

TRIAL INTERACTIVE V10.5.4 - PATCH RELEASE NOTES - VERSION 1.0





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2. Version History

Author	Revision #	Date	Comment
Yogesh Inamdar	0.1	07-May-2024	Pre-Release Notes issued
Yogesh Inamdar	0.2	09-May-2024	Added the Open Defects section.
Yogesh Inamdar	0.3	17-May-2024	<p>Added the following features</p> <ul style="list-style-type: none">• TTI-3711• TTI-3712 <p>Added the following defects</p> <ul style="list-style-type: none">• TRL-14166• TRL-14488• TRL-14730• TRL-14837• TRL-14861• TRL-14871• TRL-14872 <p>Removed the following</p> <ul style="list-style-type: none">• TTI-2864• TTI-3398• TTI-3550• ETMF-1100• TRL-14488
Yogesh Inamdar	0.4	23-May-2024	<p>Added the following features</p> <ul style="list-style-type: none">• TTI-3710• TTI-3562
Yogesh Inamdar	0.5	27-May-2024	<p>Added the following Defects</p> <ul style="list-style-type: none">• TRL-14868• TRL-14873• TRL-14921
Yogesh Inamdar	0.6	30-May-2024	<p>Added the following</p> <ul style="list-style-type: none">• TRL-14421• TRL-14462• TRL-14838• TRL-14846• TRL-14881• TRL-14972 <p>Removed the following</p> <ul style="list-style-type: none">• TTI-2926• TTI-3414• TTI-3664• TRL-14291• TRL-14091
Yogesh Inamdar	1.0	31-May-2024	Initial version finalized



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	10.5.4
Release Type	Patch

5. Definitions / Acronyms

Term	Definition/Description
21 CFR Part 11	The part of the United States Code of Federal Regulations 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
eISF	Electronic Investigative Site File
ERES	This document provides guidance in the United States for using electronic systems, records, and signatures in clinical investigations.
eTMF	Electronic Trial Master File
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.
KPI	Key Performance Indicator
OOTB	Out of the Box
SAAS	Software as a Service
sFTP	A secure File Transfer Protocol
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SQA	Software Quality Assurance
SSU	Study Start-Up
TI	Trial Interactive
TP	TransPerfect

6. Release Overview

This patch release includes minor, low-impact improvements and defect resolutions. Please see the table below in the next section for the release schedule.



7. Release Schedule

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

Schedule	
Date of Release	31-May-2024
Estimated US MTI Upgrade Date/Time:	31-May-2024 9:00 PM ET
Estimated EU MTI Upgrade Date/Time:	31-May-2024 9:00 PM CET
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your TransPerfect Project Manager.

8. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the Trial Interactive v10.5.4 platform.

System Requirements	
Operating System	<ul style="list-style-type: none"> Windows Version 7 or higher <p>All currently supported Mac OSX releases</p>
Browser	<ul style="list-style-type: none"> Microsoft Edge: Version 88 and later Google Chrome: Current release and earlier Mozilla Firefox: Current and ESR releases Apple Safari: Current release and earlier NOTE: TI Digital Sign requires that pop-up blockers are turned off for the Trial Interactive domain.
Client Software	<ul style="list-style-type: none"> For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally. For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred). Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. <p>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®.</p>
Optional Add-Ons	<ul style="list-style-type: none"> DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) Adobe Sign (Latest Adobe Document Cloud Version) <p>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.</p>

