Master File (eTMF)	The zero-case message does not appear when no results are returned after applying a filter. Users expect a message indicating that there are zero results and that they should clear the applied filters. However, no such message or indication is displayed, leaving users unaware of why no results are visible.	Minor	This issue impacts the usability of the grid view. Correct system behavior has been restored.
TRL-16293	Trial Master File (eTMF)	An incorrect tooltip appears when an Admin user without access to a linked room attempts to access it. Instead of displaying a tooltip indicating “no access to the room,” the system shows an “Unpublished room” tooltip.	Minor	This issue had a minor impact on the tooltip functionality for Admin users accessing linked rooms. Correct system behavior has been restored.
TRL-16610	Platform	Users have reported discrepancies in eSignature email notifications. Some links within the notifications are not functioning as expected, and users are receiving an excessive number of notifications. Additionally, premature eSignature notifications are being sent when documents are signed. This is causing confusion and inconvenience for users.	Major	This issue has a major impact on eSignature email notifications. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16623	Trial Master File (eTMF)	The link URL logic fails for users immediately after login. When accessing a specific URL copied from the application and pasting it into an incognito browser session, the user is redirected to the domain page instead of the intended page. This issue persists until the URL is re-entered after logging in.	Major	This issue had a major impact on the functionality of direct URL navigation for users after login. Correct system behavior has been restored.
TRL-16699	Platform	The user has observed that the Contact form has missing fields in Form Settings. After removing old hardcoded fields, an issue was identified: Certain fields, such as "TI Client Contact Id" - \$SponsorContactId\$, are now missing. Previously, this field could be enabled through the User Form Settings for Contact (Include in: Contact) and was used for API integrations.	Critical	This issue has a critical impact on user configurations and API functionality. Correct system behavior will be restored by reintroducing the missing fields with their original functionality.
TRL-16810	Trial Master File (eTMF)	A User with the Reader + RAI role (Full Access) is unable to export a document. When selecting a document and clicking the Export button, the Document option is greyed out and non-functional, preventing the user from initiating the export process.	Minor	This issue had a minor impact on the export functionality, preventing users with the Reader + RAI role (Full Access) from exporting documents. Correct system behavior has been restored.
TRL-16811	Trial Master File (eTMF)	Users with the Reader + RAI Role who have no access to download are able to click on the Action dropdown however, after clicking, nothing happens, and the dropdown does not appear. The expected behavior is that the Action button should be disabled for users without access to download to ensure consistency across the application.	Minor	This issue has a minor impact on the Reader + RAI Role users who does not have the permission to download. Correct system behavior has been restored by disabling the Action button for these users.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16852	Platform	Users are unable to drag or reposition the Auto-naming Rule window in the Document Types Management section. When the browser window is zoomed out to less than 90%, the Auto-naming Rule window becomes inaccessible.	Minor	This issue has a minor impact on the usability of the Auto-Naming Rule configuration. Correct system behavior has been restored.
TRL-16978	Trial Master File (eTMF)	A User is unable to remove a document from the redaction process and mark it as unrestricted. The document is currently in the "Waiting for Redaction" status.	Minor	This issue has a minor impact on the usability of the redaction process. Correct system behavior has been restored.
TRL-16992	Trial Master File (eTMF)	Users are unable to search for Site Contacts using the keyword search functionality. While the search works correctly when using the Site Name, it fails to return any results when searching by Contact Email Address or Contact Name.	Minor	This issue has a minor impact on Site Contact search functionality. Correct system behavior has been restored.
TRL-17173	Platform	As an Editor Workflow Approver with full access to a document are unable to assign a placeholder to the document. This issue affects the workflow functionality.	Critical	This issue has a critical impact on document (Editor) workflow functionality. Correct system behavior has been restored.
TRL-17193	Trial Master File (eTMF)	<p>Users in a Trial Interactive room have not received swim lane notifications since 22-Nov-2024. Despite verifying the workflow stages and the notification preferences in the user profile, the issue persists.</p> <p>Furthermore, enabling the nightly and mini newsletters for all workflow options and uploading a document did not resolve the problem.</p>	Major	This issue had a major impact on the notification functionality in the Trial Interactive Tralquest room, hindering users' ability to receive workflow-related updates. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17221	Trial Master File (eTMF)	An issue has been identified where the submission dates and times for general queries are missing in certain statuses. When a sender submits a general query for a document, the query submission time is not visible for queries in the “Pending” and “In Progress” statuses. However, the query submission time is displayed correctly for queries in the “Resolved” status. This inconsistency affects the ability to track the timeline for general queries effectively.	Major	This issue had a major impact on the ability to track general query timelines, affecting workflow transparency for queries in the “Pending” and “In Progress” statuses. Correct system behavior has been restored.
TRL-17250	Trial Master File (eTMF)	The client is unable to sign documents due to a “Server Error” message encountered during the signing process. When a user attempts to sign a document, the system displays the following error: “ <i>Server Error (The cause is in the Log file).</i> ” This issue prevents users from completing the signing process and impacts document workflows.	Critical	This issue had a critical impact on the document signing functionality. Correct system behavior has been restored.
TRL-17258	Trial Master File (eTMF)	The User noted that after clicking on the Potential Duplicates button. The Potential Duplicates window appears; however, it doesn’t have the document’s metadata.	Major	This issue has a major impact on the Potential Duplicates window’s Document Metadata. Correct system behavior has been restored.
