TRIAL INTERACTIVE V10.5.1 - PATCH - RELEASE NOTES - VERSION 1.0

1.   Table of Contents

2. Version History

Author	Revision #	Date	Comment
Yogesh Inamdar	0.1	01-Dec-2023	Initial Document Creation
Yogesh Inamdar	0.2	13-Dec-2023	Added the 'Open Defects' section.
Yogesh Inamdar	0.3	14-Dec-2023	Removed the following feature: • TTI-3340 Added the following Defects: • TRL-11133 • TRL-11815 • TRL-12797 • TRL-13090 • TRL-13140 • TRL-13147 • TRL-13150 • TRL-13152 • TRL-13153 • TRL-13187 • TRL-13209 • TRL-13210 • TRL-13214 • TRL-13221 • TRL-13264 • TRL-13292 • TRL-13306 • TRL-13309 • TRL-13310 • TRL-13399
Yogesh Inamdar	0.4	14-Dec-2023	Updated the Open Defects section with the following: • TRL-12589 • TRL-12715 • TRL-12719 • TRL-12761 • TRL-12913 • TRL-12935 • TRL-13018 • TRL-13112 • TRL-13169 • TRL-13202 • TRL-13212 • TRL-13216 • TRL-13243 • TRL-13244 • TRL-13257 • TRL-13261 • TRL-13268 • TRL-13269 • TRL-13270 • TRL-13319

			• TRL-13369 • TRL-13404 • TRL-13409 • TRL-13437 • TRL-13460
Yogesh Inamdar	0.5	15-Dec-2023	Added the following: • TRL-13115 • TRL-13181 • TRL-13200 • TRL-13201 • TRL-13210

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 Pre-Release Notes. The end-users of the system can use the Pre-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 Pre-Release Notes and the Final Release Notes, but due to Trial Interactive's Agile Software Development methodology, we 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	10.5.1
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.
Annex 11	The European Union's guidance for using electronic records and signatures in the pharmaceutical industry.
API	Application Programming Interface
CRO	Clinical Research Organization
CTMS	Clinical Trial Management System
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
KPI	Key Performance Indicator
LMS	Learning Management System
MFA	Multi-Factor Authentication
OOTB	Out of the Box
sFTP	A secure File Transfer Protocol
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SSO	Single Sign On
SSU	Study Start-Up
TI	Trial Interactive
TP	TransPerfect

6. System Overview

A. TRIAL INTERACTIVE

TransPerfect's *Trial Interactive* has been used successfully by TransPerfect customers for over 15 years in hundreds of clinical trials to store critical trial documents as part of the Electronic Trial Master File. Trial Interactive's platform is a web-based and mobile-enabled software-as-a-service (SaaS) application that provides eClinical solutions for eTMF and content management, Study Start-Up, and various other tools used in conducting a clinical trial. Trial Interactive's products deliver a wide range of benefits to any organization looking to leverage new efficiencies and opportunities in their Trial Master File, clinical trial management, content management, and eLearning:

- An electronic Trial Master File archive that meets all regulatory, security, access, and storage requirements in all countries and regions.

- A Clinical Trial Management System (CTMS) that meets all eClinical requirements for managing and tracking clinical studies and works seamlessly with the eTMF, Content Management, Learning Management, Mobile app, and other Trial Interactive solutions.

- A fully hosted SaaS solution that is 21 CFR Part 11, Annex 11, ERES, GDPR, and GxP compliant.

- A single access point for all trial content as well as sponsor and site personnel documentation.

- Supports a series of TMF workflows, including document import and indexing, quality review, audit and inspection, document certification, remote monitoring, redaction, and the capture of other Clinical Trial documentation.

- Effective management of documents that are created internally or externally. Trial Interactive is the only solution that provides a best practice and validation-ready approach to creating, collecting, reviewing, and finalizing documents bound for the eTMF archive.

- A thin-client, consumer-grade user interface that supports most major browsers and a mobile app that supports iOS and Android devices.

- A powerful, flexible technical stack with many integration options, including an API, Event Service Bus, sFTP Dropbox, and Corporate Directory Integration with Single Sign On.

