TRIAL INTERACTIVE MYTI V2.0 - RELEASE NOTES - VERSION 1.0

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2.   Version History

Author	Revision #	Date	Comment
Yogesh Inamdar	0.1	13-Feb-2024	Initial Document Creation
Yogesh Inamdar	0.2	15-Mar-2024	Removed the following: MA-14 MA-21 MA-132
Yogesh Inamdar	0.3	11-Apr-2024	• CTMS-1332 has been renamed to myTI-231 • Removed MYTI-231
Yogesh Inamdar	0.4	18-Apr-2024	Removed the following: • MA-60 • MYTI-181 • MYTI-200 • MYTI-201 • MYTI-212 • MYTI-214
Yogesh Inamdar	0.5	19-Apr-2024	Removed the following: • MA-87 • MA-100 Added the following: • MYTI-181
Yogesh Inamdar	0.6	19-Apr-2024	Updated 'Config Change?' and 'Enabled by Default?' sections for MYTI-160
Samrie Getahun	1.0	26-Apr-2024	Initial version finalized.
Yogesh Inamdar	1.1	06-Jun-2024	Revision update performed to record the requirement name change for requirement myTI-231 entry at v0.3 in Version History.

3.   Purpose

The purpose of this document is for **TransPerfect** to disseminate information to end-users (internal and clients) prior to a system release and detail the new features and important changes. This is performed several weeks in advance of the Upgrade Date by issuing Pre-Release Notes. The end-users of the system can use the Pre-Release Notes to evaluate if their intended use of the system will be impacted by the changes introduced in the system release. The Final Release Notes are then issued once the internal Validation Package has been reviewed/approved by Trial Interactive Quality Assurance. The Final Release Notes will contain the final list of items in the scope of the Release.

> NOTE: **TransPerfect** will make commercial best efforts to minimize the differences between the Pre-Release Notes and the Final Release Notes, but due to Trial Interactive's Agile Software Development methodology, we cannot guarantee there will be no changes in scope.

4.   Scope

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

System In Scope	
System Name	Trial Interactive - myTI
System Version	v2.0
Release Type	Major

5.   Definitions / Acronyms

Term	Definition/Description
21 CFR Part 11	The part of the United States Code of Federal Regulations regulates electronic records and electronic signatures.
Annex 11	The European Union's guidance for using electronic records and signatures in the pharmaceutical industry.
API	Application Programming Interface
CRO	Clinical Research Organization
CTMS	Clinical Trial Management System
ERES	This document provides guidance in the United States for using electronic systems, records, and signatures in clinical investigations.
GDPR	The General Data Protection Regulation is a set of rules by the European Union regarding data privacy rights.
GxP	An abbreviation generally accepted to refer to accepted standards of good practices.
IDP	Identity Provider
KPI	Key Performance Indicator
LMS	Learning Management System
MFA	Multi-Factor Authentication
OOTB	Out of the Box
sFTP	A secure File Transfer Protocol
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SSO	Single Sign On
SSU	Study Start-Up
TI	Trial Interactive
TP	TransPerfect

6. System Overview

A. TRIAL INTERACTIVE – ETMF

Trial Interactive's electronic Trial Master File (eTMF) is a secure, cloud-based solution enabling real-time collaboration for both sponsors and CROs, supplying value and ease of use for trial stakeholders across the board and now bringing enhanced transparency and visibility to your trial. Trial Interactive's eTMF can help your organization:

- Ensure quality with a customized workflow for indexing and approval powered by AI and machine learning.

- Stay current with required document lists and placeholders based on the TMF Reference Model. Placeholders and required document lists ensure that all expected and essential documents are captured in your final TMF.

- Track timeliness with KPI metrics dashboards that measure document intake from receipt to submission through QC and finalization.

- Encourage better compliance with an eTMF that tracks responsibility and actively requests documents when they are due, supporting queries for document corrections through email or upload.

- Confirm and maintain the validity of the eTMF before inspections using quality review audit capabilities to support oversight, periodic reviews, and inspection readiness.

- Ensure overall reportable eTMF Heath with Key Performance Indicator (KPI) metrics, reports, and portfolio dashboards for eTMF health, timeliness, quality, and completeness.

- Plan amendments, visits, and other key trial events and milestones while creating placeholders for the expected documents that need to be collected, including due dates and responsibility to help track eTMF health and timeliness.

- Automate the classification and metadata extraction of the TMF using powerful AI auto-coding with human-aided machine learning.

- eClinical platform interoperability provides a seamless connection and data flow between the eTMF and other critical applications such as a site portal, eISF and site binders, content management, document authoring, study startup, and clinical trial management systems.

