

TRIAL INTERACTIVE MYTI V 2.1 – RELEASE NOTES – 1.0







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1. Version History

Author	Revision #	Date	Comment
Salil Joshi	0.1	29-Nov-2024	Initial Document Creation.
Salil Joshi	0.2	03-Dec-2024	Added the following open defects • TIMO-6421 • TIMO-6422



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: **Trans**Perfect 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	MyTI					
System Version	2.1					
Release Type	Minor					



4. Definitions / Acronyms

Term	Definition/Description
JIRA	A proprietary issue-tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management
SQA	Software Quality Assurance
TestRail	A web-based test management software that facilitates software quality assurance; it produces reports on a release candidate and documents the nature and category of bugs
21 CFR Part 11	The part of the United States Code of Federal Regulations that 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 laid out 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
TP	TransPerfect
TI	Trial Interactive



5. System Overview

A. TRIAL INTERACTIVE

TransPerfect's *Trial Interactive* has been used successfully by TransPerfect customers for over 15 years in hundreds of clinical trials to store critical trial documents as part of the Electronic Trial Master File. Trial Interactive's platform is a web-based and mobile-enabled software-as-a-service (SaaS) application that provides eClinical solutions for eTMF and content management, Study Start-Up, and various other tools used in conducting a clinical trial. Trial Interactive's products deliver a wide range of benefits to any organization looking to leverage new efficiencies and opportunities in their Trial Master File, clinical trial management, content management, and eLearning:

- An electronic Trial Master File archive that meets all regulatory, security, access, and storage requirements in all countries and regions.
- A Clinical Trial Management System (CTMS) that meets all eClinical requirements for managing and tracking clinical studies and works seamlessly with the eTMF, Content Management, Learning Management, Mobile app, and other Trial Interactive solutions.
- A fully hosted SaaS solution that is 21 CFR Part 11, Annex 11, ERES, GDPR, and GxP compliant.
- A single access point for all trial content as well as sponsor and site personnel documentation.
- Supports a series of TMF workflows, including document import and indexing, quality review, audit and inspection, document certification, remote monitoring, redaction, and the capture of other Clinical Trial documentation.
- Effective management of documents that are created internally or externally. Trial Interactive is the only solution that provides a best practice and validation-ready approach to creating, collecting, reviewing, and finalizing documents bound for the eTMF archive.
- A thin-client, consumer-grade user interface that supports most major browsers and a mobile app that supports iOS and Android devices.
- A powerful, flexible technical stack with many integration options, including an API, Event Service Bus, SFTP Dropbox, and Corporate Directory Integration with Single Sign On.
- Increases teamwork and collaboration via one global view of clinical trials, training, and supporting documentation.
- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of reviews and authoring solutions.
- Dashboards and reports that provide KPIs, measurable metrics, simple Excel exports, as well as complex standardized and custom reports.
- Adaptable, built-in machine learning features such as auto-classification and metadata extraction enable AI auto-coding capabilities.
- A full-featured eLearning system designed for GxP compliance, study training, and virtual investigator meetings.

Effectively manage the entire clinical trial process from protocol conception through closeout.



B. 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

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, activities, and the correct confirmation and follow-up letters are defined.

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.



6. Release Overview

A. BIOMETRIC AUTHENTICATION FOR ESIGNATURES

MYTI-169 - Unlock a new level of convenience in GlobalLearn in MyTI! Learners can now eSign courses directly from their mobile devices using biometric authentication wherever they are. No more manual logins – just fast, secure electronic signatures for an effortless training experience. This enhanced mobile learning experience includes:

- Biometric login and eSignature: Electronically sign courses with ease.
- **Dedicated access for non-TI users:** Streamlined entry for all.
- Course Completion Dashlet: Track progress with Not Started, In Progress, and Completed statuses.
- **Assigned Training Requirements:** Easy access to the assigned training courses.
- **View Issued Certificates:** Easily access earned certificates.

Enhance the learning experience with seamless, mobile-friendly eSignatures!

B. INSTANT ACCESS TO PRIVACY POLICY

MYTI-226 - In this release, the Privacy Policy link is now available directly on the login page and within the app interface for all users. This enhancement ensures effortless access to important privacy information and compliance with Google Play's User Data policy

Stay compliant, stay informed – privacy has never been more accessible!

