

TRIAL INTERACTIVE V10.6.1 – RELEASE NOTES – V1.0



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2. Version History

| Author | Revision # | Date | Comment |
|--------------|------------|-------------|---|
| Samuel Pawar | 0.1 | 20-Dec-2024 | First Draft Created |
| Samuel Pawar | 0.2 | 03-Jan-2025 | <p>Added Features:</p> <ul style="list-style-type: none"> • TTI-3886 • TTI-3912 • TTI-3098 • Report-167 <p>Added Defect Resolutions:</p> <ul style="list-style-type: none"> • TRL-13226 • TRL-14219 • TRL-16680 • TRL-16714 • TRL-16828 • TRL-16847 • TRL-16864 • TRL-16872 • TRL-16874 • TRL-16892 • TRL-16893 • TRL-16905 • TRL-16946 • TRL-16977 • TRL-17053 <p>Removed Features:</p> <ul style="list-style-type: none"> • TTI-3886 • TTI-3902 • TTI-3912 • TTI-3960 • TTI-3937 <p>Removed Defect Resolutions:</p> <ul style="list-style-type: none"> • TRL-16559 • TRL-13226 <p>Added Open Defects table.</p> |
| Samuel Pawar | 1.0 | 03-Jan-2025 | Initial version finalized. |
| Samuel Pawar | 1.1 | 08-Aug-2025 | Updated description for feature ETMF-696 |