- Email and study correspondence inbox with relevance checks captures all email correspondence for each study. Once a correspondence email is sent in, it is rendered to PDF and may be selected for inclusion in a separate interface by study staff. Attachments are checked for duplicates and are linked back to the original email. Emailing documents and site correspondence securely into the eTMF ensures GCP compliance.

- Document redaction, manipulation, and certification allow selected team members to remove personal information to meet data privacy requirements and repair, split, and merge documents. Additionally, document certification helps ensure proper paper disposal.

Additional features of the Trial Interactive eTMF include:

- A mobile content capture app that supports both iOS and Android, with support for CRA reconciliation, metadata classification, query management, training, redaction, and offline mode.

- Drag and drop emails and documents to import them automatically or drop them onto placeholders for auto-assignment.

- Full query and task management capability with three types of queries for requesting, verifying, and responding via email, web, and mobile apps.

- Automatic alerts and reminders with notifications and a daily digest.

- Built-in eSignature and digital signature solution for 21 CFR Part 11 and ER/ES compliance with pre-defined signature blocks, pages, and digital certificate.

- Universal document viewer that supports and renders over 300 document formats.

- Multi-document view with built-in document comparisons, bulk editing, page rotation, deletion, reordering, and annotations.

- Global search provides cross-study search results for documents, document types, full-text, contacts, sites, and other record types, with facets, filtering, and other advanced features.

- Configurable grid filters, column selection, saved public/private views, and built-in reporting tools for ad-hoc exports.

- Standard and ad-hoc reports that support all metadata fields and the ability to add columns to standard reports or fully customize your exports.

- Completeness view showing TMF structure, final documents, planned documents/placeholders, and required documents.

- Configurable support for the latest TMF reference model with full auto-routing and auto-naming rules.

- Automatic duplicate document detection and comparison verifies that a document is unique and does not have a duplicate in the eTMF archive based on identical metadata or an exact copy or duplicate scan.

B. TRIAL INTERACTIVE – STUDY START-UP (SSU)

Trial Interactive Study Start-up (SSU) is a cloud-based solution to manage essential documents per the regulatory requirements for site activation and IP release. Trial Interactive SSU can help your organization:

- Send the Regulatory Package and templates to sites with the list of required documents.

- A configurable one or two-step workflow for reviewing and approving collected required documents.

- TI Study Start-Up makes it easy to see what documents are missing and what documents need urgent attention to avoid unnecessary delays in submission and approval.

- TI Study Start-Up makes it easy to see the sites most likely to activate the fastest. Identify those sites during the process so you can make sure there are no distractions in the submission and approval process.

- Set and automatically track milestones and tasks. Ensure all study start-up processes are being managed effectively and completed on time.

- Effectively track site contracts and budgets with a dedicated section for managing them.

- Create submission packages for submission to regulatory agencies.

- Get real-time updates on package submissions for realistic estimates of site activation timelines.

- Real-time distribution of required document packages, tracking progress, IRB/EC submission, and meeting dates, providing realistic timeline projections and prediction of site activation timeframes.

- Efficiently manage protocol amendments, including tracking and sending reminder emails with just a button click.

- Robust OOTB reports for cycle time calculations, missing documents, and history of collected documents.

- Automatically create sites and site contacts for sites approved in Trial Interactive eFeasibility.

- Request for certified translated copies of documents to manage your global regulatory requirements.

C. COLLABORATE

Trial Interactive provides an online collaborative workspace, which enables collaborative and controlled document authoring, review, and approval. Designed to include 21 CFR Part 11 compliant workflows and approvals, the solution offers an end-to-end service platform for your

organization's content management and document control requirements. These collaborative rooms allow users to benefit from the following solutions:

- Study Collaborate and the CTMS Collaboration Rooms are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and ultimately shared with the eTMF.

- Site Collaborate/eISF and Remote Monitoring Rooms are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and ultimately send it to the eTMF.

- The Quality Document Management solution provides controlled document workflows to an organization for use by clinicians, quality assurance, R&D, and other life sciences teams to collaboratively author, review, approve, sign off on, make effective, train, and distribute regulated content and documents.

TI Collaborate can provide your organization with:

- A single place to share and collaborate on clinical documentation.

- The ability to align document work streams with regulatory compliance practices for document authoring, approval, control, and related training.

- The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation and to fully automate the training management process through the LMS.

- The ability to co-author and collaborate with other authors in real time on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.

- The ability to complete the end-to-end document process with an electronic and digital signature for document approvals.

- The ability to send documents for certified translation through TransPerfect TransPort, track their status, and receive back the translated copies and certificates.

- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.

- The ability to follow critical processes for metadata, approval, and signoffs by publishing or sharing directly with the TMF.

