

TI CTMS V3.0.1 – RELEASE NOTES V1.0



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1. Version History

Author	Revision #	Date	Comment
Mansi Kandhare	0.1	22 Aug 2025	Initial Version: Pre-Release Notes issued
Mansi Kandhare	0.2	29 Aug 2025	The following changes have been made since the issuance of the Pre-Release Notes: Added Open Defects table
Mansi Kandhare	1.0	05-Sep-2025	Document Finalized

2. 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 advanced of Upgrade Date by issuing Pre-Release Notes. The end-users of the system can use the Pre-Release Notes in evaluating if their intended use of the system will be impacted with 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 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.

3. Scope

The scope of this document applies to the release of the following computerised system:

System In Scope	
System Name	TI CTMS
System Version	3.0.1
Release Type	Patch

4. Definitions / Acronyms

Term	Definition/Description
21 CFR Part 11	Part 11 of Title 21 of the United States Code of Federal Regulations
AP	Activity Plan
APT	Activity Plan Template
CCR	CTMS Collaborate Room
CTMS	Clinical Trial Management System
EDC	Electronic Data Capture
ER/ES	Use of Electronic Records and Electronic Signatures in Clinical Investigations
eTMF	Electronic Trial Master File
GDPR	General Data Protection Regulation
GxP	A general reference to good practices related to Document, Clinical, Manufacturing, etc.
ICFs	Informed Consent Forms
IAM	Identity and Access Management
IS	Interactive Voice/Web Response System
myTI	Trial Interactive's mobile application
TP	TransPerfect
TI	Trial Interactive
UI	User Interface

5. Release Overview

A. CTMS-1836: ENHANCED INTEROPERABILITY WITH EFEASIBILITY

CTMS will now receive status updates from eFeasibility

B. CTMS-1910: IMPROVED SORTING

The system will now provide the ability for users to sort by custom fields.

C. CTMS-1915: IMPROVED SITE VISIT CALENDAR

Cross study site visit calendar will now display unblinded site visits with limited data to maintain the blind.

D. CTMS-1920: IMPROVED SEARCH FUNCTIONALITY

Expanded study level searching, e.g., users can now search by protocol number

E. CTMS-1929: IMPROVED STUDY ACCESS PERMISSIONS

Study Managers can easily identify locked sites and are unable to modify site level permissions for locked sites.

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 (All timezones are in ET)	
Date of Release	05-Sep-2025
Estimated US MTI Upgrade Date/Time:	06/Sep/2025 12:00 AM
Estimated EU MTI Upgrade Date/Time:	06/Sep/2025 12:00 AM
Estimated China MTI Upgrade Date/Time:	N/A
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your TransPerfect Customer Success Manager.

7. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use TI CTMS 3.0.1 platform.

System Requirements	
Operating System	<ul style="list-style-type: none"> Windows Version 7 or higher All currently supported Mac OSX releases iOS and Android for myTI mobile app (see myTI recent release notes)
Browser	<ul style="list-style-type: none"> Microsoft Edge: Version 88 and later Google Chrome: Current release and earlier. Mozilla Firefox: Current and ESR releases. Apple Safari: Current release and earlier. <p>NOTE: TI Sign requires that pop-up blockers be disabled for the Trial Interactive domain.</p>
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.
CTMS Platform Compatibility	Trial Interactive v10.7 supports this version of TI CTMS v3.0.1
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).

8. Changes

Legend for Impacts

TI CTMS v3.0.1 has been released with these enhanced features and defect fixes. These tables use the following definitions of customer Impact:

- **Blocker:** A Blocker defect refers to a critical issue that completely prevents further progress in development or testing.
- **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.

Legend for Offering/Room Types

- Electronic Trial Master File (eTMF)
- Clinical Trial Management System (CTMS)
- CTMS Collaborate Room (CCR)
- eFeasibility
- GlobalLearn
- Mobile Trial Interactive (myTI)
- Study Start-Up (SSU)

A. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1836	CTMS, eFeasibility	<p>The system has been enhanced to support integration with eFeasibility for streamlined status management. With this update:</p> <p>The system now receives status updates from eFeasibility.</p> <p>It captures and stores the associated status dates for each update received, enabling historical tracking of site feasibility changes.</p> <p>New fields have been added to the Site Details page to reflect eFeasibility related data.</p>	Yes	No	Minor	<p>Impact: This improvement has a minor impact on the sites.. This integration improves inter-system communication, and eliminates duplicate data entry.</p>
CTMS-1910	CTMS	This enhancement now supports sorting by user-defined custom fields within configurable grids. This enhancement allows users to organize and view grid data more effectively based on custom field values defined in their configuration.	No	Yes	Minor	<p>Impact: This improvement has a minor impact on custom views.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1915	CTMS	<p>This enhancement allows for users to view unblinded site visit reports within the cross-study Site Visit Calendar. To maintain appropriate data visibility, the system restricts the viewable information to the following fields only:</p> <ul style="list-style-type: none"> • Visit Name • Visit Type • Owner • Study Name • Site Name 	No	Yes	Minor	<p>Impact: This improvement has a minor impact on the cross-study Site Visit Calendar.</p>
CTMS-1920	CTMS	The system has been enhanced to improve the search functionality within the Studies grid. Users can now search by protocol number, with support for both full and partial matches. The protocol number field has been added to the searchable index, allowing users to quickly locate studies based on protocol identifiers.	No	Yes	Minor	<p>Impact: This improvement has a minor impact on the Studies grid.</p>
CTMS-1928	CTMS	This improvement will provide the ability for users to remove the Favorite column from the list of selected columns within the manage visible columns functionality.	No	Yes	Minor	<p>Impact: This improvement has a minor impact on manage visible columns.</p>
CTMS-1929	CTMS	This improvement provides the ability to identify locked sites when assigning study access permissions. This enhancement helps users distinguish which sites are locked during the permission assignment process.	No	Yes	Minor	<p>Impact: This improvement has a minor impact on study access permissions.</p>

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-13402	CTMS	An issue was observed where a Server Gateway Timeout error is displayed when saving changes in the Domain Settings.	Minor	This bug had a minor in the Domain Settings. The resolution ensures that the error will not be displayed.
TICTMS-13588	CTMS	An issue was observed where the records outside the selected date range appear in the results, and some relevant records are excluded.	Minor	This bug had a minor impact on filtering the records. The resolution ensures that the records are displayed according to selected completed date.
TICTMS-14265	CTMS	On the Settings page, the values in brackets are generated for multi-value fields within Study Auto naming.	Minor	This bug had a minor on the Settings page. The resolution ensures that the values in brackets will no longer be displayed.
TICTMS-14325	CTMS	An issue was observed where a Contact Role column within the Contacts page is displayed in uppercase as per the import file.	Minor	This bug had a minor on the Contacts imports. The resolution ensures that the values in the Contact Role column will display per the system definition and not the import definition.
TICTMS-14341	CTMS	On the My Page dashboard, only a subset of the site visits for the selected day are displayed, leading to incomplete information for the user.	Minor	This bug had a minor impact on the My Page Cross study Site Visit calendar. The resolution ensures that all site visits scheduled for the selected day will be visible in the Day view of the Site Visits Calendar.
TICTMS-14378	CTMS	On the My Page within Milestones , the Comments field displays without values when the view is not created.	Minor	This bug has a minor impact on Milestone. The resolution will ensure that when the view is created the Comments field displays with the value.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-14425	CTMS	Users assigned as Site Owners did not receive the 'Visit Approaching' email notification; they only received the 'Visit Created' email.	Minor	This bug has a minor impact on email notifications for Site Owners. The resolution will ensure that Site Owners receive both the 'Visit Created' and 'Visit Approaching' emails.
TICTMS-14448	CTMS	On the 'Add Subjects' screen, under the 'Previous' tab, verified ICFs (Informed Consent Forms) are not appearing in the grid.	Minor	This bug had a minor impact on the Add Subjects screen. The resolution ensures that all previously verified ICFs should be displayed in the grid on the 'Previous' tab to allow users to reference when adding subjects.
TICTMS-14462	CTMS	Draft milestone templates cannot be deleted if the template has a related child template.	Minor	This bug had a minor impact on the Milestone Templates page. The resolution will ensure that draft templates can be successfully deleted.
TICTMS-14483	CTMS	The Potential Site and its associated data are not displayed in Study Activities Dashlets.	Minor	This bug has a minor impact on the Study Activities dashlet. The resolution will ensure that the potential sites and its data is displayed on the Study Activities Dashlets.
TICTMS-14494	CTMS	After performing a Site Import, one of the Saved Views displays incorrect data in the Organization Type column.	Minor	This bug has a minor impact on the display of site data within saved views. The resolution will ensure that the details are accurately reflected in the saved views.
TICTMS-14504	CTMS	Users are encountering an issue where exporting 'All' Site Visits, application is taking an unusually long time to complete the export.	Minor	This bug has a minor impact on the site visits export process. The resolution will ensure an improved export speed for large volumes of Site Visit data.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-14524	CTMS	On the Site Visit view, the Confirmation Letter column displays an incorrect message.	Minor	This bug had a minor impact on displaying links to confirmation letters.. The resolution ensures that the proper link is displayed.
TICTMS-14525	CTMS	In the "My Page" dashboard, the Site Visits Calendar does not display Unblinded visits when accessed by a Blinded user.	Minor	This bug had a minor impact on cross-study Site Visit Calendar view. The resolution ensures the correct system behavior.
TICTMS-14560	CTMS	An issue was identified where the option to Add Site Visit Reason Cancellation is incorrectly displayed as "Add Subject Visit Reason Cancellation" on the Study Settings > Site Visit Cancellation Reason page.	Minor	This bug had a minor impact on Study Settings > Site Visit Cancellation Reason page. The resolution ensures the correct text is displayed to the user.
TICTMS-14689	CTMS	On the Activities page, when the first comment is added, the system automatically sets the user as the modifier.	Minor	This bug had a minor impact on Activities page. The resolution ensures the correct system behavior by defining that the modifier is the user, who added the comment.
TICTMS-14811	CTMS	In the "My Page" dashboard, the Site Visits Calendar does not display Potential Site Visits in the dashlets.	Minor	This bug had a minor impact on cross-study Site Visit Calendar view. The resolution ensures the correct system behavior.

