TRIAL INTERACTIVE V10.5.2 - PATCH - RELEASE NOTES - VERSION 1.0

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2.   Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	02-Feb-2024	Pre-Release Initial Draft Creation
Yogesh Inamdar	0.2	07-Feb-2024	Added the following: • TRL-12936 • TRL-13097 • TRL-13123 • TRL-13243 • TRL-13246 • TRL-13261 • TRL-13269 • TRL-13369 • TRL-13384 • TRL-13386 • TRL-13409 • TRL-13411 • TRL-13441 • TRL-13462 • TRL-13468 • TRL-13482 • TRL-13505 • TRL-13507 • TRL-13542 • TRL-13602 • TRL-13604 • TRL-13605 • TRL-13611 • TRL-13623 • TRL-13766 • TRL-13772 • TRL-13846 • TRL-13856 • TRL-13858 • TRL-13898 • TTI-3513
Yogesh Inamdar	0.3	09-Feb-2024	Added the following: • TRL-12064 • TRL-12814 • TRL-13755 • TRL-13097 • TRL-13936 • TRL-13943
Steve Clark	0.4	09-Feb-2024	Added the following: • TTI-3582 • TTI-3583 • TTI-3584 • TTI-3585 • TTI-3587 • TTI-3588 • TTI-3589 • TTI-3590

			• TTI-3591 • TTI-3592 • TTI-3593 • TRL-12889 • TRL-13715 Removed the following: • TTI-2959 • TTI-3249 • TTI-3398 • TRL-12814 • TRL-13268 • TRL-13384 • TRL-13755
Steve Clark	1.0	15-FEB-2024	Added the Following • TTI-3586

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, 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	10.5.2
Release Type	Patch

5.   Definitions / Acronyms

Term	Definition/Description
JIRA	A proprietary issue-tracking product developed by Atlassian, used for bug tracking, issue tracking, and project management
SQA	Software Quality Assurance
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.
TP	TransPerfect
TI	Trial Interactive
MDE	Metadata Extraction
PI	Principal Investigator
CCR	CTMS Collaborate Room
TMFQ	Trial Master File Quality
QC	Quality Control
IRBs	Institutional Review Board

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	16-Feb-2024
Estimated US MTI Upgrade Date/Time:	16-Feb-2024 9:00 PM ET
Estimated EU MTI Upgrade Date/Time:	16-Feb-2024 11:00 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 to use the Trial Interactive v10.5.2 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 v10.5.2 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.

A.   NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
TTI-3210	CTMS Collaborate	With this enhancement, the system restricts reviewer access for document content edits in CTMS Visit Reports. Now, reviewers are only able to add comments on documents that they are reviewing as a part of the workflow.	Yes	No	MINOR	Editor and above. This improvement has a minor impact on the CTMS Site Visit review process.

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
TTI-3340	Study Start-Up (SSU)	With this improvement, users have a new metadata field associated with IRBs, which allows a user to select one of the several IRBs assigned to a site as the main IRB for the site. • If the IRB selected as the Main IRB is a Central IRB, the site profile inherits the IRB Meetings Schedules and submission deadline from the IRB profile. • If the IRB selected as the Main IRB is local, the site profile does not inherit the IRB Meetings Schedule and Submission deadline from the IRB profile but instead leaves these fields as input fields for the Start-Up Specialist.	No	No	Minor	Editor. This improvement has a minor impact on the IRB selection as a part of Site Management in SSU.
TTI-3513	Collaborate	This improvement assists in ensuring that documents are routed to the correct room. This improvement provides an option for users to indicate which eTMF room should be used as the 'Unblinded' eTMF room related to a study. Only 2 eTMF rooms may be associated to any given study profile, 1 blinded and 1 unblinded.	Yes	No	MINOR	SuperAdmin. This improvement has a minor impact on publishing documents from the CTMS Collaborate Room (CCR) to the linked eTMF rooms.