C. DRAFTS AND AUTOSAVE DOCUMENTS AND METADATA

MYTI-228 - With this release, CRAs can now save documents and metadata as drafts in the app, allowing them to pick up where they left off whenever it's convenient. Users can save Metadata entries in case of network disruptions, so the progress is always protected.

Stay productive, stay connected, and never lose the work again with this seamless document management solution!

D. UPLOAD DOCUMENTS DIRECTLY FROM MOBILE DEVICES

MYTI-229 - Users can access stored documents in their mobile device making it convenient to upload documents into the MyTI app!

Easily upload multiple documents directly from the mobile device straight into the eTMF, irrespective of the place and time.

Stay efficient and easily upload documents at a later time as per the need!

E. CONTROLLED ACCESS TO CONFIDENTIAL AGREEMENT DOCUMENTS

MYTI-233 - To ensure secure document access, users can no longer open Confidential Agreement documents via the Cross-Room search without authenticating their credentials to access the Confidential Agreement document.

A real-time popup notification will now appear to users when attempting to search for Confidential Agreement documents on the MyTI homepage or within a room, ensuring a seamless and secure workflow.

F. SMART SEARCH IN MYTI

MYTI-234 - Experience the power of smart search with our latest release! The MyTI search screen now allows users to search for documents effortlessly using keywords, no matter which study room they belong to.

Enjoy a faster, more intuitive search experience that makes required documents instantly available.

G. ADD URL LINKS

MYTI-237 - With this improvement, CRAs can now add URL links to activity, subject, contacts, site visits, and more directly into the metadata screen.

H. EMAIL ID OPTIONAL IN CONTACT CREATION

MYTI-238 - With this enhancement, CRAs can create contacts within CTMS without the mandatory email address requirement. While a message will recommend adding an email, users can easily proceed without it, streamlining the contact creation process.

I. SITE VISIT REPORTS: REAL-TIME STATUS NOTIFICATION

MYTI-239 - This release enhances the site visit report management within the CCR, making the review process faster and more efficient for CRAs.

Key features include:

- **Real-Time Notifications:** Report authors receive real-time alerts when site visit reports are rejected, no extra navigation is needed.
- **Direct Rejections:** Reviewers can now reject reports for text-related issues within the CCR, without requiring revisions to CTMS data.
- Status Transitions: Easily track reports as they move from 'Submitted' or 'Revised' to 'Rejected.'
- Clear Dashlet Updates: Status changes are instantly visible on the respective dashlets.

These improvements offer faster feedback, greater clarity, and less hassle in managing site visit reports.

J. DUPLICATE DOCUMENT DETECTION

MYTI-241 - With this enhancement, the system automatically detects if a document from the mobile device has already been uploaded, preventing unnecessary duplication.

Now, when adding a document, users will see an instant popup notification if a duplicate is detected.

K. AUTOMATIC OFFLINE DOCUMENT SAVING

MYTI-242 - With this release, documents are automatically saved to the Offline Queue if the connection is interrupted while working online.

When disruptions occur, the **Submit** button seamlessly switches to **Save**, ensuring the documents are queued for submission once the connectivity is restored.

This new feature, keeps the document submission process uninterrupted, even without a steady connection!

L. MYTI APP NEW LOGO

MYTI-252 - The myTI app now sports a modernized look with the newly crafted logo, featured on the login screen and throughout all key areas. The upgraded app logo replaces the old one across both iOS and Android, delivering a cohesive, elevated brand experience.

With this improvement, myTI users enjoy a high-resolution logo that's optimized for any screen—whether on iPhone, or Android. Compliant with Apple and Google design standards, this enhanced design ensures seamless user experience across every device.



7. Release Schedule

Once approved for release on the date noted below, this version will be deployed to the Multi-tenant (MTI) environment during the normal maintenance windows:

Schedule (All time zones are in ET)						
Date of Release	06-Dec-2024					
Estimated Availability for App Store and Google Play Store Date/Time:	06/Dec/2024 5:00 PM					
Date of Dedicated Client Upgrade:	For information about upgrading your dedicated instance to this new version, please contact your TransPerfect Project Manager.					



8. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the myTI v2.1 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 v2.0 and higher
Global Learn	GlobalLearn v2.5



9. Changes

Legend for Impacts

MyTI v2.1 has been released with these 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.

Legend for Offering

- Electronic Trial Master File (eTMF)
- Clinical Trial Management System (CTMS)
- CTMS Collaborate Room (CCR)
- GlobalLearn/Learning Management System (LMS)
- Mobile Trial Interactive (myTI)
- Platform



A. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-169	GlobalLearn (LMS)	In GlobalLearn, learners might be required to take the training and eSign a course on the go via their mobile devices and wherever they are located. Currently, users can log in using biometrics but are required to perform functions like eSignature by logging in manually. To cater to this requirement, users can now electronically sign a course using the eSignature functionality introduced in MyTI. This enhanced mobile experience for learners will also include the following capabilities. • Dedicated authentication for non-TI users • Display the Course Completion dashlet showing courses with the Not Started, In Progress, and Completed statuses. • View the list of assigned training. • Ability to retrieve transcripts. • View Issued Certificates. • Ability to electronically sign a course.	No	Yes	Minor	Affected Users: Learners. Impact: This improvement will enable learners to access, complete, and electronically sign a course using biometric authentication within the application.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-226	Platform	 With this release, the privacy policy link will now be available directly on the login page and within the app interface. With the introduction of the Privacy Policy: The system prominently displays a link to the privacy policy in the myTI application ensuring it is easily accessible from the main menu or settings. The privacy policy link is clear, understandable, and leads to the most accurate version of the document. The link remains functional at all times and mechanisms are implemented to track user interactions for compliance monitoring. 	No	Yes	Minor	Affected Users: All Users. Impact: The availability of the privacy policy link within the app will provide easy access to the users and ensure compliance with Google Play's User Data policy.
MYTI-228	Trial Master File (eTMF)	Users can now save documents as drafts in the system for later completion of metadata entry and submission.	No	Yes	Minor	Affected Users: Editors. Impact: This new feature enables editors to save inprogress documents for later completion and automatically save metadata entries ultimately mitigating the risk of data loss due to network disruptions.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-229	myTI (MYTI) Trial Master File (eTMF)	 This new feature enables CRAs to upload multiple documents from the mobile device directly to the eTMF through the MyTI application. The key functionalities include: Support for single and multiple document selection from the mobile device for upload. User-initiated upload process that requires confirmation to ensure secure document transfer. Real-time display of upload progress, providing visibility into the status of the transfer. Notifications for upload success or errors. 	No	Yes	Minor	Affected Users: CRA. Impact: This new feature provides CRAs the flexibility to upload documents directly through mobile devices.
MYTI-233	Trial Master File (eTMF)	This feature enhancement prevents users from opening a Confidential Agreement document without first authenticating their login to view the document.	No	Yes	Minor	Affected Users: Editor. Impact: This improvement has a minor impact on the cross-room search functionality on the MyTI home page and in a room.
MYTI-234	Platform Trial Master File (eTMF)	With this enhancement, Users are now able to search for documents using keywords, regardless of the study room in which they were created or saved.	No	Yes	Minor	Affected Users: Site User. Impact: This enhancement has a minor impact on the search functionality and screen in MyTI.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-237	CTMS	This improvement will implement the URL dynamic fields for activity, subject, contacts, site visits, subject visits, etc. The key features include the following: • Clickable URL link • Error message is displayed if non-URL text is entered.	No	Yes	Minor	Affected Users: CRA. Impact: This improvement allows CRAs to insert a URL link into the respective field on the metadata screen while adding a document.
