

# TRIAL INTERACTIVE V10.5.3 - PATCH-RELEASE NOTES - VERSION 1.0





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## 2. Version History

| Author        | Revision # | Date        | Comment  |
|---------------|------------|-------------|--|
| Samuel Pawar  | 0.1        | 09-Apr-2024 | Initial Document Creation  |
| Samuel Pawar  | 0.2        | 12-Apr-2024 | <p>Added the following:</p> <ul style="list-style-type: none"><li>• TTI-3647</li><li>• TTI-3659</li><li>• TTI-3660</li><li>• TTI-3663</li><li>• TTI-3664</li><li>• TTI-3666</li><li>• REPORT-117</li><li>• TRL-8297</li><li>• TRL-13943</li><li>• TRL-14159</li><li>• TRL-14547</li></ul> <p>Removed the following:</p> <ul style="list-style-type: none"><li>• TTI-3398</li><li>• TTI-3623</li><li>• TTI-3648</li></ul> |
| Anuj Thapar   | 0.3        | 19-Apr-2024 | Removed<br>TTI-3550<br>TTI-3664  |
| Steven Clarke | 1.0        | 19-Apr-2024 | Initial version finalized.   |



### 3. Purpose

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



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



## 4. Scope

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

| System In Scope |                   |
|-----------------|-------------------|
| System Name     | Trial Interactive |
| System Version  | 10.5.3            |
| Release Type    | Patch             |



## 5. Definitions / Acronyms

| Term           | Definition/Description   |
|----------------|--|
| SQA            | Software Quality Assurance   |
| TP             | TransPerfect   |
| TI             | Trial Interactive  |
| 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   |
| 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.   |
| eTMF           | Electronic Trial Master File   |
| KPI            | Key Performance Indicator  |
| CTMS           | Clinical Trial Management System   |
| OOTB           | Out of the Box   |
| sFTP           | A secure File Transfer Protocol  |
| SLA            | Service Level Agreement  |
| SOP            | Standard Operating Procedure   |
| SSU            | Study Start-Up   |
| SAAS           | Software as a Service  |



## 6. 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.

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## B. TRIAL INTERACTIVE - ETMF

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

- Ensure quality with the ability to have a customized workflow for indexing and approval powered by AI and machine learning.
- Stay current with required document lists and placeholders based on the TMF Reference Model. Placeholders and required document lists ensure that all expected and essential documents are captured in your final TMF.
- Track timeliness with KPI metrics dashboards that measure document intake from receipt to submission through QC and finalization.
- Encourage better compliance with an eTMF that tracks responsibility and actively requests documents when they are due, supporting queries for document corrections through email or upload.
- Confirm and maintain the validity of the eTMF before inspections using quality review audit capabilities to support oversight, periodic reviews, and inspection readiness.
- Ensure overall reportable eTMF Health with Key Performance Indicator (KPI) metrics, reports, and portfolio dashboards for eTMF health, timeliness, quality, and completeness.
- Plan amendments, visits, and other key trial events and milestones while creating placeholders for the expected documents that need to be collected, including due dates and responsibility to help track eTMF health and timeliness.
- Automate the classification and metadata extraction of the TMF using powerful AI auto-coding with human-aided machine learning.
- eClinical platform interoperability provides a seamless connection and data flow between the eTMF and other critical applications such as a site portal, eISF and site binders, content management, document authoring, study startup, and clinical trial management systems.





- Email and study correspondence inbox with relevance checks captures all email correspondence for each study. Once a correspondence email is sent in, it is rendered to PDF and may be selected for inclusion in a separate interface by study staff. Attachments are checked for duplicates and are linked back to the original email. Emailing documents and site correspondence securely into the eTMF ensures GCP compliance.
- Document redaction, manipulation, and certification allow selected team members to remove personal information to meet data privacy requirements and repair, split, and merge documents. Additionally, document certification helps ensure proper paper disposal.

Additional features of the Trial Interactive eTMF include:

- A mobile content capture app that supports both iOS and Android, with support for CRA reconciliation, metadata classification, query management, training, redaction, and offline mode.
- Drag and drop emails and documents to import them automatically or drop them onto placeholders for auto-assignment.
- Full query and task management capability with three types of queries for requesting, verifying, and responding via email, web, and mobile apps.
- Automatic alerts and reminders with notifications and a daily digest.
- Built-in eSignature and digital signature solution for 21 CFR Part 11 and ER/ES compliance with pre-defined signature blocks, pages, and digital certificate.
- Universal document viewer that supports and renders over 300 document formats.
- Multi-document view with built-in document comparisons, bulk editing, page rotation, deletion, reordering, and annotations.
- Global search provides cross-study search results for documents, document types, full-text, contacts, sites, and other record types, with facets, filtering, and other advanced features.
- Configurable grid filters, column selection, saved public/private views, and built-in reporting tools for ad-hoc exports.
- Standard and ad-hoc reports that support all metadata fields and the ability to add columns to standard reports or fully customize your exports.
- Completeness view showing TMF structure, final documents, planned documents/placeholders, and required documents.
- Configurable support for the latest TMF reference model with full auto-routing and auto-naming rules.
- Automatic duplicate document detection and comparison verifies that a document is unique and does not have a duplicate in the eTMF archive based on identical metadata or an exact copy or duplicate scan.



