

TI CTMS V3.1 – RELEASE NOTES V1.0



Table of Contents

1.	Version History	3
2.	Purpose	4
3.	Scope	5
4.	Definitions / Acronyms	6
5.	System Overview	7
6.	Release Overview	11
7.	Release Schedule	13
8.	Hardware and Software Requirements	14
9.	Changes.....	15
10.	Open Defects.....	39
11.	Customer Support	40
12.	Approvals	42

1. Version History

Author	Revision #	Date	Comment
Mansi Kandhare	0.1	17-Oct-2025	Initial Document Creation
Mansi Kandhare	1.0	21-Nov-2025	<p>The following updates were made:</p> <ul style="list-style-type: none"> • Added Defects Resolutions table • Added Open Defects table • Updated Changes table: Impact field updated to match the Legend for Impacts <p>Initial version finalized.</p>

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 advance of the 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	v3.1
Release Type	Minor

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
JIRA	A proprietary issue tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management
SQA	Software Quality Assurance
Testiny	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

5. 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 products deliver a wide range of benefits to any organization looking to leverage new efficiencies and opportunities in 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 and sponsor and site personnel documentation.
- Support 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.
- Increased 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, and 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. MAIN FUNCTIONS AND INTERFACES

Trial Interactive’s Clinical Trial Management System (CTMS) is a secure, cloud-based solution that enables the collection and management of trial-related data in a single location. TI CTMS provides the ability for clinical studies team members, such as study managers and CRAs, to plan, collaborate, and track clinical data with specific attention to monitoring requirements. This is the industry’s first CTMS with a modern user experience and a mobile-first interface. TI CTMS can help your organization:

- Provide a single source of truth for all trial-related data and information, with an intuitive planning and tracking structure,
- Track and view product, program, study, country, site, organization, contact, subject, and subject visit data in real-time,
- Ensure quality with support for adjustable, best-practice CTMS workflows that ensure completion of critical trial requirements. Reduce risk by confirming that plans are followed per SOP with controls in place to prevent issues,
- Track timeliness with KPI metrics dashboards that provide an integrated real-time view of Clinical Trial data,
- Confirm a fully updated CTMS prior to inspections with quality oversight, periodic reviews, and operational checks,
- Plan study-related activities such as site visits, communications, training, and other key trial Milestones with due dates and responsibilities using visit schedules and activity plan templates,
- Manage trial-related documentation with a built-in Content Management System and integrated eTMF, along with many other offerings,
- Support flexibly, company-specific workflows and SOPs with a full set of custom fields, record statuses, and field validation,
- Improve quality through standardized business practices and record-keeping,
- Provide trial insights through drill-down Study and portfolio dashboards, and,
- Streamline clinical processes to reduce costs.

Additional features of the Trial Interactive CTMS include:

- A mobile visit report App that supports both iOS and Android, with support for questionnaires, activity tracking, CRA Reconciliation, training, document capture, and offline mode.
- Pre-defined, best-in-class CTMS Activity Plans for consistent trial execution and

operational checks.

- Built-in Site and IRB correspondence tracking, Email capabilities to keep close track of all back-and-forth activity.
- Automatic Notifications, Alerts, and Reminders with emails and a daily digest.
- Standard and Ad-hoc reports that support all custom metadata fields and the ability to add columns to standard reports or fully customize.
- Full support for clinical data integrations, including EDC, Payments, and IXRS, either directly or through a technical partner. Fields may be pulled from EDC and included in CTMS reporting.
- Well-developed classroom and lab training courses with an integrated LMS and eLearning for study and site training.
- Simpler and less administrative: Assign ownership to Studies, Sites, and Countries with central admin optional. Study and Site owners may then fully manage their record types, inviting and revoking access by start, end dates, and role.
- Track everything that is trial-related in the form of a configured set of activities with types and subtypes that may all have their own configured fields and statuses.

6. Release Overview

A. SITE VISIT – WORKFLOWS

Site Visit Review Workflow

The TI CTMS v3.1 release introduces enhanced review workflows, enabling site visit reviewers to provide comments directly against individual content records captured during a site visit when generating site visit related documents from within CTMS.

This functionality streamlines collaboration, improves review accuracy, and ensures issues are identified and resolved quickly.

