

# TRIAL INTERACTIVE V10.6.3 – RELEASE NOTES – V1.1



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## 1. Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	13-Mar-2025	Initial Document Creation
Samuel Pawar	0.2	28-Mar-2025	<p>Features:</p> <ul style="list-style-type: none"> <li>• Added: <ul style="list-style-type: none"> <li>○ TTI-3919</li> <li>○ TTI-3945</li> <li>○ TTI-3695</li> <li>○ TTI-3793</li> <li>○ TTI-4100</li> </ul> </li> <li>• Removed: <ul style="list-style-type: none"> <li>○ TTI-3967</li> <li>○ TTI-3921</li> </ul> </li> </ul> <p>Defect Resolutions:</p> <ul style="list-style-type: none"> <li>• Added: <ul style="list-style-type: none"> <li>○ TRL-17427</li> <li>○ TRL-17025</li> <li>○ TRL-17477</li> <li>○ TRL-17686</li> <li>○ TRL-17724</li> <li>○ TRL-17728</li> <li>○ TRL-17743</li> <li>○ TRL-17523</li> <li>○ TRL-17671</li> </ul> </li> <li>• Removed: <ul style="list-style-type: none"> <li>○ TRL-17545</li> <li>○ TRL-16978</li> <li>○ TRL-17500</li> </ul> </li> </ul> <p>Added Open Defects table.</p>
Samuel Pawar	1.0	28-Mar-2025	Initial version finalized.
Samuel Pawar	1.1	11-Jun-2025	<p>Updated description for Defect Resolution:</p> <ul style="list-style-type: none"> <li>• TRL-17356</li> </ul>

## 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 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:** **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 there will be no changes in scope.

### 3. Scope

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

System In Scope	
System Name	Trial Interactive
System Version	v10.6.3
Release Type	Patch

## 4. Definitions / Acronyms

Term	Definition/Description
<b>21 CFR Part 11</b>	The part of the United States Code of Federal Regulations that regulates electronic records and electronic signatures.
<b>API</b>	Application Programming Interface
<b>Annex 11</b>	The European Union’s guidance for using electronic records and signatures in the pharmaceutical industry.
<b>CRO</b>	Clinical Research Organization
<b>CSM</b>	Customer Success Manager
<b>CTMS</b>	Clinical Trial Management System
<b>DICOM</b>	Digital Imaging and Communications in Medicine
<b>ERES</b>	This document provides guidance in the United States for using electronic systems, records, and signatures in clinical investigations.
<b>GDPR</b>	The General Data Protection Regulation is a set of rules laid out by the European Union regarding data privacy rights.
<b>GxP</b>	An abbreviation generally accepted to refer to accepted standards of good practices.
<b>IDP</b>	Identity Provider
<b>JIRA</b>	A proprietary issue-tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management.
<b>KPI</b>	Key Performance Indicator
<b>LMS</b>	Learning Management System
<b>MDE</b>	Metadata Extraction
<b>MFA</b>	Multi-Factor Authentication
<b>OOTB</b>	Out of the Box
<b>SFTP</b>	A secure File Transfer Protocol
<b>SLA</b>	Service Level Agreement
<b>SOP</b>	Standard Operating Procedure
<b>SQA</b>	Software Quality Assurance
<b>SQL</b>	Structured Query Language
<b>SSO</b>	Single Sign On
<b>SSU</b>	Study Start-Up
<b>TI</b>	Trial Interactive
<b>TP</b>	TransPerfect
<b>Testiny</b>	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)	
<b>Date of Release</b>	28-Mar-2025
<b>Estimated US MTI Upgrade Date/Time:</b>	28/Mar/2025 9:00 PM
<b>Estimated EU MTI Upgrade Date/Time:</b>	28/Mar/2025 5:00 PM
<b>Estimated China MTI Upgrade Date/Time:</b>	04/Apr/2025 12:00 AM
<b>Date of Dedicated Client Upgrade:</b>	For information about upgrading your dedicated instance to this new version, please contact your <b>TransPerfect</b> Customer Success Manager.



## 7. Hardware and Software Requirements

The following describes the hardware and software requirements to use the Trial Interactive v10.6.3 platform.

