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: Nuance Communications, Inc.

Product Name(s): Nuance Electronic Quality Measures

Version Number(s): 23.1

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2071.Nuan.23.05.1.231213

Developer Real World Testing Plan Page URL: https://www.nuance.com/healthcare/provider-solutions/quality-management-solutions/quality-measures/cures-act-real-world-testing.html

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]

[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):	Nuance Electronic Quality Nuance Electronic Quality Measures
Version Number(s):	22.2
CHPL ID(s):	15.04.04.2071.Nuan.22.04.1.221220
Date(s) Withdrawn:	12/31/2023
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.]	The data for the results of this report came from version 22.2

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.

Between August 29th, 2022, and February 28th, 2023, we have captured the audit logs of the above listed certification criteria from our Production servers. We analyzed the data that was sent from the clients to determine the measures that were submitted, the number of records received, the success and failure rate, and the data accuracy. Our process includes working with clients to ensure that the data submitted is accepted into our system and resolving any issues with the data in a timely manner.

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.

[X] No, none of my products include these voluntary standards.

Standard (and version)	
Updated certification criteria and associated product	
Health IT Module CHPL ID	
Conformance measure	

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.

The care setting used for testing results is Acute Care Facilities.

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.

(from 85 FR 25766)

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)
Ability to record clinical quality data, and to create the QRDA 1 export file for the measures selected by a provider for a selected time period.	170.315(c)(1) Clinical quality measures (CQMs) – record and export		For 2022 reporting period, there were 186,350 Patient records loaded into the system for our 29 clients.	
Ability to import a QRDA 1 file for the measures selected by a provider for a selected time period, and to properly calculate each measure outcome.	170.315(c)(2) Clinical quality measures (CQMs) — import and calculate		For 2022 reporting period, there were 363,724 encounters loaded into the system for our 29 clients.	

Ability to import a QRDA 1 file for the measures selected by a provider for a selected time period, and to properly calculate each measure outcome.	170.315(c)(2) Clinical quality measures (CQMs) — import and calculate		11 Measures were selected by all clients: Measure Hosps Visits ED-2 4 91,648 Opid-1 29 158,277 PC-1 1 4,112 PC-5 1 4,304 PC-6 1 9 STK-2 27 43,336 STK-3 7 12,392 STK-5 15 16,024 STK-6 27 43,288 VTE-1 17 869,032 VTE-2 6 272,368	
Enable a user to electronically create a data file for transmission of clinical quality measurement data in the QRDA I or QRDA III formats for the facility or an individual patient, in accordance with published standards	170.315(c)(3) Clinical quality measures (CQMs) — report		All reports reflect the data that was submitted from the 29 hospitals that included the 186,350 patients that were loaded. 331,058 QRDA 1 files were created and submitted on behalf of the clients.	

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.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe
Update of Electronic Clinical Quality Measures to new 2023	**Acute Care Facilities**	**GA of release 09/30/22**
Data Collection and Review	**Acute Care Facilities**	**10/1/22-2/28/23**
Real World Test Plan creation and submission 2022	**Acute Care Facilities**	**10/24/23**
Conduct Real World Testing	**Acute Care Facilities**	**9/1/22-01/31/23**
Submit Real World Testing results	**Acute Care Facilities**	**1/31/24**