Key capabilities include:

- **Granular Feedback** – Reviewers can add comments directly to specific content records within a site visit.
- **Collaborative Review** – Facilitates clear communication between reviewers and site visit owner.
- **Improved Accuracy** – Ensures feedback is tied to the exact record, reducing ambiguity.

B. STATUS AUTOMATION

Automation Engine

TI CTMS v3.1 introduces the ability to have automated status updates, enabling statuses to change dynamically based on the completion of dependent actions within the system based on the business defined scenarios.

This functionality reduces manual effort, minimizes errors, and ensures timely updates.

Key capabilities include:

- **Automated Triggers** – Statuses update can be automatically populated when prerequisite is completed.
- **Real-Time Accuracy** – Keeps study related data current without manual intervention.
- **Reduces Administrative Burden** – Eliminates repetitive status updates, saving time for users.
- **Improved Oversight** – Provides a clear and reliable view of trial progress for better decision making.

C. ACTIVITY WORKFLOWS

Activity Record Workflows

The TI CTMS v3.1 release introduces the ability to route activity records, such as protocol deviations, through configurable workflows to support structured review and approval processes.

This standardizes oversight, improves accountability, and ensures critical activities follow defined procedures with full traceability.

Key Capabilities include:

- **Workflow Routing** – Activity records (e.g., protocol deviations) can be routed through defined workflows.
- **Standardization** – Ensures consistent handling of deviations and other activity records per business process.
- **Traceability & Compliance** – Captures all workflow actions for audit trails and regulatory readiness.

D. SITE VISIT – CHECKLIST

Dependent Sub-Questions

TI CTMS v3.1 enhances site visit checklists with dependent sub-questions, dynamically adjusting follow-up questions based on a user’s response.

This feature streamlines data entry, improves report accuracy, and ensures site visit documentation captures only relevant information.

Key capabilities include:

- **Dynamic Questioning**– Sub-questions automatically display or hide based on the response to a parent question.
- **Simplified Data Capture** – Reduces clutter by removing irrelevant questions from the checklist once the parent response is captured.
- **Improved Accuracy** – Ensures only applicable responses are captured and included in the site visit report.
- **Efficiency & Usability** – Provides a cleaner, more intuitive checklist experience for site visit owners.

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 (All time zones are in ET)	
Date of Release	21-Nov-2025
Estimated US MTI Upgrade Date/Time:	13/Dec/2025 12:00 AM
Estimated EU MTI Upgrade Date/Time:	06/Dec/2025 4:00 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.

8. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the TI CTMS v3.1 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 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 v3.1
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).

9. Changes

Legend for Impacts

TI CTMS v3.1 release includes 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-551	CTMS	<p>With this improvement, the system now provides the ability to automatically trigger Subject status based on the occurrence of subject visit dates and states.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Ability to map subject statuses to subject visit types. • Ability to apply subject status automatically when the mapped subject visit type has a defined status and date. • Subject status is populated with the subject visit completed date. • Ensuring the enrollment summaries/actuals update automatically to reflect the subject status change. 	Yes	No	Minor	<p>Impact: This improvement has a minor impact on Subject status and on the subject visit dates to ensure consistent status management.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-702	CTMS	<p>This enhancement shall enable users to define individual site-level site visit frequencies based on varying conditions.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Interim Monitoring Visits (IMVs) can now be defined as every 30 days during enrollment and every 90 days during maintenance, based on site status. • IMV schedule may vary by site status, not only by study. • When defined, the system displays the study-level site visit frequency for reference. 	Yes	No	Minor	<p>Impact: This improvement has a minor impact on the site-level site visit frequencies.</p>

CTMS-1141	CTMS	<p>With this improvement, the system will notify a visit owner when a site visit is started outside of the study defined site visit window. The system will display “Out of Window” within the Visit Window Compliance field, and provide the ability to capture an explanation.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Added functionality for site visit owners to record out-of-window visits by selecting a predefined reason and providing an explanation. • Introduced the ability to manage the list of Out-of-Window Reasons at both the domain and study level, enabling administrators to customize and maintain reason lists. • Out-of-Window Reason and related details are now displayed in the visit’s general information section, allowing reviewers and approvers to clearly view the selected reason and supporting explanation during the review process. • The system will suppress Out-of-Window information on the site visit completion window and visit general information when the visit occurred within the scheduled window, ensuring details are only shown when applicable. • Out-of-Window reason capture is supported for site visit types without a defined window, ensuring reasons can be documented consistently even when no window criteria exist. 	Yes	Yes	Minor	<p>Impact: This feature has a minor impact on the Visit Window Compliance field.</p>
-----------	------	---	-----	-----	-------	---

