REAL WORLD TESTING PLAN FOR 2025

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: Integra Connect Newco, LLC

Product Name(s): IntegraCloud EHR

Version Number(s): 20.28.09

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2964.Inte.20.02.1.221122

Developer Real World Testing Page URL: https://www.integraconnect.com/company/certifications/

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 do not 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 the 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)

Integra Connect has upgraded to include standards[1]: 170.315(b)(11) Decision Support Intervention and 170.315(g)(10)(v) Standardized API for patient and population services- Patient Revocation. Any additional updates to meet 2025 Certification Standards will be added to the 2025 Real World Test plan as and when such implementations occur.

IntegraCloud EHR is marketed exclusively to outpatient and ambulatory Oncology clinics.

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.

Except for 170.315(b)(11) and 170.315(g)(10), None of the following criteria were updated to the Cures Update version of criteria prior to August 31, 2021. As a result, testing is scheduled to be conducted against the 2015 Edition version of the criteria for those criteria. For 170.315(b)(11) and 170.315(g)(10), testing is to be conducted against the updated Cures Update standards of those provisions as reflected in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing", as amended.

Criterion	Metric	Care Setting	Relied Upon Software	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 Oncology	Interoperability Engine offered by EMR Direct	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	Ambulatory Oncology	Interoperability Engine offered by EMR Direct	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	Ambulatory Oncology	Rcopia offered by DrFirst	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(b)(10) Electronic Health Information export- Single patient And Patient Population export	Over a 90-day period: 1) Single patient EHI export: Number of times a data export was performed 2) Patient population EHI Export: Number of times functionality was used to export a patient population	Ambulatory Oncology	Minerva offered by Agilon Health f/k/a mphrX	This criterion requires the ability of a certified Health IT module to create a timely export file, that is in an electronic and computable format, with all a single patient's electronic health information. This criterion also requires the ability to create an export file for a patient population. Testing this criterion: It is expected that authorized users will have the ability to share EHI for a patient and patient populations using this function. We will use system logs to monitor the volume of patient and population requests. We will validate errors rates and monitor error logs to ensure the function is operating properly. We do not anticipate high utilization of this product and therefore plan to demonstrate the feature is available and functions as expected through interactive testing.

170.315(b)(11) Decision Support interventions (DSI)	Over a Decision support Intervention (DSI) Over a 90-day period: 1) Record the number of times end users commented on decision support information 2) Record the number of times decision support information was invoked	Ambulatory Oncology	N/A	This Criterion requires health IT developers to actively present to users of decision support interventions the source attributes so users have sufficient information to determine if the information is trustworthy. In addition, end users must have the ability to evaluate and comment on the decision support information. Our expectation is there will be low to 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) 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	Ambulatory Oncology	FigMD – Pegasus Quality Platform offered by FIGmd Inc.	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 to 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 to 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, whether by using unencrypted email or encrypted methods.	Ambulatory Oncology	Interoperability Engine offered by EMR Direct	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(g)(7) Application access — patient selection	1) Number of requests for a patient ID or token 2) Number of requests that provided sufficient information to provide a valid response 1) Number of follow-up requests made using the provided patient ID or token	Ambulatory Oncology	N/A	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. We intend to record the frequency that patient ID requests are received by providers via API 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(g)(9) Application access — all data request	1) Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token 3) Number of requests for a patient's Summary Record made by an application via an all-data category request using a valid patient ID or token for a specific date range	Ambulatory Oncology	N/A	This criterion requires the certified Health IT module to provide an API and supporting documentation that enables external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API 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 (g)(10) Standardized FHIR Server API for patient and population services	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 3) Number of patient access revocation requests	Ambulatory Oncology	Minerva offered by Agilon Health f/k/a mphrX	This criterion requires the certified Health IT module to provide a FHIR Server API and supporting documentation that enables external applications to request patient data by category from the certified Health IT FHIR Server. This criterion also requires the support of patient access revocation at the patient request. 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. We are also going to record the frequency that a patient has requested to revoke access of a valid token. Our expectation is there will be zero adoption of this certified capability by our users or patients, 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	2) Number of Direct Messages sent 3) Number of Delivery Notifications received 4) Number of Direct Messages received	Ambulatory Oncology	Interoperability Engine offered by EMR Direct	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, because, to date, there is 0 adoption to date of the API criteria.

Integra Connect will leverage interactive testing for the following criteria:

- § 170.315(b)(10) Electronic Health Information export for single patient and patient populations
- § 170.315(b)(11) Decision Support Intervention (DSI)
- § 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

Justification for this approach

FHIR Server API Criteria and electronic health information export will be tested via interactive testing because there is no adoption for API certified capabilities to date.

Integra Connect reached out to client managers and clients to investigate why API criteria are not being used and determined that there was a continued lack of desire to utilize the FHIR Server API.

Integra Connect has disseminated the API developer-centric documentation to the client management team and plans to update API documentation to make it more client-centric and will produce an implementation guide to support adoption.

Until then, Integra Connect will plan to demonstrate that the certified FHIR API capabilities and electronic data export features are available in the IntegraCloud EHR production environment and ready for clients to use in the Real World.

High Level Interactive Test Plan

- **Care Settings**: Oncology only, in the outpatient setting
- **Test Environment: All** interactive testing will be performed in a live, production environment that is hosted in a centralized, SaaS architecture. All 5 clinics are hosted in the SaaS environment with their databases segregated.
    - Integra Connect will use a test facility setup on the production API server to demonstrate that the API certified capabilities are live in production and ready to be adopted, to reduce the burden of performing interactive testing on customers.
- **Test Data**: An Integra implementation specialist will log into the Test EHR and set up 3 patients of different ages, diagnoses and relevant treatment information, with data that is representative of the Oncology care setting. Data that is close to typical Oncology Real-World data will be used in order to reduce the risk of exposure of PHI from using live patient data.
- **Test Plan:**
    - For each of the 3 patients, Postman will be used to:
        - Submit demographics to identify the patient and receive a token to be used to query for subsequent data for the patient
        - Query for each of the CCDS fields for the patient
        - Query for the patient's CCD document
- **Expected outcomes:**
    - Patient ID is accepted, and token is returned
    - Patient CCDS is visible is returned correctly for all 3 test patients as discreet data fields
    - Patient CCDS is visible is returned correctly for all 3 test patients as a CCD document

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in the second quarter of 2025. Each phase is expected to take 90-days to complete, with report writing to occur end of 2025/early 2026.

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

Authorized Representative Name: Joshua Boxer

Authorized Representative Email: joshua.boxer@integraconnect.com

Authorized Representative Phone: 561-354-5395

Authorized Representative Signature: Joshua A. Boxer

Date: 11/14/2024