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 | v10.6.1 |
| 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 | 03-Jan-2025 |
| Estimated US MTI Upgrade Date/Time: | 03/Jan/2025 9:00 PM |
| Estimated EU MTI Upgrade Date/Time: | 03/Jan/2025 5:00 PM |
| Estimated China MTI Upgrade Date/Time: | 10/Jan/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 v10.6.1 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 v10.6.1 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 |
|------------|--------------------------|---|----------------|---------------------|--------------|---|
| ETMF-696 | Trial Master File (eTMF) | <p>With this enhancement, users can now fulfill placeholders directly from the metadata coding panel during document type selection and approval. This improvement streamlines the process of assigning documents to placeholders, reducing manual tracking and improving efficiency.</p> <p>Key Features:</p> | No | Yes | Minor | <p>Affected Users: All eTMF users who are involved in document coding and approval workflows. Editor and above.</p> <p>Impact: This improvement has a minor impact on the</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/Risk | Comment / Impact Analysis |
|------------|-------------------|--|----------------|---------------------|-------------|---|
| | | <ul style="list-style-type: none"> When saving a document, users are prompted with a list of matching placeholders based on document type and metadata, with options to “Skip for Now”. When there is a single matching placeholder that aligns with document type, site, country, and contact (including placeholders within events), the document will be auto-assigned to the placeholder. If multiple events contain matching placeholders, users will be prompted to manually select the correct placeholder instead of automatic assignment, ensuring accuracy. | | | | Placeholder Fulfilment section in the Metadata Coding Panel. |
| TTI-3098 | Collaborate (CMS) | <p>This new capability allows Superadmins to import and migrate both major and minor current document versions, with automatic placement into Change Control workflows.</p> <p>Users can now import documents from an Excel spreadsheet with new options to import versions. Imported documents are automatically placed in the specified workflow, with correct metadata assignment, including workflow settings, version numbers, effective dates, and periodic review details.</p> | No | No | Minor | <p>Affected User: Super-Admin.</p> <p>Impact: This improvement has a minor impact on migrations and Change Control Documents.</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/Risk | Comment / Impact Analysis |
|------------|-------------------------|--|----------------|---------------------|-------------|--|
| | | A new structured import capability for Change Control documents has been introduced, enabling users to import multiple versions while maintaining accurate associations with a common document profile. This enhancement supports critical metadata fields required for regulatory and review cycles, ensuring a streamlined and error-free import process for large-scale content migrations. | | | | |
| TTI-3410 | Collaborate (CMS), CTMS | Document Owners and Authors can now compare original visit reports with newly regenerated versions in two different ways. They can still do it side by side as is currently supported, showing the regenerated and original version with text changes side by side. They can now also compare the regenerated version to the original one with a 'merge comparison'. This merges the old and the new together, allowing the user to accept or reject the changes made against the document. This also enables users to view comments from the original report to the new version, replying to those comments and showing the comments in-line with the selected text, improving efficiency and accuracy in managing visit reports. | No | Yes | Minor | <p>Affected Users: Editor and above.</p> <p>Impact: This improvement has a minor impact on the visit reports comparison functionality.</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/ Risk | Comment / Impact Analysis |
|------------|-------------------|---|----------------|---------------------|--------------|---------------------------|
| | | <p>Key Features:</p> <ul style="list-style-type: none"> • (Original) Side-by-Side Comparison: View the original and regenerated reports simultaneously with highlighted differences, including added or modified content. • Merge, Accept, and Decline Capability: Show the original Comments and Accept formatted text and data from the original report to the new one while retaining formatting. • Comment Visibility: Access and view all comments from the original report during comparison. • Protected Original Report: Ensure the original report remains un-editable while still allowing data and comments to be referenced and copied. <p>Important Notes:</p> <ul style="list-style-type: none"> • When CRAs and Reviewers choose to 'Compare Versions', they will be prompted at times to accept all changes. They should choose Yes in order to ensure they will see all the | | | | |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/Risk | Comment / Impact Analysis |
|------------|-------------------|---|----------------|---------------------|-------------|---------------------------|
| | | <p>changes and comments in the merged report.</p> <ul style="list-style-type: none"> When CRAs regenerate a report and view it, they must choose to 'Compare Versions' against the prior version before they will see the comments from the original report. From here they may respond to the comments if desired. When Reviewers view a regenerated report, they must choose to 'Compare Versions' against the prior version in order to see the comments from the original report. From here they may respond to the comments if desired. When CRAs or Reviewers make additional comments or respond to comments during their review, they must be sure to save their changes. If they instead 'Leave Compare Mode', their comment changes will not be saved. | | | | |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/ Risk | Comment / Impact Analysis |
