

# TI CTMS V3.0 - RELEASE NOTES V1.1



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## 1. Version History

Author	Revision #	Date	Comment
Salil Joshi	0.1	06-Jun-2025	Initial Document Creation
Salil Joshi	0.2	13-Jun-2025	Added Open Defects
Salil Joshi	1.0	19-Jun-2025	Document Finalization
Salil Joshi	1.1	08-Aug-2025	Updated feature description for CTMS-1842

## 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 computerized system:

System In Scope	
System Name	TI CTMS
System Version	3.0
Release Type	Major

## 4. Definitions / Acronyms

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

## 5. Release Overview

### A. AUTOMATE: STUDY CREATION POWERED BY AI

**CTMS-378:** Leverage Automate’s large language model (LLM) to accelerate study setup by uploading protocol documents directly into CTMS. Automate scans the document and extracts key data to assist in the creation of a study profile, reducing manual user entry, improving efficiency, and ensuring data consistency.

#### Key Benefits

- **Streamlines Study Profile Creation:** Automate reduces setup time by pre-populating study fields using protocol content.
- **Reduces Manual Data Entry Errors:** AI-driven data extraction minimizes the risk of inconsistencies
- **Supports Standardization Across Studies:** Ensure consistent data entry from protocol to system fields.

### B. MY PAGE: A CENTRALIZED AND INFORMATIVE LANDING PAGE

**CTMS-1613:** The introduction of ‘My Page’ transforms the way users interact with the CTMS by providing an intuitive, centralized cross-study landing page to view upcoming events, reminders, and empowering users to work smarter, faster, and more efficiently.

#### Key Benefits

- **Centralized Location:** Access all the key updates in one place, whether it’s upcoming activities, milestones, or site visits, without navigating multiple menus.
- **Quick Links:** Direct links guide users to pending milestones, upcoming visits, or overdue activities, saving time.
- **Global Search:** Global search makes locating associated data across the application easy.
- **Dashlets:** Configure and view the important data through dashlets for:
  - Activities
  - Milestones
  - Site Visits
  - Site Visit Calendar

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## C. IMOPORTING: ACTIVITIES, SITES, AND SITE CONTACTS

**CTMS-1646, CTMS-1679, CTMS-1807:** CTMS now supports the import of activity records, sites, and site contacts using structured templates. This enhancement simplifies data entry and speeds up the population of records across multiple studies.

### Key Benefits

- **Accelerates Data Entry:** Import templates allow users to quickly load large volumes of structured data.
- **Improves Data Accuracy:** Standardized formats reduce the likelihood of manual entry errors.
- **Enables Cross-Study Efficiency:** Supports bulk updates and centralized data management across studies.



## 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 times zones are in ET)	
<b>Date of Release</b>	20-Jun-2025
<b>Estimated US MTI Upgrade Date/Time:</b>	21/Jun/2025 4:00 AM
<b>Estimated EU MTI Upgrade Date/Time:</b>	21/Jun/2025 4:00 AM
<b>Estimated China MTI Upgrade Date/Time:</b>	Not Applicable
<b>Date of Dedicated Client Upgrade:</b>	For information about upgrading your dedicated instance to this new version, please contact your <b>TransPerfect</b> Customer Success Manager.

## 7. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the TI CTMS 3.0 platform.

System Requirements	
<b>Operating System</b>	<ul style="list-style-type: none"> <li>• Windows Version 7 or higher</li> <li>• All currently supported Mac OSX releases</li> <li>• iOS and Android for myTI mobile app (see myTI release notes)</li> </ul>
<b>Browser</b>	<ul style="list-style-type: none"> <li>• Microsoft Edge: Version 88 and later</li> <li>• Google Chrome: Current release and earlier.</li> <li>• Mozilla Firefox: Current and ESR releases.</li> <li>• Apple Safari: Current release and earlier.</li> </ul> <p><b>NOTE:</b> TI Sign requires that pop-up blockers be disabled for the Trial Interactive domain.</p>
<b>Client Software</b>	<ul style="list-style-type: none"> <li>• For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally.</li> <li>• For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred).</li> <li>• Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer.</li> </ul>
<b>CTMS Platform Compatibility</b>	Trial Interactive v10.7 supports this version of TI CTMS v3.0
<b>Optional Add-Ons</b>	<ul style="list-style-type: none"> <li>• DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions)</li> <li>• Adobe Sign (Latest Adobe Document Cloud Version).</li> </ul>

## 8. Changes

### Legend for Impacts

TI CTMS v3.0 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-378	CTMS	<p>Currently, users spend considerable time authoring and compiling study profile information based on study protocol documents.</p> <p>To ensure accuracy within CTMS, users with 'Create Study' access can now generate a CTMS study profile by scanning a protocol synopsis or full protocol document. Users can upload a document through the CTMS interface by dragging and dropping a file in the 'Create Study' form. The system will extract data from the uploaded document to create the study profile. After a complete scan of the document is completed by Automate an acknowledgement panel will appear within the creation window, displaying the AI-generated data points that users must review and confirm this before saving the study record.</p>	Yes	No	Major	<b>Impact:</b> This improvement has a major impact on the study profile creation through the use of Automate and the scanning of a protocol-related document.
CTMS-448	CTMS, CTMS Collaborate Room (CCR), myTI	CTMS now supports capturing the system-defined operating time zone at the domain level, ensuring accurate date and time management across multiple time zones for site visit reports. Ensuring that the date and time displayed related to site visit reports are consistent.	Yes	Yes	Critical	<b>Impact:</b> This improvement has a critical impact on the consistency of the date and time display for site visit reports.
CTMS-747	CTMS, eFeasibility	With this release, users can now create potential sites based on various data points	No	Yes	Major	<b>Impact:</b> This new feature has a major impact on the creation

