



Flatiron Health Real World Testing Plan 2025

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”
- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, [89 FR 1192](#) (March 11, 2024) (**HTI-1 Final Rule**)
 - [Section III.E](#) – “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.28.02.1.221221

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)

Standard (and version)	Flatiron has elected to participate in the SVAP process, certifying to criteria 170.315 (g)(10): Standardized API for patient and population services using the HL7 US Core Implementation Guide 4.0.0 based on FHIR Version R4
Updated certification criteria and associated product	170.315 (g)(10): Standardized API for patient and population services
CHPL Product Number	15.04.04.3010.Onco.28.02.1.221221
Method used for standard update	Cures Update Certification Testing
Date of ONC ACB notification	November 16, 2022
Date of customer notification (SVAP only)	November 17, 2022
Conformance method and measurement/metrics	Recorded in RWT Plan



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. Flatiron has partnered with MaxMD for direct messaging and electronic referrals and DrFirst for controlled substance e-prescribing functionality in OncoEMR. Additional certified capability is available within the OncoEMR license (patient and FHIR APIs, 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.



Criteria	Metric	Justification and Expected Outcome
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: <ol style="list-style-type: none"> 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 	<p>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.</p> <p>Relied Upon Software:</p> <ul style="list-style-type: none"> • Flatiron leverages FirstDataback to support the translation of FDB identifiers to the minimum RxNorm Code Set for medication list and allergy medication that need to be translated. • Flatiron leverages Symedical, a terminology tool, to support required minimum vocabulary code sets (SNOMED, LOINC).
170.315(b)(3) Electronic prescribing	Over a 90-day period: <ol style="list-style-type: none"> 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed 	<p>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, 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.</p> <p>Relied Upon Software: Flatiron has partnered with the Surescripts, DrFirst, and First Databank for e-prescribing functionality in OncoEMR.</p>



Criteria	Metric	Justification and Expected Outcome
<p>170.315(b)(10) Electronic Health Information Export</p>	<p>Over a 90-day period:</p> <ol style="list-style-type: none"> 1) Number of single-patient electronic health information exports completed 2) Number of patient population electronic health information exports completed 	<p>This criterion requires the ability of a certified Health IT module to enable a user to create an export file with all of a single patient’s electronic health information and do so without developer assistance. Additionally, certified Health IT modules must allow for the exportation of entire patient populations and include all of the electronic health information that can be stored at the time of certification.</p> <p>Flatiron intends to demonstrate the required certified capabilities are effective by demonstrating how many single patient electronic health information exports were completed by our customers during the 90 day reporting period, and how many patient population exports were completed during the 90 day reporting period. This will demonstrate that not only are our customers able to export their patient data that Flatiron has the ability to export patient populations when requests are made from our customer base.</p> <p>Our expectation is there will be low to medium utilization by customers for single patient electronic health information export and low utilization for the exportation of patient populations due to the availability of other interoperability methods for EHI Exchange as well as high OncoEMR customer retention.</p> <p>Relied Upon Software: Flatiron utilizes the following to meet the (b)(10) criteria requirements:</p> <ul style="list-style-type: none"> ● Snowflake (version 7.40.0) ● AWS Aurora (version PostgreSQL 13.9), ● AWS Amazon Elastic Container Service (no version number) ● AWS S3 (no version number) ● AWS S3 Batch Operations (no version number) ● AWS EMR (version emr-6.8.0)
<p>170.315(c)(1) Clinical quality measures (CQMs)</p>	<p>Over a 90-day period:</p> <ol style="list-style-type: none"> 1) Number of measures recorded during the period 2) Number of QRDA Category 1 files exported (attempted, successful) 	<p>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.</p>



Criteria	Metric	Justification and Expected Outcome
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	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 CCD 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: <ul style="list-style-type: none"> ● Flatiron has partnered with Amazon Pinpoint to support transmit functionality in OncoEMR. ● Flatiron leverages FirstDataback to support the translation of FDB identifiers to the minimum RxNorm Code Set for medication list and allergy medication that need to be translated. ● Flatiron leverages Symedical, a terminology tool, to support required minimum vocabulary code sets (SNOMED, LOINC).



Criteria	Metric	Justification and Expected Outcome
<p>170.315(f)(1) Transmission to immunization registries</p>	<p>Over 3 separate unique 10-day periods within a 90-day window:</p> <ol style="list-style-type: none"> 1) Number of immunization records created and transmitted to the immunization record 2) Total number of immunization history/forecasts requested from the immunization registry 	<p>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 transmitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used.</p> <p>Due to system reporting capabilities, we will measure this metric for all customers, not the selected cohort used for other testing scenarios.</p> <p>Relied Upon Software:</p> <ul style="list-style-type: none"> • Flatiron has partnered with Infor Cloverleaf to support the delivery of immunization data. • Flatiron leverages FirstDataback to support the translation of FDB identifiers to the minimum RxNorm Code Set for medication list and allergy medication that need to be translated. • Flatiron leverages Symedical, a terminology tool, to support required minimum vocabulary code sets (SNOMED, LOINC).
<p>170.315(f)(4) Transmission to cancer registries</p>	<p>Over 3 separate unique 10-day periods within a 90-day window:</p> <ol style="list-style-type: none"> 1) Number of cancer case data records created and transmitted 	<p>This criterion requires the ability of a certified Health IT module to transmit cancer case information to a registry using a specified format. Flatiron intends to record the frequency that cancer case data is transmitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used.</p> <p>Our expectation is there will be moderate utilization by providers with a high success rate.</p> <p>Relied Upon Software:</p> <ul style="list-style-type: none"> • Flatiron has partnered with Infor Cloverleaf to support the delivery of cancer case reports. • Flatiron leverages FirstDataback to support the translation of FDB identifiers to the minimum RxNorm Code Set for medication list and allergy medication that need to be translated. • Flatiron leverages Symedical, a terminology tool, to support required minimum vocabulary code sets (SNOMED, LOINC).