TRL-16084	Study Start-Up (SSU)	In the SSU > Contacts module, users are unable to update fields such as Prefix, First Name, Last Name, Suffix, and Middle Name.	Minor	This issue had a minor impact on the ability to update contact details in the SSU module. Correct system behavior will be restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17266	Trial Master File (eTMF)	<p>The Sites Import functionality is experiencing the following issues:</p> <p>File Upload Error: When attempting to upload a .xlsx file via Sites Import, the system incorrectly displays an error message stating that the file should be a .xlsx file, even though the uploaded file is already in the correct format.</p> <p>File Path Issue: During the upload process, the file path displayed in the interface does not reflect the actual local file path. Instead, it always shows C:\fakepath as the file location.</p>	Major	This issue had a major impact on the Sites Import functionality, causing confusion and preventing successful uploads of valid .xlsx files. Correct system behavior has been restored.
TRL-17306	CTMS	<p>Site Visit Owners encountered the error 6017 messages in CTMS UI while attempting to generate a Site Visit Report.</p> <p>The Report Generation primarily failed due to the Username and Email Address mismatch.</p>	Critical	This issue had a critical impact on the Site Visit Report Generation process. Correct system behavior has been restored.
TRL-17307	Study Start-Up (SSU)	<p>When logged in as an Editor user in the Site Team group or Site Team/Site Activation Members group, the option to add or edit contacts in the Site Contacts grid is not available. Editor users in these groups should have access to add or edit contacts for sites created in the SSU room.</p> <p>However, there are no buttons to perform these actions. The same issue occurs when an Editor user in the Site Activation Members group accesses the SSU module. They should be able to add or edit contacts to the site, but this functionality is not available.</p>	Major	This issue had a major impact on the Editor level users in the Site Team and Site Activation members groups. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17323	Platform	The Add Assignee functionality is not working correctly. The assigned user does not receive the query email because the attachment file cannot be downloaded due to a file path encryption issue.	Critical	This issue has a critical impact on the Assign functionality. The assigned user does not receive the query email, which may delay or prevent timely responses. Correct system behavior has been restored.
TRL-17341	Trial Master File (eTMF)	<p>Users are encountering an issue in the CRA Reconciliation module where they are unable to change the "Visit status" to any option other than "Verified."</p> <p>The system allows users to select one of the other three available status options, but after saving and refreshing the documents, the status reverts back to the previous one.</p> <p>The status change remains only when "Verified" is selected, while the other three options revert to the earlier state.</p>	Major	<p>This issue has a major impact on users' ability to properly update and track visit statuses within the CRA Reconciliation module.</p> <p>Correct system behavior has been restored, allowing users to successfully change the visit status to any of the available options.</p>
TRL-17375	Trial Master File (eTMF)	When logged in as a manager, the "Add User" option incorrectly appears on the home screen. Managers should not have access to this feature. While they cannot proceed with adding a user, they can still view restricted information, including all Groups	Major	This issue had a major impact on the 'Add Users' process if the user has Manager level access. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17392	Platform	<p>A user reported that when exporting document metadata, the date appears in American format (MM/DD/YYYY) instead of European format (DD/MM/YYYY).</p> <p>After setting the European date format in Settings > General > About > Date Format, the date column reflects the correct format. However, the comment column still displays the date in American format (MM/DD/YYYY).</p>	Minor	<p>This issue had a minor impact on the date format functionality.</p> <p>Correct system behavior has been restored.</p>
TRL-17445	Platform	<p>The changes made earlier were to provide TI Analytics option only to elevated super admins, which needs to be reverted. Currently, even admins are unable to access the TI Analytics option. The TI Analytics option should be made available to both admins and Super-Admins.</p>	Critical	<p>This issue had a critical impact on the TI Analytics options for Admins and Super Admins.</p> <p>Correct system behavior has been restored.</p>
TRL-17476	Trial Master File (eTMF)	<p>Users have observed that there are two watermark options in the room settings: background and foreground. However, after testing both options, user have found that they produce identical results, with no visible difference in the watermark placement.</p>	Major	<p>This issue has a major impact on the watermark settings functionality. Users are unable to distinguish between the background and foreground watermark options as both produce identical results. Correct system behavior has been restored.</p>
TRL-17500	Trial Master File (eTMF)	<p>The user has identified an issue in the eTMF instance where, after approving the Confirmation Letter and Visit Report and marking them as effective, the documents fail to transfer to the linked eTMF room.</p>	Critical	<p>This issue had a critical impact on the document synchronization within the eTMF instance.</p> <p>Correct system behavior has been restored.</p>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17523	Platform	A User is unable to complete the eSignature process when a document is sent to three users for signing. While the first two users can successfully sign the document, the third user encounters an error message ("Server error: The cause is in the log file") and is unable to sign.	Minor	This issue has a minor impact on the usability of the eSignature functionality, as it prevents the completion of the signing process when multiple users are involved. Correct system behavior has been 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 Clients 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 by 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 PM can submit Ideas to our Perfective Change Management on your behalf




Focus Group

Meet with other Trial Interactive customers for an immersive Focus Group:


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

11. Approvals

Product Owner

Name: Jay Smith	Title: Senior Director, Product Management
Signature: Reason for signature: Date:	 <i>Electronically signed by: Jay Smith Reason: I approve this document. Date: Feb 26, 2025 09:06 EST</i>

Quality Assurance

Name: Conor McCabe	Title: Sr QA Specialist
Signature: Reason for signature: Date:	 <i>Electronically signed by: Conor McCabe Reason: I approve this document Date: Feb 26, 2025 15:08 GMT+1</i>