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
TTI-3555	Study Start-Up (SSU)	This improvement updates the existing logic for site activation in SSU so that, even if there is no required document specified for IRBs or Countries in the room settings, these entitles will appear in their respective grids. In the absence of required documents, the progress bar for these entities appears as 100% complete, allowing for activation/approval of the entity.	No	Yes	MINOR	Editor. This improvement has a minor impact on the Study Start-up entity completion logic.
TTI-3564	CTMS Collaborate	This improvement allows users to view comments made on a document from the 'view-only' mode. If the comment is added, Users no longer have to check the document out or begin a Revision process to see the comments.	Yes	No	MINOR	All Users. This Improvement has a minor impact on the CTMS Site Visit Reports workflow.
TTI-3582	eTMF, Collaborate, SSU	This improvement makes changes, at the Domain level, to fields associated with room creation in Trial Interactive. The field labeled "Study Sponsor" has been renamed "TI Client." Another 'Sponsor' field has been created in order to facilitate CTMS integration as well.	No	Yes	MINOR	SuperAdmins. This improvement has a minor impact on the fields involved in room creation.

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
TTI-3583	eTMF, Collaborate, SSU	When users perform an advanced search in TI, they have the ability to save the search for future use. Occasionally, a room's metadata field configuration may change between uses of the saved search in such a way that the metadata fields used in the search are no longer able to be used. This improvement creates warning messages which indicate that some or all of the required fields were excluded from searches by a room administrator.	No	Yes	MINOR	All users. This improvement has a minor impact on warning messages associated with searching in TI.

TTI-3584	SSU	This improvement makes a series of changes to document handling and options under the Site, Country, IRB/EC, and Amendment sections of SSU:	No	Yes	MINOR	Editor and above. This improvement has a minor impact on the SSU User Interface.
		1. **The "Add to Cart" button has been removed for placeholders.**				
		2. **Make the "Email" button functional when placeholders are selected.**				
		3. **Modifications have been made to the toolbar buttons when a placeholder is selected.**				
		4. **The visibility/useability of the '+' sign for placeholders has been improved by making both the sign and text clickable.**				
		5. **The "Add Doc" button has been added to both the "Non-Required" and "All Uploads" tabs.**				
		6. **The "More" button has been updated so that the following options are expanded and collapsed: Import, Email, Export, and Columns.**				
		7. **The 'Import' button was added to all tabs and now remains available after selecting documents.**				
		8. **The 'Reject' button icon has been changed to an 'X'**				
		9. **Document and placeholder options were updated so that, when something**				

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
		is selected, only relevant options are displayed. 10. **When the selected items have no common actions, a message will now be displayed indicating that there are "No available actions."** 11. **The "Submit to Review" button has been moved to the toolbar.**				
TTI-3585	eTMF	This improvement makes UX improvements to the Related Documents functions. Specifically, the 'Related' tab of the metadata panel now has a toggle switch to show all related documents in the room as well as an associated tooltip to assist in explaining the functionality. By default, this switch is off, only showing the relationships associated to the current document.	No	Yes	MINOR	All users. This improvement has a minor impact on the UX associated with related Documents.
TTI-3586	Collaborate	For CTMS Collaborate document workflows, this improvement removes the ability for a document owner to review their own document. If a user is designated as the document owner for a document, the 'Approve' and 'Reject' options will not be displayed on the workflow user interface.	No	Yes	MINOR	CTMS users involved in visit report workflows. This improvement has a minor impact on the visit report workflow UI.