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1207	CTMS	<p>With this enhancement, the site visit reports functionality allows for the inclusion of previous enrollment statistics, providing reviewers with additional context and historical data during report review.</p> <p>Key features:</p> <ul style="list-style-type: none"> • The system now auto-populates the Previous Site Visit reference when the corresponding field is filled in with visit general information. • Users can update or change the Previous Site Visit selection directly from the visit general information section. • The system will utilize the enrollment statistics from the defined Previous Site Visit. 	No	Yes	Minor	<p>Impact: This feature has a minor impact on the site visit reports.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1230	CTMS	<p>This enhancement will provide the ability to define auto-naming rules for Site Visits (Monitoring) at the Global and Study level.</p> <p>Key features:</p> <ul style="list-style-type: none"> To define whether auto-naming should be applied to the Site Visit Name field. To configure auto-naming rules for site visit names at both the domain and study levels. At the Site level, the Visit Name field within Site Visits currently functions as a free-text field. Admins can specify that no auto-naming rules will be used 	Yes	No	Major	Impact: This improvement has an impact on the Site Visits.

CTMS-1378	CTMS	<p>With this improvement, the users have the ability to send activity records through a defined workflow.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Introduced the ability to define workflows for activity records within CTMS. • Users can send activity records through workflows involving roles such as reviewers and approvers. • The system supports conditional workflows, where completing one step triggers the requirement for the next step. • Each workflow step can be assigned to specific individuals within a study, with due dates set for completion. • Workflow progress is clearly tracked, allowing users to identify the current step of any activity record. • Notifications are automatically sent to users assigned to workflow steps. • Completed workflow steps are recorded, enabling activity records to proceed to the next defined step. • Workflow names must be unique; duplicate workflow names are not permitted. • Activity records that have already gone through workflows can be easily identified (e.g., deviations previously reviewed in earlier review cycles). 	Yes	No	Minor	<p>Impact: This improvement has a minor impact on the activity records within CTMS.</p>
-----------	------	---	-----	----	-------	--

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1434	CTMS	<p>This enhancement introduces the ability to create sub-questions within site visit checklists within each individual section.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Added support for creating checklists with a leading question and multiple sub-questions. • When applied to a site visit, sub-questions are displayed under the leading question according to the checklist design. • Sub-question dependencies are enforced, ensuring responses align with the checklist configuration. 	No	Yes	Critical	Impact: This improvement has a Critical impact on the site visit checklists.
CTMS-1497	CTMS	This improvement will provide a Details view within the Study Enrollment Dashboard.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Study Enrollment Dashboard.
CTMS-1531	CTMS	With this enhancement, activities created while answering a site visit checklist question will now reference the Visit Checklist. Indicating that the activity originated from a CRA's response to a checklist question, providing clear context for the reviewer.	No	Yes	Major	Impact: This improvement has a Major impact on the activity record created during a site visit.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1544	CTMS	<p>This enhancement enables the use of a Rich Text field in the Site Visit Report Checklist Comments section, allowing for more detailed and formatted input when generating site visit report directly out of CTMS.</p> <p>Key features:</p> <ul style="list-style-type: none"> • The system shall provide the use of: <ul style="list-style-type: none"> ○ Bullets ○ Special characters (e.g., &) ○ Retain the spacing used in CTMS or how the text is captured in a Word document and is copied/pasted into the CTMS. 	No	Yes	Major	<p>Impact: This improvement has a major impact on the Rich Site Visit Report Checklist Comments section for CTMS generated site visit reports.</p>
CTMS-1559	CTMS	<p>This enhancement introduces an in-app notification that alerts users when a document generation process is complete.</p>	No	Yes	Minor	<p>Impact: This improvement has a minor impact on document generation.</p>
CTMS-1627	CTMS	<p>This enhancement allows for the deletion of site visit types that are unused and not linked to any site visit checklist template.</p>	No	Yes	Major	<p>Impact: This improvement has a major impact on the site visit types.</p>
CTMS-1632	CTMS	<p>With this enhancement, the ability to export data from the grid within the Milestone Templates global library.</p>	No	Yes	Minor	<p>Impact: This improvement has a Minor impact on exporting.</p>