|------------|--------------------------|--|----------------|---------------------|--------------|---|
| TTI-3797 | Trial Master File (eTMF) | Users can now download the original file associated with a query, even before it is resolved. This enhancement allows teams to access and review native documents, such as Word files, without waiting for query resolution. | No | Yes | Major | <p>Affected Users: Editor and above.</p> <p>Impact: This improvement has a major impact on the downloading functioning while viewing the query.</p> |
| TTI-3839 | Platform | <p>This improvement removes UserName-Email validation to check that the UserName of one user can't be the same as the Email Address of another user.</p> <p>Additionally, API logic has been updated, including GetUserByUserName, to ensure users are only identified by their UserName and not by Email Address. This change eliminates potential conflicts where a UserName matches another user's Email Address.</p> | No | Yes | Major | <p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on the UserName email validation in the platform.</p> |
| TTI-3885 | Study Start-Up (SSU) | The document management process between SSU and eTMF has been refined to enhance control and efficiency. Only Admin users will now have the ability to manually move documents from SSU to eTMF, ensuring tighter access control. | No | Yes | Minor | <p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on handling eTMF and SSU documents.</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/ Risk | Comment / Impact Analysis |
|------------|-------------------|--|----------------|---------------------|--------------|--|
| TTI-3894 | Platform | <p>The "Copy/Share" button in the Document Cart has been renamed back to "Copy" in the following scenarios:</p> <ol style="list-style-type: none"> 1. Collaborate rooms with the "Publishing" distribution mode selected. 2. Collaborate rooms with "Sharing" distribution mode selected and "Enable Documents Distribution" is disabled. <p>In all other cases, the button is "Share". This change ensures consistency and clarity in button labeling based on room settings.</p> | No | Yes | Minor | <p>Affected Users: All Users.</p> <p>Impact: This improvement has a minor impact on the "Copy/Share" button in the Document Cart.</p> |
| TTI-3955 | Collaborate | <p>Acknowledgment recipients will now automatically receive appropriate access to the associated document(s), ensuring a seamless and secure workflow:</p> <ul style="list-style-type: none"> • Automatic Access: Recipients are granted Reader access with download capability to the specific documents included in the acknowledgment if they do not already have access. • Access Enhancement: If recipients already have Reader access without download capability, download access is added. | No | Yes | Minor | <p>Affected Users: Site User and above.</p> <p>Impact: This improvement ensures that acknowledgment recipients can view and download documents securely while maintaining document-level access controls</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/Risk | Comment / Impact Analysis |
|------------|-------------------|---|----------------|---------------------|-------------|---------------------------|
| | | <ul style="list-style-type: none"> • No Redundancy: If recipients have better access, no changes are made. • Dynamic Updates: When acknowledgments are edited, new recipients are added to the access list, while removed recipients lose their access unless they have separate existing permissions. • Access Revocation: If an acknowledgment is cancelled, recipients lose access, and permissions revert to the parent folder. <p>Design Details:</p> <ul style="list-style-type: none"> • Temporary Access Control Lists (ACLs) ensure that recipients only gain access to the specific documents included in the acknowledgment. • Implicit unique groups are created for each acknowledgment, dynamically managing recipient access for added or removed users. • Multiple acknowledgments for the same or different documents are managed with separate groups, maintaining isolated access for each acknowledgment. | | | | |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/Risk | Comment / Impact Analysis |
|------------|--------------------------|--|----------------|---------------------|-------------|---|
| TTI-3973 | Trial Master File (eTMF) | <p>The TI eTMF Dashboard now has a new dashlet, "Submitted Documents for Billing," which allows users to cross-reference their billing reports with submitted documents.</p> <p>Key Features:</p> <ul style="list-style-type: none"> • Billing Date Range: Displays submissions of the current month, aligning with the billing cycle. • Submission Metrics: Shows the total number of documents submitted within the specified date range. <p>This improvement streamlines billing analysis by providing a tailored view of document submissions for each billing cycle.</p> | Yes | No | Minor | <p>Affected Users: Editor and above.</p> <p>Impact: This improvement has a minor impact on the TI eTMF dashboard.</p> |
| TTI-3977 | Trial Master File (eTMF) | <p>When the toggle for the <i>Inspector Role</i> is enabled in the Quality Review Module, users assigned this role will no longer have access to the Report Module in the waffle menu. This enhancement ensures role-based access control and maintains focus on tasks relevant to the inspector's responsibilities.</p> | No | Yes | Minor | <p>Affected Users: Inspector Role</p> <p>Impact: This improvement has a minor impact on the Quality Review Module with the Inspector view</p> |
| Report-167 | Collaborate | <p>The 'Acknowledgement' Report has been improved to display additional fields</p> | Yes | No | Minor | <p>Affected Users: All</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact/Risk | Comment / Impact Analysis |
|------------|-------------------|---|----------------|---------------------|-------------|--|
| | | including Generated Name, Title, and Site Number. | | | | Impact: This improvement has minor impact on the Users as this improvements makes this report more useful by providing additional relevant information. |

