



2022 Real World Testing Plan

Management Plus 7.0

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2022 Real World Testing Plan – Management Plus 7.0

Revision History

The Revision History table below provides a record of all revisions made to this document throughout its life cycle. Updates are tracked by the version number, the date of the revision, the author, and a description of the change.

Version	Date	Author	Description of Change
2021.1	6.14.2021	Lora Woltz	Draft
2022.1	11.01.2022	Lora Woltz	Update for 2023 Submission

General Information

General Information	
Plan Report ID Number: (ONC-ACB use only)	2023RWTP_MANv7
Developer Name	Eye Care Leaders, LLC
Product Name	Management Plus
Version Number(s)	7.0
Certified Health IT	2015 edition
Product List (CHPL) ID(s)	15.04.04.1864.Mana.07.00.1.171231
Developer Real World Testing Page URL	https://eyecareleaders.com/about-eye-care-leaders/onc-certification/

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 2023**.

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
Management Plus	7.0	(b)(1), (b)(2), (b)(6), (e)(1)

Table 1.0

1.1.2 Criterion Detail

§170.315	Criterion Name	Criterion Description (includes, not limited to)
(b)(1)	Transitions of Care	Software must be able to create, send and receive transitions of care/ referral summaries via edge protocol; be able to detect valid and invalid transitions of care/referral summaries; display the data received in the transition of care/referral summary in human readable format; allow for the individual display of each section
(b)(2)	Clinical Information and Incorporation	Software can properly match a received Transition of Care/ Referral Summary to the correct patient; allow user to electronically and simultaneously display the patient's active data for medication, allergies and problem list from at least two list sources in a single view; User can review, validate and incorporate a patient's medication list, allergies and problem list; software can create a C-CDA document that includes the reconciled and incorporated data
(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
(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 3rd party

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.

Management Plus EHR Version 7.0, hereafter may also be referred to as Health IT Module or CEHRT, supports multiple certification criteria:

- 170.315(b)(1) Transitions of Care
- 170.315(b)(2) Clinical Information Reconciliation and Incorporation
- 170.315(b)(6) Data Export
- 170.315(e)(1) View, Download and Transmit

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 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	15.04.04.1864.Mana.07.00.1.171231
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)(1) Transitions of Care
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	15.04.04.1864.Mana.07.00.1.171231
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)(2) Clinical Information Reconciliation and Incorporation
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	15.04.04.1864.Mana.07.00.1.171231
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	15.04.04.1864.Mana.07.00.1.171231
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

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 Health IT Module is conformant to the following certification criteria:
 - o 170.315(b)(1) Transitions of Care
 - o 170.315(b)(2) Clinical Information Reconciliation and Incorporation
 - o 170.315(b)(6) Data Export
 - o 170.315(e)(1) View, Download and Transmit
- The Health IT Module is specifically marketed to ophthalmology and optometry practice settings. RWT will demonstrate that the Health IT Module exchanges EHI in the expected manner in ophthalmology care settings, specifically the interoperability related criteria of creating, sending, and receiving the CCDA, providing health information to the patient and providing patient data on demand.
- RWT will demonstrate that the Health IT Module supports Edge Protocol via STMP transport.

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	01/31/2023

Subject Matter Expert	
Test Environments Ready	03/31/2023
Perform Real World Testing	Q2 and Q3 2023
Report status of scheduling and/or testing issues, successes, remediation needs, fixes, deviations from test plan etc.	06/30/2023
Soft deadline for testing completion	10/31/2023
Hard deadline for testing completion	12/31/2023
Detailed Test Data results submission	01/15/2024
Test Summary Report Finalized	01/31/2024
Test Summary Report Submission to ACB	02/15/2024

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(b)(1) Transitions of Care	(i)(A) Send transition of care/referral (i)(B) Receive transition of care/referral
170.315(b)(2) Clinical Information Reconciliation and Incorporation	(ii) Correct Patient – received transition of care/referral can be correctly matched to the specific patient (iii) Reconciliation – user can review, validate, and incorporate a patient’s medication list, allergies, and problems list
170.315(b)(6) Data Export	(iii)(A) Set Time and Date (iii)(B)(1) Execute at any time (iv) Location Configuration
170.315(e)(1) View Download and Transmit	(i)(A)(1) View ambulatory summary in human readable format in the patient portal

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 1: (Single Patient): 170.315(b)(1) Transitions of Care

- **Measure 1:** Conformance to 170.315(b)(1)(i)(A) Transitions of care – Sending – This measure will track the export of CCD created by the CEHRT and monitor the ability to share the CCD with the intended recipient using Edge protocols.
- **Measure 2:** Conformance to 170.315(b)(1)(ii)(B) Transitions of care – Receiving – This measure will track the ability of the CEHRT to display the data received in the transition of care/referral summary in human readable format

Measure Justification: The CEHRT has been developed to provide the eye care provider the ability to document, store and share EHI regarding a patient’s visit in an ambulatory care setting. The CEHRT allows for the creation of the patient health information based on the patient visit, and according to the Consolidated Clinical Document Architecture (CCDA) template categories. The CEHRT allows for the sharing of CCDs between providers and patients both within and outside of the healthcare practice of care within using Edge protocols.

