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.

INTRODUCTION

This document contains a list of the steps taken to conduct the annual Real World Testing requirements for ONC certification. The Results within this document were reviewed as Screenshots and spreadsheets for their compliance with the criteria defined in the test plan. These artifacts will be maintained by the health IT developer for audit purposes or further requests.

GENERAL INFORMATION

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

Product Name(s): **CGM MEASURES**

Version Number(s): **2023.1**

Certified Health IT Product List (CHPL) Product Number(s): **15.02.04.2700.MEAS.23.02.1.230911**

Developer Real World Testing Plan Page URL: https://www.cgm.com/usa_en/products/electronic-health-records/cgm-measures-mips-dashboard.html

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.

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to ***perform as intended by conducting and measuring observations of interoperability and data exchange***", our test plan focused on capturing and documenting the number of instances that certified capability was successfully utilized in the real world.

Per the test plan, we leveraged the following to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing

Adoption rate was used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might be accounted for by patient volume, location or provider preference among other reasons. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments were used to measure which certified actions were performed at the conclusion of a given time period where the minimum time period was 90 days and longer where possible. These results are typically obtained by generating reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

This approach allowed for the successful testing and obtaining results for each criterion. Detailed below in the **Metrics and Outcomes** section the reader will find evidential data in the form of a Summative result(s) or Interactive test outcome for each certified criteria for **CGM MEASURES**

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	CHPL Product Number	Conformance Measure

Care Setting(s)

CGM MEASURES is marketed to integrate with CompuGroup Medical's existing ambulatory EHR clientele for participation in the MIPS program

Care Setting	Justification
Primary Care	C1-C3 criteria is used similarly across all ambulatory care settings
General Specialties (Endocrinology, Urology, OBGYN, etc)	

Metrics and Outcomes

Real World Testing measures as defined in their Real World Test plan. Data was collected by tracking counts of user actions per the defined metrics. Outcomes are listed as Pass, Pass with Exception, or Fail determined by the success of obtaining testing results. Results are referenced in the Outcome Details table with further supporting documentation available upon request.

Associated Criterion(a)	Measurement/Metric	Relied Upon Software	Outcomes	Challenges Encountered
170.315(c)(1-3) Clinical quality measures (CQMs)	Over a 270 day performance period 1) Total number of Quality Measures recorded over the period 2) Total number of CCDA data files imported over the period (used to record data from EHR) 3) Total number of QRDA1 files imported / exported over the period 4) Total Number of QRDA3 aggregate reports generated over the period	N/A	PASS 1) 374 total 21 unique 2) 59265 3) 0 imported 14066 exported 4) 56	*Data was successfully collected for all providers against all metrics. See Summative Description for details.*

Outcome Details

The following sections contain additional descriptions and test results supporting documentation to provide more context for the testing outcomes defined in the **Metrics and Outcomes** table above.

170.315(c)(1-3) Clinical Quality Measures (CQMs)

Summary Description
Over the 270-day period, there were a total of 132 registered providers, of which 56 actively tracked electronic Clinical Quality Measure (eCQM) outcomes using data recorded in the Electronic Health Record (EHR). These providers selected 21 unique eCQMs, resulting in a total of 374 combined eCQMs. During this period, 59,265 Consolidated Clinical Document Architecture (CCDA) files were imported for data recording, while 14,066 Quality Reporting Document Architecture (QRDA1) files were exported, with no imports. Notably, one provider accounted for a disproportionately high number of exports (4,662), likely due to exporting the same set of files multiple times. Additionally, 56 QRDA3 files were exported by 11 unique providers, with 4 of these providers exporting 5 or more QRDA3 files during the period. The data collected over this 270-day period in this year's plan—compared to the one-year period of prior plans—shows an overall increase in activity, which can be attributed to heightened participation among CGM eMDs providers. We anticipate a continued gradual increase in these numbers over the next year as more eMDs providers actively use CGM measures.
Justification
These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format. C2 requires a certified Health IT module must be able to import data from a QRDA Category 1 formatted file and calculate the CQMs based on that data. C3 requires a certified Health IT module must be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS.

To demonstrate the certified capability is available and effective, regardless of the frequency it is used, we intend to document: the number of imported CCDA files which are utilized to record the required data in the Health IT module (as captured in the EHR) and used to calculate CQM score. We also intend to document the number of CQM files imported or exported, as well as confirm successful upload of QRDA3 to QPP. Our expectation is there will be high utilization by active providers with a high success rate
Results Supporting Documents
Supporting Documents available upon request

KEY MILESTONES

Includes a list of key milestones that were met during the Real World Testing process. Includes details on how and when CGM MEASURES implemented measures and collected data.

Key Milestone	Care Setting	Date/Timeframe
CGM MEASURES executed Summative testing to show that the criterion are functional.	-Primary Care -General Specialties	Data collected from 01/01/2024 to 09/27/2024

ATTESTATION

This Real World Testing Results Report 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: 12/15/2024

[i] https://www.federalregister.gov/d/2020-07419/p-3582