System Requirements	
<b>Operating System</b>	<ul style="list-style-type: none"> <li>Windows Version 7 or higher</li> <li>All currently supported Mac OSX releases</li> <li>iOS and Android for my mobile app (see myTI release notes)</li> </ul>
<b>Browser</b>	<ul style="list-style-type: none"> <li>Microsoft Edge: Version 88 and later</li> <li>Google Chrome: Current release and earlier</li> <li>Mozilla Firefox: Current and ESR releases</li> <li>Apple Safari: Current release and earlier</li> <li>NOTE: TI Sign requires that pop-up blockers be disabled for the Trial Interactive domain.</li> </ul>
<b>Client Software</b>	<ul style="list-style-type: none"> <li>For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally.</li> <li>For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred).</li> <li>Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer.</li> <li>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®.</li> </ul>
<b>Optional Add-Ons</b>	<ul style="list-style-type: none"> <li>DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions)</li> <li>Adobe Sign (Latest Adobe Document Cloud Version)</li> <li>Optional: SAS Viewer or compatible software must be installed for SAS Datasets. The free version is available here: <a href="https://support.sas.com/downloads/browse.htm?fil=&amp;cat=74">https://support.sas.com/downloads/browse.htm?fil=&amp;cat=74</a></li> </ul>

## 8. Changes

### Legend for Impacts

Trial Interactive v10.6.3 has been released with these enhanced features and defect fixes. These tables use the following definitions of customer Impact:

- **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.
- **Blocker** - A Blocker defect refers to a critical issue that completely prevents further progress in development or testing.
- **None** - This is a cosmetic or extremely minor change with no impacts or risks.