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## C. TRIAL INTERACTIVE - STUDY START-UP (SSU)

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

- Send the Regulatory Package and templates to sites with the list of required documents.
- A configurable one or two-step workflow for reviewing and approving collected required documents.
- TI Study Start-Up makes it easy to see what documents are missing and what documents need urgent attention to avoid unnecessary delays in submission and approval.
- TI Study Start-Up makes it easy to see the sites most likely to activate the fastest. Identify those sites during the process so you can make sure there are no distractions in the submission and approval process.
- Set and automatically track milestones and tasks. Ensure all study start-up processes are being managed effectively and completed on time.
- Effectively track site contracts and budgets with a dedicated section for managing them.
- Create submission packages for submission to regulatory agencies.
- Get real-time updates on package submissions for realistic estimates of site activation timelines.
- Real-time distribution of required document packages, tracking progress, IRB/EC submission, and meeting dates, providing realistic timeline projections and prediction of site activation timeframes.
- Efficiently manage protocol amendments, including tracking and sending reminder emails with just a button click.
- Robust OOTB reports for cycle time calculations, missing documents, and history of collected documents.
- Automatically create sites and site contacts for sites approved in Trial Interactive eFeasibility.
- Request for certified translated copies of documents to manage your global regulatory requirements.

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## D. COLLABORATE

Trial Interactive provides an online collaborative workspace, which enables collaborative and controlled document authoring, review, and approval. Designed to include 21 CFR Part 11 compliant workflows and approvals, the solution offers an end-to-end service platform for your organization's content management and document control requirements. These Collaborate rooms allow users to benefit from the following solutions.



- Study Collaborate and the CTMS Collaboration Rooms are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and ultimately shared with the eTMF.
- Site Collaborate/eISF and Remote Monitoring Rooms are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and ultimately send it to the eTMF.
- The Quality Document Management solution provides controlled document workflows to an organization for use by clinicians, quality assurance, R&D, and other life sciences teams to collaboratively author, review, approve, sign off on, make effective, train, and distribute regulated content and documents.

TI Collaborate can provide your organization with:

- A single place to share and collaborate on clinical documentation.
- The ability to align document work streams with regulatory compliance practices for document authoring, approval, control, and related training.
- The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation and to fully automate the training management process through the LMS.
- The ability to co-author and collaborate with other authors in real time on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.
- The ability to complete the end-to-end document process with an electronic and digital signature for document approvals.
- The ability to send documents for certified translation through TransPerfect TransPort, track their status, and receive back the translated copies and certificates.
- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.

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

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## **E. TRIAL INTERACTIVE'S CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)**

Trial Interactive's Clinical Trial Management System (CTMS) is a secure, cloud-based solution that enables the collection and management of trial-related data in a single location. TI CTMS provides the ability for clinical studies team members, such as study managers and CRAs, to plan, collaborate, and track clinical



data with specific attention to monitoring requirements. This is the industry's first CTMS with a modern user experience and a mobile-first interface. TI CTMS can help your organization:

- Provide a single source of truth for all trial-related data and information, with an intuitive planning and tracking structure,
- Track and view product, program, study, country, site, organization, contact, subject, and subject visit data in real-time,
- Ensure quality with support for adjustable, best-practice CTMS workflows that ensure completion of critical trial requirements. Reduce risk by confirming that plans are followed per SOP with controls in place to prevent issues,
- Track timeliness with KPI metrics dashboards that provide an integrated real-time view of Clinical Trial data,
- Confirm a fully updated CTMS before inspections with quality oversight, periodic reviews, and operational checks,
- Plan study-related activities such as site visits, communications, training, and other key trial Milestones with due dates and responsibilities using visit schedules and activity plan templates,
- Manage trial-related documentation with a built-in Content Management System and integrated eTMF, along with many other offerings,
- Support flexibly, company-specific workflows and SOPs with a full set of custom fields, record statuses, and field validation,
- Improve quality through standardized business practices and record-keeping,
- Provide trial insights through drill-down Study and portfolio dashboards, and,
- Streamline clinical processes to reduce costs.
- Additional features of the Trial Interactive CTMS include:
  - A mobile visit report App that supports both iOS and Android, with support for questionnaires, activity tracking, CRA Reconciliation, training, document capture, and offline mode.
  - Pre-defined, best-in-class CTMS Activity Plans for consistent trial execution and operational checks.
  - Built-in Site and IRB correspondence tracking, Email capabilities to keep close track of all back-and-forth activity.
  - Automatic Notifications, Alerts, and Reminders with emails and a daily digest.
  - Standard and Ad-hoc reports that support all custom metadata fields and the ability to add columns to standard reports or fully customize.



- Full support for clinical data integrations, including EDC, Payments, and IXRS, either directly or through a technical partner. Fields may be pulled from EDC and included in CTMS reporting.
- Well-developed classroom and lab training courses with an integrated LMS and eLearning for study and site training.
- Simpler and less administrative: Assign ownership to Studies, Sites, and Countries with central admin optional. Study and Site owners may then fully manage their record types, inviting and revoking access by start, end dates, and role.
- Track everything that is trial-related in the form of a configured set of activities with types and subtypes that may all have their own configured fields and statuses.

