

MYTI V 2.2 – RELEASE NOTES

Version 1.0



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1. Version History

| Author | Revision # | Date | Comment |
|-------------|------------|-------------|---|
| Salil Joshi | 0.1 | 21-Feb-2025 | Pre-Release Notes issued. |
| Salil Joshi | 0.2 | 10-Apr-2025 | <p>The following updates have been made:</p> <p><u>Improvements/Enhancements</u></p> <ul style="list-style-type: none"> Added <ul style="list-style-type: none"> MYTI-268 MYTI-269 MYTI-270 MYTI-271 Removed <ul style="list-style-type: none"> MYTI-261 (Refer to Section 6. Release Overview) MYTI-245 MyTI-199 <p><u>Defect Resolutions</u></p> <ul style="list-style-type: none"> Added <ul style="list-style-type: none"> TIMO-6539 TIMO-6599 TIMO-6600 <p><u>Updated Feature Descriptions</u></p> <ul style="list-style-type: none"> MYTI-264 MYTI-270 |
| Salil Joshi | 1.0 | 11-Apr-2025 | Initial version finalized. |

2. Purpose

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



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

3. Scope

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

| System In Scope | |
|-----------------|-------|
| System Name | myTI |
| System Version | v2.2 |
| 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 | 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

Trial Interactive's application 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. CYBER SECURITY TESTING ENHANCEMENTS

MYTI-261 - The application's security is enhanced to ensure compliance with security standards by addressing minor findings identified during cybersecurity testing. These enhancements ensure application security and compliance with industry security regulations providing users with a reliable experience.

This is considered a backend application improvement, that updated security configuration settings. Accordingly the change is not represented in the table below (Section 9.0 Changes).

B. EDITABLE INDEX POSITION FIELD

MYTI-262 - myTI users can adjust the index position of an existing document from the Document View screen. The Index Position field is now editable, allowing documents to be moved to a different folder, while maintaining security i.e., If a user lacks permission to move a document across folders, a clear error alert will be displayed. This enhancement provides users a greater flexibility in managing their documents and placeholders ensuring a smooth workflow and improved user experience.

C. AUTO LOGOUT

MYTI-263 – The Auto Logout feature enhances session security by automatically logging users out after periods of inactivity or multiple failed login attempts ensuring security and a seamless user experience.

Key Enhancements

- Users are automatically logged out after a period of inactivity, with a clear notification being displayed.
- Entering incorrect credentials during document submission or the eSignature process triggers automatic logout, with a notification.
- Users attempting to manually eSign a course with invalid credentials in GlobalLearn will be logged out.
- In CTMS, users receive a timely notification before automatic logout.

D. MOBILE FRIENDLY DOCUMENT AND VIDEO VIEWER

MYTI-264 – The Document and Video Viewer has been enhanced to offer a mobile-friendly viewing experience on both Android and iOS devices During course sessions, documents will now automatically display in full-screen mode when in landscape orientation, providing a user-friendly experience.

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 | 11-Apr-2025 |
| Estimated Availability for App Store and Google Play Store Date/Time: | 11/Apr/2025 5:00 PM |
| Date of Dedicated Client Upgrade: | For information about upgrading your dedicated instance to this new version, please contact your TransPerfect Customer Success Manager. |

8. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the myTI v2.2 platform.

| System Requirements | |
|-----------------------------------|---|
| iOS | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 v2.1 and higher. |
| Global Learn | GlobalLearn v2.5.1 and higher. |

9. Changes

Legend for Impacts

myTI v2.2 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)
- Collaborate
- GlobalLearn
- Mobile Trial Interactive (myTI)

