EFEASIBILITY V2.5.3 – PATCH RELEASE NOTES V1.0

1.   Table of Contents

2.   Version History

Author	Revision #	Date	Comment
Badr Safiullah	1.0	09-May-2022	Initial document creation

3.   Purpose

The purpose of this document is for **Trans**Perfect 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.

4.   Scope

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

System In Scope	
System Name	eFeasibility
System Version	v2.5.3
Release Type	Patch

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

Trial Interactive

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 Clinical Trial Management System (CTMS) that meets all eClinical requirements for the management and tracking of Clinical Studies and works seamlessly with the eTMF, Content Management, Learning Management, Mobile app, and other Trial Interactive solutions.

- A fully hosted solution that is 21 CFR Part 11, Annex 11, ERES, GDPR, HIPAA, HITRUST, ISO 27001, 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 indexing, quality review, audit and inspection, document certification, remote monitoring, redaction, 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 devices.

- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of reviews and authoring solutions.

- A full-featured eLearning system designed specifically for GxP compliance, Study Training, and Virtual Investigator Meetings.

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 are 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

A. EF-108 - ADDING NEW QUESTION TYPE FOR COUNTING

This new feature adds a new question type with counter that is not editable - Acknowledge question type, with content restriction for numbers. The system allows the numbering with any characters with counter. The response is non-editable and greyed out. The system assigns an incremental number for the responses received only. The system provides a reference of this auto-generated number in Post-submission Thank You email response.

B. EF-110 – NEW TYPE OF FORM. RECURRING FORM.

This new feature allows to use new form types - Recurring form. A new type of form (Recurring form) is added. It is available under the Submitter Portal. A new tab for Recurring Form is added. Submitter can create a Recurring Form from the Submitter portal.

C. EF-111 – REPORT TAB-CHANGE FORMAT OF THE DATES

With this improvement the system shall display dates in a standard format across the application and would no longer display the day of the week, and the time.

D. EF-112 – ADD AN ABILITY TO CREATE PDF FROM DRAFT

This improvement allows user to generate and download a PDF for the Form while in draft stage.

8.   Release Schedule

eFeasibility v2.5.3 is a minor release focused on new features/improvements. This document is the specific Release Notes for the v2.5.3 release. 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	03-Jun-2022
Estimated MTI Upgrade Time:	03-June-2022 3 AM to 8 AM EDT

9.   Hardware and Software Requirements

The following describes the hardware and software requirements in order to use the eFeasibility v2.5.3 platform.

System Requirements	
OS	• Windows Version 7 or higher • All 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)

10.   Changes

eFeasibility v2.5.3 has been released with these new/enhanced features and defect fixes.

Theses 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. NEW/ENHANCED FEATURES

Feature ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
		New Features		
EF-108	eFeasibility	With v2.5.3 a new question type called 'Acknowledge Question' will be available. This question type would auto-generate and assign a number to the responses received. Form Managers shall be able to prefix the auto-numbering with alphabetic characters. Additionally the confirmation/ Thank-you email to the Form respondent shall quote this acknowledgement number.	MAJOR	Editors, Manager: This new question type will be an improvement to the existing library of question types as this question type can be used for assigning a sequential-reference number for the responses received.

Feature ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
EF-110	eFeasibility	With v2.5.3 Managers shall have the ability to create a recurring form which can be assigned to Registered Submitters. The new form type would be available to the Registered Submitters on eFeasibility. Registered Submitters shall be able to use this new Form type to create multiple responses on the fly.	MINOR	Submitter, Manager: This new feature shall allow Managers to create a Form that needs to be filled multiple times by the same Submitter without the need to resend the Form again.
Improvements				
EF-111	eFeasibility	The dates under the Reports tab of the Form have been standardized and will no longer display the day of the week.	MINOR	All Users: This minor improvement standardizes the dates across all fields in the Reports tab. This improvement will help users using Formula based reporting.
EF-112	eFeasibility	With v2.5.3 Form Editors and Managers shall have the ability to download the draft Form as a PDF file.	MAJOR	Editors, Managers: With this improvement the Users shall no longer have to publish a Form in order to generate a PDF file for the Form. The system shall Users to download the Form while in draft state itself.
EF-113	eFeasibility	With v2.5.3 an improvement has been made to optimize the standalone (without CDA) Survey response page for mobile phones.	MAJOR	Form Respondents: With this improvement Form respondents would enjoy a better user experience when they access and submit Form responses using their mobile phone.