- Increases teamwork and collaboration via one global view of clinical trials, training, and supporting documentation.

- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of reviews and authoring solutions.

- Dashboards and reports that provide KPIs, measurable metrics, simple Excel exports, as well as complex standardized and custom reports.

- Adaptable, built-in machine learning features such as auto-classification and metadata extraction enable AI auto-coding capabilities.

- A full-featured eLearning system designed for GxP compliance, study training, and virtual investigator meetings.

- Effectively manage the entire clinical trial process from protocol conception through closeout.

B. TRIAL INTERACTIVE - ETMF

Trial Interactive's electronic Trial Master File (eTMF) is a secure, cloud-based solution enabling real-time collaboration for both sponsors and CROs, supplying value and ease of use for trial stakeholders across the board and now bringing enhanced transparency and visibility to your trial. Trial Interactive's eTMF can help your organization:

- Ensure quality with the ability to have a customized workflow for indexing and approval powered by AI and machine learning.

- Stay current with required document lists and placeholders based on the TMF Reference Model. Placeholders and required document lists ensure that all expected and essential documents are captured in your final TMF.

- Track timeliness with KPI metrics dashboards that measure document intake from receipt to submission through QC and finalization.

- Encourage better compliance with an eTMF that tracks responsibility and actively requests documents when they are due, supporting queries for document corrections through email or upload.

- Confirm and maintain the validity of the eTMF before inspections using quality review audit capabilities to support oversight, periodic reviews, and inspection readiness.

- Ensure overall reportable eTMF Heath with Key Performance Indicator (KPI) metrics, reports, and portfolio dashboards for eTMF health, timeliness, quality, and completeness.

- Plan amendments, visits, and other key trial events and milestones while creating placeholders for the expected documents that need to be collected, including due dates and responsibility to help track eTMF health and timeliness.

- Automate the classification and metadata extraction of the TMF using powerful AI auto-coding with human-aided machine learning.

- eClinical platform interoperability provides a seamless connection and data flow between the eTMF and other critical applications such as a site portal, eISF and site binders, content management, document authoring, study startup, and clinical trial management systems.

- Email and study correspondence inbox with relevance checks captures all email correspondence for each study. Once a correspondence email is sent in, it is rendered to PDF and may be selected for inclusion in a separate interface by study staff. Attachments are checked for duplicates and are linked back to the original email. Emailing documents and site correspondence securely into the eTMF ensures GCP compliance.

- Document redaction, manipulation, and certification allow selected team members to remove personal information to meet data privacy requirements and repair, split, and merge documents. Additionally, document certification helps ensure proper paper disposal.

Additional features of the Trial Interactive eTMF include:

- A mobile content capture app that supports both iOS and Android, with support for CRA reconciliation, metadata classification, query management, training, redaction, and offline mode.

- Drag and drop emails and documents to import them automatically or drop them onto placeholders for auto-assignment.

- Full query and task management capability with three types of queries for requesting, verifying, and responding via email, web, and mobile apps.

- Automatic alerts and reminders with notifications and a daily digest.

- Built-in eSignature and digital signature solution for 21 CFR Part 11 and ER/ES compliance with pre-defined signature blocks, pages, and digital certificate.

- Universal document viewer that supports and renders over 300 document formats.

- Multi-document view with built-in document comparisons, bulk editing, page rotation, deletion, reordering, and annotations.

- Global search provides cross-study search results for documents, document types, full-text, contacts, sites, and other record types, with facets, filtering, and other advanced features.

- Configurable grid filters, column selection, saved public/private views, and built-in reporting tools for ad-hoc exports.

- Standard and ad-hoc reports that support all metadata fields and the ability to add columns to standard reports or fully customize your exports.

- Completeness view showing TMF structure, final documents, planned documents/placeholders, and required documents.

- Configurable support for the latest TMF reference model with full auto-routing and auto-naming rules.

- Automatic duplicate document detection and comparison verifies that a document is unique and does not have a duplicate in the eTMF archive based on identical metadata or an exact copy or duplicate scan.

