

TRIAL INTERACTIVE GLOBAL LEARN V2.3 –RELEASE NOTES – VERSION 1.1





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2. Version History

| Author | Revision # | Date | Comment |
|----------------|------------|-------------|---|
| Yogesh Inamdar | 0.1 | 13-Feb-2023 | Initial Document Creation |
| Yogesh Inamdar | 0.2 | 21-Feb-2023 | Added 'Defects Resolutions 'section |
| Yogesh Inamdar | 0.3 | 08-Mar-2023 | Removed: TILMS-5183, TILMS-3600, TILMS-3460 |
| Yogesh Inamdar | 1.0 | 09-Mar-2023 | Initial version finalized. |
| Yogesh Inamdar | 1.1 | 08-Sep-2023 | Added the following TILMS-5230 |

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 in evaluating 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 Global Learn |
| System Version | 2.3 |
| Release Type | Minor |

5. Definitions / Acronyms

| Term | Definition/Description |
|----------|--|
| CFR | Code of Federal Regulations |
| CRO | Contract Research Organization |
| CTMS | Clinical Trial Management System |
| ER/ES | Electronic Record / Electronic Signature |
| (e)TMF | (Electronic) Trial Master File |
| GL | Global Learn |
| iOS | Apple device Operating System |
| KPI | Key Performance Indicator |
| JIRA | A proprietary issue-tracking product developed by Atlassian, used for bug tracking, issue tracking, and project management |
| MTI | Multi-tenant Instance |
| SaaS | Software as a Service |
| 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 |
| TP | TransPerfect |
| TI | Trial Interactive |

6. System Overview

A. GLOBAL LEARN

Trial Interactive’s [Global Learn](#) is a compliance-focused learning management system that enables sponsors, CROs, and sites to experience exponential savings in study training logistics with compliance learning integrated with TI eTMF and clinical content collaboration solutions. The integrated experience creates a seamless flow from clinical document authoring, review, and approval to training delivery to archival in the eTMF. Key features:

- A single access point for a single view of compliance assurance.
- With the “My Transcript” feature, Global Learn users have a consolidated view of their complete training history, including reported external training outside of Global Learn.
- Visual dashboards help with quick insights. Learners can monitor their progress while managers benefit from a single view of learning compliance.
- Rather than enrolling staff in one course at a time, assign an entire collection of training specific to a defined training group.
- A fully hosted solution that is 21 CFR Part 11, ERES, and GxP compliant.

Global Learn can help your organization:

- Track and manage live, in-person, and virtual training course for blending training
- Get better insight into compliance and make actionable decisions through Visual Dashboards
- Designate due dates for each course (with training completion reminders) so learners move progressively through their training and have it completed in an appropriate timeframe
- Maintain a consolidated view of the complete training history, including reported external training outside of Global Learn
- Streamline compliance training processes and reduce costs

Global Learn supports core regulatory requirements, including:

- Comprehensive audit trails
- Record protection and their accurate and ready retrieval
- Security by design (including unique login credentials and levels of access)
- Course archival options

7. Release Overview

This is a Minor release introducing minor, low-impact improvements and defect resolutions included.

A. CLASSROOM TRAINING

Classroom training is synchronous training given to any learner outside the learning management system. A site classroom training example is the site initiation visit (SIV) which may include in-person training by the site monitor or CRA that site staff or site personnel either self-register for available sessions or are registered for sessions by the site monitor, CRA, or some other sponsor staff member or training administrator.

An example of classroom training may be as follows:

- Physicians need to be trained in person at a site or some other location on a medical device procedure prior to performing the said procedure or other research-related activities

Evidence of training is typically captured via an attendance log or sign-in sheet signed by the learner after completing the training.

B. EXTERNAL TRAINING

External trainings are synchronous trainings given to any learner outside the learning management system.

A site external training example is the site initiation visit (SIV) which may include in-person trainings, a site monitor, or CRA. Some examples or scenarios of these trainings are as follows:

- During an SIV, a site monitor notices the site isn't compliant with GDP and provides an ad hoc training overview to site personnel.
- Another scenario is a physician that is trained in person at a site or some other location on a medical device procedure prior to performing said procedure

Evidence of training is typically captured via an attendance log or sign-in sheet signed by the learner after completing the training.

The same site external training may also occur subsequently for other site personnel later.

8. 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 | |
|--|--|
| Date of Release | 10-Mar-2023 |
| Estimated US MTI Upgrade Date/Time: | 10-Mar-2023 |
| Estimated EU MTI Upgrade Date/Time: | N/A |
| 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 Trial Interactive Global Learn v2.3 system.

| System Requirements | |
|-------------------------|--|
| Operating System | <ul style="list-style-type: none"> Windows Version 7 or higher All currently supported Mac OSX releases iOS and Android for myTI mobile app (see myTI release notes) |
| Browser | <ul style="list-style-type: none"> Microsoft Edge: Version 88 and later Google Chrome: Current release and earlier Mozilla Firefox: Current and ESR releases Apple Safari: Current release and earlier NOTE: TI Digital Sign through MSB requires that pop-up blockers are disabled for the Trial Interactive domain. NOTE: Microsoft® concluded support of Internet Explorer™ 11 in January 2022. Internet Explorer™ 11 is no longer supported in 10.4. |
| Client Software | <ul style="list-style-type: none"> For full support when online editing, Microsoft Office 2016 or higher (Office 365 is preferred) is required when editing locally. For MS Word document generation, online editing is recommended, and all templates must be minimally created using Microsoft Office 2016 (Office 365 is preferred). Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. Optional: Drag and Drop from Outlook to Trial Interactive is supported on Windows 10® for Chrome® and Edge® browsers. A plug-in is available for support of this feature on Internet Explorer® and Firefox®. |
| Optional Add-Ons | <ul style="list-style-type: none"> DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) Adobe Sign (Latest Adobe Document Cloud Version) Optional: For SAS Datasets, SAS Viewer or compatible software must be installed. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74 |

10. Changes

Trial Interactive Global Learn v2.3 has been released with these enhancements, features, and defect fixes. This table uses 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.
- Medium - There may be a small impact on business in specific use cases, but it must be enabled before configuration.
- Minor - There may be a small impact on business in specific use cases.

