2022 Real World Testing Plan
Eye Care Leaders, LLC

Plan Submission Year: 2021
For Testing Year: 2022

For Certified Electronic Health Record Technology:
Regulatory Compliance Platform Version 1.4

General Information	
Plan Report ID Number: (ONC-ACB use only)	2022RWTP_RCPv1.4
Developer Name	Eye Care Leaders, LLC
Product Name	Regulatory Compliance Platform
Version Number(s)	1.4
Certified Health IT	2015 edition
Product List (CHPL) ID(s)	15.04.04.2998.Regu.14.02.0.201005
Developer Real World Testing Page URL	https://eyecareleaders.com/about-eye-care-leaders/onc-certification/

Table of Contents

1 Introduction

This test plan describes the testing approach and overall framework that will drive the testing of Eye Care Leaders, LLC's 2015 edition CEHRT software modules in order to comply to the ONC Health IT Certification program's Real World Testing Conditions of Certification requirement described in § 170.405 Real World Testing Version 1.1.

This document introduces:

- The scope of applications under test w/ associated criterion subject to real world testing
- Justification for Real World Testing Approach
- The testing methods/methodologies that will be used to demonstrate real world interoperability and conformance to the full scope of the certifications requirements
- The care setting description and justification of the care setting
- SVAP description (as applicable)
- Key real world testing milestone schedule
- Description of expected outcomes
- Measurement / Metric detail
- Justification of the real world testing approach

This test plan version (2020.1) is associated with the testing to be conducted in **CY 2022**.

1.1 Scope

1.1.1 Applications in Scope

The following Eye Care Leaders' CEHRT software platforms are subject to the real-world testing procedures outlined in this test plan for criterion certified to that platform, and as listed on the Certified Health IT Product List, as of August 31, 2020.

Platform	Version	Criterion to be Tested
Regulatory Compliance Platform	1.4	(b)(6), (c)(1)

Table 1.0

1.1.2 Criterion Detail

§170.315	Criterion Name	Criterion Description (includes, not limited to)
(b)(6)	Data Export	Software enables a user to set time and location configuration options when creating an export summary for one or more patients; must be able to limit the ability of users who can create export summaries; Enable a user to create export summaries using the CCD template; User must be able to execute these capabilities without developer assistance
(c)(1)	Clinical Quality Measurement – record and Export	Software must be able to record all of the data that would be necessary to calculate each CQM that the technology is certified for; user must be able to export a data file at any time and without developer assistance

Table 1.1: Note that full regulation text is available on the HealthIT.gov website for each criteria listed above.

Only functionality that is specific to the performance of successfully completing a task related to the criterion listed in Table 1.1 will be included in the real world testing execution.

2 Justification for Real World Testing Approach

Eye Care Leaders, LLC Certified Health IT Modules are sold only to the Ophthalmology / Optometry specialty care settings. The certified functionality under test works the same for each care setting therefore the Real-World Testing plan will be applied to the Ophthalmology specialty care setting for the purposes of providing Real World Testing Results.

Regulatory Compliance Platform Version 1.4 supports multiple certification criteria:

- **170.315(b)(6) Data Export**
- **170.315(c)(1) Clinical Quality Measurement- Record and Export**

The purpose of the system test is to demonstrate real world interoperability and conformance to the full scope of the platform's certifcation criterion's requirements and to evaluate the end-to-end system specifications and functionality related to specific certified criteria for the application under test (AUT). The system test will involve the external workings of the software from the user's perspective.

Scenario Testing can be used to best define the functionality related to the criteria to be tested. **Use Case** will represent the action(s) that are required to achieve the expected outcome of the test scenario. **API** testing will be used to test application programming interfaces where applicable. API testing is used to determine if the health IT's API meets expectations for functionality, reliability, performance and security. Therefore, Eye Care Leaders, LLC will use Test Scenario, Use Case and API (where applicable) based system testing methodologies in parallel to conduct the system test on the fully integrated applications, including external peripherals (HISP) as applicable, to check how components interact with each other and with the system as a whole during interoperability related actions that are defined in §170.140 Real World Testing Version 1.1.