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
	myTI	<p>related to a Contact and/or an organization record. The system uses First Name and Last Name for the selected Contact or Organization in the creation of potential sites. The system will utilize the domain-level defined site views for viewing sites within the selected sites list within the modal window.</p> <p>Additionally, the system provides users with the following capabilities when creating potential sites:</p> <ul style="list-style-type: none"> <li>• Display a summary list before bulk creation of potential sites based on all search criteria.</li> <li>• View the results of the bulk potential site creation process, including any failures with their corresponding reasons.</li> <li>• Allow assignment of a potential status to the list of sites.</li> <li>• Restricts the assignment of a non-potential status to a site at the time of creation.</li> </ul> <p>Furthermore, the following lists of data will be used to derive the possible potential site list:</p> <ul style="list-style-type: none"> <li>• Global Contacts</li> <li>• Global Organizations</li> <li>• Sites</li> <li>• Site Contacts</li> </ul>				of potential sites based on extensive search criteria.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-999	CTMS	<p>With this improvement, users can now access and review a cross-study activity listing.</p> <ul style="list-style-type: none"> <li>Apply filters within the cross-study activities list.</li> <li>Pull in custom fields within the cross-study activities view.</li> <li>Configure and save the cross-study activities view.</li> <li>Retrieve an export of all records from the cross-study activities view.</li> </ul>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on reviewing activity records across studies.
CTMS-1145	CTMS	<p>The latest enhancement to the 'Add Custom Field' form now displays a tooltip explaining the meaning of the 'Regular Expression' option selected as a Field Validation type.</p> <p>This enhancement improves clarity by helping users understand the purpose of 'Regular Expression' when configuring custom text fields within a domain.</p>	Yes	Yes	Minor	<b>Impact:</b> This enhancement has a minor impact on custom fields.
CTMS-1424	CTMS	The latest improvement now provides the ability to apply the maintenance banner across multiple domains simultaneously.	No	Yes	Critical	<b>Impact:</b> This improvement has a critical impact on CTMS support.
CTMS-1502	CTMS, CTMS Collaborate Room (CCR), myTI, Study Start Up (SSU)	Currently, CTMS has three fields on the 'Study Details' page to define partners working on a particular study, i.e., Monitoring Partner, Data Management Partner, and Lab Handling Partner. Each field allows for the selection of a single organization. CTMS now allows for the definition of multiple organizations as partners and users can also	Yes	Yes	Major	<b>Impact:</b> This feature has a major impact on study organization and partner tracking.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
	Trial Master File (eTMF)	<p>now indicate that a single organization is more than one type of partner (service provider).</p> <p>A new field with the label 'Service Provided' is introduced in the Study &gt; Organizations section, where users can select multiple options for services provided by an organization.</p> <p>Additionally, the 'Partner Information' section will no longer be visible in 'Study Details', and the partner details will be migrated to the Organizations section at the study level. The values within the partner information section will now be converted to one of the options in the 'Service Provided' field as defined below:</p> <ul style="list-style-type: none"> <li>Monitoring Partner Organization will now be displayed as 'Clinical Monitoring'</li> <li>Data Management Partner Organization will now be displayed as 'Data Management'</li> <li>Lab Handling Partner Organization will now be displayed as 'Laboratory Services'.</li> </ul>				
CTMS-1534	CTMS	With the latest enhancement to the Countries section in the Settings menu, a checkbox is now available at the top of the list to allow for bulk selection of records.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on domain Settings > Countries.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1599	CTMS	<p>The keyboard navigation is improved across the application and the system now defaults to the first field in the modal window as the active cursor.</p> <p>This improvement saves time, enabling value selection directly through the keyboard.</p>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on the overall user experience.
CTMS-1613	CTMS	<p>This improvement introduces an informative and centralized landing page, i.e., My Page. This provides a centralized location for users to view relevant information such as upcoming activities, milestones, and site visits. Users can now easily review and access data associated with milestones, activities, or site visits as well as filter data to perform cross-study exports.</p> <p>Additionally, CTMS utilizes the following criteria when presenting data to the user:</p> <ul style="list-style-type: none"> <li>• Activity records are displayed when the logged-in user is an 'Activity Owner'.</li> <li>• Site Visits records are display where the logged-in user is a 'Site Visit Owner'.</li> <li>• Milestones records are displayed where the logged-in user is an 'Entity Owner', i.e., site, country, or study.</li> </ul>	No	Yes	Major	<b>Impact:</b> The introduction of My Page has a major impact on the Dashboards.
CTMS-1618	CTMS	<p>With the latest enhancements, users can now retrieve an export of Subject Visit Types from the Study Settings section.</p>	No	Yes	Minor	<b>Impact:</b> This enhancement has a minor impact on exports.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		This enhancement allows users to review the list of visits outside of CTMS.				
CTMS-1646	CTMS	<p>With this improvement, CTMS allows for users to import sites for a study using a pre-defined import template.</p> <p><b>High-level Site Import behavior:</b></p> <ul style="list-style-type: none"> <li>• Users can download the site import template for population and use.</li> <li>• Creation of the site through the import feature will utilize user-defined study access and global access permission.</li> <li>• Users can define a Global Organization Identifier to associate imported sites with an existing global organization record. If none is defined, a new global organization record will be created.</li> <li>• Users can define the 'Type' for any global organization record to be created as a result of the site import, without the need to define it within the import file. The 'Type' column within the import template enables users to define different types of values for each organization if desired.</li> <li>• Site Numbers must be unique when importing sites.</li> <li>• Site Numbers are used to identify site records when importing site record update files.</li> <li>• CTMS uses the Principal Investigator's (PI) first, middle, and last names from</li> </ul>	No	Yes	Major	<b>Impact:</b> The improvement has a major impact of sites and importing.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		existing site records to determine a match with update files. If there is not a 100% match, a new PI record will be created for the site. If a 100% match exists but the import file includes a prefix and/or suffix, the system will update the existing PI record to include the prefix and/or suffix.				
CTMS-1650	CTMS	<p>The improvement expands the view functionality to the Organization/Sponsor level &gt; Sites view.</p> <p>Users can now customize the ‘Sites’ view to retrieve site-specific details at the Sponsor and Organization level.</p>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on configuring the site view at the sponsor and organization level.
CTMS-1679	CTMS	<p>The introduction of the activity import feature enables users with ‘manage’ permissions for an entity to import activity records. Additionally, users can identify a previously imported activity record to be updated.</p> <p>Users can import activity records based on the following generic rules:</p> <ul style="list-style-type: none"> <li>• Custom fields will utilize the system field name as a column header within the import file.</li> <li>• Users need to import site-level, country-level, or study-level activities independently and specify within the</li> </ul>	No	Yes	Major	<b>Impact:</b> The improvement has a major impact of activities and importing.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>wizard at the entity level that they are attempting to import.</p> <ul style="list-style-type: none"> <li>• Users need to utilize existing Type/Subtype combinations when importing.</li> <li>• Users need to state which activity record field(s) should be utilized to identify potential matches/existing activity records as a match in the activities import file for updating activity records.</li> <li>• Data removals within the update import file will not be considered as system removal.</li> <li>• The import of the OOTB Responsible Party field and custom fields that allow for the selection of an existing record (e.g., contact or organization) is restricted.</li> <li>• Subject ID is mandatory while importing subject-related activities.</li> <li>• While importing subject-related activity records for multiple subjects, users need to separate the IDs by ‘;’.</li> <li>• Users can update the activity records within an activity plan, but cannot associate a new activity record with an existing activity plan as part of the import.</li> </ul>				
CTMS-1717	CTMS	The improvement expands the view functionality to the Studies view. Users can now customize the Studies list view.	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on configuring the study-level view.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1766	CTMS	The latest improvement to the 'Activity Type/Subtype' section in Settings allows users to view the display order for custom fields.	Yes	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on activity type/subtype configuration.
