



Real World Testing Plan
Eye Care Leaders, LLC

Plan Submission Year: 2021
For Testing Year:2022

For Certified Electronic Health Record Technology:
Medflow EHR Version 9.0

General Information	
Plan Report ID Number: (ONC-ACB use only)	2022RWTP_MEDv9
Developer Name	Eye Care Leaders, LLC
Product Name	Medflow
Version Number(s)	9.0
Certified Health IT	2015 edition
Product List (CHPL) ID(s)	15.04.04.2998.Medf.09.00.1.171220
Developer Real World Test Page URL	https://eyecareleaders.com/about-eye-care-leaders/onc-certification/

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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
Medflow	9.0	(b)(1), (b)(2)
Regulatory Compliance Platform	1.4	Assists in (b)(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
(b)(2)	Clinical Information and Incorporation	Software can properly match a received Transition of Care/ Referral Summary to the correct patient; User can review, validate and incorporate a patient's medication list, allergies and problem list

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.

Medflow EHR Version 9.0, hereafter may also be referred to as Health IT Module or CEHRT, supports multiple certification criteria 170.315(b)(10) Transitions of Care and 170.315(b)(2) Clinical Information Reconciliation and Incorporation

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	15.04.04.2998.Medf.09.00.1.171220
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	15.04.04.2998.Medf.09.00.1.171220
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

4 Care Settings

4.1 Settings of Care Description

Medflow EHR Version 9.0 is 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)(1) Transitions of Care**
 - **170.315(b)(2) Clinical Information Reconciliation and Incorporation**
- 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.
- RWT will demonstrate that the Health IT Module supports SMTP transport protocol

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/or 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(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

7.1 Measure Use Case(s)

Use Case 1: (Single Patient) Metrics: 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: Verification of the created patient record export does require interaction with a system external to the organization (and with a different vendor).

The CEHRT utilizes Updox 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. Updox provides API Reporting that will allow for the retrieval of details about the transmissions of all DSM transmissions.

It is anticipated that the transmission details will include, but are not limited to, the following scenarios to verify transmissions success or failure:

Scenario	MDN Status
When receiving a Direct message	Processed
When receiving a Direct message <u>and</u> successfully delivering to the Edge Client <u>and</u> sending HISP requested a Dispatched MDN	Dispatched
When receiving a Direct message <u>and</u> unable to deliver to Edge Client	Failure
When sending a Direct message <u>and</u> counterparty HISP doesn't send a Processed MDN within 60 minutes	Failure

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 CCD 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) 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.

7.2 Relied Upon Software

Medflow EHR Version 9.0 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 for the client in production
- **Network** – LAN / Internet installed by the client in the real business and user environment.
- **Computer** – to access the CEHRT in real world.
- **Synthetic Patient Data** – In certain situations, such as when the certified function under test is not naturally performed by the target practice during the RWT period date range, it may be necessary to use synthetic patient data. In those situations, 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)	
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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

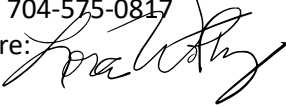
Step #	Step Details	Expected Results	Actual Results	Performs to Expectation

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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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
2021.1	11.08.2021	Lora Woltz	Final