2022 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 170.405). 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.**

- 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) (**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 plan. Each section provides a field for submitting responses and/or 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: CareEvolution

Product Name(s): HIEBus™

Version Number(s): 2015 Edition Core

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1200.HIEB.15.00.1.171127

Developer Real World Testing Page URL: https://careevolution.com/onc_certification.html

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[i].

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.

At this time, the Certified Health IT Module is marketed for the inpatient care setting. For this reason, the Real World Testing plan will apply to this care setting. There are several certification criteria which are deployed together to support interoperability in production systems and can be tested simultaneously. A few certification criteria are not currently deployed in any production environments, and these will be addressed in the plan details. The criteria which will be tested at this time are §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; and §170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM. Additionally, the following certification criteria will also be tested should they become deployed in a production environment prior to the end of the Real World Testing period: §170.315 (b)(1): Transitions of Care; §170.315 (f)(1): Transmission to Immunization Registries; §170.315 (f)(2): Transmission to Public Health Agencies - Syndromic Surveillance; §170.315 (f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results.

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?*

Standard (and version)	All standards versions are those specified in the 2015 Edition Common Clinical Data Set.

Updated certification criteria and associated product	n/a
Health IT Module CHPL ID	15.04.04.1200.HIEB.15.00.1.171127
Method used for standard update	n/a
Date of ONC ACB notification -	n/a
Date of customer notification (SVAP only)	n/a
Conformance measure	n/a
USCDI -updated certification criteria (and USCDI version)	none

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 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) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
CCDA exchange	This measure will track usage of various ways to share CCDA documents among patients and providers
Public health reporting	This measure will track usage of reporting to public health agencies
API usage	This measure will assess usage of the API to retrieve patient data using 3rd party apps

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
EHI exchange	§170.315 (b)(1): Transitions of Care (pending production use) §170.315(e)(1): View, download, and transmit to 3rd party

	§170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM
Public health reporting	§170.315 (f)(1): Transmission to Immunization Registries (pending production use) §170.315 (f)(2): Transmission to Public Health Agencies - Syndromic Surveillance (pending production use) §170.315 (f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results (pending production use)
API usage	§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

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification
EHI exchange	The system includes functionality to exchange transition of care summaries among providers, as well as with patients via a patient portal where patients can view, download, or transmit their EHI. The system also includes HISP functionality to facilitate interoperable exchange between various EHRs and other entities such as HIEs. This metric will provide information on the types of exchange taking place in production environments as well as its frequency of usage.
Public health reporting	The system includes the capability to generate messages for public health reporting of immunizations, syndromic surveillance, and reportable lab results; however at this time this functionality is not deployed in any production environments. Should this change during the testing period, this metric will analyze the status of public health reporting including message volumes and error rates.
API usage	The system supports an API endpoint to allow 3rd party apps to retrieve patient data. This metric will utilize myFHR, a representative app which uses the API, to verify that supported data elements are able to be retrieved for patients. In addition, this metric will demonstrate successful usage of the API by other apps registered in production environments.

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
Inpatient	The Certified Health IT Module supports the interoperable exchange of patient data by inpatient hospitals; while it could also be accessed in ambulatory settings, the certified functionality addressed by this plan is deployed in production inpatient environments for the benefit of the hospital network. It is not currently deployed in any standalone ambulatory environments, nor is it marketed for that setting.

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
EHI Exchange	System logs, audit logs, and email logs will be reviewed to determine the frequency and mechanism used to exchange transition of care documents across providers, as well as viewing, downloading, or transmitting EHI by patients using the patient portal. Log data will be de-identified and analyzed to validate the proper functioning of the various exchange transport mechanisms implemented and to calculate metrics on usage volumes and error rates. It is expected that providers and patients are able to utilize the methods provided to exchange EHI, and that error rates do not increase over time.
Public health reporting	Pending deployment of this functionality to a production environment, reporting logs will be inspected to determine message volume and error rates. It is expected that messages are able to be generated successfully and accepted by public health agencies successfully without error rates deviating from initial baseline.

API usage	Logs from the myFHR app will be de-identified and analyzed to validate the proper operation of the API, including successful patient selection and retrieval of CCDS data elements with a minimal number of errors. Additionally, internal system logs tracking API usage across apps will be de-identified and analyzed to validate the proper operation of the API by multiple registered apps. It is expected that data access issues are rare; error rates will be tracked to establish a baseline for the initial testing year.

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on 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/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Start of collection period for information as laid out in the above Real World Testing plan.	Inpatient	January 1, 2022
End of data collection period for Real World Testing plan	Inpatient	December 31, 2022
Quarterly check-in to identify issues with data collection	Inpatient	Quarterly, 2022
De-identification of logs and analysis of data collected	Inpatient	January 15, 2023
Real World Testing Results report creation and submission to ACB (per their instructions)	Inpatient	February 15, 2023

ATTESTATION

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

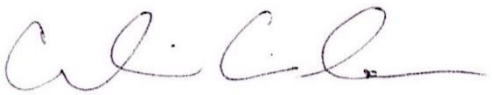
Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.[ii]

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.

Authorized Representative Name: Celina Corridore

Authorized Representative Email: celina@careevolution.com

Authorized Representative Phone: 614-653-7373



Authorized Representative Signature:

Date: November 12, 2021

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[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766) [ii] https://www.federalregister.gov/d/2020-07419/p-3582