### 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/Risk	Comment / Impact Analysis
TTI-3695	Collaborate	<p>An email notification system has been added to inform document owners and proxy owners when documents, such as visit reports and letters, are automatically shared or copied from the CCR room to the linked eTMF room. This enhancement ensures better visibility and eliminates uncertainty around document publication.</p> <p><b>Key Functionality:</b></p> <ul style="list-style-type: none"> <li>• Notifications are triggered upon successful or failed auto-sharing from the CCR room to the eTMF.</li> <li>• Emails include key document details and failure reasons (if applicable).</li> <li>• Notifications are sent from the Collaborate room, even if the document owner lacks access to the eTMF.</li> <li>• The Newsletter Notification format has also been updated to reflect this change.</li> </ul>	Yes	No	Minor	<p><b>Affected User:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on an email Notification when the document is auto-sharing/copying from the CCR room to the linked eTMF room.</p>
TTI-3793	eTMF	<p>This improvement has added the expand all option to the quality review module to allow documents to be assigned to auditor in bulk. The subfolder will be expanded in order to select the document to reassign to another auditor.</p>	No	Yes	Minor	<p><b>Affected User:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Quality Review Module Expand Functionality.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
TTI-3919	SSU	<p>To enhance user awareness, the Country Status is now displayed in the left panel of the Site view.</p> <p>The Site Panel now highlights the country's status when <b>Closed, Rejected, or Cancelled</b>. Even if all site requirements and IRB/EC progress are met, the site <b>cannot be activated</b> if the country has one of these statuses. This update ensures that users are immediately informed of any country-level restrictions that impact site activation, preventing unnecessary delays and improving workflow efficiency.</p>	No	Yes	Minor	<p><b>Affected User:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Country Status in the left panel of the Site view.</p>
TTI-3945	Platform	<p>A feature enables specific filter fields in the data grid to dynamically populate lists of values based on available data within the current record scope. This enhancement improves filtering accuracy and efficiency in document profile-based views.</p> <p><b>Key Features:</b></p> <ul style="list-style-type: none"> <li>• <b>Configurable Filter Fields:</b> Room administrators and managers can enable data-driven lists for designated fields in Room Settings &gt; Document Form.</li> <li>• <b>Dynamic Value Population:</b> Configured filter fields pull unique values from the current data set and update dynamically as data changes.</li> </ul>	Yes	No	Critical	<p><b>Affected User:</b> All Users.</p> <p><b>Impact:</b> This improvement has a critical impact on document filtering by enabling dynamic value population in filter fields. It enhances user experience, improves efficiency, and ensures data consistency in the document module.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<ul style="list-style-type: none"> <li>• <b>Improved User Experience:</b> Users see dropdowns or selection lists populated with relevant values when interacting with configured filter fields.</li> <li>• <b>Performance Optimization:</b> Efficient loading mechanisms, such as caching or indexing, minimize delays, especially for large datasets.</li> <li>• <b>Configuration Interface:</b> A new “Filter Dropdown List” attribute in the advanced UI allows super admins to enable or disable data-driven lists for specific fields.</li> <li>• <b>Error Handling:</b> If no values are available for a selected filter field, a message “No values available” will be displayed.</li> <li>• <b>Default Enabled Fields:</b> Includes fields such as Category, Document Type, Site, Contact Name, Submission Date, Workflow Stage, and Language, and so on.</li> </ul>				
TTI-4100	Platform	<p>The metadata panel is now fully adjustable again, allowing users to resize its width by clicking and dragging the border. Previously, restrictions on resizing made it difficult to view long document names or adjust the panel for better workspace management.</p> <p>This enhancement restores flexibility, enabling users to widen or narrow the</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Metadata Panel resizing functionality.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		metadata panel as needed without fully closing it, improving overall usability.				