9. Changes

Trial Interactive v10.5.4 has been released with these enhanced features and defect fixes. This table uses 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-2898	Collaborate	This improvement makes the Contact Type field mandatory when creating a site user (only in an eISF solution.)	No	Yes	MINOR	Administrators. This improvement has a minor impact on the user invitation UI.
TTI-3073	Study Start-Up (SSU)	<p>This new feature focuses on the Status history of Countries with the following enhancements-</p> <ul style="list-style-type: none"> • The system now records and displays the history of change in the Country's Status. • The system has a new button on the country details page that displays the country status history. • The Country Status History is now displayed in a modal window. 	No	Yes	MINOR	All Users. This new feature enhances the system user experience of the Countries section in Study Start-Up.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3547	eTMF, Collaborate, Study Start-Up (SSU)	This improvement allows the audit trail to track all manual placeholder activities, such as adding, deleting, or modifying metadata fields. Additionally, this enhanced functionality includes audit logging for the addition or removal of automatic placeholders generated through required document settings.	No	Yes	MINOR	Administrators. This improvement has a minor impact on placeholder activity tracking via the audit trail.
TTI-3562	eTMF, Collaborate	The improvement allows TI's audit trails to capture the 'Reason for Signature' when a document is signed with TI Sign or TI Digital Sign.	No	Yes	MINOR	Editor or above. This improvement has a minor impact on eSignature-related data captured in the audit trail.
TTI-3577	eTMF	With this improvement, the eTMF will now inherit CTMS Site and Organization names from CTMS when integration has been enabled between these elements of the TI Platform. The Site name in the eTMF will be overridden from the CTMS instance, even if 'Auto-Generate' is enabled.	No	Yes	MINOR	All Users. This improvement has a minor impact on the CTMS- eTMF integration regarding site names.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3620	eTMF	This improvement allows users with appropriate permissions to manage contact information directly from the eTMF coding panel during document indexing and review. The improved user interface validates the updated information and generates audit trail entries for all modifications executed.	No	Yes	MINOR	Editor and above. This improvement has a minor impact on managing contact data.
TTI-3623	eTMF	This improvement provides users with the ability to delete document types from the system via user interface or API. Upon the deletion, the associated audit configuration data, including any references in Audits, is automatically removed from the system. Additionally, this process ensures the maintenance of data integrity and prevents data loss.	No	Yes	MINOR	Super Admins. This improvement enhances the Quality Review Audit process. Only users with appropriate permissions can initiate the deletion of Document Types and associated audit configuration data.
TTI-3648	eTMF	<p>When searching for queries within a TI eTMF room, “Orphaned Queries” queries for which the associated document no longer exists, either through deletion or rejection, could not be accessed or responded to. Users were presented with a “Topic does not exist” error message.</p> <p>This improvement allows users to locate, access, and respond to these orphaned queries.</p>	No	Yes	MINOR	All Users. This improvement enhances the Queries Module user experience and helps the users resolve queries with or without placeholders.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3670	Study Start-Up (SSU)	With this improvement, the editor-level users with the Start-Up Specialist action enabled can see the reason the Regulatory Reviewer rejected the document in the Document Metadata Panel.	No	Yes	MINOR	Editors. This improvement has a minor impact on the SSU Documents Management and enhances user authority.
TTI-3703	Study Start-Up (SSU)	This improvement enhances the IRB Approval. When an IRB is approved, it will not transmit/overwrite the IRB Submission and Approval dates to the Sites. The improved IRB Submission and Approval date for Main IRB will be input field from the Site Profile Page. It will pass on this data for the main IRB only to the Sites -> IRB -> Metadata Panel field. Also, under the metadata panel, this field will be greyed out. For the IRBs that are not main, the input field will be available in the metadata panel.	No	Yes	MINOR	Editors. This improvement enhances the SSU IRB/EC Approvals and protects the data from being overwritten.
TTI-3710	Study Start-Up (SSU)	This improvement provides a warning popup message whenever a user is attempting to restore a document that was deleted from a placeholder in SSU whenever another document has been uploaded to fulfill the same placeholder.	No	Yes	MINOR	Admin. This improvement has a minor impact on user notifications associated with restoring deleted documents in SSU rooms.
TTI-3711	eTMF, Study Start-Up (SSU)	This improvement sets the Convert Non-PDF to PDF checkbox disabled when the PDF Conversion is turned on to the Automatic option from the Document Conversion settings.	No	Yes	MINOR	Admins. This improvement has a minor impact on the Study Start-Up Document Management.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3712	eTMF, Study Start-Up (SSU)	With this improvement, the system now displays a notification about the applied changes after updating the contact information from the Contacts metadata panel.	No	Yes	MINOR	Editors and above. This improvement has a minor impact on the system notifications. This enhances the eTMF/SSU Contacts management.
TTI-3714	eTMF, Study Start-Up (SSU)	This improvement implements hover-over information for an empty placeholder. The users can now see the additional information for Contact Type and Contact Name; especially when such placeholders are Investigative Site Category.	No	Yes	MINOR	Editors. This improvement has a minor impact on the Study Start-Up Document Management.
TTI-3715	eTMF, Study Start-Up (SSU)	With this improvement, the users can now see the additional information for Contact Type and Contact Name; when such placeholders are Investigative Site Category in the bulk document import and assigning them to placeholders in eTMF.	No	Yes	MINOR	Editors and above. This improvement has a minor impact on the eTMF Document Activities and enhances the Required Documents user experience.
TTI-3719	eTMF	With this improvement, the Working Documents view now displays all Index folders in the Staging area.	No	Yes	MINOR	Editor and above. This improvement has a minor impact on the system user experience.

