REAL WORLD TESTING PLAN 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.

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). ONCdoes 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 efforthas 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
- 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 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: Citiustech.Inc

Product Name(s): Perform+ Regulatory

Version Number(s): BIC2022

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2694.BICL.22.08.0.211116

Developer Real World Testing Plan Page URL: https://8759937.fs1.hubspotusercontent-na1.net/hubfs/8759937/assets/pdfs/2024-Real-world-Testing-Plan.pdf

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.

Real World Testing Measurements The measurements for our real world testing plan are described below. Measurement contains:
- *Associated ONC criteria*
- *Testing Methodology used*
- *Description of the measurement/metric*
- *Justification for the measurement/metric*
- *Expected outcomes in testing for the measurement/metric*
- *Care settings which are targeted*

All measurements were chosen to best evaluate compliance with the certification criteria and interoperability of exchanging electronic health information (EHI).

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

Reporting: This methodology uses the reporting capabilities of the product to examine functionality performed in the system. A typical example of this is the measure reporting done for the measure calculation. This methodology often provides historical measurement reports which can be accessed at different times of the year and evaluate interoperability of product functionality, and it can serve as a benchmark for evaluating real world testing over multiple time intervals. Compliance and/or Tool: This methodology uses inspection to evaluate if EHR is compliant to the ONC criteria requirements. It can be done through inspection testing or utilize various tools to measure or evaluate compliance and interoperability.

Survey/Self-Test: This methodology evaluates interoperability and compliance of Perform+ Regulatory (Change in product branding) Module capabilities through feedback from users. Test patients will include data elements that are typically used in that provider setting in order to be representative of Real World use cases. ONC has recognized that self-testing can be a viable method for evaluation and compliance.

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 Product Number 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)	Not applicable
Updated certification criteria and associated product	Not applicable
CHPL Product Number	Not applicable
Method used for standard update	Not applicable
Date of ONC ACB notification	Not applicable

Date of customer notification (SVAP only)	Not applicable
Conformance measure	Not applicable
USCDI updated certification criteria (and USCDI version)	Not applicable

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
Inpatient clinical quality measure	This measure is tracking and counting how many eCQM quality measures were successfully reported on by the Perform+ Regulatory product to CMS over the course of a given interval.

Criterion	Metric	Care setting	Justification and expected outcome
§170.315(c) (2-3)-clinical quality measures (CQMs)	Inpatient clinical quality measures: 1) Number of measures recordedduring the period 2) Number of QRDA Category 1files exported 3) Number of QRDA Category1files imported (if applicable) 4) Number of QRDA Category3 aggregate report(s) created over the period	General Acute care and critical access hospital	Justification: These criteria will be tested together. C2 -requires a certified Health IT module must be able to import data from a QRDA Category1 formatted file and calculate the CQMs based on that data. C3 - requires a certified Health IT module must be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capabilityis available and effective, regardless of the frequency it is used. A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the Perform+

			Regulatory product can do calculations on the eCQM and survey clients to confirm that they are accepted by CMS. 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. Expected outcome: • Exported CQMs contain data as expected • QRDA files are able to be imported and calculations run as expected • QRDA I and QRDA III are generated correctly • It is compliant with the certification criteria, including the required technical standards and vocabulary codes sets. • A successful measure submission indicates compliance to the underlying ONC criteria.

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your Real World Testing plan for any metrics that would involve use of that software in testing.

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Inpatient clinical quality measure	§170.315(c)(2)-Import and calculated	
	§170.315(c)(3)-Report(cures)	

Justification for Selected Measurement/Metric

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

Measurement/Metric	Justification
Inpatient clinical quality measure	These criteria will be tested together. C2 -requires a certified Health IT module must be able to import data from a QRDA Category 1 formatted file and calculate the

	CQMs based on that data. C3 - requires a certified Health IT module must be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the Perform+ Regulatory product can do calculations on the eCQM and survey clients to confirm that they are accepted by CMS. 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.

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
General Acute care and critical access hospital	The Certified Health IT Developer markets its Modules in Emergency department (ED)/ Impatient settings only, so this is the only care setting in which RealWorld Testing is to occur.
Multi facility hospital system	The Certified Health IT Developer markets its Modules in Emergency department (ED)/ Impatient settings only, so this is the only care setting in which RealWorld Testing is to occur.

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
Inpatient measure	• Exported CQMs contain data as expected • QRDA files are able to be imported and calculations run as expected • QRDA I and QRDA III are generated correctly • It is compliant with the certification criteria, including the required technical standards and vocabulary codes sets. • A successful measure submission indicates compliance to the underlying ONC criteria

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
ONC certification	Inpatient care settings	30th October 2021
Follow-up with providers and authorized representatives ona regular basis to understand anyissues arising with the data Submission.	Inpatient care settings	31st March 2022
During the last quarter of the year 2023, the CY 2024 Real world test plan will be completed according to theONC and the ONC-ACB requirements and expectations. Test plan will be prepared for submission before the end of the year.	Inpatient care settings	1st November 2023
If any non-compliance is observed, we will notify the ONC- ACB of the findings and make the necessary changes as required	Inpatient care settings	April – June 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: Madhu Madhanan

Authorized Representative Email: madhumadhanan@citiustech.com

Authorized Representative Phone: +1(877)248-4871

Authorized Representative Signature:

Date:

29-Oct-2023

[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