REAL WORLD TESTING PLAN FOR 2024

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.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning 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 the 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. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. 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 expects 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. **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 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 plan. Each section provides a field for submitting responses and/or explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

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

Developer Name: Modernizing Medicine Gastroenterology, Inc.

Product Name(s): gGastro

Version Number(s): **6**

Certified Health IT Product List (CHPL) Product Numbers(s): 15.04.04.3031.gGas.GA.10.1.221207

Developer Real World Testing Page URL: https://www.modmed.com/2015-edition-cures-act-update-gi/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing.[i]

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan 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**", 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 uNITED sTATES CORE DATA FOR INTEROPERATBILITY (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.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✔ Identify Standard Versions
- ✔ Indicate what certification criteria in which product(s) has been updated
- ✔ If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products
- ✔ CHPL Product Number for each Health IT Module
- ✔ Method used for standard update (e.g., SVAP)
- ✔ Date notification sent to ONC-ACB
- ✔ If SVAP, date notification sent to customers
- ✔ Measure used to demonstrate conformance with updated standard(s)
- ✔ Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?

Standard (and version)	N/A
Updated certification criteria and associated product	
CHPL Product Number	
Method used for standard update	
Date of ONC ACB notification	
Date of customer notification (SVAP only)	
Conformance measure	
USCDI updated certification criteria (and USCDI version)	

CARE SETTINGS

The expectation is that a developer's Real World Testing plan will address 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. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Gastroenterology	gGastro is marketed exclusively to Gastroenterology providers

MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen meet the intent and purpose of Real World Testing.

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).

Measurement/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.

Measurement/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.

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 minimum 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 or added prior to August 31, 2023.

Criterion	Measurement/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	Gastroenterology	**Justification:** 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. **Test Methodology:** 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. 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. **Expected Outcomes:** 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 CCDA received 2) Number of CCDA received and patient matched 3) Number of CCDA received and reconciled	Gastroenterology	**Justification:** 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. **Test Methodology:** 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. **Expected Outcomes:** 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	Gastroenterology	**Justification:** This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. **Test Methodology:** 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 (DrFirst). 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. Relied upon software: DrFrist. **Expected Outcomes:** Our expectation is there will be high utilization by providers with a high success rate.
170.315**(b)(6)** Data export	Over a 90-day period: 1) Number of times a data export was performed for a single patient or multiple patients	Gastroenterology	**Justification:** This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCDA format according to specified standards and vocabulary code sets. **Test Methodology:** 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. Therefore, we intend to demonstrate the certified capability is available and effective, regardless of the frequency it is used. **Expected Outcomes:** Our expectation is there will be very low 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	Gastroenterology	**Justification & Test Methodology:** 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. **Expected Outcomes:** 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	Gastroenterology	**Justification:** 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. **Test Methodology:** 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. **Expected Outcomes:** 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 **(g)(10)** Standardized FHIR Server API for patient and population services	Over a 90-day period: 1) Number of requests for a patient's data made by an application via the FHIR server using a valid patient ID or token 2) Number of requests for a patient's data made by an application via the FHIR Server at a data category request using a valid patient ID or token for a specific date range	Gastroenterology	**Justification:** This criterion requires the certified Health IT module to provide a FHIR Server API and supporting documentation that enable external applications to request patient data by category from the certified Health IT FHIR Server. **Test Methodology:** We intend to record the frequency that patient data requests by category are received by providers and fulfilled via FHIR Server API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. **Expected Outcomes:** Our expectation is there will be moderate utilization by providers with a high success rate.

170.315**(h)(1)** Direct Project	Over a 90-day period: 1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received	Gastroenterology	**Justification:** 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. **Test methodology:** 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. **Expected Outcomes:** 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, because there is 0 adoption to date of the criteria.

(gGastro) will leverage interactive testing for the following criteria :
- § 170.315(a)(9) Clinical Decision Support
- § 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

High Level Interactive Test Plan

- **Care Settings**: gGastro is currently used in the Gastroenterology specialty care setting.
- **Test Environment:** All interactive testing will be performed in a customer's live, production environment.
  - o The plan for interactive testing the criteria described below in the real world will be to partner with provider representatives from different specialties where the certified Health IT module is deployed to demonstrate that this certified capability works in the real world and that it works the same way in all specialty settings.
  - o Modernizing Medicine will use a conference based platform to perform/watch/record the testing workflows and keep the evidence of the results as appendices for results reporting and in the event of any audit by the ACB or ONC.
- **Test Data**: Interactive testing will be performed using test patient data in conjunction with a Clinician in the live production environment in order to be as representative as possible of real-world patient data in the provider's specialty domain. This will be done as a precaution to reduce the risk of exposure of PHI.

Criterion	Interactive Test Plan	Justification and Expected Outcome
170.315**(a)(9)** Clinical Decision Support	Modernizing Medicine will partner with 1 gGastro customer, to enter test patients into their production environment and measure: 1) Number of interactions that are acted upon by clinicians. 2) Number of drug interaction alerts received by clinicians.	**Justification:** This criterion requires the ability of a certified Health IT module to support development, adoption, and implementation of CDS to improve health care decision making and better outcomes for patients. **Expected Outcomes:** We intend to demonstrate the required certified capabilities by demonstrating how often a CDS interaction is triggered and number of times they are acted upon. Interactions may include drug and preventative care alerts.
170.315 **(f)(7)**: Transmission to Public Health Agencies - Health Care Surveys	Modernizing Medicine will partner with 1 gGastro customer practice to create 2 test patients and generate a Health Care Survey for the Outpatient Setting CCDA document for each patient.	**Justification**: Gastroenterology clinics have not been asked to report to any specific registries using Health Care Surveys, so currently this certified capability is not in use. **Expected Outcomes:** Visual inspection will be used to confirm that each of the CCDA documents that is generated contains all the expected information per the National Health Care Surveys standards.
170.315 **(g)(7)**: Application Access - Patient Selection meets 170.315 170.315 **(g)(9)**: Application Access - All Data Request	Modernizing Medicine will partner with 1 gGastro customer, to enter test patients into their production environment and then use the gGastro dashboard UI to verify their identity and query for their token for subsequent queries. The patient will follow these high-level steps: ● Test user logs into the test app as a 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:** Modernizing Medicine anticipates that as RESTful standards mature and consolidate, we will see more adoption of the API certified capability in the Real World, but to date there have not been any app developers who have built applications for our specialized customer base. Modernizing Medicine is hoping that when we update the API to the latest FHIR R4 standard, that we will see more updates from the app developer community. **Expected outcomes**: ● Patient ID is accepted, and token is returned ● Patient CCDS data is visible in the app as either discrete data fields or as a CCDA

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in the first quarter of 2024. Each phase is expected to take 90-days to complete, with report writing to occur at the end of 2024/early 2025.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Gastroenterology	90-days
Data collection	Gastroenterology	90-days
Review and collate data	Gastroenterology	90-days
Writing report	Gastroenterology	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.[ii]

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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Authorized Representative Signature: *Ida Mantashi*

Date: 11/30/23