### Event, Activity, and Document Sharing

A Clinical Trial Management System can track all trial activities as well as the collection of documents and evidence that must ultimately be published to the eTMF. Within CTMS, site visits and all related documentation related to the visit can be finalized and seamlessly transferred to the eTMF. Ensuring study team members have immediate access to all trial-related data and site visit documentation.

CTMS 1.6, in combination with Trial Interactive 10.5, will introduce the following capabilities:

- All site visits configured in the CTMS can trigger Site Events in the eTMF. These
- Events may then trigger required documents and placeholder creation in TI.
- Visit status changes can trigger Events, Required Documents, and Placeholders
- within Trial Interactive, including eTMF rooms, Site Collaborate, and the CTMS
- Collaborative Workspace.

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## **F. TRIAL INTERACTIVE'S 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 that is 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 courses 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 patch release includes minor, low-impact improvements and defect resolutions. Please see the table below in the next section for the release schedule.

## 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                                   |  |
|--|--|
| <b>Date of Release</b>                     | 19-Apr-2024  |
| <b>Estimated US MTI Upgrade Date/Time:</b> | 19-Apr-2024 9:00 PM ET   |
| <b>Estimated EU MTI Upgrade Date/Time:</b> | 19-Apr-2024 9:00 PM CET  |
| <b>Date of Dedicated Client Upgrade:</b>   | For information about upgrading your dedicated instance to this new version, please contact your <a href="#">TransPerfect</a> Project Manager. |





## 9. Hardware and Software Requirements

The following describes the hardware and software requirements to use the Trial Interactive v10.5.3 platform.

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

## 10. Changes

Trial Interactive v10.5.3 has been released with these enhanced features. 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.
- **Minor** - There may be a small impact on business in specific use cases.

### A. NEW/ENHANCED FEATURES

| Feature ID | Offering Impacted                            | Description  | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis  |
|------------|--|--|----------------|---------------------|--------|--|
| CTMS-1482  | Trial Master File (eTMF)                     | <p>This improvement enhances the automatic room creation process by providing the users with the ability to state the study category within the study settings. These settings will allow the selection of a CCR template based on the study category.</p> <p>This enhancement helps customers who have multiple CCR master templates. The enhanced automatic room creation process helps the CTMS instance to guide the TI application for using the desired CCR master template.</p> | Yes            | No                  | MINOR  | Editor and above. This improvement has a minor impact on Study Settings.                                       |
| TTI-2916   | Collaborate (CMS), Document Management (DMS) | This improvement adds plugin functionality to the OnlyOffice document viewer, allowing users to make use of more complex document creation and maintenance tools.  | No             | Yes                 | MINOR  | Editor and above. This improvement has a minor impact on tools available while editing documents online in TI. |

| Feature ID | Offering Impacted        | Description  | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis  |
|------------|--------------------------|--|----------------|---------------------|--------|--|
| TTI-2926   | Trial Master File (eTMF) | <p>This improvement makes changes to what auditors and audit managers can do within the TI Quality Review module.</p> <ul style="list-style-type: none"> <li>Auditors and Audit Managers no longer lose access to a reviewed document once a 'final' status is awarded. Users are now able to make changes to these statuses so that a pass/fail error does not become permanent.</li> <li>An Auditor or Audit Manager, given adequate permissions, can edit metadata after saving their work as long as another user, such as an Audit Responder, has not claimed the document for review.</li> <li>When the Auditor and Audit manager make any changes to the document, a prompt message asks for the 'Reason for Change.'</li> <li>Comments from Auditors and Audit Managers are now recorded independently and can be identified as such on the audit report.</li> </ul> | No             | Yes                 | MINOR  | Editor and above. This improvement has a minor impact on the Quality Review Audit Module, allowing users more flexibility to ensure that document reviews are recorded accurately. |

| Feature ID | Offering Impacted                                   | Description   | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis   |
|------------|---|---|----------------|---------------------|--------|---|
| TTI-3249   | Platform  | <p>This improvement returns certain document functions (Delete, Copy Link, View Document Security, Add to Cart) to the three-dot document actions menu. Other functions have been added to the menu bar above the grid (Check Out, Convert to PDF, Send for Signature, Ask a Question).</p> <p>Options available to individual users depend upon access permissions and room configuration.</p>   | No             | Yes                 | MINOR  | All users depend upon access rights and room configuration. This improvement has a minor impact on the search results UI. |
| TTI-3414   | Trial Master File (eTMF), Collaborate CMS, Platform | <p>This feature brings a range of improvements to the Import Documents functionality in TI eTMF, as detailed in the list below.</p> <ul style="list-style-type: none"> <li>• The eTMF Module's import function has been updated to allow users to manually assign files to unfulfilled placeholders.</li> <li>• Users can filter the list of unfulfilled placeholders by following categories: IRB, Site, and Country.</li> <li>• When the user clicks 'Assign Placeholders,' the system will provide a list of required documents based on the assigned metadata.</li> <li>• Users can easily drag and drop the unfulfilled placeholders from the list directly into the files being imported.</li> <li>• Users have the flexibility to assign only some of the documents being imported to the 'Required Document' list.</li> </ul> | Yes            | Yes                 | MINOR  | Editor and Above. These improvements have a minor impact on the Import Document window in TI eTMF.                        |