B. DEFECT RESOLUTIONS

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|--|--------|--|
| TRL-10165 | Platform | The date format set for the room (e.g., YYYY/MM/DD) is not reflected in the grid display, even though it is correctly applied in the metadata view. For instance, the grid displays dates in a different format (e.g., 06 Dec 2022), leading to inconsistency across fields. | Minor | This issue had a minor impact on the grid display functionality, causing inconsistencies in date format presentation between the grid and metadata panel. Corrected system behavior has been restored. |
| TRL-14219 | eTMF | Sorting users by Organization in the User Management table does not work properly. When attempting to sort by ascending or descending order, the functionality does not display the correct order. | Minor | This issue had a minor impact on the usability of the User Management sorting functionality. Corrected system behavior has been restored. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|---|--------|---|
| TRL-16182 | Platform | Documents cannot be pushed to eTMF after being moved back to SSU following an incorrect process. Additionally, "Push all documents" did not move all documents to another site. | Major | This issue had a major impact on document transfer workflows between SSU and eTMF, causing disruptions. Corrected system behavior has been restored. |
| TRL-16378 | eTMF | When performing a domain search across multiple rooms (e.g., Rooms, Documents, Users, etc.), the displayed time zone is based on the server time zone rather than the browser's time zone. | Minor | This issue had a minor impact on cross-room search functionality, causing time zone-related inconsistencies in data display for users across different time zones. Correct system behavior will be restored with the resolution. |
| TRL-16503 | eTMF | When the Organizations module is enabled for a room and folders are autogenerated based on a predefined template, these folders remain locked and cannot be edited or deleted even if folder generation or the entire Organizations module is disabled for the room. This issue restricts users from managing the autogenerated folders, including the root folder and the folders named after the organization, leading to limitations in folder management and flexibility. | Minor | This issue had a minor impact on folder management, limiting users' ability to edit or delete autogenerated folders when the Organizations module is disabled. Correct system behavior will be restored with the resolution. |
| TRL-16532 | eTMF | When filters are hidden on a page, they reappear after the page is refreshed, even though the user had previously set them to be hidden. This behavior causes inconvenience by forcing users to repeatedly hide the filters after every page refresh. | Minor | This issue had a minor impact on the user interface, disrupting the expected filter visibility settings and requiring additional actions from users to re-hide the filters after refreshing the page. Correct system behavior will be restored with the resolution. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|--|----------|---|
| TRL-16680 | SSU | When creating an Amendment and adding a document to the placeholder, followed by approving it as a Start-Up Specialist, the document remains in "Pending for Reg Reviewer" status. The document is not visible to the Regulatory Reviewer for approval. | Minor | This issue had a major impact on the document review workflow for Amendments, delaying the approval process by the Regulatory Reviewer. Corrected system behavior has been restored. |
| TRL-16714 | eTMF | The Administrative Workflow group is not visible in the MTI US Client room when searching under the " Include: All " filter, despite being available in the training room it was cloned from. This issue prevents users from accessing the Administrative Workflow group through the expected search behavior. | Major | This issue had a minor impact on the User Group. Corrected system behavior has been restored. |
| TRL-16820 | eTMF | When manually typing the Document Date for a document, an error occurs during the first attempt, stating, "The value is too small. Minimum value is Mon Jan 01 1753 00:00:00 GMT+0553 (India Standard Time)." However, when the document date is updated again on the second attempt, it is captured correctly without any error. The issue is observed for date formats set as D-M-YY or DD/MM/YYYY in the user profile. | Critical | This issue had a critical impact on document date entry functionality. Corrected system behavior has been restored. |
| TRL-16825 | eTMF | The metadata panel does not shrink completely. Users are unable to resize the panel, and field labels remain fixed to the left of fields instead of appearing above them when resizing. | Major | This issue had a major impact on the metadata panel functionality, restricting users' ability to customize the panel layout for better usability. Corrected system behavior has been restored. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|---|--------|---|
| TRL-16828 | eTMF | When selecting multiple users to change their access, a "No data" message appears in the dropdown. However, selecting a single user displays the access levels correctly. This issue occurs in all rooms for MTI US/EU after the upgrade to version 10.6. | Minor | This issue had a major impact on access management workflows, preventing bulk user access changes. Corrected system behavior has been restored. |
| TRL-16839 | eTMF | The Query Date displayed in the Cross Room Search view is inconsistent with the Query Date shown in the Metadata panel and Queries view. In the Cross Room Search view, the Query Date is displayed as today's date, while in the Metadata panel and Queries view, it correctly reflects the actual date when the query was raised. | major | This issue had a major impact on query data consistency across views, potentially confusing users. Corrected system behavior has been restored. |
| TRL-16847 | eTMF | The "IRB/EC" field in the Metadata panel gets blank after saving. The issue is reproducible in multiple rooms, including test environments, and also occurs in MTI EU. | Minor | This issue had a major impact on metadata entry workflows, causing data loss when saving the "IRB/EC" field. Corrected system behavior has been restored. |
| TRL-16848 | eTMF | Users were unable to preview document templates across all MTI US rooms. An error message was displayed: "To edit office documents and collaborate, integrate ONLYOFFICE Docs into your sync&share app." This issue prevented users from viewing document templates directly within the platform. | Major | This issue had a major impact on document template functionality, limiting users' ability to preview templates efficiently. Corrected system behavior has been restored. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|--|---------|---|
