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.

<u>A Real World Testing plan template</u> 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, <u>85 FR 25642</u> (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:

Product Name(s): Universal EHR

Version Number(s): 2.0.0

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2478.Univ.02.00.1.19-312/

Developer Real World Testing Plan Page URL: https://www.universalehr.com/rwt/default.aspx

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):	
Version Number(s):	

CHPL Product Number(s):	
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.

Universal EHR is marketed to outpatient clinic care settings, and as such utilized Real World Testing with a clinic working closely to conduct and measure observations of interoperability. The measures used in the approach of our Real World Testing Plan for 2022 and this document uses metrics and data gathered from internal reporting and using audit logs.

Results within this document demonstrate successful interoperability through quantifiable values obtained through summative assessment and through surveying individuals involved in real world testing within the scope of the certification. Several measures have seen little to none adoption rate of the associated certified capability, which could be accounted by clinician/provider preference and specific workflows which consider implementation of the given real-world measure to be an obstacle in day-to-day activity.

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 o	r USCDI	standards.	(If yes,	please
C	omplete the ta	able below	•						

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

Standard (and version)	
Updated certification criteria and associated product	
CHPL Product Number	
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.

Outpatient Settings – Universal EHR is currently marketed only to ambulatory/outpatient settings.

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 <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 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)
Measure 1: Send Patient Health Information Via Direct Messaging	170.315(b)(1): Transitions of Care	PhiMail server	This measure tracks how many CCDAs were reportedly sent through Direct Messaging. Our clinicians have the ability to generate a CCDA within a patient chart and must then send it through the PhiMail server, in which can then be counted and tracked within the reporting interval. Practice Setting: Outpatient Primary Care Reporting Interval: January 1, 2022 – December 31, 2022 CCDAs Transmitted through Direct Messaging: 0 Analysis: Although the functionality to send CCDAs through direct messaging is available through our PhiMail server, authorized recipients such as referred providers almost always did not have their own direct message mailbox to send to. Our clinicians fax the required patient data and history, leaving direct messaging with CCDAs with little adoption.	
Measure 2: Incorporating	170.315(b)(2): Clinical		This measure tracks how many CCDAS were reportedly received	

Patient Health Information via Direct Messaging	Information Reconciliation and Incorporation		and incorporated into our system from a third party using direct messaging. Practice Setting: Outpatient Primary Care Reporting Interval: April 1, 2022 – June 30, 2022 CCDAs Received and Reconciled: 0 Analysis: While the functionality to import CCDAs from third parties is available to our clinicians, it has seen little to no adoption from clinicians using our system. Most of our clinicians state this to be due to inputting patient data themselves, leaving this functionality unused in regular workflow.	
Measure 3: Number of Electronic Prescriptions Successfully Sent	170.315(b)(3): Electronic Prescribing	NewCropRX	This measure tracks and compares the number of new prescriptions created through our system using the NewCropRX interface. All prescriptions from our prescribers dating this year were queried to obtain the Final Status code, in which Success and Verified are counted as successful prescriptions, while Failure counted as failed prescriptions concerning this measure. Practice Setting: Outpatient Primary Care Reporting Interval: January 1, 2022 December 31, 2022 Total Prescriptions Sent: 83,797 Successful/Verified Prescriptions: 83,573 Prescriptions with Failure: 223	

		Analysis: Universal EHR utilizes the NewCropRX interface for providers to prescribe medication for patients. The prescription data (including send status and medication information) is transmitted and updated in our system after the NewCropRX interface is closed. Prescribers we surveyed stated that the majority of prescription failures were due to user errors with the interface, most of which were fixed by redoing the prescription.	
Measure 4: Export Patient Data	170.315(b)(6): Data Export	This measure tracks the number of exports of a batch of individual patient data through the functionality available in the EHR. Practice Setting: Outpatient Primary Care Reporting Interval: January 1, 2022 December 31, 2022 Successful Batch Exports: O Results: The functionality to export data for multiple patients has remained for the most part unused.	
Measure 5: Report of Clinical Quality Measures	170.315(c)(1): CQM – Record and Export 170.315(c)(2): CQM – Import and Calculate 170.315(c)(3): CQM – Report	This measure tracks which CQM measures were generated and submitted from Universal EHR to CMS. Practice Setting: Outpatient Primary Care Reporting Interval: April 1, 2022 – June 30, 2022 CQMs Successfully Generated and Submitted to CMS: 6	