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
TTI-3587	CTMS Collaborate (CCR)	This improvement makes changes to how and when information regarding visit report rejection is communicated from the workflow review in the CCR to the CTMS site visit report. It will ensure that the CTMS provides a report status of 'Rejected' only at the point where the report author has determined to reject and regenerate the report. This is because the report author has the option to revise the report again, sending it back through an additional review cycle.	No	Yes	MINOR	CTMS users with site visit report visibility. This improvement has a minor impact on the way that the CCR and the CTMS share workflow data.
TTI-3588	SSU	This improvement updates the template file for the investigative site import tool. The column named "Investigative Site" on the template file has been changed to match the field name in the system "Site Name."	No	Yes	MINOR	Editor and above. This improvement has a minor impact on site import.
TTI-3589	eTMF	When contact data is imported from the CTMS to the related eTMF, some contacts were not being successfully received in the eTMF due to a minor mismatch in the names of the contact type field. This improvement allows the eTMF to receive the contact data even when the name of the field is mismatched. The system now defaults to a value of 'Other' where a mismatch is detected.	No	Yes	MINOR	All users. This improvement has a minor impact on CTMS to eTMF interoperability.
TTI-3590	eTMF	This improvement adds a time component to the "Published Date" field in order to facilitate accurate time zone conversion, helping to ensure that the correct date is displayed at all times.	No	Yes	MINOR	All users. This improvement has a minor impact on metadata collection and display.