CTMS-1773	CTMS	Company Administrators now have additional capabilities, enabling them to access and configure details within Settings > General: <ul style="list-style-type: none"> <li>• Links</li> <li>• Breadcrumbs</li> <li>• Mock Data</li> </ul>	Yes	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on the Company Administrators' capabilities to configure additional settings.
CTMS-1775	CTMS, eFeasibility	The latest improvement to the Sites grid within a study profile enables sharing a site list from CTMS to eFeasibility, ensuring the reduction of duplicate efforts for site entries across multiple applications. <p><b>Key Features:</b></p> <ul style="list-style-type: none"> <li>• Ability to share an updated sites list via a click of a button between CTMS and eFeasibility.</li> <li>• Review and confirm the first and last names for sites that are being shared.</li> <li>• Support for sharing sites with a valid email address.</li> </ul>	Yes	No	Critical	<b>Impact:</b> This improvement has a critical impact on CTMS to eFeasibility interoperability.
CTMS-1779	CTMS	The 'Auto Naming' settings section within the domain settings is enhanced to allow users to include additional metadata fields/properties for inclusion in the auto-naming rules.	Yes	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on the 'Auto-Naming'.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1787	CTMS	The Audit Trail functionality is enhanced to reflect the export action within the audit trail.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on the Audit Trail.
CTMS-1789	CTMS	The latest enhancement provides clarification to users within Domain Settings when a system-defined item cannot be modified because it is a part of a workflow or system operation.	Yes	Yes	Minor	<b>Impact:</b> This enhancement has a minor impact on Domain Settings.
CTMS-1794	CTMS, CTMS Collaborate Room (CCR), myTI, Study Start Up (SSU), Trial Master File (eTMF)	<p>Previously, users were shown the message 'This contact is using the site address' and were restricted from editing the site contact's address when the site address was selected.</p> <p>The Site Contacts feature has been enhanced with the following improvements:</p> <ul style="list-style-type: none"> <li>The site address is now displayed in the quick view panel when the 'Use Site Address' toggle is enabled in the 'Create Contact in Site' window.</li> <li>Users can now edit the site contact address when the site address is being used for the site contact.</li> <li>Users can assign the site address as the contact address for an existing site contact that was not previously using the site address.</li> </ul>	No	Yes	Major	<b>Impact:</b> This enhancement has a major impact on site contact address tracking.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1795	CTMS	The latest enhancement now enables users to import subjects and subject visits at the site level using a pre-defined template, following the same import functionality, rules at the study level.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on importing subjects.
CTMS-1796	CTMS, myTI	<p>This feature introduces the following capabilities to allow CRAs to distinguish between virtual and in-person ICF verifications.</p> <ul style="list-style-type: none"> <li>Users can view additional details related to ICF verifications for a subject.</li> <li>Users can differentiate the type of ICF verification performed (e.g., manual verification or verification conducted as part of a visit).</li> <li>For ICFs verified during a site visit, the system displays the method of the visit, distinguishing between remote and in-person verification.</li> </ul>	No	Yes	Major	<b>Impact:</b> This feature has a major impact on viewing additional details related to the ICF verifications for a subject.
CTMS-1797	CTMS	The latest improvement notifies an unblinded user regarding the risk of containing unblinded content when exporting activities.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on exporting activities.
CTMS-1799	CTMS, myTI	This improvement allows users to identify subjects that have no verifications and associate them with a site visit to perform verifications.	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on Subjects within a Site Visit.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1800	CTMS Collaborate Room (CCR), myTI, Study Start Up (SSU), Trial Master File (eTMF)	The latest improvement now allows capturing addresses without requiring a postal code. Additionally, this improvement allows importing records with a postal code in any format.	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on handling postal codes within an address.
CTMS-1801	CTMS	This improvement updates the tooltip for the 'Site Name' field to display a clearer message on auto-naming, enhancing clarity for users.	No	Yes	Minor	<b>Impact:</b> This improvement has a major impact on user experience.
CTMS-1802	CTMS, CTMS Collaborate Room (CCR), myTI, Study Start Up (SSU), Trial Master File (eTMF)	The site creation process is now enhanced and restricts the use of '/' within the 'Site Name' field on the 'Create Site' form and also within the site auto-naming rule.	Yes	Yes	Critical	<b>Impact:</b> This improvement has a critical impact on Site Auto-naming Rules.
CTMS-1805	CTMS	The 'Statuses' setting under the Domain settings is enhanced to display a user-friendly message when users attempt to deactivate or delete status values set as 'Default'.	No	Yes	Minor	<b>Impact:</b> This enhancement has a minor impact on deleting or deactivating default status values.
CTMS-1806	CTMS	The improvement expands the view functionality to Site Visits, allowing for users to customize the Site Visits view.	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on Site Visits.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1807	CTMS	<p>This improvement enables users to import site contacts at the site level. To successfully import contacts, users must:</p> <ul style="list-style-type: none"> <li>• Provide a site identifier for each contact record.</li> <li>• Specify which contact field(s) should be utilized to identify potential matches/existing contact records as a match in the site import file column(s)</li> <li>• If the user provides a 100% matching email address with a different type, the email address is imported as an additional email address for the contact.</li> </ul> <p>Additionally, when importing phone numbers and email addresses, the system will perform the following actions.</p> <p><u>Phone Numbers:</u></p> <ul style="list-style-type: none"> <li>• Allow for one 'Primary' phone number for an imported site contact.</li> </ul> <p><u>Email Addresses:</u></p> <ul style="list-style-type: none"> <li>• Allow for one 'Primary' email address for an imported site contact.</li> </ul>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on site contacts and importing.
CTMS-1808	CTMS, myTI	Activity records created within a site visit, now include information to identify the site visit.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on activity records created within a site visit.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		This improvement improves visibility within the user interface to indicate whether an activity was created during a site visit.				
CTMS-1809	CTMS, myTI	<p>Currently, the ‘Mechanism’ field under study details is used to track information about the investigational product and its administration within a study. However, the OOTB values available within this field are routes of administration.</p> <p>For TI CTMS to be accurate with the OOTB use with no customizations, the ‘Mechanism’ field under Settings &gt; Lookups &gt; Fields is renamed to ‘Routes’.</p>	Yes	Yes	Major	<b>Impact:</b> This improvement has a major impact on Study Details.
CTMS-1811	CTMS	<p>A cross-study ‘Site Visits Calendar’ has been introduced at the domain-level on the ‘My Page’ dashboard, enabling users to view site visits in a calendar format.</p> <p>This calendar offers functionality similar to the study-level site visits calendar, while providing sufficient details to identify the associated study and site for each visit.</p>	No	Yes	Major	<b>Impact:</b> The introduction of the cross-study ‘Site Visits Calendar’ at the domain level shows all the site visits across all studies to review CRA resourcing and visit schedules.
CTMS-1812	CTMS	<p>The latest improvement to the Site Visits Calendar now displays additional details along with the visit status, such as:</p> <ul style="list-style-type: none"> <li>• Visit Owner</li> <li>• Site Name</li> <li>• Study Name</li> </ul>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on the Site Visits Calendar view.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1815	CTMS	<p>The export functionality at the site level is now enhanced to allow users to export all records, such as:</p> <ul style="list-style-type: none"> <li>• Site Organizations</li> <li>• Site Contacts</li> <li>• Site Team Members</li> <li>• Site Milestones</li> <li>• Site Visits</li> <li>• Site Activity Plans – Plans In Use</li> </ul>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on increasing the number of records that can be included in the exports.
CTMS-1820	CTMS	<p>Previously, users would have to add a contact at the organization level by accessing the organization record and navigating to the contact’s section.</p> <p>With the latest improvement, users can now add an organization to a contact record without navigating to the organization.</p>	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on the global contact and organization record association.
CTMS-1821	CTMS	<p>The improvement to the subject visit schedule now removes the visit windows from the subject visit validation and allows for what appears as overlapping visits based on varying anchor visits.</p>	No	Yes	Critical	<b>Impact:</b> This improvement has a critical impact on the additional variations allowed in the subject visit schedules.
CTMS-1822	CTMS	<p>This improvement automatically enables the ‘Milestone Predecessor’ toggle by default when a new study profile is created.</p>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on the milestone tracking.
CTMS-1825	CTMS	<p>The lookup values available in the ‘Indication’ field within ‘Products’ and ‘Studies’ under</p>	Yes	Yes	Major	<b>Impact:</b> This improvement has a major impact on the Indication lookup for Products