		CMS 2 (Depression Screening), CMS 124 (Cervical Cancer Screening), CMS 125 (Breast Cancer Screening), CMS 130 (Colorectal Cancer Screening), CMS 165 (Controlling Blood Pressure), Quality #39 (Osteoporosis Screening) Analysis: Six CQMs were generated within the three month period and were all able to be submitted to CMS. Our results show that this module functionality is working as expected, but is not used regularly.	
Measure 6: Patient Portal Use	170.315(e)(1): View, download, and transmit to 3 rd party	This measure tracks the number of times a unique patient accessed their patient portal, such as to view encounter notes, lab and radiology results, audit log history, and other patient data. This value will be compared with the total number of patients seen by our providers this year, tracked by the number of unique patients with encounters from within the reporting interval. Practice Setting: Outpatient Primary Care Reporting Interval: January 1, 2022 — December 31, 2022 Patient Portal Logins: 889 Patients with Encounters: 16,957 Analysis: While the patient portal is functional and available to patients, it seems that the system is not commonly used by patients. Patients are able to log in to view their individual patient data at any time using the Universal EHR patient portal, but are not required to as test results and other	

		information can also be obtained in-person at the clinic or through the patient's telephone.	
Measure 7: Transmission to Immunization Registries	170.315(f)(1): Transmission to Immunization Registries	This measure tracks the number of immunization records successfully transmitted to immunization records to CAIR (California Immunization Registry). This value will be compared with the total number of immunization records reported within the reporting interval. Practice Setting: Outpatient Primary Care Reporting Interval: April 1, 2022 – June 30, 2022 Immunization Records: 1412 Transmissions: 0 Analysis: Our clinicians reported that all immunizations were manually transmitted to CAIR	
		(California Immunization Registry). As a result, immunization records were transmitted but the HL7 functionality was unused.	
Measure 8: Transmission to Public Health Agencies – Syndromic Surveillance	170.315(f)(2): Transmission to Public Health Agencies – Syndromic Surveillance	This measure tracks the number of successful transmissions of syndromic surveillance data to the state's registry via HL7 format.	
Carremanes	- Cur ve manes	Practice Setting: Outpatient Primary Care	
		Reporting Interval: January 1, 2022 – December 31, 2022	
		Transmissions of Syndromic Surveillance: 0	
		Analysis: Since our clinicians had not been requested to send	

		syndromic data to any registries in particular, this functionality has seen little to no adoption from our clinicians and providers.
Measure 9: Compliance of API Resource Query Support	170.315(g)(7): Application access – patient selection 170.315(g)(8): data category request 170.315(g)(9): all data request	This measure tracks the number of successful API accesses through the Universal EHR API concerning certifications 170.315(g)(7), 170.315(g)(8), 170.315(g)(9). Since adoption rate for this API was expected to be low or none, testing the functionality instead using synthetic patient data. Practice Setting: Outpatient Primary Care Reporting Interval: January 1, 2022 — December 31, 2022 Testing Results: 2 Successful API accesses Analysis: Although the Universal EHR API functionality is available to third parties and patients, it has seen little adoption. Our test results indicate that a user should be able to successfully access and connect to the server.
Measure 10: Direct Project	170.315(h)(1): Electronic Exchange – Direct Project	Practice Setting: Outpatient Primary Care Track electronic exchange of patient data through service like direct project. Reporting Interval: January 1, 2022 – December 31, 2022 Analysis: Out of the providers that are participating in the Real World Testing, none had used the functionality to exchange patient data through direct project.

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
Release of RWT Documentation provided to authorized providers and representatives testing the measurements and metrics.	Outpatient	12/15/2021
Initialize data collection of RWT measurements	Outpatient	1/1/2022
Meet with authorized providers and representatives to ensure RWT protocols are being followed.	Outpatient	2/1/2022
Follow up with authorized providers and representatives to check on data collection	Outpatient	3/1/2022
Meet with authorized providers and representatives to ensure RWT protocols and guidelines are being followed and are effective.	Outpatient	6/1/2022
End of Real World Testing data collection period, start of finalization of data for analysis.	Outpatient	1/1/2023