Feature ID	Offering Impacted	Description	Config Change?	Enabled By Default?	Impact	Comment / Impact Analysis
TTI-3591	eTMF, SSU, Collaborate	This improvement adds a character limit to the Inbox, SSU Inbox, and Communication Inbox, fields in the Edit Room window at the Domain Level. These field limits now match those present inside the Settings area of the room.	Yes	Yes	MINOR	SuperAdmin. This improvement has a minor impact on the UI for editing room information at the domain level.
TTI-3592	eTMF	This improvement removes the 'Download Document' button from the TI Document Viewer for users whose access level is indicated as 'Regulatory Agency Inspector.'	No	Yes	MINOR	Users indicated as Regulatory Agency Inspectors. This improvement has a minor impact on TI Viewer functionality.
TTI-3593	eTMF	Previously, if a query was raised on a document placeholder, it was possible that a document might be submitted to fulfill the placeholder both via upload and as a response to the generated query, resulting in two unique document ID numbers associated with the same document requirement. This improvement make adjustments in the system logic applied to this situation so that this situation results in only one document ID number with the query being reassigned automatically to the first matching document.	No	Yes	MINOR	All users. This is a minor improvement to system logic in order to facilitate correct processing of submitted documents when a query is also opened on the placeholder being fulfilled.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-9653	eTMF	An Incorrect Workflow stage ID error is displayed when a user rejects a visit report in a workflow on the signature step from the metadata panel.	MINOR	Editor and above. This bug has a minor impact on the document workflow actions. The resolution resets the correct system behavior where the document is processed with a 'Rejected' status.
TRL-12064	eTMF	The Super Admins experienced that the Communication module and Communication Inbox was not getting disabled from the settings and when creating a room.	MINOR	Super Admins. This bug has a minor impact on the communications module settings and communication inbox processing. The resolution restores the correct system behavior.
TRL-12889	eTMF	Users noted that, while performing a search, if a filter was added and a value selected utilizing the search-ahead typing function, the selector menu was not disappearing as expected.	MINOR	All users. This issue had a minor impact on the search UX. Correct system behavior has been restored.
TRL-12936	SSU	SSU users found that, after uploading a document to a requirement, the grid view was not refreshed as expected and still indicated that the requirement was unfulfilled.	MINOR	Editor and above. This issue had a minor impact on the required documents grid in SSU. Correct system behavior has been restored.
TRL-12941	eTMF	The Super Admin level users are not able to disable all the KPI cards from the default dashboard view. The system displays all checkboxes as checked, and the reader-level users can also access the KPI cards and click them.	MINOR	Super-Admins. This bug has a minor impact on the KPI dashboard configuration. The resolution restores the correct process, and the KPI cards are available per the user hierarchy and actions enabled.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13097	SSU	The admins could see No Value for the Active, Main Contact, and Provide Documents columns that they added in the Contacts of a Site Profile.	MINOR	Admins and above. This bug has a minor impact on Contact fields. The resolution restores the correct display of values entered.
TRL-13123	SSU	When an admin-level user opens the Amendments tab in the Site Profile and selects any amendment, the document metadata displays the category field as empty.	MINOR	Admins and above. This bug has a minor impact on the Site Amendment Document Metadata. The resolution restores the correct category displayed.
TRL-13154	eTMF	When an admin-level user creates a subfolder under a template folder in the modify index page, the delete icon is initially displayed before saving the folder. However, after saving the folder, the delete icon disappears, preventing users from deleting the folder as expected.	MINOR	Admin Users. This issue had a minor impact on creating a subfolder in Modify Index. Correct system behavior has been restored.
TRL-13243	SSU	For users with Admin and above-level access, when opening the Documents tab and selecting a placeholder, the system displays the 'Placeholder' button with Add and Add to Cart options.	MINOR	Admins and above. This bug has a minor impact on the Placeholder option's user interface. The resolution displays only the 'Add Document' option when a placeholder is selected.
TRL-13246	SSU	The IRB/EC value is not specified in the metadata panel of a selected Placeholder in an IRB/EC profile.	MINOR	Admins. This bug has a minor impact on the Placeholder metadata. The resolution restores the IRB/EC values for the selected Placeholder.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13261	SSU	The admin-level users can see the Edit button displayed for the IRB/EC and Site Profile in a Country profile.	MINOR	Admins. This bug has a minor impact on the IRB/EC and Site Profile. The resolution restores the correct controls where the IRB/EC and Site Profile are not editable, and the site profile for local IRB/EC 'IRB/EC Submission date' and 'IRB/EC Approval date' fields are editable.
