

EFEASIBILITY V2.7.1 - RELEASE NOTES V1.0







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1. Version History

Author	Revision #	Date	Comment
Mansi Kandhare	0.1	18-Jun-2025	Initial Document Creation
Mansi Kandhare	0.2	23-Jun-2025	Added below feature: EF-190
Mansi Kandhare	1.0	10-Jul-2025	Added Open defects Added closed defects
			Document 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 eFeasibility						
System Version	2.7.1					
Release Type	Minor					



4. Definitions / Acronyms

Term	Definition/Description
JIRA	A proprietary issue tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management
SQA	Software Quality Assurance
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
TP	TransPerfect
TI	Trial Interactive



5. System Overview

A. SYSTEM DESCRIPTION

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 & apos's products deliver a wide range of benefits to any organization looking to leverage new efficiencies and opportunities in 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 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 and sponsor and site personnel documentation.
- Support 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.
- Increased 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, and complex standardized and custom reports.
- Adaptable, built-in machine learning features such as auto-classification and metadata extraction enable Al auto-coding capabilities.
- Integrations into other Trial Interactive products (GlobalLearn, myTl, CTMS) to provide a comprehensive set of solutions to effectively manage the entire clinical trial process from protocol conception through closeout.

B. EFEASIBILITY

eFeasibility is the configurable survey application within the Trial Interactive e-clinical platform. E-client feasibility workflows make it easy to select site contacts, configure questionnaires, schedule questionnaire emails to site contacts, collect responses and other essential documentation, analyze incoming responses with real-time reporting, and rank site contacts to



reduce the cycle time and get qualified sites into study start-ups. eFeasibility has the following features:

- Question Templates with Scoring: eFeasibility allows our users to configure questions based on their clinical trial and business needs. The system is intuitive and easy to use, so creating your questionnaires is painless. Once you have configured your templates, you can then leverage them for future studies, saving time on designing questionnaires. Less time with setup means a quicker path to survey responses and site activation.
- Contact Management: eFeasibility provides an easy way to manage, import, and export distribution lists. Review the history of every survey and study to which a site contact has responded.
- CDA Document Capture with E-Signature: With our built-in CDA process and e-signature feature, eFeasibility streamlines this process for each investigator before or during the questionnaire responses collection.
- Email Scheduling: Schedule emails for sending questionnaires at specific dates and times.
- Reports: Clients can configure and export the response of a questionnaire into CSV or Excel files. Customize report headers and select survey response data to evaluate KPIs based on your clinical needs.
- Intelligent Question Forms: eFeasibility allows our clients to create complex, logic-based questions.
- Integration with eTMF: Site Feasibility responses are required in your TMF. With integration
 into our eTMF solution clients can easily add their responses to a designated folder in the
 eTMF room.
- CFR 21 Part 11, ER/ES, GxP and Annex 11 Compliant: eFeasibility maintains compliance with all current and emerging regulations critical to clinical operations.



6. Release Overview

A. CTMS-EFEASIBILITY INTEGRATION FOR SITE LIST EXCHANGE

EF-163: This new feature streamlines the feasibility process by enabling Feasibility Managers to filter and export Site and Contact lists from CTMS based on parameters such as location, therapeutic area, and past participation. The filtered list can be directly imported as a Contact Group in eFeasibility.



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 11-Jul-2025						
Estimated US MTI Upgrade Date/Time:	ne: 11/Jul/2025 4:00 AM					
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 eFeasibility v2.7.1 platform.

HW/SW Requirements	Details
os	Windows Version 7 or higherAll currently supported Mac OSX releases
Browser	 Internet Explorer: Version 11 or later Edge: Version 20 or later (officially supported versions by Microsoft only) Chrome: Current release and previous Firefox: Current and ESR releases OS X Safari: Current release and previous NOTE: Microsoft® stopped supporting Internet Explorer™ 8 and Internet Explorer™ 9 in January 2016 and will stop support for Internet Explorer™ 10 in January 2020. Beginning with the release of TI 10, we no longer support Internet Explorer™ 10. Users accessing TI with this and older browsers will see, in some cases, a degraded experience and may have trouble using certain features.
Client Software	 For Edit Online Support, Microsoft Office 2010 SP1 or higher Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. 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
Optional Add- Ons	 DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) Adobe Sign (Latest Adobe Document Cloud Version)



9. Changes

Legend for Impacts

eFeasibility v2.7.1 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

eFeasibility

A. **NEW/ENHANCED FEATURES**

Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
		This feature brings interoperability with TI CTMS, whereby the Study Manager is able to push the shortlisted Sites list from CTMS to eFeasibility				Affected User: All users.
EF-163	eFeasibility	Seamless Contact Group Creation: Potential Sites/Contacts can be imported directly into eFeasibility as a Contact Group, enabling a quick start to the Feasibility process without manual data entry.	Yes	No	Minor	Impact: This improvement has a minor impact on synchronization across CTMS and eFeasibility