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1649	CTMS	<p>This enhancement will allow for a user to generate a Site Visit report with all associated/tracked data without the need to generate a report through the use of Collaborate/CCR.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Audit trail now includes status history along with the associated user and date for documents generated. • Unnecessary blank lines are no longer displayed. • Users can now select the preferred Site Visit Report template for document rendering. 	No	No	Critical	Impact: This improvement has a critical impact on the Site Visit report generation.
CTMS-1656	CTMS	<p>This enhancement will provide the ability to create an activity record regardless of location through a quick action button.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Activity creation fields are auto-populated based on the user's current system location. • Users can update or override these pre-populated fields when creating an activity record via the quick action button. 	No	Yes	Major	Impact: This improvement has a major impact on activity records.
CTMS-1672	CTMS	<p>This enhancement will introduce access to the User Management grid without having access permissions.</p>	No	Yes	Major	Impact: This improvement has a major impact on the User Management grid.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1684	CTMS	<p>This improvement will provide the ability for a site visit reviewer to record comments during the Site Visit review workflow.</p> <p>Key features:</p> <ul style="list-style-type: none"> Individual reviewer comment fields are now available within site visits and are editable only by the assigned reviewer during the review process. Visit owners can view reviewer comments but cannot edit or delete them (read-only access). Reviewers can revise or remove their comments when a site visit is resubmitted for review. Reviewers are restricted from modifying site visit data while performing their review. 	Yes	No	Minor	Impact: This improvement has a minor impact on the Site Visit review workflow.
CTMS-1737	CTMS	This enhancement introduces the ability to set dependencies of checklist question comment fields based on question responses provided.	No	Yes	Critical	Impact: This improvement has a critical impact on Site Visit Checklist Templates.
CTMS-1769	CTMS	<p>This enhancement will provide the ability to define the system automation dependencies/automation workflow.</p> <p>Automation results are recorded in the audit trail, clearly indicating that the action was system-generated.</p>	No	No	Minor	Impact: This improvement has a minor impact on the automation workflows.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1788	CTMS	<p>This improvement will account for the impact on site visit report within CTMS when a reviewer unclaims a visit (visit report).</p> <p>Admins now have the ability to unclaim a review. Once unclaimed, another user can start the review.</p>	Yes	Yes	Minor	Impact: This improvement has a minor impact on the site visit reports.
CTMS-1791	CTMS	<p>This improvement will add a filter by Site Status within the following locations:</p> <ul style="list-style-type: none"> • Organization > Sites • Contacts > Sites • Program > Sites • Product > Sites • Study > Dashboard > Study Enrollment • Study > Dashboard > Study Timeline • Study > Dashboard > Activities • Study > Site Visits • Country > Dashboard > Country Timeline • Country > Dashboard > Activities 	No	Yes	Minor	Impact: This improvement has a minor impact on filtering.
CTMS-1792	CTMS	<p>This enhancement will provide the ability to automatically set subject statuses based on the completion of subject visits.</p>	Yes	No	Major	Impact: This improvement has a major impact on Automation of subject statuses.
CTMS-1803	CTMS	<p>This enhancement will provide the ability to capture site visit report statuses when CTMS is not utilized for site visit report generation.</p>	No	No	Major	Impact: This improvement has a major impact on the site visit report tracking.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1810	CTMS	<p>This enhancement will now alert users when a subject's Informed Consent Signature Date is earlier than the Informed Consent Effective Date, helping prevent data entry errors and ensuring compliance.</p> <p>Key features:</p> <ul style="list-style-type: none"> A warning pop-up is now displayed when saving an Informed Consent record where the Signature Date is earlier than the Effective Date. Data entry is not restricted in this case, allowing users to proceed in situations where the Effective Date may be incorrect rather than the subject's Signature Date. 	No	Yes	Minor	Impact: This improvement has a minor impact on Subject Informed Consent tracking.
CTMS-1813	CTMS	This enhancement will now provide the ability to filter addition site related field within a view.	No	Yes	Major	Impact: This improvement has a major impact on filtering.