C. TRIAL INTERACTIVE - STUDY START-UP (SSU)

Trial Interactive Study Start-up (SSU) is a cloud-based solution to manage essential documents per the regulatory requirements for site activation and IP release. Trial Interactive SSU can help your organization:

- Send the Regulatory Package and templates to sites with the list of required documents.

- A configurable one or two-step workflow for reviewing and approving collected required documents.

- TI Study Start-Up makes it easy to see what documents are missing and what documents need urgent attention to avoid unnecessary delays in submission and approval.

- TI Study Start-Up makes it easy to see the sites most likely to activate the fastest. Identify those sites during the process so you can make sure there are no distractions in the submission and approval process

- Set and automatically track milestones and tasks. Ensure all study start-up processes are being managed effectively and completed on time.

- Effectively track site contracts and budgets with a dedicated section for managing them.

- Create submission packages for submission to regulatory agencies.

- Get real-time updates on package submissions for realistic estimates of site activation timelines.

- Real-time distribution of required document packages, tracking progress, IRB/EC submission, and meeting dates, providing realistic timeline projections and prediction of site activation timeframes.

- Efficiently manage protocol amendments, including tracking and sending reminder emails with just a button click.

- Robust OOTB reports for cycle time calculations, missing documents, and history of collected documents.

- Automatically create sites and site contacts for sites approved in Trial Interactive eFeasibility.

- Request for certified translated copies of documents to manage your global regulatory requirements.

D. COLLABORATE

Trial Interactive provides an online collaborative workspace, which enables collaborative and controlled document authoring, review, and approval. Designed to include 21 CFR Part 11 compliant workflows and approvals, the solution offers an end-to-end service platform for your organization's content management and document control requirements. These collaborate rooms allow users to benefit from the following solutions:

- Study Collaborate and the CTMS Collaboration Rooms are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and ultimately shared with the eTMF.

- Site Collaborate/eISF and Remote Monitoring Rooms are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and ultimately send it to the eTMF.

- The Quality Document Management solution provides controlled document workflows to an organization for use by clinicians, quality assurance, R&D, and other life sciences teams to collaboratively author, review, approve, sign off on, make effective, train, and distribute regulated content and documents.

TI Collaborate can provide your organization with:

- A single place to share and collaborate on clinical documentation.

- The ability to align document work streams with regulatory compliance practices for document authoring, approval, control, and related training.

- The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation and to fully automate the training management process through the LMS.

- The ability to co-author and collaborate with other authors in real time on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.

- The ability to complete the end-to-end document process with an electronic and digital signature for document approvals.

- The ability to send documents for certified translation through TransPerfect TransPort, track their status, and receive back the translated copies and certificates.

- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.

- The ability to follow critical processes for metadata, approval, and signoffs by publishing or sharing directly with the TMF.

7.   Release Overview

This patch release includes minor, low-impact improvements and defect resolutions. Please see the table below.

8.   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	
Date of Release	15-Dec-2023
Estimated US MTI Upgrade Date/Time:	15-Dec-2023 09:00 PM ET
Estimated EU MTI Upgrade Date/Time:	15-Dec-2023 09:00 PM CET
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your **TransPerfect** Project Manager.

9. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the Trial Interactive v10.5.1 platform.

System Requirements	
Operating System	• Windows Version 7 or higher • All currently supported Mac OSX releases • iOS and Android for myTI mobile app (see myTI release notes)
Browser	• Microsoft Edge: Version 88 and later • Google Chrome: Current release and earlier • Mozilla Firefox: Current and ESR releases • Apple Safari: Current release and earlier • NOTE: TI Digital Sign requires that pop-up blockers are turned off for the Trial Interactive domain.
Client Software	• For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally. • For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred). • Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. • Optional: Drag and Drop from Outlook to Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available to support this feature on Internet Explorer® and Firefox®.
Optional Add-Ons	• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) • Adobe Sign (Latest Adobe Document Cloud Version) • Optional: SAS Viewer or compatible software must be installed for SAS Datasets. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74

10.   Changes

Trial Interactive v10.5.1 has been released with these enhanced features and defect fixes.