Feature ID	Offering Impacted	Description	Config Change?	Enabled by Default?	Impact	Comment / Impact Analysis
EF-173	eFeasibility	This feature update resolves issues related to the incorrect display of special characters (e.g., ©, ®, ™, ñ, é) in both form fields and downloaded PDF documents.	No	Yes	Minor	Affected User: All users. Impact: This improvement has a minor impact on the entering or viewing forms and PDFs.
EF-190	eFeasibility	With this improvement the full file name displayed will be a clickable hyperlink, allowing users to open attachments directly with a single click, improving usability and reducing steps	No	Yes	Minor	Affected User: Site Users. Impact: This improvement has a minor impact on the hyperlink for the attachment/references.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF- 5417	eFeasibility	In the CDA module, the Digital Signature status displayed in the Overview tab is fetched incorrectly.	Major	This bug has a major impact on the Digital Signature status in the Overview tab. Correct system behavior will be restored.
TPTEF- 5441	eFeasibility	On the Approving Sites > Overview page, the green tick icon indicating a Site's approved status is not displaying in the Approval Status column	Trivial	This bug had a trivial impact on the Approval Status Column on Overview Page. The resolution ensures the green tick icon is displayed in the approval status column.



Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF- 5444	eFeasibility	In the eAcknowledgement module, the Protocol Title is incorrectly displayed in areas where the eAcknowledgement Title should be shown.	Trivial	This bug had a trivial impact on the eAcknowledgement module. Correct system behavior will be restored.
TPTEF- 5470	eFeasibility	There is a mismatch between the content displayed on the e-Feasibility web form and the corresponding PDF output. Specifically, the generated PDF contains unexpected markings and additional text that are not present on the web form.	Major	This bug had a major impact on the e- Feasibility web form and the corresponding PDF output. Correct system behavior will be restored.
TPTEF- 5477	eFeasibility	An error occurs when branching logic attempts to display a comment field that is marked as "Required" and initially hidden.	Major	This bug had a major impact on form submission failures. The resolution ensures that the required comment fields are displayed correctly.
TPTEF- 5482	eFeasibility	Survey responses are not being saved for questions configured as dropdown-type fields.	Critical	This bug had a critical impact on the Survey responses. The resolution resets the system correct behaviour by saving the selected answer in the survey and reflecting it in the submitted response.
TPTEF- 5483	eFeasibility	As a Manager, the Phone Number and Extension values are not displayed correctly in the generated PDF.	Major	This bug had a major impact on the Phone Number and Extension values. The resolution resets the system correct behaviour that display the country code and extension.
TPTEF- 5485	eFeasibility	As a Manager, an issue is observed where, if a recipient enters a currency symbol as part of a survey response, the submitted answer displays invalid characters or encoding errors instead of the intended symbol.	Minor	This bug had a minor impact on the invalid characters. Correct system behavior will be restored.



Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF- 5486	eFeasibility	An issue is observed when the sub-question field answers were not displayed in the generated PDF file.	Minor	This bug had a minor impact on the sub-question field answers. Correct system behavior will be restored by displaying all sub-questions with values.
TPTEF- 5487	eFeasibility	An issue is observed where PDF files did not display submitted answers when the 'Do you want to display form confirmation page?' option was disabled.	Major	This bug had a major impact on the PDF files. Correct system behavior will be restored by displaying all answer correctly.
TPTEF- 5490	eFeasibility	The 'Save as PDF' button in the Completed Surveys section is not functioning. When users attempt to download a survey response as a PDF, no file is generated.	Minor	This bug had a minor impact on the 'Save as PDF' button in the Completed Surveys section. Correct system behavior will be restored.
TPTEF- 5491	eFeasibility	An issue is observed where a downloaded supplementary form incorrectly displayed the title of the main form.	Minor	This bug had a minor impact on the supplementary form. Correct system behavior will be restored by displaying the correct name.



10. Open Defects

eFeasibility v2.7.1 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
TPTEF- 5414	eFeasibility	The corresponding project activity log entry does not capture the Group Name associated with the deleted group when a user deletes a group.	Minor	This bug has a minor impact on the Project Activity Group Name. The information is however captured in the database.
TPTEF- 5431	eFeasibility	In the Recurring Form functionality, users with the Submitter role are currently able to edit recurring forms.	Minor	This bug has a minor impact on the Recurring Form functionality.
TPTEF- 5489	eFeasibility	When a contact is created individualy it appears that the Manager is not able to assign it to a Group.	Minor	This bug has a minor impact on the Custom Groups. While it might appear so the contact appears in the assigned group after a lag of a minute.



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:	