Solutions within the Room Type:

Trial Interactive QDMS

- The Trial Interactive QDMS leverages the TI Content Management functionality in-built Document Type management and configurable folder structure to provide a Quality Document Management System solution for controlled QMS documentation.

Trial Interactive eISF

- Trial Interactive's eISF solution reduces administration and improves speed and compliance for site personnel, CRAs, and study teams. Digital investigative site binder processes maintain certified copies of source file documentation and essential documents required for each clinical study. A seamless, connected eTMF allows for automatic indexing of essential documents to the TMF. The ability to conduct remote site monitoring, when needed, recommended by the FDA and EMA, helps CRAs work more efficiently in today's increasingly virtual environment while reducing travel expenses.

D.   MYTI

eClinical Access Anytime, Anywhere

Trial Interactive Mobile "MyTI" is a fully-featured mobile app for the Trial Interactive platform that supports iOS and Android devices across all TI products. CRAs, Sites, and Sponsors save time when scanning, uploading, certifying, and coding trial documents in real time to Trial Interactive, as well as reviewing, approving, and eSigning documents.

- **Document Capture** – Capture content and metadata securely in a compliant fashion.
- **TMF Workstreams** – Once captured, upload, certify, index, and capture metadata for secure archival. Respond to tasks and queries right from the app.
- **Site Portals** – Enable site personnel to capture content in their Site Portal and Regulatory Binders.
- **CTMS Visit Reports** – Schedule Site Visits, fill in questionnaires, and capture action items and open issues.
- **eSignatures and Approvals** – Complete document workflows, review content, approve content, and sign.
- **Training Support** – Access and track required training courses.

Trip Monitoring

Trial Interactive's myTI is a comprehensive mobile-first monitoring system designed to provide Clinical Research Associates (CRAs) with a complete monitoring solution for investigative site visits.

- The monitoring report, complete with questionnaires, action items, and issues, may be created, and a final report may be submitted.
- Visits may be scheduled on-the-fly with approvals.
- Activities are captured.
- Queries may be responded to as necessary.

- Regulatory Binder reconciliation may be completed within the app, which has a direct connection to the eTMF.
- Documents can be scanned in a secure, compliant fashion with easy-to-use software that allows for optional document-certified copy and metadata capture.
- Phones and tablets are supported using either iOS or Android.

The monitoring trip report may be fully completed on the app or maybe begun on the app and completed using the TI CTMS web application.

- Questionnaires are answered within the app based on questionnaire templates generated using the web application.
- A reconciliation report is automatically included in the generated monitoring visit report.
- Issues may be captured as they are found, as well as a list of action items.
- The follow-up letter, along with the report, may be submitted for collaborative review and approval directly from your phone or tablet.

Visit scheduling is also available from the app.

- As visits are scheduled, they are registered in the CTMS.
- Depending on the date, time, and location detected by the app, the correct visit is automatically assigned.
- Based on the visit type, the appropriate schedule, questionnaires, and activities are defined, as well as the correct confirmation and follow-up letters.

Create questionnaires as re-usable templates:

- Site Initiation Visit templates are provided, along with templates for Monitoring Visits and Closeout Visits.
- Questionnaire templates are matched with MSWord® templates for the report itself and the letters.
- Data collected from the mobile device or the web UI are incorporated into the report, which is generated into the final document and sent around for collaborative review and approval, depending on the desired workflow.

- The final report is signed off using TI Sign eSignature or optionally using DocuSign® or Adobe Sign® for submission back to the sponsor organization.

Issues and Action items are captured in the mobile device and tracked as Activities in the CTMS.

- Issues captured at the time of the visit are included in the visit report.
- Action Items are tracked as activities against the site for follow-up and completion before the next visit.
- The final Trip Monitoring Report may be generated directly from the mobile device.

7.   Release Overview

A.   MYTI-194- FAVORITE

Mark a Study as a Favorite

Users will be able to define a record as a personal favorite within CTMS or myTI, and the indication will be displayed within both applications once data synchronization has occurred between them.

The ability to designate a record as a favorite allows users to quickly navigate through long lists without having to utilize custom filters. Favorites can also be used when sorting lists to reduce the number of relevant records displayed.

B.   MYTI-193- SITE VISIT SCHEDULING

Schedule a Site Visit

CRAs can schedule site visits and track visit schedules in myTI 2.0. In particular, users can track the site visit and the associated monitoring visit report. Visit schedules may be defined based on the monitoring plan and then executed through a built-in workflow that supports the required workflow of the monitoring visit report, with attendant questionnaires, document templates, confirmation, and follow-up letters.

C.   MYTI-213- VISIT CHECKLIST

Site Visit Checklist

- Supports flexible questionnaire templates that can be classified and matched with the correct report templates.

- Includes basic questions and answers and free-text responses. These questionnaires work on all supported devices, including tablets.