| TRL-16852 | eTMF | Users were unable to drag or reposition the Auto-naming Rule window in the Document Types Management screen. Even minimizing the screen did not resolve the issue, as the Auto-naming Rule window remained hidden behind the user interface, making it inaccessible. | Trivial | This issue had a trivial impact on the usability of the Auto-naming Rule configuration, limiting users' ability to manage and adjust the window as needed. Corrected system behavior has been restored. |
| TRL-16855 | eTMF | After the previous release, two user rooms in the MTI US production instance, which previously displayed 100% completion on the eTMF Health dashlet, began showing open placeholders. This discrepancy was reported as an issue by the client, impacting the accuracy of the eTMF Health metrics for the affected rooms. | Minor | This issue had a minor impact on the eTMF Health dashlet, leading to inconsistencies in placeholder reporting and completion metrics. Corrected system behavior has been restored. |
| TRL-16856 | eTMF | When performing a keyword search in a specific view, the search results are displayed as expected. However, if the user switches to a different folder, the document ID disappears from the search bar while the search continues to run in the background. To view other documents in the new folder, users are forced to either refresh the browser or explicitly cancel the search. | Minor | This issue had a minor impact on the eTMF Health dashlet, leading to inconsistencies in placeholder reporting and completion metrics. Corrected system behavior has been restored. |
| TRL-16864 | Platform | In MTI US and MTI EU, the full Room Name is not visible directly. Users can only view the full Room Name by hovering over it. | Minor | This issue had a minor impact on room name visibility, requiring additional user action to view full names. Corrected system behavior has been restored. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|--|----------|--|
| TRL-16872 | Platform | Users are facing an issue while accessing the template folder in the room settings. It shows "Application encountered a system error." It also shows a "Save Changed" prompt while switching from one option to another under Sites. | Major | This issue had a major impact on room configuration workflows, disrupting template access and causing unnecessary interruptions when navigating Sites. Corrected system behavior has been restored. |
| TRL-16874 | Platform | User noted a problem with the Index Outline Tab in specific Room on the MTI EU platform. It keeps showing a "Loading" sign and doesn't open properly. | Critical | This issue had a critical impact on a specific room. Corrected system behavior has been restored. |
| TRL-16892 | Platform | In MTI US and MTI EU, the Change Log History for Template Folders displays null dates instead of properly formatted date values. This occurs after making changes to a template folder and saving them. | Minor | No Other functionality is affected by this issue. Corrected system behavior has been restored. |
| TRL-16893 | eTMF | Users noted an issue with the Related Folder Path in Document Type Management. The pathway is not translating correctly. | Major | This issue had a major impact on document type configuration, leading to inconsistencies in related folder pathway translations. Corrected system behavior has been restored. |
| TRL-16898 | eTMF | A server error occurs when saving a document after updating metadata or selecting its version in the side panel. This issue prevents the document from being saved successfully. | Major | This issue significantly impacts document versioning and metadata updates, hindering users from saving updated documents. Corrected system behavior has been restored. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|---|----------|--|
| TRL-16905 | eTMF | When navigating through Index folders using keyboard arrow keys, there is no visual indication of the user's movement within the folder structure. This makes it difficult to track navigation and locate specific folders. | Minor | This issue had a minor impact on the usability of folder navigation, reducing efficiency and potentially causing user frustration. Corrected system behavior has been restored. |
| TRL-16938 | eTMF | The "Activity Type" dropdown in the document history displays the Activity Type ID instead of the correct name "Open Document Metadata." | Minor | This issue had a minor impact on the document history functionality, leading to unclear activity selection. Corrected system behavior has been restored to display the appropriate activity name. |
| TRL-16939 | eTMF | Users reported an issue where a document signed using the TI Digital Signature is not reflected as signed in the system. | Critical | This issue has a critical impact on the TI Digital Signature. Corrected system behavior will be restored. |
| TRL-16946 | eTMF | Users observed that the text "Document Control" is appearing below the document title, when the document is ready to include in the change control workflow. | Major | This issue had a minor impact on user interface for Change Control workflows. Corrected system behavior has been restored. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|--|--------|--|
| TRL-16959 | eTMF | When the "Enable Causality Tracking for final documents metadata edit" is disabled in settings, the editor still needs to provide a reason when mass coding for non-final documents. | Minor | This issue had a minor impact on the Mass Coding for final documents. Corrected system behavior has been restored. |
| TRL-16977 | eTMF | Users encounter a "Database Error" message, and the screen freezes while attempting to edit an existing Quality Review in the Quality Review module. This prevents further actions and disrupts the editing process. | Major | This issue had a major impact on the Quality Review module, blocking users from editing existing reviews and causing system instability. Corrected system behavior has been restored. |
| TRL-17053 | eTMF | When a name is edited in a module, the updated name does not override the breadcrumb, causing a mismatch between the displayed breadcrumb and the edited module name. | Minor | This issue had a minor impact on user navigation, creating inconsistencies in breadcrumb displays. Corrected system behavior has been restored. |