TTI-4106	Collaborate	<p>This enhancement improves the merge compare functionality for visit reports, enabling users to more effectively compare, review, and copy content between a rejected version and its newly regenerated counterpart. The goal is to streamline the editing process and preserve valuable feedback.</p> <p><b>Key Improvements:</b></p> <ul style="list-style-type: none"> <li>The regenerated visit report is now set as the baseline during comparison, allowing users to selectively accept content from the previously rejected version.</li> <li>Users can now view both versions side-by-side within the editor, making it easy to compare content and copy information between documents.</li> <li>These enhancements aim to reduce redundant effort for CRAs and ensure continuity in feedback and report refinement.</li> <li>Functionality is designed for visit reports within CTMS, but lays the groundwork for broader support within Collaborate.</li> <li>All comments from the original (rejected) report are retained and visible during the comparison</li> </ul>	No	Yes	Minor	<p><b>Affected User:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the comparison functionality of the last rejected version of the visit report and the newly regenerated version.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		process, enabling users to review and respond.				
TTI-4146	Collaborate	<p>This improvement improves the R&amp;A process by ensuring site names are accurately filled in when sending notifications to Site User recipients. It also ensures each Site User receives the R&amp;A only once, even if they are associated with multiple clinical sites.</p> <p><b>Key Features:</b></p> <ul style="list-style-type: none"> <li>• <b>Site Association for R&amp;A Recipients:</b> Automatically associates site names with Site User recipients to ensure accurate reporting.</li> <li>• <b>One-Time Notification:</b> Ensures each Site User receives the R&amp;A or notification only once, regardless of their affiliation with multiple sites.</li> <li>• <b>Enhanced Reporting:</b> The report will show the correct site associations for each recipient, helping the users to track which site each user was notified or acknowledged from.</li> <li>• <b>Pre-fill Site Data:</b> The site(s) associated with a user will be pre-filled during R&amp;A creation, preventing reporting issues and making it easier to view the associated sites.</li> <li>• <b>Updated Site Selection Logic:</b> Users can now be selected across all sites, not just the ones previously selected, ensuring</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the Site Names when sending an R&amp;A to Site User Recipients.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact/Risk	Comment / Impact Analysis
		<p>complete site data for notifications.</p> <ul style="list-style-type: none"> <li><b>Metadata Export:</b> Added ability to export R&amp;A and compliance information from the R&amp;A status screen for easier tracking and reporting.</li> </ul>				
TTI-4147	Collaborate	<p>This improvement enabled the bulk import function for editor users, allowing them to efficiently upload multiple records at once. Drag and Drop functionality is also working smoothly for editors.</p>	No	Yes	Minor	<p><b>Affected Users:</b> Editor and Above.</p> <p><b>Impact:</b> This improvement has a minor impact on the bulk import functionality for editor-level users.</p>
Report-183	eTMF	<p>This improvement updates the column titles in the Quality Review Audit Summary Report for better clarity. The following changes have been made:</p> <ul style="list-style-type: none"> <li>"% quality of a quality review" to "% of Documents Passed"</li> <li>"No. of published docs in the room" to "Number of Published Documents in the QR Audit"</li> </ul>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement impacts the column titles in the Quality Review Audit Summary Report.</p>
Report-185	Collaborate	<p>This improvement enhances the Study Level Acknowledgement Report by adding a new column, 'Contact User Name Email Address,' after the existing 'Contact User Name' column. This change provides additional clarity by including the email address associated with each contact user in the report.</p>	No	Yes	Minor	<p><b>Affected Users:</b> All Users.</p> <p><b>Impact:</b> This improvement has a minor impact on the Study Level Acknowledgement Report by adding a new column, 'Contact User Name Email Address.'</p>



