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2025 Real World Testing Plan
Regulatory Compliance Platform 2.0

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 date the revisions were made, the version number, a brief description of the changes made and reason, as well as the name of the reviser and the approver.

Effective Date	Version #	Change Description/ Reason	Created/Revised by	Reviewed by	Approved by
10.29.2024	2025.1	2025 Update, add b10	Lora Woltz	Lora Woltz	Lora Woltz

Product Information

Product Information	
Plan Report ID Number: (ONC-ACB use only)	2025RWTP_RCPv2
Developer Name	Sightview EHR Holdings, LLC
Product Name	Regulatory Compliance Platform
Version Number(s)	2.0
Certified Health IT	ONC Certification Criteria for Health IT
Product List (CHPL) ID(s)	15.04.04.2998.Regu.02.03.1.221230
Developer Real World Testing Page URL	ONC Certification | Sightview

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Introduction

This test plan describes the testing approach and overall framework that will drive the testing of Sightview EHR Holdings, LLC ONC Certification Criteria for Health IT 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 1.4.

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 (2025.1) is associated with the testing to be conducted in **CY 2025**.

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, 2024.

Platform	Version	Criterion to be Tested
Regulatory Compliance Platform	2.0	(b)(10)

Table 1

1.1.2 Criterion Detail

§170.315	Criterion Name	Criterion Description (includes, not limited to)
(b)(10)	EHI Export	EHR Software enables a user to timely create an export file(s) with all of a single patient's electronic health information stored at the time of certification; A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. The export file is in an electronic and computable format.

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

Sightview EHR Holdings, LLC Certified Health IT Modules are sold only to the Ophthalmology / Optometry specialty care settings as part of an integrated CEHRT system. 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.

The Regulatory Compliance Platform 2.0, hereafter may also be referred to as Health IT Module or CEHRT, supports multiple certification criteria subject to Real World Testing:

- **170.315(b)(10) EHI Export**

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. Therefore, Regulatory Compliance Platform 2.0, will use Test Scenario, Use Case 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 1.4.

The testing will be performed by the Product Compliance Officer with assistance by individual developers, subject matter experts or support team leads as required. 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. 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). Regulatory Compliance Platform performs EHI exporting via the use of an integrated EHR software platform.

3 Standards Updates

Standard (and version)	All Standards included in C-CDA R2.1
Certification criteria	**170.315(b)(10) EHI Export**
Health IT Module CHPL ID	15.04.04.2998.Regu.02.03.1.221230
Health IT Module Product ID	15.04.04.2998.Regu.02.03.1.221230
Method used for standard update	Minimum Standard Code Sets
Date of ONC-ACB notification	Not Applicable
Date of customer notification (SVAP only)	Not Applicable
USCDI-updated certification criteria (and USCDI version)	Version 1

4 Care Settings

4.1 Settings of Care Description

Sightview EHR Holdings, LLC 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	Sightview Software, LLC 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 used in 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)(10) EHI Export

The Regulatory Compliance Platform, henceforth called RCP is not a standalone product and is only provided in combination with one of Sightview Software, LLC EHR products. RCP is not intended to be actively marketed but is a ONC Certified Health IT Module. RWT will demonstrate that the RCP, when integrated with an Sightview Software, LLC EHR, exchanges EHI in the expected manner in ophthalmology care settings, specifically the interoperability related criteria of providing health information via EHI Export.

6 Key Milestones

Key Milestone	Date / Timeframe
Preparation of templates, instructions, forms, and schedules to be released to the platform's Subject Matter Experts as needed	01/31/2025
Test Environments Ready	03/31/2025
Perform Real World Testing	Q2, Q3, Q4 2025
Interim Report status of scheduling and/or testing issues, successes, remediation needs, fixes, deviations from test plan etc.	06/30/2025
Soft deadline for testing completion	09/31/2025
Hard deadline for testing completion	12/31/2025
Detailed Test Data results submission	01/15/2026
Test Summary Report Finalized	01/31/2026
Preparation of templates, instructions, forms, and schedules to be released to the platform's Subject Matter Experts as needed	01/31/2025

7 Measures Used

The CEHRT is certified to multiple criteria that must comply with 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)(10) EHI Export	(i)(D) Export is available in electronic and computable format

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) Metrics: 170.315(b)(10) EHI Export

- Measure 1: Conformance to 170.315(b)(10)(i)(D) – Electronic Format – This measure will track the ability of the CEHRT to create the EHI Export file in an electronic and computable format.

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: The RCP requires the use of a Sightview Software, LLC integrated EHR platform to perform EHI exporting as the USCDI data elements received from the integrated EHR is duplicative of the data elements included in the EHI Export File generated by the EHR. EHR System logs and audit file records will be reviewed during the testing period to determine the frequency of data export requests. EHI Export is not widely used in the daily clinic scenario so it may be necessary for the Tester 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. For this reason, we intend to demonstrate that the functionality is available and can be successfully utilized by the client, regardless of the frequency of use.

Expected Outcomes: It is expected that the authorized users will be able to generate an electronic and computable EHI export file using the export function on demand. It is expected that there will be a very low rate of usage with a high success rate.

7.2 Relied Upon Software

The Regulatory Compliance Platform 2.0 requires the use of an integrated CEHRT Sightview EHR Module as relied upon software for the following certified functions: 170.315(b)(10) EHI Export.

1. The integrated CEHRT is responsible for the generation of the actual patient health information that is transmitted to the RCP and included in the EHI Export file.

Real World Testing may utilize multiple EHRs to best demonstrate the interoperability of 170.315(b)(10) EHI Export between the EHR and the RCP.

8 Test Methods

8.1 Test Requirements and Resources

- 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 a user environment in the 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 USCDI, 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 USCDI v. 1., allergies, medications, care plans, ICD10 and CPT codes as needed to align with the scenario and use case under test

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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

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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