TRL-13263	eTMF	Users are having issues while working in Dark Mode within the system; the screens display in an unusual and undesirable manner, showing black and white stripes instead of dark mode.	MINOR	All User. This issue had a minor impact on the system's dark mode. Correct system behavior has been restored.
TRL-13268	SSU	Users noted that they were unable to apply a status of 'Closed' to an active site.	MINOR	Editors and above. This issue had a minor impact on SSU site status functionality. Correct system behavior has been restored.
TRL-13269	SSU	The Super-Admin level users cannot activate a closed site since the 'Change Status' button is disabled.	MINOR	Super Admins. This bug has a minor issue with the Site Activation. With the resolution, the Super-Admins can activate the closed sites.
TRL-13279	eTMF	Users are not able to select the view created by the user" in the manage view.	MINOR	All User. This issue had a minor impact on the Manage view in the Documents Module. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13369	SSU	In a Country Profile, when a Placeholder is selected, and an invalid file type is uploaded via drag-and-drop, the page is frozen, and an empty error message is displayed.	MINOR	Admins. This bug has a minor impact on the placeholder submission process. The resolution resets the warning message for the incorrect file types with the text ''One or several files you are trying to upload are restricted by security reasons.'
TRL-13384	SSU	In rooms where the option to allow documents to be submitted without attachments was disabled, users found that they were still able to click the 'Add' button on the upload form without adding an attachment. An error message was then displayed.	MINOR	Editor and above. This issue had a minor impact on document uploads without attachments in SSU. The 'Add' button is no longer enabled in this situation.
TRL-13386	SSU	There is a continuous loading spinner displayed when the admin level users try to attach an invalid URL to add a placeholder in a Country's Documents tab.	MINOR	Admins. This bug has a minor impact on the placeholder submission process. The resolution resets the warning message for the incorrect URL types with the text 'Only HTTP/HTTPS links are available.' The 'Add' button is disabled until the valid URL is entered.
TRL-13409	SSU	In a Site, when any of the documents is selected, the Email button is displayed despite of the 'Enable Email Send' option is disabled in the settings.	MINOR	Admins. This issue has a minor impact on the Site Documents settings. The resolution restores the correct system behavior.
TRL-13411	SSU	The system does not display the IRB/EC progress when an IRB/EC was added/deleted for the Site Profile.	MINOR	Admins. This bug has a minor impact on the IRB/EC updates. The resolution resets the correct progress update for the added/deleted IRB/EC.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13422	eTMF	An error is consistently displayed when attempting to submit a document for eSignature. This issue affects all rooms and all types of documents within the system.	MINOR	All User. This issue had a minor impact on the e-signature. Correct system behavior has been restored.
TRL-13425	CTMS Collaborate	In CTMS Collaborate Room, when the users try to state a site visit report for revision, the system displays the Revise and Regenerate buttons in the edit mode, and no Compare button is available after Revision. In the CTMS instance, the report is still displayed in the returned status.	MINOR	Editor and above. This bug has a minor impact on the CTMS report revision process. The resolution resets the correct system behavior where the report document is updated as a new version in the Collaborate room and is displayed as Manual revision status in the CTMS.
TRL-13441	SSU	The modal paddings are missed for a recently uploaded document in a Site's Site Profile-Documents tab.	MINOR	Admins. This bug has a minor impact on the document modal's user interface. The resolution restores the correct modal display.
TRL-13462	SSU	The IRB progress does not take into account the IRBs without the Required Documents.	MINOR	All Users. This bug has a minor impact on the IRB progress display. Correct system behavior has been restored.
TRL-13468	SSU	When a non-required document is uploaded to a Site Profile, and it is approved, the system does not display the Received Data, and the QC Review Status is not applied to the document.	MINOR	Admins. This bug has a minor impact on the non-required documents' approval. The resolution restores the correct system behavior.
TRL-13482	SSU	The 'Previous' button is missed on the second step of the amendment creation in the Study Start-Up.	MINOR	Admins. This bug has a minor impact on the Create Amendment page's user interface. The resolution displays the 'Previous' button on the second step of the Amendment Creation window.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13491	eTMF	The user noted that the 'Edit Advanced Validation' field at the document type level is no longer working for some rooms.	MINOR	All Users. This issue had a minor impact on the Document Types in Settings. Correct system behavior has been restored.
TRL-13498	eTMF	When a user attempts to export documents and selects the "Include Metadata" option within the export options page, the "Export Documents" process remains in a perpetual loading state. This problem occurs in both the View Index and the Search View.	MINOR	All Users. This issue had a minor impact on the exporting documents from the View Index and Search View. Correct system behavior has been restored.