**B. DEFECT RESOLUTIONS**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15272	SSU	A user without access to the site receives an incorrect information message when attempting to activate the SSU site. The displayed message states: <i>"To activate the Site, the following condition needs to be fulfilled: Activate the country of the site."</i> However, the issue was not pertaining to the Country requiring activation, but the right access for the user to activate the site.	Minor	This issue had a minor impact on site activation by displaying an incorrect info message. <b>Correct system behavior has been restored.</b>
TRL-16812	eTMF	User noted an issue "Delete Document" action is added to the Actions Taken drop-down, but when searching using this action, No Records is returned, despite the fact that there is a deleted document in the room. Audit Trail filtered by Delete Document action returns results ONLY if the search is performed by Document ID.	Minor	This issue has a minor impact on the deleted document search. <b>Correct system behavior has been restored.</b>
TRL-17025	eTMF, SSU	When updating custom contact fields in both the <b>eTMF</b> and <b>SSU</b> modules, the changes are not saved. Despite modifying the fields and clicking <b>Save</b> , the custom field values remain empty upon rechecking. This issue prevents users from storing necessary contact details, impacting data consistency and usability.	Critical	This issue had a critical impact on saving the contact information in the Custom Contacts fields. <b>Correct system behavior has been restored.</b>
TRL-17163	SSU	This bug fix has resolved an issue where the <b>Submitted Name</b> field was not auto-populating when users uploaded a document to a <b>Site Placeholder</b> . With this fix, the field will now prefill as expected, ensuring a smoother and more efficient document upload process.	Minor	This issue had a minor impact on the document upload process by preventing the <b>Submitted Name</b> field from auto-populating when uploading a document to a site placeholder. <b>Correct system behavior has been restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17356	eTMF	The user is unable to upload any document to the specific room. A warning message is displayed during the upload process: <i>"Exception occurred in Create topic."</i> As a result, the documents are not uploaded.	Blocker	This issue had an impact on the document upload functionality. <b>Correct system behavior has been restored.</b>
TRL-17427	eTMF	<p>The Select/Unselect All button now functions as expected when selecting sites for Read &amp; Acknowledge (R&amp;A). Users can reliably select or deselect all sites without random selections or inconsistent behavior.</p> <p>Users can now properly enable and edit the <b>"Contact is responsible for Read &amp; Acknowledge Documents"</b> checkbox. Previously, the checkbox became greyed out when editing a contact under a site, preventing modifications. This issue has been fixed, restoring full functionality.</p>	Major	This issue had a major impact on the Select/Unselect All button, Malfunction and Contact Checkbox functionality. <b>Correct system behavior has been restored.</b>
TRL-17477	Platform	<p>A user encountered an issue when sending documents for signature in CCR rooms. When selecting CRA as the document Author and CSM as the document Reviewer, the system automatically removes one of the signers in certain cases. This behavior occurs only the first time the document is sent for signature and is difficult to replicate consistently.</p> <p>The issue was observed in production, with an attached MP4 video demonstrating the bug. At 0:26 in the video, the problem occurs when the user assigns CSM as the Reviewer and then clicks into the white space under the Reviewer field, at which point the reviewer disappears. The Reviewer (CSM) disappears after being added, preventing proper document routing.</p>	Major	This issue had a major impact on the document signature workflow in CCR rooms, specifically affecting the ability to retain assigned reviewers. The system intermittently removes the reviewer when selecting <b>CSM as the Reviewer</b> and clicking into the white space under the reviewer field. <b>Correct system behavior has been restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17491	eTMF	When a user attempts to import a document and selects the "Investigative Site" category in the Fill Metadata tab, the 'Select Site' dialog does not display any available sites, despite a site being present in the room.	Major	This issue prevents users from selecting an investigative site when importing a document. <b>Correct system behavior has been restored.</b>
TRL-17523	eTMF	There is an issue with the eSignature functionality in the system. When a document is sent to three users for eSignature, only two users are able to successfully sign. The third user, attempting to sign last, encounters a server error ("The cause is in the log file") and is unable to complete the signature process.	Major	This issue had a major impact on the signature functionality. <b>Correct system behavior has been restored.</b>
TRL-17662	eTMF	In the MTI US instance, attempting to add an existing user to a room resulted in the error message: "Error while creating and registering users for room." Due to this error, users were not successfully added to the room.	Major	This issue had a major impact on user management by preventing the addition of existing users to a room due to an error. <b>Correct system behavior has been restored.</b>
TRL-17671	SSU	Users are experiencing an issue in SSU where IRB document placeholders are not appearing as expected under the "Required Documents" tab at the site level. Although IRB documents have been correctly set up with the PI and Sub-Investigator assigned as responsible parties, and the site contacts have been marked as "Responsible for providing documents," only one of the three configured document types is appearing.	Major	This issue had a major impact on the IRB document Placeholders. <b>Correct system behavior has been restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17686	SSU	In Site Activation, a discrepancy has been observed in the previous version where a reported Site remains incomplete at 95% despite having no missing documents and no pending placeholders. Additionally, the system displays an inconsistency in the Required Documents Count: The system shows 21 required documents, but the grid only displays 20 documents.	Minor	This issue had a minor impact on the Site completion calculation and required documents display, causing incorrect status representation. <b>Correct system behavior has been restored.</b>
TRL-17724	eTMF	Users are experiencing an issue in MTI US, where attempting to view Queries by Site in the Queries Module results in a “ <b>Error</b> ” warning message. This prevents users from accessing query details for the affected site.	Minor	This issue had a minor impact on the <b>Queries Module</b> , restricting access to queries for the affected site. <b>Correct system behavior has been restored.</b>
TRL-17728	eTMF	A reader user is unable to e-sign a document using TI Digital Signature (MSB) when accessing it via the e-signing portal. The document is sent to the user through an email from the <b>TI Room</b> , but when the user attempts to access it, the page appears empty instead of displaying the document for signing. However, <b>TI E-Sign functions as expected</b> , allowing the user to e-sign the document and revoke access afterwards.	Blocker	This issue had an impact on the <b>TI Digital Signature (MSB)</b> workflow. <b>Correct system behavior has been restored.</b>
TRL-17743	eTMF	Users are experiencing an issue when creating a Quality Review document, query results in the wrong user name appearing in the <b>Auditor-Name</b> field. When an assigned auditor attempts to create a query, the system incorrectly populates another user’s name in the query email template.	Major	This issue had a major impact on the Audit Name field in the Quality Review Module. <b>Correct system behavior has been restored.</b>

