

# REAL WORLD TESTING PLAN 2025

## BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result.

**While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

## INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan. Each section provides a field for submitting responses and explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information required for



developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

## GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: **Ehnote Inc.**

Product Name: **Ehnote**

Version Number(s): **v1.0**

Certified Health IT Product List (CHPL) ID(s):

**15.04.04.3171.EHNO.01.00.1.231025**

Developer Real World Testing Page URL:

<https://ehnote.com/certification/certification-link>

## JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing.

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified 2 capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

## STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ Identify standard versions
- ✓ Indicate what certification criteria in which product(s) has been updated
- ✓ If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products
- ✓ *CHPL ID for each Health IT Module*
- ✓ Method used for standard update (e.g., SVAP)
- ✓ Date notification sent to ONC-ACB
- ✓ *If SVAP, date notification sent to customers*
- ✓ Measure used to demonstrate conformance with updated standard(s)
- ✓ Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?

<b><i>Standard (and version)</i></b>	N/A
<b><i>Updated certification criteria and associated product</i></b>	N/A
<b><i>Health IT Module CHPL ID</i></b>	N/A
<b><i>Method used for standard update</i></b>	N/A
<b><i>Date of ONC ACB notification</i></b>	N/A
<b><i>Date of customer notification (SVAP only)</i></b>	N/A
<b><i>Conformance measure</i></b>	N/A

## MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module’s scope of certification. Describe the method for measuring how the approach(es) chosen to meet the intent and purpose of Real-World Testing.

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

### Description of Measurement/Metric

*Describe the measure(s) used to support the overall approach to Real World Testing.*

Criteria	Measurement/Metric	Description
Referrals (§170.315(b)(1))	Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	As part of Real-World Testing, we will be evaluating outpatient: 170.315(b)(1) criteria. Our goal is to enhance patient care by providing secure information to referrals.
Clinical information reconciliation export (§170.315(b)(2))	Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA	The Ehnote supports all kinds of Clinical information reconciliation and incorporation criteria which can be demonstrated by exporting the patient information on a regular basis which adheres to the C- CDA standards. Clinical information data export like medical history, Surgical history, allergies etc. over 3 months will demonstrate this measure. Data will be verified manually.
Electronic Health Information Export (§ 170.315(b)(10))	1) Export the patient EHI data for single and multiple patients without developer assistance.  2)EHI exported data are available in both computable and human readable format.	This will demonstrate the portal as a key tool for the users to export electronic health information (EHI) for a single and multiple patients at any time the user chooses without developer assistance.

<p>Patient Engagement (§170.315(e)(1))</p>	<p>Over a 90-day period:</p> <ol style="list-style-type: none"> <li>1) Number of views of health information by a patient or authorized representative</li> <li>2) Number of downloads of health information by a patient or authorized representative</li> <li>3) Number of transmissions of health information by a patient or authorized representative using email</li> </ol>	<p>This measure tracks and counts how many patients are logged into and accessed their patient portal account and email transmissions from the portal over a given interval (3 months). The goal of the approach for Patient Engagement is to demonstrate and validate the patient activities through logs which will give us details about how many patients make use of patient engagement functionality through the patient portal. This data will be provided for 3 months.</p>
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<p>Application access— patient selection § 170.315(g)(7)</p>	<ol style="list-style-type: none"> <li>1) Number of requests for a patient ID</li> <li>2) Number of requests that provided sufficient information</li> <li>3) Number of follow-up requests made using the provided patient ID</li> </ol>	<p>As part of the Real World Testing, we will be evaluating the 170.315(g)(7) Application access - patient selection criteria and test if the Ehnote application should be able to show selected patient’s information, about demographics data, visit history, disease history, surgeries done, prescribed medicine, allergies.</p>
<p>Application access— all data request § 170.315(g)(9)</p>	<ol style="list-style-type: none"> <li>1) Number of requests for a patient’s Summary Record made by an application via an all data category request using a valid patient ID</li> <li>2) Number of requests for a patient’s Summary Record made by an application via an all data category</li> </ol>	<p>As part of the Real World Testing, We will be evaluating the 170.315(g)(9) criteria and test the patient's Summary Record, if the Data is coming as desired.</p>
<p>Standardized API for Patient and Population Services § 170.315(g)(10)</p>	<p>This measure is counting how many API applications can be registered, authenticated, and actively working with our EHR. The metric will provide a numeric value to indicate both how often this interoperability feature is being used as well as its compliance to the requirement.</p>	<p>This measure will be tracking and counting how many successful 3 rd party API client applications can access patient data elements via our API over the course of a given interval. The interval for this measure will be three (3) months.</p>
<p>Direct project § 170.315(h)(1)</p>	<p>Over a 90-day period:</p> <ol style="list-style-type: none"> <li>1) Number of Direct Messages sent</li> <li>2) Number of Delivery Notifications received</li> <li>3) Number of Direct Messages received</li> </ol>	<p>Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from “outside” developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used.</p>

### Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
Care Coordination	§170.315(b)(1) Transitions of care
Care Coordination	§170.315(b)(2) Clinical information reconciliation and incorporation
Patient Engagement	§ 170.315(b)(10) Electronic Health Information Export
Patient Engagement	§170.315(e)(1) View, download, and transmit to 3rd party
Application Programming Interfaces	§ 170.315(g)(7) Application access— patient selection
Application Programming Interfaces	§ 170.315(g)(9) Application access— all data request
Application Programming Interfaces	§ 170.315(g)(10) Standardized API for Patient and Population Services
Direct Project	§ 170.315(h)(1) Direct Project

### Justification for Selected Measurement/Metric

*Explain the measurement/metric selected to conduct Real World Testing.*

Criteria	Justification
Transitions of care (§170.315(b)(1))	This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards. However, it is not possible to consistently and reliably demonstrate that all required standards were used because not all CCDAs created in a real-world setting contain all the necessary data elements. We intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
Clinical information reconciliation export (§170.315(b)(2))	This criterion requires the ability of a certified Health IT module to take a CCDa received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. We intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective.
Electronic Health Information Export (§ 170.315(b)(10))	Exporting electronic health information (EHI) data by users for patients on demand. And the export can be done for single or multiple patients, the exported data can should be in both computable and human readable formats. The system will be able to record how many exports are been done on demand.
Patient Engagement (§170.315(e)(1))	This use case has three metrics which measure real world interoperability actions of patients and their secure portals. This measure will provide a numeric value to indicate both how often patients log into their patient portal to view, download, or transmit their health data. These activities show how patients commonly utilize a patient portal as well as the breadths of its use with other health care entities

Interoperability and Data Exchange (§ 170.315(g)(7))	Ehnote provides access to specific patient data through Carefluence, this will provide a metric on the use of APIs to access patient data. This will be verified through the review of the log files. We intend to record the frequency that patient ID requests are received by providers via API to demonstrate the certified capability is available and effective.
Application access— all data request § 170.315(g)(9)	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature
Standardized API for Patient and Population Services (§ 170.315(g)(10))	A successful measure increment indicates compliance to the underlying ONC criteria. It will show that a 3rd party client can be authenticated, that the patient record can be properly identified and selected, and that the EHR can make patient data accessible via its API interface.
Direct project (§ 170.315(h)(1))	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received through our 3 <sup>rd</sup> party integration called EMR Direct.

### Care Setting(s)

The expectation is that a developer’s Real World Testing plan will address each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Ehnote is a cloud based EHR/EMR for ophthalmology	Ehnote is a cloud based EHR that has been designed for ophthalmology specialty.

### Expected Outcomes

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

- 1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
- 2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
- 3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes
Transitions of care (§170.315(b)(1))	It is expected that the user is able to create a CCD format for patient data transitions with the help of secure access that also includes the reason for referral, and the name and contact information of the provider. It is expected that the user is able to create a Summary Document.
Clinical information reconciliation export (§170.315(b)(2))	All the Clinical information reconciliation data like medications, medical history, allergy, surgery history etc. can be exported manually without any errors or losing any data. This will make sure that no data has been lost and it is accurate. We are expecting high utilization with zero errors
Electronic Health Information Export (§ 170.315(b)(10))	The Real-World Testing will demonstrate that users are enabled to export patients EHI data. They can: 1) Create patient EHI data 2) Export EHI data for both single and multiple patients at any time without developer assistance 3) EHI exported data are available in both computable and human readable format Expectation is low utilization by clinicians with a high success rate.
Patient Engagement (§170.315(e)(1))	The measurements will produce numeric results over a given time interval of a minimum of three (3) months. We will utilize various reports and audit logs to determine our measure count with the test data. For all measures, a successful increment indicates compliance to the underlying ONC criteria. It will show that test patients can log into their patient portal to access their test patient data and transmit their health data to a 3rd party. We will use the measure counts to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts. Our expectation is there will be good utilization by our clients for view, download and transmit with a high success rate for all certified capabilities.



Interoperability and Data Exchange (§ 170.315(g)(7))	Log files obtained during Real World Testing will be identified and used for analysis to validate the proper operation of criteria g(7) with less than 1 percent error rate experienced by our clients. We have added interactive testing methodology for these capabilities to the test plan to demonstrate the feature is available and functions as expected should any users elect to begin using this feature
Application access— all data request § 170.315(g)(9)	The real-world testing will be identified and validated for accuracy and conformance with 170.315(g)(9) criteria using the test data, with less than 1 percent errors. We have added interactive testing methodology for these capabilities to the test plan to demonstrate the feature is available and functions as expected should any users select to begin using this feature.
Standardized API for Patient and Population Services § 170.315(g)(10)	Our expectation is there will be moderate utilization by providers with a high success rate using test data.
Direct project § 170.315(h)(1)	Our expectation is there will be moderate utilization by providers with a high success rate using test data.

**Key Milestones:**

How and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/time frame during which data will be collected.

Key Milestone	Care Setting	Date/Time Frame
Real World Testing plan submission	Ophthalmology	90 Days
Begin collection of information as laid out by the plan	Ophthalmology	90 Days
Follow-up with providers and authorized persons to understand any issues arising with the data collection.	Ophthalmology	90 Days



## **ATTESTATION**

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.<sup>#</sup>

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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