



2022 Real World Testing Plan
Eye Care Leaders, LLC

Plan Submission Year: 2021
For Testing Year: 2022

For Certified Electronic Health Record Technology:
myCare Portal Version 3.0

General Information	
Plan Report ID Number: (ONC-ACB use only)	2022RWTP_MCPv3
Developer Name	Eye Care Leaders, LLC
Product Name	myCare Portal
Version Number(s)	3.0
Certified Health IT	2015 edition
Product List (CHPL) ID(s)	15.04.04.2998.myCa.03.01.0.191231
Developer Real World Testing Page URL	https://eyecareleaders.com/about-eye-care-leaders/onc-certification/

Table of Contents

General Information.....	1
Plan Report ID Number: (ONC-ACB use only).....	1
Developer Name	1
Eye Care Leaders, LLC	1
Product Name.....	1
myCare Portal.....	1
Version Number(s).....	1
3.0	1
Certified Health IT.....	1
2015 edition	1
Product List (CHPL) ID(s).....	1
Developer Real World Testing Page URL.....	1
1 Introduction	3
1.1 Scope	4
1.1.1 Applications in Scope	4
1.1.2 Criterion Detail	4
2 Justification for Real World Testing Approach	5
3 Standards Updates.....	6
4 Care Settings.....	8
4.1 Settings of Care Description.....	8
4.2 Settings of Care Justification.....	8
5 Overall Expected Outcomes.....	9
6 Schedule of Key Milestones	9
7 Measures Used	10
7.1 Measure Use Case(s)	11
8 Test Methods	14
8.1 Test Requirements and Resources	14
8.2 Justification of Mirrored Environment and Synthetic Data.....	14
8.3 Testing Process Template Example	15
9 Attestation.....	16
10 Terms/Acronyms	17

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 (2021.1) 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
myCare Portal	3.0	(e)(1), (g)(7-9)

Table 1.0

1.1.2 Criterion Detail

§170.315	Criterion Name	Criterion Description (includes, not limited to)
(e)(1)	View, Download and Transmit	Patient (and authorized representative) must be able to use internet based technology to view, download and transmit their health information to a 3 rd party
(g)(7)	Application Access – Patient Selection	Software must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to execute request for patient data; Documentation must be provided via publicly available hyperlink
(g)(8)	Application Access – Data Category Request	Software must respond to requests for patient data (based on ID or other token); for each individual data categories specified in the Common Clinical Data Set and return full set of data for that category; respond to request for patient data associated with specific date and date range; Documentation must be provided via publicly available hyperlink
(g)(9)	Application Access – All Data Request	Software must respond to requests for patient data (based on ID or other token); return data in a summary record format ; respond to request for patient data associated with specific date and date range; Documentation must be provided via publicly available hyperlink

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

All 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.

myCare Portal Version 3.0, hereafter may also be referred to as Health IT Module or CEHRT, supports multiple certification criteria:

- **170.315(e)(1) View, Download and Transmit**
- **170.315(g)(7) Application Access – Patient Selection**
- **170.315(g)(8) Application Access – Data Category Request**
- **170.315(g)(9) Application Access – All Data Request**

The purpose of the system test is to demonstrate real world interoperability and conformance to the full scope of the platform's certification 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 be 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 mitigation 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.myCa.03.01.0.191231
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.myCa.03.01.0.191231
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(e)(1) View Download and Transmit
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.myCa.03.01.0.191231
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(g)(7) Application Access – Patient Selection
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.myCa.03.01.0.191231
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(g)(8) Application Access – data category request
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.myCa.03.01.0.191231
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(g)(9) Application Access – All Data Request
USCDI-updated certification criteria (and USCDI version)	None

4 Care Settings

4.1 Settings of Care Description

All Eye Care Leaders CEHRT platforms 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 myCare Portal 3.0 is conformant to the following certification criteria:
 - **170.315(e)(1) View, Download and Transmit**
 - **170.315(g)(7) Application Access – Patient Selection**
 - **170.315(g)(8) Application Access – Data Category Request**
 - **170.315(g)(9) Application Access – All Data Request**
- The myCare Portal is not a standalone product and is only provided for use in combination with one of Eye Care Leaders’ EHR products. myCare Portal is specifically marketed for use in ophthalmology and optometry practice settings as is in conjunction with the Eye Care Leaders EHR. RWT will demonstrate that the myCare Portal functions promote interoperability by providing health information to the patient by capturing the CCD created by the EHR and allowing the authorized user, patient or authorized patient representative to view, download or transmit their EHI. Additionally, myCare Portal provides on demand API functionality for integrated EHRs

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 CEHRT 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(e)(1) View Download and Transmit	(i)(A)(1) View ambulatory summary in human readable format in the patient portal
170.315(g)(7) Application Access - Patient Selection	(i) Identify a patient and return an ID or token that can be used by the application to execute requests for the patient's data
170.315(g)(8) Application Access - Data Category Request	(i)(A) API routine returns full set of data for each category of the CCD for the unique patient.
170.315(g)(8) Application Access - Data Category Request	(i)(B)(1) API responds to request for patient data for a specific date
	(i)(B)(2) API responds to request for patient data for a specific date range
	(i)(A) API responds to request for patient data for all data categories of the CCD for the unique patient.
170.315(g)(9) Application Access – All Data Request	(i)(B) API responds to request for patient data for a specific date or date range

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 CEHRT manages multiple functions for the same patient, the following criteria may be tested simultaneously:

Use Case 2 (Single Patient): 170.315(e)(1) View, Download and Transmit

- Measure 1: Conformance to 170.315(e)(1)(i)(A)(1) – View - This measure will track the ability of the patient/authorized patient representative of the myCare Portal to view in human readable format an ambulatory summary that has been sent to the patient portal.