Theses table uses the following definitions of customer Impact:

- **Critical** - A core functionality returns invalid results or does not function as expected.

- **Major** - This improvement or defect resolution has an impact on basic functionality.

- **Minor** - There may be a small impact on business in specific use cases.

A.   NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
ETMF-2323	Trial Master File (eTMF)	This improvement allows users to configure a room so that both Mass Coding and Causality Tracking are enabled simultaneously.	No	Yes	MINOR	Manager, Admin, and above. This improvement has a minor impact on room configuration options.
TTI-2703	CTMS, CTMS Collaborate Room (CCR)	When the reviewer rejects a visit report generated from the CTMS, the document owner now has the capability to either regenerate it from the CTMS, or to edit the report, incorporating comments and changes, and resend the report back for another review. It is not always necessary to completely regenerate the document in order to correct the errors noted. This improvement allows a report to be corrected and resubmitted without having to regenerate it from scratch.	No	Yes	MINOR	All Users with CRA access. This improvement has a minor impact on reviewing and versioning site visit reports in the CCR.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-2906	Trial Master File (eTMF)	With this improvement, users can assign a document to a placeholder from the eTMF Health Dashlet and placeholder metadata panel. Additionally, users can search for documents from the 'Assign Document' panel to add them to a placeholder.	No	Yes	MINOR	Editor and above. This improvement has a minor impact on assigning documents to placeholders.
TTI-3118	Trial Master File (eTMF)	With this improvement, the system uses only the Room-based time zone for any conversion instead of the user-based time zone.	No	Yes	MINOR	All Users. This improvement has a minor impact on time zone conversion.
TTI-3152	Trial Master File (eTMF)	With this improvement, when fulfilling a placeholder with a document, the system now replaces the Submitted Name value with the filename of the document being used to fulfill the placeholder. Previously, the Submitted Name associated with the placeholder was used by default.	No	Yes	MINOR	Editor and above. This improvement has a minor impact on document metadata when fulfilling placeholders.
TTI-3267	Trial Master File (eTMF)	With this improvement, for users who make use of the 'Assign' feature in the Event Manager, the system no longer adds "[Placeholder]" to the front of the submitted name. The system now uses the submitted name without any changes.	No	Yes	MINOR	Editor and above. This improvement has a minor impact on fulfilling placeholders via the event manager.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3379	CTMS Collaborate Room (CCR)	When users create a monitoring visit report via TI CTMS, there is a need to control the access rights to that file based on the access rights assigned to the user for the study in the CTMS. With this improvement, users who are indicated as Reviewers are limited to a 'comment only' mode, and users who are indicated as the Document Owner are taken directly into 'edit' mode so that the document can be finalized.	Yes	No	MINOR	Editor and above. This improvement has a minor impact on file access rights for visit reports generated in the CCR via the CTMS.
TTI-3382	Trial Master File (eTMF) Collaborate (CMS)	TI recently introduced the ability to 'Expand All' and view all files contained in the selected folder as well as the child folders based on the index structure. With this improvement, this functionality is rolled out to the 'Working Documents' view of the Documents module.	No	Yes	MINOR	All Users. This improvement has a minor impact on the document index navigation.
TTI-3397	Trial Master File (eTMF), Study Start-Up (SSU), Collaborate (CMS), Site Portal (eISF)	This improvement allows users to create manual relationships to documents that are one-to-one and that do not relate other files to which one of the related files may have been previously linked. This gives users additional control over manual document relationships created via the Related Documents feature released in TI v10.5. Additionally, by selecting 'All' on the Related panel, the user may view all relationships of that type in the room.	No	Yes	MINOR	Editor and above. This improvement has a minor impact on creating manual document relationships.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3400	SSU	This feature allows for advanced validation to be configured for metadata fields required for site creation in SSU.	No	Yes	MINOR	Admin. This improvement has a minor impact on metadata configuration for site creation.
TTI-3403	Trial Master File (eTMF)	This improvement makes the Expand toggle switch available for the Index Root Folder, allowing users to view all documents in the index without having to navigate to a sub-folder.	No	Yes	MINOR	All Users. This improvement has a minor impact on index navigation and viewing document records in the grid.
TTI-3524	Trial Master File (eTMF), Study Start-Up (SSU), Collaborate (CMS), Site Portal (eISF)	Users who perform a cross-room search sometimes have access to a room, which requires a Confidentiality Agreement to be agreed to prior to entering the room. In cases such as these, we do not want users to be able to view these documents without indicating agreement first. With this improvement, users are not able to view documents directly from the search results if they are located in a room that requires a Confidentiality Agreement. If a user attempts to do so, a warning message is displayed.	No	Yes	MINOR	All Users. This improvement has a minor impact on viewing documents from the search results grid.
TTI-3525	Trial Master File (eTMF), Study Start-Up (SSU),	This improvement makes UI changes to the popup that appears to confirm the cancellation of a requested job in TI or if the user attempts to leave a page without first saving their changes. These changes are intended to make these popups more user-friendly.	No	Yes	MINOR	All Users. This improvement has a minor impact on the user interface when canceling jobs or abandoning changes.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3526	Trial Master File (eTMF)	This improvement creates a 'Remove Site from Audit Configuration' checkbox, which appears in the confirmation window when a user deletes a site from the list of sites for the study. When this checkbox is enabled, any pending documents from the deleted site(s) in audits are removed as well.	No	Yes	MINOR	Admins. This improvement has a minor impact on documents included in audits for sites being deleted from the eTMF.