| Feature ID | Offering Impacted        | Description  | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis   |
|------------|--------------------------|--|----------------|---------------------|--------|---|
| TTI-3573   | Trial Master File (eTMF) | With this improvement, users who set a required document placeholder as Not Applicable will be presented with an option to make the same requirement Not Applicable for all other sites in the same country.   | No             | Yes                 | MINOR  | Admins. This improvement has a minor impact on the efficiency of document placeholder management. |
| TTI-3574   | Study Start-Up (SSU)     | <p>This improvement brings a range of updates to the Import Documents functionality in SSU, as detailed in the list below:</p> <ul style="list-style-type: none"> <li>For the SSU module the import function has been updated to allow users to assign files to unfulfilled placeholders manually.</li> <li>Users can filter the list of unfulfilled placeholders by IRB, Site, and Country.</li> <li>When a user opts to assign placeholders, the system provides a list of the required documents.</li> <li>Users can drag and drop the placeholder from the list directly into the documents being imported.</li> </ul> | No             | Yes                 | MINOR  | Editor and above. These improvements have a minor impact on the Import Document window in TI SSU. |
| TTI-3590   | Trial Master File (eTMF) | This improvement adds a time component to the data in the 'Published Date' field to allow for accurate time zone conversions as needed.  | No             | Yes                 | MINOR  | All users. This improvement has a minor impact on metadata collection and time zone conversion.   |
| TTI-3593   | Trial Master File (eTMF) | This improvement disallows the addition of multiple documents to a single placeholder via separate routes (i.e., direct upload and query response).  | No             | Yes                 | MINOR  | All users. This improvement has a minor impact on document assignment to a placeholder.           |

| Feature ID | Offering Impacted                              | Description   | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis  |
|------------|--|---|----------------|---------------------|--------|--|
| TTI-3598   | Trial Master File (eTMF), Study Start Up (SSU) | This improvement introduces a KPI heat map option in Settings, which allows the configuration of selected colours for heat maps.  | Yes            | No                  | MINOR  | Admin and above. This improvement has a minor impact on the KPI heat map in the settings.        |
| TTI-3619   | Trial Master File (eTMF), Study Start Up (SSU) | With this improvement, moving documents from the regular inbox to the SSU documents area is now prohibited.   | No             | Yes                 | MINOR  | All Users. This improvement has a minor impact on the SSU Module.                                |
| TTI-3621   | Study Start-Up (SSU)                           | When submitting a Regulatory Packet, users will be presented with a confirmation window with details of the contents of the package.  | No             | Yes                 | MINOR  | All Users. This improvement has a minor impact on the SSU Module.                                |
| TTI-3622   | Trial Master File (eTMF)                       | With this improvement now in a Site profile, any updated Site information made by the user will not override the previous changes.  | No             | Yes                 | MINOR  | All Users. This Improvement has a minor impact on the eTMF/Sites.                                |
| TTI-3625   | Quality Documents (QDMS)                       | This improvement implements a checkbox so that users who are creating or editing workflows can indicate whether or not the document owner should be notified when a document is approved or rejected within a step of the workflow process. | Yes            | No                  | MINOR  | Admins and SuperAdmins. This improvement has a minor impact on workflow configuration options.   |
| TTI-3644   | Trial Master File (eTMF)                       | This improvement is a set of back-end enhancements designed to improve the processing time for documents in TI.   | No             | Yes                 | MINOR  | All users. This improvement has a minor impact on automated document processing functions in TI. |
| TTI-3645   | Platform                                       | This improvement consolidates the various entity-specific status tabs in the domain settings area so that they appear in one tab.   | Yes            | Yes                 | MINOR  | Super Admin. This improvement has a minor impact on the domain-level status UI.                  |

| Feature ID | Offering Impacted        | Description   | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis  |
|------------|--------------------------|---|----------------|---------------------|--------|--|
| TTI-3646   | CTMS, Collaborate (CMS)  | This improvement automatically enables the 'Document Distribution' action for users who are indicated as Document Owners for visit reports and letters. Where rooms are linked, and document distribution is enabled, users can now automatically share these documents across TI rooms.  | No             | Yes                 | MINOR  | CRA Users. This improvement has a minor impact on user actions related to document distribution.               |
| TTI-3647   | Trial Master File (eTMF) | With this improvement, the existing string translations for language localization have been updated.  | No             | Yes                 | MINOR  | All users. This improvement has a minor impact on language localization.                                       |
| TTI-3649   | Trial Master File (eTMF) | For a specific client's integration with an external EDC system, this improvement enables integration with the 'Expiration Date' field.   | Yes            | No                  | MINOR  | All users for this specific client. This improvement has a minor impact on the specific integration requested. |
| TTI-3659   | Study Start-Up (SSU)     | This improvement allows the system to require telephone and fax numbers for sites which conform to local number conventions.  | No             | Yes                 | MINOR  | Editor and above. This improvement has a minor impact on the site data UI.                                     |
| TTI-3660   | Study Start-Up (SSU)     | This improvement makes minor updates to the document import window in SSU. Importing a document with metadata in SSU requires all required metadata fields to be filled in. The system issues a warning if all required fields are not filled in and the import cannot be completed until all required information is provided. | Yes            | Yes                 | MINOR  | Editor and above. This improvement has a minor impact on the SSU Document Import UI.                           |

