TRIAL INTERACTIVE V10.5.5 – RELEASE NOTES - VERSION 1.0

1. Table of Contents

2.   Version History

Author	Revision #	Date	Comment
Samuel Pawar	0.1	20-June-2024	Initial document creation
Samuel Pawar	0.2	26-June-2024	Added features: TTI-3701 TTI-3747
Samuel Pawar	0.3	27-June-2024	Updated Metadata for features.
Samuel Pawar	0.4	28-June-2024	Added features: TTI-3740 TTI-3752 TTI-3753 TTI-3754
Samuel Pawar	0.5	02-July-2024	Added Defect Resolution section and Open Defects sections.
Samuel Pawar	0.6	04-July-2024	Added Defects: TRL-13978 TRL-14815 TRL-15213 TRL-15250 Added Feature: TTI-3760
Anuj Thapar	0.7	05-July-2024	Removed: TTI-3754 TRL-15250 TRL-15109
Anuj Thapar	1.0	12-Jul-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 Release Notes. The end-users of the system can use the Release Notes to evaluate if their intended use of the system will be impacted by the changes introduced in the system release. The Final Release Notes are then issued once the internal Validation Package has been reviewed/approved by Trial Interactive Quality Assurance. The Final Release Notes will contain the final list of items in the scope of the Release.

	NOTE: **TransPerfect** will make commercial best efforts to minimize the differences between the 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	v10.5.5
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 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	12-July-2024
Estimated US MTI Upgrade Date/Time:	12-July-2024 9:00 PM ET
Estimated EU MTI Upgrade Date/Time:	12-July-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.

7. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the Trial Interactive v10.5.5 platform.

System Requirements	
Operating System	• Windows Version 7 or higher All currently supported Mac OSX releases
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.

8. Changes

Trial Interactive v10.5.5 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-3683	Trial Master File (eTMF)	With this improvement, In the 'Related' tab on the metadata panel, the related document name will now prioritize the Generated Name. If the 'Generated Name' is not available, it will default to the 'Submitted Name.	No	Yes	Minor	All Users. This improvement has a minor impact on the Related Document tab UI that is in the metadata panel.
TTI-3701	Trial Interactive File (eTMF), CTMS	With this enhancement, the CTMS and eTMF sites will be linked using the Protocol ID and System Site ID—unique identifiers for each study and site. This process ensures that once a site is linked, it remains permanently bound, even if the site ID is later modified. An option to break incorrect site links has also been added to prevent errors. NOTE: Normally, in a CTMS-linked Study, if a Site is added to CTMS, the Site is automatically created in any TI Rooms within that Study profile. However, if a Site has been added to a TI Room that should be linked to a Site in a CTMS Study, this can now be linked up through a service desk request.	Yes	No	Minor	Admin and SuperAdmin. This improvement has a minor impact on the CTMS Site and eTMF Site linking.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3740	Trial Master File (eTMF)	With this improvement, the Potential Duplicates Window has been enhanced. Previously, the default fields available for comparison were Title, Document Hash (Checksum), and Original Document Hash. Now introduces two new fields to the column options: Document Status, and Document ID, Filename, Category, Generated Name, Date Type, and Document Date.	No	Yes	Minor	All User. This improvement has a minor impact on the Potential Duplicate window.
TTI-3741	Study Start-Up (SSU)	This enhancement streamlines the process and provides clear instructions to users when selecting the option to move all documents to eTMF. • Only Amendment documents marked as complete will be moved to eTMF. • The system now provides a pop-up modal listing collected and approved amendments not marked as complete, prompting the user to mark them as complete. • When the User opts to select the documents to be moved to eTMF: • The system will now display a notification under each Amendment tab of the activation wizard if the Amendment has not been marked as complete. Additionally, when documents are moved to eTMF, a copy will be retained in SSU and will not disappear from SSU.	No	Yes	Minor	Editor and above. This improvement has a minor impact on handling SSU Amendments.
TTI-3745	Study Start-up (SSU)	This new feature introduces an "Add and Approve" button for adding documents to placeholders in Study Start-Up, streamlining the process by allowing users to add and approve documents simultaneously. This enhancement eliminates the need for individual approval clicks, significantly reducing the time required when handling multiple documents.	No	Yes	Minor	Admin and above. This new feature has a minor impact on Adding and Approving documents to a placeholder in Study Start Up (SSU).