B.   DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-11133	eTMF, Collaborate	Users faced an issue with document versions. After an online edit of a document in a collaborative workspace, the system displayed the document version before editing.	MINOR	Editor and above. This issue had a minor impact on the document versions In collaborative workspace. The resolution resets the correct version displayed in the document metadata.
TRL-11815	eTMF	Users noted that, when navigating from a document view to a new folder, the 'Document View' stayed instead of reverting to the 'Grid View' of the new folder as expected.	MINOR	All users. This issue had a minor impact on folder and grid navigation. Correct system behavior has been restored.
TRL-12797	eTMF	Users noted that the server or user time zone was being presented related to documents in the eTMF rather than the room time zone as expected.	MINOR	All users. This issue had a minor impact on time zone info. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-12827	Platform	Users noted that when a Room's details were opened, the Inbox Domain information was not visible or was not grayed out as intended.	MINOR	SuperAdmin users. This issue had a minor impact on room information management at the domain/data room level. Correct system behavior has been restored.
TRL-12936	SSU	When users added a document to an unfulfilled document placeholder in SSU, the grid was not automatically refreshed as expected.	MINOR	Editor and above. This issue had a minor impact on the SSU document UI. Correct system behavior has been restored.
TRL-13031	eTMF	Users occasionally encountered a database error when attempting to download the file resulting from a metadata export.	MINOR	All Users. This issue had a minor impact on downloading exported data. Correct system behavior has been restored.
TRL-13037	SSU	Users were experiencing intermittent issues with the Budgets and Contracts area in SSU. Occasionally, the screen would fail to load completely, and other times, the option was missing from the user's navigation links.	MINOR	Editor and above users with access to SSU. This issue had a minor impact on the Budgets and Contracts functionality. Correct system behavior has been restored.
TRL-13049	eTMF, SSU	A required document configured to be a site-level IRB requirement did not appear under the list of expected documents for the site as expected.	MINOR	Admin users. This issue had a minor impact on document placeholder generation for site-level IRB document requirements. Correct system behavior has been restored.
TRL-13090	Collaborate	Users noted that, when a document version was updated, the filename was appended with unexpected characters.	MINOR	Editor and above. This issue had a minor impact on file naming. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13106	eTMF, SSU, Collaborate	The document count numbers next to folders in the index panel were displayed in the incorrect font.	MINOR	All users. This issue had a minor impact on the user interface for the Index panel. Correct system behavior has been restored.
TRL-13115	SSU	When activating a site in SSU, users discovered that they were unable to select IRB/EC documents to be published to the eTMF as a part of the site activation process.	MINOR	Editors and above. This issue had a minor impact on document migration from SSU to the eTMF. Correct system behavior has been restored.
TRL-13140	eTMF	Users found that they were unable to locate Active sites in the Site metadata field when coding documents.	MINOR	Editor and above. This issue had a minor impact on applying document metadata. Correct system behavior has been restored.
TRL-13147	eTMF	Users attempting to mark multiple unfulfilled document placeholders as 'Not Applicable' were unable to do so because the button was greyed out. This was only the case when more than one placeholder was selected.	MINOR	Admins. This issue had a minor impact on placeholder management. Correct system behavior has been restored.
TRL-13150	eTMF	An error message is displayed when the IRB search was attempted in the Settings module.	MINOR	All Users. This issue had a minor impact on the system user interface. The resolution removes the error message, and the search works well.
TRL-13152	eTMF	When an admin-level user configured a view called 'Virtual Field Test' and switches to the same and conducts sort by 'PI First Name,' PI Last Name,' and 'Principle Investigator, ' the system displayed a database error.	MINOR	All Users. This issue had a minor impact on the system user interface. The resolution removes the error message.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13153	eTMF	There was an issue experienced when sorting the document type in alphabetical order in the 'View by eTMF Completeness' and 'View by Status.' The sorting doesn't work.	MINOR	All users. This issue had a minor impact on the system user experience. The resolution resets the correct sort function.