TRL-13501	eTMF	In the system, there is a defect where the page count and document count values are not getting updated under the Settings page in the About section. Even though documents are being processed for the page count where, the user can see the page count number in the processed folder section. However, the values are not displayed in the settings.	MINOR	All Users. This issue had a minor impact on Settings. Correct system behavior has been restored.
TRL-13505	SSU	The IRB/EC progress is displayed as 0% when an approved IRB/EC with collected documents is uploaded.	MINOR	Admins. This bug has a minor impact on the IRB/EC progress display. The resolution resets the correct progress display.
TRL-13507	eTMF, SSU	The added existing IRB/EC is not displayed in the list in the Site Profile under the eTMF module.	MINOR	Admins. This issue has a minor impact on the IRB/EC addition in the institutions. Correct system behavior has been restored.
TRL-13522	CTMS	Within the CTMS (Clinical Trial Management System) Integration, there is a defect where the confirmation popup is inaccurately named "Regenerate report" instead of the correct name, which should be "Revise report."	MINOR	All Users. This issue had a minor impact on CTMS Integration. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13524	eTMF	In the system, when a user creates an Audit profile and attempts to publish a document to it, a defect occurs. After clicking the "Publish Document" option, the page enters an endless spinning state, and the user is unable to proceed by clicking "Yes" or "No" to publish the document to the Audit profile.	MINOR	Editor and above. This issue had a minor impact on Documents Quality Review Settings. Correct system behavior has been restored.
TRL-13539	SSU	In the SSU module, the regulatory approver encounters a defect where they are unable to Approve/Reject documents. When the user navigates to the regulatory review, the Approve/Reject button is greyed out, but when the user selects the document, the Approve/Reject button disappears.	MINOR	All User. This issue had a minor impact on the Regulatory Review in the SSU Module. Correct system behavior has been restored.
TRL-13542	SSU	The admins without Start-Up action could see the created documents.	MINOR	Admins. This bug has a minor impact on the admin's user authority. The resolution restores the correct system behavior. The created documents are displayed only if the admins have the Study Start-Up action.
TRL-13584	eTMF	When checking a user's access group, the System group is not displayed by default, and the user has to be manually included in the System group for it to appear in their user's access groups.	MINOR	Editor and above. This improvement has a minor impact on User Management.
TRL-13597	eTMF	PDF conversion functionality is not functioning as expected across all instances of the system. The documents, which are supposed to be converted to PDF, remain stuck in an "In Progress" status and do not get successfully converted to PDF format.	MINOR	All User. This issue had a minor impact on the eTMF Module. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13602	SSU	The admin-level users experienced the non-availability of all the Central IRB/ECs for selection on the 'Select Option' window when creating a new Site.	MINOR	Admins. This issue has a minor impact on the Site Creation process. The resolution resets all the central IRB/ECs available for selection while creating a new site.
TRL-13604	SSU	When creating a new site, the admins could see incorrect pagination on the Add IRB/EC step after selecting all IRB/ECs.	MINOR	Admins. This issue had a minor impact on the site creation process. Correct system behavior has been restored.
TRL-13605	SSU	The counts displayed near the IRB/ECs tabs are incorrect. The system does not count the IRBs without the required documents.	MINOR	Admins. This bug has a minor impact on the IRB/EC page's count. The correct count display has been restored.
TRL-13611	SSU	For a created site with Central IRB/EC added as a main, the site metadata fields 'IRB/EC Submit Date' and 'IRB/EC Approval Date for IRB/EC' are empty. The site profile does not inherit from the main IRB/EC.	MINOR	Admins. This issue has a minor impact on the central IRB inheritance to the created site. The resolution resets the correct system behavior.
TRL-13615	eTMF	In the eTMF module, users encounter a defect where they are unable to edit or create contacts. When attempting to do so, a blank page is displayed.	MINOR	Editor and above. This issue had a minor impact on editing or creating a contact in the eTMF Module. Correct system behavior has been restored.
TRL-13623	SSU	In the metadata panel of a selected IRB/EC profile, the Status History is displayed empty.	MINOR	Admins. This issue has a minor impact on the metadata panel of the IRB/EC profile. Correct system behavior has been restored.
TRL-13653	SSU	When users attempt to click on an existing site contact at the Domain level, they encounter a "Network Error" pop-up. This issue prevents users from accessing or interacting with the site contact.	MINOR	All User. This issue had a minor impact on Site contact from SSU. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13666	eTMF	The users receive email notifications multiple times for signature documents when the parallel signature request is selected, and there are multiple signatories.	MINOR	Editor and above. This bug has a minor impact on the signature notifications. The resolution resets the correct system behavior.