B. CROSS-PRODUCT IMPROVEMENTS

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3610	CTMS, Collaborate, eTMF	<p>Users of TI's CTMS are familiar with the site visit report workflow interface, which guides users through the editing, review, and signature process for these documents.</p> <p>With this improvement, confirmation and follow-up letters will now follow a workflow process in a similarly efficient user interface, removing the need to manually locate and sign documents via the CCR.</p>	Yes	No	MINOR	Editors and above. This improvement enables the Collaborate CTMS Workflow process and interface for site-visit-related letters.

C. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-11422	eTMF	The eSignature type, 'TI Sign,' is not populated automatically, though it is set at the domain level. This type is now populated per expectation.	MINOR	Admins. This bug has a minor impact on the eSignature domain settings. The resolution resets the correct system behavior.
TRL-12814	eTMF	The system displays the Server or User Time Zone for a Room instead of the Room Time Zone. This is resolved; it now shows the Room Time Zone.	MINOR	All Users. This bug has a minor impact on the system's time zone. The resolution resets the room time zone as expected.
TRL-13312	Study Start-Up (SSU)	Instead of the standard * sign to denote the field is a required field, the system was displaying the text 'This field is Required' in the following sections: <ul style="list-style-type: none"> - When adding a communication log - When adding an IRB to a Site - When Adding a Site Contact 	MINOR	Admins. This bug has a minor impact on the SSU user interface. The text message is now replaced with an asterisk mark.
TRL-13437	Study Start-Up (SSU)	When a user opens any site profile and opens the Required /Non-required tab to import an already collected document type file, the import is finished with a 510 error.	MINOR	Editors and above. This bug has a minor impact on the SSU document management. The resolution resets the correct system behavior.
TRL-13622	eTMF	When a user saves a grid view, it is displayed as greyed out and is not selectable.	MINOR	Editors and above. This bug has a minor impact on the grid views. The resolution resets the correct system behavior.
TRL-13851	Study Start-Up (SSU)	The Site Export file displays the 'Investigative Site Name' title for the field name 'Institution Name' in the grid.	MINOR	Admins. This bug has a minor impact on the SSU Site Export. The resolution resets the correct fields display.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14076	eTMF	When trying to 'Export All Users' and 'Export Audit Trail' from the User Management module, the export does not display anything; only the header is displayed.	MINOR	Admins. This bug has a minor impact on the User and Audit Trail exports. The resolution sets the correct display.
TRL-14144	eTMF	Users noted that the manage view function is not working in a specific room in the Multi-Tenant Instance.	MINOR	Admins. This bug has a minor impact on the system user interface. The resolution resets the correct system behavior.
TRL-14166	eTMF, Collaborate	The 'Share' folder is seen in the first position in the Index tree of a room. The users with editor-level roles are able to view the documents in the shared folder by default, even though the documents are restricted at other folder levels. This has been addressed; now, the document folder security is correctly followed.	MINOR	All Users. This bug has a minor impact on the system folders' position in a document index. The resolution restores the correct index structure.
TRL-14183	Study Start-Up (SSU)	A deleted document is not restored when a user tries to restore it without review, choosing the No option.	MINOR	Editor and above. This bug has a minor impact on the SSU deleted documents. The resolution resets the correct system behavior.
TRL-14184	Study Start-Up (SSU)	In the Study Start-Up, when a User tries to add a document in the By Site view, the Category and Site are not predefined.	MINOR	Editors and above. This bug has a minor impact on the SSU Site Document management. The resolution resets the Investigative Site is selected by default as a category.
TRL-14209	eTMF	The Editor-level users can upload bulk documents from the 'Add' option of the documents module despite the 'Enable Mass Import for Editors' being unchecked in the Documents settings.	MINOR	Editors. This bug has a minor impact on the editor users' document upload access. The resolution resets the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14249	eTMF	The Auditors or Audit Managers cannot change the status of an audited document from passed to failed and vice-versa. This has been resolved.	MINOR	Admins. This bug has a minor impact on the Quality Review Audit documents. The resolution resets the correct system behavior.
TRL-14252	eTMF Collaborate	The auto-coded fields are not automatically filled in when adding a single document to a folder. This has been corrected; these fields are now filled out.	MINOR	Editor and above. This issue has a minor impact on the Document Type Management settings. The resolution restores the correct system behavior.