TRL-13181	SSU	When SSU sends reminder emails regarding missing documents, users find that the email is missing document details.	MINOR	Editor and above. This issue had a minor impact on email notifications from SSU.
TRL-13187	eTMF	Users noted that the document date was not appearing as entered after applying date metadata to a document.	MINOR	Editor and above. This issue had a minor impact on the display of entered metadata. Correct system behavior has been restored.
TRL-13200	SSU	Users utilizing the Documents Cart in SSU noted that the document count was incorrect for documents that had been added to the cart.	MINOR	All users. This issue had a minor impact on the Documents Cart UI in SSU. Correct system behavior has been restored.
TRL-13201	SSU	Users in SSU who attempted to view documents via the 'Posted Date' view noted that the documents were not displayed in the correct order.	MINOR	All users. This issue had a minor impact on the document UI in SSU. Correct system behavior has been restored.
TRL-13209	eTMF	When a user clicked on a KPI tile in an eTMF room and then selected a country displayed, the user was taken to the Home page rather than to the country profile as expected.	MINOR	All users. This issue had a minor impact on linking in the KPI dashlets. Correct system behavior has been restored.
TRL-13210	eTMF	Users who attempted to view detailed Confidence Level information of a document which was coded via automated data entry received an error message.	MINOR	All users in rooms where TI Automate is utilized. This issue had a minor impact on the Confidence Level UI. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13213	eTMF	Users noted that the document and requirement tabs were displayed in reverse order during the event creation process and that the Responsible Party was not populating with the expected value.	MINOR	Editor and above users. This issue had a minor impact on the event creation UI.
TRL-13214	eTMF	Double-clicking a folder from the document index is seen as the folder expanded, but it is not expanded in real.	MINOR	All Users. This issue had a minor impact on the system user interface. The resolution restores correct system behavior.
TRL-13220	SSU	When attempting to replace an attached file in SSU, users are being presented with the new file upload form with all metadata fields reset.	MINOR	Editor and above. This issue had a minor impact on SSU file management. Correct system behavior has been restored.
TRL-13221	eTMF, Collaborate	Users attempting to expand a parent folder via double clicking noted that this functionality was no longer working.	MINOR	All users. This issue had a minor impact on index navigation. Correct system behavior has been restored.
TRL-13264	eTMF	When users attempted to select the Date Type via the metadata field, they were unable to do so.	MINOR	Editor and above. This issue had a minor impact on the document metadata UI. Correct system behavior has been restored.
TRL-13292	SSU	Start Up Specialist users noted that, after a document had been approved by the Regulatory Reviewer, the initial document approval was no longer visible in the Required view of site documents. This error also resulted in the document being indicated as 'Missing' and there were issues experienced when attempting to re-upload or apply the document to the placeholder.	MINOR	Editor and above. This issue had a minor impact on the SSU document workflow. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13306	Platform	Users noted that system group names were not updated when a room name was changed.	MINOR	SuperAdmin users. This issue had a minor impact on displaying the name of system groups. Correct system behavior has been restored.
TRL-13309	SSU	Users in a specific client's rooms noted that a custom field value indicating the presence of wet-ink signatures was not sticking and being applied to the document when saved.	MINOR	Editor and above users for the impacted client. This issue had a minor impact on document metadata display. Correct system behavior has been restored.
TRL-13310	eTMF, SSU	Users attempting to create an IRB/EC via the Settings area in a TI room were unable to use the search function to locate the IRB/EC during the creation process.	MINOR	Admin users. This issue had a minor impact on the Settings UI for adding IRB/ECs to the room. Correct system behavior has been restored.
TRL-13399	SSU	Users on the EU multi-tenant-instance noticed that the PI last name was missing in the displayed site name despite the last name value being added to the site naming pattern in the room settings.	MINOR	All users. This issue had a minor impact on site name display. Correct system behavior has been restored.

