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: Quest Diagnostics Incorporated

Product Name(s): Quanum EHR

Version Number(s): 2020

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2928.Quan.20.03.1.200623

Developer Real World Testing Page URL:

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)

Quest Diagnostics has not updated Quanum EHR to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of the 2022 Real World Test.

CARE SETTINGS

Quest Diagnostics does not market Quanum EHR any differently for different provider types. Nor does Quest track the types of providers who acquire Quanum EHR. The provider type is a configurable field in the EHR that is completed by the provider at their discretion. Not all providers declare their care setting or specialty, and sometimes they may change it unexpectedly. Altering this field has no impact on the behavior of the EHR itself.

Care Setting	Justification
Primary Care	Larger focus on preventative care than most specialty providers. Not limited to a single organ group. This results in a workflow that is more likely to incorporate more features of the software.
Specialties	Larger focus on remedial care than primary care providers. Typically specialize in a single organ group. This results in a workflow with a narrower field of use than most primary care providers.
Undeclared	Not all providers declare a specialty or care setting so they cannot be grouped with other care settings.

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.

None of the following criteria were updated to the Cures Update version of criteria prior to August 31, 2021. As a result, all testing is scheduled to be conducted against the 2015 Edition version 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	• Primary Care • Specialties • Undeclared	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 moderate utilization by providers with a high success rate.
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	• Primary Care • Specialties • Undeclared	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 low utilization by providers with a high success rate.

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	• Primary Care • Specialties • Undeclared	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 high utilization by providers with a high success rate.
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	• Primary Care • Specialties • Undeclared	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 moderate utilization by providers with a high success rate.

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	• Primary Care • Specialties • Undeclared	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 moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.
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	• Primary Care • Specialties • Undeclared	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 moderate utilization by providers with a high success rate.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available. Quest has not had any uptake in the following criteria because Quest already had functionality which has serviced customers for years:

- 170.315(b)(6) Data export
- 170.315(g)(7-9) Application access

High Level Interactive Test Plan:

- **Care Settings**: Quest is currently used in the Primary care and Specialty Medicine care settings.
- **Test Environment:** All interactive testing will be performed in a live, production environment.
    - The plan for interactive testing the criteria described below in the real world will be to engage with two (2) customer providers in a primary care and specialty settings, where the certified Health IT module is deployed as a representative sample to show that this certified capability works in the real world and that it works the same way in all settings.
- **Test Data**: Interactive testing will be performed using standard test patient data in the live production environment in order to be as representative as possible of real-world deployments. Precautions will be taken to reduce the risk of exposure of PHI.
    - 2 test patients are already set up and regularly used in the live production environment for the purposes of training users.

Criterion	Interactive Test Plan	Justification and Expected Outcome
170.315(b)(6) Data export	Quest will partner with a customer in each of the Primary Care and Specialty clinical settings, and will export CCDAs for Real World patients. CCDAs will be visually inspected over a recording teleconference. The CCDAs will remain on the provider system in order to reduce the risk of exposing PHI. Quest will perform the following exports: - export CCDA for 2 patients, using the single export function - export batch CCDAs for all patients with encounters in a given week.	**Justification:** The only scenario where we expected providers to consider using a CCDA export. is the case where they need to export patients for data backup for offline use if the internet goes down in order to view patients in a CCDA viewer. Quest has already integrated features which provide the 170.315(b)(6) Data Export functionality. Most of the time when providers communicate patient information, they do it in a message style or they use Direct, or even fax. For communicating CCDAs to patients, most of our customers use the Quest Diagnostics portal. They have not really needed a CCDA export feature. It took 10 years to get 117 practices out of 2000 to adopt direct. This is now entrenched and they don't want to use other features. The rest of the providers have not prioritized promoting interoperability and have other priorities. **Expected outcomes:** o For the individual patient export, the CCDAs will be visually inspected to confirm that the CCDAs exported for the individual test patients are well formed and contain the expected data. o For the batch export, the number of patients exported will be verified against the number of patients encountered for the week.

170.315 (g)(7): Application Access - Patient Selection meets170.315 (g)(8): Application Access - Data Category Request meets170.315 (g)(9): Application Access - All Data Request	Using the two (2) test patients in each of the two (2) care settings, Quest will use a Quest developed app to demonstrate that a patient user can request their own data using an API from a production environment. We will mimic the typical Real-World provider workflow where a patient is provided with a PIN letter during the encounter with the provider, and then the patient will use the PIN letter to verify their identify and query for their token for subsequent queries. The patient will follow these high-level steps: • Test user logs into test app as patient and looks up their test results. • Test app queries the API for discrete CCDS fields • Test app queries the API for patient CCDA documents	**Justification:** Quest has a proprietary patient portal where patients can get their lab results and provider data directly from providers so the need is already met. Additionally, no app developers have approach Quest to develop an app to connect to Quanum EHR API for patients. Providers send data to each other using Direct, but have not requested an API workflow at this time. While Quanum EHR does use FHIR capability to connect to HIEs and other functionality and have found other ways for API capability to be effective, the way the g7-g9 criteria have not been adopted as developed at this time. **Expected outcomes**: • Patient ID is accepted, and token is returned • Patient CCDS data is visible in the app as either discreet data fields or as a CCDA

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2022. Each phase is expected to take 90-days to complete, with report writing to occur end of 2022/early 2023.

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

ATTESTATION

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.

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