Measure Justification: The CEHRT includes the ability to transfer the human readable health summary to the proprietary patient portal where the patient can view, download, and transmit the health care summary. The transitions of care, referrals and patient health care summaries are shared between organizations and the patient portal using Edge Protocol technology. Health Summaries are generated for each patient visit and for each update to the health record upon finalization of the patient exam by the overseeing provider.

Test Methodology: The myCare Portal will require an integrated Eye Care Leaders, LLC CEHRT to generate the patient's health care summary. Audit and system logs will be generated and reviewed to determine the frequency and success versus error rate of health summary transport to the patient portal. Log files may be de-identified and used for analysis of the ability to view the health summary record from the portal account.

Expected Outcome: It is expected that a health summary file will be generated and sent to the patient's portal account and that the health summary can be viewed in human readable format. Viewing of the health summary is contingent upon the patient having portal access and the finalization of the patient chart by the overseeing provider. It is also expected that the health summary will be generated for each patient encounter or update to the patient record.

Use Case 6 (Single Patient): 170.315(g)(7),(8) and (9) Application Access

The following criteria may be tested simultaneously:

Use Case 6A: 170.315(g)(7) Application Access – Patient Selection

- Measure 1: Conformance to 170.315(g)(7)(i) – Identify – This measure will track the ability of the API to identify a patient and return an ID or token that can be used by the application to execute requests for the patient's data

Use Case 6B: 170.315(g)(8) Application Access – Data Category Request

- Measure 1: Conformance to 170.315(g)(8)(i)(A) – Individual Category Request - This measure will track the ability of the API routine to return a full set of data for each category of the CCD for the unique patient.
- Measure 2: Conformance to 170.315(g)(8)(i)(B))1) – Specific Date Request - This measure will track the ability of the API to respond to a request for patient data for a specific date
- Measure 3: Conformance to 170.315(g)(i)(B)(2) - This measure will track the ability of the API to respond to a request for patient data for a specific date range

Use Case 6C: 170.315.(g)(9) Application Access- All Data Request

- Measure 1: Conformance to 170.315(g)(9)(i)(A) – Unique Patient – all records - This measure will track the ability of the API to respond to a request for patient data for all data categories of the CCD for the unique patient.

- Measure 2: Conformance to 170.315(g)(9)(i)(B)- Date/Date Range Request - API responds to request for patient data for a specific date or date range

Measure Justification for 170.315(g)(7-9): APIs enable patients to view, download, or transmit their health information using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT. API technology is intended to accommodate the full range of API certified functionalities to pull patient data for a single patient. These measures will look at the performance of the certified API technology to manage multiple functionalities at once. Performance will pertain to token creation and the ability of the API to pull category specific data and all category data for the chosen date or date range.

Test Methodology: The API requires an active patient portal account along with an Eye Care Leaders, LLC CEHRT. RWT will review the ability of the CEHRT to authenticate user credentials to create a token for the unique patient and then the ability to access the PHI data for the patient with the search criteria or input through the patient application. Data accessed can be downloaded in the form of a CDA XML or by HTML human readable format. Date ranges and CDA subsections may be queried separately or together.

System logs will be reviewed for error codes indicating a bad request response or unauthorized credentials. Log files will be de-identified and used for analysis to ensure proper functionality. The API feature of the CEHRT is not utilized in normal day to day practice. The API feature of the CEHRT is not utilized in normal day to day practice. Real World Testing may require the direct initiation of an API event(s) by the CEHRTS's RWT team in conjunction with the CEHRT client's application under test.

Expected Outcomes: It is expected that the CEHRT will perform API calls with a minimum of error. The API feature of the myCare Portal is not utilized in normal day to day practice. Real World Testing may require the direct initiation of an API event(s) by the myCare Portal's RWT team in conjunction with the CEHRT client's application under test. Error rates will be tracked and trended over time.

7.2 Relied Upon Software

myCare Portal Version 3.0 requires the use of the CEHRT Module: Regulatory Compliance Platform (RCP) Version 1.4. for the following certified functions: 170.315(e)(1) View, Download, and Transmit

1. The RCP assists the EHR module with supporting certified capability related to care coordination and patient engagement including the creation of electronic health information documents (CCD) required for referrals, transitions of care and to share with the patient; the CCD is then passed from the EHR to the Portal using RCP.
2. Send/receive messages and attached documents to/from the HIPS via Direct Edge Protocol

Furthermore, myCare Portal Version 3.0 requires the use of an Eye Care Leaders, LLC certified EHR to provide the patient health information that is populated on the CCD. Real World Testing may utilize multiple EHRs to best demonstrate the interoperability of 170.315(e)(1) View, Download, and Transmit between the EHR and the myCare Portal.

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 publicly available hyperlink.
- **Test or staging environment** – this environment is to be ready to accept an installed and functional copy of the CEHRT to be tested
- **Installed CEHRT** - is to be configured to exactly mirror the CEHRT in use by the client in production
- **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 triggered 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.

Authorized Representative Name: Lora Woltz

Authorized Representative Email: lora.woltz@eyecareleaders.com

Authorized Representative Phone: 704-927-9800

Authorized Representative Signature:

A handwritten signature in black ink, appearing to read "Lora Woltz", written over the signature line.

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
RWT	Real World Testing

REVISION HISTORY

Version	Date	Author	Description of Change
2021.1	6.14.2021	Lora Woltz	Draft