B. DEFECT RESOLUTIONS

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-4350	eFeasibility	When editing a submitted response for a required question the system would allow the Manager to reset the answer and update the response without validating if an answer to the required question has been entered.	MINOR	With this fix the system shall enforce the Manager updating the response to provide the answer to the required question.
TPTEF-4842	eFeasibility	For the Submitter profile the 'Recent Activity' tab does not display the most recent Form created by the Submitter	MAJOR	The issue has been fixed. The 'Recent Activity' activity tab now correctly displays the most recent Form created by the Submitter.
TPTEF-4850	eFeasibility	Adding Contacts to a Group by Drag-and-drop did not work	MAJOR	The issue has been fixed. Users can now Drag-and-drop Contacts to add them to a group.
TPTEF-4638	eFeasibility	The options under the 'Select' dropdown menu under the CDA tab were not aligned and displaying correctly.	MINOR	The issue has been fixed. The options are now displayed correctly.
TPTEF-4198	eFeasibility	While configuring Contact information, for System Generated Question, with questions with multiple answer options, the system would associate the same information with all answer options.	MINOR	The issue has been fixed. Contact Field Association of System Generated Question works as intended.
TPTEF-4622	eFeasibility	In the section for analyzing Reports, the PDF file would have overlapping words in PDF if there were many answer options for the question	MINOR	The issue has been fixed. The PDF file generates as expected.
TPTEF-4583	eFeasibility	While previewing Form in draft stage, the system would display the numbering of the questions incorrectly by affixing the question numbers with Section number.	MINOR	The issue has been fixed. The question numbers are displayed correctly.

Ticket(s) ID	Offering Impacted	Description	Impact	Comment / Impact Analysis
TPTEF-4730	eFeasibility	The system would occasionally provide an error when deleting a question from a draft Form.	MAJOR	The issue has been fixed. 'Delete' icon works correctly now.
TPTEF-4785	eFeasibility	In Single or Multiple Choice question types, if an answer option spanned two lines, it would overlap the next option and not display correctly	MINOR	This issue has been fixed and the long answer options displays correctly without overlap.
TPTEF-4790	eFeasibility	Select Users were facing issues while logging into the eFeasibility application and would be directed to another group page,	MAJOR	The issue has been fixed.
TPTEF-4541	eFeasibility	When analyzing reports sometimes the details of the tooltips would appear in the downloaded PDF	MINOR	The issue has been fixed. The PDF files no longer display the tooltips.

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:

Phone	Email	Business Hours
US: 888-391-5111 (TOLL-FREE)	help@trialinteractive.com	Available twenty-four (24) hours a day, seven (7) days a week, three-hundred-sixty-five (365) days a year
European Union, Madrid, Spain +44 (20) 45182755	eu.help@trialinteractive.com	Monday – Friday, 9AM – 6PM CET.
Investigative Site Support	iss@trialinteractive.com	Monday – Friday, 8:30AM – 6PM EST

(212) 400-8856 +44 (20) 45182755	eu.iss@trialinteractive.com	Monday – Friday, 9AM – 6PM CET

B. REQUESTING FUTURE ENHANCEMENTS

If you would like to submit requests for enhancing the system, please submit your ideas through one of the following methods:

Project Manager

(PM)

Customer Experience Program (CEP)

Your PM can submit Ideas to our Perfective Change Management on your behalf	Meet with other Trial Interactive customers for an immersive CEP Forum: • Focus Group • 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: Scott Jordan	Title: Director, QA and Systems Validation
Signature: Reason for signature: Date:	