TRL-14280	Collaborate	When users check out and check in a document, the effective date and version are visible in the Approved Word document. However, these details disappear after converting the document into a signed PDF. In the signed PDF, placeholders such as \$EffectiveDate\$ and \$EffectiveVersion\$ appear instead of the actual effective date and version. Despite being set correctly in the Content Control Setting and Form Setting, this issue persists.	MINOR	All Users. This issue has a minor impact on documents converted into PDF for E-signature using MSB docs. With the resolution in place, the PDF copy now correctly displays the Effective Date and Effective Version. Correct system behavior has been restored.
TRL-14298	Study Start-Up (SSU)	The editor-level users can see the Add button in the Document dropdown menu and by right-clicking in the All Documents tab of an activated site even after the “Do not allow addition of new documents for a site after the activation” option is enabled in room settings.	MINOR	Editors. This bug has a minor impact on the site’s document management user authority. The resolution resets the correct system behavior.
TRL-14309	Study Start-Up (SSU)	The active sites appear in the sites dropdown menu to the editors when they click the Import button, and the “Do not allow addition of new documents for a site after the activation” option is enabled in room settings.	MINOR	Editors. This bug has a minor impact on the site’s document management. The resolution resets the correct system behavior and the active sites are now not presented in the list.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14462	eTMF	The document upload process is providing an issue where the Auto Indexing is not working even though it is activated in the settings. The documents are imported into the selected folder and not to the Default when selecting 'Add Multiple Documents.'	MINOR	Editors and above. This bug has a minor impact on the document settings and index management. The resolution resets the correct system behavior.
TRL-14468	eTMF	The system allows to send blank emails. There is no asterisk for the body text.	MINOR	All Users. This bug has a minor impact on the TI Emails user interface. The resolution makes the body text mandatory.
TRL-14478	eTMF	Even though the option "Enable File as Attachment" is disabled in the room settings, the File as Attachment option still appears when creating a query from the Audit/quality review module. Also, the users are able to send a document as an attachment via email.	MINOR	Editors and above. This bug has a minor impact on the document settings. The resolution resets the correct system behavior.
TRL-14512	eTMF	The Super Admins cannot delete the Manual and Translation relation type from the Documents settings.	MINOR	Super Admins. This bug has a minor impact on the document settings. The resolution resets the correct system behavior.
TRL-14547	eTMF	The Super Admins cannot see the Originated from Room ID with the correct name when the open change log option is selected in a client profile from the domain settings.	MINOR	Super Admins. This bug has a minor impact on the domain settings. The resolution resets the correct system behavior.
TRL-14566	Study Start-Up (SSU)	The Rejection Reason for a rejected document is not seen in the View by Regulatory Review in the Study Start-Up.	MINOR	All Users. This bug has a minor impact on the system user interface. The resolution resets the correct display.
TRL-14580	eTMF	The users cannot mark a document as obsolete that has been processed from an Administrative Workflow.	MINOR	All Users. This bug has a minor impact on the document management. The resolution resets the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14612	eTMF	A file imported corresponding to Amazon S3 and exported in the Audit Trail; the export does not have the activity 'Open Document.'	MINOR	Admins. This bug has a minor impact on the Audit Trail export. The resolution resets the correct system behavior.
TRL-14619	Study Start-Up (SSU)	The options File as link and File as Attachment are greyed out in the email window under the Study Start-Up module. However, the same option is active in the eTMF module.	MINOR	Editor and above. This bug has a minor impact on the SSU emails. The resolution resets the correct options.
TRL-14628	eTMF	An incorrect signature notification is displayed as 'Document is declined successfully' for a signed document.	MINOR	Editor and above. This bug has a minor impact on the signature notifications. The resolution resets the correct notification.
TRL-14685	eTMF Study Start-Up (SSU)	There is an inability observed when trying to add a user with Admin-level access as a Site Contact.	MINOR	Admins. This bug has a minor impact on the system user authority. The resolution resets the correct system behavior.
TRL-14730	Study Start-Up (SSU)	The users experienced an erroneous system behavior when editing a site contact in some of the sites. After checking the options 'Provide Documents and Main Contact,' it gets saved, but these options are seen unchecked in the Site Profile.	MINOR	Admins. This bug has a minor impact on the Site Contact management. The resolution restores the correct display.
TRL-14746	eTMF, Study Start-Up (SSU)	When a document is imported, and the category selected is 'Site' and then the Investigative Site is selected, the corresponding metadata does not appear in the metadata panel after importing the document.	MINOR	Editors and above. This bug has a minor impact on the site documents metadata. The resolution resets the correct system behavior.