11.   Known Defects

Trial Interactive v10.5.1 has been released with the following known defects. 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-12589	SSU	Users are experiencing an error that kept Editor members of the Site Activation group from editing, deleting, activating, or deactivating contacts in the site profile.	MINOR	Editor users are assigned as members of the Site Activation group. This issue has a minor impact on the site information management.
TRL-12715	eTMF	Users utilizing TI Automate noted that when accessing the Confidence Score information for a document via the metadata panel, the expected notification regarding the data was not displayed.	MINOR	All users in rooms utilizing TI Automate. This issue has a minor impact on viewing confidence score information.
TRL-12719	eTMF	While reviewing documents in the Quality Review module of a TI room, auditor users with full access granted as a part of the audit scope and Editor access permissions were unable to edit document metadata.	MINOR	Editor users designated as auditors with full access to the audit. This issue has a minor impact on document metadata management in the Quality Review module.
TRL-12761	eTMF, Collaborate	Users have noted that, on occasion, when utilizing a link from a TI email newsletter to navigate to a document within a TI room, the wrong document is opened. This does not repeat when the link is clicked a second time.	MINOR	All users. This issue has a minor impact on document linking within TI rooms.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-12913	SSU	Users noted that an active site's status could be manually updated to non-participating.	MINOR	Editor and above users with access to SSU. This issue has a minor impact on site status management in SSU.
TRL-12935	SSU	Users have noted that documents deleted from SSU do not have the Restore and Purge options available in the Deleted Documents view.	MINOR	Admins. This issue has a minor impact on deleted document functionality.
TRL-13018	SSU	Users attempting to approve or reject documents submitted in SSU for an active site were not able to do so.	MINOR	Editor and above. This issue has a minor impact on document review in SSU.
TRL-13112	SSU	In rooms where the 'Allow paper documents' option has been enabled, users discovered that they were unable to approve/reject documents without opening them.	MINOR	Editors and above. This issue has a minor impact on the regulatory review UI in SSU.
TRL-13121	SSU	When a document was rejected via the SSU review process and a user replaced the attached file, the document status was not reset to 'Pending' as expected.	MINOR	Editors and above. This issue has a minor impact on document status management in SSU.
TRL-13169	SSU	Users noted that the 'Activate Site' button was available for sites that had been rejected and which had no collected documents.	MINOR	Editor and above. This issue has a minor impact on site status management in SSU.
TRL-13202	SSU	When importing documents to SSU, users who indicated the Site to which the document should be associated found that the value was not retained in the metadata field once the upload was completed.	MINOR	Editor and above. This issue has a minor impact on document metadata during the upload process in SSU.
TRL-13212	SSU	Users attempting to import files to SSU via a drag-and-drop were unable to complete the upload.	MINOR	Editor and above. This issue has a minor impact on the upload process in SSU.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13216	SSU	In rooms where document conversion to PDF is enabled, users who imported documents to sites in SSU noted that documents were not being converted to PDF as expected.	MINOR	Editor and above. This issue has a minor impact on file type management.
TRL-13243	SSU	Users attempting to upload documents to an unfulfilled document placeholder in SSU noted that the 'Add' button did not display in the menu bar as expected but was replaced by a 'Placeholder' dropdown menu.	MINOR	Editor and above. This issue has a minor impact on the SSU document UI.
TRL-13244	eTMF	Users for a specific client instance indicated that they were unable to see the KPI Heatmap menu in the Settings module.	MINOR	Admins in rooms on the dedicated client instance. This issue has a minor impact on KPI Heatmap settings management.