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>Domain Settings have been updated to include new values and remove existing ones.</p> <p>This improvement reduces the number of customizations needed and better aligns with standard clinical trial indications.</p>				and Studies under Domain Settings.
CTMS-1826	CTMS	The lookup values in the 'Therapeutic Area' field within 'Studies' under Domain Settings have been updated to add new values, modify some existing values, and remove others.	Yes	No	Major	<b>Impact:</b> This improvement has a major impact on the lookup values for Therapeutic Area within Studies under Domain Settings.
CTMS-1827	CTMS	The system is enhanced to be more user-friendly when scrolling and displaying records for the 'Edit Permissions' modal window in User Management.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.
CTMS-1828	CTMS	The system filtering within the 'Edit Permission' window in User Management has been enhanced. When users search for a parent entity, any associated child entities will also appear in the results.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.
CTMS-1829	CTMS, CTMS Collaborate Room (CCR), myTI, Study Start Up (SSU), Trial Master File (eTMF)	<p>The latest enhancement to Site Visits now requires users to specify a reason when the site visit status is set to 'Cancelled'.</p> <ul style="list-style-type: none"> <li>Users can select a cancellation reason from the newly added 'Reason for Cancellation' dropdown field.</li> <li>Users can define values for this field.</li> <li>The cancellation action is logged and</li> </ul>	Yes	Yes	Major	<b>Impact:</b> This improvement has a major impact on Site Visit tracking.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<p>displayed in the Audit Trail.</p> <ul style="list-style-type: none"> <li>The 'Reason for Cancellation' field is displayed only when the status is set to 'Cancelled'.</li> <li>Users can view this field in the Quick View.</li> <li>The cancellation reason is accessible and usable in Analytics for reporting purposes.</li> </ul> <p>This improvement provides better visibility into cancellation trends and supports compliance and reporting needs.</p>				
CTMS-1835	CTMS, myTI	<p>The system has been enhanced to allow users to define a time zone for organizations and link it to site records created under that organization.</p> <p>The time zone field can be configured by navigating to Domain Settings &gt; Fields &gt; Organizations/Sponsors.</p>	No	Yes	Major	<b>Impact:</b> This enhancement has a major impact on record-related time zone documentation.
CTMS-1838	CTMS	<p>This improvement enhances the 'Scope' column within the custom view functionality by having a more user-friendly way to refer to the 'Scope' in which a record is related.</p>	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.
CTMS-1839	CTMS	<p>This improvement extends the view functionality by allowing users to view a cross-study sites list at the domain level. The system will apply the domain settings rather than study-specific settings for the cross-</p>	Yes	Yes	Major	<b>Impact:</b> This improvement has a major impact on displaying site lists.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		study site listing. Additionally, users can export a cross-study site list based on the defined views.				
CTMS-1840	CTMS	<p>The export functionality is improved, enabling users to export all records from the following grids within the application.</p> <ul style="list-style-type: none"> <li>• Sponsors</li> <li>• Program</li> <li>• Products</li> <li>• Studies</li> <li>• User Management</li> <li>• Study &gt; Milestones</li> <li>• Study &gt; Countries</li> <li>• Study &gt; Organizations</li> <li>• Study &gt; Contacts</li> <li>• Study &gt; Team</li> <li>• Study &gt; Site Visits</li> </ul> <p>This improvement removes the restriction of exporting only 100 records.</p>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on the export functionality.
CTMS-1842	CTMS	<p>This latest improvement to the calendar view allows users to export the calendar as an image in PDF and PNG file formats. This improvement allows users to view the calendar outside of the system.</p>	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.
CTMS-1843	CTMS	<p>The enhancement to the 'Import' templates includes a distinguisher and highlights the minimum required fields to complete an</p>	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		import. However, the distinguisher will not be displayed for the conditionally required fields.				
CTMS-1845	CTMS, myTI	<p>This improvement now allows users to configure their instance of CTMS to allow for CRAs to enter any 'Sent Date' for 'Confirmation Letters' and 'Follow-Up Letters'.</p> <p>CRAs can now also specify a date before the letter generation date.</p>	Yes	No	Major	<b>Impact:</b> This improvement has a major impact on site visit-related document tracking.
CTMS-1846	CTMS, myTI	<p>Currently, CRAs can generate a follow-up letter only after the site visit report is submitted for review.</p> <p>This enhancement allows CRAs to generate a follow-up letter immediately after a site visit is created.</p>	Yes	No	Major	<b>Impact:</b> This enhancement has a major impact on generating the follow-up letter for site visits.
CTMS-1847	CTMS	The improvement to the 'Fields' under domain settings supports the creation of a custom field to capture money values. Users can now define this custom field across all the entities. Additionally, the system also supports the utilization of ISO currency codes.	Yes	Yes	Major	<b>Impact:</b> This improvement has a major impact on custom fields.
CTMS-1850	CTMS, myTI	This improvement allows users to access the subjects' quick view panel within a Site Visit > Add Subjects modal window.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1852	CTMS	The latest improvement to the Study Settings now allows users to export the data within the study settings.	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on export functionality.
CTMS-1854	CTMS, myTI	<p>The latest improvement to the Site Visit Report section of a Site Visit now makes the actions clearer to the user.</p> <p>Users will now see clear indications about the system's behavior upon clicking the following buttons:</p> <ul style="list-style-type: none"> <li>• <b>Generate Report Preview:</b> Clicking on this button displays that the site visit will not be locked.</li> <li>• <b>Create Visit Report:</b> Clicking on this button will indicate site visit will be locked.</li> <li>• <b>View Rejected Report:</b> Displays when the user has a report with the status 'Rejected'.</li> </ul> <p>This improvement provides clarity by displaying the outcome of each action within the Site Visit Report section.</p>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on user experience.
CTMS-1863	CTMS	<p>The 'Site Visit Report Review Status' dashlet is now enhanced to display the following additional columns within the 'Visit Owner' tab.</p> <ul style="list-style-type: none"> <li>• Submission Due Date</li> <li>• Confirmation Letter Sent Date</li> </ul>	No	Yes	Major	<b>Impact:</b> This enhancement 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
		<ul style="list-style-type: none"> <li>Follow-up Letter Sent Date</li> </ul> <p>This enhancement allows users to see if the site visit report was submitted on time.</p>				
CTMS-1868	CTMS	<p>With this enhancement, the system now automatically saves the initial filters and sorting options initially selected by the user, eliminating the need for reconfiguration when navigating away and navigating back to a system location.</p>	No	Yes	Major	<p><b>Impact:</b> This improvement has a major impact on user experience.</p>
CTMS-1877	CTMS	<p>Previously, CRAs could generate a confirmation letter only before a site visit report was generated and submitted for review.</p> <p>With this improvement, a user can configure CTMS to allow for CRAs to generate a confirmation letter at any time.</p> <p>This functionality is controlled as part of the domain configuration and general settings within the UI.</p>	Yes	No	Major	<p><b>Impact:</b> This enhancement has a major impact on generating the confirmation letters for site visits.</p>
CTMS-1881	CTMS	<p>The latest enhancement to the subject visit window within a site visit report introduces a subject visit quick view, accessible while reviewing subject visits.</p>	No	Yes	Major	<p><b>Impact:</b> This improvement has a major impact on site visit subjects.</p>
CTMS-1882	CTMS	<p>With this enhancement, users can now:</p> <ul style="list-style-type: none"> <li>Access and review a cross-study milestones listing.</li> </ul>	No	Yes	Major	<p><b>Impact:</b> This improvement has a major impact on reviewing milestone records across studies.</p>