Criteria	Metric	Justification and Expected Outcome
170.315(f)(5) Electronic case reporting	Over a 90-day period: 1) Count of eICR messages going out over the Public Health Case reporting Interface	This criterion requires the ability of a certified Health IT module to create a case report based on a patient visit or encounter matched to a trigger code. Flatiron intends to capture the eICR messages that are generated and sent over Public Health Interfaces during the 90-day test period. We expect a moderate degree of use of eCR functionality as customers onboard with public health agencies. Relied Upon Software: Flatiron leverages the eCR Now FHIR App and MaxMD’s certified (h)(2) Direct Project, Edge Protocol, and XDR/XDM functionality to support our eCR workflow.
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	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	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 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	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, 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. Relied Upon Software: <ul style="list-style-type: none"> • Flatiron leverages FirstDataback to support the translation of FDB identifiers to the minimum RxNorm Code Set for medication list and allergy medication that need to be translated. • Flatiron leverages Symedical, a terminology tool, to support required minimum vocabulary code sets (SNOMED, LOINC).



Criteria	Metric	Justification and Expected Outcome
170.315(g)(10) Standardized API for patient and population services	<ol style="list-style-type: none"> 1) Capture the total number of applications utilized by customers during a reporting period 2) Capture total number of times users or systems utilize applications to access information for multiple patients during a reporting period 	<p>This criterion requires the certified Health IT module to offer two types of API-enabled services: one focused on a single patient’s data and the other on multiple patients’ data. This will be achieved through the utilization of Fast Healthcare Interoperability Resources (FHIR) standards.</p> <p>The approach for gauging the adoption and usage of these APIs involves tracking the total number of external and Flatiron-supported applications that invoke our customers’ FHIR APIs within their live environments. We will monitor the frequency with which applications utilize the platform to connect to our customers’ live environments for the purpose of reviewing FHIR data elements which can include USCDI information.</p> <p>Additionally, we will record the instances in which third-party applications connect to the FHIR APIs to access data pertaining to multiple patients. These data points will be amassed over a 90-day period. Our chosen method for data collection will be summative metrics. We anticipate a moderate level of API utilization.</p> <p>Relied Upon Software:</p> <ul style="list-style-type: none"> • Flatiron leverages FirstDataback to support the translation of FDB identifiers to the minimum RxNorm Code Set for medication list and allergy medication that need to be translated. • Flatiron leverages Symedical, a terminology tool, to support required minimum vocabulary code sets (SNOMED, LOINC).

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(g)(7) Application access—patient selection
- 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 (g)(7): Application Access - Patient Selection meets 170.315	Flatiron will use Swagger as a test app against the production deployment of the Flatiron API server.	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.
(g)(9): Application Access - All Data Request	<p>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.</p> <p>Flatiron will use Swagger to mimic the workflow of a provider user querying the API for patients using a third-party app.</p>	<p>Flatiron implemented the API criteria according to ONC standards, and currently has a publicly-accessible Patient API.</p> <p>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.</p> <p>Expected outcomes:</p> <ul style="list-style-type: none"> ● 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 third quarter of 2025. Each phase is expected to take 90-days to complete, with report writing to occur at the end of 2025/early 2026.

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	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315(b)(1) Transitions of care	Summative metrics	Q3 2025 (work with HISP)	90 day window - Q3/Q4 2025	Q4 2025
170.315(b)(2) Clinical information reconciliation and incorporation	Summative metrics	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315(b)(3) Electronic prescribing	Summative metrics	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315 (b)(10) Electronic Health Information Export	Summative metrics	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315(c)(1) Clinical quality measures (CQMs)	Summative metrics	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315(e)(1) View, download, and transmit to 3rd party	Summative metrics	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025



Criteria	Method	Scheduling / Logistics	Collect, review & collate data	Write report
170.315(f)(1) Transmission to immunization registries	Summative metrics	<i>None required</i>	Over 3 separate unique 10-day periods within a 90-day window: Q3/Q4 2025	Q4 2025
170.315(f)(4) Transmission to cancer registries	Summative metrics	<i>None required</i>	Over 3 separate unique 10-day periods within a 90-day window: Q3/Q4 2025	Q4 2025
170.315(f)(5) Electronic case reporting	Summative metrics	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315 (g)(7): Application Access - Patient Selection meets 170.315	Interactive test plan	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025
170.315(g)(9): Application Access - All Data Request	Interactive test plan	<i>None required</i>	90 day window - Q3/Q4 2025	Q4 2025 (posted to CHPL 3/15/2026)
170.315(g)(10): Standardized API for Patient & Population Services	Summative metrics	<i>None Required</i>	90 day window - Q3/Q4 2025	Q4 2025 (posted to CHPL 3/15/2026)



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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Authorized Representative Signature:

Signed by:
Kate Estep
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Date: 10/30/2024