TRL-14748	Collaborate	The users are able to view the 'Effective Period' and 'Next Review Date' options in the document upload window, even after enabling the option 'The Periodic Review Not Required' in the document type settings.	MINOR	Editors and above. This bug has a minor impact on the Document Type Management. The resolution restores the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14770	eTMF, Collaborate	There is an error displayed when a user selects the TI Signature (Serial) for a document that is under Change Control Workflow.	MINOR	Admins. This bug has a minor impact on the TI Signatures. The resolution restores the correct system behavior.
TRL-14820	eTMF, Study Start-Up (SSU)	There is a continuous loading spinner observed when a document is added to a site category and the Investigative Site.	MINOR	Editor and above. This bug has a minor issue on the system user interface. The resolution resets the correct system behavior.
TRL-14831	eTMF	The users experienced a continuous loading spinner when clicking on a site visit report that was generated in CTMS.	MINOR	Editor and above. This bug has a minor issue on the system user interface. The resolution resets the correct system behavior.
TRL-14837	Collaborate	The system does not display the document version number for the documents that are approved and signed.	MINOR	All Users. This bug has a minor impact on the document version control. The resolution resets the correct system behavior.
TRL-14838	eTMF, Study Start-Up (SSU)	The users with site permission are not able to sort the investigative sites by site number.	MINOR	Editor and above. This bug has a minor impact on the Site Documents Management. The resolution resets the correct system behavior.
TRL-14846	eTMF	The system does not display the Activity Log when two or more users are selected in the User Management.	MINOR	Admins. This bug has a minor impact on the user management. The resolution restores the correct system behavior.
TRL-14853	eTMF, Study Start-Up (SSU)	The system does not display the option to select the site stage folder when a site editor with the rights to upload site-related documents tries to upload documents to a site.	MINOR	Editor and above. This bug has a minor impact on the Site Documents Management. The resolution resets the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14861	eTMF	The users are getting a 'Database Error' warning message when they try to add attachments to a placeholder.	MINOR	Editors and above. This bug has a minor impact on the placeholder attachments. The resolution removes the error, and the attachments are added successfully.
TRL-14866	Study Start-Up (SSU)	There is a defect in the date picker. It gets closed automatically when a user tries to click it from the Reg Pack Send Date in the Site Edit window.	MINOR	Editor and above. This bug has a minor impact on the system user interface and was stipulated to Chrome browser users only. The resolution restores the correct system behavior.
TRL-14868	eTMF	The users experienced the inability to remove the metadata for documents approved in a workflow.	MINOR	Editor and above. This bug has a minor impact on the document management. The resolution restores the correct system behavior.
TRL-14871	eTMF	The Document Owner field keeps blinking and taking too long to pull the data and update the display.	MINOR	Editor and above. This bug has a minor issue on the system user interface. The resolution will reset the correct system behavior.
TRL-14872	eTMF	The 'Effective Date' is not inserted even if entered as effective immediately to a document when it is sent for approval and signature.	MINOR	Editor and above. This bug has a minor impact on the document's effective date. The resolution restores the correct system behavior.
TRL-14873	eTMF	The users experienced issues with the document upload function, where there was an error message seen with the drag-and-drop method, and with the Browse files, only the first selected file was imported.	MINOR	Editors and above. This bug has a minor impact on the document upload. The resolution restores the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14881	eTMF, Study Start-Up (SSU)	The users experienced the inability to update the Address of a closed site. The system displays a warning and users aren't able to update without adding the Effective Closure Date & Closure Comments.	MINOR	Editors and above. This bug has a minor impact on the Site Management. The resolution resets the correct system behavior.
TRL-14899	Study Start-Up (SSU)	The 'Document Source' column is missing in the SSU module's grid view.	MINOR	All Users. This bug has a minor impact on Study Start Up's user interface. The resolution restores the correct display.
TRL-14921	eTMF, Study Start-Up (SSU)	The users are unable to remove the IRB-EC name in the metadata of a document that is approved in a workflow.	MINOR	Editor and above. This bug has a minor impact on the document management. The resolution resets the correct function.
TRL-14972	eTMF	When trying to export the 'Required Documents' from Room Settings, the system displays an error.	MINOR	Admins. This bug has a minor impact on the Required Documents export. The resolution resets the correct system display.