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		<ul style="list-style-type: none"> <li>Apply filters within the cross-study milestones list, i.e., create a milestone listing with custom fields, etc.</li> <li>Pull in custom fields within the cross-study milestones view.</li> <li>Configure and save a custom cross-study milestones view.</li> <li>Retrieve an export of all records from the cross-study milestones view.</li> </ul>				
CTMS-1883	CTMS	<p>With this improvement, users can now:</p> <ul style="list-style-type: none"> <li>Access and review a cross-study site visit listing.</li> <li>Apply filters within the cross-study site visit list.</li> <li>Pull in custom fields within the cross-study site visits view.</li> <li>Retrieve an export of all records from the cross-study site visits view.</li> </ul>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on reviewing site visit records across studies.
CTMS-1884	CTMS	<p>With the latest release, the foundational user interface improvements are introduced to streamline navigation, improve visual clarity, and enhance overall usability.</p>	No	Yes	Major	<b>Impact:</b> This improvement refreshes the CTMS user interface for an enhanced experience.
CTMS-1887	CTMS	<p>The 'Description' field in the 'Create Activity' creation is now optional.</p> <p>Users can now create an activity without being required to add a description.</p>	Yes	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on activity records.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1891	CTMS, myTI	<p>Previously, once users selected an option using a radio button, they could not clear the selection.</p> <p>With the latest enhancement, users can now deselect a radio button by clicking on it again, allowing them to leave the field undefined if desired.</p>	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on user experience.
CTMS-1896	CTMS, myTI	<p>Previously, site visit reports generated before the definition of study-specific settings defaulted their due date to the visit end date, and this date remained unchanged even after the study submission and approval expectations were configured within the study settings.</p> <p>With this improvement, the system is enhanced to automatically recalculate the due date for any 'unapproved' site visit report when the study settings for submission and approval timelines are updated.</p>	No	Yes	Major	<b>Impact:</b> This improvement has a major impact on the submission and due date recalculations for unapproved site visit reports.
CTMS-1897	CTMS, myTI	This improvement removes the automatic insertion of a comma before the suffix in contact and user names.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on the display of a User or Contact name.
CTMS-1898	CTMS	The improvement will enhance site address filtering, allowing users to get a list of site addresses of one particular type for all sites.	No	Yes	Minor	<b>Impact:</b> This improvement has a minor impact on the site filtering abilities.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
CTMS-1909	CTMS, myTI	This improvement extends the character limit for the Study Number field and now supports up to 20 characters in this field.	No	Yes	Major	<b>Impact:</b> This improvement has a minor impact on the character limit for the Study Number field.

