

MYTI V2.3 - RELEASE NOTES VERSION - 1.0







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Version History

Author	Revision #	Date	Comment
Janki Prajapati	0.1	26-Sep-2025	Pre-Release Notes issued
Janki Prajapati	0.2	24-Oct-2025	Feature Removed: • MYTI-278
Janki Prajapati	1.0	07-Nov-2025	Feature Added: MYTI-278 Feature Removed: MYTI-267 Added: Defect Resolutions & Open Defect Tables 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: **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 computerised system:

System In Scope					
System Name	myTI				
System Version	2.3				
Release Type	Minor				



Definitions / Acronyms 4.

Term	Definition/Description			
21 CFR	The part of the United States Code of Federal Regulations that regulates			
Part 11	electronic records and electronic signatures.			
Annex 11	The European Union's guidance for using electronic records and signatures in the			
Allilex 11	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.			
IAM	Identity and Access Management			
IDP	Identity Provider			
JIRA	A proprietary issue tracking product, developed by Atlassian, used for bug			
	tracking, issue tracking, and project management			
KPI	Key Performance Indicator			
LMS	Learning Management System			
MFA	Multi-Factor Authentication			
ООТВ	Out of the Box			
sFTP	Secure File Transfer Protocol			
SLA	Service Level Agreement			
SOP	Standard Operating Procedure			
SQA	Software Quality Assurance			
SSO	Single Sign On			
SSU	Study Start-Up			
Testiny	A web-based test management software that facilitates software quality			
	assurance; it produces reports on a release candidate and documents the nature			
	and category of bugs			
TI	Trial Interactive			
TP	TransPerfect			



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 Al 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 'myTl' is a fully-featured mobile app for the Trial Interactive platform that supports iOS and Android devices across all Tl 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 myTl 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. REFRESHED ICONS AND IMPROVED INDEX FIELD PLACEMENT

MYTI-259 - The application interface has been updated with refreshed icons and an improved placement of the Index field to deliver a more intuitive user experience.

Key Features:

- **Updated Icons:** Icons for adding documents, placeholders, and the Index field have been redesigned to reflect a modern, consistent look.
- Repositioned Index Field: The Index field remains accessible on the same screen but has been moved to a more prominent location for faster access.
- UI Improvements: These enhancements streamline navigation and usability, ensuring a smoother and more user-friendly interface.

B. IN-APP NOTIFICATION FUNCTION

MYTI-273 – The In-App Notifications function introduces a streamlined way for users to stay informed of activities within their eTMF room.

The notification flow is designed to be intuitive and non-disruptive. Once a user enters a room, the notification bell becomes available, and a red indicator highlights new activity. Notifications are always contextual to the room the user is in, and they can be clicked to complete assigned tasks. After interaction, the notification automatically disappears from the Notification Center, maintaining a clean and focused view.

Key Enhancements:

- Real-time visibility of workflow-related activities, eSignature approvals, and document queries.
- Notifications are room-specific, reducing unnecessary noise and improving relevance.
- One-click access to complete tasks directly from the notification.
- Automatic dismissal of notifications once accessed, supporting a clutter-free experience.

C. ETMF HEALTH COMPLETENESS – UPLOAD

MYTI-274 - The eTMF Health Dashboard has been enhanced with direct upload functionality for missing and overdue documents.

Key Features:

- **Prioritized Overdue Items:** Overdue documents are automatically displayed at the top of the dashboard, helping users identify and act on critical gaps quickly.
- **Direct Upload Action:** Users can now upload documents directly from the eTMF Health Dashboard whenever an item is flagged as missing.
- Clear Call-to-Action: Missing documents include a visible and actionable upload option, minimizing delays and improving efficiency.
- Additional Entry Point: The dashboard now serves as an extra channel for uploading documents, ensuring eTMF timeliness and compliance.

D. NOTIFICATION BELL ICON FOR ROOM LEVEL ACTIVITY

MYTI-278 - A Notification Bell icon has been added at the room level, allowing users to view and temporarily store notification activity directly within the room.

E. MY PROFILE - ABILITY TO ENABLE NOTIFICATIONS

MYTI-279 – This feature has been enhanced to allow users to enable or disable the setting for receiving In-App Notification.

F. PRIORITY VIEW FOR OVERDUE DOCUMENT IN UNFULFILLED TAB

MYTI-280 - The eTMF Health dashboard has been enhanced to prioritize overdue documents within the Unfulfilled tab, improving visibility and actionability.

Key Features:

- Overdue Document Prioritization: All overdue documents are automatically displayed at the top of the Unfulfilled tab by default, allowing users to take immediate action.
- **Visual Indicators:** Overdue documents are display with a red warning icon, while Submitted or Missing states continue to be shown with clear status labels.

G. OVERDUE DOCUMENT COUNTER DISPALYED IN THE ETMF HEALTH DASHBOARD BAR

MYTI-281 - The eTMF Health dashboard has been enhanced with a dedicated counter that track overdue documents, which are now displayed prominently in the progress bar.

H. ETMF HEALTH DASHBOARD: DOCUMENT STATUS LABLES

MYTI-282 - The eTMF Health dashboard has been enhanced with document status labels.

