REAL WORLD TESTING RESULTS REPORT TEMPLATE

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (Certification 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 and results reports.

A 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. To accompany the plan template, ONC has also provided this results report template.

While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). 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 results report will include a list of these 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 Certification Program requirements referenced in this resource.

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Certification Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - Section VII.B.5 — *"Real World Testing"*

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

GENERAL INFORMATION

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

Product Name(s): i-heal 2.0

Version Number(s): 2.0

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.1575.ihea.02.00.1.191007

Developer Real World Testing Plan Page URL: https://www.healogics.com/2015-certified-ehr-technology/

Developer Real World Testing Results Report Page URL [if different from above]:

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	**Reason** [Describe the reason this change occurred]	**Impact** [Describe what impact this change had on the execution of your Real World Testing activities]

[OPTIONAL] WITHDRAWN PRODUCTS

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

Product Name(s):	
Version Number(s):	
CHPL Product Number(s):	
Date(s) Withdrawn:	
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

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

Please refer to page 6 through 12.

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.

Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).

☑ Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below.

☐ No, none of my products include these voluntary standards.

Standard (and version)	HL7 FHIR US Core Implementation Guide STU 4.0.0
Updated certification criteria and associated product	170.315(g)(10) and i-heal 2.0
CHPL Product Number	15.04.04.1575.ihea.02.00.1.191007
Conformance measure	

Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within 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.

List each care setting that was tested.

All Healogics Real World Testing was conducted in outpatient-ambulatory wound care practices.

Metrics and Outcomes

Health IT developers should detail outcomes from their testing that 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)

Health IT developers could also detail outcomes that did 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 their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
#1, #2	(b)(2)(h)(1)	Secure Exchange Sol	Successful	N/A
#3	(b)(3)	Surescripts	Successful	N/A

KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe

Healogics i-heal 2.0 Real-World Test Plan

Testing Measurements

For each measurement, a testing methodology is used. For our test plan, we use the following methodologies.

- Reporting/Logging: This methodology uses the logging or reporting capabilities of the EHR to examine functionality performed in the system. A typical example of this is the measure reporting done for the automate measure calculation required in 315(g)(2), but it can also be aspects of the audit log or customized reports from the EHR. This methodology often provides historical measurement reports which can be accessed at different times of the year and evaluate interoperability of EHR functionality, and it can serve as a benchmark for evaluating real world testing over multiple time intervals.

RWT Measure #1 Transition of Care C-CDA

Associated Criteria: 315(b)(1), (h)(1)
Additional Software Needed: Secure Exchange Direct Messaging

Testing Methodology: Reporting/Logging

Measurement Description: This use case is tracking how many C-CDAs are created and successfully sent from the EHR Module to a 3rd party during a transition of care event using Direct messaging over the course of a given interval.

Measurement Justification:
This use case has one measure capture. It will provide a numeric value to indicate both how often this interoperability feature is being used as well as its compliance to the requirement. This measure indicates that the EHR can create a C-CDA patient summary record, including ability to record all clinical data elements, and by sending the C-CDA patient summary record, the EHR demonstrates successful interoperability of an exchanged patient record with a 3rd party. This measurement shows support for Direct Edge protocol in connecting to a HISP for successful transmission which reveals compliance to the associated criteria listed above.

Measurement Expected Outcome:
We will test a sample of our user base to get reporting values on C-CDAs sent as well as performance of C-CDA error detection.

Measure #1: Report the numbers of C-CDAs sent over a three (3) month period.

This metric can come from different reports, including Automated Measure (315.g.2) reports. A successful measure increment indicates compliance to the underlying ONC criteria, including successful creation of the C-CDA patient summary record and recording the required clinical data elements. In sending the C-CDA patient summary record, the EHR will demonstrate ability to

confirm successful interoperability of an exchanged patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP.

Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Results for Measure #1: From 10/1/2022-12/30/2022 our clients transmitted 3 C-CDAs, indicating a low usage. As a result, we will continue to educate our end-users on the availability and purpose of the functionality.

RWT Measure #2 Incorporating Problem List, Medications, Allergies

Associated Criteria: 315(b)(2)
Additional Software Needed: Secure Exchange Direct Messaging

Testing Methodology: Reporting/Logging

Measurement Description: This is a measure to determine how often you are using the C-CDA incorporate and update feature.

Measurement Justification:
This measure will validate, through reporting, users to determine real world interoperability and usability, specifically how often are C-CDAs received from 3rd parties incorporated into the patient record and then updating the patient's problem list, medication list, and medication allergy list with the clinical data contained in the C-CDA.

The use of reporting can often provide more information on the impact and value of an interoperability element than a standard software test evaluation without incorporating individual user bias. This reporting measure will reveal if users are using the C-CDA incorporate feature of their EHR to update their patient's record with current or new information from another source. Through this means of testing, we can determine compliance to the associated criteria listed above in real world use.

Measurement Expected Outcome:
This metric can come from different a direct query of the database regarding the number of C-CDA documents have been imported into a patient record. A successful measure increment indicates compliance to the underlying ONC criteria, including successful import of the C-CDA patient summary record and recording the required clinical data elements. In incorporating the C-CDA patient summary record, the EHR will demonstrate ability to confirm successful interoperability of an exchanged patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP.

Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Results for Measure #2: From 10/1/2022-12/30/2022 our clients incorporated 8 C-CDAs, indicating a rather low usage. As a result, we will continue to educate our end-users on the availability and purpose of the functionality.

RWT Measure #3 Electronic Prescriptions

Additional Software Needed: Surescripts (integrated within i-heal)

Associated Criteria: 315(b)(3)

Testing Methodology: Reporting/Logging

Measurement Description: This use case is tracking and counting how many New Rx electronic prescriptions were created and successfully sent from the EHR Module to a pharmacy destination over the course of a given interval.

Measurement Justification:
This use case measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a New Rx Script electronic prescription message and transmit it to a pharmacy, typically via the Surescripts Network. This use case will also show successful integration with our ePrescribing partner Surescripts and through its completion will reveal compliance to the associated criteria listed above.

Measurement Expected Outcome:
We will test a sample of our user base to get reporting values on New Rx electronic prescriptions sent as well as controlled substance usage.

Measure #3: Report the number of New Rx electronic prescriptions sent over a three (3) month period. The measurement will produce numeric results over a given interval which can be derived from a direct query of the database. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

A successful ePrescription indicates compliance to the underlying ONC criteria. It will show that the EHR can create the New Rx message and send over a production network, like the Surescripts Network, to a pharmacy. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Results for Measure #3: From 10/1/2022-12/30/2022 our end-users sent 25,981 new prescriptions. This indicates high usage and confirms users have a general understanding of the prescription module functionality.

RWT Measure #4 Quality Measures

Associated Criteria: 315(c)(1)-(c)(3)

Testing Methodology: Reporting/Logging

Measurement Description: This measure is tracking and counting how many Quality Measures (eCQMs) were successfully reported on by the EHR Module to CMS during their submission period for MIPS Quality reporting.

Measurement Justification:
This measure will provide a count and list of electronic clinical quality measures (eCQMs) which are calculated and submitted to CMS. Clinical quality measures are only used for the respective CMS programs and any production measures should utilize the submission to CMS. CQM measures 315(c)(1)-(c)(3) all work collectively together in the eCQM functionality of the EHR module, justifying combining this measurement for all three measures.

Measurement Expected Outcome:
The measurement will a count and list of eCQMs submitted to CMS over a given interval. We will ask our customer users to report on the number eCQMs they successfully reported on to CMS which reveals compliance to the associated criteria listed above.

A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the EHR can do calculations on the eCQM and that they are accepted by CMS. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure result to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Results for Measure #4: In 2022, we had 61 providers use our system to successfully report data to CMS, totaling 549 individual measures. This confirms our users have a general understanding of the eCQM module functionality.

RWT Measure #5 Patient Portal Use

Associated Criteria: 315(e)(1)

Testing Methodology: Reporting/Logging

Measurement Description: This use case is tracking and counting how patients are given access to their portal account over the course of a given interval.

Measurement Justification:
This use case measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a new patient portal account and give the patient access to it.

The use of reporting can often provide more information on the impact and value of the patient portal element than a standard software test evaluation without incorporating individual user bias. The patient portal is intended to support patient engagement with their health records, and the ability to transmit their patient data, as a C-CDA or human readable copy, can be a useful feature.

Measurement Expected Outcome:
We will contact a sample of our user base to get reporting values on patient portal access as well as patients use of the portal's interoperability features.

Measure #1: Report the number of new patient accounts created over a three (3) month period.

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

Results for Measure #5: From 10/1/2022-12/30/2022, 28 patients created new patient portal accounts. This indicates successful interoperability.

RWT Measure #6 API Access

Associated Criteria: 315(g)(7)-(9)

Testing Methodology: Reporting/Logging

Measurement Description: This is a reporting measure to determine how many different systems or applications are connecting to your EHR via the API.

Measurement Justification
We do not know how many of our customers are using the API functionality, so we believe the best means to evaluate real world interoperability is to utilize logging/reporting to determine this criteria's use. This measure will verify through reports/logs to determine real world interoperability and usability, specifically how many 3rd party systems or applications are integrated and using the EHR's API interface.

Utilizing reporting/logging can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. API capabilities are an important component of the modern health IT system, and utilization of API resources will help improve patient care and care coordination.

Measurement Expected Outcome:
Applications will be able to successfully utilize API's that are developed by Healogics for the consumption of external applications. The measurement will a count and list all applications who have or are connecting to i-heal API's in a given period of time, defined as a 3 month period. The count of distinct applications connecting to i-heal via API will derived from database reporting.

A successful test of this measure indicates compliance to the underlying ONC criteria. It will show that the EHR has external API available to and that they are able to successfully retrieve data. Successfully completing this measure also implies that applications can utilize the API's. A result of no applications connecting to these available API's will not indicate a failure of this measure in a real-world setting, it will simply indicate that no external applications have chosen to utilize these API's despite the availability of these API's.

Results for Measure #6: From 10/1/2022-12/30/2022, we had 12 applications access our APIs. This indicates successful integration with 3rd party applications.