**B. DEFECT RESOLUTIONS**

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-2611	CTMS	<p>The sort function on the ‘Associate Activity Plan Templates to Study’ modal and the ‘Activity Plan Templates’ main screen was not working as expected.</p> <p>When sorting in ascending order, the list incorrectly displayed sites, while descending order displayed countries.</p>	Minor	This bug had a minor impact on the sort functionality. The resolution restores the correct system behavior.
TICTMS-5417	CTMS	When users changed the language in the CTMS application, the date fields incorrectly displayed the letter 'd' instead of the date in the localized format.	Minor	This bug had a minor impact on the display of localized date format. The resolution restores the correct system behavior.
TICTMS-6640	CTMS	An issue was observed across the application where dropdown lists remained static and did not move in sync with the modal windows when users attempted to reposition the modal windows.	Minor	This bug had a minor impact on the dropdown lists within the modal windows. The resolution ensures that dropdown lists move in sync with the modal window when repositioned.
TICTMS-6908	CTMS	The study level ‘Country Details’ section did not save the changes when users edited the ‘First Site Enrolled’ and ‘Last Site Closed’ fields.	Minor	This bug had a minor impact on the study-level country details section. The resolution ensures that the edits are appropriately saved.
TICTMS-7197	CTMS	On the ‘Create Activity Plan Template’ screen, the search field behaved incorrectly by reopening the activities list instead of adding the selected activity after displaying the search results.	Minor	This bug had a minor impact on the search function on the ‘Create Activity Plan Template’. The resolution ensures that the selected activities are added to the template.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-7714	CTMS	The 'In chart (number of studies)' text, on the Dashboard > Studies dashlet, displayed different numbers when different grouping were selected from the 'Group By' dropdown.	Minor	This bug had a minor impact on the Studies dashlet. The resolution removes the 'In chart (number of studies)' text.
TICTMS-7719	CTMS	Users observed that in the Studies dashlet, the donut chart displayed overlapping or tightly packed chart options when 20 items were shown.	Minor	This bug had a minor impact on the visual presentation of the Studies dashlet within the Dashboard. The resolution ensures that chart captions are properly spaced and no longer appear glued together.
TICTMS-8881	CTMS	Clicking on a Site Team Attendee name within a site visit did not open a new window and instead displayed an error.	Minor	This bug had a minor impact on accessing Site Visit Team attendee details. The resolution ensures a new window is opened upon clicking the attendee's name and it is highlighted.
TICTMS-8982	CTMS	An issue was identified on the Activities page within a site visit record, where clicking the 'Next' button after editing activity details, without saving the changes, resulted in the next activity being incorrectly selected.	Trivial	This bug had a trivial impact on the Activities page. The resolution ensures that the correct activity remains selected unless changes are explicitly saved.
TICTMS-10690	CTMS	The 'Extension' field within the 'Phone Numbers' section of the 'Create Organization' modal had an issue where spaces entered along with the numbers were not automatically trimmed.	Minor	This bug had a minor impact on the 'Extension' field on the 'Create Organization' modal. The resolution ensures that the spaces are trimmed when the focus is lost from the field.
TICTMS-11061	CTMS	The 'Time Zone' filter displayed inconsistent time zone lists between the domain-level 'Contacts' page and the quick view panel.	Minor	This bug had a minor impact on the functionality of the 'Time Zone' filter at the domain level. The resolution ensures both the quick view panel and the main 'Contacts' page now display a consistent list of time zones.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-11149	CTMS	The formatting buttons in the 'General Comment' section of a site visit were not functioning correctly when users attempted to apply text formatting.	Minor	This bug had a minor impact on the Visit General Information page. The resolution ensures that the formatting is applied correctly.
TICTMS-11229	CTMS	An issue was observed across all view grids in the application, where clicking the browser's 'Back' button failed to return the user to the previous page.	Minor	This bug had a minor impact on the navigation across all application views. The resolution restores the correct system behavior.
TICTMS-11652	CTMS	The system ignored the dynamic field validation rule for 'Rich Text' and 'Text Area' and successfully imported records even when the character limit defined for the custom field was exceeded.	Minor	This bug had a minor impact on the import process. The resolution ensures that the dynamic validation rule is enforced, preventing the import of records that exceed the character limit, with clear error indications provided.
TICTMS-11948	CTMS	The search functionality within the 'Scope Type' filter on the 'Activities' window at the Study level did not work as expected.	Minor	This bug had a minor impact on the filter's search capability. The resolution ensures that the search within the Scope Type filter functions correctly.
TICTMS-11993	CTMS	The Quick View panel for Subject, Subject Visit, and Informed Consent was not updating after unlocking the imported and locked records for Subject, Subject Visit Informed Consent respectively.	Trivial	This bug had a trivial impact on the Quick View panel, where updates were not reflected after unlocking imported records for Subject, Subject Visit, or Informed Consent. The resolution ensures the Quick View panel now accurately displays updates immediately upon unlocking these records.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-12055	CTMS	<p>The export file of 'CRA Visit Report Performance dashlet' displayed the following incorrect data for multiple columns.</p> <ul style="list-style-type: none"> <li>• '0' was exported for the following:               <ul style="list-style-type: none"> <li>○ Activities Count</li> <li>○ Attendees Count</li> <li>○ Locations Count</li> <li>○ Subjects Count</li> <li>○ Verified ICFs</li> <li>○ Verified Subject Visits</li> </ul> </li> <li>• Empty values were exported for the following               <ul style="list-style-type: none"> <li>○ Check List Info</li> </ul> </li> </ul>	Minor	<p>This bug had a minor impact on the data display in the export file of the CRA Visit Report Performance dashlet. The resolution ensures that correct data is exported and displayed in the export file.</p>
TICTMS-12195	CTMS	<p>The Quick View panel of an activity at the Study level did not display a comma before the suffix of a contact in the custom contact field.</p>	Major	<p>This bug had a major impact on the display of custom contact fields within the Quick View panel of activity records. The resolution ensures that the comma is displayed before contact's suffix in the custom contact fields.</p>
TICTMS-12949	CTMS	<p>The Site Visit Subjects window did not display the 'Proceed Without Saving?' dialog box when users navigated between subjects.</p>	Minor	<p>This bug had a minor impact on the Site Visit Subjects window. The resolution ensures that the 'Proceed Without Saving' dialog box is displayed when user navigates between subjects.</p>
TICTMS-13044	CTMS	<p>When exporting Sponsors, Organizations, or Contacts with no views configured, the 'Addresses' and 'Parent Organization: Addresses' columns are included in the export, but with no values.</p>	Minor	<p>The bug had a minor impact on the export functionality. The resolution ensures that the system correctly populates these fields regardless of view configuration.</p>