Test Methodology: The CEHRT utilizes Secure Exchange Solutions (SES Direct) as the HISP to perform authentication, encryption, trust verification and acknowledgement of responsibility to deliver the message utilizing SMTP transport protocol as specified in the Applicability Statement for Direct Secure Health Transport when securely routing messages from a sender’s address to an intended recipient’s address. SES Direct provides API Reporting that will allow for the retrieval of details about the transmissions of all DSM transmissions.

Comparative Summaries will be collected using EHR audit and system logs to determine the frequency of and the transport mechanism used by providers. Log files obtained during Real World Testing will be de-identified and used for analysis to ensure that the creation and export of CCDA files is reflected in the API reporting provided by the HISP.

Expected Outcomes: It is expected that providers will be able to share EHI using the transmission mechanisms provided. It is expected that a higher rate of success will be seen for the creating and sending of a CCD versus the receipt of an external CCD. This is because of the lack of control over the quality of data occurring in an externally generated CCD and errors may exist that prohibit the acceptance of the CCD into the EHR.

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 CEHRT 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: 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 3: (Single Patient) Metrics: 170.315(b)(2) Clinical Information Reconciliation and Incorporation

- **Measure 1:** Conformance to 170.315(b)(2)(ii) Clinical Information Reconciliation and Incorporation – Correct Patient – This measure will track the ability of the CEHRT that a received transition of care/referral can be correctly matched to the specific patient
- **Measure 2:** Conformance to 170.315(b)(2)(ii) Clinical Information Reconciliation and Incorporation – Reconciliation – This measure will track the ability that a user of the CEHRT can review, validate, and incorporate a patient's medication list, allergies, and problems list from a correctly matched transition of care/referral

Measure Justification: Transitions of Care and/or referrals may be received electronically internally from provider to provider within the practice or externally from a different provider. Correctly matching the incoming or received health record to the appropriate patient and then performing the reconciliation of medication lists, allergies and problems is vital to patient safety and demonstrates the intention of data interoperability. The CEHRT allows for the receipt of an inward bound patient health summary, patient/record matching of the incoming transition of care and/or referral and reconciliation of medications, medication allergies and problem lists associated with the incoming CCD.

Test Methodology: The EHR will utilize a combination of audit and system logs to record the success or failure of actions related to patient matching and

reconciliation within the EHR. The volume of naturally occurring transition of care or referrals received by the target clinic during the chosen RWT period cannot be anticipated prior to testing. In which case, the EHR's RWT team may initiate transactions involving synthetic patient data in order to generate a sufficient volume of transactions to demonstrate the measure.

Expected Outcomes: It is expected that providers will be able to match and reconcile the medications, allergies and problem lists to the correct patient using the mechanisms provided. Error rates are to be tracked and trended over time.

Use Case 4: (Single 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 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 CEHRT can 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: System logs and audit file records 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.

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.

7.2 Relied Upon Software

Management Plus EHR Version 7.0 requires the use of the CEHRT Module: Regulatory Compliance Platform (RCP) Version 1.4. for the following certified functions: 170.315(b)(1) Transitions of Care:

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 required for referrals, transitions of care and to share with the patient;
2. Send/receive messages and attached documents to/from the HIPS via Direct Edge Protocol

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.
 - o 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)

Preconditions

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

Test Data Requirement

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 Key Milestones

9.1 Milestones

Describes when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Test plan finalized	Done by ACB	01/01/22
Test Template released to platforms	Internal	01/01/2022 - 01/31/22
Set up mirror test environments	Ambulatory Specialty Care	01/31/2022
Develop use cases	Ambulatory Specialty Care	01/31/2022
Data preparation complete	Ambulatory Specialty Care	01/31/2022
Testing period opens	Ambulatory Specialty Care	02/01/2022
Testing Period closes	Ambulatory Specialty Care	10/31/2022
Testing completed for all Platforms	Ambulatory Specialty Care	11/01/2022
Non-conformity reports prepared	Internal	11/30/2022
Test Results Summary due to ONC HIT Certification Manager	Internal	01/01/2023
Test Results Report	Internal	02/15/2023

Finalized		
Test Results Report Submission	Internal	02/15/2023
Report uploaded to CHPL	Done by ACB	03/15/2023

10 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: Lora Woltz

Date: 11/03/2022

11 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