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3747	Trial Master File (eTMF), Study Start-Up (SSU), CTMS Collaborate)	With this enhancement, the auto-filing functionality for final site visit documents from a CTMS Collaborate Room (CCR) has been expanded. Previously limited to rooms with the eTMF room type, this functionality now includes rooms with the Study Start-Up (SSU) room type.	Yes	No	Minor	All Users. This improvement has a minor impact on the CTMS Collaborate Room and Study Start-Up Room.
TTI-3748	Study Start-Up (SSU)	When a (Start-up Specialist) SUS sends out Regulatory Package emails, the system will now run a check to validate if any recipients have a dummy system-generated email. If any recipient has a dummy email, the system will provide an alert message to the SUS, notifying them that the Regulatory Package email will not be delivered. This improvement ensures that SUS users are aware of any invalid email addresses, enhancing the accuracy and reliability of email communications.	No	Yes	Minor	Editor and above. This improvement has a minor impact on email alertness when sending out Regulatory packages.
TTI-3752	CTMS Collaborate	This improvement ensures that the stepper will be hidden when a letter is created without a workflow.	No	Yes	Minor	Editor and above. This improvement has a minor impact on Collaborate CTMS Workflows,
TTI-3753	Collaborate	This improvement introduced a new validation for admin workflows. When an admin workflow is "presented" for a document, the system will check if the document has undergone the e-sign process. If the document has completed an "esign" step, the system will restrict the selection of any admin workflow that lacks an e-signature step. If the user attempts to choose such a workflow, the system will display a message: "You can't use this workflow since it doesn't have an e-signature step," providing clear guidance on why the selection is not allowed.	No	Yes	Minor	Admin and Above. This improvement has a minor impact on Collaborative Workspace.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
TTI-3760	Start-Up (SSU), CTMS	This improvement enhanced the status updates for Sites and Countries. SSU will restrict CTMS from changing statuses according to the status sheet where SSU governs the status. Status updates for Sites and Countries should only occur in SSU, with CTMS receiving these updates from SSU.	No	Yes	Minor	All Users. This improvement has a minor impact on status updates for Sites and Countries.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-13978	eTMF	Following the version 10.5.1 release, the "Investigative Site" was renamed to "Sites". However, the Metadata field in Form settings across all rooms still displays "Investigative Site" instead of "Sites".	Minor	All users are affected. This issue has a minor impact on the metadata field in Form settings, causing confusion due to inconsistent terminology. Correct system behavior has been restored.
TRL-14815	eTMF	Users noted in the settings, that the index location of a document type is not updated when the document type name is changed.	Minor	All users are affected. This issue can lead to confusion and difficulties in locating documents, as the index location does not reflect the updated document type name. Correct system behavior has been restored.
TRL-14840	eTMF	Clients have reported that documents finalized in one workflow are appearing in the QC1 clarification folder of another workflow, even though the documents were never processed through that workflow.	Minor	Editor and above. This issue had a minor impact on document tracking and quality control processes. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-14845	eTMF	Users noted an issue with the Email Recipients functionality in the email options. Autofill-suggested emails are displayed under the Subject field instead of the Recipients field. Note: This issue occurred in the Microsoft Edge browser, and it has been cross-checked in other browsers (Google Chrome, Firefox) where no autofill suggested details are displayed.	Minor	All Users. This issue had a minor impact on Email Recipient's functionality. Correct system behavior has been restored.
TRL-15009	Study Start-up (SSU)	User members of the Sites Team Group, who do not have access to Sites, have enabled actions related to Documents. When adding or importing documents, users encounter the following error: "User does not have access to parent topic."	Minor	All Users of the Sites Team Group. This issue significantly impacts the Document management functionality for members of the Sites Team Group without access to Sites. Users are unable to add or import documents, which disrupts workflow and document management processes. Correct system behavior has been restored.
TRL-15017	eTMF, Study Start-up (SSU), Collaborate	Users observed the text overlapping issues in Query in multiple Instance Versions (UI Bug).	Minor	All Users. This issue had a minor impact on the user interface, causing text to overlap in query results across multiple instance versions. Functionality. Correct system 13behavior has been restored.
TRL-15063	eTMF, Study Start-up (SSU), Collaborate	The user enabled the dark theme from their profile, and when they checked the room settings, the font visibility was low. Clicking on the document type made it reflect properly. The document Type folder in Settings is not visible in the dark theme.	Minor	All Users. This issue had a minor impact on the user interface, specifically in the dark theme, where the Document Type folder in Settings was not visible.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15067	eTMF	Users encountered a 'User does not have access to the topic' error when clicking 'Go to Document Profile' after finalizing a document via eSign. This occurred because the document was routed to a folder the user didn't have access to. Document Owners could see the document in the simplified UI but couldn't open the profile using the 'Document Profile' button.	Minor	All Users. This issue had a moderate impact on document accessibility and workflow efficiency. Document Owners were unable to access document profiles through the 'Document Profile' button, which hindered their ability to manage and review their documents. Correct system behavior has been restored.