10. Open Defects

Trial Interactive v10.5.4 has been released with these known issues, in addition to Known issues identified in Operation Qualification. 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-14815	eTMF	The index location of a document type is not updated when the document type name is changed from the settings.	MINOR	Admins. This issue has a minor impact on document type management. The future resolution will reset the correct name change behavior.
TRL-14221	eTMF, Study Start-Up (SSU)	Whenever a document is uploaded to a Site, the upload processing icon is not clearly visible.	MINOR	Editor and above. This issue has a minor impact on the system user interface. The future resolution will correct the display.



11. Customer Support

A. REPORTING ISSUES WITH THE RELEASE

Once **TransPerfect Trial Interactive** releases a system into a Production environment, the Support Service department is responsible for providing Clients and Authorized Users with technical support via phone or email. This support shall consist of commercial best efforts by **TransPerfect** to provide the User or the Client's designated personnel or helpdesk, with but not limited to the following:

- Error corrections and temporary workarounds
- Technical assistance relating to the operation of the system
- Processing service requests
- Processing configuration change requests

TransPerfect will respond 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)

Your PM can submit Ideas to our
Perfective Change Management on
your behalf



Customer Experience Program (CEP)


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:	 <i>Electronically signed by: Jay Smith Reason: I approve this document Date: May 31, 2024 16:41 EDT</i>

Quality Assurance

Name: Scott Jordan	Title: Director, QA and Systems Validation
Signature: Reason for signature: Date:	 <i>Electronically signed by: Scott Jordan Reason: I approve this document. Date: May 31, 2024 16:43 EDT</i>