TRL-13245	SSU	Users noted that when attempting to apply metadata to documents in SSU, some required fields were missing from the metadata panel.	MINOR	Editor and above. This issue has a minor impact on document metadata management.
TRL-13257	SSU	While in the documents area of a site in SSU, users noted that the values in the metadata panel were editable before the user actually clicked on the 'Edit' button to enable editing. Still, the Save button was not displayed unless the 'Edit' button was clicked.	MINOR	Editor and above. This issue has a minor impact on the document metadata UI.
TRL-13261	SSU	Users discovered that site profile data was editable when accessing the information via the Country profile.	MINOR	Editor and above. This issue has a minor impact on site profile management.
TRL-13268	SSU	Users discovered that, for active sites, the Change Status button is disabled, preventing them from further changing the status of the site to 'closed.'	MINOR	Editor and above. This issue has a minor impact on site status management.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13269	SSU	Users discovered that, for closed sites, the Change Status button is disabled, preventing them from further changing the status of the site.	MINOR	Editor and above. This issue has a minor impact on site status management.
TRL-13270	SSU	In rooms where the setting 'Allow users to select the documents which should be published to the eTMF' is disabled, users noted that, when marking a site as not participating, they were presented with the option to select documents to be moved to the eTMF.	MINOR	Editors and above. This issue has a minor impact on the UI for non-participating sites.
TRL-13272	SSU	Users performing regulatory review of documents in SSU noted that the metadata fields appeared in the metadata panel in an editable state, although there was no Save button.	MINOR	Editors and above. This issue has a minor impact on the Regulatory Review UI.
TRL-13319	SSU	When attempting to assign a document to a site during import in SSU, users were not able to select the correct site if the site did not have any collected documents.	MINOR	Editors and above. This issue has a minor impact on assigning metadata during import.
TRL-13361	Collaborate	Superadmin users noted a discrepancy in backend system database behavior during document checkout.	MINOR	Superadmin. This issue has a minor impact on system database behavior.
TRL-13369	SSU	When users attempted to upload an invalid file type (ex. ddl) via drag and drop, the UI froze, and an empty error message was displayed.	MINOR	Editor and above. This issue has a minor impact on document uploads in SSU.
TRL-13404	SSU	Users noted that the Documents grid was not being refreshed after documents were uploaded via import.	MINOR	Editor and above. This issue has a minor impact on the document grid UI in SSU.
TRL-13409	SSU	The 'Email' button is displayed for a document profile in a site despite being disabled in the Documents Module Settings.	MINOR	Editor and above. This issue has a minor impact on the email settings.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13437	SSU	The system displays a 510 error when a document with collected document type is uploaded to a Site.	MINOR	Editor and above. This issue has a minor impact on document uploads in SSU.
TRL-13493	SSU	Users in rooms configured to review non-required documents as a part of the SSU document workflow noted that the status of the non-required documents is not being displayed as expected.	MINOR	Editor and above. This issue has a minor impact on the SSU Documents UI.

12.   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 in accordance with the levels of priority as reasonably determined by **TransPerfect**. Support Services will be available at all times via phone and email from **TransPerfect** Service Desk centers set forth below:

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

B. REQUESTING FUTURE ENHANCEMENTS

If you would like to submit requests for enhancing the system, please submit your ideas through one of the following methods:

Project Manager

(PM)

Customer Experience Program (CEP)

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

13.   Approvals

Product Owner

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

Quality Assurance

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