A. NEW/ENHANCED FEATURE

| Feature ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|------------|-------------------|--|--------|---|
| GL-793 | Global Learn | <p>Course Creator level users can now:</p> <ul style="list-style-type: none"> - Enter standard data for course creation fields - Click on created face-to-face eLearning activity after going through the course creation wizard - Create single/multiple sessions for classroom training events within courses they create; select which sessions are required or optional via self-booking - Configure classroom training event completion criteria - Enroll learners in a classroom training course as a pool of potential attendees for classroom training - Mark learner attendance and view/export attendance data of their learners/training groups per session <p>Learner-level users can now:</p> <ul style="list-style-type: none"> - View corresponding classroom training courses from the 'My Courses' Dashlet if enrolled directly in respective trainings and sessions - View multiple sessions and register themselves via the enabled 'self-register' option - See only those sessions that were previously enrolled by the Course creator without self-registration | MINOR | This feature enhances classroom training and course management. This impacts all users. |

| | | | | |
|--------|--------------|---|-------|--|
| GL-794 | Global Learn | <p>Course creators can now utilize the course creation wizard to enter external training data for training outside of the LMS.</p> <p>Choose the date of the learner’s training and map single or multiple learners to the added external training evidence document.</p> <p>You have the option of selecting evidence of external training methods like self-upload by learner, eSign, or upload.</p> <p>After this is done, course creators will be able to view a summary of the mapping of learners and evidence of training for selected methods.</p> <p>Additionally, there is the capability to send an email notification when eSign is selected as evidence of an external training method.</p> <p>External Training documents, when self-upload by the learner, require the course creator or training administrator to approve the submitted document. In this release, we have introduced Document Approval Workflow as part of this external training improvement.</p> <p>My Transcripts External Training has also been improved. All trainings with the external training attribute are listed on this page, i.e., external training courses with associated evidence of external training OR evidence documents for external trainings not tied to a course. Documents added without an associated course must also go through the Document Approval Workflow that a user with the right person approves to confirm that the submitted document is sufficient evidence of training.</p> | MINOR | This feature enhances external training and course management. This impacts all users. |
|--------|--------------|---|-------|--|

B. DEFECT RESOLUTIONS

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|---|--------|--|
| TILMS-4195 | Global Learn | A learner-level user sees a disturbed user interface when he tries to eSign a course he is enrolled in and completed. | MINOR | Learners. This bug has a minor impact on the system user interface; the resolution resets the correct. |
| TILMS-4170 | Global Learn | No users match if a company admin enters the name with space on the Manage group users page. | MINOR | Company Admins. This bug has a minor impact on the system user experience; the resolution resets the correct system behavior. |
| TILMS-4096 | Global Learn | Email notifications about re-enrollment in recurring courses and refresher courses are not sent | MINOR | Learners. This bug has a minor impact on the system email notifications; the resolution resets the correct email communications. |
| TILMS-4030 | Global Learn | The course creators experienced erroneous system behavior as the topic was not getting marked | MINOR | Course Creators. This bug has a minor impact on the course creation module. The resolution resets the correct system behavior. |
| TILMS-3948 | Global Learn | Username and password fields get outstepped on the eSign pop-up when a user tries to eSign a course. | MINOR | All Users. This bug has a minor impact on the system user interface; the resolution resets the correct. |
| TILMS-3902 | Global Learn | After deleting the same role, a learner-level user is displayed as a Site Coordinator. | MINOR | Learners. This bug has a minor impact on user management. The resolution resets the correct system behavior. |

| Ticket(s) ID | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------------|-------------------|--|--------|---|
| TILMS-3834 | Global Learn | A Site Coordinator level user can see the My Direct Reports and Course Management page even after the site is deleted he is associated to. | MINOR | All Users. This bug has a minor impact on user management and system settings. The resolution resets the correct system behavior. |
| TILMS-3278 | Global Learn | The 'X' button overlaps the Due option on the 'Create Single Course' pop-up screen when a Company Admin level user tries to create a course from the Content Library within the Company Dashboard. | MINOR | All Users. This bug has a minor impact on the system user interface; the resolution resets the correct. |
| TILMS-5230 | Global Learn | Group owner/site coordinator receives certificates of completed but not esigned courses for group/ site users. | MINOR | Group owners. This bug has a minor impact on course management. The resolution resets the correct certificate communications. |

11. Open Defects

Global Learn v2.3 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 | Offering Impacted | Description | Impact | Comment / Impact Analysis |
|--------|-------------------|-------------|--------|------------------------------|
| N/A | N/A | N/A | N/A | N/A |

12. 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.

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)

Your PM 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

13. Approvals

Quality Assurance

| | |
|--|-------------------------------------|
| Name: Conor McCabe | Title: Quality Assurance Specialist |
| Signature: Reason for signature: Date: | |