REAL WORLD TESTING PLAN

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 170.556 and 170.523(i)). 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 to develop 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 for 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 which 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. 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 would expect 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. 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.

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide – Coming Soon
- 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 Program.

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

GENERAL INFORMATION

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

Developer Name: InterSystems Corp.

Product Name(s): HealthShare Personal Community

Version Number(s): 12.2; 2018.1; 2019.1; 2019.2; 2020.1; 2020.2

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2988.Heal.PC.00.1.170810; 15.04.04.2988.Heal.PC.01.1.181101; 15.04.04.2988.Heal.PC.02.1.190916; 15.04.04.2988.Heal.PC.03.1.200413; 15.04.04.2988.Heal.PC.04.1.210112; 15.04.04.2988.Heal.PC.04.1.210212

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

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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 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.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

We are using a 2-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing

Adoption rate will be 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 indicate a potential problem, of which there could be several different causes. 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 will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted 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.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

InterSystems has not updated HealthShare Personal Community to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of the 2022 Real World Test.

CARE SETTINGS

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 and health information exchanges who may use the system directly themselves or offer it to their customers.

Care Setting	Justification
HIE	HealthShare Personal Community helps Health Information Exchanges meet their compliance requirements for themselves and their customers by providing a solution that meets their clinical and business workflow requirements. HealthShare Personal Community provides high-quality reports to demonstrate the ease of patient access. Additionally, the system makes it easy to access and share data with other healthcare providers in the community.
IDN	HealthShare Personal Community helps Integrated Delivery Networks meet their compliance requirements by providing a solution that meets their clinical and business workflow requirements. HealthShare Personal Community provides high-quality reports to demonstrate the ease of patient access. Additionally, the system makes it easy to access and share data with other healthcare providers in the community.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of licensed installs/users of Personal Community • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of Personal Community	Identify the total number of *active* installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

SUMMATIVE ASSESSMENT METRICS

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine "success" via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

All versions of the certified Health IT module have no major functional changes for the criteria to be tested or their associated workflows, but not all versions are currently being used. Where possible, metrics will be extrapolated across as many different versions as possible.

None of the following criteria were updated to the Cures Update version of criteria prior to August 31, 2021. As a result, all testing is scheduled to be conducted against the 2015 Edition version of the criteria.

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Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(e)(1) View, download, and transmit to 3rd party	Over a 90-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, whether sent via encrypted or unencrypted email	• HIE • IDN	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.
170.315(g)(7) Application access — patient selection	1) Number of requests for a patient ID or token (success or failed) 2) Number of requests that provided sufficient information to provide a valid response (successful login)	• HIE • IDN	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.
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	• HIE • IDN	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.

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	• HIE • IDN	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.

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2022. Each phase is expected to take 90-days to complete, with report writing to occur end of 2022/early 2023.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	• HIE • IDN	90-days
Data collection	• HIE • IDN	90-days
Review and collate data	• HIE • IDN	90-days
Writing report	• HIE • IDN	90-days

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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