Key Features:

- **Direct Upload Action:** When a document is marked as **Missing**, users see a clear call-to-action on the dashboard that allows them to upload it immediately.
- Status Labels for Clarity: Each document is assigned a clear status label:
 - Missing
 - Submitted
 - Overdue (highlighted with a red icon).

I. ETMF HEALTH ADDED FILTERS

MYTI-284 - The eTMF Health Dashboard has been enhanced with additional filtering options, users can now sort and filter records by Title, Completeness Status, and Document Type, allowing users to quickly locate and analyze relevant information.



J. DOCUMENT STATUS TRACKING IN ETMF VIEW

MYTI-285 - This feature introduces fulfillment status that separate documents into Fulfilled and Unfulfilled categories, along with clear sorting options for easier navigation. Each document is also tagged with a status label i.e., Missing, Submitted, or Overdue etc., with overdue items highlighted by a red warning icon.

Key Enhancements:

- Fulfillment Tabs: Separate views for Fulfilled and Unfulfilled documents with counts for each.
- **Document Status Labels:** Clear status indicators (Missing, Submitted, Overdue) with visual red warning icons for overdue items.
- Sorting and Navigation: Simplified document sorting for quicker access.
- Due Dates and Metadata: Due dates and document type/category displayed under each document.
- Visual Indicators: Overdue and missing documents highlighted for immediate visibility.



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 timezones are in ET)						
Date of Release	07-Nov-2025					
Estimated Availability for App Store and Google Play Store Date/Time:	07/Nov/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 myTl v2.3 platform.

	System Requirements						
 Operating System 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 v2.1 and higher.						
Global Learn	GlobalLearn v2.5.1 and higher.						



9. Changes

Legend for Impacts

myTl v2.3 has been released with these enhanced features and defect fixes. These tables use the following definitions of customer Impact:

- Blocker: A Blocker defect refers to a critical issues that completely prevents further progress in development or testing.
- Critical: A core functionality returns invalid results or does not function as expected.
- Major: This Defect has an impact on basic functionality.
- Minor: There may be a small impact on business in specific use cases.

Legend for Offering/Room Types

- Electronic Trial Master File (eTMF)
- Clinical Trial Management System (CTMS)
- Collaborate
- GlobalLearn
- Mobile Trial Interactive (myTl)

A. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-25) myTl	This UI-only update modernizes the Document view in the Index. Icons for Add Document, Add Placeholder, and Index have been refreshed for clarity and moved to the page header for easier access, previously, these actions were hidden. The Index field stays on the same screen but it is moved to a more visible, easy-to-reach position for faster access.	No	Yes	Minor	Affected Users: Manager Impact: This enhancement has an minor impact on the user interface of document view in the index.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-278	eTMF	This User Interface enhancement introduces a Notification Bell icon at the room level, providing users with a centralized location to view important updates and actions.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has a minor impact on bell icon, when the system prompt the notification.
MYTI-273	myTI	This feature introduces in-app notifications for eTMF rooms. After a user selects a room, a bell icon appears in the header; a red badge indicates new items. The Notification Center shows only roomspecific notifications. Selecting a notification opens the related screen to complete the task, and the notification is dismissed immediately on click. Key features: User assigned to a workflow step User assigned an eSignature approval for a document. Query issued on a document where the user is the owner.	No	Yes	Major	Affected Users: All Users Impact: This enhancement has a major impact on app notifications for eTMF room.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-274	myTI	The eTMF Health Dashboard is now actionable for completeness. It surfaces missing and overdue documents across studies, with overdue items pre-filtered to the top. Key features: Shows missing and overdue documents for a user's studies. Overdue items appear first by default (pre-filtered) for immediate action. Upload call-to-action appears on Missing items; upload directly from the dashboard. Dashboard serves as an additional entry point for uploads; status updates after upload. Respects existing permissions, validations, auto-filing, and audit trail.	No	Yes	Minor	Affected Users: Editor Impact: This enhancement has a minor impact on eTMF Health Dashboard.
MYTI-279	eTMF	This improvement now provides the ability to a user to enable or disable the notifications setting with in the app settings.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has a minor impact on the user's ability to configure the notifications.

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-280	eTMF	This feature ensures that overdue documents are automatically displayed at the top of the list within the Unfulfilled tab. By prioritizing overdue items, users can take immediate action without needing to filter or manually search. Clear visual indicators highlight overdue documents with a red warning icon, while submitted or missing documents are shown with distinct labels.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has a minor impact on the unfulfilled tab.
MYTI-281	myTI	This feature introduces an overdue documents counter in the eTMF Health Dashboard progress bar. Users can now see the total count of overdue documents directly in the dashboard, providing clear visibility into pending actions and improving tracking of document compliance.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has an minor impact on eTMF Health Dashboard progress bar.
MYTI-282	myTI	This feature introduces document status labels in the eTMF Health dashboard, allowing users to quickly identify documents as Missing, Submitted, or Overdue (with a red icon indicator). When a document is marked as missing, users are now provided with a clear call-to-action to upload it directly from the dashboard, ensuring faster resolution and improved document management.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has an impact on eTMF Health dashboard, with Missing, Submitted, or Overdue documents