D.   MYTI-209-CONTACTS

Organizations and Contacts

MyTI allows you to manage a comprehensive contact database of organizations, including Investigators. Both sponsor and site contacts can be managed, as well as their relationships with each organization. Contacts may be managed both at the global level as well as in each study and site level. Additional capabilities include:

- Address types are managed for each contact, with support for multiple locations/addresses per contact to accommodate various clinics, health centers, and hospital organizations associated with the contact.

- The study role is captured for each site contact, supporting complex scenarios for sub-investigators and CRAs.

- Rosters are available for the study team, the site team, and multiple teams at the Sponsor and Organization. All rosters are searchable and reportable to standard formats. A Study Owner can manage the team independently if desired, including tracking end dates for trial participation.

E. MYTI-219 DOCUMENT GENERATION- LETTERS

Site Visit letters

MyTI 2.0 supports the creation of site-visit-related letters and reports all the way through to the final, signed PDF version.

- Establish central templates for the site visit questionnaires, capture the branding, form, and format of the site visit report, and create letters and other critical site communication documents.

- Full support for TI Collaborate authoring and review of the monitoring visit report with the key site collaborators.

- eSignature support for 21 CFR Part 11 electronic signatures

F. MYTI-205 SEARCH

Cross Room Document Search

- Cross-study document search will deliver efficiency and complete access to every document related to Rooms the user has access to. By simply typing a series of keywords into a search query field, all the documents that met the search criteria would be displayed.

- Smart Search by Folder

- When searching for documents in myTI, sometimes it is easy to search by a folder name in the eTMF rather than another piece of metadata. In myTI 2.0, you can search this way, simplifying access to documents.

- CRA Reconciliation Filtering

- When reconciling documents in myTI 2.0, it's often easiest to sort and filter them by status, showing just the documents you need to reconcile by the date entered. MyTI 2.0 provides these filters and sorts within the UI.

G. MYTI-191- OFFLINE AND SECURE

All functionality in the app follows these precepts:

- Conditions of poor connectivity or no connection still allow the operation of myTI, including trip reports, image capture, and other features in offline mode. When connectivity is poor, all responses and documents are temporarily cached in encrypted, session-based memory on the device.
- Once connectivity is restored, all content is sent to the server and removed from the device. If the device is compromised in any way, data cannot be accessed or retrieved from the encrypted, session-based memory.
- No data is permanently stored on the phone in any circumstances.
- In this way, visit reports may be accessible offline, and documents may be captured in locations with no connection.

H. MYTI-183- TRAINING DASHBOARD

My Training Dashlet

Training can sometimes be done better on the go. Required coursework can be completed without sitting behind a computer. With myTI 2.0, all required courses are now available from the app, showing users what they still need to complete and what has been completed. Learners can also filter and search through courses via the dashlet.

Access Required Training

In myTI 2.0, when each course is selected, it may be opened via an in-app browser. Assessments are done, videos are watched, and SOPs are read and confirmed from the app.

Responsive Design of Global Learn

Training occasionally has to be done on the go. Required coursework can be completed without sitting behind a computer. With myTI 2.0, all required courses are now available from the app, showing users what they still need to complete and what has been completed.

8.   Release Schedule

Once myTI v2.0 is approved for release on the date noted below, this version will be deployed to the Mobile App stores during the normal maintenance windows.

If you're interested in using the app before it's available in the app stores, please contact your Project Manager for more information:

Schedule	
Date of Release	26-Apr-2024
Estimated Apple App Store Upgrade:	24-May-2024
Estimated Google Play Store Upgrade:	24-May-2024
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your TransPerfect Project Manager.

9. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the myTI V2.0 platform.

System Requirements	
iOS	• OS Version: iOS 14 and higher. • Tested and verified on iPhone 13, XS **Supported Devices:** any iPhone device that supports iOS version 13 or higher.
Android	• OS Version: 11 and higher • Tested and verified on Samsung Galaxy S20, LG V30, Google Pixel **Supported Devices:** any Android device that supports version 11 or higher, including Samsung Galaxy S9, Samsung Galaxy S8, LG V30, and Google Pixel.
Trial Interactive Platform	Trial Interactive 10.4.2 and higher. Supports Multi-Tenant and Dedicated Instances of Trial Interactive.
CTMS	CTMS v1.4 and higher.
GlobalLearn	GlobalLearn v2.4

10. Changes

Trial Interactive myTI V 2.0 has been released with these new/enhanced features.

These tables use the following definitions of customer Impact:

- **Critical** - A core functionality returns invalid results or does not function as expected.

- **Major** - This Defect has an impact on basic functionality.

- **Minor** - There may be a small impact on business in specific use cases.

A. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MA-121	myTI, eTMF	This improvement incorporates the ability to enable multi-factor authentication when logging into myTI.	Yes	No	MINOR	All users. This improvement has a minor impact on logging into the application.
MYTI-142	myTI, eTMF, CTMS, Global Learn	This improvement changes the myTI Home Page, which allows users to access and view relevant applications they have enabled on the app, including CTMS and eTMF information and any study-relevant Global Learn training assigned to them.	Yes	No	MINOR	All users. These improvements enhance the system user interface and enable users to easily access study and eTMF-related information via the dashboard.
MYTI-159	myTI, CTMS	This improvement allows users to view, capture, and manage relevant dates associated with a site visit.	No	Yes	MINOR	CRA. This improvement has a minor impact on-site visit date tracking.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-160	myTI, Platform	With this improvement, depending upon the user's access and system integrations enabled, the dashboard is now organized based on Study and then any affiliated study rooms/sites.	No	Yes	MINOR	All Users. This improvement has a minor impact on the user interface.
MYTI-163	myTI, CTMS	This feature allows study personnel to create CTMS site visits as necessary from within the myTI application.	Yes	No	MINOR	CRA users. This feature has a minor impact on the site visit management.
MYTI-170	myTI, eTMF, CTMS, Global Learn,	This new feature adds a '+' icon to the navigation bar, allowing users to scan and upload a new document.	Yes	Yes	MINOR	All Users. This new feature enhances the system user experience.
MYTI-171	myTI, CTMS	This improvement adds CTMS-related roles and permissions to myTI's offline mode, allowing users to view site-visit-related information in offline mode so long as it was downloaded when the device was online.	No	Yes	MINOR	All users with CTMS integration. This improvement has a minor impact on available data in offline mode.
MYTI-172	myTI, eTMF, CTMS, Global Learn	This improvement corrects the date and time information displayed to a user based on the user's time zone settings.	Yes	Yes	MINOR	All Users. This improvement has a minor impact on the system user interface.
MYTI-173	myTI, eTMF, Global Learn,	This improvement introduces a navigation menu across the bottom of the screen in myTI, making it easier to locate important options, actions, and areas of the app.	No	Yes	MINOR	All Users. This improvement has a minor impact on the system user interface.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-174	myTI, CTMS	This improvement allows users to add attendees to a CTMS site visit.	No	Yes	MINOR	CRA. This improvement has a minor impact on-site visit management.
MYTI-175	myTI, CTMS	This improvement allows users to create new activities in the CTMS while the application is in offline mode. It also prevents users from editing existing activities while in offline mode.	No	Yes	MINOR	All Users. This improvement has a minor impact on activities management while in offline mode.
MYTI-178	myTI, eTMF	This improvement allows myTI to navigate the user back to the page they were working on when using the navigation menu to go between different areas of the application.	No	Yes	MINOR	All Users. This improvement has a minor impact on user navigation.
MYTI-181	myTI, CTMS	This improvement allows users to edit general site visit information while in offline mode.	No	Yes	MINOR	All Users. This improvement has a minor impact on Site Visit management while in offline mode.
MYTI-182	myTI, CTMS	This improvement allows users to complete the site visit checklist while in offline mode.	No	Yes	MINOR	All Users. This improvement has a minor impact on Site Visit management while in offline mode.
MYTI-183	myTI, Global Learn	This improvement introduces a My Courses dashlet to Global Learn and enables users with assigned courses to track their status and complete their training via an in-app browser.	Yes	Yes	MINOR	All Users. This improvement enhances the user interface for Global Learn users.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-186	myTI, CTMS	This improvement makes minor string corrections to the myTI/CTMS user interface.	No	Yes	MINOR	All Users. This improvement has a minor impact on the system user interface.
MYTI-187	myTI, eTMF	With this improvement, users can perform a cross-study room search for documents from the home-screen search bar.	No	Yes	MINOR	Editor and above. This improvement enhances the system user experience.
MYTI-188	myTI, eTMF, CTMS	This improvement makes minor user interface updates to the Site Dashboard within myTI.	No	Yes	MINOR	All users. This improvement has a minor impact on the site-level UI.
MYTI-191	myTI, CTMS	This improvement allows users to upload documents and update CTMS data while in offline mode. The system will sync this data when it gets online. The users will get updates on their offline activities, including errors and issues encountered during the process. myTI will maintain a log of all the offline activities performed.	No	Yes	MINOR	Editor and above. This improvement enhances the CTMS uses' authorities in the offline mode.
MYTI-192	myTI, eTMF, CTMS	This improvement moves the network status bar to the bottom of the screen for easier visibility.	No	Yes	MINOR	All users. This improvement has a minor impact on the UI.
MYTI-193	myTI, CTMS	This improvement allows users to track multiple dates in relation to site visits created within myTI or the CTMS.	No	Yes	MINOR	CRA. This improvement has a minor impact on Site Visit data entry.
