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 – Coming Soon
- 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: Objective Medical Systems, LLC

Product Name(s): OMS EHR

Version Number(s): 3.1.0.00; 4.0.0.00

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2086.OMSE.03.01.1.210610; 15.04.04.2086.OMSE.04.02.1.211203

Developer Real World Testing Page URL: https://objectivemedicalsystems.com/rwt-test-plan_oms_2023/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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***", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. 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 live settings.

We are using a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing

Adoption rate will be 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 indicate a potential problem, of which there could be several different causes. 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 will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted 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.

Interactive testing will be used to demonstrate conformance to requirements where the adoption rate of a given certified capability is zero and to demonstrate ongoing compliance with updated standards and code sets (SVAP). Interactive tests will require a live test as opposed to examining historical usage statistics. The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

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

Objective Medical Systems is currently working on the following SVAP measures and expect it to be ready by Dec 2022:

1. § 170.315(b)(1) Transitions of care

2. § 170.315(b)(2) Clinical information reconciliation and incorporation

3. § 170.315(c)(3) Clinical quality measures (CQMs) — report

4. § 170.315(e)(1) View, download, and transmit to 3rd party

5. § 170.315(h)(1) Direct Project

6. § 170.315(f)(7) - Transmission to public health agencies — health care surveys

7. § 170.315(g)(9) Application access - all data request

8. § 170.315(g)(10) - Standardized API for patient and population services

CARE SETTINGS

OMS EHR is marketed exclusively to ambulatory Cardiology private practices.

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 installs/users of EHR • 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 licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of EHR	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.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed separately	Identify which certified capabilities are licensed separately from the base EHR license. Examples may include eRx, CQMs, public health, etc.
Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of ***active*** installs/users of a given certified capability.

SUMMATIVE ASSESSMENT METRICS

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 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

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. In cases where it is not possible to determine "success" via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

The following criteria are being updated to the Cures Update version of criteria. As a result, all testing is scheduled to be conducted against the 2022 Edition of the criteria.

Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(b)(1) Transitions of care	Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	Ambulatory Cardiology	This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies and intolerance list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA	Ambulatory Cardiology	This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.

170.315(b)(3) Electronic prescribing	Over a 90-day period: 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed	Ambulatory Cardiology	This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(c)(1-3) Clinical quality measures (CQMs)	Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA Category 1 files exported 3) Number of QRDA Category 1 files imported (if applicable) 4) Number of QRDA Category 3 aggregate report(s) created over the period	Ambulatory Cardiology	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. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.

170.315(e)(1) View, download, and transmit to 3rd party	Over a 90-day period: 1) Number of views of health information by a patient or authorized representative 2) Number of downloads of health information by a patient or authorized representative 3) Number of transmissions of health information by a patient or authorized representative using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using encrypted method	Ambulatory Cardiology	This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(h)(1) Direct Project	1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received 4) Number of Delivery Notifications sent	Ambulatory Cardiology	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available. OMS will demonstrate that the certified capabilities are available and operating in Real World production systems and awaiting adoption.

OMS will use interactive testing for the following criteria:

- §170.315(b)(6) Data export
- §170.315(f)(7) Transmission to public health agencies — health care surveys
- 170.315 (g)(7): Application Access - Patient Selection
- 170.315.(g)(9): Application Access - All Data Request
- 170.315.(g)(10): Standardized API for Patient and Population Services

High Level Interactive Test Plan:

- **Care Settings**: Cardiology
- **Test Environment:** All interactive testing will be performed in a live, production environment. OMS will partner with a Cardiology clinic customer and engage that clinic's system administrator to participate in these interactive tests in their production environment.
    - OMS will use recorded teleconferences for visual inspection of results to capture the evidence of the testing. For privacy and security purposes, the recording will be stored on the participating clinic's network for the period of 1 year in the event that the ONC will seek to examine the evidence supporting the results of interactive testing.
- **Test Data**: Interactive testing will be performed using live patient data in the live production environment except where specified below for security reasons. Precautions will be taken to reduce the risk of exposure of PHI.

