REAL WORLD TESTING PLAN

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). 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 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"
- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, 89 FR 1192 (March 11, 2024) (**HTI-1 Final Rule**)
    - Section III.E — "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: 20241025spe

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 Plan Page URL: https://www.spectramedix.com/spectramedix-health-it-certification-documents

JUSTIFICATION FOR REAL WORLD TESTING APPROACH.

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
4. (b)(10) Electronic Health Information export – filter and export

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Standard (and version)	**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	**Not Applicable**
Conformance method and measurement/metric(s)	**Not Applicable**

MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

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

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

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Measure-1: Clinical data loading and eCQM calculation.	§170.315(b)(10) Electronic Health Information export §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

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)

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

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)

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

Key Milestone	Care Setting	Date/Timeframe
Planned data collection begins	Hospital	Jan, 2025
Analyzing the collected data	Hospital	Quarterly, 2025
Follow-up with the authorized representatives on a regular basis to understand any issues regarding the data collection	Hospital	Quarterly, 2025
End of Real-World Testing for the period, and final collection of data for the final analysis and report creation	Hospital	Dec 31st, 2025
Report creation	Hospital	Jan 10th, 2026
Submit RWT report to ACB	Hospital	Jan 15th, 2026

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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Date: 10/10/2024

[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