| Feature ID | Offering Impacted           | Description  | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis  |
|------------|-----------------------------|--|----------------|---------------------|--------|--|
| TTI-3663   | Study Start-Up (SSU)        | This improvement makes minor adjustments to the location of the IRB Submission and Approval date fields on the Site Creation interface.  | No             | Yes                 | MINOR  | Editor and above. This improvement has a minor impact on the Site Creation UI.   |
| TTI-3666   | CTMS Collaborate Room (CCR) | This improvement allows the system to successfully import site information automatically via the CTMS to CCR integration whenever a user is creating site visit-related documentation.   | No             | Yes                 | MINOR  | Editor and above. This improvement has a minor impact on CTMS to CCR integration.  |
| REPORT-117 | Trial Master File (eTMF)    | <p>With this improvement, the Query Report has been updated to include the following data:</p> <ul style="list-style-type: none"> <li>• ‘Aging of Queries’ to indicate the time between query initiation and the date that the report was run.</li> <li>• ‘Traceability Information’ including document type, country, site, artifact, and a link to the query.</li> </ul> | No             | Yes                 | MINOR  | All users with access to run this report. This improvement has a minor impact on the Query Report.   |
| Report-122 | Trial Master File (eTMF)    | This improvement aims to provide distinct reporting capabilities that separate queries related to missing documents from those related to existing documents. The report offers clear categorization or filtering options to differentiate between these two types of queries.   | No             | Yes                 | MINOR  | This improvement has a minor impact on the Queries Reports and provides the enhancement for differentiating Queries on Missing and Existing Documents. |
| Report-124 | Trial Master File (eTMF)    | This improvement adds the Ageing of Queries and Traceability Information with enhanced comprehensive details in the Timeliness Reports.  | No             | Yes                 | MINOR  | This improvement enhances the Timeliness Reports’ traceability.  |



| Feature ID | Offering Impacted                              | Description  | Config Change? | Enabled By Default? | Impact | Comment / Impact Analysis   |
|------------|--|--|----------------|---------------------|--------|---|
| REPORT-138 | Trial Master File (eTMF)                       | This improvement adds an organizational attribute to hide and remove the Adhoc widget at the Cross-Study level without affecting the Study Room level ad hoc configuration.                              | Yes            | Yes                 | MINOR  | This improvement has a minor impact on the Adhoc reporting at the cross-study level.  |
| REPORT-139 | Trial Master File (eTMF)                       | This improvement updates the message when available rooms are not chosen for KPI Dashboards. The updated message is "Kindly contact your administrator to add all available rooms to the KPI Dashboard." | No             | Yes                 | MINOR  | This improvement enhances the report information for chosen rooms.  |
| REPORT-140 | Trial Master File (eTMF)                       | TI v10.5.3 updates the saving logic for the 'Dashboard Configuration' window. Now, users can make multiple changes and save them all.  | No             | Yes                 | MINOR  | This improvement enhances the KPI Dashboard configuration and removes the current system behaviour where the system saves only the last change executed by the user in the dashboard configuration. |
| REPORT-141 | Trial Master File (eTMF), Study Start-Up (SSU) | Ad hoc reports are now improved with the implementation of a feature that allows users to be selected by name and email address. Moreover, the UI is improved with the scroll and border appearance.     | No             | Yes                 | MINOR  | This improvement enhances the ad-hoc reports user experience.   |
| REPORT-142 | Trial Master File (eTMF), Study Start-Up (SSU) | This improvement adds titles for the columns in the 'Default Rooms' tab, helping users understand what columns they will see on the dashlets.  | No             | Yes                 | MINOR  | All Users. This improvement enhances the view of the reports' portfolio dashlets.   |

## B. DEFECT RESOLUTIONS

| Ticket(s) ID | Offering Impacted        | Description  | Impact | Comment / Impact Analysis   |
|--------------|--------------------------|--|--------|---|
| TRL-7864     | Trial Master File (eTMF) | Users noted that when a query was created in the second step of a two-step workflow, the approver from the first step was not automatically added to the CC line on the query email. | MINOR  | Editor and above. This bug had a minor impact on workflow query functionality. The correct system behavior has been restored.   |
| TRL-8297     | Platform                 | Users noted that they were unable to select multiple users when performing a user history search via the Audit Trail module.   | MINOR  | Admin. This bug had a minor impact on the Audit Trail UI. Correct system behavior has been restored.  |
| TRL-9653     | CTMS Collaborate (CCR)   | Users received an error when a CTMS visit report was approved in the workflow but then the signer refused to sign the document.  | MINOR  | All users taking part in the CTMS visit report workflow. This issue had a minor impact on the successful completion of the workflow in this specific set of circumstances. Correct system behavior has been restored. |
| TRL-12533    | Trial Master File (eTMF) | A user encountered an error when attempting to regenerate document names for site-level documents.   | MINOR  | Admin. This bug had a minor impact on document name regeneration. Correct system behavior has been restored.  |
| TRL-12927    | SSU                      | When a user imports a document from a particular site view, the metadata is not checked at the top, and the site is not predefined based on the site.                                | MINOR  | Editor and Above. This bug has a minor impact on the import functionality. The correct system behavior has been restored.   |
| TRL-13193    | SSU                      | Users have observed that when they select an active site, the "Send Red Packet" button becomes enabled rather than disabled.   | MINOR  | Admin Users, this bug has a minor impact on Site Visits. The correct system behavior has been restored.   |
| TRL-13202    | SSU                      | The 'Site' field, is previously unspecified when a user tries to import and upload a file.   | MINOR  | Super Admin, this bug has a minor impact on the import functionality. The correct system behavior has been restored.  |

