Real World Testing Plan 2023

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 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 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. 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"

General Information

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

Developer Name: Flatiron Health

Product Name(s): OncoEMR®

Version Number(s): 2.8

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.3010.Onco.28.01.1.181214

Developer Real World Testing Plan Page URL: https://flatiron.com/certification/

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, Flatiron Health (referred to as Flatiron moving forward) 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.

Flatiron is 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. Flatiron will conduct interactive testing on specified criteria in a non-production environment, consistent

with ONC's guidance that the developer may, "use synthetic patient data in lieu of or in addition to real patient data in real or simulated/test scenarios, executed in environments that mirror production environments."

Standards Updates (including standards version advancement process-SVAP and USCDI)

Flatiron's 2023 Real World Testing will test criteria that have been updated to include all USCDI v1 data elements before the ONC Cures Act deadline of 12/31/22.

Standard (and version)	As is required by the 21st Century Cures Act, all standards versions for relevant criteria will be updated to USCDI v1 by the end of this calendar year (2022) with a planned certification date of 11/16/22
Updated certification criteria and associated product	The following certification criteria will be updated to USCDI v1 for the OncoEMR product before the end of this calendar year (2022): ● (b)(1) Transitions of care ● (b)(2) Clinical information reconciliation and incorporation ● (e)(1) View, download, and transmit to 3rd party ● (g)(6) Transmission to public health agencies - antimicrobial use and resistance reporting ● (g)(9) Application access - all data request
CHPL Product Number	15.04.04.3010.Onco.28.01.1.181214
Method used for standard update	Cures Update Certification Testing
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	Recording in RWT Plan Document
USCDI updated certification criteria (and USCDI version)	The plan documents the support of all USCDI v1 data elements

Care Settings

OncoEMR is marketed solely to ambulatory Oncology 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). OncoEMR requires a one-time implementation fee for installation plus annual subscription fees which cover software licenses, customer support, software upgrades and services required to meet Promoting Interoperability objectives and measures. Additional certified capability is available within the OncoEMR license (patient API, CQM file export, MIPs functionality/reporting, CareSpace patient portal).

Metric	Description
Number of installs of the EHR	Identify the total number of installs of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active users of EHR	Identify the total number of ***active*** users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

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 Flatiron elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs. In most cases, Flatiron elected to record these metrics from a *representative* sampling of customers.

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, Flatiron 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, the test plan is currently written to be conducted against the 2015 Edition version of the criteria. However, some of the certified capabilities of OncoEMR may be updated to the Cures Update versions of the criteria prior to the execution of the test plan. These changes will be reflected in the test results report as required.

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 (attempted, successful) 3) Number of CCDAs received via edge protocols	Ambulatory Oncology	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, Flatiron intends 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. **Relied Upon Software:** Flatiron has partnered with MaxMD Direct mdEmail to obtain data on direct messaging and electronic referrals.
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1) Number of times a user reconciled medication list data 2) Number of times a user reconciled allergies and intolerance list data 3) Number of times a user reconciled problem list data	Ambulatory Oncology	This criterion requires the ability of a certified Health IT module to take data 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, Flatiron intends 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	Ambulatory Oncology	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

	2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed		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, Flatiron intends 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. **Relied Upon Software:** Flatiron has partnered with the Surescripts, DrFirst, and First Databank for e-prescribing functionality in OncoEMR. ● Surescripts Clinical Direct Messaging: e-Prescribing ● DrFirst - EPCS Gold ● First Databank
170.315(b)(6) Data export	Over a 90-day period: 1) Number of times a data export was performed	Ambulatory Oncology	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. 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. Therefore, we intend 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(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 (attempted, successful)	Ambulatory Oncology	This criterion 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. Flatiron intends to record the frequency that CQM files are 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 (attempted, successful) 3) Total number of transmissions of health information by a patient or authorized representative (attempted, successful) 4) Number of transmissions of health information by a patient or authorized representative using unencrypted method 5) Number of transmissions of health information by a patient or authorized representative using encrypted method	Ambulatory Oncology	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. Flatiron intends 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. **Relied Upon Software:** Flatiron has partnered with Amazon Pinpoint to support transmit functionality in OncoEMR.
170.315(f)(1) Transmission to immunization registries	Over 3 separate unique 10-day periods within a 90-day window: 1) Number (or percentage) of immunization records submitted to the immunization record 2) Total number (or percentage) of immunization history/forecasts requested from the immunization registry	Ambulatory Oncology	This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. Flatiron intends to record the frequency that immunization data is submitted to registries by 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, although there may be changes in 2022 given recent state guidelines and CMS proposed rules on more stringent reporting requirements.
170.315(f)(4) Transmission to	Over 3 separate unique 10-day periods within a 90-day window:	Ambulatory Oncology	This criterion requires the ability of a certified Health IT module to transmit cancer case information to a registry using a specified format.

cancer registries	1) Total number of cancer registry data records created and submitted		Flatiron intends to record the frequency that cancer case information is submitted to registries by 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(g)(7) Application access — patient selection	Over a 90-day period: 1) Number of requests for a patient ID or token 2) Number of requests that provided sufficient information to provide a valid response 3) Number of follow-up requests made using the provided patient ID or token	Ambulatory Oncology	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)(8) Application access — data category request	Over a 90-day period: 1) Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token 2) Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token for a specific date range	Ambulatory Oncology	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request patient data by category from the certified Health IT module. We intend to record the frequency that patient data requests by category 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)(9) Application access — all data request	Over a 90-day period: 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	Ambulatory Oncology	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable 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,

	2) 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		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 due to lack of adoption of the certified capability. Individual justifications for why each criterion has had low adoption are specified in the table below.

