REAL WORLD TESTING PLAN TEMPLATE

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: ezCaretech Co., Ltd.

Product Name(s): BESTCare

Version Number(s): 2.0G, 2.0B

Certified Health IT: Drummond Group

Product List (CHPL) ID(s): 15.04.04.2610.BEST.02.00.1.200604, 15.04.04.2610.BEST.02.00.1.180423

Developer Real World Testing Page URL: https://global.ezcaretech.com/onc/onc_2015.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.

In BESTCare 2.0G product, there are 3 criteria which need to have a real world test.
(b)(10) : Clinicians export all stored EHIs for a single patient or the entire patient population.
(f)(2) : Clinicians will create and transmit the required PHIN Messaging Guide for Syndromic Surveillance to public health agencies.
(f)(4) : Clinicians will use to determine interoperability and usability, specifically how many messages were sent to cancer registries. Currently, there is no client or provider who requested to integration with cancer registries.

In BESTCare 2.0B product, there are 17 criteria which need to have a real world test.
(b)(1) : Clinicians use the Patient Summary Outbound menu where they can send CDA. Thousands of files are exchanged going in and out of BESTCare, and this measure will investigate the transmission that are being sent out of the system to ensure clinicians are accurately transmitting files.
(b)(2) : Clinicians receive CDA and see a visual display of inbound files to incorporate. Some data classes and data elements will be reconciled, and USCID will be used.
(b)(10) : Clinicians export all stored EHIs for a single patient or the entire patient population.
(b)(11) : Limited set of identified users select both evidence-based and predictive decision support interventions, access to complete and up-to-date source attribute fields and information in plain language text, and record / access / change source attribute information.

(c)(1), (c)(2), (c)(3) : There is a dedicated team supporting eCQM from updating measures to reporting and exporting files. Clients are required to create QRDA III to report the clinical quality measurements data collected.
(f)(1) : When there is immunization interface with its state registry, Order Entry works with the state to start the onboarding process. State registry testing should be done for a bi-directional interface. Every state registry is different in what they test and how long testing will take.
(f)(2) : Clinicians will create and transmit the required PHIN Messaging Guide for Syndromic Surveillance to public health agencies.
(f)(3) : Clinicians will provide the most public health benefit. State agencies provide statistics that can be very helpful to patient care, epidemiologists and government for identifying disease outbreaks and epidemics.
(f)(5) : The requirements are to attain the capability of maintaining the table for Trigger codes, identifying the encounters which meet the trigger, generating the electronic case report, and transmitting to public health agencies. Currently, there is no client or provider who requested the integration with health agencies.
(f)(6) : Clinicians will demonstrate the value of using electronic health records to generate reports for submission to public health agencies.
(f)(7): Clinicians will determine interoperability and usability, specifically how many CCDA documents were generated and successfully sent to public health agencies.
(g)(7), (g)(9), (g)(10) : The measurement will focus on tracking live production API requests and responses from registered application. The application will be actively engaging clinicians to work to learn about end use best practices.

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)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A

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)	b.1, b.2, b.11, g.6, g.9, g.10 (v.3)

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
Data derived from network server and test tools	Single instance of demonstrating interoperability or data exchange
Success or failure rates	Count of creating CCDAs vs. Count of sending CCDAs are equal. Count of incorporating CCDA vs. Count of reconciling CCDAs are equal. Success rate for extracting QRDA1 is over 90%. Success rate for extracting HL7 messages is over 90%. Success rate for sending HL7 message is over 90%. Success rate for requesting from API is over 90%. Success rate for responding from API is over 90%.

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
Data derived from network server and test tools	(b)(1), (b)(2)

Success or failure rates	(b)(1), (b)(2), (b)(10), (b)(11), (c)(1), (c)(2), (c)(3), (f)(1), (f)(2), (f)(3), (f)(4), (f)(5), (f)(6), (f)(7), (g)(7), (g)(9), (g)(10)

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

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

Measurement/Metric	Justification
Data derived from network server and test tools	Single instance of demonstrating interoperability or data exchange
Success or failure rates	Count of creating CCDAs vs. Count of sending CCDAs are equal. Count of incorporating CCDA vs. Count of reconciling CCDAs are equal. Success rate for extracting QRDA1 is over 90%. Success rate for extracting HL7 messages is over 90%. Success rate for sending HL7 message is over 90%. Success rate for requesting from API is over 90%. Success rate for responding from API is over 90%.

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
Ambulatory	Both BESTCare2.0G and BESTCare2.0B have capability to cover ambulatory settings for outpatient visits.
Inpatient	Both BESTCare2.0G and BESTCare2.0B have capability to cover inpatient settings.

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 <u>not</u> 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
Standards and code sets	*(b)(1), (b)(2), (b.11), (f)(4) : Based on the implementation guide, the technical standards and the vocabulary code sets (e.g. SNOMED-CT, RxNorm, LOINC, etc.) will be used to create a file.* *(f)(1), (f)(2), (f)(3) : Based on the implementation guide, a standard message will be created.* *(c)(1)~(3) : Based on the implementation guide, a reporting will be generated.* *(g)(7), (g)(9) : Based on the implementation guide, a standard message will be created.*
Success Rate	*(b)(1) : Files are being sent successfully 90% of the time.* *(b)(2) : It is expected that practices understand the benefits of data reconciliation and incorporation and will reconcile patient data more than once per year.* *(f)(1) : It is expected that once immunization integration testing has started*

	with the state, the practice go live date will be within 30 days. *(f)(2) : 90% of success rate of receiving and processing messages.* *(f)(3) : 90% of success rate of sending and processing messages.* *(f)(4) : It is expected that practices understand the benefits of data to registry, and will send the data more than once per year.* *(f)(5) : It is expected that practices understand the benefits of interfaced data, and will send the data more than once per year.* *(f)(6) : It is expected that practices understand the benefits of interfaced data, and will send the data more than once per year.* *(f)(7) : It is expected that practices understand the benefits of interfaced data, and will send the data more than once per year.* *(g)(7), (g)(8), (g)(9), (g)(10) : 90% success rate of all API traffic.*

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
Apply based on the implementation guides	BESTCare2.0B Ambulatory & Inpatient Settings	~06/30/2026
Apply based on the implementation guides	BESTCare2.0G Ambulatory & Inpatient Settings	~07/31/2026
Prepare real world testing	BESTCare2.0G Ambulatory & Inpatient Settings	~08/31/2026
Proceed real world testing	BESTCare2.0G Ambulatory & Inpatient Settings	~09/30/2026
Prepare real world testing	BESTCare2.0G Ambulatory & Inpatient Settings	~10/30/2026
Proceed real world testing	BESTCare2.0G Ambulatory & Inpatient Settings	~11/31/2026

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: EUNSOL LEE

Authorized Representative Email: eunsol@ezcaretech.com

Authorized Representative Phone: +82-10-2885-4365

Authorized Representative Signature: 

Date: 12/19/2025

[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