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-283	myTI	This enhancement introduces support for viewing document icons in landscape mode, providing a consistent and improved user experience across device orientations. Users can now access and interact with document icons seamlessly whether in portrait or landscape mode.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has an minor impact on the Orientation mode.
MYTI-284	myTI	This feature introduces new filtering options in the eTMF Health dashboard, allowing users to sort and filter records by Title, Completeness Status, and Document Type. These filters improve navigation and make it easier to locate and analyze documents within the health dashboard.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has an impact on the eTMF Health dashboard to short and filter the records.
MYTI-285	myTI	This feature introduces enhanced document status tracking in the Trial View, allowing users to quickly identify fulfilled, unfulfilled, missing, submitted, or overdue documents directly from the mobile application. Users can also view due dates, sort documents, and access clear metadata and visual indicators for improved navigation and compliance tracking.	No	Yes	Minor	Affected Users: Site User Impact: This enhancement has an impact on Document status tracking in eTMF view.
MYTI-286	myTI	This update ensures compliance with Google Play requirements by raising the target API level for Android. This change provides users with a safer and more secure app experience.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has a impacts on the targeted level API for Android.



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
MYTI-287	myTI	This improvement supports updates introduced with IAM 1.1 to ensure compatibility and enhanced functionality within myTl. It covers validation of authentication flows and alignment with related changes in the IAM portal. Key Features: Validation of SSO login flows. Biometric and manual login tracking. Review of related IAM portal changes. Expanded and updated test coverage.	Yes	Yes	Minor	Affected Users: : All Users Impact: This enhancement has an minor impact on login and authentication processes.
MYTI-288	myTI	This improvement adds support for edge- to-edge layout on Android, ensuring compatibility as Android 16 enforces this behavior With edge-to-edge, the UI spans the full display, drawing behind system bars for a modern, immersive experience. Key Features: • Full-screen rendering across the entire display. • Proper handling to avoid UI breakage when system bars overlap. • Compliance with Android 16 enforcement of edge-to-edge.	No	Yes	Minor	Affected Users: All Users Impact: This enhancement has an impact on the overall rendering of the Android User-interface .



B. DEFECT RESOLUTIONS

Ti	cket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
	ГІМО- 6826	myTI	The myTl home page did not display the CTMS Study section when users logged in to the application.	Blocker	This bug impacted the visibility of CTMS studies within the application. The resolution now displays the studies sections with studies the user is associated with.



10. Open Defects

myTl v2.3 has been released with these known issues. This table uses the following definitions of severity:

- Blocker: A Blocker defect refers to a critical issues that completely prevents further progress in development or testing.
- Critical: A core functionality returns invalid results or does not function as expected.
- Major: This Defect has an impact on basic functionality.
- Minor: There may be a small impact on business in specific use cases.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-6829	myTI	An incorrect error message is displayed when viewing a document with Redaction (RDC) enabled but without an image. Instead of showing the 'No Image for Document' message with the image preview, an error message appears.	Minor	This bug has a minor visual impact on the document view screen for RDC-enabled documents without images. Correct system behavior will be restored by displaying the preview image.
TIMO-6885	myTI Users reorder images in the Document Preview screen and save the changes, the updated sequence is not reflected correctly. The documents appear in an incorrect order after reordering.		Minor	This bug has a minor impact on the document display sequence during document preview. Correct system behavior will be restored by applying the order of the Docs that are reordered.
TIMO-6888 myTl Swipe back gesture is not functioning correctly on certain screens in the iOS Emulator. When attempting to swipe right to navigate back, no action occurs and the Company code screen is displayed.		Minor	This bug has a minor usability impact on navigation within the iOS Emulator. Correct system behavior will be restored by returning back to the login screen.	



Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TIMO-7027	myTI	The progress bar value in the Visit Checklist screen blinks, when the device orientation is changed to landscape. The same behavior is observed for questions with the <i>Scale</i> type in the Visit Checklist section.	Minor	This bug has a minor visual impact on the Visit Checklist interface. Correct system behavior will be restored and the progress bar value does not blink.
TIMO-7072	The fields are displayed while the letter/report is generating in the Confirmation Letter screen. During the generation process, field elements appear on the screen instead of only showing the loading animation.		Minor	This bug has a minor visual impact on the Confirmation Letter generation process. Correct system behavior will be restored by displaying only animation.
TIMO-7225	myTI	The See more button in the <i>Add Response</i> view is cropped when the user who sent the query has a long email address, making it partially hidden on the screen.	Minor	This bug has a minor visual impact on the <i>Query</i> interface. Correct system behavior will be restored by displaying 'See More' button.



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:





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)



Customer Focus Group

Your CSM can submit Ideas to our Perfective Change Management on your behalf Meet with other Trial Interactive customers for an immersive Focus Group Forum:

- Focus Group Q&A
- Early Access
- Hosted Beta
- Usability Studies

12. Approvals

Product Owner

Name: Anuj Thapar	Title: Senior Product Manager	
Signature:		
Reason for signature:		
Date:		

Quality Assurance

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