## 9. Open Defects

Trial Interactive v10.6.3 has been released with these known issues. This table uses the following definitions of severity:

- **Critical** – A core functionality returns invalid results or does not function as expected.
- **Major** – This Defect has an impact on basic functionality.
- **Blocker** - A Blocker defect refers to a critical issue that completely prevents further progress in development or testing.
- **Minor** – There may be a small impact on business in specific use cases.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-11642	Platform	When users perform a document search by entering the full name of the document, the search results populate correctly. However, when users search using only a partial name of the document, no results are returned. This issue is inconsistent with expected behavior, where partial searches should retrieve matching documents.	Minor	This issue has a minor impact on the search functionality. <b>Correct system behavior will be restored.</b>
TRL-12195	Platform	Users noted an issue with a specific room in the MTI US instance, where Regulatory Packet emails sent from the room to the Main Contact are not using the correct email domain configured at the room level. Instead, the system is incorrectly pulling the email domain from the cross-study level, leading to misaligned sender information.	Minor	This issue has a minor impact on the email functionality while sending the Regulatory Packet. <b>Correct system behavior will be restored.</b>
TRL-13555	Platform	User noted an issue MTI US instance reporting an issue during document coding. When the user selects Category: Site and then Investigative Site, the Site field becomes grayed out, and the site details disappear upon choosing the document type. However, once the document is approved, the Investigative Site details reappear. Additionally, the user encounters a "Network Error"	Minor	This issue has a minor impact on the visibility of Site details. <b>Correct system behavior will be restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15019	eTMF	User has noted that the Manager-level users are automatically assigned group actions upon creation, even if not added to any group.	Minor	This issue causes new Manager-level users to receive default group actions that cannot be removed, despite not being associated with a group. <b>Correct system behavior will be restored to prevent unintended action assignments.</b>
TRL-15324	eTMF	Editor-level users in the "General Query Responder" group are unable to assign queries, as the "Add Assignee" option is grayed out in the General Query module.	Minor	This issue has a minor impact on assigning the queries for editor-level users. <b>Correct system behavior will be restored.</b>
TRL-15397	Platform	User has noted that the signature in a Document is viewable in the Original viewer but not in the TI Document viewer.	Minor	This issue has a minor impact on viewing the document in the TI document viewer. <b>Correct system behavior will be restored.</b>
TRL-16021	eTMF	When performing a room search on the Home Page, the submission date is displayed using the server's time zone instead of the room's configured time zone.	Minor	This issue has a minor impact on the room search on the Home Page. <b>Correct system behavior will be restored.</b>
TRL-16345	Platform	In the Setting - client management user noted that not all controls are displayed on the organization tab when editing.	Minor	This issue has a minor impact on the organization's controls visibility. <b>Correct system behavior will be restored.</b>
TRL-16899	Collaborate	User noticed an issue in MTI US that the alignment for Rows and Columns in the grid view is jumbled if we oversize the header row.	Minor	This issue has a major impact on the Alignment in the grid view for rows and Columns. <b>Correct system behavior will be restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-16959	eTMF	Users are experiencing an issue in the major previous version where mass coding non-final documents still requires a reason, even when the "Enable Causality Tracking for final documents metadata edit" setting is disabled. When an editor attempts to mass code metadata for non-final documents, the system incorrectly prompts for a reason.	Minor	This issue has a minor impact on the Mass Coding functionality when Enable Causality Tracking is Not Enabled. <b>Correct system behavior will be restored.</b>
TRL-17005	eTMF	Certain finalized documents are showing the message "This document profile does not have an associated document" when accessed. Initially, the documents opened with a visible file size (e.g., 369.6KB), but later attempts showed no file size, indicating possible corruption. There are no related errors in the logs.	Minor	This issue has a impact on access to the finalized document in the Study. <b>Correct system behavior will be restored.</b>
TRL-17023	Platform	<p>Users have identified an issue in the MTI US instance related to the metadata updates in QDMS rooms. When checking a particular document, the "Last Updated By" column displays "System Account-Account" instead of an actual user.</p> <p>Upon reviewing the Document History, we observed the following entry:</p> <ul style="list-style-type: none"> <li>• Updated by: System <b>Account-Account</b></li> <li>• Heading: Metadata Field was Updated</li> <li>• Activities Details: Is Signed, old: "", new: ""</li> </ul> <p>This indicates that the system is automatically updating metadata fields—even when there is no meaningful change—which is not desired behavior</p>	Minor	This issue has a minor impact on the metadata history tab. <b>Correct system behavior will be restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17141	Platform	There is an issue where, upon uploading a single document using a client-provided Word template, the system does not retain the original font formatting. After the document is uploaded and processed through the Workflow or E-Signature stages, the font changes from Calibri to Times New Roman.	Minor	This issue has a major impact on the font formatting consistency. <b>Correct system behavior will be restored.</b>
TRL-17167	eTMF	User noted that password password-protected document is not opening in the TI viewer.	Minor	This issue has a major impact on accessing the password-protected document in TI Viewer. <b>Correct system behavior will be restored.</b>
TRL-17187	Platforms	In the MTI US instance, there is an issue where the text color in the footer cannot be changed to black when editing fillable fields using the Content Control settings. Even after updating the color to black and saving the changes, the footer text remains grey.	Minor	This issue has a major impact on the Content Control Setting. <b>Correct system behavior will be restored.</b>
TRL-17228	Platform	User noted an issue when trying to view Excel or PowerPoint in the document template; users are unable to do that.	Minor	This issue has a major impact on viewing the Excel or PowerPoint in the document templates. <b>Correct system behavior will be restored.</b>
TRL-17321	eTMF	In the system, when a contact is deactivated from a site, the metadata updates correctly to show "Not Specified." However, the contact's name still remains in the Document Name, as defined by the auto-naming rule. Even after regenerating the names from Room Settings, the Document Name does not update to reflect the removal of the deactivated contact.	Minor	This issue has a major impact on the Metadata updates for contacts. <b>Correct system behavior will be restored.</b>



Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17467	Platform	We are facing an issue in the MTI instance where a specific document in a reported room cannot be opened in either TI or Original View. Additionally, when exporting the checksum file via SFTP, the document details are missing.	Minor	This issue has a minor impact on accessing the document in TI and Original Viewer. <b>Correct system behavior will be restored.</b>
TRL-17469	eTMF	The user reported an issue where a document is not opening correctly in the TI Viewer. Replicated the issue in a test room, and the behavior remained the same. However, after enabling OnlyOffice-supported file extensions for .pdf, the document opened and displayed correctly.	Minor	This issue has a major impact on accessing the document in TI Viewer. <b>Correct system behavior will be restored.</b>
TRL-17675	Platform	Users are experiencing an issue where adding a new contact to a site is not working as expected. When attempting to add the contact, the Save button remains unresponsive, preventing the contact from being saved.	Minor	This issue has a major impact on adding a new contact on the site. <b>Correct system behavior will be restored.</b>
TRL-17709	eTMF	Users have encountered an issue in the MTI US instance, where several sites with a status of "Non-participating" are incorrectly showing as "No" in the Grid view. Instead of Yes.	Minor	This issue has a major impact on the Site with Non-Participating Status. <b>Correct system behavior will be restored.</b>
TRL-17732	eTMF	In the MTI US instance, we are unable to select all sites in the Safety Letter Acknowledgement screen. When selecting sites from the search results, only those on the first page are selected, and the selections are lost upon navigating to the next page.	Minor	This issue has a minor impact on the Site search functionality when sending the document for reading and acknowledgment. <b>Correct system behavior will be restored.</b>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-17782	eTMF	There is an issue with the "Copy to Another Room" functionality where, if a user marks the document as Final during the copy process, the document is incorrectly moved to the Staging folder instead of the final index location. Room settings have been verified—Document Finalization is enabled, and the document types and related folder configurations are properly set up in both source and target rooms.	Minor	This issue has a minor impact on the "Copy to Another Room" Functionality. <b>Correct system behavior will be restored.</b>
TRL-17821	Platform	Users are facing an issue where if users try to open the Workflow Query response, we are not able to view the Query Response Document. It shows only a blank screen.	Minor	This issue has a minor impact on viewing the Query Response Document. <b>Correct system behavior will be restored.</b>
TRL-17842	eTMF	Users have identified an issue where the Audit Trail page in the Collaborate Room does not display the E-Signature activity in the dropdown when a document is signed via the Change Control Workflow.	Minor	This issue has a impact on the Audit Trail Activity. <b>Correct system behavior will be restored.</b>
TRL-17545	eTMF	The Contact name on the placeholder is showing wrong on the room. When viewing the eTMF Completeness View, the Sub-Investigator's first name is displaying incorrectly.	Minor	This issue had a major impact on the eTMF Completeness View. <b>Correct system behavior will be restored.</b>

## 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 according to 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

<p>US: 888-391-5111 (TOLL-FREE)</p>	<p><a href="mailto:help@trialinteractive.com">help@trialinteractive.com</a></p>	<p>Available twenty-four (24) hours a day, seven (7) days a week, three-hundred-sixty-five (365) days a year</p>
<p>European Union, Madrid, Spain +44 (20) 45182755</p>	<p><a href="mailto:eu.help@trialinteractive.com">eu.help@trialinteractive.com</a></p>	<p>Monday – Friday, 9 AM – 6 PM CET.</p>
<p>China +86 (755) 66856062</p>	<p><a href="mailto:cn.help@trialinteractive.com">cn.help@trialinteractive.com</a></p>	<p>Monday – Friday, 9 AM – 6 PM Beijing Time</p>

## 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



### Focus Group

Meet with other Trial Interactive customers for an immersive CEP Forum:

- 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:	

### Quality Assurance

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