10. Open Defects

Trial Interactive v10.6.1 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.
- **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 | eTMF | Users reported that searching for documents using the full document name works correctly. However, when searching with a partial name or keywords from the middle of the document name, the system does not return any results. | Minor | This issue has a minor impact on searching for a document by partial name. Correct system behavior will be restored with the resolution. |
| TRL-14887 | SSU | Advanced validation in SSU does not function as expected when IRB/EC Submit or Approval Dates are used. | Minor | This issue has a minor impact on the accuracy of data validation for IRB/EC dates. Correct system behavior will be restored with the resolution. |
| TRL-16084 | SSU | In SSU > Contacts, the fields for Prefix, First Name, Last Name, Suffix, and Middle Name could not be updated. Although the updated values were sent from the UI, they were not saved in the system. | Minor | This issue had a minor impact on the SSU contacts fields. Correct system behavior will be restored with the resolution. |
| TRL-16377 | eTMF | When performing a domain search for a specific room, the submission date is displayed in MDT instead of the room's configured timezone. | Minor | This issue has a minor impact on search functionality, as it causes inconsistencies in the displayed submission date relative to the room's timezone. Correct system behavior will be restored with the resolution. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|---|--------|--|
| TRL-16559 | eTMF | A database error occurred when attempting to revoke access for a user who is also listed as the Principal Investigator (PI) for a site. This prevented the access revocation process from completing successfully. | Minor | This issue had a minor impact on user access management, specifically for users designated as Principal Investigators. Corrected system behavior will be restored. |
| TRL-16992 | eTMF | The keyword search functionality for site contacts is not returning results when searching by contact email address or contact name , even though searches by site name work as expected. | Minor | This issue had a minor impact on the search functionality. Corrected system behavior will be restored. |

11. 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 CSM 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

12. Approvals

Product Owner

| | |
|--|-------------------------------|
| Name: Katherina Cianciarelli | Title: Senior Product Manager |
| Signature: Reason for signature: Date: | |

Quality Assurance

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