TRL-13677	eTMF	When a user creates a room that is cloned, there is a defect where the events from the source room are not updated or copied over to the newly created room.	MINOR	Admin. This issue had a minor impact on the Event Triggers. Correct system behavior has been restored.
TRL-13710	eTMF	Users are experiencing a "No Data Found" issue in the Data type and IFC type in metadata fields.	MINOR	Admin. This issue had a minor impact on entering data in Metadata Fields. Correct system behavior has been restored.
TRL-13715	SSU eTMF	Users in domains where custom date and text fields were enabled and intended for import using the Site Import tool, noted that the custom fields did not import as expected when using the site import worksheet.	MINOR	Editor and above. This issue had a minor impact on users in specific domains wherein the configuration impacted site import functionality. Correct system behavior has been restored.
TRL-13755	eTMF	When a user is added to a specific workflow, they can see other workflows of which they are not a part. Users should only be able to view the workflows they are associated with.	MINOR	All Users. This issue had a minor impact on viewing a workflow in the Quality Review. Correct system behavior has been restored.
TRL-13766	SSU	The email field in the Contact Information section is placed at the bottom and the search and add recipients becomes a bit hard for the users.	MINOR	All Users. This issue has a minor impact on the contact creation on a site. The resolution sets the email field on the top of the screen, making it user-friendly.
TRL-13772	SSU	The system does not display an error when an existing site principal investigator is specified and then changed from the Site Details.	MINOR	Admins. This bug has a minor impact on the principal investigator change process. The resolution resets the error message.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13774	eTMF	While using the TI Sign provider for signing documents, a defect has been identified where the File Size column in the database records a value of 0 for signed documents.	MINOR	All Users. This issue had a minor impact on the TI Signature feature for document signing. Correct system behavior has been restored.
TRL-13838	eTMF	When a user creates an event in the Event Manager, all required document types, including those that are not enabled as event-driven in the settings, are displayed. The unchecked event-driven document type appears in Event Requirement.	MINOR	Admin. This issue had a minor impact on creating an event in the Event manager. Correct system behavior has been restored.
TRL-13846	SSU	After selecting a site and clicking the metadata toolbar, the users can see that the metadata fields are editable, but the 'Save' button is missing.	MINOR	Admins. This issue has a minor impact on the site metadata edit. The resolution resets the 'Edit' mode for the metadata.
TRL-13853	SSU	In the SSU module, two metadata fields, "Provide Documents" and "Main Contact," were initially enabled by default; now, the same fields are disabled. This alteration has led to confusion among users.	MINOR	All Users. This issue had a minor impact on two metadata fields for all SSU rooms. Correct system behavior has been restored.
TRL-13856	SSU	The eTMF -Countries section displays all the metadata fields in one section for a selected country.	MINOR	Admins. This issue has a minor impact on the Countries' metadata in the eTMF module. The resolution adds the sections 'General Information' with system fields and 'Additional Information' with the custom fields.
TRL-13858	SSU	On some of the tooltips 'No Data Found' is displayed despite the country having assigned sites. This issue is experienced in the eTMF-Countries section.	MINOR	Admins. This issue has a minor impact on the Sites' tooltip. The correct tooltips are restored.
TRL- 13898	SSU	The users are unable to create an Amendment with a back date from the SSU-Amendments section. However, this is possible from the Settings module-Create Amendments.	MINOR	Admins. This issue has a minor impact on Amendment creation. The correct system behavior is restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13907	eTMF, SSU	A site contact name updated is displayed incorrect in the contacts grid.	MINOR	All Users. This issue has a minor impact on site contacts management. The resolution resets the correct name displayed.
TRL-13936	eTMF, SSU	The users observed that the Principal Investigator's last name is mission in many of the site names.	MINOR	All Users. This issue has a minor impact on site contacts management. The resolution resets the correct name displayed.
TRL-13943	eTMF	A document with effective date metadata injection with esignature when is added to a workflow and approved, the metadata injection is not displayed. The field is displayed as empty.	MINOR	Admins. This issues has a minor impact on the metadata injection. The resolution resets the correct metadata displayed.

11. Customer Support

C. 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

D. 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

12. Approvals

Product Owner

Name: Jay Smith	Title: Senior Director, Product Management
Signature: Reason for signature: Date:	

Quality Assurance

Name: Ankush Sharma	Title: Computer Systems Validation Specialist
Signature: Reason for signature: Date:	