

EFEASIBILITY V 2.5.2 – RELEASE NOTES V1.0





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2. Version History

Author	Revision #	Date	Comment
Anuj Thapar	1.0	13-Sep-2021	Final Release Notes issued.



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 advanced of Upgrade Date by issuing Pre-Release Notes. The end-users of the system can use the Pre-Release Notes in evaluating if their intended use of the system will be impacted with the changes introduced in the system release. The Final Release Notes are then issued once the internal Validation Package has been reviewed/approved by Trial Interactive Quality Assurance. The Final Release Notes will contain the final list of items in scope of the Release.



NOTE: TransPerfect will make commercially reasonable 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.

4. Scope

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

System In Scope	
System Name	eFeasibility
System Version	V2.5.2
Release Type	Hotfix



5. Definitions / Acronyms

Term	Definition/Description
JIRA	A proprietary issue tracking product, developed by Atlassian, used for bug tracking, issue tracking, and project management
SQA	Software Quality Assurance
TestRail	A web-based test management software that facilitates software quality assurance; it produces reports on a release candidate and documents the nature and category of bugs
TP	TransPerfect
TI	Trial Interactive



6. System Overview

TransPerfect's **Trial Interactive** has been used successfully by TransPerfect customers for over 10 years in hundreds of Clinical Trials for the storage of 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 as well as eFeasibility, Content Management, Learning Management, Study Start Up, Clinical Trial Management, and a variety of other tools used in the conduct of a Clinical Trial. The Trial Interactive Platform has the following features:

- An electronic Trial Master File archive that meets all regulatory, security, access and storage requirements in all countries and regions.
- A fully hosted solution that is 21 CFR Part 11, Annex 11, ERES, GDPR, HIPAA, and GxP compliant.
- A single access point for all trial content and documentation for both sponsor and site personnel.
- Support of a series of TMF workflows including document import and coding, quality review, audit and inspection, document certification, and the capture of other Clinical Trial documentation.
- A thin-client, consumer-grade user interface that supports most major browsers as well as a mobile app that supports both iOS and Android phones and tablets.
- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of review and authoring solutions.
- A full-featured eLearning system designed specifically for GxP compliance.

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-up. 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 a CSV or Excel files. Customize report headers and selected 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 to our eTMF solution our clients can easily add of their responses into 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.



7. Release Overview

eFeasibility v2.5.2 is a release focused on bug fixes and defects resolution. This document is the specific Release Notes for the v2.5.2 release.



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	15-Sep-2021
Estimated US MTI Upgrade Date/Time:	3 AM to 8 AM EDT
Estimated EU MTI Upgrade Date/Time:	Not Applicable
Date of Dedicated Client Upgrade:	Not Applicable

9. Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the eFeasibility v2.5.2 platform.

System Requirements	
Operating System	<ul style="list-style-type: none"> Windows Version 7 or higher All currently supported Mac OSX releases
Browser	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) Adobe Sign (Latest Adobe Document Cloud Version)

10. Changes

eFeasibility v2.5.2 has been released with these enhanced 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** - This change will have an impact on business in specific use cases, for specific offerings.
- **Minor** - There may be a small impact on business in specific use cases.

A. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-4633	PDF Download	When a sub-question, without a title, is added to a form a colon (:) is wrongly displayed in the PDF file,	Minor	Low Impact: This issue has been resolved. The downloaded file does not display the colon any more.
TPTEF-4621	PDF Download	When a form with sub-questions is downloaded as PDF file, the sub-question does not appear in the downloaded file.	Medium	Low Impact: This issue has been fixed. The downloaded file correctly displays the sub-question.
TPTEF-4623	PDF Download	Form response when downloaded as PDF file would not display the question numbering.	Medium	Low Impact: This issue has been resolved. The downloaded file correctly displays the question numbering.
TPTEF-4632	PDF Download	When a form is download as a PDF, and has a table, the downloaded file displays an additional horizontal line break	Minor	Low Impact: The issue has been fixed. The downloaded PDF file does not display the additional line break.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-4640	Reports	The Date format for the field 'Date Responded' was showing the date in an irregular format, where the year was showing after the time stamp.	Minor	Low Impact: The issue has been fixed. The responded date now shows the date in the correct format.
TPTEF-4641	Contacts	The Import functionality for Contacts is returning an error as it is not able to map the mandatory field for email.	Major	Low Impact: The issue has been fixed and the systems now allows to import contacts as expected.