| Ticket(s) ID | Offering Impacted        | Description   | Impact | Comment / Impact Analysis  |
|--------------|--------------------------|---|--------|--|
| TRL-13212    | SSU                      | Users noted that they are unable to proceed with document import if the file was uploaded using the drag-and-drop method.                       | MINOR  | Super Admin. This bug has a minor impact on the import drag-and-drop functionality. Correct system behavior has been restored.                             |
| TRL-13236    | SSU                      | Users have identified an issue with the country flag for the phone number in the site profile being displayed incorrectly.                      | MINOR  | Admin Users. This bug has a minor impact on the Site Profile's Country flag phone number. Correct system behavior has been restored.                       |
| TRL-13257    | SSU                      | When users access the document tab and select any document's metadata fields, a user can edit the metadata without clicking on the edit button. | MINOR  | Super Admin. This bug has a minor impact on the Document's Metadata fields. Correct system behavior has been restored.                                     |
| TRL-13335    | Collaborate (QMS)        | A user indicated that they did not receive the expected email notifying them that there was a document that required their signature.           | MINOR  | Users in the impacted room: This bug had a minor impact on eSignature notifications. The correct system behavior has been restored.                        |
| TRL-13380    | SSU                      | When a site profile is getting created, redundant APIs are getting called.  | MINOR  | Admin. This bug has been resolved and has a minor impact on the Investigative Site Profile creation method.  |
| TRL-13404    | SSU                      | Users noted that when a document is uploaded using the import function, the grid fails to refresh automatically.                                | MINOR  | Super Admin. This bug has a minor impact after importing the document. The grid fails to refresh automatically. Correct system behavior has been restored. |
| TRL-13622    | Trial Master File (eTMF) | Several users indicated that they were unable to successfully set a new default view of the document grid.                                      | MINOR  | Users in the impacted room. This bug had a minor impact on data grid view management. Correct system behavior has been restored.                           |

| Ticket(s) ID | Offering Impacted        | Description   | Impact | Comment / Impact Analysis   |
|--------------|--------------------------|---|--------|---|
| TRL-13650    | SSU                      | Site closure status can only be modified/changed by a Super Admin once marked as closed.  | MINOR  | Super Admin. This bug has a minor impact on a Site Status modification. Correct system behavior has been restored.                    |
| TRL-13653    | Platform                 | Users received a 'Network Error' message when attempting to click on a site contact while searching for the Domain level.                         | MINOR  | Admin users. This bug had a minor impact on search result linking at the domain level. Correct system behavior has been restored.     |
| TRL-13786    | Platform                 | Users noticed a discrepancy in viewing document date and time data when using personal time zone settings.  | MINOR  | All users. This bug had a minor impact on user-specific date and time zone data displayed. Correct system behavior has been restored. |
| TRL-13796    | Collaborate              | Several documents required the effective date and review date to be changed for a few documents.  | MINOR  | Users in the specified room. This issue had a minor impact on data entry. Correct system behavior has been restored.                  |
| TRL-13807    | Trial Master File (eTMF) | A user attempted to reply to a query with an attachment whose filename had a special character in it, '&.' The document failed to load correctly. | MINOR  | All Users. This bug had a minor impact on query response functionality. Correct system behavior has been restored.                    |
| TRL-13943    | Collaborate              | Users noted that, after a document passed through an administrative workflow, the Effective Date data injection field was cleared.                | MINOR  | Admin. This issue had a minor impact on data injection fields in administrative workflows. Correct system behavior has been restored. |
| TRL-13962    | Trial Master File (eTMF) | Users in a specific room indicated that exporting the required document caused an error where they received the same requirement multiple times.  | MINOR  | All users. This bug had a minor impact on export functionality in the impacted room. Correct system behavior has been restored.       |