CTMS-1824	CTMS	This enhancement will update the out of the box values for the Products > Type lookup, to align with pharmaceutical industry standards.	Yes	No	Minor	Impact: This improvement has a minor impact on Products > Types.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1848	CTMS	<p>This improvement will provide the ability to capture a draft state of a site visit and create a "Draft" version of a site visit to prevent data loss.</p> <p>Key features:</p> <ul style="list-style-type: none"> The system now clearly highlights when a site visit is in draft status, ensuring users understand it must be saved to become part of the permanent site visit record. The system explicitly identifies which data is not yet saved as part of the permanent record, providing transparency and reducing the risk of incomplete documentation. 	No	Yes	Minor	Impact: This improvement has a Minor impact on the Site Visit records saving.
CTMS-1851	CTMS	This enhancement enables users to apply site-level saved Subject views directly within the Site Visit > Subjects view.	No	Yes	Major	Impact: This improvement has a major impact on the Site Visit > Subjects view.
CTMS-1855	CTMS	<p>This improvement will allow users to edit the Co-Sponsor field for Study > Organizations.</p> <p>Users can now add, update, or remove the Co-Sponsor designation for a study as needed.</p>	No	Yes	Minor	Impact: This improvement has a Minor impact on the Study > Organizations tracking.
CTMS-1869	CTMS	This improvement will add the site visit report Submitted Due date column to the Site Visit Report Review Status dashlet.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Site Visit Report Review Status dashlet.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1890	CTMS	This enhancement will provide the ability to utilize a workflow for site visits.	Yes	No	Critical	Impact: This improvement has a critical impact on the
CTMS-1893	CTMS	<p>This improvement will provide Minor User Interface improvements for the overall customer experience.</p> <ul style="list-style-type: none"> • Import Status window • Site Visit Navigation within Domain settings • Add a Tooltip on the Statuses Page in Settings • Filters updates for consistency • Bottom toolbar is removed on the site visit page • Activity button is added to the main toolbar. • Changes in labels • Adjust the visual status selector • Improve the display of Email/Phone type in the grid. • My Page: Clicking the "Site" column value should open the Site page in another browser tab. • Milestones Quick View: Incorrect positioning of the 'General Information' portlet in the QV. • Adjust color generation logic (statuses and lookups). • Warnings and confirmations about unsaved data in a uniform style. 	No	Yes	Critical	Impact: This improvement has a critical impact on the User Interface page.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1900	CTMS	This improvement will now clearly inform users when a custom field is or is not set as required at the activity type or subtype level because it is already defined as required at the domain level.	No	Yes	Major	Impact: This improvement has a Major impact on the activity type/subtype custom fields.
CTMS-1902	CTMS	This enhancement will add a tool tip to the user, letting them know what date field the Study Settings > Monitoring Information regarding site visit windows.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Study Settings > Monitoring Information regarding site visit windows.
CTMS-1903	CTMS	This improvement will expand the view functionality to the Study > Organization’s grid view.	No	Yes	Major	Impact: This improvement has a Major impact on the Study > Organization’s grid view.
CTMS-1904	CTMS	<p>This enhancement will improve how a user works with existing activity records within a site visit.</p> <p>Key features:</p> <ul style="list-style-type: none"> • Users can now apply saved views within the Add Activities modal of the Site Visit > Activities view. • Creation of new views is not supported within site visits. • The Site Visit field has been added to the Activities grid within a site visit for improved visibility and filtering. 	No	Yes	Major	Impact: This improvement has a Major impact on the activity records within a site visit.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1905	CTMS	This enhancement will expand the view functionality to the Site > Contacts grid view.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Site > Contacts grid view.
CTMS-1906	CTMS	This enhancement will now display a health card-style modal window to the user when completing a site visit. The Health Card now clearly indicates which fields become non-editable once the site visit status is set to Completed.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Site Visits.
CTMS-1911	CTMS	This enhancement will expand the filtering set on Study Settings > Subjects > Subject Visit Schedules.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Study Settings > Subjects > Subject Visit Schedules.