MYTI-194	myTI, CTMS	This improvement allows users to designate a study or site as a favorite, remove that designation, and sort or filter lists by	No	Yes	MINOR	All users. This improvement has a minor impact on the grid User Interface.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-196	myTI, CTMS	This new feature allows the CRA-level users to capture subjects and review their related information at different levels of hierarchy, such as Site and Site visits. The users can perform the following- • To mark site subjects as favorites. • To sort the site subjects based on Subject IDs, Status, Screen Number, Subject Initials, Site, and DOB • Add, Edit, and delete a visit in the Subject Visits tab • Filter and Sort Parameters: Visit date, Status, type, and Site Visit Date	No	Yes	MINOR	Editor and above with CRA access. This new feature enhances the Site Subjects' user experience and provides CRAs with more means of action.
MYTI-197	myTI, CTMS	This improvement allows the system to grant additional access permissions for the CTMS users. These access permissions will clearly indicate the actions the users may perform at the entity level.	No	No	MINOR	All CTMS users. This improvement enhances the CTMS user access permissions.
MYTI-204	myTI, CTMS	This new feature allows the users to view notifications from when the user made offline updates to their site visit or document uploads when selecting the offline Queue tab.	Yes	Yes	MINOR	All CTMS users. This new feature enhances the offline work mode for the CTMS users.
MYTI-205	myTI, eTMF	With this improvement, users can easily access the Sites documents index with a 'Browse' button.	No	Yes	MINOR	All users. This improvement has a minor impact on the system user interface.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-206	myTI, eTMF, CTMS	This improvement adds a name-based and predictive search for the Studies and Study Rooms.	No	Yes	MINOR	All Users. This improvement has a minor impact on the system user experience.
MYTI-207	myTI, eTMF, CTMS	This improvement adds specific labeling at Site and Room levels to easily identify a site/room. Additionally, the system now displays if there is no data or zero states for sites/ study rooms with a generic icon and text message.	No	Yes	MINOR	All Users. This improvement has a minor impact on the Site/Study Rooms user experience.
MYTI-208	myTI, CTMS	This new feature allows users to track site visits and associate individuals with them. Users with respective accesses (CRA, CRA Managers, CTMS Site Team Member, and System Administrator) will be able to plan site visits, capture and record visit details, and send confirmation letters to eTMF.	Yes	Yes	MINOR	All CTMS users. This new feature improves the CTMS Site Visits flow by giving the CRAs and site team members additional access permissions.
MYTI-209	myTI, CTMS	With this new feature, users can now manage contacts on a site level. They can add a contact, sort, and filter contacts based on CTMS web functionalities, manually search for contacts, and mark contacts as favorites.	No	Yes	MINOR	All CTMS users. This new feature has a minor impact on site contact management.
MYTI-211	myTI	This new feature brings real-time functionality to dashlets within studies and rooms. Users can now seamlessly implement counters, display key metrics, and ensure dynamic updates for a more insightful and responsive experience.	No	No	MINOR	All Users. This new feature enhances the room and study navigations within the application.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-213	myTI, CTMS	With this new feature, the following abilities are incorporated into the CTMS Survey Engine visit checklists- • The ability to display annotated visit report text • To use alphanumeric characters for creating and organizing the checklist questions • Ability to expand the character limit for checklist question guidelines • Customizable 'Red text' in Visit Checklist by question • Review and ensure the text displays correctly	No	Yes	MINOR	Editor and above. This new feature enhances the CTMS Visit Checklists' user authorities.
MYTI-215	myTI, CTMS	With this new feature, users will now have access to their current active Studies on the application dashboard. Selecting a study will enable the users to enter and manage information related to the studies' sites, subjects, and activities.	No	Yes	MINOR	All CTMS users. This new feature enhances the system user experience, and the users can manage their active studies from the application.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-219	myTI, CTMS	This new feature implements a visual indicator for document generation and the in-app notification system. • The visual indicator will provide the users with the document generation progress. Moreover, the users can perform any actions or navigate within different sections of the application when the document generation is in progress. • The in-app notification system will notify users when a document is generated and ready for review. • The in-app notification system will display the notifications for visit reports, confirmation letters, and follow-up letters.	No	Yes	MINOR	All CTMS Users. This new feature enhances the system user interface and user experience.
MYTI-220	myTI	This new feature provides a tabbed interface on the dashboard that represents various system dashlets.	No	Yes	MINOR	All Users. This new feature enhances the system user interface.