The testing will be performed by the Subject Matter Expert of the CEHRT and the Certification Manager with assistance by individual developers or support team leads as required, hereby known as the RWT Team. The RWT team will provided a list of measures to monitor over a pre-chosen 90-day period during the testing year using a designated client(s) production environments. The measures chosen are meant to reflect performance that will best demonstrate interoperability in a real world scenario as is outlined in this Real World Testing Plan. The RWT team will be required to report on the success and error rate for specific actions related to the chosen measures. In certain cases, synthetic patient data may be used for data entry simulation. All nonconformities must be documented and a mediation strategy detailed for each nonconformity. All nonconformities must be reported to ONC within 30 days of discovery.

Verification of the created patient record export does require interaction with a system external to the organization (and with a different vendor).

3 Standards Updates

This Section includes both required and voluntary standards update information, as applicable.

Standard (and version)	All Standards included in C-CDA R2.1
Updated certification criteria and associated product	None
Health IT Module CHPL ID	15.04.04.2998.Regu.14.02.0.201005
Health IT Module Product ID	Not Applicable
Method used for standard update	Minimum Standard Code Sets
Date of ONC-ACB notification	Not Applicable
Date of customer notification (SVAP only)	Not Applicable
Conformance measure	**170.315(b)(6) Data Export**
USCDI-updated certification criteria (and USCDI version)	None

Standard (and version)	All Standards included in C-CDA R2.1
Updated certification criteria and associated product	None
Health IT Module CHPL ID	15.04.04.2998.Regu.14.02.0.201005
Health IT Module Product ID	Not Applicable
Method used for standard update	Minimum Standard Code Sets
Date of ONC-ACB notification	Not Applicable
Date of customer notification (SVAP only)	Not Applicable
Conformance measure	**170.315(c)(1) Clinical Quality Measurement - Record and Export**
USCDI-updated certification criteria (and USCDI version)	None

4 Care Settings

4.1 Settings of Care Description

The Regulatory Compliance Platforms is integrated for use by Eye Care Leaders CEHRT platforms, which are considered to be an **Ambulatory Specialty Care Practice** type care setting for use in ophthalmology practices.

4.2 Settings of Care Justification

Care Setting	Justification
Ambulatory Specialty Care Practice – Ophthalmology and Optometry	Eye Care Leaders provides CEHRT that supports healthcare professionals in ophthalmology and optometry in outpatient ambulatory environments only. Ophthalmology and optometry are considered to be specialized areas of medicine. The software allows users to perform a wide range of functions that focus on all aspects of the patient's eye examination. The software is not used in other types of settings of care. Since the patient base, exam type and documentation content of ophthalmologists encompass all and more aspects of patient care as optometry, all Real World Testing scenarios will be focused on the ophthalmology practice.

5 Overall Expected Outcomes

- RWT will demonstrate that the Health IT Module is conformant to the following certification criteria:
  - **170.315(b)(6) Data Export**
  - **170.315(c)(1) Clinical Quality Measurement- Record and Export**
- The Regulatory Compliance Platform, henceforth called RCP is not a standalone product and is only provided in combination with one of Eye Care Leaders' EHR products. RCP is not intended to be actively marketed but is a separately 2015 Edition certified health IT module. RWT will demonstrate that the RCP, when integrated with an Eye Care Leaders EHR, exchanges EHI in the expected manner in ophthalmology care settings, specifically the interoperability related criteria of providing health information via Data Export and creating and exporting Clinical Quality Measure data.