CTMS-1912	CTMS	Users can now select all statuses for inclusion in the 'Enrollment Summary' section of a site visit record, eliminating the need to select and save each status individually.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Enrollment Summary of a site visit record.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1914	CTMS	<p>CTMS now supports the use of electronic signature capture for site visit reports at the following two key points:</p> <ul style="list-style-type: none"> • Author's Signature at the time of report submission. • Reviewers' Signature at the time of report approval. <p>Capturing electronic signatures directly within CTMS improves compliance, enhances audit readiness, and streamlines report workflows by eliminating the need for manual signature processes after approval.</p>	Yes	Yes	Minor	Impact: This improvement has a Minor impact on the capturing of electronic signatures for site visit reports directly within CTMS.
CTMS-1916	CTMS	The system now supports the ability to send the full list of study-defined milestone templates data to TI.	No	Yes	Minor	Impact: This improvement has a Minor impact on the sharing of study-defined milestone templates to TI.
CTMS-1931	CTMS	This improvement will provide a user-friendly and comprehensible error message will now be displayed when the record import fails during a site import.	No	Yes	Minor	Impact: This improvement has a Minor impact on site importing.
CTMS-1932	CTMS	The improvement allows Super Administrators to define site visit report templates and access controls associated with site visit report templates definition and document generation at the domain level.	Yes	No	Major	Impact: This improvement has a Major impact on the defining site visit report templates.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1934	CTMS	This improvement provides a link to the user's profile within CTMS. The existing TI link has been replaced with a User Profile link, which allows users to update their profile details directly within CTMS.	No	Yes	Major	Impact: This improvement has a Major impact on the user profile.
CTMS-1935	CTMS	This improvement enables the addition of 'Actual' enrollment tracking fields from the Subject and Recruitment section into cross-study views. Users can now customize cross-study lists to include enrollment statistics.	No	Yes	Major	Impact: This improvement has a major impact on the cross-study views.
CTMS-1936	CTMS	This improvement to the Site Visit Review Workflow triggers notifications to the user assigned to each step within the workflow. This improvement helps users stay informed of assigned tasks, status changes, and pending reviews without requiring manual follow-up and checking of site visits.	No	Yes	Minor	Impact: This improvement has a Minor impact on the Site Visit Review Workflows.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1937	CTMS	<p>The 'My Tasks' section has been added to the 'My Page' tab on the dashboard, providing each logged-in user with a personalized view of their assigned tasks.</p> <p>Key Features:</p> <ul style="list-style-type: none"> • Displays all tasks assigned to the logged-in user. • Shows key attributes related to the task. • Allows sorting and filtering of tasks. • Displays tasks that are past due. • Removes tasks from the list once no further action is required. <p>This addition of the 'My Tasks' section improves visibility and ensures that users can act on tasks requiring their attention.</p>	No	Yes	Minor	Impact: This improvement has a Minor impact on the 'My Page' tab within the dashboard.
CTMS-1941	CTMS	<p>The spelling error in the Studies > Product Type list values has been addressed.</p> <p>The value previously displayed as 'Concomitant' has been updated to the correct spelling: 'Concomitant'.</p>	Yes	Yes	Minor	Impact: This improvement has a Minor impact on the Product Type values.
CTMS-1944	CTMS	<p>This improvement will provide the ability to 'Disable Site Visit Forecasting' setting from the site's Settings section, allowing for customers to disable study-level site visit forecasting at the site level.</p>	No	Yes	Minor	Impact: This improvement has a Minor impact on individual site visit forecasting at the site level.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1945	CTMS	<p>This enhancement enables the association of one or more document types with a milestone template at the domain, sponsor, and study levels.</p> <p>The system uses the document type list from the eTMF/TI and includes the associated document type when sending a milestone to eTMF/TI.</p>	Yes	No	Minor	<p>Impact: This improvement has a Minor impact on capturing the document types for milestone templates.</p>
CTMS-1948	CTMS	<p>This enhancement updates the logic used to determine visit window compliance within the CTMS Visit Management module. The system will now utilize the Site Visit Start Date—rather than the End Date—to evaluate whether a visit occurred within the defined window, ensuring alignment with operational expectations for visit scheduling and performance tracking.</p>	No	Yes	Minor	<p>Impact: This improvement has a Minor impact on Site Visit windows.</p>