9. Open Defects

TI CTMS v3.0.1 has been released with these known issues. This table uses the following definitions of severity:

- **Blocker:** A Blocker defect refers to a critical issue that completely prevents further progress in development or testing.
- **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
TICTMS-10081	CTMS	The Contacts export file displayed an inconsistency in the Time Zone field, where the information in the export did not match the details displayed in the Quick View panel.	Minor	This bug has a minor impact on information consistency between the contacts export file and the quick view panel details. Correct system behavior will be restored.
TICTMS-11972	CTMS	The Sort functionality on the Site Visit Report Review Status dashlet did not work as expected and was inconsistent with the standard sorting behavior <ul style="list-style-type: none"> • In Ascending order, the values were incorrectly sorted as A-Z followed by a-z. • In Descending order, the values were incorrectly sorted as a-z followed by A-Z, 	Minor	This bug has a minor impact on the sort functionality on the Site Visit Report Review Status dashlet. The resolution will restore the correct sorting behavior as follows <ul style="list-style-type: none"> • Ascending Order: A, a followed by Z, z. • Descending Order: Z, z followed by A, a.
TICTMS-12014	CTMS	The system allowed users to perform a bulk update of activities, countries and sites even when a previous bulk update is still in progress.	Minor	This bug had a minor impact on the bulk edit process for activities, countries and sites. Correct system behavior will be restored.
TICTMS-12066	CTMS	The 'Generated Date' for Site Visit Confirmation Letters was incorrectly updated even when the attempt to regenerate the letters was unsuccessful.	Minor	This bug has a minor impact on the confirmation letter regeneration process. The resolution will ensure the 'Generated Date' is only updated upon successful regeneration.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-13017	CTMS	The navigation breadcrumbs section displayed the Product breadcrumb alongside Sponsor and Program, even though the Product breadcrumb was disabled in the domain settings.	Minor	This bug has a minor impact on the navigation breadcrumbs within the application. Correct system behavior will be restored.
TICTMS-13084	CTMS	The 'Failure Reason' dialog box did not display the complete list of failure reasons when the Study Settings import process failed.	Minor	This bug has a minor impact on the display of the failure reasons. Correct system behavior will be restored.
TICTMS-13225	CTMS	The export file of Import Status records from the Domain Settings did not include all 'Import Failed Reasons' when exporting to XLSX format with all records selected.	Minor	This bug has a minor impact on exporting Import Status records. Correct system behavior will be restored.
TICTMS-13759	CTMS	Within the Subject and Recruitment modules, certain number fields display a default value of "0" while others display as empty. This inconsistency is present on the UI (Studies grid) and in exported files.	Minor	This bug has a minor impact on Study Details page. Correct system behavior will be restored.
TICTMS-14384	CTMS	Site Import: When two Site records are imported into the same Organization with matching by Org enabled, the system incorrectly creates duplicate Organization records.	Minor	This bug has a minor impact on the Site import functionality. Correct system behavior will be restored.
TICTMS-14438	CTMS	The Sites export file, retrieved in CSV and XLSX formats, did not capture and include the following Organization-related fields during export: <ul style="list-style-type: none"> • Committee Type • IRB/EC Number • Meeting Frequency 	Minor	This bug has a minor impact on the display of details in the Site export file. The resolution will ensure that correct data is exported for each column.

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 Client 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	support.ctms@trialinteractive.com OR 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.

B. REQUESTING FUTURE ENHANCEMENTS

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



Customer Success Manager (CSM)

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

Customer Focus Group

Meet with other Trial Interactive customers for an
immersive Focus Group Forum:

- Focus Group Q&A
- Early Access
- Hosted Beta
- Usability Studies

11. Approvals

Product Owner

Name: Hope Weisser	Title: Senior Product Manager
Signature:	
Reason for signature:	
Date:	

Quality Assurance

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