6 Schedule of Key Milestones

Key Milestone	Date / Timeframe
Release of test documentation including but not limited to templates, instructions, forms, and schedules to be released to the platform's Subject Matter Expert	01/31/2022
Test Environments Ready	03/31/2022
Perform Real World Testing	Q2 and Q3 2022
Report status of scheduling and/or testing issues, successes, remediation needs, fixes, deviations from test plan etc.	06/30/2022
Soft deadline for testing completion	10/31/2022
Hard deadline for testing completion	12/31/2022
Detailed Test Data results submission	01/15/2023
Test Summary Report Finalized	01/31/2023
Test Summary Report Submission to ACB	02/15/2023

7 Measures Used

The RCP is certified to multiple criteria that must comply to Real World Testing requirements. The following outlines the measures and metrics used to demonstrate conformance to the following certification criterion:

Measurement/Metric	Description
170.315(b)(6) Data Export	(iii)(A) Set Time and Date
	(iii)(B)(1) Execute at any time
	(iv) Location Configuration
170.315(c)(1) Clinical Quality Measurement – create and export	(1)(i) record all data necessary to calculate CQMS for certification
	(1)(ii) export a data file formatted in accordance with the corresponding version of the QRDA standard

7.1 Measure Use Case(s)

The measure use cases listed below have been chosen to demonstrate interoperability in real world use. To cover all criteria, multiple use cases are required for this plan. Because the RCP manages multiple functions for the same patient, the following criteria may be tested simultaneously:

Use Case 4: (Single / Multi Patient) Metrics: 170.315(b)(6) Data Export

- Measure 1: Conformance to 170.315(iii)(A) Set Time and Date – This measure will track the ability of the user of the CERHT to enable a user to set time and location configuration options when creating an export summary for one or more patients
- Measure 2: Conformance to 170.315(b)(6)(iii)(B)(1) – Execute at any time – This measure will track the ability of the CEHRT to create an export summary in real time (i.e., on demand).
- Measure 3: Conformance to 170.315(b)(6)(iv) – Location Configuration – This measure will track the ability of the CEHRT to permit a user to select a local or network storage location

Measure Justification: The RCP allows the Eye Care Leaders EHR user to share patient healthcare information for a single patient or a group of patients with an external organization using an export function. This information is typically shared when there is a need for the full patient record and should be executable on demand, according to the date and time and destination location chosen by the requestor.

Test Methodology: RCP File generator has the responsibility to interact with the appropriate EHR database and collect required information to generate CCDA files. Audit logs will record user actions and will be reviewed during the testing period to determine the frequency of data exporting requests. It may be necessary for the RWT team to initiate the export request as a naturally occurring Data Export request may not be done by the target clinic during the chosen RWT period. Log files obtained during RWT will be de-identified and reviewed to validate the proper functionality of the request process. Additionally, Exception Handlers and Coding logs will be reviewed for errors.

Expected Outcomes: It is expected that the authorized users will be able to share EHI using the export function. Error rates will be tracked and trended over time.

Use Case 5 (Single Patient/Multi-Patient): 170.315(c)(1) Clinical Quality Measurement – Record and Export

- Measure 1: Conformance to 170.315(c)(1)(i) – Record - This measure will track the ability of the CEHRT to able to record all of the data that would be necessary to calculate each CQM that the technology is certified for individual patients
- Measure 2: Conformance to 170.315(c)(1)(ii) – Export - This measure will track the ability of the CEHRT to be able to export a data file for single patient and multiple patients, formatted in accordance with the corresponding version of the QRDA I standard.

Measure Justification: The RCP is designed to allow the EHR user to capture specific certified clinical quality measures for QRDA I file creation and export to a designated destination file or URL. This allows for the quality measure data to be uploaded and calculated for the CMS MIPS Quality category by third party vendors, specifically Clinical Data Registries OR Qualified Clinical Data Registries.

Testing Methodology: Sixteen (16) Clinical Quality measures are certified by the Regulatory Compliance Platform. The target clinic(s) may or may not utilize all 16 measures. Multiple EHRs and target clinics may be required to demonstrate the full array of CQMs. QRDA I files will be de-identified and reviewed for appropriate measure inclusion or exclusion. An SFTP or similar server may be configured to simulate 3rd party receipt of data, if necessary. Comparison of data against a CDR or QCDR utilized by the clinic may be performed to validate data accuracy, if available.

