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**)
    - o 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.

INTRODUCTION

This document contains a list of the steps taken to conduct the annual Real World Testing requirements for ONC certification. The Results within this document were reviewed as spreadsheets for their compliance with the criteria defined in the test plan. These artifacts will be maintained by the health IT developer for audit purposes or further requests.

GENERAL INFORMATION

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

Product Name(s): **HealthShare Personal Community**

Version Number(s): 2018.1; 2019.1; 2020.1; 2020.2; 2021.2

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2988.Heal.PC.06.0.221228; 15.04.04.2988.Heal.PC.02.0.221228; 15.04.04.2988.Heal.PC.05.0.221227; 15.04.04.2988.Heal.PC.03.0.221228; 15.04.04.2988.Heal.PC.05.0.221228

Developer Real World Testing Plan Page URL: https://www.intersystems.com/healthcare-standards-certifications/#meaningful-use

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]
No screenshots provided	Not provided from customer	N/A

[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):	N/A
Version Number(s):	N/A
CHPL Product Number(s):	N/A
Date(s) Withdrawn:	N/A
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.]	N/A

SUMMARY OF TESTING METHODS AND KEY FINDINGS

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*", our original test plan focused on capturing and documenting the number of instances that certified capability was successfully utilized in the real world. In instances where no evidence exists due to low or zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we tested and demonstrated the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

As per the test plan, we leveraged a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing

Adoption rate was used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might be accounted for by patient volume, location or provider preference among other reasons. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments were used to measure which certified actions were performed at the conclusion of a given time period where the minimum time period was 90 days and longer where possible. These results are typically obtained by generating reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

Interactive testing was used to demonstrate conformance to requirements where the adoption rate of a given certified capability is zero and to demonstrate ongoing compliance with updated standards and code sets (SVAP). Interactive tests were live tested as opposed to examining historical usage statistics. The goal being to demonstrate the certified Health IT module being used in a way consistent within a practice or care setting.

This approach allowed for the successful testing and obtaining results for each criterion. Detailed below in the **Metrics and Outcomes** section the reader will find evidential data in the form of a Summative result(s) or Interactive test outcome for each certified criteria for HealthShare Personal Community product.

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.

[X] No, none of my products include these voluntary standards.

Standard (and version)	Updated certification criteria and associated product	CHPL Product Number	Conformance Measure
N/A	N/A	N/A	N/A

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.

HealthShare Personal Community is marketed primarily to organizations who use multiple electronic medical record systems with multiple patient portals who desire to unify their portals under a single offering. We primarily work with large health systems (IDNs) and health information exchanges (HIEs) who may use the system directly themselves or offer it to their customers.

Metrics and Outcomes

Within this section is a list of the results collected from the **HealthShare Personal Community** solution Real World Testing measures as defined in their Real World Test plan. Outcomes are listed as Pass, Pass with Exception, or Fail determined by the success of obtaining testing results. This determination was based on a thorough review by the InterSystems team. A link is included within the Outcomes column in the table below to a subsequent Outcomes Details table. This second table matches each outcome with additional detailed information such as supporting resources and descriptions of the tests that were performed.

Key components include:
- Customer created a comprehensive Test Results Report which details customer environment, patient data utilized for tests, locations of testing
- Customer attempted Summative and/or Interactive Testing
- Customer collected audit logs to support spreadsheets and as necessary, screen shots that demonstrate proof of Interactive Testing for each criteria with "0" values in Summative Testing. These files are referenced and remain on file with InterSystems.

The following metrics were measured by viewing audit logs in the client's live production system for one Site - 5/1/23 - 9/1/23. For each test, the audit report criteria showing the auditing information being reported was provided. The resultant report was then saved to show the usage (or lack thereof) of the criterion.

Associated Criterion(a)	Measurement/Metric	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
170.315(e)(1) View, download, and transmit to 3rd party	Over a 120-day period: 1) Number of views of health information by a patient or authorized representative 2) Number of downloads of health information by a patient or authorized representative 3) Number of transmissions of health information by a patient or authorized representative using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using encrypted method	N/A	Pass 1) 26,490 2) 1,591 3) 0 4) 118	N/A

170.315(g)(7) Application access — patient selection	1) Number of requests for a patient ID or token 2) Number of requests that provided sufficient information to provide a valid response		Pass 1) 43,221 2) 31,858	
170.315(g)(8) Application access — data category request	1) Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token 2) Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token for a specific date range		Pass 1) 30,000+ requests over 55 different categories 2) 30,000+ requests over 55 different data categories	
170.315(g)(9) Application access — all data request	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 or token 2) Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token for a specific date range		Pass 1) 0 2) 0	

Outcome Details

The following sections contain additional descriptions and test results supporting documentation to provide more context for the testing outcomes defined in the **Metrics and Outcomes** table above.

