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
- 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"*

GENERAL INFORMATION

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

Developer Name: **SpectraMedix**

Product Name(s): **VBP Performance Suite**

Version Number(s): **11**

Certified Health IT Product List (CHPL) ID(s): **15.07.05.2359.SPEC.01.00.1.230309**

Developer Real World Testing Page URL:
https://focusanalytics.spectramd.com:9100/VBP%20Performance%20Suite%20-%20Real%20World%20Testing/

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.

The VBP Performance Suite portal provides the capability to import the patient's Claims/Encounter data and clinical through an FTP API, calculates the clinical quality measures as per the measure specification, and allows the use to generate QRDA Category I and III reports from the portal. In addition to that, the portal displays the calculated measures, and the measure values. The portal also ensures the required security norms, which are at par with the ONC's privacy and security criteria. All the test methodologies focus on the following certification criteria;

1. (c)(1) Clinical quality measures (CQMs) — record and export
2. (c)(2) Clinical quality measures (CQMs) — import and calculate
3. (c)(3) Clinical quality measures (CQMs) — report (Cures)

In order to test the functionalities at the real time, the following metrics been used;

1. **Clinical data loading and eCQM calculation**: The objective of choosing this metric is to track the functionalities that are at par with the criteria C1 and C2, which includes the recording and exporting data, and importing and calculating the eCQM measures. Through this metric, all the necessary sections for each of the certification criteria [example - §170.315(c)(1)(i), (ii), (c)(2)(i), (ii)] will be tracked periodically, and do the needful changes in the system if needed.

2. **Generating QRDA I and III files:** This measure will be executed after the first metric, and through this metric the criteria C3 (§170.315(c)(3)(i)) will be tested.

The two metrics that has been chosen to be measured will cover the complete flow of functionalities that are covering the certification criteria C1, C2 and C3. All the errors and results will be tracked and trended over time. Therefore, tracking these metrics in an ongoing manner will provide a step-by-step approach to measure and trend the functional status of the application, the level of adherence to the certification criteria, and, ongoing interoperability and functionality will be demonstrated. This will be achieved through the detailed test methodologies included in the plan.

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?*

Standards (and versions)	**None**
Updated certification criteria and associated product	**None**
Health IT Module CHPL ID	**15.07.05.2359.SPEC.01.00.1.230309**
Date of ONC-ACB notification	**Not Applicable**
Date of customer notification (SVAP only)	**Not Applicable**
Conformance measure	**Not Applicable**
USCDI-updated certification	**Not Applicable**
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
Measure – 1: Clinical data loading and eCQM calculation.	This measure will test the functionality of recording the clinical data from the external system through FTP API, importing the data into the database from the external system, calculate the eCQM measures as per the measure specifications, and display the measure data in the portal.
Measure-2: Generating QRDA I and III files.	This measure will test the functionality of downloading the measure data in the form of QRDA I and/or III (§170.315(c)(3)).

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria. The SQL Server 2017 Enterprise Edition is relied upon software for the c3 criterion.

Measurement/Metric	Associated Certification Criteria
Measure-1: Clinical data loading and eCQM calculation.	§170.315(c)(1)(i) - Record all data necessary to calculate CQMs §170.315(c)(1)(ii)- Export a data file §170.315(c)(2)(i) - Import a data file §170.315(c)(2)(ii) - Calculate each CQM
Measure-2: Generating QRDA I and III files.	§170.315(c)(3)(i) - create a data file for transmission of CQM data in QRDA Category I and Category III

Justification for Selected Measurement/Metric

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

Measurement/Metric	Justification
Measure-1: Clinical data loading and eCQM calculation.	The VBP Performance Suite application ingests the patient data from the external system through FTP API, loads the data in the stagging tables and does a data completeness check, followed by converting it into FHIR format which will be used for the eCQM measure calculation. This metric will help to measure about the completeness of the data recording and importing from the external systems, calculating the measures, displaying the calculated measure data in the portal. Test Methodology: The system logs will be used for identifying that • All the records that were there in the FTP server are successfully moved into the system's staging tables without missing any records • Next to that, in the landing tables without missing any records • All the data elements are complete • All the necessary data required for calculating the eCQMs are properly codified after the it converted into FHIR. Besides the data recording and importing, the system logs will be used for assessing that the measure calculation logic is running for all the eCQMs. Visual inspection will ensure that the portal is displaying data for all the measures required to be calculated in the portal. This test methodology will primarily test the conformance of the implementation.
Measure-2: Generating QRDA I and III files.	This metric should be tracked as a next step of the first metric. Once the eCQM calculation is over, and the data is visible in the portal, the user can generate QRDA category I and III files. The objective of this metric is to assess the functionality of generating QRDA files as per the certification criteria §170.315(c)(3), **Test Methodology:** System logs and audit logs will be used to ensure that • Visual inspection will be performed to ensure that all the eCQMs in the portal has valid data. • Manual process will be performed to check the QRDA files generation and export. This test methodology will primarily test the conformance of the implementation.

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
Hospital Care Setting	The objective of choosing this care setting is as follows; • The VBP Performance Suite is being marketed in this type of care setting. • The system will be able to ingest the real time patient data from the hospital system and thus the product will be able to demonstrate that all the capabilities that are certified are consistent during the real time testing in the live environment. • The chosen measures will be based on the real time patient data throughout the year; hence the certified health IT developer will get the test results for ongoing interoperability and functionalities.

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
Measure-1: Clinical data loading and eCQM calculation.	It is expected that – a) All the patient data from the external system will be ingested in the VBP Performance Suite with the assurance of data completeness, b) All the required eCQM measures are being calculated c) VBP Performance Suite portal displays the e CQM results. The errors in these processes will be tracked, analysed and trended over time.
Measure-2: Generating QRDA I and III files.	It is expected that – a) All the measures are visible in the portal and has relevant data. b) Successful generation of the QRDA category I and III files in the form of XML and ZIP files. The errors in these processes will be tracked, analysed and trended over time.

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
Planned data collection begins	Hospital	Jan, 2024
Analysing the collected data	Hospital	Quarterly, 2024
Follow-up with the authorized representatives on a regular basis to understand any issues regarding the data collection	Hospital	Quarterly, 2024
End of Real-World Testing for the period, and final collection of data for the final analysis and report creation	Hospital	Dec 31st, 2024
Report creation	Hospital	Jan 10th, 2025
Submit RWT report to ACB	Hospital	Jan 15th, 2025

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.

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Authorized Representative Phone: +91-9654643039

Authorized Representative Signature: Gaurav Bhati

Date: 12/10/2023

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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