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-11972	CTMS	<p>The Sort functionality on the Site Visit Report Review Status dashlet did not work as expected and was inconsistent with the standard sorting behavior</p> <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	<p>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</p> <ul style="list-style-type: none"> Ascending Order: A, a followed by Z, z. Descending Order: Z, z followed by A, a.
TICTMS-12206	CTMS	Exporting a large number of activity records takes an unusually long time to complete.	Minor	This bug has a Minor impact on the Export functionality. The resolution will reduce the time to complete the export process.
TICTMS-14438	CTMS	<p>The Sites export file, retrieved in CSV and XLSX formats, did not capture and include the following Organization-related fields during export:</p> <p>Committee Type</p> <ul style="list-style-type: none"> IRB/EC Number Meeting Frequency Committee Type 	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.
TICTMS-15199	CTMS	The Study Status field is not available in Site Views.	Major	This bug has a major impact on the Home > Sites and Study > Sites. The resolution will ensure the system correct behavior.
TICTMS-13591	CTMS	Dynamic/custom defined grid view is reset to default after page refresh on the Organizations page.	Minor	This bug has a minor impact on grid view functionality. The resolution will ensure the system correct behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-14080	CTMS	For Contact Organization, only users with read access to contacts and organization can add an organization under a contact.	Minor	This bug has a minor impact on managing organizations for a contact. The resolution will ensure that a user with read access to contacts and organization cannot associate an organization to a contact.
TICTMS-14173	CTMS	Updates to Organization addresses are not displayed within the quick view after saving the record.	Minor	This bug has a minor impact on viewing organization records within the quick view. The resolution will ensure that the quick view displays address updates upon saving the record.
TICTMS-14253	CTMS	An Asterisk is displayed next to a view name even when no changes have been made.	Minor	This bug has a minor impact on the user experience, leading the user to believe there are unsaved changes. The resolution will ensure that users receive proper indications when working with views.
TICTMS-14382	CTMS	Incorrect behavior, additional options are displayed that are not relevant, within the Parent Plan dropdown when creating activity plan templates.	Minor	This bug has a minor impact on the user when creating an activity plan template. The resolution will ensure that the list of available values displays only relevant options.
TICTMS-14418	CTMS	Planned Date field is not displayed within the Apply Activity Plan window.	Minor	This bug has a minor impact on the user when applying an activity plan. The resolution will ensure that the Planned Date field is displayed to the user.
TICTMS-14516	CTMS	My Page > Site Visit calendar, a user with unblinded access permissions cannot click on the name of an unblinded site visit.	Minor	This bug has a minor impact on My Page > Site Visit calendar. The resolution will ensure that users with the proper permission can access the link on an unblinded visit name.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-14522	CTMS	During study creation the primary products list is not filtered after the primary program is selected.	Minor	This bug has a minor impact on the list of available products for select. The resolution will ensure that the list of products is relevant based on previous program selection.
TICTMS-14529	CTMS	CTMS is sorting incorrectly by Report Status Date on Site > Site Visits, error message is displayed and extra empty pages are show within the pagination.	Minor	This bug has a minor impact on filtering of site visits within a site. The resolution will ensure that the user is able to sort and receive the correct results.
TICTMS-14870	CTMS	Leave Without Saving window is displayed when a user updates the Site Auto-naming rule.	Minor	This bug has a minor impact on system performance when defining a site auto-naming rule. The resolution will ensure the system performs as expected and does not display the saving message when not expected.
TICTMS-14900	CTMS	Activities export does not include comments when a dynamic/custom view is not defined by the user.	Minor	This bug has a minor impact on export activity records. The resolution will ensure that comments are included within an activity export while using ootb views.
TICTMS-14903	CTMS	Milestone export does not include parent milestone comments when a dynamic/custom view is not defined by the user.	Minor	This bug has a minor impact on export parent milestone records. The resolution will ensure that comments are included within a milestone export while using ootb views.
TICTMS-14910	CTMS	Site location address only appears for potential sites after a page refresh.	Minor	This bug has a minor impact on system performance when viewing site details. The resolution will ensure the appropriate data is displayed to the user when viewing a site detail.

10. Open Defects

TI CTMS v3.1 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-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-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-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-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.

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 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

12. Approvals

Product Owner

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

Quality Assurance

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