11. Open Defects

eFeasibility v2.5.2 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.
- **Medium** - This change will have an impact on business in specific use cases, for specific offerings.
- **Minor** - There may be a small impact on business in specific use cases.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-3058	Forms	The first answer choice disappears when making it a required question.	Minor	Low Impact. The issue is known to occur only in Internet Explorer. The User is required to re-enter the answer option.
TPTEF-3166	Search	Search by 'Recipient' does not work well when the search string contains special characters.	Minor	Low Impact. The Users can filter results from the Reports section to achieve desired results.
TPTEF-3405	Edit Response	Unnecessary rows are appeared in the email during mass update	Minor	Low Impact: The additional row in the notification email remains blank and should be ignored.
TPTEF-3412	Date-Time Stamp	Origami Document has dates by server Time Zone instead of User Time Zone	Minor	Low Impact. The issue has no direct impact on any of the functionality.
TPTEF-3415	Contacts	Custom contact field is not deleted from 'Available Columns' in 'Report Configuration' Dialog.	Minor	Low Impact. The Users can ignore this field, as it does not impact the functionality and only provides an additional field in the generated reports.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-3840	Styles	Bold style for section description doesn't work	Minor	Low Impact: The User can use regular font or other formatting options.
TPTEF-3946	User Access	The system is not asking for password after closing and reopening the browser.	Minor	Low Impact: The issue persists if the user reopens the same the same browser within 30 minutes of closing the browser. Users are advised to log out of the application before closing the browser.
TPTEF-3972	User Access	Auto log out instance if the system is open in two/more tabs	Minor	Low Impact. The system is designed to auto log out the user after 30 minutes of inactivity. However, to avoid auto log out Users are advised to work in single tab or log back in.
TPTEF-4122	User Access	User is not logged out if 'Stay logged in' was chosen before	Minor	Low Impact: Users are advised to log out physically when exiting the session.
TPTEF-4198	Contact	The Contact Field Association is duplicated if the second field is empty during the creation of the question in System Generated Questions	Minor	Low Impact: It is recommended that contact fields should be associated only in draft forms.
TPTEF-4236	Forms	Statuses 'Pending Verification' and 'In Review' are messed up	Minor	Low Impact: In exceptional cases the CDA status is wrongly shown. However, the overall functionality remains unaffected.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-4247	Forms	Resend to TMF' does not work if initially was a mistake in the Integration settings	Minor	Low Impact: This error is noted only when the integration setting is incorrect. When corrected the issue is not reproducible.
TPTEF-4322	Distribution	Text format changes are not saved when send as PDF	Minor	Low Impact: There is no impact on the actual functionality. As a workaround the users can update the text of the email from Templates section.
TPTEF-4450	Reports	[Analyze Report] 'Save' button ignores sorting changes using drag and drop	Minor	Low Impact: As a workaround Users can use up and down arrow buttons to instead of dragging and dropping.
TPTEF-4460	Styles	Text Formatting issues for creating templates	Minor	Low Impact: This is a formatting issue when creating templates
TPTEF-4481	Contact	Contact Mapping does not take in to account the international code for phone numbers	Minor	Low Impact: Respondents can override and add the international code.
TPTEF-4482	User Access	Application freezes when try to sign with invalid credentials	Minor	Low Impact: This issue has been observed only when invalid credentials are used to sign into the application.
TPTEF-4608	Reports	Analyze Report: Only Bar charts are available for analyzing Matrix type questions	Minor	Low Impact: This is due to the nature of question type where multiple questions and answer options are analyzed together.

12. Approvals

Product Owner

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

Quality Assurance

Name: Scott Jordan	Title: Director, QA & Systems Validation
Signature: Reason for signature: Date:	