| Ticket(s) ID | Offering Impacted              | Description  | Impact | Comment / Impact Analysis  |
|--------------|--------------------------------|--|--------|--|
| TRL-13978    | Trial Master File (eTMF)       | Users noted a script error where ‘Investigative Site’ had not been updated as expected to ‘Site’ in the Forms Settings menu of the Settings area.  | MINOR  | Admin. This issue had a minor impact on the UI of the Forms Settings menu. Correct system behavior has been restored.          |
| TRL-13989    | Trial Master File (eTMF), CTMS | The error occurs when a reviewer signs a blinded report without access to the designated folder.   | MINOR  | All Users. This issue had a minor impact on the Visit Report Dashboard. Correct system behavior has been restored.             |
| TRL-13991    | Platform                       | Users noted that, when performing a document search at the domain level, the export option was not visible.  | MINOR  | All Users. This issue had a minor impact on the Search UI. Correct system behavior has been restored.                          |
| TRL-14074    | Platform                       | When exporting room data, the ‘Service Offering’ field was exporting the ID of the service offering rather than the name as would be expected.   | MINOR  | Super Admin. This bug had a minor impact on room data exports. Correct system behavior has been restored.                      |
| TRL-14076    | Trial Master File (eTMF)       | Users attempting to export all user data or export audit trial data from inside the Users Management module in a room were unable to successfully export the data and were receiving a header but no data. | MINOR  | Admins. This bug had a minor impact on room user data exports in the impacted room. Correct system behavior has been restored. |
| TRL-14110    | Trial Master File (eTMF)       | When creating a contact for a site, users found that the ‘Provide Documents’ field was absent.   | MINOR  | Editor and above. This bug had a minor impact on on-site contact maintenance. Correct system behavior has been restored.       |
| TRL-14124    | Collaborate                    | Users attempting to edit documents online encountered an occasional warning message indicating that the changes could not be saved.  | MINOR  | Editor and above. This bug had a minor impact on online editing functionality. Correct system behavior has been restored.      |
| TRL-14130    | Study Start-Up (SSU)           | Users encountered a ‘Network error’ message when attempting to assign a user to the Start-Up Specialist role via the Mass Coding function.   | MINOR  | Editor and above. This bug had a minor impact on on-site management. Correct system behavior has been restored.                |

| Ticket(s) ID | Offering Impacted        | Description   | Impact | Comment / Impact Analysis   |
|--------------|--------------------------|---|--------|---|
| TRL-14133    | SSU                      | Users noted that when entering information during site creation, details such as our website, telephone, and email address are not being saved.           | MINOR  | Super Admin. This bug has a minor impact on catching the details while creating the site. Correct system behavior has been restored.      |
| TRL-14145    | Collaborate (QDMS)       | Users noted that there was a variance in the configuration for the eSign Role field which could not be explained via examination of the change log.       | MINOR  | Admin. This issue had a minor impact on the eSign Role configuration. Correct system behavior has been restored.                          |
| TRL-14158    | SSU                      | For a site where the local IRB/EC is added as main, the users are not able to change the IRB/EC dates via the site profile. The date fields are disabled. | MINOR  | Editors and above. This bug has a minor impact on the site profile management. The resolution resets the dates fields editable.           |
| TRL-14159    | SSU                      | Users noticed that, when creating a room with SSU enabled, there was an error message displayed in which there was a typo.                                | MINOR  | Super Admins. This had a minor impact on room creation error messages. Correct spelling has been restored.                                |
| TRL-14170    | Trial Master File (eTMF) | Users noted that they were unable to successfully utilize the machine translation function. The results displayed a blank text.                           | MINOR  | All users. This issue had a minor impact on the machine translation function. Correct system behavior has been restored.                  |
| TRL-14177    | Trial Master File (eTMF) | Users noted that they were unable to add users with Admin or Super Admin user roles as site contacts when attempting this function at the domain level.   | MINOR  | Super Admin. This bug had a minor impact on on-site contact functionality at the domain level. Correct system behavior has been restored. |
| TRL-14183    | SSU                      | Users noted that if they choose to restore a deleted document without reviewing the data, it won't be restored.   | MINOR  | Admin. This bug has a minor impact on the Deleted document restoring process. Correct system behavior has been restored.                  |

| Ticket(s) ID | Offering Impacted        | Description  | Impact | Comment / Impact Analysis  |
|--------------|--------------------------|--|--------|--|
| TRL-14193    | Trial Master File (eTMF) | Users were unable to successfully perform an export of a specific room's configuration settings.   | MINOR  | Super Admin. This bug had a minor impact on configuration data export. Correct system behavior has been restored.                                    |
| TRL-14198    | Trial Master File (eTMF) | Users attempting to create a custom field setting and assign the correct value to a contact were unable to get the value to save as expected when applied to a contact.                | MINOR  | Admin. This bug had a minor impact on custom metadata creation and application. Correct system behavior has been restored.                           |
| TRL-14206    | Collaborate              | Users noted that, when performing a folder search, they experienced significant slowness.  | MINOR  | All users. This issue had a minor impact on folder search performance time. Correct system behavior has been restored.                               |
| TRL-14208    | Trial Master File (eTMF) | Users in a specific room attempted to update the title of two documents. Despite receiving a notification that the change was done successfully, the documents' titles were unchanged. | MINOR  | Editor and above. This bug had a minor impact on document management in the impacted room. Correct system behavior has been restored.                |
| TRL-14209    | Trial Master File (eTMF) | It was noted that when a room was configured so that mass upload for Editor users was disabled, they were still able to perform a mass upload via the 'Add' button.                    | MINOR  | Editor and above. This bug had a minor impact on room configuration settings. Correct system behavior has been restored.                             |
| TRL-14213    | Trial Master File (eTMF) | A user in a specific room indicated that, when attempting to invite a new user to the room via the Regular Invitation, they were unable to click the 'Save' button.                    | MINOR  | Admin users in the impacted room. The issue had a minor impact on new user creation in the impacted room. Correct system behavior has been restored. |
| TRL-14220    | Trial Master File (eTMF) | While adding users to groups, it was noted that the organization to which the users were associated was not always displayed.  | MINOR  | Admin users. This issue had a minor impact on the user selection UI for group management. Correct system behavior has been restored.                 |