MYTI-221	myTI	This new feature enhances the system user interface by displaying interactive texts when the screen loads, such as when the initial app, room, or network connectivity issue occurs.	No	Yes	MINOR	All Users. This new feature enhances the application user interface.
MYTI-222	myTI	With this new feature, admin-level users can enable/disable screenshot capture using the company code settings. This will help them prevent or allow users in their organization from using the screenshot option.	Yes	No	MINOR	Admins. This new feature has a minor impact on the application settings.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-3328	CTMS	A task is performed to reset the Site Visit filters, such as planned date filters, Activity Status Filters, Site owner filters, and so on.	MINOR	CTMS Users. This task enhances the system's user experience with the appropriate filter resets.
TIMO-3330	CTMS	This task is performed to enhance the user interface for the Site Visit Attendees list and Attendees filters, where the users can sort the visit attendees and apply filters by presence and role.	MINOR	CTMS Users. This task enhances the application's user interface.
TIMO-3334	CTMS	A task is performed to add the freeze mode to the Site locations screen. When the freeze mode is on, users cannot add a location.	MINOR	CTMS Users. This task enhances the site locations' user permissions.
TIMO-3335	CTMS	This task is performed to enable the 'Search for Address' field where the users can search and add the addresses to add the locations.	MINOR	CTMS Users. This task has a minor impact on the site locations.
TIMO-3336	CTMS	This task implements a pop-up message on the Create Location screen when users try to enter a long name for a town or city.	MINOR	CTMS Users. This task has a minor impact on the Create Location page's user interface.
TIMO-3337	CTMS	This task adds the sorting options for each column when users add existing locations. The Organization name is set as default.	MINOR	CTMS Users. This task has a minor impact on the Create Location page's user interface.
TIMO-3338	CTMS	If a Site Visit is in 'Completed' status, the button 'Remove Location' is displayed but cannot be tapped.	MINOR	CTMS Users. This task has a minor impact on the site visit statuses. The resolution removes the 'Remove Location' button for the sites in Completed status.
TIMO-3340	CTMS	This task makes the' Add existing subject' function the same way as the CTMS web version.	MINOR	CTMS Users. This task has a minor impact on the application user experience.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-3341	CTMS	A task is executed to implement the following interfaces in the Subject creation function of the application. • Calendar pop-up for the 'Status Date' field. • Calendar pop-up for the 'Date of Birth' field. • Cancel Message when entering some data.	MINOR	CTMS Users. This task has a minor impact on the subject creation process.
TIMO-3343	CTMS	This task adds the Subject additional information screens that match the CTMS web user interface.	MINOR	CTMS Users. This task has a minor impact on the Subject information.
TIMO-3344	CTMS	This task removes the incorrect sorting of selected Screening Failure and Early Termination reasons.	MINOR	CTMS Users. This task has a minor impact on the subject history.
TIMO-3346	CTMS	This task removes the 'Verify Subject' button from the bottom of the Verification tab of the Subject visit screen.	MINOR	CTMS Users. This task has a minor impact on the subject verification.
TIMO-3348	CTMS	A task is performed to include the 'Sort By' options and filters in the Site Visit Activities module.	MINOR	CTMS. This task has a minor impact on the application's user experience.
TIMO-3349	CTMS	This task implements the Search for the Visit Activities and Attendees. Additionally, it implements a message when the user cancels adding activities.	MINOR	CTMS Users. This task has a minor impact on the Add Activities functionality.
TIMO-3350	CTMS	The create activity user interface has been enhanced with the ability to add symbols, long texts, and screen orientation.	MINOR	CTMS Users. This task has a minor impact on the Activity management.
TIMO-3353	CTMS	A task is executed, and the users can now edit dates for Complete/Submitted/Revised/Approved site statuses but not for Cancelled ones.	MINOR	CTMS Users. This task has a minor impact on the Site Visit management.
TIMO-3354	CTMS	This task updates a popup message for editing the checklist template. The application now does not display the Checklist tab when the checklist template is not selected in the Site Visit.	MINOR	CTMS Users. This task has a minor impact on the Site Visit management.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-3355	CTMS	When a user opens the Questions screen, selects some answers, and taps the Previous button without saving, there is no Cancel button.	MINOR	CTMS Users. This task has a minor impact on the site visit questions and implements the Cancel button on the Questions screen.
TIMO-3356	CTMS	This task updates the 'Reviewer' field on the Visit Reports screen. The field will be empty for the 'Not Started' and 'In Progress' statuses. It will remain empty for the 'Submitted' status until the reviewer approves or rejects the report.	MINOR	CTMS Users. This task has a minor impact on the site visit reports user interface.
TIMO-3358	CTMS	This task updates the message when a confirmation letter's sent date is updated/changed.	MINOR	CTMS Users. This task has a minor impact on the site visit confirmation letter.