Criterion	Metric	Care Setting	Interactive Test Plan	Justification and Expected Outcome
§170.315 (b)(6) Data export	Over a 90-day period: 1) Number of times CCDAs exported for single patient 2) Number of times CCDAs exported for batch of patients		OMS will partner with one Cardiology clinic customer and engage with the clinic's system administrator to export CCDAs for 5 Real-World cardiology patients. *For security reasons, these CCDs will be stored on-prem in the Cardiology clinic and will not be exported or uploaded to any tools. Visual inspection will be used to ensure that the CCDs are correctly formed and include the expected CCDS data elements.	**Justification:** OMS Health developed the Data export capability anticipating a use case to support exporting of CCDAs if a patient is leaving the practice, either individually or a batch export for data migration. This certified capability is live and available in production for all clinics, but none of the cardiology practices that use the OMS EHR have needed to use the feature to date. **Expected Outcome:** • CCDs are generated for a single patient as well as a batch of patients by date of encounter • CCDs are well formed and contain all the CCDS data elements for the patient.

§170.315 (f)(7) Transmission to public health agencies — health care surveys	Over a 90-day period: 3) Number of times Healthcare surveys exported		OMS will partner with a cardiology clinic customer to generate the HealthCare Survey files for 2 Real World patients and use visual inspection to verify that they contain the required sections. To prevent unnecessary exposure of PHI, these files will be generated and stored locally on an on-premise hard drive at the clinic. OMS will use a recorded teleconference for the visual inspection, and the teleconference recording will be stored locally on the client's network for 1 year in the event that ONC seeks to examine the evidence supporting the results of this interactive test.	**Justification:** OMS works with Pinnacle as a specialized Cardiology registry and developed the Health Care Surveys certified capability to send Health Care Surveys to the Pinnacle registry. To date, OMS client providers have reported that the requirement to download Health Care Surveys and manually upload them to the Pinnacle registry requires resources to be available to do that which is not a priority for the practice. **Expected Outcome:** • Exported health survey for each patient is a well formed CDA R2 document and contains all the expected CCDS elements for the patient.
170.315 (g)(7): Application Access - Patient Selection meets170.315	Over a 90-day period: 4) Number of times Patient is selected 5) Number of times CCDA data categories are returned 6) Number of times CCDA documents are returned		Objective Medical Systems will partner with a cardiology clinic customer to use Postman to make API calls for 2 Test Patients. OMS will work with the System administrator at the clinic to create 2 test patients with test data that represents a typical cardiology patient. Test patients will be used to limit exposure of PHI to external tools. Once the patients are set up, OMS will use PostMan (Inferno tool in case of g10) to:	**Justification:** OMS built the OMS Health API functionality anticipating a primary use case supporting clinics sharing data with other institutions for a referral, payor or research workflow. We anticipated that other institutions would access the API to build capabilities to pull data about specific patients after the consent, authentication and other security considerations are in place. The API certified capabilities are available and configured for use in all OMS practices. To date, our understanding is that application vendors have not approached these
(g)(10): Standardized API for Patient and Population Services				

(g)(9): Application Access - All Data Request			• Send demographic data in order to identify and select the patient and receive a token for us in subsequent queries • Query for patient data for both patients, for all CCDS categories • Query for a CCDA document	clinics to leverage this API functionality, so it has not yet been adopted. The API is using the latest, FHIR R4 standard in order to promote adoption. We are hoping that as FHIR adoption increases with 21st Century Cures focus, that this adoption will increase as well. If there is adoption by end of 2022, we will provide summative metrics for this criterion instead, however we anticipate that this is more likely in 2023. **Expected Outcome:** • Patient is selected and token is returned for both patients • CCDS data categories are returned for both patients and include the expected data • CCDA document is returned for both patients and include the expected data

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

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

Real World test planning will commence in third 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	Ambulatory Cardiology	90-days
Data collection	Ambulatory Cardiology	90-days
Review and collate data	Ambulatory Cardiology	90-days
Writing report	Ambulatory Cardiology	90-days

ATTESTATION

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

Note: The plan must be approved by a Health IT Developer authorized representative capable of binding the Health IT Developer for execution of the plan and include the representative's contact information.[i]

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: Anand Aravind

Authorized Representative Email: anand.aravind@omshealth.com

Authorized Representative Phone: 404-520-9541

Authorized Representative Signature: Anand A

Date: 10/27/2022

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