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: GetReal Health.

Product Name(s): InstantPHR / CHBase

Version Number(s): CHBase (V19) and InstantPHR (V20)

Certified Health IT

Product List (CHPL) ID(s):

- **15.04.04.1533.CHBa.19.02.1.190805**
- **15.04.04.1533.Inst.20.02.1.190916**

Developer Real World Testing Page URL: https://getrealhealth.com/certifications/

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 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing via User Stories

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 running 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 will be 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 will require a live test as opposed to examining historical usage statistics. Interactive tests will be demonstrated by defining "user stories". The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

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

GRH has not updated InstantPHR/CHBase 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 our Real World Test.

CARE SETTINGS

InstantPHR and CHBase is marketed as a patient facing front end to EHR systems. CHBase functions as the data repository while InstatntPHR serves as the front-end application.

Healthcare provider organization customers purchase licenses from GRH through a master license agreement that governs the term, scope, and use of the license by their patients.

Care Setting	Justification
Patient Engagement	For any patient to use InstantPHR / CHBase, the patient's provider (ambulatory setting) or Healthcare Organization (Inpatient / Acute / Surgery Center etc.) must have a license agreement with GRH. InstantPHR / CHBase provides the patient access to the same medical record available through the providers EHR.

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 EHR~~ • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Installs = 1 User Count • Total user accounts 157899 • Total patient records 208160

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed separately	1. CHBase 2. InstatnPHR
Number of installs/users who licensed a certified capability	1 (CPSI)
Number of installs/users that have used the certified capability in the preceding 365 days	1 (CPSI)

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.

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.

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 using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using encrypted method	Patient Engagement	All four metrics requested can be provided. 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 2) Number of requests that provided sufficient information to provide a valid response 3) Number of follow-up requests made using the provided patient ID or token	Patient Engagement	All three metrics requested can be provided. As per §170.315(g)(7) Application access — patient selection, the CEHRT must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. User is able to login to CHBase and select the patient record they are managing before a third-party patient facing app registered with CHBase is able to access the patient data using an access token provided by CHBase for the selected patient record. The reporting portal accurately reports counts based on the captured metrics for the selected reporting period. Our expectation is there will be moderate utilization by patients for the XML API and no adoption for the FHIR API.

170.315 (g)(8): Application Access - Data Category Request	1) Number of patients where data was accessed by an application accessing data via a data category request using a valid patient ID or token 2) Total number of data categories requeste 3) Number of times each of the data categories was requested 4) Total number of data categories requested for a specific date range	Patient Engagement	All four metrics requested can be provided. As per §170.315(g)(8) Application access — data category request, the CEHRT must respond to requests for patient data for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in a computable format. The API must also be able to respond to requests for a date or date range. The patient facing app provides the requested data for each of the CCDS data categories based on a date or date range using CHBase FHIR STU3 API. The reporting portal accurately reports counts based on the captured metrics for the selected reporting period. Our expectation is there will be moderate utilization by patients for the XML API and no adoption for the FHIR API.
170.315 (g)(9): Application Access - All Data Request	1) Number of patients where data was accessed by an application accessing data via an all data category request. 2) Total number of data categories requested 3) Total number of data categories requested for a specific date range	Patient Engagement	All three metrics requested can be provided. As per §170.315(g)(9) Application access — all data request, the CEHRT's API should be able to provide Consolidated CDA files in accordance with HL7 C-CDA Release 2.1 IG containing all the data classes and elements in the ONC prescribed Common Clinical Data Set for a date or date range. The patient facing app provides the CCD file to the user using CHBase FHIR STU3 API. The reporting portal accurately reports counts based on the captured metrics for the selected reporting period. Our expectation is there will be moderate utilization by patients for the XML API and no adoption for the FHIR API.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria ONLY **where metrics are not available**, either because:

- There is 0 adoption of the criteria in the real world, either due to unanticipated lack of interest or other factors. Where applicable, these factors are described below.
- There is good adoption of the criteria, but the certified capabilities were developed without anticipating the collection of metrics in mind, so real world demonstration of the criteria is provided to demonstrate that it functions in the real world.

G7-G9 API Functionality

Criterion	Interactive Test Plan	Care Setting	Justification and Expected Outcome
170.315 (g)(7): Application Access - Patient Selection	1. 1. We need to install/deploy IPHR and CHBase in a test environment 2. 2. Onboard test Patients in the Database 3. 3. Load encounter and related health data. 4. 4. Various Patient logging-in and viewing/downloading health Data	Patient Engagement	Reporting Portal should accurately account the count of metrics captured for g(7).
170.315 (g)(8): Application Access - Data Category Request	1. We need to install/deploy IPHR and CHBase in a test environment 2. Onboard test Patients in the Database 3. Load encounter and related health data. 4. Various Patient logging-in and viewing/downloading their and authorized user's health Data for given date range.	Patient Engagement	Reporting Portal should accurately account the count of metrics captured for g(8).
170.315 (g)(9): Application Access - All Data Request	1. We need to install/deploy IPHR and CHBase in a test environment 2. Onboard test Patients in the Database 3. Load encounter and related health data. 4. Various Patient logging-in and viewing/downloading and transmitting CCD 5. 5. Measure the counts for VDT using the reporting portal.	Patient Engagement	Reporting Portal should accurately account the count of metrics captured for g(9).

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	Patient Engagement	90-days
Data collection	Patient Engagement	90-days
Review and collate data	Patient Engagement	90-days
Writing report	Patient Engagement	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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