Expected Outcome: It is expected that the CEHRT will evaluate and record Clinical Quality Measure data according to measure inclusion/exclusion eligibility into a QRDA I file and that the CEHRT can export a QRDA I data file for a single patient or for multiple patients.

8 Test Methods

8.1 Test Requirements and Resources

The following elements are required to support the overall RWT effort for all levels within the software platform:

- **Signed Client Consent Form** – this agreement is to be signed by an authorized representative of the client site and provides consent to access the client database for RWT purposes and acknowledges understanding of the purpose of RWT and that the RWT plan and results will be posted via pubilicly available hyperlink.
- **Test or staging environment** – this environment is to be ready to accept an installed and funtional copy of the CEHRT to be tested
- **Installed CEHRT -** is to be configured to exactly mirror the CEHRT in use by the client in prodution
- **Network –** LAN / Internet to simulate the real business and user environment.
- **Computer –** to simulate user environment in real world.
- **Synthetic Patient Data –** In order to protect patient identity**,** the CEHRT development team will use synthetic patient data to model the demographics and medical history of realistic patient health data. This modeled data will mirror a typical patient encounter(s) in order to generate the system and use case outcomes that are subject to RWT.
    - Data will include all elements found in the Common Clinical Data Set, allergies, medications, care plans, ICD10 and CPT codes as needed to align with the scenario and use case under test.
- **Trading Partner Access** – allows for third party confirmation of successful send/receipt of CCDA.

8.2 Justification of Mirrored Environment and Synthetic Data

Synthetic Patient Data – In order to protect patient identity**, or to initiate the use of certified functionality that may not be naturally trigged by the client,** the CEHRT development team may use synthetic patient data to model the demographics and medical history of realistic patient health data. This modeled data will mirror a typical patient encounter(s) in order to generate the system and use case outcomes that are subject to RWT.
Data will include all elements found in the Common Clinical Data Set, allergies, medications, care plans, ICD10 and CPT codes as needed to align with the scenario and use case under test

8.3 Testing Process Template Example

Health IT Module Name and Version:	**Certified Criterion:**	
Test Case ID:	**Test Case Description:**	
Created By	**Reviewed By**	**Regulation Text Citation:**

QA Tester's Log

Tester's Name		**Date Range Tested**		**Test Case (Pass/Fail/Not Executed)**	

S #	Preconditions:
1	Test environment configured
2	Access to accepted browser
3	Installed Health IT Module
4	Valid Username and password
5	Test data available
6	Interoperability Hub available

S #	Test Data Requirement
1	
2	
3	
4	

Test Conditions

Step #	Step Details	Expected Results	Actual Results	Performs to Expectation

Non-Conformities

TC Step #	Non-Conformity Description	Expected Results	Mitigation Strategy	Retest Date	Retest Results

9 Attestation

This Real-World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the Health IT Developer's Real World Testing requirements.

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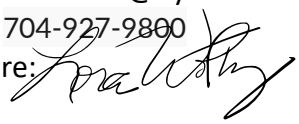
Authorized Representative Signature: 
Date: 11/12/2021

10 Terms/Acronyms

Make a mention of any terms or acronyms used in the project

TERM/ACRONYM	DEFINITION
API	Application Program Interface
AUT	Application Under Test
CCD	Continuity of Care Document
CCDA	Common Clinical Data Architecture
CCDS	Common Clinical Data Set
CEHRT	Certified Electronic Health Record Technology
CHPL	Certified Health Product Listing
EHR	Electronic Health Record
LAN	Local Area Network
PHI	Protected Health Information
RCP	Regulatory Compliance Platform
RWT	Real World Testing

REVISION HISTORY

Version	Date	Author	Description of Change
2021.1	6.14.2021	Lora Woltz	Draft
	11/12/2021	Lora Woltz	Final Draft