Flatiron will leverage interactive testing for the following criteria:

- §170.315(b)(6) Data export
- § 170.315(g)(7) Application access—patient selection
- § 170.315(g)(8) Application access—data category request
- § 170.315(g)(9) Application access—all data request

High Level Interactive Test Plan:

- **Care Settings**: All interactive testing will be performed specifically targeting Oncology practice settings and real world data exchanges in the Oncology space.
- **Test Environment:** All interactive testing will be performed in a live, staging environment. See table below for details.
    - Flatiron will record the tests via a video recording as a means of walking through the intended workflow for the criteria and capture evidence that the functionality works as expected in the Real-World deployment.
- **Test Data**: Interactive testing will be performed using specially developed test patient data in the live staging environment. Test patients will be created using the data elements that are typically used by Oncology providers. Flatiron will ensure that the test data entered for each patient includes the minimum necessary to meet the data requirements for each criterion being tested using the interactive testing method.

Criterion	Interactive Test Plan	Justification and Expected Outcome
§170.315(b)(6) Data export	Flatiron will test this functionality in our own staging environments. Testing will not be done in a customer's live environment to	**Justification:** Flatiron has logging to show internal (Flatiron employee) users leveraging this tool in a production environment, however to date our oncology practices

	avoid disruption to workflows, reporting, and data. Flatiron will enter 5 test patients with typical data as used in our care setting and then: 1. Export them as individual C-CDAs by searching for the patient by name 2. Export them as a batch by selecting multiple patients Flatiron will not plan to export all patients in the Oncology clinic to reduce the risk of exposure of PHI, and will focus the export only on the subset of test patients entered for this purpose. Flatiron will use visual inspection of the exported C-CDAs to confirm that they are exported per the certified requirements.	do not utilize the Batch Export C-CDAs because of other existing workflows in OncoEMR and CareSpace patient portal to pull the same information. For example - Single export: ● Patients can use the CareSpace patient portal to pull their own C-CDAs. For example - Batch export: ● Practices send C-CDAs through outbound referral workflows that do not leverage the Batch Export C-CDA tool. ● If a practice needs many patients' C-CDAs when a practice is transitioning from OncoEMR to another tool, or when a practice is merging with another practice's OncoEMR instance, Flatiron has backend tools to do this to support data migration for small Oncology providers. **Expected Outcomes:** ● Individual CCD export generates a CCD that passes visual inspection and contains the expected data elements and code sets ● Batch CCDs are exported that pass visual inspection and include the expected test patients
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	Flatiron will use Swagger as a test app against the production deployment of the Flatiron API server. Flatiron will set up new test patients so as not to expose PHI, but these test patients will be set up in the manner of Real-World Oncology patients, using diagnoses, medications, and other codesets typically found in the Oncology setting. Flatiron will use Swagger to mimic the workflow of a provider user querying the API for patients using a third-party app.	**Justification:** Flatiron developed the API functionality to support both patients and providers, but the main use case was to enable other providers and their vendors to query Flatiron API servers for patient data. Flatiron implemented the API criteria according to ONC standards, and currently has a publicly-accessible Patient API. There is currently no adoption by any developers, so Flatiron will plan to use interactive testing to demonstrate that this certified capability is available in the production environment and that lack of adoption is not caused by lack of availability. For the 21st Cures update, Flatiron plans to adopt the FHIR standard for their API functionality and hopes to see more adoption.

		Expected outcomes: • Query for a token using test patient demographics - demographics are returned • Token is used to query for CCD as well as discrete data, data is returned and visible to the user in Swagger

Schedule of Key Milestones

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

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

Criteria	Method	Scheduling / Logistics	Collect, review & collate data	Write report
Adoption metrics	Overall	*None required*	90 day window - Q1/Q2 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315(b)(1) Transitions of care	Summative metrics	Q1 2022 (work with HISP)	90 day window - Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315(b)(2) Clinical information reconciliation and incorporation	Summative metrics	*None required*	90 day window - Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315(b)(3) Electronic prescribing	Summative metrics	*None required*	90 day window - Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315(c)(1) Clinical quality measures (CQMs)	Summative metrics	*None required*	90 day window - Q1 2023	Q4 2023 (posted to CHPL 3/15/2024)

170.315(e)(1) View, download, and transmit to 3rd party	Summative metrics	*None required*	90 day window - Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315(f)(1) Transmission to immunization registries	Summative metrics	*None required*	Over 3 separate unique 10-day periods within a 90-day window: Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315(f)(4) Transmission to cancer registries	Summative metrics	*None required*	Over 3 separate unique 10-day periods within a 90-day window: Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
§170.315(b)(6) Data export	Interactive test plan	*None required*	Test plan executed & recorded at some point b/t Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
170.315 (g)(7): Application Access - Patient Selection meets170.315	Interactive test plan	*None required*	Test plan executed & recorded at some point b/t Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
(g)(8): Application Access - Data Category Request meets170.315	Interactive test plan	*None required*	Test plan executed & recorded at some point b/t Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)
(g)(9): Application Access - All Data Request	Interactive test plan	*None required*	Test plan executed & recorded at some point b/t Q2/Q3 2023	Q4 2023 (posted to CHPL 3/15/2024)

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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