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-13113	CTMS	An additional Enrollment Tracking column was incorrectly exported for a status not added to the Enrollment Tracking section in Domain Settings.	Minor	This bug had a minor impact on the export functionality for Enrollment Tracking settings. The resolution ensures that the system captures and displays the correct number of statuses in the exported file.
TICTMS-13173	CTMS	<p>An issue was observed where the search function did not work properly in the 'Visit Type' field.</p> <p>A similar issue was observed for all locations with the lists of Subject Visits, such as:</p> <ul style="list-style-type: none"> <li>• Site/Subject - Subject Visits</li> <li>• Subject Quick View in Study, Country, and Site.</li> </ul>	Minor	This bug had a minor impact on the search function. The resolution ensures that the search component uses the 'Visit Type' and the 'Visit Name' field in any Subject Visit grids.
TICTMS-13213	CTMS	<p>The exported Organizations data file did not include the Parent Organization Phones, Emails, and Type fields.</p> <p>Additionally, some fields contained incorrect values in the exported file.</p>	Minor	This bug had a minor impact on the exported Organization data. The resolution ensures that all Organization values are now correctly exported and accurately reflected in the file.
TICTMS-13254	CTMS	The Card View for Site Visits did not display the complete visit information for a specific site when Start Date, End Date, and daily duration were specified.	Minor	This bug had a minor impact on the Site Visits Card View. The resolution ensures that all site visit details are now fully displayed in the card view.
TICTMS-13306	CTMS	The 'Primary Site Organization' History dialog box did not display the records where the user has changed the Primary Organization.	Minor	This bug had a minor impact on the 'Primary Site Organization' history. The resolution ensures that all details are correctly displayed in the 'Primary Site Organization' History dialog box.



Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-13394	CTMS	The 'Scope Title' and 'Scope Type' were not populated until the 'Scope' field was added to the Study Contacts grid.	Major	This bug has a major impact on the Study Contacts grid. The resolution ensures that 'Scope Title' and 'Scope Type' fields should display data even if the 'Scope' column is not added to the grid.
TICTMS-13449	CTMS	The 'Merge' contact form is empty if the name is an exact match, even though other fields are slightly different.	Critical	This bug had a critical impact on the 'Merge' contact form. The resolution ensures that the merge contact form is displayed even if there is a slight difference in the name.
TICTMS-13453	CTMS	The 'Visit Owner' tab in the 'Site Visit Report Review Status' dashlet did not display accurate results when the 'Visit Planned Date' filter was applied.	Minor	This bug had a minor impact on the date filtering within the Site Visit Report Review Status dashlet. The resolution ensures that accurate results are displayed when the 'Visit Planned Date' filter is applied.
TICTMS-13455	CTMS	An issue was identified where certain sites did not receive published milestones, while others received duplicate milestone entries.	Critical	This bug had a critical impact on the milestones at the site level. The resolution ensures that sites receive all published milestones when created and when new milestones are published, they are retroactively added.
TICTMS-13464	CTMS	The 'Region' filter on the Countries grid within a study displayed only the regions configured at the domain level and did not include regions defined in the Study Settings.	Major	This bug had a major impact on the 'Regions' filter within the Study Countries grid. The resolution ensures that regions configured at the domain and study level are displayed in the 'Regions' filter.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-13478	CTMS	When exporting Subjects with Subject Visits included, the 'Subject Visits' tab in the exported file displayed all custom fields for Site, Subjects, and Subject Visits, disregarding the configuration defined in the Study Settings.	Major	This bug had a major impact on the Subject export functionality. The resolution ensures that data is now captured and exported in accordance with the configurations defined in the Study Settings.
TICTMS-13542	CTMS	The 'Bulk Edit' panel of the activities at the study level did not show options when the checkboxes for 'Dates' and 'Checkbox Group' were selected. Additionally, the 'Edit Records' window displays IDs instead of entity names when the fields are selected and filled. <ul style="list-style-type: none"> <li>• Org</li> <li>• Orgs</li> <li>• Contact</li> <li>• Address</li> <li>• Subject</li> </ul>	Major	This bug has a major impact on the Bulk Edit functionality within the study activities. The resolution ensures that users can update the Checkbox Group and Dates custom fields using bulk edit.
TICTMS-13654	CTMS	The 'Email' field in the Reviewers section of the Study Settings continued to display the old email address, even after the Admin user updated the reviewer's email in IAM for a user assigned as a blinded reviewer.	Major	This bug had a major impact on the Reviewers section in the Study Settings. The resolution ensures that the updated email address is reflected in the 'Email' field for the blinded reviewer.
TICTMS-13809	CTMS	The system incorrectly restricted the manual entry of site-level enrollment statistics when subject tracking is turned off for a study.	Critical	This bug had a critical impact on the manual entry of site-level enrollment statistics. The resolution ensures that users can define the enrollment summary for the study and manually track subject numbers even if subject tracking is turned off.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-13823	CTMS	The Study view at the domain level failed to display data for 'Regions', despite the regions being correctly configured at the study level.	Major	This bug had a major impact on the visibility of 'Regions' within the Study view at the domain level. The resolution ensures that all regions configured for a study are now displayed correctly.
TICTMS-13848	CTMS	The export file of the Activities grid displayed that system and custom date fields are exported incorrectly with different date formats.	Major	This bug had a major impact on the Activities export. The resolution ensures that the system and custom dates are exported and displayed in a consistent format.
TICTMS-13947	CTMS	The header section was truncated on the 'Export Site Visit Checklist Template' window.	Major	This bug had a major impact on exporting the Site Visit Checklist. The resolution ensures that the header section is now displayed correctly on the 'Export Site Visit Checklist Template' window.
TICTMS-14082	CTMS	Users were unable to add comments for specific questions in the Site Visit Checklist.	Critical	This bug had a critical impact on the Site Visit Checklists. The resolution ensures that users can add comments to the question in the checklist.
TICTMS-14369	CTMS	<p>Unique identifiers did not function correctly for certain custom fields:</p> <ul style="list-style-type: none"> <li>For Date-type custom fields, existing records were not updated as expected; instead, duplicate entries were created.</li> <li>For Number-type custom fields, the import process failed, preventing updates to existing records.</li> </ul>	Minor	This bug had a minor impact on the Activity Import process involving custom fields. The resolution ensures that imports complete successfully without errors, and existing records are properly updated rather than duplicated.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TICTMS-14431	CTMS	When attempting to open the detailed view in the Site Visits Calendar with a large number of site visits, an error message was displayed stating: "Payload Too Large."	Minor	This bug had a minor impact on the Site Visits Calendar. The resolution ensures that a large number of site visits can be displayed without triggering any errors.
TICTMS-14453	CTMS	An issue was encountered when exporting the site list in CSV file format.  The export file displayed some columns as empty while the 'Design' column contained only one value.	Minor	This bug had a minor impact on the export functionality for sites. The resolution ensures that correct data is exported for each column.

## 9. Open Defects

TI CTMS v3.0 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	<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"> <li>• In Ascending order, the values were incorrectly sorted as A–Z followed by a–z.</li> <li>• In Descending order, the values were incorrectly sorted as a–z followed by A–Z,</li> </ul>	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"> <li>• Ascending Order: A, a followed by Z, z.</li> <li>• Descending Oder: Z, z followed by A, a.</li> </ul>
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.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
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.
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-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-13588	CTMS	The Study Milestones page did not display any records when the 'Completed Date' filter was applied.	Minor	This bug has a minor impact on the Study Milestone filters. 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.

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-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"> <li>• Committee Type</li> <li>• IRB/EC Number</li> <li>• Meeting Frequency</li> </ul>	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-14448	CTMS	Users are encountering an issue where the 'Verified ICFs' are not displaying in the grid on the 'Previous Subjects' tab of the Add Subjects modal window.	Minor	This bug has a minor impact on the display of 'Verified ICFs'. The resolution will ensure that the 'Verified ICFs' are displayed in the grid on 'Add Subjects' > 'Previous' tab.
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 is taking an unusually long time to complete.	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-14525	CTMS	The Site Visits Calendar dashlet on My Page did not display the unblinded visits for blinded users. However, the unblinded visits were displayed when viewed the 'Detailed View' window.	Minor	This bug has a minor impact on the Site Visits Calendar dashlet on My Page. The resolution will ensure that unblinded visits are displayed for blinded users.



## 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

<p>US: 888-391-5111</p>	<p><a href="mailto:support.ctms@trialinteractive.com">support.ctms@trialinteractive.com</a></p> <p>OR</p> <p><a href="mailto:help@trialinteractive.com">help@trialinteractive.com</a></p>	<p>Available twenty-four (24) hours a day, seven (7) days a week, three-hundred-sixty-five (365) days a year</p>
<p>European Union, Madrid, Spain</p> <p>+44 (20) 45182755</p>	<p><a href="mailto:eu.help@trialinteractive.com">eu.help@trialinteractive.com</a></p>	<p>Monday – Friday, 9 AM – 6 PM CET.</p>

## 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 TI CTMS 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:	