REAL WORLD TESTING PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). 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 to develop 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 for 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 which 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. 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 would expect 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. 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 Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**Century Cures final rule**)
  - ↳ *Section VII.B.5 — "Real World Testing"*

GENERAL INFORMATION

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

Developer Name: CompuGroup Medical US

Product Name(s): CGM MEASURES

Version Number(s): 1.1.0

Certified Health IT: 2015

Product List (CHPL) ID(s): 15.02.04.2700.A070.01.01.1.211103

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

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

CGM MEASURES is a web-based Certified Health Information Technology module that integrates with CompuGroup Medical's existing ambulatory EHRs for Quality Measure reporting. Because the criteria certified to and identified by ONC for Real World Testing are closely related, we will test these criteria simultaneously: 170.315(c)(1) – Clinical Quality Measures (CQMs) – Record and Export, 170.315(c)(2) – Clinical Quality Measures (CQMs) – Import and Calculate, 170.315(c)(3) – Clinical Quality Measures (CQMs) – Report.

The test plan focuses on capturing and documenting the number of instances that a certified capability is successfully utilized in the "Real World". This is consistent with 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*".

Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements and is performed in addition to testing conducted during the development lifecycle and certification process. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in the "Real World".

We have proposed the following approach to demonstrate successful Real-World implementations

- Adoption Rates
- Real World Assessment

Adoption Rates will be used to determine if/when a 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 may indicate (but do not necessarily prove) a certified capability's usefulness and practical value. Although low rates of implementation and usage may indicate a potential problem, other factors and considerations may contribute. It is not the sole purpose of this exercise to identify 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.

Real World Assessments will be performed to measure the number of certified actions performed by clients over a given time period. Data will be collected by running reports and examining audit logs from within the Certified Health IT Module, and where possible determine if the actions were successful vs unsuccessful.

Simulation testing for 170.315(c)(1-3) Clinical quality measures (CQM) was not included in the test plan as comparable validation testing is performed extensively during the development lifecycle and the during the certification process using the Cypress Test Tool.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

CGM MEASURES voluntarily updated to conform to the standards referenced for the 2015 CURES Edition 170.315(c)(3) criteria.

Criteria	2015 CURES EDITION - Standard
170.315(c)(3) – Clinical Quality Measures (CQMs) – Report	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022

Date of ONC-ATB Notification	10/14/2022
Date of Customer Notification	11/01/2022
USCDI - updated criteria	None

CARE SETTINGS

CGM MEASURES is marketed to integrate with CompuGroup Medical's existing ambulatory EHR clientele for participation in the MIPS program. Although C1-C3 criteria is used similarly by participating providers, we will conduct testing for the following active care settings:

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

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Care setting(s) that are addressed
- ✓ Justification for selected measurement/metric
- ✓ Expected Outcomes

ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of licensed providers of Health IT Module • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Identify the total number of provider licenses of the Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of HIT Module	Identify the total number of ***active*** installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

REAL WORLD ASSESSMENT

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases we elected to record these metrics over a full year to reflect the performance periods typically required for compliance with the federal incentive programs (MIPS).

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. We will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

Successful upload of QRDA3 to QPP demonstrates conformance to CURES Edition criteria for 170.315(c)(3) – Clinical Quality Measures (CQMs) – Report

Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(c)(1-3) Clinical quality measures (CQMs)	Over a 1-year 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		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

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2023. Each phase is expected to take 90-days to complete, with report writing to occur end of 2023/early 2024.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	ALL	90-days
Data collection	ALL	90-days
Review and collate data	ALL	90-days
Writing report	ALL	90-days

ATTESTATION

The Real World Testing plan must include the following attestation signed by the Health IT Developer Authorized representative.

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.

Authorized Representative Name: Neil Simon

Authorized Representative Email: nsimon@emds.com

Authorized Representative Phone: 469-863-8300

Authorized Representative Signature: Neil Simon

Date: 12/9/2022