MYTI-238	CTMS	With this improvement, the system no longer mandates the entry of the email address while creating a contact within CTMS. However, the 'Email Address' field displays a message recommending the inclusion of an email address, but users can still proceed without entering one in the respective field.	No	Yes	Minor	Affected Users: CRA. Impact: This improvement has a minor impact on the contact creation screen within a site where CRAs can create a contact even without an email address.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-239	CTMS CTMS Collaborate Room (CCR)	With this release, the system introduces an enhanced functionality for managing site visit reports within the CCR. The key features include the following. • Report authors will receive a notification about the site visit report rejection by the report reviewer without additional navigation in CCR. • Users can now reject a site visit report directly within the CCR for issues related to manually entered text, without requiring revisions to CTMS data. This streamlines the review process and minimizes unnecessary data adjustments. • Support for status transitions, allowing the Site Visit Report status to move from "Submitted" to "Rejected." • These status changes will be reflected in the corresponding dashlets, providing clear visibility into the report's current state.	No	Yes	Minor	Affected Users: CRA. Impact: This feature enables CRAs to know whether the report has been rejected in more real-time without additional navigation to the document within the CCR.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-241	Trial Master File (eTMF)	This feature identifies duplicate documents based on certain criteria and notifies the user before completing the submission. The system identifies duplicates based on an exact match of the following attributes: • File Name: Identical file names • File Type: Identical file types This new feature restricts users from submitting duplicate documents by notifying them.	No	Yes	Minor	Affected Users: All Users. Impact: This enhancement displays a notification popup on the Add Document form if a duplicate is detected.
MYTI-242	Trial Master File (eTMF)	With this release, the system saves documents and metadata to the Offline Queue if connectivity is lost while processing in online mode. When a connection disruption occurs, the Save button will replace the Submit button, and the documents will be queued up for submission in the Offline Queue.	No	Yes	Minor	Affected Users: CRA. Impact: This feature has a minor impact on the Offline Queue where CRAs can see the automatically saved documents when connectivity is lost.
MYTI-252	myTI (MYTI)	The myTI application has been updated featuring the newly designed logo on the login screen and throughout all other areas where the logo appears. The previous appicon has been replaced with the new myTI logo on both iOS and Android platforms, providing a unified and modernized visual identity.	No	Yes	Minor	Affected Users: All Users. Impact: This improvement ensures that the app icon adheres to Apple's and Google's design guidelines and myTI users can see a high-resolution version of the logo incorporated, optimized for various screen sizes, including iPhone, iPad, and Android devices.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-255	туті (МҰТІ)	With this feature improvement, the users are enabled to perform the search functionality using the 'Smart Search' feature to make the search feature convenient and user-friendly by no longer tapping the search button by entering the 'Recipients' screen. Also, the search does not reset if the users change tabs.	No	Yes	Minor	Affected User: Editor. Impact: This improvement has a minor impact on the search functionality on the Recipients' screen.
MYTI-256	CTMS myTI (MYTI)	This improvement enhances Admins and Comment Creator's ability to revisit and edit the previously entered comments for an activity.	No	Yes	Minor	Affected Users: Admin Impact: This improvement has a minor impact on the 'Edit' functionality in Activities.
MYTI-257	туті (МҰті)	With this improvement, the 'Duration' field on the Create and Edit Site Visit screen will be hidden. Site Users accessing the Site Visit screen can no longer see this field.	No	Yes	Minor	Affected Users: Site Users. Impact: This improvement has a minor impact on the Create and Edit Site Visit screen.



B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
-	-	-	-	-



10. Open Defects

MyTI 2.1 has been released with these known issues. This table uses the following definitions of severity:

- 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
TIMO- 6421	МуТІ	MyTI users encountered an issue where they could not log in using biometric authentication. An error appeared on the login page when attempting to use biometrics for login.	Minor	Affected Users: All users Impact: This bug has a minor impact on the login process using biometric authentication.
TIMO- 6422	МуТІ	The Document View screen displayed an error when MyTI users attempted to open a PDF document from the Docs tab in a TI room.	Minor	Affected Users: All users Impact: This bug has a minor impact on opening and viewing a PDF document from the Docs tab of a TI room.



11. Customer Support

A. REPORTING ISSUES WITH THE RELEASE

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

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

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







Email

Business Hours

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



B. REQUESTING FUTURE ENHANCEMENTS

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



Project Manager

(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:	Title:	
Signature:		
Reason for signature:		
Date:		

Quality Assurance

Name:	Title:
Signature:	
Reason for signature:	
Date:	