170.315(e)(1) View, Download, and Transmit to 3rd Party

Summary Description
Pass   **Method:** Summative Testing The purpose of this test was to show that the EHR provides patients access to a patient portal with the ability to view, download, and send their health care records for the designated care settings. A query on historical audit logs for 120-day periods was performed for the 170.315(e)(1) criterion. The resulting totals show that this module was active throughout the period and therefore demonstrates a compliant result. Exception made for number of transmissions of health information by a patient or authorized representative using unencrypted email due to security requirements that prevent unencrypted email and/or connections. Internal security requirements override need for unencrypted email as well as functionality was proven to be available via encrypted connections.
Justification
This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.
Results Supporting Documents
Please Contact InterSystems for any Results spreadsheets and screenshots if required.

170.315(g)(7) Application Access — Patient Selection

Summary Description
Pass   **Method:** Summative Testing The purpose of this test was to show that the EHR is able to fulfill an API request that enables external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. A query on historical audit logs for 120-day periods was performed for the 170.315(g)(7) criterion. The resulting totals show that this module was active throughout the period and therefore demonstrates a compliant result.
Justification
This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. 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, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.
Results Supporting Documents
Please Contact InterSystems for any Results spreadsheets and screenshots if required.

170.315(g)(8) Application Access — Data Category Request

Summary Description

Pass	**Method:** Summative Testing

The purpose of this test was to show that the EHR is able to fulfill an API request that enables external applications to request patient data categories from the certified Health IT module.

A query on historical audit logs for 120-day periods was performed for the 170.315(g)(8) criterion. The resulting totals show that this module was active throughout the period and offers 53 different categories of patient data for query. The totals for each metric are the same due to requirement to input a date range. This therefore demonstrates a compliant result.

Justification

This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request patient data by category from the certified Health IT module. We intend to record the frequency that patient data requests by category 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 low utilization by providers with a high success rate.

Results Supporting Documents

Please Contact InterSystems for any Results spreadsheets and screenshots if required.

170.315(g)(9) Application Access — All Data Request

Summary Description

Pass	**Method:** Summative Testing

The purpose of this test was to show that the EHR is able to fulfill an API request that enables external applications to request all categories of patient data defined in the CCDS from the certified Health IT module.

A query on historical audit logs for 120-day periods was performed for the 170.315(g)(9) criterion. The resulting totals show that this module was active throughout the period. The totals for each metric are the same due to requirement to input a date range. This therefore demonstrates a compliant result.

Justification

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 low utilization by providers with a high success rate.

Results Supporting Documents

Please Contact InterSystems for any Results spreadsheets and screenshots if required.

KEY MILESTONES

Includes a list of key milestones that were met during the Real World Testing process. Includes details on how and when InterSystems implemented measures and collected data.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Large IDNs and HIE	Q1 2023
Data collection	Large IDNs and HIE	Sep 2023
Review and Collect Data	Large IDNs and HIE	Q3 2023
Writing Report	Large IDNs and HIE	Q4 2023
InterSystems executed summative testing to show that the criteria are functional. The following metrics were pulled from transaction logs as detailed in the outcomes section above: • 170.315 (e)(1) View, Download, and Transmit to 3rd Party • 170.315(g)(7) Application access—patient selection • 170.315(g)(8) Application access—data category request • 170.315(g)(9) Application access—all data request	Large IDNs and HIEs	5/1/23 - 9/1/23
InterSystems executed interactive testing to show that the criterion is functional. The following metrics were tested interactively as detailed in the outcomes section above:	N/A	N/A

ATTESTATION

The Real World Testing Results Template must include the following attestation signed by the Health IT Developer Authorized representative.

Note: The Results 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.[i]

This Real World Testing Results Report 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.

Authorized Representative Name:_____Dimitri Fane_____

Authorized Representative Email:_____fane@intersystems.com_____

Authorized Representative Phone:_____(617)621-0600._____

Authorized Representative Signature:_____

Date:_____27, Oct 2023_____

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[i] https://www.federalregister.gov/d/2020-07419/p-3582