TRL-15068	eTMF, Study Start-up (SSU), Collaborate	When the user changes the KPI card heatmap, the changes are not registered in the changelog. As a result, the changelog appears empty. This issue occurs for all instances in TI.	Minor	All Users. This issue significantly impacted tracking changes made to the KPI card heatmap. Users were unable to see any modifications in the changelog. Correct system behavior has been restored.
TRL-15069	Collaborate	The system injects Effective Date ($EffectiveDate$) content controls in the wrong format. Previously, the format was "DD /MM / YYYY" (e.g., "31 MAY 2024"), but it currently injects dates in the "YYYY /MM / DD" format.	Minor	All Users. This issue had a minor impact on document date formatting and consistency. Correct system behavior has been restored.
TRL-15117	Collaborate	Users noted when using Team Edit and trying to add a reference document, the button does not function. Users are unable to add reference documents to any files that are in Team Edit mode.	Minor	All Users. This issue had a minor impact on the collaborative editing process, as users could not add necessary reference documents while using Team Edit. Correct system behavior has been restored.
TRL-15122	Platform	When navigating to My Profile > Notification > All Rooms and selecting a room, there are no options to enable a subscription However, if the Favorites tab is selected and a favourite room is chosen, the list for notification emails is visible.	Minor	All Users. This issue had a minor impact on managing notifications for All Rooms. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15133	eTMF	Users noted that when raising a query from the Q&A module, they should automatically be directed to the metadata page. However, users are redirected to the Q&A home page after sending the query email, and the document metadata page closes automatically. This issue causes delays as users must navigate back, reselect options, and save their changes. Additionally, if users forget to update the reasons again, the document remains in the claim folder instead of moving to the clarification folder.	Minor	The user who has access to raise a query. This issue significantly impacts the efficiency and accuracy of handling queries in the Q&A module. Correct system behavior has been restored.
TRL-15144	Study Start-up (SSU)	Users noted that the 'submitted name' field should not be required while uploading a document in the SSU room after choosing the placeholder. However, it is currently being marked as a required field.	Minor	All Users. This issue had a minor impact on the document upload process in the SSU room.
TRL-15150	Study Start-Up (SSU)	When trying to replace a document in the Study Start-Up module, the Replace Attachment/URL feature is not available for any documents. However, the Replace Attachment/URL option is visible for eTMF documents.	Minor	All Users. This issue moderately impacted document management within the Study Start-Up module. Correct system behavior has been restored.
TRL-15185	eTMF	Users reported an issue in the time zone behavior within the TI Task Module. When setting a reminder date and time for a task, the displayed time in the task module differs from the initially set time.	Minor	All Users. This issue significantly impacts the accuracy and reliability of task scheduling within the TI Task Module. The discrepancy in reminder times can lead to missed or incorrect task reminders. Correct system behavior has been restored.
TRL-15207	eTMF	Users noted for a specific room that they are unable to select a previously created view in "View by Document Type." When users select a view and then press "Select," no results are displayed.	Minor	All users in the affected room. This issue has a minor impact on a specific room present in TI. Correct system behavior has been restored.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TRL-15213	eTMF	Users are unable to enable the "Document as Final" checkbox next to the Communication Inbox in the Edit Room window. When attempting to enable the "Document as Final" (Communication Inbox) checkbox in the Edit Room window, the setting can be saved without any error, but the checkbox remains disabled. However, if the same "Document as Final" checkbox is enabled in Room Settings, it appears as enabled at the domain level in the Edit Room window as well.	Minor	All Users. This bug had a minor impact on enabling the "Document as Final" checkbox. Correct system behavior has been restored.
TRL-15250	Study Start-Up (SSU)	When adding a site contact and designating it as the Main Contact and provide documentation, the contact initially appear correctly. However, upon adding a Start-up Specialist to the same site, the added Main Contact is removed from the site.	Minor	All Users: In order work around this issue the users were required to go back and add the Site Contact again. However, this issue has now been resolved and the Site Contact would be added as expected.

9. Open Defects

N/A

10. Customer Support

A. REPORTING ISSUES WITH THE RELEASE

Once **TransPerfect Trial Interactive** releases a system into a Production environment, the Support Service department is responsible for providing 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 centres 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   **Customer Experience Program (CEP)**

(PM)

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

11. Approvals

Product Owner

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

Quality Assurance

Name: Scott Jordan	Title: Director, QA and Systems Validation
Signature: Reason for signature: Date:	