TIMO-3618	myTI, eTMF	The users with Query Responder access experienced an issue where the Query Response message under the Activity tab of a queried document did not have a See More button.	MINOR	Editors and above. This bug has a minor impact on the Query document view. The resolution resets the correct display.
TIMO-3640	myTI, eTMF	On the Add New Task screen, when a user taps the Add Attachments and waits for a long time, the pop-up does not disappear after the timeout logout.	MINOR	Editor and above. This bug has a minor impact on the automatic logout function. The resolution resets the correct application behavior.
TIMO-3681	myTI, eTMF	The 'Update Document Image' button is enabled for an Editor or above-level user despite the selected document being deleted on the web instance.	MINOR	Editor and above. This bug has a minor impact on the Expired documents. The resolution resets the correct system behavior.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-3733	CTMS	A task is performed to match the application's following functionalities with the CTMS web version- • Document date on the Search screen • Sort by on the Search screen • Doc Status on the Search screen • Sort by the Review Report and Site Visits Report sections • Submitted Date on the Review Report and Site Visits Report sections • Country on the Sites screen	MINOR	CTMS Users. This task has a minor impact on the application's filters.
TIMO-3889	myTI, eTMF	iOS users experienced that when the Fingerprint/ Face ID is removed from the phone settings, no Touch ID (Face ID) is displayed on the application.	MINOR	All Users. This bug has a minor impact on the iOS user security. The resolution restores the correct behavior.
TIMO-3971	CTMS	This task adds the specific hint text in the CTMS Site Visits and Attendees search.	MINOR	CTMS Users. This task has a minor impact on the search function.
TIMO-3985	CTMS	This task implements the CTMS Offline mode, where the application displays all the site visits to the users when they are offline. The site visits display the time stamp and outdated site visits.	MINOR	CTMS. This task enhances the system's offline functioning.
TIMO-4244	CTMS	A task is performed to provide the users with the ability to perform sorting on the Confirmation Letter, Follow-Up Letter, and Add Locations screens.	MINOR	CTMS Users. This task has a minor impact on the application's user interface.
TIMO-4363	myTI, eTMF	When users try to open the map from the application to update and view the site address, it does not open.	MINOR	All Users. This bug has a minor impact on the site dashboard. The resolution resets the map function well.
TIMO-4537	CTMS	This task implements the text for an unblinded site visit: "This activity contains confidential information and is visible by only unblinded team members."	MINOR	CTMS Users. This task has a minor impact on the unblinded site visits.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-4753	myTI, eTMF	The application displays two popups – 'Login to enable Biometrics' in your profile and 'Verify your identity' when the fingerprint is from the phone settings, and it turns on Biometric.	MINOR	All Users. This bug has a minor impact on the system's user security. The resolution restores the correct behavior.
TIMO-4754	myTI, eTMF	The users could not see the cursor on the username field when they are in the certified submission type in the new document screen when biometrics are disabled.	MINOR	Editors and above. This bug has a minor impact on the application's user interface. The resolution restores the cursor to its position.
TIMO-4785	myTI, eTMF	The users cannot submit documents when the 'Offline Queue' tab is opened, and there are some documents for submission with fill submission mode on.	MINOR	Editors and above. This bug has a minor impact on the document submission. The resolution resets the correct system behavior.
TIMO-4787	myTI, eTMF	The 'Biometric Configuration' is seen as grey in the user profile.	MINOR	All Users. This bug has a minor impact on the system user interface. The resolution resets the red color to the Biometric Configuration.

11. Customer Support

A. REPORTING ISSUES WITH THE RELEASE

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

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

TransPerfect will respond in accordance with the levels of priority as reasonably determined by **TransPerfect**. Support Services will be available at all times via phone and email from **TransPerfect** Service Desk centers set forth below:

Phone	Email	Business Hours
US: 888-391-5111 (TOLL-FREE)	help@trialinteractive.com	Available twenty-four (24) hours a day, seven (7) days a week, three-hundred-sixty-five (365) days a year
European Union, Madrid, Spain +44 (20) 45182755	eu.help@trialinteractive.com	Monday – Friday, 9 AM – 6 PM CET.
China +86 (755) 66856062	cn.help@trialinteractive.com	Monday – Friday, 9 AM – 6 PM Beijing Time

E. REQUESTING FUTURE ENHANCEMENTS

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

Project Manager (PM)	Customer Experience Program (CEP)
Your PM can submit Ideas to our Perfective Change Management on your behalf.	Meet with other Trial Interactive customers for an immersive CEP Forum: • Focus Group • Early Access • Hosted Beta • Usability Studies

12. Approvals

Product Owner

Name: Samrie Getahun	Title: Product Manager, Trial Interactive R&D
Signature: Reason for signature: Date:	

Quality Assurance

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