A. NEW/ENHANCED FEATURES

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact | Comment / Impact Analysis |
|------------|-------------------|--|----------------|---------------------|--------|---|
| MYTI- 262 | myTI | myTI users can now change the index position of an existing document within the application. The Index Position field is now editable in the Document View screen, allowing users to move documents to a different folder. If a user does not have permission to move a document across folders, an error alert will be displayed. | No | Yes | MINOR | <p>Affected Users: All Users</p> <p>Impact: This enhancement has a minor impact on modifying the metadata fields of an existing document.</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact | Comment / Impact Analysis |
|------------|-------------------|--|----------------|---------------------|--------|---|
| MYTI- 263 | myTI | <p>The latest release of myTI introduces improvements the Auto Logout feature. Users will now be automatically logged out of the application in case of inactivity or if incorrect credentials are entered for a specific number of times.</p> <p>Key Features</p> <ul style="list-style-type: none"> • Users are automatically logged out due to inactivity, with a proper notification being displayed. • When entering incorrect credentials during document submission or the eSignature process, users are automatically logged out, and a relevant notification is shown. • For GlobalLearn courses, users are logged out if invalid credentials are entered while eSigning a course manually • In CTMS, users receive a timeout notification before being automatically logged out. | No | Yes | MINOR | <p>Affected Users: All Users</p> <p>Impact: This feature has a minor impact on the process of automatically signing out of the application across various modules integrated with myTI.</p> |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact | Comment / Impact Analysis |
|------------|-------------------|---|----------------|---------------------|--------|--|
| MYTI- 264 | myTI | The latest enhancement now makes the Document and Video viewer mobile-friendly while taking a course on Android and iOS devices. This enhancement now displays documents in full-screen mode when viewed in landscape orientation. | No | Yes | MINOR | Affected Users: All Users Impact: This improvement has a minor impact on the mobile and document viewer ensuring documents and videos are displayed in full-screen mode when viewed in landscape orientation. |
| MYTI-268 | myTI | The myTI application now has the option to view the eTMF Health Dashboard directly within the application. The dashboard displays the relevant eTMF information on a single screen. Each field within the dashboard dashlet supports drill-down, allowing users to access more information. | No | Yes | MINOR | Affected Users: All Users Impact: The inclusion of the eTMF Health Dashboard in the application ensures uniform data presentation and user experience maintaining consistent dashboard data between the myTI application and the web version. |
| MYTI-269 | myTI | The latest improvement to the myTI application removes the 'Index Position' field when rapid scan is enabled. | No | Yes | MINOR | Affected Users: All Users Impact: This improvement has a minor impact on updating the 'Index Position' metadata field when rapid scan is enabled. |

| Feature ID | Offering Impacted | Description | Config Change? | Enabled by Default? | Impact | Comment / Impact Analysis |
|------------|-------------------|---|----------------|---------------------|--------|--|
| MYTI-270 | myTI | <p>With the latest enhancement, the 'Document Submission' popup maintains its portrait orientation even if landscape mode is on.</p> <p>This enhancement ensures a consistent and optimal display of the popup regardless of the device orientation.</p> | No | Yes | MINOR | <p>Affected Users: All Users</p> <p>Impact: This improvement has a minor impact on the display of 'Document Submission' popup in the myTI application.</p> |
| MYTI -271 | myTI | <p>With the latest enhancement, myTI users can now view and upload files in the following formats including:</p> <ul style="list-style-type: none"> • . docs • . xlsx • . jpg • . png • . heic • . bmp • . gif • . psd <p>This enhancement increases flexibility allowing users to work with different file formats within the application.</p> | No | Yes | MINOR | <p>Affected Users: All Users</p> <p>Impact: This improvement has a minor impact on the display of file types that can be added from the device.</p> |

B. DEFECT RESOLUTIONS

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|-----------------|----------------------|---|----------|---|
| TIMO-6421 | myTI | myTI users encountered an issue where they could not log in using biometric authentication if Multi-Factor Authentication (MFA) was enabled. An error appeared on the login page when attempting to use biometrics for login. | Minor | This bug had a minor impact on signing into the myTI application via biometrics if MFA is enabled. The resolution ensures that users can sign in to the application via biometrics even also if MFA is enabled. |
| TIMO-6458 | myTI | Users accessing the myTI application using SSO observed that the 'Set Password' option in the 'My Profile' section is grayed out but remains clickable. | Major | This bug has a major impact on the 'My Profile' section within the application. The resolution restores the correct system behavior ensuring the 'Set Password' option is fully disabled and non-clickable for SSO users. |
| TIMO-6539 | myTI | Clicking the 'View All' button of the 'Favorite Documents' section within the Site Dashboard, displayed a white screen. | Critical | This bug has a critical impact on the 'Site Dashboard'. The resolution ensures that the 'Favorite Document' screen opens to display all the documents marked as favorites by the users after clicking on the 'View All' button. |
| TIMO-6599 | myTI | The myTI application crashed when users attempted to submit a document by selecting the 'Send a Certified Copy' option. | Critical | This bug had a critical impact on the submitting a document by a certified submission. The resolution ensures that the document submission popup is displayed when users submit a document by a certified submission. |
| TIMO-6600 | myTI | When users attempt to scan a document, a black screen appears instead of the live camera image. | Critical | This bug had a critical impact on the myTI home page. The resolution ensures that a live camera image is displayed when users select +Add > Scan on the myTI home page. |

10. Open Defects

myTI v2.2 is being released with no open defects to report that impair the functionality for the end-user.

11. Customer Support

A. REPORTING ISSUES WITH THE RELEASE

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

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

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



Phone



Email



Business Hours

| | | |
|---|--|---|
| US: 888-391-5111 (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:



Customer Success Manager (CSM)

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



Customer Experience Program (CEP)

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 |
| Signature: Reason for signature: Date: | |

Quality Assurance

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