

# REAL WORLD TESTING RESULTS REPORT 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 and results reports.

[A 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. To accompany the plan template, ONC has also provided this results report template.

While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). 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 results report will include a list of these 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 Certification 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 results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

## GENERAL INFORMATION

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

Developer Name: Verana Health

Product Name(s): Verana Quality Measures

Version Number(s): 1

Certified Health IT Product List (CHPL) Product Number(s): 15.07.09.3092.VE05.01.01.1.230118

Developer Real World Testing Plan Page URL: <https://www.veranahealth.com/solutions/physician-solutions/verana-quality-measures/>

Developer Real World Testing Results Report Page URL [if different from above]:

## [OPTIONAL] CHANGES TO ORIGINAL PLAN

*If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.*

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	Reason [Describe the reason this change occurred]	Impact [Describe what impact this change had on the execution of your Real World Testing activities]
None		



## [OPTIONAL] WITHDRAWN PRODUCTS

*If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.*

Product Name(s):	
Version Number(s):	
CHPL Product Number(s):	15.07.07.3092.VE05.01.00.1.211116
Date(s) Withdrawn:	
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

## SUMMARY OF TESTING METHODS AND KEY FINDINGS

*Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.*

*If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.*

*Note: A single Real World Testing results report may address multiple products and certification criteria for multiple care settings.*

The real world testing demonstrates that Verana Health Quality platform is compliant with c(1), c(2) and c(3) (Cures Act) criteria against which it is currently certified. The functionality for generating and downloading QRDA files was available to practices via the Verana Quality measures platform.

Our testing methods included, recording quality measures based on receiving clinical data, uploading of real world files into the system, verification of successful processing and validation of expected functionality within the Verana Quality Measures software application and appropriate calculation of the Quality Measure performance.

In testing of the real world data and files, we validated different versions of implementation during processing to prevent incorrect or corrupt data from being processed. More details are outlined in the 170.315 (c ) (2) testing result below. Additionally, we verified the ability to record quality measures across our clients for the 170.315 (c) (1) criterion.

For several of the Measurements outlined for 170.315(c) criteria, we had zero user adoption. In lieu of zero adoption, we conducted testing on synthetic data to ensure expected outcomes were met for the certified product.

## 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.*

*Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).*

☒ Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below.

☐ No, none of my products include these voluntary standards.

Standard (and version)	QRDA Implementation Guide Standard and Version: HL7 QRDA Implementation Guide Categor QRDA Implementation Guide Category III CMS Implementation Guide
Updated certification criteria and associated product	170.315(c)(1) - Clinical quality measures (CQMs) — record and export § 170.315(c)(2) - Clinical measures (CQMs) — import and calculate § 170.315(c)(3) - Clinical
CHPL Product Number	15.07.09.3092.VE05.01.01.1.230118
Conformance measure	N/A

### Care Setting(s)

*The expectation is that a developer's Real World Testing is conducted within 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.*

*List each care setting that was tested.*

We targeted Outpatient care in the Ophthalmology and Neurology specialties - Outpatient individual primary care office visits.  
 Our intent was to sample for primary care office visit however the majority of our certified functionality was not adopted by our users.  
 The results of this report are based on real world files requested from our clients for real world testing purposes.

### Metrics and Outcomes

*Health IT developers should detail outcomes from their testing that 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.

Health IT developers could also detail outcomes that did 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 their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA Category 1 and QRDA 3 files exported (attempted, successful)	170.315(c)(1) Clinical quality measures — record and export	N/A	For the period ending December 31st, we had a total of 27,457 quality measures recorded across our clients. During this period, we had zero adoption of QRDA exports. In order to validate our export functionality, we used synthetic data in non-production environments to export QRDA 1 and QRDA 3 files. This testing is part of our standard regression testing regularly conducted on the Verana Quality Measures product to ensure the certified functionality functions as expected.	No technical challenges. Users have exported data for reporting purposes via JSON files and not QRDA formats.
Over a 90-day period: 1) Number of users who are able to upload QRDA 1 files and are able to successfully calculate the relevant measures. 2) Number of measures that have been successfully calculated across different provider /practices.	170.315 (c)(2) Clinical quality measures— import and calculate	N/A	For the entire period of 2023, we had zero adoption of this functionality. We did request and receive 7,415 real world files across 10 quality measures for calculations from our practices. Upon processing these files, we encountered challenges in	In the files provided by our clients, we had data formatting issues from the originating system preventing processing in our system.  Issues encountered include field extension dates, missing TIN/NPI, unexpected Root and Extensions values and outdated value sets.

3) Number of performance errors identified.			processing. To confirm that the system was processing appropriate QRDA I files, we ran sample data using third party certification tooling to ensure our system processed correctly formatted files.	
Over a 90-day period:  1) How many data files with and without error have been created.	§ 170.315(c)(3) Clinical quality measures—report—	N/A	We had zero adoption of this functionality in 2023. In order to validate our file reporting functionality, we used synthetic data in non-production environments to export QRDA 1 and QRDA 3 files. This testing is part of our standard regression testing regularly conducted on the Verana Quality Measures product to ensure the certified functionality functions as expected.	No technical challenges. Users have exported data for reporting purposes via JSON files and not QRDA formats.

## KEY MILESTONES

*Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.*

Key Milestone	Care Setting	Date/Timeframe
Identify Clients for Participation	Primary Care - Outpatient individual primary care office visits.	Q1 2023
Data Collection from Clients and Testing	Primary Care - Outpatient individual primary care office visits.	Q2 through Q4 2023
Report Created and Submitted to ONC - ACB	Primary Care - Outpatient individual primary care office visits.	Q1 2024



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CERTIFICATION PROGRAM

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