| Ticket(s) ID | Offering Impacted        | Description   | Impact | Comment / Impact Analysis  |
|--------------|--------------------------|---|--------|--|
| TRL-14224    | Collaborate              | Users noted that for several documents, any changes to metadata were not being successfully saved.  | MINOR  | Editor and above users in the impacted room. This issue had a minor impact on metadata management for the specified documents. Correct system behavior has been restored.                      |
| TRL-14266    | SSU                      | Users have observed that when editing any site email domain field, there's no validation for the site email and no tooltip explaining how this field functions.                           | MINOR  | Super Admin. This bug has a minor impact on validating the site email domain field. Correct system behavior has been restored.   |
| TRL-14279    | Trial Master File (eTMF) | Users noted that in the site 'Edit History' records, users' names were recorded with their first name twice.  | MINOR  | Editor and above. This bug had a minor impact on the change history data display. Correct system behavior has been restored.   |
| TRL-14293    | Trial Master File (eTMF) | Users noted some inconsistency in the completeness of data displayed on the eTMF Health dashlet.  | MINOR  | All users. This bug had a minor impact on the dashlet data displayed. Correct system behavior has been restored.   |
| TRL-14352    | SSU                      | Sorting malfunctions when semicolons are present within values on the site visits.  | MINOR  | Admin. This bug has a minor impact on the site visits of special characters. Correct system behavior has been restored.  |
| TRL-14377    | SSU                      | The system does not display all the 'Not Applicable' sites in the SSU Amendments. Some of the sites are displayed if the user selects any site in the grid.                               | MINOR  | Editor and above. This bug has a minor impact on the Not Applicable sites' display. The resolution resets the correct system behavior, and the 'Not Applicable' sites are displayed correctly. |
| TRL-14417    | Trial Master File (eTMF) | Users noted that document requirements entered in the site-specific document requirement area were not being displayed as expected in the eTMF Completeness view of the documents module. | MINOR  | All users. This bug had a minor impact on the eTMF Completeness view. Correct system behavior has been restored.   |



| Ticket(s) ID | Offering Impacted        | Description   | Impact | Comment / Impact Analysis  |
|--------------|--------------------------|---|--------|--|
| TRL-14418    | Trial Master File (eTMF) | Users noted that dates were not being displayed as expected in the site-specific requirement change log.  | MINOR  | Editor and above. This bug had a minor impact on the change log data displayed. Correct system behavior has been restored.                               |
| TRL-14456    | Trial Master File (eTMF) | Users noted that the email option in the Document Cart was visible even though it was disabled in the room configuration.                               | MINOR  | Administrators. This bug had a minor impact on room configuration. Correct system behavior has been restored.  |
| TRL-14457    | Platform                 | A user's dedicated instance was not loading as expected.  | MINOR  | All users on the dedicated instance specified. This bug had a minor impact on the UI for the client involved. Correct system behavior has been restored. |
| TRL-14547    | Platform                 | SuperAdmin users noted that, when viewing the Event Manager change log at the domain level, the 'Originated From Room ID' presented an incorrect value. | MINOR  | SuperAdmins. This issue had a minor impact on the domain level change history data displayed. Correct system behavior has been restored.                 |

## 11. Open Defects

TI v10.5.3 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(s) ID | Offering Impacted | Description   | Impact | Comment / Impact Analysis  |
|--------------|-------------------|---|--------|--|
| TRL-14652    | eTMF              | In the eTMF Sites module, when a user attempts to clear the Site Reader and/or Site Editors fields with a general removal of all listed users, the changes are not saved as expected. | MINOR  | Admin and above. This bug has a minor impact on the site permissions user interface. |



## 12. Customer Support

### A. REPORTING ISSUES WITH THE RELEASE

Once **TransPerfect Trial Interactive** releases a system into a Production environment, the Support Service department provides 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 by 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<br>(TOLL-FREE)                       | <a href="mailto:help@trialinteractive.com">help@trialinteractive.com</a>       | Available twenty-four (24) hours a day,<br>seven (7) days a week, three-hundred-<br>sixty-five (365) days a year |
| European Union,<br>Madrid, Spain<br>+44 (20) 45182755 | <a href="mailto:eu.help@trialinteractive.com">eu.help@trialinteractive.com</a> | Monday – Friday, 9 AM – 6 PM CET.  |
| China<br>+86 (755) 66856062                           | <a href="mailto:cn.help@trialinteractive.com">cn.help@trialinteractive.com</a> | Monday – Friday, 9 AM – 6 PM Beijing<br>Time   |

## C. 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

### Product Owner

|  |                                      |
|--|--------------------------------------|
| Name: Anuj Thapar                            | Title: <b>Senior Product Manager</b> |
| Signature:<br>Reason for signature:<br>Date: |                                      |

### Quality Assurance

|  |   |
|--|---|
| Name: Scott Jordan                           | Title: <b>Director, QA and Systems Validation</b> |
| Signature:<br>Reason for signature:<br>Date: |   |